The Heart Failure (HF) Solution of Tomorrow, Today

10.5% of the Medicare population has an HF diagnosis and it currently represents 34% of all Medicare spending. In total, this is the most expensive aggregate population in Medicare.

Early HF detection may provide an opportunity for total cost-of-care reduction, better clinical outcomes, and improved patient satisfaction. There are very few populations this small that have significant potential for value-based payment savings and return on investment (ROI). In most instances, the Sensinel™ CPM System does not require substantial capital and staff investment.

Home monitoring solutions today like weigh scales, blood pressure cuffs, and pulse oximeters do not necessarily provide HF-specific clinical information in advance that helps avoid acute episodes. To be effective, an HF monitoring solution must be easy to use, scalable, and accurate. It must also reduce data overload and false positives for care management teams and clinicians.

The Sensinel CPM System is a next-generation, noninvasive solution that aims to enable better home monitoring for HF patients.

For more information, please visit sensinel.analog.com.

Sensinel CPM System at a Glance

End-to-End Solution

Sensinel by Analog Devices™ is designed to deliver quality solutions that can provide cost-effective care, enhance patient engagement, and increase customer satisfaction. The data our system collects can enable better clinical management of this patient population.

Data Review and Patient Monitoring

- Collect and review data that is specific to HF decompensation, including heart sounds, lung fluids, thoracic impedance, respiratory rate, variability, tidal volume, and single-lead ECG
- Review and identify out-of-range measurements

Nurse Triage Team

- Assess and follow up with patient
- Engage and triage patients escalated from data management and patient monitoring
- Provide 24-hour care team notification
- Escalate patient needs based on established protocols and clinical review
- Choice to use Analog Devices' triage or own team

Key Highlights

- Measure specific indicators of HF decompensation
- Review/identify patient clinical parameter threshold breaches
- Nurse triage follow-up with escalated patients
- Send clinical data and threshold breaches daily
- Care team receipt of escalated patient fax notifications

- Clinical provider team enabled to follow-up and enage in management of patient
- Provide performance data analytics
- Share trended data with clinical provider team
- 24/7 customer support at 1-800-AnalogD (1-800-262-5643)

Clinical Monitoring and Care Team Services
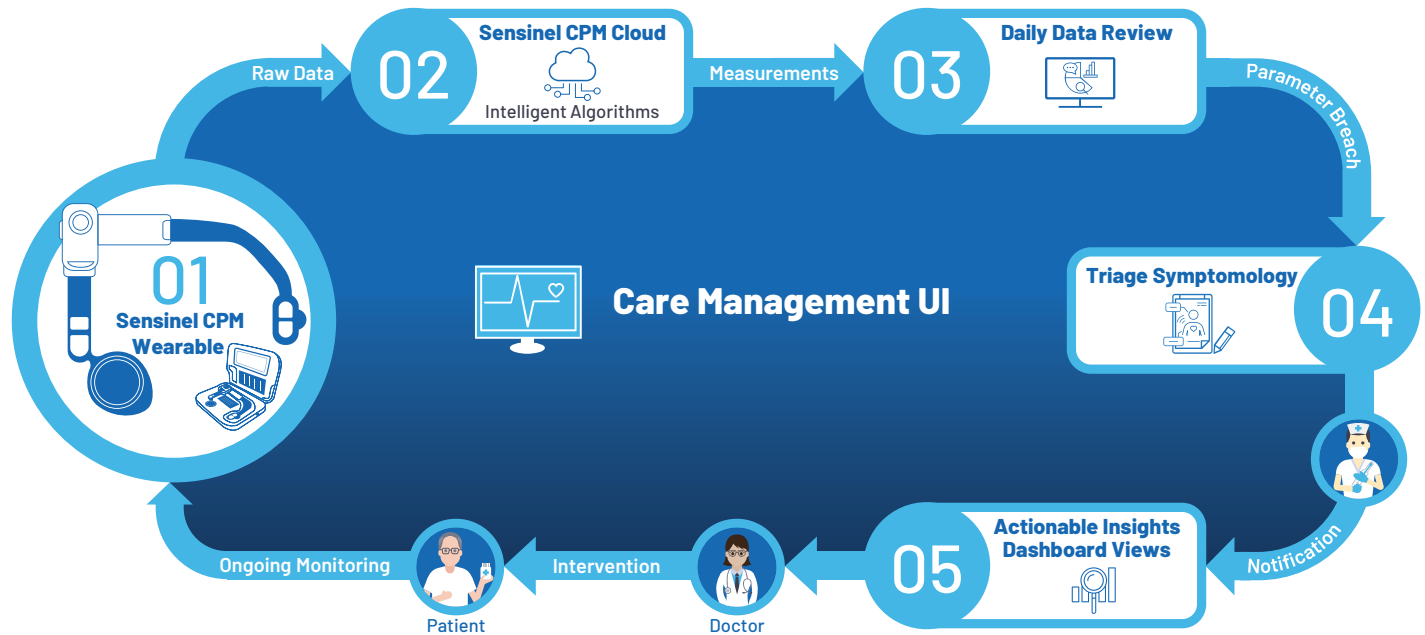
The Sensinel CPM Wearable collects HF-specific measurements and automatically uploads this data to the secure cloud where it is trended daily (via intelligent algorithms). There is an option to engage remote triage nurses to monitor and analyze this patient data to synthesize a holistic view of the patient. These nurses combine both the patient's clinical data and reported symptoms to determine the patient's condition. This allows the triage nurses to proactively address at-risk patients before a potential HF-decompensation event occurs.

Medical and/or care management staff are only engaged as clinically appropriate, minimizing the number of day-to-day calls to patients for whom regular or daily review of cardiopulmonary measurement data is desired or needed. This triage service can be provided by ADI's clinical partners or performed by your clinical team.

After the patients with increased risk are identified, the triage nurse notifies the appropriate care team member (physician, nurse, heart failure clinic manager). Escalation protocols for patient follow-up can be flexibly integrated into a practice's proven workflow so as not to overburden the clinical practice.

Clinicians who have received escalation notices can further reference the Sensinel dashboards for patients under their care and can further reference their patients' data in the Sensinel System's patient dashboard to facilitate discussions with either the triage nurse and/or their patients. This enables enhanced clinical decision-making on the next treatment steps (for example, contacting the patient for a consultation, adjusting medications and/or diet, or having the patient come into an office or clinic visit).
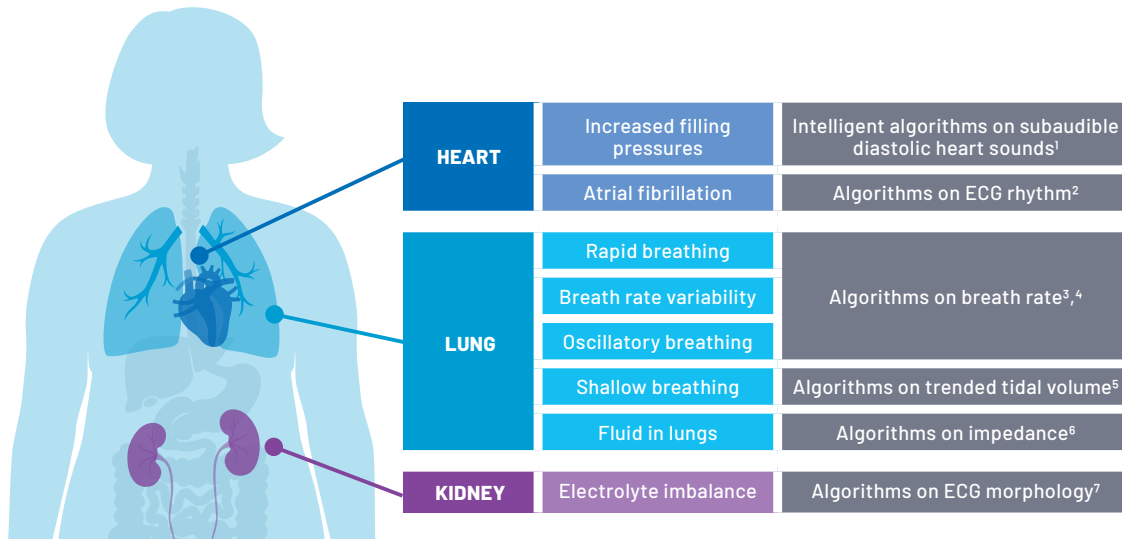
The process of using highly specific measurements combined with intelligent algorithms to assist in identifying high risk patients enables the care management team to focus on at-risk patients.

The solution measures clinically relevant physiological parameters for determining the onset of HF decompensation.

Value Proposition

Benefits of the Sensinel System

- Externally measures key presymptomatic indicators of HF in less than 5 minutes per application from the comfort of a patient's home care setting

- Supports patient adherence through ease of use and smooth CPM Wearable self-application (intuitive design)

- Designed to improve patient engagement by connecting care through the home and giving patients peace of mind

- Potential to reduce alert fatigue and false positives

- Trends HF-specific indicators for heart and lung functions

- Allows clinicians to assess data in advance that may be indicative of acute HF decompensation to allow early and simple intervention

- Goal to improve outcomes and lower costs through value-based care and payment performance

HEART	Increased filling pressures	Intelligent algorithms on subaudible diastolic heart sounds[1]
	Atrial fibrillation	Algorithms on ECG rhythm[2]
LUNG	Rapid breathing	Algorithms on breath rate[3,4]
	Breath rate variability	
	Oscillatory breathing	
	Shallow breathing	Algorithms on trended tidal volume[5]
	Fluid in lungs	Algorithms on impedance[6]
KIDNEY	Electrolyte imbalance	Algorithms on ECG morphology[7]

[1] Devi G. Nair, MD, FHRS, Roy Gardner, MD, Ramesh Hariharan, Roy Small, Qi An, Pramod Thakur, and John Boehmer. "Baseline S3 Measured Using Implanted Accelerometer Is More Prominent in Patients with Heart Failure Decompensation." *Heart Rhythm*, Vol. 12, No. 5 Supplement: S372 to 424, 2015.

[2] Anne Margreet De Jong, Alexander H. Maass, Silke U. Oberdorf-Maass, Dirk J. Van Veldhuisen, Wiek H. Van Gilst, and Isabelle C. Van Gelder. "Mechanisms of Atrial Structural Changes Caused by Stretch Occurring Before and During Early Atrial Fibrillation." *Cardiovascular Research*, Vol. 89, No. 4, March 2011.

[3] Massimo Pozzoli, Giovanni Cioffi, Egido Traversi, Gian Domenico Pinna, Franco Cobelli, and Luigi Tavazzi. "Predictors of Primary Atrial Fibrillation and Concomitant Clinical and Hemodynamic Changes in Patients with Chronic Heart Failure: A Prospective Study in 344 Patients with Baseline Sinus Rhythm." *Journal of the American College of Cardiology*, Vol. 32, No. 1, July 1998.

[4] Alessandro Capucci, Giulio Molon, Michael Gold, Yi Zhang, Robert Sweeney, Viktoria Averina, and John Boehmer. "Rapid Shallow Breathing Worsens Prior to Heart Failure Decompensation." *Journal of Cardiac Failure*, Vol. 20, No. 8, August 2014.

[5] J. P. Boehmer et. al. *Heart Rhythm*, Vol. 10, No. 5 Supplement: S1-S554, 2013.

[6] Piotr Ponikowski, Stefan D. Anker, Tuan Peng Chua, Darrel Francis, Waldemar Banasiak, Phillip A. Poole-Wilson, Andrew J. S. Coats, and Massimo Piepoli. "Oscillatory Breathing Patterns During Wakefulness in Patients With Chronic Heart Failure Clinical Implications and Role of Augmented Peripheral Chemosensitivity." *Circulation*, Vol. 100, No. 24, December 1999.

[7] Harry Feld and Steven Priest. "A Cyclic Breathing Pattern in Patients with Poor Left Ventricular Function and Compensated Heart Failure: A Mild Form of Cheyne-Stokes Respiration?" *Journal of the American College of Cardiology*, Vol. 21, No. 4, March 1993.

Cardiopulmonary Management System

Industry advances in technology are making home management, early detection of worsening HF symptoms, and the reduction of hospitalizations possible.

The Sensinel CPM System is designed to monitor patients at home before they decompensate or experience a worsening HF episode. This is made possible through advanced technology that, when applied according to the manufacturer's instructions, delivers accurate, reliable daily data measurements that allow clinicians to make timely decisions. All of this is done without burdening the healthcare staff with an overwhelming amount of information, resulting in alert fatigue.
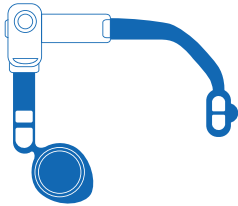
■ Sensinel CPM Wearable

The CPM Wearable is a device that measures key HF-specific parameters in less than 5 minutes per application from the comfort of a patient's home care setting.

The CPM Wearable, when not in use, is stored in the base station. The base station charges, stores, and uploads data. It utilizes cellular connectivity and does not require a Wi-Fi or an internet connection.

❙ Sensinel Intelligent Algorithms

The intelligent algorithm trends the data daily from raw measurements acquired from the Sensinel CPM Wearable sensors and electrodes. The derived measurements, along with trending data, are then displayed in the Sensinel CPM System patient dashboard as potentially actionable clinical data for review by the patient's care team.

❙ Sensinel Actionable Insights

Single modality measurements are insufficient in determining the clinically relevant information required for physicians to make decisions and act on their patients' behalf. Multimodal sensor measurements record key aspects of HF physiology (reducing false alerts), resembling information gathered from an outpatient visit. This provides the specific, relevant data (actionable insights) most needed by clinicians to make significant decisions in their patients' treatment plan.

Problem

Patients living with a chronic condition like heart failure face many difficulties. In 2020, approximately 1.5 million patients with worsening chronic heart failure were treated in an acute care setting (hospital and/or emergency room). On average, 50% of admitted heart failure patients are readmitted within 6 months of discharge. In 2020, Medicare spent $776 billion, with 34% ($264 billion) spent on patients with heart failure.[1]

Current remote patient monitoring systems that utilize weigh scales, blood pressure cuffs, and pulse oximeters are manual, can be cumbersome, and don't guarantee patient adherence. These models cannot detect the early hemodynamic changes that occur in HF patients prior to a decompensation event.

34% Of all Medicare expenses are attributed to just **10.5%** of all Medicare patients.[2]

65% Of HF exacerbations are seen in the ER.[3]

30% Of admitted HF patients are readmitted within **60** days.[4]

THE LEADING REASON

Unobserved and untreated gradual fluid accumulation over several days leads to acute decompensation and hospitalization.

[1]Akshay Desi and Lynne W. Stevenson. "Rehospitalization for Heart Failure." *Circulation*, Vol. 126, No. 4, July 2012.

[2]"The Cost Burden of Worsening Heart Failure in the Medicare Fee for Service Population: an Actuarial Analysis." Milliman, March 2017.

[3]Kohei Hasegawa, Yusuke Tsugawa, Carlos A. Camargo, Jr., and David F. M. Brown. "Frequent Utilization of the Emergency Department for Acute Heart Failure Syndrome." *Circulation: Cardiovascular Quality and Outcomes*, Vol. 7, No. 5, August 2014.

[4]Muhammad Shahzeb Khan, Jayakumar Sreenivasan, Nroman Lateef, Marwan S. Abougergi, Stephen J. Greene, Tariq Ahmad, Stefan D. Anker, Gregg C. Fonarow, and Javed Butler. "Trends in 30- and 90-Day Readmission Rates for Heart Failure." *Circulation: Heart Failure*, Vol. 14, No. 4, April 2021.