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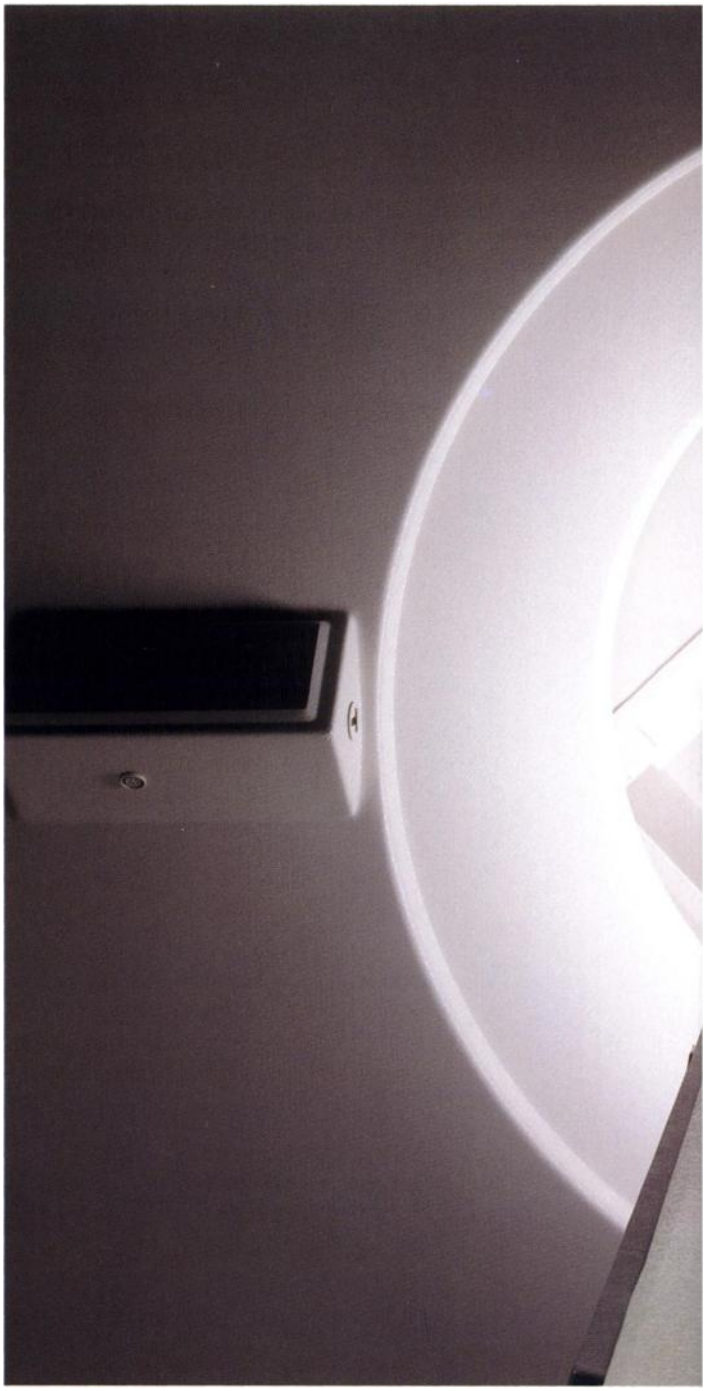

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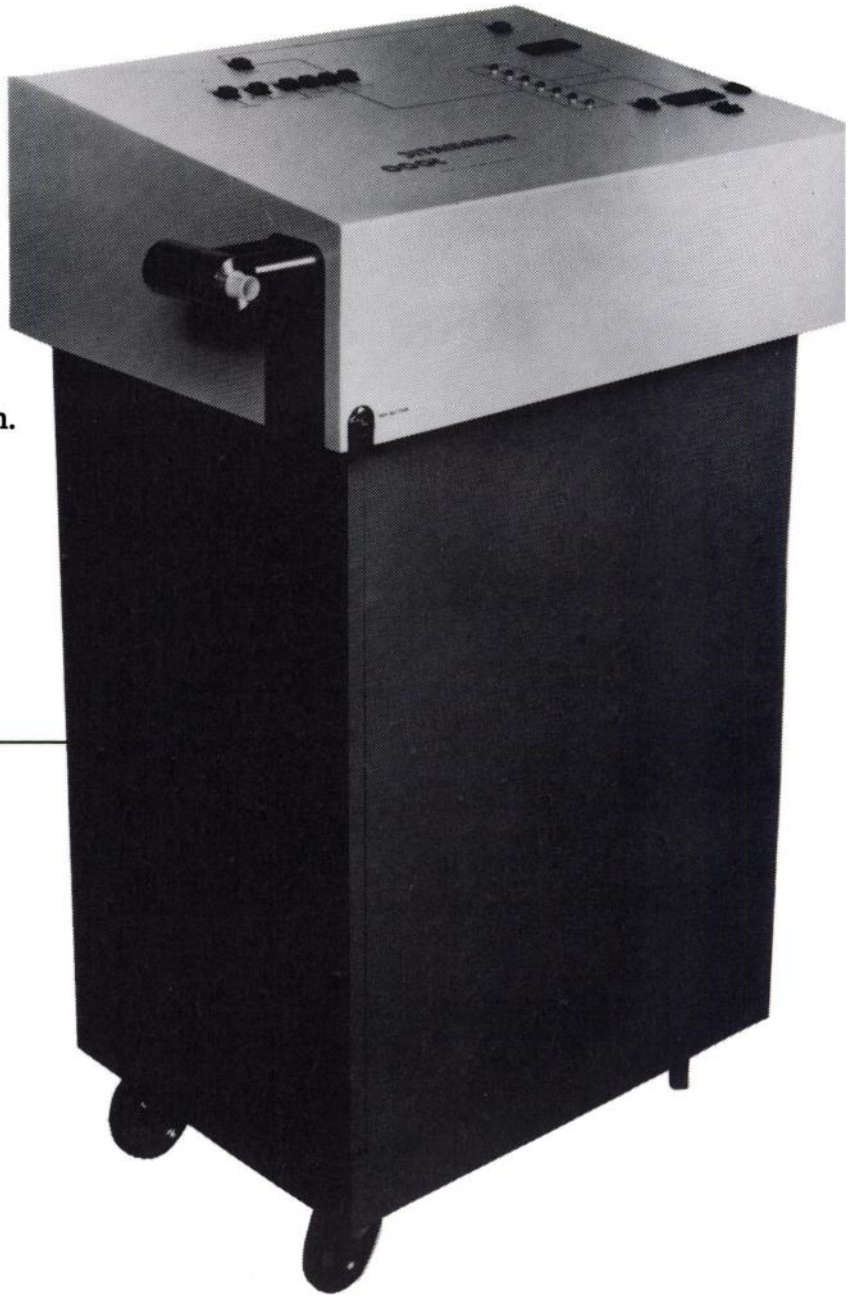

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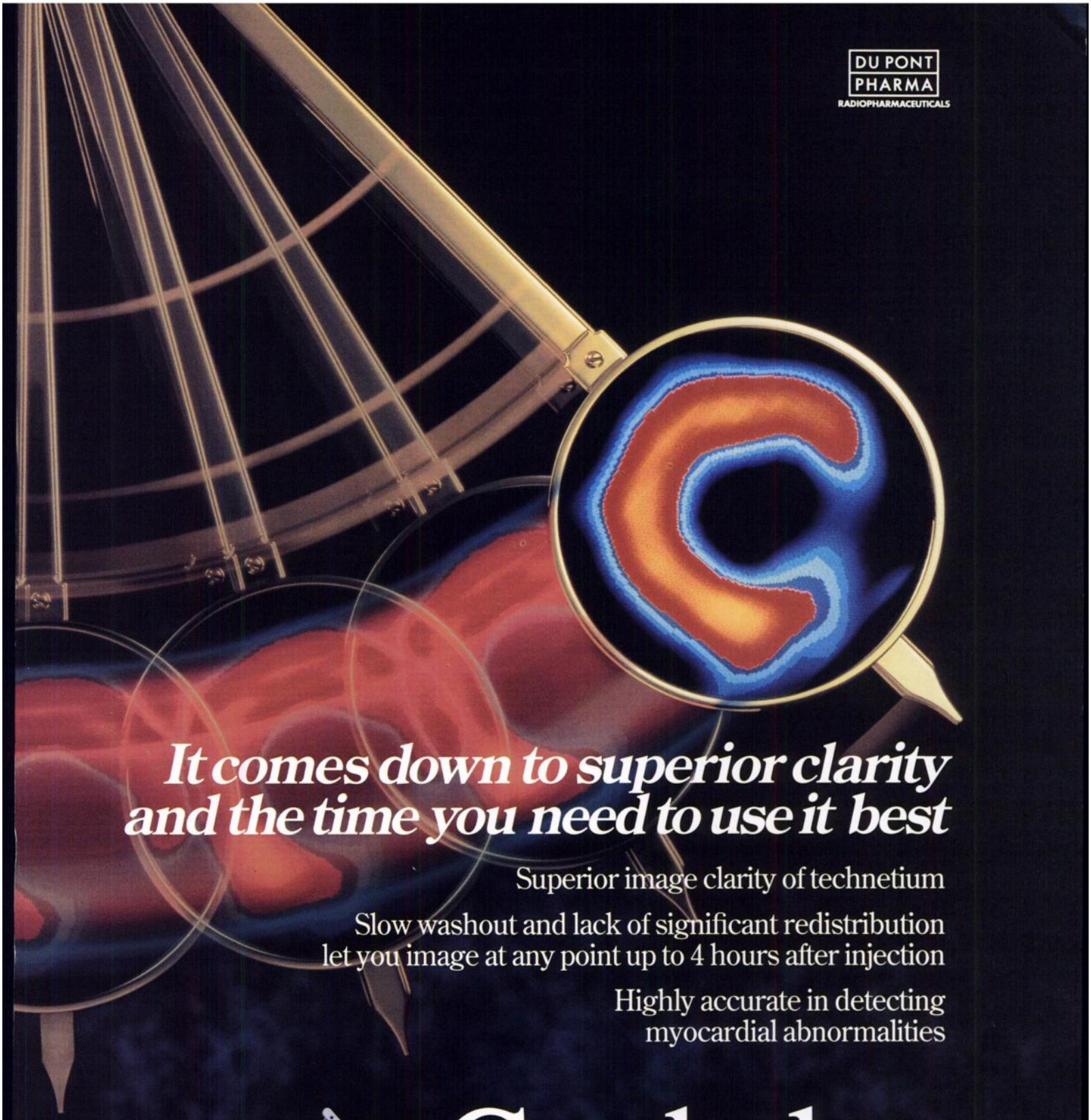

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Highly accurate in detecting myocardial abnormalities

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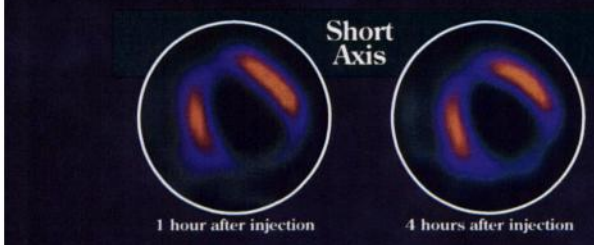
Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts

Please see reverse for brief summary of prescribing information.



CARDIOLITE scans (SPECT) from a 62-year-old male with three prior myocardial infarctions (LFOV camera equipped with a high-resolution collimator, 64 x 64 matrix, 180° arc RAO to LPO, 64 projections, 25 s/projection).

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts

Please see reverse for feature and benefit highlights.

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

F O R D I A G N O S T I C U S E

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

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

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.

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

CONTRAINDICATIONS: None known.

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

PRECAUTIONS:

GENERAL

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

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the 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/30 mCi) 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 (≥ 20 μg/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 (9 mg/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, 8 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

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

370 to 1110 MBq (10 to 30 mCi)

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

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

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

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

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

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

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.

HOW SUPPLIED: Du Pont's CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi is supplied as a 5 mL 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 and 5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at room temperature (15 to 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 US 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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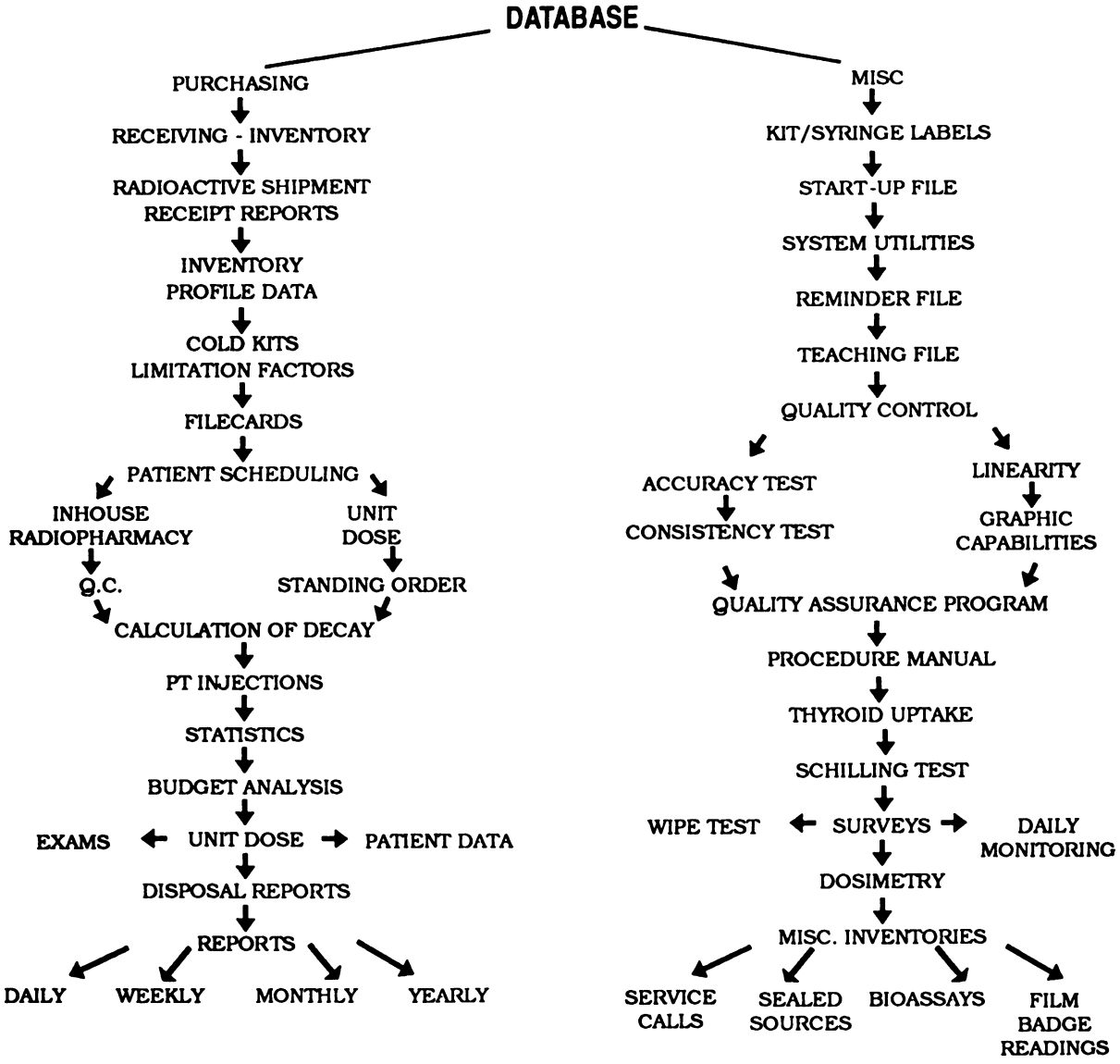

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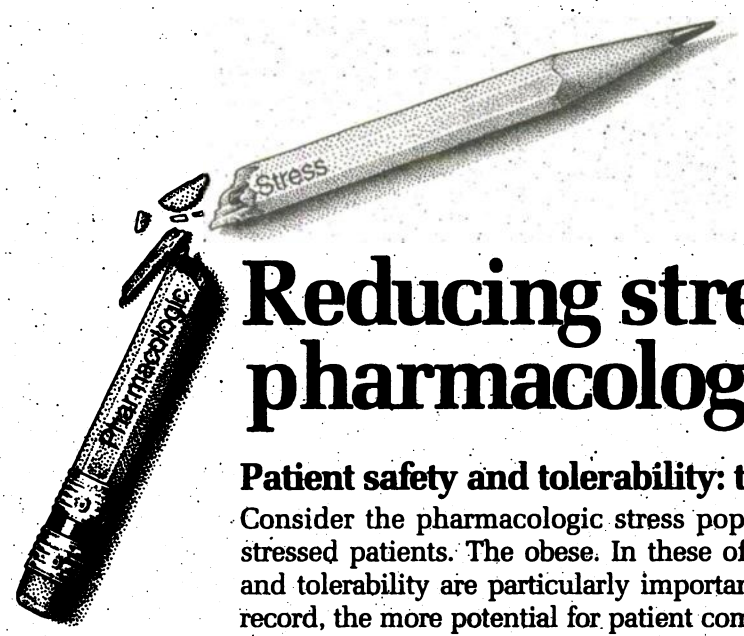


Reducing stress in pharmacologic stress testing

Patient safety and tolerability: the stress factors

Consider the pharmacologic stress population. Old patients. Frail patients. Submaximally stressed patients. The obese. In these often vulnerable or compromised patient types, safety and tolerability are particularly important. The more certain an agent's safety and tolerability record, the more potential for patient comfort and physician confidence. Use of an agent with a proven tolerability and safety record can reduce the overall stress to the patient, while easing the emotional stress to the physician.

A safety record that spans more than a decade

I.V. Persantine® (dipyridamole USP) has a safety profile established in over a decade of clinical testing.[1,2*] And, based on information from over 250,000 patient studies, I.V. Persantine is generally well tolerated.[†] Such an established record in pharmacologic stress creates a standard by which to compare other agents.

Generally well-tolerated stress begins with smooth, gradual onset of effect

Pharmacologic stress with I.V. Persantine takes effect smoothly with a 4-minute infusion, followed within 5 minutes with the appropriate thallium dose. This allows the patient to become accustomed to the "stressing" process more gradually: there is no "sudden impact." Additionally, the time is short enough to allow an expedient, relatively uncomplicated imaging procedure.

Convenient, easy-to-follow protocol minimizes procedural frustrations

The procedural logistics of pharmacologic stress can be another source of emotional stress to the physician or staff. With I.V. Persantine, there's a flexible, easy-to-follow protocol. No infusion pump needed. No need for site-specific injection. And no extra I.V. line for the imaging agent.

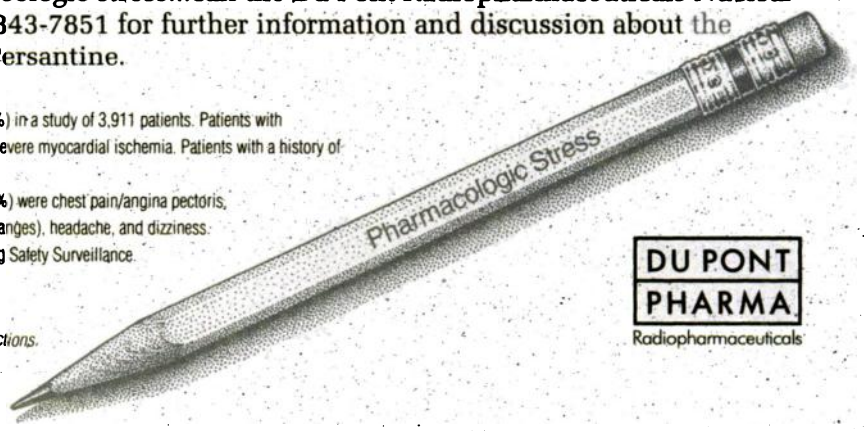
When you stress more assured, you can rest more assured

Based on its proven safety profile and generally well-tolerated effect, I.V. Persantine sets a solid foundation to help reduce the stress that can sometimes be associated with pharmacologic stress.

Stress the facts in pharmacologic stress...call the Du Pont Radiopharmaceuticals Nuclear Cardiology Hotline at 1-800-343-7851 for further information and discussion about the proven safety profile of I.V. Persantine.

*Severe adverse events have occurred infrequently (<0.3%) in a study of 3,911 patients. 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.
In the same study, the most frequent adverse events (>2%) were chest pain/angina pectoris, electrocardiographic changes (most commonly, ST-T changes), headache, and dizziness.
†Du Pont Merck Pharmaceutical Company Post-Marketing Safety Surveillance.

Please see brief summary of prescribing information on reverse for contraindications, warnings, and adverse reactions.



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I.V. PERSANTINE®

(dipyridamole USP) Injection 5mg/ml

References: 1. Ranhosky A, Kempthorne-Rawson J, et al. *Circulation.* 1990;81:1205-1209. **2.** Data on file, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Conn.

I.V. PERSANTINE®

(dipyridamole USP) Injection 5mg/ml

Brief Summary of Prescribing Information

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 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 up to 142 weeks in females) and rats (up to 111 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 previously (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 shown in the following table:

	Incidence (%) of Drug-Related Adverse Events
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%).

OVERDOSAGE No cases of overdosage in humans have been reported. It is unlikely that overdosage will occur because of the nature of use (i.e., single intravenous administration in controlled settings). See WARNINGS.

Caution Federal law prohibits dispensing without prescription.

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Radiopharmaceuticals

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Abstract Inquiries to:
Wilfrido M. Sy, MD, Chairman,
Scientific Program Review Committee
(North and South America)
The Brooklyn Hospital Center
Department of Nuclear Medicine
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Tel: (718) 403-8225 Fax (718) 403-8879

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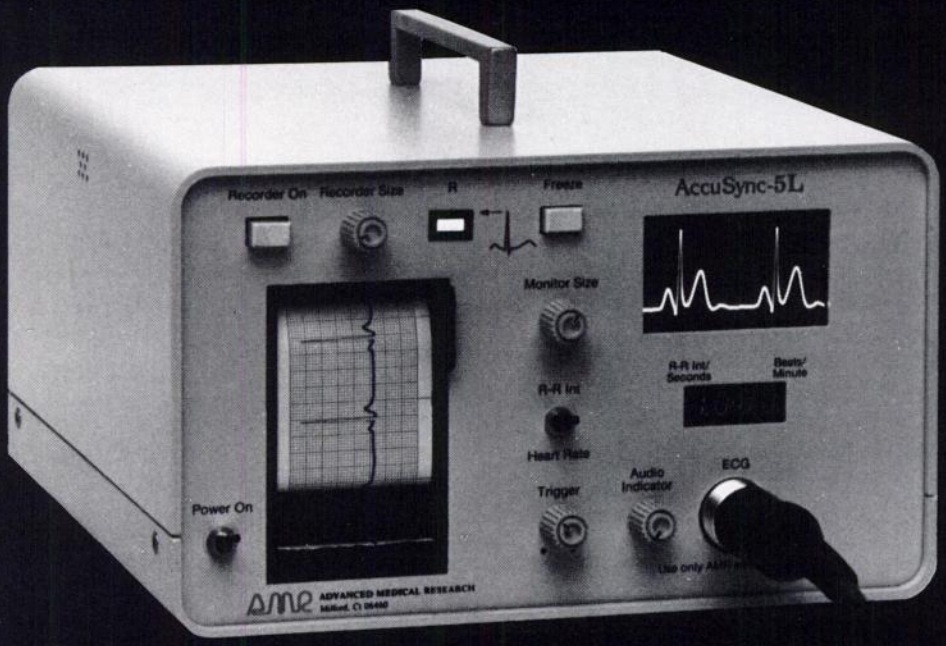

AccuSync-5L Features

- Isolation Amplifier for Patient Safety
- Digital CRT Monitor
- ECG Strip Chart Recorder
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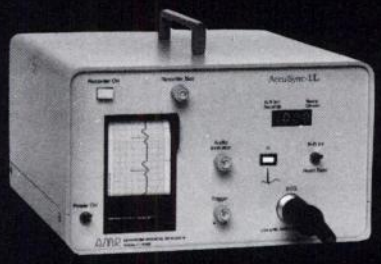
- Event Marker (optional)
- Audio Indicator

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.
AccuSync-3R		All **AccuSync-1L** features with the exception of the Strip Chart Recorder and Playback Mode.
AccuSync-4R		All **AccuSync-3R** features with the exception of the Heart Rate/R-R interval display.

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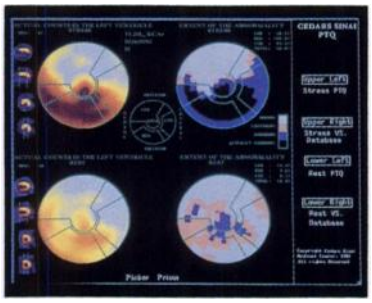

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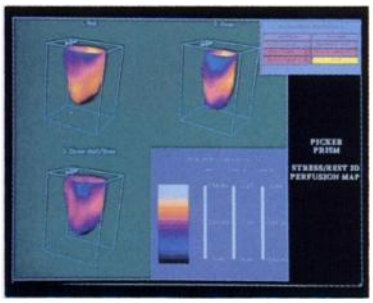

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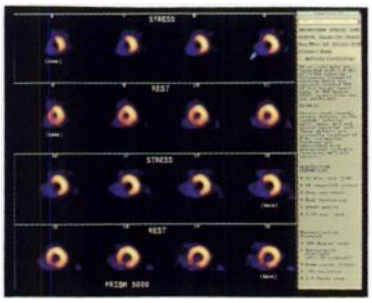
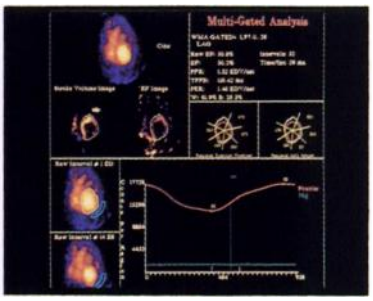
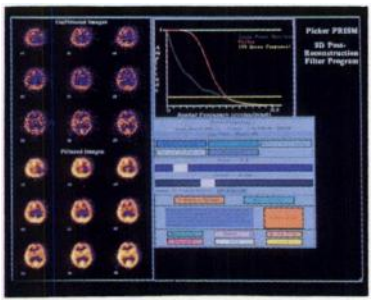


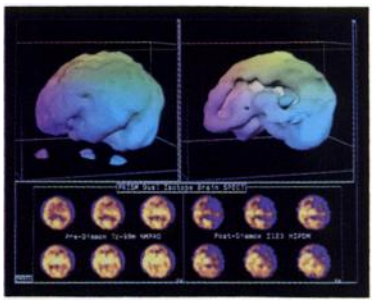
Oblique cardiac slices at stress and re-distribution



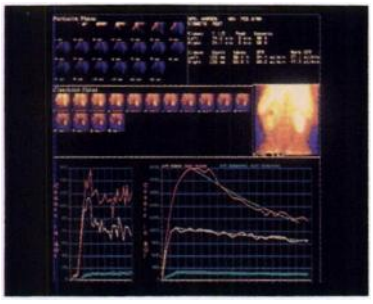
MGA+ (multi-gated analysis) Program



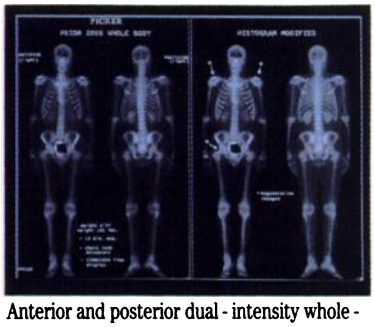
3-D Post-Reconstruction Filter Program



Dual Isotope 3-D images and slices



Renogram analysis time activity curves



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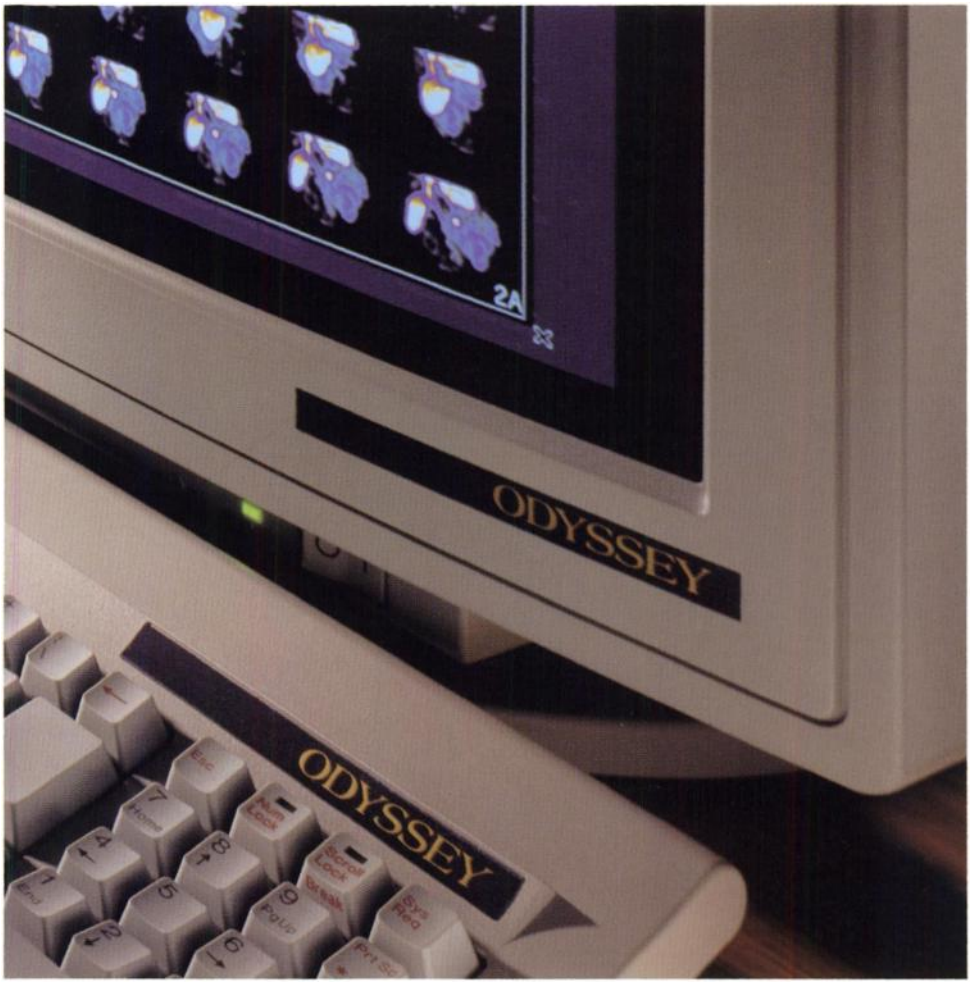

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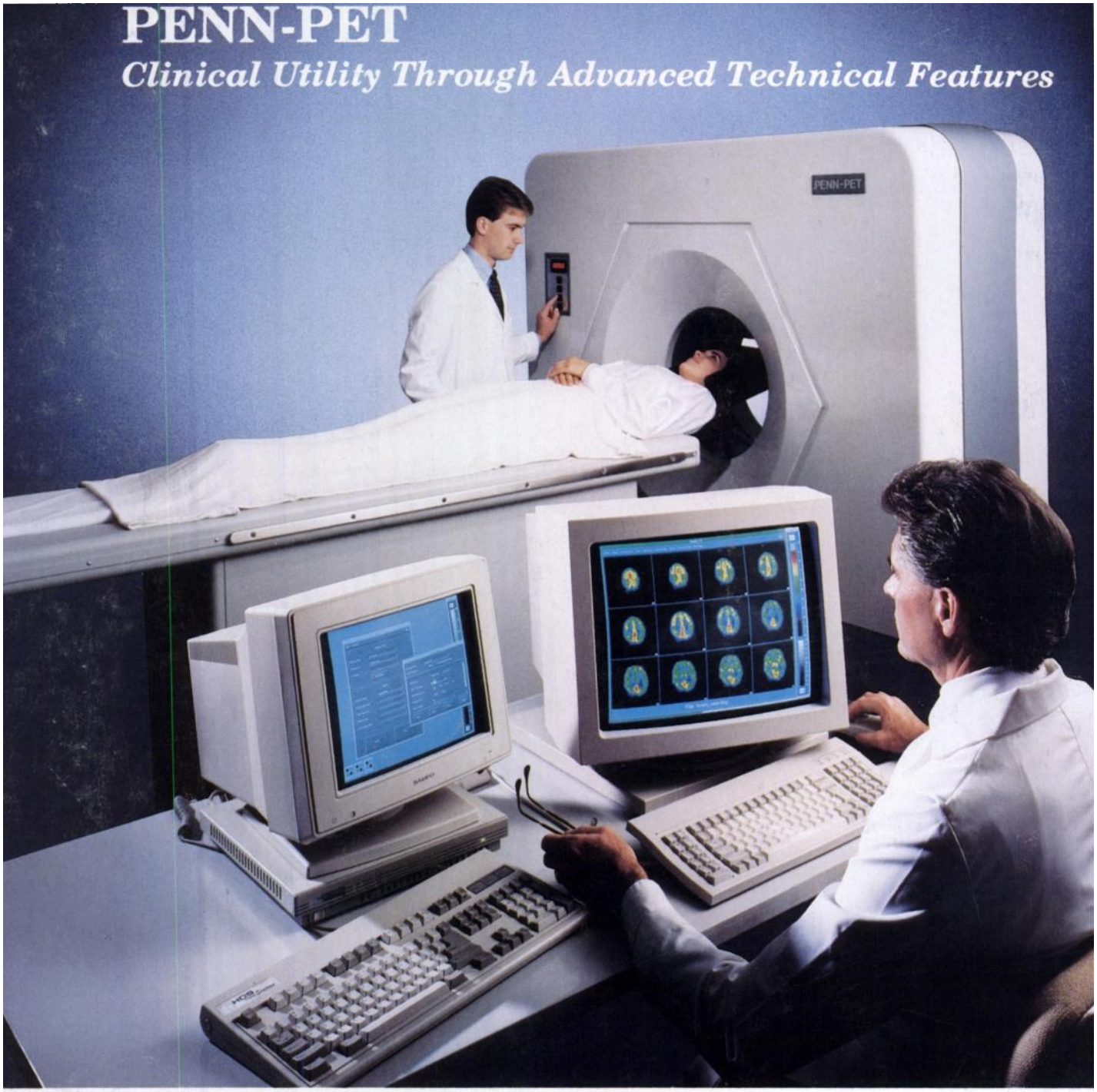

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