provides a visual or audible display of the heart sounds.

(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.


§ 870.2400 **Vectorcardiograph.**

(a) **Identification.** A vectorcardiograph is a device used to process the electrical signal transmitted through electrocardiograph electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

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

§ 870.2450 **Medical cathode-ray tube display.**

(a) **Identification.** A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.

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

§ 870.2600 **Signal isolation system.**

(a) **Identification.** A signal isolation system is a device that electrically isolates the patient from equipment connected to the commercial power supply received from a utility company. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.

(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.


§ 870.2620 **Line isolation monitor.**

(a) **Identification.** A line isolation monitor is a device used to monitor the electrical leakage current from 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.


§ 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.


§ 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).