

#### **Company Presentation**

April 2023







www.cardiacsense.com





### **Executive Summary**

Most advanced medical watch With FDA and CE certification

Worldwide distribution agreements represent tens of millions of dollars in sales

Target markets (size of billions):

- Arrhythmias monitoring
- Early detection of chronic patients' exacerbation
- Comfortable vital sign monitoring

Developing a chip with same medical functionalities for all wearable devices

Unique differentiation: proprietary sensors provide continuous monitoring of arrhythmias and early detection of exacerbation of chronic patients at medical level accuracies

Led by a strong management team with \$28M raised to date



# CardiacSense Watch Widest array of sensors, some unique to CardiacSense



### CardiacSense Solution for Hospital Environments Ring featuring miniaturized sensors, hospital gateways

- Continuous:
  - ✓ Pulse Rate
  - ✓ Oxygen Saturation
  - ✓ Arrhythmia detection
  - ✓ Respiratory Rate
  - ✓ Blood Pressure
  - ✓ ECG (with add on)
- Wireless communication
- Emergency button (replace wired button)
- Patient Identification (replace plastic wristband)
- Single charge per stay





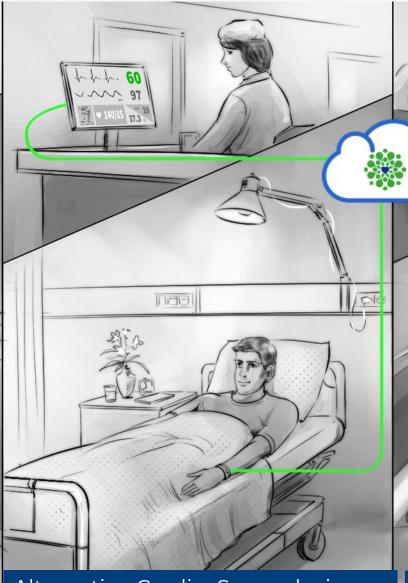
### One ring to replace them all!

Starting 2025

Compelling Use Case – Hospital Bedside Monitoring



Current bed-side monitoring with multiple wired equipment

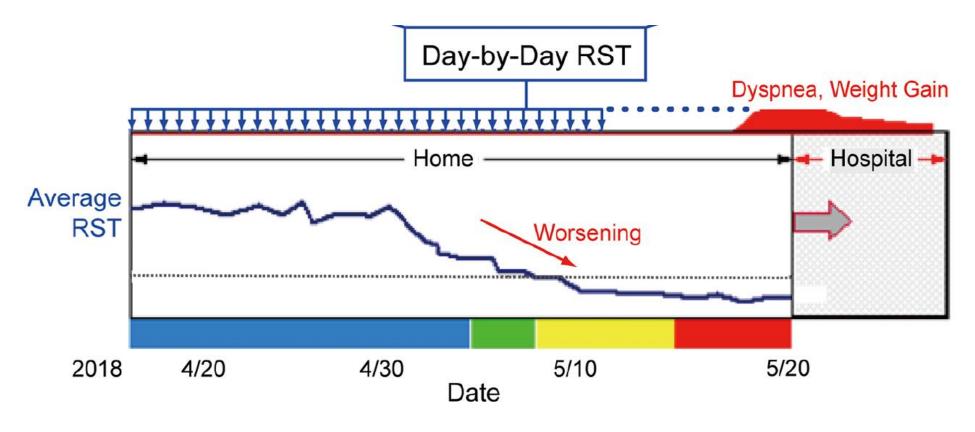


Alternative CardiacSense device monitoring replaces multiple equipment and wiring "spaghetti"

CardiacSense device monitoring can continue post-release and/or for at-home hospitalization

# Respiratory Rate Variability used for early detection of CHF exacerbations

Annual cost of rehospitalization of CHF subjects in the US is \$50B!

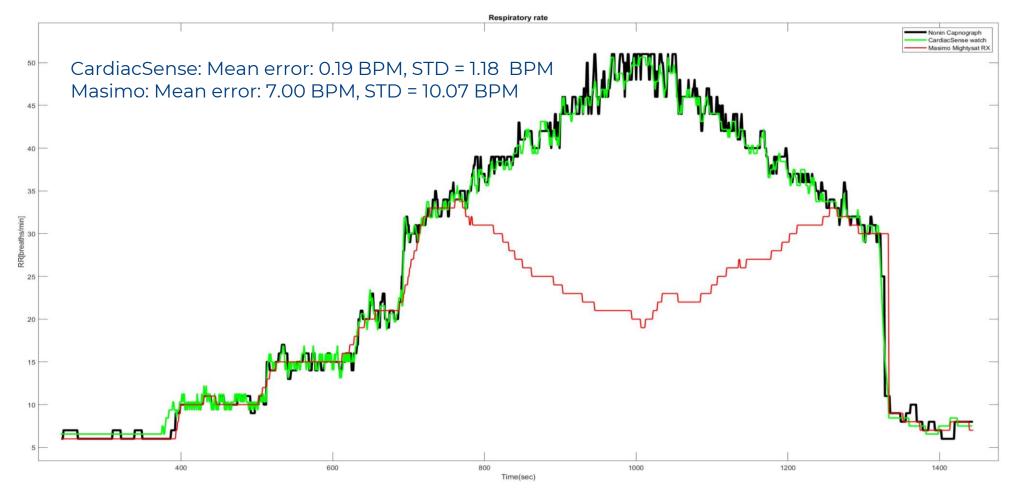


Circulation Journal, Circ J 2022; **86:** 1081 – 1091, doi: 10.1253/circj.CJ-21-0590



## **Respiratory Rate (RR) Variability**

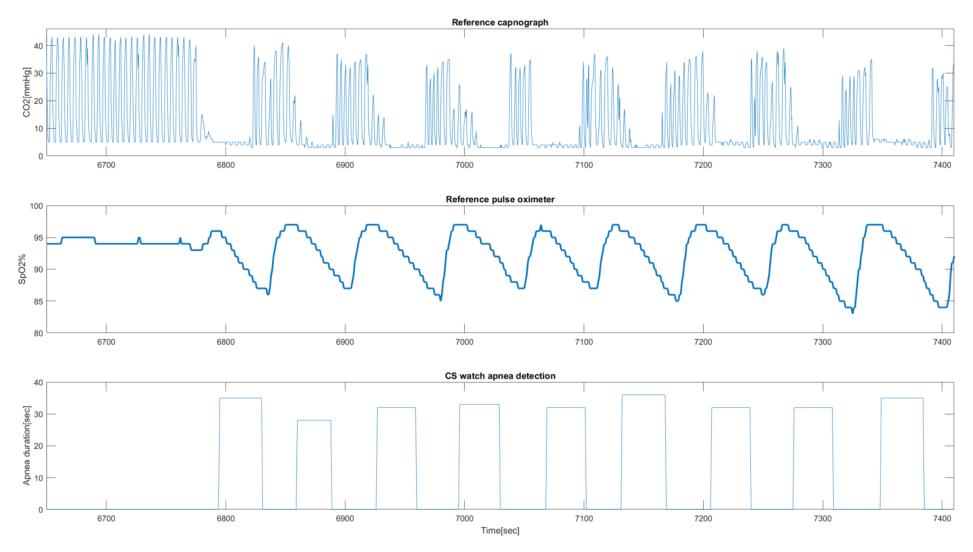
Main parameter providing early warning for chronic illness exacerbation CardiacSense vs. Capnograph Vs. Masimo







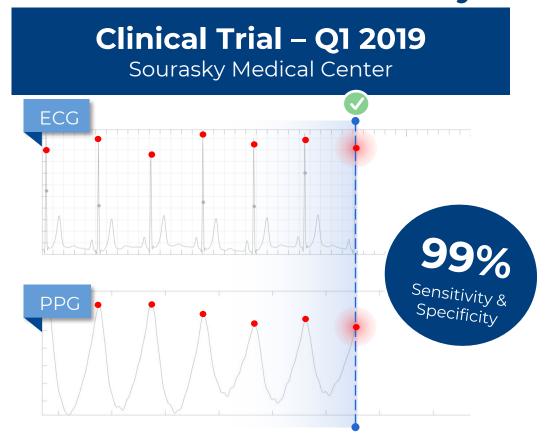
## **Unique Technology for Sleep Apnea Detection**





#### **Beat-by-beat Detection of Pulse Rate (PPG)**

CardiacSense is the only company cleared for this indication that is mandatory for arrhythmia detection



#### FDA, CE & NMPA threshold:

over 96% beat-to-beat sensitivity between ECG and PPG across 24 patients





over 56 beat-to-beat sensitivity between

ECG and PPG across 56 patients

### FDA, CE & NMPA Protocol for <u>AF Detection</u> Clearance

#### **Pivotal Clinical Trial – Q4 2019**

Sourasky Medical Center, Rambam Medical Center, Sheba Medical Center



#### FDA, CE & NMPA threshold:

over 95% consistency between medical watch and cardiologist diagnostic of AF detection across 30 patients



### **CardiacSense Report: Normal rhythm** The only report to show full electro-mechanical analysis



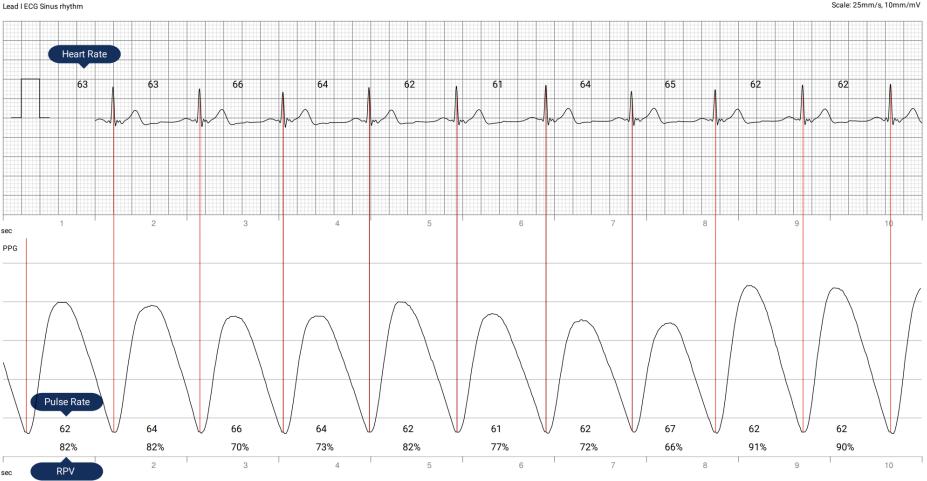
Cardiac Sense

**Detailed Screening Report** 

CS 00014597

Eldad Shemesh, 022425417 - Feb 19, 2023-06:40 pm, CS

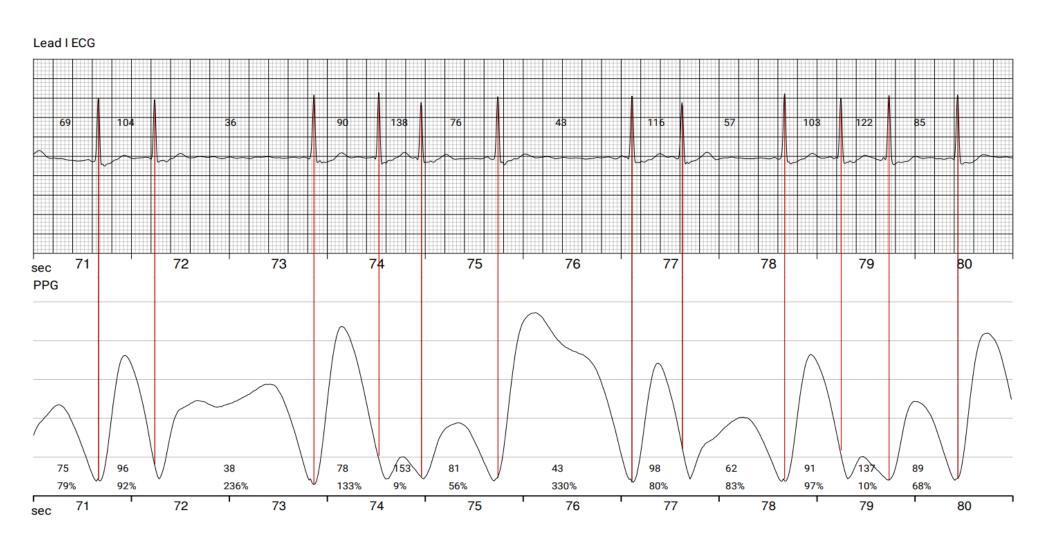












# CardiacSense Report: Atrial Fibrillation The only report to show full electro-mechanical analysis

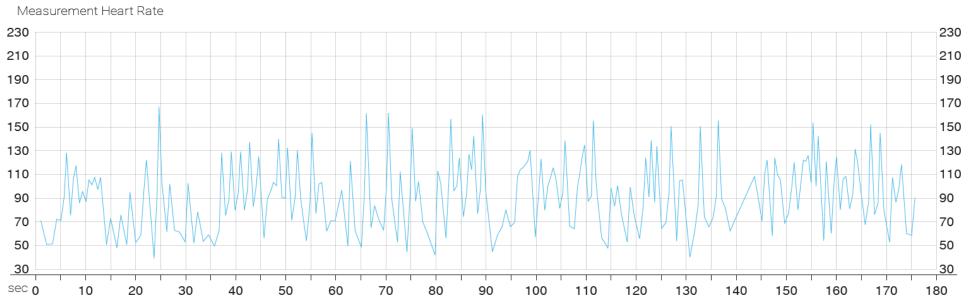




#### **Detailed Measurement Report**

Personal Info		Medical Info reported by the user				Measurements			
		COPD	No	Sleep Apnea	No	Stroke	No	Heart Rate	93 <sub>bpm</sub>
		CHF	No	Diabetes	No	Heart attack - MI	No	Blood	mmHg
		A-Fib	Permanent	Asthma	No	Vascular Disease	No	Pressure Respiratory	Ah .
		Hypertension	No	Epilepsy	No	CHA <sub>2</sub> DS <sub>2</sub> -VAS Score	1	Rate	00 16 rpm
AF detecte	ed	PI - 2.62 %		PWV - 4.48 meter/sec				SpO2	O <sub>2</sub> 98 %

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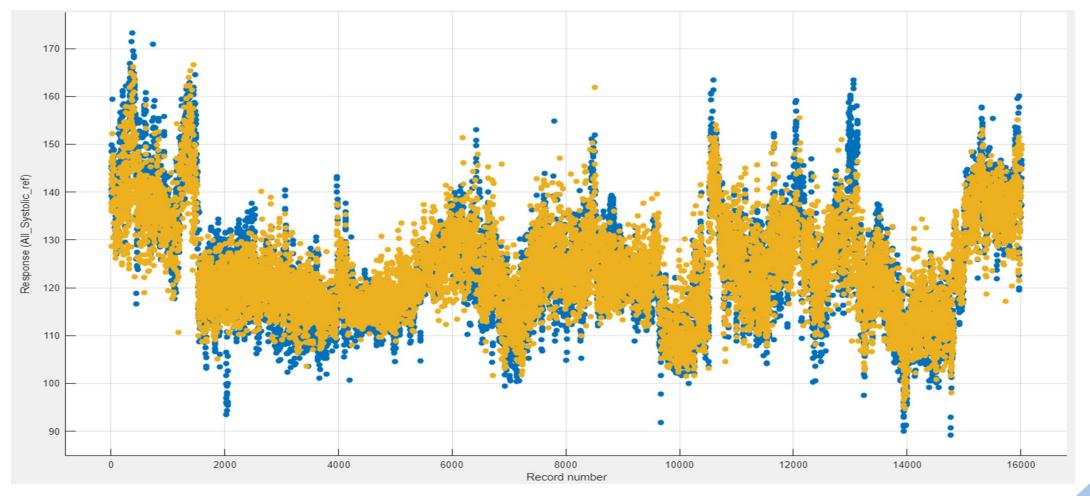


PI (Perfusion Index) - The ratio of the pulsatile blood flow to the non-pulsatile blood flow.

PWV (Pulse Wave Velocity) - The velocity at which the blood pulse propagates. It may be used by your physician to estimate the measure of arterial stiffness/health.

## Non-inflating Blood Pressure Measurement Breakthrough Meets FDA & CE requirements





FDA & CE Requirement: Standard Deviation of 8 mmHg. Reference is arterial line (blue) CardiacSense results (orange): Standard Deviation of 6.3 mmHg (over 10 subjects)





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Medical Indication	CE Mark	FDA Clearance			
Beat-by-Beat Heart Rate (ECG)		Cleared (CSF3)			
Continuous Average Pulse Rate (PPG)	1 (007)	Clinical trial successful (99.8%) Submission in Q2-2023 Clearance expected in Q3-2023 (CSF4)			
Continuous Beat-by-Beat Pulse Rate - <u><b>Unique</b></u>	Approved (CS3)				
Continuous Detection of A-Fib by PPG - <u>Unique</u>		Part of the 27 arrhythmias			
Detection of A-Fib by ECG					
Oxygen Saturation (SpO2)		Cleared (CSF3)			
Continuous Average Respiratory Rate	Approved (CS4)	Clinical trial in Q3-2023 Clearance expected in Q4-2023 (CSF5)			
Arrhythmia screening by PPG - <u>Unique</u> 27 arrhythmias analysis by ECG - <u>Unique</u>	Submission in Q2-2023 Approval in Q1-2024 (CS5)	DeNovo Clearance expected in 2024 (CSF6)			
Early detection of exacerbation for CHF patients	Submission in Q2-2	Submission in Q2-2024, Approval in Q4-2024 (CS7)			
Calibration-free Blood Pressure - <u><b>Unique</b></u>		Clinical trial in 2023 Submission in Q2-2024, Approval in Q4-2024 (CS7)			
Sleep Apnea	Clinical trial in 2024 Submission in Q3-2024, Approval in 2025 (CS8)				

#### **CardiacSense - Clinical Timeline**

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•	•	•
•	•	•

Medical Indication	CE Mark	FDA Clearance	Subjects in clinical trial	Estimated cost	
Beat-by-Beat Heart Rate (ECG)		Cleared (CSF3)			
Continuous Average Pulse Rate (PPG)		Clinical trial successful (99.8%) Submission in Q2-2023			
Continuous Beat-by-Beat Pulse Rate - <b>Unique</b>	Approved (CS3)	Clearance expected in Q3-2023 (CSF4)			
Continuous Detection of A-Fib by PPG - <b>Unique</b>		Part of the 27			
Detection of A-Fib by ECG		arrhythmias			
Oxygen Saturation (SpO2)		Cleared (CSF3)			
Continuous Average Respiratory Rate	Approved (CS4)	Clinical trial in Q3-2023 Clearance expected in Q4-2023 (CSF5)	30	\$150K	
Arrhythmia screening by PPG - <u>Unique</u> 27 arrhythmias analysis by ECG - <u>Unique</u>	Submission in Q2-2023 Approval in Q1-2024 (CS5)	DeNovo Clearance expected in 2024 (CSF6)	50	\$250K	
Early detection of exacerbation for CHF patients	Submission in Q2-2024, Approval in Q4-2024 (CS7)		100	\$500K	
Calibration-free Blood Pressure - <b>Unique</b>	Clinical trial in 2023 Submission in Q2-2024, Approval in Q4-2024 (CS7)		200	\$1,000K	
Sleep Apnea	Submission in Q3	trial in 2024 -2024, Approval in 2025 (CS8)	100	\$500K	

#### Summary

- 5 clinical trials
- Estimated cost of \$2.4M
- Spread over 2 years



## CardiacSense Vs. Competitors - Regulatory Approvals

<b>Medical Indication</b>	cardiacsense	Apple Watch 8	Google (Verily)	Biobeat	Fitbit	Aktiia	Whithings
Beat by Beat Heart Rate		$\bigcirc$	$\bigcirc$	$\otimes$	$\bigcirc$	$\bigotimes$	$\bigcirc$
Beat by Beat Pulse Rate	$\odot$	×***	×***	× ***	×***	$\overline{\mathbf{x}}$	×**
Detection of A-Fib by PPG	$\bigcirc$	× *	× *	$\otimes$	× *	$\overline{\mathbf{x}}$	$\overline{\mathbf{x}}$
Detection of of A-Fib by ECG		$\bigcirc$	$\bigcirc$	$\otimes$	$\bigcirc$	$\overline{\mathbf{x}}$	$\bigcirc$
Continuous Respiratory Rate		$\overline{\mathbf{x}}$	$\overline{\mathbf{x}}$	$\overline{\otimes}$	$\otimes$	$\overline{\mathbf{x}}$	$\overline{\mathbf{x}}$
Blood Oxygen Saturation (SpO2)		$\overline{\mathbf{x}}$	$\overline{\mathbf{x}}$	$\bigcirc$	$\otimes$	$\overline{\mathbf{x}}$	$\bigcirc$
Blood Pressure 2024		$\overline{\mathbf{x}}$	$\overline{\mathbf{x}}$	× **	$\overline{\mathbf{x}}$	$\bigcirc$	$\overline{\mathbf{x}}$
<b>Detection of all types of arrhythmias</b> 2024		$\otimes$	$\otimes$	$\otimes$	$\otimes$	$\otimes$	$\overline{\mathbf{x}}$
<b>Early detection of CHF exacerbation</b> 2024		$\overline{\mathbf{x}}$	$\otimes$	$\otimes$	$\otimes$	$\otimes$	$\otimes$

<sup>\* &</sup>quot;Irregular rhythm suggestive of AF"



<sup>\*\*</sup> Blood pressure trend – not absolute

<sup>\*\*\*</sup> Average pulse rate and not beat-by-beat

# System-on-Module (SOM) Chip Boosts commercial opportunities



- Significantly reduces:
  - Hardware cost
  - Physical size
  - Power consumption



- Drives sales growth and data collection
- Enables "Big Data" company



- Regulatory-cleared as a standalone medical device
- Accelerates time-to-market without needing clinical trials



 The "CardiacSense inside" of all wearables and phones

#### **Production: 2025**



#### CardiacSense Total Sales Forecast, In \$M



Note: for reference, wearable sales expected to reach 700M units by 2025





#### **Thank You**

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