

MAR - 8 2000

K992912

CARDIAC PATHWAYS CORPORATION
Premarket Notification

Cardiac Pathways Tracking System

510(k) SUMMARY

Indications

The Cardiac Pathways Tracking System catheters are indicated for cardiac electrophysiological mapping and delivering diagnostic pacing stimuli. In addition, the Tracking catheters are used with the Arrhythmia Mapping and Tracking System to provide catheter location information.

Device Description

The Cardiac Pathways Arrhythmia Mapping and Tracking System allows the recording, viewing, and analysis of intracardiac electrograms and EKG signals to aid in the diagnosis and localization of cardiac arrhythmias. The System also allows the recording, viewing, and annotation of diagnostic electrophysiology (EP) catheter positions and electrode positions. The system facilitates the simultaneous recording of signals through connections to standard EP mapping catheters, specialized EP mapping catheters, and a 12-lead EKG.

The Cardiac Pathway Arrhythmia Mapping and Tracking System is intended for use in applications of diagnostic EP mapping and consists of the following:

- a signal recording computer system for interpreting mapping signals and documenting locations of catheters and catheter electrodes,
- electrogram signal amplifier electronics,
- ultrasound transmit and receive electronics,
- a set of diagnostic electrophysiology reference catheters containing ultrasound ranging transducers and mapping electrodes (referred to as Reference Catheters, RV Reference Catheters, and CS Reference Catheters),
- one or more diagnostic electrophysiology tracking catheters containing ultrasound ranging transducers and mapping electrodes (referred to as Tracking Catheters, Steerable Catheters, and Radii Catheters with Tracking),
- cabling to connect transducers and electrodes to recording equipment, and
- software for interfacing the electronics and displaying catheter locations to the operator.

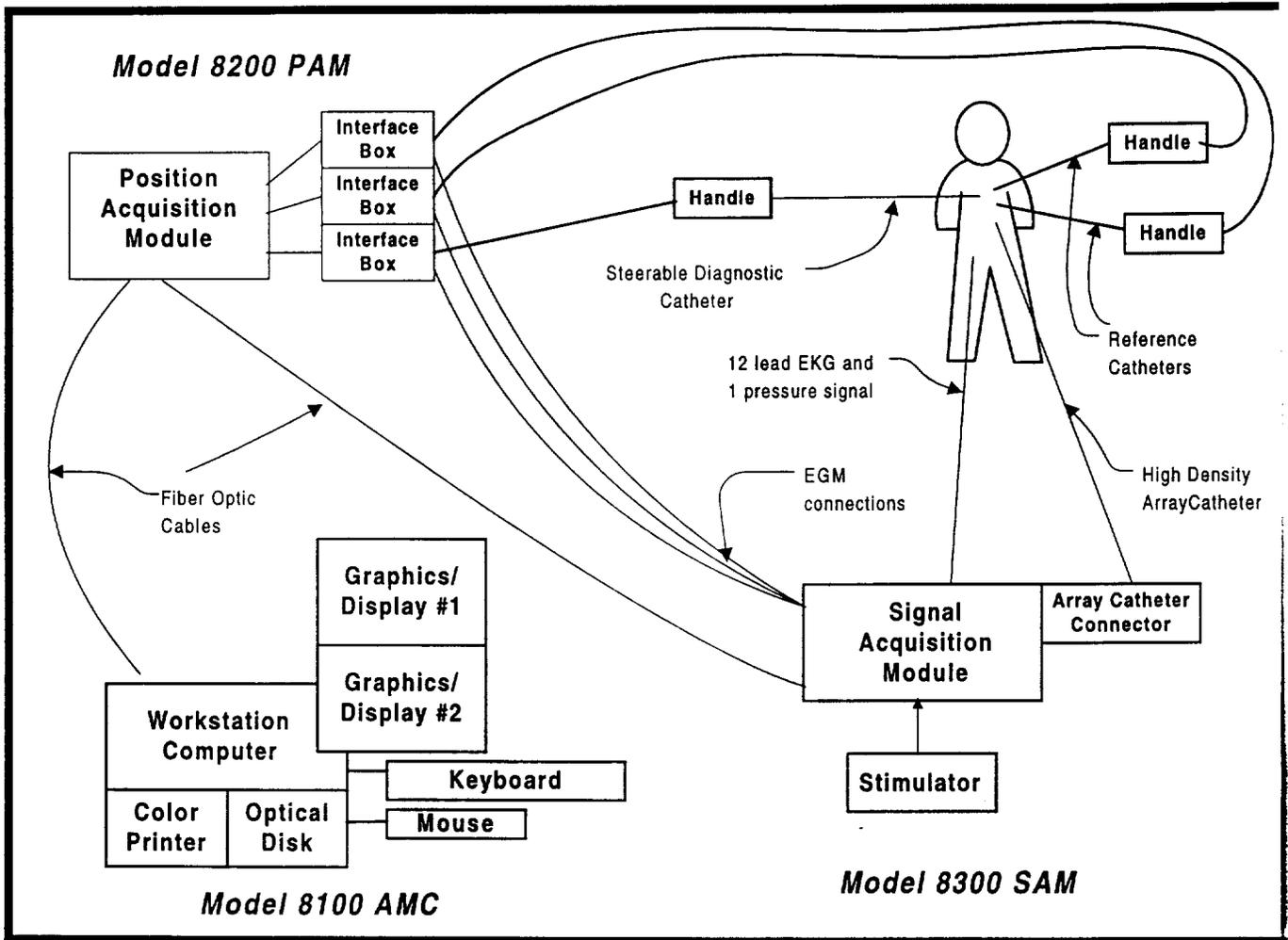


Figure 1: Arrhythmia Mapping and Tracking System

The system can be used either with standard electrophysiology catheters or with the specially designed diagnostic catheters that provide information regarding catheter position during the procedure.

System Overview

As shown in Figure 1 above, the Arrhythmia Mapping and Tracking System consists of these main components:

1. Model 8100 Mapping Computer – a Sun UltraSPARC computer with a high-speed fiber optic communication link, consisting of:
 - Two monitors – one containing a real time screen that displays live signals and the other containing an analysis screen that displays real-time catheter positions, recorded signals, journal events, and a main menu bar for accessing dialogs and controls

- An internal optical disk drive – for storing patient data on removable optical disks
 - A laser printer – for printing the analysis screens and isochronal maps in color, and printing signals and the contents of the journal in black and white
 - An uninterruptible power supply – for ensuring the system continues to operate for approximately 5 minutes when there is a power failure.
2. Model 8200 Position Acquisition Module (PAM) – an ultrasound transmit and receive instrument that uses ultrasound ranging techniques to measure the distance between transducers that are mounted on specialized diagnostic EP catheters. Distance data measured by the PAM is transferred to the Mapping Computer for processing.
 3. Model 8300 Signal Acquisition Module (SAM) – an amplifier system that filters cardiac signal data and transfers it to the Mapping Computer for processing and display.

The following signal sources can be connected to the SAM:

1. one or more standard EP catheter electrodes (up to 48 auxiliary inputs) from any standard diagnostic catheters or the specially designed Cardiac Pathways tracking catheters,
2. a 64-electrode high-density array catheter
3. a pacing input from an external pacing stimulator, which the Mapping System software can route to any catheter bipole or unipole
4. a 12-lead EKG, and
5. a pressure transducer

The SAM collects these signals, applies gain and filter settings as programmed through the Mapping System software, samples them at 3 kHz, and transfers them to the Mapping Computer over the fiber optic data link for further processing and display.

The following signal sources can be connected to PAM:

1. two specialized EP catheters referred to as *reference catheters* for the positioning system,
2. one to five additional specialized EP catheters referred to as *tracking catheters* for the positioning system, and
3. one signal ground connection that is common between the SAM and the PAM

The PAM transmits ultrasound pulses to transducers built into the specialized reference catheters. It then measures the time delay between the transmit pulse and the reception of the sound wave on the other transducers that are on the reference catheters and tracking

catheters. These time measurements are directly proportional to the distance between the transducers. The distance/time data is transferred to the Mapping Computer over the fiber optic data link for further processing and ultimately for the display of the catheter representations in 3D orientation. This use of ultrasound transducers is known as *ultrasound ranging*.

A continuous cycle of transmit pulses is sent in round-robin fashion to each of the transducers on the Reference Catheters. The resulting reception from each transmit pulse on each of the other transducers on the Reference and Tracking Catheters is used to determine the distance between all the transducers. The Arrhythmia Mapping and Tracking System software uses the distance information to triangulate 3D coordinates for all transducers. Because the dimensional and the constructional characteristics of the catheters are known by the Arrhythmia Mapping Computer, it uses the 3D coordinate information along with the catheter information to reconstruct a 3D graphical representation of the catheter positions and orientation. The resulting 3D graphical image of the catheter is adjustable as a 3D graphical object on the computer screen.

The Arrhythmia Mapping and Tracking System has the following features:

- Accepts input electrogram signals from:
 - standard EP catheters – up to 48 inputs
 - high density catheter arrays – up to 64 inputs
 - a 12-lead EKG and a pressure transducer
- Accepts catheter position data from specialized EP catheters. Up to 28 channels of position data may be communicated from the PAM to the Mapping Computer.
- Routes a pacing signal from an external pacing stimulator to any connected bipole or unipole.
- Displays up to 16 real time signals (one Signal Page), and allows rapid switching among twenty such user-defined Signal Pages.
- Displays real-time signals at a maximum sweep speed of 800mm/S. A triggered sweep feature can be used to stabilize the display of signal complexes, allowing the point of early activation to be determined with high resolution.
- Displays real-time catheter position graphics that are gated to the EKG to filter heart movement artifacts. One of the catheters in the graphical display can be selected for displaying a *real time tip*. This utilizes a graphical circle with a disappearing tail to indicate tip movement in “real time” to facilitate catheter steering.
- Displays real-time heart rate (one second average) and ventricular cycle length (beat-to-beat) from any EKG signal.
- Allows for adjustment of signal filters and gain over a wide range of values.

- Records signals and catheter positions to the optical disk via continuous recording of the 16 real-time signals and/or an 8-second snapshot recording of the Signal Page, EKGs, and the 64-inputs from a high density array catheter.
- With Auto Save enabled, automatically initiates recording during pacing or when the heart rate exceeds specified thresholds. Automatically aligns recorded signals with the last pulse in the pacing train.
- Provides tools to make time measurements, add text, and quickly zoom in to review and analyze signals. Keyboard shortcuts are provided for most common features such as recording, changing signal gain, and changing sweep speed.
- Provides tools to recall and display the 3D position of a catheter relative to stored annotations and electrograms.
- Provides tools to adjust the 3D view of the graphical representation of the catheter positions.
- Automatically detects catheter movement from the original positions, after an initial reference position is selected by the operator, and indicates correct position information for the operator.
- Automatically detects RF interference with the ultrasound ranging circuits, freezes the display for the operator, and then resumes real-time display when the interference stops.
- Automatically generates color-coded isochronal maps from high density array signal data using a peak slope or peak amplitude detection algorithm to place activation marks.
- Prints color isochronal maps, signals, and the events from the journal for archiving with the patient record.

Catheter Overview

The two types of Reference Catheters, that are positioned in the CS and RV and are used to form the reference frame for the Tracking System, have nearly identical functional requirements. Both catheters have a fixed-curve 6F distal shaft section and a 7F proximal braided shaft. The fixed-curve provides for directional placement of the catheter in the CS or RV. The braided shaft provides torque control for catheter placement. All catheters contain electrodes used for EP mapping. Non-tracking versions of the CS and RV Reference Catheters are nearly identical to their counterparts but have no transducers for tracking catheter position. They contain only EP electrodes for collection of diagnostic cardiac electrograms.

The Reference Catheter designed for typical EP usage in the CS has 4 ultrasound transducers, nine 1 mm EP ring electrodes, and one 2 mm EP tip electrode. To position the catheter within the CS, the catheter is introduced into either a jugular or subclavian vein and advanced into the superior vena cava. The catheter is then passed through the chamber of the right atrium into the os of the CS. The catheter is advanced into the CS

until the distal tip of the catheter is at or near the left heart border. The ultrasound transducers are spaced on the distal portion of the catheter shaft so that a single transducer resides in the right atrium and distal transducers reside within the CS so that the most distal transducer is at or near the left heart border. The EP tip electrode provides an atraumatic tip for the catheter.

The Reference Catheter designed for typical EP usage in the RV has 4 ultrasound transducers, three 1 mm EP ring electrodes, and one 2 mm EP tip electrode. The catheter is introduced into a femoral vein and advanced into the inferior vena cava and right atrium. The catheter is then passed across the tricuspid valve, and the distal tip is positioned in the RV apex. The ultrasound transducers are spaced on the distal portion of the catheter shaft to approximately cover the distance from the mid point of the right atrium above the tricuspid valve to the apex of the RV. The EP ring electrode and the tip electrode spacing are arranged in a commonly used configuration for recording electrograms and pacing from the RV. The EP tip electrode provides an atraumatic tip for the catheter.

Reference Catheters are deployed at the beginning of an EP mapping procedure. Once in place, they are not moved until the end of the procedure. The ultrasound transducers on these catheters provide a fixed reference frame that is used to determine the position of ultrasound transducers that are integrated into other mapping catheters, for example Tracking Catheters. The Arrhythmia Mapping and Tracking System contains software that generates 3D graphical representations of the Reference and Tracking Catheters based on the position of their transducers. These graphical representations are used to facilitate navigation and placement of these catheters during the procedure. The Reference Catheters have EP electrodes for both sensing and pacing. They are intended to replace competitive RV mapping/pacing and CS mapping/pacing catheters in EP procedures. The Reference Catheters provide EP functionality that is equivalent to currently used CS and RV mapping and pacing catheters.

The Tracking Catheters used with the system are steerable, deflectable EP mapping and pacing catheters that contain three ultrasound transducers, one tip electrode, and three ring electrodes. The Tracking Catheter is placed into any heart chamber and is used to record activation patterns to diagnose arrhythmias. The Tracking Catheter is rendered as a 3D graphical catheter representation. Since the third transducer is proximal to the deflection point of the catheter, the computer image displays the curve of the catheter

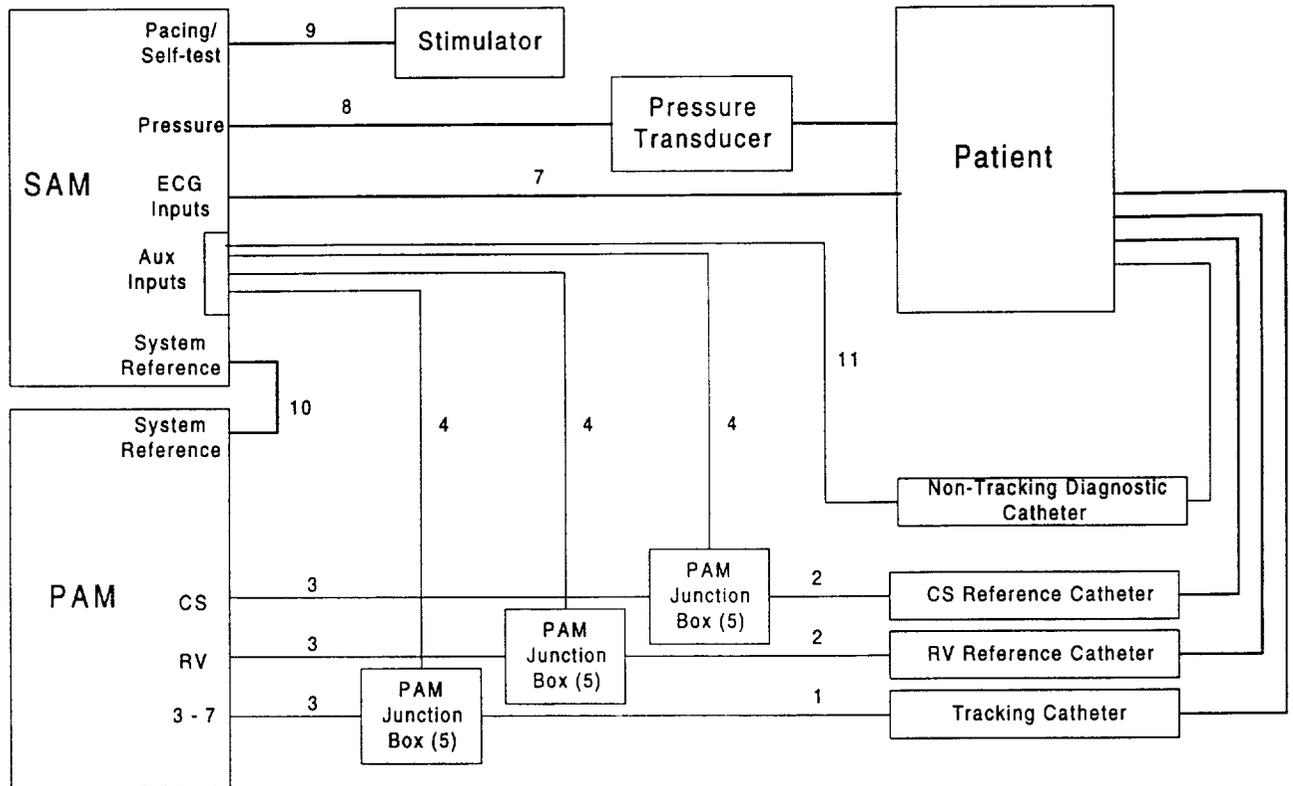
Overall system accuracy of distance measurements and catheter images is a function of transducer performance, electrical system performance, and software performance. As demonstrated with bench testing, the accuracy of the representation of tip location is < 1mm.

Arrhythmia Mapping and Tracking System Cables

The Arrhythmia Mapping and Tracking System comes with the cables and adapters listed in the table below. To facilitate the process of connecting the system components, several of the cables have a colored label near each connector that matches the color of the label near the corresponding connector on the device to which the cable connects.

| | Model No. | Cable/ Adaptor | Distal Connection | Distal Color Label | Proximal Connection | Proximal Color Label | Length |
|----|----------------------|--|--------------------------------|--------------------|---|-----------------------------|-----------|
| 1 | 2053 | Tracking Catheter to PAM Junction Box | Tracking Catheter | N/A | PAM Junction Box | Purple | 8 feet |
| 2 | 2058 | Reference Catheter to PAM Junction Box | Reference Catheter | N/A | PAM Junction Box | Purple | 8 feet |
| 3 | 2054 | Pam Junction Box to PAM | PAM Junction Box | Green | PAM | Green | 1 foot |
| 4 | 2056 | PAM Junction Box to SAM | PAM Junction Box | Yellow | SAM (auxiliary input) | N/A | 2.5 feet |
| 5 | 2061 | PAM Junction Box | Tracking or Reference Catheter | Purple | PAM (via PAM Junction Box to PAM cable); SAM (via PAM Junction Box to SAM cable) | Green (PAM) Yellow (SAM) | N/A |
| 6 | 2059 | PAM self test | PAM | Green | PAM self test connector | Orange | 1.5 feet |
| 7 | 2013 2018 2019 | Patient Cable and Lead Sets | ECG leads on patient | N/A | SAM (ECG connector) | N/A | 10 feet |
| 8 | many | Pressure Interface | pressure transducer | N/A | SAM (pressure input connector) | N/A | various |
| 9 | 2039 | Pacing Stimulator | pacing stimulator | N/A | SAM (pacing/self-test input) | N/A | 12.5 feet |
| 10 | 2060 | PAM to SAM System Reference | PAM system reference input | N/A | SAM (system reference input and either right leg, aux, or array catheter reference) | N/A | 2 feet |
| 11 | 2063 | Non-Tracking Catheter to SAM | Non-Tracking Catheter | N/A | SAM (auxiliary input) | N/A | 8 feet |

The following block diagram depicts how the cables interconnect the system components. The numbers in the figure correspond to the row numbers in the table above. Descriptions and Drawings follow the block diagram.



1) Tracking Catheter to PAM Junction Box Cable

The Tracking Catheter to PAM Junction Box Cable connects a Tracking Catheter to the Arrhythmia Mapping and Tracking System. The cable connects the Tracking Catheter to the PAM Junction Box. The PAM Junction Box end of the cable has a purple label that matches a purple label around the connector of the PAM Junction Box. The cable is pictured below.

2) Reference Catheter to PAM Junction Box Cable

The Reference Catheter to PAM Junction Box Cable connects a CS or RV Reference Catheter to the Arrhythmia Mapping and Tracking System. The cable connects the Reference Catheter to the PAM Junction Box. The PAM Junction Box end of the cable has a purple label that matches a purple label around the connector of the PAM Junction Box. The cable is pictured below.

The cable is pictured below.

3) PAM Junction Box to PAM Cable

The PAM Junction Box to PAM Cable connects the PAM Junction Box to the PAM. It contains connections for the ultrasound transducers on the Reference and Tracking Catheters. Both ends of the cable have a green label to match the green labels around the connectors on the PAM and the PAM Junction Box. The ends of the cable are identical. The cable is pictured below.

4) PAM Junction Box to SAM Cable

The PAM Junction Box to SAM Cable connects the PAM Junction Box to the SAM. It contains connections for the EP electrodes on the Reference and Tracking Catheters. The end of the cable that connects to the PAM junction box has a yellow label to match the yellow label around the corresponding connector on the PAM junction box. The cable is pictured below.

5) PAM Junction Box

The PAM Junction Box splits the conductors for the ultrasound transducers and EP electrodes into two separate connectors. One side of the box connects to either the Tracking Catheter cable or Reference Catheter cable. This connector has a purple label around it to match the purple label on the Tracking or Reference Catheter cables. The other side of the box has two connectors, one for the PAM Junction Box to PAM Cable and the other for the PAM Junction Box to SAM Cable. These have color coded labels as well, green for the PAM connector and yellow for the SAM connector. A picture of the PAM Junction Box is shown below.

6) PAM Self Test Cable

This cable allows the user to perform a self-test of the PAM hardware. One end of the cable has an orange label and connects into a self-test socket on the front panel of the PAM with an orange label around it. When this end of the cable is connected, the system enters a self-test mode. The AMC software provides a dialog box that displays the results of the test. The other end of the cable has a green label to match the green labels around each of the transducer connectors on the PAM front panel. The user selects a socket to test by physically connecting this end of the cable into the corresponding socket. The cable is pictured below.

7) Patient EKG Cable and EKG Leads (snap type or pinch type) **Part of earlier 510(k) filed by Cardiac Pathways and determined by FDA to be substantially equivalent.**

8) Pressure Interface Cable (from Medex, Utah Medical, Ohmeda, Hewlett-Packard, or Namic) **Part of earlier 510(k) filed by Cardiac Pathways and determined by FDA to be substantially equivalent.**

9) Pacing Stimulator Cable (with pin adaptors) **Part of earlier 510(k) filed by Cardiac Pathways and determined by FDA to be substantially equivalent.**

10) PAM to SAM System Reference Cable

The PAM to SAM System Reference Cable has three protected pin connectors, a single protected pin connector on one end and two on the other end. All three connectors are tied to a single conductor. There are two purposes for the cable. One purpose is to select the reference for the signal amplifiers in the SAM. Typically a Right Leg reference is used in this application, however the operator may select an electrode from a catheter as the amplifier system reference. The reference is selected by utilizing the end of the cable with two connectors as a jumper between the system reference socket and either the right leg, auxiliary reference, or high density array catheter reference sockets on the front panel of the SAM. The second purpose of the cable is to provide a system reference for the PAM. This is done by connecting the single connector end of the cable into the system reference input for the PAM. The System Reference Cable is pictured below.

11) Safety Socket Adaptor **Part of earlier 510(k) filed by Cardiac Pathways and determined by FDA to be substantially equivalent.**

12) Self-Test Adaptor **Part of earlier 510(k) filed by Cardiac Pathways and determined by FDA to be substantially equivalent.**

Predicate Devices

The Arrhythmia Mapping and Tracking System is substantially equivalent to the Biosense Carto™ System manufactured by Cordis Webster.

The Steerable Diagnostic Electrophysiology Catheter is substantially equivalent to the Radii™ Diagnostic Electrophysiology Catheter manufactured by Cardiac Pathways and the Navi-Star® Catheter manufactured by Cordis Webster.

The RV Diagnostic Electrophysiology Catheter is substantially equivalent to the Fixed Curve Diagnostic Electrophysiology Catheter manufactured by Cordis Webster and the Ref-Star® Catheter manufactured by Cordis Webster.

The CS Diagnostic Electrophysiology Catheter is substantially equivalent to the 5F SUPRA CS™ Diagnostic Electrophysiology Catheter manufactured by Cordis Webster and the Ref-Star® Catheter manufactured by Cordis Webster.

Performance Data

The Arrhythmia Mapping and Tracking System was subjected to a battery of electrical and functional tests to verify that the devices met the specifications. Testing included,

but was not limited to, electrical safety, verification that certain electrical parameters were within specification, and functional performance. The devices individually and collectively met the specifications. Software verification testing was also performed on the system and the software was deemed acceptable for clinical use. The Reference Diagnostic Electrophysiology Catheters (RV and CS), the Steerable Diagnostic Electrophysiology Catheters, and the various cables for use with the Arrhythmia Mapping and Tracking System were subjected to a battery of electrical and mechanical tests to verify that the devices met the specifications. Electrical testing included, but was not limited to, assessment for continuity and short circuits, DC impedance, AC impedance, capacitance, dielectric strength, and current leakage. The accuracy of the transducers was also tested. Mechanical testing included, but was not limited to, assessment of joint strengths, torque response, and the ability to withstand multiple deflections. The devices met the electrical and mechanical specifications. Accuracy of the tracking function was assessed *in vitro* and *in vivo*. The accuracy was comparable to the predicate device and appropriate for the clinical application. Biocompatibility testing was performed with the catheters and indicated that the devices did not elicit toxicological responses.



MAR - 8 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Debra S. Echt, M.D.
Vice President
Clinical Research and Regulatory Affairs
Cardiac Pathways Corporation
995 Benecia Avenue
Sunnyvale, CA 94086

Re: K992912
Arrhythmia Mapping and Tracking System
Regulatory Class: II (two)
Product Code: DRF and DQK
Dated: December 8, 1999
Received: December 9, 1999

Dear Dr. Echt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Debra S. Echt, M.D.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS

The Cardiac Pathways Tracking diagnostic catheters are indicated for cardiac electrophysiological mapping and delivering pacing stimuli. In addition, the Tracking and Reference Catheters are used with the Arrhythmia Mapping and Tracking System to provide catheter location information.

C. Appal Maheshan for Celia Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 992912