

§ 870.1110

emits an alarm when the blood pressure falls outside a pre-set upper or lower limit.

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

§ 870.1110 Blood pressure computer.

(a) *Identification*. A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

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

§ 870.1120 Blood pressure cuff.

(a) *Identification*. A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

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

§ 870.1130 Noninvasive blood pressure measurement system.

(a) *Identification*. A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of transducers placed on the surface of the body.

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

§ 870.1140 Venous blood pressure manometer.

(a) *Identification*. A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

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

§ 870.1200 Diagnostic intravascular catheter.

(a) *Identification*. An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

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

§ 870.1210 Continuous flush catheter.

(a) *Identification*. A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.

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

§ 870.1220 Electrode recording catheter or electrode recording probe.

(a) *Identification*. An electrode recording catheter or an electrode recording probe is a device used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum-tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.

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

§ 870.1230 Fiberoptic oximeter catheter.

(a) *Identification*. A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

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

§ 870.1240 Flow-directed catheter.

(a) *Identification*. A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.

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

§ 870.1250 Percutaneous catheter.

(a) *Identification*. A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.