CardiaCare™

Non-invasive Neuromodulation Therapy for Atrial Fibrillation

2025 ICI – Innovation in Cardiovascular Interventions

Problem

Atrial Fibrillation is becoming a rapidly-growing global epidemic

Prevalence	Poor QoL	Progressive Disease	Medical Burden
10M (US)	**Palpitations**	**1-in-5 in 1yr**	**$36B** (US)
60M (Total); 10% CAGR	Fatigue | Anxiety	Paroxysmal → Permanent	500k hospitalizations

AF drastically increases cardiovascular morbidity & mortality risk

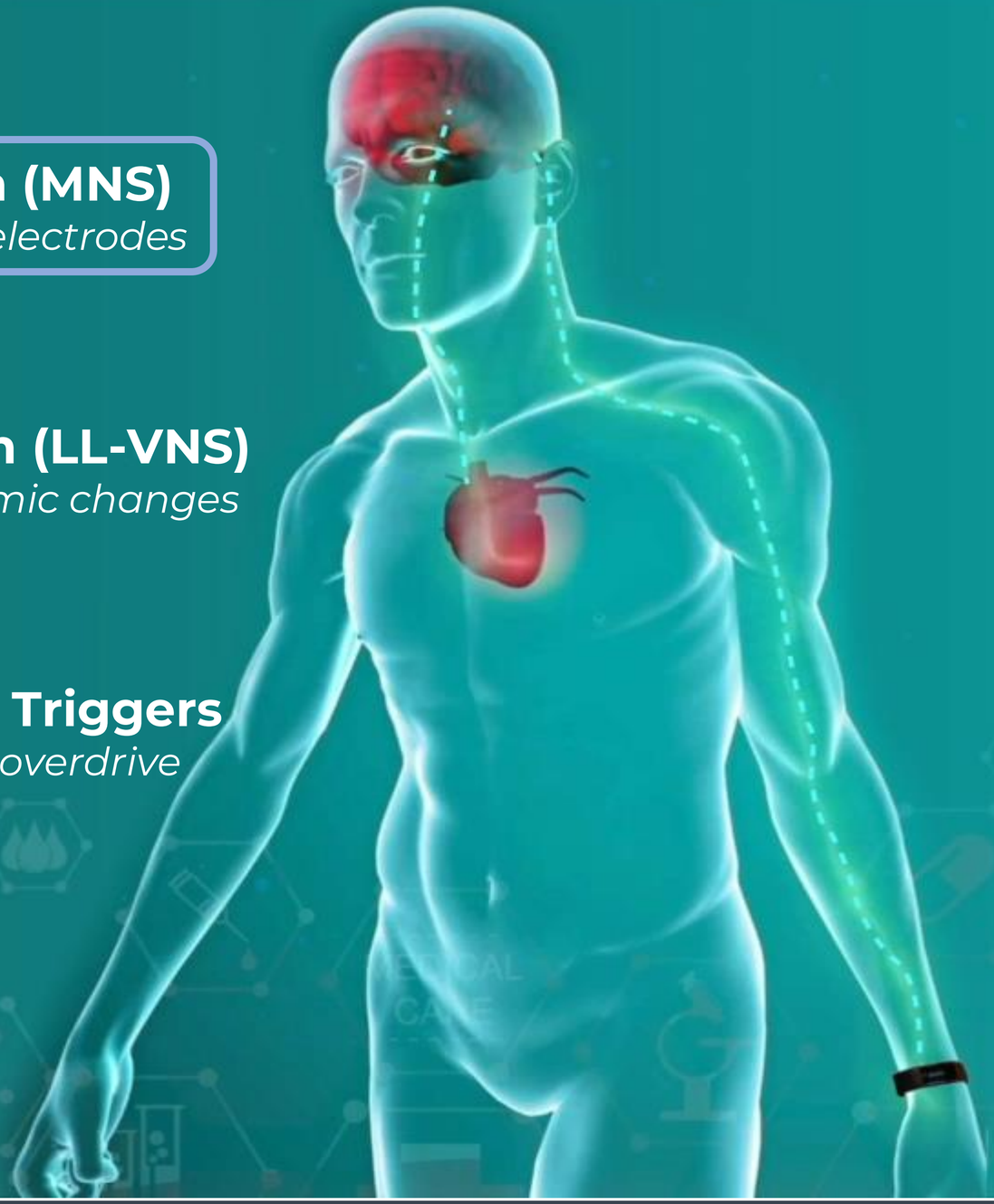
5x	4x	2x
Stroke	Heart Failure	Heart Attack

CardiaCare Solution

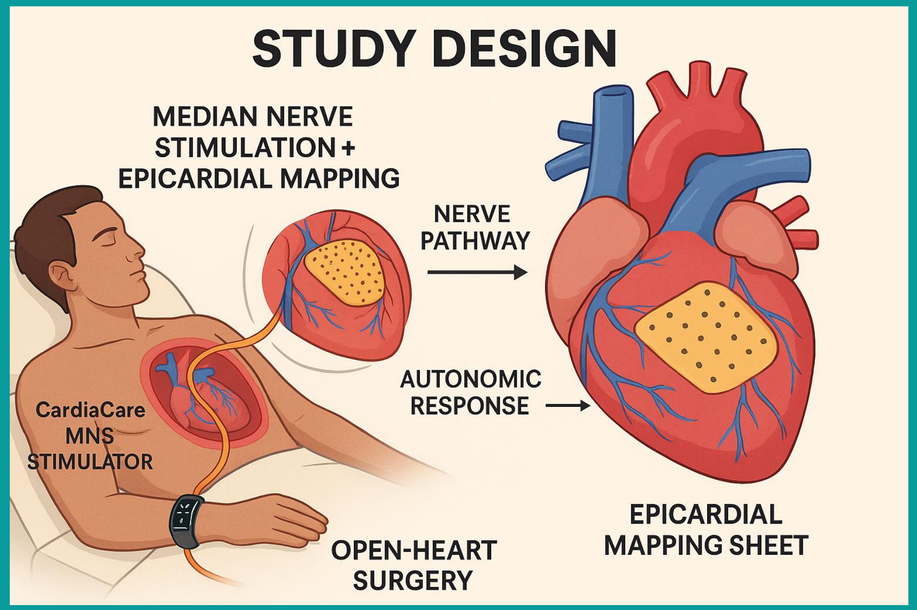
Median Nerve NeuroStim (MNS)
Transcutaneous stim via device electrodes

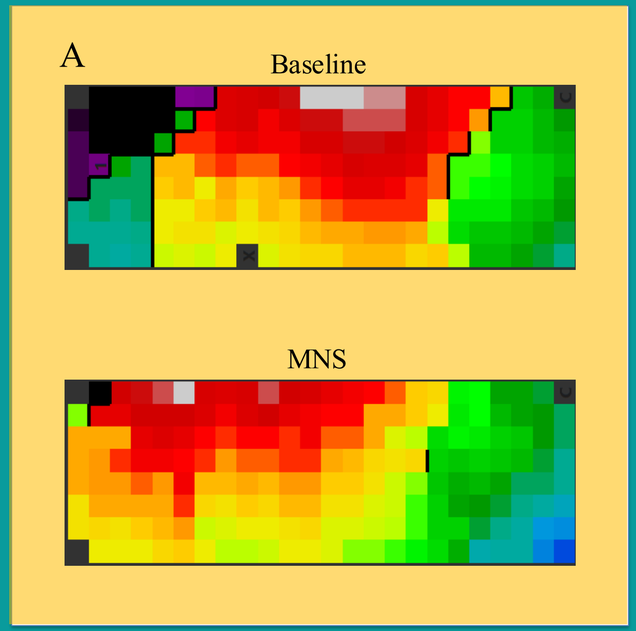
Low-Level Vagus Nerve Stim (LL-VNS)
Benefits of VNS with no hemodynamic changes

Reduction in Arrhythmia & Triggers
Downregulation of sympathetic overdrive



Proven Mechanism of Action
from Direct Epicardial Mapping





Parameter	Change During MNS	Meaning	Anti-Arrhythmic Effect
Voltage	↑	Better tissue excitability	Improved conduction
Slope	↑	Sharper activation	Cleaner signals
LV area	↓	Less scar-like substrate	Fewer arrhythmic zones
TAT	↓	Faster activation	Improved synchrony
Fractionation	↓	Less chaotic conduction	Stabilized activation
CV	↑	Faster propagation	Reduced reentry risk

CardiaCare Solution: Therapy + Monitoring All-in-One

Reduce AF
Burden + Symptoms

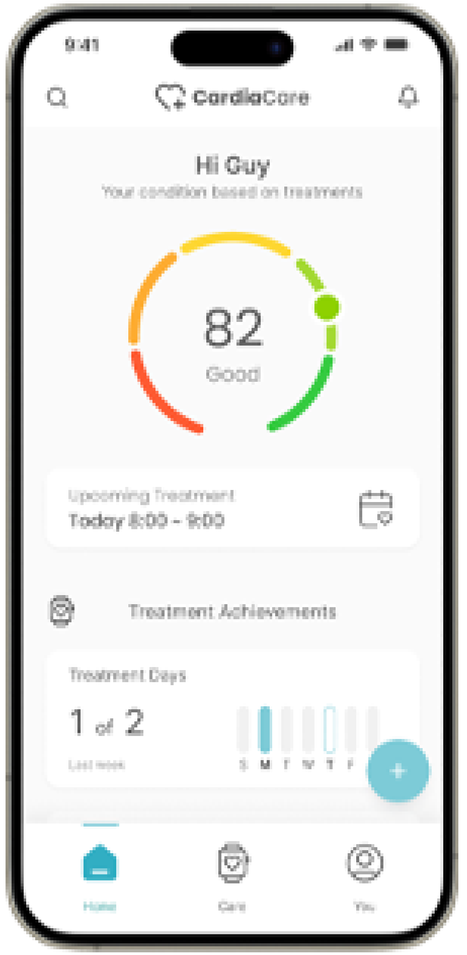
Cardiac Monitoring
ECG + PPG

Restore Balance
to Autonomics

AI / ML
Cloud Analytics

Neurostimulation
20 min, 3x / week therapy

AF Detection
Alert MD + Patient



Patient App
MD Dashboard Not Shown

Closed-Loop | Personalized | Non-Invasive

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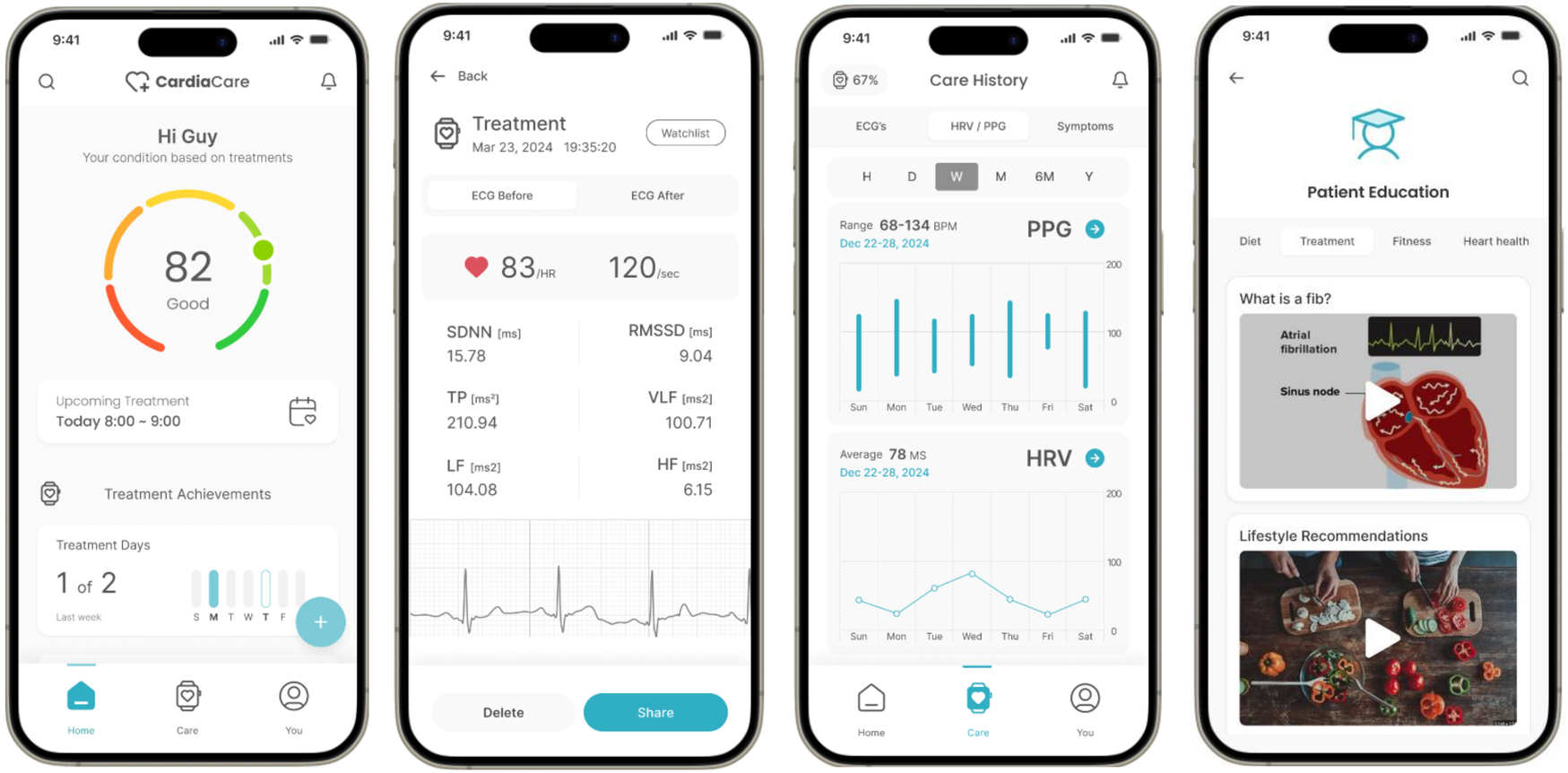
CardiaCare Solution: Therapy + AI Monitoring All-in-One



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Clinical Study Results: Cumulative & Acute Benefits on AF Control

Background

The autonomic nervous system has an important role in the initiation and maintenance of AF. Median nerve stimulation (MNS) is a non-invasive electrical stimulation therapy which induces a low-level Vagus nerve effect and has demonstrated favorable affects on atrial electrophysiology and reduction of inflammation in early studies.

Objective

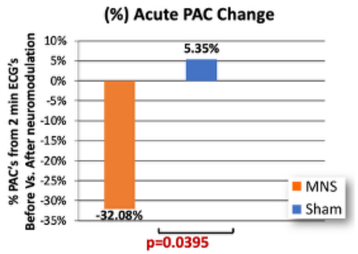
The BEAT-AF study (Breaking Ectopic Atrial Trends in AF) aimed to assess the effect of a novel wearable home-care neuromodulation and ECG monitoring device that performs Median Nerve stimulation in reducing atrial arrhythmias (AA) and symptoms in PAF patients.

Method

BEAT-AF was a 2-center, sham-controlled, double-blinded, 12-week pilot home-care RCT. Eligible PAF patients with AF burden of 0.5% - 25% as captured by a 14-day ECG patch, were randomized 1:1 to sham stimulation or MNS using a wristband-like wearable device (CardiaCare). The physician-directed regimen was 20-min of neuromodulation sessions performed 2-3 x per week, and up to once daily for symptoms or ECG findings detected and verified by the device ECG monitor as being AA (AF/AT or PACs).

Results

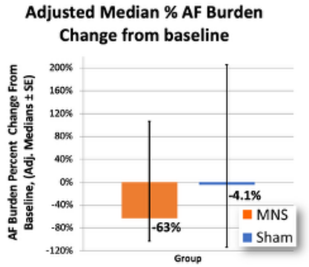
For the 31-pt cohort (n=15 MNS / n=16 Sham; age 67.3±9.7 yrs; 8 F; CHADS-VASc 2.6±1.7; median baseline AF burden was 4.9% [IQR 5.2%]), protocol adherence (performed/planned ratios) was good at 0.80 (MNS) & 0.78 (Sham).



Based on the immediate pre-/post-treatment device ECG recordings, MNS significantly reduced the PAC burden by 32.1% (vs +5.4% with Sham, p=0.039, **Fig 1**).

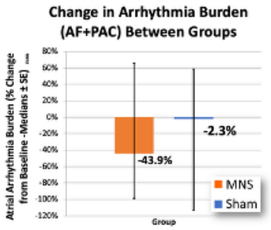
Fig 1. Mean PAC change in 2 min ECG's Before Vs. Immediately after neuromodulation sessions as captured by CardiaCare single lead ECG

Results (Cont.)



The adjusted median AF burden was reduced by 63% in the active MNS group vs 4.1% in sham group (p=0.42, **Fig 2**)

Fig 2. Median AF burden change from baseline measured by ambulatory 14-days ECG Patch (Bittium™)



The adjusted median composite atrial arrhythmia burden (AF+PAC) was reduced by 43.9% in the active MNS group vs 2.3% in Sham (p=0.38, **Fig 3**)

Fig 3. Median composite Atrial arrhythmia burden change from baseline measured by ambulatory 14-day ECG Patch (Bittium™)

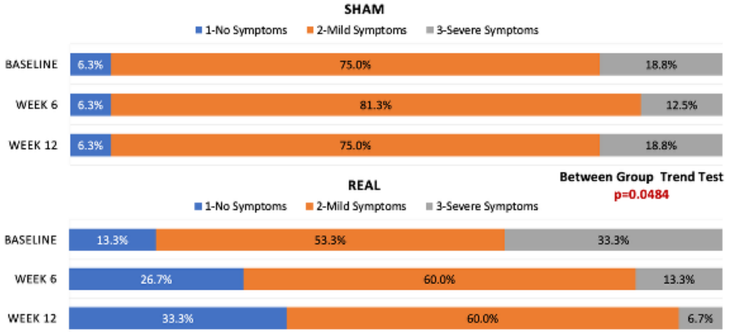
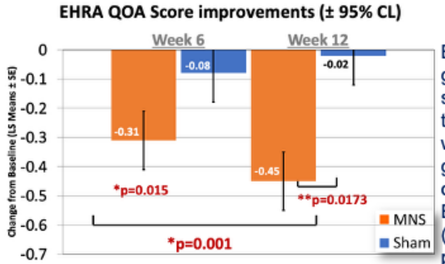
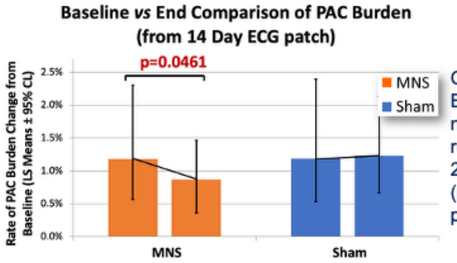


Fig 4. Change in symptom severity from baseline to week 12 by EHRA symptoms & life quality questionnaire (assessed by a blinded physician)



By EHRA class, the active MNS group had a reduction of 80% in severe-class III symptoms (33% to 6.7%, p= 0.0484), no change was observed in the sham group (**Fig 4**). The MNS group only showed improvements in EHRA scores at wks 6 and 12 (0.45 vs 0.02 reduction; p=0.017 at wk 12, **Fig 5**).

Fig 5. Change in EHRA score from bassline to weeks 6 and 12



Comparing baseline to 12-wk ECG patches, there were also numeric, but non-significant reductions in PAC burden by 21% (p=0.046; MNS) vs 2.7% (p=0.94; Sham) (between group p=0.46; **Fig 6**)

Fig 6. Mean PAC burden change from bassline to week 12 measured by ambulatory 14-day ECG Patch (Bittium™)

Conclusion

In paroxysmal AF patients, ambulatory non-invasive median nerve neuromodulation with a novel wrist-band wearable significantly reduced PAC burden and improved symptomatology and quality of life (and possibly reduced AF). Large multicenter powered studies of AF treatment with MNS are therefore warranted.

Study results were presented at Heart Rhythm Society Annual Meeting in April 2025

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Clinical Study Results: Cumulative & Acute Benefits on AF Control

N=31 patients (1:1 randomization)
Sham-controlled, Double-blinded, 3-months therapy*
**Adjuvant therapy to SoC medical management*

63% **Less AFib** AF Burden* - baseline to 3 mo
Gold standard; "% of Time in AF";* ***20-30% is clinically meaningful*

80% **Fewer Severe Symptoms** EHRA* - baseline to 3 mo
**Physician-assessed (blinded) patient symptoms & activity levels*

32% **Reduced Precursors** PACs* - after 20 min therapy
**PAC: Premature beats; when untreated accumulate to more AF episodes*

Study results were presented at Heart Rhythm Society Annual Meeting in April 2025

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AF Market Opportunity (US)

Paroxysmal AF (PAF):
4M pts (~40% of AF)

$9.6B TAM

Total AF Prevalence (US): 10M pts

CardiaCare Potential Across the Continuum of AF

Early AF	Pre-Ablation	Post-Ablation
First Line*	Paroxysmal AF	PAF & Persistent AF
	>90% of Market	**<10% of Market**
	250k+ PAF diagnoses / yr	**500k+ ablations / yr**
	CAGR: 10%+	CAGR: 15%+
	Need: alternative to drugs	**Need: post-op durability**
	Target: General Cardiologist	Target: Cardiac EP

*First Line Therapy indication will require post-market data against AADs

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Intellectual Property

Core IP Strengths:

- **First closed-loop therapy + monitoring device**: comprehensive AFib solution
- **Extensive clinical know-how**: 10+ years of development; origin in clinical practice
- **Proprietary stimulation parameters**: unique modulation for different indications
- **Large database**: treatments, ECGs, symptom logs, AF trigger logs, etc.

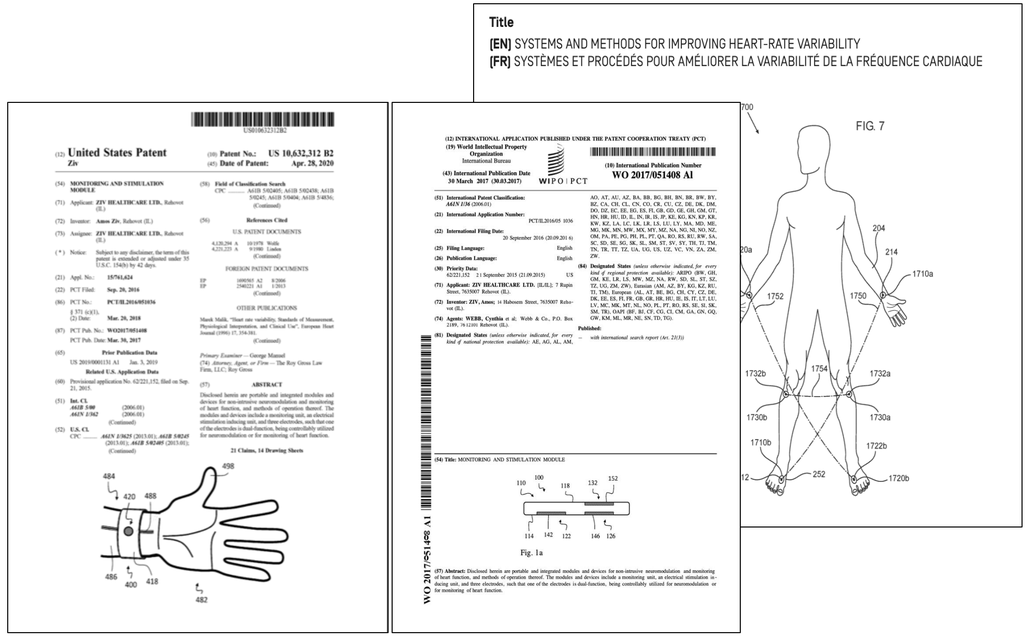
Patents:

2 - Granted

US, Israel, EU, Japan, India, China, Korea, Brazil, etc.
Earliest priority date in 2015

2 - Pending

Filing Applications for Additional Indications:
Other arrhythmias, cardiovascular, neurovascular



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Business Model & Reimbursement

Therapy DME Pricing: $3k - $5k / patient* [paid by CMS / insurance]

Reimbursement Pathway: Durable Medical Equipment (DME)

*Capped-rental model: 13 monthly payments

*New HCPCS II code: initial coverage by CMS, then by commercial payors

Successful DME reimbursement examples for wearable, at-home therapy devices:

- Noctrix Health: $5k / patient; motor therapy for restless leg syndrome
- Koya Medical: $4-5k / patient; lymphedema wearable compression therapy
- Kestra Medical: $3k / patient; wearable defibrillator (IPO in 2025; NYSE: KMTS)
- Cala Health: $3-4k / patient; motor therapy for essential hand tremors

Recurring SaaS Platform: $20 - $40 / patient / mo* [paid by MD / clinic]

-Service fee for providing remote patient monitoring (RPM) platform to Cardiologists / EPs

-Provider can utilize existing RPM billing codes for patient management, generating $70-$160 / mo

Codes: 99453, 99454, 99457, 99458, 99490

Est. COGS Target @ high-volume: $250 / device (~90% GM) [US manufacturing]

Leadership Team

Amir Soltanianzadeh
CEO

Amos Ziv
Founder & CSO

Tsahi Holand
Co-Founder & CTO

Kenneth Nelson
Board Chair

John Slump
Board Member

Team Highlights:

- **Multiple exits** (6 M&A, 1 IPO): total enterprise value = ~$4.8B
- **Market expertise**: cardiovascular therapies & remote monitoring
- **Worn multiple hats**: operators, investors, & industry execs
- **Lived the continuum**: clinical → product → sales → IPO / M&A

Prof. Vivek Reddy, MD
Senior Medical Advisor
Global Leader in Cardiac EP
Mt. Sinai Hospital, NY

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