Showed multiple low-density regions involving white and gray matter in the parietal and occipital areas. Thought to be related to an inflammatory process, less likely an embolic insult. A confirmatory diagnosis was not possible.

Repeat CT (5/16/88)
Showed some change to the low attenuation areas—appearing larger and more confluent than previously noted. The pattern was atypical for infarction. Again, infectious etiology for the abnormality was entertained and diagnosis nonconfirmatory.

Images Courtesy of Deaconess Hospital Boston, MA

For additional information on the use of SPECTamine in stroke diagnosis, contact your local Medi-Physics Territory Manager, or call the SPECTamine® Hotline 1-800-451-7732.

Please see adjacent page for summary of product information.
A Case Study:
61-year-old female postop aorta bifemoral graft with a complicated 7-month postoperative course including renal failure, diverticulitis, Candida sepsis, multiple enteric cutaneous fistuluous with multiple surgical procedures.

On 5/6/88, patient was noted to have two generalized seizures.
On 5/16/88, patient began to deteriorate neurologically. Complained of blindness.

SPECT Study (5/19/88)
Demonstrated bilaterally posterior cerebral artery infarction. Subsequent neurologic exams and clinical course confirmed diagnosis.

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SPECTamine®
Iofetamine HCl I 123 Injection

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

**DIAGNOSTIC - FOR INTRAVENOUS USE**

**DESCRIPTION:** SPECTamine® Iofetamine HCl I 123 Injection, is supplied as a sterile, aqueous, isotonic sodium chloride solution for intravenous administration. Each milliliter of the solution contains 37 megabequerels (1 millicurie) of iofetamine HCl I 123 at calibration time, 0.15 milligram iofetamine HCl, 0.017 milliliter sodium phosphate, and 8.0 milligrams sodium chloride for isotonicity. The pH is adjusted to 4.5-6.0 with sodium hydroxide or hydrochloric acid. SPECTamine contains no bacteriostatic preservative. The radioauidic composition at calibration time is not less than 94.7 percent I 123, not more than 4.8 percent I 124, and not more than 0.5 percent all others (I 125, I 128, I 130 and Te 121). The radioauidic composition at the 6-hour expiration time is not less than 93.1 percent I 123, not more than 6.2 percent I 124, and not more than 0.7 percent all others.

**INDICATIONS AND USAGE:** SPECTamine (iofetamine HCl I 123 Injection) is recommended for use as a liquid-soluble brain-imaging agent. It has been shown to be useful in the evaluation of nonaccidental stroke especially when used within 96 hours of onset of focal neurological deficit. The rates of agreement between abnormal images and the neurological examination suggestive of ischemic cerebrovascular insufficiency, appear to increase with the severity of symptoms. Its usefulness for the measurement of cerebral blood flow has not been established.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** SPECTamine (iofetamine HCl I 123 Injection) should not be administered to individuals with known hypersensitivity to sympathomimetic amines or to those individuals taking monoamine oxidase inhibitors.

**PRECAUTIONS:**

**General**
Some primate (Macaca fascicularis) studies have shown marked eye uptake of iofetamine HCl I 123. Localization has not been studied in the isolated human eye however in vivo images suggest the concentration of iofetamine HCl I 123 is below the level of detection. Individual human variations in pharmacokinetics of this drug and the long-term effect on the eye have not been evaluated.

The contents of the vial are radioactive. Adequate shielding of the preparation must be maintained at all times.

Do not use after the expiration time and date (6 hours after calibration time) stated on the label. Potassium Iodide Oral Solution should be administered before the examination to minimize thyroid uptake of iodine 123.

The prescribed iofetamine HCl I 123 dose should be administered as soon as practical from the time of receipt of the product (i.e., as close to calibration time or before, if possible), in order to minimize the fraction of radiation exposure due to relative increase of radionuclides contaminants with time.

To minimize radiation dose to the bladder, the patient should be encouraged to drink fluids and void frequently.

SPECTamine, as well as other radioactive drugs, must be handled with care. 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. Radiopharmacists should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides, and who have experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

**Drug Interactions**
There has been a single report of elevated diastolic hypertension (about 30 mm Hg) occurring 18 hours after administration of SPECTamine in a patient maintained on therapeutic doses of valproic acid. Concurrent use of monoamine oxidase (MAO) inhibitors and compounds containing the amphetamine structure has been known to result in hypertensive crisis. Caution, therefore, should be exercised when administering SPECTamine (iofetamine HCl I 123 Injection) to individuals taking medications known to potentiate the effects of sympathomimetic amines. It is recommended that SPECTamine not be administered during or within 14 days following administration of MAO inhibitors.

**Symptomatic amines may affect the biodistribution of SPECTamine and, thus, may influence the image quality and diagnostic utility of the image.**

Cardiovascular, Metabolic, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility in male or female animals. The Ames test was negative for mutagenic effects.

**Pregnancy Category C**
Animal reproduction studies have not been conducted with SPECTamine. It is also not known whether SPECTamine can cause fetal harm when administered to a man or a pregnant woman or can affect reproduction capacity. SPECTamine should be given to a pregnant woman only if clearly needed.

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

**Nursing Mothers**
Since iodine I 123 is excreted in human milk, formula feeding should be substituted for breast feeding if the agent must be administered to the mother during lactation.

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

**ADVERSE REACTIONS:** In a clinical study in 93 patients with sudden onset of focal neurological deficit, e.g., cerebral infarction, 7 patients died within 2 to 55 days after administration. The deaths were considered to be a result of the disease state. Although there was no concurrent control group, statistics from historical controls support this evaluation.

There is evidence suggesting that the administration of 1 to 2 milligrams of iofetamine HCl, the carrier in SPECTamine, may increase systolic blood pressure by about 10 mm Hg. In a patient with a history of hypertension, there has been a single report of sudden onset of hypertension and dizziness with transient chest tightness which occurred 5-10 minutes after administration of SPECTamine. One case of transient unilateral hearing loss also was reported several hours after the use of SPECTamine in a patient with a coincidental upper respiratory infection. As with all organic-iodine-containing compounds, the possibility of allergic reactions must be considered.

**Hypersensitivity:** SPECTamine is supplied in nominal 3.5 ml vials as a sterile, pyrogenic, aqueous, isotonic sodium chloride solution for intravenous injection. Each milliliter contains 37 megabequerels (1 millicurie) of iofetamine HCl I 123 at calibration time. It is available in individual vials containing 111 megabequerels (3 millicuries) of iofetamine HCl I 123 at calibration time in a volume of 3 ml. Vials are packaged in individual lead shields with plastic outer container.

**PRODUCT INFORMATION ISSUED DECEMBER 1987**

Medi-Physics, Inc.
140 East Ridgewood Avenue
Paramus, NJ 07652

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This product information was prepared by Medi-Physics, Inc. for use by its customers. It is not intended for use by the general public. For specific information on product use, consult the product package insert.
NRC REQUIREMENT:

“A licensee shall survey for removable contamination, once each week, all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.”

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BRIEF SUMMARY

THALLIUS CHLORIDE TI 201 INJECTION
Diagnostic–For Intravenous Use

DESCRIPTION–Thallous Chloride TI 201 Injection is supplied in an isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. Each milliliter contains 37 megabecquerels (1 microcurie) Thallous Chloride TI 201 at calibration time, made isotonic with 9 milligrams sodium chloride and preserved with 0.9% (v/v) benzyl alcohol. The pH is adjusted to between 4.6 to 7.0 with sodium hydroxide. Thallium TI 201 is clytoxon produced. At the time of calibration it contains no more than 1.0% Thallium TI 202, no more than 0.25% radionuclids Lead and no less than 99% Thallium TI 201 as a percentage of total activity. No carrier has been added.

INDICATIONS AND USAGE—Thallous Chloride TI 201 may be useful in myocardial perfusion imaging and for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS–None known.

WARNINGS–When studying patients suspected or known to have myocardial infarction or ischemia, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedures. 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 on the quality of Thallous Chloride TI 201 images of marked alterations in blood glucose, insulin or pH (such as is found in diabetes melitus). Attention is directed to the fact that thallium is a potassium analog and, since the transport of potassium is affected by these factors, the possibility exists that the Thallous Chloride TI 201 may be affected.

General–This drug should not be used after six (6) days from the calibration date, or nine (9) days from date of manufacture, whichever comes first.

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility—No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential or whether this drug affects fertility in males or females.

Pregnancy Category C–Animal reproductive studies have not been conducted with Thallous Chloride TI 201. It is also not known whether Thallous Chloride TI 201 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Thallous Chloride TI 201 should be given to a pregnant woman only if clearly needed.

Ideally, examination using radiopharmaceutical drug products—especially those elective in nature—of women of childbearing capability should be performed during the first ten days following the onset of menses.

Nursing Mothers–it is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, as a general rule nursing should not be undertaken if a patient is administered radioactive material.

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

ADVERSE REACTIONS–A single adverse reaction to the administration of Thallous Chloride TI 201 has been reported consisting of potassium supplementation, nausea and a diffuse rash which responded to antihistamines and steroids within one hour.

DOSAGE AND ADMINISTRATION–The recommended adult (70 kg) dose of Thallous Chloride TI 201 is 37 to 74 MBq (1 to 2 mCi). Thallous Chloride TI 201 is intended for intravenous administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if contents are turbid.

Waterproof gloves should be worn during the handling procedures.

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

With a shielded sterile syringe, aseptically withdraw the material for use.

For restating Thallous Chloride TI 201 studies, imaging should begin 10 to 20 minutes after injection. Myocardial-to-background ratios are improved when patients are injected upright and in the fasting state; the upright position reduces the hepatic and gastric Thallium TI 201 concentration.

When utilized in conjunction with exercise stress testing, Thallous Chloride TI 201 should be administered at the inception of a period of maximum stress which is sustained for approximately 30 seconds after injection. Imaging should begin within ten minutes after administration to obtain maximum target-to-background ratios. Several investigators have reported that within two hours after the completion of stress testing the target-to-background ratios may decrease significantly in lesions that are attributable to transient ischemia.

HOW SUPPLIED—Thallous Chloride TI 201 is supplied in a sterile, non-pyrogenic solution for intravenous administration. Each ml contains 37 MBq (1 mCi) Thallous Chloride TI 201 at calibration time, 9 mg sodium chloride and 0.9 percent (w/v) benzyl alcohol. The pH is adjusted to between 4.6 to 7.0 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available in the following quantities of radioactivity: 74, 111, 148, 296, and 333 megabecquerels (2, 3, 4, 8, and 9 millicuries) of Thallium TI 201.

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co-editors: barry a. siegel, md and peter t. kirchner, md

the society of nuclear medicine presents nuclear medicine: self-study program i, the first volume of a comprehensive series that will cover all areas of nuclear medicine. it has been designed to help physicians, scientists, pharmacists, and technologists expand their knowledge of the clinical, basic science and technical aspects of nuclear medicine.

nuclear medicine: self-study program i is the successor to the highly acclaimed nuclear medicine review syllabus, which reviewed the major advances in nuclear medicine of the 1970's. nuclear medicine review syllabus, under the editorship of peter kirchner, md, sold 4,000 copies, more than any other snm title for nuclear medicine physicians. nuclear medicine: self-study program i covers the advances in nuclear medicine since the publication of the nuclear medicine review syllabus, and features many of the same contributors.

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Call for Abstracts for Works-in-Progress

The 1989 Scientific Program Committee solicits the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 36th Annual Meeting in St. Louis. Works-in-Progress accepted for the program will be published in a separate on-site show directory that will be distributed to all those who attend the meeting. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- INSTRUMENTATION
- COMPUTERS AND DATA ANALYSIS
- RADIOASSAY
- RADIOPHARMACEUTICAL CHEMISTRY
- DOSIMETRY/RADIOBIOLOGY
- NUCLEAR MAGNETIC RESONANCE
- CLINICAL SCIENCE APPLICATIONS
  - Bone/Joint
  - Cardiovascular
  - Endocrine
  - Gastroenterology
  - Infectious Disease
  - Neurology
  - Oncology/Hematology
  - Pediatrics
  - Pulmonary
  - Renal/Hypertension
  - and Immunology

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work to the JNM for immediate review. A complete educational program for technologist will be offered and technologists are encouraged to submit abstracts of their work for consideration. The official abstract form for Works-in-Progress may be obtained from the September 1988 issue of the JNM or by calling or writing:

The Society of Nuclear Medicine
Att: Abstracts
136 Madison Avenue, New York, NY 10016-6760
Tel: (212)889-0717
FAX: (212)545-0221

Deadline for Works-in-Progress is Thursday, April 7, 1989.

Call for Abstracts for Scientific Papers
Call for Abstracts for Scientific Exhibits

The 1989 Scientific Program Committee and Scientific Exhibits Subcommittee solicits the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 36th Annual Meeting in St. Louis. Abstracts accepted for the program will be published in a special supplement to the May issue of The Journal of Nuclear Medicine. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- INSTRUMENTATION
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- RADIOASSAY
- RADIOPHARMACEUTICAL CHEMISTRY
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- NUCLEAR MAGNETIC RESONANCE
- CLINICAL SCIENCE APPLICATIONS
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  - Cardiovascular
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Deadline for receipt of abstracts for Scientific Papers is Thursday, January 12, 1989.
Deadline for receipt of abstracts for Scientific Exhibits is Thursday, January 19, 1989.
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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.

**Manual Gamma Counter**

Packard Instrument Company introduces its RIASTAR manual benchtop multidetector gamma counting system. This compact unit is designed for easy operation, high sample throughput, and total quality assurance for today’s laboratories. Available in 5, 10, and 20 detector versions, the RIASTAR systems feature individual user RiaCards. RiaCards protect protocols and make sample processing fast and simple. An exclusive automatic counting technique increases throughput and productivity. Counting is automatic when a sample tray is loaded. No additional keyboard programming is required. RiaSmart software is used with a built-in PC-compatible computer, stand-alone printer, and monitor, and includes all major fitting methods. Worklists, customized calculations, and print formats are basic features, as well as real time curve editing, curve storage, and template capabilities. The RIASTAR systems perform over a 15–500 keV energy range in two counting regions. Detector crosstalk connection can be applied for higher energy regions. A spillup and spillover correction feature is used for dual label assays. Total quality assurance is provided through a built-in Instrument Performance Assessment feature. Optional Expert QC software allows users to monitor up to 12 quality control parameters for each of 60 protocols. Packard Instrument Company, 2200 Warrenville Rd., Downers Grove, IL 60515 Attm. Jim Vondran (312)969-6000.

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**Portable Survey Meters**

Victoreen announces a new line of microprocessor-based, portable survey meters. The instruments in Victoreen’s 450-series measure and display dose rate, integral dose, and maximum dose rate (freeze capability). Each survey meter in the 450-series uses proven ionization chamber technology and features CMOS microprocessor-based operation, automatic ranging, automatic zeroing, and a unique analog/digital liquid crystal display. The display has a 100 element bar graph and a 2½ digit readout which also displays the units of measure and flashes when the radiation detected exceeds a preset alarm limit. The product line includes the Model 450, Model 450E, Model 450B, and the Model 450P survey meters. The Model 450 is a general purpose instrument for measuring beta-gamma radiation. It has a removable cap-type shield. The 450E is an extended version of the Model 450 with a 500,000 mR/h or 5mSv/h full-scale range. The Model 450B is similar to the Model 450 but has a slide-type shield. The Model 450P has a pressurized ion chamber and measures beta-gamma radiation from background to 5000 mR/h or 50 mSv/h. It is ideally suited for high-sensitivity measurement applications such as measuring leakage and/or scattered radiation, beams, and pinholes. The 450-series instruments are housed in a moisture-proof case measuring 4” × 8” × 6” and weighing 1.4 lb. Operating temperature range is −20°C to +50°C. Victoreen, Inc., 6000 Cochran Rd., Cleveland, OH 44139-3395.

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**Bone Densitometry Attachment**

Van Mullekom Nuclear Fields B.V. has developed a special device which makes it possible to measure, with the aid of a gamma camera, the calcium content of bones in patients suffering from metabolic bone diseases. The new device consists of a lightweight metal attachment arm which is fixed to a specially focused collimator and which holds a point source of 153Gd of 180 mCi at its extremity facing the camera. The attachment arm has been developed for application on a wide range of existing gamma cameras. The dual photon absorption technique for determining bone mineral content is based on the measurement of radiation transmission of two separate photon energies through a medium consisting of bone. The radioisotope has two well-defined energy peaks of 44 and 100 keV. The amount of 153Gd which is used in the gamma camera method is only 20% of that needed for the scanner system. Consequently a substantially lower radiation dose is administered. Using the gamma camera method, the acquisition time is only ten min. Moreover, the bone densitometry attachment can be fitted to the gamma camera simply and rapidly. Van Mullekom Nuclear Fields B.V., PO Box 136, 5830 AC Boxmeer, The Netherlands.

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**PET Brochure**

Scanditronix, Inc. has released a new brochure on PET and the company’s instrumentation. The 16-page, four-color brochure discusses the advantages of PET technology and how it works. Numerous photographs and patient studies support the text. Scanditronix’ reliable, versatile PET subsystems are also reviewed — brain and whole body imagers; cyclotron and targets for radioisotope production; and chemistry systems for producing labeled molecules. Other services available from Scanditronix — including facility planning and technical support, financial planning, and construction services — are outlined. Scanditronix, Inc., 106 West ern Ave., Essex, MA 01929 Attm. Steve Kendall.

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