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Subpart C—Cardiovascular Monitoring Devices

§ 870.2050 Biopotential amplifier and signal conditioner.

(a) *Identification*. A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

(b) *Classification*. Class II (performance standards).

§ 870.2060 Transducer signal amplifier and conditioner.

(a) *Identification*. A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.

(b) *Classification*. Class II (performance standards).

§ 870.2100 Cardiovascular blood flowmeter.

(a) *Identification*. A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

(b) *Classification*. Class II (performance standards).

§ 870.2120 Extravascular blood flow probe.

(a) *Identification*. An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

(b) *Classification*. Class II (performance standards).

§ 870.2300 Cardiac monitor (including cardiotachometer and rate alarm).

(a) *Identification*. A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(b) *Classification*. Class II (performance standards).

§ 870.2310 Apex cardiograph (vibrocardiograph).

(a) *Identification*. An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.

(b) *Classification*. Class II (performance standards).

§ 870.2320 Ballistocardiograph.

(a) *Identification*. A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.

(b) *Classification*. Class II (performance standards).

§ 870.2330 Echocardiograph.

(a) *Identification*. An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

(b) *Classification*. Class II (performance standards).

§ 870.2340 Electrocardiograph.

(a) *Identification*. An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.

(b) *Classification*. Class II (performance standards).

§ 870.2350 Electrocardiograph lead switching adaptor.

(a) *Identification*. An electrocardiograph lead switching adaptor is a passive switching device to which electrocardiograph limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

(b) *Classification*. Class II (performance standards).