

Food and Drug Administration, HHS

§ 870.2840

subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2640 Portable leakage current alarm.

(a) *Identification.* A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2675 Oscillometer.

(a) *Identification.* An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

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

§ 870.2700 Oximeter.

(a) *Identification.* An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

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

§ 870.2710 Ear oximeter.

(a) *Identification.* An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

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

§ 870.2750 Impedance plebograph.

(a) *Identification.* An impedance plebograph is a device used to provide a visual display of the venous pulse or

drainage by measuring electrical impedance changes in a region of the body.

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

§ 870.2770 Impedance plethysmograph.

(a) *Identification.* An impedance plethysmograph is a device used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs.

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

§ 870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.

(a) *Identification.* A hydraulic, pneumatic, or photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.

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

§ 870.2800 Medical magnetic tape recorder.

(a) *Identification.* A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

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

§ 870.2810 Paper chart recorder.

(a) *Identification.* A paper chart recorder is a device used to print on paper, and create a permanent record of the signal from, for example, a physiological amplifier, signal conditioner, or computer.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2840 Apex cardiographic transducer.

(a) *Identification.* An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by