US010055625B2

(12) **United States Patent**
Feng et al.

(10) **Patent No.: US 10,055,625 B2**
(45) **Date of Patent: Aug. 21, 2018**

(54) **IMAGING BARCODE READER WITH COLOR-SEPARATED AIMER AND ILLUMINATOR**

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(73) Assignee: **Hand Held Products, Inc.**, Fort Mill, SC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/470,971**

(22) Filed: **Mar. 28, 2017**

(65) **Prior Publication Data**

US 2017/0300728 A1 Oct. 19, 2017

(30) **Foreign Application Priority Data**

Apr. 15, 2016 (CN) 2016 1 0233259
Apr. 15, 2016 (CN) ..... 2016 2 0314790 U

(51) **Int. Cl.**
G06K 7/10 (2006.01)
G06K 7/14 (2006.01)
G06K 19/06 (2006.01)

(52) **U.S. Cl.**
CPC ***G06K 7/10732*** (2013.01); ***G06K 7/10811*** (2013.01); ***G06K 7/10881*** (2013.01); ***G06K 7/1417*** (2013.01); ***G06K 19/06037*** (2013.01)

(58) **Field of Classification Search**
CPC .. G06K 7/10; G06K 9/36; G06K 9/80; G06K 15/12; G06K 5/00; G06K 7/14; G03B 7/08; G06F 17/00
(Continued)

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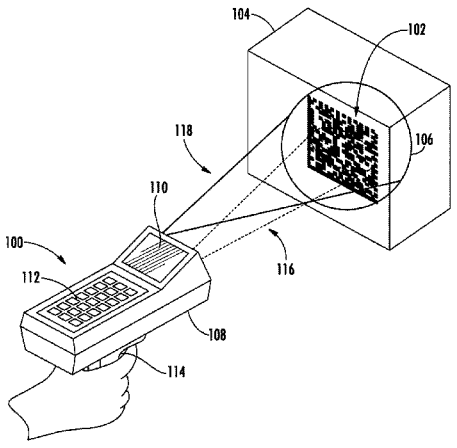
(74) *Attorney, Agent, or Firm* — Additon, Higgins & Pendleton, P.A.

(57) **ABSTRACT**

A scanner for machine-readable symbols, such as barcodes and two-dimensional matrix symbols, employs at least two different light frequencies (colors). The first frequency supports accurate aiming of the scanner at a symbol. The second frequency supports illumination of a machine-readable symbol so that the reflected illumination light can be read at the second frequency by the scanner's optical imaging element. Employing two different light frequencies enables both aiming and scanning to occur simultaneously, while the aiming process does not interfere with the scanning process. It enables the aiming frequency to be used for additional purposes, such as providing signaling to a user of the scanner. In an embodiment, two distinct light sources are used in the scanner to provide the different light frequencies. In an embodiment, various color filters are employed to separate and distinguish light frequencies. In an embodiment, signal processing may be employed to digitally distinguish multiple separate frequencies in light reflected from the symbol.

20 Claims, 7 Drawing Sheets



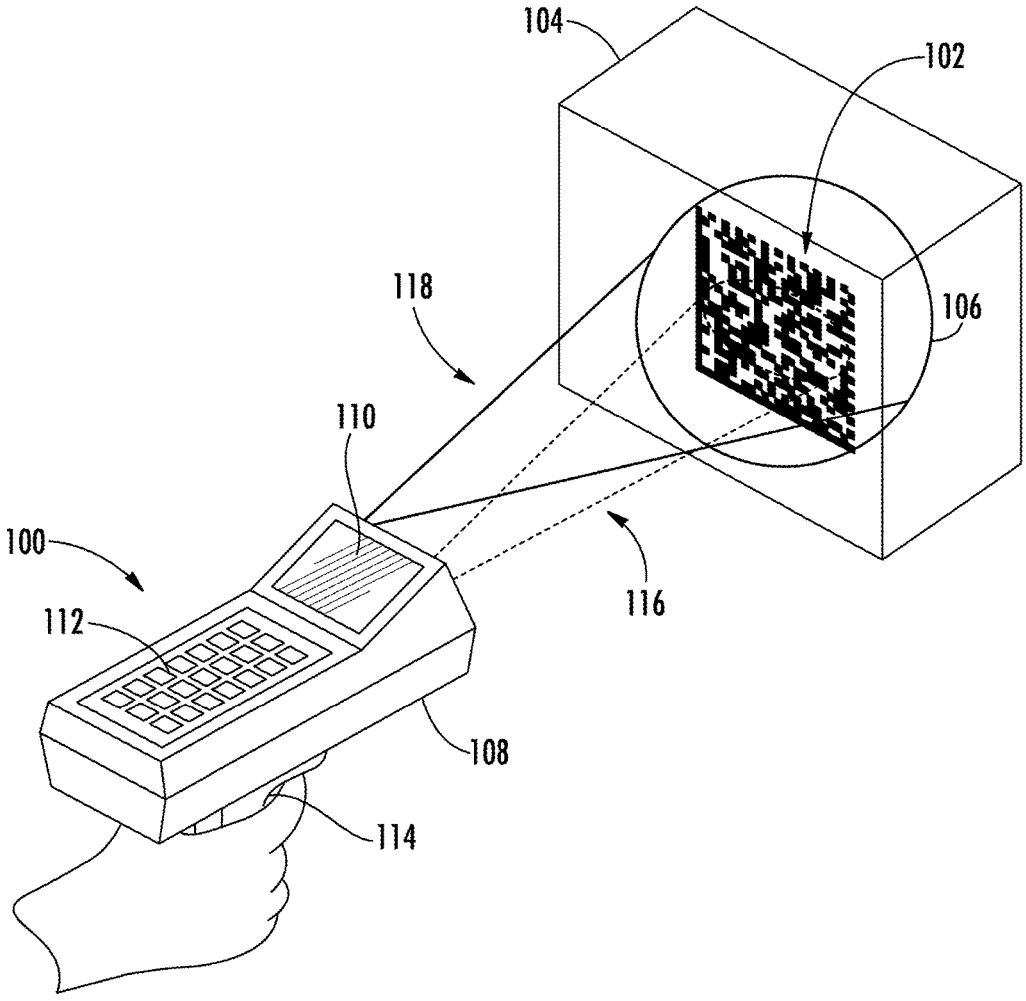


FIG. 1

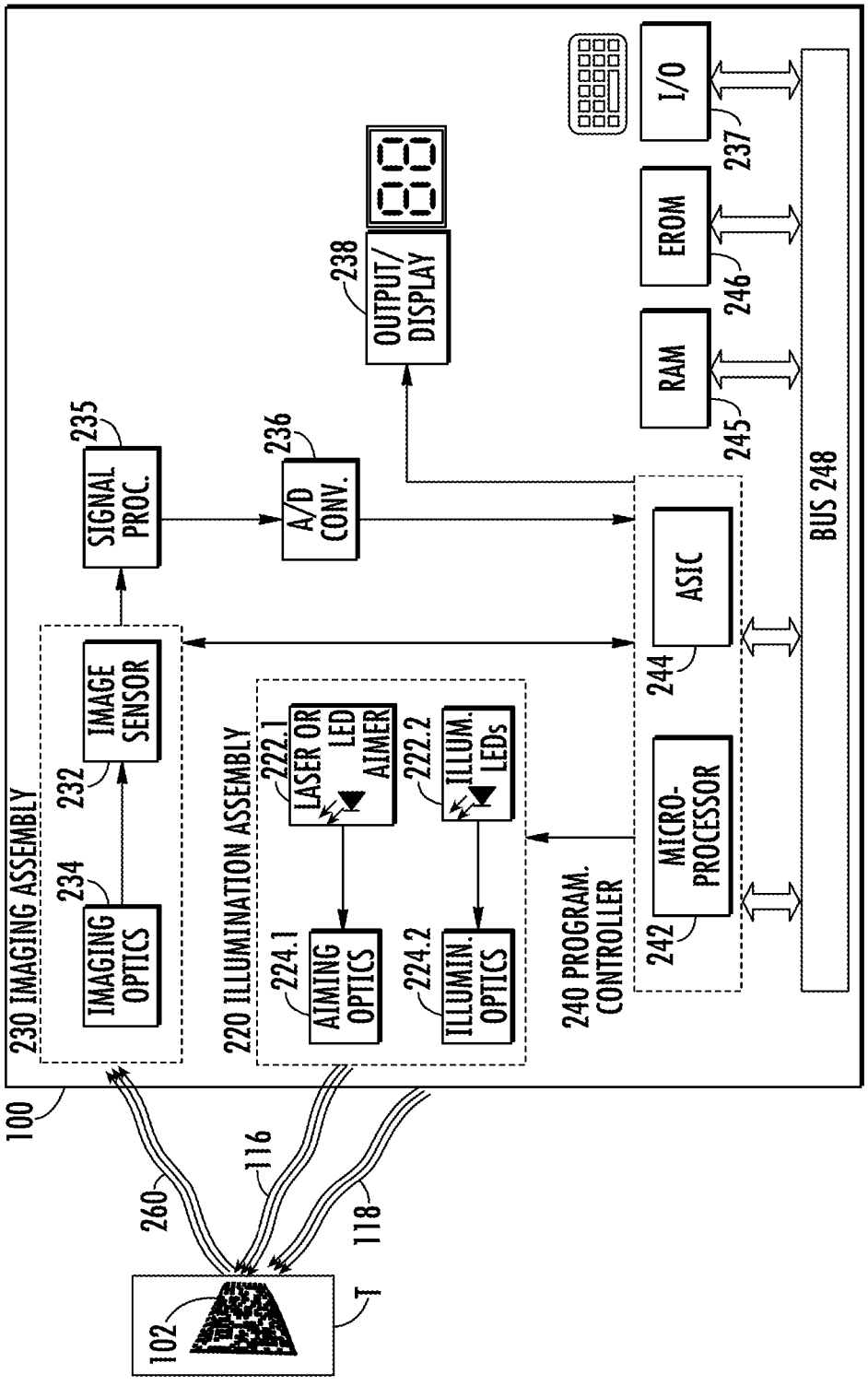

100
230 IMAGING ASSEMBLY
IMAGING OPTICS
234
IMAGE SENSOR
232
SIGNAL PROC.
235
220 ILLUMINATION ASSEMBLY
LASER OR LED AIMER
222.1
ILLUM. LEDs
222.2
AIMING OPTICS
224.1
ILLUMIN. OPTICS
224.2
240 PROGRAM. CONTROLLER
MICRO-PROCESSOR
242
ASIC
244
A/D CONV.
236
OUTPUT/ DISPLAY
238
RAM
245
EROM
246
I/O
237
BUS 248
260
116
118
102
T

FIG. 2

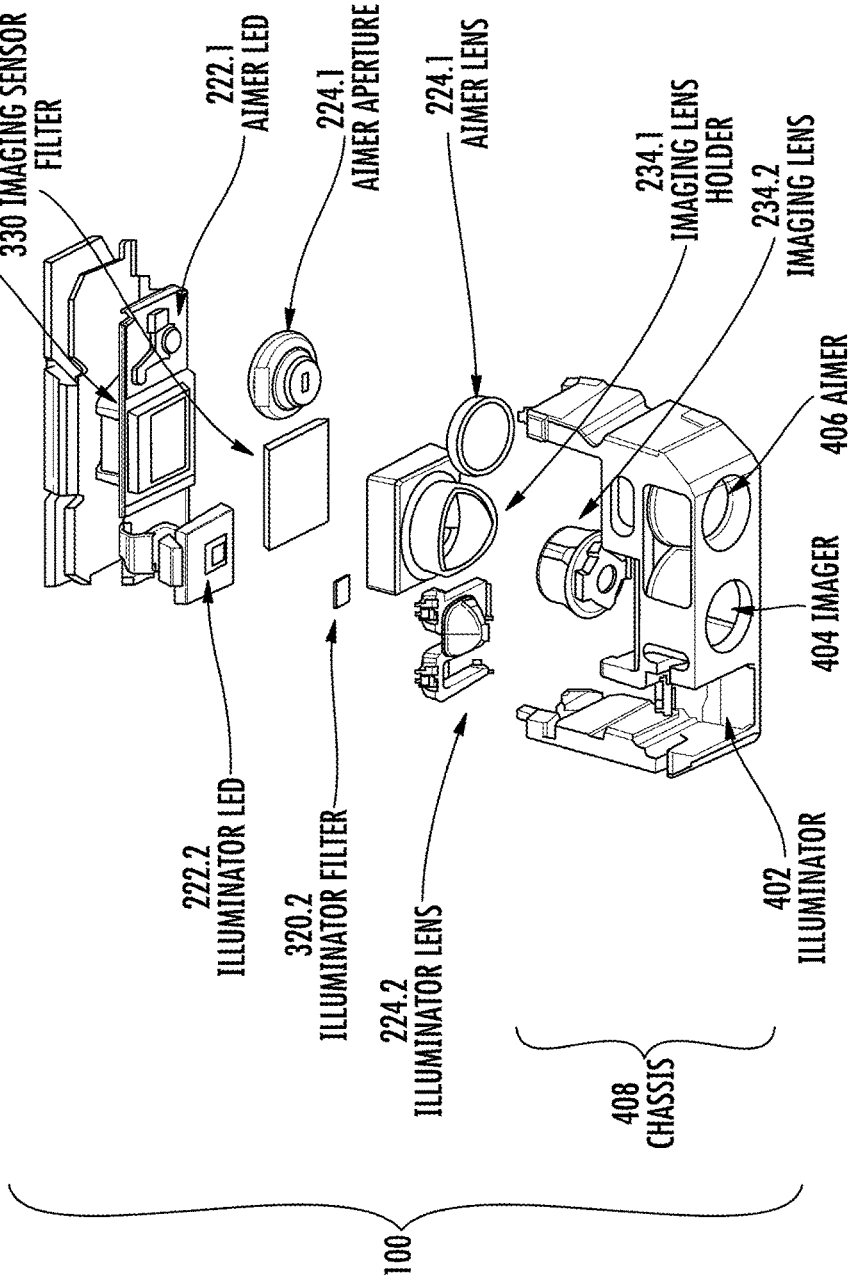

232 IMAGING SENSOR
330 IMAGING SENSOR FILTER
222.1 AIMER LED
224.1 AIMER APERTURE
224.1 AIMER LENS
234.1 IMAGING LENS HOLDER
234.2 IMAGING LENS
406 AIMER
404 IMAGER
402 ILLUMINATOR
222.2 ILLUMINATOR LED
320.2 ILLUMINATOR FILTER
224.2 ILLUMINATOR LENS
408 CHASSIS
100

FIG. 4

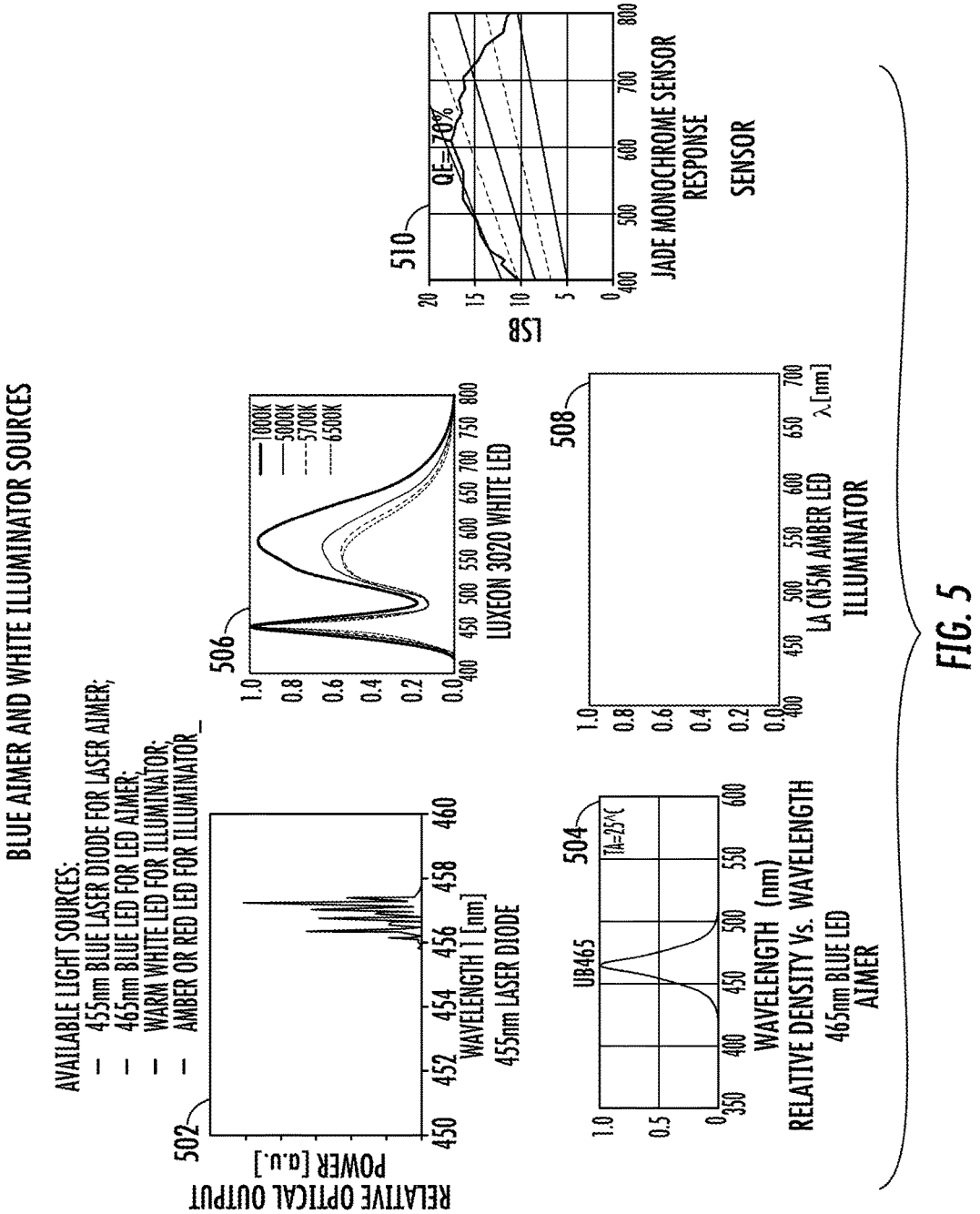

BLUE AIMER AND WHITE ILLUMINATOR SOURCES
AVAILABLE LIGHT SOURCES:
455nm BLUE LASER DIODE FOR LASER AIMER;
465nm BLUE LED FOR LED AIMER;
WARM WHITE LED FOR ILLUMINATOR;
AMBER OR RED LED FOR ILLUMINATOR_
502
RELATIVE OPTICAL OUTPUT
POWER [a.u.]
WAVELENGTH 1 [nm]
455nm LASER DIODE
506
1000K
5000K
5700K
6500K
LUXEON 3020 WHITE LED
504
UB465
Ta=25°C
WAVELENGTH (nm)
RELATIVE DENSITY Vs. WAVELENGTH
465nm BLUE LED
AIMER
508
λ [nm]
LA CN5M AMBER LED
ILLUMINATOR
510
QE=70%
LSB
JADE MONOCHROME SENSOR
RESPONSE
SENSOR

FIG. 5

COLOR BLOCKING FILTER OPTIONS

AVAILABLE FILTER OPTIONS:

— COMMONLY USED PST COLOR BARCODE SCANNER WINDOW. AMBER WINDOW CAN SEPARATE BLUE AIMER FROM WHITE ILLUMINATOR RED WINDOW CAN EVEN ALLOW TO USE GREEN AIMER WITH RED ILLUMINATOR);

— LOW COST ROSCO FILM FILTER. #10 YELLOW FILTER CAN BLOCK BLUE AIMER AND FILTER OUT BLUE PORTION OF WHITE LED ILLUMINATOR

— CUSTOM BAND PASS FILTER (NO IR-CUT FILTER NEED)

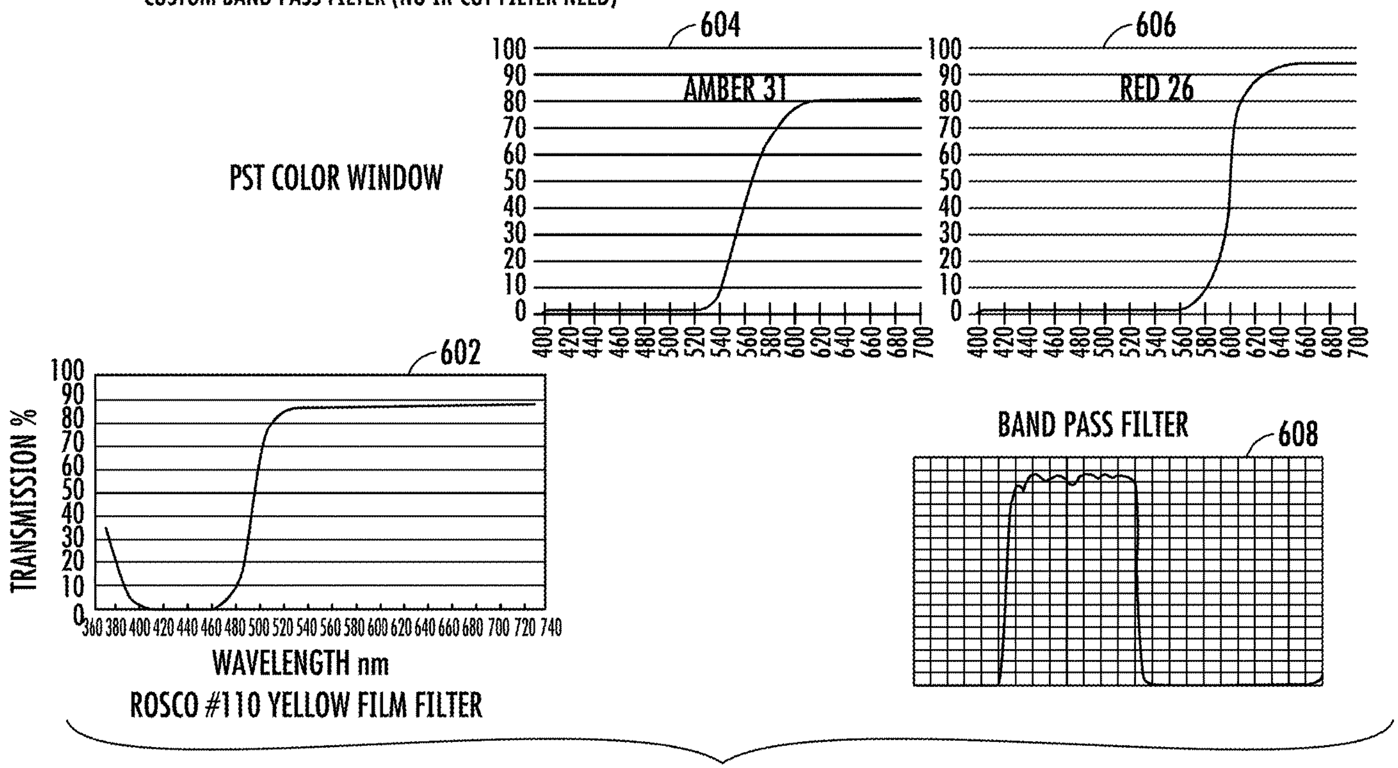


FIG. 6

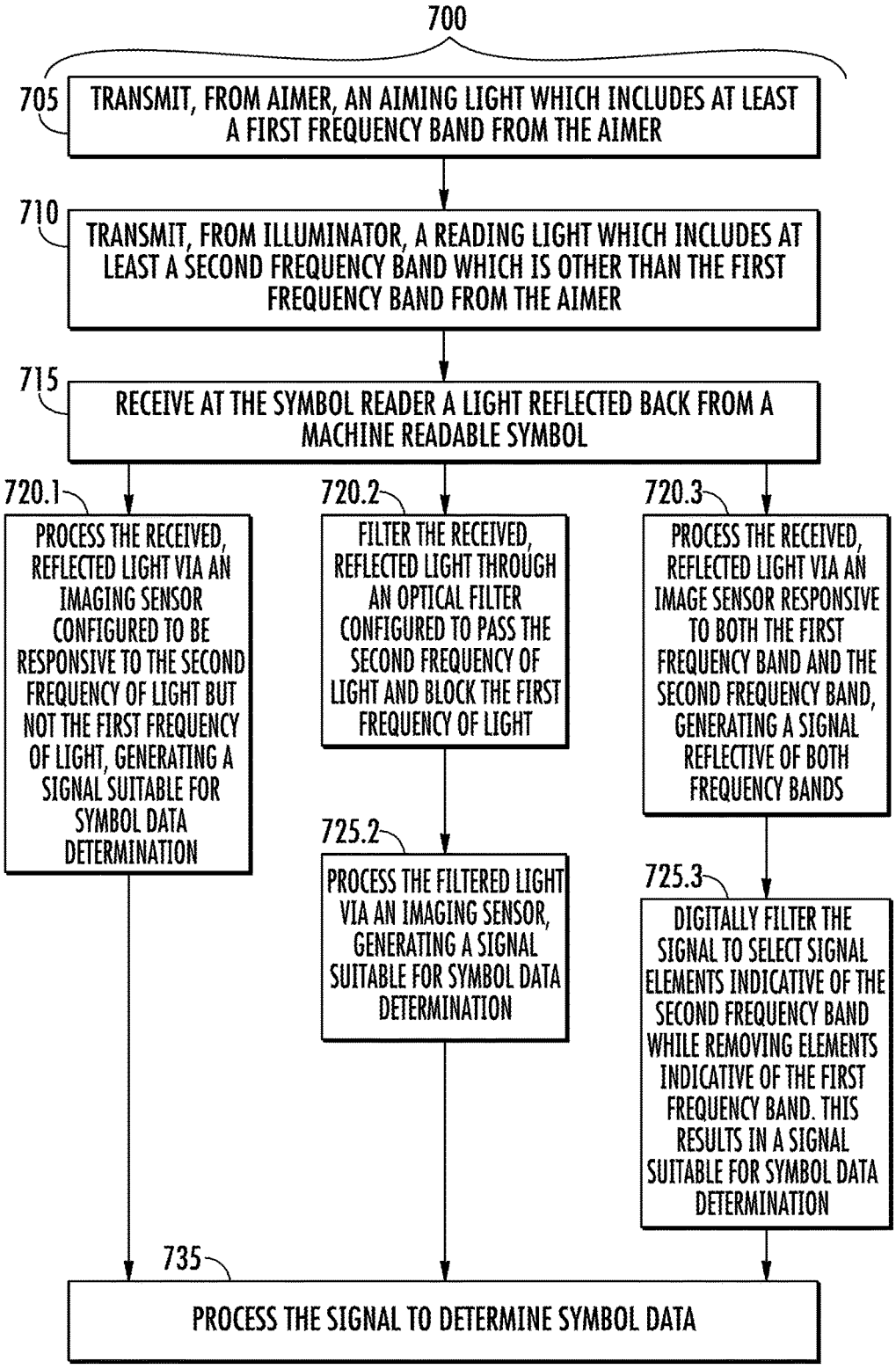

700
705
TRANSMIT, FROM AIMER, AN AIMING LIGHT WHICH INCLUDES AT LEAST A FIRST FREQUENCY BAND FROM THE AIMER
710
TRANSMIT, FROM ILLUMINATOR, A READING LIGHT WHICH INCLUDES AT LEAST A SECOND FREQUENCY BAND WHICH IS OTHER THAN THE FIRST FREQUENCY BAND FROM THE AIMER
715
RECEIVE AT THE SYMBOL READER A LIGHT REFLECTED BACK FROM A MACHINE READABLE SYMBOL
720.1
PROCESS THE RECEIVED, REFLECTED LIGHT VIA AN IMAGING SENSOR CONFIGURED TO BE RESPONSIVE TO THE SECOND FREQUENCY OF LIGHT BUT NOT THE FIRST FREQUENCY OF LIGHT, GENERATING A SIGNAL SUITABLE FOR SYMBOL DATA DETERMINATION
720.2
FILTER THE RECEIVED, REFLECTED LIGHT THROUGH AN OPTICAL FILTER CONFIGURED TO PASS THE SECOND FREQUENCY OF LIGHT AND BLOCK THE FIRST FREQUENCY OF LIGHT
725.2
PROCESS THE FILTERED LIGHT VIA AN IMAGING SENSOR, GENERATING A SIGNAL SUITABLE FOR SYMBOL DATA DETERMINATION
720.3
PROCESS THE RECEIVED, REFLECTED LIGHT VIA AN IMAGE SENSOR RESPONSIVE TO BOTH THE FIRST FREQUENCY BAND AND THE SECOND FREQUENCY BAND, GENERATING A SIGNAL REFLECTIVE OF BOTH FREQUENCY BANDS
725.3
DIGITALLY FILTER THE SIGNAL TO SELECT SIGNAL ELEMENTS INDICATIVE OF THE SECOND FREQUENCY BAND WHILE REMOVING ELEMENTS INDICATIVE OF THE FIRST FREQUENCY BAND. THIS RESULTS IN A SIGNAL SUITABLE FOR SYMBOL DATA DETERMINATION
735
PROCESS THE SIGNAL TO DETERMINE SYMBOL DATA

FIG. 7

IMAGING BARCODE READER WITH COLOR-SEPARATED AIMER AND ILLUMINATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of Chinese Patent Application for Invention No. 201610233259.X for an Imaging Barcode Reader with Color-Separated Aimer and Illuminator filed Apr. 15, 2016 at the State Intellectual Property Office of the People's Republic of China. The present application also claims the benefit of Chinese Patent Application for Utility Model No. 201620314790.5 for an Imaging Barcode Reader with Color-Separated Aimer and Illuminator filed Apr. 15, 2016 at the State Intellectual Property Office of the People's Republic of China. Each of the foregoing patent applications is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to a method and apparatus for decoding machine-readable symbols, and more particularly, to a method and apparatus for aiming a symbol reader and illuminating the machine-readable symbol.

BACKGROUND

Machine-readable symbols (MRSs) provide a means for encoding information in a compact printed form (or embossed form) which can be scanned and then interpreted by an optical-based symbol detector. Such machine-readable symbols are often attached to (or impressed upon) product packaging, food products, general consumer items, machine parts, equipment, and other manufactured items for purposes of machine-based identification and tracking.

One exemplary type of machine-readable symbol is a bar code that employs a series of bars and white spaces vertically oriented along a single row. Groups of bars and spaces correspond to a codeword. The codeword is associated with an alpha-numeric symbol, one or more numeric digits, or other symbol functionality.

To facilitate encoding of greater amounts of information into a single machine-readable symbol, two-dimensional (2D) bar codes have been devised. These are also commonly referred to as stacked, matrix and/or area bar codes. 2D matrix symbologies employ arrangements of regular polygon-shaped cells (also called elements or modules), typically squares. The specific arrangement of the cells in 2D matrix symbologies represents data characters and/or symbology functions.

In this document the terms "barcode" and "symbol" are employed interchangeably, both generally referring to machine-readable symbols, whether linear or two-dimensional.

Symbol readers (or barcode readers), also referred to as scanners, are employed to read the matrix symbols using a variety of optical scanning electronics and methods. In order to properly scan a symbol, the symbol must be within a field of view of a reader. Some readers are hand-held, and can be aimed at a symbol; other readers are fixed in location, and a symbol (and the object to which the symbol is attached) must be placed within a field of view of the reader.

Either way, a symbol scanner may project an "aimer pattern" or "aimer beam"—a pattern of light—which may indicate the scanner's center of the field-of-view; the aimer pattern may also project/include corner patterns to indicate the edges of the field of view. Proper alignment or overlap of the projected aimer pattern with the target symbol indicates that the scanner is properly aimed for scanning.

Once the scanner and symbol are properly aligned to have the symbol in the field of view of the scanner, the scanner proceeds with image capture via an imaging element. The aimer beam typically must be turned off when the imaging element captures a symbol image, because the aimer pattern is visible to the imager and becomes noise superimposed on the symbol. Existing aimers, even if centered on a specific color (red, amber, green), all have high intensity in wavelengths to which the image sensors are sensitive. As a result, aimer illumination of a symbol is easily captured, which can disrupt symbol interpretation. In other words, the imager cannot reliably capture the symbol's image when aimer is on. This is true for most commonly used image sensors with electronic rolling shutters. Consequently, the time spent with the aimer being "on" (illuminating the symbol) directly reduces the imager barcode reader response speed.

In the alternative, for global shutter image sensors, reduced response speed may be less of a problem, as the aimer can be on during the shutter-closed portion of the whole image capture cycle. But for the global shutter image sensors, the short on-period aimer also becomes less visible because of the limitation of the aimer light source output power. An on-and-off aimer also introduces a flashing pattern which induces eye fatigue in users.

One approach to resolving this problem is to use a constant-on aimer with less contribution to the overall image illumination; for example the aimer pattern may be thin or have dotted line patterns. However, for 2D symbols with high density, poor print quality, or with 2D codes with lower redundancy rates, this trade-off will introduce poor decode rate.

Therefore, there exists a need for a system and method for both aimer illumination and symbol capture illumination which avoids time-sharing between the aiming process and symbol capture, yet still achieves a high level of accurate performance in symbol decoding.

SUMMARY

Accordingly, in one aspect, the present invention uses different colors of light, that is, different frequencies or different frequency bands, to bandwidth-separate the aimer patterns from the image capture illumination. This enables the symbol scanner to capture the symbol image even while the aimer-light is always on. In one embodiment, the color separation may be achieved by adding a color blocking filter to block the aimer pattern from reaching the image sensor. The image sensor then becomes effectively color-blind to the aimer color. The image captured with such device is aimer pattern free.

Alternatively, the color separation can be also implemented via software image processing with commonly used color image sensors, without the need of color blocking filter. However, software color-image filtering may result in some degradation to the image quality; may reduce decode performance; may introduce longer decode time; or may necessitate increased processor cost.

Some of the advantages of a color separated aimer, may include:

The aimer pattern can be full frame, indicating complete frame of the field-of-view (FOV), center mark, as well as a near center best decode zone;

the aimer pattern can also include some indicating marks, such as decode status (for example, ready to trigger, busy in decoding, success decode or failure decode);

the aimer pattern can also possibly indicate decode condition, such as too far or too close for decoding.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an exemplary hand-held symbol reader acquiring data from a machine-readable symbol.

FIG. **2** is an internal block diagram of an exemplary symbol reader for acquiring data from a machine-readable symbol.

FIG. **3** is an internal block diagram of an exemplary symbol reader for acquiring data from a machine-readable symbol.

FIG. **4** is an exploded view of internal structural components of an exemplary symbol reader for acquiring data from a machine-readable symbol.

FIG. **5** illustrates spectrum properties of several exemplary lights sources which may be employed in conjunction with an exemplary symbol reader for acquiring data from a machine-readable symbol.

FIG. **6** illustrates spectrum properties of several exemplary optical filters which may be employed in conjunction with an exemplary symbol reader for acquiring data from a machine-readable symbol.

FIG. **7** is a flow-chart of an exemplary method, performed by an exemplary symbol reader, for aiming the symbol reader and reading a symbol via the symbol reader using at least two distinct frequency bands of light.

DETAILED DESCRIPTION

In the following description, certain specific details are set forth in order to provide a thorough understanding of various embodiments. However, one skilled in the art will understand that the invention may be practiced without these details. In other instances, well-known structures associated with imagers, scanners, and/or other devices operable to read machine-readable symbols have not been shown or described in detail to avoid unnecessarily obscuring descriptions of the embodiments.

Unless the context requires otherwise, throughout the specification and claims which follow, the word "comprise" and variations thereof, such as, "comprises" and "comprising" are to be construed in an open sense, that is as "including, but not limited to."

Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

The headings provided herein are for convenience only and do not interpret the scope or meaning of the claimed invention.

Color, Frequency, and Frequency Bands

Throughout the discussion below, it will be understood that a reference to a "color", a "color of light" or a "frequency of light", whether a generic reference to "color" or a reference to a specific color (such a blue, red, yellow, etc.), may refer not just to a single frequency. Instead, such a reference to a first color or a first frequency may refer to a band of frequencies which is suitably narrow to be distinguished (for example via optical filters) from a second color at a second band of frequencies. So for example, "red" may refer to a range of frequencies (approximately 405 THz to 480 THz) which are associated with the color red as perceived by humans, and which can be distinguished from other colors such as blue (approximately 610 to 665 THz) or yellow (approximately 510 to 540 THz), etc.

A color may refer to the entire range of frequencies conventionally ascribed to a particular color, or to one or more subsets of that range, with the understanding that a particular frequency range selected in practice will be suitable for the specified application (such as imaging a 2D symbol). In different embodiments, different frequency ranges within a general frequency range may be employed (e.g., different bands within the "green spectrum"). In practical application a projected frequency of light, or a received frequency of light, may extend marginally into the frequency band of an adjacent color; or a projected light may have multiple frequency bands, but with a specified frequency or frequency band dominating in intensity to an extent that makes the projected light be effectively of the one dominant frequency band.

It is also understood that in practical application, a specified frequency band may overlap the domain of two or even three common colors (e.g., a specified frequency band may comprise adjacent portions of the green and yellow bands).

The term "broadband," as used herein, refers to a light emission which substantially spans full multiple bands of conventional colors, for example from red through green, or yellow through blue, with no one band being substantially dominant in intensity. "Broadband" may also refer to emissions of multiple bands which are non-adjacent, but typically include multiple different conventionally named colors. "Broadband" may also refer to a light emission which is white, that is, spanning substantially all visible colors (red through blue). In general, the terms "frequency band" or "color" may be understood as being substantially narrower in frequency range, and distinguishable from, a broadband emission.

In many cases in this document, specific colors are not specified, and reference is made rather to a first frequency band or second frequency band; it will be understood that in specific embodiments, particular separate colors may be assigned for each band as suitable for the application at hand.

It will also be understood that while reference is mostly made herein to "colors", "frequencies or light", or "frequency bands", such descriptions could as easily be made in terms of wavelengths of light. The choice of "colors" or "frequencies" is for convenience only. In general, "color" or "colors", and "frequency" or "frequencies", are employed interchangeably in this document.

Listed here for example only, and without limitation, are some of the frequency ranges which may be conventionally assigned to various visible colors:

red: approx. 405 to 480 THz or 700 to 625 nm;

orange: approx. 480 to 510 THz or 625 to 590 nm;

amber: variously assigned at the border of orange and yellow, but typically centered at approx. 504 THz or 595 nm;

yellow: approx. 510 to 540 THz or 590 to 560 nm;

green: approx. 540 to 580 THz or 560 to 520 nm;

cyan: approx. 580 to 610 THz or 520 to 495 nm;

blue: approx. 610 to 665 THz or 495 to 450 nm;

violet: approx. 665 to 790 THz or 450 to 380 nm.

writing the code for the software and or firmware would be well within the skill of one of ordinary skill in the art in light of this disclosure.

In addition, those skilled in the art will appreciate that the control mechanisms taught herein are capable of being distributed as a program product in a variety of tangible forms, and that an illustrative embodiment applies equally regardless of the particular type of tangible instruction bearing media used to actually carry out the distribution. Examples of tangible instruction bearing media include, but are not limited to, the following: recordable type media such as floppy disks, hard disk drives, CD ROMs, digital tape, flash drives, and computer memory.

The various embodiments described above can be combined to provide further embodiments. These and other changes can be made to the present systems and methods in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to include all machine-readable symbol scanning and processing systems and methods that read in accordance with the claims. Accordingly, the invention is not limited by the disclosure, but instead its scope is to be determined entirely by the following claims.

What is claimed is:

1. A scanner, comprising:
an aimer configured to provide aiming light comprising at least one aiming frequency to support aiming of the scanner at a machine-readable symbol (MRS);
an illuminator configured to provide reading light comprising at least one reading frequency which illuminates the MRS to support optical reading of the MRS; and
an imaging sensor having an optical filter configured to block the at least one aiming frequency and to transmit the at least one reading frequency, the imaging sensor configured to:
receive light reflected by the MRS, and
convert the reflected light to an electrical signal suitable for signal processing by the scanner;
wherein the illuminator comprises an illuminator filter configured to block the at least one aiming frequency.

2. The scanner of claim **1**, wherein:
the aimer is configured to provide aiming light which consists essentially of a first frequency;
the illuminator is configured to provide reading light of a second frequency which is different from the first frequency; and
the imaging sensor is configured to be responsive to the second frequency and to not be responsive to the first frequency.

3. The scanner of claim **1**, wherein:
the aimer is configured to provide aiming light which consists essentially of a first frequency;
the illuminator is configured to provide reading light of a second frequency which is different from the first frequency;
the optical filter is configured to block the first frequency and to transmit the second frequency; and
the optical filter is configured and arranged to filter along an optical path which conveys the light reflected from the MRS to the imaging sensor.

4. The scanner of claim **1**, wherein:
the aimer is configured to provide aiming light which consists essentially of a first frequency;
the illuminator is configured to provide reading light of a second frequency which is different from the first frequency;
the optical filter is configured to block the first frequency and to transmit the second frequency; and
the optical filter is interposed between the image sensor and the MRS.

5. The scanner of claim **1**, wherein:
the aimer is configured to provide aiming light which consists essentially of a first frequency;
the illuminator is configured to provide reading light comprising a plurality of frequencies, the plurality of frequencies comprising at least a second frequency which is different from the first frequency; and
the imaging sensor is configured to be responsive to at least the second frequency and to not be responsive to the first frequency.

6. The scanner of claim **1**, wherein:
the aimer is configured to provide aiming light which consists essentially of a first frequency;
the illuminator is configured to provide reading light comprising a plurality of frequencies, the plurality of frequencies comprising at least a second frequency which is different from the first frequency;
the optical filter is configured to block the first frequency and to transmit the second frequency; and
the optical filter is configured and arranged to filter along an optical path which conveys the light reflected from the MRS to the imaging sensor.

7. The scanner of claim **1**, wherein:
the aimer is configured to emit a first plurality of frequencies;
the at least one reading frequency being a frequency which is not emitted by the aimer; and
the imaging sensor is configured to be responsive to the at least one reading frequency.

8. The scanner of claim **7**, wherein the aimer comprises:
an aimer light source which emits the first plurality of frequencies and emits the at least one reading frequency; and
an aimer filter configured to block the at least one reading frequency.

9. The scanner of claim **1**, wherein:
the aimer is configured to emit a first plurality of frequencies;
the at least one reading frequency being a frequency which is not emitted by the aimer;
the optical filter is configured to transmit light of the least one reading frequency and block light of the first plurality of frequencies emitted by the aimer.

10. The scanner of claim **1**, wherein the aimer is configured to generate a visual indicator of at least one of:
a data of the machine-readable symbol;
an instruction for operation of the electronic scanner;
an electronic scanner function;
an electronic scanner status; and
an electronic scanner activity.

11. The scanner of claim **10**, wherein the aimer is configured to generate the visual indicator via at least one of:
an aimer light source which emits a plurality of colors;
a plurality of aimer light sources, each light source of the plurality emitting a different color;
an aimer filter configured to select a color from among a plurality of colors emitted by the aimer; and
an image projector element.

12. The scanner of claim 1, wherein:

the aimer and the illuminator are configurable to be operable simultaneously; and

the imaging sensor is configured to acquire the MRS while the aiming light is being emitted.

13. The scanner of claim 1, wherein the aimer is configured to emit a full-frame light pattern comprising a complete field-of-view of the MRS.

14. The scanner of claim 1, wherein the imaging sensor comprises:

a photosensitive element to convert the received reflected light to an electrical signal; and

a signal processing module configured to remove, from the electrical signal, a signal element representative of the aiming light reflected from the MRS.

15. A scanner, comprising:

an aimer to provide aiming light to support aiming of the scanner at a machine-readable symbol (MRS);

an illuminator to provide reading light which illuminates the MRS to support optical reading of the MRS; and

an imaging sensor comprising a light-to-electricity conversion element and a signal filter module, and configured so that upon receiving light reflected from the MRS:

the light-to-electricity conversion element converts the received light reflected from the MRS to a first electrical signal; and

the signal filter module performs a signal filtering operation to extract, from the first electrical signal, a second electrical signal representative of the received reading light suitable for determining a data content of the MRS by the scanner.

16. The scanner of claim 15, wherein the imaging sensor is configured to distinguish a first light frequency which is present in the reading light and which is not present in the aiming light.

17. The scanner of claim 16, comprising an optical bandpass filter configured to pass the first light frequency and to block a second light frequency.

18. The scanner of claim 15, wherein:

the imaging sensor is configured so that upon receiving light reflected from the MRS the imaging sensor distinguishes, in the received light, aiming light reflected from the MRS from reading light reflected from the MRS.

19. The scanner of claim 18, wherein the signal filtering module is configured to dynamically select, from among a plurality of frequencies of the received reading light, an optimum frequency to convert to the electrical signal suitable for determining the data content of the MRS.

20. The scanner of claim 19, wherein the selection of the optimum frequency is determined based on at least one of:

an ambient light spectrum impinging on the MRS; and

an optical signal-to-noise ratio optimization with respect to the imaging sensor.

* * * * *

US010282526B2

(12) **United States Patent**
Nichols

(10) **Patent No.: US 10,282,526 B2**
(45) **Date of Patent: May 7, 2019**

(54) **GENERATION OF RANDOMIZED PASSWORDS FOR ONE-TIME USAGE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 136 days.

(21) Appl. No.: **14/963,943**

(22) Filed: **Dec. 9, 2015**

(65) **Prior Publication Data**

US 2017/0169198 A1 Jun. 15, 2017

(51) **Int. Cl.**
G06F 21/31 (2013.01)

(52) **U.S. Cl.**
CPC ***G06F 21/31*** (2013.01)

(58) **Field of Classification Search**
CPC G06F 21/31
See application file for complete search history.

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U.S. Appl. No. 14/715,916 for Evaluating Image Values filed May 19, 2015 (Ackley); 60 pages.
(Continued)

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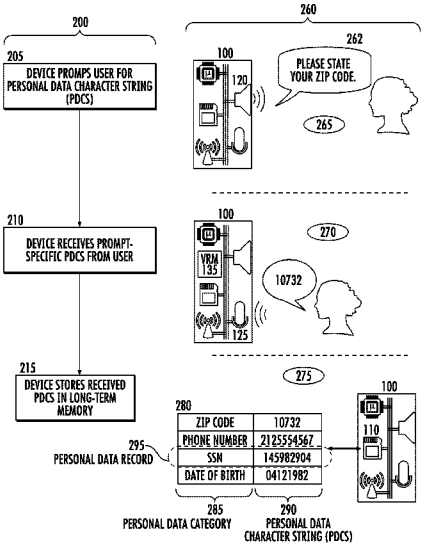
(57) **ABSTRACT**

An electronic device dynamically generates a password for one-time only usage. The one-time password is constructed by placing, in a random sequential order: (i) several randomly chosen digits and (ii) several digits, which are randomly selected from personal identification numbers, which were previously provided by an authorized user. The current user of the device is presented with a natural-language password hint, which describes the sequence of digits in the password. Only the authorized user knows the personal identification numbers; and so is able to construct, on-the-fly, the one-time password, and present that password to the device. The password hint may be presented aloud, in audio form, and the password may be entered into the device via speech. If someone nearby hears the hint and/or the password, they cannot use it at a later time to gain device control or data access, since the password is only valid the one time.

21 Claims, 4 Drawing Sheets



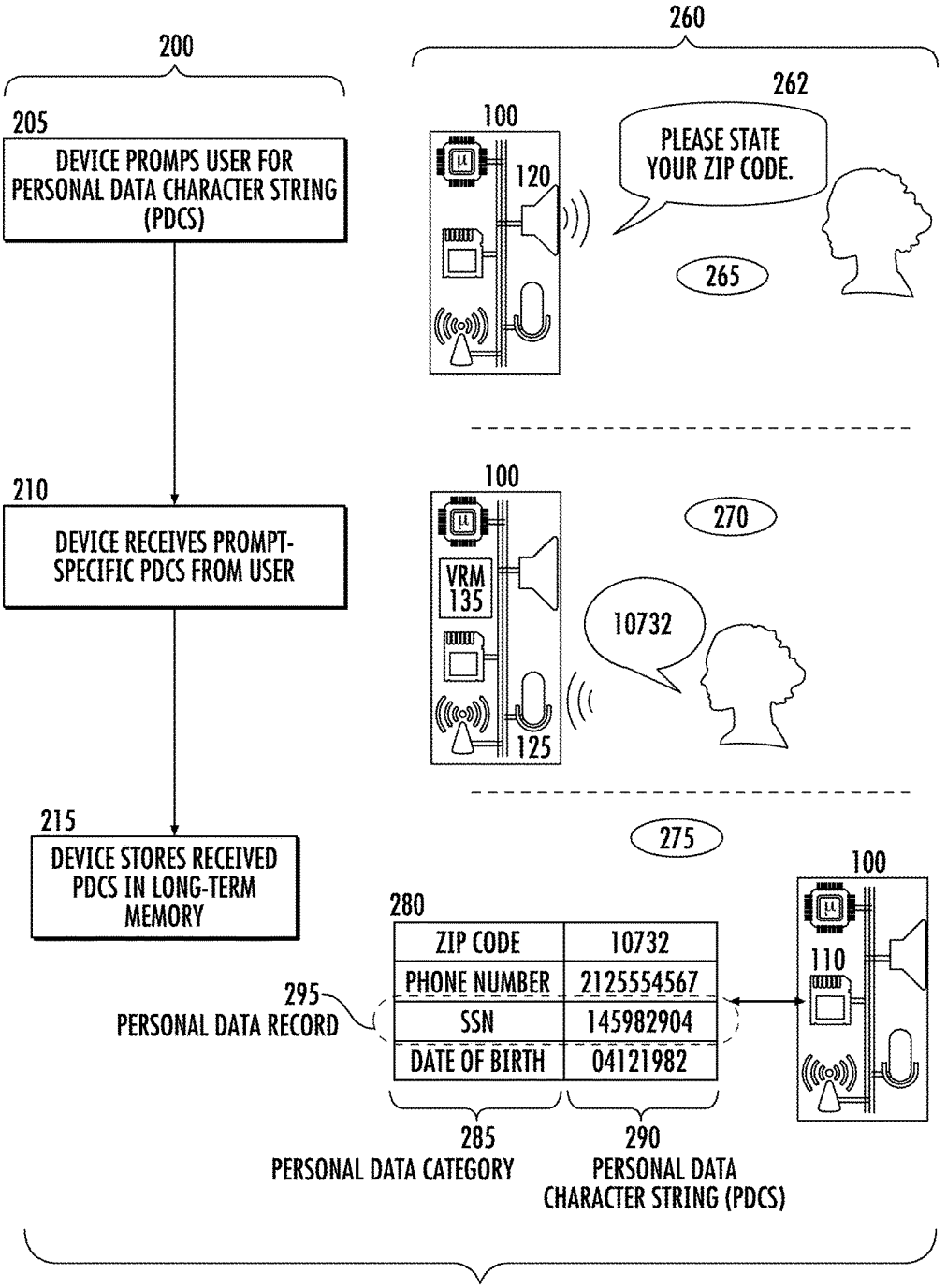

200
205
DEVICE PROMPS USER FOR PERSONAL DATA CHARACTER STRING (PDCS)
210
DEVICE RECEIVES PROMPT-SPECIFIC PDCS FROM USER
215
DEVICE STORES RECEIVED PDCS IN LONG-TERM MEMORY
260
262
100
120
PLEASE STATE YOUR ZIP CODE.
265
100
VRM 135
270
10732
125
275
100
110
280
ZIP CODE 10732
PHONE NUMBER 2125554567
SSN 145982904
DATE OF BIRTH 04121982
295
PERSONAL DATA RECORD
285
PERSONAL DATA CATEGORY
290
PERSONAL DATA CHARACTER STRING (PDCS)

FIG. 2

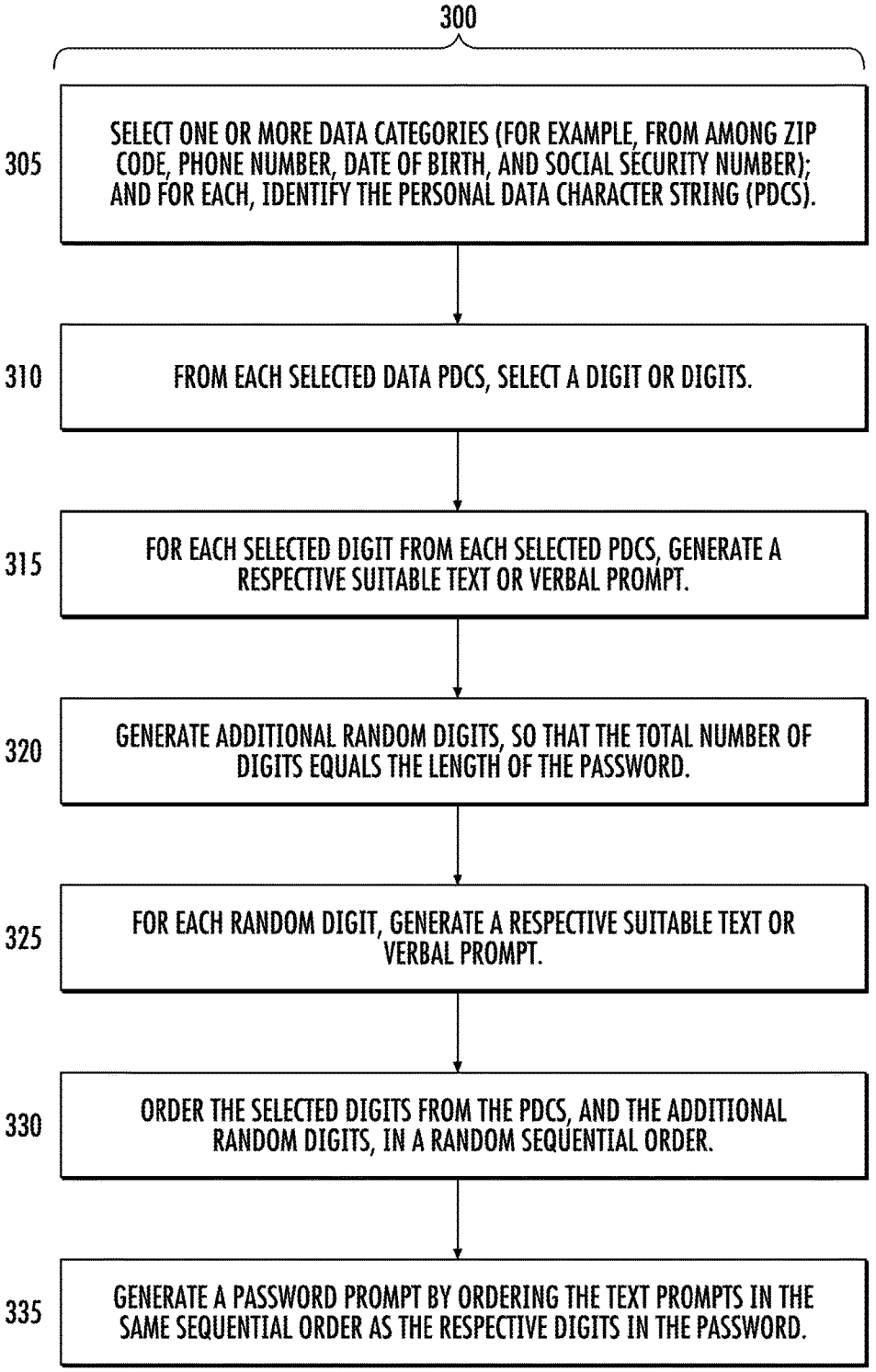

300
305
SELECT ONE OR MORE DATA CATEGORIES (FOR EXAMPLE, FROM AMONG ZIP CODE, PHONE NUMBER, DATE OF BIRTH, AND SOCIAL SECURITY NUMBER); AND FOR EACH, IDENTIFY THE PERSONAL DATA CHARACTER STRING (PDCS).
310
FROM EACH SELECTED DATA PDCS, SELECT A DIGIT OR DIGITS.
315
FOR EACH SELECTED DIGIT FROM EACH SELECTED PDCS, GENERATE A RESPECTIVE SUITABLE TEXT OR VERBAL PROMPT.
320
GENERATE ADDITIONAL RANDOM DIGITS, SO THAT THE TOTAL NUMBER OF DIGITS EQUALS THE LENGTH OF THE PASSWORD.
325
FOR EACH RANDOM DIGIT, GENERATE A RESPECTIVE SUITABLE TEXT OR VERBAL PROMPT.
330
ORDER THE SELECTED DIGITS FROM THE PDCS, AND THE ADDITIONAL RANDOM DIGITS, IN A RANDOM SEQUENTIAL ORDER.
335
GENERATE A PASSWORD PROMPT BY ORDERING THE TEXT PROMPTS IN THE SAME SEQUENTIAL ORDER AS THE RESPECTIVE DIGITS IN THE PASSWORD.

FIG. 3

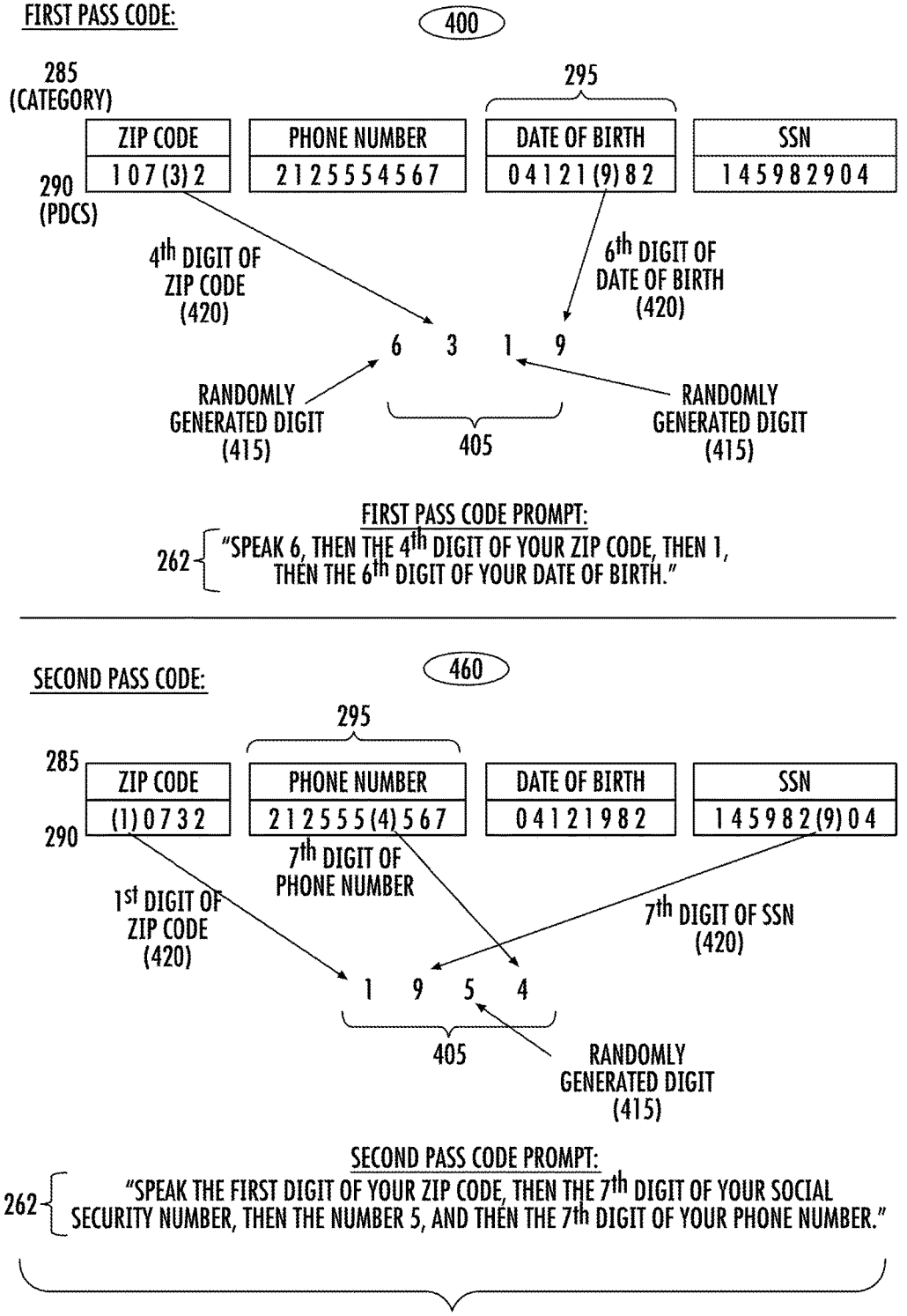

FIRST PASS CODE:
400
285
(CATEGORY)
295
ZIP CODE
PHONE NUMBER
DATE OF BIRTH
SSN
290
(PDCS)
1 0 7 (3) 2
2 1 2 5 5 5 4 5 6 7
0 4 1 2 1 (9) 8 2
1 4 5 9 8 2 9 0 4
4th DIGIT OF ZIP CODE (420)
6th DIGIT OF DATE OF BIRTH (420)
6 3 1 9
RANDOMLY GENERATED DIGIT (415)
405
RANDOMLY GENERATED DIGIT (415)
FIRST PASS CODE PROMPT:
262
"SPEAK 6, THEN THE 4th DIGIT OF YOUR ZIP CODE, THEN 1, THEN THE 6th DIGIT OF YOUR DATE OF BIRTH."
SECOND PASS CODE:
460
295
285
ZIP CODE
PHONE NUMBER
DATE OF BIRTH
SSN
290
(1) 0 7 3 2
2 1 2 5 5 5 (4) 5 6 7
0 4 1 2 1 9 8 2
1 4 5 9 8 2 (9) 0 4
7th DIGIT OF PHONE NUMBER
1st DIGIT OF ZIP CODE (420)
7th DIGIT OF SSN (420)
1 9 5 4
405
RANDOMLY GENERATED DIGIT (415)
SECOND PASS CODE PROMPT:
262
"SPEAK THE FIRST DIGIT OF YOUR ZIP CODE, THEN THE 7th DIGIT OF YOUR SOCIAL SECURITY NUMBER, THEN THE NUMBER 5, AND THEN THE 7th DIGIT OF YOUR PHONE NUMBER."

FIG. 4

FOR WIRELESS CHARGING AND EAS DEACTIVATION, filed Jun. 24, 2015 (Xie et al.).

In the specification and/or figures, typical embodiments of the invention have been disclosed. The present invention is not limited to such exemplary embodiments. The use of the term "and/or" includes any and all combinations of one or more of the associated listed items. The figures are schematic representations and so are not necessarily drawn to scale. Unless otherwise noted, specific terms have been used in a generic and descriptive sense and not for purposes of limitation.

What is claimed is:

1. An electronic device configured for password protection, said electronic device comprising:

a processor; and

a memory communicatively coupled to the processor;

wherein:

said memory is configured to store a personal data character string (PDCS) and an associated description of the PDCS, wherein the characters of the PDCS represent personal data associated with an authorized user of the electronic device; and

said processor is configured to:

select at random, a subset of characters from the characters of the PDCS, the subset comprising one or more characters of the PDCS;

generate a one-time password comprising a combination of the one or more selected characters of the PDCS;

generate a prompt, via a speaker, configured to request the authorized user to provide the one-time password, wherein the prompt comprises an ordinal placement corresponding to each of the one or more selected characters of the PDCS coupled with the associated description of the PDCS;

receive an input, via a microphone, corresponding to the authorized user having provided the one-time password; and

provide user access in response to the receipt of the input corresponding to the authorized user having provided the one-time password.

2. The electronic device of claim **1**, wherein the processor is further configured to generate the password by combining the one or more selected characters of the PDCS in a random sequential order.

3. The electronic device of claim **1**, wherein the processor is further configured to:

generate one or more additional characters; and

generate the one-time password as a combination of:

the one or more selected characters of the PDCS; and

the one or more additional characters.

4. The electronic device of claim **1** further comprising a user interface which is communicatively coupled to the processor, wherein said user interface is configured to:

present a data prompt comprising a data category of said PDCS; and

to receive a data value responsive to the data prompt, wherein:

said received data value is stored in the memory as the PDCS associated with the data category.

5. The electronic device of claim **4**, wherein said user interface comprises at least one of:

an audio user interface; and

a voice reception interface.

6. The electronic device of claim **4**, wherein the data prompt comprises a data category for a data value which is distinctively associated with the authorized user.

7. The electronic device of claim **6**, wherein the generated one-time password consists of one or more digits selected from among a plurality of digits of the stored PDCS.

8. The electronic device of claim **1**, wherein the processor is further configured to generate a description of said generated one-time password, said description comprising:

(a) a data category of the personal data of the PDCS;

(b) a description of any additional characters of said generated one-time password; and

(c) a description of an ordering, within the generated one-time password, of the one or more selected characters the additional characters.

9. A computer-readable, non-transitory storage medium storing instructions that, when executed by a processor of an electronic device, causes the processor to execute a method for password access, the method comprising:

storing in a memory of the electronic device a personal data character string (PDCS) and an associated description of the PDCS, wherein the characters of the PDCS represent personal data associated with an authorized user of the electronic device;

selecting at random, via the processor, a subset of characters from the characters of the PDCS, the subset comprising one or more characters of the PDCS; and

generating, via the processor, a one-time password comprising a combination of the one or more selected characters of the PDCS;

generating, via the processor, a prompt, on a speaker, configured to request the authorized user to provide the one-time password, wherein the prompt comprises an ordinal placement corresponding to each of the one or more selected characters of the PDCS coupled with the associated description of the PDCS; and

receiving, via the processor, an input, on a microphone, corresponding to the authorized user having provided the one-time password; and

provide user access in response to the receiving of the input corresponding to the authorized user having provided the one-time password.

10. The computer-readable, non-transitory storage medium of claim **9**, wherein the method further comprises generating the one-time password by combining the one or more selected characters of the PDCS in a random sequential order.

11. The computer-readable, non-transitory storage medium of claim **9**, wherein the method further comprises:

generating via the processor one or more additional characters; and

generating via the processor the one-time password as a combination of:

the one or more selected characters of the PDCS; and

the one or more additional characters.

12. The computer-readable, non-transitory storage medium of claim **9**, wherein the method further comprises:

presenting, via a user interface of the electronic device, a data prompt comprising a data category of said PDCS; and

receiving, via the user interface of the electronic device, a data value responsive to the data prompt, wherein:

said received data value is stored in the memory as the PDCS associated with the data category.

13. The computer-readable, non-transitory storage medium of claim **12**, wherein the data prompt comprises a data category for a data value which is distinctively associated with the authorized user.

14. The computer-readable, non-transitory storage medium of claim **9**, wherein the generated one-time pass-

word consists of one or more digits selected from among a plurality of digits of the stored PDCS.

15. The computer-readable, non-transitory storage medium of claim **9**, wherein the method further comprises generating a description of said generated one-time password, said description comprising:

(a) a data category of the personal data of the PDCS;

(b) an ordinal placement of the one or more selected characters within the PDCS;

(c) a description of any additional characters of said generated one-time password; and

(d) a description of an ordering, within the generated one-time password, of:

the selected characters referred to by (a) and (b), and the additional characters of (c).

16. In an electronic device comprising a processor and a memory which is communicatively coupled to said processor, a method for password access, the method comprising:

storing in the memory of the electronic device a personal data character string (PDCS) and an associated description of the PDCS, wherein the characters of the PDCS represent personal data associated with an authorized user;

selecting at random, via the processor of the electronic device, a subset of characters from the characters of the PDCS, the subset comprising one or more characters of the PDCS;

generating, via the processor of the electronic device, a one-time password comprising a combination of the one or more selected characters of the PDCS;

generating, via the processor of the electronic device, a prompt, on a speaker, configured to request the authorized user to provide the one-time password, wherein the prompt comprises an ordinal placement corresponding to each of the one or more selected characters of the PDCS coupled with the associated description of the PDCS; and

receiving, via the processor of the electronic device, an input, on a microphone, corresponding to the authorized user having provided the one-time password; and

providing, via the processor of the electronic device, user access in response to the receiving of the input corresponding to the authorized user having provided the one-time password.

17. The method of claim **16**, further comprising generating the one-time password by combining the one or more selected characters of the PDCS in a sequential order which is randomly determined.

18. The method of claim **16**, wherein the ordinal placement corresponding to a selected character comprises the ordinal placement of the selected character in the PDCS, counting from left to right.

19. The method of claim **16**, wherein the personal data comprises information being non-unique to the authorized user.

20. The method of claim **16**, wherein the personal data comprises a zip code and the associated description of the personal data comprises the words "zip code".

21. The method of claim **16**, wherein the personal data comprises a name and wherein the associated description of the personal data comprises an identification of the name.

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US 20210139167A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2021/0139167 A1**

Dunning et al. (43) **Pub. Date: May 13, 2021**

(54) **MONITORING OF A REVOLVING COMPONENT EMPLOYING TIME-SYNCHRONIZED MULTIPLE DETECTORS**

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(73) Assignee: **GE AVIATION SYSTEMS LIMITED**, Gloucestershire (GB)

(21) Appl. No.: **16/677,631**

(22) Filed: **Nov. 7, 2019**

Publication Classification

(51) **Int. Cl.**

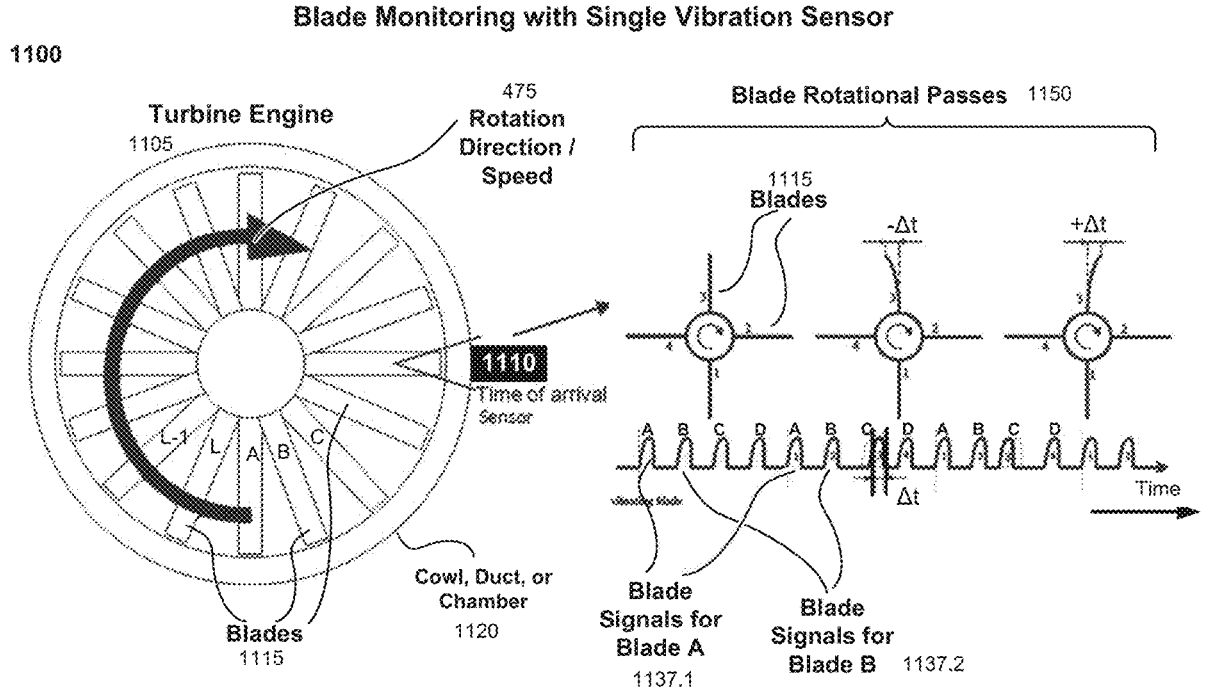
B64F 5/60	(2006.01)
G07C 5/02	(2006.01)

(52) **U.S. Cl.**

CPC . ***B64F 5/60*** (2017.01); ***G07C 5/02*** (2013.01)

(57) **ABSTRACT**

A system and method for acquiring accurate vibration data, time of arrival, or other mechanical state for a mechanical system with rotary elements, such as a planetary gear system with multiple planet gears that rotate relative to a central sun gear, or blades in a turbine engine. Multiple vibration sensors are arranged at spaced intervals along the exterior of the gear system (such as along the ring gear of the system or the exterior housing of the system). Each vibration sensor is so situated as to periodically detect vibrations from each one of the planet gears in succession, as the planet gears rotate around the central sun gear. Using timing and gear-system configuration information, a determination is made as to which gear is being sensed by any one sensor at any time; also determined is which teeth of each gear are being sensed by a particular sensor at any one time. The system and method consolidates the vibration data from multiple sensors to determine a consolidated vibration profile for each planet gear.



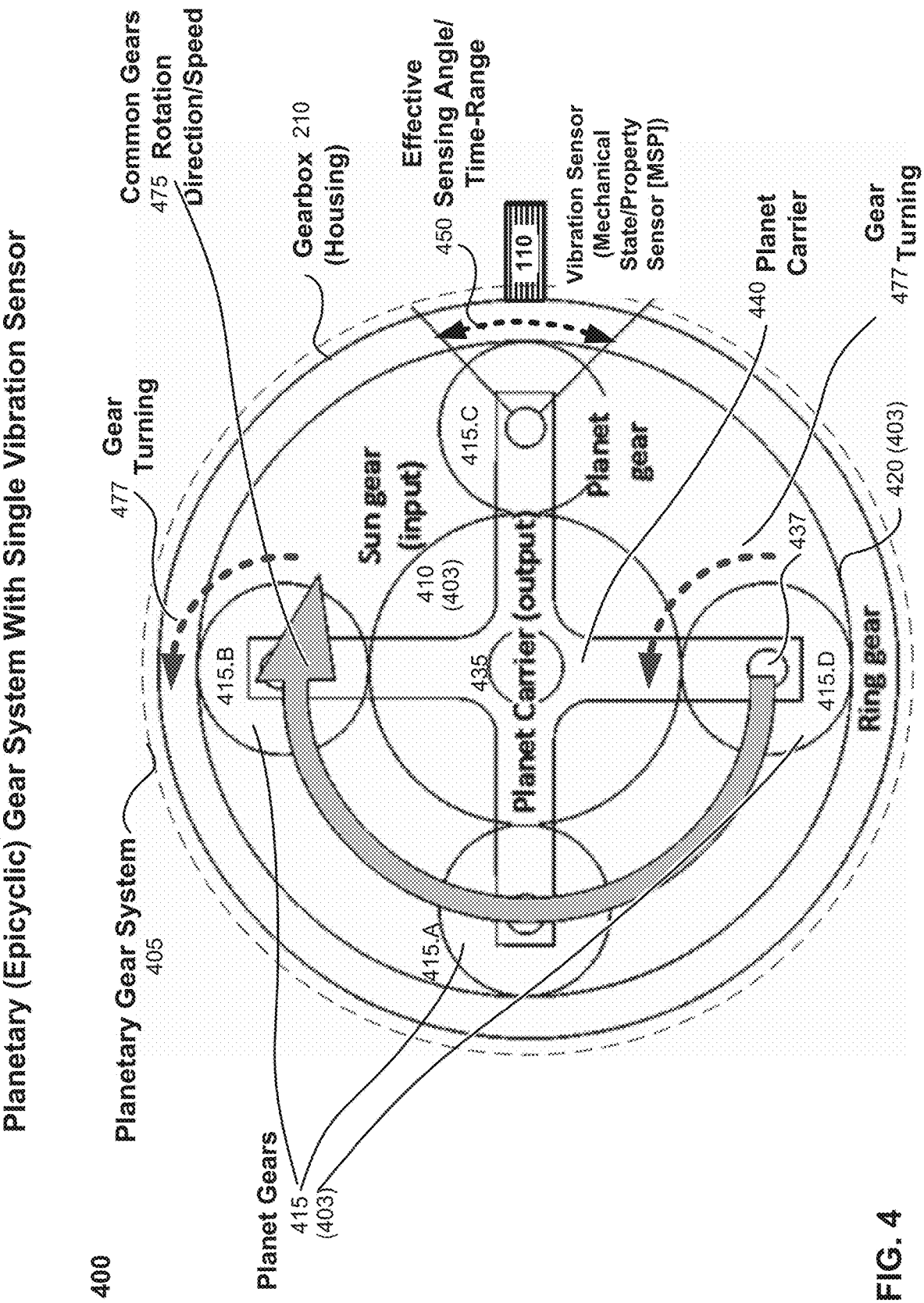

Planetary (Epicyclic) Gear System With Single Vibration Sensor
400
Planetary Gear System
405
Common Gears
475 Rotation Direction/Speed
Gearbox 210
(Housing)
Effective
450 Sensing Angle/
Time-Range
110
Vibration Sensor
(Mechanical
State/Property
Sensor [MSP])
440 Planet
Carrier
Gear
477 Turning
477 Gear
Turning
Sun gear
(input)
410
(403)
415.C
Planet
gear
Planet Carrier (output)
435
415.B
415.A
Planet Gears
415
(403)
437
415.D
Ring gear
420 (403)

FIG. 4

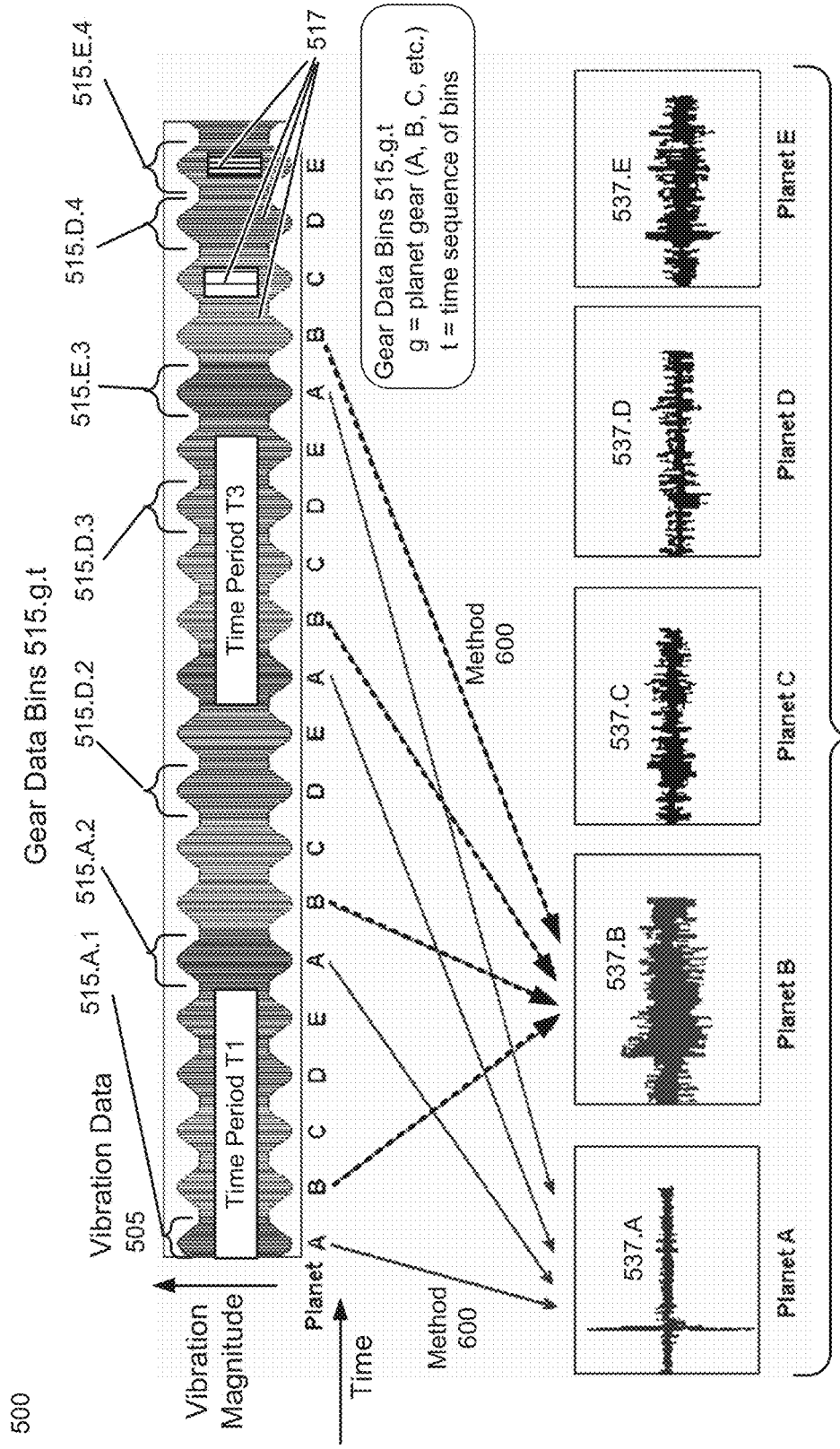

Vibration Data Acquisition Process From A Single Vibration Sensor
500
Vibration Data
505
Vibration Magnitude
Time
Gear Data Bins 515.g.t
515.A.1
515.A.2
515.D.2
515.D.3
515.E.3
515.D.4
515.E.4
517
Time Period T1
Time Period T3
Planet A B C D E A B C D E A B C D E
Gear Data Bins 515.g.t
g = planet gear (A, B, C, etc.)
t = time sequence of bins
Method 600
Method 600
537.A
537.B
537.C
537.D
537.E
Planet A
Planet B
Planet C
Planet D
Planet E
Vibration Profiles 520.X

FIG. 5

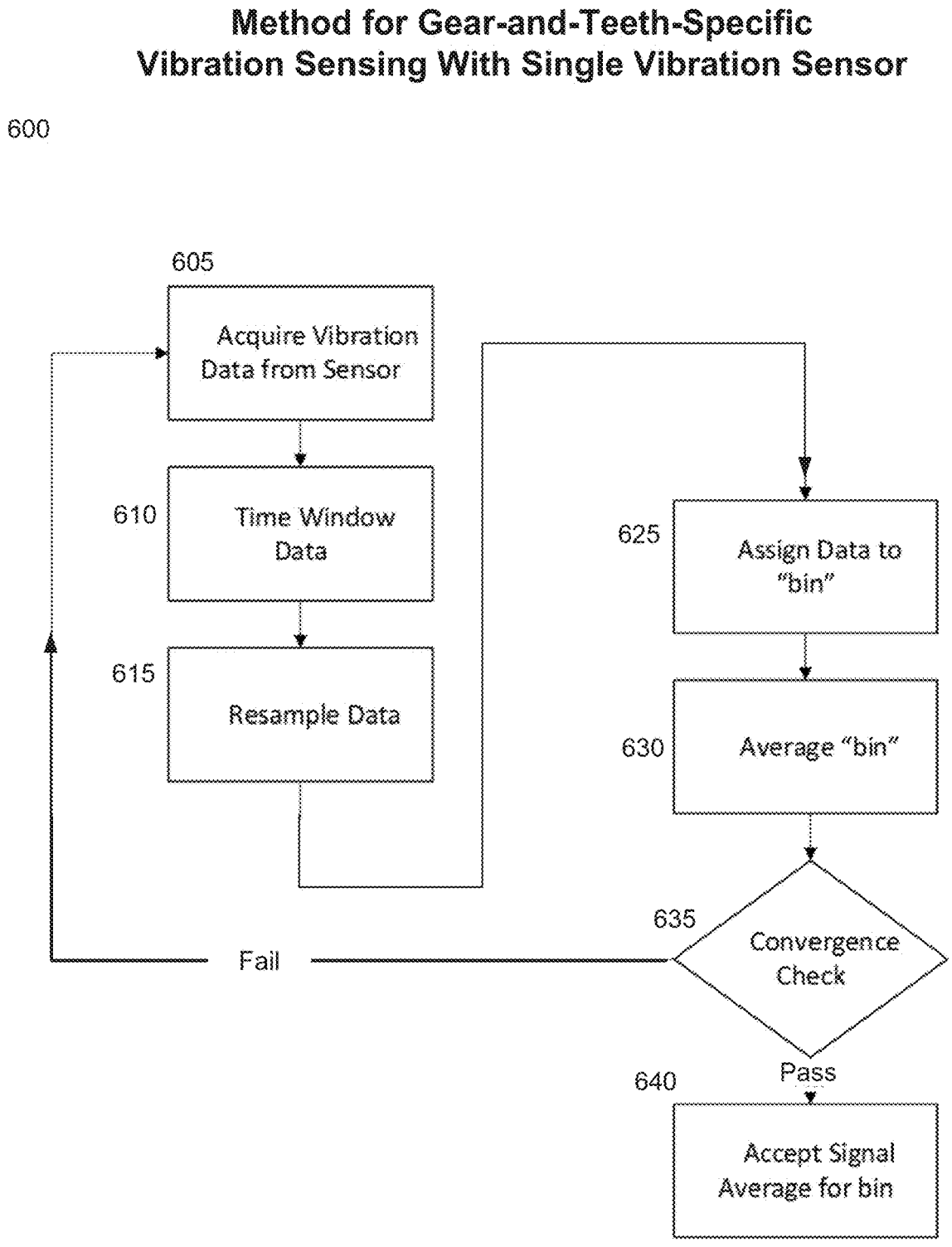

Method for Gear-and-Teeth-Specific Vibration Sensing With Single Vibration Sensor
600
605
Acquire Vibration Data from Sensor
610
Time Window Data
615
Resample Data
625
Assign Data to "bin"
630
Average "bin"
635
Convergence Check
Fail
Pass
640
Accept Signal Average for bin

FIG. 6

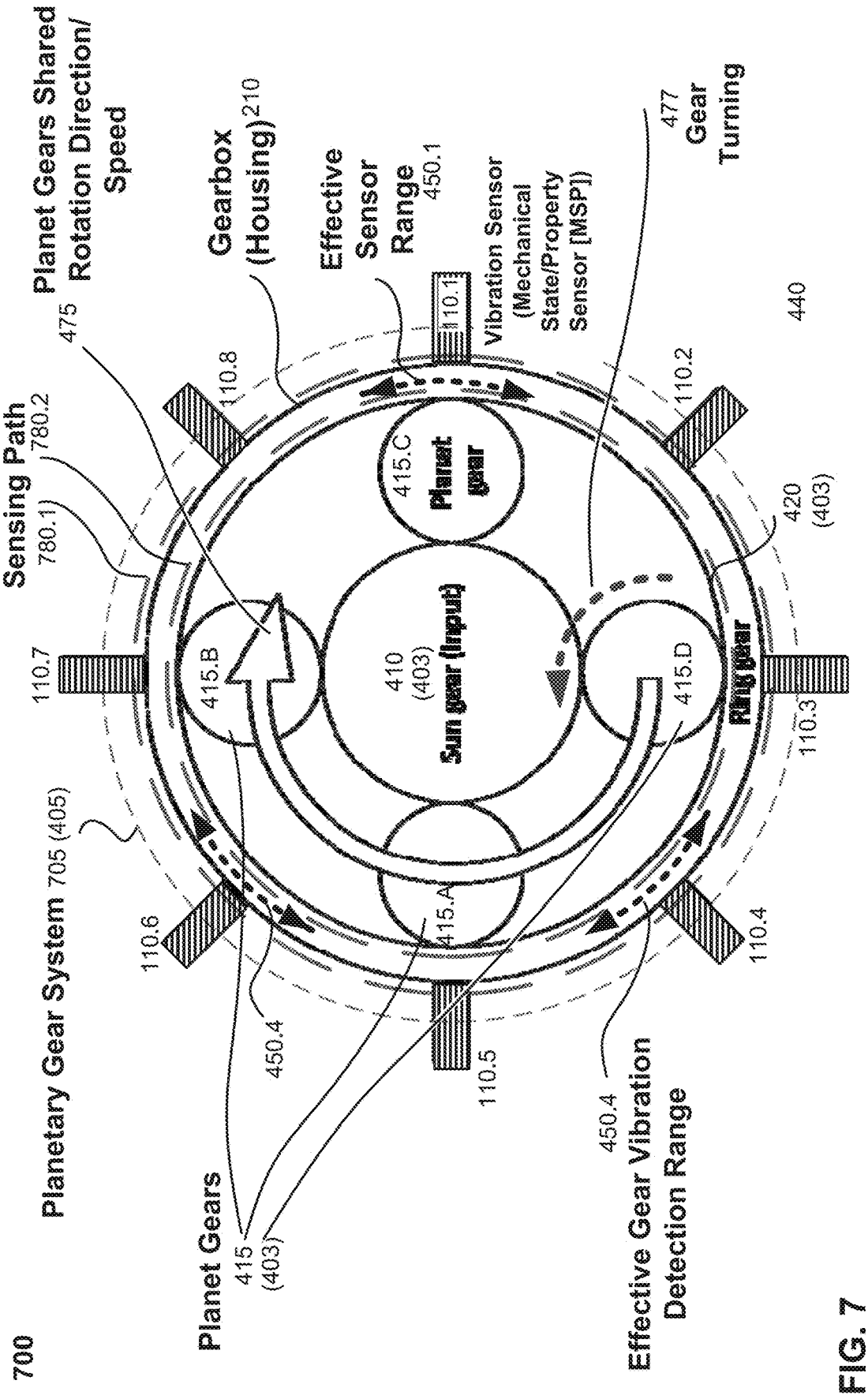

Planetary (Epicyclic) Gear System With Multiple Vibration Sensors
700
Planetary Gear System 705 (405)
Planet Gears
415 (403)
Sensing Path
780.1
780.2
Planet Gears Shared Rotation Direction/ Speed
475
Gearbox (Housing) 210
Effective Sensor Range
450.1
Vibration Sensor (Mechanical State/Property Sensor [MSP])
110.1
Gear Turning
477
440
110.2
110.3
110.4
110.5
110.6
110.7
110.8
415.A
415.B
415.C
415.D
Planet gear
410 (403)
Sun gear (Input)
Ring gear
420 (403)
450.4
450.4
Effective Gear Vibration Detection Range

FIG. 7

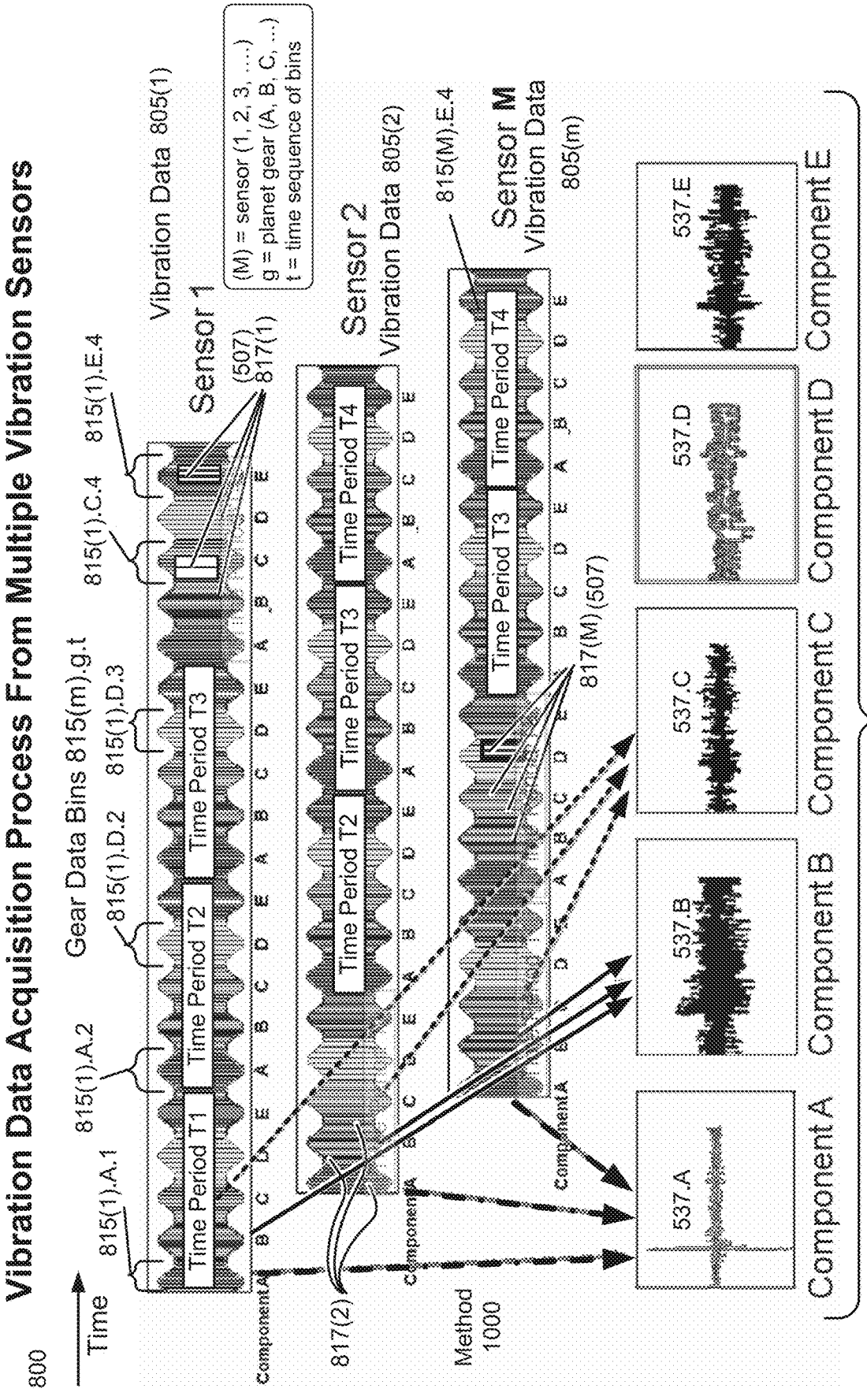

800
Vibration Data Acquisition Process From Multiple Vibration Sensors
Time
Gear Data Bins 815(m).g.t
815(1).A.1
815(1).A.2
815(1).D.2
815(1).D.3
815(1).C.4
815(1).E.4
Vibration Data 805(1)
Sensor 1
(507)
817(1)
(M) = sensor (1, 2, 3, ...)
g = planet gear (A, B, C, ...)
t = time sequence of bins
Time Period T1
Time Period T2
Time Period T3
Time Period T4
Sensor 2
Vibration Data 805(2)
815(M).E.4
Sensor M
Vibration Data
805(m)
817(2)
817(M)
(507)
Method
1000
537.A
537.B
537.C
537.D
537.E
Component A
Component B
Component C
Component D
Component E
Vibration Profiles 820.g

FIG. 8

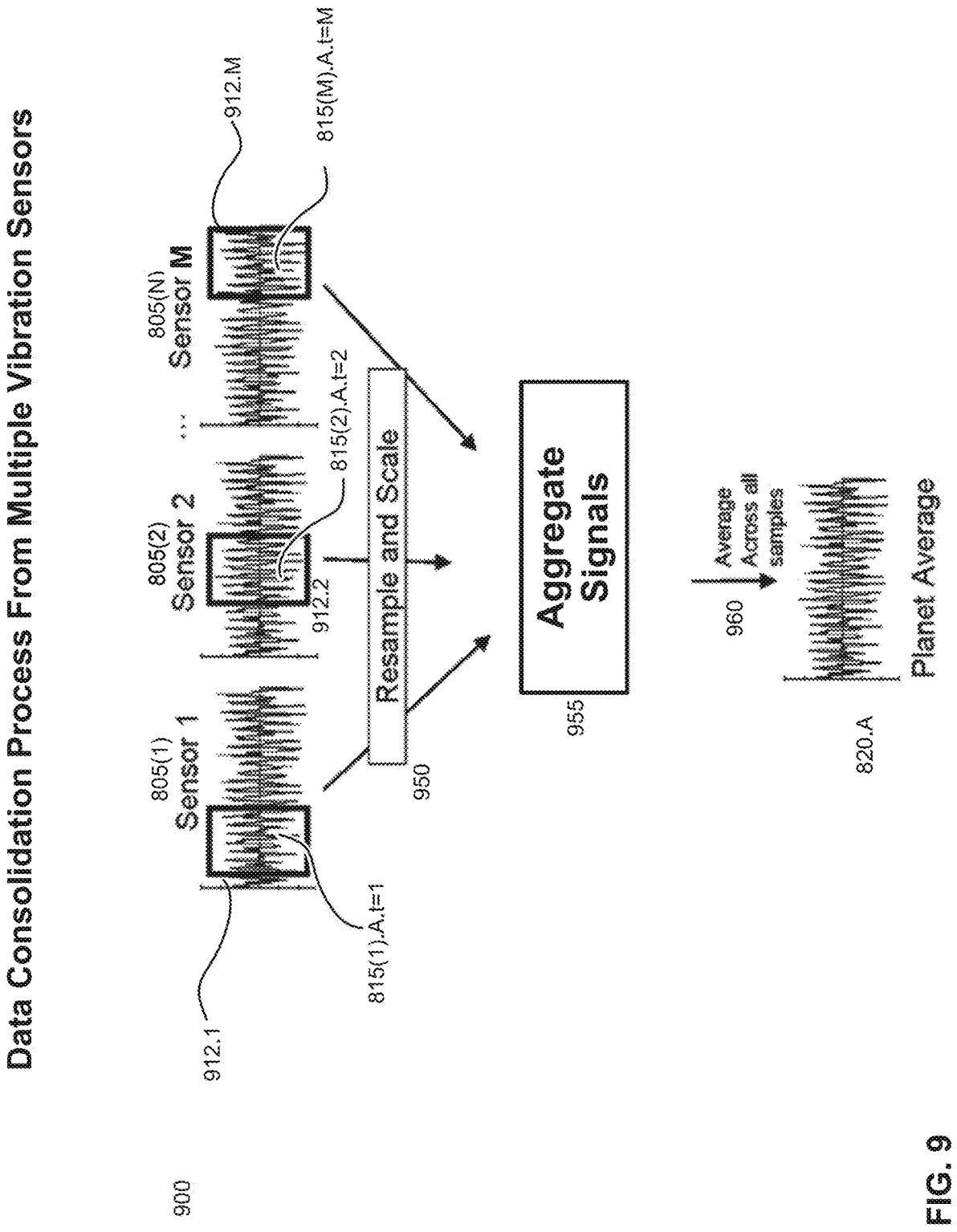

Data Consolidation Process From Multiple Vibration Sensors
900
805(1)
Sensor 1
912.1
815(1).A.t=1
805(2)
Sensor 2
912.2
815(2).A.t=2
805(N)
Sensor M
912.M
815(M).A.t=M
Resample and Scale
950
Aggregate Signals
955
960
Average Across all samples
820.A
Planet Average

FIG. 9

Method for Gear-and-Teeth-Specific Vibration Sensing With Multiple Vibration Sensors

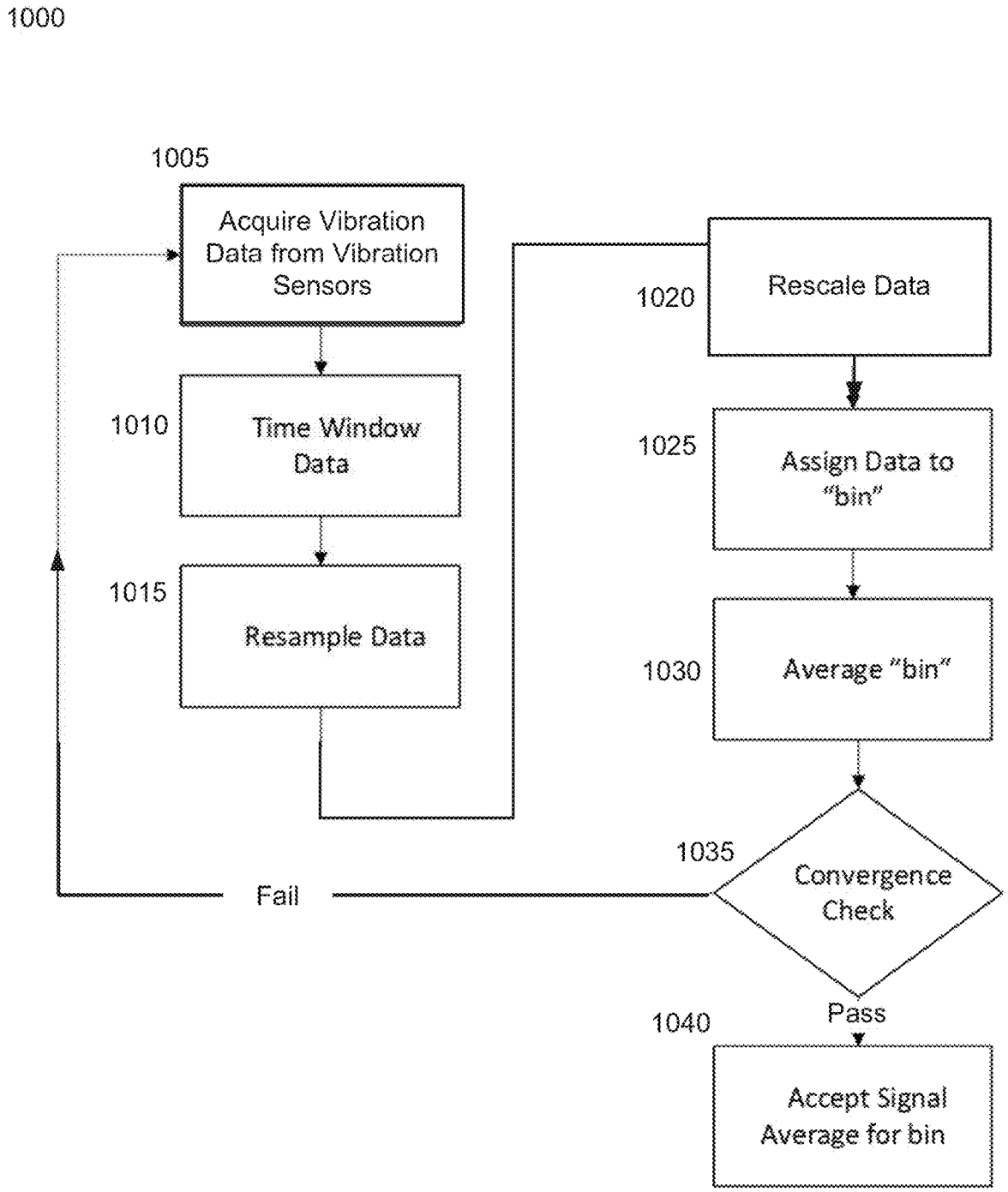


FIG. 10

sensors. As above, normalization may be achieved by, for example and without limitation, software processing or adjusting gain on a signal.

[0198] Monitoring of continuous components: In an alternative embodiment, the present system and method, employing multiple sensors, may be used to provide improved health monitoring for a continuous component which is subject to spatial translation within a larger system. For example, multiple cameras or optical sensors may monitor the condition(s) of portions of a rapidly moving fan belt or chain (which may in turn move or be moved by multiple stationary gears). Real-time "snap shot" sensing of a fan belt or chain may be employed to maintain a continuous monitor of the entire condition of the fan belt or chain.

[0199] The methods disclosed herein thereby reduce the number of revolutions (or other path traversals) required to build up an accurate picture of component health for dynamically moving components. For example, in a planetary gear system **705**, increasing the number of sensing locations at which planet gears **415** are tracked around the gearbox **210**, fewer revolutions are required to obtain a complete vibration signal for each planet gear **415** (as opposed to systems with a single sensor).

[0200] Non-transportation systems: While the present system and method has been described herein with respect to vibration monitoring of rotary elements of a vehicle, many other mechanical and electron mechanical systems employ rotary gear systems and other rotary functional elements as well. For example, wind turbines and other automatic gearboxes have rotary mechanical components including planetary gear systems and blades. All such systems may also benefit from vibration monitoring via the present system and method.

VII. CONCLUSION

[0201] Alternative embodiments, examples, and modifications which would still be encompassed by the disclosure may be made by those skilled in the art, particularly in light of the foregoing teachings. Further, it should be understood that the terminology used to describe the disclosure is intended to be in the nature of words of description rather than of limitation.

[0202] Those skilled in the art will also appreciate that various adaptations and modifications of the preferred and alternative embodiments described above can be configured without departing from the scope of the disclosure. Therefore, it is to be understood that, within the scope of the appended claims, the disclosure may be practiced other than as specifically described herein.

[0203] The present invention has been described above with the aid of functional building blocks illustrating the implementation of specified functions and relationships thereof. The boundaries of these functional building blocks have been arbitrarily defined herein for the convenience of the description. Alternate boundaries can be defined so long as the specified functions and relationships thereof are appropriately performed.

[0204] For example, various aspects of the present invention can be implemented by software, firmware, hardware (or hardware represented by software such, as for example, Verilog or hardware description language instructions), or a combination thereof. After reading this description, it will become apparent to a person skilled in the relevant art how to implement the invention using other computer systems and/or computer architectures.

[0205] It should be noted that the simulation, synthesis and/or manufacture of the various embodiments of this invention can be accomplished, in part, through the use of computer readable code, including general programming languages (such as C or C++), hardware description languages (HDL) including Verilog HDL, VHDL, Altera HDL (AHDL) and so on, or other available programming and/or schematic capture tools (such as circuit capture tools).

[0206] This computer readable code can be disposed in any known computer usable medium including semiconductor, magnetic disk, optical disk (such as CD-ROM, DVD-ROM) and as a computer data signal embodied in a computer usable (e.g., readable) transmission medium (such as a carrier wave or any other medium including digital, optical, or analog-based medium). As such, the code can be transmitted over communication networks including the Internet and intranets. It is understood that the functions accomplished and/or structure provided by the systems and techniques described above can be represented in a core (such as a GPU core) that is embodied in program code and can be transformed to hardware as part of the production of integrated circuits.

[0207] It is to be appreciated that the Detailed Description section (and not the Summary and Abstract sections) is primarily intended to be used to interpret the claims. The Summary and Abstract sections may set forth one or more but not all exemplary embodiments of the present invention as contemplated by the inventor(s), and thus, are not intended to limit the present invention and the appended claims in any way.

What is claimed is:

1. A method for obtaining mechanical state/property data for a plurality of mechanical elements engaged in a periodic rotation within a mechanical system, the method comprising:

from each respective sensor of a plurality of mechanical state/property (MSP) sensors attached along a surface which is part of or proximate to the exterior of the mechanical elements, the plurality of MSP sensors being spaced apart from each other along a sensing path of the periodic rotation of the mechanical elements, obtaining at a hardware processor of a processing unit a respective time-continuous MSP sensor signal indicative of a sensed mechanical property of the plurality of mechanical elements;

for a first time-continuous mechanical data signal from a first MSP sensor of the plurality of MSP sensors:

determining via the hardware processor a first series of respective consecutive time windows when each respective mechanical element passes within a sensing range of the first MSP sensor;

based on the first series of time windows, determining a respective first plurality of time-separated gear data bins which each includes first mechanical property sensor data for only one respective specific mechanical element of the plurality of mechanical elements;

for a second time-continuous vibration signal from a second MSP sensor of the plurality of MSP sensors:

determining via the hardware processor a second series of respective consecutive time windows when each respective mechanical element passes within a sensing range of the second MSP sensor;

based on the second series of time windows, determining a respective second plurality of time-separated gear data bins which each includes second MSP sensor data for only the one respective specific mechanical element;

determining via the hardware processor that a first gear data bin from the first plurality of gear data bins occurs over a first time interval t;

determining via the hardware processor that a second gear data bin from the second plurality of gear data bins occurs over a second time interval t+1, wherein the second time interval is successive to the first time interval t; and

combining via the hardware processor the first gear data bin and the second gear data bin as successive first and second successive gear data bins, wherein the hardware processor establishes a first element-specific mechanical state/property profile for the one specific mechanical element, the profile indicative of the mechanical/state property of the one specific mechanical element over an extended time interval which includes the time interval t and the time interval t+1.

2. The method for obtaining vibration data of claim **1**, further comprising:

repeating the method steps for additional MSP sensors of the plurality of MSP sensors, wherein the mechanical state/property profile for the one specific mechanical element includes all the MSP data for the one specific mechanical element from all of the MSP sensors of the plurality of MSP sensors.

3. The method for obtaining vibration data of claim **1**, further comprising performing the method steps for a second specific mechanical element which is different from the one specific mechanical element, wherein the method establishes a second element-specific mechanical state/property profile for the second specific mechanical element.

4. The method of claim **1**, wherein the mechanical elements are planet gears and the sensors are vibration sensors configured to detect vibrations from the planet gears, and

wherein the method comprises generating at the microprocessor, from the vibration sensor data from the plurality of vibration sensors, a vibration profile for the one specific planet gear of the plurality of planet gears.

5. The method for obtaining vibration data of claim **4**, further comprising:

repeating the method steps for additional vibration sensors of the plurality of vibration sensors, wherein the vibration profile for the one planet gear includes all the vibration data for the one specific planet gear from all the vibration sensors of the plurality of vibration sensors.

6. The method for obtaining vibration data of claim **4**, further comprising:

performing the method steps for a second specific planet gear which is different from the one specific planet gear, wherein the hardware processor establishes a second gear-specific vibration profile for the second specific planet gear.

7. The method for obtaining vibration data of claim **4**, further comprising applying teeth-specific time windows to obtain vibration data for a specific tooth of the one specific planet gear.

8. The method of claim **1**, wherein the mechanical elements are a plurality of turbine blades of a turbine

the MSP sensors are time-of-arrival (TOA) sensors configured to detect a time of arrival of a turbine blade in proximity to a TOA sensor, and

the method comprises generating at the microprocessor a TOA profile for one specific blade of the plurality of turbine blades.

9. The method for obtaining TOA data of claim **8**, further comprising:

repeating the method steps for additional TOA sensors of the plurality of TOA sensors, wherein the TOA profile for the one specific blade includes all the TOA data for the one specific blade from all the TOA sensors of the plurality of TOA sensors.

10. The method for obtaining TOA data of claim **8**, further comprising:

performing the method steps for a second specific blade which is different from the one specific blade, wherein the hardware processor establishes a second blade-specific TOA profile for the second specific blade.

11. The method of obtaining mechanical state/property data for the plurality of mechanical elements of claim **1**, further comprising:

scaling the MSP data from the MSP sensors to compensate for sensor-specific or sensor-location specific variations in mechanical/state property detection in the plurality of MSP sensors.

12. A method for obtaining vibration data for a plurality of mechanical components engaged in a periodic rotation within a mechanical system, the method comprising:

from each respective sensor of a plurality of vibration sensors attached along a surface which is part of or proximate to the exterior of the mechanical elements of the mechanical elements, the plurality of vibration sensors being spaced apart from each other along a path of the periodic rotation of the mechanical elements, obtaining at a hardware processor a plurality of time-continuous vibration sensor signals, each respective vibration sensor signal indicative of successively detected vibrations from the plurality of rotating mechanical components as detected by each respective vibration sensor of the plurality;

applying via the hardware processor respective synchronous time windows to each of the plurality of vibration sensor signals to identify respective sets of associated vibration data bins for each respective mechanical component; and

aggregating via the hardware processor the vibration data bins which are associated with each specific mechanical component of the rotating plurality of mechanical components to generate a plurality of respective vibration profiles for the each respective mechanical component of the rotating plurality of mechanical components.

13. The method of claim **12**, wherein:

the respective synchronous time windows are a set of sensor-specific time windows, each time window spanning a sensing period of time when a single mechanical component is within a sensing range of a single vibration sensor;

each synchronous time window of the set being associated with a different sensor; and

each synchronous time window occurs at a different specific times;

US010740855B2

(12) **United States Patent**
Lesik et al.

(10) **Patent No.: US 10,740,855 B2**
(45) **Date of Patent: Aug. 11, 2020**

(54) **SUPPLY CHAIN TRACKING OF FARM PRODUCE AND CROPS**

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(72) Inventors: **Joseph R. Lesik**, Greenburg, PA (US); **Brian Sutton**, North Huntingdon, PA (US)

(73) Assignee: **HAND HELD PRODUCTS, INC.**, Fort Mill, SC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 601 days.

(21) Appl. No.: **15/378,124**

(22) Filed: **Dec. 14, 2016**

(65) **Prior Publication Data**

US 2018/0165771 A1 Jun. 14, 2018

(51) **Int. Cl.**
G06Q 50/02 (2012.01)
G06Q 10/08 (2012.01)

(52) **U.S. Cl.**
CPC ***G06Q 50/02*** (2013.01); ***G06Q 10/087*** (2013.01)

(58) **Field of Classification Search**
CPC G06Q 10/087; G06Q 50/02
See application file for complete search history.

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(74) *Attorney, Agent, or Firm* — Alston & Bird LLP

(57) **ABSTRACT**

A device, system, and method are disclosed whereby farm produce harvested at a particular time and location can be tracked throughout the food supply chain, from farm or orchard to consumer market. If farm produce in the market is found to be unhealthy, contaminated, or otherwise unsuited for human consumption, the system and method enables identification of the source of harvesting, and so identification of other produce which was harvested at substantially the same time and location. This enables improved identification and containment of any problems in the produce food supply chain.

20 Claims, 7 Drawing Sheets

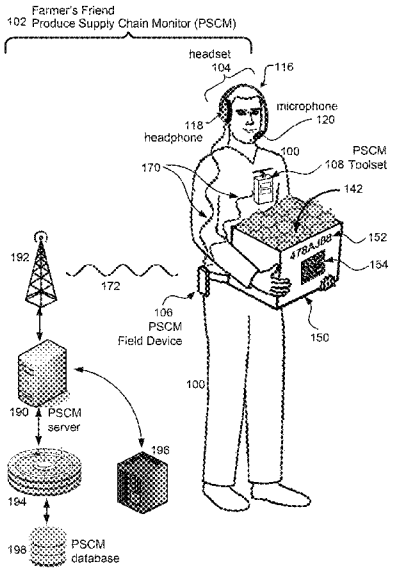


FIG. 1B

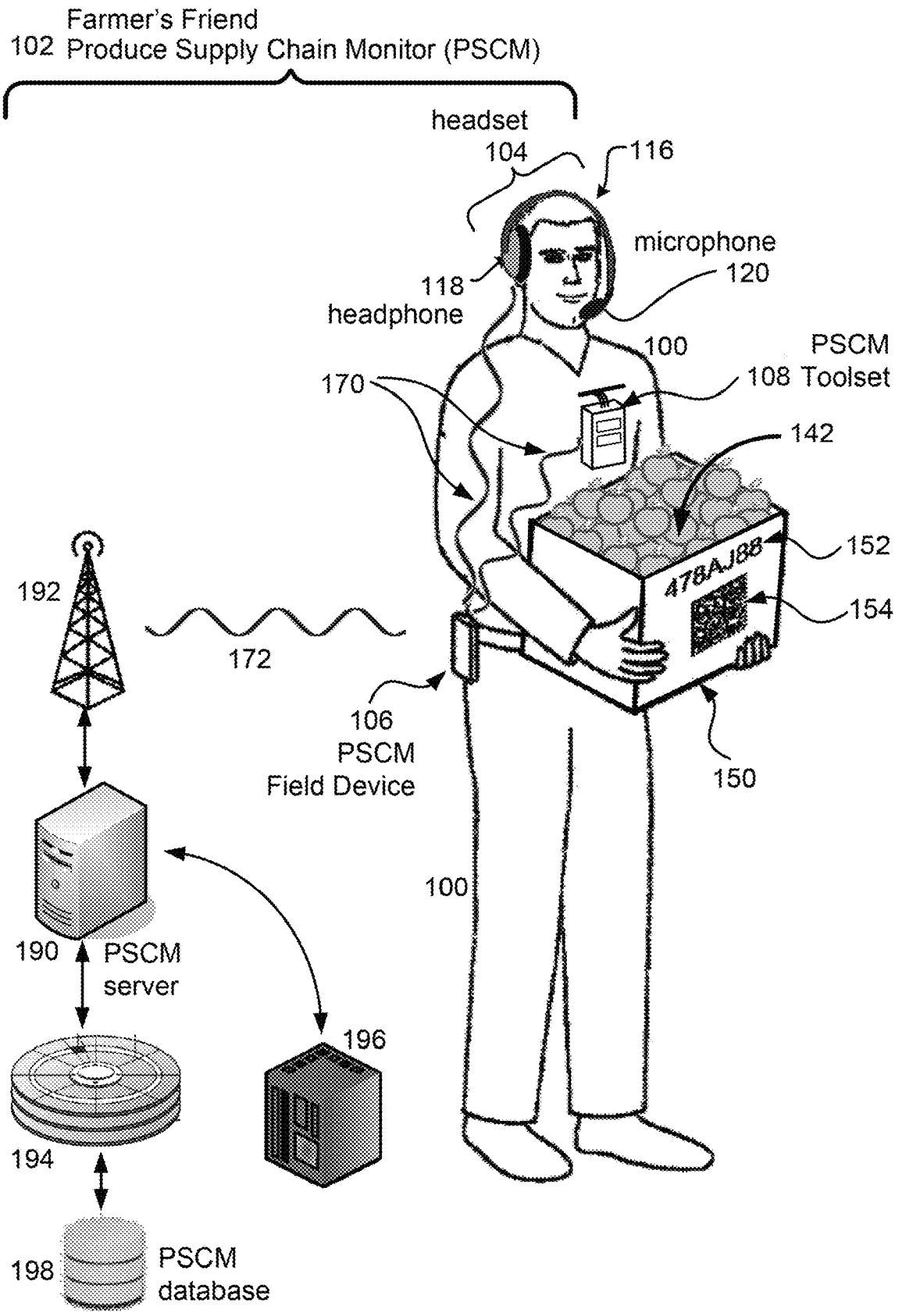
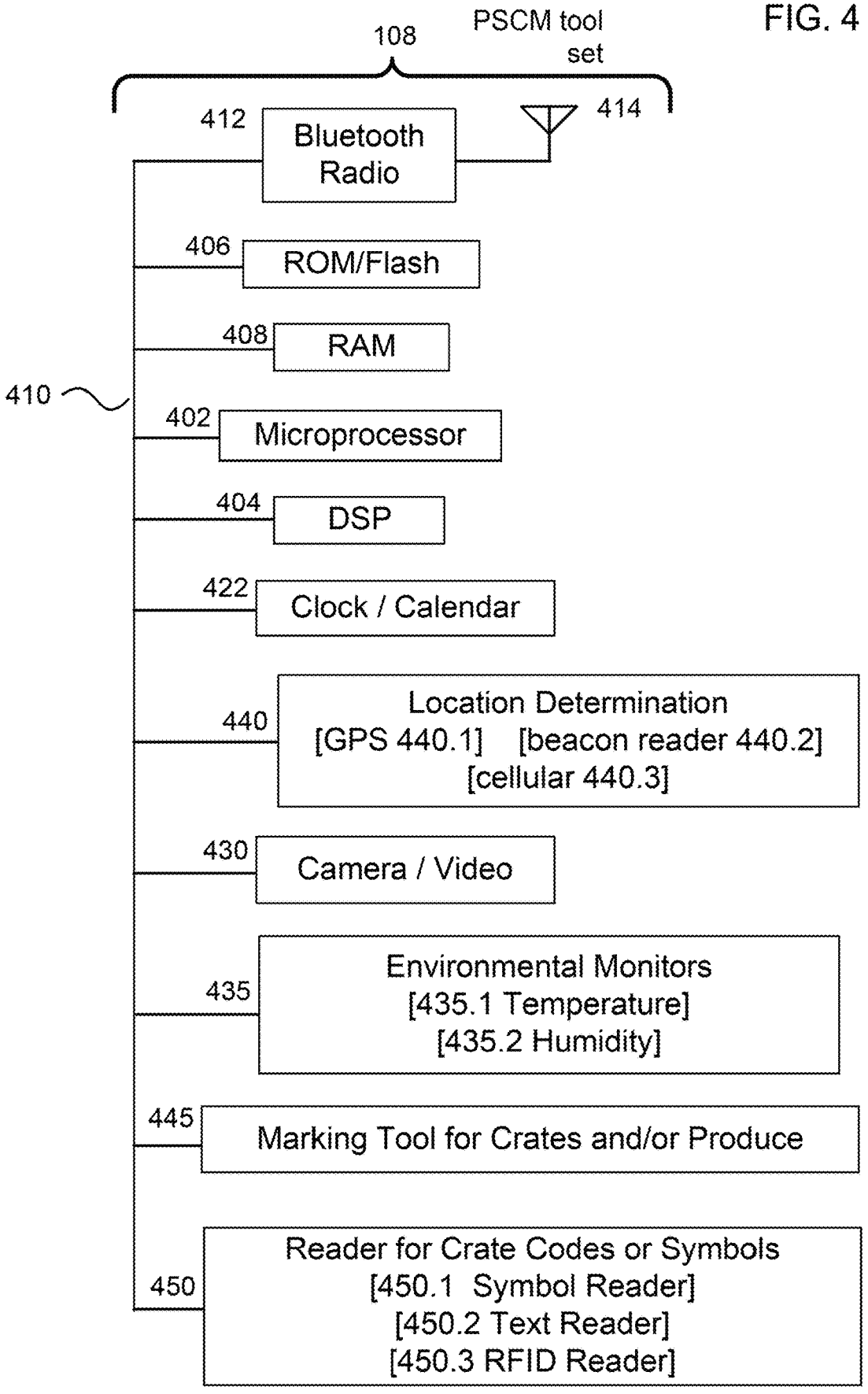

Farmer's Friend
102 Produce Supply Chain Monitor (PSCM)
headset
104
116
microphone
120
118
headphone
100
PSCM
108 Toolset
170
142
152
478AJ88
154
192
172
106
PSCM
Field Device
150
100
190
PSCM
server
196
194
198
PSCM
database

FIG. 4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RAM
410
402
Microprocessor
404
DSP
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Clock / Calendar
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Location Determination
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[cellular 440.3]
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Camera / Video
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Environmental Monitors
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Reader for Crate Codes or Symbols
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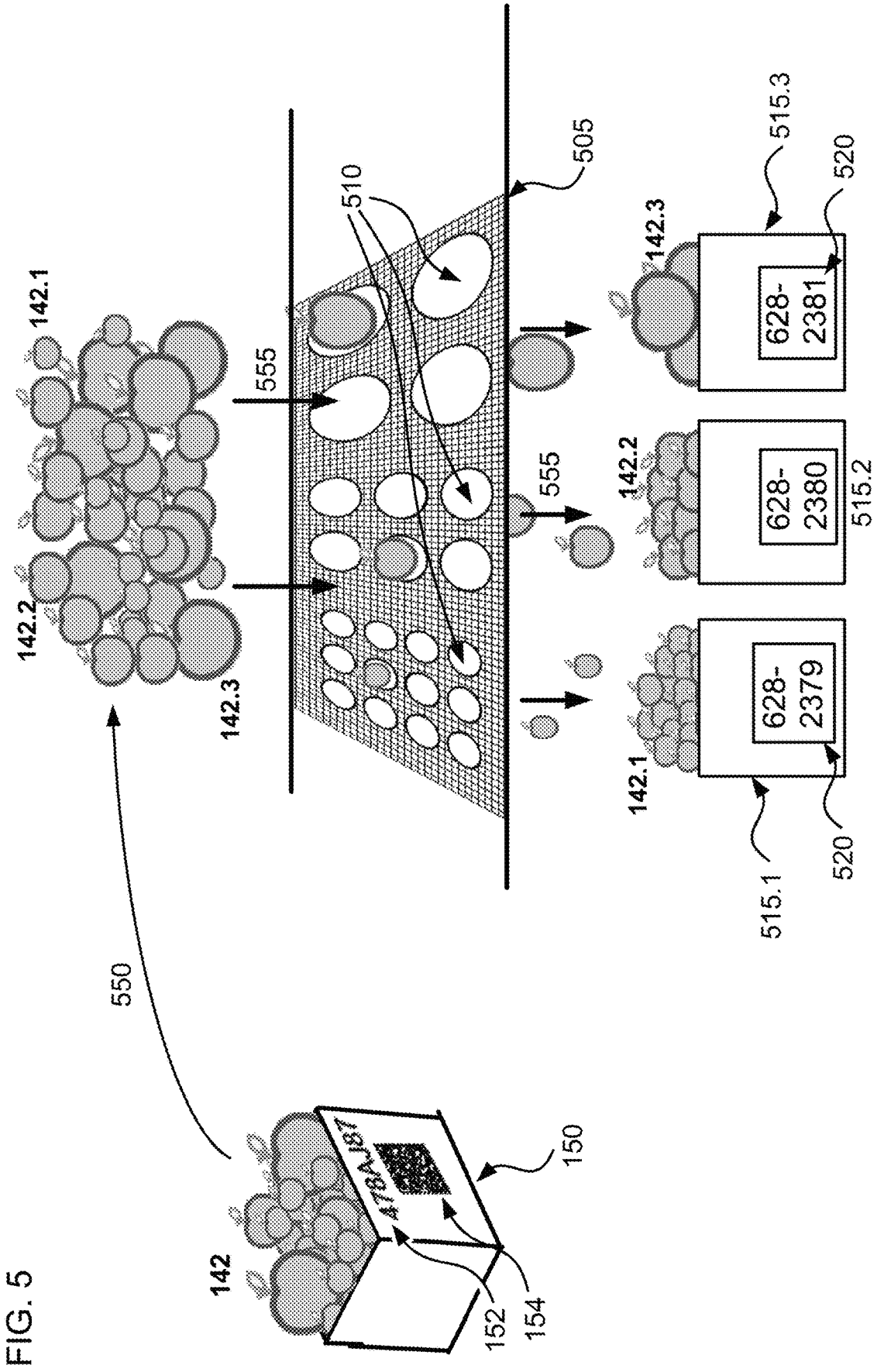
[450.2 Text Reader]
[450.3 RFID Reader]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154
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142.1
142.2
142.3
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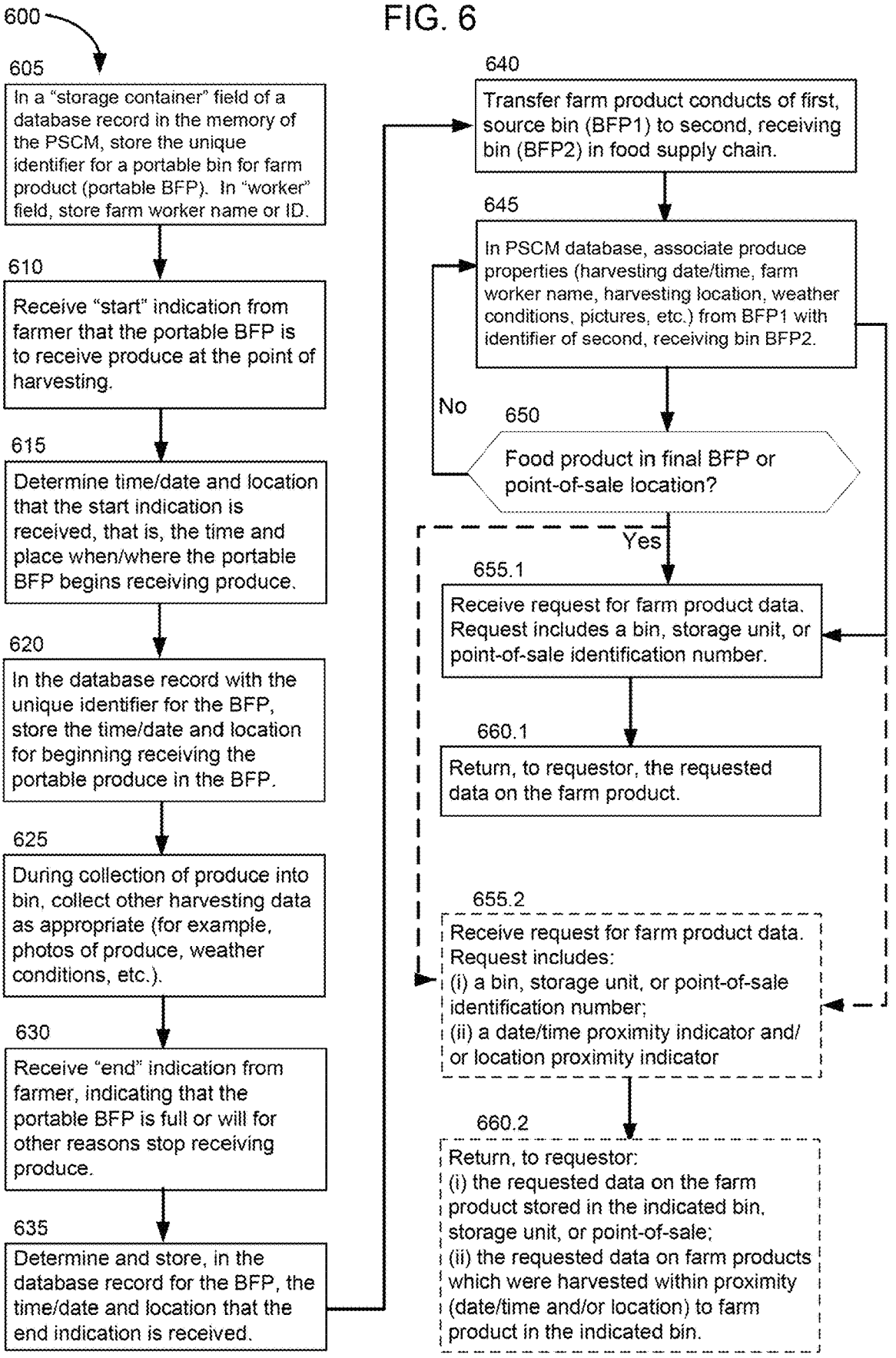
628-2379
628-2380
628-2381

FIG. 5

FIG. 6


600
605
In a "storage container" field of a database record in the memory of the PSCM, store the unique identifier for a portable bin for farm product (portable BFP). In "worker" field, store farm worker name or ID.
610
Receive "start" indication from farmer that the portable BFP is to receive produce at the point of harvesting.
615
Determine time/date and location that the start indication is received, that is, the time and place when/where the portable BFP begins receiving produce.
620
In the database record with the unique identifier for the BFP, store the time/date and location for beginning receiving the portable produce in the BFP.
625
During collection of produce into bin, collect other harvesting data as appropriate (for example, photos of produce, weather conditions, etc.).
630
Receive "end" indication from farmer, indicating that the portable BFP is full or will for other reasons stop receiving produce.
635
Determine and store, in the database record for the BFP, the time/date and location that the end indication is received.
640
Transfer farm product conducts of first, source bin (BFP1) to second, receiving bin (BFP2) in food supply chain.
645
In PSCM database, associate produce properties (harvesting date/time, farm worker name, harvesting location, weather conditions, pictures, etc.) from BFP1 with identifier of second, receiving bin BFP2.
No
650
Food product in final BFP or point-of-sale location?
Yes
655.1
Receive request for farm product data. Request includes a bin, storage unit, or point-of-sale identification number.
660.1
Return, to requestor, the requested data on the farm product.
655.2
Receive request for farm product data. Request includes:
(i) a bin, storage unit, or point-of-sale identification number;
(ii) a date/time proximity indicator and/or location proximity indicator
660.2
Return, to requestor:
(i) the requested data on the farm product stored in the indicated bin, storage unit, or point-of-sale;
(ii) the requested data on farm products which were harvested within proximity (date/time and/or location) to farm product in the indicated bin.

SUPPLY CHAIN TRACKING OF FARM PRODUCE AND CROPS

FIELD OF THE INVENTION

The present invention relates to a method and apparatus for product recognition, inventory tracking, and monitoring; and more particularly, to a method and apparatus for tracking and quality monitoring farm produce and other farm crops from their point-of-origin in the field to their point-of-processing and/or point-of-sale.

BACKGROUND

For food consumers, food producers, and government regulatory agencies alike, food safety is an ever-growing concern. One reflection of this is the U.S. Food Safety Modernization Act (FSMA), legislation signed into law by President Obama on Jan. 4, 2011. The U.S. Food and Drug Administration (FDA) states in a fact sheet on its web site (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm), "Background on the FDA Food Safety Modernization Act (FSMA)":

"The FDA Food Safety Modernization Act (FSMA) . . . enables FDA to better protect public health by strengthening the food safety system . . . . Mandatory produce safety standards: FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables . . . . New authorities include: 1 . . . . Enhanced product tracing abilities: FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a food-borne illness outbreak." (Bold emphasis added.)

Even as this document is being prepared (May/June 2016), the FDA has established regulations under the FSMA, and is engaged in further active rulemaking to implement the FSMA. For more information on the FSMA and related rulemaking, see also http://www.pma.com/topics/food-safety/fsma.

The FSMA is expected to touch every segment of the produce business from farm to fork. "Produce" is a general term for a group of farm-produced crops and goods, especially fruits and vegetables, but possibly also including meats, grains, oats, etc. The term "produce" commonly implies that the farm products, as presented to consumers in stores, are fresh and generally in the same state as where they were harvested.

Rules are that are affected by the FSMA pertain to, among other areas: 1. Preventive Control Rules for Human Foods; 2. Sanitary Food Transportation Regulation; and 3. Traceability Regulations (yet to be proposed).

An organization called GS1 serves businesses in twenty-five industries in the United States by facilitating industry initiatives, and administrating the GS1 System of standards. GS1 develops and implements industry and company-level solutions and standards to optimize business processes, including supply chain management standards. (See http://www.gs1us.org/for more information.) Among those standards have been voluntary produce traceability initiatives with GS1 marking requirements. (See https://www.gs1us.org/gs1_us_search?q=fresh%20foods %20booklet for more information.)

Under the FSMA, GS1 marking requirements or similar requirements may become legally required. These requirements could be driven by the retailers (through liability concerns) or by new regulations. (See https://www.youtube.com/watch?v=K-sOQJHytxk for a video with more information.)

Further, in addition to government requirements and regulations, safety- and health-conscious consumers and consumer organizations increasingly call upon food producers to ensure and enhance the safety of the food chain.

As indicated in the quoted material above, one area of concern is the safety of produce, typically fruits and vegetables. Fruits and vegetables are subject to diseases and are exposed to numerous chemicals (fertilizers and others), and are potentially subject to spoilage during shipment.

Ideally, then, food producers should be able to provide a detailed accounting of produce and environments to which the produce is subject, from first picking on the farm, through the entire transport and processing chain, and straight to the consumer end consumer. This is especially desirable for produce which will reach the end consumer with little or no processing—that is, raw fruits and vegetables for direct consumer consumption. However, tracking can also be valuable for fruits and vegetables which are to be processed (chopped, pureed, or otherwise modified) and mixed with other ingredients.

As produce is often farmed and transported by persons who may not be experts in data management or data tracking, there is a challenge in recording and maintaining a record of produce from point of origin to point of processing or point of sale.

What is needed, then, is an improved system and method for recording and tracking data pertinent to the quality of produce which is grown and harvested on a farm, and maintaining a track of that data from the harvesting on the farm to at least a designated point-of-processing, and more typically to the point-of-consumer-sale.

SUMMARY

In modern production environments, such as factories, it is increasingly common for human operators to be able to record data and to engage in manual activities in a "hands-free" data mode, typically via speech control. This typically entails the use of portable electronic voice-processing devices which can detect human speech; interpret the speech; and process the interpreted speech to recognize words, to record data, and/or to control integrated or nearby electronic systems.

Voice-driven systems typically include at least one microphone and at least one hardware processor-based device (e.g., computer system) which is operated in response to human voice or spoken input, for instance spoken commands and/or spoken information.

In many of these exemplary applications it is also advantageous or even necessary for the human operators to be mobile. For applications in which mobility is desirable, the human operators may wear a headset and a portable processor-based device.

For reasons which will become apparent below, the portable processor device is also referred to in this document as a Produce Supply Chain Monitor (PSCM) field device. The headset typically includes at least one loud-speaker and/or microphone. The portable processor-based device typically takes the form of a wearable computer system. The headset is communicatively coupled to the portable processor-based device, for instance via a coiled wire or a wireless connection, for example, a Bluetooth connection.

In some applications, the portable processor-based device (PSCM field device) may in turn be communicatively coupled to a host or backend computer system (e.g., server computer). For reasons which will become apparent below, the backend server is also referred to in this document as the PSCM server. In many applications, two or more portable processor-based devices (clients) may be communicatively coupled to the host or backend computer system/server.

The server may function as a centralized computer system providing computing and data-processing functions to various human workers via respective portable processor-based devices and headsets.

Applications to Farming and Food Chain Monitoring:

Such voice-driven systems can also be used to enhance monitoring of the food chain. To be advantageously employed in a farming environment, such voice-driven system may benefit from enhancement by attachment or inclusion of various environmental sensors, which can record data pertinent to food safety. They may also benefit from the addition of bin, container or barrel marking tools to label produce harvesting bins/containers/barrels; or a barcode reader or RFID reader to read a barcode or RFID tag already associated with a bin and used to identify the bin. Other elements may be included as well.

Accordingly, in one aspect, present system and method is also referred to in this document as a Produce Supply Chain Monitor system and method, or PSCM. A produce supply chain monitor system may be used by produce and farm industry workers, providing them with the tools they needed to meet all of the emerging FSMA regulations, while keeping their and hands and eyes free to do their jobs. In an embodiment, the system and method features electronics and supporting software which are to be worn in the field by a farm-worker, the system including:

(i) a wearable speech recognition headset or a headset with microphone coupled to a processor-based device, also known as a PSCM field device, which includes speech recognition capabilities;

(ii) a wide-area-network (WAN) radio enabling communication between the farm workers and central servers; in an alternative embodiment, the PSCM system and method may use cellular communications (substantially similar to that used in consumer cell phones) to upload data to a central data server, or PSCM server. In an alternative embodiment, the system may feature means to upload data to a central server via a wired-connection or via a shorter-range wireless connection (for example, a wireless local area network (WLAN) which may be based on 802.11 (Wi-Fi) protocols.);

(iii) a location assessment system, for example, GPS receivers, to identify the location where produce is first picked;

(iv) a marking tool to mark and identify produce storage units, such as harvesting crates or bins, which hold the freshly picked produce; an alternative embodiment may employ a crate-scanning tool to detect existing identification markers on harvesting bins; and

(v) suitable application software to support all the above.

In another aspect, the present system and method, also referred to herein as a produce supply chain monitor (PSCM) system and method, solves the problem by integrating elements which may include a voice-enabled mobile supply chain tracking system, a location sensor, for example a GPS sensor, and possibly other sensors such as video or a camera to record the condition of fruit or vegetables at the time of picking. Other sensors may be used as well.

The PSCM system records produce data at the time of picking, and associates the data with a suitable tracking number, for example a harvesting bin number (for a harvesting bin with multiple samples of the produce from a common source, such as a common tree) or even a label number associated with individual produce. Data may be recorded visually, or as voice information by the farmer picking the produce. Data may be transmitted from the point of picking to a central server via a wide area network.

The information is transmitted to a central server or other central PSCM processor. If the tracking method for the produce is maintained (even across transfers to various transportation or point-of-sale containers) for the duration of the food chain, then origin information can readily be obtained for produce at the processing or consumer end of the food chain.

Accordingly, in another aspect, the present system and method solves the problem by integrating software-based monitoring and control into the food chain and its associated farming, transport, and food processing processes. The software integrates elements which may include a mobile supply chain tracking system that includes voice recognition capabilities, a location sensor, for example a GPS sensor, and possibly other sensors such as video or a camera to record the condition of fruit or vegetables at the time of picking. The software may make operable other sensors which may be employed as well. The software directs the food supply chain system to record produce data at the time of picking, and to associate the data with a suitable tracking number. The tracking number may for example be a harvesting bin number (for a harvesting bin with multiple samples of the produce from a common source, such as a common tree) or even a label number associated with individual produce. The software may direct the system to record data visually, or as voice information by the farmer picking the produce, or as a text transcription of the voice information provided by the farmer.

Distribution and Availability of Produce-Related Information:

The software is so configured that produce-related information is transmitted to a central server or other central processor. If the software maintains the tracking method for the produce for the duration of the food chain, then origin information can readily be obtained for produce at the processing or consumer end of the food chain.

For example, sometimes diseases are discovered in produce which is already in the marketplace (that is, on sale or sold to consumers). Currently, it may be difficult or impossible to identify exactly when the diseased produce was picked and/or where it was picked.

With the present system and method, in the event that produce is found, at some point, to be diseased or contaminated, the point of original can be identified, along with other produce harvesting bins that were obtained as the same location. In this way, sources of disease or contamination can be readily identified and isolated.

BRIEF DESCRIPTION OF THE DRAWINGS

At points throughout this document as appropriate, FIGS. **1**A and **1**B may be referred to collectively as FIG. **1**.

FIG. **1**A is a view of an exemplary produce orchard where the present system and method may be applied.

FIG. **1**B is a view of an exemplary produce supply chain monitor (PSCM) according to one exemplary embodiment of the present system and method.

In addition, those skilled in the art will appreciate that the control mechanisms taught herein are capable of being distributed as a program product in a variety of tangible forms, and that an illustrative embodiment applies equally regardless of the particular type of tangible instruction bearing media used to actually carry out the distribution. Examples of tangible instruction bearing media include, but are not limited to, the following: recordable type media such as floppy disks, hard disk drives, CD ROMs, DVDs, digital tape, flash drives, and other such computer memory devices and hardware as may be available.

The various embodiments described above can be combined to provide further embodiments. These and other changes can be made to the present systems and methods in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to include all voice-recognition systems that read in accordance with the claims. Accordingly, the invention is not limited by the disclosure, but instead its scope is to be determined entirely by the following claims.

What is claimed is:

1. A method for a portable electronic system to track produce harvested on a farm, the method comprising:

storing, via a processor of the portable electronic system, in a memory of the portable electronic system, a unique identifier associated with a harvesting bin;

receiving, via a microphone of the portable electronic system, a voice command from a worker;

filtering, by an audio filtering circuitry of the portable electronic system, the received voice command to distinguish an acceptable worker speech sample from a background speech sample, wherein the received voice command is filtered by comparing the received voice command to speech samples stored in the memory of the portable electronic system;

converting, via the microphone of the portable electronic system, the filtered voice command into a digital signal comprising an indication that the harvesting bin is to receive the produce at a harvesting location;

determining a harvesting time, for the harvesting bin to receive the produce that is harvested, based on the indication and a timer of the portable electronic system;

determining coordinates of the harvesting location at the harvesting time based on the indication and a location detector of the portable electronic system;

detecting, via at least one sensor of said portable electronic system, a condition of the produce at the harvesting time and the harvesting location; and

associating, via the processor and the memory of the portable electronic system, the harvesting time, the harvesting location, and the condition of the produce with the identified harvesting bin which receives the produce upon harvesting and storing the association of the harvesting time, the harvesting location, and the condition with the identified harvesting bin in the memory.

2. The method of claim **1**, wherein storing the unique identifier associated with the harvesting bin comprises:

marking, via a marking tool of the portable electronic system, the unique identifier on the harvesting bin which receives the produce upon harvesting; and

storing the unique identifier in the memory of the portable electronic system.

3. The method of claim **2**, wherein marking the unique identifier on the harvesting bin via the marking tool comprises marking the harvesting bin via at least one of:

imprinting a printed label on the harvesting bin via at least one of an ink stamping mechanism, a label printer, an ink spray printer, or a laser marking tool;

programming an electronic display affixed to the harvesting bin via an electronic remote control device; or

encoding an RFID tag attached to the harvesting bin via an RFID writer.

4. The method of claim **1**, wherein a unique code or a symbol is previously imprinted on, embedded in, programmed into, or attached to the harvesting bin at a time prior to the harvesting bin's use for harvesting, and associating the unique identifier with the harvesting bin; and

further comprising reading, via a reader of the portable electronic system, the unique code or the symbol.

5. The method of claim **1**, wherein the indication that the harvesting bin is to receive the produce at the harvesting location further comprises:

receiving, via a mechanical or a graphical interface of the portable electronic system, a manually entered command selection from the worker harvesting said produce.

6. The method of claim **1**, further comprising:

receiving, via a user interface of the portable electronic system, an indication of at least one of that the harvesting bin has been filled with the produce or that no more produce is available to fill the harvesting bin;

determining a harvesting time when the produce harvesting into the harvesting bin is completed based on the indication and the timer of the portable electronic system;

determining coordinates of the harvesting location of the completion of harvesting of the produce into the harvesting bin based on the indication and the location detector of the portable electronic system;

detecting, via the at least one sensor of said portable electronic system, a condition of the produce at the harvesting time and the harvesting location of the completion of harvesting of the produce; and

associating, via the processor and the memory of the portable electronic system, the harvesting time, the harvesting location, and the condition of the produce associated with the completion of harvesting of the produce into the harvesting bin with the identified harvesting bin which received the produce.

7. A method to track produce harvested on a farm, the method comprising:

receiving, via a microphone of a portable electronic system, a voice command from a worker;

filtering, by an audio filtering circuitry of the portable electronic system, the received voice command to distinguish an acceptable worker speech sample from a background speech sample, wherein the received voice command is filtered by comparing the received voice command to speech samples stored in a memory of the portable electronic system;

converting, via the microphone of the portable electronic system, the filtered voice command into a digital signal comprising an indication that a harvesting bin is to receive the produce at a harvesting location;

determining a harvesting time, for a harvesting bin to receive the produce that is harvested, based on a timer of a portable electronic system configured to be operated by the worker harvesting said produce;

US 20110082350A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2011/0082350 A1

(43) Pub. Date: Apr. 7, 2011

Koh

(54) **ASSESSING A DEGREE OF VASCULAR BLOCKAGE OR RISK OF ISCHEMIA**

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(21) Appl. No.: **12/573,735**

(22) Filed: **Oct. 5, 2009**

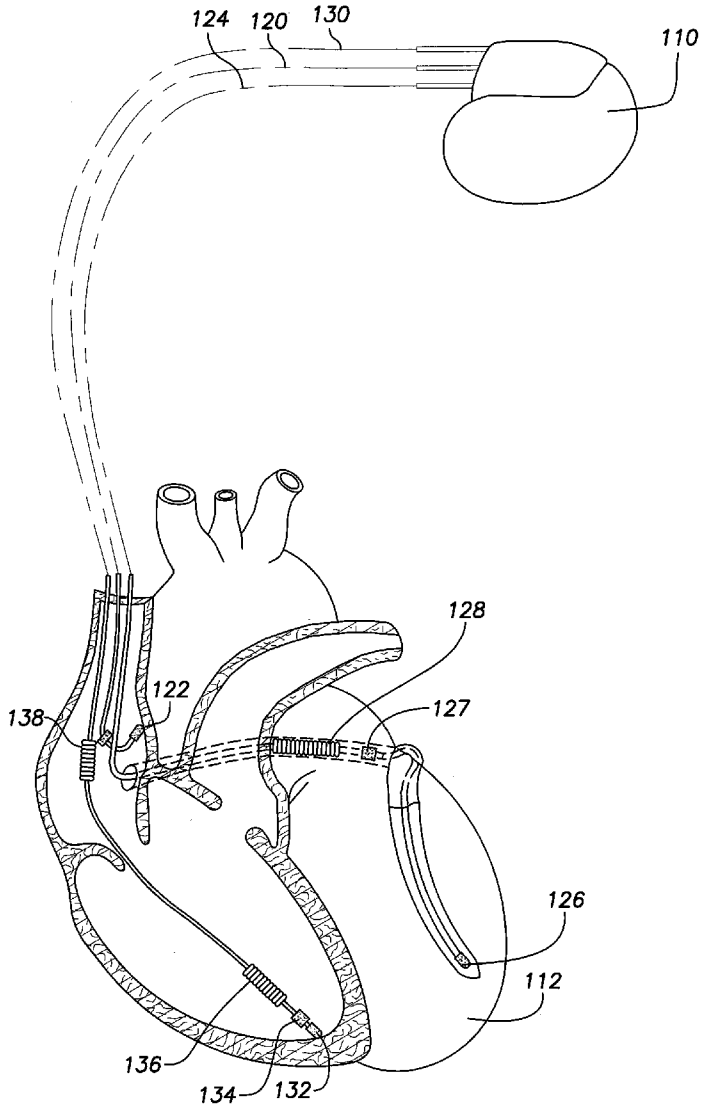
Publication Classification

(51) **Int. Cl.**
A61B 5/0205 (2006.01)

(52) **U.S. Cl.** **600/301**; 600/484

(57) **ABSTRACT**

A system and method for determining a patient's degree of cardiac vascular blockage or, equivalently, a patient's risk of cardiac ischemia, based on the time interval between the onset of exercise activity and the onset of an episode of cardiac ischemia. In one embodiment, an implantable cardiac device may obtain an EGM and possibly other measures of patient physiologic activity. These measures are used to determine when the patient has initiated exercise activity. Analysis of the EGM then detects an elevated or depressed ST segment, which typically indicates an episode of cardiac ischemia. The time interval between the onset of exercise and the onset of ischemia is a metric reflecting the patient's degree of vascular blockage or, equivalently, the patient's risk of ischemia. Other metrics may be derived, such as a substantially workload-level invariant measure determined as the product of the exercise workload level and the ischemia onset time interval.



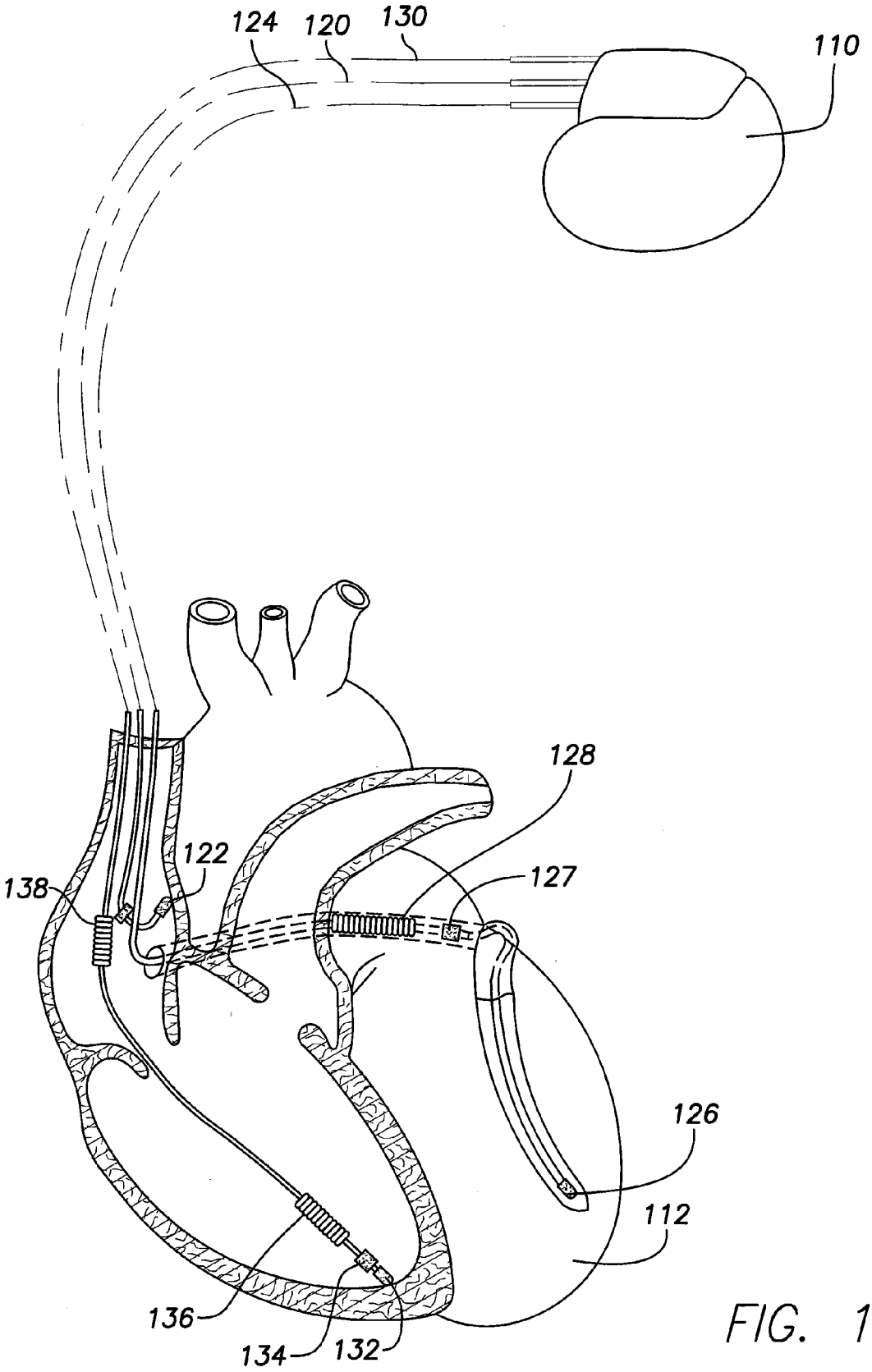


FIG. 1

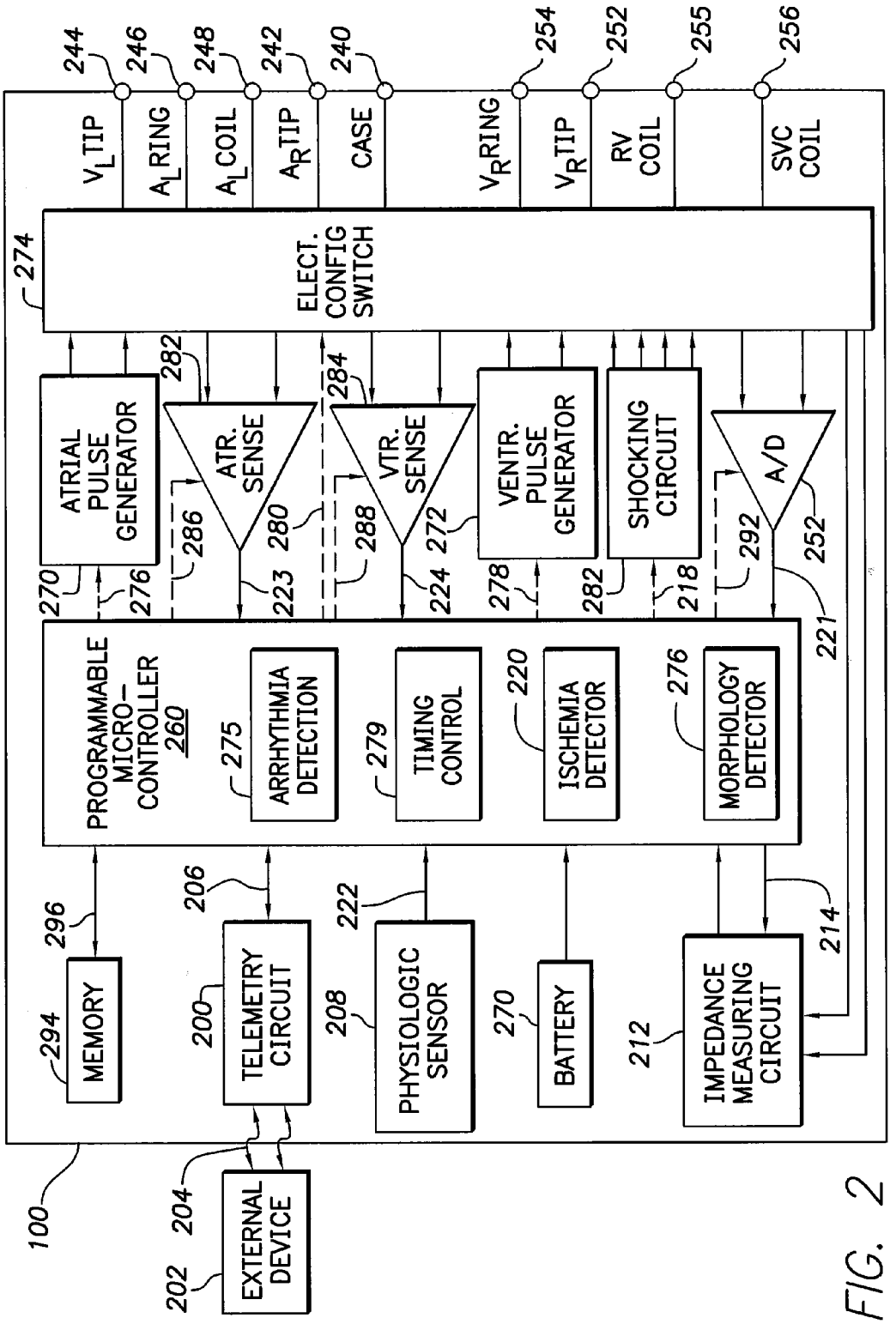

244
246
248
242
240
254
252
255
256
V_LTIP
A_LRING
A_LCOIL
A_RTIP
CASE
V_RRING
V_RTIP
RV COIL
SVC COIL
274
ELECT. CONFIG SWITCH
282
284
ATRIAL PULSE GENERATOR
ATR. SENSE
VTR. SENSE
VENTR. PULSE GENERATOR
SHOCKING CIRCUIT
A/D
286
280
288
272
292
252
270
276
223
224
278
282
218
221
PROGRAMMABLE MICRO-CONTROLLER 260
275
ARRHYTHMIA DETECTION
279
TIMING CONTROL
220
ISCHEMIA DETECTOR
276
MORPHOLOGY DETECTOR
296
206
222
214
294
MEMORY
200
TELEMETRY CIRCUIT
208
PHYSIOLOGIC SENSOR
270
BATTERY
212
IMPEDANCE MEASURING CIRCUIT
100
204
202
EXTERNAL DEVICE

FIG. 2

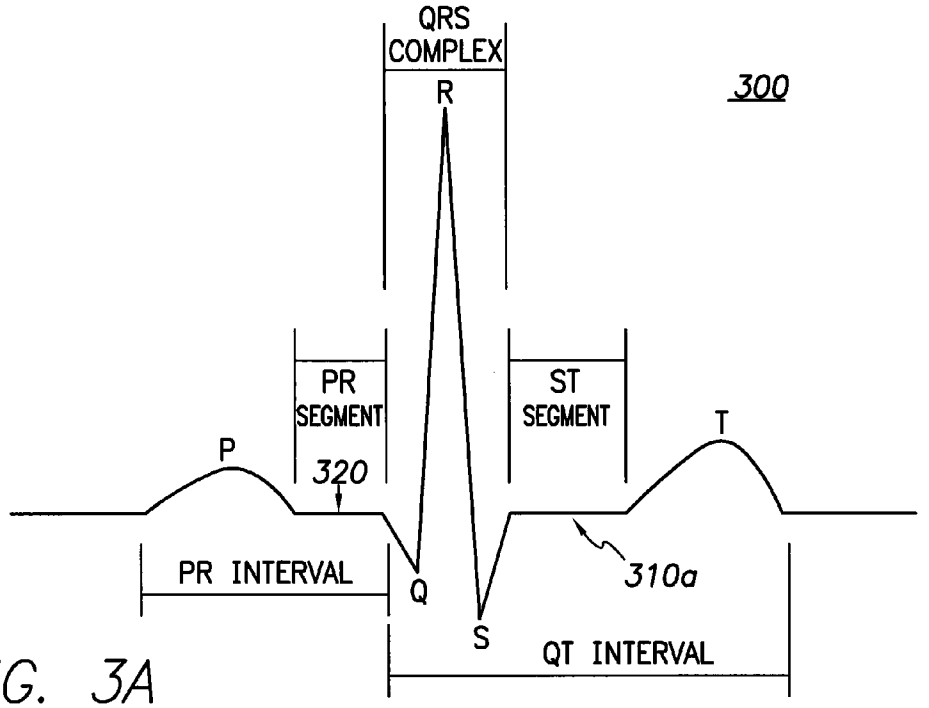

QRS
COMPLEX
R
300
PR
SEGMENT
320
ST
SEGMENT
T
P
PR INTERVAL
Q
S
310a
QT INTERVAL

FIG. 3A

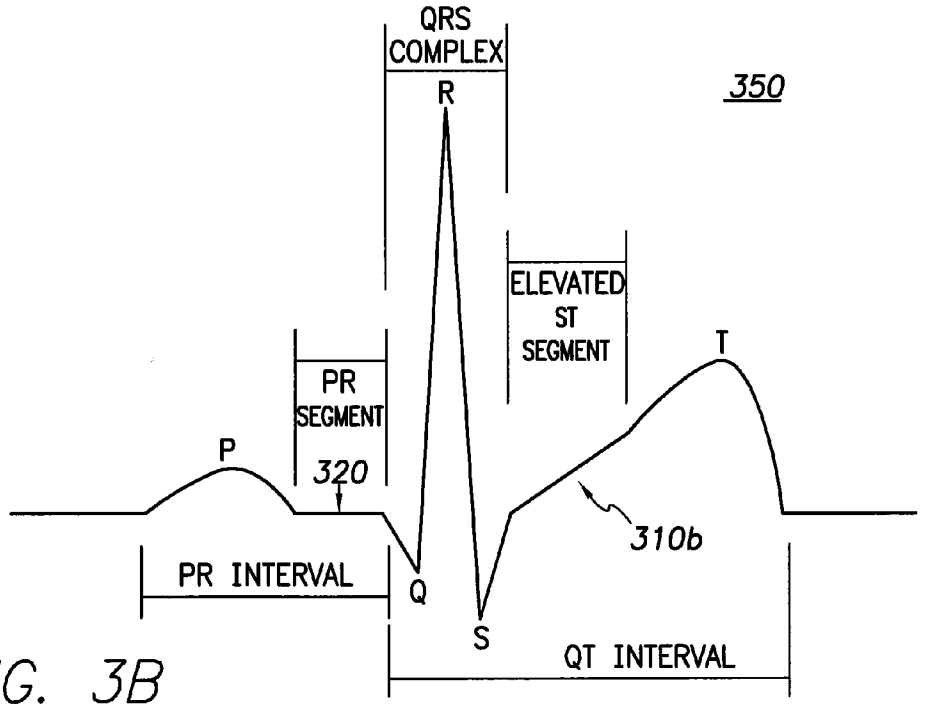

QRS
COMPLEX
R
350
ELEVATED
ST
SEGMENT
T
PR
SEGMENT
320
P
310b
PR INTERVAL
Q
S
QT INTERVAL

FIG. 3B

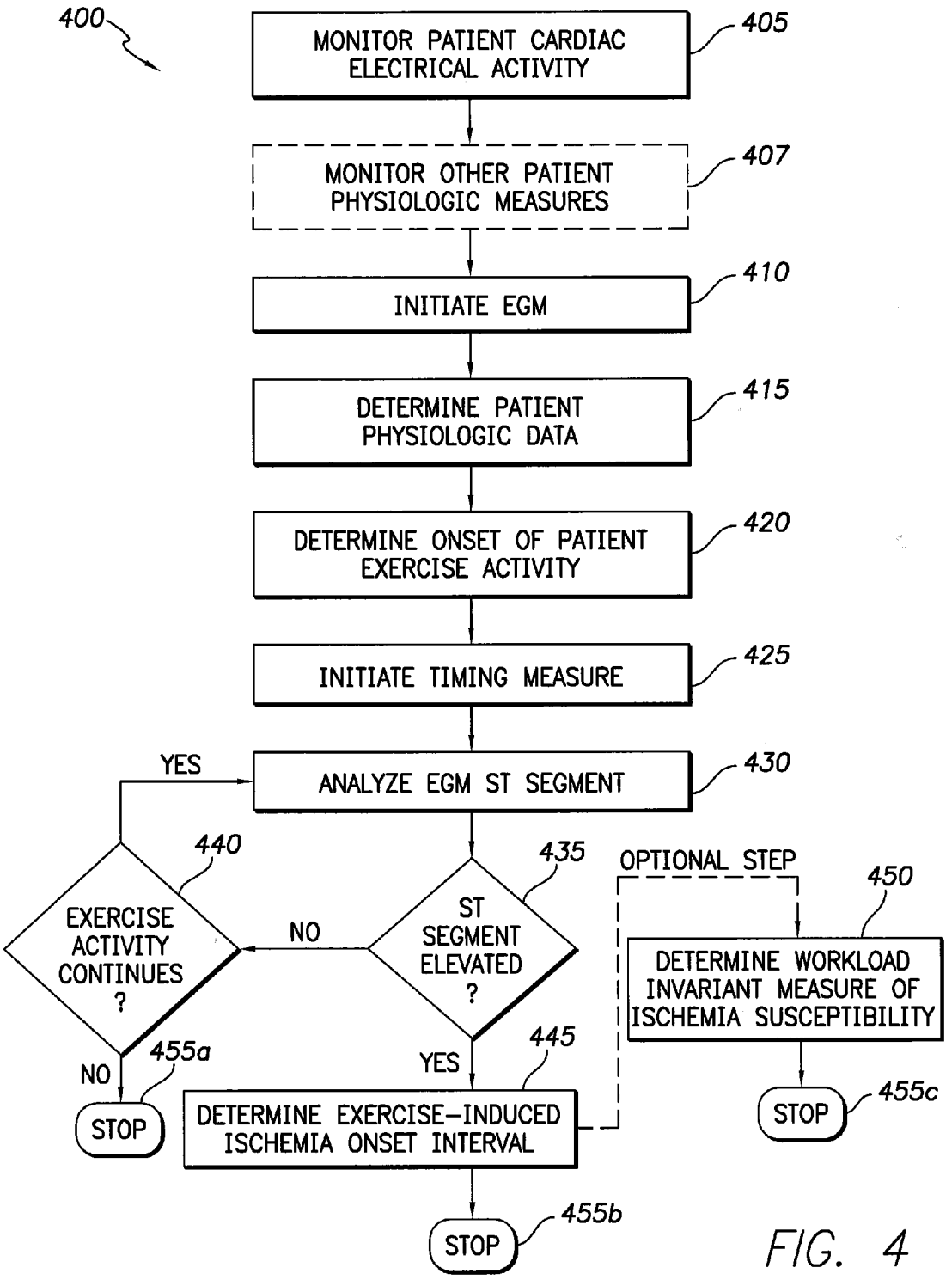

400
MONITOR PATIENT CARDIAC ELECTRICAL ACTIVITY
405
MONITOR OTHER PATIENT PHYSIOLOGIC MEASURES
407
INITIATE EGM
410
DETERMINE PATIENT PHYSIOLOGIC DATA
415
DETERMINE ONSET OF PATIENT EXERCISE ACTIVITY
420
INITIATE TIMING MEASURE
425
YES
ANALYZE EGM ST SEGMENT
430
440
EXERCISE ACTIVITY CONTINUES ?
NO
435
ST SEGMENT ELEVATED ?
OPTIONAL STEP
450
DETERMINE WORKLOAD INVARIANT MEASURE OF ISCHEMIA SUSCEPTIBILITY
NO
455a
STOP
YES
445
DETERMINE EXERCISE-INDUCED ISCHEMIA ONSET INTERVAL
STOP
455c
STOP
455b

FIG. 4

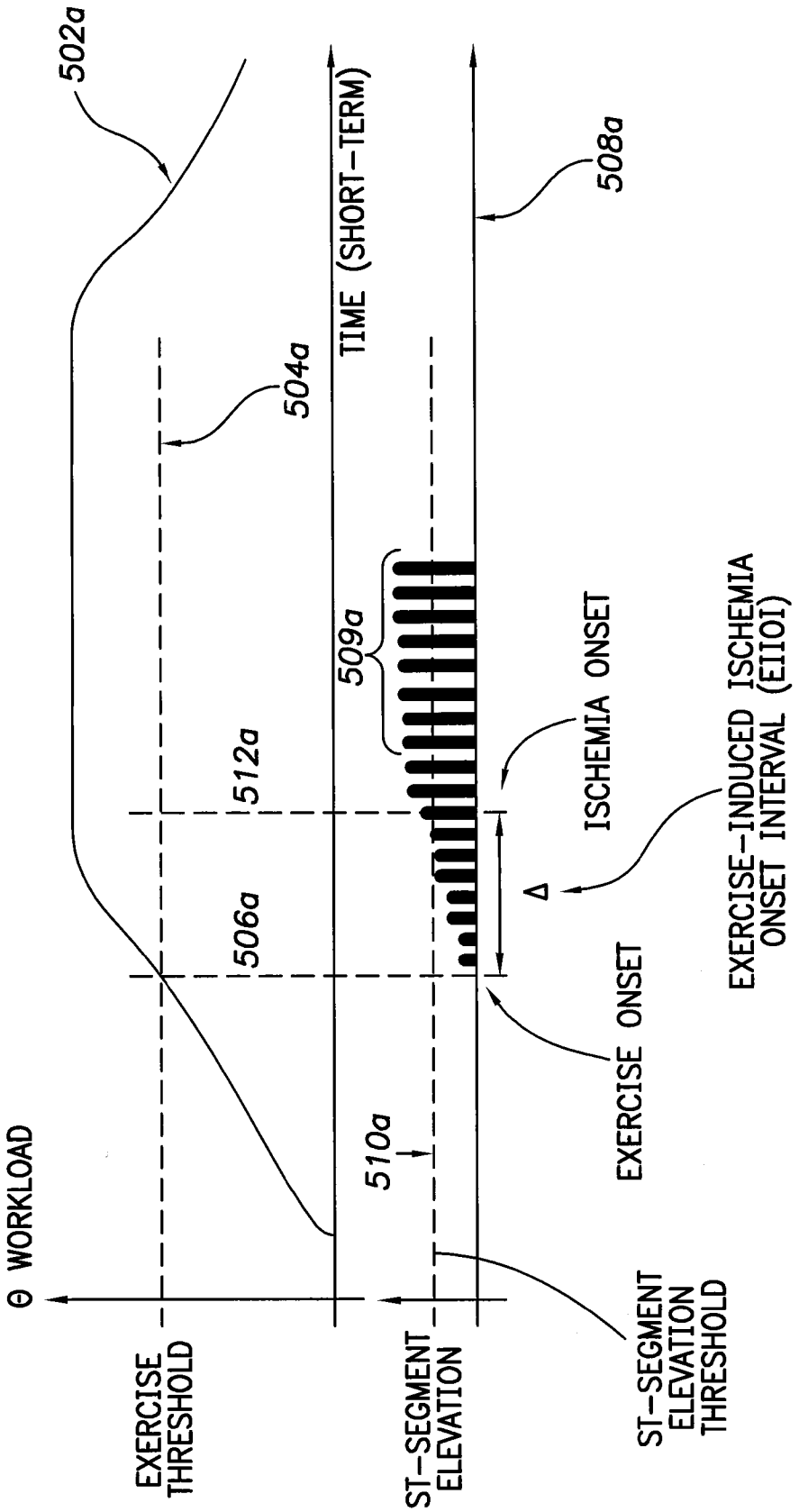

502a
504a
TIME (SHORT-TERM)
508a
509a
512a
506a
ISCHEMIA ONSET
Δ
EXERCISE-INDUCED ISCHEMIA ONSET INTERVAL (EIIOI)
EXERCISE ONSET
510a
Θ WORKLOAD
EXERCISE THRESHOLD
ST-SEGMENT ELEVATION
ST-SEGMENT ELEVATION THRESHOLD

FIG. 5A

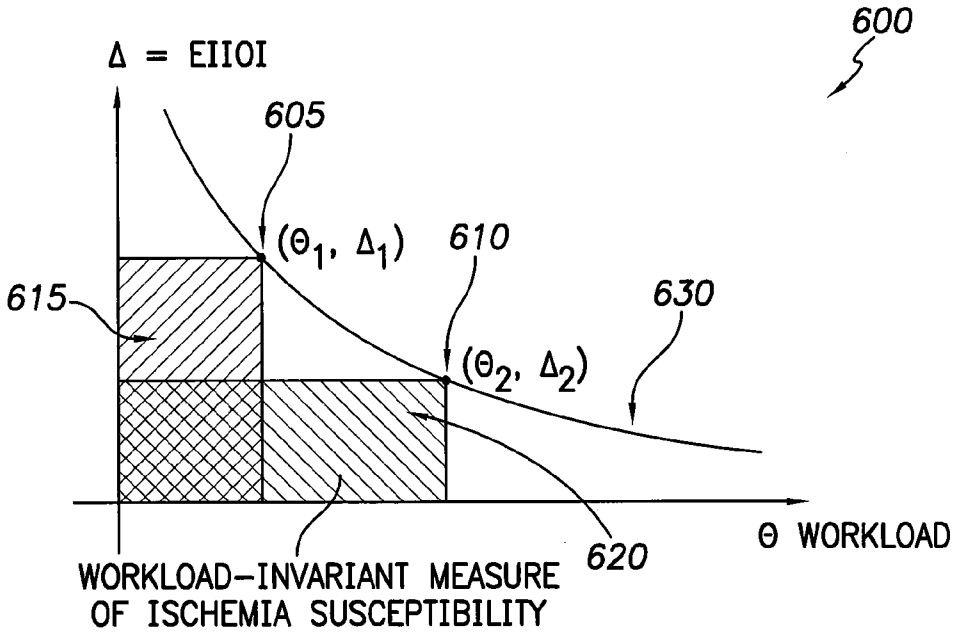

600
Δ = EIIOI
605
(Θ1, Δ1)
610
615
630
(Θ2, Δ2)
620
Θ WORKLOAD
WORKLOAD-INVARIANT MEASURE
OF ISCHEMIA SUSCEPTIBILITY

FIG. 6A

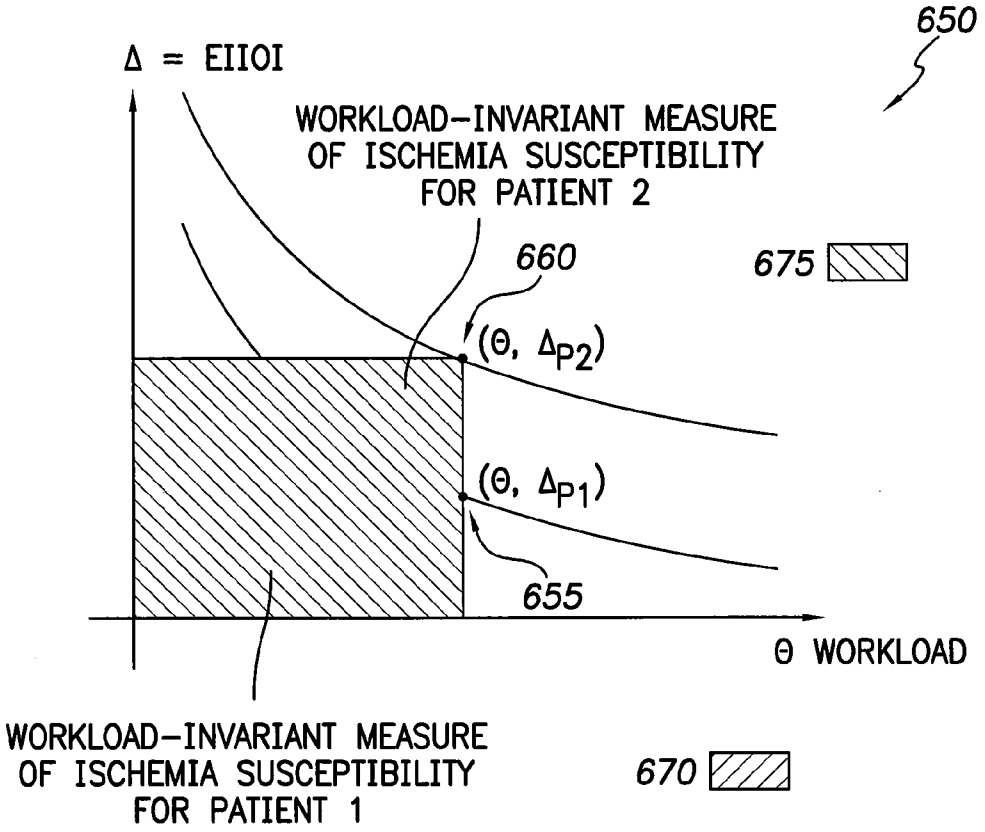

650
Δ = EIIOI
WORKLOAD-INVARIANT MEASURE
OF ISCHEMIA SUSCEPTIBILITY
FOR PATIENT 2
660
675
(Θ, ΔP2)
(Θ, ΔP1)
655
Θ WORKLOAD
WORKLOAD-INVARIANT MEASURE
OF ISCHEMIA SUSCEPTIBILITY
FOR PATIENT 1
670

FIG. 6B

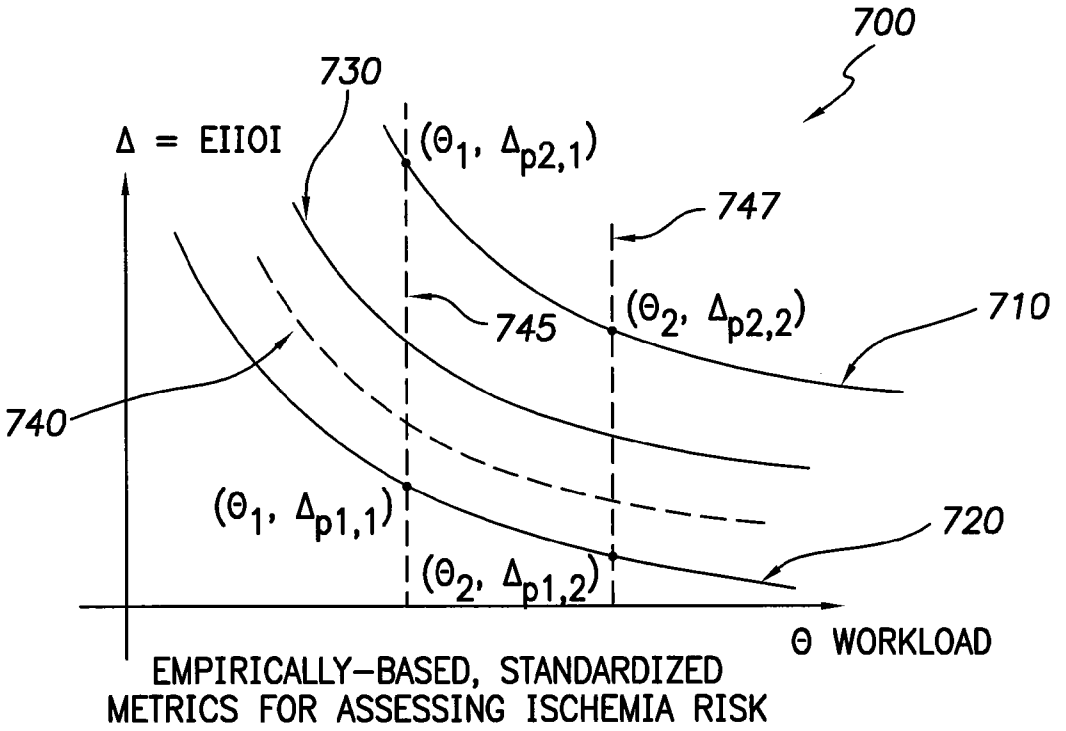

700
730
Δ = EIIOI
(Θ1, Δp2,1)
747
745
(Θ2, Δp2,2)
710
740
(Θ1, Δp1,1)
720
(Θ2, Δp1,2)
Θ WORKLOAD
EMPIRICALLY–BASED, STANDARDIZED
METRICS FOR ASSESSING ISCHEMIA RISK

FIG. 7A

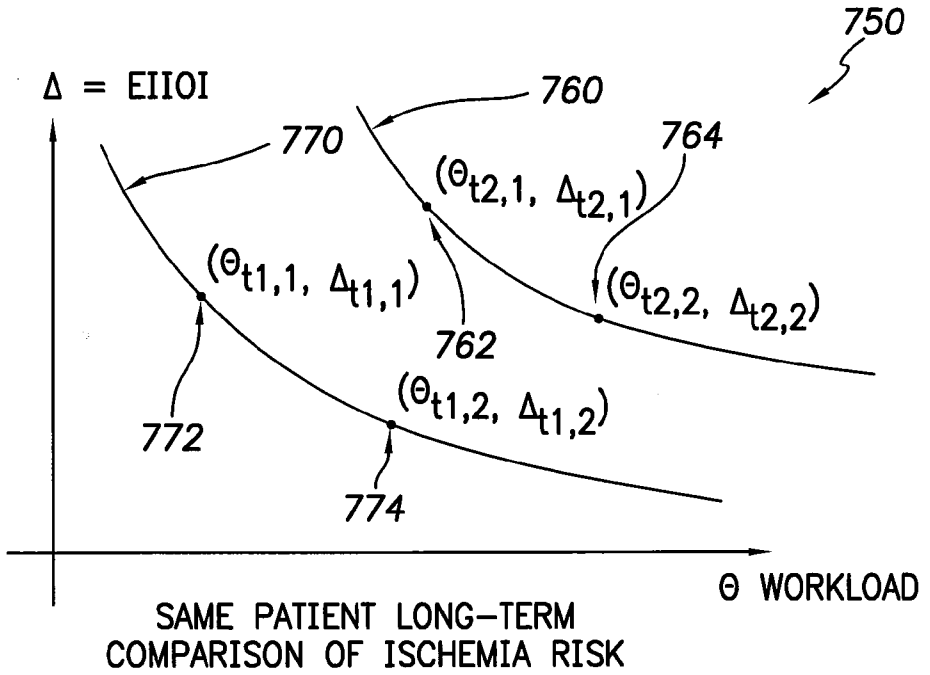
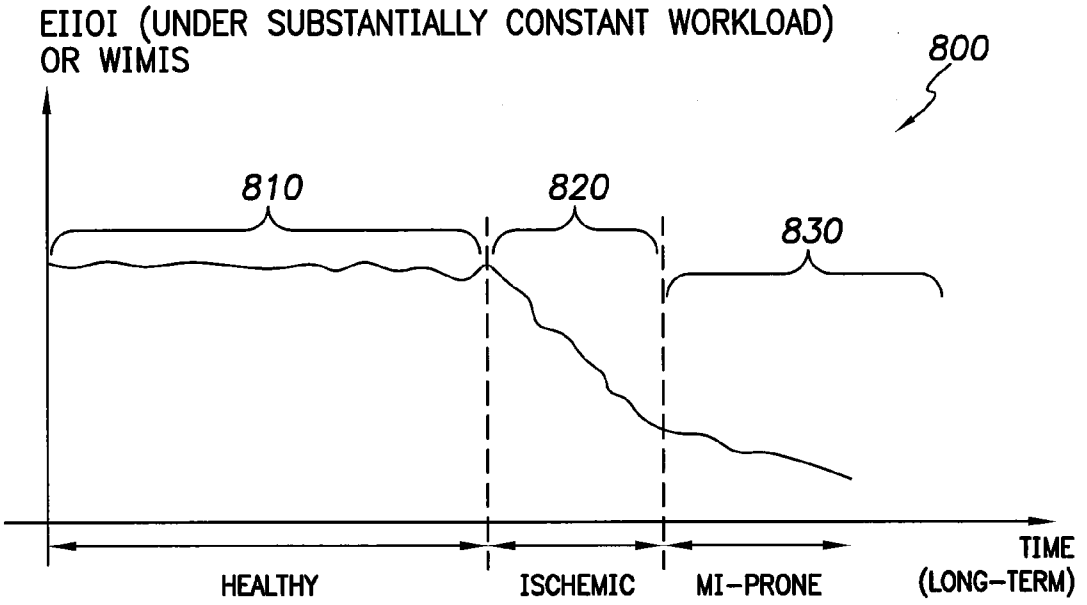
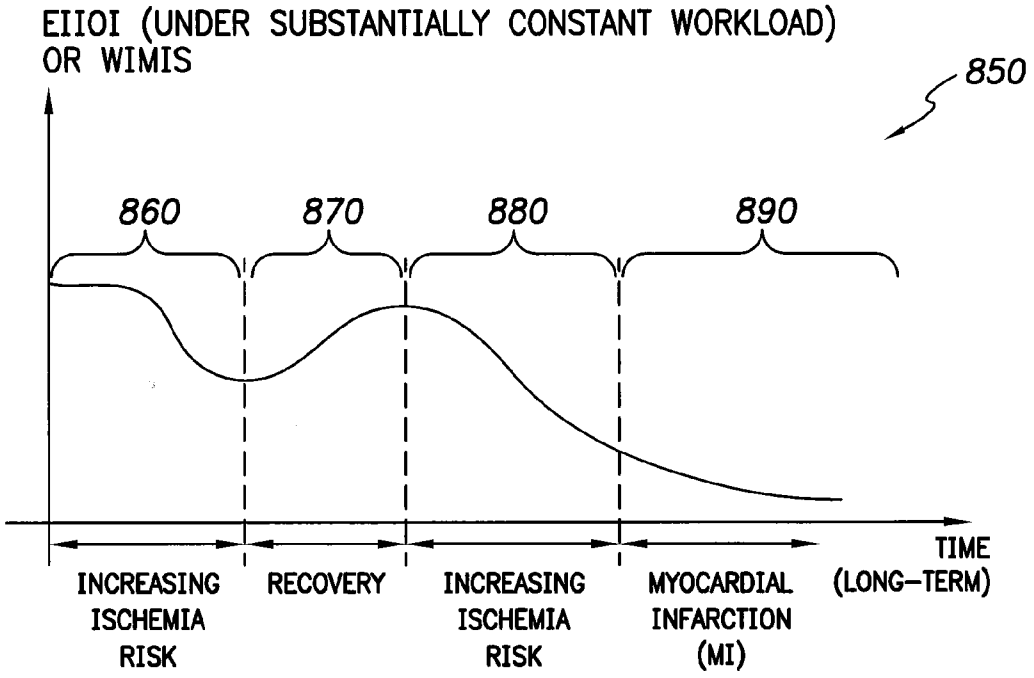

750
Δ = EIIOI
760
770
764
(Θt2,1, Δt2,1)
(Θt1,1, Δt1,1)
(Θt2,2, Δt2,2)
762
772
(Θt1,2, Δt1,2)
774
Θ WORKLOAD
SAME PATIENT LONG–TERM
COMPARISON OF ISCHEMIA RISK

FIG. 7B



SAME PATIENT LONG-TERM
COMPARISON OF ISCHEMIA RISK

FIG. 8A



SAME PATIENT LONG-TERM
COMPARISON OF ISCHEMIA RISK

FIG. 8B

ASSESSING A DEGREE OF VASCULAR BLOCKAGE OR RISK OF ISCHEMIA

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is related to commonly owned, co-pending U.S. application Ser. No. 11/611,105 to Steve Koh, filed Dec. 14, 2006, entitled "Exercise Compliance Monitoring and Benefit Assessment via a Composite Physiologic Signal Determined by Implanted Physiologic Sensor," the disclosure of which is incorporated herein by reference as though set forth in full below.

FIELD OF THE INVENTION

[0002] The present invention relates generally to implantable cardiac devices and, more particularly, to methods and systems for determining a degree of cardiac coronary blockage or risk of ischemia using an implantable cardiac device.

BACKGROUND

[0003] Myocardial ischemia is a cardiac function disorder wherein there exists insufficient blood flow to the muscle tissue of the heart, most commonly due to narrowing of the coronary arteries. Ischemia may lead to necrosis of cardiac muscle, especially if the narrowing of the arteries is severe or if an ischemic episode is sufficiently prolonged. Conventionally, an episode of myocardial ischemia may be diagnosed by monitoring changes in an electrocardiogram (e.g., a surface electrocardiogram (ECG), or an internal electrogram (EGM) obtained by leads implanted in the heart). The pattern of cardiac electrical activity shown on an ECG or EGM is conventionally labeled with letters of the alphabet corresponding to various peaks and valleys, e.g., 'P', 'Q', 'R', 'S', and 'T'. The segments or intervals connecting these peaks and valleys are conventionally labeled as the 'PR interval', 'PR segment', 'QRS segment', etc.

[0004] Myocardial ischemia is typically diagnosed based on abnormalities detected in the ST segment of an ECG or EGM. In particular, an elevated ST segment in an ECG is typically indicative of an episode of myocardial ischemia. However, particularly in an EGM, in some instances it may be that ST segment depression (i.e., a lowering of the level of the ST segment) may be indicative of ischemia. This is discussed further below.

[0005] In a resting patient or patient engaged in moderate activity, even a patient with significant narrowing of the coronary arteries, there may be no detectable signs of ischemia. In other words, there may be no symptoms of oxygen insufficiency, and an ECG or EGM may not indicate any abnormalities in the ST segment. As a result, narrowing of the arteries may not become apparent until severe coronary artery blockage has developed, at which point the patient's health may be significantly compromised. In some cases, cardiac ischemia may not be symptomatic or may be difficult to even detect until the patient is experiencing a coronary episode, for example, during unusually heavy exercise such as shoveling snow. Such undetected ischemia may even precipitate a heart attack. The detection of ST segment elevation during emergency medical treatment may be too late for prophylactic measures (e.g., dietary changes, exercise, cholesterol-reducing medicines, etc.) to prevent or control coronary disease.

[0006] What is needed, then, is a method and system of ongoing monitoring to detect a degree of vascular blockage prior to the onset of severe cardiac impairment. In the event a patient has already experienced a major coronary episode and has received treatment (for example, by-pass surgery), what is needed is a means of ongoing monitoring to ensure that vascular blockage does not return; or that if it does return, it can be detected early enough for treatment to prevent another major coronary episode.

BRIEF SUMMARY

[0007] Methods and systems are presented to determine a degree of coronary vascular blockage or, equivalently, a degree of risk of cardiac ischemia. In an exemplary embodiment, an implantable cardiac device (ICD) is used to monitor patient cardiac activity while the patient is engaged in exercise. Data obtained from the ICD may be used both to determine when the patient has begun exercising, and also to determine the onset of ST segment elevation or ST segment depression, which may be indicative of cardiac ischemia. The time interval between the onset of exercise and the onset of ST segment elevation or ST segment depression may be used as a metric to indicate a degree of coronary blockage, wherein a shorter time interval may reflect a higher degree of coronary vascular blockage. A combined metric based on both the level of exercise activity and the onset interval for ST segment elevation or depression may also be used.

[0008] It should be noted that throughout this document, reference is made both to "a method or system of assessing or determining a degree of cardiac vascular blockage", and also to "a method or system of assessing a degree of risk of cardiac ischemia". Reference is also made to "a measure of ischemia susceptibility". For purposes of the present method and system, a "degree of cardiac vascular blockage", a "degree of risk of cardiac ischemia", a "measure of ischemia susceptibility" and similar terms are considered to be synonymous concepts, and the indicated phrases and substantially analogous phrases are used interchangeably throughout.

[0009] Further features and advantages of the methods and systems presented herein, as well as the structure and operation of various example methods and systems, are described in detail below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS/FIGURES

[0010] The accompanying drawings, which are incorporated herein and form part of the specification, illustrate the methods and systems presented herein for assessing a degree of vascular blockage by measuring the time between onset of workload and onset of ST segment elevation or ST segment depression. Together with the description, the drawings further serve to explain the principles of and to enable a person skilled in the relevant art(s) to make and use the methods and systems presented herein. In the drawings, like reference numbers indicate identical or functionally similar elements. Further, the drawing in which an element first appears is typically indicated by the leftmost digit(s) in the corresponding reference number (e.g., an element numbered **302** first appears in FIG. **3**).

[0011] FIG. **1** is a simplified diagram illustrating an example implantable cardiac device (ICD) in electrical communication with a patient's heart by means of three leads suitable for delivering multi-chamber stimulation and pacing therapy and for detecting cardiac electrical activity.

[0012] FIG. **2** is a functional block diagram of an example ICD that can detect cardiac electrical activity and analyze cardiac electrical activity, as well as provide cardioversion, defibrillation, and pacing stimulation in four chambers of a heart.

[0013] FIGS. **3**A and **3**B illustrate an electrogram (EGM) or electrocardiogram (ECG) indicative of healthy cardiac function and an EGM or ECG indicative of an episode of cardiac ischemia, respectively.

[0014] FIG. **4** is a process flowchart for an exemplary method for assessing a degree of cardiac vascular blockage or, equivalently, a degree of risk of cardiac ischemia, by measuring the time between onset of workload or patient exercise activity and onset of ST segment elevation which is indicative of myocardial ischemia.

[0015] FIGS. **5**A, **5**B, and **5**C each provide a graphical illustration of exemplary methods of determining the time between the onset of patient workload or exercise activity and the time of onset of ST segment elevation.

[0016] FIGS. **6**A and **6**B illustrate an exemplary method for calculating a measure of ischemia susceptibility which is substantially invariant with respect to the exercise workload imposed on the patient at the time the measure is obtained.

[0017] FIGS. **7**A and **7**B illustrate exemplary analysis processes by which assessments may be made of a degree of vascular blockage for a patient, based on prior historical data.

[0018] FIG. **7**C illustrates a comparison between an exemplary ideal curve of substantially work-load invariant ischemia susceptibility and an exemplary curve based on data points which cluster about the ideal curve.

[0019] FIG. **8**A and FIG. **8**B illustrate an exemplary method of assessing a long term change in vascular blockage or ischemia risk for a patient.

DETAILED DESCRIPTION

1. Overview

[0020] The following detailed description of methods and systems for assessing a degree of vascular blockage by measuring the time between onset of workload and onset of ST segment elevation or ST segment depression refers to the accompanying drawings that illustrate exemplary embodiments consistent with these methods and systems. Other embodiments are possible, and modifications may be made to the embodiments within the spirit and scope of the methods and systems presented herein. Therefore, the following detailed description is not meant to limit the methods and systems described herein. Rather, the scope of these methods and systems is defined by the appended claims.

[0021] It would be apparent to one of skill in the art that the methods and systems for assessing a degree of vascular blockage by measuring the time between onset of workload and onset of ST segment elevation or ST segment depression, as described below, may be implemented in many different embodiments of hardware, software, firmware, and/or the entities illustrated in the figures. Any actual software and/or hardware described herein is not limiting of these methods and systems. Thus, the operation and behavior of the methods and systems will be described with the understanding that modifications and variations of the embodiments are possible, given the level of detail presented herein.

[0022] In particular, while the methods and systems herein are described using an exemplary embodiment which may employ an implantable cardiac device (ICD) to measure cardiac electrical activity and perform an EGM, the methods and systems described herein for assessing a degree of vascular blockage may also be implemented via an external electrocardiograph which provides an ECG, or may also be implemented via other hardware and software configurations which may be partially external and partially internal to the patient.

[0023] Before describing in detail the methods and systems for assessing a degree of vascular blockage by measuring the time between onset of workload and onset of ST segment elevation or ST segment depression, it is helpful to describe an example environment in which these methods and systems may be implemented. The methods and systems described herein may be particularly useful in the environment of an ICD.

[0024] An ICD is a physiologic measuring device that is implanted in a patient to monitor cardiac function and to deliver appropriate electrical therapy, for example, pacing pulses, cardioverting and defibrillator pulses, and drug therapy, as required. ICDs include, for example, pacemakers, cardioverters, defibrillators, implantable cardioverter defibrillators, implantable cardiac rhythm management devices, and the like. Such devices may also be used in particular to monitor cardiac electrical activity and to analyze cardiac electrical activity. The term "implantable cardiac device" or simply "ICD" is used herein to refer to any implantable cardiac device. FIGS. **1** and **2** illustrate such an environment which may be used to implement the methods and systems described herein for detecting a degree of cardiac vascular blockage or a risk of ischemia.

2. Exemplary ICD in Electrical Communication with a Patient's Heart

[0025] FIG. **1** illustrates an exemplary ICD **110** in electrical communication with a patient's heart **112** by way of three leads, **120**, **124** and **130**, suitable for delivering multi-chamber stimulation and pacing therapy. To sense atrial cardiac signals and to provide right atrial chamber stimulation therapy, ICD **110** is coupled to implantable right atrial lead **120** having at least an atrial tip electrode **122**, which typically is implanted in the patient's right atrial appendage.

[0026] To sense left atrial and ventricular cardiac signals and to provide left-chamber pacing therapy, ICD **110** is coupled to "coronary sinus" lead **124** designed for placement in the "coronary sinus region" via the coronary sinus for positioning a distal electrode adjacent to the left ventricle and/or additional electrode(s) adjacent to the left atrium. As used herein, the phrase "coronary sinus region" refers to the vasculature of the left ventricle, including any portion of the coronary sinus, great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible by the coronary sinus.

[0027] Accordingly, exemplary coronary sinus lead **124** is designed to receive atrial and ventricular cardiac electrical signals and to deliver left ventricular pacing therapy using at least a left ventricular tip electrode **126**, left atrial pacing therapy using at least a left atrial ring electrode **127**, and shocking therapy using at least a left atrial coil electrode **128**.

[0028] ICD **110** is also shown in electrical communication with the patient's heart **112** by way of implantable right ventricular lead **130** having, in this embodiment, a right ventricular tip electrode **132**, a right ventricular ring electrode **134**, a right ventricular (RV) coil electrode **136**, and a superior

vena cava (SVC) coil electrode **138**. Typically, right ventricular lead **130** is transvenously inserted into heart **112** so as to place right ventricular tip electrode **132** in the right ventricular apex so that RV coil electrode **136** will be positioned in the right ventricle and SVC coil electrode **138** will be positioned in the SVC.

[0029] Accordingly, exemplary right ventricular lead **130** is capable of receiving cardiac electrical signals, as well as delivering stimulation in the form of pacing and shock therapy to the right ventricle.

3. Functional Elements of an Exemplary ICD

[0030] FIG. **2** shows a simplified block diagram of ICD **110**, which is capable of treating both fast and slow arrhythmias with stimulation therapy, including cardioversion, defibrillation, and pacing stimulation; ICD **110** is also capable of detecting cardiac electrical signals, and in particular is capable of detecting myocardial ischemia via detection of an elevated or depressed (i.e., lowered) ST segment. While a particular multi-chamber device is shown, it is shown for illustration purposes only, and one of skill in the art could readily duplicate, eliminate or disable the appropriate circuitry in any desired combination to provide a device capable of detecting suitable cardiac electrical signals for a variety of cardiac monitoring, health assessment, and health maintenance purposes including, for example and without limitation, performing an EGM, detecting ST segment elevation or depression in an EGM, and detecting cardiac ischemia.

[0031] A housing **240** of ICD **110**, shown schematically in FIG. **2**, is often referred to as the "can," "case" or "case electrode" and may be programmably selected to act as the return electrode for all "unipolar" modes. Housing **240** may further be used as a return electrode for shocking purposes alone or in combination with one or more of coil electrodes, **128**, **136**, and **138**, which are shown in FIG. **1**. Housing **240** further includes a connector (not shown) having a plurality of terminals, **242**, **244**, **246**, **248**, **252**, **254**, **256**, and **258** (shown schematically and, for convenience, the names of the electrodes to which they are connected are shown next to the terminals). As such, to achieve right atrial sensing and pacing, the connector includes at least a right atrial tip terminal (AR TIP) **242** adapted for connection to atrial tip electrode **122** (shown in FIG. **1**).

[0032] To achieve left chamber sensing, pacing and shocking, the connector includes at least a left ventricular tip terminal (VL TIP) **244**, a left atrial ring terminal (AL RING) **246**, and a left atrial shocking terminal (AL COIL) **248**, which are adapted for connection to left ventricular ring electrode **126**, left atrial tip electrode **127**, and left atrial coil electrode **128** (all shown in FIG. **1**), respectively.

[0033] To support right chamber sensing, pacing, and shocking the connector also includes a right ventricular tip terminal (VR TIP) **252**, a right ventricular ring terminal (VR RING) **254**, a right ventricular shocking terminal (RV COIL) **256**, and an SVC shocking terminal (SVC COIL) **258**, which are configured for connection to right ventricular tip electrode **132**, right ventricular ring electrode **134**, RV coil electrode **136**, and SVC coil electrode **138** (all shown in FIG. **1**), respectively.

[0034] At the core of ICD **110** is a programmable microcontroller **260**, which may control the various modes of stimulation therapy and may also control the collection and analysis of cardiac electrical activity data. As is well known in the art, microcontroller **260** typically includes a microprocessor, or equivalent control circuitry, designed specifically for controlling the delivery of stimulation therapy and for the analysis of cardiac electrical activity, and can further include RAM or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. Typically, microcontroller **260** includes the ability to process or monitor input signals (including, but not limited to, data concerning cardiac electrical activity) as controlled by a program code stored in a designated block of memory.

[0035] The details of the design of microcontroller **260** may not be critical to the techniques presented herein. Rather, any suitable microcontroller **260** can be used to carry out the functions described herein. The use of microprocessor-based control circuits for performing timing and data analysis functions are well known in the art. Microcontroller **260** may include dedicated hardware, firmware, or software for the analysis of cardiac electrical signals.

[0036] Representative types of control circuitry that may be used with the techniques presented herein include the microprocessor-based control system of U.S. Pat. No. 4,940,052 (Mann et. al.) and the state-machines of U.S. Pat. Nos. 4,712,555 (Thornander et al.) and 4,944,298 (Sholder). For a more detailed description of the various timing intervals used within ICDs and their inter-relationship, see U.S. Pat. No. 4,788,980 (Mann et. al.). The '052, '555, '298 and '980 patents are incorporated herein by reference.

[0037] As shown in FIG. **2**, an atrial pulse generator **270** and a ventricular pulse generator **272** generate pacing stimulation pulses for delivery by right atrial lead **120**, right ventricular lead **130**, and/or coronary sinus lead **124** (shown in FIG. **1**) via an electrode configuration switch **274**. It is understood that in order to provide stimulation therapy in each of the four chambers of the heart, atrial and ventricular pulse generators **270** and **272** may include dedicated, independent pulse generators, multiplexed pulse generators, or shared pulse generators. Pulse generators **270** and **272** are controlled by microcontroller **260** via appropriate control signals **276** and **278**, respectively, to trigger or inhibit the stimulation pulses.

[0038] Microcontroller **260** further includes timing control circuitry **279**, which is used to control pacing parameters (e.g., the timing of stimulation pulses) as well as to keep track of the timing of refractory periods, post ventricular atrial refractory period (PVARP) intervals, noise detection windows, evoked response windows, alert intervals, marker channel timing, etc., which are well known in the art. Examples of pacing parameters include, but are not limited to, atrioventricular (AV) delay, interventricular (RV-LV) delay, atrial interconduction (A-A) delay, ventricular interconduction (V-V) delay, and pacing rate. Timing control circuitry **279** may also be used to determine the duration of cardiac events, or be used to determine the duration of intervals in a cardiac EGM, such as the duration of the ST segment. Timing control circuitry **279** may also provide other timing information which is useful in the analysis of an EGM.

[0039] Switch **274** includes a plurality of switches for connecting the desired electrodes to the appropriate I/O circuits, thereby providing complete electrode programmability. Accordingly, switch **274**, in response to a control signal **280** from microcontroller **260**, determines the polarity of the stimulation pulses (e.g., unipolar, bipolar, combipolar, etc.) by selectively closing the appropriate combination of switches (not shown) as is known in the art. Switch **274**, in response to a control signal **280** from microcontroller **260**,

[0063] Some or all of these metabolic measures or movement measures, or other measures which reflect a level of patient exercise or patient activity, may be obtained via ICD **110**. ICD **110** may also have the necessary software, firmware, or hardware to determine when the respective metabolic, movement, or other exercise or activity thresholds have been exceeded, thus indicating patient exercise.

[0064] ICD **110** additionally includes a battery **210**, which provides operating power to a load that includes all of the circuits shown in FIG. **2**.

4. Determination of an Episode of Cardiac Ischemia via Elevated ST Segment or Depressed ST Segment

[0065] Myocardial ischemia is a condition where there is an inadequate supply of blood to the heart, resulting in an insufficient supply of oxygen for adequate oxygenation of the cardiac muscle. Prolonged ischemia, or ischemia of shorter duration but of sufficient severity, may result in damage to the cardiac tissue. Ischemia is typically caused by partial or complete blockage of one or more of the coronary arteries.

[0066] In the case of severe or complete blockage of a coronary artery, ischemia may exist even when the patient is at rest or engaged in minimal activity. In more moderate cases of coronary blockage, however, the reduced blood supply to the cardiac muscle may still provide sufficient oxygenation when the patient is at rest or engaged in moderate activity. However, when a patient engages in exercise at a significant level of workload, or is engaged in other activities which significantly increase the heart's demand for oxygen, the available blood flow through the partially blocked arteries may be insufficient to meet the increased demand for oxygenation. The result may be a transitory episode of cardiac ischemia, which subsides when the level of activity (and hence the demand for oxygen) decreases.

[0067] FIG. **3**A and FIG. **3**B together illustrate diagnosis of an episode of cardiac ischemia. FIG. **3**A illustrates a representative view **300** of an ECG (also known as an EKG) or EGM, which may be obtained from a patient via an electrocardiograph or ICD **110**, respectively, the ECG or EGM being a graphical representation of cardiac electrical activity. In an exemplary embodiment, the present method may obtain an EGM via an ICD **110**; for brevity, the discussion here will refer exclusively to an EGM obtained via an ICD **110**, it being understood that the present method may equally be implemented by obtaining an EKG via an electrocardiograph.

[0068] EGM **300** is indicative of the functioning of a heart which is receiving adequate oxygenation. The ST segment **310***a* represents the electrical activity during the interval between the ventricular depolarization (following ventricular contraction) and ventricular repolarization (in preparation for the next contraction). The ST segment **310** is substantially horizontal and substantially level or nearly level with the PR segment **320**, indicating the cardiac tissue can maintain a membrane potential. This in turn indicates adequate tissue oxygenation.

[0069] FIG. **3**B illustrates a representative view of an EGM **350** which may be indicative of cardiac ischemia. In particular, the elevation and sloping of the ST segment **310***b* is typically indicative of insufficient oxygen being delivered to the cardiac tissue. It should be noted that, depending on the exact location, extent, and degree of the ischemia, the nature of the ST segment elevation may vary. For example, in some ischemias, the ST segment **310***b* may still be substantially horizontal, but may be elevated above the level of the PR segment **320** to a degree that is medically significant.

[0070] As noted above, in an EGM the cardiac electrical vectors may vary depending on the pairs of leads used for signal measurement in the heart (for example, LV_{tip}-can, RV_{tip}-can, LV_{ring}-RV_{ring}, LV_{tip}-RV_{tip}, etc). As a result, in some instances ST segment depression (i.e., a lowering and/or downsloping of the ST segment), rather than ST segment elevation, may be indicative of ischemia. For convenience and brevity, in the discussion which follows reference is made primarily to ST segment elevation, and the accompanying figures illustrate ST segment elevation, as a determining indicator of cardiac ischemia.

[0071] It will be appreciated that the choice of ST segment elevation as an indicator of cardiac ischemia is by way of exemplary embodiments only. Those skilled in the relevant art(s) will appreciate that the present system and method, as described herein, may equally well be employed in contexts where a measurement of ST segment depression is indicative of cardiac ischemia. ST segment elevation and ST segment depression, possibly in association with an upslope or downslope of the ST segment, may also be referred to jointly as ST segment variation.

[0072] It should be further understood that while graphical views of an EGM **300**, **350** are presented here for purposes of illustrating the present method for determining a degree of vascular blockage, it is possible to implement algorithms (via hardware, firmware, or software) which may automatically and analytically determine ST segment elevation or depression based on EGM data without any requirement for visual presentation or human interpretation of a plot or graph. Such algorithms may be implemented within an ICD **110**, or may be implemented in an external computer or other health assessment instrumentation to which an ICD **110** has downloaded EGM data.

[0073] In one embodiment of the present invention, ST segment elevation or depression may be determined by first determining a reference height or amplitude. The reference amplitude may be, for example and without limitation, the amplitude of the QRS complex, where the amplitude may be measured from the value (e.g., the voltage) of the resting PR segment or ST segment (which are normally at the baseline of the EGM) to the voltage of the peak point (i.e., the R-point) of the QRS complex. Once the amplitude of the QRS complex is determined, a further determination may be made of ST segment elevation if the segment is elevated from its resting state voltage to some percentage value, for example, 10% or 20%, of the amplitude (in volts) of the QRS complex. Analogous criteria may apply to determining ST segment depression, but with a corresponding decrease in voltage.

[0074] In an alternative embodiment, ST segment elevation or depression may be determined if the ST segment is elevated or depressed by some specific voltage value. In a clinical setting, where an EKG may be shown on a strip of paper, an elevation of the ST segment by one or a few millimeters may be considered clinically significant. An algorithm for determining ST segment elevation or depression may be based on knowing how many measured volts (for example, 0.05 mVolts) may correspond to a two millimeter elevation on a physical strip of paper. The precise voltage may vary substantially depending on the voltages being detected by the ICD technology in use. Similar considerations, e.g., percentage change or absolute voltage values, may apply to using the

slope of the ST segment as an indicator of ST segment elevation or ST segment depression.

[0075] More generally, the exact parameters used to determine ST segment elevation or ST segment depression, such as a degree of segment elevation or depression or a degree of segment slope, may be chosen in part based on criteria which may be found in the literature of the art, which may be established via clinical studies, and which may also be varied for purposes of setting different ischemia detection thresholds. The shape of the ST segment variation may also vary depending on lead vector variation.

5. Methods and Systems for Assessing Degree of Vascular Blockage by Measuring the Time between Onset of Workload and Onset of ST Segment Elevation

[0076] FIG. **4** illustrates an exemplary method **400** for making an assessment of a degree of vascular blockage or, equivalently, an assessment of ischemia susceptibility, by measuring the time between onset of an exercise workload and the onset of ST segment elevation, which may be an indication of myocardial ischemia.

[0077] Method **400** begins with step **405** wherein monitoring of cardiac electrical activity is initiated. As discussed above, cardiac monitoring may be done via an internal ICD or may be performed via an external electrocardiograph.

[0078] In optional step **407** (where the dotted lines indicate being optional), other physiologic measures may be initiated as well, such as measuring a patient blood pressure. A process of measuring a patient's motion, such as via an implanted accelerometer, may also be initiated.

[0079] Step **410** involves initiating an electrogram (EGM) or electrocardiogram (ECG or EGK), where an ECG is typically performed by an external electrocardiograph and the EGM would typically be performed by an ICD. The EGM or ECG is created based on the cardiac electrical activity monitored in step **405**. The ECG or EGM may serve two purposes. One purpose is to assess the ECG or EGM for an elevated ST segment, which is indicative of an episode of ischemia. A second purpose may be to obtain measurements of pulse (i.e., heart rate) which may be used to determine an onset of patient exercise activity. An activity sensor, e.g., an accelerometer, may also be used to detect exercise.

[0080] In an exemplary embodiment, the present method may obtain an EGM via an ICD **110**; for brevity, the remainder of the discussion will refer exclusively to an EGM obtained via an ICD **110**, it being understood that the present method may equally be implemented by obtaining an ECG via an electrocardiograph.

[0081] In step **415**, patient physiologic data is determined. As already indicated, some of this data, such as a patient pulse rate, may be obtained from the EGM. Other pertinent physiologic data, such as blood pressure, respiration rate, or other relevant physiologic factors may be obtained from other monitoring devices which may be associated with an ICD or other monitoring equipment.

[0082] In step **420**, the onset of patient exercise activity is assessed. Typically, this is determined by assessing that some measure of the patient's metabolic activity or, equivalently, some measure of the patient's physiologic activity has passed a certain threshold. For example, pulse rate, respiration rate, or blood pressure may exceed a certain metabolic threshold, indicating that patient exercise activity has commenced. The metabolic threshold may also be referred to as an exercise threshold.

[0083] In general, there may exist a preferred threshold or workload level which is considered to be indicative of patient exercise. The precise level of this threshold level of patient exercise activity may vary depending on the individual patient, and may be a parameter which may be set as part of the process or method to determine the degree of vascular blockage. In general, a number of methods may be employed to determine when patient physiologic activity or patient movement has crossed an established threshold, thus indicating the onset of patient exercise activity.

[0084] In an exemplary embodiment of the present method, a composite physiologic signal such as a cardiac health index (CHI) may be used to determine when a patient is engaged in exercise. For a detailed discussion of determination of exercise via a composite physiological signal, which may combine heart rate, pulse rate, blood pressure, and possibly other physiologic signals, and possibly other indicators such as an accelerometer reading, see the commonly-owned, co-pending related U.S. patent application Ser. No. 11/611,105 to Steve Koh, filed Dec. 14, 2006, entitled "Exercise Compliance Monitoring and Benefit Assessment Via a Composite Physiologic Signal Determined by Implanted Physiologic Sensor", the disclosure of which is incorporated by reference herein.

[0085] The present method requires that a determination be made of the time interval between the onset of patient activity and the assessment of an elevated ST segment. In step **425** timing is initiated. Typically, timing will be initiated at substantially the same time that a determination has been made that a patient is engaged in exercise activity. In one embodiment of the present method, timing may be initiated by storing in a database or other storage the time when exercise has begun. In an alternative embodiment, timing may be initiated by initiating a stopwatch or stopwatch-like measuring system, i.e., a timer, wherein the stopwatch is initiated when patient exercise activity commences.

[0086] Step **430** represents the initiation of an analysis loop in which the ST segment of the EGM is analyzed.

[0087] As discussed above, an elevated ST segment is considered to be indicative of an episode of cardiac ischemia. The exact parameters which are used to determine that the ST Segment is elevated above a normal or acceptable level, i.e., to determine an onset of cardiac ischemia, are based on criteria which are well known in the art and which furthermore may be fine-tuned to reflect individual aspects of an individual patient's cardiac condition. In general, the criteria may be indicative both of an absolute elevation of the ST Segment, and possibly of an increased slope of the ST Segment.

[0088] In step **435** an assessment is made as to whether the ST segment is elevated, which indicates the onset of a cardiac ischemic episode. If the answer is no, step **440** determines whether or not exercise activity continues. This assessment will be made using substantially the same metrics or analysis methods used in step **420** to determine the onset of patient exercise activity.

[0089] If patient exercise activity has ceased, then in step **455**A the method stops. A recording may be made of the time when exercise activity ceased, or of the time interval between when exercise commenced and when exercise ceased. It may also be recorded that no episode of ischemia was detected during the interval, which may indicate either a healthy

patient, or that the exercise interval was too short for a meaningful determination to be made of patient susceptibility to ischemia.

[0090] If in step **440** a determination is made that exercise continues, then the method returns to step **430** where an analysis of the EGM is again made. The loop continues in this fashion, assessing in step **435** whether there is an elevated ST segment—if not, then determining in step **440** whether or not exercise activity continues. If exercise activity continues, the loop through steps **430**, **435**, and **440** repeats as necessary.

[0091] If in step **435** a determination is made that there is an elevated ST segment, then in step **445** an exercise induced ischemia onset interval is determined. In one embodiment of the present method, this determination is made by comparing the time when exercise activity commenced and the time when the ischemia episode is recorded. In an alternative embodiment, the determination of the time interval may be made by stopping the timer which was initiated with the onset of patient exercise activity in step **425**. Once the exercise-induced ischemia onset interval has been determined, this data may be stored in a short-term or long-term memory or database. In some embodiments, only a subset of the exercise-induced ischemia onset intervals may be stored, or other summary values, such as average exercise-induced ischemia onset intervals, may be stored.

[0092] Following step **445**, step **455**B stops the present method, meaning that an exercise-induced ischemia onset interval (EIIOI) has been determined and recorded. Alternatively, following step **445**, optional step **450** may be performed. In step **450** a determination is made of a workload-invariant measure of ischemia susceptibility. The workload-invariant measure of ischemia susceptibility, which may also be known as a representative patient ischemia value, is discussed further below. Following step **450**, the method stops at step **455**C.

6. Methods of Analysis for Determining a Degree of Cardiovascular Blockage

[0093] It should be noted that in the discussion which follows as well as in the accompanying drawings, the Greek letter θ is used to represented a level of workload or level of patient exercise activity, which may be measured via any of several different specific metrics as discussed further below. Further, the Greek letter Δ is used to represent the length or duration of a time interval, and specifically a time interval between the onset of patient exercise activity and the detection of an ischemic episode in the patient. This same time interval Δ may otherwise be known as an exercise-induced ischemia onset interval, or EIIOI.

[0094] FIGS. **5**A, **5**B, and **5**C each provide a graphical illustration of the method of the analysis for determining a degree of cardiovascular blockage.

[0095] FIG. **5**A has two plots in parallel to each other, where a short-term time axis is in parallel in both plots, where short-term may be a matter of seconds, minutes, or possibly a longer time, and where the time scale of both plots is the same. The upper plot **502***a* indicates a level of workload, θ, which is experienced by a patient, where the workload θ may generally be construed as a level of exercise activity deliberately undertaken by the patient for the purpose of ascertaining a level of patient cardiac vascular blockage or risk of ischemia.

[0096] The plot line **502***a* indicates the level of workload or exercise activity which the patient is experiencing. This may be measured by a measure of physiologic activity, but may also be measured via an accelerometer or other device for detecting patient motion or activity. For example, and without limitation, the workload may be a level of difficulty on a treadmill, or a rate of cycling on a stationary cycle, or some other exercise workload or stress which is placed on the patient for the purpose of inducing an increase in cardiac activity. Horizontal exercise threshold line **504***a* indicates a level of workload at which it is considered that the patient has commenced exercise.

[0097] On the time axis is indicated a time of exercise onset **506***a*. Once exercise onset has begun, the EGM is analyzed to determine a level of ST segment elevation, shown by the thin vertical bars of ST segment elevation on lower plot **508***a*. When the level of ST segment elevation has crossed the ST segment elevation threshold **510***a*, it is determined that ischemia has been induced in the patient. This point in time is indicated by vertical line **512***a*.

[0098] A value delta (Δ) shown below the horizontal time axis indicates the time interval between line **506***a* and **512***a*, which is considered to be the exercise-induced ischemia onset interval (EIIOI). According to the present method, the shorter the EIIOI interval, the greater the likelihood of ischemia episodes for the patient, or the greater the degree of vascular blockage which may be responsible for ischemia episodes.

[0099] FIG. **5**B is similar to FIG. **5**A, but FIG. **5**B illustrates that, as a matter of practical measurement, the level of exercise activity that is the workload level θ may be determined by assessing a physiologic signal such as heart rate, respiration rate, blood pressure, a composite health index (or CHI) which combines multiple physiologic signals, or similar value. The value of the physiologic signal or composite physiologic signal is reflected in plotline **502***b*. Not shown but possibly included may also be a value of an accelerometer rating or some other value which indicates a level of physical patient movement.

[0100] Once again, when the physiologic signal has crossed a certain exercise threshold level **504***b*, it is deemed that exercise has commenced, as noted by vertical line **506***b*. The ST segment elevation is then measured from that point forward on plot **508***b*, and as reflected in vertical bars **509***b*. When the ST segment elevation has crossed an ST segment elevation threshold **510***b*, it is concluded that exercise induced ischemia has occurred at time **512***b*.

[0101] The duration Δ between the onset of exercise **506***b* and the episode of ischemia **512***b* is the exercise-induced ischemia onset interval (EIIOI).

[0102] FIG. **5**C illustrates an exemplary analysis method for determining a degree of cardiac vascular blockage in a patient. In this case the workload level θ, shown on plot **502***c*, is determined by a different physiologic signal, namely the internal blood oxygen concentration level, SVO_2. When this level, plotted on plotline **502***c*, decreases below an exercise threshold level **504***c*, this is taken as an indication that patient physiologic activity has increased to a point where exercise has commenced. The time is indicated by vertical line **506***c*. Once again a timing mechanism is initiated, which may involve the recording of the time of exercise onset, or the initiation of a timer, and the timing continues until the point of ischemia onset is reached. This point in time, indicated by vertical line **512***c*, is determined when the ST segment elevation values **509***c* shown on plot **508***c* cross the ST segment elevation threshold **510***c*.

[0103] The time interval Δ between exercise onset and ischemia onset is once again the exercise-induced ischemia onset interval, or the EIIOI. A longer EIIOI indicates that the patient was able to exercise for a longer period of time before the onset of ischemia. This may reflect a lower susceptibility to ischemia or, equivalently, a lower degree of coronary artery blockage. Similarly, a shorter EIIOI may reflect a higher patient susceptibility to ischemia or, equivalently, a higher degree of coronary blockage.

7. Workload-Invariant Measure of Ischemia Susceptibility

[0104] In order to determine a variation in a patient's cardiac health over an extended period of time, which may comprise weeks, months, or even years, it is desirable to be able to compare the degree of coronary blockage or, equivalently, the patient's susceptibility to ischemia, over time. Equally, it may be desirable to conduct empirical studies which may establish standardized metrics for a degree of coronary blockage or ischemia risk. Such studies may comprise determining the degree of ischemia vulnerability for patients in various age brackets, body weight/height classes, categories of prior medical history, etc.

[0105] Whether establishing comparisons between the same patient over a period of time, or comparisons between different patients, it may not always be practical to ensure that the same level of exercise difficulty or the same level of patient workload was employed when different measurements were taken. Hence, it is desirable to have a measure of vascular blockage or ischemia susceptibility which is substantially independent of the level of exercise workload required of the patient during testing. This may be known as a workload-invariant measure of ischemia susceptibility or, alternatively, as a representative patient ischemia value.

[0106] FIG. **6**A illustrates a calculation of a workload-invariant measure of ischemia susceptibility (WIMIS). The measure entails taking a product of two values:

$$\text{WIMIS}=\text{workload}\times\text{EIIOI}(=\theta\times\Delta)$$

[0107] There are a number of options for the type of value used to represent the patient workload at the time the EIIOI was measured. In one embodiment, the workload may be measured based on an external measure of patient activity, such as a level of difficulty of a treadmill used by the patient during testing. However, because physical test equipment may vary, obtaining standardized measures in this way may prove difficult. A more robust measure of workload may be the threshold level of patient physiologic activity used to determine the onset of exercise. For example, the composite health index (CHI) discussed above may be employed. Other workload measures may be employed as well.

[0108] FIG. **6**A illustrates how a WIMIS curve may be determined for a patient over a relatively short-term period of time, such as a few days or a few weeks, when it may be the case that the patient's health has neither improved or declined significantly. Over this relatively short-term period of time, the patient may be tested on several occasions to determine an EIIOI at different workload levels. The resulting sets of points (workload, EIIOI) or equivalently, (θ, Δ), may be plotted as shown in plot **600**. In FIG. **6**A, two such points **605**, **610** are shown, which may reflect measurements made on different days. (Typically, it may not be desirable to perform two such tests at times very close to each other, such as within a few hours of each other, or within the same day, since a patient may need a time such as several hours, or possibly a day or more, to recover from the exertions of a single test.)

[0109] The product of the values θ**1** and Δ**1** of patient test point **605** is shown as the shaded area **615**, which represents the WIMIS associated with point **605**. Similarly, the product of the values θ**2** and Δ**2** of patient test point **610** is shown as the shaded area **620**, which represents the WIMIS associated with point **610**. Assuming the patient's degree of cardiac coronary blockage remains substantially unchanged over the short-term time between the two testing episodes, it may be seen from plot **600** that the two areas **615** and **620** may be expected to be substantially the same. It may further be expected that a plotline **630** of multiple such points may be expected to substantially conform to an equation of the form:

$$\text{workload}\times\text{EIIOI}=\text{WIMIS}_{fixed}$$

[0110] where WIMIS_{fixed} is some fixed value.

It should be noted that in actual application, measured pairs of points (workload, EIIOI) may not have a product: workload× EIIOI which is exactly equal to WIMIS_{fixed}. Rather, it is expected that measured points will tend to cluster around a curve which can be represented by the equation:

$$\text{workload}\times\text{EIIOI}=\text{WIMIS}_{fixed}$$

[0111] The curve or plotline associated either with this equation, or associated with a substantially reasonable match or substantially best-fit match to actually measured WIMIS points for a patient, may be known variously as a WIMIS curve or WIMIS plotline, an ischemia risk curve, an ischemia risk plotline, a vascular blockage assessment curve, a vascular blockage assessment plotline, or by similar terms.

[0112] It should be further noted that a patient may suffer from a sudden and potentially severe cardiac episode, which dramatically decreases cardiac performance. In these events, it may be the case that measurements of the WIMIS made shortly after the cardiac episode no longer substantially conform to the WIMIS_{fixed} value determined prior to the cardiac episode. Similarly, medications or other treatments which result in relatively sudden, and relatively dramatic improvements in overall cardiac health my result in relatively sudden increases in measured values for WIMIS_{fixed}. Therefore, the use of the calculation:

$$\text{WIMIS}=\text{workload}\times\text{EIIOI}$$

as a workload-invariant measure of coronary vascular blockage should be employed with discretion, and with suitable considerations of patient clinical history in mind.

[0113] Finally, it should be noted that the WIMIS curve illustrated, and the associated equation, assumes that the actual level of physical exertion required by the patient will increase as the workload measure increases. This is typically the case for many of the possible workload measures discussed above, such as pulse rate, respiration rate, blood pressure, for many possible values of a composite health index (CHI), and for typical accelerometer readings.

[0114] However, some possible measures of patient workload, such as patient blood oxygen level, typically have lower values when the actual level of patient exercise increases. In such cases, another formulation or equation may be better suited to indicate a workload-invariant measure of ischemia susceptibility, or WIMIS. For example, if decreasing workload values, such as decreasing measures of blood oxygen concentration level, correspond to an actual increase in physi-

[0145] determine a level of patient exercise activity;

[0146] determine a time of onset of patient exercise activity;

[0147] determine an episode of ischemia in a patient;

[0148] analyze an EGM or ECG for ST segment elevation as a means to determine the onset of an ischemic episode;

[0149] determine a time interval between the onset of exercise activity or other workload and the onset of an ischemic episode;

[0150] characterize a degree of cardiac vascular blockage or risk of ischemia in whole or in part in terms of the time between the onset of exercise activity on the onset of an ischemic episode;

[0151] characterize related metrics of cardiac vascular blockage or risk of ischemia, including but not limited to substantially workload-invariant measures of cardiac vascular blockage or risk of ischemia, based in whole or in part on the time between the onset of exercise activity and the onset of an ischemic episode, the level of patient exercise activity, and/or possibly on other biometric and physiologic factors;

[0152] make comparisons between the degree of cardiac vascular blockage or risk of ischemia between different patients based in whole or in part on the time between the onset of exercise activity and the onset of an ischemic episode, the level of patient exercise activity, and/or possibly on other biometric and physiologic factors; and

[0153] make long term assessments of the changes in a patient's degree of cardiac vascular blockage or risk of ischemia based in whole or in part on the time between the onset of exercise activity and the onset of an ischemic episode, the level of patient exercise activity, and/or possibly on other biometric and physiologic factors.

10. Conclusion

[0154] It is to be appreciated that the Detailed Description section, and not the Abstract section, is intended to be used to interpret the claims. The Abstract section may set forth one or more but not all exemplary embodiments of the present method and system as contemplated by the inventor(s), and thus, are not intended to limit the present method and system and the appended claims in any way.

What is claimed is:

1. A method for assessing a degree of cardiac vascular blockage in a patient comprising:

(a) determining an onset of patient exercise activity;

(b) determining an onset of myocardial ischemia; and

(c) determining a time interval between the onset of the patient exercise activity and the onset of myocardial ischemia,

wherein a shorter time interval indicates a greater degree of vascular blockage and a longer time interval indicates a lesser degree of vascular blockage.

2. The method of claim **1**, wherein step (a) further comprises at least one of:

determining that a measure of patient metabolic activity has crossed a metabolic activity threshold;

determining that a measure of patient movement has crossed a patient movement threshold;

determining that a measure of external activity has crossed an external activity threshold; or

determining that a measure of a duration of exercise activity has crossed an activity duration threshold.

3. The method of claim **2**, wherein determining that the measure of patient metabolic activity has crossed the metabolic activity threshold comprises measuring at least one of a patient heart rate, a patient blood pressure, a patient respiration rate, or a patient blood oxygen concentration level.

4. The method of claim **2**, wherein determining that a measure of patient metabolic activity has crossed a metabolic activity threshold further comprises measuring the patient metabolic activity via an implanted physiologic measuring device.

5. The method of claim **2**, wherein determining that a measure of patient acceleration has crossed an acceleration threshold further comprises measuring the patient acceleration via an implanted accelerometer.

6. The method of claim **1**, wherein step (b) further comprises:

obtaining at least one of an electrocardiogram (ECG) or an electrogram (EGM) of the patient during the patient exercise activity; and

determining the onset of myocardial ischemia by determining an onset of at least one of:

an elevation of an ST segment in the ECG or EGM of the patient;

a depression of the ST segment in the ECG or EGM of the patient;

a change of slope of the ST segment in the ECG or EGM of the patient; or

a variation of shape of the ST segment in the ECG or EGM of the patient.

7. The method of claim **1**, further comprising calculating a representative patient ischemia value, wherein the representative patient ischemia value is a product of the time interval and a level of patient workload;

wherein the level of patient workload is indicative of the level of patient exercise activity corresponding to the determination of the time interval; and

wherein if a first representative patient ischemia value for a patient and a second representative patient ischemia value for the patient have a substantially equal value, the substantial equality of the first and second values indicates a substantially similar level of ischemia for the patient.

8. The method of claim **1**, further comprising determining a plurality of time intervals for the patient, wherein the plurality of time intervals are determined over a period of time, wherein the period of time is comprised of a plurality of days.

9. The method of claim **8**, further comprising at least one of storing the plurality of time intervals, storing a subset of the plurality of time intervals, or calculating and storing a set of representative patient ischemia values, wherein each representative patient ischemia value is indicative of at least one of a patient time interval or a plurality of patient time intervals.

10. The method of claim **9**, further comprising analyzing the plurality of stored values to determine at least one of a patient trend of cardiac vascular blockage over the period of time, a patient risk of ischemia, or a patient risk of myocardial infarction.

11. A method for assessing a degree of risk of cardiac ischemia in a patient comprising:

(a) determining an onset of patient exercise activity;

(b) obtaining a measure of patient cardiac electrical activity during the patient exercise activity;

(c) analyzing the measure of patient cardiac electrical activity to determine an onset of myocardial ischemia; and