

Product number/ REF:
10-003

Manufacturer:
Icentia Inc. 2750, Einstein, Quebec, QC Canada G1P 4R1

Description and Instructions for use

The CardioSTAT medical device is a portable, battery-operated, single-use, single-channel digital ECG recorder that can record electrical signals associated with heart activity. It is indicated for use on patients who require a long-term, continuous ECG recording, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The CardioSTAT ECG recorder is applied on the torso of an adult patient, who has been prescribed an ECG recording. It is worn during their activities of daily living at home, work, etc. Patient interaction with the recorder is achieved through the event button which allows reporting of symptomatic events during the recording period.

Product safety information

The following warnings and cautions must be considered to ensure safety.

Warnings

Do not apply CardioSTAT recorder on breached or compromised skin surfaces.

Do not use the CardioSTAT recorder on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies.

Do not use CardioSTAT recorder for patients known to have cardiac conditions that could result in immediate danger to the patient or where inpatient monitoring should be prescribed.

Remove CardioSTAT recorder and electrodes before defibrillating patient.

Do not use CardioSTAT recorder on patients wearing a pacemaker, implantable defibrillator, neuro-simulator, or any other type of active implantable device.

Do not use CardioSTAT recorder on patients who will be subjected to an oxygen-rich environment, flammable anesthetic, or other flammable agents.

Do not reuse the CardioSTAT recorder on multiple patients. It is a single patient use device.

Reuse may cause incorrect patient data, incomplete to no recording, and patient may experience cross contamination.

Choking hazard. Small parts, plastic bags. Keep away from children and pets.

Cautions

Do not use any parts that appear damaged.

Proper skin preparation is essential for optimal ECG signal quality.

Proper electrodes placement is essential for optimal ECG signal recording.

CardioSTAT recorder and electrodes must be removed from a patient about to undergo energy delivery procedures to the upper torso such as diathermy therapy, Transcutaneous Electrical Nerve Stimulation (TENS), diagnostic or therapeutic ultrasound, radiation therapy, electro-surgery, or X-ray.

CardioSTAT recorder and electrodes are designed to be showerproof. They are not designated to be immersed in water or any other liquid.

Avoid touching both electrodes connectors at the same time or putting them in contact with metal surfaces, as this might activate the recorder unintentionally.

Usage of expired electrodes can provide impaired recording and affect how the recorder stays in place on the patient.

Carefully check the patient information and recorder ID in the patient diary to ensure accurate ECG report delivery.

Carefully follow the instructions on removing the electrodes to avoid damaging the skin.

Poor contact of the electrodes with the skin can negatively affect recording quality. Electrodes and adhesives should be replaced when they become loose.

Avoid rough handling of the recorder to preserve its integrity. If the recorder receives an important impact during wear, or in case of doubt, place contact Icentia technical support.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CardioSTAT recorder. Otherwise, degradation of the performance of this equipment could result.