

AO 120 (Rev. 08/10)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
 filed in the U.S. District Court District of Delaware on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED 3/18/2022	U.S. DISTRICT COURT District of Delaware
PLAINTIFF Bardy Diagnostics, Inc.		DEFENDANT Vital Connect, Inc.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 11,051,743 B2	7/6/2021	Bardy Diagnostics, Inc.
2		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
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Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

VitalConnect Ex. 1007

Page 1 of 255



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
17/119,945	11051743	3792	9200



Correspondence Address/Fee Address Change

The following fields have been set to Customer Number 183791 on 12/07/2021

- Correspondence Address
- Maintenance Fee Address

The address of record for Customer Number 183791 is:

183791
Cascadia Intellectual Property
P.O. Box 3029
Lynnwood, WA 98046



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE	REQUEST ID
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	151100

Acknowledgement of Loss of Entitlement to Entity Status Discount

The entity status change request below filed through Private PAIR on 10/27/2021 has been accepted.

CERTIFICATIONS:

Change of Entity Status:

✕ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be notification of loss of entitlement to small or micro entity status, as applicable.

This portion must be completed by the signatory or signatories making the entity status change in accordance with 37 CFR 1.4(d)(4).

Signature:	/Leonid Kisselev/
Name:	Leonid Kisselev
Registration Number:	70440



APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	07/06/2021	11051743	127.2029.US.CON	7323

22895 7590 06/16/2021

CASCADIA INTELLECTUAL PROPERTY
12360 Lake City Way NE, Ste 501
SEATTLE, WA 98125

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Jason Felix, Vashon Island, WA;
Bardy Diagnostics, Inc., Seattle, WA;
Jon Mikalson Bishay, Seattle, WA;
Gust H. Bardy, Carnation, WA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

76	20090076349		2009-03-19	Libbus et al.	
77	20090076397		2009-03-19	Libbus et al.	
78	20090076401		2009-03-19	Mazar et al.	
79	20090076559		2009-03-19	Libbus et al.	
80	20090216132		2009-08-27	Orbach	
81	20090270747		2009-10-29	Van Dam et al.	
82	20090292194		2009-11-26	Libbus et al.	
83	20090131759		2009-05-21	Sims et al.	
84	20100022897		~~2012-01-28~~ 01/2010	Parker et al.	
85	20100056881		2010-03-04	Libbus et al.	
86	20100081913		2010-04-01	Cross et al.	

Change(s) applied
to document,
/S.B./
5/13/2021

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

97	8460189		2013-06-11	Libbus et al.	
98	8473047		2013-06-25	Chakravarthy et al.	
99	8478418		2013-07-02	Fahey	
100	8591430		2013-11-26	Amurthur et al.	
101	8620418		2013-12-31	Kuppuraj et al.	
102	8684925		2014-04-01	Manicka et al.	
103	8688190		~~2012-04-01~~ 04/2014	Libbus et al.	
104	8718752		2014-05-06	Libbus et al.	
105	8744561		2014-06-03	Fahey	
106	8774932		2014-07-08	Fahey	
107	8790257		2014-07-29	Libbus et al.	

Change(s) applied
to document,
/S.B./
5/13/2021

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

106	20060229522		2006-10-12	Keith E. Barr	
107	20060111642		2006-05-25	Baura et al.	
108	20080091089		2008-04-17	Guillory et al.	
109	20040049120		2004-03-11	Cao et al.	
110	20060100530		~~2011-05-11~~ 05/2006	Kliot et al.	
111	20120220835		2012-08-30	Wayne Chung	
112	20140107509		2014-04-17	Banet et al.	
113	20030028811		2003-02-06	Walker et al.	
114	20130087609		2013-04-11	Nichol et al.	
115	20120232929		2012-09-13	Bettina Experton	
116	20120059668		2012-03-08	Baldock et al.	

Change(s) applied
to document,
/S.B./
5/13/2021

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

73	20120078127		2012-03-29	McDonald et al.	
74	20110288605		2011-11-24	Kaib et al.	
75	20040163034		2004-08-19	Colbath et al.	
76	20020016798		2002-02-07	Sakai	
77	20070131595		2007-06-14	Jansson et al.	
78	20090012979		2009-01-08	Bateni et al.	
79	20100174229		2010-07-08	Hsu et al.	
80	20100177100		2010-07-15	Carnes et al.	
81	20140180027		~~1971-03-09~~ 06/2014	Mark J. Buller	
82	20100312188		2010-12-09	Robertson et al.	
83	20150250422		2015-09-10	Lasse Bay	

Change(s) applied
to document,
/S.B./
5/13/2021

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

40	20070038057	2007-02-15	Nam et al.
41	20130077263	2013-03-28	Oleson et al.
42	20120165645	2012-06-28	Russel et al.
43	20140215246	~~2015-09-29~~ 07/2014	Lee et al.
44	20160217691	2016-07-28	Kadobayashi et al.
45	20050275416	2005-12-15	Hervieux et al.
46	20040207530	2004-10-21	Nielsen, Wyn Y.
47	20090088652	2009-04-02	Kathleen Tremblay
48	20090062897	2009-03-05	AXELGAARD; JENS
49	20060030767	2006-02-09	Lang et al.
50	20130225966	2013-08-29	Macia Barber et al.

Change(s) applied
to document,
/S.B./
5/13/2021

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

22895 7590 04/30/2021
CASCADIA INTELLECTUAL PROPERTY
12360 Lake City Way NE, Ste 501
SEATTLE, WA 98125

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Natalia Deymonaz	(Typed or printed name)
/Natalia Deymonaz/	(Signature)
June 4, 2021	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	7323

TITLE OF INVENTION: ELECTROCARDIOGRAPHY PATCH

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	07/30/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	600-301000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Krista A. Wittman

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Bardy Diagnostics, Inc.

Bellevue, Washington

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Krista A. Wittman/

Date June 4, 2021

Typed or printed name Krista A. Wittman

Registration No. 59594

Electronic Patent Application Fee Transmittal

Application Number:	17119945			
Filing Date:	11-Dec-2020			
Title of Invention:	ELECTROCARDIOGRAPHY PATCH			
First Named Inventor/Applicant Name:	Jason Felix			
Filer:	Krista A. Wittman/Natalia Deymonaz			
Attorney Docket Number:	127.2029.US.CON			
Filed as Small 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:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				600

Electronic Acknowledgement Receipt

EFS ID:	42895626
Application Number:	17119945
International Application Number:	
Confirmation Number:	7323
Title of Invention:	ELECTROCARDIOGRAPHY PATCH
First Named Inventor/Applicant Name:	Jason Felix
Customer Number:	22895
Filer:	Krista A. Wittman/Natalia Deymonaz
Filer Authorized By:	Krista A. Wittman
Attorney Docket Number:	127.2029.US.CON
Receipt Date:	04-JUN-2021
Filing Date:	11-DEC-2020
Time Stamp:	13:35:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$600
RAM confirmation Number	E202164D35382267
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	IssueFeePayment.pdf	429760	no	1
			526a64e2f443768a8940bae5e3c89eca61e84715		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30106	no	2
			bd88c034bcc3b89bccfe3511ca64eb3b1870cc66		
Warnings:					
Information:					
Total Files Size (in bytes):			459866		
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. <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.					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22895 7590 04/30/2021
CASCADIA INTELLECTUAL PROPERTY
12360 Lake City Way NE, Ste 501
SEATTLE, WA 98125

EXAMINER

MANUEL, GEORGE C

ART UNIT

PAPER NUMBER

3792

DATE MAILED: 04/30/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	7323

TITLE OF INVENTION: ELECTROCARDIOGRAPHY PATCH

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	07/30/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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12360 Lake City Way NE, Ste 501
SEATTLE, WA 98125

Certificate of Mailing or Transmission

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(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	7323

TITLE OF INVENTION: ELECTROCARDIOGRAPHY PATCH

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	600-301000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	7323
22895	7590	04/30/2021	EXAMINER	
CASCADIA INTELLECTUAL PROPERTY			MANUEL, GEORGE C	
12360 Lake City Way NE, Ste 501			ART UNIT	
SEATTLE, WA 98125			PAPER NUMBER	
			3792	
DATE MAILED: 04/30/2021				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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 30 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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 disclosure of these records is required by the Freedom of Information Act.
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 Cooperation Treaty.
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 inspection, 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 a Federal or State law.

Notice of Allowability	Application No. 17/119,945	Applicant(s) Felix et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Terminal Disclaimer, filed 4/26/2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-20. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

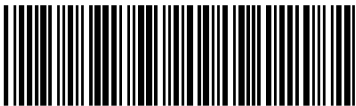
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____.	6. ☐ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____.	7. ☐ Other ____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. ____.	

/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	
--	--

Search Notes 	Application/Control No. 17/119,945	Applicant(s)/Patent Under Reexamination Felix et al.
	Examiner GEORGE MANUEL	Art Unit 3792

CPC - Searched*		
Symbol	Date	Examiner
A61B5/335, A61B5/259, A61B5/0006, A61B5/282, A61B5/0022, A61B5/02055, A61B5/14532, A61B5/14542, A61B5/6823, A61B5/6833, A61B5/6833, A61B5/7405, A61B5/7455, A61N5/7475, A61B5/349, A61B5/021, A61B5/03, A61B5/0816, A61B5/1118, A61B5/14551, A61B2560/0214, A61B2560/0443, G16H40/67	01/20/2021	GM
A61B5/335, A61B5/259, A61B5/0006, A61B5/282, A61B5/0022, A61B5/02055, A61B5/14532, A61B5/14542, A61B5/6823, A61B5/6833, A61B5/6833, A61B5/7405, A61B5/7455, A61N5/7475, A61B5/349, A61B5/021, A61B5/03, A61B5/0816, A61B5/1118, A61B5/14551, A61B2560/0214, A61B2560/0443, G16H40/67, G16H40/63	04/29/2021	GM

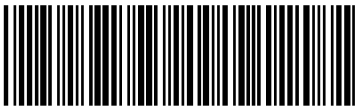
CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search Conducted.	01/20/2021	GM
EAST Search Updated. Interference Search History Printout.	04/29/2021	GM
Inventor Name Search Conducted.	04/29/2021	GM

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<i>Search Notes</i> 	Application/Control No. 17/119,945	Applicant(s)/Patent Under Reexamination Felix et al.
	Examiner GEORGE MANUEL	Art Unit 3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61B	A61B2560/0214, 2560/0443, 5/0006, 5/0022, 5/02055, 5/021, 5/03, 5/0816, 5/087, 5/1118, 5/14532, 5/14542, 5/14551, 5/259, 5/282, 5/335, 5/349, 5/6823, 5/6833, 5/7405, 5/7455, 5/7475	04/29/2021	GM
G16H	40/63, 40/67	04/29/2021	GM

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Issue Classification 	Application/Control No. 17/119,945	Applicant(s)/Patent Under Reexamination Felix et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	

CPC						
Symbol					Type	Version
A61B	/	5	/	335	F	2021-01-01
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A61B	/	5	/	7405	I	2013-01-01
A61B	/	5	/	14542	I	2013-01-01
G16H	/	40	/	67	I	2018-01-01
A61B	/	5	/	6823	I	2013-01-01
A61B	/	5	/	0006	I	2013-01-01
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A61B	/	5	/	0816	A	2013-01-01
A61B	/	5	/	1118	A	2013-01-01
A61B	/	5	/	087	A	2013-01-01
A61B	/	2560	/	0443	A	2013-01-01
A61B	/	5	/	349	A	2021-01-01

CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
	/		/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	29 April 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

Issue Classification 	Application/Control No. 17/119,945	Applicant(s)/Patent Under Reexamination Felix et al.
	Examiner GEORGE MANUEL	Art Unit 3792

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B5/335	/	5	/ 335

NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	29 April 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

Issue Classification 	Application/Control No. 17/119,945	Applicant(s)/Patent Under Reexamination Felix et al.
	Examiner GEORGE MANUEL	Art Unit 3792

☒ Claims renumbered in the same order as presented by applicant	☐ CPA	☒ T.D.	☐ R.1.47
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CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19										
	2		11		20										
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	4		13												
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	7		16												
	8		17												
	9		18												

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure 8

Bibliographic Data

Application No: 17/119,945

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /GEORGE MANUEL/

Examiner's Signature

Initials

Title: ELECTROCARDIOGRAPHY PATCH

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/11/2020	600	3792	127.2029.US.CON
RULE			

APPLICANTS

Bardy Diagnostics, Inc., Seattle, WA, UNITED STATES

INVENTORS

Jason Felix, Vashon Island, WA, UNITED STATES

Jon Mikalson Bishay, Seattle, WA, UNITED STATES

Gust H. Bardy, Carnation, WA, UNITED STATES

CONTINUING DATA

This application is a CON of 16241929 01/07/2019 PAT 10888239

16241929 is a CON of 15818437 11/20/2017 PAT 10172534

15818437 is a CON of 15256266 09/02/2016 PAT 9820665

15256266 is a CON of 14082071 11/15/2013 PAT 9433367

14082071 is a CIP of 14080717 11/14/2013 PAT 9545204

14082071 is a CIP of 14080725 11/14/2013 PAT 9730593

14080717 has PRO of 61882403 09/25/2013

14080725 has PRO of 61882403 09/25/2013

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

12/22/2020

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

ADDRESS

CASCADIA INTELLECTUAL PROPERTY

12360 Lake City Way NE, Ste 501

SEATTLE, WA 98125

UNITED STATES

FILING FEE RECEIVED

\$830

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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L5	148	((("Bishay") near3 ("Jon") near3 ("Mikalsen"))).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/29 14:37
L6	595	((("Bardy") near3 ("Gust") near3 ("H"))).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/29 14:42
L7	83	((("BARDY") near3 ("DIAGNOSTICS") near3 ("INC"))).AS,AANM.	USPAT	OR	OFF	2021/04/29 15:35

EAST Search History (Interference)

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4/29/2021 3:38:32 PM

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EAST Search History

EAST Search History (Prior Art)

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S27	137	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive with backing) AND ((A61B2560/0214 OR A61B2560/0443 OR A61B5/0006 OR A61B5/0022 OR A61B5/02055 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/087 OR A61B5/1118 OR A61B5/14532 OR A61B5/14542 OR A61B5/14551 OR A61B5/259 OR A61B5/282 OR A61B5/335 OR A61B5/349 OR A61B5/6823 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61B5/7475 OR G16H40/63 OR G16H40/67).CPC.)	US-PGPUB	OR	ON	2021/04/28 18:26
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EAST Search History (Interference)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17119945
	Filing Date		2020-12-11
	First Named Inventor	Jason Felix	
	Art Unit	3792	
	Examiner Name	George C. Manuel	
	Attorney Docket Number	127.2029.US.CON	

U.S.PATENTS						Remove
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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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
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(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
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Art Unit	3792	
Examiner Name	George C. Manuel	
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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
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Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
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Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
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Art Unit	3792	
Examiner Name	George C. Manuel	
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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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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	/Krista A. Wittman/	Date (YYYY-MM-DD)	2021-02-08
Name/Print	Krista A. Wittman	Registration Number	59594

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17119945
	Filing Date	2020-12-11
	First Named Inventor	Jason Felix
	Art Unit	3792
	Examiner Name	George C. Manuel
	Attorney Docket Number	127.2029.US.CON

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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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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
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Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	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
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Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
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Attorney Docket Number	127.2029.US.CON

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EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	04/28/2021
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*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.

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Application Number	17119945
Filing Date	2020-12-11
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Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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	/Krista A. Wittman/	Date (YYYY-MM-DD)	2021-02-08
Name/Print	Krista A. Wittman	Registration Number	59594

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.**

Privacy Act Statement

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 Cooperation Treaty.
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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Felix et al.) Group Art Unit: 3792
5)
Serial No. 17/119,945) Examiner:
) George C. Manuel
Filed: December 11, 2020)
)
10 For: Electrocardiography Patch)

RESPONSE TO FIRST OFFICE ACTION

Commissioner for Patents
15 P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Manuel:

In response to the First Office Action mailed on January 25, 2021, for the
20 above-referenced patent application, please enter the following amendments and
remarks. This response is being timely filed within three months of the mailing
date of the Office action, which occurred on a weekend.

Amendments to the Specification begin on page 2.

A Listing of Claims begin on page 3.

25 **Remarks** begin on page 7.

Electronic Acknowledgement Receipt

EFS ID:	42557284
Application Number:	17119945
International Application Number:	
Confirmation Number:	7323
Title of Invention:	ELECTROCARDIOGRAPHY PATCH
First Named Inventor/Applicant Name:	Jason Felix
Customer Number:	22895
Filer:	Krista A. Wittman/Natalia Deymonaz
Filer Authorized By:	Krista A. Wittman
Attorney Docket Number:	127.2029.US.CON
Receipt Date:	26-APR-2021
Filing Date:	11-DEC-2020
Time Stamp:	18:16:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		OAResp.pdf	363111	yes	7
			c3be6c88b1a2e47f78e8391911cc362d57cbb0f1		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Applicant Arguments/Remarks Made in an Amendment	7	7
	Claims	3	6
	Specification	2	2
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:

Information:

Total Files Size (in bytes):	363111
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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.

REMARKS

Claims 1-20 are pending and remain.

The specification has been amended to update reference to a commonly-
assigned application, which has issued since the filing of this application. No new
5 matter has been entered.

Double patenting:

Claims 1-20 stand rejected on the ground of nonstatutory double patenting
as unpatentable over Claims 1-20 of U.S. Patent No. 10,888,239.

Applicant filed a terminal disclaimer on the same date as the filing of this
10 response. Accordingly, withdrawal of the rejection for double patenting is
respectfully requested.

Allowable Subject Matter:

Claims 1-20 stand rejected but would be allowable subject to filing an
acceptable terminal disclaimer. A terminal disclaimer has been filed on the same
15 date as the filing of this response.

The prior art made of record and not relied upon has been reviewed by the
applicant and is considered to be no more pertinent than the prior art references
already applied.

Claims 1-20 are believed to be in condition for allowance. Entry of the
20 foregoing amendments is respectfully requested. Reconsideration of the claims
and a Notice of Allowance are earnestly solicited. Please contact the undersigned
at (206) 381-3900 regarding any questions or concerns associated with the present
matter.

Respectfully submitted,

25

Dated: April 26, 2021

By: /Krista A. Wittman/
Krista A. Wittman, Esq.
Reg. No. 59,594

30 Cascadia Intellectual Property
12360 Lake City Way NE, Suite 501
Seattle, WA 98125

Telephone: (206) 381-3900
Facsimile: (206) 381-3999

OA Resp

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

- 1 1. (original) An electrocardiography patch, comprising:
2 a backing comprising an elongated strip with a mid-section connecting
3 two ends of the backing, wherein the mid-section is narrower than the two ends of
4 the backing;
5 an electrocardiographic electrode on each end of the backing to capture
6 electrocardiographic signals;
7 a flexible circuit comprising a pair of circuit traces electrically coupled to
8 the electrocardiographic electrodes; and
9 a wireless transceiver to communicate at least a portion of the
10 electrocardiographic signals.
- 1 2. (original) An electrocardiography patch according to Claim 1,
2 further comprising:
3 an accelerometer provided on the backing.
- 1 3. (original) An electrocardiography patch according to Claim 1,
2 further comprising:
3 a physiology sensor provided on the backing to measure body
4 temperature.
- 1 4. (original) An electrocardiography patch according to Claim 1,
2 wherein each of the ends of the backing is rounded on an outer edge.
- 1 5. (original) An electrocardiography patch according to Claim 1,
2 further comprising:
3 a physiology and activity sensor provided on the backing to measure one
4 or more of heart rate, temperature, blood pressure, movement, sleep, footsteps,
5 calories burned and estimated blood glucose level.

1 6. (original) An electrocardiography patch according to Claim 1,
2 wherein the electrocardiographic signals are converted to a different format and
3 processed.

1 7. (original) An electrocardiography patch according to Claim 6,
2 wherein the formatted electrocardiographic signals are retrieved by one of a
3 server, a client computer and a mobile device via the wireless transceiver.

1 8. (original) An electrocardiography patch according to Claim 1,
2 wherein the electrodes are exposed on a contact surface of the backing.

1 9. (original) An electrocardiography patch according to Claim 1,
2 further comprising:
3 a hydrocolloid adhesive provided on at least a portion of a contact surface
4 of the backing.

1 10. (original) An electrocardiography patch according to Claim 9,
2 wherein the hydrocolloid adhesive is provided on the ends of the backing, on the
3 contact surface.

1 11. (original) An electrocardiography monitor, comprising:
2 a backing comprising an elongated strip with a mid-section connecting
3 two ends of the backing, wherein the mid-section is narrower than the two ends of
4 the backing;
5 an electrocardiographic electrode on each end of the backing to capture
6 electrocardiographic signals;
7 a flexible circuit comprising a pair of circuit traces electrically coupled to
8 the electrocardiographic electrodes;
9 a wireless transceiver to communicate at least a portion of the
10 electrocardiographic signals;
11 a battery on one of the ends of the backing;
12 a processor powered by the battery; and

13 memory electrically interfaced with the processor and operable to store
14 samples of the electrocardiographic signals.

1 12. (original) An electrocardiography monitor according to Claim 11,
2 further comprising:
3 an accelerometer provided on the backing.

1 13. (original) An electrocardiography monitor according to Claim 11,
2 further comprising:
3 a physiology sensor provided on the backing to measure body
4 temperature.

1 14. (original) An electrocardiography monitor according to Claim 11,
2 wherein each of the ends of the backing is rounded on an outer edge.

1 15. (original) An electrocardiography monitor according to Claim 11,
2 further comprising:
3 a physiology and activity sensor provided on the backing to measure one
4 or more of heart rate, temperature, blood pressure, movement, sleep, footsteps,
5 calories burned and estimated blood glucose level.

1 16. (original) An electrocardiography monitor according to Claim 11,
2 wherein the electrocardiographic signals are converted to a different format and
3 processed.

1 17. (original) An electrocardiography monitor according to Claim 16,
2 wherein the formatted electrocardiographic signals are retrieved by one of a
3 server, a client computer and a mobile device via the wireless transceiver.

1 18. (original) An electrocardiography monitor according to Claim 11,
2 wherein the electrodes are exposed on a contact surface of the backing.

1 19. (original) An electrocardiography monitor according to Claim 11,
2 further comprising:

3 a hydrocolloid adhesive provided on at least a portion of a contact surface
4 of the backing.

1 20. (original) An electrocardiography monitor according to Claim 19,
2 wherein the hydrocolloid adhesive is provided on the ends of the backing, on the
3 contact surface.

Amendments to the Specification

On page 1, lines 6-15 please replace the existing paragraph with the following substitute paragraph:

5 This non-provisional patent application is a continuation of ~~U.S. Patent~~
~~Application, Serial No. 16/241,929, filed January 7, 2019, pending, U.S. Patent~~
10 ~~No. 10,888,239, issued January 12, 2021,~~ which is a continuation of U.S. Patent
No. 10,172,534, issued January 8, 2019, which is a continuation of U.S. Patent
No. 9,820,665, issued November 21, 2017, which is a continuation of U.S. Patent
No. 9,433,367, issued September 6, 2016, which is a continuation-in-part of U.S.
10 Patent No. 9,545,204, issued January 17, 2017 and a continuation-in-part of U.S.
Patent No. 9,730,593, issued August 15, 2017, and further claims priority under
35 U.S.C. § 119(e) to U.S. Provisional Patent application, Serial No. 61/882,403,
filed September 25, 2013, the disclosures of which are incorporated by reference.

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	17119945	
Filing Date	11-Dec-2020	
First Named Inventor	Jason Felix	
Attorney Docket Number	127.2029.US.CON	
Title of Invention	ELECTROCARDIOGRAPHY PATCH	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
Bardy Diagnostics, Inc.	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 10888239 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.		

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ☒ Small Entity ☐ Micro Entity ☐ Regular Undiscounted	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number <u>59594</u> ☐ A sole inventor ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ☐ A joint inventor; all of whom are signing this request	
Signature	/Krista A. Wittman/
Name	Krista A. Wittman

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
 Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	17119945			
Filing Date:	11-Dec-2020			
Title of Invention:	ELECTROCARDIOGRAPHY PATCH			
First Named Inventor/Applicant Name:	Jason Felix			
Filer:	Krista A. Wittman/Natalia Deymonaz			
Attorney Docket Number:	127.2029.US.CON			
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				170

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17119945

Filing Date: 11-Dec-2020

Applicant/Patent under Reexamination: Felix

Electronic Terminal Disclaimer filed on April 26, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

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Electronic Acknowledgement Receipt

EFS ID:	42557061
Application Number:	17119945
International Application Number:	
Confirmation Number:	7323
Title of Invention:	ELECTROCARDIOGRAPHY PATCH
First Named Inventor/Applicant Name:	Jason Felix
Customer Number:	22895
Filer:	Krista A. Wittman/Natalia Deymonaz
Filer Authorized By:	Krista A. Wittman
Attorney Docket Number:	127.2029.US.CON
Receipt Date:	26-APR-2021
Filing Date:	11-DEC-2020
Time Stamp:	18:10:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 170
RAM confirmation Number	E20214PI10121439
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Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30166	no	2
			a70b223bcf59ad13d7f67b2ff80b77e12afd4cd5		
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 17/119,945		Filing Date 12/11/2020		☐ To be Mailed			
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *				x \$50 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$240 =					
☐ 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).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL					
APPLICATION AS AMENDED - PART II											
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	04/26/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0			x \$50 =		0	
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0			x \$240 =		0	
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE		0	
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/POLIN ANG/			
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The "Highest Number Previously Paid For" (Total or Independent) is the highest number 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
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON

CONFIRMATION NO. 7323

22895
CASCADIA INTELLECTUAL PROPERTY
12360 Lake City Way NE, Ste 501
SEATTLE, WA 98125

PUBLICATION NOTICE



OC000000124550006

Title:ELECTROCARDIOGRAPHY PATCH

Publication No.US-2021-0093219-A1

Publication Date:04/01/2021

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Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17119945
	Filing Date		2020-12-11
	First Named Inventor	Jason Felix	
	Art Unit	3792	
	Examiner Name	George C. Manuel	
	Attorney Docket Number	127.2029.US.CON	

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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	8200320		2012-06-12	Kovacs	
	2	5511553		1996-04-30	Segalowitz	
	3	8668653		2014-03-11	Nagata et al.	
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	7	5957857		1999-09-28	Hartley	
	8	5601089		1997-02-11	Bledsoe et al.	

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Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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Examiner Name	George C. Manuel
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	1	20060264730		2006-11-23	Stivoric et al.	
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Attorney Docket Number		127.2029.US.CON

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Attorney Docket Number		127.2029.US.CON

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	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
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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.

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Signature	/Krista A. Wittman/	Date (YYYY-MM-DD)	2021-02-08
Name/Print	Krista A. Wittman	Registration Number	59594

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.**

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EFS ID:	41868027
Application Number:	17119945
International Application Number:	
Confirmation Number:	7323
Title of Invention:	ELECTROCARDIOGRAPHY PATCH
First Named Inventor/Applicant Name:	Jason Felix
Customer Number:	22895
Filer:	Krista A. Wittman/Natalia Deymonaz
Filer Authorized By:	Krista A. Wittman
Attorney Docket Number:	127.2029.US.CON
Receipt Date:	08-FEB-2021
Filing Date:	11-DEC-2020
Time Stamp:	18:03:32
Application Type:	Utility under 35 USC 111(a)

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Inventor(s): Felix et al. Serial No.: 17/119,945 Filed: December 11, 2020 Title: Electrocardiography Patch Attorney Docket No.: 127.2029.US.CON	Group Art Unit: 3792 Examiner: George C. Manuel
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(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- under 37 CFR 1.97(c) together with either a:
 Statement under 37 CFR 1.97(e), or
 a \$130.00 fee under 37 CFR 1.17(p), or
(After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- under 37 CFR 1.97(d) together with a:
 Statement under 37 CFR 1.97(e), and
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Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

Pursuant to 37 CFR 1.98(d), copies of other patents, publications, pending U.S. applications or other information listed in the Information Disclosure Statement are not required to be provided because these items were previously cited by or submitted to the U.S. Patent & Trademark Office in a prior U.S. Patent No. 10,888,239, issued January 12, 2021, which is a continuation of U.S. Patent No. 10,172,534, issued January 8, 2019, which is a continuation of U.S. Patent No. 9,820,665, issued November 21, 2017, which is a continuation of U.S. Patent No. 9,433,367, issued September 6, 2016, which is a continuation-in-part of U.S. Patent No. 9,545,204, issued January 17, 2017, and a continuation-in-part of U.S. Patent No. 9,730,593, issued August 15, 2017, the priority filing dates of which are claimed under 35 U.S.C. 120. Furthermore, pursuant to 609.02 MPEP, no prior art cited by the U.S. Patent & Trademark Office in the prior application is required to be submitted.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,

Customer No. 22895

/Krista A. Wittman/
Krista A. Wittman, Esq.
Attorney/Agent for Applicant(s)
Reg. No. 59,594

Date: February 8, 2021

Telephone No.: (206) 381-3900

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17119945
	Filing Date		2020-12-11
	First Named Inventor	Jason Felix	
	Art Unit	3792	
	Examiner Name	George C. Manuel	
	Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
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Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

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First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17119945
Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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STATEMENT BY APPLICANT**
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Filing Date		2020-12-11
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Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
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Application Number	17119945
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Filing Date		2020-12-11
First Named Inventor	Jason Felix	
Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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**INFORMATION DISCLOSURE
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Art Unit		3792
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Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Art Unit		3792
Examiner Name	George C. Manuel	
Attorney Docket Number		127.2029.US.CON

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STATEMENT BY APPLICANT**
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Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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Art Unit	3792	
Examiner Name	George C. Manuel	
Attorney Docket Number	127.2029.US.CON	

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Art Unit		3792
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Attorney Docket Number		127.2029.US.CON

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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First Named Inventor	Jason Felix	
Art Unit	3792	
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Attorney Docket Number	127.2029.US.CON	

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Attorney Docket Number	127.2029.US.CON	

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**INFORMATION DISCLOSURE
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**INFORMATION DISCLOSURE
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17119945
Filing Date	2020-12-11
First Named Inventor	Jason Felix
Art Unit	3792
Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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FOREIGN PATENT DOCUMENTS

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	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	2008057884	WO		2008-05-15	Welch Allyn, Inc.		
	2	19955211	DE		2001-05-31	Siemens AG		
	3	2003032192	WO		2003-04-17	Studico PTY LTD		
	4	2006014806	WO		2006-02-09	Gabroski et al.		
	5	2007092543	WO		2007-08-16	The Leland Stanford Junior University		
	6	2008010216	WO		2008-01-24	BIOPAD LTD		
	7	2009112976	WO		2009-09-17	Fong et al.		
	8	2009112978	WO		2009-09-17	Bishay et al.		
	9	2009112979	WO		2009-09-17	Crawford et al.		

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Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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11	2006009767	WO	2006-01-26	Neuronetrix, Inc.
12	2009036306	WO	2009-03-19	Corventis, Inc.
13	00/78213	WO	2000-12-28	Aspect Medical Systems, Inc.

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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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	15 Of The Hottest Wearable Gadgets, URL < http://thehottestgadgets.com/2008/09/the-15-hottest-wearable-gadgets-001253 > (Web page cached on September 27, 2008).	
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	3	Bharadwaj et al., Techniques for Accurate ECG signal processing, EE Times, URL < www.eetimes.com/document.asp?doc_id=1278571 > (February 14, 2011).	
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Attorney Docket Number	127.2029.US.CON

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21	Zio Event Card, URL < http://www.irhythmtech.com/zio-solution/zio-event/ > (Web page cached on March 11, 2013.)
22	Zio Patch System, URL < http://www.irhythmtech.com/zio-solution/zio-system/index.html > (Web page cached on September 8, 2013.)

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*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.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Filing Date	2020-12-11
First Named Inventor	Jason Felix
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Examiner Name	George C. Manuel
Attorney Docket Number	127.2029.US.CON

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	/Krista A. Wittman/	Date (YYYY-MM-DD)	2021-02-08
Name/Print	Krista A. Wittman	Registration Number	59594

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.**

Privacy Act Statement

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 Cooperation Treaty.
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.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/119,945	12/11/2020	Jason Felix	127.2029.US.CON	7323
22895	7590	01/25/2021		
CASCADIA INTELLECTUAL PROPERTY			EXAMINER	
12360 Lake City Way NE, Ste 501			MANUEL, GEORGE C	
SEATTLE, WA 98125				
			ART UNIT	PAPER NUMBER
			3792	
			MAIL DATE	DELIVERY MODE
			01/25/2021	PAPER

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.

Office Action Summary**Application No.**

17/119,945

Applicant(s)

Felix et al.

Examiner

GEORGE MANUEL

Art Unit

3792

AIA (FITF) Status

Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 12/11/2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 12/11/2020 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☐ Other: ____.

Paper No(s)/Mail Date ____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 10.888.239. Although the claims at issue are not identical, they are not patentably distinct from each other because the present claims are directed to obvious features incorporated in the electrocardiography patch device as claimed in claims 1-20 of U.S. Patent No. 10.888.239. The skilled artisan would recognize narrowing a mid-section between the two ends of the backing obviously reduces weight by eliminating unnecessary material. Likewise, it is obvious to provide an accelerometer to measure movement, and a hydrocolloid adhesive to attach the device to a patient.

Allowable Subject Matter

Claims 1-20 are rejected, but would be allowable subject to filing an acceptable Terminal Disclaimer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Paquet (US 2012/0029300) discloses a related wireless monitoring patch.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

The examiner can normally be reached on regular business days.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at

<http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit: 3792

1/20/2021

<i>Notice of References Cited</i>	Application/Control No. 17/119,945		Applicant(s)/Patent Under Reexamination Felix et al.	
	Examiner GEORGE MANUEL		Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20120029300-A1	02-2012	Paquet; Pierre	G16H40/67	600/300
	B					
	C					
	D					
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FOREIGN PATENT DOCUMENTS

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	N					
	O					
	P					
	Q					
	R					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 17/119,945	Applicant(s)/Patent Under Reexamination Felix et al.
	Examiner GEORGE MANUEL	Art Unit 3792

CPC - Searched*		
Symbol	Date	Examiner
A61B5/335, A61B5/259, A61B5/0006, A61B5/282, A61B5/0022, A61B5/02055, A61B5/14532, A61B5/14542, A61B5/6823, A61B5/6833, A61B5/6833, A61B5/7405, A61B5/7455, A61N5/7475, A61B5/349, A61B5/021, A61B5/03, A61B5/0816, A61B5/1118, A61B5/14551, A61B2560/0214, A61B2560/0443, G16H40/67	01/20/2021	GM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search Conducted.	01/20/2021	GM

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	314	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal) AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)	US-PGPUB	OR	ON	2021/01/20 16:41
L2	6	"10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.	USPAT	OR	ON	2021/01/20 16:52
L3	6	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (mid adj section)	USPAT	OR	ON	2021/01/20 17:35
L4	5	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (battery and memory and samples)	USPAT	OR	ON	2021/01/20 17:43
L5	6	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (hydrocolloid)	USPAT	OR	ON	2021/01/20 19:28
L6	6	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (adhesive)	USPAT	OR	ON	2021/01/20 19:29
L7	5	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (accelerometer)	USPAT	OR	ON	2021/01/20 19:31
L8	6	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (attach\$4)	USPAT	OR	ON	2021/01/20 20:37
L9	6	("10888239".pn. or "10172534".pn. or "9820665".pn. or "9433367".pn. or "9730593".pn. or "9545204".pn.) and (irritat\$4)	USPAT	OR	ON	2021/01/20 20:38
L10	254	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer) AND ((A61B5/335 OR	US-PGPUB	OR	ON	2021/01/20 21:06

		A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)				
L11	233	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive) AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)	US-PGPUB	OR	ON	2021/01/20 21:07
L12	131	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive with backing) AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)	US-PGPUB	OR	ON	2021/01/20 21:16
L13	1	"20120029300" and "29"	US-PGPUB	OR	ON	2021/01/20 21:21
L14	97	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive with backing) AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)	USPAT	OR	ON	2021/01/20 21:25
L15	40	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive with backing and mid adj section same narrow\$4)	USPAT	OR	ON	2021/01/20 21:53

		AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)				
L16	50	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive with backing and mid adj section same narrow\$4) AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)	US-PGPUB	OR	ON	2021/01/20 21:55
L17	50	(electrocardiogra\$4 and electrode and flex\$4 with circuit and wireless with transceiver and signal and accelerometer and adhesive with backing and mid adj section same narrow\$4)	US-PGPUB	OR	ON	2021/01/20 21:58
L18	84	(electrocardiogra\$4 and electrode and flex\$4 and mid adj section same narrow\$4) AND ((A61B5/335 OR A61B5/259 OR A61B5/0006 OR A61B5/282 OR A61B5/0022 OR A61B5/02055 OR A61B5/14532 OR A61B5/14542 OR A61B5/6823 OR A61B5/6833 OR A61B5/6833 OR A61B5/7405 OR A61B5/7455 OR A61N5/7475 OR A61B5/349 OR A61B5/021 OR A61B5/03 OR A61B5/0816 OR A61B5/1118 OR A61B5/14551 OR A61B2560/0214 OR A61B2560/0443 OR G16H40/67).CPC.)	US-PGPUB	OR	ON	2021/01/20 22:00
L19	91	(electrocardiogra\$4 and electrode and flex\$4 and mid adj section same narrow\$4)	US-PGPUB	OR	ON	2021/01/20 22:00
L20	91	(electrocardiogra\$4 and electrode and mid adj section same narrow\$4)	US-PGPUB	OR	ON	2021/01/20 22:05
L21	1	(electrocardiogra\$4 and electrode and mid adj section same reduc\$4)	US-PGPUB	OR	ON	2021/01/20 22:07
L22	146	(electrode and mid adj section same reduc\$4)	US-PGPUB	OR	ON	2021/01/20 22:08
L23	152	(electrode and mid adj section same narrow\$4)	US-PGPUB	OR	ON	2021/01/20 22:11

EAST Search History (Interference)

<This search history is empty>

1/20/2021 10:25:00 PM

C:\Users\gmanuel\Documents\EAST\Workspaces\01_20_2021.wsp

**PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION
UNDER 37 CFR 1.102(c)(1)**

Application Information

Application Number	17119945	Confirmation Number	2289	Filing Date	11-Dec-2020
Attorney Docket Number (optional)	127.2029.US.CON	Art Unit	3792	Examiner	
First Named Inventor	Jason Felix				
Title of Invention	ELECTROCARDIOGRAPHY PATCH				

Attention: Office of Petitions

An application may be made special for advancement of examination upon filing of a petition showing that the applicant is 65 years of age, or more. No fee is required with such a petition. See 37 CFR 1.102(c)(1) and MPEP 708.02 (II).

APPLICANT HEREBY PETITIONS TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION IN THIS APPLICATION UNDER 37 CFR 1.102(c)(1) and MPEP 708.02 (II) ON THE BASIS OF THE APPLICANT'S AGE.

A grantable petition requires one of the following items:

- (1) Statement by one named inventor in the application that he/she is 65 years of age, or more; or
- (2) Certification by a registered attorney/agent having evidence such as a birth certificate, passport, driver's license, etc. showing one named inventor in the application is 65 years of age, or more.

Name of Inventor who is 65 years of age, or older

Given Name	Middle Name	Family Name	Suffix
Gust	H.	Bardy	

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the format of the signature.

Select (1) or (2) :

- ☐ (1) I am an inventor in this application and I am 65 years of age, or more.
- ☒ (2) I am an attorney or agent registered to practice before the Patent and Trademark Office, and I certify that I am in possession of evidence, and will retain such in the application file record, showing that the inventor listed above is 65 years of age, or more.

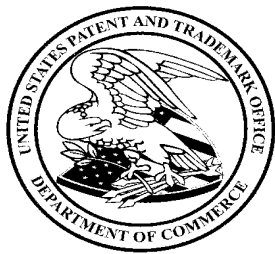
Signature	/Krista A. Wittman/		
Name	Krista A. Wittman	Registration Number	59594

Privacy Act Statement

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 Cooperation Treaty.
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.



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P.O. Box 1450
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In re Application of
Jason Felix

Application No. 17119945

Filed: December 11, 2020

Attorney Docket No. 127.2029.US.CON

:

:

:DECISION ON PETITION TO MAKE SPECIAL
:UNDER 37 CFR 1.102(c)(1)

:

This is a decision on the electronic petition under 37 CFR 1.102 (c)(1), filed 07-JAN-2021 to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section II.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c)(1), MPEP § 708.02, Section II : Applicant's Age must include a statement by applicant or a registered practitioner having evidence that applicant is at least 65 years of age. No fee is required.

Accordingly, the above-identified application has been accorded "special" status and will be taken up for action by the examiner upon the completion of all pre-examination processing.

Telephone inquiries concerning this electronic decision should be directed to the Electronic Business Center at 866-217-9197.

All other inquiries concerning either the examination or status of the application should be directed to the Technology Center.

Electronic Acknowledgement Receipt

EFS ID:	41584139
Application Number:	17119945
International Application Number:	
Confirmation Number:	7323
Title of Invention:	ELECTROCARDIOGRAPHY PATCH
First Named Inventor/Applicant Name:	Jason Felix
Customer Number:	22895
Filer:	Krista A. Wittman/Natalia Deymonaz
Filer Authorized By:	Krista A. Wittman
Attorney Docket Number:	127.2029.US.CON
Receipt Date:	07-JAN-2021
Filing Date:	11-DEC-2020
Time Stamp:	17:43:29
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	Petition automatically granted by EFS	petition-request.pdf	38162	no	2
			b7b7c6892b2ebf257bf032c169e5370e2ff8e392		

Warnings:

VitalConnect Ex. 1007

Information:	
Total Files Size (in bytes):	38162
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. <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.	



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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
17/119,945	12/11/2020		830	127.2029.US.CON	20	2

CONFIRMATION NO. 7323

22895
CASCADIA INTELLECTUAL PROPERTY
12360 Lake City Way NE, Ste 501
SEATTLE, WA 98125

FILING RECEIPT



Date Mailed: 12/22/2020

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Jason Felix, Vashon Island, WA;
Jon Mikalson Bishay, Seattle, WA;
Gust H. Bardy, Carnation, WA;

Applicant(s)

Bardy Diagnostics, Inc., Seattle, WA;

Power of Attorney: The patent practitioners associated with Customer Number 22895

Domestic Priority data as claimed by applicant

This application is a CON of 16/241,929 01/07/2019 PAT 10888239
which is a CON of 15/818,437 11/20/2017 PAT 10172534
which is a CON of 15/256,266 09/02/2016 PAT 9820665
which is a CON of 14/082,071 11/15/2013 PAT 9433367
which is a CIP of 14/080,717 11/14/2013 PAT 9545204
which claims benefit of 61/882,403 09/25/2013
and said 14/082,071 11/15/2013
is a CIP of 14/080,725 11/14/2013 PAT 9730593
which claims benefit of 61/882,403 09/25/2013

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

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: 12/22/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/119,945**

Projected Publication Date: 04/01/2021

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

ELECTROCARDIOGRAPHY PATCH

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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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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community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/119,945	
APPLICATION AS FILED - PART I							
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *	x 240 =	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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
			TOTAL	830		TOTAL	
* If the difference in column 1 is less than zero, enter "0" in column 2.							
APPLICATION AS AMENDED - PART II							
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)
	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))					OR	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR	
				TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)
	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))					OR	
	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.							

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	127.2029.US.CON
	First Named Inventor	Jason Felix
	Title	ELECTROCARDIOGRAPHY PATCH
	Priority Mail Express® Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☒ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>30</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets <u>8</u>] 6. Inventor's Oath or Declaration [Total Pages <u>3</u>] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☒ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☒ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☒ Other: Filing Fee \$830 _____ _____ _____ _____
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***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS					
☒ The address associated with Customer Number: <u>22895</u> OR ☐ Correspondence address below					
Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	
Signature	/Krista A. Wittman/			Date	December 11, 2020
Name (Print/Type)	Krista A. Wittman			Registration No. (Attorney/Agent)	59594

This collection of information is required by 37 CFR 1.53(b). 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 12 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.**

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

Privacy Act Statement

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 disclosure of these records is required by the Freedom of Information Act.
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 Cooperation Treaty.
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 inspection 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.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	127.2029.US.CON
		Application Number	
Title of Invention	ELECTROCARDIOGRAPHY PATCH		
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	
	Jason		Felix		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Vashon Island	State/Province	WA	Country of Residence	US

Mailing Address of Inventor:

Address 1	P.O. Box 1053				
Address 2					
City	Vashon Island	State/Province	WA		
Postal Code	98070	Country	US		

Inventor	2				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Jon	Mikalson	Bishay		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Seattle	State/Province	WA	Country of Residence	US

Mailing Address of Inventor:

Address 1	1824 5th Avenue West				
Address 2					
City	Seattle	State/Province	WA		
Postal Code	98119	Country	US		

Inventor	3				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Gust	H.	Bardy		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		127.2029.US.CON	
		Application Number			
Title of Invention	ELECTROCARDIOGRAPHY PATCH				
City	Carnation	State/Province	WA	Country of Residence	US
Mailing Address of Inventor:					
Address 1	29216 NE 52nd Street				
Address 2					
City	Carnation	State/Province	WA		
Postal Code	98014	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.			
Customer Number	22895		
Email Address	info@cascadiaip.com	Add Email	Remove Email

Application Information:

Title of the Invention	ELECTROCARDIOGRAPHY PATCH		
Attorney Docket Number	127.2029.US.CON	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	8	Suggested Figure for Publication (if any)	8

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.

VitalConnect Ex. 1007

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	127.2029.US.CON
		Application Number	
Title of Invention	ELECTROCARDIOGRAPHY PATCH		

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	22895		

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)	
	Continuation of		16241929	2019-01-07	
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16241929	Continuation of	15818437	2017-11-20	10172534	2019-01-08
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15818437	Continuation of	15256266	2016-09-02	9820665	2017-11-21
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15256266	Continuation of	14082071	2013-11-15	9433367	2016-09-06
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14082071	Continuation in part of	14080717	2013-11-14	9545204	2017-01-17

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		127.2029.US.CON	
		Application Number			
Title of Invention		ELECTROCARDIOGRAPHY PATCH			
Prior Application Status		Expired		Remove	
Application Number		Continuity Type		Prior Application Number	
140801717		Claims benefit of provisional		61882403	
Prior Application Status		Patented		Remove	
Application Number		Continuity Type		Prior Application Number	
14082071		Continuation in part of		14080725	
Filing Date (YYYY-MM-DD)		Patent Number		Issue Date (YYYY-MM-DD)	
2013-11-14		9730593		2017-08-15	
Prior Application Status		Expired		Remove	
Application Number		Continuity Type		Prior Application Number	
14080725		Claims benefit of provisional		61882403	
Filing or 371(c) Date (YYYY-MM-DD)		2013-09-25			
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					

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).

			Remove
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

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	127.2029.US.CON
		Application Number	
Title of Invention	ELECTROCARDIOGRAPHY PATCH		

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	127.2029.US.CON
		Application Number	
Title of Invention	ELECTROCARDIOGRAPHY PATCH		

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	Bardy Diagnostics, Inc.	
Mailing Address Information For Applicant:		
Address 1	316 Occidental Ave South	
Address 2	Suite B310	
City	Seattle	State/Province WA
Country	US	Postal Code 98104
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:

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	127.2029.US.CON
		Application Number	
Title of Invention	ELECTROCARDIOGRAPHY PATCH		

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.				
				Remove
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				
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.				Add

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

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	/Krista A. Wittman/		Date (YYYY-MM-DD)	2020-12-11
First Name	Krista A.	Last Name	Wittman	Registration Number
				59594
Additional Signature may be generated within this form by selecting the Add button.				Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	127.2029.US.CON
		Application Number	
Title of Invention	ELECTROCARDIOGRAPHY PATCH		

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.**

Privacy Act Statement

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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 Cooperation Treaty.
- 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.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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

Title of Invention	Remote Interfacing Of Extended Wear Electrocardiography And Physiological Sensor Monitor
-------------------------------	--

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 _____
filed on _____

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

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LEGAL NAME OF INVENTOR

Inventor: Jason Felix

Date (Optional):

11/14/2013

Signature:

Jason Felix

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

**Title of
Invention**

**Remote Interfacing Of Extended Wear Electrocardiography And Physiological Sensor
Monitor**

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 _____

filed on _____

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.

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LEGAL NAME OF INVENTOR

Inventor: **Jon Mikalson Bishay**

Date (Optional): **11-14-2013**

Signature:

Jon Mikalson Bishay

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.**

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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	Remote Interfacing Of Extended Wear Electrocardiography And Physiological Sensor Monitor
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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 _____

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LEGAL NAME OF INVENTOR

Inventor: Gust H. Bardy

Date (Optional): _____

Signature: Gust H. Bardy

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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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

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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:

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22895



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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Bardy Diagnostics, 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)

Name

Gust H. Bardy

Title

CEO, Bardy Diagnostics, Inc.

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.



Total of 1

forms are submitted.

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Fig. 1.

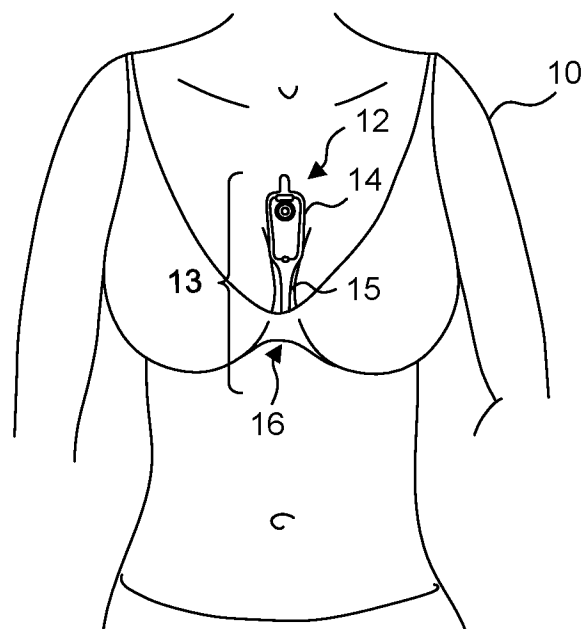


Fig. 2.

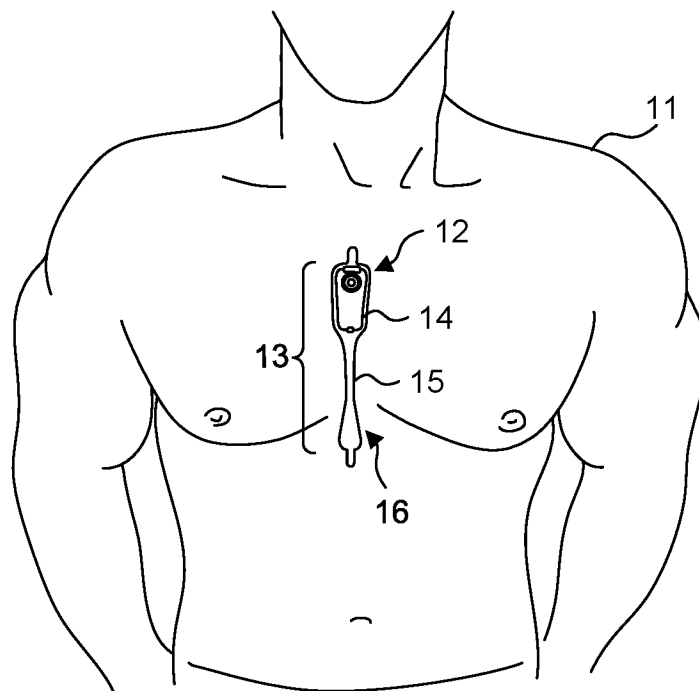


Fig. 3.

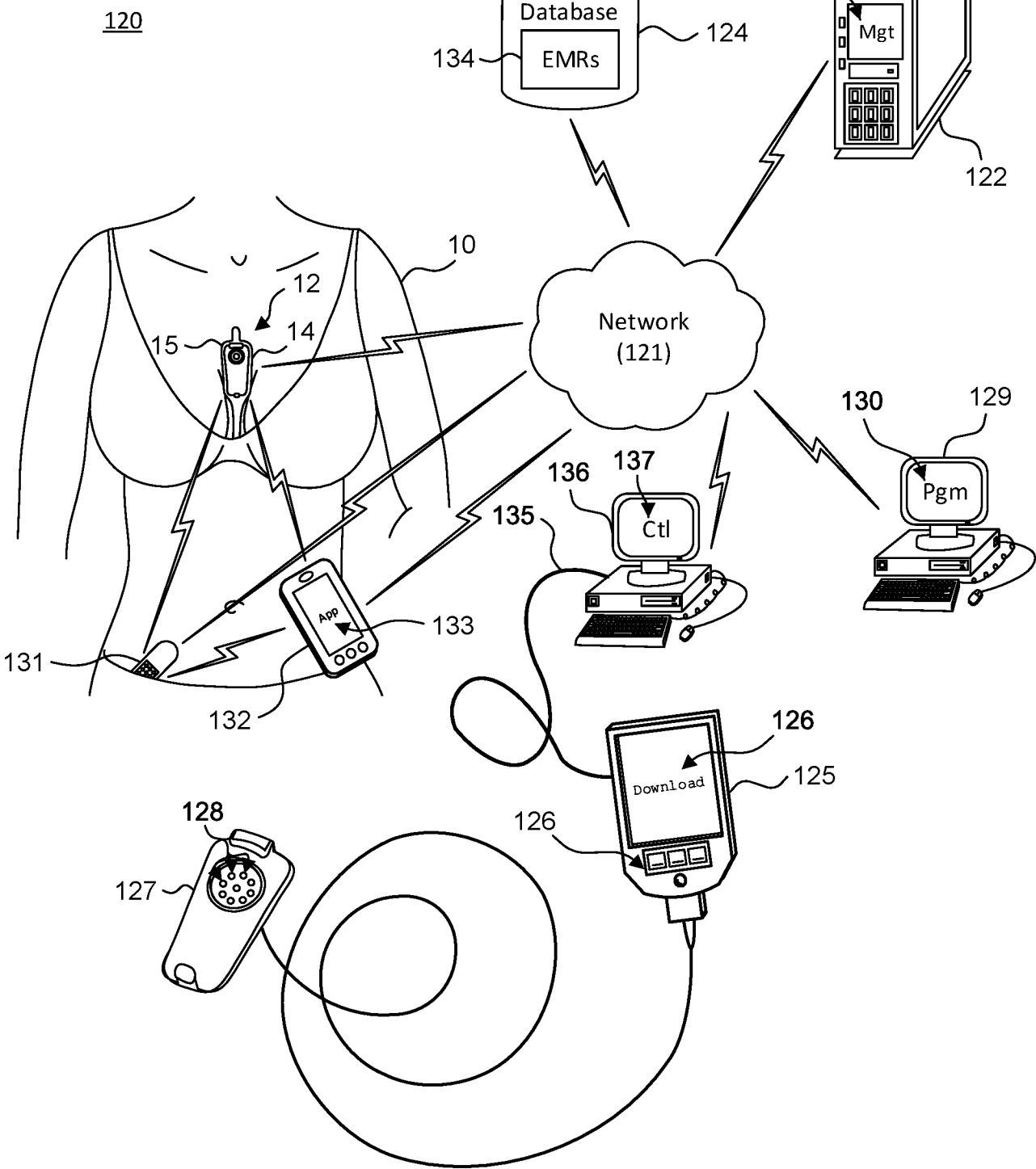


Fig. 4.

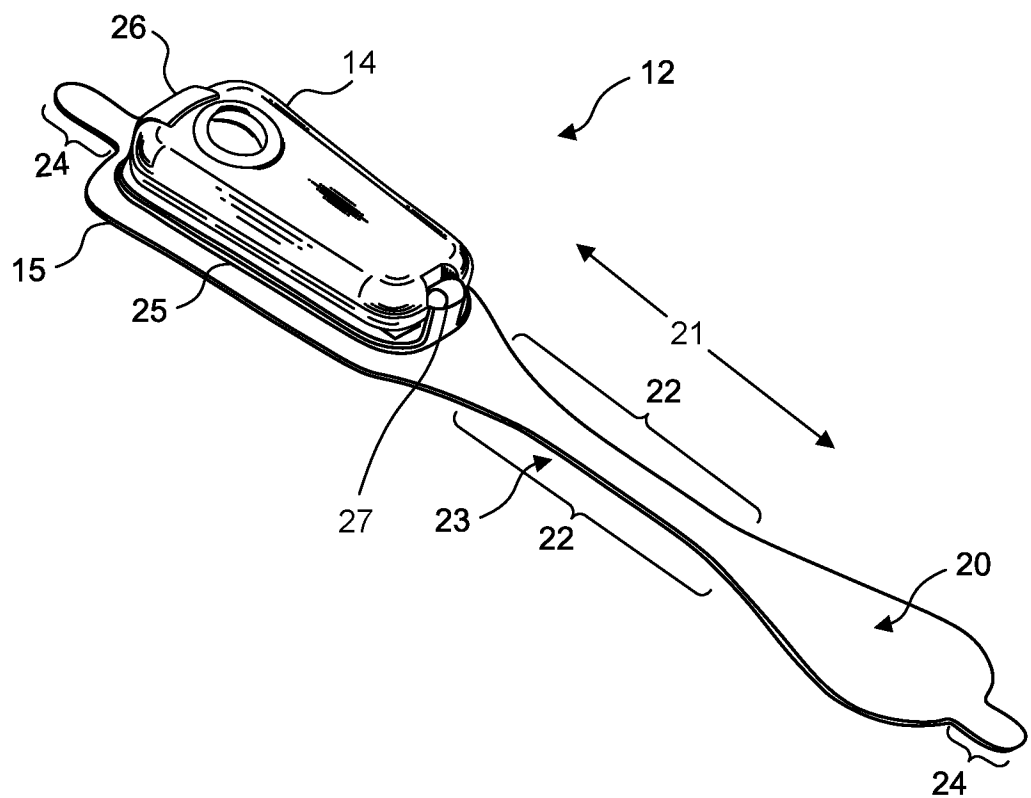


Fig. 5.

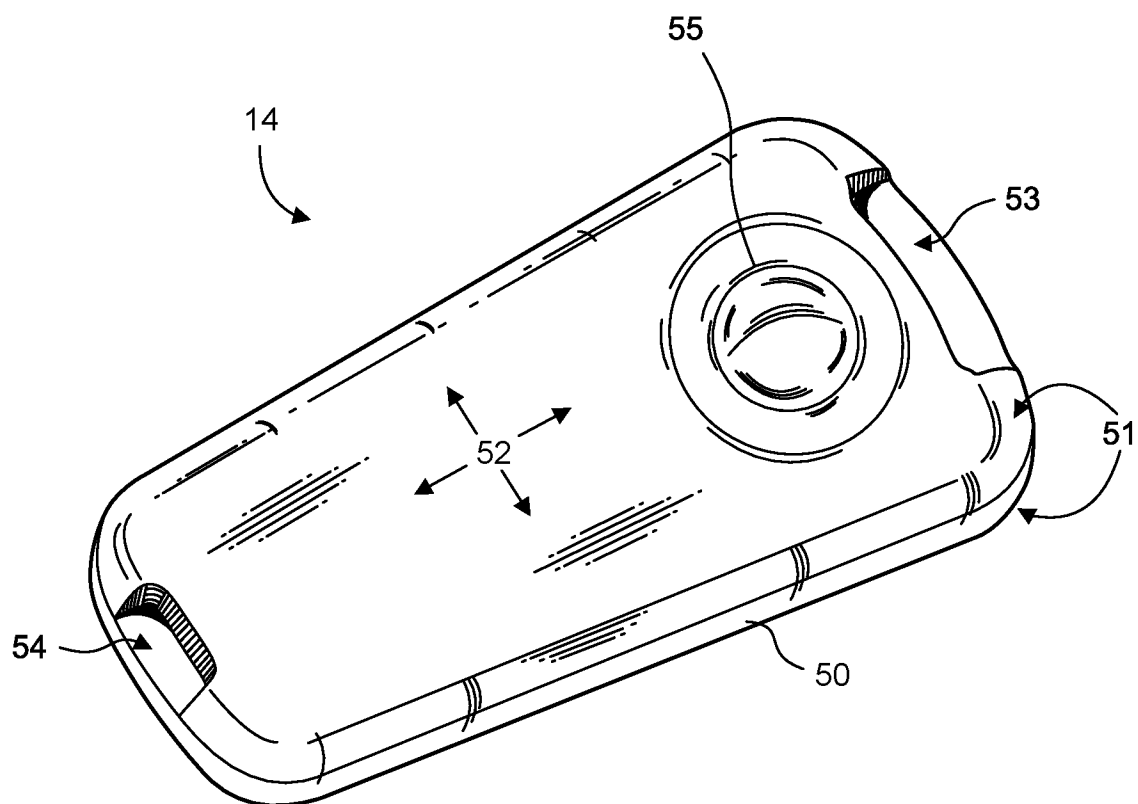


Fig. 6.

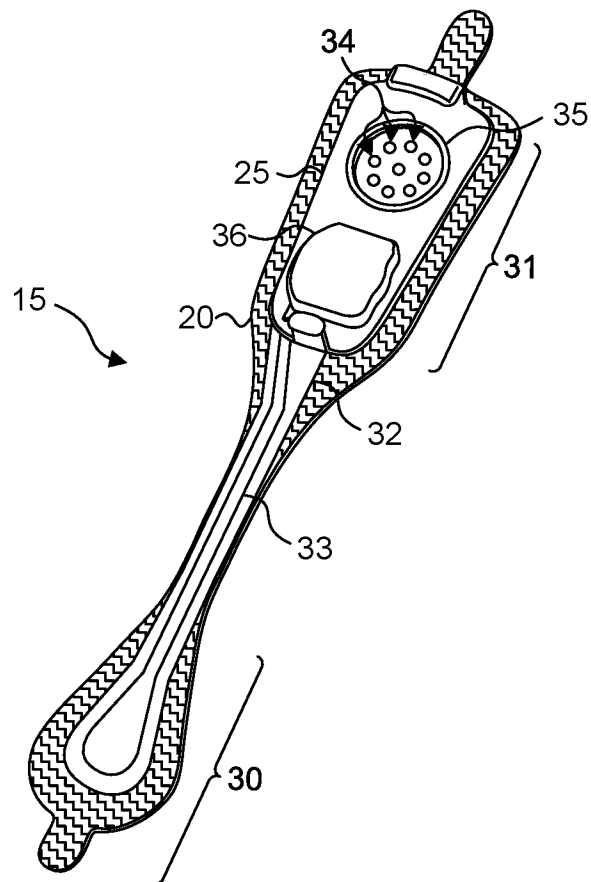


Fig. 7.

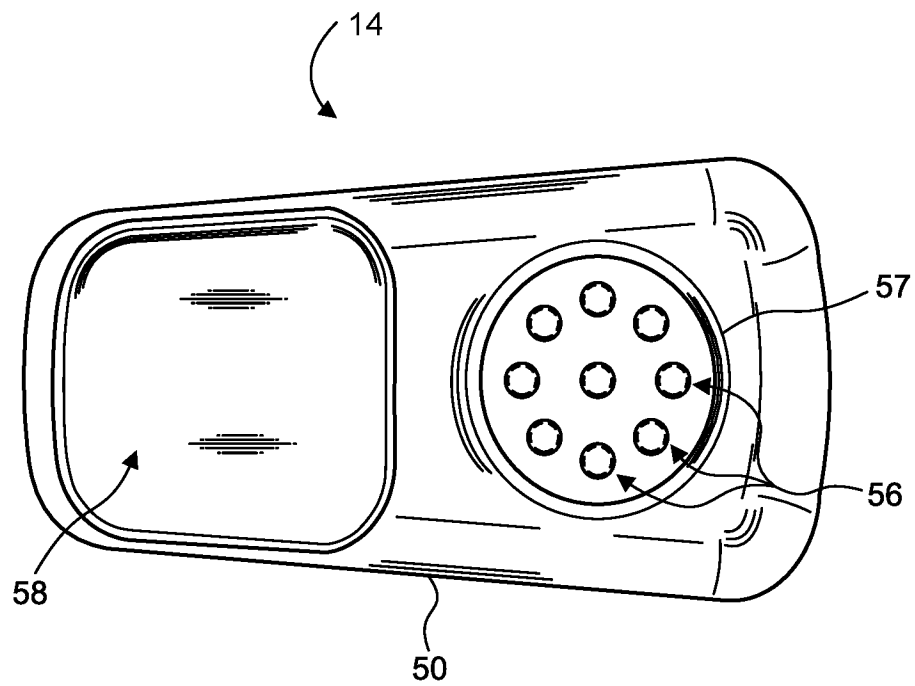


Fig. 8.

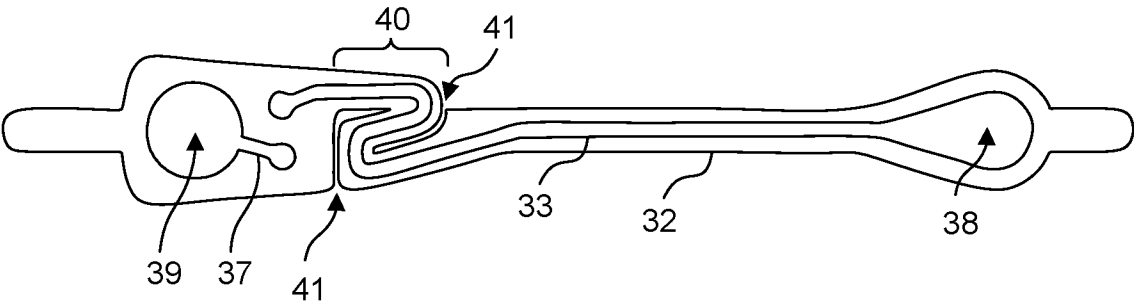


Fig. 9.

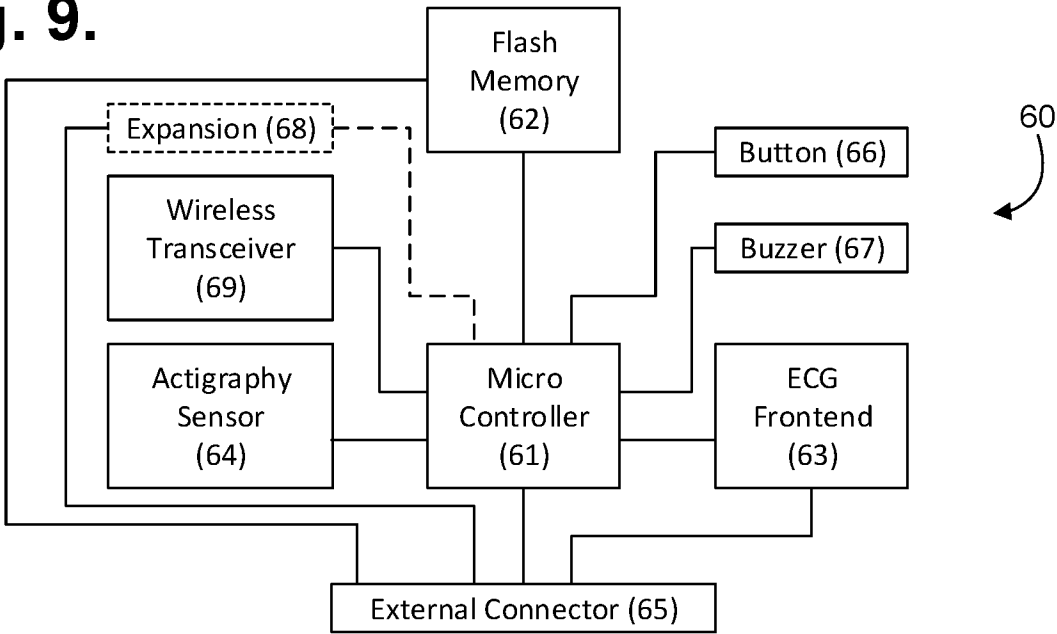


Fig. 10.

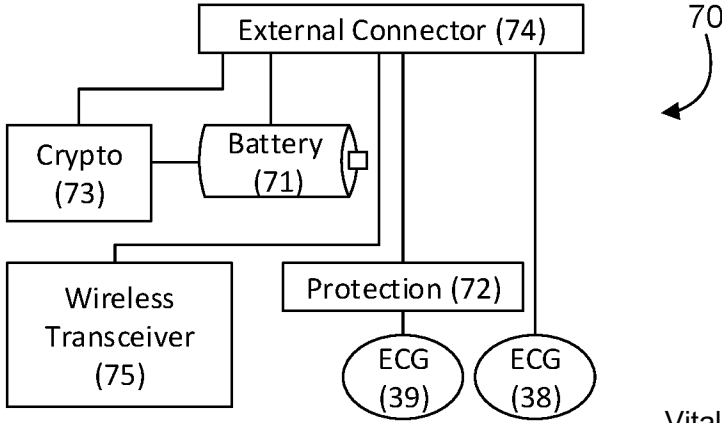


Fig. 11.

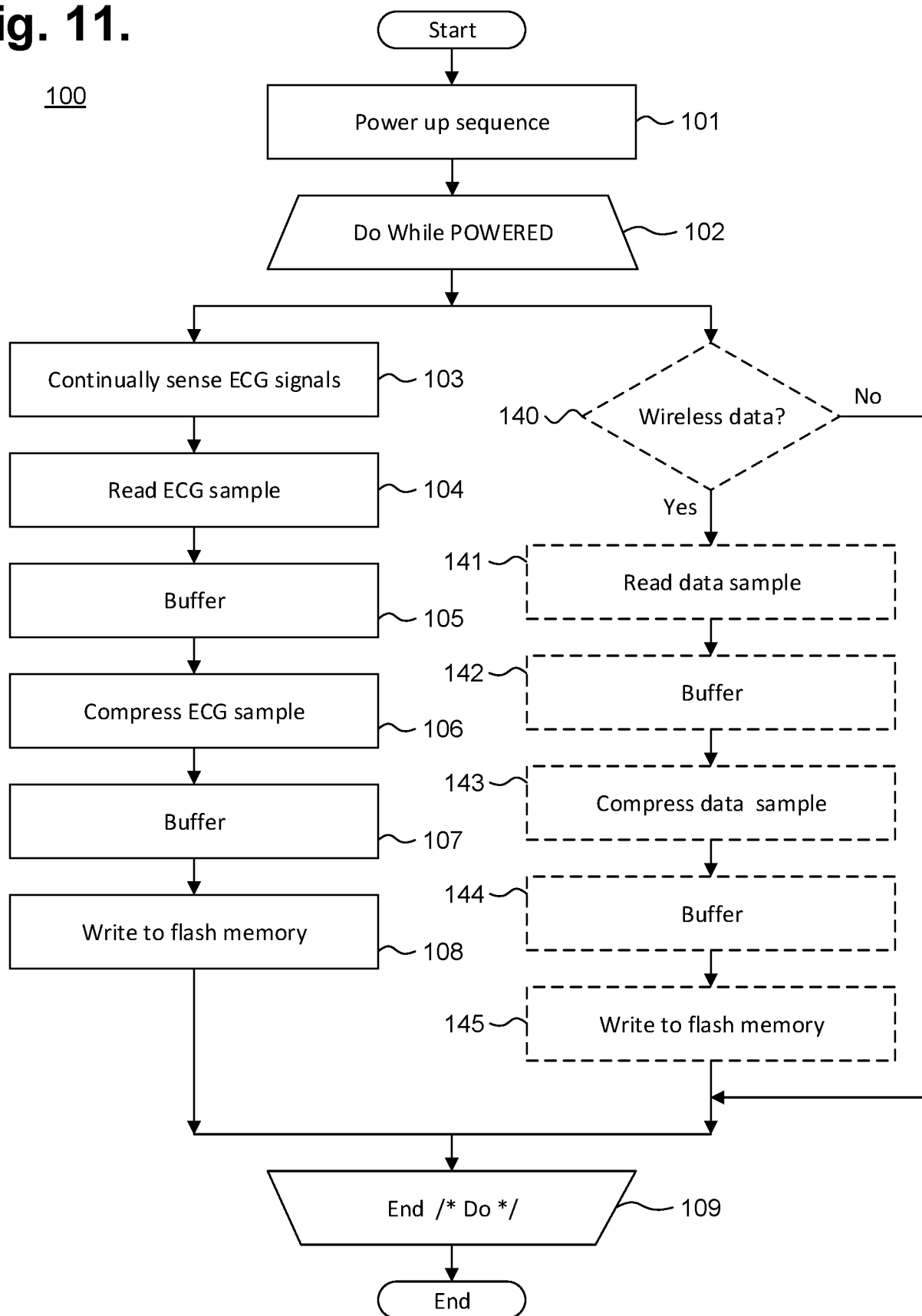


Fig. 12.

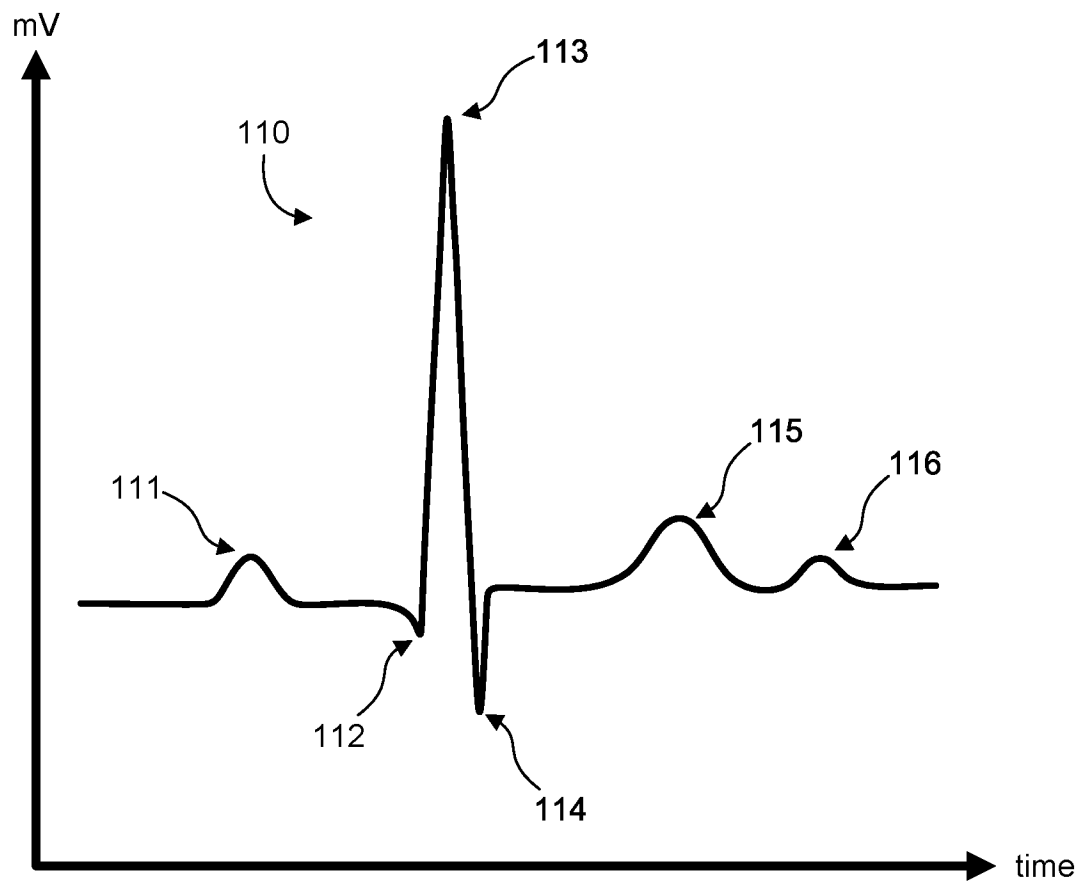
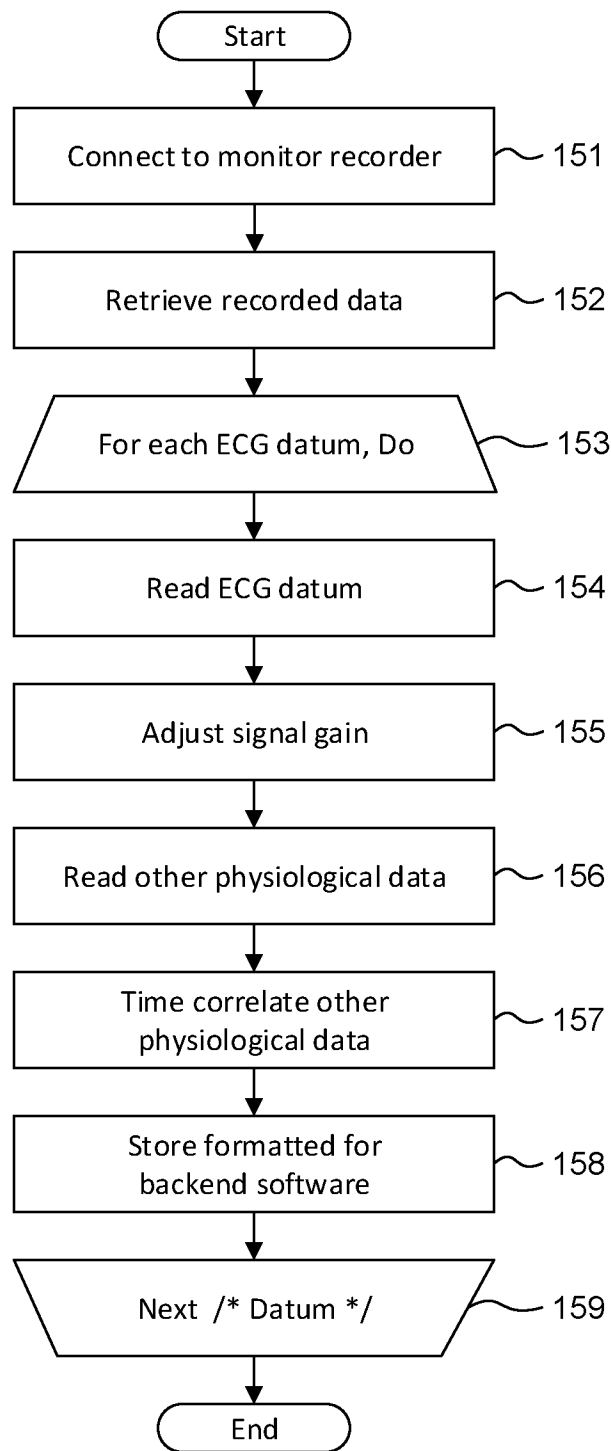


Fig. 13.

150



ELECTROCARDIOGRAPHY PATCH

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This non-provisional patent application is a continuation of U.S. Patent Application, Serial No. 16/241,929, filed January 7, 2019, pending, which is a continuation of U.S. Patent No. 10,172,534, issued January 8, 2019, which is a continuation of U.S. Patent No. 9,820,665, issued November 21, 2017, which is a
10 continuation of U.S. Patent No. 9,433,367, issued September 6, 2016, which is a continuation-in-part of U.S. Patent No. 9,545,204, issued January 17, 2017 and a continuation-in-part of U.S. Patent No. 9,730,593, issued August 15, 2017, and further claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent application, Serial No. 61/882,403, filed September 25, 2013, the disclosures of
15 which are incorporated by reference.

FIELD

 This application relates in general to electrocardiographic monitoring and, in particular, to an electrocardiography patch.

BACKGROUND

20 The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac
25 electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recordation to derive

heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically
5 recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic
10 conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

15 Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the “gold standard” of ECG monitoring, yet achieving a 30-day
20 observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient’s ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of
25 acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental
30 contaminants, as well as perspiration, skin oil, and dead skin cells from the patient’s body, can get between an ECG electrode, the non-conductive adhesive

used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the

patient from the physician office to a specialized center within the hospital or clinic.

5 The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherance from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

25 In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+ FuelBand, manufactured by Nike Inc., Beaverton, OR, for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart

phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording
5 ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and “life tracking”-type data into long-term ECG and physiological data monitoring.

10 SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient’s chest along the sternum oriented top-to-bottom. The
15 placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow “hourglass”-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch
20 anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called “smart phones,” to download monitoring data either in real-time or in batches. The monitor recorder
25 can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sensor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography
30 patch. The remotely-interfaceable electrocardiography patch includes a backing formed of a strip of material and an electrocardiographic electrode on each end of

the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least one of the electrocardiographic signals and other physiological measures with one or more of a physiology and activity
5 sensor, communication device, server, and personal computer.

A further embodiment provides an electrocardiography patch. A backing forms an elongated strip with a mid-section connecting two ends of the backing. The mid-section is narrower than the two ends of the backing. An electrocardiographic electrode is provided on each end of the backing to capture
10 electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

A still further embodiment provides an electrocardiography monitor. A backing forms an elongated strip with a mid-section connecting two ends of the
15 backing. The mid-section is narrower than the two ends of the backing. An electrocardiographic electrode is provided on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals. A battery is
20 positioned on one of the ends of the backing and a processor is powered by the battery. A memory is electrically interfaced with the processor and operable to store samples of the electrocardiographic signals

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of
25 the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhesed between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

30 In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best

location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature,
5 respiratory rate, blood sugar, oxygen saturation, and blood pressure, as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be
10 realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

15 BRIEF DESCRIPTION OF THE DRAWINGS

FIGURES 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIGURE 3 is a functional block diagram showing a system for remote
20 interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIGURE 4 is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIGURE 5 is a perspective view showing the monitor recorder of
25 FIGURE 4.

FIGURE 6 is a perspective view showing the extended wear electrode patch of FIGURE 4 without a monitor recorder inserted.

FIGURE 7 is a bottom plan view of the monitor recorder of FIGURE 4.

FIGURE 8 is a top view showing the flexible circuit of the extended wear
30 electrode patch of FIGURE 4 when mounted above the flexible backing.

FIGURE 9 is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIGURE 4.

FIGURE 10 is a functional block diagram showing the circuitry of the extended wear electrode patch of FIGURE 4.

5 FIGURE 11 is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIGURE 4.

FIGURE 12 is a graph showing, by way of example, a typical ECG waveform.

10 FIGURE 13 is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that
15 includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGURES 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor 12, including a monitor recorder 14 in accordance with one embodiment, respectively fitted to the sternal region of a female patient 10 and a
20 male patient 11. The wearable monitor 12 sits centrally (in the midline) on the patient's chest along the sternum 13 oriented top-to-bottom with the monitor recorder 14 preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor 12 can be corrected post-monitoring, as further described *infra*. The electrode patch 15 is shaped to fit
25 comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline 16 (or immediately to either side of the sternum 13). The distal end of the electrode patch 15 extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch 15, located under the monitor
30 recorder 14, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor 12 in a location at the sternal
midline 16 (or immediately to either side of the sternum 13) significantly
improves the ability of the wearable monitor 12 to cutaneously sense cardiac
electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent,
5 the QRS interval signals in the ECG waveforms that indicate ventricular activity,
while simultaneously facilitating comfortable long-term wear for many weeks.
The sternum 13 overlies the right atrium of the heart and the placement of the
wearable monitor 12 in the region of the sternal midline 13 puts the ECG
electrodes of the electrode patch 15 in a location better adapted to sensing and
10 recording P-wave signals than other placement locations, say, the upper left
pectoral region or lateral thoracic region or the limb leads. In addition, placing
the lower or inferior pole (ECG electrode) of the electrode patch 15 over (or near)
the Xiphoid process facilitates sensing of ventricular activity and provides
superior recordation of the QRS interval.

15 When operated standalone, the monitor recorder 14 of the extended wear
electrocardiography and physiological sensor monitor 12 senses and records the
patient's ECG data into an onboard memory. In addition, the wearable monitor
12 can interoperate with other devices. FIGURE 3 is a functional block diagram
showing a system 120 for remote interfacing of an extended wear
20 electrocardiography and physiological sensor monitor 12 in accordance with one
embodiment. The monitor recorder 14 is a reusable component that can be fitted
during patient monitoring into a non-conductive receptacle provided on the
electrode patch 15, as further described *infra* with reference to FIGURE 4, and
later removed for offloading of stored ECG data or to receive revised
25 programming. The monitor recorder 14 can then be connected to a download
station 125, which could be a programmer or other device that permits the
retrieval of stored ECG monitoring data, execution of diagnostics on or
programming of the monitor recorder 14, or performance of other functions. The
monitor recorder 14 has a set of electrical contacts (not shown) that enable the
30 monitor recorder 14 to physically interface to a set of terminals 128 on a paired
receptacle 127 of the download station 125. In turn, the download station 125

executes a communications or offload program 126 (“Offload”) or similar program that interacts with the monitor recorder 14 via the physical interface to retrieve the stored ECG monitoring data. The download station 125 could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder 14. Still other forms of download station 125 are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder 14, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described *infra* with reference to FIGURE 13. The formatted data can then be retrieved from the download station 125 over a hard link 135 using a control program 137 (“Ctl”) or analogous application executing on a personal computer 136 or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer 136 or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described *infra* with reference to FIGURE 13. Note that formatted data stored on the personal computer 136 would have to be maintained and safeguarded in the same manner as electronic medical records (EMRs) 134 in the secure database 124, as further discussed *infra*. In a further embodiment, the download station 125 is able to directly interface with other devices over a computer communications network 121, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server 122 to remotely interface with the download station 125 over the network 121 and retrieve the formatted data or other information. The server 122 executes a patient management program 123 (“Mgt”) or similar application that stores the retrieved formatted data and other information in a secure database 124 cataloged in that patient’s EMRs 134. In addition, the patient management program 123 could

manage a subscription service that authorizes a monitor recorder 14 to operate for a set period of time or under pre-defined operational parameters.

The patient management program 123, or other trusted application, also maintains and safeguards the secure database 124 to limit access to patient EMRs 134 to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database 124. The physician would execute an application program 130 ("Pgm"), such as a post-monitoring ECG analysis program, on a personal computer 129 or other connectable computing device, and, through the application 130, coordinate access to his patient's EMRs 134 with the patient management program 123. Other schemes and safeguards to protect and maintain the integrity of patient EMRs 134 are possible.

The wearable monitor 12 can interoperate wirelessly with other wearable physiology and activity sensors 131 and with wearable or mobile communications devices 133. Wearable physiology and activity sensors 131 encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient's body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors 131 are capable of wireless interfacing with wearable or mobile communications devices 133, particularly smart mobile devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The wearable or

mobile communications device 133 executes an application (“App”) that can retrieve the data collected by the wearable physiology and activity sensor 131 and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer’s exercise efforts. Still other
5 wearable or mobile communications device 133 functions on the collected data are possible.

The wearable or mobile communications devices 133 could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor 131 to a server 122, or, similarly, the wearable physiology and activity
10 sensor 131 could itself directly provide the collected data to the server 122. The server 122 could then merge the collected data into the wearer’s EMRs 134 in the secure database 124, if appropriate (and permissible), or the server 122 could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor 131.
15 Still other server 122 functions on the collected data are possible.

Finally, the monitor recorder 14 can also be equipped with a wireless transceiver, as further described *infra* with reference to FIGURES 9 and 10. Thus, when wireless-enabled, both wearable physiology and activity sensors 131 and wearable or mobile communications devices 133 could wirelessly interface
20 with the monitor recorder 14, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server 122, analysis, or other purpose. In addition, the monitor recorder 14 could wirelessly interface directly with the server 122, personal computer 129, or other computing device connectable over
25 the network 121, when the monitor recorder 14 is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder 14 are possible.

During use, the electrode patch 15 is first adhered to the skin along the sternal midline 16 (or immediately to either side of the sternum 13). A monitor
30 recorder 14 is then snapped into place on the electrode patch 15 to initiate ECG monitoring. FIGURE 4 is a perspective view showing an extended wear electrode

patch 15 with a monitor recorder 14 in accordance with one embodiment inserted. The body of the electrode patch 15 is preferably constructed using a flexible backing 20 formed as an elongated strip 21 of wrap knit or similar stretchable material with a narrow longitudinal mid-section 23 evenly tapering inward from both sides. A pair of cut-outs 22 between the distal and proximal ends of the electrode patch 15 create a narrow longitudinal midsection 23 or “isthmus” and defines an elongated “hourglass”-like shape, when viewed from above.

The electrode patch 15 incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch 15 is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch 15 incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled “Extended Wear Electrocardiography Patch,” No. 9,545,204, issued January 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs 22 and longitudinal midsection 23 help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs 22 and longitudinal midsection 23 further allow better conformity of the electrode patch 15 to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs 22 and longitudinal midsection 23 help the electrode patch 15 fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch 15 are possible.

The monitor recorder 14 removably and reusably snaps into an electrically non-conductive receptacle 25 during use. The monitor recorder 14 contains electronic circuitry for recording and storing the patient’s electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch 15, such as described in commonly-assigned U.S. Patent, entitled “Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor,” No.

9,730,593, issued August 15, 2017, the disclosure which is incorporated by reference. The non-conductive receptacle 25 is provided on the top surface of the flexible backing 20 with a retention catch 26 and tension clip 27 molded into the non-conductive receptacle 25 to conformably receive and securely hold the
5 monitor recorder 14 in place.

The monitor recorder 14 includes a sealed housing that snaps into place in the non-conductive receptacle 25. FIGURE 5 is a perspective view showing the monitor recorder 14 of FIGURE 4. The sealed housing 50 of the monitor recorder 14 intentionally has a rounded isosceles trapezoidal-like shape 52, when viewed
10 from above, such as described in commonly-assigned U.S. Design Patent, entitled "Electrocardiography Monitor," No. D717,955, issued November 18, 2014, the disclosure of which is incorporated by reference. The edges 51 along the top and bottom surfaces are rounded for patient comfort. The sealed housing 50 is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high,
15 excluding a patient-operable tactile-feedback button 55. The sealed housing 50 can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button 55 is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent 53 and tension detent 54 are molded along the edges of the top surface of the housing 50 to respectively
20 engage the retention catch 26 and the tension clip 27 molded into non-conductive receptacle 25. Other shapes, features, and conformities of the sealed housing 50 are possible.

The electrode patch 15 is intended to be disposable. The monitor recorder 14, however, is reusable and can be transferred to successive electrode patches 15
25 to ensure continuity of monitoring. The placement of the wearable monitor 12 in a location at the sternal midline 16 (or immediately to either side of the sternum 13) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch 15
30 anywhere within the general region of the sternum 13.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch 15, which increases patient comfort and satisfaction, while the monitor recorder 14 ensures ECG monitoring continuity with minimal effort. A monitor recorder 14 is merely unsnapped from
5 a worn out electrode patch 15, the worn out electrode patch 15 is removed from the skin, a new electrode patch 15 is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder 14 is snapped into the new electrode patch 15 to reinitiate and continue the ECG monitoring.

10 During use, the electrode patch 15 is first adhered to the skin in the sternal region. FIGURE 6 is a perspective view showing the extended wear electrode patch 15 of FIGURE 4 without a monitor recorder 14 inserted. A flexible circuit 32 is adhered to each end of the flexible backing 20. A distal circuit trace 33 and a proximal circuit trace (not shown) electrically couple ECG electrodes (not
15 shown) to a pair of electrical pads 34. The electrical pads 34 are provided within a moisture-resistant seal 35 formed on the bottom surface of the non-conductive receptacle 25. When the monitor recorder 14 is securely received into the non-conductive receptacle 25, that is, snapped into place, the electrical pads 34 interface to electrical contacts (not shown) protruding from the bottom surface of
20 the monitor recorder 14, and the moisture-resistant seal 35 enables the monitor recorder 14 to be worn at all times, even during bathing or other activities that could expose the monitor recorder 14 to moisture.

In addition, a battery compartment 36 is formed on the bottom surface of the non-conductive receptacle 25, and a pair of battery leads (not shown)
25 electrically interface the battery to another pair of the electrical pads 34. The battery contained within the battery compartment 35 can be replaceable, rechargeable or disposable.

The monitor recorder 14 draws power externally from the battery provided in the non-conductive receptacle 25, thereby uniquely obviating the need for the
30 monitor recorder 14 to carry a dedicated power source. FIGURE 7 is a bottom plan view of the monitor recorder 14 of FIGURE 4. A cavity 58 is formed on the

bottom surface of the sealed housing 50 to accommodate the upward projection of the battery compartment 36 from the bottom surface of the non-conductive receptacle 25, when the monitor recorder 14 is secured in place on the non-conductive receptacle 25. A set of electrical contacts 56 protrude from the bottom surface of the sealed housing 50 and are arranged in alignment with the electrical pads 34 provided on the bottom surface of the non-conductive receptacle 25 to establish electrical connections between the electrode patch 15 and the monitor recorder 14. In addition, a seal coupling 57 circumferentially surrounds the set of electrical contacts 56 and securely mates with the moisture-resistant seal 35 formed on the bottom surface of the non-conductive receptacle 25.

The placement of the flexible backing 20 on the sternal midline 16 (or immediately to either side of the sternum 13) also helps to minimize the side-to-side movement of the wearable monitor 12 in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing 20 due to compressional and torsional forces, a layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing 20, but only on the distal end 30 and the proximal end 31. As a result, the underside, or contact surface of the longitudinal midsection 23 does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection 23 forms a crimp relief that respectively facilitates compression and twisting of the flexible backing 20 in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing 20, the flexible circuit 32 is only able to bend and cannot stretch in a planar direction. The flexible circuit 32 can be provided either above or below the flexible backing 20. FIGURE 8 is a top view showing the flexible circuit 32 of the extended wear electrode patch 15 of FIGURE 4 when mounted above the flexible backing 20. A distal ECG electrode 38 and proximal ECG electrode 39 are respectively coupled to the distal and proximal ends of the flexible circuit 32. A strain relief 40 is defined in the flexible circuit 32 at a location that is partially underneath the battery compartment 36 when the flexible circuit 32 is affixed to the flexible backing 20. The strain relief 40 is laterally

extendable to counter dislodgment of the ECG electrodes 38, 39 due to tensile and torsional forces. A pair of strain relief cutouts 41 partially extend transversely from each opposite side of the flexible circuit 32 and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit 32 in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder 14 are provided through a micro controlled architecture. FIGURE 9 is a functional block diagram showing the component architecture of the circuitry 60 of the monitor recorder 14 of FIGURE 4. The circuitry 60 is externally powered through a battery provided in the non-conductive receptacle 25 (shown in FIGURE 6). Both power and raw ECG signals, which originate in the pair of ECG electrodes 38, 39 (shown in FIGURE 8) on the distal and proximal ends of the electrode patch 15, are received through an external connector 65 that mates with a corresponding physical connector on the electrode patch 15. The external connector 65 includes the set of electrical contacts 56 that protrude from the bottom surface of the sealed housing 50 and which physically and electrically interface with the set of pads 34 provided on the bottom surface of the non-conductive receptacle 25. The external connector includes electrical contacts 56 for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector 65 of the monitor recorder 14 and the device into which the monitor recorder 14 is attached, whether an electrode patch 15 or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector 65 also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder 14, and performance of other functions.

Operation of the circuitry 60 of the monitor recorder 14 is managed by a microcontroller 61. The micro-controller 61 includes a program memory unit containing internal flash memory that is readable and writeable. The internal

flash memory can also be programmed externally. The micro-controller 61 draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. The microcontroller 61 connects to the ECG front end circuit 63 that measures raw cutaneous electrical signals and generates an analog
5 ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry 60 of the monitor recorder 14 also includes a flash memory 62, which the micro-controller 61 uses for storing ECG monitoring data and other physiology and information. The flash memory 62 also draws power externally
10 from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory 62 enables the microcontroller 61 to store digitized ECG data. The communications bus further enables the flash memory 62 to be directly accessed externally over
15 the external connector 65 when the monitor recorder 14 is interfaced to a download station.

The circuitry 60 of the monitor recorder 14 further includes an actigraphy sensor 64 implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller 61 by independent
20 initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder 14 if, for instance, the monitor recorder 14 has been inadvertently installed upside down, that is, with the monitor recorder 14 oriented on the electrode patch 15 towards the patient's feet,
25 as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Patent No. 9,737,224, issued August 22, 2017, the disclosure of which is incorporated by reference.

The circuitry 60 of the monitor recorder 14 includes a wireless transceiver 69 that can provides wireless interfacing capabilities. The wireless transceiver 69
30 also draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. The wireless transceiver 69 can be

implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder 14; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller 61 includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch 15 or other source, can interface to the microcontroller 61 over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry 60 of the monitor recorder 14, or can be provided on the electrode patch 15 with communication with the micro-controller 61 provided over one of the electrical contacts 56. The physiology sensor can include an SpO₂ sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Patent No. 9,364,155, issued June 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry 60 of the monitor recorder 14 includes patient-interfaceable components, including a tactile feedback button 66, which a patient can press to mark events or to perform other functions, and a buzzer 67, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer 67 can be used by the microcontroller 61 to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry 60 of the monitor recorder 14 are possible.

While the monitor recorder 14 operates under micro control, most of the electrical components of the electrode patch 15 operate passively. FIGURE 10 is a functional block diagram showing the circuitry 70 of the extended wear electrode patch 15 of FIGURE 4. The circuitry 70 of the electrode patch 15 is

electrically coupled with the circuitry 60 of the monitor recorder 14 through an external connector 74. The external connector 74 is terminated through the set of pads 34 provided on the bottom of the non-conductive receptacle 25, which electrically mate to corresponding electrical contacts 56 protruding from the bottom surface of the sealed housing 50 to electrically interface the monitor recorder 14 to the electrode patch 15.

The circuitry 70 of the electrode patch 15 performs three primary functions. First, a battery 71 is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle 25. The battery 71 is electrically interfaced to the circuitry 60 of the monitor recorder 14 as a source of external power. The unique provisioning of the battery 71 on the electrode patch 15 provides several advantages. First, the locating of the battery 71 physically on the electrode patch 15 lowers the center of gravity of the overall wearable monitor 12 and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing 50 of the monitor recorder 14 is sealed against moisture and providing power externally avoids having to either periodically open the housing 50 for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder 14 off line for hours at a time. In addition, the electrode patch 15 is intended to be disposable, while the monitor recorder 14 is a reusable component. Each time that the electrode patch 15 is replaced, a fresh battery is provided for the use of the monitor recorder 14, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder 14 is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller 61. Requiring those additional sensors or components to draw power from a source external to the monitor recorder 14 keeps power considerations independent of the monitor recorder 14. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry 60.

Second, the pair of ECG electrodes 38, 39 respectively provided on the distal and proximal ends of the flexible circuit 32 are electrically coupled to the set of pads 34 provided on the bottom of the non-conductive receptacle 25 by way of their respective circuit traces 33, 37. The signal ECG electrode 39 includes a protection circuit 72, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry 70 of the electrode patch 15 includes a cryptographic circuit 73 to authenticate an electrode patch 15 for use with a monitor recorder 14. The cryptographic circuit 73 includes a device capable of secure authentication and validation. The cryptographic device 73 ensures that only genuine, non-expired, safe, and authenticated electrode patches 15 are permitted to provide monitoring data to a monitor recorder 14, such as described in commonly-assigned U.S. Patent No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry 70 of the electrode patch 15 includes a wireless transceiver 75, in lieu the including of the wireless transceiver 69 in the circuitry 60 of the monitor recorder 14, which interfaces with the microcontroller 61 over the microcontroller's expansion port via the external connector 74.

The monitor recorder 14 continuously monitors the patient's heart rate and physiology. FIGURE 11 is a flow diagram showing a monitor recorder-implemented method 100 for monitoring ECG data for use in the monitor recorder 14 of FIGURE 4. Initially, upon being connected to the set of pads 34 provided with the non-conductive receptacle 25 when the monitor recorder 14 is snapped into place, the microcontroller 61 executes a power up sequence (step 101). During the power up sequence, the voltage of the battery 71 is checked, the state of the flash memory 62 is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller 61 and the electrode patch 15 are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps 102-109) is continually executed by the microcontroller 61. During each iteration (step 102) of the processing loop, the ECG frontend 63 (shown in FIGURE 9) continually senses the cutaneous ECG electrical signals (step 103) via the ECG electrodes 38, 29 and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step 104) by the microcontroller 61 by sampling the analog ECG signal output front end 63. FIGURE 12 is a graph showing, by way of example, a typical ECG waveform 110. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave 111 has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave 112, followed by a larger upward deflection of an R-wave 113, and terminated with a downward waveform of the S wave 114, collectively representative of ventricular depolarization. The T wave 115 is normally a modest upward waveform, representative of ventricular depolarization, while the U wave 116, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor 12, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step 105), pending compression preparatory to storage in the flash memory 62 (step 106). Following compression, the compressed ECG

digitized sample is again buffered (step 107), then written to the flash memory 62 (step 108) using the communications bus. Processing continues (step 109), so long as the monitoring recorder 14 remains connected to the electrode patch 15 (and storage space remains available in the flash memory 62), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder 14 also continuously receives data from wearable physiology and activity sensors 131 and wearable or mobile communications devices 133 (shown in FIGURE 3). The data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps 102-109) continually executed by the microcontroller 61. During each iteration (step 102) of the processing loop, if wireless data is available (step 140), a sample of the wireless is read (step 141) by the microcontroller 61 and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller 61. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step 142), pending compression preparatory to storage in the flash memory 62 (step 143). Following compression, the compressed wireless data sample is again buffered (step 144), then written to the flash memory 62 (step 145) using the communications bus. Processing continues (step 109), so long as the monitoring recorder 14 remains connected to the electrode patch 15 (and storage space remains available in the flash memory 62), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder 14 stores ECG data and other information in the flash memory 62 (shown in FIGURE 9) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder 14 must first be converted into a format suitable for use by third party post-monitoring analysis software. FIGURE 13 is a flow diagram showing a method 150 for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor 12 in accordance with one embodiment. The method 150 can be implemented in software and execution

of the software can be performed on a download station 125, which could be a programmer or other device, or a computer system, including a server 122 or personal computer 129, such as further described *supra* with reference to FIGURE 3, as a series of process or method modules or steps. For convenience,
5 the method 150 will be described in the context of being performed by a personal computer 136 or other connectable computing device (shown in FIGURE 3) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method 150 by a computer system would be analogous *mutatis mutandis*.

10 Initially, the download station 125 is connected to the monitor recorder 14 (step 151), such as by physically interfacing to a set of terminals 128 on a paired receptacle 127 or by wireless connection, if available. The data stored on the monitor recorder 14, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step 152) over a hard link 135
15 using a control program 137 (“Ctl”) or analogous application executing on a personal computer 136 or other connectable computing device.

The data retrieved from the monitor recorder 14 is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be
20 used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps 153-159) in an iterative processing loop. During each iteration (step 153), the ECG datum is read (step 154) and, if necessary, the gain of the ECG signal is adjusted (step 155) to compensate, for instance, for relocation or replacement of the electrode patch 15
25 during the monitoring period.

In addition, depending upon the configuration of the wearable monitor 12, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For
30 instance, actigraphy data may have been sampled by the actigraphy sensor 64 based on a sensed event occurrence, such as a sudden change in orientation due to

the patient taking a fall. In response, the monitor recorder 14 will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory 62 by the micro-controller 61. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide
5 the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other
10 information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step 156) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological data (or other information)
15 was noted (step 157). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step 158) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is
20 embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder 14, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would
25 then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder 14, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data
30 in a separate manner, are possible.

Processing continues (step 159) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

- While the invention has been particularly shown and described as
- 5 referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

- 1 1. An electrocardiography patch, comprising:
2 a backing comprising an elongated strip with a mid-section connecting
3 two ends of the backing, wherein the mid-section is narrower than the two ends of
4 the backing;
5 an electrocardiographic electrode on each end of the backing to capture
6 electrocardiographic signals;
7 a flexible circuit comprising a pair of circuit traces electrically coupled to
8 the electrocardiographic electrodes; and
9 a wireless transceiver to communicate at least a portion of the
10 electrocardiographic signals.
- 1 2. An electrocardiography patch according to Claim 1, further
2 comprising:
3 an accelerometer provided on the backing.
- 1 3. An electrocardiography patch according to Claim 1, further
2 comprising:
3 a physiology sensor provided on the backing to measure body
4 temperature.
- 1 4. An electrocardiography patch according to Claim 1, wherein each
2 of the ends of the backing is rounded on an outer edge.
- 1 5. An electrocardiography patch according to Claim 1, further
2 comprising:
3 a physiology and activity sensor provided on the backing to measure one
4 or more of heart rate, temperature, blood pressure, movement, sleep, footsteps,
5 calories burned and estimated blood glucose level.
- 1 6. An electrocardiography patch according to Claim 1, wherein the
2 electrocardiographic signals are converted to a different format and processed.

1 7. An electrocardiography patch according to Claim 6, wherein the
2 formatted electrocardiographic signals are retrieved by one of a server, a client
3 computer and a mobile device via the wireless transceiver.

1 8. An electrocardiography patch according to Claim 1, wherein the
2 electrodes are exposed on a contact surface of the backing.

1 9. An electrocardiography patch according to Claim 1, further
2 comprising:
3 a hydrocolloid adhesive provided on at least a portion of a contact surface
4 of the backing.

1 10. An electrocardiography patch according to Claim 9, wherein the
2 hydrocolloid adhesive is provided on the ends of the backing, on the contact
3 surface.

1 11. An electrocardiography monitor, comprising:
2 a backing comprising an elongated strip with a mid-section connecting
3 two ends of the backing, wherein the mid-section is narrower than the two ends of
4 the backing;
5 an electrocardiographic electrode on each end of the backing to capture
6 electrocardiographic signals;
7 a flexible circuit comprising a pair of circuit traces electrically coupled to
8 the electrocardiographic electrodes;
9 a wireless transceiver to communicate at least a portion of the
10 electrocardiographic signals;
11 a battery on one of the ends of the backing;
12 a processor powered by the battery; and
13 memory electrically interfaced with the processor and operable to store
14 samples of the electrocardiographic signals.

1 12. An electrocardiography monitor according to Claim 11, further
2 comprising:

3 an accelerometer provided on the backing.

1 13. An electrocardiography monitor according to Claim 11, further
2 comprising:

3 a physiology sensor provided on the backing to measure body
4 temperature.

1 14. An electrocardiography monitor according to Claim 11, wherein
2 each of the ends of the backing is rounded on an outer edge.

1 15. An electrocardiography monitor according to Claim 11, further
2 comprising:

3 a physiology and activity sensor provided on the backing to measure one
4 or more of heart rate, temperature, blood pressure, movement, sleep, footsteps,
5 calories burned and estimated blood glucose level.

1 16. An electrocardiography monitor according to Claim 11, wherein
2 the electrocardiographic signals are converted to a different format and processed.

1 17. An electrocardiography monitor according to Claim 16, wherein
2 the formatted electrocardiographic signals are retrieved by one of a server, a client
3 computer and a mobile device via the wireless transceiver.

1 18. An electrocardiography monitor according to Claim 11, wherein
2 the electrodes are exposed on a contact surface of the backing.

1 19. An electrocardiography monitor according to Claim 11, further
2 comprising:
3 a hydrocolloid adhesive provided on at least a portion of a contact surface
4 of the backing.

1 20. An electrocardiography monitor according to Claim 19, wherein
2 the hydrocolloid adhesive is provided on the ends of the backing, on the contact
3 surface.

ABSTRACT

An electrocardiography patch is provided. A backing forms an elongated strip with a mid-section connecting two ends of the backing. The mid-section is narrower than the two ends of the backing. An electrocardiographic electrode is provided on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

Electronic Patent Application Fee Transmittal

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Filing Date:				
Title of Invention:	ELECTROCARDIOGRAPHY PATCH			
First Named Inventor/Applicant Name:	Jason Felix			
Filer:	Krista A. Wittman/Natalia Deymonaz			
Attorney Docket Number:	127.2029.US.CON			
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Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
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UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
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Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
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Total in USD (\$)				830

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Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1256784	no	9
			e4c9df93263370a16be3b53a84a64f0d06259f84		
Warnings:					
Information:					
3	Oath or Declaration filed	Declarations.pdf	265032	no	3
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4	Power of Attorney	POA.pdf	114141	no	1
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Warnings:					
Information:					
6		Application.pdf	267513	yes	30
			33ca9a06d2545c44cf49ba7c023c6bcd664a3d92		
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			VitalConnect Ex	1007	

	Specification	1	26
	Claims	27	29
	Abstract	30	30

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