MPI Indium DTPA In 111

(Pentetate Indium Disodium In 111)

In Cisternography

Cisternography presents the dynamics of CSF flow

When you need to know *function*—
cisternography is useful in the evaluation of:

- Patients who may need ventricular shunts
- Shunt patency and/or site of blockage
- Patients with symptoms of "normal pressure" hydrocephalus
- Patients with symptoms of "communicating" hydrocephalus
- CSF rhinorrhea patients

CLINICAL CRITERIA

"An ideal radiopharmaceutical for cisternography would satisfy the following criteria: (I) physiologically governed by CSF flow, (II) adequate half-life for desirable period of study, (III) photons suitable for scanning, (IV) low radiation dose, (V) least probable chemical toxicity, and (VI) controlled pharmaceutical quality. Chelated ^{111}In satisfies all these conditions."[1]

COMPARISON OF TWO RADIOPHARMACEUTICALS USED IN EVALUATION OF CEREBROSPINAL FLUID PATHWAYS[2]

	^{169}Yb DTPA	^{111}In DTPA
Physical Half-Life	32 days	2.8 days
Biological Half-Life	12 hours	10 hours
Useful Photons (energy MeV)	0.177, 0.198	0.173, 0.247
Useful Photons (% disintegration)	0.57	1.85
Whole Body Dose (rads)	0.069/500 μCi	0.039/500 μCi
Spinal Cord Surface Dose (rads)	8.0/500 μCi*	1.9/500 μCi*

*Dose to spinal cord and brain surface

[1] Chelated ^{111}In: An ideal radiopharmaceutical for cisternography, F. Hosain, D. Phil., and P. Som, D.V.M.M.S. British Journal of Radiology, 45:677-679, Sept. 1972.

[2] Preparation, Physiology and Dosimetry of ^{111}In Labeled Radiopharmaceuticals for Cisternography, David Goodwin, M.D., Chung Hun Song, B.S., Roland Finston, Ph.D. and Philip Matin, M.D., Radiology, 109:91-98, July 1973.

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FOR COMPLETE PRESCRIBING INFORMATION PLEASE CONSULT PACKAGE INSERT, A SUMMARY OF WHICH FOLLOWS:

MPI Indium DTPA In 111

(Pentetate Indium Disodium In 111)

DESCRIPTION: MPI Indium DTPA In 111 is a diagnostic drug for intrathecal use. It is available as a sterile, apyrogenic, isotonic, aqueous solution, buffered to pH 7 to 8. At calibration time each milliliter contains 1 millicurie of Pentetate Indium Disodium In 111 (no-carrier-added), 20 to 50 micrograms of pentetic acid, and sodium bicarbonate for pH adjustment. *The drug is to be discarded after single use.* Radionuclidic purity at calibration time is at least 99.0% with less than 0.1% Indium In 114m and 0.1% Zinc Zn 65. The concentration of each radionuclidic contaminant changes with time.

INDICATIONS AND USAGE: Pentetate Indium Disodium In 111 is recommended for use in radionuclide cisternography.

CONTRAINDICATIONS: None known.

WARNINGS: The contents of the vial are radioactive. Adequate shielding of the preparation must be maintained at all times.

Since the drug is excreted by the kidneys, caution should be exercised in patients with severely impaired renal function.

PRECAUTIONS:
Pentetate Indium Disodium In 111, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel, and to minimize radiation exposure to the patients consistent with proper patient management.

Do not use after the expiration time and date (7 days after calibration time) stated on the label.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, or whether Pentetate Indium Disodium In 111 affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with MPI Indium DTPA In 111. It is also not known whether Pentetate Indium Disodium In 111 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Pentetate Indium Disodium In 111 should be given to a pregnant woman only if clearly needed.

PRECAUTIONS: 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 Pentetate Indium Disodium In 111 is administered to a nursing mother.

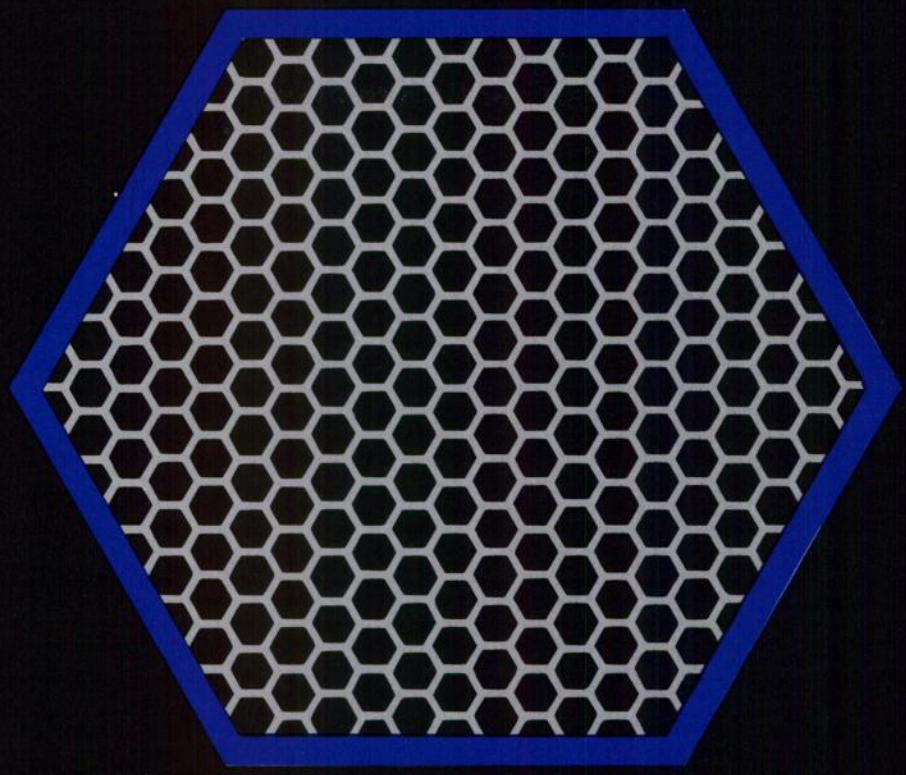
Pediatric Use

Safety and effectiveness in children have not been established.

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

ADVERSE REACTIONS: Aseptic meningitis and pyrogenic reactions have been rarely (less than 0.4%) observed following cisternography with Pentetate Indium Disodium In 111.

HOW SUPPLIED: Pentetate Indium Disodium In 111 (no-carrier-added) is supplied in single dose glass vials, each containing 1.5 ml of solution with a concentration of 1 millicurie per ml and a total activity of 1.5 millicurie per vial at calibration time.



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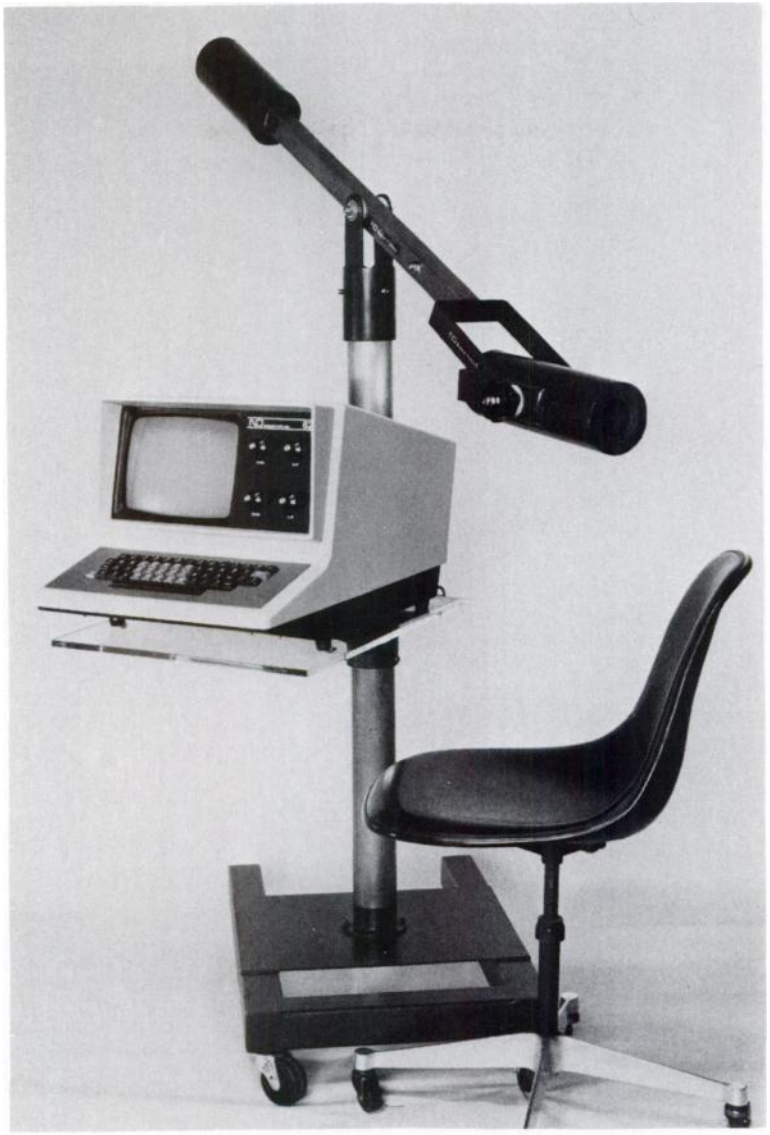

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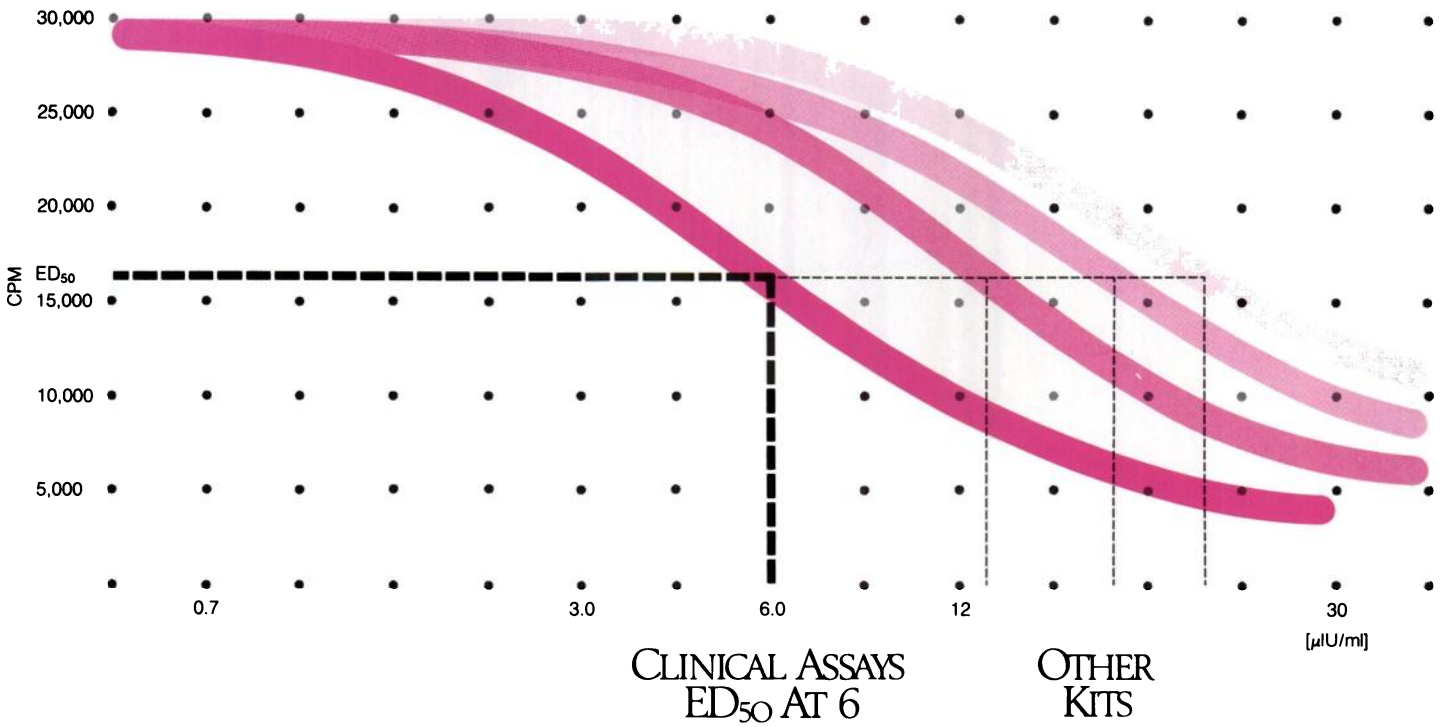

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MPI DMSA KIDNEY REAGENT

(Technetium Tc 99m Succimer Kit)

- Localizes in the renal cortex
- Highest target to background ratio of Tc 99m agents[1,2]
- Low excretion rate[2,3]
- DMSA is the renal cortical imaging agent of choice. Even in patients with obstructed or dilated collecting systems, an accurate comparison of relative cortical uptake without interfering activity in the pelvocalyceal structures can be made.[4,5]

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1. Enlander D. et al: Renal Cortical Imaging in 35 Patients: Superior Quality With 99m Tc-DMSA. J. Nuc. Med. 15: 743–749, 1974.
2. Daly M.J. et al: Differential Renal Function Using Technetium-99m Dimercaptosuccinic Acid (DMSA): In Vitro Correlation. J. Nuc. Med. 20: 63–66, 1979.
3. Handmaker H. et al: Clinical Experience With 99m Tc-DMSA (Dimercaptosuccinic Acid), a New Renal-imaging Agent. J. Nuc. Med. 16: 28–32, 1975.
4. Taylor A.: Delayed Scanning With DMSA: A Simple Index of Relative Renal Plasma Flow. Radiology 136: 449-453, 1980.
5. Handmaker H: Nuclear Renal Imaging in Acute Pyelonephritis. in Freeman L. Blaufox MD (eds.): Update on Radionuclide Assessment of the Kidney (I): Semin. Nuclear Medicine 12: 246–253, 1982.

MPI DMSA Kidney Reagent (Technetium Tc 99m Succimer Kit)

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

DESCRIPTION: Each reagent ampul of the kit contains 2.2 ml of a sterile, pyrogen free aqueous solution containing 1.2 mg of succimer and 0.42 mg of anhydrous stannous chloride in aqueous solution under a nitrogen gas atmosphere. When sterile, oxidant-free, pyrogen-free sodium pertechnetate Tc 99m in isotonic saline is combined with the reagent, following the instructions provided with the kit, a complex is formed. Administration is by intravenous injection for diagnostic use.

The succimer component of MPI Kidney Reagent consists of more than 90% meso isomer and less than 10% d,l isomer.

INDICATIONS AND USAGE: MPI DMSA Kidney Reagent is to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders.

CONTRAINDICATIONS: None known.

WARNINGS: None.

PRECAUTIONS: General

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 carcinogenesis potential or whether Technetium Tc 99m Succimer affects fertility in males or females.

PREGNANCY CATEGORY C: Animal reproduction studies have not been conducted with the MPI DMSA Kidney Reagent either with or without Tc 99m.

It is also not known whether Technetium Tc 99m alone or with Succimer can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be administered to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

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

PEDIATRIC USE: Safety and effectiveness in children have not been established.

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.

MPI DMSA Kidney Reagent should be formulated within 30 minutes prior to clinical use.

The product must be used within 30 minutes after preparation. Any unused portion should be discarded after that time.

Some patients with advanced renal failure may exhibit poor renal intake of Tc 99m DMSA. It has been reported that satisfactory images may be obtained in some of these patients by delaying imaging for up to 24 hours.

ADVERSE REACTIONS: Rare instances of syncope, fever, nausea and maculopapular skin rash have been reported.

HOW SUPPLIED: Each kit package contains the following components:

(1) Five sealed glass reagent ampuls, each containing 2.2 ml of a sterile, pyrogen-free aqueous solution of 1.2 mg succimer and 0.42 mg anhydrous stannous chloride. The solution is under a nitrogen gas atmosphere.
(2) Five sterile and pyrogen-free mixing vials (10 ml).
(3) Five mixing vial labels.
(4) Five courtesy record labels.
(5) One package insert.

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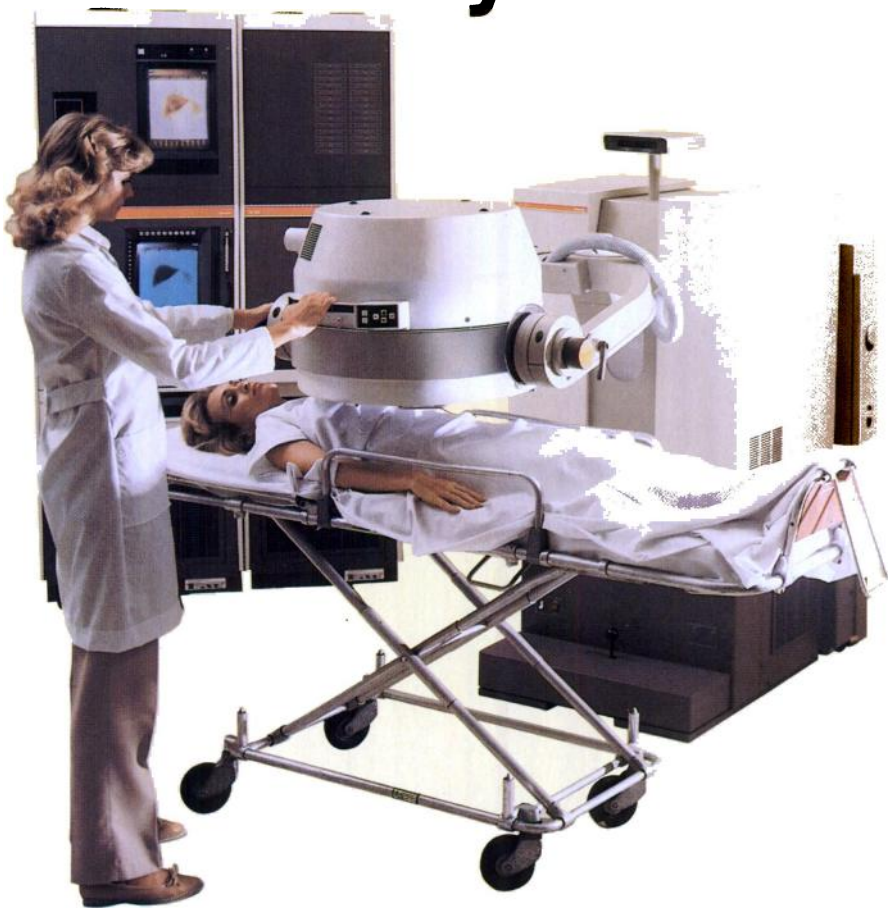

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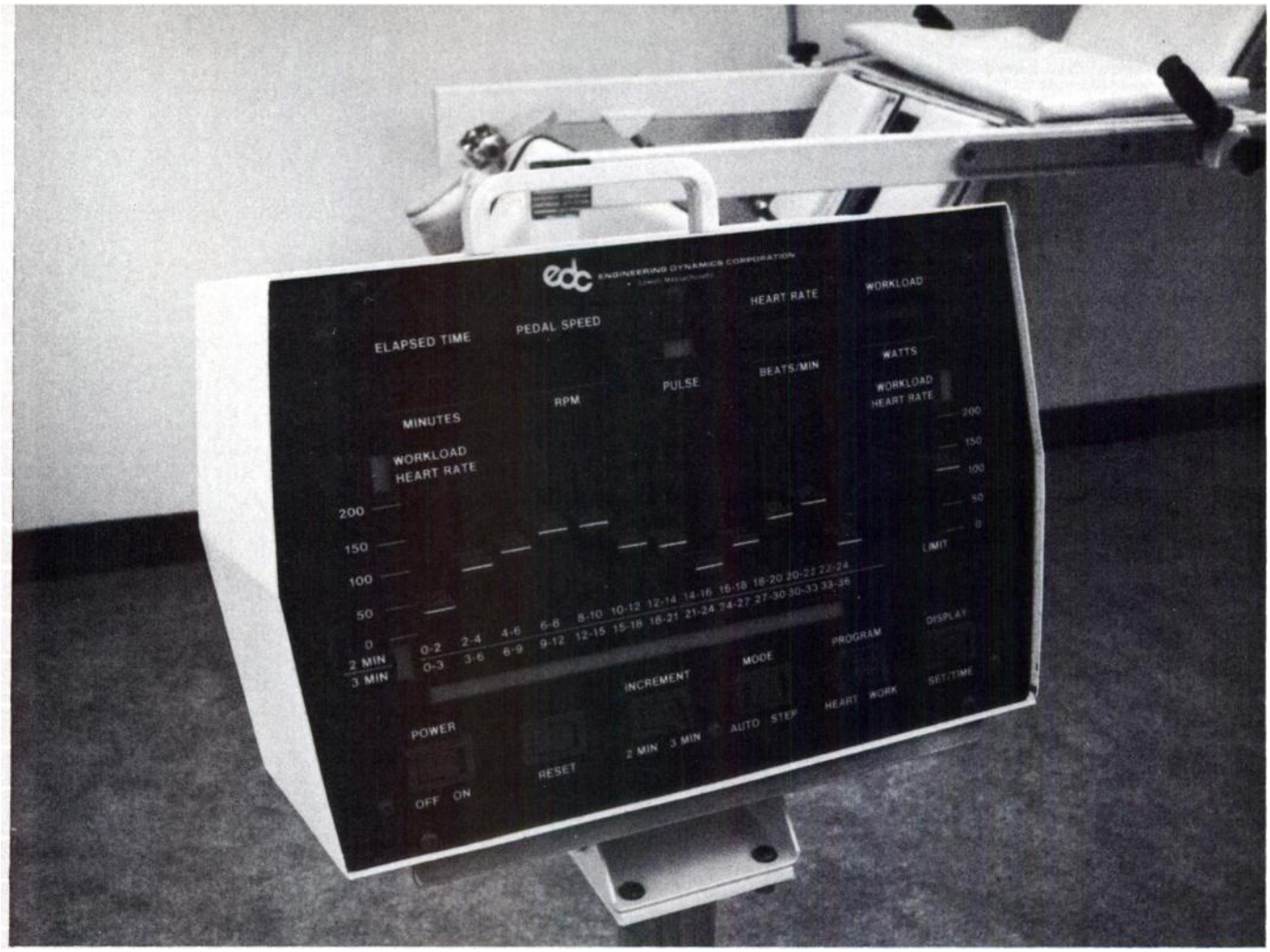

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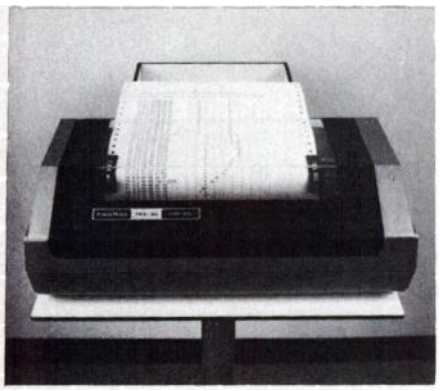

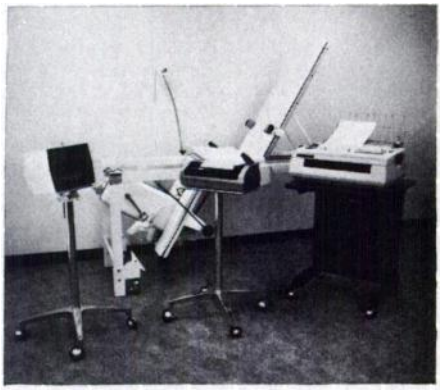

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NEN announces

PYROLITE™

Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates Kit

our new blood pool imaging agent

☐ High target-activity concentration
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☐ Rapid, simple preparation

INDICATIONS AND USAGE: Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates may be used as a bone imaging agent to delineate areas of altered osteogenesis.

Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates may also be useful in myocardial imaging as an adjunct in the diagnosis of acute myocardial infarction. False negative images can occur if done too early in the evolutionary phase of the infarct or too late in the resolution phase. False positive images have been reported following coronary bypass graft surgery, in unstable angina pectoris, old myocardial infarcts, and in cardiac contusions.

PYROLITE is a blood pool imaging agent which may be used for gated cardiac blood pool imaging. When administered intravenously thirty minutes prior to the intravenous administration of sodium pertechnetate Tc 99m approximately 75% of the injected activity remains in the blood pool.

CONTRAINDICATIONS: None known.

WARNINGS: It has been reported that false-positive or false-negative brain scans may result when brain scans using sodium pertechnetate Tc 99m are performed after a bone scan has been done using an agent containing stannous chloride, e.g., a pyrophosphate or polyphosphate bone agent. Therefore, in those cases where both brain and bone scans are indicated, the brain scan should be performed first, if feasible. Alternatively, another brain imaging agent, such as Technetium Tc 99m Pertechnetate DTPA, may be employed.

PRECAUTIONS: Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the vial, appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible for the next 4-6 hours, if not contraindicated by the patient's cardiac status.

Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates should be used within six hours of preparation.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates affects fertility in males or females.

Pregnancy Category C

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse affects on the fetus. Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates should be used in pregnant women only when 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.

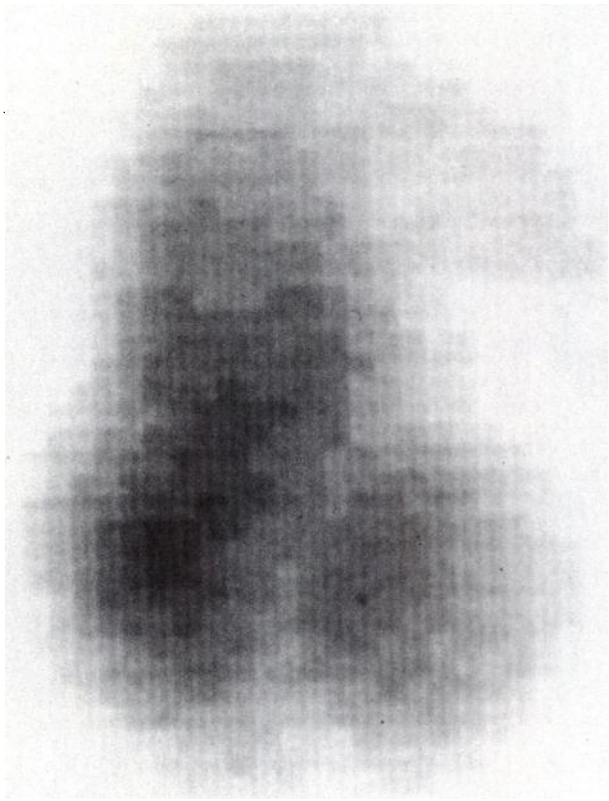
Pediatric Use

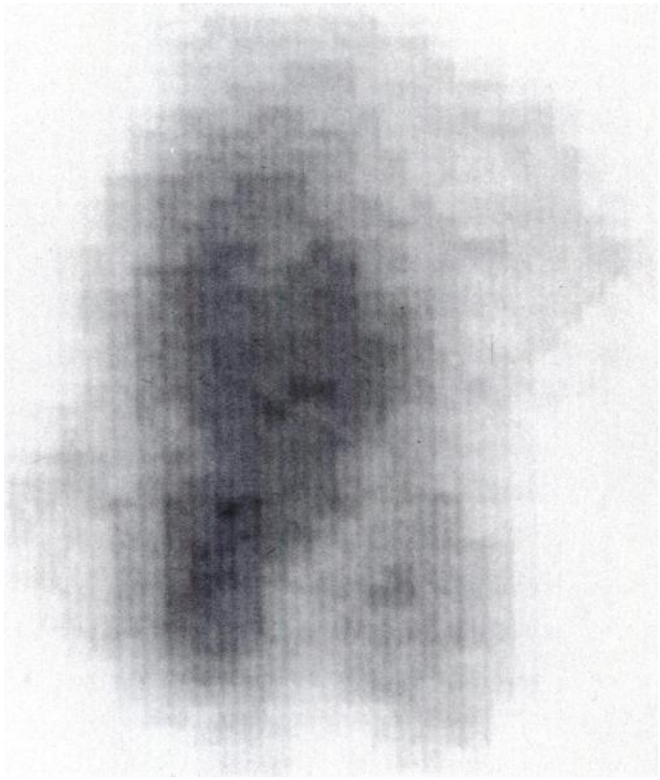
Safety and effectiveness in children have not been established.

General

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

ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates have been reported.





DOSAGE AND ADMINISTRATION: The suggested dose range for i.v. administration to be employed in the average patient (70kg) is:

Bone imaging: 5-15mCi Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates

Scanning post-injection is optimal at about 3-4 hours

Myocardial Imaging: 10-20mCi Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates

Scanning post-injection is optimal at 60-90 minutes.

Blood pool imaging: 5-20mCi of sodium pertechnetate Tc 99m.

For blood pool imaging the PYROLITE kit is reconstituted with three to four ml of sterile sodium chloride injection, U.S.P. and sufficient solution is injected intravenously to yield a patient dose of 14-42mg Sodium (Pyro- and Trimeta-) Phosphates (to provide a range of 3-15μg of tin per kilogram body weight). Five to thirty minutes later, 5 to 20mCi of sodium pertechnetate Tc 99m is administered intravenously. Imaging can begin at once for "first pass" studies and after about five minutes for static blood pool imaging.

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

The components of the PYROLITE Kit 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 Sodium (Pyro- and Trimeta-) Phosphates is prepared by simply adding 3-7 ml of sodium pertechnetate Tc 99m solution to the vial and swirling for about one minute.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Shielding should be utilized when preparing the Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates.

HOW SUPPLIED: NEN's PYROLITE™ Technetium Tc 99m Sodium (Pyro- and Trimeta-) Phosphates Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each vial contains in lyophilized form:

Sodium Pyrophosphate—10mg

Sodium Trimetaphosphate—30mg

Stannous Chloride ($SnCl_2 \cdot 2H_2O$) (Minimum)—0.95mg

Total Tin, maximum (as stannous chloride $SnCl_2 \cdot 2H_2O$)—1.8mg

Prior to lyophilization the pH is adjusted to between 4.5-5.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen. Store at room temperature (15°-30°C). Contains no bacteriostatic preservative.

Included in each five vial kit is one (1) package insert and twelve (12) radiation labels. Included in each thirty vial kit is one (1) package insert and seventy-two (72) radiation labels.

Catalog Number NRP-430 (5-Vial Kit)
Catalog Number NRP-430C (30-Vial Kit)

February 1983

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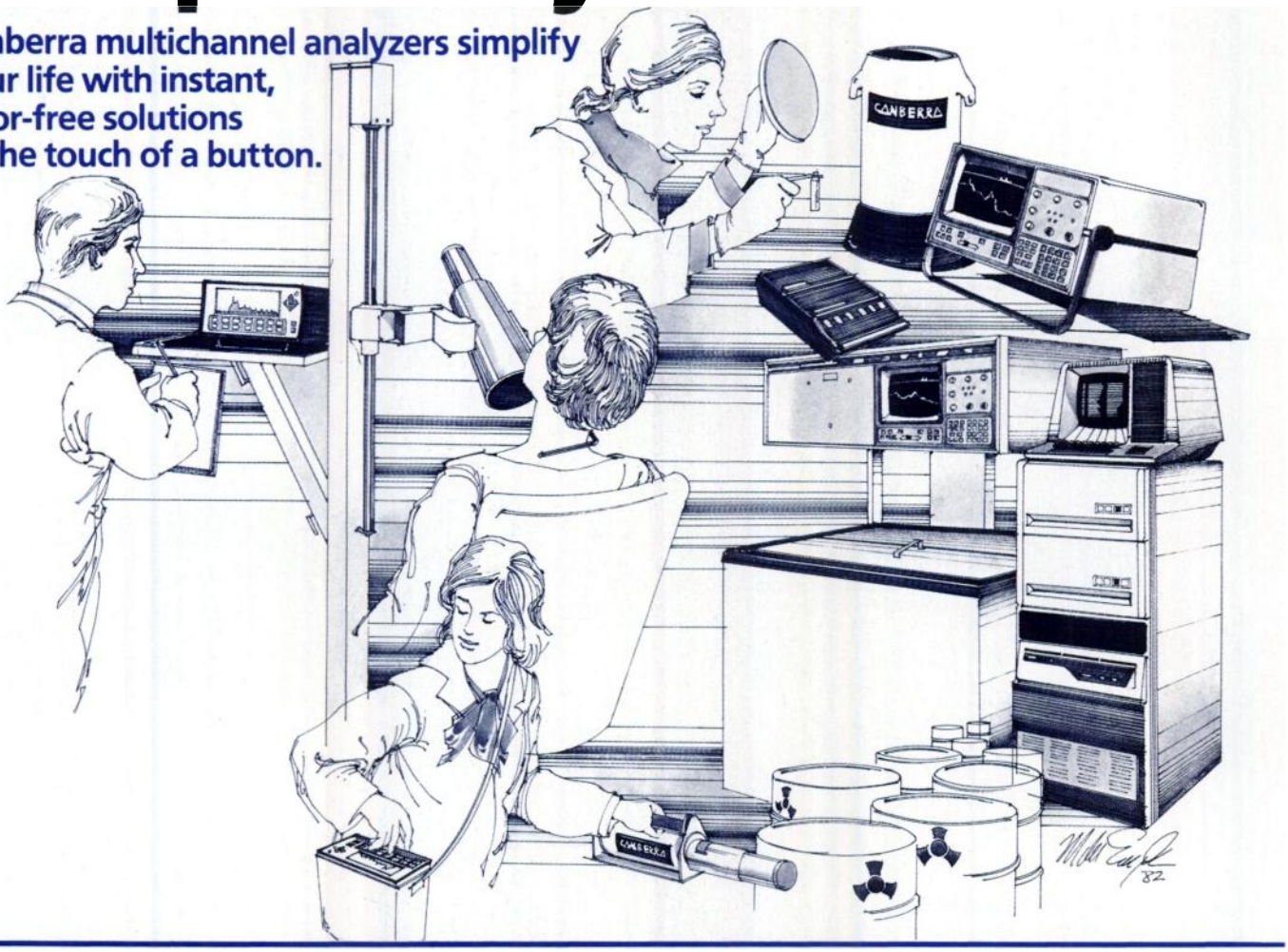

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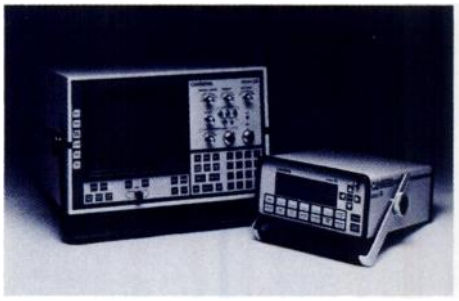

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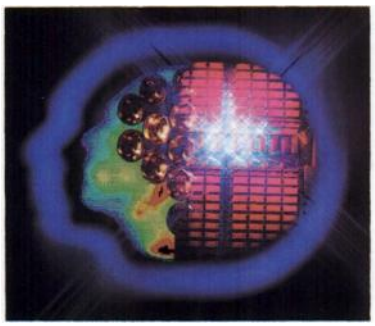

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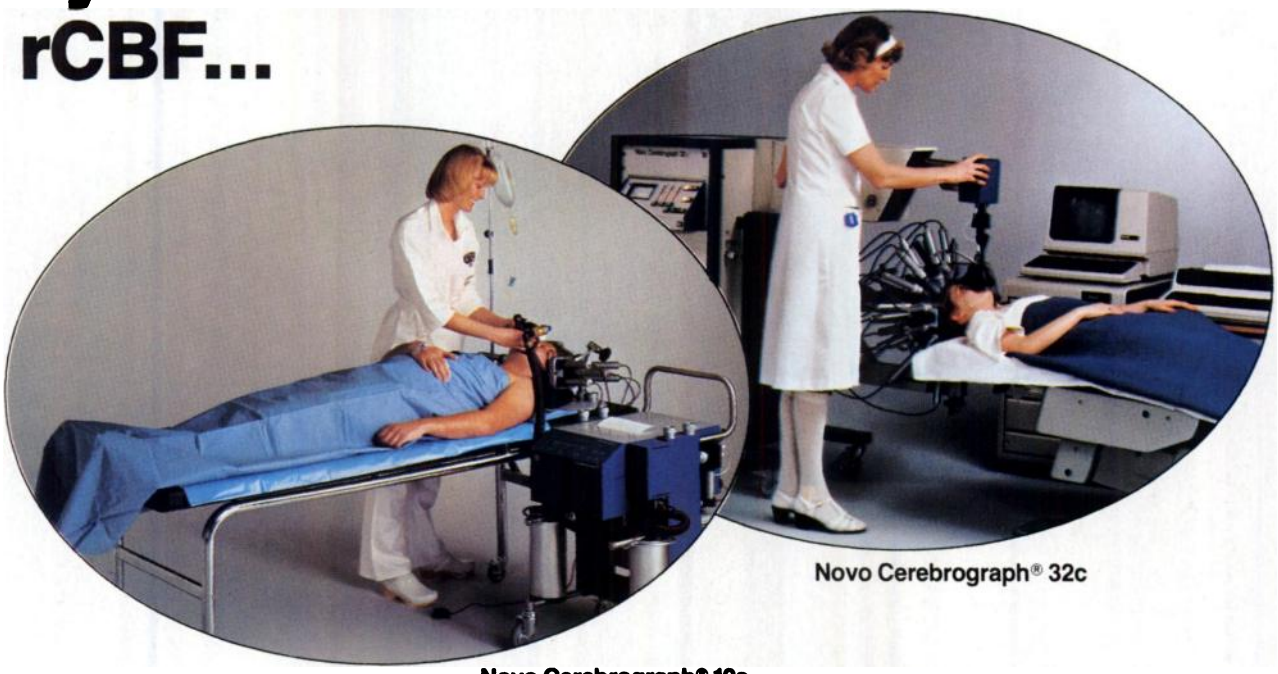

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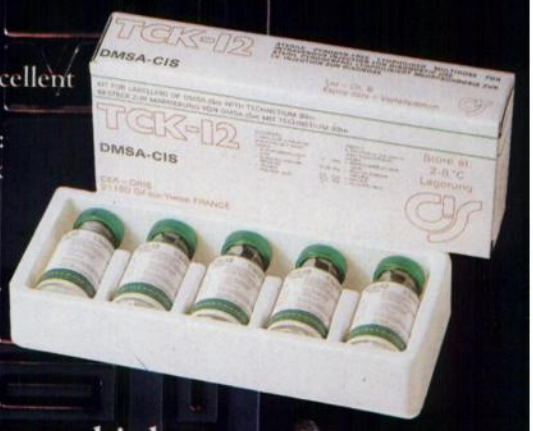

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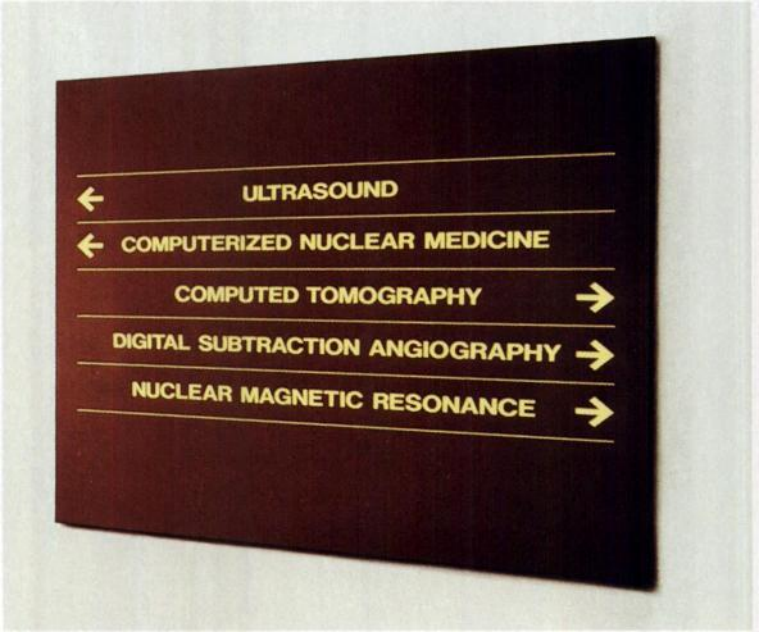

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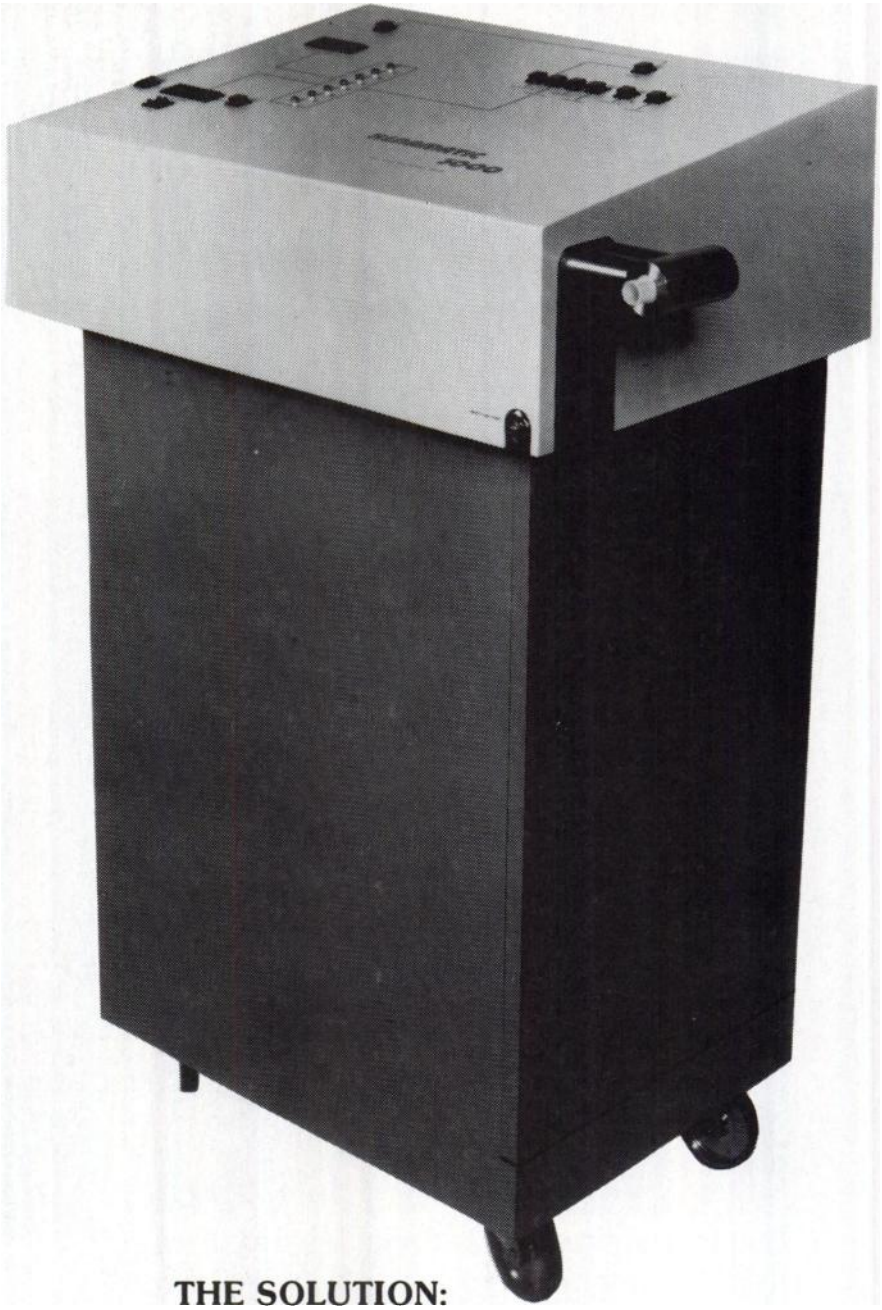

THE PROBLEM:
You would like to do the lung perfusion images first, look at the images and decide if a ventilation study is called for.

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:
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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.

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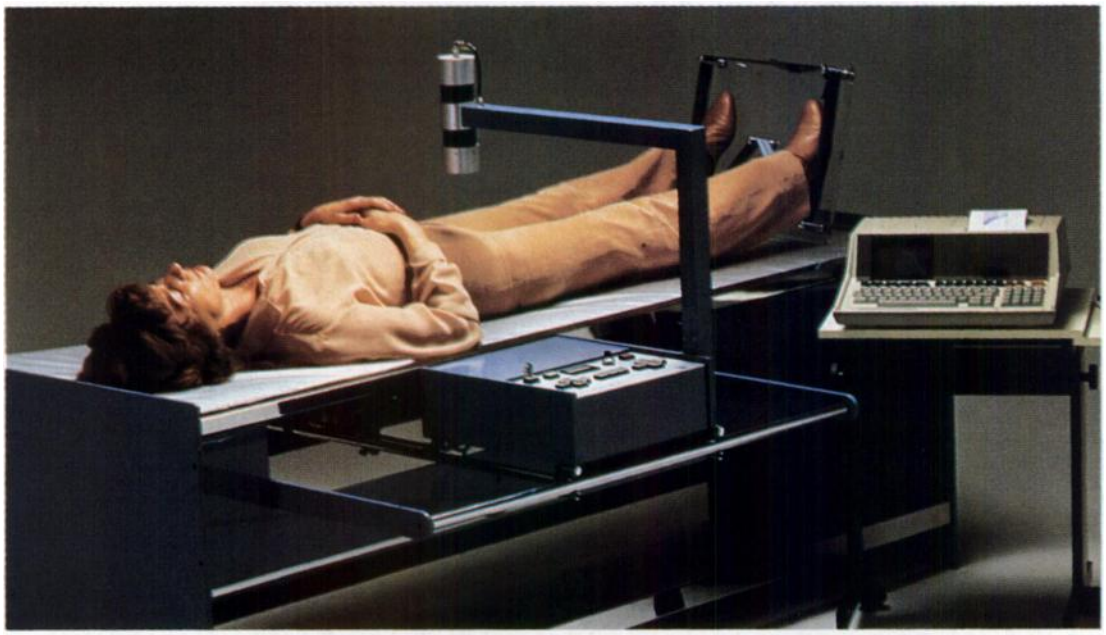

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Novo provides the most advanced technique—dual photon emission—for more reliable data. BMC-LAB22a utilizes this advanced technique in analyzing the axial skeleton, the site where predominant bone resorption occurs, for faster detection of osteoporosis, renal osteodystrophy and osteopenia.

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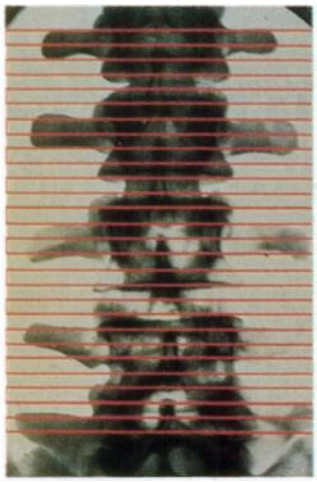

BMC-LAB22a provides VDC display of scanned bone, as well as hard copy and scan reports from an integral printer.

Constant right-angle view with ease and safety

Four convenient pushbutton programs scan the lumbar spine and right and left femoral necks, as well as separate vertebrae. This gives a constant right-angle view without moving the patient. Minimal radiation dosage is received, so repeated measurements can be performed.

Advanced software allows for ease of operation, without special training. And special safety features lower the incidence of accidental and superfluous radiation exposure. Special precautions are not required.

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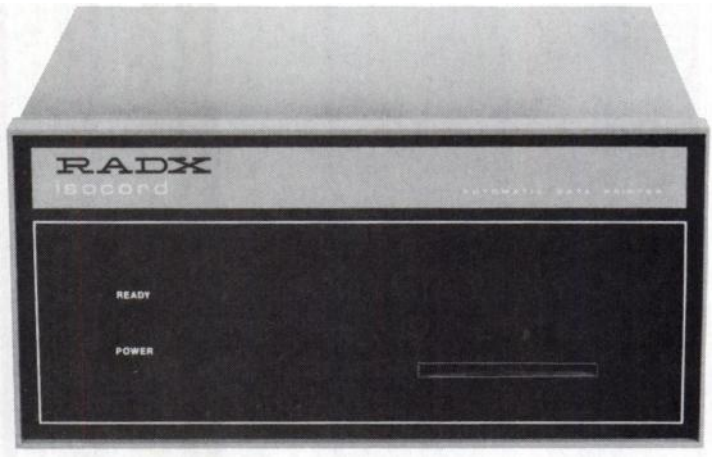

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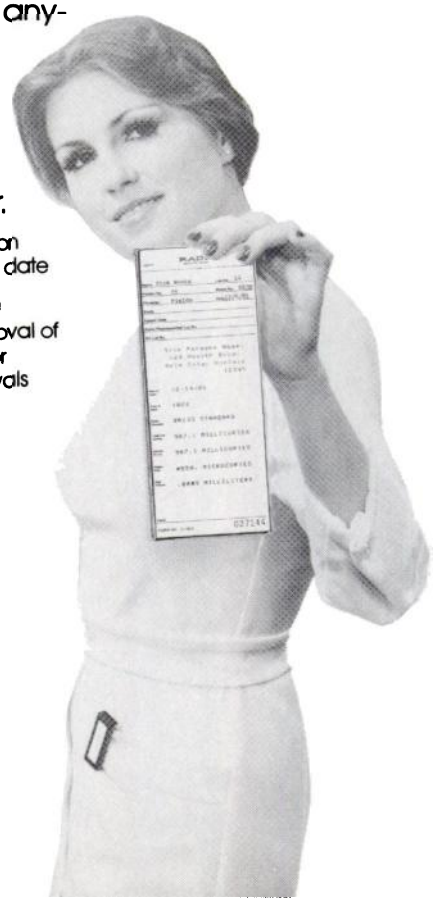

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XENON 127

Xenon Xe 127 Gas—Exclusively from Mallinckrodt

Photon energies higher than technetium Tc 99m permit perfusion/ventilation study sequence not practical with Xenon Xe 133.

"The 140-keV gamma photon from ^{99m}Tc has a Compton scatter peak at about 80 keV [which] cannot be distinguished from the [81 keV] photopeak of ^{133}Xe."[1] Xenon 127's higher photon energies (172 and 203-keV) give you optimal visualization without potential image degradation from technetium Tc 99m. You can perform the perfusion study first and select the best view for the ventilation study.

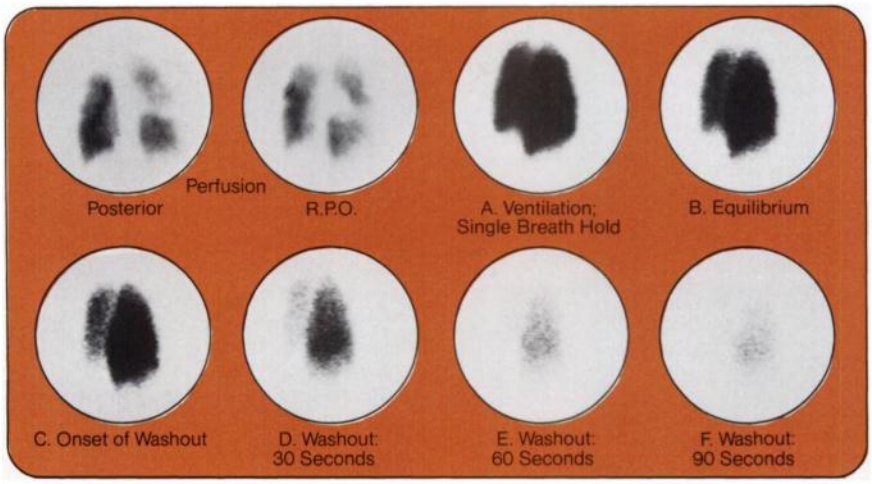
Higher usable photon yield than Xenon Xe 133 gives you diagnostic information you need with substantially lower millicurie dosage administered to the patient.

The lung radiation dose from Xenon Xe 127 is approximately 1/6 that of Xenon Xe 133 for equal information densities[2] Studies report excellent images with Xenon Xe 127 gas[1,2] "The clearer washout images...are probably due to better penetration through the chest wall with an improved lung-to-background ratio."[2]

Longer shelf-life than Xenon Xe 133 Gas and Krypton Kr 81m Gas means Xenon Xe 127 Gas can always be at hand when you need it.

Krypton Kr 81m Gas generators must be ordered for the day needed; Xenon Xe 133 Gas must be ordered weekly. Xenon Xe 127 Gas, however, can be ordered monthly. It is available for delivery the first of each month, calibrated for the fifteenth day of the month.

Lung Perfusion Study with Technetium Tc 99m Albumin Aggregated (MAA) and Ventilation Study with Xenon Xe 127 Gas



Patient:
A 26-year old male paraplegic with recent history of chest pain.

Perfusion Study:
3.0 mCi Technetium Tc 99m MAA.

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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Diagnostic Products Division
Mallinckrodt, Inc.
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Please see next page for Xenon 127 prescribing information.

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 days[1] 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 days[2] decays by isomeric transistion 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 days[2] 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 Days[3]

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

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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, 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:

1. If required, attach needle or other appropriate connector[6] to the Luer-Lok fitting of the Xenomatic II Xenon Gas Dispenser.
2. Remove lead filled plastic cap from Xenon Xe 127 Gas unit dose shield to expose the top of the 2.0 milliliter vial.
3. 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.
4. Connect the Xenomatic II Xenon Gas Dispenser to the breathing device or spirometer.
5. Squeeze the trigger *firmly and completely* one or more times to transfer the gas from the vial into the breathing device.[7]
6. After transfer, press shield release latch in the handle and remove the shield.
7. 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.
8. 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.
9. To clean the Xenomatic II Xenon Gas Dispenser, simply wipe with mild detergent. DO NOT IMMERSE 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:

1. Check the dose calibrator for proper response with the secondary standard.
2. Insert the Xenon Xe 127 Gas unit dose vial in the dose calibrator and measure the apparent radioactivity of the Xenon Xe 127.
3. 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.

[1] Atkins, 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.

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

[3] Preparations 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.

[4] Atkins, 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.

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

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

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

REFERENCES

1. Coates G, Nahmias C: Xenon-127, A Comparison with Xenon-133 for Ventilation Studies. *J Nucl Med* 18:221-225, 1977.

2. Atkins HL, Susskind H, Klopper JF, et al: A Clinical Comparison of Xe-127 and Xe-133 for Ventilation Studies. *J Nucl Med* 18:653-659, 1977.

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Blood Pool Imaging
Phosphotec is also a blood pool imaging agent which may be used for gated cardiac blood pool imaging.

CONTRAINDICATIONS: None known.

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

PRECAUTIONS: General
The lyophilized contents of the Phosphotec reaction vial are to be administered to the patient only as an intravenous solution.

Any sodium pertechnetate Tc 99m solution which contains an oxidizing agent is **not** suitable for use with Phosphotec (Technetium Tc 99m Pyrophosphate Kit).

When reconstituted with sodium pertechnetate Tc 99m, Phosphotec must be used within 6 hours. **When reconstituted with Sodium Chloride Injection USP** for blood pool imaging, use the solution within 30 minutes.

Technetium Tc 99m pyrophosphate as well as other radioactive drugs must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patient and occupational workers consistent with proper patient management.

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.

Bone Imaging
Both prior to and following administration of the technetium Tc 99m pyrophosphate, the patient should be encouraged to drink fluids and to void as often as possible thereafter to minimize radiation exposure to the bladder and background interference during imaging.

Cardiac Imaging
The patient's cardiac condition should be stable before beginning the cardiac imaging procedure. If not contraindicated by the patient's cardiac status, patients should be encouraged to drink fluids and to void as often as possible in order to reduce unnecessary radiation exposure to the bladder. Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections. False-positive and false-negative myocardial scans may occur; therefore, the diagnosis of acute myocardial infarction depends on the overall assessment of laboratory and clinical findings.

Blood Pool Imaging
The reconstituted agent should be injected by direct venipuncture. Heparinized catheter systems should be avoided, as interference with red blood cell tagging will result.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to determine any carcinogenic potential or impairment of fertility in males or females.

Teratogenic Effects: Pregnancy Category C
Animal reproduction studies have not been conducted with technetium Tc 99m pyrophosphate. It is also not known whether technetium Tc 99m pyrophosphate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m pyrophosphate should be administered 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
Caution should be exercised when technetium Tc 99m pyrophosphate is administered to a nursing woman. Technetium Tc 99m is excreted in human milk during lactation; therefore, formula-feedings should be substituted for breast-feedings.

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

ADVERSE REACTIONS: Some hypersensitivity reactions have been associated with pyrophosphate use.

HOW SUPPLIED: Phosphotec (Technetium Tc 99m Pyrophosphate Kit) is supplied in a kit containing 10 reaction vials (5 ml size).

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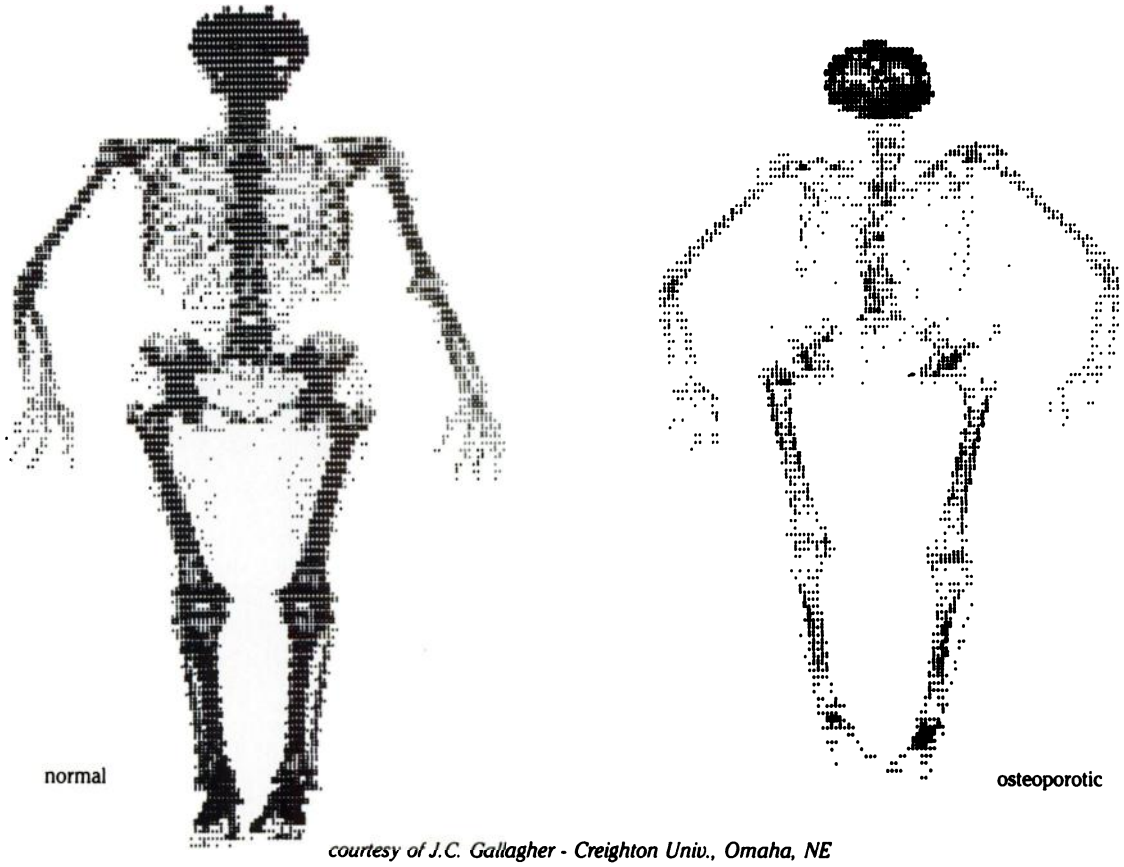

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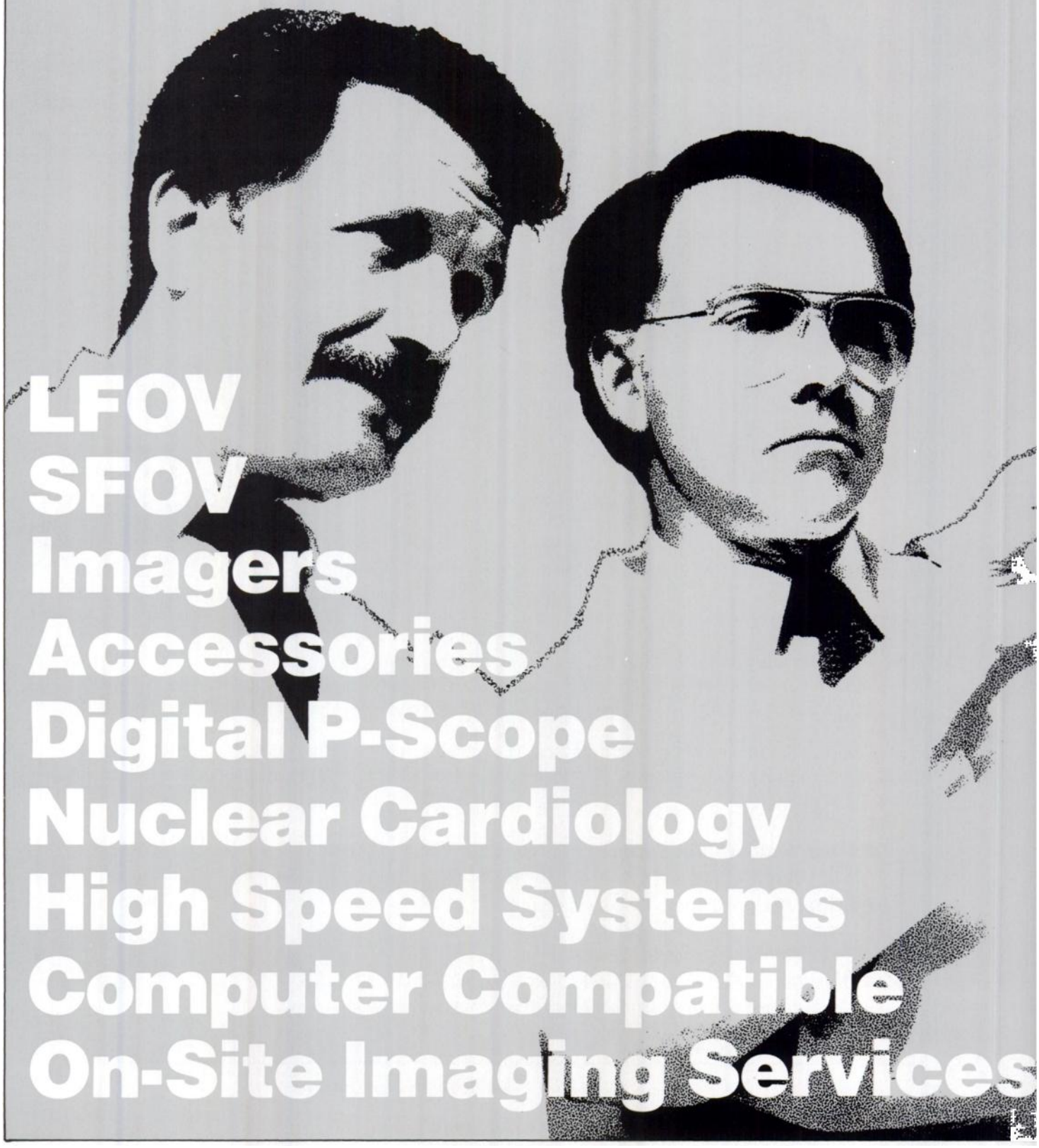

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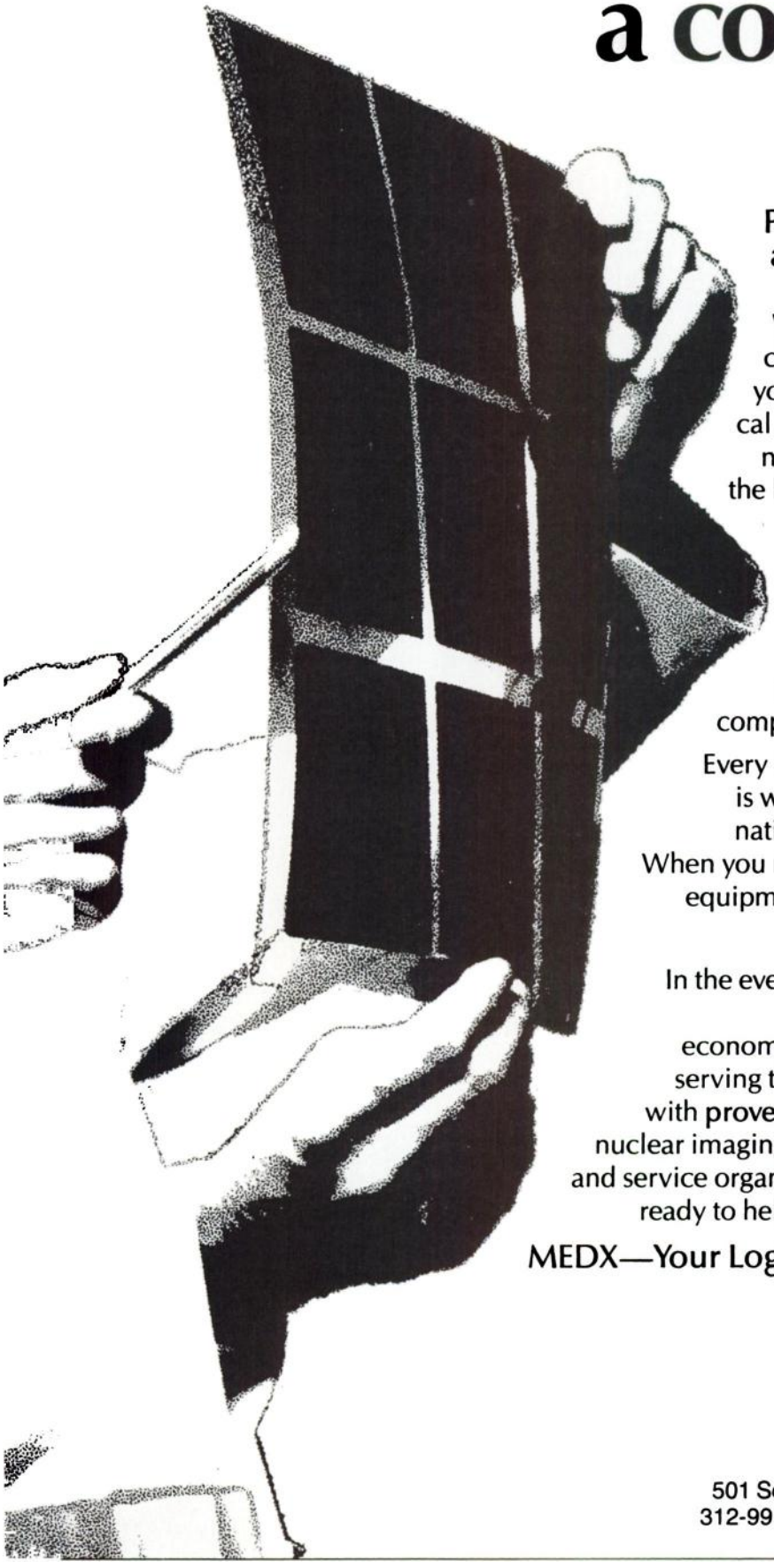

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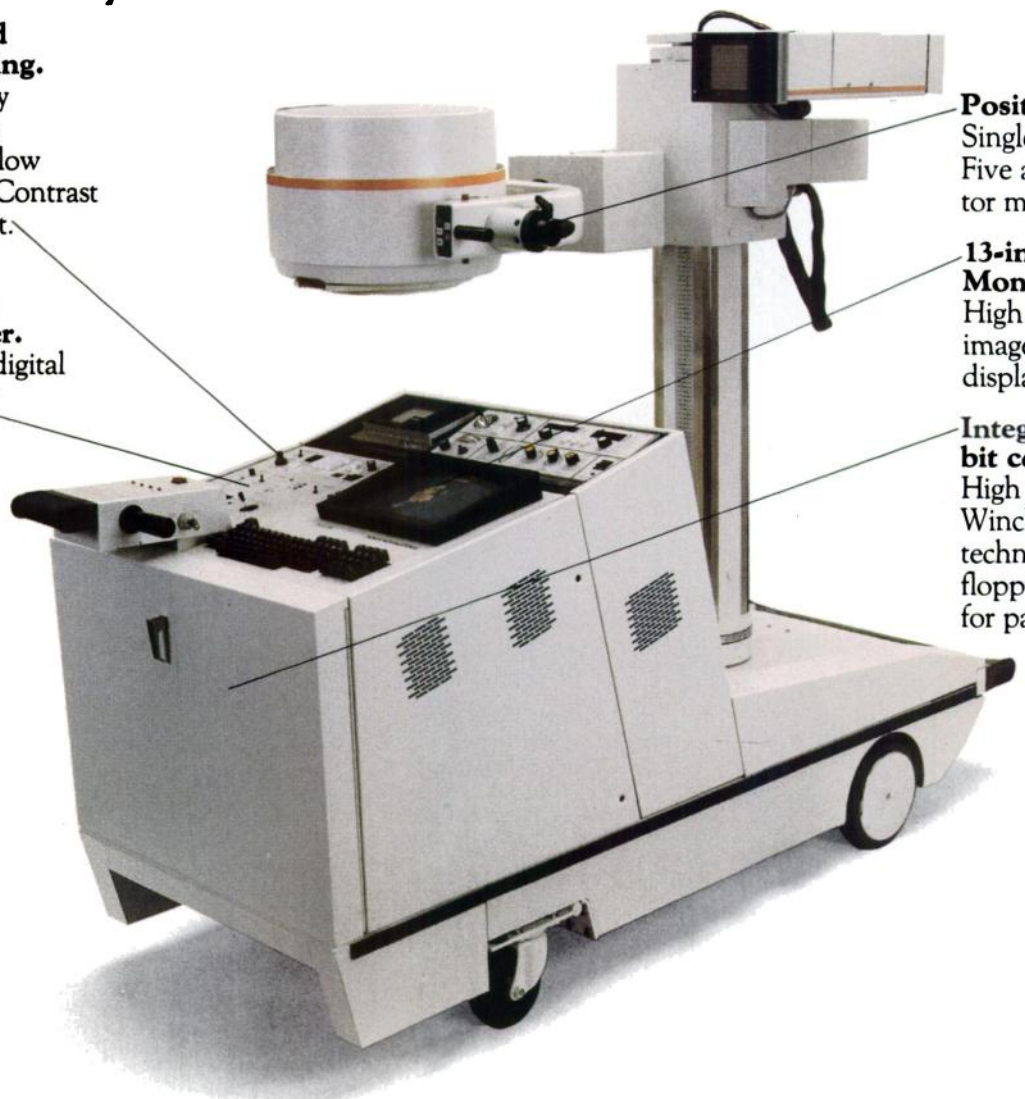

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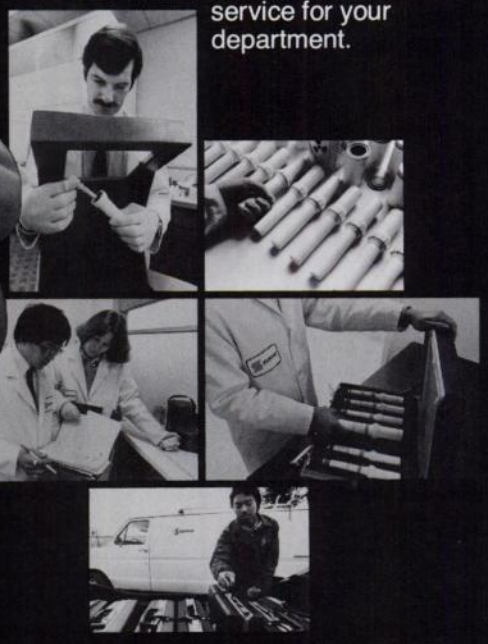

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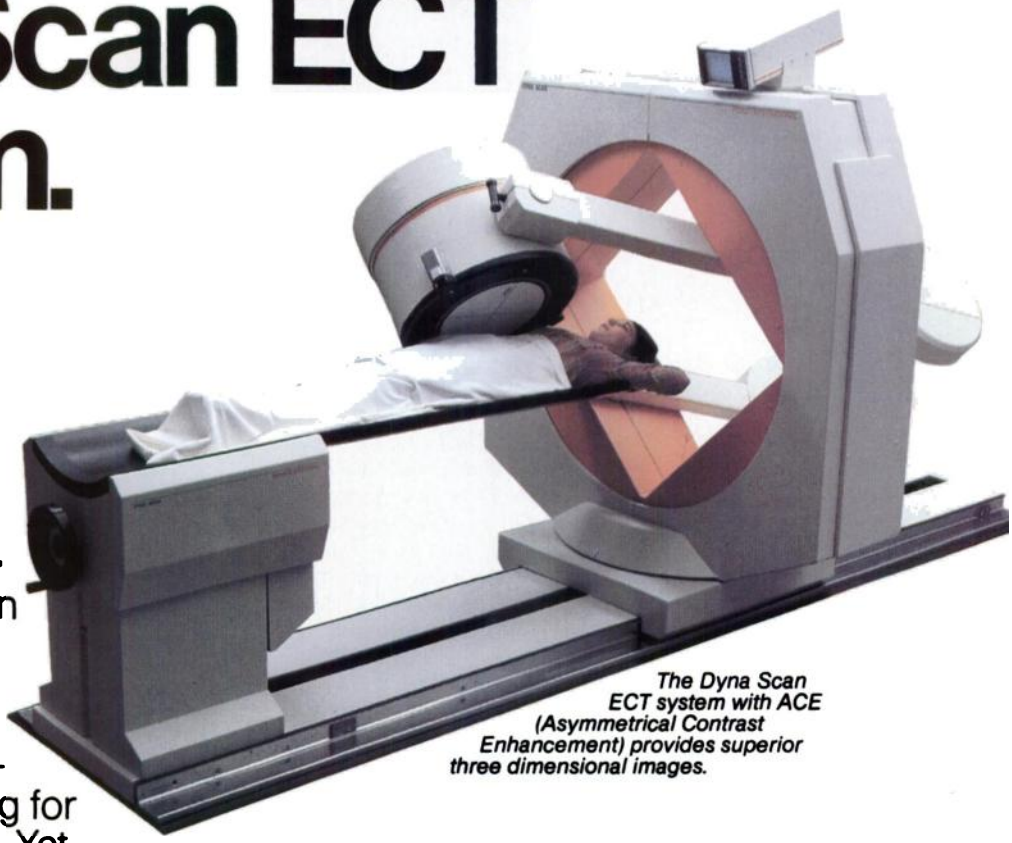

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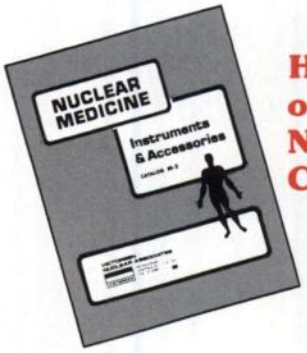

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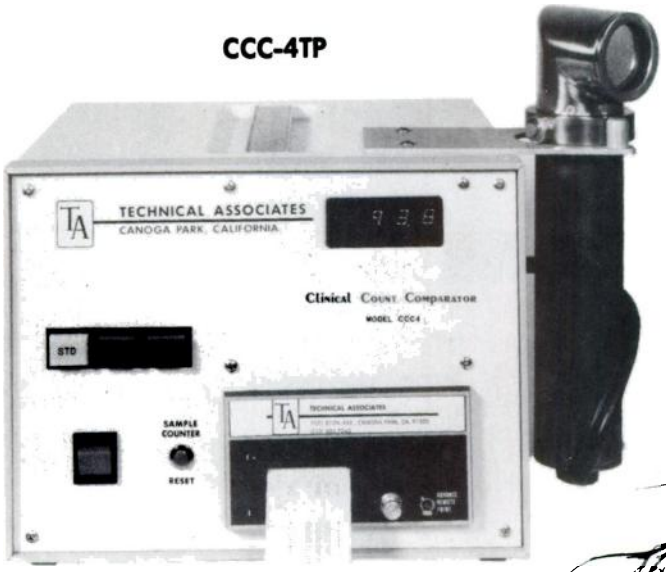

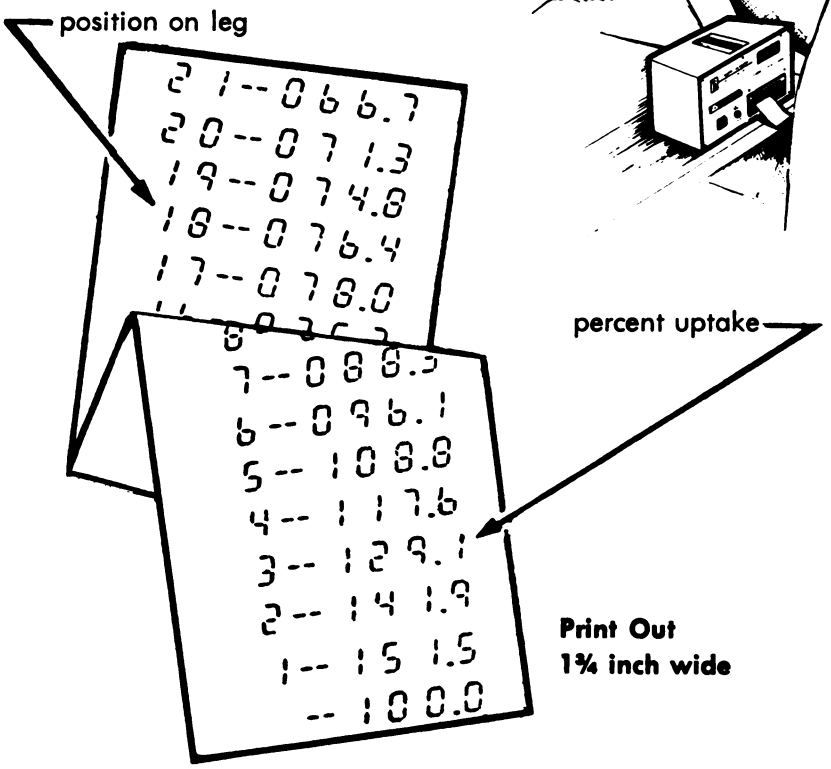

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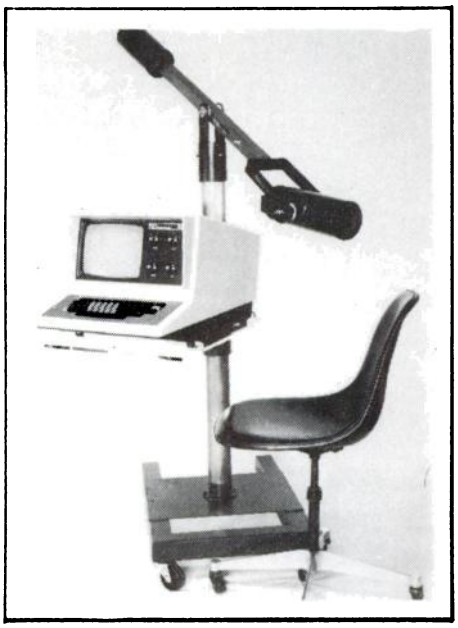

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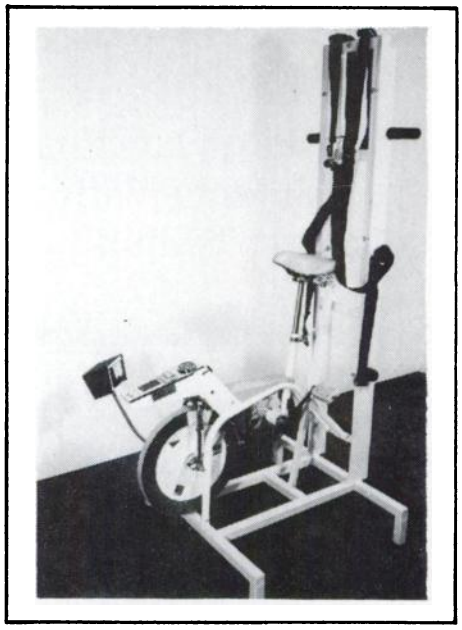

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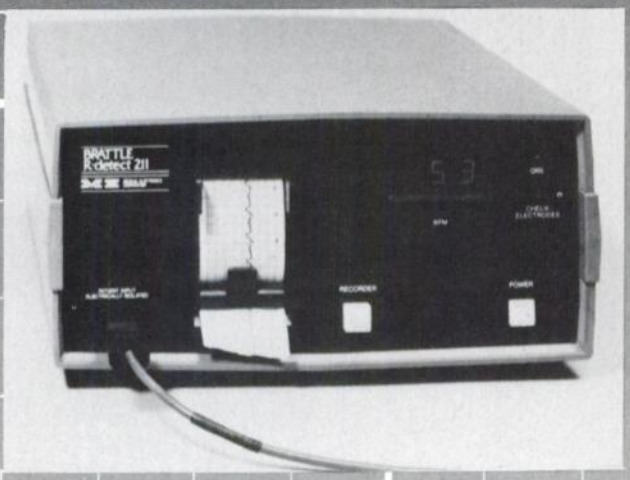

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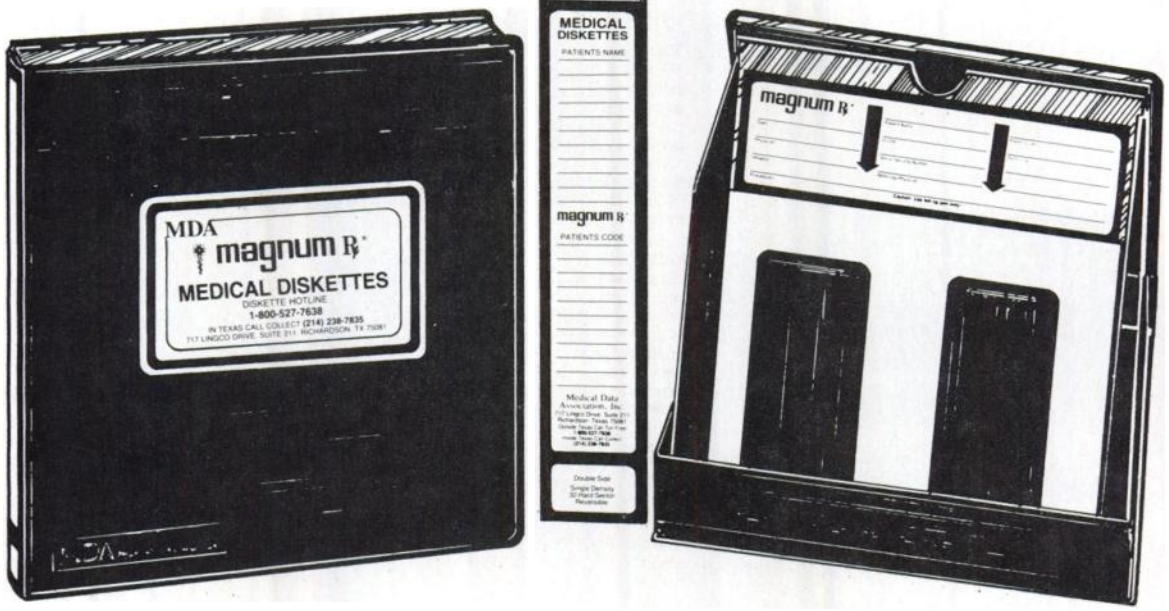

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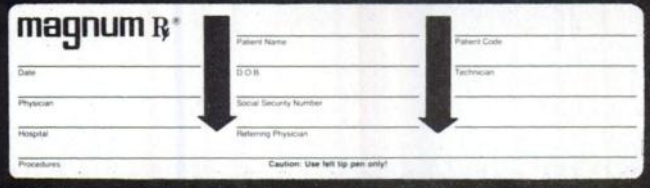

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NUCLEAR RADIOLOGIST. The Department of Radiology at The University of Florida College of Medicine is currently recruiting for the position of Section Chief of Nuclear Radiology Service at the Gainesville Veterans Administration Hospital, to begin January 1, 1984. Certification in Diagnostic Radiology desirable. One or more years additional training in nuclear radiology desirable. Instructor to Assistant Professor rank and salary subject to qualifications and experience. Application deadline is December 1, 1983. Contact Clyde M. Williams, MD, Chairman, Department of Radiology, University of Florida, Box J-374 JHMHC, Gainesville, FL 32610. An equal employment/affirmative action employer.

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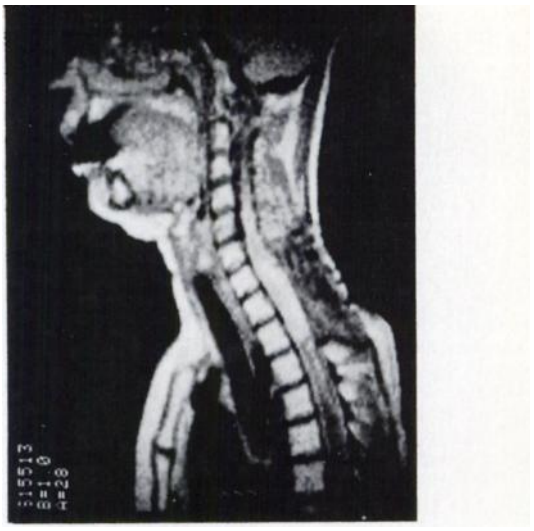

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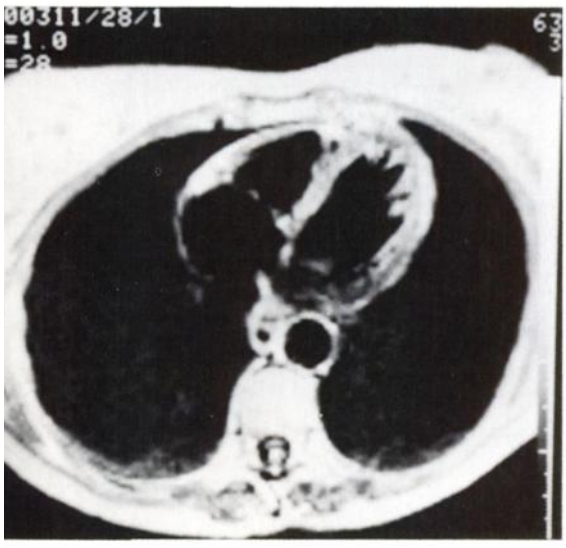

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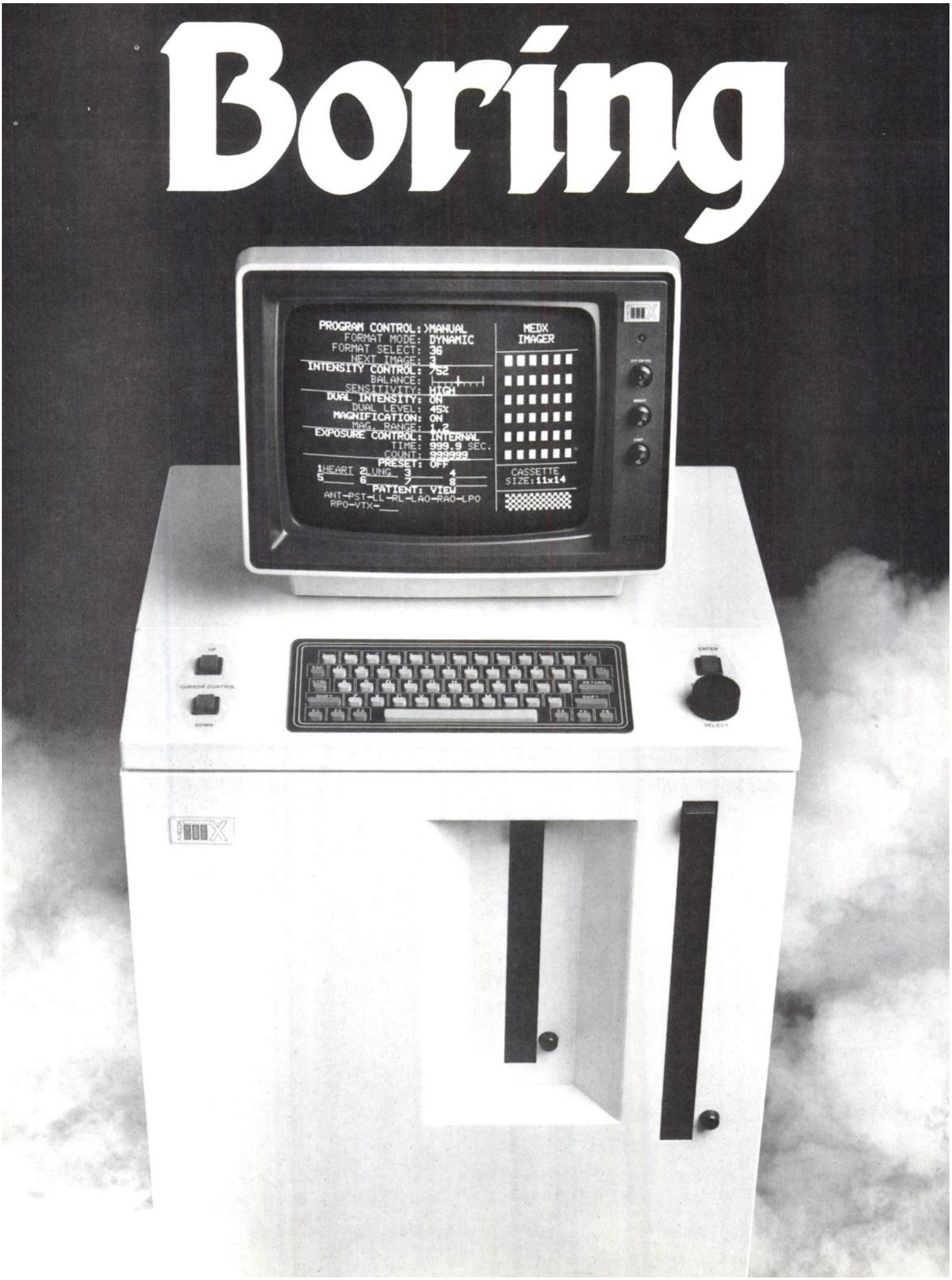
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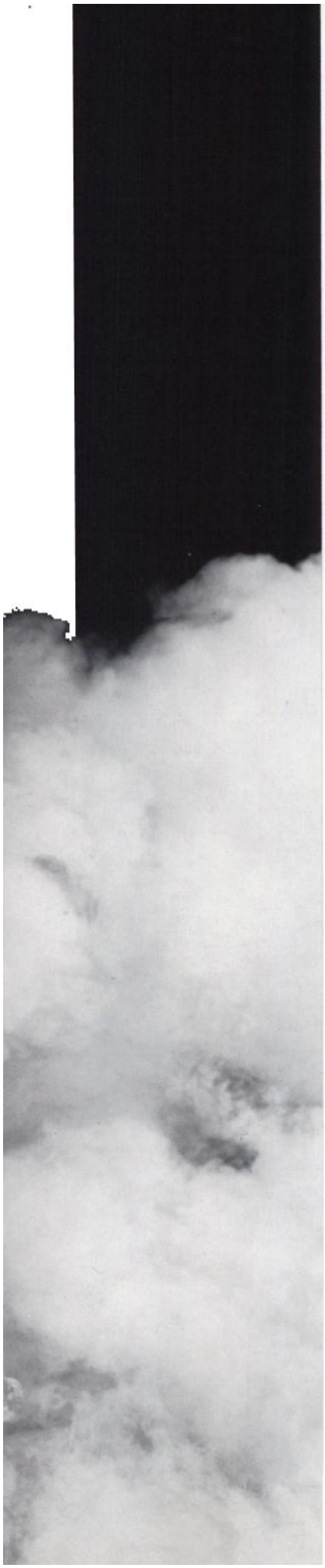

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