

4/12/99

K983102

Appendix IV

510(K) Summary
Cambridge Heart Model CH 2000 Cardiac Diagnostic System
510(k) Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

The following information as presented in the 510(k) Supplement to expand the Intended Use, Indications For Use and Promotional Claims for the Cambridge Heart CH 2000 Cardiac Diagnostic System. The CH 2000 (K950018) and Zymed Model 2010 Holter Scanner (Zymed, Inc.) (K955015) contain data supporting a Substantial Equivalence determination.

1. General

The Cambridge Heart CH 2000 with Alternans Option is a computer (PC) based diagnostic electrocardiograph (ECG) designed for the measurement of T-wave alternans and the recording of electrocardiograms and vector cardiograms at rest and during ECG stress testing. It is substantially equivalent to:

- Cambridge Heart Model CH 2000 (Cambridge Heart, Inc. Bedford, Mass). Premarket Notification K981697

In addition the alternans option is equivalent to:

- Zymed Model 2010 Holter Scanner (Zymed, Inc.) Pre-market Notification K955015

2. Indications for Use

The CH 2000 is intended for the measurement of T-wave alternans and recording of electrocardiograms and vector cardiograms at rest and during ECG stress testing. The presence of T-wave alternans in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The CH 2000 should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests.

3. Device Description

The Cambridge Heart CH 2000 Cardiac Diagnostic System is a computer-based ECG exercise tolerance test system designed for use in hospitals, offices and clinical cardiology laboratories.

The CH 2000 incorporates the following features:

- Recording of electrocardiograms and vector cardiograms with high-resolution laser printer or thermal recorder output.
- Measurement of T-wave alternans.
- Controlling resting and exercise stages of treadmill and bicycle ergometer stress tests based on standard and user-customized protocols.
- Computation of ST-level and slope, plus supplemental measurements including ST-integral and ST-index.
- Diagnostic-quality color CRT display on a swivel-tilt mounting.
- Baseline and artifact filters to remove artifact without ST-segment distortion.
- Detection of pacemaker functioning and visible pacemaker spikes displayed on the ECG.

Exercise Equipment: The CH 2000 has been designed and tested for use with the Trackmaster TM-400 and TM-425 treadmills, manufactured by Patex International, Inc. and the Lode Corival 400 bicycle ergometer, distributed by the Quinton Instrument Company and other treadmills and bicycle ergometers cleared for use for exercise stress testing.

Patient Electrodes: Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the CH 2000.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res Electrode (Ref: # K962115) in conjunction with other patient electrodes designed and approved specifically for use during exercise stress testing.

4. Standard Hardware Components

System Cart: Mounts computer, display, keyboard, and output devices. Dimensions assembled (approximate); 58 x 25.75 x 27 in.

Computer and Keyboard: IBM compatible, including hard disk, floppy disk and interface cards.

Display:	15-inch color monitor on swivel/tilt bracket.
ECG Amplifier	The ECG Amplifier is embodied in the PM-2 (PM-1 optional) patient module. 12 leads/10 electrodes. Plugs into computer.
Printer:	Windows 95 compatible printers, Strip Chart Recorder.
Serial Treadmill Interface:	Standard RS-232 interface allows computer control of speed and incline. Works with Trackmaster TM-400 & TM-425 treadmills. (Requires optional RS-232 interface cable.)
Serial Bicycle Interface:	Standard RS-232 interface allows computer control of resistance and measurement of RPM for compatible serial ergometers. (Requires optional RS-232 interface cable).
Software:	System and diagnostic software is provided on floppy disk.
Shipping Containers:	Cart, Computer and Display are shipped in a single container.

5. **Standard Hardware Accessories**

Patient Cable: Set of 10 separately detachable lead wires which meet the requirements of 21CFR 898.12 and comply with IEC-601-1; 56.3c part 1.1, General Requirements for Safety

Individual patient leads are either not detachable, or user detachable with female socket connections such that no conductive surface is exposed when unconnected.

User Manuals: Operators manual supplied with every system. Service manual supplied upon request. Physicians Guide to T-Wave Alternans Processing supplied with alternans option. T-Wave Alternans Reader Training Course manual supplied in conjunction with training course.

6. **Optional Hardware Components**

Alternans Option: Patient Module (PM-1), Tachometer Display Module (TM-1), Digital Signal Processor (DSP), High Resolution Electrode Patient Leads, High Resolution Electrodes (package of 7).

High Resolution electrodes, alternans software, ergometer and interface cable are required for T-wave alternans measurement and are purchased in addition to the basic CH 2000.

Analog Interface Option: Provides interface to the following devices:

Quinton Q Series and 90 Series Treadmills.

Marquette 1800 Series Analog Treadmills.

Lode Corival Ergometer.

The analog interface option also provides analog ECG and TTL R-Wave trigger outputs. Requires the use of optional interface cables for each application.

Serial interface cable: RS-232 cable for connection to compatible bicycles and treadmills.

Serial bicycle: Seca Cardiotest 100.

Optical disk: 640 megabyte read/write optical disk

7. Software

The Cambridge Heart CH 2000 software is designed to :

- Input a standard 12 lead, or 12 lead + XYZ ECG lead configuration
- Display ECG traces on a CRT monitor
- Record ECG traces on a printer
- Detect QRS complexes and compute heart rate
- Compute ECG median beats
- Detect fiducial points on the ECG median beats
- Compute ST and T wave measures (alternans)
- Execute standard exercise protocols with specified stages and stage times.

8. Principles of Operation

The CH 2000 is a computer-controlled system for performing cardiac stress and T-Wave alternans tests. ECG signals are acquired from a patient using 10-lead and 14-lead connections for standard stress and T-wave alternans

measurements respectively. Within a patient-attached module, signals are digitized with 22-bits resolution, allowing capture of signals over the full offset range according to ANSI/AAMI EC11. Digitized signals are coupled through an optical isolation barrier and sent serially through a cable to the computer. The patient-attached module is powered through a small transformer, assuring that leakage and withstand requirements per ANSI/AAMI and IEC standards are met.

The CH 2000 computer is a Pentium PC running a Windows™ operating system. Running the CH 2000 application software, it is used to process digitized ECG data, display standard stress-test measures, and print standard-stress and T-wave alternans reports. The application software also controls exercise treadmills and ergometers via the computer serial ports.

The application software performs heart rate and ST-T computations, QRS detection and Median Beat calculations. Alternans measures are computed using the Spectral Method (reference Smith, JM et al. Circulation 1988; 77:110-21).

9. Similarities and Differences

A. Product Labeling

The comparison table for the Cambridge Heart CH 2000 and the Zymed 2010 was generated from the referenced pre-market notifications and product brochures supplied by the manufacturers for each of the devices. The comparison clearly illustrates that the systems are very similar regarding intended use, physical characteristics, target population, and safety characteristics.

B. Indications for Use/ Intended Use

The Cambridge Heart CH 2000 and the Zymed 2010 are intended for patients for whom the recording of electrocardiograms and vector cardiograms by a physician are indicated for the diagnostic and prognostic evaluation of patients with known, suspected or at risk of cardiovascular disease.

Both the CH 2000 alternans option and the Zymed 2010 are used to analyze recorded ECG data to aid in the diagnosis of risk of arrhythmia.

Copies of the labeling for the equivalent devices are provided at the end of this section.

C. Physical Characteristics

All three devices have very similar physical and technical characteristics. No changes of physical characteristics have been made to the Cambridge Heart CH 2000 which are the subject of this submission.

D. Target Population

All three devices are used specifically for the evaluation of patients with known or suspected cardiovascular disease.

E. Safety Characteristics

All three devices meet the requirements of IEC 60601-1

10. Labeling and Description of Substantially Equivalent Devices

(Please refer to following pages)

1. Comparison Table

	<u>Cambridge Heart, Inc.</u> <u>CH 2000</u> <u>(new)</u>	<u>Cambridge Heart, Inc.</u> <u>CH 2000</u> <u>K950018</u>	<u>Zymed, Inc.</u> <u>Model 2010</u> <u>K955015</u>
Device Description	<p>Computerized system to record and measure electrocardiographic (ECG) data at rest and during exercise stress test.</p> <p>Computes measurements of ST segment level and slope at rest and during physiological stress.</p> <p>Analyzes recorded ECG data to measure T-wave alternans at rest and during exercise for diagnosis of risk of arrhythmia.</p>	<p>Computerized system to record and measure electrocardiographic (ECG) data at rest and during exercise stress test.</p> <p>Computes measurements of ST segment level and slope at rest and during physiological stress.</p> <p>Analyzes recorded ECG data to measure T-wave alternans at rest and during exercise.</p>	<p>Computerized system to measure and analyze recorded electrocardiographic (ECG) data.</p> <p>Computes ST segment level and slope.</p> <p>Analyzes recorded ECG data for measuring ectopic rates and other parameters for diagnosis of risk of arrhythmia.</p>
Intended Use	<p>The CH 2000 is intended for the measurement of T-wave alternans and recording of electrocardiograms and vector cardiograms at rest and during ECG stress testing.</p> <p>The presence of T-wave alternans in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death). The CH 2000 should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests.</p>	<p>For the recording of electrocardiograms and vector cardiograms by a physician, or under the direction of the physician, at rest and during ECG stress testing.</p> <p>The correlation of the alternans results with a specific clinical diagnosis or prognosis, when the alternans are not visually apparent on the standard ECG has not been clinically established.</p>	<p>For the analysis of recorded electrocardiogram data. Three channels of recorded patient ECGs are utilized by the sophisticated arrhythmia analysis program to detect abnormalities.</p>
Safety	IEC 60601	IEC 60601	IEC 60601
Analysis Software	Multichannel QRS detection, ST-segment analysis, morphology analysis, T-wave alternans analysis	Multichannel QRS detection, ST-segment analysis, morphology analysis, T-wave alternans analysis	Multichannel QRS detection, ST-segment analysis, morphology analysis, arrhythmia analysis