SIEMENS

Positively Clinical PET

All the testimony suggests that the positive clinical advantages offered by Positron Emission Tomography are second to none. When combined with Siemens experience servicing the world's largest installed PET base, the same positive clinical advantages can be yours.

Providing you with unequalled patient throughput, Siemens is your partner in PET from beginning to end. The positive clinical advantage is gained with:

- Complete and flexible product line able to meet any institution's research and clinical demands
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- High speed reconstruction processing with Advanced Computational System (ACS)
- SUN® SPARCstation with software tools for qualitative and quantitative analysis
- Superior image quality with less than 5 mm equal resolution in all 3 dimensions
- High patient throughput resulting from system's ease-of-use

For positive clinical advantages in PET Neurology, Cardiology and Oncology—look for Siemens from beginning to end.

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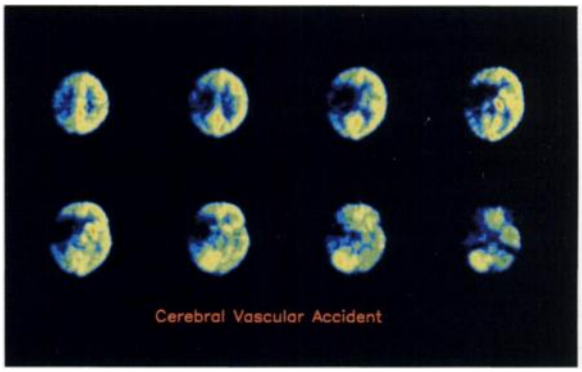
Siemens...
technology in caring hands

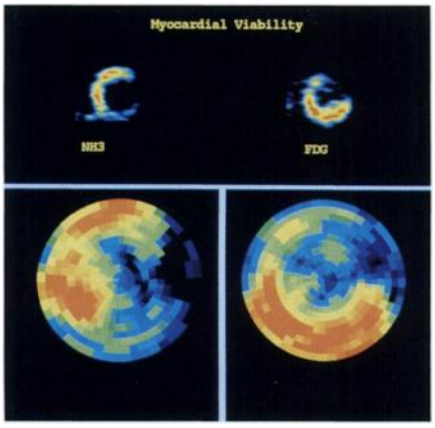
NEUROLOGY



"PET has the ability to measure biochemical responses to disease in the brain prior to gross changes in anatomy and, in some cases, prior to symptom onset resulting in early diagnosis and improved patient management."

John C. Mazziotta, M.D., Ph.D.
President of Institute for Clinical PET (ICP)
Vice-Chairman of Neurology
Professor of Neurology and Radiology
UCLA School of Medicine

CARDIOLOGY



"PET is the only reliable technique currently available to assess myocardial viability. This information is often invaluable in making therapeutic decisions."

Peter Alagona, Jr., M.D.
Associated Medical Director
St. Joseph's Positron Center

ONCOLOGY

"PET provides unique non-invasive information on behavior, treatment response, and recurrence rate of solid tumors. Clinical PET promises to greatly impact the practice of oncology."

Mathis P. Frick, M.D.
Professor and Chairman
Department of Radiology
Creighton University School of Medicine

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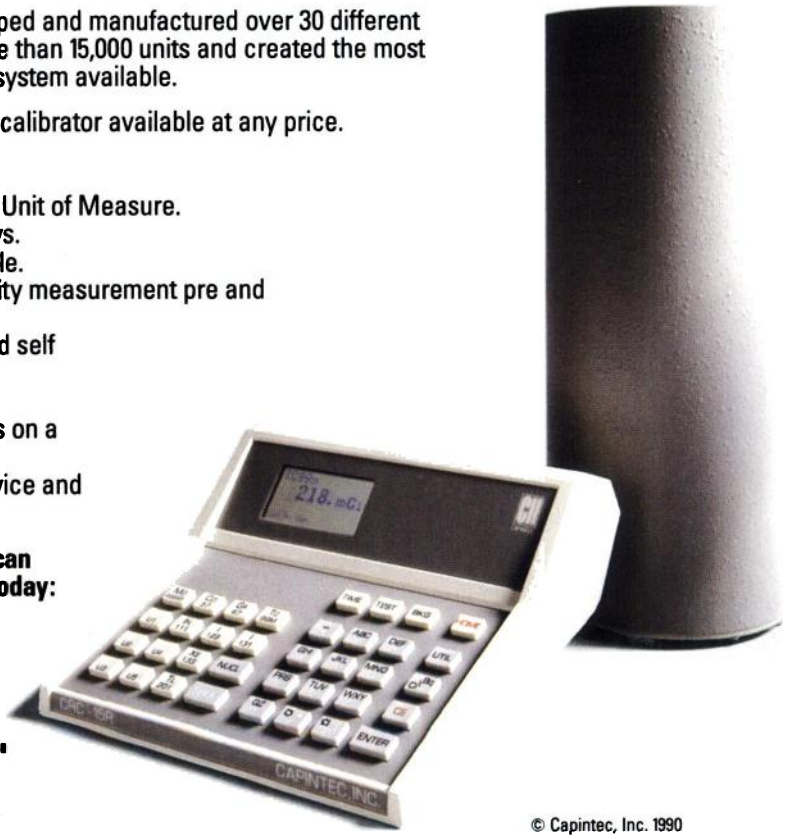

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Toll Free (800) 631-3826 or (201) 825-9500
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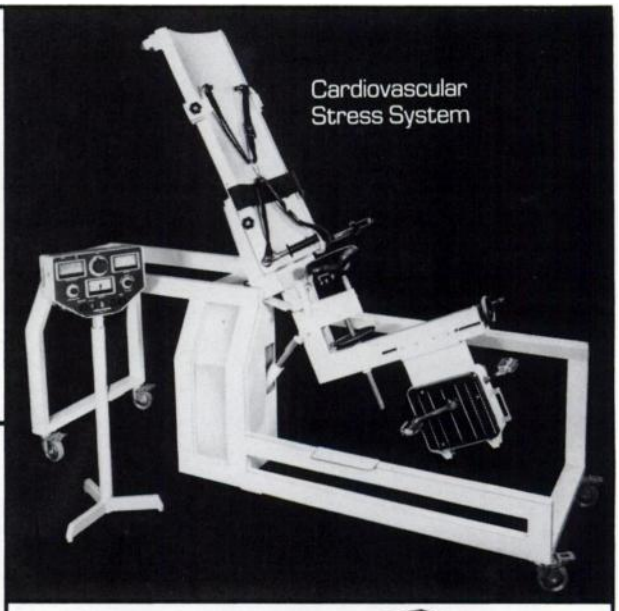

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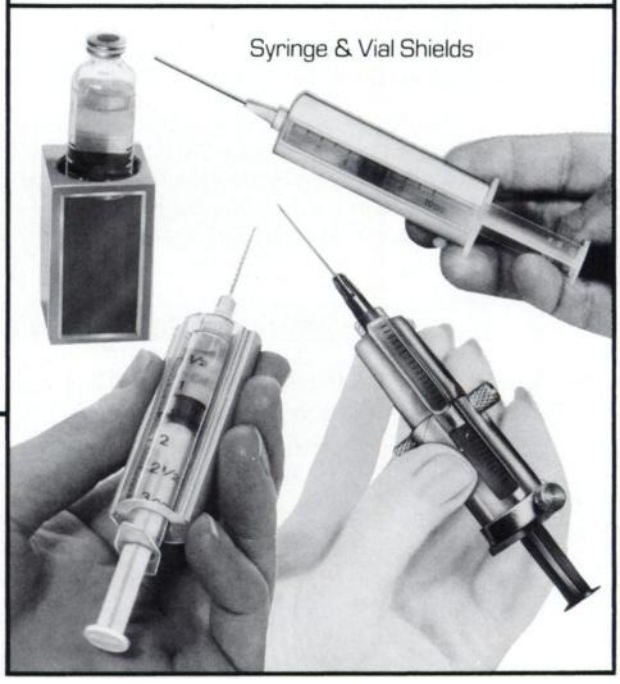

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ELUMATIC III

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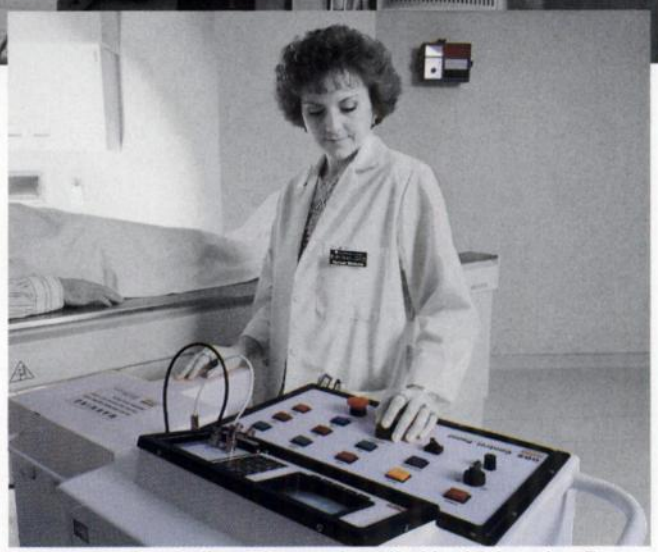
Planning a PET Facility? Victoreen Provides Support . . . Before and After . . .

Victoreen works with you to provide personnel and environmental protection wherever radioactive materials are used or produced.

Let Victoreen help you get your new PET facility off to a good start. Our staff can help you plan and implement an environmental monitoring system customized to fit your needs.

In addition, if you plan to use ^{15}O, our Model 8301 Gas Delivery System enables you to administer gaseous radiopharmaceuticals to the patient. And the release of waste gas can be delayed by our Model 8303 Gas Trap for 10 half-lives reducing radioactive emissions by a factor of 1000.

And don't forget - Victoreen is a full line supplier of survey meters, thermoluminescence dosimetry, personal dosimetry, dose calibrators, and many other Nuclear Medicine accessories.



Victoreen's Gas Delivery System installed in the Imaging Room at Kettering Medical Center in Kettering, Ohio.

For additional information call Victoreen's Customer Service Department (216) 248-9300 or access Vic-Net℠ Customer Service Bulletin Board (216) 248-9043 using your personal computer at 300-1200-2400 Baud, no parity, 8 data bits, 1 stop bit.

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Are you sure that you're getting the

For the right answers to the hard questions, look to GE. No other company offers the comprehensive experience—and resources—you need for a confident investment in PET.

1. How close are clinical applications?

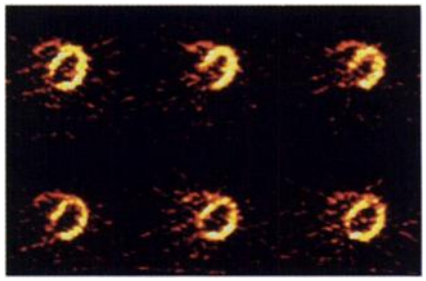
We're very encouraged—in light of the work we're doing with leading institutions in the U.S. and Europe. While some studies are strictly at the research stage, we're also seeing strong evidence of PET's ability to contribute to patient management in cardiology, neurology and oncology. The following chart highlights some emerging applications we feel are most important.

PET: Technology in Transition

	Current Patient Management Indications	Ongoing Research
Cardiology	► Determining myocardial tissue viability. ► Assessing coronary artery disease (CAD).	► Assessing the effectiveness of drug therapy.
Neurology	► Determining seizure foci in epileptic patients.	► Demonstrating biochemical changes associated with behavior disorders such as schizophrenia. ► Differential diagnosis of dementia types such as Alzheimer's and multi-infarct.
Oncology	► Distinguishing recurrent tumor growth from radiation necrosis.	► Sizing and grading of various tumor types. ► Assessing oncologic dose response by monitoring therapy.

2. What about reimbursement?

The good news is that reimbursement is linked to the demonstration of clinical efficacy. Evidence is mounting that PET can improve patient care in such areas as brain and cardiac disorders. Better methods of managing such disorders could dramatically improve the outlook for many patients, while reducing health care costs.

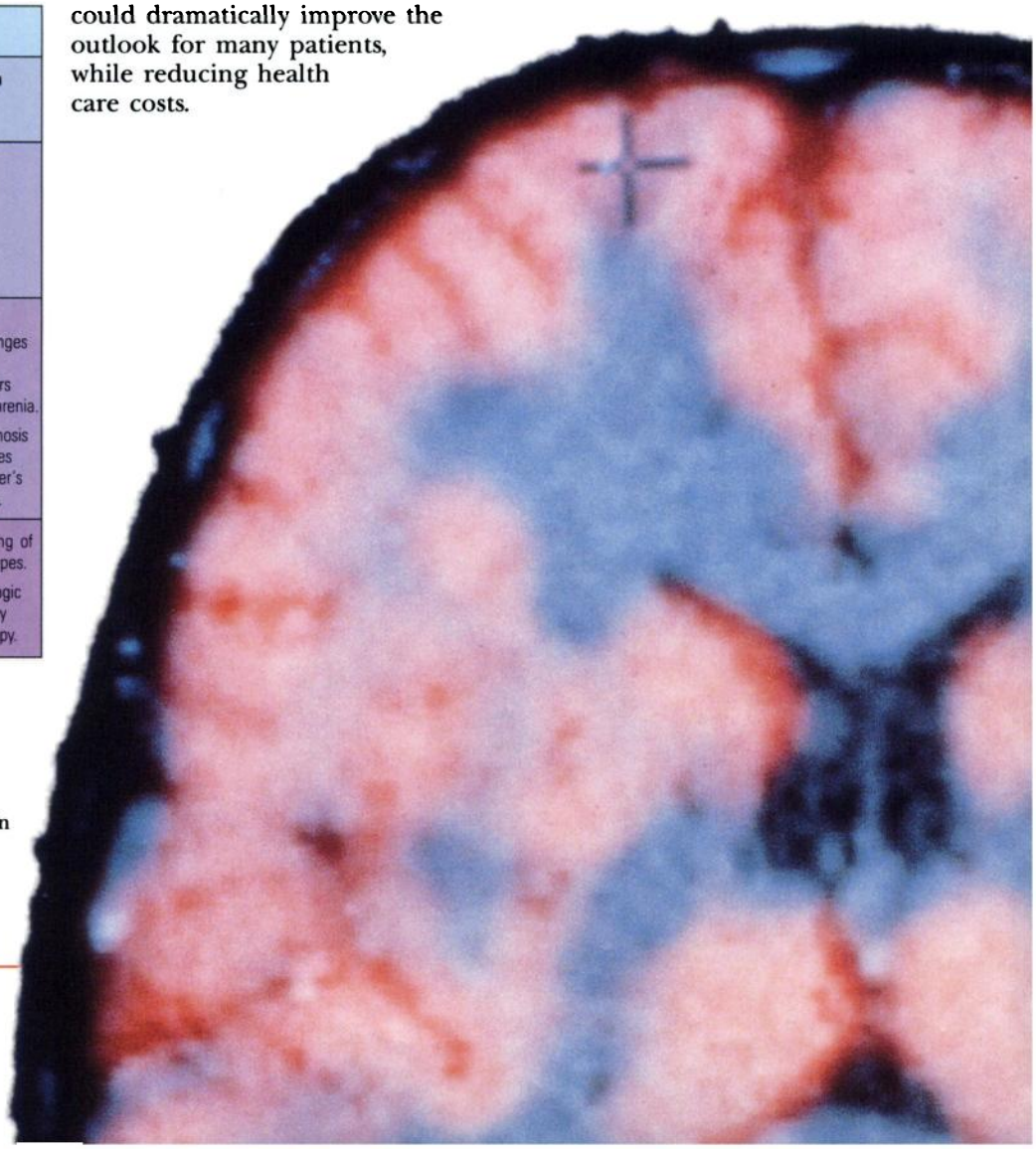


Images courtesy of Uppsala PET Center, Uppsala, Sweden

Reimbursement involves many complex issues that GE is working to resolve, along with PET practitioners, medical societies, regulatory agencies, insurance companies and provider organizations.

3. How do I begin PET site planning?

By talking to the company who has installed more MR systems than any other manufacturer. Site planning came of age with MR. It is now a highly



Combined PET/MR image courtesy of McConnell Brain Imaging Center, Montreal Neurological Institute

big picture in PET?

technical and vitally important part of equipment planning. No other company can match GE's track record for successful installations of complex imaging equipment. Our architects and siting engineers can help you throughout the PET siting process, from preliminary evaluation to system installation.

4. How is GE addressing training and staffing?

From two different approaches. First, through product design. GE engineers are working to simplify scanner operation and tracer production in order to:

- ► Require fewer specialized personnel.
- ► Allow cross-training of technologists.
- ► Simplify training requirements.

By making PET systems easier to operate, GE designers are helping to simplify staffing and training requirements.

Secondly, GE is sponsoring training programs at Uppsala PET Center and Massachusetts General Hospital. Feedback from these sites is shaping the clinically-oriented training programs we provide to new PET customers.

5. What about the economics of PET?

As you know, the sticker price is only part of the equation. Siting, staffing, maintenance and clinical throughput—among other issues—also impact financial planning for PET. GE Medical Systems can help. We routinely assist customers in assessing the short-term and long-range economic impact of new technologies and developing financial strategies for cost-effective acquisition.

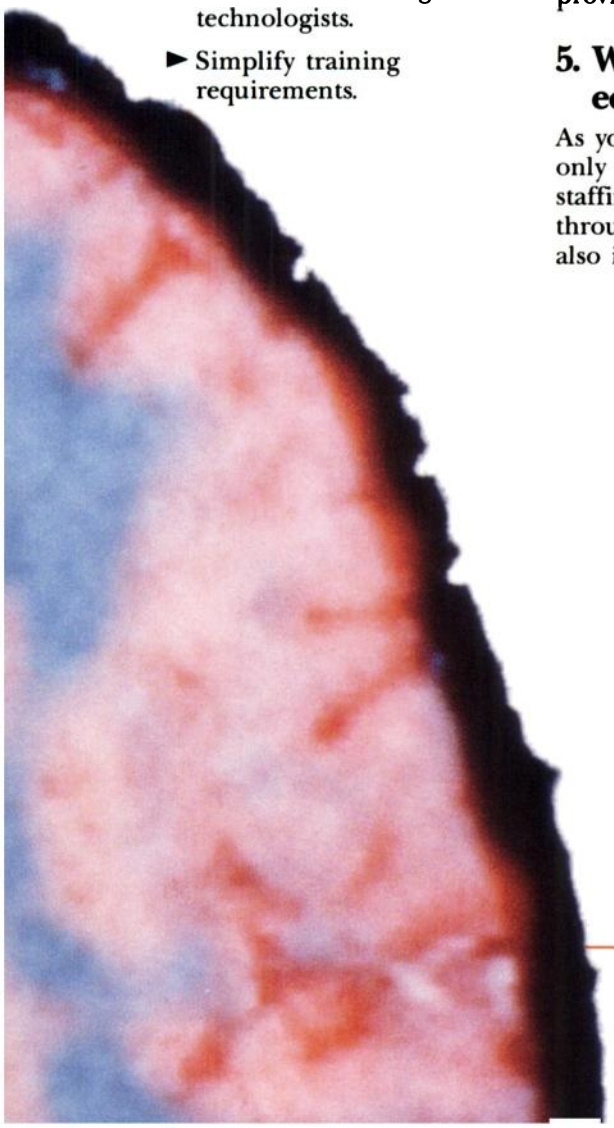
6. At this early stage, how do I avoid technology that will become obsolete?

By proceeding cautiously right now, and looking for a manufacturer with a proven commitment to product continuum. That company is GE. Take MR, for instance. The Signa® MR systems that we shipped 7 years ago are still compatible with every software upgrade and option available today. No other manufacturer can make that claim. And when you're considering a long-term investment in PET, it's important to know that the continuum philosophy is in place and will work for you as well.

7. How do I get the complete picture?

By calling us—the sooner, the better in your planning process. Because a solid investment in PET begins with the right answers—and the right company.

1-800-433-5566



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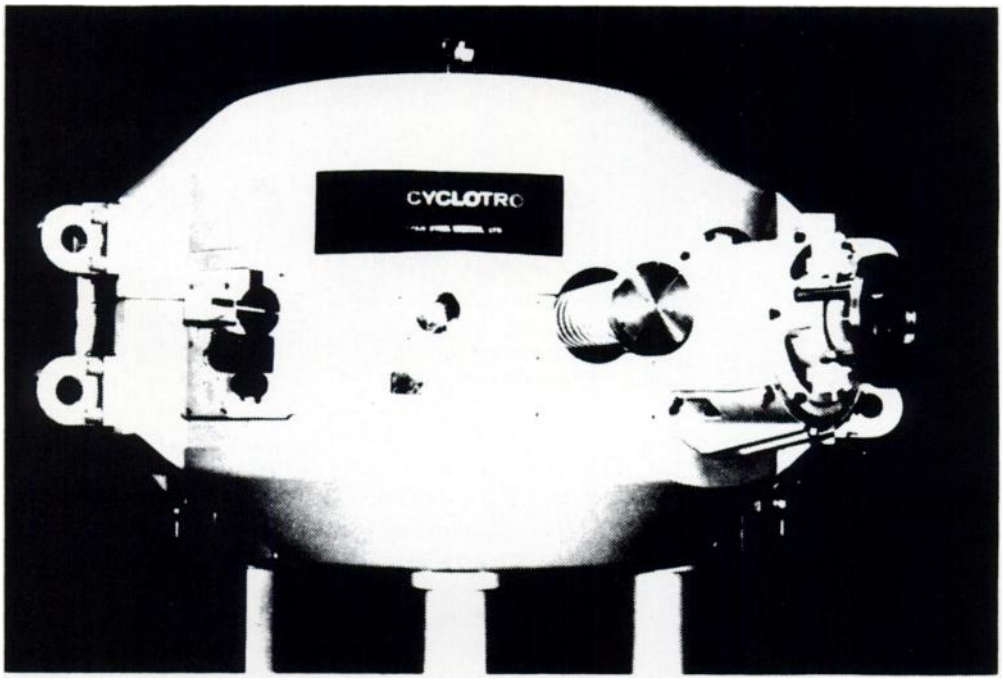
JSW
BABY CYCLOTRON



THE WORLD'S TOP LABORATORIES HAVE INTRODUCED JSW CYCLOTRONS.

- Montreal Neurological Institute (Canada)
- Brookhaven National Laboratory (U.S.A.)
- University of Pennsylvania (U.S.A.)
- National Institutes of Health (U.S.A.)
- Kernforshungsanlage Jülich GmbH (F.R. Germany)
- Washington University (U.S.A.)

JSW IS THE LEADING MAKER OF CYCLOTRONS IN JAPAN.

- JSW has installed 11 (eleven) cyclotrons in research and medical institutes, which is 70% of the cyclotron market in Japan.

QUITE A FEW REASONS FOR RECOMMENDING A JSW CYCLOTRON.

- RELIABILITY
- SIMPLE OPERATION
- STATE-OF-THE-ART DEFLECTOR SEPTUM; OBVIATES THE NEED FOR REPLACEMENT
- HIGH BEAM EFFICIENCY
- EXCELLENT AFTER-SALE SERVICE
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NEW!
CardioTec®
(Kit for the Preparation of Technetium Tc 99m Teboroxime)
THE ONLY TECHNETIUM-BASED AGENT FOR STRESS AND REST
QUICK...
CLEAR...
CLEAN...
CardioTec® Myocardial Perfusion Study
Results

INTRODUCING CARDIOTEC®

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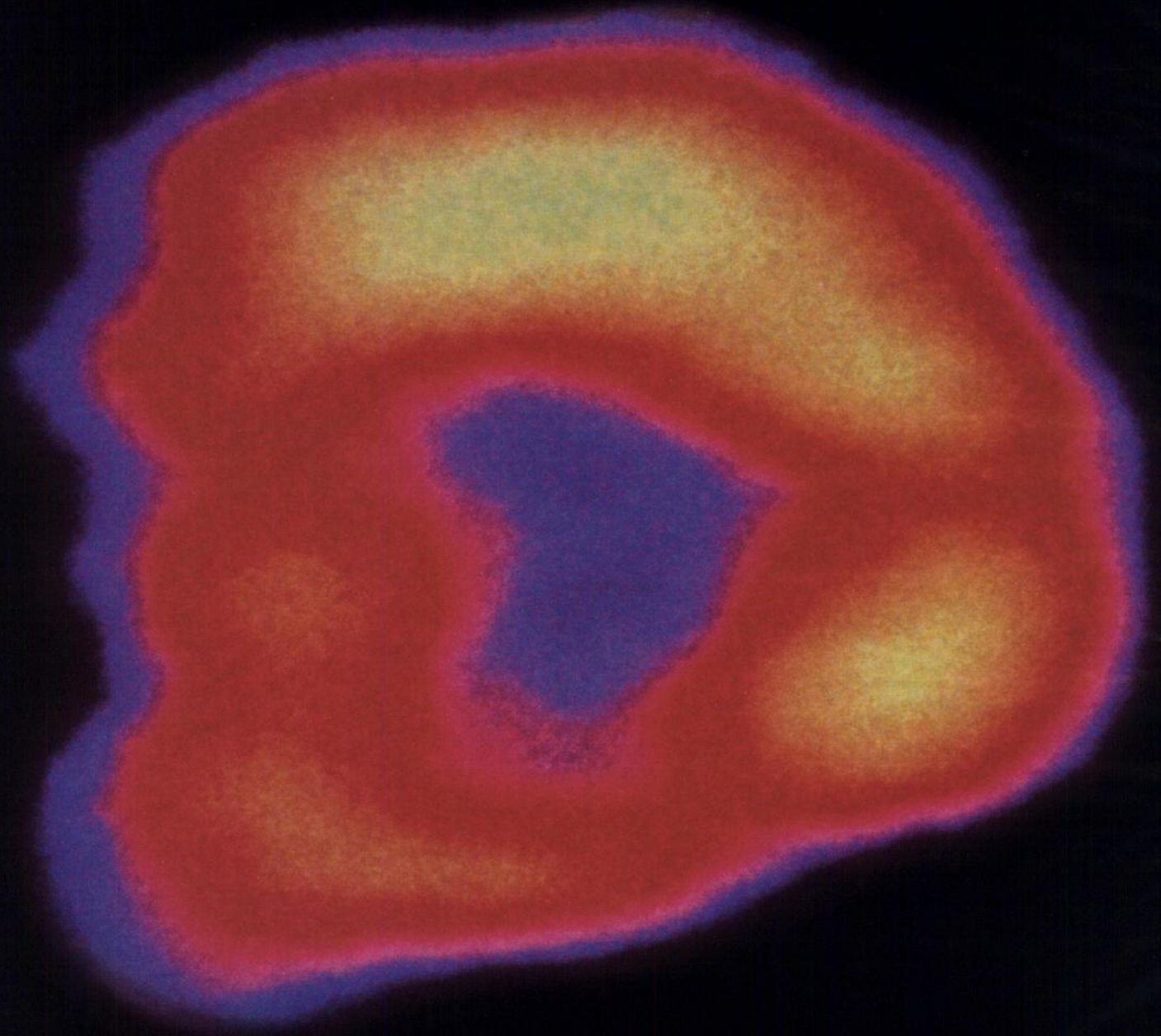
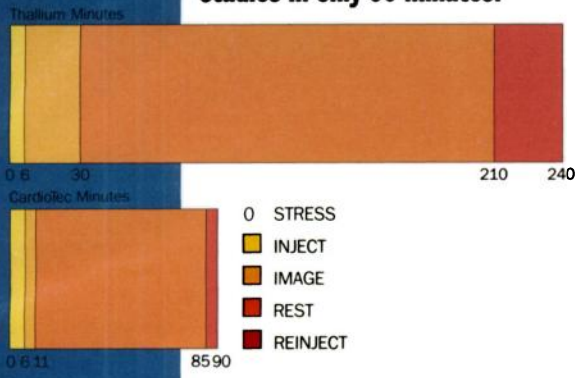
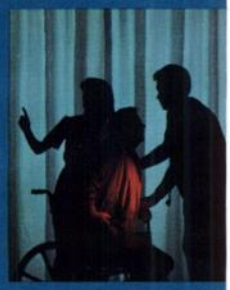


EFFICIENCY REDEFINED

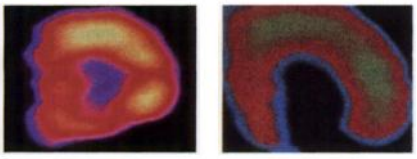
QUICK...
permits complete stress and rest studies in only 90 minutes!

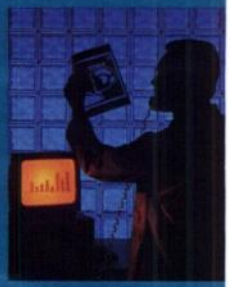




The rapid uptake and washout of CardioTec enables you to start imaging two minutes after injection, and complete a resting-state study within 90 minutes![1] CardioTec speed may let you begin patient treatment earlier, enabling patients to return home sooner, improving throughput and scheduling.

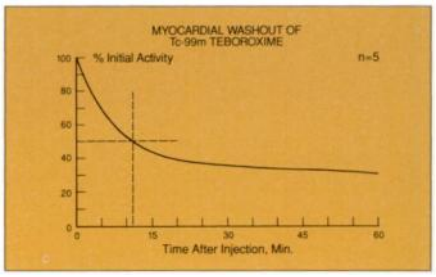
CLEAR...
sharp images enhance diagnostic ability





Good spatial resolution, high myocardial extraction, sensitivity and specificity enhance the ability to distinguish myocardial ischemia and infarction.[1]

CLEAN...
rapid clearance; greater patient comfort



MYOCARDIAL WASHOUT[1]

CardioTec redefines efficiency in myocardial perfusion imaging. *Potential uses for myocardial perfusion agents include imaging patients undergoing post-angioplasty (PTCA), post-surgical (CABG) and post-medicinal (thrombolysis).*

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

CardioTec®

(Kit for the Preparation of Technetium Tc 99m Teboroxime)

Please see the brief summary of prescribing information for CardioTec on the adjacent page.

SQUIBB Diagnostics

Cardiotec®

Kit for the Preparation of Technetium Tc 99m Teboroxime

FOR DIAGNOSTIC USE

DESCRIPTION

Each 5 mL reaction vial contains a sterile, nonpyrogenic, lyophilized formulation of 2.0 mg cyclohexanedione dioxime, 2.0 mg methyl boronic acid, 2.0 mg pentetic acid, 9.0 mg citric acid, anhydrous; 100 mg sodium chloride, 50 mg gamma cyclodextrin and 0.058 mg (maximum) total tin expressed as stannous chloride ($SnCL_2$), 0.020 mg (minimum) stannous chloride ($SnCl_2$). The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The contents of the vial are lyophilized and sealed under nitrogen at the time of manufacture. No bacteriostatic preservative is present.

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

General

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

Contents of the kit before preparation are not radioactive. However, after the addition of sodium pertechnetate Tc 99m injection, adequate shielding of the final preparation must be maintained.

The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration.

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

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

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.8 rads/50 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

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

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

Pregnancy Category C

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

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

Nursing Mothers

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

Pediatric Use

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

ADVERSE REACTIONS

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

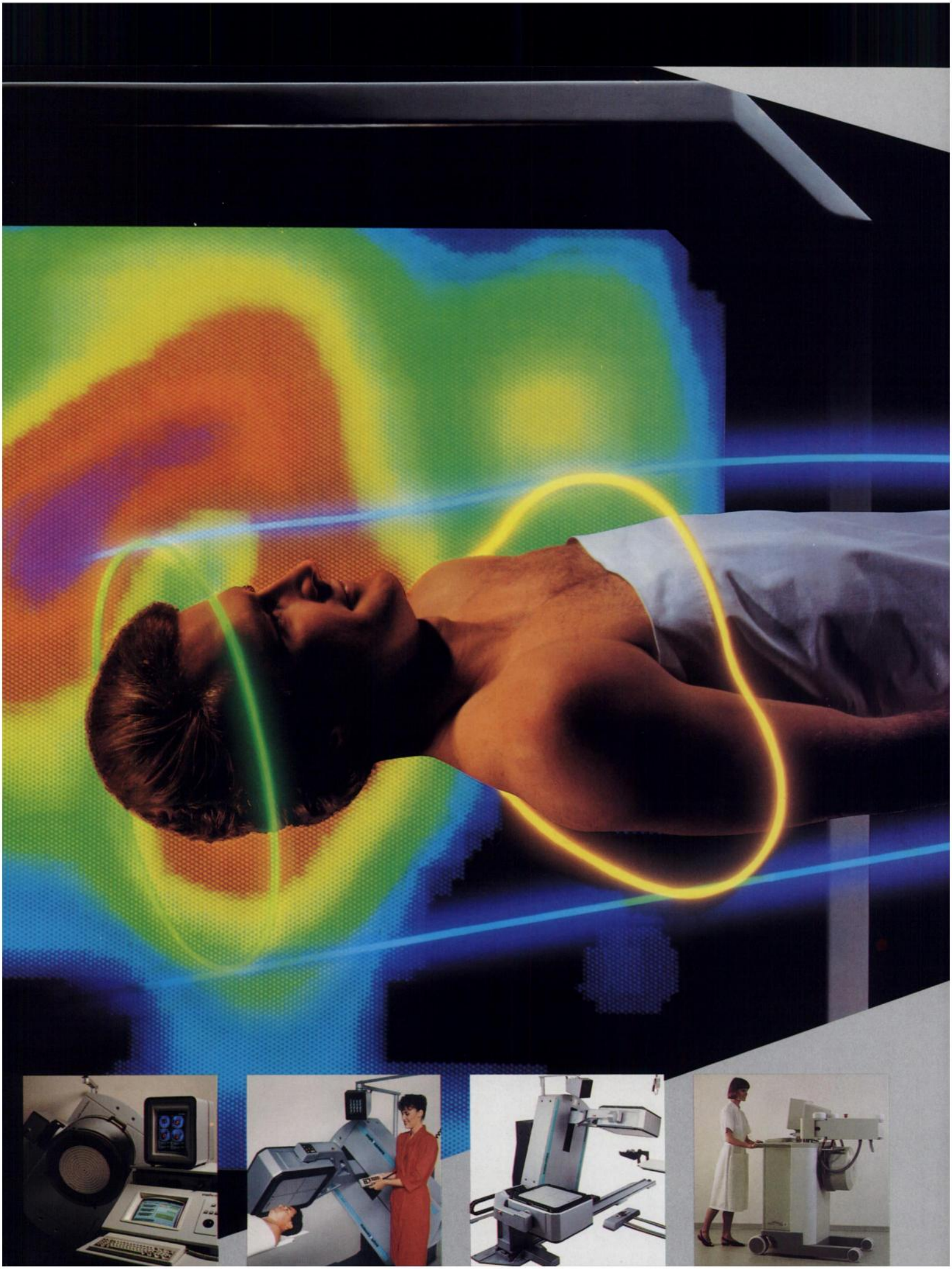
HOW SUPPLIED

Cardiotec® (Kit for the Preparation of Technetium Tc 99m Teboroxime) is supplied in kits of 5, 10, and 25 reaction vials.
(J4-282A)

SQUIBB™ Diagnostics

Reference
1. Data on file, Squibb Diagnostics.

550-502 Issued: March 1991 Printed in U.S.A.



The sophycamera family.
One vision. Many perspectives.

sopha's digital vision

sopha is always first to see it: the connection between digital technology and high performance nuclear imaging.

And that means we can build exclusive advantages into our sophycamera family.

Advantages such as industry-leading detector technology. High-precision robotics. And universal data compatibility.

Advantages such as our digital touchscreen, which makes system control simple and reproducible.

And our new sophy flash-logic processor, which delivers a ten-fold speed advantage over array and RISC architectures.

That's what sopha's digital vision is all about: performance unavailable anywhere else.

sopha's diverse digital family

For every imaging perspective, the sophycamera family offers a specialized system:

- the sophycamera CARDIO, a dedicated cardiac imager
- the sophycamera DS7 circular, a general-purpose/SPECT imager
- the sophycamera DSX rectangular, a general-purpose/SPECT imager
- the sophycamera DSX bodyTrak, a multihead WB/SPECT imager
- the sophycamera DSM, a mobile SFOV imager.

The result?

sopha's digital technology, plus our comprehensive service and support, make the sophycamera family the best value in nuclear medicine today.

And that's an advantage from any perspective.

sopha medical

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"...100% INCREASE IN PET SITES IN TWO YEARS...

It is clear that PET has turned the clinical corner. Clinical PET has proven itself to be of significant influence in the field of diagnostic imaging. The unique information provided by PET is rapidly changing the treatment approach of physicians around the world. "

Markus Schwaiger, MD

Conference Chairman

Associate Professor, Internal Medicine
Director, Cardiovascular Nuclear Medicine
University of Michigan Medical Center
Ann Arbor, Michigan

OCTOBER 24-26, 1991

THIRD ANNUAL INTERNATIONAL PET CONFERENCE

WASHINGTON, DC

Sponsored by

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Institute for Clinical PET

PET: Positron Emission Tomography

This conference has been designed to specifically meet the needs of those professionals in Cardiology, Neurology, Oncology, Radiology and Nuclear Medicine who are involved in ordering, evaluating or interpreting clinical PET studies; Hospital Administrators and all members of the PET community who want to...

Stay Current on the 3r's of PET:

- Regulatory Issues
- Reimbursement
- Radiochemistry and Instrumentation
  - Neurological Applications
  - Evaluation of Malignancies
  - Cardiovascular Applications

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FOR MORE INFORMATION: Institute for Clinical PET (ICP), 205 National Press Building, Washington, DC 20045, Phone 202-466-4274, Fax 703-765-3795.

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☐ Please register me for the Third Annual International PET Conference and send a program for the Conference.
☐ Please send me a Conference program which includes details on the schedule, hotel and travel discounts and ICP membership.

Name _____ Degree(s) _____
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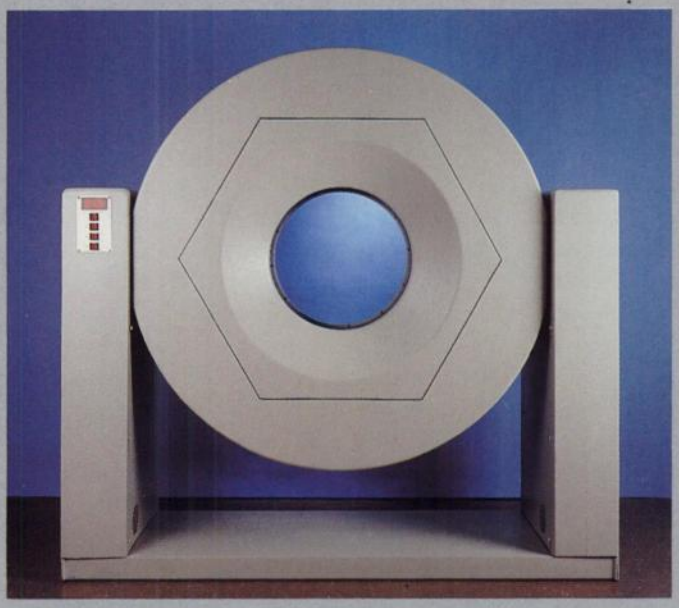

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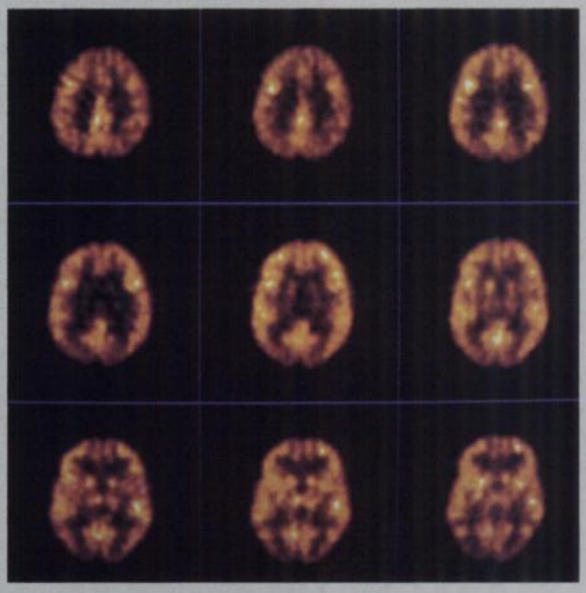

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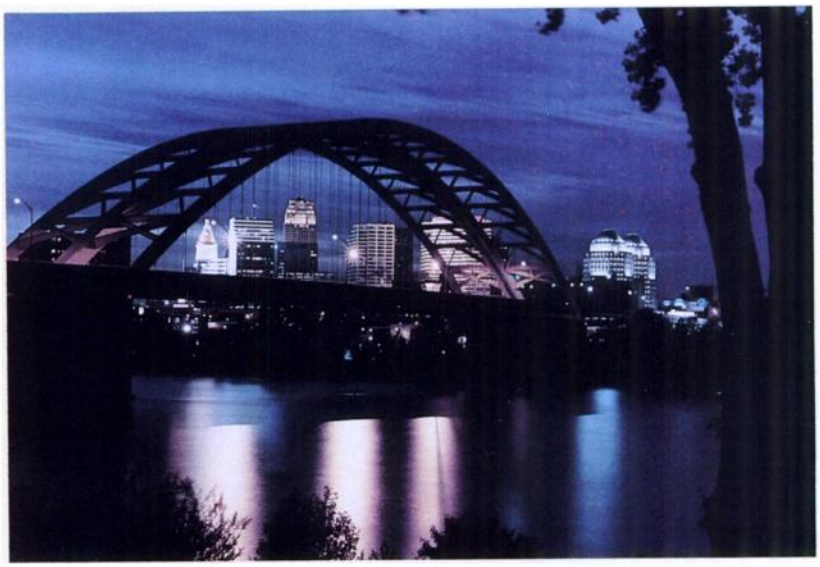

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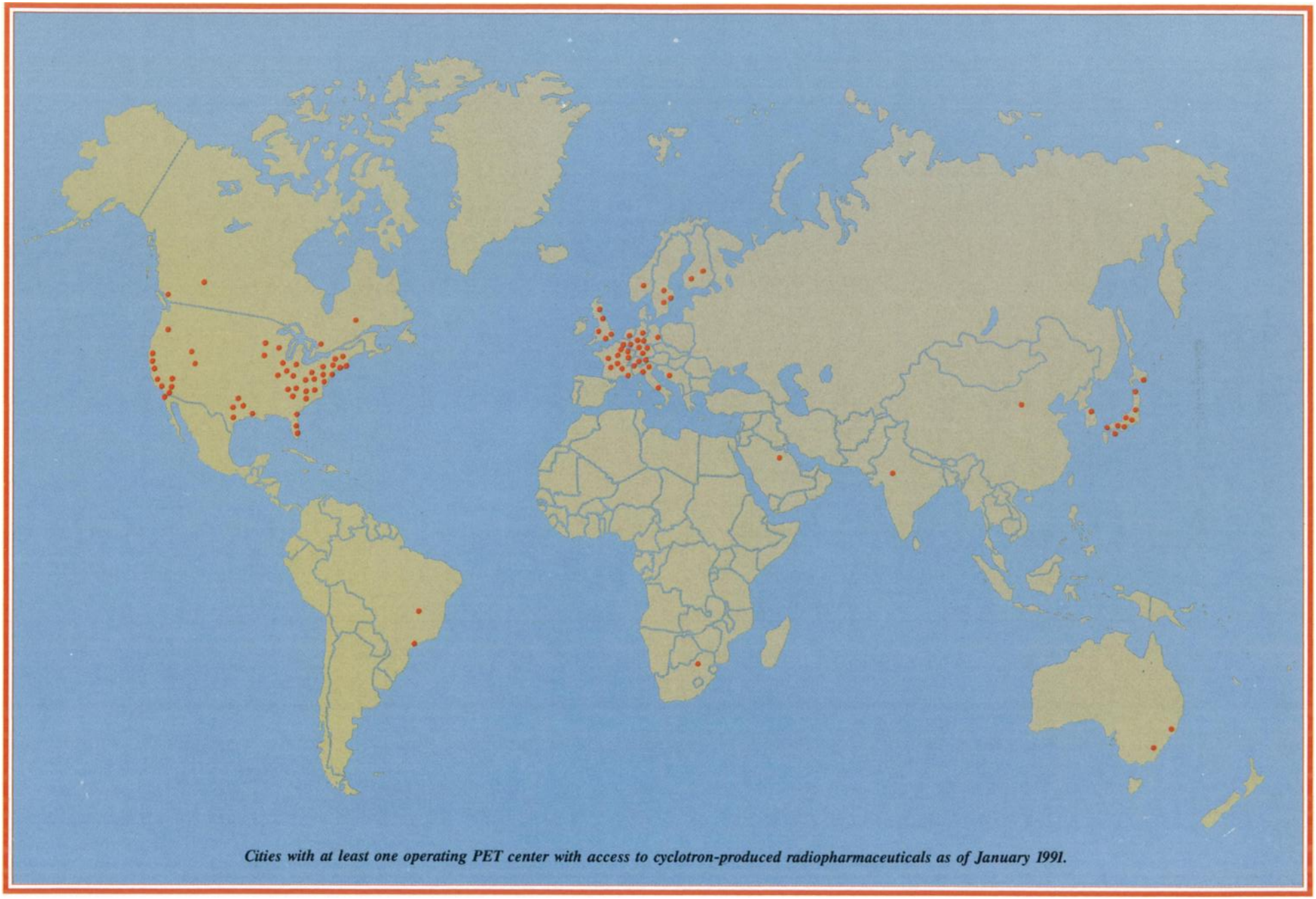

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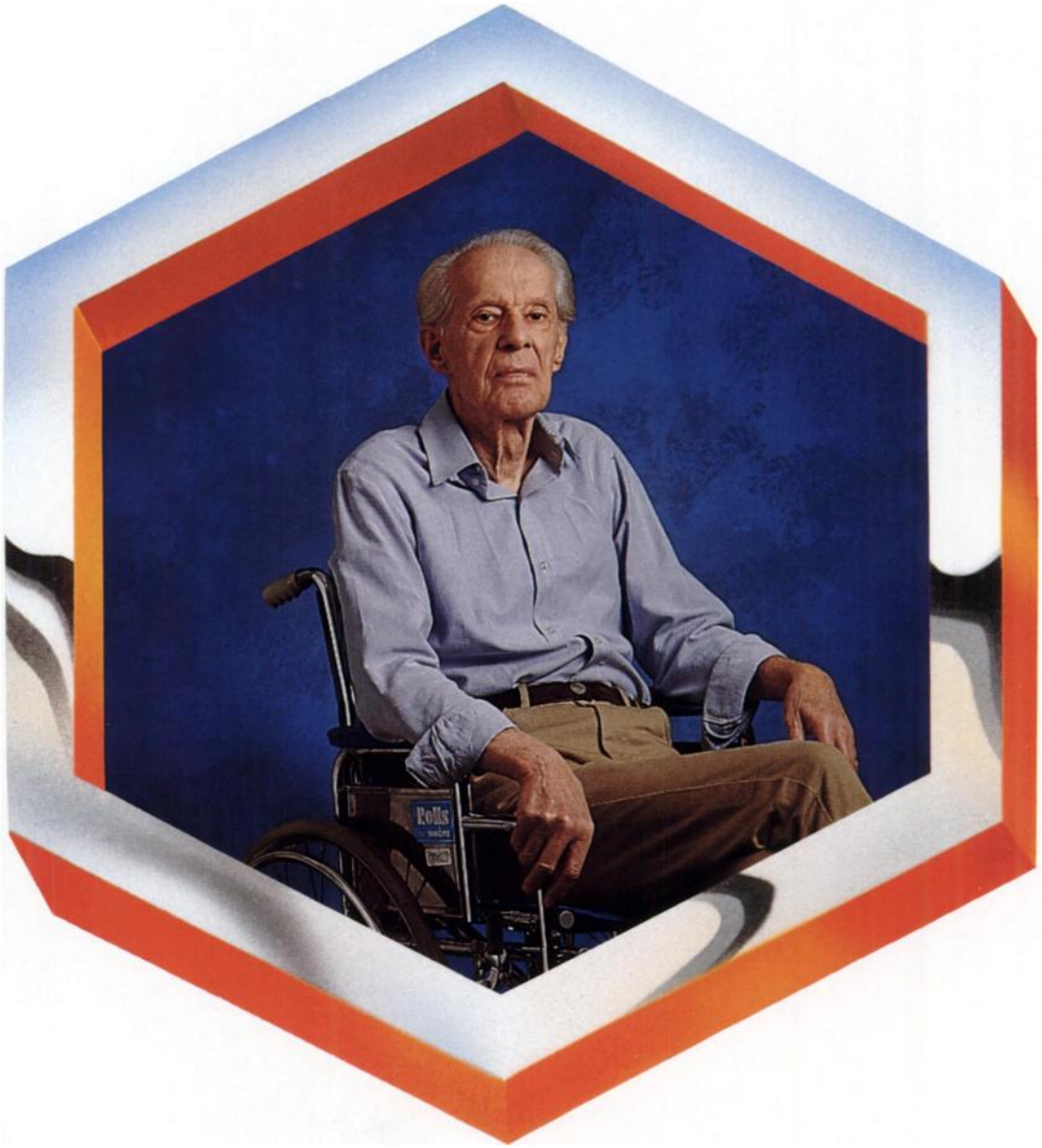

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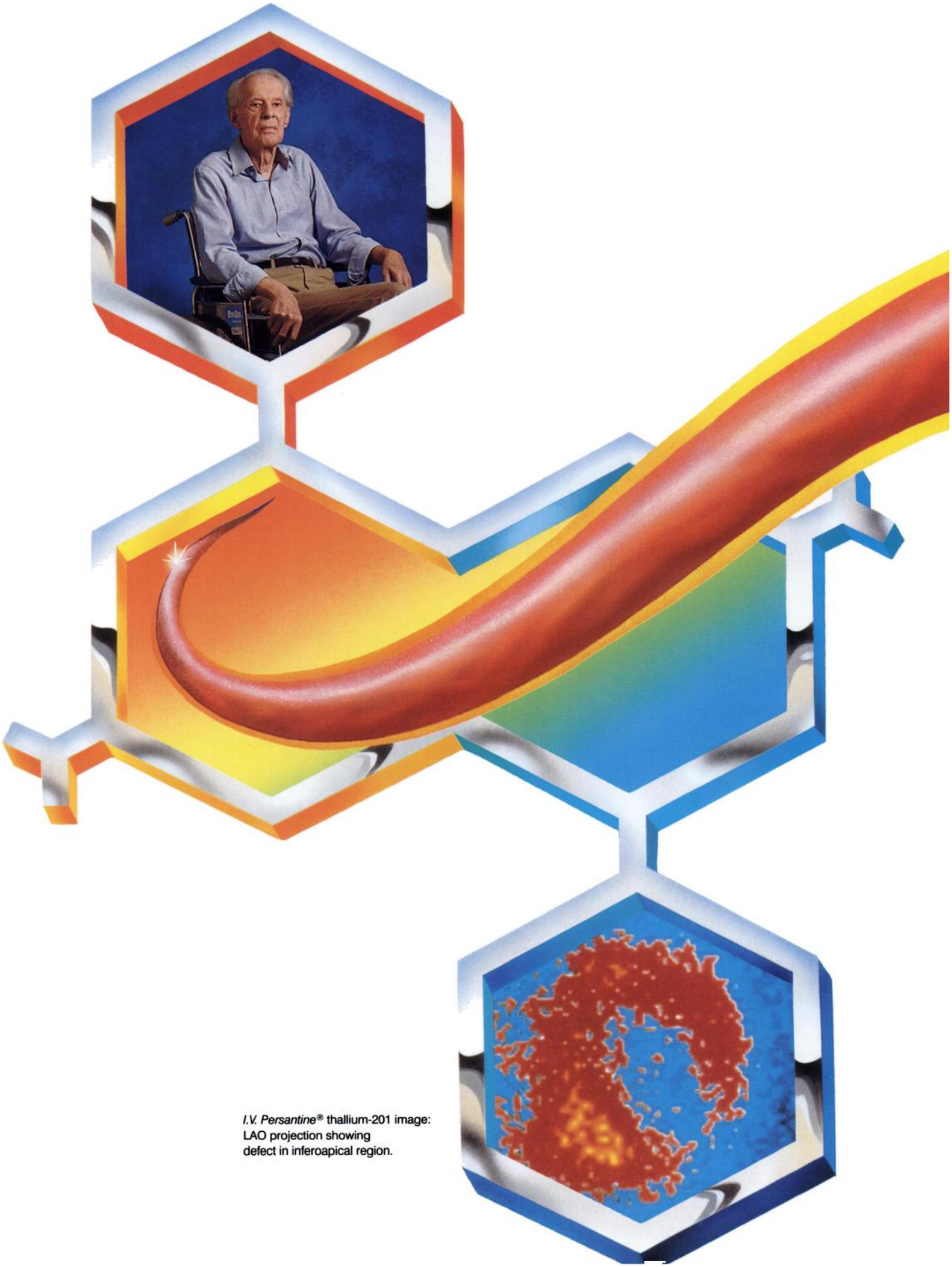

I.V. Persantine® thallium-201 image:
LAO projection showing
defect in inferoapical region.

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  - Those with compromised peripheral vascular or cardiovascular status
  - Those with prohibitive physical disabilities or frailty
  - Those on concurrent pharmacologic therapy such as beta-blockers
- Equivalent in sensitivity and specificity to exercise stress testing with thallium in detection of CAD[2]
- Safety profile established in over 10 years of clinical testing[3,4‡]
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†Patients with a history of unstable angina may be at a greater risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm.

‡Side effects are usually mild and can include chest pain, dizziness, headache, hypotension, and nausea.

References:
1. Iskandrian AS, Heo J, Askenase A, et al: *Am Heart J* 1988; 115:432-443.
2. Leppo JA: *J Nucl Med* 1989; 30:281-287.
3. Ranhosky A, Kempthorne-Rawson J, et al: *Circulation* 1990; 81:1205-1209.
4. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT.

Please see prescribing information on last page of ad for contraindications, warnings, and adverse reactions.

DUPONT

THALLOUS CHLORIDE Tl 201
DIAGNOSTIC FOR
INTRAVENOUS USE

DESCRIPTION: Thallous Chloride Tl 201 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The aqueous solution at the time of calibration contains 37MBq/ml (1mCi/ml) Thallous Chloride Tl 201. The pH is adjusted with hydrochloric acid and/or sodium hydroxide solution. It is made isotonic with 9mg/ml sodium chloride and is preserved with 9mg/ml benzyl alcohol.
Thallium Tl 201 is cyclotron produced with no carrier added and contains no less than 98% Thallium Tl 201 as a percentage of total activity with contaminants less than 0.3% Thallium Tl 200, 1.2% Thallium Tl 202, and 0.2% Lead Pb 203 expressed as a percentage of Tl 201 activity at calibration.
It is recommended that Thallous Chloride Tl 201 be administered close to calibration time to minimize the effect of higher levels of radionuclide contaminant.

INDICATIONS AND USAGE: Thallous Chloride Tl 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also have prognostic value regarding survival, when used in the clinically stable patient following the onset of symptoms of an acute myocardial infarction, to assess the site and size of the perfusion defect.
Thallous Chloride Tl 201 may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).
It is usually not possible to differentiate recent from old myocardial infarction, or to differentiate exactly between recent myocardial infarction and ischemia.
Thallous Chloride Tl 201 is indicated also for the localization of sites of parathyroid hyperactivity in patients with elevated serum calcium and parathyroid hormone levels. It may also be useful in pre-operative screening to localize extrathyroidal and mediastinal sites of parathyroid hyperactivity and for post-surgical reexamination. Thallous Chloride Tl 201 has not been adequately demonstrated to be effective for the localization of normal parathyroid glands.

CONTRAINDICATIONS: None known.

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

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

GENERAL: Do not use after the expiration time and date (5 days maximum after calibration time) stated on the label.
Do not use if contents are turbid.
The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.
Thallous Chloride Tl 201, as all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.
Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential, or whether Thallous Chloride Tl 201 affects fertility in males or females.
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.
Pregnancy Category C: Adequate reproductive studies have not been conducted in animals with Thallous Chloride Tl 201. It is also not known whether Thallous Chloride Tl 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride Tl 201 should not be given to a pregnant woman except when benefits clearly outweigh the potential risks.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, nursing should not be undertaken when a patient is administered radioactive material.
Pediatric Use: Safety and effectiveness in children below the age of 18 have not been established.
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.

ADVERSE REACTIONS: A single adverse reaction to the administration of Thallous Chloride Tl 201 has been reported consisting of hypotension accompanied by pruritus and a diffuse rash which responded to antihistamines and steroids within one hour.

HOW SUPPLIED: Thallous Chloride Tl 201 for intravenous administration is supplied as a sterile, nonpyrogenic solution containing at calibration time 37MBq/ml (1mCi/ml) of Thallous Chloride Tl 201, 9mg/ml sodium chloride, and 9mg/ml of benzyl alcohol. The pH is adjusted with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 81.4, 122.1, 162.8, 244.2, 325.6 and 366.3MBq (2.2, 3.3, 4.4, 6.6, 8.8 and 9.9mCi) of Thallous Chloride Tl 201.
Store at room temperature (15-30°C).

DU PONT

E.I. du Pont de Nemours & Co.
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Printed in U.S.A.
August 1988

IV PERSANTINE®
(dipyridamole USP) **For Intravenous Injection**
Prescribing Information

INDICATIONS AND USAGE IV Persantine® (dipyridamole USP) is indicated as an alternative to exercise in thallium myocardial perfusion imaging for the evaluation of coronary artery disease in patients who cannot exercise adequately.

CONTRAINDICATIONS Hypersensitivity to dipyridamole.

WARNINGS Serious adverse reactions associated with the administration of intravenous Persantine® (dipyridamole USP) have included fatal and non-fatal myocardial infarction, ventricular fibrillation, symptomatic ventricular tachycardia, transient cerebral ischemia, and bronchospasm.
In a study of 3911 patients given intravenous Persantine as an adjunct to thallium myocardial perfusion imaging, two types of serious adverse events were reported: 1) four cases of myocardial infarction (0.1%), two fatal (0.05%); and two non-fatal (0.05%); and 2) six cases of severe bronchospasm (0.2%). Although the incidence of these serious adverse events was small (0.3%,10 of 3911), the potential clinical information to be gained through use of intravenous Persantine thallium imaging (see Indications and Usage noting the rate of false positive and false negative results) must be weighed against the risk to the patient. Patients with a history of unstable angina may be at a greater risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm during IV Persantine use.
When thallium myocardial perfusion imaging is performed with intravenous Persantine, parenteral aminophylline should be readily available for relieving adverse events such as bronchospasm or chest pain. Vital signs should be monitored during, and for 10-15 minutes following, the intravenous infusion of Persantine and an electrocardiographic tracing should be obtained using at least one chest lead.
Should severe chest pain or bronchospasm occur, parenteral aminophylline may be administered by slow intravenous injection (50-100 mg over 30-60 seconds) in doses ranging from 50 to 250 mg. In the case of severe hypotension, the patient should be placed in a supine position with the head tilted down if necessary, before administration of parenteral aminophylline. If 250 mg of aminophylline does not relieve chest pain symptoms within a few minutes, sublingual nitroglycerin may be administered. If chest pain continues despite use of aminophylline and nitroglycerin, the possibility of myocardial infarction should be considered. If the clinical condition of a patient with an adverse event permits a one minute delay in the administration of parenteral aminophylline, thallium-201 may be injected and allowed to circulate for one minute before the injection of aminophylline. This will allow initial thallium perfusion imaging to be performed before reversal of the pharmacologic effects of Persantine on the coronary circulation.

PRECAUTIONS See WARNINGS.
Drug Interactions Oral maintenance theophylline may abolish the coronary vasodilatation induced by intravenous Persantine® (dipyridamole USP) administration. This could lead to a false negative thallium imaging result.
Carcinogenesis, Mutagenesis, Impairment of Fertility In studies in which dipyridamole was administered in the feed at doses of up to 75 mg/kg/day (9.4 times* the maximum recommended daily human oral dose) in mice (up to 128 weeks in males and females) there was no evidence of drug related carcinogenesis. Mutagenicity tests of dipyridamole with bacterial and mammalian cell systems were negative. There was no evidence of impaired fertility when dipyridamole was administered to male and female rats at oral doses up to 500 mg/kg/day (63 times* the maximum recommended daily human oral dose). A significant reduction in number of corpora lutea with consequent reduction in implantations and live fetuses was, however, observed at 1250 mg/kg/day.
*Calculation based on assumed body weight of 50 kg.
Pregnancy Category B Reproduction studies performed in mice and rats at daily oral doses of up to 125 mg/kg (15.6 times* the maximum recommended daily human oral dose) and in rabbits at daily oral doses of up to 20 mg/kg (2.5 times* the maximum recommended daily human oral dose) have revealed no evidence of impaired embryonic development due to dipyridamole. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.
*Calculation based on assumed body weight of 50 kg.
Nursing Mothers Dipyridamole is excreted in human milk.
Pediatric Use Safety and effectiveness in children have not been established.

ADVERSE REACTIONS Adverse reaction information concerning intravenous Persantine® (dipyridamole USP) is derived from a study of 3911 patients in which intravenous Persantine was used as an adjunct to thallium myocardial perfusion imaging and from spontaneous reports of adverse reactions and the published literature.
Serious adverse events (fatal and non-fatal myocardial infarction, severe ventricular arrhythmias, and serious CNS abnormalities) are described above (see WARNINGS).
In the study of 3911 patients, the most frequent adverse reactions were: chest pain/angina pectoris (19.7%), electrocardiographic changes (most commonly ST-T changes) (15.9%), headache (12.2%), and dizziness (11.8%).
Adverse reactions occurring in greater than 1% of the patients in the study are chest pain/angina pectoris (19.7%), headache (12.2%), dizziness (11.8%), electrocardiographic abnormalities/ST-T changes (7.5%), electrocardiographic abnormalities/extrasystoles (5.2%), hypotension (4.6%), nausea (4.6%), flushing (3.4%), electrocardiographic abnormalities/tachycardia (3.2%), dyspnea (2.6%), pain unspecified (2.6%), blood pressure lability (1.6%), hypertension (1.5%), paresthesia (1.3%), fatigue (1.2%).
Less common adverse reactions occurring in 1% or less of the patients within the study included:
Cardiovascular System: Electrocardiographic abnormalities unspecified (0.8%), arrhythmia unspecified (0.6%), palpitation (0.3%), ventricular tachycardia (0.2% see WARNINGS), bradycardia (0.2%), myocardial infarction (0.1% see WARNINGS), AV block (0.1%), syncope (0.1%), orthostatic hypotension (0.1%), atrial fibrillation (0.1%), supraventricular tachycardia (0.1%), ventricular arrhythmia unspecified (0.03% see WARNINGS), heart block unspecified (0.03%), cardiomyopathy (0.03%), edema (0.03%).
Central and Peripheral Nervous System: Hypothesia (0.5%), hypertonia (0.3%), nervousness/anxiety (0.2%), tremor (0.1%), abnormal coordination (0.03%), somnolence (0.03%), dysphonia (0.03%), migraine (0.03%), vertigo (0.03%).
Gastrointestinal System: Dyspepsia (1.0%), dry mouth (0.8%), abdominal pain (0.7%), flatulence (0.6%), vomiting (0.4%), eructation (0.1%), dysphagia (0.03%), tenesmus (0.03%), appetite increased (0.03%).
Respiratory System: Pharyngitis (0.3%), bronchospasm (0.2% see WARNINGS), hyperventilation (0.1%), rhinitis (0.1%), coughing (0.03%), pleural pain (0.03%).
Other: Myalgia (0.9%), back pain (0.6%), injection site reaction unspecified (0.4%), diaphoresis (0.4%), asthenia (0.3%), malaise (0.3%), arthralgia (0.3%), injection site pain (0.1%), rigor (0.1%), earache (0.1%), tinnitus (0.1%), vision abnormalities unspecified (0.1%), dysgeusia (0.1%), thirst (0.03%), depersonalization (0.03%), eye pain (0.03%), renal pain (0.03%), perineal pain (0.03%), breast pain (0.03%), intermittent claudication (0.03%), leg cramping (0.03%).
Caution Federal law prohibits dispensing without prescription.

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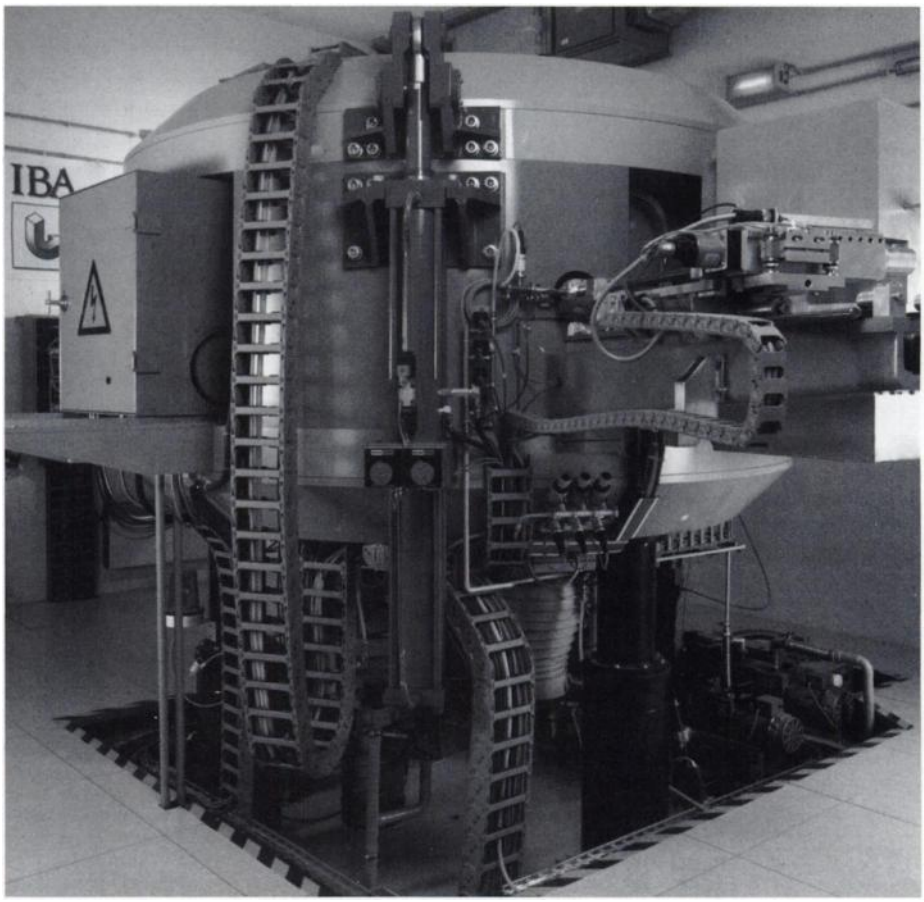
ERASME HOSPITAL REINFORCES ITS DIAGNOSTIC CAPABILITIES WITH A CYCLONE 30

By André De Laet, Chief editor of TECHNOPOLE

The University of Brussels (ULB) has chosen IBA's Cyclone 30 to equip its new Positron Emission Tomography (P.E.T.) Center located at Erasme Hospital in Brussels. The Cyclone 30 cyclotron complements existing diagnostic and research capabilities serving Belgium's university hospitals.

Designed, manufactured and installed from IBA's headquarters in Louvain-la-Neuve, the Erasme cyclotron is only one of ten Cyclone 30s sold within the past 3 years and one of five already operational around the world. Having passed the acceptance tests, the 30 MeV, negative-ion cyclotron was officially accepted by the hospital in October 1990.

The co-directors of the new P.E.T. center, Dr. André Luxen, an organic chemist, and Dr. Serge Goldman, a neuropsychiatrist, met with André De Laet, chief editor of Belgian high-technology magazine «Technopole» who reports:



Cyclone 30 at Erasme Hospital, Brussels.

Q : What kinds of diagnostic techniques are used at the Erasme Hospital ?

Dr. Goldman : This hospital has developed quite a number of diagnostic techniques. Some of these have been devoted to the advancement of medical imaging. Efforts to create tools for increasingly precise but non-invasive examination of the human body have led to the development and routine application of techniques which were practically unknown as little as 10 years ago. These techniques include : echography, computerized axial tomography using X-rays or magnetic nuclear resonance, digitalized angiography and others.

Q : How does the hospital intend to use the CYCLONE 30 ?

Dr. Luxen : The radioisotope department performs about 10,000 examinations a year. These typically include explorations of the skeletal structure, lungs, heart, thyroid, liver, brain and kidneys as well as searches for sites of infection and inflammation. P.E.T. scanning provides important information about functional changes in metabolism. One of the objectives of the new P.E.T. center will be to improve the possibilitiy of comparing all the valuable information obtained by using a variety of imaging techniques.

Q : What progress in dynamic studies do you expect to make with this new capability ?

Dr. Luxen : Because positron emission tomography allows dynamic studies, researchers finally have access to biochemical or pharmacological parameters, enzymes, receptors localization and quantification and other information not otherwise available with animal models.

Q : In what particular areas have Erasme researchers directed their attention ?

Dr. Goldman : The brain and the heart are the two organs which receive special atten-

tion in our research programs. Our studies focus on neuronal glucose uptake in several psychiatric disorders; on the integrity of the dopaminergic system (Parkinson's Disease); and on problems of cardiology and oncology. Other studies focus on disorders of the nervous system (dementia, degeneration, etc.).

Q : What were the deciding factors in choosing a cyclotron from IBA ?

Dr. Luxen : My time in the United States with a major P.E.T. center strongly influenced me to direct my career towards the life sciences. I was then given the opportunity to apply my knowledge to the creation of a cyclotron department in Brussels. IBA, which at the time was only a small company, made a proposal based on the new negative-ion technology. Bear in mind that there were only four cyclotron builders in the world. In retrospect, choosing such a young company might appear somewhat limiting and risky. However, we very quickly became convinced that IBA had the most interesting offer.

Having used positive-ion technology for a number of years in the U.S., I was very familiar with its capabilities. Obviously, this experience helped me to accurately evaluate the advantages of the new negative-ion technology. It also allowed me to fully appreciate the ease of operation offered by the Belgian equipment. I feel certain that our collaboration with IBA on future developments will be equally fruitful.

Q: What future developments do you have in mind ?

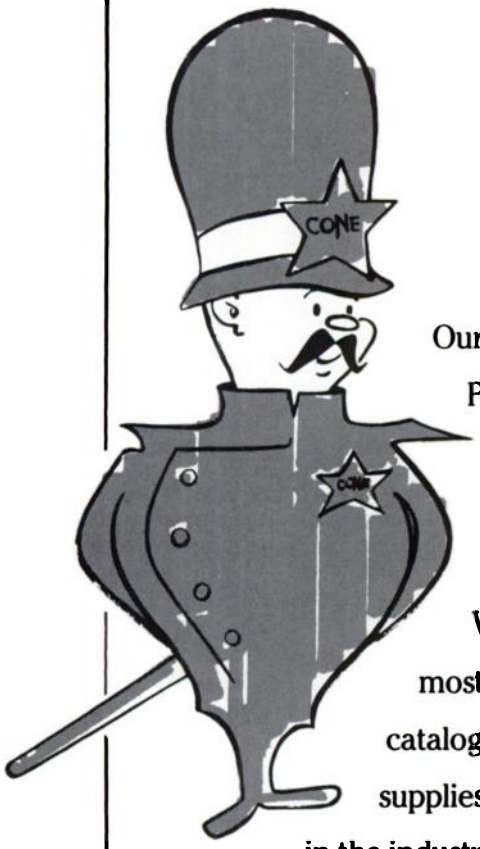
Dr. Luxen : IBA supplied a turn-key system - from the very source which feeds the cyclotron to delivery of radiolabelled biological compounds. Cyclotrons are extremely complex systems and IBA supplied fully compatible equipment. It is highly reliable in use and the possibilities for development (e.g. diversification of the radiopharmaceuticals) are numerous. The possibility of upgrading the equipment with add-on features - some of which may not yet have even been imagined - is one of Cyclone 30's greatest advantages. Thanks to its power, Cyclone 30 gives researchers the opportunity to go beyond the limits set by machines of lower beam energy.

Q : What are the principal benefits of working with IBA ?

Dr. Luxen : In my opinion, IBA offers three major advantages : their «turn-key» solution, i.e. total control of labelled compound ; their conscientious compliance to deadlines; and Cyclone 30's abundant energy. IBA has developed a range of lower-energy cyclotrons specifically designed to cover the requirements of P.E.T technology. But with Cyclone 30, Erasme Hospital will be able to expand its research much further. Because a cyclotron represents a 20-year investment, it is important to have long-term plans and to keep a sharp eye on ever-evolving requirements. ■

Located just outside of Brussels, Belgium, the Erasme University Hospital has a 1500-bed capacity and an annual budget equivalent to about 135 million US$. The workforce totals 2500 employees including 850 nurses and 400 medical doctors. In 1989, Erasme Hospital handled some 20,000 medical examinations. 28,000 patients were treated in the Emergency Ward and 25,000 patients were hospitalized for 24 hours or longer. Ever since its founding in 1977, the objectives set by the management have been to offer the population the best in specialized medical care, to pursue modern clinical teaching and training and to contribute to the advancement of medical research at all levels. Today, in line with these objectives, Erasme Hospital's contribution in the field of grafting for example, is widely recognized. In addition to Cyclone 30, the Erasme P.E.T. center has acquired a fully equipped radiochemical laboratory. It includes a range of automated processing units developed by IBA to perform chemical syntheses for immediate administration to patients. The Center also uses a high-resolution Siemens P.E.T. scanner which can simultaneously image up to 15 planes of any organ in the body.

The new P.E.T. Center Directors : Dr. André Luxen and Dr. Serge Goldman, with reporter André De Laet (from left to right).



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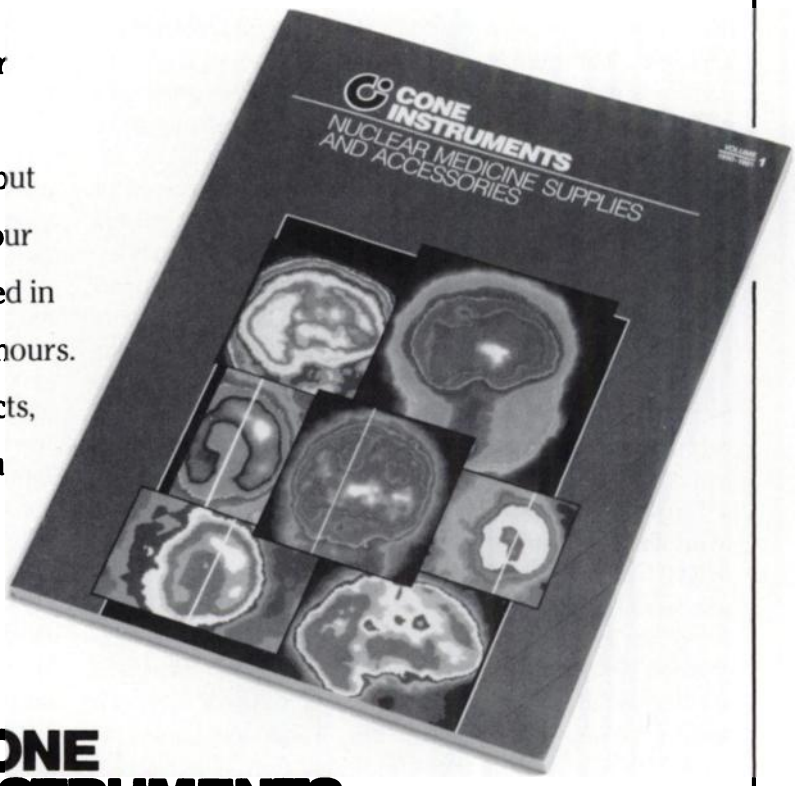

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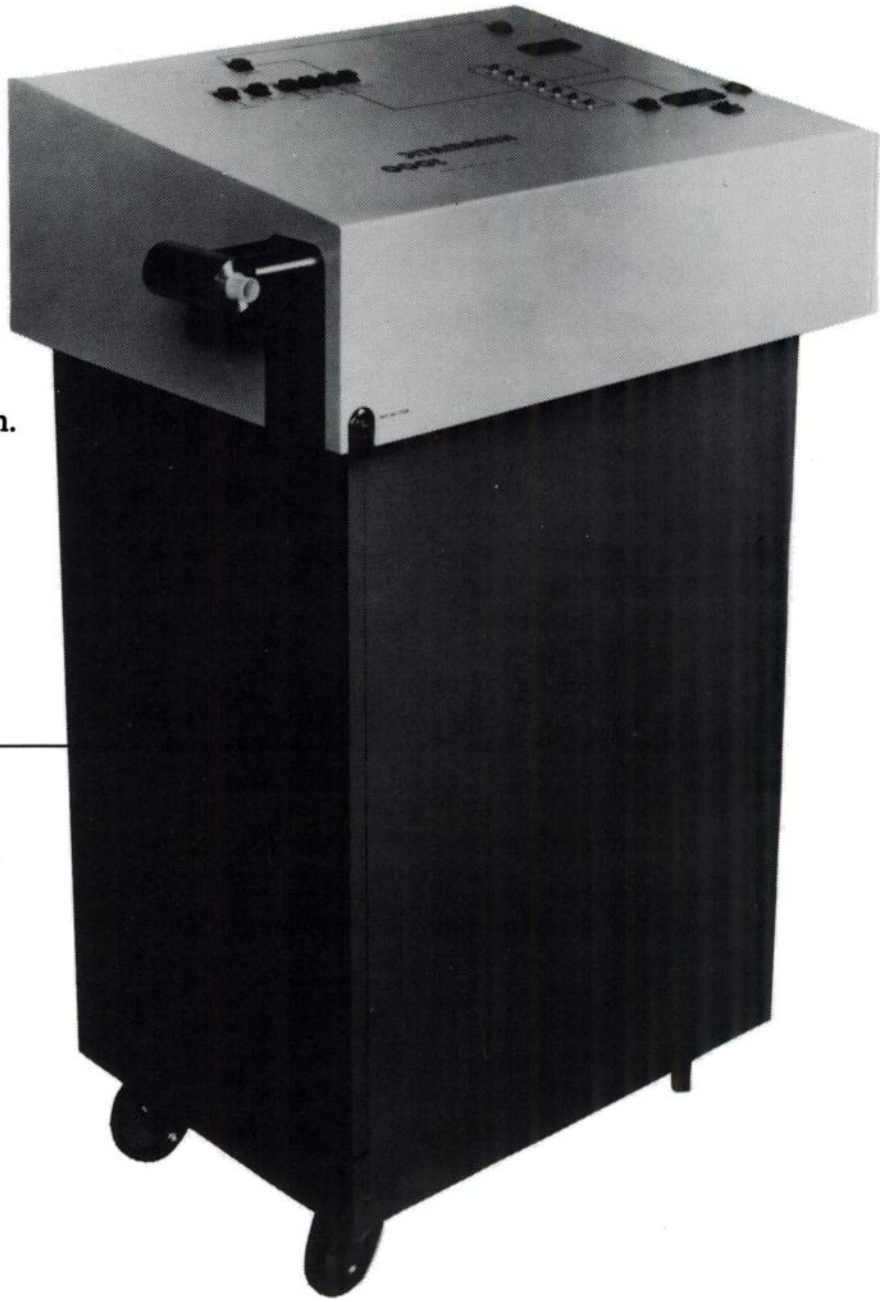

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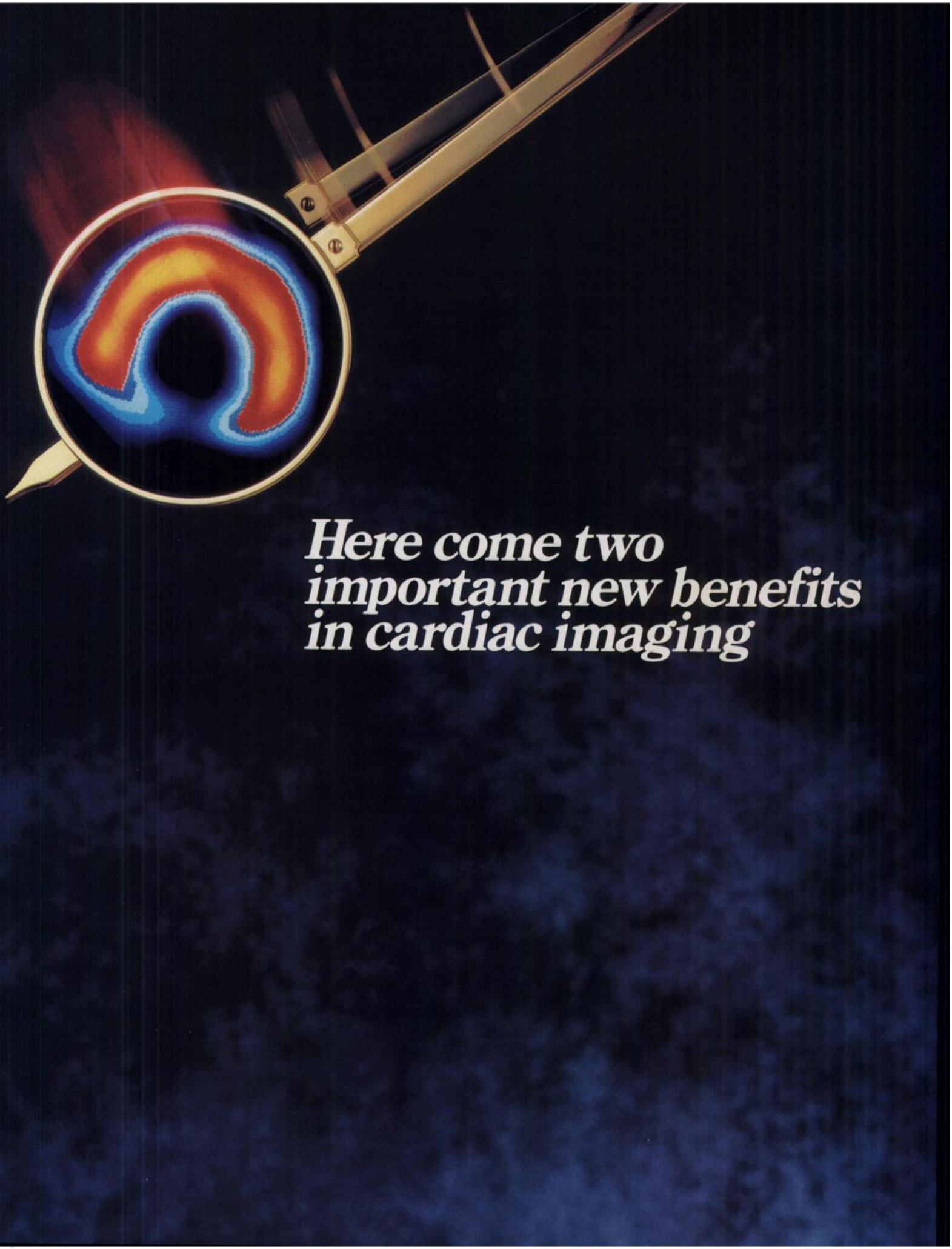
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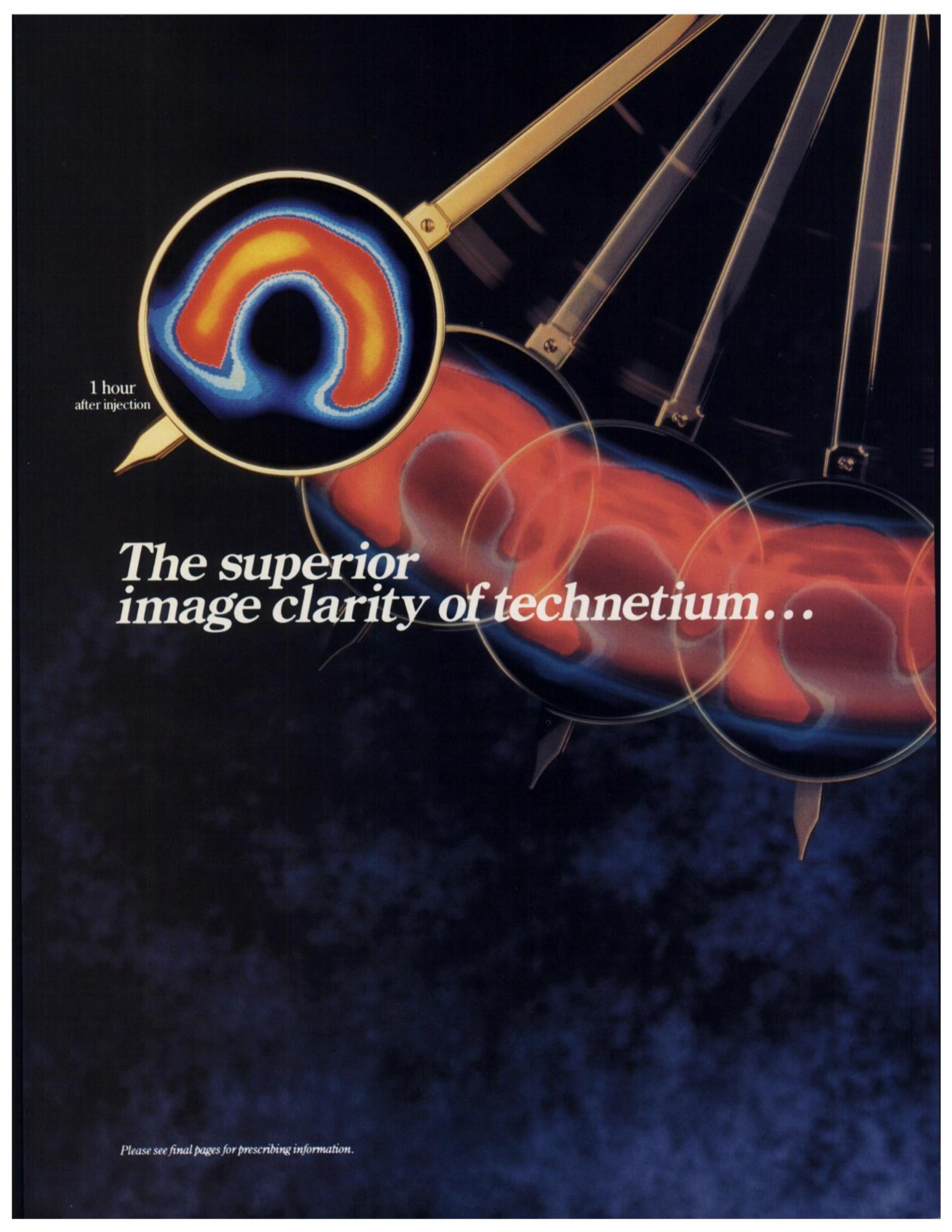
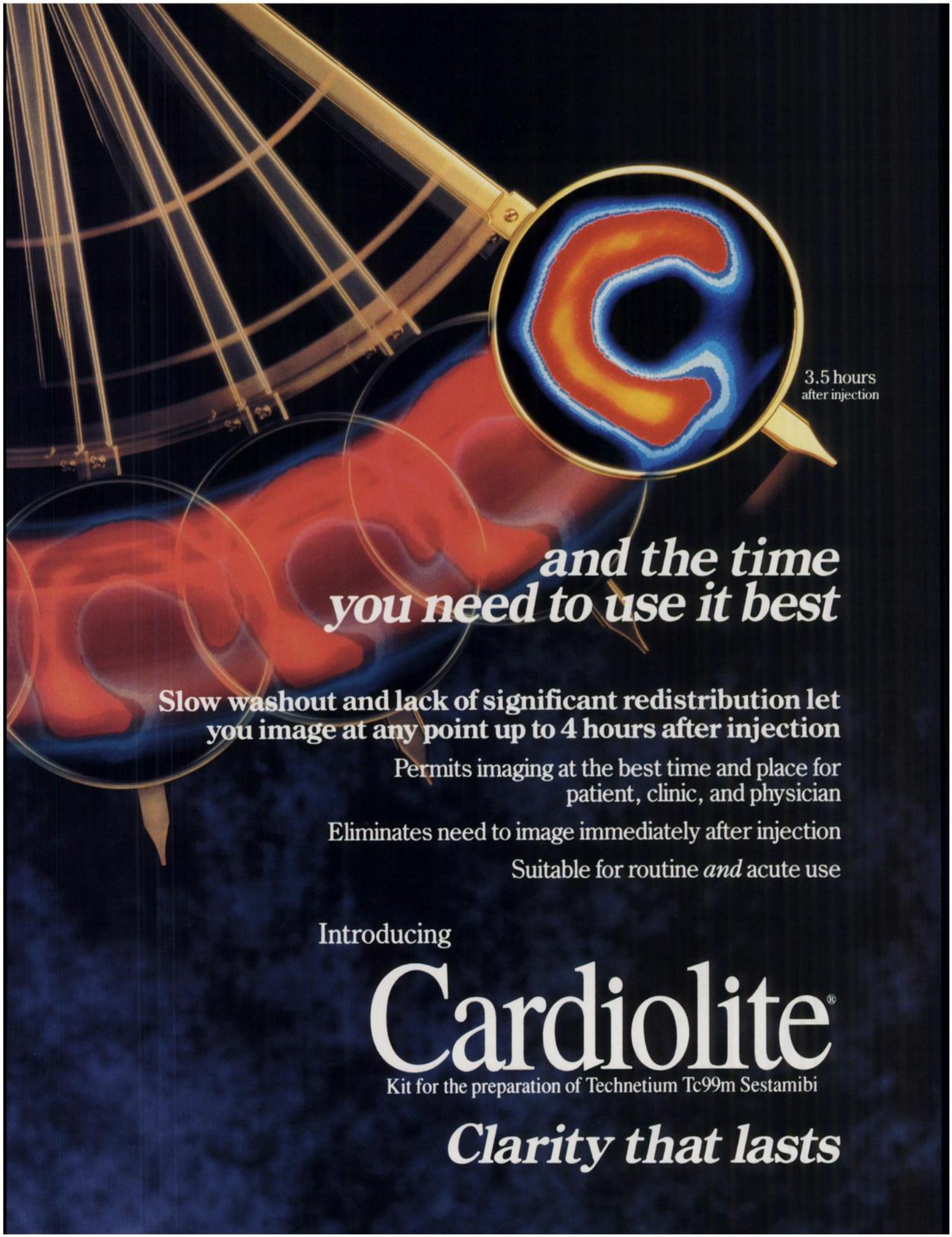


The superior image clarity of technetium...

Please see final pages for prescribing information.



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Slow washout and lack of significant redistribution let you image at any point up to 4 hours after injection

Permits imaging at the best time and place for patient, clinic, and physician

Eliminates need to image immediately after injection

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Introducing

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Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts

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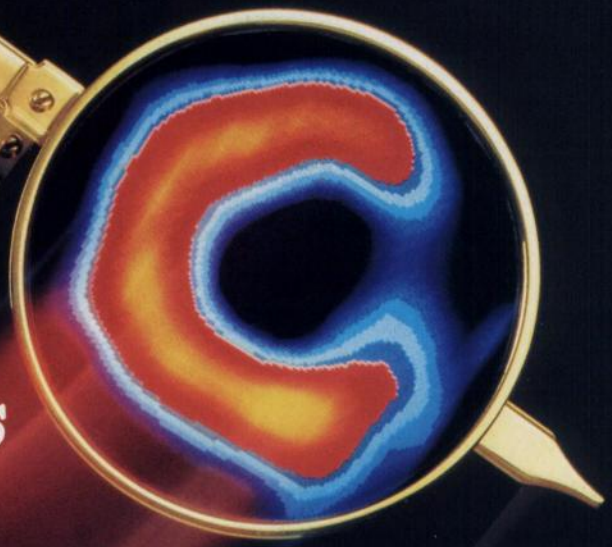
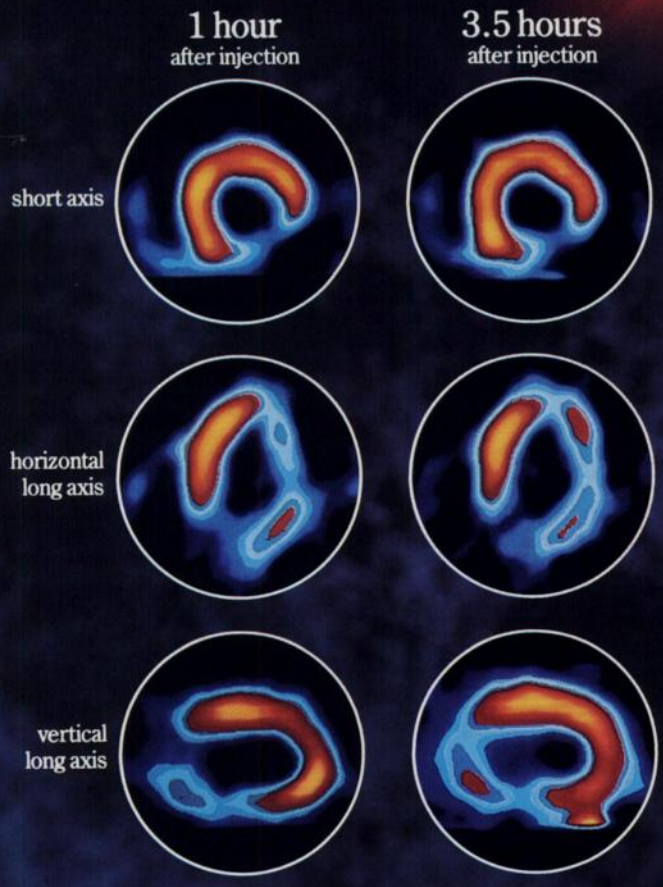




CARDIOLITE scans (SPECT) from a 61-year-old female 8 days following acute MI (LFOV camera, high-resolution collimator, 64 x 64 matrix, 180° arc RAO to LPO, 64 projections, 25 s/projection)

High degree of accuracy in detection of myocardial abnormalities

In blinded studies, CARDIOLITE imaging was 83% to 96% sensitive and 79% to 100% specific in detecting myocardial infarction, when compared with final diagnoses[1]

Reassuring safety profile

No known contraindications
Few adverse reactions

Of 2780 patients in worldwide trials, approximately 8% experienced a transient metallic taste following injection. A few cases of transient headache, mild nausea, flushing, and non-itching rash have also been reported. In worldwide commercial experience, one patient showed signs and symptoms consistent with seizure 8 to 10 min after injection. No other adverse reactions specifically attributable to the use of CARDIOLITE have been reported.[1]

Reference
1. Data on file, Du Pont File H-23531.

DU PONT PHARMA
Radiopharmaceuticals

Please see final pages for prescribing information.

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts

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 to 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.

PHYSICAL CHARACTERISTICS

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.02 hours.[1] Photons that are useful for detection and imaging studies are listed in Table 1.

Table 1. Principle Radiation Emission Data

Radiation	Mean %/ Disintegration	Mean Energy (keV)
Gamma-2	89.07	140.5

[1]Kocher, David C., Radioactive Decay Data Tables, DOE/TIC-11026, 108 (1981).

EXTERNAL RADIATION

The specific gamma ray constant for Tc99m is 5.4 microcoulombs/kg-MBq-hr (0.78R/mCi-hr) at 1cm. The first half value layer is 0.017cm of Pb. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. To facilitate control of the radiation exposure from Megabequerel (millicurie) amounts of this radionuclide, the use of a 0.25cm thickness of Pb will attenuate the radiation emitted by a factor of 1,000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.017	0.5
0.08	10^{-1}
0.16	10^{-2}
0.25	10^{-3}
0.33	10^{-4}

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in Table 3.

Table 3. Physical Decay Chart; Tc99m Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	8	.398
1	.891	9	.355
2	.794	10	.316
3	.708	11	.282
4	.631	12	.251
5	.562		
6	.501		
7	.447		

*Calibration Time

CLINICAL PHARMACOLOGY: Technetium Tc99m Sestamibi is a cationic Tc99m complex which has been found to accumulate in viable myocardial tissue in a manner analogous to that of Thallous Chloride Tl-201. Scintigraphic images obtained in animals and man after the intravenous administration of the drug have been comparable to those obtained with Thallous Chloride Tl-201 in normal and abnormal myocardial tissue.

The major pathway for clearance of Tc99m Sestamibi is the hepatobiliary system. Activity from the gall bladder appears in the intestines within one hour of injection. Twenty-seven percent of the injected dose is excreted in the urine, and approximately thirty-three percent of the injected dose is cleared through the feces in 48 hours. The agent is excreted without any evidence of metabolism.

Pulmonary activity is negligible even immediately after injection. Blood clearance studies indicate that the fast clearing component clears with a $t_{1/2}$ of 4.3 minutes at rest. At five minutes postinjection about 8% of the injected dose remains in circulation. There is less than 1% protein binding of Technetium Tc99m Sestamibi in plasma. The myocardial biological half-life is approximately six hours after a rest injection. The biological half-life for the liver is approximately 30 minutes after a rest injection. The effective half-life of clearance (which includes both the biological half-life and radionuclide decay) for the heart is approximately 3 hours, and for the liver is approximately 28 minutes, after a rest injection. The ideal imaging time reflects the best compromise between heart count rate and surrounding organ uptake.

A study in a dog myocardial ischemia model reported that Technetium Tc99m Sestamibi undergoes myocardial distribution (redistribution), although more slowly and less completely than Thallous Chloride Tl-201. A study in a dog myocardial infarction model reported that the drug showed no redistribution of any consequence. Definitive human studies to demonstrate possible redistribution have not been reported. In patients with documented myocardial infarction, imaging revealed the infarct up to four hours post dose.

Animal studies have shown that myocardial uptake is not blocked when the sodium pump mechanism is inhibited. Myocardial uptake which is coronary flow dependent is 1.2% of the injected dose. The following table illustrates the biological clearance as well as effective clearance (which includes biological clearance and radionuclide decay) of Tc99m Sestamibi from the heart and liver.

[Organ concentrations expressed as percentage of injected dose; data based on an average of 5 subjects.]

	Heart		Liver	
Time	Biological	Effective	Biological	Effective
5 mins.	1.2	1.2	20	20
30 mins.	1.1	1.0	12	11.3
1 hour	1.0	0.9	5.6	5.0
2 hours	1.0	0.8	2.2	1.7
4 hours	0.8	0.5	0.7	0.4

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction.

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

CONTRAINDICATIONS: None known.

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

PRECAUTIONS:

GENERAL

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

The active intermediate, $Cu(MIBI)_4BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations ($\geq 20\mu g/ml$), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $Cu(MIBI)_4BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (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.

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 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. One patient demonstrated signs and symptoms consistent with seizure, eight to ten minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

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

370-1110MBq (10-30mCi)

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

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY).

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

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

Store at room temperature (15-30°C) before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70 kg) 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/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq
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

Stabin, M., July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

INSTRUCTIONS FOR PREPARATION OF Technetium Tc99m Sestamibi

Preparation of the Technetium Tc99m Sestamibi from the Kit for the preparation of Technetium Tc99m Sestamibi is done by the following aseptic procedure:

a. Prior to adding the Sodium Pertechnetate Tc99m Injection to the vial, tear off a radiation symbol and attach it to the neck of the vial.
b. Waterproof gloves should be worn during the preparation procedure. Remove the plastic disc from the vial and swab the top of the vial closure with alcohol to sanitize the surface.
c. Place the vial in a suitable radiation shield with a fitted radiation cap.
d. With a sterile shielded syringe, aseptically obtain additive-free, sterile, non-pyrogenic Sodium Pertechnetate Tc99m Injection [925-5550MBq, (25-150mCi)] in approximately 1 to 3ml.
e. Aseptically add the Sodium Pertechnetate Tc99m Injection to the vial in the lead shield. Without withdrawing the needle, remove an equal volume of headspace to maintain atmospheric pressure within the vial.
f. Swirl the contents of the vial for a few seconds.
g. Remove the vial from the lead shield and place upright in a boiling water bath for 10 minutes. Timing for 10 minutes is begun as soon as the water begins to boil again.
h. Remove the vial from the water bath, place in the lead shield and allow to cool for fifteen minutes.
i. Using proper shielding, the vial contents should be visually inspected. Use only if the solution is clear and free of particulate matter and discoloration.
j. Assay the reaction vial using a suitable radioactivity calibration system. Record the Technetium Tc99m concentration, total volume, assay time and date, expiration time and lot number on the vial shield label and affix the label to the shield.
k. Store the reaction vial containing the Technetium Tc99m Sestamibi at room temperature (15-30°C) until use; at such time the product should be aseptically withdrawn. Technetium Tc99m Sestamibi should be used within six hours of preparation. The vial contains no preservative.

Note: Adherence to the above product reconstitution instructions is recommended.

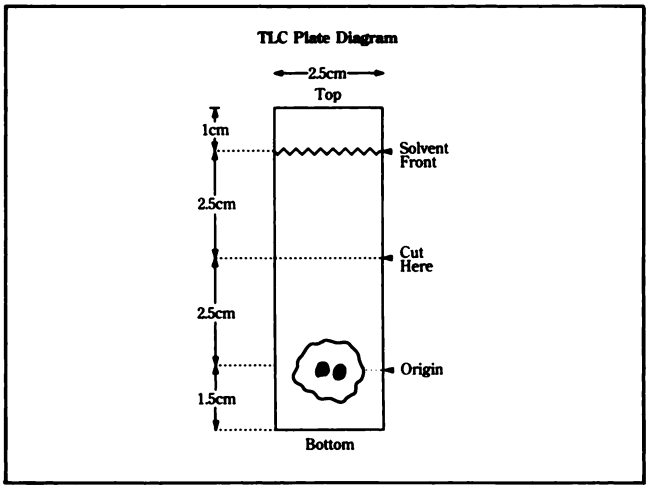
Product should be used within 6 hours after preparation.

Final product with radiochemical purity of at least 90% was used in the clinical trials that established safety and effectiveness. The radiochemical purity was determined by the following method.

DETERMINATION OF RADIOCHEMICAL PURITY IN Technetium Tc99m Sestamibi

1. Obtain a Baker-Flex Aluminum Oxide coated, plastic TLC plate, #1 B-F, pre-cut to 2.5cm x 7.5cm.
2. Dry the plate or plates at 100°C for 1 hour and store in a desiccator. Remove pre-dried plate from the desiccator just prior to use.
3. Apply 1 drop of ethanol* using a 1ml syringe with a 22-26 gauge needle, 1.5cm from the bottom of the plate. THE SPOT SHOULD NOT BE ALLOWED TO DRY.
4. Add 2 drops of Technetium Tc99m Sestamibi solution, side by side on top of the ethanol* spot. Return the plate to a desiccator and allow the sample spot to dry (typically 15 minutes).
5. The TLC tank is prepared by pouring ethanol* to a depth of 3-4mm. Cover the tank and let it equilibrate for ~10 minutes.
6. Develop the plate in the covered TLC Tank in ethanol* for a distance of 5cm from the point of application.
7. Cut the TLC plate 4cm from the bottom and measure the Tc99m activity in each piece by appropriate radiation detector.
8. Calculate the % Tc99m Sestamibi as:

$$\% \text{ Tc99m Sestamibi} = \frac{\mu\text{Ci Top Piece}}{\mu\text{Ci Both Pieces}} \times 100$$



*The ethanol used in this procedure should be 95% or greater. Absolute ethanol (99%) should remain at ≥95% ethanol content for one week after opening if stored tightly capped, in a cool dry place.

HOW SUPPLIED: Du Pont'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 room temperature (15-30°C) before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each thirty (30) vial kit is 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 identified in 35.100 and 35.200 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

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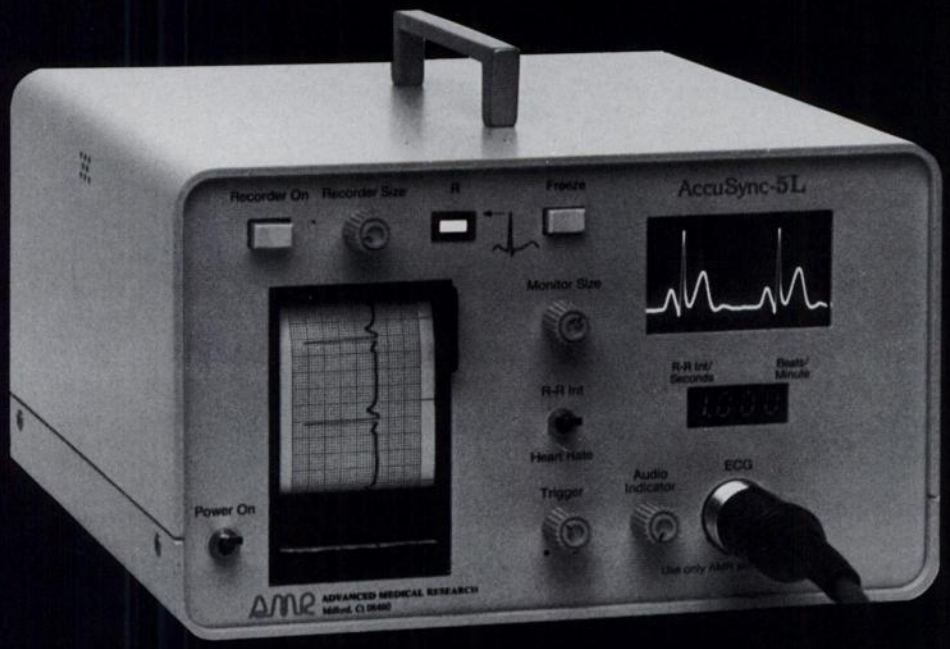

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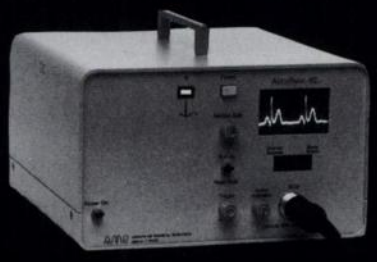
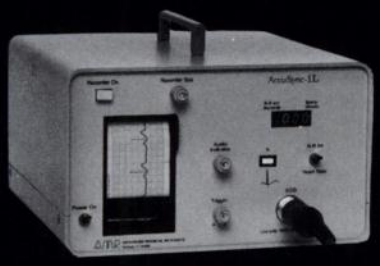
MODEL		FEATURES
AccuSync-6L		All **AccuSync-5L** features with the exception of the Strip Chart Recorder.
AccuSync-1L		All **AccuSync-5L** features with the exception of the Digital CRT Monitor.
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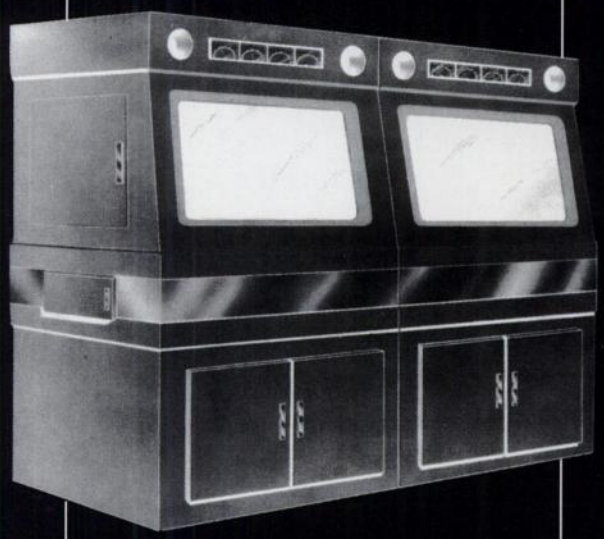

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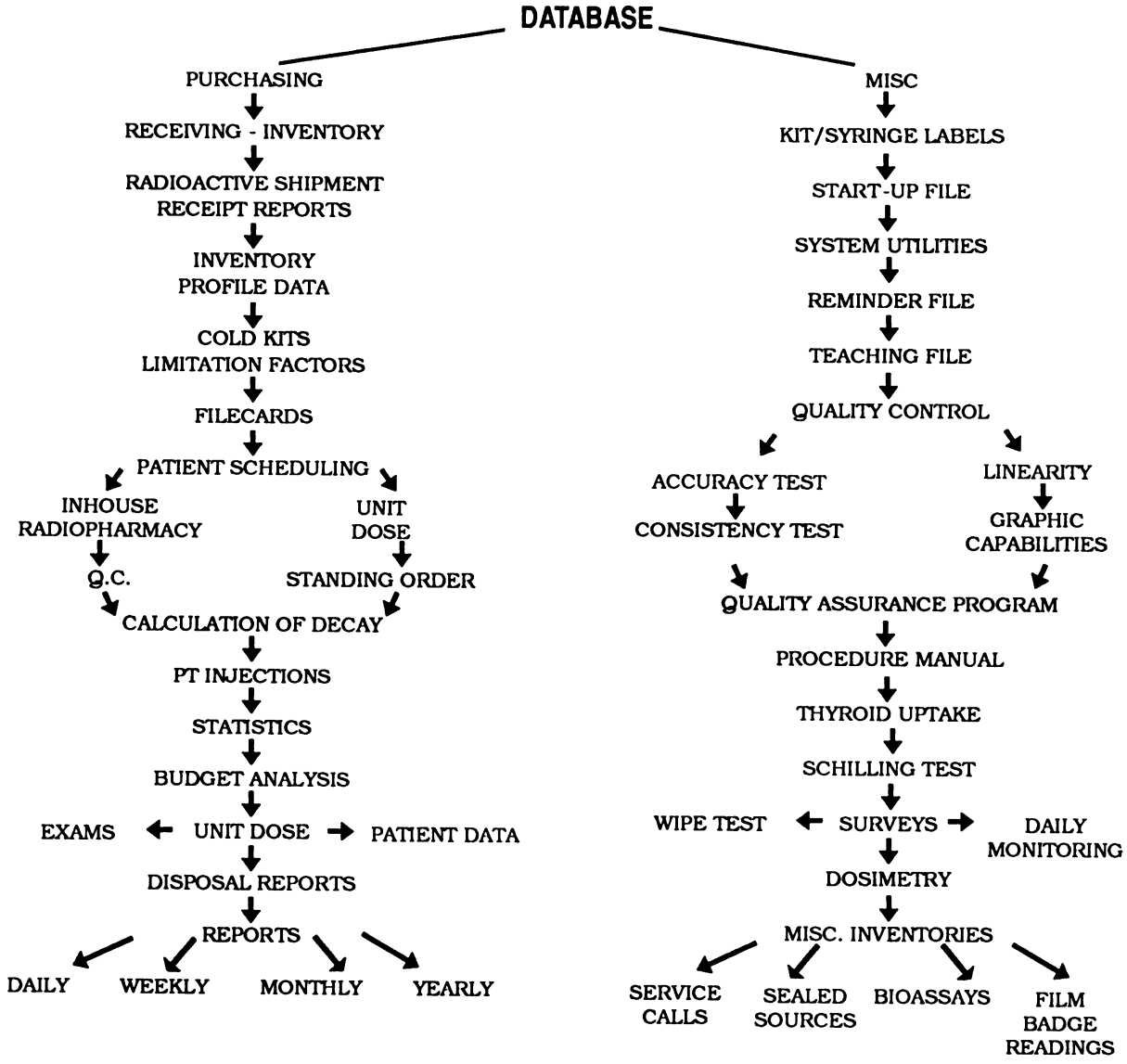

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The Scintillation Camera, 1988. *Simmons et al.*	$30.00	$ 35.00		
MIRD Primer for Absorbed Dose Calculations, 1988. *Loevinger et al.*	$35.00	$ 50.00		
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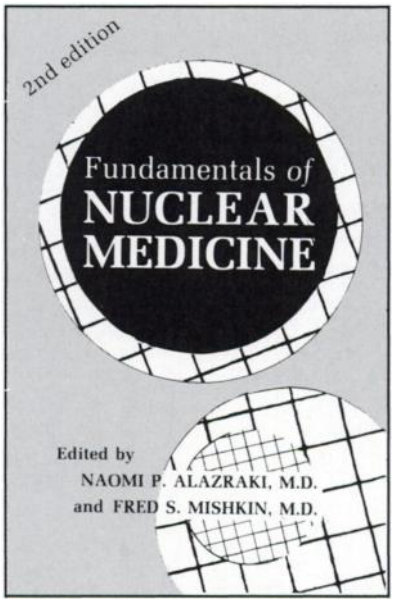

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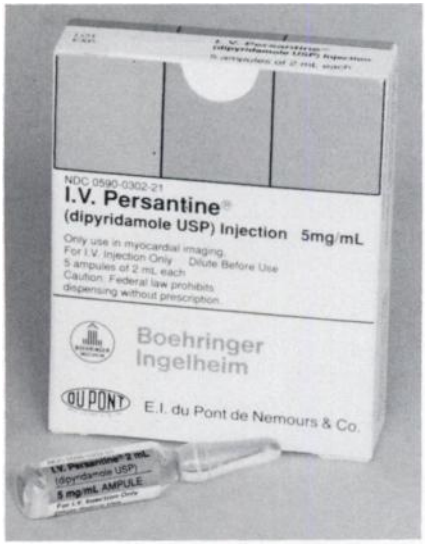
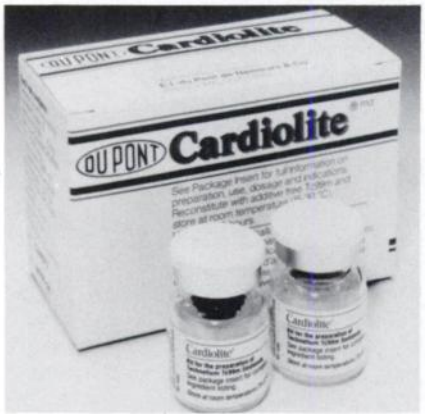
FDA Approves I.V. Persantine



Du Pont Merck Pharmaceutical Company has received approval from the FDA to market I.V. Persantine® (dypyridamole USP), the first pharmacologic alternative to excercise in thallium stress testing for evaluation of coronary artery disease in patients who cannot exercise adequately. The drug will be used to evaluate thousands of patients with suspected heart disease who cannot perform exercise testing on a treadmill or whose tests are unsatisfactory. I.V. Persantine, which is indicated as an adjunct to thallium myocardial perfusion imaging, simulates the physiological effect of exercise by increasing coronary blood flow pharmacologically. I.V. Persantine/thallium testing could be used annually for as many as half a million patients previously unable to be tested effectively. Thallium studies using I.V. Persantine have been conducted at more than 100 clinical sites in the United States and worldwide since 1978, and I.V. Persantine has been available in the United Kingdom since 1987. Persantine is a registered trademark of Boehringer Ingelheim International GmbH. The intravenous form of the drug will be marketed, manufactured, and distributed in the U.S. by Du Pont Merck under an exclusive licensing agreement with Boehringer Ingelheim Pharmaceuticals, Inc. **Roger Morris, External Affairs Dept., Du Pont Company, Wilmington, DE 19898. (302) 992-4747.**

Circle Reader Service No. 101

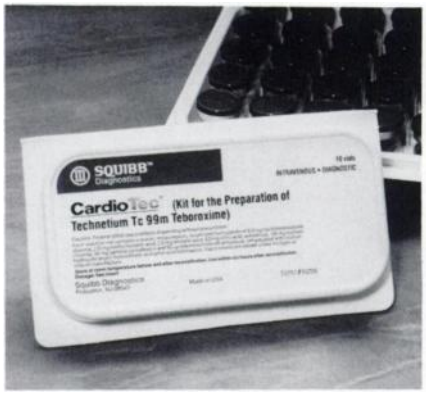
FDA Approves Cardiolite



Du Pont Merck has received approval from the FDA to market its new technetium agent, Cardiolite® (technetium ^{99m}Tc sestamibi), for use in pinpointing heart attack damage, evaluating perfusion, and determining pumping efficiency in a single study. The agent allows imaging of the heart up to four hours after injection, enabling physicians to first stabilize heart attack patients and then to aquire images that show the heart as it appeared during the heart attack. Following treatment with clot dissolving drugs, Cardiolite can be injected again. A comparison of the original and follow-up images identifies heart tissue saved by the initial therapy. Cardiolite is a nonradioactive preparation that can be stocked in hospitals to make it convenient for emergency and routine examinations. It is transformed into a tracer when combined with technetium. Cardiolite is suitable for planar and SPECT imaging camera systems. The technetium agent offers distinct advantages over thallium. While Cardiolite can be stocked, thallium doses are radioactive when shipped and must be ordered for each study, thus requiring advance scheduling of patients. Also, the four-hour time period for imaging after injection with Cardiolite is more than fifteen times longer than the period during which thallium can be imaged. **Roger Morris, External Affairs Dept., Du Pont Company, Wilmington, DE 19898. (302) 992-4747.**

Circle Reader Service No. 102

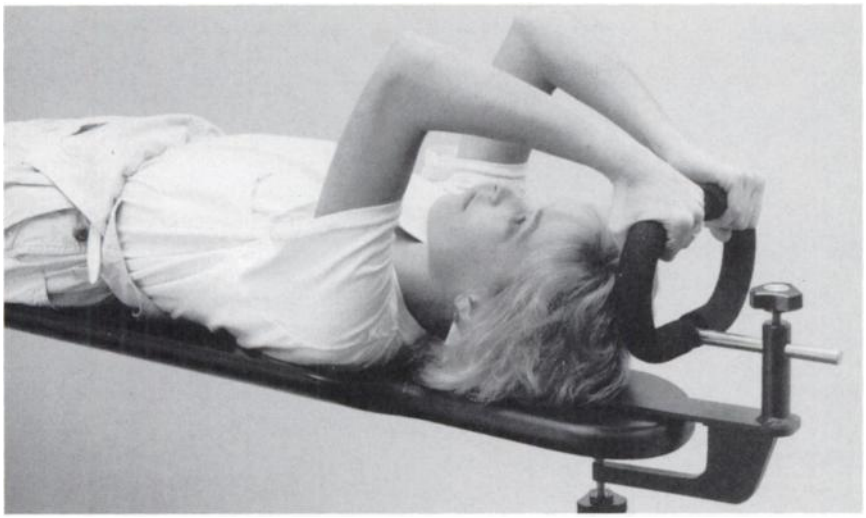
FDA Approves CardioTec



Squibb Diagnostics, a division of Bristol-Myers Squibb company, has received approval from the FDA to market its new technetium agent, CardioTec® (kit for the preparation of technetium ^{99m}Tc teboroxime), for use in myocardial perfusion studies, both at rest and at stress. CardioTec has received a therapeutic rating of 1B from the FDA for a new chemical entity representing a modest therapeutical gain over existing marketed agents. CardioTec can easily be prepared on site as needed and the agent allows physicians to image the heart within five minutes of its administration to the patient. The speed with which it can be used, coupled with the production of high-quality images, offers physicians the opportunity to make quick therapeutic decisions about possible lifesaving therapy for patients suffering from or at risk for myocardial infarction. CardioTec is the first of a new class of imaging agents known as BATOs (boronic acid adducts of technetium dioximes) indicated for evaluating coronary blood flow. BATO compounds readily cross cell membranes, including those of the myocardium, even at high flow rates characteristic of patient exercise or pharmacologic intervention. Rapidly eliminated from the heart, BATO compounds allow repeat studies to be performed quickly, including the imaging of a patient's status before and possibly after intervention. The rapidity of the studies offers greater patient convenience and potential for significant cost savings. Using CardioTec, a typical stress/rest study can be completed within 1½ to 2 hours with only 20 minutes of total camera time needed, while a thallium study usually requires 4 or more hours for completion, including 50 minutes of camera time. Squibb Diagnostics has established CardioTec Learning Centers at key locations across the country including Worcester, MA; Philadelphia, PA; Providence, RI; Houston and Dallas, TX; Fairfield and Roseville, CA; Chicago, IL; and Richmond, VA. **Janet Skidmore, Industry and Public Affairs, Bristol-Myers Squibb Company, P.O. Box 4000, Princeton, NJ 08543. (609) 921-5615.**

Circle Reader Service No. 103

SPECT Hand Grips



Atomic Products Corporation has developed SPECT Hand Grips for positioning a patient within the confines of a SPECT imaging table. For most imaging applications, the patient's arms must be kept away from the torso. Atomic's Hand Grips provide the patient with comfortable, stable arm support away from the imaging area. The Hand Grip is mounted to the head of the table and can be adjusted to accommodate a variety of patient arm positions over a 10-inch travel. These grips are comfortably cushioned and can be used with any manufacturer's SPECT table. **Atomic Products Corporation, P.O. Box 702, Shirley, NY 11967. (516) 924-9000.**

Circle Reader Service No. 104

Parallel Image Processing Accelerator

Ektron Applied Imaging, Inc., a Kodak subsidiary, introduces the EktronBOSS™ Parallel Image Processing Accelerator for Sun workstations. Using EktronBOSS, workstations can run at supercomputer speed. Image processing applications that once took hours can now be accomplished in seconds. EktronBOSS consists of a set of three boards that plug into an expansion chassis. Different combinations of these boards can be used to configure image processing subsystems with peak performance ranging from 500 to over 5,000 MIPS and from 70 to over 700 MFLOPS. Medical imaging applications can be developed using a powerful set of software tools supplied with the EktronBOSS. The accelerator's systems are scalable. Once application software is written, that same software can be run on larger, more powerful, EktronBOSS configurations. **Marketing/ Sales, Ektron Applied Imaging, Inc., 23 Crosby Drive, Bedford, MA 01730. (617) 275-0475.**

Circle Reader Service No. 105

X-Ray Densitometers

Lunar Corporation has received FDA 510K registration for its DPX-L and DPX-alpha dual-energy X-ray bone densitometers. These instruments are comparable to the standard DPX densitometer but provide spine and femur scans in the AP projection in only two minutes. This is 2 to 4 times faster than non-Lunar densitometers. Lateral spine scans require only four minutes, compared to twelve minutes on a standard DPX. The DPX-alpha is a smaller version of the DPX-L model and is designed for specialty clinics and smaller imaging centers. Its compact space requirements (1.6 m^2) is half the size of competitive instruments. Lunar is also introducing its Achilles Ultrasound Densitometer. This instrument utilizes both speed-of-sound and attenuation in the os calcis, an area of purely trabecular bone, to provide precise skeletal evaluation. **Lunar Corporation, 313 West Beltline Highway, Madison, WI 53713. (608)274-2663 or (800) 445-8627.**

Circle Reader Service No. 106

Plain-Form Hydrometers

Nagle Company and Ever Ready Thermometer Company introduce safe, break-resistant ERTCO/Nalgene™ plain-form hydrometers. These are polycarbonate alternatives to fragile glass hydrometers. They are shatterproof and crystal clear. Each hydrometer is individually calibrated and accurate to plus or minus one scale division to meet ASTM specifications. They are available in three specific gravity ranges for fluids heavier than water, two Sugar Brix ranges, and one Salt range. **Jorge Pardo, Marketing Communications, Nalge Company, A Subsidiary of Sybron Corporation, P.O. Box 20365, Rochester, NY 14602. (716) 586-8800.**

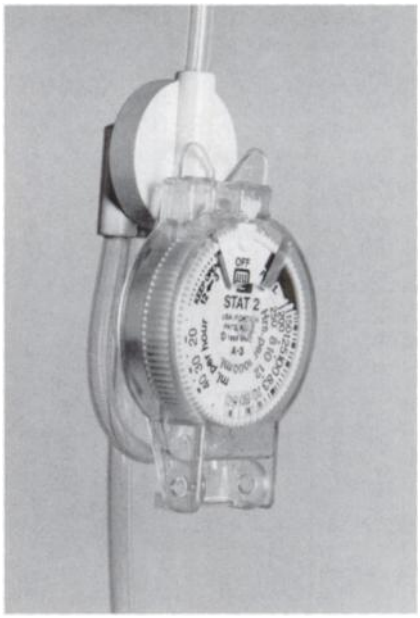
Circle Reader Service No. 107

Thermal Desorption System

Scientific Instrument Services introduces the new Short Path Thermal Desorption System for use in GC/MS for the identification and quantitative determination of both volatile and semi-volatile samples in complex matrices. Due to its novel design, this new system eliminates the problems observed with other desorption systems. The system is fully compatible with all gas chromatographic techniques and detectors including systems interfaced to mass spectrometers and infrared spectrometers. **Santford V. Overton, Product Manager, Scientific Instrument Services, Inc., Route 179, RD 2, Box 198, Ringoes, NJ 08551. (201) 788-5550.**

Circle Reader Service No. 108

I.V. Pumpette



Master Medical Corporation introduces the Stat 2™ I.V. Pumpette, which delivers constant i.v. flow rates using gravity. The Pumpette automatically maintains i.v. flow rates under changing conditions, whether the i.v. bag is full or almost empty. Changes in bed height do not affect the set rate, and the rate remains accurate no matter what changes in position the patient may make, from lying down to standing up. Fluctuations in venous pressure do not require re-setting of the rate, and the set rate is accurate over hours or days. The inexpensive and disposable Stat 2 Pumpettes are available in a variety of i.v. set configurations. They have full-dial visibility and are easy to use. Some situations still require an alarm or higher pressure from an electronic pump but the need for them is now greatly reduced. **Master Medical Corporation, 7033 E. First Ave., Scottsdale, AZ 85251. (602) 957-9111 or (800) 962-8573.**

Circle Reader Service No. 109

Call for Abstracts for Works-in-Progress

The Society of Nuclear Medicine
38th
Annual Meeting
Tuesday, June 11–
Friday, June 14,
1991
Cincinnati, OH
Cincinnati
Convention
Center

The 1991 Scientific Program Committee and the Scientific & Teaching Sessions Committee solicit the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 38th Annual Meeting in Cincinnati, OH. Works-in-Progress accepted for the program will be published in a separate on-site show directory that will be distributed to all those who attend the meeting. The accepted Works-in-Progress will also be published in the September issue of the *The Journal of Nuclear Medicine* and, for the Technologist Section, in the September issue of the *Journal of Nuclear Medicine Technology*. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- **INSTRUMENTATION AND DATA ANALYSIS**
- **RADIOASSAY**
- **RADIOPHARMACEUTICAL CHEMISTRY**
- **DOSIMETRY/RADIOBIOLOGY**
- **NUCLEAR MAGNETIC RESONANCE CHEMISTRY**
- **CLINICAL SCIENCE APPLICATIONS**
  - **Bone/Joint**
  - **Cardiovascular (clinical and basic)**
  - **Endocrine**
  - **Gastroenterology**
  - **Neurology (clinical and basic)**
  - **Oncology (non-antibody)**
  - **Immunology (antibody)**
  - **Pediatrics**
  - **Pulmonary**
  - **Renal/Electrolyte/Hypertension**
  - **Hematology/Infectious Disease**

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

Deadline for receipt of abstracts for Works-in-Progress is Monday, April 15, 1991.

The official abstract form for Works-in-Progress may be obtained from the October 1990 issue of the *JNM* or by calling or writing:

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

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Rubidium-82
Infusion System

The CardioGen-82 System also improves patient throughput and scheduling efficiency by enabling you to perform multiple studies in a short time.

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Please see adjacent page for brief summary of prescribing information.

SQUIBB Diagnostics

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