Sensinel™ CPM System Performance Validation

The ADI Sensinel™ CPM (Cardiopulmonary Management) System (referred to as the Sensinel™ CPM System) is a non-invasive device prescribed by a licensed medical professional to measure and trend physiological parameters, including thoracic impedance, respiration rate, relative tidal volume, ECG, skin temperature, and heart auscultation sounds from a patient living with cardio-pulmonary condition(s). The Sensinel™ CPM System provides the Clinical Care Team with daily physiological measurements and trends, enabling them to monitor patient status and aid in clinical decision making.

To validate the performance of the various measures provided by the Sensinel™ CPM System, clinical studies were conducted with both healthy and patients with a variety of cardiopulmonary conditions representing the intended population. The goal of this white paper is to present the results of the Sensinel CPM System's clinical validation studies and some bench validation data.

Figure 1 Sensinel™ Secure Wearable Device

Table 1 Performance Summary

Heart Rate	Accuracy within ±10 % or ±5 bpm
Respiration Rate	Accuracy within ±2 brpm
Relative Tidal Volume	Correlation coefficient greater than 0.95 to clinically measured tidal volume
Thoracic Impedance	Precision less than 3 ohms
Heart Sounds Auscultation	Auscultation bandwidth of 10-2000 Hz
Skin Temperature	Accuracy and precision within 0.3 degrees C

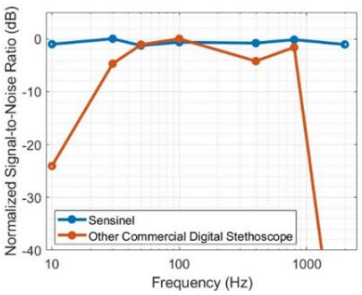

Figure 2 Auscultation Frequency Response

Heart Sounds Auscultation

Heart sounds auscultation allows clinicians to assess potentially pathologic heart sounds such as the third heart sound. Diastolic heart sounds are known to have significant low frequency content making them difficult to hear. Measuring these sounds with a device capable of detecting low frequencies has been shown to be predictive of heart failure events[1]. The frequency response of the Sensinel™ CPM System in the range of 10 to 2000 Hz is relatively flat allowing it to detect low frequency sounds.

Heart Rate Accuracy

Heart rate is computed from analysis of the ECG recording, which identifies the QRS complexes. Based on the interval between them, the heart rate is derived. Its accuracy is validated in the clinical study, bench testing as well as in component testing as summarized below.

Table 2 Heart Rate Accuracy

Bench Validation	Accuracy within ±10 % or ±5 bpm, whichever is greater (per IEC 60601-2-27: 2011, Clause 201.12.1.101.15)
Component Validation	Accuracy of heart rate to irregular rhythm (per IEC 60601-2-27:2011, Section 201.7.9.2.9.101 b) 4) Ventricular bigeminy: 80 ± 1 bpm Slow alternating ventricular bigeminy: 60 ± 1 bpm Rapid alternating ventricular bigeminy: 120 ± 1 bpm Bidirectional systoles: 90 ± 1 bpm

[1] M. Cao, C. Schulze, R. Gardner, Q. An, P. Thakur, J. Thompson, J. Boehmer, P1577
Device-measured third heart sound predicts heart failure events better than auscultated third heart sound, EP Europace, Volume 19, Issue suppl_3, June 2017, Pages iii332–iii333, https://doi.org/10.1093/ehjci/eux158.203

Respiration Rate Accuracy and Relative Tidal Volume Correlation

The Sensinel™ CPM System provides a measure of respiration rate and relative tidal volume. These parameters are measured daily and trended over time allowing the care team to detect alterations in a patient's respiratory patterns.

Respiration rate (RR) and relative tidal volume (rTV) are computed from a thoracic bio-impedance signal which is modulated by the expansion and contraction of the thoracic cavity including the lungs. The demonstrated accuracy is sufficient to indicate patients with respiratory distress such as shortness of breath. The accuracy of the RR and the correlation of rTV was validated on the 40 healthy participants whose ages range from 21 to 71 years old with an approximately even split between female and male (clinicaltrials.gov identifier NCT05445206). The reference RR is established by manual scoring of a simultaneously acquired capnography waveform. The results are summarized below.

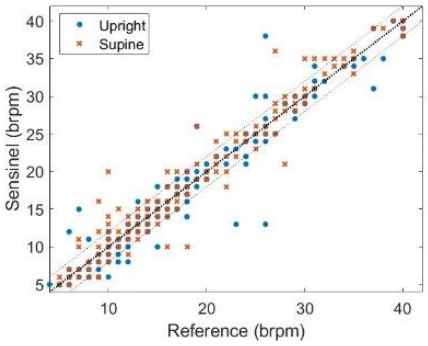

Figure 3 Sensinel CPM System RR estimate compared to the reference RR.

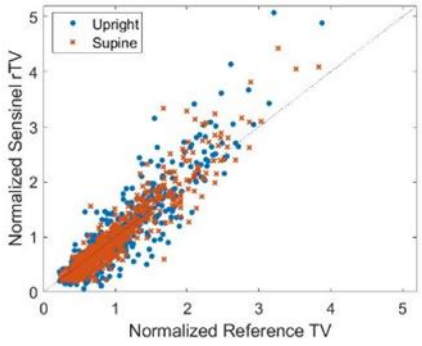

Figure 4 Correlation between Sensinel CPM System relative tidal volume to reference tidal volume

Table 3 Respiration Rate Accuracy

	Supine	Upright
% of errors within ±2brpm	96.3	95.7
Mean Absolute Error (brpm)	0.49	0.49
Root Mean Squared Error (brpm)	1.20	1.34
7.5% Percentile Error (brpm)	-1.00	-1.00
92.5% Percentile Error (brpm)	1.00	1.00

Table 4 Relative Tidal Volume Correlation

	Supine	Upright
Mean	0.96	0.95
95% Lower Bound	0.95	0.93
95% Upper Bound	0.97	0.97

Thoracic Impedance Precision

Thoracic impedance has been used for a long time in implantable systems to monitor changes in fluid levels[2]. The Sensinel™ System utilizes proprietary algorithms to separate artifacts commonly encountered by non-invasive devices (such as the quality of skin contact) from the actual thoracic impedance. Thoracic bio-impedance is computed from a thoracic bio-impedance spectroscopy measurement acquired using four electrodes of the Sensinel™ wearable device. The thoracic impedance is sufficiently precise to indicate trends related to the fluid status in the thoracic cavity. The precision of the thoracic impedance was validated on 20 patients with a variety of cardiopulmonary conditions (clinicaltrials.gov identifier: NCT04865640). The age ranges were from 38 to 86 years old. The results are summarized in the table below.

Table 5 Thoracic Impedance Precision

	Estimate (Ohms)	95% Upper Bound (Ohms)
Variability without removing the device	2.08	2.38
Variability with removing the device	2.75	3.13

[2] Yu, Cheuk-Man, et al. Intrathoracic Impedance Monitoring in Patients with Heart Failure, Circulation, vol. 112, no. 6, 9 Aug. 2005, pp. 841–848, https://doi.org/10.1161/circulationaha.104.492207