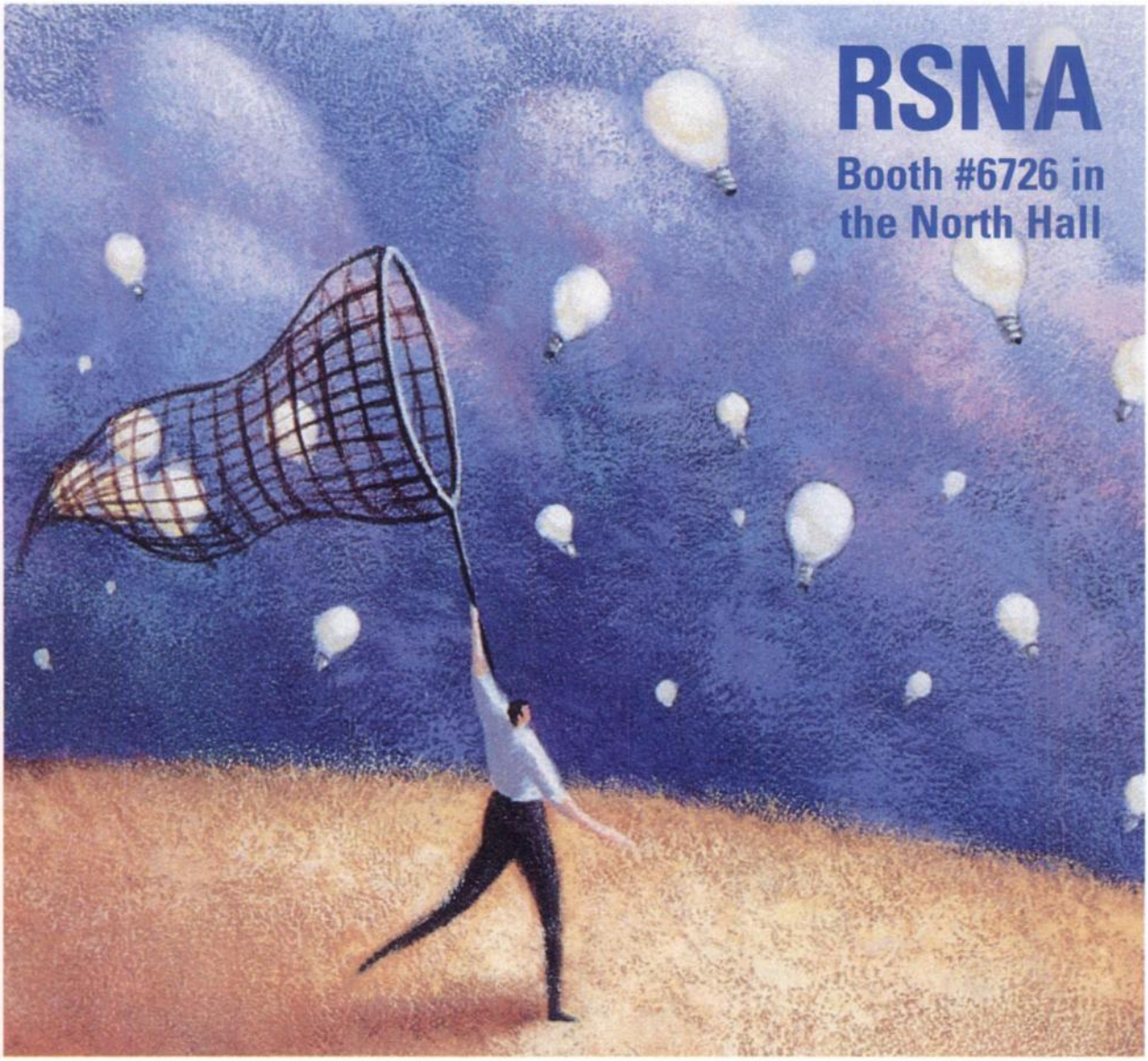
# SIEMENS

# Come see how we gathered your ideas into innovative solutions.




You talked. We listened. Now we're ready to unveil the results of our innovative thinking. To discover how our solutions-driven technology and consultative services can help you better manage your resources, visit our RSNA booth or call 1-800-848-0010 and ask for Dept. CO-001 for more detailed information.

**Siemens Medical Systems, Inc.**
186 Wood Avenue South, Iselin, NJ 08830

Siemens medical
Solutions that help

***In personnel radiation dosimetry, no one handles the details with finer precision and control than Landauer.***

Our Gardray® film dosimeters, for instance. Every film strip is sealed in a laminate of paper, plastic and aluminum to minimize any potential damage or image change due to light, dampness and other environmental conditions. Filters are specially molded for the badge to account for exposure from the front and rear.

The film is used to gather a volume of wearer dosimetry data for analysis and archival retention in our system.

The film packet itself is securely held in a small, convenient-to-use badge. This holder is specially designed for easy, rapid loading and unloading of the packet.

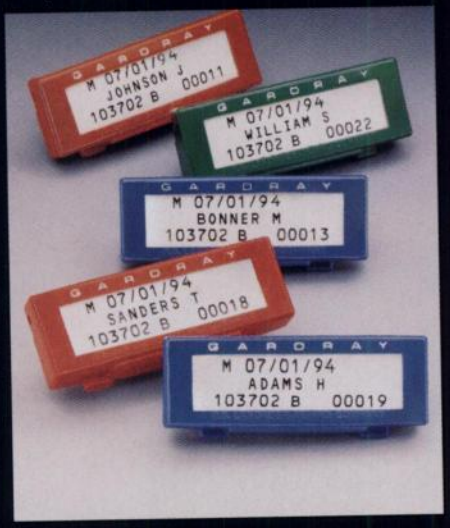
***Integrity of identification***

With Landauer's film dosimeter, the wearer's name and other pertinent data are printed on each label, which is an integral part of the film packet.

In addition, the packet is marked with a unique reference number which links that dosimeter with the specific user for the wear date.

This number is printed on both label and packet, and punched into the film strip itself for fail-safe identification. Bar coding of each dosimeter further assures accurate, realtime tracking in our laboratory, and even provides you with a means to track unreturned badges at your own site.

Other features help in identifying your badges too. Four holder colors are available for special identification needs within your facility, and dosimeter labels are color-coded by wear period to enable easy verification of correct usage.




***Unique quality assurance measures***

Landauer's state-of-the-art processing equipment includes the fastest, most reliable film readers available in the industry.

Sophisticated, automated reading coupled with continual review by skilled viewers provide an ongoing series of quality control checks. Technicians continually check information to verify data and ensure accuracy.

After exposure data is calculated and made available to you, the film is ultimately placed in a climate controlled saltmine facility for our exclusive archival storage—a truly permanent record available for your review if the need arises in future years.

As a testament to our QA efforts, our film service, like our TLD service, is NVLAP-accredited in all categories.

***Reports that make your job easier***

Reports from our compact badges provide you with an enormous variety of data including: quarterly, year-to-date and lifetime totals; personal data and identification; explanatory information on exposures and other pertinent information useful in your program management.

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In film, in TLD—in every service we provide—Landauer for 40 years has pioneered the development of radiation dosimetry technology.

Because of our careful attention to the little details, we're clearly your superior choice for reliable, accurate radiation monitoring.

# LANDAUER

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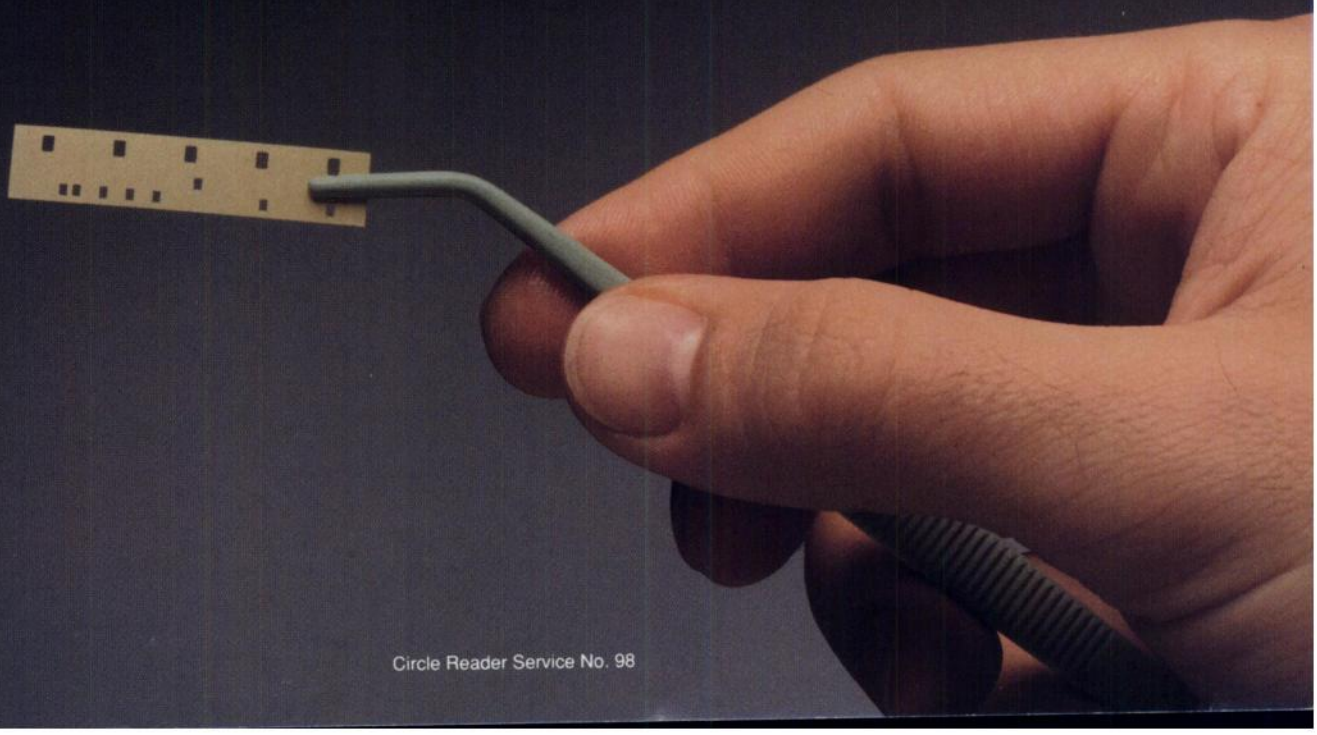
2 Science Road Glenwood, Illinois 60425-1586
Telephone: (708) 755-7000 Facsimile: (708) 755-7016

RSNA Booth #7511.

## *We're very big on little details.*



Circle Reader Service No. 98


# CAPRAC®-R

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## NOT JUST FOR WIPE TESTING

The ***CAPRAC-R Well Counting System*** offers:

- Speed
- Accuracy
- Economy
- PLUS an abundance of performance-boosting features.

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Using the General Counting Section, the ***CAPRAC-R*** can replace older systems for any type of gamma counting that performs RIA's or other lab procedures.

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The ***CAPRAC-R*** monitors ultra-low levels of activity in as little as 6 seconds using NaI detector for 1 nCi while giving preliminary isotope identification through gamma spectroscopy.

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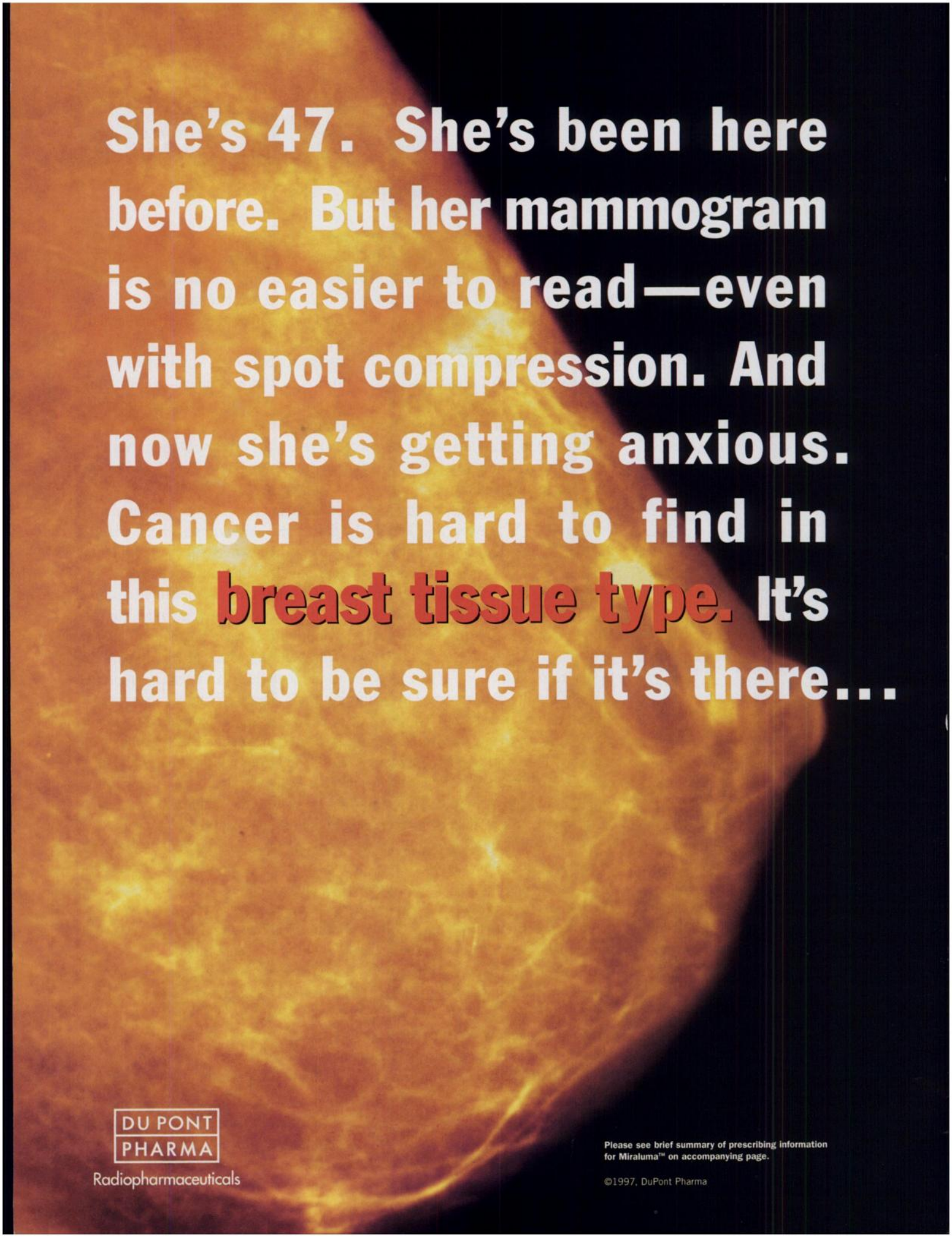
Peoples Republic of China

**RSNA Booth #2641.**


She's 47. She's been here before. But her mammogram is no easier to read—even with spot compression. And now she's getting anxious. Cancer is hard to find in this breast tissue type. It's hard to be sure if it's there...
DU PONT PHARMA
Radiopharmaceuticals
Please see brief summary of prescribing information for Miraluma™ on accompanying page.
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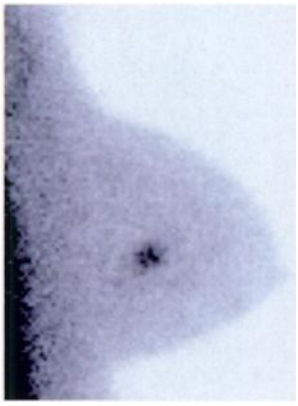
# is it there?



Right lateral view, biopsy-confirmed infiltrating ductal carcinoma

**New Miraluma™—the next step toward an answer when confronted with a difficult mammogram. Miraluma™ is an effective adjunct to mammography that can detect lesions even in dense breast tissue.**

**The diagnostic sensitivity of Miraluma™ is decreased in tumors <1 cm in largest dimension. There have been rare reports of signs and symptoms consistent with severe hypersensitivity and seizure after administration of Technetium Tc 99m Sestamibi.**

**For more information, call Technical Services at 1-800-635-2683 or access the DuPont Radiopharmaceuticals Web site at www.radiopharm.com**

NEW miraluma™

Kit for the preparation of
Technetium Tc 99m Sestamibi

**The next step toward an answer**

# miraluma™

Kit for the preparation of
Technetium Tc 99m Sestamibi

FOR DIAGNOSTIC USE

**INDICATIONS AND USAGE:** Breast Imaging: MIRALUMA™, Kit for the Preparation of Technetium Tc99m Sestamibi, is indicated for planar imaging as a second line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass.

MIRALUMA™ is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.

Myocardial Imaging: 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, arrhythmia, 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.

Technetium Tc99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized uticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE® imaging. Patients who receive CARDIOLITE® or MIRALUMA™ imaging are receiving the same drug. Caution should be exercised and emergency equipment should be available when administering Technetium Tc99m Sestamibi. Also, before administering either CARDIOLITE® or MIRALUMA™, patients should be asked about the possibility of allergic reactions to either drug.

**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 sufficient to stop the test reported during controlled studies (two-thirds were cardiac patients) were:

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

**Information for Patients**

CARDIOLITE® and MIRALUMA™ are different names for the same drug. Patients should be advised to inform their health care provider if they had an allergic reaction to either drug or if they had an imaging study with either drug.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5 rads/30 mCi 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, $Cu(MIBI)_4BF_4$, 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 (≥ 20 µg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $Cu(MIBI)_4BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, > 600 × 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 the pediatric population have not been established.

**ADVERSE REACTIONS:** Adverse events were evaluated in 3741 adults who were evaluated in clinical studies. Of these patients, 3068 (77% men, 22% women, and 0.7% of the patient's genders were not recorded) were in cardiac clinical trials and 673 (100% women) in breast imaging trials. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). Adverse events reported at a rate of 0.5% or greater reported after receiving Technetium Tc99m Sestamibi administration are shown in the following table:

**Table 9**
**Selected Adverse Events Reported In > 0.5% Of Patients Who Received Technetium Tc99m Sestamibi In Either Breast or Cardiac Clinical Studies***

| Body System | Breast Studies | Cardiac Studies | | |
|---|---|---|---|---|
| | Women n = 673 | Women n = 685 | Men n = 2361 | Total n = 3046 |
| Body as a Whole | 21 (3.1%) | 6 (0.9%) | 17 (0.7%) | 23 (0.8%) |
| Headache | 11 (1.6%) | 2 (0.3%) | 4 (0.2%) | 6 (0.2%) |
| Cardiovascular | 9 (1.3%) | 24 (3.5%) | 75 (3.2%) | 99 (3.3%) |
| Chest Pain/Angina | 0 (0%) | 18 (2.6%) | 46 (1.9%) | 64 (2.1%) |
| ST segment changes | 0 (0%) | 11 (1.6%) | 29 (1.2%) | 40 (1.3%) |
| Digestive System | 8 (1.2%) | 4 (0.6%) | 9 (0.4%) | 13 (0.4%) |
| Nausea | 4 (0.6%) | 1 (0.1%) | 2 (0.1%) | 3 (0.1%) |
| Special Senses | 132 (19.6%) | 62 (9.1%) | 160 (6.8%) | 222 (7.3%) |
| Taste Perversion | 129 (19.2%) | 60 (8.8%) | 157 (6.6%) | 217 (7.1%) |
| Parosmia | 8 (1.2%) | 6 (0.9%) | 10 (0.4%) | 16 (0.5%) |

* Excludes the 22 patients whose gender were not recorded.

In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of the patients. In 10 of these patients the pain appears to be associated with biopsy/surgical procedures.

The following adverse reactions have been reported in ≤0.5% of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent ; transient arthritis; angioedema, arrythmia, dizziness, syncope, and severe hypersensitivity characterized by dyspnea, hypotension, bradycardia, asthenia, abdominal pain, vomiting, pruritis, rash, and urticaria within two hours after a second injection of Technetium Tc99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dry mouth, fever, and fatigue have also been attributed to administration of the agent.

**DOSAGE AND ADMINISTRATION:** For Breast Imaging: The recommended dose range for I.V. administration of MIRALUMA™ is a single dose of 740-1110 MBq (20 - 30 mCi).

For Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE® in a single dose to be employed in the average patient (70Kg) is 370-1110MBq (10-30mCi).

DU PONT PHARMA

**Marketed by**
DuPont Radiopharmaceutical Division
The DuPont Merck Pharmaceutical Company
331 Treble Cove Road
Billerica, Massachusetts USA 01862
For Ordering Tel: Toll Free 800-225-1572
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RSNA Booth #2912.

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Why? The clinical evidence speaks for itself. PET users around the world continue to report positive impact on patient outcomes while reducing their total cost of patient care. That's a powerful clinical statement.

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**GE Medical Systems**

*Now Available*

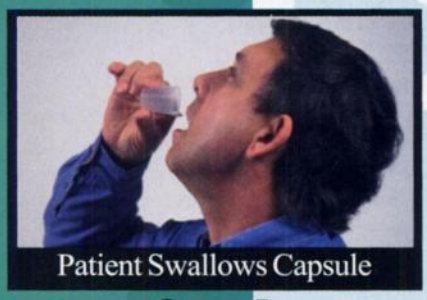
# What the World

Introducing
The Global Diagnostic for H. pylori

# PYtest®

## one microcurie C-14 urea capsule

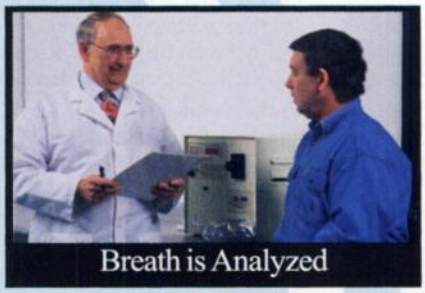
**PYtest** incorporates accuracy and cost containment in one test.


Patient Swallows Capsule

**Step 1**

Breath is Collected

**Step 2**


Breath is Analyzed

**Step 3**

**PYtest** will keep you one step ahead...

... developed for your patients and your practice,

... if H. pylori testing is your business, keep it simple, call for your informational packet today.

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Medicine for the New Millenium

TRI-MED Specialties Inc.

Please see summary on the following page

# is Coming to...

# PYtest® ( $^{14}$C-urea Capsules)

## Description

PYtest ($^{14}$C-urea capsules) is intended for use in the detection of gastric urease as an aid in the diagnosis of *Helicobacter pylori* (*H.pylori*) infection in the human stomach. The test utilizes a liquid scintillation counter for the measurement of $^{14}CO_2$ in breath samples. The capsules are to be used when analysis is planned at the site where the sample is taken.

PYtest capsule is a gelatin capsule for oral administration containing 1μCi of $^{14}$C labeled urea. The urea is adsorbed on sugar spheres and colored yellow with fluorescein.

**Data on $^{14}$C-urea:**
Structural Formula: ($^{14}$C-urea): $NH_2\ ^{14}CONH_2$
Radiation emission: beta-emission, 49 $keV_{mean}$, 156 $keV_{max}$, no other emissions
External emission: No external radiation hazard. Low-energy beta emissions only. Maximum range of 0.3 mm in water.
Radiological Half-life: 5730 years
Maximum effective dose equivalent (EDE) : 0.3 mrem/μCi

### Clinical Pharmacology

The urease enzyme is not present in mammalian cells, so the presence of urease in the stomach is evidence that bacteria are present. The presence of urease is not specific for *H.pylori,* but other bacteria are not usually found in the stomach.

To detect *H.pylori,* urea labeled with $^{14}$C is swallowed by the patient. If gastric urease from *H.pylori* is present, urea is split to form $CO_2$ and $NH_3$ at the interface between the gastric epithelium and lumen, and the $^{14}CO_2$ is absorbed into the blood and exhaled in the breath.

Following ingestion of the capsule by a patient with *H.pylori*, $^{14}CO_2$ excretion in the breath peaks between 10 and 15 minutes and declines thereafter with a biological half-life of about 15 minutes. $^{14}$C-urea that is not hydrolyzed by *H.pylori* is excreted in the urine with a half-life of approximately 12 hours. About 10% of the $^{14}$C remains in the body at 72 hours and is gradually excreted with a biological half-life of 40 days.

### Clinical Studies

Two studies were performed. In both studies, patients with gastrointestinal symptoms underwent the breath test and an endoscopy. During the endoscopy, biopsy samples were taken from antral gastric mucosa for histological analysis (2 samples, Giemsa stain) and rapid urease test (1 sample, CLOtest®). Breath samples were mailed to the TRI-MED lab where they were read in a liquid scintillation counter. Results were reported as disintegrations per minute (DPM). Analysis for accuracy used the ten minute breath sample. A breath sample DPM <50 was defined as a negative result. DPM ≥200 was defined as a positive result. DPM in the range of 50-199 was classified as indeterminate.

### Indications and Usage

PYtest ($^{14}$C-urea breath test) is indicated for use in the detection of gastric urease as an aid in the diagnosis of *H.pylori* infection in the human stomach. The test utilizes a liquid scintillation counter for the measurement of $^{14}CO_2$ in breath samples.

### Contraindications

None

### Warnings

None

### Precautions

**General:** After the patient ingests the $^{14}$C urea capsule, the sample collected for test purposes is for in vitro diagnostic use only.

A false positive test could occur in patients who have achlorhydria. Very rarely, a false positive test may occur due to urease associated with Helicobacters other than *H.pylori* (i.e. *Helicobacter heilmanni*).

**Limitations of the Test:**

- The test has been evaluated in outpatients attending for elective endoscopy.
- Test results should be evaluated with clinical signs and patient history when diagnosing H. *pylori* infection.
- The performance characteristics of the test have not been established for monitoring the efficacy of antimicrobial therapies for the treatment of *H.pylori* infection.
- A negative result does not completely rule out the possibility of *H. pylori* infection. If clinical signs and patient history suggest *H. pylori* infection, repeat the PYtest or use an alternative diagnostic method.

**Radioactivity:** Persons concerned about very low doses of radioactivity may postpone the test or may decide to use an alternative means of diagnosis. The test produces radiation exposure equal to 24 hours of normal background. In animal experiments, such low doses of radiation do not carry measurable risk.

Preclinical studies were not conducted on $^{14}$C-urea. The estimated dose equivalent received from a single administration of PYtest (1μ $^{14}$C -urea) is about 0.3 mrem. An individual radiation dose of 5-10 mrem is below regulatory concern as recommended by the Nuclear Regulatory Commission.

**Information for Patients:** It is necessary for the patient to fast for 6 hours before the test. The patient should also be off antibiotics and bismuth for 1 month, and proton pump inhibitors and sucralfate for 2 weeks prior to the test. Instruct the patient not to handle the capsule directly as this may interfere with the test result. The capsule should be swallowed intact. Do not chew the capsule.

**Carcinogenesis, mutagenesis, impairment of fertility:**

No studies have been conducted with $^{14}$C- urea to evaluate its potential for carcinogenicity, impairment of fertility, or mutagenicity.

**Drug Interactions:** Antibiotics, proton pump inhibitors, sucralfate, and bismuth preparations are known to suppress *H.pylori*. Ingestion of antibiotics or bismuth within 4 weeks and proton pump inhibitors or sucralfate within 2 weeks prior to performing the test may give false negative results.

**Pregnancy:** Pregnancy category C. Animal reproduction studies have not been conducted with PYtest ( $^{14}$C- urea). It is also not known whether PYtest can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PYtest should be given to a pregnant woman only if clearly needed.

**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 PYtest is administered to a nursing woman.

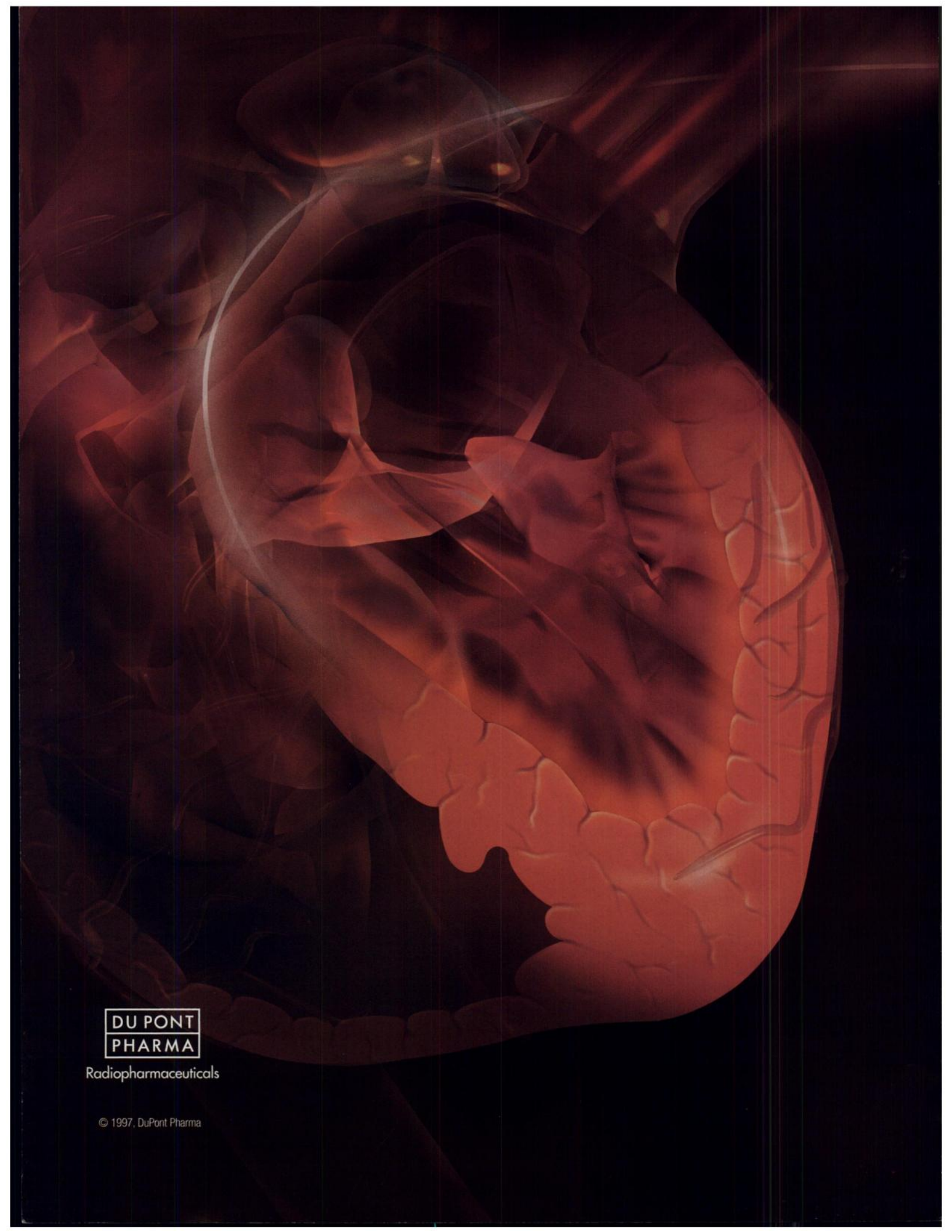
**Pediatric use:** Clinical studies in children have not been conducted. However, PYtest is expected to work the same in children as in adults. While the dose (1 capsule) does not need to be adjusted, the child must be able to swallow the intact capsule and blow into a straw.

### Adverse Reactions

No adverse reactions were reported in clinical trials.

### Overdosage

Risk from radiation is negligible even with a 1000 capsule overdose (0.3 rem). If overdose occurs the patient may drink one glass of water (150 mL) every hour to hasten excretion of the isotope. Maximum excretion of urea is achieved at a urine output of ≥ 2.0 mL/min.



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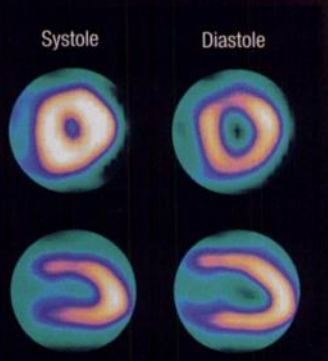
PHARMA
Radiopharmaceuticals

# Inside Information.

## Perfusion and function in one test: clinically relevant information.

**Cardiolite® provides:**

- **Both** stress perfusion and resting function **(wall motion, wall thickening, a quantifiable and reproducible measure of ejection fraction)**[1,2]
- Enhanced diagnostic confidence with a high negative predictive value: **A normal stress test correlates with a <1% annualized cardiac event rate**[3-5]
- Clinically relevant information in a range of situations—such as **risk assessment, evaluation post-MI, and for chest pain management**




LVEF=51%

Gated SPECT images with CARDIOLITE®

For more information, contact DuPont Pharma at 1-800-362-2668 or www.radiopharm.com

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.

# Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

**The Confidence You Want—The Information You Need**

RSNA Booth #2912.

# Brief Summary

# Cardiolite®

## Kit for the preparation of Technetium Tc99m Sestamibi

**F O R  D I A G N O S T I C  U S E**

**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 (1.5rads/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, $[Cu(MIBI)_4]BF_4$, 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 (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ 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 × 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**

| | Estimated Radiation Absorbed Dose | | | |
|---|---|---|---|---|
| | REST | | | |
| | 2.0 hour void | | 4.8 hour void | |
| Organ | 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 |
| | STRESS | | | |
| | 2.0 hour void | | 4.8 hour void | |
| Organ | 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.

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All other business: 800-362-2668
(For Massachusetts and International, call 508-667-9531)

513121-0296 2/96

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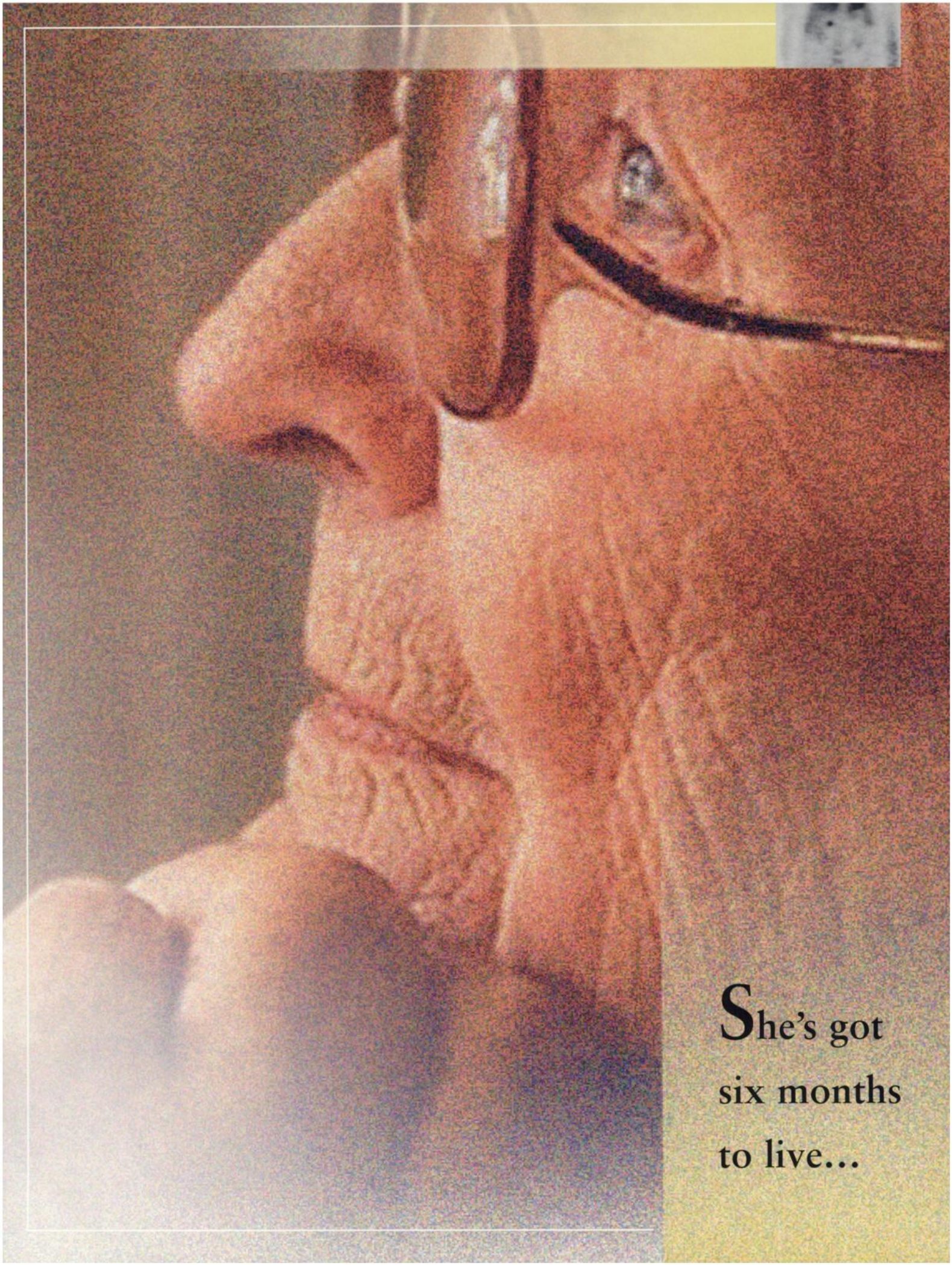
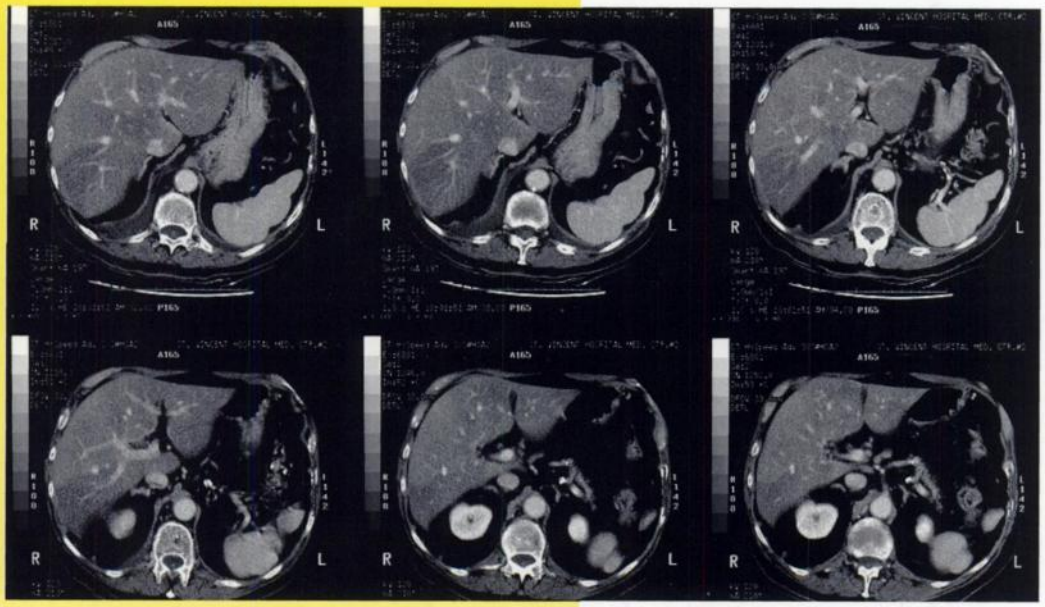
**REFERENCES:** 1. Nichols K, DePuey EG, Rozanski A. Automation of gated tomographic left ventricular ejection fraction. *J Nucl Cardiol.* 1996;3:475-482. 2. Chua T, Kiat H, Germano G, et al. Gated technetium-99m sestamibi for simultaneous assessment of stress myocardial perfusion, post-exercise regional ventricular function and myocardial viability. *J Am Coll Cardiol.* 1994;23:1107-1114. 3. Stratmann HG, Williams GA, Wittry MD, et al. Exercise technetium-99m sestamibi tomography for cardiac risk stratification of patients with stable chest pain. *Circulation.* 1994;89:615-622. 4. Berman DS, Hachamovitch R, Kiat H, et al. Incremental value of prognostic testing in patients with known or suspected ischemic heart disease: a basis for optimal utilization of exercise technetium-99m sestamibi myocardial perfusion single-photon emission computed tomography. *J Am Coll Cardiol.* 1995;26:639-647. 5. Hachamovitch R, Berman DS, Kiat H, et al. Exercise myocardial perfusion SPECT in patients without known coronary artery disease. *Circulation.* 1996;93:905-914.


She's got
six months
to live...

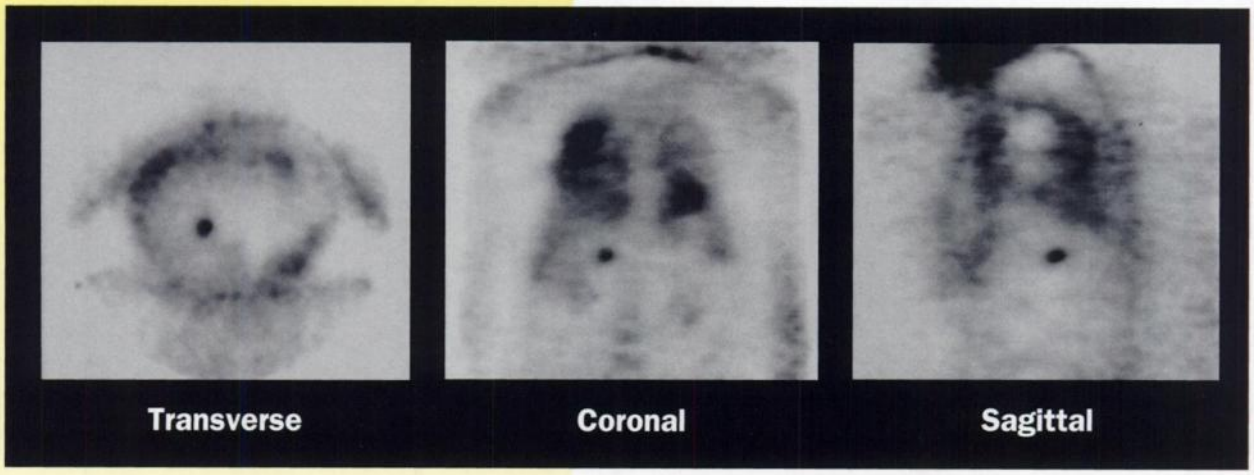


*The CT shows no evidence of adrenal mass.*

Wouldn't you prefer to see both

the CT and MCD images

Images courtesy of St. Vincent's Hospital and Medical Center, New York, NY




*The MCD study on the ADAC Vertex reveals metastasis in the right adrenal gland.*

before making a treatment decision for this patient?

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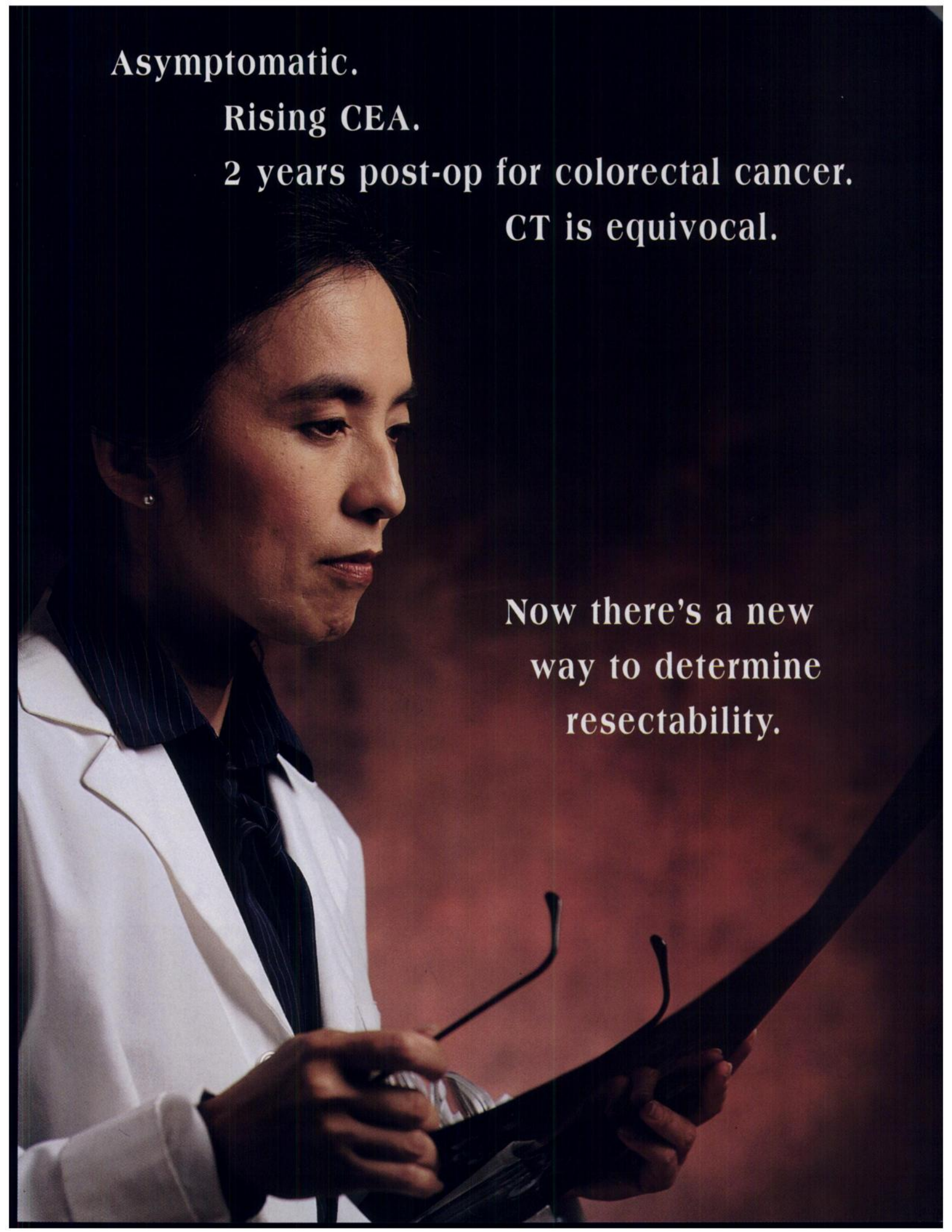
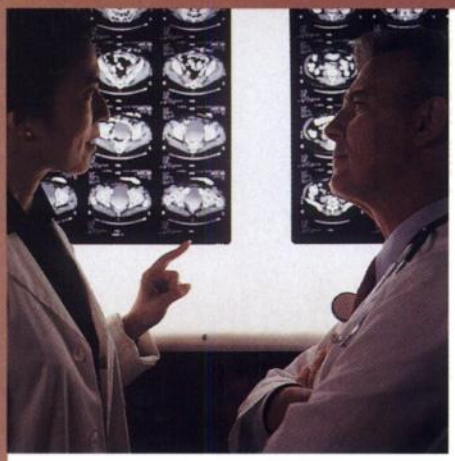

Asymptomatic.
Rising CEA.
2 years post-op for colorectal cancer.
CT is equivocal.
Now there's a new
way to determine
resectability.



INTRODUCING

# CEA-SCAN®
## (Arcitumomab)

# SENSITIVE IMAGING TO HELP DRIVE MANAGEMENT DECISIONS

CEA-Scan is a new imaging agent that enhances your pre-operative determination of colorectal cancer resectability. CEA-Scan is indicated, in conjunction with standard diagnostic evaluations, for detection of the presence, location and extent of recurrent and/or metastatic colorectal carcinoma involving the liver, extra-hepatic abdomen and pelvis in patients with a histologically confirmed diagnosis of colorectal carcinoma.

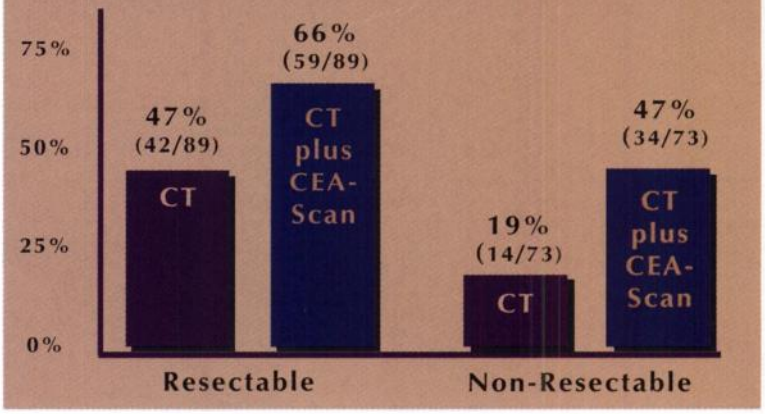
Surgery confirms that CEA-Scan with CT can help you make decisions concerning surgical resectability. Compared to CT alone, CEA-Scan with CT:

- Identified 59/89 versus 42/89 patients with resectable disease, a 40% increase in detection rate
- Identified 34/73 versus 14/73 patients with non-resectable disease, or more than twice as many
- In patients with negative or equivocal CT (occult disease), reduced the number of false-negative patients from 59 to 23, a 60% decrease.[1]

CEA-Scan has a 97% positive predictive value for lesions when concordant with CT (146 true-positive lesions versus 4 false-positives).

## BETTER IDENTIFICATION OF RESECTABLE/NON-RESECTABLE DISEASE

Comparison of surgical outcomes correctly identified by CT vs CT plus CEA-Scan (n=209)




## IMPROVES SENSITIVITY

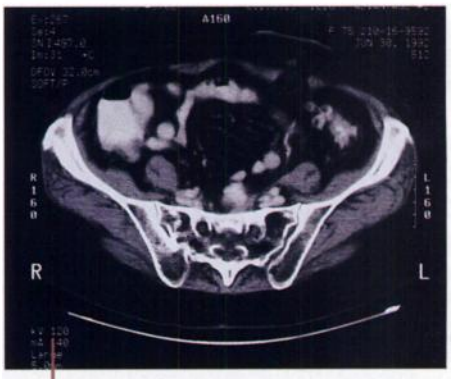
Sensitivity and specificity of CEA-Scan vs standard diagnostic methods (SDM)[1]

| | SDM | | CEA-Scan |
|---|---|---|---|
| Sensitivity | 57.9% (103/178) | *P*=0.006 | 71.3% (127/178) |
| Specificity | 84.4% (27/32) | *P*=0.12 | 62.5% (20/32) |

## SENSITIVE, SAME-DAY IMAGING

CEA-Scan enables improved colorectal cancer detection compared to standard diagnostic methods (SDM, 95% of which were CT).

- In general, CEA-Scan was more sensitive and less specific in the abdomen and pelvis than CT[1]
- However, direct comparisons of the performance characteristics of SDM to CEA-Scan are difficult to interpret, since the results of SDM were entry criteria for both Phase 3 protocols.




*Patient underwent abdominoperineal resection in 1987. Presented 5 years post-op with negative CT and rising CEA.*

## ADVANCED TECHNOLOGY

CEA-Scan offers the advantages of Fab' fragment design.

- Short biological half-life (13±4 hours) and rapid blood clearance improve tumor-to-background ratios[2]
- Minimal liver metabolism allows hepatic imaging
- Small fragment size enhances renal clearance
- Fragment technology provides lower immunogenicity

## ESTABLISHED SAFETY PROFILE

Over 400 patients who have received CEA-Scan have been evaluated for human anti-mouse antibody (HAMA).

- <1% showed an elevation of HAMA levels
- Limited data are available regarding the safety of re-administration

In the patients studied with CEA-Scan, one patient each developed the following minor self-limiting adverse effects: transient eosinophilia, nausea, bursitis, urticaria, generalized itching, headache, upset stomach and fever. Out of a total of over 500 patients receiving the product to date, there has been a single report of an apparent grand mal epileptic seizure in a severely hypertensive patient that was "possibly related" to CEA-Scan infusion.


*CEA-Scan abdominal SPECT image indicating tumor uptake (T, arrow). Surgery confirmed the positive CEA-Scan image.*

## HELPING YOU MAKE DECISIONS ABOUT TUMOR RESECTABILITY

*Manufactured by:*
IMMUNOMEDICS, INC.

*Distributed by:*
MALLINCKRODT MEDICAL

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

References:
1. Moffat FL Jr., Pinsky CM, Hammershaimb L, et al. Clinical utility of external immunoscintigraphy with the IMMU-4 technetium-99m-Fab' antibody fragment in patients undergoing surgery for carcinoma of the colon and rectum. Results of a pivotal, Phase III trial. *J Clin Oncol.* 1996;14:2295-2305.
2. Tempero M, Brand R, Holdeman K, Matamoros A. New imaging techniques in colorectal cancer. *Semin Oncol.* 1995; 22(5):448-471.

# CEA-SCAN®
## (Arcitumomab)

For the Preparation of Technetium Tc 99m Arcitumomab.
Sterile, Non-Pyrogenic, Lyophilized Powder for Intravenous Use Only.

**DESCRIPTION**

CEA-Scan® is a radiodiagnostic agent consisting of a murine monoclonal antibody Fab' fragment, arcitumomab, formulated to be labeled with $^{99m}$Technetium [$^{99m}$Tc].[1] The active component, arcitumomab, is a Fab' fragment generated from IMMU-4, a murine $IgG_1$ monoclonal antibody produced in murine ascitic fluid supplied to Immunomedics, Inc., by Charles River Laboratories. IMMU-4 is purified from the ascitic fluid and is digested with pepsin to produce $F(ab')_2$ fragments and subsequently reduced to produce the 50,000-dalton arcitumomab. Each vial contains the non-radioactive materials necessary to prepare one patient dose. CEA-Scan® is a sterile, lyophilized formulation, containing 1.25 mg of arcitumomab and 0.29 mg stannous chloride per vial, with potassium sodium tartrate tetrahydrate, sodium acetate trihydrate, sodium chloride, acetic acid, glacial, hydrochloric acid, and sucrose. The imaging agent, technetium Tc 99m CEA-Scan®, technetium Tc 99m arcitumomab, is formed by reconstitution of the contents of the CEA-Scan® vial with 30 mCi of [$^{99m}$Tc] sodium pertechnetate in 1 ml of Sodium Chloride for Injection, USP. The resulting solution is pH 5-7 and for intravenous use only. Following administration, the labeled antibody can be visualized by common nuclear medicine instrumentation.

**INDICATIONS**

CEA-Scan® (Arcitumomab) is indicated, in conjunction with standard diagnostic evaluations (e.g., additional imaging evaluation), for detection of the presence, location and extent of recurrent and/or metastatic colorectal carcinoma involving the liver, extrahepatic abdomen and pelvis in patients with a histologically confirmed diagnosis of colorectal carcinoma. CEA-Scan® provides additional information in patients with no evidence of disease by standard diagnostic modalities (SDM) in whom recurrence or metastasis is suspected based upon elevated or rising serum CEA, and in patients with evidence of metastatic or recurrent disease on SDM. A retrospective analysis suggests that these data can be useful in the evaluation of patients in whom surgical intervention (biopsy, exploratory laparotomy and surgical resection) is under consideration.

CEA-Scan® is not indicated for the differential diagnosis of suspected colorectal carcinoma or as a screening tool for colorectal cancer. CEA-Scan® is not intended for readministration or for assessment of response to treatment. (see PRECAUTIONS)

**CONTRAINDICATIONS**

CEA-Scan® should not be administered to patients who are hypersensitive to products of murine origin or to Technetium [Tc-99m.]

**WARNINGS**

Anaphylactic and other hypersensitivity reactions can occur following administration of mouse protein to patients. Although serious reactions of this type have not been observed in clinical trials after CEA-Scan® administration, medications for the treatment of hypersensitivity reactions, e.g., epinephrine, antihistamines and corticosteroids, should be available for immediate use in the event of an allergic reaction during administration of this agent.

**PRECAUTIONS**

**General**

CEA-Scan® is to be interpreted in conjunction with standard diagnostic modalities. A negative or positive CEA-Scan® by itself should not be utilized in the diagnostic evaluation of colorectal cancer. Discordant results are substantially less predictive than concordant results.

CEA-Scan® should not be used as a screening test for colorectal cancer.

Limited data are available regarding the safety of readministration.[2] There are no data to support the efficacy of CEA-Scan® readministration. CEA-Scan® should be used only once in each patient.

The components of CEA-Scan® are sterile and non-pyrogenic. It is essential to follow preparation directions carefully and to adhere to strict aseptic procedures during preparation of CEA-Scan® [$^{99m}$Tc]. The contents of the vial are intended only for use in the preparation of CEA-Scan® [$^{99m}$Tc] and are not to be administered directly to patients.

The contents of the vial before preparation are not radioactive. However, after $^{99m}$Tc-pertechnetate is added, adequate shielding of the preparation must be maintained. Appropriate safety measures should be used to minimize radiation exposure to clinical personnel and patients, consistent with proper patient management.

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

***Imaging Interpretation***

General

There are limited data to determine the imaging characteristics and efficacy of the CEA-Scan® (Arcitumomab) in detection of lesions outside of the abdominopelvic cavity.[2,3]

Areas of potential false-positive readings, particularly with planar imaging, may be observed near the major bloodpool organs (heart, major vessels, etc.) at very early imaging times, near the sites of antibody fragment metabolism (kidneys and urinary bladder), and in the intestines and gallbladder. Late imaging may also aid in the evaluation of suspected normal bowel activity.

With regard to imaging of tumor near the kidneys or urinary bladder, it is advisable to have the patient void urine prior to acquisition of imaging data to decrease bladder activity. Careful SPECT imaging near the kidneys and bladder has been helpful.

Porta Hepatis Region

Precise localization of lesions in the region of the porta hepatis has been difficult. Lesions within the porta hepatis region may be present within the liver or the portal nodes. At the time of surgical exploration, such lesions (which if nodal would preclude resection of hepatic metastases) should be explored first.

False-Positive Lesions

There were 52 false-positive lesions observed in 41 patients from a total of 209 surgically explored subjects in the two pivotal trials. Thirty-five of these lesions were in occult disease patients. Of the 52 false-positive lesions, 11 were observed in the liver, 17 in the extra-hepatic abdomen, and 24 in the pelvis. A pathological correlate to the lesions was infrequently documented; these included granulomas in the liver (1 instance), adhesions with or without suture granulomas (4 cases), surgical incision site (1 case). Descriptions of false-positive lesions within the abdomen were suggestive of colonic activity in several cases.

Hot, Rimmed, and Cold Lesions

Only hot or rimmed lesions should be considered as positive for tumor. Lesions that are rimmed or cold usually fill in as hot or rimmed, respectively, with time.[3,4] Often, large lesions, due to poor vascularization or central necrosis, will appear to be cold.

**Information for Patients**

Murine monoclonal antibodies are foreign proteins, and their administration can induce human anti-mouse antibodies (HAMA). While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine antibody-based immunoassays (e.g., serum CEA assays), could compromise the efficacy of *in vitro* or *in vivo* diagnostic or therapeutic murine antibody-based agents, and may increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could affect the future use of other murine-based products, including CEA-Scan®, and they should be advised to discuss prior use of murine-based antibody products with their physicians. (see Heterologous Protein Administration)

*Heterologous Protein Administration*

The presence of HAMA and human anti-mouse fragment antibodies have been reported in patients before and after receiving CEA-Scan® (<1% of patients develop HAMA to the antibody fragment). While hypersensitivity reactions to CEA-Scan® have not been observed to date, it is possible that such reactions could occur, resulting in anaphylactic shock, serum sickness or death. In addition, patients who have previously received murine monoclonal antibody products are more likely to have HAMA. When considering the use of the CEA-Scan® in patients who have previously received murine antibody-based products, physicians should be aware of the potential for HAMA to increase the risk of allergic reactions and to alter clearance and biodistribution. The quality or sensitivity of the imaging study may then be compromised.

**Drug/Laboratory Test Interactions**

The presence of HAMA in serum may interfere with two-site murine antibody-based immunoassays, such as assays for CEA and CA-125. If HAMA is known or suspected to be present, the clinical laboratory should be notified that interference may occur.

CEA-Scan® may interfere with serum assays for assessment of serum levels of CEA. Therefore, any determination of serum CEA should be made prior to injection with CEA-Scan®. Assays for serum CEA should not be performed within 7 days after injection of CEA-Scan®.

No data are available on possible drug interactions. Do not mix or administer CEA-Scan® with other products. Sufficient time should be allowed for clearance and radioactive decay before and after the use of this product and other products using radionuclides.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term animal studies have been performed to evaluate the carcinogenic or mutagenic potential of Technetium Tc 99m arcitumomab or to determine its effects on fertility in males or females.

**Pregnancy - Category C**

Animal reproduction studies have not been conducted with CEA-Scan®. It is also not known whether it can cause fetal harm or affect reproductive capacity when administered to a pregnant woman. CEA-Scan® should be used during pregnancy only if, in the opinion of the physician, the information to be gained justifies the potential risk to the fetus. Examinations using a radiopharmaceutical in a woman of child-bearing capability should be performed during the first 8-10 days following the onset of menses, if possible.

**Lactation**

Before administering a radioactive medicinal product to a mother who is breast feeding, consideration should be given whether the investigation could be reasonably delayed until the mother has ceased breast feeding. If the use of the product is deemed to be clinically indicated, breast feeding should be interrupted, the expressed milk discarded, and formula feedings substituted for breast feeding.

**Pediatric Use**

Safety and diagnostic accuracy in persons under 21 years of age have not been established.

**ADVERSE REACTIONS**

In the patients studied with CEA-Scan®, one patient each developed the following minor self-limiting adverse effects: transient eosinophilia, nausea, bursitis, urticaria, generalized itching, headache, upset stomach and fever. Out of a total of over 500 patients receiving the product to date, there has been a single report of an apparent grand mal epileptic seizure in a severely hypertensive patient that was "possibly related" to CEA-Scan® infusion.

Over 400 patients who have received CEA-Scan® have been evaluated for HAMA by Immunomedics using ELISA methodology. Fewer than 1% of the patients showed an elevation of HAMA levels to fragment after being injected with CEA-Scan®. If the physician suspects HAMA based on an adverse reaction or altered biodistribution pattern, and deems that a HAMA assay is clinically warranted, he/she should telephone Immunomedics, Inc., at 800 327-7211, between 8:30 a.m. and 5:00 p.m. Eastern Standard Time, for information on procedures to be followed for submission of patient serum for assessment of HAMA directed against mouse monoclonal antibody fragments.

**OVERDOSAGE**

Intravenous infusion of intact IgG and $F(ab')_2$ of IMMU-4 in doses of up to 25 mg or arcitumomab at doses up to 10 mg have not shown any serious adverse reaction.

**HOW SUPPLIED**

Package containing one (1) vial, with a single-use dose of 1.25 mg lyophilized arcitumomab. The product should not be used beyond the expiration date printed on the label.

**REFERENCES**


1. Hansen HJ, Jones AL, Sharkey RM, Grebenau R, Blazejewski N, Kunz A, Buckley MJ, Newman ES, Ostella F, Goldenberg DM. Preclinical evaluation of an 'instant' $^{99m}$Tc-labeling kit for antibody imaging. *Cancer Res.* 1990;50:794-798.
2. Data on File at Immunomedics, Inc.
3. Moffat FL, Pinsky CM, Hammershaimb L, Petrelli NJ, Patt YZ, Whaley FS, Goldenberg DM, and the Immunomedics Study Group. Clinical utility of external immunoscintigraphy with the IMMU-4 technetium-99m-Fab' antibody fragment in patients undergoing surgery for carcinoma of the colon and rectum. Results of a pivotal, Phase III trial. *J Clin Oncol* 1996;14:2295-2305.
4. Behr T, Becker W, Hanappel E, Goldenberg DM, Wolf F. Targeting of liver metastases of colorectal cancer with IgG, $F(ab')_2$, and Fab' anti-carcinoembryonic antigen antibodies labeled with $^{99m}$Tc: the role of metabolism and kinetics. *Cancer Res.* 1995;55:5777s-5785s.



**Immunomedics, Inc.**
**300 American Road**
**Morris Plains, NJ 07950**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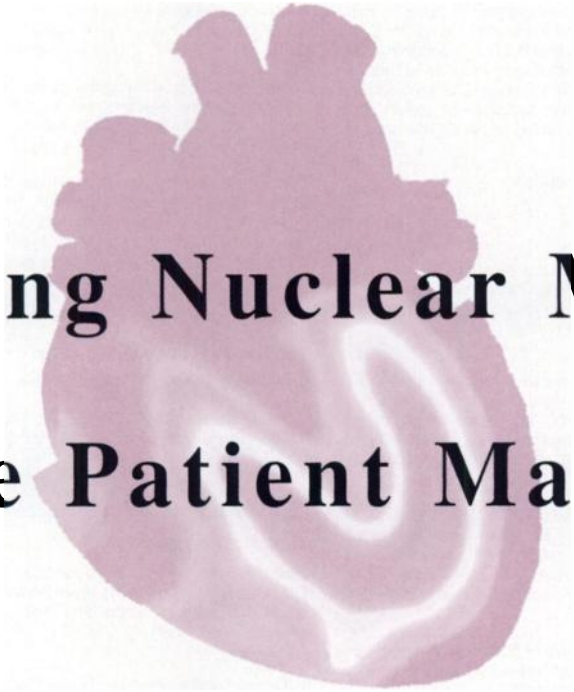

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**THALLIUM**
Thallous Chloride-201

**ADENOSCAN®**
adenosine

**HSA**
Tc99m Albumin Injection

**PYP**
Tc99m Pyrophosphate

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**Brief Summary**

# MYOVIEW™

## 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-dioxa-6,9-diphospha-tetradecane], 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-gluconate, 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)

| | Absorbed radiation dose | | | |
|---|---|---|---|---|
| | Exercise | | Rest | |
| Target Organ | 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 $8.61 \times 10^{-3}$ mSv/MBq and $1.12 \times 10^{-2}$ mSv/MBq after exercise and rest respectively.

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

Distributed by: Medi-Physics, Inc., Amersham Healthcare
2636 S. Clearbrook Dr., Arlington Heights, IL 60005
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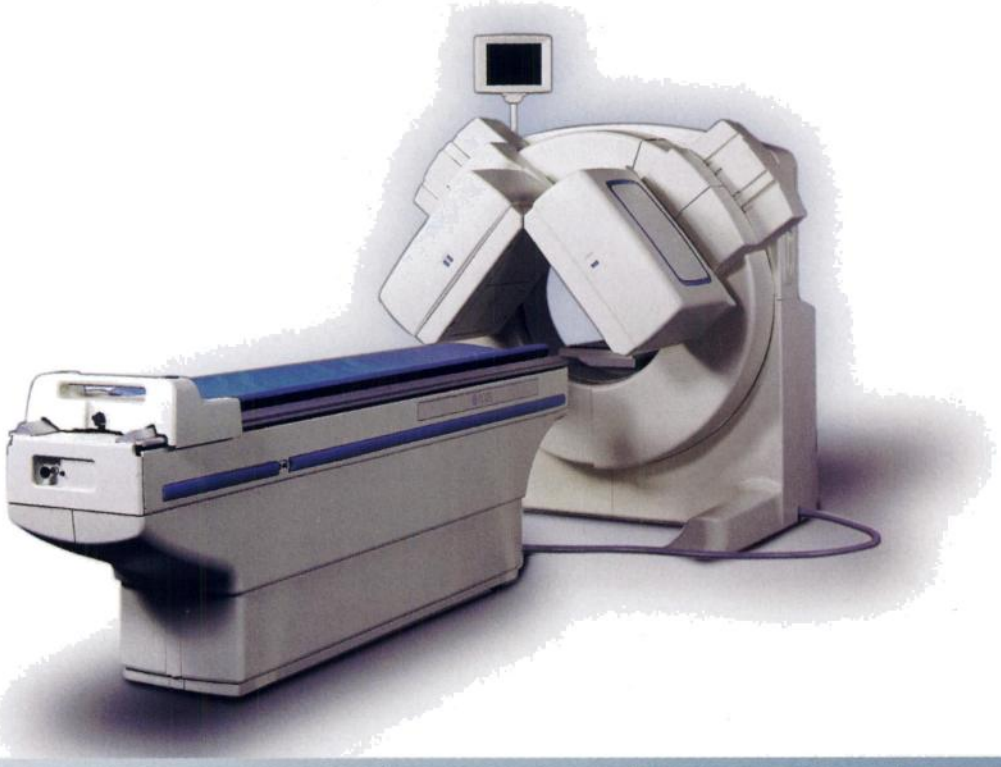

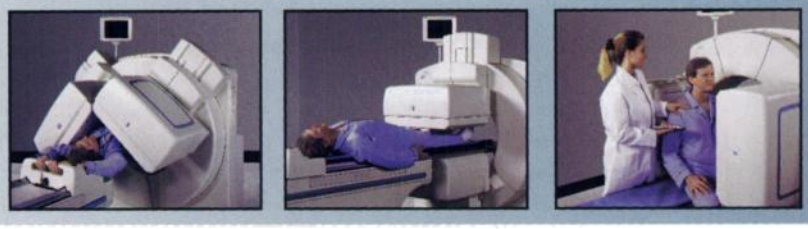

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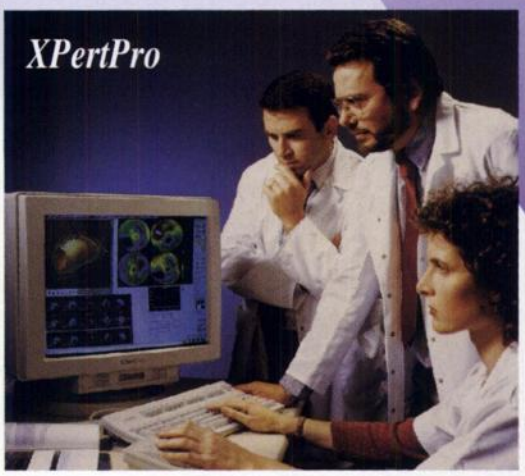


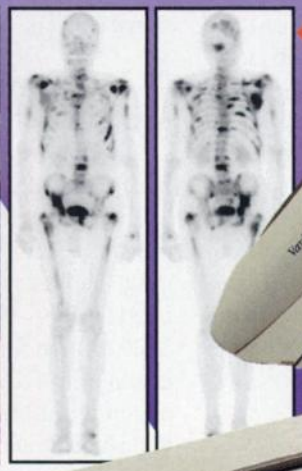

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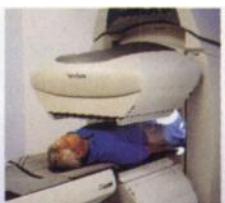

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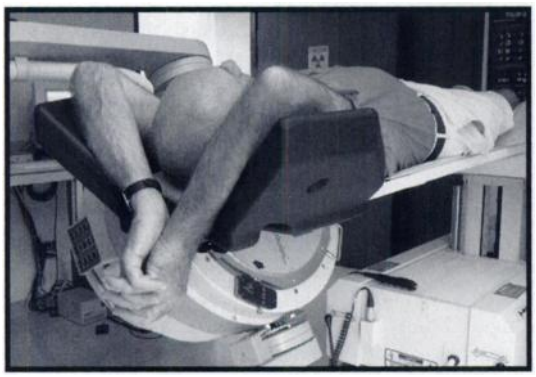

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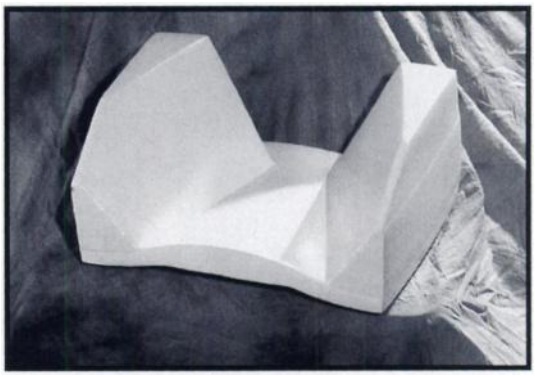

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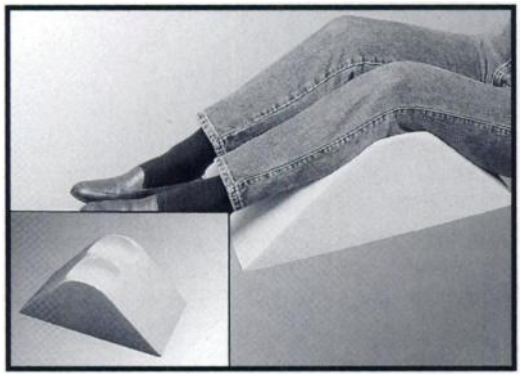

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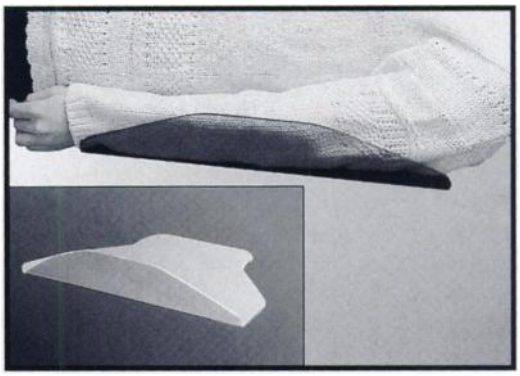

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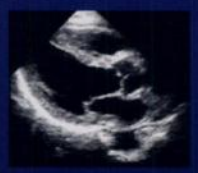
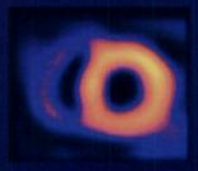


ECHOCARDIOGRAPHY



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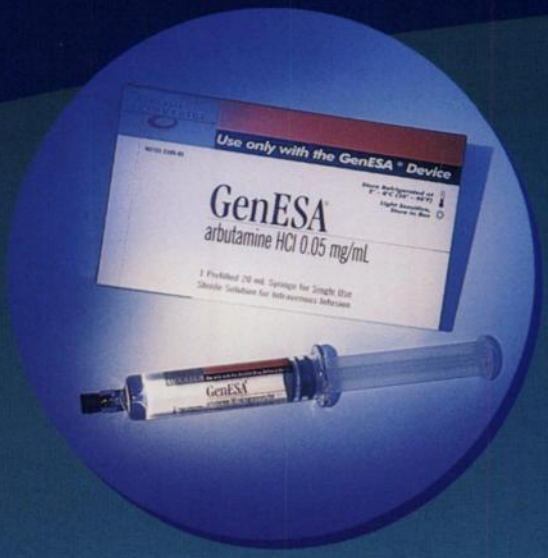


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Arbutamine HCl is supplied in a convenient, ready-to-use syringe—no mixing or dilution required

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You select a maximum heart rate limit (HR Target) and rate of heart rate increase (HR Slope) appropriate for each patient

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- Simulates the cardiac effects of exercise—without atropine
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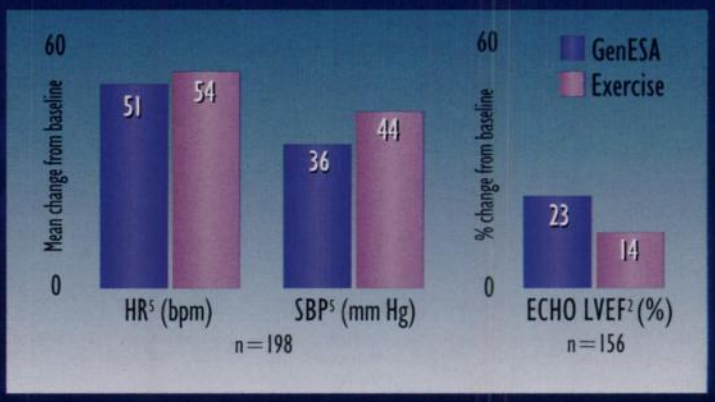
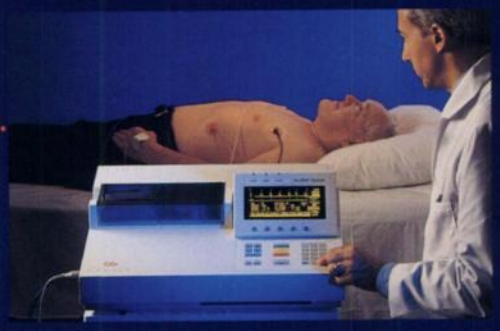
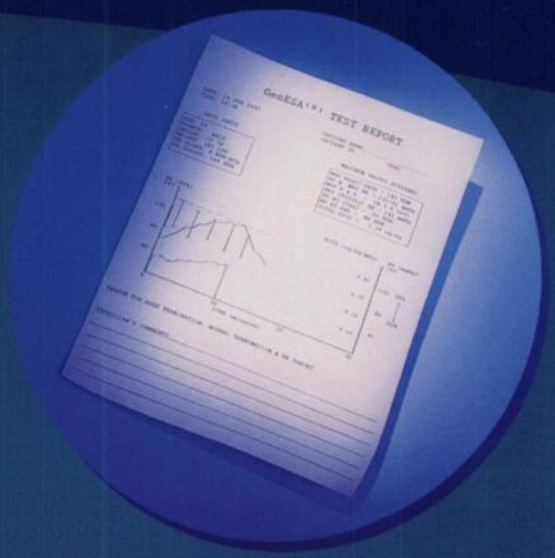


IMAGING IN PATIENTS UNABLE TO EXERCISE ADEQUATELY

# System

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Useful alerts warn of potential problems

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During clinical trials involving 2082 patients with known or suspected CAD, the most frequently reported adverse events were tremor (15%), angina pectoris (12%), nonserious cardiac arrhythmias (12%), headache (9%), and hypotension (6%). Overall incidence of serious adverse events considered related to arbutamine infusion was <0.5% and included 3 episodes of ventricular fibrillation, 1 episode of sustained ventricular tachycardia, 3 episodes of atrial fibrillation, 1 myocardial infarction, and 2 cases of severe angina.[2] Majority of events were mild and all resolved without sequelae.

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NEW

# GenESA®

## arbutamine HCl injection 0.05 mg/mL

**Simplifies pharmacologic stress testing**

Please see brief summary of important Prescribing Information on adjacent pages.

**References:** 1. Young M, Pan W, Wiesner J, et al. Characterization of arbutamine: a novel catecholamine stress agent for diagnosis of coronary artery disease. *Drug Development Research.* 1994;32:19-28. 2. Data on file. Gensia Automedics, Inc. San Diego, Calif. 3. Kiat H, Iskandrian AS, Villegas BJ, Starling MR, Berman DS. Arbutamine stress thallium-201 single-photon emission computed tomography using a computerized closed-loop delivery system: multicenter trial for evaluation of safety and diagnostic accuracy. *J Am Coll Cardiol.* 1995;26(5):1159-1167. 4. Cohen JL, Chan KL, Jaarsma W, et al. Arbutamine echocardiography: efficacy and safety of a new pharmacologic stress agent to induce myocardial ischemia and detect coronary artery disease. *J Am Coll Cardiol.* 1995;26(5):1168-1175. 5. Dennis CA, Pool PE, Perrins EJ, et al. Stress testing with closed-loop arbutamine as an alternative to exercise. *J Am Coll Cardiol.* 1995;26(5):1151-1158.

## GenESA® (arbutamine HCl injection 0.05 mg/mL)

**Brief Summary**

**For Intravenous Infusion only with the GenESA® Device**

**DESCRIPTION**

GenESA is a synthetic catecholamine with chronotropic and inotropic properties. Chemically, arbutamine hydrochloride is (R)-4-[1-hydroxy-2-[[4-(4-hydroxyphenyl)-butyl]amino]ethyl]-1,2-benzenediol hydrochloride and is an off-white amorphous solid, which is freely soluble in water and ethanol, but is practically insoluble in diethyl ether and hexane. GenESA is formulated in an isotonic, buffered vehicle (pH 3.8) in a 20 mL prefilled syringe.

**CLINICAL TRIALS**

The usefulness of diagnostic tests can be defined in various ways. Measures of sensitivity (ability of test to identify diseased patients, in this case the rate of positive stress tests in patients with positive angiograms) and specificity (ability of test to identify people without disease, in this case the rate of negative stress tests in patients with negative angiograms) are frequently used. The problem is that the usefulness of a test can depend not only on sensitivity and specificity but on prevalence of the disease. Thus, for example, even a very sensitive test will be of minimal use in a population where almost all patients have the disease; for example, if 100% of patients have the disease, even 90% sensitivity will mean an "error rate" (declaring no disease when disease was present) in 10% of patients. In addition to sensitivity and specificity, therefore, tests are often described in terms of positive predictive fraction (the rate of correctness of a positive test) and negative predictive fraction (the rate of correctness of a negative test).

In clinical studies, patients underwent coronary angiography and GenESA® System testing with radionuclide perfusion imaging (using thallium-201 or technetium-99m sestamibi) or with echocardiography. For purposes of these studies, an angiogram was considered positive if it demonstrated at least one ≥ 50% diameter stenosis of a major coronary artery; the GenESA System test was considered positive if perfusion defects were seen by radionuclide imaging or if wall motion abnormalities were noted on echocardiography, at baseline or during stress.

The following discussion gives both (1) a sensitivity/specificity/positive and negative predictive value analysis (in patients with a high-risk for CAD, and in those with a lower-risk) and (2) an overall analysis that relates the information provided by the test relative to a prior estimate (based on a standard algorithm) of the likelihood of CAD being present.

1. Sensitivity/Specificity

The ability of radionuclide and echocardiographic tests to predict the results of coronary angiography were assessed in 234 and 389 patients, respectively. In the high-risk studies, patients were selected based on coronary angiographic evidence of CAD obtained within 12 weeks prior to the GenESA System test with thallium imaging or echocardiography. Patients were also included if coronary angiography was scheduled within 4 weeks following the GenESA System test. All studies were read without knowledge of other results. In the lower-risk studies, patients were selected if coronary angiography had been performed within 12 weeks before or after the GenESA System test and results were re-read blindly after the study to give a similar assessment of the test. Except for the lower risk echocardiography study, the results based on blinded readings are shown in **Table 1.** The blinded re-reading of the echocardiograms from the lower risk study was technically inadequate, and the results shown for that study are based on non-blinded readings.

**Table 1**
**Sensitivity, Specificity and Predictive Fractions for Radionuclide Imaging or Echocardiography with the GenESA System**

| Study | Sensitivity | Specificity | Positive Predictive Fraction | Negative Predictive Fraction |
|---|---|---|---|---|
| Radionuclide Imaging | | | | |
| High Risk | 97/112 (87%) | 2/8 (25%) | 97/103 (94%) | 2/17 (12%) |
| Lower Risk | 51/81 (63%) | 21/33 (64%) | 51/63 (81%) | 21/51 (41%) |
| Thallium | 10/16 (63%) | 7/12 (58%) | 10/15 (67%) | 7/13 (54%) |
| Sestamibi | 41/65 (63%) | 14/21 (67%) | 41/48 (85%) | 14/38 (37%) |
| Echocardiography | | | | |
| High Risk | 110/131 (84%) | 4/16 (25%) | 110/122 (90%) | 4/25 (16%) |
| Lower Risk | 137/194 (71%) | 32/48 (67%) | 137/153 (90%) | 32/89 (36%) |

Note that although sensitivity and specificity are in general independent of prevalence, it is possible that in this case prevalence (or, more likely, the presence of various factors related to CAD) does influence the test results, e.g., by giving more false positives in the high risk group (and thus lower specificity).

Note also that in a very high-risk group, use of the test may give less than satisfactory overall advice although (see next section) the ability to predict the result of angiography in any given patient may be improved. Thus, even with a high sensitivity of 87% for radionuclide imaging, 15/112 patients with CAD were identified as not having it, and of 8 patients without CAD, 6 were identified as having it. The test is most helpful where the likelihood that the patient has arterial disease is neither very high nor very low.

2. Predictive Value of the GenESA System Test

Another approach to considering results of GenESA System testing is to describe the impact of the test result on the estimated likelihood of CAD based on the patients' defined risk, utilizing all available data about the patient. Using an algorithm developed by Pryor, DB, et al. (Am J Med 1983; 75:771-80), the 424 patients with demographic data available who underwent coronary angiography and GenESA System testing assessed with perfusion imaging or echocardiography were categorized as having a low (<20%), intermediate (20-80%) or high (>80%) likelihood of CAD. The characteristics of the three groups are summarized in **Table 2.**

**Table 2**
**Characteristics of 424 Patients Who Each Underwent Coronary Angiography and had a GenESA System Test Assessed with Radionuclide Imaging or Echocardiography**

| Pretest CAD likelihood<br>Group called<br>% (N) of Patients | <20%<br>"Low"<br>4% (17) | 20-80%<br>"Intermediate"<br>26% (112) | >80%<br>"High"<br>70% (295) |
|---|---|---|---|
| Age ≥ 65 years<br>Male | 6% (1)<br>18% (3) | 23% (26)<br>55% (61) | 37% (110)<br>89% (261) |
| Typical Angina<br>Atypical Angina | 0% (0)<br>47% (8) | 19% (21)<br>48% (54) | 79% (233)<br>16% (46) |
| Hyperlipidemia<br>Diabetes<br>Smoking | 41% (7)<br>18% (3)<br>24% (4) | 56% (63)<br>16% (18)<br>30% (34) | 61% (181)<br>21% (62)<br>37% (110) |
| Prior MI<br>MI on ECG<br>ST-T Abnormality | 0% (0)<br>0% (0)<br>18% (3) | 16% (18)<br>0% (0)<br>21% (23) | 54% (159)<br>27% (79)<br>36% (106) |
| # Patients with:<br>1 Risk Factor<br>2 Risk Factors<br>3 Risk Factors<br>4 Risk Factors<br>≥ 5 Risk Factors<br>Mean (±SD) # Risk Factors/ Patient | <br>35% (6)<br>59% (10)<br>6% (1)<br>0% (0)<br>0% (0)<br>1.7 (0.6) | <br>5% (6)<br>32% (36)<br>38% (42)<br>23% (26)<br>2% (2)<br>2.8 (0.9) | <br>0% (0)<br>2% (5)<br>22% (64)<br>29% (85)<br>48% (141)<br>4.6 (1.3) |
| Angiography positive | 23% (3) | 70% (72) | 92% (244) |

As summarized in **Table 3** (and as would be seen with any other less-than-perfect test), the performance of the GenESA System varied from one subgroup to another; it was most uniformly accurate in patients with an intermediate pre-test likelihood of disease.

**Table 3**
**Predictive Value of GenESA System Testing when used with Radionuclide Imaging or Echocardiography**

| Pretest probability of positive angiogram | N | Positive GenESA Test | Positive GenESA test was correct (angiogram positive) | Negative GenESA Test | Negative GenESA test was correct (angiogram negative) |
|---|---|---|---|---|---|
| Radionuclide Imaging | | | | | |
| Low | 9 | 3 (33%) | 0 (0%) | 6 (67%) | 6 (100%) |
| Intermediate | 50 | 28 (56%) | 22 (79%) | 22 (44%) | 10 (46%) |
| High | 174 | 135 (78%) | 126 (93%) | 39 (22%) | 7 (18%) |
| Echocardiography | | | | | |
| Low | 13 | 5 (38%) | 2 (40%) | 8 (62%) | 7 (88%) |
| Intermediate | 103 | 57 (55%) | 47 (83%) | 46 (45%) | 21 (46%) |
| High | 265 | 207 (78%) | 193 (93%) | 58 (22%) | 7 (12%) |

It is difficult for any diagnostic test to contribute information when the pretest probability of disease is extremely low or extremely high. As the pretest likelihood gets higher and higher, a positive test result provides a smaller and smaller increment of information, while a negative test result is more and more likely to be a false negative. Conversely, as the pretest likelihood of disease approaches zero, positive test results are more and more likely to be false positives. These considerations are of course applicable to all diagnostic tests, not just to the GenESA System.

To interpret the data another way, one can estimate the post-test likelihood of CAD, given the pre-test likelihood and the result of a GenESA System test (Diamond GA, et al, NEJM 1979; 300:1350-58). These results are shown in **Table 4** for perfusion imaging and echocardiography and confirm the general discussion of the previous paragraph.

**Table 4**
**Post-Test Likelihood of Coronary Artery Disease Given the Pre-Test Likelihood and the Result of GenESA System Testing Assessed with Radionuclide Imaging or Echocardiography**

| Pre-Test Likelihood | Post-Test Likelihood after Radionuclide Imaging | | Post-Test Likelihood after Echocardiography | |
|---|---|---|---|---|
| | with positive GenESA test | with negative GenESA test | with positive GenESA test | with negative GenESA test |
| 10% | 16 | 4 | 16 | 5 |
| 20% | 30 | 9 | 30 | 10 |
| 30% | 43 | 15 | 43 | 15 |
| 40% | 54 | 22 | 54 | 22 |
| 50% | 64 | 29 | 63 | 30 |
| 60% | 72 | 38 | 72 | 39 |
| 70% | 80 | 49 | 80 | 50 |
| 80% | 87 | 62 | 87 | 63 |
| 90% | 94 | 79 | 94 | 79 |

## GenESA® (arbutamine HCl injection 0.05 mg/mL)

**INDICATIONS AND USAGE**

The GenESA System delivers arbutamine, a catecholamine, through a closed-loop, computer-controlled drug-delivery system to elicit acute cardiovascular responses similar to those produced by exercise. In patients with suspected coronary artery disease (CAD) who cannot exercise adequately, stress induction with the GenESA System is indicated as an aid in diagnosing the presence or absence of CAD.

The effectiveness of the GenESA System has been demonstrated in clinical studies using radionuclide myocardial perfusion imaging to predict the results of coronary angiography. These studies were in patients with high and lower risks of CAD and utilized blinded, central reading of images. Estimates of sensitivity, specificity and predictive values are presented in the "Clinical Trials" section.

Although the effectiveness of the GenESA System was also assessed in similar clinical studies utilizing echocardiography to predict the results of coronary angiography, the blinded, central reading of the images from the lower-risk echocardiography study was technically inadequate. Estimates of sensitivity, specificity and predictive values, based on the non-blinded readings of echocardiograms at the local study sites, are presented for the lower-risk patients (see Clinical Trials). For the study of high-risk patients, the estimates are based on valid, blinded, central reading of images.

Like exercise testing, cardiac stress testing with the GenESA System must always be performed under the direct supervision of a physician, and cardiac emergency equipment and supplies (defibrillator, intravenous β-blocker, etc.) must always be available. Arbutamine must not be administered without use of the GenESA® Device.

**CONTRAINDICATIONS**

Arbutamine is contraindicated in patients with idiopathic hypertrophic subaortic stenosis, in patients with a history of recurrent sustained ventricular tachycardia, in patients with congestive heart failure (NYHA Class III or IV), and in patients who have shown previous manifestations of hypersensitivity to arbutamine. The GenESA System must not be used in the presence of an implanted cardiac pacemaker or automated cardioverter/defibrillator.

**WARNINGS**

During clinical trials that included 2082 patients with known or suspected coronary artery disease, arbutamine administration was associated with 10 **serious adverse events**, including 3 episodes of ventricular fibrillation, 1 episode of sustained ventricular tachycardia, 3 episodes of atrial fibrillation (see Table 6 for a summary of all arrhythmias reported as adverse events), 1 myocardial infarction and 2 cases of severe angina. Two of the three cases of ventricular fibrillation occurred after the GenESA Device had detected a plateau in HR response and had terminated arbutamine infusion, but the physician restarted the infusion. There were no deaths.

The incidence of serious adverse events is thus low, less than 0.5%. Nevertheless, the potential information to be gained through the use of arbutamine, delivered using the GenESA Device (see **INDICATIONS and USAGE**), must be weighed against the potential risks to each patient.

Arbutamine may precipitate or exacerbate supraventricular and ventricular **arrhythmias** and its administration is not recommended in patients with a history of sustained arrhythmias of this nature. Given the proarrhythmic effects of certain **antiarrhythmic drugs**, particularly Class 1 agents such as quinidine, lidocaine and flecainide, arbutamine should not be administered to patients receiving such therapy.

Supraventricular or ventricular arrhythmias can occur during the administration of arbutamine (see **ADVERSE REACTIONS**) with isolated premature ventricular and atrial contractions being the most frequent arrhythmias. Most arrhythmias were self-limiting and all resolved without sequelae. If any arrhythmias are of clinical concern, drug infusion should be discontinued immediately and appropriate therapy (e.g., intravenous β-blockers - see **OVERDOSAGE**) administered, if necessary. The GenESA Device is not designed to detect arrhythmias. Appropriate monitoring equipment, such as a diagnostic quality ECG machine, must therefore be used during a GenESA System test. The GenESA Device administers arbutamine based upon HR response and it is possible that, in the presence of an arrhythmia, the GenESA Device may register an inaccurate HR. The ECG should be monitored carefully and appropriate action, including, if necessary, discontinuation of drug infusion, taken in the event of inaccurate HR detection.

Arbutamine may cause rapid increases or paradoxical decreases in HR and systolic blood pressure. Discontinuation of arbutamine infusion results in reversal of these effects. The infusion may be restarted, if considered clinically appropriate (see **DOSAGE AND ADMINISTRATION**).

The safety of arbutamine administration in patients with recent (within 30 days) myocardial infarction has not been formally evaluated. The administration of arbutamine is not recommended in patients with **unstable angina**, mechanical left ventricular outflow obstruction such as severe valvular **aortic stenosis, uncontrolled systemic hypertension**, a **cardiac transplant**, a history of cerebrovascular accident or peripheral vascular disorder resulting in cerebral or aortic aneurysm. In addition, arbutamine is not recommended in patients with narrow angle **glaucoma** or **uncontrolled hyperthyroidism**.

Arbutamine should not be administered to patients receiving **digoxin, atropine** (or other anticholinergic drugs) or **tricyclic antidepressants**. As the dosing of arbutamine is based on the HR response of the patient, the use of atropine to enhance the chronotropic response to arbutamine is not recommended.

Reactions suggestive of hypersensitivity have been reported occasionally with the administration of other catecholamines (such as Dobutrex® [dobutamine]). Like other parenterally administered catecholamines, GenESA contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes, in certain susceptible individuals. The overall prevalence of **sulfite sensitivity** in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than nonasthmatic individuals. No such reactions have been reported with arbutamine.

**PRECAUTIONS - (See WARNINGS)**

During the administration of arbutamine, as with any parenteral catecholamine, ECG and blood pressure should be continuously monitored. The GenESA Device provides such monitoring capabilities but a diagnostic quality ECG machine must also be used to monitor the ECG.

Like other catecholamines, arbutamine can produce a transient reduction in serum potassium concentration, rarely to hypokalemic levels. In one study, the transient decrease in serum potassium after arbutamine was greater in patients with arrhythmias (N=168), than those without arrhythmias (N=72).

Overall, changes in serum potassium in patients with clinically significant arrhythmias were not clearly different from those seen in other patients.

As seen with other catecholamines, GenESA infusion is associated with a transient increase in corrected QT interval, as measured from the surface ECG. This effect did not appear to be associated with an increased incidence of arrhythmias.

The acute use of the GenESA System for diagnostic testing makes it unlikely that alterations in renal and /or hepatic function will influence the safety and diagnostic efficacy of a GenESA System test.

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

Arbutamine is intended for single-dose use only and therefore animal carcinogenicity or long-term toxicity studies have not been performed.

Arbutamine was shown to be non-genotoxic in the Ames bacterial reverse mutation assay, with and without S9 mix, and in the mouse micronucleus test. Arbutamine was positive in the human lymphocyte chromosomal aberration assay (>66 μg/mL) and in the mouse lymphoma cell assay (>39 μg/mL).

Studies to determine the effect of arbutamine on the impairment of fertility have not been performed.

***Pregnancy: Teratogenic Effects***

***Pregnancy Category B***

Reproduction studies performed in rats and in rabbits at doses up to 0.9 and 0.36 mg/kg/day I.V., respectively (4 and 12 times the maximum recommended human dose on a mg/m² basis), revealed no evidence of harm to the fetus. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, arbutamine should be used during pregnancy only if clearly needed.

# GenESA® (arbutamine HCl injection 0.05 mg/mL)

**Drug Interactions**

Beta-adrenergic antagonists may attenuate the response to arbutamine and should be withdrawn, as recommended in the relevant product labeling, at least 48 hours before conducting a GenESA® System test. There was no evidence of drug-drug interactions in clinical studies in which arbutamine was administered concurrently with other drugs, including platelet aggregation inhibitors, nitrates, and calcium channel blockers.

**ADVERSE REACTIONS**

Adverse events were recorded during controlled clinical trials in 2082 patients with known or suspected coronary artery disease. Serious adverse events (ventricular and atrial fibrillation, and severe cardiac ischemia) are described above (see **WARNINGS**).

The most frequently reported adverse events in the 2082 patients were: tremor (15%), angina pectoris (12%), non-serious cardiac arrhythmias (12%), headache (9%), and hypotension (6%). Adverse events occurring in ≥1% of the 2082 patients are shown in **Table 5**:

**Table 5**
**Incidence of Most Frequent(≥1%) Adverse Events with Arbutamine**

| | Incidence (%) of Adverse Events | | Incidence (%) of Adverse Events |
|---|---|---|---|
| Tremor | 15 | Hot flushes | 3 |
| Angina pectoris | 12 | Nausea | 3 |
| Cardiac arrhythmias | 12 | Paresthesia | 2 |
| Ventricular | 6 | Anxiety | 1.9 |
| Supraventricular | 4 | Pain (non-specific) | 1.8 |
| Headache | 9 | Increased sweating | 1.5 |
| Hypotension | 6 | Fatigue | 1.3 |
| Chest pain | 4 | Taste perversion | 1.3 |
| Dizziness | 4 | Dry mouth | 1.1 |
| Dyspnea | 4 | Hypoesthesia | 1.0 |
| Palpitation | 4 | Vasodilation | 1.0 |
| Flushing | 3 | | |

Other adverse events, considered at least possibly related to arbutamine administration and occurring in <1% of the 2082 patients, and seen at least twice, are listed by body system.

- Cardiovascular: myocardial ischemia (0.1%) - see **WARNINGS**. ST segment depression (0.6%), hypertension (0.4%).
- Body as a Whole: asthenia (0.4%), malaise (0.2%), rigors (0.2%), back pain (0.1%).
- Central and Peripheral Nervous System Disorders: twitching (0.3%).
- Gastrointestinal System: abdominal pain (0.1%).
- Psychiatric Disorders: nervousness (0.7%), agitation (0.2%).
- Respiratory System Disorders: coughing (0.2%), bronchospasm (0.1%).
- Other: rash (0.2%), abnormal lacrimation (0.1%), application site reaction (0.1%).

Cardiac arrhythmias were reported as adverse events, if symptomatic or considered clinically significant, by the physician supervising the stress test. Overall cardiac arrhythmias, as identified by the investigator as adverse events, are shown in **Table 6**:

**Table 6**
**Incidence of Arrhythmias Reported as Adverse Events**

| | Incidence of Arrhythmias Reported as Adverse Events (N = 2082) |
|---|---|
| Total number of patients | 251 (12%) |
| Ventricular | 130 (6.2%) |
| Ventricular fibrillation | 3 (0.1%) |
| Ventricular tachycardia | 37 (1.8%) |
| Other ventricular* | 106 (5.1%) |
| Supraventricular | 79 (3.8%) |
| Supraventricular tachycardia | 39 (1.9%) |
| Atrial fibrillation | 20 (1.0%) |
| Other supraventricular** | 24 (1.2%) |
| Junctional | 16 (0.8%) |
| Bradycardia | 23 (1.1%) |
| Sinus tachycardia | 18 (0.9%) |
| Heart Block† | 3 (0.1%) |
| Sinus arrhythmia | 1 (0.05%) |

*Includes premature ventricular contractions (PVCs), couplets, triplets (rate ≤ 100 bpm), multifocal PVCs, ventricular bigeminy/trigeminy and idioventricular rhythm

**Includes premature atrial contractions and atrial arrhythmia (coronary sinus rhythm)

†Includes sinoatrial block and right bundle branch block

NOTE: Patients may have experienced more than one arrhythmia

**OVERDOSAGE - (See WARNINGS)**

Because arbutamine delivery is controlled by the GenESA® Device to give a defined increase in heart rate, overdosage is unlikely to occur. The maximum total dose permitted by the GenESA Device is 10 μg/kg. If overdosage occurs it should be short-lived, as arbutamine is metabolized rapidly, and most effects would be extensions of arbutamine's pharmacologic effects.

The symptoms of toxicity due to excessive dosing are those of catecholamine excess: tremor, headache, flushing, hypotension, dizziness, paresthesia, nausea, hot flushes, angina, increased sweating and anxiety. The positive chronotropic and inotropic effects of arbutamine on the myocardium may cause tachyarrhythmias, hypertension, myocardial infarction and ventricular fibrillation. If arbutamine is ingested, unpredictable absorption may occur from the mouth and gastrointestinal tract.

Treatment - initial actions include discontinuing administration, establishing an airway and ensuring adequate oxygenation and ventilation. Severe signs or symptoms (angina, tachyarrhythmias, ST segment abnormalities, hypotension) may be successfully treated with an intravenous β-blocker, such as metoprolol, esmolol or propranolol, at I.V. doses of 7.5-50 mg, 10-80 mg and 0.5-2 mg, respectively. Other treatment, such as sublingual nitrates, should be used if considered clinically appropriate. Given the rapid elimination of arbutamine, forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion are unlikely to be required for arbutamine overdosage.

**DOSAGE AND ADMINISTRATION**

**Before using the GenESA System, it is essential to read and understand the GenESA System Directions For Use in addition to this section of labeling. The GenESA System Directions for Use describe the complete operating instructions for the GenESA Device and the delivery of arbutamine.**

GenESA must be administered from the prefilled syringe and must not be diluted or transferred to another syringe. GenESA is intended for direct intravenous infusion ONLY with the GenESA Device.

The GenESA Device comprises a single channel ECG (R wave) detector, a non-invasive blood pressure monitor, computer software (closed-loop algorithm) which controls drug delivery, an intravenous syringe pump, display functions and an operator key pad. The GenESA Device individualizes the dosing regimen of arbutamine according to the HR response of the patient using the closed-loop algorithm. The physician selects the desired rate of HR rise (HR SLOPE) (range 4-12 bpm/min) and the maximum HR to be achieved (HR TARGET) for each patient test. The choice of HR Slope should be based upon the desired duration of the test and the rate of HR rise, judged by the physician, to be most appropriate. The maximum infusion rate delivered by the GenESA Device is 0.8 μg/kg/min and the maximum total dose is 10 μg/kg. The GenESA Device includes a "HOLD HR" feature that, when activated, allows HR to be maintained at approximately that level for up to 5 minutes.

"Heart rate saturation" (a flattening or plateau of the HR response to increasing dose of arbutamine) describes the maximal HR response to arbutamine and is an endpoint of the GenESA System test. If such a flattening or plateau of the HR response is detected when the HR is ≤ 40 bpm above the baseline level, restart of the arbutamine infusion is allowed. If the HR is >40 bpm above baseline and a HR saturation alarm occurs, restart of the arbutamine infusion is prevented by the GenESA Device (since it is unlikely that any further clinically significant increase in HR will occur following restart and there is a potential risk of serious cardiac arrhythmias (see **WARNINGS**)).

The infusion of arbutamine should be terminated when a diagnostic endpoint (e.g. ST segment deviation on ECG) has been reached, if clinically significant symptoms or arrhythmias occur, or if clinically appropriate for any other reason. Following completion of the infusion, the patient should be monitored (using the GenESA Device or other means), until HR and blood pressure have returned to acceptable levels.

For Basic Operating Instructions and other essential information on the use of the GenESA System, see the Quick Reference pull-out cards attached to the GenESA Device.

CAUTION: Federal (USA) law prohibits dispensing without a prescription.

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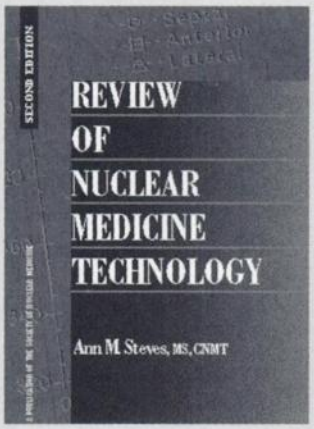


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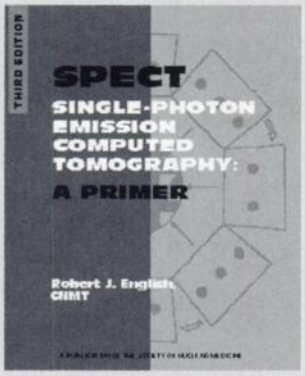


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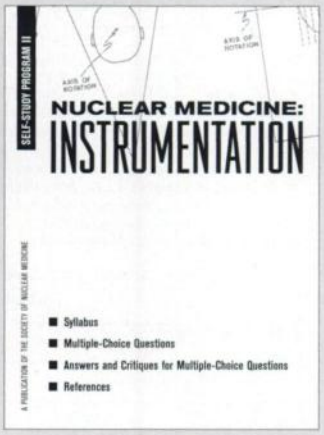


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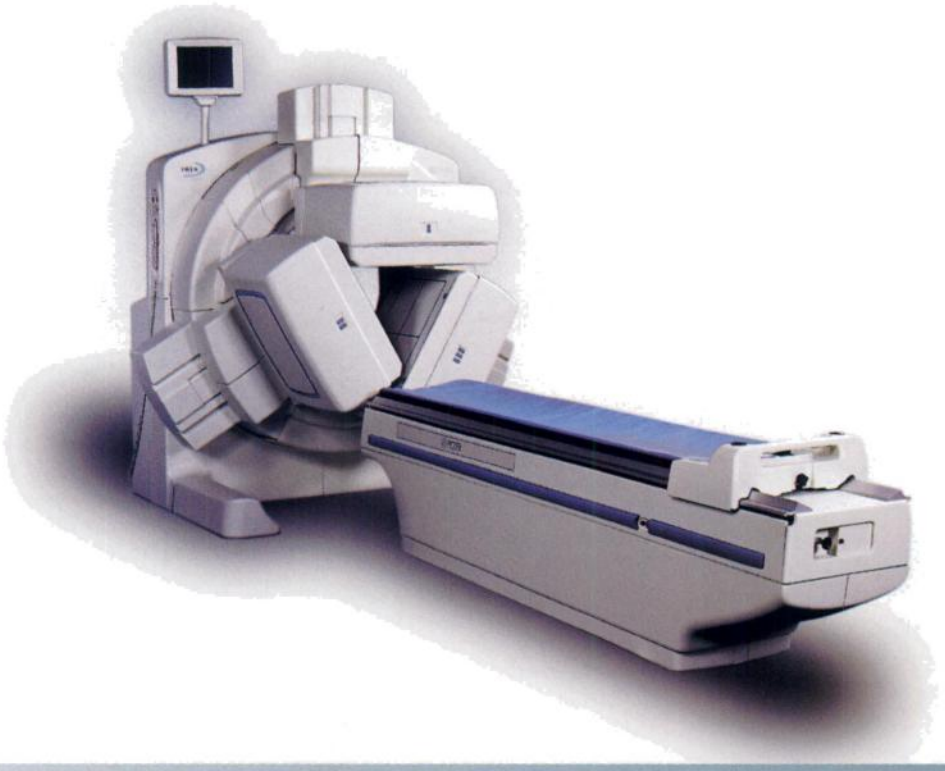

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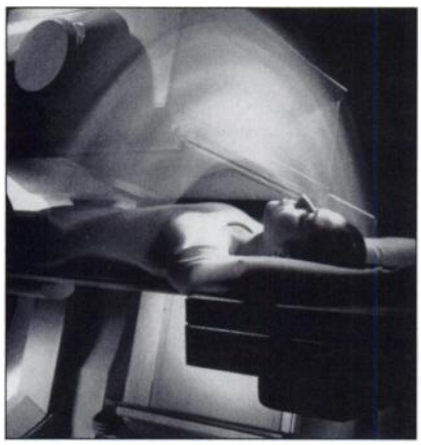
## Toshiba Now Offers Variable-Angle Gamma Camera



Toshiba America Medical Systems, through a nonexclusive agreement with the Nuclear Medicine Group of Siemens Medical Systems, has added the Toshiba E.CAM™, a new emission imaging system, to its nuclear medicine product line. It is designed for SPECT. Toshiba is combining the latest computer platform from SUN Microsystems, the UltraSPARC™, with the E.CAM variable-angle, dual-head gamma camera to offer a new system for whole-body emission tomography and general imaging procedures.

Features of the E.CAM include 90° imaging capability for enhanced cardiac throughput; works-in-progress 511 keV imaging and coincidence-capable detectors; a complete selection of collimators, including pinhole; robotics that ensure greater patient comfort and technologist efficiency; and the ability of the image processor to meet connectivity and networking requirements. **Toshiba America Medical Systems, Inc., Catherine M. Eilts, 2441 Michelle Dr., Tustin, CA 92681-2068. Phone: (714) 669-4140. Siemens Medical Systems, Inc., Steve Kuehn, 186 Wood Ave. South, Iselin, NJ 08830. Phone: (908) 321-4500. Fax: (908) 494-2250.**

## New Treatment for Cancer Bone Pain Receives FDA Clearance

CYTOGEN Corporation and DuPont Merck Radiopharmaceuticals have received clearance from the U.S. Food and Drug Administration to market Quadramet® ($^{153}$Sm lexidronam injection) to treat the severe pain associated with cancers that have spread to bone. Quadramet was developed by CYTOGEN under a license from Dow Chemical Co. and is to be manufactured and marketed by DuPont Merck Radiopharmaceuticals.

Quadramet is indicated for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions that are enhanced on radionuclide bone scans. Osteoblastic (bone-forming) bone lesions are most commonly associated with advanced prostate, breast and lung cancer.

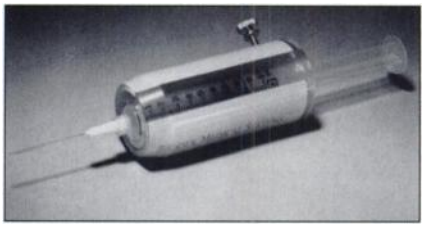
Radiation therapy of the external spot form is only able to target a limited area of painful bone metastases, unlike Quadramet, which can relieve pain caused by multiple osteoblastic bone metastases that are often present throughout the entire skeleton.

Patients who respond to Quadramet may begin to experience pain relief within 1 wk after injection. Any Quadramet not taken up by the bone is rapidly excreted from the body within 6 hr. This will minimize radiation exposure to the normal bone marrow, limiting the myelosuppressive effects of Quadramet. This myelosuppressive effect is temporary and typically returns to pretreatment levels within 8 wk.

Before administration of Quadramet, the patient's current clinical and hematologic status and history of bone marrow response to treatment with myelotoxic agents should be considered, and clinical benefits should outweigh the risks.

Quadramet is a bone pain therapy agent that, once injected into a patient, targets the sites of new bone formation, thereby concentrating on areas that have been invaded with metastatic tumor. It can be administered as a single intravenous injection on an outpatient basis. **DuPont Merck, Andrea Scibelli, 331 Treble Cove Rd., 600-2, North. Billerica, MA 01862. Phone: (508) 671-8924 or (800) 599-5744, ext. 8924.**

## Biodex Simplifies Beta Shielding



Biodex Medical Systems has designed the Pro-Tec B™ syringe shield specifically for administering $^{89}$Sr, $^{32}$P and other beta-emitting radiopharmaceuticals. Biodex is also now offering a lucite syringe shield for beta protection that allows 360° visibility and has expanded its line of Pro-Tec syringe shields for higher radiation protection. **Biodex Medical Systems, Inc., Brookhaven R&D Plaza, 20 Ramsay Rd., Box 702, Shirley, NY 11967-0702. Phone: (800) 224-6339. Fax: (516) 924-9241.**

## Imation Receives Presidential Green Chemistry Challenge Award

Imation Corp. has received the Presidential Green Chemistry Challenge Award for its DryView™ Laser Imaging technology.

Imation's DryView Laser Imaging technology uses photothermography, which is unlike wet film-processing systems that use chemical developer, fixer solution and wash water. Film produced through photothermography is exposed by an infrared laser diode and is processed by heat instead of by wet chemistry. Since no wet chemistry is involved in the process, there is no hazardous waste.

The Presidential Award was established in 1995 by President Clinton to promote pollution prevention through partnerships between the EPA and industry. To qualify for the award, Imation's DryView technology had to offer human health and/or environmental benefits, be generally applicable to a large and broad segment of chemical manufacturers, users or society and be innovative and of scientific merit.

Imation estimates that 5% of the waste associated with medical imaging wet chemistry film processing in the U.S. should be eliminated by the end of 1997 through use of DryView Laser Imagers.

The DryView 8700 Laser Imager costs less than the most inexpensive wet laser imager and is two to three times faster than any other dry 14-in × 17-in laser imager. It also delivers diagnostic-quality medical film images. **Imation Corp., Jason Thunstrom, Manager, External Communications. Phone: (612) 704-3164 or (888) 966-3456.**

## Positions Available

**Nuclear Medicine Residency Positions (2)**

Nuclear Medicine residency positions (2) are available at the University of Missouri Health Sciences Center beginning July 1, 1998. One or two years of prior ACGME approved clinical training is preferred. The program is fully accredited by ACGME. The department is equipped with new, modern equipment and provides comprehensive training in all aspects of diagnostic nuclear medicine including nuclear cardiology, SPECT - PET and therapeutic nuclear medicine. Contact: Amolak Singh, MD, Professor of Radiology, Program Director and Chief, Division of Nuclear Medicine, MU Health Sciences Center, One Hospital Drive, Room M202, Columbia, MO 65212. Phone: (573) 882-7955. Fax: (573) 884-5557.

**PET Fellowship**

Research fellowship in PET at the Northern California PET Imaging Center affiliated with the University of California, Davis, for one year starting 7/1/98. A leading clinical and research facility, 800 studies per year in oncology, neurology and cardiology. BC/BE applicant expected to participate in interpretation of studies, oncologic PET research and presentation of results and teaching. Please send curriculum vitae to: Peter E. Valk, MD, Northern California PET Imaging Center, 3195 Folsom Blvd., Sacramento, CA 95816.

**Research Fellowship in PET and Therapy with Monoclonal Antibodies**

Research fellowship in PET and therapy with monoclonal antibodies available. The Division of Nuclear Medicine at the Hospital of the University of Pennsylvania has 2 openings for a 2-year fellowship in modern imaging (PET, SPECT and functional MRI) and therapy techniques in an academically oriented environment. Candidates with previous training in nuclear medicine and some experience in research are desirable. Qualified applicants send a CV to: Abass Alavi, MD, Chief of the Division of Nuclear Medicine, Dept. of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce St., Philadelphia, PA 19104. Phone: (215) 662-3069. E-mail: alavi@darius.pet.upenn.edu. The University of Pennsylvania is an Affirmative Action/Equal Opportunity Employer.

## Research Associate
## Research Assistant Professor

The SPECT Laboratory within the Radiology Department of Duke University has an opening for a Ph.D. level Research Associate interested in single photon emission computed tomography (SPECT). Candidtaes having 10 or more relevant publications in peer reviewed journal may be considered for the position of Research Assistant Professor. The successful candidate will work with a dedicated group of scientists developing new SPECT geometries and reconstruction techniques. Experience with nuclear medicine instrumentation, SPECT reconstruction algorithms, nuclear physics and/or image processing is highly desirable. An appropriate candidate would have an experimental nuclear physics background coupled with expertise in mathematics and/or theoretical physics. Software experience in UNIX, FORTRAN and C is useful. Submit curriculum vitae and a list of graduate courses to: Ronald Jaszczak, Ph.D., Department of Radiology/Nuclear Medicine, DUMC-3949, Duke University Medical Center, Durham, NC 27710. Fax: (919) 682-7122. (rjj@dec3.me.duke.edu)

*Duke University is an Equal Opportunity/ Affirmative Action Employer.*

## Nuclear Medicine Physician

The Department of Radiological Sciences of the University of Oklahoma Health Sciences Center has an opening for a staff radiologist with specialization in nuclear medicine. Faculty rank and remuneration will depend on credentials and experience. Members of the nuclear medicine section provide coverage for the University Hospital (adult), Children's Hospital of Oklahoma and the Department of Veterans Affairs Medical Center in Oklahoma City. The section performs approximately 10,000 studies/year in aggregate. The individual selected will have primary responsibility at University Hospital, but will be expected to provide cross-coverage within the other unit. In addition, the individual will spend at least on day a week covering other areas of radiology and will be included in radiology on-call coverage. If interested, please contact **Joe C. Leonard, MD, Chief Pediatric Imaging Service, Children's Hospital of Oklahoma, P.O. Box 26307, Oklahoma City, OK 73126.**

**ELGEMS** - Is an equally owned joined venture between GE Medical Systems (GEMS Milwaukee, WI) and Elscint Ltd., located in Haifa, Israel. **ELGEMS** was established to develop and manufacture leading edge Nuclear Medicine Imaging products which will be distributed by both partners.

In **ELGEMS** located in Haifa, Israel, you will encounter a people oriented company, quality driven work environment that encourages excellence and teamwork.

**ELGEMS** invites you to explore the opportunity and join us at our Haifa facilities as a:

### Nuclear Medicine Product Manager to take part in setting innovative directions for our future products and clinical applications.

***Responsibilities:***

Define products and applications, be in contact with luminary and research sites, participate in professional trade shows, visits to customer sites and prioritize long term R & D efforts.

***Qualifications:***

- In depth knowledge of the clinical applications and the Physics/Electronics & Computer principles of the NM systems with degree in Physics.
- Proven record of 3-5 years of clinical experience and/or in marketing & applications support.
- Excellent organizational, inter-personal, verbal & written skills in English including the ability to give presentations.

### Nuclear Medicine Applications Specialist in the Marketing Group.

***Responsibilities:***

Define products and applications for the R & D Group, test systems and coordinate validation in final stages of development.

***Qualifications:***

- Nuclear Medicine technologist with 2-3 years of practical experience.

### Nuclear Medicine Applications Developer in R & D Group.

***Responsibilities:***

Develop clinical applications in "C" and macro languages. Be in contact with research sites and leading universities in the Nuclear Medicine field.

***Qualifications:***

- Physicist or Mathematician with practical experience in algorithms development.
- Extensive background in development of software clinical applications.
- Preference will be given to candidates with in depth knowledge/degree in Biomedical engineering.

**To apply:** Please submit a detailed resume that clearly illustrates you qualifications, work history, as well as contact names/telephone numbers of work and character references to the following address:

ELGEMS, Human Resources
P.O. Box 550, Tirat Carmel 30 200, Israel
972-4-8310 399/420 (Office), 972-4-8310 515 (Fax)
E Mail: nurit_ophir@elgems.com

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The PET centre of the **King Faisal Specialist Hospital & Research Centre**, a 530+ bed tertiary referral centre in Riyadh, Saudi Arabia, is seeking **2 RADIOCHEMISTS.** Successful candidates will support the R&D activities of an active radiochemistry/radiopharmacy group.

**SR. PET RADIOCHEMIST** with a Ph.D. and a minimum of 2 years experience in production of C-11 and F-18 labeled radiopharmaceuticals for human PET studies developing radiolabeling and radioanalytical procedures and novel radiotraces. Knowledge of GMP and excellent publication record.

**PET RADIOCHEMIST** with a BS (Masters preferred) and 3 years of hands-on experience in radiolabeling with positron emitting radioisotopes.

**Benefits include:**

- **Potentially tax free salary**
- **Free transportation**
- **30 day annual leave with ticket to point of origin**
- **Free furnished housing**
- **Free medical care**

For more information, please send your resume to: **HCA International**
*USA:* **Washington Square, Suite 311, 222 2nd Avenue North, Nashville, TN 37201 or call 1-800-932-4685.**
*Canada:* **Sussex Centre, 50 Burnhamthorpe Road, West, Suite 401, Mississauga, ON Canada L5B 3C2 or call 1-888-672-1222.** EOE

HCA *International*

## Nuclear Medicine Technologist

Mt. Diablo Medical Center's Diagnostic Imaging Department is seeking a Nuclear Medicine Technologist to perform routine Nuclear Medicine and Nuclear Cardiology procedures. You must have CNMT or ARRT (NM) certification, CA state license, and 2+ years' experience. For consideration, please send resume to: Mt. Diablo Medical Center, Human Resources, P.O. Box 4110, Concord, CA 94524-4110. Fax: (510) 674-2439. EOE.

JOHN MUIR MT. DIABLO
HEALTH SYSTEM

## Society of Nuclear Medicine
## 45TH ANNUAL MEETING
# *Critical Dates*

| Item | | | Due Date |
|---|---|---|---|
| **ABSTRACT FORMS** | | | |
| Scientific Papers | October Issue of JNM | Important change | 1/8/98 |
| Scientific Exhibits | October Issue of JNM | Important change | 1/8/98 |
| **REGISTRATION FORM** | January and February Issues of JNM | | 5/6/98 |
| **HOUSING FORM** | January and February Issues of JNM | | 5/6/98 |

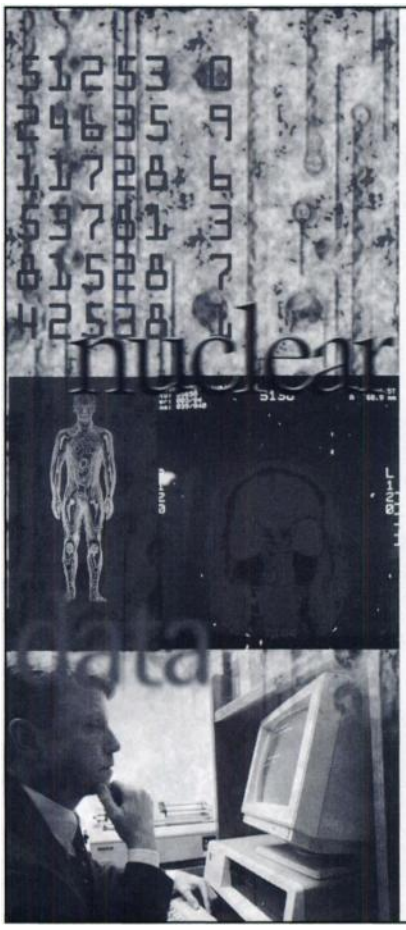
**DON'T FORGET THE MID-WINTER MEETING IN LAS VEGAS, NEVADA**

**DATE:** January 28 – February 3, 1998

**LOCATION:** The Alexis Park Resort

**EDUCATION PROGRAM SPONSOR:** The Computer and Instrumentation Council

***For the most current meeting information, please visit our web site at www.snm.org***

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# Updates on Tomography in Nuclear Medicine: Positron and SPECT

LOCATION AND DATES

**Alexis Park Resort in Las Vegas, Nevada**

Monday, February 2, through Tuesday, February 3, 1998

**For More Information...**

Please visit the Society of Nuclear Medicine Home Page at **www.snm.org** or call SNM Department: Meeting Services (703) 708-9000, ext. 229

Need help in deciding your next equipment purchase? Learn about positron tomography in PET, 511 keV SPECT, and coincidence imaging with gamma cameras. Learn about attenuation corrections in SPECT and positron tomography. Come and attend presentations from both clinical and physical scientists.

| Rates | Before 1/6/98 | On/After 1/6/98 |
|---|---|---|
| **Physicians/Scientists** | | |
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| Nonmembers | $250.00 | $295.00 |
| **Technologists** | | |
| Members | $95.00 | $125.00 |
| Nonmembers | $125.00 | $155.00 |
| Students | $75.00 | $75.00 |

45th SNM ANNUAL MEETING

*See you in*

# TORONTO

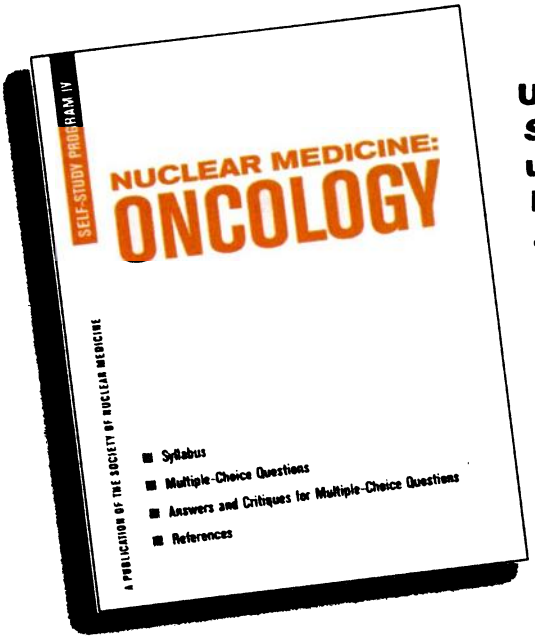
*June 7-11, 1998*

**Society of Nuclear Medicine**
Department: Meeting Services
1850 Samuel Morse Drive
Reston, Virginia 20190-5316
703-708-9000, fax 703-709-9274
http://www.snm.org

# Renew Your Perspective on Nuclear Medicine Oncology and CardiologyWith SNM's All-New Self-Study Series

**Whether you're a nuclear medicine resident preparing for your board exams, or a veteran clinician, the new Nuclear Medicine Self-Study Program series will meet your self-assessment needs.**

**Two all-new Self-Study series—Oncology and Cardiology—offer eight topic booklets, with a new topic booklet to be published every three months. Along with an authoritative syllabus review of the topic, each booklet includes an extensive list of annotated references, questions, and answers with critiques.**

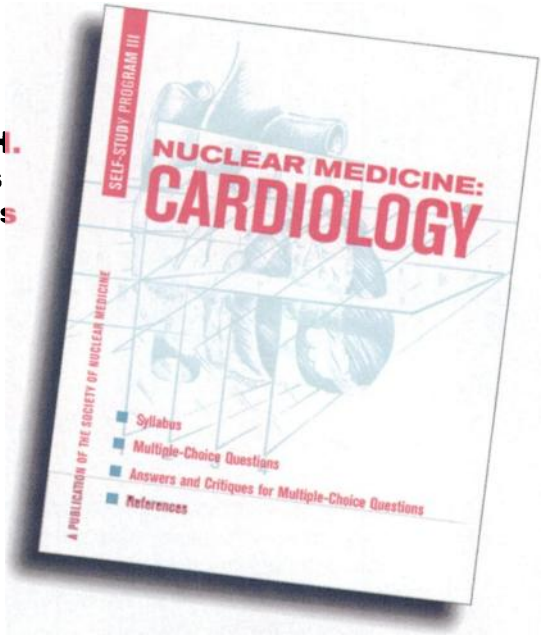



**Under the Senior Editorship of Thomas P. Haynie, *Self-Study IV: Nuclear Medicine Oncology* is under way. The first topic booklet, "Nuclear Medicine Oncology: An Overview," is now available from Matthews Medical Books. Future topic booklets (and dates) are—**

■ "Non-Antibody Tumor Imaging" (Oct. 1997) ■ "Antibody Tumor Imaging" (Feb. 1998) ■ "PET Tumor Imaging" (June 1998)
■ "Non-Antibody Cancer Therapy" (Sept. 1998) ■ "Antibody Cancer Therapy" (Dec. 1998) ■ "Bone Cancer Therapy" (March 1998) ■ "The Future of Nuclear Medicine Oncology" (June 1999).

***Self-Study III: Nuclear Medicine Cardiology* (Elias H. Botvinick, Senior Editor), will commence its series in September with "Physical and Technical Aspects of Nuclear Cardiology." Following booklets in the quarterly series will include:**

■ "Radionuclide Assessment of Congenital Heart Disease"
■ "Myocardial Perfusion Imaging by Single Photon Radionuclides I"
■ "Myocardial Perfusion Imaging by Single Photon Radionuclides II"
■ "Radionuclide Ventriculography" ■ "Imaging Acute Myocardial Infarction" ■ "Cardiac Positron Imaging" ■ "Scintigraphy with Pharmacologic Stress."




**To order individual topic booklets—or to be placed on a mailing list for notification as each new booklet appears—**
**simply call Matthews Medical Books at their toll-free number:**
**800-633-2665 (outside the U.S., 314-432-1401).**

# SNM PATIENT PAMPHLET SERIES

*Promoting Confidence Through Understanding*

**The newly expanded SNM Patient Pamphlet Series is a necessity for every nuclear medicine facility. It is designed to help inform your patients about nuclear medicine and the specific procedure they will undergo.**


## General Information Pamphlet

The *Benefits of Nuclear Medicine* provides a general overview of nuclear medicine, information about various nuclear medicine procedures and answers the most commonly asked questions. This pamphlet is a must for every nuclear medicine facility. (.40 ¢ /copy) (Minimum order 50 copies)

## Subject-Specific Pamphlets

Each subject-specific pamphlet provides a general explanation about nuclear medicine and descriptions of specific examinations. Your patients will take comfort in knowing what to expect before, during and after the procedure. (.40 ¢ /copy) (Minimum order 50 copies)

**NUCLEAR MEDICINE BONE IMAGING**
- Details common conditions bone scans are used to detect
- Bone imaging in children

**NUCLEAR MEDICINE RENAL IMAGING IN CHILDREN**
- General information about renal imaging in children
- Radionuclide Cystography
- Diuretic Renal Scintigraphy
- Cortical Renal Scintigraphy

**CARDIAC NUCLEAR IMAGING STRESS-REST TEST**
- Includes preparation guidelines for all aspects of the test

**NUCLEAR MEDICINE BRAIN IMAGING**
- General information about brain imaging
- Perfusion Imaging
- Stress-Rest Testing
- Cisternography

**NUCLEAR MEDICINE LIVER AND HEPATOBILIARY IMAGING**
- General information about liver and hepatobiliary imaging
- Hepatobiliary Imaging in children

***A Patient's Guide to Nuclear Medicine*** **and** ***Guidelines for Patients Receiving Radioiodine Treatment,*** **the cornerstones of the series, are still available.**

**For Spanish-speaking patients, *Guidelines for Patients Receiving Radioiodine Treatment* is available in Spanish. Look for other Spanish-language SNM Patient Pamphlet titles appearing in 1997.**

**To receive a complimentary sample of any SNM patient pamphlet, contact Stacey Silver at 703-708-9000 x223 or e-mail your request (and mailing address) to ssilver@snm.org**

**To order individual pamphlets, contact Matthews Medical Books at: 800-633-2665, or outside the U.S. call 314-432-1401**

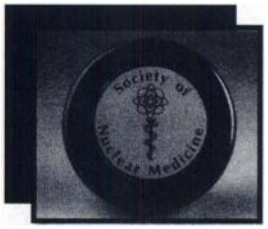
**Visit the SNM web site http://www.snm.org**

# Professional Pride

## #NMI02

## #NMI03

Promote your profession with classic elegance. These SNM gold finished pins are perfect on a lapel or as a tie tack. ¾" round or rectangle.



## #NMI04

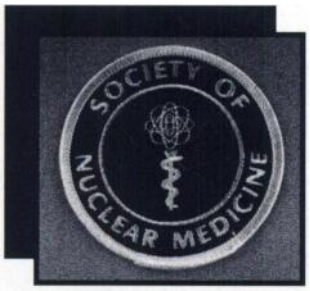
Grace your desk with this 3" diameter ebony marble paperweight with silver SNM medallion plate. A keepsake you'll treasure for years to come.

## #NM202

Perfect on the golf course or off, this polo-style shirt combines the quality of Fruit-of-the-Loom® with the SNM embroidered emblem.
Available in White, Cardinal Red & Royal Blue
Sizes: M, L, XL, 2X*

## #NMI00

This distinguished 13 oz. presidential collection clear glass mug is tastefully accented with a gold rim and SNM embossed gold logo.
Microwavable!!!!




## #NMI01

This handsome blue and white embroidered SNM patch is the perfect accompaniment to any garment. Celebrate your profession by purchasing one for each member of your staff.

## #NM204

Versatile SNM extra large duffel bag features durable Denier fabric with strap handles, outside pocket and adjustable shoulder strap.

## #NMI07

Show your SNM team spirit by wearing this natural cotton twill cap. One size fits all, your choice of visor colors:
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## #NM200

Like your favorite sweater, this heavyweight taslan nylon jacket with trail fleece lining and embroidered SNM logo will be irreplaceable.
Available in Royal Blue, Navy or Black
Sizes: S, M, L, XL, 2X*, 3X*

*Please See Ordering Information on next page.*

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# 1997 ★ PR STARS ★ CONTEST

## new prizes!

**1st Place:**

$600 for the Institution and $600 for the Individual. Plus up to $600 in airfare to the 1998 SNM Annual Meeting in Toronto.

**2nd Place:**

$400 for the Institution and $400 for the Individual.

**3rd Place:**

$250 for the Institution and $250 for the Individual.

**Mail or fax your entry information by December 1, 1997 to:**


Society of Nuclear Medicine
1997 PR Stars Contest
1850 Samuel Morse Dr.
Reston, VA 20190-5316

*Fax*
**703-708-9018**

*Telephone*
**703-708-9000**


One of the goals of the Society of Nuclear Medicine Technologist Section (SNM-TS) has been to take an active role in educating the public and the medical community about nuclear medicine procedures and the benefits of this functional imaging modality.

This is the official entry for the 1997 PR Stars Contest sponsored by the SNM-TS and Technology Imaging Services. Please fill out the entry form and complete the requested information on the reverse side. Based on the information you provide, a panel of judges will evaluate the entries using the point system outlined on the reverse side of this page and select a winner. All entrants must be a Nuclear Medicine Technologist and staff members of a hospital or nuclear medicine facility. Entries must be postmarked no later than December 1, 1997.

**Entrant Information:**

Your Name: .....

Hospital/Facility: .....

Address: .....

City: .....

State: .....

Zip: .....

Telephone: .....

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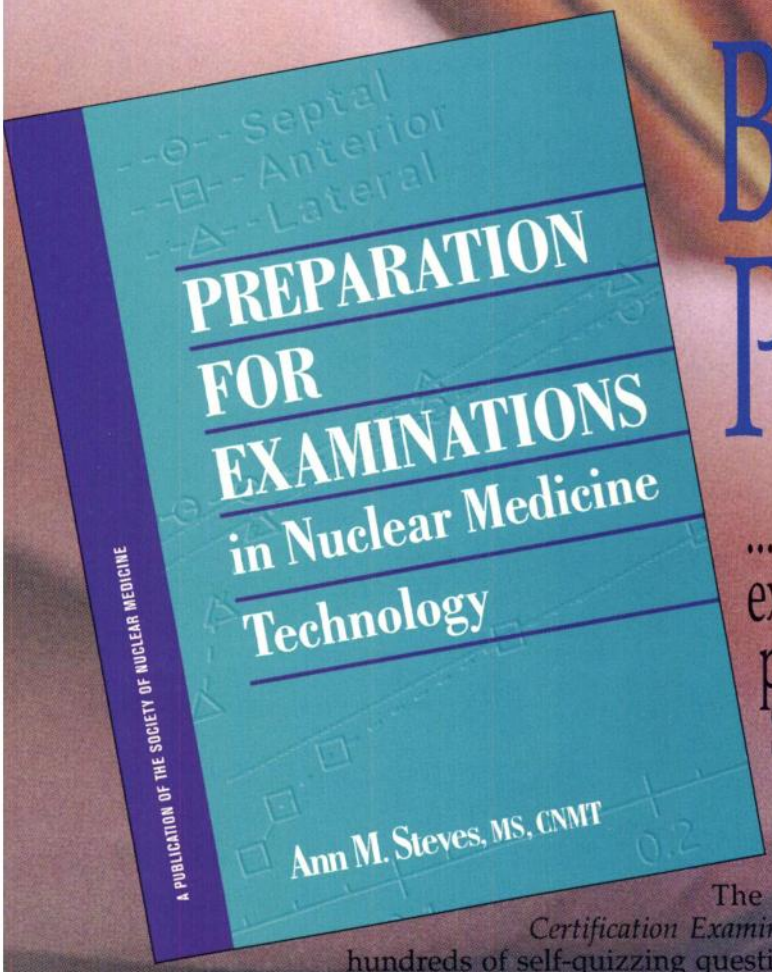



# Boost Your Performance...

## ... on national certification examinations, with two new exam preparation texts from the Society of Nuclear Medicine Technologist Section—

The brand-new, illustrated *Preparation for Certification Examinations in Nuclear Medicine Technology* contains hundreds of self-quizzing questions and answers to help you perform at your peak. Mirroring the structure of those on national certification exams, these multiple-choice questions cover–

**Radiopharmacy • Radiation Safety • Instrumentation • Patient Care • Clinical Procedures**

Each answer is accompanied with thorough, easy-to-understand explanations and source references for more information.

And if your library doesn't include the recently updated *The Review of Nuclear Medicine Technology*, you're missing the single most effective exam study text you can own. New material includes the latest information on NRC regulations, recently introduced radiopharmaceuticals, and an expanded section on the rapidly growing field of nuclear cardiology.

And if you buy BOTH "Preparation" and the "Review," you'll save $5.00 off the "Preparation" cover price.

It's easy to order. Simply call the SNM's distributor, Matthews Medical Books, at their toll-free number–

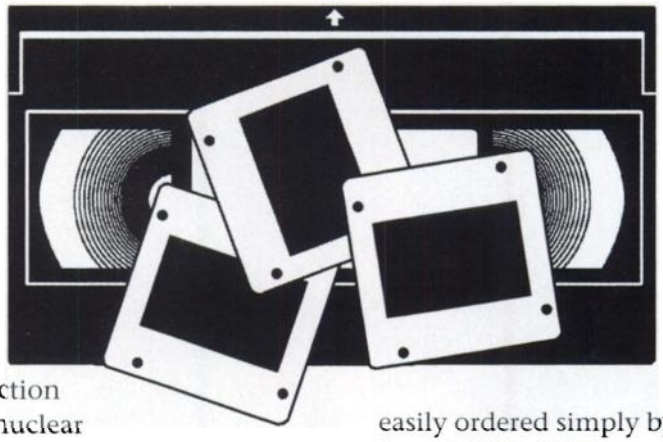
**1-800-633-2665 (non-U.S. 314-432-1401, or Fax: 314-432-7044).**

# Are you in need of Continuing Education credit?

# No funds or time to travel to regional or national meetings?

# LET THE INFORMATION COME TO YOU!

One of the valuable tools the Society of Nuclear Medicine (SNM) and Society of Nuclear Medicine Technologist Section (SNM-TS) have to offer everyone in the field of Medicine are the audiovisuals offered in the Society of Nuclear Medicine Educational Programs catalog.



Viewing an SNM educational program offers the next best thing to real time interaction with leading experts in nuclear medicine. When you're watching an SNM video or using one of the popular Pocket Lecture Series slide programs, you benefit from the most up-to-date information in the field.

## The 1996-1997 Catalog contains:

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**◗ Audio tapes from the 1996 Annual Meeting**

### *Ordering is Easy*

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A N N O U N C I N G

# The American Board of Science In Nuclear Medicine 1998 Certification Examination

## The 1998 examination will be given Sunday, June 7, 1998 in Toronto, Canada, in conjunction with the 45th Annual Meeting of the Society of Nuclear Medicine.



The examination is written and consists of two parts - **Part One** (3.5 hours) assesses knowledge of basic aspects of Nuclear Medicine Science. **Part Two** (2.5 hours) examines in depth the knowledge of a predetermined subspecialty area of the candidate's choice including:

- Nuclear Medicine Physics and Instrumentation
- Nuclear Pharmaceutical Science and Radiochemistry
- Radiation Protection

### General Requirements for Examination

Applicants for admission to the examination shall submit evidence demonstrating that they have met the following standards:

- A minimum of a Master's Degree with a major in a field of physical, pharmaceutical, biological, or engineering science.
- Doctorate Level - Satisfactory completion of a two-year documented formal training program in a Nuclear Medicine Science or three years full-time experience in Nuclear Medicine.
- For Master's Level - Satisfactory completion of a two-year documented formal training program in a Nuclear Medicine Science or five years experience in Nuclear Medicine.
- Membership in an appropriate professional organizaion related to activities in the field of Nuclear Medicine.

**Completed Applications must be postmarked by March 13, 1998. The examination fee is $650. ($550 refundable if you do not qualify)**

For applications and more information, please contact:

Kristen Kreisher
Associate Coordinator
American Board of Science in Nuclear Medicine
c/o Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316
Tel: (703) 708-9000, ext. 227
Fax: (703) 708-9013

The American Board of Science in Nuclear Medicine was established in 1976 by the Society of Nuclear Medicine, the American College of Nuclear Physicians (ACNP), and the American College of Nuclear Medicine (ACNM) to "develop procedures and standards to examine candidates and to issue certification to those individuals who successfully satisfy the requirements established by the Board." Certification examinations have been given annually since 1979.

## CALL FOR ABSTRACTS FOR SCIENTIFIC PAPERS AND SCIENTIFIC EXHIBITS

**the Society of Nuclear Medicine**

**45th Annual Meeting**

**June 7- June 11, 1998**

**Toronto, Canada**

The 1998 Scientific Program Committee, and the Scientific & Teaching Sessions Committee solicit the submission of abstracts from members and non-members of the Society of Nuclear Medicine for the 45th Annual Meeting in Toronto, Canada. Accepted Scientific Paper and Scientific Exhibit abstracts will be published in a special supplement to the May issue of *The Journal of Nuclear Medicine* and accepted Technologist Section abstracts will be published in the June issue of the *Journal of Nuclear Medicine Technology*. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- Instrumentation and Data Analysis
- Radioimmunoassay
- Radiopharmaceutical Chemistry
- Dosimetry/Radiobiology
- Clinical Science Applications:
  - Bone/Joint
  - Cardiovascular (clinical, basic, and PET)
  - Endocrine
  - Gastroenterology
  - Neurosciences: Basic, Neurology and Psychiatry
  - Pediatrics
  - Pulmonary
  - Renal/Electrolyte/Hypertension
  - Hematology/Infectious Disease
  - Oncology Diagnosis (antibody)
  - Oncology Diagnosis (non-antibody)
  - Oncology Diagnosis (FDG)
  - Oncology/Therapy

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work for immediate review to JNM, and for the technologist section, to JNMT.

The Scientific Paper and Exhibit abstract form can be obtained in the October 1997 JNM. You can also obtain an abstract form by writing to:

The Society of Nuclear Medicine
Attn: Abstracts
1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: (703)708-9000, x 228
Fax: (703)709-9274
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**DEADLINE FOR RECEIPT OF ABSTRACTS FOR SCIENTIFIC PAPERS IS THURSDAY, JANUARY 8, 1998.**

**DEADLINE FOR RECEIPT OF ABSTRACTS FOR SCIENTIFIC EXHIBITS IS THURSDAY, JANUARY 8, 1998.**

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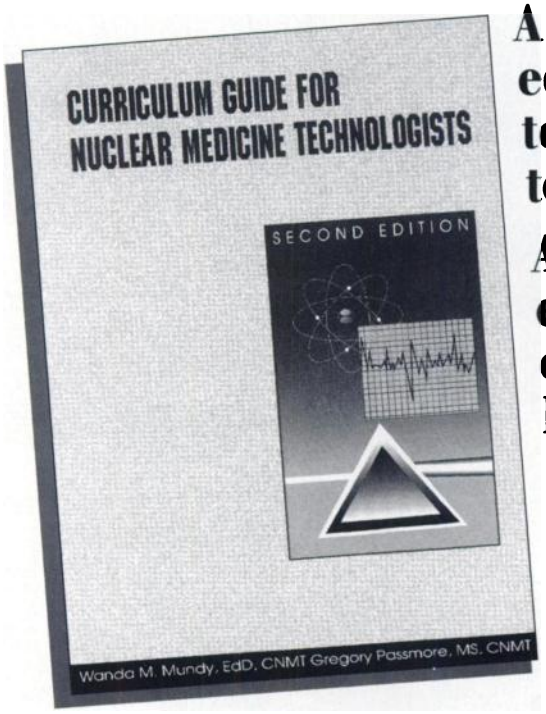
***Wanda M. Mundy, EdD, CNMT, Gregory Passmore, MS, CNMT***

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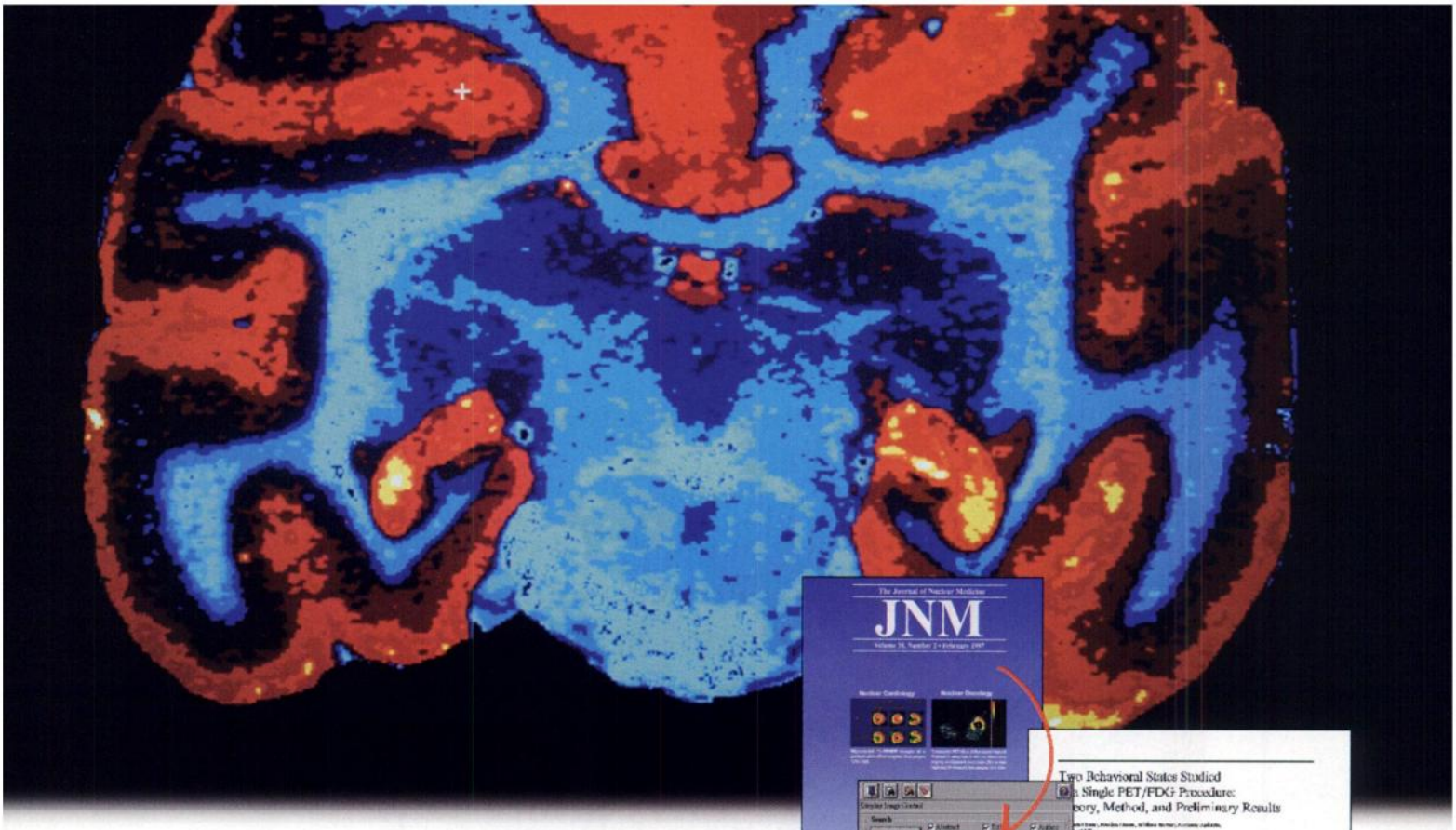


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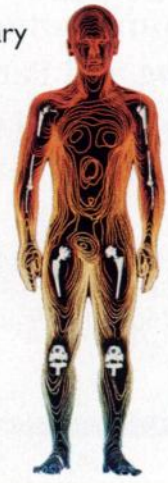

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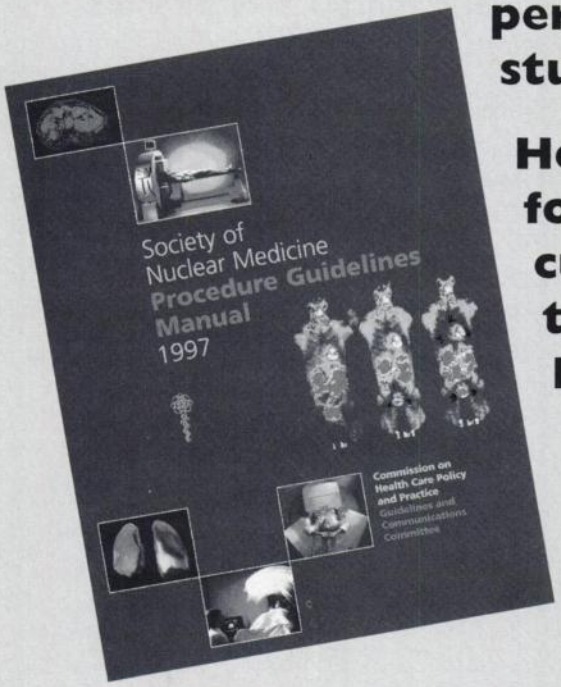


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## C O N T E N T S  I N C L U D E

# 1998-1999 FELLOWSHIP ANNOUNCEMENTS

## DUPONT PHARMA/SNM FELLOWSHIP PROGRAM FOR RESEARCH IN NUCLEAR CARDIOLOGY

The Society of Nuclear Medicine (SNM) Awards Committee is pleased to announce that a fellowship for $20,000 is available for July 1, 1998.

The objective of this fellowship is to (1) Encourage physicians to enter the field of Nuclear Cardiology and (2) Support clinical research in one of the following applications for gated SPECT, heart failure, risk stratification in CAD or CAD in women. Funds can be used to support the research and/or salary of the investigator. Preference will be given to those new to the field of nuclear cardiology. The fellowship recipient will be announced at the next SNM Annual Meeting, June, 1998 in Toronto Canada. Application deadline: 1/15/1998.

For more information and an application contact:
Society of Nuclear Medicine, SNM Awards Committee,
1850 Samuel Morse Drive, Reston, VA 20190-5316
Phone: 703-708-9000 Fax: 703-708-9015

## ANNUAL MALLINCKRODT/SNM FELLOWSHIP PROGRAM FOR RESEARCH AND/OR DEVELOPMENT IN NUCLEAR MEDICINE

Mallinckrodt Inc. is pleased to announce the Annual Fellowship of $20,000 for a physician fellow active in nuclear medicine research and/or development is available for July 1, 1998.

The award is to further a research project involving the development of single-photon radiopharmaceuticals or beta emitters to be used in nuclear medicine oncology. Applicants are asked to submit their curriculum vitae, a detailed account of their research project (including prior accomplishments pertaining to the project), two letters supporting the application and future plans. The fellowship recipient will be announced at the next SNM Annual Meeting, June, 1998 in Toronto Canada. Application deadline: 1/15/98.

For more information and an application contact:
Society of Nuclear Medicine, SNM Awards Committee,
1850 Samuel Morse Drive, Reston, VA 20190-5316
Phone: 703-708-9000 Fax: 703-708-9015

## DUPONT PHARMA/SNM FELLOWSHIP PROGRAM FOR RESEARCH IN NUCLEAR ONCOLOGY

The Society of Nuclear Medicine (SNM) Awards Committee is pleased to announce that a fellowship for $10,000 is available for July 1, 1998.

The objective of this fellowship is to (1) Encourage physicians to enter the field of Nuclear Oncology and (2) Support clinical research in the area of Technetium Tc 99m labeled compounds for breast imaging as a complement to mammography. Funds can be used to support the research and/or salary of the investigator. Preference will be given to those new to the field of Nuclear Oncology. The fellowship recipient will be announced at the next SNM Annual Meeting, June, 1998 in Toronto Canada. Application deadline: 1/15/1998.

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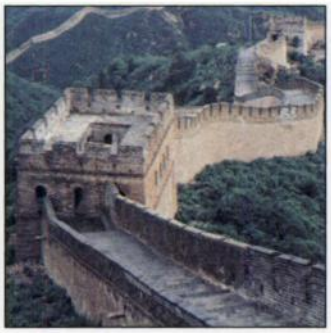

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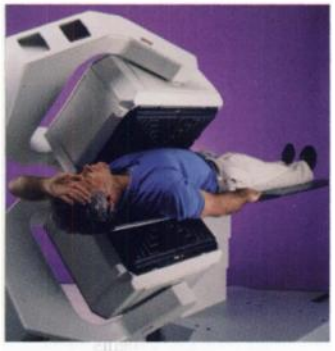

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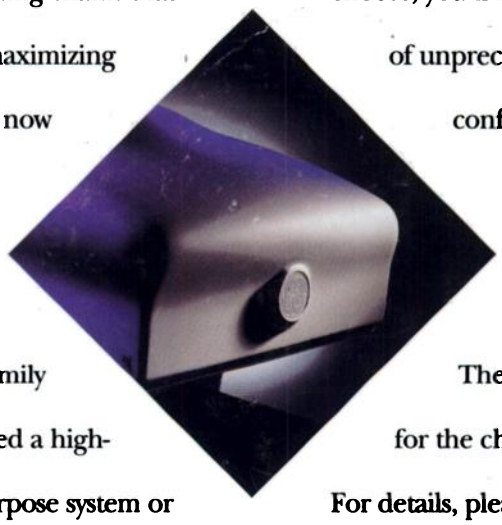

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