which a patient sits, that is used to determine the patient’s lung volume changes.

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

§ 868.1780 Inspiratory airway pressure meter.

(a) **Identification.** An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient’s airway during maximal inspiration.

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

§ 868.1800 Rhinoanemometer.

(a) **Identification.** A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient’s nasal passages.

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

§ 868.1840 Diagnostic spirometer.

(a) **Identification.** A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient’s lungs.

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

§ 868.1850 Monitoring spirometer.

(a) **Identification.** A monitoring spirometer is a device used to measure continuously a patient’s tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient’s ventilatory status.

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

§ 868.1860 Peak-flow meter for spirometry.

(a) **Identification.** A peak-flow meter for spirometry is a device used to measure a patient’s maximum ventilatory flow rate.

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

§ 868.1870 Gas volume calibrator.

(a) **Identification.** A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the output of gas volume measurement instruments by delivering a known gas volume.

(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 § 868.9.


§ 868.1880 Pulmonary-function data calculator.

(a) **Identification.** A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

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

§ 868.1890 Predictive pulmonary-function value calculator.

(a) **Identification.** A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

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

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) **Identification.** A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.

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

§ 868.1910 Esophageal stethoscope.

(a) **Identification.** An esophageal stethoscope is a nonpowered device that is inserted into a patient’s esophagus to enable the user to listen to heart and breath 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 § 868.9.