PROVISIONAL PATENT APPLICATION — DRAFT

WEARABLE APPARATUS AND METHOD FOR MULTI-MODAL PHYSIOLOGICAL SENSING AND RESPONSIVE, FAIL-SAFE CLOSED-LOOP NEUROSTIMULATION

Applicant: Dreamz Tech Inc.

Inventor: Nir Cafri

Prepared: August 8, 2026

PROVISIONAL APPLICATION COVER SHEET DATA (37 C.F.R. § 1.51(c)(1)) — for completion by applicant/counsel at filing:

• Title of the Invention: as above.

• Inventor: Nir Cafri — residence (city, state/country): [TO BE COMPLETED].

• Applicant / Assignee: Dreamz Tech Inc. [confirm inventor-to-assignee assignment documentation is executed before filing in the applicant's name].

• Correspondence Address: [TO BE COMPLETED].

• Entity Status (determines filing fee): [ ] Micro entity [ ] Small entity [ ] Undiscounted — to be determined by counsel before payment.

• Attorney Docket No.: [TO BE ASSIGNED, optional].

• Enclosed: this specification, drawings (6 sheets, FIGS. 1–6), and this cover sheet.

NOTICE: This document is an inventor-prepared draft intended as a complete starting point for a U.S. provisional patent application under 35 U.S.C. § 111(b). It is not legal advice and has not been reviewed by a registered patent attorney or agent. Before filing, this draft should be reviewed by qualified patent counsel, who should independently confirm the adequacy of the written description and enablement, freedom-to-operate, inventorship and ownership/assignment, entity status for fee purposes, and compliance with 37 C.F.R. § 1.51 and other applicable formal requirements.

A targeted prior-art review is summarized in the accompanying inventor disclosure notes. Independent claims 1, 20, and 24 are drafted at the genus level—reciting a wearable "body" rather than a sleep mask specifically, and a "target state associated with a reduction in physiological arousal" rather than sleep onset specifically—to center novelty on (a) a non-EEG-mandatory, multi-modal (motion, temperature, and PPG and/or EEG) session-relative readiness classification requiring multi-condition, multi-interval agreement, and (b) a distributed fail-safe control architecture in which a locally enforced, non-remotely-increasable safety ceiling and autonomous fallback behavior do not depend on continued correctness or availability of a remote inference. Dependent claims 2–3 and 23 narrow the apparatus and method claims back to the illustrated sleep-mask, sleep-onset embodiment for defense-in-depth. This combination was not located, as such, in the reviewed prior art, which instead separately shows EEG-centric closed-loop sleep stimulation headbands, multi-sensor sleep masks without this fail-safe architecture, and generic stimulation safety limits. See the closing prior-art notes preceding the

claims for reference numbers and design-around rationale.

PRACTICAL NOTE FOR COUNSEL (PROVISIONAL FILING): A provisional application does not require claims (37 C.F.R. § 1.51(c)(1)), is not examined, and its filing fee does not depend on the number or form of claims — the 20-total/3-independent excess-claims fee rule that applies to non-provisional utility filings is not applicable here. No oath/declaration or information disclosure statement is required at provisional filing, though the prior-art references identified in the inventor's design-around notes should be carried forward for disclosure in the later non-provisional filing. This provisional will automatically expire twelve months after its filing date; to preserve the priority date established here, a corresponding non-provisional application (or a PCT application claiming priority to this filing) must be filed before that deadline. If any public disclosure, offer for sale, or commercial use of the invention has occurred or is planned, file promptly and consult counsel regarding the applicable U.S. grace period and foreign filing implications, since most jurisdictions outside the U.S. require absolute novelty with no grace period.

WEARABLE APPARATUS AND METHOD FOR MULTI-MODAL PHYSIOLOGICAL SENSING AND RESPONSIVE, FAIL-SAFE CLOSED-LOOP NEUROSTIMULATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not applicable.

FIELD OF THE INVENTION

[0002] The present disclosure relates generally to wearable devices for physiological sensing and neurostimulation, and more particularly to a wearable apparatus incorporating multiple physiological sensing modalities—including motion, skin temperature, and at least one of photoplethysmography (PPG) and electroencephalography (EEG) sensing—coupled to a closed-loop, fail-safe electrical neurostimulation controller that adapts stimulation parameters to a wearer's inferred physiological state. In the illustrated embodiments the apparatus is configured as a sleep mask and the target physiological state is a sleep-onset state, though, as explained in Section VII below, neither the mask form factor nor the sleep-onset target state is required in every embodiment.

BACKGROUND OF THE INVENTION

[0003] Difficulty falling asleep affects a substantial portion of the population and is commonly addressed through pharmacological sleep aids, which carry known risks of dependency, next-day grogginess, and diminishing efficacy with continued use. Non-pharmacological alternatives, including transcranial electrical stimulation and other forms of neuromodulation, have shown promise for reducing the time required to fall asleep, but existing wearable implementations present practical obstacles to everyday consumer use.

[0004] Certain existing wearable stimulation devices rely on electroencephalography (EEG) as the primary or exclusive sensing modality used to determine when and how to deliver stimulation. EEG acquisition of adequate signal quality typically requires one or more electrodes placed at specific scalp

locations, careful attention to electrode-skin contact, and signal processing that is sensitive to motion artifact, muscle activity, and electrode impedance drift. These requirements can increase device cost, complicate industrial design, and degrade the user experience of a device intended to be worn while attempting to fall asleep.

[0005] Other existing wearable sleep devices combine physiological sensing with stimulation but do not adequately address the consequence of a lost or degraded communication link between a sensing/inference subsystem and a stimulation subsystem. Where physiological inference is performed on a companion computing device (for example, a smartphone application) and communicated wirelessly to a wearable stimulator, a communication interruption, a stale or invalid inference, or a fault condition local to the wearable device can leave the stimulator without current guidance. Depending on device design, this can result in stimulation continuing unmodified, continuing at a prior elevated setting, or otherwise failing to move safely toward a reduced or zero output state.

[0006] There remains a need for a wearable apparatus that can determine a wearer's physiological readiness for a target state using sensing modalities that do not require EEG—while remaining compatible with EEG sensing as an additional or alternative modality where available—and that incorporates a stimulation control architecture in which a local, non-remotely-increasable safety limit and an autonomous fallback behavior are enforced independently of the continued availability or correctness of information received from a companion computing device.

[0007] While facilitating a reduction in the time required to fall asleep is a primary motivating application described herein, the described sensing and control architecture is not limited to that application. A need also exists for a wearable, multi-modal physiological sensing and fail-safe neurostimulation architecture that can be configured, using the same or additional sensor modalities, to target other physiological states associated with reduced arousal, such as those relevant to relaxation, meditation, stress-reduction, or focus applications, without redesigning the underlying sensing and safety architecture for each application.

[0008] The apparatus, systems, and methods described herein address these needs.

SUMMARY OF THE INVENTION

[0009] In one aspect, a wearable apparatus is provided, comprising a body configured to be worn about at least a portion of a user's head; a motion sensor; a temperature sensor; a first physiological sensor selected from the group consisting of a PPG sensor, an EEG sensor, and a combination thereof; one or more stimulation electrodes; a wireless communication interface; and a local controller. The local controller receives, via the wireless communication interface, a requested stimulation parameter and a readiness classification derived from the motion signal, the temperature signal, and an output of the first physiological sensor relative to a subject-specific, session-relative baseline. The local controller

determines a local stimulation limit as the lesser of the requested stimulation parameter and a locally stored, non-remotely-increasable safety ceiling, and causes the stimulation electrodes to deliver stimulation according to a stimulation parameter set that is one of a plurality of ordered sets that progressively reduce stimulation amplitude and/or duty cycle as the readiness classification advances toward a target state associated with a reduction in physiological arousal of the user. Responsive to a failure of the received readiness classification to satisfy a freshness criterion, the local controller autonomously transitions the stimulation electrodes to a predetermined safe output state.

[0010] In some embodiments, the body is embodied as a sleep mask configured to cover at least the user's eyes, and the target state is a sleep-onset state; other embodiments described in Section VII use a different wearable body form factor, a different target state, or both, without changing the underlying sensing and fail-safe control architecture.

[0011] In some embodiments, the readiness classification is derived without use of an EEG signal, using instead a heart-rate-variability metric derived from the PPG sensor and normalized to a session-specific baseline, a duration of continuous stillness derived from the motion sensor, and a rate of change of skin temperature derived from the temperature sensor, with classification gated on multi-condition agreement persisting across a plurality of evaluation intervals.

[0012] In other embodiments, the first physiological sensor comprises an EEG sensor whose output—for example, a spectral feature associated with reduced cortical arousal—is used in place of, or to confirm or override, the PPG-derived classification, with the apparatus configured to fall back to the non-EEG classification when EEG signal quality is insufficient.

[0013] In another aspect, methods of operating such an apparatus are provided, including establishing a baseline, computing the readiness classification, transitioning among ordered stimulation parameter sets, and executing a fail-safe transition upon loss of fresh guidance.

[0014] In another aspect, a non-transitory computer-readable medium is provided storing instructions that, when executed by a processor of a computing device in wireless communication with the wearable apparatus, cause the computing device to compute the readiness classification and transmit a bounded stimulation request to the apparatus.

[0015] These and other aspects, features, and advantages will be apparent from the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 is a block diagram illustrating an example wearable apparatus, in an illustrated embodiment a sleep apparatus, and an associated remote computing device, according to one or more embodiments.

[0017] FIG. 2 is a diagram illustrating an example arrangement of sensors and stimulation electrodes on a body embodied as a sleep mask, according to one or more embodiments.

[0018] FIG. 3 is a flow diagram illustrating an example process for establishing a baseline and computing a readiness classification from motion, temperature, and PPG and/or EEG signals, according to one or more embodiments.

[0019] FIG. 4 is a state diagram illustrating an example progression of ordered stimulation parameter sets as a function of the readiness classification, according to one or more embodiments.

[0020] FIG. 5 is a diagram illustrating an example distributed, fail-safe control architecture in which a local controller enforces a non-remotely-increasable safety ceiling and autonomous fallback behavior, according to one or more embodiments.

[0021] FIG. 6 is an example timeline illustrating physiological signal trends and corresponding stimulation parameter transitions over the course of a use session, according to one or more embodiments.

[0022] It will be appreciated that the drawings are illustrative and not necessarily to scale, and that certain features may be exaggerated for clarity.

DRAWINGS

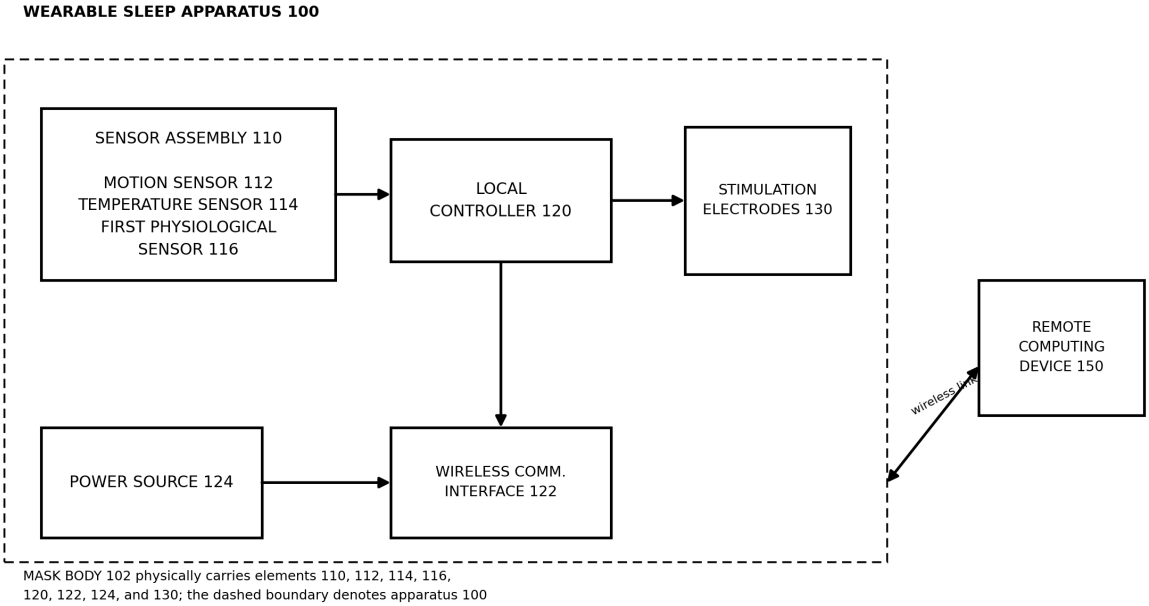

FIG. 1

FIG. 1 – Wearable apparatus 100 and remote computing device 150.

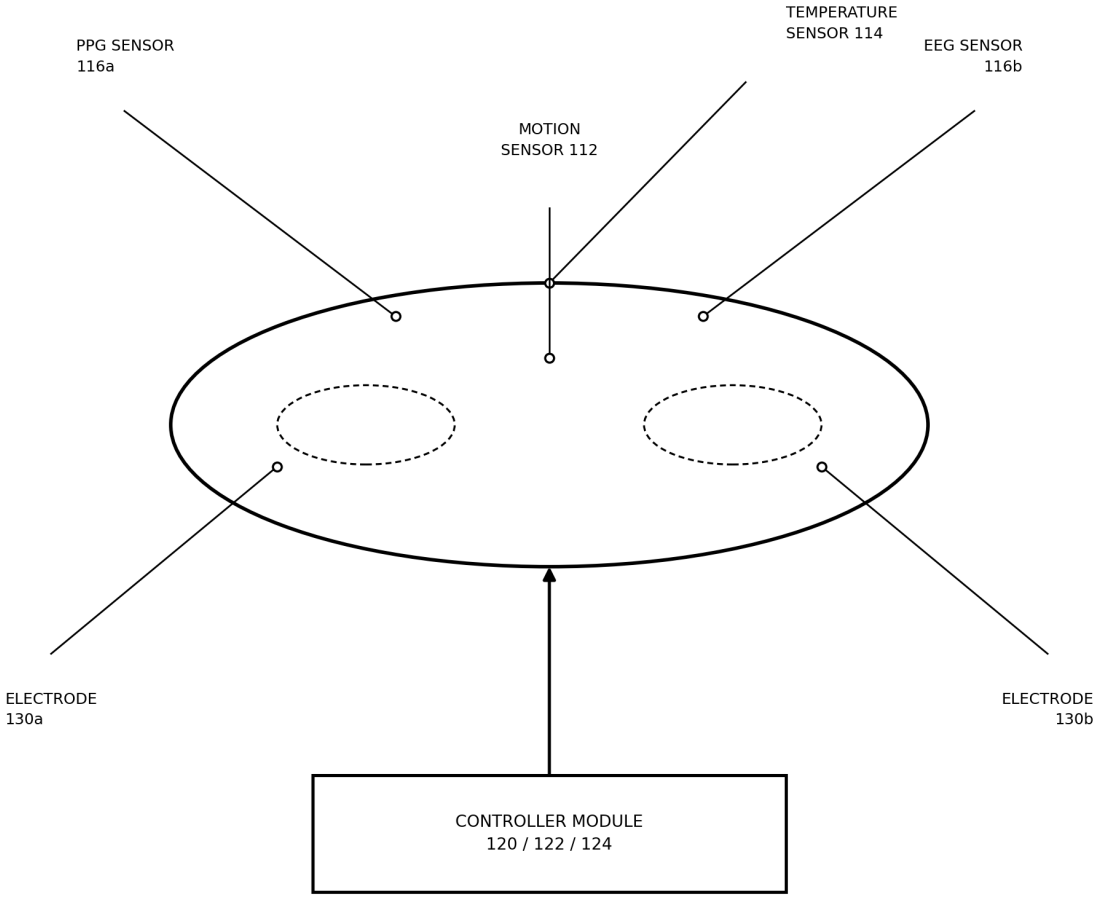

FIG. 2

FIG. 2 – Example sensor and electrode placement on body 102, illustrated as a sleep mask.

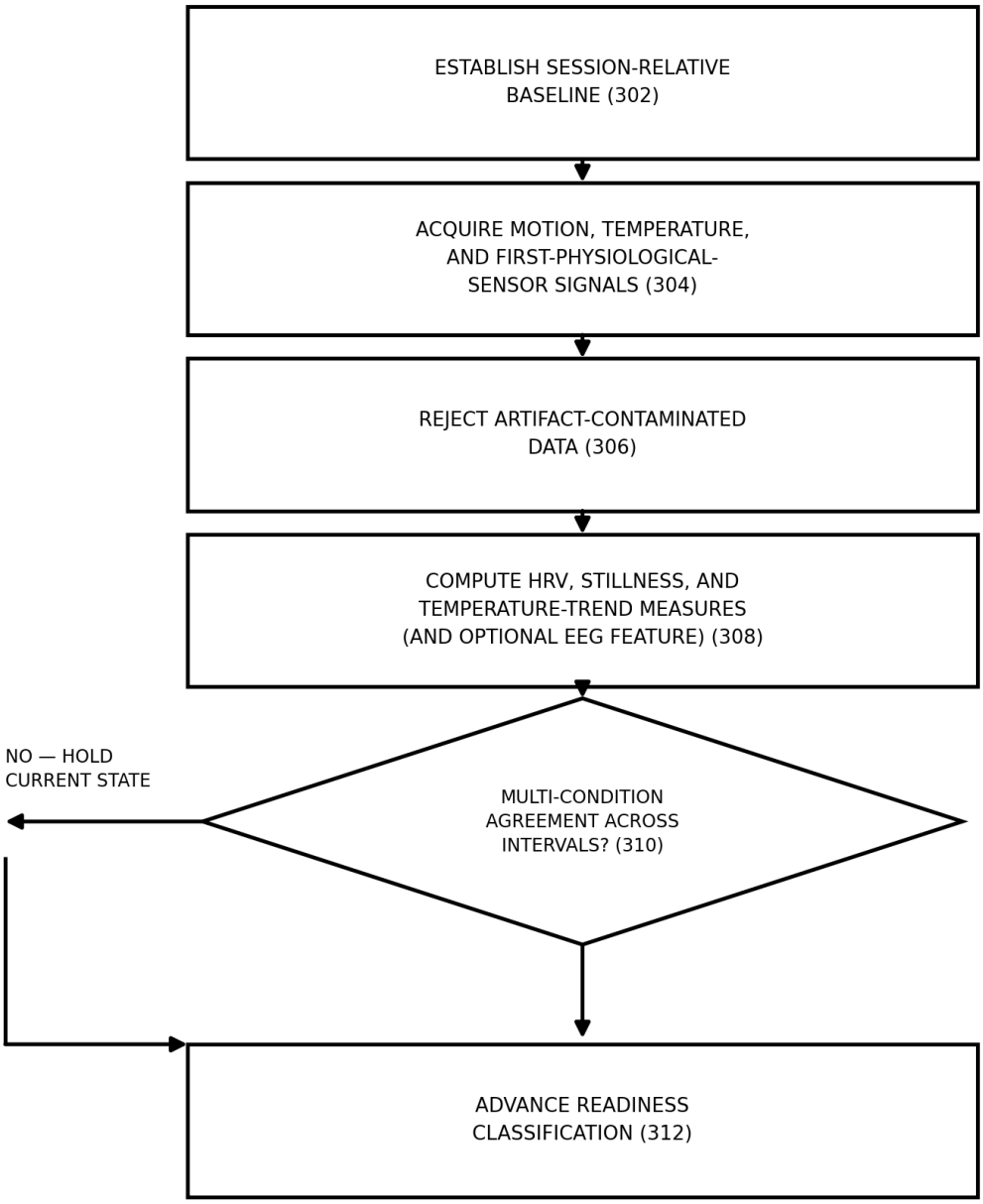

FIG. 3

FIG. 3 – Readiness classification process.

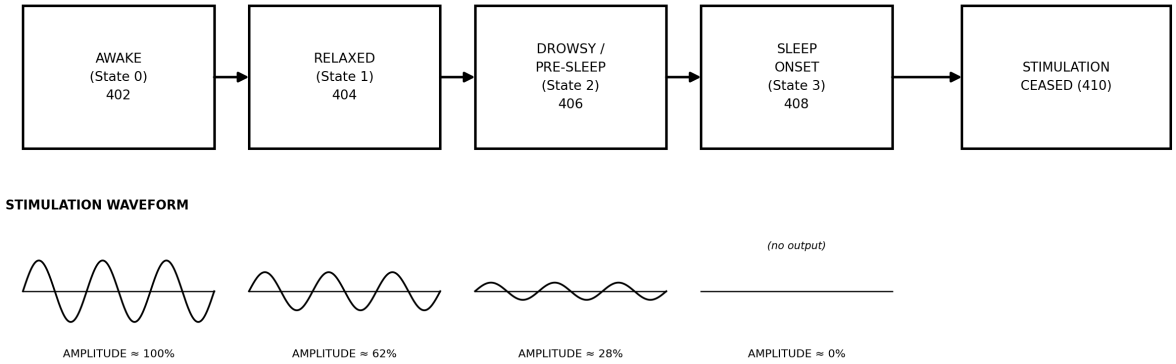

FIG. 4

FIG. 4 – Ordered stimulation parameter sets.

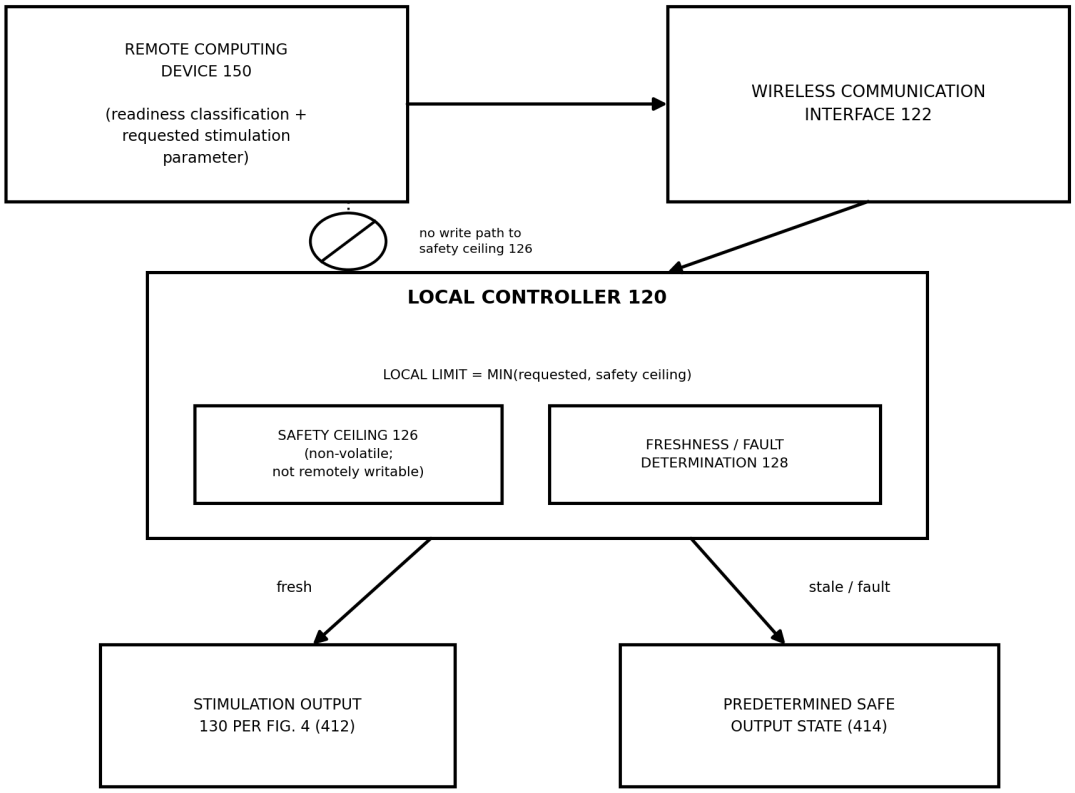

FIG. 5

FIG. 5 – Distributed, fail-safe control architecture.

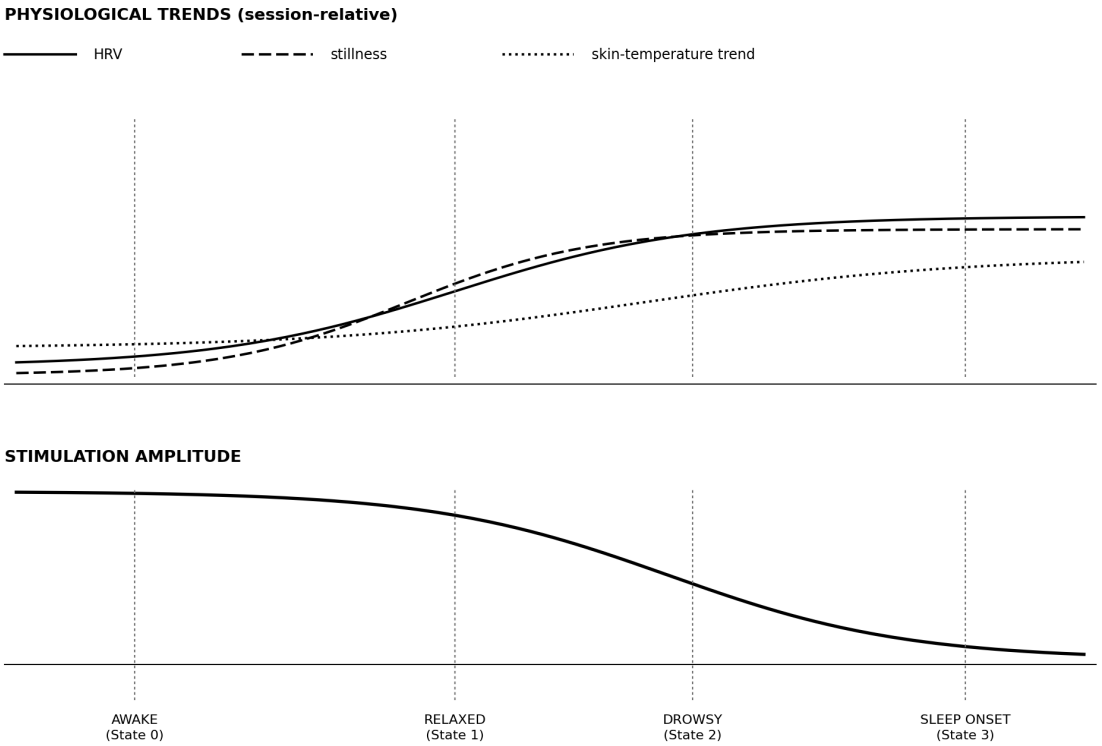

FIG. 6

FIG. 6 – Example session timeline.

DETAILED DESCRIPTION OF THE INVENTION

[0023] The following detailed description describes a wearable apparatus, and associated systems and methods, in which physiological signals obtained from a wearer are used to infer a readiness state relevant to a target physiological state, and in which electrical stimulation delivered to the wearer is adapted according to the inferred state through a fail-safe, distributed control architecture. The primary examples below describe a sleep mask worn over the eyes and a sleep-onset target state, but neither the mask form factor nor the sleep-onset target state is required: the described sensing and control architecture may be embodied in a headband, a periorbital patch, or another head-worn article, and may be configured to target physiological states other than sleep onset, as further described in Section VII.

I. System Overview

[0024] Referring to FIG. 1, an example wearable apparatus 100 includes a body 102 (illustrated in FIGS. 1–2 as a sleep mask; see Section VII for alternative body form factors), a sensor assembly 110, one or more stimulation electrodes 130, a local controller 120, a wireless communication interface 122, and a power source 124. The sensor assembly 110 includes a motion sensor 112 (for example, a three-axis accelerometer or an accelerometer-gyroscope combination), a temperature sensor 114 (for example, a thermistor or digital temperature sensor positioned to contact or be proximate to the wearer's skin), and a first physiological sensor 116. The first physiological sensor 116 is selected from the group consisting of a photoplethysmography (PPG) sensor, an electroencephalography (EEG) sensor, and a combination of a PPG sensor and an EEG sensor, as further described below. The apparatus 100 is configured to communicate wirelessly (for example, via Bluetooth Low Energy) with a remote computing device 150, such as a smartphone or other mobile computing device executing a companion application.

[0025] The local controller 120 comprises one or more processors, volatile and non-volatile memory, and associated analog and digital circuitry configured to sample the sensor assembly 110, to generate and deliver an electrical stimulation waveform via the stimulation electrodes 130, and to communicate with the remote computing device 150 via the wireless communication interface 122. In some embodiments, part or all of the physiological inference described below is performed by the remote computing device 150, with the local controller 120 responsible for safety enforcement and waveform generation; in other embodiments, part or all of the inference is performed locally by the local controller 120. Distribution of computation between the apparatus 100 and the remote computing device 150 does not limit the scope of the safety architecture described in Section V below, which is defined by the relationship between locally enforced limits and externally supplied requests regardless of where the requests originate.

II. Sensor Placement and Signal Acquisition

[0026] Referring to FIG. 2, in one example arrangement, the temperature sensor 114 and at least a portion of the first physiological sensor 116 are positioned at a periorbital or forehead region of the body 102 where they contact or are proximate to the wearer's skin when the apparatus 100 is worn. Where the first physiological sensor 116 includes a PPG sensor, the PPG sensor comprises an optical emitter and a corresponding photodetector positioned to obtain a pulsatile blood-volume signal from skin at the temple, forehead, or periorbital region. Where the first physiological sensor 116 includes an EEG sensor, the EEG sensor comprises one or more dry or semi-dry electrodes positioned at forehead locations (for example, at or near Fp1, Fp2, and/or Fpz in the international 10-20 system), together with a reference and/or ground electrode.

[0027] The motion sensor 112 outputs a motion signal from which the local controller 120 or the remote computing device 150 derives a measure of gross body and head movement, including a duration of continuous stillness. The temperature sensor 114 outputs a temperature signal from which a distal or facial skin-temperature trend is derived. A rise in distal skin temperature, reflecting peripheral vasodilation, is associated with the approach of sleep onset in many individuals; embodiments described herein use the direction and rate of change of this signal, rather than an absolute temperature value alone, as an input to the readiness classification described below, because absolute skin temperature varies substantially across individuals and environments.

[0028] Where the first physiological sensor 116 includes a PPG sensor, the pulse signal is processed to identify individual pulse events and to compute a beat-to-beat interval series. Intervals associated with a detected motion or signal-quality artifact are excluded prior to further processing. A heart-rate-variability (HRV) metric (for example, RMSSD or another interval-variability statistic) is computed from the artifact-cleaned interval series.

[0029] Where the first physiological sensor 116 includes an EEG sensor, the brain-activity signal is processed to extract one or more spectral or event-related features associated with reduced cortical arousal or with early sleep-onset physiology, such as attenuation of alpha-band power, an increase in low-frequency (delta/theta) power, or detection of a characteristic sleep-onset waveform. A signal-quality metric (for example, derived from electrode-skin impedance or from signal amplitude/variance consistent with poor contact) is computed concurrently.

III. Baseline Establishment and Readiness Classification

[0030] Referring to FIG. 3, upon initiation of a use session, the apparatus 100 or the remote computing device 150 establishes a subject-specific, session-relative baseline from an initial portion of the session (for example, the first several minutes), during which sensor signals are sampled without requiring a classification decision. The baseline includes, in embodiments using PPG, a baseline heart rate and/or baseline interval-variability value, and, in embodiments using EEG, a baseline spectral profile.

Establishing the baseline within the current session, rather than relying solely on a population-average or previously stored value, allows the readiness classification to be sensitive to session-to-session and individual variation in autonomic and thermoregulatory physiology.

[0031] Following baseline establishment, the apparatus 100 or the remote computing device 150 periodically evaluates the current motion, temperature, and first-physiological-sensor signals relative to the baseline and classifies the wearer among an ordered plurality of readiness states—for example, an active/awake state, one or more intermediate relaxed or drowsy states, and a most-advanced state referred to herein, and in the claims, as the target state. In the primary examples below the target state is a sleep-onset state; Section VII describes embodiments in which the target state corresponds to a different physiological condition associated with reduced arousal.

[0032] In an embodiment in which the first physiological sensor 116 comprises a PPG sensor and does not rely on an EEG signal, the classification requires agreement, across a plurality of successive evaluation intervals, among at least two of: (a) the HRV metric relative to its session baseline exceeding a threshold ratio; (b) a duration of continuous stillness derived from the motion signal exceeding a stillness threshold; and (c) the rate of change of the temperature signal satisfying a trend criterion. Requiring agreement across multiple modalities and persistence across multiple evaluation intervals, rather than triggering on a single favorable reading from a single sensor, reduces the likelihood that a transient artifact or a momentarily favorable single-sensor reading results in a premature advance of the readiness classification.

[0033] In an embodiment in which the first physiological sensor 116 comprises an EEG sensor, the classification additionally or alternatively incorporates the extracted EEG feature described in paragraph [0029], for example, requiring the EEG feature to be consistent with reduced cortical arousal for a minimum duration before advancing the classification.

[0034] In an embodiment in which the first physiological sensor 116 comprises both a PPG sensor and an EEG sensor, the readiness classification is computed from the PPG-derived signal as described in paragraph [0032], and the EEG-derived feature is used to confirm or override that classification when the concurrently computed EEG signal-quality metric exceeds a quality threshold. When the EEG signal-quality metric does not exceed the quality threshold—for example, because of poor electrode contact—the apparatus 100 or the remote computing device 150 relies on the PPG-, motion-, and temperature-derived classification without requiring EEG confirmation. This graceful-degradation behavior allows the apparatus to benefit from EEG sensing when available and reliable, without making the availability of a high-quality EEG signal a prerequisite for adapting stimulation.

IV. Stimulation Subsystem and Progressive Parameter Transitions

[0035] Referring to FIG. 4, the local controller 120 stores or receives a plurality of ordered stimulation parameter sets, each associated with a respective readiness classification and each specifying at least a stimulation amplitude and a duty cycle (ratio of stimulation-on duration to stimulation-off duration), and, in some embodiments, a stimulation waveform shape (for example, sinusoidal, ramped, or pulsed) and/or a stimulation frequency. As the readiness classification advances from an awake state toward the target state (for example, a sleep-onset state), the local controller 120 transitions among the ordered stimulation parameter sets such that at least one of stimulation amplitude and duty cycle is progressively reduced. In some embodiments, stimulation waveform shape also changes across the progression. Responsive to the readiness classification indicating the target state and persisting across a plurality of successive evaluation intervals, the local controller 120 ceases delivery of the electrical stimulation signal.

[0036] Progressively reducing stimulation intensity as the wearer approaches the target state, rather than maintaining a constant stimulation level or abruptly ceasing stimulation upon a single favorable reading, is intended to reduce the likelihood that continued or abruptly discontinued stimulation disturbs the process of reaching that state—for example, the sleep-onset process, in embodiments where the target state is a sleep-onset state.

V. Distributed, Fail-Safe Control Architecture

[0037] Referring to FIG. 5, in embodiments in which the readiness classification is computed, in whole or in part, by the remote computing device 150, the remote computing device 150 transmits to the apparatus 100, via the wireless communication interface 122, a requested stimulation parameter (for example, a requested amplitude and/or a requested stimulation parameter set index) together with an indication of the current readiness classification. The local controller 120 is configured to determine a local stimulation limit as the lesser of the requested stimulation parameter and a safety ceiling value stored in a non-volatile memory of the local controller 120 at the time of manufacture or configuration. In some embodiments, the safety ceiling value is not writable via the wireless communication interface 122 during ordinary operation, such that no instruction receivable from the remote computing device 150 can cause the apparatus 100 to exceed the safety ceiling.

[0038] The local controller 120 further determines whether the received readiness classification satisfies a freshness criterion—for example, whether the time elapsed since the most recently received readiness classification exceeds an expected update interval communicated by the remote computing device 150, or a default timeout value. Responsive to the freshness criterion being satisfied, the local controller 120 causes the stimulation electrodes 130 to deliver stimulation according to the local stimulation limit and the stimulation parameter set associated with the received readiness classification, as described in Section IV. Responsive to the freshness criterion not being satisfied—for example, because of a wireless disconnection, an application fault, or an excessively delayed update—the local

controller 120 autonomously transitions the stimulation electrodes 130 to a predetermined safe output state without further dependence on the wireless communication interface 122.

[0039] In some embodiments, the predetermined safe output state is selected, from among a plurality of candidate safe output states, according to a detected fault classification. For example, a brief wireless interruption may result in the local controller 120 retaining a most-recently accepted stimulation parameter set for a bounded duration before transitioning to a reduced-output preset, while a detected thermal condition at the body 102 or an invalid sensor reading may result in immediate cessation of stimulation.

[0040] When transitioning the stimulation electrodes 130 to a reduced or zero output state, whether responsive to a fault condition or responsive to a readiness classification indicating the target state, the local controller 120 is configured to command a neutral or zero output level at a digital-to-analog converter or equivalent output stage prior to disabling a power stage or supply rail associated with the stimulation electrodes 130, so as to avoid an uncontrolled output transient during shutdown.

[0041] Because the time-critical waveform-generation and safety-enforcement functions described above are performed by the local controller 120 independent of the continued availability, correctness, or timeliness of communication from the remote computing device 150, the apparatus 100 is able to guarantee bounded worst-case stimulation behavior even when the remote computing device 150 is unavailable, delayed, or compromised.

VI. Example Method

[0042] FIG. 3, described above, additionally illustrates an example method of operation: (a) establishing a session-relative baseline; (b) acquiring motion, temperature, and first-physiological-sensor signals; (c) rejecting artifact-contaminated data; (d) computing a readiness classification requiring multi-condition agreement persisting across multiple evaluation intervals; (e) transmitting a requested stimulation parameter and the readiness classification to the local controller 120; (f) at the local controller 120, clamping the requested stimulation parameter to a locally stored safety ceiling and verifying freshness; and (g) delivering stimulation according to the resulting parameters, or transitioning to a safe output state if freshness is not satisfied.

VII. Additional Embodiments and Variations

[0043] While the foregoing description references a mask-form-factor apparatus and a sleep-onset target state, the sensing and control architecture described herein is not limited to either. As used herein and in the claims, the term "body" encompasses any wearable structure configured to position the recited sensors and electrodes relative to the user, including but not limited to a sleep mask (as illustrated in FIGS. 1–2), a headband, a cap, a strap-based periorbital patch, or an apparatus integrated with another head-worn article. Likewise, the "target state" recited in the claims is not limited to a

sleep-onset state; in embodiments directed to applications other than facilitating sleep onset, the readiness classification, the ordered stimulation parameter sets, and the fail-safe control architecture described above may be configured with thresholds, evaluation-interval durations, and target-state criteria appropriate to a relaxation, meditation, stress-reduction, or focus application, using the same physiological sensing modalities described above, additional sensing modalities suited to the alternative application, or both. The stimulation electrodes 130 may be formed from a variety of conductive materials, including silver or silver/silver-chloride (Ag/AgCl) conductive elements, and may be arranged in bipolar, multipolar, or array configurations.

[0044] The sensor assembly 110 may include additional sensors not required by every embodiment, including a pulse-oximetry channel, a respiration sensor, an electrooculography (EOG) sensor, or additional accelerometer/gyroscope axes, whose outputs may be used to further refine the readiness classification described above or to support ancillary sleep-tracking or other physiological-monitoring functionality.

[0045] The specific thresholds, evaluation-interval durations, numbers of ordered readiness states, and numbers of ordered stimulation parameter sets described above are illustrative; different implementations may use different numbers of states, different threshold values (which may be fixed, user-adjustable, or adaptively learned over multiple sessions), and different combinations of the described physiological modalities, without departing from the architecture described herein.

[0046] Computation described above as being performed by the local controller 120 or by the remote computing device 150 may, in various embodiments, be reallocated between these components, performed by a third device (for example, a cloud server in communication with the remote computing device 150), or performed by additional distributed components, provided that the fail-safe relationship described in Section V—namely, that a locally enforced safety ceiling and fallback behavior cannot be overridden or bypassed by a remotely supplied instruction—is preserved.

INVENTOR'S PRIOR-ART DESIGN-AROUND NOTES

[0047] A targeted, non-exhaustive prior-art search identified wearable devices combining sleep-related physiological sensing with electrical or other neurostimulation, including devices in which EEG sensing is used to gate transcranial electrical stimulation during sleep, devices combining forehead PPG, motion, and stimulation electrodes in a sleep mask or eye-mask form factor, and devices verifying stimulation delivery using biosensors including heart rate and temperature. The claims that follow are drafted at the genus level with respect to the wearable structure and the target physiological state—reciting a "body" and a "target state associated with a reduction in physiological arousal" rather than a sleep mask and sleep onset specifically—so as to center novelty on (i) the specific combination of a session-relative, multi-condition, multi-interval readiness gate spanning motion, temperature, and PPG and/or EEG signals, together with (ii) a distributed control architecture in which a local, non-remotely-increasable safety ceiling and an autonomous, fault-classified fallback are enforced independent of the correctness or continued availability of a remote inference—rather than on the sleep mask form factor, the sleep-onset application, the general proposition of sensing a physiological signal and stimulating in response to it, or the general proposition of imposing a maximum output limit. Dependent claims narrow to the illustrated sleep-mask, sleep-onset embodiment to provide defense-in-depth if the broader independent claims are narrowed or challenged during prosecution or litigation. This search is not a substitute for a professional patentability or freedom-to-operate opinion.

CLAIMS (OPTIONAL — INCLUDED FOR REFERENCE; NOT REQUIRED FOR PROVISIONAL FILING)

A provisional application filed under 35 U.S.C. § 111(b) is not required to include claims and will not be examined; unlike a non-provisional filing, no formal “claims” section is a prerequisite to according this document a filing date. The claim set below is nevertheless included, drafted in standard non-provisional claim form, so that (a) the specification and drawings above can be checked against a concrete, defined scope to confirm adequate written description and enablement before the priority date is fixed, and (b) counsel has a ready starting point when preparing the non-provisional or PCT application that must be filed within twelve months to claim the benefit of this filing. These claims are not a formal part of the provisional filing unless and until re-filed with a later application.

What is claimed is:

1. A wearable neurostimulation apparatus, comprising: a body configured to be worn about at least a portion of a user's head; a motion sensor coupled to the body and configured to output a motion signal indicative of movement of the user; a temperature sensor coupled to the body and configured to output a temperature signal indicative of a skin temperature of the user; a first physiological sensor coupled to the body and selected from the group consisting of a photoplethysmography (PPG) sensor configured to output a pulse signal, an electroencephalography (EEG) sensor configured to output a brain-activity signal, and a combination of the PPG sensor and the EEG sensor; one or more stimulation electrodes coupled to the body and configured to deliver an electrical stimulation signal to the user; a wireless communication interface; and a local controller coupled to the motion sensor, the temperature sensor, the first physiological sensor, the one or more stimulation electrodes, and the wireless communication interface, the local controller configured to: receive, via the wireless communication interface, a requested stimulation parameter and a readiness classification derived at least in part from the motion signal, the temperature signal, and an output of the first physiological sensor relative to a subject-specific baseline established during a current use session; determine a local stimulation limit as the lesser of the requested stimulation parameter and a safety ceiling stored in the local controller, wherein the safety ceiling is not increasable via the wireless communication interface; determine whether the readiness classification satisfies a freshness criterion; responsive to the readiness classification satisfying the freshness criterion, cause the one or more stimulation electrodes to deliver the electrical stimulation signal according to the local stimulation limit and a stimulation parameter set associated with the readiness classification, wherein the stimulation parameter set is one of a plurality of ordered stimulation parameter sets that progressively reduce at least one of stimulation amplitude and stimulation duty cycle as the readiness classification advances toward a target state associated with a reduction in physiological arousal of the user; and responsive to the readiness classification

failing to satisfy the freshness criterion, cause the one or more stimulation electrodes to transition to a predetermined safe output state independent of further communication received via the wireless communication interface.

2. The apparatus of claim 1, wherein the body comprises a sleep mask configured to cover at least the user's eyes when worn.

3. The apparatus of claim 1, wherein the target state comprises a sleep-onset state of the user.

4. The apparatus of claim 1, wherein the first physiological sensor comprises the PPG sensor, and wherein the readiness classification is derived without use of the brain-activity signal.

5. The apparatus of claim 1, wherein the first physiological sensor comprises the EEG sensor.

6. The apparatus of claim 1, wherein the first physiological sensor comprises both the PPG sensor and the EEG sensor, and wherein the readiness classification is computed from the pulse signal and is confirmed or overridden using a feature extracted from the brain-activity signal when a signal-quality metric of the brain-activity signal exceeds a quality threshold, and is computed from the pulse signal without reliance on the brain-activity signal when the signal-quality metric does not exceed the quality threshold.

7. The apparatus of claim 1, wherein the motion signal indicates a duration of continuous stillness of the user, and wherein the readiness classification requires the duration to exceed a stillness threshold.

8. The apparatus of claim 1, wherein the temperature signal indicates a rate of change of the skin temperature over a session-relative interval, and wherein the readiness classification requires the rate of change to satisfy a trend criterion.

9. The apparatus of claim 4, wherein the pulse signal is processed to compute a heart-rate-variability metric normalized to a subject-specific baseline value established during an initial portion of the current use session.

10. The apparatus of claim 9, wherein the readiness classification is determined only responsive to agreement among at least two of: the heart-rate-variability metric, a duration of continuous stillness derived from the motion signal, and a rate of change of the temperature signal, wherein the agreement persists across a plurality of successive evaluation intervals.

11. The apparatus of claim 9, wherein pulse intervals contaminated by a detected artifact are excluded prior to computing the heart-rate-variability metric.

12. The apparatus of claim 1, wherein the plurality of ordered stimulation parameter sets further includes an increasing ratio of a stimulation-off duration to a stimulation-on duration as the readiness classification advances.

13. The apparatus of claim 1, wherein the plurality of ordered stimulation parameter sets further includes a change in stimulation waveform shape as the readiness classification advances.

14. The apparatus of claim 1, wherein the local controller is further configured to cause cessation of the electrical stimulation signal responsive to the readiness classification indicating the target state and persisting across a plurality of successive evaluation intervals.

15. The apparatus of claim 1, wherein the freshness criterion comprises an expected update interval communicated via the wireless communication interface, and wherein the readiness classification is determined to fail the freshness criterion when a time elapsed since a most recently received readiness classification exceeds the expected update interval.

16. The apparatus of claim 1, wherein the predetermined safe output state is selected, from among a plurality of candidate safe output states, according to a fault classification comprising at least a wireless disconnection, a stale readiness classification, and a thermal condition detected at the body.

17. The apparatus of claim 1, wherein the local controller, when transitioning the one or more stimulation electrodes to the predetermined safe output state, is configured to command a neutral output level at a digital-to-analog converter prior to disabling a power stage supplying the one or more stimulation electrodes.

18. The apparatus of claim 1, wherein the safety ceiling is defined at a time of manufacture or configuration and stored in a non-volatile memory of the local controller that is not writable via the wireless communication interface during ordinary operation.

19. The apparatus of claim 1, wherein the local controller is further configured to retain a most-recently accepted stimulation parameter set for a bounded duration following an interruption of the wireless communication interface, and to transition to the predetermined safe output state upon expiration of the bounded duration without a renewed communication.

20. A method of operating a wearable neurostimulation apparatus comprising a body, a motion sensor, a temperature sensor, a first physiological sensor selected from the group consisting of a PPG sensor, an EEG sensor, and a combination thereof, one or more stimulation electrodes, a wireless communication interface, and a local controller, the method comprising: establishing, during an

initial portion of a use session, a subject-specific baseline from at least the first physiological sensor; acquiring, during the use session, a motion signal, a temperature signal, and an output of the first physiological sensor; deriving a readiness classification from the motion signal, the temperature signal, and the output of the first physiological sensor relative to the baseline; receiving, at the local controller via the wireless communication interface, a requested stimulation parameter associated with the readiness classification; determining, at the local controller, a local stimulation limit as the lesser of the requested stimulation parameter and a safety ceiling stored at the local controller, the safety ceiling not being increasable via the wireless communication interface; determining whether the readiness classification satisfies a freshness criterion; responsive to the freshness criterion being satisfied, delivering, via the one or more stimulation electrodes, an electrical stimulation signal according to the local stimulation limit and a stimulation parameter set selected from a plurality of ordered stimulation parameter sets that progressively reduce at least one of stimulation amplitude and stimulation duty cycle as the readiness classification advances toward a target state associated with a reduction in physiological arousal of the user; and responsive to the freshness criterion not being satisfied, autonomously transitioning the one or more stimulation electrodes to a predetermined safe output state independent of further communication received via the wireless communication interface.

21. The method of claim 20, wherein deriving the readiness classification comprises computing a heart-rate-variability metric from a pulse signal output by the PPG sensor, normalizing the heart-rate-variability metric to the baseline, and requiring agreement, persisting across a plurality of successive evaluation intervals, among at least two of the normalized heart-rate-variability metric, a duration of continuous stillness derived from the motion signal, and a rate of change of the temperature signal.

22. The method of claim 20, wherein the first physiological sensor comprises both the PPG sensor and the EEG sensor, and wherein deriving the readiness classification comprises computing a classification from a pulse signal output by the PPG sensor and confirming or overriding the classification using a feature extracted from a brain-activity signal output by the EEG sensor when a signal-quality metric of the brain-activity signal exceeds a quality threshold.

23. The method of claim 20, wherein the body comprises a sleep mask configured to cover at least the user's eyes when worn, and wherein the target state comprises a sleep-onset state of the user.

24. A non-transitory computer-readable medium storing instructions that, when executed by one or more processors of a computing device configured for wireless communication with a wearable neurostimulation apparatus comprising a body, a motion sensor, a temperature sensor, a first physiological sensor selected from the group consisting of a PPG sensor, an EEG sensor, and a

combination thereof, and one or more stimulation electrodes, cause the computing device to: receive, from the wearable apparatus, a motion signal, a temperature signal, and an output of the first physiological sensor; establish a subject-specific baseline from at least the output of the first physiological sensor during an initial portion of a use session; compute a readiness classification from the motion signal, the temperature signal, and the output of the first physiological sensor relative to the baseline, wherein the readiness classification is computed only responsive to agreement, persisting across a plurality of successive evaluation intervals, among at least two physiological measures derived from the motion signal, the temperature signal, and the output of the first physiological sensor; and transmit, to the wearable apparatus, a requested stimulation parameter bounded by a value associated with the readiness classification and an indication of the readiness classification, for enforcement by a local controller of the wearable apparatus against a locally stored safety ceiling.

25. The non-transitory computer-readable medium of claim 24, wherein the instructions further cause the computing device to transmit, to the wearable apparatus, an expected update interval for use by the local controller in determining whether a subsequently transmitted readiness classification is stale.

ABSTRACT

A wearable apparatus includes a body carrying a motion sensor, a temperature sensor, a first physiological sensor selected from a photoplethysmography (PPG) sensor, an electroencephalography (EEG) sensor, or a combination thereof, and one or more electrical stimulation electrodes. A local controller receives a requested stimulation parameter and a readiness classification derived from the sensor signals relative to a session-specific baseline, clamps the requested parameter to a locally stored, non-remotely-increasable safety ceiling, and delivers stimulation according to one of a plurality of ordered parameter sets that progressively reduce amplitude and/or duty cycle as the classification advances toward a target state associated with a reduction in physiological arousal, such as a sleep-onset state. Responsive to a stale or missing readiness classification, the local controller autonomously transitions stimulation to a predetermined safe state independent of continued wireless communication. In certain embodiments the classification is derived without an EEG signal, using pulse-derived heart-rate variability, motion-derived stillness, and a skin-temperature trend gated on multi-condition, multi-interval agreement; in other embodiments an EEG-derived feature confirms or substitutes for the pulse-derived classification. In illustrated embodiments the body is a sleep mask.