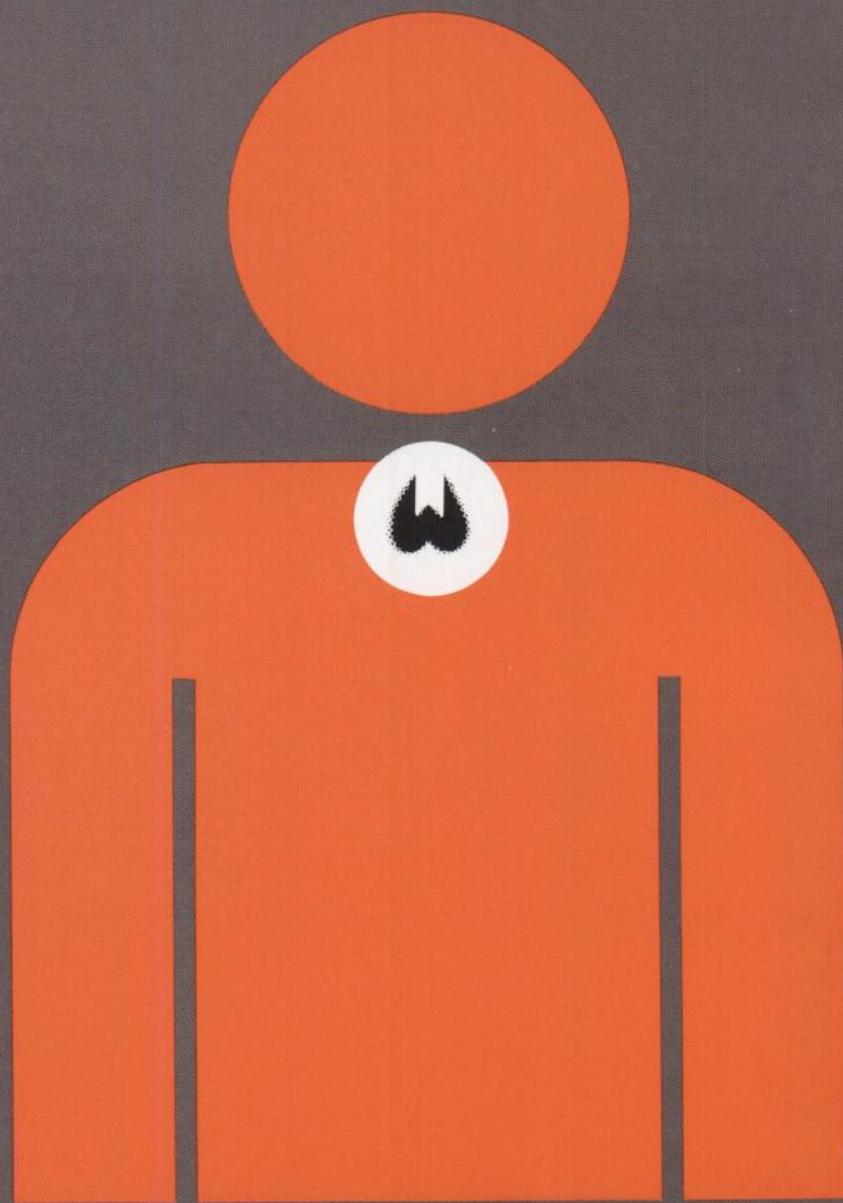


# Sodium Iodide I 123 for thyroid studies



medi+physics™

# One of the safest decisions you'll ever have to make...and as easy as 1,2,3.

Consider the benefits of MPI-Iodine-123 and your course of action becomes clear. Don't you and your patients deserve these important benefits?

## Greater patient safety because of reduced radiation absorbed dose.

Substitution of I 131 with MPI-Iodine-123 reduces the absorbed radiation dose more than 24 times to the thyroid gland.

**Compare:**

Maximal Thyroid Uptake %	Rads/100 $\mu$ Ci MPI-Iodine-123	Rads/100 $\mu$ Ci I 131
5	1.05	26.0
15	3.19	80.0
25	5.36	130.0

**High counting statistics.** MPI-Iodine-123 159 keV gamma rays are detected more than 3 times as efficiently on Anger-type cameras as the 364 keV gamma rays emitted by I 131. You get a higher count rate with MPI-Iodine-123 than with equivalent amounts of I 131 on gamma cameras. Therefore, scintiphotos can be obtained more rapidly.

**Images that demonstrate true thyroid function.** MPI-Iodine-123 is organified by the thyroid so images obtained will depict total thyroid function—not the trapping mechanism alone.

**You save money** when MPI-Iodine-123 is delivered with other Medi-Physics products. Your Medi-Physics representative will be glad to show you how you can receive MPI-Iodine-123 without delivery charges in certain areas. Call for full information about MPI-Iodine-123, our reliable shipping procedures and other products you can receive along with MPI-Iodine-123.

## Use the appropriate toll-free number:

Outside California 800-227-0483

Inside California 800-772-2446

**medi+physics™**

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

### SODIUM IODIDE I 123 CAPSULES AND SOLUTION FOR ORAL ADMINISTRATION DIAGNOSTIC

**DESCRIPTION:** Sodium iodide I 123 for diagnostic use is supplied as capsules and in vials as an aqueous solution for oral administration. At calibration time each capsule has an activity of 100 microcuries and each vial contains solution with a total specific concentration of 2 millicuries per ml at calibration time.

**INDICATIONS:** Sodium iodide I 123 is indicated for use in the diagnosis of thyroid function and imaging.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** This radiopharmaceutical should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses. However, when studies of thyroid function are clinically

indicated for members of these special population groups, use of I 123 would be preferable to the use of I 131 in order to minimize radiation dosage.

**PRECAUTIONS:** Sodium iodide I 123 as well as other radioactive drugs must be handled with care, and appropriate safety measures should be taken to minimize radiation exposure to the patient consistent with proper patient management. The prescribed I 123 dose should be administered as soon as practicable in order to minimize the fraction of radiation exposure due to relative increase of radionuclidic contaminants with time. The uptake of I 123 may be decreased by recent administration of iodinated contrast materials, by intake of stable iodine in any form, or by thyroid, anti-thyroid and certain other drugs. Accordingly, the patient should be questioned carefully regarding diet, previous medication, and procedures involving radiographic contrast media.

**ADVERSE REACTIONS:** There were nine adverse reactions reported in a series of 1,393 administrations. None of these were attributed to I 123. Five adverse reactions, consisting of gastric upset and vomiting, were attributed to a filler in the

capsule. Two cases of headache and a case of nausea and weakness were attributed to the fasting state. One case of garlic odor in the breath was presumed to be attributable to the presence of tellurium.

**DOSAGE AND ADMINISTRATION:** The recommended oral dose range for diagnostic studies of thyroid function in the average adult patient (70 kg) is from 100 to 400 microcuries. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Concentration of I 123 in the thyroid gland should be measured in accordance with standardized procedures.

**SPECIAL CONSIDERATION:** 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.

**HOW SUPPLIED:** Sodium iodide I 123 for oral administration is supplied in glass vials and in capsules.

# Hewed out of solid tradition

Searle's new Pho/Gamma V is a worthy addition to the proven Pho/Gamma scintillation camera series. Designed for the clinic or laboratory looking for cost-effective instrumentation, the Pho/Gamma V features the advanced, high-speed electronics of the Pho/Gamma LFOV in a standard field of view camera. It also offers a large assortment of parallel-hole, pin-hole, diverging-converging and spot-converging collimators.

#### EASE OF OPERATION

Like the Pho/Gamma LFOV, the Pho/Gamma V has eleven factory pre-set isotope windows for operator convenience. Automatic peaking assures remarkable reproducibility from study to study and from day to day.

#### TRIPLE PEAK CAPABILITY

Window width and energy level can also be set independently on 3 analyzers for unique isotopes and special studies. Thus, your facility can take full advantage of the diagnostic potential in multi-peak nuclides such as Gallium 67. This is especially important in soft-tissue studies where high sensitivity and superior resolution are vital.

#### IMPROVED ELECTRONICS

New ratio correction circuitry allows wider window widths, shortens study times and increases patient throughput. Other electronic innovations include pulse-pair pile-up rejection and event buffering circuitry. As a result, the Pho/Gamma V is capable of count rates up to 200,000 cps, which is sufficient for even highly specialized techniques such as dynamic cardiac studies.

#### INSTRUMENTATION BACKED BY SUPERIOR SERVICE

Searle Service is one of the largest, highly trained Service Organizations in the nation. This trained and knowledgeable group is dedicated to maintaining highest quality instrument performance in your laboratory.

The Pho/Gamma V is the most advanced standard field of view scintillation camera available today. Like other instruments in the famous Pho/Gamma line, it consistently delivers high quality images to give the physician maximum diagnostic support.

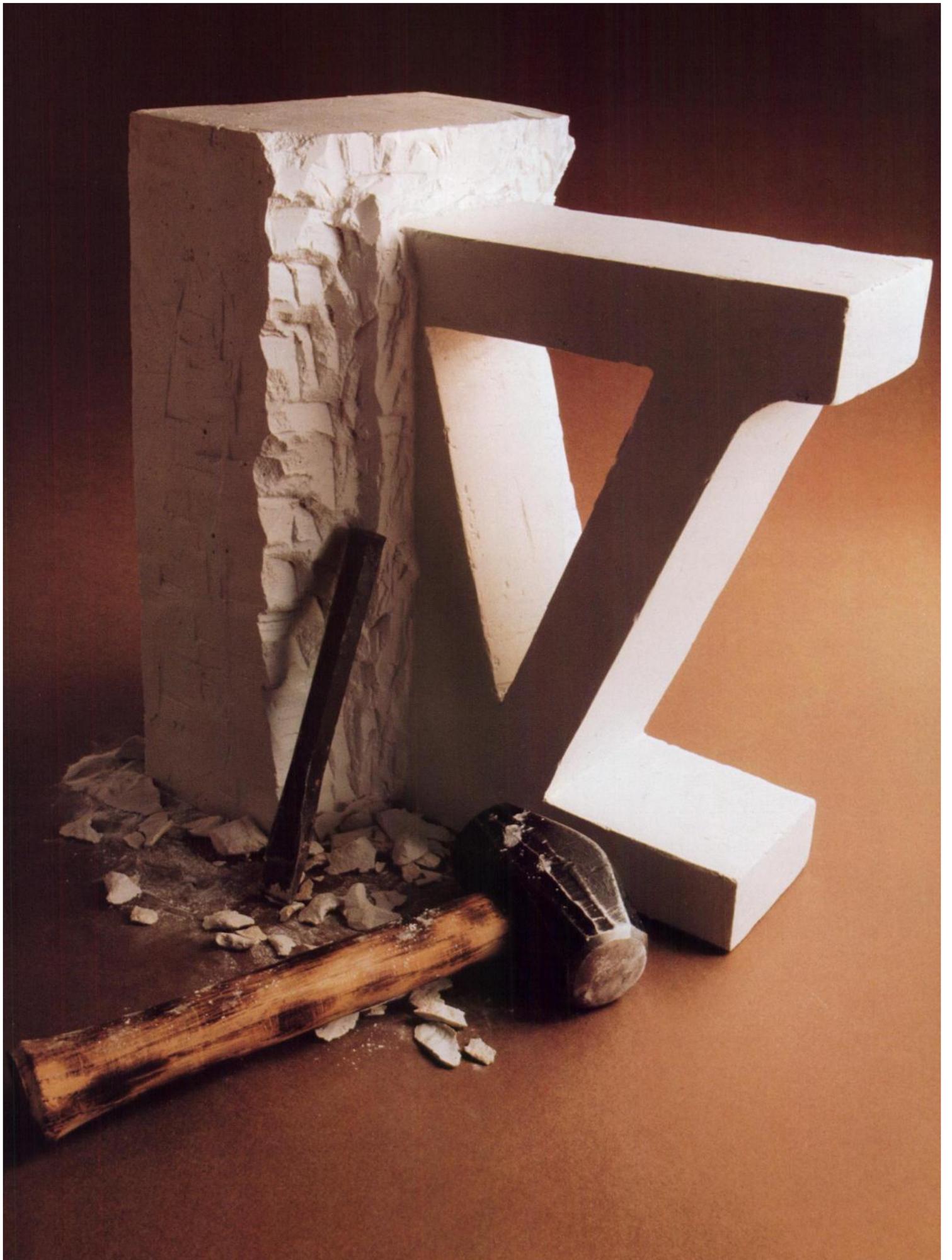
*For more information on the Pho/Gamma V system, including the unique Micro Dot™ Imager and Scintiscan™ Whole Body Table, call your Searle representative or write: Searle Radiographics, Inc., 2000 Nuclear Drive, Des Plaines, IL 60018. Telephone: (312) 298-6600.*

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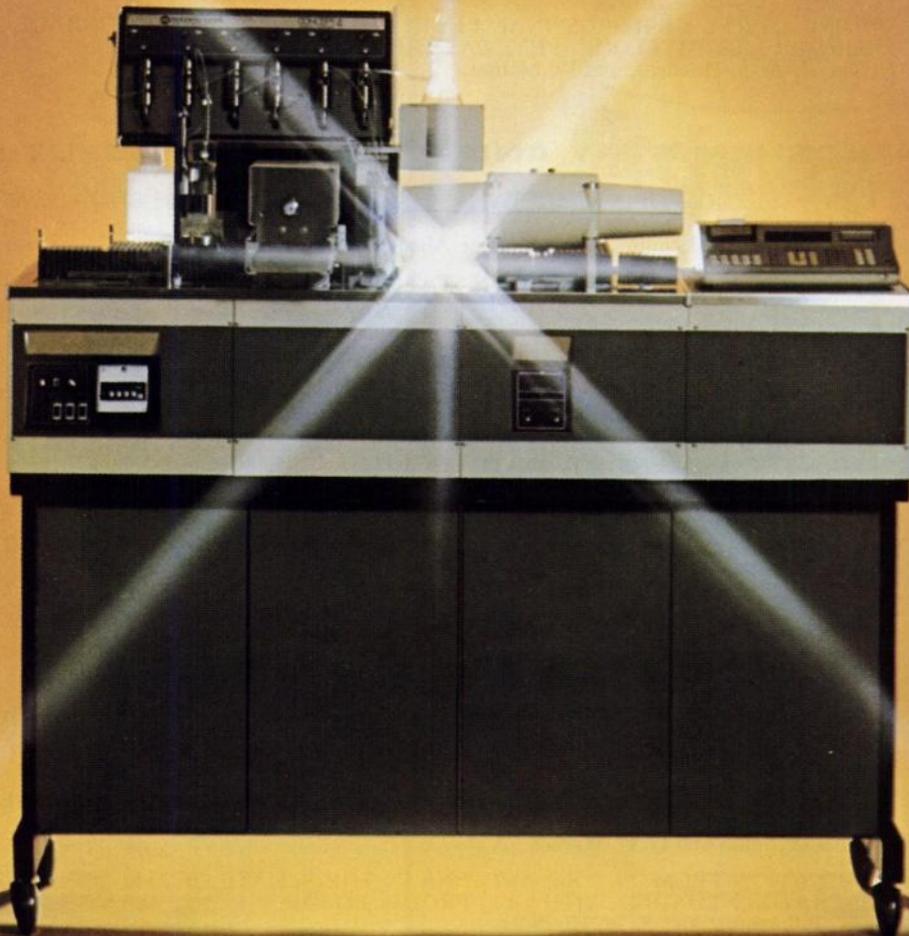
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easy - safe - rapid

To produce 99m Tc-labelled albumin particles  
for the perfusion scintigraphy. Maximum concentration in the lungs

**Storage:**

at room temperature up to 25°C

**Labelling kit:**

12 ml vial with tin-II-human  
albumin particles,  
lyophilized

**Specifications of the injection solution:**

Volume: 1-10 ml

Human albumin: 0.25-2.5 mg/ml

Sn<sup>2+</sup>: 0.0045-0.045 mg/ml

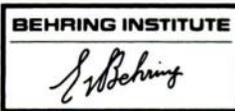
NaCl: 9.2-10.8 mg/ml

Technetium-99m: approx. 10<sup>-6</sup> mg/ml

pH: 5-6

Stability: approx. 8 hours

Content of 99m TcO<sub>4</sub><sup>-</sup>: < 1% of total activity.



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Europe: NEN Chemicals GmbH, D-6072 Dreieichenhain, W. Germany, Daimierstrasse 26, Postfach 1240, Tel: (06103) 85034.

# Advances in Plain Language Control of Data Systems from varicam

```

NEXT PROGRAM NAME ? DEF11
(VIEW, )ROI NUMBER ? 5,11
QUADRANT? 21

BUG READY...
NUMERIC TO MOVE BUG
SHIFT TO GO FAST
SPACE TO FIX POINT
OR TO CLOSE ROI

ROI INSIDE OR OUTSIDE LINE? 11
ROI INSIDE OR OUTSIDE LINE? 11
REPEAT? N1

NEXT PROGRAM NAME ? _

```

Interactive R.O.I. selection dialogue.

```

NEXT PROGRAM NAME ? DR011
ERASE ? N1
QUADRANT? 21
(VIEW, )ROI NUMBER ? 5,11
ROI NUMBER? 1
REPEAT? 1

NEXT PROGRAM NAME ? DISP1
VIEW NUMBER(,FIRST, LAST)? 11
BACKGROUND SUBTRACT ? 1
SATURATION LEVEL? 1
CYCLES OF GRAY? 1
ERASE ? 1
QUADRANT? 1
REPEAT? 1

NEXT PROGRAM NAME ? _

```

Display program dialogue.

```

NEXT PROTOCOL NAME? LIVER1
CURRENT PATIENT IS: ROBINSON-CRUSOE D SS56789
THIS PROTOCOL COLLECTS THREE STATIC VIEWS, THE FIRST
IS THE ANTERIOR, THE NEXT THE RIGHT LATERAL AND THE
LAST THE POSTERIOR.
NORMALISATION IS DONE WITH THE 'DIV' CORR. MTX.

STUDY NUMBER (12)? 127/741
NAME (30)? JONES D1
NUMBER (SS ETC) (14)? SS3451

CURRENT PATIENT IS: JONES D SS345
ADD, DELETE, LIST OR SELECT ? 1

NOW POSITION THE PATIENT SUPINE WITH THE LIVER AND
SPLEEN VISIBLE ON THE PERSISTENCE 'SCOPE.

TYPE CR TO GO ? 1
HIT SPACE BAR TO STOP EARLY
AGAIN, RESTART, KILL OR STOP? 31
VIEW NUMBER = 11; NUMBER OF MATRICES = 1

NOW POSITION THE PATIENT LYING ON THE LEFT SIDE.
TYPE CR TO GO ? _

```

Typical protocol control dialogue (customer prepared).

```

G = GENERATE PROTOCOL
R = RUN PROTOCOL
T = TAPE STORAGE OF DATA
S = SEARCH FOR DATA ON TAPE
M = NAME NEXT PROGRAM
U = USER PROGRAM DEVELOPMENT
L = LEAVE SYSTEM
H = HELP

ACTION? 1

NEXT PROGRAM NAME ? M0001
+ - * OR /? -1
FIRST VIEW
VIEW NUMBER(,FIRST, LAST)? 11
PERCENTAGE OF FIRST ? 561
SECOND VIEW
VIEW NUMBER(,FIRST, LAST)? 21
PERCENTAGE OF SECOND? 671
VIEW NUMBER = 71; NUMBER OF MATRICES = 1

NEXT PROGRAM NAME ? _

```

Matrix mathematical operations program dialogue.



VARICAM's operator dialogue is designed to require the minimum of operator initiative and expertise, whilst preserving flexibility.

In the manual mode of operation modules are specified in reply to the question "next program name?" These are named obviously such as "MXOP" for matrix operations or "ERASE" for erase. Subsequent parameters of operation are requested by VARICAM as required in plain language.

In the protocol mode, modules are chained together and fixed (or variable) parameters are specified. Protocols are used to automate routine workloads; the comment facility enabling the principle user to ensure that consistent procedures are used by all operators.

Ease of use is an extremely important factor often overlooked—at its least it can allow an expert user to work at optimum speed, at its best it can make the difference between a 'computer-lay' technician's enthusiasm or complete inability to drive the system at all.



varian radiation division  
611 Hansen Way, Palo Alto, California 94303, USA.  
Telephone (415) 493-4000

European Enquiries: Molesey Road, Walton-on-Thames, Surrey, England  
Telephone: (093 22) 28971 Telex: 261351

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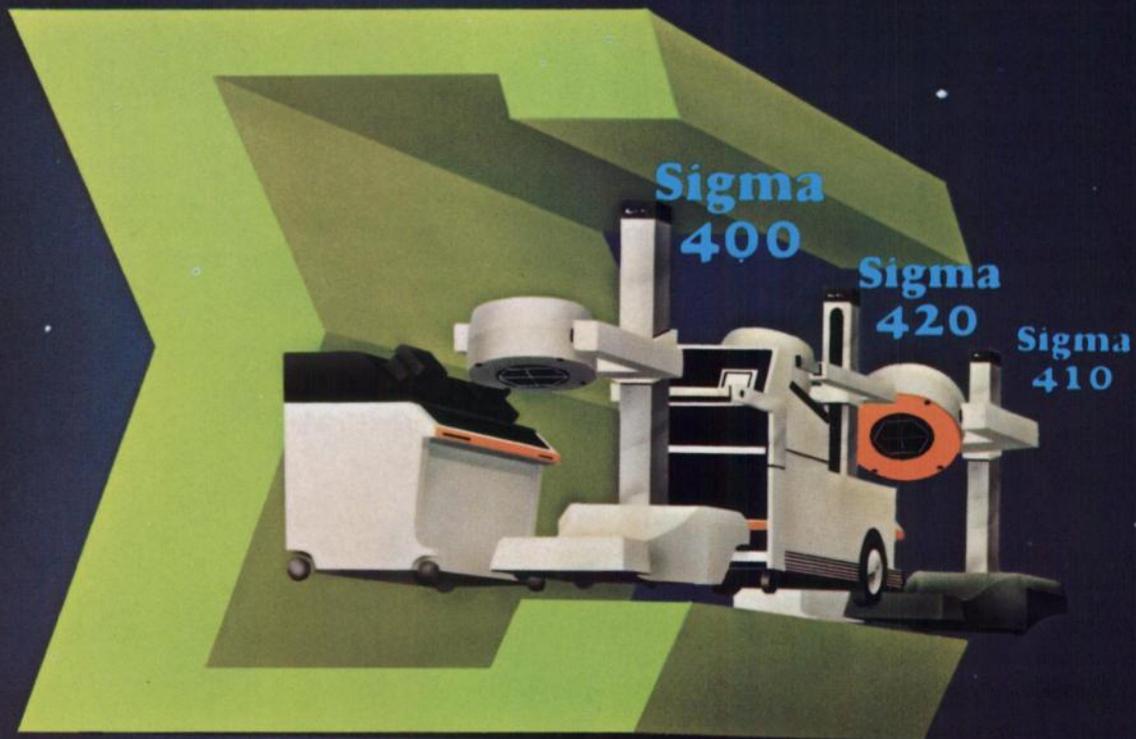
**Simple setup for increased throughput and optimized performance; and**

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# Designed for a new environment

## **MOBILITY AND FLEXIBILITY**

When movement of a critically ill patient is risky... but the diagnostic support of nuclear imaging is indicated, consider Searle's new Pho/Gamma L.E.M. Compact and maneuverable, the L.E.M. can easily be moved to the patient's environment in the emergency room, ICU or CCU where heart, lung, brain and renal studies can be done without compromising patient comfort and safety.

## **PROVEN ELECTRONICS**

The L.E.M. has the same high-speed electronics as Searle's proven Pho/Gamma LFOV. It has six factory pre-set isotope windows for operator convenience. Automatic peaking assures remarkable reproducibility from study to study and from day to day. Window width and energy level can be set independently on 2 analyzers for dual-peak isotopes and special studies.

## **INCREASED PATIENT THROUGHPUT**

New ratio correction circuitry allows wider window widths, shortens study times and increases patient throughput. Other electronic innovations include pulse-pair pile-up rejection and event buffering circuitry. As a result, the L.E.M. is capable of count rates up to 200,000 cps.

## **CHOICE OF COLLIMATORS**

The L.E.M. offers a wide selection of lightweight collimators for optimum resolution under any conditions. With its converging collimation capabilities, it offers significant improvement in resolution of deep-seated structures. Renal studies, for example, yield images of such clarity that it is possible to obtain even oblique views of diagnostic quality.

## **TAILORED FOR SPECIAL APPLICATIONS**

In heart imaging, the L.E.M. can be "gated" for systolic or diastolic studies, and the high count rate capability makes it suitable for advanced techniques such as dynamic cardiac imaging. The L.E.M. reveals midline brain lesions with unequalled clarity in static studies with the converging collimator. Parallel-hole and diverging collimation is used for large-area studies, such as lung imaging for pulmonary emboli.

## **INSTRUMENTATION BACKED BY SUPERIOR SERVICE**

Searle Service is one of the largest highly trained Service Organizations in the nation. This trained and knowledgeable group is dedicated to maintaining highest quality instrument performance in your laboratory.

*For more information about the Pho Gamma L.E.M., including sample studies, call your Searle representative or write: Searle Radiographics, Inc. 2000 Nuclear Drive, Des Plaines, IL 60018. Telephone: (312) 298-6600.*

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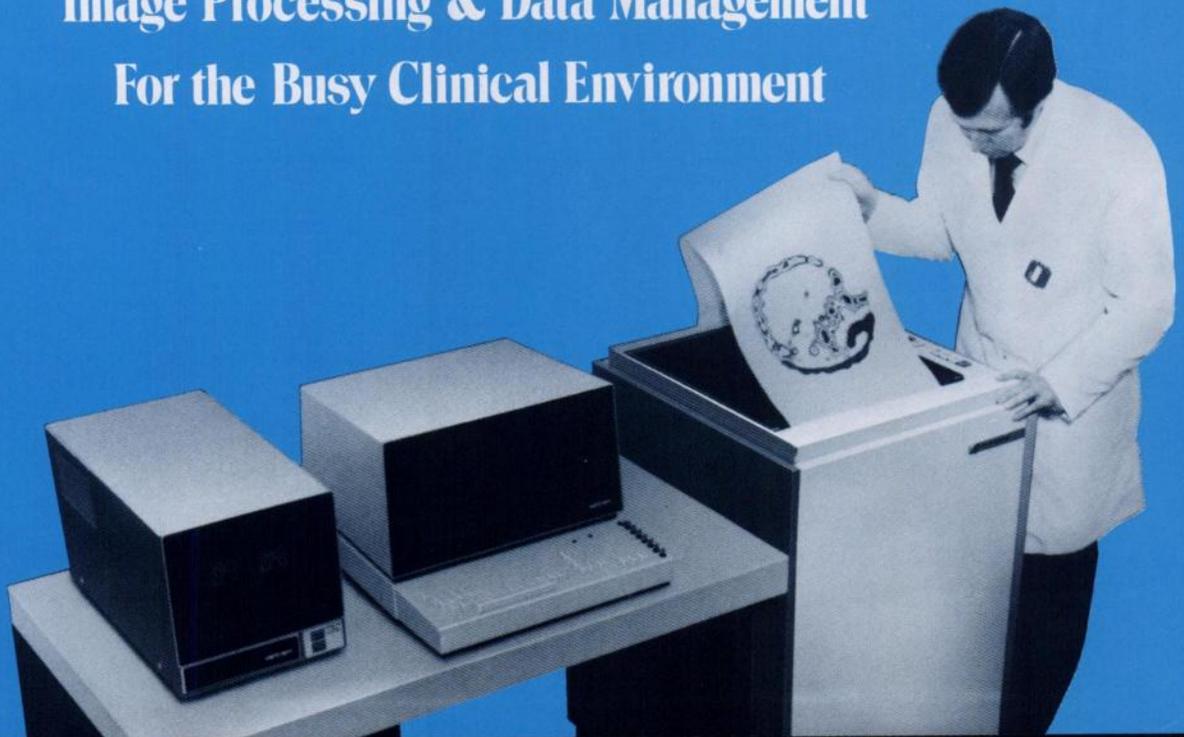
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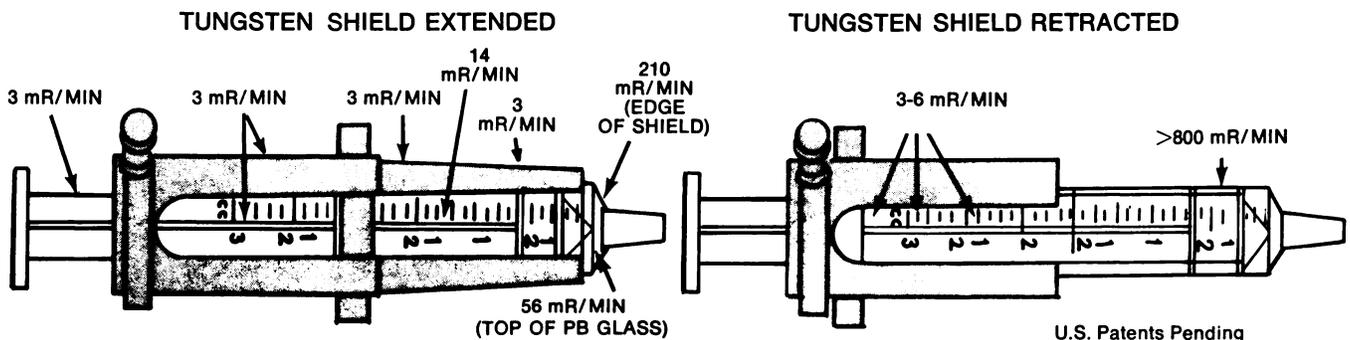
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\*CONCEIVED and DESIGNED BY: J. Howley, H. Tipton, A. Jones, M. Dickinson, M. Green, and G. Johnston. National Institutes of Health, Bethesda, Md.

SHIELDING PERFORMANCE CHART COMPLIMENTS OF: J. Howley, Radiation Safety Services, National Institutes of Health, Bethesda, Md.

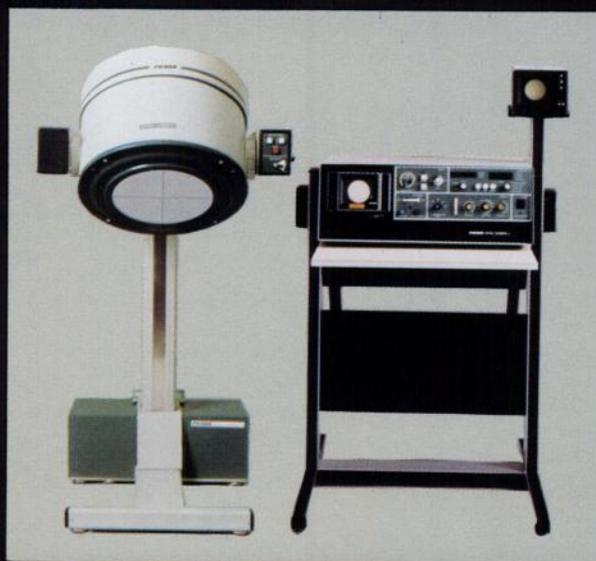
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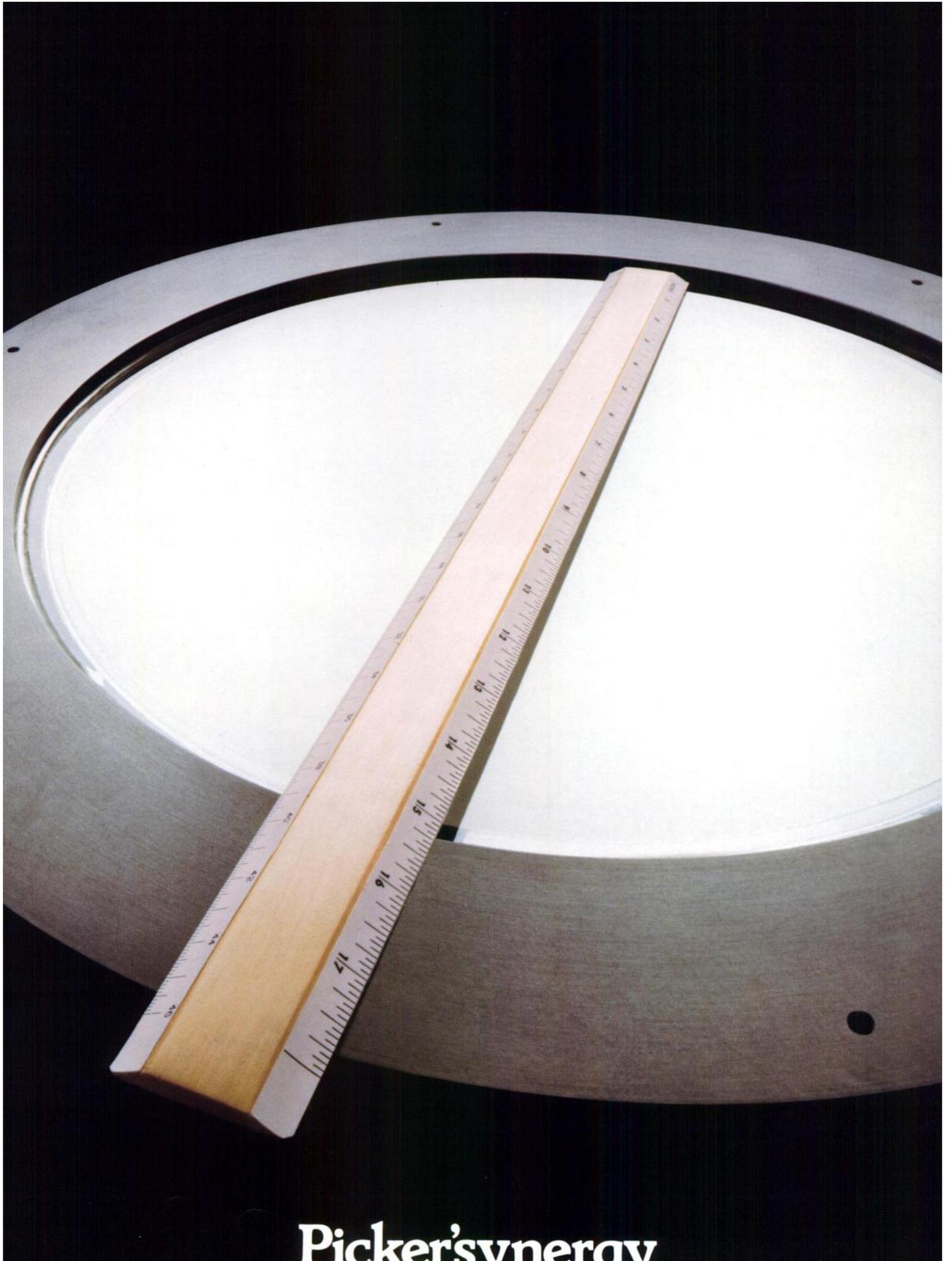
delivers the kind of results that today's clinicians demand.

This demonstrable quality of our nuclear capabilities is a result of what we call Picker's synergy — the complete interfacing of systems and services for improved diagnostic visualization.

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and M. DONALD BLAUFOX, M.D., Ph.D.

It is the aim of this volume to aid in an understanding of ultrasound techniques and how they may relate to nuclear medicine procedures in diagnosing a patient's problem. A knowledge of the capabilities and limitations of each method should help the clinician to utilize them with optimal results.

An introductory article on ultrasound methodology provides a clear orientation. Two separate articles extensively review the applications of echocardiography to congenital and acquired heart disease. Throughout the book, correlation with radionuclide studies is presented, where applicable.

1976, 176 pp., illus., \$13.50/£8.25  
ISBN: 0-8089-0968-1

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by CHARLES H. MANDELL, M.D.

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Among the outstanding features of this new work are: first lung scan atlas utilizing gamma camera images; first anatomic models of lung segments specifically illustrating segmental scan architecture in an easily indexed section; use of six views to illustrate normal and pathologic entities, with visual demonstration of frequent superior images utilizing this expanded technique; multiple tables outlining the common range of disease entities producing various specific scan patterns.

1976, 208 pp., illus., \$28.00/£17.10  
ISBN: 0-8089-0960-6

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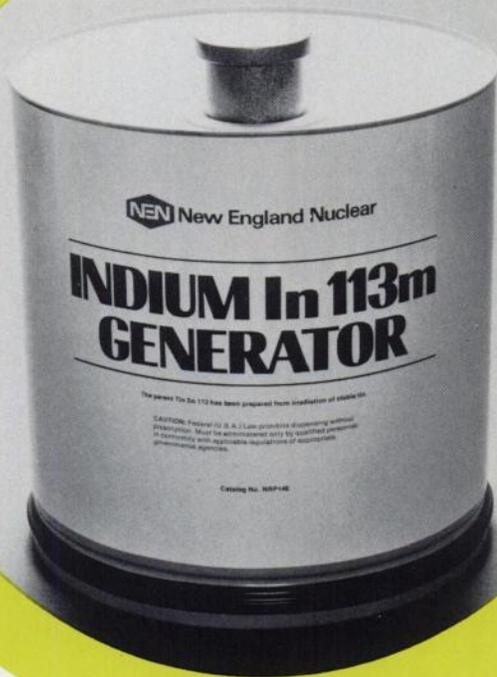
Your results tell you how good we make it

You might guess from our name that we're in the business of providing products used in diagnostic evaluation. But only the quality of the images you obtain will tell you how well we make them.

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Just place the vial on the elution needle.

The sterile, pyrogen-free Indium 113m is automatically drawn from the generator.

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Quality assured – pretested for sterility, pyrogenicity, Tin Sn 113 breakthrough, zirconium ion and flow characteristics.

Each generator contains a 0.22 micron final filter.

**Indications:** Ionic Indium Chloride In 113m eluted from the NEN Indium In 113m Generator may be used directly as a blood pool imaging agent or as the radioactive label in the synthesis of other Indium In 113m radiopharmaceuticals.

**Contraindications:** Radiopharmaceuticals containing Indium In 113m should not be used in patients with a history of allergy to such agents.

**Warnings:** Indium Chloride In 113m should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceutical drug products, especially those elective in nature of a woman of childbearing capability should be performed during the first few (approximately ten) days following the onset of menses.

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

**Precautions:** In order to assure the sterility and non-pyrogenicity of the eluate, the Generator must be eluted according to the operating instructions. It is essential that the user adhere to strict aseptic procedure. The eluate should be crystal clear and any eluate appearing hazy or containing particulate material should not be used. Testing of the eluate for tin breakthrough and zirconium breakthrough should be performed after each elution. Periodic recertification of the sterility of the eluate is recommended beginning two (2) weeks after the calibration date.

Indium Chloride In 113m is eluted in acid solution. Therefore, slow intravenous injection over at least 30 seconds of no more than 1.0cc is advised. Indium In 113m remains in solution at a pH below 3.0; raising the pH above that level results in the formation of a colloidal hydroxide.

Each patient dose should be determined by a suitable radioactivity calibration system immediately prior to administration.

**Adverse Reactions:** To date, no adverse reactions based on the use of this agent have been reported. However, several reports have been published documenting the occurrence of transient hypotensive episodes after prolonged patient recumbency for placental imaging. This is probably due to physiologic compression of the inferior vena cava by pelvic contents and has been completely reversible spontaneously without the necessity for pharmacologic intervention.

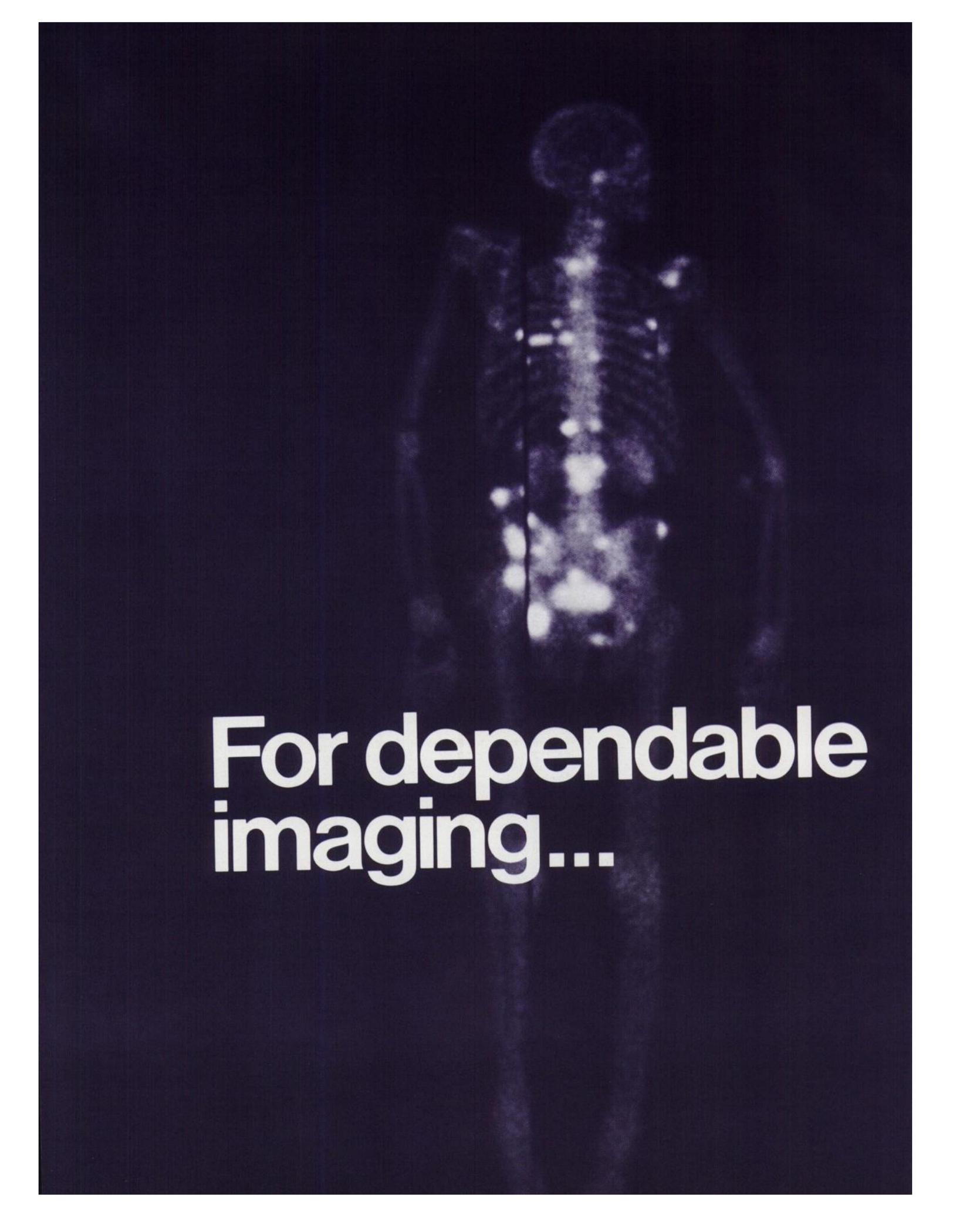
**Dosage and Administration:** Ionic Indium Chloride In 113m is administered intravenously for blood pool imaging. The suggested dose for the average 70 kg patient is 0.5-4.0mCi and imaging can be performed within minutes after injection.

Indium Chloride In 113m can also be incorporated into radiopharmaceuticals according to procedures determined and approved by each user institution to assure sterility and non-pyrogenicity of the final product.

**How Supplied:** The NEN Indium In 113m Generator is available with column loadings of 5mCi to 100mCi of Tin Sn 113 on the day of calibration, yielding sterile, non-pyrogenic In 113m as the chloride upon elution. Expiration date is 6 months after calibration.

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**For dependable  
imaging...**

Dependable imaging of skeletal lesions —that's what bone scanning is all about. And that's what the unique, dry-mix formulation and stable PCP bond of Osteoscan assure. Osteoscan's diphosphonate formulation, when labeled with  $^{99m}\text{Tc}$ , provides:

- dependably high tagging efficiency
- rapid blood and soft tissue clearance to assure high target-to-nontarget ratio
- excellent in vivo stability
- low tin level—to minimize the potential for liver uptake and interference with subsequent brain scans

For further information about Osteoscan, please contact: Arnold Austin, Technical Manager, Professional Services Division, Procter & Gamble (513) 977-8547.

# the dependable diphosphonate



PROCTER & GAMBLE

# OSTEOSCAN<sup>®</sup>

(5.9MG DISODIUM ETIDRONATE, 0.16MG STANNOUS CHLORIDE)

SKELETAL IMAGING AGENT

In Europe, contact: Philips-Duphar B.V.,  
Cyclotron and Isotope Laboratories, Petten, Holland.



PROCTER & GAMBLE

# OSTEOSCAN<sup>®</sup>

(5.9MG DISODIUM ETIDRONATE, 0.16MG STANNOUS CHLORIDE)

SKELETAL IMAGING AGENT



## PRODUCT INFORMATION

Before using, please consult the full Package Insert included in each kit.

## DESCRIPTION

Each vial of OSTEOSCAN contains 5.9 mg disodium etidronate and 0.16 mg stannous chloride as active ingredients. Upon addition of ADDITIVE-FREE <sup>99m</sup>Tc-pertechnetate, these ingredients combine with <sup>99m</sup>Tc to form a stable soluble complex.

## ACTIONS (CLINICAL PHARMACOLOGY)

When injected intravenously, <sup>99m</sup>Tc-labeled OSTEOSCAN has a specific affinity for areas of altered osteogenesis. Areas of bone which are undergoing neoplastic invasion often have an unusually high turnover rate which may be imaged with <sup>99m</sup>Tc-labeled OSTEOSCAN.

Three hours after intravenous injection of 1 ml <sup>99m</sup>Tc-labeled OSTEOSCAN, an estimated 40-50% of the injected dose has been taken up by the skeleton. At this time approximately 50% has been excreted in the urine and 6% remains in the blood. A small amount is retained by the soft tissue. The level of <sup>99m</sup>Tc-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques.

## INDICATIONS

OSTEOSCAN is a skeletal imaging agent used to demonstrate areas of altered osteogenesis.

## CONTRAINDICATIONS

None.

## WARNINGS

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

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

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

The <sup>99m</sup>Tc-generator should be tested routinely for molybdenum breakthrough and aluminum. If either is detected, the eluate should not be used.

## PRECAUTIONS

Both prior to and following <sup>99m</sup>Tc-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the <sup>99m</sup>Tc-labeled OSTEOSCAN injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

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

## ADVERSE REACTIONS

None.

## DOSAGE AND ADMINISTRATION

The recommended adult dose of <sup>99m</sup>Tc-labeled OSTEOSCAN is 1 ml with a total activity range of 10-15 mCi. <sup>99m</sup>Tc-labeled OSTEOSCAN should be given intravenously by slow injection over a period of 30 seconds within eight (8) hours after its preparation. Optimum scanning time is 3-4 hours postinjection.

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

## SETHOTOPE<sup>®</sup> Selenomethionine Se 75 Injection

Sethotope (Selenomethionine Se 75 Injection) is a sterile, nonpyrogenic, aqueous solution of L-selenomethionine providing a specific activity of not less than 25 microcuries per mcg. of selenium at the time of manufacture. The product also contains not more than 3 mg. L-methionine as a carrier, not more than 12 mg. 2-aminoethanethiol as an antioxidant, sodium chloride for isotonicity, and 0.9% (w/v) benzyl alcohol as a preservative.

**CONTRAINDICATIONS:** At present, there are no known contraindications to the use of Selenomethionine Se 75 Injection.

**WARNINGS:** This radiopharmaceutical should not be administered to patients who are pregnant or who may become pregnant or during lactation unless the information to be gained outweighs the possible potential risks from the radiation exposure involved.

The transplacental transport and long biologic half-time of this agent may result in significant radiation exposure to the fetus. Since selenomethionine <sup>75</sup>Se is excreted in milk during lactation, formula-feedings should be substituted for breast-feedings.

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.

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

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

Fasting prior to administration may enhance the hepatic uptake of the agent which may result in degradation of pancreatic image quality.

**ADVERSE REACTIONS:** At present, adverse reactions have not been reported following administration of Selenomethionine Se 75 Injection.

For full prescribing information, consult package insert.

**HOW SUPPLIED:** Sethotope (Selenomethionine Se 75 Injection) is available in multiple dose vials in potencies of 0.25 millicurie, 0.5 millicurie, and 1 millicurie. Complete assay data for each vial are provided on the container.



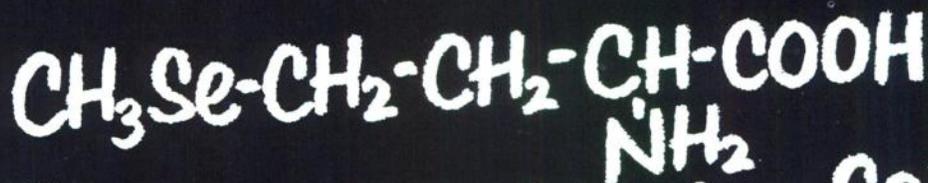
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E. R. Squibb & Sons, Inc.  
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Princeton, N.J. 08540

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# For pancreas imaging

# Sethotope<sup>®</sup>

## Selenomethionine Se 75 injection



**(L)** selenomethionine Se 75  
*Biosynthetic*

### High pancreas specificity

Selenomethionine is a structural analog of the amino acid, methionine, in which the selenium has been substituted for the sulfur atom. Chemically and biologically, they behave alike, including a relatively high degree of uptake in the pancreas during protein synthesis.

### Levorotatory compound

Radioactive selenomethionine can be produced in racemic form by chemical synthesis from <sup>75</sup>Se. At Squibb, however, selenomethionine is prepared *biosynthetically* by extracting it from the protein product of yeast grown on a low sulfur medium containing <sup>75</sup>Se of high specific activity. This compound is levorotatory.

### Specific activity

Squibb L-selenomethionine <sup>75</sup>Se provides a specific activity of not less than 25 microcuries per microgram of selenium at the time of manufacture.

**Sethotope<sup>®</sup>**  
**Selenomethionine Se 75**  
**Injection**

See opposite page for brief summary.



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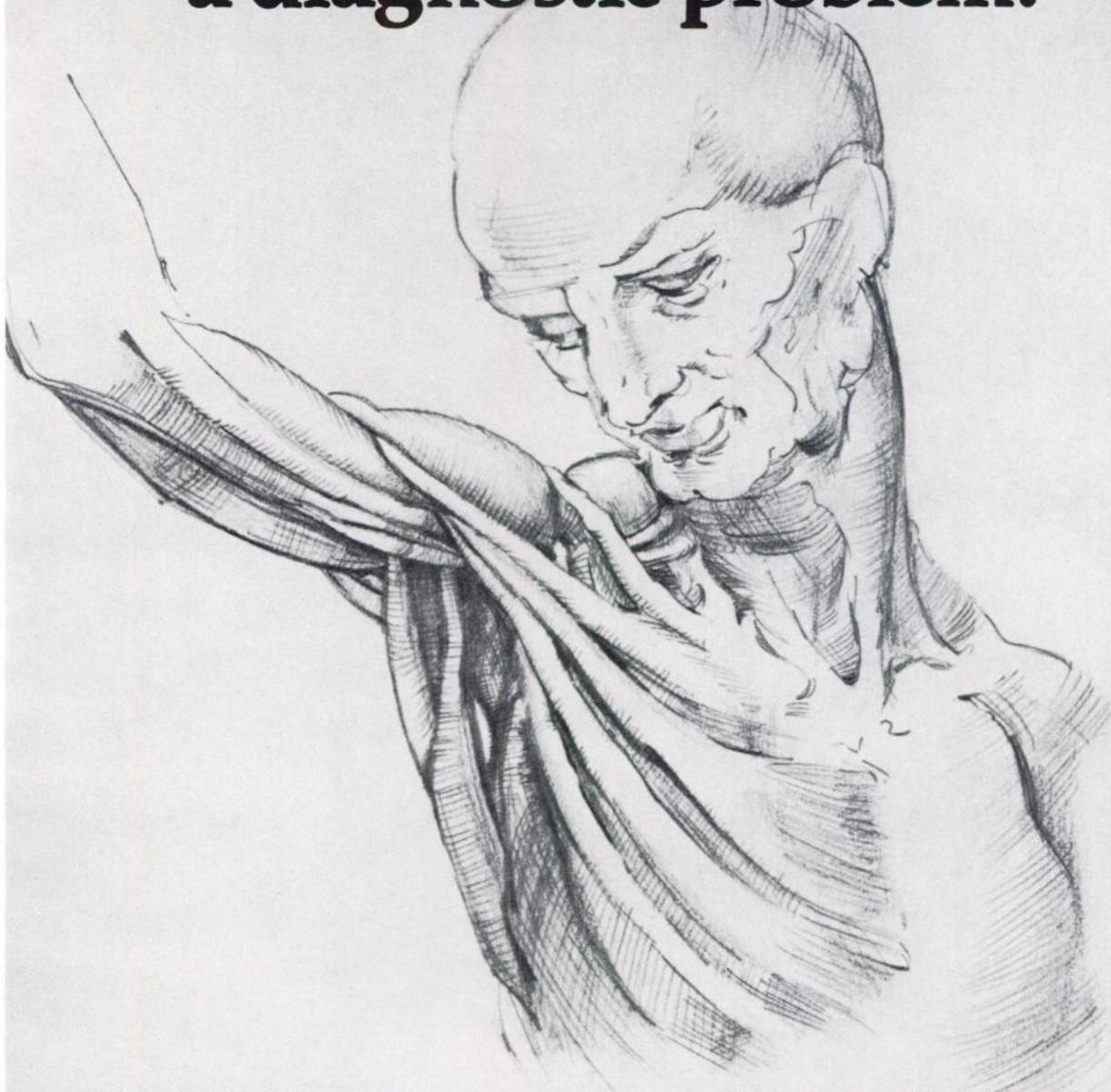
***“...with whole-body scans taking over more of the nuclear imaging load, Cleon is the clear choice.”***



**cleon**

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# Rheumatic diseases: a diagnostic problem?



Diagnosis of individual rheumatic diseases can present problems. Our simple test, the anti-DNA Kit, can give vital information to aid that diagnosis.

The kit provides the first standardized assay to consistently and reliably measure anti-DNA antibodies. High circulating levels of these antibodies are closely linked with systemic lupus erythematosus (SLE). In doubtful cases, the kit offers excellent discrimination

between SLE and rheumatoid arthritis and is particularly valuable as a follow-up to ANF tests. Results show that the kit is also useful as a means of monitoring disease activity, providing the physician with guidance on drug therapy.

The kit is a simple radioassay – a matter of routine for any clinical laboratory with a gamma counter. Please write or 'phone for further information.

## Anti-DNA kit



**Amersham/Searle**  
AMERSHAM / SEARLE CORPORATION:  
An Activity of G. D. Searle & Co. and the Radiochemical Centre

Product described in '76 CLR page 213.

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Telephone: Toll free: 800-323-9750 – Telex: 28-2452  
In Illinois, Alaska, Puerto Rico, & Hawaii: 312-593-6300  
400 Iroquois Shore Road/Oakville, Ontario  
Telex: 069-82286 – Telephone: 416-844-8122

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*The GE commitment to nuclear medicine:  
complete equipment, software and service.*

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## GE: new ideas solve nuclear needs.

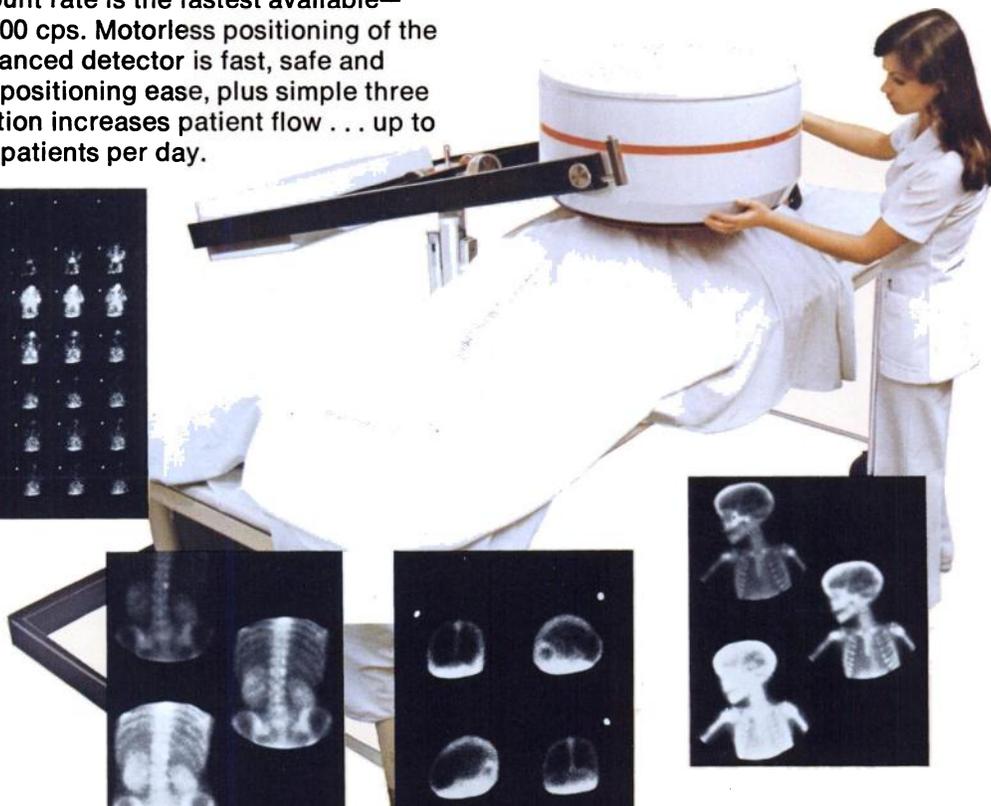
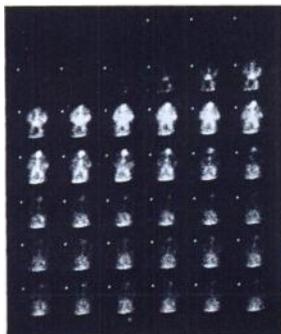
Innovative systems are needed to meet the many needs of today's nuclear departments. That's why GE has combined new product ideas with proven concepts to provide the latest in nuclear capability.

### **MaxiCamera system: largest field of view delivers unprecedented image quality.**

MaxiCamera™ system's 400 mm field of view—the largest of any scintillation unit—offers nuclear departments important new advantages. The big field allows imaging of both lungs at the same time—reducing lung study time by more than 30%. Large livers can also be imaged rapidly and easily. MaxiCamera system handles whole body scanning, yet the unit requires only a 6 x 12 foot area. Image quality is outstanding, with 18% to 40% more resolution elements than other large detector cameras. The unmatched intrinsic resolution is better than 3.2 mm. Count rate is the fastest available—up to 200,000 cps. Motorless positioning of the counterbalanced detector is fast, safe and quiet. This positioning ease, plus simple three step operation increases patient flow . . . up to 50% more patients per day.

### **GE Formatter system: records much faster with no data loss.**

During dynamic studies, valuable diagnostic information may be lost if the formatter cannot keep pace with the camera. Now General Electric offers a formatter that records data as fast as the camera detects it, with no data loss. GE Formatter system records up to 10 frames per second . . . many times faster than any other unit. This makes the GE Formatter the system of choice for dynamic studies. You can record up to 42 dynamic images on one 8 x 10 film, using economical, standard photographic cassettes. Standard multiple formats are available: 35, 70 and 105 mm. Valuable floor space is conserved because all formatter and camera controls are combined in one compact cabinet, occupying just 4½ square feet.





### **PortaCamera system: nuclear department on wheels.**

This compact, mobile scintillation unit is easily wheeled throughout the hospital to facilitate studies on immobile patients. The PortaCamera™ system weighs less than 1,000 lbs., about half the weight of most other portable cameras. The counterbalanced detector allows fast, precise positioning at a touch. A conveniently located, integral console includes all controls and oscilloscope. Easy two-step operation increases patient throughput potential. PortaCamera system also serves as an excellent, low-cost backup unit for ICU, CCU, surgery and emergency rooms.



### **GE computer capability improves diagnostic data.**

Med II™ is a complete image processing and data analysis system. It allows the physician to use the latest GE computer capability to maximize diagnostic information. The Med II system is a second-generation, push-button

operated unit with a comprehensive library of nuclear medicine programs: left ventricular ejection fraction, left to right shunt, cardiac output, renal function, gated blood pool studies, ventricular volume, and many more. Combined, the Med II, MaxiCamera and GE Formatter units provide the most powerful nuclear diagnostic system available today.

MedStor™ is a moderately priced image storage and processing system which can be used with any scintillation camera, including the PortaCamera. The MedStor system provides computer-controlled playback of static and dynamic data, allows selection of up to four regions of interest, and simultaneously generates up to 4 time/activity histograms. The system is pre-programmed, with easy-to-operate push-button control. Image information can be accessed as rapidly as 6 images per second.

### **Nuclear parts and service in 8 hours or less.**

When your nuclear equipment needs service, GE will provide parts and professionals . . . fast. Our highly trained nuclear service specialists are strategically located throughout the country. One is located near you, for fast response. And General Electric has developed a new computerized parts inventory system. This new service links over 30 GE parts depots nationwide, and keeps them fully stocked at all times. You receive parts from the nearest depot, usually within 8 hours. Transportation costs are minimized, and your nuclear equipment is back serving patients sooner.

Unmatched equipment; the latest diagnostic software; and prompt, reliable service: that's the GE commitment to nuclear medicine. Find out how that commitment can benefit your department. Talk to your GE representative about the systems shown here and our full line of nuclear equipment.

General Electric Medical Systems,  
Milwaukee, Toronto, Madrid.

# **GE: for the newest in nuclear.**

**GENERAL  ELECTRIC**

# NEW IMPROVED SIMPLIFIED

## [<sup>57</sup>Co] VITAMIN B<sub>12</sub>    [<sup>125</sup>I] FOLATE RADIO ASSAY KITS

	<sup>57</sup> Co Vitamin B <sub>12</sub>	<sup>125</sup> I Folate
<b>FEATURING:</b>		
• SUPERSENSITIVITY	33 pg	0.1 ng
• LINEAR RANGE	100 - 2,400 pg/ml	1 - 32 ng/ml
• TOTAL INCUBATION TIME	45 minutes	45 minutes
• PRECISION (within-run) C.V.	3.5%	3%
• PRECISION (run-to-run) C.V.	6%	7%

- LINEAR PLOT (log-logit paper provided)
- SEPARATION BY CHARCOAL-DEXTRAN *TABLET*
- PRE-MEASURED INDIVIDUAL CALIBRATORS
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T-3 RIA	[ <sup>3</sup> H] Cortisol RIA
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[ <sup>3</sup> H] Aldosterone (no Chromatography)	[ <sup>125</sup> I] Gentamicin RIA
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## Diagnostic Products

CORPORATION

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# **POWERTROL Instrument Power Protection!**



**POWERTROL** was designed to protect electronic equipment from power line fluctuations. Intermittent loss of power, brown-outs, emergency power change over, and normal power company line transients can seriously damage electronic equipment.

**POWERTROL** will render immunity to your equipment. Simply plug **POWERTROL** into any AC outlet and forget about potential power related failures.

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# Count on it.



# Gammacord II<sup>®</sup>

**Gammacord II System:** Multi-isotope gamma counter with optional automated printer and sample handler. **Central Processing Unit:** 6 preset windows for commonly used gamma emitters, variable window to read any isotope in 15 to 2,000 KEV range; sequenced "memory" for up to 50 samples; direct readout in CPM and % retention; automatic background subtraction; counts for preset time or accuracy level. **Automatic Printer:** gives hard-copy results: ID number, % retention, CPM and % CV for each sample. **Automatic Sample Handler:** up to 50 samples per interchangeable carousel; self-contained drainage; easily accessible external mechanism.

Available for purchase or rental directly from Ames Company.

**Ames Company**  
Division Miles Laboratories, Inc.  
Elkhart Indiana 46514  
In Canada: 77 Belfield Rd., Rexdale, Ontario



**Need a lot of gamma counting? Need a little?  
Expanding your capacity? This is the only modular  
system you can tailor to handle *your* work load.**

**The Ames Gammacord II does everything the  
more expensive counters can do ... and less. So, you're  
never locked into *more* automation than you need.**

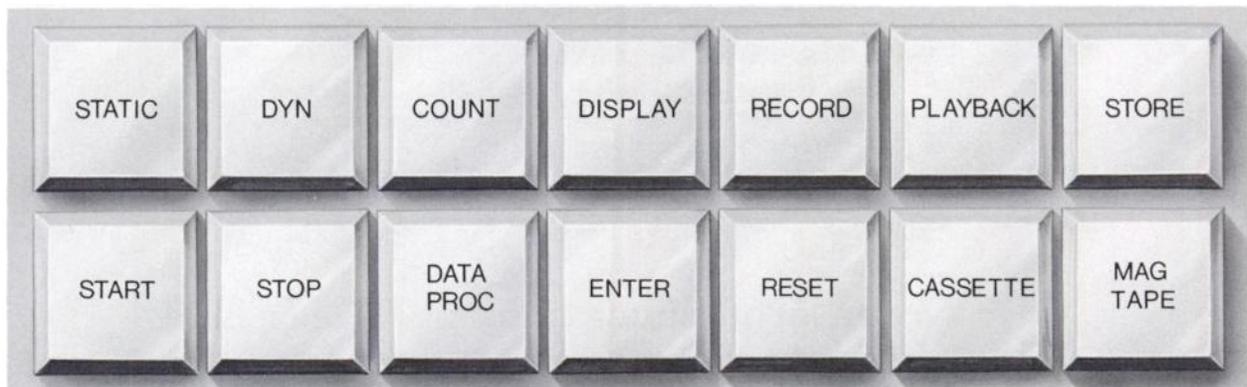
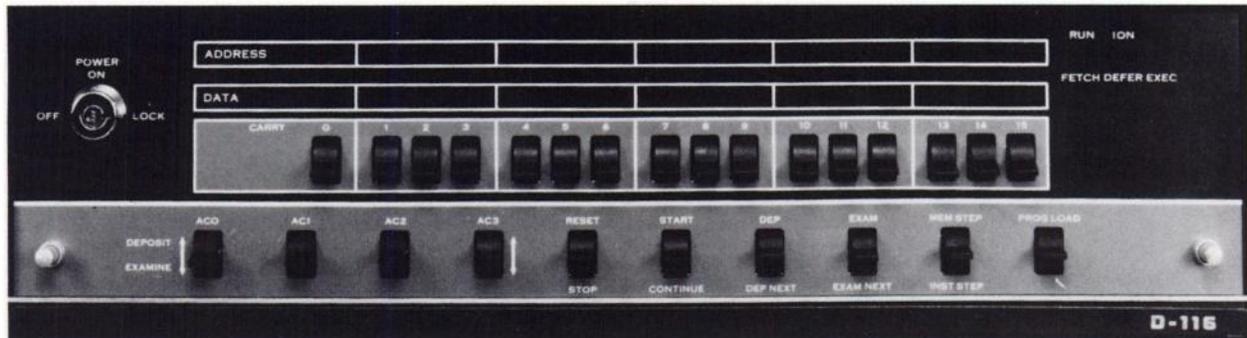
**Versatile. Sophisticated. Compact. Easy to operate.  
Gammacord II can "grow" with the small and medium-  
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# SEVENTY SEVEN REASONS:

**2. A gamma camera system with a simple-to-use, integral computer incorporating the most comprehensive software programs in nuclear medicine.**



**Consider:**

- System Seventy Seven is the result of ten years of development in perfecting a computerized gamma camera.
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**SYSTEM SEVENTY SEVEN** provides the user with the speed, power and versatility of a computer with the pushbutton ease of operation of a pocket calculator; in fact, it improves on the pocket calculator by back-lighting only those buttons which are subsequent legitimate operations. Its software program library implements complex computer operations, relieving the operator of plugging, time-consuming routines. Time is left for medicine. The back-lighted pushbuttons activate the respective computer software; thus providing rapid, easy computerized manipulation of clinical data without sacrificing the user's decision-making flexibility and integrity.

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# **NEW... automatic**

# **XDS**

## **(Xenon Delivery System)**

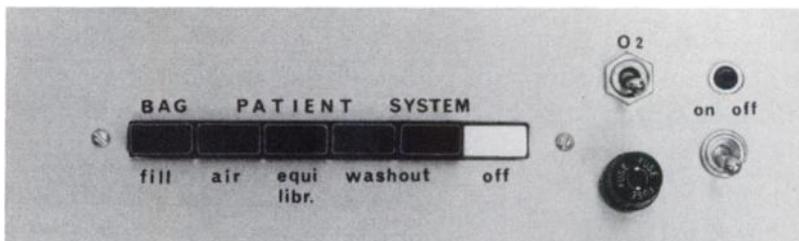
**For the busy department that demands operating ease, speed and efficiency in ventilation and perfusion studies using any radioactive xenon**



- Push-button control.
- All functions facilitated by two internal blowers.
- Resistance-free patient breathing.
- Uses 20-liter breathing bags in fully-shielded chamber.
- Accepts any radioactive xenon ...  $^{133}\text{Xe}$ ,  $^{127}\text{Xe}$ ,  $^{125}\text{Xe}$ .

XDS makes lung function studies easier for both the patient and the technologist. With "up-front" push-button controls and two internal blowers doing the work, the patient enjoys resistance-free breathing; the technologist has full control of each programmed function at his fingertips. Studies are fast, efficient and effortless.

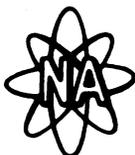
**XDS—** the system with the versatility and performance features of more-expensive systems.



### **Control Panel**

Each programmed function is controlled by two in-system blowers which are independent of the patient's breathing efforts. From "Fill" to "System Washout" the blowers automatically balance the breathing circuits, providing resistance-free patient breathing and complete system clearance.

For full details,  
write for Bulletin 217-B



**NUCLEAR ASSOCIATES, INC.**  
Subsidiary of  
**RADIATION-MEDICAL PRODUCTS CORP.**

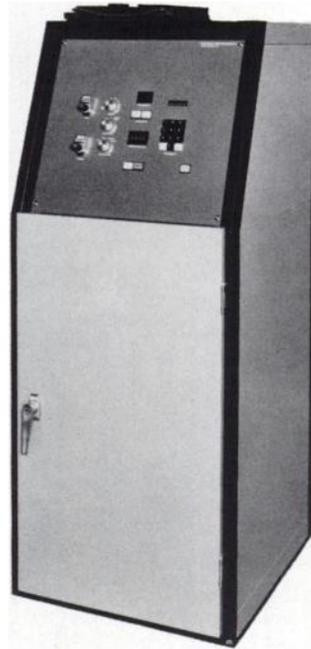
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# State of the art in gamma camera hard copy recording.



## Multi-Imager 1

Multi-Imager 1 employs the CRT of the gamma camera to record static, dynamic, and whole body imaging procedures on transparency format. The highly versatile Multi-Imager 1 offers film size formats of 5x7 and 8x10, yielding superior quality transparency scintiphotos recorded on a wide range of x-ray film processor compatible films. Up to 30 images can be recorded on a single sheet of film in ten different formats. In addition to the usual 1, 4, and 16 image formats, Multi-Imager 1 offers seven further choices to yield the exact diagnostic format required. For example, Multi-Imager 1 offers a 6 image format to allow recording of static studies that require a fifth and sixth view, and a 30 image format for dynamic studies that require more than sixteen frames. For whole body imaging, the 2 image format records side by side AP and PA views on the same sheet of film. Static, dynamic, and different size images can be mixed on the same sheet of film.



## Multi-Imager 4

Multi-Imager 4 yields unmatched performance in gamma camera hard copy recording. A built in high resolution CRT, state of the art microprocessor technology, and electronically synchronized multiple lens optics provide a very small dot size on 8x10 format without increasing the pulse pair resolution dead time of the gamma camera system. The fast lens system of Multi-Imager 4 is compatible with both conventional x-ray film and the slower single emulsion radiographic films that provide the best image quality. Up to 64 images can be recorded in ten different formats. The dual intensity recording mode allows simultaneous acquisition of whole body or static views at two different intensity levels. Positive patient identification is achieved through a nine digit keyboard LED system.

**Both Multi-Imager 1 and Multi-Imager 4 can provide thousands of dollars in annual film cost savings and are compatible with all gamma cameras. Mail coupon to receive detailed information and sample clinical studies.**

## # MATRIX INSTRUMENTS

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(201) 767-1750

**Mail coupon to receive sample clinical studies.**

Please send Multi-Imager System literature and sample studies.

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# MODEL 145 LOCALIZATION MONITOR

## Detection of Deep Vein Thrombosis

and other in vivo applications



- CPS & PERCENTAGE READOUT
- COMPACT & PORTABLE
- BATTERY OPERATED (3 D cells)
- FULLY TRANSISTORISED
- LINEAR SCALE & WIDE RANGE
- RECORDER OUTPUT
- VARIABLE DEPTH COLLIMATOR
- UNLIMITED CHANNEL SELECTION
- MANUFACTURED & SERVICED IN THE U. S. A.
- CLINICALLY PROVEN FOR OVER ONE YEAR

### CONTROLS

High voltage  
Threshold  
Window  
Battery test  
Response (fast & slow)  
CPS or percent switch  
Reset

For DEEP VEIN THROMBOSIS DETECTION, the Model 145 offers the important features of portability, standard D cell operation yielding at least 100 hours of uncycled use, unlimited channel selection, and prompt servicing.

Using I-125 labelled fibrinogen and the Model 145, early detection of deep vein thrombosis of the legs can be accomplished. With the Model 145, the leg is scanned after intravenous injection of the labelled fibrinogen. As a thrombosis develops, the radioactive fibrinogen is detected with the Model 145 and measured directly in percentage, where 100% is determined over the precordial area.

### SPECIFICATIONS

RANGE: 30, 100, 300, 1000, 3000 cps  
and 0 - 120%

TIME CONSTANT: Fast 2 sec., slow 14 sec.

SIZE: 4½ x 5½ x 8 inches (HxWxL exclusive  
of handle).

WEIGHT: 6.5 lbs total

DETECTOR: 1mm x 1 inch NaI (TL) mounted  
on PMT and 7 mg/cm<sup>2</sup> aluminum  
window. Optional - 1 inch x 1 inch  
NaI (TL) detector with thin window  
at extra cost.

**j&s**

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# NEW non-invasive diagnostic methods

## Featuring Kevex X-ray fluorescence systems



### I. In Vitro: The Kevex-Ray® Stable Tracer Analyzer.

X-ray fluorescence analysis in-vitro affords tracer studies in new and conventional areas *without* the use of radioactive tracers, i.e., replacing them with *stable tracers*.

- established applications in:

**KINETICS OF X-RAY CONTRAST AGENTS  
GLOMERULAR FILTRATION RATE (GFR)  
RED CELL VOLUMES (RCV)  
EXTRACELLULAR FLUID VOLUME  
PLASMA VOLUME (ECFV)**

- high specificity and sensitivity, wide ( $10^5$ ) dynamic range (from ppm to %)
- no radiation exposure to patient or personnel, with increased capabilities for serial studies and studies of normals
- no storage, handling, or disposal of short half-life radioactive materials
- simple, accurate, cost effective

#### References

1. Kaufman L., Price, D. C. (Eds): *Semiconductor Detectors in Medicine*, CONF-730321, Washington, D. C., U. S. Atomic Energy Commission, 1973.
2. Kaufman L., Wilson C. J.: Determination of extracellular fluid volume by fluorescence excitation analysis of bromine., *Journal of Nuclear Medicine* 14:812, 1973.
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4. Guesry P., Kaufman L., Orloff S., et al: Measurement of glomerular filtration rate by fluorescent excitation of nonradioactive meglumine iothalamate., *Clin Nephrol* 3:134, 1975.



### II. In Vivo: The Kevex-Scan III B X-ray Fluorescence Thyroid Analyzer.

- High resolution thyroid imaging *without* radioactive tracer
- Quantitative total iodine information with calibration
- Very low local radiation dose-zero whole body dose
- Complementary and unique information of thyroid disease state via the endogenous iodine distribution
- Adaptable to most conventional rectilinear scanner systems (Picker, Ohio Nuclear, Nuclear Chicago, Baird-Atomic, etc.)
- Adaptable for dedicated operation, or in parallel with Na(I) uptake detector

For information write or call:  
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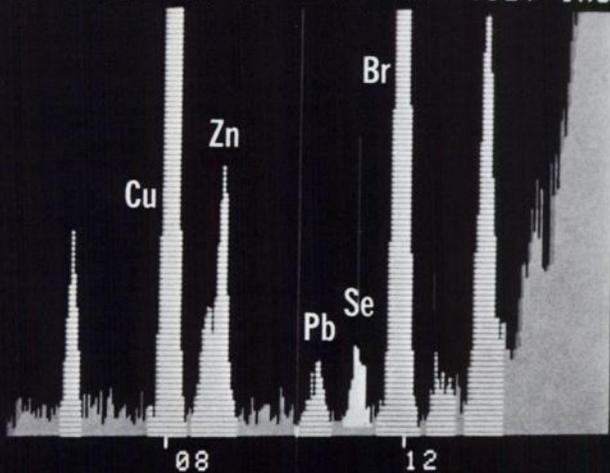
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C&EN May 3, 1976

# Heart disease, cancer linked to trace metals

The possibility that variations in dietary and environmental levels of selenium, copper, zinc, and perhaps other metals

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Spectrum for copper, zinc and selenium obtained from two microliters of human breast fluid.

The ability to analyze many trace elements simultaneously and nondestructively is what x-ray energy spectrometry is all about. Now, new developments by Kevex provide medical researchers, the pharmaceutical industry and process control engineers with high-speed analytical capabilities that offer far more potential than traditional techniques such as AA.

In this instance, the Kevex x-ray energy spectrometer measured the zinc-to-copper ratio and selenium concentration in two microliters of human breast fluid. A recent study shows a positive correlation between coronary mortality in 47 U.S. cities and the ratio of zinc-to-copper in cow milk of those areas. The connection between low cancer rate and high selenium diet was also reported for both cancer of the colon and breast cancer. (C & E News May 3, 1976).

The new Kevex ULTRA-TRACE™ x-ray energy spectrometer can analyze a fraction of a billionth of a gram of selenium in human breast fluid—total analysis time per determination—5 minutes! ULTRA-TRACE™ is an innovation that combines many seemingly disconnected analytical parameters, each marginally effective, into an integrated system of great usefulness. Are you interested in nondestructive multi-element trace analysis? For more information contact Kevex at:



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# The new Elscint Mobile 1

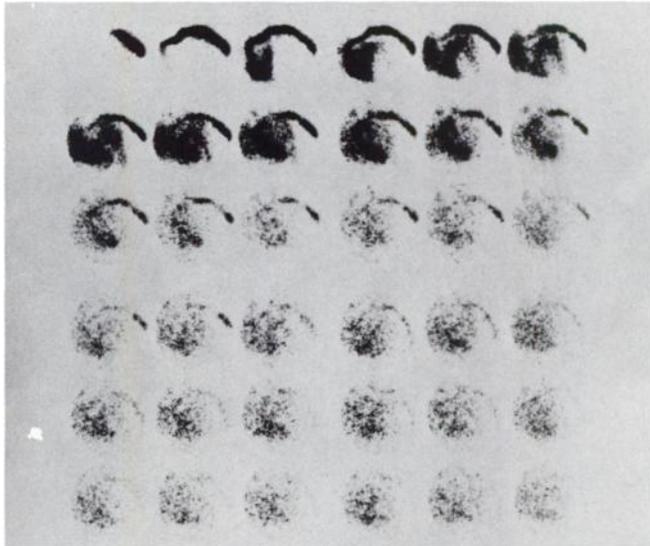
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Elscont's new MOBILE 1 gamma camera offers you the quality and performance of a stationary camera with the fluid mobility of a cat. It moves rapidly yet safely wherever needed. The detector head raises smoothly into position with fully automated two speed controls. Over or under the patient. Swings to either side or in front. The new MOBILE 1 camera is quiet and efficient to give you high quality results with maximum flexibility.

### Mobile 1: Exceptional performance in a mobile camera

Results, of course, must be the ultimate measure of any diagnostic system. Here, Elscint is second to none. The MOBILE 1 provides a full 12" FOV with bar resolution better than 3.2 mm. It images at rates

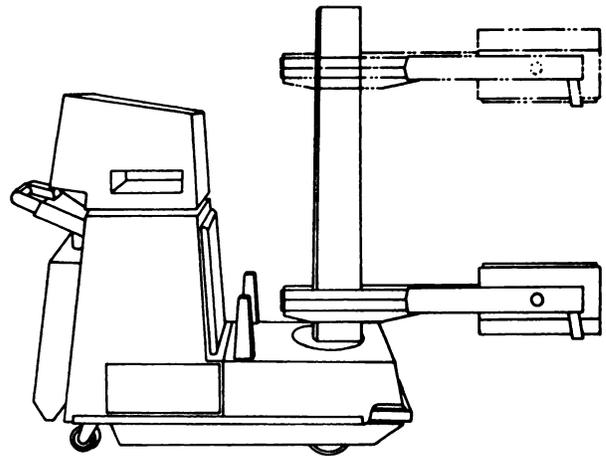


to 200,000 cps. (less than 1.5  $\mu$ s deadtime) and its usable energy range extends beyond 200 KeV for use with  $^{81m}\text{Kr}$  (190 KeV),  $^{99m}\text{TC}$  (140 KeV) or  $^{201}\text{Tl}$  (70 KeV), or other usable radionuclides within this range. It thus performs as a regular stationary camera for both static and dynamic studies as well as a mobile patient bedside unit. An optional data storage/replay system acquires and records at up to 150,000 cps for later replay or processing, adding time marks for re-framing as fast as 100 frames/sec.

### Mobile 1: Maximum maneuverability

Extreme ease and convenience of movement are major features of the MOBILE 1. Its under-30" width and

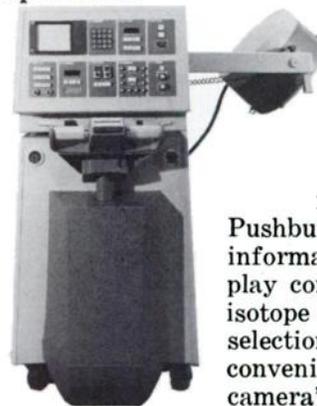
compact overall size enable passage through any doorway or narrow hall. Its low profile facilitates excellent forward visibility while in motion and its low center of gravity produces high stability even with full detector extension. Three speed forward and reverse drive and short-turning-radius power steering permit rapid long distance travel as well as precise



Designed for over and under patient imaging

positioning at bedside with safety interlocks provided to prevent accidental bumping into objects or people. The MOBILE 1 can pass over a 20 mm obstacle and climb a 10% slope rapidly yet will not run away on downslopes. Positive-locking brakes assure firm positioning and are automatically applied upon release of the control handle.

### Mobile 1: Convenient controls for easy operation



All of the operating features employed in our latest stationary cameras are provided in the Mobile 1 with the added convenience of a swivel-mounted operating console.

Pushbuttons ease input of patient information, data recording, display control, scaler operation, and isotope selection. Patient rotation selection and region of interest are conveniently controlled as well. The camera's persistence scope faces

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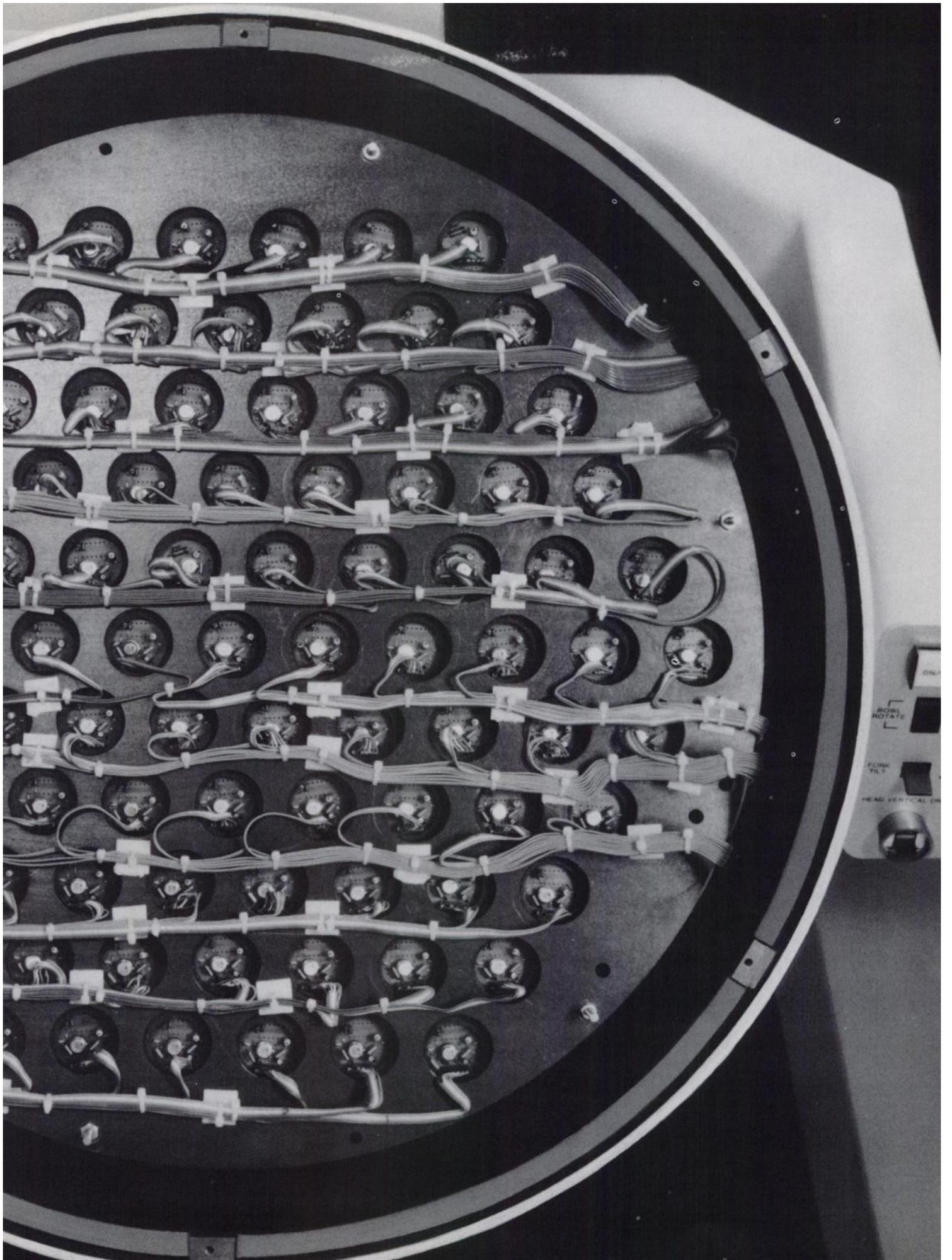
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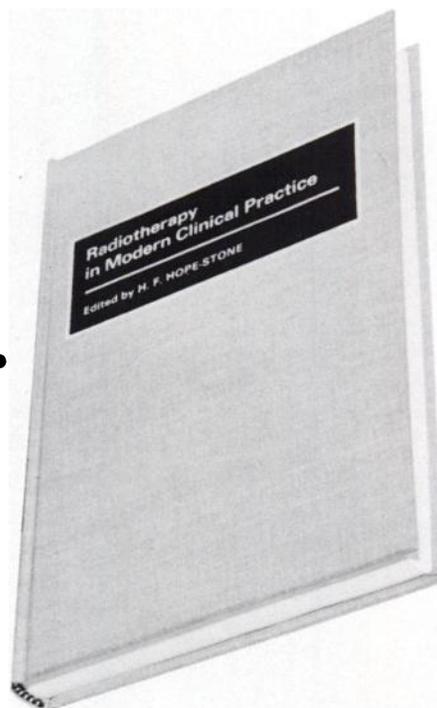
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Edited by H. F. Hope-Stone, M.B., B.S., L.R.C.P., M.R.C.S., F.R.C.R., D.M.R.T.; with 11 contributors. May, 1976. 358 pages plus FM I-X, 6¼" × 9¼", illustrated. Price, \$24.50.

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By A. J. Moss, Jr., Ph.D.; Glenn V. Dalrymple, M.D.; and Charles M. Boyd, M.D.; with 12 contributors. September, 1976. Approx. 176 pages, 6¼" × 9¼", 53 illustrations. About \$11.95.

A New Book!

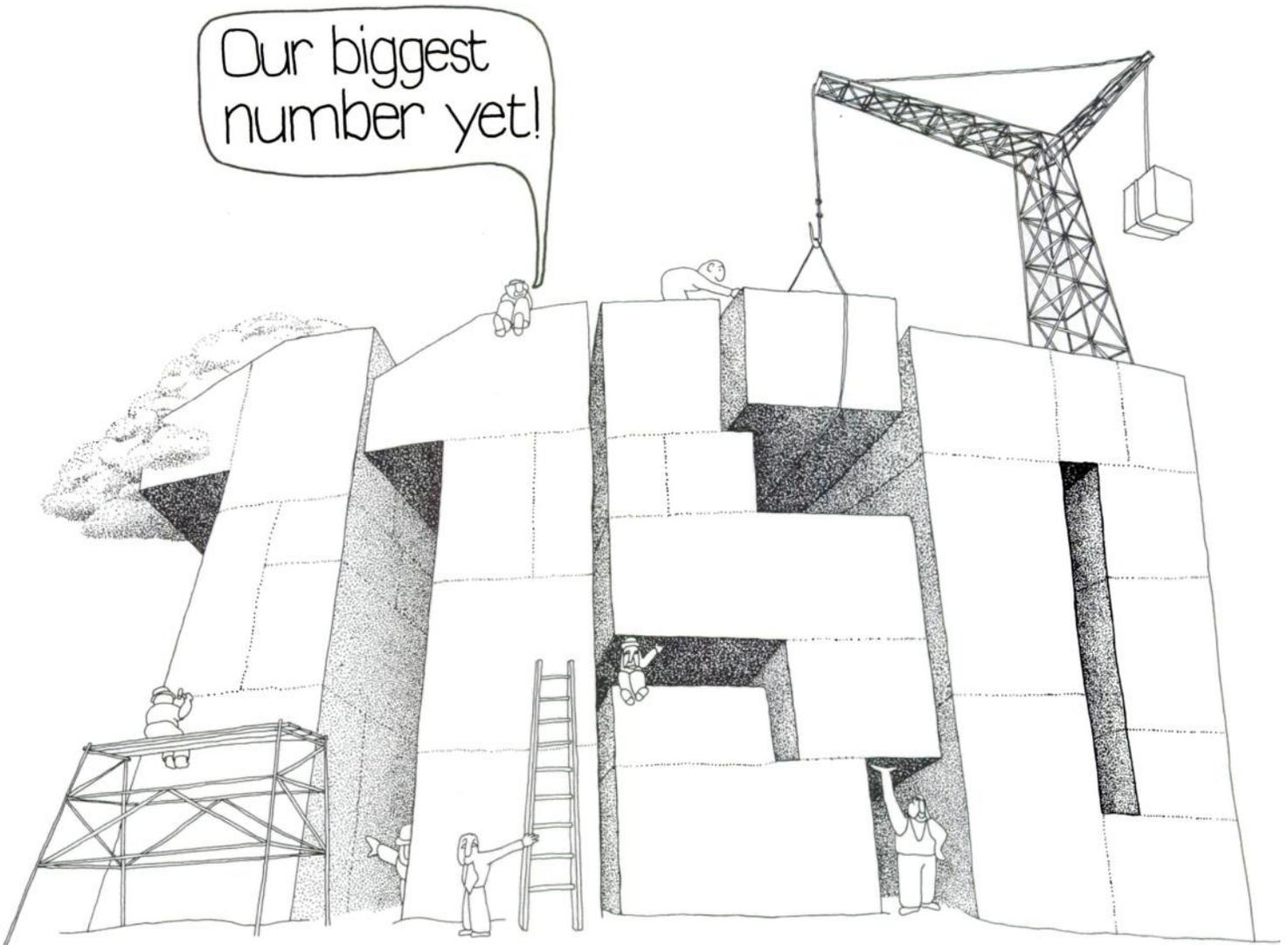
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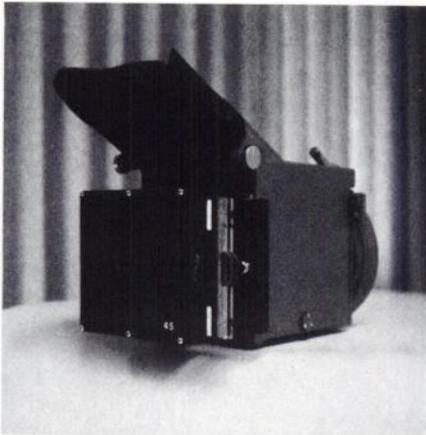
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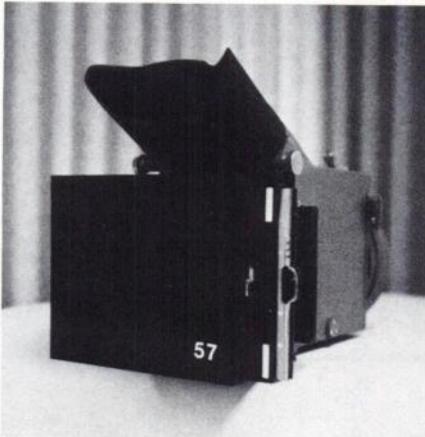
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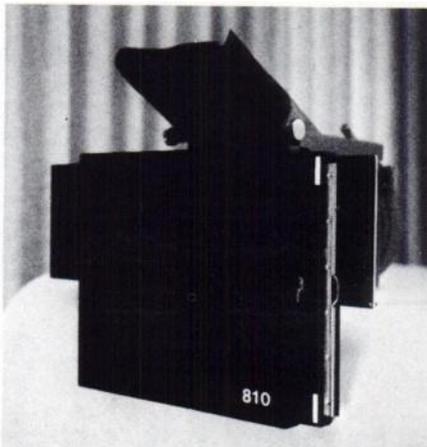
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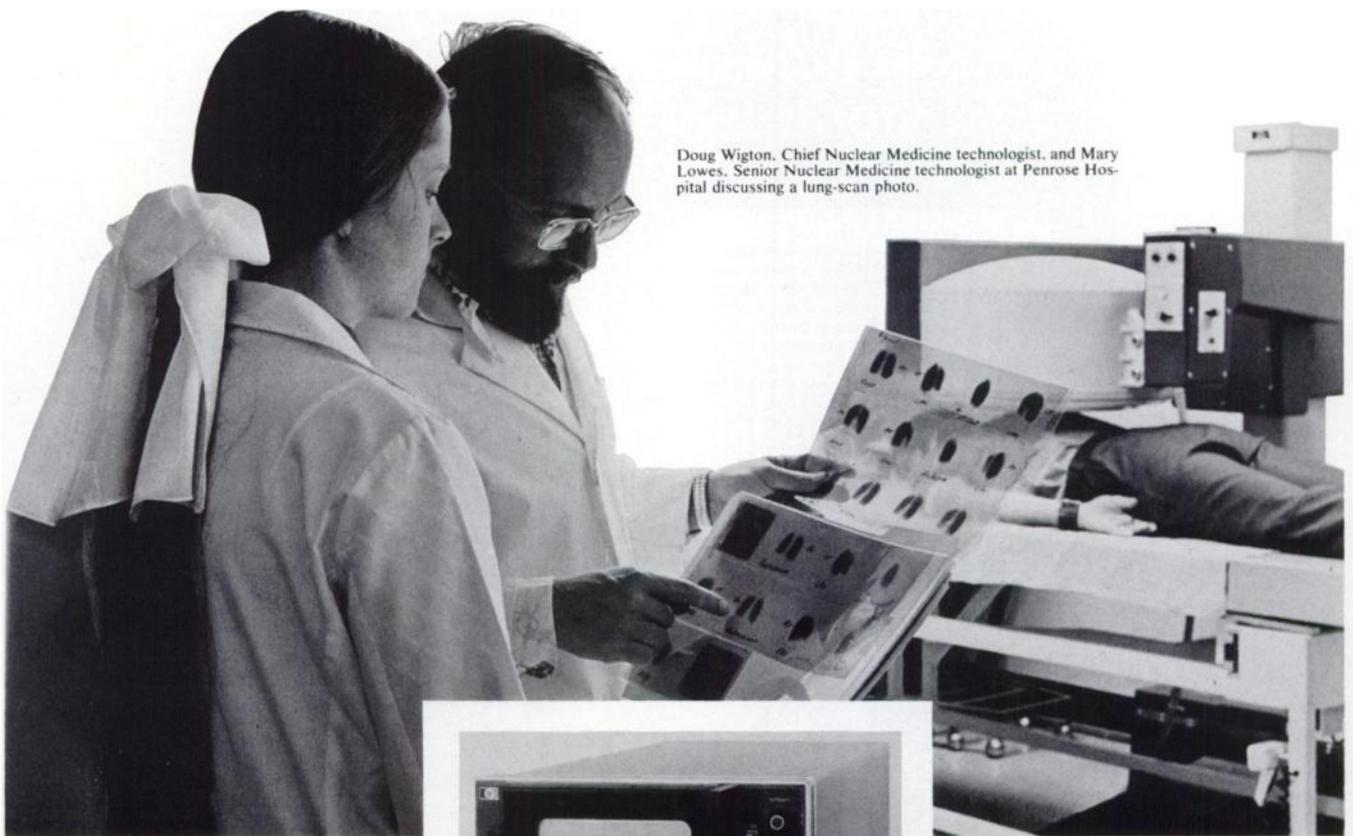
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\*As shown at the 22nd Annual Meeting of the S.N.M. in Philadelphia, PA.

# For diagnostic imaging, picture quality is crucial.



Doug Wigton, Chief Nuclear Medicine technologist, and Mary Lowes, Senior Nuclear Medicine technologist at Penrose Hospital discussing a lung-scan photo.

Nuclear physicians making diagnostic images want displays that show every detail, for accurate diagnosis of the patient's condition. That means sharp images with excellent contrast and uniform light output. The kind of picture quality that's necessary to spot even the smallest item of medical significance.

To get resolution and picture quality like that, a growing number of hospitals rely on HP displays. Fred Gydesen, MD/BS in Physics, Chief of Nuclear Medicine at Penrose and Memorial Hospitals in Colorado Springs, Colorado, finds that good diagnostic images are easier to achieve with HP displays. He and his colleagues use the variable persistence and storage capabilities of the HP 1335A, to dynamically position the patient before the scan. Then they use the exceptionally bright and uniform light output of the 1332A non-storage display to take photographs.

The 1335A gives them excellent detailing as each area of the body is scanned. The display's very small spot size



focuses uniformly over the entire 8 x 10 division screen regardless of writing speed or intensity level. This eliminates the need to refocus at each intensity setting and assures crisp images, even around the outer edges of the screen.

For photographing selected areas, the 1332A display gives them a large viewing area (9.6 x 11.9 cm), a bright, uniform image at fast scan rates, and extremely good resolution—an ideal combination for producing quality photographs.

These displays offer a variety of operating features that can speed and simplify your work. And they're designed to integrate easily into a variety of racks, cabinets or systems. If you need bright, high-resolution displays for your medical and instrumentation systems, ask your local HP field engineer for details on the 1332A and 1335A. Ask him about the new 1333A too. Its extremely small spot size 0.20 mm (0.008 in.) provides new levels of picture quality for photographic applications.

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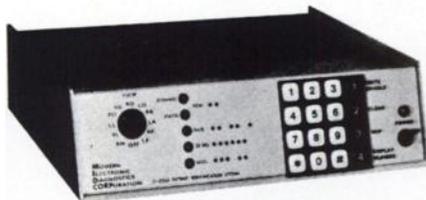
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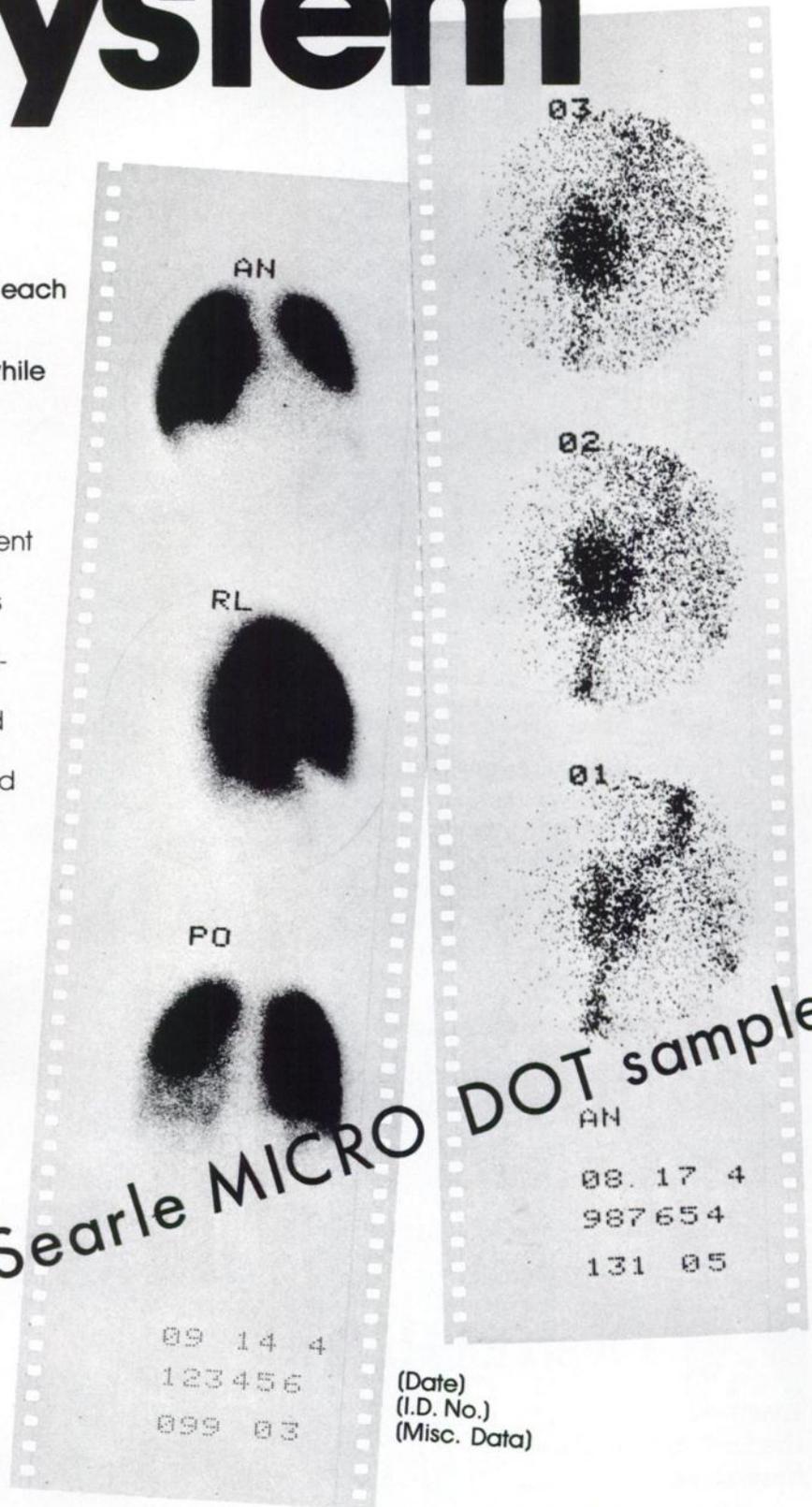
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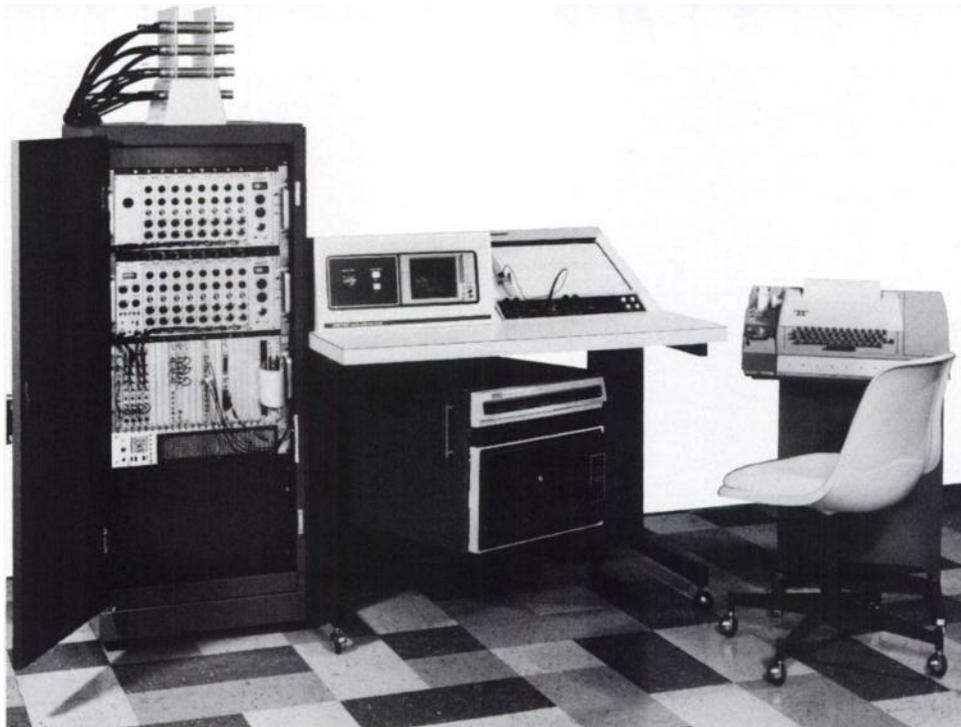
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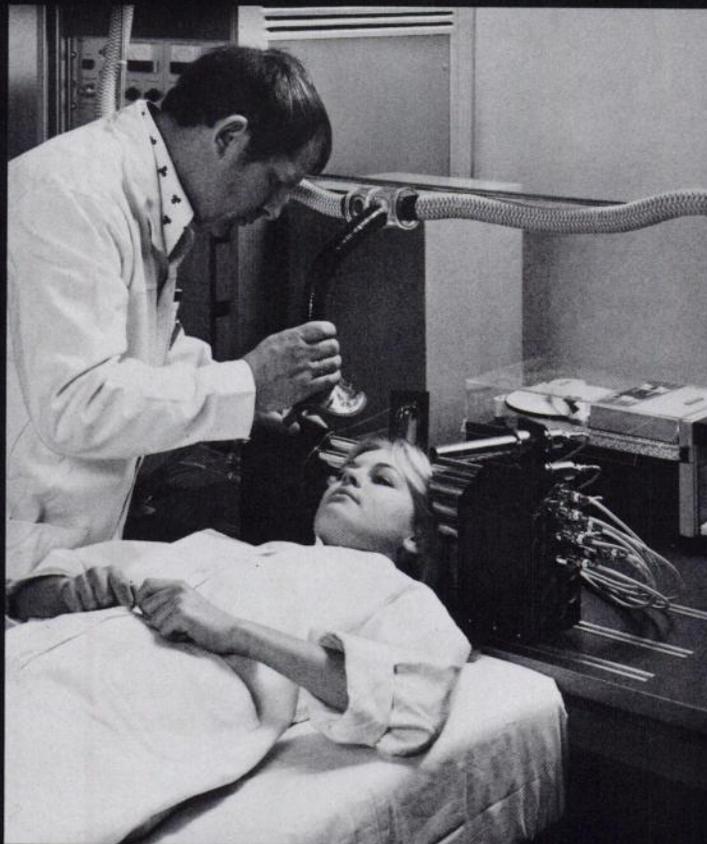
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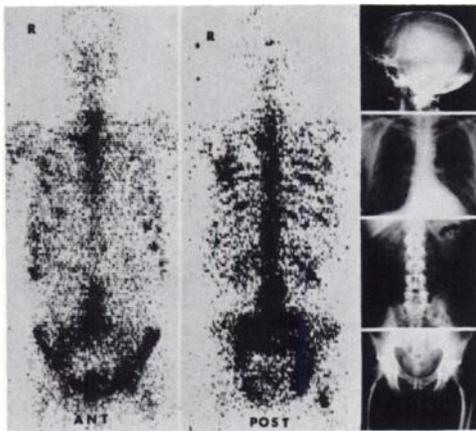
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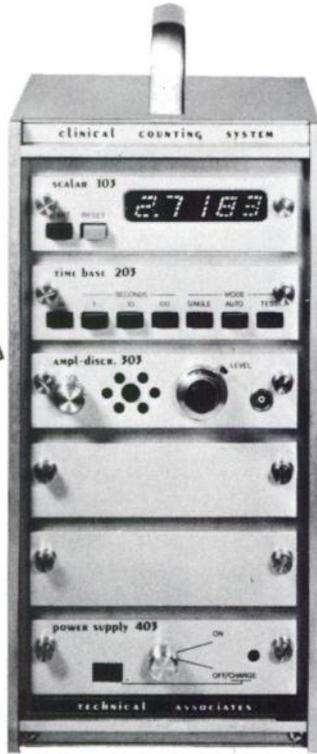
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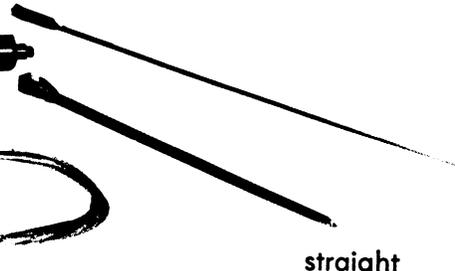
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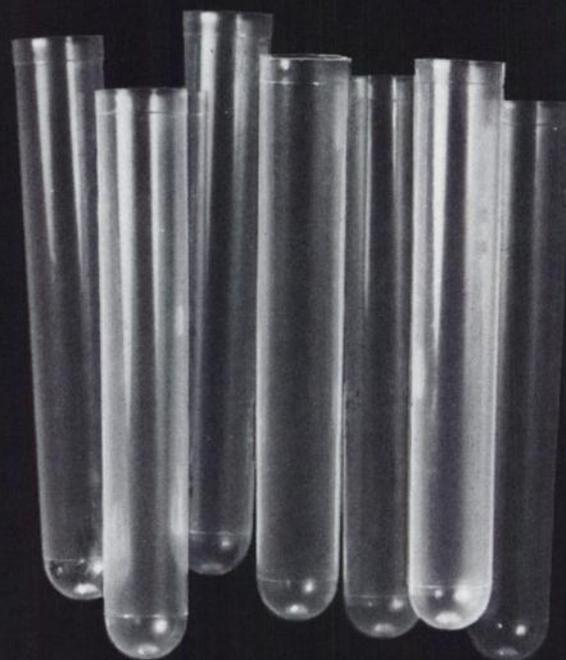
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References: 1) Burnett, G. H.; Conklin, R. L.; Wasson, G. W.; MacKinney, A. A.; Clin. Chem. 19 No.7 725, 1973. 2) Holtzman, J. L.; Shafer, R. B.; Erickson, R. R.; Clin. Chem. 20 No. 9 1194, 1974.



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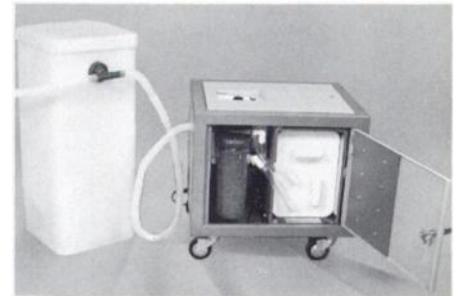
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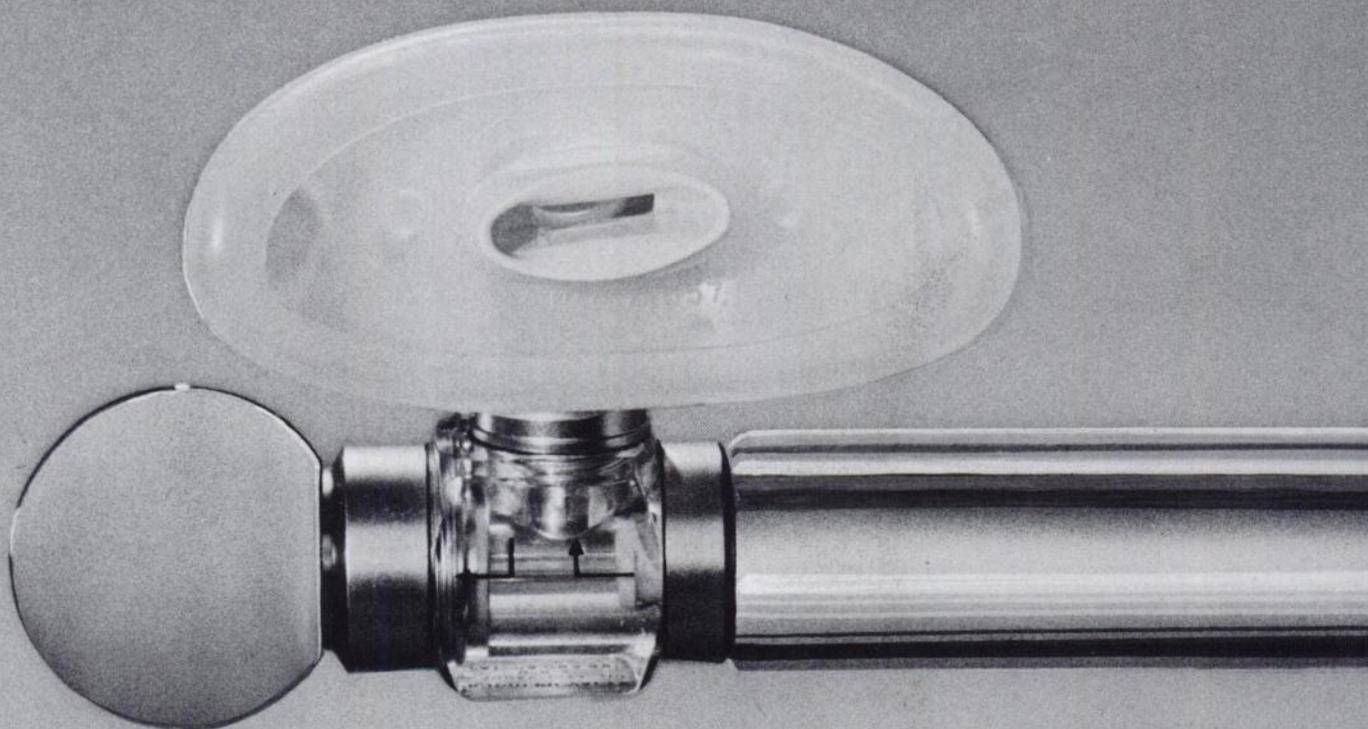
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1. Obrist, W. D. et al, "Determination of Regional Cerebral Blood Flow by Inhalation of Xenon-133", Circulation Research, XX,124-134, January 1967.

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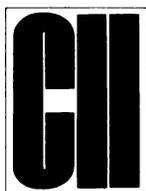
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**DESCRIPTION** - The kit contains 6 sterile vials containing 9-11 mg. of pyrogen-free aggregated albumin (human), 0.67 - 0.83 mg. stannous chloride, and 18 mg. sodium chloride. When sterile, pyrogen-free sodium perchlorate Tc99m is added to the vial, technetium-labelled macroaggregated human serum albumin (Technetium MAA Tc 99m Technetium Macroaggregates) is formed. The particles of aggregated albumin in the kit are formed by the denaturation of Normal Serum Albumin (Human) USP through heat and pH adjustment. Sodium hydroxide of hydrochloric acid may be present in variable amounts. At least 95% of the macroaggregated particles are between 10 and 100 microns in size, the great bulk, (as seen on a microscope slide) being an average of 10 to 70 microns. None are larger than 150 microns. Vial counts indicate that each vial contains  $6.8 \pm 0.8$  million particles per mg. The labelling efficiency is essentially quantitative and the bound Tc-MAA remains stable *in vitro* throughout the useful period after preparation.

Application has been filed with the U. S. Nuclear Regulatory Commission for distribution of this reagent kit to persons licensed pursuant to §35.14 and §35.100, Group III of CFR Part 35, or under equivalent licenses of agreement states; and is still pending.

**ACTIONS** - Following intravenous injection, Technetium MAA Tc 99m is rapidly transported by the blood stream to the lungs. The aggregates do not enter the tissues of the lungs, but remain in the pulmonary vasculature. When pulmonary blood flow is normal, the material is carried throughout the entire lung field; when pulmonary blood flow is diminished or obstructed by a disease process, the particles are correspondingly prevented in part or in whole from passage through the affected portion of the pulmonary vasculature.

Technetium Macroaggregates remain in the lungs for variable amounts of time depending on particle size. The particles disappear from the lungs in exponential fashion with the larger-sized aggregates having the longer half-life; particles ranging from 10 to 90 microns in diameter usually have a half-life of 2 to 8 hours. Apparently, the aggregates are temporarily trapped by the narrow pulmonary capillaries where the particles are broken down until they are small enough to pass. In rats 4.3% of the Tc 99m remains in the lungs after 24 hours.

Although the particles of macroaggregates remain for a time in the pulmonary capillaries, they do not appear to interfere even temporarily with pulmonary blood flow or ventilation in the dosage required for lung scanning. This is evidenced by the fact that these doses do not produce any respiratory distress nor any tachycardia, even in patients severely ill with pulmonary and/or cardiac disorders.

Once the albumin particles leave the lungs, they are carried to the liver, where they are removed from the blood stream primarily by the Kupffer cells. There, the particles are phagocytized and rapidly metabolized.

**INDICATIONS** - Scintillation scanning of the lungs with Technetium Macroaggregates is indicated as an adjunct to other diagnostic procedures whenever information about pulmonary vasculature is desired. The most useful clinical applications of lung scanning have been outlined by one investigator: 1) The diagnosis of pulmonary embolism; 2) differentiation of focal conditions such as bullae or cysts from diffuse pulmonary disorders; 3) determination of the degree of pulmonary vascular obliteration in parenchymal disease; and 4) evaluation of the patient's ability to withstand pulmonary surgery.

Perhaps the most frequently useful indication for the lung scan has been the early detection of pulmonary emboli. The lung scan is uniquely able to demonstrate the existence of an embolism before radiological signs become apparent. Although an area of increased radiolucency on the chest film may suggest an embolism, X-ray findings do not usually become apparent until the embolism has produced signs of ischemia or infarction. Once an embolism has been diagnosed, information obtained from the scan is of value in determining the desirability of surgical embolotomy, while subsequent scans provide information on the effectiveness of surgical or anticoagulant therapy.

Lung scanning is similarly helpful in the diagnosis of various types of malignancies affecting the lungs. Again, scanning is of value in locating the affected areas, in determining the need for and probable effectiveness of surgery or of radiation therapy, and in following up the benefits of treatment.

Useful information is also provided by the scan in the diagnosis or evaluation of other pulmonary problems, such as pneumonia, atelectasis pleural effusion, pulmonary tuberculosis, parenchymal disease, emphysema and chronic asthmatic bronchitis.

**CONTRAINDICATIONS** - The presence of right to left shunts which would allow Technetium MAA Tc 99m injected in a systemic vein to reach a systemic artery is contraindication to the use of this material. Particulate material such as Technetium MAA Tc99m should not be administered to patients with evidence of severe restriction to pulmonary blood flow such as may be present in pulmonary hypertension.

**WARNINGS** - Technetium MAA Tc99m should not be administered to patients who are pregnant, or during lactation unless the benefits to be gained outweigh the potential hazards.

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

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

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

To insure the integrity of this product use needles in gauge sizes 18 to 21.

**ADVERSE REACTIONS** - No adverse reactions have been observed with this product. However Vincent et al (3) have recorded the only immediate and fatal reaction following infusion of Tc 99m macroaggregates (technetium labelled macroaggregates). This was in a seven-year-old child who had severe pulmonary vascular disease. The exact size of the particles used was not disclosed, and in the summary of the publication "it is suggested that this type of reaction will continue to be rare and that it will probably be somewhat predictable on the basis of clinical and laboratory evidence of severe pulmonary hypertension. Such a patient might be scanned safely by strict control of macroaggregates dose, size range and mean particle size".

The literature has recorded two adverse reactions to lung scanning with I-131 labelled macroaggregates. Wagner et al (4) observed that urticaria developed in a young girl several hours after lung-scanning procedure with iodine-131 macroaggregates where Lugol's solution was administered to block the thyroid gland. The subject had a history of angio-edema. The reaction may have been caused by either material. Dworin et al (5, 6) reported "I-131-labelled macroaggregated albumin highly suspect as the causative agent" in the death of a woman who was scanned for the possibility of demonstrating pulmonary embolism. With a 2½-year history of adenocarcinoma of the breast she had severe and rapidly progressive edema. Prior to scanning, the nasal administration of oxygen was interrupted. "Within 1 or 2 minutes after injection of 300 uCi of I-131 labelled macroaggregates albumin (11 mg. of albumin or 0.219 mg. per kilogram of body weight) she complained of lightheadness and became cyanotic, diaphoretic, and agitated with distended neck veins. The initial pulse rate of 50 rose to 140 with a fall in blood pressure to 100/30. Oxygen therapy relieved the profound dyspnea and cyanosis. An electrocardiogram 40 minutes later was compatible with acute cor pulmonale. Within several hours she had returned to her pre-scan status, but on the next day the temperature rose, dyspnea increased and she died 26 hours after the lung scan. We have continued lung scanning but limit the albumin to 0.020 mg. per kilogram, reject lots with more than 15 percent of particles over 40 microns and require two minutes for injection".

More recently, Williams (7) has reported a severe reaction immediately after injection of macroaggregated albumin (MAA) particles followed by death six hours later (while the patient was undergoing right-heart catheterization). Like those previously reported, it occurred in a patient with severe chronic pulmonary hypertension due to disease of the pulmonary vascular bed. The patient died in right heart failure. Post-mortem examination revealed "severe atheroma and thickening of all the pulmonary arteries but no macroscopic evidence of emboli. The right heart was hypertrophied and dilated".

Transient neurological complications following intra-arterial injection of I-131 labelled macroaggregates have been reported (3).

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7. Williams, J. O., *Brit. J. Radiol.* 47, 61-63 (1974)

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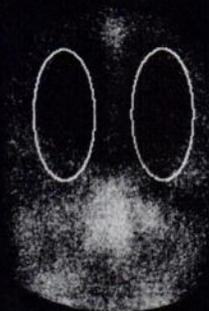
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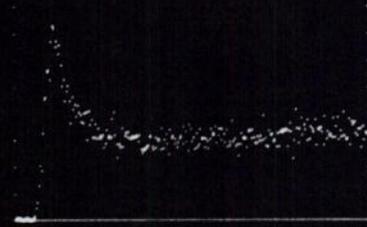


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Cerebral Flow Curve, right hemisphere



Anterior Cerebral View showing position of regions of interest in right and left hemispheres



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Requests for further information (include C.V. and reference list) should be directed to:

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**Stanford University Medical Center**  
**Stanford, CA 94305**



**DESCRIPTION:** Each Dicipac® Kit consists of five single-test cylinders, a vial of Cobalt 57 (Co 57) standard, and a vial of Cobalt 58 (Co 58) standard. Each test cylinder contains a capsule of cyanocobalamin Co 58 (vitamin B<sub>12</sub> Co 58), a capsule of cyanocobalamin Co 57 (vitamin B<sub>12</sub> Co 57) bound to human gastric juice, and an ampule of unlabelled cyanocobalamin for injection.

**ACTIONS:** Oral vitamin B<sub>12</sub> is normally coupled with intrinsic factor (IF) contained in the gastric juice secreted by the stomach and the vitamin B<sub>12</sub> combined with intrinsic factor is absorbed in the terminal ileum. Only intrinsic factor bound vitamin B<sub>12</sub> is absorbed by this route. Following parenteral administration or gastrointestinal absorption, cyanocobalamin is bound to plasma proteins and distributed to the liver and blood forming organs.

**INDICATIONS:** Dicipac Kit consisting of cyanocobalamin Co 58 and cyanocobalamin Co 57 combined with human intrinsic factor is used to assess vitamin B<sub>12</sub> absorption in the diagnosis of malabsorption due to the lack of intrinsic factor, e.g. Addisonian (pernicious) anemia, and as a diagnostic adjunct in other defects of intestinal absorption.

**CONTRAINDICATIONS**  
None

**WARNINGS:** This radiopharmaceutical should not be administered to patients who are pregnant or during lactation unless the information to be gained outweighs the potential hazards.

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

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

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

The test should not be started within 24 hours of a therapeutic dose (1000 µg) of vitamin B<sub>12</sub> or within 24 hours of a loading dose of vitamin B<sub>12</sub> given for the Schilling test.

If bone marrow examinations are to be done, they should precede the administration of this test, as the flushing parenteral dose of vitamin B<sub>12</sub> may alter the bone marrow picture.

**ADVERSE REACTIONS**  
None

**DOSAGE AND ADMINISTRATION:** One purple/white capsule containing 0.25 µg cyanocobalamin Co 57 (nominal activity 0.5 µCi at activity date) bound to human gastric juice for oral administration.

One red/ivory capsule containing 0.25 µg cyanocobalamin Co 58 (nominal activity 0.8 µCi at activity date) for oral administration.

One ampule of unlabelled cyanocobalamin (1 mg) for intramuscular injection.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Care must be taken when measuring the activity in the Co 57 and Co 58 capsules because of the small amount of radioactivity present.

**ADMINISTRATION AND TEST PROCEDURE:** The Dicipac test is performed in a manner similar to the Schilling test, however, with this test both Co 58 cyanocobalamin and Co 57 cyanocobalamin bound to intrinsic factor are administered simultaneously. Thus, both vitamin B<sub>12</sub> absorption and response to intrinsic factor are measured with the Dicipac test.

Both Dicipac capsules are orally administered to a fasting patient, who is instructed to collect all urine for the next 24 hours. An intramuscular injection of non-radioactive vitamin B<sub>12</sub> is administered to the patient up to two hours after the radioactive capsules are administered.

After the total volume of urine is measured, aliquots are taken for counting. The urine samples and the Co 57 and Co 58 standards provided with the Dicipac Kit are counted using dual isotope counting procedures. This data is used to calculate the percent excretion of each radionuclide and the ratio of the percent excretion of Co 57 to the percent excretion of Co 58.

\*Refer to "The Technical Information for the Performance of the Dicipac Test" brochure provided with the Dicipac Kit for further information on procedural techniques.

**INTERPRETATION OF RESULTS:** The usual percent excretion values and the ratios obtained with Dicipac are presented in Table I.

Table I. Results of 24-hour urine excretions and  $\frac{\text{Co 57}}{\text{Co 58}}$  ratios with Dicipac:

Diagnosis	Mean values % (usual range)		$\frac{\text{Co 57}}{\text{Co 58}}$ ratio
	Co 57 + I.F.	Co 58	
Normals	18 (10-42)	18 (10-40)	0.7-1.3
Pernicious anemia and certain gastric lesions	9 (6-12)	3 (0-7)	>1.7
Malabsorption syndromes not caused by lack of I.F.	<6	<6	0.7-1.3

A small number of patients have been found to excrete a "normal" (i.e., >10%) amount of Co 58, but these individuals exhibit elevated ratios (>1.4). The clinical significance of these findings is presently unclear.

**PHYSICAL CHARACTERISTICS:** Cobalt-57 decays by electron capture with a physical half life of 270 days. The primary gamma energy of Co 57 is about 122 KeV. Cobalt-58 decays by electron capture and positron and gamma emissions with a physical half life of 71 days. The primary gamma energy of Co 58 is 811 KeV. Photons that are useful for counting are listed in Table I.<sup>1,2</sup>

Table I. Principal Radiation Emission Data

Co 57	Radiation	Mean %/disintegration	Mean Energy (KeV)
	Gamma -2	87.1	121.9
Gamma -3	9.6	136.3	
Co 58	Beta -1	15.0	203.7
	Gamma -1	99.4	810.5
Annihilation Radiation		30.0	511.0

<sup>1</sup>Dillman, L.T., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, Supplement No. 2, MIRD pamphlet No. 4, J. Nucl. Med., p. 27, 1969.

<sup>2</sup>Dillman, L.T., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, part 2, Supplement No. 4, MIRD pamphlet No. 6, J. Nucl. Med., p. 16, 1970.

The specific gamma ray constant for Co 57 is 1.0 R/mCi-hr at 1 cm. For Co 58 it is 5.5 R/mCi-hr at 1 cm. The half value layer for Co 57 is 0.2mm of Pb. For Co 58 it is 9mm of Pb.

To correct for physical decay of these radionuclides, the fractions that remain at selected time intervals before and after the day of calibration are shown in Table II.

This table is not needed for routine calculation, as all counting is relative to the standards which have been prepared from the same batch of each of the radionuclides as the corresponding cyanocobalamin capsules.

Table II. Physical Decay Chart: Co 57, half life 270 days; Co 58, half life 71 days

Weeks Before Activity Date	Co 57 µCi		Co 58 µCi	
	Activity Date	Weeks After	Activity Date	Weeks After
10	0.60	1.48		
9	0.59	1.38	1	0.49
8	0.58	1.38	2	0.48
7	0.57	1.29	3	0.47
6	0.56	1.21	4	0.47
5	0.55	1.13	5	0.46
4	0.54	1.05	6	0.45
3	0.53	0.98	7	0.44
2	0.52	0.92	8	0.43
1	0.51	0.86	9	0.43
0*	0.50	0.80	10	0.42

\*Activity date

**RADIATION DOSIMETRY:** The estimated absorbed radiation doses<sup>1</sup> to an average patient (70 kg) following the oral administration of one Dicipac capsule of Co 57 and one of Co 58 at calibrated nominal activities of 0.5 µCi and 0.8 µCi, respectively, are shown in Table I.

Table I. Radiation Doses

Tissue	Absorbed Radiation Dose	
	(rads/0.5 µCi Co 57 + Intrinsic Factor) Normal and Pernicious Anemia	(rads/0.8 µCi Co 58) Normal Pernicious Anemia
Liver*	0.065	0.14
Stomach	0.00041	0.00027
Small Intestine	0.00007	0.00043
Upper Large Intestine	0.00013	0.00070
Lower Large Intestine	0.00030	0.0018
Testes*	0.0026	0.0074
Ovaries*	0.0033	0.010
Whole-body*	0.0050	0.012

\*The administration of a flushing dose of non-radioactive B<sub>12</sub> will decrease the dose to the liver, gonads, and whole-body from Co 57 and Co 58 by about 30%.

<sup>1</sup>Method of Calculation: A Schema for Absorbed-Dose Calculation for Biologically Distributed Radionuclides, Supplement No. 1, MIRD pamphlet No. 1, J. Nucl. Med., p. 7, 1968.

**HOW SUPPLIED:** Each Dicipac Kit consists of five single-test cylinders and two 8 ml vials containing the standard solutions. The vial containing the blue solution is the Co 57 standard and the vial containing the yellow solution is the Co 58 standard. Each standard solution is prepared so that 1 ml of solution is equivalent to 2% of the total activity of each of the corresponding capsules.

Each cylinder contains two capsules and an ampule of unlabelled cyanocobalamin (1 mg). The red/ivory capsule contains 0.25 µg Co 58 cyanocobalamin (nominal activity 0.8 µCi at activity date). The purple/white capsule contains 0.25 µg Co 57 cyanocobalamin (nominal activity 0.5 µCi at activity date) bound to human gastric juice.

Dicipac Kits should be stored at 4°C and not used after the expiry date stated on the label.



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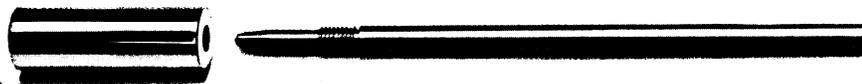
Supplied as  $^{57}\text{Co}$  (2 and 3mCi) and  $^{133}\text{Ba}$  (0.5 and 1.0mCi) in two sizes, to check the uniformity and resolution of conventional and wide field-of-view gamma cameras, and for transmission imaging. The maximum acceptable variation in activity over the entire active area, is  $\pm 1\%$  of the mean value. Each uniformly active plastic component is surrounded by inactive plastic and enclosed in an anodized aluminium casing. A shielded storage case is supplied with each source.

## Anatomical marker sources

**Spot sources** are available as a 1 mm bead of  $^{57}\text{Co}$  or  $^{133}\text{Ba}$  (10 and 100 $\mu\text{Ci}$ ). Features include a welded plastic capsule, point source geometry with a visible active bead, and colour coding for quick identification of nuclide and activity. They are packed in sets of three in shielded boxes; replacements are available separately.



**Pen point tracers** have a 1 mm diameter bead of  $^{57}\text{Co}$  (100 $\mu\text{Ci}$ ) sealed in the tip of a ball-point pen shaped holder with a brass shield for the active end.



**Flexible sources** are 50cm x 4mm diameter;  $^{57}\text{Co}$  (100 $\mu\text{Ci}$ ) is dispersed in an inner core of active plastic, sealed in an inactive PVC tube, and closed by aluminium caps.



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$^{129}\text{I}$  (0.1  $\mu\text{Ci}$ ) gamma/X-ray spectrum is virtually identical to  $^{125}\text{I}$ , and has a half-life of  $1.57 \times 10^7$  years. Calibration in terms of  $^{125}\text{I}$  is available. The length is 100mm, maximum diameter 15mm—suitable for most manual and automatic counters. Active material is sealed in a plastic capsule attached to a handling rod. Other nuclides  $^{241}\text{Am}$ ,  $^{133}\text{Ba}$ ,  $^{57}\text{Co}$ ,  $^{60}\text{Co}$ ,  $^{137}\text{Cs}$ ,  $^{54}\text{Mn}$ ,  $^{22}\text{Na}$ ,  $^{75}\text{Se}$ ,  $^{123m}\text{Te}$ ,  $^{88}\text{Y}$  and mock  $^{131}\text{I}$ .

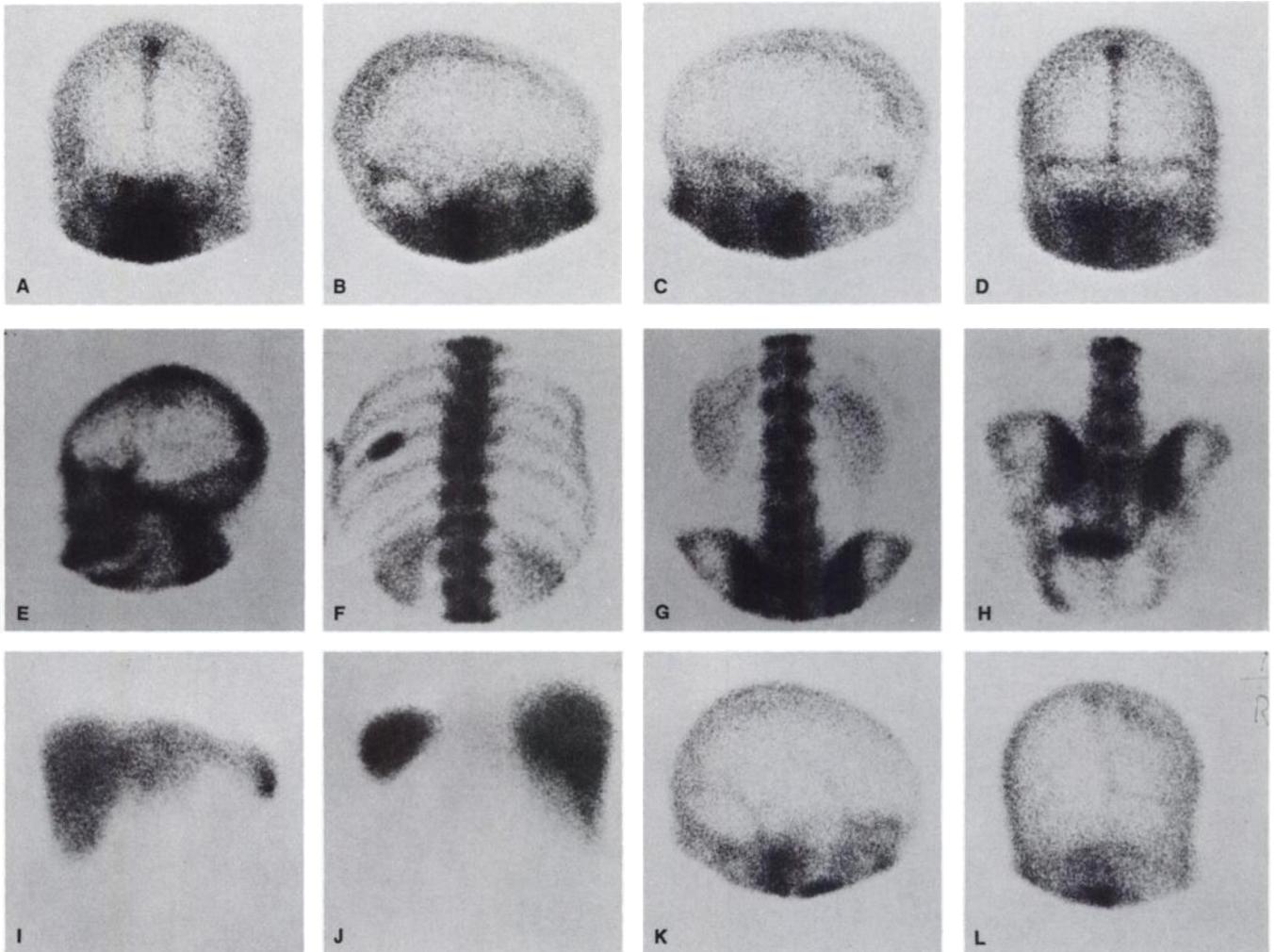
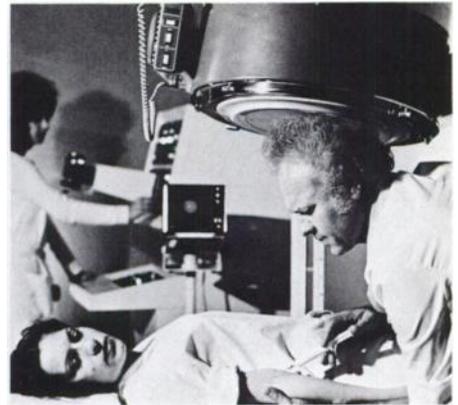


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**A, B, C, D.** Normal brain scan multi-image display with CE-1-7 (37 p.m.t.) camera.

**E, F, G, H.** Positive bone scan patient: CCL-4 Ultrafine — resolution collimator; 400,000 counts accumulated in 90-220 seconds per view; 15 mCi <sup>99m</sup>Tc pyp; 5 hours post injection.

**I, J.** Anterior and posterior liver scans: CCL-4 Ultrafine — resolution collimator; 400,000 counts; 3 mCi <sup>99m</sup>Tc sulfur

colloid; ½ hour post injection. 56 sec. for anterior; 66 sec. for posterior.

**K, L.** Right lateral and posterior brain scans with Elscint CE-1-7 (37 p.m.t.) camera: CCL-4 Ultrafine — resolution collimator; 400,000 counts; 15 mCi <sup>99m</sup>Tc; 2 hours post injection. 172 sec. for posterior; 169 sec. for right lateral. History: head trauma 2 months prior to brain scan.

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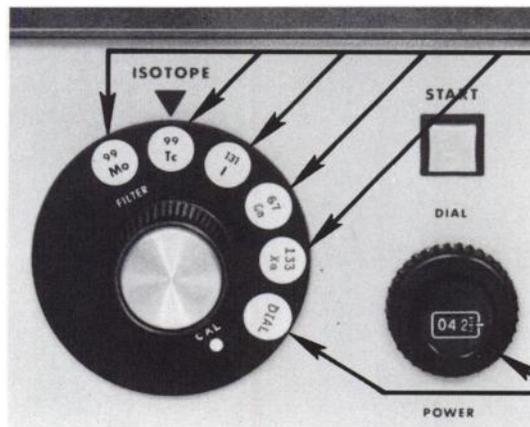
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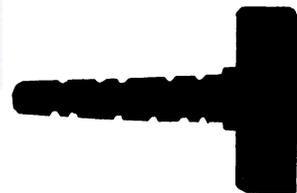
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## TECHNETIUM-99M DTPA(TIN)

Brief summary of package insert. Before using, please consult the full package insert included in every kit.

### DESCRIPTION

The kit contains 10 vials, each vial containing 5 mg sterile, pyrogen-free Sodium salt of Diethylenetriamine-pentaacetic Acid (DTPA) and 0.25 mg Stannous Chloride.

Administration is by intravenous injection for diagnostic use. The product as supplied is sterile and pyrogen-free.

When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the vial, a chelate, Technetium Tc 99m DTPA is formed.

### HOW SUPPLIED

Diagnostic Isotopes' Technetium Tc 99m DTPA Kit (Chelate) is supplied as a sterile, pyrogen-free kit containing 10 vials. Each vial contains 5 mg of Sodium salt of DTPA and 0.25 mg of  $\text{SnCl}_2$ . The pH is adjusted with HCl or NaOH prior to lyophilization. Following lyophilization the vials are sealed under a nitrogen atmosphere.

### CLINICAL PHARMACOLOGY

Following its intravenous administration, Technetium Tc 99m DTPA rapidly distributes itself throughout the extracellular fluid space from where it is (promptly) cleared from the body by glomerular filtration. There should be little or no binding of the chelate by the renal parenchyma. A variable percentage of the Technetium Tc 99m DTPA binds to serum proteins; this ranges from 3.7% following the single injection to approximately 10% if the material is continuously infused. Although the chelate gives useful information on the glomerular filtration rate, the variable percent which is protein bound leads to a measured glomerular filtration rate which is lower than the glomerular filtration rate as determined by inulin clearances.

Technetium Tc 99m DTPA tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. The chelate does not accumulate in the choroid plexus.

Since Technetium Tc 99m DTPA is excreted by glomerular filtration, the images of the kidneys obtained in the first few minutes after injection represent the vascular pool within the kidney. Subsequent images of the kidneys represent radioactivity which is in the urine of both the collecting system and the renal pelvis.

### INDICATIONS AND USAGE

Technetium Tc 99m DTPA may be used to perform kidney imaging, brain imaging, to assess renal perfusion, and to estimate glomerular filtration rate.

### CONTRAINDICATIONS

None known.

### WARNINGS

Technetium Tc 99m DTPA should not be administered to children or to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards.

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

### PRECAUTIONS

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

To minimize 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.

*Pregnancy Category C:* Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m DTPA should be used in pregnant women only when clearly needed.

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

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

### ADVERSE REACTIONS

No adverse reactions specifically attributable to the use of Technetium Tc 99m DTPA have been reported.

### DOSAGE AND ADMINISTRATION

The suggested dose range for I.V. administration to be employed in the average patient (70 kg) is:

Kidney imaging and glomerular filtration rate estimation: 3 to 5 mCi.

Brain imaging or renal perfusion: 10 to 20 mCi.

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Each DTPA kit contains 10 vials. The product is sterile, pyrogen-free, has a labeling efficiency of over 95% and a shelf life of one year . . . all good reasons for ordering now.

*See opposite page for a brief summary of the package insert.*



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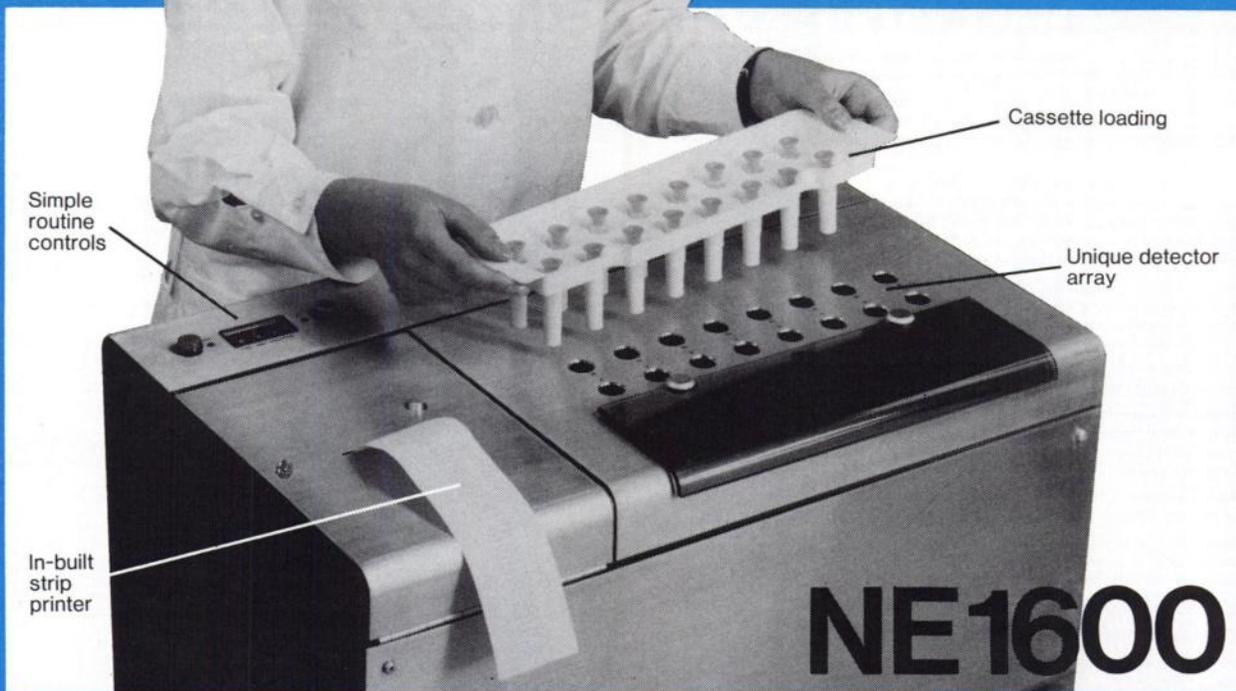
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people  
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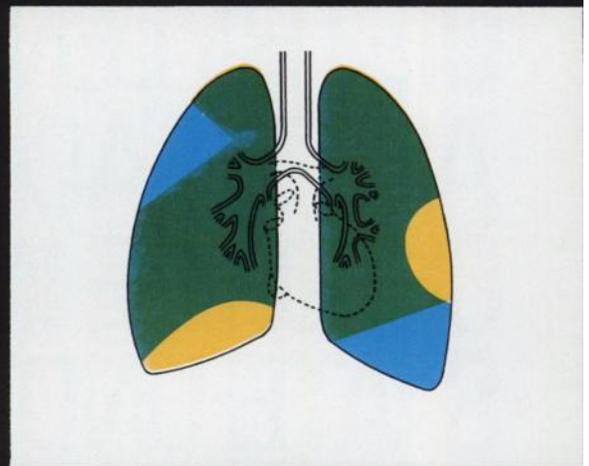
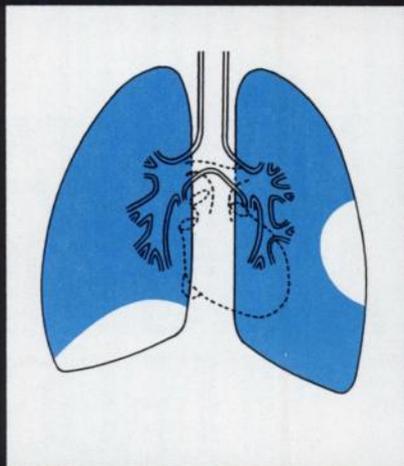
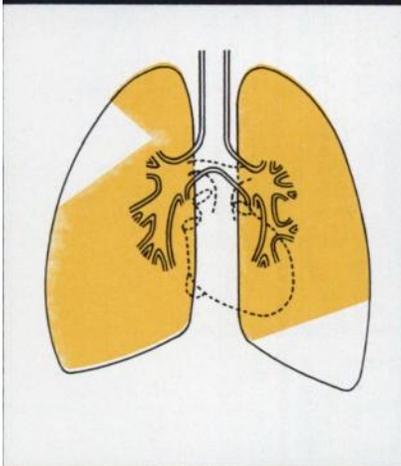
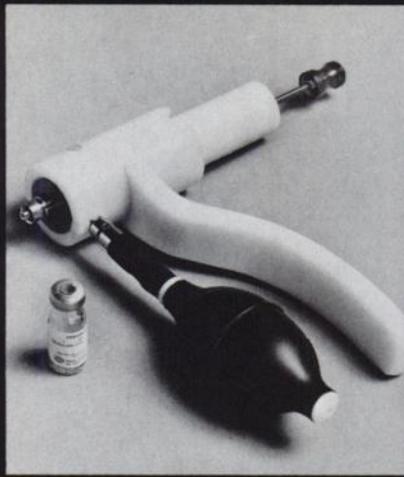
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DTPA becomes Technetium-99m DTPA (Tin) after adding sodium pertechnetate Tc-99m. Technetium-99m DTPA may be used to perform kidney imaging, brain imaging, to assess renal perfusion and to estimate glomerular filtration rate.

Each DTPA kit contains 10 vials. The product is sterile, pyrogen-free, has a labeling efficiency of over 95% and a shelf life of one year . . . all good reasons for ordering now.

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<sup>1</sup>Urokinase Pulmonary Embolism Trial. A National Cooperative Study. *Circulation* (Suppl 11) 47:11-61. 1973 (April)

<sup>2</sup>Wagner, Henry N. Jr., Strauss, H. William. *Radioactive Tracers In The Differential Diagnosis of Pulmonary Embolism*. Progress in Cardiovascular Diseases, Vol. XVII, No. 4 (January/February), 1975.

# PULMOLITE™ – Aggregated Albumin (Human) Agent.

## FOR DIAGNOSTIC USE

**Indications and Usage:** Tc 99m Aggregated Albumin (Human) is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary perfusion.

Specifically, the distribution of the agent reflects regional pulmonary perfusion and may be helpful in the evaluation of such clinical conditions as pulmonary embolus, chronic obstructive lung disease, congenital anatomic abnormalities, and pulmonary abscess. It can also be used in conjunction with a suitable liver imaging agent for the performance of lung-liver scans to detect subphrenic abscesses.

**Contraindications:** The safety of Aggregated Albumin in patients with right-to-left cardiac shunts has not been demonstrated, and its use in such patients is contraindicated. The use of Tc 99m Aggregated Albumin is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

**Warnings:** Although not reported to date, the possibility of allergic reactions should be considered in patients who receive multiple doses. This radiopharmaceutical preparation should not be administered to pregnant or lactating women, or persons under 18 years of age unless the benefits to be gained outweigh the potential hazards.

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

Theoretically, the intravenous administration of any aggregated material such as Aggregated Albumin imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of Aggregated Albumin is possibly hazardous in acute cor pulmonale and other states of severely impaired pulmonary blood flow. Although not reported with NEN's Tc 99m Aggregated Albumin (Human) the literature contains four reports of deaths occurring after the administration of Aggregated Albumin to patients with pre-existing severe pulmonary hypertension.

### Precautions:

#### GENERAL

Tc 99m Aggregated Albumin (Human) as well as any radioactive agent, must be handled with care. Once Pertechnetate Sodium 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.

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

The use of Bacteriostatic Sodium Chloride Injection as a diluent for Pertechnetate Sodium Tc 99m may adversely affect the biologic distribution of the prepared agent, and its use is not recommended.

#### CARCINOGENESIS

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

#### 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 effects on the fetus. PULMOLITE Aggregated Albumin (Human) Agent should be used in pregnant women only when clearly needed.

#### NURSING MOTHERS

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

#### PEDIATRIC USE

Safety and effectiveness in children have not been established.

**Adverse Reactions:** Although no adverse reactions have been reported using NEN Technetium Tc 99m Aggregated Albumin (Human), rare instances of hemodynamic or idiosyncratic reactions to other preparations of Aggregated Albumin have been recorded.

**Dosage and Administration:** The recommended intravenous dose range for the average patient (70kg) is 2 to 4 millicuries.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Re-suspend particles in syringe immediately prior to injection by repeated inversion of the the syringe.

(If blood is drawn into syringe, any unnecessary delay prior to injection may lead to clot formation in situ.) Slow injection is recommended, and for optimum results, imaging should begin as soon as possible after injection.

PULMOLITE should be used within eight hours after aseptic reconstitution with Pertechnetate Sodium Tc 99m. For optimum results the time should be minimized. After reconstitution, the vial should be stored at 2°C to 8°C.

The vial contains no bacteriostat.

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

**How Supplied:** PULMOLITE Aggregated Albumin (Human) Agent, is supplied in kits of five (5) or thirty (30) vials, sterile and non-pyrogenic, each vial containing in lyophilized form:

Aggregated Albumin (Human) - 1.5mg  
Normal Human Serum Albumin - 10mg  
Sodium Chloride - 10mg  
Stannous Chloride - 0.012-0.070mg

PULMOLITE contains no preservative; after reconstitution the shielded vial should be stored at 2°C to 8°C.

Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

## Xenon Xe 133 Gas (CALIDOSE™) Dispensing System.

**Indications:** Inhalation of Xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

**Contraindications:** To date, no known contraindications to the use of Xenon Xe 133 gas have been reported.

**Warnings:** This radiopharmaceutical should not be administered to pregnant or lactating women unless the benefits to be gained outweigh the potential hazards.

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

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

**Precautions:** As in the use of any other radioactive material care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental regulations. Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic. Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity to the laboratory environs not specifically protected by exhaust systems.

**Adverse Reactions:** To date, no adverse reactions based on the use of Xenon Xe 133 gas have been reported.

**Dosage and Administration:** Xenon Xe 133 gas is administered by inhalation from closed respirator systems or spirometers. The suggested activity range employed for inhalation by the average adult patient (70 kg) is:

Pulmonary function including imaging: 2-30 mCi in 3 liters of air.

Cerebral blood flow: 10-30 mCi in 3 liters of air.

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

**How Supplied:** The Xenon Xe 133 gas is supplied as part of the CALIDOSE™ system, consisting of 2 ml unit dose vials and the CALIDOSE dispenser\* for shielded dispensing.

Normally vials containing either 10 or 20 mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100 mCi/vial are available.

\*Patent Pending



**New England Nuclear  
Radiopharmaceutical Division**

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Telephone 617-667-9531

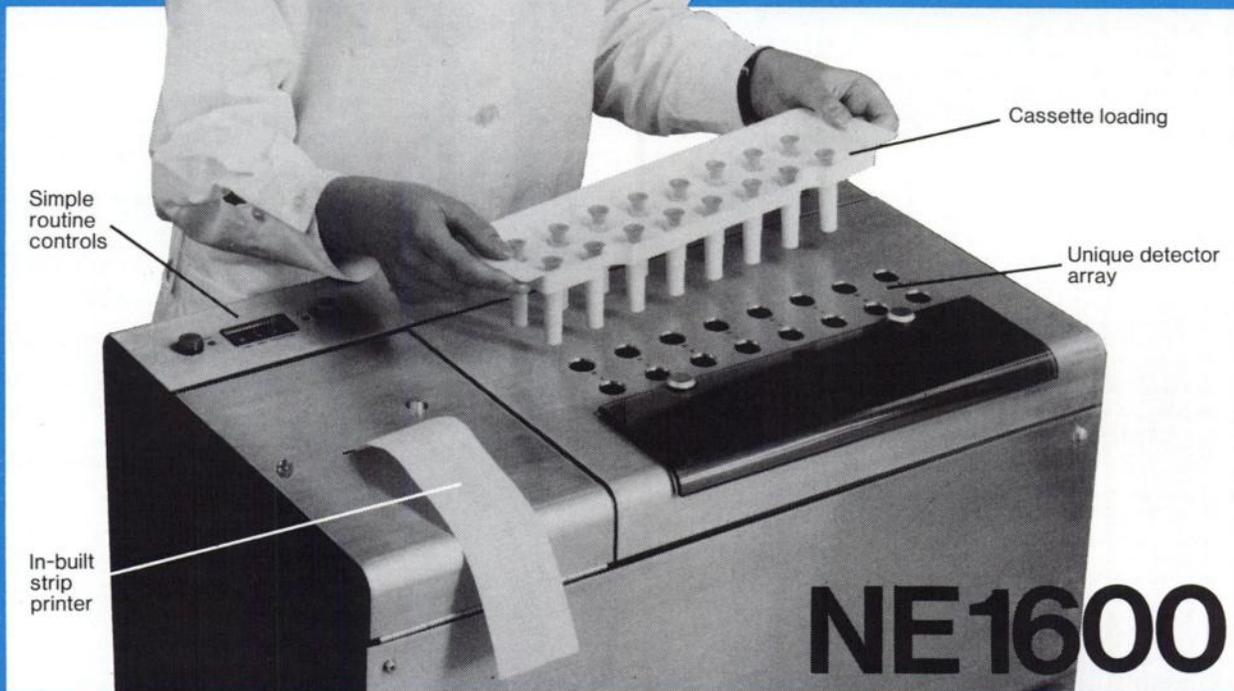
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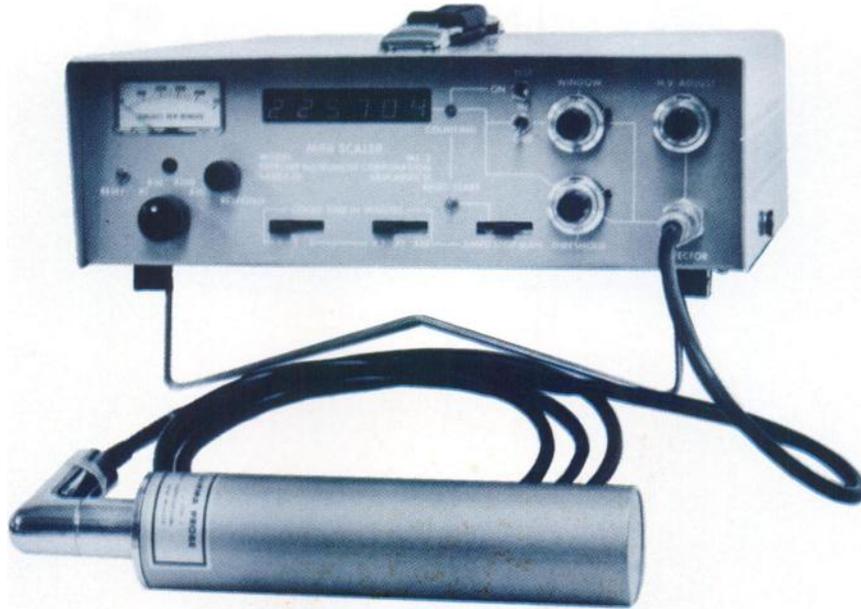


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# <sup>125</sup>I Fibrinogen Monitor, Model MS-2F\*



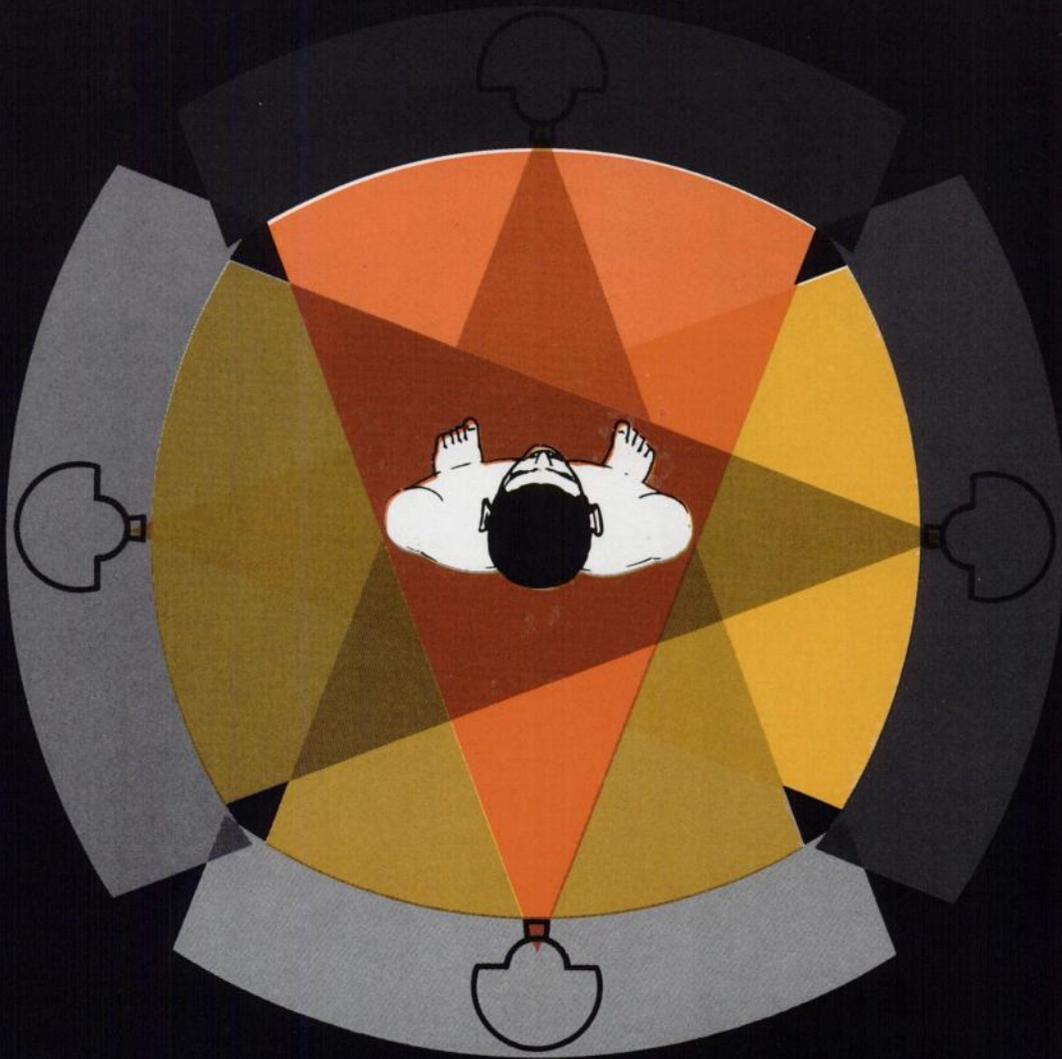
\*The MS-2F has been designed to meet Abbott Radiopharmaceutical specifications for use for detection of <sup>125</sup>I tagged Fibrinogen for deep vein thrombosis.

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# **Varian Introduces the 6-Second Whole-Body CT Scanner**



**A New Era in  
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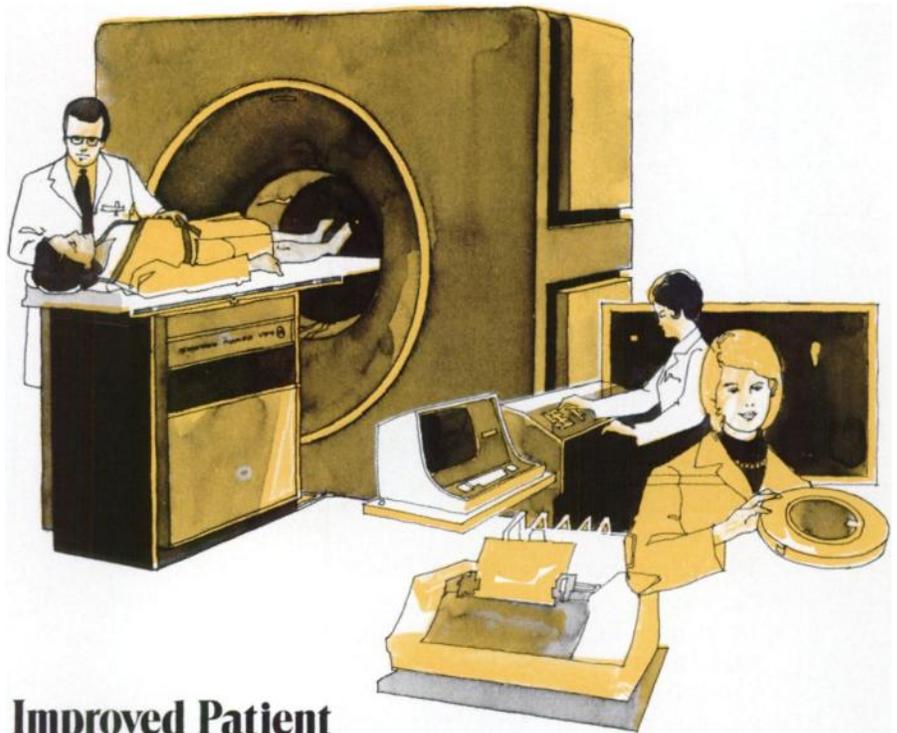
## Superior Design

Varian's CT Scanner utilizes fan beam geometry. X-rays are collimated into a fan-shaped beam and collected by approximately 300 high-efficiency Xenon-Krypton detectors. X-ray tube and detectors rotate as a unit, scanning the full patient cross-section throughout the entire 360 degrees.

The Varian-developed slip-ring construction eliminates cable flexing, and provides a base for faster than 6-second data acquisition in the future.

## Compatible with the Future

The design concepts of the Varian system assure compatibility with inevitable developments in the rapidly advancing CT technology. Equally important, Varian's total corporate involvement and close control over the major components in the CT Scanner System—Rotating Gantry, Xenon-Krypton Detector, Computer, and X-ray source—facilitate prompt incorporation of new technological advances.



## Improved Patient Handling

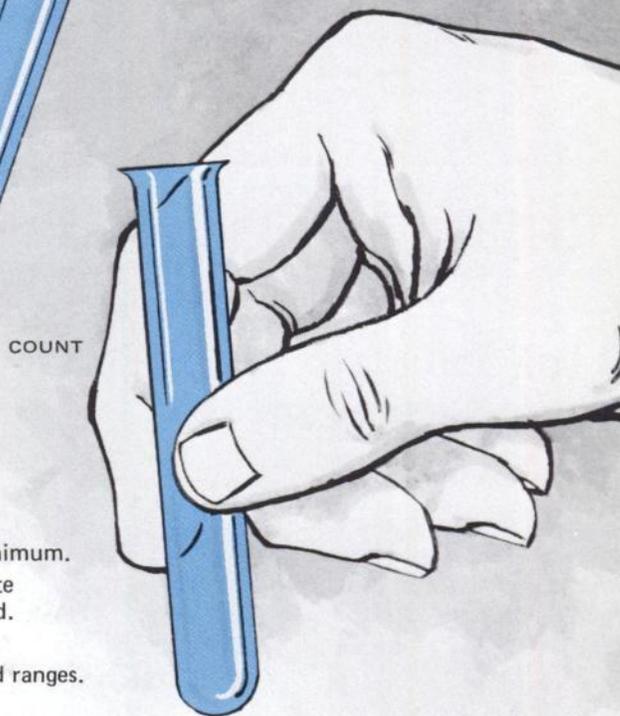
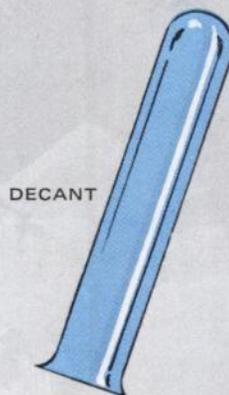
The new Scanner is a carefully engineered patient and user-oriented system. For example, the 90 cm-diameter aperture will accommodate your largest patients. Patient positioning within the rotating gantry is facilitated by a low-power laser alignment system and computer driven patient couch.

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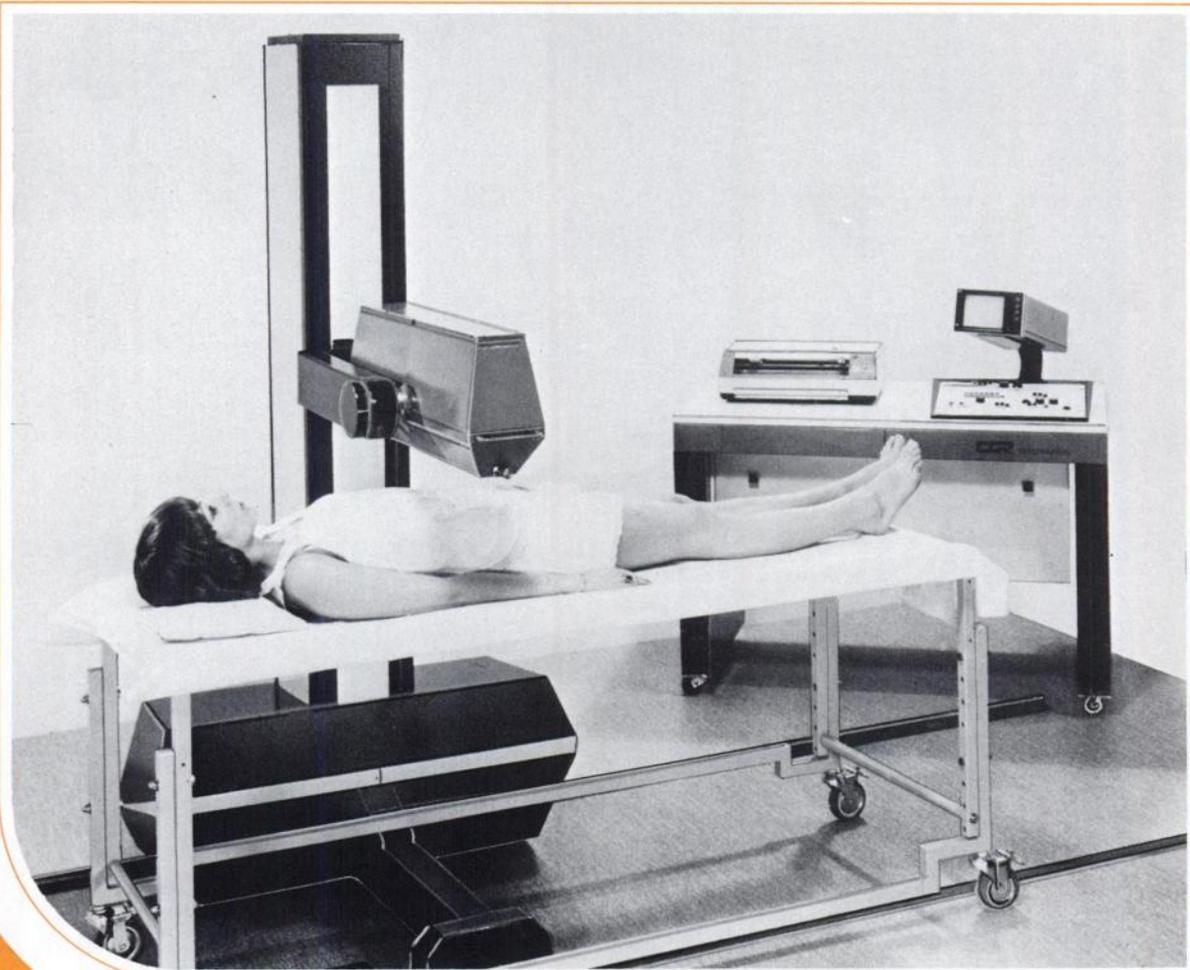
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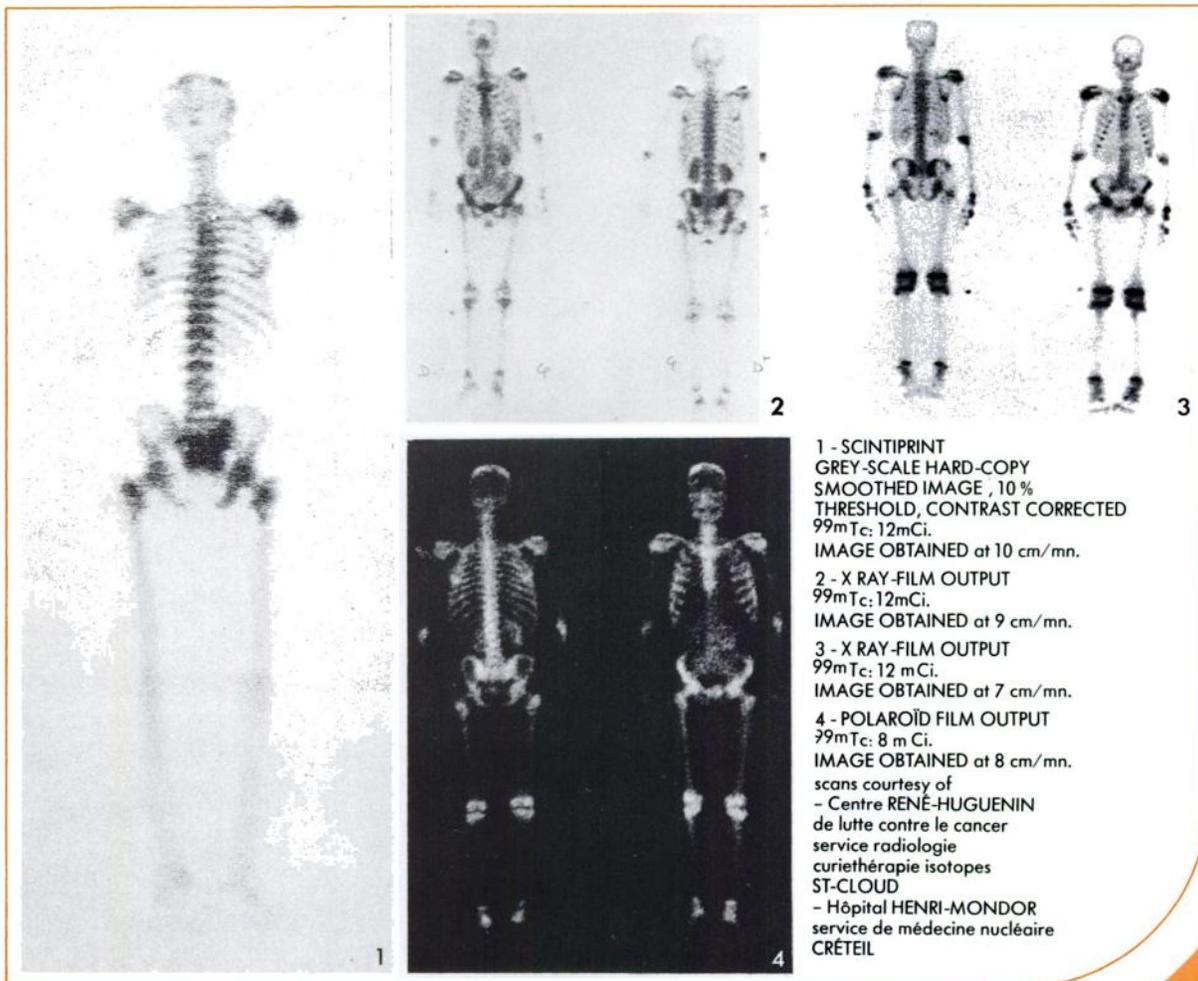
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