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510(K) SAFETY AND EFFECTIVENESS SUMMARY

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Classification Name: Defibrillator Tester \$870.5325 with Pacemaker Analyzer \$870.3630?
(non-invasive pacer analysis only)

Common Name: Defibrillator Analyzer with Pacemaker Analyzer Feature

Proprietary Name: Models QED-6, QED-6M and QED-6H Defibrillator Analyzer with optional Universal Pacemaker Load Adapter

Establishment Registration Number: 1217454

Device Description and Intended Use: The QED-6 comprises a series of defibrillator analyzers with pacemaker analysis features. The devices have identical hardware, which can be factory modified via software to configure various options. The devices are intended to be used to:

A) Analyze the energy which is delivered by defibrillator, including Joules, peak current, peak voltage and 01' I rshoot. Output to a printer or oscilloscope in order to "playback" the defibrillator pulse waveform and output the other information which the analyzer has recorded. These features are on all models, QED-6, QED-6M, and QED-6H.

B) Measures synchronization time (cardiovascular delay time) of synchronized defibrillators. All models QED-6, QED-6M and QED-6H.

C) Output a variety of performance and arrhythmia waveforms to the defibrillator paddles or ECG jacks for monitor verification. Models QED-6M and QED-6H.

D) Measure charge time of defibrillator Models QED-6M and QED-6H.

E) Analyze the output signals of non-invasive pacemakers, such as the transthoracic types which are present on some defibrillator, such as the Physio Controls® LifePak™ 8.- On Model QED6-H.

- The QED-6 series all have bi-directional RS232 computer interfaces to allow for integration with Bio-Tek's equipment management system. This feature allows our programs, such as OTIS™ to automatically control a test sequence and retain the data for historical records.

The QED-6M and QED-6H also have the ability to allow the operator to preprogram up to 28 test sequences with test limits for energy.

The device is normally expected to be used by Biomedical Engineers (or Technicians) in a hospital setting, third party calibration technicians in laboratory settings, and Original Equipment Manufacturers or by Service personnel wherever a defibrillator could be used.

Similarity to other devices: The QED-6 incorporates features which are similar to those on the Bio-Tek QED-5, Defibrillator Analyzer K904 159/& and the Bio-Tek PMA- 1, Pacemaker Analyzer K903' 66/~ which are two different types of devices. It is also similar to the Dynatech Nevada impulse 4000 Defibrillator/ Transcutaneous Pacemaker Analyzer K941404. The technology used is similar to the predicates.

Tests were conducted by the Bio-Tek development Engineers in order to verify proper performance of the QED-6 hardware and software. The following tests were conducted and the device met specifications for all of them.

Defibrillator Analyzer: Load; Power measurement range/accuracy on the low side of the resistor network and through the paddles; voltage accuracy on low side of the resistor network and through the paddles; synchronization measurement function,
Pacemaker Analyzer: BPM; Sensed refractory period, pulsed refractory period; volts, pulse rate, and pulse width

The results from a Hewlett-Packard Pagewriter 200i Cardiograph Model 1770A, S/N CNA4001536 which has an interpretive function indicated that the QRS and arrhythmia waveforms are correctly Programmed. The performance waveforms were verified to be correct with an oscilloscope.

In summary the testing established that the QED-6 series met their marketing specifications and were similar to the

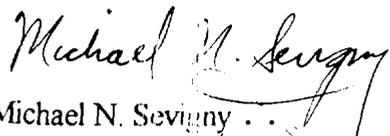
Potential system hazards were classified as those that could affect the functionality of the system and those that could affect user safety. The primary system function hinds which were reviewed and addressed were:

- A) the serial output was filtered to prevent defibrillator pulses from "leaking" to the printer or other connected device;
- B) Originally a square wave was utilized for the R wave in the pacing mode, which was misread by some monitors. This was addressed by using the trapezoidal waveform;
- C) the QED-6 will beep twice/second upon power up to indicate an incorrectly inserted or defective ram chip, or will beep four times/second to indicate an incorrectly inserted, misprogramed or defective EPROM.

Potential user hazards were addressed by:

- A) designing the device as a battery operated unit thus utilizing extra low safety voltage;
- B) utilizing a plastic case similar to the predicate QED-5 to minimize the chance of contact with high voltage during discharge; and
- C) warnings to the operators to take care when discharging into the unit. Additionally personnel who discharge defibrillator, especially the Bio-Medical Engineering staff which will be the primary users of the QED-6 are usually trained in the recognition of potential electrical hazards due to the nature of their jobs.

The above information is certified to be truthful and accurate to the best of my knowledge.


Michael N. Sevigny . . .
Quality Assurance Manager