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510(k) SUMMARY

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PROPRIETARY NAME Quest Exercise Stress System

COMMON NAME Stress System

CLASSIFICATION NAME Unknown

The Burdick Quest Exercise Stress System is substantially equivalent to the Quinton Q4500 Stress Test System and the Burdick E350i Electrocardiograph.

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Device Description

This instrument (**QUEST**) is a computerized exercise stress testing system which provides a method for dynamic exercise evaluation performed by the patient who walks on a treadmill in which the speed and elevation can be adjusted (automatically or manually) to suit a variety of graded exercise protocols, or when the patient pedals an electronically braked bicycle ergometer. If the test subject is unable to walk, isometric exercise can be performed using a handheld dynamometer, or by injecting the patient with heart rate stimulants to stress the myocardial system. In each case this instrument is used to present real-time ECG waveforms and calculations to qualified medical personnel while providing automatic or manual control of the exercise equipment. Paper reports are commonly produced.

It contains a viewing screen of sufficient size to accommodate easy reading of important patient and test parameters such as heart rate, test time, ECG waveforms and ST indications. To minimize distractions to the operators and patients during tests, no alarms are used and user-defined prompting encourages timely entry and recording of important test data (such as blood pressure).

Paper test records can be obtained from the thermal recording system incorporated into the design. Formats for the test summaries and data obtained during the test are selectable, enhancing its usage for a variety of test facilities. The ability to produce print records of ECG waveforms during exercise and recovery are continuously made available to the users.

Processing of the incoming ECG signal from the (10) electrode sites results in a real time display, heart rate determination, ST measurement indices and values, ectopic beat detection, pacemaker detection, and optionally, interpretation of the resting ECG signals. Further calculations support exercise parameters such as METS, target heart rate, calories, distance, and protocol timers.

Interfaces are provided to enable connection to Burdick's T600 treadmill, an Ergomed 840 Bike ergometer, standard electronically braked bike ergometers, non-invasive blood pressure equipment, oximetry devices supporting serial communications protocols, and computer communications equipment such as printers, fax/modems and networks. The measurement devices typically return a value to be displayed on-screen and **Quest** is not involved in making the actual measurements. In addition, analog outputs provide a selection of ECG signals, ergometer speed and grades, and exercise data (heart rate, workload, etc.). A digital QRS pulse output is available as a trigger typically used for echocardiography, nuclear imaging equipment, or pulmonary gas exchange equipment.

The computer system is based on an industry standard computer chip and uses a standard software operating system. Custom circuits are fabricated by Burdick and integrated with standard assemblies purchased from outside suppliers

Intended Use

Quest is designed to provide ECG information and data to qualified medical personnel for the purpose of assessing the patient's cardiac response to exercise. It is to be used in hospitals, clinics, or physician offices by a qualified and licensed physician, or by trained staff under the direct supervision of that physician.

Stress-test or exercise electrocardiography is used a) when the diagnosis of coronary artery disease is suspected, b) to determine the physical performance characteristics of a patient, c) for post myocardial infarction assessment, or d) for cardiac rehabilitation. The test involves the recording of the electrocardiogram during dynamic or, occasionally, isometric exercise. The diagnostic value of exercise testing primarily concerns either ST segment depression present in myocardial ischemia, or elevation seen in infarcts (in comparison to P-Q segment as the isoelectric line). In addition it is important to consider the patient's blood pressure response and physical symptoms. Disease assessment is most prominent in, but not limited to, adult patients.

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This instrument can also serve as an adult resting interpretive electrocardiograph with the addition of Burdick's resting interpretive program.

This instrument is not intended to interpret any exercise test results but is to be used as an aid for the physician to determine normal or abnormal response of the patient to exercise.

Quest is not intended for long term monitoring of patient ECG signals. Specifically it does not substitute for recommended cardiac monitoring devices recognized by AAMI EC13 especially in the area of alarms.

Similarities to Currently Marketed Products

Function:

Quest and the Quinton Instruments Q4500 serve the same function; i.e. to assist in performing and monitoring an Exercise Stress Test. This includes the following generic functions:

1. Controlling a treadmill/ergometer in accordance with a programmed protocol
2. Acquiring and displaying at least 3 channels of real time ECG data
3. Generating paper recordings of the ECG
4. Measuring heart rate and ST-segment levels during exercise
5. Detecting Ventricular Ectopic Beats
6. Generating Summary Reports following the test

Quest and the Burdick, Inc. E350i both serve the functions of a resting electrocardiograph, namely:

1. Acquiring 12 channels of real time ECG data
2. Generating paper recordings of the ECG
3. Generating ECG measurements and interpretation using the Burdick GRI program

ECG Acquisition

Quest and both listed predicate devices comply with the AAMI Standard for Diagnostic Electrocardiographs and share similar performance specifications for:

1. Leads acquired
2. Frequency response
3. Input impedance
4. Patient isolation
5. Sensitivity

Display

Quest and the Q4500 each use a raster scan CRT as the display device and display a minimum of three (3), user selectable channels of real time ECG data along with other related test information

Recorder

Quest and both listed predicate devices each utilize an eight (8) inch 200 DPI (vertical resolution) thermal dot matrix recorder. This is the same recording technology used by most commercially available Electrocardiographs and Stress Systems.

This recording device is used to generate multi-channel real time and formatted ECG records. These recordings can be programmed or requested manually.