



# medi+physics<sup>®</sup>

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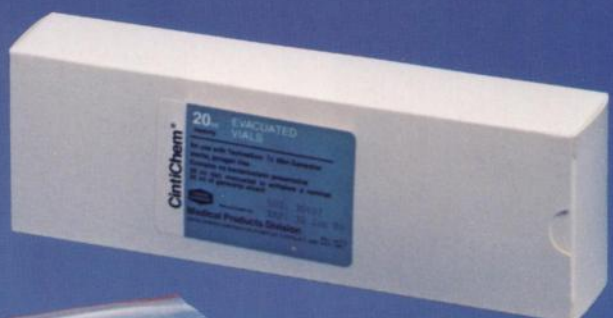


Techetium Tc 99m Generator

Secondary shield to further reduce radiation



5cc and 10cc elution vials



20ml elution vials available on request



Elution vial shield



Sterile needle pack and labels furnished with each generator

Adaptors for various elution vials



TECHNETIUM 99m

# GENERATORS

## Techneium Tc 99m Generators for the Production of Sodium Pertechnetate Tc 99m



Loads either from the top ... or ...



... from the side.



OPEN/CLOSED valve for additional security.

### Featuring:

- Indicated for use in adults and children for urinary bladder imaging (direct isotopic cystography).
- The only Generator with an "open/closed" valve to eliminate possible leakage, both during shipment and in your hot lab.
- Unique horizontal elution procedure increases ease of use and eliminates needle-vial alignment problems.
- A new sterile needle is utilized for each elution, reducing the chances of a septic or pyrogenic situation occurring in routine clinical usage. This method is superior to competitive dry column systems where the same needle assembly is used for the life of the product.
- Fission product molybdenum 99 is used in the Technetium 99m Generator to provide Sodium Pertechnetate Tc99m activity concentrations sufficient for bolus injections.
- Internal saline reservoir eliminates the need to stock saline vials.
- Evacuated elution vials are available in 5cc, 10cc, and 20cc volumes, allowing you to optimize the elution concentration to meet your needs.
- Optimum shielding design minimizes radiation to personnel in work areas, providing maximum protection.
- Generator is compact, providing for optimum maneuverability. Generator handle and shipping carton provide for ease in handling and lifting.



medi+physics®

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SUBSIDIARY OF HOFFMANN-LA ROCHE INC.

### TECHNETIUM Tc 99m GENERATOR for the Production of Sodium Pertechnetate Tc 99m

**DESCRIPTION:** The Technetium Tc 99m Generator is prepared with fission produced Molybdenum Mo 99 adsorbed on alumina in a lead-shielded column and provides a means for obtaining sterile pyrogen-free solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be crystal clear. With a pH of 4.5-7.5, hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

Each eluate of the generator should not contain more than 0.15 microcurie of the Molybdenum Mo 99 per millicurie Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the generator eluate, both of which must be determined by the user before administration.

**INDICATIONS AND USAGE:** Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placenta localization; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux.

Sodium Pertechnetate Tc 99m is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. In general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

**PRECAUTIONS:** 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 insure minimum radiation exposure to occupational workers.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

#### Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium

Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m 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, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

#### Nursing Mothers

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

#### Pediatric Use

See **Indications and Usage, dosage** and administration. See also description of additional risk under **warnings**. 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.

The generator should not be used after 16 days from the date and time of calibration.

At time of administration, the solution should be crystal clear.

**ADVERSE REACTIONS:** Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

**HOW SUPPLIED:** Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 830 millicuries up to 16,600 millicuries (in approximately 830 millicurie increments) of Molybdenum Mo 99 as of 10:00 P.M. Eastern Time of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of:

- 1) sterile generator,
- 2) Sodium Chloride Injection source,
- 3) 10 cc sterile evacuated vials,
- 4) sterile needles,
- 5) elution vial shield\*
- 6) finished drug labels.

Elution vials in 5 cc and 20 cc sizes are available upon request.

\*initial order only

The TECHNETIUM Tc 99m GENERATOR should not be used after sixteen (16) days from the date and time of calibration.

Jointly manufactured by:

**CINTICHEM, INC.** and  
Tuxedo, N.Y. 10987

June, 1983  
**UNION CARBIDE CORPORATION**  
Tuxedo, N.Y. 10987



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- Easy preparation.
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- Earlier imaging: pictures from one hour after injection

**International CIS goes faster in bone imaging.**



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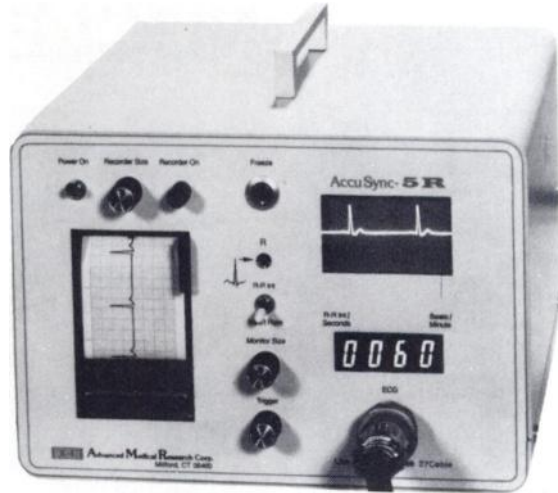
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The finest R-wave Triggering device available for computerized gated cardiac studies.

## AccuSync-5R Features

- Isolation Amplifier for Patient Safety.
- Digital CRT Monitor.
- ECG Strip Chart Recorder.
- Heart Rate/R-R int.
- Trigger Pulse LED.
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- R-Trigger Output, Compatible with all Computers.
- ECG Output.
- Playback Mode.
- Event Marker



### MODEL

### FEATURES

#### AccuSync-6

All **AccuSync-5R** features with the exception of the Strip Chart Recorder.

#### AccuSync-IR

All **AccuSync-5R** features with the exception of Digital CRT Monitor.

#### AccuSync-2

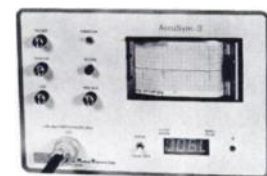
All **AccuSync-IR** features incorporated into a Module designed to fit into certain Mobile cameras.

#### AccuSync-3

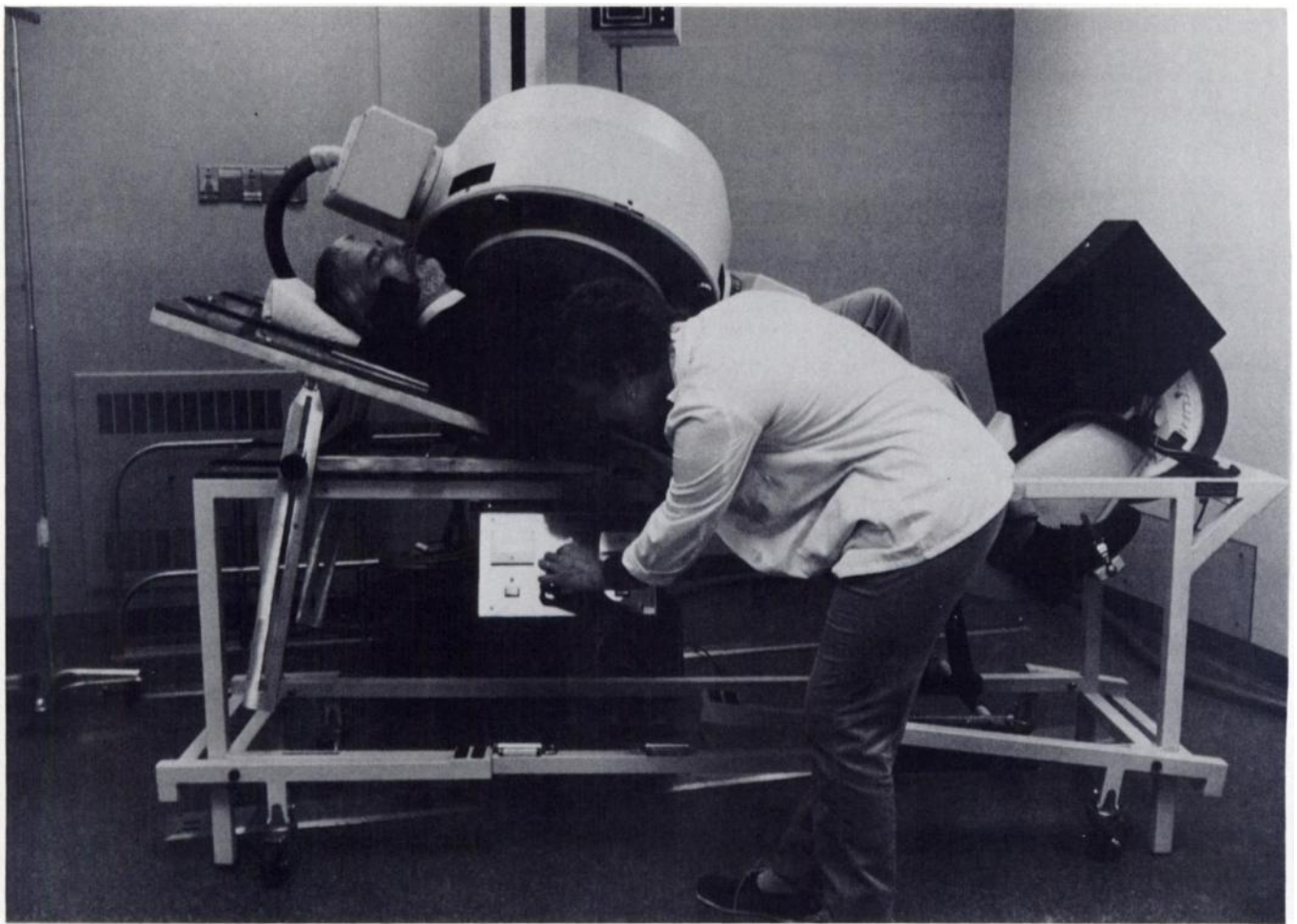
All **AccuSync-IR** features with the exception of the Strip Chart Recorder and Playback Mode.

#### AccuSync-4

All **AccuSync-3** features with the exception of the Heart Rate/R-R int. display.



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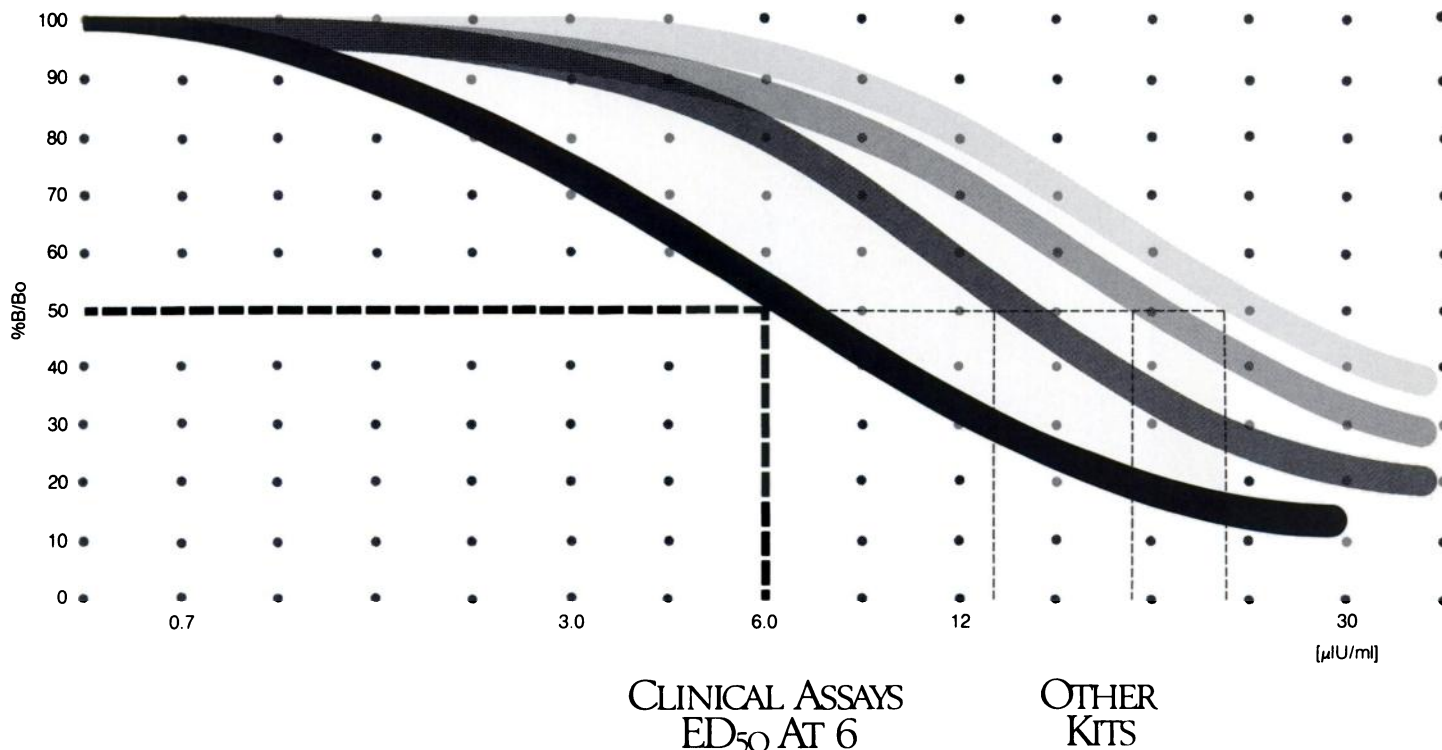
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human serum-based standards, a highly specific antibody, and an overnight incubation that optimizes kinetics. These combine to bring you an ED<sub>50</sub> of 6 — where you really need it.

### A higher count rate, too.

This high sensitivity TSH also has a high count rate which can speed sample throughput and improve precision.

Call toll-free for clinical data:  
800-225-1241.

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GAMMADAB<sup>®</sup> HS hTSH RIA Kit, technical information, or an evaluation kit, call toll-free, or collect within Massachusetts, 617-492-2526. Or write Clinical Assays, 620 Memorial Drive, Cambridge, MA 02139. TELEX: 921461 CLASS CAM.

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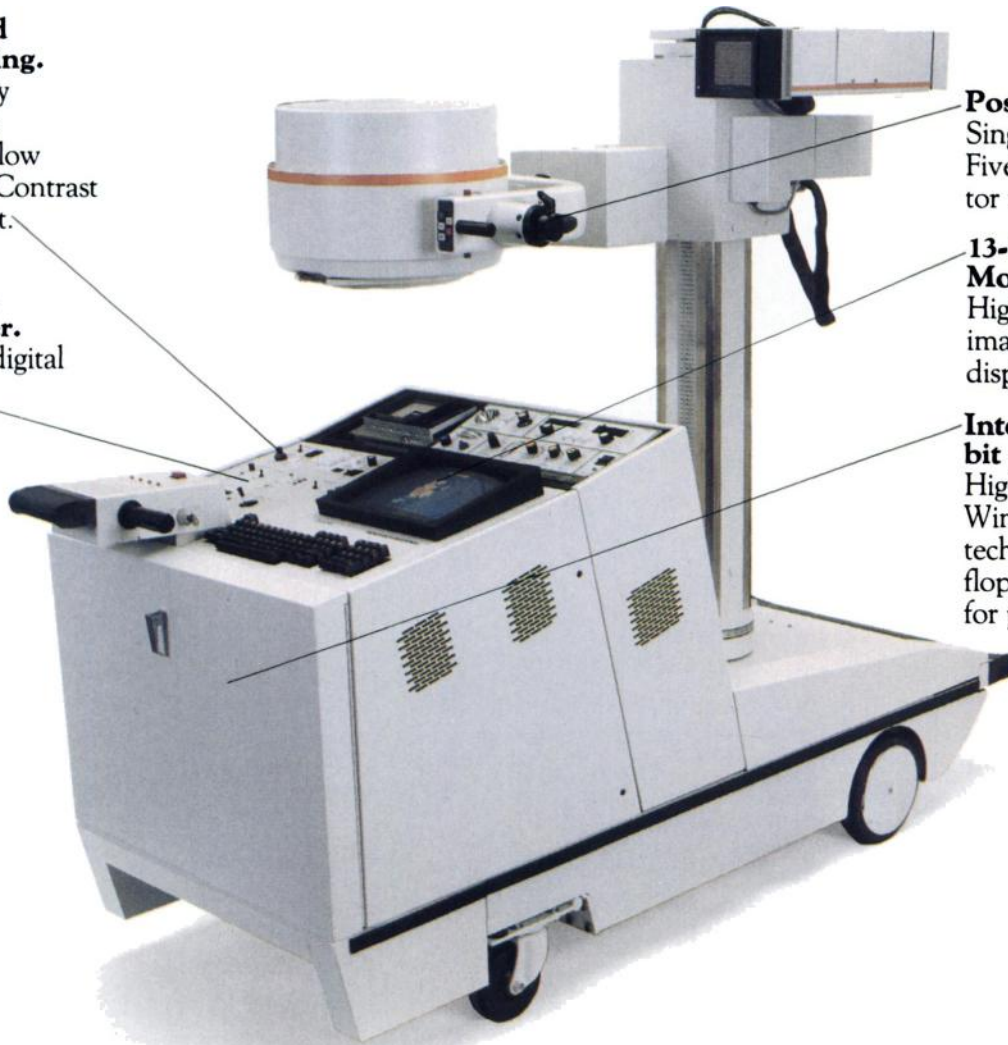


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## New Data Mo™ Computerized Mobile Camera System from Picker International.

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Picker International's new *Data Mo* is a completely integrated mobile camera and computer. Its mobility brings all the benefits of high resolution imaging and quantitative analysis right to the patient. Fully supported software is available for your clinical setting. Use the *Data Mo* in intensive care, cardiac care unit or emergency room. Even right in the Nuclear

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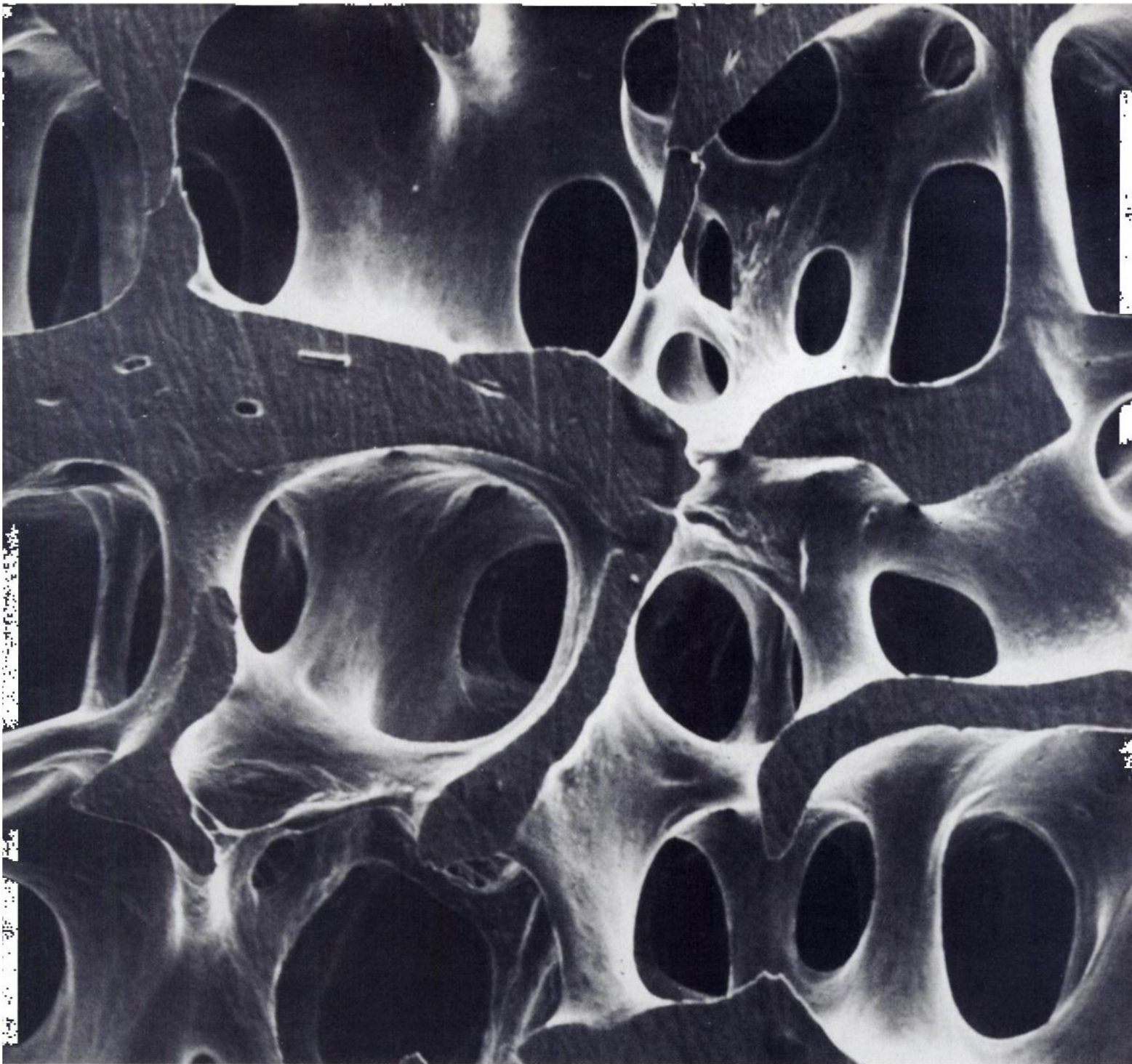
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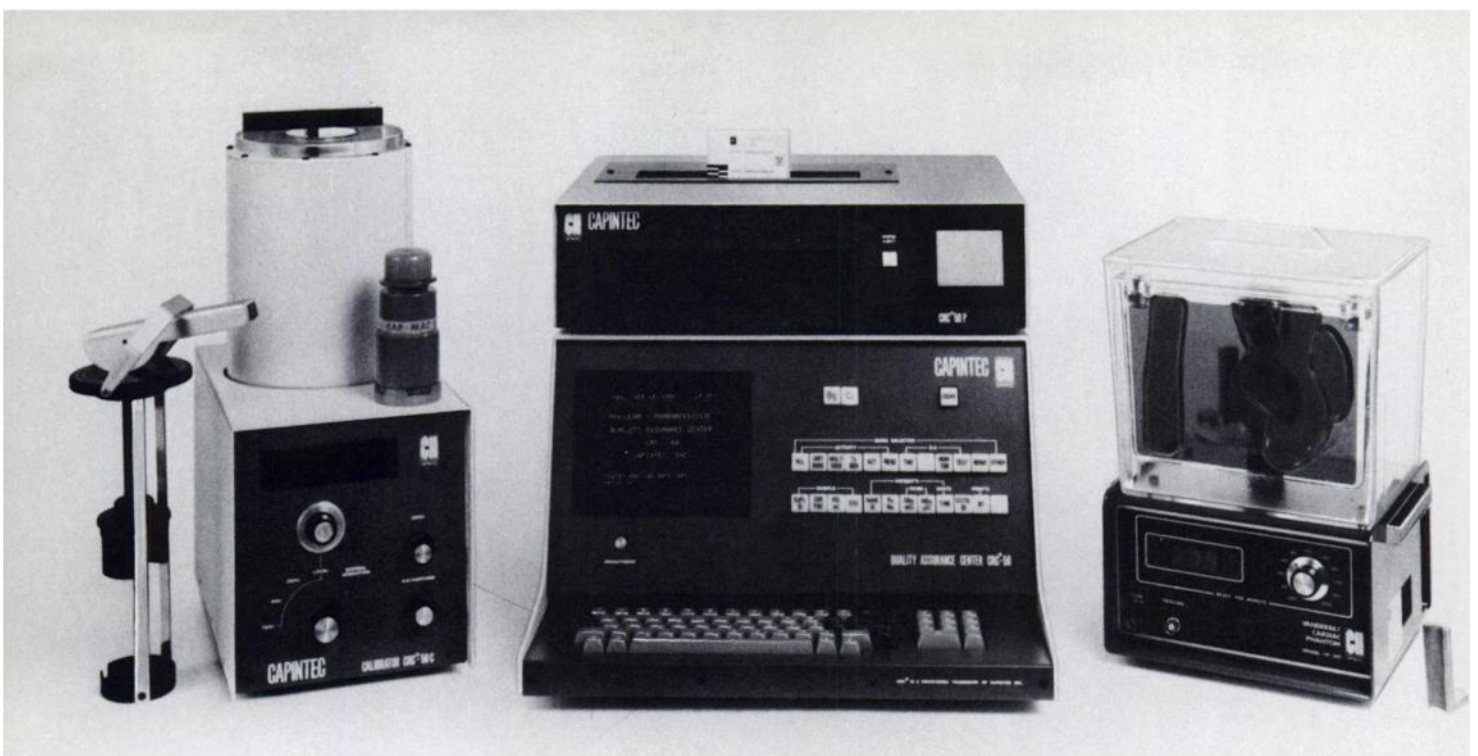
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All the radionuclide dose calibration data you need is at your fingertips with the CRC-50. The compact modular system provides future dose planning, inventory control, and record keeping capabilities. You'll have push-button access to ten program modes, CRT display, both ticket and page-size reports plus a minicassette record — all together in an easy-to-operate, easy-to-own system.

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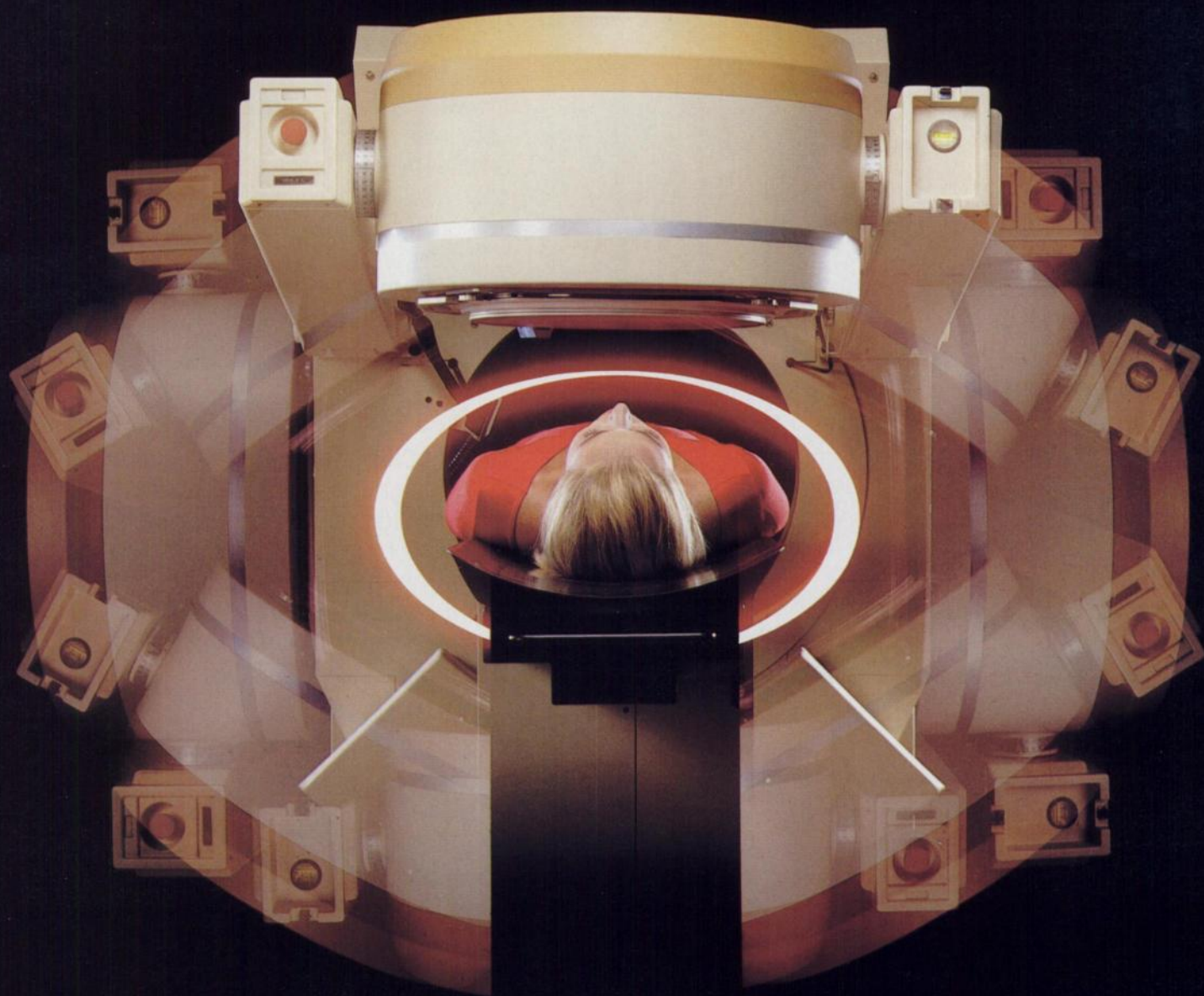
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apex SPECT systems

# Homing in on Perfection



elscint



Elscont revolutionized the practice of Nuclear Medicine with the world's first digital gamma camera systems. Today, this forward-looking company is still in the lead - with the world's best system for Single Photon Emission Computerized Tomography: *Apex 415 ECT*. *Apex ECT* systems include all the advantages of the Apex family of digital integrated gamma cameras, plus some other remarkable features which keep them far ahead: total clinical capability, vast computer power, circular or elliptical orbit of rotation, full flexibility in clinical reporting, and operator-selectable Continuous or Step-and-shoot modes.



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### **Universal NM System**

Innovatively designed to include all Nuclear Medicine functions, Apex ECT is a high-quality, easily-positioned gamma camera system for conventional use, as well as a capable whole-body scanner for single- or dual-pass bone scans, above or below the table. It is also the most versatile rotational ECT scanner on the market, fully upgradeable to accommodate future developments.

## **apex SPECT**

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Apex ECT has its own high-powered integrated multiprocessor; unlike most competitive systems, it needs no accessory stand-alone computer. A built-in high speed array processor enables near-instantaneous reconstruction - only 3.5 seconds per slice. In addition, the Apex computer controls acquisition and display functions, and all detector movements. Sophisticated attenuation correction algorithms insure highest image verity, regardless of body contour:

## **apex SPECT**

### **Getting Closer for Better Resolution**

In NM imaging, the distance between the radiating organ and the detector is a major factor in achieving high resolution. Apex ECT narrows the gap: its elliptical orbit of rotation approximates the body's cross-sectional profile, permitting the detector to get closer than the conventional circular orbit.

# elscont

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#### **Elscont European Operations**

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## apex SPECT

### Covering all the Angles

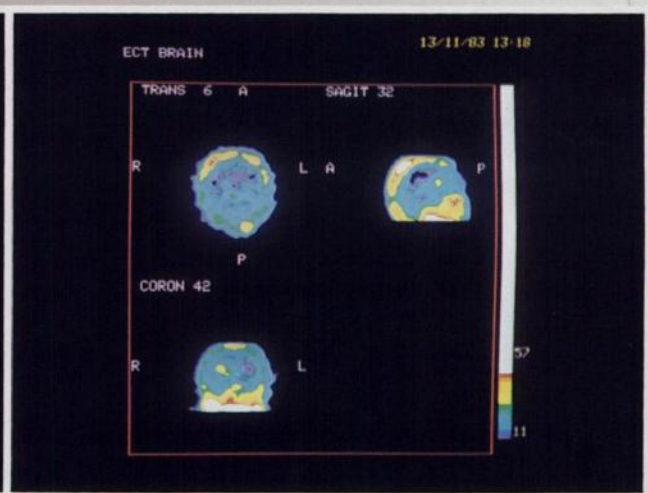
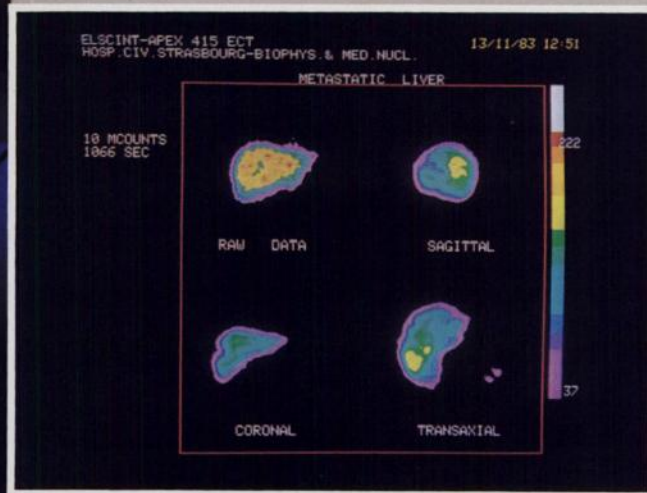
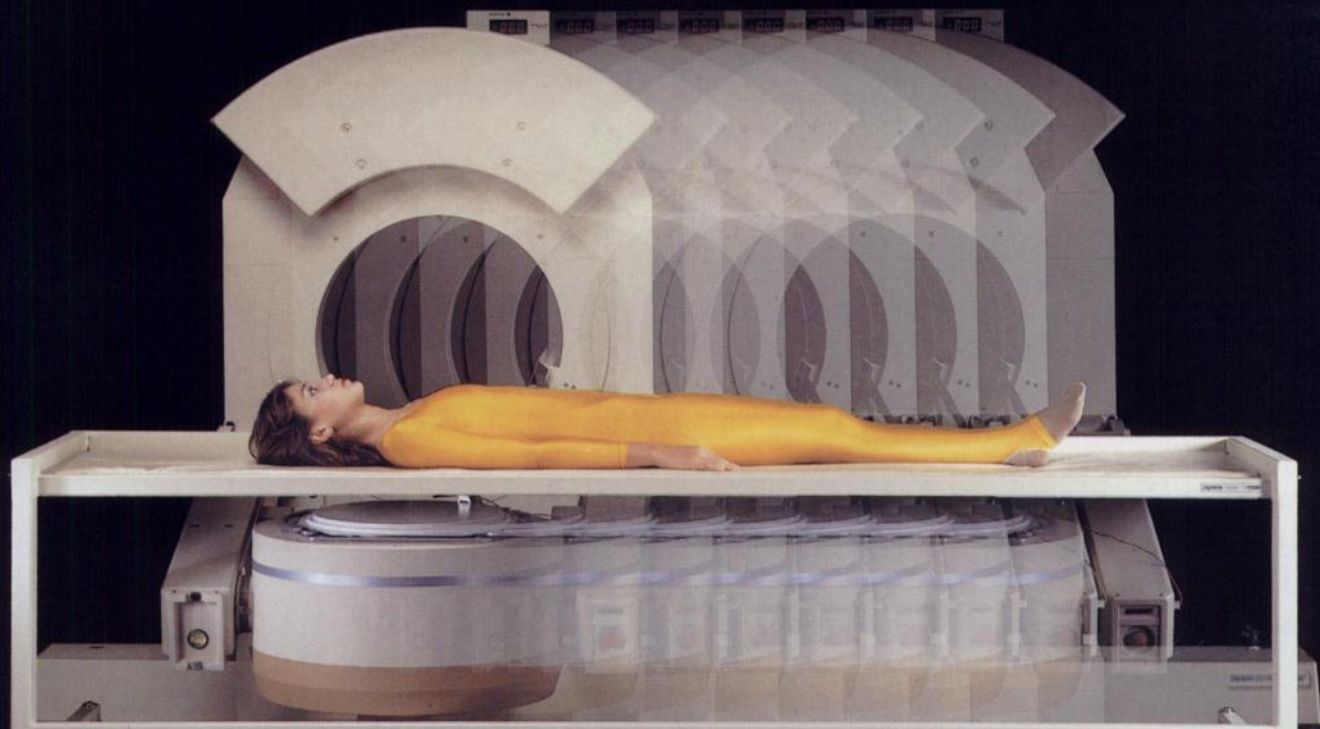
Apex ECT's sophisticated software enables reconstruction of slices at virtually any angle, along any clinically useful plane. Data for transaxial, sagittal and coronal planes are automatically output by the computer. Clinical reports can be prepared directly on-screen, complete with clinical images and all necessary alphanumeric information. Hard copy is produced on standard X-ray film by Elscint's FORMAX™ multifformat camera.

## apex SPECT

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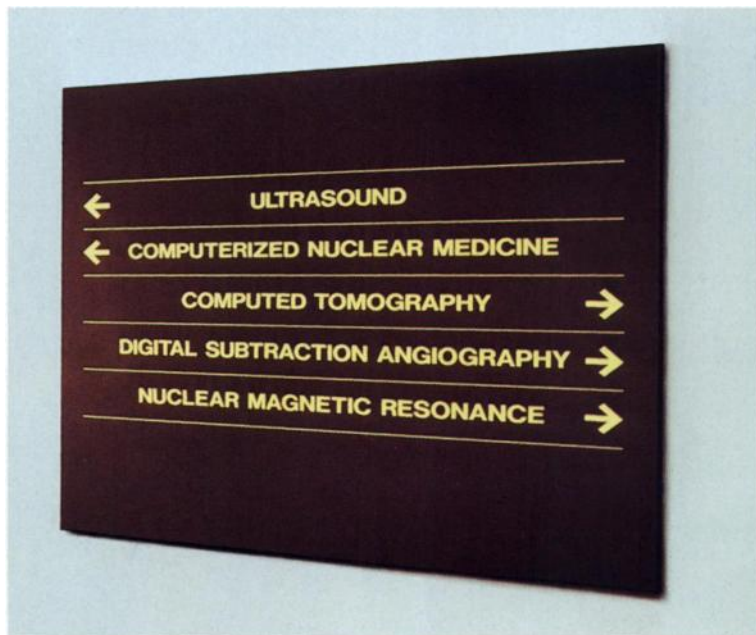
In Step-and-shoot mode, particularly applicable to gated Thallium tomographic studies, the rotational steps are precision-controlled by the Apex ECT computer. A 180° arc begins and ends at any operator-selected position.





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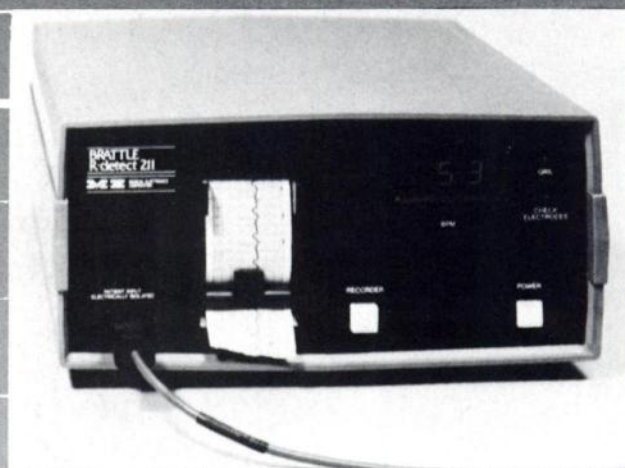


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The BRATTLE R-DETECT automatically adjusts the threshold level . . . there is *no* manual setting needed.



**MODEL 210**



**MODEL 211**

The BRATTLE R-DETECT offers you fully automatic R-wave triggering and is compatible with all nuclear medicine computers. In addition, the model 211 has a strip chart with EKG and event marker indicating the exact location of the R-DETECT signal.

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- Fully automatic threshold
- Only two electrodes
- High heartrate capability . . . ideal for stress testing
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- Flashing LED indicates QRS
- LED indicates faulty electrode connections
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# ME

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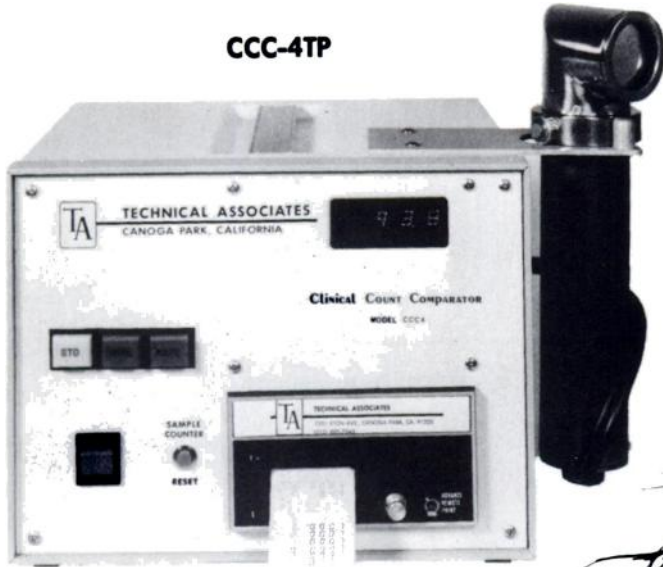
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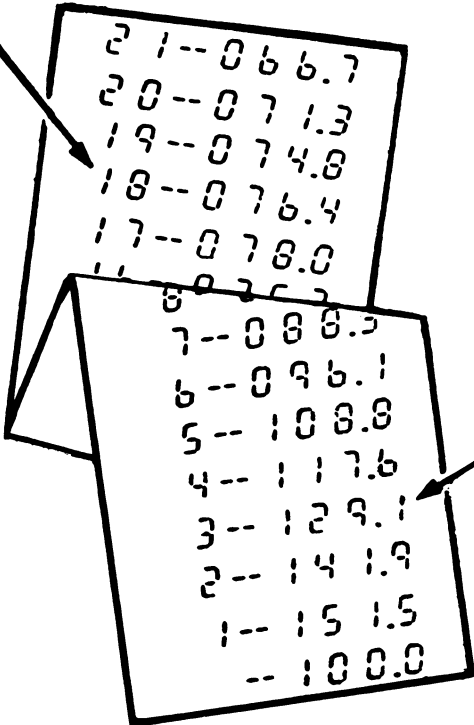
# thrombosis

detection of DVT using I-125 fibrinogen

CCC-4TP



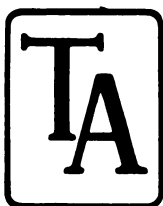
position on leg



percent uptake

Print Out  
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- Direct **digital percent** readout
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- **Bedside** operation
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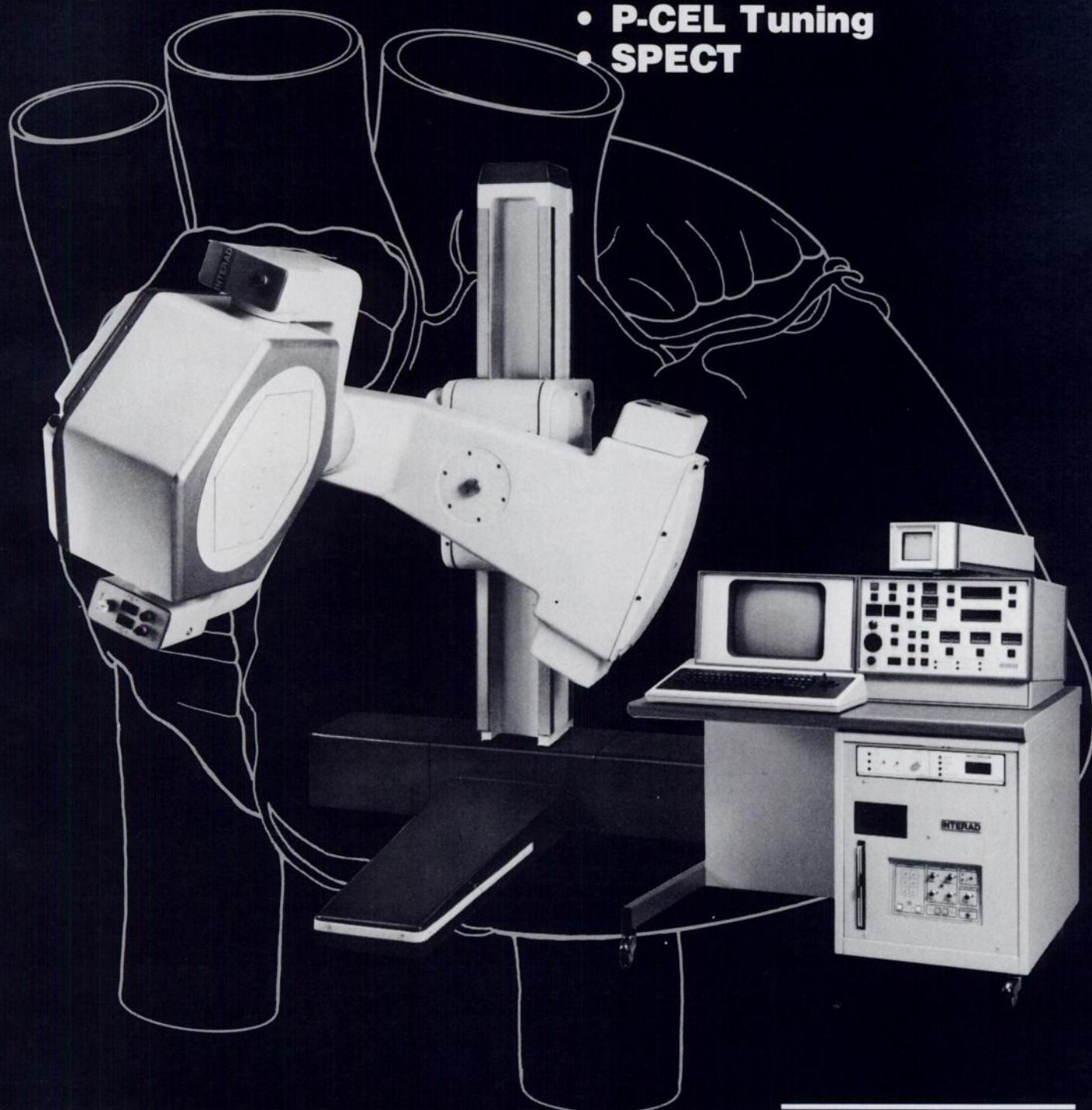
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\*Ref: Anger, H.O. - Testing the Performance of Scintillation Cameras, LBL-2027, May 1973



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# Space/time quantitative thallium imaging

## Daniel S. Berman, MD

Director, Nuclear Cardiology  
Cedars-Sinai Medical Center  
Associate Clinical Professor of Radiology  
University of California, Los Angeles  
School of Medicine



## Ernest V. Garcia, PhD

Director, Nuclear Medicine Computer Sciences  
Cedars-Sinai Medical Center  
Adjunct Assistant Instructor of Radiology  
University of California, Los Angeles  
School of Medicine



## Jamshid Maddahi, MD

Director, Nuclear Cardiac Stress Testing  
Cedars-Sinai Medical Center  
Assistant Professor of Medicine  
University of California, Los Angeles  
School of Medicine



At Cedars-Sinai Medical Center, we have developed a computerized technique for analyzing both the regional myocardial distribution and the washout of thallium-201. The technique combines some of the most useful aspects of previously described quantitative approaches to thallium imaging with certain unique display features. Our studies so far<sup>1,2</sup> have convinced us that the method yields objective, highly accurate results and, more important, provides valuable information that often cannot be obtained by visual inspection alone of thallium-201 scintigrams.

### Space/time quantitation

The method we have developed for simultaneous spatial and temporal quantitation of myocardial thallium distribution uses a computer to

- perform interpolative background subtraction of the images. This approach to myocardial background subtraction—as first described by Goris and colleagues,<sup>3</sup> and modified by Watson et al<sup>4</sup>—appears to provide the most satisfactory approximation of the true background contribution.
- generate and display maximal circumferential profiles representing the myocardial distribution of thallium in the immediate-postexercise and 4-hour delayed images. Following the approach suggested by Burow et al<sup>5</sup> and Vogel and associates,<sup>6</sup> the profiles are constructed by the computer for the post-exercise images from the maximal-count-per-pixel values along 60 radii spaced at 6° intervals.

- generate and display washout circumferential profiles. These profiles are computer-constructed by subtracting, point for point, the 4-hour distribution profile from the initial postexercise profile, and then dividing by the initial profile. This yields a percent washout rate for each region around the myocardium.
- compare both the initial distribution profile and the percent washout profile with previously established normal profiles. Our normal profiles are drawn from a population of patients with less than a 1% likelihood of coronary disease on the basis of Bayesian analysis. This approach avoids the pitfalls inherent in defining as normals either patients with normal coronary arteriography (who, in fact, may have nonatherosclerotic ischemic disease) or “normal volunteers” (who may have occult coronary disease).

Operator interaction is confined to selecting the ventricular region of interest for background subtraction; visual determination of the center of the ventricle (and thus the maximum radius to which the computer will search); and locating the apex. Of these three operator-dependent steps, location of the apex is most critical. The computer automatically assigns the selected apex to the 90° position for comparison of the curves for washout calculation and for comparison of patient results with our normal values.

### Displaying the data

Finally, the computer displays the quantitative data in a way that is very easy to comprehend and interpret. In addition to curves of initial distribution, 4-hour distribution and percent washout for the anterior, 45° LAO and 70° LAO views, the display shows a series of three concentric ellipses that permits immediate identification of segments with abnormal perfusion and/or washout.

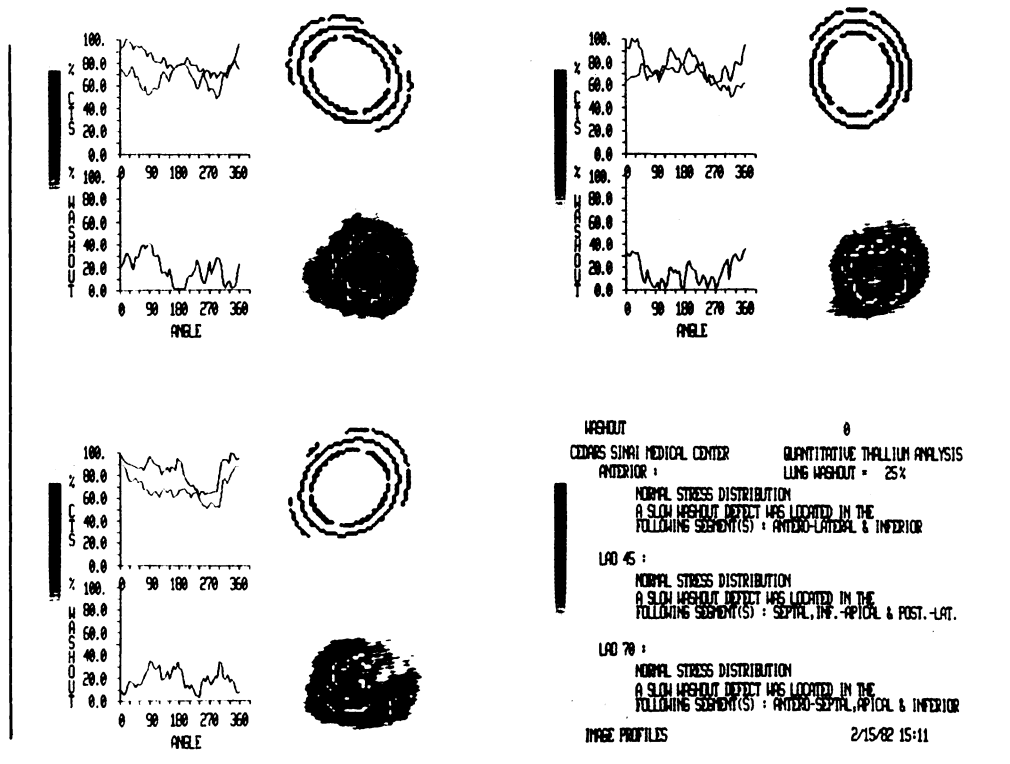
The innermost of these three ellipses is a reference indicating the position of the myocardium. The middle ellipse corresponds to initial postexercise thallium distribution, and the outer ellipse to the percent washout for each region. Consecutive unbroken ellipses in each view suggest a normal study—with no regions of perfusion deficit or abnormal washout. Gaps in the middle ellipse represent abnormal regional perfusion; gaps in the outer ellipse represent abnormal regional washout. Regional abnormalities are determined by the computer by comparison with the lower limits of normal established for both perfusion and washout from our normal population.

### Improved thallium imaging

We believe that our program overcomes some of the limitations associated with reliance on visual interpretation of thallium-201 images. The first of these, as most experienced observers would admit, is the *subjectivity* of visual analysis and the consequent variability of reported sensitivity and specificity values. In our recently reported study,<sup>2</sup> the sensitivity



Quantitative thallium study demonstrating significant three-vessel coronary disease. On visual inspection, the study was read as normal. The unbroken middle ellipses in all views suggest no perfusion defects—consistent with the visual interpretation. However, gaps in the outer ellipses indicate washout abnormalities in the distribution of each of the major coronary arteries. Angiography revealed 90% stenoses of each of the proximal arteries.



and specificity for detection of coronary artery disease were 93% and 90%, respectively—compared to 91% and 86% for visual interpretation. More important, interobserver agreement was 93% with the quantitative technique—higher than reported for visual interpretation, and suggesting that high sensitivity and specificity values could be routinely obtained in every nuclear cardiology laboratory.

Another reported problem is the relative insensitivity of visual analysis for identifying individual-vessel coronary lesions. Visual reading relies on the fact that the initial myocardial distribution of thallium reflects relative, not absolute, differences in uptake between ischemic and nonischemic regions. Thus, in a patient with multivessel disease, some areas with diminished perfusion may appear relatively normal compared with a more severely hypoperfused region. In the worst case, significant three-vessel disease with balanced reduction in blood flow may not be seen as abnormal by visual inspection of the images.

Our technique overcomes this limitation by quantifying regional thallium washout, thus permitting us to compare each region with itself over time rather than with other regions. Because ischemic regions demonstrate altered washout, we can thus identify areas supplied by stenosed vessels which might be undetected by visual region-to-region comparison alone.

How successful have we been in identifying individual diseased vessels? In our recent study, we detected left anterior descending disease with a

sensitivity of 80% (compared to 56% for visual inspection), left circumflex disease with a sensitivity of 63% (compared to 34%) and right coronary disease with a sensitivity of 94% (compared to 65%). In addition, our sensitivity for distinguishing coronary arteries with moderate disease was 70%, compared to 35% by visual inspection.

### Clinical implications

The increased sensitivity and specificity of our program, and the enhanced interobserver agreement, have important implications not only for detection of coronary disease, but also for patient prognosis. We know from angiographic studies that the likelihood of major cardiac events may be related to the location and extent of a patient's coronary disease. The ability to identify individual-vessel disease—especially in patients with multiple-vessel involvement—that we have demonstrated with our quantitative approach to thallium imaging suggests that such potentially prognostic information can now be obtained noninvasively, with the attendant advantages of reduced patient inconvenience and lower cost.

### References

1. Garcia E, Maddahi J, Berman D, et al: *J Nucl Med* 22:309, 1981.
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3. Goris ML, Daspit SG, McLaughlin P, et al: *J Nucl Med* 17:744, 1976.
4. Watson DD, Beller GA, Berger BC, et al: *Software* 6:4, 1979.
5. Burow RD, Pond M, Schafer AW, et al: *J Nucl Med* 20:771, 1979.
6. Vogel RA, Kirch DL, LeFree MT, et al: *J Nucl Med* 19:730, 1978 (abst).

Please see following page for brief summary of prescribing information

# Thallous Chloride TI 201

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

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

**CONTRAINDICATIONS:** None known.

**WARNINGS:** 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 thallium TI 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.

Thallous Chloride TI 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 or whether Thallous Chloride TI 201 affects fertility in males or females.

**Pregnancy Category C.** Animal reproductive studies have not been conducted with Thallous Chloride TI 201. It is also not known whether Thallous Chloride TI 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride TI 201 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.

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**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.

The expiration date for Thallous Chloride TI 201 is a maximum of five days post-calibration.

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

**DOSAGE AND ADMINISTRATION:** The recommended adult (70kg) dose of Thallous Chloride TI 201 is 1-1.5mCi. Thallous Chloride TI 201 is intended for intravenous administration only.

For patients undergoing resting thallium studies, imaging is optimally begun within 10-20 minutes after injection. Several investigators have reported improved myocardial-to-background ratios when patients are injected in the fasting state, in an upright posture, or after briefly ambulating.

Best results with thallium imaging performed in conjunction with exercise stress testing appear to be obtained if the thallium is administered when the patient reaches maximum stress and when the stress is continued for 30 seconds to one minute after injection. Imaging should begin within ten minutes post-injection since target-to-background ratio is optimum by that time. Several investigators have reported significant decreases in the target-to-background ratios of lesions attributable to transient ischemia by two hours after the completion of stress testing.

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**HOW SUPPLIED:** Thallous Chloride TI 201 for intravenous administration is supplied as a sterile, non-pyrogenic solution containing at calibration time, 1mCi/ml of Thallous TI 201, 9mg/ml sodium chloride, and 9mg/ml of benzyl alcohol. The pH is adjusted to between 5-7 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 2.2, 4.4 and 6.6 millicuries of Thallous TI 201.

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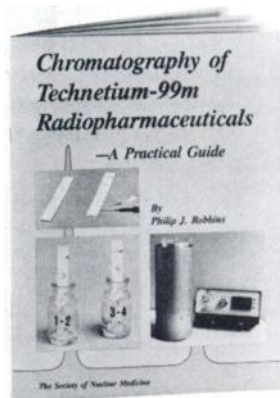
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ACQUISITION TIME (HH:MM:SS)	0:00:10	PROBE DISTANCE (CM)	25
BACKGROUND CPM	606.000	10:01:04	5-JAN-84
CAPSULE CPM	69912.000	10:01:23	5-JAN-84
BACKGROUND CPM	606.000	10:01:04	5-JAN-84
CAPSULE CPM (D)	69884.461	10:01:50	5-JAN-84
PATIENT CPM	14100.000	10:01:51	5-JAN-84
THYROID UPTAKE 1	19.478%		
BACKGROUND CPM	606.000	10:01:04	6-JAN-84*
CAPSULE CPM (D)	19766.197	10:03:28	6-JAN-84
PATIENT CPM	4464.000	10:04:52	6-JAN-84
THYROID UPTAKE 2	20.135%		
BACKGROUND CPM	606.000	10:01:04	6-JAN-84*
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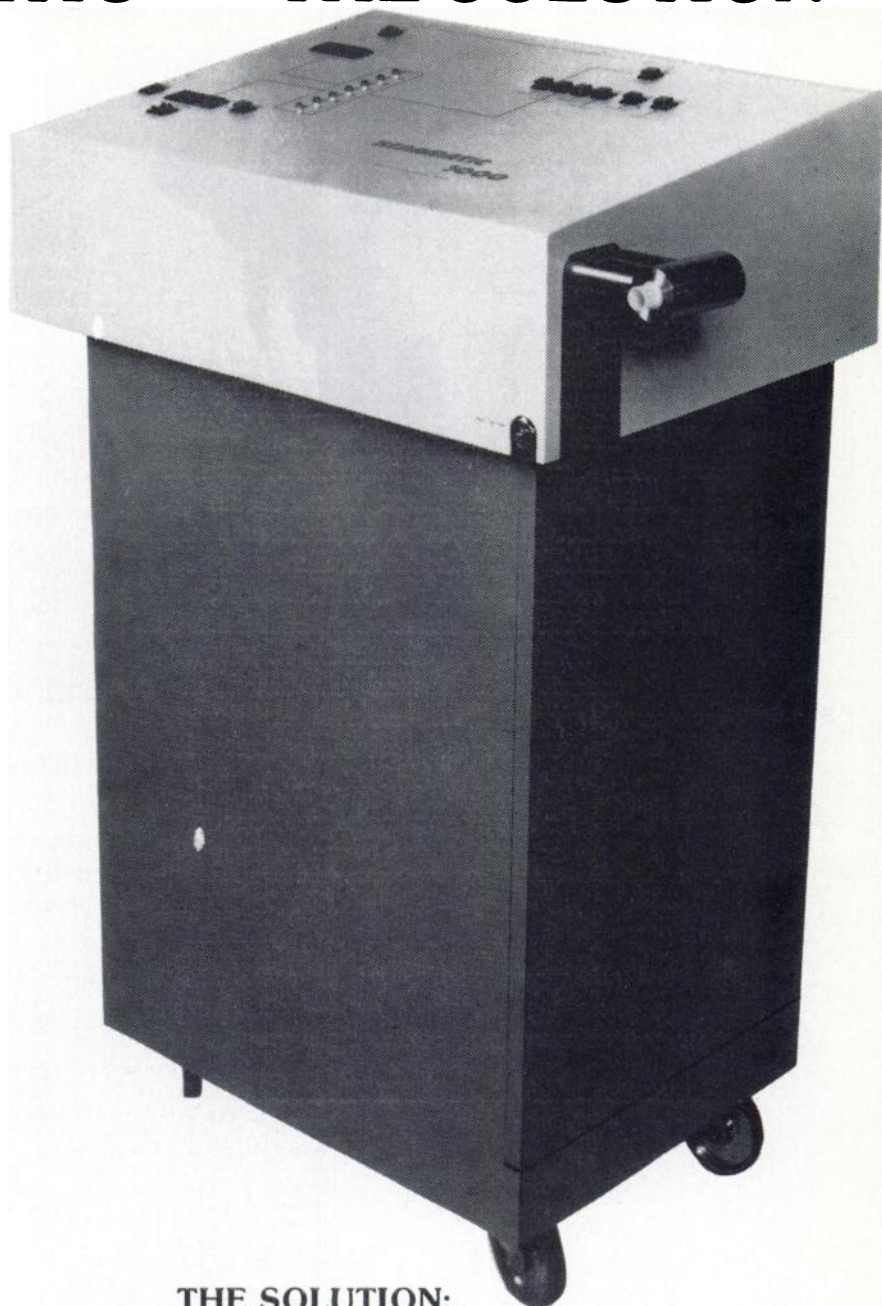
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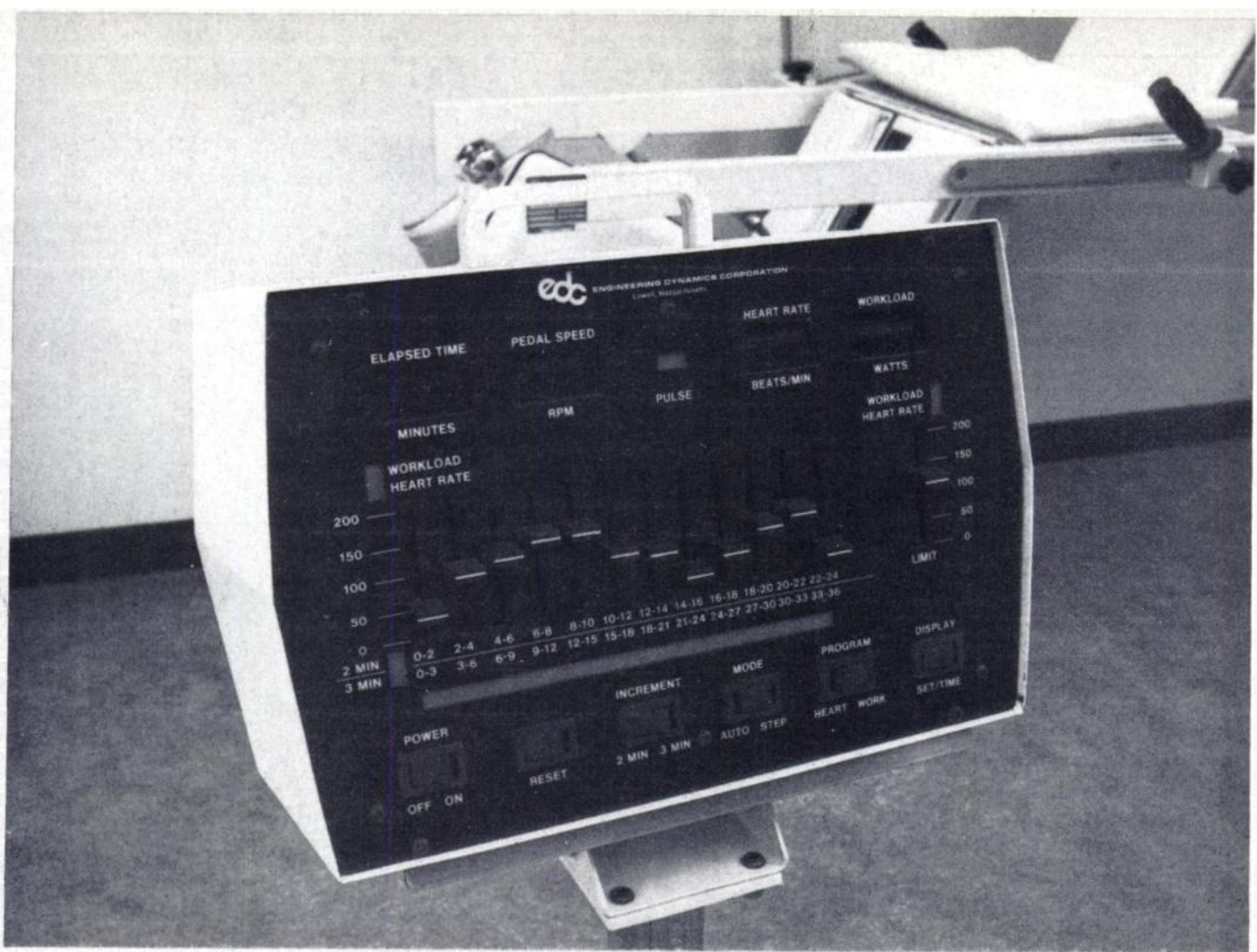
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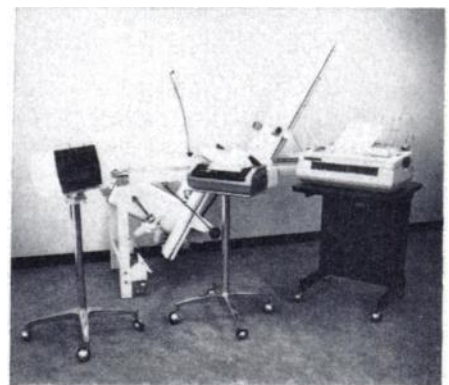
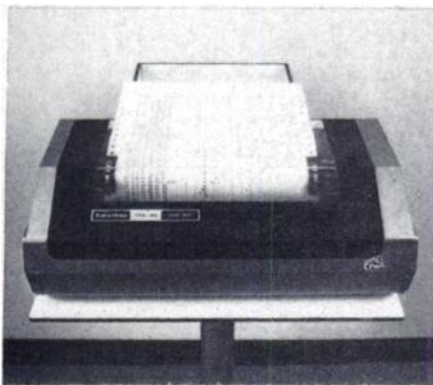
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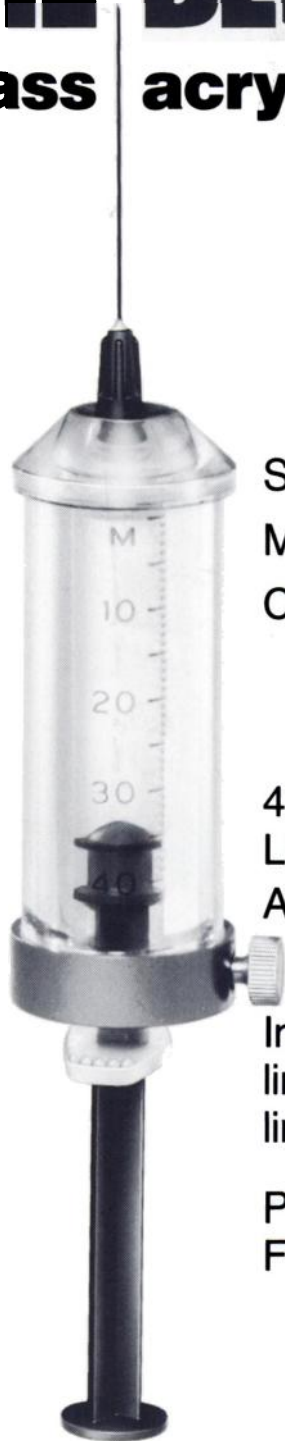


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