Electrocardiographic Services Framework

Various diagnostic devices and services are available to physicians for ambulatory electrocardiographic services. The Centers for Medicare & Medicaid Services (CMS) has created a framework to categorize such devices. CMS would create a new category if published, peer-reviewed clinical studies demonstrate that the new device is superior to devices in existing categories.

Ambulatory electrocardiographic devices are divided into two broad categories. The first category includes non-activated, continuous recording devices. A "non-activated" device does not require a specific trigger or action to capture and record electrocardiographic data. The second category includes patient or event-activated intermittent recording devices. Each of these categories is further described below.

Non-activated, continuous recording devices are known as Holter monitors. A Holter monitor is a device that captures and records a real-time, continuous EKG waveform of a patient's heart rhythm while the patient is engaged in daily activities. The data is stored on magnetic tape or other media. A physician does not review the gathered electrocardiographic data until after the device is removed from the patient. A Holter monitor is generally worn continuously for 24 or 48 hours, during which time the patient may keep a diary of activities and symptoms.

A patient or event-activated intermittent recording device continuously monitors, but does not continuously record, EKG waveforms. The device requires a specific trigger to initiate the recording of electrocardiographic data. Such triggers include, but are not limited to, deliberate action by the patient (usually upon noticing onset of symptoms; "patient activated"), or programmed instructions allowing the device to automatically recognize and record specific waveforms or waveform patterns that may or may not produce patient symptoms ("event-activated").

Patient or event-activated intermittent recording devices are designed either with or without a memory loop. The memory loop maintains and stores EKG waveforms for a programmed time interval preceding triggering events. Older event recorders do not contain a memory loop and are unable to record EKG waveforms prior to triggering events. Patient or event-activated intermittent recording devices may transmit stored data to various locations via telephone or other method.

Also, memory loop recorders may be either insertable or non-insertable. (Note: The words insertable and implantable are used interchangeably.) Insertable memory loop recorders are surgically placed under the patient's skin in the upper chest. Insertable memory loop recorders may remain in place for up to a year, rarely longer, before they are explanted. Non-insertable memory loop recorders are external devices that collect data via electrodes that make contact with a patient's skin. Non-insertable memory loop recorders are usually used for up to 30 days, sometimes longer.

Memory loop recording devices can be further categorized as to whether or not the recorded EKG data is reviewed by a physician before the device is removed from the patient. When EKG data is reviewed prior to device removal, the recorder is considered "attended"; absent such review, it is considered "non-attended".

Generally, the selection of a particular type of device is based on the frequency with which the patient's symptoms, thought to be related to cardiac dysrhythmia, occur.

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