

Heart Failure Management: The Future Is Here with the Sensinel CPM System

APPLICATION NOTE

■ Challenges

Heart failure (HF) decompensation often goes unrecognized until it is too late due to the nonspecific symptoms patients experience such as shortness of breath, fatigue and weakness, persistent cough, and swelling (edema) in the legs, ankles, and feet, among others. Most patients are at home when they experience a worsening HF event. Unfortunately, by the time a person deems these symptoms as serious, it is often too late, and patients require transportation and treatment in an emergency room and/or hospital setting.

HF patients present many treatment challenges. Historically, it has been difficult to remotely monitor critical patient parameters that provide early identification of an impending heart failure episode in the home without burdening physicians with an overwhelming amount of irrelevant information or false alerts.¹ Additionally, high maintenance monitoring can lead to low patient compliance with no demonstrated improvement in clinical outcomes. Invasive devices can help predict decompensation and an impending HF event, but they require a risky cardiac surgical procedure.^{2,3}

The need for an at-home, remote solution that generates clinically actionable data where the care team can monitor patients, identify them at increased risk for worsening HF, intervene early, and adjust treatment regimens in a virtual, non-acute care setting is imperative. Shifting the focus of physiological monitoring to the virtual setting, this solution will facilitate the integration into existing care pathways and help physicians provide patient-specific treatment or therapy adjustments to avoid unexpected ER visits or inpatient hospitalizations.

This at-home remote solution must:

- Monitor a full range of physiological parameters for the heart, lung, and kidneys that are clear indicators of a worsening HF
- Provide timely, accurate, and actionable data to the care team
- Easily integrate into existing care plans and information systems without overloading them with data
- Be easy to use to promote higher levels of patient compliance
- Demonstrate economic savings among HF patients with advanced disease
- Improve patient outcomes, satisfaction, and quality of care

¹ Radhakrishna, Bowles, and Zettek-Sumner. "Contributors to Frequent Telehealth Alerts Including False Alerts for Patients with Heart Failure: A Mixed Methods Exploration." *Applied Clinical Informatics*, Vol. 4, No. 4, October 2013.

■ Solution

Introducing the new Sensinel CPM System by Analog Devices, a cardiopulmonary medical device being utilized to support a heart failure disease management solution.

The system utilizes the Sensinel CPM Wearable and base station, a cardiopulmonary medical device, to shift the focus of chronic care from the hospital, ICU, and ER. It does this by providing data to facilitate physicians' detection and treatment of cardiopulmonary conditions, such as heart failure, at home.



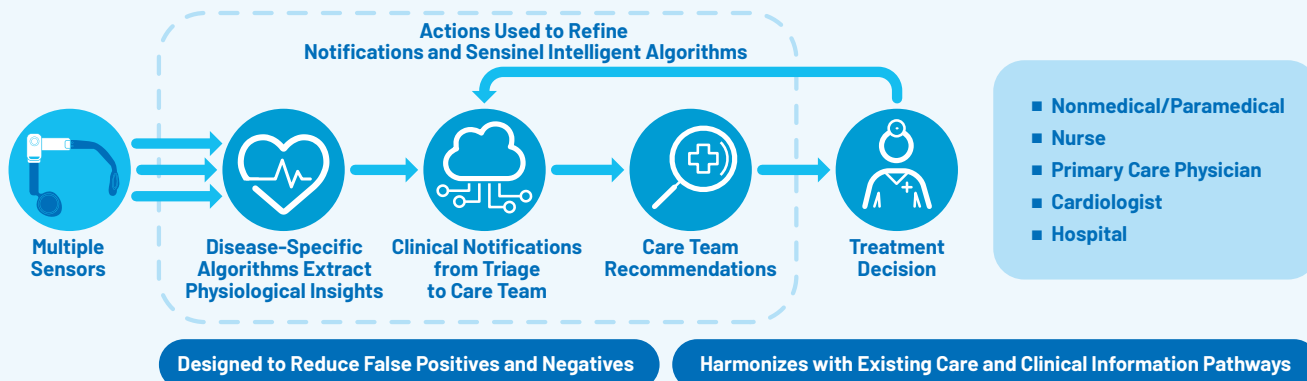
This system is a noninvasive, wearable form factor that measures physiological parameters in under 5 minutes/application from the comfort of a patient's home. Highly sensitive and specific cardiopulmonary physiological data, shown to be predictive of emergent cardiopulmonary episodes weeks in advance,⁴ is automatically measured, uploaded, analyzed, and trended to help care teams identify patients who are at-risk for worsening events, such as HF decompensation. Care teams receive actionable data in advance allowing them to provide early notification and escalations before an event occurs. Optional monitoring and triaging of data by clinical partners has the potential to reduce information overload through the delivery of timely escalations to the correct care setting. This system is designed to enable early intervention, reduce false alerts, and lower the likelihood of costly ER visits and hospitalizations.

Now physicians will have the information to help understand what's on the horizon for their patients. They will be armed with data to facilitate anticipation of potential acute episodes in advance to allow early and preventative intervention.

² Sashini Senarath, Geoff Fernie, and Atena Roshan Fekr. "Influential Factors in Remote Monitoring of Heart Failure Patients: A Review of the Literature and Direction for Future Research." *Sensors*, June 2021.

³ Dominic P. Recco, Nathalie Roy, Alexander J. Gregory, and Kevin W. Loddell. "Invasive and Noninvasive Cardiovascular Monitoring Options for Cardiac Surgery." *JTCVS Open*, June 2022.

⁴ John P. Boehmer, Ramesh Hariharan, Fausto G. Devecchi, Andrew L. Smith, Giulio Molon, Alessandro Capucci, Qi An, Viktoria Averina, Craig M. Stolen, Pramodsingh H. Thakur, Julie A. Thompson, Ramesh Warier, Yi Zhang, and Jagmeet P. Singh. "A Multisensor Algorithm Predicts Heart Failure Events in Patients with Implanted Devices: Results from the MultiSENSE Study." *JACC: Heart Failure*, Vol. 5, No. 3, March 2017.



How It Works

The Sensinel CPM System can be used for adult patients who have a range of cardiopulmonary conditions, such as HF. It can be used for those with heart failure with preserved ejection fraction (HFpEF) or heart failure with reduced ejection fraction (HFrEF). The CPM System measures nine physiological parameters at home in less than 5 minutes per application. It uses cellular networks (no internet, smartphone, or tablet interface required for patients).

The system collects a mix of important and actionable measurements and uploads them to the Sensinel CPM cloud. The data is sufficiently specific

to reduce the likelihood for false positives and provide potentially actionable information to the care team. All measurements are trended daily. ADI's clinical data review partner team assesses patient data daily to identify which patients require clinical triage. They determine when to notify a patient care team that it needs to further assess a patient who is indicating the potential for an HF decompensation event.

Indications for use: the system is for spot checking and does not have continuous monitoring capability, does not produce alarms, and is not intended for active, real-time patient monitoring.

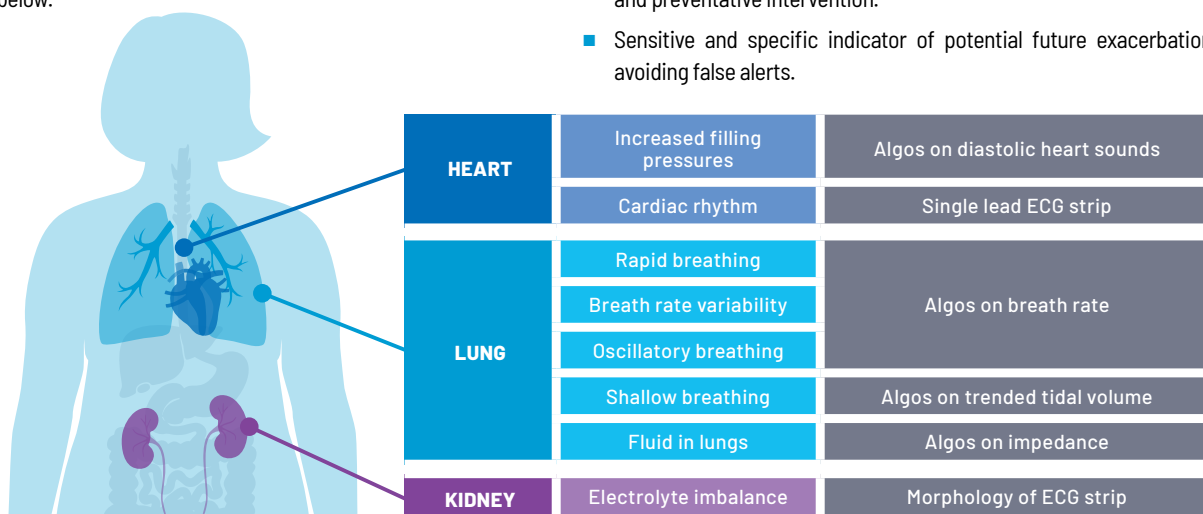
Who Is Measured?

- General care patients 18 years of age and older, including those who have been diagnosed with HF and are at risk for worsening HF episodes; can be HFpEF or HFrEF. The device is contraindicated for patients with life threatening arrhythmias requiring immediate medical intervention.

What Do We Measure?

- Critical physiological measurements that represent the function of multiple organs and multiple parameters. See table and diagram below.

- Measurements are sufficiently sensitive and specific to allow for care team anticipation of potential acute episodes to enable early and preventative intervention.
- Sensitive and specific indicator of potential future exacerbation avoiding false alerts.



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.

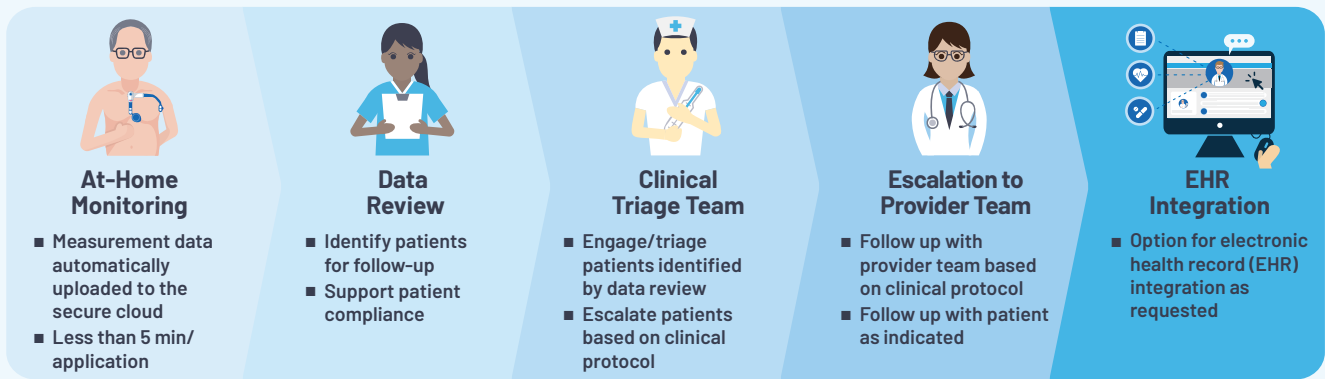
³ Massimo Pozzoli, Giovanni Cioffi, Egido Traversi, Gian Domenico Pinna, Franco Cobelli, and Luigi Tavazzi. "Predictors of Primary Atrial Fibrillation and Concomitant Clinical and Hemodynamic Changes in Patients with Chronic Heart Failure: A Prospective Study in 344 Patients with Baseline Sinus Rhythm." *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.

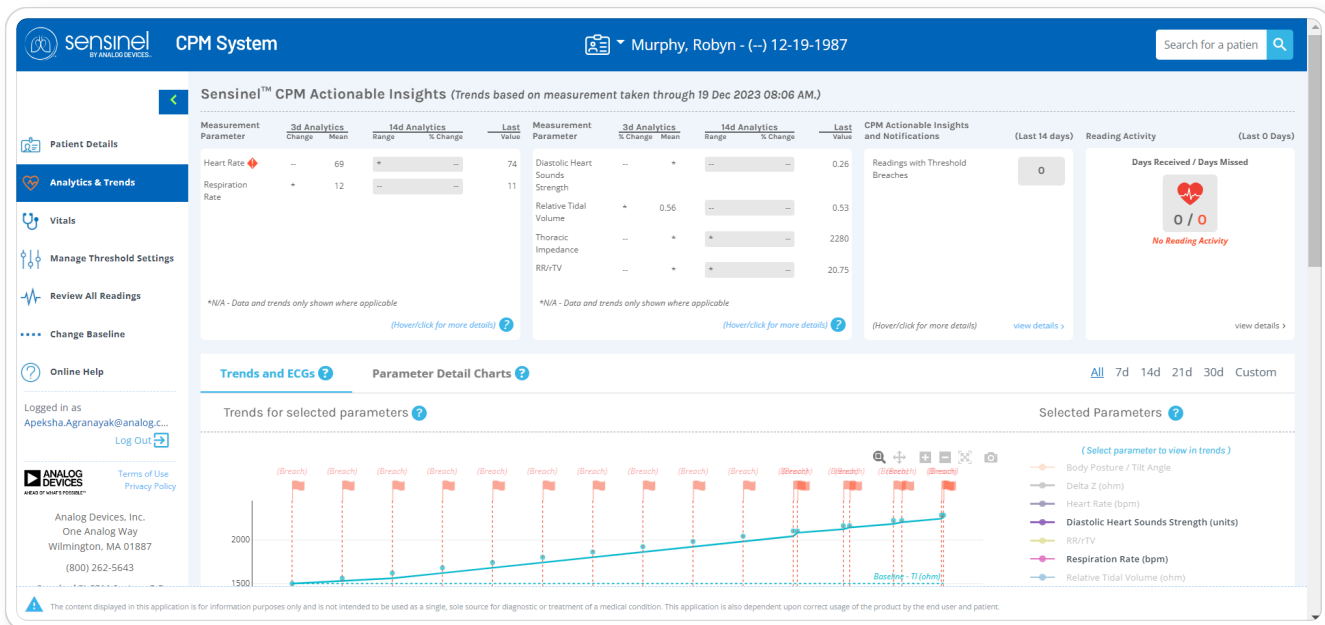


■ Components

System hardware used by the patient to collect data includes:

- Sensinel CPM Wearable collects measurements
- Cellular-connected base station transmits data to secure cloud
 - Charges and stores CPM Secure Wearable
- Disposable adhesives adhere CPM Wearable to center and left side of chest
- Optional alignment tool allows for repeatable positioning of CPM Wearable on left side of chest
- Mobile application used by clinical care team to guide initial CPM Wearable setup and collect patient baseline data
- Software and intelligent algorithms trend measured data, allowing a clinical care team to view patient measurements and analyze trends

Patient Dashboards



Individual Patient Profile ▲

■ Early HF Detection Drives Cost Savings

Insight-Based Digital Management Helps Avoid Treatment in an Expensive Setting

In a value-based model, the ability to identify and treat a patient prior to a potential acute HF event becomes critical in both improving and reducing the cost associated with HF management. The top 25% most expensive Medicare FFS patients cost on average \$80,228 per patient per year,¹ and the average cost per HF hospitalization per patient is \$13,807.² Shifting monitoring of physiological parameters related to HF to the home care setting and regularly reviewing critical indicators of worsening HF creates substantial opportunity for higher levels of patient satisfaction and greater cost savings.

The Heart Failure Management Program powered by the Sensinel CPM System has the potential to fundamentally transform how HF is managed and may provide the following cost-of-care benefits:

- Less patient out-of-pocket expense due to a reduction in higher cost utilization (ED, hospital, SNF, etc.)
- Higher plan and clinician member satisfaction scores to support Medicare Star rating performance and Medicare's quality program
- A total cost-of-care reduction to improve financial performance, especially in the growing value-based payment environment
- Improved care management productivity due to optimized throughput (care management time is reduced for data gathering on high risk HF patients, thereby reducing overall patient population management cost)

¹ Tyler Engel, Kathryn Fitch, and Jocelyn Lau. "The Cost Burden of Worsening Heart Failure in the Medicare Fee for Service Population: An Actuarial Analysis." Milliman, March 2017.

² Plan members with advanced HF represent 2.6% of MA population or 25% of MA HF population.

■ Solution Highlights/Benefits

- ✓ The noninvasive Sensinel CPM Wearable measures multiple parameters to provide valuable information to the care team in less than 5 minutes/application from the comfort of a patient's home
- ✓ Easy patient self-application promotes higher patient compliance
- ✓ Uses cellular network (no internet, smartphone, or tablet interface required for patients)
- ✓ Option for EHR integration as requested
- ✓ Includes intelligent algorithms and data trends to enable forecasting of potential HF events to reduce alert fatigue and false positives
- ✓ Trends HF-specific measurements for the heart, lung, and other parameters, allowing clinicians to review trends and intervene early in advance of a worsening HF condition
- ✓ Drive value-based care and payment performance by improving outcomes and lowering costs

■ About Analog Devices, Inc.

Analog Devices, the creator of the Sensinel System, is a global high performance technology leader with fully integrated, next-generation solutions and a purpose-driven mindset. We aim to intelligently bridge the physical and digital through the relentless pursuit of innovative technologies that improve lives and planetary health for generations to come. Visit analog.com.



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