

# Nephroflow<sup>®</sup>

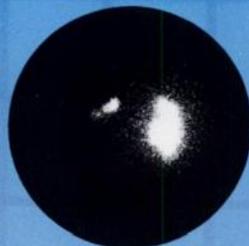
Iodohippurate Sodium I123 Injection

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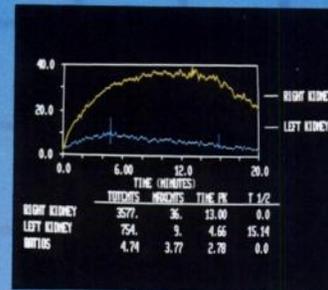
**CLINICAL TASK:** Evaluate differential renal function in a patient with multiple bladder and ureteral surgeries, still having recurring urinary tract infections.<sup>1</sup>



2-4 min.



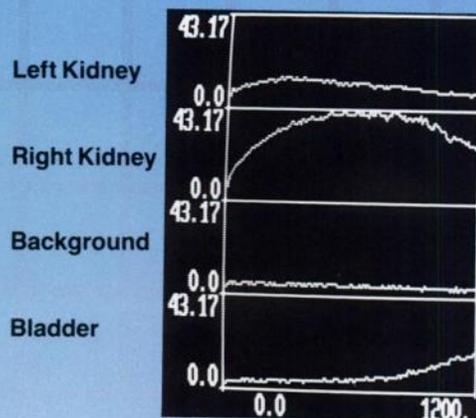
6-8 min.



10-12 min.



20-24 min.



I123 Renogram

**CONCLUSION:** Right hydronephrosis in a somewhat chronically obstructive appearing pattern. Small, poorly functioning left kidney contributing approximately 14% to total renal function.

### Better Data Density—Better Statistics—Higher Detector Efficiency

<sup>1</sup>Courtesy St. Joseph Hospital, Orange, Calif.

# Nephroflow<sup>®</sup>

For the past 20 years you have used I131 Iodohippurate for your renal studies. Now I123 Iodohippurate is available for your use. Use Nephroflow – The physics are better, the statistics are better and the detection efficiency is better. Move into the future.

## Comparison of I123 and I131

Characteristic	I123	I131
Mode of Decay	Electron capture	Beta <sup>-</sup>
Half-Life	13.2 hours	193 hours
Principal Gamma Energy (keV)	159	364
Intensity	84%	82%
Half-Value layer, lead, cm	0.037	0.24
Detection Efficiency: 1/4" NaI (TI) crystal	74.5%	22.5%



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NEPHROFLOW<sup>®</sup>  
IODOHIPPURATE SODIUM I 123 INJECTION

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

**DESCRIPTION:** Nephroflow<sup>®</sup> is supplied as a sterile, apyrogenic, aqueous, isotonic sodium chloride solution for intravenous administration. Each milliliter of the solution contains 37 megabecquerels (1 millicurie) Iodohippurate Sodium I 123 at calibration time, 2 milligrams Iodohippurate Sodium, 1 percent benzyl alcohol (as a preservative), 9 milligrams sodium chloride for isotonicity, and up to 0.1 percent alcohol. The solution is buffered with 1.2 milligrams per milliliter sodium phosphate, monobasic and 0.05 milligrams per milliliter sodium phosphate, dibasic (at time of manufacture) and the pH is adjusted to 7.0–8.5 with sodium hydroxide or hydrochloric acid. The radionuclidic 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 126, I 130, Na 24, Te 121). The radionuclidic composition at expiration time is not less than 85.5 percent I 123, not more than 12.9 percent I 124, and not more than 1.6 percent all others. The ratio of the concentration of I 123 to I 124 changes with time.

**INDICATIONS AND USAGE:** Nephroflow is a diagnostic aid in determining renal function, renal blood flow, and urinary tract obstruction, and as a renal imaging agent.

**CONTRAINDICATIONS:** None Known.

**WARNINGS:** None Known

**PRECAUTIONS:**

*General*

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 (24 hours after calibration time) stated on the label.

The prescribed Iodohippurate Sodium 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 as possible) in order to minimize the fraction of radiation exposure due to relative increase of radionuclidic contaminants with time.

The dose to the bladder wall will be reduced significantly if the patient is encouraged to void within 2 hours after the drug is administered. The dose to the other target organs will also be substantially reduced.

Iodohippurate Sodium I 123, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical

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personnel. Care should also be taken to minimize radiation exposure to the patient 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 and whose experience and training have been approved by the appropriate government 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 effects on fertility in male or female animals.

*Pregnancy Category C*

Animal reproduction studies have not been conducted with this drug. It is also not known whether Iodohippurate Sodium I 123 can cause fetal harm when administered to a pregnant woman, or can affect reproductive capacity. Iodohippurate Sodium I 123 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 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:** As with all organic iodine containing compounds, the possibility of allergic reactions must be kept in mind. Nausea, vomiting, and fainting have been reported in conjunction with the administration of Iodohippurate Sodium I 123.

**HOW SUPPLIED:** Nephroflow is supplied in nominal 3.5 ml vials as a sterile, apyrogenic, aqueous, isotonic sodium chloride solution for intravenous injection. Each milliliter contains 37 megabecquerels (1 millicurie) of Iodohippurate Sodium I 123 at calibration time.

It is available, in individual vials, in the following sizes:

MPI Catalog No. 2041; 1 ml and 37 megabecquerels (1 mCi) per vial,  
MPI Catalog No. 2042; 2 ml and 74 megabecquerels (2 mCi) per vial.

Vials are packaged in individual lead shields with plastic outer container.

**RADIOISOTOPE RECORD**  
 Date: Jul 16, 1984  
 Time: 8:11 A.M.  
 Isotope: Tc-99m  
 Sample # 1  
 Activity: 798. mCi  
 Volume: 20.0 ml  
 Conc: 39.9 mCi/ml  
 99Mo: 27.8 uCi  
 Mo/Tc: .034 uCi/mCi

**RADIOISOTOPE RECORD**  
 Date: Jul 16, 1984  
 Time: 8:12 A.M.  
 Isotope: Tc-99m  
 Sample # 1  
 Dose: 5.00 mCi

**Isotope Decay Chart**

8:30 A.M.  
 38.5 mCi/ml  
 .13 ml  
 Mo: .036 uCi/mCi

9:00 A.M.  
 36.3 mCi/ml  
 .14 ml  
 Mo: .038 uCi/mCi

9:30 A.M.  
 34.3 mCi/ml  
 .15 ml  
 Mo: .040 uCi/mCi



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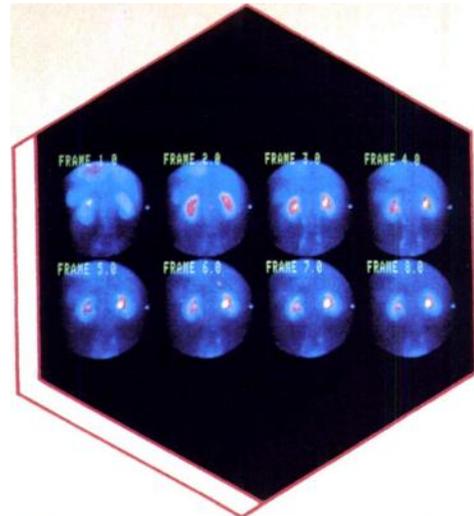
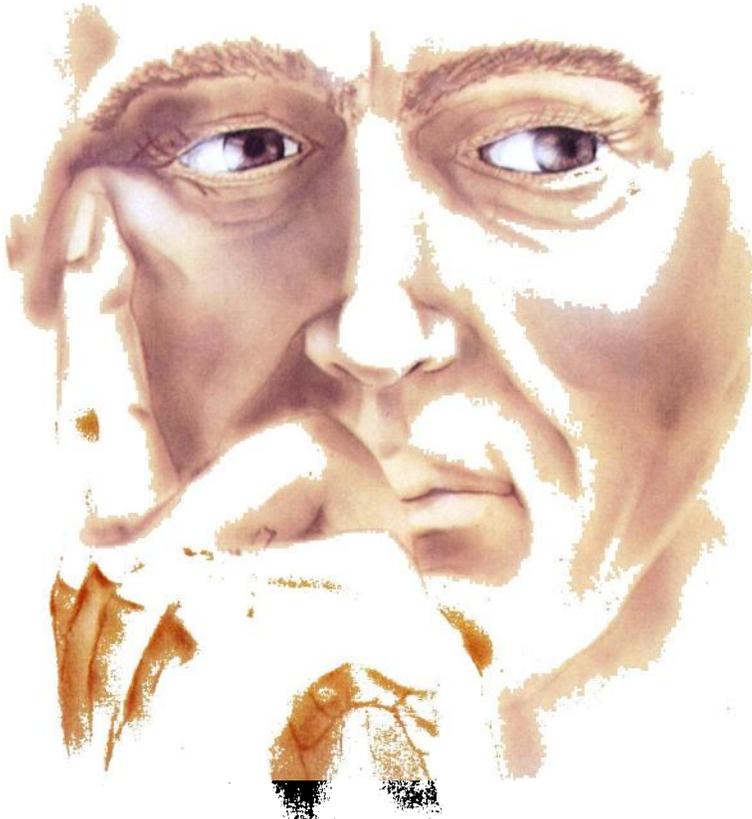


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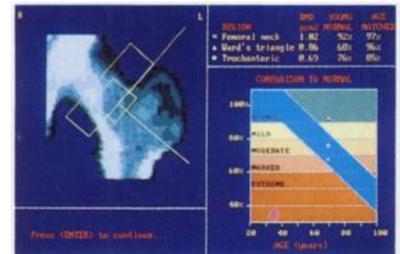
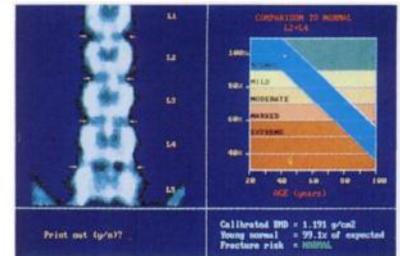
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	DPA	QCT
MARROW DOSE	2 mrem	1000 mrem
COST	\$100	\$300
SITES	SEVERAL	SPINE
ACCURACY	2-4%	25%
PRECISION	2%	5%
INTERSCANNER VARIATION	<2%	>10%
PATIENT ACCEPTANCE	GOOD	FAIR

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# SPECT '86

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## THE JOINT ACNP/SNM SPECT SYMPOSIUM

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Presented by the American College of Nuclear Physicians and The Society of Nuclear Medicine, based on the results of surveys conducted at the 1984 and 1985 SNM Annual Meetings, SPECT Imaging was nominated as the single most desired symposia topic. The Symposium is designed for radiologists, nuclear medicine physicians, and nuclear medicine technologists who wish to increase their knowledge of SPECT utilization. A national panel of distinguished speakers will present topics to include:

- How SPECT works
- Patient set-up for SPECT
- SPECT brain imaging
- Pediatric applications
- Orthopedic applications
- Cardiac imaging
- SPECT in the community hospital
- Quality control

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## DATE AND LOCATION

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Monday-Tuesday, September 22-23, 1986  
The Washington Marriott Hotel  
1221 22nd Street, NW  
Washington, D.C. 20037  
202-872-1500

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## HOTEL RESERVATIONS

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A block of rooms has been set aside at the special rate

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of \$104/single and \$124/double at the Marriott Washington Hotel, 1221 22nd Street, NW, Washington, D.C. (202-872-1500). Use any major credit card to make your reservation. Indicate that you are with the American College of Nuclear Physicians to be sure you receive the preferential rate.

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## SPECT LUNCHEON

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There will be a luncheon for symposium attendees on both days of the meeting to give everyone time to relax and meet with colleagues. If you would like to attend one or both of the luncheons, please check the appropriate box on the registration form and include an additional \$18.00 for each luncheon.

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## 14 HRS. AMA CATEGORY 1 CREDIT 1.1 VOICE Credits

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## THE FEE

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	Before Sept. 12	On or After Sept. 12
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Nonmembers	205.00	225.00
<b>Technologists</b>		
Members	\$ 75.00	\$ 95.00
Nonmembers	105.00	125.00
<b>Students</b>	50.00	

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For more information, please contact the **Education & Meetings Department**, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016 (212)889-0717.

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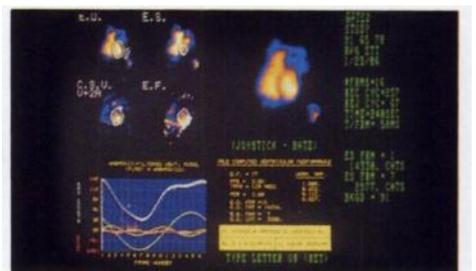
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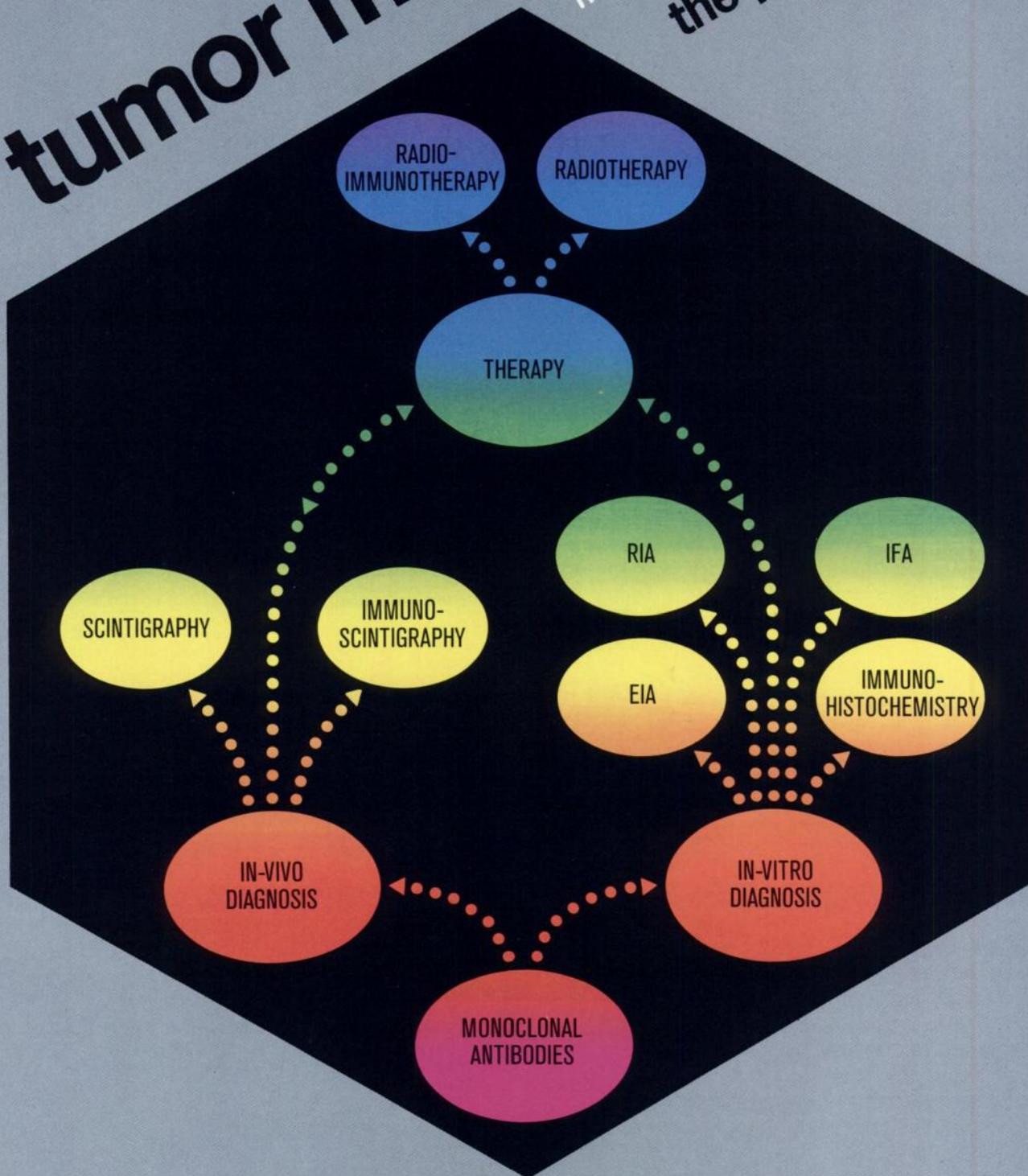
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Edited by **D.M. Wieland, M.C. Tobes, and T. Mangner**, University of Michigan, Ann Arbor, MI

This book discusses the design, development, evaluation, and application of analytical and chromatographic techniques in radiopharmaceutical chemistry. Leaders in the field of nuclear medicine describe and critically evaluate information that until now has been scattered throughout the literature. Newcomers will appreciate the careful coverage of basic information; experienced practitioners will benefit from the in-depth treatment of new techniques and technical commentaries in each chapter.

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**Contents:** **Thin-Layer Chromatography.** Instrumental Evaluation of Thin-Layer Chromatograms, *C.F. Poole, H.T. Butler, M.E. Coddens, and S.A. Schuette*. Radioanalytical Techniques: ITLC, TLC, Mini-Columns, and Electrophoresis, *A.P. Carpenter, Jr.* Radio-Thin-Layer Chromatogram Imaging Systems—Performance and Design, *S.J. Hays*. Detection of Radiochromatograms and Electropherograms with Position-Sensitive Wire Chambers, *H. Filthuth*. **High Pressure Liquid Chromatography** Components for the Design of a Radio-HPLC System, *A.D. Nunn and A.R. Fritzberg*. Overall Radio-HPLC Design, *C.A. Mathis, R.M. Jones, and J.H. Chasko*. Quantitation of Radiolabeled Molecules Separated by High Pressure Liquid Chromatography, *M.J. Kessler*. Flow Detector Designs: Build Your Own or Buy?, *R.D. Hichwa*. **Applications.** Radio-HPLC: Application to Organics and Metal Chelate Chemistry, *A.R. Fritzberg and A.D. Nunn*. Concepts and Techniques Used in Metabolic Tracer Studies, *J.R. Barrio, R.E. Keen, D.C. Chugani, G. Bida, N. Satyamurthy, and M.E. Phelps*. Development of No-Carrier-Added Radiopharmaceuticals with the Aid of Radio-HPLC, *D.S. Wilbur*. From Cyclotron to Patient via HPLC, *M.R. Kilbourn, M.J. Welch, C.S. Dence, and K.R. Lechner*. Potential Artifacts in the Chromatography of Radiopharmaceuticals, *T.J. Mangner*. HPLC of Radiolabeled Antibodies, *D.J. Hnatowich*

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Softcover format, 8½ x 11", 163 pp. Publication date: July 1984

### **ABBREVIATED CONTENTS**

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**NUCLEAR MEDICINE PHYSICIAN**. High volume, nine-man radiology group in major West Virginia city seeks a partner board certified in nuclear medicine, excellent income potential, fringe benefits,

interviewing & relocating expenses, contact: Randy Garner, Jackson and Coker, 400 Perimeter Ctr. Terr., Suite 760 SNM, Atlanta, GA 30346, (404)393-1210.

**NUCLEAR MEDICINE PHYSICIAN**. The Veterans Administration Medical Center, Seattle, Washington and the University of Washington School of Medicine are seeking a board certified or board eligible nuclear medicine physician at the assistant professor level. Strong interest and experience in research and teaching are essential, and computer aptitude and experience are desirable. The hospital is in a new facility with state-of-the-art imaging and computer systems and the professional staff includes a medical imaging physicist and computer programmer. Starts July 1, 1987. Contact: John Harley, MD, Chairman, Search Committee, VA Medical Center, 1660 S. Columbian Way, Seattle, WA 98108. EOE.

**DIRECTOR—IMAGING RESEARCH CENTER** for department of radiology. Responsible for directing and developing research efforts in PET, magnetic resonance imaging and spectroscopy, nuclear medicine and radiology. MD with training in radiology/nuclear medicine or PhD in physics/chemistry required. Send CV to Albert Moss, MD, Radiology SB-05, University of Washington, Seattle, WA 98195.

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#### Physicist

**PHYSICIST.** Medical physics group seeks an individual with expertise in health physics applied to nuclear medicine and diagnostic radiology. MS degree preferred, but will consider a candidate with a BS degree and appropriate experience. Excellent salary and benefits. Send resume and salary requirements to: Jack J. Merkin, MS, Bio-Med Associates, 4 Main Street, Flemington, NJ 08822.

#### Resident

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**NUCLEAR MEDICINE RESIDENCY.** The Division of Nuclear Medicine of the Department of Radiology of the New York Hospital-Cornell Medical Center invites applications for its accredited residency program in nuclear medicine beginning July 1, 1987. Requests for information and applications should be directed to: Dr. Salil Sarkar, Program Director, New York Hospital-Cornell Medical Center, 525 East 68th St., New York, NY 10021. An Affirmative Action/Equal Opportunity Employer.

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The University of California is an equal opportunity, affirmative action employer.

Requests for further information (include CV) should be directed to:

Myron Pollycove, MD  
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Applications, to include curriculum vitae, bibliography, a statement of career and research goals and the names of three references, should be sent to:

David M. Goldenberg, ScD, MD  
President  
Center for Molecular Medicine and Immunology  
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# NUCLEAR MEDICINE TECHNOLOGIST

Pitt County Memorial Hospital, a 550+ bed acute care teaching hospital, is currently accepting applications for a Nuclear Medicine Technologist. Qualified candidates must possess an Associate degree in Radiologic Technology and have ARRT or SNMT certification or be registry eligible and obtain either certification within one year. Pitt County Memorial Hospital offers competitive salaries and excellent benefits package. For immediate consideration, send resume to:



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The Eleanor Capron Rehabilitation Center, affiliated with The Penrose Health System in Colorado Springs, Colorado, has an opportunity for a Nuclear Medicine Technologist, ARRT (N) Registered NMTCB, board certified. Must have experience in general imaging, SPECT, nuclear cardiology and computer processing.

Please send your resume to: Dave Seyfert, HRD Dept., Penrose Health Systems, P.O. Box 7021, Colorado Springs, CO 80933. EOE.



**NUCLEAR MEDICINE PHYSICIAN**

Position open in University Hospital for ABNM certified physician, interested in academic Nuclear Medicine. Ample opportunity for research and development work. Interest in radiochemistry/radiopharmacy appreciated. Please send resume to: D. Pavel, MD, M/C 931, University of Illinois at Chicago, Box 6998, Chicago, IL 60680. An equal opportunity employer.

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## Solution for Potentiation and Stabilization of Immunochemicals

Panbaxy Laboratories, Inc. has introduced PANA-SERA-PLUS, a reagent for substantially potentiating and stabilizing antisera, antigens, enzyme conjugates, and other immunologically active compounds as used in in vitro immunoassay systems. The basis of action of PANA-SERA-PLUS is the chemical interaction of proteins and polymers in presence of free Ca, H, Cl ions and light. When allowed to react in well balanced and optimal concentration, antisera have shown to become substantially potent in their reactivity and avidity. The antisera thus treated remain stable and reactive for prolonged periods of time, even at room temperature in certain instances. PANA-SERA-PLUS is supplied as ready to use reagent, in 10-, 25-, 50-, and 100-ml bottles. The reagent is stable at room temperature for over 6 mo if used as directed. The 10 ml size is sufficient for potentiating ~ 50 ml of antisera. Detailed instructions for use of PANA-SERA-PLUS are supplied with each bottle. Panbaxy will offer consultation and technical support on this and other products. **Panbaxy Laboratories, Inc., 7503 Standish Place, Rockville, MD 20855.**

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## FreezeFrame Video Recorder for Prints and Slides from Video

Polaroid Corporation has introduced the FreezeFrame Video Recorder which delivers high quality instant color prints or slides from video images. Designed and developed jointly by Polaroid and Toshiba Corporation, the recorder features digital freeze field capture, advanced raster fill technology, color preview capability, NTSC signal

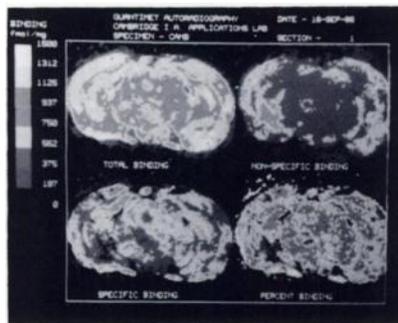


acceptance, and RGB computer input. Polaroid instant film selections for the recorder include AutoFilm Type 339 color prints, Polachrome 35-mm slides, and PolaPan 35-mm black and white slides. The system also accepts conventional 35-mm slide and negative films. Polaroid will begin distribution of the FreezeFrame Video Recorder through industrial video dealers in the United States in mid-1986. **Polaroid Corporation, 575 Technology Square, Cambridge, MA 02139.**

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## Micas System 5 Computer

Nodecrest Ltd. has introduced the Micas System 5 computer. The unit is currently available with a fully configurable database/word processing package, together with image archiving/viewing from a range of



different computer system modalities and will be available in the near future for radiotherapy planning and nuclear medicine. The CPU is based upon a 32 bit Motorola 68020 with 68881 floating point coprocessors. Operating under UNIX 4.2 BSD and programmable in C FORTRAN, ASSEMBLER and PASCAL, and using ETHERNET, operating at up to 10 Mbits/sec transfer rate, it offers users an expandable system. **Nodecrest Ltd., Sprint Industrial Estate, Chertsey Road, Byfleet KT14 7BD, England.**

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## New High Speed Image Analyzer

Cambridge Instruments Inc. has introduced the Autorad 60, a dedicated Quantimet 970 image analyzer, to improve the speed, accuracy, and reproducibility of autoradiographic analysis. The Autorad 60 includes

field-tested software routines which permit neurological studies of local cerebral glucose utilization (via 2-deoxyglucose method), cerebral blood flow, and receptor site binding. An Autorad 60 incorporates a DEC LSI 11/73 computer and uses special high resolution, low noise imaging. The system may be upgraded for autoradiographic grain counting, or expanded to a full Quantimet 970 system to allow user-created programs and applications or modifications of the existing program. **Cambridge Instruments, Inc., 40 Robert Pitt Drive, Monsey, NY 10952.**

Circle Reader Service No. 104

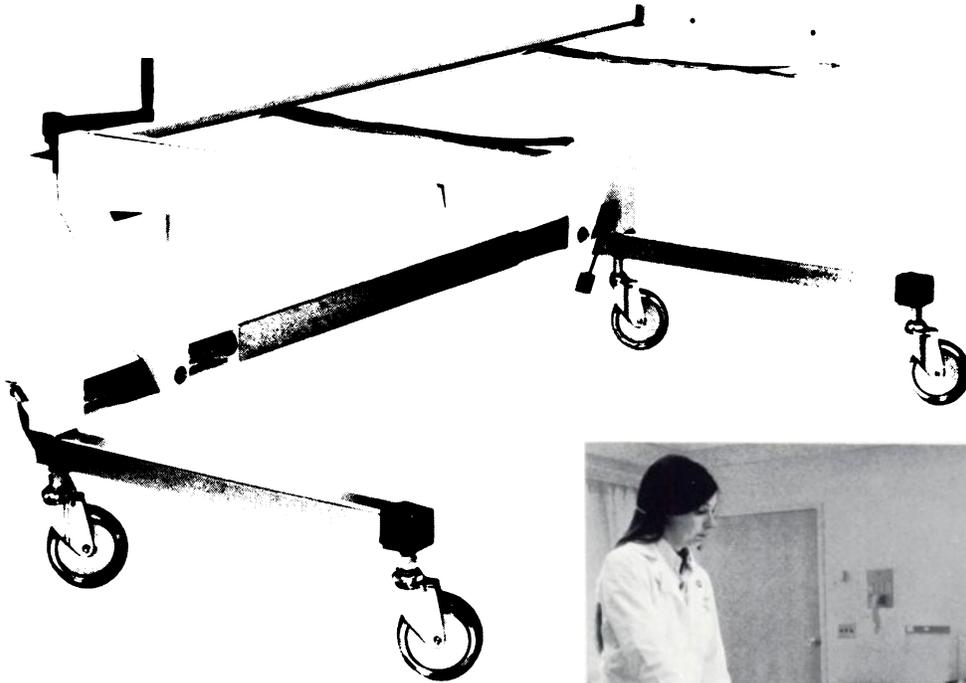
## Picker Expands PCS Nuclear Medicine Computer Series

Picker International has introduced a number of new computer systems to its PCS nuclear medicine computer offerings. The systems are available either as part of a turn-key nuclear camera package or as stand-alone nuclear computer systems and may be used in a network configuration. The basic system is limited to certain options and is geared for processing or acquisition only systems. Designed for table top operation, the system is equipped with a keyboard and text monitor, 12-in. black/white image monitor, a 40MB Winchester storage disk and short computer rack. It can be used as multiple nodes in a nuclear medicine network. The mobile offering with 80MB Winchester storage disk includes a tilting, removable 9-in. amber text and 9-in. black/white image monitor assembly and compact keyboard. Readily removable units provide flexibility for standing or sitting operation. The mobile system interfaces to major cameras and computers through the widely compatible floppy media. A number of options are available including an array processor. The expandable configuration is built on an open architecture, featuring a foreground terminal as standard that allows the user to utilize the long periods of acquisition time to simultaneously process or review previously acquired data. Available with short or tall racks, the expandable system is equipped with 80MB Winchester storage disk as standard, with larger sizes available. **Picker International, 595 Miner Road, Highland Heights, OH 44143.**

Circle Reader Service No. 105

# GOOD NEWS.

**we've made it better!**



**New widefield  
XYZ imaging table**



## **Designed to meet the new technology of today's modern imaging.**

The new Panoramic wide field XYZ imaging Table will accommodate all cameras and allows the clinician easy flexible operation. The main design component is the open cantilever style. In addition, the unique placement of the  $\frac{3}{8}$ " plexiglass top permits flush positioning of the camera from below, eliminating the inches of "dead space" associated with other tables.

- For large field of view cameras, including G.E. Maxicameras.
- The camera can be placed flush to plexiglass top from underneath the table.
- No obstructions to the camera movement.
- Easy patient access.
- Vertical height adjustment.
- 6" wheels for easy mobility.
- XY top adjustment.
- Lightweight.
- 2 Velcro restraining straps.

## **Atomic Products Corporation**

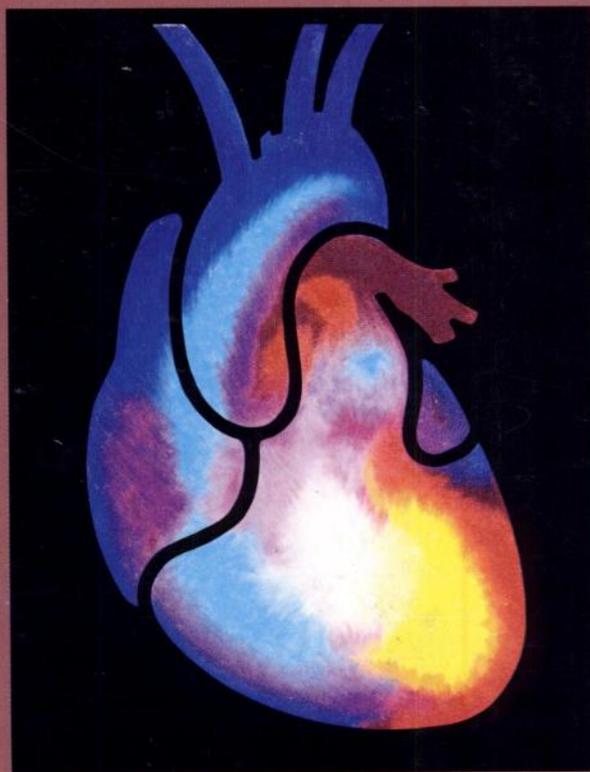
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# Technetium Tc 99m **HSA** Multidose and Unit Dose

## Kits for the Preparation of Technetium Tc 99m Albumin Injection Diagnostic—For Intravenous Use

- **Easy to Prepare:** Just add sterile water, Sodium Pertechnetate Tc 99m Injection, then gently shake. Requires no electrolytic equipment or time-consuming procedures.
- **Unit Dose and Multidose Kits** are cost effective. They allow you to prepare the vial size that best meets your daily scheduling and immediate dosage needs.
- **Color Coding:** Kit packaging and labels are color coded for easy identification.
- **Activity Range:** Up to 100 mCi may be added to Multidose vial and 30.0 mCi to Unit Dose vial.
- **High Blood Concentrations:** Normal human serum albumin, since it is a natural blood component, leaves the vascular space at a rate slow enough to permit imaging procedures.
- **No interference** from activity which normally accumulates in the bone, as with "high-tin" pyrophosphate compounds. Also, only a single patient injection is necessary.



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To Order  
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### Technetium Tc 99m HSA Multidose and Unit Dose

#### Kits for the Preparation of Technetium Tc 99m Albumin Injection

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

#### DIAGNOSTIC—FOR INTRAVENOUS USE

##### DESCRIPTION

The kit consists of 10 multidose reaction vials each containing a lyophilized mixture of 21 mg Albumin Human and 0.23 mg stannous tartrate under a nitrogen atmosphere. Hydrochloric acid was added prior to lyophilization for pH adjustment. All components are sterile and pyrogen-free. When a solution of sterile and pyrogen-free Sodium Pertechnetate Tc 99m Injection is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Albumin Injection is formed with a labeling efficiency of 90% or greater. The product so derived has a pH of 2.5-3.3 and is intended for intravenous injection. The precise structure of Technetium Tc 99m Albumin Injection is not known at this time. The Albumin Human used in this preparation was nonreactive when tested for hepatitis B surface antigen (HB<sub>s</sub>Ag) by radioimmunoassay.

##### Unit Dose

The kit consists of 10 unit dose reaction vials each containing a lyophilized mixture of 7 mg Albumin Human and 0.08 mg stannous tartrate under a nitrogen atmosphere. Hydrochloric acid was added prior to lyophilization for pH adjustment. All components are sterile and pyrogen-free. When a solution of sterile and pyrogen-free Sodium Pertechnetate Tc 99m Injection is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Albumin Injection is formed with a labeling efficiency of 90% or greater. The product so derived has a pH of 2.5-3.3 and is intended for intravenous injection. The precise structure of Technetium Tc 99m Albumin Injection is not known at this time. The Albumin Human used in this preparation was nonreactive when tested for hepatitis B surface antigen (HB<sub>s</sub>Ag) by radioimmunoassay.

**INDICATIONS AND USAGE:** Technetium Tc 99m Albumin Injection is used as an agent for imaging the heart blood pool and to assist in the detection of pericardial effusion.

**CONTRAINDICATIONS:** The use of Technetium Tc 99m Albumin Injection is contraindicated in persons with a history of hypersensitivity reactions to products containing Albumin Human.

**WARNINGS:** In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure appropriate clinical monitoring and treatment are maintained in accordance with safe accepted procedures.

##### PRECAUTIONS:

##### General

The contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc 99m Injection is added, adequate shielding of the final preparation must be maintained.

Hypersensitivity reactions are possible whenever protein-containing materials, such as Technetium Tc 99m labeled Albumin Human, are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

The Technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc 99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Albumin Injection should be stored at 2-8°C and discarded 3 hours after formulation.

Technetium Tc 99m Albumin Injection, as well as other radioactive drugs must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients, consistent with proper patient management.

The contents of the vial are intended only for use in the preparation of Technetium Tc 99m Albumin Injection and are NOT to be administered directly to the patient.

The components of the kit are sterile and pyrogen-free. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation of the radiodiagnostic.

The use of bacteriostatic sodium chloride as a diluent for Sodium Pertechnetate Tc 99m Injection may adversely affect the biological distribution of the prepared agent, and its use is not recommended.

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.

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

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential, or whether Technetium Tc 99m Albumin Injection affects fertility in males or females.

##### Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Albumin Injection. It is also not known whether Technetium Tc 99m Albumin Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Albumin Injection should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman 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:** To date, a single report has been received suggesting a hypersensitivity reaction manifested by cough and rash reversible by administration of antihistamines. Hypersensitivity reactions are theoretically possible whenever protein containing preparations are used and epinephrine, antihistamines and corticosteroids should be available for use.

##### HOW SUPPLIED:

##### Kit Contents

##### Multidose

10 STERILE REACTION VIALS (10 cc, silver aluminum overseal), each containing 21 mg Albumin Human and 0.23 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment. The vial contents are under a nitrogen atmosphere.

20 PRESSURE-SENSITIVE LABELS for final preparation of Technetium Tc 99m Albumin Injection.

1 PACKAGE INSERT

##### Unit Dose

10 STERILE REACTION VIALS (5 cc, gold aluminum overseal), each containing 7 mg Albumin Human and 0.08 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment. The vial contents are under a nitrogen atmosphere.

20 PRESSURE-SENSITIVE LABELS for final preparation of Technetium Tc 99m Albumin Injection.

1 PACKAGE INSERT

##### Storage

Store kit contents and final preparation at 2-8°C. Do not freeze.