

K960665

510(k) SUMMARY

MAY - 7 1996

1. COMPANY INFORMATION.

Name (Manufacturer) : Individual Software GmbH
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Date Prepared : February 16, 1996

2. DEVICE NOMENCLATURE.

Trade Name : ECHO-COM for MS-Windows Version 2.0

Common Name : Cardiac Data Analysis Program

Classification Name : Computer Diagnostic, Programmable
[74 DQK, 870.1425]

3. PREDICATE DEVICE.

Digisonics, Inc. : 'Echo Reading Station' (Modification of
'Echo-Comp' echocardiography analysis
program)

510(k) Number : K800766

SE Decision : April 24, 1980

4. DEVICE DESCRIPTION.

The ECHO-COM device is a proprietary software program for cardiac data analysis designed for installation in an IBM-compatible personal computer (PC) and use with an MS-DOS Windows operating platform. Certain dedicated hardware items are provided with the software. The PC itself and the general-purpose peripheral hardware necessary to complete the system are supplied by or obtained from local vendors.

The dedicated hardware supplied with the ECHO-COM system consists of a real-time frame grabber, ECG trigger kit, control panel, hardlock, and video cable. The digitizer card interface for the frame grabber has sufficient memory for the processing and storage of color images. This frame grabber captures all available information from the ultrasound system with which it is used during on-line operation including ECG trigger pulses and scale markers for distance measurements. The ECG trigger pulses permit time-gated cine loop recording, optimizing the system for the performance of stress-echo examinations.

ECHO-COM software is designed to offer exceptional flexibility during either on-line or off-line operation. Images and cine loops may be archived in a variety of commonly used formats, including Macintosh, permitting integration into a wide range of networking systems such as InterNet and CompServe for convenient transfer of data to remote locations.

A Review Module is provided that enables users to perform measurement, calculation, and documentation of stored images and loops at the workstation. An Examination Scheme Editor permits the user to supplement the pre-programmed protocols with customized examination approaches to conform with local requirements and preferences. Data from 2-D, M-mode, and Doppler examinations can be combined as desired. Levels and scanning positions for stress-echo examinations can be freely selected. The Report and Formula Editor enables the user to add custom-designed report formats and supplementary calculation formulae to the standard menu.

A comprehensive range of cardiac ultrasound examination programs is provided including stress-echo test computations, semi-quantitative wall motion scoring, wall thickness evaluation, left ventricular volume studies, left ventricular function, color coding, M-mode functions, and Doppler functions.

The disc summation method for quantitation of left ventricular volumes by two-dimensional echocardiography, as recommended by the American Society of Echocardiography, is employed. The tolerance levels utilized in the ECHO-COM program are based directly on the range of normal values adopted by the American Society of Echocardiography. All other equations and formulae included in the ECHO-COM program are based on accepted mathematical principles or derived from the published literature.

5. INTENDED USES.

The ECHO-COM for MS-Windows Version 2.0 cardiac software program is recommended for quantitative analysis of M-mode, B-mode, and Doppler ultrasound data. The system may be employed adjunctively in the performance of stress echocardiography in patients with suspected coronary artery disease either on-line by direct connection to the video signal output port of a suitable diagnostic ultrasound system or off-line by retrieving and processing previously stored data. The system permits the use of either standard or customized examination protocols, data analysis formulae, and report formats.

6. COMPARISON WITH PREDICATE DEVICE.

The intended uses of the predicate device, the Digisonics cardiac analysis program, are very similar to those recommended for the subject device. Both are intended for use as work stations to organize findings generated during echocardiographic examinations, and both facilitate calculations and quantitative analysis.

The subject device and the predicate device are also very similar in product concept. Both systems are software programs designed for use with an IBM-compatible PC using an MS-Windows operating platform. Both provide the clinician with computerized worksheets with graphics which are used to generate reports presenting the results of an echocardiographic examination.

Both systems may be employed on-line utilizing a data transfer linkage for interface to a suitable ultrasound instrument or off-line by either entering numeric values manually or calling up information from a database. Both programs incorporate formulae for quantitative data analysis based on the published work of recognized authorities in the field, and both allow the user to input additional formulae. Both program provide standard report formats and allow the user to customize formats when desired.

The principal differences between the ECHO-COM and the Digisonics system relate to on-line operation. The ECHO-COM is designed to accomplish ECG-gated cine loop recording which is valuable in the performance of stress-echo studies. Also, the ECHO-COM utilizes an advanced frame grabber which captures the distance measurement markers when transferring the ultrasound image, permitting operator verification of the accuracy of the dimensional information calculated by the ultrasound system in use.

The similarities and differences between the subject and predicate devices are presented in tabular form on the following page. It is concluded that the differences in technical characteristics between the two products are not significant in that there are no features of the subject device that raise new questions with respect to safety nor that could result in a decrease of effectiveness as compared to the predicate device.

7. PERFORMANCE DATA.

a. Hardware Performance. Hardware performance depends primarily on the PC and peripherals selected. Minimum and optimal specifications for use in the selection of hardware are given in the system operating manual to insure compatibility and proper performance. For the signal transfer functions performed by the dedicated hardware, an important consideration is the prevention of interference due to electrical potentials between interconnected units. This concern is addressed by the use of a UL listed high density mounting type photocoupler that provides an isolation voltage between input and output of 5,000V rms.

**COMPARISON OF TECHNICAL FEATURES: SUBJECT DEVICE
VS. PREDICATE DEVICE**

CHARACTERISTIC	SUBJECT DEVICE Cone Instruments ECHO-COM for Windows	PREDICATE DEVICE Digisonics Echo Reading Station
Required Computer	IBM-compatible PC Minimum RAM 8 MB	IBM-compatible PC RAM 8 MB ✓
Operating Platform	MS-DOS 3.3 or higher MS-Windows 3.1 or higher	MS-DOS 6.3 MS-Windows 3.11
Operating Options	On-line (interfaced with ultrasound system) or off-line	On-line (interfaced with ultrasound system) or off-line ✓
Video Capture	Frame grabber, ECG-gated cine loop recording	"Echo-Link" (fiber optics)
Downloading Capabilities	Black & white or color images, numeric data, ECG trigger pulses, distance markers	Black & white or color images, numeric data
Ultrasound Modes Accepted	2-D, M-mode, Doppler	2-D, M-mode, Doppler ✓
Database	Archiving of images, cine loops, and reports with graphics; convenient retrieval	Archiving of reports with graphics; convenient retrieval
Report Formats	Standard or customized by user	Standard or customized by user ✓
Calculation Formulae	Standard (based on published authors) or user defined	Standard (based on published authors) or user defined ✓
Measurement Data Verification	User can compare against values generated by basic ultrasound system	User can compare against values generated by basic ultrasound system ✓
Data Transfer	Networking via InterNet, Compu-Serve, etc.	Network compatible; fax capability

b. Software Performance. Software performance can be evaluated by comparing the numeric values calculated by the ECHO-COM for MS-Windows program against corresponding values generated by the echocardiographic system itself. Software performance has been successfully validated through checks conducted in hospitals under typical clinical operating conditions in addition to internal testing throughout the software development cycle.

c. Quality Assurance. All product design, production, testing, and service procedures are conducted in accordance with the following international quality standards: ISO 9001":1994 and ISO 9004-2:1991.

8. CONCLUSION.

The ECHO-COM for MS-Windows Version 2.0 cardiac software program is closely similar in both intended use and technologic characteristics to the predicate device. The product raises no new questions regarding safety or effectiveness. All pertinent product data and all required certifications have been filed with the Food and Drug Administration. Cone Instruments, Inc. concludes that the subject device is substantially equivalent to devices of the same classification previously legally introduced into interstate commerce in the United States.