

KL955015

510(K) SUMMARY

Submitter:

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Trade Name: Zymed Holter Scanner; Model 2010 Plus
Common Name: Holter Analyzer
Classification Name: Arrhythmia Detector/Medical Cathode-Ray Tube Display

Legally marketed device to which S.E. is claimed:

- Zymed Holter Scanner Model 2010; 510(k) #K930806

Description: A Zymed Holter Scanner system consists of a series of interface devices to include a central monitoring computerized unit, a high Resolution Super VGA raster graphics display monitor, a minimum 500 megabites hard disk drive for two 36-hour digital tape readings, Intel Pentium System Board CPU, 8 megabites of RAM, built in math co-processor, cassette tape drive, mouse and keyboard, 3.5 " floppy disk drive, and a laser printer.

Over 1000 final reports can be stored on line, the operating system is DOS compatible, and Holter reports can be transmitted via facsimile systems.

The analysis software package includes standard, pediatric, and AFib to name a few, and the user can program individual custom styles. Other programmable software features include ECG display; scanning speed up to 240 X real time; scanning styles to include retrospective, prospective, superimposition, and paging; auto stops; highlighting; noise algorithm; color schemes, and report formats. The system provides 3-channel QRS detection/arrhythmia analysis, 3-channel ST segment analysis, full disclosure, automatic 2 of 3 channel morphology analysis, customized report software, HRV-Time Domain, and Pacemaker evaluation display.

The system dimensions include:

Tower:

Width: 9.5" (24CM); Height: 25.5" (64.7CM)
Depth: 19" (48.2CM); Weight 36lbs (16.35KG)

Printer:

Width: 16.4" (41.6CM); Height: 11.7" (29.7CM)
Depth: 15.9" (40.3CM); Weight; 37lbs (16.8KG)

Graphics Display:

Width: 14.3" (36.3CM); Height: 14.5" (36.8CM)
Depth: 14.9" (37.8CM); Weight; 26.2lbs (11.9KG)

The System meets UL544 and CSA601 compliance and is ETL Listed.

Intended Use: The Model 2010 Plus was designed for the busy Holter environment that places a premium on throughput analysis. This powerful computer provides the "muscle" to analyze even the most difficult recordings quickly and accurately.

Three channels of recorded patient ECG are utilized by the sophisticated arrhythmia analysis program to detect abnormalities. The system provides a number of clinical tools such as individual ECG printouts, trend data analysis, HRV time domain, and full disclosure to enable the clinician to review a patients cardiac performance.

The 2010-Plus gives the flexibility to process Holter recordings prospectively or retrospectively. Prospective interaction lets the technician supervise the analysis by viewing the ECG chronologically and fine-tuning the arrhythmia processor on-line for error-free results. Superimposition, paging, or a combination of both techniques can be used for prospective scanning. Or, the system can automatically analyze the data in approximately 12 minutes. Once the preliminary analysis is complete, the technician can use powerful retrospective tools to validate and edit the report.

A review of the technological characteristics compared to the predicate device are:

<u>Platform:</u>	<u>2010 Plus (new)</u>	<u>2010 (old)</u>
Type	IBM PC Compatible	Same
CPU	Intel Pentium	486
RAM	8 Megs	Same
Hard Disk	Min 500 Megs	Same
Display	Super VGA	Same

Data Acquisition:

Channels	2 or 3	Same
Resolution	8 bits	Same
Playback Speed	240X real time	Same

Software:

Operating System	DOS	Same
Final Reports stored on-line	Over 1000	Same
FAX Ready	Yes	Same
Full Disclosure	Yes	Same
Customized report SW	Yes	Same
3-Channel ST Segment Analysis	Yes	Same
3-Channel QRS Detection/Arrhythmia Analysis	Yes	Same
HRV-Time Domain	Yes	No
Pacemaker Evaluation Display	Yes	Same

The primary difference between the two Zymed Systems is the microprocessor speed - 486 VS Pentium, and the addition of an HRV-Time Domain SW module. Performance between the two systems is almost identical and clearly supports a claim of substantial equivalence.