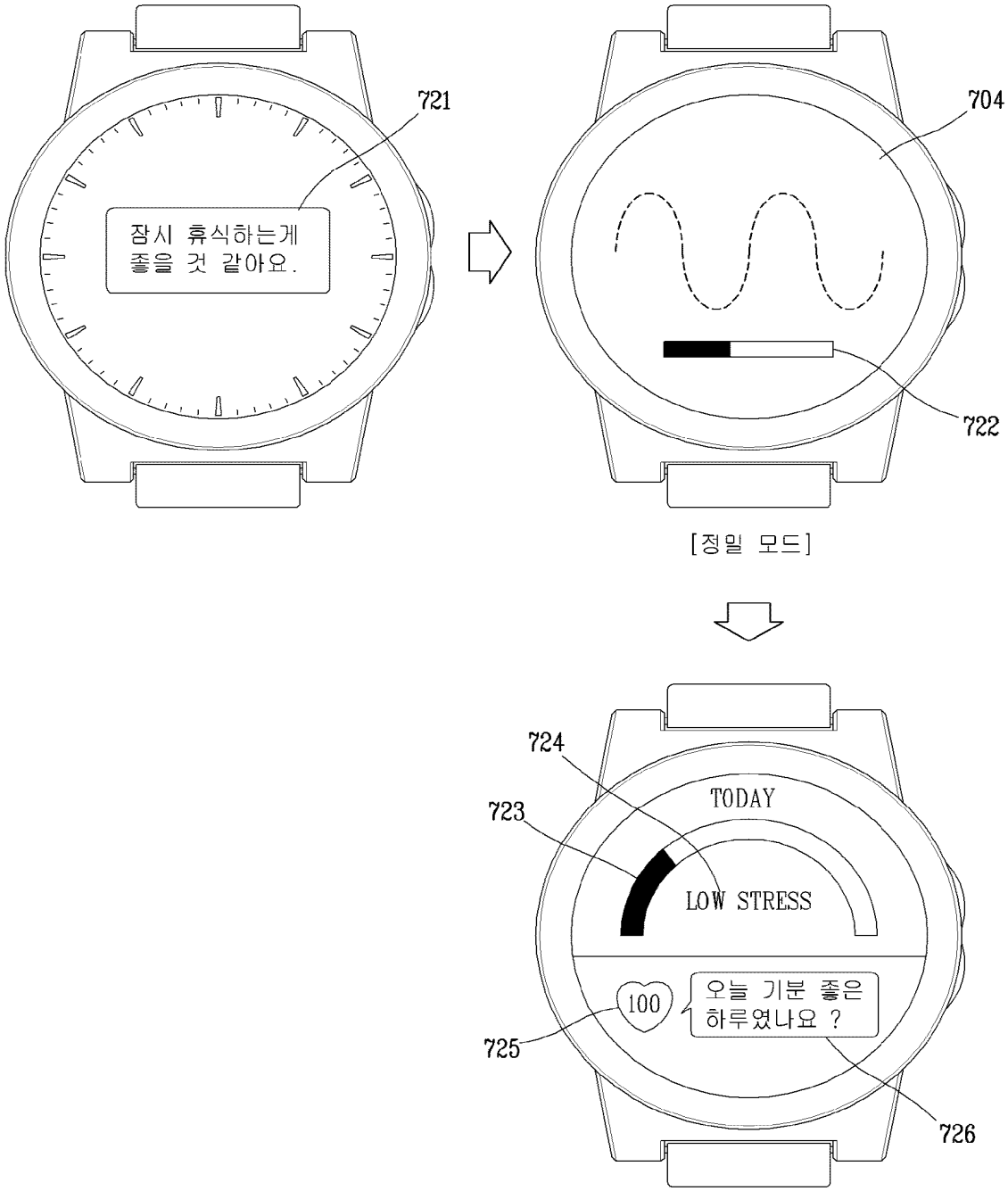
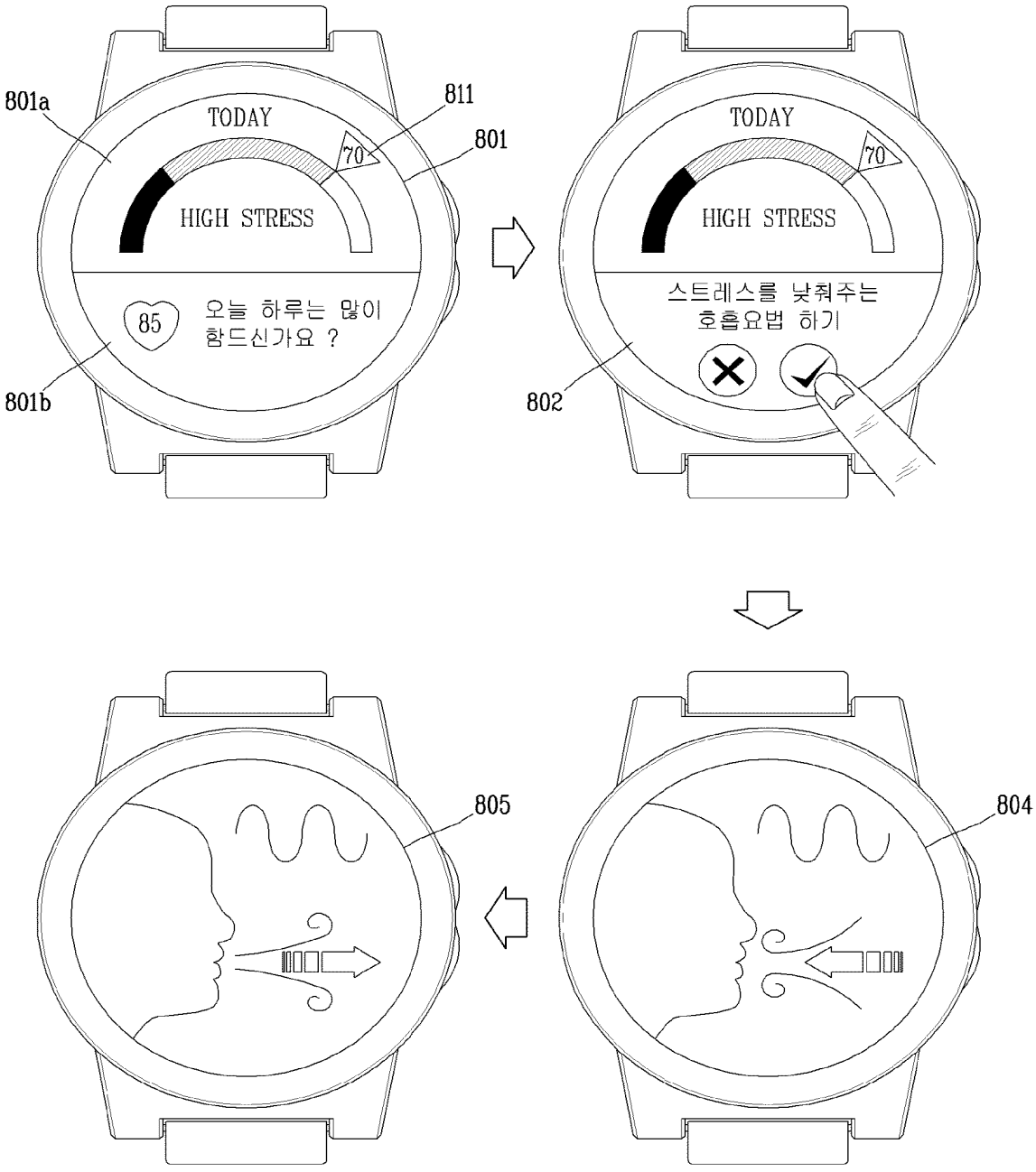
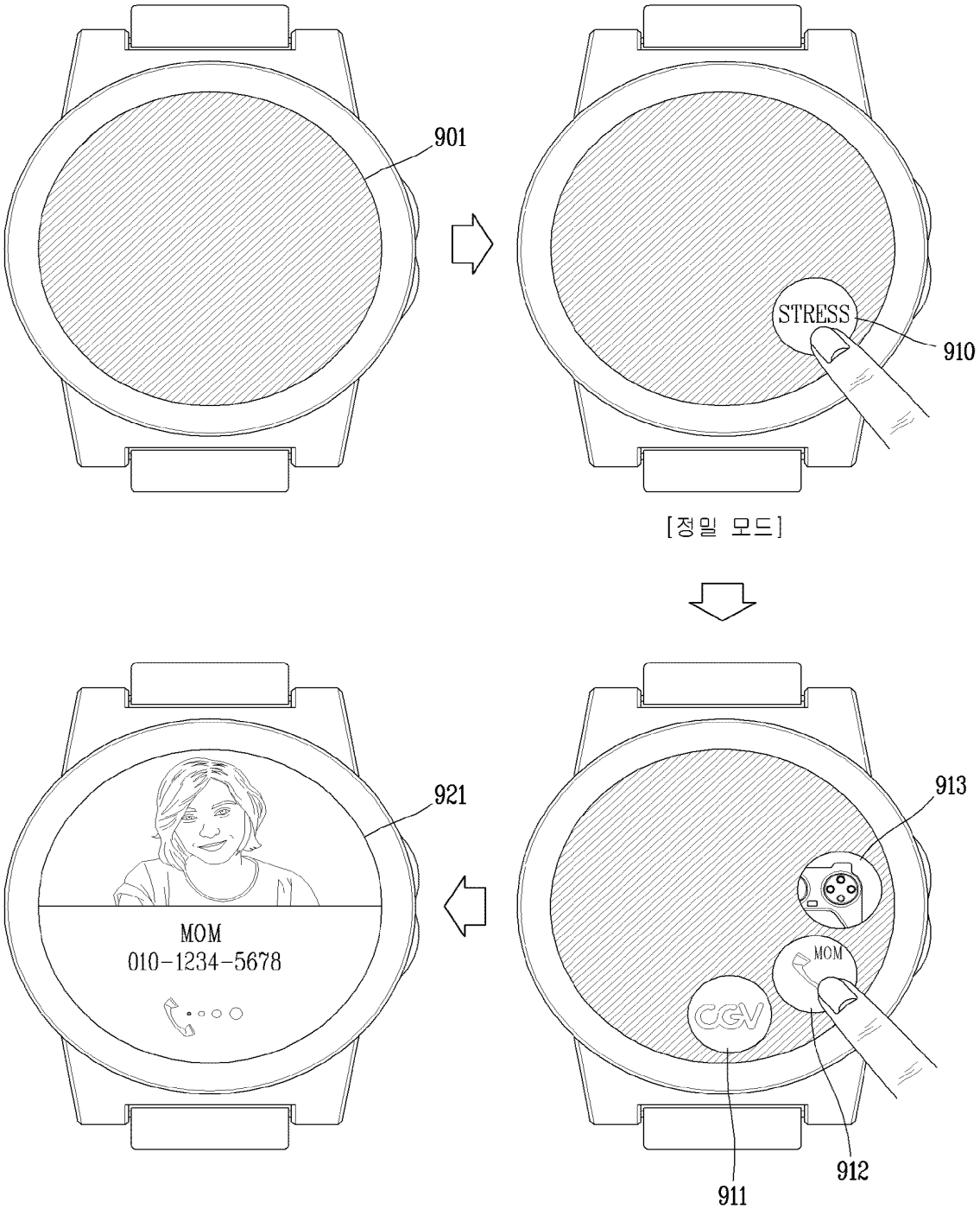
[도7b]


721
잠시 휴식하는게
좋을 것 같아요.
704
722
[정밀 모드]
724
TODAY
723
LOW STRESS
100
오늘 기분 좋은
하루였나요 ?
725
726

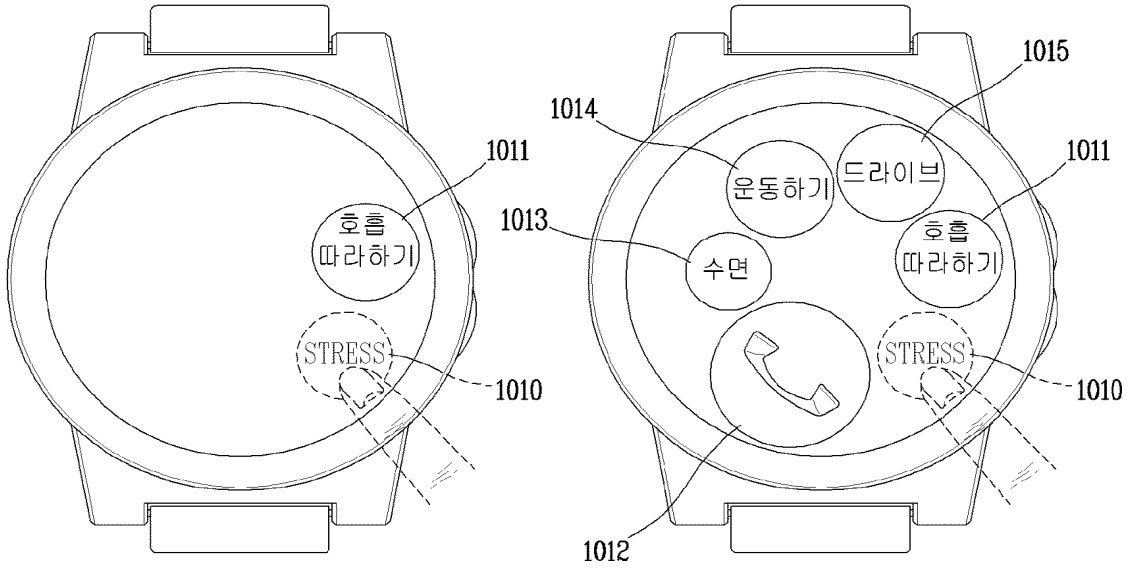
[도8]


801a
811
801
TODAY
70
HIGH STRESS
85
오늘 하루는 많이
함드신가요 ?
801b
TODAY
70
HIGH STRESS
스트레스를 낮춰주는
호흡요법 하기
802
804
805

[도9]

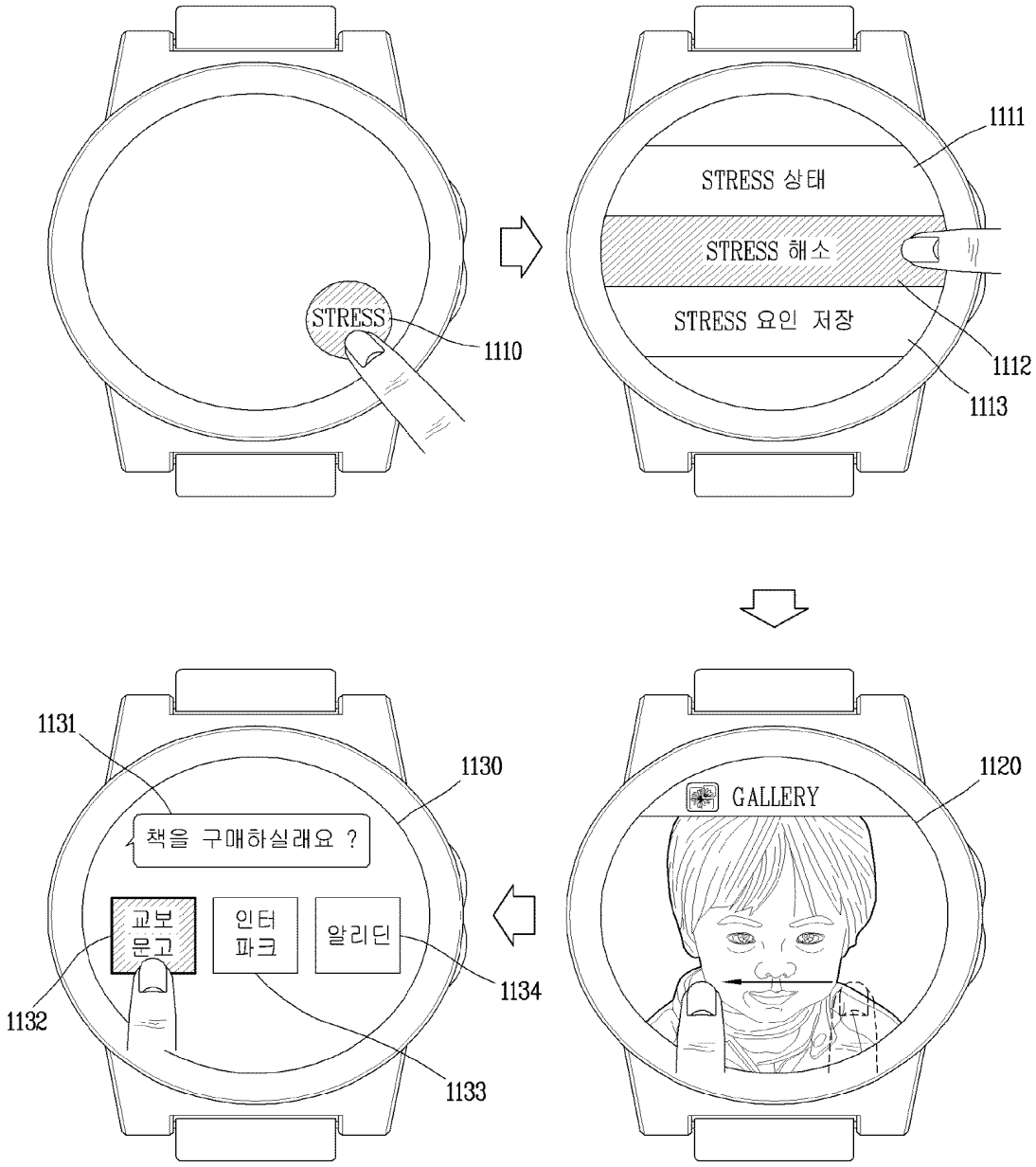


[도10]

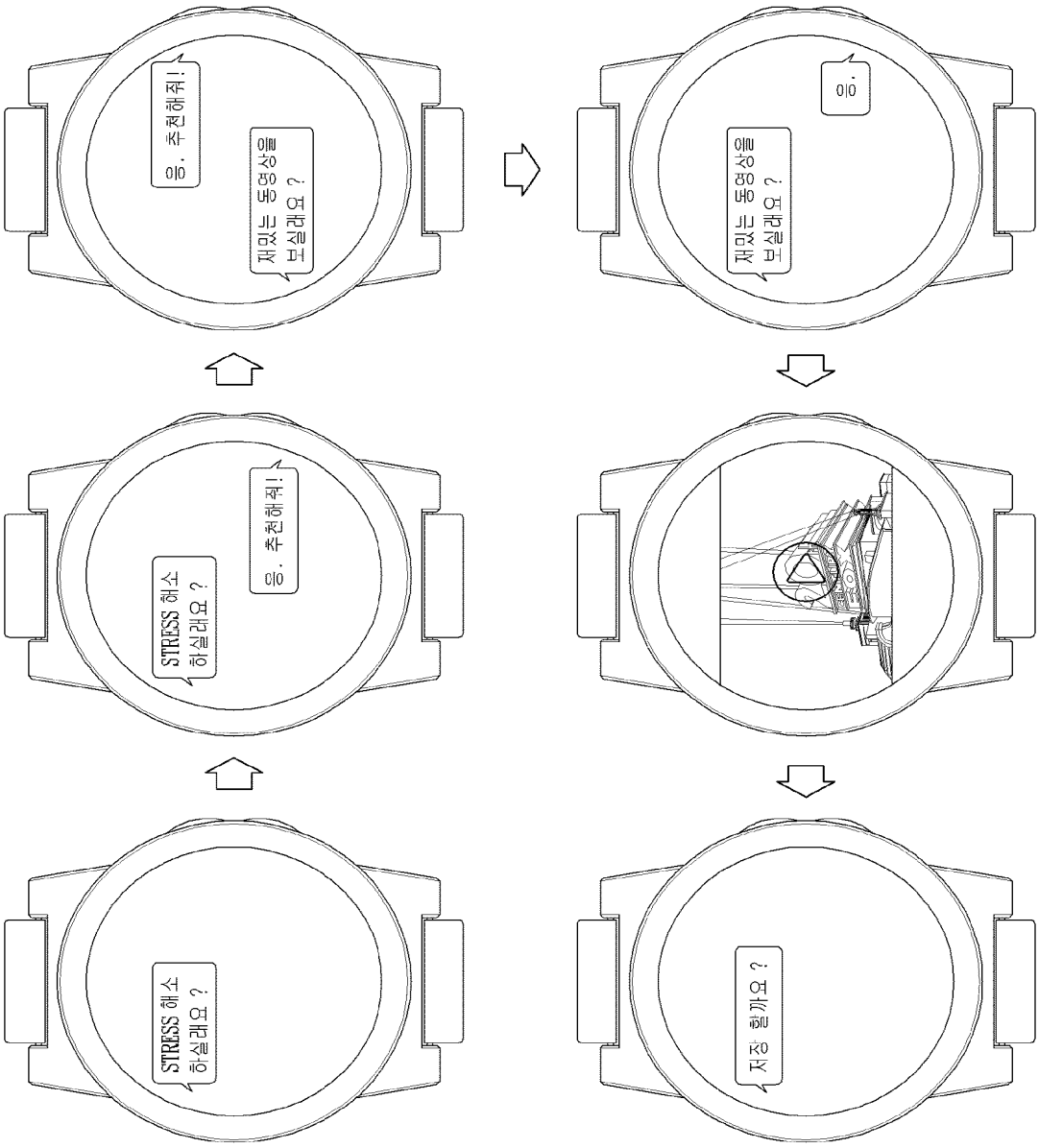


[COMPANY] [HOME]

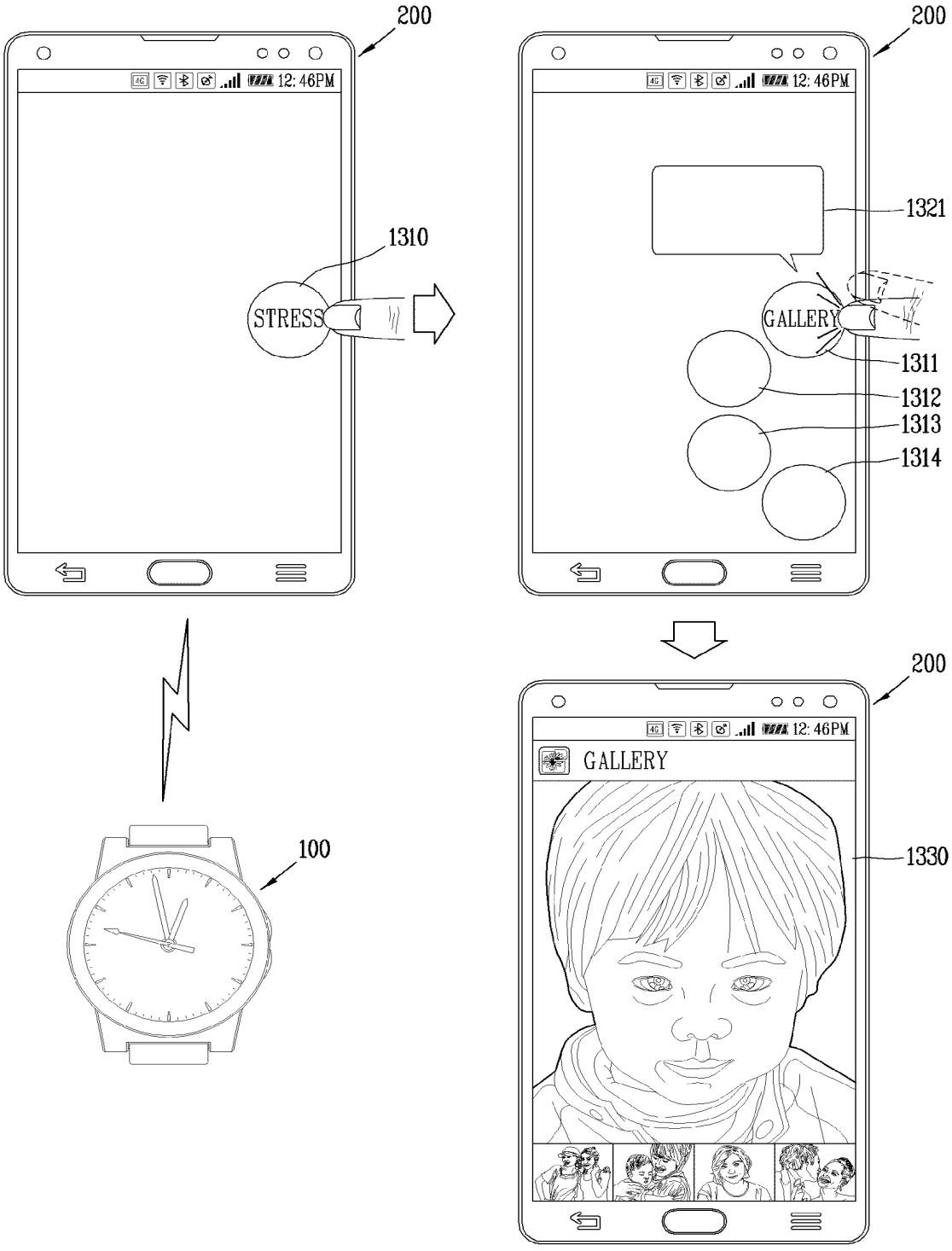
[도11]


STRESS
1110
1111
STRESS 상태
STRESS 해소
STRESS 요인 저장
1112
1113
GALLERY
1120
1130
1131
책을 구매하실래요 ?
교보 문고
인터 파크
알리딘
1132
1133
1134

[도12]


응. 추천해줘!
재밌는 동영상을 보실래요 ?
응.
재밌는 동영상을 보실래요 ?
STRESS 해소 하실래요 ?
응. 추천해줘!
STRESS 해소 하실래요 ?
저장 할까요 ?

[도13]


200
12: 46PM
1310
STRESS
200
12: 46PM
1321
GALLERY
1311
1312
1313
1314
100
200
12: 46PM
GALLERY
1330

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2015/013155

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/00(2006.01)i, A61B 5/11(2006.01)i, G06F 1/16(2006.01)i, G06F 1/32(2006.01)i, G06F 3/041(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/00; B60W 50/16; G06F 19/00; A61B 5/145; G06Q 50/22; B60W 50/14; H04B 1/40; A61B 5/11; G06F 1/16; G06F 1/32; G06F 3/041

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models: IPC as above
Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS (KIPO internal) & Keywords: wearable, stress, index, state, measurement

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KR 10-1570430 B1 (LG ELECTRONICS INC.) 20 November 2015 See abstract, paragraphs [11]-[190], claims 1, 2 and figures 1a-5a.	1-18
Y	KR 10-2015-0047158 A (SAMSUNG ELECTRONICS CO., LTD.) 04 May 2015 See abstract, paragraphs [19]-[42], claims 4-7 and figures 4, 16.	1-18
Y	KR 10-2014-0130272 A (I.M. BIO CO., LTD.) 10 November 2014 See abstract, paragraphs [31]-[32], claim 8 and figure 6.	17,18
A	US 2015-0216458 A1 (SEIKO EPSON CORPORATION) 06 August 2015 See abstract, claims 1-7 and figure 1.	1-18
A	KR 10-1531567 B1 (SONG, Yo Soon et al.) 25 June 2015 See abstract, claims 1, 4, 8 and figures 1-9.	1-18

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 AUGUST 2016 (24.08.2016)	**24 AUGUST 2016 (24.08.2016)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 189 Seonsa-ro, Daejeon 302-701, Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer

Telephone No.

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
809 of 1413

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2015/013155

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **19-22**
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 19 to 22 pertain to a diagnostic method, and thus pertain to subject matter on which the International Searching Authority is not required to carry out an international search under the provisions of PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
810 of 1413

Patent document cited in search report	Publication date	Patent family member	Publication date
KR 10-1570430 B1	20/11/2015	NONE	
KR 10-2015-0047158 A	04/05/2015	US 2015-0120205 A1	30/04/2015
KR 10-2014-0130272 A	10/11/2014	KR 10-1478220 B1	02/01/2015
US 2015-0216458 A1	06/08/2015	CN 104814745 A EP 2901924 A1 JP 2015-142663 A	05/08/2015 05/08/2015 06/08/2015
KR 10-1531567 B1	25/06/2015	KR 10-2015-0057185 A	28/05/2015

국 제 조 사 보 고 서

국제출원번호
PCT/KR2015/013155

A. 발명이 속하는 기술분류(국제특허분류(IPC))

A61B 5/00(2006.01)i, A61B 5/11(2006.01)i, G06F 1/16(2006.01)i, G06F 1/32(2006.01)i, G06F 3/041(2006.01)i

B. 조사된 분야

조사된 최소문헌(국제특허분류를 기재)
A61B 5/00; B60W 50/16; G06F 19/00; A61B 5/145; G06Q 50/22; B60W 50/14; H04B 1/40; A61B 5/11; G06F 1/16; G06F 1/32; G06F 3/041

조사된 기술분야에 속하는 최소문헌 이외의 문헌
한국등록실용신안공보 및 한국공개실용신안공보: 조사된 최소문헌란에 기재된 IPC
일본등록실용신안공보 및 일본공개실용신안공보: 조사된 최소문헌란에 기재된 IPC

국제조사에 이용된 전산 데이터베이스(데이터베이스의 명칭 및 검색어(해당하는 경우))
eKOMPASS(특허청 내부 검색시스템) & 키워드: 웨어러블, 스트레스, 지수, 상태, 측정

C. 관련 문헌

카테고리*	인용문헌명 및 관련 구절(해당하는 경우)의 기재	관련 청구항
Y	KR 10-1570430 B1 (엘지전자 주식회사) 2015.11.20 요약, 문단번호 [11]-[190], 청구항 1,2 및 도면 1a-5a 참조.	1-18
Y	KR 10-2015-0047158 A (삼성전자주식회사) 2015.05.04 요약, 문단번호 [19]-[42], 청구항 4-7 및 도면 4,16 참조.	1-18
Y	KR 10-2014-0130272 A (주식회사 아이엠바이오) 2014.11.10 요약, 문단번호 [31]-[32], 청구항 8 및 도면 6 참조.	17,18
A	US 2015-0216458 A1 (SEIKO EPSON CORPORATION) 2015.08.06 요약, 청구항 1-7 및 도면 1 참조.	1-18
A	KR 10-1531567 B1 (송요순 등) 2015.06.25 요약, 청구항 1,4,8 및 도면 1-9 참조.	1-18

☐ 추가 문헌이 C(계속)에 기재되어 있습니다.

☒ 대응특허에 관한 별지를 참조하십시오.

* 인용된 문헌의 특별 카테고리:

"A" 특별히 관련이 없는 것으로 보이는 일반적인 기술수준을 정의한 문헌

"E" 국제출원일보다 빠른 출원일 또는 우선일을 가지나 국제출원일 이후에 공개된 선출원 또는 특허 문헌

"L" 우선권 주장에 의문을 제기하는 문헌 또는 다른 인용문헌의 공개일 또는 다른 특별한 이유(이유를 명시)를 밝히기 위하여 인용된 문헌

"O" 구두 개시, 사용, 전시 또는 기타 수단을 언급하고 있는 문헌

"P" 우선일 이후에 공개되었으나 국제출원일 이전에 공개된 문헌

"T" 국제출원일 또는 우선일 후에 공개된 문헌으로, 출원과 상충하지 않으며 발명의 기초가 되는 원리나 이론을 이해하기 위해 인용된 문헌

"X" 특별한 관련이 있는 문헌. 해당 문헌 하나만으로 청구된 발명의 신규성 또는 진보성이 없는 것으로 본다.

"Y" 특별한 관련이 있는 문헌. 해당 문헌이 하나 이상의 다른 문헌과 조합하는 경우로 그 조합이 당업자에게 자명한 경우 청구된 발명은 진보성이 없는 것으로 본다.

"&" 동일한 대응특허문헌에 속하는 문헌

국제조사의 실제 완료일	국제조사보고서 발송일
2016년 08월 24일 (24.08.2016)	2016년 08월 24일 (24.08.2016)

ISA/KR의 명칭 및 우편주소
대한민국 특허청
(35208) 대전광역시 서구 청사로 189,
4동 (둔산동, 정부대전청사)
팩스 번호 +82-42-481-8578

심사관
김연경
전화번호 +82-42-481-3325

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

국 제 조 사 보 고 서

국제출원번호
PCT/KR2015/013155

제2기재란 일부 청구항을 조사할 수 없는 경우의 의견(첫 번째 용지의 2의 계속)

PCT 제17조(2)(a)의 규정에 따라 다음과 같은 이유로 일부 청구항에 대하여 본 국제조사보고서가 작성되지 아니하였습니다.

1. ☒ 청구항: 19-22
이 청구항은 본 기관이 조사할 필요가 없는 대상에 관련됩니다. 즉,
청구항 제19항 내지 제22항은 진단 방법에 관한 것이므로 PCT 조약 제17조(2)(a)(i) 및 PCT 규칙 39.1(iv)의 규정에 의하여 국제조사기관이 국제 조사할 의무가 없는 대상에 해당됩니다.

2. ☐ 청구항:
이 청구항은 유효한 국제조사를 수행할 수 없을 정도로 소정의 요건을 충족하지 아니하는 국제출원의 부분과 관련됩니다. 구체적으로는,

3. ☐ 청구항:
이 청구항은 종속청구항이나 PCT규칙 6.4(a)의 두 번째 및 세 번째 문장의 규정에 따라 작성되어 있지 않습니다.

제3기재란 발명의 단일성이 결여된 경우의 의견(첫 번째 용지의 3의 계속)

본 국제조사기관은 본 국제출원에 다음과 같이 다수의 발명이 있다고 봅니다.

1. ☐ 출원인이 모든 추가수수료를 기간 내에 납부하였으므로, 본 국제조사보고서는 모든 조사 가능한 청구항을 대상으로 합니다.

2. ☐ 추가수수료 납부를 요구하지 않고도 모든 조사 가능한 청구항을 조사할 수 있었으므로, 본 기관은 추가수수료 납부를 요구하지 아니하였습니다.

3. ☐ 출원인이 추가수수료의 일부만을 기간 내에 납부하였으므로, 본 국제조사보고서는 수수료가 납부된 청구항만을 대상으로 합니다. 구체적인 청구항은 아래와 같습니다.

4. ☐ 출원인이 기간 내에 추가수수료를 납부하지 아니하였습니다. 따라서 본 국제조사보고서는 청구범위에 처음 기재된 발명에 한정되어 있으며, 해당 청구항은 아래와 같습니다.

이의신청에 관한 기재

☐ 출원인의 이의신청 및 이의신청료 납부(해당하는 경우)와 함께 추가수수료가 납부되었습니다.

☐ 출원인의 이의신청과 함께 추가수수료가 납부되었으나 이의신청료가 보정요구서에 명시된 기간 내에 납부되지 아니하였습니다.

☐ 이의신청 없이 추가수수료가 납부되었습니다.

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

국제조사보고서에서 인용된 특허문헌	공개일	대응특허문헌	공개일
KR 10-1570430 B1	2015/11/20	없음	
KR 10-2015-0047158 A	2015/05/04	US 2015-0120205 A1	2015/04/30
KR 10-2014-0130272 A	2014/11/10	KR 10-1478220 B1	2015/01/02
US 2015-0216458 A1	2015/08/06	CN 104814745 A EP 2901924 A1 JP 2015-142663 A	2015/08/05 2015/08/05 2015/08/06
KR 10-1531567 B1	2015/06/25	KR 10-2015-0057185 A	2015/05/28

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/143,959
	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	G. Jackson
	Attorney Docket Number	P38213US2/77770000489102

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	9801562	B1	2017-10-31	Host-madsen, Anders	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20130114100	A1	2013- 05-09	Torii et al.	
	2.	20140081118	A1	2014-03-20	Reinhold et al.	
	3.	20140240349	A1	2014-08-28	Tuukkanen, Marko T.	
	4.	20160301761	A1	2016-10-13	Sanchez-sandoval et al.	
	5.	20170000359	A1	2017-01-05	Kohli et al.	
	6.	20170274149	A1	2017-09-28	Aeschlimann, Andreas	
	7.	20180000426	A1	2018-01-04	Li, Yelei	
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	1.	2015/187799	WO	A1	2015-12-10	Amgen Inc.		
	2.	2016/161152	WO	A1	2016-10-06	University Of Pittsburgh - Of The Commonwealth System Of Higher Education		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1.	"Graphs and Charts", Online available at: <https://www.teachervision.com/lesson-planning/Graph-chart-teacher-resources, retrieved on December 12, 2018, 4 pages.	
	2.	Search Report and Opinion received for Danish Patent Application No. PA201870599, mailed on December 21, 2018, 9 pages.	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Randy Omid/	Date (YYYY-MM-DD)	2019-02-04
Name/Print	Randy Omid	Registration Number	67,439

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(54) Title: SYSTEMS AND METHODS FOR REMOTELY PROCESSING DATA COLLECTED BY A DRUG DELIVERY DEVICE

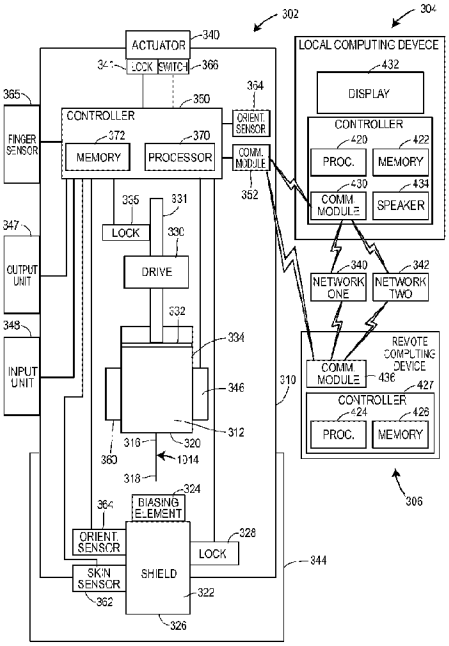


FIG. 3

(57) Abstract: Systems and methods are disclosed for processing sensor data collected by a drug delivery device with an external computing device. The drug delivery device may include a reservoir and a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient. The drug delivery device may further include one or more sensors configured to generate sensor data representative of a condition and/or operational state of the drug delivery device, and a communication module configured to transmit information to the external computing device. The external computing device may process the information received from the drug delivery device according to information stored in a memory of the external computing device to determine the condition or the operational state of the drug delivery device and/or generate instructional or informational prompts to be displayed to a user or patient.

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SYSTEMS AND METHODS FOR REMOTELY PROCESSING DATA COLLECTED BY A DRUG DELIVERY DEVICE

Cross-Reference to Related Application

[0001] The priority benefit of U.S. Provisional Patent Application No. 62/007,007, filed June 3, 2014, is claimed, and the entire contents thereof are expressly incorporated herein by reference.

Background

[0002] The present disclosure generally concerns systems and methods for use with drug delivery devices and relating to the processing of sensor data collected by the drug delivery devices to determine their condition and/or operational state and improve their usability for patients and other users.

[0003] Drugs can be administered through the use of drug delivery devices, such as autoinjectors or on-body injectors or infusers. These devices may replace older delivery systems using the combination of a syringe and a vial containing the drug or medicament, or a pre-filled syringe. Autoinjectors and on-body injectors may be used to automate the injection and delivery or administration process, thereby simplifying the process for certain patient groups or sub-groups for which use of the syringe/vial combination or pre-filled syringe systems is disadvantageous, whether because of physiological or psychological impediments.

[0004] Even with the use of drug delivery devices, such as autoinjectors, patients may experience challenges during the initial use of the drug delivery device after they have been prescribed a drug that is delivered or administered through the use of a drug delivery device. For example, the user may be uncertain whether the injection should be delayed after a drug delivery device has been removed from cold storage, such as in a refrigerator, and if the injection should be delayed, how long it should be delayed. Additionally, the user may be uncertain whether the medication inside the drug delivery device is the medication prescribed for them. Further, the user may be uncertain whether the medication has expired. Still further, the user may also be uncertain if the actions and their sequence necessary to correctly operate the drug delivery device.

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[0005] In addition, the condition and use of drug delivery devices is of importance to other parties, such as drug device manufacturers, pharmacies, health care providers and insurers. For instance, information regarding the condition of the drug delivery device along the supply chain may be relevant to whether the drug delivery device will be in good working order when it arrives for use with the patient. Information regarding the location of the drug delivery device along the supply chain may be relevant to the manufacturer and the pharmacy to ensure that adequate supplies are available for the pharmacy to delivery to the user. The compliance information mentioned above may be important to the healthcare providers and insurers, as well as to the patient, because compliance with a therapy regimen may have a direct impact on the success of the therapy.

[0006] To address some of the foregoing challenges, it is possible to include one or more sensors onboard the drug delivery device to monitor its condition and use. However, the analysis, storage, communication and other processing of sensor data collected by the one or more sensors may require the use of relatively expensive computer hardware including microprocessors, memories, Internet-accessible communication modules, etc. Since the drug delivery device may be a disposable, single-use device, or otherwise have a limited lifespan, it may be undesirable from an economic perspective to incorporate such expensive computer hardware into the drug delivery device itself.

[0007] As set forth in more detail below, the present disclosure sets forth various systems and methods that embody advantageous alternatives to existing drug delivery systems and methods, and that may address one or more of the challenges or needs mentioned above.

Summary

[0008] According to an aspect of the disclosure, a system includes a drug delivery device and an external computing device. The drug delivery device may include a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, one or more sensors configured to generate sensor data representative of at least one of a condition or an operational state

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of the drug delivery device, and a first communication module coupled to the one or more sensors and configured to transmit the sensor data. The external computing device may include a second communication module configured to receive the sensor data from the first communication module, a processor coupled to the second communication module, and a memory coupled to the processor. The memory may store non-transitory computer-readable instructions that, when executed by the processor, cause the processor to determine at least one of the condition or the operational state of the drug delivery device based on the sensor data.

[0009] According to another aspect of the disclosure, a system includes a drug delivery device and an external computing device. The drug delivery device may include a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, one or more sensors, a first communication module, and a first controller coupled to the one or more sensors and the first communication module. The first controller may be configured to use the one or more sensors to determine at least one of a condition or an operational state of the drug delivery device, and control the first communication module to transmit a communication representative of the condition or the operational state of the drug delivery device. The external computing device may include a second communication module configured to receive the communication from the first communication module, a display, a memory, and a second controller coupled to the display, the memory, and the second communication module. The second controller may be configured to control the display to display at least one of an instructional prompt or an informational prompt based on the communication from the first communication module.

[0010] According to yet another aspect of the disclosure, a method of using a system comprising a drug delivery device and an external computing device is provided. The drug delivery device may include a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, one or more sensors configured to generate sensor data, and a first communication module. The external computing device may include a memory and a second communication module. The method may include: (a) collecting sensor data with the drug delivery device; (b) transmitting the sensor data from the drug delivery device with

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the first communication module; (c) receiving the sensor data from the drug delivery device at the external computing device with the second communication module; and (d) determining, with the external computing device, at least one of a condition or an operational state of the drug delivery device based on the sensor data.

[0011] According to still another aspect of the disclosure, a method of using a system comprising a drug delivery device and an external computing device is provided. The drug delivery device may include a reservoir and a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient. The external computing device may include a memory. The method may include: (a) determining at least one of a condition or an operational state of the drug delivery device; (b) transmitting a communication representative of the condition or the operational state from the drug delivery device; (c) receiving the communication from the drug delivery device at the external computing device; and (d) processing the communication received from the drug delivery device according to information stored in the memory of the external computing device.

Brief Description of the Drawings

[0012] It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the figures may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some figures are not necessarily indicative of the presence or absence of particular elements in any of the exemplary embodiments, except as may be explicitly delineated in the corresponding written description. None of the drawings are necessarily to scale.

[0013] Fig. 1 is a schematic diagram of a drug delivery system according an embodiment of the disclosure in communication with one or more computing devices and one or more networks;

[0014] Fig. 2 is a block diagram of a method of operating a drug delivery system according to another embodiment of the disclosure;

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[0015] Fig. 3 is a schematic illustration of a system including a drug delivery device, a local computing device, and a remote computing device interconnected with communication links and networks;

[0016] Fig. 4 is a schematic illustration of a drug delivery device with an attachable controller that may be used in the interactive drug delivery system of Fig. 3;

[0017] Fig. 5 is a flowchart illustrating the operation of the drug delivery device according to Fig. 3;

[0018] Fig. 6 is a flowchart illustrating the operation of the interactive drug delivery system according to Fig. 3;

[0019] Fig. 7 is a simulated screenshot of a display of the local computing device according to a first state subsequent to removal of the drug delivery device from cold storage;

[0020] Fig. 8 is a simulated screenshot of a display of the local computing device according to a second state prior to device application;

[0021] Fig. 9 is a simulated screenshot of a display of the local computing device according to a third state subsequent to device application but prior to injection;

[0022] Fig. 10 is a simulated screenshot of a display of the local computing device according to a fourth state subsequent to injection but prior to completion;

[0023] Fig. 11 is a simulated screenshot of a display of the local computing device according to fifth state subsequent to completion;

[0024] Fig. 12 is a flowchart illustrating the operation of the controller associated with the drug delivery device of the system of Fig. 3;

[0025] Fig. 13 is a flowchart illustrating the operation of the local computing device of the system of Fig. 3; and

[0026] Fig. 14 is a flowchart illustration the operation of the local computing device according to another embodiment.

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Detailed Description

[0027] This disclosure is directed to a plurality of systems including a drug delivery device, and to a plurality of methods for using the drug delivery system. In particular, the systems and methods involve the determination of one or more states, which states may be determined through the use of one or more sensors in combination with one or more controllers. The sensors may rely on mechanical, electrical or chemical sensing mechanisms, and the controllers may be mechanical, electrical or electro-mechanical. By way of example and not by way of limitation, the states may relate to the operation of the drug delivery device, or to the condition of the drug delivery device. The system and methods may use the state determination to control the operation of the drug delivery device, and/or may communicate the state determination to other devices, such as third-party servers that may collect, process and/or further disseminate the state determinations received from the system including the drug delivery device, the one or more sensors, and the one or more controllers. In addition or in the alternative, the systems and methods may communicate the state determination to local computing devices, such as a mobile computing device (e.g., cell phone).

[0028] A drug delivery system according to the disclosure may include a drug delivery device having a reservoir (which may also be referred to as a primary container, e.g. a syringe, vial or cartridge). The reservoir may contain a drug, which may also be referred to as a medication or a medicament. The drug may be, but is not limited to various biologicals such as peptides, peptibodies, or antibodies. The drug may be in a fluid or liquid form, although the disclosure is not limited to a particular state (e.g., no differentiation is intended between a solution, a gel, or a lyophilized product for example). The drug delivery device also includes delivery cannula having a first end connected to or connectable in fluid communication with the reservoir and a second end to be inserted within a patient. As used herein, the term "delivery cannula" or "cannula" is hereby defined to mean a tube that can be inserted into the body for the delivery of fluid. A cannula may include a rigid or semi-rigid needle or blunt cannula, or may be in a flexible form, by example and not by way of limitation. The cannula may be integrated with the other elements of the drug delivery device, or the cannula may be separate from the other elements of the drug delivery until immediately prior to use. According to

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certain embodiments, the drug delivery device may further include an inserter to introduce the second end into the patient, although this is not required according to each embodiment of the disclosure. The inserter may or may not be withdrawn back into the device, thereby leaving the cannula in a patient.

[0029] Considering the foregoing description of the drug delivery device, the device may be characterized as an autoinjector or an on-body injector or infuser (the reference to injector intended to include also a reference to an infuser, to the extent that a difference is suggested). Autoinjectors may be single-use devices, administering a single dose during a single application of the device to the user's skin, although autoinjectors are not limited to only single-use devices – they may be multi-use devices as well. On-body injectors may be multi-use devices, administering multiple doses during one or more applications of the device to the user's skin, although on-body devices may also be used as single-use devices. Either autoinjectors or on-body injectors may have assemblies or sub-assemblies that are reusable, in that the assemblies may be used and re-used by refilling the reservoir, by removing an empty reservoir and replacing it with a filled reservoir, or by replacing the cannula, for example.

[0030] As noted above, the system or method according to the disclosure will determine one or more states relative to the drug delivery device.

[0031] For example, the system or method may determine if the drug delivery device is in one or more operational states (i.e., a state relating to the operation of the drug delivery device to deliver the drug to the patient). A non-exhaustive list of the general operational states may include (i) packaged/ready for distribution; (ii) packaged/distributed; (iii) unpackaged/ready for administration; (iv) sterile barrier removed; (v) device applied; (vi) cannula injected (or inserted); (vii) drug delivery initiated; (viii) drug delivery completed; and (ix) device removed. The system or method may determine specific operational states within each of the general operational states; for example, the system or method may determine if plunger has been moved from a first end of a bore (defining a drug reservoir) to a second end of the bore to determine if the drug delivery device is in the "drug delivery complete" state.

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[0032] Furthermore, the system or method may determine if the drug delivery device is in one or more condition states (i.e., a state relating to the condition of the drug delivery device, not necessarily related to the operation of the drug delivery device to deliver the drug to the patient). A non-exhaustive list of condition states may include (i) age (e.g., taken with respect to a manufacturing date or an expiration date); (ii) sterility/contamination; (iii) temperature; (iv) temperature history; and (iv) orientation. The determination of a condition state may be considered as part of the determination of an operational state; for example, the determination of the temperature state may be considered as part of the determination of the "ready for administration" state. Alternatively, the operational and condition states may be determined separately.

[0033] These states may be determined through the use of one or more sensors. The sensors may be particular to a condition state to be determined: for example, a thermocouple disposed adjacent to the reservoir may be used to determine the temperature state of the drug delivery device. The sensors may be particular to an operational state to be determined: for example, a switch may be coupled to a needle guard to determine when a needle cap has been removed to determine the "sterile barrier removed" operational state, the switch being open when the needle cap is disposed over the second end of the cannula and the switch being closed when the needle guard is not disposed over the second end of the cannula. Sensors may be used to determine both a condition state and an operational state: for example, the thermocouple may be used to determine the temperature condition state of the device (or more particularly, the drug), and/or the thermocouple may be used to determine the "ready for administration" operational state.

[0034] The system or method may use the determined states to control the operation of the drug delivery device. For example, the system may include a controller that is coupled to the sensor and may be coupled to one or more of the assemblies or subassemblies of the drug delivery device described above, or to one or more additional assemblies or subassemblies of the drug delivery device. The controller may be adapted structurally or programmed (if electrical or electro-mechanical) to activate or to inhibit these assemblies or subassemblies in accordance with the determined states. For example, the drug delivery device may include a lockout that limits or completely inhibits

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the operation of the injector, and the controller may activate the lockout in a reversible fashion if the temperature state of the drug delivery device (and in particular, the drug in the reservoir) is below, or excessively above, a threshold state.

[0035] The system or method may communicate the determined state(s) to another device or system, which communication may be performed in conjunction with use of the determined state(s) to control the operation of the drug delivery device. For example the system or method may communicate the determined state(s) with a networked device using a communication link. In this sense, a networked device is intended to include any device that communicates with at least one other device over a communication link, and might include communication with a device such as mobile device (e.g., cell phone or mobile computing device) using a Bluetooth connection or a computing device using a Wi-Fi connection, for example. The networked device may communicate the determined states to other computing devices remote from the drug delivery system over the network that includes the networked device such as a server. According to certain embodiments of the present disclosure, the system communicates directly with the network (i.e., without an intermediate networked device – the system would be a networked device) or directly with a remote computing device such as a server (using, for example, a 3G antenna). The state information communicated over network, may then be used, for example, to determine if a patient is in compliance, or if a class of drug delivery devices is exhibiting a systemic malfunction. The state information may be used in other manners as well.

[0036] The systems and methods may also include control of the drug delivery device according to information relating to the identity of the drug, the drug delivery device, or the user, and/or communication of this identity information. Identity information relating to the drug may include a drug name, a drug concentration, dose information, a lot number or serial number, and a date of manufacture and/or expiration. Identity information relating to the drug delivery device may include a device type (e.g., autoinjector, on-body injector), a lot number or serial number, and a date of manufacture. Identity information relating to the user may include a patient name, demographic information, and patient subgroup information. This information may be referred to as "static" information, in contrast to the state information discussed above.

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[0037] As to the communication of the information, and in particular relative to the identity information discussed immediately above, it will be recognized that not all information may be useful, desired, or even accessible to every different party whether for convenience, patient privacy or data security concerns.

[0038] Fig. 1 illustrates a drug delivery system 100 according to an embodiment of the disclosure. The drug delivery system 100 may be associated with a patient 102, who may use the drug delivery system 100 to inject a drug as part of a therapeutic regime. The drug delivery system 100 may communicate with a computing device (e.g. server) 104 via one or more intermediate computing devices and/or one or more networks. In turn, the server 104 may communicate with the drug delivery system 100, the patient 102, and one or more computing devices (with their associated parties) via one or more intermediate computing devices and/or one or more networks. As is also illustrated in Fig. 1, the server 104 may communicate directly with the drug delivery system 100, using a 3G antenna for example.

[0039] For example, the drug delivery system 100 is illustrated as communicating with a mobile computing device 110 (e.g., a smartphone) via a first communication link 112, and with a computing device (e.g., a personal computer or dedicated hub) 114 via a second communication link 116. Both links 112, 116 may operate according to a near field communication protocol, such as Bluetooth, for example. The mobile computing device 110 may communicate with a cellular network 118 via a communication link 120, while the other computing device 114 may communicate with a hard-wired network (e.g., local area network or wide area network) 122 via a communication link 124. These networks 118, 122 may also communicate with the server 104.

[0040] The networks 118, 122 may facilitate communication between the server 104 and one or more parties associated with the patient 102, such as his or her caregiver 130, support giver 132, and healthcare provider 134, via their mobile computing devices (e.g., smartphones). The server 104 may also be in communication with one or more computing devices (e.g., servers) associated with one or more additional parties associated with the patient 102. For example, a healthcare system server 140, a payment server 142, a pharmacy server 144, a distributor server 146, and a governmental agency

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server 148 are illustrated in communication with the server 104 via the network 122. It will also be recognized that the networks 118, 122 may be in communication with each other.

[0041] Referring to Fig. 2, possible methods of operating one or more computing devices in communication with a drug delivery system are now discussed in the context of a method 200. It will be recognized that the method 200 may be carried out by a single computing device, such as the server 104 illustrated in Fig. 1. Alternatively, the actions discussed with respect to Fig. 2 may be carried out by multiple computing devices, such as the mobile device 110 or computing device 114 in conjunction with the server 104.

[0042] The method 200 begins at block 202 with a determination as to whether a report has been received from the drug delivery system. If no report has been received, the method 200 waits at block 202. Once it is determined that a report has been received at block 202, the method 200 proceeds to block 204.

[0043] At block 204, the report received from the drug delivery system is used to update one or more records. In this regard, the one or more computing devices adapted or programmed to carry out the method 200 may perform the actions of retrieving the one or more records from storage in one or more memory storage devices, writing the information received from the drug delivery device into the one or more records, and then storing the one or more records in the one or more memory storage devices. The one or more memory storage devices may be part of the one or more computing devices, may be separate from the one or more computing devices, or may include one or more of the memory storage devices that are part of the one or more computing devices and one or more memory storage devices that are separate from the one or more computing devices (i.e., the record is stored at the computing device and in backup storage separate and possibly remote from the computing device).

[0044] As mentioned above, the report may be used to update one or more records. For example, there may be one record for the individual patient that is stored in a patient record database. The patient record may be used, for example, to track the compliance of the individual patient (e.g., patient 102) with his or her regime(s). There may also be a

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record for the drug delivery system used by the individual patient that is stored in a drug delivery system database. The drug delivery system record may be used to store information regarding the drug delivery system throughout the life of the drug delivery system. The drug delivery system record may be accessed by the drug delivery system manufacturer or the drug provider for quality control purposes (e.g., to monitor individual instances of the drug delivery system for faults or failures attributable for to the drug delivery system, or to track the environmental condition histories of one or more drug delivery systems for patterns that may assist in determining improvements in the design, packaging, shipment or handling of the drug delivery systems). There may also be record for drug used in the drug delivery system that is stored in a drug database. This record may be used in a similar fashion to the drug delivery system record for quality control purposes.

[0045] In addition to the updating the records at block 204, the computing device adapted or programmed to carry out the method 200 may be adapted or programmed to carry out one or more actions based on the information in the report received from the drug delivery system. For example, the computing device may be adapted or programmed to carry out an action at block 206. This action may require not only the information received in the report and/or stored previously in the record updated at block 204, but may require additional information such as from other patient records, drug system delivery records and/or drug records. If this is the case, the determination may be made at block 208 that these other records need to be accessed, and the information retrieved at block 210 (e.g., by retrieving these other records from the patient, drug delivery system and drug databases and reading the information from these records once retrieved). The action may then be carried out at block 222.

[0046] As one example, the one or more computing devices adapted or programmed to carry out the method 200 may be adapted or programmed to use the information received in the report to prepare a compliance history for the patient, which compliance history tracks uses of instances of the drug delivery system by the individual patient relative to his or her treatment regime to determine how successful the patient has been in following the treatment regime and which compliance history may be stored in the patient record. In addition, the one or more computing devices may determine if a pharmacy should be

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contacted to order delivery of additional drug delivery devices for the individual patient, and may generate a communication to be sent to the pharmacy to order the delivery of additional drug delivery systems. Further, the one or more computing devices may determine if a reminder should be sent to the patient, via the mobile device 110 for example, to improve or support compliance with the individual patient's treatment regime, in which case the one or more computing devices may generate a communication to be sent to the patient or user of the device. Further, the one or more computing devices may determine that the operation of the drug delivery device should be modified because of a conditional state received from the drug delivery device, for example. For example, the one or more computing devices may determine that the drug delivery system should be locked to prevent its use because of the temperature history of the drug in the drug delivery system, for example. In this case, the one or more computing devices may generate a communication, in the form of a signal for example, to be sent to the drug delivery system to lock the drug delivery device that is part of the drug delivery system. Other possible actions are discussed in detail below, although this discussion is for illustrative purposes only and is not intended to be limiting.

[0047] Depending on the action taken at block 212, or even if it is determined at block 206 that no action need be taken, the method 200 may proceed to blocks 214, 216, 218 where determinations are made if the computing device should make contact with other parties (block 214), interact with the patient (or user, if not the same as the patient) (block 216) or control the drug delivery device that is part of the drug delivery system (block 218). For example, as discussed above, the action taken at block 212 may involve the generation of communications or signals to be sent to third parties, such as the pharmacy, to the patient, or to the drug delivery device. In such a case, the one or more computing devices may carry out the actions of block 220, 222, 224 as dictated by the determinations made at blocks 214, 216, 218. Alternatively, the one or more computing devices may carry out the actions of blocks 220, 222, 224 even if it is determined that no action need be taken at block 206. For example, the one or more computing devices may forward certain information to third parties 220 based solely on the receipt of the information in a report from the drug delivery device, such that there is no need to separately determine that an action need be taken in regard to the information received

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(i.e., the communication is automatically sent based on the fact that the information has been received, with the one or more computing devices acting as a repeater station for such information). The receipt of information from the drug delivery device may also prompt communications to be sent to the patient/user or control signals to be sent to the drug delivery system without a separate determination that such action need be taken, the communication or control signal being sent simply because certain information and/or reports were received from the drug delivery system.

[0048] Having made the determinations at blocks 214, 216, 218 and carried out the actions of blocks 220, 222, 224, the method 200 may return to block 202 to await the next report. It will be recognized that the one or more computing devices may perform the actions of the method 200 in parallel for each of the reports received from different instances of the drug delivery system, or may perform this steps in sequence for each report. If performed in parallel, the one or more computing devices may determine if action is to be taken in regard to one report, while the one or more computing devices may be interacting with another patient in regard to the information contained in the report received from that patient. Furthermore, the one or more computing devices carrying out the method 200 need not be adapted or programmed to carry out each of the actions described above according to every embodiment of the one or more computing devices. For example, one of the one or more computing devices may be adapted or programmed to update records for each patient and to determine if an interaction with that patient is required, while another of the one or more computing devices may be adapted or programmed to update records for each drug delivery device and to determine is a control signal should be sent to the drug delivery device, while another one of the one or more computing devices does not update any record, but is adapted or programmed to access, for example, a patient record and determine if the pharmacy needs to be contacted to order additional instances of the drug delivery system for the patient associated with the patient record accessed and to generate the communication if the order of additional instances of the system is required.

[0049] It will be appreciated that the method 200, above, touches only a fraction of the possible state and identity information that may be used to control and/or monitor the drug delivery device and that may be communicated between the drug delivery system

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and the one or more computing devices, as well as how that information is used by the drug delivery system and the one or more computing devices. Additional embodiments are possible according to the disclosure.

[0050] For example, a non-limiting matrix of state and identity information may include the following:

[0051] Condition State Information:

Temperature
Shock or vibration exposure
Light exposure
Color and/or turbidity (as relates to the drug)
Orientation
Geographic position
Temporal information

[0052] Operational State Information:

Device removed from package
Device removed from cold storage (e.g., refrigerator)
Device/drug temperature ready for administration
Delivery triggered
Device applied to patient
Device applied at correct location/orientation on patient
Cannula inserted into patient and/or inserted into correct tissue
Delivery in progress
Delivery complete
Error has occurred

[0053] Device Identity Information:

Drug name or identification, concentration, and/or amount
Security and/or anti-counterfeiting information
Patient prescription/therapeutic regime

[0054] Patient Identity Information:

Point of Care diagnostics on patient

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Self-analyzed measure of progress

Fingerprint, pin, or other secure identification information

[0055] This information may be used to control the drug delivery system or device, to be communicated to other computing devices, or otherwise to be used, and an exemplary listing of certain additional uses is included below. The listing and additional comments below is not intended to supersede, but to augment the discussion above, and is intended to be non-limiting.

[0056] As one example, the drug delivery system or the one or more computing devices may make a determination regarding the authenticity of the drug and its compliance with manufacturing standards. Such a determination may be made by the drug delivery device at block 208 of method 200, for example. The determination may be made based on the temperature, shock or vibration exposure, and/or light exposure of the drug delivery device/drug (or a history of one or more of these conditions) and color and/or turbidity of the drug (as determined by an optical inspection). This determination may result in control of the drug delivery device to either lock or unlock the device, according to the determination made. See blocks 206-412 and 218, 224 of the method 200.

[0057] As another example, the drug delivery system or the one or more computing devices may make a determination whether the drug is appropriate for the patient. See block 206-212 of method 200. The determination may be made based on one or more of the items of device of patient identify information listed above, and may also result in control of the drug delivery device to either lock or unlock the device, according to the determination made. See blocks 206-212 and 218, 224 of method 200.

[0058] As a further example, the drug delivery system or the one or more computing devices may make a determination whether the dose has been correctly administered. This determination may be carried out after determining that the drug is appropriate for the patient and/or that the drug is authentic (e.g., not counterfeit) and is in compliance with manufacturing standards. See the preceding paragraphs. The determination whether the dose has been correctly administered may depend on one or more of the types of operational state information listed above. This information may be used to update the

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patient record, determine the patient compliance or therapy progress, and may prompt communication with the pharmacy regarding a refill, or with the payer (e.g., insurance company) to authorize payment for the drug delivery device. See blocks 204-214 of method 200, and servers 142, 144 of Fig. 1.

[0059] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination regarding the operational state of the drug delivery device, and to generate instructional messages to guide the user through the actions required for the proper use of the drug delivery device. The determination may be based on any of the operational state information listed above, and the instructions generated may be dictated by the actions that need to be performed after the operational state that has just occurred. Implementation of interactive instructions that follow the changing states of the drug delivery device may help the user have confidence in administration of the drug.

[0060] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that other people nearby are taking the same medication. See blocks 206-212 of method 200. This determination may be made based on the drug identity information and the patient identity information, in combination with the drug delivery system geographic location information. This determination may prompt a communication with the patient (see blocks 216, 222 of method 200) regarding local support networks of persons with similar conditions and/or taking similar drugs or medication to permit the patient to receive support and encouragement from such networks. Alternatively, the determination may prompt a communication with the local support network(s) (see blocks 214, 220 of method 200) to provide support and encouragement to the patient. As s further alternative, the determination may prompt a personalized intervention communication to be sent to the patient (again, see blocks 216, 222 of method 200).

[0061] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination whether the patient is not in compliance with their therapy regime. See blocks 206-212 of method 200. The determination may be based in part on the drug identification information, such as the

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prescribed treatment regime, in part on condition state information, such as the passage of time, and in part on the operational state information, such as where the drug delivery device is removed from the packaging but where no additional operational state information is determined, reported or received during the passage of time from the removal from packaging operational state. Based on this information, the drug delivery system and/or the one or more computing devices may determine that an interaction with the patient should be generated, such as an alert may be displayed or sent to patient. See blocks 216, 222 of method 200. Furthermore, the drug delivery system and/or one or more computing devices may determine that a communication should be generated to be displayed or sent to a healthcare provider, caregiver, support giver and/or payer to encourage adherence to regime. See blocks 214, 220 of method 200.

[0062] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the patient needs more medication (a refill). See blocks 206-212 of method 200. The determination may be based in part on the drug identity information, such as the prescribed treatment regime, and in part on the operational state information, such as where the drug delivery has been completed. Based on this information, the one or more computing devices may generate a communication that is sent to the payer and/or pharmacy to request a prescription refill. See blocks 214, 220 of method 200.

[0063] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the injection was not performed correctly. See blocks 206-212 of method 200. The determination may be based in part on operational state information, in comparison with information that may be collected and stored regarding conventional norms in operation. Alternatively or additionally, a comparison between the determined, reported or received operational states may permit a determination to be made that the injection was not performed correctly. For example, the determination, reporting or receipt of operational state information indicating that the drug delivery is complete without operation state information indicating that device was triggered, that the device was applied to the patient, and/or that the cannula was inserted may indicate that the drug delivery device has failed to perform correctly, is faulty or was operated incorrectly.

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[0064] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that patient's condition is improving. The determination may be based in part on patient identity information, such as point-of-care diagnostics performed on the patient (e.g., blood glucose test or other testing) or self-analysis reporting, and in part on the determination, reporting or receipt of operational state information, such as where the drug delivery has been completed. The determination may rely upon an overall trend as opposed to individual determinations or reports, as it is believed that data or reporting trends are usually more indicative of improvement in a patient's condition than the patient's condition as determined at individual instances for serious diseases. As such, the information gathered regarding the patient and the operational state of the drug delivery system/device may be combined with combined with therapy compliance history. This determination may result in individualized interventions to be generated, which interventions (such as encouraging messages and other forms of positive reinforcement) may increase persistence in therapy.

[0065] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination of the time of day (or week, month, etc.) that the patient usually takes their medication. This determination may be based, in part, on the patient record in which time information is associated with operational state information, such as relates to the triggering of the drug delivery device or the completion of the drug delivery. This determination may also rely on device identity information, such as the prescribed treatment regime. Based on this determination, the one or more computing devices may generate a reminder communication that is sent, for example, to the mobile device 110 to alert the patient that the time is approaching for them to administer their next dose. As the usefulness of reminders is enhanced when there is reasonable access to the drug delivery device and an opportunity for its use, it is beneficial to reinforce a patients decision to take their medication at a particular time during the day, week, month, etc. Based on this determination, the one or more computing devices may also generate a personalized intervention, such as a message of encouragement to be used as a positive reinforcement.

[0066] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination where the patient usually takes

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their medication. This determination may be based, in part, on the patient record in which geographic position information is associated with operational state information, such as relates to the triggering of the drug delivery device or the completion of the drug delivery. This determination may also rely on device identity information, such as the prescribed treatment regime. Based on this determination, the one or more computing devices may generate a reminder communication that is sent, for example, to the mobile device 110 to alert the patient that the time is approaching for them to administer their next dose when they are at or near the geographic location where the patient usually uses the drug delivery system. As the usefulness of reminders is enhanced when there is reasonable access to the drug delivery device and an opportunity for its use, it is beneficial to reinforce a patient's decision to take their medication when they are in the usual location where they take their medication. Based on this determination, the one or more computing devices may also generate a personalized intervention, such as a message of encouragement to be used as a positive reinforcement.

[0067] Of course, the determinations regarding the usual time and location of the use of the drug delivery device may be combined, and the one or more computing devices may generate a message only when the patient or user is at or near their usual location of use at or near the time they usually use the drug delivery device.

[0068] While the foregoing has focused principally on the determinations made by the drug delivery system and/or one or more computing devices concerning the patient or the patient's use of the drug delivery device, determinations may be made with reference to the drug delivery device or the drug before the drug delivery device is made available to the patient or user.

[0069] For example, the drug delivery system or the one or more computing devices may use the information to make a determination whether delivery of a certain number of doses of a particular drug has arrived (e.g., instances of a drug delivery device containing the particular drug), for example, at a particular distributor or pharmacy location. This determination may be made based in part on the geographic location information and in part on the drug identify information. Based on this information, the one or more computing devices may generate a communication that is sent to the pharmacy or

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distributor (via the pharmacy or distributor server, for example) to inform them of the delivery of the drug delivery device. The pharmacy or distributor may use such a smart drug delivery device to simplify their logistics and inventory systems, for example.

[0070] Along similar lines, the drug delivery system or the one or more computing devices may use the information to make a determination that one or more of the drug delivery devices have been damaged en route to a particular distributor or pharmacy location. The determination may be made based in part on the geographic location information and in part on the drug identify information. The determination may also be based in part on condition state information, such as the temperature, shock/vibration exposure, light exposure or color and/or turbidity of the drug, whether determined at a particular time or over a period of time (i.e., a history as established in the drug delivery device record or the drug record). The determination may also or instead be based in part on the age of the product relative to its manufacture date or expiration date. The determination may also or instead be based in part on operational state information, such as the removal of a sterility barrier from the second end of the cannula of the drug delivery device. Based on this information, the one or more computing devices may generate a communication that is sent to the pharmacy or distributor (via the pharmacy or distributor server, for example) to inform them that the drug delivery device has been damaged or expired. The pharmacy or distributor may use such a smart drug delivery device to expedite the distributor's or the pharmacy's replacement of the damaged or expired product and prevent delays in patient therapy, for example.

[0071] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the product is as stated and has not been counterfeited. Such a determination may be based on the drug identity information, such as the name, concentration and amount of the product and the security and anti-counterfeiting measures associated with the drug. The determination made by the one or more computing devices may cause a communication to be generated, which communication may be transmitted to a governmental agency (e.g., customs/immigration officials) via the governmental agency server, to distributors and/or pharmacies via their respective servers, and/or patients and caregivers via their personal mobile devices.

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[0072] As still further alternatives, certain determinations made by drug delivery systems and/or one or more computing devices operating according to embodiments of the disclosure may be used to control the drug delivery device remotely (i.e., without the controlling device being present in the same geographic location (e.g., room, building, or city) as the drug delivery device).

[0073] For example, the drug delivery system or the one or more computing devices may use the information to make a determination that the device needs to be controlled to prevent accidental operation. The determination may be based in part on the drug identity information in combination with, for example, certain patient identity information, such as biometric information in the form of a fingerprint. If it is determined that a party that is not authorized to use the drug delivery device is attempting to use the drug delivery device, then the one or more computing devices may generate a signal to be sent to the drug delivery system to lock the drug delivery device or to keep it locked until the drug delivery system is accessed by the patient or user for which it is intended.

[0074] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the patient associated with the drug delivery device is in a particular group or subgroup of patients or users that require or prefer a particular mode of operation for the drug delivery device. This determination may be made in part using information regarding the identity of the patient and the drug. Based on this determination, the drug delivery system and/or the one or more computing devices may generate a signal that customizes the operation of the drug delivery device. For example, the drug delivery device may be customized as to the sounds and/or lights used to alert the patient to various condition or operational states according to the specific market segment or patient population associated with the patient. As one example, different sounds may be used with pediatric patients than adult patients, louder sounds may be used with patients with hearing loss, and different lights or light sequences may be used with color-blind patients. Such control of the drug delivery device through the drug delivery system and/or one or more computing devices may reduce costs for drug delivery by permitting a single drug delivery device to be used that adapts to patient via software, rather than to use a plurality of different drug delivery

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device types, each of which has different hardware from the other types of drug delivery devices.

[0075] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the drug delivery device has not performed properly, and to generate a communication in that regard to the manufacture of the drug delivery device. The manufacturer may then determine modifications and/or improvements to enable proper administration of drug and can implement checks for sensed information and relay errors if it is not followed or is not successful.

[0076] As has been mentioned above, the drug delivery system and/or one or more computing devices in communication with the drug delivery system need not be adapted or programmed to carry out every action listed in Fig. 2.

[0077] Figs. 3-14 illustrate additional embodiments of systems and methods in which some or all of the processing of sensor data or other information collected by a drug delivery device is performed by one or more computing devices external to the drug delivery device. Furthermore, the systems and methods of Figs. 3-14 permit a user to interact with the components of the system to address one or more of the challenges experienced by patients during the initial use of the drug delivery device and/or during the prolonged use of the drug delivery device (e.g., in maintaining adherence with a treatment regimen). To achieve interactivity, the system may sense or determine different types of information regarding the drug delivery device, including operational state information (e.g., whether medicament delivery is complete), condition information (e.g. temperature), and identity information (e.g., the name of the medicament). The drug delivery device may communicate this information to a local and/or remote computing device so that the local and/or remote computing device may provide this information and/or instructions to the user. The communication of the information from the drug delivery device may be based on the type of information to be communicated, for example. The drug delivery device may then determine if the user has taken the correct action in response to the information and/or instructions displayed on the local and/or

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remote computing device, which information may then be communicated to the local and/or remote computing device for further processing.

[0078] In general, to achieve the foregoing functionalities, the systems and methods illustrated in Figs. 3-14 may have an associated controller (which controller may include a processor and memory) that is in communication with a first communication module (which may be a transmitter, a transmitter and receiver pair, or a transceiver), the first communication module may be connected via a communication link to a second communication module (which may be a receiver, a transmitter and receiver pair, or a transceiver) associated with the local and/or remote computing device (which computing device may also include a controller with a processor and memory). The local computing device may be in communication with the remote computing device, such that the drug delivery device (or more particularly, the controller associated with the drug delivery device) may communicate with the local computing device over a first communication link, and then the local computing device may communicate with the remote computing device over a second communication link.

[0079] While the drug delivery device described below is configured as an autoinjector, in other embodiments, the drug delivery device may be configured as a on-body injector.

[0080] Fig. 3 illustrates an embodiment of a system 300 including a drug delivery device 302, a local computing device 304 and a remote computing device 306. While the system 300 includes both a local computing device 304 and a remote computing device 306, not all embodiments according to this disclosure include both a local computing device 304 and a remote computing device 306.

[0081] The drug delivery device 302 may be in the form of an autoinjector, and thus is adapted for hand-held use and application against the skin of the patient. The drug delivery device 302 includes a housing 310 in which are disposed assemblies or structures that introduce a delivery cannula into the patient, and that eject a drug or medicament from a reservoir 312 through the delivery cannula into the patient. According to certain embodiments, the same assemblies or structures that introduce the delivery cannula into the patient may also eject the drug or medicament from the

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reservoir through the delivery cannula into the patient. The drug delivery device 302 may also include assemblies or structures that connect the delivery cannula to the reservoir, that withdraw the delivery cannula into the housing 310 through an opening in the housing 310 (not illustrated), or that deploy other structures that will prevent contact with the delivery cannula once the delivery cannula has been removed from the patient. Even additional assemblies and structures are possible. The specific embodiment of the drug delivery device 302 discussed below is thus by way of example and not by way of limitation.

[0082] Accordingly, the drug delivery device 302 includes a reservoir 312 and a delivery cannula 314 having a first end 316 (e.g., a proximal end) that may be connected or connectable in fluid communication with the reservoir 312 and a second end 318 (e.g., a distal end) that may be inserted into a patient. The delivery cannula 314 may be, for example, a rigid needle having a beveled edge that may be sized such that the second end 318 of the needle 314 is received under the skin so as to deliver a subcutaneous injection of the medicament within the reservoir 312. The first end 316 of the needle 314 may be disposed through a wall 320 of the reservoir 312, and thus be connected in fluid communication with the reservoir 312. Alternatively, the first end 316 of the needle 314 may be disposed only partially through the wall 320 (which wall 320 may be a resalable septum or stopper, for example) such that the first end of the needle 314 may not be connected in fluid communication until the second end 318 of the needle 314 is inserted into the patient. In such a circumstance, the first end 316 of the needle 314 may thus be described as connectable in fluid communication with the reservoir 312, although it will be recognized that there are other mechanisms by which the first end 316 of the needle 314 may be connectable, but not connected, in fluid communication with the reservoir 312.

[0083] The drug delivery device 302 includes a shield 322 (e.g., a needle shield) that may be deployed at least after the injection has been completed to limit access to the second end 318 of the needle 314. According to certain embodiments, the shield 322 may have a biasing element 324 (such as a spring) that extends the shield 322 from the housing 310 such that a distal end 326 of the shield 322 extends beyond the second end 318 of the needle 314 except when the shield 322 is disposed against the skin and the

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insertion of the needle 314 is actuated. In fact, the insertion of the needle 314 may be actuated according to certain embodiments of the drug delivery device 302 by disposing the distal end 326 of the shield 322 on or against the skin of the patient.

[0084] The drug delivery device 302 may also include a lock 328 (e.g., a ratchet) that is coupled to the shield 322 and configured to limit or prevent movement of the shield 322 relative to the housing 310 of the drug delivery device 302 such that the distal end 326 of the shield 322 extends from the housing 310 a sufficient distance to limit or prevent contact with the second end 318 of the needle 314, for example, after the needle 314 has been removed or separated from the skin of the patient. In some embodiments, the lock 328 may be coupled to a controller (e.g., controller 350 described in more detail below) which can selectively activate or deactivate the lock 328 based on different types of information regarding the drug delivery device 302, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. When the lock 328 is activated by the controller 350, the lock 328 may be configured to limit or prevent movement of the needle shield 322 relative to the housing 310. When the lock 328 is deactivated by the controller 350, the lock 328 may be configured to allow movement of the needle shield 322 relative to the housing 310.

[0085] The drug delivery device 302 also includes at least one drive 330 that may be used to insert the second end 318 of the needle 314 into the skin of the patient, and to eject the drug or medicament from the reservoir 312 through the delivery cannula 314 into the patient. The drive 330 may include one or more springs, according to certain embodiments. According to other embodiments, the drive 330 may include a source of pressurized gas or a source of a material that undergoes a phase change, such that the escaping gas or phase changing material provides a motive force that may be applied to the reservoir 312 to eject the drug therefrom. According to still other embodiments, the drive 330 may include an electromechanical system, such as may include a motor for example, although such an electromechanical system may be more appropriate for the on-body autoinjector or infuser described above. Other embodiments of the drive 330 are also possible.

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[0086] In one embodiment, the drive 330 may be coupled to a plunger 331 and/or a stopper 332 (e.g., a wall) disposed in the reservoir 312 to move that stopper 332 in a distal direction toward the delivery cannula 314. In accordance with such an embodiment, the stopper 332 may be a stopper that is fixed to a distal end of the plunger 331 and received within a bore 334. The plunger 331, in conjunction with the drive 330, may move the stopper 332 along a longitudinal axis of the drug delivery device 302 through the bore 334 from a proximal end of the bore 334 to a distal end of the bore 334, and thereby eject the medicament from the reservoir 312.

[0087] In some embodiments, the drive 330 may also cooperate with the stopper 332 and/or the bore 334 to move the reservoir 312 relative to the housing 310 so as to move the second end 318 of the needle 314 relative to the housing 310 and into the patient. According to those embodiments wherein the drive 330 cooperates with the stopper 332, this may occur before the first end 316 of the needle 314 is in fluid communication with the reservoir 312. According to those embodiments wherein the drive cooperates with the bore 334, the drive may include one component (e.g., first spring) that cooperates with the bore 334 to move the reservoir 312 and needle 314 relative to the housing 310, and a second component (e.g., second spring) that cooperates with the stopper 332 to move the stopper 332 relative to the bore 334.

[0088] The drug delivery device 302 may also include a lock 335 that is coupled to the plunger 331 and configured to limit or prevent movement of the plunger 331 relative to the housing 310 of the drug delivery device 302 so that the stopper 332 cannot be advanced to discharge the medicament from the reservoir 312 to the patient. In some embodiments, the lock 335 may be coupled to a controller (e.g., controller 350 described in more detail below) which can selectively activate or deactivate the lock 335 based on different types of information regarding the drug delivery device 302, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. When the lock 335 is activated by the controller 350, the lock 335 may be configured to limit or prevent movement of the plunger 331 relative to the housing 310. When the lock 335 is deactivated by the controller 350, the lock 328 may be configured to allow movement of the plunger 331 relative to the housing 310.

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[0089] The drive 330 may be associated with an actuator 340. The actuator 340 may activate the drive 330 to cause the drive 330 to insert the needle 314 and eject the drug from the reservoir 312 through the needle 314 into the patient. The actuator 340 may, according to certain embodiments, be the needle shield 322, as explained above. According to other embodiments, such as the one illustrated in Fig. 3, the actuator 340 may be a button that may be manually depressed by the user or patient once the drug delivery device 302 is placed disposed on or against the patient's skin. A lock 341 may be coupled to the actuator 340 and configured to limit or prevent movement of the actuator 340 so that the actuator 340 cannot be used to activate the drive 330. In some embodiments, the lock 341 may be coupled to a controller (e.g., controller 350 described in more detail below) which can selectively activate or deactivate the lock 341 based on different types of information regarding the drug delivery device 302, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. When the lock 341 is activated by the controller 350, the lock 341 may be configured to limit or prevent movement of the actuator 340 relative to the housing 310. When the lock 341 is deactivated by the controller 350, the lock 341 may be configured to allow movement of the actuator 340 relative to the housing 310.

[0090] The drug delivery device 302 may also include a removable sterile barrier 344 that is disposed about one or more of a distal end of the housing 310, the needle shield 322, and the second end 318 of the delivery cannula 314. The removable sterile barrier 344 may be removably attached to the distal end of the housing 310 as shown in Fig. 3. In some embodiments, the removable sterile barrier 344 may form an interference or snap fit with the distal end of the housing 310. A frictional force associated with the interference or snap fit may be overcome by manually pulling the removable sterile barrier 344 in a direction away from a housing 310. The removable sterile barrier 344, when attached to the drug delivery device 302, may reduce the risk of contamination of the delivery cannula 314 and other elements disposed within the drug delivery device 302.

[0091] Additionally, the drug delivery device 302 may include a heating element 346 coupled to the exterior of the reservoir 312 and configured to warm the medicament

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inside the reservoir 312 through, for example, conductive heating. The heating element 346 may be coupled to the controller 350 so that the controller 350 can selectively activate or deactivate the heating element 346 based on different types of information regarding the drug delivery device 302, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. In some embodiments, the heating element 346 may include an electrically conductive coil that is wrapped around the exterior of the reservoir 312. In other embodiments, the heating element may include an electrically conductive coil wrapped around the cannula 314. Alternatively, or additionally, a cooling element (not illustrated) may be coupled to the reservoir 312 and controllable by the controller 350 in a manner similar to the heating element 346.

[0092] The drug delivery device 302 may also include an output unit 347 coupled to the housing 310 and configured to notify the patient or user of information related to the drug delivery device 302. The output unit 347 may be coupled to the controller 350 so that the controller 350 can selectively activate or deactivate the output unit 347 based on different types of information regarding the drug delivery device 302, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. The output unit 347 may be any device suitable for conveying information to the patient or user including a display (e.g., a liquid crystal display), a touchscreen, a light (e.g., a light emitting diode), a vibrator (e.g., an electro-mechanical vibrating element), a speaker, and/or an alarm, among other devices.

[0093] The drug delivery device 302 may also include an input unit 348 coupled to the housing 310 and configured to allow a user or patient to input information (e.g., password information) to be used by the controller 350. In some embodiments, the input unit 348, the output unit 347, and even the fingerprint sensor 365, may be a single device such as a touchscreen. In other embodiments, the input unit 348 may be a separate device from the output unit 347 such as a keyboard or button.

[0094] As illustrated in Fig. 3, the reservoir 312, the biasing element 324, the locks 328, 335, 341, the plunger 331, the stopper 332, and the drive 330, and the heating

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element 346 are disposed within the housing 310, along with at least part of the delivery cannula 314. Also disposed within the housing 310 is a controller 350, a communication module 352 (e.g., a wireless transmitter), and at least one sensor or switch. According to the embodiment illustrated in Fig. 3, four sensors are included: a temperature sensor 360, a skin sensor 362, at least one orientation sensor 364, and a fingerprint sensor 365. The sensors 360, 362, 364, and 365 may each generate sensor data (e.g., raw or unprocessed data) related to a respective measured property or aspect of the drug delivery device 302. The sensor data may be representative of at least one of a condition or operational state of the drug delivery device 302. Additionally, the drug delivery device 302 includes a switch 366. The controller 350 is coupled to the communication module 352, the locks 328, 335, 341, the sensors 360, 362, 364, 365, the heating element 346, the fingerprint sensor 365, the output unit 347, the input unit 348, and the switch 366. The controller 350 may be configured to process the sensor data generated by the sensors 360, 362, 364, and 365 to determine a condition and/or operational state of the drug delivery device 302. The controller 350, the communication module 352, one or more of the sensors 360, 362, 364, 365 and the switch 366 may be packaged together as a single module, or each component may be fabricated separately and coupled once the components are disposed within the housing 310. According to certain embodiments, each electrical component may be integrated into the structure of the device 302 associated with that electrical component (e.g., the sensors 362 and 364 may be integrated into the shield 322). In some embodiments, the controller 350, the communication module 352, one or more of the sensors 360, 362, 364, 365, and/or the switch 366 may be packaged together inside the removable sterile barrier 344

[0095] The controller 350 may include at least one processor 370 (e.g., a microprocessor) and a memory 372 (e.g., a random access memory (RAM), a non-volatile memory such as a hard disk, a flash memory, a removable memory, a non-removable memory, etc.). The controller 350 may also include or be coupled to a power supply, e.g. a battery. The processor 370 may be programmed to carry out the actions that the controller 350 is adapted to perform and the memory 372 may include one or more tangible non-transitory readable memories having executable, computer-readable, non-transitory instructions stored thereon, which instructions when executed by the at

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least one processor 370 may cause the at least one processor 370 to carry out the actions that the controller 350 is adapted to perform. Alternatively, the controller 350 may include other circuitry that carries out the actions that the controller is adapted to perform.

[0096] The memory 372 may store the identity information discussed above. The identity information may be stored in the memory 372 prior to the start of execution of any of the methods discussed above. The identity information may include, by way of example and not by way of limitation, a unique identifier, the name of the drug, the dosage, an expiration date, and information regarding the identity of the patient for whom the drug was prescribed. With this information, the controller 350 or a local computing device (e.g., a smartphone) may make a determination regarding the patient that is about to receive the drug, and provide appropriate informational and/or instructional prompts. As an alternative to memory 372, the identity information may be contained in a QR code label or RFID tag associated with the drug delivery device 302.

[0097] The communication module 352 may be any of a number of different communication modules used to communicate with a local computing device (e.g., a smartphone) and/or a remote computing device (e.g., a server operated by the device manufacturer). According to one embodiment, the communication module 352 may be a Bluetooth and/or Bluetooth Low Energy module that is on-board with the controller 350. The communication module 352 is used to transmit information from the drug delivery device 302 to the local computing device 304. Alternatively, other wireless protocols may be used by the communication module 352, such as radio-frequency identification (RFID), Zigbee, Wi-Fi, near field communication (NFC), and others. In fact, the communication may be sent along a hardwired connection, rather than using the electromagnetic (EM) spectrum. As defined herein, a communication transmitted and/or received between the module 352, the local computing device, and/or the remote computing device may be in the form of a hardwired signal or EM signal or a pattern of such signals, for example.

[0098] The temperature sensor 360 may be disposed proximate to the reservoir 312 so that the temperature of the drug in the reservoir 312 may be determined. Alternatively,

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the temperature sensor 360 may simply be disposed in the housing 310, so that an approximate temperature of the drug in the reservoir 312 and of the drug delivery device 302 generally may be determined. According to an embodiment, the temperature sensor 360 may be an on-board temperature sensor 360 attached to the processor 370.

[0099] The skin sensor 362 may be attached to or associated with the shield 322 to determine when the drug delivery device 302 is disposed on or against the patient's skin. According to one embodiment, the skin sensor 362 is a pressure sensor. According to other embodiments, the skin sensor 362 may be a capacitance sensor, resistance sensor, or inductance sensor. The skin sensor 362 or the switch 366 (which is attached to or associated with the actuator 340) may be used to determine when the drug delivery device 302 is activated or actuated, depending on the design and operation of the drug delivery device 302 that is used to actuate the drive 330, in accordance with the discussion above. It may also be the case that a signal from the skin sensor 360 is used to determine that the drug delivery device 302 has been activated even when the shield 322 is not used as the actual actuator, the underlying assumption being that the movement of the shield 322 is necessarily related to the actuation of the device 302.

[0100] The orientation sensors 364, of which there may be at least two as illustrated, may be associated with the shield 322 (or that portion of the housing 310 adjacent the shield 322) and the controller 350 (which may be, as illustrated, disposed at the other end of the drug delivery device 302 or the housing 310 from the shield 322). The orientation sensors 364 may be magnetometers, for example. In particular, the orientation sensor 364 associated with the controller 350 may be an on-board magnetometer. The orientation sensors 364 may be used to determine the orientation of the drug delivery device 302 (in particular, the housing 310) relative to the injection site (or more particularly, relative to the placement of the drug delivery device 302 on or against the patient's skin).

[0101] It will be recognized that the arrangement of the components of the drug delivery device 302 within the housing 310 is but one embodiment of this disclosure. For example, Fig. 4 illustrates a second embodiment of the drug delivery device 302, wherein

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certain components of the drug delivery device 302 are disposed outside the drug delivery device 302.

[0102] According to this embodiment, the drug delivery device 302 may include the housing 310, the reservoir 312, the needle 314, the shield 322, the biasing element 324, the lock 328, the drive 330, and the button 340. Furthermore, the sensors 362, 364 and the switch 366 may be disposed within the housing 310. A separate module 400 is provided within a housing 402 in which the controller 350, communication module 352, and on-board temperature and orientation sensors 360, 364 are disposed. The fingerprint sensor 365, the output unit 347, and the input unit 348 may be disposed on the exterior of the module 130 so that a user or patient can interact with them. In some embodiments, the communication module 352 may be disposed within the housing 310 rather than within the module 400.

[0103] The module 400 may be adapted to be attached to an exterior surface 404 of the housing 310; for example the module 400 may have an annular or C-shape with a central aperture sized so that an end 406 of the drug delivery device 302 may be disposed within the aperture, and the module 400 held in place by the mating geometries. According to certain embodiments, the module 400 may be moveable relative to the drug delivery device 302, such that movement of the module 400 relative to the housing 310 may activate the autoinjector (e.g., by depressing the button 340), in which case the switch 366 may actually be disposed within the housing 402 of the module 400. According to other embodiments, the exterior surface 404 of the housing 310 and the module 400 may have cooperating connectors. As a further alternative, a fastener may be provided on the housing 310 or the module 400 that cooperates with a feature of the other of the housing 310 or the module 400 to attach or secure the module 400 to the housing 310, whether reversibly or irreversibly. One example of such a fastener may be a set screw on the module 400 that cooperates with a recess on the surface 404 of the housing 310.

[0104] The exterior surface 404 of the housing 310 may also have one or more contacts 408 that mate with contacts 410 on an exterior surface 412 of the housing 402 of the module 400. The mating contacts 408, 410 couple the sensors 362, 364, the locks 328, 335, 341, the heating element 346, and the switch 366 inside the drug delivery

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device 302 with the controller 350 inside the module 400 (i.e., the sensors 362, 364, the locks 328, 335, 341, the heating element 346, and the switch 366 are coupleable with the controller 350, as may be the communication module 352 according to the certain embodiments described above wherein the module 352 is disposed in the housing 310 as well). The contacts 408, 410 may contact each other, or the contacts may mate without having to physically contact each other, in which case the contacts 408, 410 may be provided below the surfaces 404, 412 of the housings 310, 402.

[0105] The separation of the controller 350, communication module 352 and other components into a module 400 may permit the module 400 to be used with multiple instances of the drug delivery device 302. In this regard, the module 400 may be considered to be the reusable portion of the drug delivery device 302/module 400 combination (which may be referred to as the drug delivery device 302 for purposes of this disclosure), while the drug delivery device 302 may be considered to be the disposable portion of the drug delivery device 302. By isolating the more expensive components into the reusable module 400 and the less expensive components (including certain sensors) into the disposable drug delivery device 302, the overall cost of the autoinjector may be optimized. This arrangement of the components in the module 400 and the drug delivery device 302 may also facilitate the manufacture and sterilization of the drug delivery device 302 and module 400.

[0106] Returning to Fig. 3, the local computing device 304 may be in the form of at least one computing device including at least one processor 420 (e.g., microprocessor) and a memory 422 (e.g., a random access memory (RAM), a non-volatile memory such as a hard disk, a flash memory, a removable memory, a non-removable memory, etc.). The at least one processor 420 and the memory 422 may be incorporated into a controller 423 of the local computing device 304 and/or may be configured separately. Likewise, the remote computing device 306 may be in the form of at least one computing device including at least one processor 424 (e.g., microprocessor) and memory 426 (e.g., a random access memory (RAM), a non-volatile memory such as a hard disk, a flash memory, a removable memory, a non-removable memory, etc.). The at least one processor 424 and the memory 426 may be incorporated into a controller 427 of the local computing device 304 and/or may be configured separately. The processors 422, 424 may

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be programmed to carry out actions described below relative to the methods of Figs. 6, 13, and 14, and the memories 422, 426 may include one or more tangible non-transitory computer-readable memories having computer-executable instructions stored thereon (for example, in the form of a custom Mobile Application, or an App for short, or other software module), which instructions when executed by the processors 422, 424 may cause the processors 422, 424 to carry out the actions described below relative to the methods of Figs. 6, 13, and 14. Alternatively, the local computing device 304 and the remote computing device 306 may include other circuitry that carries out the actions described below relative to the method of Figs. 6, 13, and 14.

[0107] In fact, according to certain embodiments of this disclosure, the local computing device 304 may carry out the actions of Figs. 6, 13, and 14independent of the remote computing device 306. According to other embodiments, the local computing device 304 may carry out certain of the actions of Figs. 6, 13, and 14, while the remote computing device 306 carries out other of the actions of Figs. 6, 13, and 14. For example, according to certain embodiments the processor(s) 420 may control components of the local computing device 304 permitting communication with the controller 350 and/or the user, but may not make the determinations as to the content of those communications, the determinations relative to the content of the communications being made at the remote computing device 306.

[0108] According to the illustrated embodiment, the local computing device 304 is a mobile computing device (e.g., a smartphone, smartwatch, tablet computer, etc.) while the remote computing device 306 is a server. In some embodiments, the local computing device 304 can include generally any computing device capable of processing data and being synched to and in communication with the drug delivery device 302 such as, for example, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, etc. According to other embodiments, the local computing device 304 may be a dedicated device such as a hub or gateway that can establish a communication link with the communication module 352 and potentially the remote computing device 306, where communication with the remote computing device 306 is necessary or desirable.

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[0109] To carry out the actions of the methods described in Figs. 6, 13, and 14, the local computing device 304 may further include a communication module 430 for wireless communication with the communication module 352 of the drug delivery device 302, for example by using Bluetooth/Bluetooth Low Energy protocol. Alternatively, other wireless protocols may be used by the communication module 352, such as radio-frequency identification (RFID), Zigbee, Wi-Fi, near field communication (NFC), cellular, and others. The local computing device 304 may also include a display 432 to be used to communicate instructions to the user. The local computing device 304 may include other output devices other than the display 432 to communicate with the user, such as a speaker 434 for example. The speaker 434 may be controlled by the processor(s) 420 to provide an audible form of the instructions displayed in written form on the display 432.

[0110] The local computing device 304 may also include one or more communication modules, which may be the same as or different from the communication module 430, that may be used to communicate with one or more networks 440, 442. For example, the network 440 may be a wireless radio frequency network, such as a cellular mobile device network, while the network 442 may be a network of computing devices, such as the Internet. As is illustrated in Fig. 6, the networks 440, 442 may be in communication with each other, such that the local computing device 304 may communicate with the remote computing device 306 over the network 440, the network 442 or a combination of the networks 440, 442. The remote computing device 424 may include a communication module 436 to receive communications from the networks 440, 442.

[0111] While the terms "local" and "remote" have been used to describe the local computing device 304 and the remote computing device 306, these terms have not been selected to require a particular spatial or geographical distance between the devices 304, 306. Instead, the terms have been used to suggest a relative proximity to the user, and the fact that the remote computing device 306 is not required to be at the same physical location as the user and the drug delivery device 302. According to certain embodiments, it is possible, even likely, that the remote computing device 306 may be located in a different geographic location than the user and the drug delivery device 302, for example a different city, state or country.

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[0112] The local computing device 304 and the remote computing device 306 are each separate from, and spaced apart from, the drug delivery device 302 and therefore may each be considered to be an "external computing device" relative to the drug delivery device 302.

[0113] Before describing the interaction and communication of information between the drug delivery device 302, the local computing device 304, and the remote computing device 306, a method 500 of operating the drug delivery device 302 is described with reference to Fig. 5. The method 500 begins at block 502 with the removal of the drug delivery device 302 from cold storage, such as a refrigerator. Because the medicament in the reservoir 312 is cold, it is desirable to delay use at block 504 for some period of time after the drug delivery device 302 is removed from cold storage to permit the device 302 and the drug to warm. The warming of the device 302 and the drug may improve the performance and reliability of the operation of the device 302 and/or the delivery of the drug. Alternatively, the warming of the device 302 and the drug may be to minimize discomfort associated with delivery of the drug when cold. In any event, after a delay at block 504, the method 500 continues to block 506. While this description applies to removal of an autoinjector from cold storage, it should be apparent that the method can apply equally well to whether the device is too warm when removed from storage.

[0114] At block 506, the packaging is removed from about the drug delivery device 302. For example, a removable, disposable cover may be disposed over the second end 318 of the needle 314 during storage to preserve sterility and prevent accidental contact. This cover may be removed by the user prior to placement and actuation of the device, as well as any other packaging that limits or prevents the use of the device (e.g., an external safety lock). Once the packaging is removed at block 506, the drug delivery device 302 is applied to the patient's skin at block 508. The drug delivery device 302 is then positioned in a particular orientation to the body of the patient at block 510.

[0115] With the drug delivery device 302 on or against the skin and in the correct position, the user is ready to actuate the drug delivery device 302 at block 512. For example, the user may depress the button 340 or press the drug delivery device 302 in the direction of the skin, causing relative motion between the housing 310 of the drug

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delivery device 302 and the shield 322, which relative motion actuates the device. Having actuated the drug delivery device 302, the user waits for the completion of the delivery at block 514.

[0116] The completion of the delivery of the drug by the drug delivery device 302 may be signaled to the user in a number of different ways. For example, the drug delivery device 302 may have a window in the side of the housing 310 that permits visualization of the reservoir 312, and in particular the movement of the stopper 332 along the bore 334 of the reservoir 312. As an alternative, the drug delivery device 302 may include a noise-making device, such as a ratchet or clicker, that actuates when the drug delivery is complete. Once the delivery is complete, the drug delivery device 302 may be removed and disposed of at block 516.

[0117] As mentioned above, a user (which may be the patient or alternatively the health care provider) may have difficulty with any or all of the steps of the method 500. For example, the user may be uncertain whether to delay use (block 504) or how long to delay use. Alternatively, the user may not apply the device 302 against the skin (block 508) or the drug delivery device 302 may be improperly positioned (block 510). The user may be uncertain how to determine that delivery is complete (block 514) and thus may administer less than the entire dose. The user may confuse the sequence of steps outlined in the method 500, or may simply forget to or decide not to perform any of the steps of the method 500.

[0118] Referring to Fig. 6, a method 600 is provided for using the interactive drug delivery system 300 to limit the likelihood that the user will fail to carry out the steps of the method 500. While the method 600 describes the operation of the entire system 300, further methods are provided in Figs. 12 and 13 that may be carried out by the controller 350 of the drug delivery device 302, the local computing device 304, and/or the remote computing device 306. Method 600 is also discussed with reference to the simulated screenshots of Figs. 7-11.

[0119] The method 600 begins at block 602, wherein the system 300 determines that the drug delivery device 302 has been removed from cold storage. In particular, the temperature sensor 360 is used to determine that a temperature change has occurred

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relative to the drug delivery device 302, in particular an increase in temperature. This change in temperature is communicated from the drug delivery device 302 to the local computing device 304, which is operating software, such as a Mobile Application, that permits this information to be received from the drug delivery device 302 and used to generate a series of instructions and information prompts for the user which are displayed on the display 432 of the local computing device 304, as illustrated in Figs. 7-11. According to certain embodiments, the local computing device may control the display 432 to display instructions or informational prompts not only according to the communication received, but also according to information stored on the local computing device 304 or received by the local computing device 304 (i.e., other than the communication). According to the method 600, a first instructional prompt may be displayed by the local computing device 304 at block 604 that the user should wait before proceeding with the operation of the device (see Fig. 7).

[0120] The method 600 then continues at block 606, wherein the temperature sensor 360 is monitored to determine if the temperature of the drug delivery device 302 has increased above a desired threshold (i.e., T1). If the temperature has not increased above the threshold, the system 300 continues to monitor the temperature at block 606. Otherwise, the method 600 continues to block 608, wherein a further instructional prompt may be displayed by the local computing device 304 that the user may proceed with the operation of the drug delivery device 302 (see Fig. 8).

[0121] The method 600 may then continue with additional instructional prompts displayed by the local computing device 304 at blocks 610, 612 for the user to remove any packaging (e.g., a needle cover) and to apply the drug delivery device 302 to the patient's skin. The system 300 then monitors the skin sensor 362 to determine if the drug delivery device 302 has been applied to the skin at block 614. If the drug delivery device 302 has not been applied, then the method 600 remains at block 614; if the drug delivery device 302 has been applied, then the method 600 continues to block 616.

[0122] At block 616, a further instructional prompt may be displayed by the local computing device 304 that the user should position the drug delivery device 302 on the skin. For example, it may be desirable for the drug delivery device 302 to be positioned

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on the skin such that the needle 314 will enter the skin at a right angle or orthogonally to the skin. The system 300 may use the orientation sensors 364 to monitor the orientation of the device at block 618, and further instructional prompts may be displayed by the local computing device 304 for the user to alter the position of the device 302 relative to the skin at block 620. See Fig. 9. Once the system determines that the position of the drug delivery device 302 is acceptable, the method may proceed to block 622.

[0123] At block 622, an instructional prompt may be displayed by the local computing device 304 that the user should actuate the drug delivery device 302. The system 300 may then monitor the switch 366 to determine that the user actuates the button 340, before continuing to block 626. At block 626, an instructional prompt may be displayed by the local computing device 304 that the user should wait for completion of the drug delivery. See Fig. 10. Also at block 626, the local computing device 304 may display informational prompts letting the user know that a certain amount of the drug has been delivered. See also Fig. 10. This informational prompt may depend on determinations made based on additional sensors that, for example, monitor the travel of the stopper 332 in the bore 334 of the reservoir 312. Alternatively, the informational prompt may be based on an estimate of the completion state based on timed trials performed using other instances of the drug delivery device 302 with the drug being delivered or administered.

[0124] At the same time, the system 300 may continue to monitor the orientation sensors 364 at block 628 to determine that the drug delivery device 302 remains in position relative to the patient's skin. Instructional prompts to reposition the drug delivery device 302 may be displayed by the local computing device 304 per block 630 in addition to or in substitution for the information prompts displayed per block 626. The system 300 also determines if the drug delivery is compete at block 632, which determination may be made based on monitoring of sensors, e.g., associated with the stopper 332, or based on estimates based on timed trials, for example. In fact, the determinations made at blocks 628 and 632 may be combined, with the instructional prompt displayed per block 630 occurring only if the autoinjector should be repositioned and the delivery is not complete.

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[0125] Once the system 300 determines that the drug delivery is complete, the method 600 continues to block 634, where an informational prompt may be displayed by the local computing device 304 that the delivery is complete and that the device may be removed and disposed of (see Fig. 11), and block 636, where a report of the completion of the drug delivery by the user using the drug delivery device 302 is provided, for example, to the remote computing device 306.

[0126] As mentioned above, the method 600 describes the operation of the entire system 300. However, the operation of the entire system 300 may also be described in terms of the actions performed by the drug delivery device 302 and the local computing device 304. The individual operations of each device 302, 304, and the cooperation between the devices 302, 304, is now described with reference to Figs. 12 and 13. It should be noted that, in an alternative embodiment, some or all of the actions performed by the local computing device 304 with regard to Fig. 13 may be performed by the remote computing device 306.

[0127] With reference first to Fig. 12, a method 700 is provided relative to the operation of the controller 350. The method 700 begins at block 702, with the controller 350 monitoring the temperature sensor 360 to determine if the drug delivery device 302 has been removed from cold storage. When the controller 350 determines that the temperature has increased, corresponding to a probable removal from cold storage, the controller 350 controls the communication module 352 to transmit a communication (in the form of a signal) at block 704 to the local computing device 304 that the autoinjector 304 has been removed from cold storage.

[0128] With reference now to Fig. 13, a method 800 carried out by the local computing device 304 starts at block 802 with the receipt by the local computing device 304 (or more particularly, the communication module 430) of the communication transmitted by the drug delivery device 302 (or more particularly, the communication module 352) that the drug delivery device 302 has been removed from cold storage. The method 800 continues to block 804, where the processor 420 of the controller 423 controls the display 432 to display an instructional prompt to the user instructing the user to wait before using the drug delivery device 302. Prior to displaying the instructional prompt at block 804,

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the processor 420 of the controller 423 may process (e.g., compare) the communication received from the drug delivery device 302 at block 802 with or according to information stored in the memory 422 of the local computing device 304 to determine if the sensed temperature is acceptable for a patient to use the drug delivery device 302. The instructional prompt may be displayed at block 804 in response to a determination that the sensed temperature is not acceptable for a patient to use the drug delivery device 302. Subsequently, at block 806, the local computing device 304 (or more particularly, the processor 420) may monitor the module 430 for the next communication from the drug delivery device 302.

[0129] Returning to Fig. 12, method 700 continues with the controller 350 monitoring the temperature sensor 360 at block 706 to determine when the temperature sensed by the temperature sensor 360 exceeds a threshold temperature. When the controller 350 determines that the sensed temperature exceeds a threshold temperature, the controller 350 controls the communication module 352 to transmit a communication to the local computing device 304 that the temperature has been achieved at block 708. In some embodiments, the controller 350 may control the communication module 352 to transmit a communication representative of the temperature of the drug delivery device 302 and, upon receipt, the controller 423 of the local computing device 304 may compare the sensed temperature to information (e.g., threshold temperature information indicating a minimum temperature or temperature range) stored in the memory 422 of the local computing device 304 to determine if the sensed temperature is acceptable for a patient to use the drug delivery device 302.

[0130] Upon receipt of a temperature communication at block 806 of Fig. 13, the method 800 continues at block 808, where the processor 420 controls the display 432 to display an informational prompt instructing the user that the temperature of the drug delivery device 302 is now suitable or acceptable for use. The method 800 continues on to blocks 810 and 812, where the processor 420 controls the display 432 to display instructional prompts to the user that the user is to remove any packaging and to apply the drug delivery device 302 to the patient's skin. The method 800 then continues at block 814 to monitor the communication link for the next communication from the drug delivery device 302.

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[0131] In some embodiments, the controller 350 may evaluate a temperature history of the drug delivery device 302 to determine the range and duration of temperatures experienced by the drug delivery device 302 in the past to determine if the temperature history renders the drug delivery device 302 or its medicament unacceptable for use. If so, the controller 350 may control the communication module 352 to transmit a communication to the local computing device 304 that the temperature history of the drug delivery device 302 renders it unsuitable for use, and the controller 423 of the local computing device 304 controls the display 423 to display an informational prompt instructing the patient not to use the device. In some embodiments, the evaluation of the temperature history may be performed by the controller 423 of the local computing device 304 by comparing temperature history received from the drug delivery device 302 with information stored in the memory 422 of the local computing device 304 to determine if the temperature history is acceptable for a patient to use the drug delivery device 302.

[0132] Next, the method 700 continues with the controller 350 monitoring the skin sensor 362 to determine if the drug delivery device 302 has been applied to the patient's skin at block 710 of Fig. 12. When the controller 350 determines that the drug delivery device 302 has been applied to the patient's skin, the controller 350 controls the communication module 352 at block 712 to transmit a communication to the local computing device 304 that the drug delivery device 302 has been applied.

[0133] Upon receipt of the communication of skin application, as determined at block 814 of Fig. 13, the method 800 continues to block 816 with the processor 420 controlling the display 432 to display an instructional prompt instructing the user or patient that the drug delivery device 302 must be aligned with respect to the patient's skin. The instructional prompt may include illustrations of the proper manner in which the device is to be positioned relative to the patient's skin. In order to generate the instructional prompt at block 816, the processor 420 may process (e.g., compare) the communication received from the drug delivery device 302 at block 814 with or according to information stored in the memory 422 of the local computing device 304.

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[0134] The method 800 may then proceed to block 818, wherein the processor 420 monitors the communication link for any error communications received from the drug delivery device 302 regarding the position and/or orientation of the device (see blocks 714, 716 of method 700 of Fig. 12), and controls the display 432 to display an instructional prompt to the user at block 820 if an error communication is received. The error communication may include an indication of the type of positional and/or orientation error occurring, such that the instructional prompt displayed may be tailored to provide specific guidance (e.g., "Tilt Right" or "Tilt Left"). In order to generate the instructional prompt at block 820, the processor 420 may process (e.g., compare) the error communications received from the drug delivery device 302 at block 818 with or according to information stored in the memory 422 of the local computing device 304. The method 800 further continues to block 822, with the processor 420 monitoring the communication link for a further communication from the drug delivery device 302 and cycling between blocks 818, 822 until such a further communication is received.

[0135] As reflected in Fig. 12, the controller 350 is monitoring the orientation sensors 364 at this time to determine if the drug delivery device 302 is properly oriented at block 714. The controller 350 will control the communication module 352 to transmit one or more error communications at block 716 if the position of the device 302 is incorrect, and a device positioned communication at block 718 when the device 302 is correctly positioned. In some embodiments, the controller 350 may control the communication module 352 to transmit a communication representative of the orientation of the delivery device 302 and, upon receipt, the controller 423 of the local computing device 304 may compare the sensed orientation with information stored in the memory 422 of the local computing device 304 to determine if the sensed orientation is acceptable for a patient to use the drug delivery device 302 to delivery its medicament to the patient.

[0136] Upon receipt of the correct position communication, as determined at block 822 of Fig. 13, the method 800 continues at block 824 with the processor 420 controlling the display 432 to display an instructional prompt to the user to actuate the drug delivery device 302, starting the delivery of the drug. In order to generate the instructional prompt at block 822, the processor 420 may process (e.g., compare) the communications received from the drug delivery device 302 at block 822 with or according to information stored in

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the memory 422 of the local computing device 304. The method 800 then continues to block 826, where the processor 420 monitors the communication link for the next communication from the drug delivery device 302.

[0137] At the same time, the controller 350 is monitoring the switch 366 to determine if the button 340 has been depressed, or if other action has been taken to actuate the drug delivery device 302, as indicated at block 720 of Fig. 12. Once the controller 350 has received a signal from the switch that the button 340 has been depressed, for example, the controller 350 controls the communication module 352 to transmit a device actuated communication to the local computing device 304, as indicated at block 722.

[0138] Upon receipt of the device actuated communication, as determined at block 826 of Fig. 13, the method 800 continues at block 828 with the processor 420 controlling the display 432 to display an informational prompt to the user that the injection has begun. In order to generate the instructional prompt at block 828, the processor 420 may process (e.g., compare) the communications received from the drug delivery device 302 at block 826 with or according to information stored in the memory 422 of the local computing device 304.

[0139] The method 800 may continue to blocks 830, 832 where the processor 420 monitors the communication link for any error communication relative to the position of the device (block 830) and controls the display 432 to display an instructional prompt to the user to reposition the device (block 832). See also blocks 724 and 726 of method 700 of Fig. 12. The method 800 further continues to block 834, where the processor 420 monitors the communication link for a further communication from the drug delivery device 302. While illustrated as separate blocks, it will be recognized that the actions of blocks 830 and 834 may be combined in a single block.

[0140] Until such communication is received, the method 800 repeats blocks 828, 830, 834 (and as circumstances dictate, block 832). It will be recognized that during repeated iterations of block 828, the processor 420 may control the display 432 to provide informational prompts to the user that reflect progress toward the delivery of the drug from the drug delivery device 302. Consequently, the repetition of block 828 is not

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intended to indicate that the same informational prompt is repeatedly displayed to the user, although that might be done according to certain embodiments.

[0141] Returning to the method 700 of Fig. 12, the controller 350 continues to monitor the orientation sensors 364 at block 724 (and transmit error communications at block 726, as required) until the controller 350 determines that the injection is complete at block 728. While these actions are illustrated as different blocks in Fig. 12, the actions of blocks 724 and 728 may be combined. When the controller 350 determines that the injection is compete at block 728, then the controller 350 controls the communication module 352 to send a delivery complete communication to the local computing device 304 at block 730.

[0142] It will be recognized that the determination made at block 728 may be made, as indicated above, based on monitoring of the signals received from one or more sensors associated with the reservoir 312. Alternatively, the determination at block 728 may be made based on a timer set according to an estimate of the time required to eject the drug completely from the reservoir 312 according previously performed time trials. According to other embodiments, the controller 312 may not make the determination that the delivery is complete, but rather this determination may be made by the local computing device 304, for example based on the receipt of the device actuated communication, a timer monitored or maintained by the processor 420, and an estimate of the time required to eject the drug completely from the reservoir 312 according to previously performed time trials.

[0143] However, according to the illustrated embodiment, the delivery complete communication is transmitted to the local computing device 304, and the method 800 continues at blocks 834, 836 at Fig. 13 with the receipt of the communication by the local computing device 304 (block 834) and the processor 420 controlling the display 432 to display an informational prompt to the user that the delivery has been completed and/or an instructional prompt to safely discard the drug delivery device 302. The processor 420 may then format and transmit a report indicative of completion of the drug delivery to the patient to the remote computing device 306 regarding the operation of the device 302 at block 838.

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[0144] While the structure and operation of embodiments of a system 300 according to this disclosure has been discussed above, it will be recognized that further variants of this system 300 and its methods of operation may be described.

[0145] For example, while the foregoing suggests that the communications (other than the error communications) carry some identifying information that makes each unique (e.g., the delivery complete communication), this need not be the case according to all embodiments. For example, the local computing device 304 may simply wait for the next non-error communication received from the drug delivery device 302, and on the basis that a further non-error communication has been received, the local computing device may move to the next action of method 800. As such, all of the non-error communications may be indistinguishable from each other.

[0146] As an additional example, in addition to the information that is transmitted from the drug delivery device 302 to the local computing device 304 above, the drug delivery device 302 may include in memory 372 identity information regarding the drug and/or the device 302. This identity information may be transmitted to the local computing device 304 before or at the same time the controller 350 controls the communication module 352 to transmit the initial "device out" communication of block 704 of Fig. 12, or with the reporting that occurs at block 636 in Fig. 6. The information may include, by way of example and not by way of limitation, a unique identifier, the name of the drug, the dosage, and the expiration date. Alternatively, this information may be contained in a QR code label or RFID tag associated with the drug delivery device 302, and the local computing device processor 420 may control the display 432 to display an instructional prompt to the user for the user to use the local computing device 304 to obtain this information. In any event, the method 800 of Fig. 13 may include displaying informational prompts to the user based on this information, and even instructional prompts should the local computing device 304 determine that the drug product is not appropriate for use by the user because, for example, the drug is incorrect, the dosage is incorrect, or the expiration date is past due.

[0147] Along similar lines, the identifying information may include information regarding the identity of the patient for whom the drug was prescribed. With this

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information, the local computing device 304 may make a determination regarding the patient that is about to receive the drug, and provide appropriate informational and/or instructional prompts. In conjunction with the drug identity information discussed above, and the local computing device 304 may use this information to address the five Rights in Medication Administration: Right Patient, Right Drug, Right Dose, Right Time, and Right Route.

[0148] The local computing device 304 may also operate to display information prompts in the form of reminders to follow the prescribed treatment regimen. In fact, the remote computing device 306 may interact with and/or control one or more local computing devices 304 that display the reminder information prompts. The remote computing device 306 may control the timing and/or content of the displayed reminder information prompts based on information received from the one or more local computing devices 304. For example, the remote computing device 306 may determine that one or another message is best suited for (e.g., most effective with) users where the one or more local computing devices 304 evidence a particular type of use or behavior pattern on the part of these users, and may control the timing and/or content of the reminder information prompts accordingly. Other informational prompts that may be displayed on the local computing device may include personal injection histories, or general educational material regarding efficacy expectations for patients on the prescribed treatment regimen.

[0149] By processing communications from the drug delivery device 302 at the local computing device 304 according to the method 800, the data processing and/or storage burden on the drug delivery device 302 may be reduced. Furthermore, the drug delivery device 302 may not be required to have a display for providing informational and/or instructional prompts to the patient or user. Accordingly, the method 800 permits the use of relative simple and/or inexpensive computer hardware onboard the drug delivery device 302, which may be desirable from an economic perspective, especially if the drug delivery device 302 is a disposable, single-use device, or otherwise has a limited lifespan.

[0150] To further reduce the data processing and/or storage burden on the drug delivery device 302, the drug delivery device 302 may transmit the sensor data (e.g., raw

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or unprocessed data) from one or more of the sensors 360, 362, 364, and 365 to the local computing device 304 and/or the remote computing device 306 without processing sensor data, or with very minimal processing of the sensor data, prior to its transmission. Accordingly, in such an embodiment, the local computing device 304 and/or the remote computing device 306, as opposed to the drug delivery device 302, may process the sensor data to determine the condition and/or operational state of the drug delivery device 302. Besides transmitting the sensor data to the local computing device 304 and/or the remote computing device 306, the drug delivery device 302 may not be required to process the sensor data. This configuration may free the drug delivery device 302 from having to include a controller 350, processor 370, and/or memory 372, thereby reducing the cost and complexity of the drug delivery device 302. In such an embodiment, the only computer-related electronics onboard the drug delivery device 302 may be the sensors 360, 362, 364, and 365 and the communication module 430.

[0151] An example of a method, designated by reference numeral 900, in which the local computing device 304, as opposed to the drug delivery device 302, processes the sensor data to determine at least one of a condition and/or an operational state of the drug delivery device 302 will now be described with reference to Fig. 14. In some embodiments, some or all of the steps of the method 900 may be performed by the remote computing device 306 instead of the local computing device 304. The method 900 begins at block 902 with the local computing device 304 receiving, at the communication module 430, sensor data generated by the temperature sensor 360 and transmitted from the communication module 352 of the drug delivery device 302. Next, at block 904, the sensor data received at block 902 may be processed (e.g., analyzed) by the processor 420 of the local computing device 304 according to information stored in the memory 422 of the local computing device 304 to determine a temperature or a temperature history of the drug delivery device 302.

[0152] The method 900 then continues to block 906 where the processor 430 compares the temperature or temperature history determined at block 904 with information stored in the memory 422 to determine if the temperature or temperature history is acceptable for the patient to use the drug delivery device 302. In some embodiments, the processor 430 may compare the temperature to a threshold temperature and determines that the

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temperature is acceptable only if the temperature exceeds the threshold temperature. In embodiments where the temperature history is evaluated, the processor 430 may compare the temperature history with an acceptable temperature range to determine if, and how long, the drug delivery device 302 was outside the acceptable temperature range in the past.

[0153] In response to a determination that the temperature or temperature history is not acceptable at block 906, the processor 430 may control the display 432 to display an instructional prompt to the user instructing the user to wait before using the drug delivery device 302 (or to never use the drug delivery device if the temperature history is unacceptable, for example) at block 907, and subsequently the method 900 may return to block 902. In response to a determination that the temperature or temperature history is acceptable at block 906, the processor 430 may control the display 432 to display instructional prompts instructing the user that the temperature or temperature history of the drug delivery device 302 is acceptable for use, to remove any packaging from the drug delivery device, and to apply the drug delivery device 302 to the patient's skin, at, respectively, blocks 908, 910, and 912.

[0154] Subsequently, the method 900 continues on to block 914, where the local computing device 304 receives, at the communication module 430, sensor data generated by the skin sensor 362 and transmitted from the communication module 352 of the drug delivery device 302. Next, at block 916, the sensor data received at block 914 may be processed (e.g., analyzed) by the processor 420 of the local computing device 304 according to information stored in the memory 422 of the local computing device 304 to determine if the drug delivery device 302 is disposed on or against a skin of the patient. In response to a determination that the drug delivery device 302 is not applied to the patient's skin at block 916, the method 900 may return to block 912. In response to a determination that the drug delivery device 302 is applied to the patient's skin at block 916, the processor 430 may control the display 432 to display an instructional prompt instructing the user to correctly or properly orient the drug delivery device 302 relative to the patient's skin at block 917.

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[0155] Next, the method 900 continues on to block 918, where the local computing device 304 receives, at the communication module 430, sensor data generated by the orientation sensors 364 and transmitted from the communication module 352 of the drug delivery device 302. Then, at block 920, the sensor data received at block 918 may be processed (e.g., analyzed) by the processor 420 of the local computing device 304 according to information stored in the memory 422 of the local computing device 304 to determine the orientation of the drug delivery device 304. The method 900 then continues to block 922 where the processor 430 compares the orientation determined at block 904 with information stored in the memory 422 to determine if the orientation of the drug delivery device relative to the patient's skin is acceptable. In response to a determination that the drug delivery device 302 is not correctly oriented relative to the patient's skin at block 922, the processor 430 may control the display 432 to display an instructional prompt instructing the user to reposition or reorient the drug delivery device 302 at block 924, and subsequently the method 900 may return to block 918. In response to a determination that the drug delivery device 302 is properly oriented relative to the patient's skin at block 922, the processor 430 may control the display 432 to display an instructional prompt instructing the user to actuate the drug delivery device 302 to deliver the medicament to the patient at block 926. In some embodiments, the drug delivery device 302 may be actuated by manually depressing the actuator 340.

[0156] The method 900 then continues on to block 928, where the local computing device 304 receives, at the communication module 430, sensor data generated by the switch 366 and transmitted from the communication module 352 of the drug delivery device 302. Then, at block 930, the sensor data received at block 928 may be processed (e.g., analyzed) by the processor 420 of the local computing device 304 according to information stored in the memory 422 of the local computing device 304 to determine if the drug delivery device 304 has been actuated. In response to a determination that the drug delivery device 302 has not been actuated at block 930, the method 900 may return to block 928. In response to a determination that the drug delivery device 302 has been actuated at block 930, the processor 430 may control the display 432 to display an instructional prompt instructing the user to wait for completion of a delivery of a medicament from the reservoir to the patient at block 932.

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[0157] Next, the method 900 continues on to block 934, where the local computing device 304 receives, at the communication module 430, sensor data generated by the orientation sensors 364 and transmitted from the communication module 352 of the drug delivery device 302. Then, at block 936, the sensor data received at block 934 may be processed (e.g., analyzed) by the processor 420 of the local computing device 304 according to information stored in the memory 422 of the local computing device 304 to determine the orientation of the drug delivery device 304. The method 900 then continues to block 938 where the processor 430 compares the orientation determined at block 904 with information stored in the memory 422 to determine if the orientation of the drug delivery device relative to the patient's skin is acceptable. In response to a determination that the drug delivery device 302 is not correctly oriented relative to the patient's skin at block 938, the processor 430 may control the display 432 to display an instructional prompt instructing the user to reposition or reorient the drug delivery device 302 at block 940, and subsequently the method 900 may return to block 934. In response to a determination that the drug delivery device 302 is properly oriented relative to the patient's skin at block 938, the processor 430 may control the display 432 to display an instructional prompt instructing the user to wait for completion of a delivery of a medicament from the reservoir 312 to the patient at block 941.

[0158] The method 900 then continues to block 942, where the local computing device 304 receives, at the communication module 430, sensor data generated by a medicament fluid level sensor (not illustrated) associated with the reservoir 312 and transmitted from the communication module 352 of the drug delivery device 302. Then, at block 944, the sensor data received at block 942 may be processed (e.g., analyzed) by the processor 420 of the local computing device 304 according to information stored in the memory 422 of the local computing device 304 to determine if delivery of the medicament from the reservoir 312 to the patient has been completed. In some embodiments, the determination of the completion of medicament delivery may not be based on sensor data received from the drug delivery device 302, but instead on a timer monitored or maintained by the processor 420 and an estimate of the time required to eject the drug completely from the reservoir 312 according to previously performed time trials.

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[0159] In response to a determination that the delivery of the medicament from the reservoir 312 to the patient is not complete at block 944, the processor 430 may control the display 432 to display an instructional prompt instructing the user to wait for completion of a delivery of a medicament from the reservoir 312 to the patient at block 946, and subsequently the method 900 may return to block 942. In response to a determination that the drug delivery device 302 is properly oriented relative to the patient's skin at block 944, the processor 430 may control the display 432 to display an instructional prompt instructing the user to discard the drug delivery device 302 at block 948.

[0160] Subsequently, the method 900 may proceed to block 950 where the processor 420 generates a report representative of completion of delivery of the medicament to the patient and controls the communication module 430 to transmit the report to another external computing device (e.g., the remote computing device 306) and/or to the drug delivery device 302.

[0161] The above description describes various sensors and sensor systems which can be used in combination with a drug delivery device for detecting a condition and/or operational state of the drug delivery device. Additional or alternative sensors and sensor systems can also be incorporated in the drug delivery devices described above, including any combination of the sensors and sensor systems disclosed in the co-filed International patent application entitled "Drug Delivery System and Method of Use" and having Attorney Docket No.: 32263/48365A, the entirety of which is hereby incorporated by reference.

[0162] The above description describes various systems and methods for use with a drug delivery device. It should be clear that the system, drug delivery device or methods can further comprise use of a medicament listed below with the caveat that the following list should neither be considered to be all inclusive nor limiting. The medicament will be contained in a reservoir. In some instances, the reservoir is a primary container that is either filled or pre-filled for treatment with the medicament. The primary container can be a cartridge or a pre-filled syringe.

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[0163] For example, the drug delivery device or more specifically the reservoir of the device may be filled with colony stimulating factors, such as granulocyte colony-stimulating factor (G-CSF). Such G-CSF agents include, but are not limited to, Neupogen® (filgrastim) and Neulasta® (pegfilgrastim). In various other embodiments, the drug delivery device may be used with various pharmaceutical products, such as an erythropoiesis stimulating agent (ESA), which may be in a liquid or a lyophilized form. An ESA is any molecule that stimulates erythropoiesis, such as Epogen® (epoetin alfa), Aranesp® (darbepoetin alfa), Dynepo® (epoetin delta), Mircera® (methyoxy polyethylene glycol-epoetin beta), Hematide®, MRK-2578, INS-22, Retacrit® (epoetin zeta), Neorecormon® (epoetin beta), Silapo® (epoetin zeta), Binocrit® (epoetin alfa), epoetin alfa Hexal, Abseamed® (epoetin alfa), Ratioepo® (epoetin theta), Eporatio® (epoetin theta), Biopoin® (epoetin theta), epoetin alfa, epoetin beta, epoetin zeta, epoetin theta, and epoetin delta, as well as the molecules or variants or analogs thereof as disclosed in the following patents or patent applications, each of which is herein incorporated by reference in its entirety: U.S. Patent Nos. 4,703,008; 5,441,868; 5,547,933; 5,618,698; 5,621,080; 5,756,349; 5,767,078; 5,773,569; 5,955,422; 5,986,047; 6,583,272; 7,084,245; and 7,271,689; and PCT Publication Nos. WO 91/05867; WO 95/05465; WO 96/40772; WO 00/24893; WO 01/81405; and WO 2007/136752.

[0164] An ESA can be an erythropoiesis stimulating protein. As used herein, "erythropoiesis stimulating protein" means any protein that directly or indirectly causes activation of the erythropoietin receptor, for example, by binding to and causing dimerization of the receptor. Erythropoiesis stimulating proteins include erythropoietin and variants, analogs, or derivatives thereof that bind to and activate erythropoietin receptor; antibodies that bind to erythropoietin receptor and activate the receptor; or peptides that bind to and activate erythropoietin receptor. Erythropoiesis stimulating proteins include, but are not limited to, epoetin alfa, epoetin beta, epoetin delta, epoetin omega, epoetin iota, epoetin zeta, and analogs thereof, pegylated erythropoietin, carbamylated erythropoietin, mimetic peptides (including EMP1/hematide), and mimetic antibodies. Exemplary erythropoiesis stimulating proteins include erythropoietin, darbepoetin, erythropoietin agonist variants, and peptides or antibodies that bind and activate erythropoietin receptor (and include compounds reported in U.S. Publication

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Nos. 2003/0215444 and 2006/0040858, the disclosures of each of which is incorporated herein by reference in its entirety) as well as erythropoietin molecules or variants or analogs thereof as disclosed in the following patents or patent applications, which are each herein incorporated by reference in its entirety: U.S. Patent Nos. 4,703,008; 5,441,868; 5,547,933; 5,618,698; 5,621,080; 5,756,349; 5,767,078; 5,773,569; 5,955,422; 5,830,851; 5,856,298; 5,986,047; 6,030,086; 6,310,078; 6,391,633; 6,583,272; 6,586,398; 6,900,292; 6,750,369; 7,030,226; 7,084,245; and 7,217,689; U.S. Publication Nos. 2002/0155998; 2003/0077753; 2003/0082749; 2003/0143202; 2004/0009902; 2004/0071694; 2004/0091961; 2004/0143857; 2004/0157293; 2004/0175379; 2004/0175824; 2004/0229318; 2004/0248815; 2004/0266690; 2005/0019914; 2005/0026834; 2005/0096461; 2005/0107297; 2005/0107591; 2005/0124045; 2005/0124564; 2005/0137329; 2005/0142642; 2005/0143292; 2005/0153879; 2005/0158822; 2005/0158832; 2005/0170457; 2005/0181359; 2005/0181482; 2005/0192211; 2005/0202538; 2005/0227289; 2005/0244409; 2006/0088906; and 2006/0111279; and PCT Publication Nos. WO 91/05867; WO 95/05465; WO 99/66054; WO 00/24893; WO 01/81405; WO 00/61637; WO 01/36489; WO 02/014356; WO 02/19963; WO 02/20034; WO 02/49673; WO 02/085940; WO 03/029291; WO 2003/055526; WO 2003/084477; WO 2003/094858; WO 2004/002417; WO 2004/002424; WO 2004/009627; WO 2004/024761; WO 2004/033651; WO 2004/035603; WO 2004/043382; WO 2004/101600; WO 2004/101606; WO 2004/101611; WO 2004/106373; WO 2004/018667; WO 2005/001025; WO 2005/001136; WO 2005/021579; WO 2005/025606; WO 2005/032460; WO 2005/051327; WO 2005/063808; WO 2005/063809; WO 2005/070451; WO 2005/081687; WO 2005/084711; WO 2005/103076; WO 2005/100403; WO 2005/092369; WO 2006/50959; WO 2006/02646; and WO 2006/29094.

[0165] Examples of other pharmaceutical products for use with the device may include, but are not limited to, antibodies such as Vectibix® (panitumumab), Xgeva™ (denosumab) and Prolia™ (denosamab); other biological agents such as Enbrel® (etanercept, TNF-receptor /Fc fusion protein, TNF blocker), Neulasta® (pegfilgrastim, pegylated filgastrim, pegylated G-CSF, pegylated hu-Met-G-CSF), Neupogen® (filgrastim , G-CSF, hu-MetG-CSF), and Nplate® (romiplostim); small molecule drugs

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such as Sensipar® (cinacalcet). The device may also be used with a therapeutic antibody, a polypeptide, a protein or other chemical, such as an iron, for example, ferumoxytol, iron dextrans, ferric glyconate, and iron sucrose. The pharmaceutical product may be in liquid form, or reconstituted from lyophilized form.

[0166] Among particular illustrative proteins are the specific proteins set forth below, including fusions, fragments, analogs, variants or derivatives thereof:

[0167] OPGL specific antibodies, peptibodies, and related proteins, and the like (also referred to as RANKL specific antibodies, peptibodies and the like), including fully humanized and human OPGL specific antibodies, particularly fully humanized monoclonal antibodies, including but not limited to the antibodies described in PCT Publication No. WO 03/002713, which is incorporated herein in its entirety as to OPGL specific antibodies and antibody related proteins, particularly those having the sequences set forth therein, particularly, but not limited to, those denoted therein: 9H7; 18B2; 2D8; 2E11; 16E1; and 22B3, including the OPGL specific antibodies having either the light chain of SEQ ID NO:2 as set forth therein in Figure 2 and/or the heavy chain of SEQ ID NO:4, as set forth therein in Figure 4, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

[0168] Myostatin binding proteins, peptibodies, and related proteins, and the like, including myostatin specific peptibodies, particularly those described in U.S. Publication No. 2004/0181033 and PCT Publication No. WO 2004/058988, which are incorporated by reference herein in their entirety particularly in parts pertinent to myostatin specific peptibodies, including but not limited to peptibodies of the mTN8-19 family, including those of SEQ ID NOS:305-351, including TN8-19-1 through TN8-19-40, TN8-19 con1 and TN8-19 con2; peptibodies of the mL2 family of SEQ ID NOS:357-383; the mL15 family of SEQ ID NOS:384-409; the mL17 family of SEQ ID NOS:410-438; the mL20 family of SEQ ID NOS:439-446; the mL21 family of SEQ ID NOS:447-452; the mL24 family of SEQ ID NOS:453-454; and those of SEQ ID NOS:615-631, each of which is individually and specifically incorporated by reference herein in their entirety fully as disclosed in the foregoing publication;

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[0169] IL-4 receptor specific antibodies, peptibodies, and related proteins, and the like, particularly those that inhibit activities mediated by binding of IL-4 and/or IL-13 to the receptor, including those described in PCT Publication No. WO 2005/047331 or PCT Application No. PCT/US2004/37242 and in U.S. Publication No. 2005/112694, which are incorporated herein by reference in their entirety particularly in parts pertinent to IL-4 receptor specific antibodies, particularly such antibodies as are described therein, particularly, and without limitation, those designated therein: L1H1; L1H2; L1H3; L1H4; L1H5; L1H6; L1H7; L1H8; L1H9; L1H10; L1H11; L2H1; L2H2; L2H3; L2H4; L2H5; L2H6; L2H7; L2H8; L2H9; L2H10; L2H11; L2H12; L2H13; L2H14; L3H1; L4H1; L5H1; L6H1, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

[0170] Interleukin 1-receptor 1 ("IL1-R1") specific antibodies, peptibodies, and related proteins, and the like, including but not limited to those described in U.S. Publication No. 2004/097712, which is incorporated herein by reference in its entirety in parts pertinent to IL1-R1 specific binding proteins, monoclonal antibodies in particular, especially, without limitation, those designated therein: 15CA, 26F5, 27F2, 24E12, and 10H7, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the aforementioned publication;

[0171] Ang2 specific antibodies, peptibodies, and related proteins, and the like, including but not limited to those described in PCT Publication No. WO 03/057134 and U.S. Publication No. 2003/0229023, each of which is incorporated herein by reference in its entirety particularly in parts pertinent to Ang2 specific antibodies and peptibodies and the like, especially those of sequences described therein and including but not limited to: L1(N); L1(N) WT; L1(N) 1K WT; 2xL1(N); 2xL1(N) WT; Con4 (N), Con4 (N) 1K WT, 2xCon4 (N) 1K; L1C; L1C 1K; 2xL1C; Con4C; Con4C 1K; 2xCon4C 1K; Con4-L1 (N); Con4-L1C; TN-12-9 (N); C17 (N); TN8-8(N); TN8-14 (N); Con 1 (N), also including anti-Ang 2 antibodies and formulations such as those described in PCT Publication No. WO 2003/030833 which is incorporated herein by reference in its entirety as to the same, particularly Ab526; Ab528; Ab531; Ab533; Ab535; Ab536; Ab537; Ab540; Ab543; Ab544; Ab545; Ab546; A551; Ab553; Ab555; Ab558; Ab559; Ab565; AbF1AbFD; AbFE; AbFJ; AbFK; AbG1D4; AbGC1E8; AbH1C12; AblA1; AblF; AblK, AblP; and

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AblP, in their various permutations as described therein, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

[0172] NGF specific antibodies, peptibodies, and related proteins, and the like including, in particular, but not limited to those described in U.S. Publication No. 2005/0074821 and U.S. Patent No. 6,919,426, which are incorporated herein by reference in their entirety particularly as to NGF-specific antibodies and related proteins in this regard, including in particular, but not limited to, the NGF-specific antibodies therein designated 4D4, 4G6, 6H9, 7H2, 14D10 and 14D11, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

[0173] CD22 specific antibodies, peptibodies, and related proteins, and the like, such as those described in U.S. Patent No. 5,789,554, which is incorporated herein by reference in its entirety as to CD22 specific antibodies and related proteins, particularly human CD22 specific antibodies, such as but not limited to humanized and fully human antibodies, including but not limited to humanized and fully human monoclonal antibodies, particularly including but not limited to human CD22 specific IgG antibodies, such as, for instance, a dimer of a human-mouse monoclonal hLL2 gamma-chain disulfide linked to a human-mouse monoclonal hLL2 kappa-chain, including, but limited to, for example, the human CD22 specific fully humanized antibody in Epratuzumab, CAS registry number 501423-23-0;

[0174] IGF-1 receptor specific antibodies, peptibodies, and related proteins, and the like, such as those described in PCT Publication No. WO 06/069202, which is incorporated herein by reference in its entirety as to IGF-1 receptor specific antibodies and related proteins, including but not limited to the IGF-1 specific antibodies therein designated L1H1, L2H2, L3H3, L4H4, L5H5, L6H6, L7H7, L8H8, L9H9, L10H10, L11H11, L12H12, L13H13, L14H14, L15H15, L16H16, L17H17, L18H18, L19H19, L20H20, L21H21, L22H22, L23H23, L24H24, L25H25, L26H26, L27H27, L28H28, L29H29, L30H30, L31H31, L32H32, L33H33, L34H34, L35H35, L36H36, L37H37, L38H38, L39H39, L40H40, L41H41, L42H42, L43H43, L44H44, L45H45, L46H46,

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L47H47, L48H48, L49H49, L50H50, L51H51, L52H52, and IGF-1R-binding fragments and derivatives thereof, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

[0175] Also among non-limiting examples of anti-IGF-1R antibodies for use in the methods and compositions of the present invention are each and all of those described in:

(i) U.S. Publication No. 2006/0040358 (published February 23, 2006), 2005/0008642 (published January 13, 2005), 2004/0228859 (published November 18, 2004), including but not limited to, for instance, antibody 1A (DSMZ Deposit No. DSM ACC 2586), antibody 8 (DSMZ Deposit No. DSM ACC 2589), antibody 23 (DSMZ Deposit No. DSM ACC 2588) and antibody 18 as described therein;

(ii) PCT Publication No. WO 06/138729 (published December 28, 2006) and WO 05/016970 (published February 24, 2005), and Lu et al. (2004), J. Biol. Chem. 279:2856-2865, including but not limited to antibodies 2F8, A12, and IMC-A12 as described therein;

(iii) PCT Publication No. WO 07/012614 (published February 1, 2007), WO 07/000328 (published January 4, 2007), WO 06/013472 (published February 9, 2006), WO 05/058967 (published June 30, 2005), and WO 03/059951 (published July 24, 2003);

(iv) U.S. Publication No. 2005/0084906 (published April 21, 2005), including but not limited to antibody 7C10, chimaeric antibody C7C10, antibody h7C10, antibody 7H2M, chimaeric antibody *7C10, antibody GM 607, humanized antibody 7C10 version 1, humanized antibody 7C10 version 2, humanized antibody 7C10 version 3, and antibody 7H2HM, as described therein;

(v) U.S. Publication Nos. 2005/0249728 (published November 10, 2005), 2005/0186203 (published August 25, 2005), 2004/0265307 (published December 30, 2004), and 2003/0235582 (published December 25, 2003) and Maloney et al. (2003), Cancer Res. 63:5073-5083, including but not limited to antibody EM164, resurfaced EM164, humanized EM164, huEM164 v1.0, huEM164 v1.1, huEM164 v1.2, and huEM164 v1.3 as described therein;

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(vi) U.S. Patent No. 7,037,498 (issued May 2, 2006), U.S. Publication Nos. 2005/0244408 (published November 30, 2005) and 2004/0086503 (published May 6, 2004), and Cohen, et al. (2005), Clinical Cancer Res. 11:2063-2073, e.g., antibody CP-751,871, including but not limited to each of the antibodies produced by the hybridomas having the ATCC accession numbers PTA-2792, PTA-2788, PTA-2790, PTA-2791, PTA-2789, PTA-2793, and antibodies 2.12.1, 2.13.2, 2.14.3, 3.1.1, 4.9.2, and 4.17.3, as described therein;

(vii) U.S. Publication Nos. 2005/0136063 (published June 23, 2005) and 2004/0018191 (published January 29, 2004), including but not limited to antibody 19D12 and an antibody comprising a heavy chain encoded by a polynucleotide in plasmid 15H12/19D12 HCA (γ4), deposited at the ATCC under number PTA-5214, and a light chain encoded by a polynucleotide in plasmid 15H12/19D12 LCF (κ), deposited at the ATCC under number PTA-5220, as described therein; and

(viii) U.S. Publication No. 2004/0202655 (published October 14, 2004), including but not limited to antibodies PINT-6A1, PINT-7A2, PINT-7A4, PINT-7A5, PINT-7A6, PINT-8A1, PINT-9A2, PINT-11A1, PINT-11A2, PINT-11A3, PINT-11A4, PINT-11A5, PINT-11A7, PINT-11A12, PINT-12A1, PINT-12A2, PINT-12A3, PINT-12A4, and PINT-12A5, as described therein; each and all of which are herein incorporated by reference in their entireties, particularly as to the aforementioned antibodies, peptibodies, and related proteins and the like that target IGF-1 receptors;

[0176] B-7 related protein 1 specific antibodies, peptibodies, related proteins and the like ("B7RP-1," also is referred to in the literature as B7H2, ICOSL, B7h, and CD275), particularly B7RP-specific fully human monoclonal IgG2 antibodies, particularly fully human IgG2 monoclonal antibody that binds an epitope in the first immunoglobulin-like domain of B7RP-1, especially those that inhibit the interaction of B7RP-1 with its natural receptor, ICOS, on activated T cells in particular, especially, in all of the foregoing regards, those disclosed in U.S. Publication No. 2008/0166352 and PCT Publication No. WO 07/011941, which are incorporated herein by reference in their entireties as to such antibodies and related proteins, including but not limited to antibodies designated therein as follow: 16H (having light chain variable and heavy chain variable sequences SEQ ID

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NO:1 and SEQ ID NO:7 respectively therein); 5D (having light chain variable and heavy chain variable sequences SEQ ID NO:2 and SEQ ID NO:9 respectively therein); 2H (having light chain variable and heavy chain variable sequences SEQ ID NO:3 and SEQ ID NO:10 respectively therein); 43H (having light chain variable and heavy chain variable sequences SEQ ID NO:6 and SEQ ID NO:14 respectively therein); 41H (having light chain variable and heavy chain variable sequences SEQ ID NO:5 and SEQ ID NO:13 respectively therein); and 15H (having light chain variable and heavy chain variable sequences SEQ ID NO:4 and SEQ ID NO:12 respectively therein), each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

[0177] IL-15 specific antibodies, peptibodies, and related proteins, and the like, such as, in particular, humanized monoclonal antibodies, particularly antibodies such as those disclosed in U.S. Publication Nos. 2003/0138421; 2003/023586; and 2004/0071702; and U.S. Patent No. 7,153,507, each of which is incorporated herein by reference in its entirety as to IL-15 specific antibodies and related proteins, including peptibodies, including particularly, for instance, but not limited to, HuMax IL-15 antibodies and related proteins, such as, for instance, 146B7;

[0178] IFN gamma specific antibodies, peptibodies, and related proteins and the like, especially human IFN gamma specific antibodies, particularly fully human anti-IFN gamma antibodies, such as, for instance, those described in U.S. Publication No. 2005/0004353, which is incorporated herein by reference in its entirety as to IFN gamma specific antibodies, particularly, for example, the antibodies therein designated 1118; 1118*; 1119; 1121; and 1121*. The entire sequences of the heavy and light chains of each of these antibodies, as well as the sequences of their heavy and light chain variable regions and complementarity determining regions, are each individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication and in Thakur et al. (1999), Mol. Immunol. 36:1107-1115. In addition, description of the properties of these antibodies provided in the foregoing publication is also incorporated by reference herein in its entirety. Specific antibodies include those having the heavy chain of SEQ ID NO:17 and the light chain of SEQ ID NO:18; those having the heavy chain variable region of SEQ ID NO:6 and the light chain variable

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region of SEQ ID NO:8; those having the heavy chain of SEQ ID NO:19 and the light chain of SEQ ID NO:20; those having the heavy chain variable region of SEQ ID NO:10 and the light chain variable region of SEQ ID NO:12; those having the heavy chain of SEQ ID NO:32 and the light chain of SEQ ID NO:20; those having the heavy chain variable region of SEQ ID NO:30 and the light chain variable region of SEQ ID NO:12; those having the heavy chain sequence of SEQ ID NO:21 and the light chain sequence of SEQ ID NO:22; those having the heavy chain variable region of SEQ ID NO:14 and the light chain variable region of SEQ ID NO:16; those having the heavy chain of SEQ ID NO:21 and the light chain of SEQ ID NO:33; and those having the heavy chain variable region of SEQ ID NO:14 and the light chain variable region of SEQ ID NO:31, as disclosed in the foregoing publication. A specific antibody contemplated is antibody 1119 as disclosed in the foregoing U.S. publication and having a complete heavy chain of SEQ ID NO:17 as disclosed therein and having a complete light chain of SEQ ID NO:18 as disclosed therein;

[0179] TALL-1 specific antibodies, peptibodies, and the related proteins, and the like, and other TALL specific binding proteins, such as those described in U.S. Publication Nos. 2003/0195156 and 2006/0135431, each of which is incorporated herein by reference in its entirety as to TALL-1 binding proteins, particularly the molecules of Tables 4 and 5B, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publications;

[0180] Parathyroid hormone ("PTH") specific antibodies, peptibodies, and related proteins, and the like, such as those described in U.S. Patent No. 6,756,480, which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind PTH;

[0181] Thrombopoietin receptor ("TPO-R") specific antibodies, peptibodies, and related proteins, and the like, such as those described in U.S. Patent No. 6,835,809, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind TPO-R;

[0182] Hepatocyte growth factor ("HGF") specific antibodies, peptibodies, and related proteins, and the like, including those that target the HGF/SF:cMet axis (HGF/SF:c-Met),

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such as the fully human monoclonal antibodies that neutralize hepatocyte growth factor/scatter (HGF/SF) described in U.S. Publication No. 2005/0118643 and PCT Publication No. WO 2005/017107, huL2G7 described in U.S. Patent No. 7,220,410 and OA-5d5 described in U.S. Patent Nos. 5,686,292 and 6,468,529 and in PCT Publication No. WO 96/38557, each of which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind HGF;

[0183] TRAIL-R2 specific antibodies, peptibodies, related proteins and the like, such as those described in U.S. Patent No. 7,521,048, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind TRAIL-R2;

[0184] Activin A specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Publication No. 2009/0234106, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind Activin A;

[0185] TGF-beta specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Patent No. 6,803,453 and U.S. Publication No. 2007/0110747, each of which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind TGF-beta;

[0186] Amyloid-beta protein specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in PCT Publication No. WO 2006/081171, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind amyloid-beta proteins. One antibody contemplated is an antibody having a heavy chain variable region comprising SEQ ID NO:8 and a light chain variable region having SEQ ID NO:6 as disclosed in the foregoing publication;

[0187] c-Kit specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Publication No. 2007/0253951, which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind c-Kit and/or other stem cell factor receptors;

[0188] OX40L specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Publication No. 2006/0002929, which is

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incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind OX40L and/or other ligands of the OX40 receptor; and

[0189] Other exemplary proteins, including Activase® (alteplase, tPA); Aranesp® (darbepoetin alfa); Epogen® (epoetin alfa, or erythropoietin); GLP-1, Avonex® (interferon beta-1a); Bexxar® (tositumomab, anti-CD22 monoclonal antibody); Betaseron® (interferon-beta); Campath® (alemtuzumab, anti-CD52 monoclonal antibody); Dynepo® (epoetin delta); Velcade® (bortezomib); MLN0002 (anti- α4ß7 mAb); MLN1202 (anti-CCR2 chemokine receptor mAb); Enbrel® (etanercept, TNF-receptor /Fc fusion protein, TNF blocker); Eprex® (epoetin alfa); Erbitux® (cetuximab, anti-EGFR / HER1 / c-ErbB-1); Genotropin® (somatropin, Human Growth Hormone); Herceptin® (trastuzumab, anti-HER2/neu (erbB2) receptor mAb); Humatrope® (somatropin, Human Growth Hormone); Humira® (adalimumab); insulin in solution; Infergen® (interferon alfacon-1); Natrecor® (nesiritide; recombinant human B-type natriuretic peptide (hBNP); Kineret® (anakinra); Leukine® (sargamostim, rhuGM-CSF); LymphoCide® (epratuzumab, anti-CD22 mAb); Benlysta™ (lymphostat B, belimumab, anti-BlyS mAb); Metalyse® (tenecteplase, t-PA analog); Mircera® (methoxy polyethylene glycol-epoetin beta); Mylotarg® (gemtuzumab ozogamicin); Raptiva® (efalizumab); Cimzia® (certolizumab pegol, CDP 870); Soliris™ (eculizumab); pexelizumab (anti-C5 complement); Numax® (MEDI-524); Lucentis® (ranibizumab); Panorex® (17-1A, edrecolomab); Trabio® (lerdelimumab); TheraCim hR3 (nimotuzumab); Omnitarg (pertuzumab, 2C4); Osidem® (IDM-1); OvaRex® (B43.13); Nuvion® (visilizumab); cantuzumab mertansine (huC242-DM1); NeoRecormon® (epoetin beta); Neumega® (oprelvekin, human interleukin-11); Neulasta® (pegylated filgastrim, pegylated G-CSF, pegylated hu-Met-G-CSF); Neupogen® (filgrastim , G-CSF, hu-MetG-CSF); Orthoclone OKT3® (muromonab-CD3, anti-CD3 monoclonal antibody); Procrit® (epoetin alfa); Remicade® (infliximab, anti-TNFα monoclonal antibody); Reopro® (abciximab, anti-GP IIb/IIia receptor monoclonal antibody); Actemra® (anti-IL6 Receptor mAb); Avastin® (bevacizumab), HuMax-CD4 (zanolimumab); Rituxan® (rituximab, anti-CD20 mAb); Tarceva® (erlotinib); Roferon-A®-(interferon alfa-2a); Simulect® (basiliximab); Prexige® (lumiracoxib); Synagis® (palivizumab); 146B7-CHO (anti-IL15 antibody, see U.S. Patent No. 7,153,507);

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Tysabri® (natalizumab, anti-α4integrin mAb); Valortim® (MDX-1303, anti-B. anthracis protective antigen mAb); ABthrax™; Vectibix® (panitumumab); Xolair® (omalizumab); ETI211 (anti-MRSA mAb); IL-1 trap (the Fc portion of human IgG1 and the extracellular domains of both IL-1 receptor components (the Type I receptor and receptor accessory protein)); VEGF trap (Ig domains of VEGFR1 fused to IgG1 Fc); Zenapax® (daclizumab); Zenapax® (daclizumab, anti-IL-2Rα mAb); Zevalin® (ibritumomab tiuxetan); Zetia® (ezetimibe); Orencia® (atacicept, TACI-Ig); anti-CD80 monoclonal antibody (galiximab); anti-CD23 mAb (lumiliximab); BR2-Fc (huBR3 / huFc fusion protein, soluble BAFF antagonist); CNTO 148 (golimumab, anti-TNFα mAb); HGS-ETR1 (mapatumumab; human anti-TRAIL Receptor-1 mAb); HuMax-CD20 (ocrelizumab, anti-CD20 human mAb); HuMax-EGFR (zalutumumab); M200 (volociximab, anti-α5β1 integrin mAb); MDX-010 (ipilimumab, anti-CTLA-4 mAb and VEGFR-1 (IMC-18F1); anti-BR3 mAb; anti-C. difficile Toxin A and Toxin B C mAbs MDX-066 (CDA-1) and MDX-1388); anti-CD22 dsFv-PE38 conjugates (CAT-3888 and CAT-8015); anti-CD25 mAb (HuMax-TAC); anti-CD3 mAb (NI-0401); adecatumumab; anti-CD30 mAb (MDX-060); MDX-1333 (anti-IFNAR); anti-CD38 mAb (HuMax CD38); anti-CD40L mAb; anti-Cripto mAb; anti-CTGF Idiopathic Pulmonary Fibrosis Phase I Fibrogen (FG-3019); anti-CTLA4 mAb; anti-eotaxin1 mAb (CAT-213); anti-FGF8 mAb; anti-ganglioside GD2 mAb; anti-ganglioside GM2 mAb; anti-GDF-8 human mAb (MYO-029); anti-GM-CSF Receptor mAb (CAM-3001); anti-HepC mAb (HuMax HepC); anti-IFNα mAb (MEDI-545, MDX-1103); anti-IGF1R mAb; anti-IGF-1R mAb (HuMax-Inflam); anti-IL12 mAb (ABT-874); anti-IL12/IL23 mAb (CNTO 1275); anti-IL13 mAb (CAT-354); anti-IL2Ra mAb (HuMax-TAC); anti-IL5 Receptor mAb; anti-integrin receptors mAb (MDX-018, CNTO 95); anti-IP10 Ulcerative Colitis mAb (MDX-1100); anti-LLY antibody; BMS-66513; anti-Mannose Receptor/hCGβ mAb (MDX-1307); anti-mesothelin dsFv-PE38 conjugate (CAT-5001); anti-PD1mAb (MDX-1106 (ONO-4538)); anti-PDGFRα antibody (IMC-3G3); anti-TGFß mAb (GC-1008); anti-TRAIL Receptor-2 human mAb (HGS-ETR2); anti-TWEAK mAb; anti-VEGFR/Flt-1 mAb; anti-ZP3 mAb (HuMax-ZP3); NVS Antibody #1; and NVS Antibody #2.

[0190] Also included can be a sclerostin antibody, such as but not limited to romosozumab, blosozumab, or BPS 804 (Novartis). Further included can be therapeutics

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such as rilotumumab, bixalomer, trebananib, ganitumab, conatumumab, motesanib diphosphate, brodalumab, vidupiprant, panitumumab, denosumab, NPLATE, PROLIA, VECTIBIX or XGEVA. Additionally, included in the device can be a monoclonal antibody (IgG) that binds human Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9), e.g. U.S. Patent No. 8,030,547, U.S. Publication No. 2013/0064825, WO2008/057457, WO2008/057458, WO2008/057459, WO2008/063382, WO2008/133647, WO2009/100297, WO2009/100318, WO2011/037791, WO2011/053759, WO2011/053783, WO2008/125623, WO2011/072263, WO2009/055783, WO2012/0544438, WO2010/029513, WO2011/111007, WO2010/077854, WO2012/088313, WO2012/101251, WO2012/101252, WO2012/101253, WO2012/109530, and WO2001/031007.

[0191] Also included can be talimogene laherparepvec or another oncolytic HSV for the treatment of melanoma or other cancers. Examples of oncolytic HSV include, but are not limited to talimogene laherparepvec (U.S. Patent Nos. 7,223,593 and 7,537,924); OncoVEXGALV/CD (U.S. Pat. No. 7,981,669); OrienX010 (Lei et al. (2013), World J. Gastroenterol., 19:5138-5143); G207, 1716; NV1020; NV12023; NV1034 and NV1042 (Vargehes et al. (2002), Cancer Gene Ther., 9(12):967-978).

[0192] Also included are TIMPs. TIMPs are endogenous tissue inhibitors of metalloproteinases (TIMPs) and are important in many natural processes. TIMP-3 is expressed by various cells or and is present in the extracellular matrix; it inhibits all the major cartilage-degrading metalloproteases, and may play a role in role in many degradative diseases of connective tissue, including rheumatoid arthritis and osteoarthritis, as well as in cancer and cardiovascular conditions. The amino acid sequence of TIMP-3, and the nucleic acid sequence of a DNA that encodes TIMP-3, are disclosed in U.S. Patent No. 6,562,596, issued May 13, 2003, the disclosure of which is incorporated by reference herein. Description of TIMP mutations can be found in U.S. Publication No. 2014/0274874 and PCT Publication No. WO 2014/152012.

[0193] Also included are antagonistic antibodies for human calcitonin gene-related peptide (CGRP) receptor and bispecific antibody molecule that target the CGRP receptor

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and other headache targets. Further information concerning these molecules can be found in PCT Application No. WO 2010/075238.

[0194] Additionally, a bispecific T cell engager antibody (BiTe), e.g. Blinotumomab can be used in the device. Alternatively, included can be an APJ large molecule agonist e.g., apelin or analogues thereof in the device. Information relating to such molecules can be found in PCT Publication No. WO 2014/099984.

[0195] In certain embodiments, the medicament comprises a therapeutically effective amount of an anti-thymic stromal lymphopoietin (TSLP) or TSLP receptor antibody. Examples of anti-TSLP antibodies that may be used in such embodiments include, but are not limited to, those described in U.S. Patent Nos. 7,982,016, and 8,232,372, and U.S. Publication No. 2009/0186022. Examples of anti-TSLP receptor antibodies include, but are not limited to, those described in U.S. Patent No. 8,101,182. In particularly preferred embodiments, the medicament comprises a therapeutically effective amount of the anti-TSLP antibody designated as A5 within U.S. Patent No. 7,982,016.

[0196] It should be noted that the configurations of the various embodiments of the drug delivery devices and drug delivery systems described herein are illustrative only. Although only a few embodiments of the of the drug delivery devices and drug delivery systems have been described in detail in this disclosure, those skilled in the art who review this disclosure will readily appreciate that many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, orientations, etc.) without materially departing from the novel teachings and advantages of the subject matter of this disclosure. For example, any combination of one or more of the sensors and/or controllable elements described herein may be incorporated into one or more of the drug delivery systems and drug delivery devices described herein. Also, the order or sequence of any process or method steps described herein may be varied or re-sequenced, in any combination, according to alternative embodiments. Furthermore, any combination of one or more of the elements of one or more of the claims set forth at the end of this disclosure is possible.

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[0197] Although the preceding text sets forth a detailed description of different embodiments of the invention, it should be understood that the legal scope of the invention is defined by the words of the claims set forth at the end of this patent. The detailed description is to be construed as exemplary only and does not describe every possible embodiment of the invention because describing every possible embodiment would be impractical, if not impossible. Numerous alternative embodiments could be implemented, using either current technology or technology developed after the filing date of this patent, that would still fall within the scope of the claims defining the invention.

[0198] It should also be understood that, unless a term is expressly defined in this patent using the sentence "As used herein, the term '_____' is hereby defined to mean..." or a similar sentence, there is no intent to limit the meaning of that term, either expressly or by implication, beyond its plain or ordinary meaning, and such term should not be interpreted to be limited in scope based on any statement made in any section of this patent (other than the language of the claims). To the extent that any term recited in the claims at the end of this patent is referred to in this patent in a manner consistent with a single meaning, that is done for sake of clarity only so as to not confuse the reader, and it is not intended that such claim term be limited, by implication or otherwise, to that single meaning. Finally, unless a claim element is defined by reciting the word "means" and a function without the recital of any structure, it is not intended that the scope of any claim element be interpreted based on the application of 35 U.S.C. §112, sixth paragraph.

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What is claimed is:

1. A system comprising:

a drug delivery device comprising:

a reservoir;

a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient;

one or more sensors configured to generate sensor data representative of at least one of a condition or an operational state of the drug delivery device; and

a first communication module coupled to the one or more sensors and configured to transmit the sensor data; and

an external computing device comprising:

a second communication module configured to receive the sensor data from the first communication module;

a processor coupled to the second communication module; and

a memory coupled to the processor, the memory storing non-transitory computer-readable instructions that, when executed by the processor, cause the processor to determine at least one of the condition or the operational state of the drug delivery device based on the sensor data.

2. The system of claim 1, the external computing device comprising a display coupled to the processor.

3. The system of claim 2, wherein the non-transitory computer-readable instructions include instructions that cause the processor to control the display to display at least one of an instructional prompt or an informational prompt based on: (i) at least one of the condition or the operational state of the drug delivery device, and (ii) information stored in the memory of the external computing device.

4. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine

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a temperature or a temperature history of the drug delivery device based on the sensor data.

5. The system of claim 4, wherein the non-transitory computer-readable instructions include instructions that cause the processor to compare the temperature or the temperature history of the drug delivery device to information stored in the memory of the external computing device to determine if the temperature or the temperature history of the drug delivery device is acceptable.

6. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if the drug delivery device is disposed on or against a skin of the patient based on the sensor data.

7. The system of claim 6, wherein the non-transitory computer-readable instructions include instructions that cause the processor to, in response to a determination that the drug delivery device is disposed on or against the skin of the patient, control the display to display an instructional prompt instructing a user to correctly orient the drug delivery device relative to the skin of the patient.

8. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine an orientation of the drug delivery device based on the sensor data.

9. The system of claim 8, wherein the non-transitory computer-readable instructions include instructions that cause the processor to:

compare the orientation of the drug delivery device to information stored in the memory of the external computing device to determine if the orientation of the drug delivery device relative to a skin of the patient is acceptable, and

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in response to a determination that the orientation of the drug delivery device is acceptable, control the display to display an instructional prompt instructing a user to actuate the drug delivery device.

10. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if the drug delivery device has been actuated by a user based on the sensor data.

11. The system of claim 10, wherein the non-transitory computer-readable instructions include instructions that cause the processor to, in response to a determination that the drug delivery device has been actuated by the user, control the display to display an instructional prompt instructing a user to wait for completion of a delivery of a medicament from the reservoir to the patient.

12. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if a delivery of a medicament from the reservoir to the patient has been completed based on the sensor data.

13. The system of claim 12, wherein the non-transitory computer-readable instructions include instructions that cause the processor to, in response to a determination that the delivery of the medicament from the reservoir to the patient has been completed, control the display to display an instructional prompt instructing a user to discard the drug delivery device.

14. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine an amount of medicament remaining in the reservoir based on the sensor data.

15. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine

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if the removable sterile barrier has been removed from the distal end of the delivery cannula based on the sensor data.

16. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to determine if the distal end of the delivery cannula is inserted into the patient based on the sensor data.

17. The system of any one of the preceding claims, wherein the non-transitory computer-readable instructions include instructions that cause the processor to:

generate a report representative of at least one of the condition or the operational state of the drug delivery device; and

control the second communication module to transmit the report to a remote computing device.

18. The system of any one of the preceding claims, wherein:

the drug delivery device comprises a controllable element; and

the non-transitory computer-readable instructions include instructions that cause the processor to:

generate an instruction for controlling the controllable element; and

control the second communication module to transmit the instruction to the first communication module.

19. The system of claim 18, the controllable element comprising a lock that, when activated, is configured to prevent movement of at least one of: (i) a needle shield disposed about the distal end of the delivery cannula, (ii) a plunger disposed in the reservoir, or (iii) an actuator configured to trigger the drug delivery device.

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20. The system of claim 19, the controllable element comprising a heating element configured to heat a medicament in the reservoir or the delivery cannula when activated.

21. The system of any one of the preceding claims, the one or more sensors comprising a temperature sensor configured to detect a temperature of a medicament within the reservoir.

22. The system of any one of the preceding claims, the one or more sensors comprising a skin contact sensor including at least one of a pressure sensor, a capacitance sensor, a resistance sensor, or an inductance sensor.

23. The system of claim 22, the skin contact sensor being mounted on a needle shield disposed about the distal end of the delivery cannula.

24. The system of any one of the preceding claims, the one or more sensors comprising an orientation sensor.

25. The system of claim 24, the orientation sensor comprising a magnetometer.

26. The system of any one of the preceding claims, the drug delivery device comprising an autoinjector.

27. The system of any one of the preceding claims, the external computing device comprising at least one of a smartphone, a smartwatch, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, or a tablet computer.

28. The system of any one of the preceding claims, the first communication module being configured to communicate with the second communication module via at

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least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

29. The system of any one of the preceding claim, wherein the reservoir comprises a medicament.

30. The system of claim 28, the medicament being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

31. A system comprising:

a drug delivery device comprising:

a reservoir;

a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient;

one or more sensors;

a first communication module;

a first controller coupled to the one or more sensors and the first communication module, the first controller being configured to:

use the one or more sensors to determine at least one of a condition or an operational state of the drug delivery device, and

control the first communication module to transmit a communication representative of at least one of the condition or the operational state of the drug delivery device; and

an external computing device comprising:

a second communication module configured to receive the communication from the first communication module;

a display;

a memory; and

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a second controller coupled to the display, the memory, and the second communication module, the second controller being configured to control the display to display at least one of an instructional prompt or an informational prompt based on the communication from the first communication module.

32. The system of claim 31, wherein:

the first controller is configured to:

use the one or more sensors to determine a temperature or a temperature history of the drug delivery device, and

control the first communication module to transmit a communication representative of the temperature or the temperature history of the drug delivery device; and

the second controller is configured to:

compare the temperature or the temperature history of the drug delivery device to information stored in the memory of the external computing device to determine if the temperature or the temperature history of the drug delivery device is acceptable; and

in response to a determination that the drug delivery device has an acceptable temperature or an acceptable temperature history, control the display to display an instructional prompt instructing a user to dispose the drug delivery device on or against a skin of the patient.

33. The system of any one of claims 31 or 32, wherein:

the first controller is configured to:

use the one or more sensors to determine if the drug delivery device contacts a skin of a patient, and

control the first communication module to transmit a communication representative of contact between the drug delivery device and the skin of the patient; and

in response to a determination that the drug delivery device contacts the skin of the patient, the second controller is configured to control the display to display an

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instructional prompt instructing a user to correctly orient the drug delivery device relative to the skin of the patient.

34. The system of any one of claims 31 to 33, wherein:

the first controller is configured to:

use the one or more sensors to determine an orientation of the drug delivery device, and

control the first communication module to transmit a communication representative of the orientation of the drug delivery device; and

in response to a determination that the orientation of the drug delivery device is acceptable, the second controller is configured to control the display to display an instructional prompt instructing a user to actuate the drug delivery device.

35. The system of any one of claims 31 to 34, wherein:

the first controller is configured to:

use the one or more sensors to determine if the user has actuated the drug delivery device, and

control the first communication module to transmit a communication indicating that the drug delivery device has been actuated by the user; and

in response to a determination that the drug delivery device has been actuated by the user, the second controller is configured to control the display to display an instructional prompt instructing a user to wait for completion of a delivery of a medicament from the reservoir to the patient.

36. The system of any one of claims 31 to 35, wherein:

the first controller is configured to:

use the one or more sensors to determine if a delivery of a medicament from the reservoir to the patient has been completed, and

control the first communication module to transmit a communication representative of completion of delivery of a medicament from the reservoir to the patient; and

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in response to a determination that the delivery of the medicament from the reservoir to the patient has been completed, the second controller is configured to control the display to display an instructional prompt instructing a user to discard the drug delivery device.

37. The system of any one of claims 31 to 36, the one or more sensors comprising a temperature sensor configured to detect a temperature of a medicament within the reservoir.

38. The system of any one of claims 31 to 37, the one or more sensors comprising a skin contact sensor including at least one of a pressure sensor, a capacitance sensor, a resistance sensor, or an inductance sensor.

39. The system of claim 8, the skin contact sensor being mounted on a needle shield disposed about the distal end of the delivery cannula.

40. The system of any one of claims 31 to 39, the one or more sensors comprising an orientation sensor.

41. The system of claim 40, the orientation sensor comprising a magnetometer.

42. The system of any one of claims 31 to 41, the drug delivery device comprising an autoinjector.

43. The system of any one of claims 31 to 42, the external computing device comprising at least one of a smartphone, a smartwatch, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, or a tablet computer.

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44. The system of any one of claims 31 to 43, the first communication module being configured to communicate with the second communication module via at least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

45. The system of any one of claims 31 to 44, wherein the reservoir comprises a medicament.

46. The system of claim 45, the medicament being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

47. A method of using a system comprising a drug delivery device and an external computing device, the drug delivery device comprising a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, one or more sensors configured to generate sensor data, and a first communication module, the external computing device comprising a memory and a second communication module, the method comprising:

collecting sensor data with the drug delivery device;

transmitting the sensor data from the drug delivery device with the first communication module;

receiving the sensor data from the drug delivery device at the external computing device with the second communication module;

determining, with the external computing device, at least one of a condition or an operational state of the drug delivery device based on the sensor data.

48. The method of claim 47, comprising displaying at least one of an instructional prompt or an informational prompt according to: (i) at least one of the

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condition or the operational state of the drug device, and (ii) information stored in the memory of the external computing device.

49. The method of any one of claims 47 or 48, wherein the determining of the at least one of the condition or the operational state of the drug delivery device comprises determining, with the external computing device, a temperature or a temperature history of the drug delivery device based on the sensor data.

50. The method of claim 49, comprising:

comparing the temperature or the temperature history of the drug delivery device to information stored in the memory of the external computing device to determine if the temperature or the temperature history of the drug delivery device is acceptable; and

in response to a determination that the drug delivery device has an acceptable temperature or an acceptable temperature history, displaying an instructional prompt instructing a user to dispose the drug delivery device on or against a skin of the patient.

51. The method of any one of claims 47 to 50, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, if the drug delivery device is disposed on or against a skin of a patient based on the sensor data.

52. The method of claim 51, comprising, in response to a determination that the drug delivery device is disposed on or against the skin of the patient, controlling the display to display an instructional prompt instructing a user to correctly orient the drug delivery device relative to the skin of the patient.

53. The method of any one of claims 47 to 52, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, an orientation of the drug delivery device based on the sensor data.

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54. The method of claim 53, comprising:

comparing the orientation of the drug delivery device to information stored in the memory of the external computing device to determine if the orientation of the drug delivery device relative to a skin of a patient is acceptable; and

in response to a determination that the orientation of the drug delivery device is acceptable, displaying an instructional prompt instructing a user to actuate the drug delivery device.

55. The method of any one of claims 47 to 54, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, if the drug delivery device has been actuated by a user based on the sensor data.

56. The method of claim 55, comprising, in response to a determination that the drug delivery device has been actuated by the user, displaying an instructional prompt instructing a user to wait for completion of a delivery of a medicament from the reservoir to the patient.

57. The method of any one of claims 47 to 56, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the external computing device, if a delivery of a medicament from the reservoir to a patient has been completed based on the sensor data.

58. The method of claim 57, comprising, in response to a determination that the delivery of the medicament from the reservoir to the patient has been completed, displaying an instructional prompt instructing a user to discard the drug delivery device.

59. The method of any one of claims 47 to 57, comprising:

generating, with the external computing device, a report representative of at least one of the condition or the operational state of the drug delivery device; and

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controlling the second communication module to transmit the report to a remote computing device.

60. The system of any one of claims 47 to 59, the drug delivery device comprising an autoinjector.

61. The system of any one of claims 47 to 60, the external computing device comprising at least one of a smartphone, a smartwatch, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, or a tablet computer.

62. The system of any one of claims 47 to 61, the first communication module being configured to communicate with the second communication module via at least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

63. The system of any one of claims 47 to 62, wherein the reservoir comprises a medicament.

64. The system of claim 63, the medicament being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

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65. A method of using a system comprising a drug delivery device and an external computing system, the drug delivery device comprising a reservoir and a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within a patient, the external computing device comprising a memory, the method comprising:

determining at least one of a condition or an operational state of the drug delivery device;

transmitting a communication representative of at least one of the condition or the operational state from the drug delivery device;

receiving the communication from the drug delivery device at the external computing device; and

processing the communication received from the drug delivery device according to information stored in the memory of the external computing device.

66. The method of claim 65, comprising displaying at least one of an instructional prompt or an informational prompt according to: (i) the communication received from the drug delivery device, and (ii) the information stored in the memory of the external computing device.

67. The method of any one of claims 65 or 66, wherein the determining of the at least one of the condition or the operational state of the drug delivery device comprises determining, with the drug delivery device, a temperature or a temperature history of the drug delivery device based on the sensor data.

68. The method of claim 67, comprising:

comparing the temperature or the temperature history of the drug delivery device to the information stored in the memory of the external computing device to determine if the temperature or the temperature history of the drug delivery device is acceptable; and

in response to a determination that the drug delivery device has an acceptable temperature or an acceptable temperature history, displaying an instructional prompt instructing a user to dispose the drug delivery device on or against a skin of the patient.

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69. The method of any one of claims 65 to 68, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the drug delivery device, if the drug delivery device is disposed on or against a skin of a patient based on the sensor data.

70. The method of claim 69, comprising, in response to a determination that the drug delivery device is disposed on or against the skin of the patient, displaying an instructional prompt instructing a user to correctly orient the drug delivery device relative to the skin of the patient.

71. The method of any one of claims 65 to 70, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the drug delivery device, an orientation of the drug delivery device based on the sensor data.

72. The method of claim 71, comprising:

comparing the orientation of the drug delivery device to the information stored in the memory of the external computing device to determine if the orientation of the drug delivery device relative to a skin of a patient is acceptable; and

in response to a determination that the orientation of the drug delivery device is acceptable, displaying an instructional prompt instructing a user to actuate the drug delivery device.

73. The method of any one of claims 65 to 72, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the drug delivery device, if the drug delivery device has been actuated by a user based on the sensor data.

74. The method of claim 73, comprising, in response to a determination that the drug delivery device has been actuated by the user, displaying an instructional prompt

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instructing a user to wait for completion of a delivery of a medicament from the reservoir to the patient.

75. The method of any one of claims 65 to 74, the determining of the at least one of the condition or the operational state of the drug delivery device comprising determining, with the drug delivery device, if a delivery of a medicament from the reservoir to a patient has been completed based on the sensor data.

76. The method of claim 75, comprising, in response to a determination that the delivery of the medicament from the reservoir to the patient has been completed, displaying an instructional prompt instructing a user to discard the drug delivery device.

77. The method of any one of claims 65 to 76, the drug delivery device comprising an autoinjector.

78. The method of any one of claims 65 to 77, the external computing device comprising at least one of a smartphone, a smartwatch, or a tablet computer.

79. The method of any one of claims 65 to 78, the first communication module being configured to communicate with the second communication module via at least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

80. The method of any one of claims 65 to 79, wherein the reservoir comprises a medicament.

81. The method of claim 16, the medicament being selected from the group consisting of: TNF inhibitors, antibodies to the calcitonin gene-related peptide receptor, granulocyte colony stimulating factors, erythropoiesis stimulating agents, apelin receptor agonists, antibodies to proprotein convertase subtilisin/kexin Type 9 (PCSK9), and tissue inhibitors of metalloproteinases.

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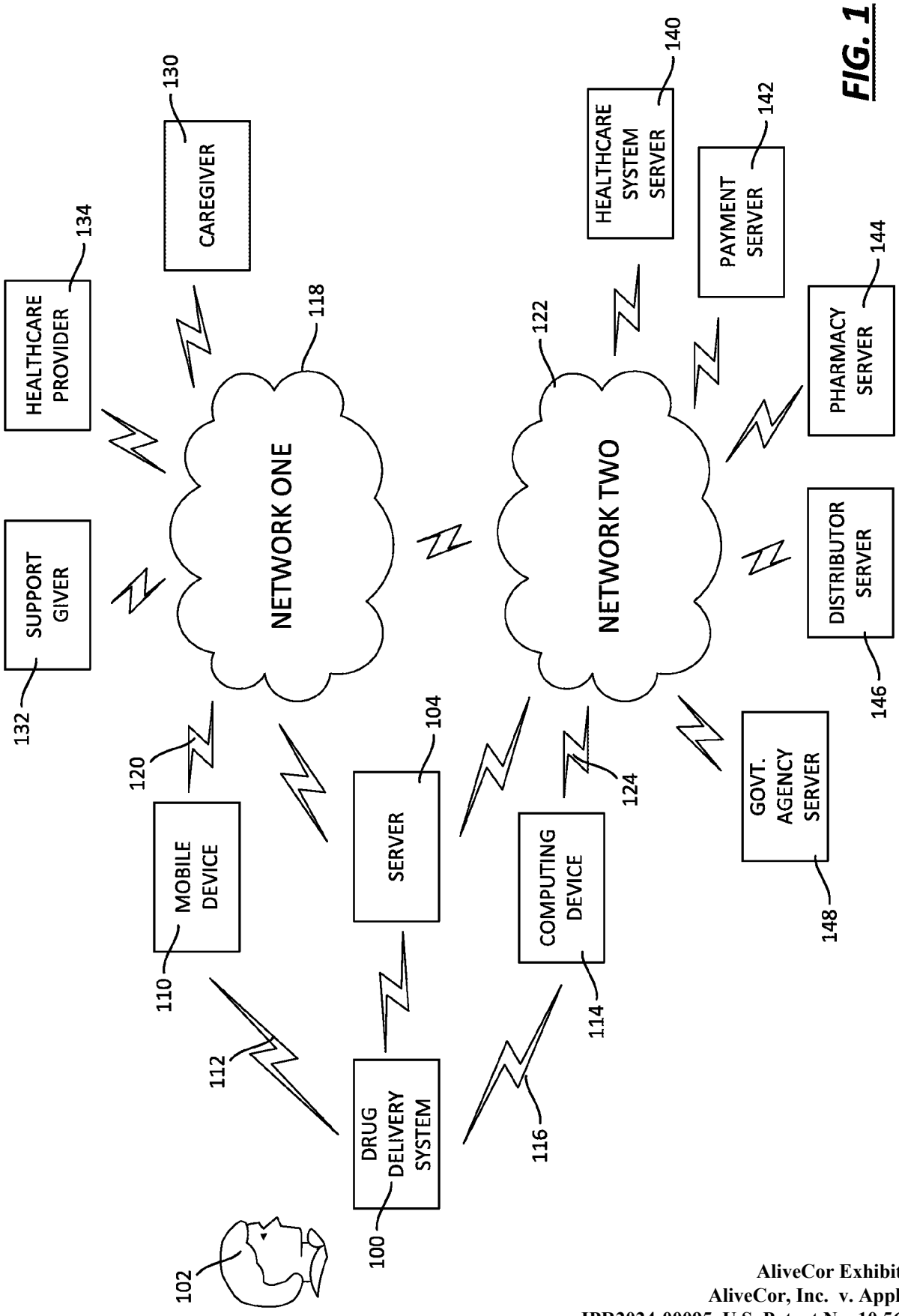

HEALTHCARE PROVIDER
134
CAREGIVER
130
HEALTHCARE SYSTEM SERVER
140
PAYMENT SERVER
142
PHARMACY SERVER
144
SUPPORT GIVER
132
NETWORK ONE
118
NETWORK TWO
122
DISTRIBUTOR SERVER
146
120
MOBILE DEVICE
110
SERVER
104
COMPUTING DEVICE
114
124
GOVT. AGENCY SERVER
148
112
DRUG DELIVERY SYSTEM
100
116
102

FIG. 1

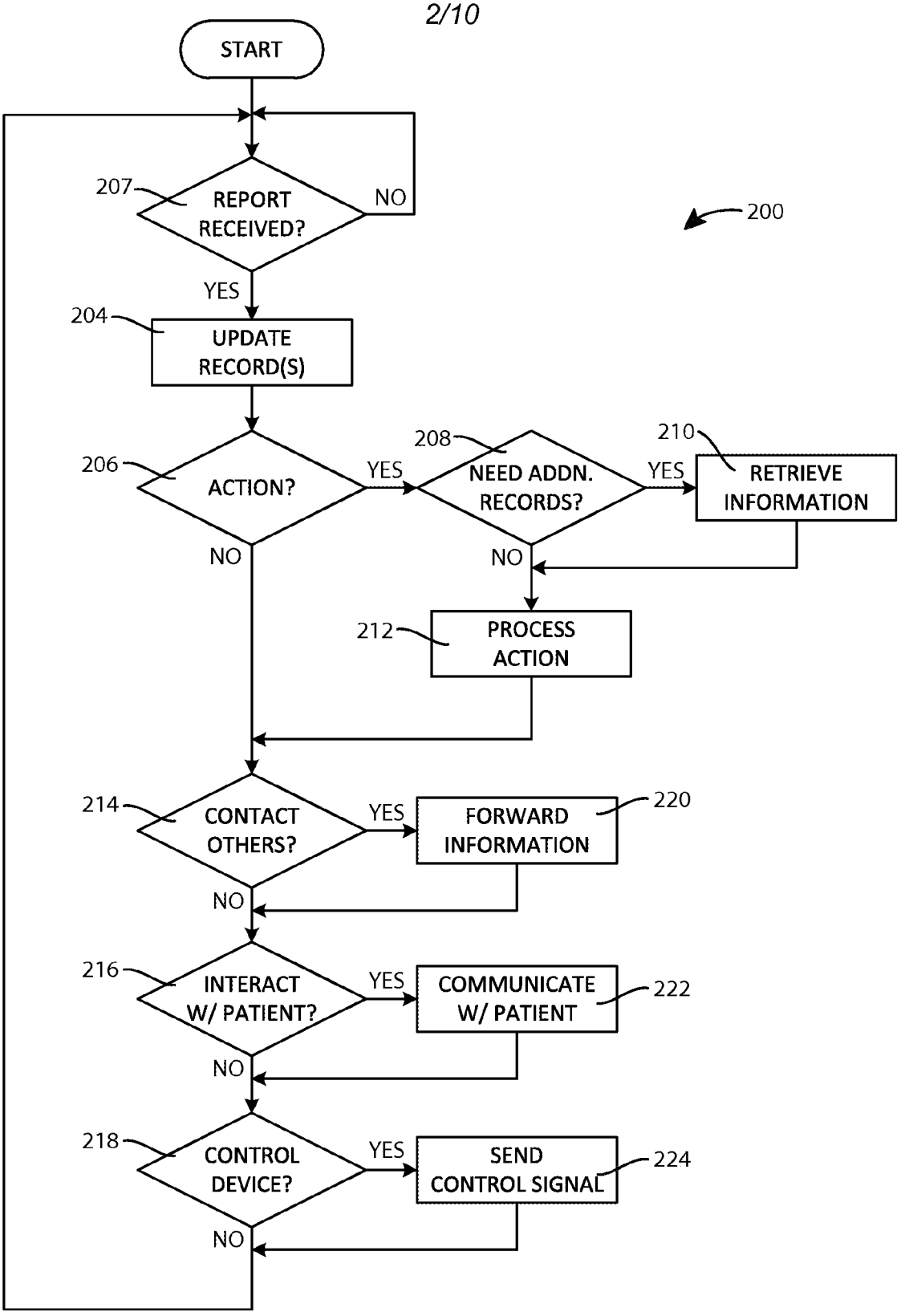

START
207
REPORT RECEIVED?
NO
YES
200
204
UPDATE RECORD(S)
206
ACTION?
YES
208
NEED ADDN. RECORDS?
YES
210
RETRIEVE INFORMATION
NO
NO
212
PROCESS ACTION
214
CONTACT OTHERS?
YES
FORWARD INFORMATION
220
NO
216
INTERACT W/ PATIENT?
YES
COMMUNICATE W/ PATIENT
222
NO
218
CONTROL DEVICE?
YES
SEND CONTROL SIGNAL
224
NO

FIG. 2

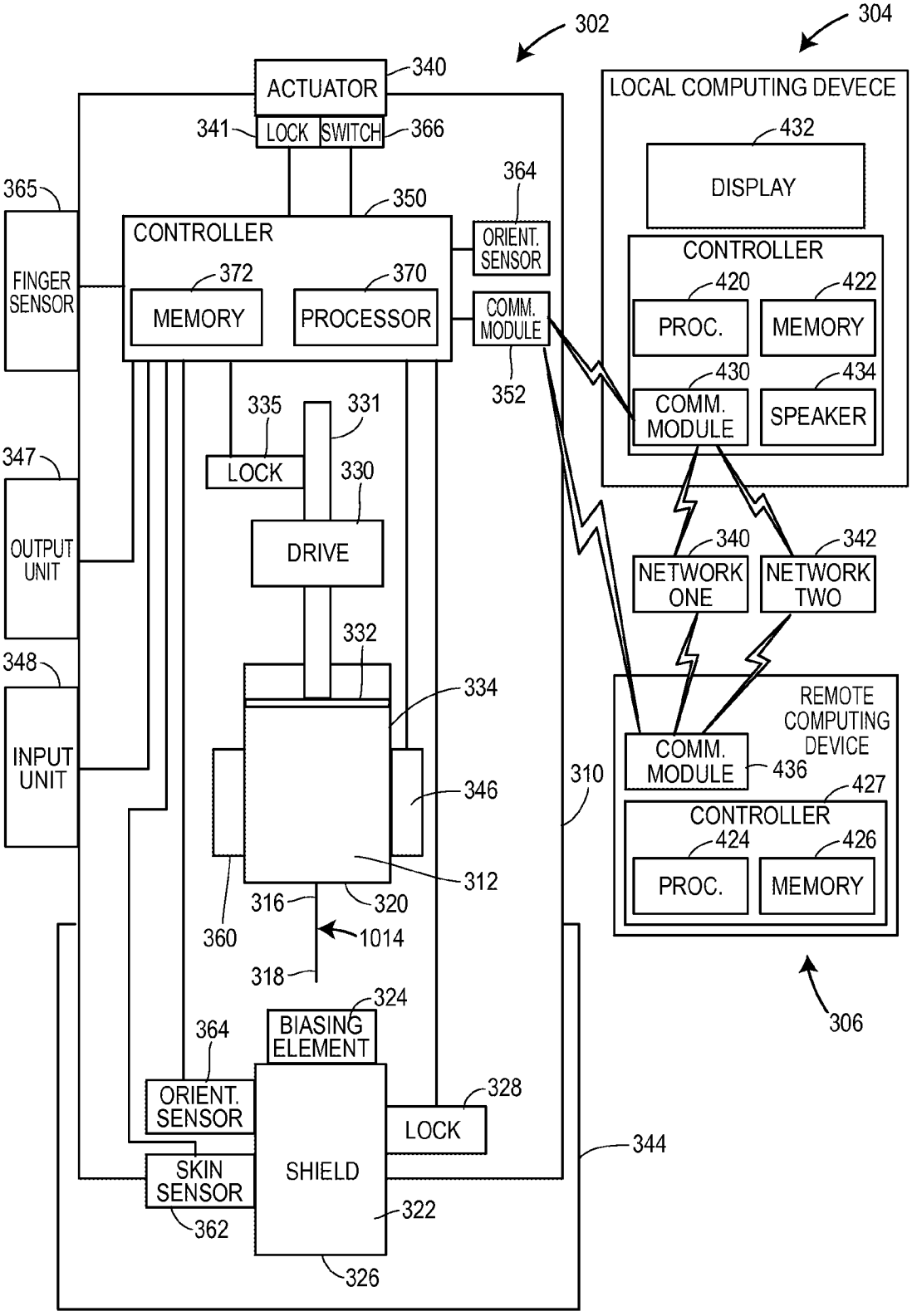


FIG. 3

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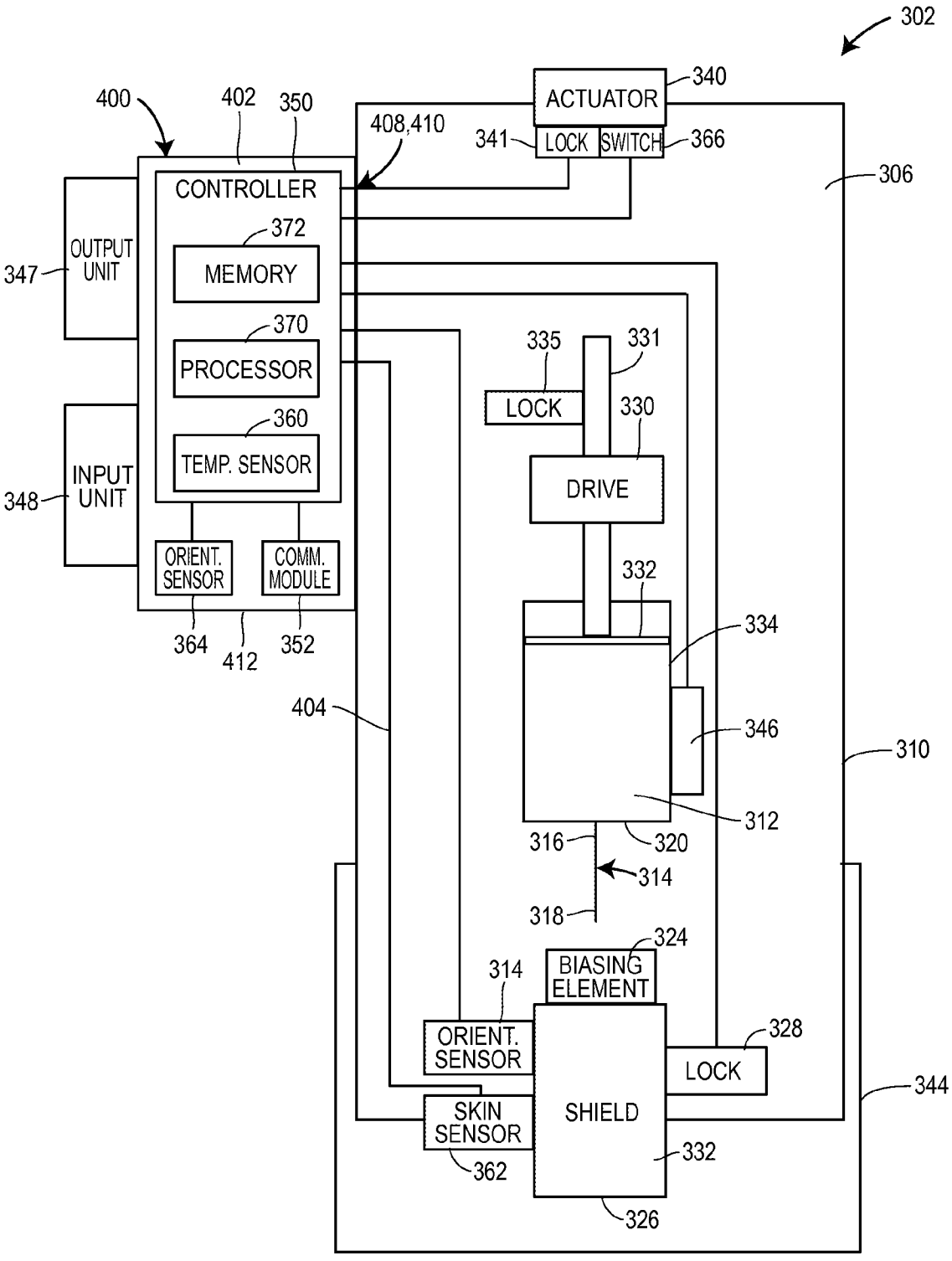

302
400
402
350
408,410
ACTUATOR
340
341
LOCK
SWITCH
366
306
CONTROLLER
372
MEMORY
OUTPUT UNIT
347
370
PROCESSOR
360
TEMP. SENSOR
INPUT UNIT
348
ORIENT. SENSOR
COMM. MODULE
364
412
352
335
331
LOCK
330
DRIVE
332
334
404
346
310
312
316
320
314
318
324
BIASING ELEMENT
314
ORIENT. SENSOR
328
LOCK
344
SKIN SENSOR
SHIELD
362
332
326

FIG. 4

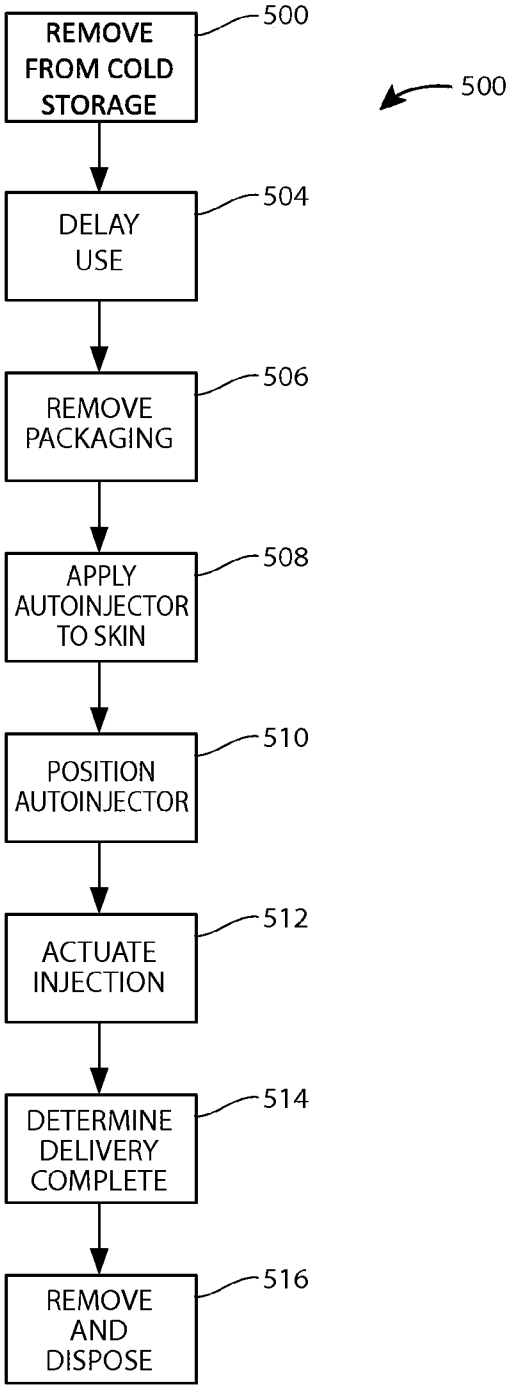

REMOVE FROM COLD STORAGE
500
500
DELAY USE
504
REMOVE PACKAGING
506
APPLY AUTOINJECTOR TO SKIN
508
POSITION AUTOINJECTOR
510
ACTUATE INJECTION
512
DETERMINE DELIVERY COMPLETE
514
REMOVE AND DISPOSE
516

FIG. 5

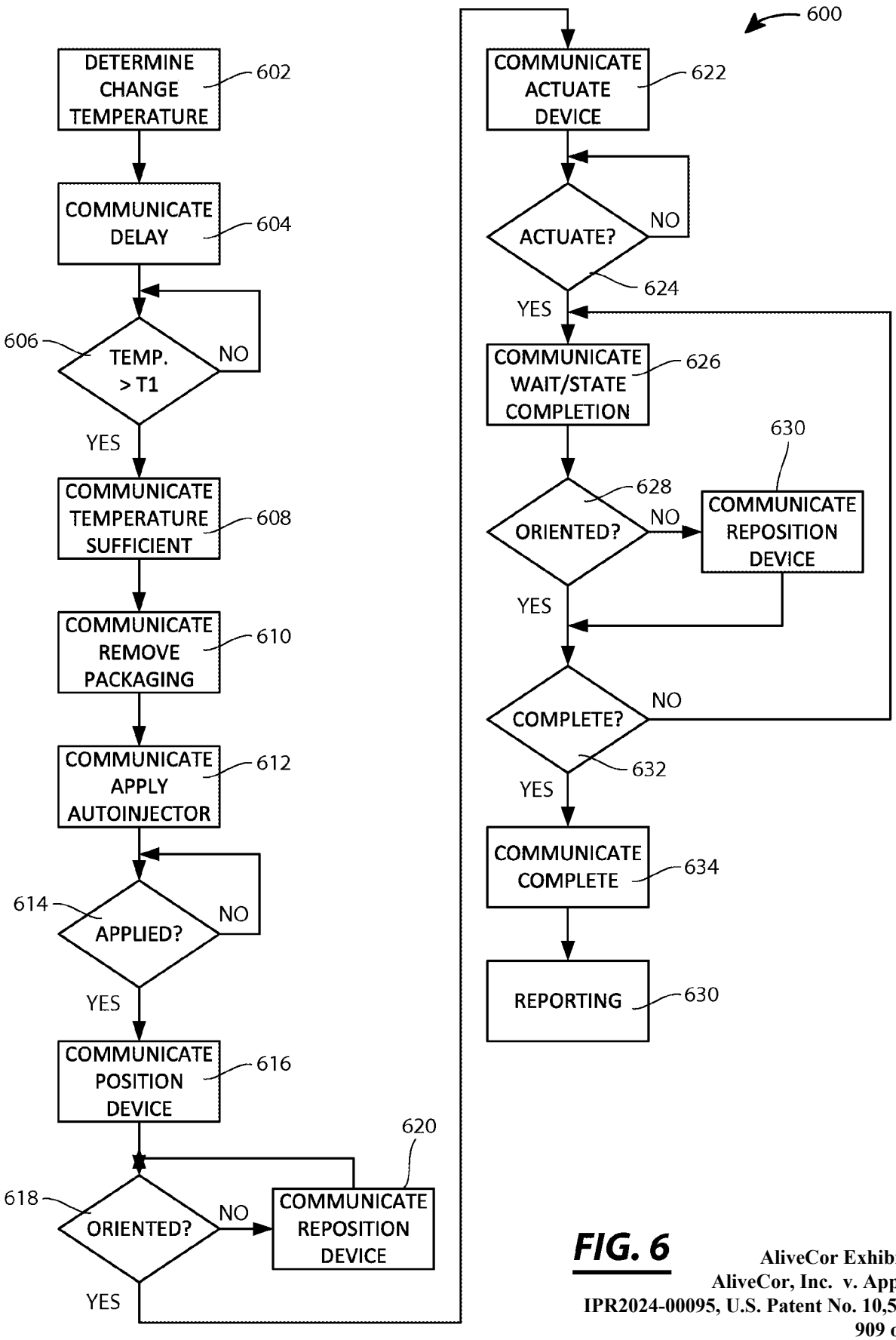


FIG. 6

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FIG. 7



FIG. 8

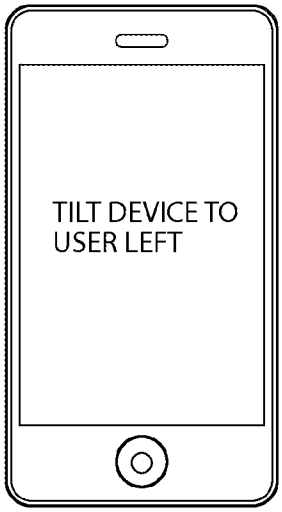


FIG. 9



FIG. 10



FIG. 11

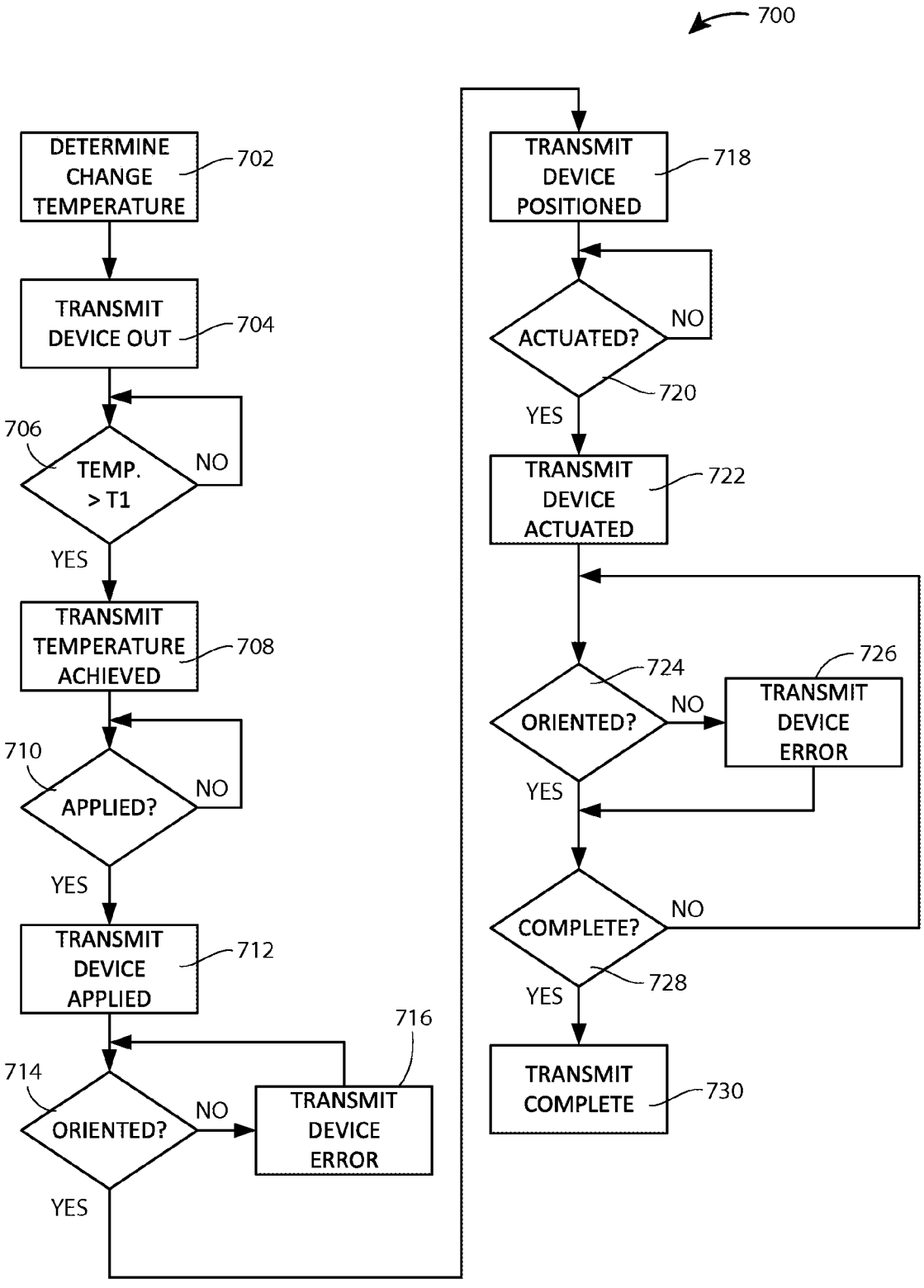


FIG. 12

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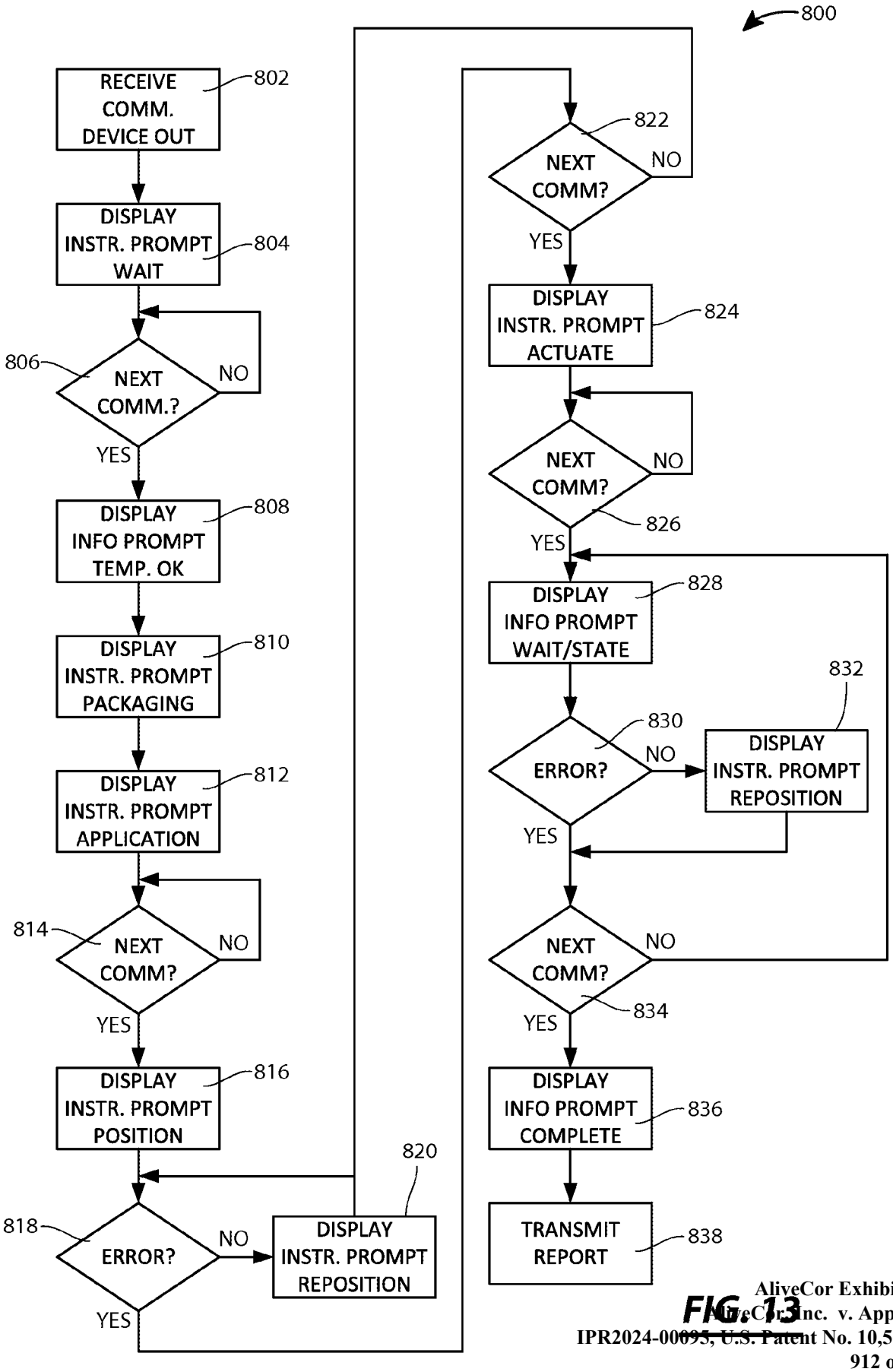


FIG. 13

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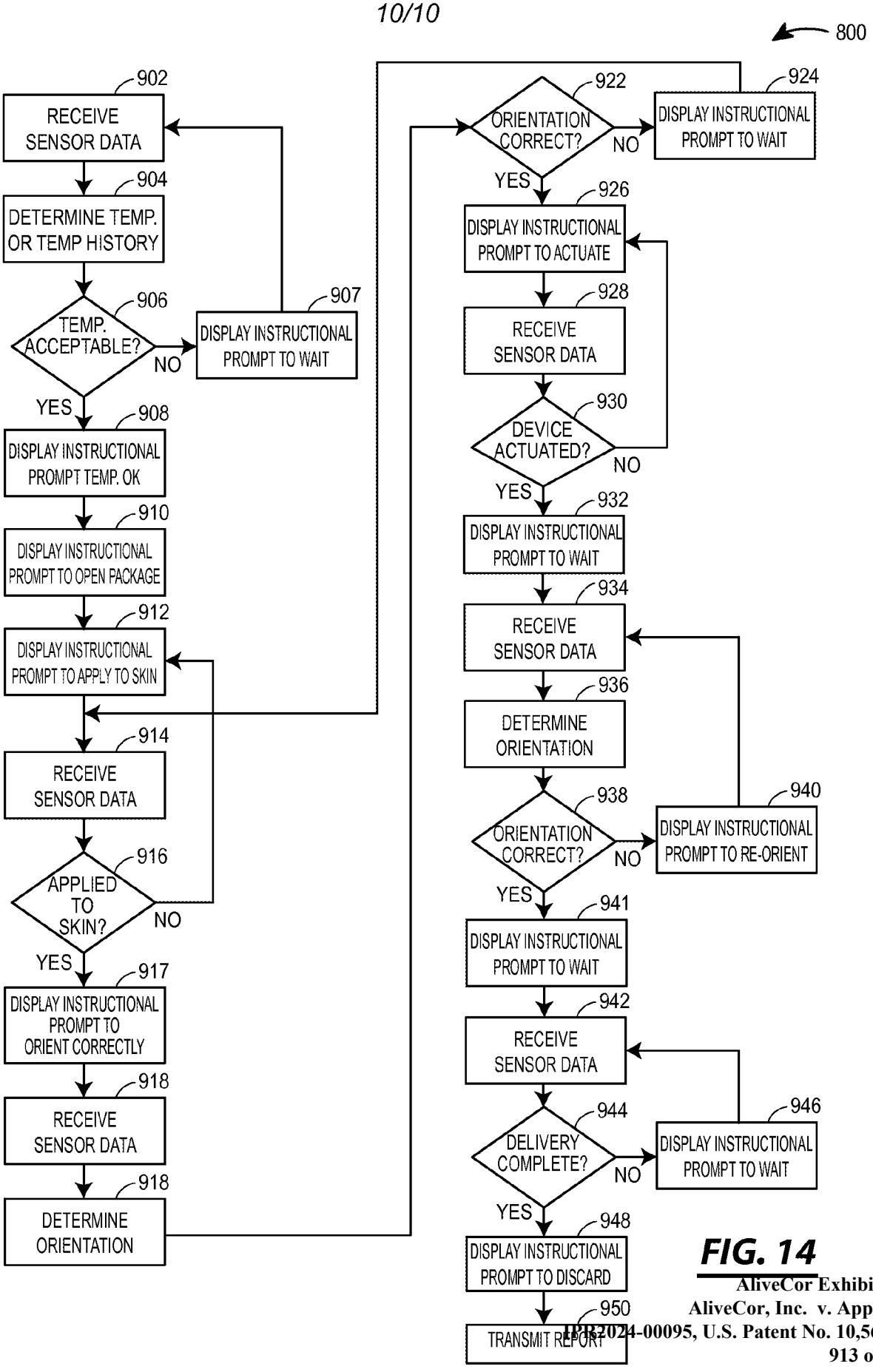

800
902
RECEIVE SENSOR DATA
904
DETERMINE TEMP. OR TEMP HISTORY
906
TEMP. ACCEPTABLE?
NO
907
DISPLAY INSTRUCTIONAL PROMPT TO WAIT
YES
908
DISPLAY INSTRUCTIONAL PROMPT TEMP. OK
910
DISPLAY INSTRUCTIONAL PROMPT TO OPEN PACKAGE
912
DISPLAY INSTRUCTIONAL PROMPT TO APPLY TO SKIN
914
RECEIVE SENSOR DATA
916
APPLIED TO SKIN?
NO
YES
917
DISPLAY INSTRUCTIONAL PROMPT TO ORIENT CORRECTLY
918
RECEIVE SENSOR DATA
918
DETERMINE ORIENTATION
922
ORIENTATION CORRECT?
NO
924
DISPLAY INSTRUCTIONAL PROMPT TO WAIT
YES
926
DISPLAY INSTRUCTIONAL PROMPT TO ACTUATE
928
RECEIVE SENSOR DATA
930
DEVICE ACTUATED?
NO
YES
932
DISPLAY INSTRUCTIONAL PROMPT TO WAIT
934
RECEIVE SENSOR DATA
936
DETERMINE ORIENTATION
938
ORIENTATION CORRECT?
NO
940
DISPLAY INSTRUCTIONAL PROMPT TO RE-ORIENT
YES
941
DISPLAY INSTRUCTIONAL PROMPT TO WAIT
942
RECEIVE SENSOR DATA
944
DELIVERY COMPLETE?
NO
946
DISPLAY INSTRUCTIONAL PROMPT TO WAIT
YES
948
DISPLAY INSTRUCTIONAL PROMPT TO DISCARD
950
TRANSMIT REPORT

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/033935

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F19/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/178462 A1 (MOBERG SHELDON B [US] ET AL) 21 July 2011 (2011-07-21) abstract; figures 1, 5, 8-11, 13,14,16 paragraph [0036] - paragraph [0047] paragraph [0104] - paragraph [0128] -----	1-81
A	US 2014/088554 A1 (LI PO-YING [US] ET AL) 27 March 2014 (2014-03-27) abstract figure 1 paragraph [0010] - paragraph [0012] paragraph [0029] - paragraph [0036] -----	1-81
A	US 5 658 250 A (BLOMQUIST MICHAEL L [US] ET AL) 19 August 1997 (1997-08-19) abstract column 3, line 25 - column 7, line 42 -----	1-81

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2015	12/08/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kürten, Ivayla

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/033935

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011178462 A1	21-07-2011	NONE	
US 2014088554 A1	27-03-2014	US 2014088554 A1	27-03-2014
		WO 2014047638 A1	27-03-2014
US 5658250 A	19-08-1997	AU 7323994 A	13-02-1995
		US 5658250 A	19-08-1997
		WO 9502426 A1	26-01-1995

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(19) World Intellectual Property Organization
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A61B 5/0408 (2006.01)

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PCT/US2016/025333

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31 March 2016 (31.03.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/140,671 31 March 2015 (31.03.2015) US

(71) Applicants: **UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION** [US/US]; 200 Gardner Steel Conference Center, Thackeray and O'hara Streets, Pittsburgh, PA 15260 (US). **UPMC** [US/US]; 600 Grant Street, Pittsburgh, Pennsylvania 15219 (US).

(72) Inventors: **MENDENHALL, George, Stuart**; 120 North Woodland Road, Pittsburgh, PA 15232-2849 (US). **JONES, Matthew**; 1 Gustave L. Levy Place, New York, NY 10029-5674 (US).

(74) Agent: **DUNCAN, Sandon, M.**; Klarquist Sparkman, LLP, One World Trade Center, Suite 1600, 121 SW Salmon Street, Portland, OR 97204 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: WEARABLE CARDIAC ELECROPHYSIOLOGY MEASUREMENT DEVICES, SOFTWARE, SYSTEMS AND METHODS

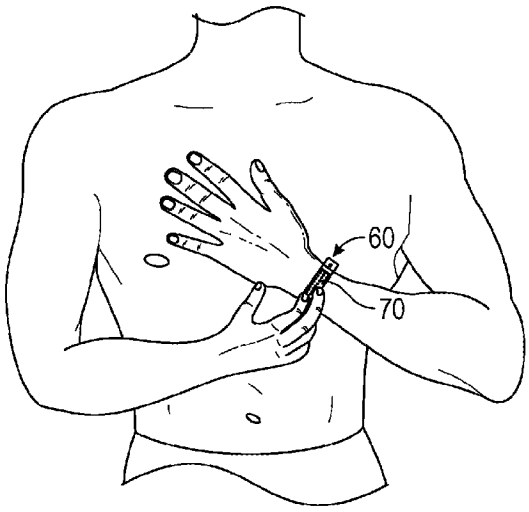


FIG. 18

(57) Abstract: Disclosed are wearable devices, such as rings and bracelets, for monitoring and diagnosing cardiovascular conditions of a wearer, along with related systems, algorithms and methods. The disclosed wearable devices can continuously monitor the wearer's cardiovascular status by measuring heart rate, motion, blood oxygenation, and/or other properties of the wearer. Disclosed wearable devices can further comprise three EKG electrodes, including a first electrode on the inner surface adapted to detect a signal from the finger/wrist, a second electrode on the outer surface adapted to detect a cardiovascular signal from a finger of the opposing hand, and a third electrode on the outer surface of the frame adapted to detect a cardiovascular signal from a EKG lead location on the wearer' s chest or leg. The wearable devices can be linked wirelessly to a mobile device that the person can interact with, and can further be linked to other distributed system components and healthcare providers.

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Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

WEARABLE CARDIAC ELECTROPHYSIOLOGY MEASUREMENT DEVICES, SOFTWARE, SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Patent Application No. 62/140,671, filed March 31, 2015, which is incorporated herein by reference in its entirety.

ACKNOWLEDGMENT OF GOVERNMENT SUPPORT

This invention was made with government support under (IIP-1449702) awarded by the (National Science Foundation) and with government support under (TR000005) awarded by the National Institutes of Health. The government has certain rights in the invention.

FIELD OF THE DISCLOSURE

This application relates to wearable electronic measurement and computing devices, and related systems, for use in cardiovascular healthcare.

BACKGROUND

Heart disease, stroke and other cardiovascular diseases are leading global causes of death. However, many cardiovascular diseases are preventable through early detection and treatment (e.g., of arrhythmia or atrial fibrillation), attention to genetic predisposition, nutrition, and activities of daily living. Multiple forces worsen the current situation, including the aging population, finite capacity to deliver care to at risk populations, the tendency to provide care in an episodic clinical environment as opposed to real-time continuous care delivery, and the pressure to reduce the cost of healthcare. The ratio of those needing care to those capable of providing care continues to rise resulting in a growing need for systems and tools capable of remote monitoring and care delivery to high risk populations.

Current wearable devices do not have the ability to reconstruct leads from a traditional 12 lead EKG. In addition, they lack the capacity to continuously monitor and evaluate events reflective of arrhythmias and other cardiovascular conditions. FDA cleared, non-invasive, ambulatory devices lack the ability for long term patient monitoring, potentially missing clinically relevant events.

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SUMMARY

The disclosed technology provides wearable devices and related systems and methods for monitoring and determining cardiovascular conditions of a wearer.

Disclosed wearable devices can comprise a wearable band (e.g., a ring or bracelet) comprising an annular or partially annular frame configured to be worn around a first body part of a person (e.g., a finger or wrist), the frame having an inner surface that faces the first body part and an outer surface that faces away from the first body part. The band can further comprise a first electrode on the inner surface of the frame adapted to detect a cardiovascular signal from the first body part, a second electrode on the outer surface of the frame adapted to detect a cardiovascular signal from a second body part of the wearer (e.g., a finger of the opposing hand) when the second body part is touched against the second sensor, and a third electrode on the outer surface of the frame, generally opposite from the second electrode, adapted to detect a cardiovascular signal from a EKG lead location on the wearer's body (e.g., the chest or leg) when the third electrode is touched against the EKG lead location while being worn on the first body part.

Some disclosed wearable devices can further comprise a sensor on the inner surface of the frame for measuring blood oxygen saturation of the wearer, a sensor on the inner surface of the frame for measuring bioimpedence of the skin of the first body part or dry skin potential between two separated points on the skin of the first body part, and/or other sensors on the inner surface of the device. Such sensors can be adapted to continuously monitor the wearer's cardiovascular status while the wearer is wearing the device to detect or predict cardiac arrhythmia or other cardiac abnormalities in the wearer.

Some disclosed wearable devices can simulate a 12-lead EKG by touching the third sensor to a plurality of EKG lead locations on the wearer's body while simultaneously touching the second body part to the second electrode. At each EKG location, the on-off status and polarity of each of the three electrodes can be configured to simulate one or more different traces of a conventional 12-lead EKG.

Also described herein are cardiac monitoring systems that can comprise any of the disclosed wearable device and a mobile computing device paired with the wearable device via wireless communication. The system can also include distributed elements, such as cloud servers, medical records databases, and computing devices associated with healthcare personnel associated with the person.

Some disclosed methods comprise: continuously monitoring a person's heart rate, motion, and/or blood oxygen levels using a device worn by the person; and based on the monitoring, determining potential arrhythmia in the person. The methods can further comprise determining that

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the person's heart rate is outside of a predetermined threshold range; assessing the level of the person's motion; determining whether purposeful motion is occurring, and/or determining whether blood oxygen levels are above or below a threshold value. Based on the assessments and determinations, the method can include prompting the person to input information regarding their symptoms. The methods can further comprise recommending treatment actions, such as vagal maneuvers, contacting related people with warning, sending alerts to the person, and/or notifying emergency services.

Some disclosed methods comprise: inducing a person to place a device worn by the person on a first body part against a first EKG lead location (e.g., chest or leg) on the person's body, such that a first electrode of the device contacts the first body part on which the device is worn and such that a second electrode of the device contacts the first EKG lead location, wherein the first body part is part of a first limb of the person (e.g., a finger or wrist); inducing the person to place a second body part against a third electrode of the device while the second electrode is in contact with first EKG lead location and the first electrode is in contact with the first body part, wherein the second body part is part of a second limb of the person (e.g., finger on opposite hand); and obtaining EKG signals from the person using the first, second, and third electrodes of the device. EKG signals obtained using such methods can simulate EKG signals obtained using conventional 12-lead EKG devices.

The foregoing and other features and advantages of the disclosed technology will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 show an exemplary wearable ring that includes sensors and other technology for measuring physiological properties of the wearer to monitor and/or diagnose cardiovascular health conditions.

FIG. 3 shows the ring of FIGS. 1 and 2 worn on a person's finger.

FIG. 4 shows a mobile computing device that can be linked with disclosed wearable devices to provide interaction with the wearer, provide computational and storage services, and/or communicate with other entities.

FIG. 5 shows a person with a ring on a finger touching a sensor of the ring to a lead location on the chest to measure cardiovascular properties of the wearer.

FIG. 6 shows a person with a ring on a finger touching a sensor of the ring with a finger of the other hand to measure cardiovascular properties of the wearer.

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FIG. 7 shows exemplary EKG lead locations on the human anatomy.

FIG. 8 is a flow chart illustrating an exemplary method wherein a person experiences symptoms, initiates cardiovascular measurement using the worn ring, and the data is transmitted to a health care provider for interpretation.

FIG. 9 shows an exemplary distributed system including a patient with a wearable device and a connected mobile computing device, a medical records database, and a health care provider, all in communication with one another.

FIG. 10 shows an exemplary distributed system including a wearable device, a mobile computing device, and a cloud based server system.

FIG. 11 shows an exemplary wearable ring that includes a detachable battery component that can be recharged using a wireless recharging station.

FIGS. 12-15 show an exemplary wearable bracelet that includes sensors and other technology for measuring physiological properties of the wearer to monitor and/or diagnose cardiovascular health conditions.

FIG. 16 is a flow chart illustrating an exemplary method wherein a person experiences symptoms, initiates cardiovascular measurement using the worn bracelet, and the data is transmitted to a health care provider for interpretation.

FIG. 17 is a flow chart illustrating an exemplary method wherein the worn bracelet determines that a cardiovascular event may have occurred and prompts the wearer to initiate cardiovascular measurement using the worn bracelet, and the data is transmitted via a linked mobile computing device to health care providers for interpretation and follow-up health care.

FIG. 18 shows a person wearing the bracelet of FIG. 12 touching a sensor of the bracelet to an EKG lead location on the chest and simultaneously touching another sensor of the bracelet with the opposite hand.

FIG. 19 shows an exemplary chart plotting heart rate data collected by a wearable device.

FIG. 20 shows exemplary charts plotting oxygen saturation data collected by a wearable device.

FIG. 21 shows an exemplary system comprising a bracelet and a ring worn on the same hand and linked together.

FIG. 22 is a diagram illustrating exemplary hardware components of the system of FIG. 21.

FIGS. 23-27 are various view of an exemplary wearable bracelet that includes sensors and other technology for measuring physiological properties of the wearer to monitor and/or diagnose cardiovascular health conditions.

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FIG. 28 shows an exemplary user interface related to a diagnostic algorithm based on measurements of a wearer's activity and heart rate.

FIG. 29 shows another exemplary user interface related to a diagnostic algorithm based on EKG lead measurements taken using a worn device.

FIGS. 30-38 are flow charts illustrating exemplary diagnostic algorithms disclosed herein.

DETAILED DESCRIPTION

Disclosed herein are wearable devices, related systems, and methods for monitoring, measuring, diagnosing, analyzing, storing and/or communicating cardiovascular health conditions, such as arrhythmia, coronary blockage, infarction, ischemia, bradycardia, tachycardia, stroke, etc., and related data for the person wearing the device. The wearable devices can include bands or other devices worn on or around various body parts, such as a finger, wrist, arm, ankle, leg, abdomen, chest, neck, and/or any combination thereof. Specific examples of wearable bands include rings, bracelets, watches, hand bands, arm bands, anklets, and leg bands. Related systems can include a mobile computing device operated by the wearer or another person associated with the wearer, such as smartphones, tablet computers, personal computers, etc. Related systems can further include distributed elements, such as cloud based servers, health records databases, emergency service providers, relatives or other contacts, and/or health care providers. The wearable device and/or other system components can include processors, memory, wired and wireless communication systems, power supplies and recharging means, user interface devices, and/or other components. Further, various software programs, algorithms, firm wear, computer readable media and storage devices, and/or other means for storing or accessing computer readable instructions for implementing disclosed algorithms and methods can be included in the disclosed technology.

The disclosed wearable device can include sensors and/or other technology configured to measure or determine various characteristics and signals associated with the physiological properties of the wearer and electrophysiological or electromyography functions of the human heart and cardiovascular system. Exemplary sensors can include sensors for measuring heart rate, oxygen saturation levels of blood, blood pressure, EKG signals, temperature, electrical transmissivity of the skin, physical multi-axis motion and acceleration of the wearer orientation of the wearer, location of the wearer, time, and/or other properties and activities of the wearer. For example, the device or system can calculate algorithmically blood pressure using methods correlating systolic blood pressure and applying techniques such as Pulse Transit Time (PTT) and Pulse Wave Velocity (PWV). Such information can be recorded, analyzed, stored, and/or

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communicated to other system components. The wearable devices sensors may comprise, for example, an infrared emitter-detector pair to measure blood oxygen saturation, PTT, and/or PWV, galvanic skin sensors, a silver nanowire to measure bioimpedence or dry skin potential between two separated points on the body, a multi-axis accelerometer, a magnetometer, a gyroscope, a heat flux sensor, GPS device, and/or various other sensors.

The cardiac electrophysiology measurement and condition management system, tools, devices, and methods disclosed herein can enable profiling, customization, and/or personalization of a window which defines, on an individual basis, an aberrant or life threatening event which could trigger an alert to 911, EMS or other caregiver. Measured and/or determined characteristics of the wearer can be compared to analogues to medical standards, such as sinus rhythm standards including the PR Interval, the PR Segment, the QRS Complex, the ST Segment and/or the QT Interval, to determine the existence of an aberrant or life threatening event or condition.

Disclosed devices can also include various user interface features, such as a display, hard and/or soft input panels, vibration or haptic notification devices, audio notification devices, lights or other visual notification devices, microphones or audio receivers, and wireless communication systems such as wifi, Bluetooth, Bluetooth Low Energy, near-field RF, cellular, etc. Disclosed devices and systems may also include voice activation and interaction capabilities utilizing voice recognition functionality, such as SIRI or Dragon Voice recognition software, which can be used for example to initiate an "I need help" sequence triggering an alert to 911, EMS or other caregiver action.

In some embodiments, feedback regarding aggregate clinical status is immediately relayed to the patient for change in medical therapy based on the cardiac rhythm observed from the device at the current time or via specified integrative criteria of past time. This may occur without use of any ancillary devices and communicated by the device itself via flashing indicator, color change, tactile alert, or other indicator.

Disclosed methods can include continuous monitoring and/or automated detection of aberrant or life threatening changes in heart rate, motions, oxygenations, and/or other characteristics, reflective of arrhythmic events, derived from combining and processing multiple inputs from the wearable devices. Some disclosed methods can include real time synthesis of any one, multiple selected, or all of the traces of a full 12 lead EKG set using signal-averaged techniques and algorithms by touching of the wearable device(s) to different parts of the body and incorporating any or all of the resident sensors. For example, in an exemplary method, upon sensing a potential arrhythmia, the wearer can generate a full 12-lead EKG using electrodes in the ring/bracelet and visual cues from a paired smart phone application, whereupon the smart phone

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application assesses the EKG data and/or transfers EKG data to a cloud based server for assessment. Abnormal EKG strips can then be delivered to pre-designated healthcare providers and/or emergency personnel. In addition, warning messages can be delivered to family members or other associates of the wearer.

Some methods can include aggregation and analysis of non-patient specific data sets to identify high risk individuals, inform population management methods, enhance the standard of care and/or provide timely coaching and behavioral modification cues.

FIGS 1 and 2 illustrate one exemplary wearable ring 10 according the disclosed technology. The ring 10 includes an annular frame or body 12 having an inner surface that faces the skin of the finger and an outer surface facing away from the finger, an inner electrode 14 on the inner surface, a palmar electrode 16 on the outer surface, a dorsal electrode 18 on the outer surface, a pulse oximetry sensor 20, a galvanic skin sensor 22, and a button 24 that can be pressed to activate various functions of the ring, such as initiating an algorithms or synching the ring to a computing device via Bluetooth or other wireless means. FIG. 3 shows the ring 10 worn on a patient's finger with the dorsal electrode 18 at the back side of the hand and the palmar electrode 16 at the palm side of the hand.

FIG. 4 shows an exemplary mobile computing device 30 (e.g., smart phone, tablet, etc.) that can be linked to the ring 10 via wireless communication means and can be used by the patients or another person to interact with the system. The device 30 can include interface devices such as a display that provides prompts or instructions 32 to the wearer. In FIG. 4, for example, the device 30 is prompting the wearer of the ring 10 to place a finger from the opposite hand on the dorsal electrode to initiate a diagnostic sequence, in response to a cardiovascular event having been possibly detected.

FIG. 6 shows the wearer placing a finger of the opposite hand on the dorsal electrode 18 of the ring 10 to carry out a two-electrode measurement/diagnostic process. In the position of FIG. 6, the inner electrode 14 is also touching the skin of the finger on which the ring is worn, but the palmar electrode 16 is not active.

FIG. 5 shows another position wherein the person wearing the ring 10 places the palmar electrode 16 of the ring 10 against his chest, for example at a precordial lead location. In this position, the inner electrode 14 is also touching the skin of the finger on which the ring is worn, but the dorsal electrode 16 is not active. The positions of FIGS. 5 and 6 can be combined in a position wherein the palmar electrode 16 is touching the patient's chest/leg/other body part and the patient has one or more fingers from the opposite hand touching the dorsal electrode 16, such that all three electrodes 14, 16, 18 are in contact with different parts of the patient's body can be used

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simultaneously. Depending on the purpose and/or what part of the body the palmar electrode 16 is touching, the three electrodes 14, 16, 18 can be controlled and utilized in different combinations and manners, including switching the polarity of each electrode as needed for various measurement/diagnostic purposes. FIG. 7 shows the locations of several EKG lead locations to which the palmar electrode 16 can be touched to measure specific EKG lead data. A full 12 lead EKG data set can be determined from as few as four or five precordial lead readings, for example.

FIG. 8 shows an exemplary user-initiated method wherein a person notices symptoms at 34, the user initiates a measurement process by touching the dorsal electrode 18 with a finger at 36, the ring 10 measures and collects data at 38, and the data is sent to a healthcare provider for analysis and interpretation at 40. The healthcare provider can then determine appropriate subsequent actions, such as further testing, emergency care, etc.

FIG. 9 shows an exemplary distributed system that includes the patient 42 wearing the ring 10 or other disclosed wearable device and utilizing a smart phone to communicated data to and from a medical records database or other information source/server 44 and a physician or other healthcare provider 46. The healthcare provider 46 can interpret the data generated by the wearable device along with other patient data and non-patient information and instruct the patient accordingly.

FIG. 10 provides a schematic diagram of an exemplary distributed system 50 that includes a wearable device, a smartphone, and a cloud based server. The wearable device in the system 50 can include various components, such as a central processing unit (CPU), a galvanic skin response sensor, an analog to digital EKG convertor, a pulse oximetry module, an accelerometer, a haptic driver motor, RAM storing various algorithms (such as for arrhythmia detection, R-R atrial fibrillation detection, fitness algorithms, fall detection algorithms, and/or stair climbing vs. walk discrimination), sandbox RAM, an LED module, firmware, and/or a Bluetooth receiver (or other wireless communication means). The smartphone of the system 50 can include related applications, such as for fitness parameter tracking, text messaging and phone notification, and video/audio/haptic prompts for actions (e.g., EKG lead generation). The cloud based server of the system 50 can include various applications and data storage, and can carry out various methods, such as EKG interpretation, routine baseline EKG intervals and morphology assessment, etc.

FIG. 11 illustrates an exemplary wearable ring device that includes a main ring portion 52 (similar to the ring 10 described herein) and a detachable battery portion 54. For example, the batter portion 54 can include an indicator 56 to show when it is running low on power and needs to be recharged. The battery portion 54 can be detached from the main portion 52 can recharged by placing the battery portion in proximity to a wireless recharging station 58, for example. The main

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portion 52 can include a secondary power supply, so that the device can remain continuously active even when the detachable battery portion 54 is detached and being recharged. Analogous embodiments of wearable bracelets and other wearable devices can similarly include detachable and rechargeable battery portions.

FIGS. 12-15 illustrate an exemplary wearable bracelet 60 that can be worn on a patient's wrist (or as a band at other locations such as the arm, ankle, or leg) and that is similar to the ring 10 in function. The bracelet 60 comprises an annular frame or body 62 (e.g., TPU, hypoallergenic rubber, or other flexible material) having an inner surface that faces the skin of the wrist and an outer surface facing away from the wrist, an inner electrode 66 on the inner surface, a dorsal electrode 70 on the outer surface (FIG. 14), a palmar/ventral electrode 76 (FIG. 15) on the outer surface, a pulse oximetry sensor and/or a galvanic skin sensor 68 on the inner surface, a display 72, and a button 74 that can be pressed to activate various functions of the bracelet, such as initiating an algorithms or synching the bracelet to a computing device via Bluetooth or other wireless means. The electrodes 66, 70, 76 can include copper/gold/platinum plating or other surface material of high electrical conductivity. The electrodes can also include small bumps or teeth to improve electrical signal detection. The bracelet 60 can include an adjustable clasp 64 to secure snuggly it around the wrist and ensure the inner electrode 66 and sensors 68 are adjacent to the skin. FIG. 18 shows the bracelet worn on a patient's wrist with the dorsal electrode 70 at the back side of the wrist and the ventral electrode 76 at the underside of the wrist.

FIG. 16 shows an exemplary user-initiated method wherein a person wearing the bracelet 60 notices symptoms at 80, the person initiates a measurement process by touching the dorsal electrode 70 with a finger at 82, the bracelet 60 measures and collects EKG and other data at 84, and the data is sent to a healthcare provider for analysis and interpretation at 86. The healthcare provider can then determine appropriate subsequent actions, such as further testing, emergency care, etc.

FIG. 17 shows an exemplary device-initiated method wherein the bracelet 60 (e.g., while continuously monitoring a wearer) determines that a cardiac event may have occurred at 88, the bracelet communicates to a mobile device that displays instructions to the wearer to initiate diagnostic actions at 90, the wearer initiates a measurement process by touching the dorsal electrode 70 with a finger at 92, the bracelet 60 measures and collects EKG and other data and transmits the data to the smart phone at 94, and the data is sent to a healthcare provider or other analyst for analysis and interpretation at 96. A healthcare provider can then determine appropriate subsequent actions at 98, such as further testing, emergency care, change is lifestyle, etc.

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FIG. 18 shows the wearer placing the ventral electrode 76 against an EKG lead location on his chest while simultaneously touching the dorsal electrode 70 with his fingers. This position can be part of an EKG data collection method wherein the patient repeats a similar actions while touching the ventral electrode to various different EKG lead locations on his body. Depending on the purpose and/or what part of the body the ventral electrode 76 is touching, the three electrodes 66, 70, 76 can be controlled and utilized in different combinations and manners, including switching the polarity of each electrode as needed for various measurement/diagnostic purposes. FIG. 7 shows the locations of several EKG lead locations to which the ventral electrode 76 can be touched to measure specific EKG data.

FIG. 19 is a chart showing exemplary EKG data that can be measured and utilized by the disclosed wearable devices. FIG. 20 includes two charts showing exemplary pulse oximetry data that can be measured and utilized by the disclosed wearable devices. The disclosed device can be capable of measuring EKG and pulse oximetry data at a high level of precision that is sufficient for interpretation using various interpretation techniques and/or at least as precise as data typically obtained by EKG equipment used in a hospital, emergency facility, or by emergency personnel outside of a medical facility.

FIGS. 21 and 22 illustrate an exemplary system 106 that includes both a wearable ring 108 and a wearable bracelet 110. The ring and bracelet can be linkable via wireless communication and/or linkable via wired connection 112 as shown. In such a system, the ring 108 can be made more compact and comfortable as the ring 108 can include fewer components compared to the ring 10 disclosed herein. Some of the hardware components can be relocated from the ring to the bracelet 110, such as computing, storage, power source, and/or communication components. The ring 108 can still include some component, such as one or more electrodes (e.g., an inner electrode and/or one or two outer electrodes, and optionally a pulse oximetry sensor and/or a galvanic skin sensor). The bracelet 110 can include any of the components disclosed herein in relation to the ring 10 or bracelet 60, for example. The ring and bracelet can operate together to carry out any of the various functions and methods disclosed herein.

FIGS. 23-27 illustrate another exemplary bracelet 120 that can function similar to either of the bracelets 60 and 110 disclosed herein. The bracelet 120 includes a frame 122 coupled to straps 124 for securing around the wrist or arm. The frame 122 can house various components, including a display 126, button 128 for initiating action and/or synching to a mobile device or a ring, a I/O port 130 for wired connection to other devices such as a ring or battery charger, an inner panel 131 that faces the skin of the wrist and includes various sensors/electrodes 132/134/136 (e.g., EKG electrode, pulse oximetry sensor, galvanic skin sensor, etc.), a battery 138, a removable

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memory/storage device 140, a processor, wireless communication device, and/or various other mechanical/electronic/computing devices. The bracelet 120 may lack one or both of the outer electrodes of the bracelet 60, and instead a paired ring can include such electrodes. In use, a wearer may touch their ringer to an outer dorsal electrode on either the bracelet 120 or a paired ring. Similarly, the wearer may touch a palmar electrode on a paired ring to EKG lead locations rather than using an electrode on the bracelet for that purpose. A paired ring can be charged via wired connection to the I/O port on the bracelet, by wireless charging, or other means.

FIG. 28 shows an exemplary user interface, such as can be displayed on a paired mobile computing device or a healthcare providers computer, which indicates an activity assessment 150, a heart rate assessment 152, an EKG waveform readout 156, and a resulting message 154 that include a diagnosis, prompt for further actions, recommendations for activity modifications, etc.

FIG. 29 shows another exemplary user interface, such as can be displayed on a paired mobile computing device or a healthcare providers computer, which indicates a first electrode status 160, a second electrode status 162, a third electrode status 164, and a list of producible leads 166 based on the electrode statuses 160/162/164. The list 164 can indicated which EKG leads can be produced using the wearable device with the three electrodes in the current polarity status. In the illustrated example, electrode 1 has a negative polarity, electrode 2 is off, and electrode 3 has a positive polarity. In this configuration, the wearable device can be used to produce EKG lead II. By adjusting the polarity status of the three electrodes of the wearable device, all 12 of the conventional EKG leads can be produced by the wearer while touching the device to the different lead locations in sequence. The user interface can instruct the wearer wear on the body to place the palmar/ventral electrode for each EKG lead measurement, and the software of the device/smartphone can determine how to adjust the polarity status of each electrode for each EKG lead location.

FIGS. 30-38 are flow charts that illustrate various exemplary algorithms/methods that can be performed by the disclosed wearable devices, mobile computing devices, and/or other system components. The illustrated algorithms can be used to continuously monitor a patient to look for possible cardiac event and help predict or warn of possible future cardiac events before they occur so that the wearer can avoid the events, reduce the effects of the events, and/or seek health care or other help in a minimal amount of time. Cardiac events that can be predicted before they occur and/or sensed while or after they occur include arrhythmia, atrial fibrillation, coronary blockage, ischemia, infarction, tachycardia, bradycardia, stroke, etc.

FIG. 30 illustrates a method wherein the wearable device continuously monitors the wearer's heart rate (e.g., using a bioimpedence heart rate sensor), with optional spot SPO2 sensor

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confirmation (e.g., dual peak detection), to determine if the heart rate is at least 100 bpm for at least 30 seconds. Different threshold values for the bpm and period can be used as appropriate. If the measured heart rate does not meet the threshold values, then the device/system can continue to monitor the wearer. If the measured heart rate does meet the threshold values, then motion assessment can be performed (e.g., in 30 second intervals). The motion assessment can be performed using sensors such as accelerometer, gyroscope, GPS, etc. The result of the motion assessment can be one of several threshold ranges, such as no motion, mild intensity (greater than X m/s but less than Y m/s), moderate intensity (at least Y m/s but less than Z m/s), or high intensity (at least Z m/s), as illustrated.

As illustrated in FIG. 31, if moderate or high intensity is detected, the method can check if the motion is sustained for a certain time, such as at least one minute. If not, the method can continue surveillance of the wearer. If the high/moderate motion is sustained, then the method can check if the wearer's heart rate exceeds their maximum age-predicted heart rate (MAPHR), e.g., greater than 220 minus their age in years. If the heart rate does not exceed the MAPHR, then the method can continue surveillance of the wearer. If the heart rate does exceed the MAPHR, then the method can determine that potential arrhythmia has been detected. Similarly, if the motion assessment results in no motion or mild motion while the heart rate is elevated, then the method can determine that potential arrhythmia has been detected. When potential arrhythmia is detected, the method can cause the system to deliver a prompt to the wearer (e.g., waiting for 30 seconds for the wearer to respond). If no response is submitted by the wearer, the method can check if the wearer's heart rate and motion are undetectable, and if so it can deliver a prompt and message a designated emergency contact. If the heart rate is undetectable and purposeful motion is sensed, then the method can cause a troubleshoot sensor prompt. If heart rate is still elevated, the method can deliver a prompt to the wearer and message a designated contact.

As illustrated in FIG. 32, if potential arrhythmia is detected and a response to the symptom prompt is submitted by the wearer indicating the wearer is experiencing symptoms, then the method can check if arrhythmia is still detected. If not, the event can be logged. If arrhythmia is still detected, then the method can log the event and continue surveillance and reassess symptoms every so often, such as every five minutes, for a certain number of times, such as two times. The method can also prompt the wearer to touch the wearable device to generate an EKG rhythm strip analysis. If after a period of time, such as five minutes, the wearer's heart rate is still elevated, if symptoms not reported, the method can wait another five period of time and check for symptoms again, and if the heart rate is still elevated after two periods of time, such as 10 minutes, the method can recommend vagal maneuvers, medical attention, and/or optionally messaging a designated contact.

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If symptoms are reported at any step after the potential arrhythmia is detected and the wearer is prompted for symptoms, the method can check if arrhythmia is still detected. If not, the event can be logged. If arrhythmia is still detected, then the method can recommend vagal maneuvers (e.g., with a video demonstration on a smartphone), medical attention, and/or optionally messaging a designated contact. The method can also prompt the wearer to touch the wearable device to generate EKG analysis.

As illustrated in FIG. 33, after recommending vagal maneuvers, medical attention, and/or messaging a designated contact, the method can determine if the arrhythmia is aborted, in which case the event can be logged and close medical follow up can be recommended, or if arrhythmia is still detected, in which case the method can recommend immediate medical attention and message a designated contact. The method can continue to periodically prompt the wearer to touch the wearable device to generate EKG analysis.

As illustrated in FIG. 34, if a message is sent to a designated contact, and no response is acknowledged (e.g., by a reply text), then the method can wait for a period, such as two minutes, and re-send the message to the designated contact. If still no response is received, the method can cause a message to be sent to a secondary contact, and so on until a response is received.

FIG. 35 illustrates a method wherein the wearable device continuously monitors the wearer's heart rate (e.g., using a bioimpedence heart rate sensor), with optional spot SPO2 sensor confirmation (e.g., dual peak detection), to determine if the heart rate is less than 50 bpm, optionally over a certain period. Different threshold values for the bpm and period can be used as appropriate. If the measured heart rate drops below the threshold value, then motion assessment can be performed (e.g., as described above with FIG. 30). If no purposeful movement is detected (e.g., less than X m/s for at least Y seconds), then the method can measure the wearer's blood oxygen level using pulse oximetry. If the oxygenation is at least 90%, the method can determined the wearer is likely asleep and active sleep mode, in which the method can continue surveillance of the wearer until motion is detected. If oxygenation is less than 90%, the method can deliver a vibratory and/or audible alert to the wearer to establish wakefulness, and record the event. If an input from the wearer is then received, the method can recommend routine medical follow-up if they wearer is symptom free. If no input is received from the wearer in response to the alert, the method can message a designated contact, such as 911.

If the method detects purposeful movement (e.g., at least X m/s for at least Y seconds), the method can deliver a symptom prompt to the wearer. If no response is submitted to the prompt, the method can check if the wearer's heart rate and motion are undetectable, and if so it can deliver a prompt to the wearer and message a designated emergency contact. If the heart rate is

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undetectable/uninterpretable, then the method can cause a troubleshoot sensor prompt. If the heart rate is still low, the method can re-deliver a symptom prompt to the wearer.

As illustrated in FIG. 36, if the heart rate is low, purposeful movement is detected, and the wearer responds to the symptom prompt that the wearer is experiencing symptoms, the method can check if a low heart rate event is still detected. If not, the event can be logged, and if so, then the method can recommend medical attention and optionally message a designated contact. If the wearer responds to the symptom prompt that no symptoms present, the method can check if a low heart rate event is still detected. If not, the event can be logged and the method can optionally provide the option of lowering the minimum heart rate threshold (such as from 50 bpm to a lower rate). If the heart rate is still low, the event can be logged and the method can continue surveillance and reassess for symptoms every five minutes, or other interval. If after 10 minutes, or other interval, if still no symptoms are detected and the heart rate is still low, the method can determine that an asymptomatic bradycardia event is likely occurring. In that case, the method can optionally message to a designated contact or medical personnel. The method can optionally provide the option of lowering the minimum heart rate threshold (such as from 50 bpm to a lower rate).

FIG. 37 illustrates a method of irregular rhythm detection over a prolonged period, such as 24 hours, using normalized absolute difference (NADiff) of continuous RR interval input (see WO 2009124187 A1, for example, for more information regarding the NADiff of continuous RR intervals, which is incorporated herein by reference). If a normal NADiff is detected, the method can continue periodic irregular rhythm assessment, such as every 24 hours. If an abnormal NADiff is detected, the method can prompt the wearer to check for any symptoms the wearer experienced during the prior time period, such as the last 24 hours. If not symptoms are reported, then the method can recommend routine medical follow-up evaluation, and if symptoms are detected, the method can recommend rhythm assessment with symptom onset and medical follow-up.

FIG. 39 illustrates a method following chest pain or palpitations experienced by the wearer, either following a prompt for symptoms or otherwise. If the wearer experiences chest pains or palpitations, the wearer can input that information using a smartphone app, or other input means. The method can assess the symptoms of the wearer and initiate a symptom assessment mode. The method can then cause the smartphone, or other device, to display videos/pictures/text instructions demonstrating placement of the wearable device at a series of EKG lead points on the wearer's body to produce a 12 lead EKG report, or other EKG report. The instructions provided to the wearer can give step-by-step instructions of where to place the palmar/ventral electrode against the wearer's body, how long to hold it, etc. The method can also control which of the electrodes to turn on for each lead placement and what polarity each electrode has for each lead placement.

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Once the EKG data is receive, the method can assess the EKG data to determine if the EKG data is normal, abnormal, or uninterpretable. If the EKG data is abnormal, the method can recommend immediate medical attention and optionally transmit the EKG data to a designated healthcare provider. The method can also prompt the wearer for a message to a designated personal contact. If no user response is received, the method can try again, or else send a message to a secondary designated personal contact. If the EKG data is normal, the method can check if symptoms are still present. If symptoms are still present, the method can recommend medical attention and optionally transfer EKG data to a designated healthcare provider and/or message a designated personal contact. If no symptoms are present, the method can recommend routine medical follow-up and optionally transmit the EKG data to a designated healthcare provider. If the EKG data is uninterpretable, the method can recommend repeating the EKG generation and assessment steps to get new EKG data. If the new EKG is uninterpretable, the method can continue heart rate based assessment and optionally automatically send an error message to technical support personnel.

Any of the disclosed methods can be implemented using computing hardware and/or as computer-executable instructions stored on one or more computer-readable storage devices (e.g., one or more optical media discs, volatile memory components (such as DRAM or SRAM), or nonvolatile memory components (such as flash memory or hard drives)) and executed on a computer (e.g., any commercially available computer, including smart phones or other mobile devices that include computing hardware). The term computer-readable storage device does not include communication connections, such as signals and carrier waves. Any of the computer-executable instructions for implementing the disclosed techniques as well as any data created and used during implementation of the disclosed embodiments can be stored on one or more computer-readable storage device. The computer-executable instructions can be part of, for example, a dedicated software application or a software application that is accessed or downloaded via a web browser or other software application (such as a remote computing application). Such software can be executed, for example, on a single local computer (e.g., any suitable commercially available computer) or in a network environment (e.g., via the Internet, a wide-area network, a local-area network, a client-server network (such as a cloud computing network), or other such network) using one or more network computers.

For clarity, only certain selected aspects of software-based implementations of the disclosed methods are described. Other details that are well known in the art are omitted. For example, the disclosed technology is not limited to any specific computer language or program. For instance, the disclosed technology can be implemented by software written in C++, Java, Perl, JavaScript,

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Adobe Flash, or any other suitable programming language. Likewise, the disclosed technology is not limited to any particular computer or type of hardware.

Any methods or functionality described herein can be performed, at least in part, by one or more hardware logic components, instead of software. For example, and without limitation, illustrative types of hardware logic components that can be used include Field-programmable Gate Arrays (FPGAs), Program-specific Integrated Circuits (ASICs), Program-specific Standard Products (ASSPs), System-on-a-chip systems (SOCs), Complex Programmable Logic Devices (CPLDs), etc.

The innovations disclosed herein may be implemented in diverse general-purpose or special-purpose computing systems. Exemplary suitable computing environments in which the described innovations may be implemented can comprise any of a variety of computing devices (e.g., desktop computer, laptop computer, server computer, tablet computer, media player, gaming system, smartphone, mobile device, etc.). For example, the computing environment can include one or more processing units and memory. The processing units can execute computer-executable instructions. A processing unit can be a general-purpose central processing unit (CPU), processor in an application-specific integrated circuit (ASIC) or any other type of processor. The system can include tangible memory, such as volatile memory (e.g., registers, cache, RAM), non-volatile memory (e.g., ROM, EEPROM, flash memory, etc.), or some combination of the two, accessible by the processing unit(s). The memory can store software for implementing one or more methods described herein, in the form of computer-executable instructions suitable for execution by the processing unit(s).

For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatuses, and systems should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatuses, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

Characteristics and features described in conjunction with a particular aspect, embodiment, or example of the disclosed technology are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or

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all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The invention is not restricted to the details of any foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

Although the operations of some of the disclosed methods are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods.

As used herein, the terms "a", "an", and "at least one" encompass one or more of the specified element. That is, if two of a particular element are present, one of these elements is also present and thus "an" element is present. For example, reference to "a sensor" includes a plurality of such sensors and equivalents thereof known to those skilled in the art, and so forth, and reference to "the sensor" is a reference to one or more such sensors and equivalents thereof known to those skilled in the art, and so forth. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each separate value as well as intermediate ranges are incorporated herein as if it were individually recited herein.

The terms "a plurality of" and "plural" mean two or more of the specified element. As used herein, the term "and/or" used between the last two of a list of elements means any one or more of the listed elements. For example, the phrase "A, B, and/or C" means "A", "B,", "C", "A and B", "A and C", "B and C", or "A, B, and C." As used herein, the term "coupled" generally means physically or electrically or wirelessly coupled or linked and does not exclude the presence of intermediate elements between the coupled items absent specific contrary language.

In view of the many possible embodiments to which the principles of the disclosed technology may be applied, it should be recognized that the illustrated embodiments are only examples and should not be taken as limiting the scope of the disclosure. Rather, the scope of the disclosure is at least as broad as the following claims. We therefore claim all that comes within the scope of the following claims.

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CLAIMS:

1. A wearable band comprising:

a frame configured to be worn around a first body part of a person, the frame having an inner surface that faces the first body part and an outer surface that faces away from the first body part;

a first electrode on the inner surface of the frame, the first electrode adapted to detect a cardiovascular signal from the first body part;

a second electrode on the outer surface of the frame, the second electrode adapted to detect a cardiovascular signal from a second body part of the wearer, on which the band is not worn, when the second body part is touched against the second sensor; and

a third electrode on the outer surface of the frame, generally opposite from the second electrode, the third electrode adapted to detect a cardiovascular signal from a EKG lead location on the wearer's body, apart from the first and second body parts, when the third electrode is touched against the EKG lead location while being worn on the first body part.

2. The wearable band of claim 1, wherein the band comprises a ring and the first body part is a finger.

3. The wearable band of claim 1, wherein the band comprises a bracelet and the first body part is a wrist or arm.

4. The wearable band of any one of claims 1-3, further comprising a sensor on the inner surface of the frame for measuring blood oxygen saturation of the wearer.

5. The wearable band of any one of claims 1-4, further comprising a sensor on the inner surface of the frame for measuring bioimpedence of the skin of the first body part or dry skin potential between two separated points on the skin of the first body part.

6. The wearable band of any one of claims 1-5, wherein the band is configured to continuously monitor the wearer's cardiovascular status to detect or predict cardiac arrhythmia in the wearer.

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7. The wearable band of any one of claims 1-6, wherein the band can simulate a 12-lead EKG by touching the third sensor to a plurality of EKG lead locations on the wearer's body while simultaneously touching the second body part to the second electrode.

8. The wearable band of any one of claims 1-7, further comprising a button or other input device that can be activated to synch the wearable band to a mobile computing device via wireless communication.

9. The wearable band of any one of claims 1-8, further comprising a button or other input device that can be activated to initiate a cardiovascular measurement of the wearer.

10. The wearable band of any one of claims 1-9, wherein the band further comprises a processor, memory, wireless communication device, and a power source.

11. The wearable band of any one of claims 1-10, wherein the band further comprises a motion sensor or accelerometer.

12. The wearable band of any one of claims 1-11, wherein the band further comprises a position sensor or orientation sensor.

13. The wearable band of any one of claims 1-12, wherein the band further comprises a body temperature sensor.

14. The wearable band of any one of claims 1-13, wherein the band further comprises a visual display screen.

15. The wearable band of any one of claims 1-14, wherein the band further comprises a speaker or audio signal generator.

16. The wearable band of any one of claims 1-15, wherein the band further comprises a vibratory or haptic signal generator.

17. The wearable band of any one of claims 1-16, wherein the at least one of the first, second, and third electrodes comprises small bumps or teeth.

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18. The wearable band of any one of claims 1-16, further comprising a detachable battery portion that is detachable from the frame of the band and wirelessly rechargeable.

19. The wearable band of claim 18, further comprising a second battery that remains coupled to the frame when the detachable battery portion is detached from the frame.

20. The wearable band of claim 18 or claim 19, wherein the detachable battery portion is annular.

21. A cardiac monitoring system, comprising:

the wearable band of any one of claims 1-20; and

a mobile computing device paired with the wearable band via wireless communication.

22. The system of claim 21, further comprising a cloud server or medical records database in wireless communication with the mobile computing device.

23. A cardiac monitoring system, comprising:

a first wearable band comprising the wearable band of any one of claims 1-20; and

a second wearable band;

wherein one of the first and second wearable bands comprises a ring, and the other of the first and second wearable bands comprises a bracelet, and the ring and bracelet are linked for communication therebetween.

24. A method of monitoring a person's cardiovascular health, comprising:

inducing a person to place a device worn by the person on a first body part against a first EKG lead location on the person's body, such that a first electrode of the device contacts the first body part on which the device is worn and such that a second electrode of the device contacts the first EKG lead location, wherein the first body part is part of a first limb of the person;

inducing the person to place a second body part against a third electrode of the device while the second electrode is in contact with first EKG lead location and the first electrode is in contact with the first body part, wherein the second body part is part of a second limb of the person; and

obtaining EKG signals from the person using the first, second, and third electrodes of the device.

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25. The method of claim 24, further comprising repeating the method of claim 24 with the second electrode in contact with a second EKG lead location on the person's body.

26. The method of claim 24, further comprising repeating the method of claim 24 a sufficient number of times with the second electrode touching different EKG lead locations during each repetition to generate an EKG recording that simulates a full 12-lead EKG recording.

27. The method of any one of claims 24-26, wherein inducing the person to place the worn device against the first EKG lead location is performed by causing EKG measurement instructions to be displayed on a mobile computing device linked to the device.

28. The method of any one of claims 24-27, wherein inducing the person to place the worn device against the first EKG lead location is based on a warning determination derived from continuous monitoring on the person's cardiovascular health using the device.

29. The method of claim 28, wherein the continuous monitoring indicates likely arrhythmia.

30. The method of any one of claims 28-29, wherein the continuous monitoring indicates tachycardia.

31. The method of any one of claims 28-30, wherein the continuous monitoring indicates a bradycardia.

32. The method of any one of claims 28-31, wherein the continuous monitoring indicates the person's blood oxygen level is outside of a predetermined range.

33. The method of any one of claims 24-32, further comprising storing the obtained EKG signals in memory on the device or on a linked mobile computing device.

34. The method of any one of claims 24-33, further comprising transmitting the obtained EKG signals from the device to a linked mobile computing device.

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35. A method of monitoring a person's cardiovascular condition, comprising:

continuously monitoring a person's heart rate, blood oxygen levels, or both, using a device worn by the person;

based on the monitoring, determining that the person's heart rate is outside of a predetermined threshold range;

based on the heart rate determination, assessing the person's motion; and

based on the motion assessment, determining potential arrhythmia in the person.

36. The method of claim 35, wherein determining that the person's heart rate is outside of a predetermined threshold range comprises determining that the person's heart rate is above a threshold value for a predetermined time period.

37. The method of claim 35 or claim 36, wherein assessing the person's motion comprises assessing the person's motion over a predetermined time period.

38. The method of any one of claims 35-37, wherein assessing the person's motion comprises determining that the person's motion is above a threshold value, and the method further comprises determining that the person's heart rate is above the person's MAPHR.

39. The method of any one of claims 35-37, wherein assessing the person's motion comprises determining that the person's motion is below a threshold value.

40. The method of any one of claims 35-39, further comprising, after determining potential arrhythmia, prompting the person to input information regarding symptoms the person is experiencing.

41. The method of any one of claims 35-40, further comprising, after determining potential arrhythmia, inducing the person to perform vagal maneuvers.

42. The method of any one of claims 35-41, further comprising, after determining potential arrhythmia, prompting the person to touch the device with a finger on a hand opposite from the limb on which the device is worn to obtain EKG data.

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43. The method of any one of claims 35-42, further comprising, after determining potential arrhythmia, prompting the person to touch an electrode of the device with a finger on a hand opposite from the limb on which the device is worn, and prompting the person to touch another electrode of the device to an EKG lead location on the person's chest or leg to obtain EKG data.

44. The method of any one of claims 35-43, further comprising, after determining potential arrhythmia, sending a message to a predetermined contact person or healthcare provider.

45. The method of any one of claims 35-44, further comprising, after determining potential arrhythmia, alerting 911 or other emergency service provider.

46. The method of claim 35, wherein determining that the person's heart rate is outside of a predetermined threshold range comprises determining that the person's heart rate is below a threshold value.

47. The method of claim 46, wherein the motion assessment comprises detecting for purposeful motion of the person.

48. The method of claim 47, wherein detecting for purposeful motion comprises determining a lack of purposeful motion and the method further comprises subsequently determining that the person's blood oxygen saturation level is below a predetermined threshold using the device.

49. The method of claim 48, wherein the determining that the person's blood oxygen saturation level is below a predetermined threshold is succeeded by delivering a vibratory or audible alert to the person to establish wakefulness of the person.

50. The method of claim 47, wherein detecting for purposeful motion comprises determining the presence of purposeful motion and the method further comprises subsequently prompting the person to input information regarding symptoms the person has experienced or is experiencing.

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51. The method of any one of claims 35-50, further comprising detecting for abnormal cardiac rhythm in the person over an extended period using normalized absolute difference (NADiff) of continuous RR interval input.

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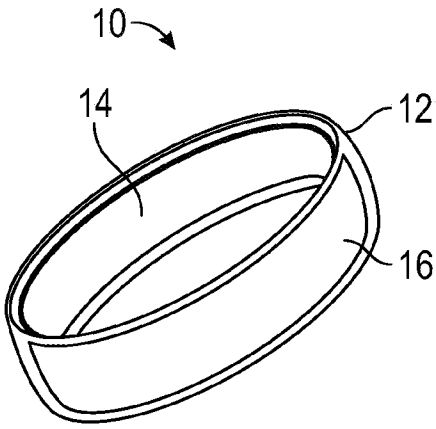


FIG. 1

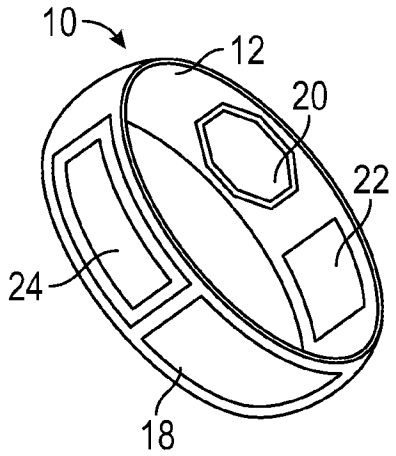


FIG. 2

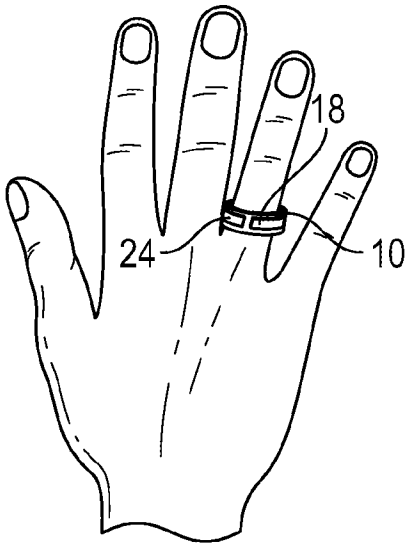


FIG. 3

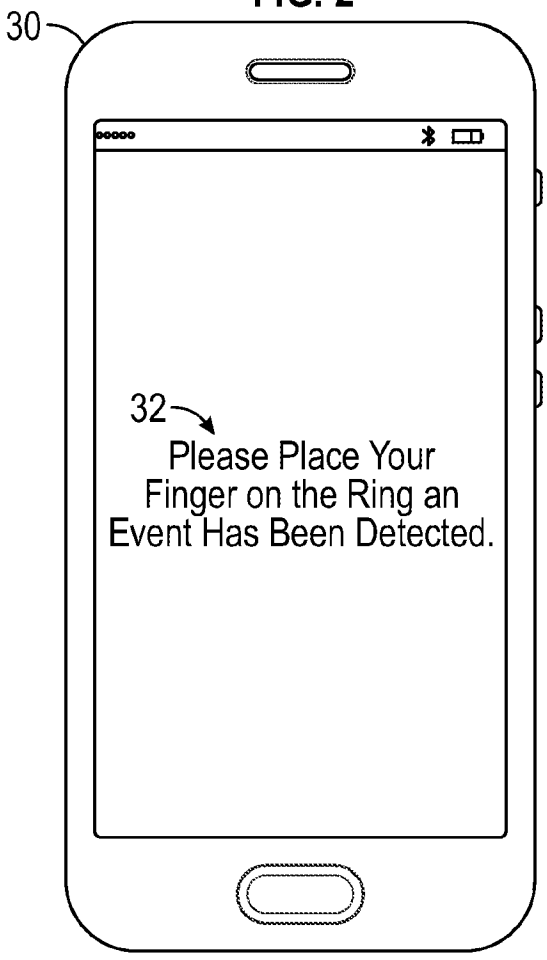


FIG. 4

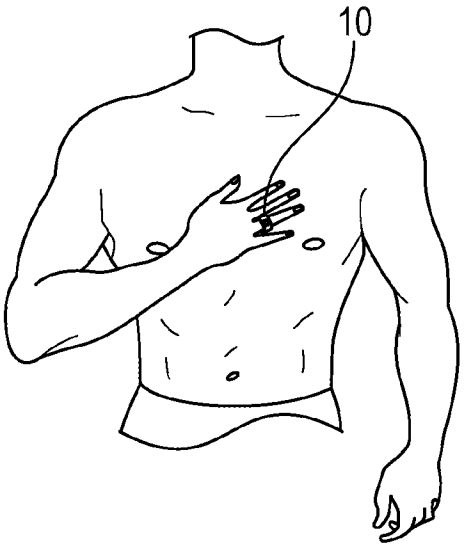


FIG. 5

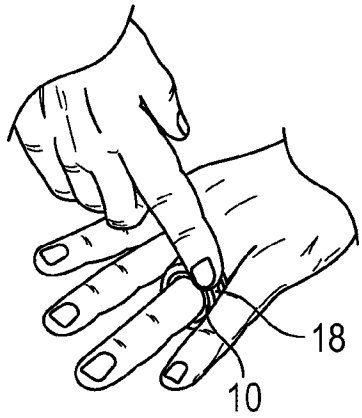


FIG. 6

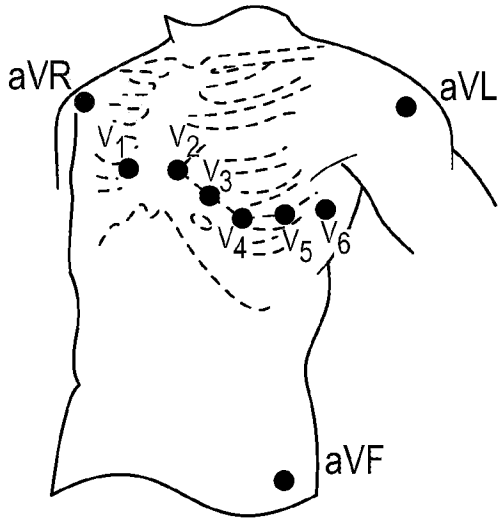


FIG. 7

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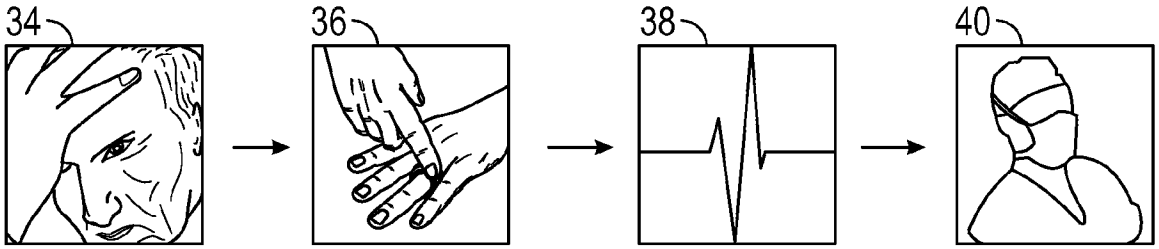

34
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FIG. 8

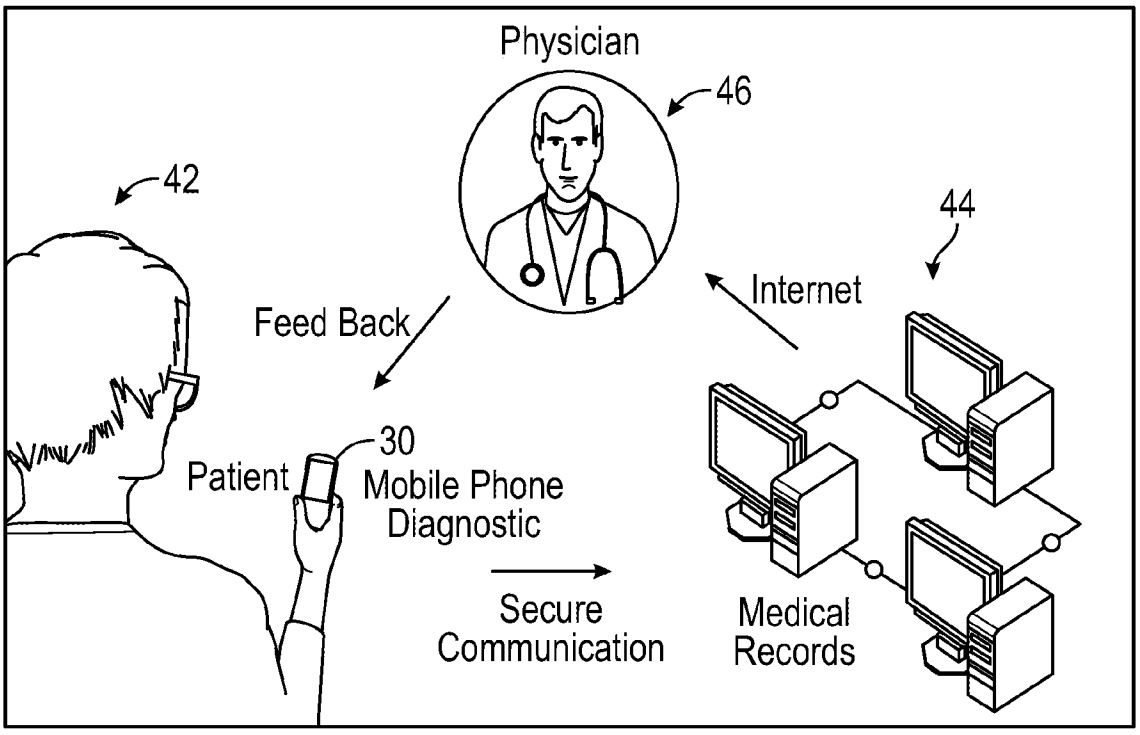

Physician
46
42
44
Internet
Feed Back
30
Patient
Mobile Phone
Diagnostic
Secure
Communication
Medical
Records

FIG. 9

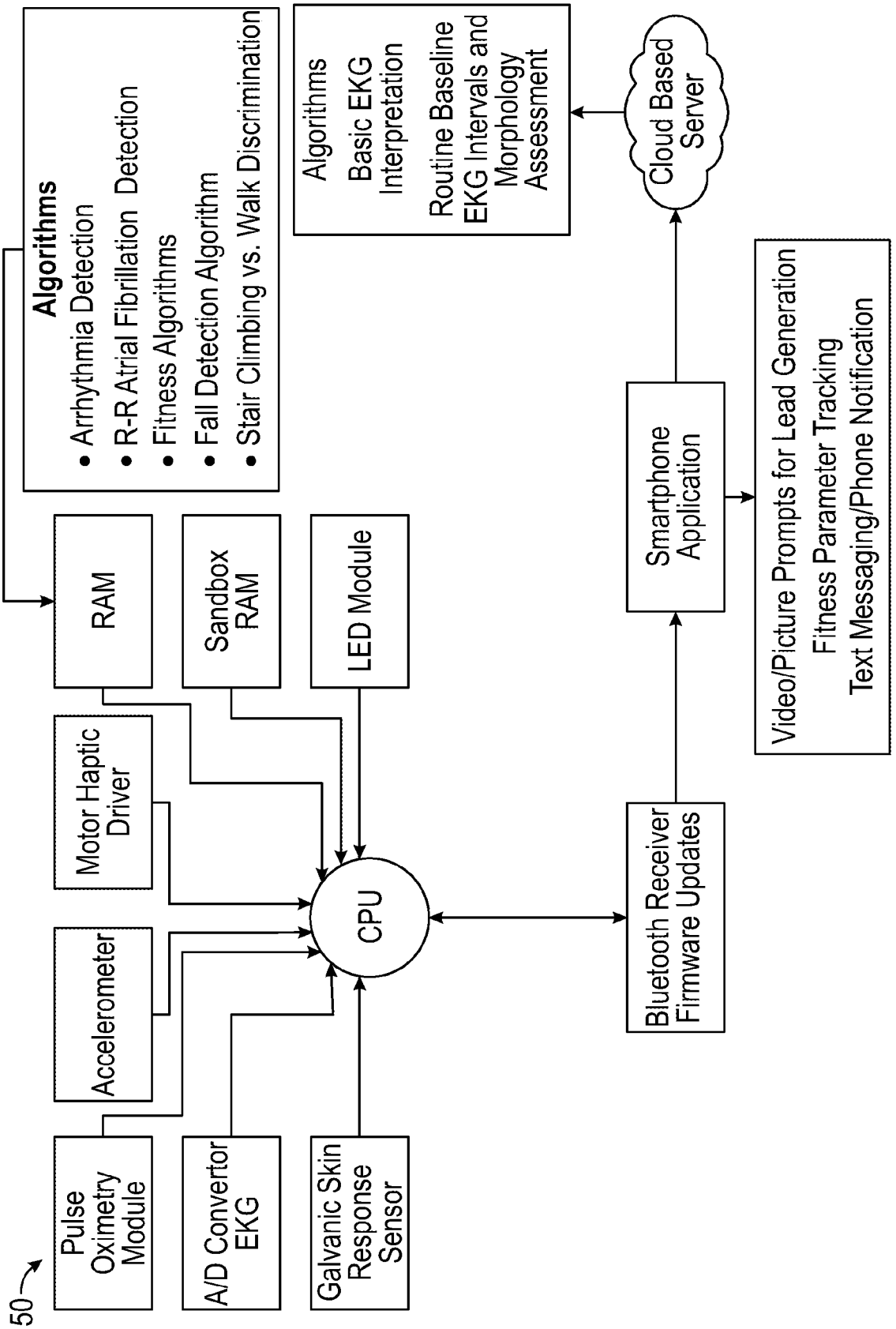

50
Pulse Oximetry Module
A/D Convertor EKG
Galvanic Skin Response Sensor
Accelerometer
Motor Haptic Driver
CPU
RAM
Sandbox RAM
LED Module
Algorithms
• Arrhythmia Detection
• R-R Atrial Fibrillation Detection
• Fitness Algorithms
• Fall Detection Algorithm
• Stair Climbing vs. Walk Discrimination
Bluetooth Receiver Firmware Updates
Smartphone Application
Algorithms
Basic EKG Interpretation
Routine Baseline EKG Intervals and Morphology Assessment
Cloud Based Server
Video/Picture Prompts for Lead Generation
Fitness Parameter Tracking
Text Messaging/Phone Notification

FIG. 10

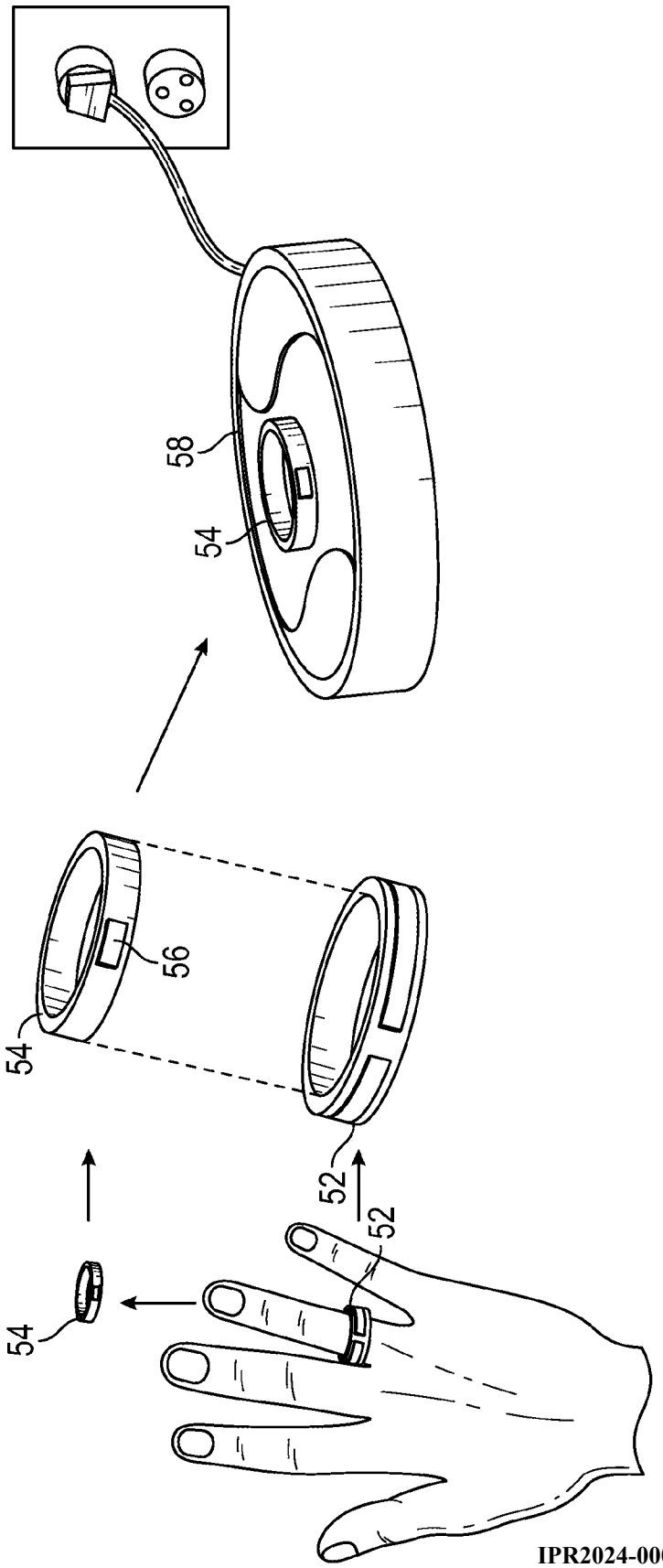


FIG. 11

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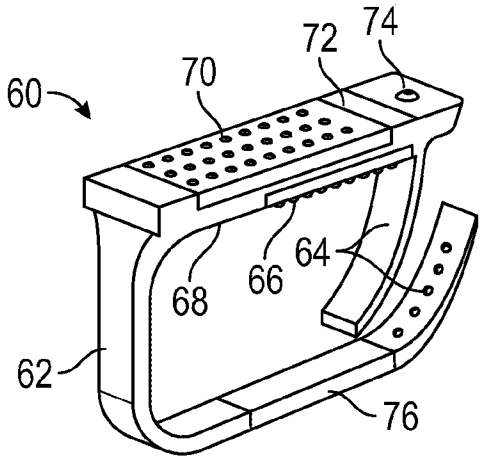


FIG. 12

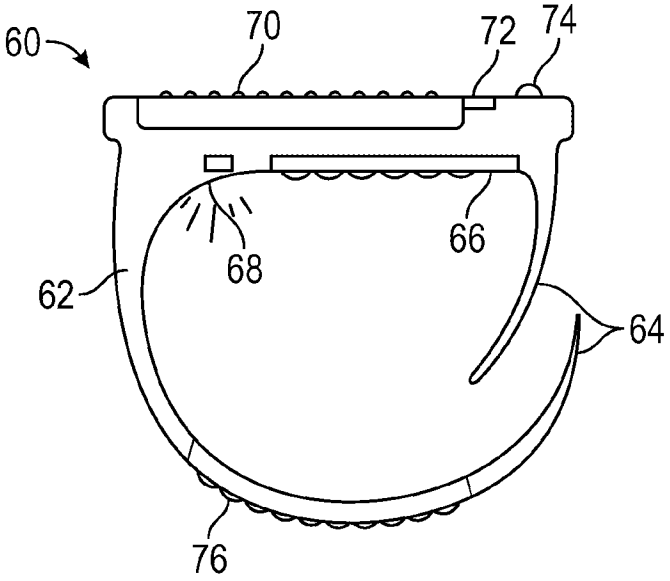


FIG. 13

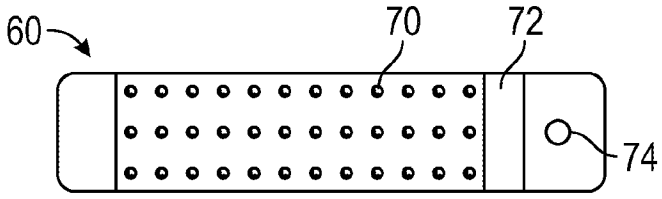


FIG. 14

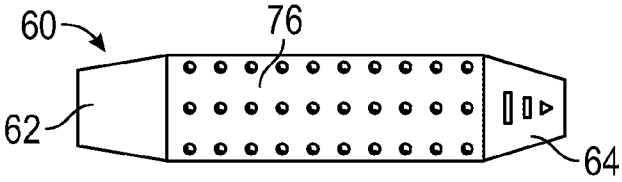


FIG. 15

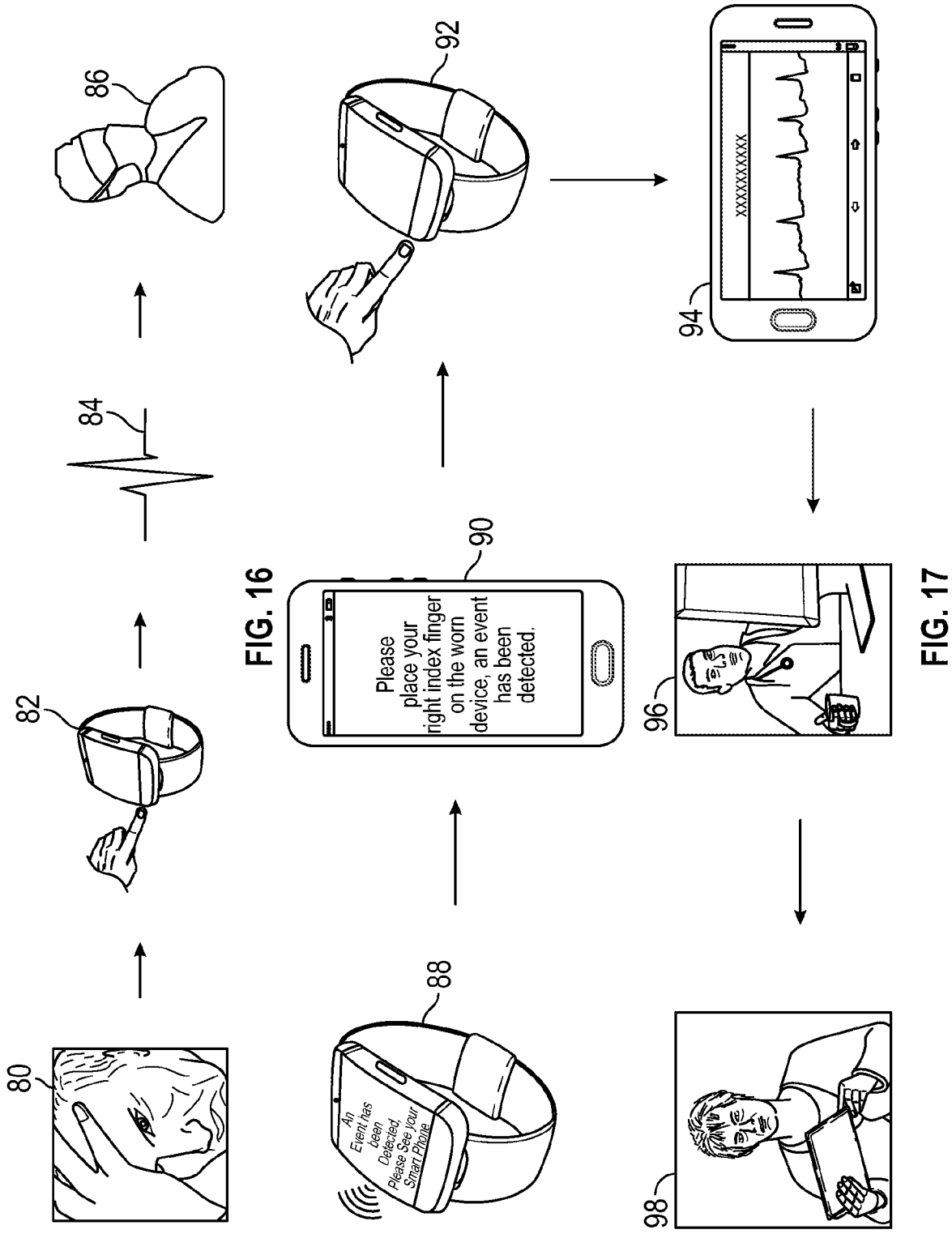

80
82
84
86
88
90
92
94
96
98
Please place your right index finger on the worn device, an event has been detected.
An Event has been Detected, Please See your Smart Phone
XXXXXXXXXX

FIG. 16

FIG. 17

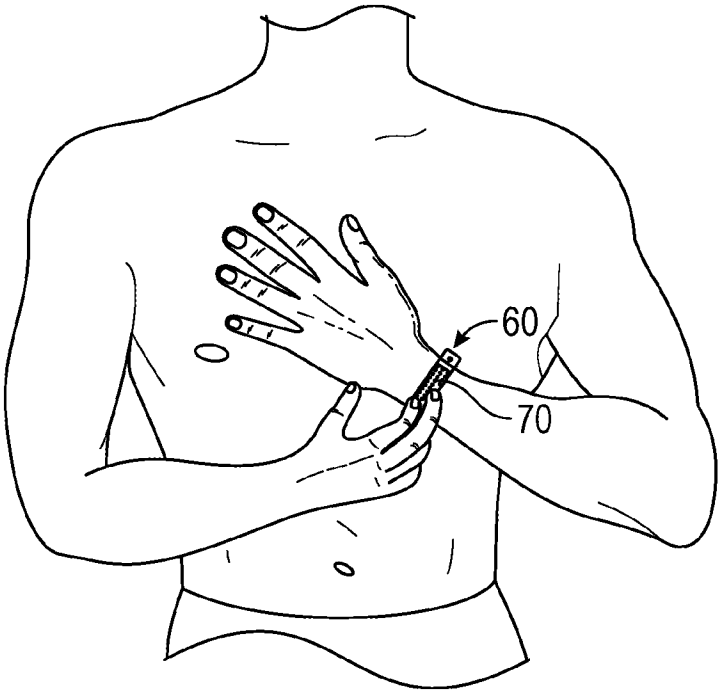


FIG. 18

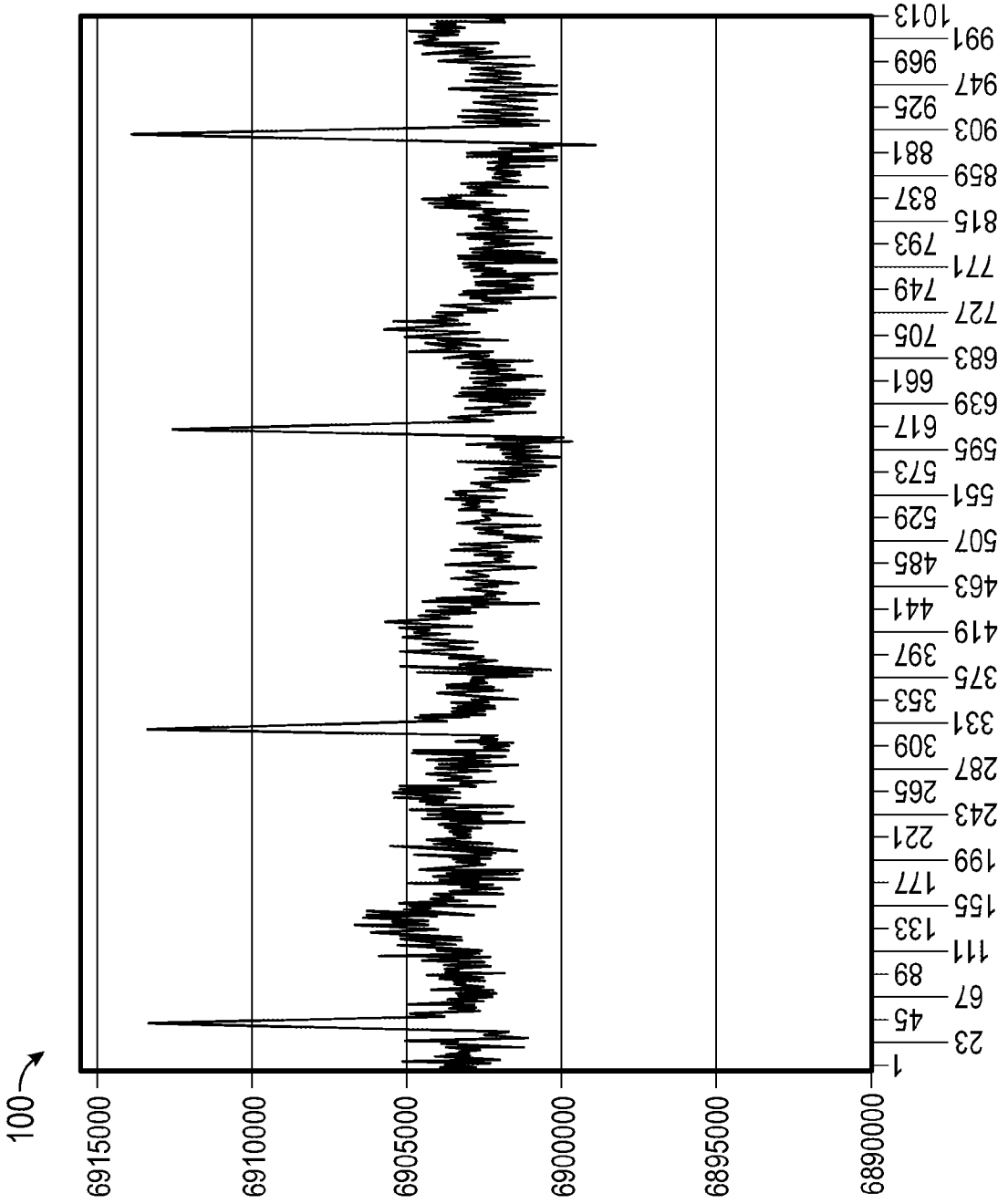

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6915000
6910000
6905000
6900000
6895000
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89
111
133
155
177
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221
243
265
287
309
331
353
375
397
419
441
463
485
507
529
551
573
595
617
639
661
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881
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969
991
1013

FIG. 19

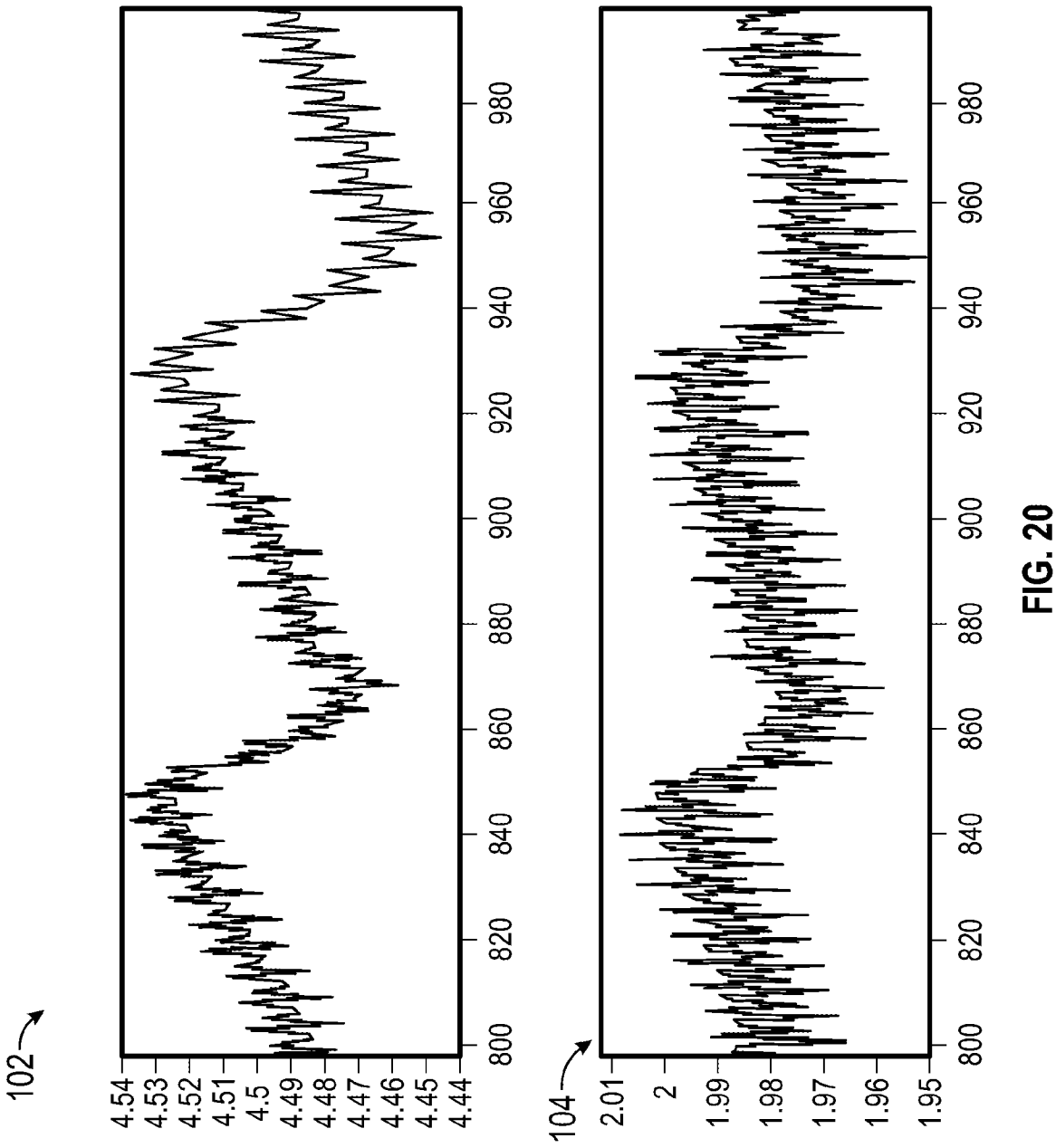

102
4.54
4.53
4.52
4.51
4.5
4.49
4.48
4.47
4.46
4.45
4.44
800
820
840
860
880
900
920
940
960
980
104
2.01
2
1.99
1.98
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FIG. 20

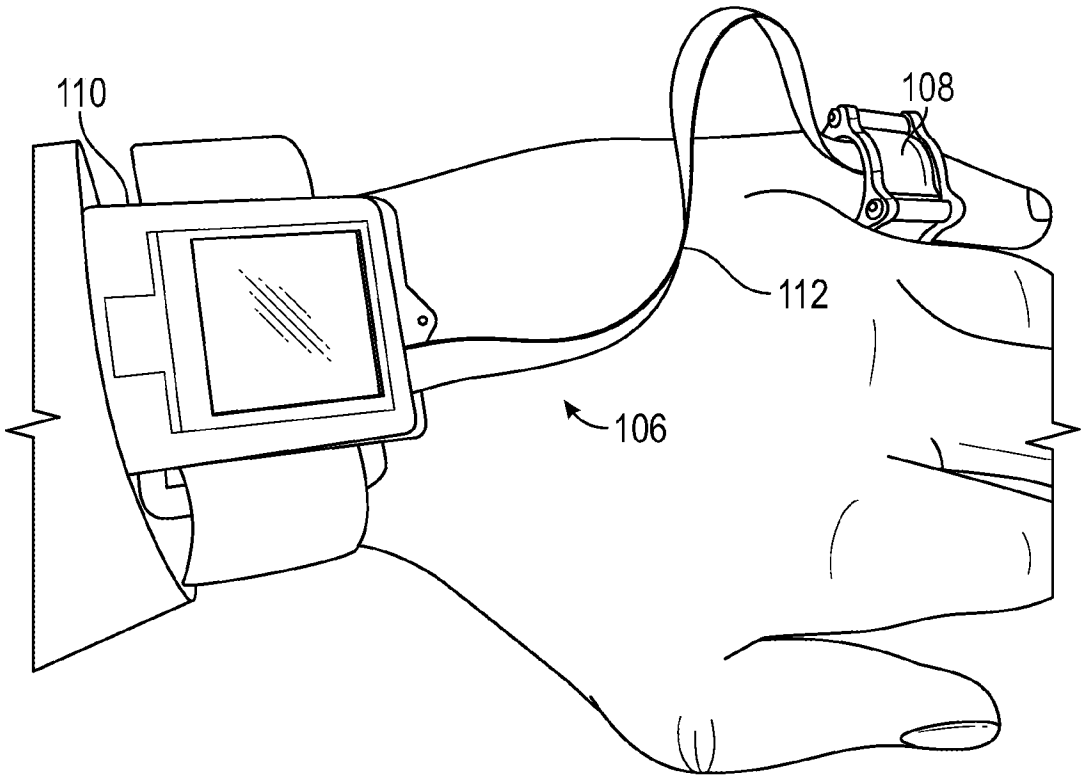


FIG. 21

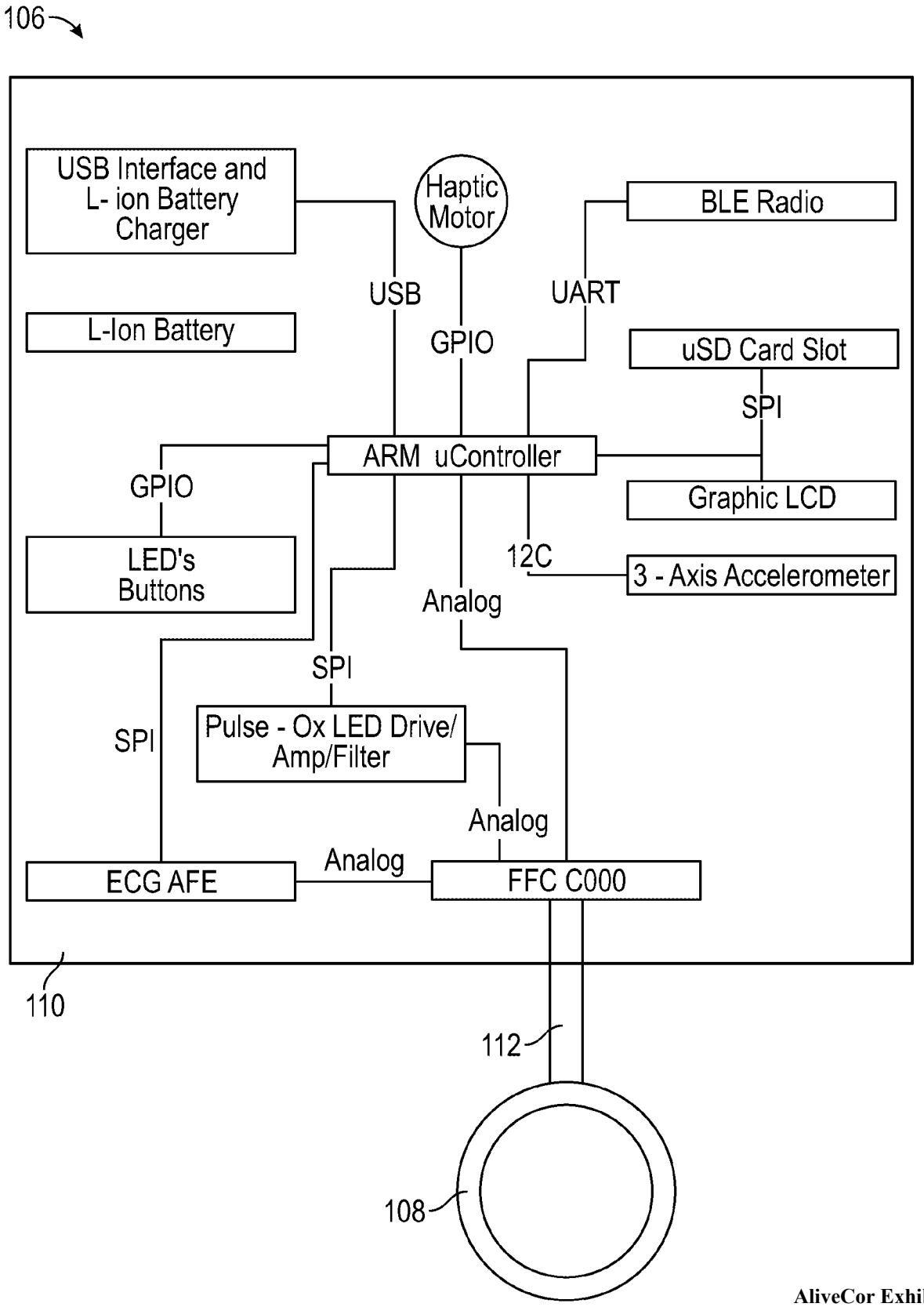


FIG. 22

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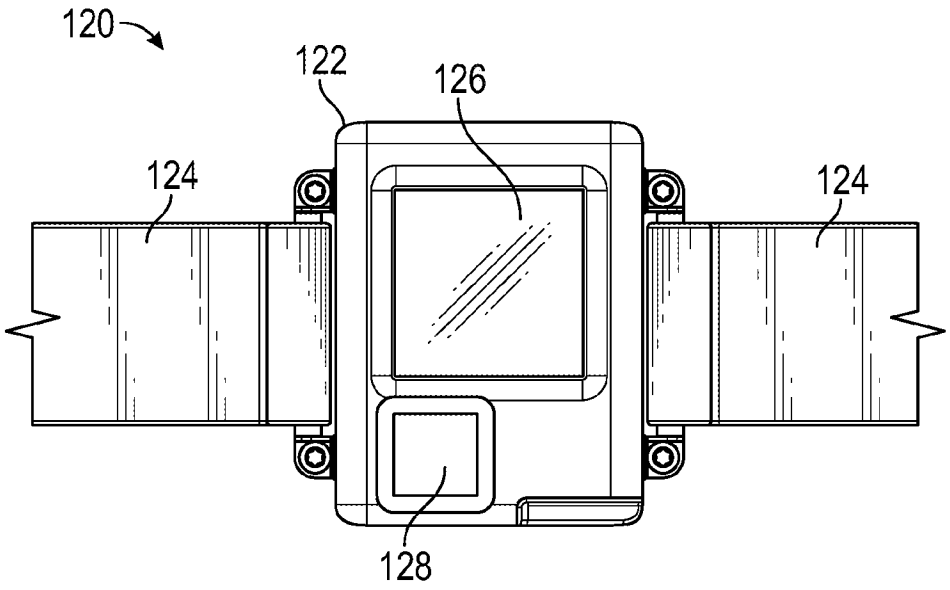


FIG. 23

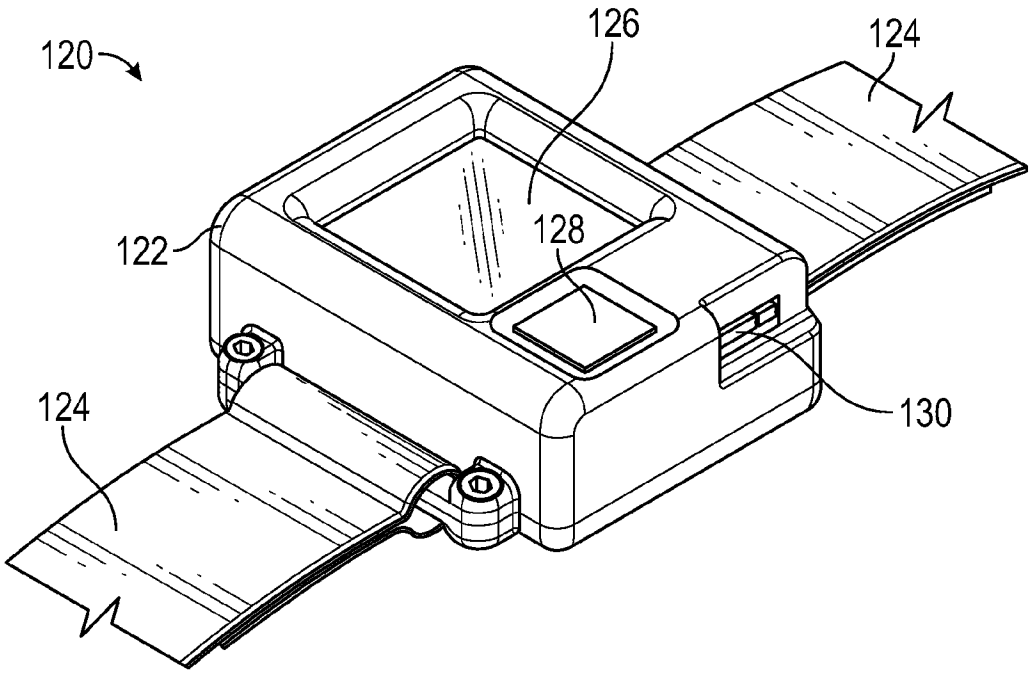


FIG. 24

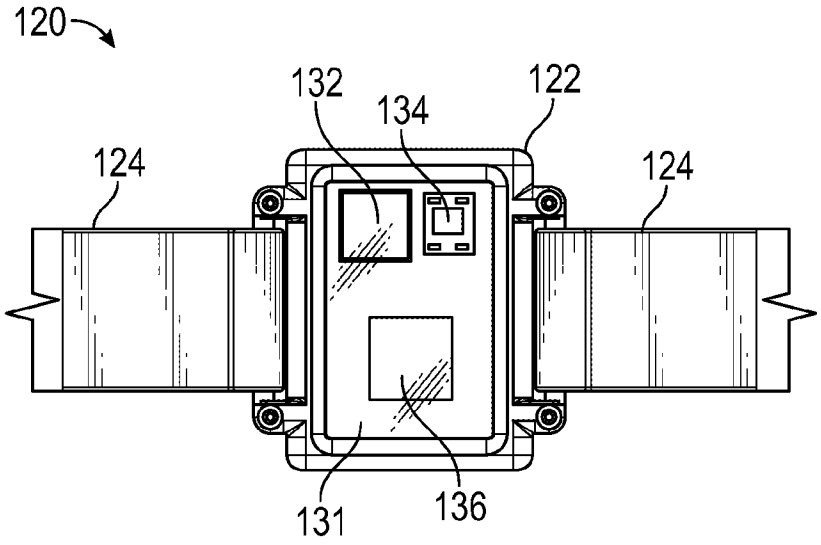


FIG. 25

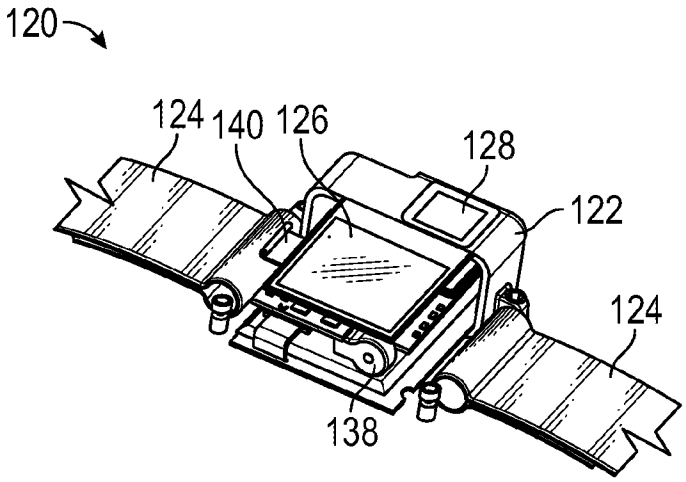


FIG. 26

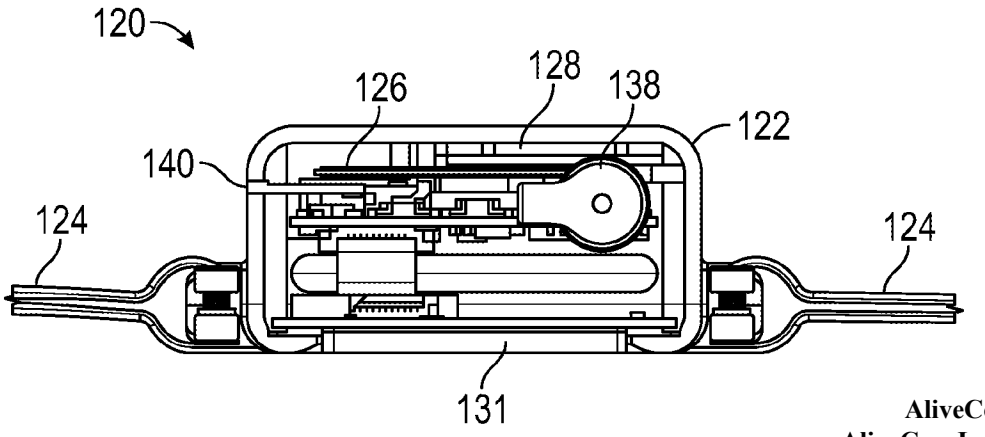


FIG. 27

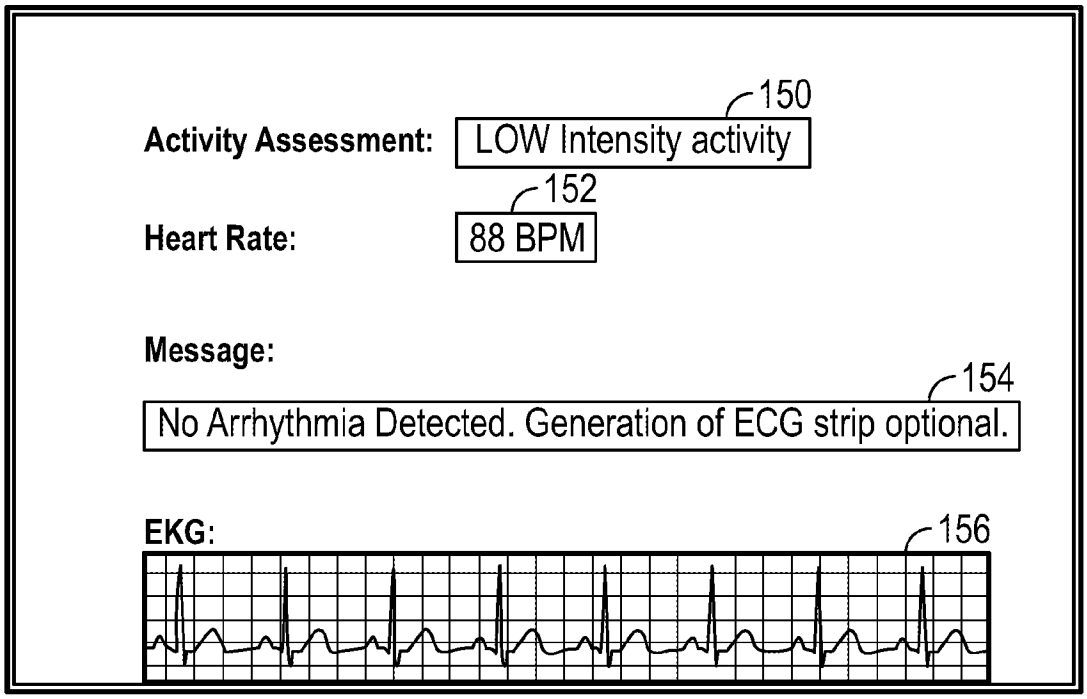

150
Activity Assessment:
LOW Intensity activity
152
Heart Rate:
88 BPM
Message:
154
No Arrhythmia Detected. Generation of ECG strip optional.
EKG:
156

FIG. 28

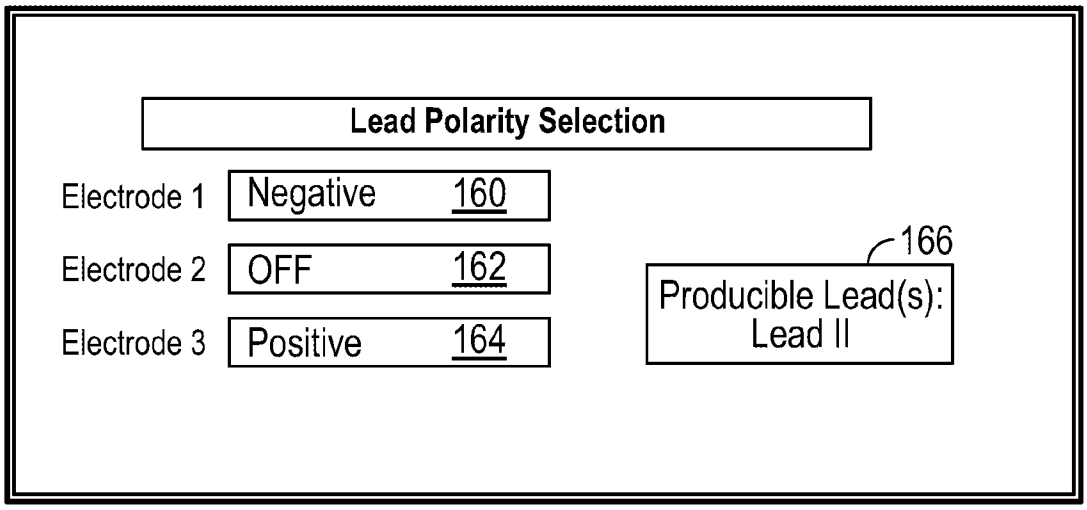

Lead Polarity Selection
Electrode 1
Negative
160
Electrode 2
OFF
162
Electrode 3
Positive
164
166
Producible Lead(s):
Lead II

FIG. 29

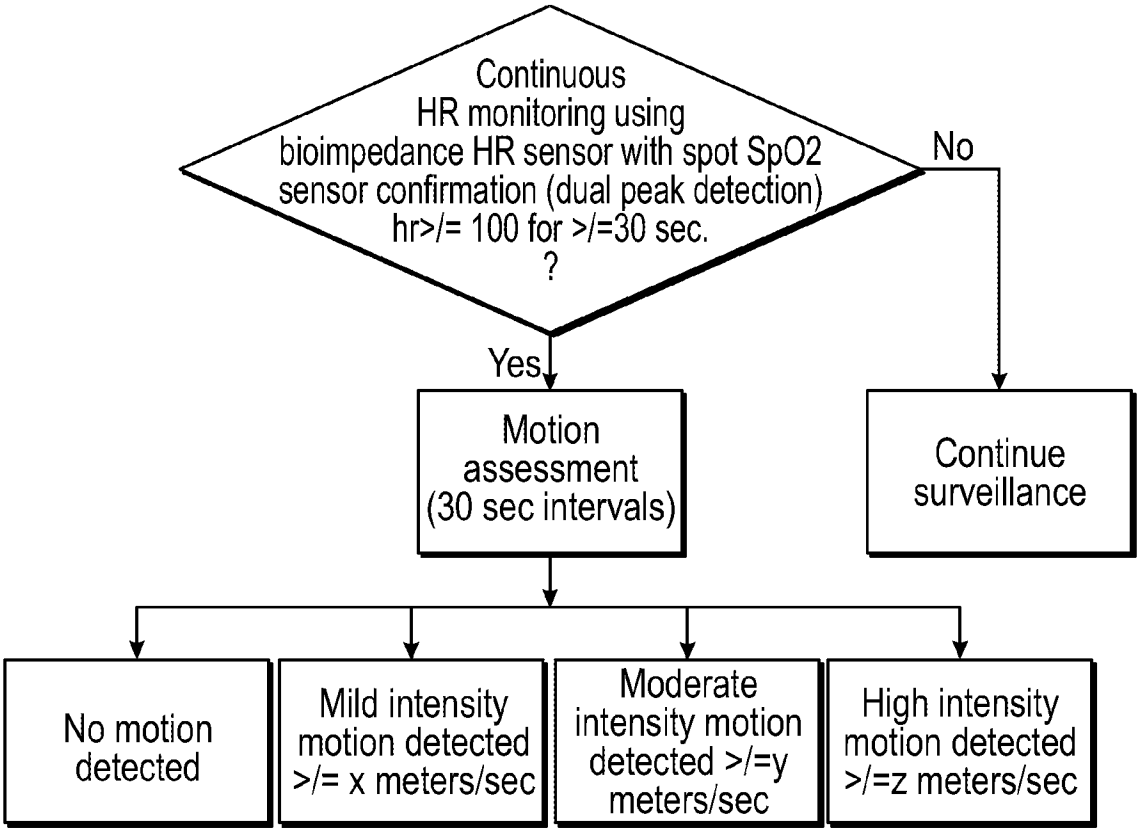

Continuous HR monitoring using bioimpedance HR sensor with spot SpO2 sensor confirmation (dual peak detection) hr>/= 100 for >/=30 sec. ?
No
Yes
Motion assessment (30 sec intervals)
Continue surveillance
No motion detected
Mild intensity motion detected >/= x meters/sec
Moderate intensity motion detected >/=y meters/sec
High intensity motion detected >/=z meters/sec

FIG. 30

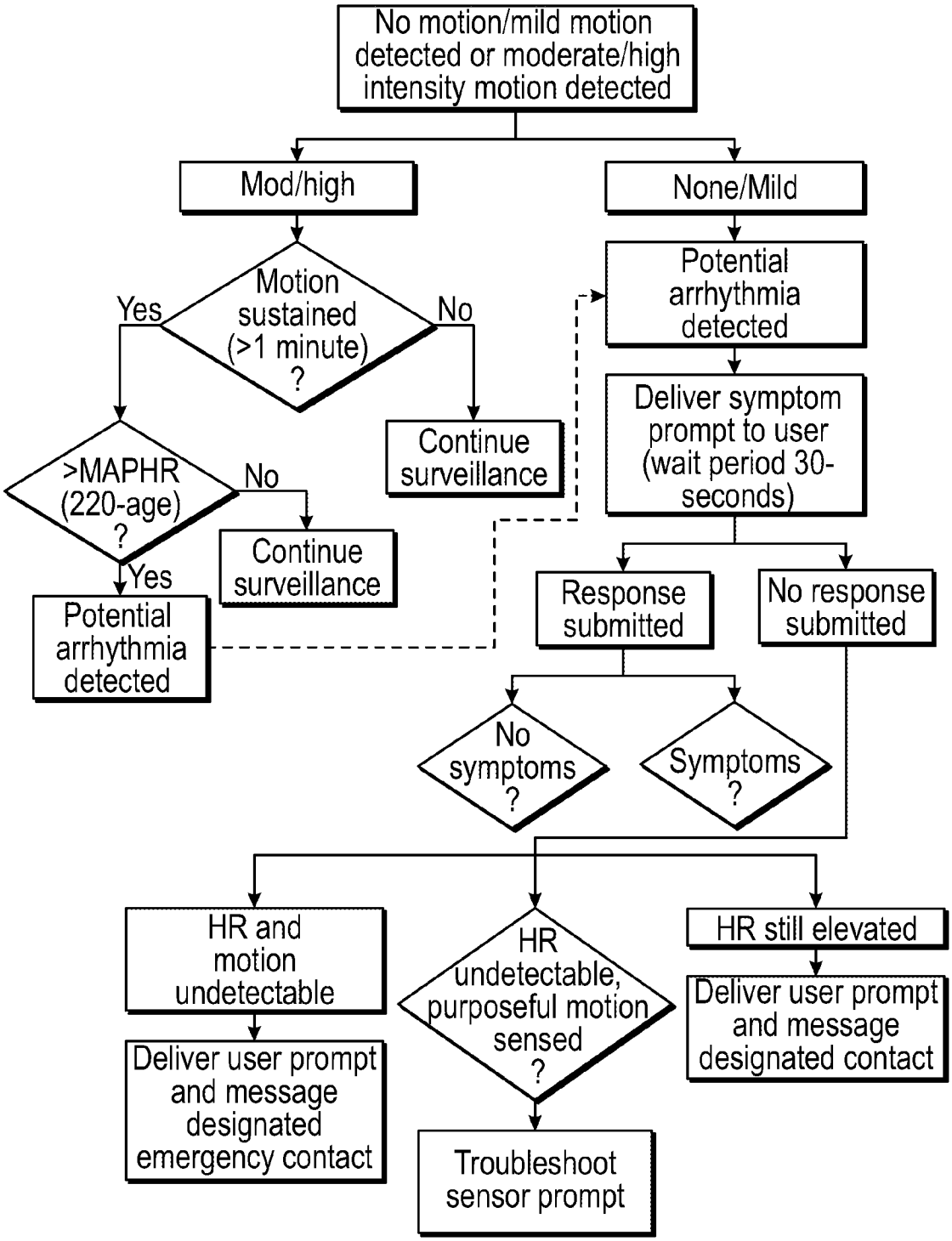


FIG. 31

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
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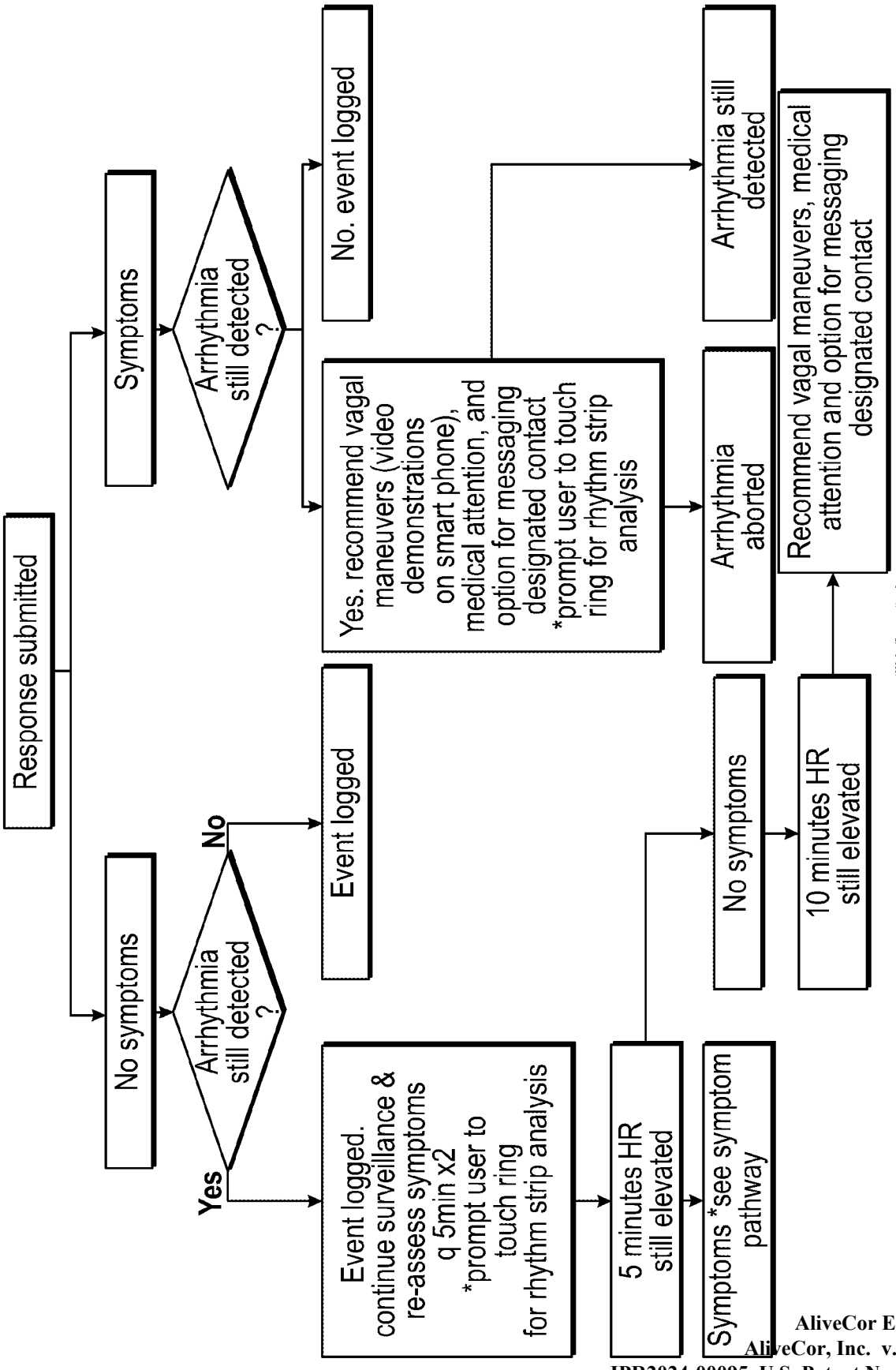


FIG. 32

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
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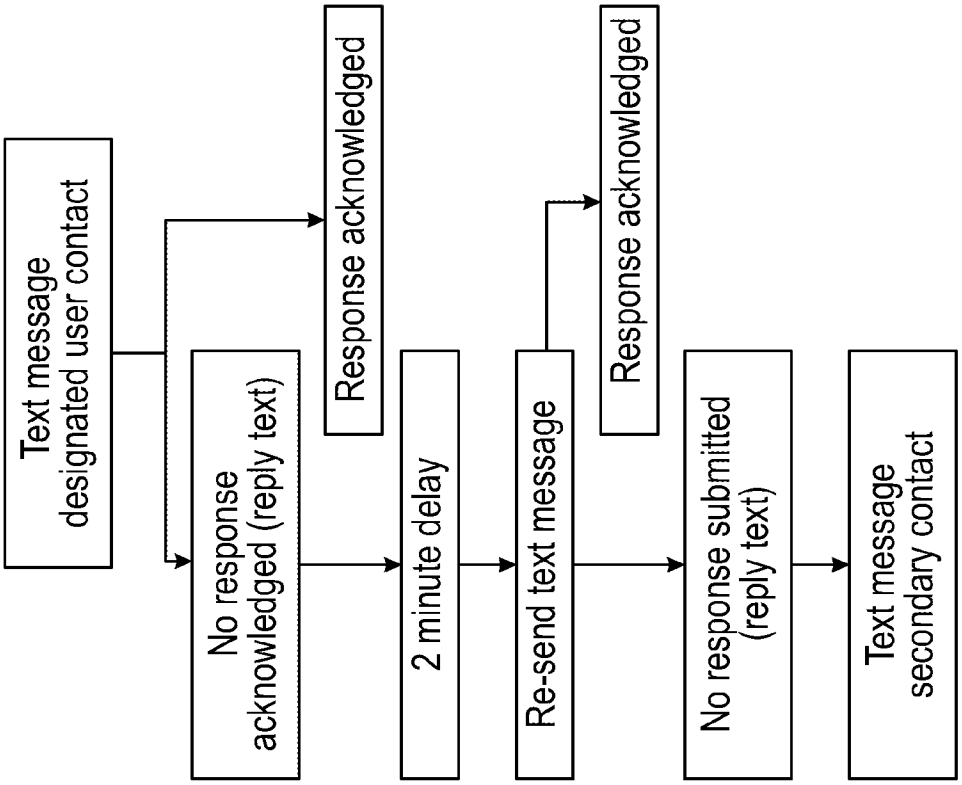

Text message designated user contact
No response acknowledged (reply text)
Response acknowledged
2 minute delay
Re-send text message
Response acknowledged
No response submitted (reply text)
Text message secondary contact

FIG. 34

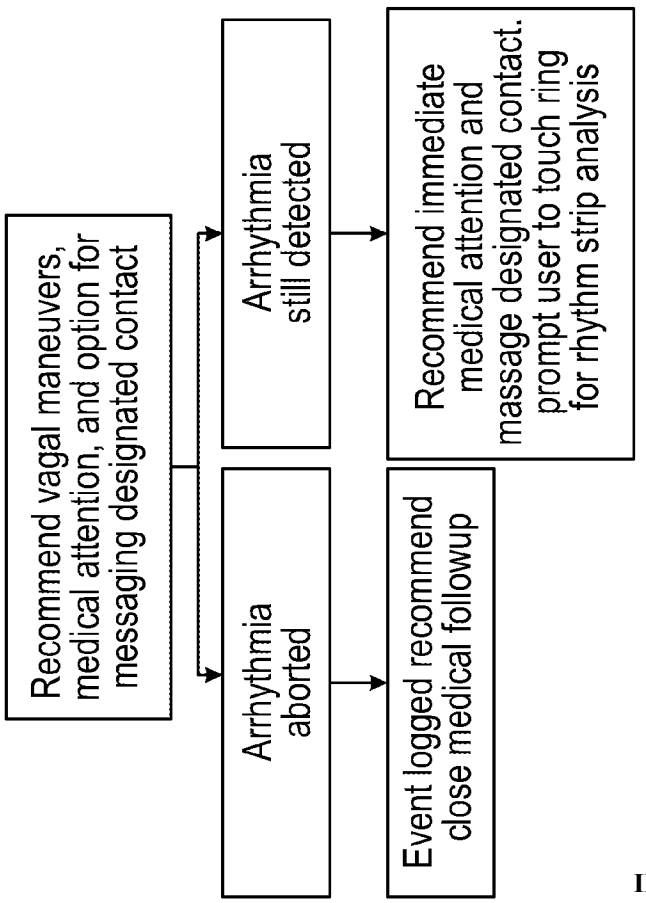

Recommend vagal maneuvers, medical attention, and option for messaging designated contact
Arrhythmia aborted
Event logged recommend close medical followup
Arrhythmia still detected
Recommend immediate medical attention and massage designated contact. prompt user to touch ring for rhythm strip analysis

FIG. 33

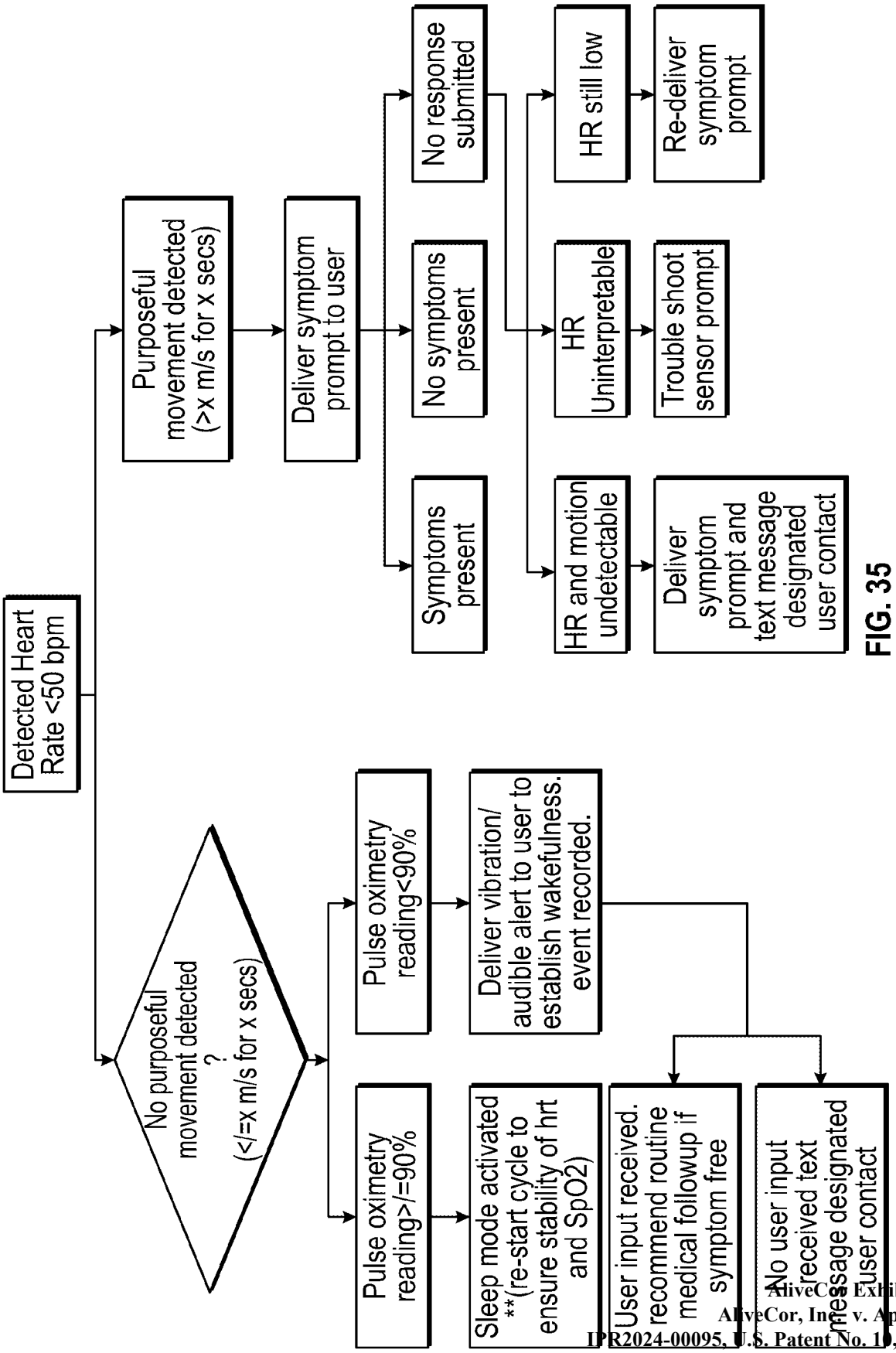


FIG. 35

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
961 of 1413

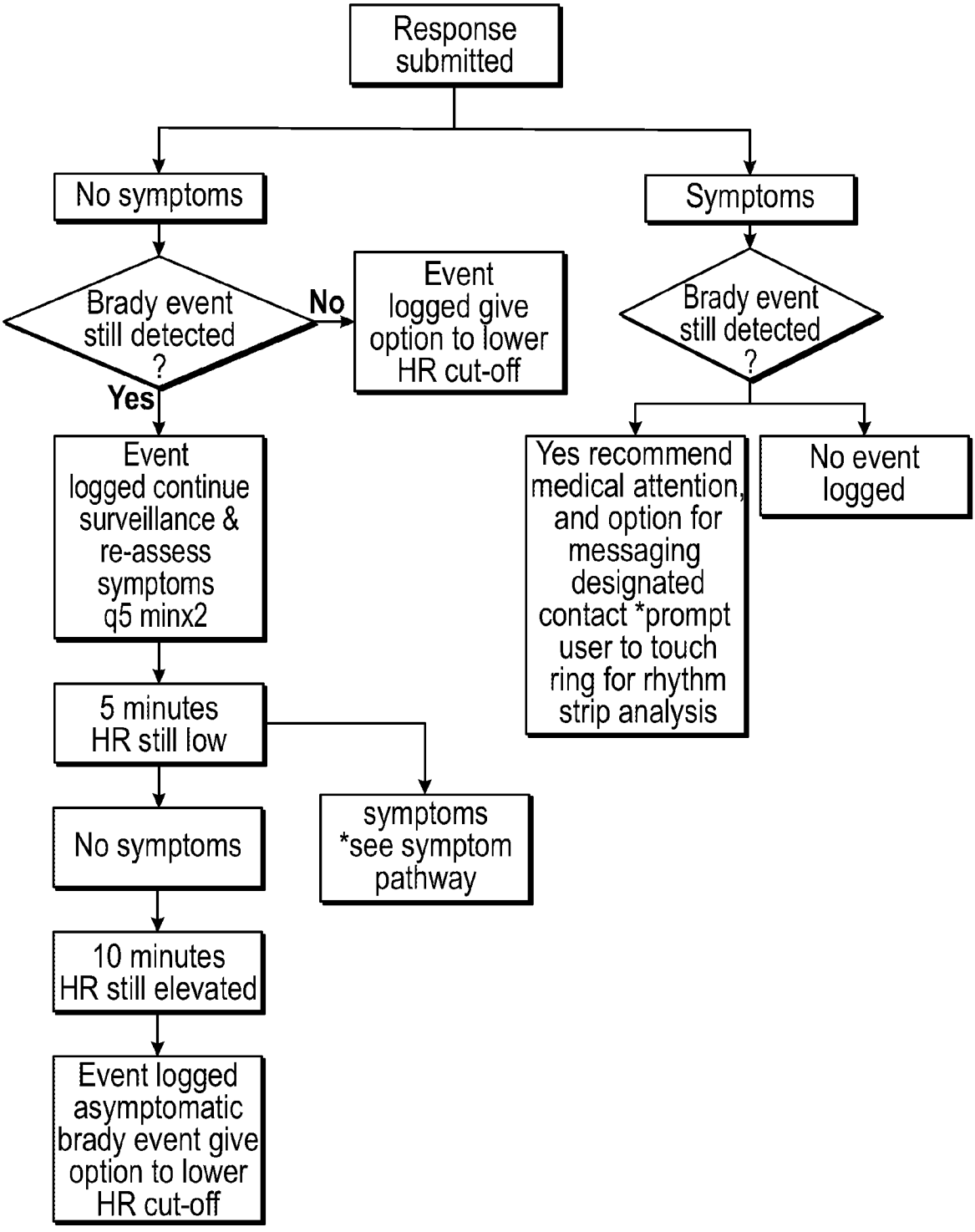

Response submitted
No symptoms
Symptoms
Brady event still detected ?
No
Event logged give option to lower HR cut-off
Yes
Event logged continue surveillance & re-assess symptoms q5 minx2
5 minutes HR still low
symptoms *see symptom pathway
No symptoms
10 minutes HR still elevated
Event logged asymptomatic brady event give option to lower HR cut-off
Brady event still detected ?
Yes recommend medical attention, and option for messaging designated contact *prompt user to touch ring for rhythm strip analysis
No event logged

FIG. 36

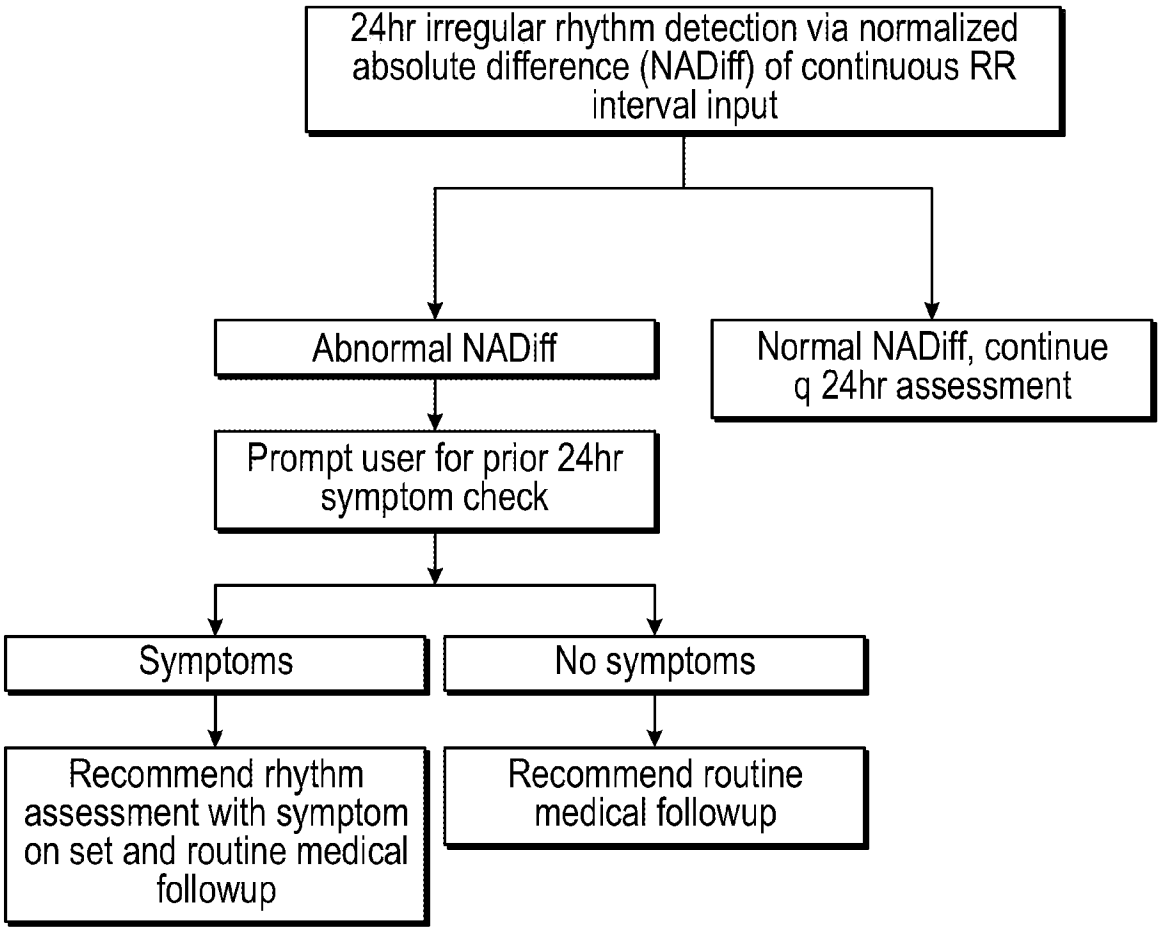

24hr irregular rhythm detection via normalized absolute difference (NADiff) of continuous RR interval input
Abnormal NADiff
Normal NADiff, continue q 24hr assessment
Prompt user for prior 24hr symptom check
Symptoms
No symptoms
Recommend rhythm assessment with symptom on set and routine medical followup
Recommend routine medical followup

FIG. 37

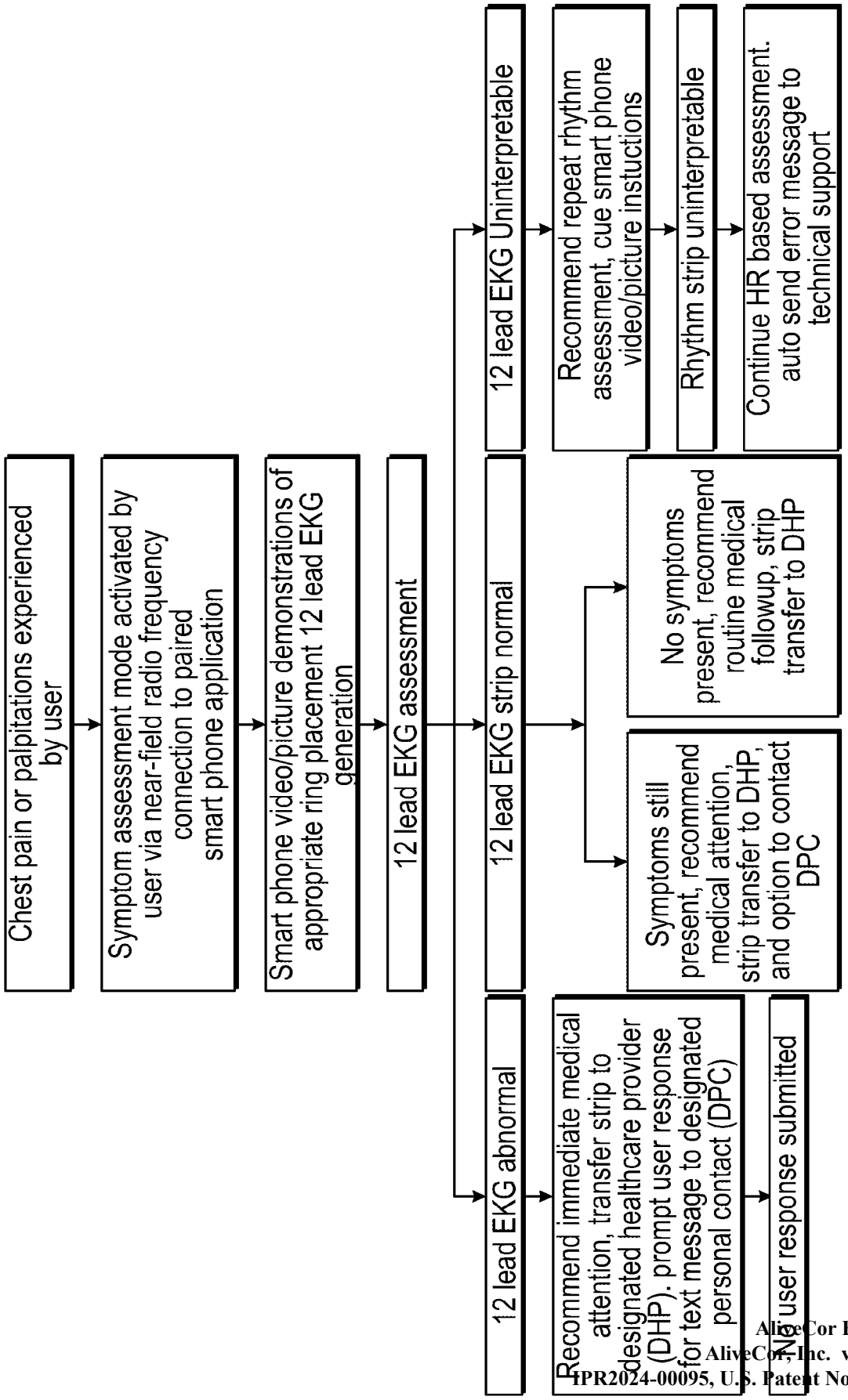


FIG. 38

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IPR2024-00095, U.S. Patent No. 10,568,533
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/025333

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 24-51
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 24-51 pertain to a diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

2. ☒ Claims Nos.: 19,22,29
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 19, 22 and 29 are unclear, because they refer to multiple dependent claims 18, 21 and 28 which do not comply with PCT Rule 6.4(a).

3. ☒ Claims Nos.: 5-18,20-21,23,28,30-34,38-45,51
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/025333

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/0404(2006.01)i, A61B 5/0408(2006.01)i, A61B 5/0456(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/0404; G06F 15/00; A61B 5/024; H04B 15/00; A61B 5/0205; A61B 5/0402; A61B 5/0408; A61B 5/0456

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: wearable, band, detect, cardiac, electrode, heart, rate

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010-0076331 A1 (HSIAO-LUNG CHAN et al.) 25 March 2010 See paragraphs [16]-[18], claim 1 and figures 1-3A.	1-4
A	US 2010-0286532 A1 (JONATHAN FARRINGDON et al.) 11 November 2010 See paragraphs [80],[166], claims 2-10 and figures 13-21.	1-4
A	KR 10-2011-0012784 A (BIONET CO., LTD.) 09 February 2011 See paragraph [64], claims 1-9 and figure 8.	1-4
A	JP 2007-195693 A (MATSUSHITA ELECTRIC WORKS LTD.) 09 August 2007 See paragraphs [30]-[39],[48]-[52], claims 1-6 and figures 1-4,9.	1-4
A	US 2002-0111777 A1 (DANIEL DAVID) 15 August 2002 See paragraphs [44]-[65], claims 1-9 and figures 1-5.	1-4

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 June 2016 (21.06.2016)	**27 June 2016 (27.06.2016)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer
KIM, Yeon Kyung
Telephone No. +82-42-481-3325

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AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/025333

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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IPR2024-00095, U.S. Patent No. 10,568,533
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Electronic Acknowledgement Receipt

EFS ID:	35042303
Application Number:	16143959
International Application Number:	
Confirmation Number:	6224
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Customer Number:	150004
Filer:	Peter Jung-Hyon Yim/Swarnava chakraborty
Filer Authorized By:	Peter Jung-Hyon Yim
Attorney Docket Number:	P38213US2/77770000489102
Receipt Date:	04-FEB-2019
Filing Date:	27-SEP-2018
Time Stamp:	14:44:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P38213US2_IDS.pdf	177686 bba61e04c9c2e41386cf3ed87c042fe457a39779	no	3

Warnings:

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Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO_2015187799_A1.pdf	15481077 2eaa27f641d314470fb855eac8ee755c90bee461	no	98
Warnings:					
Information:					
3	Foreign Reference	WO_2016161152_A1.pdf	8278524 3a3799f6a7aa889041da5bbe36f985c8f06b96de	no	53
Warnings:					
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4	Non Patent Literature	Graph_and_charts_2018_4.pdf	118209 a0f84521f2e0c51ac942d124b6e0287f6da60790	no	4
Warnings:					
Information:					
5	Non Patent Literature	PA201870599_DKSR_12_21_2018.pdf	2632284 e01fae3943590c521eb1f92266b768f9859cf7f1	no	9
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	USER INTERFACES FOR HEALTH MONITORING

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/143,959 filed on 09-27-2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

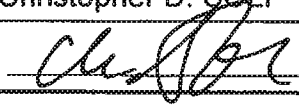
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Christopher D. SOLI Date (Optional): 11-2-2018

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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IPR2024-00095, U.S. Patent No. 10,568,533
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PTO/AIA/01 (06-12)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	USER INTERFACES FOR HEALTH MONITORING

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/143,959

filed on 09-27-2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Matthew W. CROWLEY Date (Optional) :

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	USER INTERFACES FOR HEALTH MONITORING

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/143,959

filed on 09-27-2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Bradley W. GRIFFIN Date (Optional) :

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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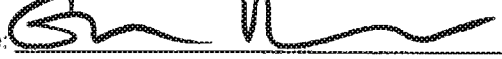
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LEGAL NAME OF INVENTOR

Inventor: Gary Ian BUTCHER Date (Optional): 11/02/2018

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Roxanne BRITTAIN Date (Optional): 1/14/19

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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Electronic Acknowledgement Receipt

EFS ID:	34875134
Application Number:	16143959
International Application Number:	
Confirmation Number:	6224
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Customer Number:	150004
Filer:	Brian B. Ho/Staci Berry
Filer Authorized By:	Brian B. Ho
Attorney Docket Number:	P38213US2/77770000489102
Receipt Date:	16-JAN-2019
Filing Date:	27-SEP-2018
Time Stamp:	16:09:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	P38213US2_Decs1.pdf	2343299 6439c4d73c2a87f086d3d10d3d7941f58ca5a226	no	5

Warnings:

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

Information:	
Total Files Size (in bytes):	2343299

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/143,959
	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	B. N. Nganga
	Attorney Docket Number	P38213US2/77770000489102

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	9712629	B2	2017-07-18	Molettiere et al.	
	2.	9813642	B1	2017-11-07	Chen et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	20040017300	A1	2004-01-29	Kotzin et al.	
	2.	20060152372	A1	2006-07-13	Stout, Todd	
	3.	20080200312	A1	2008-08-21	Tagliabue, Roberto	
	4.	20100010832	A1	2010-01-14	Boute et al.	
	5.	20110098928	A1	2011-04-28	Hoffman et al.	
	6.	20110245623	A1	2011-10-06	Chutani et al.	
	7.	20120317167	A1	2012-12-13	Rahman et al.	
	8.	20130231947	A1	2013-09-05	Shusterman, Vladimir	
	9.	20140142403	A1	2014- 05-22	Brumback et al.	
	10.	20140240122	A1	2014-08-28	Roberts et al.	
	11.	20140336796	A1	2014-11-13	Agnew, John	
	12.	20150217163	A1	2015-08-06	Amis et al.	
	13.	20150220883	A1	2015-08-06	Bfar et al.	
	14.	20160062582	A1	2016-03-03	Wilson et al.	
	15.	20160235374	A1	2016-08-18	Miller et al.	
	16.	20170053542	A1	2017-02-23	Wilson et al.	
	17.	20170300186	A1	2017-10-19	Kuhar et al.	
	18.	20170357520	A1	2017-12-14	De Vries et al.	
	19.	20180064356	A1	2018-03-08	Mendenhall et al.	
	20.	20180329584	A1	2018-11-15	Williams et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1.	2006/046648	WO	A1	2006-05-04	Sharp KK		

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
978 of 1413

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	B. N. Nganga
	Attorney Docket Number	P38213US2/77770000489102

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1.	International Search Report and Written Opinion received for PCT Patent Application No. PCT/US2018/031662, mailed on September 27, 2018, 17 pages.	
	2.	Invitation to Pay Addition Fees and Partial International Search Report received for PCT Patent Application No. PCT/US2018/031662, mailed on July 16, 2018, 13 pages.	
	3.	Office Action received for Danish Patent Application No. PA201870601, mailed on December 13, 2018, 8 pages.	
	4.	Search Report and Opinion received for Danish Patent Application No. PA201870602, mailed on December 19, 2018, 8 pages.	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (03-15)
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	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	B. N. Nganga
	Attorney Docket Number	P38213US2/77770000489102

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Randy Omid/	Date (YYYY-MM-DD)	2019-01-16
Name/Print	Randy Omid	Registration Number	67,439

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(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
2006 年5 月4 日 (04.05.2006)

PCT

(10) 国際公開番号
WO 2006/046648 A1

(51) 国際特許分類:
A61B 5/00 (2006.01) *G06Q 50/00* (2006.01)

(21) 国際出願番号: PCT/JP2005/019792

(22) 国際出願日: 2005 年10 月27 日 (27.10.2005)

(25) 国際出願の言語: 日本語

(26) 国際公開の言語: 日本語

(30) 優先権データ:
特願 2004-312584
2004 年10 月27 日 (27.10.2004) JP

(71) 出願人 (米国を除く全ての指定国について): シャープ株式会社 (SHARP KABUSHIKI KAISHA) [JP/JP]; 〒5458522 大阪府大阪市阿倍野区長池町２２番２２号 Osaka (JP).

(72) 発明者; および

(75) 発明者/出願人 (米国についてのみ): 佐藤 文代 (SATOH, Fumiyo) [JP/—]. 曽根 基樹 (SONE, Motoki) [JP/—]. 和辻 徹 (WATSUJI, Toru) [JP/—]. 山本 義春 (YAMAMOTO, Yoshiharu) [JP/—].

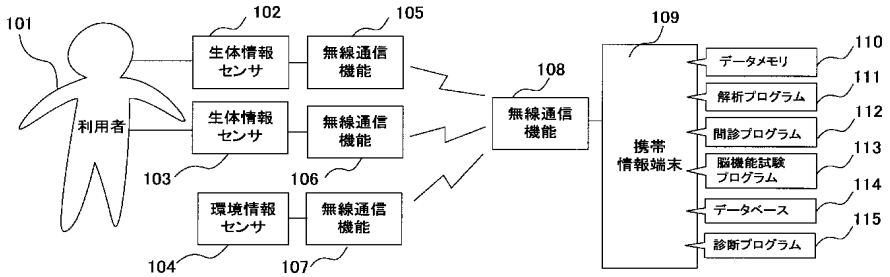
(74) 代理人: 藤本 英介, 外(FUJIMOTO, Eisuke et al.); 〒1000014 東京都千代田区永田町二丁目１４番２号山王グランドビルヂング３階３１７区藤本特許法律事務所内 Tokyo (JP).

(81) 指定国 (表示のない限り、全ての種類の国内保護が可能): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

[続葉有]

(54) **Title:** HEALTHCARE APPARATUS AND PROGRAM FOR DRIVING THE SAME TO FUNCTION

(54) 発明の名称: 健康管理装置及びこれを機能させるためのプログラム



101... USER
102... BIOMETRIC INFORMATION SENSOR
103... BIOMETRIC INFORMATION SENSOR
104... ENVIRONMENTAL INFORMATION SENSOR
105... WIRELESS COMMUNICATION FUNCTION
106... WIRELESS COMMUNICATION FUNCTION
107... WIRELESS COMMUNICATION FUNCTION
108... WIRELESS COMMUNICATION FUNCTION
109... MOBILE INFORMATION TERMINAL
110... DATA MEMORY
111... ANALYZING PROGRAM
112... DIAGNOSIS-BY-ASKING-QUESTIONS PROGRAM
113... BRAIN FUNCTION TESTING PROGRAM
114... DATABASE
115... DIAGNOSIS PROGRAM

(57) **Abstract:** A mobile information terminal (109) stores, in a time sequence, measurement information transferred from sensors into a data memory (110). A CPU of the mobile information terminal (109) analyzes the measurement results by use of an analysis program (111) to determine whether any of the measurement results indicates any extraordinary value. If the output result of the analysis program (111) indicates any response that is different from a normal one, then the mobile information terminal activates a diagnosis-by-asking-questions program. The CPU uses the diagnosis-by-asking-questions program (112) to ask questions so as to determine whether the extraordinary biometric information extracted from the sensors is caused by any deficiencies such as fault conditions or omissions of the sensors, or by a variation in the psychological condition of the user, or by a variation in the physical condition of the user. Answers to the questions are entered by the user (101) itself into the mobile information terminal (109). This is used for home-based medical care and telemedicine or directed to support such a diagnosis of disease or such a health maintenance that is difficult for any medical institutions to provide.

(57) 要約: 携帯情報端末１０９は、各センサから転送された計測情報をデータメモリ１１０に時系列で保存する。携帯情報端末１０９のＣＰＵは、解析プログラム１１１により、計測結果の解析を行い、計測結果が異常値を示していないかどうかを判定する。解析プログラム１１１の出力結果が通常と異なる反応を示した時、携帯情報端末は問診プログラムを起動する。問診プログラム１１２によりＣＰＵは、センサから抽出した生体情報の

[続葉有]

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
981 of 1413

WO 2006/046648 A1

(84) 指定国 (表示のない限り、全ての種類の広域保護が可能): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), ユーラシア (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), ヨーロッパ (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

添付公開書類:
— 国際調査報告書

２文字コード及び他の略語については、定期発行される各*PCT*ガゼットの巻頭に掲載されている「コードと略語のガイダンスノート」を参照。

異常が、センサの故障や脱落などの不具合によるものか、利用者の心理状態の変化によるものか、あるいは、体調の変化によるものかを判断するための質問を行う。問診に対する回答は、利用者１０１自らが、携帯情報端末１０９に入力する。在宅医療や遠隔医療用として、あるいは、医療機関による健康診断では測ることのできない病気の診断や健康維持をサポートするようにする。

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明 細 書

健康管理装置及びこれを機能させるためのプログラム

技術分野

[0001] 本発明は、心身の健康管理を行う健康管理装置及びこれを機能させるためのプログラムに関するものである。

背景技術

[0002] 近年、在宅医療や遠隔医療の必要性と、医療機関による健康診断の実施では判定できない病気の常時検診を可能とするため、医療機関で利用するような高性能医療機器ではなく、在宅、遠隔で計測可能な携帯型の健康診断機器が開発されてきた。また、高齢者医療や、介護の重度を軽減するような介護予防の観点からも、在宅型、携帯型の健康管理機器の開発が必要とされている。

[0003] 携帯型の健康診断機器として、特許文献1の携帯型の健康モニタが提案されている。一般に医療機関による健康診断だけでは、病気の症状が悪い状態の時のデータを常に計測できないという問題がある。この問題を解決するために、特許文献1の携帯型の健康モニタでは、生体情報の計測結果である生理学的データと、主観的な健康状態を記録したデータからなるデータベースと、データ管理機能をもつ健康モニタシステムを提案している。この携帯型健康モニタでは、被験者から得られる複数の生理学的および主観的データを、時系列データとして収集することや、モニタ機器からデータベースに定期的にデータをアップロードする通信システム機能をもつことによって、自動的に、非侵襲で計測する機能をもち、また、被験者の心理的状態や活動・環境情報の主観的レポートを作成する機能をもつことによって、客観的な生理学データと主観的なデータを、時系列で整備し、被験者／患者の健康ヒストリを作ることが可能となっている。前記主観的なデータは、医者などの指示により予め設定された時刻に収集されるものであり、モニタリングによって得られた前記生理学的データとは無関係に収集され、下記発明の解決しようとする課題に記載した問題点を有する。

[0004] また、一般に被検者の生体情報が、日常値において大きくばらつきがあるため被検者の身体異常発生は正確に検知できないという問題がある。特許文献2では、この問

題を解決するため、被検者の血圧、脈拍、呼吸数、血中酸素濃度の生体情報のうち、少なくとも一つの生体情報を測定する生体情報測定装置と加速度センサの情報をネットワークで伝送し、複数のデータに異常があった場合警告を発するシステムを提案している。しかし、本公知技術も、センサと取り付け方法、センサからのデータの識別方法等に問題があり、下記発明の解決しようとする課題に記載した問題点を有する。

[0005] また、生体情報を連続的に計測すると共に、適時問診によりその時の精神状態を効率よく収集する、特許文献3の携帯型生態情報収集装置が提案されている。

本公知技術では、定期的及び生体情報に大きな変化が生じた時、気分や精神状態についての質問を表示し、利用者に入力させ、生体情報と精神情報を同じ時系列で収集し、効率的な精神情報の収集を可能としている。しかし、本公知技術は、データ収集のみが可能な携帯装置であり、下記発明の解決しようとする課題に記載した問題点を有する。

特許文献1:US Patent No. 6095985(US)

特許文献2:特開2003－220039号公報

特許文献3:特開2003－290176号公報

発明の開示

発明が解決しようとする課題

[0006] 特許文献1の携帯型健康モニタでは、計測した生体データ(生理学的データ)と問診による主観的データとを時系列データとしてデータベースに単に蓄積しているだけである。従って、利用者の心身の健康状態の変化をリアルタイムで判断し、その変化に応じた対処手段を決定し、利用者に直ちに警告を与えたり、状態の改善を促したりすることができない。

[0007] また、特許文献2の携帯装置においては、複数の生体情報を収集するセンサを設け、平均化や総合的判断を行うことにより、携帯型または簡易型センサに特有の周囲の雑音による計測誤差やセンサの脱落による計測誤りを軽減できるとしている。このように複数のセンサによって計測精度を上げた結果を用いて、信頼性の高い緊急通報が行うことが可能としている。しかしながら、複数センサを用いて計測精度を上げた

としても、利用者の心理状態の変化、例えば、人前で緊張したなどという正常な心理状態の変化にも、センサは異常値を出力してしまう。従来の携帯装置は、このような正常な心理状態の変化に対しても異常警告を発してしまい、実際の遠隔医療などに用いる場合には、情報の信頼性が低く、実用的でない。さらに、複数のセンサを設けることにより、センサの脱落によって計測精度が著しく低下することを防いではいるが、センサ脱落による計測の欠落を防ぐことや、またセンサが脱落したことを確認することはできない。

[0008] また、特許文献3の情報収集装置においては、生体情報と精神情報(問診結果)を時系列情報として蓄積することで、その情報を治療に役立てることはできるが、それらの情報をもとに診断し、その診断結果に基づく改善方法を提示することはできない。したがって、医師などの診断を仰がなければ、健康状態がどのように推移しているか確認できず、緊急な措置が必要な健康状態に問題がある場合であっても、自らがその状態を知ることができない。

またその改善方法の実施の結果、生体情報(体調)がどのように変化したかも、利用者自らが確認することもできない。したがって、医師等の診断なしには、健康管理装置を提供することはできない。

[0009] そこで、本発明は、上記公知技術の問題点を解決するものであり、在宅医療や遠隔医療用として、あるいは、医療機関による健康診断では測ることのできない病気の診断や健康維持をサポートする健康管理装置及びこれを機能させるためのプログラムの提供を目的としたものである。さらに、実用レベルでの信頼性の高いデータ取得、リアルタイムでの身体の通常とは異なる状態の検出、その状態の原因解明、異常を引き起こした原因の排除あるいは症状の改善を目的とした携帯型の健康管理装置及びこれを機能させるためのプログラムの提供を目的としたものである。

課題を解決するための手段

[0010] 第1の発明は、生体情報または生体の周囲の環境情報を計測するセンサと、前記センサの計測結果を解析する解析手段と、利用者に質問を行い、回答を入力させる問診手段と、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の状態を判断する診断手段と、前記診断手段が判断する生体の状態に基づいて

情報を通知する通知手段と、を備えることを特徴とする健康管理装置である。

[0011] 第2の発明は、第1の発明記載の健康管理装置において、センサ部分は装置本体とは分離可能であり、センサ出力と本体との間でセンサ計測結果データの通信を行う通信手段を有することを特徴とする。

[0012] 第3の発明は、第1の発明記載の健康管理装置において、携帯電話または携帯端末であることを特徴する。

[0013] 第4の発明は、第1の発明記載の健康管理装置において、前記解析手段、前記問診手段、前記診断手段、および前記通知手段を含む装置本体と前記センサとは分離可能であり、前記センサと前記装置本体との間でセンサ計測結果の通信を行うセンサ通信手段を有することを特徴とする。

[0014] 第5の発明は、第1の発明記載の健康管理装置において、情報を出力する出力デバイスをさらに備え、前記通知手段は、前記出力デバイスにより情報を出力することを特徴とする。

[0015] 第6の発明は、第1の発明記載の健康管理装置において、他の装置と通信する外部装置通信手段を備え、前記通知手段は、前記外部装置通信手段により情報を他の装置に情報を通知することを特徴とする。

[0016] 第7の発明は、第1の発明記載の健康管理装置において、前記問診手段は、前記解析手段の解析結果が所定の条件を満たした場合に質問を行うことを特徴とする。

[0017] 第8の発明は、第1の発明記載の健康管理装置において、前記問診手段は、あらかじめ定められたスケジュールに基づいて質問を行うことを特徴とする。

[0018] 第9の発明は、第1の発明記載の健康管理装置において、前記通知手段は、生体の症状が生じた原因情報を通知することを特徴とする。

[0019] 第10の発明は、第1の発明記載の健康管理装置において、前記通知手段は、生体の症状を改善するための改善情報を通知することを特徴とする。

[0020] 第11の発明は、第9の発明記載の健康管理装置において、前記改善情報は、少なくとも投薬の種類、投薬の使用量、または投薬の時刻のいずれかを含むことを特徴とする。

[0021] 第12の発明は、第1の発明記載の健康管理装置において、前記診断手段は、前

記解析手段の解析結果と前記問診手段の問診結果とをそれぞれ点数化し、前記解析結果の点数と問診結果の点数との加算値に基づいて生体の状態を判断することを特徴とする。

[0022] 第13の発明は、第1の発明記載の健康管理装置において、前記解析手段は、前記センサの現在の計測値と過去の計測値とに基づいて解析結果を生成することを特徴とする。

[0023] 第14の発明は、第1の発明記載の健康管理装置において、前記解析手段の解析結果に基づいて前記センサの設置の異常を通知する異常通知手段を備えることを特徴とする。

[0024] 第15の発明は、第1の発明記載の健康管理装置において、生体の反応を試験する反応試験手段を備え、前記反応試験手段による反応結果に基づき、前記問診結果の妥当性を判断することを特徴とする。

[0025] 第16の発明は、第1の発明記載の健康管理装置において、前記センサは生体の振動を検出する振動センサを含み、前記解析手段は、前記振動センサで検出した過去の振動の周期性に対する現在の振動の周期性のずれを解析し、前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の心身症に関する状態を判断することを特徴とする。

[0026] 第17の発明は、第1の発明記載の健康管理装置において、前記センサは生体の体温を検出する体温センサを含み、前記解析手段は、前記体温センサで検出した体温があらかじめ定められた値を越えているか否かを解析し、前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の心身症に関する状態を判断することを特徴とする。

[0027] 第18の発明は、第1の発明記載の健康管理装置において、前記センサは、生体の振動を検出する振動センサ、および、生体の体温を検出する体温センサを含み、前記解析手段は、前記振動を検出する振動センサで検出した過去の振動の周期性に対する現在の振動の周期性のずれ、および、前記体温センサで検出した体温があらかじめ定められた値を越えているか否か、を解析し、前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の心身症に関する状態

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を判断することを特徴とする。

[0028] 第19の発明は、第1の発明記載の健康管理装置において、前記センサは、ガス濃度を検出するガスセンサを含み、前記解析手段は、前記ガスセンサで検出したガス濃度があらかじめ定められた値を越えているか否かを解析し、前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の化学物質過敏症に関する状態を判断することを特徴とする。

[0029] 第20の発明は、第19の発明記載の健康管理装置において、前記通知手段は、当該ガスセンサの設置された位置からの退去を促すメッセージを通知することを特徴とする。

[0030] 第21の発明は、第1の発明記載の健康管理装置において、前記センサは生体の振動を検出する振動センサを含み、前記解析手段は、前記振動センサで検出した振動の周期性に基づき1日の生活リズムを取得し、取得した前記1日の生活リズムに基づき解析緒果を生成し、前記診断手段は、前記解析手段の解析席発と前記問診手段の問診結果とに基づいて生体の慢性疲労症候群に関する状態を判断することを特徴とする。

[0031] 第22の発明は、第21の発明記載の健康管理装置において、前記センサは、照度を検出する照度センサを含み、前記解析手段は、前記照度センサで検出した照度に基づいて昼夜判断情報を生成し、前記振動センサで検出した振動の周期性と前記昼夜情報とに基づき1日の生活リズムを取得することを特徴とする。

[0032] 第23の発明は、第1の発明記載の健康管理装置において、振動または脈拍または心拍または体温のうち、少なくとも一つ以上を計測するセンサを用いて、ダイエットまたは食事療法に関する健康管理を行うことを特徴とする。

[0033] 第24の発明は、第1の発明記載の健康管理装置において、振動または発話のうち少なくとも一つ以上の生体情報を計測するセンサを用いて、介護予防に関する健康管理を行うことを特徴とする。

[0034] 第25の発明は、第1の発明記載の健康管理装置において、振動または脈拍または心拍または呼吸のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、無呼吸症候群に関する健康管理を行うことを特徴とする。

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[0035] 第26の発明は、第1の発明記載の健康管理装置において、振動または脈拍または心拍または発話のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、痴呆症に関する健康管理を行うことを特徴とする。

[0036] 第27の発明は、第1の発明記載の健康管理装置において、振動または脈拍または心拍のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、パーキンソン病に関する健康管理を行うことを特徴とする。

[0037] 第28の発明は、第1の発明記載の健康管理装置において、振動または脈拍または心拍または体温または発話のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、脳卒中に関する健康管理を行うことを特徴とする。

[0038] 第29の発明は、第1の発明記載の健康管理装置において、脈拍または心拍または体温のうち、少なくとも一つ以上の生体情報と免疫に関する生体情報を計測するセンサを用いて、精神障害に関する健康管理を行うことを特徴とする。

[0039] 第30の発明は、生体情報または生体の周囲の環境情報を計測するセンサの計測結果を解析する第1のステップと、利用者に質問を行い、回答を入力させる第2のステップと、前記第1のステップの解析結果と前記第2のステップの問診結果とに基づいて生体の状態を判断する第3のステップと、前記第3のステップが判断する生体の状態に基づいで備報を通知する第4のステップと、をコンピュータに実行させることを特徴とする健康管理プログラムである。

発明の効果

[0040] 本発明による健康管理装置は、一つあるいは複数のセンサから得られた身体に関する生理情報と環境情報を解析し、解析結果に通常と異なる反応が現れた場合、利用者に問診を行い、利用者自らが問診に対する回答を入力する。この問診では、利用者の主観情報を得ることができる。以上の結果、センサの計測情報すなわち客観情報と、この客観情報と連動した問診による主観情報とを併用して診断を行っており、利用者の体調が通常と異なっているかどうかが、従来では成しえなかった高い信頼性でリアルタイムに検出することができ、このため、従来方法と比べ極めて正確な健康管理を実施することができる。

[0041] 利用者の体調が通常と異なっているかどうかとは、例えば、

1）病状が悪化又は改善したこと

2）利用者の努力目標（ダイエットなど）が達成に向かっているか失敗に向かっているか3）利用者が服用した薬の効果（痛みや熱など）が効いているか効いていないかなどを指す。

[0042] また、健康管理装置本体とセンサを分離可能として装置本体とセンサが通信でデータをやり取りするので、利用者は、センサを簡単に取り付けでき、非拘束、非侵襲で、常時、生体の状態変化を計測することが可能である。さらに、健康管理装置を携帯電話にすれば、持ち運びも容易となる。

[0043] また、本発明は、外部の他の装置へ通信する通信手段を備えて、センサの計測結果を解析した結果と、患者への問診結果に基づいて、医者や家族などに知らせる緊急通報が可能となる。

[0044] また、問診手段が、解析手段によるセンサ情報の解析結果に基づいて質問を行ったり、スケジュールに基づいて質問を行うので、症状に合わせた適切な質問を行うことができ、また患者の記憶に頼らずに、必要な時刻に問診情報を得ることができる。

[0045] また、利用者の状態が通常と異なり、病状の悪化が判断された場合などは、通知手段が症状の原因や改善情報を通知することにより、警告や改善すべき点を利用者に即座に知らせることができ、病気の悪化が防げ、また、早急な体調改善への手助けが可能な健康管理装置を提供することが可能となる。

[0046] また、解析結果と問診結果を点数化して判断することにより、装置が簡単に演算で判断可能となり、適切で素早い診断が可能となる。

[0047] また、携帯情報端末等の健康管理装置に、測定結果あるいは解析結果の利用者の過去のパターンをデータベースとして具備し、解析プログラムにおいて現在の計測結果と利用者の過去のデータベースと比較することで、利用者の体調の変化を精度よく解析することができる。

[0048] また、解析結果と、解析結果と連動した問診結果を併用した診断を行うことにより、携帯型及び遠隔型での常時測定環境で問題となる、センサの取り外しや脱落などによる異常なデータを、携帯情報端末において判断することが可能となり、信頼性の高いデータを得ることができる。また、センサが外れていることが確認された場合は、利

用者にそれを通知することによって、正常な装着を促すこともできる。

[0049] また、生体反応を試験して問診結果と比較することにより、さらに正確な診断が可能となる。

[0050] また、携帯情報端末に、疾病ごとの解析結果や問診結果の特徴的パターンをデータベースとして具備し、診断プログラムにおいて解析手段の結果または問診手段の結果と疾病データベースとを比較することにより、さらに正確な診断を行う健康管理装置を実施することができる。

[0051] 本発明の健康管理装置は、現在病気であることが判明している患者に対しては、身体の状態異常が顕著なときには、処方する投薬量を多くし、また異常が見られないような場合には投薬を控えるようにすることで、投薬量の制御や副作用の反応の情報収集に利用することができる。また、投薬リマインダーと組み合わせて、従来にはなかった効果的な投薬支援が可能となる。

図面の簡単な説明

[0052] [図1]本発明による健康管理装置の構成を示す図である。

[図2]本発明における健康(病気)管理対象とセンサによる測定項目を示すである。

[図3]本発明における健康管理装置の処理の流れを示すフローチャートである。

[図4]本発明による慢性疲労症候群を対象とした健康管理装置を実施する構成図である。

[図5]本発明による化学物質過敏症を対象とした健康管理装置の実施例における、患者が体調の変化を起こすガスの種類と濃度を示す表である。

[図6]本発明による化学物質過敏症を対象とした健康管理装置の実施例における、問診内容とその回答結果を示す表である。

符号の説明

[0053] 101 : 利用者

102、103 : 利用者の生体情報を計測するセンサ

104 : 利用者の周囲の環境情報を計測するセンサ

105～108 : 無線通信機能

109 : 携帯情報端末

110 ： 携帯情報端末に搭載されるデータメモリ

111 ： 携帯情報端末に搭載される解析プログラム

112 ： 携帯情報端末に搭載される問診プログラム

113 ： 携帯情報端末に搭載される脳機能試験プログラム

114 ： 携帯情報端末に搭載されるデータベース

115 ： 携帯情報端末に搭載される診断プログラム

301 ： 体温情報を計測する温度センサ

302 ： 体動情報を計測する振動センサ

303 ： 携帯情報端末

発明を実施するための最良の形態

[0054] まず図1を用いて、健康管理装置の全体の構成と各機能の起動、制御の流れを説明する。図1は本発明による心身健康管理装置の構成を示しており、利用者が生体情報を計測するセンサを二つ装着し、利用者の周囲の環境情報を計測するセンサを一つ携帯している場合の例である。

[0055] 健康管理装置は、利用者101の生体情報を計測する一つあるいは複数のセンサ102、103と、場合によっては一つあるいは複数の周囲の環境情報計測するセンサ104と、携帯情報端末109により構成される。各センサ102～104と携帯情報端末109には、それぞれセンサ102～104の計測データを携帯情報端末109に転送し、また携帯情報端末109から各センサ102～104に設定情報などを転送することが可能な無線通信機能105～108が装備されている。

こうして、装置本体とセンサを無線通信を介して分離可能となるので、利用者がセンサを装着しやすくなるメリットがある。

[0056] 今回センサと携帯情報端末は無線通信機能を介して情報の転送を行うが、必ずしも無線通信を用いて伝送する必要はなく、有線通信を用いることもできる。また、環境センサや生体センサを組み込んだ携帯情報端末を用いることもできる。

[0057] また、携帯情報端末109には、データメモリ110と、計測データを解析する解析プログラム111と、利用者の健康状態に関する質問や利用者の置かれた環境に関する質問を行う問診プログラム112と、脳の機能を計る脳機能試験プログラム113と、解析プ

ログラム111の結果と問診プログラム112の結果から健康状態の診断を行う診断プログラム115とが装備されている。そして、携帯情報端末109のCPUは、解析プログラム111と、問診プログラム112と、脳機能試験プログラム113と、診断プログラム115とに基づいて、解析手段と、問診手段と、脳機能試験手段と、診断手段として機能する。

また、診断をより正確に行うために、病気の症状と計測結果の解析とを結びつける診断データベース114が装備されていてもよい。

[0058] 本実施例では、センサの計測データの解析、問診、診断のプログラムを携帯情報端末109において実行しているが、同様の処理能力のある端末であれば良く、例えば、携帯電話や電子辞書を用いて実施することも可能であり、持ち運びも容易となる。

[0059] 利用者101は、体の一部に生体情報を計測するセンサ102、103を一つあるいは複数装着するが、生体情報を計測するセンサとは、例えば、手首、脚、あるいは腰などに加速度計を装着することにより身体の活動度を計測する振動センサ、身体の傾きを計測する傾斜センサ、身体の回転度合いを計測するジャイロセンサ、身体の向きを計測する磁気センサ、耳、手首、手の指などに装着し脈拍、血流、血中酸素飽和度を測定する脈拍・血流センサ、耳や脇の下などに装着する体温センサ、胸などに装着し胸などの動きを計測する呼吸センサまたは心拍計、耳や顔の一部にマイクを装着し利用者の発話を分析する発話センサ、他筋電計、バイオセンサなどが挙げられる。

[0060] また、利用者101は周囲の環境情報を計測するセンサ104を携帯する場合もある。周囲の環境情報を計測するセンサとは、例えば、ガスセンサ、GPSによる位置センサ、気温を計測する温度センサ、湿度センサ、気圧計、雨量・積雪計、環境雑音を計測するマイク、空気中の微粒子量を計測するパーティクルカウンタ、電磁波を計測する電磁界強度センサ、物体の通過・接近を計測するIRやカメラを使った人感センサ、地震計、あるいは照度センサなどがある。

[0061] 装着するあるいは携帯するセンサの種類は、利用者の健康と病気の管理項目に応じて選定される。健康管理の対象（予防／状態管理する病気など）と装着するセンサ

の種類、特にその計測項目の例を、図2に示す。

[0062] 次に、図3に示すフローチャートを用いて、本発明のデータと処理の流れを説明する。ステップS11から処理を始める。生体情報を計測するセンサ102、103及び環境情報を計測するセンサ104は、無線通信機能105～108を用いて、計測結果の情報を携帯情報端末109に転送する(ステップS12)。計測した情報の転送は、ストリーミングでもいいが、センサ側で計測データを蓄積し、定期的に情報を転送しても良い。

[0063] 携帯情報端末109は、各センサから転送された計測情報をデータメモリ110に時系列で保存する。次に、携帯情報端末109のCPUは、解析プログラム111により解析手段として機能し、各センサの計測結果の解析を行い(ステップS13)、計測結果が異常値を示していないか、あるいは、通常と異なるかどうかを判定する(ステップS14)。解析プログラム111は、利用者101の携帯するセンサの種類と数、及び予防あるいは検診する病気(健康管理対象の)の種類に応じて解析プログラムを用意しておく。

[0064] 解析プログラム111の出力結果が通常と異なる反応(異常値)を示した時、携帯情報端末109は問診プログラム112を起動する(ステップS15)。問診プログラム112によりCPUは、センサからの生体情報に異常があった場合に起動する以外に、スケジュールによる起動、利用者が自分の体調の変化を認識したりあるいは体調に不安が生じたときなどに利用者が直接問診プログラム112を起動することが可能である。

[0065] 問診プログラム112によりCPUは、センサから抽出した生体情報の異常が、センサの故障や脱落などの不具合によるものか、利用者の心理状態の変化によるものか、あるいは、体調の変化によるものかを判断するための質問を行う。実際には、利用者の周囲環境、利用者の心理状態に関するアンケートを行い、利用者の主観的情報を抽出しする。問診に対する回答は、利用者101自らが、携帯情報端末109に入力する。(ステップS16)

[0066] 次に、CPUは、脳機能試験プログラム113を起動し(ステップS17)、脳の機能を計測する。計測した生体情報、解析プログラム111の出力結果、及び問診及び脳機能試験プログラム113を実行した結果は、データメモリ110に時系列で蓄積される。

[0067] 次にステップS18で、データ診断プログラム115によりCPUは、取得した結果を評価し、あるいはデータベース114との比較や、医療辞書を参照することにより症状の

兆候が出ているかどうかの判定を行い、処理を終了する(ステップS19)。

[0068] 診断プログラム115の結果から、症状の状況通知、症状の改善方法、および機器の装着状況の改善要請などを利用者に通知する。利用者への通知は、携帯情報端末109をはじめセンサ機器や通知専用のデバイスの、音声出力、振動出力、LED表示、及びディスプレイ表示機能などを用いて行う。

[0069] また、その結果は、携帯情報端末109が公衆網やIP網との通信機能を持つ場合には、医療機関や利用者の家族などに通知することも可能である。例えば、医療機関のサーバや家族のパソコン等に通知を行い、さらに医師や家族からの問診や処置の通知を携帯情報端末109に行なうことも可能となる。このようにこれら装置による健康管理システムを構築することも可能である。

[0070] 本発明の実施の形態では、診断結果や変化した原因等を直ちに患者に通知することで、患者は気をつけるべき行動、次にとるべき行動、現在の症状等を認識できる。記録された体動のデータと問診結果を後日医師にもって行くことで、頻繁に通院しなくても医師は正しく患者の病状を知ることができる。

[0071] 次に、本発明の健康管理装置を慢性疲労症候群患者に適用した場合の実施例を示す。

慢性疲労症候群は、倦怠感、抑鬱状態、思考力の障害、微熱などが長期にわたり続く症状を示し、米国厚生省疾病管理・予防センター(CDC)の改訂基準診断基準項目の中に、記憶または集中力の障害、睡眠障害、体動後の回復しにくい疲労感が挙げられている。

これらの症状は、病院内での検査だけでは明確に診断できず、現在は、医師と患者の問診により、患者の記憶を頼りに症状を把握している。また治療に当たっては、問診時に過去の記憶に基づいて患者が発言した主観的な内容を元に、病状が回復したか否かを医師が判断していた。

[0072] しかしながら、患者毎に病状の受け止め方が異なることが多く、最近の研究によれば、患者は最後に感じた苦痛や、最も激しかった苦痛を印象的に覚えている。しかしながら、それ以前に発生した苦痛や、苦痛の強度は弱くとも連続的に発生した苦痛の方が、医師にとっては重要であることが多いにも関わらず、知ることが出来ないとい

う問題がある。このような患者毎の受け止め方の違いや、記憶の曖昧さが生じるため、患者の記憶による正確な診断は困難である。そのため、患者は頻繁に通院し医師の診断を受ける必要があり、患者の負担が大きくなっている。

[0073] そこで近年、患者の主観的な記憶に頼るような診断方法ではなく、慢性疲労症候群の客観的な数値による診断を可能とする研究がなされている。

[0074] (1)Kyoko Ohashi, Yoshiharu Yamamoto, Benjamin H, Natelson, "Activity rhythm degrades after strenuous exercise in chronic fatigue syndrome", Physiology&Behavior 77(2002)39－44

[0075] (2)Ohashi, K. G. Bleijenberg, S. Van der Warf, J. Prins, L. A. N. Amaral, B. H. Natelson, and Y. Yamamoto、"Decreased Fractal Correlation in Diuranal Physical Activity in Chronic Fatigue Syndrome", Methods of Information in Medicine 43:26－29, 2004

[0076] 文献(1)によると、人の睡眠状態と覚醒状態の生活リズムは、通常24時間で繰り返す周期性を持っている。しかし慢性疲労症候群患者の前記リズムは、激しい運動をした後にその周期性が崩れ、通常の24時間からずれを生じる。この傾向は、健康な人には起こりにくく、慢性疲労症候群患者によく現れる。具体的には、手首に振動センサを取り付け、振動センサによって人の体動情報を取得し、人の一日の生活リズムであるMCP(M
ean Circadian Period)を算出する。人が激しい運動をした後のMCP値は、健康な人では23．86時間であるのに対し、慢性疲労症候群患者では24．20時間となることがわかっている。被験者が激しい運動をした後のMCP値を求めることにより、被験者の慢性疲労症候群の可能性を判定することが可能である。本発明では、解析プログラムの一例として本MCP値による判別方法を用いる。

[0077] 文献(2)によると、健康な人は慢性疲労症候群患者に比べて昼夜の活動の差が顕著であり、また、健康な人と慢性疲労症候群患者では活動の突発性にも差を生じる。手首に振動センサを取り付け体動の情報を取得し、WTNMM(Wavelet Transform Negative Modulus Maxima)法を用いてτを、あるいはDFA(Detrended Fluctuation Analysis)法を用いてαを計算した結果には、慢性疲労症候群患者と健常者の間に

明らかな数値差が生じる。これらの数値差により慢性疲労症候群患者と健常者との判別を行うことが可能である。

[0078] 以下に、WTNMM法によるτ、およびDFA法によるαの計算方法を簡単に説明する。WTNMMは、変動のマルチフラクタル性を解析する手法であり、まず、以下のようにウェーブレット変換を行う。

[0079] [数1]

$$T\psi[f](b,a)=\frac{1}{a}\int_{-\infty}^{\infty}\{f(t)\psi((t-b)/a)\}dt$$

[0080] ここで、f(t)は時刻tにおけるゼロクロス値である。ゼロクロス値とは体動情報であり、手首に取り付けた振動センサのAC成分を取り出し、0．01G以上の加速度が起こる数をカウントした値である。このカウント値は、利用者が覚醒時にある時はその増加は大きく、逆に睡眠時では、その増加は非常に小さい、といった傾向を示す値ある。Ψ(x)は、マザーウェーブレットと呼ばれ、非特許文献2においては、ガウス関数を3回微分した結果を使用している。具体的には以下の式2である。

[0081] [数2]

$$\psi(x)=x(3-x^2)e^{-0.5x^2}$$

[0082] TΨ[f](b，a)は、時刻(t＝b)におけるf(t)に含まれるある区間周波数aの成分の大きさを示す。

式1で得られたTΨ[f](b，a)の中で、区間minTで、a^T(＜a)におけるウェーブレット関数の谷を抽出し、和を取る。具体的には、後述する式3のようになる。抽出した部分の和をaのτ乗に比例すると仮定して、τの値を近似により求める。(健常者と慢性疲労症候群患者ではτの値に明らかな数値差が生じるため、閾値を用いて、健常者と慢性疲労症候群患者の判別に用いることができる。)

τは関数fに急な変化があるかないかを示す数値であり、τの値が大きい場合、急峻な変動があり、小さい場合は緩やかな変動であることを意味する。

[0083] [数3]

$$z(a) = \sum_{b \in \{\min T\}} \left| \inf_{a' < a} \{T\psi[f](a', b)\} \right| \quad \approx \quad a^{\tau}$$

[0084] 一方、DFAはフラクタル揺らぎのモデルであるフラクショナルブラウン運動の理論を応用したものである。関数をあるタイムスケールnで分割すると、フラクショナルブラウン運動の時系列は、次のように表すことができる。

[0085] [数4]

$$F(n) \quad \approx \quad n^{\alpha}$$

[0086] ここで、～は分布の一致を意味する。F(n)は、振動データ(ゼロクロス値)の単位時間あたりの累積値を求め、現在の単位時間の累積値から過去の単位時間当たりの累積平均値を引いた値である。このF(n)の分布がnのα乗の分布と一致すると仮定する。

[0087] ゼロクロス値の変動は、α＝1．5ではブラウン運動の変動を意味する。αが1．5より小さい場合は、ゼロクロス値が過去に増加傾向があったが現在は減少傾向がある時、あるいは、過去に減少傾向があったが現在は増加傾向をもつ時、のいずれかであることを示している。αが1．5より大きい場合は、ゼロクロス値は、過去および現在も増加傾向にある時、あるいは過去に減少及び現在も減少傾向がある時、のいずれかであることを示している。

[0088] 以上のような、慢性疲労症候群患者と健常者の、客観的な数値による診断手法を本発明の解析プログラムの一部に応用する。

本発明の健康管理装置を慢性疲労症候群患者に適用した場合の実施例を、図4を用いて説明する。特に、生体の情報を収集するセンサとして振動センサ301及び温度センサ302を使用した場合について、計測結果の解析方法、解析結果を基にした病状の診断、及び問診方法を示す。

[0089] 本実施例では、直ちに診断結果や変化した原因等を患者にフィードバックすること

で、患者は気をつけるべき行動、次にとるべき行動、現状の症状等を認識できる。記録された体動のデータとアンケート結果を後日医師にもって行くことで、頻繁に通院しなくても医師は正しく患者の病状を知ることができる。

[0090] 利用者は、図4のように手首には振動センサ301を、脇の下に温度センサ302を装着し、それぞれ体温情報と体動情報とを収集する。手首に取り付けた振動センサは腕時計型である場合があり、現在手首での計測が一般的であるが、装着箇所は必要に選択でき限定されない。

各センサは無線通信機能を用いて、体温情報と体動情報を携帯情報端末303に転送する。各データを受信したとき、携帯情報端末は、解析プログラムを起動する。

[0091] つぎに、この解析プログラムの具体的な方法を以下に説明する。

慢性疲労症候群の可能性があると判断する条件を以下3つ設ける。

1. 体温センサの計測結果から、微熱がある(37.0℃以上)と判断された場合

2. 過去の問診の結果から過去3日以内に激しい運動をした場合で、かつ振動センサの測定結果を非特許文献1記載の計算方法でMCPを求め、その値が24.2時間以上であった場合

3. 振動センサの測定結果を非特許文献2記載の計算方法で、WTNMMのτ及びDFAのαを求め、τが0.9以下又は、αが1.5以下であった場合

[0092] これら三つ条件のうち、二つ又は三つとも満たしている場合に、慢性疲労症候群の疑いが高いと判断する。また、一つだけ又は一つも満たさない場合には、慢性疲労症候群の疑いは低いと判断する。次に体調の悪化傾向や回復傾向の体調の変化を診断するために、ある時刻tにおける体調係数をm(t)とし、次のように定義する。

[0093] 時刻tにおけるセンサデータを解析し、上記の3つの条件に対して、

三つ全ての条件を満たす時はm(t)=−3とし、

二つの条件だけが満たされる時はm(t)=−1とし、

一つの条件だけが満たされる時はm(t)=1とし、

あるいは一つの条件も満たさない時はm(t)=3とする。

すなわち、ある時刻tにおいて、m(t)=−3のとき、被験者は慢性疲労症候群の傾向が非常に強く、逆に、m(t)=3であれば、慢性疲労症候群の傾向が少ないことを

意味する。

[0094] また、時刻tより前の時刻(t－1)の解析結果である体調係数m(t－1)を用い、m(t)－m(t－1)を計算する。m(t)－m(t－1)＜0の時、時間(t－1)のときと比べ時間tでは症状が悪化していると判断し、m(t)－m(t－1)＞0の時、症状が改善していると判断する。

[0095] 症状が変化しているかどうかを調べるだけであれば、m(t)×m(t－1)を計算し、この値が正の数であれば、時刻(t－1)と時刻tでは症状は同じ傾向にあり、逆に負の数であれば、現在症状は前の症状から変化があると判断することができる。

[0096] また、最近の症状が悪い傾向にある患者に警告する必要がある場合、数時間前の時刻(t－i)から現在の時刻tまでの体調係数の和Σm(t－i)の和を求め、この値がある閾値以下になる時に非常に症状が悪いと判断して、患者に警告することもできる。

[0097] 例えば、解析結果の過去3回分と閾値に－7を用いて、症状の悪い状態が続いていると判断する場合には、次の条件式を満たす時、利用者の症状は悪い状態が続いていると判断することができる。

[0098] [数5]

$$\sum_{i=0}^{2} m(t-i) \quad < \quad -7$$

[0099] また、センサの情報を解析することにより、被験者が正しくセンサを体に装着しているかどうかを検出することもできる。振動センサを例に取ると、体動がほとんどない場合(例えば、30分のゼロクロス値が10以下)、体を動かしていないというよりはむしろ、振動センサが体から取り外された可能性があると判断できる。

[0100] また、体温センサを例に取ると、体温が非常に低い(例えば、35℃以下の)場合、体温が本当に低いというよりは体温センサを正しく体に設置されていない可能性があると判断することができる。

[0101] いずれのセンサの場合も、センサが体から外れている可能性がある場合、問診機能、無線通信機能、およびアラームなどの利用者への通知機能を用いて、センサの

装着異常を利用者に確認する。

[0102] 利用者に正常な装着を促すことによって、装着状況の改善ができ、また、装着異常でないことが確かめられれば、センサの故障や利用者の真の体調の悪さを判別することも可能となり、さらに、医師や健康・医療機関等本人以外に通知する場合は誤報を減らすこともできる。

以上により、センサの計測精度や、解析及び診断の精度を高めることが可能となる。

[0103] 次に、問診プログラムの実施例について説明する。

本発明では、次の三つの場合に問診プログラムを起動する。問診プログラムが起動され、利用者に問診(アンケート)を促すために、センサ機器や携帯情報端末のアラーム機能や振動機能により利用者に問診する旨を通知する。

[0104] 1. 解析プログラムの結果による問診プログラムの起動

前記の解析プログラムの実施形態により、体調の変化が見られた場合、すなわち$m(t) \times m(t-1) < 0$となった時に問診プログラムを起動する。あるいは、顕著な症状の悪化傾向が判断された時、すなわち数時間前の時刻(t－a)から現在の時刻tまでの体調係数の和$\Sigma m(t-a)$が閾値を下回った時に問診プログラムを起動する。

[0105] このような利用者へのアンケートは、頻繁に行った時には利用者が面倒に感じて正しく回答しなくなるため、体調の変化や症状の悪化傾向のあった時でかつ過去1時間以内に問診を行わなかった時に、問診プログラムを起動することも可能である。

[0106] 2. スケジュールによる問診プログラムの起動

予め設定された時刻に問診プログラムを起動する。この場合、一日数回程度行い、設定された時刻になった時、携帯情報端末において自動的にプログラムが起動される。問診の実行時刻は、例えば、起床直後、9時、14時、20時、就寝前等とし、設定された時刻になると問診プログラムが起動し、また利用者への通気機能により問診時刻であることが通知される。

[0107] 3. 利用者の意思による問診プログラムの起動

利用者の操作による問診プログラムの起動も可能とする。

利用者が体調不良と認識したとき、あるいは利用者が体調に不安を感じた時に利

用者自らが操作し、問診プログラムを起動する。

[0108] このような問診プログラム起動方法の目的は、利用者が体調不良を感じた時の、具体的な症状、周囲の環境などを正確に記録し、医師との問診時に正確に伝えることができるようにすることである。また、利用者が病気に対する不安を感じている時には、センサデータの解析結果と問診結果の比較から、利用者に状況を知らせることで不安を解消することである。

[0109] 問診(利用者へのアンケート)の内容は、利用者の主観的情報と環境情報を得るための質問を行う。以下にその例を示す。

[0110] 1. 利用者の行動や周辺の状況に関するアンケート

○今どこにいますか(自宅、学校、乗り物、その他)

○今何をしていますか(立っている、歩いている、座っている、横になっている)

○食事の内容

○利用者の認識している状態として、くつろいでいるか緊張しているか

[0111] これらの利用者の行動や周辺の状況に関するアンケートは、体調が良い時、あるいは悪い時に利用者はどのような環境に居たのかを、統計的に計ることができる。

[0112] 2. 利用者の症状や気分関するアンケート

○症状に関しするアンケート

集中できない、疲労感、頭痛・頭重、のどの痛み、からだの痛み、腹痛・吐気、眩暈等○気分に関するアンケート

はつらつとした気分か、暗い気分か、気がかりであるか、うれしいか、嫌な気分か、不安な気分か、楽しい、沈んでいる、心配、など

[0113] これらのアンケートに対する回答方法は、そのような気分かどうかを、是か非かで回答するだけではなく、どちらに偏っているかの程度を、例えば20段階で回答する形式をとることもできる。

[0114] 以上のようなアンケート結果は、慢性疲労症候群による体調の悪化かどうかを判断する要素として用いることができる。

例えば、解析プログラムの結果、体調係数m(t)が低く、すなわち慢性疲労症候群の症状が高く、かつアンケート結果から疲労感が強いという結果が得られた場合、利

用者は慢性疲労症候群の傾向が強いことがより正確に判断される。

[0115] 逆に、m(t)が高く慢性疲労症候群の症状が低いのにもかかわらず、アンケートで疲労感が強いという結果が出た場合には、慢性疲労症候群以外の疾病である可能性ある。上記のように、アンケート結果を用いて、より正確な診断を行うことが可能である。

[0116] 問診の終了後、脳機能試験プログラムを行っても良い。一般に脳の機能を調べるCPTと呼ばれるテストがある。脳機能試験プログラムは、これにゲーム性を持たせ形態で、利用者に実施する。

[0117] 以下に、本発明の脳機能試験の例を示す。

★、◆、▲のキャラクターが画面に一秒ごとに表示される。例えば★や▲が出た場合に、特定のボタンを押し、◆が出た場合にはボタンを押さないというルールを設ける。キャラクターが1秒間隔で30秒間ランダムに表示され、利用者は表示されたキャラクターを認知し、ボタンを押すか押さないかを判断する。利用者の回答の正解率などを評価する。このテスト結果が悪い場合は、利用者は脳機能に何ら支障がある可能性があると判断できる。

[0118] 次に、診断プログラムでは、センサの計測データの解析結果、問診結果、及び脳機能試験の結果を総合的に判断し、例えば、それぞれの結果に点数として換算し、合計点数を用いて、総合的診断を行う。診断結果は、利用者に即座に通知される、医師あるいは家族に公衆回線を介して通知される、あるいは携帯情報端末に記録され後日病院での健康診断に用いることができる。

[0119] 利用者への通知の例を以下に示す。

診断結果から慢性疲労症候群の症状が悪いと判断された場合、「症状が悪くなっています。数日前に激しい運動をしたことも原因でしょう。無理な運動は避けてください。」など、症状、原因、改善方法を通知する。また、診断結果が改善傾向にあれば、「調子がだいぶ良くなってきたようですね。完治までもう少しです。」、症状の判断付かない場合などでは、「風邪などの可能性もあります。必要があれば病院で診察することをお勧めします。」などを通知する。

[0120] 以上のように、症状が悪い場合にはその症状の原因が何にあるのかの解析結果も

含めて利用者に通知し、また利用者に症状を改善するために何をすべきかを通知することもできる。

[0121] このように、本発明は、リアルタイムにオンサイトで、計測されたデータを解析し、問診を行い、その結果を、利用者に知らせることによって、病気の症状が悪化することを抑制し、症状の改善の助けとなる。

[0122] 以上に、センサの計測データの解析方法、問診、脳機能試験プログラムの内容、利用者へ通知するメッセージの例を示したが、この内容に限ることはない。特に、慢性疲労症候群の症状が悪い兆候か良い兆候かを判断する方法は、他の方法で実施することも可能である。

[0123] また、慢性疲労症候群に関しての解析プログラム、問診プログラムの例を示したが、本発明は他の病気に関しても同様にデータ解析と問診内容から、より正確な診断を行う携帯健康管理装置として実施することも可能である。

[0124] また、今回は慢性疲労症候群に本発明の健康管理装置を適用する場合に、生体情報を収集するセンサのみを用いた例を示したが、利用者の周囲の環境情報を収集するセンサを用いて、さらに正確な診断が可能となる。

[0125] 例えば、さらに環境センサとして照度センサを加えた時は、昼夜の活動をより明確に区別でき、また睡眠時の体動等から睡眠の深さ等を計測でき、自律神経の状態も加えて判断できるため、より正確で総合的な診断が可能となる。同様に、音センサを用い利用者周囲の雑音を計測すれば、雑踏環境あるいは静かな環境に利用者が居る時における身体活動の違いを判別できるため、抑鬱状態をより正確に把握できる。また、相手と会話を続けることができるか、それともすぐに会話が終わるかなどの、会話のレスポンスの程度が判断できるため、倦怠感をより正確に判断できる。

[0126] 次に、環境センサを用いた本発明の実施例として、化学物質過敏症に対する健康管理装置の例を示す。

シックハウス症候群に代表されるような化学物質過敏症は、化学物質が患者に暴露されなければ、患者の体調は普通の状態と全く変わらない。そのため、化学物質過敏症患者が医師の診断を受ける場合、その場で症状の原因となる化学物質が暴露されるわけではないため、診断が困難となる。したがって、化学物質過敏症による症

状があり、発作が起き、患者が苦しんでいたとしても、医師はその状態を診断できず、医師は患者に確認するのみで診断を下さなければならない。

[0127] また、患者自身も発作が激しくなってからでは、動くことも困難になり、状態の悪化に苦しむ結果となる。そこで、本発明では、上記の問題を解決する健康管理装置を提供することが可能である。

[0128] 本発明による健康管理装置を化学物質過敏症の健康管理に用いた例を示す。

化学物質過敏症に対する健康管理装置は、ガス濃度を検出する環境センサと、前記慢性疲労症候群の例と同様の問診機能等を有する携帯情報端末により構成される。

問診プログラムは、ガスセンサによりガス濃度が閾値を超えたときに起動する、あるいは利用者が体調の変化を感じたときなどに利用者自身が起動する、あるいはスケジューリングにより起動することが可能である。

[0129] ガスが暴露された時と通常の状態の時とで、化学物質過敏症患者と健常者に問診を行った場合に顕著な差が得られることを確認している。図5及び図6は、化学物質過敏症患者13名と、健常者12名の実験結果である。図5は、患者が体調の変化を起こすガスの種類と濃度を示す。また、図6は患者に、動悸や吐き気などの身体症状と、不安などの気分とに関する問診を行い、ガス暴露時の症状が出ている状態と通常状態とを比較し、問診結果に有意な差が認められた問診内容を示している。図6から、これらの問診を行うことによって、患者に化学物質過敏症の症状がでているか否かを判断することができることがわかる。また、図5から、化学物質過敏症患者は、健常者とは全く異なり、非常に低いガス濃度で症状を起こすことがわかる。図5のガス濃度の結果と、図6の問診内容の結果を、本発明のガスセンサの通常と異なる値の判定、及び問診内容として採用する。

[0130] そこで、本発明では、ガス濃度を比較的低い濃度で検出し(ホルムアルデヒドでは、例えば10ppbなど)、利用者が発作を起こす前の利用者自らが回答することが可能な状態で、問診プログラムを起動し、問診内容として図6記載の身体症状と気分に関する質問を行う。問診の回答結果から、診断プログラムは化学物質過敏症の兆候有りか無しかを判断し、化学物質過敏症の兆候有り判断された場合、利用者にそのガ

ス濃度を通知し、また、その場所からの回避を勧める。

[0131] 以上のように、化学物質過敏症の症状（発作）でる前の兆候の段階で問診を行い、発作が起こる前の利用者自身が行動できる段階で前兆を検知することができるため、患者は速やかにその場を立ち去り、症状を軽減する行動（例えば、薬を服用するなど）をとることができる。

[0132] また、化学物質過敏症の症状を客観的に診断でき、症状の原因となるガスの種類、兆候や症状の発生するガス濃度が判断できるため、医師は適切な診断、処方が可能となる。

本実施例では、ガスセンサとして、携行しやすい自動ガス検知器や検知菅を用いたが、昨今技術革新が進み小型化されているIRを用いたガスセンサや、超小型ガスクロマトグラフィーを用いてもよい。

[0133] また、化学物質過敏症患者は、日中だけでなく夜間でも、心拍変動や身体活動に異常がみとめられるため、ガスセンサ以外に、心拍計や振動センサを備える健康管理装置により、症状の兆候診断をさらに正確に行うことも可能である。

請求の範囲

[1] 生体情報または生体の周囲の環境情報を計測するセンサと、

前記センサの計測結果を解析する解析手段と、

利用者に質問を行い、回答を入力させる問診手段と、

前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の状態を判断する診断手段と、

前記診断手段が判断する生体の状態に基づいて情報を通知する通知手段と、

を備えることを特徴とする健康管理装置。

[2] 請求項1記載の健康管理装置において、

センサ部分は装置本体とは分離可能であり、

センサ出力と本体との間でセンサ計測結果データの通信を行う通信手段を有することを特徴とする健康管理装置。

[3] 請求項1記載の健康管理装置において、

携帯電話または携帯端末であることを特徴する健康管理装置。

[4] 請求項1記載の健康管理装置において、

前記解析手段、前記問診手段、前記診断手段、および前記通知手段を含む装置本体と前記センサとは分離可能であり、

前記センサと前記装置本体との間でセンサ計測結果の通信を行うセンサ通信手段を有することを特徴とする健康管理装置。

[5] 請求項1記載の健康管理装置において、

情報を出力する出力デバイスをさらに備え、

前記通知手段は、前記出力デバイスにより情報を出力することを特徴とする健康管理装置。

[6] 請求項1記載の健康管理装置において、

他の装置と通信する外部装置通信手段を備え、

前記通知手段は、前記外部装置通信手段により情報を他の装置に情報を通知することを特徴とする健康管理装置。

[7] 請求項1記載の健康管理装置において、

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前記問診手段は、前記解析手段の解析結果が所定の条件を満たした場合に質問を行うことを特徴とする健康管理装置。

[8] 請求項1記載の健康管理装置において、

前記問診手段は、あらかじめ定められたスケジュールに基づいて質問を行うことを特徴とする健康管理装置。

[9] 請求項1記載の健康管理装置において、

前記通知手段は、生体の症状が生じた原因情報を通知することを特徴とする健康管理装置。

[10] 請求項1記載の健康管理装置において、

前記通知手段は、生体の症状を改善するための改善情報を通知することを特徴とする健康管理装置。

[11] 請求項9記載の健康管理装置において、

前記改善情報は、少なくとも投薬の種類、投薬の使用量、または投薬の時刻のいずれかを含むことを特徴とする健康管理装置。

[12] 請求項1記載の健康管理装置において、

前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とをそれぞれ点数化し、前記解析結果の点数と問診結果の点数との加算値に基づいて生体の状態を判断することを特徴とする健康管理装置。

[13] 請求項1記載の健康管理装置において、

前記解析手段は、前記センサの現在の計測値と過去の計測値とに基づいて解析結果を生成することを特徴とする健康管理装置。

[14] 請求項1記載の健康管理装置において、

前記解析手段の解析結果に基づいて前記センサの設置の異常を通知する異常通知手段を備えることを特徴とする健康管理装置。

[15] 請求項1記載の健康管理装置において、

生体の反応を試験する反応試験手段を備え、

前記反応試験手段による反応結果に基づき、前記問診結果の妥当性を判断することを特徴とする健康管塩装置。

[16] 請求項1記載の健康管理装置において、

前記センサは生体の振動を検出する振動センサを含み、

前記解析手段は、前記振動センサで検出した過去の振動の周期性に対する現在の振動の周期性のずれを解析し、

前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の心身症に関する状態を判断することを特徴とする健康管理装置。

[17] 請求項1記載の健康管理装置において、

前記センサは生体の体温を検出する体温センサを含み、

前記解析手段は、前記体温センサで検出した体温があらかじめ定められた値を越えているか否かを解析し、

前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の心身症に関する状態を判断することを特徴とする健康管理装置。

[18] 請求項1記載の健康管理装置において、

前記センサは、生体の振動を検出する振動センサ、および、生体の体温を検出する体温センサを含み、

前記解析手段は、前記振動を検出する振動センサで検出した過去の振動の周期性に対する現在の振動の周期性のずれ、および、前記体温センサで検出した体温があらかじめ定められた値を越えているか否か、を解析し、

前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の心身症に関する状態を判断することを特徴とする健康管理装置。

[19] 請求項1記載の健康管理装置において、

前記センサは、ガス濃度を検出するガスセンサを含み、

前記解析手段は、前記ガスセンサで検出したガス濃度があらかじめ定められた値を越えているか否かを解析し、

前記診断手段は、前記解析手段の解析結果と前記問診手段の問診結果とに基づいて生体の化学物質過敏症に関する状態を判断することを特徴とする健康管理装置。

[20] 請求項19記載の健康管理装置において、

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前記通知手段は、当該ガスセンサの設置された位置からの退去を促すメッセージを通知することを特徴とする健康管理装置。

[21] 請求項1記載の健康管理装置において、

前記センサは生体の振動を検出する振動センサを含み、

前記解析手段は、前記振動センサで検出した振動の周期性に基づき1日の生活リズムを取得し、取得した前記1日の生活リズムに基づき解析結果を生成し、

前記診断手段は、前記解析手段の解析席発と前記問診手段の問診結果とに基づいて生体の慢性疲労症候群に関する状態を判断することを特徴とする健康管理装置。

[22] 請求項21記載の健康管理装置において、

前記センサは、照度を検出する照度センサを含み、

前記解析手段は、前記照度センサで検出した照度に基づいて昼夜判断情報を生成し、前記振動センサで検出した振動の周期性と前記昼夜情報とに基づき1日の生活リズムを取得することを特徴とする健康管理装置。

[23] 請求項1記載の健康管理装置において、

振動または脈拍または心拍または体温のうち、少なくとも一つ以上を計測するセンサを用いて、ダイエットまたは食事療法に関する健康管理を行うことを特徴とする健康管理装置。

[24] 請求項1記載の健康管理装置において、

振動または発話のうち少なくとも一つ以上の生体情報を計測するセンサを用いて、介護予防に関する健康管理を行うことを特徴とする健康管理装置。

[25] 請求項1記載の健康管理装置において、

振動または脈拍または心拍または呼吸のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、無呼吸症候群に関する健康管理を行うことを特徴とする健康管理装置。

[26] 請求項1記載の健康管理装置において、

振動または脈拍または心拍または発話のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、痴呆症に関する健康管理を行うことを特徴とする健康管理装

置。

[27] 請求項1記載の健康管理装置において、

振動または脈拍または心拍のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、パーキンソン病に関する健康管理を行うことを特徴とする健康管理装置。

[28] 請求項1記載の健康管理装置において、

振動または脈拍または心拍または体温または発話のうち、少なくとも一つ以上の生体情報を計測するセンサを用いて、脳卒中に関する健康管理を行うことを特徴とする健康管理装置。

[29] 請求項1記載の健康管理装置において、

脈拍または心拍または体温のうち、少なくとも一つ以上の生体情報と免疫に関する生体情報を計測するセンサを用いて、精神障害に関する健康管理を行うことを特徴とする健康管理装置。

[30] 生体情報または生体の周囲の環境情報を計測するセンサの計測結果を解析する第1のステップと、

利用者に質問を行い、回答を入力させる第2のステップと、

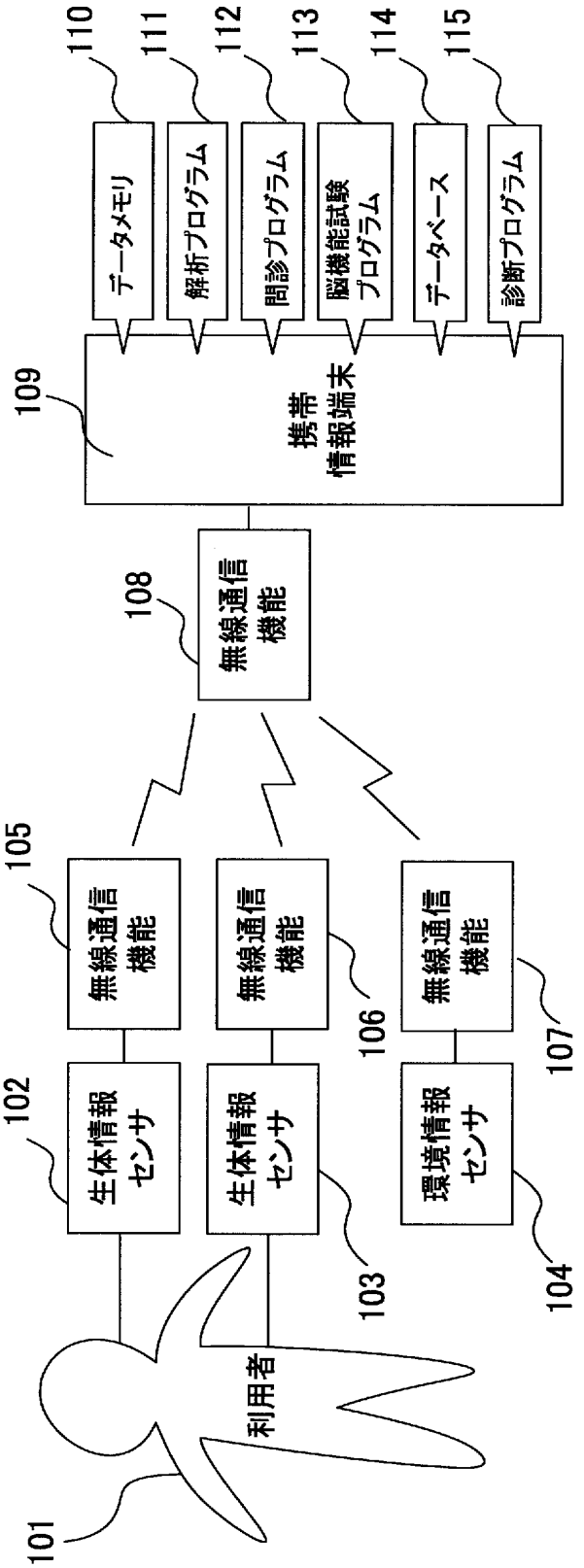
前記第1のステップの解析結果と前記第2のステップの問診結果とに基づいて生体の状態を判断する第3のステップと、

前記第3のステップが判断する生体の状態に基づいで備報を通知する第4のステップと、

をコンピュータに実行させることを特徴とする健康管理プログラム。

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[図1]

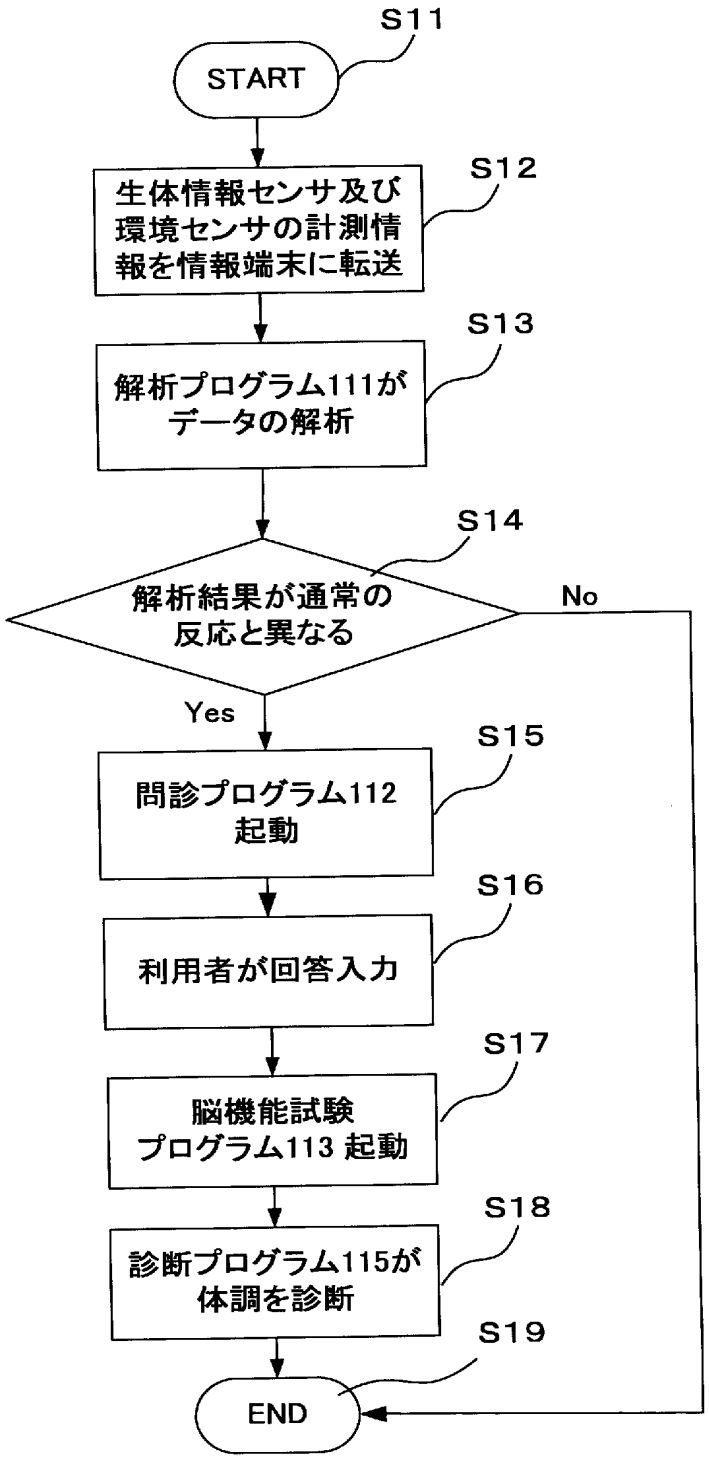


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[図2]

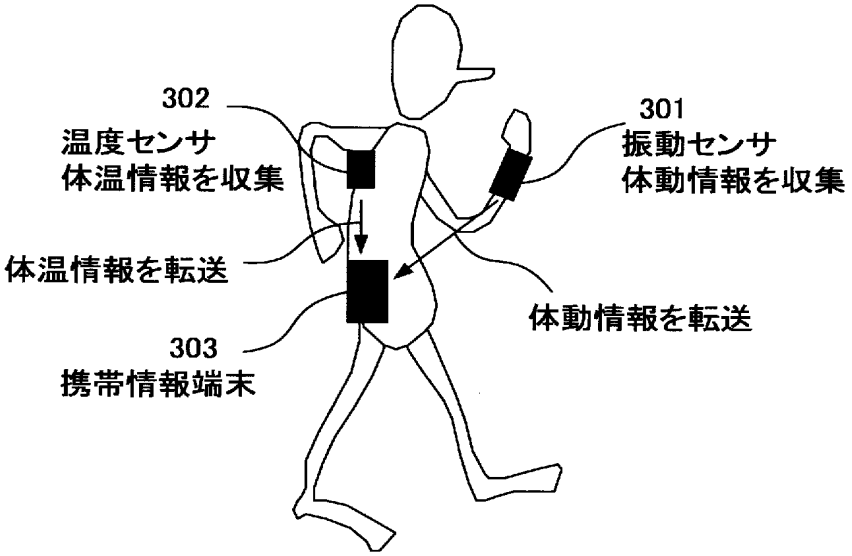
健康管理対象	センサの種類(計測項目)
ダイエット	振動(体動)、脈拍、体温
介護予防	振動(体動)、発話
心身症(自律神経失調症、慢性疲労症候群など)	振動(体動)、脈拍／心拍、体温、発話
精神障害(躁鬱病など)	振動(体動)、脈拍／心拍、発話
無呼吸症候群	振動(体動)、脈拍／心拍、呼吸
痴呆症(アルツハイマー病など)	振動(体動)、脈拍／心拍、発話
パーキンソン病	振動(体動)、脈拍／心拍
脳卒中	振動(体動)、脈拍／心拍、体温、発話
感染症免疫疾患	脈拍／心拍、体温、免疫(バイオ)センサ
化学物質過敏症	振動(体動)、脈拍／心拍、呼吸、ガスセンサ

[図3]



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[図4]



[図5]

ガスの種類	濃度
ホルムアルデヒド	16.50 ppb
アセトアルデヒド	7.20 ppb
トルエン	19.30 ug/m3
パラジクロルベンゼン	0.001 ug/m3

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[図6]

化学物質過敏症患者の症状がある時とない時における問診内容とその回答結果

問診内容	症状がある時		通常状態	
	回答ｽｺｱ	標準誤差	回答ｽｺｱ	標準誤差
集中できない	30.07	1.88	20.56	7.22
忘れっぽい	24.02	1.33	17.98	9.02
のどの痛みがある	32.58	1.81	21.01	9.12
頭痛がある	25.94	1.92	11.77	6.40
筋肉の痛みがある	12.03	1.38	6.34	6.91
吐き気がある	9.20	1.35	1.37	5.67
息切れする	8.94	1.42	1.91	5.14
目のかゆみ・異常がある	36.39	1.97	24.86	7.72
めまい・立ちくらみがする	13.47	1.42	4.19	6.24
鼻水・鼻づまりがある	26.03	1.48	18.96	7.25
動悸がする	11.06	1.44	2.79	4.99
不安	64.84	4.30	47.72	28.50
肯定的気分	41.90	3.82	59.69	20.41
否定的気分	44.53	3.64	20.86	21.14
抑うつ	302.56	5.87	261.14	27.01

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2005/019792

A. CLASSIFICATION OF SUBJECT MATTER
A61B5/00(2006.01), ***G06Q50/00***(2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B5/00(2006.01), ***G06Q50/00***(2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1922-1996	Jitsuyo Shinan Toroku Koho	1996-2005
Kokai Jitsuyo Shinan Koho	1971-2005	Toroku Jitsuyo Shinan Koho	1994-2005

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	JP 2002-238863 A (Kabushiki Kaisha Atekku Komyunikeshon), 27 August, 2002 (27.08.02), Full text; all drawings (Family: none)	1,2,4,5,7, 10,11,13,30 3,6,8,9,12, 14-29
Y	JP 2003-93355 A (Omron Corp.), 02 April, 2003 (02.04.03), Full text; all drawings (Family: none)	3
Y	JP 2003-319912 A (Higashinihon Medikomu Kabushiki Kaisha), 11 November, 2003 (11.11.03), Full text; all drawings (Family: none)	6

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search 15 December, 2005 (15.12.05)	Date of mailing of the international search report 27 December, 2005 (27.12.05)
Name and mailing address of the ISA/ Japanese Patent Office Facsimile No.	Authorized officer Telephone No.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2005/019792

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP 2000-271090 A (Matsushita Electric Works, Ltd.), 03 October, 2000 (03.10.00), Full text; all drawings (Family: none)	8,9,15
Y	JP 2002-143097 A (Kuniaki OTSUKA), 21 May, 2002 (21.05.02), Full text; all drawings (Family: none)	12,16-29
Y	JP 2004-181218 A (Seiko Instruments Inc.), 02 July, 2004 (02.07.04), Full text; all drawings (Family: none)	14

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国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２００５／０１９７９２

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　***A61B5/00*** (2006.01)，***G06Q50/00*** (2006.01)

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　***A61B5/00*** (2006.01)，***G06Q50/00*** (2006.01)

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２００５年
日本国実用新案登録公報	１９９６－２００５年
日本国登録実用新案公報	１９９４－２００５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求の範囲の番号
Ｘ	ＪＰ　２００２－２３８８６３　Ａ（株式会社アーテックコミュニケーション）２００２．０８．２７　全文　全図（ファミリーなし）	1, 2, 4, 5, 7, 10, 11, 13, 30
Ｙ		3, 6, 8, 9, 12, 14-29
Ｙ	ＪＰ　２００３－９３３５５　Ａ（オムロン株式会社）２００３．０４．０２　全文　全図（ファミリーなし）	3
Ｙ	ＪＰ　２００３－３１９９１２　Ａ（東日本メディコム株式会社）２００３．１１．１１　全文　全図（ファミリーなし）	6

☑ Ｃ欄の続きにも文献が列挙されている。　☐ パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの

「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
１５．１２．２００５	２７．１２．２００５

国際調査機関の名称及びあて先	特許庁審査官（権限のある職員）	２Ｑ	８４０５
日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	本郷　徹 電話番号　０３－３５８１－１１０１　内線　３２９０		

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Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求の範囲の番号
Ｙ	ＪＰ　２０００－２７１０９０　Ａ（松下電工株式会社）２０００．１０．０３　全文　全図（ファミリーなし）	8, 9, 15
Ｙ	ＪＰ　２００２－１４３０９７　Ａ（大塚邦明）２００２．０５．２１　全文　全図（ファミリーなし）	12, 16-29
Ｙ	ＪＰ　２００４－１８１２１８　Ａ（セイコーインスツルメンツ株式会社）２００４．０７．０２　全文　全図（ファミリーなし）	14

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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To:
Ho, Brian B.
DENTONS US LLP
P.O. Box 061080
Wacker Drive Station,
Willis Tower
Chicago, IL 60606-1080
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*	27 September 2018 (27-09-2018)
Applicant's or agent's file reference P33605WO1	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2018/031662	International filing date *(day/month/year)* 8 May 2018 (08-05-2018)
Applicant APPLE INC.	

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46).

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

   How? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with any applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	BROUWERS, Marja Tel: +31 (0)70 340-1037

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
P33905WO1		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2018/031662	8 May 2018 (08-05-2018)	15 May 2017 (15-05-2017)

Applicant

APPLE INC.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 6A
      ☒ as suggested by the applicant
      ☐ as selected by this Authority, because the applicant failed to suggest a figure
      ☐ as selected by this Authority, because this figure better characterizes the invention
   b. ☐ none of the figures is to be published with the abstract

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/031662

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-23

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/031662

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F1/16 G06F3/0488 A61B5/11
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/058336 A1 (BLAHNIK JAY [US] ET AL) 3 March 2016 (2016-03-03) figures 48-53,60-66,70-72,79-94 paragraph [0346] paragraph [0397] - paragraph [0442]	1-23

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 July 2018	27/09/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	De Meyer, Arnaud

Form PCT/ISA/210 (second sheet) (April 2005)

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/031662

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016058336 A1	03-03-2016	AU 2015312215 A1	06-10-2016
		AU 2018200428 A1	08-02-2018
		CN 106537397 A	22-03-2017
		CN 108133742 A	08-06-2018
		DE 112015002326 T5	23-03-2017
		DK 201570666 A1	25-07-2016
		DK 201570668 A1	25-07-2016
		DK 201670656 A1	19-09-2016
		DK 201770191 A1	27-03-2017
		EP 3129907 A2	15-02-2017
		EP 3333740 A1	13-06-2018
		JP 2017532069 A	02-11-2017
		JP 2018124998 A	09-08-2018
		KR 20170003608 A	09-01-2017
		TW 201628556 A	16-08-2016
		US 2016058336 A1	03-03-2016
		US 2016058337 A1	03-03-2016
		US 2017281057 A1	05-10-2017
		US 2018206766 A1	26-07-2018
		WO 2016036582 A2	10-03-2016

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-23

how to modify the interface of D1 so as to avoid having to validate the workout goals every time

---

2. claims: 24-34

how to modify the interface of D1 so as to allow listening to music during the workout

---

3. claims: 35-49

how to modify the device of D1 so as to allow chatting during the workout

---

4. claims: 50-62

how to modify the interface of D1 so as to allow the user to assess his heart beat during the workout

---

5. claims: 63-75

how to modify the device of D1 so as to alert the user of a possible heart condition

---

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
PCT/US2018/031662

TITLE:

APPLICANT: APPLE INC.

IPC CLASSIFICATION: G06F1/16, G06F3/0488, A61B5/11

EXAMINER: De Meyer, Arnaud

CONSULTED DATABASES: WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: G06F1/163, G06F3/04886, A61B5/11

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
Graphical user interface for an activity tracker, e.g. smart watch.

EPO FORM P0472

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2018/031662	08.05.2018	15.05.2017

International Patent Classification (IPC) or both national classification and IPC
INV. G06F1/16 G06F3/0488 A61B5/11

Applicant
APPLE INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Telephone No. +31 70 340-0

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 24-75

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 24-75

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-23

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-23
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-23
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations

   see separate sheet

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Re Item IV

Lack of unity of invention

1 Reference is made to the following document:

D1 US 2016/058336 A1 (BLAHNIK JAY [US] ET AL) 3 March 2016 (2016-03-03)

2 This Authority considers that the application does not meet the requirements of unity of invention and that there are 5 inventions.

group 1: claims 1-23

group 2: claims 24-34

group 3: claims 35-49

group 4: claims 50-52

group 5: claims 63-75

The reasons, for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

Document D1 (by default, references in parentheses apply to this document) discloses a method, comprising:
at an electronic device with a display, a touch-sensitive surface, and a physical activity tracking sensor (fig.49 and [0400]):
displaying a scrollable list of affordances associated with physical activities (fig.49 and [0400]);
displaying a first change workout metrics affordance corresponding to a first affordance of the scrollable list of affordances (fig.51 and [0403]);
receiving a user input ([0404]);
in accordance with a determination that the user input is detected, launching a physical activity tracking function associated with the selected first affordance (fig.51-52 and [0404]: start button 5114);
in accordance with a determination that the user input is detected at the first change workout metrics affordance, displaying a user interface configured to change a workout metric (fig.51-52 and [0403]-[0404]); and

measuring the heart rate of the user ([0346]).

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This is the common matter linking together the independent claims of the different groups. This common matter does not comprise a single general inventive concept, because it is known from D1.

2.1 The technical features, representing the difference over the non-inventive common matter, of groups 1-5 are:

group 1: Claim 1 specifies that the physical activity tracking function can be launched directly from the scrollable list of affordances, i.e. the graphical user interface includes a shortcut;

group 2: Claim 24 specifies the interactions between the workout functions and an audio application;

group 3: Claim 35 specifies exchanging message with an external device during the workout;

group 4: Claim 50 specifies means for comparing different heart rate data for at least two activities; and;

group 5: Claim 63 specifies displaying a heart rate alert.

The objective technical problems respectively solved by these distinguishing features are:

group 1: how to modify the interface of D1 so as to avoid having to validate the workout goals every time;

group 2: how to modify the interface of D1 so as to allow listening to music during the workout;

group 3: how to modify the device of D1 so as to allow chatting during the workout;

group 4: how to modify the interface of D1 so as to allow the user to assess his heart beat during the workout;

group 5: how to modify the device of D1 so as to alert the user of a possible heart condition.

The distinguishing features are different and address different technical problems. Hence, the claims comprise neither the same, nor corresponding special technical features, so the technical relationship between the subject matter of the claims required by Rule 13.2 PCT is lacking and the claims are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.

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Consequently the application does not meet the requirement for unity of invention.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims 1 and 18-23 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 Claim 1: Document D1 (by default, references in parentheses apply to this document) discloses a method, comprising:
at an electronic device with a display, a touch-sensitive surface, and a physical activity tracking sensor (fig.49 and [0400]):
displaying a scrollable list of affordances associated with physical activities (fig.49 and [0400]);
displaying a first change workout metrics affordance corresponding to a first affordance of the scrollable list of affordances (fig.51 and [0403]);
receiving a user input ([0404]);
in accordance with a determination that the user input is detected ~~at the first affordance in the scrollable list of affordances~~, launching a physical activity tracking function associated with the selected first affordance (fig.51-52 and [0404]: start button 5114); and
in accordance with a determination that the user input is detected at the first change workout metrics affordance, displaying a user interface configured to change a workout metric (fig.51-52 and [0403]-[0404])

The subject-matter of claim 1 differs from D1 in that:

claim 1 specifies that the physical activity tracking function can be started directly from the list of activities, whereas D1 discloses selecting the activity and then validating the goals (fig.51-52 and [0404]: start button 5114).

The technical effect of this distinguishing feature is to start the workout more quickly.

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The associated objective technical problem is formulated as how to modify the interface of D1 so as to avoid having to validate the workout goals every time.

Faced with this technical problem, the skilled person would implement the possibility for starting the workout without going through the submenu, i.e. a shortcut.

3.2 Claims 18-23: The objection in §3.1 above also applies, mutatis mutandis to the subject-matter of claims 18-23.

4 Dependent claims 2-17 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

4.1 Claim 2: D1 discloses determining workout completion and providing different types rewards ([0329]). however, D1 does not disclose that the rewards unlock new goals. This difference only address the non-technical problem of how to keep the user motivated (Guidelines G-II, 3.5 Schemes, rules and methods for performing mental acts, playing games or doing business).

4.2 Claim 3: Disclosed by D1 (fig.51-52 and [0404]: if the user does not press start button 5114).

4.3 Claim 4: Disclosed by D1 (fig.51-53).

4.4 Claim 5: Disclosed by D1 (fig.51-52 and [0404]: when the new metrics is initially displayed).

4.5 Claim 6: Disclosed by D1 (fig.51: buttons 5108 and 5110).

4.6 Claim 7: Disclosed by D1 (fig.51-52 and [0404]: start button 5114).

4.7 Claim 8: D1 discloses different sports (fig.49). It would be obvious to implement only tracking metrics that are relevant for a given sport in order to avoid wasting energy.

4.8 Claim 9: The tracking of D1 is inevitably performed using a tracking sensor.

4.9 Claim 10: Disclosed by D1 (fig.49 and [0400]).

4.10 Claim 11: Disclosed by D1 (fig.49).

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4.11 Claim 12: Using an animation is an alternative choice regarding how to present the information (Guidelines G-II, 3.7 Presentations of information).

4.12 Claims 13-15 and 17: Disclosed by D1 (fig.70-71 and [0434]-[0435]).

4.13 Claim 16: D1 discloses the aggregated performance views for different workouts (fig.72 and 79-94).

Re Item VIII

Certain observations on the international application

5 Although claims 18 and 21 (mediums) have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

The same objection also applies for claims 19, 20, 22 and 23 (devices).

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Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO/ISA)

General information

For all international applications, the competent International Searching Authority (**ISA**) will establish an international search report (**ISR**) accompanied by a written opinion of the International Searching Authority (**WO/ISA**). The **WO/ISA** may be responded to by

- filing informal comments with the **International Bureau of WIPO (IB)** (where no demand for international preliminary examination (**demand**) is filed)
- filing amendments under Art. 19 PCT (this can be done whether or not a **demand** is filed)
- filing amendments under Art. 34 PCT and/or formal observations in response to objections raised in the **WO/ISA** (where a **demand** *is* actually filed)

This document explains these possibilities.

Filing informal comments

After receipt of the **ISR and WO/ISA**, the applicant may file informal comments on the **WO/ISA, directly with the IB** (see International Search and Preliminary Examination Guidelines 2.15). These will be communicated to the designated/elected Offices, together with the International Preliminary Report on Patentability (**IPRP**) at 30 months from the priority date.

Amending claims under Art. 19 PCT

The applicant may file **amended claims** under Art. 19 PCT, **directly with the IB** by the later of the following dates:

- 2 months from the date of mailing of the **ISR** and the **WO/ISA**
- 16 months from the priority date

However, any such amendment received by the **IB** after the expiration of the applicable time limit shall be **considered to have been received on time** by the **IB**, if it reaches it **before** the technical preparations for international publication have been completed (the 15th day prior to the date of publication, see PCT Applicant's Guide, International Phase, 9.013).

For further information, please see Rule 46 PCT as well as form PCT/ISA/220.

Please also note that, when filing amended claims under Art. 19 PCT, such amendments shall be **accompanied by a letter** identifying the amendments made and also the basis for the amendments in the application as originally filed (Rule 46.5(b) PCT). Where a **demand** is filed, failure to comply with this requirement may result in the amendments being ignored in the International Preliminary Examination Report (**IPER**), see Rule 70.2(c-*bis*) PCT.

3NSOOCID: <XS_____20070401ICK_1_>

Filing a demand for international preliminary examination

In principle, the **WO/ISA** will be considered to be the written opinion of the International Preliminary Examining Authority (**IPEA**). Where the **WO/ISA** issued by the **EPO** as **ISA** gives a positive opinion on the international application and the invention to which it relates, filing a **demand** with the **EPO** as **IPEA** would normally be unnecessary, since a positive IPRP would anyway be established by the IB based on the WO/ISA (see also further below).

If the applicant wishes to file a **demand** (for example, to allow him to argue his case in international preliminary examination with regard to objections raised in a negative **WO/ISA** before the **IPEA** issues an **IPER**), this must be done before expiration of **3 months after the date of mailing of the ISR and WO/ISA** or **22 months after priority date**, whichever expires later (Rule 54*bis* PCT). Amendments under Art. 34 PCT can be filed with the IPEA, normally at the same time as filing the demand (Rule 66.1(b) PCT) or within the time limit set for reply to any written opinion issued during international preliminary examination by the **IPEA**.

If a **demand** is filed at the **EPO as IPEA** and no comments/amendments have been received by the time the **EPO** starts drawing up the **IPER** (Rule 66.4*bis* PCT), the **WO/ISA** will be transformed by the **IPEA** into an **IPER** (also called the **IPRP (Chapter II)** which would merely reflect the content of the **WO/ISA** (OJ 10/2011, 532). The **demand** can still be withdrawn (Art. 37 PCT).

Please also note that, when filing amendments under Art. 34 PCT, such amendments shall be accompanied by a letter which identifies the amendments made and also the basis for the amendments in the application as originally filed (Rule 66.8(a) PCT). Failure to comply with this requirement may result in the amendments being ignored in the **IPER (IPRP (Chapter II))**, see Rule 70.2(c-*bis*) PCT.

Filing a request for supplementary international search

The applicant may, with the **IB**, file a request for **supplementary international search** under Rule 45*bis*.1 PCT. The present **ISR** and **WO/ISA** may also be taken into account in the execution of that supplementary international search, provided that these are available to the Authority charged with this task before it starts the supplementary search (Rule 45*bis*.5 PCT).

This kind of request **cannot be filed specifying the ISA** who did the **international search**.

More information on this topic can be found in the **PCT Applicant's Guide**, Chapter 8 (http://www.wipo.int/pct/en/guide/ip08.html).

End of the international phase

Where no **demand** is filed, at the end of the international phase, the **IB** will transform the **WO/ISA** into the IPRP (PCT Chapter I) (Rule 44*bis* PCT), which will then be transmitted together with possible informal comments to the designated Offices. Where a demand is filed, the **WO/ISA** is not transformed into an **IPRP (Chapter I)** by the **IB**, but rather the **IPEA** will establish an **IPER**, (the IPER is the same as the IPRP (PCT Chapter II), see Rule 70.15 PCT).

BNSDOCID: <XS_____2007840103CK_1_>

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
Ho, Brian B.
DENTONS US LLP
P.O. Box 061080
Wacker Drive Station,
Willis Tower
Chicago, IL 60606-1080
ETATS-UNIS D'AMERIQUE

PCT

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

(PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

Date of mailing *(day/month/year)*: 18 July 2018 (18-07-2018)

Applicant's or agent's file reference: P33905WO1

PAYMENT DUE within **ONE MONTH** from the above date of mailing

International application No.: PCT/US2018/031662

International filing date *(day/month/year)*: 8 May 2018 (08-05-2018)

Applicant: APPLE INC.

1. This International Searching Authority

(i) considers that there are 5 *(number of)* inventions claimed in the international application covered by the claims indicated on an extra sheet.

(ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an extra sheet.

(iii) [X] has carried out a partial international search (see Annex) [ ] will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see extra sheet

(iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, the amount indicated below:

EUR 1.775,00	x	4	=	EUR 7.100,00
Fee per additional invention		number of additional inventions		currency/total amount of additional fees

3. The applicant is informed that, according to Rule 40.2(a), **the payment of any additional fee may be made under protest**, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive, where applicable, subject to the payment of a protest fee.

Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of EUR 875,00 *(currency/amount)*.

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. [ ] Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority:
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040
Fax: (+31-70) 340-3016

Authorized officer:
BROCKHUIS-KUURSTRA, Lena
Tel: +31 (0)70 340-1915

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Registered Mail

INVITATION TO PAY ADDITIONAL FEES

International application No.
PCT/US2018/031662

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-23

how to modify the interface of D1 so as to avoid having to validate the workout goals every time

---

2. claims: 24-34

how to modify the interface of D1 so as to allow listening to music during the workout

---

3. claims: 35-49

how to modify the device of D1 so as to allow chatting during the workout

---

4. claims: 50-62

how to modify the interface of D1 so as to allow the user to assess his heart beat during the workout

---

5. claims: 63-75

how to modify the device of D1 so as to alert the user of a possible heart condition

---

This Authority considers that the application does not meet the requirements of unity of invention and that there are 5 inventions.
group 1: claims 1-23
group 2: claims 24-34
group 3: claims 35-49
group 4: claims 50-52
group 5: claims 63-75
The reasons, for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:
Document D1 (by default, references in parentheses apply to this document) discloses a method, comprising:
at an electronic device with a display, a touch-sensitive surface, and a physical activity tracking sensor (fig.49 and [0400]):
displaying a scrollable list of affordances associated with physical activities (fig.49 and [0400]);
displaying a first change workout metrics affordance corresponding to a first affordance of the scrollable list of affordances (fig.51 and [0403]);
receiving a user input ([0404]);
in accordance with a determination that the user input is detected,

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launching a physical activity tracking function associated with the selected first affordance (fig.51-52 and [0404]: start button 5114); in accordance with a determination that the user input is detected at the first change workout metrics affordance, displaying a user interface configured to change a workout metric (fig.51-52 and [0403]-[0404]); and measuring the heart rate of the user ([0346]).
This is the common matter linking together the independent claims of the different groups. This common matter does not comprise a single general inventive concept, because it is known from D1.

The technical features, representing the difference over the non-inventive common matter, of groups 1-5 are:
group 1: Claim 1 specifies that the physical activity tracking function can be launched directly from the scrollable list of affordances, i.e. the graphical user interface includes a shortcut;
group 2: Claim 24 specifies the interactions between the workout functions and an audio application;
group 3: Claim 35 specifies exchanging message with an external device during the workout;
group 4: Claim 50 specifies means for comparing different heart beats data for at least two activities; and;
group 5: Claim 63 specifies displaying a heart rate alert.

The objective technical problems respectively solved by these distinguishing features are:
group 1: how to modify the interface of D1 so as to avoid having to validate the workout goals every time;
group 2: how to modify the interface of D1 so as to allow listening to music during the workout;
group 3: how to modify the device of D1 so as to allow chatting during the workout;
group 4: how to modify the interface of D1 so as to allow the user to assess his heart rate during the workout;
group 5: how to modify the device of D1 so as to alert the user of a possible heart condition.
The distinguishing features are different and address different technical problems. Hence, the claims comprise neither the same, nor corresponding special technical features, so the technical relationship between the subject matter of the claims required by Rule 13.2 PCT is lacking and the claims are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.
Consequently the application does not meet the requirement for unity of invention.

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Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/US2018/031662

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.

3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.

4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/058336 A1 (BLAHNIK JAY [US] ET AL) 3 March 2016 (2016-03-03) figures 48-53,60-66,70-72,79-94 paragraph [0346] paragraph [0397] - paragraph [0442]	1-23

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Form PCT/ISA/206 (Annex, first sheet) (July 1992; reprint January 2004)

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Patent Family Annex

Information on patent family members

International Application No
PCT/US2018/031662

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016058336 A1	03-03-2016	AU 2015312215 A1	06-10-2016
		AU 2018200428 A1	08-02-2018
		CN 106537397 A	22-03-2017
		CN 108133742 A	08-06-2018
		DE 112015002326 T5	23-03-2017
		DK 201570666 A1	25-07-2016
		DK 201570668 A1	25-07-2016
		DK 201670656 A1	19-09-2016
		DK 201770191 A1	27-03-2017
		EP 3129907 A2	15-02-2017
		EP 3333740 A1	13-06-2018
		JP 2017532069 A	02-11-2017
		KR 20170003608 A	09-01-2017
		TW 201628556 A	16-08-2016
		US 2016058336 A1	03-03-2016
		US 2016058337 A1	03-03-2016
		US 2017281057 A1	05-10-2017
		WO 2016036582 A2	10-03-2016

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Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
PCT/US2018/031662

TITLE: DISPLAYING A SCROLLABLE LIST OF AFFORDANCES ASSOCIATED WITH PHYSICAL ACTIVITIES

APPLICANT: APPLE INC.

IPC CLASSIFICATION: G06F1/16, G06F3/0488, A61B5/11

EXAMINER: De Meyer, Arnaud

CONSULTED DATABASES: WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: G06F1/163, G06F3/04886, A61B5/11

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
Graphical user interface for an activity tracker, e.g. smart watch.

EPO FORM P054A42

Application no:
Demande n°:
Anmelde-Nr: PCT/US2018/031662

DISCLAIMER

The attached provisional opinion on the patentability of the first invention searched serves only as information.
A reply addressing the points raised in the opinion is **not** required and will **not** be taken into account when issuing the final search report and opinion on patentability.

AVERTISSEMENT

L'avis provisoire ci-joint sur la brevetabilité de la première invention recherchée ne sert qu'à titre d'information.
Une réponse abordant les points soulevés dans l'avis n'est **pas** nécessaire et ne sera **pas** prise en compte lors de l'établissement du rapport final de la recherche et de l'avis sur la brevetabilité.

DISCLAIMER

Die beigefügte vorläufige Stellungnahme zur Patentierbarkeit der ersten geprüften Erfindung dient lediglich zur Information.
Eine Antwort auf die erhobenen Punkte in der Stellungnahme ist **nicht** erforderlich und bleibt bei der Erstellung des endgültigen Recherchenberichts und der Stellungnahme zur Patentierbarkeit **unberücksichtigt**.

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Re Item IV

Lack of unity of invention

1 Reference is made to the following document:

D1 US 2016/058336 A1 (BLAHNIK JAY [US] ET AL) 3 March 2016 (2016-03-03)

2 This Authority considers that the application does not meet the requirements of unity of invention and that there are 5 inventions.

group 1: claims 1-23

group 2: claims 24-34

group 3: claims 35-49

group 4: claims 50-52

group 5: claims 63-75

The reasons, for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

Document D1 (by default, references in parentheses apply to this document) discloses a method, comprising:
at an electronic device with a display, a touch-sensitive surface, and a physical activity tracking sensor (fig.49 and [0400]):
displaying a scrollable list of affordances associated with physical activities (fig.49 and [0400]);
displaying a first change workout metrics affordance corresponding to a first affordance of the scrollable list of affordances (fig.51 and [0403]);
receiving a user input ([0404]);
in accordance with a determination that the user input is detected, launching a physical activity tracking function associated with the selected first affordance (fig.51-52 and [0404]: start button 5114);
in accordance with a determination that the user input is detected at the first change workout metrics affordance, displaying a user interface configured to change a workout metric (fig.51-52 and [0403]-[0404]); and

measuring the heart rate of the user ([0346]).

This is the common matter linking together the independent claims of the different groups. This common matter does not comprise a single general inventive concept, because it is known from D1.

2.1 The technical features, representing the difference over the non-inventive common matter, of groups 1-5 are:

group 1: Claim 1 specifies that the physical activity tracking function can be launched directly from the scrollable list of affordances, i.e. the graphical user interface includes a shortcut;

group 2: Claim 24 specifies the interactions between the workout functions and an audio application;

group 3: Claim 35 specifies exchanging message with an external device during the workout;

group 4: Claim 50 specifies means for comparing different heart rate data for at least two activities; and;

group 5: Claim 63 specifies displaying a heart rate alert.

The objective technical problems respectively solved by these distinguishing features are:

group 1: how to modify the interface of D1 so as to avoid having to validate the workout goals every time;

group 2: how to modify the interface of D1 so as to allow listening to music during the workout;

group 3: how to modify the device of D1 so as to allow chatting during the workout;

group 4: how to modify the interface of D1 so as to allow the user to assess his heart beat during the workout;

group 5: how to modify the device of D1 so as to alert the user of a possible heart condition.

The distinguishing features are different and address different technical problems. Hence, the claims comprise neither the same, nor corresponding special technical features, so the technical relationship between the subject matter of the claims required by Rule 13.2 PCT is lacking and the claims are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.

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Consequently the application does not meet the requirement for unity of invention.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims 1 and 18-23 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 Claim 1: Document D1 (by default, references in parentheses apply to this document) discloses a method, comprising:
at an electronic device with a display, a touch-sensitive surface, and a physical activity tracking sensor (fig.49 and [0400]):
displaying a scrollable list of affordances associated with physical activities (fig.49 and [0400]);
displaying a first change workout metrics affordance corresponding to a first affordance of the scrollable list of affordances (fig.51 and [0403]);
receiving a user input ([0404]);
in accordance with a determination that the user input is detected ~~at the first affordance in the scrollable list of affordances~~, launching a physical activity tracking function associated with the selected first affordance (fig.51-52 and [0404]: start button 5114); and
in accordance with a determination that the user input is detected at the first change workout metrics affordance, displaying a user interface configured to change a workout metric (fig.51-52 and [0403]-[0404])

The subject-matter of claim 1 differs from D1 in that:

claim 1 specifies that the physical activity tracking function can be started directly from the list of activities, whereas D1 discloses selecting the activity and then validating the goals (fig.51-52 and [0404]: start button 5114).

The technical effect of this distinguishing feature is to start the workout more quickly.

The associated objective technical problem is formulated as how to modify the interface of D1 so as to avoid having to validate the workout goals every time.

Faced with this technical problem, the skilled person would implement the possibility for starting the workout without going through the submenu, i.e. a shortcut.

3.2 Claims 18-23: The objection in §3.1 above also applies, mutatis mutandis to the subject-matter of claims 18-23.

4 Dependent claims 2-17 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

4.1 Claim 2: D1 discloses determining workout completion and providing different types rewards ([0329]). however, D1 does not disclose that the rewards unlock new goals. This difference only address the non-technical problem of how to keep the user motivated (Guidelines G-II, 3.5 Schemes, rules and methods for performing mental acts, playing games or doing business).

4.2 Claim 3: Disclosed by D1 (fig.51-52 and [0404]: if the user does not press start button 5114).

4.3 Claim 4: Disclosed by D1 (fig.51-53).

4.4 Claim 5: Disclosed by D1 (fig.51-52 and [0404]: when the new metrics is initially displayed).

4.5 Claim 6: Disclosed by D1 (fig.51: buttons 5108 and 5110).

4.6 Claim 7: Disclosed by D1 (fig.51-52 and [0404]: start button 5114).

4.7 Claim 8: D1 discloses different sports (fig.49). It would be obvious to implement only tracking metrics that are relevant for a given sport in order to avoid wasting energy.

4.8 Claim 9: The tracking of D1 is inevitably performed using a tracking sensor.

4.9 Claim 10: Disclosed by D1 (fig.49 and [0400]).

4.10 Claim 11: Disclosed by D1 (fig.49).

4.11 Claim 12: Using an animation is an alternative choice regarding how to present the information (Guidelines G-II, 3.7 Presentations of information).

4.12 Claims 13-15 and 17: Disclosed by D1 (fig.70-71 and [0434]-[0435]).

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4.13 Claim 16: D1 discloses the aggregated performance views for different workouts (fig.72 and 79-94).

Re Item VIII

Certain observations on the international application

5 Although claims 18 and 21 (mediums) have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

The same objection also applies for claims 19, 20, 22 and 23 (devices).

AliveCor Exhibit 1002
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Important Information

General:

- The **claims cannot be changed** at this point in the procedure, the transmitted report is **not** the international search report (see Art. 19 PCT).
- Any payment has to be made **directly** to this ISA, payments to other entities will not be accepted.
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- An **extension of** the set **time limit** can only be granted for cases that fall under the provisions of Rule 80.6 PCT.
- The **amount of the additional search fee** depends on the amount **due on the international filing date.**
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Electronic Acknowledgement Receipt

EFS ID:	34865816
Application Number:	16143959
International Application Number:	
Confirmation Number:	6224
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Customer Number:	150004
Filer:	Peter Jung-Hyon Yim/Swarnava Chakraborty
Filer Authorized By:	Peter Jung-Hyon Yim
Attorney Docket Number:	P38213US2/77770000489102
Receipt Date:	16-JAN-2019
Filing Date:	27-SEP-2018
Time Stamp:	01:49:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P38213US2_IDS.pdf	179686 edbf789c9b1aeea79d1a3f27d2b76ebf7e249605	no	3

Warnings:

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Information:					
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2	Foreign Reference	WO_2006046648_A1.pdf	1959781 b8c169a0b6f9cdc99ee713f9b0887e799652c1eb	no	40
Warnings:					
Information:					
3	Non Patent Literature	PCTUS2018031662_ISRWO_09_27_2018.pdf	17330294 9e42a2dcf052bbb2e892423614b840c4e706e744	no	19
Warnings:					
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4	Non Patent Literature	PCTUS2018031662_INVT_07_16_2018.pdf	1291433 f3a4d72cf81568e742b95d523e7181e39abb7230	no	13
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Information:					
5	Non Patent Literature	PA201870601_DKOA_12_13_2018.pdf	864231 4d1a3b0766b5078ad218515a60224f238d6f1c49	no	8
Warnings:					
Information:					
6	Non Patent Literature	PA201870602_DKSR_12_19_2018.pdf	2576334 73e5b05b7857a8d16de2d056ec3a74f19728358e	no	8
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PLUS Search Results for S/N 16143959, Searched Tue Jan 15 14:00:33 EST 2019

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/143,959
	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	B.N. NGANGA
	Attorney Docket Number	P38213US2/77770000489102

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, where Relevant Passages or Relevant Figures Appear	T[5]
	1.	2017/037242	WO	A1	2017-03-09	Tomtom International B.V.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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AliveCor Exhibit 1002
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	G. Jackson
	Attorney Docket Number	P38213US2/77770000489102

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Approved for use through 07/31/2016. OMB 0651-0031
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	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	G. Jackson
	Attorney Docket Number	P38213US2/77770000489102

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/143,959
	Filing Date	2018-09-27
	First Named Inventor	Christopher D. SOLI
	Art Unit	3792
	Examiner Name	G. Jackson
	Attorney Docket Number	P38213US2/77770000489102

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Randy Omid/	Date (YYYY-MM-DD)	2018-12-20
Name/Print	Randy Omid	Registration Number	67439

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
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(71) Applicant: **TOMTOM INTERNATIONAL B.V.** [NL/NL]; De Ruijterkade 154, 1011 AC Amsterdam (NL).

(72) Inventors: **BAYLEY, Stephen**; De Ruijterkade 154, 1011 AC Amsterdam (NL). **MAGNIEZ, Clement, Albert, Ann**; De Ruijterkade 154, 1011 AC Amsterdam (NL). **JACKSON, Stephen, Michael**; De Ruijterkade 154, 1011 AC Amsterdam (NL).

(74) Agent: **DOBSON, Adrian**; De Ruijterkade 154, 1011 AC Amsterdam (NL).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Published:
— *with international search report (Art. 21(3))*

(54) **Title**: HEART RATE MONITOR

Figure 4a

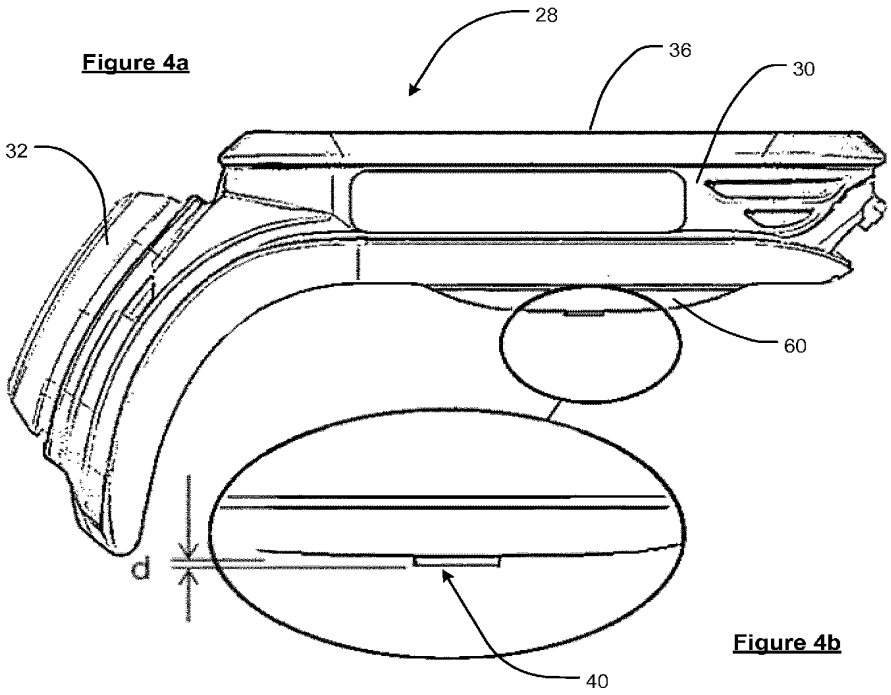


Figure 4b

(57) **Abstract**: A heart rate monitor comprises a housing (30) and an optical heart rate (OHR) sensor within the housing (30). The OHR sensor comprises a sensing unit (40) including at least one light emitter (42a, 42b) arranged to emit light into the skin of a user and a photodetector (44) arranged to sense light reflected through the skin of the user. The housing (30) comprises a domed portion (60). The sensing unit (40) is exposed through a surface of the domed portion (60) and protrudes above the surface of the domed portion (60).

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HEART RATE MONITOR

Field of the Invention

This invention relates to heart rate monitors, and more specifically to heart rate monitors comprising an optical heart rate (OHR) sensor. Furthermore the invention relates to a wearable heart rate monitor comprising an OHR sensor and to the mounting of such a monitor using a wrist strap. The heart rate monitor may be provided as a fitness watch, for example with the heart rate monitor is removably mounted to a wrist strap. Illustrative embodiments of the invention relate to devices for monitoring athletic performance, e.g. that can be worn during an exercise activity (running, cycling, swimming, hiking, skiing, weightlifting, etc.), which can track, display and record the heart rate of the user at particular moments during a workout.

Background of the Invention

Conventional heart rate monitors typically take the form of a sensor mounted to a chest strap. The capacitive sensor detects the heart's electrical activity through the skin. This requires the chest strap to mount the sensor close to the heart and to hold it firmly against the skin. A user wears the chest strap and a corresponding device, such as a wrist watch, which is wirelessly linked to the heart rate sensor to receive and display heart rate information. Alternatively the sensor mounted to the chest strap might be linked to a non-wearable display device such as a mobile phone or a treadmill controller.

Alternatively, some heart rate monitors can be worn on the wrist rather than using a chest strap. These pulse monitors require a user to touch a finger against a pad to provide a pulse rate. However this type of monitor requires the user to stop exercising to take the pulse reading and tends to be less accurate than the chest strap monitors.

More recently, strapless heart rate monitors have taken the form of wrist-worn devices that use optical sensing of the volume of blood under the skin. WO 2013/042070 A1 discloses an optical heart rate monitor that includes a housing in the form of a watch for wearing on the wrist or arm of a user. The monitor comprises an LED arranged to emit light into the skin of a user, where it is partially absorbed by the underlying blood vessels, and a photodetector arranged to sense light reflected back through the skin. The monitor processes the sensor signals and determines a pulse and/or heart rate for display.

Optical heart rate monitors must be mounted in stable contact with the skin during the use to avoid motion artefacts and ensure reliable measurements. Furthermore, ambient light artefacts can reduce measurement quality, for example when a user moves between locations of different ambient lighting, e.g. between shadow and direct sunlight. In WO 2013/042070 A1 an optical high-pass filter is used when detecting the reflected light signals so as to filter out ambient infrared light.

It is desired, in at least embodiments of the present invention, to provide an improved heart rate monitor.

Summary of the Invention

A first aspect of the present invention provides a heart rate monitor comprising a housing and an optical heart rate (OHR) sensor within the housing, the OHR sensor comprising a sensing unit including at least one light emitter arranged to emit light into the skin of a user and a photodetector arranged to sense light reflected through the skin of the user, wherein the housing comprises a domed portion, the sensing unit being exposed through a surface of the domed portion, and wherein the sensing unit protrudes above the surface of the domed portion.

According to the present invention, the housing comprises a domed portion that acts to press against the skin of a user when the monitor is worn during use. This helps to form a good area of contact against the skin. Furthermore, because the sensing unit protrudes above the surface of the domed portion, the sensing unit may press slightly into the wearer's skin so that substantially no ambient light can reach the photodetector. As a result, the photodetector may not need to include an optical filter to remove light artefacts. Furthermore, it is believed that such a structure may also have the dual effect of preventing or reducing motion artefacts by helping to hold the sensing unit in a fixed position against the skin even when a user is moving during exercise. This is particularly suitable when a strap is used to hold the monitor against the surface of a curved limb such as an arm or leg, for example a wrist strap. The present invention is therefore able to overcome the problems outlined above.

The applicant has found that the protrusion of the sensing unit preferably has a minimum of 0.1 mm so as to ensure good contact with the skin of a wearer. Thus in preferred embodiments the sensing unit protrudes above the surface of the domed portion by at least 0.1 mm. The applicant has appreciated that it is desirable for the protrusion of the sensing unit to be limited so that the heart rate monitor is not uncomfortable to wear. Preferably the sensing unit protrudes above the surface of the domed portion by up to 0.8 mm and further preferably up to 0.5 mm.

The depth of the sensing unit may be increased so as to achieve its protrusion. However this may require a bespoke package to be manufactured for the sensing unit. In a preferred set of embodiments the sensing unit is mounted on a circuit board by a riser. By providing a riser between the circuit board and the sensing unit, a standard sensing unit package may be used.

The applicant has recognised that a potential issue with the protrusion of the sensing unit beyond the surface of the housing is an increased risk of damage caused by the ingress of moisture or dirt. This may particularly be a problem in embodiments where the heart rate monitor is provided as a fitness watch and the sensing unit is therefore likely to be assaulted by sweat and/or contaminants (water, dirt, etc.) from the external environment. In a preferred set of embodiments the heart rate monitor further comprises a sealant around the sensing unit. In such examples the sensing unit may be exposed through an aperture in the surface of the domed portion and the sealant may fill the aperture. Suitable sealants may include silicone or polyurethane. In preferred examples the sealant may comprise epoxy resin.

The OHR sensor may comprise any suitable sensing unit including one, two, three or more light emitters. The light emitters preferably comprise light emitting diodes (LEDs). In a preferred set of

embodiments, the sensing unit comprises at least two, and preferably three, light emitting diodes of different wavelengths. A suitable OHR sensor is, for example, Osram BioMon SFH7050. This sensor features three LEDs – green (535 nm), red (660 nm) and IR (940 nm) - and a large area photodiode to maximize signal level. The infrared LED can advantageously be used as a proximity sensor to indicate when the sensing unit is in contact with skin. This allows the OHR sensor to automatically start measurements when the monitor is mounted to the skin or to display an out of reach message. Although it is sufficient to drive only one LED (e.g. green) for heart rate monitoring, for pulse oximetry applications the red and infrared LEDs may be driven alternately.

While enjoying the benefits of a sensing unit that protrudes slightly from the housing of the heart rate monitor, it is preferable that the OHR sensor is compact so that the heart rate monitor can also be made thin. This is particularly advantageous for a wrist-worn monitor. In a preferred set of embodiments the sensing unit is fully integrated as a package having a depth of less than 1 mm.

There will now be described some general features of the heart rate monitor that may be combined with one or more of the embodiments outlined above.

The housing of the heart rate monitor is preferably configured as a single integral casing, and which is preferably sealed so as to be water resistant, to allow the monitor to be used for wet weather outdoor exercise and for swimming.

The OHR sensor may comprise a processor and a battery. The processor may be arranged to analyse light signals received, e.g. at the photodetector, for the purposes of display and/or transmission. The OHR sensor may comprise a memory connected to the processor. This means that HR data can be stored by the device and downloaded later. The OHR sensor may comprise an input/output (I/O) device for transferring data to and from the device and for providing power to recharge the battery. In some examples the OHR sensor may simply act as a sensor hub, collecting and/or transmitting heart rate data for display by another device. This may allow the heart rate monitor to be minimised in size.

In a preferred set of embodiments, the heart rate monitor comprises a display for displaying heart rate information to a user. The display may, for example, comprise a liquid crystal display (LCD). Further preferably the heart rate monitor comprises an input device for controlling the OHR sensor and/or the display. Such an input device can enable a user to change relevant functions, such as applicable HR zones. In various embodiments the input device is spaced apart from the display. In embodiments where the monitor is mounted to a wrist strap, the input device is preferably spaced apart from the display in a longitudinal direction of the strap. The display may be configured to display alphanumeric characters or icons such that upper parts of the characters or icons are arranged towards a first side of the housing and the lower parts of the characters or icons are arranged towards a second, opposite side of the housing. The input device is preferably spaced apart from the display in a direction from said first side to said second side. This configuration is useful when a user wears the display on the back of the wrist, as the user is easily able to view the display whilst controlling the device via the input device that is spaced apart from the display. Less preferably, the input device may be spaced apart from the display in a direction from said second side to said

first side of the housing. This configuration may be useful, for example, when the monitor is strapped to the handle bars of a bicycle or strapped to another vehicle, as the display can be directed towards the user whilst the user has easy access to the input device from above.

The input device is preferably configured to control the display and associated electrical components in use. For example, the input device may be configured for navigating through a menu displayed on the display. For example, the input device may control the functioning of the OHR sensor. The input device is therefore electrically connected to electronic components in the housing. For example, a ribbon lead may extend between the housing and the input device.

The input device preferably has a substantially planar surface arranged substantially parallel to and above an upper surface of the module. The input device is preferably configured to detect the movement of a user's finger across the substantially planar surface so as to provide an input to control the monitor, e.g. for navigating a menu displayed on the display.

The input device may therefore comprise a touchpad (or trackpad) utilising, for example, capacitive sensing to conductance sensing to translate the motion of a user's finger into an input to control the OHR sensor. The touchpad may comprise a one-dimensional touchpad, and which is capable of sensing motion along a single axis, e.g. left-right or up-down. In other more preferred embodiments, the touchpad may comprise a two-dimensional touchpad, and which is capable of sensing motion in any direction, or at least left-right and up-down, on the plane defined by the substantially planar surface of the input device. In other, albeit less preferred embodiments, the input device may comprise a pointing stick (or trackpad) that senses the force applied by a user's finger, e.g. by using a pair of resistive strain gauges, and translates it into an input to control the monitor.

Alternatively, the input device may comprise a two-way button having a continuous pressing surface and two actuators, the button being configured such that when a first portion of the pressing surface is depressed a first of said actuators is actuated so as to provide a first input to control the module, and when a second portion of the pressing surface is depressed a second of said actuators is actuated so as to provide a second input to control the monitor.

Alternatively, the input device may comprise a four-way button having a continuous pressing surface and four actuators, the button being configured such that when a first portion of the pressing surface is depressed a first of said actuators is actuated so as to provide a first input to control the monitor, when a second portion of the pressing surface is depressed a second of said actuators is actuated so as to provide a second input to control the monitor, when a third portion of the pressing surface is depressed a third of said actuators is actuated so as to provide a third input to control the monitor, and when a fourth portion of the pressing surface is depressed a fourth of said actuators is actuated so as to provide a fourth input to control the monitor. The pressing surface described herein is preferably a substantially planar surface parallel to and above a portion of a lower surface that contacts a user's limb in use. It is also contemplated that the input device may comprise any one or more mechanically actuated buttons or non-mechanically actuated buttons, such as virtual buttons on a touch-sensitive user interface, as desired.

The input device is preferably additionally, or alternatively, configured to be operated by being pressed in a direction that is substantially perpendicular to its substantially planar surface, in a direction from the upper surface towards the lower surface. This enables the user to use a single finger to operate the input device. The user does not need to use a second finger of the same hand to counter-balance the pressing of the input device, because the input device is arranged such that it is pressed against the wrist of the user wearing the monitor.

In preferred embodiments in which the input device is configured to both detect the movement of a user's finger across the substantially planar surface and be pressed against the limb of the user, e.g. where the input device comprises a depressible touch pad, the detected motion of the user's finger is used to navigate a menu for identifying a function to be selected, and the depression of the input device is used to select the identified function.

In addition, or alternatively, the display is preferably substantially planar and arranged in a first plane and the input device has a substantially planar pressing surface arranged in a second plane, wherein the first and second planes are at angles to each other, wherein the angle between the first and second planes is less than 90 degrees, optionally between 20 and 70 degrees. In other words, the planes are imaginary intersecting planes and the sides of the planes facing the user's arm or wrist in use define an angle between them at the intersection, wherein the angle is preferably greater than 90 degrees and less than 180 degree. By providing the surfaces at an angle to each other, the user is enabled a good viewing angle of the display whilst operating the input device, when the monitor is mounted to a user's wrist in use. As the input device is spaced away from the display housing, and hence away from the back of the user's wrist and around the side of the wrist in use, said angle also enables the input device to be orientated such that when it is pressed it is pressed against the user's wrist such that the user's wrist provides the counter-force necessary to balance the pressing force. The input device is therefore able to be operated with a single finger and without needing a second finger on the same hand to counter-balance the pressing force as in conventional watches having buttons around the periphery of the display.

In addition, or alternatively, the display preferably has a casing that is physically connected to the input device by a connecting portion, wherein the connecting portion is curved or angled along a direction from the display to the input device. The connecting portion may be curved or angled such that, when the display is arranged on top of a user's wrist in use, the connecting portion curves or otherwise extends around the wrist such that the input device is located on a side of the user's wrist. The monitor is preferably configured such that the input device is located on the medial side of the user's wrist when the display is located on the back of the wrist, the medial side being the side facing the user's body when the back of the hand is facing vertically upwards. In other less preferred embodiments a wrist strap may form said connecting portion that connects the display casing and the input device. The strap may be flexible or formed from one or more pivotable sections so as to flex or pivot to form the curved or angled connecting portion.

The heart rate monitor preferably comprises a processor configured to control the OHR sensor and the display. The display may visually display heart rate (HR) information such as one or more of: current HR

(bpm), average HR (bpm), maximum HR, minimum HR; current HR zone; a graphical representation of HR changes over time; and a graphical representation of the proportion of time spent in each of a plurality of HR zones over time. In addition, or alternatively, the heart rate monitor may comprise an audio output, e.g. a beeper, and/or a haptic output, e.g. a vibrator, to alert a user to changes in the HR data.

The present invention also provides a fitness watch comprising a heart rate monitor as described above. In other words, the heart rate monitor may take the form of a fitness watch and every reference herein to a heart rate monitor may alternatively be taken as a reference to a fitness watch. Such a fitness watch preferably comprises a processor for controlling the heart rate monitor and any other components of the watch. The processor may be connected to means for tracking the location of a user as he or she moves from one location to another, e.g. by using information received from global navigation satellite signals, or by accessing and receiving information from WiFi access points or cellular communication networks. In preferred embodiments the watch comprises a global navigation satellite system (GNSS) receiver, such as a GPS and/or GLONASS receiver, for receiving satellite signals indicating the position, and optionally speed, of the receiver (and thus user) at a particular point in time, and which receives updated information at regular intervals. As will be appreciated, this adds the functionality of tracking the location of the user as he or she moves from one location to another. The GNSS receiver may comprise an antenna, e.g. in the form of a patch antenna, for use in determining the location and movements of the user.

Alternatively, or in addition, the fitness watch may further comprise one or more of: a GPS receiver, a speed sensor, a cadence sensor, an accelerometer, a gyroscope, an altimeter, a pressure sensor (e.g. diving depth gauge), an electronic compass, vibration device for indicating alerts to a user, a wireless communications device (for example capable of transmitting signals from one or more body-worn sensors), such as a Bluetooth module (e.g. capable of using the Bluetooth Low Energy (BLE) protocol). In embodiments where the watch comprises a wireless communications device, this may be arranged to receive data from other sensors, such as a foot pod sensor or a speed/cadence sensor. The wireless communications device may be arranged to communicate with an external heart rate monitor, for example a monitor mounted on a chest strap worn by the user. In addition, or alternatively, the wireless communications device may be arranged to transmit data to one or more external devices (e.g. a mobile phone device).

The watch may comprise one or more electrical connectors for electrically connecting to a dock or cable for charging the battery and/or for transferring data to or from the processor. It is contemplated that any known electrical connector may be employed. In preferred embodiments, however, the one or more electrical connectors comprise electrical contacts, which may be flat and arranged substantially in line with, or recessed in, the lower surface of the housing (e.g. for contacting with corresponding pogo pins in a docking system). The electrical contacts may be located in any portion of the lower surface of the housing as desired, although in preferred embodiments the electrical contacts are located in the lower surface under the input device, e.g. distal from the display. This allows the user to see the display when the watch is positioned in a docking system.

In at least some embodiments, the heart rate monitor may be permanently mounted to a strap to form a fitness watch. For example, the heart rate monitor may be integrated with the strap. However, in various embodiments of the present invention, the heart rate monitor may be removably mounted to a wrist strap. For example, the strap may comprise a central mount to which the heart rate monitor is removably connected. This can allow the heart rate monitor to be repeatedly engaged and disengaged from the strap, for example so that a user can dock the heart rate monitor to allow for the transfer of power and/or data, e.g. using a docking station connected to a computer. In addition, or alternatively, the same strap may be used interchangeably to mount different heart rate monitors or other units, such as a watch module including location determining means, e.g. a global navigation satellite system (GNSS) receiver, such as GPS and/or GLONASS.

The central mount provided by the strap may comprise a physical connector for the heart rate monitor, for example a mechanical and/or magnetic connection system. In a preferred set of embodiments the central mount comprises an aperture in the strap, e.g. into which the heart rate monitor can be inserted. The heart rate monitor may comprise one or more projections and/or recesses for releasably engaging with corresponding features of the aperture. Preferably the strap comprises at least two apertures and, in embodiments where the heart rate monitor comprises a display and an input device, the display and input device each project through a respective aperture in the strap.

The present invention in accordance with any of its further aspects or embodiments may include any of the features described in reference to other aspects or embodiments of the invention to the extent it is not mutually inconsistent therewith.

Advantages of these embodiments are set out hereafter, and further details and features of each of these embodiments are defined in the accompanying dependent claims and elsewhere in the following detailed description.

Brief Description of the Drawings

Various aspects of the teachings of the present invention, and arrangements embodying those teachings, will hereafter be described by way of illustrative example with reference to the accompanying drawings, in which:

Figure 1 shows a perspective view of a heart rate monitor module;

Figure 2 shows the module of Figure 1 as viewed from the underside;

Figures 3a and 3b show, respectively, a side sectional view and a close-up of the module; and

Figures 4a and 4b show a side view and a close-up, respectively, of the module;

Figure 5 is a schematic illustration of electronic components of a fitness watch according to a preferred embodiment; and

Figure 6 is a schematic illustration of the manner in which a fitness watch may receive information over a wireless communication channel.

Detailed Description of the Preferred Embodiments

Preferred embodiments of the present invention will now be described with particular reference to a fitness or sports watch having access to Global Positioning System (GPS) data. Fitness or sports watches of the type described are often worn by athletes to help them during their runs or workouts, e.g. by monitoring the speed and distance of the user and providing this information to the user. It will be appreciated, however, that the device could be arranged to be carried by a user or connected or "docked" in a known manner to a vehicle such as a bicycle, kayak, or the like.

In general, GPS is a satellite-radio based navigation system capable of determining continuous position, velocity, time, and in some instances direction information for an unlimited number of users. Formerly known as NAVSTAR, the GPS incorporates a plurality of satellites which orbit the earth in extremely precise orbits. Based on these precise orbits, GPS satellites can relay their location to any number of receiving units.

The GPS system is implemented when a device, specially equipped to receive GPS data, begins scanning radio frequencies for GPS satellite signals. Upon receiving a radio signal from a GPS satellite, the device determines the precise location of that satellite via one of a plurality of different conventional methods. The device will continue scanning, in most instances, for signals until it has acquired at least three different satellite signals (noting that position is not normally, but can be determined, with only two signals using other triangulation techniques). Implementing geometric triangulation, the receiver utilizes the three known positions to determine its own two-dimensional position relative to the satellites. This can be done in a known manner. Additionally, acquiring a fourth satellite signal will allow the receiving device to calculate its three dimensional position by the same geometrical calculation in a known manner. The position and velocity data can be updated in real time on a continuous basis by an unlimited number of users.

Figure 5 is an illustrative representation of electronic components of a sports watch 200 according to a preferred embodiment of the present invention, in block component format. It should be noted that the block diagram of the device 200 is not inclusive of all components of the device, but is only representative of many example components.

The device 200 includes a processor 202 connected to an input device 212, such as a depressible touchpad (or trackpad), and a display screen 210, such as an LCD display. The device 200 can further include an output device arranged to provide audible information to a user, such as alerts that a certain speed has been reached or a certain distance has been travelled.

Figure 5 further illustrates an operative connection between the processor 202 and a GPS antenna/receiver 204. Although the antenna and receiver are combined schematically for illustration, the antenna and receiver may be separately located components. The antenna may be of any suitable form, but in preferred embodiments is a GPS patch antenna.

The device 200 further includes an accelerometer 206, which can be a 3-axis accelerometer arranged to detect accelerations of the user in x, y and z directions. The accelerometer may act as a

pedometer for use when/if there is a loss of GPS reception, and/or may act to detect stroke rate when the fitness watch is being used during swimming. Although the accelerometer is shown to be located within the device, the accelerometer may also be an external sensor worn or carried by the user, and which transmits data to the device 200 via the transmitter/receiver 208.

The device may also receive data from other sensors, such as a foot pod sensor 222 or a heart rate sensor 226. The foot pod sensor may, for example, be a piezoelectric or micro-electro-mechanical systems (MEMS) accelerometer that is located in or on the sole of the user's shoe. Each external sensor is provided with a transmitter and receiver, 224 and 228 respectively, which can be used to send or receive data to the device 200 via the transmitter/receiver 208.

The processor 202 is operatively coupled to a memory 220. The memory resource 220 may comprise, for example, a volatile memory, such as a Random Access Memory (RAM), and/or a non-volatile memory, for example a digital memory, such as a flash memory. The memory resource 220 may be removable. As discussed in more detail below, the memory resource 220 is also operatively coupled to the GPS receiver 204, the accelerometer 206 and the transmitter/receiver 208 for storing data obtained from these sensors and devices.

Further, it will be understood by one of ordinary skill in the art that the electronic components shown in Figure 5 are powered by a power source 218 in a conventional manner. The power source 218 may be a rechargeable battery.

The device 200 further includes an input/output (I/O) device 216, such as a plurality of electrical contacts or a USB connector. The I/O device 216 is operatively coupled to the processor, and also at least to the memory 220 and power supply 218. The I/O device 216 is used, for example, to: update firmware of processor 220, sensors, etc; transfer data stored on the memory 220 to an external computing resource, such as a personal computer or a remote server; and recharge the power supply 218 of the device 200. Data could, in other embodiments, also be sent or received by the device 200 over the air using any suitable mobile telecommunication means.

As will be understood by one of ordinary skill in the art, different configurations of the components shown in Figure 5 are considered to be within the scope of the present application. For example, the components shown in Figure 5 may be in communication with one another via wired and/or wireless connections and the like.

In Figure 6 the watch 200 is depicted as being in communication with a server 400 via a generic communications channel 410 that can be implemented by any number of different arrangements. The server 400 and device 200 can communicate when a connection is established between the server 400 and the watch 200 (noting that such a connection can be a data connection via mobile device, a direct connection via personal computer via the internet, etc.).

The server 400 includes, in addition to other components which may not be illustrated, a processor 404 operatively connected to a memory 406 and further operatively connected, via a wired or wireless connection, to a mass data storage device 402. The processor 404 is further operatively connected to

transmitter 408 and receiver 409, to transmit and send information to and from device 200 via communications channel 410. The signals sent and received may include data, communication, and/or other propagated signals. The functions of transmitter 408 and receiver 409 may be combined into a signal transceiver.

The communication channel 410 is not limited to a particular communication technology. Additionally, the communication channel 410 is not limited to a single communication technology; that is, the channel 410 may include several communication links that use a variety of technology. For example, the communication channel 410 can be adapted to provide a path for electrical, optical, and/or electromagnetic communications, etc. As such, the communication channel 410 includes, but is not limited to, one or a combination of the following: electric circuits, electrical conductors such as wires and coaxial cables, fibre optic cables, converters, radio-frequency (RF) waves, the atmosphere, empty space, etc. Furthermore, the communication channel 410 can include intermediate devices such as routers, repeaters, buffers, transmitters, and receivers, for example.

In one illustrative arrangement, the communication channel 410 includes telephone and computer networks. Furthermore, the communication channel 410 may be capable of accommodating wireless communication such as radio frequency, microwave frequency, infrared communication, etc. Additionally, the communication channel 410 can accommodate satellite communication.

The server 400 may be a remote server accessible by the watch 200 via a wireless channel. The server 400 may include a network server located on a local area network (LAN), wide area network (WAN), virtual private network (VPN), etc.

The server 400 may include a personal computer such as a desktop or laptop computer, and the communication channel 410 may be a cable connected between the personal computer and the watch 200. Alternatively, a personal computer may be connected between the watch 200 and the server 400 to establish an internet connection between the server 400 and the watch 200. Alternatively, a mobile telephone or other handheld device may establish a wireless connection to the internet, for connecting the watch 200 to the server 400 via the internet.

The server 400 is further connected to (or includes) a mass storage device 402. The mass storage device 402 contains a store of at least digital map information. This digital map information can be used, together with data from the device, such as time-stamped location data obtained from the GPS receiver 204 and data indicative of motion of the wearer obtained from the accelerometer 206, footpad sensor 222, etc, to determine a route travelled by the wearer of the device 200, which can then be viewed by the wearer.

As will be appreciated, the watch 200 is designed to be worn by a runner or other athlete as they undertake a run or other similar type of workout. The various sensors within the watch 200, such as the GPS receiver 204 and the accelerometer 206, collect data associated with this run, such as the distance travelled, current speed, etc, and display this data to the wearer using the display screen 210.

Figures 1 to 4 provide an example of a fitness monitoring module that can be removably connected to a wrist strap (not shown), such as one as discussed above. In some embodiments the module 28 could

take the form of a fitness watch module, in particular a GNSS, e.g. GPS, watch module. In other embodiments the module 28 takes the form of a heart rate monitor module, which may or may not include GNSS watch capabilities.

Figure 1 shows a perspective view of a heart rate monitor module 28 comprising a housing 30 and a display 36 exposed at an upper surface of the housing 30. An input device 32 is spaced apart from the display 36. The substantially planar display 36 is controlled by the input device 32 to display heart rate information to a user. The display 36 may comprise a liquid crystal display (LCD). In addition to the LCD, the display includes an illumination 34, for example an LED that shines through the otherwise opaque frame of the LCD.

The illumination 34 is controlled by a processor in the watch module 28 to convey information relating to a user's heart rate. In one example, the illumination 34 blinks at the approximate frequency of the heart rate, thereby providing for visualisation of the heart rate at a glance. In addition, or alternatively, in another example the colour of the illumination 34 represents a particular heart rate zone. The illumination 34 may blink according to the following colour scheme:

HEART RATE ZONE	COLOUR
1. Recover	Turquoise
2. Fat Burn	Blue
3. Endure	Green
4. Speed	Purple
5. Sprint	Red

The input device 32 is connected to the main housing 30 by a curved flange 38 that extends away from the housing 30. The curved flange 38 extends away from the housing 30 such that it curves around a user's wrist when the module is mounted to a wrist strap (not shown). The input device 32 is located so as to be arranged on the side of the user's wrist in use. The input device 32 has a substantially planar pressing surface for the user to interact with the module 28. The user can thereby press the pressing surface in a direction perpendicular to the pressing surface so as to control the module 28, e.g. to select desired functions within the menu system of the heart rate monitor. In this example the input device 32 takes the form of a four-way button.

The location of the input device 32 being arranged on the curved flange 38 such that it sits against the side of the user's wrist in use has a number of important advantages. For example, this enables the user to interact with the module 28 using only a single finger. More specifically, the user is able to push the pressing surface of the input device 32 with one finger because the user pushes the surface into the user's wrist around which the watch 28 is strapped. This is in contrast to conventional heart rate monitors or watches wherein buttons are arranged around the peripheral edges and the user must press the button with on finger and use a thumb on the other edge of the watch to counter-balance the pressing force. As seen in Figure 1, for example, the plane defined by the substantially planar display 36 is arranged at an angle to the

plane defined by the input device 32, the dihedral angle between the two planes being less than 90 degrees, and typically between 20 and 70 degrees.

Figure 2 shows a perspective view of the heart rate module 28 from the underside. The curved flange 38 that extends from the main housing 30 may have electrical connectors (not seen) arranged at a distal end thereof. These electrical connectors may be used in order to electrically connect the module 28 to a dock in order to recharge a battery within the module 28 and/or to extract data from or input data to the module 28. The lower surface of the housing 30 comprises a domed portion 60 that extends over an optical heart rate (OHR) sensor. A sensing unit 40 of the OHR sensor protrudes through an aperture in the domed portion 60. In this example the sensing unit 40 comprises a pair of light emitting diodes 42a, 42b (e.g. two green LEDs, or a green LED and an infrared LED) and a photodetector 44. When the module 28 is mounted to a wearer's wrist, the sensing unit 40 sits on the front or back of the wrist in contact with the skin. The domed portion 60 applies pressure so that the module 28 is less likely to move when it is worn, while the protrusion of the sensing unit 40 presses into the skin so as to prevent or reduce the ingress of ambient light to the photodetector 44.

Figures 3a and 3b show in detail how the sensing unit 40 is mounted on a riser 48 on top of a printed circuit board 50. The depth of the riser 48 determines how far the sensing unit 40 protrudes beyond the surface of the domed portion 60. The side view of Figures 4a and 4b shows how the sensing unit 40 protrudes from the surface of the domed portion 60 by a distance d. The distance d is at least 0.1 mm.

The OHR sensing unit 40 may be operatively connected to a processor in the module 28 that can process data signals relating to pulse and/or heart rate. The processor is typically connected to a memory and a power supply, e.g. a battery. The battery may be recharged when the module 28 is docked using its I/O port, for example in the form of the electrical connectors mentioned above. The same electrical connectors may also be used to transfer data to/from the processor. In addition to the I/O port, the module 28 may include a wireless communications interface, such as a Bluetooth transceiver, that enables the module 28 to wirelessly communicate with one or more other devices to receive additional data. For example, other devices that are body-worn (e.g. an external heart rate monitor) or mounted nearby during exercise (e.g. mounted to a bike during cycling activities) may pair with the module 28 to transmit additional data. The module's user interface may allow a user to view such additional data on the display. In some embodiments the module 28 could take the form of a fitness watch module, in particular a GNSS, e.g. GPS, watch module.

The module's user interface includes the display 36 and the input device 32 already described above. Of course other user interface components may be provided instead, or as well as, those seen in the figures. Further features of a module 28 as seen in Figures 1 to 4 are described in WO 2014/135709; the contents of which are hereby incorporated by reference. In particular, it is described therein how such a module may be removably mounted to a wrist strap.

It will be appreciated that whilst various aspects and embodiments of the present invention have heretofore been described, the scope of the present invention is not limited to the particular arrangements set

out herein and instead extends to encompass all arrangements, and modifications and alterations thereto, which fall within the scope of the appended claims.

For example, whilst a preferred embodiment described in the foregoing detailed description relates to a heart rate monitor module without reference to a strap, it will be understood that the module could be mounted to a wrist strap, either permanently or removably. Furthermore, although the module has been described as having a display and/or input device, these are optional components. A suitable module may include a battery and a processor connected to one or more of: an optional display, an optional input device, a memory, a wireless transceiver, and an input/output device such as electrical contacts.

Lastly, it should be noted that whilst the accompanying claims set out particular combinations of features described herein, the scope of the present invention is not limited to the particular combinations hereafter claimed, but instead extends to encompass any combination of features or embodiments herein disclosed irrespective of whether or not that particular combination has been specially enumerated in the accompanying claims at this time.

CLAIMS:

1. A heart rate monitor comprising a housing and an optical heart rate (OHR) sensor within the housing, the OHR sensor comprising a sensing unit including at least one light emitter arranged to emit light into the skin of a user and a photodetector arranged to sense light reflected through the skin of the user, wherein the housing comprises a domed portion, the sensing unit being exposed through a surface of the domed portion, and wherein the sensing unit protrudes above the surface of the domed portion.

2. The heart rate monitor of claim 1, wherein the sensing unit protrudes above the surface of the domed portion by at least 0.1 mm.

3. The heart rate monitor of claim 2, wherein the sensing unit protrudes above the surface of the domed portion by up to 0.8 mm and preferably up to 0.5 mm.

4. The heart rate monitor of any preceding claim, wherein the sensing unit is mounted on a circuit board by a riser.

5. The heart rate monitor of any preceding claim, further comprising a sealant around the sensing unit.

6. The heart rate monitor of claim 5, wherein the sensing unit is exposed through an aperture in the surface of the domed portion and the sealant fills the aperture.

7. The heart rate monitor of claim 5 or 6, wherein the sealant comprises epoxy resin.

8. The heart rate monitor of any preceding claim, wherein the sensing unit comprises three light emitting diodes of different wavelengths.

9. The heart rate monitor of any preceding claim, wherein the sensing unit is fully integrated as a package having a depth of less than 1 mm.

10. The heart rate monitor of any preceding claim, further comprising a display for displaying heart rate information to a user.

11. The heart rate monitor of any preceding claim, further comprising one or more illumination devices in addition to the display, and wherein the one or more illumination devices are controlled: (i) so as to flash at a frequency that is dependent on heart rate information; and/or (ii) so that the colour of emitted light corresponds to a predetermined heart rate zone.

12. A watch, optionally a fitness watch, comprising the heart rate monitor of any preceding claim and a strap for securing the watch to the arm or wrist of a user.

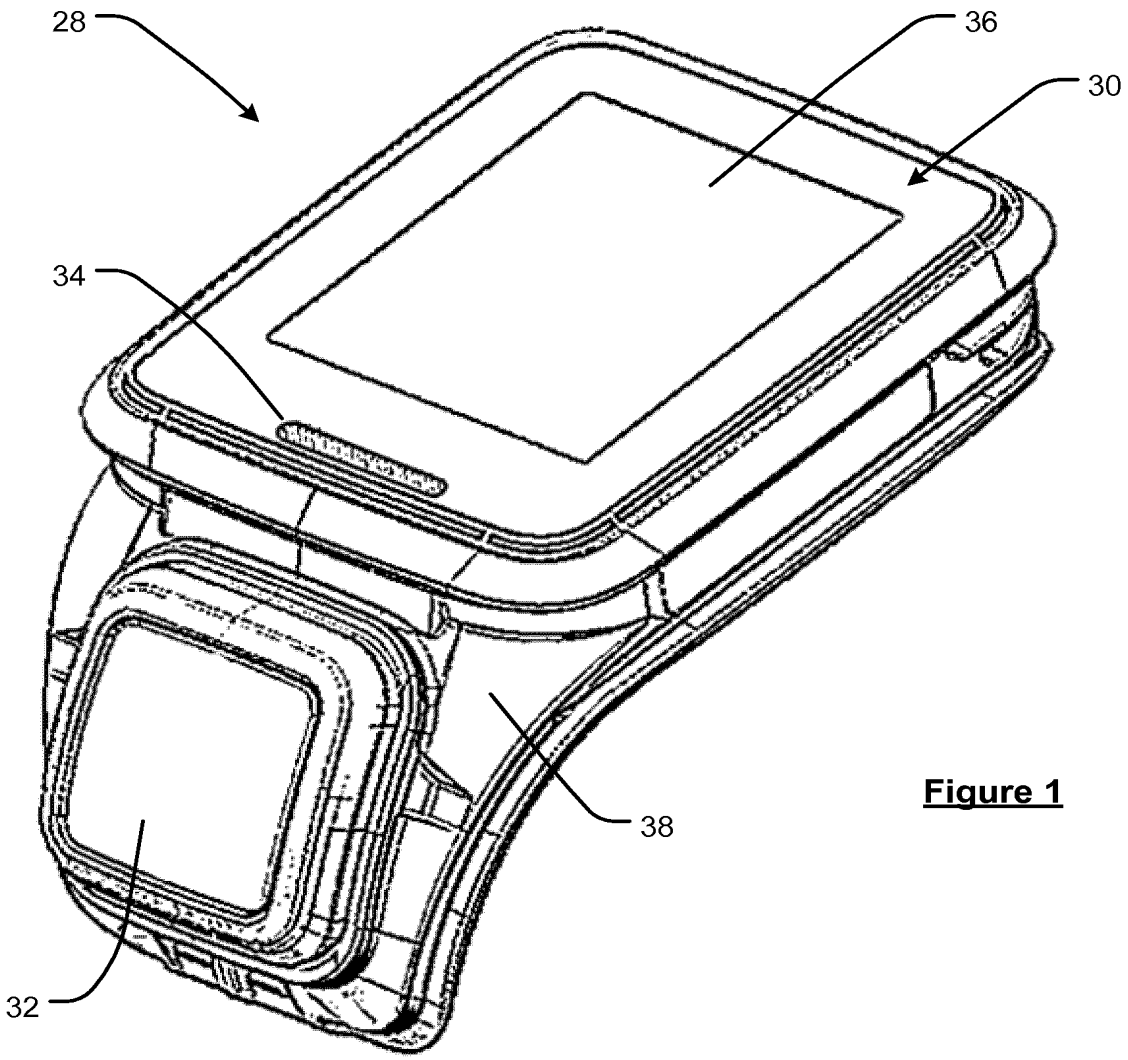


Figure 1

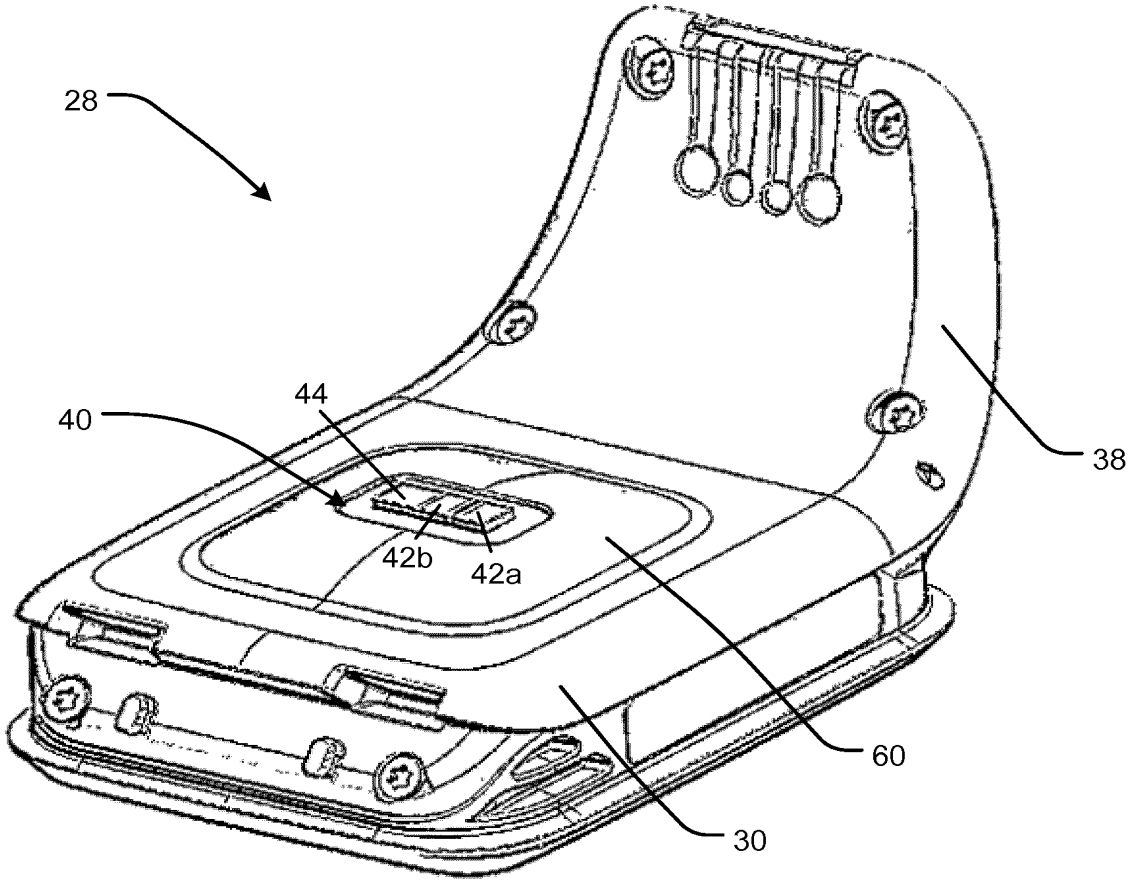


Figure 2

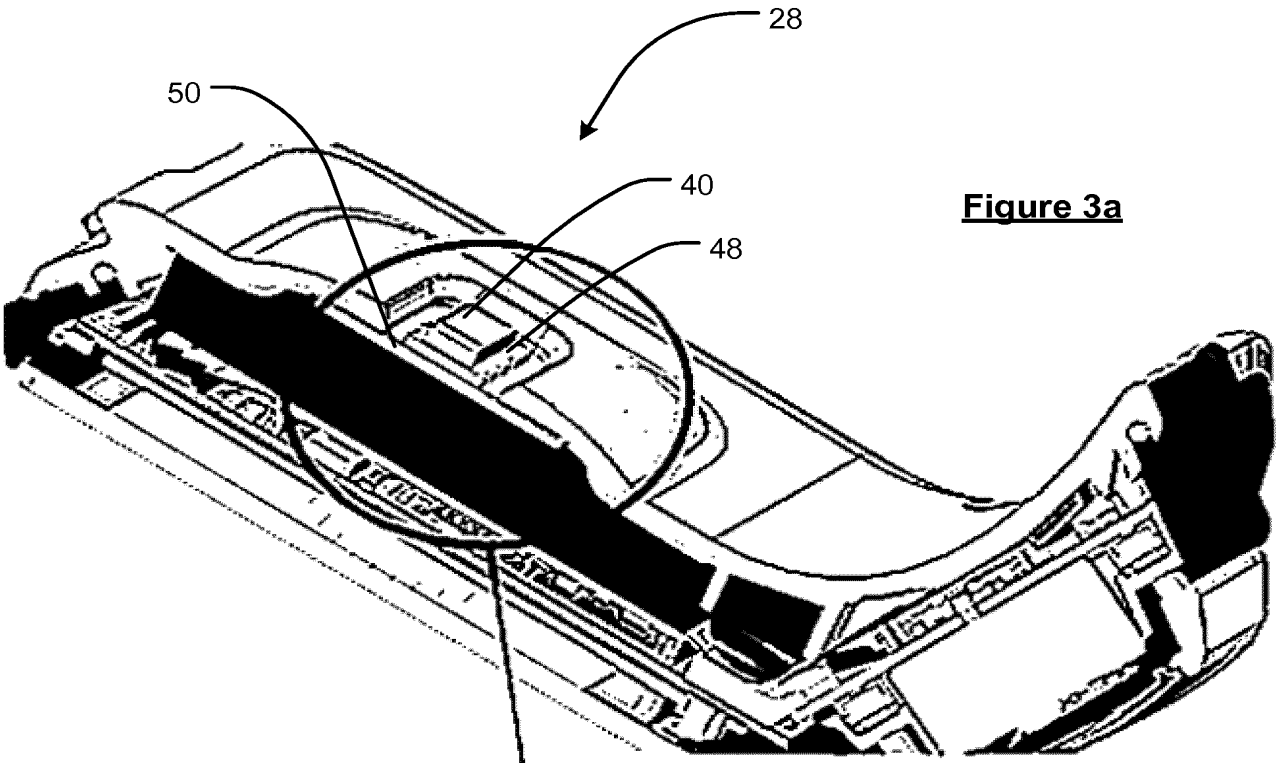


Figure 3a

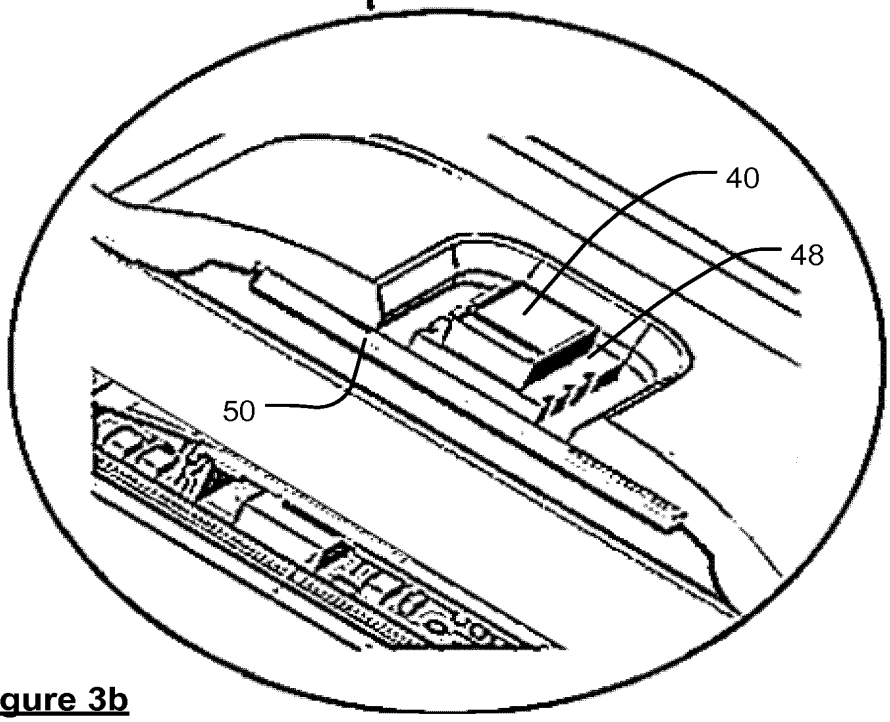


Figure 3b

Figure 4a

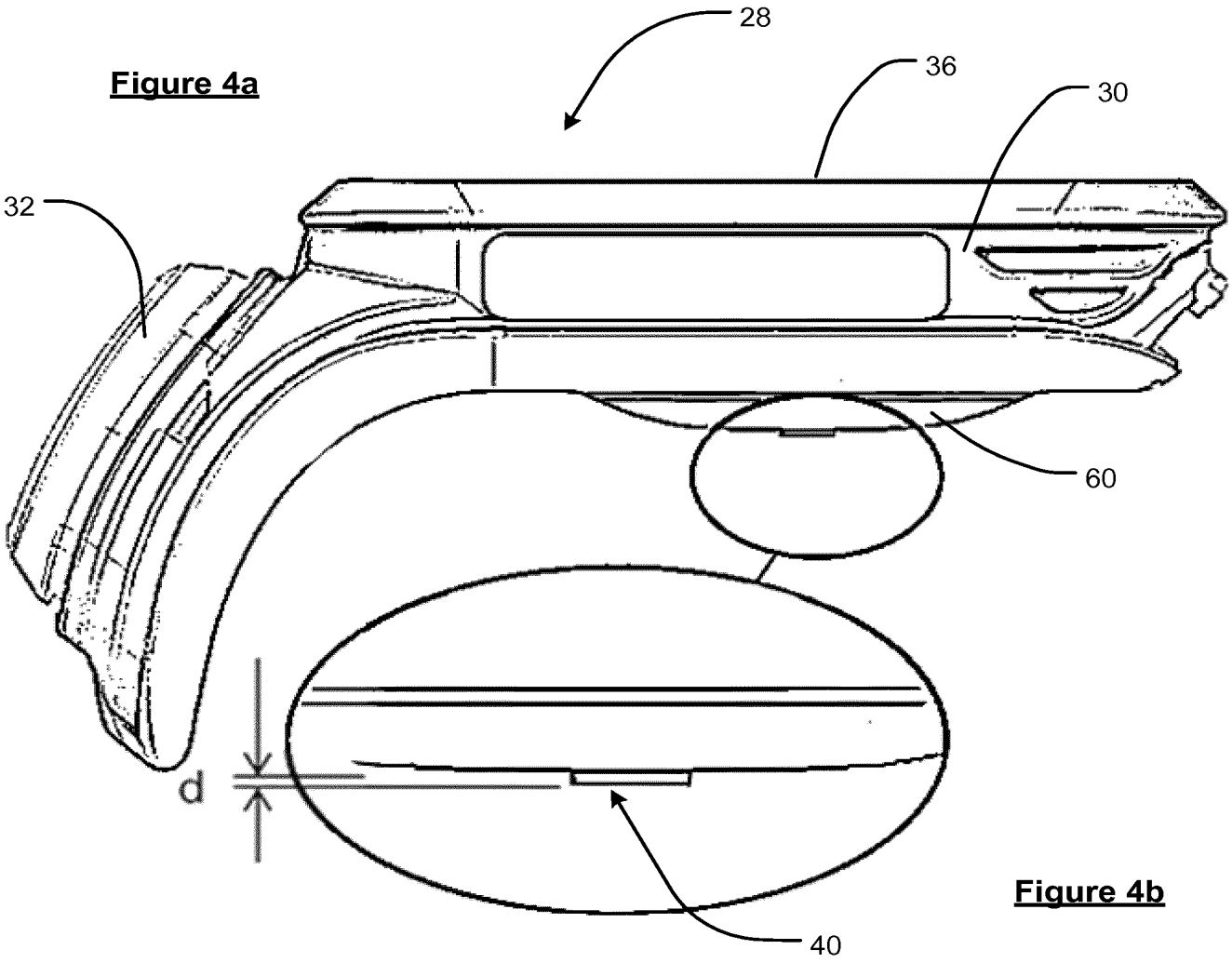


Figure 4b

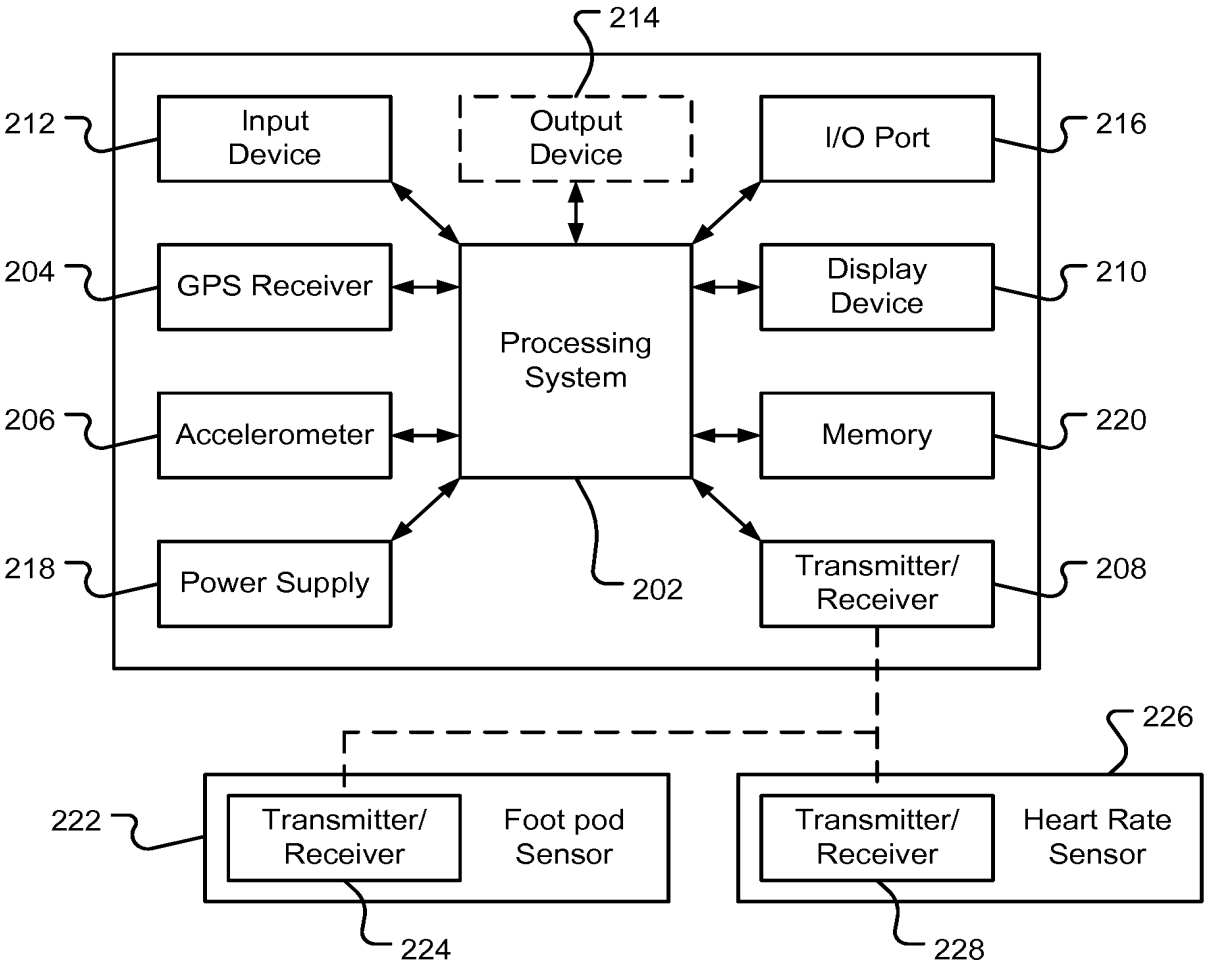


Figure 5

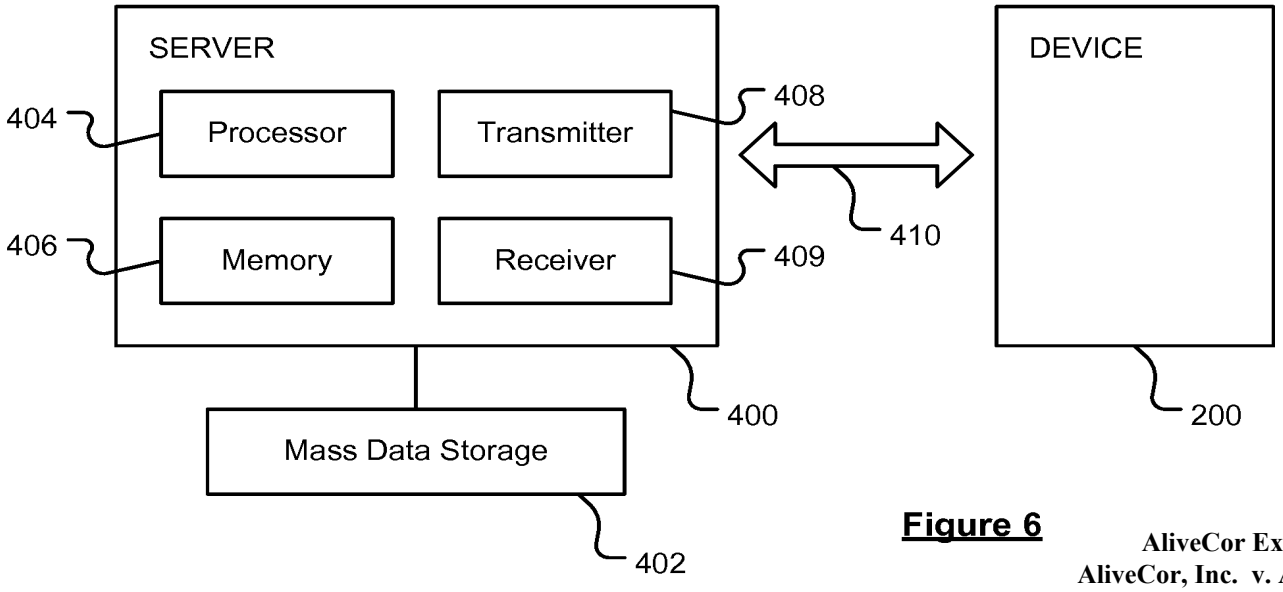


Figure 6

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1082 of 1413

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/070734

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/024 A61B5/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 781 187 A2 (SEIKO EPSON CORP [JP]) 24 September 2014 (2014-09-24) paragraph [0009] paragraph [0064] - paragraph [0068] paragraph [0103] - paragraph [0105] paragraph [0123] - paragraph [0124] figures 1A, 4, 10A, 17C -----	1-12
X	EP 2 888 996 A1 (SEIKO EPSON CORP [JP]) 1 July 2015 (2015-07-01) paragraph [0048] - paragraph [0053] paragraph [0122] - paragraph [0126] figures 3, 9 -----	1,4-6,8, 10-12

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 December 2016	19/12/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Gooding Arango

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1083 of 1413

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/267854 A1 (JOHNSON JAMI [US] ET AL) 10 October 2013 (2013-10-10) paragraph [0017] - paragraph [0021] paragraph [0028] - paragraph [0029] paragraph [0040] - paragraph [0041] figures 2C, 3C, 4 claim 10 -----	1,5,6, 8-12
X	JP 2005 270543 A (SEIKO INSTR INC) 6 October 2005 (2005-10-06) paragraph [0009] - paragraph [0012] paragraph [0046] figures 3, 4, 5, 7 -----	1,5,10, 12

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/070734

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2781187 A2	24-09-2014	CN 104055508 A	24-09-2014
		EP 2781187 A2	24-09-2014
		US 2014275949 A1	18-09-2014
EP 2888996 A1	01-07-2015	CN 104739372 A	01-07-2015
		EP 2888996 A1	01-07-2015
		JP 5880535 B2	09-03-2016
		JP 2015119911 A	02-07-2015
		US 2015173675 A1	25-06-2015
US 2013267854 A1	10-10-2013	NONE	
JP 2005270543 A	06-10-2005	JP 4485234 B2	16-06-2010
		JP 2005270543 A	06-10-2005
		WO 2005092182 A1	06-10-2005

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1085 of 1413

Electronic Acknowledgement Receipt

EFS ID:	34647843
Application Number:	16143959
International Application Number:	
Confirmation Number:	6224
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Customer Number:	150004
Filer:	Peter Jung-Hyon Yim/Swarnava Chakraborty
Filer Authorized By:	Peter Jung-Hyon Yim
Attorney Docket Number:	P38213US2/77770000489102
Receipt Date:	20-DEC-2018
Filing Date:	27-SEP-2018
Time Stamp:	08:16:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	77770000489102_IDS_Dec_20_2018.pdf	202773 127c81b95798d28da9e107a7cd713efe3290156b	no	4

Warnings:

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1086 of 1413

Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO_2017037242_A1.pdf	1353590 b38878b1d7b97c260efc44e274494ef788afdcfc	no	24
Warnings:					
Information:					
3	Non Patent Literature	SUUNTOSPARTAN_2018_47.pdf	2768213 12a90fb31d3c5f6b91bfc09750650769d05b11f4	no	47
Warnings:					
Information:					
4	Non Patent Literature	Google_2016_1.pdf	661150 7278eadc0302c89eb88ccbd712a1f5596fc6a3a8	no	1
Warnings:					
Information:					
5	Non Patent Literature	GARMIN_2018_1.pdf	13184354 e143a561853049e6e8e7bef16c7450a2399fbac5	no	42
Warnings:					
Information:					
6	Non Patent Literature	Garmin_2015_1.pdf	823712 aa69719b8fe4320ab5ec52e3d34253ec730e3b49	no	1
Warnings:					
Information:					
7	Non Patent Literature	TOMTOMMULTISPORT_2015_1.pdf	309450 1df21c78e28d147a3db5796100240401 03d02f9b	no	1
Warnings:					
Information:					
8	Non Patent Literature	GARMINFENIXACTIVITY_2017_1.pdf	115318 2f3e80a5bcb1fea26d5df84c8f3e97ac4a1c6cb0	no	1
Warnings:					
Information:					

9	Non Patent Literature	GARMINFENIX_2017_1.pdf	240102 2da14dfe290ca8667f0d23af5b56463c1e55b6c3	no	2
Warnings:					
Information:					
10	Non Patent Literature	GARMINFENIX5_2017_1.pdf	243319 83db5bc526e6a882e6c3cd24eb1a0722ce7b647f	no	2
Warnings:					
Information:					
11	Non Patent Literature	SUUNTO_2018_1.pdf	281274 bbd9066f7ebe8c7aa5d425a6f5896357e4422b5f	no	2
Warnings:					
Information:					
12	Non Patent Literature	TOMTOM_2005_1.pdf	10705023 f22ffe88fe0f6678d8e776886dbb9df1888907e6	no	44
Warnings:					
Information:					
13	Non Patent Literature	GARMINFENIXOPEN_2017_1.pdf	110863 57391ebeeff678d21a2f7d3f0a317446506cbedc	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	30999141		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/143,959	09/27/2018	Christopher D. SOLI	P38213US2/77770000489102	6224

150004 7590 11/01/2018

DENTONS US LLP - Apple
P.O. Box 061080
Wacker Drive Station, Willis Tower
Chicago, IL 60606

EXAMINER	
ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
11/01/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents.us@dentons.com
dentons_PAIR@firsttofile.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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Doc Code:
TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 16/143,959

1. THE REQUEST FILED September 27, 2018 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination
A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;

C. filing a **request for continued examination**;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Cheryl Gibson-Baylor at (571)272-3213, Office of Petitions. In his/her absence, calls may be directed to Brian W. Brown, (571)272-5338.

Cheryl Gibson-Baylor
/Cheryl Gibson-Baylor/
[*Signature*]

Petitions Paralegal Specialist
(Title)

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1091 of 1413

Office of Petitions: Routing Sheet

4700

Application No. 16143959

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application, as indicated below. For details of this decision, please see the document PET.OP.DEC filed on the same date as this document.

- [X] **GRANTED**
- [ ] **DISMISSED**
- [ ] **DENIED**

Office of Petitions: Decision Count Sheet

10

Application No. 16143959

16143959

For US serial numbers: enter number only, no slashes or commas. Ex: 10123456

For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official: GIBSON-BAYLOR, C

Count (1) - Palm Credit 16143959

Decision: GRANT

FINANCE WORK NEEDED

☐ Select Check Box for YES

GRANT

Decision Type: 643 - Track One request

643

Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED

☐ Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED

☐ Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

Printed on: 10/29/2018

Office of Petitions Internal Document - Ver. 5.0

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/143,959

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 460 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						1200
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	2920

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/143,959	09/27/2018	Christopher D. SOLI	P38213US2/77770000489102

CONFIRMATION NO. 6224

150004
DENTONS US LLP - Apple
P.O. Box 061080
Wacker Drive Station, Willis Tower
Chicago, IL 60606

INFORMAL NOTICE

OC000000103165568

Date Mailed: 10/19/2018

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Christopher D. SOLI
  Matthew W. CROWLEY
  Bradley W. GRIFFIN
  Gary Ian BUTCHER
  Roxanne BRITTAIN

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/hachristian/

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1095 of 1413

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/143,959	09/27/2018		3080	P38213US2/77770000489102	20	3

CONFIRMATION NO. 6224

FILING RECEIPT

150004
DENTONS US LLP - Apple
P.O. Box 061080
Wacker Drive Station, Willis Tower
Chicago, IL 60606

OC000000103765587

Date Mailed: 10/19/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Christopher D. SOLI, Mountain View, CA;
Matthew W. CROWLEY, San Francisco, CA;
Bradley W. GRIFFIN, Berkeley, CA;
Gary Ian BUTCHER, San Jose, CA;
Roxanne BRITTAIN, Berkeley, CA;

Applicant(s)

Apple Inc., Cupertino, CA;

Power of Attorney: The patent practitioners associated with Customer Number 150004

Domestic Priority data as claimed by applicant

This appln claims benefit of 62/657,870 04/15/2018
and claims benefit of 62/657,881 04/15/2018
and claims benefit of 62/643,699 03/15/2018
and claims benefit of 62/641,994 03/12/2018

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1096 of 1413

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 10/18/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/143,959**
Projected Publication Date: 09/12/2019
Non-Publication Request: No
Early Publication Request: No
Title

USER INTERFACES FOR HEALTH MONITORING

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1097 of 1413

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1098 of 1413

Electronic Patent Application Fee Transmittal

Application Number:	16143959
Filing Date:	
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Filer:	Brian B. Ho/Staci Berry
Attorney Docket Number:	P38213US2/77770000489102

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	160	160
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Electronic Acknowledgement Receipt

EFS ID:	33853026
Application Number:	16143959
International Application Number:	
Confirmation Number:	6224
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Customer Number:	150004
Filer:	Brian B. Ho/Staci Berry
Filer Authorized By:	Brian B. Ho
Attorney Docket Number:	P38213US2/77770000489102
Receipt Date:	27-SEP-2018
Filing Date:	
Time Stamp:	16:57:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$160
RAM confirmation Number	092818INTEFSW16575700
Deposit Account	193140
Authorized User	Staci Berry

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

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IPR2024-00095, U.S. Patent No. 10,568,533
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37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Fee Worksheet (SB06)	fee-info.pdf	30244 3b26836ed77aa4223fe0bcbac781dae42c8248c3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	30244		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	2018-09-27
First Named Inventor	Christopher D. SOLI
Title	USER INTERFACES FOR HEALTH MONITORING
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	P38213US2/77770000489102

SIGNATURE of Applicant or Patent Practitioner

Signature	/Brian B. Ho/	Date (Optional)	
Name	Brian Ho	Registration Number	60,199
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Christopher D. SOLI	Nonprovisional Application Number (if known):	Not Yet Assigned
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Brian B. Ho/	Date 2018-09-27
Name (Print/Typed) Brian Ho	Practitioner Registration Number 60199

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
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The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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Doc Code: PA..
Document Description: Power of Attorney

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 150004

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/62C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Apple Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	Aug. 2 2017
Name	BJ Watrous		
Title	Vice President & Chief IP Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

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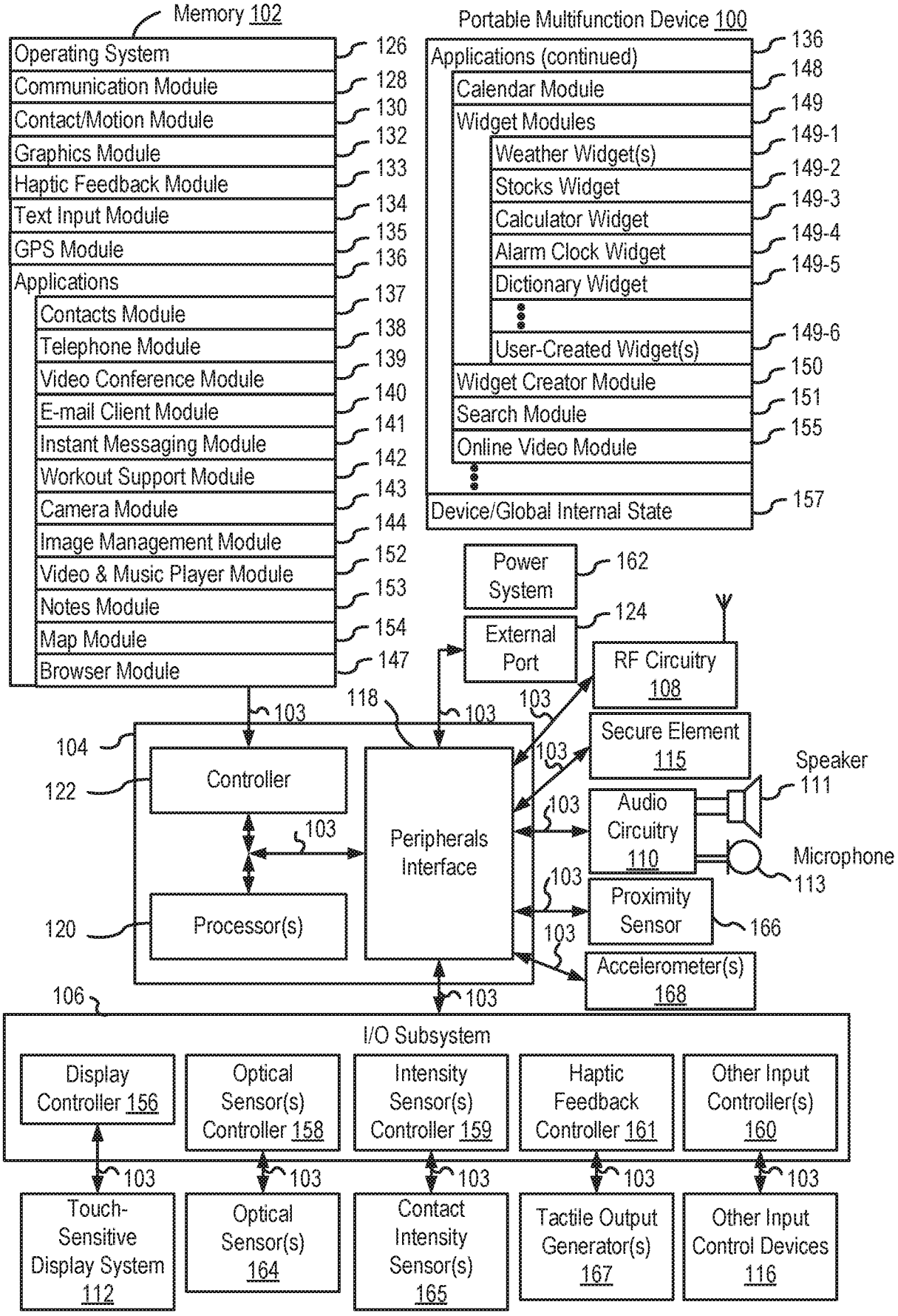

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Contact/Motion Module 130
Graphics Module 132
Haptic Feedback Module 133
Text Input Module 134
GPS Module 135
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E-mail Client Module 140
Instant Messaging Module 141
Workout Support Module 142
Camera Module 143
Image Management Module 144
Video & Music Player Module 152
Notes Module 153
Map Module 154
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Calculator Widget 149-3
Alarm Clock Widget 149-4
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Widget Creator Module 150
Search Module 151
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Power System 162
External Port 124
RF Circuitry 108
Secure Element 115
Speaker 111
Audio Circuitry 110
Microphone 113
Proximity Sensor 166
Accelerometer(s) 168
Controller 122
Peripherals Interface 118
Processor(s) 120
103
104
106
I/O Subsystem
Display Controller 156
Optical Sensor(s) Controller 158
Intensity Sensor(s) Controller 159
Haptic Feedback Controller 161
Other Input Controller(s) 160
Touch-Sensitive Display System 112
Optical Sensor(s) 164
Contact Intensity Sensor(s) 165
Tactile Output Generator(s) 167
Other Input Control Devices 116

FIG. 1A

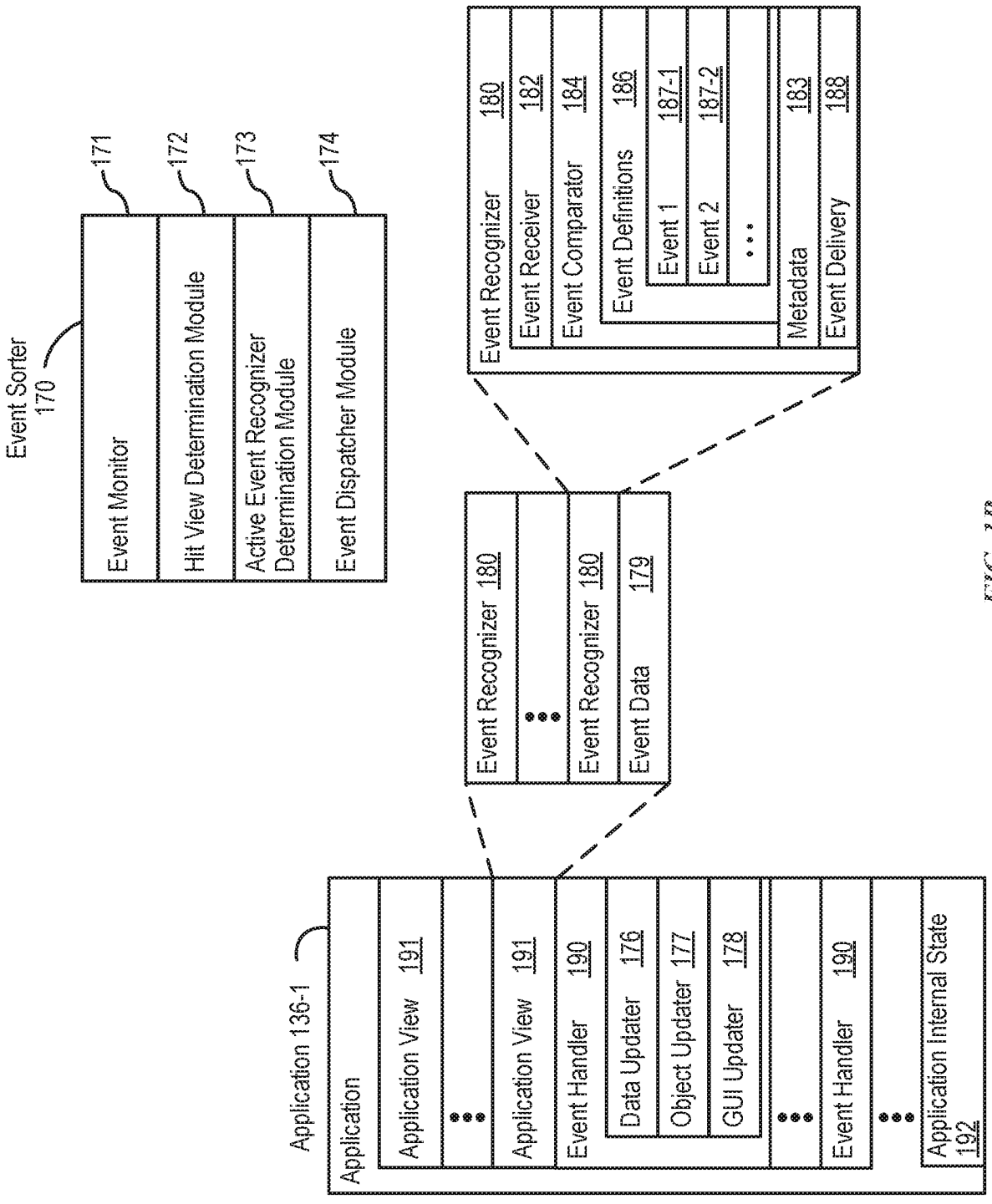

Event Sorter 170
Event Monitor
171
Hit View Determination Module
172
Active Event Recognizer Determination Module
173
Event Dispatcher Module
174
Event Recognizer 180
Event Receiver 182
Event Comparator 184
Event Definitions 186
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Event 2 187-2
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Metadata 183
Event Delivery 188
Event Recognizer 180
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Event Recognizer 180
Event Data 179
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Application View 191
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Application View 191
Event Handler 190
Data Updater 176
Object Updater 177
GUI Updater 178
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Event Handler 190
...
Application Internal State 192

FIG. 1B

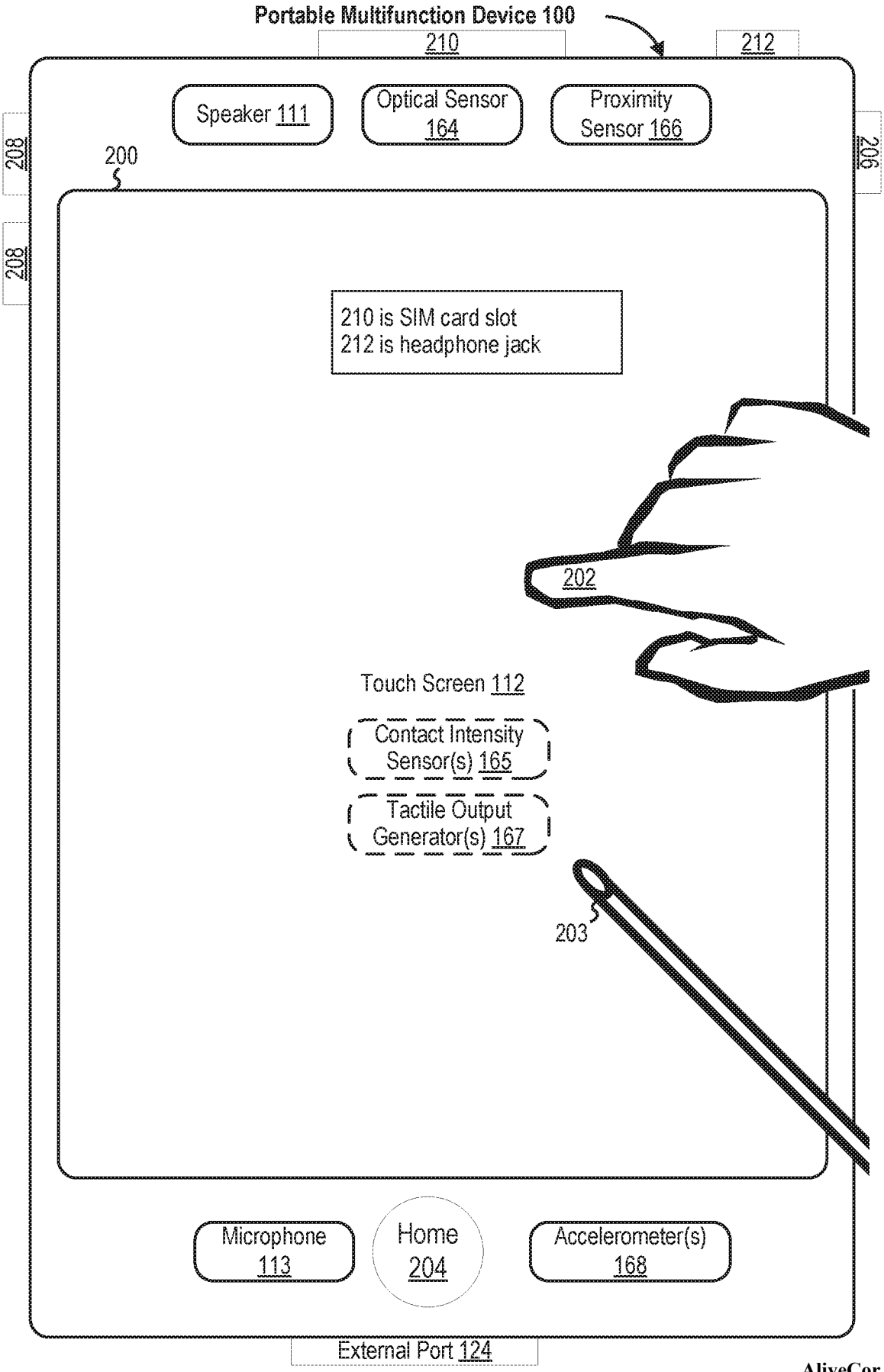

Portable Multifunction Device 100
210
212
Speaker 111
Optical Sensor 164
Proximity Sensor 166
208
208
206
200
210 is SIM card slot
212 is headphone jack
202
Touch Screen 112
Contact Intensity Sensor(s) 165
Tactile Output Generator(s) 167
203
Microphone 113
Home 204
Accelerometer(s) 168
External Port 124

FIG. 2

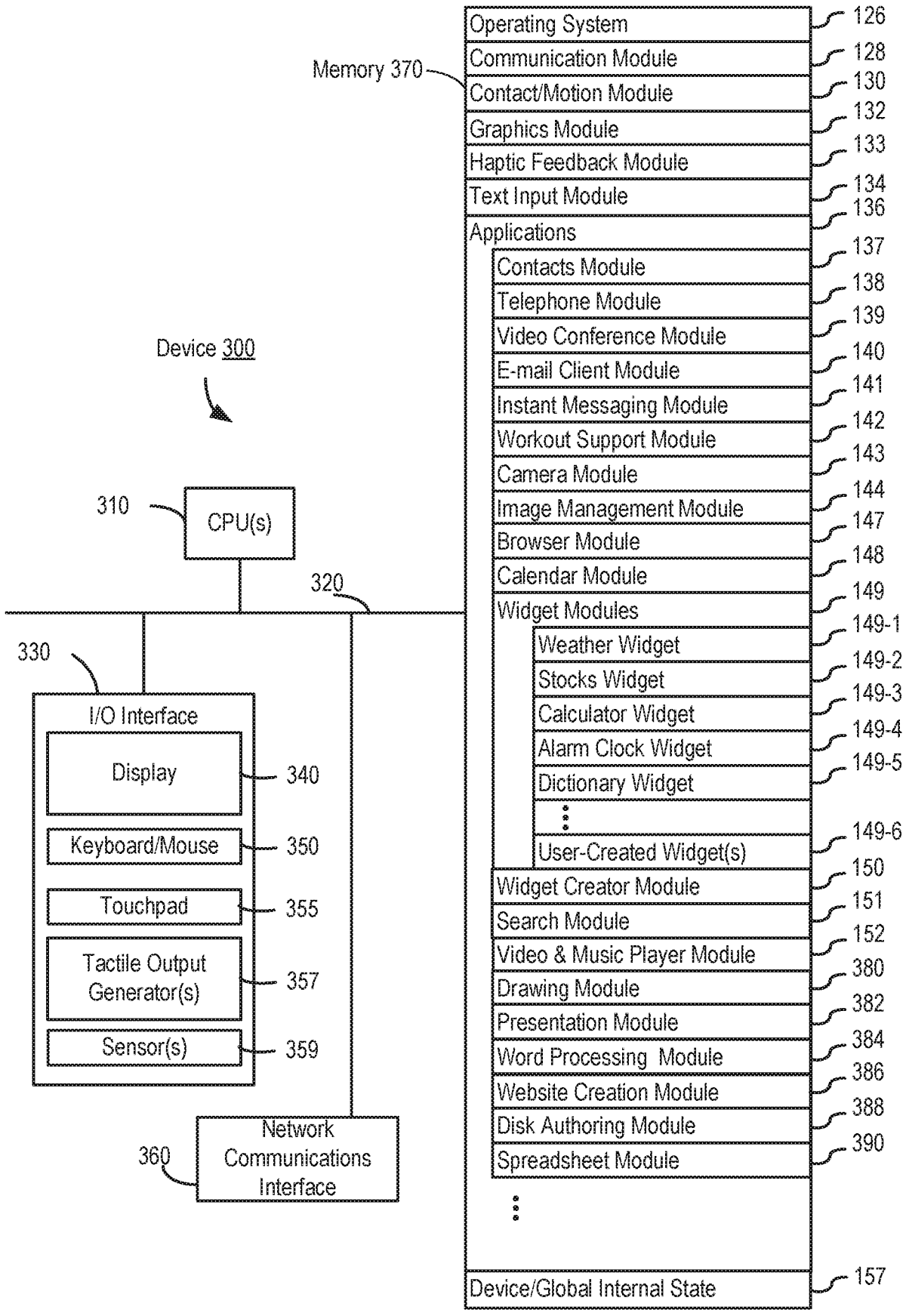
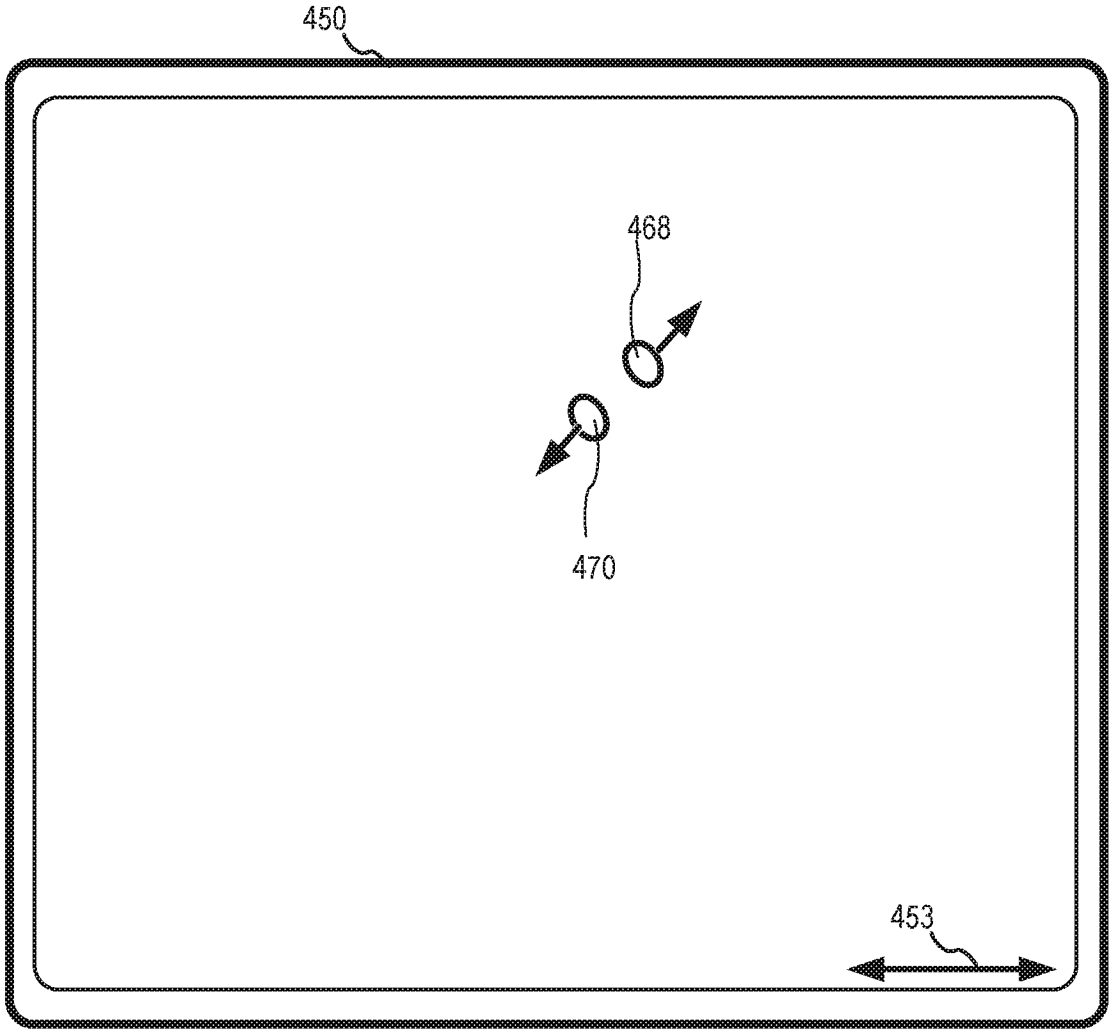

Device 300
310
CPU(s)
320
330
I/O Interface
Display
340
Keyboard/Mouse
350
Touchpad
355
Tactile Output Generator(s)
357
Sensor(s)
359
Network Communications Interface
360
Memory 370
Operating System
126
Communication Module
128
Contact/Motion Module
130
Graphics Module
132
Haptic Feedback Module
133
Text Input Module
134
Applications
136
Contacts Module
137
Telephone Module
138
Video Conference Module
139
E-mail Client Module
140
Instant Messaging Module
141
Workout Support Module
142
Camera Module
143
Image Management Module
144
Browser Module
147
Calendar Module
148
Widget Modules
149
Weather Widget
149-1
Stocks Widget
149-2
Calculator Widget
149-3
Alarm Clock Widget
149-4
Dictionary Widget
149-5
User-Created Widget(s)
149-6
Widget Creator Module
150
Search Module
151
Video & Music Player Module
152
Drawing Module
380
Presentation Module
382
Word Processing Module
384
Website Creation Module
386
Disk Authoring Module
388
Spreadsheet Module
390
Device/Global Internal State
157

FIG. 3


Portable Multifunction Device
100
Speaker 111
Optical Sensor 164
Proximity Sensor 166
400
208
208
206
405
402
Current Time 404
406
Messages 424
Tuesday
30
Calendar 426
Photos 428
Camera 430
Online Video 432
Stocks 434
280
01
Maps 436
73°
Weather 438
Clock 440
Workout Support 442
Notes 444
Settings 446
App Store
iTunes
Voice Memos
Utilities
414
410
4
6
N
W
E
S
Phone 416
Mail 418
Browser 420
iPod 422
408
Touch Screen 112
Microphone 113
Accelerometer(s) 168
204

FIG. 4A


450
468
470
453

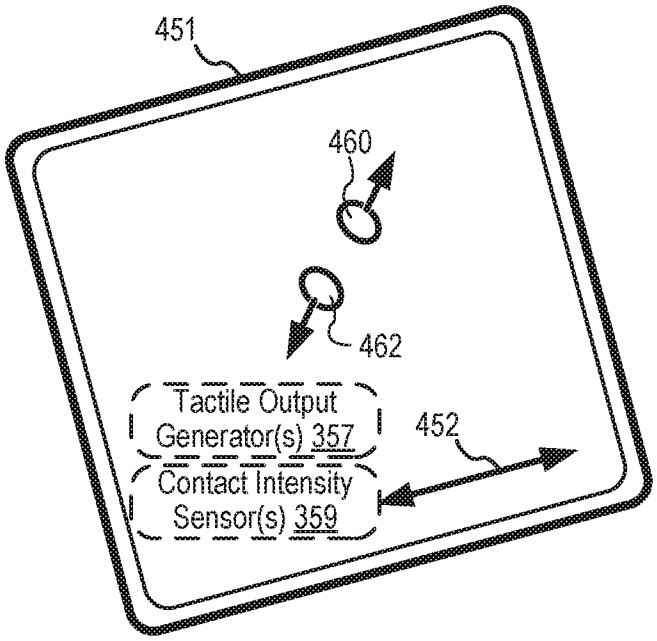

451
460
462
Tactile Output Generator(s) 357
Contact Intensity Sensor(s) 359
452

FIG. 4B

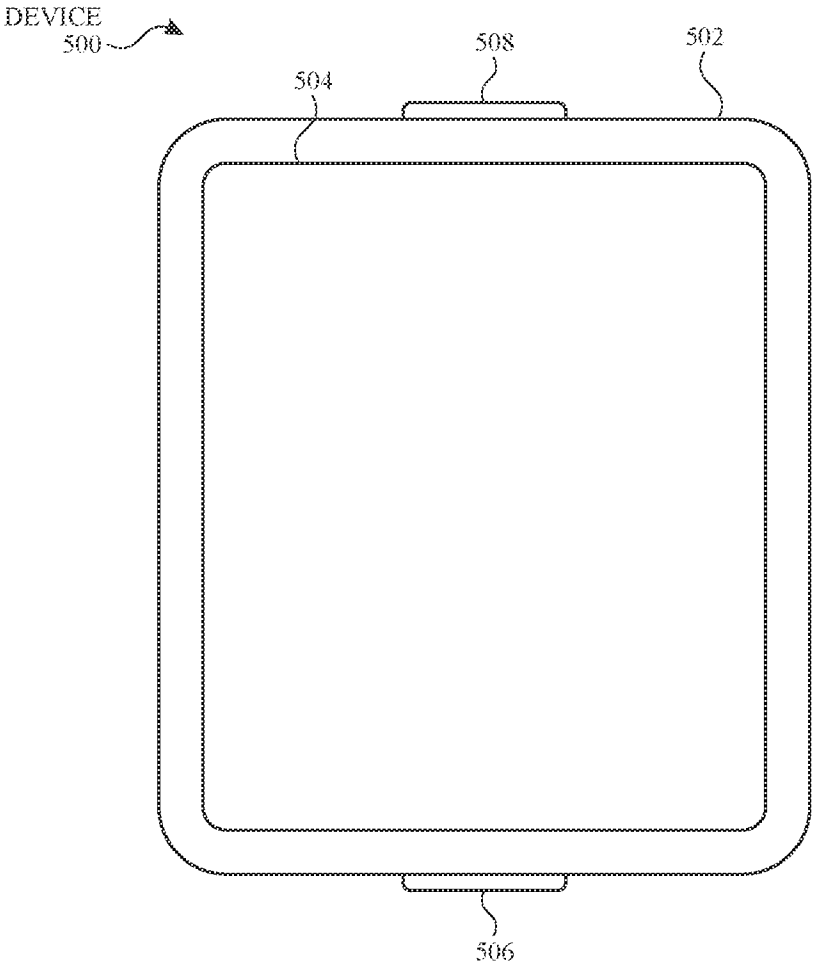


FIG. 5A

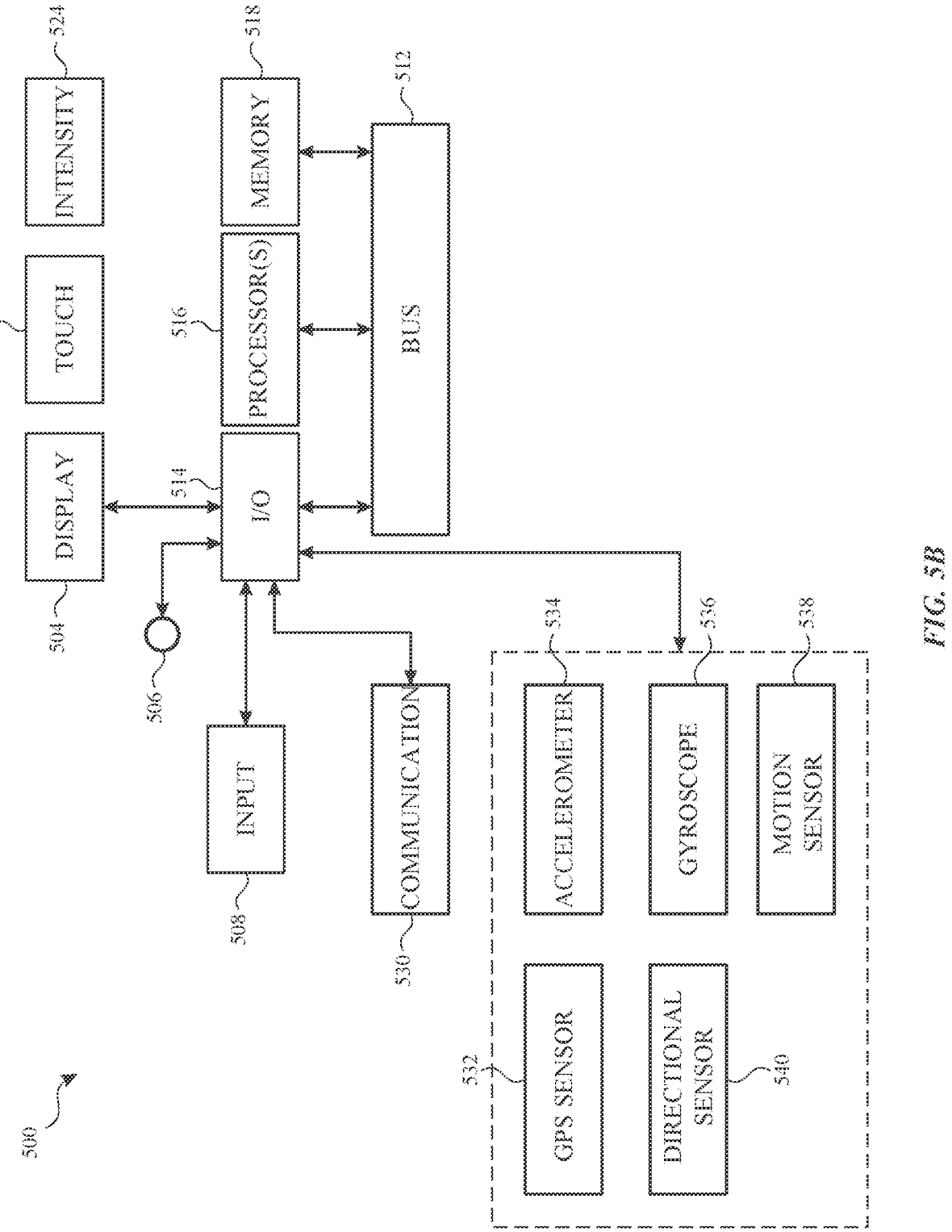

500
504
DISPLAY
522
TOUCH
524
INTENSITY
514
I/O
516
PROCESSOR(S)
518
MEMORY
512
BUS
506
508
INPUT
530
COMMUNICATION
532
GPS SENSOR
534
ACCELEROMETER
536
GYROSCOPE
538
MOTION SENSOR
540
DIRECTIONAL SENSOR

FIG. 5B

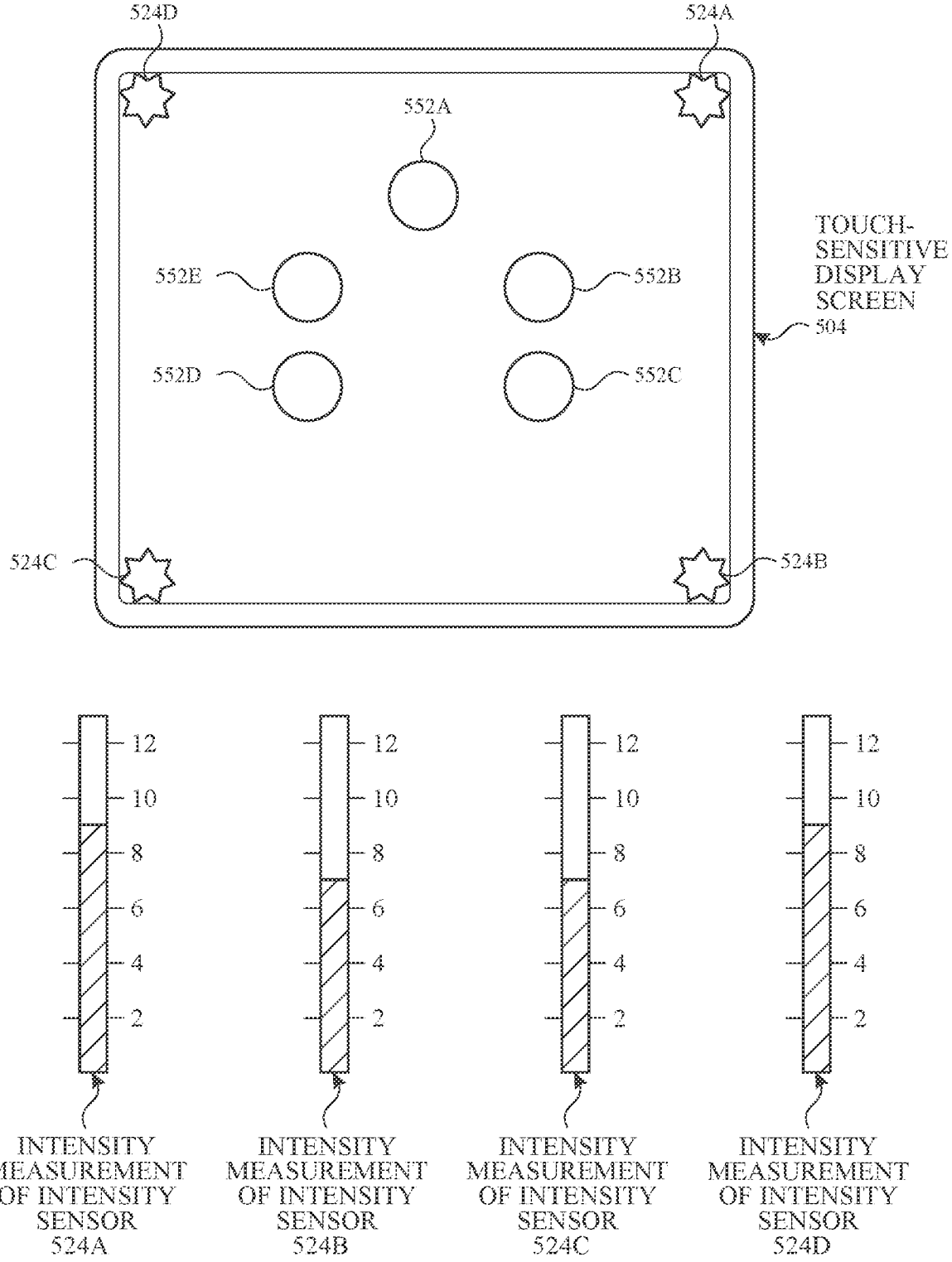

524D
524A
552A
552E
552B
552D
552C
TOUCH-SENSITIVE DISPLAY SCREEN
504
524C
524B
12
10
8
6
4
2
INTENSITY MEASUREMENT OF INTENSITY SENSOR 524A
INTENSITY MEASUREMENT OF INTENSITY SENSOR 524B
INTENSITY MEASUREMENT OF INTENSITY SENSOR 524C
INTENSITY MEASUREMENT OF INTENSITY SENSOR 524D

FIG. 5C

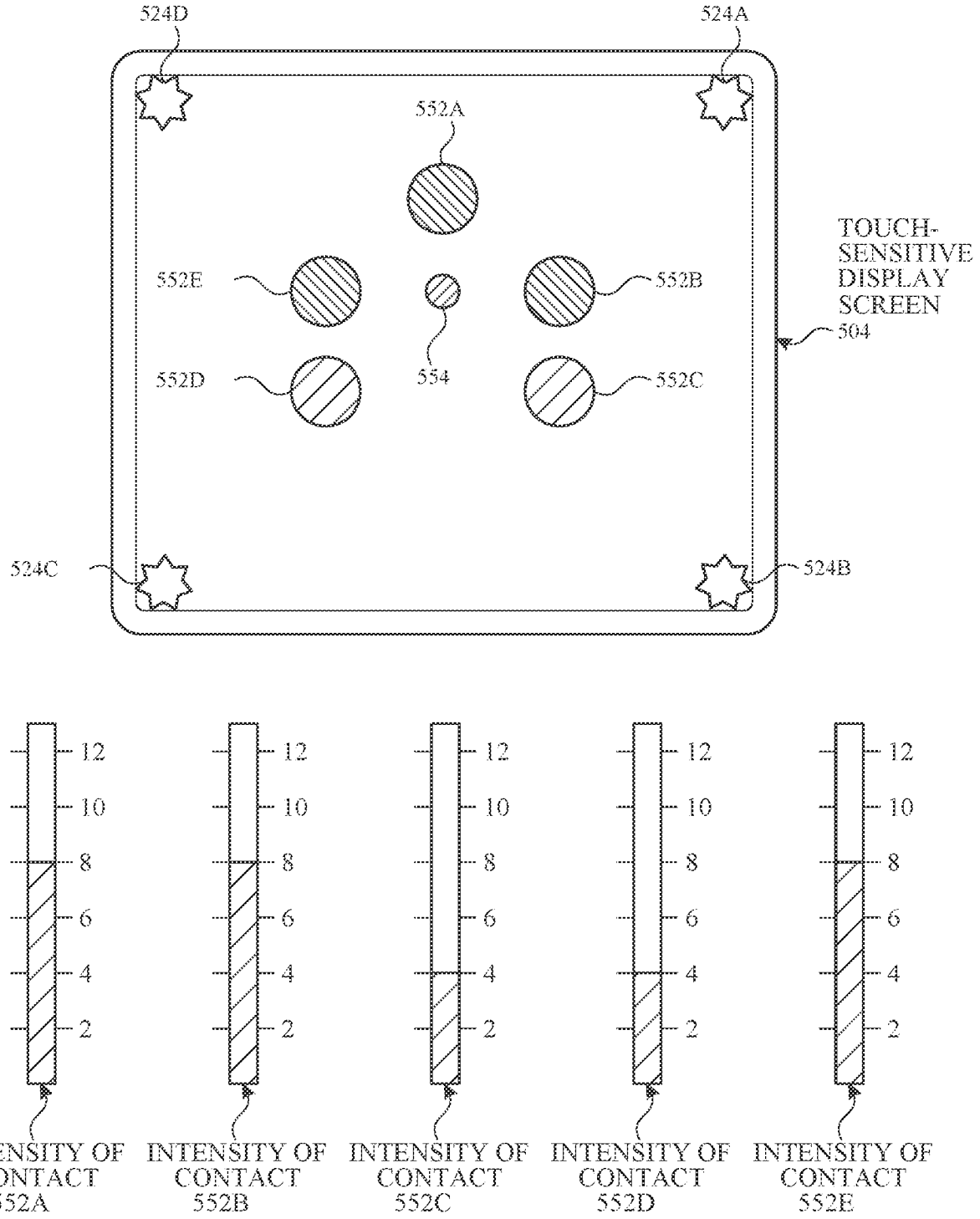

524D
524A
552A
552E
552B
554
552D
552C
TOUCH-SENSITIVE DISPLAY SCREEN
504
524C
524B
12
10
8
6
4
2
INTENSITY OF CONTACT 552A
INTENSITY OF CONTACT 552B
INTENSITY OF CONTACT 552C
INTENSITY OF CONTACT 552D
INTENSITY OF CONTACT 552E

FIG. 5D

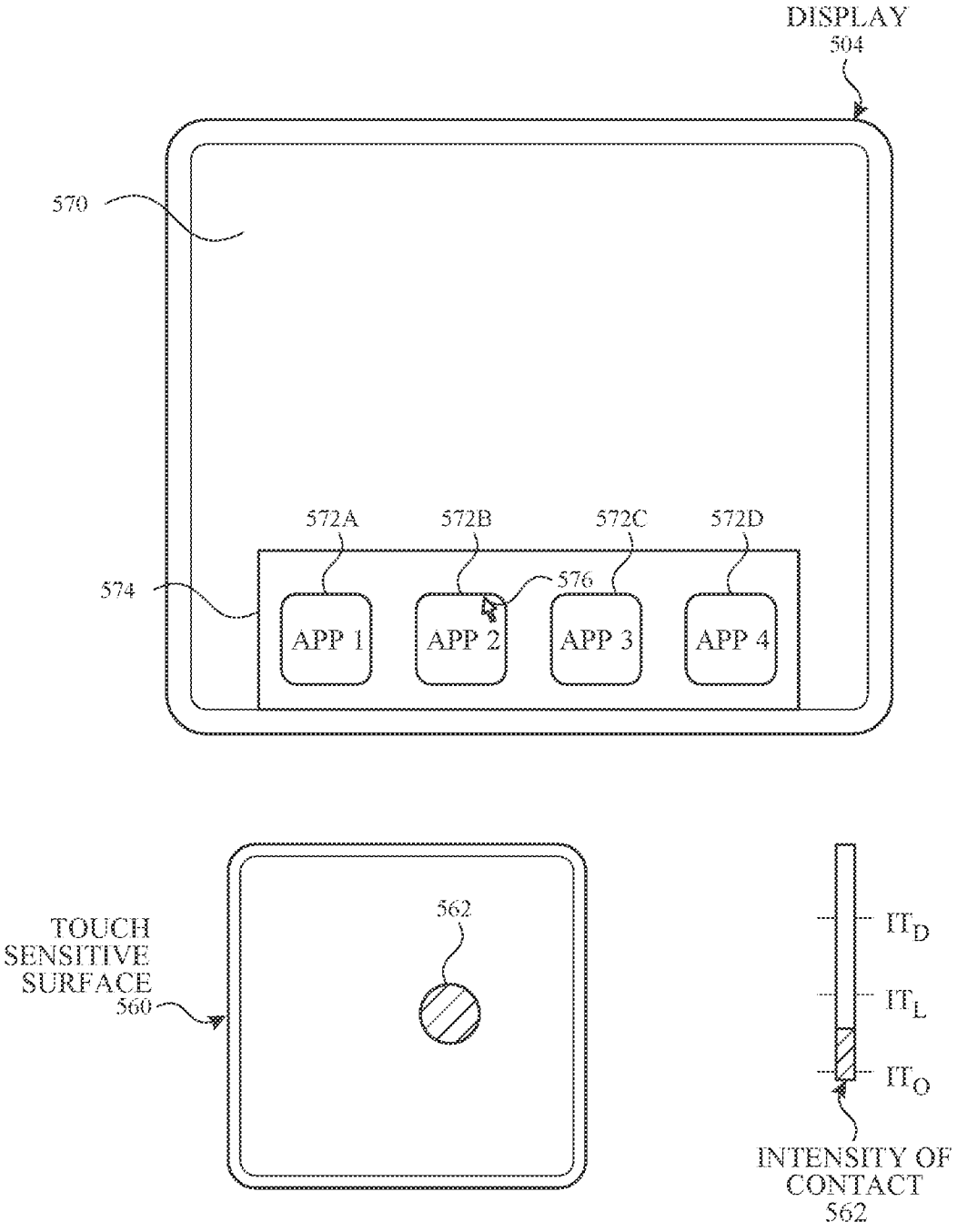

DISPLAY
504
570
572A
572B
572C
572D
574
576
APP 1
APP 2
APP 3
APP 4
TOUCH
SENSITIVE
SURFACE
560
562
IT_D
IT_L
IT_O
INTENSITY OF
CONTACT
562

FIG. 5E

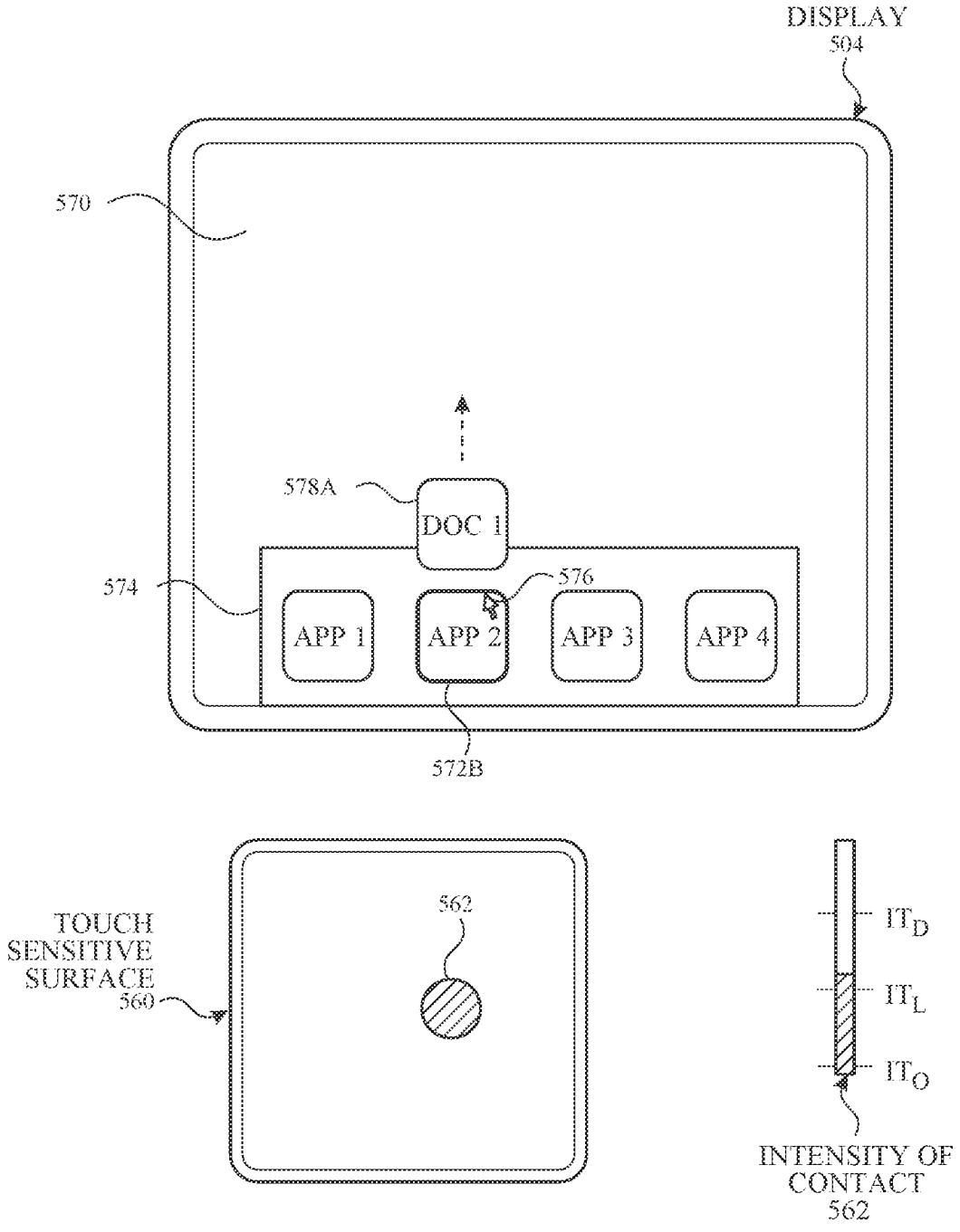

DISPLAY
504
570
578A
DOC 1
574
576
APP 1
APP 2
APP 3
APP 4
572B
TOUCH
SENSITIVE
SURFACE
560
562
IT_D
IT_L
IT_O
INTENSITY OF
CONTACT
562

FIG. 5F

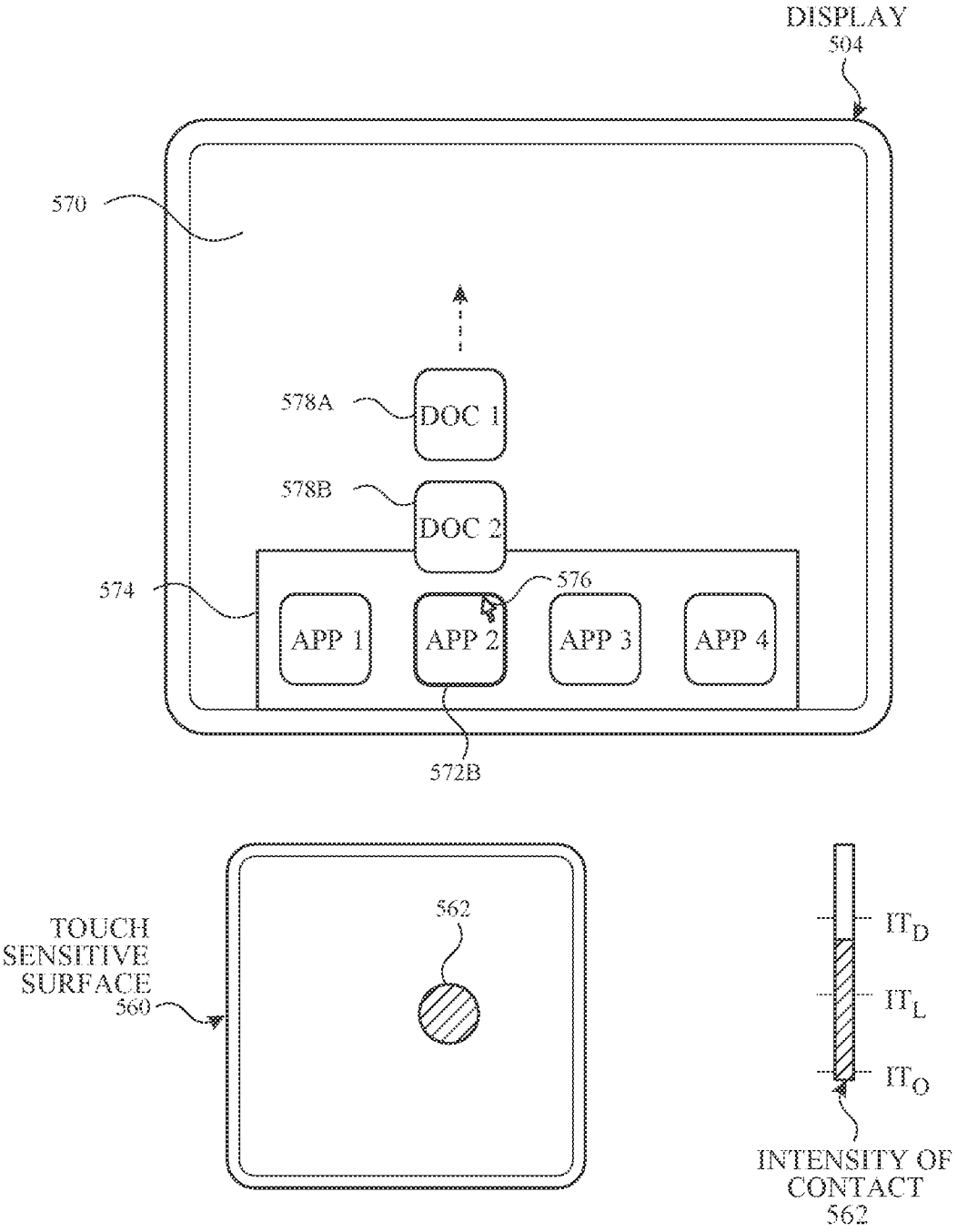

DISPLAY
504
570
578A
DOC 1
578B
DOC 2
574
576
APP 1
APP 2
APP 3
APP 4
572B
TOUCH
SENSITIVE
SURFACE
560
562
IT_D
IT_L
IT_O
INTENSITY OF
CONTACT
562

FIG. 5G

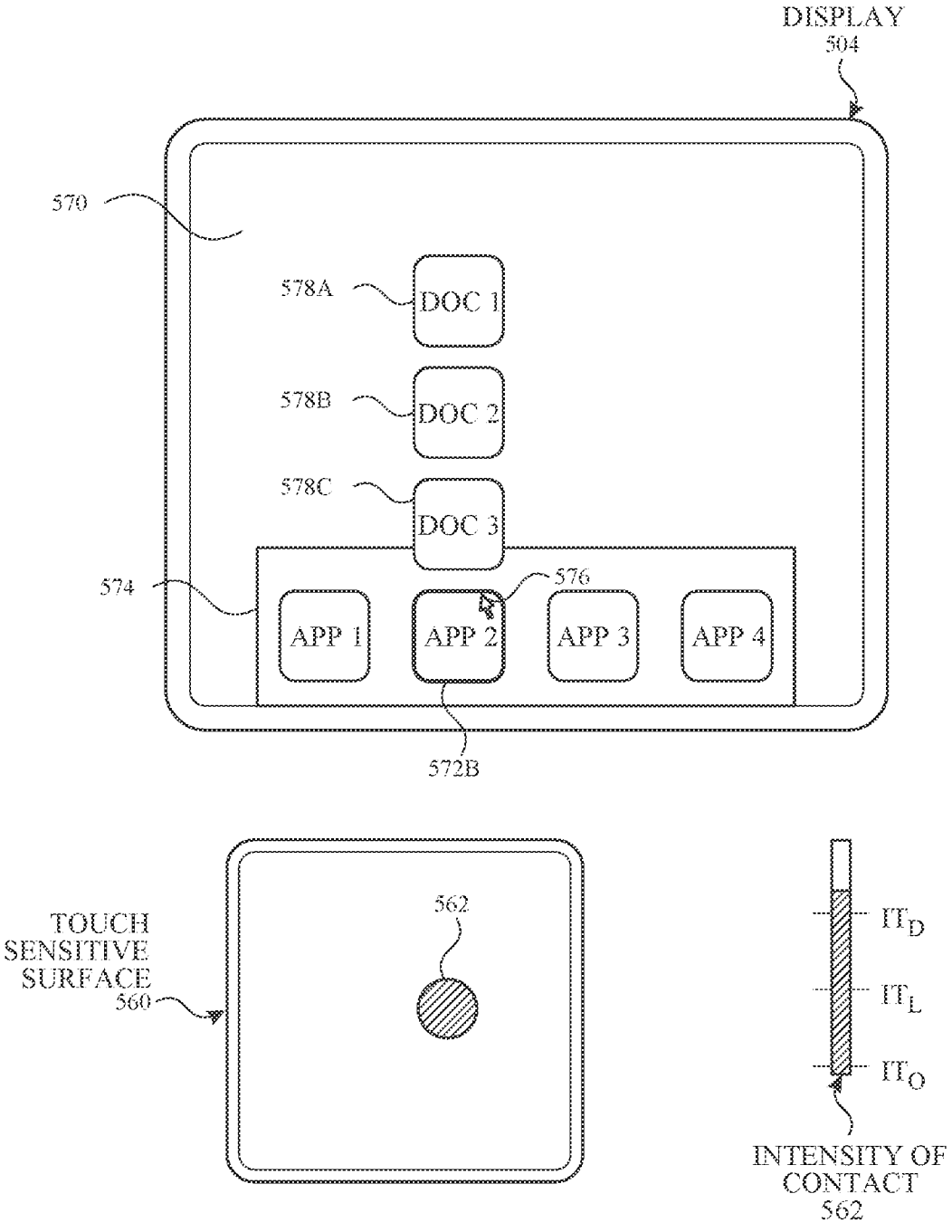

DISPLAY
504
570
578A
DOC 1
578B
DOC 2
578C
DOC 3
574
576
APP 1
APP 2
APP 3
APP 4
572B
TOUCH
SENSITIVE
SURFACE
560
562
IT_D
IT_L
IT_O
INTENSITY OF
CONTACT
562

FIG. 5H

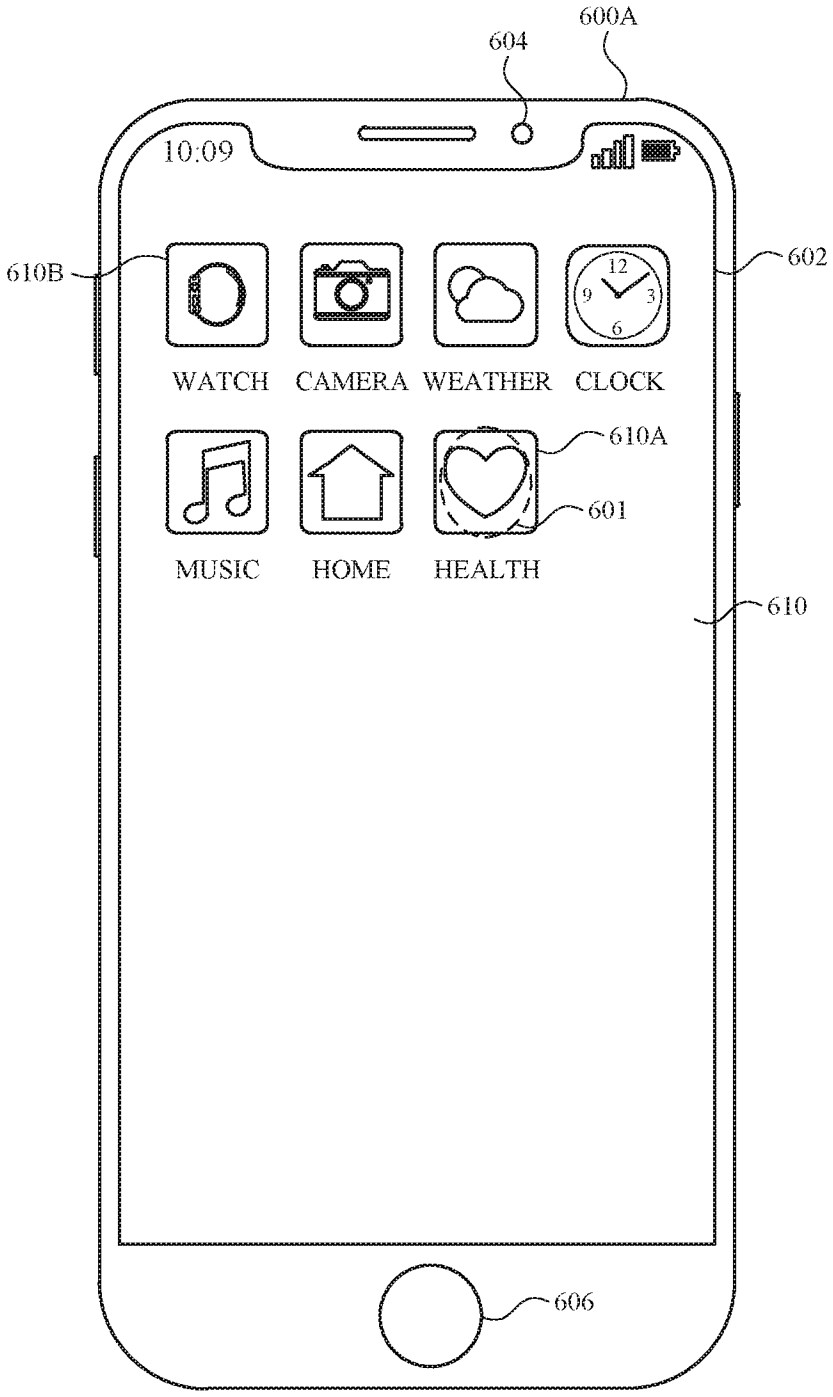

600A
604
10:09
610B
602
WATCH
CAMERA
WEATHER
CLOCK
610A
601
MUSIC
HOME
HEALTH
610
606

FIG. 6A

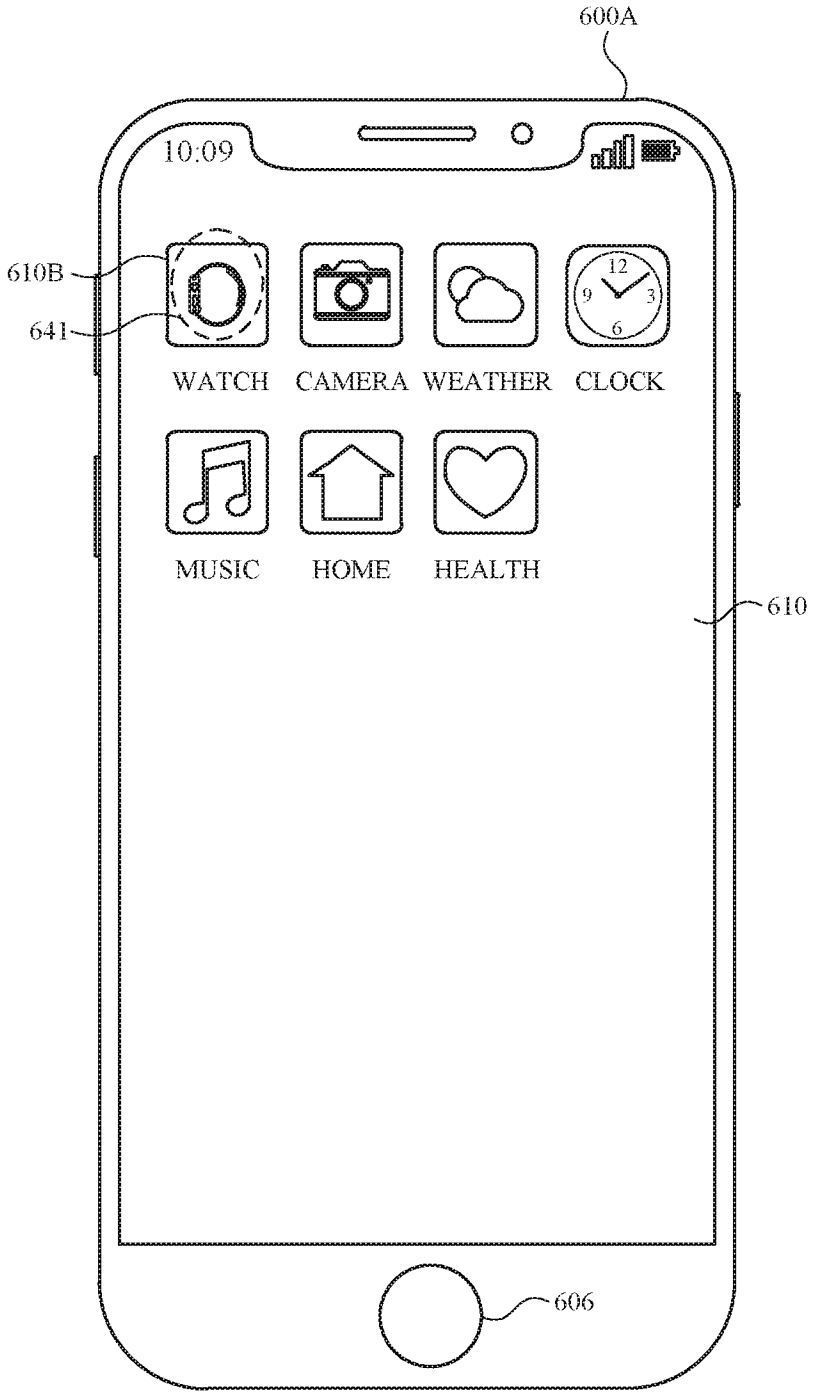

600A
10:09
610B
641
WATCH
CAMERA
WEATHER
CLOCK
MUSIC
HOME
HEALTH
610
606

FIG. 6B

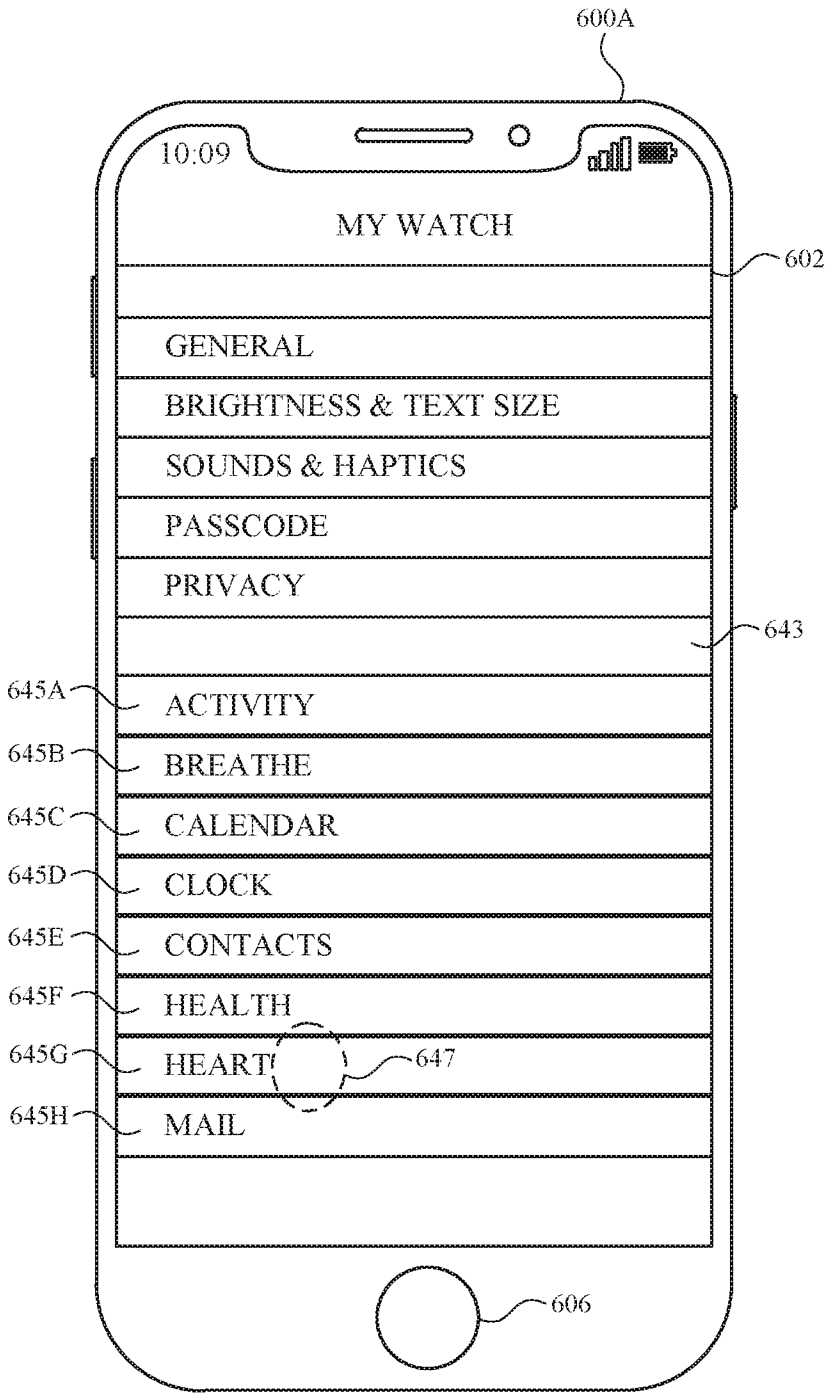

600A
10:09
MY WATCH
602
GENERAL
BRIGHTNESS & TEXT SIZE
SOUNDS & HAPTICS
PASSCODE
PRIVACY
643
645A
ACTIVITY
645B
BREATHE
645C
CALENDAR
645D
CLOCK
645E
CONTACTS
645F
HEALTH
645G
HEART
647
645H
MAIL
606

FIG. 6C

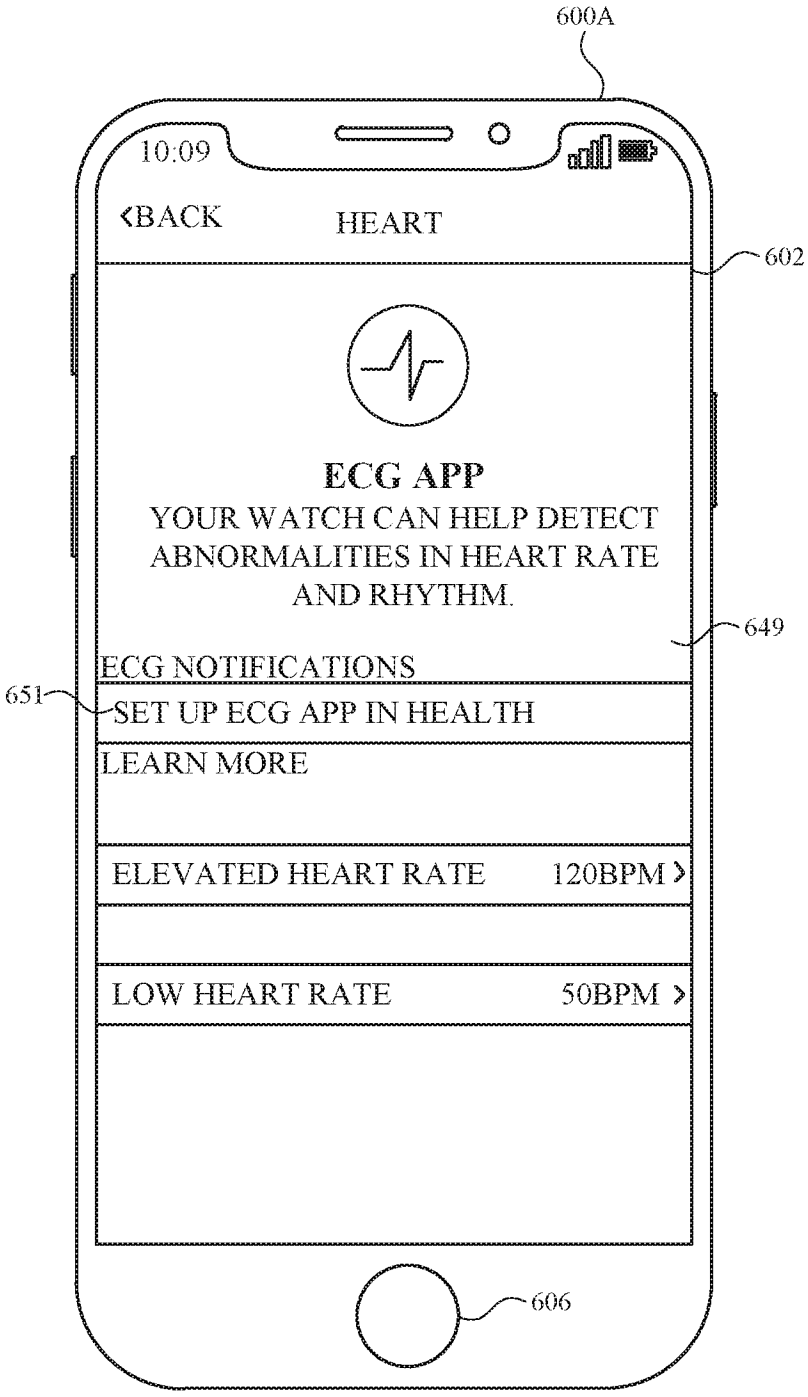

600A
10:09
<BACK
HEART
602
ECG APP
YOUR WATCH CAN HELP DETECT ABNORMALITIES IN HEART RATE AND RHYTHM.
649
ECG NOTIFICATIONS
651
SET UP ECG APP IN HEALTH
LEARN MORE
ELEVATED HEART RATE 120BPM >
LOW HEART RATE 50BPM >
606

FIG. 6D

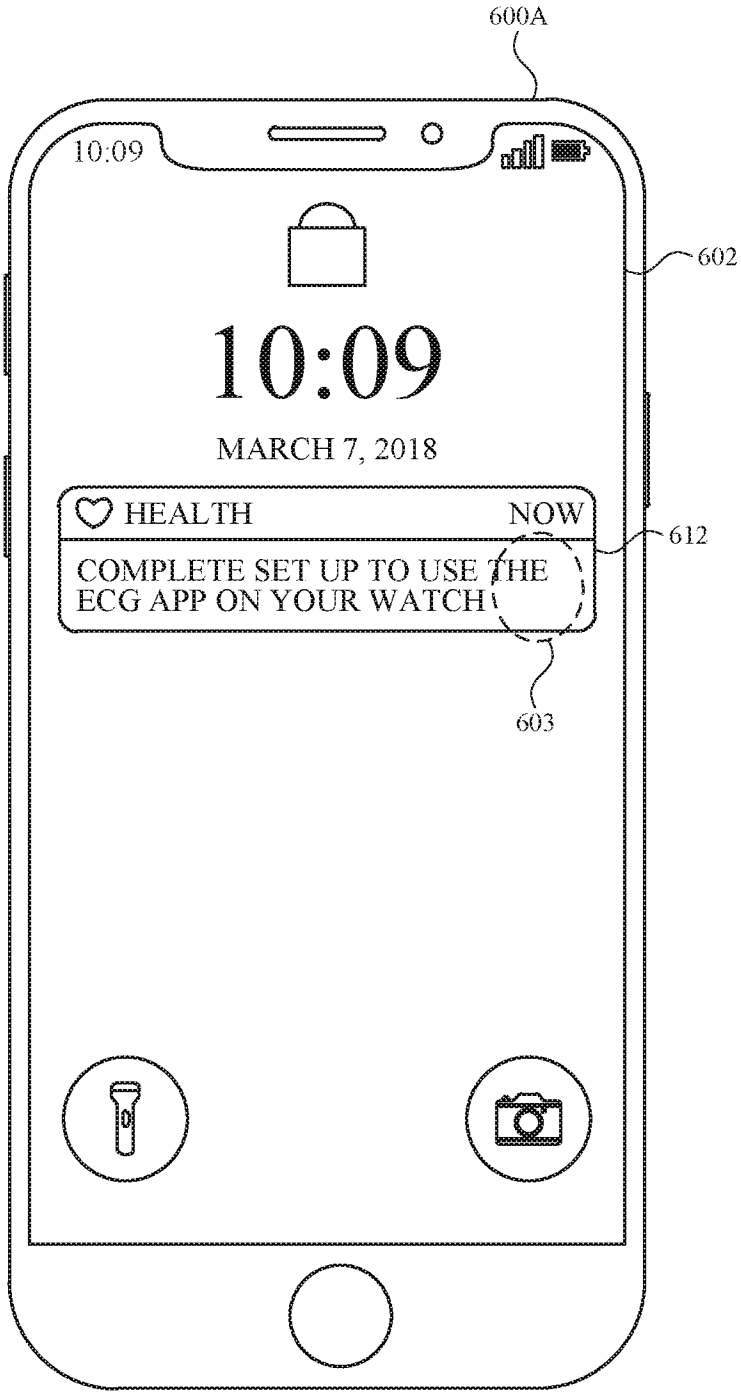

600A
10:09
602
10:09
MARCH 7, 2018
HEALTH
NOW
612
COMPLETE SET UP TO USE THE ECG APP ON YOUR WATCH
603

FIG. 6E

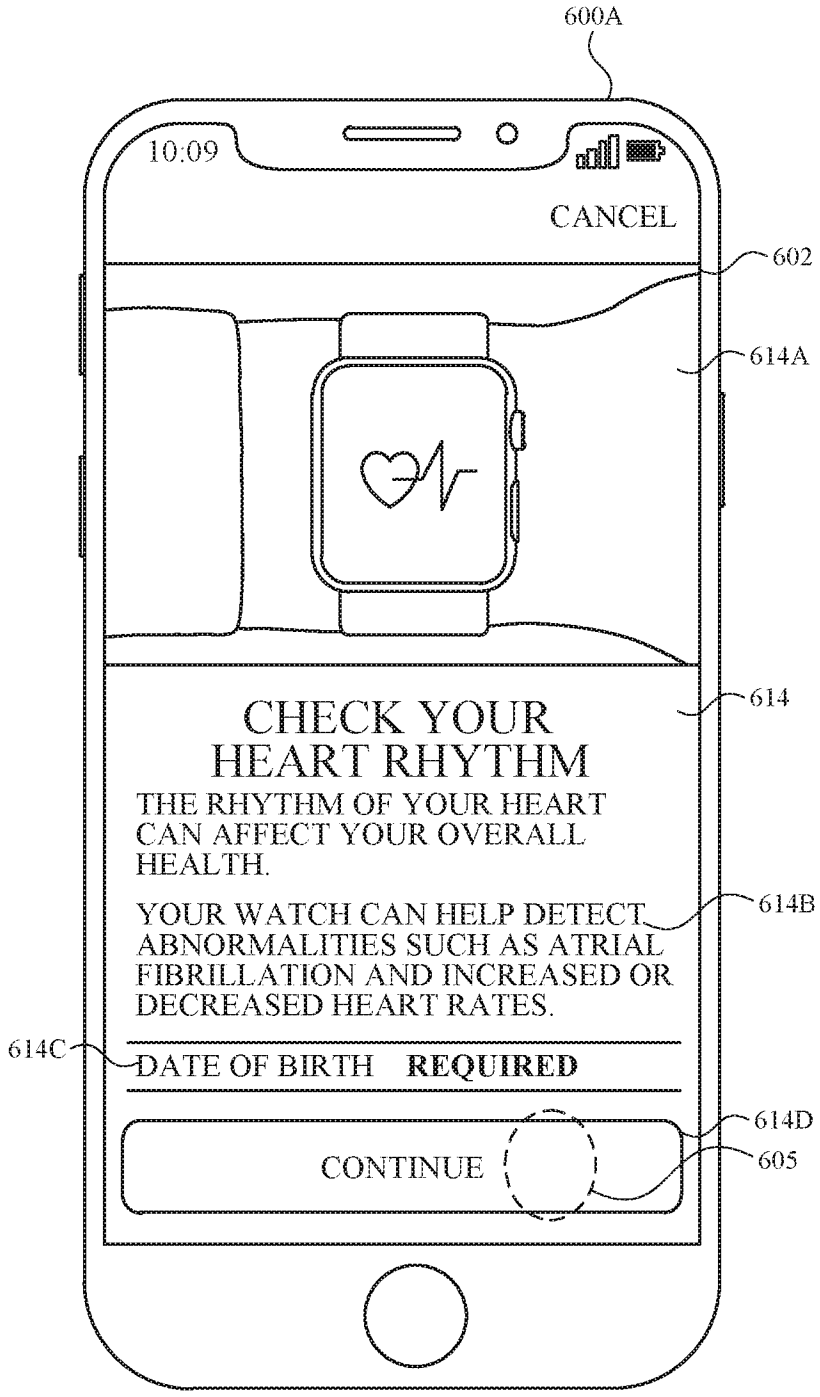

600A
10:09
CANCEL
602
614A
614
CHECK YOUR HEART RHYTHM
THE RHYTHM OF YOUR HEART CAN AFFECT YOUR OVERALL HEALTH.
YOUR WATCH CAN HELP DETECT ABNORMALITIES SUCH AS ATRIAL FIBRILLATION AND INCREASED OR DECREASED HEART RATES.
614B
614C
DATE OF BIRTH REQUIRED
614D
CONTINUE
605

FIG. 6F

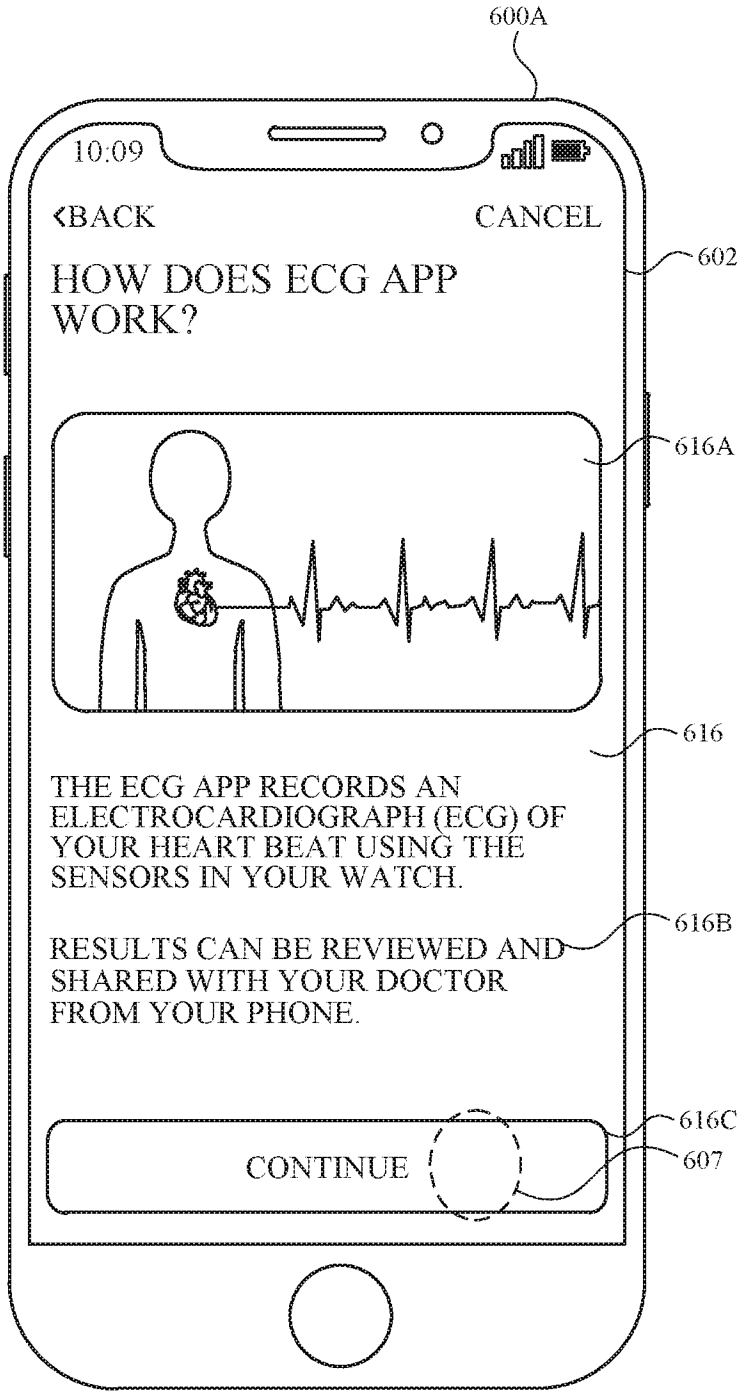

600A
10:09
‹BACK
CANCEL
602
HOW DOES ECG APP WORK?
616A
616
THE ECG APP RECORDS AN ELECTROCARDIOGRAPH (ECG) OF YOUR HEART BEAT USING THE SENSORS IN YOUR WATCH.
616B
RESULTS CAN BE REVIEWED AND SHARED WITH YOUR DOCTOR FROM YOUR PHONE.
616C
CONTINUE
607

FIG. 6G

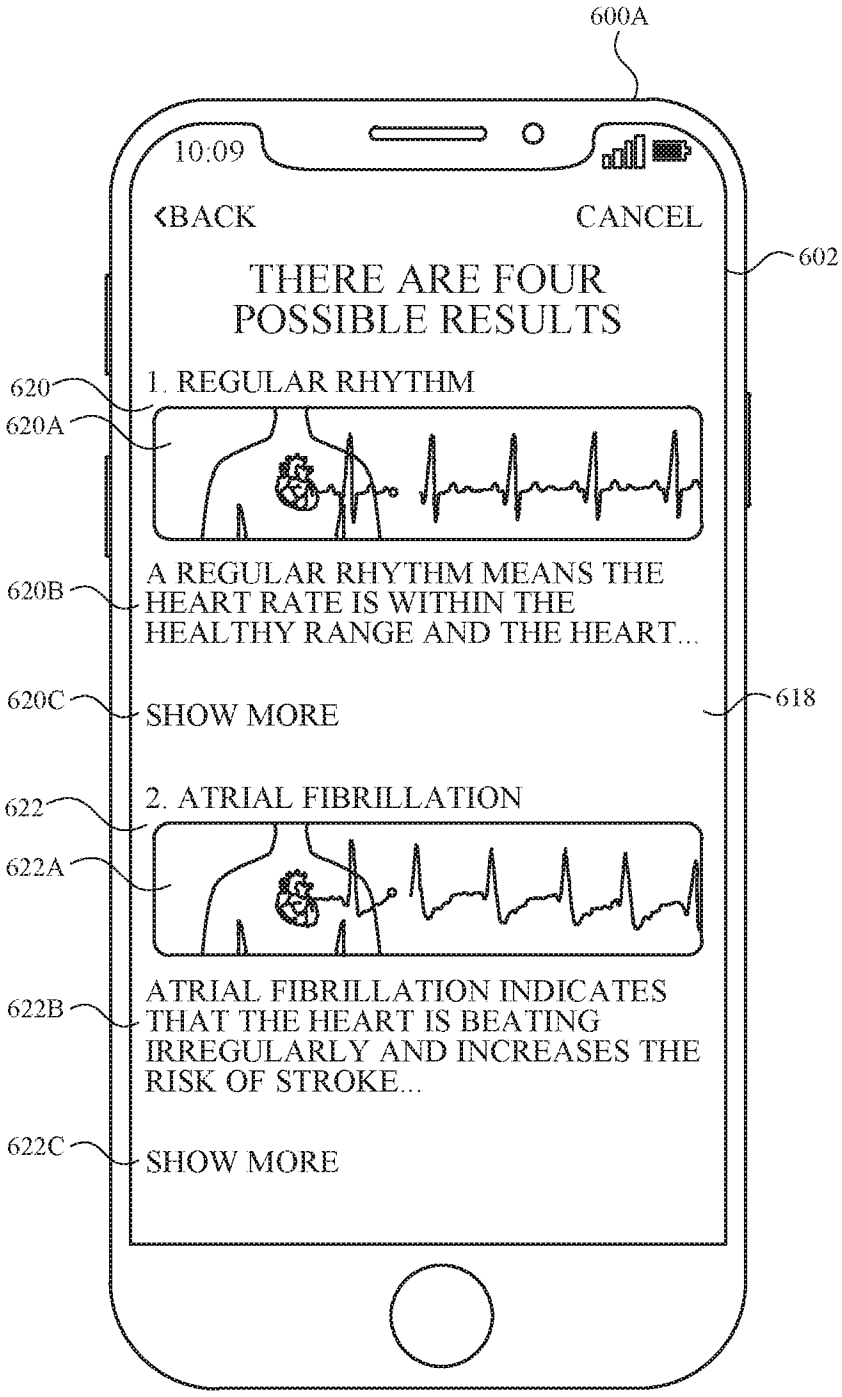

600A
10:09
‹BACK
CANCEL
602
THERE ARE FOUR POSSIBLE RESULTS
620
1. REGULAR RHYTHM
620A
620B
A REGULAR RHYTHM MEANS THE HEART RATE IS WITHIN THE HEALTHY RANGE AND THE HEART...
620C
SHOW MORE
618
622
2. ATRIAL FIBRILLATION
622A
622B
ATRIAL FIBRILLATION INDICATES THAT THE HEART IS BEATING IRREGULARLY AND INCREASES THE RISK OF STROKE...
622C
SHOW MORE

FIG. 6H

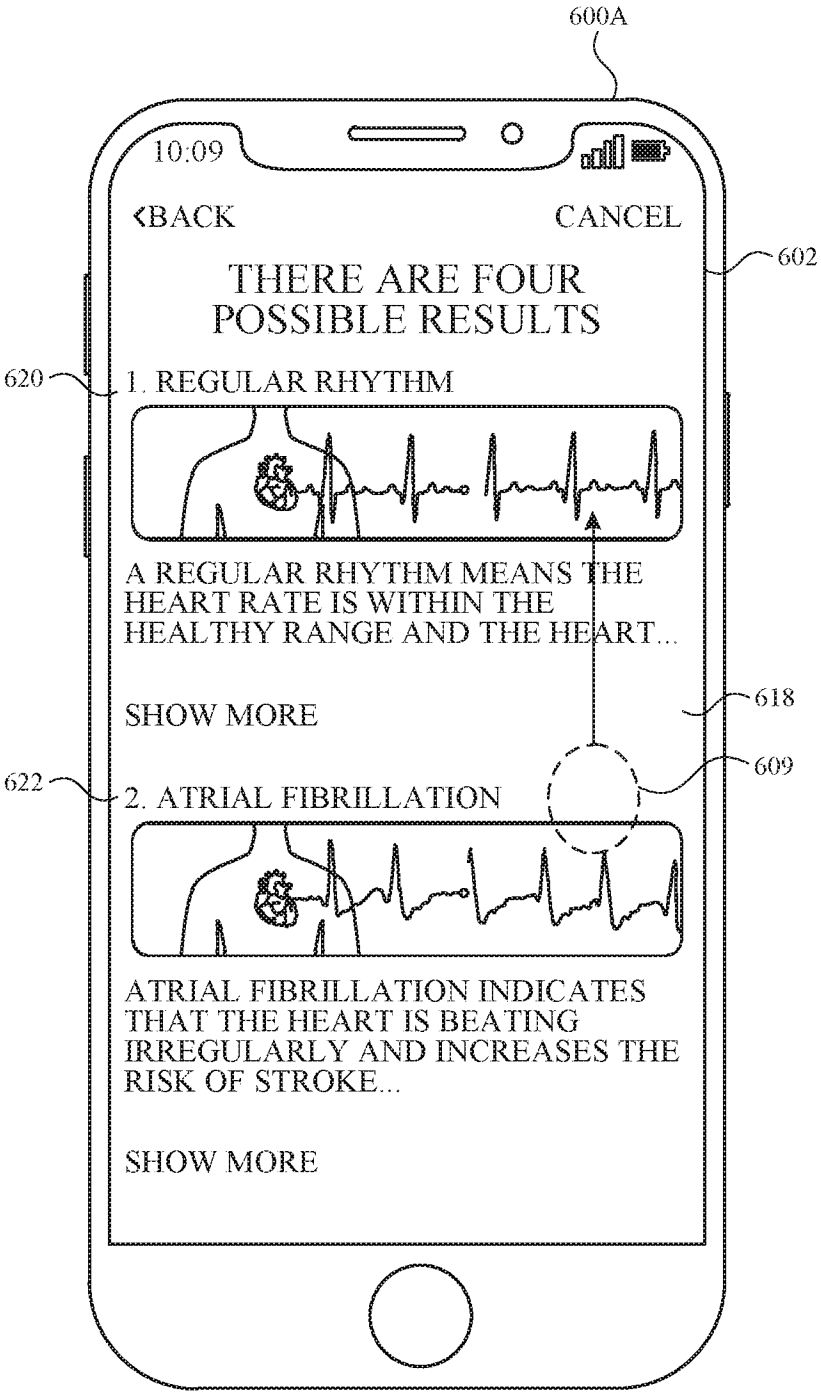

600A
10:09
‹BACK
CANCEL
602
THERE ARE FOUR POSSIBLE RESULTS
620
1. REGULAR RHYTHM
A REGULAR RHYTHM MEANS THE HEART RATE IS WITHIN THE HEALTHY RANGE AND THE HEART...
SHOW MORE
618
609
622
2. ATRIAL FIBRILLATION
ATRIAL FIBRILLATION INDICATES THAT THE HEART IS BEATING IRREGULARLY AND INCREASES THE RISK OF STROKE...
SHOW MORE

FIG. 6I

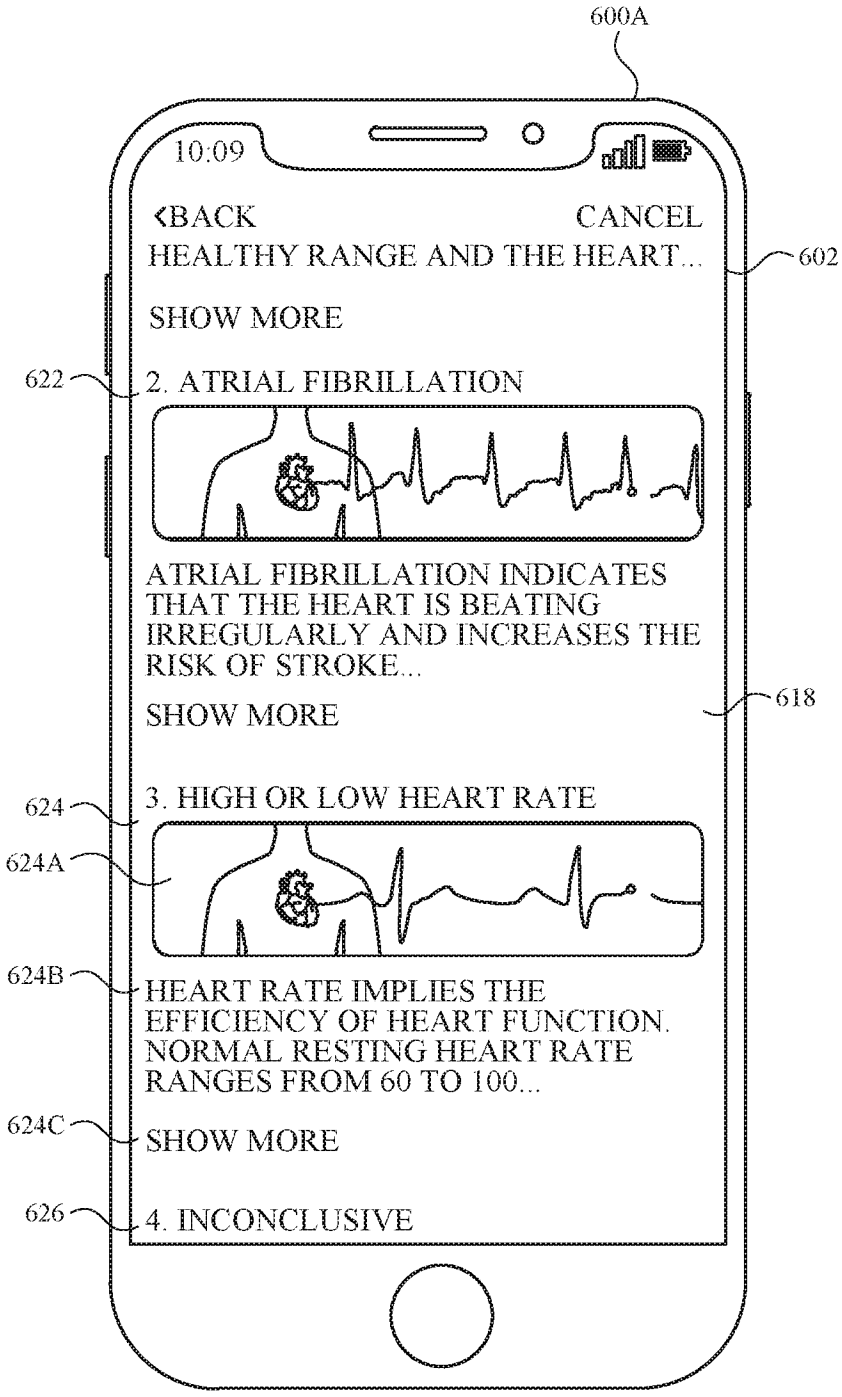

600A
10:09
‹BACK
CANCEL
HEALTHY RANGE AND THE HEART...
602
SHOW MORE
622
2. ATRIAL FIBRILLATION
ATRIAL FIBRILLATION INDICATES THAT THE HEART IS BEATING IRREGULARLY AND INCREASES THE RISK OF STROKE...
SHOW MORE
618
624
3. HIGH OR LOW HEART RATE
624A
624B
HEART RATE IMPLIES THE EFFICIENCY OF HEART FUNCTION. NORMAL RESTING HEART RATE RANGES FROM 60 TO 100...
624C
SHOW MORE
626
4. INCONCLUSIVE

FIG. 6J

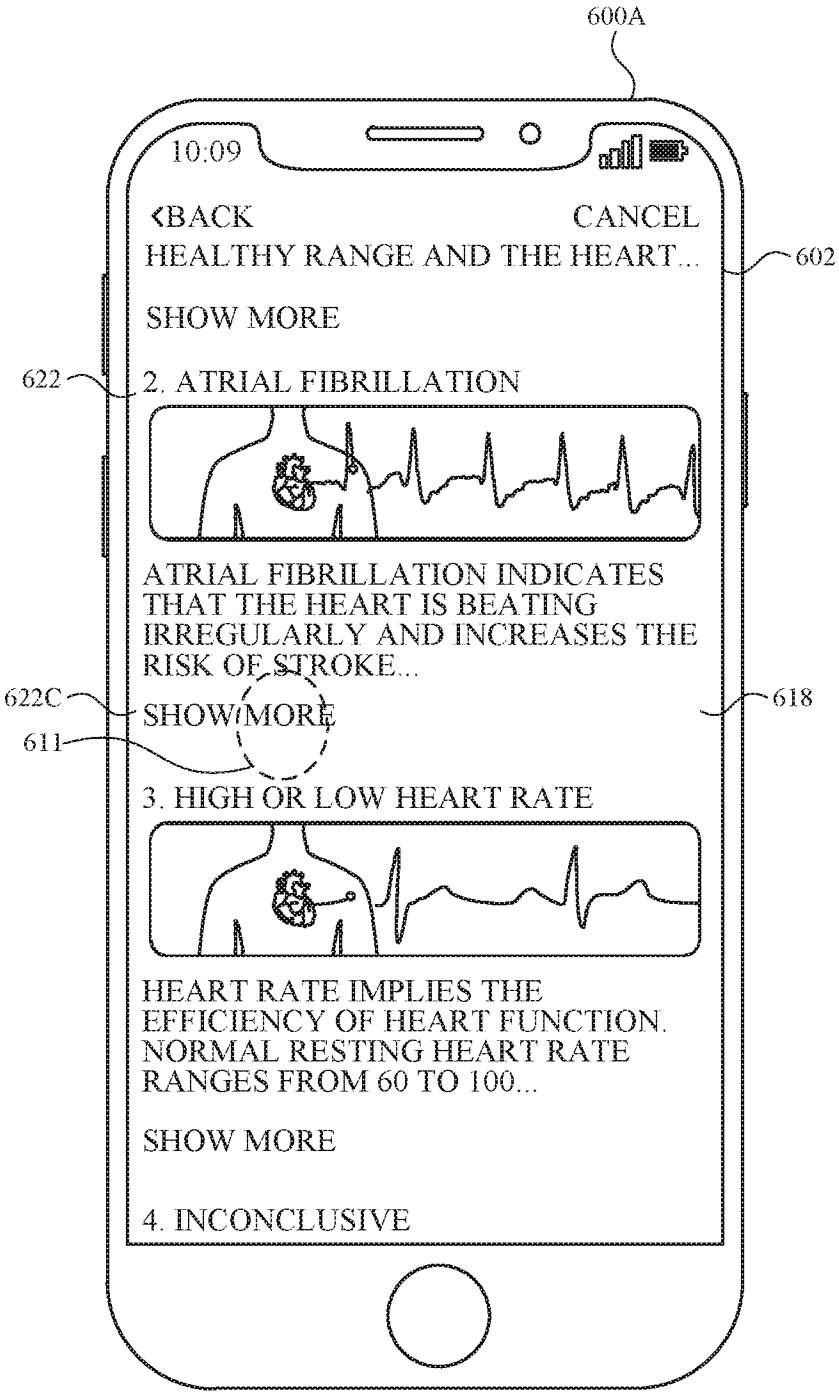

600A
10:09
‹BACK
CANCEL
HEALTHY RANGE AND THE HEART...
602
SHOW MORE
622
2. ATRIAL FIBRILLATION
ATRIAL FIBRILLATION INDICATES THAT THE HEART IS BEATING IRREGULARLY AND INCREASES THE RISK OF STROKE...
622C
SHOW MORE
618
611
3. HIGH OR LOW HEART RATE
HEART RATE IMPLIES THE EFFICIENCY OF HEART FUNCTION. NORMAL RESTING HEART RATE RANGES FROM 60 TO 100...
SHOW MORE
4. INCONCLUSIVE

FIG. 6K

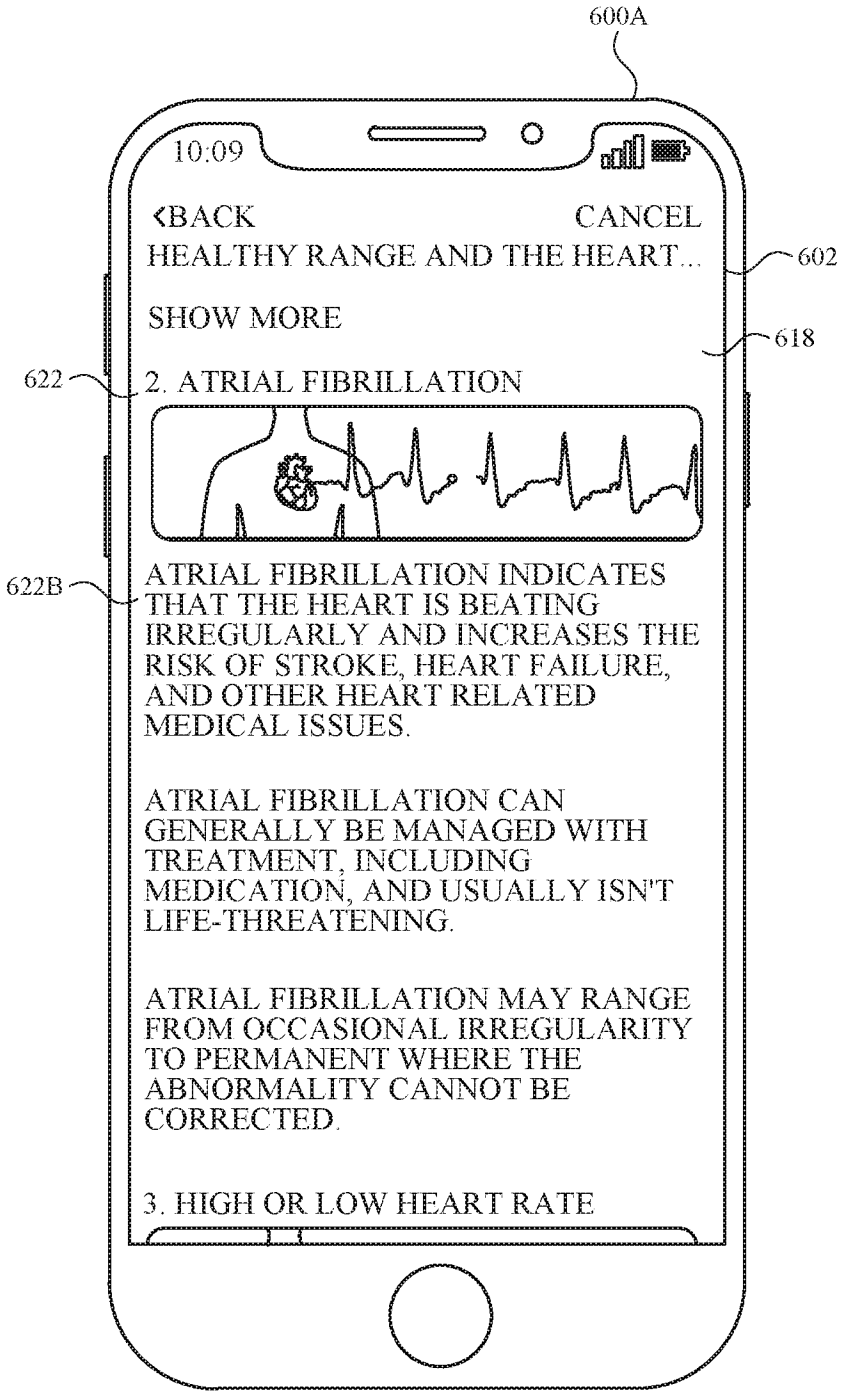

600A
10:09
‹BACK
CANCEL
HEALTHY RANGE AND THE HEART...
602
SHOW MORE
618
622
2. ATRIAL FIBRILLATION
622B
ATRIAL FIBRILLATION INDICATES THAT THE HEART IS BEATING IRREGULARLY AND INCREASES THE RISK OF STROKE, HEART FAILURE, AND OTHER HEART RELATED MEDICAL ISSUES.
ATRIAL FIBRILLATION CAN GENERALLY BE MANAGED WITH TREATMENT, INCLUDING MEDICATION, AND USUALLY ISN'T LIFE-THREATENING.
ATRIAL FIBRILLATION MAY RANGE FROM OCCASIONAL IRREGULARITY TO PERMANENT WHERE THE ABNORMALITY CANNOT BE CORRECTED.
3. HIGH OR LOW HEART RATE

FIG. 6L

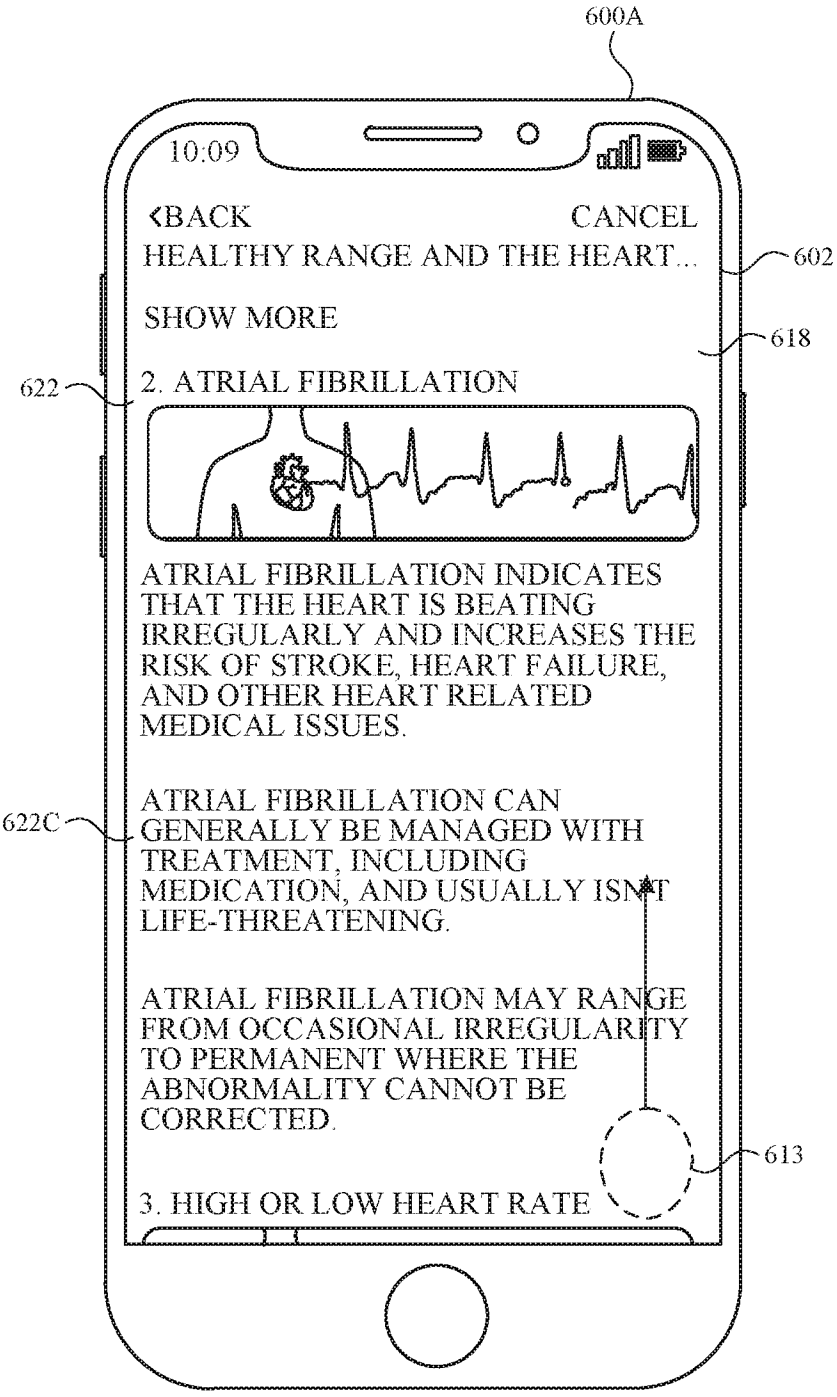

600A
10:09
‹BACK
CANCEL
HEALTHY RANGE AND THE HEART...
602
SHOW MORE
618
2. ATRIAL FIBRILLATION
622
ATRIAL FIBRILLATION INDICATES THAT THE HEART IS BEATING IRREGULARLY AND INCREASES THE RISK OF STROKE, HEART FAILURE, AND OTHER HEART RELATED MEDICAL ISSUES.
622C
ATRIAL FIBRILLATION CAN GENERALLY BE MANAGED WITH TREATMENT, INCLUDING MEDICATION, AND USUALLY ISN'T LIFE-THREATENING.
ATRIAL FIBRILLATION MAY RANGE FROM OCCASIONAL IRREGULARITY TO PERMANENT WHERE THE ABNORMALITY CANNOT BE CORRECTED.
613
3. HIGH OR LOW HEART RATE

FIG. 6M

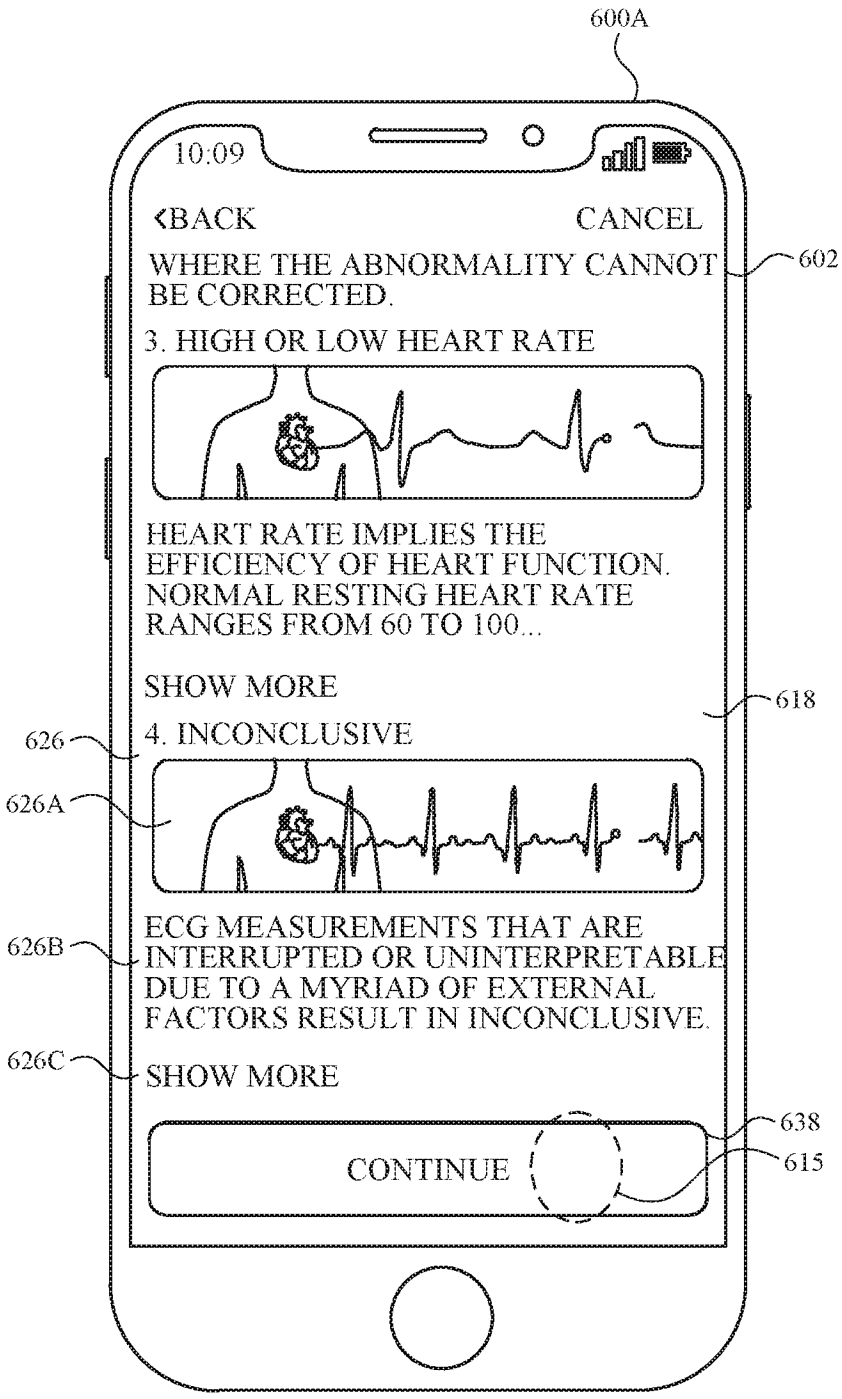

600A
10:09
‹BACK
CANCEL
WHERE THE ABNORMALITY CANNOT BE CORRECTED.
602
3. HIGH OR LOW HEART RATE
HEART RATE IMPLIES THE EFFICIENCY OF HEART FUNCTION. NORMAL RESTING HEART RATE RANGES FROM 60 TO 100...
SHOW MORE
618
626
4. INCONCLUSIVE
626A
626B
ECG MEASUREMENTS THAT ARE INTERRUPTED OR UNINTERPRETABLE DUE TO A MYRIAD OF EXTERNAL FACTORS RESULT IN INCONCLUSIVE.
626C
SHOW MORE
638
615
CONTINUE

FIG. 6N

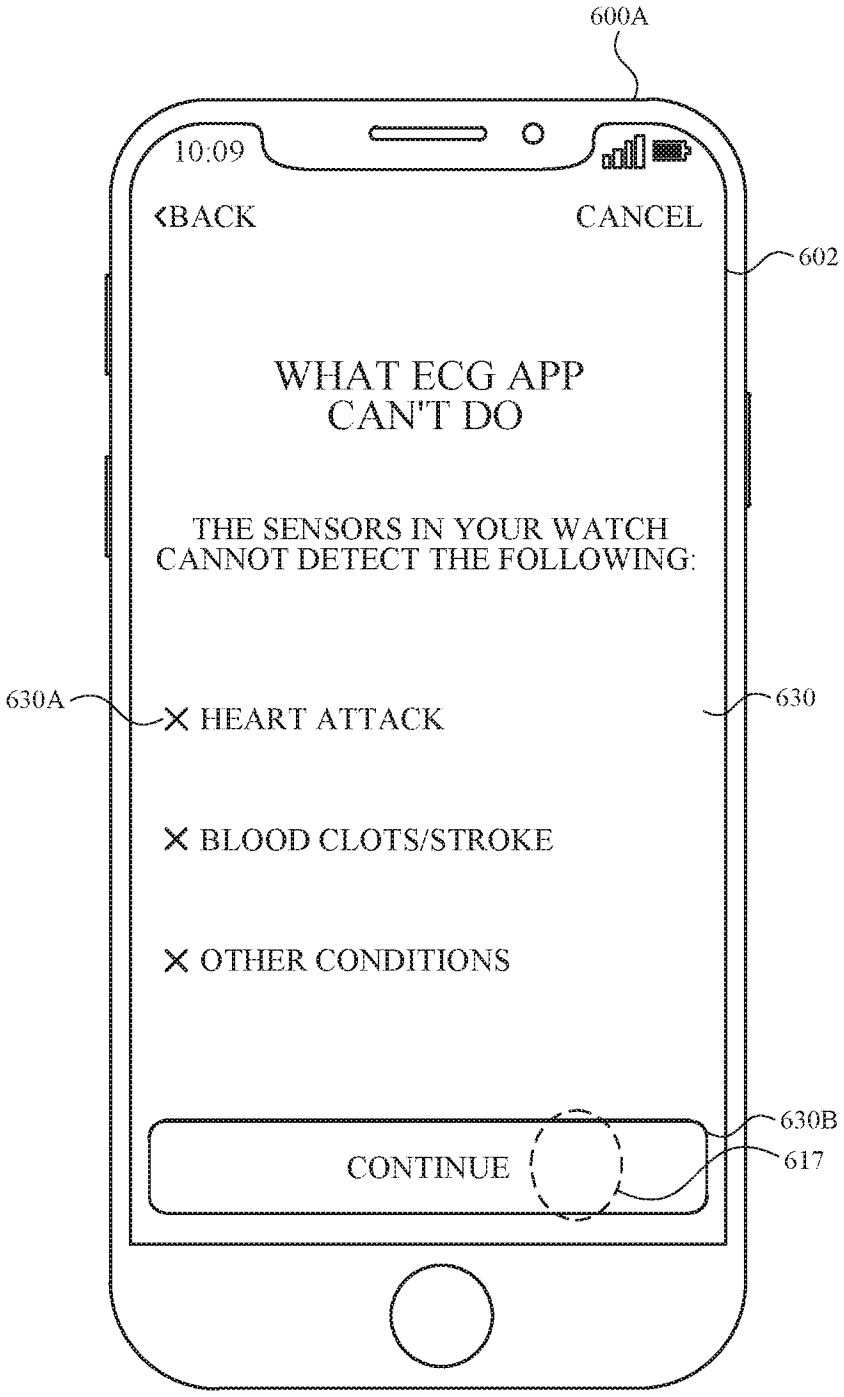

600A
10:09
‹BACK
CANCEL
602
WHAT ECG APP CAN'T DO
THE SENSORS IN YOUR WATCH CANNOT DETECT THE FOLLOWING:
630A
630
✕ HEART ATTACK
✕ BLOOD CLOTS/STROKE
✕ OTHER CONDITIONS
630B
617
CONTINUE

FIG. 6O

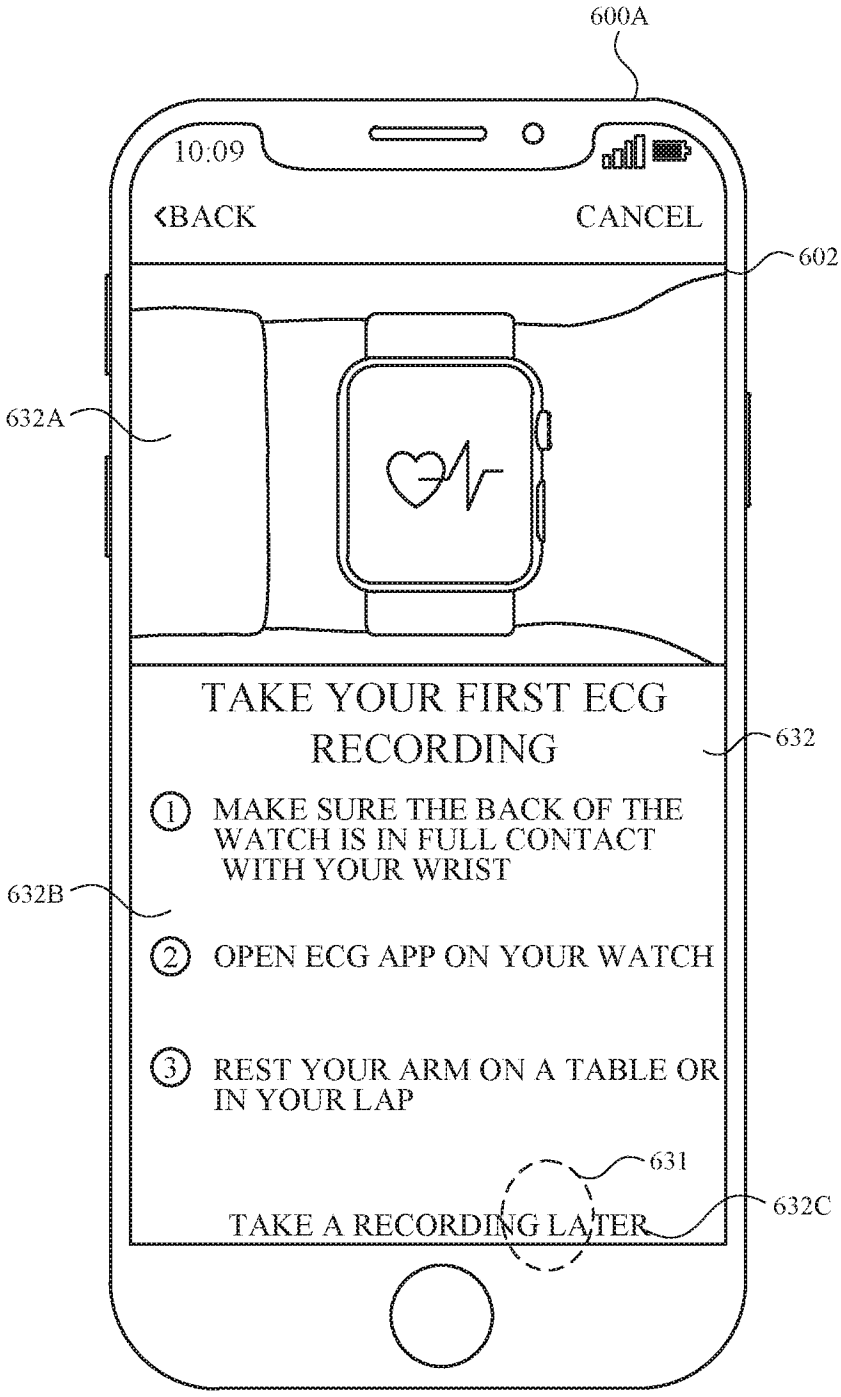

600A
10:09
‹BACK
CANCEL
602
632A
TAKE YOUR FIRST ECG RECORDING
632
1 MAKE SURE THE BACK OF THE WATCH IS IN FULL CONTACT WITH YOUR WRIST
632B
2 OPEN ECG APP ON YOUR WATCH
3 REST YOUR ARM ON A TABLE OR IN YOUR LAP
631
TAKE A RECORDING LATER
632C

FIG. 6P

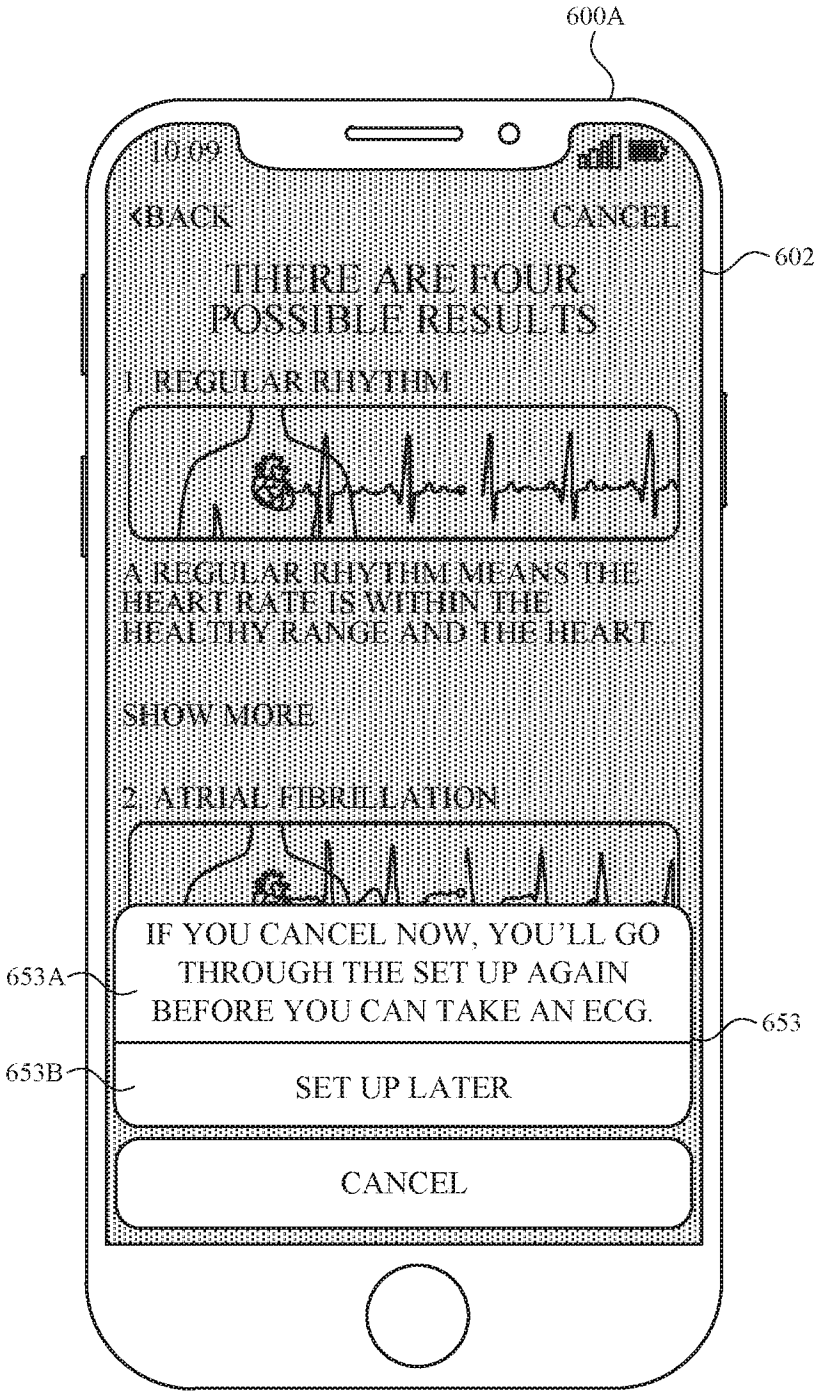

600A
10:09
BACK
CANCEL
602
THERE ARE FOUR POSSIBLE RESULTS
1. REGULAR RHYTHM
A REGULAR RHYTHM MEANS THE HEART RATE IS WITHIN THE HEALTHY RANGE AND THE HEART
SHOW MORE
2. ATRIAL FIBRILLATION
IF YOU CANCEL NOW, YOU'LL GO THROUGH THE SET UP AGAIN BEFORE YOU CAN TAKE AN ECG.
653A
653
653B
SET UP LATER
CANCEL

FIG. 6Q

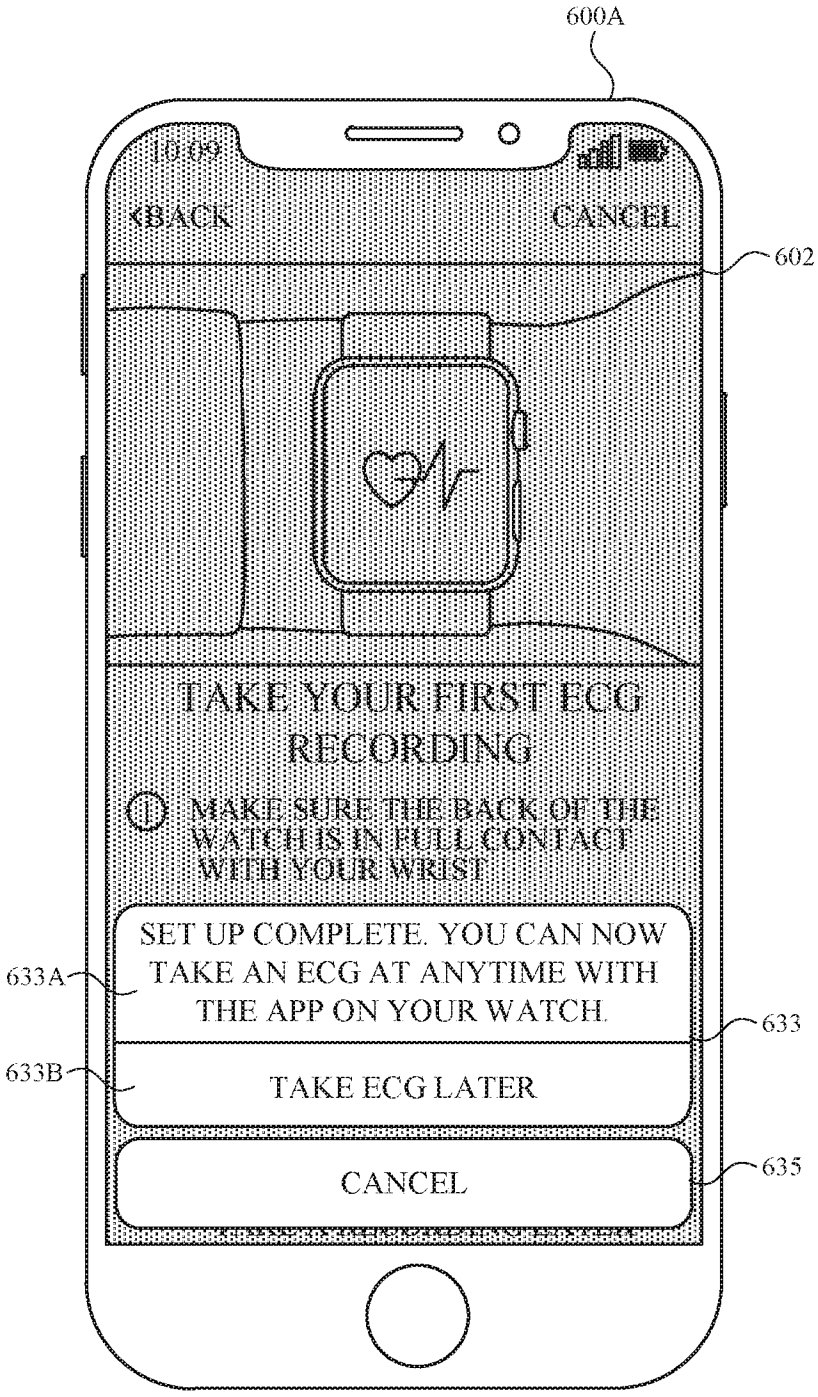

600A
10:09
BACK
CANCEL
602
TAKE YOUR FIRST ECG RECORDING
MAKE SURE THE BACK OF THE WATCH IS IN FULL CONTACT WITH YOUR WRIST
SET UP COMPLETE. YOU CAN NOW TAKE AN ECG AT ANYTIME WITH THE APP ON YOUR WATCH.
633A
633
633B
TAKE ECG LATER
CANCEL
635

FIG. 6R

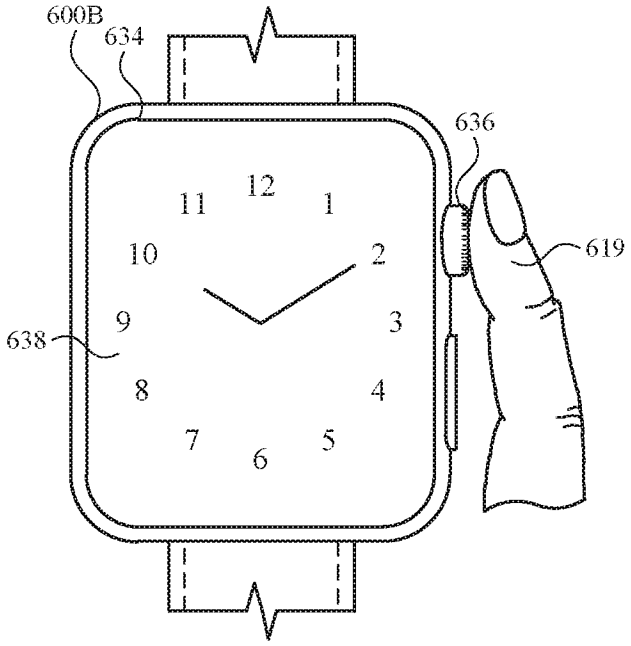


FIG. 6S

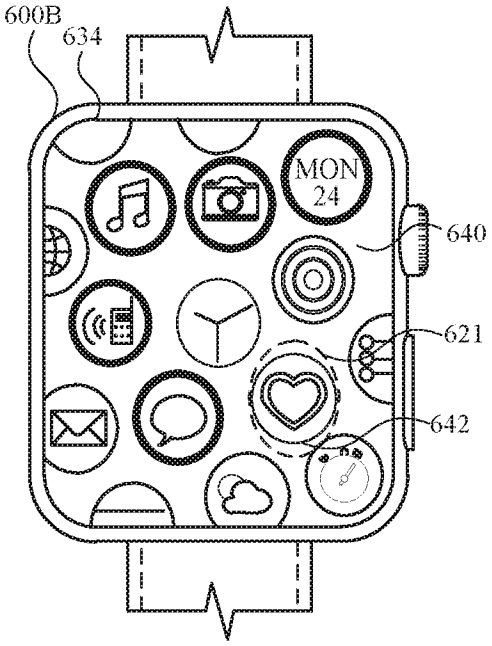


FIG. 6T

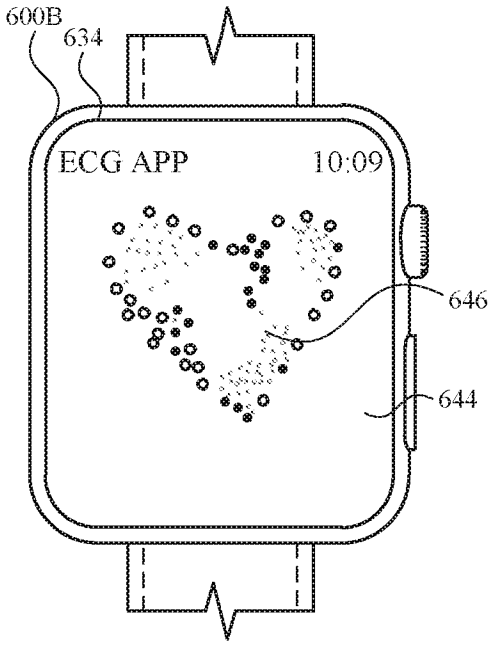


FIG. 6U

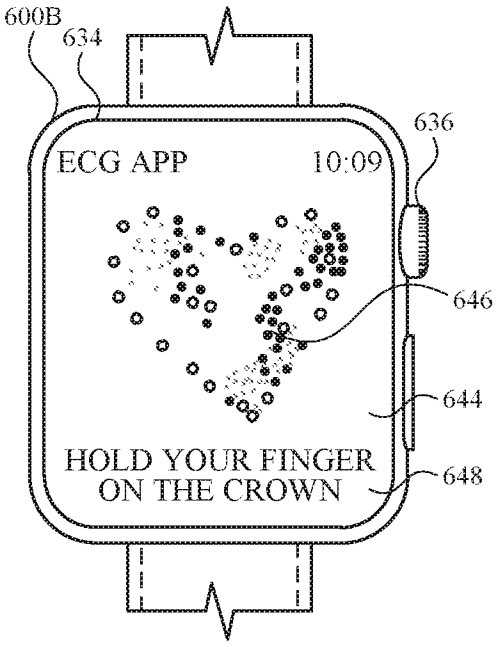


FIG. 6V

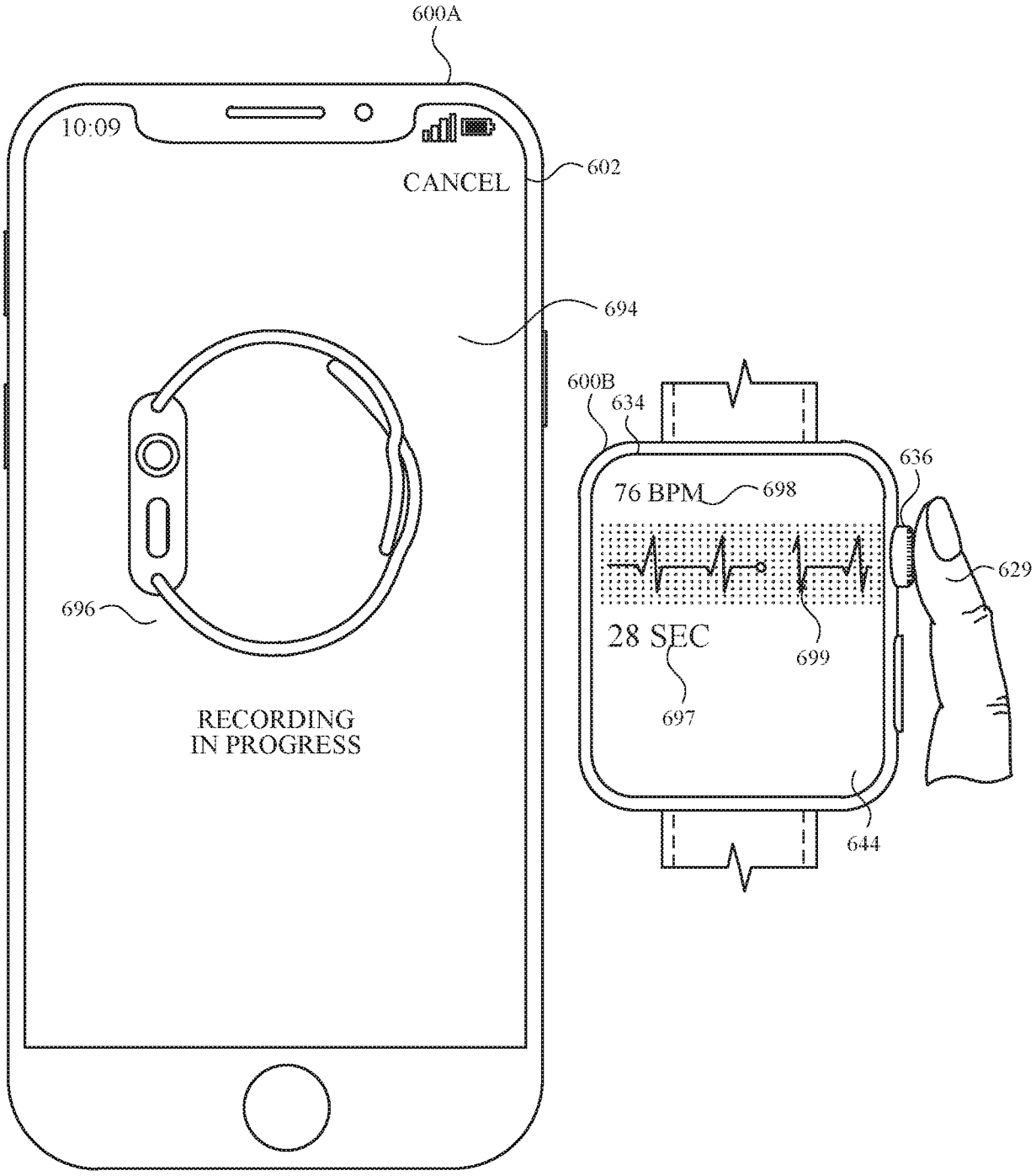

600A
10:09
CANCEL
602
694
696
RECORDING
IN PROGRESS
600B
634
636
76 BPM
698
629
28 SEC
699
697
644

FIG. 6W

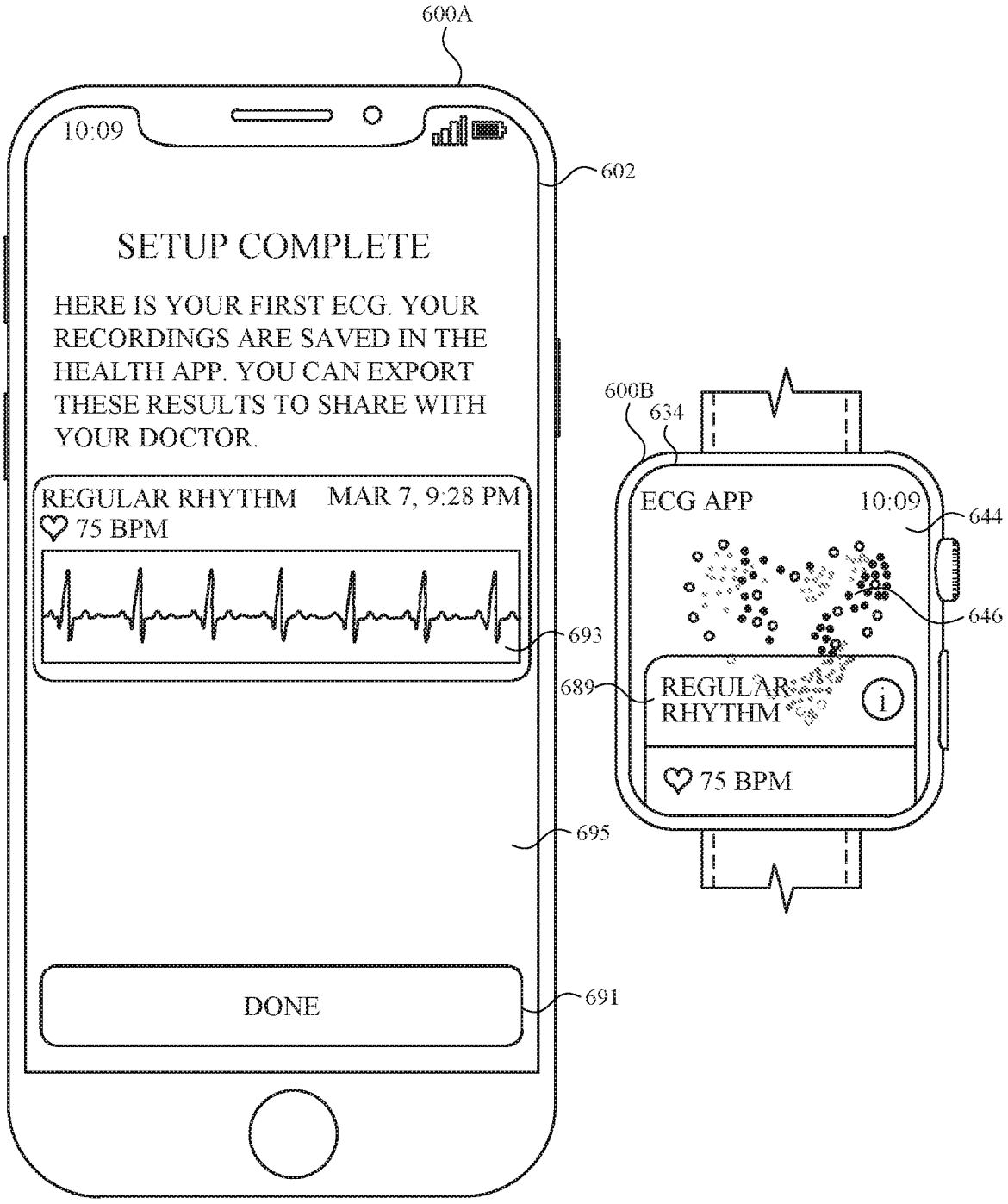

600A
10:09
602
SETUP COMPLETE
HERE IS YOUR FIRST ECG. YOUR RECORDINGS ARE SAVED IN THE HEALTH APP. YOU CAN EXPORT THESE RESULTS TO SHARE WITH YOUR DOCTOR.
REGULAR RHYTHM
MAR 7, 9:28 PM
75 BPM
693
695
DONE
691
600B
634
ECG APP
10:09
644
646
689
REGULAR RHYTHM
75 BPM

FIG. 6X

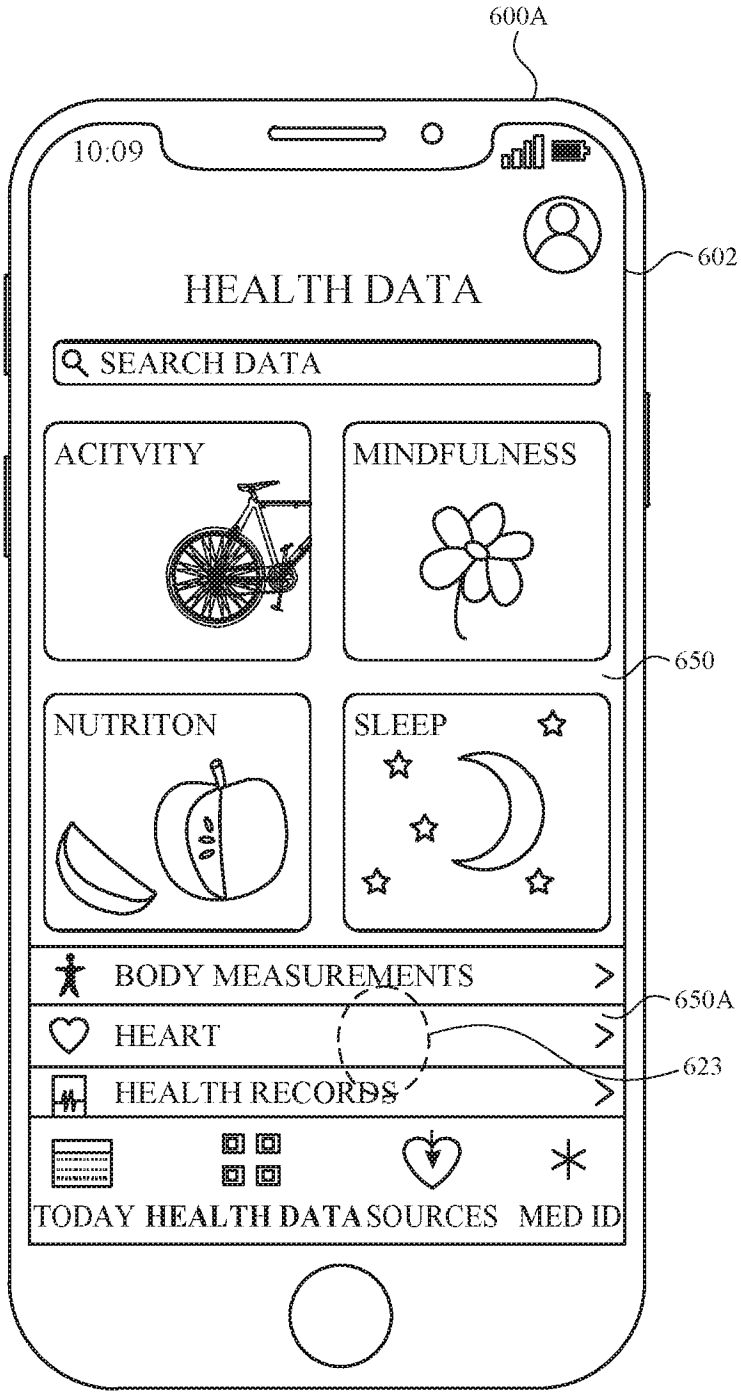

600A
10:09
602
HEALTH DATA
SEARCH DATA
ACITVITY
MINDFULNESS
650
NUTRITON
SLEEP
BODY MEASUREMENTS
650A
HEART
623
HEALTH RECORDS
TODAY
HEALTH DATA
SOURCES
MED ID

FIG. 6Y

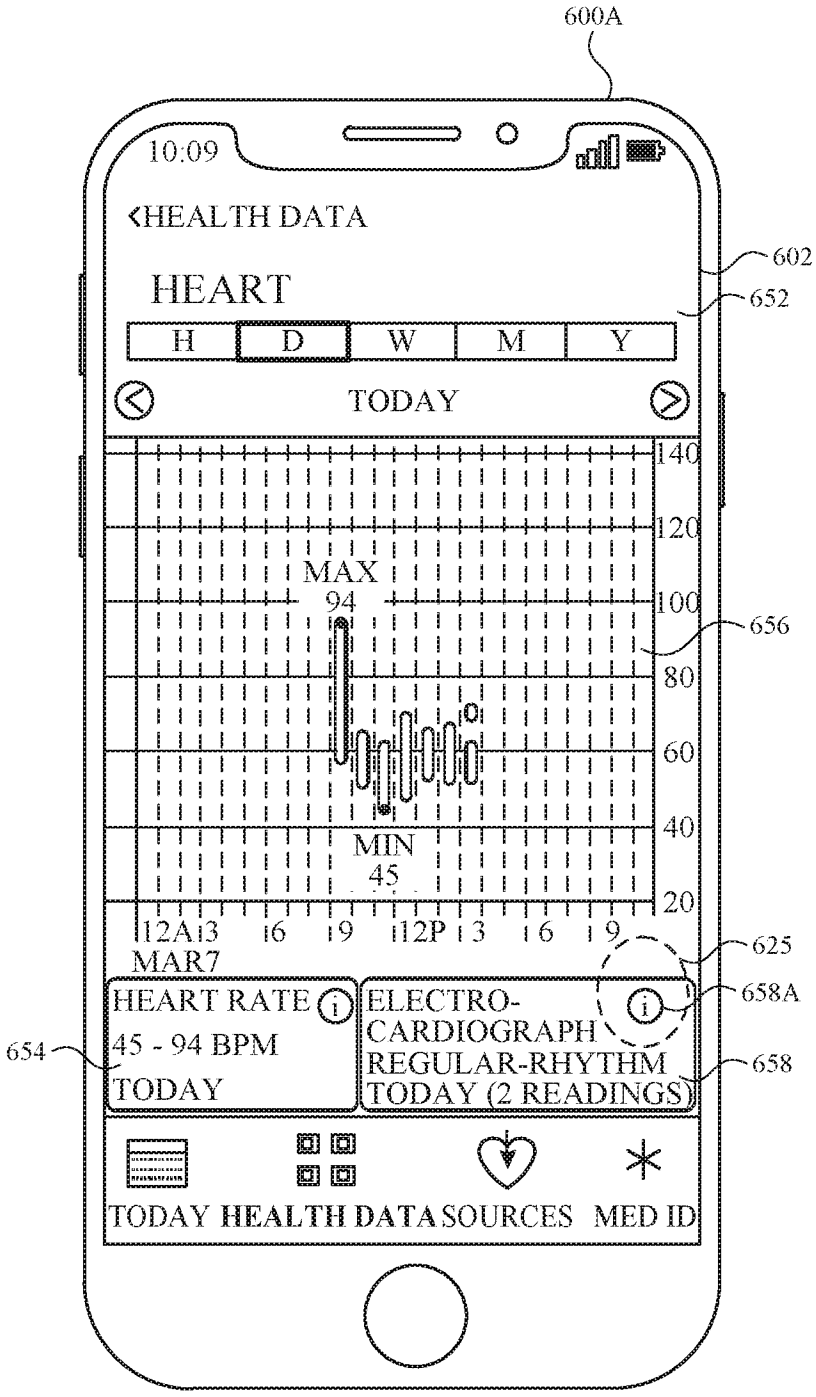

600A
10:09
HEALTH DATA
602
HEART
652
H
D
W
M
Y
TODAY
140
120
MAX
94
100
656
80
60
40
MIN
45
20
12A
3
6
9
12P
3
6
9
MAR7
625
HEART RATE
658A
45 - 94 BPM
TODAY
654
ELECTRO-
CARDIOGRAPH
REGULAR-RHYTHM
TODAY (2 READINGS)
658
TODAY
HEALTH DATA
SOURCES
MED ID

FIG. 6Z

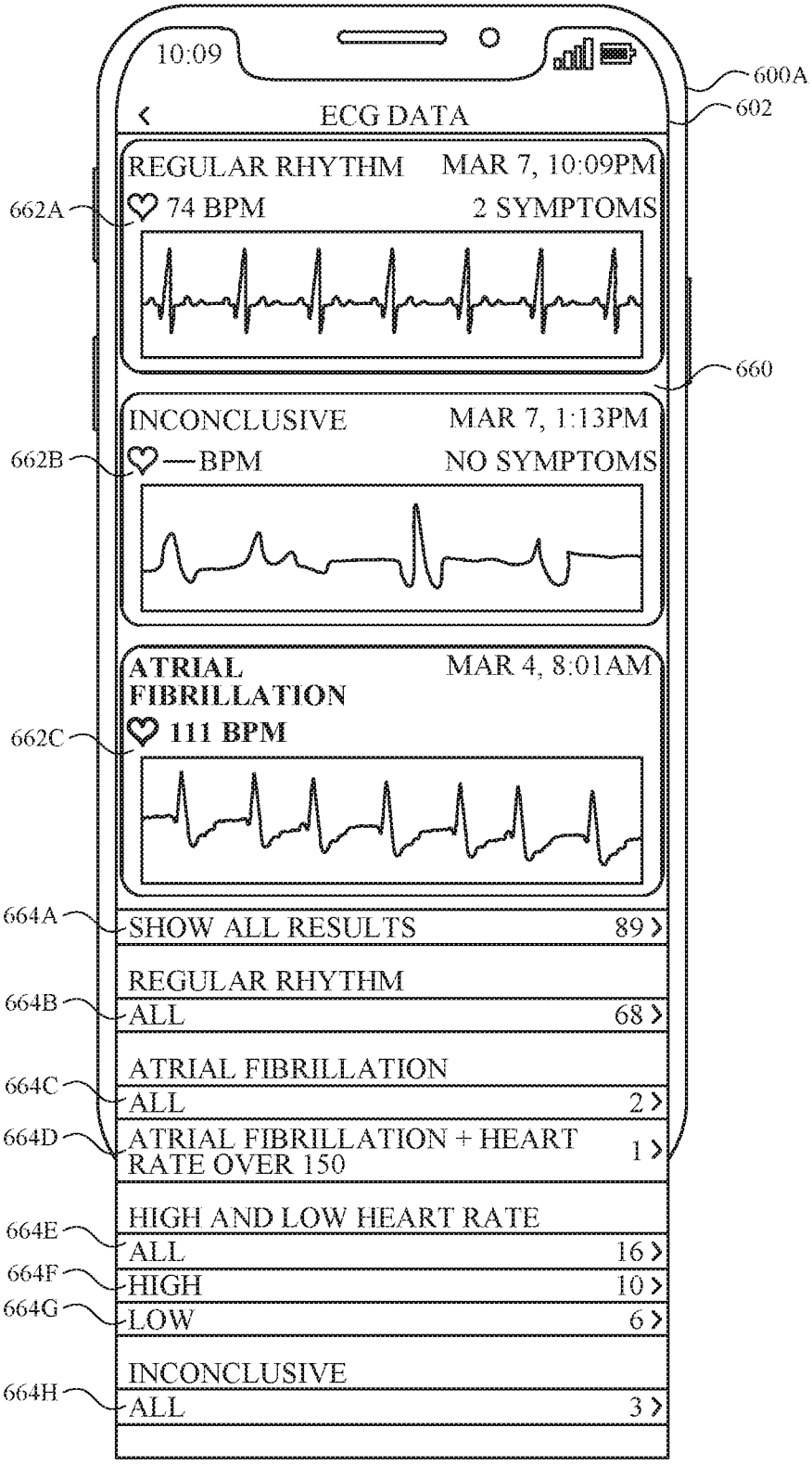

10:09
600A
602
ECG DATA
REGULAR RHYTHM
MAR 7, 10:09PM
662A
74 BPM
2 SYMPTOMS
660
INCONCLUSIVE
MAR 7, 1:13PM
662B
—BPM
NO SYMPTOMS
ATRIAL FIBRILLATION
MAR 4, 8:01AM
662C
111 BPM
664A
SHOW ALL RESULTS 89
REGULAR RHYTHM
664B
ALL 68
ATRIAL FIBRILLATION
664C
ALL 2
664D
ATRIAL FIBRILLATION + HEART RATE OVER 150 1
HIGH AND LOW HEART RATE
664E
ALL 16
664F
HIGH 10
664G
LOW 6
INCONCLUSIVE
664H
ALL 3

FIG. 6AA

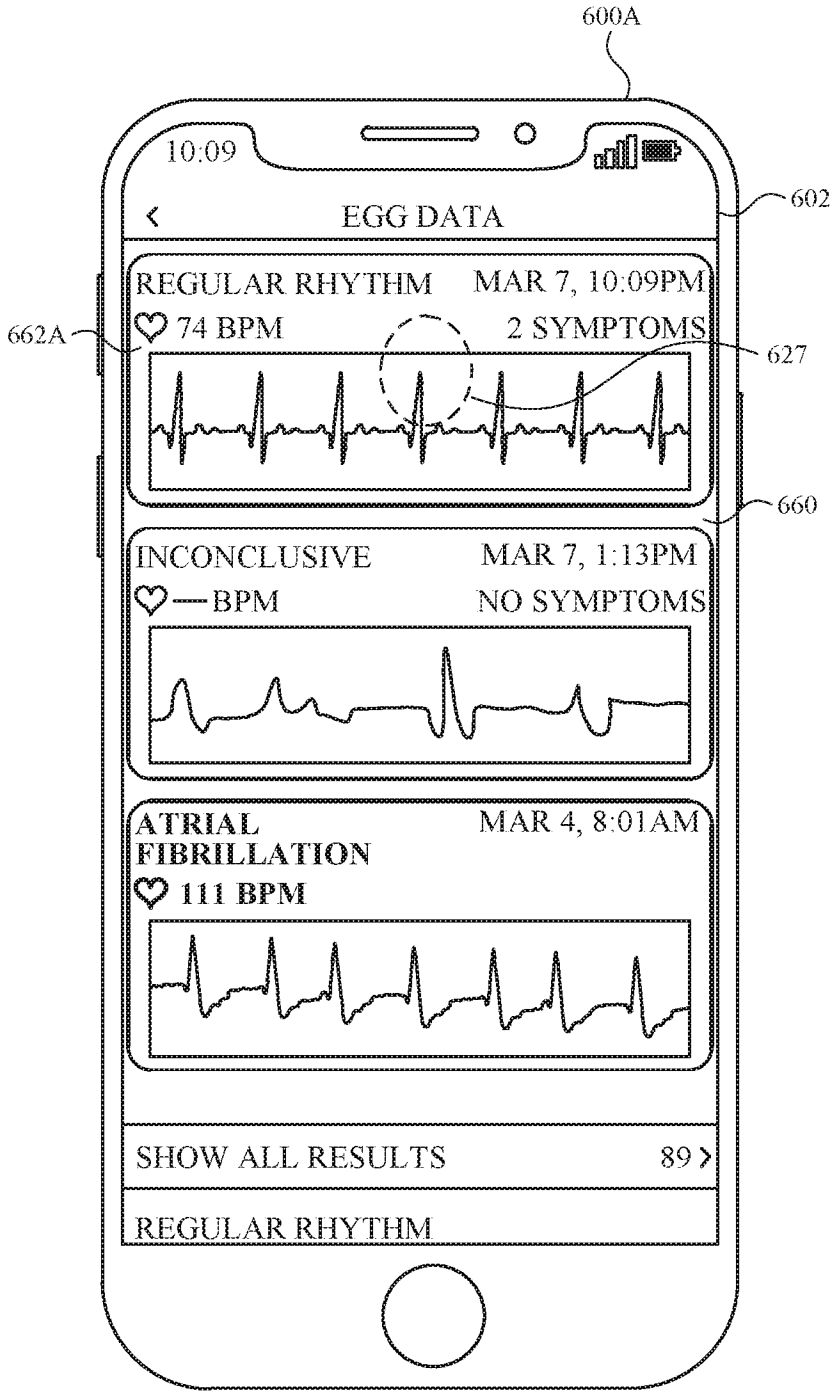

600A
10:09
EGG DATA
602
REGULAR RHYTHM
MAR 7, 10:09PM
74 BPM
2 SYMPTOMS
662A
627
660
INCONCLUSIVE
MAR 7, 1:13PM
—BPM
NO SYMPTOMS
ATRIAL FIBRILLATION
MAR 4, 8:01AM
111 BPM
SHOW ALL RESULTS
89
REGULAR RHYTHM

FIG. 6AB

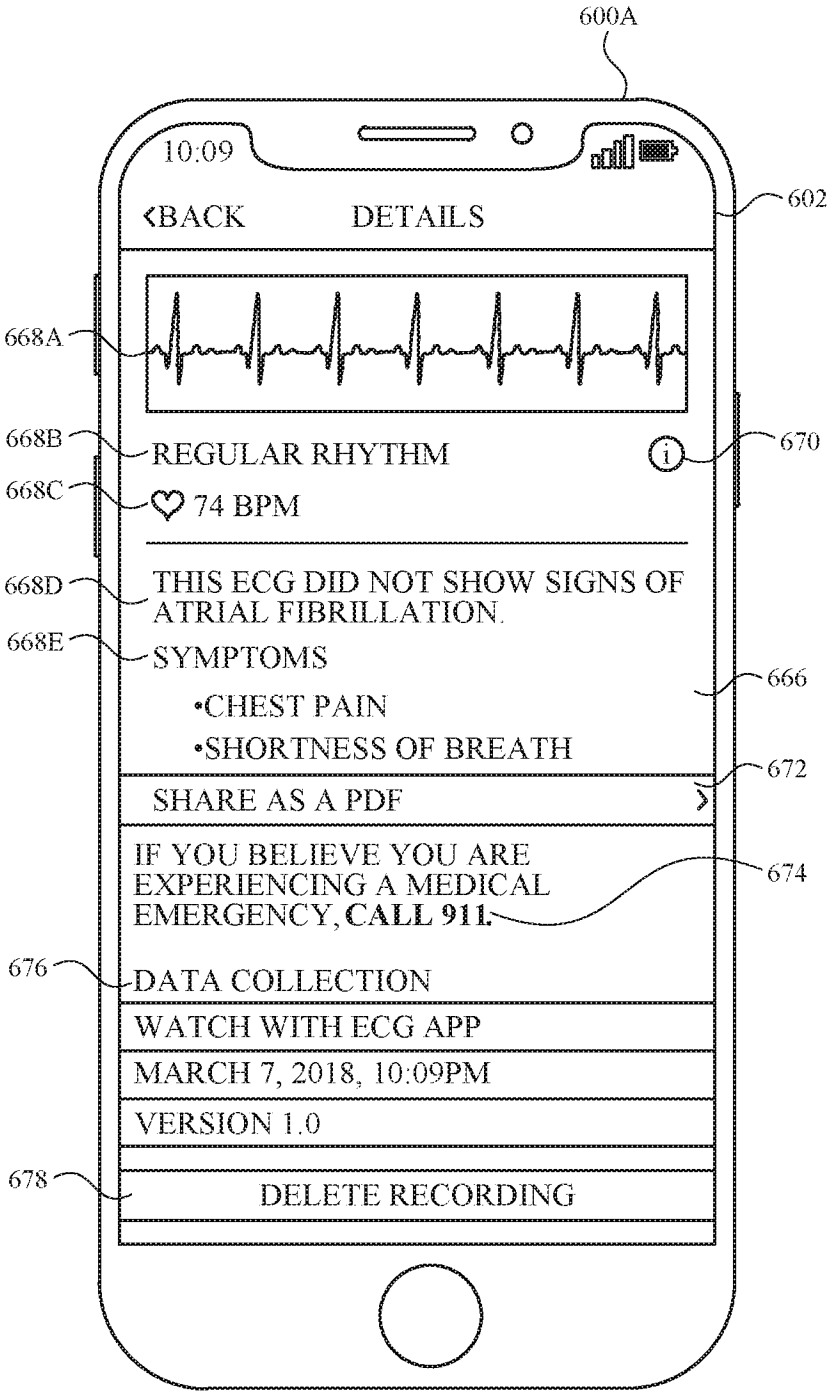

600A
10:09
‹BACK
DETAILS
602
668A
668B
REGULAR RHYTHM
670
668C
74 BPM
668D
THIS ECG DID NOT SHOW SIGNS OF ATRIAL FIBRILLATION.
668E
SYMPTOMS
666
•CHEST PAIN
•SHORTNESS OF BREATH
672
SHARE AS A PDF
IF YOU BELIEVE YOU ARE EXPERIENCING A MEDICAL EMERGENCY, CALL 911.
674
676
DATA COLLECTION
WATCH WITH ECG APP
MARCH 7, 2018, 10:09PM
VERSION 1.0
678
DELETE RECORDING

FIG. 6AC

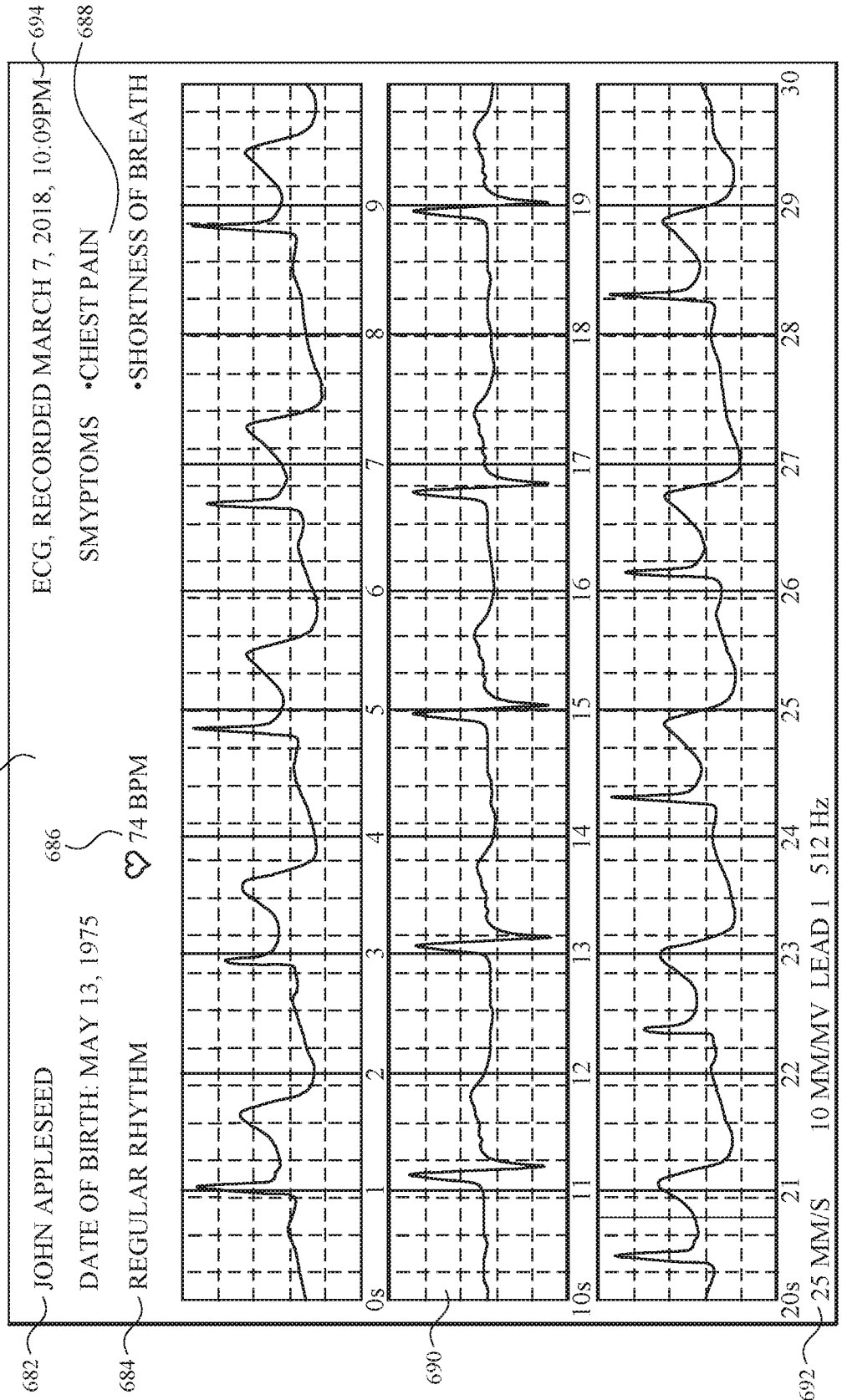

680
682
JOHN APPLESEED
DATE OF BIRTH: MAY 13, 1975
684
REGULAR RHYTHM
686
74 BPM
ECG, RECORDED MARCH 7, 2018, 10:09PM
694
SMYPTOMS
•CHEST PAIN
688
•SHORTNESS OF BREATH
690
0s
10s
20s
692
25 MM/S
10 MM/MV LEAD 1 512 Hz

FIG. 6AD

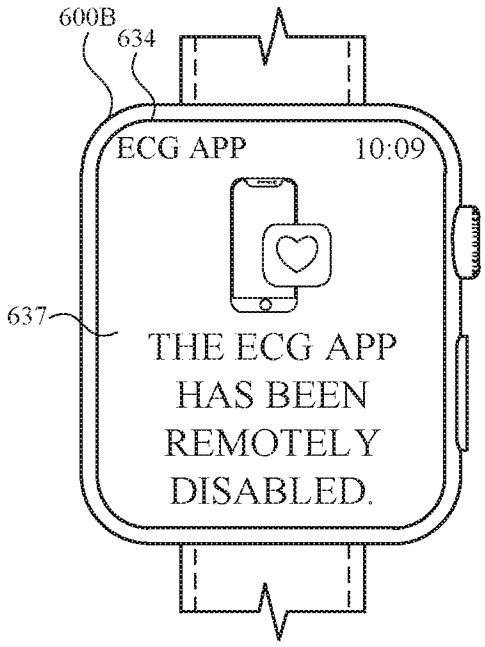

600B
634
ECG APP
10:09
637
THE ECG APP HAS BEEN REMOTELY DISABLED.

FIG. 6AE

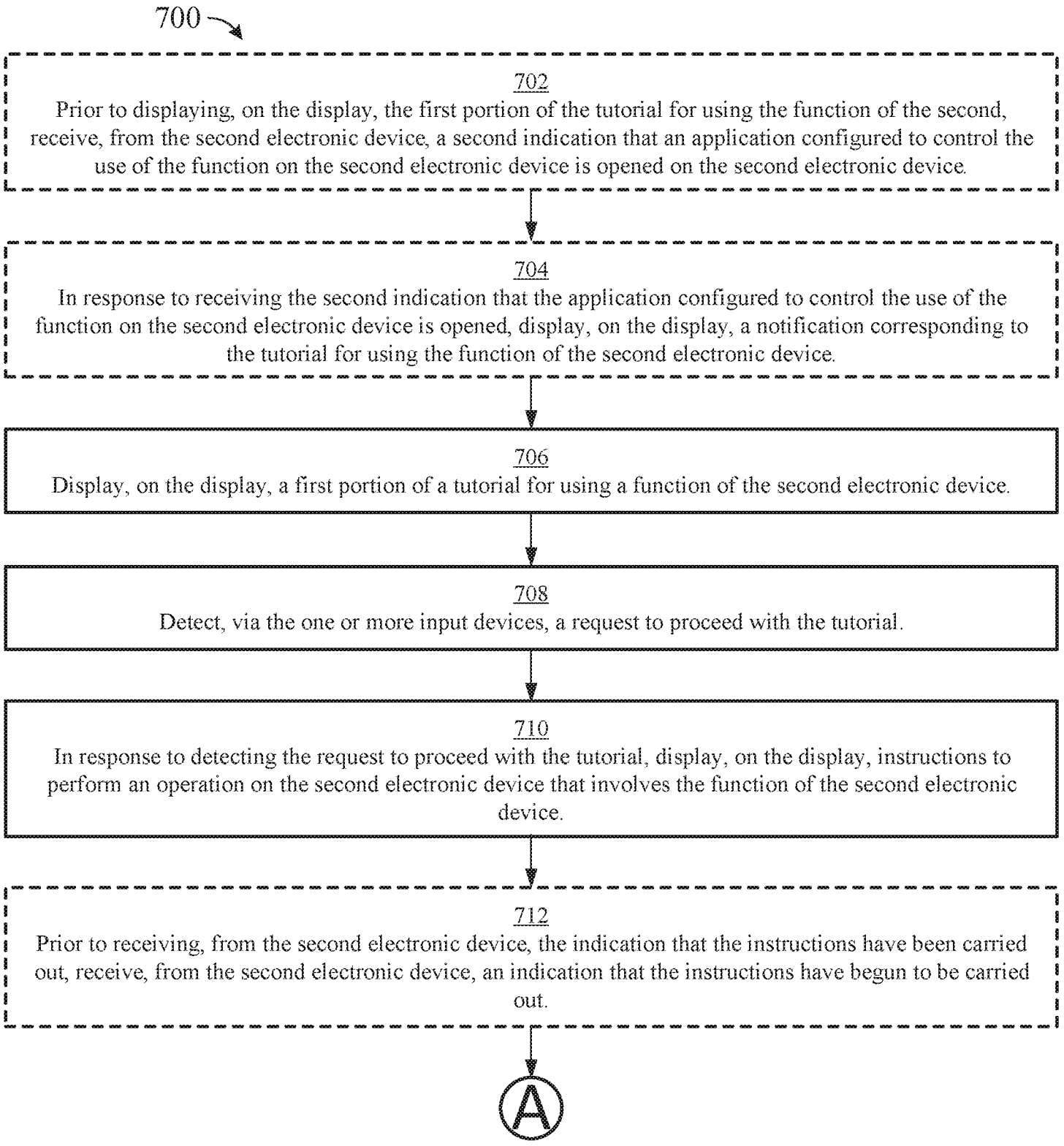

700
702
Prior to displaying, on the display, the first portion of the tutorial for using the function of the second, receive, from the second electronic device, a second indication that an application configured to control the use of the function on the second electronic device is opened on the second electronic device.
704
In response to receiving the second indication that the application configured to control the use of the function on the second electronic device is opened, display, on the display, a notification corresponding to the tutorial for using the function of the second electronic device.
706
Display, on the display, a first portion of a tutorial for using a function of the second electronic device.
708
Detect, via the one or more input devices, a request to proceed with the tutorial.
710
In response to detecting the request to proceed with the tutorial, display, on the display, instructions to perform an operation on the second electronic device that involves the function of the second electronic device.
712
Prior to receiving, from the second electronic device, the indication that the instructions have been carried out, receive, from the second electronic device, an indication that the instructions have begun to be carried out.
A

FIG. 7A

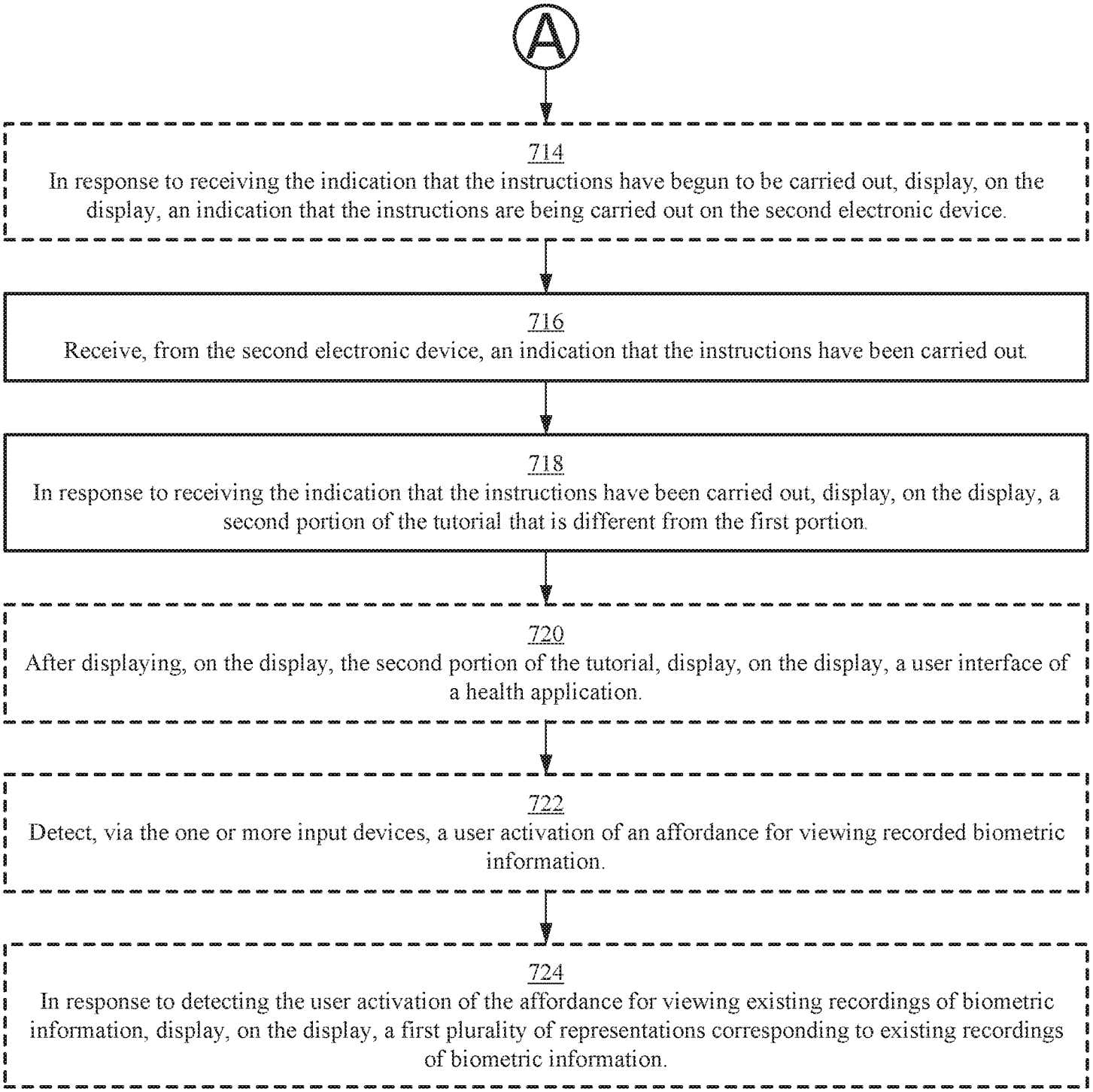

A
714
In response to receiving the indication that the instructions have begun to be carried out, display, on the display, an indication that the instructions are being carried out on the second electronic device.
716
Receive, from the second electronic device, an indication that the instructions have been carried out.
718
In response to receiving the indication that the instructions have been carried out, display, on the display, a second portion of the tutorial that is different from the first portion.
720
After displaying, on the display, the second portion of the tutorial, display, on the display, a user interface of a health application.
722
Detect, via the one or more input devices, a user activation of an affordance for viewing recorded biometric information.
724
In response to detecting the user activation of the affordance for viewing existing recordings of biometric information, display, on the display, a first plurality of representations corresponding to existing recordings of biometric information.

FIG. 7B

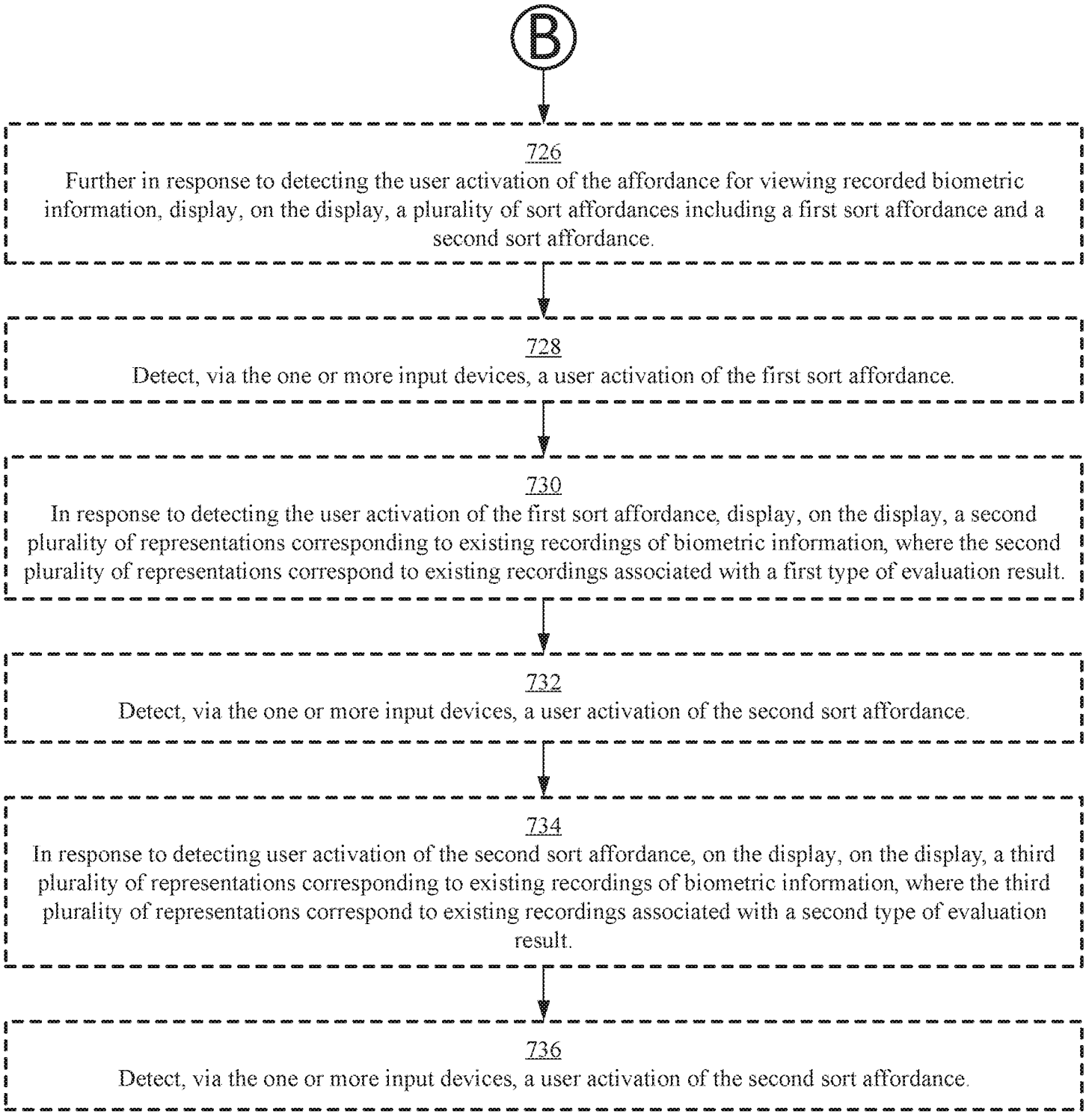

B
726
Further in response to detecting the user activation of the affordance for viewing recorded biometric information, display, on the display, a plurality of sort affordances including a first sort affordance and a second sort affordance.
728
Detect, via the one or more input devices, a user activation of the first sort affordance.
730
In response to detecting the user activation of the first sort affordance, display, on the display, a second plurality of representations corresponding to existing recordings of biometric information, where the second plurality of representations correspond to existing recordings associated with a first type of evaluation result.
732
Detect, via the one or more input devices, a user activation of the second sort affordance.
734
In response to detecting user activation of the second sort affordance, on the display, on the display, a third plurality of representations corresponding to existing recordings of biometric information, where the third plurality of representations correspond to existing recordings associated with a second type of evaluation result.
736
Detect, via the one or more input devices, a user activation of the second sort affordance.

FIG. 7C

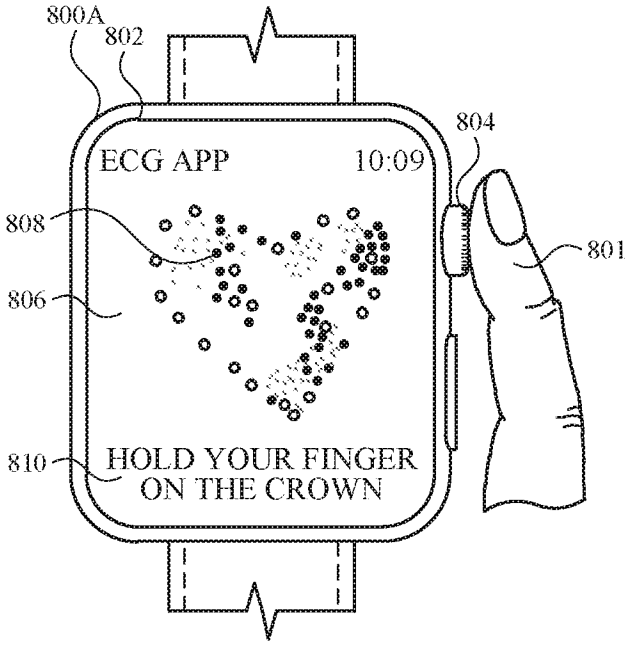


FIG. 8A

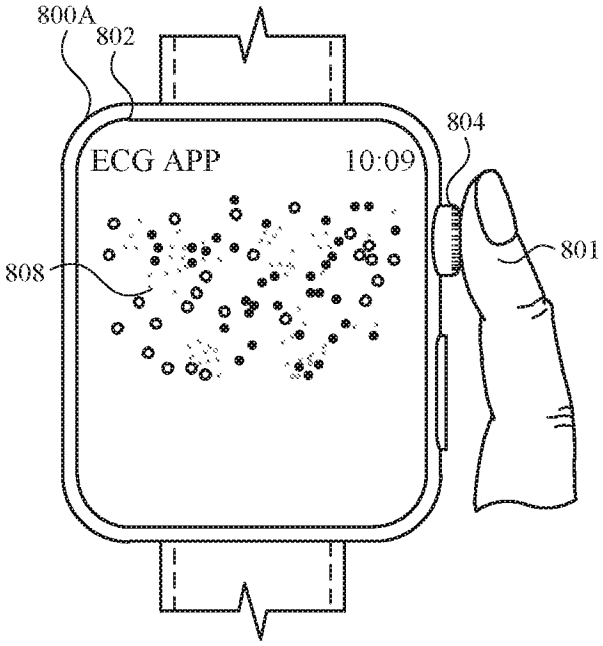


FIG. 8B

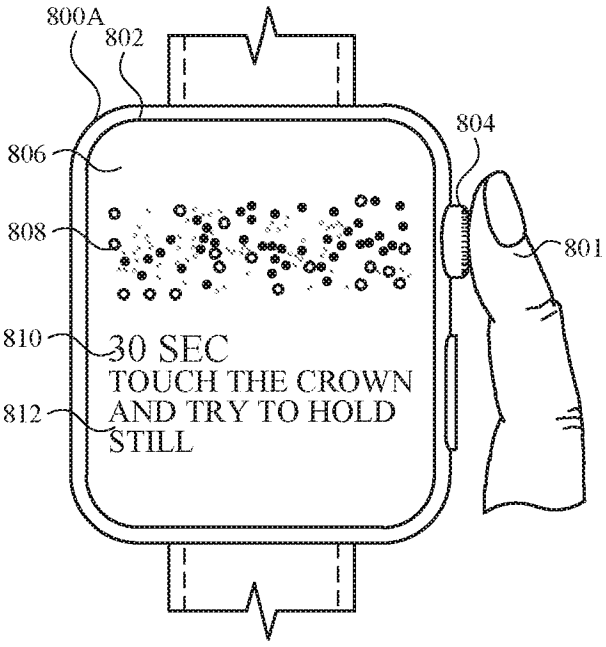


FIG. 8C

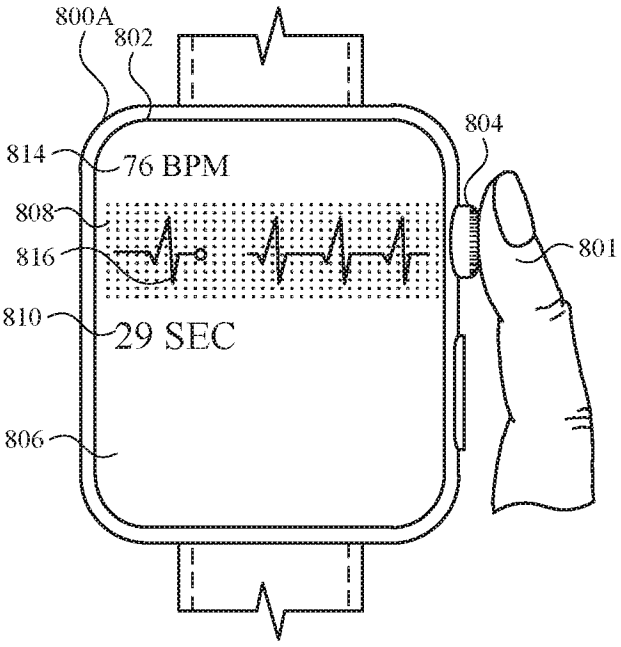


FIG. 8D

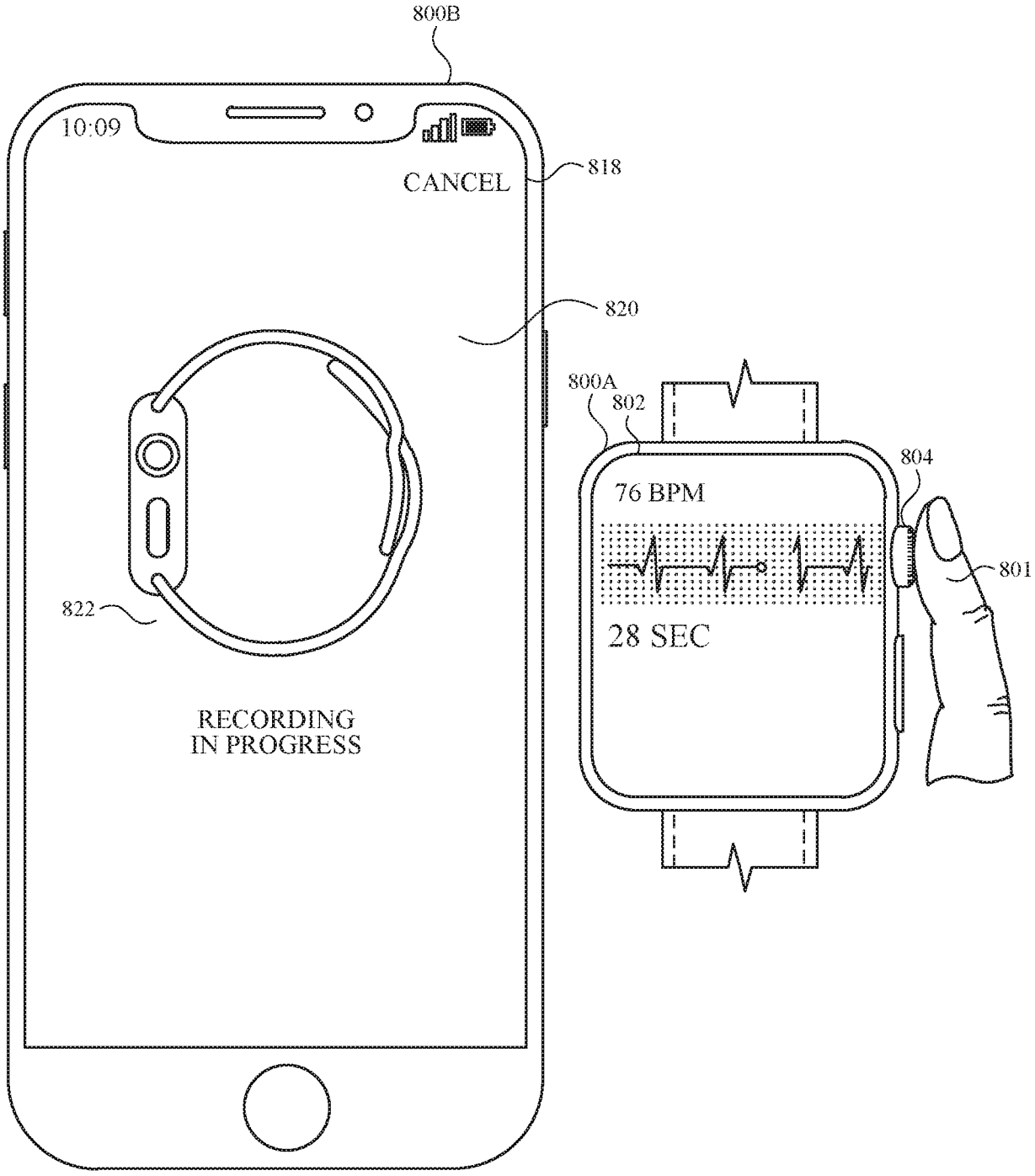

800B
10:09
CANCEL
818
820
800A
802
804
76 BPM
801
822
28 SEC
RECORDING
IN PROGRESS

FIG. 8E

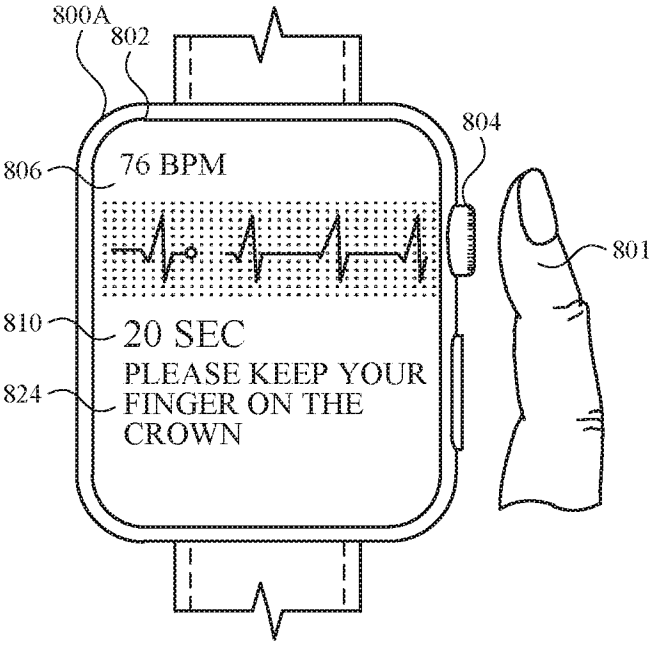


FIG. 8F

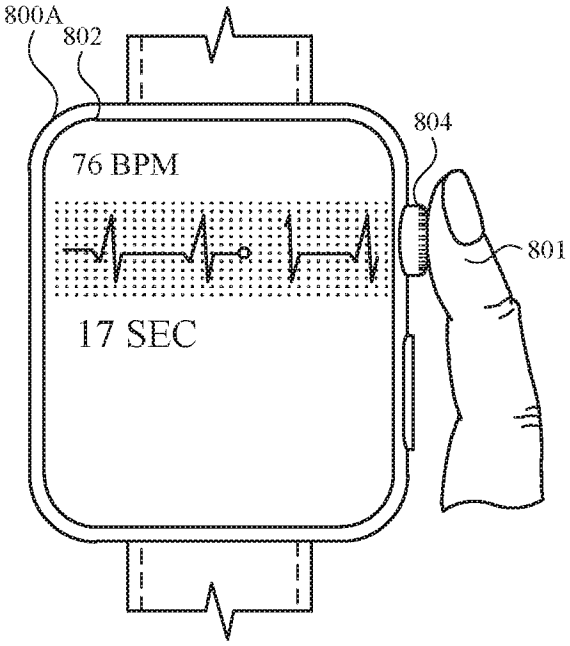


FIG. 8G

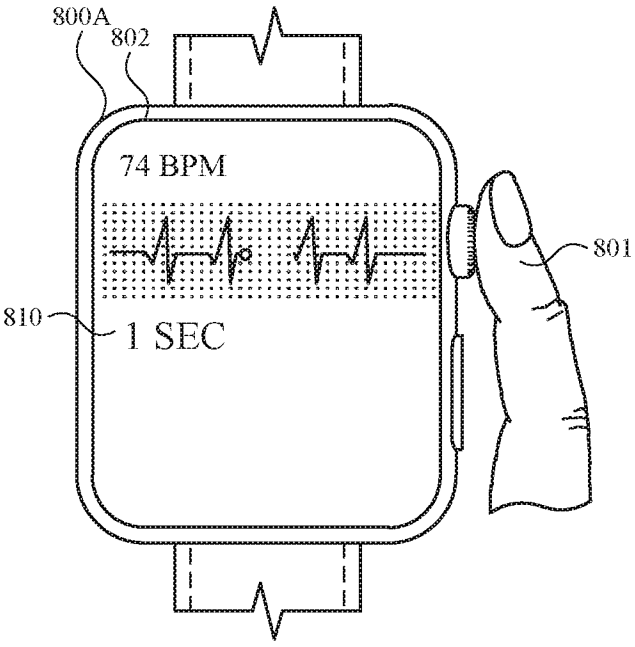


FIG. 8H

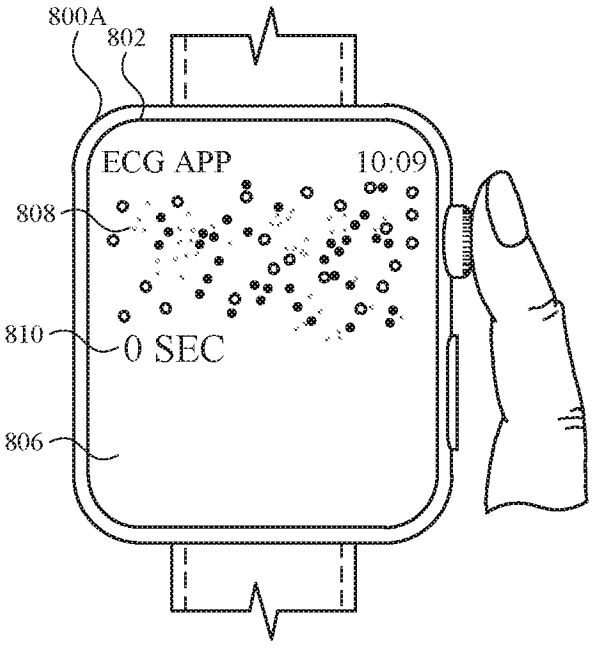


FIG. 8I

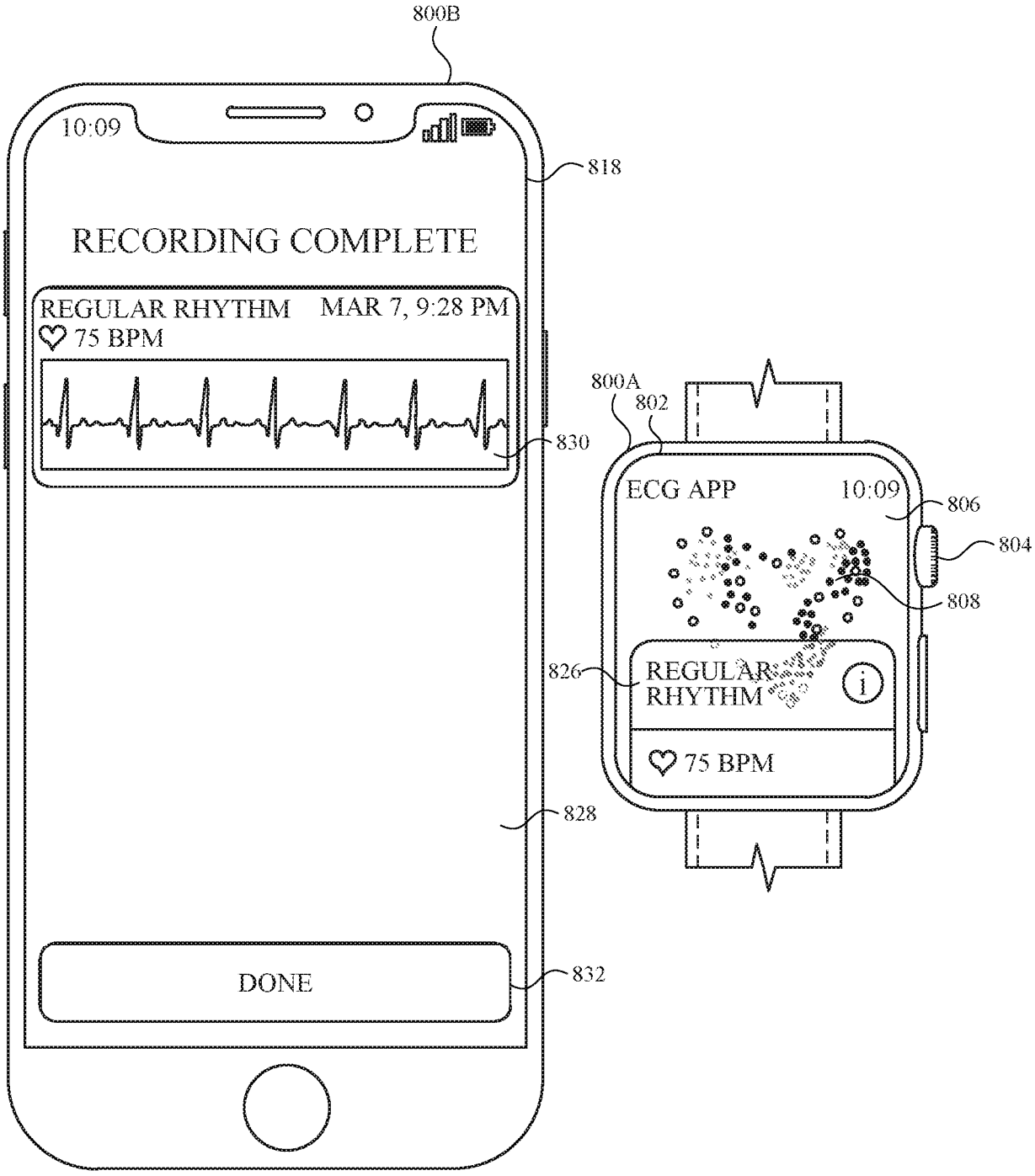

800B
10:09
818
RECORDING COMPLETE
REGULAR RHYTHM
MAR 7, 9:28 PM
75 BPM
830
800A
802
ECG APP
10:09
806
804
808
826
REGULAR RHYTHM
75 BPM
828
DONE
832

FIG. 8J

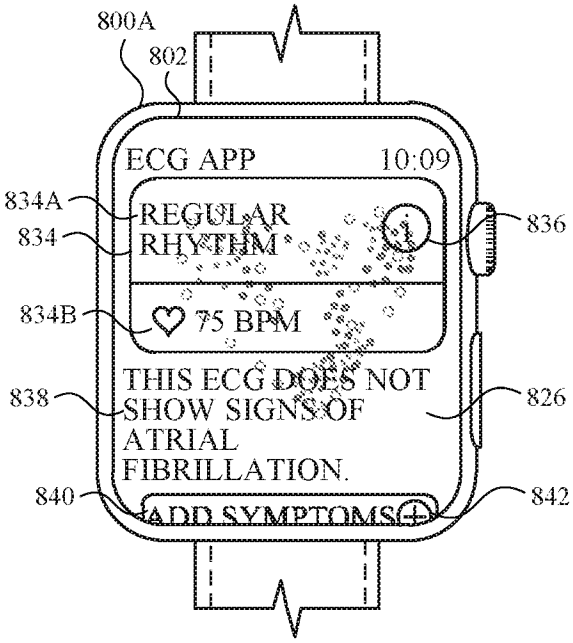

800A
802
ECG APP
10:09
834A
REGULAR
RHYTHM
834
836
834B
75 BPM
838
THIS ECG DOES NOT
SHOW SIGNS OF
ATRIAL
FIBRILLATION.
826
840
ADD SYMPTOMS
842

FIG. 8K

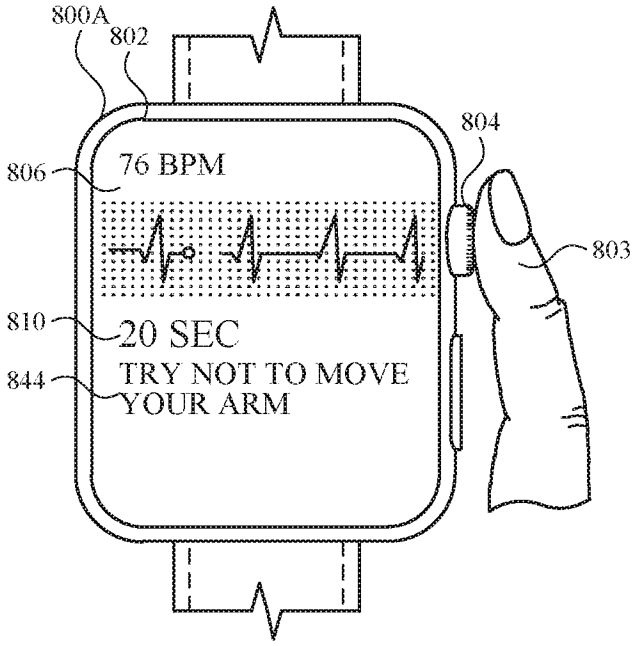


FIG. 8L

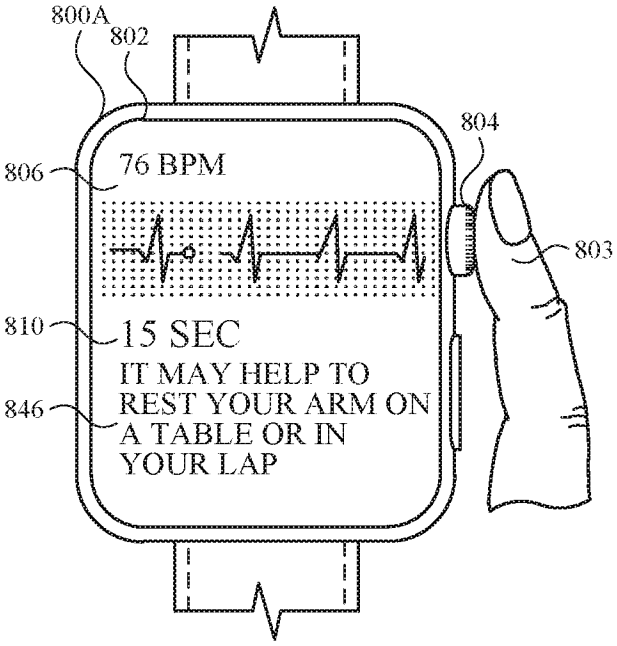


FIG. 8M

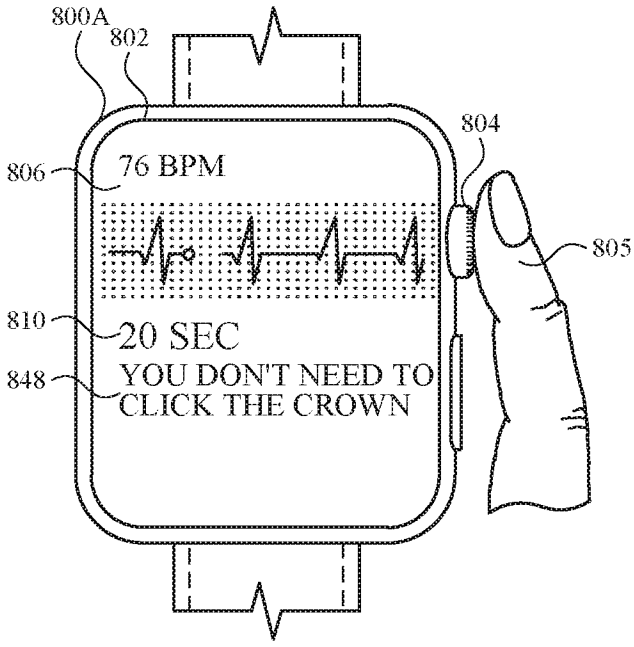


FIG. 8N

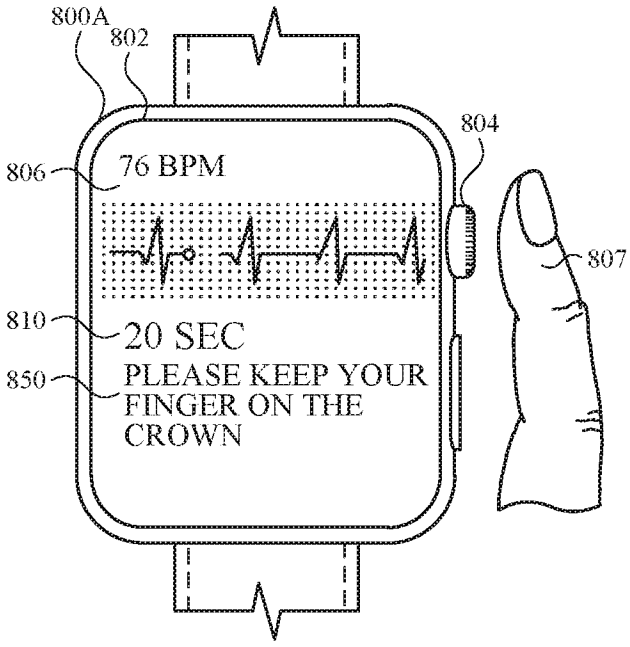


FIG. 8O

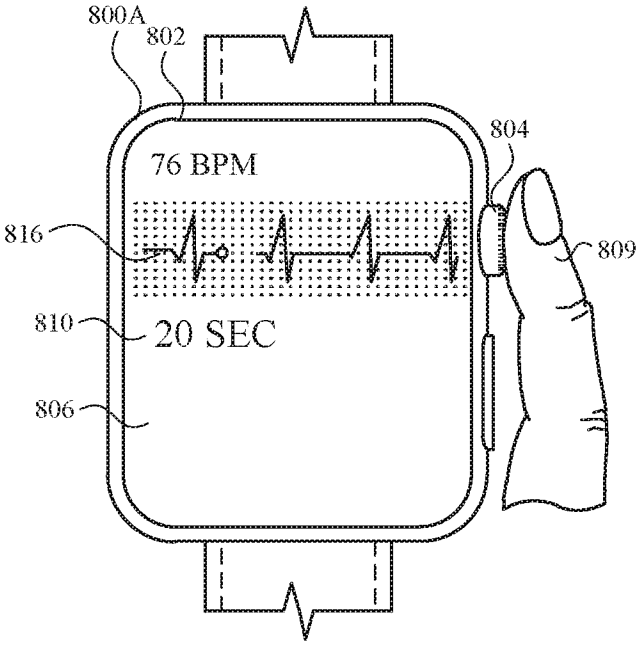


FIG. 8P

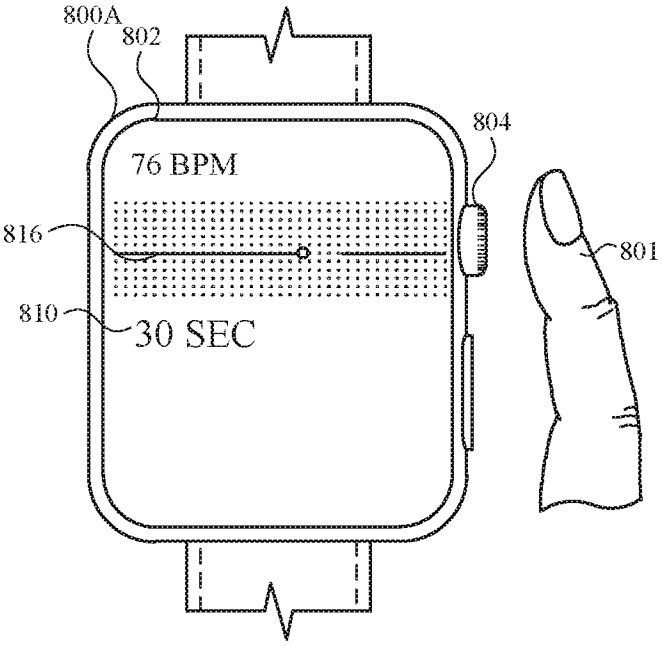


FIG. 8Q

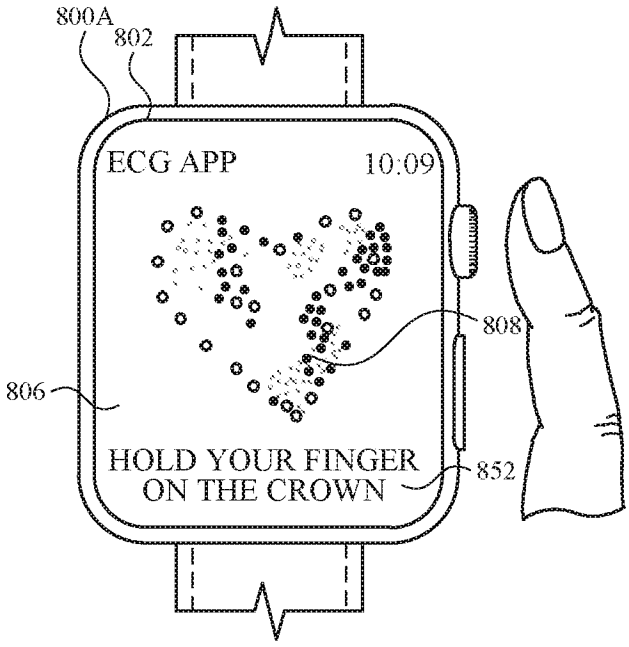


FIG. 8R

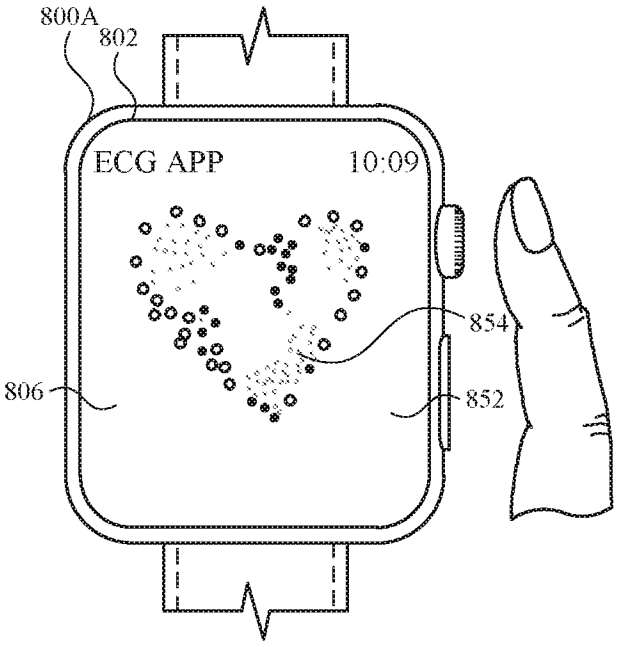


FIG. 8S

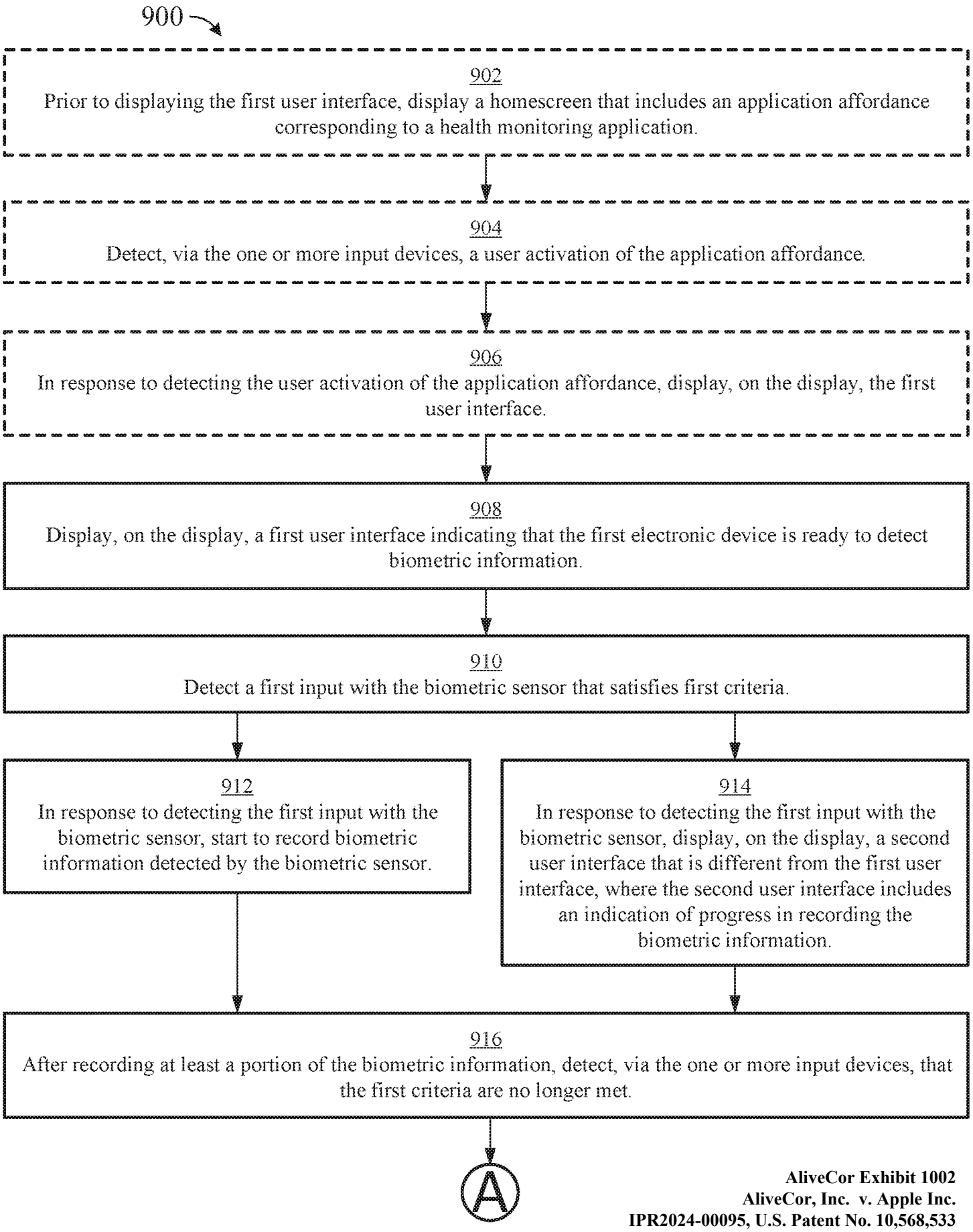

900
902
Prior to displaying the first user interface, display a homescreen that includes an application affordance corresponding to a health monitoring application.
904
Detect, via the one or more input devices, a user activation of the application affordance.
906
In response to detecting the user activation of the application affordance, display, on the display, the first user interface.
908
Display, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information.
910
Detect a first input with the biometric sensor that satisfies first criteria.
912
In response to detecting the first input with the biometric sensor, start to record biometric information detected by the biometric sensor.
914
In response to detecting the first input with the biometric sensor, display, on the display, a second user interface that is different from the first user interface, where the second user interface includes an indication of progress in recording the biometric information.
916
After recording at least a portion of the biometric information, detect, via the one or more input devices, that the first criteria are no longer met.
A

FIG. 9A

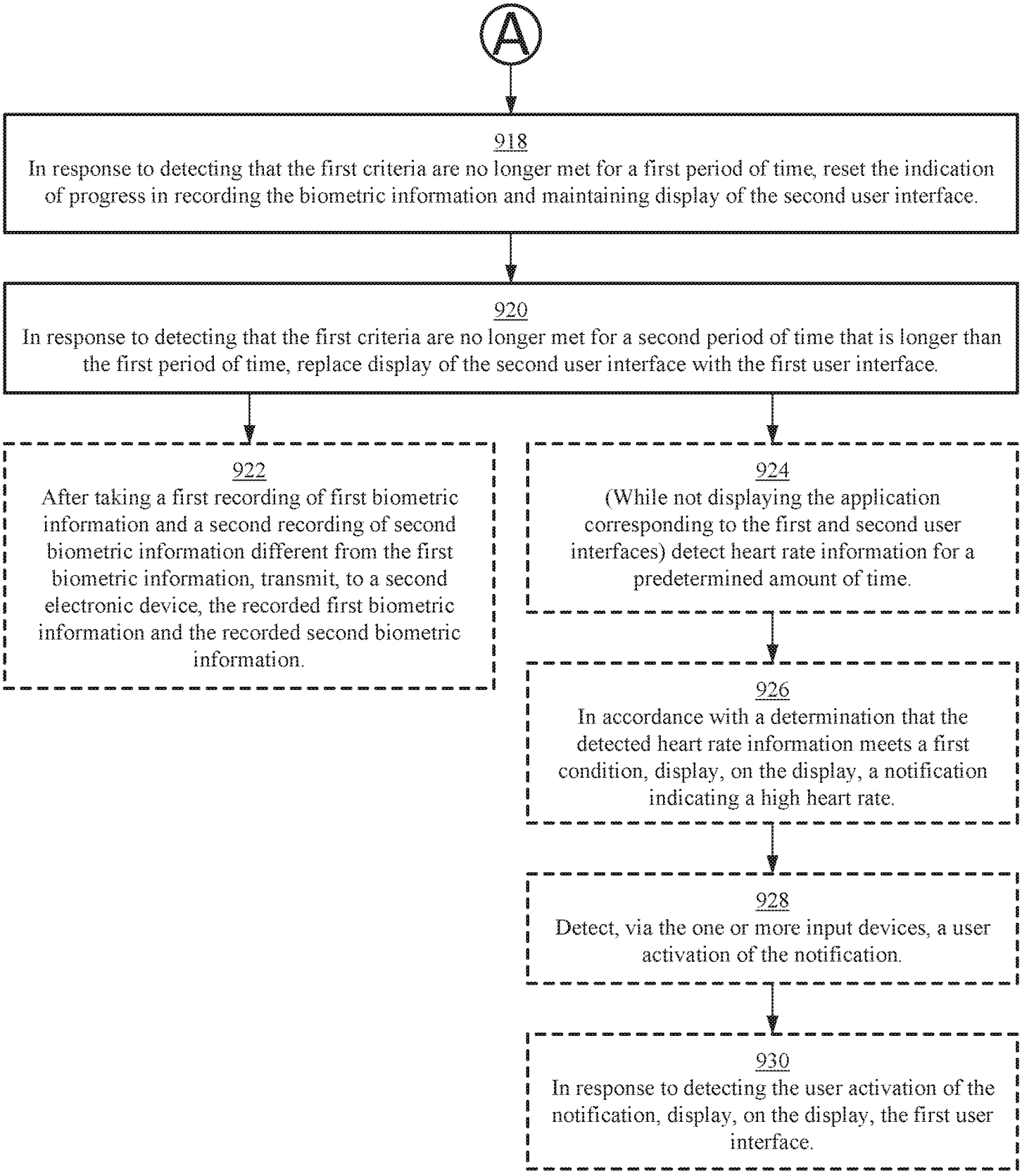

A
918
In response to detecting that the first criteria are no longer met for a first period of time, reset the indication of progress in recording the biometric information and maintaining display of the second user interface.
920
In response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replace display of the second user interface with the first user interface.
922
After taking a first recording of first biometric information and a second recording of second biometric information different from the first biometric information, transmit, to a second electronic device, the recorded first biometric information and the recorded second biometric information.
924
(While not displaying the application corresponding to the first and second user interfaces) detect heart rate information for a predetermined amount of time.
926
In accordance with a determination that the detected heart rate information meets a first condition, display, on the display, a notification indicating a high heart rate.
928
Detect, via the one or more input devices, a user activation of the notification.
930
In response to detecting the user activation of the notification, display, on the display, the first user interface.

FIG. 9B

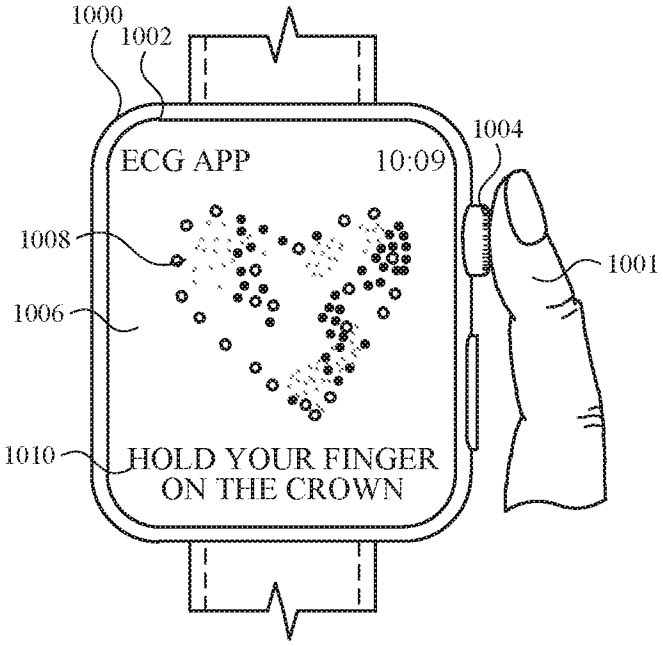


FIG.10A

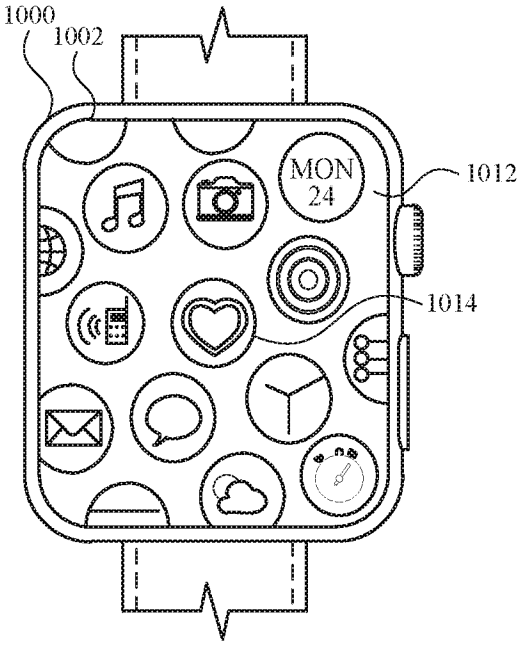


FIG. 10B

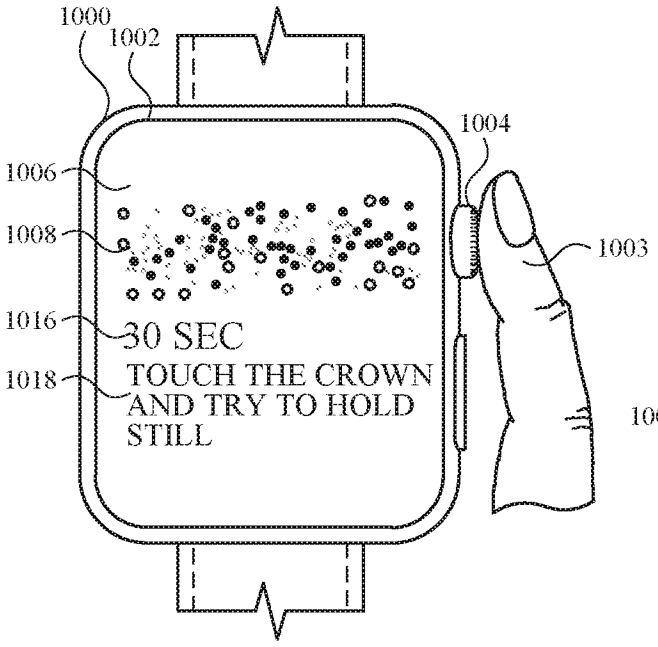


FIG. 10C

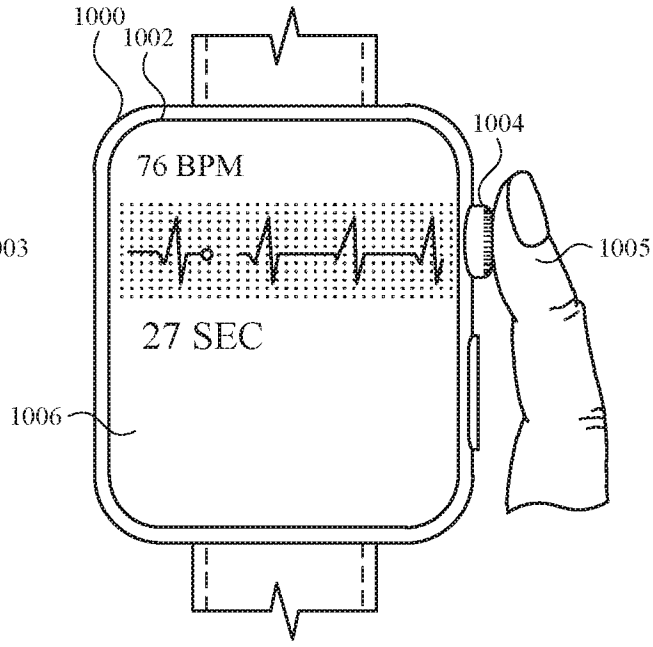


FIG. 10D

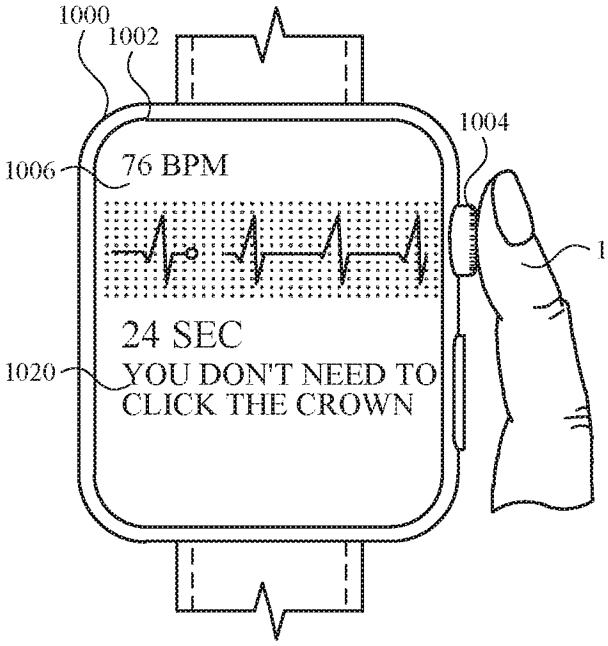


FIG.10E

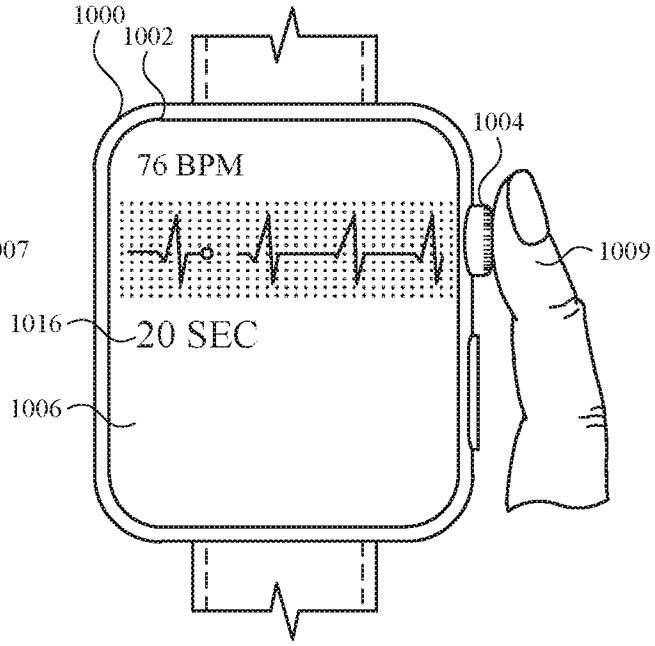


FIG. 10F

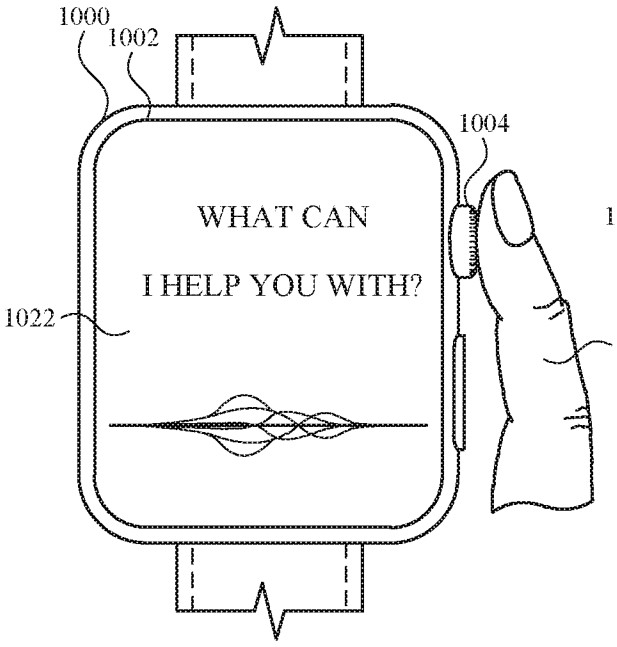


FIG. 10G

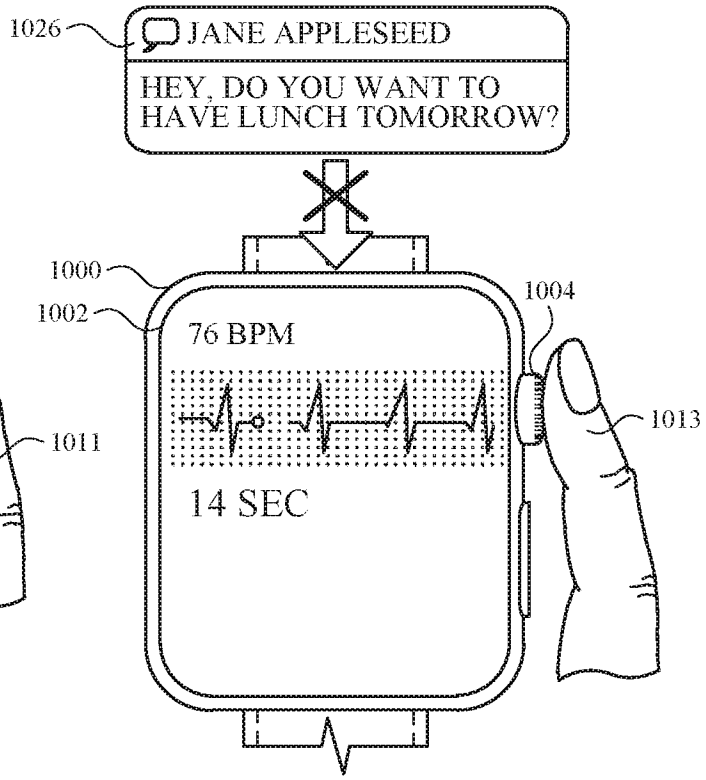


FIG. 10H

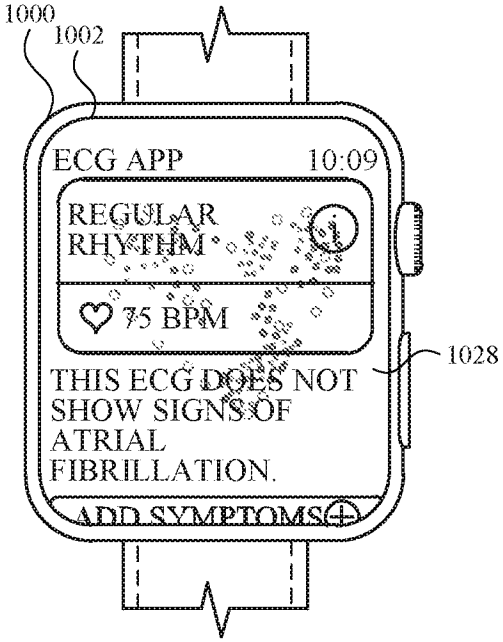


FIG.10I

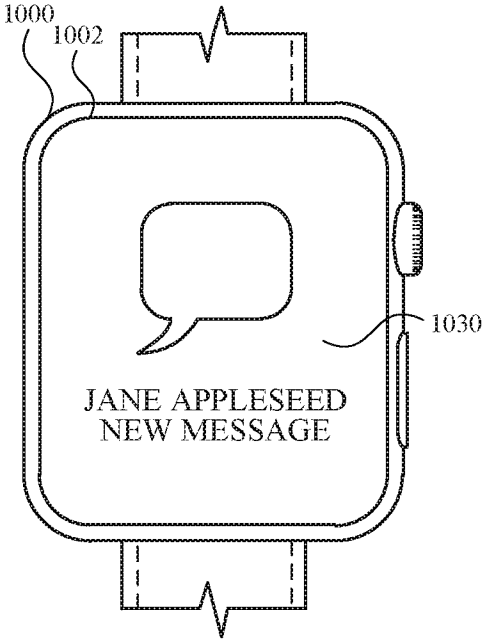


FIG. 10J

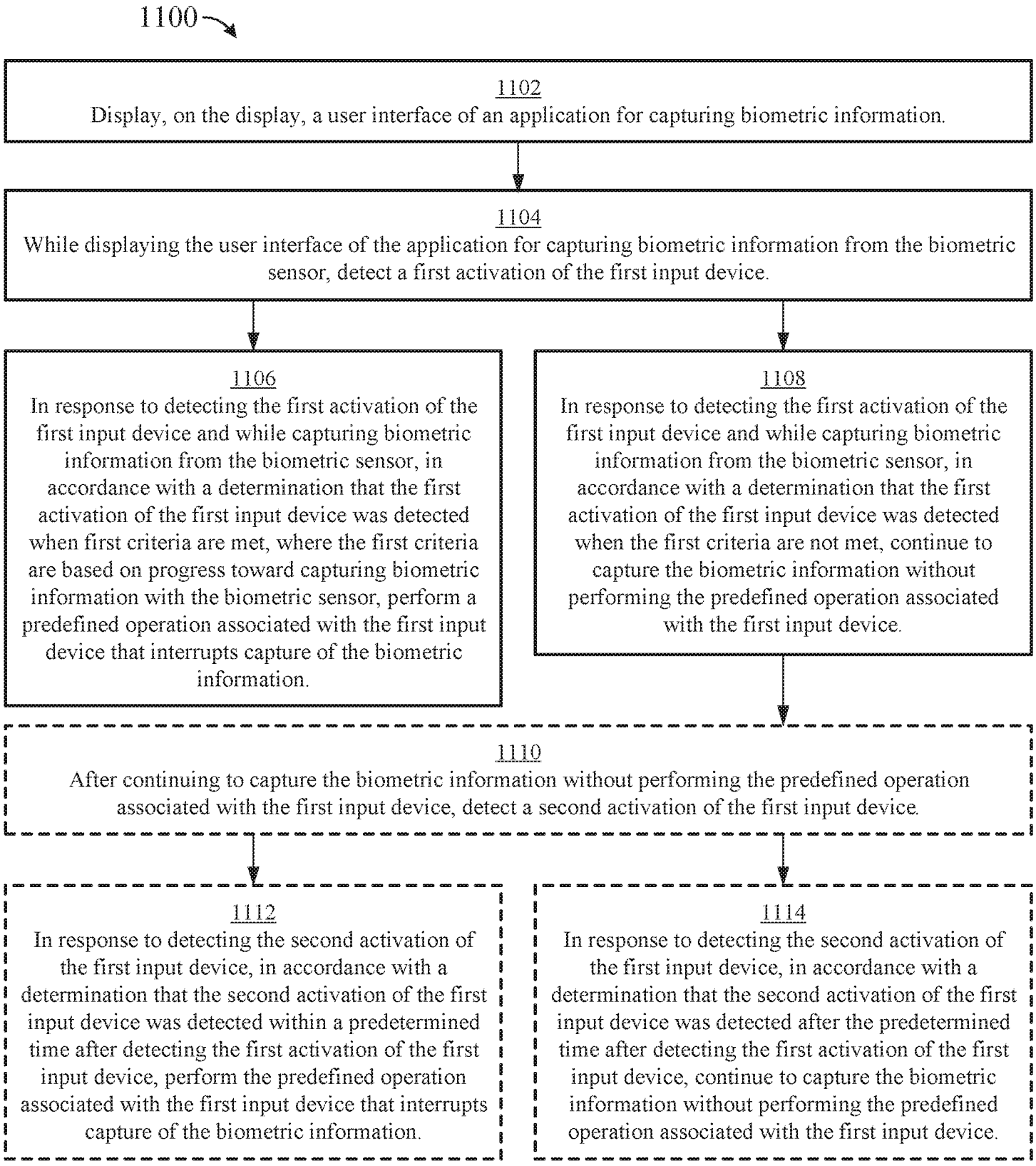

1100
1102
Display, on the display, a user interface of an application for capturing biometric information.
1104
While displaying the user interface of the application for capturing biometric information from the biometric sensor, detect a first activation of the first input device.
1106
In response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor, in accordance with a determination that the first activation of the first input device was detected when first criteria are met, where the first criteria are based on progress toward capturing biometric information with the biometric sensor, perform a predefined operation associated with the first input device that interrupts capture of the biometric information.
1108
In response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor, in accordance with a determination that the first activation of the first input device was detected when the first criteria are not met, continue to capture the biometric information without performing the predefined operation associated with the first input device.
1110
After continuing to capture the biometric information without performing the predefined operation associated with the first input device, detect a second activation of the first input device.
1112
In response to detecting the second activation of the first input device, in accordance with a determination that the second activation of the first input device was detected within a predetermined time after detecting the first activation of the first input device, perform the predefined operation associated with the first input device that interrupts capture of the biometric information.
1114
In response to detecting the second activation of the first input device, in accordance with a determination that the second activation of the first input device was detected after the predetermined time after detecting the first activation of the first input device, continue to capture the biometric information without performing the predefined operation associated with the first input device.

FIG. 11

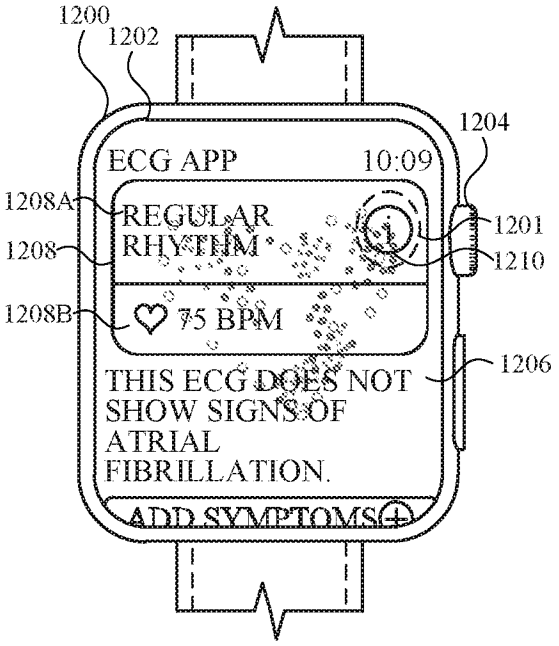


FIG.12A

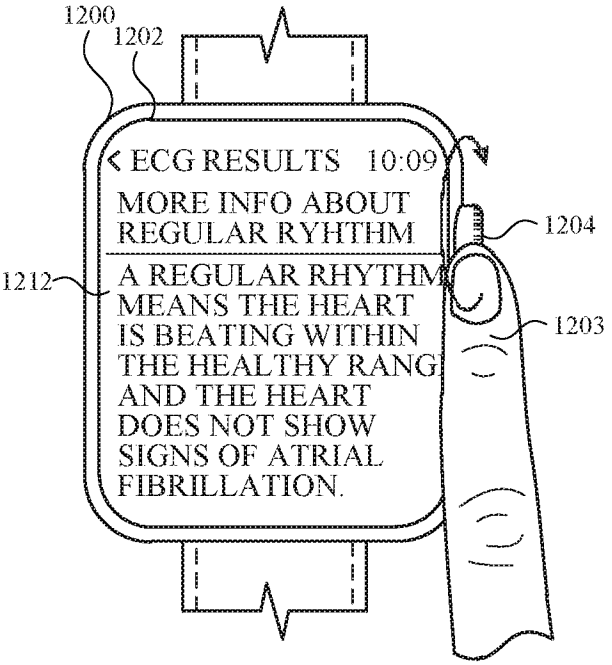


FIG. 12B

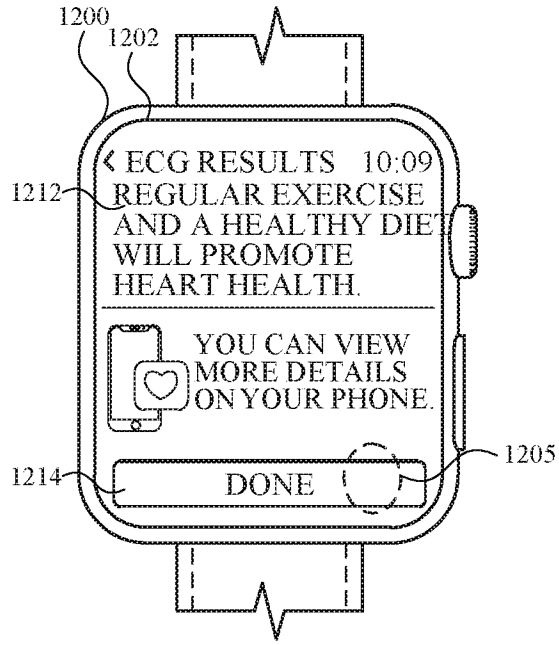


FIG. 12C

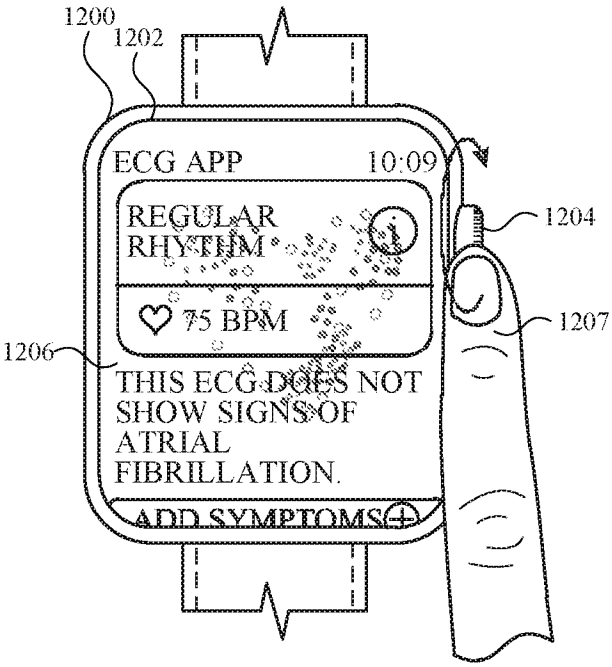


FIG. 12D

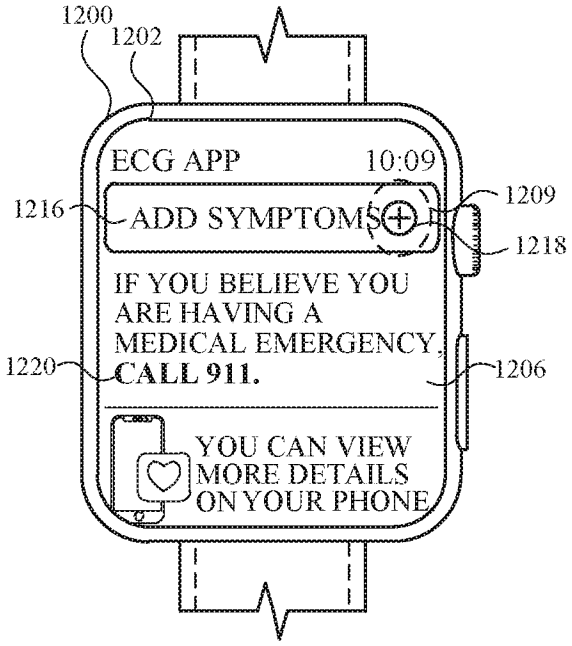


FIG.12E

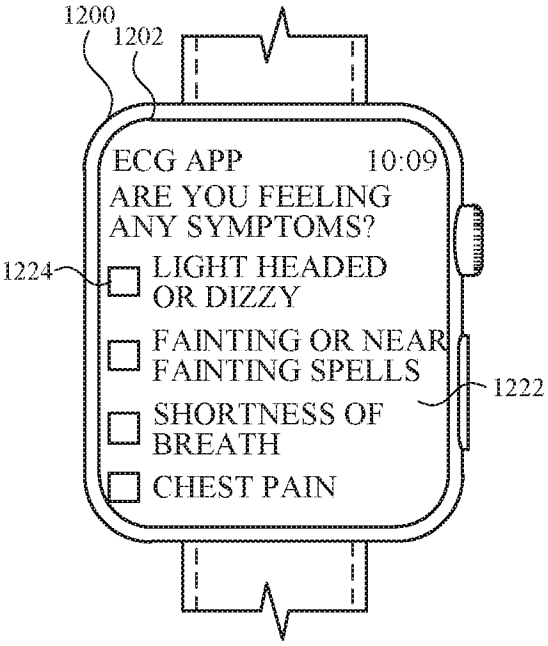


FIG. 12F

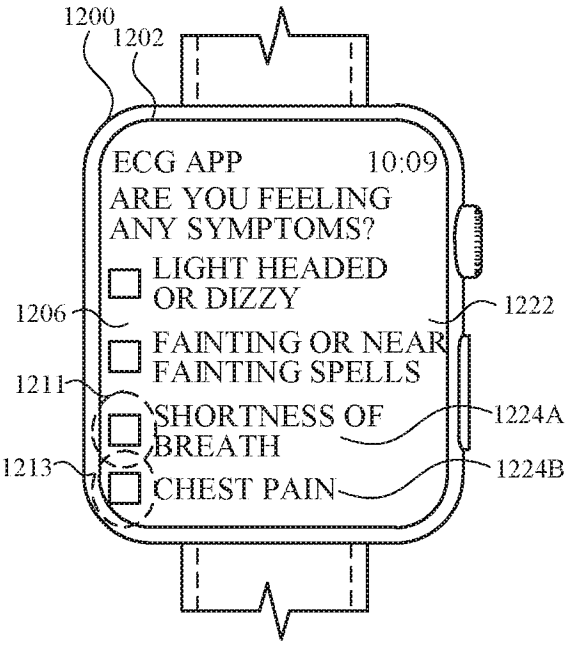


FIG. 12G

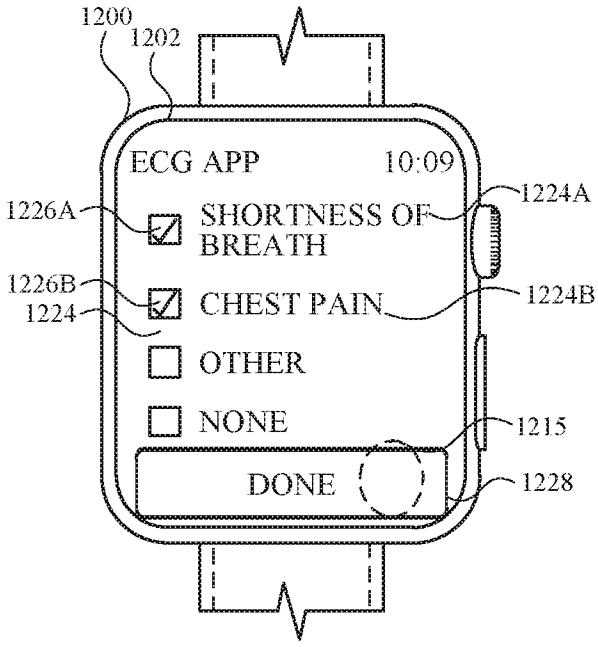


FIG. 12H

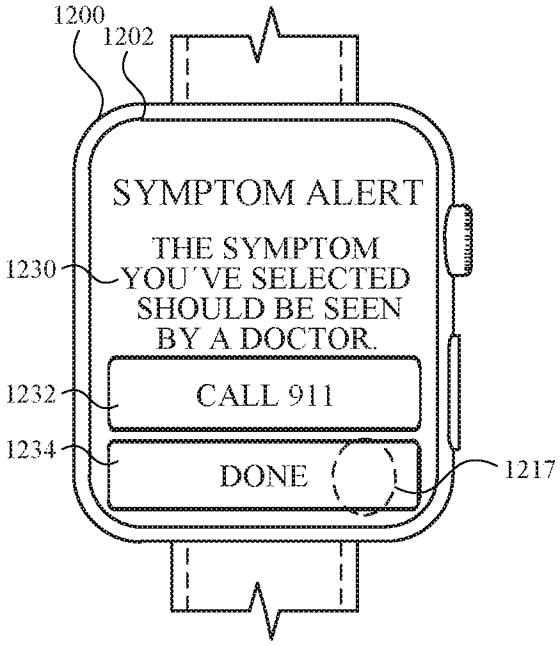


FIG.12I

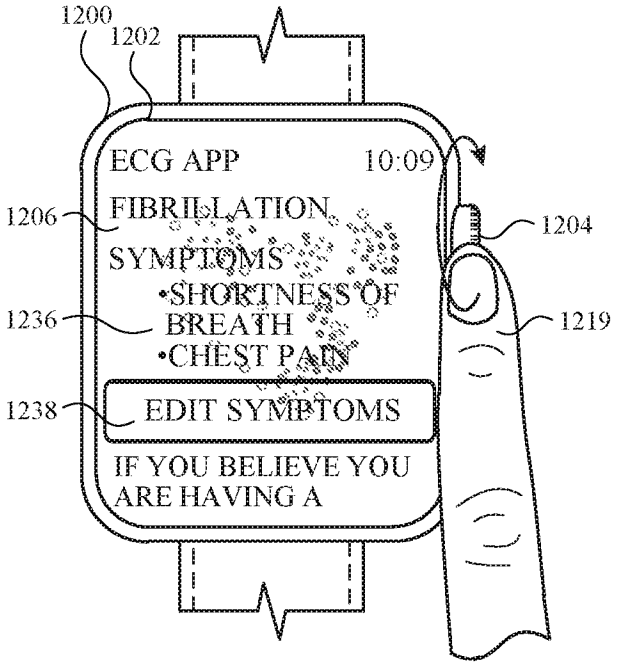


FIG. 12J

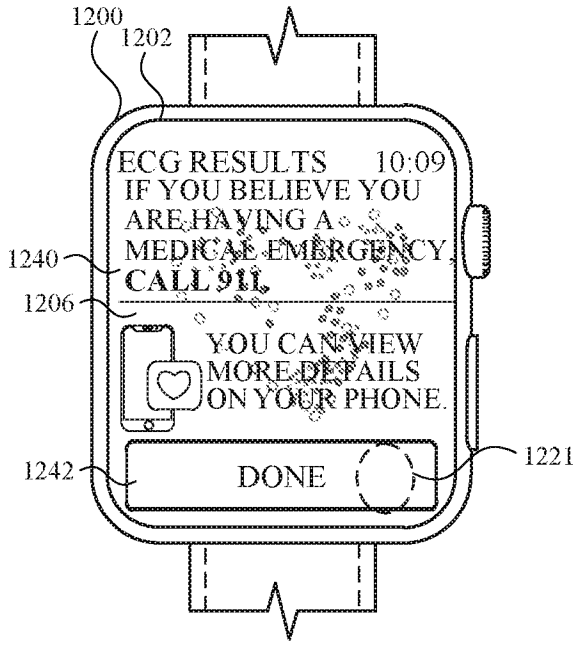


FIG. 12K

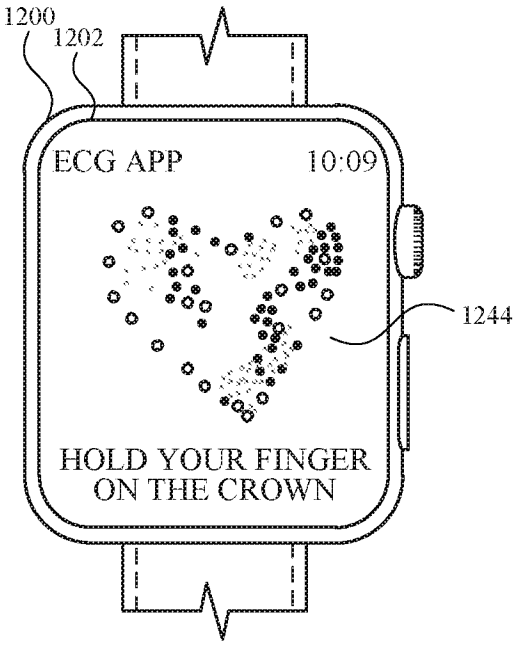


FIG. 12L

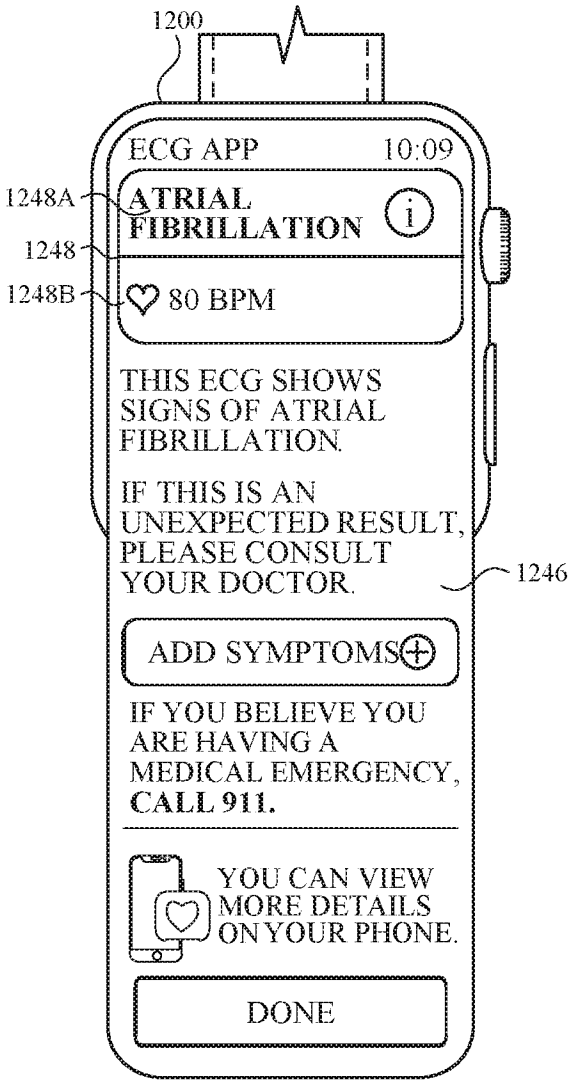


FIG. 12M

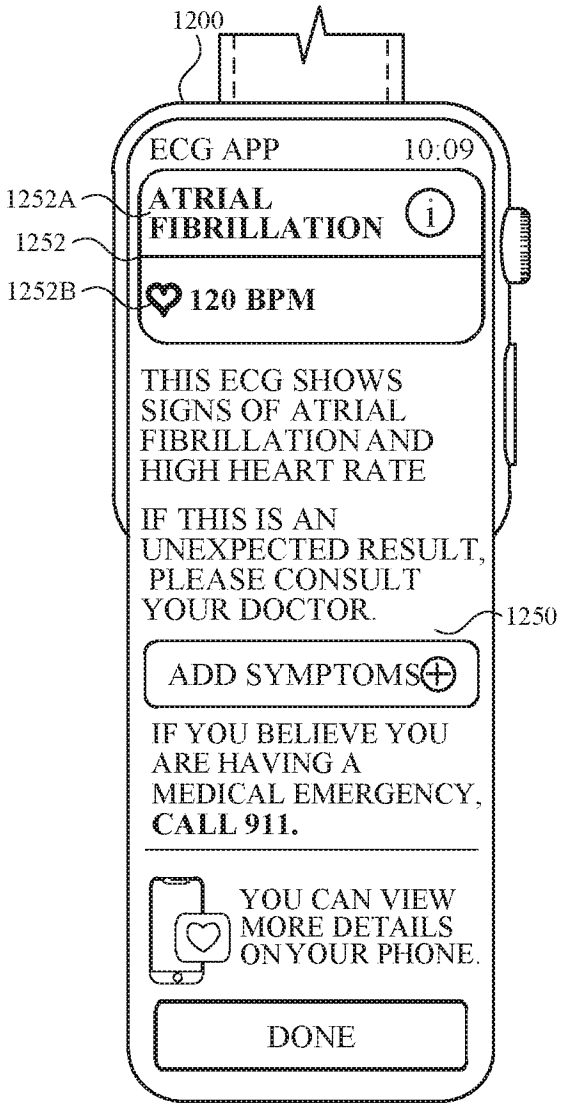


FIG. 12N

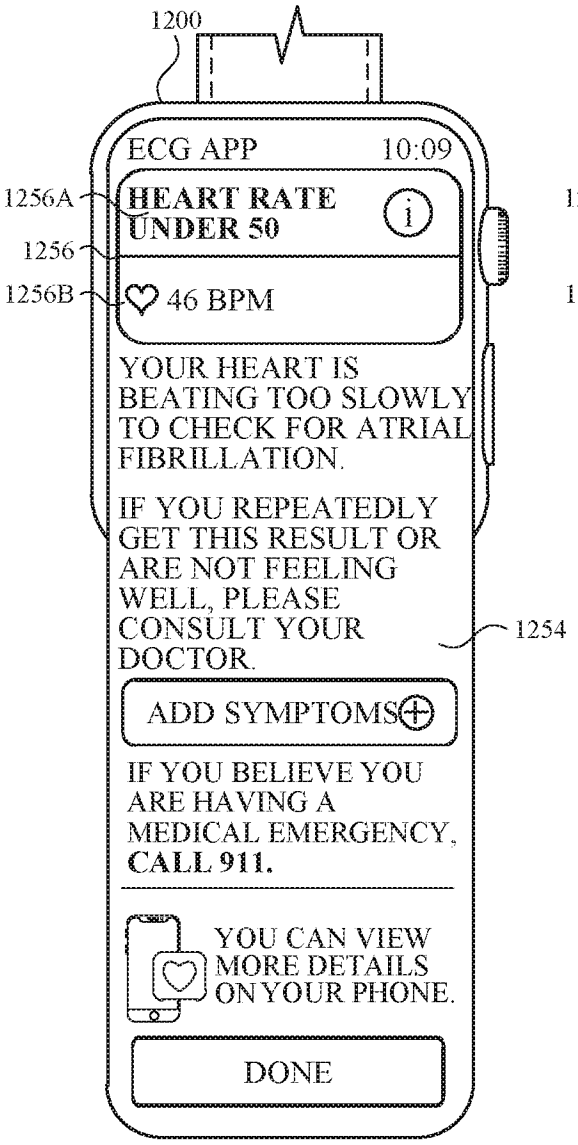


FIG. 12O

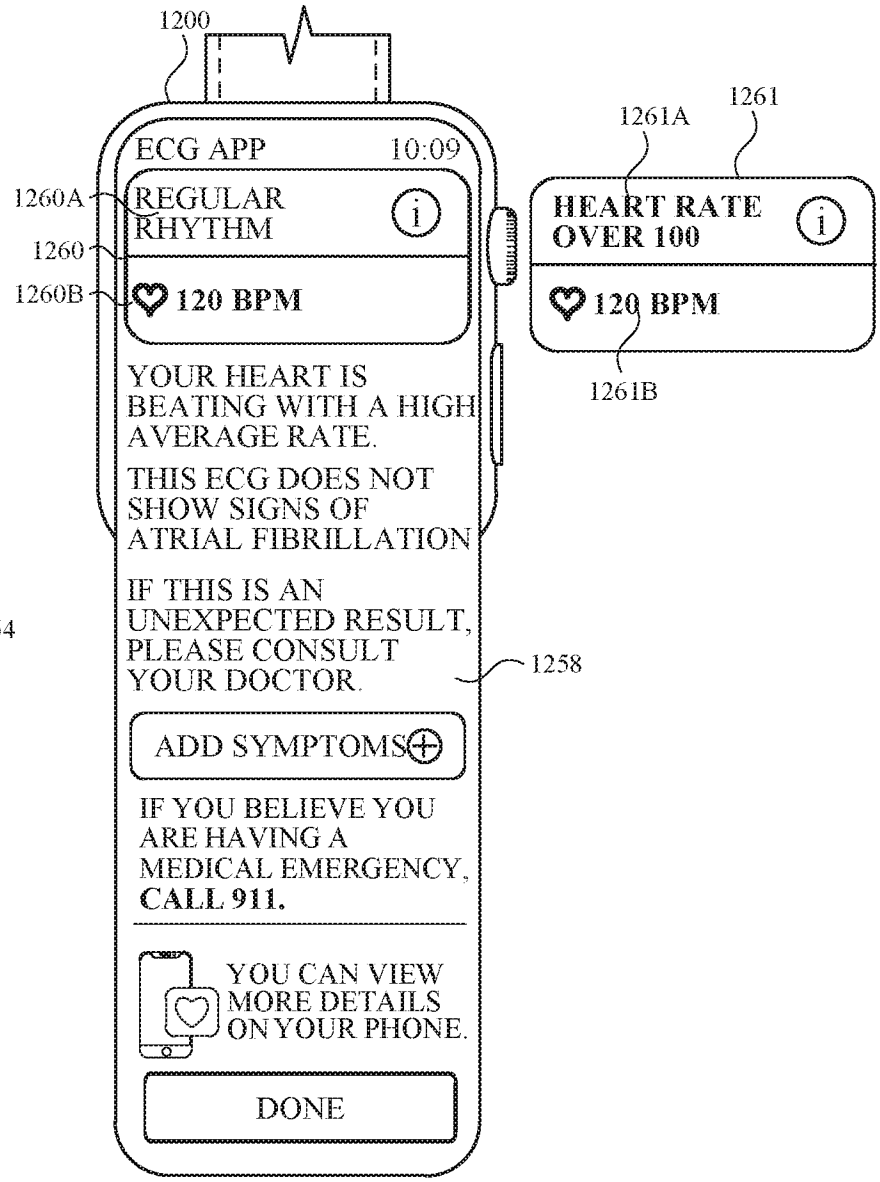


FIG. 12P

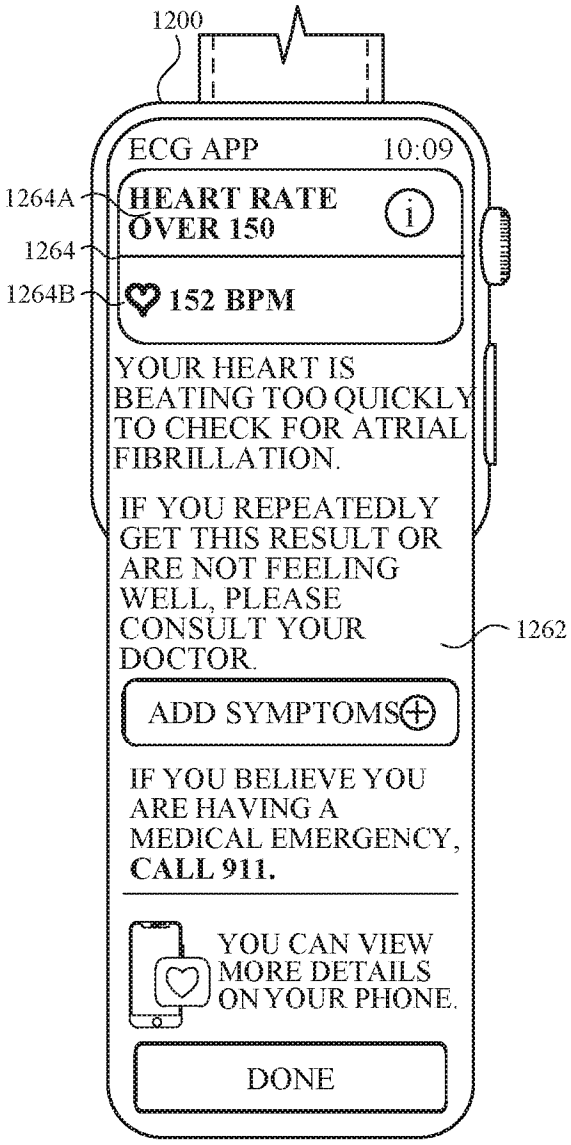


FIG. 12Q

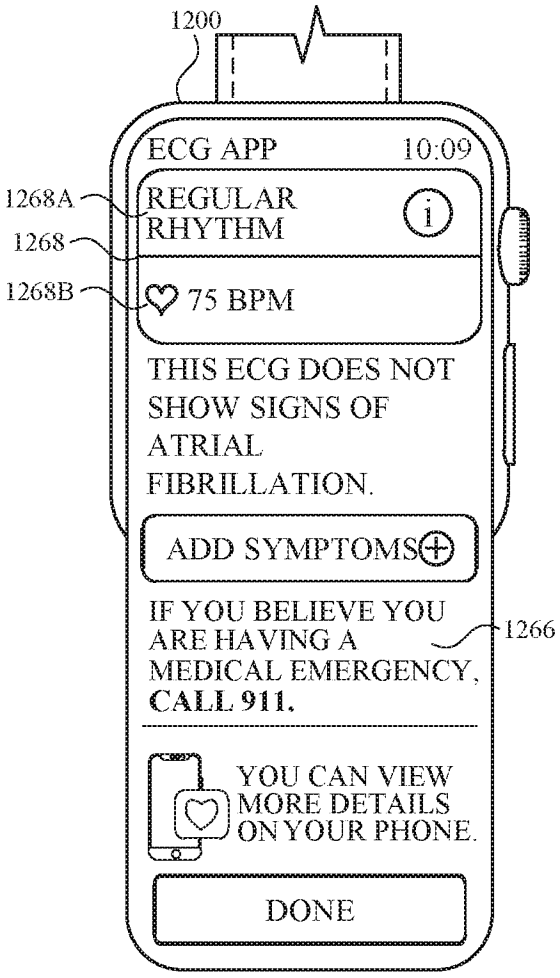


FIG. 12R

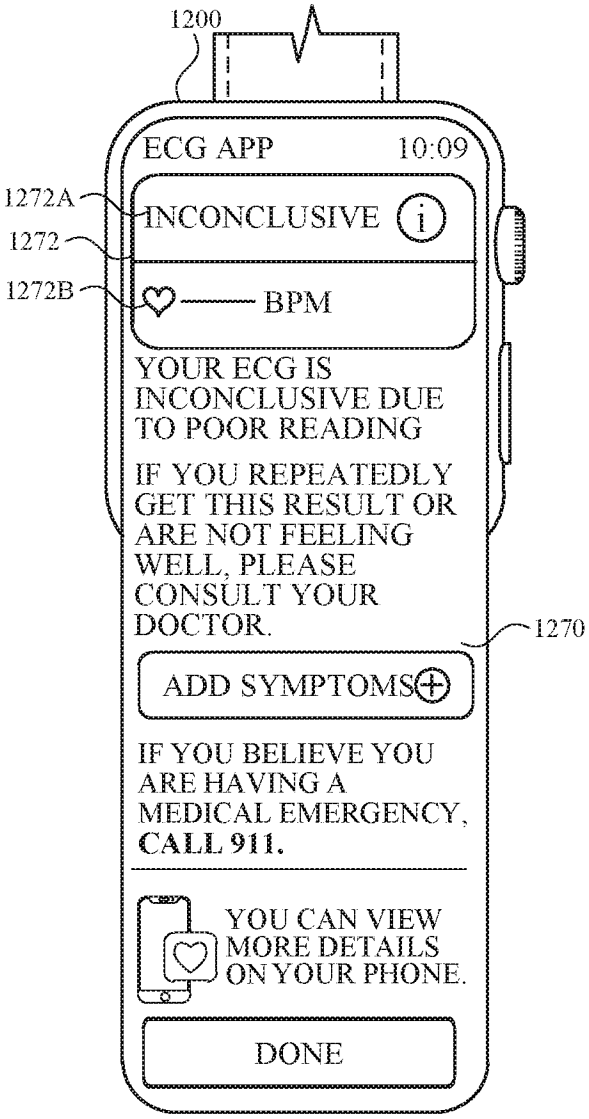

1200
ECG APP
10:09
1272A
INCONCLUSIVE
1272
1272B
BPM
YOUR ECG IS INCONCLUSIVE DUE TO POOR READING
IF YOU REPEATEDLY GET THIS RESULT OR ARE NOT FEELING WELL, PLEASE CONSULT YOUR DOCTOR.
1270
ADD SYMPTOMS
IF YOU BELIEVE YOU ARE HAVING A MEDICAL EMERGENCY, CALL 911.
YOU CAN VIEW MORE DETAILS ON YOUR PHONE.
DONE

FIG. 12S

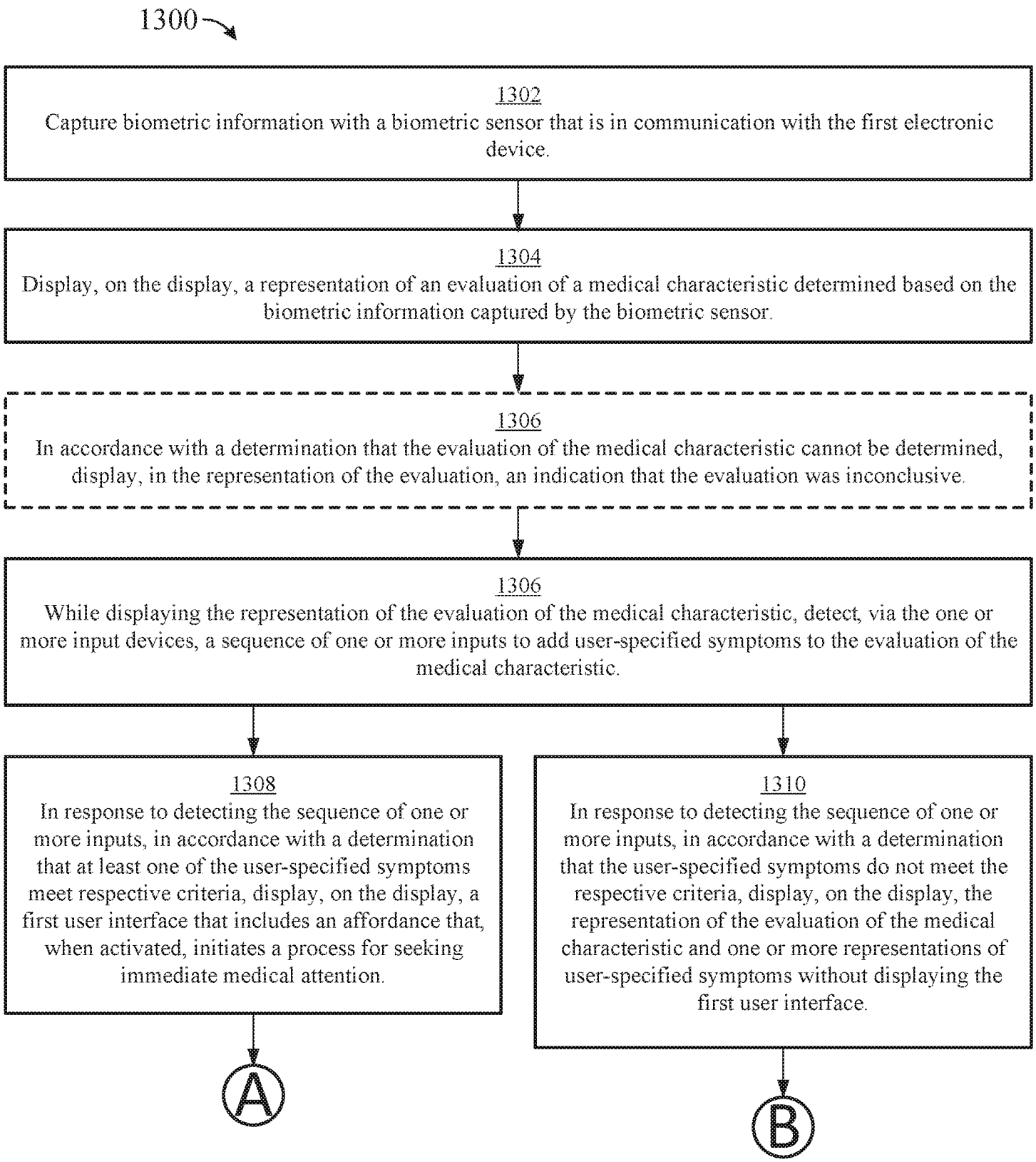

1300
1302
Capture biometric information with a biometric sensor that is in communication with the first electronic device.
1304
Display, on the display, a representation of an evaluation of a medical characteristic determined based on the biometric information captured by the biometric sensor.
1306
In accordance with a determination that the evaluation of the medical characteristic cannot be determined, display, in the representation of the evaluation, an indication that the evaluation was inconclusive.
1306
While displaying the representation of the evaluation of the medical characteristic, detect, via the one or more input devices, a sequence of one or more inputs to add user-specified symptoms to the evaluation of the medical characteristic.
1308
In response to detecting the sequence of one or more inputs, in accordance with a determination that at least one of the user-specified symptoms meet respective criteria, display, on the display, a first user interface that includes an affordance that, when activated, initiates a process for seeking immediate medical attention.
1310
In response to detecting the sequence of one or more inputs, in accordance with a determination that the user-specified symptoms do not meet the respective criteria, display, on the display, the representation of the evaluation of the medical characteristic and one or more representations of user-specified symptoms without displaying the first user interface.
A
B

FIG. 13A

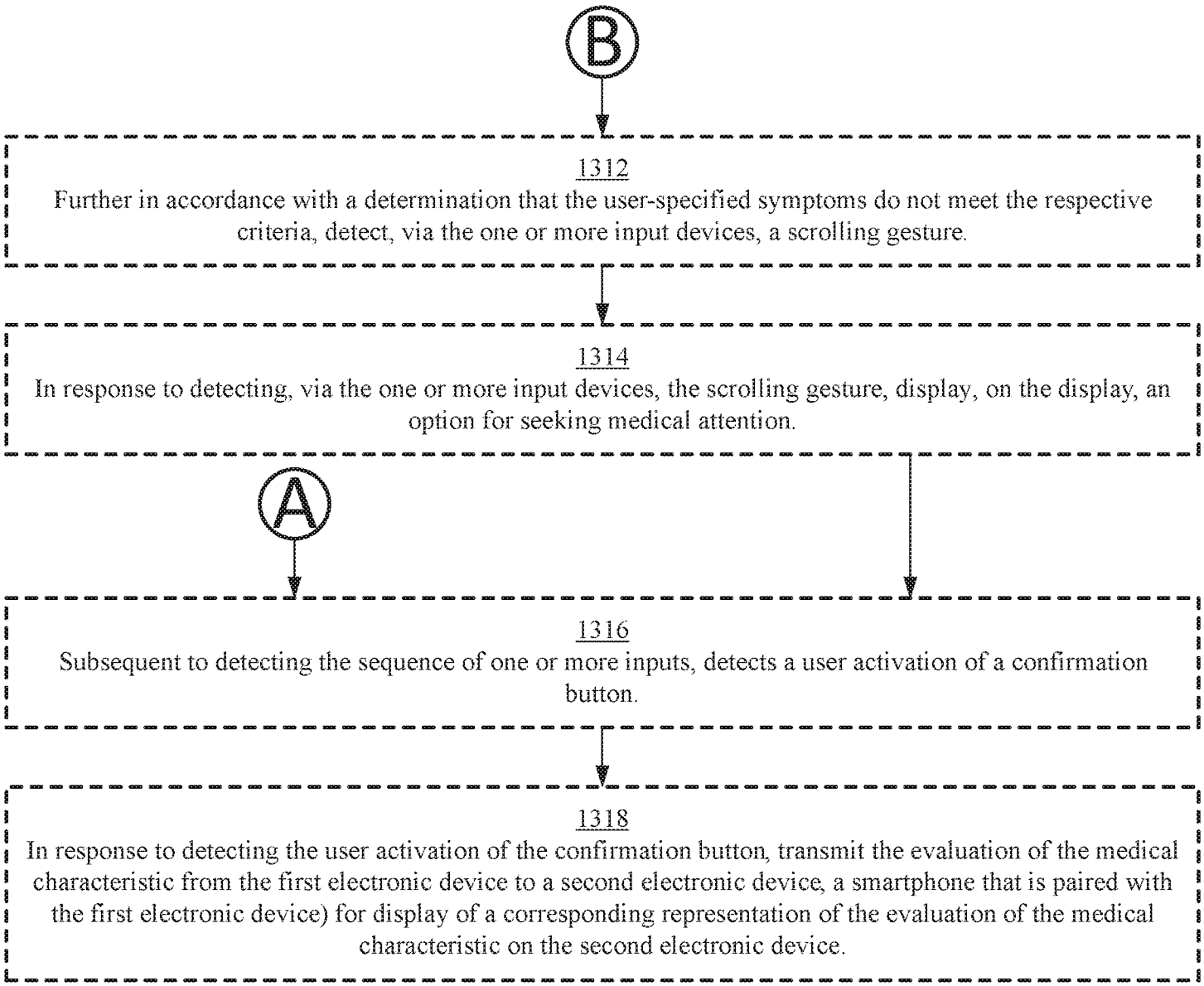

B
1312
Further in accordance with a determination that the user-specified symptoms do not meet the respective criteria, detect, via the one or more input devices, a scrolling gesture.
1314
In response to detecting, via the one or more input devices, the scrolling gesture, display, on the display, an option for seeking medical attention.
A
1316
Subsequent to detecting the sequence of one or more inputs, detects a user activation of a confirmation button.
1318
In response to detecting the user activation of the confirmation button, transmit the evaluation of the medical characteristic from the first electronic device to a second electronic device, a smartphone that is paired with the first electronic device) for display of a corresponding representation of the evaluation of the medical characteristic on the second electronic device.

FIG. 13B

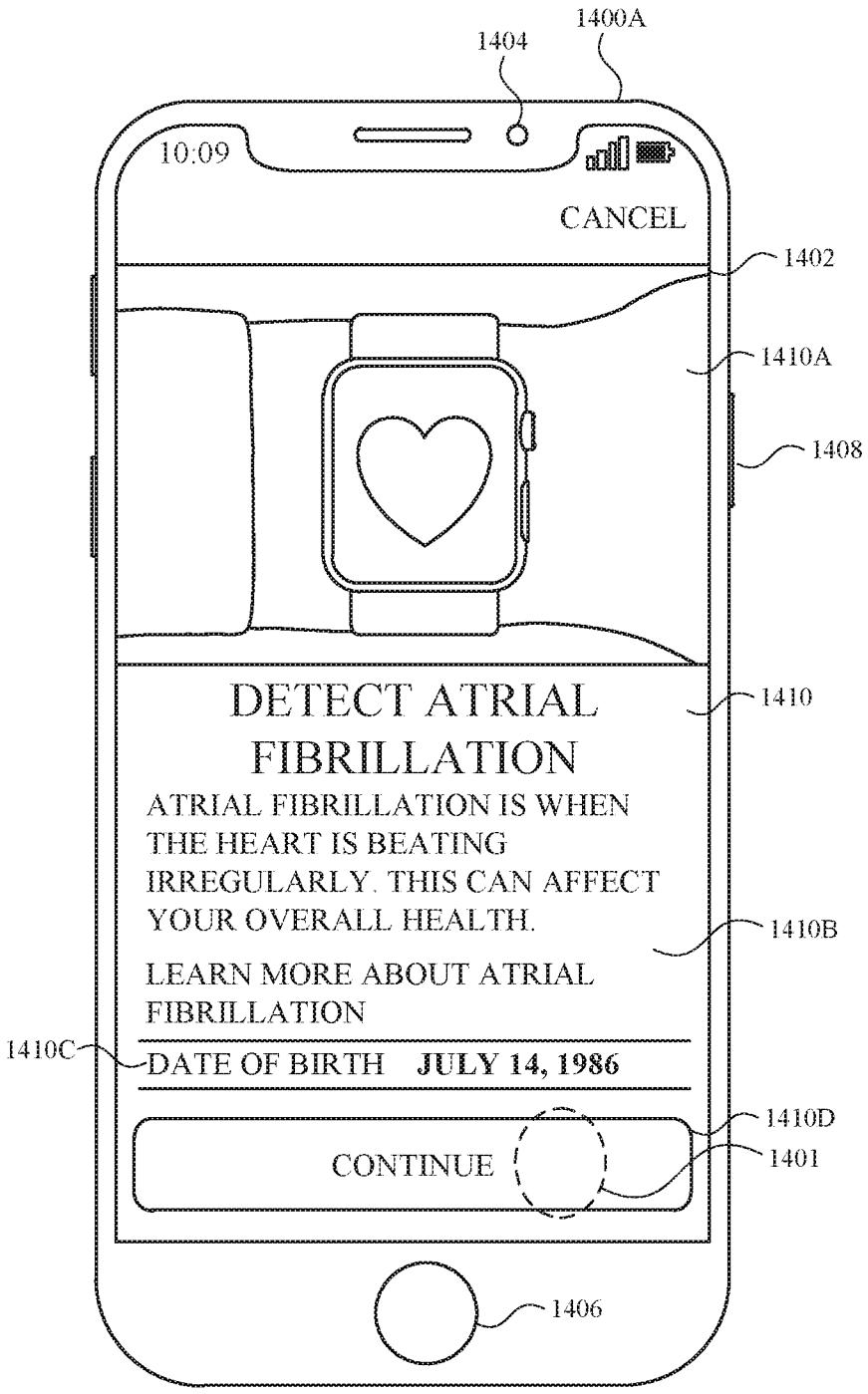

1400A
1404
10:09
CANCEL
1402
1410A
1408
DETECT ATRIAL FIBRILLATION
1410
ATRIAL FIBRILLATION IS WHEN THE HEART IS BEATING IRREGULARLY. THIS CAN AFFECT YOUR OVERALL HEALTH.
1410B
LEARN MORE ABOUT ATRIAL FIBRILLATION
1410C
DATE OF BIRTH JULY 14, 1986
1410D
CONTINUE
1401
1406

FIG. 14A

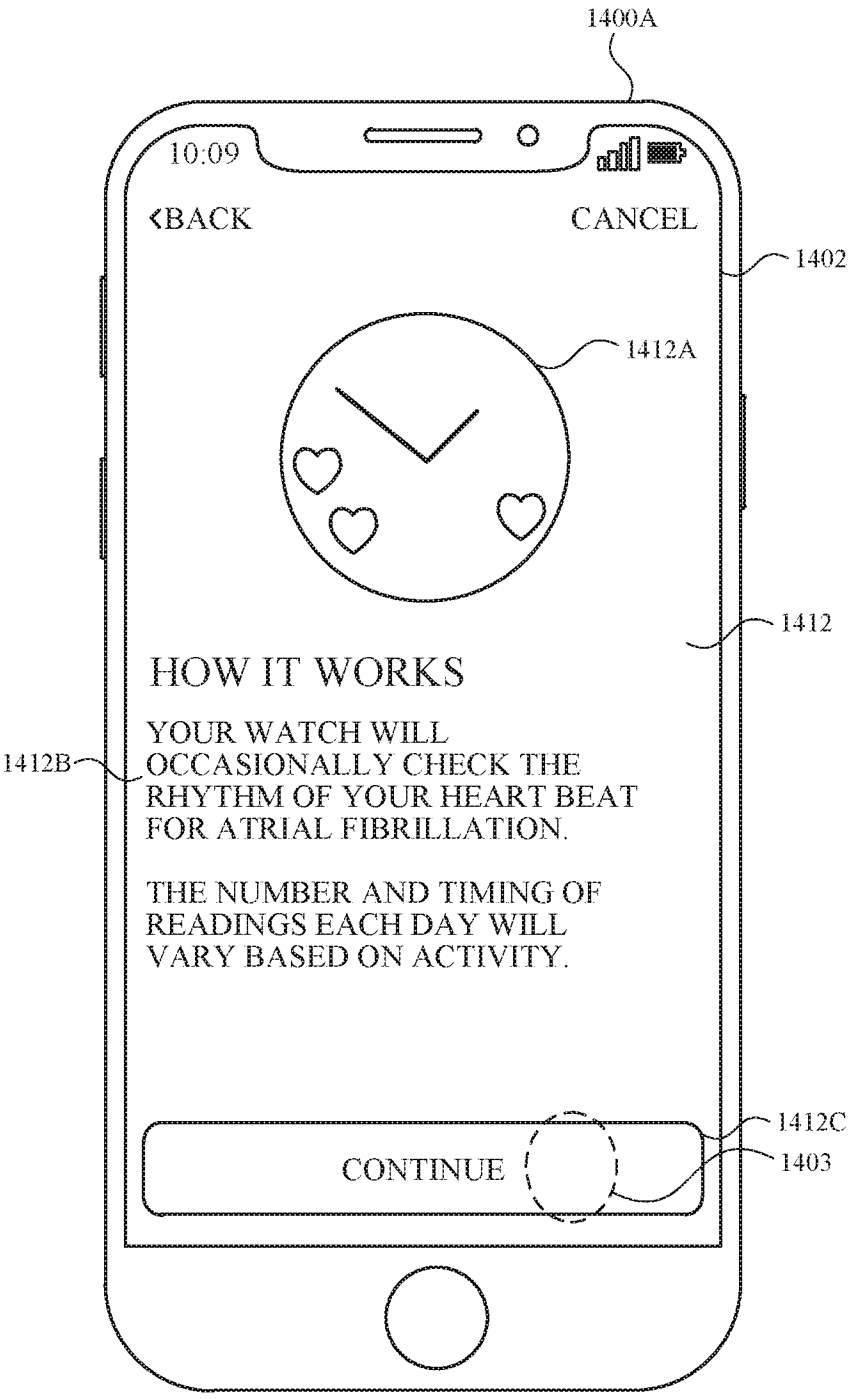

1400A
10:09
‹BACK
CANCEL
1402
1412A
1412
HOW IT WORKS
1412B
YOUR WATCH WILL OCCASIONALLY CHECK THE RHYTHM OF YOUR HEART BEAT FOR ATRIAL FIBRILLATION.
THE NUMBER AND TIMING OF READINGS EACH DAY WILL VARY BASED ON ACTIVITY.
1412C
CONTINUE
1403

FIG. 14B

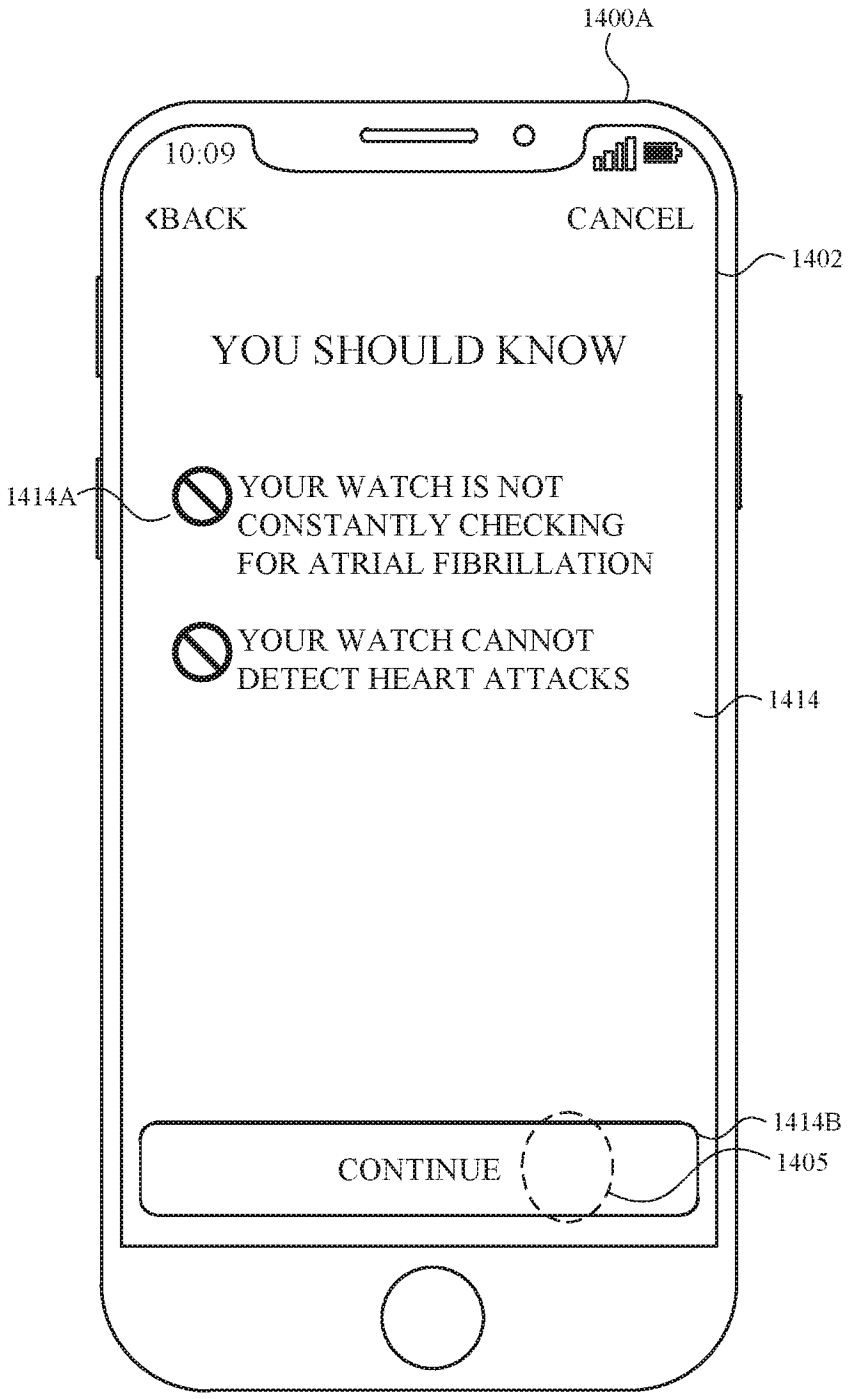

1400A
10:09
‹BACK
CANCEL
1402
YOU SHOULD KNOW
1414A
YOUR WATCH IS NOT CONSTANTLY CHECKING FOR ATRIAL FIBRILLATION
YOUR WATCH CANNOT DETECT HEART ATTACKS
1414
1414B
CONTINUE
1405

FIG. 14C

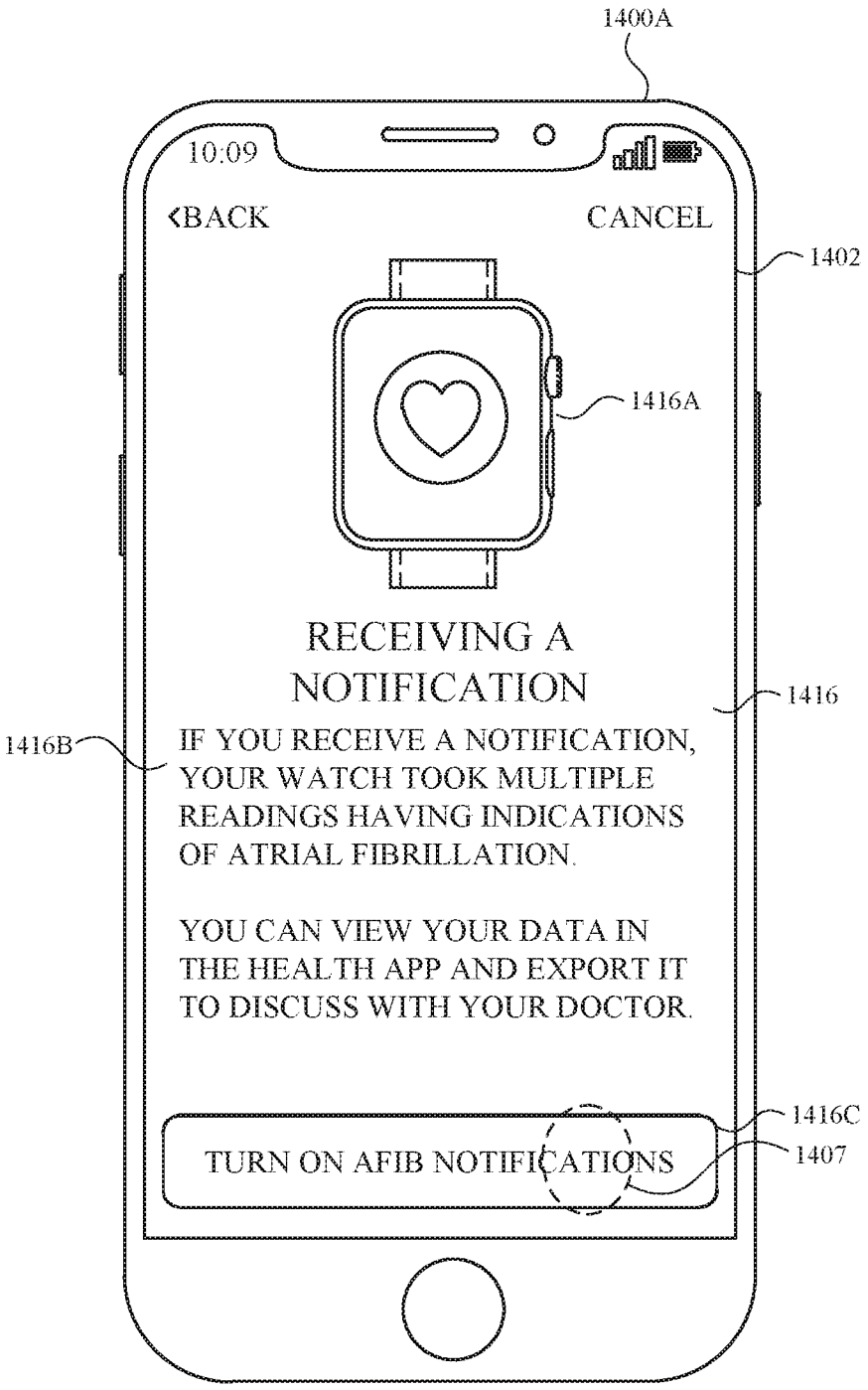

1400A
10:09
‹BACK
CANCEL
1402
1416A
RECEIVING A NOTIFICATION
1416
1416B
IF YOU RECEIVE A NOTIFICATION, YOUR WATCH TOOK MULTIPLE READINGS HAVING INDICATIONS OF ATRIAL FIBRILLATION.
YOU CAN VIEW YOUR DATA IN THE HEALTH APP AND EXPORT IT TO DISCUSS WITH YOUR DOCTOR.
1416C
TURN ON AFIB NOTIFICATIONS
1407

FIG. 14D

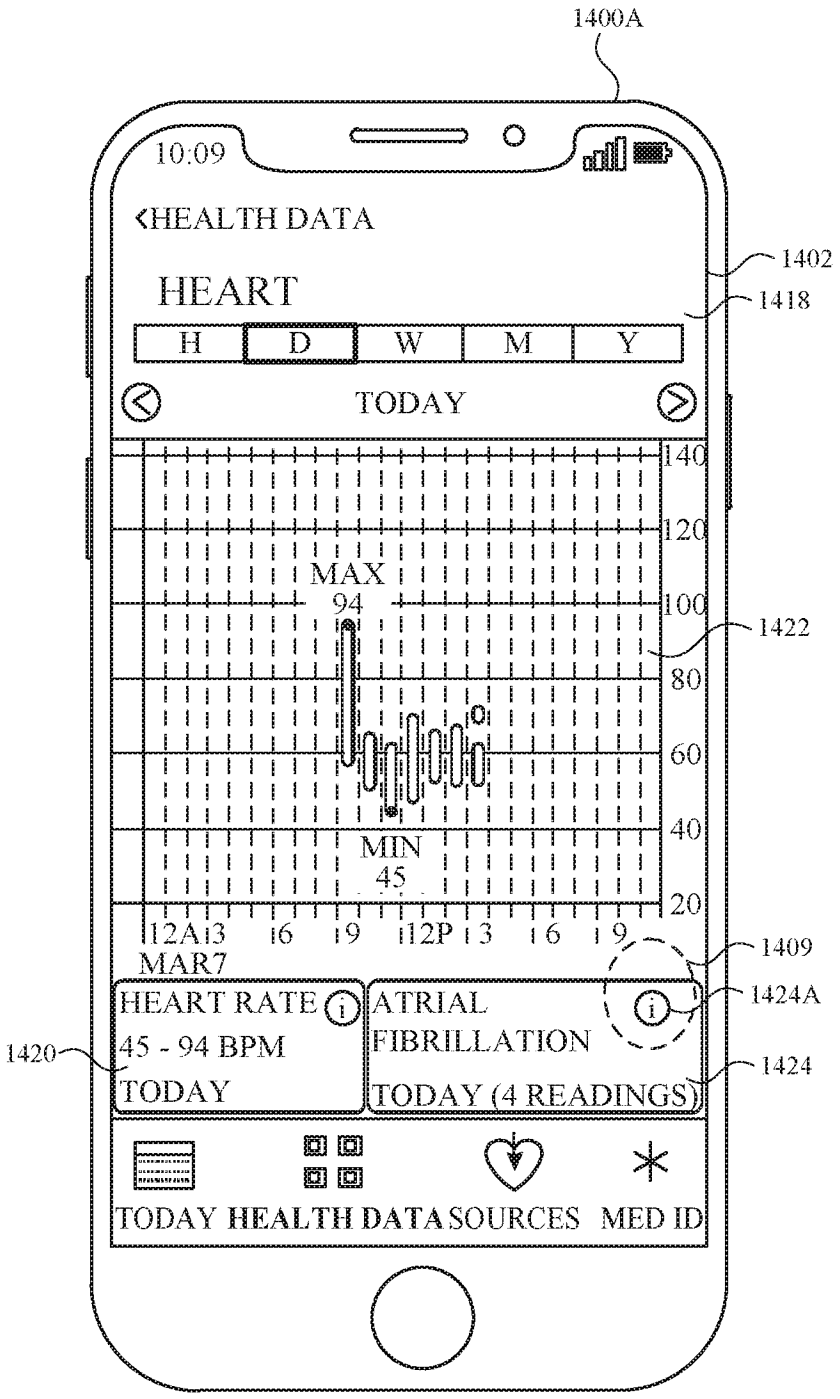

1400A
10:09
HEALTH DATA
1402
HEART
1418
H
D
W
M
Y
TODAY
140
120
MAX
94
100
1422
80
60
40
MIN
45
20
12A
3
6
9
12P
3
6
9
MAR7
1409
HEART RATE
45 - 94 BPM
TODAY
ATRIAL
FIBRILLATION
1424A
1420
TODAY (4 READINGS)
1424
TODAY
HEALTH DATA
SOURCES
MED ID

FIG. 14E

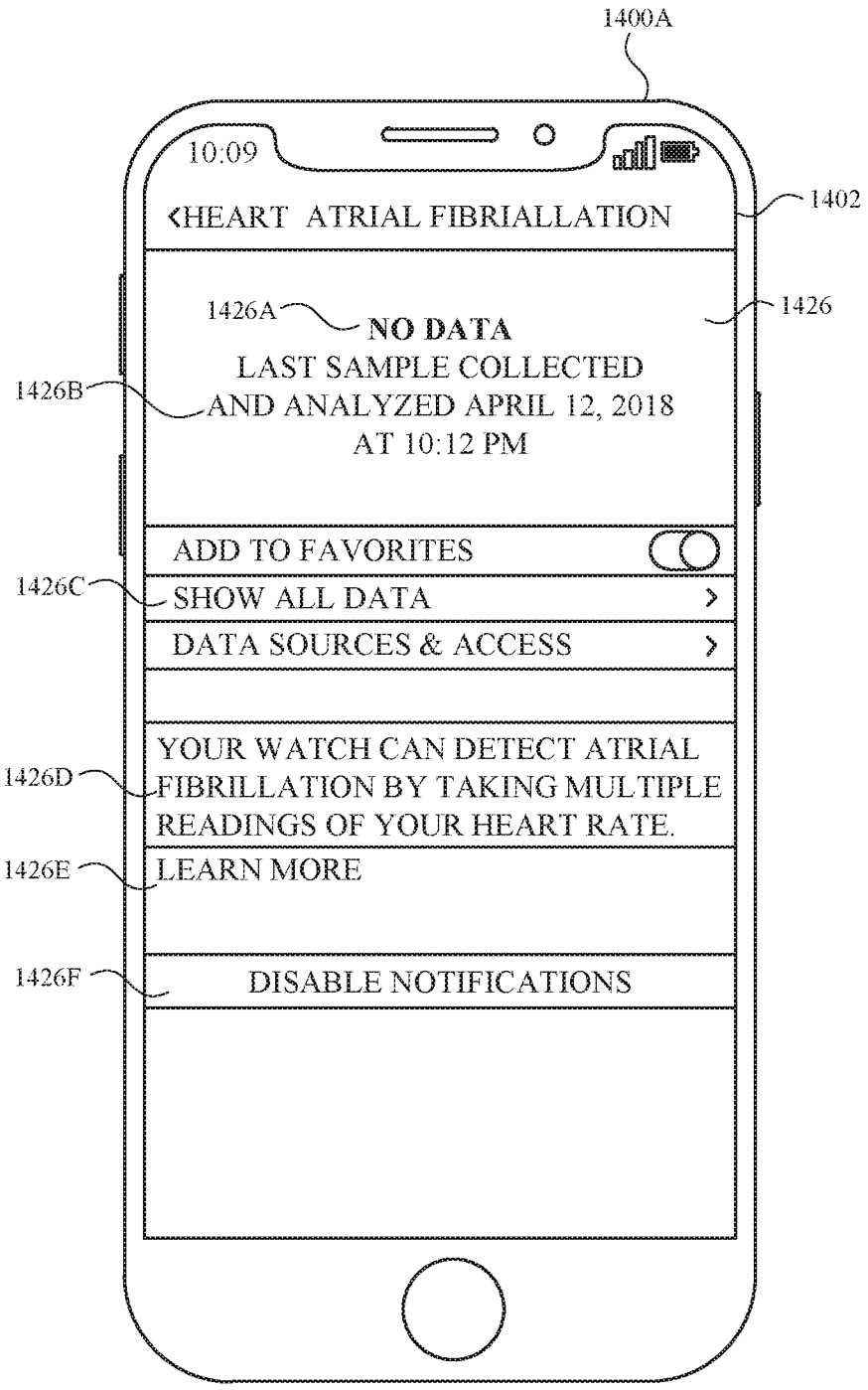

1400A
10:09
‹HEART ATRIAL FIBRIALLATION
1402
1426A
NO DATA
1426
1426B
LAST SAMPLE COLLECTED
AND ANALYZED APRIL 12, 2018
AT 10:12 PM
ADD TO FAVORITES
1426C
SHOW ALL DATA ›
DATA SOURCES & ACCESS ›
1426D
YOUR WATCH CAN DETECT ATRIAL
FIBRILLATION BY TAKING MULTIPLE
READINGS OF YOUR HEART RATE.
1426E
LEARN MORE
1426F
DISABLE NOTIFICATIONS

FIG. 14F

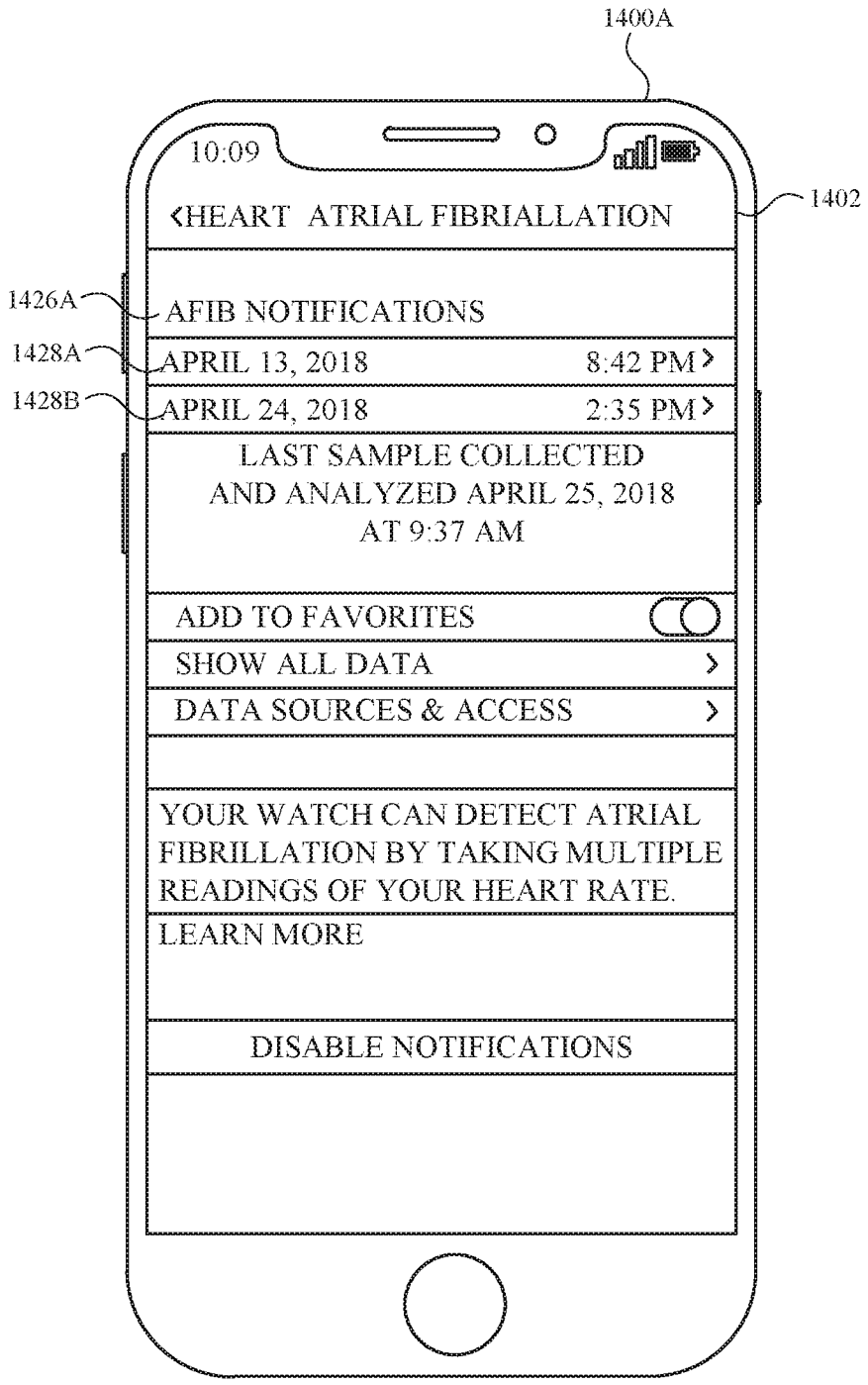

1400A
10:09
1402
HEART ATRIAL FIBRIALLATION
1426A
AFIB NOTIFICATIONS
1428A
APRIL 13, 2018 8:42 PM
1428B
APRIL 24, 2018 2:35 PM
LAST SAMPLE COLLECTED
AND ANALYZED APRIL 25, 2018
AT 9:37 AM
ADD TO FAVORITES
SHOW ALL DATA
DATA SOURCES & ACCESS
YOUR WATCH CAN DETECT ATRIAL FIBRILLATION BY TAKING MULTIPLE READINGS OF YOUR HEART RATE.
LEARN MORE
DISABLE NOTIFICATIONS

FIG. 14G

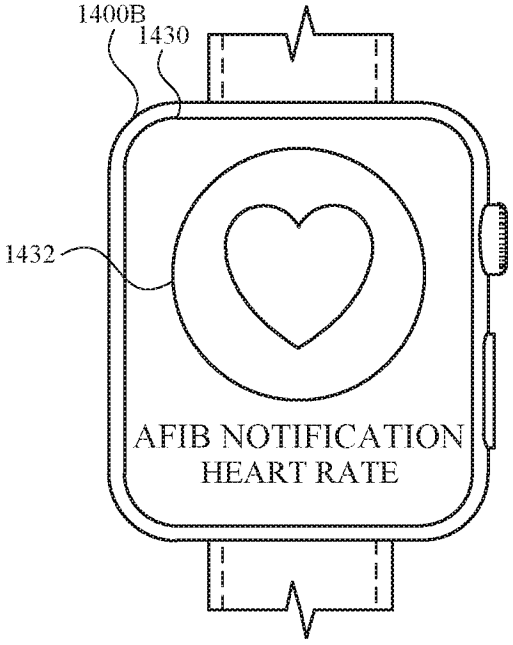


FIG. 14H

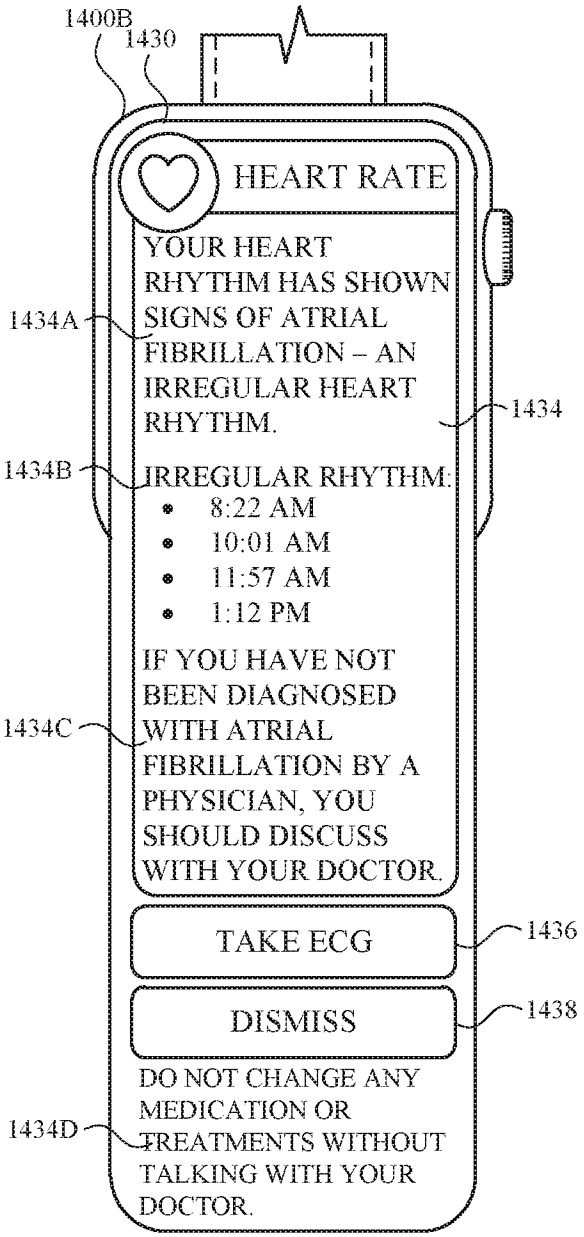


FIG. 14I

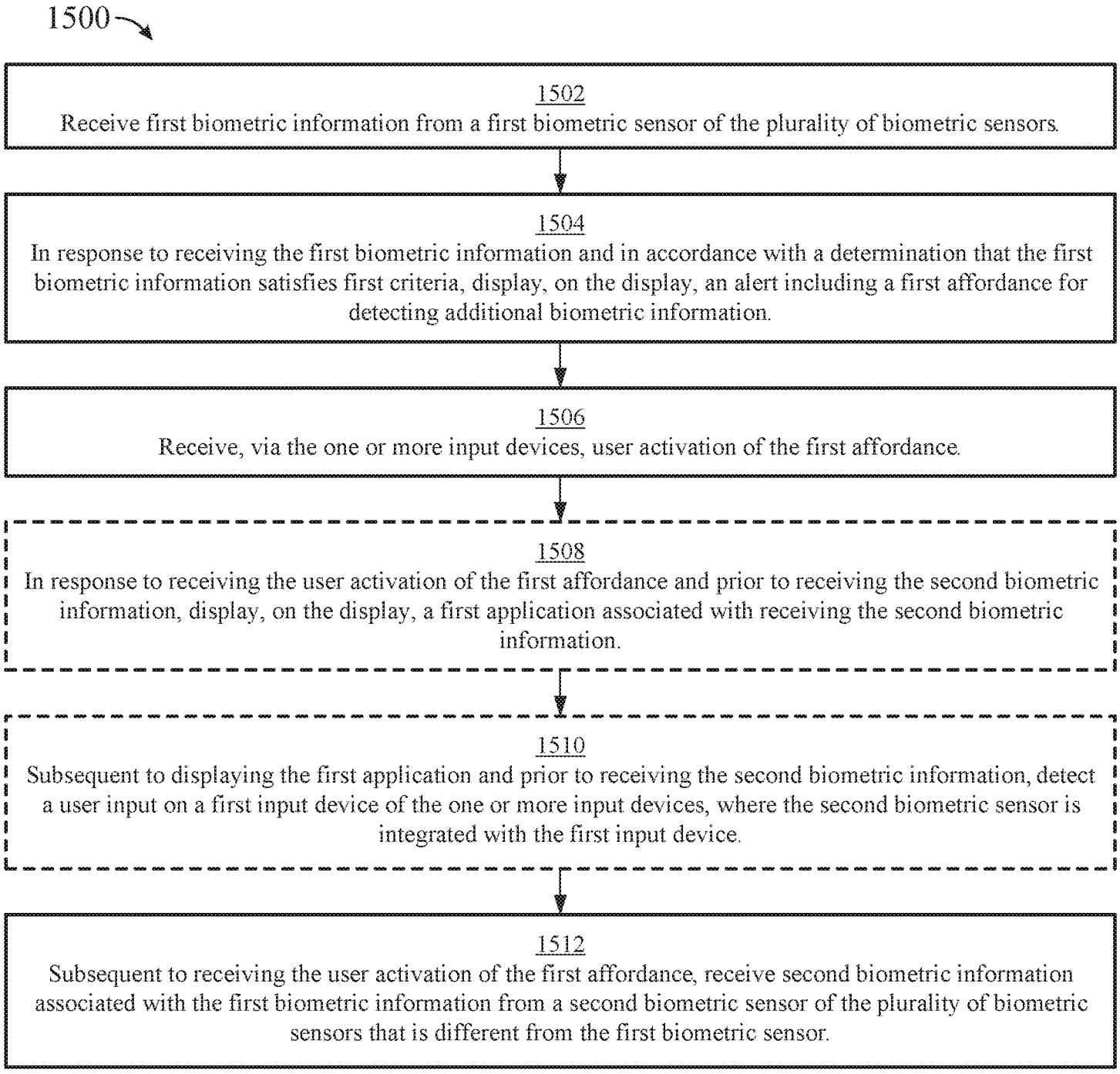

1500
1502
Receive first biometric information from a first biometric sensor of the plurality of biometric sensors.
1504
In response to receiving the first biometric information and in accordance with a determination that the first biometric information satisfies first criteria, display, on the display, an alert including a first affordance for detecting additional biometric information.
1506
Receive, via the one or more input devices, user activation of the first affordance.
1508
In response to receiving the user activation of the first affordance and prior to receiving the second biometric information, display, on the display, a first application associated with receiving the second biometric information.
1510
Subsequent to displaying the first application and prior to receiving the second biometric information, detect a user input on a first input device of the one or more input devices, where the second biometric sensor is integrated with the first input device.
1512
Subsequent to receiving the user activation of the first affordance, receive second biometric information associated with the first biometric information from a second biometric sensor of the plurality of biometric sensors that is different from the first biometric sensor.

FIG. 15

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
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Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

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State/Province	CA
Postal Code	95014
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Matthew	W.	CROWLEY	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
San Francisco	CA	US

Mailing Address of Inventor:

Address 1	c/o Apple Inc.
Address 2	One Apple Park Way
City	Cupertino
State/Province	CA
Postal Code	95014
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Bradley	W.	GRIFFIN	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

AliveCor Exhibit 1006
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

City	Berkeley	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Apple Inc.
Address 2	One Apple Park Way

City	Cupertino	State/Province	CA
Postal Code	95014	Country	US

Inventor 4 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gary	Ian	BUTCHER	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Mailing Address of Inventor:

Address 1	c/o Apple Inc.
Address 2	One Apple Park Way

City	Cupertino	State/Province	CA
Postal Code	95014	Country	US

Inventor 5 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Roxanne		BRITTAIN	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Berkeley	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Apple Inc.
Address 2	One Apple Park Way

City	Cupertino	State/Province	CA
Postal Code	95014	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. — Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1184 of 1413

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

Customer Number	150004		
Email Address	patents.us@dentons.com	Add Email	Remove Email

Application Information:

Title of the Invention	USER INTERFACES FOR HEALTH MONITORING		
Attorney Docket Number	P38213US2/77770000489102	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	76	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	150004		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62657870	2018-04-15
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62657881	2018-04-15
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62643699	2018-03-15
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62641994	2018-03-12

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Apple Inc.		
Mailing Address Information For Applicant:			
Address 1	One Apple Park Way		
Address 2			
City	Cupertino	**State/Province**	CA
Country	US	Postal Code	95014
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

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Signature:

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This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Brian B. Ho/			Date (YYYY-MM-DD)	2018-09-27
First Name	Brian	Last Name	Ho	Registration Number	60199

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P38213US2/77770000489102
	Application Number	
Title of Invention	USER INTERFACES FOR HEALTH MONITORING	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

AliveCor Exhibit 1002
AliveCor, Inc. v. Apple Inc.
IPR2024-00095, U.S. Patent No. 10,568,533
1192 of 1413

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Filer:	Brian B. Ho/Staci Berry
Attorney Docket Number:	P38213US2/77770000489102

Filed as Large Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4000	4000
Pages:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	1081	3	400	1200
Claims:				
Miscellaneous-Filing:				

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Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140

Petition:	
Patent-Appeals-and-Interference:	
Post-Allowance-and-Post-Issuance:	
Extension-of-Time:	
Miscellaneous:	
Total in USD ($)	**7060**

Electronic Acknowledgement Receipt

EFS ID:	33841816
Application Number:	16143959
International Application Number:	
Confirmation Number:	6224
Title of Invention:	USER INTERFACES FOR HEALTH MONITORING
First Named Inventor/Applicant Name:	Christopher D. SOLI
Customer Number:	150004
Filer:	Brian B. Ho/Staci Berry
Filer Authorized By:	Brian B. Ho
Attorney Docket Number:	P38213US2/77770000489102
Receipt Date:	27-SEP-2018
Filing Date:	
Time Stamp:	13:52:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$7060
RAM confirmation Number	092818INTEFSW13530500
Deposit Account	193140
Authorized User	Staci Berry

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

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37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2018_09_26_P38213US2_spec.pdf	542265 05fb94746ace0383dece379c34febfb1ab83616d	yes	154
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Abstract		154	154	
	Claims		148	153	
	Specification		1	147	
Warnings:					
Information:					
2	Appendix to the Specification	2018_09_26_P38213US1_appendix2.pdf	9029162 9aee38e4622e49e523b98b696b32dc6cfb39a944	no	60
Warnings:					
Information:					
3	TrackOne Request	2018_09_26_P38213US2_T1req.pdf	114436 44a0dba430fc733648c4a37a6532e32afded2bff	no	2
Warnings:					
Information:					
4	Power of Attorney	2018_09_26_P38213US2_poatrans.pdf	174275 4f8b6e618e3cee30595a0c5167667e38b7b2aed7	no	1
Warnings:					
Information:					
5	Power of Attorney	82POA_Apple.pdf	475107 [illegible]ddf47	no	1

Warnings:					
Information:					
6	Drawings-other than black and white line drawings	2018_09_26_P38213US2_drgs.pdf	2443260 48d659f9f7100ca17736d2ddff27468ed903e9a1	no	76
Warnings:					
Information:					
7	Application Data Sheet	2018_09_26_P38213US2_ads.pdf	1829099 363914f45c95d81282c3bcb10f9972969560d51f	no	10
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	41698 f69e18d408413a8741658480ff264630513ea0c0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	14649302		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

ABSTRACT

The present disclosure generally relates to user interfaces for health monitoring. Exemplary user interfaces for initial setup of health monitoring using a first electronic device and a second electronic device is described. Exemplary user interfaces for recording biometric information for use in health monitoring is described. Exemplary user interfaces for using an input device while recording biometric information for health monitoring is described. Exemplary user interfaces for viewing and managing aspects of health monitoring is described.

CLAIMS

What is claimed is:

1. A first electronic device, comprising:
a display;
one or more input devices including a biometric sensor;
one or more processors; and
memory storing one or more programs configured to be executed by the one or more processors, the one or more programs including instructions for:

displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information;

detecting a first input with the biometric sensor that satisfies first criteria;

in response to detecting the first input with the biometric sensor:

starting to record biometric information detected by the biometric sensor; and

displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information;

after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met;

in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and

in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

2. The first electronic device of claim 1, wherein the recorded biometric information includes an electrocardiogram recording derived from the biometric information detected by the biometric sensor.

3. The first electronic device of claim 1, wherein the one or more programs further include instructions for:

prior to displaying the first user interface, displaying a homescreen that includes an application affordance corresponding to a health monitoring application;

detecting, via the one or more input devices, a user activation of the application affordance; and

in response to detecting the user activation of the application affordance, displaying, on the display, the first user interface.

4. The first electronic device of claim 3, wherein a notification requesting the first input on the biometric sensor is displayed in the first user interface after a predetermined amount of time has passed after detecting the user activation of the application affordance.

5. The first electronic device of claim 1, wherein the biometric sensor is a contact-based sensor, and wherein the first input with the biometric sensor satisfies the first criteria when a contact is detected on the biometric sensor.

6. The first electronic device of claim 1, wherein the first user interface includes a graphical animation indicating that the first electronic device is ready to detect biometric information, wherein the graphical animation is comprised of a plurality of moving objects forming a first shape.

7. The first electronic device of claim 6, wherein the one or more programs further include instructions for:

while displaying the second user interface and recording the biometric information, displaying, within the graphical animation that is in the second shape, a visual representation of the recorded biometric information, wherein the recorded biometric information is filtered and scaled such that the visual representation of the recorded biometric information can be displayed within the graphical animation.

8. The first electronic device of claim 6, wherein the plurality of moving objects of the graphical animation transitions from the first shape to a second shape different from the first shape as the display transitions from the first user interface to the second user interface.

9. The first electronic device of claim 8, wherein the one or more programs further include instructions for:

further in response to detecting that the first criteria are no longer met for the first period of time, transitioning the plurality of moving objects of the graphical animation to an interstitial shape between the first shape and the second shape.

10. The first electronic device of claim 1, wherein the second user interface includes a graphical representation that corresponds to a visualization of the biometric information from the recorded biometric information and a timer indicating the amount of time remaining to complete the recording of the biometric information.

11. The first electronic device of claim 1, wherein the one or more programs further include instructions for:

while recording the biometric information, detecting, via the one or more input devices, that second criteria are met; and

in response to detecting that the second criteria are met, displaying, in the second user interface, a notification related to the second criteria.

12. The first electronic device of claim 11, wherein:

the second criteria is met when an amount of movement above a threshold is detected, and

the notification indicates that the amount of movement should be decreased.

13. The first electronic device of claim 11, wherein:

the second criteria is met when the amount of movement above the threshold is detected for at least a third period of time, and

the notification indicates that the first electronic device should be moved to a resting position.

14. The first electronic device of claim 11, wherein:

the second criteria is met when a second input having a type that is different from the type of the first input is detected on a first input device, and

the notification indicates that the second input should not be repeated on the first input device.

15. The first electronic device of claim 11, wherein:

the second criteria is met when the first input is no longer detected by the biometric sensor when recording of the biometric information is not yet completed, and

the notification indicates that the first input should be maintained on the biometric sensor.

16. The first electronic device of claim 1, wherein the one or more programs further include instructions for:

after taking a first recording of first biometric information and a second recording of second biometric information different from the first biometric information, transmitting, to a second electronic device, the recorded first biometric information and the recorded second biometric information.

17. The first electronic device of claim 1, wherein the one or more programs further include instructions for:

detecting heart rate information for a predetermined amount of time;

in accordance with a determination that the detected heart rate information meets a first condition, displaying, on the display, a notification indicating a high heart rate;

detecting, via the one or more input devices, a user activation of the notification; and

in response to detecting the user activation of the notification, displaying, on the display, the first user interface.

18. The first electronic device of claim 1, wherein the indication of progress is a countdown timer.

19. A non-transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices including a biometric sensor, the one or more programs including instructions for:

displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information;

detecting a first input with the biometric sensor that satisfies first criteria;

in response to detecting the first input with the biometric sensor:

starting to record biometric information detected by the biometric sensor; and

displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information;

after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met;

in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and

in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

20. A method, comprising:

at a first electronic device with a display and one or more input devices including a biometric sensor:

displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information;

detecting a first input with the biometric sensor that satisfies first criteria;

in response to detecting the first input with the biometric sensor:

starting to record biometric information detected by the biometric sensor; and

displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information;

after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met;

in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and

in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

USER INTERFACES FOR HEALTH MONITORING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to: U.S. Provisional Patent Application Serial No. 62/657,881, entitled "USER INTERFACES FOR HEALTH MONITORING," filed April 15, 2018; U.S. Provisional Patent Application Serial No. 62/657,870, entitled "USER INTERFACES FOR HEALTH MONITORING," filed April 15, 2018; U.S. Provisional Patent Application Serial No. 62/643,699, entitled "USER INTERFACES FOR HEALTH MONITORING," filed March 15, 2018; and U.S. Provisional Patent Application Serial No. 62/641,994, entitled "USER INTERFACES FOR HEALTH MONITORING," filed March 12, 2018. The contents of each of these applications are hereby incorporated by reference in their entireties.

[0002] This application relates to U.S. Provisional Patent Application Seral No. 62/554,196, entitled "WEARABLE DEVICE WITH ELECTRODES FOR SENSING BIOLOGICAL PARAMETERS," filed September 5, 2017, the contents of which are hereby incorporated by reference in their entirety and are also included in their entirety as Appendix A.

FIELD

[0003] The present disclosure relates generally to computer user interfaces, and more specifically to techniques for managing health monitoring.

BACKGROUND

[0004] Monitoring health, such as heart health using heart rhythm and heart rate information, using electronic devices is a convenient and effective method of providing and maintaining awareness of one's health. Using electronic devices enable a user to quickly and easily capture biometric information used to monitor the user's health.

BRIEF SUMMARY

[0005] Some techniques for managing health monitoring using electronic devices, however, are generally cumbersome and inefficient. For example, some existing techniques use a complex and time-consuming user interface, which may include multiple key presses or keystrokes.

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Existing techniques require more time than necessary, wasting user time and device energy. This latter consideration is particularly important in battery-operated devices.

[0006] Accordingly, the present technique provides electronic devices with faster, more efficient methods and interfaces for managing health monitoring. Such methods and interfaces optionally complement or replace other methods for managing health monitoring. Such methods and interfaces reduce the cognitive burden on a user and produce a more efficient human-machine interface. For battery-operated computing devices, such methods and interfaces conserve power and increase the time between battery charges. Such methods and interfaces enable a user to quickly and easily capture health information (thereby also incentivizing the user to frequently monitor his or her health) and to conveniently view and manage recorded health information (thereby raising awareness of the user's current health status to the user).

[0007] In accordance with some embodiments, a method performed at a first electronic device with a display and one or more input devices, wherein the first electronic device is paired with a second electronic device, is described. The method comprises: displaying, on the display, a first portion of a tutorial for using a function of the second electronic device; detecting, via the one or more input devices, a request to proceed with the tutorial; in response to detecting the request to proceed with the tutorial, displaying, on the display, instructions to perform an operation on the second electronic device that involves the function of the second electronic device; receiving, from the second electronic device, an indication that the instructions have been carried out; and in response to receiving the indication that the instructions have been carried out, displaying, on the display, a second portion of the tutorial that is different from the first portion.

[0008] In accordance with some embodiments, a non-transitory computer-readable storage medium is described. The non-transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices, wherein the first electronic device is paired with a second electronic device, the one or more programs including instructions for: displaying, on the display, a first portion of a tutorial for using a function of the second electronic device; detecting, via the one or more input devices, a request to proceed with the tutorial; in response to detecting the request to proceed with the tutorial, displaying, on the display, instructions to perform an

operation on the second electronic device that involves the function of the second electronic device; receiving, from the second electronic device, an indication that the instructions have been carried out; and in response to receiving the indication that the instructions have been carried out, displaying, on the display, a second portion of the tutorial that is different from the first portion.

[0009] In accordance with some embodiments, a transitory computer-readable storage medium is described. The transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices, wherein the first electronic device is paired with a second electronic device, the one or more programs including instructions for: displaying, on the display, a first portion of a tutorial for using a function of the second electronic device; detecting, via the one or more input devices, a request to proceed with the tutorial; in response to detecting the request to proceed with the tutorial, displaying, on the display, instructions to perform an operation on the second electronic device that involves the function of the second electronic device; receiving, from the second electronic device, an indication that the instructions have been carried out; and in response to receiving the indication that the instructions have been carried out, displaying, on the display, a second portion of the tutorial that is different from the first portion.

[0010] In accordance with some embodiments, a first electronic device is described. The first electronic device, wherein the first electronic device is paired with a second electronic device, comprises: a display, one or more input devices; one or more processors; and memory storing one or more programs configured to be executed by the one or more processors, the one or more programs including instructions for: displaying, on the display, a first portion of a tutorial for using a function of the second electronic device; detecting, via the one or more input devices, a request to proceed with the tutorial; in response to detecting the request to proceed with the tutorial, displaying, on the display, instructions to perform an operation on the second electronic device that involves the function of the second electronic device; receiving, from the second electronic device, an indication that the instructions have been carried out; and in response to receiving the indication that the instructions have been carried out, displaying, on the display, a second portion of the tutorial that is different from the first portion.

[0011] In accordance with some embodiments, a first electronic device is described. The first electronic device, wherein the first electronic device is paired with a second electronic device, comprises: a display, one or more input devices; means for displaying, on the display, a first portion of a tutorial for using a function of the second electronic device; means for detecting, via the one or more input devices, a request to proceed with the tutorial; means, in response to detecting the request to proceed with the tutorial, for displaying, on the display, instructions to perform an operation on the second electronic device that involves the function of the second electronic device; means for receiving, from the second electronic device, an indication that the instructions have been carried out; and means, in response to receiving the indication that the instructions have been carried out, for displaying, on the display, a second portion of the tutorial that is different from the first portion.

[0012] In accordance with some embodiments, a method performed at a first electronic device with a display and one or more input devices including a biometric sensor is described. The method comprises: displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information; detecting a first input with the biometric sensor that satisfies first criteria; in response to detecting the first input with the biometric sensor: starting to record biometric information detected by the biometric sensor; and displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information; after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met; in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

[0013] In accordance with some embodiments, a non-transitory computer-readable storage medium is described. The non-transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices including a biometric sensor, the one or more

programs including instructions for: displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information; detecting a first input with the biometric sensor that satisfies first criteria; in response to detecting the first input with the biometric sensor: starting to record biometric information detected by the biometric sensor; and displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information; after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met; in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

[0014] In accordance with some embodiments, a transitory computer-readable storage medium is described. The transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices including a biometric sensor, the one or more programs including instructions for: displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information; detecting a first input with the biometric sensor that satisfies first criteria; in response to detecting the first input with the biometric sensor: starting to record biometric information detected by the biometric sensor; and displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information; after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met; in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

[0015] In accordance with some embodiments, a first electronic device is described. The first electronic device comprises: a display; one or more input devices including a biometric sensor; one or more processors; and memory storing one or more programs configured to be executed by the one or more processors, the one or more programs including instructions for: displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information; detecting a first input with the biometric sensor that satisfies first criteria; in response to detecting the first input with the biometric sensor: starting to record biometric information detected by the biometric sensor; and displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information; after recording at least a portion of the biometric information, detecting, via the one or more input devices, that the first criteria are no longer met; in response to detecting that the first criteria are no longer met for a first period of time, resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and in response to detecting that the first criteria are no longer met for a second period of time that is longer than the first period of time, replacing display of the second user interface with the first user interface.

[0016] In accordance with some embodiments, a first electronic device is described. The first electronic device comprises: a display; one or more input devices including a biometric sensor; means for displaying, on the display, a first user interface indicating that the first electronic device is ready to detect biometric information; means for detecting a first input with the biometric sensor that satisfies first criteria; means, in response to detecting the first input with the biometric sensor, for: starting to record biometric information detected by the biometric sensor; and displaying, on the display, a second user interface that is different from the first user interface, wherein the second user interface includes an indication of progress in recording the biometric information; means, after recording at least a portion of the biometric information, for detecting, via the one or more input devices, that the first criteria are no longer met; means, in response to detecting that the first criteria are no longer met for a first period of time, for resetting the indication of progress in recording the biometric information and maintaining display of the second user interface; and means, in response to detecting that the first criteria are

no longer met for a second period of time that is longer than the first period of time, for replacing display of the second user interface with the first user interface.

[0017] In accordance with some embodiments, a method performed at a first electronic device with a display and one or more input devices including a first input device with an integrated biometric sensor is described. The method comprises: displaying, on the display, a user interface of an application for capturing biometric information from the biometric sensor; while displaying the user interface of the application for capturing biometric information from the biometric sensor, detecting a first activation of the first input device; in response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor: in accordance with a determination that the first activation of the first input device was detected when first criteria are met, wherein the first criteria are based on progress toward capturing biometric information with the biometric sensor, performing a predefined operation associated with the first input device that interrupts capture of the biometric information; and in accordance with a determination that the first activation of the first input device was detected when the first criteria are not met, continuing to capture the biometric information without performing the predefined operation associated with the first input device.

[0018] In accordance with some embodiments, a non-transitory computer-readable storage medium is described. The non-transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices including a first input device with an integrated biometric sensor, the one or more programs including instructions for: displaying, on the display, a user interface of an application for capturing biometric information from the biometric sensor; while displaying the user interface of the application for capturing biometric information from the biometric sensor, detecting a first activation of the first input device; in response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor: in accordance with a determination that the first activation of the first input device was detected when first criteria are met, wherein the first criteria are based on progress toward capturing biometric information with the biometric sensor, performing a predefined operation associated with the first input device that interrupts capture of the biometric information; and in accordance with a determination that the first activation of the first input

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device was detected when the first criteria are not met, continuing to capture the biometric information without performing the predefined operation associated with the first input device.

[0019] In accordance with some embodiments, a transitory computer-readable storage medium is described. The transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices including a first input device with an integrated biometric sensor, the one or more programs including instructions for: displaying, on the display, a user interface of an application for capturing biometric information from the biometric sensor; while displaying the user interface of the application for capturing biometric information from the biometric sensor, detecting a first activation of the first input device; in response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor: in accordance with a determination that the first activation of the first input device was detected when first criteria are met, wherein the first criteria are based on progress toward capturing biometric information with the biometric sensor, performing a predefined operation associated with the first input device that interrupts capture of the biometric information; and in accordance with a determination that the first activation of the first input device was detected when the first criteria are not met, continuing to capture the biometric information without performing the predefined operation associated with the first input device.

[0020] In accordance with some embodiments, a first electronic device is described. The first electronic device comprises: a display; one or more input devices including a first input device with an integrated biometric sensor; one or more processors; and memory storing one or more programs configured to be executed by the one or more processors, the one or more programs including instructions for: displaying, on the display, a user interface of an application for capturing biometric information from the biometric sensor; while displaying the user interface of the application for capturing biometric information from the biometric sensor, detecting a first activation of the first input device; in response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor: in accordance with a determination that the first activation of the first input device was detected when first criteria are met, wherein the first criteria are based on progress toward capturing biometric information with the biometric sensor, performing a predefined operation associated

with the first input device that interrupts capture of the biometric information; and in accordance with a determination that the first activation of the first input device was detected when the first criteria are not met, continuing to capture the biometric information without performing the predefined operation associated with the first input device.

[0021] In accordance with some embodiments, a first electronic device is described. The first electronic device comprises: a display; one or more input devices including a first input device with an integrated biometric sensor; means for displaying, on the display, a user interface of an application for capturing biometric information from the biometric sensor; means, while displaying the user interface of the application for capturing biometric information from the biometric sensor, for detecting a first activation of the first input device; means, in response to detecting the first activation of the first input device and while capturing biometric information from the biometric sensor, for: in accordance with a determination that the first activation of the first input device was detected when first criteria are met, wherein the first criteria are based on progress toward capturing biometric information with the biometric sensor, performing a predefined operation associated with the first input device that interrupts capture of the biometric information; and in accordance with a determination that the first activation of the first input device was detected when the first criteria are not met, continuing to capture the biometric information without performing the predefined operation associated with the first input device.

[0022] In accordance with some embodiments, a method performed at a first electronic device with a display and one or more input devices is described. The method comprises: capturing biometric information with a biometric sensor that is in communication with the first electronic device; displaying, on the display, a representation of an evaluation of a medical characteristic determined based on the biometric information captured by the biometric sensor; while displaying the representation of the evaluation of the medical characteristic, detecting, via the one or more input devices, a sequence of one or more inputs to add user-specified symptoms to the evaluation of the medical characteristic; in response to detecting the sequence of one or more inputs: in accordance with a determination that at least one of the user-specified symptoms meet respective criteria, displaying, on the display, a first user interface that includes an affordance that, when activated, initiates a process for seeking immediate medical attention; and in accordance with a determination that the user-specified symptoms do not meet the respective

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criteria, displaying, on the display, the representation of the evaluation of the medical characteristic and one or more representations of user-specified symptoms without displaying the first user interface.

[0023] In accordance with some embodiments, a non-transitory computer-readable storage medium is described. The non-transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices, the one or more programs including instructions for: capturing biometric information with a biometric sensor that is in communication with the first electronic device; displaying, on the display, a representation of an evaluation of a medical characteristic determined based on the biometric information captured by the biometric sensor; while displaying the representation of the evaluation of the medical characteristic, detecting, via the one or more input devices, a sequence of one or more inputs to add user-specified symptoms to the evaluation of the medical characteristic; in response to detecting the sequence of one or more inputs: in accordance with a determination that at least one of the user-specified symptoms meet respective criteria, displaying, on the display, a first user interface that includes an affordance that, when activated, initiates a process for seeking immediate medical attention; and in accordance with a determination that the user-specified symptoms do not meet the respective criteria, displaying, on the display, the representation of the evaluation of the medical characteristic and one or more representations of user-specified symptoms without displaying the first user interface.

[0024] In accordance with some embodiments, a transitory computer-readable storage medium is described. The transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of a first electronic device with a display and one or more input devices, the one or more programs including instructions for: capturing biometric information with a biometric sensor that is in communication with the first electronic device; displaying, on the display, a representation of an evaluation of a medical characteristic determined based on the biometric information captured by the biometric sensor; while displaying the representation of the evaluation of the medical characteristic, detecting, via the one or more input devices, a sequence of one or more inputs to add user-specified symptoms to the evaluation of the medical characteristic; in response to detecting the sequence of one or

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more inputs: in accordance with a determination that at least one of the user-specified symptoms meet respective criteria, displaying, on the display, a first user interface that includes an affordance that, when activated, initiates a process for seeking immediate medical attention; and in accordance with a determination that the user-specified symptoms do not meet the respective criteria, displaying, on the display, the representation of the evaluation of the medical characteristic and one or more representations of user-specified symptoms without displaying the first user interface.

[0025] In accordance with some embodiments, a first electronic device is described. The first electronic device comprises: a display; one or more input devices; one or more processors; and memory storing one or more programs configured to be executed by the one or more processors, the one or more programs including instructions for: capturing biometric information with a biometric sensor that is in communication with the first electronic device; displaying, on the display, a representation of an evaluation of a medical characteristic determined based on the biometric information captured by the biometric sensor; while displaying the representation of the evaluation of the medical characteristic, detecting, via the one or more input devices, a sequence of one or more inputs to add user-specified symptoms to the evaluation of the medical characteristic; in response to detecting the sequence of one or more inputs: in accordance with a determination that at least one of the user-specified symptoms meet respective criteria, displaying, on the display, a first user interface that includes an affordance that, when activated, initiates a process for seeking immediate medical attention; and in accordance with a determination that the user-specified symptoms do not meet the respective criteria, displaying, on the display, the representation of the evaluation of the medical characteristic and one or more representations of user-specified symptoms without displaying the first user interface.

[0026] In accordance with some embodiments, a first electronic device is described. The first electronic device comprises: a display; one or more input devices; means for capturing biometric information with a biometric sensor that is in communication with the first electronic device; means for displaying, on the display, a representation of an evaluation of a medical characteristic determined based on the biometric information captured by the biometric sensor; means, while displaying the representation of the evaluation of the medical characteristic, for detecting, via the one or more input devices, a sequence of one or more inputs to add user-

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specified symptoms to the evaluation of the medical characteristic; means, in response to detecting the sequence of one or more inputs, for: in accordance with a determination that at least one of the user-specified symptoms meet respective criteria, displaying, on the display, a first user interface that includes an affordance that, when activated, initiates a process for seeking immediate medical attention; and in accordance with a determination that the user-specified symptoms do not meet the respective criteria, displaying, on the display, the representation of the evaluation of the medical characteristic and one or more representations of user-specified symptoms without displaying the first user interface.

[0027] In accordance with some embodiments, a method performed at an electronic device with a display and one or more input devices, the electronic device operably connected to a plurality of biometric sensors, is described. The method comprises: receiving first biometric information from a first biometric sensor of the plurality of biometric sensors; in response to receiving the first biometric information and in accordance with a determination that the first biometric information satisfies first criteria, displaying, on the display, an alert including a first affordance for detecting additional biometric information; receiving, via the one or more input devices, user activation of the first affordance; and subsequent to receiving the user activation of the first affordance, receiving second biometric information associated with the first biometric information from a second biometric sensor of the plurality of biometric sensors that is different from the first biometric sensor.

[0028] In accordance with some embodiments, a non-transitory computer-readable storage medium is described. The non-transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of an electronic device with a display and one or more input devices, the electronic device operably connected to a plurality of biometric sensors, the one or more programs including instructions for: receiving first biometric information from a first biometric sensor of the plurality of biometric sensors; in response to receiving the first biometric information and in accordance with a determination that the first biometric information satisfies first criteria, displaying, on the display, an alert including a first affordance for detecting additional biometric information; receiving, via the one or more input devices, user activation of the first affordance; and subsequent to receiving the user activation of the first affordance, receiving second biometric information associated with the first

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biometric information from a second biometric sensor of the plurality of biometric sensors that is different from the first biometric sensor.

[0029] In accordance with some embodiments, a transitory computer-readable storage medium is described. The transitory computer-readable storage medium storing one or more programs configured to be executed by one or more processors of an electronic device with a display and one or more input devices, the electronic device operably connected to a plurality of biometric sensors, the one or more programs including instructions for: receiving first biometric information from a first biometric sensor of the plurality of biometric sensors; in response to receiving the first biometric information and in accordance with a determination that the first biometric information satisfies first criteria, displaying, on the display, an alert including a first affordance for detecting additional biometric information; receiving, via the one or more input devices, user activation of the first affordance; and subsequent to receiving the user activation of the first affordance, receiving second biometric information associated with the first biometric information from a second biometric sensor of the plurality of biometric sensors that is different from the first biometric sensor.

[0030] In accordance with some embodiments, an electronic device is described. The electronic device comprises: a display; one or more input devices; is operably connected to a plurality of biometric sensors; memory storing one or more programs configured to be executed by the one or more processors, the one or more programs including instructions for: receiving first biometric information from a first biometric sensor of the plurality of biometric sensors; in response to receiving the first biometric information and in accordance with a determination that the first biometric information satisfies first criteria, displaying, on the display, an alert including a first affordance for detecting additional biometric information; receiving, via the one or more input devices, user activation of the first affordance; and subsequent to receiving the user activation of the first affordance, receiving second biometric information associated with the first biometric information from a second biometric sensor of the plurality of biometric sensors that is different from the first biometric sensor.

[0031] In accordance with some embodiments, an electronic device is described. The electronic device comprises: a display; one or more input devices; is operably connected to a

plurality of biometric sensors; means for receiving first biometric information from a first biometric sensor of the plurality of biometric sensors; means, in response to receiving the first biometric information and in accordance with a determination that the first biometric information satisfies first criteria, for displaying, on the display, an alert including a first affordance for detecting additional biometric information; means for receiving, via the one or more input devices, user activation of the first affordance; and means, subsequent to receiving the user activation of the first affordance, for receiving second biometric information associated with the first biometric information from a second biometric sensor of the plurality of biometric sensors that is different from the first biometric sensor.

[0032] Executable instructions for performing these functions are, optionally, included in a non-transitory computer-readable storage medium or other computer program product configured for execution by one or more processors. Executable instructions for performing these functions are, optionally, included in a transitory computer-readable storage medium or other computer program product configured for execution by one or more processors.

[0033] Thus, devices are provided with faster, more efficient methods and interfaces for managing health monitoring, thereby increasing the effectiveness, efficiency, and user satisfaction with such devices. Such methods and interfaces may complement or replace other methods for managing health monitoring.

DESCRIPTION OF THE FIGURES

[0034] For a better understanding of the various described embodiments, reference should be made to the Description of Embodiments below, in conjunction with the following drawings in which like reference numerals refer to corresponding parts throughout the figures.

[0035] FIG. 1A is a block diagram illustrating a portable multifunction device with a touch-sensitive display in accordance with some embodiments.

[0036] FIG. 1B is a block diagram illustrating exemplary components for event handling in accordance with some embodiments.

[0037] FIG. 2 illustrates a portable multifunction device having a touch screen in accordance with some embodiments.

[0038] FIG. 3 is a block diagram of an exemplary multifunction device with a display and a touch-sensitive surface in accordance with some embodiments.

[0039] FIG. 4A illustrates an exemplary user interface for a menu of applications on a portable multifunction device in accordance with some embodiments.

[0040] FIG. 4B illustrates an exemplary user interface for a multifunction device with a touch-sensitive surface that is separate from the display in accordance with some embodiments.

[0041] FIG. 5A illustrates a personal electronic device in accordance with some embodiments.

[0042] FIG. 5B is a block diagram illustrating a personal electronic device in accordance with some embodiments.

[0043] FIGS. 5C-5D illustrate exemplary components of a personal electronic device having a touch-sensitive display and intensity sensors in accordance with some embodiments.

[0044] FIGS. 5E-5H illustrate exemplary components and user interfaces of a personal electronic device in accordance with some embodiments.

[0045] FIGS. 6A-6AE illustrate exemplary user interfaces for initial setup of health monitoring.

[0046] FIGS. 7A-7C illustrate a flow diagram for initial setup of heath monitoring, in accordance with some embodiments.

[0047] FIGS. 8A-8S illustrate exemplary user interfaces for recording biometric information for use in health monitoring.

[0048] FIGS. 9A-9B illustrate a flow diagram for recording biometric information for health monitoring, in accordance with some embodiments.

[0049] FIGS. 10A-10J illustrate exemplary user interfaces for using an input device for health monitoring.

[0050] FIG. 11 illustrates a flow diagram for using an input device for health monitoring, in accordance with some embodiments.

[0051] FIGS. 12A-12S illustrate exemplary user interfaces for managing aspects of health monitoring.

[0052] FIGS. 13A-13B illustrate a flow diagram for managing aspects of health monitoring, in accordance with some embodiments.

[0053] FIGS. 14A-14I illustrate exemplary user interfaces for providing a health condition alert.

[0054] FIG. 15 illustrates a flow diagram for providing a health condition alert, in accordance with some embodiments.

DESCRIPTION OF EMBODIMENTS

[0055] The following description sets forth exemplary methods, parameters, and the like. It should be recognized, however, that such description is not intended as a limitation on the scope of the present disclosure but is instead provided as a description of exemplary embodiments.

[0056] There is a need for electronic devices that provide efficient methods and interfaces for managing health monitoring. For example, there is a need for electronic devices that quickly and conveniently capture biometric information from a user to enable the user to easily monitor his or her health. For another example, there is a need for electronic devices that manage captured biometric information from the user such that the user can easily and conveniently access and view monitoring and evaluation results. For another example, there is a need for electronic devices that efficiently present evaluation results to the user to enable the user to easily understand and properly respond to the results. Such techniques can reduce the cognitive burden on a user who accesses health monitoring features, thereby enhancing productivity. Further,

such techniques can reduce processor and battery power otherwise wasted on redundant user inputs.

[0057] Below, FIGS. 1A-1B, 2, 3, 4A-4B, and 5A-5H provide a description of exemplary devices for performing the techniques for managing event notifications. FIGS. 6A-6AE illustrate exemplary user interfaces for initial setup of health monitoring. FIGS. 7A-7C illustrate a flow diagram for initial setup of heath monitoring. The user interfaces in FIGS. 6A-6AE are used to illustrate the processes described below, including the processes in FIGS. 7A-7C. FIGS. 8A-8S illustrate exemplary user interfaces for recording biometric information for use in health monitoring. FIGS. 9A-9B illustrate a flow diagram for recording biometric information for health monitoring, in accordance with some embodiments. The user interfaces in FIGS. 8A-8S are used to illustrate the processes described below, including the processes in FIGS. 9A-9B. FIGS. 10A-10J illustrate exemplary user interfaces for using an input device for health monitoring. FIG. 11 illustrates a flow diagram for using an input device for health monitoring, in accordance with some embodiments. The user interfaces in FIGS. 10A-10J are used to illustrate the processes described below, including the processes in FIG. 11. FIGS. 12A-12S illustrate exemplary user interfaces for managing aspects of health monitoring. FIGS. 13A-13B illustrate a flow diagram for managing aspects of health monitoring, in accordance with some embodiments. The user interfaces in FIGS. 12A-12S are used to illustrate the processes described below, including the processes in FIGS. 13A-13B. FIGS. 14A-14I illustrate exemplary user interfaces for providing a health condition alert. FIG. 15 illustrates a flow diagram for providing a health condition alert, in accordance with some embodiments. The user interfaces in FIGS. 14A-14I are used to illustrate the processes described below, including the processes in FIG. 15.

[0058] Although the following description uses terms "first," "second," etc. to describe various elements, these elements should not be limited by the terms. These terms are only used to distinguish one element from another. For example, a first touch could be termed a second touch, and, similarly, a second touch could be termed a first touch, without departing from the scope of the various described embodiments. The first touch and the second touch are both touches, but they are not the same touch.

[0059] The terminology used in the description of the various described embodiments herein is for the purpose of describing particular embodiments only and is not intended to be limiting. As used in the description of the various described embodiments and the appended claims, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will also be understood that the term "and/or" as used herein refers to and encompasses any and all possible combinations of one or more of the associated listed items. It will be further understood that the terms "includes," "including," "comprises," and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

[0060] The term "if" is, optionally, construed to mean "when" or "upon" or "in response to determining" or "in response to detecting," depending on the context. Similarly, the phrase "if it is determined" or "if [a stated condition or event] is detected" is, optionally, construed to mean "upon determining" or "in response to determining" or "upon detecting [the stated condition or event]" or "in response to detecting [the stated condition or event]," depending on the context.

[0061] Embodiments of electronic devices, user interfaces for such devices, and associated processes for using such devices are described. In some embodiments, the device is a portable communications device, such as a mobile telephone, that also contains other functions, such as PDA and/or music player functions. Exemplary embodiments of portable multifunction devices include, without limitation, the iPhone®, iPod Touch®, and iPad® devices from Apple Inc. of Cupertino, California. Other portable electronic devices, such as laptops or tablet computers with touch-sensitive surfaces (e.g., touch screen displays and/or touchpads), are, optionally, used. It should also be understood that, in some embodiments, the device is not a portable communications device, but is a desktop computer with a touch-sensitive surface (e.g., a touch screen display and/or a touchpad).

[0062] In the discussion that follows, an electronic device that includes a display and a touch-sensitive surface is described. It should be understood, however, that the electronic device

optionally includes one or more other physical user-interface devices, such as a physical keyboard, a mouse, and/or a joystick.

[0063] The device typically supports a variety of applications, such as one or more of the following: a drawing application, a presentation application, a word processing application, a website creation application, a disk authoring application, a spreadsheet application, a gaming application, a telephone application, a video conferencing application, an e-mail application, an instant messaging application, a workout support application, a photo management application, a digital camera application, a digital video camera application, a web browsing application, a digital music player application, and/or a digital video player application.

[0064] The various applications that are executed on the device optionally use at least one common physical user-interface device, such as the touch-sensitive surface. One or more functions of the touch-sensitive surface as well as corresponding information displayed on the device are, optionally, adjusted and/or varied from one application to the next and/or within a respective application. In this way, a common physical architecture (such as the touch-sensitive surface) of the device optionally supports the variety of applications with user interfaces that are intuitive and transparent to the user.

[0065] Attention is now directed toward embodiments of portable devices with touch-sensitive displays. FIG. 1A is a block diagram illustrating portable multifunction device 100 with touch-sensitive display system 112 in accordance with some embodiments. Touch-sensitive display 112 is sometimes called a "touch screen" for convenience and is sometimes known as or called a "touch-sensitive display system." Device 100 includes memory 102 (which optionally includes one or more computer-readable storage mediums), memory controller 122, one or more processing units (CPUs) 120, peripherals interface 118, RF circuitry 108, audio circuitry 110, speaker 111, microphone 113, input/output (I/O) subsystem 106, other input control devices 116, and external port 124. Device 100 optionally includes one or more optical sensors 164. Device 100 optionally includes one or more contact intensity sensors 165 for detecting intensity of contacts on device 100 (e.g., a touch-sensitive surface such as touch-sensitive display system 112 of device 100). Device 100 optionally includes one or more tactile output generators 167 for generating tactile outputs on device 100 (e.g., generating tactile outputs on a touch-sensitive

surface such as touch-sensitive display system 112 of device 100 or touchpad 355 of device 300). These components optionally communicate over one or more communication buses or signal lines 103.

[0066] As used in the specification and claims, the term "intensity" of a contact on a touch-sensitive surface refers to the force or pressure (force per unit area) of a contact (e.g., a finger contact) on the touch-sensitive surface, or to a substitute (proxy) for the force or pressure of a contact on the touch-sensitive surface. The intensity of a contact has a range of values that includes at least four distinct values and more typically includes hundreds of distinct values (e.g., at least 256). Intensity of a contact is, optionally, determined (or measured) using various approaches and various sensors or combinations of sensors. For example, one or more force sensors underneath or adjacent to the touch-sensitive surface are, optionally, used to measure force at various points on the touch-sensitive surface. In some implementations, force measurements from multiple force sensors are combined (e.g., a weighted average) to determine an estimated force of a contact. Similarly, a pressure-sensitive tip of a stylus is, optionally, used to determine a pressure of the stylus on the touch-sensitive surface. Alternatively, the size of the contact area detected on the touch-sensitive surface and/or changes thereto, the capacitance of the touch-sensitive surface proximate to the contact and/or changes thereto, and/or the resistance of the touch-sensitive surface proximate to the contact and/or changes thereto are, optionally, used as a substitute for the force or pressure of the contact on the touch-sensitive surface. In some implementations, the substitute measurements for contact force or pressure are used directly to determine whether an intensity threshold has been exceeded (e.g., the intensity threshold is described in units corresponding to the substitute measurements). In some implementations, the substitute measurements for contact force or pressure are converted to an estimated force or pressure, and the estimated force or pressure is used to determine whether an intensity threshold has been exceeded (e.g., the intensity threshold is a pressure threshold measured in units of pressure). Using the intensity of a contact as an attribute of a user input allows for user access to additional device functionality that may otherwise not be accessible by the user on a reduced-size device with limited real estate for displaying affordances (e.g., on a touch-sensitive display) and/or receiving user input (e.g., via a touch-sensitive display, a touch-sensitive surface, or a physical/mechanical control such as a knob or a button).

[0067] As used in the specification and claims, the term "tactile output" refers to physical displacement of a device relative to a previous position of the device, physical displacement of a component (e.g., a touch-sensitive surface) of a device relative to another component (e.g., housing) of the device, or displacement of the component relative to a center of mass of the device that will be detected by a user with the user's sense of touch. For example, in situations where the device or the component of the device is in contact with a surface of a user that is sensitive to touch (e.g., a finger, palm, or other part of a user's hand), the tactile output generated by the physical displacement will be interpreted by the user as a tactile sensation corresponding to a perceived change in physical characteristics of the device or the component of the device. For example, movement of a touch-sensitive surface (e.g., a touch-sensitive display or trackpad) is, optionally, interpreted by the user as a "down click" or "up click" of a physical actuator button. In some cases, a user will feel a tactile sensation such as an "down click" or "up click" even when there is no movement of a physical actuator button associated with the touch-sensitive surface that is physically pressed (e.g., displaced) by the user's movements. As another example, movement of the touch-sensitive surface is, optionally, interpreted or sensed by the user as "roughness" of the touch-sensitive surface, even when there is no change in smoothness of the touch-sensitive surface. While such interpretations of touch by a user will be subject to the individualized sensory perceptions of the user, there are many sensory perceptions of touch that are common to a large majority of users. Thus, when a tactile output is described as corresponding to a particular sensory perception of a user (e.g., an "up click," a "down click," "roughness"), unless otherwise stated, the generated tactile output corresponds to physical displacement of the device or a component thereof that will generate the described sensory perception for a typical (or average) user.

[0068] It should be appreciated that device 100 is only one example of a portable multifunction device, and that device 100 optionally has more or fewer components than shown, optionally combines two or more components, or optionally has a different configuration or arrangement of the components. The various components shown in FIG. 1A are implemented in hardware, software, or a combination of both hardware and software, including one or more signal processing and/or application-specific integrated circuits.

[0069] Memory 102 optionally includes high-speed random access memory and optionally also includes non-volatile memory, such as one or more magnetic disk storage devices, flash memory devices, or other non-volatile solid-state memory devices. Memory controller 122 optionally controls access to memory 102 by other components of device 100.

[0070] Peripherals interface 118 can be used to couple input and output peripherals of the device to CPU 120 and memory 102. The one or more processors 120 run or execute various software programs and/or sets of instructions stored in memory 102 to perform various functions for device 100 and to process data. In some embodiments, peripherals interface 118, CPU 120, and memory controller 122 are, optionally, implemented on a single chip, such as chip 104. In some other embodiments, they are, optionally, implemented on separate chips.

[0071] RF (radio frequency) circuitry 108 receives and sends RF signals, also called electromagnetic signals. RF circuitry 108 converts electrical signals to/from electromagnetic signals and communicates with communications networks and other communications devices via the electromagnetic signals. RF circuitry 108 optionally includes well-known circuitry for performing these functions, including but not limited to an antenna system, an RF transceiver, one or more amplifiers, a tuner, one or more oscillators, a digital signal processor, a CODEC chipset, a subscriber identity module (SIM) card, memory, and so forth. RF circuitry 108 optionally communicates with networks, such as the Internet, also referred to as the World Wide Web (WWW), an intranet and/or a wireless network, such as a cellular telephone network, a wireless local area network (LAN) and/or a metropolitan area network (MAN), and other devices by wireless communication. The RF circuitry 108 optionally includes well-known circuitry for detecting near field communication (NFC) fields, such as by a short-range communication radio. The wireless communication optionally uses any of a plurality of communications standards, protocols, and technologies, including but not limited to Global System for Mobile Communications (GSM), Enhanced Data GSM Environment (EDGE), high-speed downlink packet access (HSDPA), high-speed uplink packet access (HSUPA), Evolution, Data-Only (EV-DO), HSPA, HSPA+, Dual-Cell HSPA (DC-HSPDA), long term evolution (LTE), near field communication (NFC), wideband code division multiple access (W-CDMA), code division multiple access (CDMA), time division multiple access (TDMA), Bluetooth, Bluetooth Low Energy (BTLE), Wireless Fidelity (Wi-Fi) (e.g., IEEE 802.11a, IEEE 802.11b, IEEE 802.11g,

IEEE 802.11n, and/or IEEE 802.11ac), voice over Internet Protocol (VoIP), Wi-MAX, a protocol for e-mail (e.g., Internet message access protocol (IMAP) and/or post office protocol (POP)), instant messaging (e.g., extensible messaging and presence protocol (XMPP), Session Initiation Protocol for Instant Messaging and Presence Leveraging Extensions (SIMPLE), Instant Messaging and Presence Service (IMPS)), and/or Short Message Service (SMS), or any other suitable communication protocol, including communication protocols not yet developed as of the filing date of this document.

[0072] Audio circuitry 110, speaker 111, and microphone 113 provide an audio interface between a user and device 100. Audio circuitry 110 receives audio data from peripherals interface 118, converts the audio data to an electrical signal, and transmits the electrical signal to speaker 111. Speaker 111 converts the electrical signal to human-audible sound waves. Audio circuitry 110 also receives electrical signals converted by microphone 113 from sound waves. Audio circuitry 110 converts the electrical signal to audio data and transmits the audio data to peripherals interface 118 for processing. Audio data is, optionally, retrieved from and/or transmitted to memory 102 and/or RF circuitry 108 by peripherals interface 118. In some embodiments, audio circuitry 110 also includes a headset jack (e.g., 212, FIG. 2). The headset jack provides an interface between audio circuitry 110 and removable audio input/output peripherals, such as output-only headphones or a headset with both output (e.g., a headphone for one or both ears) and input (e.g., a microphone).

[0073] I/O subsystem 106 couples input/output peripherals on device 100, such as touch screen 112 and other input control devices 116, to peripherals interface 118. I/O subsystem 106 optionally includes display controller 156, optical sensor controller 158, intensity sensor controller 159, haptic feedback controller 161, and one or more input controllers 160 for other input or control devices. The one or more input controllers 160 receive/send electrical signals from/to other input control devices 116. The other input control devices 116 optionally include physical buttons (e.g., push buttons, rocker buttons, etc.), dials, slider switches, joysticks, click wheels, and so forth. In some alternate embodiments, input controller(s) 160 are, optionally, coupled to any (or none) of the following: a keyboard, an infrared port, a USB port, and a pointer device such as a mouse. The one or more buttons (e.g., 208, FIG. 2) optionally include an

up/down button for volume control of speaker 111 and/or microphone 113. The one or more buttons optionally include a push button (e.g., 206, FIG. 2).

[0074] A quick press of the push button optionally disengages a lock of touch screen 112 or optionally begins a process that uses gestures on the touch screen to unlock the device, as described in U.S. Patent Application 11/322,549, "Unlocking a Device by Performing Gestures on an Unlock Image," filed December 23, 2005, U.S. Pat. No. 7,657,849, which is hereby incorporated by reference in its entirety. A longer press of the push button (e.g., 206) optionally turns power to device 100 on or off. The functionality of one or more of the buttons are, optionally, user-customizable. Touch screen 112 is used to implement virtual or soft buttons and one or more soft keyboards.

[0075] Touch-sensitive display 112 provides an input interface and an output interface between the device and a user. Display controller 156 receives and/or sends electrical signals from/to touch screen 112. Touch screen 112 displays visual output to the user. The visual output optionally includes graphics, text, icons, video, and any combination thereof (collectively termed "graphics"). In some embodiments, some or all of the visual output optionally corresponds to user-interface objects.

[0076] Touch screen 112 has a touch-sensitive surface, sensor, or set of sensors that accepts input from the user based on haptic and/or tactile contact. Touch screen 112 and display controller 156 (along with any associated modules and/or sets of instructions in memory 102) detect contact (and any movement or breaking of the contact) on touch screen 112 and convert the detected contact into interaction with user-interface objects (e.g., one or more soft keys, icons, web pages, or images) that are displayed on touch screen 112. In an exemplary embodiment, a point of contact between touch screen 112 and the user corresponds to a finger of the user.

[0077] Touch screen 112 optionally uses LCD (liquid crystal display) technology, LPD (light emitting polymer display) technology, or LED (light emitting diode) technology, although other display technologies are used in other embodiments. Touch screen 112 and display controller 156 optionally detect contact and any movement or breaking thereof using any of a plurality of touch sensing technologies now known or later developed, including but not limited to

capacitive, resistive, infrared, and surface acoustic wave technologies, as well as other proximity sensor arrays or other elements for determining one or more points of contact with touch screen 112. In an exemplary embodiment, projected mutual capacitance sensing technology is used, such as that found in the iPhone® and iPod Touch® from Apple Inc. of Cupertino, California.

[0078] A touch-sensitive display in some embodiments of touch screen 112 is, optionally, analogous to the multi-touch sensitive touchpads described in the following U.S. Patents: 6,323,846 (Westerman et al.), 6,570,557 (Westerman et al.), and/or 6,677,932 (Westerman), and/or U.S. Patent Publication 2002/0015024A1, each of which is hereby incorporated by reference in its entirety. However, touch screen 112 displays visual output from device 100, whereas touch-sensitive touchpads do not provide visual output.

[0079] A touch-sensitive display in some embodiments of touch screen 112 is described in the following applications: (1) U.S. Patent Application No. 11/381,313, "Multipoint Touch Surface Controller," filed May 2, 2006; (2) U.S. Patent Application No. 10/840,862, "Multipoint Touchscreen," filed May 6, 2004; (3) U.S. Patent Application No. 10/903,964, "Gestures For Touch Sensitive Input Devices," filed July 30, 2004; (4) U.S. Patent Application No. 11/048,264, "Gestures For Touch Sensitive Input Devices," filed January 31, 2005; (5) U.S. Patent Application No. 11/038,590, "Mode-Based Graphical User Interfaces For Touch Sensitive Input Devices," filed January 18, 2005; (6) U.S. Patent Application No. 11/228,758, "Virtual Input Device Placement On A Touch Screen User Interface," filed September 16, 2005; (7) U.S. Patent Application No. 11/228,700, "Operation Of A Computer With A Touch Screen Interface," filed September 16, 2005; (8) U.S. Patent Application No. 11/228,737, "Activating Virtual Keys Of A Touch-Screen Virtual Keyboard," filed September 16, 2005; and (9) U.S. Patent Application No. 11/367,749, "Multi-Functional Hand-Held Device," filed March 3, 2006. All of these applications are incorporated by reference herein in their entirety.

[0080] Touch screen 112 optionally has a video resolution in excess of 100 dpi. In some embodiments, the touch screen has a video resolution of approximately 160 dpi. The user optionally makes contact with touch screen 112 using any suitable object or appendage, such as a stylus, a finger, and so forth. In some embodiments, the user interface is designed to work primarily with finger-based contacts and gestures, which can be less precise than stylus-based

input due to the larger area of contact of a finger on the touch screen. In some embodiments, the device translates the rough finger-based input into a precise pointer/cursor position or command for performing the actions desired by the user.

[0081] In some embodiments, in addition to the touch screen, device 100 optionally includes a touchpad (not shown) for activating or deactivating particular functions. In some embodiments, the touchpad is a touch-sensitive area of the device that, unlike the touch screen, does not display visual output. The touchpad is, optionally, a touch-sensitive surface that is separate from touch screen 112 or an extension of the touch-sensitive surface formed by the touch screen.

[0082] Device 100 also includes power system 162 for powering the various components. Power system 162 optionally includes a power management system, one or more power sources (e.g., battery, alternating current (AC)), a recharging system, a power failure detection circuit, a power converter or inverter, a power status indicator (e.g., a light-emitting diode (LED)) and any other components associated with the generation, management and distribution of power in portable devices.

[0083] Device 100 optionally also includes one or more optical sensors 164. FIG. 1A shows an optical sensor coupled to optical sensor controller 158 in I/O subsystem 106. Optical sensor 164 optionally includes charge-coupled device (CCD) or complementary metal-oxide semiconductor (CMOS) phototransistors. Optical sensor 164 receives light from the environment, projected through one or more lenses, and converts the light to data representing an image. In conjunction with imaging module 143 (also called a camera module), optical sensor 164 optionally captures still images or video. In some embodiments, an optical sensor is located on the back of device 100, opposite touch screen display 112 on the front of the device so that the touch screen display is enabled for use as a viewfinder for still and/or video image acquisition. In some embodiments, an optical sensor is located on the front of the device so that the user's image is, optionally, obtained for video conferencing while the user views the other video conference participants on the touch screen display. In some embodiments, the position of optical sensor 164 can be changed by the user (e.g., by rotating the lens and the sensor in the

device housing) so that a single optical sensor 164 is used along with the touch screen display for both video conferencing and still and/or video image acquisition.

[0084] Device 100 optionally also includes one or more contact intensity sensors 165. FIG. 1A shows a contact intensity sensor coupled to intensity sensor controller 159 in I/O subsystem 106. Contact intensity sensor 165 optionally includes one or more piezoresistive strain gauges, capacitive force sensors, electric force sensors, piezoelectric force sensors, optical force sensors, capacitive touch-sensitive surfaces, or other intensity sensors (e.g., sensors used to measure the force (or pressure) of a contact on a touch-sensitive surface). Contact intensity sensor 165 receives contact intensity information (e.g., pressure information or a proxy for pressure information) from the environment. In some embodiments, at least one contact intensity sensor is collocated with, or proximate to, a touch-sensitive surface (e.g., touch-sensitive display system 112). In some embodiments, at least one contact intensity sensor is located on the back of device 100, opposite touch screen display 112, which is located on the front of device 100.

[0085] Device 100 optionally also includes one or more proximity sensors 166. FIG. 1A shows proximity sensor 166 coupled to peripherals interface 118. Alternately, proximity sensor 166 is, optionally, coupled to input controller 160 in I/O subsystem 106. Proximity sensor 166 optionally performs as described in U.S. Patent Application Nos. 11/241,839, "Proximity Detector In Handheld Device"; 11/240,788, "Proximity Detector In Handheld Device"; 11/620,702, "Using Ambient Light Sensor To Augment Proximity Sensor Output"; 11/586,862, "Automated Response To And Sensing Of User Activity In Portable Devices"; and 11/638,251, "Methods And Systems For Automatic Configuration Of Peripherals," which are hereby incorporated by reference in their entirety. In some embodiments, the proximity sensor turns off and disables touch screen 112 when the multifunction device is placed near the user's ear (e.g., when the user is making a phone call).

[0086] Device 100 optionally also includes one or more tactile output generators 167. FIG. 1A shows a tactile output generator coupled to haptic feedback controller 161 in I/O subsystem 106. Tactile output generator 167 optionally includes one or more electroacoustic devices such as speakers or other audio components and/or electromechanical devices that

convert energy into linear motion such as a motor, solenoid, electroactive polymer, piezoelectric actuator, electrostatic actuator, or other tactile output generating component (e.g., a component that converts electrical signals into tactile outputs on the device). Contact intensity sensor 165 receives tactile feedback generation instructions from haptic feedback module 133 and generates tactile outputs on device 100 that are capable of being sensed by a user of device 100. In some embodiments, at least one tactile output generator is collocated with, or proximate to, a touch-sensitive surface (e.g., touch-sensitive display system 112) and, optionally, generates a tactile output by moving the touch-sensitive surface vertically (e.g., in/out of a surface of device 100) or laterally (e.g., back and forth in the same plane as a surface of device 100). In some embodiments, at least one tactile output generator sensor is located on the back of device 100, opposite touch screen display 112, which is located on the front of device 100.

[0087] Device 100 optionally also includes one or more accelerometers 168. FIG. 1A shows accelerometer 168 coupled to peripherals interface 118. Alternately, accelerometer 168 is, optionally, coupled to an input controller 160 in I/O subsystem 106. Accelerometer 168 optionally performs as described in U.S. Patent Publication No. 20050190059, "Acceleration-based Theft Detection System for Portable Electronic Devices," and U.S. Patent Publication No. 20060017692, "Methods And Apparatuses For Operating A Portable Device Based On An Accelerometer," both of which are incorporated by reference herein in their entirety. In some embodiments, information is displayed on the touch screen display in a portrait view or a landscape view based on an analysis of data received from the one or more accelerometers. Device 100 optionally includes, in addition to accelerometer(s) 168, a magnetometer (not shown) and a GPS (or GLONASS or other global navigation system) receiver (not shown) for obtaining information concerning the location and orientation (e.g., portrait or landscape) of device 100.

[0088] In some embodiments, the software components stored in memory 102 include operating system 126, communication module (or set of instructions) 128, contact/motion module (or set of instructions) 130, graphics module (or set of instructions) 132, text input module (or set of instructions) 134, Global Positioning System (GPS) module (or set of instructions) 135, and applications (or sets of instructions) 136. Furthermore, in some embodiments, memory 102 (FIG. 1A) or 370 (FIG. 3) stores device/global internal state 157, as shown in FIGS. 1A and 3. Device/global internal state 157 includes one or more of: active

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AliveCor, Inc. v. Apple Inc.
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application state, indicating which applications, if any, are currently active; display state, indicating what applications, views or other information occupy various regions of touch screen display 112; sensor state, including information obtained from the device's various sensors and input control devices 116; and location information concerning the device's location and/or attitude.

[0089] Operating system 126 (e.g., Darwin, RTXC, LINUX, UNIX, OS X, iOS, WINDOWS, or an embedded operating system such as VxWorks) includes various software components and/or drivers for controlling and managing general system tasks (e.g., memory management, storage device control, power management, etc.) and facilitates communication between various hardware and software components.

[0090] Communication module 128 facilitates communication with other devices over one or more external ports 124 and also includes various software components for handling data received by RF circuitry 108 and/or external port 124. External port 124 (e.g., Universal Serial Bus (USB), FIREWIRE, etc.) is adapted for coupling directly to other devices or indirectly over a network (e.g., the Internet, wireless LAN, etc.). In some embodiments, the external port is a multi-pin (e.g., 30-pin) connector that is the same as, or similar to and/or compatible with, the 30-pin connector used on iPod® (trademark of Apple Inc.) devices.

[0091] Contact/motion module 130 optionally detects contact with touch screen 112 (in conjunction with display controller 156) and other touch-sensitive devices (e.g., a touchpad or physical click wheel). Contact/motion module 130 includes various software components for performing various operations related to detection of contact, such as determining if contact has occurred (e.g., detecting a finger-down event), determining an intensity of the contact (e.g., the force or pressure of the contact or a substitute for the force or pressure of the contact), determining if there is movement of the contact and tracking the movement across the touch-sensitive surface (e.g., detecting one or more finger-dragging events), and determining if the contact has ceased (e.g., detecting a finger-up event or a break in contact). Contact/motion module 130 receives contact data from the touch-sensitive surface. Determining movement of the point of contact, which is represented by a series of contact data, optionally includes determining speed (magnitude), velocity (magnitude and direction), and/or an acceleration (a

change in magnitude and/or direction) of the point of contact. These operations are, optionally, applied to single contacts (e.g., one finger contacts) or to multiple simultaneous contacts (e.g., "multitouch"/multiple finger contacts). In some embodiments, contact/motion module 130 and display controller 156 detect contact on a touchpad.

[0092] In some embodiments, contact/motion module 130 uses a set of one or more intensity thresholds to determine whether an operation has been performed by a user (e.g., to determine whether a user has "clicked" on an icon). In some embodiments, at least a subset of the intensity thresholds are determined in accordance with software parameters (e.g., the intensity thresholds are not determined by the activation thresholds of particular physical actuators and can be adjusted without changing the physical hardware of device 100). For example, a mouse "click" threshold of a trackpad or touch screen display can be set to any of a large range of predefined threshold values without changing the trackpad or touch screen display hardware. Additionally, in some implementations, a user of the device is provided with software settings for adjusting one or more of the set of intensity thresholds (e.g., by adjusting individual intensity thresholds and/or by adjusting a plurality of intensity thresholds at once with a system-level click "intensity" parameter).

[0093] Contact/motion module 130 optionally detects a gesture input by a user. Different gestures on the touch-sensitive surface have different contact patterns (e.g., different motions, timings, and/or intensities of detected contacts). Thus, a gesture is, optionally, detected by detecting a particular contact pattern. For example, detecting a finger tap gesture includes detecting a finger-down event followed by detecting a finger-up (liftoff) event at the same position (or substantially the same position) as the finger-down event (e.g., at the position of an icon). As another example, detecting a finger swipe gesture on the touch-sensitive surface includes detecting a finger-down event followed by detecting one or more finger-dragging events, and subsequently followed by detecting a finger-up (liftoff) event.

[0094] Graphics module 132 includes various known software components for rendering and displaying graphics on touch screen 112 or other display, including components for changing the visual impact (e.g., brightness, transparency, saturation, contrast, or other visual property) of graphics that are displayed. As used herein, the term "graphics" includes any object that can be

displayed to a user, including, without limitation, text, web pages, icons (such as user-interface objects including soft keys), digital images, videos, animations, and the like.

[0095] In some embodiments, graphics module 132 stores data representing graphics to be used. Each graphic is, optionally, assigned a corresponding code. Graphics module 132 receives, from applications etc., one or more codes specifying graphics to be displayed along with, if necessary, coordinate data and other graphic property data, and then generates screen image data to output to display controller 156.

[0096] Haptic feedback module 133 includes various software components for generating instructions used by tactile output generator(s) 167 to produce tactile outputs at one or more locations on device 100 in response to user interactions with device 100.

[0097] Text input module 134, which is, optionally, a component of graphics module 132, provides soft keyboards for entering text in various applications (e.g., contacts 137, e-mail 140, IM 141, browser 147, and any other application that needs text input).

[0098] GPS module 135 determines the location of the device and provides this information for use in various applications (e.g., to telephone 138 for use in location-based dialing; to camera 143 as picture/video metadata; and to applications that provide location-based services such as weather widgets, local yellow page widgets, and map/navigation widgets).

[0099] Applications 136 optionally include the following modules (or sets of instructions), or a subset or superset thereof:

- Contacts module 137 (sometimes called an address book or contact list);
- Telephone module 138;
- Video conference module 139;
- E-mail client module 140;
- Instant messaging (IM) module 141;

- Workout support module 142;
- Camera module 143 for still and/or video images;
- Image management module 144;
- Video player module;
- Music player module;
- Browser module 147;
- Calendar module 148;
- Widget modules 149, which optionally include one or more of: weather widget 149-1, stocks widget 149-2, calculator widget 149-3, alarm clock widget 149-4, dictionary widget 149-5, and other widgets obtained by the user, as well as user-created widgets 149-6;
- Widget creator module 150 for making user-created widgets 149-6;
- Search module 151;
- Video and music player module 152, which merges video player module and music player module;
- Notes module 153;
- Map module 154; and/or
- Online video module 155.

[0100] Examples of other applications 136 that are, optionally, stored in memory 102 include other word processing applications, other image editing applications, drawing applications, presentation applications, JAVA-enabled applications, encryption, digital rights management, voice recognition, and voice replication.

[0101] In conjunction with touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, contacts module 137 are, optionally, used to manage an address book or contact list (e.g., stored in application internal state 192 of contacts module 137 in memory 102 or memory 370), including: adding name(s) to the address book; deleting name(s) from the address book; associating telephone number(s), e-mail address(es), physical address(es) or other information with a name; associating an image with a name; categorizing and sorting names; providing telephone numbers or e-mail addresses to initiate and/or facilitate communications by telephone 138, video conference module 139, e-mail 140, or IM 141; and so forth.

[0102] In conjunction with RF circuitry 108, audio circuitry 110, speaker 111, microphone 113, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, telephone module 138 are optionally, used to enter a sequence of characters corresponding to a telephone number, access one or more telephone numbers in contacts module 137, modify a telephone number that has been entered, dial a respective telephone number, conduct a conversation, and disconnect or hang up when the conversation is completed. As noted above, the wireless communication optionally uses any of a plurality of communications standards, protocols, and technologies.

[0103] In conjunction with RF circuitry 108, audio circuitry 110, speaker 111, microphone 113, touch screen 112, display controller 156, optical sensor 164, optical sensor controller 158, contact/motion module 130, graphics module 132, text input module 134, contacts module 137, and telephone module 138, video conference module 139 includes executable instructions to initiate, conduct, and terminate a video conference between a user and one or more other participants in accordance with user instructions.

[0104] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, e-mail client module 140 includes executable instructions to create, send, receive, and manage e-mail in response to user instructions. In conjunction with image management module 144, e-mail client module 140 makes it very easy to create and send e-mails with still or video images taken with camera module 143.

[0105] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, the instant messaging module 141 includes executable instructions to enter a sequence of characters corresponding to an instant message, to modify previously entered characters, to transmit a respective instant message (for example, using a Short Message Service (SMS) or Multimedia Message Service (MMS) protocol for telephony-based instant messages or using XMPP, SIMPLE, or IMPS for Internet-based instant messages), to receive instant messages, and to view received instant messages. In some embodiments, transmitted and/or received instant messages optionally include graphics, photos, audio files, video files and/or other attachments as are supported in an MMS and/or an Enhanced Messaging Service (EMS). As used herein, "instant messaging" refers to both telephony-based messages (e.g., messages sent using SMS or MMS) and Internet-based messages (e.g., messages sent using XMPP, SIMPLE, or IMPS).

[0106] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, text input module 134, GPS module 135, map module 154, and music player module, workout support module 142 includes executable instructions to create workouts (e.g., with time, distance, and/or calorie burning goals); communicate with workout sensors (sports devices); receive workout sensor data; calibrate sensors (e.g., heart rate or heart rhythm sensors) used to monitor a workout; select and play music for a workout; and display, store, and transmit workout data.

[0107] In conjunction with touch screen 112, display controller 156, optical sensor(s) 164, optical sensor controller 158, contact/motion module 130, graphics module 132, and image management module 144, camera module 143 includes executable instructions to capture still images or video (including a video stream) and store them into memory 102, modify characteristics of a still image or video, or delete a still image or video from memory 102.

[0108] In conjunction with touch screen 112, display controller 156, contact/motion module 130, graphics module 132, text input module 134, and camera module 143, image management module 144 includes executable instructions to arrange, modify (e.g., edit), or otherwise manipulate, label, delete, present (e.g., in a digital slide show or album), and store still and/or video images.

[0109] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, browser module 147 includes executable instructions to browse the Internet in accordance with user instructions, including searching, linking to, receiving, and displaying web pages or portions thereof, as well as attachments and other files linked to web pages.

[0110] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, text input module 134, e-mail client module 140, and browser module 147, calendar module 148 includes executable instructions to create, display, modify, and store calendars and data associated with calendars (e.g., calendar entries, to-do lists, etc.) in accordance with user instructions.

[0111] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, text input module 134, and browser module 147, widget modules 149 are mini-applications that are, optionally, downloaded and used by a user (e.g., weather widget 149-1, stocks widget 149-2, calculator widget 149-3, alarm clock widget 149-4, and dictionary widget 149-5) or created by the user (e.g., user-created widget 149-6). In some embodiments, a widget includes an HTML (Hypertext Markup Language) file, a CSS (Cascading Style Sheets) file, and a JavaScript file. In some embodiments, a widget includes an XML (Extensible Markup Language) file and a JavaScript file (e.g., Yahoo! Widgets).

[0112] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, text input module 134, and browser module 147, the widget creator module 150 are, optionally, used by a user to create widgets (e.g., turning a user-specified portion of a web page into a widget).

[0113] In conjunction with touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, search module 151 includes executable instructions to search for text, music, sound, image, video, and/or other files in memory 102 that match one or more search criteria (e.g., one or more user-specified search terms) in accordance with user instructions.

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[0114] In conjunction with touch screen 112, display controller 156, contact/motion module 130, graphics module 132, audio circuitry 110, speaker 111, RF circuitry 108, and browser module 147, video and music player module 152 includes executable instructions that allow the user to download and play back recorded music and other sound files stored in one or more file formats, such as MP3 or AAC files, and executable instructions to display, present, or otherwise play back videos (e.g., on touch screen 112 or on an external, connected display via external port 124). In some embodiments, device 100 optionally includes the functionality of an MP3 player, such as an iPod (trademark of Apple Inc.).

[0115] In conjunction with touch screen 112, display controller 156, contact/motion module 130, graphics module 132, and text input module 134, notes module 153 includes executable instructions to create and manage notes, to-do lists, and the like in accordance with user instructions.

[0116] In conjunction with RF circuitry 108, touch screen 112, display controller 156, contact/motion module 130, graphics module 132, text input module 134, GPS module 135, and browser module 147, map module 154 are, optionally, used to receive, display, modify, and store maps and data associated with maps (e.g., driving directions, data on stores and other points of interest at or near a particular location, and other location-based data) in accordance with user instructions.

[0117] In conjunction with touch screen 112, display controller 156, contact/motion module 130, graphics module 132, audio circuitry 110, speaker 111, RF circuitry 108, text input module 134, e-mail client module 140, and browser module 147, online video module 155 includes instructions that allow the user to access, browse, receive (e.g., by streaming and/or download), play back (e.g., on the touch screen or on an external, connected display via external port 124), send an e-mail with a link to a particular online video, and otherwise manage online videos in one or more file formats, such as H.264. In some embodiments, instant messaging module 141, rather than e-mail client module 140, is used to send a link to a particular online video. Additional description of the online video application can be found in U.S. Provisional Patent Application No. 60/936,562, "Portable Multifunction Device, Method, and Graphical User Interface for Playing Online Videos," filed June 20, 2007, and U.S. Patent Application No.

11/968,067, "Portable Multifunction Device, Method, and Graphical User Interface for Playing Online Videos," filed December 31, 2007, the contents of which are hereby incorporated by reference in their entirety.

[0118] Each of the above-identified modules and applications corresponds to a set of executable instructions for performing one or more functions described above and the methods described in this application (e.g., the computer-implemented methods and other information processing methods described herein). These modules (e.g., sets of instructions) need not be implemented as separate software programs, procedures, or modules, and thus various subsets of these modules are, optionally, combined or otherwise rearranged in various embodiments. For example, video player module is, optionally, combined with music player module into a single module (e.g., video and music player module 152, FIG. 1A). In some embodiments, memory 102 optionally stores a subset of the modules and data structures identified above. Furthermore, memory 102 optionally stores additional modules and data structures not described above.

[0119] In some embodiments, device 100 is a device where operation of a predefined set of functions on the device is performed exclusively through a touch screen and/or a touchpad. By using a touch screen and/or a touchpad as the primary input control device for operation of device 100, the number of physical input control devices (such as push buttons, dials, and the like) on device 100 is, optionally, reduced.

[0120] The predefined set of functions that are performed exclusively through a touch screen and/or a touchpad optionally include navigation between user interfaces. In some embodiments, the touchpad, when touched by the user, navigates device 100 to a main, home, or root menu from any user interface that is displayed on device 100. In such embodiments, a "menu button" is implemented using a touchpad. In some other embodiments, the menu button is a physical push button or other physical input control device instead of a touchpad.

[0121] FIG. 1B is a block diagram illustrating exemplary components for event handling in accordance with some embodiments. In some embodiments, memory 102 (FIG. 1A) or 370 (FIG. 3) includes event sorter 170 (e.g., in operating system 126) and a respective application 136-1 (e.g., any of the aforementioned applications 137-151, 155, 380-390).

[0122] Event sorter 170 receives event information and determines the application 136-1 and application view 191 of application 136-1 to which to deliver the event information. Event sorter 170 includes event monitor 171 and event dispatcher module 174. In some embodiments, application 136-1 includes application internal state 192, which indicates the current application view(s) displayed on touch-sensitive display 112 when the application is active or executing. In some embodiments, device/global internal state 157 is used by event sorter 170 to determine which application(s) is (are) currently active, and application internal state 192 is used by event sorter 170 to determine application views 191 to which to deliver event information.

[0123] In some embodiments, application internal state 192 includes additional information, such as one or more of: resume information to be used when application 136-1 resumes execution, user interface state information that indicates information being displayed or that is ready for display by application 136-1, a state queue for enabling the user to go back to a prior state or view of application 136-1, and a redo/undo queue of previous actions taken by the user.

[0124] Event monitor 171 receives event information from peripherals interface 118. Event information includes information about a sub-event (e.g., a user touch on touch-sensitive display 112, as part of a multi-touch gesture). Peripherals interface 118 transmits information it receives from I/O subsystem 106 or a sensor, such as proximity sensor 166, accelerometer(s) 168, and/or microphone 113 (through audio circuitry 110). Information that peripherals interface 118 receives from I/O subsystem 106 includes information from touch-sensitive display 112 or a touch-sensitive surface.

[0125] In some embodiments, event monitor 171 sends requests to the peripherals interface 118 at predetermined intervals. In response, peripherals interface 118 transmits event information. In other embodiments, peripherals interface 118 transmits event information only when there is a significant event (e.g., receiving an input above a predetermined noise threshold and/or for more than a predetermined duration).

[0126] In some embodiments, event sorter 170 also includes a hit view determination module 172 and/or an active event recognizer determination module 173.

[0127] Hit view determination module 172 provides software procedures for determining where a sub-event has taken place within one or more views when touch-sensitive display 112 displays more than one view. Views are made up of controls and other elements that a user can see on the display.

[0128] Another aspect of the user interface associated with an application is a set of views, sometimes herein called application views or user interface windows, in which information is displayed and touch-based gestures occur. The application views (of a respective application) in which a touch is detected optionally correspond to programmatic levels within a programmatic or view hierarchy of the application. For example, the lowest level view in which a touch is detected is, optionally, called the hit view, and the set of events that are recognized as proper inputs are, optionally, determined based, at least in part, on the hit view of the initial touch that begins a touch-based gesture.

[0129] Hit view determination module 172 receives information related to sub-events of a touch-based gesture. When an application has multiple views organized in a hierarchy, hit view determination module 172 identifies a hit view as the lowest view in the hierarchy which should handle the sub-event. In most circumstances, the hit view is the lowest level view in which an initiating sub-event occurs (e.g., the first sub-event in the sequence of sub-events that form an event or potential event). Once the hit view is identified by the hit view determination module 172, the hit view typically receives all sub-events related to the same touch or input source for which it was identified as the hit view.

[0130] Active event recognizer determination module 173 determines which view or views within a view hierarchy should receive a particular sequence of sub-events. In some embodiments, active event recognizer determination module 173 determines that only the hit view should receive a particular sequence of sub-events. In other embodiments, active event recognizer determination module 173 determines that all views that include the physical location of a sub-event are actively involved views, and therefore determines that all actively involved views should receive a particular sequence of sub-events. In other embodiments, even if touch sub-events were entirely confined to the area associated with one particular view, views higher in the hierarchy would still remain as actively involved views.

[0131] Event dispatcher module 174 dispatches the event information to an event recognizer (e.g., event recognizer 180). In embodiments including active event recognizer determination module 173, event dispatcher module 174 delivers the event information to an event recognizer determined by active event recognizer determination module 173. In some embodiments, event dispatcher module 174 stores in an event queue the event information, which is retrieved by a respective event receiver 182.

[0132] In some embodiments, operating system 126 includes event sorter 170. Alternatively, application 136-1 includes event sorter 170. In yet other embodiments, event sorter 170 is a stand-alone module, or a part of another module stored in memory 102, such as contact/motion module 130.

[0133] In some embodiments, application 136-1 includes a plurality of event handlers 190 and one or more application views 191, each of which includes instructions for handling touch events that occur within a respective view of the application's user interface. Each application view 191 of the application 136-1 includes one or more event recognizers 180. Typically, a respective application view 191 includes a plurality of event recognizers 180. In other embodiments, one or more of event recognizers 180 are part of a separate module, such as a user interface kit (not shown) or a higher level object from which application 136-1 inherits methods and other properties. In some embodiments, a respective event handler 190 includes one or more of: data updater 176, object updater 177, GUI updater 178, and/or event data 179 received from event sorter 170. Event handler 190 optionally utilizes or calls data updater 176, object updater 177, or GUI updater 178 to update the application internal state 192. Alternatively, one or more of the application views 191 include one or more respective event handlers 190. Also, in some embodiments, one or more of data updater 176, object updater 177, and GUI updater 178 are included in a respective application view 191.

[0134] A respective event recognizer 180 receives event information (e.g., event data 179) from event sorter 170 and identifies an event from the event information. Event recognizer 180 includes event receiver 182 and event comparator 184. In some embodiments, event recognizer 180 also includes at least a subset of: metadata 183, and event delivery instructions 188 (which optionally include sub-event delivery instructions).

[0135] Event receiver 182 receives event information from event sorter 170. The event information includes information about a sub-event, for example, a touch or a touch movement. Depending on the sub-event, the event information also includes additional information, such as location of the sub-event. When the sub-event concerns motion of a touch, the event information optionally also includes speed and direction of the sub-event. In some embodiments, events include rotation of the device from one orientation to another (e.g., from a portrait orientation to a landscape orientation, or vice versa), and the event information includes corresponding information about the current orientation (also called device attitude) of the device.

[0136] Event comparator 184 compares the event information to predefined event or sub-event definitions and, based on the comparison, determines an event or sub-event, or determines or updates the state of an event or sub-event. In some embodiments, event comparator 184 includes event definitions 186. Event definitions 186 contain definitions of events (e.g., predefined sequences of sub-events), for example, event 1 (187-1), event 2 (187-2), and others. In some embodiments, sub-events in an event (187) include, for example, touch begin, touch end, touch movement, touch cancellation, and multiple touching. In one example, the definition for event 1 (187-1) is a double tap on a displayed object. The double tap, for example, comprises a first touch (touch begin) on the displayed object for a predetermined phase, a first liftoff (touch end) for a predetermined phase, a second touch (touch begin) on the displayed object for a predetermined phase, and a second liftoff (touch end) for a predetermined phase. In another example, the definition for event 2 (187-2) is a dragging on a displayed object. The dragging, for example, comprises a touch (or contact) on the displayed object for a predetermined phase, a movement of the touch across touch-sensitive display 112, and liftoff of the touch (touch end). In some embodiments, the event also includes information for one or more associated event handlers 190.

[0137] In some embodiments, event definition 187 includes a definition of an event for a respective user-interface object. In some embodiments, event comparator 184 performs a hit test to determine which user-interface object is associated with a sub-event. For example, in an application view in which three user-interface objects are displayed on touch-sensitive display 112, when a touch is detected on touch-sensitive display 112, event comparator 184 performs a hit test to determine which of the three user-interface objects is associated with the touch (sub-

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event). If each displayed object is associated with a respective event handler 190, the event comparator uses the result of the hit test to determine which event handler 190 should be activated. For example, event comparator 184 selects an event handler associated with the sub-event and the object triggering the hit test.

[0138] In some embodiments, the definition for a respective event (187) also includes delayed actions that delay delivery of the event information until after it has been determined whether the sequence of sub-events does or does not correspond to the event recognizer's event type.

[0139] When a respective event recognizer 180 determines that the series of sub-events do not match any of the events in event definitions 186, the respective event recognizer 180 enters an event impossible, event failed, or event ended state, after which it disregards subsequent sub-events of the touch-based gesture. In this situation, other event recognizers, if any, that remain active for the hit view continue to track and process sub-events of an ongoing touch-based gesture.

[0140] In some embodiments, a respective event recognizer 180 includes metadata 183 with configurable properties, flags, and/or lists that indicate how the event delivery system should perform sub-event delivery to actively involved event recognizers. In some embodiments, metadata 183 includes configurable properties, flags, and/or lists that indicate how event recognizers interact, or are enabled to interact, with one another. In some embodiments, metadata 183 includes configurable properties, flags, and/or lists that indicate whether sub-events are delivered to varying levels in the view or programmatic hierarchy.

[0141] In some embodiments, a respective event recognizer 180 activates event handler 190 associated with an event when one or more particular sub-events of an event are recognized. In some embodiments, a respective event recognizer 180 delivers event information associated with the event to event handler 190. Activating an event handler 190 is distinct from sending (and deferred sending) sub-events to a respective hit view. In some embodiments, event recognizer 180 throws a flag associated with the recognized event, and event handler 190 associated with the flag catches the flag and performs a predefined process.

[0142] In some embodiments, event delivery instructions 188 include sub-event delivery instructions that deliver event information about a sub-event without activating an event handler. Instead, the sub-event delivery instructions deliver event information to event handlers associated with the series of sub-events or to actively involved views. Event handlers associated with the series of sub-events or with actively involved views receive the event information and perform a predetermined process.

[0143] In some embodiments, data updater 176 creates and updates data used in application 136-1. For example, data updater 176 updates the telephone number used in contacts module 137, or stores a video file used in video player module. In some embodiments, object updater 177 creates and updates objects used in application 136-1. For example, object updater 177 creates a new user-interface object or updates the position of a user-interface object. GUI updater 178 updates the GUI. For example, GUI updater 178 prepares display information and sends it to graphics module 132 for display on a touch-sensitive display.

[0144] In some embodiments, event handler(s) 190 includes or has access to data updater 176, object updater 177, and GUI updater 178. In some embodiments, data updater 176, object updater 177, and GUI updater 178 are included in a single module of a respective application 136-1 or application view 191. In other embodiments, they are included in two or more software modules.

[0145] It shall be understood that the foregoing discussion regarding event handling of user touches on touch-sensitive displays also applies to other forms of user inputs to operate multifunction devices 100 with input devices, not all of which are initiated on touch screens. For example, mouse movement and mouse button presses, optionally coordinated with single or multiple keyboard presses or holds; contact movements such as taps, drags, scrolls, etc. on touchpads; pen stylus inputs; movement of the device; oral instructions; detected eye movements; biometric inputs; and/or any combination thereof are optionally utilized as inputs corresponding to sub-events which define an event to be recognized.

[0146] FIG. 2 illustrates a portable multifunction device 100 having a touch screen 112 in accordance with some embodiments. The touch screen optionally displays one or more graphics within user interface (UI) 200. In this embodiment, as well as others described below, a user is

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enabled to select one or more of the graphics by making a gesture on the graphics, for example, with one or more fingers 202 (not drawn to scale in the figure) or one or more styluses 203 (not drawn to scale in the figure). In some embodiments, selection of one or more graphics occurs when the user breaks contact with the one or more graphics. In some embodiments, the gesture optionally includes one or more taps, one or more swipes (from left to right, right to left, upward and/or downward), and/or a rolling of a finger (from right to left, left to right, upward and/or downward) that has made contact with device 100. In some implementations or circumstances, inadvertent contact with a graphic does not select the graphic. For example, a swipe gesture that sweeps over an application icon optionally does not select the corresponding application when the gesture corresponding to selection is a tap.

[0147] Device 100 optionally also include one or more physical buttons, such as "home" or menu button 204. As described previously, menu button 204 is, optionally, used to navigate to any application 136 in a set of applications that are, optionally, executed on device 100. Alternatively, in some embodiments, the menu button is implemented as a soft key in a GUI displayed on touch screen 112.

[0148] In some embodiments, device 100 includes touch screen 112, menu button 204, push button 206 for powering the device on/off and locking the device, volume adjustment button(s) 208, subscriber identity module (SIM) card slot 210, headset jack 212, and docking/charging external port 124. Push button 206 is, optionally, used to turn the power on/off on the device by depressing the button and holding the button in the depressed state for a predefined time interval; to lock the device by depressing the button and releasing the button before the predefined time interval has elapsed; and/or to unlock the device or initiate an unlock process. In an alternative embodiment, device 100 also accepts verbal input for activation or deactivation of some functions through microphone 113. Device 100 also, optionally, includes one or more contact intensity sensors 165 for detecting intensity of contacts on touch screen 112 and/or one or more tactile output generators 167 for generating tactile outputs for a user of device 100.

[0149] FIG. 3 is a block diagram of an exemplary multifunction device with a display and a touch-sensitive surface in accordance with some embodiments. Device 300 need not be portable. In some embodiments, device 300 is a laptop computer, a desktop computer, a tablet computer, a

multimedia player device, a navigation device, an educational device (such as a child's learning toy), a gaming system, or a control device (e.g., a home or industrial controller). Device 300 typically includes one or more processing units (CPUs) 310, one or more network or other communications interfaces 360, memory 370, and one or more communication buses 320 for interconnecting these components. Communication buses 320 optionally include circuitry (sometimes called a chipset) that interconnects and controls communications between system components. Device 300 includes input/output (I/O) interface 330 comprising display 340, which is typically a touch screen display. I/O interface 330 also optionally includes a keyboard and/or mouse (or other pointing device) 350 and touchpad 355, tactile output generator 357 for generating tactile outputs on device 300 (e.g., similar to tactile output generator(s) 167 described above with reference to FIG. 1A), sensors 359 (e.g., optical, acceleration, proximity, touch-sensitive, and/or contact intensity sensors similar to contact intensity sensor(s) 165 described above with reference to FIG. 1A). Memory 370 includes high-speed random access memory, such as DRAM, SRAM, DDR RAM, or other random access solid state memory devices; and optionally includes non-volatile memory, such as one or more magnetic disk storage devices, optical disk storage devices, flash memory devices, or other non-volatile solid state storage devices. Memory 370 optionally includes one or more storage devices remotely located from CPU(s) 310. In some embodiments, memory 370 stores programs, modules, and data structures analogous to the programs, modules, and data structures stored in memory 102 of portable multifunction device 100 (FIG. 1A), or a subset thereof. Furthermore, memory 370 optionally stores additional programs, modules, and data structures not present in memory 102 of portable multifunction device 100. For example, memory 370 of device 300 optionally stores drawing module 380, presentation module 382, word processing module 384, website creation module 386, disk authoring module 388, and/or spreadsheet module 390, while memory 102 of portable multifunction device 100 (FIG. 1A) optionally does not store these modules.

[0150] Each of the above-identified elements in FIG. 3 is, optionally, stored in one or more of the previously mentioned memory devices. Each of the above-identified modules corresponds to a set of instructions for performing a function described above. The above-identified modules or programs (e.g., sets of instructions) need not be implemented as separate software programs, procedures, or modules, and thus various subsets of these modules are, optionally, combined or

otherwise rearranged in various embodiments. In some embodiments, memory 370 optionally stores a subset of the modules and data structures identified above. Furthermore, memory 370 optionally stores additional modules and data structures not described above.

[0151] Attention is now directed towards embodiments of user interfaces that are, optionally, implemented on, for example, portable multifunction device 100.

[0152] FIG. 4A illustrates an exemplary user interface for a menu of applications on portable multifunction device 100 in accordance with some embodiments. Similar user interfaces are, optionally, implemented on device 300. In some embodiments, user interface 400 includes the following elements, or a subset or superset thereof:

- Signal strength indicator(s) 402 for wireless communication(s), such as cellular and Wi-Fi signals;
- Time 404;
- Bluetooth indicator 405;
- Battery status indicator 406;
- Tray 408 with icons for frequently used applications, such as:
    - Icon 416 for telephone module 138, labeled "Phone," which optionally includes an indicator 414 of the number of missed calls or voicemail messages;
    - Icon 418 for e-mail client module 140, labeled "Mail," which optionally includes an indicator 410 of the number of unread e-mails;
    - Icon 420 for browser module 147, labeled "Browser;" and
    - Icon 422 for video and music player module 152, also referred to as iPod (trademark of Apple Inc.) module 152, labeled "iPod;" and
- Icons for other applications, such as:
    - Icon 424 for IM module 141, labeled "Messages;"

- Icon 426 for calendar module 148, labeled "Calendar;"
- Icon 428 for image management module 144, labeled "Photos;"
- Icon 430 for camera module 143, labeled "Camera;"
- Icon 432 for online video module 155, labeled "Online Video;"
- Icon 434 for stocks widget 149-2, labeled "Stocks;"
- Icon 436 for map module 154, labeled "Maps;"
- Icon 438 for weather widget 149-1, labeled "Weather;"
- Icon 440 for alarm clock widget 149-4, labeled "Clock;"
- Icon 442 for workout support module 142, labeled "Workout Support;"
- Icon 444 for notes module 153, labeled "Notes;" and
- Icon 446 for a settings application or module, labeled "Settings," which provides access to settings for device 100 and its various applications 136.

[0153] It should be noted that the icon labels illustrated in FIG. 4A are merely exemplary. For example, icon 422 for video and music player module 152 is labeled "Music" or "Music Player." Other labels are, optionally, used for various application icons. In some embodiments, a label for a respective application icon includes a name of an application corresponding to the respective application icon. In some embodiments, a label for a particular application icon is distinct from a name of an application corresponding to the particular application icon.

[0154] FIG. 4B illustrates an exemplary user interface on a device (e.g., device 300, FIG. 3) with a touch-sensitive surface 451 (e.g., a tablet or touchpad 355, FIG. 3) that is separate from the display 450 (e.g., touch screen display 112). Device 300 also, optionally, includes one or more contact intensity sensors (e.g., one or more of sensors 359) for detecting intensity of contacts on touch-sensitive surface 451 and/or one or more tactile output generators 357 for generating tactile outputs for a user of device 300.

[0155] Although some of the examples that follow will be given with reference to inputs on touch screen display 112 (where the touch-sensitive surface and the display are combined), in some embodiments, the device detects inputs on a touch-sensitive surface that is separate from

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the display, as shown in FIG. 4B. In some embodiments, the touch-sensitive surface (e.g., 451 in FIG. 4B) has a primary axis (e.g., 452 in FIG. 4B) that corresponds to a primary axis (e.g., 453 in FIG. 4B) on the display (e.g., 450). In accordance with these embodiments, the device detects contacts (e.g., 460 and 462 in FIG. 4B) with the touch-sensitive surface 451 at locations that correspond to respective locations on the display (e.g., in FIG. 4B, 460 corresponds to 468 and 462 corresponds to 470). In this way, user inputs (e.g., contacts 460 and 462, and movements thereof) detected by the device on the touch-sensitive surface (e.g., 451 in FIG. 4B) are used by the device to manipulate the user interface on the display (e.g., 450 in FIG. 4B) of the multifunction device when the touch-sensitive surface is separate from the display. It should be understood that similar methods are, optionally, used for other user interfaces described herein.

[0156] Additionally, while the following examples are given primarily with reference to finger inputs (e.g., finger contacts, finger tap gestures, finger swipe gestures), it should be understood that, in some embodiments, one or more of the finger inputs are replaced with input from another input device (e.g., a mouse-based input or stylus input). For example, a swipe gesture is, optionally, replaced with a mouse click (e.g., instead of a contact) followed by movement of the cursor along the path of the swipe (e.g., instead of movement of the contact). As another example, a tap gesture is, optionally, replaced with a mouse click while the cursor is located over the location of the tap gesture (e.g., instead of detection of the contact followed by ceasing to detect the contact). Similarly, when multiple user inputs are simultaneously detected, it should be understood that multiple computer mice are, optionally, used simultaneously, or a mouse and finger contacts are, optionally, used simultaneously.

[0157] FIG. 5A illustrates exemplary personal electronic device 500. Device 500 includes body 502. In some embodiments, device 500 can include some or all of the features described with respect to devices 100 and 300 (e.g., FIGS. 1A-4B). In some embodiments, device 500 has touch-sensitive display screen 504, hereafter touch screen 504. Alternatively, or in addition to touch screen 504, device 500 has a display and a touch-sensitive surface. As with devices 100 and 300, in some embodiments, touch screen 504 (or the touch-sensitive surface) optionally includes one or more intensity sensors for detecting intensity of contacts (e.g., touches) being applied. The one or more intensity sensors of touch screen 504 (or the touch-sensitive surface) can provide output data that represents the intensity of touches. The user interface of device 500

can respond to touches based on their intensity, meaning that touches of different intensities can invoke different user interface operations on device 500.

[0158] Exemplary techniques for detecting and processing touch intensity are found, for example, in related applications: International Patent Application Serial No. PCT/US2013/040061, titled "Device, Method, and Graphical User Interface for Displaying User Interface Objects Corresponding to an Application," filed May 8, 2013, published as WIPO Publication No. WO/2013/169849, and International Patent Application Serial No. PCT/US2013/069483, titled "Device, Method, and Graphical User Interface for Transitioning Between Touch Input to Display Output Relationships," filed November 11, 2013, published as WIPO Publication No. WO/2014/105276, each of which is hereby incorporated by reference in their entirety.

[0159] In some embodiments, device 500 has one or more input mechanisms 506 and 508. Input mechanisms 506 and 508, if included, can be physical. Examples of physical input mechanisms include push buttons and rotatable mechanisms. In some embodiments, device 500 has one or more attachment mechanisms. Such attachment mechanisms, if included, can permit attachment of device 500 with, for example, hats, eyewear, earrings, necklaces, shirts, jackets, bracelets, watch straps, chains, trousers, belts, shoes, purses, backpacks, and so forth. These attachment mechanisms permit device 500 to be worn by a user.

[0160] FIG. 5B depicts exemplary personal electronic device 500. In some embodiments, device 500 can include some or all of the components described with respect to FIGS. 1A, 1B, and 3. Device 500 has bus 512 that operatively couples I/O section 514 with one or more computer processors 516 and memory 518. I/O section 514 can be connected to display 504, which can have touch-sensitive component 522 and, optionally, intensity sensor 524 (e.g., contact intensity sensor). In addition, I/O section 514 can be connected with communication unit 530 for receiving application and operating system data, using Wi-Fi, Bluetooth, near field communication (NFC), cellular, and/or other wireless communication techniques. Device 500 can include input mechanisms 506 and/or 508. Input mechanism 506 is, optionally, a rotatable input device or a depressible and rotatable input device (e.g., a rotating crown), for example. Input mechanism 508 is, optionally, a button, in some examples.

[0161] Input mechanism 508 is, optionally, a microphone, in some examples. Personal electronic device 500 optionally includes various sensors, such as GPS sensor 532, accelerometer 534, directional sensor 540 (e.g., compass), gyroscope 536, motion sensor 538, and/or a combination thereof, all of which can be operatively connected to I/O section 514.

[0162] Memory 518 of personal electronic device 500 can include one or more non-transitory computer-readable storage mediums, for storing computer-executable instructions, which, when executed by one or more computer processors 516, for example, can cause the computer processors to perform the techniques described below, including processes 700 (FIGS. 7A-7C), 900 (FIGS. 9A-9B), 1100 (FIG. 11), and 1300 (FIGS. 13A-13B). A computer-readable storage medium can be any medium that can tangibly contain or store computer-executable instructions for use by or in connection with the instruction execution system, apparatus, or device. In some examples, the storage medium is a transitory computer-readable storage medium. In some examples, the storage medium is a non-transitory computer-readable storage medium. The non-transitory computer-readable storage medium can include, but is not limited to, magnetic, optical, and/or semiconductor storages. Examples of such storage include magnetic disks, optical discs based on CD, DVD, or Blu-ray technologies, as well as persistent solid-state memory such as flash, solid-state drives, and the like. Personal electronic device 500 is not limited to the components and configuration of FIG. 5B, but can include other or additional components in multiple configurations.

[0163] As used here, the term "affordance" refers to a user-interactive graphical user interface object that is, optionally, displayed on the display screen of devices 100, 300, and/or 500 (FIGS. 1A, 3, and 5A-5B). For example, an image (e.g., icon), a button, and text (e.g., hyperlink) each optionally constitute an affordance.

[0164] As used herein, the term "focus selector" refers to an input element that indicates a current part of a user interface with which a user is interacting. In some implementations that include a cursor or other location marker, the cursor acts as a "focus selector" so that when an input (e.g., a press input) is detected on a touch-sensitive surface (e.g., touchpad 355 in FIG. 3 or touch-sensitive surface 451 in FIG. 4B) while the cursor is over a particular user interface element (e.g., a button, window, slider, or other user interface element), the particular user

interface element is adjusted in accordance with the detected input. In some implementations that include a touch screen display (e.g., touch-sensitive display system 112 in FIG. 1A or touch screen 112 in FIG. 4A) that enables direct interaction with user interface elements on the touch screen display, a detected contact on the touch screen acts as a "focus selector" so that when an input (e.g., a press input by the contact) is detected on the touch screen display at a location of a particular user interface element (e.g., a button, window, slider, or other user interface element), the particular user interface element is adjusted in accordance with the detected input. In some implementations, focus is moved from one region of a user interface to another region of the user interface without corresponding movement of a cursor or movement of a contact on a touch screen display (e.g., by using a tab key or arrow keys to move focus from one button to another button); in these implementations, the focus selector moves in accordance with movement of focus between different regions of the user interface. Without regard to the specific form taken by the focus selector, the focus selector is generally the user interface element (or contact on a touch screen display) that is controlled by the user so as to communicate the user's intended interaction with the user interface (e.g., by indicating, to the device, the element of the user interface with which the user is intending to interact). For example, the location of a focus selector (e.g., a cursor, a contact, or a selection box) over a respective button while a press input is detected on the touch-sensitive surface (e.g., a touchpad or touch screen) will indicate that the user is intending to activate the respective button (as opposed to other user interface elements shown on a display of the device).

[0165] As used in the specification and claims, the term "characteristic intensity" of a contact refers to a characteristic of the contact based on one or more intensities of the contact. In some embodiments, the characteristic intensity is based on multiple intensity samples. The characteristic intensity is, optionally, based on a predefined number of intensity samples, or a set of intensity samples collected during a predetermined time period (e.g., 0.05, 0.1, 0.2, 0.5, 1, 2, 5, 10 seconds) relative to a predefined event (e.g., after detecting the contact, prior to detecting liftoff of the contact, before or after detecting a start of movement of the contact, prior to detecting an end of the contact, before or after detecting an increase in intensity of the contact, and/or before or after detecting a decrease in intensity of the contact). A characteristic intensity of a contact is, optionally, based on one or more of: a maximum value of the intensities of the

contact, a mean value of the intensities of the contact, an average value of the intensities of the contact, a top 10 percentile value of the intensities of the contact, a value at the half maximum of the intensities of the contact, a value at the 90 percent maximum of the intensities of the contact, or the like. In some embodiments, the duration of the contact is used in determining the characteristic intensity (e.g., when the characteristic intensity is an average of the intensity of the contact over time). In some embodiments, the characteristic intensity is compared to a set of one or more intensity thresholds to determine whether an operation has been performed by a user. For example, the set of one or more intensity thresholds optionally includes a first intensity threshold and a second intensity threshold. In this example, a contact with a characteristic intensity that does not exceed the first threshold results in a first operation, a contact with a characteristic intensity that exceeds the first intensity threshold and does not exceed the second intensity threshold results in a second operation, and a contact with a characteristic intensity that exceeds the second threshold results in a third operation. In some embodiments, a comparison between the characteristic intensity and one or more thresholds is used to determine whether or not to perform one or more operations (e.g., whether to perform a respective operation or forgo performing the respective operation), rather than being used to determine whether to perform a first operation or a second operation.

[0166] FIG. 5C illustrates detecting a plurality of contacts 552A-552E on touch-sensitive display screen 504 with a plurality of intensity sensors 524A-524D. FIG. 5C additionally includes intensity diagrams that show the current intensity measurements of the intensity sensors 524A-524D relative to units of intensity. In this example, the intensity measurements of intensity sensors 524A and 524D are each 9 units of intensity, and the intensity measurements of intensity sensors 524B and 524C are each 7 units of intensity. In some implementations, an aggregate intensity is the sum of the intensity measurements of the plurality of intensity sensors 524A-524D, which in this example is 32 intensity units. In some embodiments, each contact is assigned a respective intensity that is a portion of the aggregate intensity. FIG. 5D illustrates assigning the aggregate intensity to contacts 552A-552E based on their distance from the center of force 554. In this example, each of contacts 552A, 552B, and 552E are assigned an intensity of contact of 8 intensity units of the aggregate intensity, and each of contacts 552C and 552D are assigned an intensity of contact of 4 intensity units of the aggregate intensity. More generally, in

some implementations, each contact j is assigned a respective intensity Ij that is a portion of the aggregate intensity, A, in accordance with a predefined mathematical function, $Ij = A \cdot (Dj/\Sigma Di)$, where Dj is the distance of the respective contact j to the center of force, and ΣDi is the sum of the distances of all the respective contacts (e.g., i=1 to last) to the center of force. The operations described with reference to FIGS. 5C-5D can be performed using an electronic device similar or identical to device 100, 300, or 500. In some embodiments, a characteristic intensity of a contact is based on one or more intensities of the contact. In some embodiments, the intensity sensors are used to determine a single characteristic intensity (e.g., a single characteristic intensity of a single contact). It should be noted that the intensity diagrams are not part of a displayed user interface, but are included in FIGS. 5C-5D to aid the reader.

[0167] In some embodiments, a portion of a gesture is identified for purposes of determining a characteristic intensity. For example, a touch-sensitive surface optionally receives a continuous swipe contact transitioning from a start location and reaching an end location, at which point the intensity of the contact increases. In this example, the characteristic intensity of the contact at the end location is, optionally, based on only a portion of the continuous swipe contact, and not the entire swipe contact (e.g., only the portion of the swipe contact at the end location). In some embodiments, a smoothing algorithm is, optionally, applied to the intensities of the swipe contact prior to determining the characteristic intensity of the contact. For example, the smoothing algorithm optionally includes one or more of: an unweighted sliding-average smoothing algorithm, a triangular smoothing algorithm, a median filter smoothing algorithm, and/or an exponential smoothing algorithm. In some circumstances, these smoothing algorithms eliminate narrow spikes or dips in the intensities of the swipe contact for purposes of determining a characteristic intensity.

[0168] The intensity of a contact on the touch-sensitive surface is, optionally, characterized relative to one or more intensity thresholds, such as a contact-detection intensity threshold, a light press intensity threshold, a deep press intensity threshold, and/or one or more other intensity thresholds. In some embodiments, the light press intensity threshold corresponds to an intensity at which the device will perform operations typically associated with clicking a button of a physical mouse or a trackpad. In some embodiments, the deep press intensity threshold corresponds to an intensity at which the device will perform operations that are different from

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operations typically associated with clicking a button of a physical mouse or a trackpad. In some embodiments, when a contact is detected with a characteristic intensity below the light press intensity threshold (e.g., and above a nominal contact-detection intensity threshold below which the contact is no longer detected), the device will move a focus selector in accordance with movement of the contact on the touch-sensitive surface without performing an operation associated with the light press intensity threshold or the deep press intensity threshold. Generally, unless otherwise stated, these intensity thresholds are consistent between different sets of user interface figures.

[0169] An increase of characteristic intensity of the contact from an intensity below the light press intensity threshold to an intensity between the light press intensity threshold and the deep press intensity threshold is sometimes referred to as a "light press" input. An increase of characteristic intensity of the contact from an intensity below the deep press intensity threshold to an intensity above the deep press intensity threshold is sometimes referred to as a "deep press" input. An increase of characteristic intensity of the contact from an intensity below the contact-detection intensity threshold to an intensity between the contact-detection intensity threshold and the light press intensity threshold is sometimes referred to as detecting the contact on the touch-surface. A decrease of characteristic intensity of the contact from an intensity above the contact-detection intensity threshold to an intensity below the contact-detection intensity threshold is sometimes referred to as detecting liftoff of the contact from the touch-surface. In some embodiments, the contact-detection intensity threshold is zero. In some embodiments, the contact-detection intensity threshold is greater than zero.

[0170] In some embodiments described herein, one or more operations are performed in response to detecting a gesture that includes a respective press input or in response to detecting the respective press input performed with a respective contact (or a plurality of contacts), where the respective press input is detected based at least in part on detecting an increase in intensity of the contact (or plurality of contacts) above a press-input intensity threshold. In some embodiments, the respective operation is performed in response to detecting the increase in intensity of the respective contact above the press-input intensity threshold (e.g., a "down stroke" of the respective press input). In some embodiments, the press input includes an increase in intensity of the respective contact above the press-input intensity threshold and a subsequent

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decrease in intensity of the contact below the press-input intensity threshold, and the respective operation is performed in response to detecting the subsequent decrease in intensity of the respective contact below the press-input threshold (e.g., an "up stroke" of the respective press input).

[0171] FIGS. 5E-5H illustrate detection of a gesture that includes a press input that corresponds to an increase in intensity of a contact 562 from an intensity below a light press intensity threshold (e.g., "IT_L") in FIG. 5E, to an intensity above a deep press intensity threshold (e.g., "IT_D") in FIG. 5H. The gesture performed with contact 562 is detected on touch-sensitive surface 560 while cursor 576 is displayed over application icon 572B corresponding to App 2, on a displayed user interface 570 that includes application icons 572A-572D displayed in predefined region 574. In some embodiments, the gesture is detected on touch-sensitive display 504. The intensity sensors detect the intensity of contacts on touch-sensitive surface 560. The device determines that the intensity of contact 562 peaked above the deep press intensity threshold (e.g., "IT_D"). Contact 562 is maintained on touch-sensitive surface 560. In response to the detection of the gesture, and in accordance with contact 562 having an intensity that goes above the deep press intensity threshold (e.g., "IT_D") during the gesture, reduced-scale representations 578A-578C (e.g., thumbnails) of recently opened documents for App 2 are displayed, as shown in FIGS. 5F-5H. In some embodiments, the intensity, which is compared to the one or more intensity thresholds, is the characteristic intensity of a contact. It should be noted that the intensity diagram for contact 562 is not part of a displayed user interface, but is included in FIGS. 5E-5H to aid the reader.

[0172] In some embodiments, the display of representations 578A-578C includes an animation. For example, representation 578A is initially displayed in proximity of application icon 572B, as shown in FIG. 5F. As the animation proceeds, representation 578A moves upward and representation 578B is displayed in proximity of application icon 572B, as shown in FIG. 5G. Then, representations 578A moves upward, 578B moves upward toward representation 578A, and representation 578C is displayed in proximity of application icon 572B, as shown in FIG. 5H. Representations 578A-578C form an array above icon 572B. In some embodiments, the animation progresses in accordance with an intensity of contact 562, as shown in FIGS. 5F-5G, where the representations 578A-578C appear and move upwards as the intensity of contact

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562 increases toward the deep press intensity threshold (e.g., "IT_D"). In some embodiments, the intensity, on which the progress of the animation is based, is the characteristic intensity of the contact. The operations described with reference to FIGS. 5E-5H can be performed using an electronic device similar or identical to device 100, 300, or 500.

[0173] In some embodiments, the device employs intensity hysteresis to avoid accidental inputs sometimes termed "jitter," where the device defines or selects a hysteresis intensity threshold with a predefined relationship to the press-input intensity threshold (e.g., the hysteresis intensity threshold is X intensity units lower than the press-input intensity threshold or the hysteresis intensity threshold is 75%, 90%, or some reasonable proportion of the press-input intensity threshold). Thus, in some embodiments, the press input includes an increase in intensity of the respective contact above the press-input intensity threshold and a subsequent decrease in intensity of the contact below the hysteresis intensity threshold that corresponds to the press-input intensity threshold, and the respective operation is performed in response to detecting the subsequent decrease in intensity of the respective contact below the hysteresis intensity threshold (e.g., an "up stroke" of the respective press input). Similarly, in some embodiments, the press input is detected only when the device detects an increase in intensity of the contact from an intensity at or below the hysteresis intensity threshold to an intensity at or above the press-input intensity threshold and, optionally, a subsequent decrease in intensity of the contact to an intensity at or below the hysteresis intensity, and the respective operation is performed in response to detecting the press input (e.g., the increase in intensity of the contact or the decrease in intensity of the contact, depending on the circumstances).

[0174] For ease of explanation, the descriptions of operations performed in response to a press input associated with a press-input intensity threshold or in response to a gesture including the press input are, optionally, triggered in response to detecting either: an increase in intensity of a contact above the press-input intensity threshold, an increase in intensity of a contact from an intensity below the hysteresis intensity threshold to an intensity above the press-input intensity threshold, a decrease in intensity of the contact below the press-input intensity threshold, and/or a decrease in intensity of the contact below the hysteresis intensity threshold corresponding to the press-input intensity threshold. Additionally, in examples where an operation is described as being performed in response to detecting a decrease in intensity of a

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contact below the press-input intensity threshold, the operation is, optionally, performed in response to detecting a decrease in intensity of the contact below a hysteresis intensity threshold corresponding to, and lower than, the press-input intensity threshold.

[0175] As used herein, an "installed application" refers to a software application that has been downloaded onto an electronic device (e.g., devices 100, 300, and/or 500) and is ready to be launched (e.g., become opened) on the device. In some embodiments, a downloaded application becomes an installed application by way of an installation program that extracts program portions from a downloaded package and integrates the extracted portions with the operating system of the computer system.

[0176] As used herein, the terms "open application" or "executing application" refer to a software application with retained state information (e.g., as part of device/global internal state 157 and/or application internal state 192). An open or executing application is, optionally, any one of the following types of applications:

- an active application, which is currently displayed on a display screen of the device that the application is being used on;
- a background application (or background processes), which is not currently displayed, but one or more processes for the application are being processed by one or more processors; and
- a suspended or hibernated application, which is not running, but has state information that is stored in memory (volatile and non-volatile, respectively) and that can be used to resume execution of the application.

[0177] As used herein, the term "closed application" refers to software applications without retained state information (e.g., state information for closed applications is not stored in a memory of the device). Accordingly, closing an application includes stopping and/or removing application processes for the application and removing state information for the application from the memory of the device. Generally, opening a second application while in a first application

does not close the first application. When the second application is displayed and the first application ceases to be displayed, the first application becomes a background application.

[0178] Attention is now directed towards embodiments of user interfaces ("UI") and associated processes that are implemented on one or more electronic device(s), such as portable multifunction device 100, device 300, or device 500.

[0179] FIGS. 6A-6AE illustrate exemplary user interfaces for initial setup of health monitoring, in accordance with some embodiments. The user interfaces in these figures are used to illustrate the processes described below, including the processes in FIGS. 7A-7C. The exemplary user interfaces in these figures relate generally to monitoring health using recorded biometric information, and are not limited to a specific type of biometric information. Only for the sake of convenience, the exemplary user interfaces in these figures are described with reference to a type of biometric information—electrocardiogram (hereinafter "ECG") information.

[0180] FIG. 6A illustrates a first electronic device 600A (e.g., a smartphone) with a display 602 and one or more input devices. In some embodiments, the one or more input devices include a touch layer of display 602 for detecting touch input, one or more image sensors 604 (e.g., a camera, a depth sensor), a first mechanical button 606 configured to perform one or more operations (e.g., and including an integrated biometric sensor, such as a fingerprint sensor), and a second mechanical button 608 configured to perform one or more operations. In some embodiments, first electronic device 600A includes a wireless communication radio (e.g., for LTE, Bluetooth, WiFi connections). In some embodiments, first electronic device 600A is paired with a second electronic device (e.g., a smartwatch). In some embodiments, the second electronic device corresponds to second electronic device 600B described below with reference to FIGS. 6S-6X.

[0181] In FIG. 6A, first electronic device 600A is displaying, on display 602, a homescreen user interface 610 corresponding to a homescreen of the operating system running on the device. In some embodiments, homescreen user interface 610 includes a plurality of icons corresponding to different applications that are installed on the device, including a health application corresponding to icon 610A. In some embodiments, the health application can be used to

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manage a user's biometric information, such as heart rhythm information and/or heart rate information (e.g., using recorded ECG information).

[0182] In some embodiments, first electronic device 600A detects (e.g., via a touch input) a user activation 601 of icon 610A corresponding to a health application, which includes features concerning management of recordings of biometric information, including ECG information. In response to detecting user activation 601, first electronic device 600A launches the health application (e.g., by replacing display of homescreen user interface 610 with a user interface of the health application).

[0183] In some embodiments, the health application includes an ECG affordance for viewing and managing existing ECG recordings on the device, where the ECG information is recorded using a related ECG application on a second electronic device (e.g., second electronic device 600B described with reference to FIGS. 6S-6X), where the ECG application on the second electronic device (e.g., second electronic device 600B) is associated with the ECG management features of the health application on first electronic device 600A. In some embodiments, if the ECG management features have not yet been setup on first electronic device 600A (e.g., the user has not yet used the ECG recording feature), launching of the ECG management features on the health application (e.g., in response to detecting a user selection of the ECG affordance) causes display of a first page of a tutorial for performing initial setup of the ECG management features of the health application (e.g., as described with reference to FIG. 6F).

[0184] In some embodiments, homescreen user interface 610 includes a paired device application corresponding to icon 610B and associated with a device paired with first electronic device 600A (e.g., second electronic device 600B). In some embodiments, while displaying homescreen user interface 610, first electronic device 600A detects (e.g., via a tap input) a user activation 641 of icon 610B, as shown in FIG. 6B.

[0185] In some embodiments, in response to detecting user activation 641, first electronic device 600A displays, on display 602, a main user interface 643 of the paired device application, as shown in FIG. 6C. In some embodiments, the paired device application includes a plurality of application setting affordances 645A-645H corresponding to various applications installed on the paired device (e.g., second electronic device 600B), including a heart application setting

affordance 645G corresponding to a heart application (e.g., the ECG application) installed on the paired device. In some embodiments, while displaying main user interface 643 of the paired device application, the device detects (e.g., via a tap input) a user activation 647 of heart application setting affordance 645G.

[0186] In some embodiments, in response to detecting user activation 647 of heart application setting affordance 645G, first electronic device 600A displays, on display 602, an application settings page 649 for changing and/or configuring application settings of the corresponding heart application (e.g., the ECG application) on second electronic device 600B, as shown in FIG. 6D. In some embodiments, if ECG management features have not yet been setup on first electronic device 600A, application settings page 649 includes an affordance 651 (e.g., an affordance labelled "Set up ECG functionality" or "Set up ECG application in Health") for performing initial setup of the ECG management features. In some embodiments, first electronic device 600A launches the first page of the tutorial (e.g., as described with reference to FIG. 6F) in response to detecting a user activation of affordance 651.

[0187] FIG. 6E illustrates first electronic device 600A displaying, on display 602, a (selectable) notification 612 indicating (to the user of the device) that an ECG application, which is associated with the health application on first electronic device 600A, has launched (or is active) on a second electronic device (e.g., second electronic device 600B). In some embodiments, notification 612 is displayed on a lockscreen user interface of the first electronic device. In some embodiments, notification 612 is displayed in homescreen user interface 610 of the device (e.g., at a top portion of the display). In some embodiments, notification 612 is displayed over a user interface of an application (e.g., email application, web browser application) running on the device (e.g., at a top portion of the display).

[0188] In some embodiments, notification 612 indicates that initial setup (e.g., onboarding) of the ECG management features of the health application need to be performed in order to utilize ECG features of the application. In some embodiments, while displaying notification 612, first electronic device 600A detects (e.g., via a touch input) a user selection 603 of notification 612. In response to detecting user selection 603, first electronic device 600A launches a first

page of a tutorial for performing initial setup of the ECG management features and associated ECG application.

[0189] FIG. 6F illustrates first electronic device 600A displaying, on display 602, a first page 614 of the tutorial for performing initial setup of the ECG management features and associated ECG application. In some embodiments, first page 614 of the tutorial includes a graphical indication region 614A that graphically indicates (e.g., via a static image, via an animation) a function of the ECG management features and associated ECG application (e.g., recording heart rhythm information and/or heart rate information) and instructions on how to perform the function (e.g., using the associated ECG application on a smartwatch paired to the device). In some embodiments, first page 614 of the tutorial includes a text description region 614B describing a use of the ECG management features and associated ECG application (e.g., stating "Check your heart rhythm") and background information relevant to the use of the ECG management features and associated ECG application.

[0190] In some embodiments, first page 614 of the tutorial includes a date of birth entry field 614C for receiving a user input corresponding to the user's date of birth, where the user's date of birth is used to determine whether the user meets a minimum age requirement (e.g., 22 years of age) to use the features of the ECG application. In some embodiments, date of birth entry field 614C includes scrollable month, day, and year fields. In some embodiments, first page 614 of the tutorial does not include date of birth entry field 614C. In some embodiments, first page 614 of the tutorial includes (e.g., in addition to or alternatively to date of birth entry field 614C) an age restriction message (e.g., stating "You must be 22 years or older") indicating to the user that the user must meet the minimum age requirement.

[0191] In some embodiments, first page 614 of the tutorial includes an affordance 614D for proceeding with the tutorial. In FIG. 6F, while displaying first page 614 of the tutorial for performing initial setup of the ECG management features and associated ECG application, first electronic device 600A detects (e.g., via a touch input) a user activation 605 of affordance 614D for proceeding with the tutorial. In some embodiments, in accordance with a determination that the minimum age requirement is not met (e.g., a determination made in response to detecting user activation 605), first electronic device 600A displays, on display 602, an error notification

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(e.g., stating "The ECG application is not intended for use by people under 22") indicating that the user does not meet the requisite minimum age requirement. In some embodiments, the error notification is overlaid on first page 614 of the tutorial. In some embodiments, while displaying the error notification, the background of the display (displaying first page 614) is dimmed (thereby emphasizing the displayed error notification).

[0192] In some embodiments, in response to detecting user activation 605 (and in accordance with a determination that the minimum age requirement is met), first electronic device 600A displays, on display 602 (e.g., replaces display of first page 614 with), a second page 616 of the tutorial, as shown in FIG. 6G.

[0193] FIG. 6G illustrates first electronic device 600A displaying, on display 602, second page 616 of the tutorial for performing initial setup of the ECG management features and the associated ECG application (e.g., where the associated ECG application is running on or can be launched on a second electronic device, such as second electronic device 600B). In some embodiments, second page 616 of the tutorial includes an animation region 616A that graphically indicates (e.g., via a static image, via an animation) example ECG information captured using the application. In some examples, animation region 616A includes an example tachogram-animation. In some examples, the example tachogram-animation includes one or more objects that continuously move across the animation by tracking the tachogram-like portion of the animation. In some embodiments, second page 616 of the tutorial includes a text description region 616B that summarizes how the ECG information is captured from the user and how the recorded biometric information can be viewed by the user. In some embodiments, second page 616 of the tutorial includes an affordance 616C for proceeding with the tutorial.

[0194] In FIG. 6G, while displaying second page 616 of the tutorial for performing initial setup of the ECG management features and associated ECG application, first electronic device 600A detects (e.g., via a touch input) a user activation 607 of affordance 616C for proceeding with the tutorial. In some embodiments, in response to detecting user activation 607, the device displays, on display 602 (e.g., replaces display of first page 616 with), a possible results page 618 of the tutorial, as shown in FIG. 6H.

[0195] FIG. 6H illustrates first electronic device 600A displaying, on display 602, possible results page 618 of the tutorial for performing initial setup of the ECG management features and associated ECG application. In some embodiments, possible results page 618 includes a plurality of representations of possible evaluation results that can be made based on ECG information recorded using the associated ECG application on a second electronic device (e.g., second electronic device 600B).

[0196] In some embodiments, the plurality of representations of possible evaluation results shown in possible results page 618 of the tutorial include possible evaluation results corresponding to heart rhythm and heart rate that are captured from an ECG recording. In some embodiments, a first possible evaluation result is a "regular rhythm" result (or a "normal result"), which corresponds to a result where no abnormal signs were determined from the ECG recording of the user. In some embodiments, a second possible evaluation result is an "abnormal heart rhythm" result (e.g., an "Atrial Fibrillation" result) that corresponds to a result where abnormal heart rhythm signs (and, in some cases, high/low heart rate signs) were determined from the ECG recording of the user. In some embodiments, a third possible evaluation result is an "abnormal heart rate" result (e.g., a "high or low heart rate" result), which corresponds to a result where an unusually (or abnormally) high or low heart rate was determined from the ECG recording of the user (e.g., above 150 BPM or below 50 BPM). In some embodiments, a fourth possible evaluation result is an "inconclusive" result, which corresponds to a result where no evaluation result could be determined from the ECG recording of the user (e.g., because of a poor reading).

[0197] In some embodiments, as shown in FIG. 6H, possible results page 618 shows a plurality of representations of possible evaluation results, where not all of the representations are concurrently visible on the display. In FIG. 6H, a representation 620 of the first evaluation result (a "regular" result) and (a portion of) a representation of 622 of the second evacuation result (a "Atrial Fibrillation" result) is visible on the display.

[0198] In some embodiments, as shown in FIG. 6H, each representation of a possible evaluation result shown on possible results page 618 includes an animation region that includes a graphical animation (e.g., a tachogram-like animation, a beating heart animation, one or more

objects that continuously/repeatedly move across the tachogram-like animation in a particular frequency) that represents its respective evaluation result and a text region that shows a portion of a text description explaining (medical) characteristics of its respective evaluation result.

[0199] In FIG. 6H, representation 620 of a "regular" result includes an animation region 620A that includes an example animation of a "regular" result and a text region 620B that shows a portion of a text description explaining characteristics of a "regular" result, and representation 622 of an "Atrial Fibrillation" result includes an animation region 622A that includes an example animation of an "Atrial Fibrillation" result and a text region 622B that shows a portion of a text description explaining medical characteristics of an "Atrial Fibrillation" result. In some embodiments, the animations include a beating heart animation and a tachogram-like animation that in combination illustrate a rhythm and rate of heartbeats.

[0200] In some embodiments, a representation of a possible evaluation result also includes an expand affordance (e.g., a "show more" affordance) for displaying the full text description of the respective evaluation result (e.g., by expanding the text region). In FIG. 6H, representation 620 of a "regular" result includes an expand affordance 620C which, when selected (e.g., via a touch input), causes display of the full text description (e.g., which includes additional text information not shown in text region 620B) about a "regular" result, and representation 622 of an "Atrial Fibrillation" result includes an expand affordance 622C which, when selected (e.g., via a touch input), causes display of the full text description (e.g., which includes additional text information not shown in text region 622B) about an "Atrial Fibrillation" result.

[0201] In FIG. 6I, while displaying possible results page 618 with representation 620 and representation 622 visible on display 602, first electronic device 600A detects a scrolling input 609 (e.g., a scrolling touch gesture on the display). In response to detecting scrolling input 609, the device scrolls possible results page 618 such that one or more other representations of other possible evaluation results become visible on display 602, as shown in FIG. 6J.

[0202] In FIG. 6J, representation 624 of a "high or low heart rate" result is fully visible on display 602. As with the other representations of possible evaluation results, representation 624 includes an animation region 624A that includes an example graphical animation of a "high or low heart rate" result, a text region 624B showing a portion of a text description explaining

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medical characteristics of a "high or low heart rate" result, and an expand affordance 624C for expanding text region 624C to fully show all of the text of the text description. Also in FIG. 6J, representation 622 of an "Atrial Fibrillation" remains fully visible on the display while only a portion of representation 626 of an "inconclusive" result is visible on the display.

[0203] In FIG. 6K, while displaying possible results page 618 with representation 620 of a "Atrial Fibrillation" result visible on display 602, first electronic device 600A detects (e.g., via a touch input) a user activation 611 of expand affordance 622C (e.g., because the user wants to view all of the text of the text description describing the "Atrial Fibrillation" result). As shown in FIG. 6L, in response to detecting user activation 622C of expand affordance 622C, first electronic device 600A expands text region 622B of representation 622 of the "Atrial Fibrillation" result to display the full text of the text description. In some embodiments, upon expanding the text region, the expand affordance is removed from the representation. In some embodiments, upon expanding the text region, the expand affordance is replaced with a contract affordance (e.g., a "show less" affordance).

[0204] In FIG. 6M, while displaying, on display 602, possible results page 618 with an expanded text region 622C of representation 622 of an "Atrial Fibrillation" result, first electronic device detects (e.g., via a touch layer of the display) a scrolling input 613 (e.g., a scrolling touch gesture). In response to detecting scrolling input 613, the device scrolls possible results page 618 such that all of representation 626 of an "inconclusive" result is visible on the display, as shown in FIG. 6N.

[0205] In FIG. 6N, representation 626 of an "inconclusive" result is fully visible on display 602. As with the other representations of possible evaluation results, representation 626 includes an animation region 626A that includes an example graphical animation of an "inconclusive" result, a text region 626B showing a portion of a text description explaining medical characteristics of an "inconclusive" result, and an expand affordance 626C for expanding text region 626C to fully show all of the text of the text description. In some embodiments, possible results page 618 includes (e.g., at the bottom of the page), an affordance 628 for proceeding with the tutorial.

[0206] In some embodiments, as mentioned, the animations (of animations regions 620A-626A) of the plurality of representations 620-626 of possible evaluation results on possible results page 618 comprise a beating heart animation and a tachogram-like animation that in combination illustrate a rhythm and rate of heartbeats. In some embodiments, the animations are synchronized. In some examples, each animation comprises repeating loops, where each loop consists of an object (e.g., a circular object) leaving the beating heart animation and moving across the screen while tracking the tachogram-like animation. The repeating loops of the plurality of animations (of representations 620-626) are synchronized to begin and end at the on synched time intervals.

[0207] In FIG. 6N, while displaying, on display 602, affordance 628 possible results page 618 for proceeding with the tutorial, first electronic device 600A detects (e.g., via a touch input) a user activation 615 of affordance 628 for proceeding with the tutorial. In response to detecting user activation 615, first electronic device 600A displays, on display 602 (e.g., replaces display of possible results page 618 with), a limitations page 630, as shown in FIG. 6O.

[0208] In some embodiments, limitations page 630 indicates to the user (e.g., via a text description) some limitations of evaluation results determined from ECG recordings taken on the second electronic device (e.g., second electronic device 600B). In some examples, limitations page 630 includes a list 630A of one or more medical characteristics that cannot be determined from recorded ECG information (e.g., heart attack, blood clots/stroke). In some embodiments, limitations page 630 includes (e.g., at the bottom of the page), an affordance 630B for proceeding with the tutorial.

[0209] In FIG. 6O, while displaying, on display 602, limitations page 630, first electronic device 600A detects (e.g., via a touch input) a user activation 617 of affordance 630B for proceeding with the tutorial. In some embodiments, in response to detecting user activation 617 of affordance 630B, the device displays, on display 602, an instructions page 632, as shown in FIG. 6P.

[0210] In some embodiments, one or more of pages 614, 616, 618, and/or 632 of the tutorial (as shown in FIGS. 6F, 6G, 6H, and 6O, respectively) include a cancel affordance. In some embodiments, upon detecting user selection of a cancel affordance (e.g., in any one of pages 614,

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616, 618, and/or 632 of the tutorial), first electronic device 600A displays, on display 602, a notification 653, as shown in FIG. 6Q. In some embodiments, notification 653 includes an indication 653A (e.g., stating "If you cancel now, you will go through the setup again before you can take an ECG recording") informing the user that the current progress through the tutorial will be lost and the initial setup process will need to be re-initiated in order for the user to begin taking ECG recordings on second electronic device 600B. In some embodiments, notification 653 includes a confirmation affordance 653B (e.g., stating "Set up later") for confirming the cancellation of the setup process and thus exit the tutorial. In some embodiments, while displaying notification 653, the background of the display is dimmed (thereby emphasizing notification 653).

[0211] FIG. 6P shows first electronic device 600A displaying, on display 602, instructions page 632. In some embodiments, instructions page 632 includes a graphical indication region 632A and a text indication region 632B that provides instructions for how to proceed with an ECG recording using the second electronic device (e.g., second electronic device 600B). In some examples, graphical indication region 632A corresponds to graphical indication region 614A of first page 614 of the tutorial, and graphically indicates (e.g., via a static image, via an animation) a user taking an ECG recording using the second electronic device (e.g., second electronic device 600B). In some examples, text indication region 632B includes a list of instructions including required steps to perform the ECG recording on the second electronic device which can be, for example, a smartwatch with one or more biometric sensors that is paired to first electronic device 600A (e.g., second electronic device 600B).

[0212] In some embodiments, instructions page 632 includes a postpone affordance 632C (e.g., showing "Take a recording later") that enables a user to postpone taking the first ECG recording to a later time (and thus allows the user to complete the initial setup process without performing a first ECG recording). In some embodiments, while displaying instructions page 632, first electronic device 600A detects (e.g., via a touch input) a user activation 631 of postpone affordance 632C.

[0213] In some embodiments, in response to detecting user activation 631 of postpone affordance 632C, first electronic device 600A displays, on display 602, a confirmation

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notification 633, as shown in FIG. 6R In some embodiments, confirmation notification 633 is overlaid on instructions page 632. In some embodiments, confirmation notification 633 includes a text indication 633A indicating to the user that the initial setup process is complete and that the second electronic device (e.g., second electronic device 600B) is now enabled to perform ECG recordings. In some embodiments, confirmation notification 633 includes a confirm affordance 633B for acknowledging the completion of the ECG initial setup process (without taking a first ECG recording) and exiting the setup process. In some embodiments, in addition to confirmation notification 633, the device displays a cancel affordance 635 for exiting dismissing confirmation notification 633 and returning to instructions page 632. In some embodiments, while displaying confirmation notification 633 (and cancel affordance 635), the background of the display (displaying instructions page 632) is dimmed (thereby emphasizing the displayed confirmation notification).

[0214] FIGS. 6S-6X illustrate second electronic device 600B (e.g., a smartwatch) having a display 634 and one or more input devices (e.g., including a touch layer of display 634 and one or more mechanical buttons, such as a depressible, rotating crown). In some embodiments, second electronic device 600B includes one or more biometric sensors (e.g., for recording ECG information, for detecting heart rhythm and heart rate of the user) comprising one or more electrodes integrated in an input device 636 (e.g., a mechanical input device, such as a depressible, rotating crown) of second electronic device 600B. In some embodiments, the one or more biometric sensors of second electronic device 600B further comprise one or more electrodes of (e.g., integrated in) a housing portion (e.g., the backplate) of second electronic device 600B, where the one or more electrodes integrated in the input device operate in conjunction with the one or more electrodes of the housing portion to capture biometric information (e.g., ECG information). Features concerning the one or more biometric sensors of second electronic device 600B used to capture biometric information (e.g., ECG information) is described in greater detail in Appendix A. In FIG. 6S, second electronic device 600B is displaying a watch face user interface 638 (e.g., a time screen of the device).

[0215] In FIG. 6S, while displaying lock user interface 638, second electronic device 600B detects a user input 619 on input device 636. In some embodiments, user input 619 is a single press of input device 636 (e.g., such that the force of the press is past a threshold amount to cause

a "click" of input device 636). In some embodiments, in response to detecting user input 619 on input device 636, the second electronic device displays, on display 634 (e.g., replaces display of lock user interface 638 with), a home user interface 640 (e.g., corresponding to a home screen of the device, a screen that includes a plurality of icons corresponding to applications installed on the device and can be launched on the device), as shown in FIG. 6T. Home user interface 640 includes an icon 642 (e.g., an icon graphically depicted with a heart) corresponding to an ECG application installed on the device, where the ECG application on second electronic device 600B is associated with ECG management features of the health application installed on first electronic device 600A.

[0216] In FIG. 6T, while displaying, on display 634, icon 642 corresponding to the ECG application, second electronic device 600B detects (e.g., via a touch input) a user activation 621 of icon 642. In response to detecting user activation of icon 642, the device launches and displays the ECG application and displays, on display 634 (e.g., replaces home user interface 640 with), a user interface 644 of the ECG application, as shown in FIG. 6U.

[0217] In some embodiments, user interface 644 of the ECG application includes an animation 646 (e.g., a fluid animation) that depicts a particular shape (e.g., a heart). In some examples, as shown in FIG. 6U, animation 646 comprises a plurality of dynamic objects (e.g., circular objects) that form the particular shape (e.g., a heart), where the shape appears three-dimensional and is visually fluid as the plurality of dynamic objects constantly move while maintaining the structure of the shape.

[0218] In some embodiments, after a predetermined amount of time (e.g., 5 seconds) has passed from the launch and display of the ECG application on second electronic device 600B (but the device has not detected any additional inputs from the user), second electronic device 600B displays, on user interface 644 (and while maintaining display of animation 646), a notification message 648 indicating to the user that an action must be performed (by the user) to proceed with recording ECG information using the device (e.g., "Hold your finger on the crown"), as shown in FIG. 6V. In some embodiments, the user provides a user input (e.g., a contact or touch of a finger) on first input device 636 (e.g., which includes one or more integrated electrodes operating in conjunction with one or more electrodes in a housing portion

(e.g., backplate) of second electronic device 600B) to proceed with the recording of the ECG information, as instructed by notification message 648.

[0219] FIG. 6W illustrates first electronic device 600A displaying, on display 602, a recording-in-progress page 694 of the tutorial. In some embodiments, while recording ECG information on second electronic device 600B, first electronic device 600A displays, in recording-in-progress page 694 of the health application associated with the ECG application, an indication 696 that the ECG recording is being carried out on second electronic device 600B. In some examples, indication 696 includes a graphical indication portion (e.g., illustrating an image corresponding to the device being used to perform the recording) and a text indication portion (e.g., stating "Recording in Progress").

[0220] FIG. 6W also illustrates second electronic device 600B displaying, on display 634,user interface 644 of the ECG application while the ECG recording (e.g., corresponding to a user input 629 on input device 636) is being carried out. In some embodiments, while recording the ECG information, second electronic device 600B displays a BPM indicator 698 showing the heart rate being detected by the recording. In some embodiments, while recording the ECG information, second electronic device 600B further displays, over animation 646 (e.g., which, upon recording, transitions form its initial shape, such as a heart, to a grid-like pattern), a tachogram 699 that graphically depicts the ongoing recording. In some embodiments, while recording ECG information, a timer 697 continuously reflects (e.g., by counting down) the remaining time to successfully complete the recording. Features concerning aspects of performing an ECG recording (e.g., on a device such as second electronic device 600B) is described in greater detail below in FIGS. 8A-8S, 10A-10J, and 12A-12S.

[0221] FIG. 6X illustrates first electronic device 600A and second electronic device 600B (immediately) after completing the ECG recording form FIG. 6W. In some embodiments, upon completing the ECG recording, second electronic device 600B transmits (e.g., via a Bluetooth connection) data of the ECG recording to first electronic device 600A. In some embodiments, upon completing the ECG recording, second electronic device 600B transmits (e.g., via a LTE or WiFi connection) data of the ECG recording to an external server, where the external server is also accessible by first electronic device 600A. In some embodiments, second electronic device

600B can record and locally store a plurality of ECG recordings and transmit the plurality of ECG recordings to first electronic device 600A.

[0222] In some embodiments, (immediately) after completing the ECG recording, first electronic device 600A displays a summary page 695 of the tutorial, where summary page 695 includes a representation 693 of the completed recording. In some embodiments, representation 693 includes the evaluation result (e.g., "Regular Rhythm"), the heart rate reading (e.g., in BPM), and a graphical depiction (e.g., a tachogram) of the recording. In some embodiments, summary page 695 of the tutorial includes an affordance 693 for leaving the summary page. In some embodiments, summary page 695 of first electronic device 600A includes a completion button 691 for exiting the tutorial (after having completed the tutorial). In some embodiments, when the tutorial is completed without the user having taken a first ECG recording, as described with reference to FIG. 6R, representation 639 of summary page 695 is displayed without an indication of an evaluation result, a heart rate reading, and a graphical depiction of a recording (e.g., the evaluation result, heart rate reading, and graphical depiction fields are blank).

[0223] In some embodiments, (immediately) after completing the ECG recording, second electronic device 600B displays at least a portion of a corresponding summary page 689 (e.g., over user interface 644 of the ECG application with animation 646 in its initial pattern (e.g., a fluid heart-shaped pattern, as shown in FIG. 6V)). In some embodiments, summary page 689 includes the evaluation result (e.g., "Regular Result") and other related information about the completed recording. In some embodiments, summary page 689 slides onto the display from an edge of the display (e.g., a bottom edge of the display). Features concerning aspects of an ECG recording being performed on a device (e.g., second electronic device 600B) is described in greater detail below in FIGS. 12A-12S.

[0224] In some embodiments, the user can perform a plurality of ECG recordings using the ECG application on second electronic device 600B. In some embodiments, the plurality of ECG recordings are transmitted from second electronic device 600B to first electronic device 600A (or to an external server accessible by first electronic device 600A) for viewing and management via the ECG management features of the health application on first electronic device 600A.

[0225] FIG. 6Y illustrates first electronic device 600A displaying, on display 602, a health data user interface 650 of the health application (e.g., that is associated with the ECG application on second electronic device 600B) after having performed several ECG readings using second device 600B. In some embodiments, the health application is accessible via a corresponding icon on a home user interface of the operating system of first electronic device 600A.

[0226] In some embodiments, health data user interface 650 of the health application includes an affordance 650A (e.g., stating "Heart") for viewing and managing heart health information. In FIG. 6Y, while displaying health data user interface 650, first electronic device 600A detects (e.g., via a touch input) a user activation 623 of affordance 650A. In response to detecting user activation 623, the device displays, on display 602, a heart data user interface 652 corresponding to heart-specific features of the health application.

[0227] In some embodiments, heart data user interface 652 of the health application on first electronic device 600A includes a heart rate affordance 654. In some embodiments, heart rate affordance 654 includes an indication of a range of the user's heart rate measured (e.g., via second electronic device 600B) during a certain period of time (e.g., today). In some embodiments, in response to detecting a user selection on heart rate affordance 654, heart data user interface 652 displays a graphical depiction of the heart rate information summarized by heart rate affordance 654 within a graphical depiction region 656 of the user interface (and further highlights the affordance with a particular visual characteristic, such as a different color, to indicate to the user that the heart rate affordance is currently selected by the user).

[0228] In some embodiments, heart data user interface 652 of the health application on first electronic device 600A includes an ECG affordance 658. In some embodiments, ECG affordance 658 includes a summary of a heart health evaluation result (e.g., a "regular" result, a "Atrial Fibrillation" result, a "high or low heart rate" result, an "inconclusive" result) determined from one or more ECG recordings performed during a certain time period (e.g., today), and a number of recordings taken during the time period (e.g., "2 readings"). In some embodiments, ECG affordance 658 includes an information affordance 658A for viewing and managing information about existing ECG recordings (e.g., previously performed by the user on second electronic device 600B).

[0229] In FIG. 6Z, while displaying heart data user interface 652 with ECG affordance 658 visible on display 602, first electronic device 600A detects (e.g., via a touch input) a user activation 625 of information affordance 658A of ECG affordance 658. In response to detecting user activation 625 of information affordance 658A, first electronic device 600A displays, on display 602, an ECG management user interface 660, as shown in FIG. 6AA.

[0230] In some embodiments, ECG management user interface 660 (initially) displays a predetermined number (e.g., three) of representations of the most-recent evaluation result determined from corresponding most-recent ECG recordings performed on second electronic device 600B. In some embodiments, the representations of the most-recent evaluation results include a graphical portion (e.g., a tachogram) that graphically depicts the recording and a text portion that indicates the type of evaluation result (e.g., a "regular" result, an "Atrial Fibrillation" result, a "high or low heart rate" result, an "inconclusive" result) and a measured heart rate (e.g., in BPM). In some embodiments, the representations of the most-recent evaluation results include an indication of one or more user-specified symptoms associated with the result and/or the number of user-specified symptoms associated with the result. In some embodiments, if the user specified that there are no symptoms to be associated with a result, then a "no symptoms" indication is showed in the corresponding representation of the result. In some embodiments, if the user did not specify any symptoms for a result (or indicate that there are no symptoms for the result), then a symptoms indication is not shown in the corresponding representation of the result. Features related to user selection of symptoms for a respective evaluation result is described in greater detail with reference to FIGS. 12A-12S.

[0231] In some embodiments, first electronic device 600A detects a user activation of ECG affordance 658 at a location on the affordance that does not correspond to information affordance 658A. In some embodiments, in response to the user activation, first electronic device 600A replaces display of the heart rate information shown in graphical depiction region 656 of FIG. 6Z with heart rhythm information, in a graphical form.

[0232] In FIG. 6AA, heart rhythm data user interface 660 shows a representation 662A corresponding to a most-recent ECG recording, a representation 662B corresponding to a second-most-recent ECG recording, and a representation 662C corresponding to a third-most-

recent ECG recording. In some examples, representation 662A corresponds to a "regular" result, with a heart rate measurement of 74 BPM and an indication of 2 symptoms selected for the result. In some examples, representation 662B corresponds to an "inconclusive" result with no heart rate measurement determined for the result and a "no symptoms" specifically indicated by the user for the result. In some examples, representation 662C corresponds to an "Atrial Fibrillation" result, with a heart rate measurement of 111 BPM, and no indication or 0 or more selected symptoms because the user did not specify any symptoms or whether there were no symptoms for the result. Further, in some examples, because "Atrial Fibrillation" result is an abnormal result, at least a portion of representation 662C is highlighted with a particular visual characteristic (e.g., a warning color, such as yellow) that is different from a default visual characteristic.

[0233] In some embodiments, ECG management user interface 660 also includes a plurality of affordances for viewing additional/different representations of additional/different past evaluation results and sorting/filtering the existing evaluation results. In some examples, ECG management user interface 660 includes a "show all results" affordance 664A (e.g., which also indicates the number of associated existing recordings) for displaying representations of all past ECG recordings performed by the user. In some examples, ECG management user interface 660 includes a first filter affordance 664B for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to a "regular" result (e.g., representation 662A). In some examples, ECG management user interface 660 includes a second filter affordance 664C for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to a "Atrial Fibrillation" result (e.g., representation 662C). In some examples, ECG management user interface 660 includes a second filter affordance 664C for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to a "Atrial Fibrillation" result (e.g., representation 662C). In some examples, ECG management user interface 660 includes a third filter affordance 664D for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to both a "Atrial Fibrillation" result and a "high heart rate" (e.g., a heart rate over 150 BPM) result. In some examples, ECG management user interface 660 includes a fourth filter affordance 664E for

displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to both a "high heart rate" (e.g., a heart rate over 150 BPM) result and a "low heart rate" (e.g., a heart rate below 50 BPM) result. In some examples, ECG management user interface 660 includes a fifth filter affordance 664F for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to a "high heart rate" (e.g., a heart rate over 150 BPM) result. In some examples, ECG management user interface 660 includes a sixth filter affordance 664G for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to a "low heart rate" (e.g., a heart rate below 50 BPM) result. In some examples, ECG management user interface 660 includes a seventh filter affordance 664H for displaying (e.g., filtering the existing recordings to show) representations of all of the existing ECG recordings corresponding to an "inconclusive" result (e.g., because the measured heart rate was too high or too low to determine an evaluation result, because the captured ECG information was incomplete and/or unreadable to determine an evaluation result).

[0234] In FIG. 6AB, while displaying ECG management user interface 660 on display 602, first electronic device 600A detects (e.g., via a touch input) a user selection 627 of representation 662A (corresponding to a "regular" result, with a heart rate measurement of 74 BPM and an indication of 2 symptoms selected for the result). In response to detecting user selection 627, first electronic device 600A displays, on display 602 (e.g., replaces display of ECG management user interface 660 with), a details page 666 corresponding to the selected evaluation result, as shown in FIG. 6AC.

[0235] In some embodiments, a details page includes one or more descriptive items (e.g., a tachogram, a type of evaluation result, a measured BPM of the result, a presence of lack of presence of Atrial Fibrillation, one or more selected symptoms) associated with the selected evaluation result. Details page 666 corresponds to the evaluation result of representation 662A (from FIG. 6AB), which is a "regular" result. In some examples, details page 666 includes an animation 668A that graphically depicts the recording of this regular result (e.g. a tachogram representing the measured heart rhythm and heart rate data), an indication 668B that indicates the determined evaluation result of the recording (a "regular" result), an indication 668C that indicates whether one or more specific medical characteristics (e.g., Atrial Fibrillation) was

determined from the ECG recording (e.g., "This recording did not show signs of Atrial Fibrillation"), and an indication 668D that indicates (or lists) the user-specified symptoms associated with the ECG recording (e.g., "chest pain" and "shortness of breath").

[0236] In some embodiments, a details page (e.g., details page 666) includes an information affordance 670 which causes display of a text description explaining general medical characteristics of the corresponding evaluation result. In some examples, the text description corresponds to the full text description displayed in an expanded text region of possible results page 618 of the tutorial, as described above with reference to FIGS. 6H-6N.

[0237] In some embodiments, a details page (e.g., details page 666) includes a share affordance 672 for sharing a document (e.g., a PDF document) summarizing the corresponding ECG recording with an indicated external source (e.g., transmitting the document to an email account). An exemplary document generated for transmittal to the indicated external source is shown in FIG. 6AD. In some embodiments, in response to detecting a user selection of share affordance 672, first electronic device 600A generates the document and enables the user to input an intended recipient (e.g., an email account) for (automatic) transmittal of the generated document to the intended recipient.

[0238] In some embodiments, a details page (e.g., details page 666) includes an emergency contact affordance 674 (e.g., for seeking immediate medical care, for contacting 911). In some embodiments, in response to detecting a user selection of emergency contact affordance 674, first electronic device 600A initiates a phone call to an emergency contact (e.g., 911).

[0239] In some embodiments, a details page (e.g., details page 666) includes a metadata list 676 indicating one or more information items related to the ECG recording (e.g., the device used to perform the recording, the time of the recording, an operating system of the device used to perform the recording).

[0240] In some embodiments, a details page (e.g., details page 666) includes a delete affordance 678 for deleting the ECG recording (e.g., from local storage on first electronic device 600A, from local storage on the second electronic device used to perform the recording, such as second electronic device 600B, from remote storage on an external server).

[0241] FIG. 6AD illustrates a document 680 (e.g., a PDF document) generated in response to detecting a user selection of share affordance 672 from details page 666. In some examples, document 680 includes basic user information 682 (e.g., name of the user, date of birth of the user). In some examples, document 680 includes an evaluation result 684 of the ECG recording (e.g., a "regular" result, an "Atrial Fibrillation" result, a "high or low heart rate" result, an "inconclusive" result). In some examples, document 680 includes a heart rate measurement 686 of the ECG recording (e.g., in BPM). In some examples, document 680 includes a time 694 of the ECG recording. In some examples, document 680 includes a list of symptoms 688 selected by the user for the ECG recording. In some examples, document 680 includes a tachogram 690 of the ECG recording (e.g., an unfiltered, full tachogram). In some examples, document 680 includes legend information 692 describing tachogram 690.

[0242] In some embodiments, first electronic device 600A can enable and disable (e.g., via the health application and/or the paired device application described with reference to FIG. 6A) ECG recording functionality on second electronic device 600B. In some embodiments, when the ECG application is launched on second electronic device 600B while ECG recording functionality is disabled (by first electronic device 600A), second electronic device 600B displays, on display 634, an error notification user interface 637 indicating to the user (e.g., via text stating "The ECG application has been remotely disabled") that an ECG recording cannot be performed because ECG recording functionality has been disabled (by first electronic device 600A), as shown in FIG. 6AE.

[0243] FIGS. 7A-7C are a flow diagram illustrating a method for initial setup of heath monitoring, in accordance with some embodiments. Method 700 is performed at a first electronic device (e.g., 100, 300, 500, 600A) with a display and one or more input devices (e.g., a biometric sensor, a touch layer of the display), where the first electronic device is paired with a second electronic device (e.g., 600B). Some operations in method 700 are, optionally, combined, the orders of some operations are, optionally, changed, and some operations are, optionally, omitted.

[0244] As described below, method 700 provides an intuitive way for managing health monitoring. The method reduces the cognitive burden on a user for managing health monitoring,

thereby creating a more efficient human-machine interface. For battery-operated computing devices, enabling a user to manage health monitoring faster and more efficiently conserves power and increases the time between battery charges.

[0245] The first electronic device (e.g., 600A) displays (706), on the display (e.g., 602), a first portion of a tutorial (e.g., 614, 616, 618, 630, 632) for using a function (e.g., measuring heart rhythm information (an electrocardiogram) or heart rate information (BPM)) of the second electronic device (e.g., 600B) (e.g., a function performed using one or more biometric sensors of the second electronic device). Displaying the first portion of the tutorial for using the function of the second electronic device reduces the number of inputs needed by the user to initialize the first electronic device (e.g., 600A) and the second electronic device (e.g., 600B) for using the function by providing guidance on how to successfully complete the initialization process and providing important background information about using the function (e.g., without forcing the user to, without any guidance, test the function in order to learn how to use the function). Reducing the number of inputs needed to perform an operation enhances the operability of the device and makes the user-device interface more efficient (e.g., by helping the user to provide proper inputs and reducing user mistakes when operating/interacting with the device) which, additionally, reduces power usage and improves battery life of the device by enabling the user to use the device more quickly and efficiently.

[0246] In some embodiments, prior to displaying, on the display (e.g., 602), the first portion of the tutorial (e.g., 614, 616, 618, 630, 632) for using the function of the second electronic device (e.g., 600B), the first electronic device (e.g., 600A) receives (702) (e.g., via a wireless communication radio of the first electronic device), from the second electronic device (e.g., 600B), a second indication that an application configured to control the use of the function on the second electronic device (e.g., 600B) is opened (e.g., launched, initiated) on the second electronic device (e.g., 600B). Displaying the second indication that the application configured to control the use of the function on the second device (e.g., 600B) is opened provides the user with feedback about the current state of the second electronic device and visually indicates to the user that the second electronic device is ready for the operation that uses the function. Providing improved visual feedback to the user enhances the operability of the device and makes the user-device interface more efficient (e.g., by helping the user to provide proper inputs and reducing

user mistakes when operating/interacting with the device) which, additionally, reduces power usage and improves battery life of the device by enabling the user to use the device more quickly and efficiently.

[0247] In some embodiments, in response to receiving the second indication that the application configured to control the use of the function on the second electronic device (e.g., 600B) is opened, the first electronic device (e.g., 600A) displays (704), on the display (e.g., 602), a notification (e.g., 612) corresponding to the tutorial for using the function of the second electronic device. Displaying, on the display (e.g., 602), the notification corresponding to the tutorial for using the function of the second electronic device provides the user with feedback about the current state of the second electronic device and visually indicates to the user a tutorial is available on the first electronic device (e.g., 600A) to proceed with configuring the use of the function on the second electronic device. Providing improved visual feedback to the user enhances the operability of the device and makes the user-device interface more efficient (e.g., by helping the user to provide proper inputs and reducing user mistakes when operating/interacting with the device) which, additionally, reduces power usage and improves battery life of the device by enabling the user to use the device more quickly and efficiently.

[0248] In some embodiments, the notification (e.g., 612) informs the user that the application has launched on the second electronic device (e.g., 600B) and that the user can view the tutorial for using the function of the second electronic device (e.g., 600B) that relates to the launched application. In some embodiments, the first electronic device (e.g., 600A) displays, on the display (e.g., 602), the tutorial in response to detecting user selection (e.g., a tap gesture) of the notification (e.g., 612). Displaying, on the display (e.g., 602), the tutorial in response to detecting the user selection of the notification (e.g., 612) improves visual feedback by indicating to the user that the tutorial corresponding to the displayed notification has launched on the first electronic device (e.g., 600A). Providing improved visual feedback to the user enhances the operability of the device and makes the user-device interface more efficient (e.g., by helping the user to provide proper inputs and reducing user mistakes when operating/interacting with the device) which, additionally, reduces power usage and improves battery life of the device by enabling the user to use the device more quickly and efficiently.

[0249] In some embodiments, the first electronic device (e.g., 600A) displays the first portion of the tutorial (e.g., 614, 616, 618, 630, 632) in response to an input received while displaying a user interface (e.g., 643) configured to modify one or more settings of the second electronic device (e.g., 600B). Displaying the first portion of the tutorial in response to an input received while displaying a user interface configured to modify one or more settings of the second electronic device improves visual feedback by indicating to the user that the displayed tutorial is associated with an application that can be used on the second electronic device. Providing improved visual feedback to the user enhances the operability of the device and makes the user-device interface more efficient (e.g., by helping the user to provide proper inputs and reducing user mistakes when operating/interacting with the device) which, additionally, reduces power usage and improves battery life of the device by enabling the user to use the device more quickly and efficiently.

[0250] The first electronic device (e.g., 600A) detects (708), via the one or more input devices, a request to proceed with the tutorial (e.g., a user's tap input on one or more "continue" buttons, 614C, 616C, 628, 630B).

[0251] In response to detecting the request to proceed with the tutorial, the first electronic device (e.g., 600A) displays (710), on the display (e.g., 602), instructions to perform an operation (e.g., capturing/recording biometric data) on the second electronic device (e.g., 600B) that involves the function of the second electronic device (e.g., 600B). Displaying, on the display (e.g., 602) of the first electronic device (e.g., 600A), instructions to perform the operation on the second electronic device (e.g., 600B) that involves the function of the second electronic device improves visual feedback to the user indicating that the operation corresponding to the tutorial needs to be performed on the second electronic device (e.g., and not on the first electronic device). Providing improved visual feedback to the user enhances the operability of the device and makes the user-device interface more efficient (e.g., by helping the user to provide proper inputs and reducing user mistakes when operating/interacting with the device) which, additionally, reduces power usage and improves battery life of the device by enabling the user to use the device more quickly and efficiently.