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Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts

Please see reverse for brief summary of prescribing information.

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Brief Summary

**Cardiolite**

Kit for the preparation of Technetium Tc99m Sestamibi

**FOR DIAGNOSTIC USE**

**DESCRIPTION:** Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mixture of:
- Technetium 99m (as Technetium Tc99m MIBI) 5.0 mCi
- Stannous Chloride, Dihydrate, minimum (SnCl2·2H2O) 0.058 mg
- Stannous Chloride, Dihydrate, (SnCl2·2H2O) 0.058 mg
- Sodium Citrate Dihydrate, maximum (as Na2Cit·2H2O) 0.028 mg
- L-Cysteine Hydrochloride Monohydrate 1.0 mg
- Mannitol 20 mg

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

**INDICATIONS AND USAGE:** CARDIOLITE® Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction. It is also useful in the evaluation of myocardial function using the first-pass technique.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** In studying patients in whom cardiac disease is known or suspected, take care to assure continuous monitoring and treatment in accordance with safe accepted clinical procedure.

**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 preparation procedure (as outlined in the prescribing information).

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

The 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 Percitrater Tc99m Injection containing oxidants should not be used.

**DOSAGE:**

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

**RADIATION DOSE:**

- Estimated Radiation Absorbed Dose
  - 2.0 hour void
  - 4.8 hour void

**HOW SUPPLIED:**

Du Pont's CARDIOLITE® Kit for the preparation of 5 m Ci of Technetium Tc99m Sestamibi is supplied in a 5 mL vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

**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 transitory metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-tender rash have also been attributed to administration of the agent. One patient demonstrated signs and symptoms consistent with seizure, 8 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

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

- 370 to 1100 MBq (10 to 30 mCi)

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 section in full prescribing information).

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 room temperature (15 to 30°C) before and after reconstitution.

**RADIATION DOSEMETRY:** Table 4 shows the radiation doses to organs and tissues of an average patient (70 kg) per 1100 MBq (30 mCi) of Technetium Tc99m Sestamibi injected intravenously.

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 hour void</th>
<th>REST</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>radians/30 mCi</td>
<td>mGy/1100 MBq</td>
<td>radians/30 mCi</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>0.2</td>
<td>1.9</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Upper Large</td>
<td>5.4</td>
<td>5.5</td>
<td>5.5</td>
</tr>
<tr>
<td>Intestine Wall</td>
<td>3.9</td>
<td>4.0</td>
<td>4.1</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>6.6</td>
<td>6.1</td>
<td>5.8</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>0.5</td>
<td>4.9</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>0.6</td>
<td>5.7</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.2</td>
<td>0.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>0.7</td>
<td>6.4</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>0.7</td>
<td>6.8</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>1.6</td>
<td>15.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.5</td>
<td>0.4</td>
<td>3.9</td>
</tr>
<tr>
<td>Red Narrow</td>
<td>0.5</td>
<td>0.5</td>
<td>5.0</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>2.0</td>
<td>2.0</td>
<td>4.1</td>
</tr>
<tr>
<td>Wall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>4.8</td>
<td>4.8</td>
</tr>
</tbody>
</table>
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†† Side effects are usually mild and can include chest pain, dizziness, headache, hypotension and nausea.

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Please see last page of this ad for references and prescribing information, including contraindications, warnings and adverse reactions.
DESCRIPTION: Thallous Chloride Ti 201 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The aqueous solution at the time of calibration contains 37MBq/ml (1mCi/ml) Thallous Chloride Ti 201. The pH is adjusted with hydrochloric acid and/or sodium hydrosulfite. It is made isotonic with 0.9% sodium chloride and is preserved with methylparaben alcohol.

Thallium Ti 201 is a cytopathic produced with no carrier added and contains no less than 98% Thallium Ti 201 as a percentage of total activity with contaminants less than 0.3% Thallium Ti 201, 1.2% Thallous Chloride Ti 201, and 0.2% Lead Pb 200 expressed as a percentage of Thallium Ti 201 activity at calibration. It is recommended that Thallous Chloride Ti 201 be administered close to calibration time to minimize the effect of high radiation on the patient.

INDICATIONS AND USAGE: Thallous Chloride Ti 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also have prognostic value regarding survival, when used in the clinically stable patient following the onset of symptoms of an acute myocardial infarction. The site and size of the perfusion defect can be measured.

Thallous Chloride Ti 201 may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease. It is not necessarily useful in patients with elevated serum calcium and parathyroid hormone levels. It may also be used to preoperative screening to localize extrathoracic and mediastinal sites of parathyroid hyperactivity and for post-surgical reexamination. Thallous Chloride Ti 201 has not been adequately demonstrated to be effective for the localization of normal parathyroid glands.

CONTRAINdications: None known.

WARNINGS: In studying patients in whom myocardial infection or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

PREcautions: Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of Thallous Chloride Ti 201 scans. Attention is directed to the fact that thalloum is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thalloum may likewise be affected.

GENERAL: Do not use after the expiration date and time (5 days maximum after calibration time) stated on the label.

Do not use if contents are turbid. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Thallous Chloride Ti 201, as all radioactive materials, must be handled with care and used with appropriate radioactivity safety measures to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

Caution: Medical personnel, especially those with a history of allergy to thallium or other radiopharmaceuticals, should be aware of the possibility of adverse reactions.

PREcautions for Use: Safety and effectiveness in children below the age of 18 have not been established.

Adverse Reactions: Adverse reactions to the administration of Thallous Chloride Ti 201 have been reported consisting of hypotension accompanied by pruritus and a diffuse rash which responded to antihistamines and steroids within one hour.

NOW Supplied: Thallous Chloride Ti 201 for intravenous administration is supplied as a sterile, non-pyrogenic, isotonic solution at calibration time 37MBq/ml (1mCi/ml) Thallous Chloride Ti 201, 0.9% Sodium Chloride, and 0.9% of methylparaben alcohol. The pH is adjusted with hydrochloric acid and is preserved with methylparaben alcohol.

References:
8. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc.
EVOLUTION OF MULTI-DETECTOR SPECT AND WHOLE BODY SCANNING SYSTEMS

TRIAD SPECT SYSTEM. The Ultimate High Resolution, High Sensitivity, Three Detector Total Body Imaging System.

BIAD SPECT/WHOLE BODY SYSTEM. The Only Ultra-Wide UFOV Two Detector Total Body Imaging System.
MULTI-DETECTOR SPECT FOR THE 1990’s

began with

TRIAD: First Triple-Detector SPECT System
(10 years of development beginning in 1978 with
first clinical installation in 1988)

and

BIAD: First Dual-Detector System for SPECT and Whole Body Scanning
(developed following the Triad’s success, with
first clinical installation in 1989)

by

TRIONIX RESEARCH LABORATORY, INC.

SPECT FUNDAMENTALS

The principles of Single Photon Emission Computed Tomography (SPECT) based on projection image acquisition by gamma cameras and subsequent image reconstruction using filtered back projection are well established.

The key considerations in SPECT data acquisition are total sensitivity (determines imaging time); camera closeness to the patient (affects image resolution); and collimator selection (affects both sensitivity and image resolution). Once the projection data set is acquired, final SPECT image resolution and, thus, clinical efficacy is determined by the reconstruction filter, which trades off between resolution and noise.

The current SPECT objective is to achieve the best possible image resolution by improving sensitivity with multiple-detector systems.

SPECT SYSTEM DEVELOPMENT

Single Detector SPECT Systems in the 1980’s

The first prototype SPECT systems were developed in the mid-1970’s independently by John Keyes, M.D., and Ronald Jaszcak, Ph.D., then at the University of Michigan and Searle Diagnostics, respectively.

By the late 1970’s, many commercial SPECT systems had been developed, generally by adding detector rotation to existing gantries. (A summary of commercial SPECT systems available in the early 1980’s is well documented in Dr. Ronald Jaszcak’s paper, “Industrial Corner, Physical Characteristics of SPECT Systems, September, 1982”, Journal of Computer Assisted Tomography, 6 (6): 1205-1215, December, 1982).

However, a fundamental design flaw existed in these early SPECT systems. SPECT image resolution requires accurate retracing of detected photon paths. This requirement demands an extremely stable gantry to ensure correct spatial registration of each detected photon at each detector angle. Unfortunately, the early SPECT systems supported the heavy detector assembly with extended mechanical arms which flexed under gravity. Thus, SPECT image resolution suffered greatly from mechanical arm...
flex at each angle. This phenomenon resulted in the development of angle-dependent, center-of-rotation (COR) correction.

Throughout the 1980's, refinements to single-camera systems, including COR correction and the removal of the terrestrial magnetic field effects through PMT mu-metal shielding, significantly improved SPECT image quality. The overall improvement in single-detector SPECT systems naturally pointed to the development of multiple-detector SPECT systems as a way to increase sensitivity, and thus, clinical efficiency.

**Dual-Detector SPECT Systems in the 1980's**

The clinical efficiency of a dual-detector SPECT system was envisioned by Ronald Jaszczak, Ph.D., in the mid-1970's. He developed a SPECT system with two LFOV detectors mounted in a tunnel gantry. His research with this system clearly pointed to a need for substantial precision in system design and calibration for multiple-detector systems to be effective in clinical operation.

In the early 1980's, commercial dual-detector SPECT systems were developed by Siemens (ROTA camera), Picker (Dyna Scan), and Toshiba. Despite Dr. Jaszczak's previous work as outlined above, the design of these systems followed the traditional approach of supporting each detector with extended mechanical arms. Therefore, these systems suffered from the same basic flaw as the single-detector systems, except with two detectors. It was virtually impossible to create an accurate SPECT image from the acquired projection data. The result was extremely poor SPECT image quality.

As more two-detector SPECT systems underwent clinical trials, a general misconception developed that multiple-detector SPECT systems did not work.

Because manufacturers did not dispute this belief or improve system designs, two-detector SPECT systems vanished from the market until a properly designed dual-detector system was developed by Trionix in 1989, as described below.

**Triple-Detector SPECT Systems**

In late 1978, while working with Dr. Jaszczak at Searle Diagnostics Research Group, the author conceived the triple-detector system for SPECT. He believed a three-detector system could best utilize the emitted photons for both brain and torso organ imaging and improve SPECT image resolution. Of particular interest to the author was Dr. Jaszczak's work with fanbeam collimation. This work proved that sensitivity and resolution could be improved simultaneously by using a detector larger than the width of the objects with fanbeam collimation.

The triple-detector system resulted from the author's search for a multi-detector SPECT system that would be able to image both the head and the torso equally well, and satisfy the following requirements:

1. the principles of CT slice reconstruction based on filtered back projection from a set of 360 degree projection profiles was proven;
2. a 3-D object could be viewed as a stack of 2-D slices;
3. each detector should be rectangular and larger than the object width due to projection profile stacking at each angle;
4. anger scintillation gamma cameras should be used due to their 2-D nature and wide-spread use. Thus, the system could accommodate well-established, traditional imaging procedures;
5. the human body can be divided into two distinct size and shape categories: head and torso;
6. for torso organs, the detectors should be larger than the torso transaxial width;
7. for best resolution, the detectors must be close to the patient due to the depth-dependent nature of multi-channel collimation.

Research proved that triangular detector geometry with radial detector motion and parallel beam collimation best satisfied all of the above-referenced requirements. However, fanbeam collimation improved both system sensitivity and resolution for brain imaging.

Subsequently, the entire detector imaging process was verified by systematic computer simulation.
LEssonS TO Be LEARNed

We can learn several things from this short review of the evolution of multi-detector SPECT systems.

First, the professional capability of the traditional imaging equipment manufacturers cannot be trusted blindly. Market acceptance of imaging equipment should be based on clinical validation and each product's track record. In fact, the poor system design and workmanship of the major manufacturers actually impeded the advent of multi-detector SPECT systems by almost ten years.

Second, recent development activities reveal that major technology progress is not necessarily made by large companies, but by dedicated young companies where visionary innovators work steadily in the spirit of answering to the needs of the clinical community. In fact, major manufacturers' operations are usually set up for production efficiency to maximize profit. This inherently discourages any major internal changes or innovations. The 1980's probably represent a classic example of this phenomenon.

Third, health-care professionals who make equipment buying decisions and practice clinical care must strive to better understand the industrial development process. Equipment buying decisions should be based on the proven clinical validation and track record of the equipment with a focus on clinical care rather than the manufacturer's name. At the same time, the equipment manufacturers must play a leading role in encouraging innovation rather than stifling true innovators by obtaining technology after-the-fact through business maneuvering or reluctantly following an established trend.

In summary, equipment manufacturers and clinical practitioners must work together constantly to provide cost-effective, high-quality health care to the general public.

Concluding Remarks for Multi-Detector SPECT

1. Clinical Efficiency of Triple-Detector SPECT
   - Well established from long-term use at all types of institutions, from universities to private clinics.

2. Dual-Detector SPECT and Whole Body Systems
   - Now in the Early Stages of Market Development.
   - Each System Requires Careful Clinical Validation for Determination of Clinical Usefulness.

3. What Makes Innovation Possible is not Money or Company Size, but the Will-power of Steady Professionals Working with Conviction and Dedication, as Proven by Trionix.

4. The 1990's will be the Turning Point for Multi-Detector SPECT, and thus, for Nuclear Medicine.
SPECT SYSTEM DEVELOPMENT (continued)

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SPECT SYSTEM DEVELOPMENT (continued)

All this research was internally documented at Searle Diagnostics. Unfortunately, this work was terminated with the demise of Searle.

Experimental system development began when the author joined Technicare in 1982. Between mid-1982 and mid-1986, the author and his group developed the following sub-systems:

1983: detector assembly and optics;
1984: high-precision detector distortion correction method and related detector digital electronics;
1985: system gantry;
1986: complete experimental triple-detector SPECT system, named the Triad;

Upon the closing of Technicare in late 1986, the author and his key technical collaborators founded Trionix Research Laboratory, Inc. to continue Triad System development. In mid-1988, initial Triad systems were installed at Georgetown University Hospital and the Cleveland Clinic. Since, over 60 Triads have been installed in a variety of clinical settings. Today, the Triad has a reputation for clinical reliability and for providing unparalleled image resolution and shortened scanning time.

Impact of Clinical Triple-Detector SPECT System

The Triad is a clinical and an economic success across the broad spectrum of medical institutions. System sites vary from research-oriented universities to high-throughput private clinics. Triads have been in daily clinical use internationally for over a year. Currently, five Triads are installed outside the United States.

CLINICAL IMPACT: The Triad’s brain, heart, liver, bone and other SPECT images reveal unprecedented resolution and anatomical detail, particularly when viewed using new, 3-D computer displays.

Today, most Triad users direct all critical SPECT studies to their Triad and use their single-detector cameras only for planar imaging.

Triad brain image resolution is 6 to 7mm FWHM, as contrasted with the 13 to 15mm FWHM capable with single-detector SPECT systems. Current Triad brain resolution is extremely close to PET resolution. However, the Triad’s advantage is that image resolution is uniform for all 3-D slices (i.e., transverse, sagittal, and coronal). In contrast, current PET resolution is limited to the transverse plane only.

In summary, because of the Triad, clinical SPECT is undergoing a revolution, not merely an evolution, as Trionix’s marketing phrase “Revolution, not Evolution!” states.

INDUSTRIAL IMPACT: The quantum jump in Triad SPECT image resolution, along with the reduced imaging time, generated a strong market force for multi-detector SPECT systems.

Market growth caused several traditional equipment manufacturers to enter the triple-detector market, not from a sense of contribution to the Nuclear Medicine community, but purely for business reasons. These companies and products, in order of market entry are:

Picker, which had for practical purposes abandoned Nuclear Medicine in the mid-1980’s, entered the triple-detector system market in mid-1989 when they acquired Ohio Imaging. Ohio Imaging was founded by former Technicare business people who obtained the Triad prototype and its technology through behind-the-scenes corporate maneuvering during the Technicare shutdown. Ironically, due to this maneuvering, people who had nothing to do with the Triad’s development installed the first prototype Triad System (named the Prism) at Texas Southwestern Medical Center in Dallas.

The next Triad copy was introduced by Toshiba in mid-1989, as the GCA-9300A. Toshiba’s development was initiated at the urging of a Japanese physician, Dr. Hisada, after he learned of Technicare’s shutdown. This system showed impressive initial image resolution.

However after the initial introduction, four critical design flaws became apparent as the GCA-9300A underwent general clinical trials. First, the high
resolution brain images were obtained using prohibitively expensive tungsten collimators. Second, this system had an unacceptably long rotation stepping time of approximately 10 seconds, which practically ruled out its use in rapid dynamic SPECT, an imaging method which holds major promise for future clinical advances in triple-detector SPECT. Third, the energy range was limited to 140 keV, which has limited clinical use. Fourth, the system was coupled to Toshiba’s slow, archaic computer that was used in their prior product line.

After denying the clinical benefits of triple-detector systems since Trionix installed the first Triad four years ago, Siemens finally entered the market by showing their triple-detector, Multi-SPECT gantry as works-in-progress at the 1990 RSNA. Siemens’ late entry into this market is particularly ironic, as the original conception and work was done by the author 14 years ago while he was at Searle Diagnostics, a Siemens predecessor. It seems that Siemens is still far from actually having a commercial product, as, despite the showing in 1990, they apparently do not have systems working in the general clinical setting.

When we look back, the triple-detector SPECT system is the result of the combined research and development work done at three companies, Searle, Technicare, and Trionix, through the author’s persistent efforts. Currently, Trionix provides the best triple-detector system in terms of image resolution, wide application software, broad clinical validation and installed base.

Impact of Triad on Dual-Detector SPECT

The clinical success of the Triad gave impetus to dual-detector SPECT systems. Trionix had noted the clinical effectiveness of the Siemens BodyScan for whole body scanning (see Trionix Technical Notes, Volume 1, Number 1), but questioned why a two-detector system had to have clinical limitations. The success of the Triad’s clinical trials provided the proof needed to begin development of a dual-detector SPECT and whole body scan system which could be a general clinical workhorse for the 1990’s. With the clinical support of Dr. Walter Drane of the University of Florida, the Biad was developed in 1989 using the Triad technology. The first Biad, which had two ultra-wide 24” UFOV rectangular detectors, was installed at the University of Florida in late 1989.

PRESENT DUAL-DETECTOR MARKET STATUS

Most camera manufacturers displayed prototype two-detector SPECT/whole body scan systems at recent professional meetings. Some manufacturers have displayed true rectangular detectors with their prototype systems. Others, such as Picker (Prism 2000) or ADAC (Genesys), use limited 20” UFOV detectors with chamfered corners, technology developed more than 10 years ago at Technicare.

A review of the current design of some of these systems shows that many manufacturers seem to be repeating the mistakes of earlier dual-detector systems by adding too much mechanical motion which degrades SPECT resolution.

Only Trionix offers two detector sizes for its Biad SPECT/Whole Body System. A Biad with two 20” UFOV true rectangular detectors is available to compete at the low end of the camera spectrum with systems such as the Picker Prism 2000 or the ADAC Genesys. Trionix, however, is the only manufacturer to offer two 24” UFOV true rectangular detectors in a SPECT/whole body system for uncompromised imaging. Both the 20” and 24” detectors use the same advanced detector electronics used in the Triad triple-detector system.

While other manufacturers have just begun clinical use, or merely displayed prototype systems, Trionix is the only company with proven long-term clinical experience in two-detector SPECT. Added together, installed Biads represent a total of over 500 months of clinical operation, with the longest clinical experience at the University of Florida covering more than two years.
LESSONS TO BE LEARNED

We can learn several things from this short review of the evolution of multi-detector SPECT systems.

First, the professional capability of the traditional imaging equipment manufacturers cannot be trusted blindly. Market acceptance of imaging equipment should be based on clinical validation and each product’s track record. In fact, the poor system design and workmanship of the major manufacturers actually impeded the advent of multi-detector SPECT systems by almost ten years.

Second, recent development activities reveal that major technology progress is not necessarily made by large companies, but by dedicated young companies where visionary innovators work steadily in the spirit of answering to the needs of the clinical community. In fact, major manufacturers’ operations are usually set up for production efficiency to maximize profit. This inherently discourages any major internal changes or innovations. The 1980’s probably represent a classic example of this phenomenon.

Third, health-care professionals who make equipment buying decisions and practice clinical care must strive to better understand the industrial development process. Equipment buying decisions should be based on the proven clinical validation and track record of the equipment with a focus on clinical care rather than the manufacturer’s name. At the same time, the equipment manufacturers must play a leading role in encouraging innovation rather than stifling true innovators by obtaining technology after-the-fact through business maneuvering or reluctantly following an established trend.

In summary, equipment manufacturers and clinical practitioners must work together constantly to provide cost-effective, high-quality health care to the general public.

CONCLUDING REMARKS FOR MULTI-DETECTOR SPECT

1. Clinical Efficiency of Triple-Detector SPECT
   - Well established from long-term use at all types of institutions, from universities to private clinics.

2. Dual-Detector SPECT and Whole Body Systems
   - Now in the Early Stages of Market Development.
   - Each System Requires Careful Clinical Validation for Determination of Clinical Usefulness.

3. What Makes Innovation Possible is not Money or Company Size, but the Willpower of Steady Professionals Working with Conviction and Dedication, as Proven by Trionix.

4. The 1990’s will be the Turning Point for Multi-Detector SPECT, and thus, for Nuclear Medicine.
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Tuesday, June 9 – Friday, June 12, 1992
Los Angeles, CA

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- Quinton Instrument Co.

CREDIT:
Physicians receive 18.75 hours in Category I toward Physician's Recognition Award of the American Medical Association. Accreditation by The Society of Nuclear Medicine has been applied for 1.89 CEUs.

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Once your registration form is received, you will be contacted with additional information regarding details and payment.

Registration should be sent to:

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Cardiovascular Learning and Research Center
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17A
Lights! Camera! Action!

On June 9, 1992, The Society of Nuclear Medicine raises the curtain on its 39th Annual Meeting in Los Angeles. Join the cast of thousands, more than 7,000, in fact, of nuclear medicine professionals at the largest and most important meeting of its kind. Learn about the most recent advances in the science and practice of nuclear medicine, and gain valuable technical knowledge from our supporting cast of commercial producers of nuclear medicine products and services.

Continuing Education Courses
Refresher and state-of-the-art continuing education courses in chemistry, physics, quality assurance, cardiovascular nuclear medicine, PET, SPECT and NMR will supply up-to-the-minute approaches and procedures for all clinical settings.

Scientific Papers
This year's presentation of over 1,000 scientific papers and posters includes a distillation of the latest advancements and finest work achieved by outstanding scientists and physicians in the field of nuclear medicine. These papers, presented by the original authors, with over 30 subjects to choose from, will provide a unique opportunity for enhancing your knowledge or exploring new avenues in correlative areas of nuclear medicine. Ample time is allotted at these presentations for questions and discussions.

An extensive display of scientific posters and exhibits will augment the presentations.

Technologist Program
The ever-increasing importance of the role of the nuclear medicine technologist will be explored in our Technologist Program, and over 70 hours of clinical updates will provide chief and staff technologists with the latest in basic, intermediate, and advanced studies. This program will broaden expertise and enhance the technologist's contribution to nuclear medicine.

Audiovisuals, Books, Journals
The Society of Nuclear Medicine is continually adding to its library of audiovisuals, books, and other publications. A stop at the publications booth is well worth the time. Here you will find on display what the Society has to offer for year-round educational advancement.

Networking opportunities and job referral boards are available at special locations throughout the meeting as well as membership information at our membership booth.

Exposition
All the major manufacturers of nuclear medicine products and services—more than 100 in all—will be on hand to explain and demonstrate the most technologically-advanced equipment. Several companies will present User Meetings to give an in-depth understanding of their products.

Registration

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Continuing Medical Education Primary Focus of The Society of Nuclear Medicine’s 39th Annual Meeting
June 9-12, 1992
Los Angeles, California

The 39th Annual Meeting of The Society of Nuclear Medicine will be held in Los Angeles, California on Tuesday, June 9 through Friday, June 12, 1992. The Los Angeles Convention Center is the site of most of the educational activities for this meeting.

CONTINUING EDUCATION ACTIVITIES
A primary focus for every SNM Annual Meeting is the Continuing Education activities that are offered for physicians, scientists, pharmacists, and technologists. This year we are pleased to offer 11 categorical seminars and 41 continuing education courses. There will also be a Nuclear Medicine Review Course which is geared for the nuclear medicine resident preparing for the ABNM boards and others who wish to refresh their knowledge for practice in nuclear medicine.

All of the categorical seminars will take place on Monday, June 8 from 8:30 am-2:30 pm. All other continuing education sessions will occur over the dates of the meeting.

This year, for the first time, continuing medical education credits will be offered along with VOICE credits for technologist programs. The Scientific and Teaching Sessions Committee invites all physicians to participate. The Society of Nuclear Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

The Society of Nuclear Medicine is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education.

Technologist Section courses are approved for continuing education credit by the Technologist Section of The Society of Nuclear Medicine under the criteria and guidelines established by the Council on the Continuing Education Unit.

For further information contact:

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TECHNICAL EXHIBITS
Another important component of the meeting is the technical exhibition, where the most advanced products and services for the nuclear medicine practitioner will be displayed. Attendees will have the opportunity to speak with technical experts and to see demonstrations of new equipment in an atmosphere free from the pressures of their busy practices.

Suppliers to the nuclear medicine community traditionally take advantage of the Society’s Annual Meeting to showcase the innovations developed over the past year and to introduce new products. They make their greatest effort to impress and influence their most important customers—our attendees.

This year will be no different: several long-time exhibitors have increased their space, and we anticipate an even larger show, with more exhibitors than 1991’s record-breaking meeting.

SPECT BRAIN IMAGING PRACTICUM
This year’s special innovation is a hands-on brain SPECT workshop for physicians desiring to optimize their practice and interpretative skills in this area. These workshops will be offered twice each day on Wednesday and Thursday, June 9-10, 1992, 8:30 am - 10:00 am and 3:30 pm - 5:00 pm. This workshop will have a maximum of 30 registrants for each session, so early sign-up is strongly suggested. Registration for materials for this SPECT workshop will be included in the matrix mailing.
Policy — The Journal of Nuclear Medicine accepts classified advertisements from medical institutions, groups, societies, and individuals in nuclear medicine. Acceptance is limited to Positions Open, Positions Wanted, and Equipment. We reserve the right to decline, withdraw, or modify advertisements.

Rates for Classified Listings — $10.00 per line or fraction of a line (approx. 30 characters per line, including spaces). Please allow 28 characters for the first line which will appear in capital letters. Special rates for SNM members on Positions Wanted: $7.00 per line. Note: Box numbers are available for the cost of the 2 lines required.

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Terms — Payment must accompany order. Make checks payable in U.S. dollars on U.S. banks only, to: The Society of Nuclear Medicine.

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Fellowship

Fellowships in PEDIATRIC NUCLEAR MEDICINE. Harvard Medical School's Joint Program in Nuclear Medicine at the Children's Hospital and Brigham and Women's Hospital announce fellowships in Pediatric Nuclear Medicine beginning July 1992 or July 1993. This one-year fellowship will include didactic instruction, clinical, experimental and investigative training. Opportunities for advanced second-year work will also be available. Requirements for entry include training in an appropriate approved specialty or one year of general nuclear medicine. For information, please contact Dr. S. J. Adelstein, 25 Shattuck Street, Boston, MA 02115.

Fellowships in BRAIN SPECT IMAGING NUCLEAR MEDICINE. Harvard Medical School's Joint Program in Nuclear Medicine at the Children's Hospital and Brigham and Women's Hospital announce fellowships in Brain SPECT Imaging Nuclear Medicine beginning July 1992 or July 1993. This one-year fellowship will include didactic instruction, clinical experience and investigative training. Opportunities for advanced second-year work will also be available. Requirements for entry include training in an appropriate approved specialty or one year of general nuclear medicine. For information, please contact Dr. S. J. Adelstein, 25 Shattuck Street, Boston, MA 02115.

Physician

Oregon Health Sciences University, Portland, Oregon invites applications for a FACULTY POSITION available immediately. Applicants must have a current position in NUCLEAR MEDICINE or full time divided between nuclear medicine and another division of diagnostic radiology. Position requires that radiologist be a board certified in Nuclear Medicine by the American Board of Radiology (Special Competence in Nuclear Radiology) and/or American Board of Nuclear Medicine. Send CV and references to William Weidner, MD, Chairman, Diagnostic Radiology, UH-72, Oregon Health Sciences University, Portland, OR 97201. OSUH is an affirmative action equal opportunity employer.

NUCLEAR MEDICINE PHYSICIAN. Active, affiliated VA medical center is seeking a BC/BE physician to join our nuclear medicine staff. Competitive salary & benefits. Excellent location; diverse outdoor recreational opportunities. Opportunities for advancement. MD, MD, Chief of Staff, VA Medical Center, 4300 W. 7th Street Mall, Austin, TX 78725. (512) 661-9053, Ext. 604. EOE.

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NUCLEAR MEDICINE PHYSICIAN. Unique staff position available at UConn Health Center, 350 Main Street, Farmington, CT 06030. UConn Health Center is a 395-bed medical center with an active inpatient and outpatient nuclear medicine program. The position requires BC/BE in nuclear medicine. UConn Health Center is an equal opportunity/affirmative action employer.

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A suitably qualified candidate for this position will be an experienced and clinically active physician, probably with a full-time academic appointment at a major university medical centre. A record of accomplishments in clinical research and teaching, and demonstrated capabilities in administration are expected.

The remuneration and benefits package for this position is well above the average for international expatriate physicians. Salary is negotiable according to qualifications and experience and is free of local taxation. The compensation package is particularly attractive since living expenses are small. The hospital provides free, fully furnished accommodations, return airfares for the employee and dependents annually, comprehensive medical and dental care, educational assistance for dependent children and approximately 60 days of holiday and professional leave each year.

To obtain further information concerning this position, candidates are invited to send a curriculum vitae with full biographical information, professional experience and bibliography of published works, as well as the names of three professional references to:

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Topics include:
Current trends in nuclear cardiology, specifically referencing technetium radiopharmaceuticals, pharmacological stress agents, and SPECT imaging and processing trends. Also, lectures will be presented on the detection of pulmonary embolism, brain scintigraphy utilizing HMPAO, and renal imaging using MAG3. VOICE credits will be available.

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SPECT BRAIN IMAGING CLINICAL FELLOWSHIP
Department of Radiology
Section of Nuclear Medicine

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- Appreciation of clinical applications of SPECT brain imaging.
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SPONSORSHIP:
This program is sponsored by the Medical College of Wisconsin.

TUITION:
The tuition fee of $650 includes the course syllabus, handouts, breaks, breakfasts, lunches, and other amenities involved in making this a pleasant learning experience. Maximum enrollments have been established. Cancellations prior to the course will be refunded, less a $30 administrative fee.

CREDIT:
The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Accordingly, the Medical College of Wisconsin designates this continuing medical education activity as meeting the criteria for 13.00 hours in Category I toward the Physician’s Recognition Award of the American Medical Association.

Nuclear Medicine Technologists who attend the SPECT Brain Imaging Clinical Fellowship are eligible for 1.0 CME credit.

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☐ November 9–10, 1992

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Address ________________________________

City/State/Zip ________________________________

Office Phone (_____) ________________________________

_________ work address _________ home address

Registrations and payment should be sent to:

LisaAnn Trembath
SPECT Brain Imaging Fellowship Coordinator
Nuclear Medicine Division
Medical College of Wisconsin
8700 W. Wisconsin Avenue
Milwaukee, WI 53226 (414) 257-7867
Each description of the products below was condensed from information supplied by the manufacturer. The reviews are published as a service to the professionals working in the field of nuclear medicine and their inclusion herein does not in any way imply an endorsement by the Editorial Board of The Journal of Nuclear Medicine or by The Society of Nuclear Medicine.

Noise Reduction System

Siemens Medical Systems, Inc. offers active noise reduction technology directly to its MRI customers and prospects in conjunction with NCT Medical Systems, Inc. (NCTM). The NCTM/MRI system's computer analyzes noise waves and within milliseconds synthesizes an "anti-noise" waveform 180 degrees out of phase with the offensive noise. When the two waves meet, noise is significantly reduced. As a result the patient is less anxious, more comfortable, and requires less preparation time. Additionally, given the loudness of some magnets, the patient can be protected from the possibility of a threshold shift in hearing, either temporary or permanent. Patients using the system experience an average 70% reduction in the 85-105 decibels of noise generated by the gradient coils of superconducting magnets. Because the system is selective, patients can still enjoy music and hear communications from the operator during the scan. Noise Cancellation Technologies, Inc., 800 Summer Street, 5th Floor, Stamford, CT 06901. (203) 961-0500.

Reusabke Autoclavable Lowboys

Nalge Company presents the Nalgene Autoclavable Lowboys, which have a low-profile design that fits easily into tight spaces on shelves or in refrigerators. The Lowboys can be stacked three-high, have a convenient integral handgrip for safe, easy transport and are molded of polypropylene for excellent chemical resistance. They are ideal for storing and dispensing reagents, titrants, distilled water, and tolerate strong acids and bases, as well as alcohols and ketones. Two sizes are available: 8 or 15 L (2 or 4 gallon). Closure size is 63 mm. They are also guaranteed leak-proof. Communications Dept., Nalge Company, A Subsidiary of Sybron Corporation, Rochester, NY 14602. (716) 586-8800.

Intravenous Instance Timer

Master Medical Corp. introduces the Master Medical I.V. Instant Timer, which reads exact rates with the push of a button. The unit displays in ml per hour or drops per minute. Initial intravenous rates can be set and the prescribed rate confirmed quickly without having to time drops with a watch and then convert drops into ml per hour. At just 5" long and 1 1/4" at its widest, the unit tapers to the palm and fits handily into pockets while weighing less than 1 1/2 ounces. Replaceable batteries last approximately one year under average daily use conditions. The unit also times pulse and respiration rates. Master Medical Corp., 7033 1st Avenue, Scottsdale, AZ 85251. (800) 962-8573.

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SIEMENS

SPECT Marketing Position

Siemens Medical Systems, a leader in the field of high-tech medical imaging equipment, seeks a highly motivated, self-starter to join its staff as a SPECT Scientist. The individual we seek will interface with customers and field representatives to optimize utilization of complex computer hardware and software configurations. This individual will be an important resource in disseminating performance requirements and recommendations from research, engineering and product management to the customer and sales representatives. Considerable travel throughout the United States will be required.

The qualified candidate should have an MS or PhD in Computer Science or Health Physics with a minimum of 2 years clinical and technical SPECT image processing experience required.

We offer an outstanding benefit package including savings plan, retirement plan and tuition reimbursement, and a competitive salary. If you have the experience and are looking for a challenge, please send resume with salary history to:

Director, HR
Siemens Medical Systems
2501 N. Barrington Road
Hoffman Estates, IL 60195

An Equal Opportunity Employer M/F/H/V
Cardiotec®
Kit for the Preparation of Technetium Tc 99m Teboroxime

FOR DIAGNOSTIC USE

DESCRIPTION
Each 5 mL reaction vial contains a sterile, nonpyrogenic, lyophilized formulation of 2.0 mg cyclohexanedione dioxime, 2.0 mg methyl boronic acid, 2.0 mg pentetic acid, 9.0 mg citric acid, anhydrous; 100 mg sodium chloride, 50 mg gamma cyclodextrin and 0.058 mg (maximum) total tin expressed as stannous chloride (SnCl₂), 0.020 mg (minimum) stannous chloride (SnCl₂). The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The contents of the vial are lyophilized and sealed under nitrogen at the time of manufacture. No bacteriostatic preservative is present.

When sterile, pyrogen-free sodium pertechnetate Tc 99m injection is added to the vial, and the solution is heated at 100°C for 15 minutes, the diagnostic agent Technetium Tc 99m Teboroxime is formed for administration by intravenous injection. The pH of the reconstituted product is 3.7 (range 3.3 to 4.1).

INDICATIONS AND USAGE
Technetium Tc 99m Teboroxime is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected coronary artery disease using rest and stress techniques.

CONTRAINDICATIONS
None known.

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

PRECAUTIONS
General
Contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Teboroxime and are not to be administered directly to the patient.

Contents of the kit before preparation are not radioactive. However, after the addition of sodium pertechnetate Tc 99m injection, adequate shielding of the final preparation must be maintained. The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration.

The technetium Tc 99m labeling reactions involved in preparing the agent depend on maintaining the stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc-99m supply may thus adversely affect the quality of the radiopharmaceutical. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

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.

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

Tc-99m Teboroxime should be formulated no more than 6 hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.8 rads/50 mCi) is high.

Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

No long-term animal studies have been performed to evaluate carcinogenic potential or to determine the effects of Cardiotec on fertility in males or females.

Three different mutagenicity assays (a reversion test with bacteria, a chromosomal aberration assay and an in vivo mouse micronucleus assay) conducted with cold (decayed) technetium labeled Cardiotec gave negative results. Cardiotec was weakly positive for inducing forward mutations at the TK locus in L5178Y mouse lymphoma cells in the absence of metabolic activation (but only at high concentrations that were toxic to the cells and reduced growth to 33% or less relative to vehicle controls). Cardiotec was negative in this assay in the presence of metabolic activation.

Pregnancy Category C
Animal reproduction studies have not been conducted with Technetium Tc 99m Teboroxime. It is also not known whether Technetium Tc 99m Teboroxime can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Teboroxime should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards.

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

Nursing Mothers
Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

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

ADVERSE REACTIONS
Uncommon adverse reactions reported in clinical trials include metallic taste in mouth, burning at injection site, facial swelling, numbness of hand and arm, hypotension and nausea after administration of Technetium Tc 99m Teboroxime.

HOW SUPPLIED
Cardiotec® (Kit for the Preparation of Technetium Tc 99m Teboroxime) is supplied in kits of 5, 10, and 25 reaction vials.

(4-282A)

550-503

Reference
1. Data on file, Squibb Diagnostics.
Rapid uptake and washout: complete stress and rest studies in only 90 minutes.1

Sharp images: enhance diagnostic ability to distinguish ischemia and infarction.1

Rapid blood clearance: greater patient comfort.

The first technetium-based myocardial perfusion agent for rest and stress imaging.

NEW CardioTec

(Squibb Diagnostics)