SIEMENS

We Provide the Choice. You Provide the Care!

To survive in today's health care environment you have to minimize risk and maximize your investment. That's why we've design specialty collimators that expand the utility of all of our Gamma cameras—increasing your throughput capacity, improving your clinical capability, enhancing your profitability! Visit us at booth 817, at the SNM in Orlando.

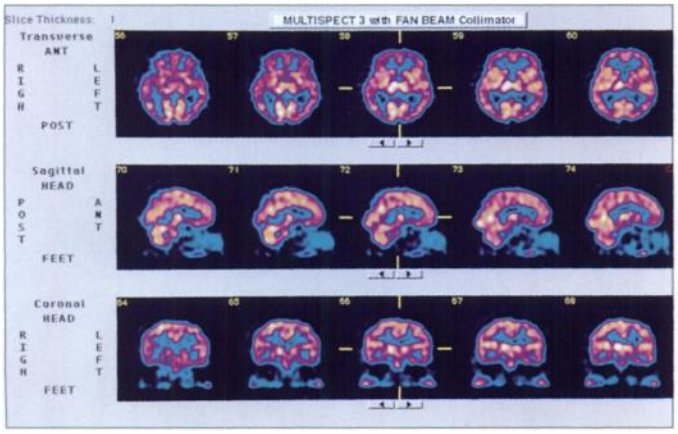
FAN BEAM

FAN BEAM collimators are designed primarily for brain imaging and the imaging of small organs that are approximately the same size as the brain.

FAN BEAM is used on the MULTISPECT 2,™ MULTISPECT 3™ and DIACAM™ Gamma camera systems.

FAN BEAM's focusing capability maximizes crystal use during imaging, and magnification capabilities effectively improve intrinsic spatial resolution.

FAN BEAM collimators provide approximately the same sensitivity as LEHR (Low Energy, High Resolution) parallel hole collimators, with an improved resolution that approaches the resolution of LEUHR (Low Energy Ultra High Resolution) collimators.

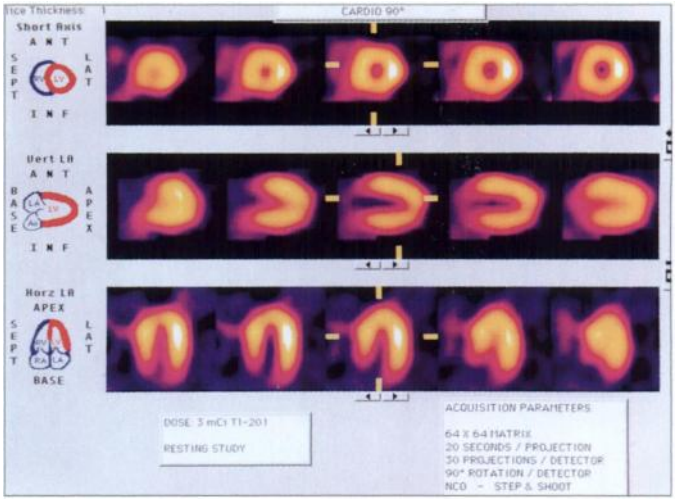


CARDIO 90° ™

CARDIO 90°collimator systems are specifically designed to enhance the MULTISPECT 3 system's performance for cardiac evaluations, perfusion and first pass studies.

CARDIO 90° improves the cardiac SPECT capabilities of the MULTISPECT 3 gamma camera system.* It consists of three collimators: two 15° slant hole (sh) collimators and one ultra high sensitivity parallel hole collimator. The benefit derived from this system is a reduction in scanning time for cardiac SPECT studies resulting in increased patient throughput.

CARDIO 90° optimizes the MULTISPECT 3 system by enabling it to acquire a 180° cardiac study by rotating only 90°. The slant hole collimators modify the performance of the MULTISPECT 3 system so that it operates as a dedicated cardiac SPECT system. The ultra high sensitivity parallel hole collimator acquires more counts faster, increasing the effectiveness of first pass studies.



Classified Advertising

Policy—*The Journal of Nuclear Medicine* accepts classified advertisements from medical institutions, groups, suppliers, and qualified specialists 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—$22.00 per line or fraction of line (approx. 50 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. $10.00 per line. *Note: Box numbers are available for the cost of the 2 lines required.*

Rates for Display Ads—Agency commissions are offered on display ads only

Full page	$1500	Quarter page	$700
Half Page	950	Eighth page	550

Publisher-Set Charges—Page $150; half page $100; quarter page $75; eighth page $50.

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

Deadline—First of the month preceding the publication date (January 1 for February issue). Please submit classified listings typed double spaced. No telephone orders are accepted.

Send Copy to—Classified Advertising Department, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760, (212) 889-0717 FAX: (212) 545-0221

Positions Available

Pharmacist

NUCLEAR PHARMACIST Independent nuclear pharmacy has positions immediately available in Evansville, IN and Paducah, KY. Interested candidates please send resumes to: Radiopharmacy, Inc., 600 N. Weinbach, Suite 910, Evansville, IN 47711. EOE.

Physician

Position in full service nuclear lab (no P.E.T.) in well-equipped and well-staffed medium-size community hospital in Midwest. Will require ABNM certification. Academic experience will receive additional consideration. Send CV to Box 602, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

NUCLEAR MEDICINE POSITION BC/BE NM Physician BC/BE in IM needed for expanded hospital-based and private OP facility in the Southeast. Practice is 50% internal medicine clinical duties with emphasis on thyroid diseases and osteoporosis. Routine NM with SPECT and Radionuclide therapy. Qualified candidates send CV to: Box 603, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

Physicist

MEDICAL PHYSICIST. Respected teaching hospital located in Chicago, IL, seeks Ph.D. with 1-2 years medical experience to join our staff. Please submit C.V., with references to: Mike Naiman, Director-Human Resources, EDGEWATER MEDICAL CENTER, 5700 N. Ashland Ave., Chicago, IL 60660. Or call, (312) 989-8600, extension 3180. eoe.

Positions Wanted

Physician

NUCLEAR MEDICINE PHYSICIAN, ABNM, ACP (Clinical Path), and ABNM-certified, seeks full or part time position. Extensive experience in SPECT, cardiology, thyroid, and computer systems. Please reply to Box 601, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

Nuclear Cardiology

CHIEF TECHNOLOGIST

HAHNEMANN UNIVERSITY, an academic health care center, seeks a Chief Technologist for our Nuclear Cardiology department. You must have a CNMT or ARRT certification, and at least 5 years of recent nuclear medicine technology experience (preferably in nuclear cardiology). Previous supervisory experience is strongly preferred.

We offer a competitive salary and comprehensive benefits package. Please send your resume to: **SML, Human Resources, Hahnemann University, Mail Stop 605, Broad & Vine, Phila., PA 19102-1192.** EOE M/F/H/V.

Hahnemann
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Diatech, Inc., a leader in the development of technetium-99m synthetic peptides for diagnostic imaging, has opportunities for outstanding scientists in the formulation/development and Quality Control areas.

Product Development/ Formulation Scientists

Candidates for these Ph.D. level positions will develop parental formulations in support of investigational dosage forms and market products. Includes preparation of technical documentation to support IND/NDA submissions as well as internal requirements for manufacturing and quality. Position titles will be dependent upon experience and qualifications.

Five to seven years experience in product development with 3-5 years experience in radiopharmaceutical product development desired; along with excellent technical problem solving skills, good oral and written communication skills are required.

Manager Quality Control

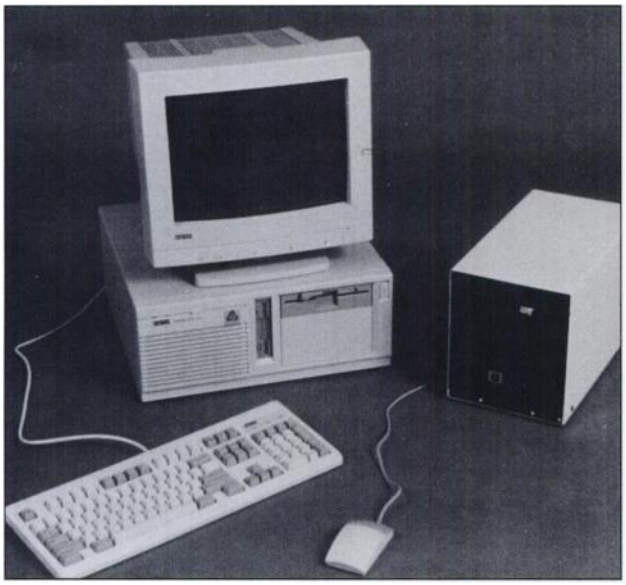
Candidate for this position will have a BS/MS in chemistry, microbiology, pharmacy or related field. This individual will be responsible for establishing and maintaining the QC systems/controls to support business goals/objectives from the development/clinical stages through product commercialization and distribution. Experience required with peptide and protein analytical methods and microbiological methods as well as CGMP's.

Qualified candidates may send a resumé, description of experience and indication of position desired to:

Diatech, Inc., 9 Delta Drive, Londonderry, NH 03053

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.

Compatability Problems Solved



GammaCon announces the GammaCon Image Translation System for image analysis between different nuclear medicine manufacturers' formats. Images can be acquired on one manufacturer's system and processed on another. GammaCon supports static, dynamic, gated, SPECT, Interfile and PC graphic formats. Images can be imported and exported from several sources including networks, 3½", 5¼" and 8" floppies, tapes and telephone lines. GammaCon adds life to older nuclear medicine systems by making them compatible with the newest file formats. Some advantages are: transferral of all available patient information, including name, date and timing marks; networks directly to many other systems; reads and writes Interfile format; operates on popular IBM-compatible PCs making the system versatile and affordable; writes standard PC graphic formats such as TIFF, PICT and PCX for incorporating images into word processing and presentation software. **Numa, Inc., 1200 Millbury St. Bldg. 9L, Worcester, MA 01607. (508) 752-8555, Fax: (508) 752-8885.**

Dose Calibrator Shielded Work Platform

The Dose Calibrator Shielded Work Platform is constructed of steel and provides a large, sturdy working surface with an opening for easy access to your dose calibrator. It can be easily mounted on standard nuclear medicine well chambers, and is specifically designed to increase technician safety and efficiency when working with radionuclide isotopes. Lead pigs containing the vial or syringe to be assayed can be placed on the working surface behind the leaded glass before opening, thus reducing technician exposure from isotopes during routine work. Spills can be reduced since vials are manipulated much closer to the dose calibrator. The glass is 10" high, 12" wide and 5/16" thick, equivalent to 2 mm of lead and can be ordered with a double pane of glass. The work platform is 10" deep, 14" wide and made of steel.

The Dose Calibrator Shielded Work Platform is constructed of steel and can be moved easily between well chambers. The platform is secured to the dose calibrator with a collar utilizing four adjustable mounting bolts. All surfaces are covered with an epoxy enamel protective coat for durability and easy cleaning. **Standard Imaging, 6213 Middleton Springs Drive, Suite 205, Middleton, WI 53562. (608) 831-0025, Fax: (608) 831-2202.**

Lighter Radiation Protection Apparel

Aukland introduces the Aukulyte Radiation Protective Apparel. This collection is 25%-30% lighter than conventional lead-lined apparel. Aukulyte is lead-free, eliminating costly and time-consuming disposal protocol and latex-free, which extends the usable life and protective integrity of the product. All apparel have a frontal rating of 0.5 mm Pb equivalence and 0.68 mm Pb equivalence for wraparound apparel. This collection features a complete line of ergonomically-designed radiation apparel, including front protection aprons, wraparounds, vest/skirt ensembles, thyroid collars and gonads. All apparel can be customized by the clinician's choice of colors, bindings, pockets or monograms, and comes with a 4-year warranty. **Aukland Medical Plastics, Inc., P.O. Box 5624, Cary, NC 27514. (919) 380-7000, Fax: (919) 467-7981.**

Portable General-Purpose Ion Chamber Survey Meter

Victoreen introduces the Model RPO-50, a portable, battery operated, general-purpose ion chamber survey meter that meets ANSI N42.17A and ANSI N42.17C standards. This design combines surface mount analog circuit technology, advanced "front end" FET sensitivity and rugged mechanical features into an easy-to-use instrument with "classic" control knobs, switches and display. The unit is environmentally sealed to protect against moisture and contamination. **Victoreen, Inc. 6000 Cochran Rd., Cleveland, OH 44139. (216) 248-9300, Fax: (216) 248-9043.**

Dual Container Sharps Shield

Biodex Medical Systems has developed a lead-lined Dual Container Sharps Shield that houses two sharps containers for decay rotation to avoid the hazards of transporting a filled sharps container before contents have fully decayed. The containers are stacked inside the shield, and when the top container is filled, the bottom container is removed for proper waste disposal. The top container is then lowered for decay while a fresh container is placed above for immediate use. The Dual Container Sharps Shield can be stationed on a countertop or wall-mounted in locations where injections are given. **Biodex Medical Systems, Brookhaven R&D Plaza, P.O. Box 702, Shirley, New York 11967. (516) 924-9000, Fax: (516) 924-9241.**

Coming Attractions...

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Nuclear Medicine Week 1994
October 2 - 8

Starring: Your Department
(With a Cast of Thousands)

The story of a little-known medical specialty that—through advanced technology, dedicated professionals, and public education—managed to survive in the changing world of health care reform.

For a sneak preview, look for buttons, stickers, and posters at the Nuclear Medicine Week booth at the Annual Meeting in Orlando!

Promotional materials for Nuclear Medicine Week and the PR Star Contest may be obtained by filling out the Direct Response page located at the back of this issue. (You can win a fabulous prize!) Mail or fax your reply to the address/phone number listed there.

Helix *Introduces :* OptiTrack™

Never again waste valuable time "**learning**" patients' body contours. Not for SPECT, not for Whole Body Scanning. Never again be concerned that the patient's slightest movement during the procedure will confuse the system's memorized contour patterns.
Why? Because nothing needs to be memorized. Helix patented ***OptiTrack*** feature eliminates these problems.
OptiTrack optronically traces the patient's contours: automatically,*on-line, in real time, while scanning.*

And *OptiTrack* always assures optimal detector to patient distance for best image quality.
All you have to do is touch the *start* key. Sounds simple? It should, because it is.

Helix OptiTrack :
Simplifies setup, improves image quality, saves time and money...

...And it works.

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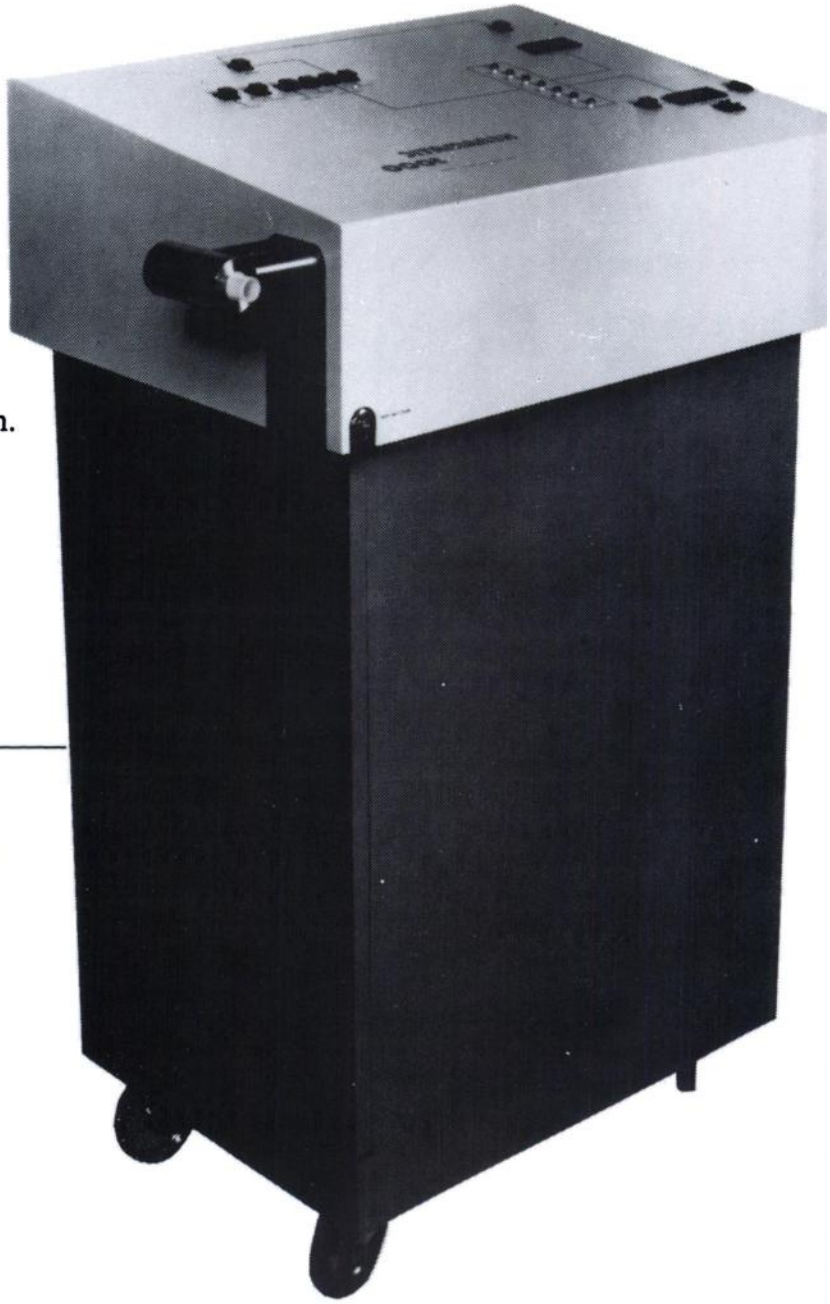
IN A FOG??

using aerosols to determine the patency of the pulmonary airway system? Use a gas (that's what the airway system is for), and Xenon (127 or 133) are gases which are safe, economical and easy to administer with the XENAMATIC™ 3000.

- Shielded for Xe 127 and Xe 133 (radiation profile available on request).
- World's only system that allows you to study patients on Ventilators.
- Largest and most efficient Xenon trap with a built-in monitor alarm system.
- Built-in O_2 monitor with digital display and control.
- A rebreathing system that saves Xenon.
- Low breathing resistance so you can study sick patients.
- Semi-automatic operation.
- Remote Control Capability.



Get out of the FOG-making business, and call today for more information on putting gases where gases belong, with the XENAMATIC.

Also available, Model 2000.

For more information, please call or write,

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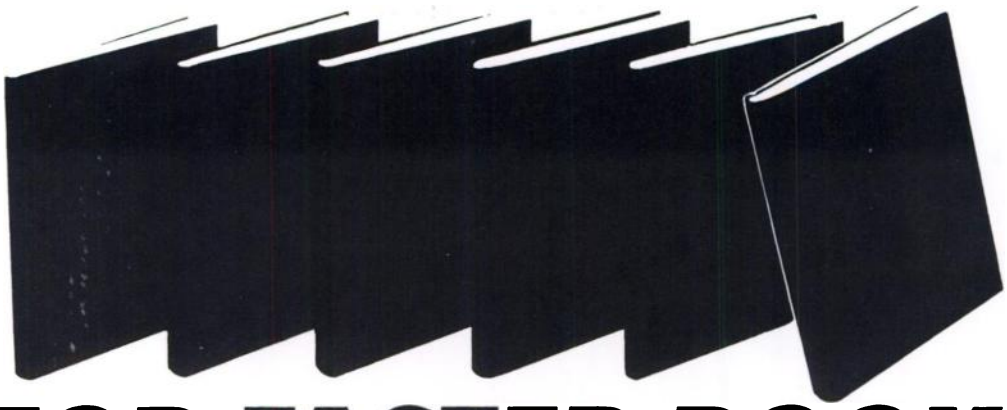

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Orders can now be placed with BookMasters, our fulfillment center.

Your orders will be delivered faster, by two or three days, because of this change. And the Society will be streamlining its operations by this move.

Mail your SNM book and pamphlet orders directly to:

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Mansfield, Ohio 44903

Or place your orders by phone using BookMasters' toll-free telephone 1-800-247-6553 or send by telefax at 1-419-281-6883.

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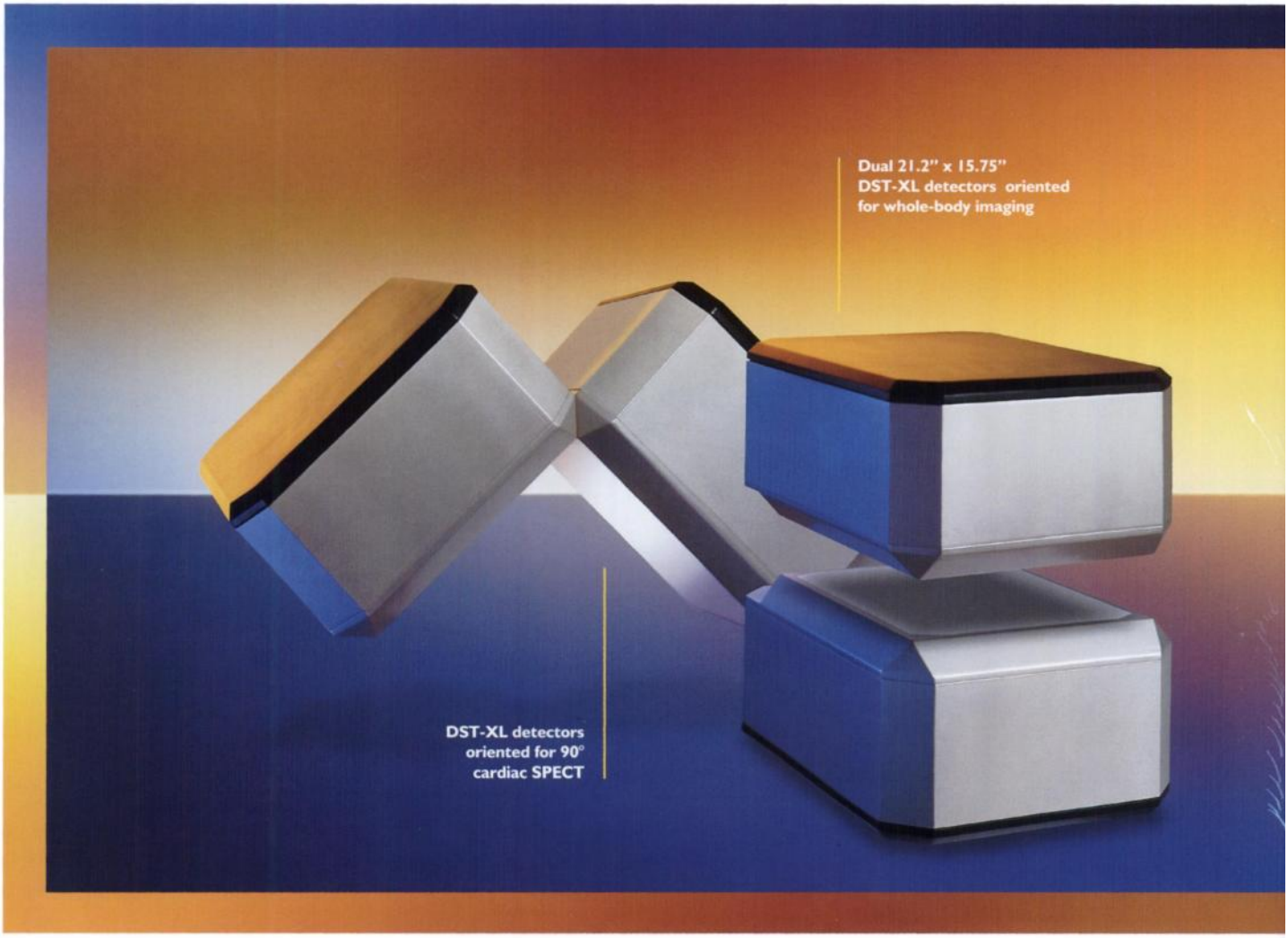
MAKING RESPONSIBLE CHOICES HAS NEVER BEEN MORE IMPORTANT THAN IT IS TODAY.



IT HAS ALSO NEVER BEEN EASIER.

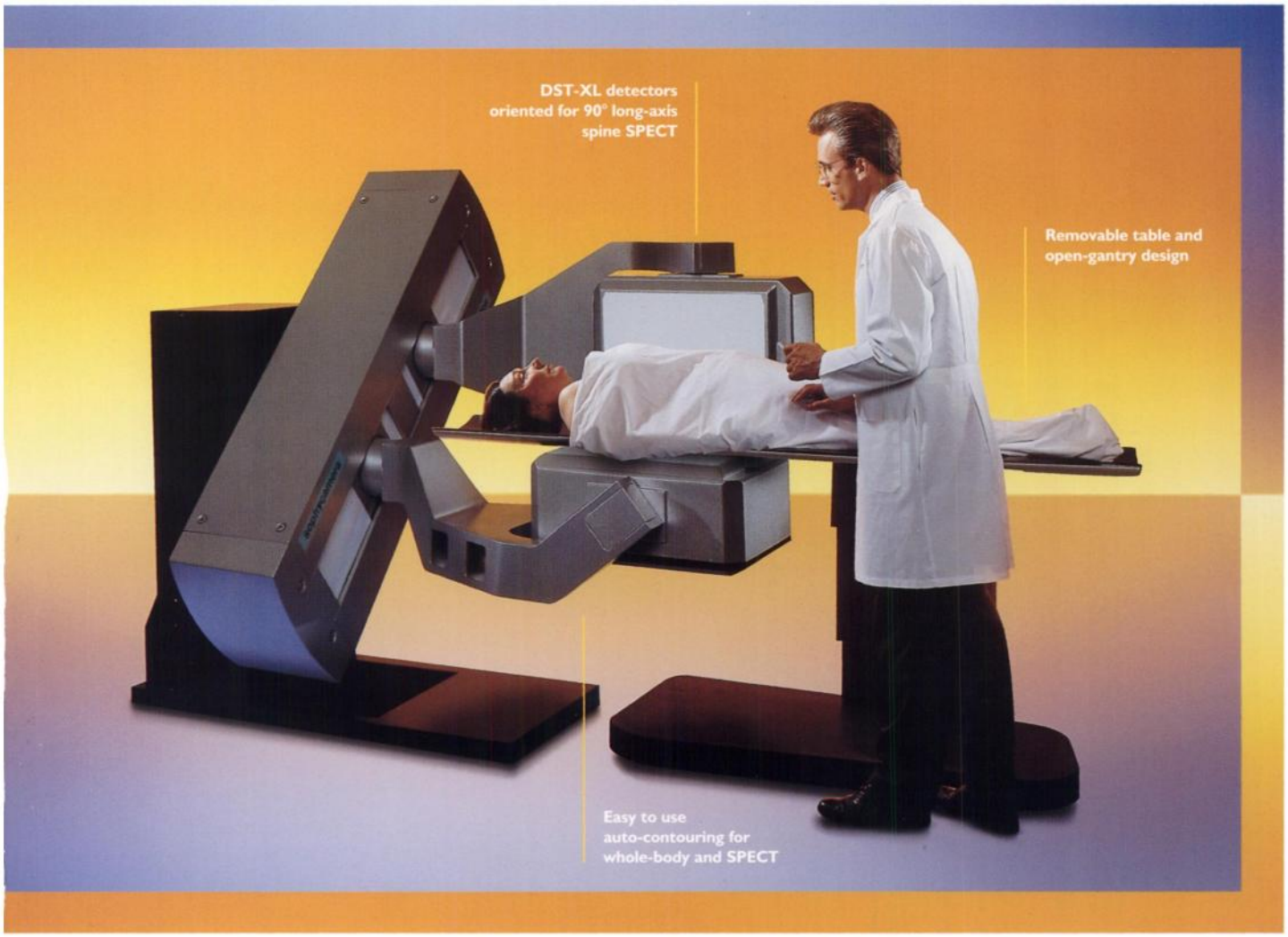
It's refreshing to know that an important choice can also be an easy one. Take the purchase of a nuclear camera in today's competitive environment.

On the one hand, you need a system optimized for your specific caseload. On the other, you need a system that provides the broadest range of studies efficiently and effectively– because today, every case is important to the success of your service.

How can you make the responsible choice? By selecting one of Sopha Medical's two variable-angle cameras: the Sophycamera DST or the new DST-XL.

The DST: General-Purpose Imaging with a Cardiac Emphasis

If you're familiar with the DST, you know that its combination of variable-angle technology (originated by Sopha) and open-gantry design (championed by Sopha) has redefined flexibility. The DST handles not only 180° single-pass whole-body studies and eight-minute 90° cardiac SPECT, but 75° or 60° bi-plane first pass, 30° brain tomography, and the complete set of general studies. And not only for ambulatory patients who can use the system bed, but for patients on a stretcher or sitting in a chair. With the DST you have the broadest applicability, and detectors optimally sized for cardiac studies.



INTRODUCING THE SOPHYCAMERA DST-XL.

The DST-XL: General-Purpose Imaging with a Whole-Body Emphasis

The DST-XL is a true variable-angle, open-gantry system, with all the applicability of the DST. But the DST-XL's jumbo detectors provide unique benefits for whole-body and spine studies. For example, angled at 90° along their 21.2" length, the DST-XL's detectors can capture a spine SPECT study in one 90° orbit. That's efficiency both you and your patient will appreciate.

DST-XL operation is exceptionally easy. The system features sophisticated auto-contouring for both whole-body and tomography, simultaneous dual-collimator changing, simultaneous dual-detector quality assurance, and motorized detector angulation.

So with the introduction of a second Sopha variable-angle system, choosing a nuclear camera has never been easier. You can select the DST for general and cardiac imaging. Or you can select the DST-XL for general and whole-body. Either way, you'll be making the responsible choice. Either way, you'll be choosing Sopha Medical.

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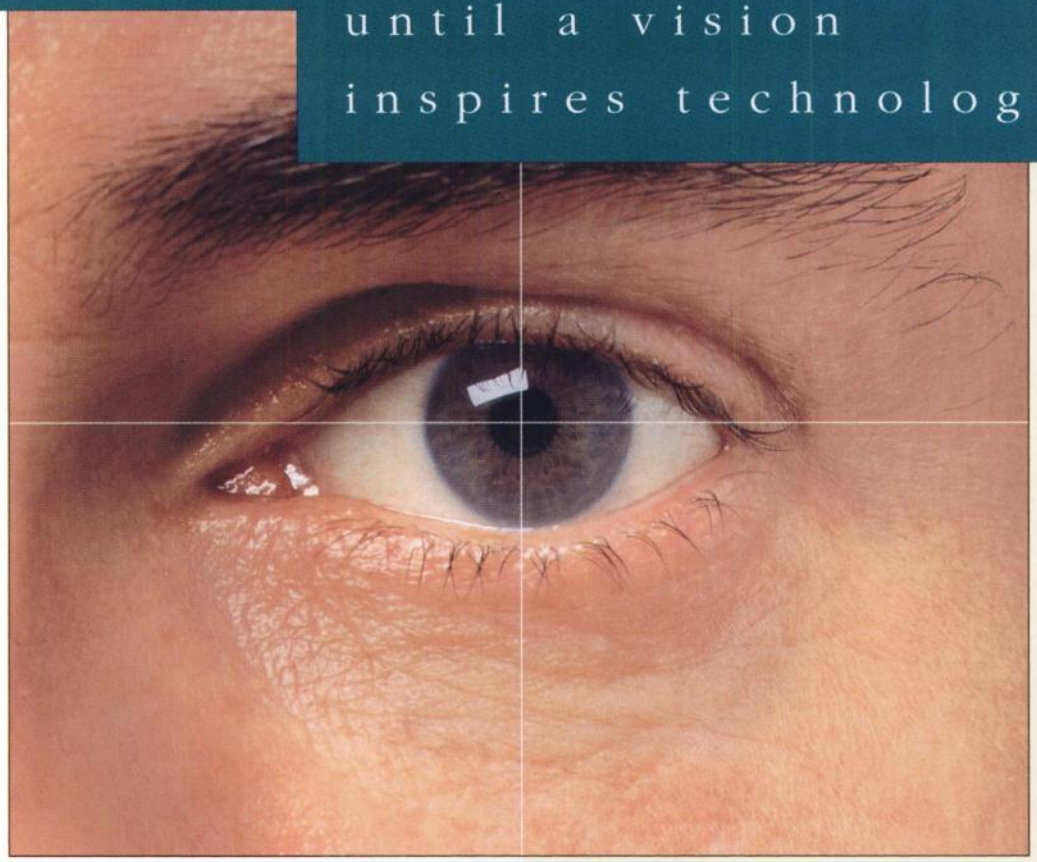
Technology doesn't produce vision until a vision inspires technology.



VISION® POWERstation

At Summit Nuclear, we have a unique vision: that advanced technology can play a vital role in health care reform by improving diagnostic performance, while reducing life-cycle costs.

This vision is achieved with cutting-edge, digital camera, computer and networking products no other company can offer. These products provide long-term cost effectiveness while offering superb clinical imaging quality. Our VISION® family of products helps detect and define disease processes early, accurately, and with maximum clinical confidence.

Nuclear imaging is all we do at Summit Nuclear. And we're capable of doing it better, due to our strategic alliances with world-class technology leaders such as IBM and Hitachi Medical Corporation. We'd like to show you our VISION family of products with advanced technology focused on providing the diagnostic and economic value you require in today's health care environment. Give us a call and discover why nuclear medicine systems with VISION are the preferred choice. **1-800-852-6924.**

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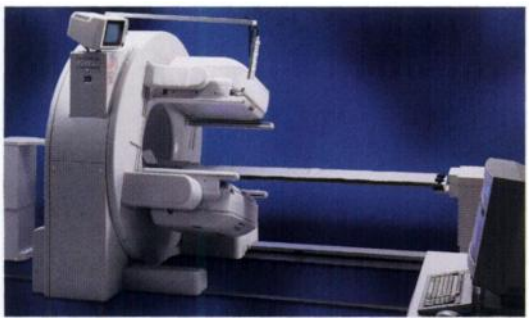
Robocontour eliminates the need for learn mode, or a tracking run, during the exam — offering the fast exam times that give you a financial edge. Toshiba's special infrared sensors in the detectors automatically and reliably rotate the detectors to conform to the shape of the patient's body during whole body and SPECT procedures. The resulting productivity gains give you the economic advantage of greatly enhanced throughput for all types of data acquisition.



Other time-savers make Toshiba's GCA-7200A dual-head gammacamera even more valuable for your bottom line: automatic SPECT or planar scanning acquisition immediately following whole-body scans; a user-friendly, multitasking operating system; and exclusive ***Optotune***™ detector-stabilizing circuitry.

So to stay on track in today's changing healthcare environment, call on Toshiba. For more information about the GCA-7200A dual-head gammacamera with ***Robocontour***, call Toshiba ASSIST™ toll-free at 1-800-521-1968.

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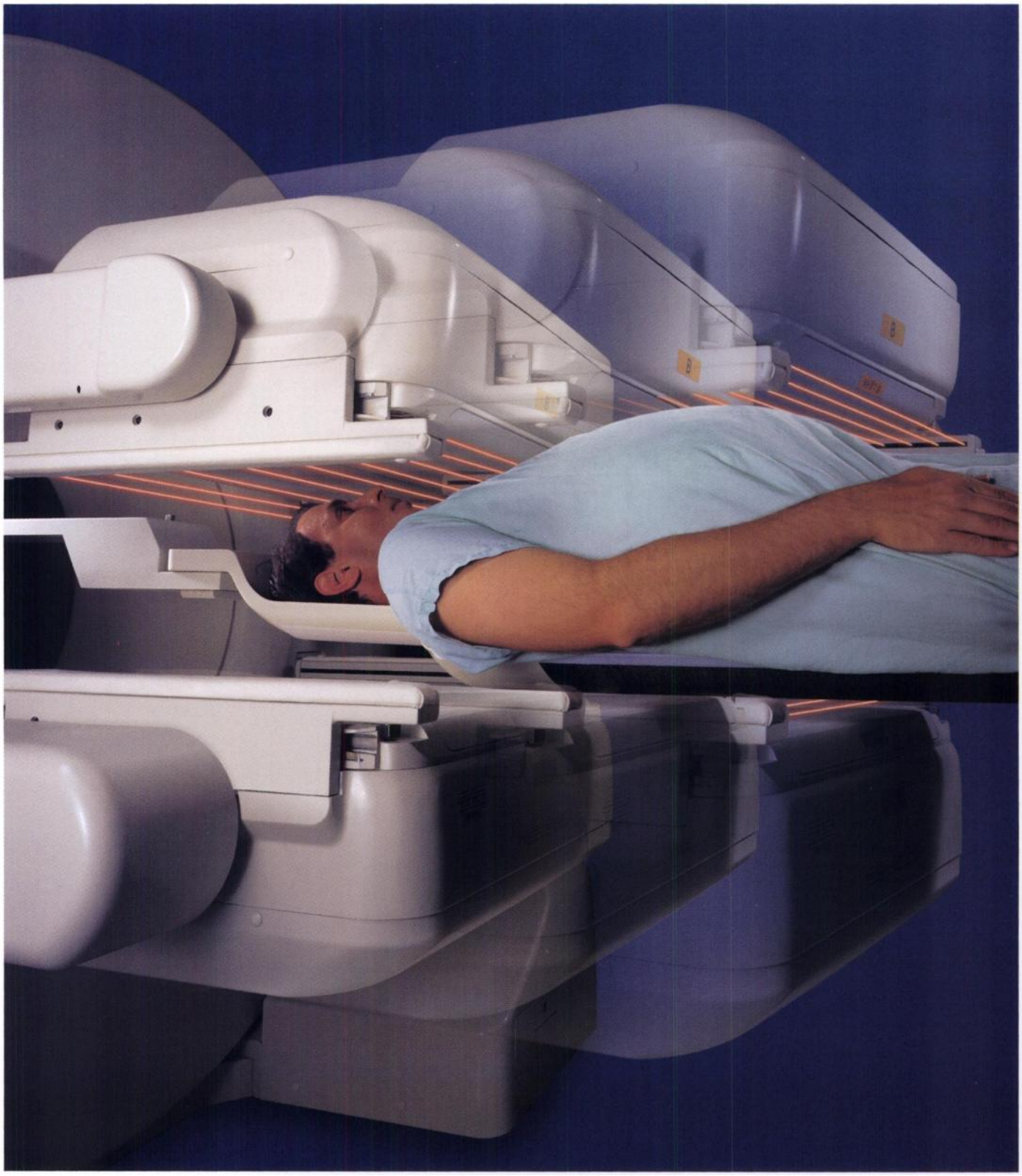

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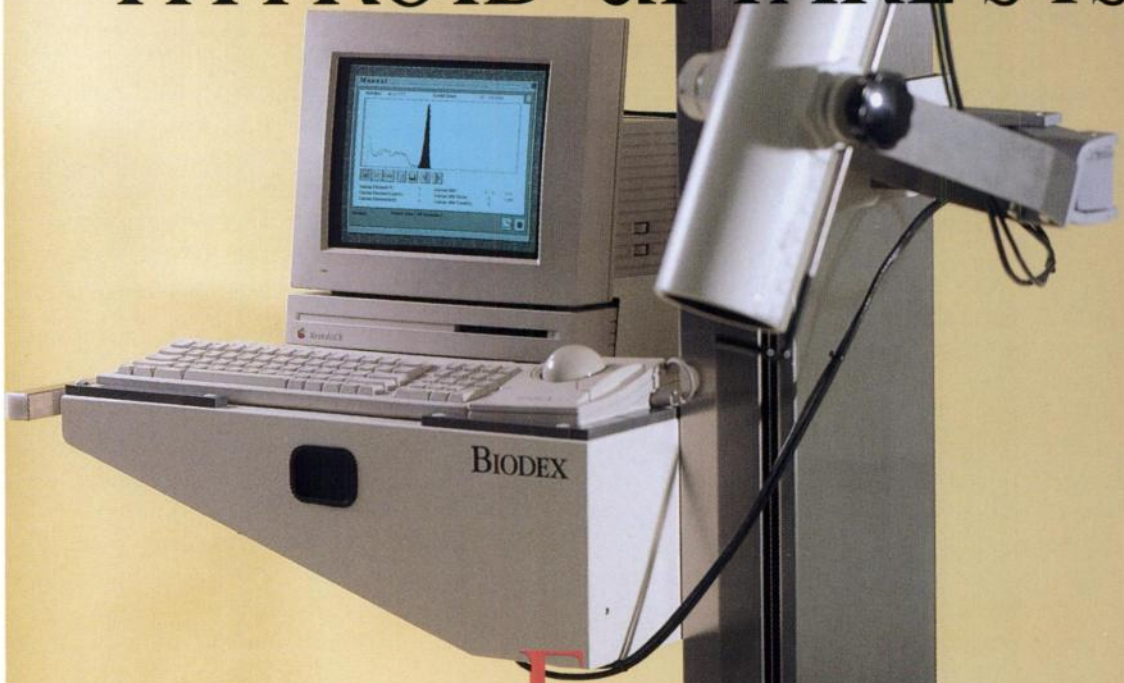

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AccuSync™

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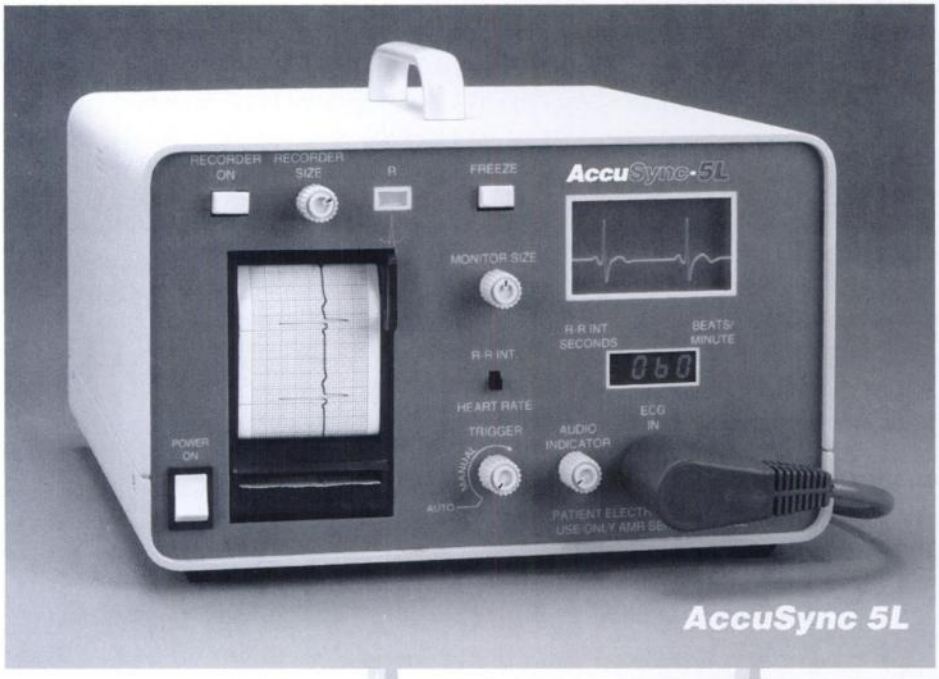
The Finest Line of Cardiac Gates Available



AccuSync 5L

For over fourteen years, Advanced Medical Research, now known as AccuSync Inc., has been serving the cardiac health care industry with the finest line of cardiac gates available in today's market.

Our dedication to service and commitment to provide you with a reliable product have built the reputation of our gates.

With a complete line of models available, you are able to choose the gate which best corresponds to your specific requirements.

The AccuSync 5L, our top model (featured at left) includes CRT monitor (visual) and Strip Chart Recorder (hard copy).

Model Specifications:

- Auto/Manual trigger control
- No delay
- ECG output
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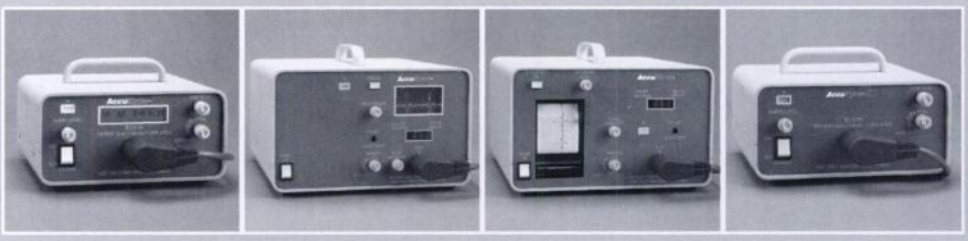
- Trigger pulse LED
- Isolation amplifier for patient safety
- Compatible with all computers

AccuSync models 5L, 6L and 1L are CSA and ETL (UL544) approved


AccuSync 3L AccuSync 6L AccuSync 1L AccuSync 4M

Model	Strip Chart	CRT Monitor	HR/R-R Int	Trigger
5L	•	•	•	•
6L		•	•	•
1L	•		•	•
3L			•	•
4M				•

Accessory and optional products available:
The AccuAmp 5, the 5 lead system available for AccuSync 5L, 6L, and 1L, transmits information through fiber optic link. Patient cables, lead wires, and BNC cables available for AccuSync models.

41st

Booth 523-525

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The Pocket Lecture Series– A New Teaching Aid

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The Series enables you to provide concise and accurate "pocket lectures" on nuclear medicine to referring physicians. When your colleagues are well-informed about benefits of nuclear medicine diagnostic tests, they'll be more likely to use them.

Each pocket-sized lecture package comprises exactly what you need for an informative and authoritative presentation—

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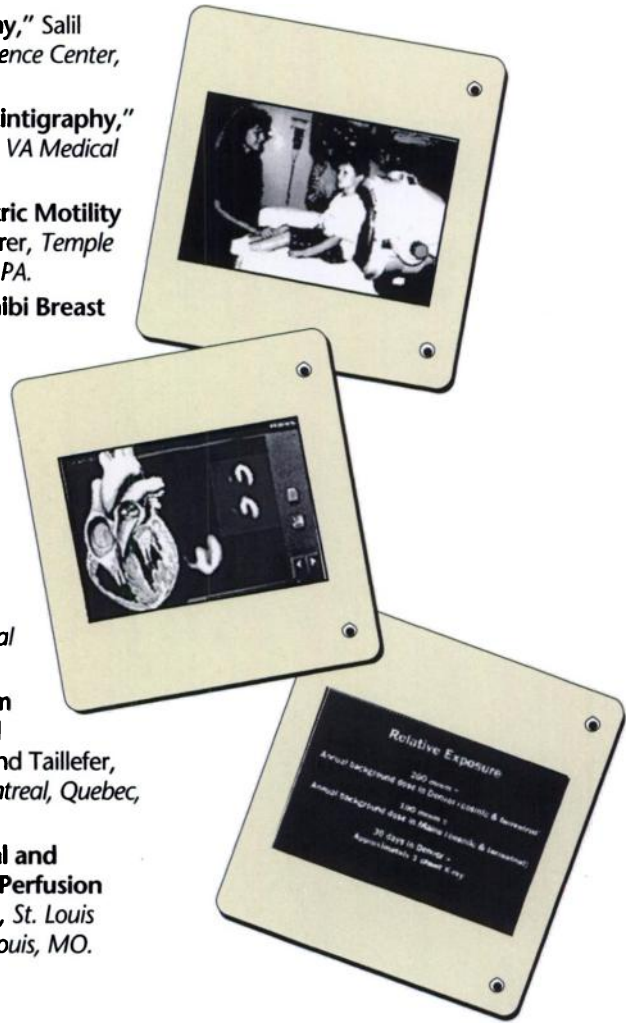
- **"Comprehensive Gastric Motility Evaluation,"** Alan Maurer, *Temple University, Philadelphia, PA.*
- **"Thallium and Sestamibi Breast Scintigraphy,"** Alan Waxman, *Cedars-Sinai Medical Center, Los Angeles, CA.*
- **"Detection of Cerebrovascular Disease with Diamox/HMPAO Scintigraphy,"** Jack Juni, *William Beaumont Hospital, Royal Oak, MI.*
- **"Double-Phase Tc-99m Sestamibi Parathyroid Scintigraphy,"** Raymond Taillefer, *Hotel Dieu Hospital, Montreal, Quebec, Canada.*
- **"Combined Functional and Perfusion Myocardial Perfusion Imaging,"** Mark Wittry, *St. Louis University Hospital, St. Louis, MO.*



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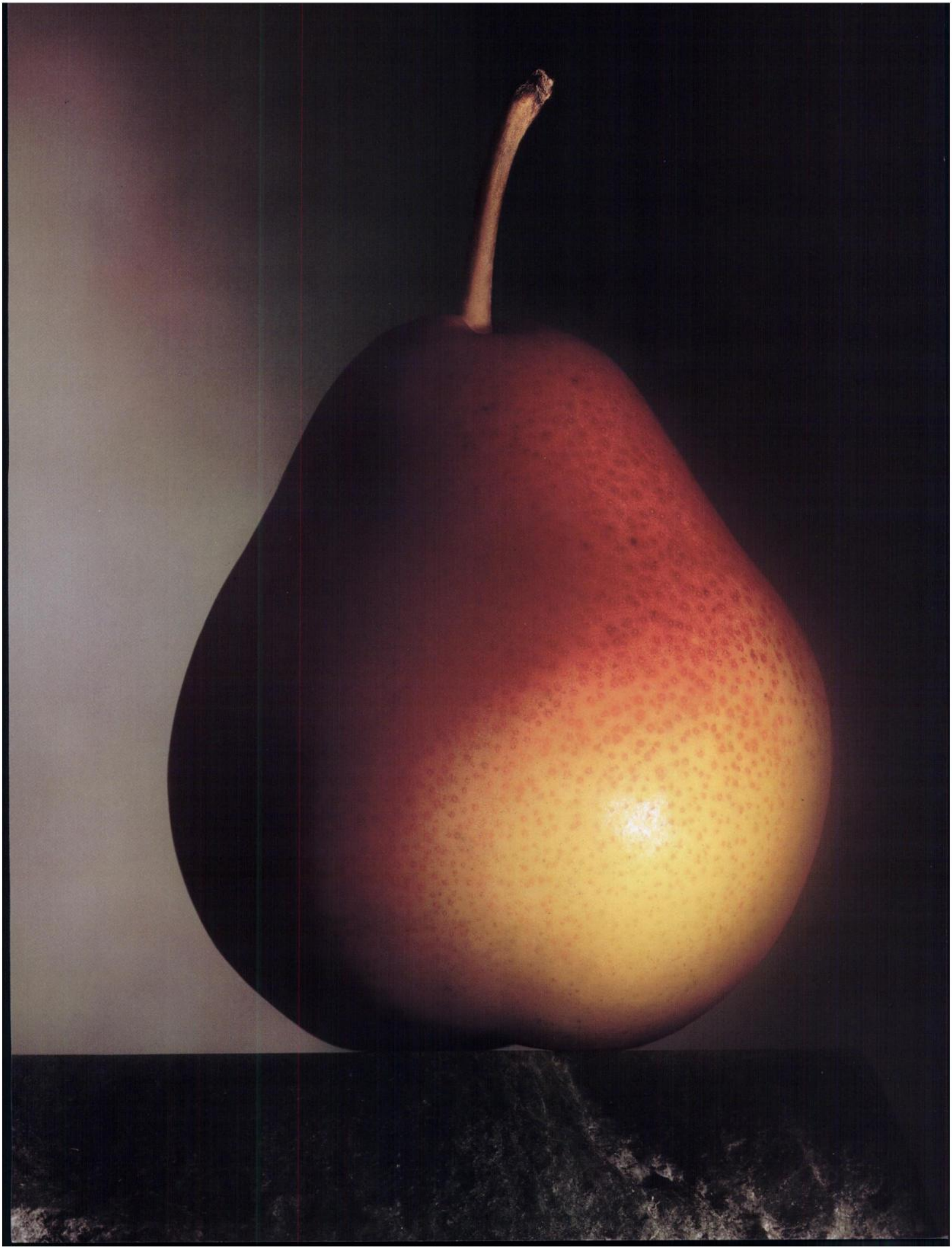

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The shape of your patients may help you recognize the potential for soft-tissue attenuation, especially in fleshy figures.

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Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

To reduce soft-tissue attenuation Cardiolite comes through

DU PONT PHARMA
Radiopharmaceuticals

Stress testing should be performed only under the supervision of a qualified physician in a laboratory equipped with appropriate resuscitation and support apparatus. There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi.

Please see brief summary of prescribing information on adjacent page.

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5ml vial contains a sterile, non-pyrogenic, lyophilized mixture of:

Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0mg
Sodium Citrate Dihydrate - 2.6mg
L-Cysteine Hydrochloride Monohydrate - 1.0mg
Mannitol - 20mg
Stannous Chloride, Dihydrate, minimum ($SnCl_2 \cdot 2H_2O$) - 0.025mg
Stannous Chloride, Dihydrate, ($SnCl_2 \cdot 2H_2O$) - 0.075mg
Tin Chloride (Stannous and Stannic) Dihydrate, maximum
(as $SnCl_2 \cdot 2H_2O$) - 0.086mg

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

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection.The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is $Tc99m[MIBI]_6^+$ where MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in the evaluation of ischemic heart disease. CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi, is also useful in the evaluation of myocardial function using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, localization in the anterior or inferior-posterior wall in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established. Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate recent myocardial infarction from ischemia.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See Precautions).

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

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

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

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

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

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

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rads/30mCi at rest, 1.2 rads/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, $[Cu(MIBI)_4]BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, > 600 × maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Technetium Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

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

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-itching rash have also been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (See WARNINGS and PRECAUTIONS). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in the wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

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

370-1110MBq (10-30mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration.

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

	Estimated Radiation Absorbed Dose			
	REST			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.4	55.5	5.4	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	6.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8
	STRESS			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.8
Gallbladder Wall	2.8	28.9	2.8	27.8
Small Intestine	2.4	24.4	2.4	24.4
Upper Large Intestine Wall	4.5	44.4	4.5	44.4
Lower Large Intestine Wall	3.3	32.2	3.3	32.2
Stomach Wall	0.5	5.3	0.5	5.2
Heart Wall	0.5	5.6	0.5	5.3
Kidneys	1.7	16.7	1.7	16.7
Liver	0.4	4.2	0.4	4.1
Lungs	0.3	2.6	0.2	2.4
Bone Surfaces	0.6	6.2	0.6	6.0
Thyroid	0.3	2.7	0.2	2.4
Ovaries	1.2	12.2	1.3	13.3
Testes	0.3	3.1	0.3	3.4
Red Marrow	0.5	4.6	0.5	4.4
Urinary Bladder Wall	1.5	15.5	3.0	30.0
Total Body	0.4	4.2	0.4	4.2

Radiopharmaceutical Internal Dose Information Center, July 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

HOW SUPPLIED: Du Pont Radiopharmaceutical's CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi, is supplied as a 5ml vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

DU PONT PHARMA
Radiopharmaceuticals

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The Du Pont Merck Pharmaceutical Co.

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METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

Simultaneously targets all sites of metastatic bone pain.

LONG-TERM PALLIATION IN ONE CONVENIENT DOSE.

- Palliation of pain demonstrated in the majority of patients.[1,2]
- One dose of Metastron provides pain relief for an average of up to 6 months.[1]
- As an adjunct to radiotherapy, 63.6% of patients receiving Metastron (10.8 mCi) had reduced pain at 6 months as compared to 35.0% of patients receiving placebo (n=42).[3]
- Preferentially incorporates into multiple sites of metastatic bone — the dose absorbed in metastatic deposits is approximately ten times that absorbed in normal bone marrow.[4,5]

ADJUNCTIVELY DELAYS THE MEDIAN TIME TO PROGRESSION OF PAIN BY 28.1 WEEKS OVER RADIOTHERAPY ALONE.

Median time to requirement for additional radiotherapy at new pain site.[3]

From a multicenter, double-blind study of 126 patients who received a single injection of either Metastron 400 MBq, 10.8 mCi or placebo with fractionated doses of local field radiotherapy (20-30 Gy).

HIGHLY EFFECTIVE NON-NARCOTIC THERAPY.

- Metastron may reduce or eliminate the need for dose escalation of narcotic analgesics.[1,3]
- Onset of pain relief is generally within 7 to 20 days — Metastron is therefore not recommended in patients with very short life expectancy.

GENERALLY WELL TOLERATED.

- A depression of white blood cell (20%) and platelet (30%) levels may occur in patients treated with Metastron — clinically significant toxicity is rare.
- Metastron should be used with caution in patients with significantly compromised bone marrow from previous treatment. Caution should also be used in patients with platelet counts below 60,000 or white blood cell counts below 2,400.
- Some patients have reported a transient increase in bone pain lasting 36 to 72 hours following an injection — this can usually be controlled with analgesics.

AN IMPROVED QUALITY OF LIFE FOR PATIENTS.

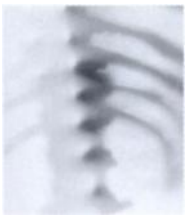
- Metastron may improve patient quality of life, as measured by assessments of mood, mobility, appetite, sleep pattern, and analgesic consumption.[1-4]

Please see following page for full prescribing information.

METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

An effective way to manage metastatic bone pain.

41st Island 939



METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

An effective way to manage metastatic bone pain.

Consult your radiation safety officer for product availability or call Amersham Healthcare/ Medi-Physics Technical Services at 1-800-554-0157.

Metastron® (Strontium-89 Chloride Injection)

Description: Metastron is a sterile, non-pyrogenic, aqueous solution of Strontium-89 Chloride for intravenous administration. The solution contains no preservative.

Each milliliter contains:		
	Strontium Chloride	10.9 - 22.6 mg
	Water for Injection	q.s. to 1 mL

The radioactive concentration is 37 MBq/mL, 1 mCi/mL and the specific activity is 2.96 - 6.17 MBq/mg, 80-167 µCi/mg at calibration. The pH of the solution is 4 - 7.5.

Physical Characteristics: Strontium-89 decays by beta emission with a physical half-life of 50.5 days. The maximum beta energy is 1.463 MeV (100%). The maximum range of ß- from Strontium-89 in tissue is approximately 8 mm.

Radioactive decay factors to be applied to the stated value for radioactive concentration at calibration, when calculating injection volumes at the time of administration, are given in Table 1.

Table 1: Decay of Strontium-89

Day*	Factor	Day*	Factor	Day*	Factor	Day*	Factor
-24	1.39	-12	1.18	+6	0.92	+18	0.78
-22	1.35	-10	1.15	+8	0.90	+20	0.76
-20	1.32	-8	1.12	+10	0.87	+22	0.74
-18	1.28	-6	1.09	+12	0.85	+24	0.72
-16	1.25	-4	1.06	+14	0.83	+26	0.70
-14	1.21	-2	1.03	+16	0.80	+28	0.68
		0 = calibration	1.00				

*Days before (-) or after (+) the calibration date stated on the vial.

Clinical Pharmacology: Following intravenous injection, soluble strontium compounds behave like their calcium analogs, clearing rapidly from the blood and selectively localizing in bone mineral. Uptake of strontium by bone occurs preferentially in sites of active osteogenesis; thus primary bone tumors and areas of metastatic involvement (blastic lesions) can accumulate significantly greater concentrations of strontium than surrounding normal bone.

Strontium-89 Chloride is retained in metastatic bone lesions much longer than in normal bone, where turnover is about 14 days. In patients with extensive skeletal metastases, well over half of the injected dose is retained in the bones.

Excretion pathways are two-thirds urinary and one-third fecal in patients with bone metastases. Urinary excretion is higher in people without bone lesions. Urinary excretion is greatest in the first two days following injection.

Strontium-89 is a pure beta emitter and Strontium-89 Chloride selectively irradiates sites of primary and metastatic bone involvement with minimal irradiation of soft tissues distant from the bone lesions. (The maximum range in tissue is 8 mm; maximum energy is 1.463 MeV.) Mean absorbed radiation doses are listed under the **Radiation Dosimetry** section.

Clinical trials have examined relief of pain in cancer patients who have received therapy for bone metastases (external radiation to indexed sites) but in whom persistent pain recurred. In a multi-center Canadian placebo-controlled trial of 126 patients, pain relief occurred in more patients treated with a single injection of Metastron than in patients treated with an injection of placebo. Results are given in the following tables.

Table 2 compares the percentage and number of patients treated with Metastron or placebo who had reduced pain and no increase in analgesic or radiotherapy re-treatment.

Table 2: Comparison of the effects of Strontium-89 and placebo, as adjunct to radiotherapy, on treatment outcome over time.

	Months Post-Treatment					
	1	2	3	4	5	6
Metastron	71.4% (n=42)	78.9% (n=38)	60.6% (n=33)	59.3% (n=27)	36.4% (n=22)	63.6% (n=22)
Placebo	61.4% (n=44)	57.1% (n=35)	55.9% (n=34)	25.0% (n=24)	31.8% (n=22)	35.0% (n=20)

At each visit, treatment success, defined as a reduction in a patient's pain score without any increase in analgesic intake and without any supplementary radiotherapy at the index site, was more frequent among patients assigned to Metastron than to placebo.

Table 3 compares the number and percentage of patients treated with Metastron or placebo as an adjunct to radiotherapy who were pain free without analgesic at the intervals shown.

Table 3: Comparison of the effects of Strontium-89 and placebo, as adjunct to radiotherapy, on reduction of pain score and analgesic score to zero.

	Months Post-Treatment						
	1	2	3	4	5	6	9
Metastron	6	5	5	3	4	4	2
	14.3% (n=42)	13.2% (n=38)	15.2% (n=33)	11.1% (n=27)	18.2% (n=22)	18.2% (n=22)	18.2% (n=11)
Placebo	3	3	2	0	1	1	0
	6.8% (n=44)	8.6% (n=35)	5.9% (n=34)	(n=24)	4.5% (n=22)	5% (n=20)	(n=17)

The number of patients classified at each visit as treatment successes who were pain free at the index site *and* required no analgesics was consistently higher in the Metastron group.

New pain sites were less frequent in patients treated with Metastron.

In another clinical trial, pain relief was greater in a group of patients treated with Metastron compared with a group treated with non-radioactive strontium-88.

Indications and Usage: Metastron (Strontium-89 Chloride Injection) is indicated for the relief of bone pain in patients with painful skeletal metastases.

The presence of bone metastases should be confirmed prior to therapy.

Contraindications: None known.

Warnings: Use of Metastron in patients with evidence of seriously compromised bone marrow from previous therapy or disease infiltration is not recommended unless the potential benefit of the treatment outweighs its risks. Bone marrow toxicity is to be expected following the administration of Metastron, particularly white blood cells and platelets. The extent of toxicity is variable. It is recommended that the patient's peripheral blood cell counts be monitored at least once every other week. Typically, platelets will be depressed by about 30% compared to pre-administration levels. The nadir of platelet depression in most patients is found between 12 and 16 weeks following administration of Metastron. White blood cells are usually depressed to a varying extent compared to pre-administration levels. Thereafter, recovery occurs slowly, typically reaching pre-administration levels six months after treatment unless the patient's disease or additional therapy intervenes.

In considering repeat administration of Metastron, the patient's hematologic response to the initial dose, current platelet level and other evidence of marrow depletion should be carefully evaluated.

Verification of dose and patient identification is necessary prior to administration because Metastron delivers a relatively high dose of radioactivity.

Metastron may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

Precautions: Metastron is not indicated for use in patients with cancer not involving bone. Metastron should be used with caution in patients with platelet counts below 60,000 and white cell counts below 2,400.

Radiopharmaceuticals should only be used 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.

Metastron, like other radioactive drugs, must be handled with care and appropriate safety measures taken to minimize radiation to clinical personnel.

In view of the delayed onset of pain relief, typically 7 to 20 days post injection, administration of Metastron to patients with very short life expectancy is not recommended.

A calcium-like flushing sensation has been observed in patients following a rapid (less than 30-second injection) administration.

Special precautions, such as urinary catheterization, should be taken following administration to patients who are incontinent to minimize the risk of radioactive contamination of clothing, bed linen and the patient's environment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from a repetitive dose animal study suggests that Strontium-89 Chloride is a potential carcinogen. Thirty-three of 40 rats injected with Strontium-89 Chloride in ten consecutive monthly doses of either 250 or 350 µCi/kg developed malignant bone tumors after a latency period of approximately 9 months. No neoplasia was observed in the control animals. Treatment with Strontium-89 Chloride should be restricted to patients with well documented metastatic bone disease.

Adequate studies with Strontium-89 Chloride have not been performed to evaluate mutagenic potential or effects on fertility.

Pregnancy: Teratogenic effects.

Pregnancy Category D. See **Warnings** section.

Nursing Mothers: Because Strontium acts as a calcium analog, secretion of Strontium-89 Chloride into human milk is likely. It is recommended that nursing be discontinued by mothers about to receive intravenous Strontium-89 Chloride. It is not known whether this drug is excreted in human milk.

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

Adverse Reactions: A single case of fatal septicemia following leukopenia was reported during clinical trials. Most severe reactions of marrow toxicity can be managed by conventional means.

A small number of patients have reported a transient increase in bone pain at 36 to 72 hours after injection. This is usually mild and self-limiting, and controllable with analgesics. A single patient reported chills and fever 12 hours after injection without long-term sequelae.

Dosage and Administration: The recommended dose of Metastron is 148 MBq, 4 mCi, administered by slow intravenous injection (1-2 minutes). Alternatively, a dose of 1.5 - 2.2 MBq/kg, 40-60 µCi/kg body weight may be used.

Repeated administrations of Metastron should be based on an individual patient's response to therapy, current symptoms, and hematologic status, and are generally not recommended at intervals of less than 90 days.

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

Radiation Dosimetry: The estimated radiation dose that would be delivered over time by the intravenous injection of 37 MBq, 1 mCi of Strontium-89 to a normal healthy adult is given in Table 4. Data are taken from the ICRP publication "Radiation Dose to Patients from Radiopharmaceuticals"-ICRP #53, Vol. 18 No. 1-4, Page 171, Pergamon Press, 1988.

Table 4: Strontium-89 Dosimetry

Organ	mGy/MBq	rad/mCi	Organ	mGy/MBq	rad/mCi
Bone Surface	17.0	63.0	Testes	0.8	2.9
Red Bone Marrow	11.0	40.7	Ovaries	0.8	2.9
Lower Bowel Wall	4.7	17.4	Uterine Wall	0.8	2.9
Bladder Wall	1.3	4.8	Kidneys	0.8	2.9

When blastic osseous metastases are present, significantly enhanced localization of the radiopharmaceutical will occur with correspondingly higher doses to the metastases compared with normal bones and other organs.

The radiation dose hazard in handling Strontium-89 Chloride injection during dose dispensing and administration is similar to that from phosphorus-32. The beta emission has a range in water of about 8 mm (max.) and in glass of about 3 mm, but the bremsstrahlung radiation may augment the contact dose.

Measured values of the dose on the surface of the unshielded vial are about 65 mR/minute/mCi.

It is recommended that the vial be kept inside its transportation shield whenever possible.

How Supplied: Metastron is supplied in a 10 mL vial containing 148 MBq, 4 mCi. The vial is shipped in a transportation shield with approximately 3 mm lead wall thickness, package insert, and two therapeutic agent warning labels.

The vial and its contents should be stored inside its transportation container at room temperature (15-25° C, 59-77° F).

The calibration date (for radioactivity content) and expiration date are quoted on the vial label. The expiration date will be 28 days after calibration. Stability studies have shown no change in any of the product characteristics monitored during routine product quality control over the period from manufacture to expiration.

This radiopharmaceutical is licensed by the Illinois Department of Nuclear Safety for distribution to persons licensed pursuant to 32 Illinois Adm. Code 330.260 (a) and Part 335 Subpart F.335.5010 or under equivalent licenses of the USNRC or an Agreement State.

THIS PRODUCT INFORMATION ISSUED JUNE, 1993. Product Code: SMS.2PA

Manufactured by: **Amersham International plc** Amersham, England

Medi-Physics, Inc. 2636 S. Clearbrook Drive Arlington Heights, Illinois 60005

References:

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* **References:**

1) Shapiro B., Copp J.E., Sisson J.C., Eyre P.L., Wallis J., Beirwaltes W.H.: Iodine-131 Meta-iodobenzylguanidine for Locating of Suspected Pheochromocytoma: Experience in 400 Cases; J. Nucl Med, 1985, 26: 576-585.

2) Pochedly, C; ed., Neuroblastoma: Tumor Biology and Therapy, CRC Press, Boca Raton, FL, 1990; ch. 8, p. 182

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BRIEF SUMMARY
Iobenguane Sulfate I 131 Injection. Diagnostic-For Intravenous Use

DESCRIPTION
Iobenguane Sulfate I 131 Injection is a sterile, pyrogen free radiopharmaceutical for intravenous injection. Each milliliter contains 0.69 mg of iobenguane sulfate, 85.1 MBq (2.30 mCi) of I 131 (as iobenguane sulfate I 131 at calibration), 0.36 mg of sodium acetate, 0.27 mg of acetic acid, 4.2 mg of sodium chloride, 0.56 mg of methyl paraben, 0.56 mg of propylparaben and 0.01 mL of benzyl alcohol. Iobenguane Sulfate I 131 is also known as I 131-meta-iodobenzylguanidine sulfate (I 131 mIBG).

INDICATIONS AND USAGE
Iobenguane Sulfate I 131 Injection is indicated as an adjunctive diagnostic agent in the localization of primary or metastatic pheochromocytomas and neuroblastomas.

CONTRAINDICATIONS
Iobenguane Sulfate I 131 is contraindicated in patients with known hypersensitivity to iobenguane sulfate.

WARNINGS
As with other I 131 containing agents, in order to decrease thyroid accumulation of I 131, block the thyroid gland with iodine. (See Dosage and Administration section)

During and following the injection, patients with known or suspected pheochromocytoma should be carefully monitored for hypertensive crises.

PRECAUTIONS
General
IOBENGUANE SULFATE I 131 IS CLEARED BY GLOMERULAR FILTRATION AND IS NOT DIALYZABLE. Caution should be exercised when administering the drug to renally impaired patients. Iobenguane Sulfate I 131 is not recommended in anephric patients. The radiation dose to the anephric patient would be substantially increased due to the delayed biological elimination of the drug. Also, because of the lack of clearance, the target-to-back ground ratios would severely compromise the outcome of the study. Iobenguane Sulfate I 131 use in patients with impaired renal function should be carefully considered. As with all radio-iodinated compounds, the patient should be well hydrated before and during examination.

Although iodinated contrast imaging agents have been confirmed to cause anaphylactic reactions in patients with hypersensitivity to iodine, the incidence of hypersensitivity reactions to Iobenguane Sulfate I 131 is rare. Since hypersensitivity or immune reactions are not concentration dependent, emergency treatment measures should be available.

Cardiac:
Electrocardiographic (ECG) changes have been documented in dogs after the administration of 18 times the mg/m^2 conversion of the maximum human dose of Iobenguane Sulfate I 131. The maximum no observable effect level (NOEL) is not known. It is unknown if Iobenguane Sulfate I 131 can produce changes in ECG recordings in man.

Drug Interactions:
There are literature reports about patients and about in-vitro systems which suggest that the following drugs have the potential to decrease uptake of Iobenguane Sulfate I 131 in neuroendocrine tumors and may lead to false negative results if administered concomitantly: anti-hypertensives (labetalol, reserpine, calcium channel blockers), amitriptyline and derivatives, imipramine and derivatives, doxepin, amoxapin, and loxapin, sympathetic-amines (phenylephrine, phenylpropalamine, pseudoephedrine, ephedrine) and cocaine. The clinical studies were not designed to show which drugs could cause false negative results. It is unknown if other drugs in the same classes have the same potential to inhibit the uptake of Iobenguane Sulfate I131. Increasing the dose of Iobenguane Sulfate I 131 dose will not overcome any potential uptake-limiting effect of these drugs.

Normal biodistribution and excretion of Iobenguane Sulfate I 131 leads to localization in adrenergic storage granules of the adrenal gland. It is also localized in salivary glands, liver, spleen and urinary bladder. As in all nuclear imaging procedures, careful positioning may be useful in distinguishing normal biodistribution of the agent from localization in sites of pathology.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Iobenguane Sulfate I 131 have not been conducted to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy (Category C):
Animal reproduction studies have not been conducted with Iobenguane Sulfate I 131. It is also not known whether Iobenguane Sulfate I 131 can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. Therefore, Iobenguane Sulfate I 131 should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:
I 131 is excreted in human milk; it is not known if Iobenguane Sulfate I 131 is excreted in human milk. Therefore, breast feeding should be substituted with formula feeding until the Iobenguane Sulfate I 131 has cleared from the body of the nursing woman.

Pediatric Use
The safety and effectiveness of Iobenguane Sulfate I 131 have been reasonably established in children with neuroblastoma and pheochromocytoma.

Safety, effectiveness, metabolism, urinary excretion and tumor specificity of Iobenguane Sulfate I 131 is unknown in neonates.

ADVERSE REACTIONS
Transient episodes of marked hypertension have been reported in patients after injection of Iobenguane Sulfate I 131. Some of these patients were on anti-hypertensives and others were not.

Nausea, vomiting and sleepiness have been reported after injection of higher than the recommended doses of Iobenguane Sulfate I 131. The no effect level for these reactions has not been identified. An episode of fever, chills and hypotension has been reported. In clinical trials, no deaths have been attributed to the drug.

DOSAGE AND ADMINISTRATION
Before administration of Iobenguane Sulfate I 131, the patient's thyroid gland should be blocked with Potassium Iodide Oral Solution (120 mg KI/day = 0.12 mL/day) or Lugol's Solution (up to 40 mg I/day = 0.3 mL/day). The blocking iodine should be administered one day before and daily for 5 to 7 days after the dose of Iobenguane Sulfate I 131.

Adults:
The recommended dose in adults is 0.5 mCi. In obese patients over 1.7 m^2 (65 kg), the dose should be 0.3 mCi/m^2 up to a maximum of 1.0 mCi.

Children:
The recommended dose in children is 0.3 mCi/m^2 up to a maximum total dose of 0.5 mCi. The minimum recommended dose for adequate imaging is 0.135 mCi.

Iobenguane Sulfate I 131 should be injected by slow intravenous infusion over 15-30 seconds (longer if necessary). Since the possibility of rebound hypertension exists, the patient's vital signs should be carefully monitored during and after injection.

In order to maintain sterility, it is essential that the user follow directions and adhere to strict aseptic procedure. As in the use of any radioactive material, care should be taken to insure minimum radiation exposure to the patient and clinical personnel.

Waterproof gloves should be worn by the user and a shielded syringe should be used during the preparation and administration of the dose. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

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

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

RADIATION DOSIMETRY
The estimated absorbed radiation doses to adults and children from an intravenous dose of Iobenguane Sulfate I 131 are shown in Table 4.*

Table 4: Estimated Absorbed Radiation Doses*: Iobenguane Sulfate I-131

Organ	Adult		15 Years		10 Years		5 Years		1 Year	
	mGy/ 37MBq	rads/ mCi	mGy/ 18.5MBq	rads/ 0.5mCi	mGy/ 18.5MBq	rads/ 0.5mCi	mGy/ 18.5MBq	rads/ 0.5mCi	mGy/ 18.5MBq	rads/ 0.5mCi
Urinary Bladder Wall	29.6	2.96	18.5	1.85	27.8	2.78	42.6	4.26	83.3	8.33
Liver	29.2	2.92	18.5	1.85	29.6	2.96	42.6	4.26	83.3	8.33
Spleen	21.8	2.18	15.7	1.57	24.1	2.41	38.9	3.89	72.2	7.22
Heart Wall	14.1	1.41	9.1	0.91	14.1	1.41	22.2	2.22	40.7	4.07
Adrenal Medulla	7.8	0.78	5.4	0.54	8.0	0.80	10.7	1.07	16.5	1.65
Gallbladder Wall	5.2	0.52	3.0	0.30	4.3	0.43	6.7	0.67	12.6	1.26
Pancreas	4.1	0.41	2.4	0.24	3.9	0.39	5.9	0.59	10.9	1.09
Thyroid	3.4	0.34	2.6	0.26	4.1	0.41	8.7	0.87	16.5	1.65
Kidneys	3.3	0.33	2.0	0.20	3.1	0.31	4.8	0.48	8.7	0.87
Uterus	3.3	0.33	2.0	0.20	3.3	0.33	5.2	0.52	9.4	0.94
Ovaries	2.7	0.27	1.7	0.17	2.8	0.28	4.3	0.43	8.1	0.81
Total Body	2.3	0.23	1.4	0.14	2.3	0.23	3.3	0.33	6.4	0.64
Testes	2.2	0.22	1.4	0.14	2.2	0.22	3.7	0.37	7.0	0.70
Brain	1.8	0.18	1.1	0.11	1.9	0.19	3.1	0.31	5.9	0.59

*ORISE, Radiation Internal Dose Information Center, Radiation Dose Estimates for I-131 mIBG Intravenous Administration.

The following organs each receive less than 1 rad per procedure: breasts, LLI wall, small intestine, stomach, ULI wall, lungs, muscle, red marrow, bone surfaces, skin and thymus.

If 0.5 mCi of Iobenguane Sulfate I 131 is used, the organ burden would be half of the doses listed above. The thyroid gland estimated burden is in the unblocked state. When the thyroid gland is blocked with Lugol's solution, uptake is minimal.

Peak scans were generally noted at 48 hours post-injection. However, serial scans at 24, 48 and 72 hours post-injection may be needed to optimally define the tumor.

HOW SUPPLIED:
Iobenguane Sulfate I 131 Injection is supplied in a 2 mL glass vial as a sterile, nonpyrogenic solution containing, at calibration time, 85.1 MBq/ml (2.3 mCi/ml) of Iobenguane Sulfate I 131 Injection. Store the drug at freezer temperature (-20 to -10°C).

NOTE:
Two to three hours prior to use, thaw the vial in the leaded container, at room temperature. Discard the unused portion of drug after 4-6 hours if kept at room temperature.

In conformance with USP recommendations, Iodine 131 preparations should not be used after the expiration date stated on the label.

NDC# 0455670100

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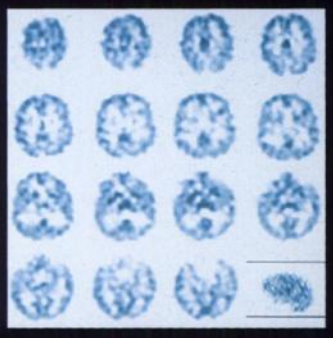

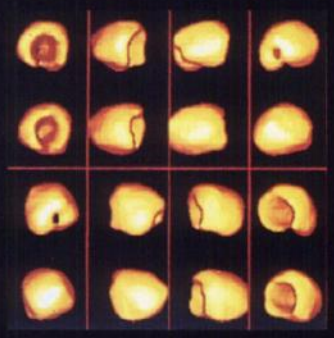

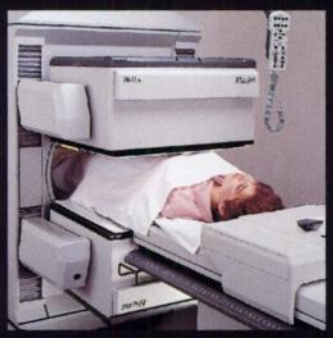

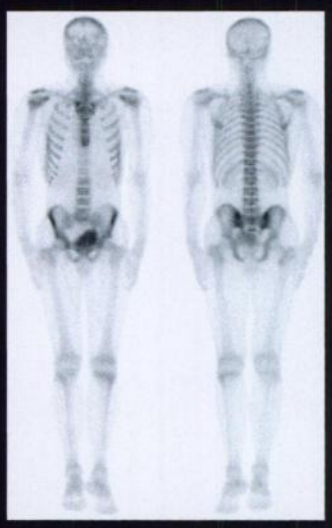

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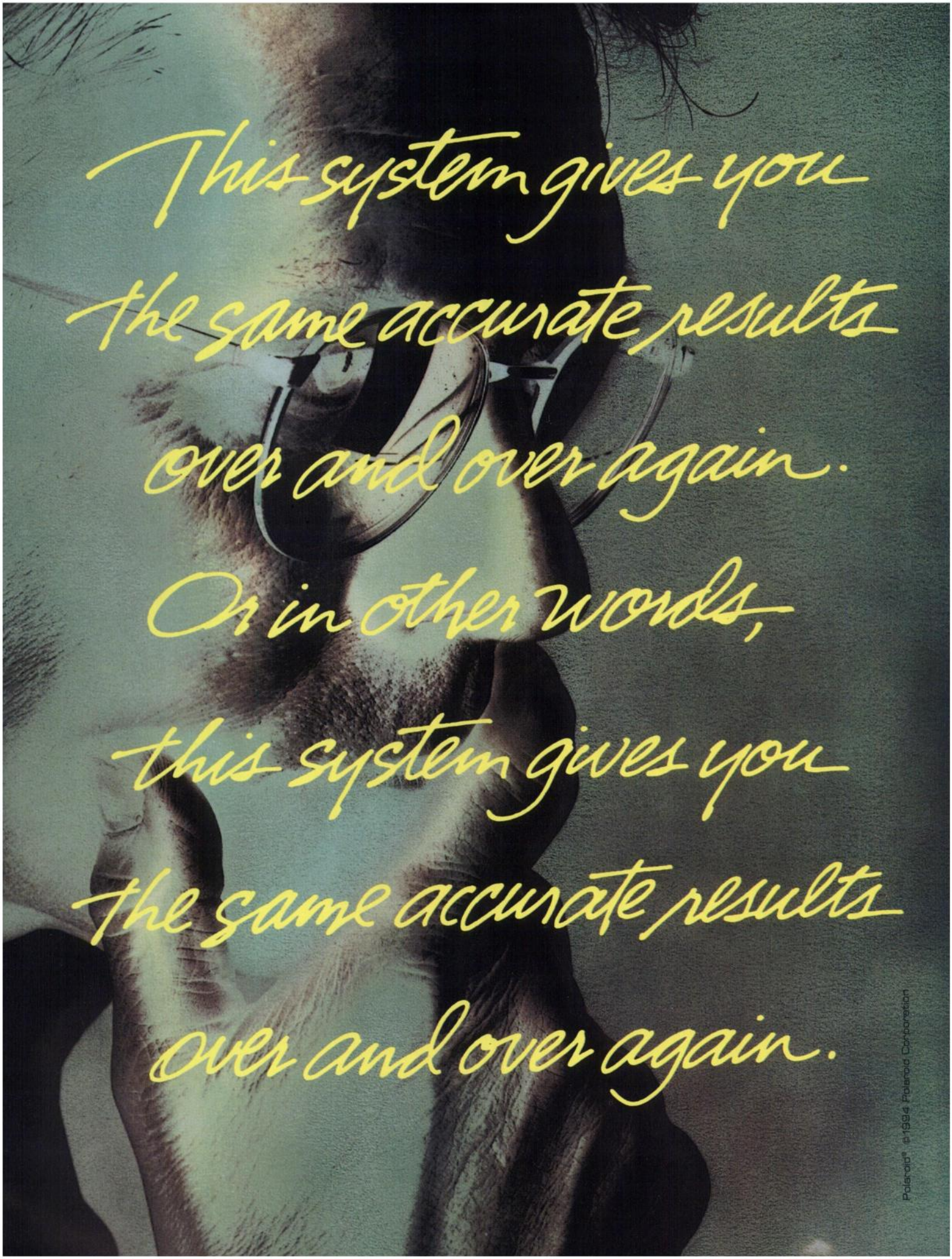
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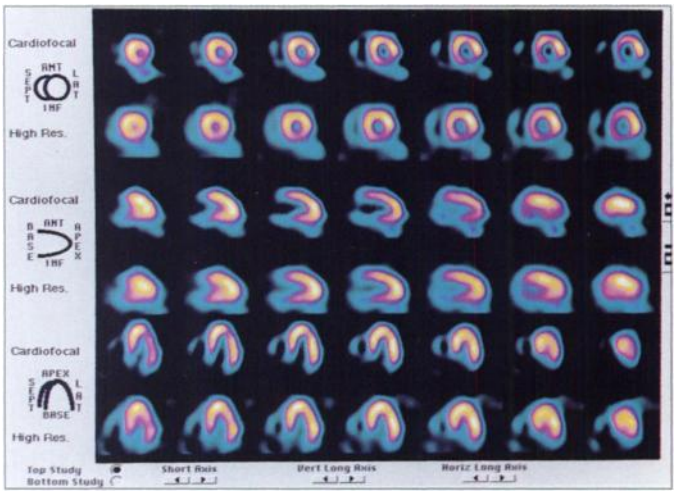

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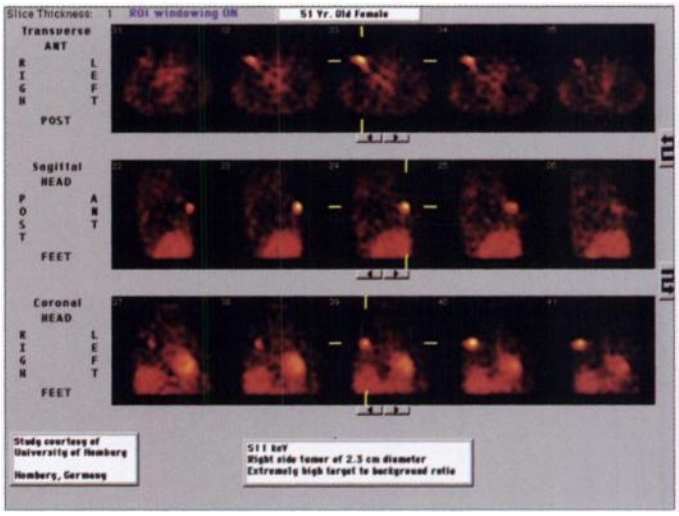

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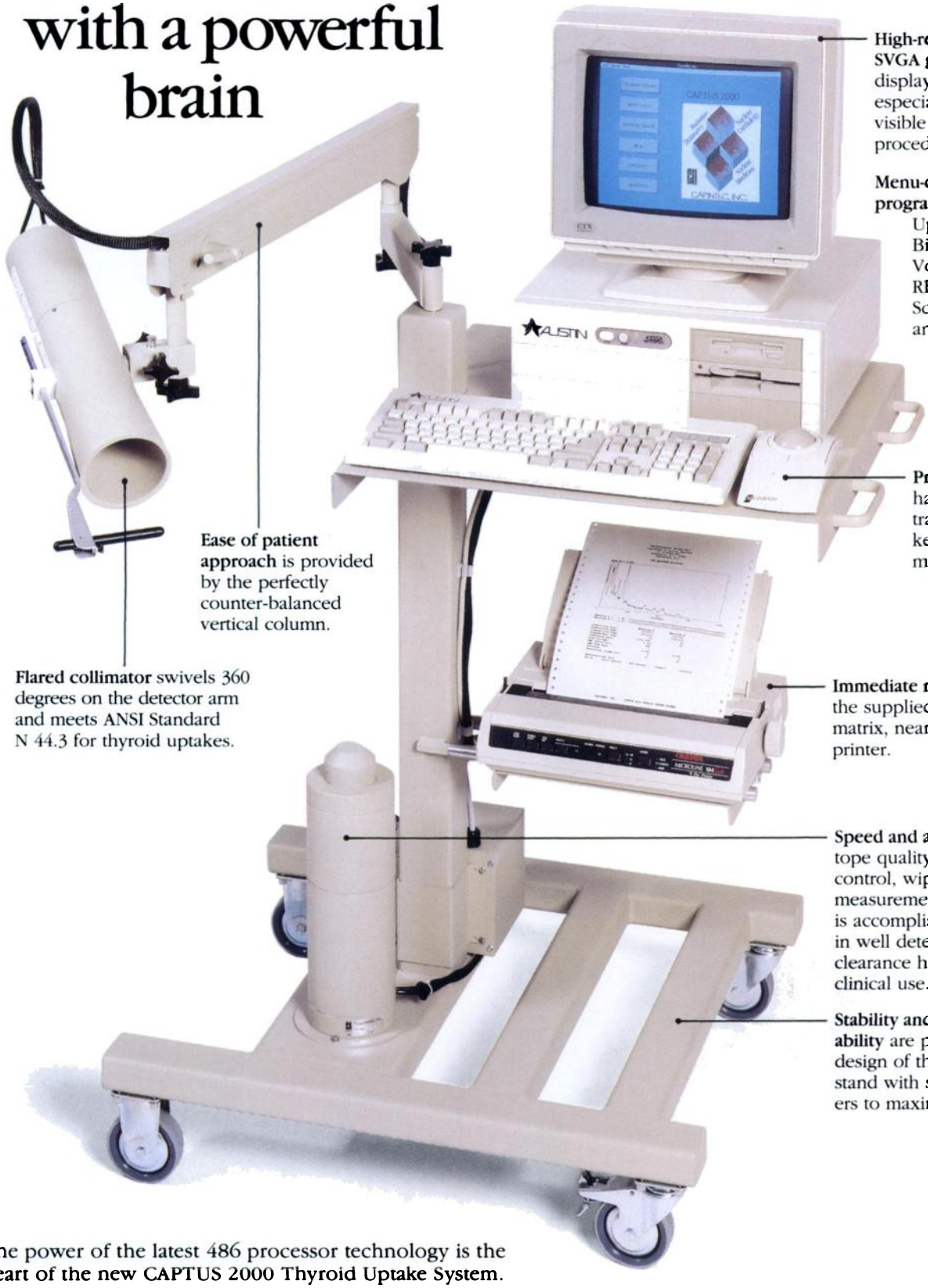

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