

Executive Summary

Warable™ is building the next generation of clinical-grade wearable diagnostics—focused on solving one of the most persistent gaps in cardiology: **the inability to reliably interpret clinically meaningful ECG signals, such as ST segment changes, outside controlled environments.**

While ECG data can now be captured almost anywhere, **accurate interpretation—particularly for ischemia detection—remains limited to supervised settings, retrospective workflows, or incomplete consumer devices.**

The Problem

We already record ECG continuously in ambulatory settings:

cardiac stress test enables real-time ST analysis—but only under controlled conditions

Holter monitors capture ST data—but require **retrospective human review**

Mobile Cardiac Outpatient Telemetry provides near real-time monitoring—but focuses on **rhythm, not ischemia**

At the same time, most cardiac events—such as Non-ST elevation myocardial infarction—do not present with obvious ST elevation.

The result: we can record cardiac signals everywhere, but we cannot reliably interpret them when and where it matters.

The Solution

Warable's core product, **PICSI**, is a medical-grade wearable platform designed to close this gap.

PICSI captures:

Multi-lead ECG (beyond single-lead consumer limitations)

Respiration and motion (IMU)

SpO₂ and additional physiological signals

These signals are streamed to **CE-VA**, Warable's cloud platform, where they are:

Preserved as **high-fidelity waveforms** (not just derived metrics)

Analyzed in real time

Interpreted in **clinical context**, not isolation

A New Model: Contextual Cardiac Monitoring

Warable is not building another ECG recorder.

We are building a system designed to enable:

context-aware interpretation of physiological signals

This includes:

ST segment trends (not single-point detection)

Multi-modal signal correlation

Longitudinal patient baselines

Integration with **patient-specific cardiac risk phenotypes**, including clinical and genomic context via platforms such as Sequencing.com

Because: **the same signal does not carry the same risk in every patient.**

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Market Opportunity

Warable is targeting the \$8–10B ambulatory cardiac monitoring market within the broader \$100B+ wearable health ecosystem.

This market is driven by:

Rising cardiovascular disease

Hospital capacity constraints

Shift to remote and value-based care

Existing solutions are:

Too limited (consumer wearables)

Too retrospective (Holter)

Too narrow (rhythm-focused systems)

Business Model

Warable combines:

Device sales (PICSI platform)

Recurring SaaS (CE-VA cloud + analytics)

Clinical monitoring workflows

Reimbursable remote patient monitoring

This creates a **high-margin, recurring revenue model** tied to clinical use—not consumer upgrade cycles.

Why Warable

Warable is built from day one for:

FDA Class II clearance

Clinical workflow integration (FHIR / HL7)

Reimbursement pathways

The team brings deep experience in:

Clinical ECG systems

Healthcare IT

Medical device development

Vision

To move wearable cardiology from signal collection to clinically meaningful interpretation.

Warable’s long-term vision is a unified platform that enables:

Continuous monitoring

Early risk detection

Context-aware clinical decision support

Bridging the gap between consumer devices and hospital-grade systems:

a new category of “middle-acuity” monitoring.