

Automated loss of pulse detection on a consumer smartwatch

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Out-of-hospital cardiac arrest is a time-sensitive emergency that requires prompt identification and intervention: sudden, unwitnessed cardiac arrest is nearly unsurvivable^{1–3}. A cardinal sign of cardiac arrest is sudden loss of pulse⁴. Automated biosensor detection of unwitnessed cardiac arrest, and dispatch of medical assistance, may improve survivability given the substantial prognostic role of time^{3,5}, but only if the false-positive burden on public emergency medical systems is minimized^{5–7}. Here we show that a multimodal, machine learning-based algorithm on a smartwatch can reach performance thresholds making it deployable at a societal scale. First, using photoplethysmography, we show that wearable photoplethysmography measurements of peripheral pulselessness (induced through an arterial occlusion model) manifest similarly to pulselessness caused by a common cardiac arrest arrhythmia, ventricular fibrillation. On the basis of the similarity of the photoplethysmography signal (from ventricular fibrillation or arterial occlusion), we developed and validated a loss of pulse detection algorithm using data from peripheral pulselessness and free-living conditions. Following its development, we evaluated the end-to-end algorithm prospectively: there was 1 unintentional emergency call per 21.67 user-years across two prospective studies; the sensitivity was 67.23% (95% confidence interval of 64.32% to 70.05%) in a prospective arterial occlusion cardiac arrest simulation model. These results indicate an opportunity, deployable at scale, for wearable-based detection of sudden loss of pulse while minimizing societal costs of excess false detections⁷.

Unanticipated loss of pulse events arising from cardiac arrest are universally understood to be time-sensitive emergencies requiring immediate intervention, most commonly cardiopulmonary resuscitation (CPR) and defibrillation^{1,2}. Early recognition is the cornerstone of successful resuscitation, in large measure owing to the enormous prognostic role of time^{3,8}. From the onset of pulselessness, a time-sensitive pathophysiology begins whereby the heart and brain become increasingly ischaemic and refractory to resuscitation⁹; survival decreases by 7–10% per minute without rescuer care¹⁰.

As direct acknowledgement of this time-sensitive relationship, modern societies allocate substantial resources to minimize the time from when someone loses their pulse to receiving resuscitation¹¹. This societal recognition has led to widespread CPR training programmes for non-medically trained individuals (that is, laypeople) to recognize, treat and call for emergency medical assistance in

potential arrest situations¹². Moreover, in recognition of the direct relationship between time to resuscitation and favourable outcomes, strategic programmes leverage automated external defibrillators to provide early defibrillation through first responders (that is, law enforcement and emergency medical technicians) or public access defibrillation programmes whereby automated external defibrillators are placed in public spaces, workplaces, schools and mass transit centres^{13–15}.

The inherent effectiveness of these rescue strategies depends on their timeliness; thus, they rely in large part on whether the event is witnessed and the witness immediately activates emergency response and engages in care. Too often, the arrest is unwitnessed and/or not recognized by the layperson. Approximately 50–75% of all out-of-hospital cardiac arrests (OHCAs) are unwitnessed and as a result have higher mortality^{16,17}. Moreover, among individuals experiencing unwitnessed

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cardiac arrests, more than half receive no attempted resuscitation at all owing to delayed discovery and a determination of futility^{18,19}.

We propose that the fundamental challenge of witness status may be meaningfully addressable given the past decade's proliferation of wearable devices capable of sensing pulseless events and, because of their connectivity, summoning help or activating an emergency response^{3,20–22}. Wearable devices capable of detecting time-sensitive emergencies offer the potential to substantially improve public health outcomes. However, the widespread adoption of wearable devices presents a unique challenge: the potential to overwhelm emergency response systems. Directly connecting devices and algorithmic classifications to 112 or 911 dispatch centres creates a risk of inundating these critical public resources with false alarms⁶. Therefore, responsible development and deployment of these devices requires careful consideration of resource stewardship. This involves making design choices that directly minimize false positives. These considerations are magnified for always-on systems that utilize wrist-based photoplethysmography (PPG), a signal that is susceptible to noise and reductions in amplitude from benign, everyday use activities²³.

Informed by these constraints and the considerable public health unmet need of unwitnessed arrest, we reasoned that a wearable-based PPG- and motion-based, multimodal model could classify loss of pulse events with meaningful sensitivity and specificity, contextualized for this specific challenge: unwitnessed loss of pulse events that are nearly unsurvivable and that excessive false positives (particularly those escalating to a call or to dispatch of emergency medical services) are not implementable from a societal perspective. By effectively transforming unwitnessed cardiac arrests into functionally witnessed events, such a system has the potential to substantially affect resuscitation opportunities and outcomes, carrying substantial public health implications. Annual OHCA incidence is approximately 350,000 individuals in the USA (about 100 per 100,000 inhabitants), and survival rates nationally are 10%, with substantial regional variability²⁴. The annual incidence and mortality of OHCA are similar in Europe, with an incidence between 67 to 170 per 100,000 inhabitants and survival rates averaging 8% (ref. 25), also with substantial regional variability (upward of 40%)²⁶.

Here we describe a multimodal, PPG- and motion-based detection system that runs on a consumer watch that identifies sudden loss of pulse events with acceptable performance at a societal scale. Figure 1 describes development of the system, consisting of: establishing a link between central pulselessness in individuals experiencing ventricular fibrillation (VF) and peripheral pulselessness induced by means of arterial occlusion; loss of pulse model development and evaluation using free-living data in which no pulseless events occurred and induced peripheral pulselessness through arterial occlusion; implementation of the loss of pulse model on a smartwatch, under design control; validation of the end-to-end loss of pulse detection system in prospective studies: specificity evaluation in two prospective, real-world false-positive evaluations over 21.6 user-years and sensitivity evaluation with induced peripheral pulselessness in 2 evaluations, including a cohort that is diverse on the basis of geography, age, sex, race and skin tone and a study consisting of stunt people simulating OHCA events with induced arterial occlusion and collapse. Table 1 shows a summary of all cohorts of individuals who were enrolled under informed consent (Institutional Review Board numbers 00068623, 00071247, 00077141, 00078212 and 00079675, Advarra (Columbia, Maryland)).

Algorithm principles of operation

The loss of pulse detection algorithm is built with three assumptions that should apply to most, although perhaps not all, unanticipated OHCA events. These assumptions are that: the transition from a pulsatile to pulseless state is rapid (of the order of seconds)^{27,28}, enabling building an algorithm based on this transition; individuals are generally

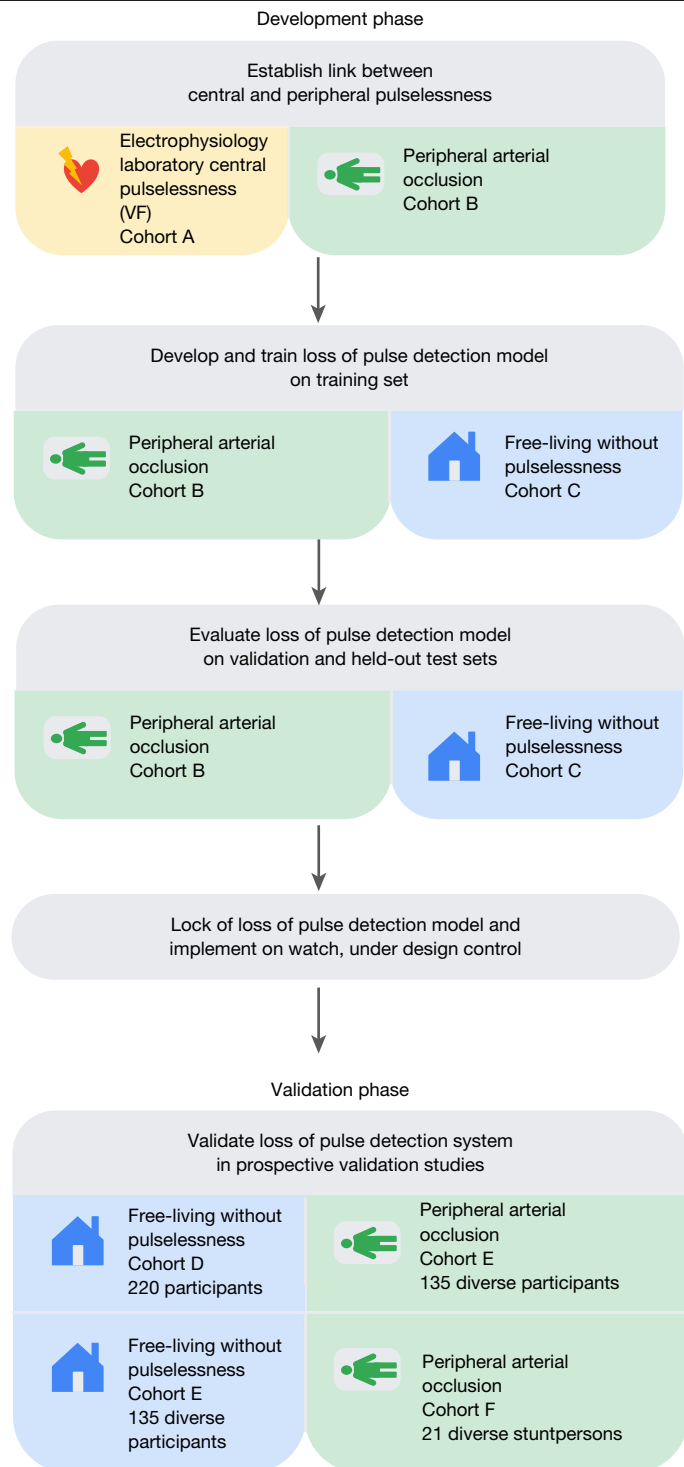


Fig. 1 | Overview of the sequential development of the loss of pulse detection algorithm and the validation of the end-to-end system. Establishing a link between central pulselessness (from VF) and peripheral pulselessness (from an arterial occlusion model) is necessary to enable algorithm development and validation because a prospective study waiting for in-the-wild OHCA to occur is prohibitive. Peripheral arterial occlusion is achieved using a specialized pneumatic tourniquet that nearly instantaneously restricts limb blood flow.

motionless after cardiac arrest and not capable of purposeful motion, allowing for such purposeful motion to serve as an indicator of a likely false positive and thus a signal to de-escalate; and individuals who are standing at the time of cardiac arrest generally experience an unbraced collapse, on the basis of literature and review of public domain footage

Table 1 | Cohorts used in development and validation

Cohort	Activity	Number of enrolled participants	Contains loss of pulse events?	Description ^a	Usage
Loss of pulse algorithm development stage					
Clinical reference (cohort A)	Electrophysiology laboratory	100	Yes	Patients under cardiac electrophysiology care with previously scheduled implanted defibrillator function testing wore a Pixel Watch configured to collect PPG and accelerometer sensor data at the wrist before, during and after induction of VF. Limitations that preclude direct model development on this dataset include: limited pulseless duration (seconds); population limited to individuals with previously scheduled procedure; artefacts from proceduralist induction of VF and implanted defibrillator shock.	Establish link between central and peripheral pulselessness: central pulseless PPG waveforms from cohort A were compared to peripheral pulseless waveforms from cohort B. This comparison informed and validated the methodology to train and validate loss of pulse detection models on peripheral pulselessness induced by arterial occlusion.
Retrospective sensitivity (cohort B)	Still (motionless) and simulated collapse	99	Yes	Participants who wore a Pixel Watch configured to collect PPG and accelerometer data simulated everyday activities (lie supine, lie laterally, stand upright or simulated collapse) while experiencing arterial occlusion through specialized pneumatic tourniquet, which can reproducibly and nearly instantaneously occlude peripheral limb blood flow. Sensor data were collected for 3.5 min for each activity, consisting of 1.5 min before arterial occlusion and 2 min after arterial occlusion.	Establish link between central and peripheral pulselessness: see above. Model development: training, validation and held-out test sets on sensor data that contained pulsatile and pulseless windows.
Retrospective specificity (cohort C)	Free-living	948	No	Participants wore a Pixel Watch configured to collect PPG and accelerometer data in free-living conditions.	Model development: training, validation and held-out test sets on sensor data that contained pulsatile data.
Prospective validation of the loss of pulse detection system conducted under design control					
Prospective specificity (cohort D)	Free-living	220	No	Participants wore a Pixel Watch configured to run the loss of pulse detection software in free-living conditions. The population was Google employees, necessitating additional validation in a more representative population in cohort E.	Prospective model validation: specificity evaluation of the end-to-end software.
Prospective sensitivity (cohort E)	Still (motionless)	135	Yes	Sensitivity component: participants wore a watch running the software while performing everyday activities in a laboratory setting (all participants experienced arterial occlusion while lying supine and prone). Participants were pulsatile for 1.5 min, and arterial occlusion was induced and maintained for 2 min. The ability of the end-to-end software to detect sudden loss of pulse and place a call was quantified.	Prospective model validation: sensitivity evaluation in diverse participants of the end-to-end software.
Prospective specificity (cohort E)	Free-living	135	No	Specificity component: participants wore a watch running the loss of pulse detection software in free-living conditions for up to 31 days. No loss of pulse events occurred in this component of the study.	Prospective model validation: specificity evaluation in diverse participants of the end-to-end software.
Prospective sensitivity in stunt people (cohort F)	Still (motionless) and simulated collapse	21	Yes	Stunt people who were trained to replicate collapses associated with OHCA wore a watch running the loss of pulse detection software in a laboratory setting. These participants experienced the same protocol as the sensitivity component of cohort E and also experienced sudden arterial occlusion followed by collapsing motion.	Prospective model validation: sensitivity evaluation in diverse participants of the end-to-end software.

^aAdditional cohort details are provided in Supplementary Table 2.

of in-the-wild cardiac arrests^{29–31}. This last assumption does not result in building for a specific fall motion signature, as such motion may be heterogeneous, but it does assume that the motion from loss of consciousness to stillness, on average, will be efficient (that is, from a motion state to a motionless state in seconds)^{29–31}.

Given those assumptions, the loss of pulse detection algorithm consists of stages of digital signal processing and machine learning that run passively in the background on a smartwatch. The system is built using several algorithmic gates that must be passed before a pulseless classification occurs and includes both passive, always-on components and active components that are triggered if earlier gates are passed. This multi-gated system is designed to optimize specificity and sensitivity for rare events, while minimizing societal costs of excess false detections; maintain battery performance; and leverage multiple wavelengths of light and current intensities on the basis of the

algorithmic stage (Fig. 2). Additional algorithm details are provided in the Methods.

Pulseless arterial occlusion mimics VF

Given the inability to follow a representative population prospectively while waiting for OHCA events to occur, our initial experiments were performed in an electrophysiology laboratory. In the electrophysiology laboratory, certain patients can experience anticipated, transient VF, under medical supervision, to test their previously implanted cardioverter defibrillator (ICD; details in Methods). We enrolled 100 participants (all previously scheduled to have this procedure), of whom 90 had usable PPG sensor data logged from a wearable smartwatch while they experienced transient pulselessness from VF. Ten participants did not have analysable data: investigational device failures occurred for

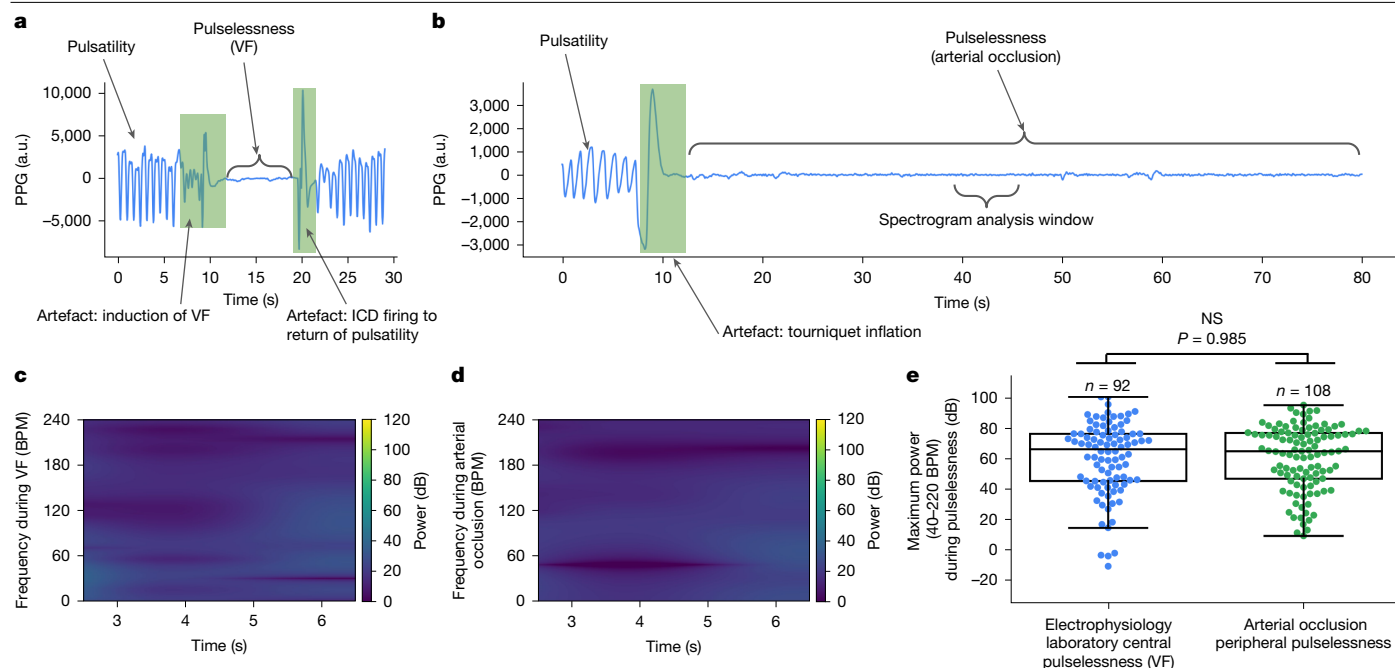


Fig. 3 | Arterial occlusion-induced peripheral pulselessness is similar to central pulselessness from VF, as measured at the wrist using PPG. **a**, Central pulselessness from VF induced in an electrophysiology laboratory is of short duration (<10 s) and contains artefacts from shocking the heart into and out of the arrhythmia. a.u., arbitrary units. **b**, Peripheral pulselessness induced through arterial occlusion is of longer duration (>60 s). **c,d**, Spectrograms of the central (**c**) and peripheral pulselessness (**d**) windows are similar and show

the absence of pulsatility at typical pulse rates, 40–220 BPM. **e**, There is no significant difference between the maximum power at these frequencies during central pulselessness and peripheral pulselessness, as assessed by comparing the medians across both groups ($P = 0.985$, Mann–Whitney U -test, two-sided). NS, not significant. The box plot shows the median, quartiles and the range of the non-outlier data points, overlaid with all individual data points.

loss of pulse detection algorithm with the training sets of wearable sensor data collected from peripherally induced pulselessness with 47 participants (cohort B) and free-living data (495 participants, cohort C). During model development, the model was run over the validation sets of both cohorts to minimize risk of overfitting. Details of these participants' demographics are provided in Supplementary Table 2. The model was developed by sweeping hyperparameters (machine learning model characteristics such as learning rate) and signal processing algorithm parameters (for example, alternating current (a.c.) component percentage decrease, duration over which a.c. component is calculated and stillness criteria). The model with characteristics that were considered to generalize to real-world OHCA was locked. The locked algorithm was evaluated retrospectively on the validation and held-out test sets of cohorts B and C (results in Supplementary Table 3). After the retrospective validation on the held-out sets, the algorithm was implemented on a smartwatch and evaluated prospectively in pre-specified studies under design control in cohorts D–F. Notably, the prospective evaluations included all algorithmic stages including those that could not be tested retrospectively: specifically, stages that require a custom PPG configuration or user input (algorithm phase 3 and thereafter).

Prospective specificity validation

We conducted two prospective studies to evaluate the false detection rate, defined as false algorithmic classification leading to a simulated call to emergency services. In these studies, conducted under informed consent and design control, participants wore a watch in free-living conditions. We quantified the number of false detections resulting in an errant call as well as the frequency of each user-facing algorithmic gate being passed (Table 2). Details of participant demographics are provided in Supplementary Table 2.

In the first study in cohort D, across 220 users in 13.92 user-years of wear time, we observed 15 haptics check-in notifications, one haptics

and audio check-in notification, and zero errant calls (Clopper–Pearson 95% CI of 0 to 0.26 calls per user-year).

We also conducted a second prospective study in cohort E across three geographically diverse locations in the USA, enriched for older populations and other demographic characteristics (Supplementary Table 2). In this cohort, we observed 16 haptics check-in notifications, two haptics and audio check-in notifications, and one errant call, corresponding to a point estimate of 0.13 calls per user-year (Clopper–Pearson 95% CI of 0.00 to 0.72), or 1 call every 7.75 user-years.

Across all 7,914 user-days (21.67 user-years) in both studies, there was one errant call; the corresponding day-level specificity was 99.987% (95% CI of 99.930% to 100.000%).

Prospective sensitivity validation

We finally evaluated the sensitivity of the sudden loss of pulse detection system in a cardiac arrest simulation model, on the basis of the foundational insight from the electrophysiology laboratory experiments and subsequent model development. The primary outcome consisted of quantifying the sensitivity of simulated calls to emergency services following rapid arterial occlusion in a supine, prone and collapsing motion condition (see Methods, cohorts E and F). The evaluation cohort was demographically diverse across age, sex, skin colour and race (Supplementary Table 2).

The sensitivity in 135 motionless (supine and prone) individuals was 72.46% (Clopper–Pearson 95% CI of 69.11% to 75.63%; Table 2). We initially planned for this cohort to simulate collapsing-type motion associated with OHCA. Shortly after starting this aspect of the protocol, there was concern that participants, particularly those >60 years old, might not be able to execute this motion faithfully³¹ and be at risk for adverse events related to the study procedure. Thus, both for participant safety and to ensure that valid data were collected, after 31 participants had been enrolled in the study, the sites and the sponsor met, and it was decided to eliminate the simulated fall or go-to-ground study procedure from the

Table 2 | Key results from prospective validation

Cohort	Activity	n	User-facing feature stage		
			Haptics notification	Haptics and audio notification	Call placed
Prospective specificity (cohort D)	Free-living	13.92 user-years ^a	0.93 per user-year (0.50–1.60) ^b	0.07 per user-year (0.00–0.40)	0.00 per user-year (0.00–0.26)
Prospective specificity (cohort E)	Free-living	7.75 user-years ^c	2.06 per user-year (1.18–3.35)	0.26 per user-year (0.03–0.93)	0.13 per user-year (0.00–0.72)
Prospective sensitivity (cohort E)	Still (motionless)	748 sessions	72.86% (69.52–76.02) ^d	72.73% (69.38–75.89)	72.46% (69.11–75.63)
Prospective sensitivity in stunt people (cohort F)	Still (motionless)	126 sessions	68.25% (59.37–76.26)	68.25% (59.37–76.26)	68.25% (59.37–76.26)
	Simulated collapse	126 sessions	54.76% (45.65–63.64)	53.97% (44.86–62.88)	53.17% (44.08–62.12)

^aThe duration in cohort D includes only days on which each watch ran the loss of pulse detection software; thus, notification and call rates are conservative overestimates.

^bFalse-positive unintentional calls per user-year presented with Clopper–Pearson 95% CIs derived from day-level specificity.

^cThe duration in cohort E includes only days on which each watch ran the loss of pulse detection software for greater than 10 h; thus, notification and call rates are conservative overestimates, as events are counted in the numerator even if they did not occur on a day with greater than 10 h of use.

^dSession-level sensitivity presented with Clopper–Pearson 95% CI.

protocol, which was under design control. Blinding was preserved and, not wanting to exclude this aspect of evaluation, a separate prospective study with 21 professionally trained stunt people, capable of safely simulating collapsing motion, was executed. We note this stunt person cohort was similarly demographically diverse to the original cohort (Supplementary Table 2). We found that these stunt people had a similar sensitivity in motionless conditions (68.25%, Clopper–Pearson 95% CI of 59.37% to 76.26%) to those in the larger cohort and that the sensitivity in the simulated collapse scenario was 53.17% (Clopper–Pearson 95% CI of 44.08% to 62.12%). The relative ratio of sensitivities between the simulated collapse and the motionless scenarios was 0.779 (bootstrap 95% CI of 0.560–1.012). We note that the first 31 participants were generally unable to comply with the simulated collapse protocol, reflected in the sensitivity across 62 sessions of 30.65% (Clopper–Pearson 95% CI of 19.56–43.65%); data from these non-compliant sessions have still been included in our overall reported sensitivity.

Across all 1,062 sessions in the prospective validation studies in cohorts E and F, the sensitivity was 67.23% (Clopper–Pearson 95% CI of 64.32% to 70.05%). Details of performance across demographic strata are provided in Supplementary Table 4. The algorithm had a latency of approximately 57 s for a pulseless classification, followed by a 20-s countdown that culminated in a simulated call to emergency services.

Discussion

In this work, we report a wrist-worn, consumer wearable device capable of detecting peripheral pulselessness with meaningful sensitivity (using an arterial occlusion model) and high specificity in free-living contexts. We also report that the PPG optical properties of VF pulselessness and pulselessness from arterial occlusion are similar. This insight is important for building detection systems given the constraint that collection of real-world OHCA events, through prospective studies, is prohibitive. We also highlight that the end-to-end algorithm had no appreciable difference in sensitivity across skin tone, sex or age strata, evidenced by overlapping confidence intervals (Supplementary Table 4).

Successful resuscitation from loss of pulse events arising from OHCA is possible but requires early recognition and coordinated, rapid response. A critical measure of evidence from observational and randomized studies of cardiac arrest resuscitation has established the fundamental health services tenets for successful resuscitation. The time-critical tenets, termed the links in the chain of survival, include the time-dependent early activation of emergency care, early

CPR, early defibrillation, expert advanced life support and expert post-resuscitation care³². The first link in the chain of survival is one of the most important³³, as recognition and activation are essential to implement subsequent effective measures for resuscitation. Yet this first link has been largely considered unmodifiable given the assumption that a human witness is required. Passive, sensing-based approaches to detect unwitnessed events challenge this paradigm.

Wearable-based detection of pulseless events using commonplace technology could have a considerable impact on resuscitation outcomes^{3,21,22,34}, particularly in unwitnessed (or unrecognized) settings for which survival is low. Differences in survival between witnessed and unwitnessed OHCA events is substantial, differing up to fourfold in high-performing resuscitation systems⁵. Conceptually, if we consider witness status as an intervention, the number needed to treat (NNT) to save one life is quite favourable from a public health intervention standpoint. To illustrate this point, consider the fourfold example above, from Seattle, Washington; a witnessed arrest represented a 20% absolute risk reduction in mortality, translating to an NNT of 5. For the approximately 50% of individuals who experience unwitnessed OHCA that receive no attempted resuscitation (100% mortality) because of futility, the NNT to save one life would probably be lower.

One report³ modelled the impact of biosensor detection on mortality from unwitnessed OHCA. The associated analyses, based on real-world Vancouver, British Columbia, 2019–2020 OHCA registry data as a base case, indicated that a biosensor that recognizes OHCA and contacts emergency services, would enable up to 117 additional survivors to hospital discharge per 1,000 OHCA³. On the basis of the associated real-world OHCA data from the Vancouver catchment area, a biosensor with sensitivity ranging from 50% to 100% could have enabled an estimated 456–1,196 additional individuals to survive over a 2-year period³.

Despite the potential promise of a passive sensing approach on a consumer device, any system deployed at scale must have adequate specificity. OHCA represents a relatively rare individual incident, and an emergency medical response system could, in theory, be readily overburdened by false-positive activations when deployed on a mass market device at population scale. As a result of this unique attribute of a mass market device, prioritizing specificity over sensitivity was a guiding principle of development of this system; higher sensitivity is readily achievable but comes at a substantial cost of false activations. Even with this approach, the epidemiological realities of positive predictive value among low-incidence events remain. This concern is

particularly acute when public resources such as emergency medical system (EMS) agencies and dispatch are involved⁶. To help address this concern, proactive communication with EMS agencies, ongoing monitoring and design choices are needed to ensure that any safety system is viable at scale and balances the competing goals to save lives and preserve public resources. One notable example, fire safety alarm systems, highlights how societies already make these trade-offs with life-saving systems. These systems have low positive predictive value (life-threatening fires are rare), and deaths arising from fires are 100 times less common compared to those from OHCA (3,800 deaths compared to 356,000 deaths annually in the USA, respectively)^{24,35}. For cardiac arrest detection, design choices to reduce public resource strain may include algorithmic cool down periods for outliers (for example, due to repeated improper loose watch wear), opt-in status or potential call centre intermediaries before EMS escalation. Unfortunately, addressing this issue by focusing system use on high-risk individuals is not a solution: a well-described epidemiological phenomenon highlights that most OHCA events arise in the low-risk general population and that cardiac arrest is many individuals' first indication of underlying heart disease^{36,37}. Truly high-risk individuals (with known advanced congestive heart failure and reduced ejection fraction, a prior arrest or known genetic predisposition) have other evidence-based pathways (for example, ICD placement, medication management and serial monitoring) to mitigate mortality risk from OHCA^{38,39}, making consumer wearables less well suited for these distinct cardiac populations requiring primary and secondary prevention.

There are three limitations to this study. First, although the algorithm was developed to identify sudden loss of pulse events, informed by real pulseless arrhythmias (VF), and includes elements present in actual out-of-hospital instances (absence of pulsatility, collapse and motionlessness), our validation approach required simulated events and may not capture the full heterogeneity of out-of-hospital pulseless events and their presentations, which could affect the stability of our estimates in real-world contexts.

In the electrophysiology laboratory experiments, central pulselessness was present for only approximately 5–10 s owing to the automated ICD shock, as intended. The loss of pulse algorithm was not trained on these central pulseless events owing to the a priori design choice to minimize false positives; requiring only 5–10 s of input would lead to an extraordinarily high false-positive rate on a wrist-worn wearable device using PPG (hence the decision to train the model using persistently pulseless data from an arterial occlusion-based method). A recent example from the literature highlights this consideration and constraint. In a proof-of-principle evaluation of a wrist-worn PPG-based detection system in people experiencing transient circulatory arrest, ref. 40 quantified specificity using intra-procedure pulsatile moments, achieving a 99.9% specificity at 1-min intervals. At first approximation, this performance may seem clinically robust, but (as reported and extrapolated outside the hospital) it would yield 338 false classifications per person annually⁴⁰.

Second, we observed degraded performance in the walking to collapsing portion of the stunt people protocol. We note this is, to some degree, expected because motion is widely acknowledged to contaminate PPG measurements^{41,42}, especially given the reduced signal quality of wrist PPG compared to measurement at the fingertip^{43,44}. The algorithm was explicitly designed to accommodate a diversity of user motion before a transition to a pulseless and still state (that is, the model was not trained explicitly on collapsing motion and was built to accommodate both motion or stillness during the pulsatile period). Although mitigating this by making the initial algorithm phases more sensitive during high motion states is technically feasible, such a mitigation would have a concomitant, material increase in false positives, which is not desired for a mass market device connected to an emergency response system.

Third, our system requires motionlessness during the period of pulselessness given that the pathophysiology of central pulselessness precludes purposeful motion. We note that such motionlessness is widely acknowledged after OHCA^{29–31}; we also acknowledge that respiration (including agonal breathing⁴⁵) and seizures (4.3% of cardiac arrest events⁴⁶) can occur post-arrest. For respiration, the wrist motion de-escalation thresholds were set so as to accommodate potential post-arrest breathing motion. Regarding seizure motion, the imprecise timing of seizure onset^{46,47} suggests that an unknown but probably sizeable fraction may occur after a call to emergency services has already been placed, on the basis of the latency of the described system. Trying to accommodate for this relatively uncommon scenario could have substantial impacts on false positives and inappropriate EMS escalation.

These described limitations highlight the challenging design trade-offs associated with development of a wrist-PPG-based detection system on a mass market device. All of these trade-offs are balanced against the status quo of unwitnessed arrest, which is nearly unsurvivable, leading to our design choice to prioritize specificity. A cost of high specificity, intended to make a system usable at a societal-level scale, can be reduced sensitivity (for example, our observed sensitivity indicates that false negatives may occur approximately one-third of the time). Addressing this consideration is paramount and requires ensuring that users understand this possibility when opting into a system. In addition, given that wearables enable data collection at massive scale, there exist opportunities for algorithm refinement with more real-world data, a compelling area for future research.

Finally, although this system was designed primarily to help address the challenge of unwitnessed arrest events in the general population, a wearable system may also credibly provide utility in witnessed arrests. In a witnessed event, the system could automatically alert emergency services, helping bystanders recognize the nature of a collapse and enable both bystanders and EMS to initiate care sooner.

Conclusions

We report the development and validation of a wearable-based automated loss of pulse detection system using a cardiac arrest simulation model through arterial occlusion and free-living conditions. Validation was enabled by the key insight that PPG measurements of pulselessness due to VF and arterial occlusion are similar. A key limitation of the study involves the need for simulation-based cardiac arrest events, highlighting the challenge inherent in building algorithms on consumer devices for this use case and the importance of further study in real-world settings. Contextualized for the challenge of unwitnessed OHCA and its near unsurvivability, the results indicate an opportunity and new paradigm, deployable at scale, for passive cardiac arrest detection on consumer wearable devices.

Online content

Any methods, additional references, Nature Portfolio reporting summaries, source data, extended data, supplementary information, acknowledgements, peer review information; details of author contributions and competing interests; and statements of data and code availability are available at <https://doi.org/10.1038/s41586-025-08810-9>.

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Methods

Principles of wrist-based PPG

Consumer wearable devices contain PPG sensors for health and wellness applications. In these systems, light-emitting diodes (LEDs) of the watch sensor emit controlled pulses of light at different wavelengths and capture the returned light using photodiodes. The emitted photons reflect off skin, tissue, bones and blood. An analogue front-end controls the LEDs and converts the analogue current received by the photodiodes into a digital PPG signal. Changes in blood volume associated with peripheral perfusion, due to contraction of the heart and transmitted through the vasculature, enable measurement of pulsatility in the PPG waveform. These devices, including the Pixel Watch family, contain wrist-detection algorithms that produce PPG sensor data only when a composite on-wrist detection sensor indicates that the device is on a user's wrist. This system can make a loss of pulse classification only if the on-wrist detection algorithm confirms that the device is on-wrist.

Loss of pulse detection algorithm details

The loss of pulse detection algorithm consists of multiple gates that must be passed for pulselessness classification, including persistent user unresponsiveness to audio, haptic and visual feedback. For a justification of the assumptions that are foundational to the algorithm design, see the 'Algorithm principles of operation' section. At a high level, these assumptions are that the transition from pulsatility to pulselessness is rapid, of the order of seconds, and that individuals are in a motionless state during pulselessness. The key steps of this algorithm are described below.

Overview of algorithm. The initial, passive algorithm identifies periods with 90% drops in the PPG a.c. component over about 30 s and accelerometer stillness over 10 s using time domain analysis, after which a convolutional neural network is run up to 9 times on 528 features that are derived from up to 72 s of sensor data (consisting of 21 features computed over 22 epochs of 5-s duration each, and 3 features computed over the entire receptive field and repeated across epochs, detailed in the 'Algorithm phase 1' section). Periods with high pulselessness probability undergo additional DSP analysis in the time and frequency domains (low autocorrelation and low signal-to-noise ratios in algorithm phases 2 and 3) to help 'search for' and thus confirm the absence of pulsatility in up to seven PPG channels. The algorithm checks for unresponsiveness by prompting the user with caustic haptic and visual feedback for up to 15 s while checking for stillness (user-facing alert stage 1). The continued absence of detectable pulsatility, motionlessness and non-responsiveness leads to an audible, haptic and visual prompt for 20 s (user-facing alert stage 2) that culminates in a call to emergency services (user-facing alert stage 3).

Pre-processing and input signal quality verification. The first step of the sudden loss of pulse detection algorithm is to ensure that the input sensor data have adequate signal quality, are not saturated, and are sampled at an appropriate frequency. As the PPG sensor is configured in reflectance mode, the number of backscattered and reflected photons measured by the photodiode is proportional to the number of emitted photons (that is, the LED current). The PPG sensor data are normalized by the LED current and undergo band-pass filtering to near-pulse frequencies (about 0.5 to 4 Hz) to maximize the signal-to-noise ratio at these frequencies. The algorithm uses this band-pass-filtered sensor data in phase 1 of the algorithm.

Algorithm phase 1. The first phase of the algorithm identifies possible pulsatile-to-pulseless transitions through DSP and quantifies the probability of sudden loss of pulse through a convolutional neural network. The signal processing algorithm is a gating algorithm that computes

the a.c. component of the band-pass-filtered PPG signal over 3 s and identifies when the a.c. component drops by 90% or greater. Large a.c. component drops accompanied by accelerometer stillness over 10 s undergo additional investigation using machine learning.

The machine learning algorithm consists of a convolutional neural network that processes features from sensor data (band-pass-filtered PPG data and approximate accelerometer magnitude). The features were engineered to require minimal computational power (linear time complexity) and memory (constant space complexity) to enable real-time computation on power-constrained wearables with minimal battery life impact, while capturing the essential characteristics that encode possible loss of pulse events. Extended Data Figure 1 shows the key characteristics of the band-pass-filtered PPG current transfer ratio during a loss of pulse event.

The 528 input features encode factors that change markedly between the pulsatile period before a sudden loss of pulse event and the pulseless period after, while minimizing the risk of overfitting to the central transition region that may differ across heterogeneous sudden loss of pulse events. The features input to the convolutional neural network consist of standard descriptive statistics such as the variability of the accelerometer sensor data (standard deviation and peak-to-peak), approximate interbeat interval of the preprocessed PPG sensor data (mean, median and standard deviation) and measures of signal fidelity (frequency-domain signal and noise levels). These features are calculated across overlapping 5-s windows over the previous 72 s with a stride length of 2 s, omitting the central 13–21 s to avoid overfitting to the transition region in Extended Data Fig. 1 (that is, the windows analysed are from the prior 1–6, 3–8, 5–10... seconds). Three of the features are calculated across the entire receptive field (PPG and accelerometer peak-to-peak and change in LED current) and are repeated across all windows. The convolutional neural network consists of nine layers (these consist of convolutions with rectified linear unit activations and a maximum pooling step following every other convolutional layer), along with a final dense layer with sigmoid activation (Supplementary Table 1). The machine learning model outputs a floating-point probability between 0 and 1, inclusive, that indicates the probability of a sudden loss of pulse event. A classification of pulselessness requires consecutive (7 of 9) and persistently high (above 0.88) machine learning probabilities (3 model runs occur every 2 s for a period of 4 s, inclusive; each model run has a receptive field of 64, 68 and 72 s) to proceed to subsequent algorithm phases.

The machine learning model was trained on sudden loss of pulse event data from cohort B. The session-level data were randomly cropped with multiple, arbitrary start and stop times from each loss of pulse session to prevent overfitting. Additional data augmentation strategies included the addition of random noise (Gaussian noise with 0 mean and up to 150 units standard deviation), data resampling, stretch and squeeze transformations (up to $\pm 20\%$) and varied transition period durations to further enable model generalizability. The model was also trained on pulsatile free-living data from cohort C that were cropped to the vicinity that passed the pre-machine learning, DSP gating algorithm.

Algorithm phase 2. The second algorithm phase confirms that the smartwatch sensor data are consistent with the physiological state of pulselessness. This consists of verifying that the PPG signal at two wavelengths (green and infrared) lacks pulsatility. The infrared PPG may capture pulsatility more sensitively than the green PPG owing to: increased skin penetration depth of infrared photons compared to green photons, which reduces the impact of aggressors such as excessive pressure on the watch face artificially reducing the green PPG signal even when the user is pulsatile; less variation across users with diverse skin tones, in part owing to a lower absorbance of the skin pigment melanin at infrared wavelengths than at green wavelengths. Infrared wavelengths have greater skin penetration depth than green

wavelengths owing to reduced optical scattering at higher wavelengths (for example, one mechanism of optical scattering is Rayleigh scattering, which is proportional to wavelength to the negative fourth power; in other words, Rayleigh scattering at infrared wavelengths centred at 940 nm should be about a factor of 10 lower than at green wavelengths centred at 528 nm).

The absence of pulsatility in algorithm phase 2 is ascertained by low signal-to-noise ratios at typical pulse rates (40–220 BPM) in the frequency domain, along with low autocorrelation in the time domain over 10 s of PPG sensor data. The absence of pulsatility causes the algorithm to proceed to phase 3.

Algorithm phase 3. The third algorithm phase attempts to confirm whether the user is truly pulseless by checking for prolonged lack of motion and the absence of pulsatility in additional PPG channels. This algorithm design was guided by the pathophysiology of central pulseless events, during which individuals become unconscious (and thus do not show purposeful movement) and the limbs are no longer perfused (that is, no pulsatility in the PPG). To improve the specificity of the algorithm and maximize the probability of detecting pulsatility if present (especially in aggressor scenarios of reduced peripheral perfusion, users with increased skin pigmentation, loose wear or excessive pressure on the watch face), this algorithm component activates a custom PPG configuration that uses multiple combinations of LEDs and photodiodes. The algorithm waits 2 s for the PPG signals to stabilize, after which 10 s of data are acquired for analysis. In other words, this algorithm phase is ‘prospective’ and adds 12 s of latency after the prior two phases detect a potential sudden loss of pulse event.

The PPG sensor data from seven PPG channels, including the green and infrared channels from the prior phase and other PPG channels with varied photodiode gain and LED current, undergo frequency-domain signal-to-noise ratio and autocorrelation analysis as in the prior phase. In addition, the accelerometer sensor data are analysed over this time period to confirm persistent user stillness. If both the PPG and accelerometer algorithms detect a state consistent with pulselessness, then the algorithm proceeds to alert stage 1 to determine whether the user is unresponsive.

Alert stage 1: haptics notification. This stage checks for user responsiveness. It is the first stage that is visible to the user. At a high level, the feature displays a notification, provides a strong haptic stimulus to the user, and looks for motion in the accelerometer indicative of user responsiveness. The haptics pattern consists of a series of long and short duration haptics at maximum intensity for 15 s. The haptics duration of 15 s is sufficiently long to minimize the risk of false positives from users who did not actually experience a loss of pulse event (by giving those users adequate opportunity to respond) while being sufficiently short to minimize the time to calling emergency services in users who experience loss of pulse events. The algorithm analyses data from the accelerometer sensor to determine whether a user responds to the haptic prompt. The design of this algorithm is broadly similar to the stillness algorithms from the prior stages with one exception: the accelerometer sensor data in all axes undergo low-pass filtering to ensure the watch haptics do not inadvertently clear the alert.

Alert stage 2: audio and haptics notification. This stage, unlike prior stages, does not consume sensor data, but consists solely of a notification displayed to the user that is accompanied by strong haptics and audio. The notification is the first time that a classification of pulselessness is shown to the user. The notification indicates that emergency services will be contacted unless the user dismisses the alert within 20 s. Unlike in the prior stage, the user cannot dismiss this alert with motion; rather, the user must tap the cancellation button on the screen to dismiss this alert. If the user does not clear the alert, then the feature will attempt to initiate a call to emergency services on the user’s behalf.

Model training and evaluation

Nomenclature and definitions of performance specifications.

Statements of model performance are based on all participants and all sessions from the three prospective cohorts, with no data exclusions (that is, all laboratory tourniquet sessions in cohorts E and F had physician-confirmed pulselessness as described below). No participants in the prospective studies were used for model training or development. The reported sensitivity was calculated as the ratio of the number of attempted calls (alert stage 3 in Fig. 2) to the number of tourniquet sessions (that is, each session contained one tourniquet-induced pulsatile-to-pulseless transition that could have been detected by the algorithm). The reported day-level specificity (and corresponding annualized frequency of user-facing alert stages) was calculated from the number of attempted calls in the free-living portions of cohorts D and E and the duration (number of days) for which the end-to-end software ran.

Cohort A—VF in electrophysiology laboratory. Individuals were consented to wear a watch from the Pixel Watch family while undergoing previously scheduled testing of their ICD. To test the ICD, patients have VF induced by a cardiac electrophysiologist⁴⁸. While wearing external defibrillator pads, the patients experience this pulseless arrhythmia to trigger their implanted device. Patients undergo this procedure while on cardiac monitors, providing gold standard labels to confirm the arrhythmia and the presence of VF. VF typically lasts between 5 and 12 s before a patient’s ICD firing, with defibrillator pads available as backup in case of ICD failure. The goal of this evaluation was to determine whether pulselessness arising from VF, as measured on the wrist by a smartwatch PPG sensor, has a similar spectral signature to pulselessness achieved by using a pneumatic tourniquet, which is a readily reproducible way to create pulselessness.

Cohort B—peripheral loss of pulse (laboratory). The sudden loss of pulse detection algorithm was trained on smartwatch sensor data collected from diverse participants (age, sex and skin tone) in whom peripheral pulselessness was safely and transiently induced. To simulate the sudden loss of pulse events, a pneumatic tourniquet (model Zimmer Biomet ATS 4000) was applied on the non-dominant forearm of participants while they were wearing the watch. A pulse fingertip oximeter (model Masimo MightySat 9909) was used as a ground truth device. A watch from the Pixel Watch family was placed on the same wrist to capture raw PPG, accelerometer and other physiological data. A blood pressure cuff (model Welch Allyn ABPM 7100) was used to measure blood pressure for screening purposes, to ensure that tourniquet pressures were not excessively high. Participants recreated common postures encountered in everyday life, namely simulated sleep (remain still in a supine or lateral posture before and after tourniquet inflation), standing upright (to obtain lower perfusion index data before and after tourniquet inflation) and motion (simulated collapse) conditions (in which participants walked and then went to ground within seconds after tourniquet inflation, to mimic collapses associated with OHCA). In all cases, sensor data were recorded for about 90 s before tourniquet inflation and 120 s after tourniquet inflation.

Cohort C—free-living pulsatile. Sensor data were acquired from free-living users who were engaging in everyday activities such as exercising, sitting, sleeping and walking. These users did not experience loss of pulse events. Data from the PPG (sampled at 25 Hz) and accelerometer (25–100 Hz) sensors were uploaded to an encrypted, access-controlled cloud server. The passive component of the sudden loss of pulse algorithm was retrospectively trained, validated and tested on these data (495, 298, and 155 participants, respectively) to estimate false-positive rates and model generalizability. Participants were randomly assigned to the training, validation or test sets, ensuring

Article

that data from each individual were assigned to one set; the validation and test sets did not include any participants that were used in training.

Cohort D—prospective evaluation in free-living users. The sudden loss of pulse detection algorithm and end-to-end software was implemented on a smartwatch in the Pixel Watch family of devices and evaluated prospectively in free-living individuals who engaged in activities similarly to cohort C. These participants also did not experience loss of pulse events.

Cohorts E and F—prospective evaluation in diverse populations. A prospective validation study was conducted to evaluate the sensitivity and specificity of the end-to-end sudden loss of pulse detection software. This consisted of cohort E across three clinical research sites and cohort F at one additional location in the USA (in the states of California, Georgia, Nebraska and Ohio in 2024). Both cohorts were of diverse demographics, with varied age, sex and skin tone. Data were collected and recorded with Google Sheets and Trialkit clinical study data management software (Crucial Data Solutions). Data analysis was performed in Google Sheets and Google Colaboratory using the Python programming language (v3.11).

Sensitivity was quantified in a laboratory setting by inducing peripheral pulselessness with a tourniquet in both cohorts E and F. The participants wore a smartwatch from the Pixel Watch family of devices running the software on their left arm, along with a ground truth fingertip pulse oximeter capable of displaying a PPG waveform (Covidien Capnostream 20 or Masimo MightySat 9099), and the tourniquet cuff. The users performed everyday activities that entailed being still (lying supine or lying prone) or undergoing motion (simulating a collapse, which consists of walking and then going to the ground, as in cohort B), after which the tourniquet was inflated to 250 mmHg to induce peripheral pulselessness and the users went to or remained motionless on the ground. Session validity was adjudicated by three physicians who reviewed the ground truth PPG waveforms to confirm the presence of peripheral pulselessness.

The specificity component of this study occurred after the in-laboratory portion was completed in cohort E. Participants wore the watch for 31 days in free-living conditions; these individuals did not experience loss of pulse events.

The sample size for cohort E was estimated a priori to be 135 participants to provide 90% power to show that the sensitivity to a pulselessness event is significantly better than 50% and the frequency of unintentional false-positive calls is significantly lower than 2 per person per year, using conservative estimates for participant dropout rates and within-participant correlation. Similarly, the sample size for cohort F was estimated to be 21 participants to provide 90% power to show that the sensitivity of cohorts E and F combined is significantly better than 50%. The sensitivity and day-level specificity are presented using

conservative Clopper–Pearson 95% CIs. The day-level specificity quantifies the probability of not placing an unintentional, false-positive call by the sudden loss of pulse detection feature on a per-day basis. To improve interpretability of the specificity, we also report the frequency of unintentional calls per user-year.

Reporting summary

Further information on research design is available in the Nature Portfolio Reporting Summary linked to this article.

Data availability

The data that support the findings of this study are not openly available owing to reasons of study participant privacy; clinical study data have been registered (NCT06430216) and submitted to regulatory agencies for their review. The informed consent agreements do not allow for sharing of participant-level data.

Code availability

A pseudocode implementation of the loss of pulse detection algorithm is available in the Supplementary Information.

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Author contributions Contributions are attributed using the CRediT nomenclature. K.S. and J. Sunshine conceptualized the work and wrote the original draft. All authors reviewed and edited the manuscript. Data were curated by K.S., A.W., A.S., E.W., T.P. and L.C.; formal analysis was performed by K.S., A.W., J.T., D. Miller and J. Sunshine.; methodology was designed by K.S., A.W., J.M., S.C., T. Giest, C.F., A.C., J.T. and J. Sunshine; investigation was performed by K.S., A.W., J.M., S.C., T.P. and C.F.; software was developed by K.S., A.W., Y.C., A.S., E.W., B.H. and T. Gadhi; validation was performed by K.S., A.W., Y.C., A.S., E.W., D. Miller, T. Gadhi and J. Sunshine; visualizations were created by K.S., E. Shi and Y.-L.L.; resources were obtained by J.M., S.C., E. Silver and L.C.; the project was administered by E. Silver, C.F., M.W., J.T. and T. Gadhi; and the project was supervised by T. Giest, D.P., E. Silver, D. McDuff, S.R., E. Shi, M.W., P.R., T.R., S.Y., A.P., S.P., P.K., M.M., M.S., J.P., B.P., A.V., J.T., J. Shreibati, D. Miller, T. Gadhi and J. Sunshine.

Competing interests The authors declare the following competing interests: this work was completed by the authors while employed at, or while collaborating with, Google. The authors have filed provisional patent applications related to this research (63/609,146).

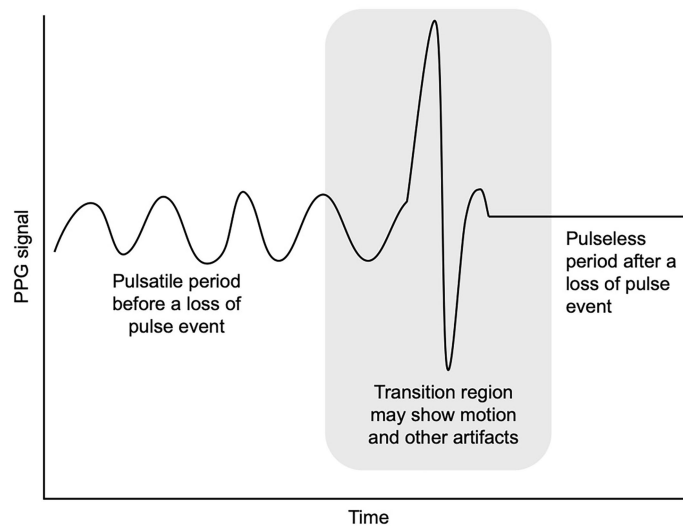
Additional information

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Extended Data Fig. 1 | The PPG signal during a typical loss of pulse event shows a sudden transition from pulsatility to pulselessness. The transition region in gray is heterogeneous across loss of pulse events, and may contain motion artifacts that contaminate the PPG signal.

Reporting Summary

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Our web collection on [statistics for biologists](#) contains articles on many of the points above.

Software and code

Policy information about [availability of computer code](#)

Data collection

Data was collected and recorded in Google Sheets and Trialkit clinical study data management software (Crucial Data Solutions). These software tools are software-as-a-service.

Data analysis

Data was analyzed in Google Sheets and in Google Colaboratory. These software tools are software-as-a-service and do not have explicit version numbers. The Python version of Google Colaboratory used in analysis was 3.11.

For manuscripts utilizing custom algorithms or software that are central to the research but not yet described in published literature, software must be made available to editors and reviewers. We strongly encourage code deposition in a community repository (e.g. GitHub). See the Nature Portfolio [guidelines for submitting code & software](#) for further information.

Data

Policy information about [availability of data](#)

All manuscripts must include a [data availability statement](#). This statement should provide the following information, where applicable:

- Accession codes, unique identifiers, or web links for publicly available datasets
- A description of any restrictions on data availability
- For clinical datasets or third party data, please ensure that the statement adheres to our [policy](#)

The data that support the findings of this study are not openly available due to reasons of study participant privacy; clinical study data have been registered (NCT06430216).

Research involving human participants, their data, or biological material

Policy information about studies with [human participants or human data](#). See also policy information about [sex, gender \(identity/presentation\), and sexual orientation](#) and [race, ethnicity and racism](#).

Reporting on sex and gender	Demographics of study participants at the cohort level are provided in Supplementary Table S2.
Reporting on race, ethnicity, or other socially relevant groupings	Demographics of study participants at the cohort level are provided in Supplementary Table S2.
Population characteristics	Demographics of study participants at the cohort level are provided in Supplementary Table S2 and additional population characteristics are in the Methods section.
Recruitment	Participants were recruited via website, email, phone calls, and posters, as detailed in the protocols for individual studies that are provided with the submission. We are not aware of any potential causes of self-selection bias that may impact the results that are presented in this manuscript. Recruitment for the prospective validation studies was performed by a 3rd party contract research organization (CRO); participants were not told the identity of the company sponsoring the research at the recruitment stage in order to minimize the risk of potential selection bias.
Ethics oversight	All cohorts were enrolled under informed consent (IRB #00068623, 00071247, 00077141, 00078212, 00079675, Advarra (Columbia, MD)).

Note that full information on the approval of the study protocol must also be provided in the manuscript.

Field-specific reporting

Please select the one below that is the best fit for your research. If you are not sure, read the appropriate sections before making your selection.

☒ Life sciences ☐ Behavioural & social sciences ☐ Ecological, evolutionary & environmental sciences

For a reference copy of the document with all sections, see nature.com/documents/nr-reporting-summary-flat.pdf

Life sciences study design

All studies must disclose on these points even when the disclosure is negative.

Sample size	The sample size of the prospective validation studies was estimated a priori. The sample size for Cohort E was estimated a priori to be 135 participants to provide 90% power, using conservative estimates for participant dropout rates and within-participant correlation. Similarly, the sample size for Cohort F was estimated to be 21 participants to provide 90% power. The sample size of Cohort A was pre-specified at 100 participants.
Data exclusions	No data were excluded from the prospective validation studies. Data from 10 (of 100) participants from Cohort A were excluded due to a lack of analyzable data: investigational device failures occurred for five participants; ventricular fibrillation was not successfully induced in four participants; and an artifact from an automated blood pressure cuff that inflated at the time of VF was present for one participant. This is described in the main text.
Replication	All attempts at replication were successful, as indicated by the consistency of results across Cohorts D and E (specificity) and Cohorts E and F (sensitivity).
Randomization	This is not applicable because all data from all participants were analyzed for the prospective validation studies.
Blinding	The investigators were blinded to the interim results of the prospective validation studies, which were performed under design control.

Reporting for specific materials, systems and methods

We require information from authors about some types of materials, experimental systems and methods used in many studies. Here, indicate whether each material, system or method listed is relevant to your study. If you are not sure if a list item applies to your research, read the appropriate section before selecting a response.

Materials & experimental systems

n/a	Involved in the study
☒	☐ Antibodies
☒	☐ Eukaryotic cell lines
☒	☐ Palaeontology and archaeology
☒	☐ Animals and other organisms
☐	☒ Clinical data
☒	☐ Dual use research of concern
☒	☐ Plants

Methods

n/a	Involved in the study
☒	☐ ChIP-seq
☒	☐ Flow cytometry
☒	☐ MRI-based neuroimaging

Clinical data

Policy information about [clinical studies](#)

All manuscripts should comply with the ICMJE [guidelines for publication of clinical research](#) and a completed [CONSORT checklist](#) must be included with all submissions.

Clinical trial registration

Study protocol

Data collection

These details are disclosed in the Methods section.

Outcomes

These endpoints were met in the prospective studies as described above and shared with, and reviewed by, regulatory agencies.

Plants

Seed stocks

Novel plant genotypes

Authentication