Rhythm Express® RX-1
Remote Cardiac Monitoring System

Intended Use

The Rhythm Express remote cardiac monitoring system is intended for use by adult patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional. The data received from the Rhythm Express device can be used by another device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express remote cardiac monitoring system is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. The Rhythm Express system communicates events from the patient to the monitoring center within one to seven minutes (assuming cell service is available) and hence is not suitable for use as a real-time arrhythmia event monitor.

Contraindications

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

Intended for Use

The RX-1 ECG monitor with arrhythmia detection is intended for use in the following indications:

• Adult patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life-threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of Brady arrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hypothyroidism or chronic lung disease.

• Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as:

a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

• Patients with palpitations with or without unknown arrhythmias to obtain correlation of rhythm with symptoms.

• Patients who require outpatient monitoring of antiarrhythmic therapy: a) monitoring of therapeutic and potential proarrhythmic effects (e.g. QT prolongation) of membrane active drugs; and b) monitoring of effective drugs to control

ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation or atrial flutter).

• Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

• Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.

• Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation/atrial flutter.

Cautions and Warnings

Wear the device and lanyard under a shirt or other garment to avoid becoming entangled in your surroundings. Disconnect Patient leads from electrodes before defibrillation. Exposure to defibrillation may damage the RX-1 device or may interfere with operation of the defibrillator. RX-1 is not intended for use as an emergency medical response system. Keep out of reach of children. This device includes use of small parts and long cords which could pose a choking or strangulation hazard to unattended children. This device captures and presents data reflecting a patient's physiological condition that, when reviewed by a trained medical professional, can be useful in determining a diagnosis. However, the data should not be used as the sole means for determining a patient's diagnosis. The RX-1 device is designed for use with standard electrodes. Some people are sensitive to the materials used in skin electrodes. If a reaction occurs, remove the device and electrodes from the body. This device is not intended for use during an MRI. Use only specified parts and accessories to maintain operator and patient safety. The RX-1 is designed to meet or exceed requirements for electromagnetic compatibility, however, some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from heavy machinery, electric blankets, and similar apparatus, resulting in non-physiological waveforms with the potential for misinterpretation. Do not allow electrodes or ECG leads to contact an electrical power source or ground. Contact could cause electrocution of the patient. Disconnect the lead wires from the electrodes prior to charging. Although the charger has been tested to assure that it meets safety standards, failure could result in electrical shock. Use only the specified, charger for this device (AC/DC adapter), as listed in the system components of this manual. Using another AC adapter may damage the device and may create a safety hazard. Do not expose the device or lead wires to autoclaving or steam cleaning, as damage could result. Recommended cleaning procedure is to wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean, soft cloth. There are no user-serviceable parts inside. Opening the case will void all warranties and could result in permanent damage. The RX-1 device has been designed to tolerate normal drops and shocks. However, excessive impact and shocks should be avoided to prevent damage to the device. The RX-1 device uses a Lithium battery. This battery may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 45° C (113° F), or incinerate. Dispose of the device in accordance with applicable local regulations. The user of this product is responsible for routine maintenance. Failure to do so may cause undue failure and possible health hazards. VivaQuant equipment is identified by the UDI, Model, and serial number on the back of the device. Take care not to deface these numbers. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. This equipment is resistant to water but should not be submerged in water. Remove device prior to entering a pool or bath and do not submerge device during cleaning and maintenance procedures. Submerging the device in water could result in damage. This equipment should not be exposed to environmental conditions outside the listed specifications.