

THE GOOD NEWS

WE HAVE TWO BRAND NEW AMAZINGLY ADVANCED
THYROID UPTAKE SYSTEMS

THE BAD NEWS

YOU HAVE TO MAKE THE EXCRUCIATING CHOICE
OF ONE OVER THE OTHER

To help you with your decision, which we agree is not an easy one, please read the following carefully. Then give us a call and we'll be pleased to discuss both systems with you further.

**Faster than a speeding bullet...
More powerful than a micro-processor... Able to test, measure & print with accuracy...**

The CAPTUS® 2000 brings the power of the latest in computer technology to your facility. It is matched with a high level 1024 MCA and modern Microsoft® Windows software plus newly released, expanded applications software, and DeskJet 540 Printer.

Its compliment of tests include an advanced Thyroid program readily adaptable to several protocols, plus: Wipe Testing using an automated peak search, Schilling, Dicopac®, Blood Volume, RBC, and Bioassay.

If it doesn't Count it, Store it, Display it, Print it, and Auto Decay-Correct it, it's not the CAPTUS® 600 Thyroid System.

Designed from the ground up by Capintec's talented engineers, the high-quality CAPTUS® 600 is truly cost-effective for performing Uptakes and Bioassay. With power to handle the heaviest workloads, the CAPTUS 600's 256-channel MCA provides features not found on any other non-computer system. But that's not all. Together with the optional well, you can use the system for Wipe Testing, Blood Volume, Schillings, RBC, Daily, and Chi-Square programs. The CAPTUS 600 features menu-driven operations with easy-to-follow prompts on its large backlit screen.

CAPTUS® 2000 Highlights

1) Computer featuring intel 486 DX2-66 CPU, 8 MB RAM, 540 MB 11 MS Hard Drive, Quad-speed CD-ROM, plus many other features and upgrade options.

2) New CAPTUS Software Version 3.01, plus MS-Dos 6.22, WFV 3.11, MS Works 3.0 & Money, on CD's.

3) Includes an archiving & retrieval utility that has been upgraded offering greater functionality.

4) The ability to add pre-dose measurements when patients have received previously administered doses.

5) Constancy button added, allowing Constancy Test to be performed by itself and recorded.

6) Allows user to measure an efficiency with any source and records for future use.

7) Compact unique Spring-Arm Floor Stand is ergonomically correct and offers great range of detector movement for ease of patient interaction and positioning.

8) On-Line telephone support for all users offers fast response to technical questions through our toll-free 800 numbers.

9) Free Cs-137 and Eu-152 Rod Sources provided.

Both the CAPTUS 600 and CAPTUS 2000 offer many configurations such as: Table Top and Wall Mounted Systems.

CAPTUS® 600 Highlights

1) Low cost Microprocessor with plenty of flexibility and muscle replaces the CAPTUS 500 system with a new look and many new features.

2) On-screen display of spectrum while counting of all tests.

3) No one wants to be just a number, the CAPTUS 600 allows the patient's name and demographics to be typed in through the keyboard.

4) Like its Big Brother, the CAPTUS 2000, the CAPTUS 600 has the ability to add pre-dose measurements.

5) Automatic peak search identifies nuclides with direct read-outs in CPM, DPM, Curie & Bequerel with energy spectrum. Plus user definable protocols for wipes.

6) Expanded QC tests added to the system speeds user through the daily routine.



CALL FOR YOUR
NEW CAPINTEC CATALOG
1-800-ASK-4-CRC
FAX: 201-825-4829

Ease of patient approach is provided by the perfectly balanced spring-arm system.

Flared collimator swivels 360 degrees on the detector arm and meets ANSI Standard N 44.3 for Thyroid Uptakes.

Speed and accuracy in radioisotope Quality Assurance, Quality Control, Wipe Tests, Lab Tests and other clinical uses are accomplished with the built-in well detector system.

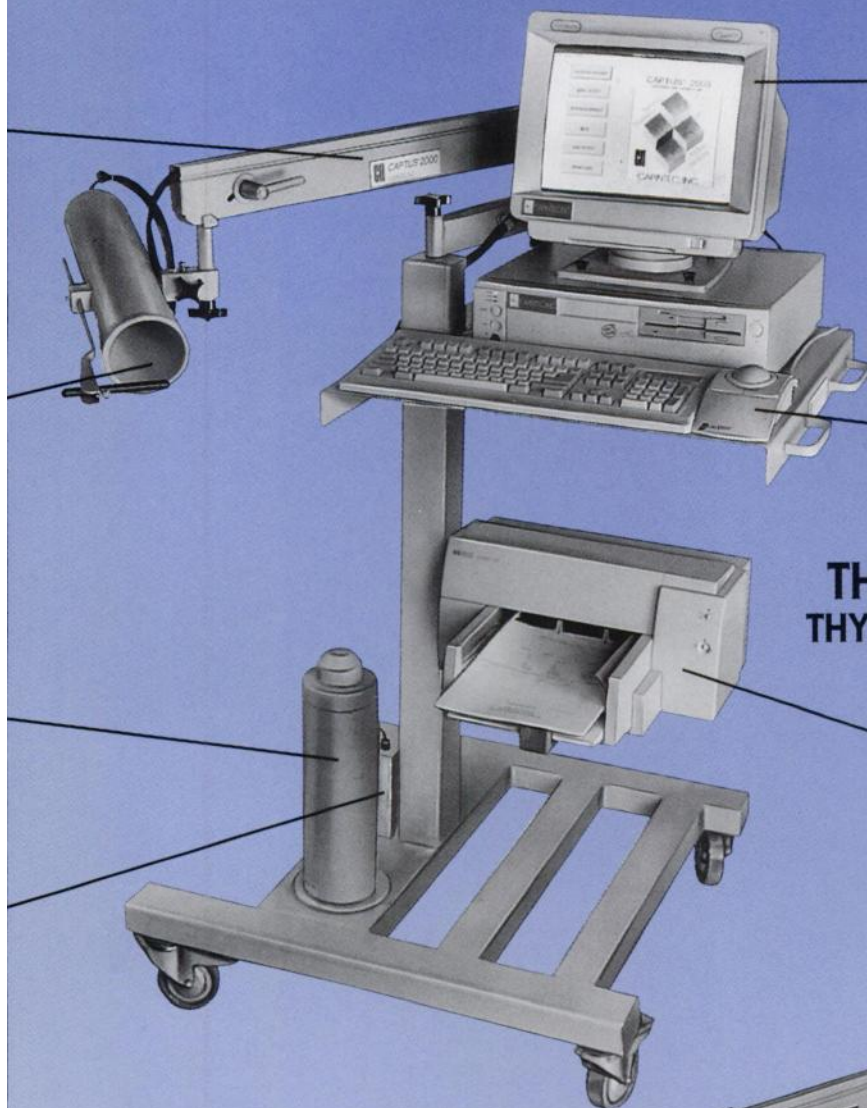
Patient and user safety through the use of an isolated transformer to insure a grounded system.

NOT JUST QUALITY. CAPINTEC QUALITY.



CAPINTEC, INC.

6 ARROW ROAD, RAMSEY N.J. 07446



High-resolution 800 x 600 SVGA color graphics

enhance displays of all programs, especially the full spectrum visible during all counting procedures.

Menu-driven applications programs

perform Thyroid Uptake, Wipe Testing, Bioassay, Blood Volume (I-125 or Cr-51), RBC Survival, Schilling Test (standard and Dicopac®), MCA functions as well as Time Activity curves.

Program speed is enhanced with the use of a track-ball addition to the keyboard.

**THE CAPTUS 2000
THYROID UPTAKE SYSTEM**

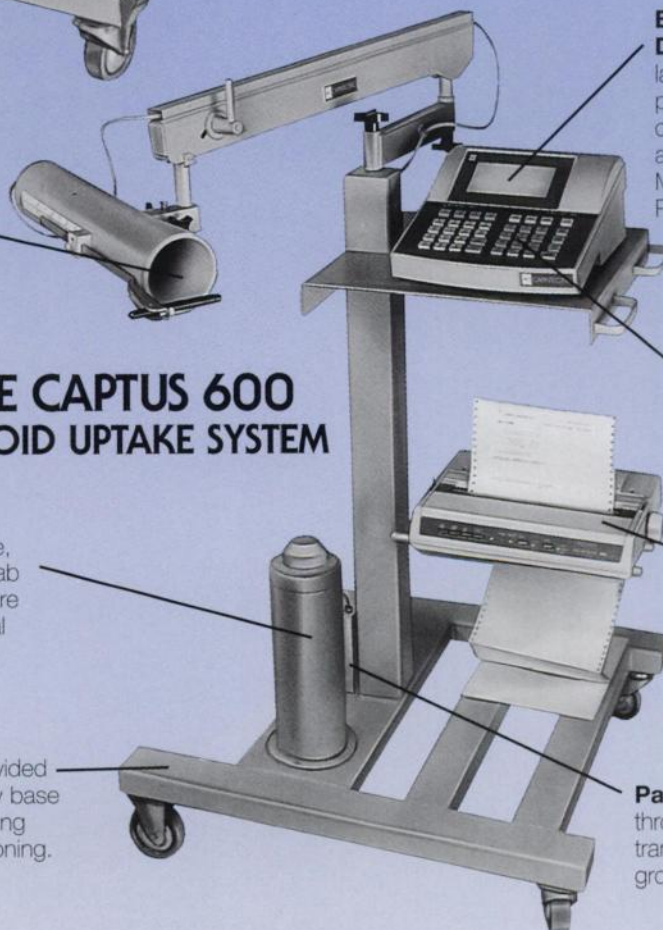
Immediate report printing on all procedures with the Hewlett Packard 540 DeskJet printer.

Flared collimator swivels 360 degrees on the detector arm and meets ANSI Standard N 44.3 for Thyroid Uptakes.

**THE CAPTUS 600
THYROID UPTAKE SYSTEM**

Speed and accuracy in radioisotope Quality Assurance, Quality Control, Wipe Tests, Lab Tests and other clinical uses are accomplished with the optional well detector system.

Stability and ease of maneuverability are provided by the design of the sturdy base and stand with swivel locking casters to maximize positioning.

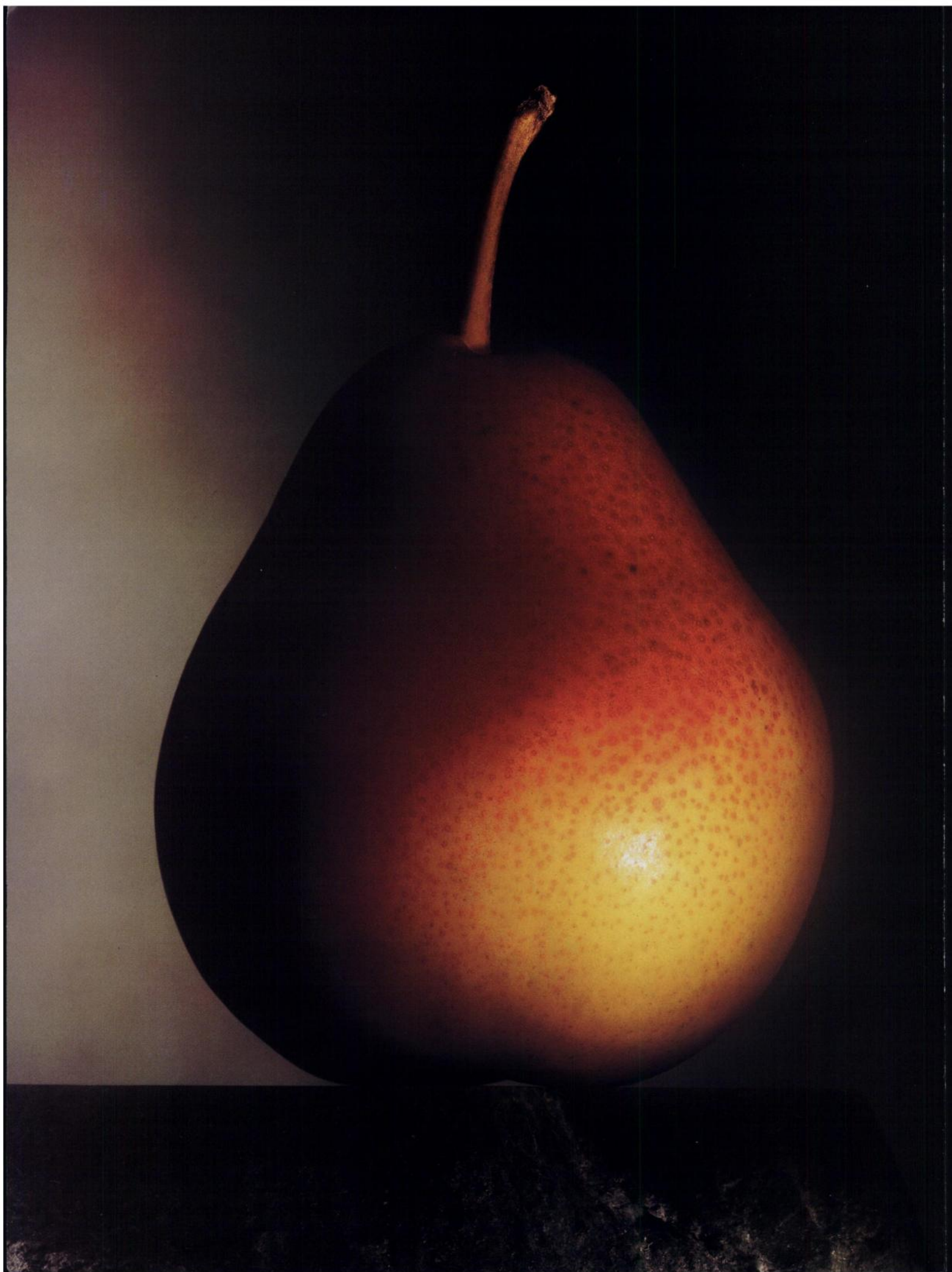


Blue (2.36" x 4.72") LCD Display with cold cathode lamp, backlit, and 128 x 256 pixel resolution features on-screen prompts and display of a full featured 256 channel MCA with presets, multiple ROI's and configuration archiving.

Convenient alpha/numeric keypad for inputting patient name, demographics, etc.

Immediate report printing on all procedures with a graphic, high-speed dot matrix, quality printer; easily displaying graphics and data for permanent records.

Patient and user safety through the use of an isolated transformer to insure a grounded system.



How to recognize a candidate for Cardiolite®

The shape of your patients may help you recognize the potential for soft-tissue attenuation, especially in fleshy figures.

For female and large-chested or obese male patients, Cardiolite comes through with higher photon energy (140 keV) to provide images with greater anatomical detail. Clear images can enhance interpretive confidence—which may reduce false-positives and equivocal cases.

Cardiolite also offers the unique advantage of direct measurement of both myocardial perfusion and ventricular function from one study.

So the next time you're faced with imaging female and large-chested or obese male patients, use Cardiolite and reduce soft-tissue attenuation.

Cardiolite

Kit for the preparation of Technetium Tc99m Sestamibi

To reduce soft-tissue attenuation Cardiolite comes through



Stress testing should be performed only under the supervision of a qualified physician in a laboratory equipped with appropriate resuscitation and support apparatus. There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi.

Please see brief summary of prescribing information on adjacent page.

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Safety and effectiveness in children below the age of 18 have not been established.

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5ml vial contains a sterile, non-pyrogenic, lyophilized mixture of:

Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0mg
Sodium Citrate Dihydrate - 2.6mg
L-Cysteine Hydrochloride Monohydrate - 1.0mg
Mannitol - 20mg
Stannous Chloride, Dihydrate, minimum ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) - 0.025mg
Stannous Chloride, Dihydrate, ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) - 0.075mg
Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) - 0.086mg

Prior to lyophilization the pH is 5.3-5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is $\text{Tc99m}[\text{MIBI}]_6^+$ where MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in the evaluation of ischemic heart disease. CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is also useful in the evaluation of myocardial function using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, localization in the anterior or inferior-posterior wall in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established. Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate recent myocardial infarction from ischemia.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See Precautions).

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

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.

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

Fatigue	35%
Dyspnea	17%
Chest Pain	16%
ST-depression	7%
Arrhythmia	1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rads/30mCi at rest, 1.2 rads/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, $[\text{Cu}(\text{MIBI})_2\text{BF}_4]$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations ($\approx 20\mu\text{g}/\text{ml}$), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[\text{Cu}(\text{MIBI})_2\text{BF}_4]$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity ($9\text{mg}/\text{kg}$, $> 600 \times$ maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Technetium Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient parosmia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

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

370-1110MBq (10-30mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration.

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

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

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

Organ	Estimated Radiation Absorbed Dose			
	REST			
	2.0 hour void		4.8 hour void	
	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.4	55.5	5.4	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	6.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8

Organ	STRESS			
	2.0 hour void		4.8 hour void	
	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.8
Gallbladder Wall	2.8	28.9	2.8	27.8
Small Intestine	2.4	24.4	2.4	24.4
Upper Large Intestine Wall	4.5	44.4	4.5	44.4
Lower Large Intestine Wall	3.3	32.2	3.3	32.2
Stomach Wall	0.5	5.3	0.5	5.2
Heart Wall	0.5	5.6	0.5	5.3
Kidneys	1.7	16.7	1.7	16.7
Liver	0.4	4.2	0.4	4.1
Lungs	0.3	2.6	0.2	2.4
Bone Surfaces	0.6	6.2	0.6	6.0
Thyroid	0.3	2.7	0.2	2.4
Ovaries	1.2	12.2	1.3	13.3
Testes	0.3	3.1	0.3	3.4
Red Marrow	0.5	4.6	0.5	4.4
Urinary Bladder Wall	1.5	15.5	3.0	30.0
Total Body	0.4	4.2	0.4	4.2

Radiopharmaceutical Internal Dose Information Center, July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

HOW SUPPLIED: Du Pont Radiopharmaceuticals' CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is supplied as a 5ml vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.



Radiopharmaceuticals

Marketed by

Du Pont Radiopharmaceutical Division
The Du Pont Merck Pharmaceutical Co.
331 Treble Cove Road
Billerica, Massachusetts, USA 01862

513121-0394
Brief Summary

3/94 Printed in U.S.A.

IN A FOG??

using aerosols to determine the patency of the pulmonary airway system? Use a gas (that's what the airway system is for), and Xenon (127 or 133) are gases which are safe, economical and easy to administer with the XENAMATIC™ 3000.

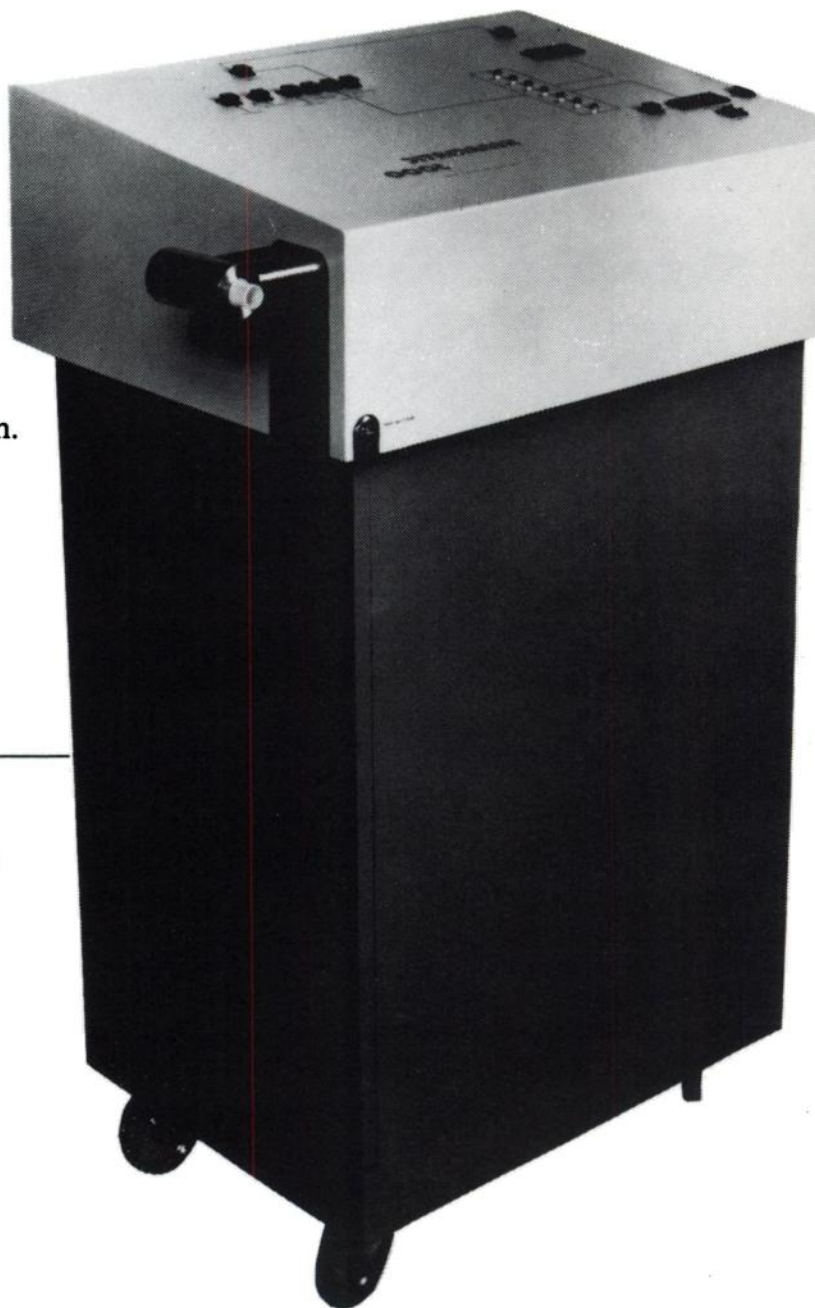
- Shielded for Xe 127 and Xe 133 (radiation profile available on request).
 - World's only system that allows you to study patients on Ventilators.
 - Largest and most efficient Xenon trap with a built-in monitor alarm system.
 - Built-in O₂ monitor with digital display and control.
 - A rebreathing system that saves Xenon.
 - Low breathing resistance so you can study sick patients.
 - Semi-automatic operation.
 - Remote Control Capability.
-

Get out of the FOG-making business, and call today for more information on putting gases where gases belong, with the XENAMATIC.

Also available, Model 2000.

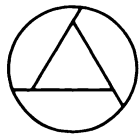
For more information, please call or write,

Circle Reader Service No. 32



DIVERSIFIED DIAGNOSTIC PRODUCTS, INC.

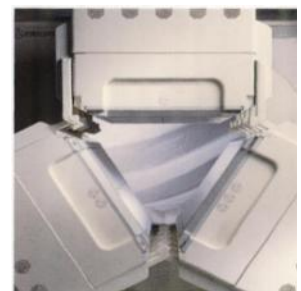
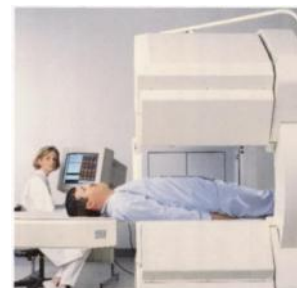
11603 Windfern
Houston, TX 77064
713-955-5323



The Next Generation

TRIAD XLT 20 Whole BodySPECT

Superior Clinical Imaging



Best Image Resolution

- PROXIMA Real-time Auto Body-Contouring
- Center-of-Rotation and Axial Alignment accuracy guaranteed to 0.1mm rms
- Angular accuracy guaranteed to 0.1° rms
- Patented linearity and X-Y shift correction

New Imaging Applications in Nuclear Medicine

- Whole BodySPECT multiple FOV SPECT
- 511 keV F-18 FDG SPECT
- Gated Cardiac SPECT/ Ejection Fraction

Imaging Complete Patient Population

- Industry-best 20 in. axial FOV
- Industry-best 30 in. patient imaging aperture
- 500 lb. patient weight capacity
- 6 ft. 4 in. patient height imaging capacity

Best Clinical Throughput

- Entire torso SPECT in one rotation
- Entire torso three planar views
- Six-view WholeBody Scan in 22 minutes
- Whole BodySPECT up to 6 ft. 4 in.
- Optimized for Oncology Applications

Patient Comfort

- 36 in. Open Access Gantry
- Elegant "Whisper-Quiet" Operation
- Extra-wide Patient Table

Efficient Clinical Operation

- QuickVIEW Swing Arm P-scope
- Automated Pre-Scan System Setup
- Simple Protocol-based Scan Setup
- State-of-the-art Sun computing speed

TRIAD XLT Products

-Triple Crown Results-

- Excellent Image Resolution:
- High Clinical Throughput:
- Elegant Whisper-Quiet Operation:

-Benefits-

- Better Diagnostic Detection
- Better Clinical Revenue
- Better Patient Acceptance

Plus

- F-18 FDG SPECT (11 mm FWHM Resolution): Metabolic Imaging Reality

Innovation Adoption Track Record

TRIAD XLT 20", Whole BodySPECT

Installation Sites	Adoptors	Delivery Month
St. Luc, UCL, Brussels, Belgium	Dr. Beckers, Dr. Pauwels	May 1994
Hospital of St. Raphael, New Haven, Connecticut	Dr. Caride	July 1994
ASAN Medical Center, Seoul, Korea	Dr. Moon, Dr. Lee	July 1994
Mt. Godinne, UCL, Yvoir, Belgium	Dr. DeCoster	September 1994
Centennial, Nashville, Tennessee	Dr. Bell	November 1994
VA Indianapolis & University of Indiana	Dr. Witt, Dr. Burt	January 1995
Roswell Park Cancer Institute, Buffalo, New York	Dr. Grossman, Dr. Bakshi	May 1995
National Institute of Health, Bethesda, Maryland	Dr. Carrasquillo, Dr. Bacharach	July 1995
Advanced Metabolic Imaging, Dallas, Texas	Dr. Hickey, Dr. Simon	July 1995

TRIAD XLT 9", Cardiac/Organ SPECT

Johns Hopkins, Baltimore, Maryland (two systems)	Dr. Natarajan	February, June 1993
VA San Francisco, UC, San Francisco, California	Dr. Gerard	February 1993
Duke, Durham, North Carolina (two systems)	Dr. Coleman, Dr. Jaszczak	June 1993, August 1994
University of Virginia, Charlottesville, Virginia	Dr. Teats, Dr. Croft	June 1993
Memorial Mission, Asheville, North Carolina	Dr. Peterson	July 1993
Austin, Heidelberg, Australia	Dr. McKay	September 1993
Pontiac Osteopathic, Pontiac, Michigan	Dr. Kottlyarov	October 1993
Royal Prince Alfred, Sidney, Australia	Dr. Eberl	November 1993
KUL, Leuven, Belgium	Dr. DeRoo, Dr. Mortelmans	December 1993
Karolinska, Stockholm, Sweden	Dr. Larsson	February 1994
Samsung Medical Center, Seoul, Korea	Dr. Kim	March 1994
Cleveland Clinic Foundation, Cleveland, Ohio	Dr. Go, Dr. McIntyre	October 1994

A Company Driven by Quality, Business Ethics,
and Long-Term Clinical Innovation

New from DuPont Radiopharmaceuticals:
High Quality and Extended Stability
in a SPECT Brain Perfusion Agent

**JUST WHAT YOU'RE
LOOKING FOR...**

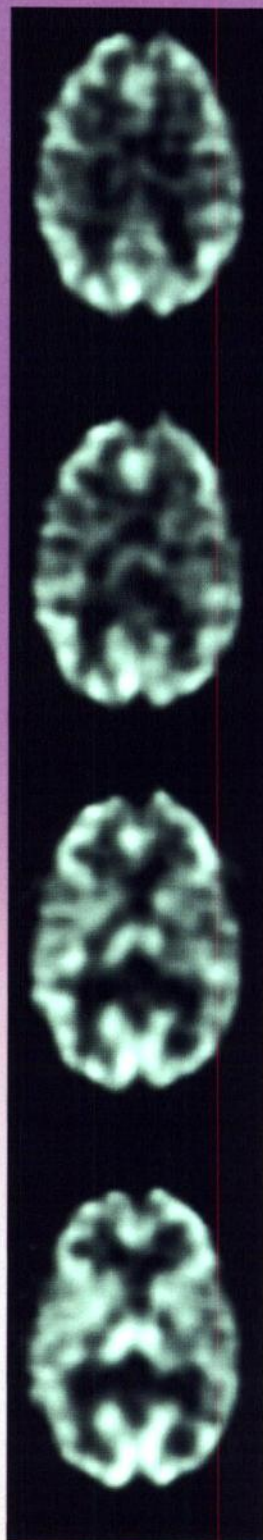


Introducing a **NEW** SPECT Brain Perfusion Agent

NEUROLITE[®]

KIT FOR THE PREPARATION OF TECHNETIUM Tc99m BICISATE INJECTION

Technetium Tc99m Bicisate should be used with caution in patients with renal or hepatic impairment since it is eliminated primarily by renal excretion. Adverse reactions are rare ($\leq 1\%$). For details, see Adverse Reactions section of the prescribing information. In clinical trials, at least one of three readers of Neurolite[®] images (blinded to all other clinical information) correctly diagnosed stroke for 85% of the subjects with stroke while unblinded interpretation of CT/MRI images resulted in the correct diagnosis of stroke in 88% of subjects with stroke. There were 11 false positive and 34 false negative interpretations of Neurolite images and 0 false positive and 31 false negative interpretations of CT/MRI results.



Normal images, using Neurolite, of a 36-year-old female.
—Courtesy of Thomas C. Hill, MD,
Deaconess Hospital, Boston, Mass

NEW

Just what you're looking for...
HIGH-QUALITY IMAGES...
EXTENDED STABILITY...



High-Definition Perfusion Images

Well-defined lesions

- ◆ Clear definition of perfusion defects as determined by visual analysis

High brain-to-background activity

- ◆ Clear delineation between brain and background structures early after injection

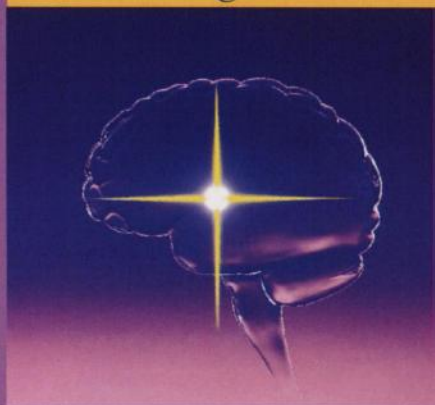
Extended In Vitro Stability

The SPECT brain agent with 6-hour stability after preparation

- ◆ Allows for more flexible patient scheduling
- ◆ Useful in the acute setting since doses can be prepared beforehand
- ◆ Enables SPECT brain imaging to be used with agitated or uncooperative patients where study delays are often encountered
- ◆ Allows for convenience of unit dosing

Please see brief summary of prescribing information at the end of this advertisement.

Introducing Neurolite®



JUST WHAT YOU'RE LOOKING FOR...

Desirable pharmacokinetics/dosimetry

- ◆ Accumulates rapidly in the brain^{1,2}
- ◆ Localizes as a function of regional brain perfusion, cellular uptake, and metabolism within the cells
- ◆ Rapid blood clearance—(< 10% remains in the blood after 1 minute, <5% after 60 minutes)
- ◆ A dosing range of 10-30 mCi of Neurolite provides the flexibility to achieve improved image quality and/or reduced imaging time¹

Simple room-temperature preparation

One-step quality control procedure

NEUROLITE®

KIT FOR THE PREPARATION OF TECHNETIUM Tc99m BICISATE INJECTION

Quality you expect. Stability you need.

Please see brief summary of
prescribing information on adjacent page.



Radiopharmaceuticals

NEUROLITE®

KIT FOR THE PREPARATION OF TECHNETIUM Tc99m BICISATE INJECTION

FOR DIAGNOSTIC USE

The following is a brief summary. For more information please see complete prescribing information.

INDICATIONS

Neurolite single photon emission computerized tomography (SPECT) is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed.

Neurolite is not indicated for assessment of functional viability of brain tissue. Also, Neurolite is not indicated for distinguishing between stroke and other brain lesions.

CONTRAINDICATIONS

None known.

WARNINGS

None known.

PRECAUTIONS

General

USE WITH CAUTION IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT. TECHNETIUM Tc99m BICISATE IS ELIMINATED PRIMARILY BY RENAL EXCRETION. WHETHER TECHNETIUM Tc99m BICISATE IS DIALYZABLE IS NOT KNOWN. DOSE ADJUSTMENTS IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT HAVE NOT BEEN STUDIED.

Patients should be encouraged to drink fluids and to void frequently during the 2-6 hours immediately after injection to minimize radiation dose to the bladder and other target organs.

Contents of the vials are intended only for use in the preparation of Technetium Tc99m Bicisate and are not to be administered directly to the patient without first undergoing the preparation procedure.

The contents of each vial are sterile and nonpyrogenic. To maintain sterility, aseptic technique must be used during all operations in the manipulation and administration of Neurolite.

Technetium Tc99m Bicisate should be used within six hours of the time of preparation.

As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other people.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. When tested in vitro, Neurolite prepared with decayed generator eluate induced unscheduled DNA synthesis in rat hepatocytes and caused an increased frequency of sister chromatid exchanges in CHO cells; but, it did not induce chromosome aberrations in human lymphocytes or cause gene mutations in the Ames test or in a CHO/HGPRT test. Unreacted bicisate dihydrochloride increased the apparent rate of gene mutation of the TA 97a strain of *S. typhimurium* in the Ames test; but, it did not demonstrate clastogenic activity in an in vivo micronucleus assay in mice.

Pregnancy: Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Technetium Tc99m Bicisate. It is also not known whether Technetium Tc99m Bicisate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, Technetium Tc99m Bicisate should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Technetium Tc99m Pertechnetate can be excreted in human milk. Therefore, formula should be substituted for breast milk until the technetium has cleared from the body of the nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

In clinical trials, Neurolite has been administered to 1022 subjects (262 normals, 760 patients). Of these, 548 (54%) were men and 473 (46%) were women. The mean age was 58 years (range 17 to 92 years). In the 760 patients who had experienced neurologic events, there were 11 (1.4%) deaths, none of which were clearly attributed to Neurolite.

A total of 60 subjects experienced adverse reactions; the adverse reaction rates were comparable in the <65 year and the >65 year age groups.

The following adverse effects were observed in ≤1% of the subjects: headache, dizziness, seizure, agitation/anxiety, malaise/somnolence, parosmia, hallucinations, rash, nausea, syncope, cardiac failure, hypertension, angina, and apnea/cyanosis.

In clinical trials of 197 patients, there were inconsistent changes in the serum calcium and phosphate levels. The cause of the changes has not been identified and their frequency and magnitude have not been clearly characterized. None of the changes required medical intervention.

DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient should be encouraged to drink fluids liberally and to void frequently.

The recommended dose range for intravenous administration for a 70 kg patient is 370 - 1110 MBq (10-30 mCi). Dose adjustments for age, weight, gender, or renal or hepatic impairment have not been studied.

The dose for the patient should be measured by a suitable radioactivity calibration system

immediately before administration to the patient. Radiochemical purity should be checked before administration to the patient.

Neurolite, like other parenteral drug products, should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with all applicable regulations.

Prior to reconstitution, vial A and vial B are stored at 15°-25°C. Protect vial A from light.

Store at room temperature (15°-30°C) after preparation.

Aseptic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves and effective shielding should be worn when handling the product.

RADIATION DOSIMETRY

The radiation doses to organs and tissues of an average patient (70 kg) for Technetium Tc99m Bicisate injected intravenously for 370 MBq (10 mCi) are shown in Table 4 and for 1110 MBq (30 mCi) are shown in Table 5.

Table 4.—Radiation Absorbed Doses From 370 MBq (10 mCi) of Technetium Tc99m Bicisate

Organ	Estimated Absorbed Radiation Dose*			
	2.0 Hr. Void		4.8 Hr. Void	
	mGy/ 370 MBq	rads/ 10 mCi	mGy/ 370 MBq	rads/ 10 mCi
Bone Surfaces	1.26	0.13	1.41	0.14
Brain	2.04	0.20	2.04	0.20
Gallbladder Wall	9.25	0.91	9.25	0.92
Intestine Wall				
(Lower Large)	4.81	0.47	5.55	0.55
Intestine (Small)	3.48	0.35	3.70	0.38
Intestine Wall				
(Upper Large)	5.92	0.61	6.29	0.63
Kidneys	2.70	0.27	2.74	0.27
Liver	1.96	0.20	2.00	0.20
Lungs	0.74	0.08	0.74	0.08
Ovaries	2.00	0.22	2.96	0.30
Red Marrow	0.89	0.09	1.00	0.10
Testes	0.81	0.08	1.33	0.13
Thyroid	1.30	0.13	1.30	0.13
Urinary Bladder Wall	11.10	1.10	27.01	2.70
Total Body	0.89	0.09	1.07	0.11

Table 5.—Radiation Absorbed Doses From 1110 MBq (30 mCi) of Technetium Tc99m Bicisate

Organ	Estimated Absorbed Radiation Dose*			
	2.0 Hr. Void		4.8 Hr. Void	
	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi
Bone Surfaces	3.77	0.39	4.22	0.42
Brain	6.11	0.61	6.11	0.61
Gallbladder Wall	27.75	2.73	27.75	2.76
Intestine Wall				
(Lower Large)	14.43	1.41	16.65	1.65
Intestine (Small)	10.43	1.05	11.10	1.14
Intestine Wall				
(Upper Large)	17.76	1.83	18.87	1.89
Kidneys	8.10	0.81	8.21	0.81
Liver	5.88	0.60	5.99	0.60
Lungs	2.22	0.23	2.22	0.23
Ovaries	5.99	0.66	8.88	0.90
Red Marrow	2.66	0.26	3.00	0.29
Testes	2.44	0.24	4.00	0.39
Thyroid	3.89	0.39	3.89	0.39
Urinary Bladder Wall	33.33	3.33	81.03	8.10
Total Body	2.66	0.27	3.22	0.33

*Dosimetry calculated using the MIRD software program at Oak Ridge Associated Universities, P.O. Box 117, Oakridge, TN, 29 July 1988.

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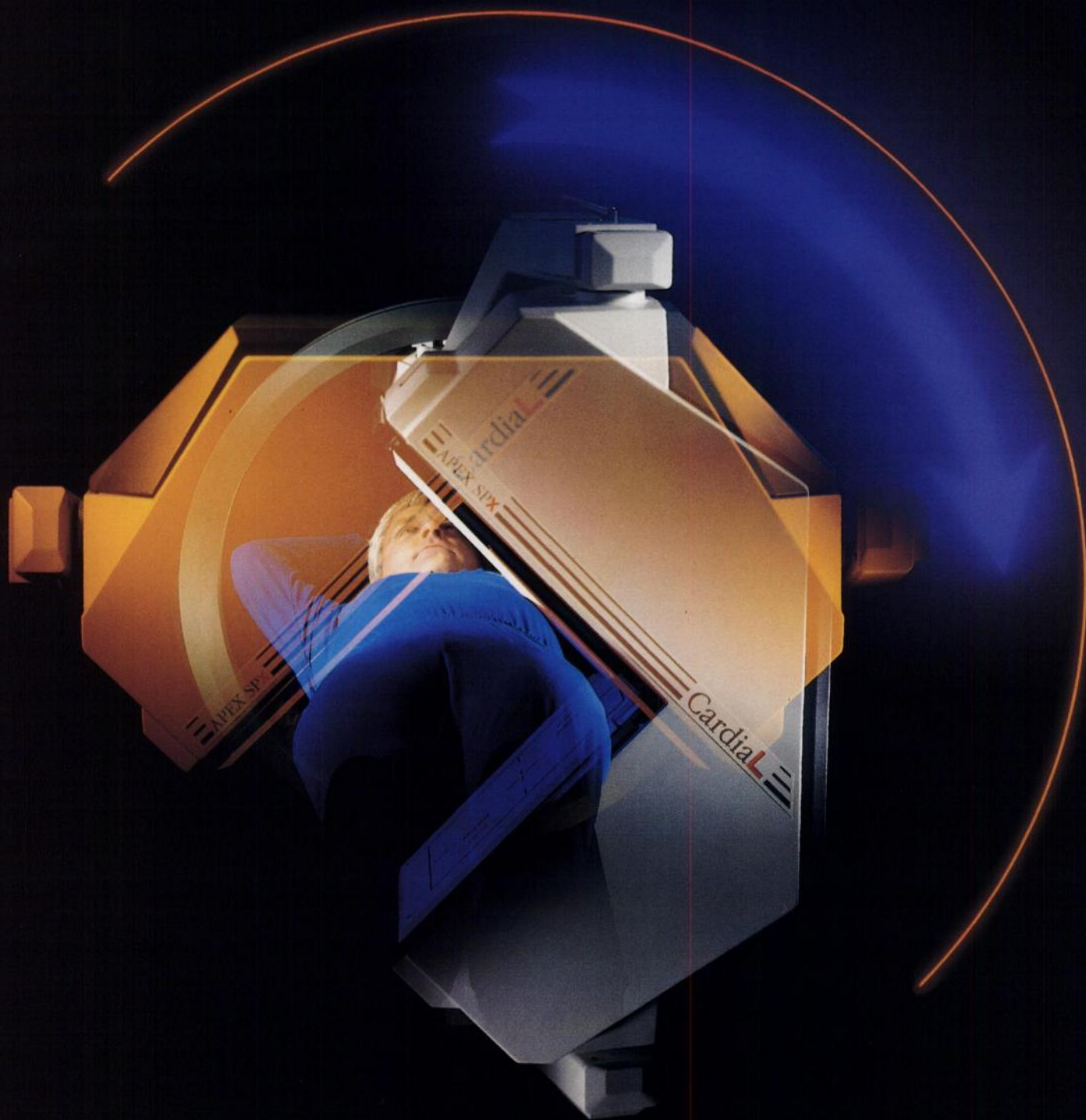
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2. Vallabhajosula S, Zimmerman RE, Picard M, et al. Technetium-99m ECD: a new brain imaging agent: in vivo kinetics and biodistribution studies in normal human subjects. *J Nucl Med.* 1989;30:599-604.

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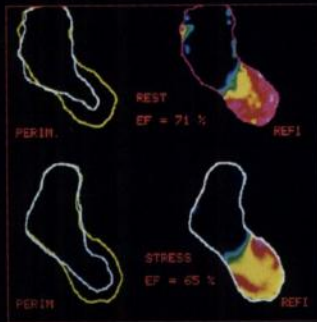
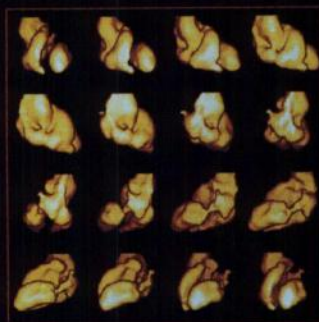
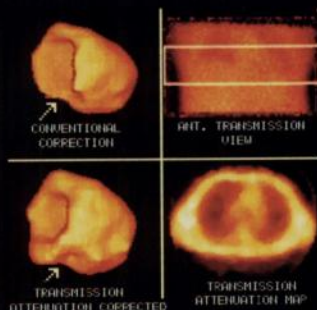


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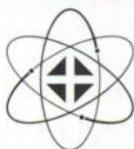
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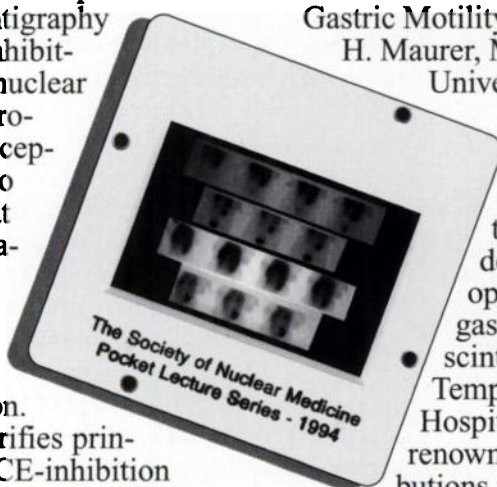
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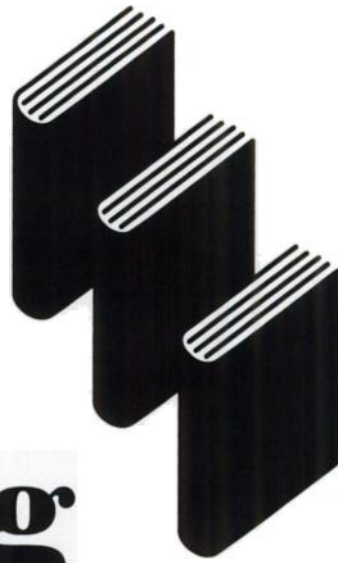
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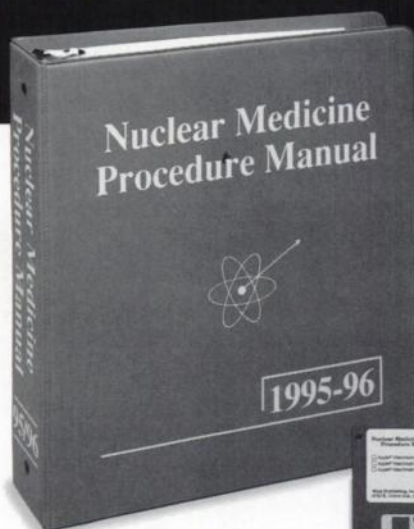
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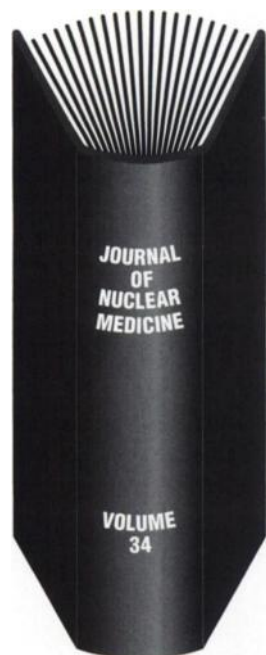
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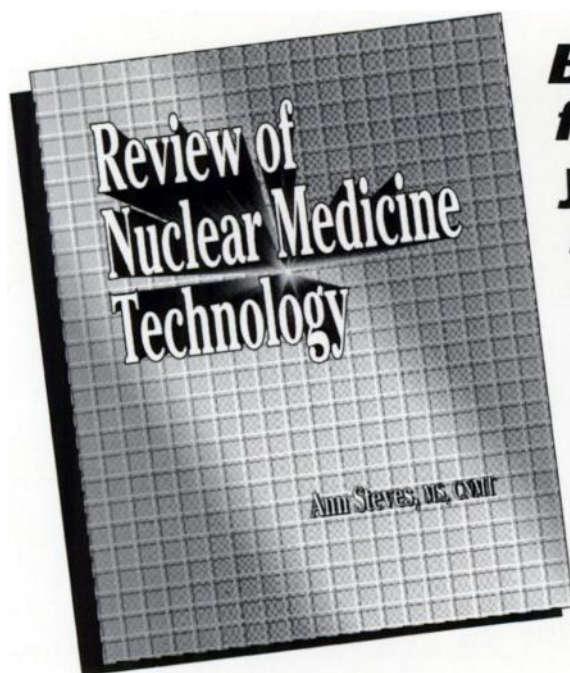
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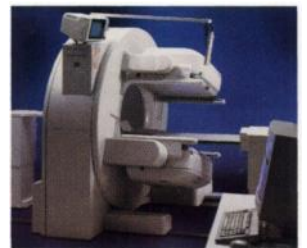


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