ASSIGNMENT

For good and valuable consideration, the receipt of which is hereby acknowledged, the person(s) named below, Skylar Payne of Santa Monica, California, Jeremy Leach of Long Island City, New York, Crystal Chi Ting Huang of West Warwick, Rhode Island, and Zakery Clarke of New York, New York (referred to as "INVENTOR" whether singular or plural) has sold, assigned, and transferred and does hereby sell, assign, and transfer to Health Rhythms, Inc., a corporation of Delaware, having a business address of 28-07 Jackson Avenue, Long Island City, New York, NY 11101 ("ASSIGNEE"), for itself and its successors, transferees, and assignees, the following:

1. The entire worldwide right, title, and interest in and to all inventions and improvements ("SUBJECT MATTER") that are disclosed in the following provisional patent application filed under 35 U.S.C. § 111(b), non-provisional patent application filed under 35 U.S.C. § 111(a), international patent application filed according to the Patent Cooperation Treaty (PCT), or U.S. national-phase patent application filed under 35 U.S.C. § 371 ("APPLICATION"):

   Application ____________, filed ______________, titled "METHOD TO DYNAMICALLY SCHEDULE MEASUREMENT OF PATIENTS FOR BEHAVIORAL HEALTH EVALUATIONS" (Attorney Docket No. 089664.0124);

2. The entire worldwide right, title, and interest in and to: (a) the APPLICATION; (b) all patent applications that claim priority to or from the APPLICATION; (c) all patent applications that the APPLICATION claims priority to or from; (d) all provisional, utility, divisional, continuation, substitute, renewal, reissue, and other patent applications related thereto which have been or may be filed in the United States or elsewhere in the world; (e) all patents (including reissues and re-examinations) which may be granted on the patent applications set forth in (a), (b), (c), or (d) above; and (f) all right of priority in the APPLICATION and in any underlying provisional or foreign patent application, together with all rights to recover damages for infringement of provisional rights.

INVENTOR agrees that ASSIGNEE may apply for and receive patents for SUBJECT MATTER in ASSIGNEE's own name.

INVENTOR agrees to do the following, when requested, and without further consideration, in order to carry out the intent of this Assignment: (1) execute all oaths, assignments, powers of attorney, applications, and other papers necessary or desirable to fully secure to ASSIGNEE the rights, titles and interests herein conveyed; (2) communicate to ASSIGNEE all known facts relating to the SUBJECT MATTER; and (3) generally do all lawful acts that ASSIGNEE shall consider desirable for securing, maintaining, and enforcing worldwide patent protection relating to the SUBJECT MATTER and for vesting in ASSIGNEE the rights, titles, and interests herein conveyed. INVENTOR further agrees to provide any successor, assign, or legal representative of ASSIGNEE with the benefits and assistance provided to ASSIGNEE hereunder.

INVENTOR represents that INVENTOR has the rights, titles, and interests to convey as set forth herein, and covenants with ASSIGNEE that the INVENTOR has not made and will not hereafter make any assignment, grant, mortgage, license, or other agreement affecting the rights, titles, and interests herein conveyed.

INVENTOR grants the attorney of record the power to insert on this Assignment any further identification that may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

This Assignment may be executed in one or more counterparts, each of which shall be deemed an original and all of which may be taken together as one and the same Assignment.

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METHOD TO DYNAMICALLY SCHEDULE MEASUREMENT OF PATIENTS FOR BEHAVIORAL HEALTH EVALUATIONS

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TECHNICAL FIELD

[0002] One technical field of the present disclosure is computer-implemented methods of &&.

BACKGROUND

[0003] The approaches described in this section are approaches that could be pursued, but not necessarily approaches that have been previously conceived or pursued. Therefore, unless otherwise indicated, it should not be assumed that any of the approaches described in this section qualify as prior art merely by virtue of their inclusion in this section.

[0004] Measurement-based care (MBC) uses patient data to inform treatment decisions, improving the quality of care and patient outcomes. MBC is a core component of many evidence-based practices. MBC is on the rise in mental health care. However there are serious challenges with available tools for measurement in mental health, such as adherence, sparsity, and bias.

[0005] Effective MBC requires taking measurement at a time when an intervention is feasible, that is, when the measurement device has a significant enough rating to warrant an intervention and it is taken early enough to apply the intervention. For example, if a patient’s rating on a patient health questionnaire (PHQ) demonstrates low symptom severity, the patient is stable, and likely needs no further intervention. On the other hand, if a rating of a patient indicates a high symptom severity less than an hour before they are hospitalized, a preventive intervention typically is impractical or impossible. Therefore, effective measurement must capture when significant changes occur early enough.

[0006] The current state of measurement in mental health is to periodically request responses to patient reported outcome measures ("PROMs" or "PROs"). In a typical healthcare setting, clinicians typically request PROMs or PROs on a set cadence or at the time of an appointment. But patients typically have appointments every three to four months, and patients still miss 20% of appointments on average.

[0007] Patients may not reach out for help if they experience a decline in their condition between scheduled appointments, and the timing of these appointments is not necessarily linked to the severity of their symptoms. Patients who are stable may do well with these regularly scheduled appointments. However, some patients experience fluctuations in their condition that can be missed by fixed appointments, and these patients may benefit from earlier intervention. Unfortunately, standard scheduling methods may not be effective at identifying these patients.

[0008] Relevant references include Fortney, J. C., Unützer, J., Wrenn, G., Pyne, J. M., Smith, G. R., Schoenbaum, M., & Harbin, H. T. (2017). A Tipping Point for Measurement-Based Care. *Psychiatric Services*, *68*(2), 179–188. https://doi.org/10.1176/appi.ps.201500439; Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2001). The PHQ-9. *Journal of General Internal Medicine*, *16*(9), 606–613. https://doi.org/10.1046/j.1525-1497.2001.016009606.x; Mitchell, A. J., & Selmes, T. (2007). Why don't patients attend their appointments? Maintaining engagement with psychiatric services. *Advances in Psychiatric Treatment*, *13*(6), 423–434. https://doi.org/10.1192/apt.bp.106.003202; Wang, P. S., Lane, M., Olfson, M., Pincus, H. A., Wells, K. B., & Kessler, R. C. (2005). Twelve-Month Use of Mental Health Services in the United States: Results From the National Comorbidity Survey Replication. *Archives of General Psychiatry*, *62*(6), 629. https://doi.org/10.1001/archpsyc.62.6.629.

[0009] Therefore, the technical field of device-based healthcare measurement has developed an acute need for better ways to schedule measurements, questionnaires, or surveys of patients via end-user mobile devices. A core concern is better technical measures for predicting when to request patients or users to provide or complete measurements.

BRIEF DESCRIPTION OF DRAWINGS

[0010] FIG. 1A illustrates a distributed computer system with which one embodiment could be implemented.

[0011] FIG. 1B illustrates a data flow diagram illustrating a set of operations that can be programmed as part of the inference logic of FIG. 1A.

[0012] FIG. 2 is a flow diagram of the programming that was deployed in a trial setting.

[0013] FIG. 3 illustrates a graph of the output of an example depression model.

[0014] FIG. 4 illustrates a computer system with which an embodiment can be implemented.

SUMMARY

[0015] The appended claims may serve as a summary of the invention.

DETAILED DESCRIPTION

[0016] 1. STRUCTURAL AND FUNCTIONAL OVERVIEW

[0017] 1.1 GENERAL OVERVIEW

[0018] In the following description, for the purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be apparent, however, that the present invention may be practiced without these specific details. In other instances, well-known structures and devices are shown in block diagram form in order to avoid unnecessarily obscuring the present invention.

[0019] The text of this disclosure, in combination with the drawing figures, is intended to state in prose the algorithms that are necessary to program a computer to implement the claimed inventions, at the same level of detail that is used by people of skill in the arts to which this disclosure pertains to communicate with one another concerning functions to be programmed, inputs, transformations, outputs and other aspects of programming. That is, the level of detail set forth in this disclosure is the same level of detail that persons of skill in the art normally use to communicate with one another to express algorithms to be programmed or the structure and function of programs to implement the inventions claimed herein.

[0020] One or more different inventions may be described in this disclosure, with alternative embodiments to illustrate examples. Other embodiments may be utilized and structural, logical, software, electrical and other changes may be made without departing from the scope of the particular inventions. Various modifications and alterations are possible and expected. Some features of one or more of the inventions may be described with reference to one or more particular embodiments or drawing figures, but such features are not limited to usage in the one or more particular embodiments or figures with reference to which they are described. Thus, the present disclosure is neither a literal description of all embodiments of one or more of the inventions nor a listing of features of one or more of the inventions that must be present in all embodiments.

[0021] Headings of sections and the title are provided for convenience but are not intended as limiting the disclosure in any way or as a basis of interpreting the claims. Devices that are described as in communication with each other need not be in continuous communication with each other, unless expressly specified otherwise. In addition, devices that are in communication with each other may communicate directly or indirectly through one or more intermediaries, logical or physical.

[0022] A description of an embodiment with several components in communication with one other does not imply that all such components are required. Optional components may be described to illustrate a variety of possible embodiments and to better illustrate one or more aspects of the invention. Similarly, although process steps, method steps, algorithms or the like may be described in a sequential order, such processes, methods, and algorithms may generally be configured to work in different orders, unless specifically stated to the contrary. Any sequence or order of steps described in this disclosure is not a required sequence or order. The steps of described processes may be performed in any order practical. Further, some steps may be performed simultaneously. The illustration of a process in a drawing does not exclude variations and modifications, does not imply that the process or any of its steps are necessary to one or more of the invention(s), and does not imply that the illustrated process is preferred. The steps may be described once per embodiment but need not occur only once. Some steps may be omitted in some embodiments or some occurrences, or some steps may be executed more than once in a given embodiment or occurrence. When a single device or article is described, more than one device or article may be used in place of a single device or article. Where more than one device or article is described, a single device or article may be used in place of the more than one device or article.

[0023] The functionality or the features of a device may be alternatively embodied by one or more other devices that are not explicitly described as having such functionality or features. Thus, other embodiments of one or more of the inventions need not include the device itself. Techniques and mechanisms described or referenced herein will sometimes be described in singular form for clarity. However, it should be noted that particular embodiments include multiple iterations of a technique or multiple manifestations of a mechanism unless noted otherwise. Process descriptions or blocks in figures should be understood as representing modules, segments, or portions of code which include one or more executable instructions for implementing specific logical functions or steps in the process. Alternate implementations are included within the scope of embodiments of the present invention in which, for example, functions may be executed out of order from that shown or discussed, including substantially concurrently or in reverse order, depending on the functionality involved.

[0024] The drawing figures and all of the description and claims in this disclosure, are intended to present, disclose and claim a technical system and technical methods in which specially programmed computers, using a special-purpose distributed computer system design, execute functions that have not been available before to provide a practical application of computing technology to the problem(s) identified in the Background In this manner, the disclosure presents a technical solution to a technical problem, and any interpretation of the disclosure or claims to cover any judicial exception to patent eligibility, such as an abstract idea, mental process, method of organizing human activity or mathematical algorithm, has no support in this disclosure and is erroneous. Each flow diagram or description of a process or algorithm is intended to illustrate aspects of the invention at the functional level at which skilled persons, in the art to which this disclosure pertains, communicate with one another to implement algorithms using programming. The flow diagrams are not intended to illustrate every instruction, method object or sub-step that would be needed to program every aspect of a working program but are provided at the same functional level of illustration that is normally used at the high level of skill in this art to communicate the basis of developing working programs.

[0025] 1.2 DISTRIBUTED COMPUTER SYSTEM EXAMPLE

[0026] FIG. 1A illustrates a distributed computer system with which one embodiment could be implemented. In one embodiment, a distributed computer system 110 comprises a health analytics server 112 that is communicatively coupled via network 114 to a plurality of different mobile computing devices 116, each hosting a mobile application 118 that is compatible with functional elements of the health analytics server. For purposes of illustrating a clear example, elements 116 are identified and described as mobile computing devices, and could include smartphones, tablet computers, smart watches, smart rings, laptop computers, or any other computer that implements a location service capable of determining a then-current geophysical location of the computing device in space. Location services can be implemented in the operating systems of the mobile computing devices interoperating with global positioning system (GPS) receivers and/or wireless networking transceivers. Each of the mobile computing devices 116 include a plurality of hardware sensors, as further described in other sections.

[0027] For purposes of illustrating a clear example, FIG. 1A shows two mobile computing devices 116, but in other embodiments, hundreds to millions of devices could be used depending upon the processing power of the health analytics server 120.

[0028] In various embodiments, the health analytics server 120 can be deployed as a server computer, multiprocessor computer, or server cluster in a private datacenter, or as one or more virtual machine instances in any of a public or private datacenter. For example, one or more computing instances and storage instances of public commercial cloud computing centers like GOOGLE CLOUD, MICROSOFT AZURE, AMAZON WEB SERVICES can be used. In one embodiment health analytics server 120 is communicatively coupled to a database 122 that is configured or programmed to digitally store inference data 124, one or more questionnaires 126, one or more suggestions 128, self-report scores 130, and subject records 132. The database 122 can be configured or organized as a relational database, object store, no-SQL database, or flat file system.

[0029] Network 114 broadly represents any combination of local area networks, wide area networks, campus networks, and/or internetworks using any of wired or wireless, satellite or terrestrial network links, and can include the public internet.

[0030] In an embodiment, the mobile device application or app 118 is programmed to passively collect and store raw sensor data 134 comprising digital signals relating to, for an individual: sleep; location; physical activity; device usage; metadata; diagnostic data; raw data summary; phone authorizations. Signals relating to the foregoing attributes or categories are digitally stored on-device in app memory. The mobile device app can be programmed to analyze the signal data and to detect vital clinical signals such as increased isolation, reduced mobility, and disrupted sleep, and to store the raw sensor data 134 on-device in app memory or app storage organized as a database, set of tables, or set of files. Or, the signal data can be collected, de-identified, encrypted or otherwise secured, and transmitted via network 114 to the health analytics server 120 that hosts a health analysis application 136 organized as one or more programs to execute the detection of clinical signals, and stored in the database 122. In either case, the collection, storage, and analysis of signal data is conducted on a de-identified basis to ensure that signal data, if compromised, cannot identify an individual user of the mobile computing device 116.

[0031] In one embodiment, the mobile device app 118 and/or health analysis application 136 are programmed to collect the foregoing data signals continuously, and to provide alerts when significant deviations occur from personalized baselines, as well as trend indicators. In some embodiments, mobile app 118 can generate self-report scores 130 that contribute to the database 122 for use in data transformation or analytical operations. The mobile app 118 can be programmed to generate and display question sets or questionnaires to the mobile computing device 116, receive input from the user, and generate the self-report scores 130 for reporting over the network 114 to the health analytics server 120.

[0032] In an embodiment, health analysis application 136 comprises inference logic 138 and risk stratification logic 140, each of which can be implemented as a set of stored program instructions that implement the functions that are further described herein in other sections. In various embodiments, the inference logic 138 can be programmed to receive or read raw sensor data 134, execute one or more algorithms or methods to transform the raw sensor data, and produce inference data 124 as output for storage in the database 122. In an embodiment, the inference logic 138 is programmed to read the inference data 124 and transform the inference data into one or more questionnaires 126, and/or one or more suggestions 128.

[0033] In an embodiment, the risk stratification logic 140 is programmed to read inference data 124 and execute one or more algorithms or methods to transform the inference data into a score value selected from among a plurality of score values in a hierarchy or strata of risk values. A risk value derived or inferred for a particular subject or user of a mobile computing device 116 can be created and stored as an attribute of a subject record, among a plurality of subject records 132 stored in the database 122, corresponding to the user or subject. The inference logic 138 and the risk stratification logic 140 are merely examples of substantive functions or applications that can be integrated into the health analysis application 136, and other embodiments may have different logic, functions, or applications.

[0034] A healthcare provider computer 130 can be communicatively coupled via network 114 to the health analytics server 120. The healthcare provider computer 142 can be used by or associated with a care team member who provides care to one or more users of the mobile computing devices 116. In an embodiment, health analytics server 120 is programmed to generate reports and views of the subject records 132 that include questionnaires 126, suggestions 128, inference data 124, score values, and other information or data that is transformed from or derived from the raw sensor data 134.

[0035] 1.3 DATA FLOW EXAMPLES

[0036] In one embodiment, the system 110 is programmed to use mobile sensing and digital phenotyping techniques to build machine-learned models across multiple sites of data which are used to predict significant changes in symptomatology across a number of conditions: depression, anxiety, suicidality, and mania. FIG. 1B illustrates a data flow diagram illustrating a set of operations that can be programmed as part of the inference logic of FIG. 1A. In an embodiment, as discussed above for FIG. 1A, a mobile computing device 116 periodically contributes raw sensor data values to the database 122. In an embodiment, at block 160, the inference logic 138 is programmed to execute inference processing to produce clinically meaningful inferences, such as sleep wakeup time, from raw sensor data, and represented in inference data that can be stored in the database 122. Examples of inferences are described further in a separate section below.

[0037] Control transfers to block 162 in which the inference logic 138 is programmed to execute aggregation of the inference data to produce aggregations of inferences over specified time windows, such as the variance over the last fourteen days, or a *t*-test between the past seven days and the period of time since the last measurement occurred. The use of *t*-tests is described further in another section below.

[0038] At block 164, the inference logic 138 is programmed to execute one or more data-driven heuristics or modeling. The aggregations of inferences are used to build heuristics and programmatic models that can determine when a measurement should occur. The resulting heuristics and models can output one or more rules or other configuration 166 that drive or control how frequently measurement must or can be done to support various use cases.

[0039] At block 168, the inference logic 138 is programmed to test whether the user associated with the mobile computing device 116 needs to conduct a measurement, based on the rules or configuration 166 in the context of the heuristics or models of block 164. At block 170, access measurement functions can occur via calls of the mobile app 118 to an application programming interface, a push notification to the mobile computing device 116, or via integration with the EHR 144.

[0040] All models of block 164 are built from datasets built across multiple sites and use cases including university research studies, pharmaceutical trials, and healthcare settings. All datasets contain a suite of clinically validated behavioral inferences built on top of mobile sensed data such as: sleep duration, location entropy, step count, etc. All models take inspiration from a circadian rhythm model of health, viewing many of these behaviors as having rhythms that are generally, but not limited to circadian cycles, where disruptions to these rhythms indicate changes in symptom severity. Because each supported condition has a different profile of symptomatology, each model has a different set of features which are deemed important.

[0041] Our features are computed first as a daily summary to map various raw data received from the mobile computing device 116 into clinically meaningful inferences at block 160. For example, the display status of the device 116 can be combined with activity data received from sensors of the device to determine when an individual is asleep. Thereafter, the inference logic 138 is programmed at block 162 to aggregate these daily features over various time windows: 7 days, 14 days, 28 days, etc. Additionally the inference logic 138 is programmed to use variations of these time windows to explicitly only consider either weekdays or weekends, thus providing an approximation of working days versus days off. In an embodiment, the most informative or predictive features for the models of block 164 are:

[0042] For DEPRESSION: Sleep end time, location entropy, Time at home, Travel diameter, Previous PHQ8 total score value.

[0043] For ANXIETY: Number of screen unlocks; First time leaving home; Sleep end time; Duration of screen unlock; Steps relative amplitude.

[0044] For SUICIDALITY: Sleep routine index; Last time arriving home; Number of location clusters.

[0045] For MANIA: Sleep end time.

[0046] Each of these models is predicting whether an individual will provide a significant measurement, defined as either: A significant change in symptom severity; e.g. a change of 5 points on the PHQ scale; a significant score which is clinically significant on its own, such as an affirmative response to question 6 on the Columbia Suicide Risk Scale (CSRS), indicating suicidal intent. When an individual will provide a significant measurement, the individual may need a change in intervention. For example, if a person begins to score much more highly on the PHQ, a change of medication, increase of dosage, or different therapeutic modality, may be required.

[0047] By using these models to determine which individuals should be measured, embodiments are programmed to maximize the ability to capture changes in clinical need. The these models can be triggered either when there is high confidence that one of the above criteria are met, or if the model has low confidence overall to ensure future iterations of the model can be improved over populations where it is uncertain. A great benefit of embodiments are that they are independent of the type of measurement device that the clinician uses or has deployed to patients. Embodiments can optimize the application of the measurement device that is already integrated into clinical workflows. This simplifies integration with existing systems. Lastly, the downstream measurement device limits the risk of false positives.

[0048] In an embodiment, the inference logic 138 and/or other elements of the application server computer are programmed to accept updates to configuration values that can change program operation in selected aspects. For example, updates to configuration values can change: How aggressively measurement is triggered (depending on the cost/risk of false positives vs false negatives); How frequently measurement must be triggered (e.g. to meet risk/compliance needs); How frequently measurement can be triggered to ensure that patients respond; Additional rules or restrictions on when to trigger measurement based on key demographics such as sex assigned at birth, age, diagnoses, etc.; How frequently to randomly request measurement

[0049] 1.4 EXAMPLE DEPLOYMENTS

[0050] An embodiment was deployed in a healthcare setting with an integrated delivery care network with a trial group of about 100 patients. The system was integrated to trigger the following measurement devices: A combined Patient Health Questionnaire (PHQ-9) and Columbia Suicide Rating Scale (CSRS) for depression/suicidality; The Generalized Anxiety Disorder rating scale (GAD-7) for anxiety; The Altman rating scale for manic episodes of bipolar disorder. Because the measurements were self-reported, any serious self-reported changes would trigger an alert to a 24/7 behavioral healthcare team.

[0051] FIG. 2 is a flow diagram of the programming that was deployed in a trial setting. The data flow of FIG. 1B was used, except that when the test of block 168 yielded an affirmative, YES, or TRUE result, at block 202, the inference logic 138 was programmed to send a PROM, such as the PHQ, to the mobile computing device 116. At block 204, the inference logic 138 was programmed to test whether the data associated with the user of the mobile computing device 116 indicated a significant rating, based on the criteria noted above. If the result was affirmative, YES, or TRUE, then at block 206, the inference logic 138 was programmed to alert a behavioral health center. Block 206 can be programmed, in an embodiment, using user- or clinician-customized rule sets to allow alerting clinical staff when the measurement device of block 202 triggers any rule indicating a significant rating or other result of interest.

[0052] The system triggered measurement for the one patient in the pilot who had shown suicidal intent as measured by the CSRS. Thus, the use of an embodiment ensured that someone from the clinical team could follow up in a timely fashion to provide the needed elevated care.

[0053] A key challenge of integrating AI systems into healthcare is developing trust in the AI solution. By keeping the prior measurement device in place at block 202, the system can reduce concern of false positives overloading clinical staff.

[0054] Embodiments also can be programmed to provide a digital companion to a pharmaceutical product. A rise in the prescription and use of fast-acting antidepressants has led to a need for trustworthy measurement. Because the drugs are fast-acting, the optimal dosing cycle must be considered carefully, and is not necessarily the same for each individual. Trials of such drugs often use a scalable, self-reported measure such as the PHQ to indicate if symptom severity is increasing, and if so, a clinician reported outcome measure such as the Hamilton Depression Rating Scale (HRDS) is used to determine whether to re-dose on a particular patient.

[0055] The models of the embodiments of this disclosure can successfully identify likely periods where a re-dose is needed in a pharmaceutical trial for a fast-acting antidepressant. FIG. 3 illustrates a graph of the output of an example depression model. In the graph 302, the Y-axis shows a health level pertaining to depression and is scaled to be between 0 and 100, where 100 is "most healthy," and the X-axis shows time at arbitrary, example dates. A region 304, starting at the low point of a decline in health condition, shows where a re-dose could occur.

[0056] 2. INFERENCE DEFINITIONS

[0057] In various embodiments, inference processing at block 160 (FIG. 1B) can comprise automatic, programmatic calculation of some or all of the following inference data values:

[0058] Sleep end time (i.e. Wake up time). To create proxies for sleep end time (also sleep start time), embodiments can be programmed with an algorithm to label each five-minute epoch as active (i.e., unlocked and/or moving for any portion of the time) or idle. After applying a moving average, embodiments can be programmed to identify the longest period of time during which the phone is idle; this is defined as the main sleep period, with the start and end of that period defined as sleep start and end.

[0059] Because this proxy for sleep time subtly assumes a person uses their phone right after they wake up, the algorithm may overestimate how long a person slept if they do not use their phone immediately after waking. To correct for this, embodiments can be programmed to additionally collect self-reported sleep information from the user to continuously measure the error of the algorithm and personalize the sleep end time by adding some measure of central tendency of the error to the raw algorithm's output.

[0060] For example, assume that embodiments are programmed to consistently output that you wake up at 10 AM, but the user actually wakes up at 8 AM and doesn't use their phone for two hours. If the user reports the real wake up time to be 8 AM, the error would be two hours and an adjustment can be applied in the future.

[0061] Location entropy. Location Entropy is computed as $LE = -\sum_{c=1}^{C} \quad p_c \, ln \, ln \, p_c$, where pc is the percentage of time that the user spent within location cluster c over the past 14 days. A 'location cluster' is initially defined by a latitude/longitude pair at which the user spent a minimum of 5 minutes. The duration of time spent at any other location within 500 meters of the centroid of location cluster c is added to the total duration at location cluster c. In this situation, the cluster's centroid is updated from its previous centroid (initialized by the first latitude/longitude pair visited in that cluster) to the mean of that centroid and the newly visited location. If a new location is visited for more than five minutes which is more than 500 meters from an existing centroid, this location initializes a new cluster. The location entropy ranges from 0 (spending the prior 14-day period at home) to lnI, where C is the number of location clusters visited. The maximum value occurs when an equal proportion of time was spent at each of the C location clusters. Embodiments are programmed to computed the mean location entropy of the days week prior to (and including) each PHQ-8 report. Participants in the analytic sample had a mean (SD) of 7.40 (1.42) repeated PHQs observations with 5+ days with location entropy observed up to 7 days prior.

[0062] Time at home. “Home” is inferred as the location an individual spent the most time at in the last 14 days, where anything within 100 meters is determined to be the same location. Time at home is the duration of time during which embodiments infer a user to be at the inferred “home” location.

[0063] Travel diameter. The largest distance (in meters) between two significant locations. A “significant” location is a location that an individual spent at least 5 minutes at and is 500 meters or more away from other significant locations.

[0064] Number of screen unlocks. Count of transitions from “screen locked” to “screen unlocked” status; effectively indicating a smartphone user has entered their PIN or used some other personal key to interact with their device.

[0065] First time leaving home. “Home” is inferred as the location an individual spent the most time at in the last 14 days, where anything within 100 meters is determined to be the same location.

[0066] First time arriving home is the first time a recorded location event was within 100 m of the inferred “home” on a particular day.

[0067] (Average) Duration of screen unlock. The amount of time between an unlock status and successive lock status.

[0068] Steps relative amplitude. A relative difference of the M10 and L5 inferences using the following calculation: (M10−L5)/(M10+L5), where: M10: A weighted mean of a user’s step counts during their most active 10 hours of the day; M5: A weighted mean of a user’s step counts during their least active 5 hours of the day. It is possible for this to overlap with sleep time, but is unlikely to be entirely sleep as embodiments are programmed to identify the least active 5 hours nearest the most active 10 hours.

[0069] Sleep routine index. Assesses the probability that an individual is awake (vs. asleep) at any two time points 24 h apart. A score of 0 implies total random sleep and wake times. A score of 1.0 implies an individual sleeps and wakes at exactly the same time. Uses previously defined sleep end time (with corresponding sleep start time) to infer when an individual is sleeping on a particular day. It computes a signal of sleep/wake at the minute granularity and compares each consecutive day for the proportion of minutes with the same status (i.e. sleep or wake). The arithmetic mean of this day-to-day proportion is the sleep routine index.

[0070] Last time arriving home. “Home” is inferred as the location an individual spent the most time at in the last 14 days, where anything within 100 meters is determined to be the same location. Last time arriving home is the last time a recorded location event was within 100 m of the inferred “home” on a particular day.

[0071] Number of location clusters. The number of significant locations a user visited, where a significant location is defined as a location where the user spent a minimum of 5 minutes and is at least 500 m away from another significant location.

[0072] 3. FEATURE ENGINEERING

[0073] The inferences described above provide day-to-day insight into a person’s behavior across many behavioral domains such as sleep, physical activity, and social activity. However, a person’s symptom severity at any particular time relates to more than just these domains on that day; it relates to patterns of behavior across those domains in the time leading up to that day. The embodiments can be programmed to use aggregations, such as arithmetic mean or standard deviation, to combine inferences. The embodiments are programmed to use many window sizes to capture behavioral context at different frequencies, such as: 7-days to capture context over the past week; 14-days to capture context over the past two weeks (a common lookback period for PROMs such as the PHQ); 28-days to capture context over the past month or approximation of a month.

[0074] In an embodiment, the inference logic 138 is programmed to align these windows to a full multiple of seven days as there can be day of week differences. In one embodiment, the inference logic 138 is programmed additionally to use windows which look at either only weekdays or weekends as a crude approximation for “working days” vs. “days off”.

[0075] In an embodiment, the inference logic 138 is programmed to use rolling *t*-tests to compare the distribution of an inference over two different time periods to assess the difference between them. For example, the inference logic 138 may compute a *t*-test on the sleep end time over the past week vs the preceding 3 weeks (total of 28 days of data). This is effectively determining “change in baseline”, where the 3 weeks are used to establish the baseline. For these *t*-tests, the inference logic 138 can be programmed to specify an additional window as a reference distribution. In addition to the window selection methods described above, embodiments can be programmed to execute the following to select a reference window: take K days preceding the last measurement (e.g. PHQ); take K days preceding a gap of G days before the start of the window (e.g. days 0 to 14 as reference and days 16 to 30 for K=14 and G=2).

[0076] 4. IMPLEMENTATION EXAMPLE – HARDWARE OVERVIEW

[0077] According to one embodiment, the techniques described herein are implemented by at least one computing device. The techniques may be implemented in whole or in part using a combination of at least one server computer and/or other computing devices that are coupled using a network, such as a packet data network. The computing devices may be hard-wired to perform the techniques or may include digital electronic devices such as at least one application-specific integrated circuit (ASIC) or field programmable gate array (FPGA) that is persistently programmed to perform the techniques or may include at least one general purpose hardware processor programmed to perform the techniques pursuant to program instructions in firmware, memory, other storage, or a combination. Such computing devices may also combine custom hard-wired logic, ASICs, or FPGAs with custom programming to accomplish the described techniques. The computing devices may be server computers, workstations, personal computers, portable computer systems, handheld devices, mobile computing devices, wearable devices, body mounted or implantable devices, smartphones, smart appliances, internetworking devices, autonomous or semi-autonomous devices such as robots or unmanned ground or aerial vehicles, any other electronic device that incorporates hard-wired and/or program logic to implement the described techniques, one or more virtual computing machines or instances in a data center, and/or a network of server computers and/or personal computers.

[0078] FIG. 4 is a block diagram that illustrates an example computer system with which an embodiment may be implemented. In the example of FIG. 4, a computer system 400 and instructions for implementing the disclosed technologies in hardware, software, or a combination of hardware and software, are represented schematically, for example as boxes and circles, at the same level of detail that is commonly used by persons of ordinary skill in the art to which this disclosure pertains for communicating about computer architecture and computer systems implementations.

[0079] Computer system 400 includes an input/output (I/O) subsystem 402 which may include a bus and/or other communication mechanism(s) for communicating information and/or instructions between the components of the computer system 400 over electronic signal paths. The I/O subsystem 402 may include an I/O controller, a memory controller and at least one I/O port. The electronic signal paths are represented schematically in the drawings, for example as lines, unidirectional arrows, or bidirectional arrows.

[0080] At least one hardware processor 404 is coupled to I/O subsystem 402 for processing information and instructions. Hardware processor 404 may include, for example, a general-purpose microprocessor or microcontroller and/or a special-purpose microprocessor such as an embedded system or a graphics processing unit (GPU) or a digital signal processor or ARM processor. Processor 404 may comprise an integrated arithmetic logic unit (ALU) or may be coupled to a separate ALU.

[0081] Computer system 400 includes one or more units of memory 406, such as a main memory, which is coupled to I/O subsystem 402 for electronically digitally storing data and instructions to be executed by processor 404. Memory 406 may include volatile memory such as various forms of random-access memory (RAM) or other dynamic storage device. Memory 406 also may be used for storing temporary variables or other intermediate information during execution of instructions to be executed by processor 404. Such instructions, when stored in non-transitory computer-readable storage media accessible to processor 404, can render computer system 400 into a special-purpose machine that is customized to perform the operations specified in the instructions.

[0082] Computer system 400 further includes non-volatile memory such as read only memory (ROM) 408 or other static storage device coupled to I/O subsystem 402 for storing information and instructions for processor 404. The ROM 408 may include various forms of programmable ROM (PROM) such as erasable PROM (EPROM) or electrically erasable PROM (EEPROM). A unit of persistent storage 410 may include various forms of non-volatile RAM (NVRAM), such as FLASH memory, or solid-state storage, magnetic disk or optical disk such as CD-ROM or DVD-ROM and may be coupled to I/O subsystem 402 for storing information and instructions. Storage 410 is an example of a non-transitory computer-readable medium that may be used to store instructions and data which when executed by the processor 404 cause performing computer-implemented methods to execute the techniques herein.

[0083] The instructions in memory 406, ROM 408 or storage 410 may comprise one or more sets of instructions that are organized as modules, methods, objects, functions, routines, or calls. The instructions may be organized as one or more computer programs, operating system services, or application programs including mobile apps. The instructions may comprise an operating system and/or system software; one or more libraries to support multimedia, programming or other functions; data protocol instructions or stacks to implement TCP/IP, HTTP or other communication protocols; file format processing instructions to parse or render files coded using HTML, XML, JPEG, MPEG or PNG; user interface instructions to render or interpret commands for a graphical user interface (GUI), command-line interface or text user interface; application software such as an office suite, internet access applications, design and manufacturing applications, graphics applications, audio applications, software engineering applications, educational applications, games or miscellaneous applications. The instructions may implement a web server, web application server or web client. The instructions may be organized as a presentation layer, application layer and data storage layer such as a relational database system using structured query language (SQL) or no SQL, an object store, a graph database, a flat file system or other data storage.

[0084] Computer system 400 may be coupled via I/O subsystem 402 to at least one output device 412. In one embodiment, output device 412 is a digital computer display. Examples of a display that may be used in various embodiments include a touch screen display or a light-emitting diode (LED) display or a liquid crystal display (LCD) or an e-paper display. Computer system 400 may include other type(s) of output devices 412, alternatively or in addition to a display device. Examples of other output devices 412 include printers, ticket printers, plotters, projectors, sound cards or video cards, speakers, buzzers or piezoelectric devices or other audible devices, lamps or LED or LCD indicators, haptic devices, actuators or servos.

[0085] At least one input device 414 is coupled to I/O subsystem 402 for communicating signals, data, command selections or gestures to processor 404. Examples of input devices 414 include touch screens, microphones, still and video digital cameras, alphanumeric and other keys, keypads, keyboards, graphics tablets, image scanners, joysticks, clocks, switches, buttons, dials, slides, and/or various types of sensors such as force sensors, motion sensors, heat sensors, accelerometers, gyroscopes, and inertial measurement unit (IMU) sensors and/or various types of transceivers such as wireless, such as cellular or Wi-Fi, radio frequency (RF) or infrared (IR) transceivers and Global Positioning System (GPS) transceivers.

[0086] Another type of input device is a control device 416, which may perform cursor control or other automated control functions such as navigation in a graphical interface on a display screen, alternatively or in addition to input functions. Control device 416 may be a touchpad, a mouse, a trackball, or cursor direction keys for communicating direction information and command selections to processor 404 and for controlling cursor movement on display 412. The input device may have at least two degrees of freedom in two axes, a first axis (e.g., x) and a second axis (e.g., y), that allows the device to specify positions in a plane. Another type of input device is a wired, wireless, or optical control device such as a joystick, wand, console, steering wheel, pedal, gearshift mechanism or other type of control device. An input device 414 may include a combination of multiple different input devices, such as a video camera and a depth sensor.

[0087] In another embodiment, computer system 400 may comprise an internet of things (IoT) device in which one or more of the output device 412, input device 414, and control device 416 are omitted. Or, in such an embodiment, the input device 414 may comprise one or more cameras, motion detectors, thermometers, microphones, seismic detectors, other sensors or detectors, measurement devices or encoders and the output device 412 may comprise a special-purpose display such as a single-line LED or LCD display, one or more indicators, a display panel, a meter, a valve, a solenoid, an actuator or a servo.

[0088] When computer system 400 is a mobile computing device, input device 414 may comprise a global positioning system (GPS) receiver coupled to a GPS module that is capable of triangulating to a plurality of GPS satellites, determining and generating geo-location or position data such as latitude-longitude values for a geophysical location of the computer system 400. Output device 412 may include hardware, software, firmware and interfaces for generating position reporting packets, notifications, pulse or heartbeat signals, or other recurring data transmissions that specify a position of the computer system 400, alone or in combination with other application-specific data, directed toward host 424 or server 430.

[0089] Computer system 400 may implement the techniques described herein using customized hard-wired logic, at least one ASIC or FPGA, firmware and/or program instructions or logic which when loaded and used or executed in combination with the computer system causes or programs the computer system to operate as a special-purpose machine. According to one embodiment, the techniques herein are performed by computer system 400 in response to processor 404 executing at least one sequence of at least one instruction contained in main memory 406. Such instructions may be read into main memory 406 from another storage medium, such as storage 410. Execution of the sequences of instructions contained in main memory 406 causes processor 404 to perform the process steps described herein. In alternative embodiments, hard-wired circuitry may be used in place of or in combination with software instructions.

[0090] The term "storage media" as used herein refers to any non-transitory media that store data and/or instructions that cause a machine to operation in a specific fashion. Such storage media may comprise non-volatile media and/or volatile media. Non-volatile media includes, for example, optical or magnetic disks, such as storage 410. Volatile media includes dynamic memory, such as memory 406. Common forms of storage media include, for example, a hard disk, solid state drive, flash drive, magnetic data storage medium, any optical or physical data storage medium, memory chip, or the like.

[0091] Storage media is distinct from but may be used in conjunction with transmission media. Transmission media participates in transferring information between storage media. For example, transmission media includes coaxial cables, copper wire and fiber optics, including the wires that comprise a bus of I/O subsystem 402. Transmission media can also take the form of acoustic or light waves, such as those generated during radio-wave and infra-red data communications.

[0092] Various forms of media may be involved in carrying at least one sequence of at least one instruction to processor 404 for execution. For example, the instructions may initially be carried on a magnetic disk or solid-state drive of a remote computer. The remote computer can load the instructions into its dynamic memory and send the instructions over a communication link such as a fiber optic or coaxial cable or telephone line using a modem. A modem or router local to computer system 400 can receive the data on the communication link and convert the data to a format that can be read by computer system 400. For instance, a receiver such as a radio frequency antenna or an infrared detector can receive the data carried in a wireless or optical signal and appropriate circuitry can provide the data to I/O subsystem 402 such as place the data on a bus. I/O subsystem 402 carries the data to memory 406, from which processor 404 retrieves and executes the instructions. The instructions received by memory 406 may optionally be stored on storage 410 either before or after execution by processor 404.

[0093] Computer system 400 also includes a communication interface 418 coupled to bus 402. Communication interface 418 provides a two-way data communication coupling to network link(s) 420 that are directly or indirectly connected to at least one communication networks, such as a network 422 or a public or private cloud on the Internet. For example, communication interface 418 may be an Ethernet networking interface, integrated-services digital network (ISDN) card, cable modem, satellite modem, or a modem to provide a data communication connection to a corresponding type of communications line, for example an Ethernet cable or a metal cable of any kind or a fiber-optic line or a telephone line. Network 422 broadly represents a local area network (LAN), wide-area network (WAN), campus network, internetwork or any combination thereof. Communication interface 418 may comprise a LAN card to provide a data communication connection to a compatible LAN, or a cellular radiotelephone interface that is wired to send or receive cellular data according to cellular radiotelephone wireless networking standards, or a satellite radio interface that is wired to send or receive digital data according to satellite wireless networking standards. In any such implementation, communication interface 418 sends and receives electrical, electromagnetic or optical signals over signal paths that carry digital data streams representing various types of information.

[0094] Network link 420 typically provides electrical, electromagnetic, or optical data communication directly or through at least one network to other data devices, using, for example, satellite, cellular, Wi-Fi, or BLUETOOTH technology. For example, network link 420 may provide a connection through a network 422 to a host computer 424.

[0095] Furthermore, network link 420 may provide a connection through network 422 or to other computing devices via internetworking devices and/or computers that are operated by an Internet Service Provider (ISP) 426. ISP 426 provides data communication services through a world-wide packet data communication network represented as internet 428. A server computer 430 may be coupled to internet 428. Server 430 broadly represents any computer, data center, virtual machine or virtual computing instance with or without a hypervisor, or computer executing a containerized program system such as DOCKER or KUBERNETES. Server 430 may represent an electronic digital service that is implemented using more than one computer or instance and that is accessed and used by transmitting web services requests, uniform resource locator (URL) strings with parameters in HTTP payloads, API calls, app services calls, or other service calls. Computer system 400 and server 430 may form elements of a distributed computing system that includes other computers, a processing cluster, server farm or other organization of computers that cooperate to perform tasks or execute applications or services. Server 430 may comprise one or more sets of instructions that are organized as modules, methods, objects, functions, routines, or calls. The instructions may be organized as one or more computer programs, operating system services, or application programs including mobile apps. The instructions may comprise an operating system and/or system software; one or more libraries to support multimedia, programming or other functions; data protocol instructions or stacks to implement TCP/IP, HTTP or other communication protocols; file format processing instructions to parse or render files coded using HTML, XML, JPEG, MPEG or PNG; user interface instructions to render or interpret commands for a graphical user interface (GUI), command-line interface or text user interface; application software such as an office suite, internet access applications, design and manufacturing applications, graphics applications, audio applications, software engineering applications, educational applications, games or miscellaneous applications. Server 430 may comprise a web application server that hosts a presentation layer, application layer and data storage layer such as a relational database system using structured query language (SQL) or no SQL, an object store, a graph database, a flat file system or other data storage.

[0096] Computer system 400 can send messages and receive data and instructions, including program code, through the network(s), network link 420 and communication interface 418. In the Internet example, a server 430 might transmit a requested code for an application program through Internet 428, ISP 426, local network 422 and communication interface 418. The received code may be executed by processor 404 as it is received, and/or stored in storage 410, or other non-volatile storage for later execution.

[0097] The execution of instructions as described in this section may implement a process in the form of an instance of a computer program that is being executed, and consisting of program code and its current activity. Depending on the operating system (OS), a process may be made up of multiple threads of execution that execute instructions concurrently. In this context, a computer program is a passive collection of instructions, while a process may be the actual execution of those instructions. Several processes may be associated with the same program; for example, opening up several instances of the same program often means more than one process is being executed. Multitasking may be implemented to allow multiple processes to share processor 404. While each processor 404 or core of the processor executes a single task at a time, computer system 400 may be programmed to implement multitasking to allow each processor to switch between tasks that are being executed without having to wait for each task to finish. In an embodiment, switches may be performed when tasks perform input/output operations, when a task indicates that it can be switched, or on hardware interrupts. Time-sharing may be implemented to allow fast response for interactive user applications by rapidly performing context switches to provide the appearance of concurrent execution of multiple processes simultaneously. In an embodiment, for security and reliability, an operating system may prevent direct communication between independent processes, providing strictly mediated and controlled inter-process communication functionality.

[0098] In the foregoing specification, embodiments of the invention have been described with reference to numerous specific details that may vary from implementation to implementation. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. The sole and exclusive indicator of the scope of the invention, and what is intended by the applicants to be the scope of the invention, is the literal and equivalent scope of the set of claims that issue from this application, in the specific form in which such claims issue, including any subsequent correction.

CLAIMS

What is claimed is:

1. A computer-implemented method, as shown and described.

2. A computer-implemented method, as shown and described in any one or more paragraphs of the disclosure and/or one or more of the drawing figures.

3. One or more non-transitory computer-readable storage media storing one or more sequences of instructions which, when executed using one or more processors, cause the one or more processors to execute a computer-implemented method, as shown and described.

4. One or more non-transitory computer-readable storage media storing one or more sequences of instructions which, when executed using one or more processors, cause the one or more processors to execute a computer-implemented method, as shown and described in any one or more paragraphs of the disclosure and/or one or more of the drawing figures.

Fig. 1A

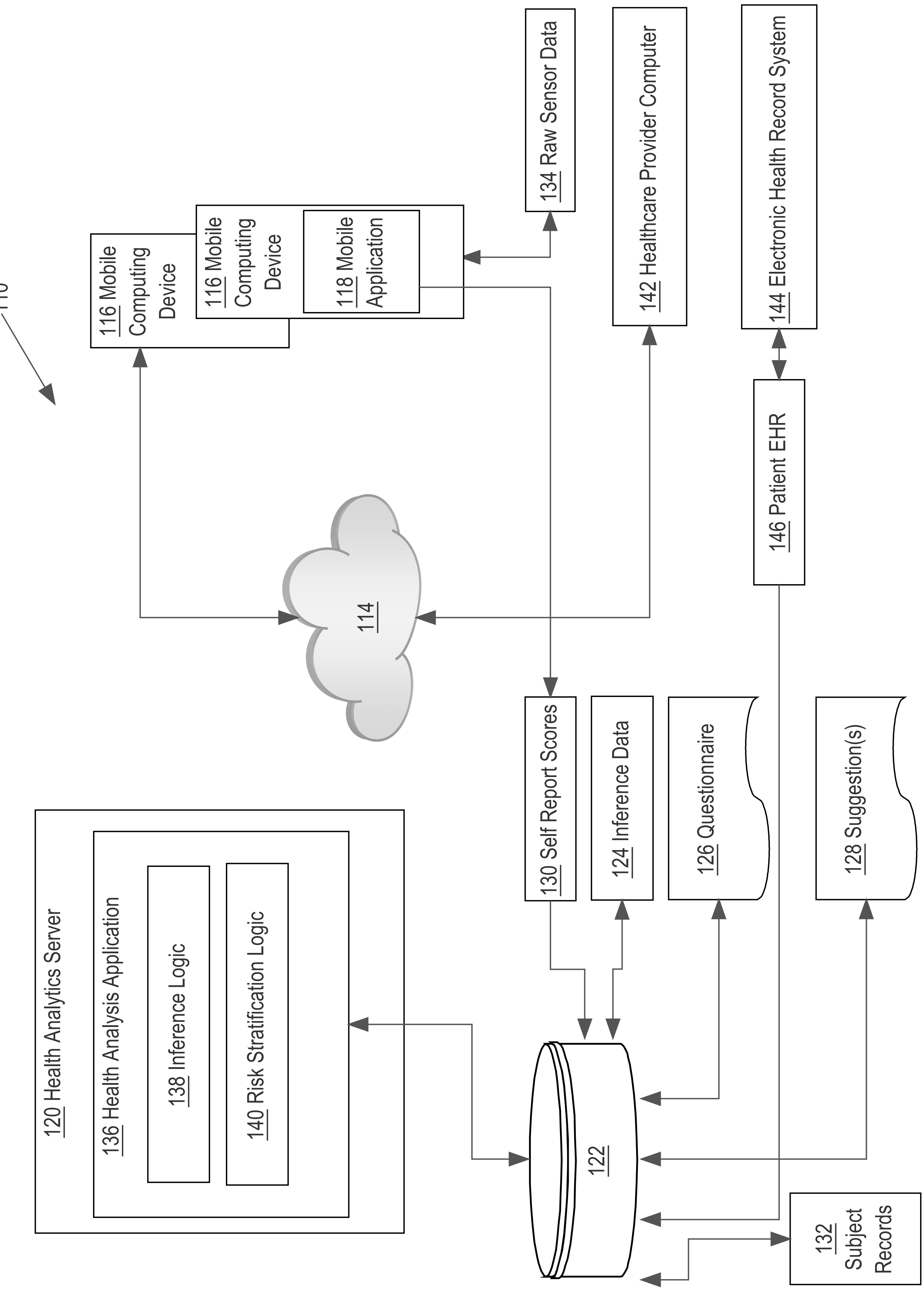

110
116 Mobile Computing Device
116 Mobile Computing Device
118 Mobile Application
134 Raw Sensor Data
142 Healthcare Provider Computer
144 Electronic Health Record System
146 Patient EHR
114
120 Health Analytics Server
136 Health Analysis Application
138 Inference Logic
140 Risk Stratification Logic
130 Self Report Scores
124 Inference Data
126 Questionnaire
128 Suggestion(s)
122
132 Subject Records

Fig. 1B

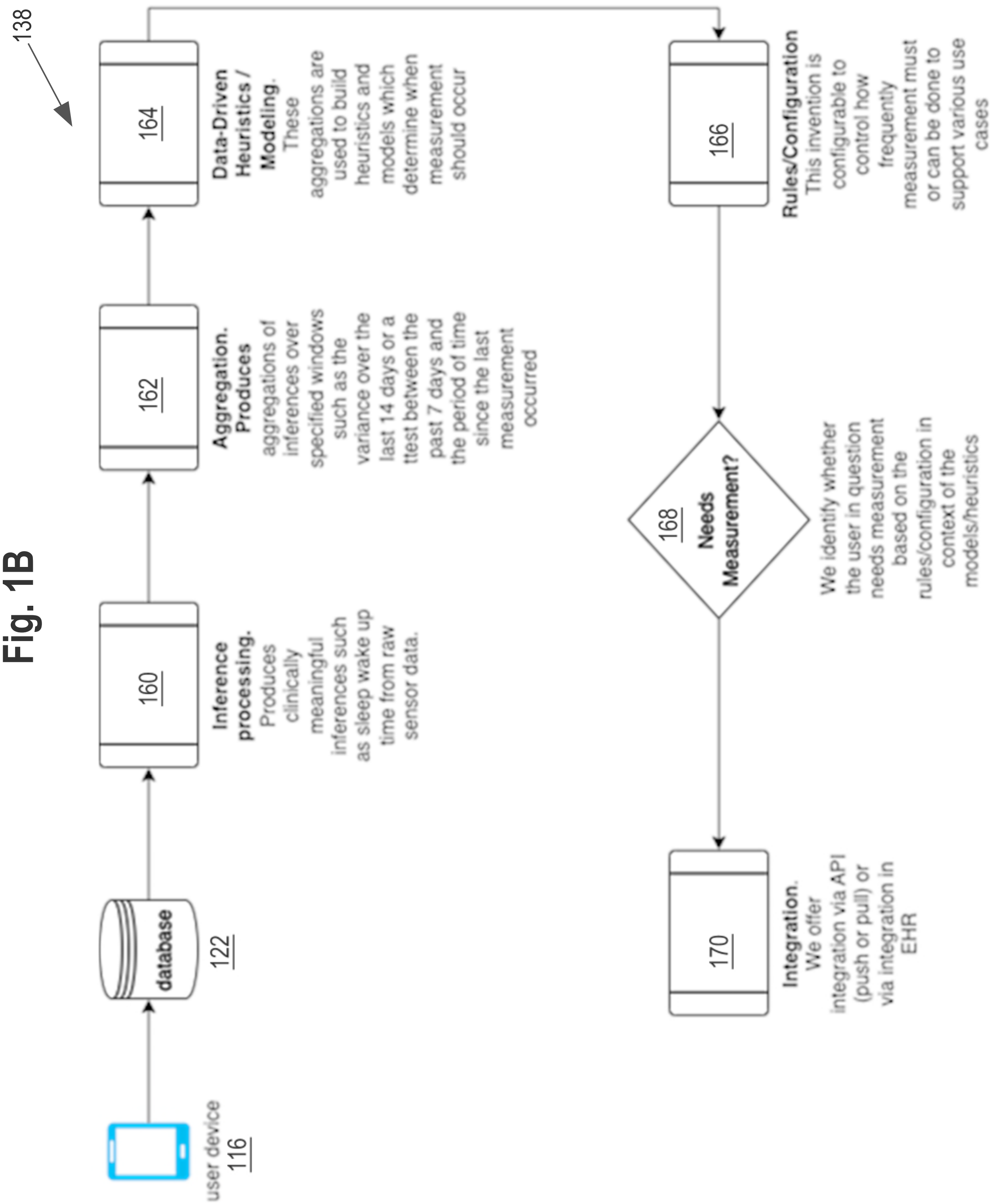
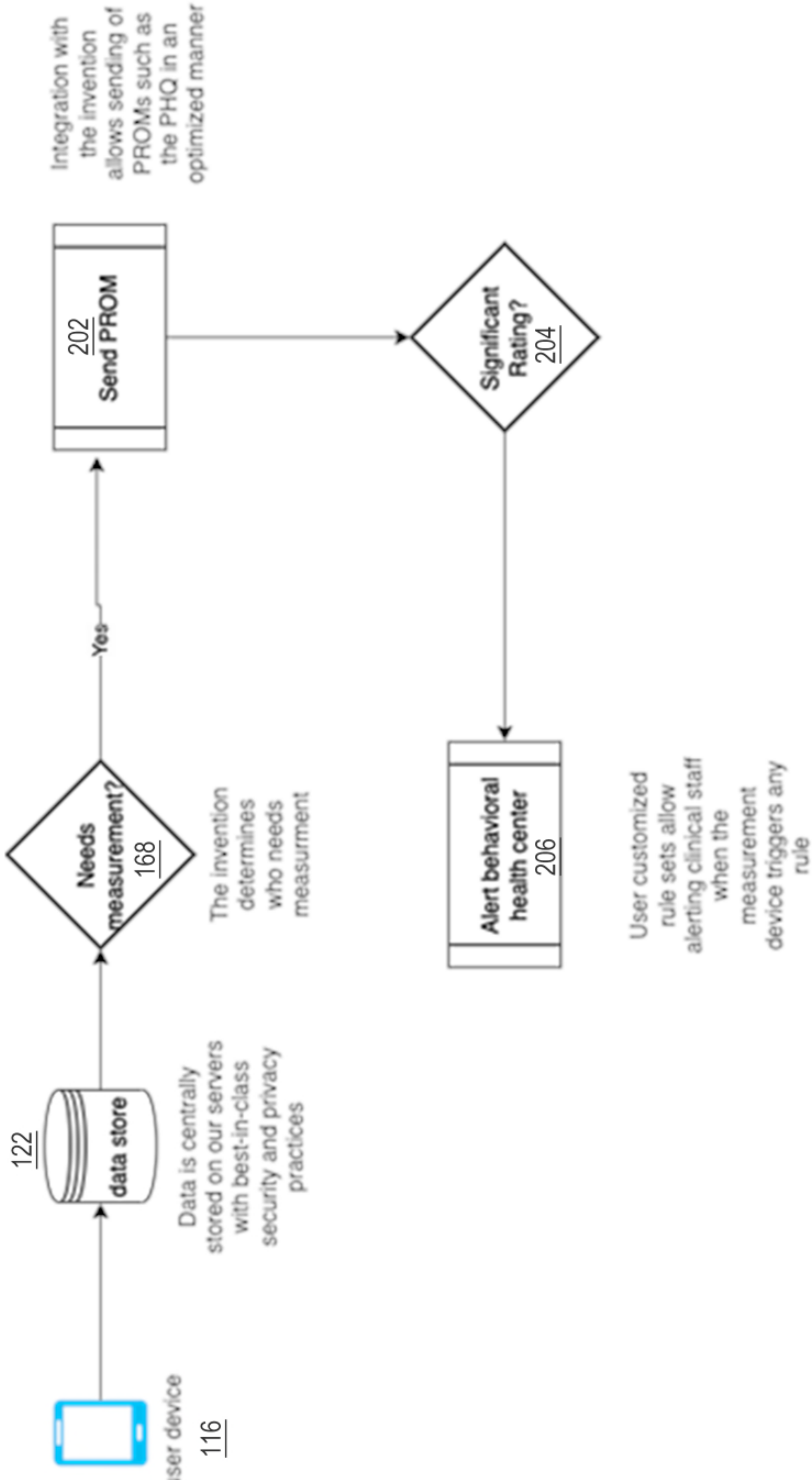
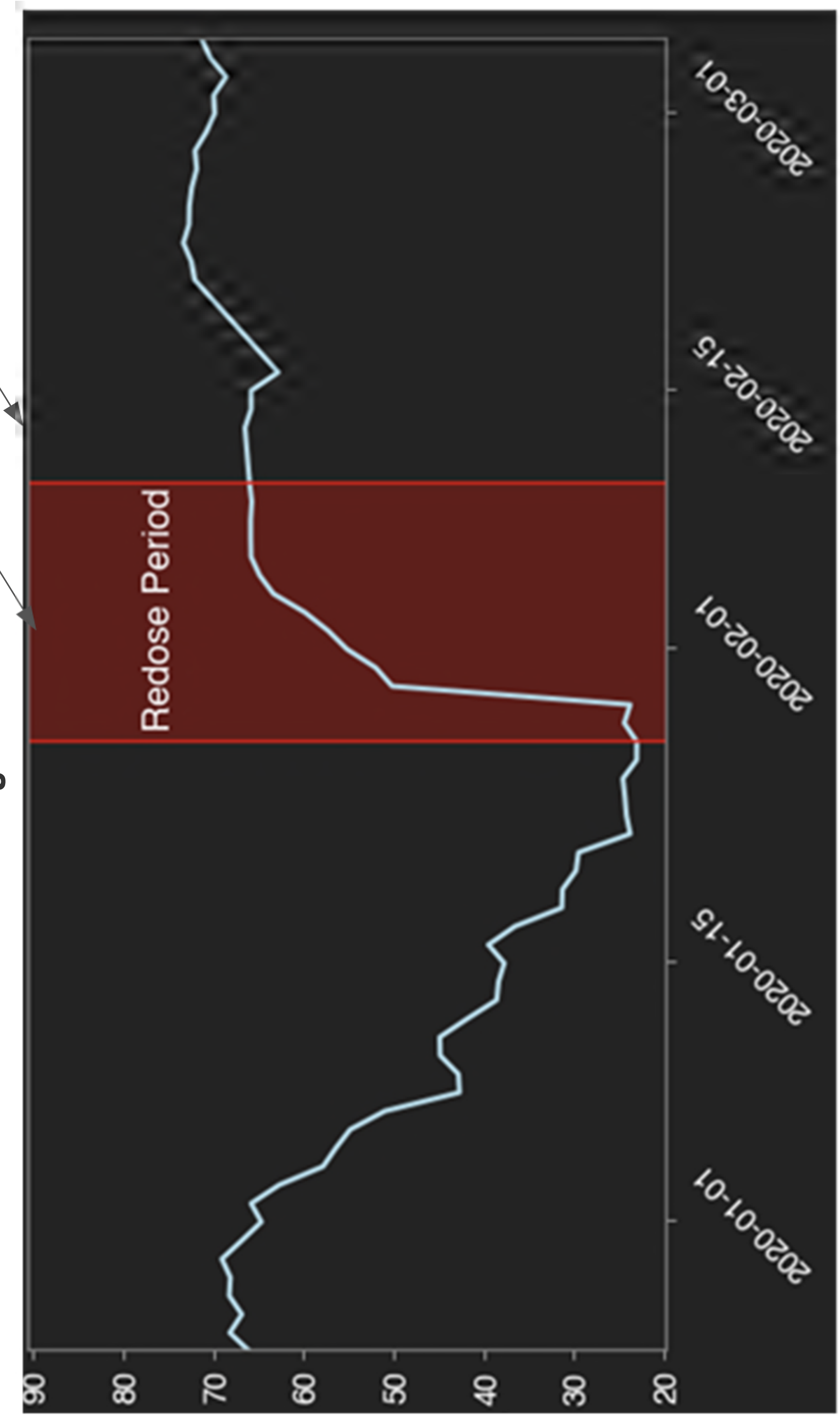

138
user device
116
database
122
160
Inference processing. Produces clinically meaningful inferences such as sleep wake up time from raw sensor data.
162
Aggregation. Produces aggregations of inferences over specified windows such as the variance over the last 14 days or a ttest between the past 7 days and the period of time since the last measurement occurred
164
Data-Driven Heuristics / Modeling. These aggregations are used to build heuristics and models which determine when measurement should occur
166
Rules/Configuration This invention is configurable to control how frequently measurement must or can be done to support various use cases
168
Needs Measurement?
We identify whether the user in question needs measurement based on the rules/configuration in context of the models/heuristics
170
Integration. We offer integration via API (push or pull) or via integration in EHR

Fig. 2


user device
116
122
data store
Data is centrally stored on our servers with best-in-class security and privacy practices
Needs measurement?
168
The invention determines who needs measurment
Yes
202
Send PROM
Integration with the invention allows sending of PROMs such as the PHQ in an optimized manner
Significant Rating?
204
Alert behavioral health center
206
User customized rule sets allow alerting clinical staff when the measurement device triggers any rule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Redose Period
90
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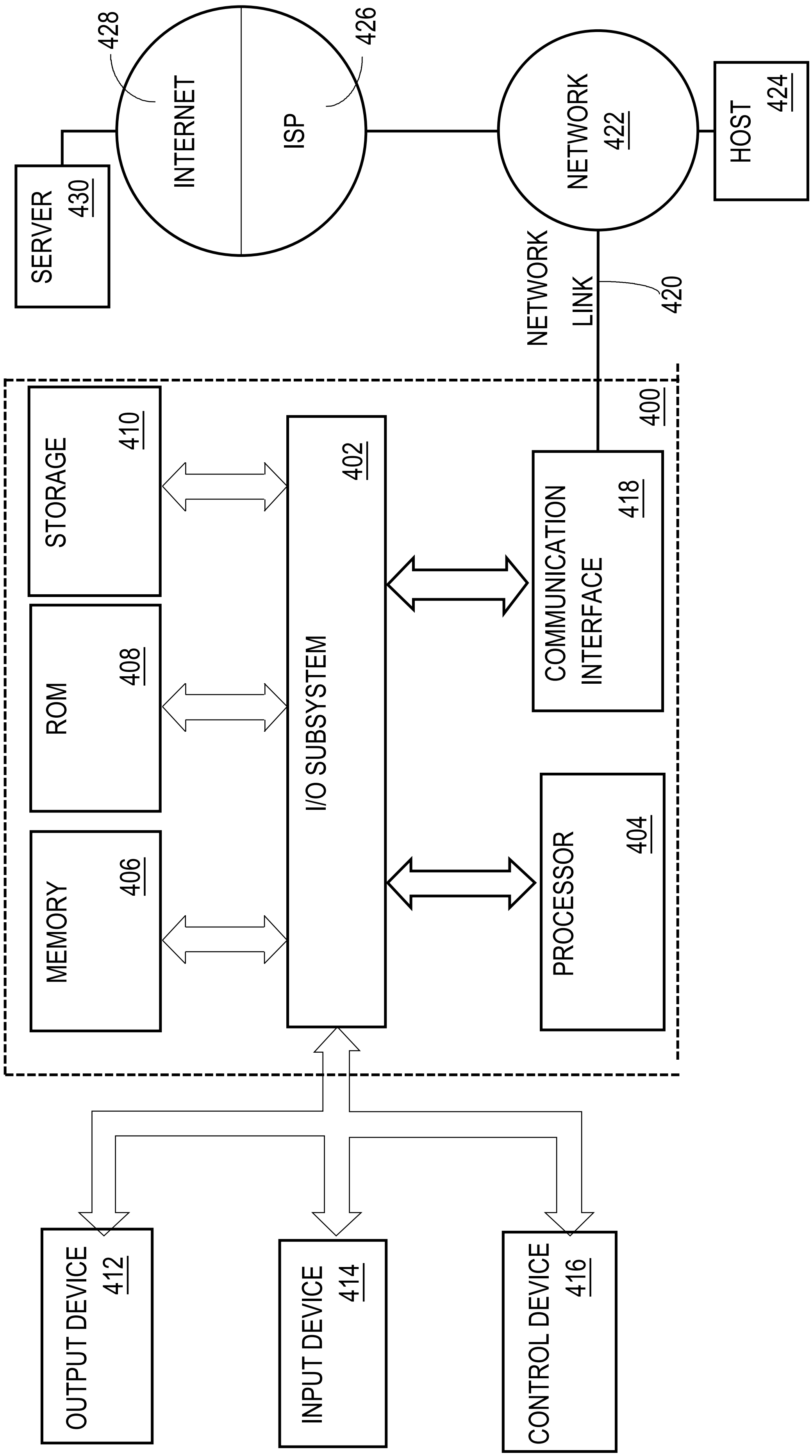
2020-02-15
2020-03-01

Fig. 3



428
426
INTERNET
ISP
SERVER
430
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422
HOST
424
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LINK
420
400
STORAGE
410
ROM
408
MEMORY
406
I/O SUBSYSTEM
402
COMMUNICATION
INTERFACE
418
PROCESSOR
404
OUTPUT DEVICE
412
INPUT DEVICE
414
CONTROL DEVICE
416

FIG. 4

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Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
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Signing Complete	Security Checked	3/24/2023 9:02:03 AM

Payment Events	Status	Timestamps

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Required hardware and software

Operating Systems:	Windows® 2000, Windows® XP, Windows Vista®; Mac OS® X
Browsers:	Final release versions of Internet Explorer® 6.0 or above (Windows only); Mozilla Firefox 2.0 or above (Windows and Mac); Safari™ 3.0 or above (Mac only)
PDF Reader:	Acrobat® or similar software may be required to view and print PDF files
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	Allow per session cookies

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