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Safety and Effectiveness Summary

The following safety and effectiveness summary has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR §807.92(a).

807.92(a)(1)

Submitter Information

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Safety and Effectiveness Summary
AccessPoint™
Biosound, Inc.

807.92(a)(2)

Trade Name: AccessPoint™
Med E-mail
DICOM Reader

Common Name: Medical Image Reading and Transport Software

Classification Name(s): Diagnostic Ultrasound 90ITX

807.92(a)(3)

Predicate Device(s)

- TomTec P90 K950279

Additional Substantial Equivalence information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4)

Device Description

Generally speaking, AccessPoint is a software product designed to provide the translation of different medical image formats into a form compatible to be displayed on a standard PC. Connection between sites including hospitals, out reach clinics, physician home and office are provided through the use of e-mail. The images and reports (patient studies) may be transported via e-mail in a secure manor (encryption of data) following standards used by the Internet and local LAN (Intranet), transport systems. A description of the various elements follow:

The AccessPoint™ software conforms to DICOM V3 service classes in the role of Service Class Reader.

Communications

Modems supported by Microsoft windows 95 and Windows NT
Network communications utilizing TCP/IP Internet Protocol definitions
E-mail utilizing POP3 and SMTP (simple mail transfer protocol) standard
as implemented in the Microsoft Windows 95, and windows NT operating system
Telecommunications standard Integrated Services Digital Network (ISDN)
Internet Service access through TCP/IP connection.

Storage

Floppy disk, hard disk, tape, and optical storage supported by Windows 95 or NT
operating system.

Image Formats

AccessPoint™ supports the requirement in the Ultrasound Application Profile
(APL-US) in the role of file set - Reader as incorporated in the DICOM version 3
definition.

Commercial Ultrasound Image Formats:

Biosound/Esaote AU3 and AU4 digital formats
Hewlett Packard DSR Tiff format
TomTec version 5 and P90 versions
MicroSonics DSR, DataVue, ImageVue formats

Data Compression

Standard compression techniques used include:

Run Length encoding as published in DICOM V3 supplement 5 also referred to
as Tiff Pack bits compression.

ISO/IEC 10918-1 JPEG baseline lossy, and Baseline lossless Compression
Audio compression ADPCM adaptive pulse code modulation supplied standard in
Windows 95 and Windows NT.

**The compression ratio is displayed on the status bar of each window
showing the operator and reader that the images displayed have been
compressed.**

Lossy compression is noted on each display screen.

Workstation

Monitor

Standard SVGA monitors are used which comply with the requirements of the Radiation Control and Health and Safety Act.

Processors and Storage

No special image processing hardware is required. Storage requirements vary based on the source of the image data as follows:

With Biosound/Esaote AU3 Ultrasound System,
128/230 MB Magneto optical 3.5" disk drive (internal)

With TomTec version 5 acquisition systems, one compatible disk drive 128/230 MB Magneto optical 3.5" disk drive (internal) SCSI controller compatible with Windows 95 or 650/1.3 MB Magneto optical disk drive SCSI controller compatible with Windows 95.

With MicroSonics DSR acquisition, one compatible disk drive 230 MB Magneto optical 3.5" disk drive (internal) SCSI controller compatible with Windows 95 or 650/1.3 MB Magneto optical disk drive, SCSI controller compatible with Windows 95.

With Hewlett Packard DSR acquisition, one compatible disk drive, 650 MB Magneto optical disk drive, SCSI controller compatible with Windows 95.

Operator Interface

Standard input devices supported by Microsoft Windows 95, and Windows NT 3.51. No special devices are required. Common implementation includes a keyboard and MS compatible mouse.

Software

The workstation uses:

Microsoft Office Professional Edition

Microsoft Windows 95, windows NT 3.51 or greater

Microsoft Plus Pack

Microsoft Internet Explorer 3.0

807.92(a)(5)

Intended Use(s)

The AccessPoint™ software is intended to translate different medical image formats into a single format suitable for display on a standard Personal Computer.

Substantial Equivalence Table

<u>Feature</u>	<u>Access Point™</u>	<u>TomTec P90 K950279</u>
Real-Time Image Playback	Yes	Yes
Slow Motion or Frame by Frame Review	Yes	Yes
Image Zoom	Variable from .5 to SVGA size	2X only
Study Comparison	Windows 95, NT facilities	Windows 3.11 Facilities
ECG Synchronized Playback	Yes	Yes
ECG Display	Yes	Yes
Patient Demographics Display	Window contains age, heart rate, BP, study type and date	Heart rate, BP, study phase
Modem Transmission	Windows 95 Windows NT standard	Custom software
E-Mail	Windows Messaging, Exchange, SMTP	No
Network Support	Windows 95, Windows NT TCP/IP standard	Windows 3.11
Comprehensive Image Serial Study Review	DICOM V3.0, TomTec, Microsonics, HP, Esaote/Biosound acquired	TomTec, MicroSonics acquired
Different Modalities Review	DICOM US, NM	Proprietary format with DICOM support
Audio Capture & Playback	Windows 95, NT facilities	Windows
Patient Data Storage Compression	DICOM Version 310 Lossy JPEG baseline, Lossless REL Lossless JPEG baseline	Proprietary patient roster JPEG lossy, JPEG lossless

Differences

<u>Feature</u>	<u>Access Point™</u>	<u>TomTec P90</u>
Acquisition of Ultrasound Images	Does not acquire images from analog composite video sources. Reads images formatted and acquired by other systems, i.e., TomTec P90, Nova Microsonics, DICOM, AU3, AU4, HP	Analog composite video NTSC/PAL, SVHS, RGB
Integration Into Ultrasound System	No	All manufacturers ultrasound systems
Proprietary Hardware	None	Digital Echo Bus™