EIC GRANT PROPOSAL · DRAFT v1.0 · JULY 2026

The Missing Vital Sign

Continuous VO_2 max as the control signal for cardiometabolic disease.

AeroGlyphics estimation & evidence **Medome** complete health record **SOAP Health** clinical intake AI

First use case: CT-derived VO_2 max estimation — MD thesis, E. Aton. Parallel track: NIH / NSF SBIR.

THE PROBLEM

Cardiometabolic disease is the largest cost in medicine — and its earliest signal goes unread.

61%

of US adults projected to have cardiovascular disease by 2050
AHA, Circulation 2024

$413B

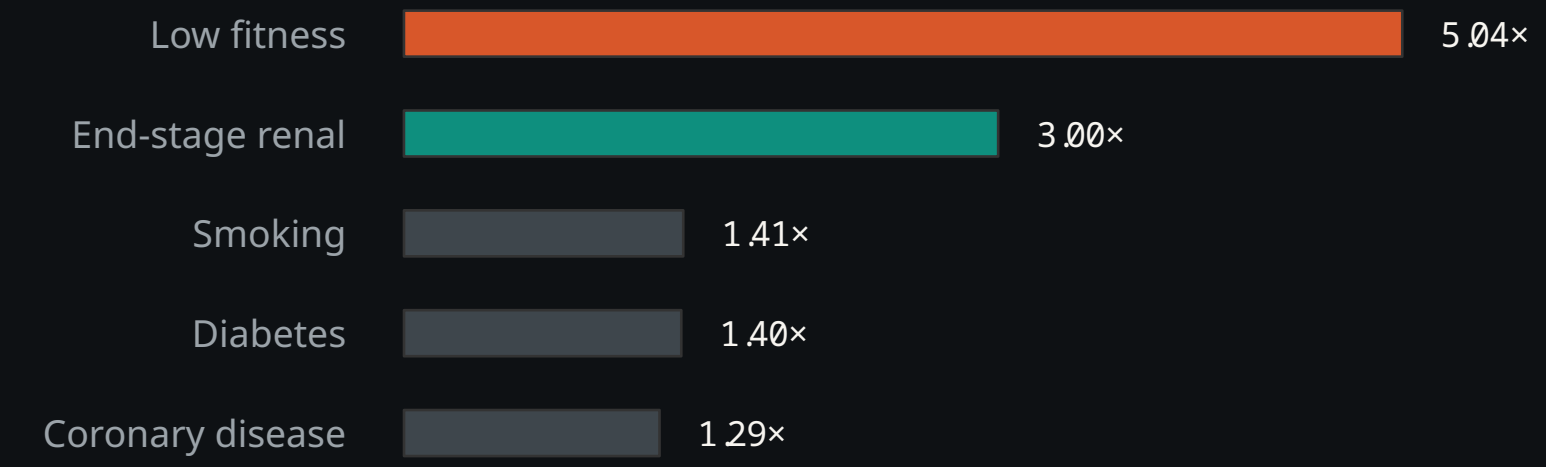
annual US cost of diagnosed diabetes — $1 of every $4 spent on care
ADA, 2023

0

clinical products managing the shared upstream signal: aerobic capacity

The shared early warning — declining VO_2 max — already exists on 560M+ wrists. Nobody treats it as a vital sign.

VO_2 max out-predicts every classic risk factor



Adjusted all-cause mortality hazard ratio vs normal-fitness reference (=1.0).
Cleveland Clinic, n = 122,007 · Mandsager, JAMA Netw Open 2018.

−14%
all-cause mortality per 1-MET gain — no ceiling (Kokkinos, JACC 2022)

−44%
for those moving unfit → fit between exams (Blair, JAMA 1995). Fitness is reversible.

WHY NOW

Three shifts converged, all inside 24 months.

01

Ubiquity

560M+ wearables passively output a VO_2 max estimate — Apple, Garmin, WHOOP, Fitbit, Oura, Polar.

02

Mandate

The AHA already calls cardiorespiratory fitness a clinical vital sign. The guideline preceded the tooling.

03

Method

State-space filtering plus physiological foundation models turn noisy free-living readings into a calibrated trajectory.

The measurement problem solved itself. The governance problem did not — that is what this grant funds.

METHODOLOGY

From wrist noise to a governed clinical signal.

01
Sense
HR, motion, pace, sleep

02
Estimate
HR–VO_2 models + calibration

03
Filter
Kalman / SLAM latent state

04
Anchor
CPET + CT radiomics

05
Predict
Survival + dosed action

CLOSED LOOP Every reading updates the latent state; every intervention response tunes the next dose. Uncertainty is a deliverable, not a footnote — we report coverage, not only correlation.

Three firsts, and one honest limit.

The honest limit

No wearable measures VO_2 max. Every number is a model estimate: ~5 mL/kg/min SEE for validated submaximal models, and ±9–10 mL/kg/min limits of agreement on a single free-living reading, degrading at fitness extremes.

We do not trust any single reading. That is the whole design.

- First fusion of state-space latent-fitness estimation with a physiological foundation model — daytime exertion and nocturnal physiology in one estimate.
- First use of routine CT radiomics as an independent reference anchor, breaking the field's single-reference dependency on CPET.
- First end-to-end governance chain: every prediction ships with provenance, calibrated uncertainty and an audit-grade evidence record.

Four layers. One governed signal.

AeroGlyphics

COORDINATOR

Estimation, state-space filtering, clinical report and public evidence surface.

Medome

PATIENT SPINE

The complete longitudinal health record — records, notes, labs and wearables in one reviewable history.

SOAP Health

CLINICIAN SURFACE

Conversational AI intake, risk and symptom assessment, SOAP-note documentation at the point of care.

GoApercu

MODEL & EVIDENCE

SleepFM-class foundation-model execution, biomarker lifecycle and evidence-release tooling. Research-use licence in hand; commercial / EEA extension in negotiation.

Each partner exploits a distinct layer — which is why this is a partnership, not a subcontract chain. Interfaces are contracts between layers; no single withdrawal invalidates the science.

FIRST USE CASE

CT-derived VO_2 max estimation — the reference anchor.

MD thesis, E. Aton. Deliberately narrow: a retrospective imaging cohort with paired exercise testing, one pre-registered primary endpoint, one publishable answer.

600 + 200

paired CT + CPET studies — 600 derivation, 200 external validation, ≥ 3 scanner vendors · WP2, M1–M18

MS2

Go / no-go at M18. Insufficient agreement → pivot to CPET-only anchoring, and publish the null.

R01

Same anchor carried into an investigator-initiated US application, company as subaward.

Cohort sizes are powered for the endpoint — ≈ 30 observations per candidate radiomic predictor, ±0.07 on the 95% CI for r. Site feasibility counts close at M1 (Annex C C04).

36 months, seven work packages, six checkpoints.

Go / no-go checkpoints: MS2 reference anchor (M18) · MS3 estimation r ≥ 0.85 vs CPET (M24) · MS4 incremental value of the sleep model (M28).

IMPACT

A reimbursable wedge, not a research artefact.

$42B→$141B

cardiovascular digital health, 2024 → 2030E, ~22.5% CAGR
Grand View, single source — internal use only until a second source lands (Annex C C11)

$120+

per patient per month already reimbursed under US Medicare RPM codes 99453/54/57/58

EU route

DiGA (DE) and PECAN (FR) fast-track schemes, plus payer and occupational-health contracts

European strategic value: model weights, reference cohorts and the biomarker governance stack stay inside the EU regulatory perimeter — in-region residency, no raw personal health data leaving without an executed DPA.

RISK

Where this could fail, and what we do about it.

Filtering fails to beat single readings	Pre-registered M24 checkpoint; fall back to a trend-detection claim. The negative result is committed to publication.
CT anchor does not generalise	Multi-site, multi-vendor cohort from day one; scanner-effect harmonisation; held-out external validation.
Regulatory class stricter than assumed	Conservative MDR + EU AI Act high-risk posture from M1. Wellness framing is explicitly not used as an evasion route.
Clinicians receive the signal but do not act	Delivered inside existing intake and record workflows; we measure acted-upon rate, not app opens.

Founding-team status is stated plainly: founder full-time, technical leads part-time pending the current round. Grant-funded posts remove that dependency on the critical path.

What is confirmed, and what is still open.

Every number here carries an owner and a status.

CONFIRMED	42 beta users across 3 clinical partner sites; pre-revenue by design	AeroGlyphics · Jul 2026
CONFIRMED	SleepFM base: 585,000+ PSG hours, ~65,000 participants, C-index ≥ 0.75 (mortality 0.84, MI 0.81, HF 0.80)	Nature Medicine 2025/2026
CORRECTED	r ≈ 0.82 for free-living VO_2 max is the Fenland study result — not an AeroGlyphics internal figure. We claim no internal correlation until WP3 paired CPET exists.	Spathis, npj Digit Med 2022
AGREED	Cohort targets: 800 retrospective imaging studies, 500 free-living wearers, 240 prospective with paired CPET	Powered per endpoint · sites at M 1
PENDING	SleepFM commercial + EEA licence extension — gates WP4 start at M6; model-agnostic fallback in place	GoApercu · Annex C C07
PENDING	Signed per-partner cost tables, PIC numbers, named site PIs, second market source	Coordinator · Annex C C01, C11, C12, C16

€3.85M, and what each euro buys.

Personnel	**€2.65M**	68.8%	≈ 252 person-months at partner rate cards. The critical path is human: filter design, radiomic derivation, protocol and regulatory authoring.
Equipment & data	**€450K**	11.7%	GPU compute for the sleep-model extension, EU-resident weight hosting, device-heterogeneity benches across ≥ 4 device families.
Clinical & regulatory	**€500K**	13.0%	Prospective study conduct, MDR technical file, AI Act high-risk conformity, DPIAs, and €120K of linked third-party site costs.
Other direct	**€250K**	6.5%	Steering travel, open-access charges including the committed negative result, consortium legal, dissemination.

Bottom-up, not top-down: person-months × each partner's own rate card. Signed cost tables are Annex C C01–C03 (PENDING at submission minus 4 weeks); expected movement is ±10% per line with the envelope held constant. Full justification in §3.8 of the proposal.

We took the stricter reading of all three.

Full checklist with owners, open questions and source references in Annex D.

EU MDR 2017/745	Software as a medical device with a diagnostic purpose. No wellness exemption claimed. Rule-11 class fixed with notified-body input, not self-asserted.	Open: IIa or IIb (D02)
EU AI Act 2024/1689	High-risk from M1 as a safety component of a regulated device. Full obligations assumed: data governance, declared uncertainty, human oversight, model card.	Open: provider of record (D07)
GDPR	Article 9 basis per site, DPIA before prospective collection, DPAs on every flow, no raw PHD leaving the EU perimeter, derived features only where possible.	Open: EU–US transfer route (D14)

Submission gate: not submitted while the MDR class, the lawful basis at each imaging site, or the EU–US transfer mechanism is unresolved. MS1 (M4) does not pass without DPIA sign-off. WP4 does not start without EU-resident hosting rights.

THE ASK

€3.85M over 36 months to make fitness a governed vital sign.

- EIC Pathfinder Open, with an EIC Transition / Accelerator follow-on pathway.
- Parallel, non-overlapping NIH SBIR Phase I ($300–500K) and NSF SBIR on the measurement-science contribution.
- €3.85M is a consortium-agreed planning envelope; signed per-partner cost tables are tracked in the Annex C checklist (C01–C03).

aeroglyphics.dev · medome.ai · soap.health · yc.goapercu.world