

**SIEMENS**

**e.c.**





## OptiCEL self-tuning digital detectors keep your nuclear systems out of the shop.

NEW OPTICEL™ DIGITAL DETECTORS. Sports cars aren't the only high-performance machines that need constant tuning. To get optimal image quality consistently, your digital gammacamera will need ongoing adjustment as well. The question is, "Will you have to sacrifice uptime to get it?" Not with OptiCEL digital detectors from Toshiba. OptiCEL digital detectors feature Optotune™, an exclusive self-tuning technology that automatically adjusts the digital detector. That means that your Toshiba gammacamera will stay up and running, not up on the rack.

Available on Toshiba's nuclear gammacamera systems, Optotune tunes the digital detector up to 512 times per second. That equates to super-crisp image quality every time, but of equal importance, it translates to exceptional reliability and maximum uptime. Digital detectors without Optotune may require service every two months to get similar tuning. And service time is downtime.

New OptiCEL digital detectors: powerful, self-tuned nuclear diagnostics designed to stay in service... and out of the shop. For more information call: 1-800-421-1968



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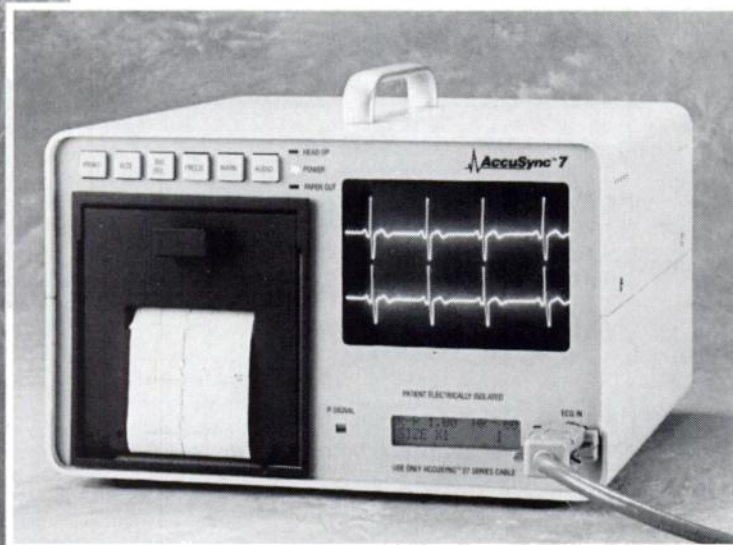
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# AccuSync<sup>®</sup> 7

## The NEW 3 or 5 lead ECG gating device for cardiac studies

AccuSync Medical Research, the manufacturer of the finest line of ecg gating devices since 1979, introduces the AccuSync 7, a 3 or 5 lead system designed to detect the R Wave with no delay.

State-of-the-art circuitry and configuration minimize the noise factors inherent during cardiac procedures. The result: **Accurate volume curve.**



- Automatic R Wave Detection
- Optional Thermal Head Printer
- Selectable ECG Signal
- Compatible with All Computers
- Light, Compact Design
- CSA/NRTL/C Approved

### The New AccuSync 7 Features:

- ❑ 5" CRT Monitor with extended display
- ❑ R trigger event marker
- ❑ LCD display indicates:  
R to R interval, Heart Rate, ECG size,  
ECG signal selection, Lead off condition
- ❑ Audio indicator
- ❑ Freeze signal capability
- ❑ 115/230V, 60/50Hz selectable
- Optional thermal head printer
- Optional playback mode
- Optional RS232 output



*The AccuSync 4M offers a low-cost trigger alternative.*

**AccuSync<sup>®</sup>**  
MEDICAL RESEARCH CORPORATION  
132 Research Drive  
Milford, CT 06460  
Tel. (203) 877-1610  
Fax: (203) 877-8972

AccuSync is a registered trademark of the AccuSync Medical Research Corporation.  
AccuSync Medical Research Corporation formerly  
Advanced Medical Research Corporation.

## Position Available

### Assistant Professor - Physicist

A vacancy for a nuclear medicine physicist at the rank of Assistant Professor is expected. Duties include clinical services and teaching. Doctoral degree in medical physics or related disciplines is required. Board certification preferred at time of appointment; required after three years of appointment. Interested persons should send a letter, current curriculum vitae and names of three professional references to: Robert Y.L. Chu, PhD, Acting Director of Medical Physics, Department of Radiological Sciences, University of Oklahoma Health Sciences Center, Post Office Box 26901, Oklahoma City, OK 73190. The University of Oklahoma is an equal opportunity/affirmative action employer.

### BC/BE Internal Medicine and Nuclear Medicine

Full-time employment in hospital-based and private practice facility for general nuclear medicine and internal medicine with emphasis on thyroid disease. Qualified candidates, send CV to: Professional Management, P.O. Box 14966, Greensboro, NC 27415.

### Division Chief of Nuclear Medicine

Peoria Radiology Associates seeks a board certified radiologist with specialty board certification in nuclear medicine. Responsibilities will include Division Chief of the Nuclear Medicine section and occasional coverage of CT, MRI, Sono and General Radiology. The successful candidate will be joining a group of 20 radiologists

with a thriving practice in a large tertiary care hospital and surrounded by community hospitals. Resident and medical student teaching will be expected. Send CV and date of availability to: Dr. G.T. Campbell, c/o Laura Lee, Peoria Radiology Associates, 530 N.E. Glen Oak Ave., Peoria, IL 61637.

### Nuclear Medicine Staff Physician

Applications are being sought for a full time nuclear medicine staff physician, Veterans Affairs Medical Center, Dallas, TX. The position includes an academic appointment in the Department of Radiology, University of Texas Southwestern Medical School. Applications must be board eligible or board certified in nuclear medicine. Cardiac, therapeutic and SPECT experience as well as strong research capabilities required. Responsibilities include teaching radiology and nuclear medicine residents. A CV and 3 letters of reference should be sent to: Ana Mello, MD, Chief, Nuclear Medicine Service, Veterans Affairs Medical Center, 4500 Lancaster Rd., Dallas, TX 75216. No telephone calls accepted. Equal opportunity employer. Applicants subject to drug testing. Smoke-free facility.

### Nuclear Medicine Technologist

Nuclear Medicine Technologist, F/T, P/T, On-Call; ARRT, NMTCB or ASCP certified. Walter Reed Army Hospital, Washington, D.C. (800) 331-8777 x601.

### Radiologist

Radiologist with considerable nuclear medicine experience including nuclear cardiology. Fax CV to: (805) 723-6882.

## Position Wanted

Experience ABNM certified physician seeks FT job. Dr. Garcia, (914) 778-2601.

Board Certified NMT/Board Certified PA seeks position combining use of both skills. S. Koehler, PA-C, CNMT. 505-254-9543.

ABNM certified, young, energetic, experienced in all aspects of general nuclear medicine, including PET seeking temporary/permanent, PT/FT job in a veterans affairs or state county hospital. Salary negotiable. Will take full responsibilities including coverage for vacation, meetings, calls, weekends, etc... Available to relocate. Beginning immediately. Please leave a message at 310-473-5137.

Nuclear medicine physician, certified ABNM, ABIM. Six years experience at major university hospital with radiology residency and major medical school affiliation. Experiences in all aspects of diagnostic and therapeutic nuclear medicine, including cardiac, pediatric, oncologic, SPECT and Sr-89/1-131 therapy. Reply to the Society of Nuclear Medicine, Box #601, 1850 Samuel Morse Drive, Reston, VA 22090-5316.

Just a reminder...

**The JNM special issues  
are available for sale.**

### May JNM-Cardiology Special Section (available after May 15, 1996)

A special cardiology section will stress the advances in myocardial perfusion imaging. Also featured: the latest research in technetium-99m-sestamibi tracers to detect vascular thromboses.

### June JNM - Oncology Special Issue (available after June 15, 1996)

Articles in this special issue will emphasize the importance of nuclear medicine in the diagnosis and management of disease and the evaluation of treatments in patients with various cancers. Other articles explore the most recent advances using somatostatin imaging tracers.

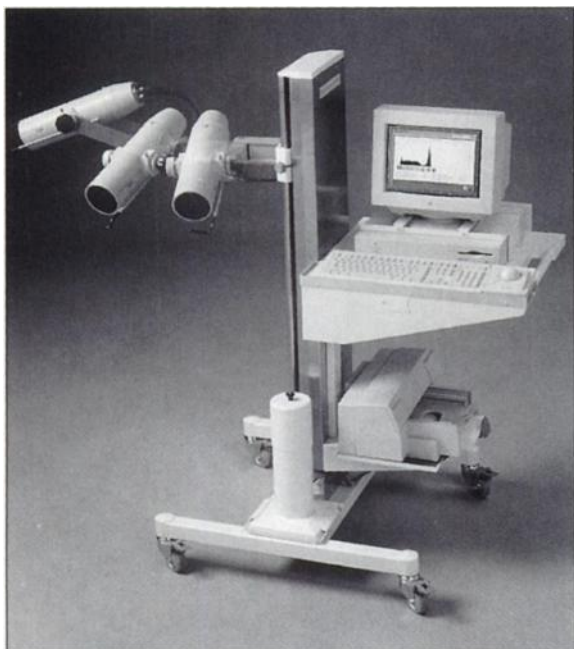
### July JNM - Neurology Special Issue (available after July 15, 1996)

Special focus articles address the role of FDG-PET in Alzheimer's and other neurologic diseases, and the use of PET and SPECT in relation to epilepsy. This issue also includes the SNM Brain Imaging Council recommendations for performing brain studies.

**To order copies of the JNM special issues, contact  
Matthews Medical Books at:  
800-633-2665 or outside the U.S. call 314-432-1401.**

Each description of the products below was condensed from information supplied by the manufacturer. The reviews are published as a service to the professionals working in the field of nuclear medicine and their inclusion herein does not in any way imply an endorsement by the Editorial Board of *The Journal of Nuclear Medicine* or by the Society of Nuclear Medicine.

### Macintosh®-based Thyroid Uptake System with Expanded Programs



Blodex Medical Systems offers a Macintosh-based thyroid uptake system packaged in the Macintosh and connected to a 1024 Channel Multi-Channel Analyzer. The system, called the Atomlab 950, displays real-time patient data and includes programs for thyroid

uptake, wipe testing, bioassay, schilling tests, administration/QA and an expanded hematology mode that includes: GFR and ERPF, RBC survival and blood volume. With 8 mb ram and a 500 mb hard drive, the system has more than enough room to include extra department software. PC only users will appreciate the Power Mac's built-in programs that reads and translates PC files. An example of some of the programs included are: a wipe test program extensive enough to satisfy new regulations and includes the ability to customize site and location and document in clear, quality report-style. All program reports are generated on a laser-quality printer on either facility letterhead or standard stationery. The Atomlab 950 can be configured with either a mobile stand for convenient use (as shown) or as a table top set up for departments with limited floorspace. Blodex Medical Systems, Brookhaven R&D Plaza, P.O. Box 702, Shirley, NY 11967-0702. Phone: (800) 224-6339. Fax: (516) 924-9241.

### Toshiba Introduces Triple-Energy Window SPECT for Scatter Correction

The triple-energy window SPECT is available from Toshiba America Medical Systems' GCA-7000 series nuclear medicine gamma cameras. One of the most significant factors degrading image quality in planar and SPECT studies is Compton scatter. Scattered photons coming from different, but unknown origins mix with true peak photons and contribute to a falsely increased count rate. As a result, organs close to each other are not well-differentiated when imaged. This problem is even more apparent when studies of different organs are conducted within a short time frame or during scans that require the use of high-energy nuclides, said Steve Sickels, manager, nuclear medicine business unit. By isolating and measuring the scattered photons and subtracting that information from the images, clean data

can be produced. Three windows, one for the main energy peak and two for scatter measurement (using a scatter estimation and subtraction algorithm) are called the triple energy window scatter correction method. The benefits of this feature are: improved image resolution and increased accuracy of image quantification, resulting in improved diagnostic accuracy. Image quality is also enhanced when radiopharmaceuticals with multiple energy peaks are used. With this scatter correction method, a dual-isotope, single acquisition produces image quality closely resembling that of a dual-isotope, dual-acquisition study. Toshiba America Medical Systems, Inc., Attn: Catherine M. Ellits, 2441 Michelle Dr., Tustin, CA 92681-2068. Phone: (714) 669-4140. Fax: (714) 730-4022.

### New CD-Rom Offers Health Science Information from 200 Publishers

J.A. Majors Company is offering a CD-Rom product, called *majors.doc* (Majors Database on CD). With the *majors.doc* CD, users can locate information on health science books and multimedia products from more than 200 publishers. Over 40,000 individual listings are incorporated in the system including titles, authors, price, bibliographic information and table of contents. This CD-Rom will allow the health care practitioner to make better buying decisions and to select more titles that meet their specific needs. In addition, researchers will be able to use *majors.doc* to review a clinical discipline for existing products in seconds. Information is updated monthly. The publishers currently represented include major health science publishing houses such as Mosby, Lippincott-Raven and McGraw-Hill and professional associations such as American Psychiatric Press and small medical presses like Lexi-Comp and Tarascon will be available. For the novice, *majors.doc* can search for a key word or allow the user to apply sophisticated searching techniques like Boolean logic to review all fields for focused topics such as pediatric leukemia or dermatologic complications with AIDS patients. The user will be able to store, retrieve, display and print data on the selected titles. J.A. Majors Company, Attn: Carolyn Lewis, P.O. Box 819074, Dallas, TX 75381-9074. Phone: (214) 888-4664. e-mail: clewis@mail.majors.com.

### The SEPTA Tomographic Imaging Table

This imaging table is designed to act as a replacement for all SPECT systems that use manually height adjusted tables. Diagnostic Plus brings forth the SEPTA tomographic imaging table. An optional pallet (carbon fiber composite construction) will support a patient up to 400 pounds and the imaging area of pallet is 14" wide by 55" long. There are two options for floor movement: (a) a two-swivel lock casters in back and two straight wheels in front allowing the table to move in and out as well as rotate. The front legs of the table can either be guided into position via locating pins in the front legs that can be depressed and released by foot or with floor tracks; or (b) a four-swivel lock casters, two in front and two in back, allowing the table to be moved sideways in tight room situations. Locating pins that can be depressed and release by foot are used to position the table accurately. Diagnostic Plus, Inc., Attn: Don Bogutski, 69 Fourth Ave., City Park, NY 11040. Phone: (516) 742-1939. Fax: (516) 742-1803.

## Attention Picker Nuclear Medicine Product Users

Eclipse Systems, Inc., is a full service company specializing in sales, service, software and consulting for nuclear medicine products including Picker SX series cameras and PCS series computers. We are authorized distributors of MSE software, and we are the originators of Total Eclipse total body imaging software for Picker SX series stands with PCS computers. Eclipse also sells and services other manufacturers' gamma camera systems including ADAC and Toshiba.

- Nuclear medicine products
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- Gamma cameras, planar and spect
- Computers
- Software
- Cardiac physiologic gates
- Imaging tables
- Video imagers

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## NuMac Computers

PowerPC Macintosh based  
Nuclear Medicine Computers

**Replace your old out-dated  
Micro Delta, ADAC and GE computers**

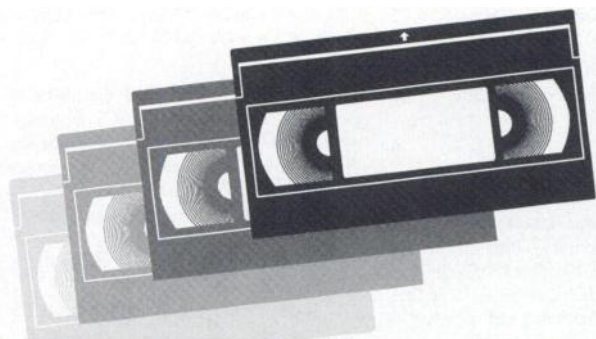
**Add speed and versatility to your  
present gamma camera**

**Gated SPECT reconstruction in 15sec**

**NuMac Computers From ONES  
The Most Cost Effective Way  
To Update Your Department**

**ONES Medical Services, Inc.**  
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## VIDEO RENTAL LIBRARY

***In the interest of providing low-cost continuing education to its membership, the SNM has established a rental program of video tapes recorded live at the Annual Meetings. All of the video tapes in the SNM 1995-1996 Audiovisual catalog are available for rental as well as purchase.***

**The rental fee of \$14.00 per tape or one coupon includes:**

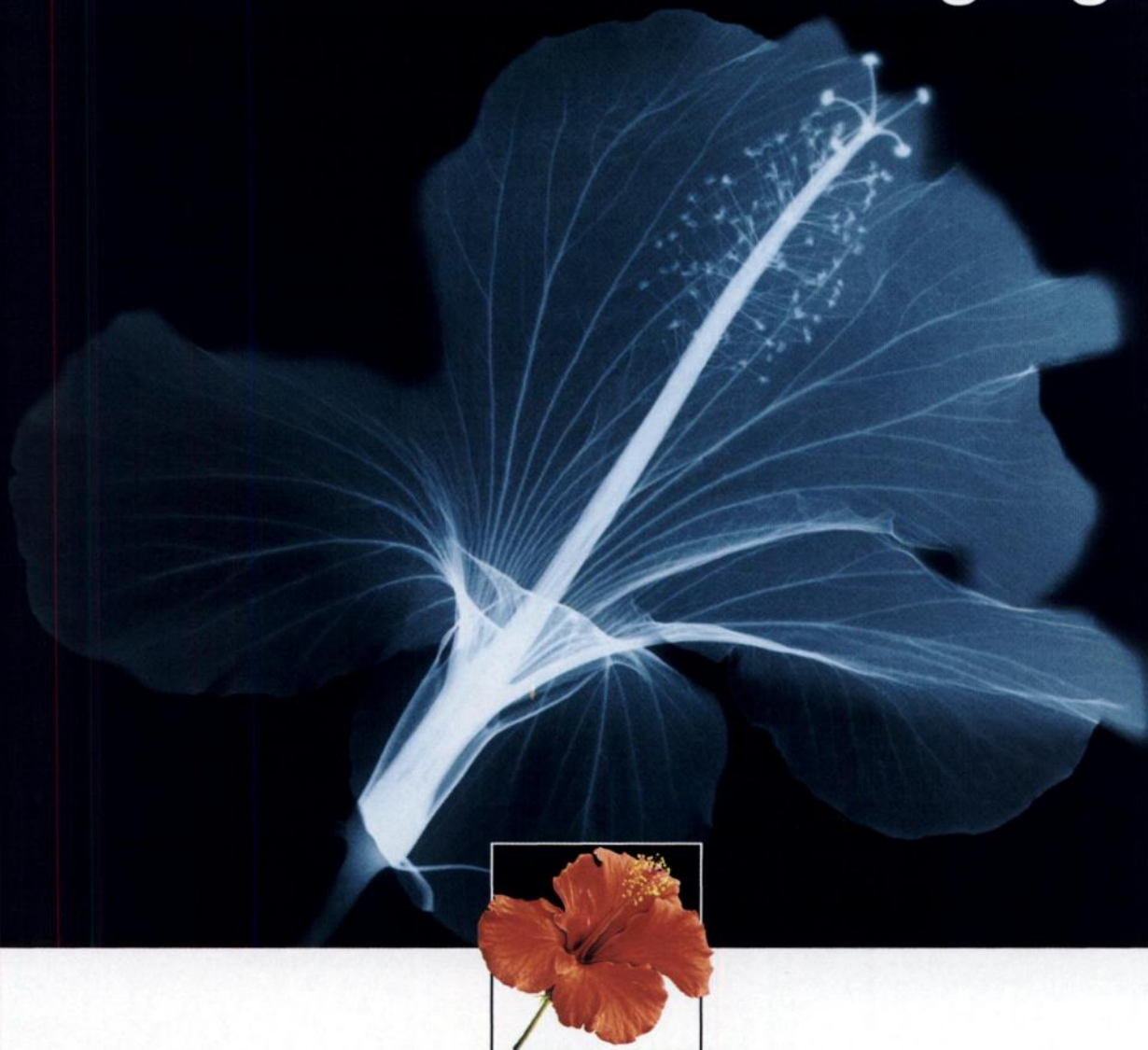
- Rental of one video tape for a two-week period.
- Shipping charges to the customer.
- One CME/VOICE evaluation form good for continuing education credit for up to 10 viewers.

Rental of a video tape costs \$14.00. Use either the order form on the back of the 1995-1996 Audiovisual catalog or acquire a coupon, worth one free rental, through one of the sponsoring companies. For coupons please contact: Bracco, Dupont, Mallinckrodt, Medi-Physics or Syncor.

If you have questions or need further information about the coupons, please contact the Society of Nuclear Medicine at (703) 708-9000, ext. 250. If you would like to order a video tape, please contact the National Audio Video, Inc. at 1-800-373-2952.



# Bracco: Experts in the nature of imaging

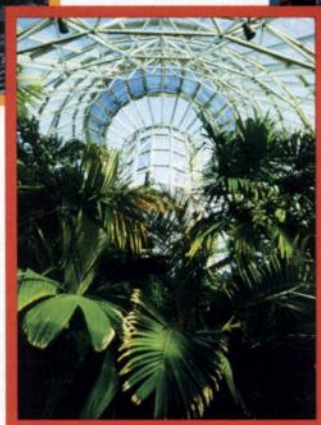
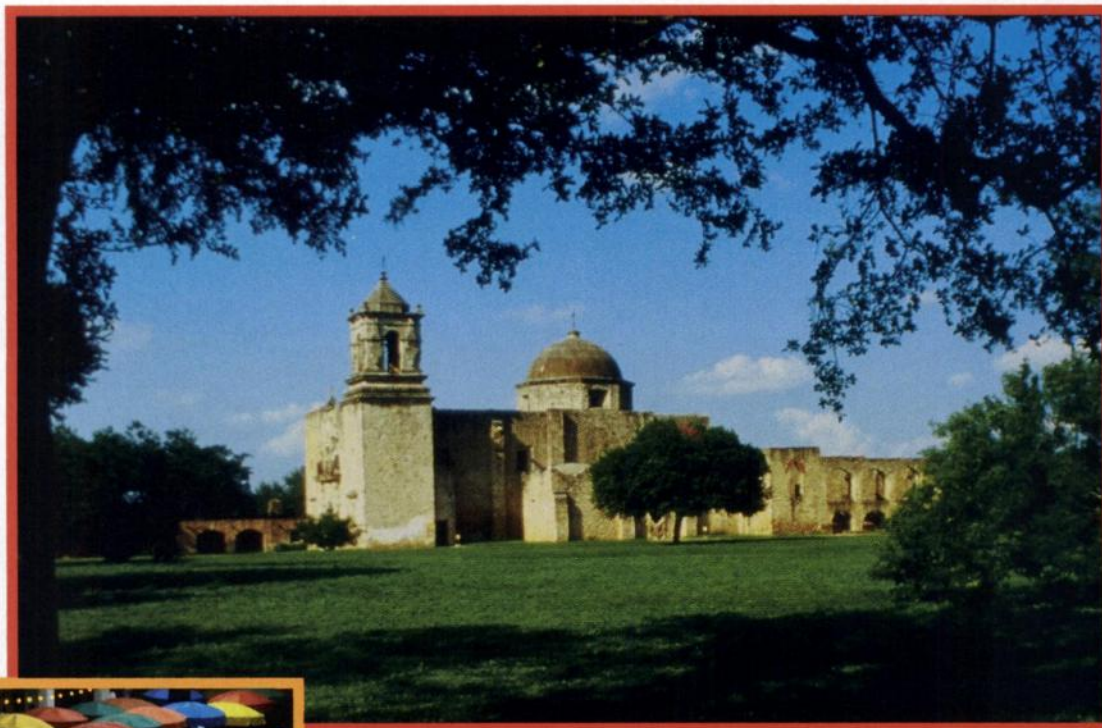


## Harmony in contrast

Bracco Diagnostics Inc. is a worldwide leader in contrast media. You can expect significant new products from us in the future and, as always, they will be backed by our excellent service and support.



***The Society of Nuclear Medicine  
Invites You to Attend the 44th  
Annual Meeting in San Antonio,  
Texas, June 1- 5, 1997.***



Mark your calendar now! The Annual Meeting Preview will be mailed to you in January, 1997. If you have questions, please contact the SNM Department: Meeting Services. (703) 708-9000 x-229 or fax (703) 709-9274. SNM's home page: <http://WWW.SNM.ORG>



A LIFETIME OF NUCLEAR IMAGING COMMITMENT CONTINUES...

# HITACHI

## *a new beginning*

For nearly three decades  
Hitachi Medical Corporation has been a major contributor to leading edge  
technological advances in nuclear medicine diagnostic instrumentation

*Our History Includes:*

**SPECTRADigital™ family...Nuclear Imaging Systems without Compromise**

**First 1024<sup>2</sup> Acquisition and Display**

**Highest Performance Circular  
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**Open Imaging and  
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**The Leading Edge SPECTRADigital™ 300ss  
Workstation Computing and Networking with  
integrated INTERFILE and DICOM standards**

**The latest in HITACHI technology, now available direct in North America, debuts in Denver  
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# HITACHI

# IS THERE NO END TO THE CHAMPIONS FROM TEXAS?

## Megatope I-131, USP Iodinated I-131 Albumin Injection

Easily detected and quantified by radiometric methods, I-131 labelled human serum albumin is a diagnostic used by clinicians and investigators to localize the placenta and cerebral neoplasms and to delineate the heart and great vessels. Megatope accumulates very slowly in the extravascular space following injection, making it a reliable tool to determine total blood and plasma volumes, cardiac output, circulation times, and cardiac and pulmonary blood volumes. Effective as a marker to determine rates of protein turnover.



## Jeanatope I-125, USP Iodinated I-125 Albumin Injection

Sensitivity and accuracy are the features that make radiolabelled human serum albumin a well-established diagnostic tool for the determination of total blood and plasma volumes. Jeanatope distributes rapidly and uniformly throughout the intravascular pool so that blood volume determinations can be made within 15 minutes after injection. Unlike classical colorimetric methods, frequent determinations can be made and are unaffected by hemolysis or blood turbidity.



**DALLAS  
1995**



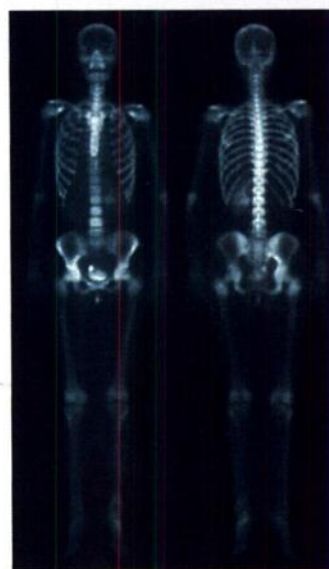
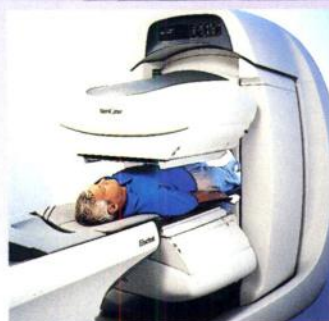
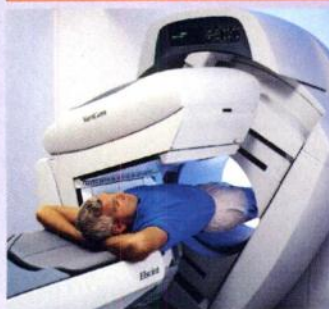
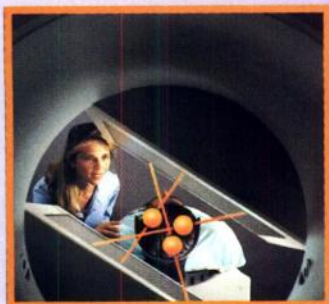
Each multi-dose vial of Megatope or Jeanatope contains approximately 10 mg of protein associated with megabecquerels (1 mCi) of I-131 or I-125, respectively, at the time of manufacture. These products are sterile, non-pyrogenic, and dissolved in phosphate-buffered saline with 0.9% benzyl alcohol as preservative. Complete assay data for each lot are provided on the container.

# ISO-TEX DIAGNOSTICS

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# VariCam *Get an angle on the future...*



## **Double-efficiency**

Whole-Body scan, featuring superior lesion detectability with OptiTrack real-time body contouring.

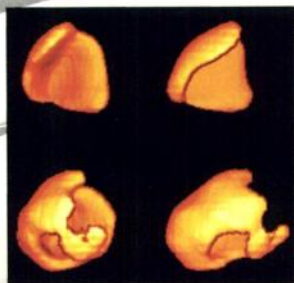
## **All-Digital, High-Energy Imaging**

### ■ **Designed for Volumetric Coincidence Detection\***

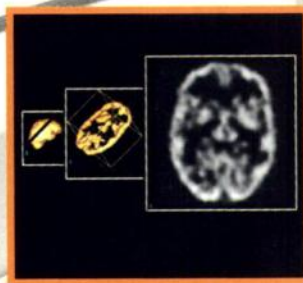
- Leading in High-Energy Imaging
- TransACT™: Transmission Attenuation Corrected Tomography

## **Robotic Design, Convertible Geometry**

- EleGantry™: Truly open, variable-angle (180°/90°) detector geometry
- OptiTrack™: Real-time fully automatic body-contoured scanning
- Evolving-Images™ with Slip-Ring technology

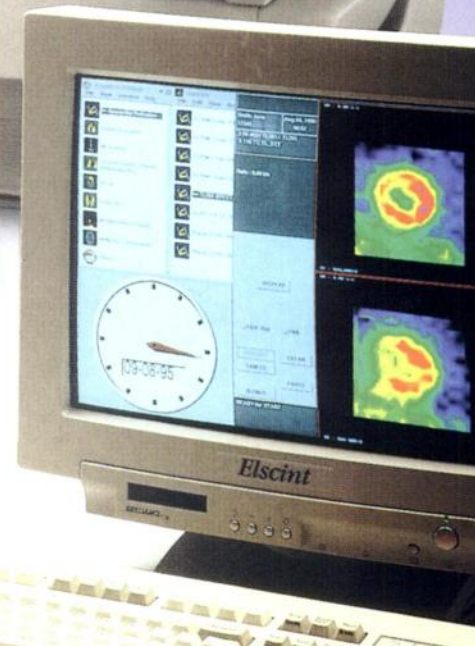


**Double double-efficiency**  
right-angle cardiac tomography: simultaneous dual-isotope FDG/MIBI SPECT. (Not for sale in U.S.)



**Double double-efficiency**  
**Volumetric Coincidence Detection**

*\*Work-in-progress*



# Elscint

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Elscint U.S.A.: (201) 342-2020; 1-800-ELSCINT

# IF YOU HAVEN'T SEEN US LATELY, YOU HAVEN'T SEEN GE NUCLEAR IMAGING.



Let's just say that if you miss us at SNM in Denver, it would be worth the trip to Copenhagen.

The new GE Nuclear Imaging Environment is like nothing you have seen before. We listened to you. Then we rethought, redesigned and reengineered.

Everything.

We've taken GENIE™ – the revolutionary acquisition, processing and review interface that redefined the concept of productivity by reducing

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Copenhagen, Denmark, September '96

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even the most complex studies to a few clicks of a mouse – and made it compatible with virtually every nuclear medicine system we've introduced in the last decade.

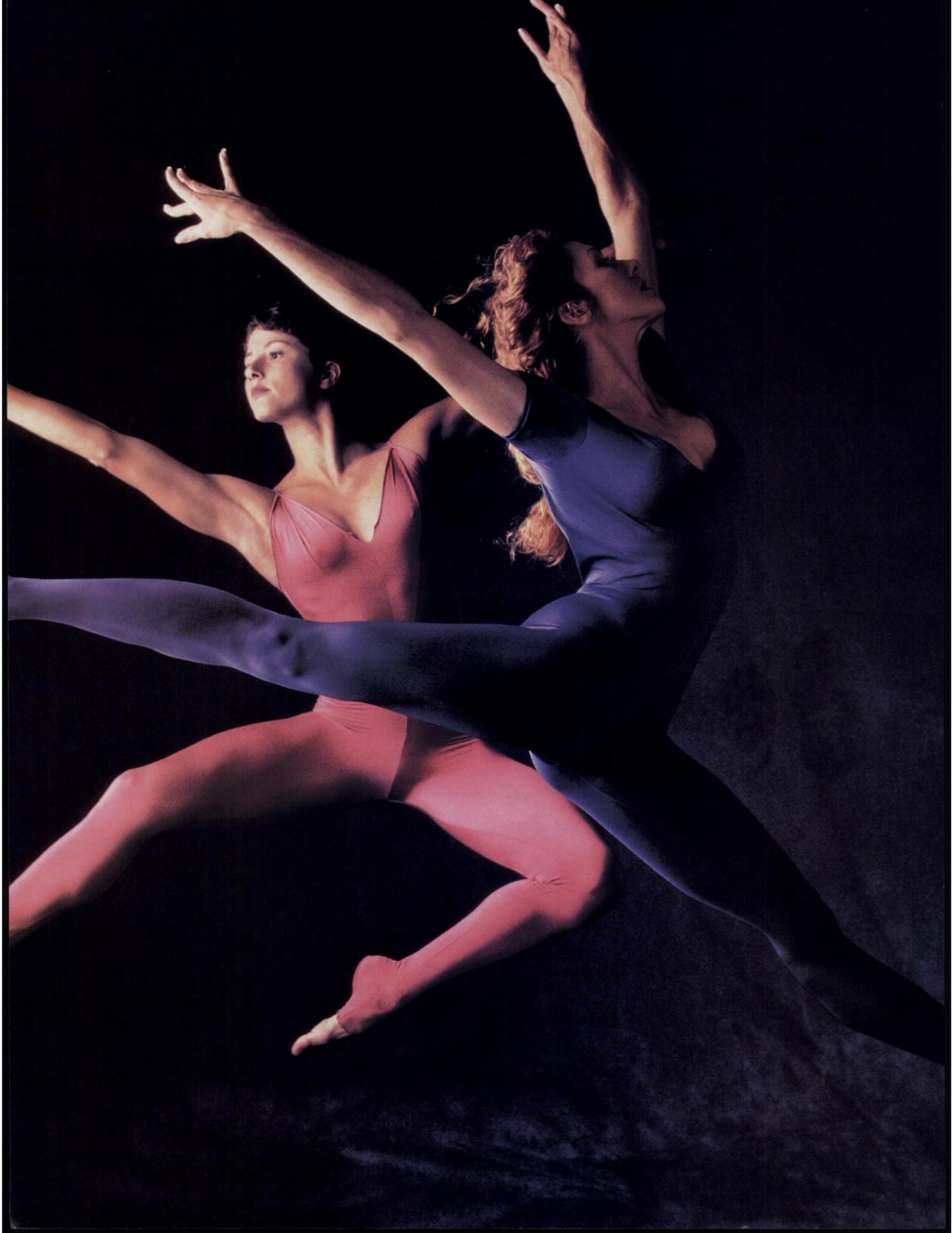
And our new Millennium™ family and Optima NX™ imaging systems take image quality, ease of use and clinical flexibility a giant leap into the future.

The GE vision of nuclear imaging. See it for yourself. We guarantee it will be an eye-opening experience.

THE GE CONTINUUM. THE RIGHT PATH.



**GE Medical Systems**  
*We bring good things to life.*



# *Confidence in motion*

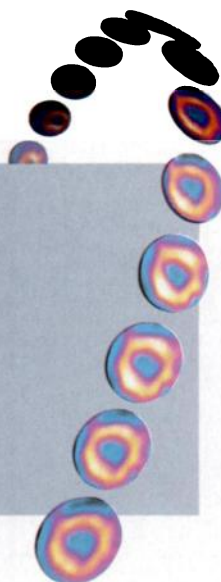
The goal of cardiac imaging is to obtain studies that allow you to accurately view the status of cardiac perfusion and function. And that's where Cardiolite® comes through.

With *gated stress Cardiolite studies*, you simultaneously obtain stress perfusion and resting function (wall motion, wall thickening, and LVEF)—that's more diagnostic information than perfusion alone, which can help you improve patient management. And, the higher photon energy (140 keV) reduces attenuation and improves image quality.

So remember, to enhance interpretive confidence and patient management, perform gated stress Cardiolite.

With gated stress Cardiolite studies you can...

- Acquire stress perfusion and resting function from one study
- Obtain function information for patients with diseases that coexist with CAD (eg, cardiomyopathies)
- Differentiate scar tissue from artifact
- Potentially reduce false-positive interpretations and the need for other costly and invasive procedures



## Cardiolite

Kit for the preparation of Technetium Tc99m Sestamibi

*To reduce the uncertainty  
Cardiolite comes through*



Radiopharmaceuticals

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.*

© 1996, DuPont Pharma

## Brief Summary

# Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

## FOR DIAGNOSTIC USE

**INDICATIONS AND USAGE:** CARDIOLITE® Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent's labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a 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).

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hypotension, bronchoconstriction and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent's labeling.

### 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 (1.5 rads/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, [Cu(MIBI)<sub>4</sub>]BF<sub>4</sub>, 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 ( $\geq 20 \mu\text{g/ml}$ ), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. [Cu(MIBI)<sub>4</sub>]BF<sub>4</sub> did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/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.

#### Pediatric Use

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

**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 (see also CLINICAL PHARMACOLOGY).

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 Radiopharmaceutical's 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  
DuPont Radiopharmaceutical Division  
The DuPont Merck Pharmaceutical Co.  
331 Treble Cove Road

Billerica, Massachusetts, USA 01862  
For ordering Tel. Toll Free: 800-225-1572  
All other business: 800-362-2668

(For Massachusetts and International, call 508-667-9531)

# MYOVIEW™

## Technetium Tc99m Tetrofosmin For Injection

*so clear...*



*so flexible!*

## Brief Summary



## Kit for the Preparation of Technetium Tc99m Tetrofosmin for injection

Diagnostic radiopharmaceutical For intravenous use only  
Code N166A

### DESCRIPTION

The Medi-Physics Myoview™ kit is supplied as a pack of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection to be used for the scintigraphic delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium. Each vial contains a pre-dispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,9-bis(2-ethoxyethyl)-3,12-dioxo-6,9-diphosphatetradecane], 30 µg stannous chloride dihydrate (minimum stannous tin 5.0 µg; maximum total stannous and stannic tin 15.8 µg), 0.32 mg disodium sulphosalicylate and 1.0 mg sodium D-glucuronate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

**Caution: Federal (USA) law prohibits dispensing without a prescription**

### CLINICAL PHARMACOLOGY

#### General

When technetium Tc99m pertechnetate is added to tetrofosmin in the presence of stannous reductant, a lipophilic, cationic technetium Tc99m complex is formed, Tc99m tetrofosmin. This complex is the active ingredient in the reconstituted drug product, on whose biodistribution and pharmacokinetic properties the indications for use depend.

#### Clinical Trials

A total of 252 patients with ischemic heart disease or atypical chest pain who had a reason for exercise stress imaging were studied in two open-label, multi center, clinical trials of Tc99m tetrofosmin (study a and study b). Of these 252 patients there were 212 (83%) males and 40 (17%) females with a mean age of 60.5 years (range 33.7 to 82.4 years). At peak exercise, maximum heart rate achieved and peak systolic blood pressure were comparable after Myoview and thallium-201 exercise studies.

All patients had exercise and rest planar imaging with Myoview and thallium-201; 191 (76%) patients also had SPECT imaging. The Myoview and thallium-201 images were separated by a mean of 5.1 days (1-14 days before or 2-14 days after Myoview). For Myoview imaging, each patient received 185-296 MBq (5-8 mCi) Tc99m tetrofosmin at peak exercise and 555-888 MBq (15-24 mCi) Tc99m tetrofosmin at rest approximately 4 hours later. For thallium-201 imaging, patients received thallium-201 55.5-74 MBq (1.5-2.0 mCi) at peak exercise.

The images were evaluated for the quality of the image (excellent, good or poor) and the diagnosis (with scores of 0 = normal, 1 = ischemia, 2 = infarct, 3 = mixed infarct and ischemia). The primary outcome variable was the percentage of correct diagnoses in comparison to the final clinical diagnosis. All planar images were blindly read; SPECT images were evaluated by the unblinded investigator. A subset of 181/252 (71%) patients had coronary angiography comparisons to the planar images of Myoview or thallium-201.

### INDICATIONS AND USAGE

Myoview is indicated for scintigraphic imaging of the myocardium following separate administrations under exercise and resting conditions. It is useful in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.

### CONTRAINDICATIONS

None known.

### WARNINGS

In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

### PRECAUTIONS

#### General

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. Adequate hydration should be encouraged to permit frequent voiding.

The contents of the Myoview vial are intended only for use in the preparation of technetium

Tc99m tetrofosmin injection and are NOT to be administered directly to the patient.

As with all injectable drug products, allergic reactions and anaphylaxis may occur.

Sometimes Tc99m labeled myocardial imaging agents may produce planar and SPECT images with different imaging information.

Technetium Tc99m tetrofosmin injection, like other radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

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

Drug Interactions: Drug interactions were not noted and were not studied in clinical studies in which Myoview was administered to patients receiving concomitant medication. Drugs such as beta blockers, calcium blockers and nitrates may influence myocardial function and blood flow. The effects of such drugs on imaging results are not known.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. Tetrofosmin sulphosalicylate was not mutagenic *in vitro* in the Ames test, mouse lymphoma, or human lymphocyte tests, nor was it clastogenic *in vivo* in the mouse micronucleus test.

### Pregnancy Category C

Animal reproduction studies have not been conducted with Myoview. It is not known whether Myoview can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Therefore, Myoview 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 pediatric patients have not been established.

### ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 26-94 years). The subjects received a mean dose of 7.67 mCi on the first injection and 22.4 mCi on the second injection of Myoview.

Deaths did not occur during the clinical study period of 2 days. Six cardiac deaths occurred 3 days to 6 months after injection and were thought to be related to the underlying disease or cardiac surgery. After Myoview injection, serious episodes of angina occurred in 3 patients. Overall cardiac adverse events occurred in 5/764 (less than 1 %) of patients after Myoview injection.

The following events were noted in less than 1 % of patients:

Cardiovascular: angina, hypertension, Torsades de Pointes  
Gastrointestinal: vomiting, abdominal discomfort  
Hypersensitivity: cutaneous allergy, hypotension, dyspnea  
Special Senses: metallic taste, burning of the mouth, smelling something

There was a low incidence (less than 4%) of a transient and clinically insignificant rise in white blood cell counts following administration of the agent.

### DOSAGE AND ADMINISTRATION

For exercise and rest imaging, Myoview is administered in two doses:

- The first dose of 5-8 mCi (185-296 MBq) is given at peak exercise.
- The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in renally or liver impaired, pediatric or geriatric patients.

### RADIATION DOSIMETRY

Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in Table 1. The values are listed in descending order as rad/mCi and µGy/MBq and assume urinary bladder emptying at 3.5 hours.

Table 1

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

Target Organ	Absorbed radiation dose			
	Exercise		Rest	
	rad/mCi	µGy/MBq	rad/mCi	µGy/MBq
Gall bladder wall	0.123	33.2	0.180	48.6
Upper large intestine	0.075	20.1	0.113	30.4
Bladder wall	0.058	15.6	0.071	19.3
Lower large intestine	0.057	15.3	0.082	22.2
Small intestine	0.045	12.1	0.063	17.0
Kidney	0.039	10.4	0.046	12.5
Salivary glands	0.030	8.04	0.043	11.6
Ovaries	0.029	7.88	0.035	9.55
Uterus	0.027	7.34	0.031	8.36
Bone surface	0.023	6.23	0.021	5.58
Pancreas	0.019	5.00	0.018	4.98
Stomach	0.017	4.60	0.017	4.63
Thyroid	0.016	4.34	0.022	5.83
Adrenals	0.016	4.32	0.015	4.11
Heart wall	0.015	4.14	0.015	3.93
Red marrow	0.015	4.14	0.015	3.97
Spleen	0.015	4.12	0.014	3.82
Muscle	0.013	3.52	0.012	3.32
Testes	0.013	3.41	0.011	3.05
Liver	0.012	3.22	0.015	4.15
Thymus	0.012	3.11	0.009	2.54
Brain	0.010	2.72	0.008	2.15
Lungs	0.008	2.27	0.008	2.08
Skin	0.008	2.22	0.007	1.91
Breasts	0.008	2.22	0.007	1.83

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 (rev). Society of Nuclear Medicine, 1976. Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1988) and gave values of 8.61 x 10<sup>-3</sup> mSv/MBq and 1.12 x 10<sup>-3</sup> mSv/MBq after exercise and rest respectively.

Manufactured by Amersham International plc - Amersham, United Kingdom  
Patent No. 5,045,302 (r)

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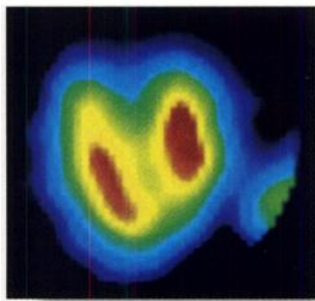
Medi-Physics, Inc., Amersham Healthcare  
2636 S. Clearbrook Dr., Arlington Heights, IL 60005  
1-800- 633-4123 (Toll Free)  
February, 1996  
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# Maximal Vasodilation

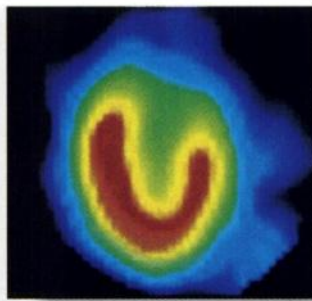
for patients unable to exercise adequately

## Imaging comparable to maximal exercise

- Interpretable images obtained in 98.7% of patients<sup>1</sup>
- Maximal coronary hyperemia achieved in 2-3 minutes
- No supplemental exercise necessary



Stress



Redistribution

## Rapid onset, short duration

- <10-second half-life minimizes post-infusion monitoring time
- Side effects usually resolve quickly

**ADENOSCAN<sup>®</sup>**  
**adenosine**

Please see brief summary of prescribing information on adjacent page for warnings, precautions and contraindications.

**Fujisawa**

1. Cerquiera MD, Verani MS, Schwaiger M, et al. Safety profile of adenosine stress perfusion imaging: results from Adenoscan multicenter trial registry. *J Am Coll Cardiol.* 1994;23:384-389.

## BRIEF SUMMARY

### For Intravenous Infusion Only

#### DESCRIPTION

Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amino-9-beta-D-ribofuranosyl-9H-purine.

Adenosine is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by warming and lowering the pH of the solution.

Each Adenoscan vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/mL and sodium chloride 9 mg/mL in Water for Injection, q.s. The pH of the solution is between 4.5 and 7.5.

#### INDICATIONS AND USAGE:

Intravenous Adenoscan is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. (See **WARNINGS**).

#### CONTRAINDICATIONS:

Intravenous Adenoscan (adenosine) should not be administered to individuals with:

1. Second- or third-degree AV block (except in patients with a functioning artificial pacemaker).
2. Sinus node diseases, such as sick sinus syndrome or symptomatic bradycardia (except in patients with a functioning artificial pacemaker).
3. Known or suspected bronchoconstrictive or bronchospastic lung disease (e.g., asthma).
4. Known hypersensitivity to adenosine.

#### WARNINGS:

##### **Fatal Cardiac Arrest, Life Threatening Ventricular Arrhythmias, and Myocardial Infarction.**

Fatal cardiac arrest, sustained ventricular tachycardia (requiring resuscitation), and nonfatal myocardial infarction have been reported coincident with Adenoscan infusion. Patients with unstable angina may be at greater risk.

##### **Sinoatrial and Atrioventricular Nodal Block**

Adenoscan (adenosine) exerts a direct depressant effect on the SA and AV nodes and has the potential to cause first-, second- or third-degree AV block, or sinus bradycardia. Approximately 8.3% of patients develop AV block with Adenoscan, including first-degree (2.8%), second-degree (2.8%) and third-degree (0.8%) heart block. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenoscan can cause sinus bradycardia. Adenoscan should be used with caution in patients with pre-existing first-degree AV block or bundle branch block and should be avoided in patients with high-grade AV block or sinus node dysfunction (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Sinus pause has been rarely observed with adenosine infusions.

##### **Hypotension**

Adenoscan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflex mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, stenotic valvular heart disease, pericarditis or pericardial effusions, stenotic carotid artery disease with cerebrovascular insufficiency, or uncorrected hypovolemia, due to the risk of hypotensive complications in these patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

##### **Hypertension**

Increases in systolic and diastolic pressure have been observed (as great as 140 mm Hg systolic in one case) concomitant with Adenoscan infusion; most increases resolved spontaneously within several minutes, but in some cases, hypertension lasted for several hours.

##### **Bronchoconstriction**

Adenoscan (adenosine) is a respiratory stimulant (probably through activation of carotid body chemoreceptors) and intravenous administration in man has been shown to increase minute ventilation ( $\dot{V}_E$ ) and reduce arterial  $PCO_2$  causing respiratory alkalosis. Approximately 28% of patients experience breathlessness (dyspnea) or an urge to breathe deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention.

Adenosine administered by inhalation has been reported to cause bronchoconstriction in asthmatic patients, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with asthma and mild to moderate exacerbation of their symptoms has been reported. Respiratory compromise has occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan should be used with caution in patients with obstructive lung disease not associated with bronchoconstriction (e.g., emphysema, bronchitis, etc.) and should be avoided in patients with bronchoconstriction or bronchospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

#### PRECAUTIONS:

##### **Drug Interactions**

Intravenous Adenoscan (adenosine) has been given with other cardioactive drugs (such as beta adrenergic blocking agents, cardiac glycosides, and calcium channel blockers) without apparent adverse interactions, but its effectiveness with these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan should be used with caution in the presence of these agents. The vasoactive effects of Adenoscan are inhibited by adenosine receptor antagonists, such as alkyxanthines (e.g., caffeine and theophylline). The safety and efficacy of Adenoscan in the presence of these agents has not been systematically evaluated. The vasoactive effects of Adenoscan are potentiated by nucleoside transport inhibitors, such as dipyridamole. The safety and efficacy of Adenoscan in the presence of dipyridamole has not been systematically evaluated. Whenever possible, drugs that might inhibit or augment the effects of adenosine should be withheld for at least five half-lives prior to the use of Adenoscan.

##### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenosine was negative for genotoxic potential in the Salmonella (Ames Test) and Mammalian Microsome Assay.

Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. In rats and mice, adenosine administered intraperitoneally once a day for five days at 50, 100, and 150 mg/kg (10-30 (rats) and 5-15 (mice) times human dosage on a mg/M<sup>2</sup> basis) caused decreased spermatogenesis and increased numbers of abnormal sperm, a reflection of the ability of adenosine to produce chromosomal damage.

##### **Pregnancy Category C**

Animal reproduction studies have not been conducted with adenosine; nor have studies been performed in pregnant women. Because it is not known whether Adenoscan can cause fetal harm when administered to pregnant women, Adenoscan should be used during pregnancy only if clearly needed.

##### **Pediatric Use**

The safety and effectiveness of Adenoscan in patients less than 18 years of age have not been established.

#### ADVERSE REACTIONS:

The following reactions with an incidence of at least 1% were reported with intravenous Adenoscan among 1421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10.8% of the side effects occurred not with the infusion of Adenoscan but several hours after the infusion terminated. Also, 8.4% of the side effects that began coincident with the infusion persisted for up to 24 hours after the infusion was complete. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Flushing	44%	Gastrointestinal discomfort	13%	Second-degree AV block	3%
Chest discomfort	40%	Lightheadedness/dizziness	12%	Paresthesia	2%
Dyspnea or urge to breathe deeply	26%	Upper extremity discomfort	4%	Hypotension	2%
Headache	18%	ST segment depression	3%	Nervousness	2%
Throat, neck or jaw discomfort	15%	First-degree AV block	3%	Arrhythmias	1%

Adverse experiences of any severity reported in less than 1% of patients include:

**Body as a Whole:** back discomfort; lower extremity discomfort; weakness.

**Cardiovascular System:** nonfatal myocardial infarction; life-threatening ventricular arrhythmia; third-degree AV block; bradycardia; palpitation; sinus exit block; sinus pause; sweating; T-wave changes; hypertension (systolic blood pressure > 200 mm Hg).

**Central Nervous System:** drowsiness; emotional instability; tremors.

**Genital/Urinary System:** vaginal pressure; urgency.

**Respiratory System:** cough.

**Special Senses:** blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; scotomas; tongue discomfort.

#### OVERDOSAGE:

The half-life of Adenosine is less than 10 seconds and side effects of Adenoscan (when they occur) usually resolve quickly when the infusion is discontinued, although delayed or persistent effects have been observed. Methylxanthines, such as caffeine and theophylline, are competitive adenosine receptor antagonists and theophylline has been used to effectively terminate persistent side effects. In controlled U.S. clinical trials, theophylline (50-125 mg slow intravenous injection) was needed to abort Adenoscan side effects in less than 2% of patients.

#### DOSAGE AND ADMINISTRATION:

For intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion.

The recommended intravenous dose for adults is 140 mcg/kg/min infused for six minutes (total dose of 0.84 mg/kg).

The required dose of thallium-201 should be injected at the midpoint of the Adenoscan infusion (i.e., after the first three minutes of Adenoscan).

Thallium-201 is physically compatible with Adenoscan and may be injected directly into the Adenoscan infusion set.

The injection should be as close to the venous access as possible to prevent an inadvertent increase in the dose of Adenoscan (the contents of the IV tubing) being administered. There are no data on the safety or efficacy of alternative Adenoscan infusion protocols.

The safety and efficacy of Adenoscan administered by the intracoronary route have not been established.

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

**CAUTION:** Federal law prohibits dispensing without prescription.

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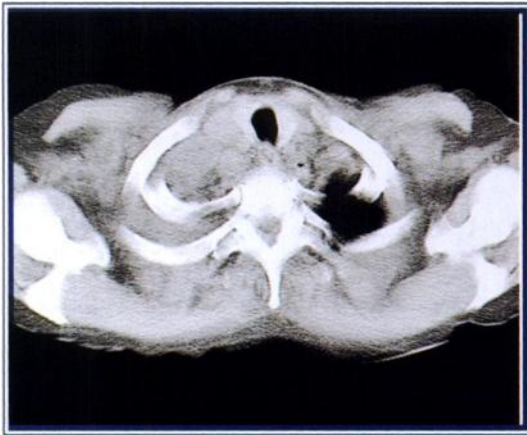
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adenosine

Neuroendocrine Tumor Case Review

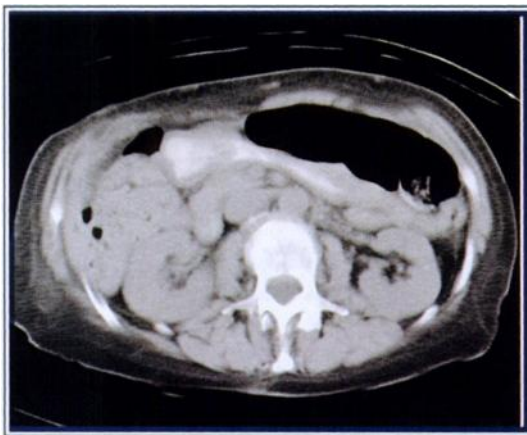
# Small Cell Lung Carcinoma

***CT showed evidence of chest involvement,  
but no definite distant metastases...***

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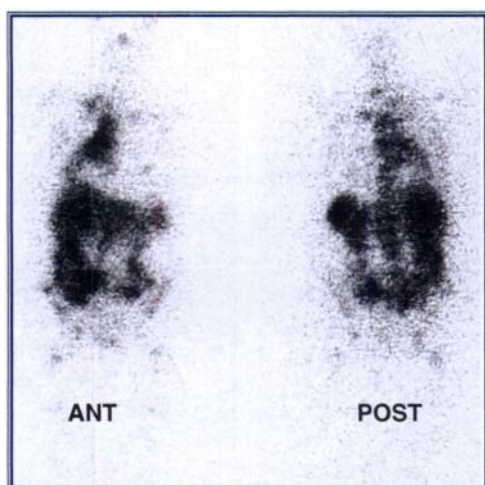


*Chest CT scans showing evidence of right retroclavicular mass, right hilar and mediastinal lymphadenopathy associated with right middle and right lower lobe consolidation, as well as possible superimposed mass and bilateral pleural effusion.*

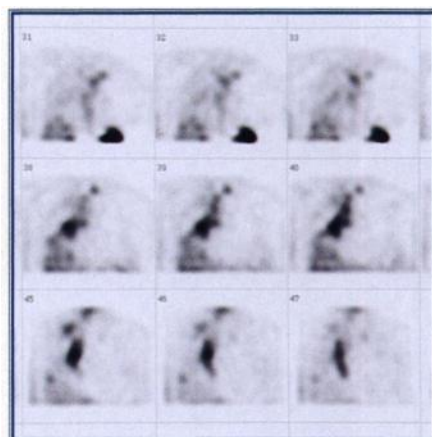


*Abdominal CT scan showing no definitive evidence of metastatic disease.*

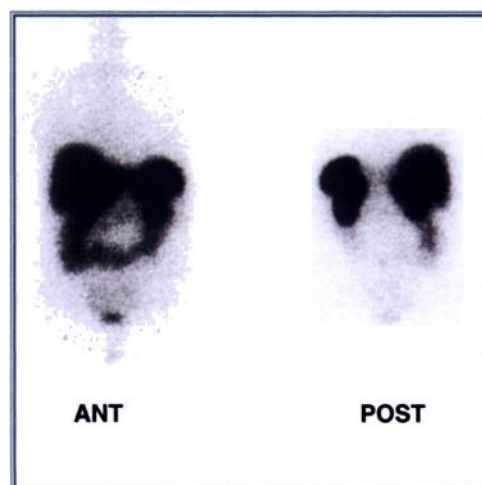
## *OctreoScan imaging identified extensive metastases, localizing chest and thoracic spine lesions*



*Initial OctreoScan whole body images  
identifying widespread disease involvement.*



*Initial OctreoScan coronal SPECT  
images localizing chest lesions.*



*OctreoScan follow-up whole body images  
showing marked overall improvement.  
(Uptake in the liver, spleen, kidneys  
and GI are normal.)*

### **Patient History**

A middle-aged female, with a history of heavy smoking, presented with increasing dyspnea, abdominal pain and changes in her mental status. Chest CT revealed extensive disease. A biopsy of a right retroclavicular mass was positive for small cell lung carcinoma. Abdominal CT showed no definite evidence of metastases.

### **OctreoScan Scintigraphy**

OctreoScan whole body imaging identified extensive activity in the head, chest, abdomen, pelvis, and spine. OctreoScan SPECT imaging localized chest lesions to the right retroclavicular, right hilar and mediastinal regions, as well as the thoracic spine, confirming the findings seen on chest CT.

### **Clinical Course**

After receiving a course of chemotherapy of cytoxan, adriamycin and vincristine, the patient's mental status improved and her shortness of breath and abdominal pain resolved. Follow-up OctreoScan studies showed marked overall improvement.

### **Decisive Clinical Information**

This case illustrates the benefits of OctreoScan imaging in the detection of small cell lung carcinoma, the whole body evaluation for distant metastases which may sometimes not be obvious on CT scanning, as well as for the follow-up of therapeutic response to treatment.

  
**OCTREOSCAN®**  
Kit for the Preparation of Indium In-111 Pentetreotide

*Please see adjacent page for brief summary of prescribing information.*



# OCTREOSCAN®

Kit for the Preparation of Indium In-111 Pentetate

## BRIEF SUMMARY OF PRESCRIBING INFORMATION

### DESCRIPTION

OctreoScan® is a kit for the preparation of indium In-111 pentetate, a diagnostic radio-pharmaceutical. It is a kit consisting of two components:

- 1) A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of 10 µg pentetate.
- 2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

Indium In-111 pentetate is prepared by combining the two kit components.



### INDICATIONS AND USAGE

Indium In-111 pentetate is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

### CONTRAINDICATIONS

None known.

### WARNINGS

DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADMIXTURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES; IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OCTREOTIDE CONJUGATE MAY FORM.

The sensitivity of scintigraphy with indium In-111 pentetate may be reduced in patients concurrently receiving therapeutic doses of octreotide acetate. Consideration should be given to temporarily suspending octreotide acetate therapy before the administration of indium In-111 pentetate and to monitoring the patient for any signs of withdrawal.

### PRECAUTIONS

#### General

1. Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Since pentetate is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium In-111 pentetate.
2. The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetate and are NOT to be administered separately to the patient.
3. Since indium In-111 pentetate is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.
4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetate. They should increase fluid intake and void frequently for one day after administration of this drug. In addition, it is recommended that patients be given a mild laxative (e.g., bisacodyl or lactulose) before and after administration of indium In-111 pentetate (see Dosage and Administration section).
5. Indium In-111 pentetate should be tested for labeling yield of radioactivity prior to administration. The product must be used within six hours of preparation.
6. Components of the kit are sterile and nonpyrogenic. To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetate.
7. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetate is not expected to cause cholelithiasis.
8. As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.
9. 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 performed with indium In-111 pentetate to evaluate carcinogenic potential or effects on fertility. Pentetate was evaluated for mutagenic potential in an in vitro mouse lymphoma forward mutation assay and an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

#### Pregnancy Category C

Animal reproduction studies have not been conducted with indium In-111 pentetate. It is not known whether indium In-111 pentetate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium In-111 pentetate should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

#### Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium In-111 pentetate is administered to a nursing woman.

#### Pediatric Use

Safety and effectiveness in children have not been established.

### ADVERSE REACTIONS

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 536 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin.

Pentetate is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetate is approximately 5 to 20 times less than for octreotide and is subtherapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

### DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labeled pentetate by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacodyl or

lactulose) be given to the patient starting the evening before the radioactive drug is administered, and continuing for 48 hours. Ample fluid uptake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insulinoma, bowel-cleansing should be undertaken only after consultation with an endocrinologist.

The recommended intravenous dose for planar imaging is 111 MBq (3.0 mCi) of indium In-111 pentetate prepared from an OctreoScan kit. The recommended intravenous dose for SPECT imaging is 222 MBq (6.0 mCi) of indium In-111 pentetate.

The dose should be confirmed by a suitably calibrated radioactivity ionization chamber immediately before administration.

As with all intravenously administered products, OctreoScan 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 applicable regulations.

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

Do not administer OctreoScan in TPN solutions or through the same intravenous line.

#### Radiation Dosimetry

The estimated radiation doses<sup>1</sup> to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.<sup>2</sup>

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetate<sup>3</sup> to a 70 kg patient

	PLANAR		SPECT	
Kidneys	54.16	5.42	108.32	10.83
Liver	12.15	1.22	24.31	2.43
Spleen	73.86	7.39	147.73	14.77
Uterus	6.34	0.63	12.67	1.27
Ovaries	4.89	0.49	9.79	0.98
Testes	2.90	0.29	5.80	0.58
Red Marrow	3.46	0.35	6.91	0.69
Urinary Bladder Wall	30.42	3.04	60.48	6.05
GI Tract				
Stomach Wall	5.67	0.57	11.34	1.13
Small Intestine	4.78	0.48	9.56	0.96
Upper Large Intestine	5.80	0.58	11.59	1.16
Lower Large Intestine	7.73	0.77	15.46	1.55
Adrenals	7.55	0.76	15.11	1.51
Thyroid	7.43	0.74	14.86	1.49
Effective Dose <sup>4</sup> Equivalent	13.03	1.30	26.06	2.61

1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration.
2. E.P. Krenning, W.H. Bakker, P.P.M. Kooij, W.A.P. Breeman, H.Y. Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reij, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Receptor Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," The Journal of Nuclear Medicine, Vol. 33, No. 5, May 1992, pp. 652-658.
3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.
4. Estimated according to ICRP Publication 53.

### HOW SUPPLIED

The OctreoScan kit, NDC 0019-9050-40, is supplied with the following components:

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
  - (i) 10 µg pentetate [N-(diethylenetriamine-N,N,N',N'-tetraacetic acid-N'-acetyl)-D-phenylalanyl-L-histidyl-L-phenylalanyl-D-tryptophyl-L-tyrosyl-L-threonyl-L-histidyl-L-threonyl cyclic (2-7) diulfide], (also known as octreotide DTPA),
  - (ii) 2.0 mg gentisic acid [2,5-dihydroxybenzoic acid],
  - (iii) 4.9 mg trisodium citrate, anhydrous,
  - (iv) 0.37 mg citric acid, anhydrous, and
  - (v) 10.0 mg inositol.

Before lyophilization, sodium hydroxide or hydrochloric acid may have been added for pH adjustment. The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

2. A 10-mL vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

In addition, the kit also contains the following items: (1) a 25 G x 5/8" needle (B-D, Monoject) used to transfer Indium In-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

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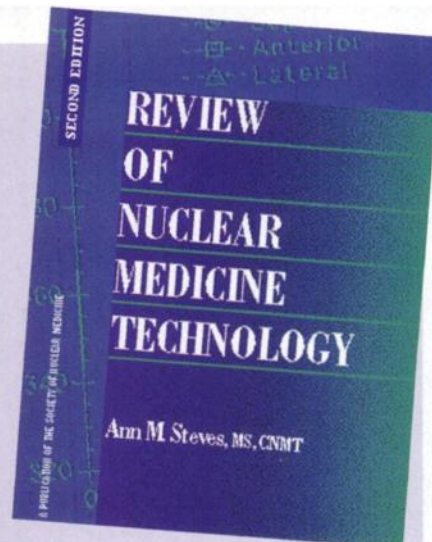
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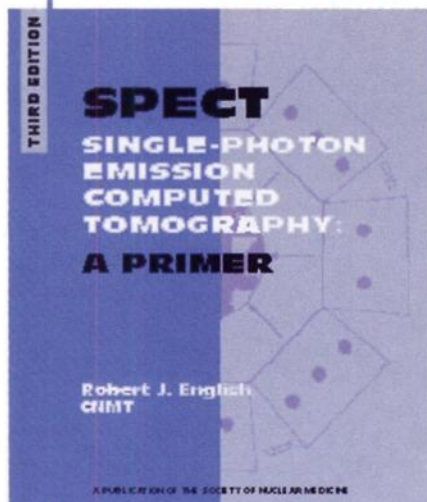
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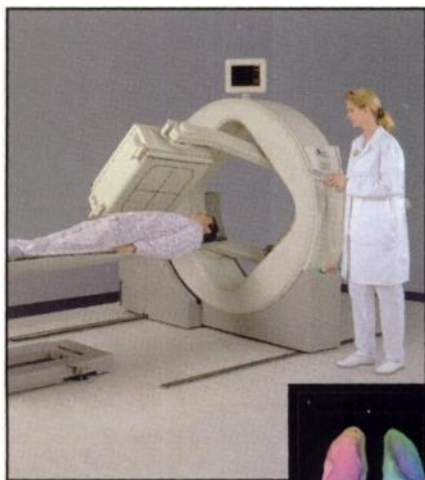
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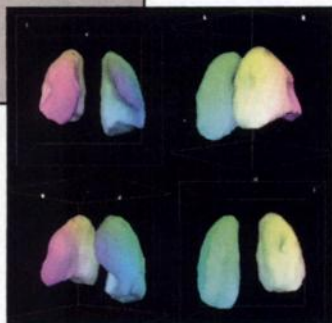


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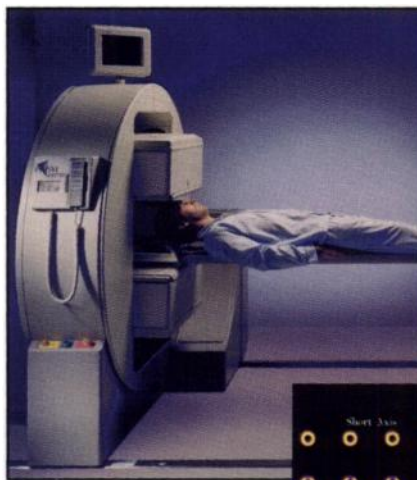


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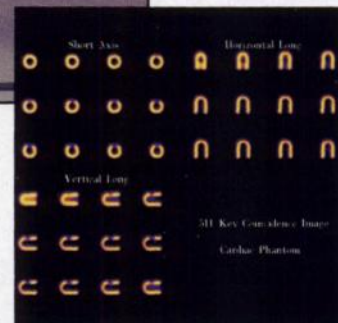


*3-D lung SPECT images.*



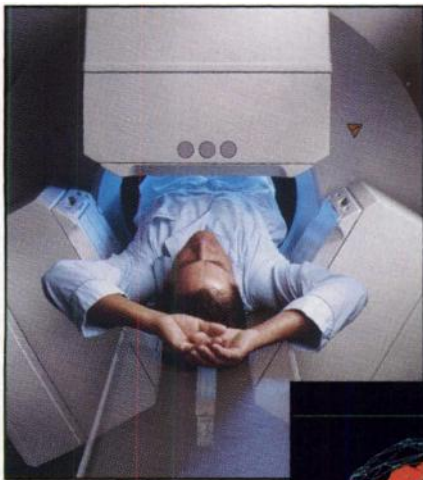
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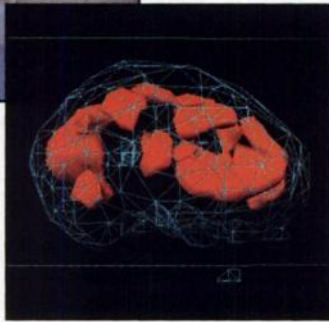
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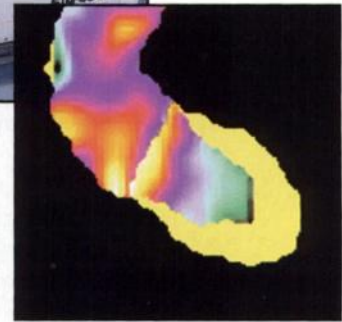


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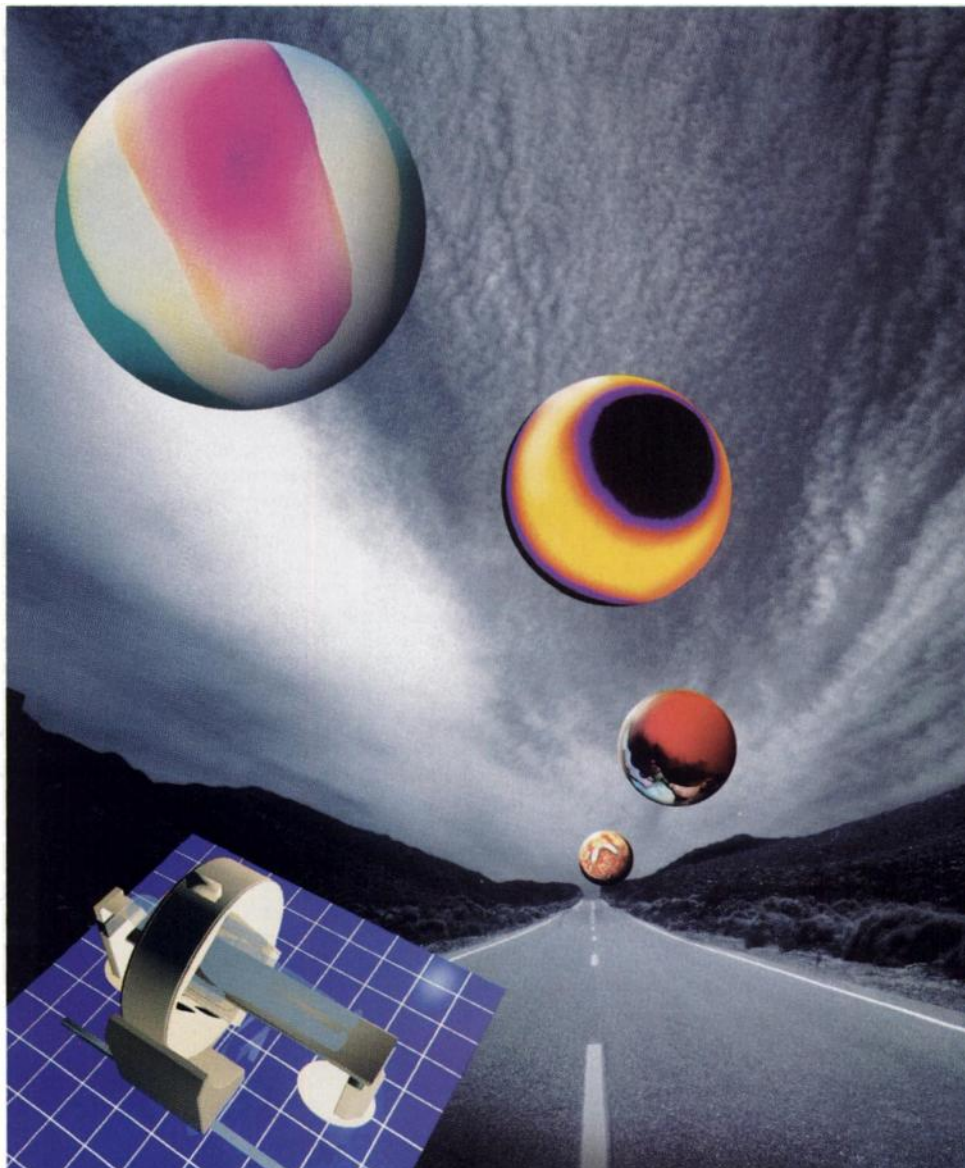
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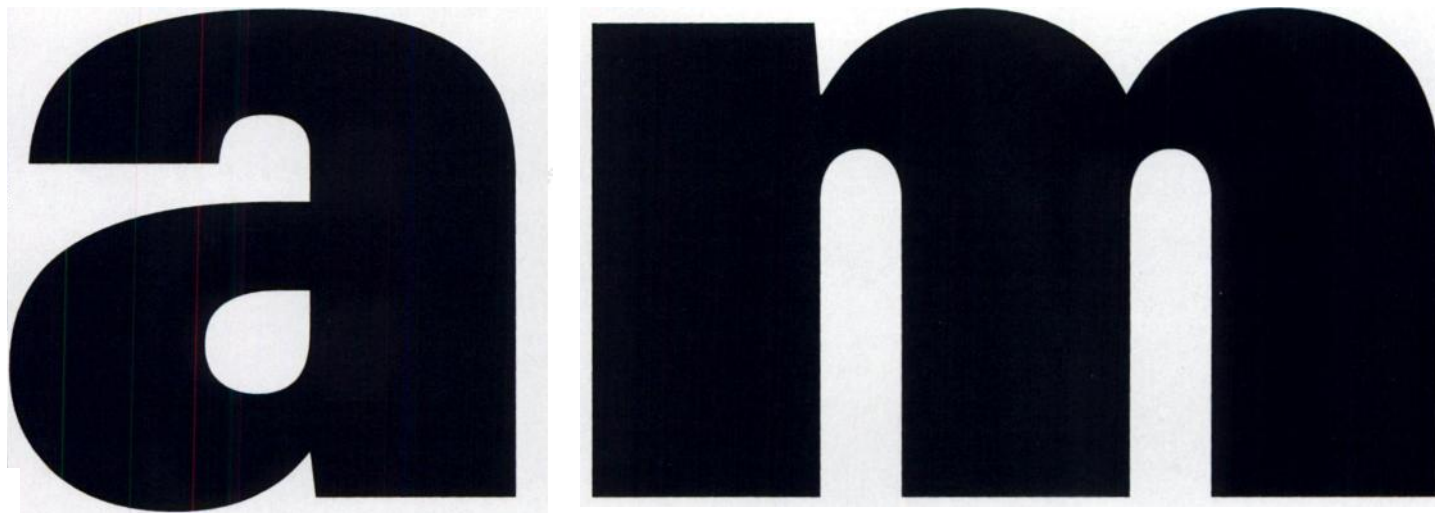


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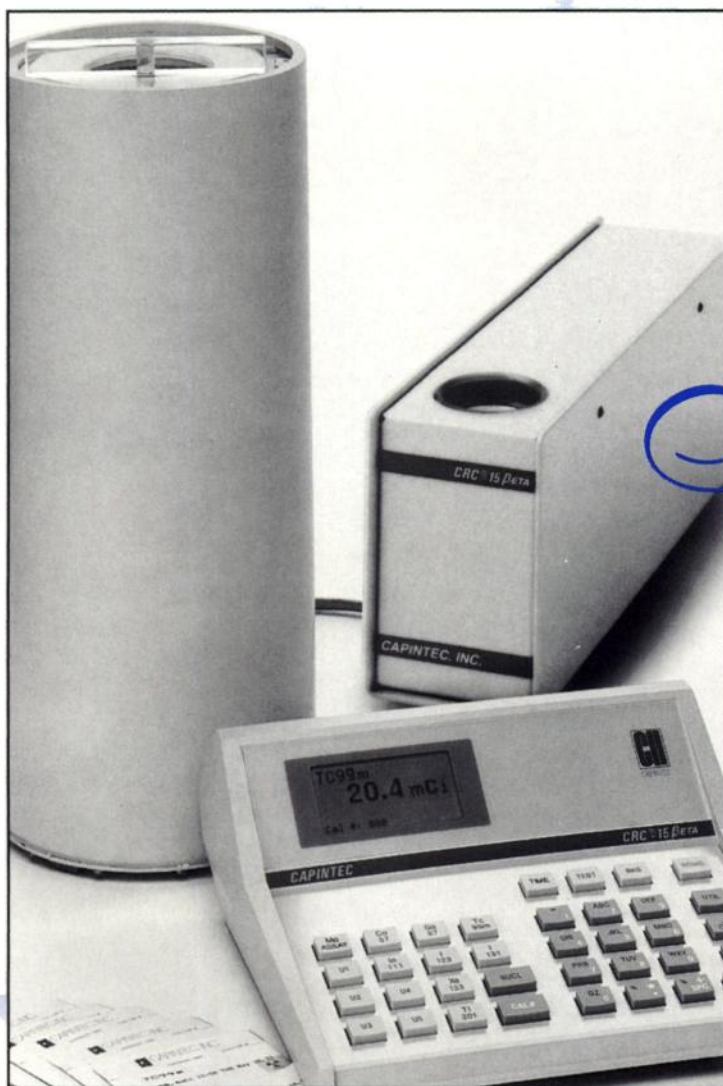
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