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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/880,712	12/25/2018	10159422	3022036 US08	9503

88750 7590 12/06/2018
Barclay Damon, LLP
Barclay Damon Tower
125 East Jefferson Street
SYRACUSE, NY 13202

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):

Steven D. Baker, Beaverton, OR;
Welch Allyn, Inc., Skaneateles Falls, NY;
Eric T. McAdams, Whitehead, UNITED KINGDOM;
James P. Welch, Mission Viejo, CA;

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.

Date: June 7, 2012

Sheet 3 of 6

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	
	Confirmation No.: 9601	
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,298,314 B1	10/02/2001	Blackadar et al.			
	6,331,444	12/18/2001	Ferrari et al.			
	6,336,365 B1	01/08/2002	Blackadar et al.			
	6,357,147 B1	03/19/2002	Darley et al.			
	6,440,067 B1	08/27/2002	DeLuca et al.			
	6,448,621	09/10/2002	Thakur			
	6,493,652 B1	12/10/2002	Ohlenbusch et al.			
	6,539,613 B1	04/01/2003	Ulmer			
	6,544,171 B2	04/08/2003	Beetz et al.			
	6,544,173	04/08/2003	West et al.			
	6,544,174	04/08/2003	West et al.			
	6,579,231 B1	06/17/2003	Phipps			
	6,586,810	07/01/2003	Thakur			
	6,623,312 B2	09/23/2003	Merry et al.			
	6,791,900 B2	09/21/2004	Tseng			
	6,847,892 B2	01/25/2005	Zhou et al.			
	6,870,484 B1	03/22/2005	Brinsfield et al.			
	6,911,727	06/28/2005	Martin et al.			
	7,318,417	01/15/2008	Lang et al.			
	7,382,247 B2	06/03/2008	Welch et al.			
	7,439,856 B2	10/21/2008	Weiner et al.			
	7,508,064	03/24/2009	Martin et al.			
	7,515,043 B2	04/07/2009	Welch et al.			
	7,515,044 B2	04/07/2009	Welch et al.			
	7,563,632	07/21/2009	Martin et al.			
	2001/0023315 A1	09/20/2001	Flach et al.			

Change(s) applied
to document
/S.R.R./
9/11/2018

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

BARCLAY DAMON LLP

Peter J. Bilinski
Partner

November 14, 2018

Via Electronic Filing System (EFS)

Mail Stop: ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number:	15/880,712
Filing Date:	January 26, 2018
First Named Inventor(s):	Steven D. Baker
Art Unit:	3762
Examiner Name:	Johnson, Nicole F.
Attorney Docket Number:	3022036 US08
Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

In response to the Notice of Allowance and Fee(s) due, mailed August 24, 2018, Applicants submit as follows:

- This Transmittal Letter (1 page);
- Part B – Fee(s) Transmittal (PTOL-85) (1 page); and
- Comments on Statement for Reasons for Allowance (2 pages)

The Commissioner is authorized to charge the issue fee, for a large entity, in the amount of \$1,000.00 to our Deposit Account 50-3010 and to charge any deficiencies or credit any excess payments to our Deposit Account No. 50-3010.

Very truly yours,

/Peter J. Bilinski/

Peter J. Bilinski
Reg. No. 35,067

PJB:scp
Enclosures

Barclay Damon Tower – 125 East Jefferson Street – Syracuse, New York 13202 barclaydamon.com
pbilinski@barclaydamon.com Direct: 315.425.2856 Fax: 315.703.7397

17524838.1

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(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)

88750 7590 08/24/2018
Barclay Damon, LLP
Barclay Damon Tower
125 East Jefferson Street
SYRACUSE, NY 13202

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.

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/880,712	01/26/2018	Steven D. Baker	3022036 US08	9503

TITLE OF INVENTION: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0	\$0	\$1000	11/26/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
JOHNSON, NICOLE F	3762	600-508000

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 03-02 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 Barclay Damon, LLP

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 has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

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

Welch Allyn, Inc.

Skaneateles Falls, NY

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

4a. The following fee(s) are submitted:

- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

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

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-3010 (enclose an extra copy of this form).

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 /Peter J. Bilinski/

Date November 14, 2018

Typed or printed name Peter J. Bilinski

Registration No. 35,067

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 15/880,712
Applicant : Steven D. Baker et al.
Filed : January 26, 2018
Art Unit : 3792
Examiner : Johnson, Nicole F.
Docket No. : 3022036 US08
Confirmation No.: 9503
Customer No. : 88,750
Title : BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A
DISPOSABLE ELECTRODE MODULE

Mail Stop: Issue Fee
Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON STATEMENT FOR REASONS FOR ALLOWANCE

Sir:

Applicant acknowledges the Examiner's Reason(s) for Allowance dated August 24, 2018. Applicant respectfully notes, however, that there may be additional reasons for allowance that have not been specifically cited, and which may apply to the allowed claims, in addition to or instead of the cited Reason(s). Applicant respectfully notes that each of the allowed claims is patentable in its own right and for other reasons raised during its prosecution or as explained in the specification of the captioned application. Moreover, as the prosecution history of the claims is clear and is not limited only to the Examiner's Reason(s), the Examiner's Reason for Allowance therefore is not binding on Applicant and no acquiescence is made by Applicant to such Reason(s).

17524755.1

U.S. Patent Application No.: 15/880,712
Paper Dated: November 14, 2018

Entry of this submission into the file is respectfully requested.

Respectfully submitted,

BARCLAY DAMON, LLP

/Peter J. Bilinski/

Date: November 14, 2018

Peter J. Bilinski
Reg. No. 35,067
Attorney for Applicant
Barclay Damon Tower
125 East Jefferson Street
Syracuse, NY 13202
Tel: (315) 425-2856
Fax: (315) 703-7397

Electronic Patent Application Fee Transmittal				
Application Number:		15880712		
Filing Date:		26-Jan-2018		
Title of Invention:		BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		
First Named Inventor/Applicant Name:		Steven D. Baker		
Filer:		Peter J Bilinski/Susanne Pelose		
Attorney Docket Number:		3022036 US08		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1000	1000

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1000

Electronic Acknowledgement Receipt	
EFS ID:	34306760
Application Number:	15880712
International Application Number:	
Confirmation Number:	9503
Title of Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	88750
Filer:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US08
Receipt Date:	14-NOV-2018
Filing Date:	26-JAN-2018
Time Stamp:	13:15:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 1000
RAM confirmation Number	111418INTEFSW00013284503010
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	Miscellaneous Incoming Letter	2018-11-14-Issue-Fee-Transmittal-Letter.pdf	142826	no	1
			4ec4b8a9d09df370ba12e851b4e6aac72302f242		
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	2018-11-14-Issue-Fee-Transmittal.pdf	116123	no	1
			6b3cf86ceaa85bbe6216cc7cf867e5f39c185ef3		
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	2018-11-14-Comments-On-Statement-For-Reasons-For-Allowance.pdf	80328	no	2
			282337818cdf6055f557acba247802aede1fbbd9		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30332	no	2
			b50c0c225c35f86f0f3e5dd42e134f551792b21e		
Warnings:					
Information:					
Total Files Size (in bytes):			369609		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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



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UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

88750 7590 08/24/2018
Barclay Damon, LLP
Barclay Damon Tower
125 East Jefferson Street
SYRACUSE, NY 13202

EXAMINER

JOHNSON, NICOLE F

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 08/24/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/880,712	01/26/2018	Steven D. Baker	3022036 US08	9503

TITLE OF INVENTION: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0	\$0	\$1000	11/26/2018

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), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

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

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Barclay Damon, LLP
Barclay Damon Tower
125 East Jefferson Street
SYRACUSE, NY 13202

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Certificate of Mailing or Transmission

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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/880,712	01/26/2018	Steven D. Baker	3022036 US08	9503

TITLE OF INVENTION: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

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
JOHNSON, NICOLE F	3762	600-508000

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- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

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

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- ☐ Payment by credit card. Form PTO-2038 is attached.
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5. Change in Entity Status (from status indicated above)

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- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

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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

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/880,712	01/26/2018	Steven D. Baker	3022036 US08	9503
88750	7590	08/24/2018	EXAMINER	
Barclay Damon, LLP			JOHNSON, NICOLE F	
Barclay Damon Tower			ART UNIT	
125 East Jefferson Street			PAPER NUMBER	
SYRACUSE, NY 13202			3762	

DATE MAILED: 08/24/2018

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 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, 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 law or regulation.

Notice of Allowability	Application No. 15/880,712	Applicant(s) BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	AIA (First Inventor to File) Status No

-- 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 arguments submitted on July 3, 2018.
☐ 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) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ 5. ☐ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____	
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/NICOLE F. JOHNSON/ Primary Examiner, Art Unit 3762	
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1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

THE EXAMINER'S STATEMENT OF REASONS FOR ALLOWABILITY

1. The following is an examiner's statement of reasons for allowance: The closest prior art, Harry (as cited in 14/880613), fails to disclose, suggest and/or teach the claimed invention since the reference is silent in regards to a monitoring device having a disposable electrode module comprising a flexible circuit layer an insulating member having an opening on opposing sides of the module, each opening sized to receive an electrode gel, in combination with the other claimed elements (e.g., see 'Arguments'.)

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Allowable Subject Matter

2. Claims 1-20 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. JOHNSON whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. Fridays).

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

Application/Control Number: 15/880,712
Art Unit: 3762

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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, Christopher Koharski can be reached on 571-272-7230. 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.

/NICOLE F. JOHNSON/
Primary Examiner, Art Unit 3762

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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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. Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	15/880,712
				Filing Date	January 26, 2018
				First Named Inventor	Steven D. Baker
				Art Unit	3762
				Examiner Name	Johnson, Nicole F.
				Attorney Docket Number	3022036 US08
Sheet	1	of	2		

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T
		Country Code ³ -Number ⁴ -Kind Code ² (# known)	MM-DD-YYYY			
	AA	WO 2006/094513 A2	09-14-2006	Coloplast A/S and Delta		

Examiner Signature	/NICOLE F LAVERT/	Date Considered	08/21/2018
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L/

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	15/880,712
				Filing Date	January 26, 2018
				First Named Inventor	Steven D. Baker
				Art Unit	3762
				Examiner Name	Johnson, Nicole F.
Sheet	2	of	2	Attorney Docket Number	3022036 US08

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AB	European Examination Report for EP 07 844 766.1; Dated: June 6, 2018; 4 pages	

Examiner Signature	/NICOLE F LAVERT/	Date Considered	08/21/2018
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1534	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:14
S2	2846	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:16
S3	717	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S4	38520	(eck or eckg or cardiac or heart) same monitor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S5	3417	S4 and (electrical same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S6	1847	S5 and (power same source)\	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S7	53826	(current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S8	33	S6 and (current same limiting) same	US-PGPUB;	OR	OFF	2013/05/11

		resistor	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			12:26
S9	33	S6 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S10	23	S9 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:27
S11	4727	(external) same ((heart or EKG or ECG) same monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
S12	2815	S11 and @py<="2009"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
S13	11	S12 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:39
S14	351	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:52
S15	3	"20030171743"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/07/16 10:50
S16	1	S15 and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2013/07/16 10:51

			IBM_TDB			
S17	1758	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:02
S18	3249	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:02
S19	829	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:03
S23	1956	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 11:56
S24	3618	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 11:59
S25	59931	(substrate same resistivity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:03
S26	7022177	S25 and ((print same pattern) same thickness)"0"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:04
S27	502	S25 and ((print same pattern) same thickness)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:04
S28	5	S27 and (medical same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2014/01/13 12:04

			JPO; DERWENT; IBM_TDB			
S29	925	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:09
S33	2367	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/09/30 15:21
S34	4254	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/09/30 15:24
S35	1095	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/09/30 15:25
S36	2559	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/21 16:08
S37	4544	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/21 16:12
S38	2559	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:27
S39	4544	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:46
S40	2049	(external same sensor) same (flexible same circuit)	US-PGPUB; USPAT;	OR	OFF	2015/02/23 08:51

			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S41	735	S40 and adhesive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:51
S42	398	S41 and (conductors or trace\$2)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:51
S44	1190	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 09:00
S45	2049	(external same sensor) same (flexible same circuit)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
S46	735	S45 and adhesive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
S47	398	S46 and (conductors or trace\$2)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
S48	7	S47 and (electrode\$2 same gel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
S49	6137	h05k3/361.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:06

S50	0	A61B5/04084.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:10
S51	1544	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:10
S52	1231	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:32
S53	2686	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:33
S54	4711	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:37
S55	0	h05k3/361.cpc ". "	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:37
S56	1580	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:37
S62	2781	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/14 19:17
S63	4863	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2015/11/14 19:17

			DERWENT; IBM_TDB			
S64	2	"20080139953" and (current same limit\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/15 11:23
S65	20	("2008/0139953").URPN.	USPAT	OR	OFF	2015/11/15 11:36
S66	23	("20020099277" "20030055478" "20030069510" "20030073915" "20050154325" "20060224072" "20080139953" "20080275327" "4082086" "4779630" "5042481" "5224479" "5343869" "5458124" "5622168" "5645063" "5921925" "6115638" "6161036" "6453186" "6572636" "6585707" "6730025").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:36
S67	1907	600/508.CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:37
S68	3569	600/509.ccls.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:37
S69	3950	600/301.ccls.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:38
S70	1716	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/15 11:38
S72	1	"20020099277" and trace\$2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/15 11:55
S73	4968	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/15 15:25
S74	2864	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/15 15:25
S75	1286	600/372.ccls.	US-PGPUB; USPAT;	OR	OFF	2016/03/15 15:25

			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
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S77	4972	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S78	2870	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S79	1286	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S80	789	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S81	1784	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:16
S82	2892	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 08:59
S83	4999	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 08:59

S84	1289	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 08:59
S85	1800	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 09:01
S90	3202	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:54
S91	5514	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:54
S92	918	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:57
S93	1413	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:58
S94	2395	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:58
S95	5	"20040260310"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 11:01
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S98	929	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/08/20 11:59
S99	2503	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/08/20 12:01
S100	1431	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/08/20 12:18

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	Examiner NICOLE F JOHNSON	Art Unit 3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner
A61B5/0484	6/25/2018	NFJ
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US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	372 & 508-509	6/25/2018	NFJ
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* 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
Inventor Search (PE2E)	6/25/2018	NFJ
EAST Search (see attachment)		
Consulted search notes from 14/880413 (same patent family)		

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
Searched all classes and subclasses from the Searched notes	Searched the USPAT, USOCR, USGPUB, EPO, JPO, DERWENT, etc databases	8/20/2018	NFJ

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A61B		5		0006	I	2013-01-01
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A61B		5		746	I	2013-01-01
A61B		5		14542	I	2013-01-01
A61B		5		6832	I	2013-01-01
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ²
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
	AA	WO 2006/094513 A2	09-14-2006	Coloplast A/S and Delta		

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(54) Title: A THREE-DIMENSIONAL ADHESIVE DEVICE HAVING A MICROELECTRONIC SYSTEM EMBEDDED THEREIN

(57) Abstract: Accordingly, the present invention relates to a three-dimensional adhesive device to be attached to the body surface of a mammal comprising a microelectronic sensing system 5 characterized by (a) a three-dimensional adhesive body made of a pressure sensitive adhesive having an upper surface and a bottom surface; (b) a microelectronic system embedded in the body of the pressure sensitive adhesive; 10 (c) one or more cover layer(s) attached to the upper surface; and (d) optionally a release liner releasable attached to the bottom surface of the adhesive device. Suitably the microelectronic system is a microelectronic sensing system capable of 15 sensing physical input such as pressure, vibration, sound, electrical activity (e.g. from muscle activity), tension, blood-flow, moisture, temperature, enzyme activity, bacteria, pH, blood sugar, conductivity, resistance, capacitance, inductance or other chemical, biochemical, biological, mechanical or electrical properties. 1

A three-dimensional adhesive device having a microelectronic system embedded therein

Field of invention

5

The invention relates to micro electronic systems predominantly for monitoring physiological or neurological conditions. More particular the invention relates to invasive and non-invasive microelectronic systems embedded in a three-dimensional adhesive device, which may be attached to the surface, suitably the skin, of a mammal. The microelectronic systems suitably utilises wireless communication and are useful for measuring ECG (Electro CardioGraphy), EMG (Electro MyoGraphy), EEG (Electro EncephaloGraphy), blood glucose, pulse, blood pressure, pH, and oxygen.

10

Background

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The attachment of sensing systems to the skin by means of pressure sensitive adhesives is well established. Thus, AMBU A/S, DK has a number of products for measuring ECG, which is attached to the skin by foam adhesives, micro-porous adhesives or hydrogel adhesives. These sensors are in general connected with wires to a monitoring device.

20

In WO 03/065926 A2 Ozgus et al disclose a wearable biomonitor with a flexible and thin integrated circuit. The patent application addresses a way to achieve high comfort of wear by using a thin layer adhesive or pads of adhesive for fixation to the skin. However, the adhesives used are occluding. The application further describes a sensor module for wireless data collection having a thin sheet of silicon comprising the circuit and a flexible power source being build into the sensor module as layers.

25

In US 5,054,488 Mus et al disclose an opto-electronic sensor for producing electrical signals representative of a physiological condition. The sensors may be attached to the body by a double-sided pressure sensitive adhesive on a polyester lining.

30

In US 5,458,124 Stanko et al disclose electro-cardiographic-electrodes being attached to the body by double-sided pressure sensitive adhesive.

In US 6,372,951 Ter-Ovanesyan et al disclose a sensor operatively connected to a disposable article, fitted to the wearer by an adhesive patch. A wide variety of body adhering compositions may be used.

5 In US 6,385,473 Haines et al disclose a laminated sensor device attached to mammalian subject with two strips of hydrocolloid adhesive. The laminated structure consists also of hydrogel in contact with hydrocolloid adhesive. The lifetime of the device is specified to 24 hrs.

10 In WO 99/59465 Feierbach et al disclose an apparatus for monitoring the physiological condition of a patient. The apparatus includes a patch having a distal side for being fixed to the patient. Also the apparatus may include an electronics housing that may be coupled with said patch. In one embodiment the surface of the apparatus may be pre-formed to the contours of a body part. The patch carrying the electronic housing may be soft and provide
15 a natural feel and may be produced from latex, silicon or another rubberised fabric. The upper surface of the patch with the electronic housing may have a smooth convex shape as illustrated in figure 2B and figure 8 of the patent. The patch is coupled to the skin of the the patient by an adhesive. Such adhesive may be a hydrocolloid skin protective adhesive manufactured by 3M. Hence the patent application teaches the use of a hydrocolloid
20 adhesive liner for fixation of a sensor having a smooth and soft backing optionally in a pre-formed shape to fit a contour of the body.

In US application 2003/0009097 A1 Sheraton et al disclose a sensor having a hydrogel electric conducting central skin contacting part and a hydrocolloid adhesive part
25 surrounding this central part for adhesion of the sensor and on said combined disc a conductive terminal connected to a wire. This construct is further protected by laminate film layers adhered to the terminal and the outer rim of adhesive. The patent application teaches the use of hydrocolloid adhesives for fixation of sensors to the skin and emphasizes the aspect of making very thin and flexible electrodes. The patent application
30 is peculiar in the sense that it combines the use of hydrocolloid adhesives and hydrogels. For any practical purpose the disclosed constructs will be useless as the moisture from the hydrogel will migrate into the hydrocolloid adhesive and disrupt this over time.

Recent developments in devices for monitoring physiological conditions are wire-less
35 types. Apart from being able to monitor a physiological condition invasively or non-

invasively and potentially compare to a reference, they are be able to process data and transmit them to a portable device. In fact the attachable device may also function as an alarm itself, e.g. by use of e.g. light emission, audio alarm or another warning signal.

5 When monitoring physiological or neurological conditions of the human body it is important that the attached microelectronic system is as comfortable to wear as possible, especially when the person carrying the device is not bedridden and shows normal physical activity or even excess physical activity like in sport or in sports medicine. The user should preferably not feel the attached microelectronic system and the monitoring should
10 preferably be kept in private. However, in this respect the known microelectronic systems suffer from several major drawbacks as described below.

Attachment to the skin by means of occlusive pressure sensitive adhesives often leads to skin irritation due to the occlusion of moisture and due to irritants, such as monomers from
15 the pressure sensitive adhesive polymer system, e.g. from for instance acrylic adhesives. Irritation may be the in form of itching and erythema and may especially develop when the adhesive device is attached for a prolonged period of time. Occlusion may also increase the risk of creating allergy to the adhesive composition. One often used way to solve the negative effects of occlusion is to use micro porous tapes, but such tapes are essentially
20 two-dimensional and thin and does not protect the microelectronic system from shear forces due to friction against clothes and the like.

In the above references, the devices are attached to the skin by thin planar adhesive layers carrying the microelectronic system as a bulky part leading to discomfort of the
25 patient or person carrying the device due to stiffness or friction against clothing and increasing the risk of involuntarily detachment from the skin. When such a device is to be used for a prolonged period of time, it is important to reduce any type of discomfort due to skin irritation or inconvenience of carrying a bulky device. Furthermore it is crucial for the signal detection that the adhesive device is kept fixed to the skin until it is deliberately
30 removed.

Proper adhesion of the device requires a fairly thick layer of the planar adhesive. However, a fairly thick layer may show a tendency of adhering at the edge to clothing or linen and by doing so a tendency to roll and detach is created.

35

Many sensors are connected to the monitoring systems with wires. The disadvantage of such a system is that the patient does not have freedom to move since the wires are attached to the sensors on the body and connected to a monitoring system. Whenever the patient wants to move he must be careful not to dislodge any of the wires attached to the sensors, and he must further pick up the monitoring system and carry it along.

None of the above mentioned references describes a body sensor device consisting of an optionally hydrocolloid containing thermoplastic pressure sensitive adhesive and/or chemically curing pressure sensitive adhesive, moulded or cast into a three-dimensional adhesive body having a micro electronic system embedded therein as according to the present invention.

The known sensors overcoming some of the above-mentioned disadvantages are not as simple and inexpensive to manufacture with respect to the adhesive part of the device as the adhesive devices of the invention.

The adhesive devices of the invention having a microelectronic system embedded therein may be produced relatively easily and besides a cover layer and optionally a release layer, without the need of any other layers in the device and is therefore commercially attractive.

With an embedment of the micro electronic components an improved protection against mechanical damage and penetration of moisture from the surrounding environment is also achieved.

Furthermore, today many types of electronics are temporarily attached to different surfaces. Especially within medical care different types of medical devices such as probes and sensors are attached to different areas of the skin in order to, for example, detect different biomedical signals or retrieve samples from a patient. Often these medical devices are only attached for a limited period of time until a disease is diagnosed or a patient's health has improved. However, some chronic diseases may require periodical monitoring, for example while the patient is sleeping, or in some cases constant monitoring is desired day and night. The medical device, which is attached to the skin of the patient, may be adapted to detect many types of signals, it could for example be a sensor for detecting one or more signals such as electromyographic (EMG) signals, electrocardiographic (ECG) signals and electroencephalography (EEG) signals.

5 Such medical devices may be broken up into at least three general elements, a microelectronic element for measuring a desired value, such as for example a biosignal; an adhesive for attaching the microelectronic element to a surface; and a power source for powering at least a part of the microelectronic circuit.

10 The different elements have different lifespan, however, since the elements are typically assembled in one inseparable unit they are all disposed after use. When looking at the elements individually it may however be understood that they have different lifespan. Thus, the adhesive element typically has a one-time use only. The power source may in some cases be reused a few times depending on the application and the size of the battery. However, the microelectronic element may be reused a large number of times thereby making it an expensive element to dispose after one use only.

15 Thus in order to improve the cost effectiveness of the medical device there exists a need to be able to reuse the element(s), which are still operable after use.

20 US 2002/0180605 discloses a method of monitoring a physiological characteristic. The method disclosed can include subsequent steps of removing adhesive pads from a sensor module and heating the sensor module in an autoclave for sterilization after data has been transferred from the sensor module to the receiver module.

Summary of the Invention

25 Accordingly, the present invention relates to a three-dimensional adhesive device comprising an microelectronic sensing system characterized by

- 30 (a) a three-dimensional adhesive body made of a pressure sensitive adhesive having an upper surface and a bottom surface;
- (b) a microelectronic system embedded in the body of the pressure sensitive adhesive;
- (c) one or more cover layer(s) attached to the upper surface; and
- (d) optionally a release liner releasable attached to the bottom surface of the adhesive device.

Suitably, the microelectronic system is a microelectronic sensing system. The microelectronic sensing system is suitably capable of sensing physical input such as pressure, vibration, sound, electrical activity (e.g. from muscle activity), tension, blood-flow, moisture, temperature, enzyme activity, bacteria, pH, blood sugar, conductivity, resistance, capacitance, inductance or other chemical, biochemical, biological, mechanical or electrical input.

Brief description of the Drawings

Figure 1 shows a die section of the shape of a typical representative of the adhesive device according to the invention. CT is the maximal thickness of the device and PT is the thickness in the periphery of the device.

Figure 2 illustrates a microelectronic system embedded/integrated in a three-dimensional (3D) adhesive. The zoom-box indicates the part of the adhesive device illustrated in figure 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12.

Figure 3 illustrates a microelectronic system (hatched box) that is completely integrated within the adhesive body.

Figure 4 illustrates that parts of the microelectronic system may be positioned in different locations integrated within the adhesive device with proper mechanical or electrical interconnection between the parts.

Figure 5 illustrates a microelectronic system, which is applied into a recess in the adhesive body. The recess is distal to skin fixation area. The microelectronic system may optionally be exchangeable, or reusable.

Figure 6 illustrates the microelectronic system in which the upper part may be exchangeable or reusable and the lower part be permanently integrated in the adhesive body.

Figure 7 illustrates that parts of the microelectronic system may be situated in different locations within the adhesive device with proper mechanical or electrical interconnection between the parts.

Figure 8 illustrates a microelectronic system, which is embedded/applied into a recess on the adhesive side of the adhesive body.

5 Figure 9 illustrates a device with a microelectronic system in which the lower part may be exchangeable or reusable and the upper part be permanently integrated in the adhesive body.

10 Figure 10 illustrates a system with some microelectronic components integrated within the adhesive body during production (small hatched box) and some microelectronic components applied later thereby establishing the necessary mechanical/electrical connections.

15 Figure 11 illustrates a microelectronic system embedded in the adhesive which system is applicable and accessible both from the distal side and the skin fixation side of the adhesive body.

20 Figure 12 illustrates a system where the microelectronic system is assembled from two parts one of which, or each of which may be exchangeable or reusable.

In all the above constructs of the invention the upper surface remains smooth irrespective the presence of components of the microelectronic system at the upper surface. This may be achieved by proper construction of the microelectronic components, encapsulation etc.

25 The constructions shown in figures 8, 9, 10, 11 and 12 are particularly suitable for microelectronic systems including an element, e.g. an electrode which should have skin contact.

30 Figures 13 -18 illustrates an embodiment of the invention where an antenna, a Central Processing Unit, a battery and electrodes are embedded in an adhesive device. Figure 13 illustrates the two-dimensional shape of the device indicating a cross-section by A-A. In Figure 15 the third dimension is shown as the cross-section A-A. The circle B from the rim of the device is further magnified in figure 16 and the circle C of the centre is like wise magnified in figure 17. Figure 14 illustrates the position of the antenna placed in the outer part of the adhesive device and being connected to the central part of the microelectronic

35

system. Figure 16 shows more in detail the building of the antenna lying embedded in the adhesive. Figure 17 shows the position of the central part of the microelectronic system with a battery, a CPU and an electrode protruding the adhesive. The battery and the CPU are enveloped in a transparent silicone rubber. Finally figure 18 illustrates the adhesive device in a three-dimensional mode.

Fig. 19 shows one embodiment of a sensor assembly according to the invention seen in a exploded perspective view.

Fig. 20 shows the embodiment of a sensor assembly in a sectional view along line XX – XX in Fig. 19.

Fig.21 shows the embodiment of a sensor assembly seen from the bottom.

Fig. 22a and 22b shows another embodiment of a device according to the invention wherein Fig. 22b shows a portion of Fig. 22a in an enlarged view.

Fig. 23 shows yet another embodiment of a device according to the invention seen in a perspective view.

Fig. 24 shows the embodiment of a device according to the invention in a sectional view along line XXIV – XXIV in Fig. 23.

Detailed description of the Invention

The present invention relates to adhesive devices having a microelectronic system embedded in an adhesive body made from a pressure sensitive adhesive.

In the following the term “three-dimensional” used when defining an element e.g. an adhesive body or device, refers to an element having a considerable varying contour when seen in cross section. Thus, for example a three-dimensional adhesive body will have a maximum thickness and a minimal thickness. According to the invention the maximum thickness will be at least twice the thickness of the minimal thickness. In a preferred

embodiment the outer rim or the peripheral edge of the adhesive device has a thickness which is less than half of the thickest part of the sensor, normally the central part.

5 In contrast to the term "three-dimensional" the term "two-dimensional" used when defining an element refers to an element, which has a generally planar surface. Thus, the maximum thickness of a two-dimensional adhesive body is below two times the minimal thickness of the adhesive body.

10 As used herein in relation to the micro electronic system or components thereof, the term "embedded", means that the pressure sensitive adhesive of the adhesive body is surrounding all or some of components of the micro electronic system, either partly or fully. Thus, the term embedded covers the situation where all sides of the system or component(s) is covered by the adhesive of the adhesive body and also the cases where not all sides of the embedded item is covered with the adhesive of the adhesive body, e.g.
15 when the item is placed in a recess or cavity in the adhesive body and is accessible from the outside.

20 As "embedded" is the general term used for the description of the way the micro electronic system is positioned in the adhesive body the term "integrated" means that the micro electronic system or specific components thereof are covered by adhesive on all sides and the term "applied" is used when the micro electronic system only is partly covered.

25 Integrated and covered on all sides also covers the situation where the integrated component is connected, e.g. electrically or otherwise to another component embedded in the adhesive body.

30 As used herein, a microelectronic "sensing" system means a microelectronic system comprising a transducer having an element capable of detecting a physiological or neurological condition.

35 As used herein through hole means a hole through the adhesive body having opening(s) at the upper surface of the adhesive body and opening(s) at the bottom surface of the adhesive body. Preferably the through hole has one opening at the upper surface and one at the bottom surface of the adhesive body. The through hole may have any suitable shape.

By the "thickness" of the adhesive device is meant the length of the shortest line which may be drawn between a specific point on the upper surface to a point on the bottom surface, or the shortest line which may be drawn between a specific point on the bottom surface to a point on the upper surface.

For the purpose of the present invention the expression "skin" is used to designate the outer surface of mammals.

As mentioned above, it has surprisingly been found that a wire-less microelectronic systems in which the micro electronic parts are embedded in a three-dimensionally shaped pressure sensitive adhesive body solve the problems of the known sensor devices.

Due to the properties of the three-dimensional pressure sensitive adhesives, an optimal protection of the micro electronic system is created. The adhesive provide sealing towards the skin surface and the adhesive device is protected from exterior liquids due to the polymeric cover layer(s) on top of the adhesive device. Furthermore the adhesive protects the embedded micro electronic parts from mechanical damage.

The adhesive bodies according to the invention are made from pressure sensitive adhesives that are shaped three-dimensionally, having a varying thickness from the centre to the peripheral edge of the adhesive body and having the micro electronic sensing system embedded within the adhesive body, suitably where the adhesive body is thickest.

A device with such a shape and suitably with bevelled edges provides a smooth interface with the skin. The adhesive device will give a gentle feel and will not tend to give friction to clothes and linen. A special advantage will be that the adhesive device will less easily involuntarily fall off due to bulkiness and adhesiveness at the edge. This is very important to the very function of the device.

Moreover, the construction of the adhesive device is simple and convenient as the adhesive body have a triple function as the means for fixation of the device to the skin, the means for protection of the microelectronic system and the means for shaping the device into a convenient shape. The construction require less components and process

steps in the assembly of the three-dimensional device and is therefore less expensive and easier to manufacture.

5 According to one embodiment of the invention, the three-dimensional adhesive body has an essentially planar bottom surface adapted to adhere to the body surface of a mammal and an smooth upper surface. The adhesive device is suitably thickest at the central part of the body and thinnest at the periphery of the body.

10 Preferably, the upper surface has a smooth convex surface, but it may in principle take any form.

The outer rim or the peripheral edge of the adhesive device must be shaped to a thickness less than half of the thickest part of the sensor, normally the central part.

15 Thus, in a further embodiment of the invention, the thickness of the adhesive device at the periphery is less than 50 % of the thickness of the adhesive device where it is thickest, suitably the thickness at the periphery is less than 25 % of the thickness of the adhesive device where it is thickest, preferred the thickness at the periphery is less than 10 % of the thickness of the adhesive device where it is thickest, and most preferred the thickness at
20 the periphery is less than 5 % of the thickness of the adhesive device where it is thickest.

The thickness at the periphery of the adhesive device is typically under 0.4 mm. In one embodiment the thickness may be between 0.01 and 0.4 mm. Suitably, the thickness at the periphery of the adhesive device is above 0.05 mm, preferably between 0.05-0.4 mm.

25 Typically the adhesive device is between 0.5 and 15 mm, more suitably between 1 – 5 mm where it is thickest, typically but not necessarily, at the centre of the adhesive body.

30 Suitably, the angle between the bottom surface of the adhesive device and a line drawn from any point of the circumference of the bottom surface and the point at the upper surface where the adhesive body is thickest is below 60 degrees, preferably below 45 degrees and most preferably below 30 degrees.

The outer rim of the adhesive body may suitably be shaped circular or oval, with or without flaps and lobes, or it may be shaped rectangular or triangular to obtain as convenient and safe a device as possible.

- 5 Normally the outer rim of the adhesive body will consist of the adhesive of the adhesive body. However, there may be embodiments where the microelectronic system or component(s) thereof, is placed in/or at the outer rim, whereby the outer rim does not solely consists of the adhesive of the adhesive body.
- 10 The pressure sensitive adhesive making up the three-dimensional adhesive body is suitably a mouldable thermoplastic or chemically curing pressure sensitive adhesive having a flexibility enabling the adhesive device to conform to the curvature of body parts while retaining its adhesive properties even under movements.
- 15 Suitable, pressure sensitive adhesives making up the adhesive body is an adhesive based on polymers selected from block-copolymers such as styrene-block-copolymers, and hydrogenated styrene-block-copolymers, amorphous poly-alpha-olefins (APAO), polyacrylics, polyvinylethers, polyurethanes, polyethylenevinylacetate, silicone or from the group of hydrogel pressure sensitive adhesives.
- 20 Pressure sensitive adhesives based on these polymers are known and the skilled person knows how to prepare adhesives based on these polymers.
- 25 The block-copolymers, such as styrene-block-copolymers, and hydrogenated styrene-block-copolymers, may suitably be selected from Styrene/ethylene-Butylene/Styrene (SEBS), Styrene/Isoprene/Styrene (SIS), and Styrene/Ethylene-Propylene/Styrene (SEPS).
- 30 The adhesive may also be based on PDMS (polydimethylsiloxane), and may suitably be a PDMS gel.
- 35 Hydrogel adhesives may also be based on or comprise amfifilic polymers, polyvinylpyrrolidone, polyvinyl alcohol, polyethyleneoxide, gelatins, natural gums and cellulose derivatives or any combinations thereof.

The pressure sensitive adhesive may be formulated according to the principles and based on the polymers listed and disclosed in the handbook of Donatas Satas: Handbook of pressure sensitive adhesive technology, Third edition.

5 In one particular embodiment of the invention, the pressure sensitive adhesive making up the adhesive body comprises hydrocolloids. The pressure sensitive adhesive comprising the hydrocolloids may be any of the above-mentioned types of pressure sensitive adhesive or any other pressure sensitive adhesive known in the art.

10 Thus, U.S. Patent No. 3,339,549 discloses a blend of a rubbery elastomer such as polyisobutylene and one or more water-soluble or water swellable hydrocolloids such as a powdery mixture of pectin, gelatine and carboxymethylcellulose. The adhesive mass has a water-insoluble film applied to one surface. A composition of this type is available commercially from E.R. Squibb & Sons Inc. under the trademark "Stomahesive" and is
15 used as a skin barrier around stomas to prevent skin breakdown by the corrosive fluids discharged by the stoma.

In adhesive compositions of this type, the polyisobutylene is responsible for provision of the adhesive properties and the dispersed hydrocolloid powders absorb fluid and render
20 the adhesive agent capable of also adhering to moist skin (wet tack). These compositions are also gaining increasing acceptance as wound dressings for dermal ulcers, burns and other exuding wounds.

In a number of embodiments, styrene copolymers have been incorporated which are
25 disclosed in a number of patent references.

Thus, US Patent No. 4,231,369 Sorensen et al. disclose an ostomy skin barrier consisting of a styrene copolymer having dispersed therein a water-soluble hydrocolloid gum and a tackifier.

30 In US Patent No. 4,367,732 Poulsen et al. disclose an ostomy skin barrier consisting of a water soluble hydrocolloid dispersed in a continuous phase consisting of a styrene copolymer, a hydrocarbon tackifier, and a plasticizer, an antioxidant, and an oily extender.

US Patent No. 4,551,490 (Doyle et al.) discloses medical grade pressure sensitive adhesive compositions comprising a homogeneous mixture of 5-30% of one or more polyisobutylenes, 3-20% of one or more styrene radial or block type copolymers having a content of diblock copolymer below 20%, mineral oil, one or more water soluble hydrocolloid gums, and a tackifier. One or more water swellable cohesive strengthening agents, an antioxidant, and various other optional ingredients also may be included within the adhesive composition.

US patent No. 5,492,943 discloses a pressure sensitive adhesive composition including a blend of two viscoelastic adhesive elastomers, specifically, high molecular weight polyisobutylene and a styrene block copolymer, which along with a plasticizer (preferably petrolatum) and a suitable tackifier and antioxidant, form a continuous phase in which hydrocolloids such as sodium carboxymethylcellulose and pectin are dispersed.

In US patent 4,867,748 Samuelsen disclose geometries of sealing pads from hydrocolloid adhesives combined with backing films and the processing of such.

The adhesive compositions disclosed in US patent No. 5,492,943 are stated to be used for wafers for adhering ostomy appliances to the skin and differ from known compositions by comprising styrene block-copolymers having a higher content of diblock copolymer, completely avoiding the use of low molecular weight polyisobutylene and furthermore by preferably not including gelatine.

Pressure sensitive adhesives containing hydrocolloids is a particularly suitable group of adhesives being characterized by having a particulate phase of hydrocolloids dispersed in the adhesive phase. An adhesive containing hydrocolloids may absorb moisture from the skin avoid occlusion of the skin, while maintaining its adhesive properties to skin. Moreover, and adhesive body containing hydrocolloids may have any thickness and still having the non-occlusive properties. A hydrocolloid adhesive may be processed as a hot melt and is easily moulded into specific shapes.

This means that the hot melt property combined with the easy moulding enables graduation of the thickness of the adhesive body from the edge of the adhesive device comprising the microelectronic system to the central parts giving a smooth non-abrupt projecting profile.

Recipes for making pressure sensitive adhesives useful for an adhesive body according to the invention are described in more detail below.

Thus, a typical pressure sensitive adhesive composition comprises a substantially
5 homogeneous mixture of 10-60 weight percent of one or more rubbery elastomeric components, 5-60% of one or more absorbent particles, 0-50% tackifier resin, 0-10% of a plasticiser and 0-60 % of a non-polar oily extender, based on the total weight of the composition.

10 The rubbery elastomeric base could be selected from the group consisting of physically cross-linked elastomers (suitably block copolymers containing polystyrene blocks), a chemically cross-linked natural or synthetic rubbery elastomer, or a rubbery homopolymer.

15 A physically cross-linked elastomer selected from block-copolymers of styrene, and one or more butadienes may be a styrene-butadiene-styrene block copolymer, a styrene-isoprene copolymer and is preferably a mixture of styrene-isoprene-styrene and styrene-isoprene block copolymers.

20 A chemically cross-linked rubbery elastomer may be e.g. butyl rubber or natural rubber.

A rubbery homopolymer may be a polymer of a lower alkene such as low density polyethylene or propylene, preferably atactic polypropylene (APP) or polyisobutylene.

25 A tackifying resin optionally used in accordance with the invention is preferably a hydrogenated tackifier resin and is more preferred selected from a group comprising polymers and copolymers of cyclopentadiene, dicyclopentadiene, alpha-pinene or beta-pinene.

30 When the physically cross-linked elastomer is a styrene-butadiene-styrene block copolymer or a styrene-isoprene-styrene block copolymer, the adhesive suitably comprise 0-10% of a plasticiser e.g. (citrofol BII, DOA).

The swelling hydrocolloid particles preferably consist of one or more water-soluble or water swelling hydrocolloid polymers or gums.

Suitable hydrocolloids include synthetic polymers that may be either linear or cross-linked, such as hydrocolloids prepared from lactams or polyvinyl pyrrolidone. Other monomers useful to prepare a synthetic hydrocolloid include acrylates, methacrylates and watersoluble amides.

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Other hydrocolloidal polymers, either naturally occurring or synthetically prepared, are useful according to the present invention. These materials include polyvinyl alcohol, polyoxyalkylenes, and naturally occurring or synthetically modified hydrocolloids such as polysaccharides, gums, and modified celluloses.

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Representative polysaccharides include starch, glycogen, hemicelluloses, pentosans, celluloses, pectin, chitosan, and chitin. Representative gums include Arabic, Locust Bean, Guar, Agar, Carrageenan, Xanthan, Karaya, Alginates, Tragacanth, Ghatti, and Furcelleran gums. Representative modified celluloses include methyl cellulose, hydroxypropyl methyl cellulose, carboxymethyl, cellulose, and hydroxypropyl cellulose.

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Preferred hydrocolloids include polysaccharides, such as starch, glycogen, hemicelluloses, pentosans, gelatin, celluloses, modified celluloses, pectin, chitosan, and chitin. Modified celluloses include methyl cellulose, hydroxypropyl methyl cellulose, carboxymethylcellulose, and hydroxypropyl cellulose. A most preferred hydrocolloid is a water soluble or swelling hydrocolloid chosen from the group consisting of polyvinyl alcohols, powdered pectin, gelatin, methyl cellulose, hydroxypropyl methyl cellulose, carboxymethyl cellulose, hydroxypropyl cellulose and mixtures thereof. In one preferred embodiment, the hydrocolloid is carboxymethyl cellulose (CMC).

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Suitable swelling colloids are small spherical particles based on cross-linked polyacrylic acid polymers. Examples of such materials may be found in U.S. Patent No. 4,867,748, EP 0 122 344, and US patent application No. 2004065232.

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Sometimes the skin for attachment of the adhesive device may be moist or even wet. In these circumstances, the normal adhesives may not give a sufficient strong and permanent attachment of the adhesive device. Specialised adhesives useful in these circumstances are hydrogel adhesives. Such adhesives are based on hydrophilic polymers and extenders enabling an even uptake of moisture over the complete skin-contacting surface of the adhesive. A wide range of compositions of such hydrophilic

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adhesives exists. Hydrophilic polyacrylates with high content of acid groups optionally being partly neutralised, is a major representative in this group of adhesives. These adhesives may be inherent adhesive or may be formulated with tackifiers and extenders to the desired adhesive properties in dry conditions. When getting moist, the adhesiveness will increase vastly depending on the formulation as the uptake of water will transform the adhesive to a more plastic state. Alternative adhesives are based on polymers like polyvinyl pyrrolidone, polyvinyl alcohol, polyethylene oxide and the like. Amphiphilic polymers or polymers which may be chemically cross-linked by radical polymerisation may be added to improve the cohesion of the adhesive and extenders like polyethylene glycol, polypropylene glycol and glycerol are typically preferred.

Adhesive compositions based on polydimethylsiloxane (PDMS) have been known since the 1970's. Recently a new subclass of PDMS based pressure sensitive adhesives has developed namely soft silicone adhesives. Soft silicone adhesives (SSA's) are two-part, solventless adhesives based on a cross-linked, silicone elastomeric structure. The cross-linking is a result of an addition reaction between a polydimethylsiloxane with vinyl groups and hydrogen functional siloxanes. The cure reaction is catalysed by a platinum complex and can occur at room temperature or can be accelerated at elevated temperature (80 degree C to 145 degree C) without the formation of by-products. Such adhesives are characterised by being soft and by conforming to the surface structure of the skin, whereby quickly wetting of the skin is achieved. Because the viscous component is minimal, the material does not flow and only small dissipation of the energy occurs when deformation pressure is applied. The result is an immediate debonding, which happens at low-peel or shears force, which for some instances may be advantageous.

Apart from being excellent skin adhesives PDMS based pressure sensitive adhesives may have the further properties of being reusable, since they can be cleaned with tap water and be reapplied to the skin.

The pressure sensitive adhesive used for making the adhesive body of the invention could also be a PDMS gel often described as a tacky gel. Examples of such commercially available systems are Dow Corning 7-9800 A&B, from Dow Corning HealthCare US or SilGel 612 from Wacker-Chemie GmbH, Burghausen, Germany, and MED-6340 from NuSil Technology, Carpinteria, USA.

The above mentioned pressure sensitive adhesive can either be used in a non-foamed version or in a foamed version. When gas bubbles are introduced into pressure sensitive adhesives during the manufacturing process a lightweight, cellular structure is produced. Such a pressure sensitive adhesive is more flexible than the non-foamed versions. (see
5 US patent No. 6,326,524 and US patent application No. 2004065232).

In general the adhesive body of the present invention has the desirable elastic, adhesive, moisture transmitting and/or absorptive properties as well as a high conformability and flexibility. The flexibility provides a composition that has the ability to conform to the
10 curvature of body parts while retaining its adhesive properties even under movements. The high initial tack at room temperature provides for easy application of the adhesive device.

The adhesive device of the invention has on the upper surface one or more cover layers of
15 any nature, preferably only one cover layer, to protect against adhesion to linen, clothes and other environment.

As a cover material, it is preferred to use a film in the form of a thermoplastic polymer film or a woven or non-woven layer. The cover layer is preferably made of an elastic material.
20 The cover layer is suitably capable of transmitting moisture and may e.g. be made from polymers such as polyolefin types e.g. polyethylene, polypropylene or polybutylene, polyamide such as nylon, polyurethane, polyvinyl acetate, polyvinyl chloride, fluorinated polyvinyl compound, polyvinylidene chloride, polyvinyl alcohol, ethylene vinyl acetate, cellulose acetate or other thermoplastic polysaccharides, polyether block amides like
25 PEBAX , block copolymers like styrene-isoprene-styrene block copolymers or ethylene acrylate block copolymers, polyesters such as polyethylene terephthalate (PET) or derivatives thereof and any laminates from such polymers. The cover layer may suitably be a thin foam layer like made from polyurethane, polyethylene or polyvinyl acetate.

30 The cover layer or film protects the integrated /embedded microelectronic components as well as the adhesive body against the environment.
In one particular embodiment of the invention, an antenna can be printed directly on the cover layer by means of conductive ink or printed metal.

Prior to application to the skin a protective release liner covers the skin contacting side of the pressure sensitive adhesive body, in order to ensure that the properties of the adhesive are preserved and that the adhesive surface is not laid open until just before the use. The release liner is suitably a siliconised or fluorinated release liner, such as a
5 siliconised or fluorinated craft paper, polyethylene, polypropylene or polyethylene terephthalate film. Suitably, the release liner is a siliconised polyethylene film, such as medium density polyethylene from the company Huhtamaki.

The microelectronic system comprises a number of components, which may be
10 assembled into one, optionally encapsulated unit, which is incorporated into the adhesive device of the invention. The components of the microelectronic sensing system may also be an assembly of the individual, optionally encapsulated, components located at different positions in the adhesive device. This embodiment of the invention covers the situation where the adhesive devices have all the individual components of the microelectronic
15 device located in different positions, as well as the situation where one or more of the components is located at a position different from the position of the rest of the components which are located at the same position.

When the components of the microelectronic device are located at different positions in
20 the adhesive device, the adhesive device also has the necessary mechanical or electrical connections between the components integrated into the adhesive body.

Thus, according to one embodiment of the invention, the entire microelectronic system is integrated into the adhesive body and is completely covered by the adhesive body on all
25 sides.

According to another embodiment of the invention, the entire microelectronic system is contained in a recess provided in the upper surface of the adhesive body facing the cover
30 layer.

According to another embodiment of the invention, the entire microelectronic system is contained in a recess provided in the adhesive bottom surface of the adhesive body.
In another embodiment of the invention, the microelectronic system is contained in a
35 through hole in the adhesive body and is accessible from both the upper surface facing the cover layer and from the adhesive bottom surface.

In an alternative embodiment of the invention, one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body on all sides and the other component(s) of the microelectronic system is located elsewhere in the adhesive body, the components of the microelectronic sensing system having the necessary mechanical and electrical connection to each other.

According to the above mentioned embodiment of the invention, one or more components of the microelectronic system may be integrated into the adhesive body and covered by the adhesive body on all sides and the rest of the microelectronic system is contained in one or more a recesses (suitably one recess) provided in the upper surface of the adhesive body facing the cover layer.

Alternatively, one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body on all sides and the rest of the microelectronic system is contained in one or more recesses (suitably one recess) provided in the adhesive bottom surface of the adhesive body.

In another alternative embodiment one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body and the rest of the microelectronic system is contained in one or more through holes (suitably one through hole) in the adhesive body and is accessible from both the upper surface facing the cover layer and the adhesive bottom surface.

In still another embodiment one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body, while other components of the microelectronic system is contained in one or more through holes (suitably one through hole) in the adhesive body and is accessible from both the upper surface facing the cover layer and the adhesive bottom surface, and the rest of the microelectronic system is contained in one or more recesses (suitably one recess) in the upper and/or bottom surface of the adhesive body.

In still an alternative embodiment one or more components of the microelectronic system is contained in one or more through holes (suitably one through hole) in the adhesive body and is accessible from both the upper surface facing the cover layer and the adhesive

bottom surface and the rest of the microelectronic system is contained in one or more recesses (suitably one recess) in the upper and/or bottom surface of the adhesive body.

5 In another suitable embodiment one or more components of the microelectronic system is contained in one or more recesses (suitably in one recess) in the upper surface of the adhesive body and the rest of the microelectronic system is contained in one or more recesses (suitably one recess) in the bottom surface of the adhesive body.

10 Where the microelectronic system or components thereof is placed in the upper surface of the adhesive body, they are suitably formed with an upper surface following the contours, or shaped to fit the upper surface of the adhesive body. This may be achieved by proper encapsulation of the components.

15 As mentioned above, the individual components, groups of individual components or all the components of the microelectronic system may be encapsulated before they are embedded into the adhesive body. Encapsulation is chosen when additional protection of the components from the environment and/or the reverse is desired, e.g. when already present in the adhesive body or during the production process leading to integration into the adhesive body. The encapsulated components of the microelectronic system are
20 connected to each other via the necessary electrical and/or mechanical connections.

In some cases it is required that the micro electronic system or components thereof are protected from humidity and/or perspiration in the adhesive since this will initiate corrosion, or needs shielding from exterior influence for other reasons. In such cases the micro
25 electronic system or components thereof is encapsulated.

A number of encapsulation techniques are known and includes coating, hot-melt encapsulation, ceramic encapsulation and glass encapsulations. Other methods for encapsulation of electric components are known in the art.

30 The microelectronic system or components thereof is suitably encapsulated in a polymer film, a polymer foil, or a polymer coating or the microelectronic system or components thereof is moulded into a polymer material, or is encapsulated in a glass or ceramic material.

35

Encapsulation by coating typically involves coating the component(s) with materials such as epoxy, PDMS (silicone), acrylate, polyurethane or UV curing resins.

Encapsulation in silicone, such as PDMS, is particularly preferred when the microelectronic components is to be placed in a through hole or a recess in the adhesive body and where it is desirable to enable easy removal or replacement of the encapsulated microelectronic component(s), as the silicone surface is easily released from the adhesive of the adhesive body. Other materials, which are easily releasable from the adhesive, may also be used for the encapsulation.

Hot-melt encapsulation typically involves incorporation of the microelectronic system or components thereof in a thermoplastic material by injection moulding. The thermoplastic material used may be selected from Styrene-block copolymers, polyurethane, ABS (acrylonitrile-butadiene-styrene copolymer), SAN (styrene-acrylonitrile copolymer), polyvinylchloride, PDMS, POM (polyoxymethylene), polystyrene, polyester, polyacrylate, polyolefines; e.g. polyethylene or polypropylene.

The components of the microelectronic system require interconnection. Each system may consist of one or more discrete components, which need to be assembled mechanically and electrically. The mechanical or electrical connection may be established by PCB (printed circuit board), snap locks, thin flexible PCB, glue etc.

In one embodiment as described above, all parts of the micro electronic sensing system is integrated in the adhesive body during production, meaning that the adhesive device with the microelectronic system has a disposable nature.

The adhesive device according to the invention may also be constructed in such a way that components of the microelectronic system may be exchanged during the lifetime of the adhesive device or may reused in a new adhesive device.

Certain components of the micro electronic system are integrated into the adhesive body during production whereas the remaining components is applied to the adhesive device of the invention afterwards, just prior to attachment on the skin, or after attachment to the skin. The components applied to the adhesive body after production of the adhesive body is typically exchangeable, or reusable.

The component, which may be exchanged, is for example the energy source, e.g. the battery.

5 In a particular embodiment of the invention the entire micro electronic system is exchangeable or reusable and may be applied to the adhesive device just prior to attachment or after it has been applied to the skin.

10 Suitably, the exchangeable component(s) or the reusable component(s) is encapsulated as described above and forms a package, which fit a recess or hole in the adhesive body.

In the case of exchangeable or reusable components they must have some sort of secure attachment to the adhesive body during use. Such attachment may be provided by an adhesive, for instance by the pressure sensitive adhesive of the adhesive body already
15 present in the indentation, the cavity of the hole in the adhesive body.

In this case it may be preferred that the encapsulation material is a material which does not adhere too strongly to the adhesive of the adhesive body, see above.

20 Alternatively, the package of the encapsulated, exchangeable or reusable components is attached to the adhesive body via mechanical couplings to the adhesive body. The above-mentioned encapsulated package containing the replaceable or reusable component(s) could thus be fitted into the adhesive body by a snap lock mechanism.

25 The encapsulation function as a housing for the microelectronic system or components thereof and is suitably formed of from injection-moulded polymer material, but could in principle be of any material and any construction.

30 The package of encapsulated microelectronic component may have any suitable shape, suitably three-dimensional shape, fitting a recess or through hole in the adhesive body. On one embodiment the encapsulated electronics will have the shape of a rod shaped capsule with rounded ends.

35 As mentioned above, the present invention uses invasive as well as non-invasive techniques for acquiring physiological data. In the case of non-invasive measurement one

5 or more metal electrodes may be used for the skin contact. However, any conductive material may be used for the skin contact, such as conducting polymers, conducting hydrogels and electrolytes. In case of invasive measurements regular needles or micro needles may be used. Such invasive techniques are already well known today e.g. for measuring oxygen or blood glucose.

10 By combining well-described components, all sorts microelectronic sensing systems may be designed and incorporated into the adhesive device of the invention. Examples of systems suited for embedment in adhesive device are systems suitable for measurement of biosensor signals, EKG, EMG, EEG, blood glucose, pulse, blood pressure, pH and oxygen.

15 The micro electronic system incorporated into the adhesive device of the invention typically requires the following components: Communication components, CPU (central processing unit), power source, storage components, transducer components, interconnections and optionally actuator components.

20 The CPU (Central Processing Unit) controls and communicates with the components of the microelectronic system. The CPU handles the execution of application software, data decisions making (like data signal processing), A/D conversion, DSP (digital signal processing), routing, timing, power management, sleep function, interruption.

25 The CPU is the component of the microelectronic system controlling other components and making the appropriate data analysis. In general, the more speed and data analysis required, the more power is needed. Therefore a sleep function is often used in order to save power. At certain times or if certain events happen (triggered by a very low power monitoring subsystem) the CPU wakes up, makes the necessary calculations, communicates with relevant components and return to sleep mode. Depending on need very rudimentary CPU to a full-fledged microcontroller can be used according to the invention.

30 The communication components control all communication to and from the microelectronic system. Suitably, the microelectronic system is a system enabling wireless communication with a receiver unit placed at a distance from the adhesive device. However, the present invention is not limited to wireless communication, such as RF-

wireless communication. Other communication means could be audible or optical communication means. The component includes the necessary electronics for achieving this wireless communication but also the antenna along with the necessary hardware and software.

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The antenna may be of different shape and form depending on frequency, power and signal form. Some antennas are useful for communicating information a few cm, others range several meters. Examples of antennas are; a coil around a small ferrite core (e.g. less than 4 mm in diameter, a flat coil with turns (diameter typically 10 mm or more), single and double wire radio antennas such as monopole or bipole antennas, and an antenna integrated in the adhesive.

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An antenna only having few turns and a large diameter e.g. 50 mm may be laminated and integrated into the adhesive body or printed or directly on the cover layer of the adhesive device. The antenna is typically made of a metal such as copper or aluminium but could also be of conductive ink.

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The power source consists of power regulating electronics, recharge electronics and an energy source, typically an internal or exchangeable battery. However other means of getting power to the microelectronic system may be suggested, such as kinetic energy conversion, fuel cells, isotope radiation, solar cells or via a radio frequency (RF) link. Further the antenna may be used for loading energy to the microelectronic system.

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Preferably the power source is a battery, and may be for one time use or it may be rechargeable.

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The storage component is for storage of the embedded system software and/or storage of data acquired during operation of the device. The storage component may be a part of the CPU, a component of its own or an exchangeable storage device such as FLASH RAM that can be removed and exchanged.

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The transducer component is a component designed to convert energy from one form to another. The transducer is typically, but not necessarily, the sensor or sensing part of the microelectronic sensing system. A transducer may thus be able to convert for example a

physical input and the transducer will usually but not necessarily convert this energy into electrical form to be interpreted by the CPU etc.

5 Examples of the physical input a transducer may convert is acceleration, chemical/gas, flow, humidity, inertia, capacitance, conductance, conductivity, current, impedance, inductance, pH, resistance, resistivity, voltage, photo detection, light, magnetism, pressure, angular, linear position, velocity, temperature, sound and mechanical force.

10 A tangible representative of the transducer is the detecting component. The detecting component is typically selected from electrodes (polar, bipolar), pressure sensors, needles with electrodes, accelerometers, photo detectors, microphones, ion specific field effect transistors (ISFET), a NTC (negative temperature coefficient) resistors, band gap detectors, ion membranes, enzyme reactors or condensers.

15 In one embodiment of the invention the transducer includes a detector for non-invasive detection, such as an electrode.

In another embodiment of the invention, the transducer includes an invasive detector, such as a needle containing an electrode.

20 An actuator is the reverse of a transducer. It converts energy from one form to another in much the same way as a transducer but in the reverse order. Usually it converts electric signals to physical signals. A tangible representative of an actuator is e.g. electrodes (for instance for neural- or neuro-stimulation), pumps, injection needles, light emission diodes (LED) or another light source, loudspeakers, current generators or chemical synthesizers.
25 A possible use of actuator is at certain events decided by the CPU to activate an alarm in the microelectronic system, such as loudspeaker or LED, or to indicate low battery.

30 Thus, the actuator may be used as a component in the system reacting to the input obtained from the transducer component such as an alarm (visible and audible), injection pump, valve etc. It can either be a one time use, a multiple use or continuous use actuator.

35 Many sensing systems are only informative systems transmitting information about the physical condition of a mammal and in this case an actuator is not needed.

5 The microelectronic system will be modular build in the sense that in a device for a given application only some of the components may be needed. Some applications will utilize fewer components and some applications may use all components. These components can be fitted into same physical ASIC (application specific integrated circuit), electrical system or subsystem, such as but not limited to, PCBs (printed circuit boards), flexible PCBs, thick film, thin film, or ceramic technologies or the system or its components may be separately encapsulated

10 RFID (Radio Frequency IDentification) tags are commercially available in various sizes, ranges and functionality. When the RFID reader applies the appropriate field (e.g. an inductive field) the basic RFID tag return a bit sequence. The sequence is programmed prior to use. RFID range varies from 1 cm to app. 2 meter for passive tags (no power source included) to over 100 meters for active tags (power source included). More
15 sophisticated RFID tags available have storage components where data can be read or stored.

The RFID tag may be incorporated into the adhesive body either as a standalone part or in combination with other microelectronic components. Complex microelectronic systems
20 can easily be made to include various forms of RFID tags without adding significantly to the complexity or price of the system. In a complex system the tag can be used as a simple track and trace component for identification of the product, such as shelf life, life time, however it can also be utilized for identification for other systems in sensor networks.

25 For a stand-alone solution the RFID tag consist basically of a RF chip and a coil. Suitable forms of the RFID tag is a RFID tag encapsulated in a glass housing, a RFID tag encapsulated in plastic/epoxy (typically pill shaped), a flat RFID tag with coil and a RF chip laminated between 2 polyimide layers, or a flat RFID tag with large coil antenna with few turns printed on or in the adhesive body and with the RF chip interconnected to the
30 antenna without any further protection/encapsulation.

These systems can be completely integrated within the adhesive body during production of the adhesive body.

The above-mentioned flat RFID tag may be sandwiched between 2 layers of pressure sensitive adhesive during production. As the RF chip is very small (1 mm x 1 mm) and the coil is flexible, no rigid encapsulation is needed. The glass encapsulated RFID tag has very good chemical resistance and small size to ensure no discomfort. The RFID tag
5 encapsulated in plastic or epoxy may be of more complex design and can be added both during and after production of the adhesive body of the invention.

The encapsulated RFID tag is a component, which may be reused, in one or more adhesive bodies. The encapsulated RFID tag is transferred from one adhesive body to another and thereby reused time after time, and is ideal for storing person specific data.
10

Normally embedded microelectronic systems incorporate some kind of sensor in its system, however this is not necessary for all applications.

The adhesive device of the invention may also be part of a network of adhesive sensor devices placed on different locations on the body. These individual adhesive devices may vary in complexity ranging from a small basic sensor system to more complex system, depending on location and sensing property. Some adhesive devices of the network have reduced functionality called RFD (reduced function devices) whereas other devices are
15 FFD (Full Function Devices).
20

The FFD devices may function at any topology and be the coordinator of the Network, or it may be a coordinator that can talk to any other device. A RFD device is limited to star topology, it cannot become a network coordinator, it talks only to a network coordinator and has very simple implementation.
25

FFDs may be a dedicated network coordinator acting as communication Hub, gateway or router within the Body Area Network (BAN) and handling communication with external unit(s). A communication Hub or gateway may have large storage capacity and store data from the sensor network, and when in proximity with external unit or when otherwise appropriate wireless transmit these data.
30

These hubs are easily integrated within the adhesive body as no skin contact or actuator is needed, and may be placed strategically on the body. As hubs will generally be larger and more centrally placed on the body, it is of great advantage that the microelectronic
35

hub may be completely integrated within an adhesive body as this reduces discomfort and visibility.

5 In case of person monitoring, the microelectronic system could incorporate GPS technology. The system is either data logging the positional data for later analysis or could transmit (e.g. via the mobile net) position. Such a system within an adhesive could be place in an inaccessible location on the body.

10 A GPS device incorporated in an adhesive body of the invention need not be a single device in itself, but could be an add-on to an adhesive devices comprising other microelectronic systems, so the system can transmit GPS at certain event such as alarms.

Thus, the adhesive device may also contain a micro electronic system where no physical contact between the detector and the skin of the mammal is necessary. Systems that do not necessarily use transducers with a detecting element are Network Hubs, network coordinators, gateways and GPS (Global Positioning System).

15

Accordingly, microelectronic systems useful for use in the adhesive device of the invention could be:

20 A glass encapsulated RFID tag comprising communication components and a CPU. The glass encapsulated components may suitably be embedded in the adhesive device as shown in figure 1.

25 An epoxy or plastic encapsulated RFID tag comprising communication components and a CPU. The epoxy /plastic encapsulated components could for example be embedded in the adhesive body as shown in figure 1 or 2.

A coil antenna and a RFID tag comprising communication components and a CPU laminated between two polyamide layers. The system may be embedded in the adhesive body as illustrated in figure 1A.

30

A coil with few turns and a non-encapsulated passive read/write RFID tag comprising storage and communication components and a CPU. The system may be embedded in the adhesive body as illustrated in figure 1A.

A passive read/write RFID tag comprising storage and communication component(s) and a CPU encapsulated in an epoxy or plastic pill. The system may be embedded in the adhesive body as illustrated in figure 2.

5

An active read/write RFID tag encapsulated in a epoxy/plastic pill comprising storage and communication components, a CPU and a battery. The system may be embedded in the adhesive body as illustrated in figure 1.

10

RFID tags of the above-mentioned type are commercially available.

The microelectronic system may also be a gateway comprising storage and communication components, a CPU and a battery encapsulated in plastic and working as a dedicated network coordinator for transmission of data to a central unit (CU). Such a microelectronic system may for example be embedded in the adhesive body as illustrated in figure 1.

15

The microelectronic system may also be a system comprising storage and communication components, a CPU, battery, GPS, components for wireless synchronisation of real time clock for data logging of GPS data, optionally encapsulated in plastic, or a system comprising storage and communication components, a CPU, battery, GPS, components for wireless synchronisation of real time clock for data logging of GPS data, mobile net for data logging and transmission of data and position to mobile phones, optionally encapsulated in plastic. These systems may also be embedded in an adhesive body as illustrated in figure 1.

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The adhesive device according to the invention may also be used for applications where body implants are applied electrical power and electrical data communications via wireless means across the skin barrier (trans-cutaneously). In these cases it is important to fix the adhesive device at an exact spot on the skin surface for long periods of time with minimal annoyance or inconvenience for the person carrying the device.

30

A typical example of wireless trans-cutaneous power transfer and electronic data communication is in implanted nerve stimulators for people who suffer from disable control of their muscles in the lower part of their leg (the drop foot syndrome). The drop foot

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stimulator is implanted inside the leg and has direct contact the nerves controlling the relevant muscles. The implant is typically powered wirelessly by means of an electromagnetic coupling between a coil or an antenna inside the leg and a coil or antenna placed nearby on the outside of the body on the skin surface.

5

The coil or antenna is connected to the electronics providing the needed power and control signals. The timing for the simulation signal is normally controlled by a pressure sensitive switch at the heel of the person or in his shoe. Often the transmission of the signals from the switch to the simulator placed on the skin of the leg is wireless.

10

These drop foot simulators will be substantially improved by using the adhesive device described in the invention. It enables reliable power and data transfer because of the very stable fixation of the external part of the simulator on the skin surface for long periods of time with minimal inconvenience. Further it can also enable better long-term fixation of the switch placed on the foot.

15

Thus, in one embodiment, the microelectronic system is useful for nerve stimulation and comprises storage and communication components, a CPU, power source and transducer for transmitting data and power to implant for nerve stimulation. The system may suitably be embedded in the adhesive body as illustrated in figure 3.

20

In another embodiment, the embedded microelectronic system is useful for surface electromyography (sEMG) or invasive electromyography. In both cases the transducer is a relatively simple 2-3 electrode device. The signal measured is a direct voltage generated by a muscle or a muscle group. In order to understand this signal it must be analysed either by the microelectronic system or stored for future analysis.

25

The data collected are transmitted to a Central Unit (CU) either when relevant, when certain events occurs or at certain time intervals. The CU is suitably a portable hardware device with wireless reception/sending capability, such as but not limited to a PDA (personal digital assistant), a mobile phone or other dedicated hardware.

30

The transducer is suitably designed to overcome or neglect the difference from time to time of the surface resistance of the skin. Dry skin has resistance of e.g. 500 kOhms and sweaty skin could be as low as 500 Ohms. This problem may be over come by utilizing a

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high impedance amplifier, where impedance is above 500 MOhms. The transducer may be designed to activate other system components on the first skin contact thereby ensuring longer lifetime.

5 The central processing unit (CPU) handles the amplification (e.g. x30-x1000) of the transducer signal, typically by differential instrumentation amplifier with rejection of common modes (unwanted signals/noise that is common for both electrodes), filtered either analogically or digitally. The CPU handles conversion of analogous signal to digital signal. Signal analysis such as rms (root mean square), FFT (Fast Fourier
10 Transformation) and digital filters combined with software are employed to achieve a data decision on certain events.

Furthermore the CPU could employ timers or sleep mode, so measurement is only during certain events or only a fraction of each second or other time period, thereby saving
15 power.

The microelectronic system also comprises storage components for storage of Software and EMG data storage in those cases where, only some or no data are transmitted wireless during data acquisition. These data may be transmitted at a later
20 time.

The power source is thought to be either a single use battery as the CPU ensures long lifetime due to power down in inactive periods, or a rechargeable battery. The rechargeable battery is recharged either through a RF link or by placing the
25 microelectronic system in a recharge cradle when the system is not in use. Several weeks of lifetime after activation are possible with one battery or charge up.

Data is transmitted to Central Unit with a protocol or method that can ensure no corruption of data. Furthermore after activation battery life condition and/or a data burst are
30 transmitted in order validate operational status of the system. On request the system will transmit storage data.

The microelectronic system for electromyography may optionally include an actuator, which at certain events decided by the CPU activates an alarm in the microelectronic
35 system, such as loudspeaker or LED. The event activating the actuator could also be

low battery.

According to this embodiment of the invention the various components are interconnected mechanically and electrically and may be encapsulated into a module. However, various components may also be integrated separately into the adhesive body. These components could be but is not limited to, the battery, the antenna and the actuator.

The various components could also be mounted on PCB (printed circuit board) or flexible PCB and coated with a protective layer and directly be embedded in the adhesive.

Thus, in a specific embodiment of the invention, the microelectronic system is a system useful for electromyography and comprises a transducer (2-3 electrodes and an Instrumentation Amplifier), a CPU (μ Controller e.g. ATMEGA 128L), a power source (e.g. battery), communication (e.g. to CU) and storage components and an actuator (LED).

This system may be embedded in the adhesive body as illustrated in figure 3 and 3A.

During sport or fitness exercise different or several of the same microelectronic systems may be used in combination. Furthermore several transducers could be used in the same adhesive device.

A fitness sensor network may thus consist of:

Adhesive devices with a muscle activity (sEMG) sensor, one for both sides of the body (arms, legs etc). The electromyography system could be designed in such a way to determine the fatigue of the muscles and indicate when muscle growth is optimal or when exercise has no benefit. Frequency analysis of the sEMG signal may be used to achieve the desired output of the measurements. Typically the adhesive devices are placed on muscle groups that are actively exercised.

Two or three adhesive devices of the invention comprising a Heart Rate (ECG) sensor system of for monitoring heart beat and heart pulse shape.

Adhesive devices comprising microelectronic systems for determining levels of fatigue poisons in muscles.

A sensor Hub/gateway centrally located on the body for storing and routing signals to either a central unit or directly communicating with fitness hardware.

5 The microelectronic system may be reusable from one fitness session to another with change or charge up of battery.

10 Thus, the adhesive device according to the invention may suitably be used for measuring physiological conditions that relate to diseases, health care surveillance, rehabilitation, sports medicine or general surveillance. Typically applications will be for patients at risk for instance when suffering from weak heart, epilepsy, fever and fever spasms, diabetes, apoplexy, arteriosclerosis and muscular dystrophy. Applications may be associated with general monitoring for optimising medication, for registering of the disease or for alarming. Other applications will be for rehabilitation in respect to monitoring of physical work, muscle strength, lung capacity, or in the sports medicine for determination of work and repetition, acceleration, heart rate, muscular stress and strength, orientation etc. Yet other applications will be for surveillance of objects or mammals in motion. Mentally disable patients or individuals like elderly people suffering from dementia will be typical for such applications.

20 The adhesive device according to the invention will preferably be wireless as this will be meaningful in respect to obtaining as smooth a shape and surface of the device as possible and still achieving the protection of the microelectronic system. In certain occasions it may, however, be important to be able to interconnect the devices by wires. This may especially be an option when the microelectronic system is divided in two parts each being present in an adhesive device as defined in the invention.

25

30 The microelectronic sensing system or the components thereof may be incorporated into the adhesive body either during production of the adhesive body, or after production of the adhesive body, e.g. just prior to application of the adhesive device to the skin, or after application of the adhesive device to the skin.

As described above, parts of the adhesive device such as parts of or the entire microelectronic system may be exchangeable or reusable.

Thus, in one aspect of the invention the present invention discloses a device comprising at least an adhesive element and a power source element, said device adapted to attach an electronic circuit, such as the microelectronic system, to a surface and to power said electronic circuit, wherein at least one of the device elements is releasable attachable to the electronic circuit; the power source element is electrical connectable to the electronic circuit; and the adhesive has at least a first area for adhering to the surface.

Such a device as described may attach and power the electronic circuit to a surface, such as e.g. the skin of a mammal, for a specific purpose. When the specific purpose is fulfilled the device and the electronic circuit is removed from the surface and the device is separated from the circuit and disposed. Thus, the elements forming the device, which are relative cheap compared to the electronic circuit, is disposed while the electronic circuit may be reused together with a new device according to the invention for attaching the electronic circuit to a surface and powering the circuit. Advantageously this allows reducing costs considerably while also protecting the environment as more components are reused than done until now.

By the terms 'releasable attachable' and 'releasable connectable' it should be understood that the device and the electronic circuit may be temporarily attached in such a way that the risk of unintentionally separating them is minimal. However the device and the electronic circuit should be attached in such a way that they may be separated if desired.

Furthermore, by the term 'electrical connectable' it should be understood that the power source element and the electrical circuit is arranged in such a way that an electrical current may be transmitted between them. This may for example be done by use of standard electrical contacts, typically made of copper alternatively gold or silver plated, or the electrical connection may be provided in a wireless manner where the power source induces a current in the electrical circuit.

Typically the electronic circuit is a microelectronic system formed of a number of microelectronic digital components and /or analog components connected with appropriate wiring. The components are typically arranged on a print circuit board whereon the proper traces and tracks are etched, electroplated, or otherwise provided on the board. Digital components may for example be microprocessors, storage elements such as RAM-blocks

and analog components may for example be resistors and capacitors provided on the print board.

5 In one embodiment the power source element is attached to the adhesive element and the adhesive element has a second area for adhering to the electronic circuit.

10 By attaching the power source element and the adhesive element to each other only one physical part is provided, avoiding that the user has to keep track of both the power source element and the adhesive element and spend time on applying both. Thus a small and discrete device, which is convenient for the user, is provided. Furthermore the electronic circuit may be adhered to the adhesive element for improved handling, as only one unit will have to be manipulated when applying the electronic circuit to the surface.

15 Advantageously a first peel force between the second area and the electronic circuit is smaller than a second peel force between the power source element and the adhesive element. This allow for easy separation of the microelectronic circuit from the device after use.

20 To further ensure that the power source element and the adhesive element do not separate from each other the power source element may at least partly be contained in the adhesive element.

25 By 'contained' it should be understood that the power source may be fully or partly embedded in the adhesive. When fully embedded only electrical contacts are exposed through the adhesive or thin flexible electrical wires are embedded in the adhesive extending from the power source to an outer surface of the adhesive where it may be brought into contact with the electronic circuit. Furthermore, within the meaning of the term contained the power source may also be partly embedded in the adhesive thereby exposing a larger section through the adhesive. This allows for a large contact surface
30 between the electronic circuit and the power source while at the same time being safely attached to the adhesive.

35 To protect the different parts of the electronic circuit it will typically be encapsulated, for example by coating it in silicone or hot-melt polymers. The encapsulation may for example be formed as a housing containing at least a part of the electronic circuit. In one

embodiment the housing may be formed of a proximal housing part and a distal housing part. The device is adapted to be releasable connectable to said housing.

5 A number of encapsulation techniques are known and includes coating, two component polymer, hot-melt polymer encapsulation, ceramic encapsulation and glass encapsulations. Other methods for encapsulation of electric components are known in the art.

10 The microelectronic system or components thereof is suitably encapsulated in a polymer film, a polymer foil, or a polymer coating or the microelectronic system or components thereof is moulded into a polymer material, or is encapsulated in a glass or ceramic material.

15 Encapsulation in silicone, such as PDMS, is particularly preferred when the microelectronic components are to be placed in a through hole or a recess in the adhesive body and where it is desirable to enable easy removal or replacement of the encapsulated microelectronic component(s), as the silicone surface is easily released from the adhesive of the adhesive body. Other materials, which are easily releasable from the adhesive, may also be used for the encapsulation.

20 In order for the adhesive element to be easily released from the housing after use the housing may advantageously be made from a material, or coated with, which allows the housing to easily release. Such a material may for example be a silicone, which often is used for release liners in different adhesive applications.

25 In yet another embodiment the at least one power source element is adapted to be received in a recess formed in the distal housing part. At least one electrical contact is provided in the distal housing providing electrical connection between the power source element and the electrical circuit.

30 By providing a recess as described above the power source element is protected from being displaced and thereby losing electrical contact with the circuit. The recess also creates a flush assembly when the power source is placed therein giving it a smooth surface which will not get caught as easy as from a surface where the power source would protrude.

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Many types of electronic circuits having many different applications and which is powered and attached to a surface may be used with the device according to the invention. The device may after use be disposed but the electronic circuit may be reused. In one
5 embodiment the device is thus adapted to be releasable connected to electronic circuit, which is a sensor circuit, said sensor circuit is to be attached to the body surface of a mammal, typically the skin.

By the term 'sensor' or 'sensing' it should be understood that a parameter of the
10 ambient environment of the electronic circuits is detected by the sensor circuit. Such parameters may among many for example be temperature, humidity, electrical signal, electrical fields, light, noise, biosignals and magnetic fields.

Thus, the invention also relates to a sensor assembly adapted to be attached to the body
15 surface of a mammal, comprising; a sensor circuit, comprising a number of electrical components; at least one power source element for powering at least one of the electrical components; at least one adhesive element for attaching the sensor assembly to the body surface of a mammal; and that at least one of the power source element and the adhesive
20 element is releasable connected to the sensor circuit.

Thus, the sensor assembly provides the advantages as disclosed above when different elements are disposable, such as the device comprising the power source and the adhesive element, and others are reused, such as the electronic circuit.

In one embodiment of the sensor assembly the sensor circuit is at least partly contained in
25 a housing where the housing is formed of a proximal housing part and a distal housing part. Advantageously a sensor assembly may be provided where a first peel force between the adhesive and the housing is smaller than a second peel force between the adhesive and the battery. This allows for easy separation of the sensor circuit from the
30 adhesive and power source elements.

Typically the sensor assembly will comprise at least one transducer attached to a proximal
35 surface of a proximal part. Together with a distal part the proximal part makes up a housing, as described earlier, for protecting at least a part of the sensor circuit. This transducer will transform different physiological signals into electrical signals. Such

transducers may for example potentiometric, calimetric, conducmetric, chemomechanical or optical.

5 To prevent that the power source accidentally moves out of electrical contact with the sensor circuit a recess may be formed in the distal housing part, the recess is adapted to receive the at least one power source and that at least one electrical contact is provided in the distal housing providing electrical connection between the at least one power source and the electrical components. The recess thus protects the power source from outside movement, for example when the adhesive moves due to movement of the surface
10 whereto the sensor assembly is attached. Additionally, by protecting the power source from outside movement the electrical connection between the power source and the microelectronic circuit is also protected from disconnection.

15 In another aspect the present invention relates to the use of a device comprising an adhesive element and a power source element, and where the device is used for attaching an electronic circuit to a surface and to power said electronic circuit, wherein said electronic circuit is releasable connectable to the adhesive element and the power source element.

20 Many sensors are connected to the monitoring systems with wires. The disadvantage of such a system is that the patient does not have freedom to move since the wires are attached to the sensors on the body and connected to a monitoring system. Whenever the patient wants to move he must be careful not to dislodge any of the wires attached to the sensors, and he must further pick up the monitoring system and carry it along.

25 Furthermore, an isolated power source, such as a battery, where no external wiring is necessary is preferred. Such isolated power source elements preferably used with the present invention are well known in the art.

30 In general, batteries may be divided into primary batteries, which are single use and secondary batteries, which are rechargeable.

35 Primary batteries are produced in various types based on different combinations of anode, cathode and electrolyte materials. Common chemistries for primary batteries include zinc-carbon, zinc chloride, alkaline manganese dioxide, silver oxide, zinc / air and lithium in

these combinations: lithium / sulfur dioxide (Li-SO₂), lithium / thionyl chloride (Li-SoCL₂), lithium / manganese dioxide (Li-MnO₂), lithium / carbon monofluoride (Li-(CF)_n), lithium / copper oxide (Li-CuO), and lithium / iodine (Li-I₂).

5 Secondary batteries are rechargeable and are typically based on Nickel Cadmium (NiCd), Nickel Metal Hydride (NiMH) or Lithium-ion technology. Secondary batteries usually have more active chemistries that need special handling and disposal.

10 Many battery sizes and cell casing exist, including standard cylindrical cells, multi-cell batteries, coin cells, pouch cells and thin film batteries.

Standard cylindrical cells and multi-cell batteries are known from common household appliances, e.g. flash lights and remote controls. This group includes the well known sizes AA, D, C, and 9V rectangular.

15 Coin or button cells are typically small, round and a few millimetres high. This group is often found in watches, hearing aids and memory backup. Since they are based on solid-state cathodes, these systems are considered very safe.

20 Duracell, Panasonic, Sony and Energizer are some of the major manufacturers of standard and coin cell batteries.

Alternatively, using pouch casings along with Lithium Polymer cells with solid electrolytes can provide another type of batteries. This provides a low cost bendable construction. The batteries are characterized by a high energy density in addition to being re-chargeable. The solid electrolyte permits safer, leak-proof cells. The foil construction allows very thin and lightweight cell designs.

25 Bullith Batteries manufactures flexible batteries based on this technology.

30 Yet another type of batteries are thin film batteries, which are based on the printing of solid state lithium polymer chemistry on a variety of substrates. They can be printed directly onto plastics, thin metal foils or paper resulting in ultra thin and flexible power sources. The batteries can be made in any shape or size, but are generally limited in energy

storage and current capacity. The batteries are very safe as they contain no caustic chemicals, cannot overheat, explode or cause electrical shock.

5 The Israeli company Powerpaper are selling products based on thin film technologies. Other companies producing this type of batteries are Oak Ridge Micro Energy Inc. and Infinite Power Solutions.

10 In one embodiment the adhesive element is formed as a three-dimensional adhesive body as described earlier, i.e. the adhesive element has a considerable thickness, typically several times thicker than the backing layer whereon it is applied.

15 The pressure sensitive adhesive making up the three-dimensional adhesive body is suitably a mouldable thermoplastic or chemically curing pressure sensitive adhesive having a flexibility enabling the adhesive device to conform to the curvature of body parts while retaining its adhesive properties even under movements.

20 The backing layer may furthermore function as a cover layer, where said backing/cover layer is provided to function as base wherein the adhesive is applied and to protect the adhesive from the outer environment, e.g. against adhesion to linen, clothes or moisture.

Furthermore, an electromechanical display system may be applied to the cover layer. Such display system may allow the user to test the charge of battery, either before adding the powered adhesive to a microelectronic system and during use.

25 Simple battery indicators known in the art may thus be used. For example a foil consisting of two contact electrode and a conductive thermochromic ink, typically liquid crystals or leucodyes, may be used.

30 When for example using a common coin battery, one electrode is in contact with the anode of the battery and the other electrode in contact with cathode of the battery. By pressing the contact device on top of battery the battery test circuitry is closed and the thermochromic ink will light up indicating battery status.

35 The cover layer or film protects the integrated /embedded microelectronic components as well as the adhesive body against the environment.

The adhesive device of the invention may be constructed in a number of ways, as it will be described in more detail below. Common for all constructions are that the three-dimensional geometries provide good protection for the microelectronics and at the same time give the device as smooth a surface as possible. Especially the shaping of the edges of the device need paid attention, otherwise linen will easily stick to them and cause rolling. Therefore the outer rim of the adhesive device with the embedded micro electronic system must be shaped to thickness less than half of the thickest part of the device, normally the central part comprising the microelectronic electronic system.

Detailed description of the drawings

Figure 1 shows a die section of the shape of a typical representative of the adhesive device according to the invention. CT relates to the maximal thickness of the device and PT to the thickness in the periphery of the device. The device does not necessarily need to be shaped symmetrically.

Figure 2 has a box showing the part of the adhesive device, which is illustrated in figures 3-12. As illustrated in figure 2 the electronic parts 101 are embedded in an adhesive body 102 with a cover layer 103 and a release liner 104.

In one embodiment of the invention, all the electrical components are assembled in one unit, which is embedded in the adhesive body and is covered on all sides with the pressure sensitive adhesive, essentially making it a disposable pad. As illustrated in figure 3 an assembly of electronic parts 101 are embedded in an adhesive body 102 with a cover layer 103 and a release liner 104.

Figure 4 illustrates that the components of the microelectronic sensing system may be positioned at different locations within the adhesive body, provided there is the required mechanical or electrical connection between the components. All components are completely embedded in the adhesive body and are covered on all sides by the pressure sensitive adhesive of the adhesive body.

The integration of all microelectronic components within the adhesive body is useful for cheap throw away one time one use devices. Because of the short usage time of the

adhesive device the electronics need little or none extra protection, such as encapsulation. The adhesive body itself acts as protection of the microelectronic components.

5 Even though all the components of the microelectronic system are covered on all sides with the adhesive body, several sensing applications (humidity, optical or chemical/gas) are still possible.

10 Systems, which may be covered on sides, may also be a RFID TAG, a Network Hub, a network coordinator, a gateway, or other systems capable of collecting, communicating and/or transmitting data. These systems would often need some kind of activation to start the system, such as a pressure contact or magnetic contact to overcome the need for large shelf life compared to the active period.

15 Figure 5 illustrates an embodiment of the invention where the microelectronic system is embedded/applied into a recess in the adhesive body. The recess is positioned in the upper surface of the adhesive body. The microelectronic system may be embedded/attached during fabrication of the adhesive body, just before or after the adhesive device has been attached to the skin. According to this embodiment of the invention, the microelectronic system may be reused.

20 Figure 6 shows a microelectronic system analogous to the system of figure 5, however, in figure 6 the system consists of two parts. One part, the upper, is exchangeable or reusable and the lower is embedded in the recess of the adhesive from start. The upper part may for instance be the power supply.

25 Figure 7 illustrates an embodiment where some components of the microelectronic system is embedded within the adhesive device during production and some components are applied in a recess in the upper surface of the adhesive body, i.e. are exchangeable or reusable. According to the invention one or more component(s) may be embedded within
30 the adhesive body and one or more component(s) may be present in a recess at the surface of the adhesive body. The necessary mechanical or electrical connection between the components are also embedded in the adhesive body. Although the figure only illustrates one, there may be two or more recesses in the upper surface of the adhesive body and there may be two or more components integrated into the adhesive body.

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The exchangeable parts in the recess may be locked in the recess by the adhesive properties of the pressure sensitive adhesive in the recess. In an alternative the microelectronic components in the recess is encapsulated in a coupling or plug designed to fit into a lock, such as a snap lock, present in the recess.

5

Figure 8 illustrates an embodiment of the invention where the microelectronic system is embedded/applied into a recess in the adhesive bottom surface of the adhesive body. The microelectronic system is embedded/attached during fabrication of the adhesive device or just before attaching the adhesive device to the skin. This system is typically used where it is required that some of the components of the system are in contact with skin either non-invasively or invasively.

10

Figure 9 illustrates an embodiment where some components of the microelectronic system is integrated within the adhesive device during production and some components are applied in a recess in the lower surface of the adhesive body, i.e. are exchangeable. According to the invention one or more component(s) may be integrated into the adhesive body and one or more component(s) may be present in a recess at the surface of the adhesive body. The necessary mechanical or electrical connection between the components are also integrated into the adhesive body. Although the figure only illustrates one, there may be two or more recesses in the bottom surface of the adhesive body and there may be two or more components integrated into the adhesive body at different locations.

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Figure 10 illustrates an embodiment where some components of the microelectronic sensing system is integrated into the adhesive device during production and some components are applied in a recess in the bottom surface of the adhesive body, i.e. are exchangeable or reusable. According to the invention one or more component(s) may be integrated separately into the adhesive body and one or more component(s) may be present in a recess at the surface of the adhesive body. Although the figure only illustrates one, there may be two or more recesses in the bottom surface of the adhesive body.

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This construction is suitable where the transducers or actuators utilize skin contact or skin penetration (e.g. electrodes and needles), whereas the rest of the microelectronic system may be embedded in the adhesive body (batteries, antenna, electrode, A/D converter, amplifier). This configuration also has several production advantages.

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Thus, figures 8, 9 and 10 illustrates a construction where the exchangeable part e.g. the battery, is attached to the adhesive part facing the patient. Prior to mounting the adhesive sensor device on dermis of the mammal the protective release liner is removed, the exchangeable battery is coupled to the rest of the microelectronic system enabling the electronic system to function. Thereafter the adhesive part of the device and the whole construction is mounted on the dermis of the patient.

After use the exchangeable part e.g. the battery, is replaced and the adhesive device may be used in the context of a new monitoring of the patient.

In order to be able to remove the battery following detachment of the adhesive device, the inner part of the recess in the adhesive device could be coated with a PDMS curable coating or other non-adhesive coating; this operation will facilitate the exchange of the battery.

The battery as well as other exchangeable components, such as the chip, may be present in a recess in the bottom surface of the adhesive body. According to this embodiment, it may be an advantageous to have the exchangeable microelectronic parts contained in a capsule, e.g. embedded in an injection-moulded capsule.

Just prior to mounting the capsule containing the microelectronic components the release liner is removed and the exchangeable capsule is attached to the adhesive body in the recess of the adhesive construction. The microelectronic components may be coated with curable PDMS or other non-adhesive coating in order to facilitate detachment of the exchangeable capsule.

When the microelectronic components have a longer life than the adhesive body, the cheap components, such as the transducer, the antenna or the power source, may be integrated into the adhesive body and the components that may be reused are placed in a recess before use.

Another application is where customised preparation or programming of the system is done prior to application.

The features and applications described in connection with figure 3 apply equally well to the embodiment illustrated in figure 5 and vice versa.

5 Figure 11 illustrates the integration of a microelectronic system within a through hole in the adhesive body providing access to the microelectronic system from both the upper surface and the bottom surface of the adhesive body. The application of the microelectronic system is possible both during production/fabrication of the adhesive or just prior to application to the skin, and/or after application to the skin.

10 Figure 12 illustrates a system where two components or assemblies of components of the microelectronic system are connected in some way. One of the components may be integrated during production, whereas the other is applied afterwards.

15 Alternatively, the components or assemblies of components are applied afterwards. This is useful where different lifetime make is feasible to exchange electronic components at different times, such as battery or transducer. Mechanical and/or electrically interconnection schemes such as snap locks or plugs are advantageous in this configuration.

20 The system illustrated in figure 4 is useful where skin contact and simultaneous access to electronic components from the upper surface is needed. One or both subsystems can be reused.

25 The features and applications described in connection with figure 5 and 8 applies equally well to the embodiment illustrated in figure 11 and vice versa.

Figures 13 - 18 illustrates an embodiment of the invention where an antenna, a central processing unit, a battery and electrodes are embedded in an adhesive device.

30 Figure 13 illustrates the two-dimensional shape of the device indicating a cross-section by A-A.

Figure 14 illustrates the position of the antenna 109 placed in the outer part of the adhesive device and being connected to the central part of the microelectronic system.

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In Figure 15 the third dimension is shown in cross-section along the line A-A in figure 13. The circle B from the rim of the device is further magnified in figure 16 and the circle C of the centre is likewise magnified in figure 17.

5 Figure 16 shows more in detail the building of the antenna lying embedded in the adhesive. This clearly shows the cover film 103 and the release liner 104 for the adhesive 102.

10 Figure 17 shows the position of the central part of the microelectronic system 1 with a battery 105, a CPU 106 and protruding the adhesive the electrode 107. The battery and the CPU is enveloped in a transparent silicone rubber 108.

Finally figure 18 illustrates the adhesive device in a perspective.

15 There are other ways of constructing an adhesive device having an embedded micro electronic system, that fulfils the basic requirement of a three-dimensional construction and the drawings may thus not be construed as limiting.

20 One special advantage of the invention is the simple and inexpensive way of preparing an adhesive body having a three-dimensional shape from a pressure sensitive adhesive.

As mentioned above, the pressure sensitive adhesives are either a thermoplastic pressure sensitive adhesive or it is a chemically curable adhesive that has the ability to be moulded into a three-dimensional shape.

25 The thermoplastic pressure sensitive adhesive may typically enter a fluid condition and achieve a moderate viscosity at above 100-120 deg C i.e. above the glass transition temperature of the composition, which makes it easy to mould the adhesive composition to the desired shape. One example may be direct moulding. In a first step the cover layer
30 is provided in the desired shape at temperatures just below the glass transition temperature of the cover film and then the necessary amount of adhesive is filled the into the mould to fill up the mould. The filling of the mould may be in two steps whenever appropriate. This will allow partly filling with the molten adhesive in a second step, placing the electronic parts in a third step and eventually filling and covering the electronic parts

with the remainder of the adhesive in a fourth step. As a last step a release liner is applied and then the adhesive device is punched out of the mould.

5 Alternatively the adhesive laminated with the cover film may be processed through compression, pressing or moulding into the desired geometry or shape at elevated temperature, but slightly below the glass transition temperature of the adhesive. Optionally the microelectronic system may be placed between two layers of adhesives and then moulded. The moulding is performed in the press at elevated temperature and if desired with the microelectronic system placed in the mould preferably in the centre of the
10 mould.

In the special embodiment where exchangeable or reusable components are a part of the adhesive device, a female and a male part of a moulding shape is required.

15 In another embodiment of the invention curable pressure sensitive adhesive is cast in the desired shape. The casting may follow the same principles as of above allowing a partial filling step of the mould with the cover film, applying the electronic components and thereafter complete the filling of adhesive in the mould and finally concluding with placing the release liner, curing if necessary and die cutting.

20 Another method is moulding by compression of adhesives having high or very high viscosity. A primary layer comprising a pressure sensitive adhesive e.g. a hydrocolloid containing block copolymer on a cover film taken from a roll enters the processing equipment as a first step, the pre-assembled, optionally encapsulated micro electronic components is placed with the appropriate distance in a second step, in a third step, a
25 secondary layer of the same or another pressure sensitive adhesive is laminated to the first layer of pressure sensitive adhesive enclosing the microelectronic part between the layers, in a fourth step said laminate is formed in a hydraulic press into a shape containing multiple projections centred upon the microelectronic part and in a fifth step the individual
30 projections are die cut to final devices.

The pressure sensitive adhesive devices can be produced according to a continuously process as described in US 6726791.

Figs. 19, 20 and 21 shows one embodiment 1 of a sensor assembly according to the invention. Figure 19 shows the sensor assembly in an exploded view. Figure 20 shows the assembly seen in section along line XX – XX in Fig. 19 when the sensor assembly is assembled. Fig. 21 shows the sensor assembly seen from the skin side, also referenced to as the proximal side, i.e. the side of the sensor assembly, which is to be attached to the skin.

The sensor assembly 1 consists of a sensor device 2 and housing element 3 which contains a microelectronic circuit 4. The sensor device 2 is made up by an adhesive element 5 and a power source element in the shape of a coin cell battery 6. The housing element 3 is made up of a distal part 7 and a proximal part 8. A recess 9 is formed in the distal part. The recess has a circumference, which is slightly larger than the circumference of the coin cell battery allowing the coin cell battery to be received in the recess.

In the recess there is provided two electrical contacts 10a, 10b for electrically connecting the microelectronic circuit 4 and the battery 6 when the battery is placed in the recess. The microelectronic circuit is made up of a number of components arranged on a print board 11. Every component will not be described herein as the circuit is well known in the art and as such not a part of the invention in itself. In general it can be mentioned that the circuit comprises an antenna 12 formed by a number of windings of a conductive material printed on the print board. The antenna transmits and receives data from a central unit placed within communication range. The central unit may for example be a personal computer which gathers data from the sensor assembly. The data is then processed according to known processes and algorithms.

The antenna 12 is connected to a microprocessor 13, which receives signals from a first transducer 14 and a second transducer 15. The first and second transducer extends from the print board through the proximal part and terminates on the proximal surface of the proximal part. Thus, when the housing is placed on the skin the first and second transducer contacts the skin surface. In order to reduce interference between the first and second transducer a barrier element 16 is placed on the proximal surface of the proximal part between the two transducers. The barrier element is formed of a dielectric material and is a well known measure in order to avoid so-called cross talk, typically causing unwanted interference, between two electronic components.

When used the battery is placed in the recess, whereby the battery is placed in contact with the electrical contacts 10a, 10b and thereby powers the microelectronic circuit. The adhesive element is then applied on the distal side of the distal part of the housing and the distal side of the battery. This secures the battery in the recess and connects the adhesive element, the power source element and the housing element into a sensor assembly. As can be seen the adhesive element has a circumference which is larger than the circumference of the housing which provides an adhesive proximal surface 17 which can be applied to the skin surface of a person or other mammal.

When the sensor assembly later is removed the adhesive element is separated from the housing element the battery is removed along with the adhesive element as the distal surface of the battery is adhesively attached to the adhesive element. The adhesive element and the battery can then be disposed and the housing element may be cleaned and stored for later use.

The adhesive element is covered by a cover layer 18 in order to protect the adhesive element from adhering to unwanted surfaces, such as the inside of worn clothing articles. The cover layer 18 also functions as backing layer whereon the adhesive material 19 is disposed during production.

Fig. 22a shows another embodiment 30 of a device according to the invention. Fig. 22b shows a section of Fig. 22a in an enlarged view. The device is made up by a two-dimensional adhesive element 31 and a power source in the shape of a coin cell battery 32 adhered to the adhesive element.

The adhesive element is formed of a backing layer 33. On the proximal side of the backing layer there is provided a first adhesive layer 34, which is covered by a first release liner 35. The distal side of the backing layer there is provided a second adhesive layer 36 to which the battery is adhered. A second release liner 37 covers the rest of the distal side of the adhesive, whereon the battery is not attached.

When applied to a surface, such as a skin surface of a person, the first release liner 35 is removed. This exposed the first adhesive layer, which may be adhered to the skin surface thereby attaching the device 30 to the skin surface. The second release liner is then

removed exposing the second adhesive layer. Not shown in the drawing, a housing containing a microelectronic system is then attached to the adhesive layer while at the same time an electrical contact on the housing is brought into electrical connection with the battery 32.

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Although such a housing as described above do not have any surface contact such as the housing described with reference to Fig. 19, the housing may still comprise sensor technology. Such sensors may simply measure the ambient temperature or the device may be applied under the nose and a sensor for measuring the breathing rhythm through the nose may be applied on the device. Alternatively the sensor may apply skin contacting transducers outside the circumference of the device, while still being adhered thereto.

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Fig. 23 shows yet another embodiment 40 of a two-dimensional device according to the invention and Fig. 24 shows a sectional view of the third embodiment along line XXIV – XXIV in Fig. 23. Here the power source element is formed as a thin film battery 41 being an integrated part of a backing layer 42.

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On the proximal side of the backing layer there is applied a first adhesive layer 43 which is covered by a first release liner 44. The distal side of the backing layer is covered by a second adhesive layer 45 which is covered by a second release liner 46. The second adhesive layer is interrupted in an area 47 allowing access to contacts 48a and 48b which provides electrical contact to the thin film battery.

20

When used the device 40 described with reference to Fig. 23 is applied in the same way as the device 30 described with reference to Fig. 22.

25

It should be understood that different types of adhesives may be used on respectively the proximal side of the backing layer and the distal side of the backing layer. While the proximal side is attached to the skin surface and thus preferably should be skin friendly, the adhesive on the distal side should preferably be of a type which provides optimal attachment to an electronic circuit or a housing containing such circuit while still allowing the device to be separated therefrom after use.

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Although the above embodiments describe releasable attachable means in shape of adhesive attachment for connecting the device to the electronic circuit other types of

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release attachable means may be used. Such releasable attachable means can for example be mechanical such as a snap lock arrangement between the battery and the recess in the housing, where the recess is formed with protruding ribs which couples with the battery. Alternatively additional coupling means may be provided on the device for coupling with complementary coupling means on the electronic circuit or the housing containing the electronic circuit, and may for example be in the shape of bayonet coupling, hooks, frictional couplings or threaded couplings.

Experimental Section

Example 1

Three batches of adhesive were produced. The adhesives were prepared by standard hot melt procedure in a Herman Linden z-blade mixer (Machine type LK 110.5), by mixing the components of elastomer (Kraton), one third of the plasticiser (DOA) and the resin (Arkon) at 130 degree C until a homogeneous mixture was achieved (30-50 minutes). The rest of the plasticiser and the hydrocolloid filler (CMC) was added and the mixture was blended for 20 minutes.

	Recipe 1	Recipe 2	Recipe 3
Kraton 1161 (Shell)	18,0	19,0	15,0
Arkon P90 (Arakawa)	32,0	36,0	
DOA (Diocetyl adipate)	5,6	7,5	
Vistanex® LM-MH (Exxon)			45,0
CMC: Blanose 9H4XF (Hercules)	44,4	37,5	40,0

Example 2

Moulded bodies of the adhesives of example 1:

Each of the adhesives according to claim 1 were applied on to a 35 micrometer thick cover film of polyethylene and a siliconised polyethylene liner was applied to the opposite side of the adhesive patch and pressed to the desired shape according to any of the illustrations 1-3 in a for the shape designed mould at 90 degree C by altering the non-cavity holding

mould to give the shape of the recess. The centre of the adhesive device was 3.4 mm and the thickness of the outer rim 0.4 mm.

Example 3

5 Moulded silicone pressure sensitive adhesive body:

Dow Corning 7-9800 A&B (mixing ration between A and B is 1:1 by weight) were used for production of a PDMS based adhesive body. A mould having a triangular shape (each side of the triangular mould having a distance of 300 mm, the center part having a thickness of 0,5 mm and the edge having a thickness of 0,1 mm) was used. The components were thoroughly mixed and applied on a 50 µm cover layer of silicone rubber lining in the female part of a triangular mould and a male mould part was placed on top, said part lined with a low density polyethylene release liner. The adhesive was cured in an oven at 100 degree C for 15 minutes. After curing the adhesive was punched out of the mould and a dent in the centre of the adhesive body device for embedment of an electronic sensing system was punched out.

Example 4

20 Moulded thermoplastic PSA adhesive body:

The components of recipe 2 in example 1 were mixed in a Herman Linden mixer and while still hot and soft, the resulting dough-like material mass was removed from the mixer and placed on a thermoplastic polyurethane cover film placed in the cavity of a moulding form and a release liner is placed on top. The second part of the mould was plane. The adhesive is compression moulded at approximately 90 degree C and 100 bar. The release liner was removed and an encapsulated microelectronic sensing system was placed at the centre of the adhesive body within the mould, the release liner was reapplied and the moulding step was repeated. Finally the resulting sensor pad was punched out.

30 Example 5

Moulded thermoplastic PSA adhesive body with integrated RFID-tag:

A pressure sensitive adhesive according to recipe 2 in example 1 were mixed in a Herman Linden mixer and while still hot and soft a minor part of the material was removed from the mixer and placed on a cover film towards the female part of a mould and a release liner was placed on top and thereafter the male part of the mould having a small protrusion

over the area corresponding to the microelectronic system of the product was applied. The whole construction is compression moulded at approximately 90 degree C and 100 bar. Hereafter the release liner was removed and a RFID tag encapsulated in polypropylene was placed in the recess of the pressure sensitive adhesive and the mould was filled up with the remaining adhesive. A release liner is attached again and the whole construction was compression moulded again. The resultant pad was punched out. The thickness of the outer rim was 0.2 mm, the central thickness was 2.5 mm and the shape was circular with a diameter 40 mm.

Example 6

In this example the micro electronic system embedded into the adhesive body consist of both the RFID tag and communication and storage components. In order to protect the micro electronic system the components are encapsulated in polyethylene. The components are integrated in the PSA during a continuous process as described in US 6726791. The primary layer comprises the cover film with pressure sensitive adhesive, the secondary layer is the encapsulated micro electronic part; and the third layer is of a mouldable layer pressure sensitive adhesive; the whole construction is combined in the moulding cavities.

Example 7

Preparation of a Hydrogel adhesive composition:

3.5 grams of PVP K-90, 17.5 grams of PVP K-25, 3.5 grams of Pemulen TR2 and 28 grams of PEG 400 were mixed as a premix. Initially the premix of the plastizicing glycols, the PVP and the cross-linked polyacrylic acid were added and mixed in a Brabender mixer at 100 degrees C for 10 minutes. Then 17.5 grams of the amphiphilic polyurethane (Tecogel 2000) was slowly added in order to ensure complete mixing of the components. After 20 minutes' mixing a macroscopically homogenous mixture was obtained. The hot adhesive from the mixing chamber was moulded into a circular adhesive body (diameter 4 cm) with a dent for a later applied micro electronic system. The thickness of the pad is 3 mm at the centre and the thickness is gradually decreasing to 0,3 mm at the edge of the pad. The adhesive device was compression moulded between a sheet of silicone paper and a 30 µm PU cover film.

Example 8

A microelectronic sensing system for invasive measurement of oxygen:

5 An adhesive according to example 1 recipe 2 was used embedment of a micro electronic system consisting of an oxygen electrode, a central processing unit, a transmitter and a battery. The shape of the adhesive body is oval (70 x 30 mm) having a centre thickness of 5 mm, an edge of 0,3 mm and an essential linear increase in thickness from the edge to centre of the pad. The adhesive body has a centrally placed through hole and a dent in the skin-contacting part of the surface of the adhesive body for the silicone covered micro electrical components.

10 The CPU, the battery and the transmitter are as described in the examples 11. The oxygen electrode was oxygen electrode product number 723 (from Diamond General, Development Corp. US).
The CPU, transmitter and battery were electrically connected and thereafter covered with a thin layer of polymeric silicone, only the electrical contact of the CPU to the electrode,
15 remains uncoated.

The tip of the electrode in the sensing device is surrounded with a medical needle with outer diameter of 0,7 mm.

20 During use the electrode and the needle are positioned in a way where the electrical contacts of the CPU are connected with corresponding contacts of the electrode.

During application of the measuring device the partly silicone covered micro electronic system was firstly applied onto the adhesive body in the dent at the skin contacting side of
25 the device. The device is applied to the skin. The needle is then positioned from the outside through the hole in the adhesive by penetrating the skin in a second step and the electrode partly enveloped in a plug is mounted through the hollow centre of the needle as a third step creating electrical contact to uncoated connections of micro electronic system.
The plug part of the electrode fits the smooth curvature of the cover film without
30 introducing recesses.

During use, the electrode may be rinsed and reapplied according to needs for achieving correct signals.

35 Example 9

Microelectronic hub embedded in adhesive sensor device according to the invention:

5 An adhesive according to example 1 recipe 1 was moulded in a first layer forming an oval shell (50 x 80 mm) having a smooth surface to one side. This surface is declining in slope towards the outer periphery and is covered with a 30 µm thin film of polyurethane i.e. placed between mould and adhesive. The opposite side of the adhesive body was formed with a centrally soft shaped indentation of approximately 2 x 10 x 15 mm for applying the microelectronic system. A siliconised release liner of polyethylene was placed on the surface with the indentation. In a second step the release liner was removed, an antenna is placed at the outer periphery of the adhesive body and the CPU and the battery was placed in the central indentation. In a final step a second layer of adhesive was applied to embed the antenna at the area of the outer periphery but not the components in the central indentation. A release liner is applied and the complete construct which was die cut to the final size. The antenna is connected to the central microelectronic parts through electrical contacting elements making reuse of the central part possible. The antenna is encapsulated in thin polyethylene terephthalate (PET)-plastic and the central microelectronic parts are encapsulated in silicone rubber.

Example 10

20 Microelectronic hub:

A construction with microelectronic hub in which the antenna as well as the battery is completely integrated in the pressure sensitive adhesive of previous example 1. This is done by letting the adhesive of the final step in example 9 cover the antenna as well the central microelectronic parts.

Example 11

25 An adhesive device having embedded a microelectronic system for human temperature sensing and alarm with no remote communication

30 An adhesive according to example 1 recipe 2 was used for embedment of a micro electronic system consisting of an temperature sensor, a central processing unit, a transmitter, battery and an OLED (Organic Light emitting Diode). The shape of the adhesive body is round (30mm) having a centre thickness of 5 mm, a peripheral edge of 0,2 mm and an essential linear increase in thickness from the edge to centre of the pad.

The adhesive body has a dent in the skin-contacting part of the surface for the silicone covered micro electrical components.

The CPU is a μ Controller ATMEGA 128L, an AVR 8bit RISC processor from ATMEL,
Battery is an Panasonic Coin cell CR3202.
OLED flexible colour display is from OSD (One Stop Display) part #OSCC 130-0.
Temperature sensor is from Pasport Ps-2125

During use the temperature sensor continuously monitors human skin temperature. At certain events determined by the micro-Controller influenced by time of day, temperature gradient compared to stored data, the system will give a visual alarm in form text or lights of relevant information at the flexible display.

The system is integrated into the adhesive and activated when peeling off the release liner and will function until end of battery.

Example 12

An adhesive device having embedded a microelectronic system for human temperature sensing and alarm with no remote communication is constructed according to example 11.

The construction of the adhesive device is identical to the one of example 11 except that instead of the OLED flexible colour display for signalling a temperature change an EL (Electro-luminescent Lamp) is used as the signalling part in the surface of the device. The part is an EL Lamp Part #: 300210KIT from Being Seen Technologies.

During use the temperature sensor continuously monitors human skin temperature. At certain events determined by the micro-Controller influenced by time of day, temperature gradient compared to stored data, the system will give a visual alarm in the form of a light.

Example 13

In one embodiment illustrated with reference to Figs. 19 – 21 the adhesive material 19 is a pressure sensitive adhesive (PSA) consisting of a hot-melt processable styrenic block copolymer with hydrocolloids, the battery is a metal cased coin cell battery and the housing is coated with a layer of PolyDiMethylSiloxane.

In Example 13 below, the peel forces between the PSA and the surface, the battery and the housing were determined:

5 The PSA is a hot-melt processable Styrenic block copolymer with hydrocolloids, which is thermo formed into the desired shape. The PSA designated A, has the following composition: 25% Kraton D1107 (Kraton Polymers), 35% Arkon P90 (a hydrogenated polycyclopentadiene from Arkawa Ltd.) 8 % DiOctylAdipate and 32% sodium carboxymethylcellulose.

10 In order to illustrate the peel force between the different parts the peel force has been determined via use of FINAT; FTM2, 25mm test sample width, 90 degrees peel angle, test speed of 300 mm/min and a resting time of 30 minutes.

With regard to peel force from skin the following test method was utilized:

15 Strips of adhesive 25 mm wide were cut from slabs of PSA composition A. A strip of adhesive tape (TESA 4124) was attached in order to prevent stretching of the samples. The samples were taped to a clamp. The skin of the volunteer was prepared by washing the underside of the forearm with diluted soap and allowing to dry at least 2 hours before the PSA was attached. The adhesive side of the sample was placed on the prepared skin.

20 The resting time for the adhesive was 30 minutes. The clamp was attached to the hook of the testing device, an Instron Tensile tester Model 5564. The forearm was placed on a movable support of the testing device, taking care to keep the end of the sample directly under the clamp in order to keep a 90-degree peel angle. The forearm was kept still while the tensile strength tester was activated to pull the adhesive up at a rate of 300 mm/min.

25 The peel value of the steady state part of the resulting graph was recorded and it was confirmed that no residue was left on the skin of the forearm.

The battery was a metal cased Manganese Dioxide Lithium coin cell battery CR2330, from Panasonic, and the microelectronic housing was coated with a layer of

30 PolyDiMethylSiloxane (PDMS); MED-1137 from NuSil Technology.

The peel forces have been determined between the adhesive and the following parts with following results and with three repetitions of the test, where s indicates the standard deviation.

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Peel force between A and PDMS coated housing	0,1 N/25mm
Peel force between A and steel	22,5 N/25mm (s= 2,3)
Peel force between A and human skin	2,5 N/25mm (s= 0,25)

- 5 Furthermore, different types of materials may be used for different parts of the device and the microelectronic circuit and/or the housing whereby different peel forces may be provided. Thus it would be possible to achieve peel forces between the PSA and the skin in the general range of 1 – 5 N/25 mm, peel forces between the PSA and the housing generally below 1 N/25mm and the peel forces between the PSA and the metal casing of
- 10 the battery generally above 20 N/25mm.

- It can thus be understood, that when the sensor assembly 1 has been applied to the skin of a user it may easily be peeled off after use, by pulling the adhesive element with a force above the peel force between the PSA and the skin. The adhesive element 5 may then
- 15 easily be separated from the housing element 3 containing the microelectronic circuit 4. As the peel force between the adhesive element and the battery 6 is much higher than between the adhesive element and the housing, the battery is practically inseparable from the adhesive element, and thus the battery will be attached to the adhesive when the adhesive is separated from the housing.

Claims:

1. A three-dimensional adhesive device to be attached to the body surface of a mammal comprising an microelectronic system **characterized by**
- 5 (a) a three-dimensional adhesive body made of a pressure sensitive adhesive having an upper surface and a bottom surface;
- (b) a microelectronic system embedded in the body of the pressure sensitive adhesive;
- (c) one or more cover layer(s) attached to the upper surface; and
- 10 (d) optionally a release liner releasable attached to the bottom surface of the adhesive device.
2. An adhesive device according to claim 1 wherein the micro electronic system is a microelectronic sensing system.
- 15 3. The adhesive device according to any of claims 1-2 wherein the three-dimensional adhesive body has an essentially planar bottom surface adapted to adhere to the body surface of a mammal and an smooth upper surface, the adhesive device being thickest at the central part of the body and thinnest at the periphery of the body.
- 20 4. The adhesive device according to any of claims 1-3 wherein the thickness of the adhesive device at the periphery is less than 50 % of the thickness of the adhesive device where it is thickest, suitably the thickness at the periphery is less than 25 % of the thickness of the adhesive device where it is thickest, preferred the thickness at the periphery is less than 10 % of the thickness of the adhesive device where it is thickest ,
- 25 and most preferred the thickness at the periphery is less than 5 % of the thickness of the adhesive device where it is thickest.
5. The adhesive device according to claim 4 wherein the thickness at the periphery of the adhesive device is more than 0.05 mm, suitably between 0.05 and 0.4 mm and the thickness where the adhesive device is thickest, is between 0.5 and 15 mm, suitably
- 30 between 1 and 5 mm.
6. The adhesive device according to any of claims 1-5 wherein the angle between the bottom surface of the adhesive device and a line drawn from any point on the circumference of the and the point at the upper surface where the adhesive body is
- 35

thickest is below 60 degrees, preferably below 45 degrees and most preferably below 30 degrees.

5 7. The adhesive device according to any of claims 1-6 wherein the pressure sensitive adhesive making up the three-dimensional adhesive body is a mouldable thermoplastic pressure sensitive adhesive having a flexibility enabling the adhesive device to conform to the curvature of body parts while retaining its adhesive properties even under movements.

10 8. The adhesive device according to any of claims 1-7 wherein the pressure sensitive adhesive is an adhesive based on polymers selected from block-copolymers such as styrene-block-copolymers, and hydrogenated styrene-block-copolymers, amorphous poly-alpha-olefins (APAO), polyacrylics, polyvinylethers, polyurethanes, polyethylvinylacetate, silicone, or from the group of hydrogel pressure sensitive
15 adhesives.

 9. The adhesive device according to claim 8 wherein the block-copolymers such as styrene-block-copolymers, and hydrogenated styrene-block-copolymers is selected from Styrene/ethylene-Butylene/Styrene (SEBS), Styrene/Isoprene/Styrene (SIS), and
20 Styrene/Ethylene-Propylene/Styrene (SEPS).

 10. The adhesive device according to claim 8 wherein the adhesive is a PolyDiMethylSiloxane based adhesive, such as a PolyDiMethylSiloxane gel.

25 11. The adhesive device according to any of claims 1-10 wherein the pressure sensitive adhesive making up the adhesive body comprises hydrocolloids.

 12. The adhesive device according to any of claims 1-10 wherein the pressure sensitive adhesive making up the adhesive body is a foamed adhesive.
30

 13. The adhesive device according to any of claims 1-12 wherein the entire microelectronic system is integrated in the adhesive body and is completely covered by the adhesive body on all sides.

14. The adhesive device according to any of claims 1-12 wherein one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body on all sides and the rest of the component(s) of the microelectronic system are located elsewhere in the adhesive body, the components of the microelectronic system having the necessary mechanical and electrical connection to each other.

15. The adhesive device according to any of claims 1-12 wherein the entire microelectronic system is contained in one or more recesses provided in the upper surface of the adhesive body facing the cover layer(s).

16. The adhesive device according to claim 14 wherein one or more components of the microelectronic sensing system is integrated into the adhesive body and is covered by the adhesive body on all sides and the rest of the microelectronic system is contained in one or more recesses provided in the upper surface of the adhesive body facing the cover layer(s).

17. The adhesive device according to any of claims 1-12 wherein the entire microelectronic system is contained in one or more recesses provided in the adhesive bottom surface of the adhesive body.

18. The adhesive device according to claim 14 wherein a one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body at all sides and the rest of the microelectronic sensing system is contained in one or more recesses provided in the adhesive bottom surface of the adhesive body.

19. The adhesive device according to any of claims 1-12 wherein the entire microelectronic system is contained in one or more through hole(s) in the adhesive body and is accessible from both the upper surface facing the cover layer(s) and the adhesive bottom surface.

20. The adhesive device according to claim 14 wherein a one or more components of the microelectronic sensing system is integrated into the adhesive body and is covered by the adhesive body and the rest of the microelectronic system is contained in one or

more through hole(s) in the adhesive body and is accessible from both the upper surface facing the cover layer and the adhesive bottom surface.

5 21. The adhesive device according to claim 14 wherein one or more components of the microelectronic system is integrated into the adhesive body and is covered by the adhesive body, other components of the microelectronic system is contained in one or more through holes in the adhesive body and is accessible from both the upper surface facing the cover layer and the adhesive bottom surface, and the rest of the microelectronic system is contained in one or more recesses in the upper and/or bottom surface of the
10 adhesive body.

 22. The adhesive device according to any of claims 1-12 wherein one or more components of the microelectronic system is contained in one or more through holes in the adhesive body and is accessible from both the upper surface facing the cover layer
15 and the adhesive bottom surface and the rest of the microelectronic system is contained in one or more recesses in the upper and/or bottom surface of the adhesive body.

 23. The adhesive device according to claims 1-12 wherein one or more components of the micro electronic system is contained in one or more recesses in the upper surface
20 of the adhesive body and the rest of the microelectronic system is contained in one or more recesses in the bottom surface of the adhesive body.

 24. The adhesive device according to any of claims 1 to 23 wherein the microelectronic system or one or more components thereof is encapsulated in a material
25 different from the adhesive body.

 25. The adhesive device according to claim 24 wherein the microelectronic system or components thereof is encapsulated in a polymer film, a polymer foil, or a polymer coating or the microelectronic system or components thereof is moulded into a polymer material,
30 or is encapsulated in a glass or ceramic material.

 26. The adhesive device according to claim 25 wherein the polymer used for encapsulation is silicone rubber.

27. The adhesive device according to claims 1-26 wherein the one or more components of the microelectronic system is accessible from outside the adhesive body, and may be replaced by a similar component during the life time of the adhesive device.
- 5 28. The adhesive device according to claim 27 wherein the component, which may be exchanged, is the energy source, e.g. the battery.
29. The adhesive device according to claims 1-26 wherein the one or more components of the microelectronic system is accessible from outside the adhesive device, and the component(s) may be reused.
- 10 30. The adhesive device according to any of claims 27 –29 wherein the replaceable component(s) or the reusable component(s) is encapsulated and form a package, which fit a recess or a through hole in the adhesive body.
- 15 31. The adhesive device according to claim 30 wherein the package of encapsulated, replaceable or reusable component(s) is fixed into the adhesive body by a mechanical doubling, suitably snap lock mechanism.
- 20 32. The adhesive device according to claim 30 wherein the package of encapsulated, replaceable or reusable component(s) is fixed to the surface of the adhesive in the recess or through hole of the adhesive body.
- 25 33. The adhesive device according to claim 30 wherein the package of encapsulated, replaceable or reusable component(s) is fixed in a recess or through hole in the adhesive body, where said recess or trough hole is provided with an inner non-adhesive surface, such as a PDMS coating.
- 30 34. The adhesive device according to any of claims 1-33 wherein the microelectronic system comprises components selected from communication component(s), CPU, power source, storage component(s), transducer component(s), actuator component(s) and mechanical and/or electrical interconnection between the components.
- 35 35. The adhesive device according to any of claims 1-34 wherein microelectronic system is a system enabling wireless communication.

- 5 36. The adhesive device according to claim 34 wherein the transducer has a detecting element selected from electrodes (polar, bipolar), a pressure sensor, a needle with an electrode, an accelerometer, a photo detector, a microphone, ISFET, an NTC resistor, a band gap detector, an ion membrane, an enzyme detector or a condenser .
37. The adhesive device according to claim 36 wherein the transducer has a non-invasive detecting element, such as electrodes, e.g. steel electrodes.
- 10 38. The adhesive device according to claim 36 wherein the transducer has an invasive detecting element, such as a needle containing an electrode.
39. The adhesive device according to claims 34-36 where there is no physical contact between the detector and the skin of the mammal.
- 15 40. The adhesive device according to claim 34 wherein the microelectronic system comprises a Network HUB, a gateway or a coordinator system.
41. The adhesive device according to claim 34 wherein the microelectronic system includes a GPS.
- 20 42. The adhesive device according to claim 34 wherein the microelectronic system includes a RFID tag.
- 25 43. The adhesive device according to claim 40 wherein the microelectronic system is a gateway comprising storage and communication components, CPU and a battery encapsulated in plastic and working as a dedicated network coordinator for transmission of data to a central unit (CU).
- 30 44. The adhesive device according to claim 41 wherein the microelectronic system is a system selected from:
- 35 - a system comprising storage and communication components, CPU, battery, GPS, components for wireless synchronisation of real time clock for data logging of GPS data optionally encapsulated in plastic, and

- a system comprising storage and communication components, CPU, battery, GPS, components for wireless synchronisation of real time clock for data logging of GPS data, mobile net for data logging and transmission of data and position to mobile phones, optionally encapsulated in plastic,

45. The adhesive device according to claim 34 wherein the microelectronic system is useful for nerve stimulation and comprises storage and communication components, CPU, power source and transducer for transmitting data and power to an implant for nerve stimulation.

46. The adhesive device according to claim 34 wherein the microelectronic system is a system useful for electromyography and comprises a transducer, CPU, power source, communication and storage components and an optionally an actuator.

47. The adhesive device according to claim 1-46, wherein the device comprises a power source element for powering said microelectronic system, wherein

- the adhesive body is releasable attached to one or more of the components of the microelectronic system,
- the adhesive body has at least a first area for adhering to the body surface, and

48. The adhesive device according to claim 47, wherein the power source element is attached to the adhesive body and the adhesive body has at least a second area for adhering to one or more of the components of the microelectronic system.

49. The adhesive device according to claim 48 or 47, wherein a first peel force between the second area and the microelectronic circuit is smaller than a second peel force between the power source and the adhesive body.

50. The adhesive device according to claim 47, 48 or 49, wherein the power source element is at least partly contained in the adhesive body.

51. The adhesive device according to claim 47, 48, 49 or 50, wherein the adhesive device is adapted to be releasable connectable to a housing containing the

microelectronic system and that the housing is formed of a proximal housing part and a distal housing part.

52. The adhesive device according to claim 51, wherein the at least one power source is adapted to be received in a recess, the recess is formed in the distal housing part and that at least one electrical contact is provided in the distal housing providing electrical connection between the power source and the microelectronic circuit.

53. A sensor assembly adapted to be attached to the body surface of a mammal, comprising

- a sensor circuit, comprising a number of electrical components,
- at least one power source for powering at least one of the electrical components,
- at least one adhesive for attaching the sensor assembly to the body surface of a mammal, and
- that at least one of the power source and the adhesive is releasable connected to the sensor circuit.

54. A sensor assembly according to claim 53, wherein the sensor circuit is at least partly contained in a housing and that the housing is formed of a proximal housing part and a distal housing part.

55. A sensor assembly according to claim 54, wherein a first peel force between the adhesive and the housing is smaller than a second peel force between the adhesive and the battery.

56. A sensor assembly according to claim 54 or 55, wherein the at least one transducer is attached to the proximal surface of the proximal part.

57. A sensor assembly according to claim 54, 55 or 56, wherein

- a recess is formed in the distal housing part, the recess is adapted to receive the at least one power source, and
- at least one electrical contact is provided in the distal housing providing electrical connection between the at least one power source and the electrical components.

58. A multi-sensor network comprising one or more adhesive devices according to claims 1-52.

59. A multi-sensor network according to claim 58 comprising an adhesive device comprising a network coordinator, at least two adhesive devices comprising a microelectronic system useful for electromyography and comprises a transducer, CPU, power source, communication and storage components and an optionally an actuator and adhesive devices comprising a microelectronic system useful for suitable for measuring heart rate.

60. A method for producing an adhesive device according to claim 1 having embedded a microelectronic system in an adhesive, said device having a cover film and a release liner characterised by the adhesive body being compression moulded.

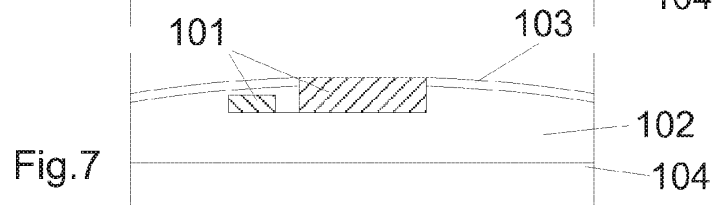
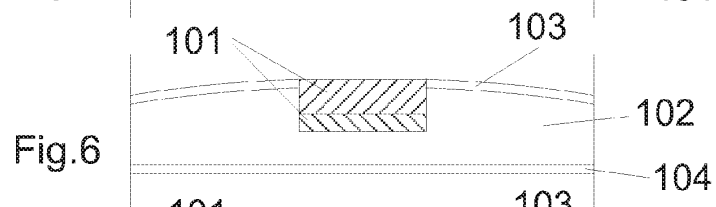
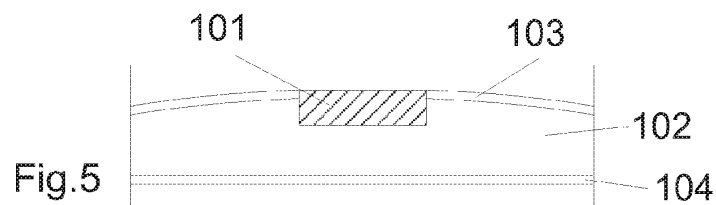
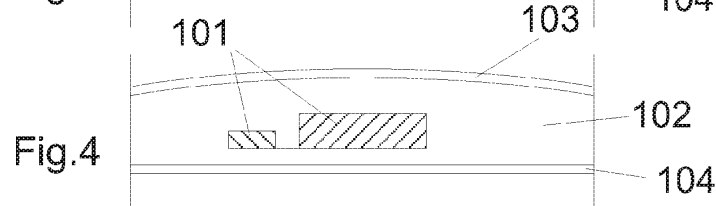
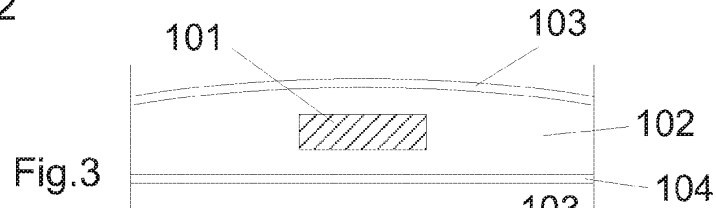
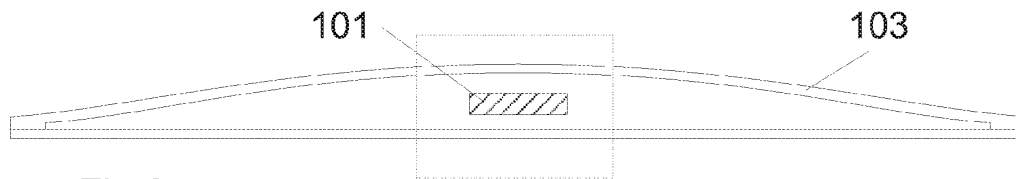
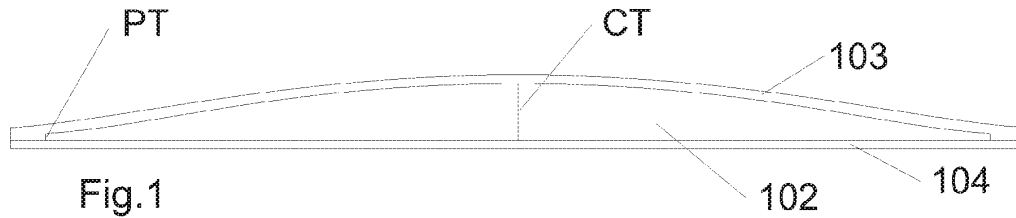
61. A method for producing an adhesive device according to claim 1 having embedded a microelectronic system in an adhesive, said device having a cover film and a release liner characterised by the adhesive body being injection moulded.

62. A method for producing an adhesive device according to claim 1 having embedded a microelectronic system in an adhesive, said device having a cover film and a release liner characterised by the adhesive body being formed by reaction moulding.

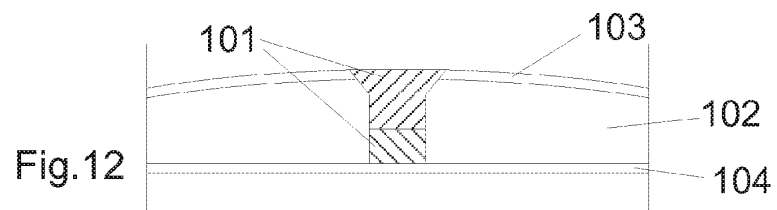
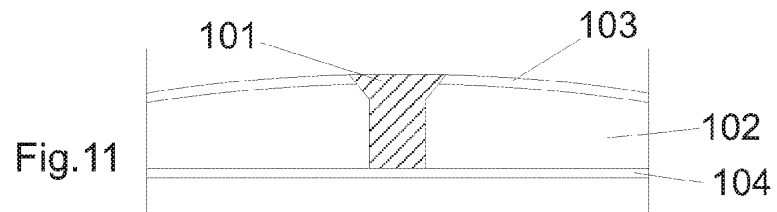
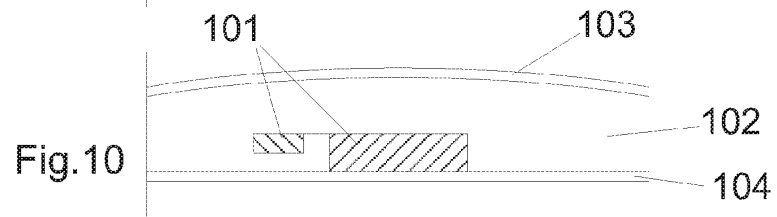
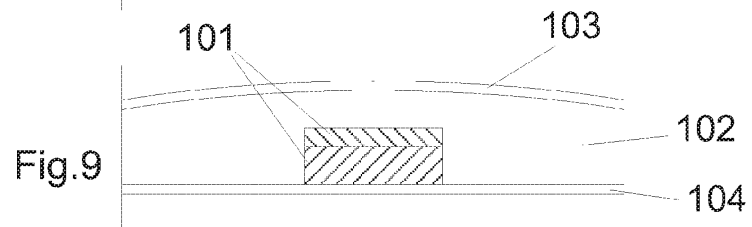
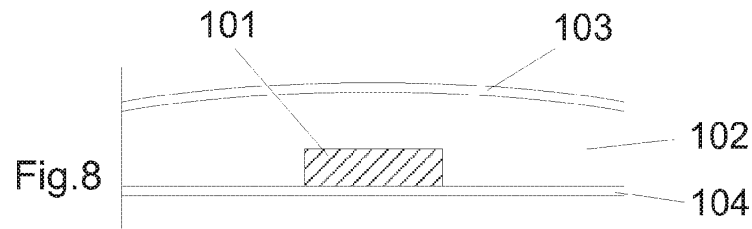
63. An adhesive device according to claim 1 having embedded a microelectronic system in the adhesive body and being connected to other electronic systems by wiring.

64. The use of a device comprising an adhesive element and a power source element, and where the device is used for attaching an electronic circuit to a surface and to power said electronic circuit, wherein said electronic circuit is releasable connectable to the adhesive element and the power source element.

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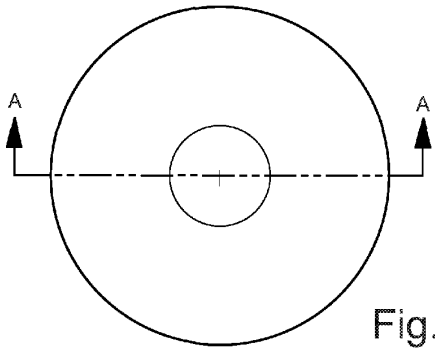


Fig.13

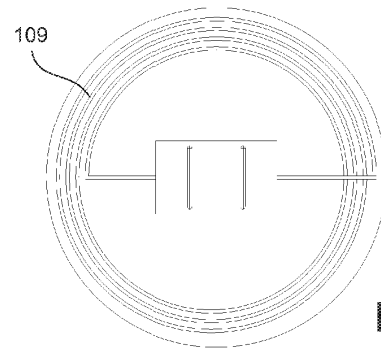


Fig.14

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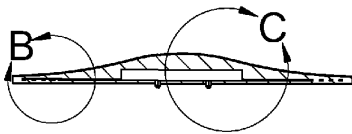


Fig.15

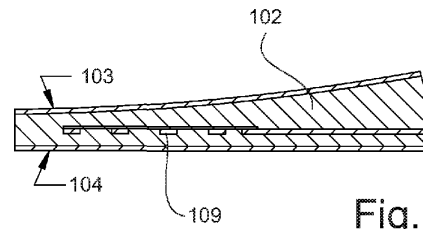


Fig.16

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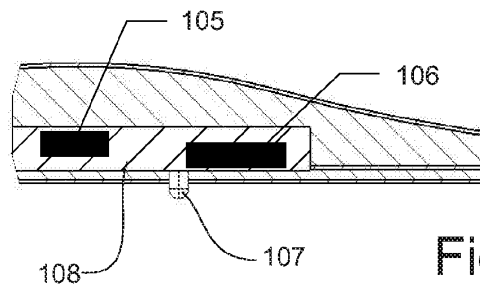


Fig.17

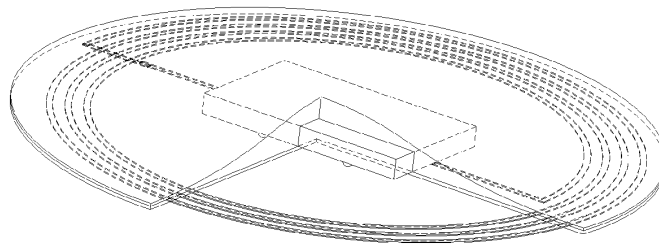
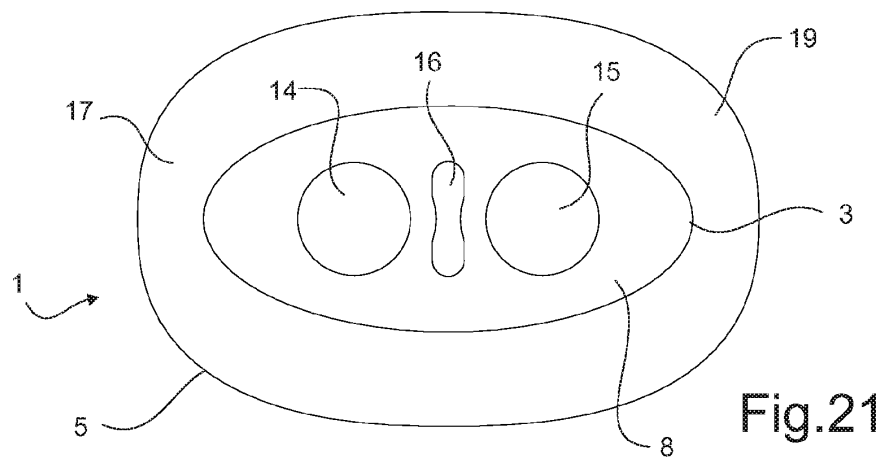
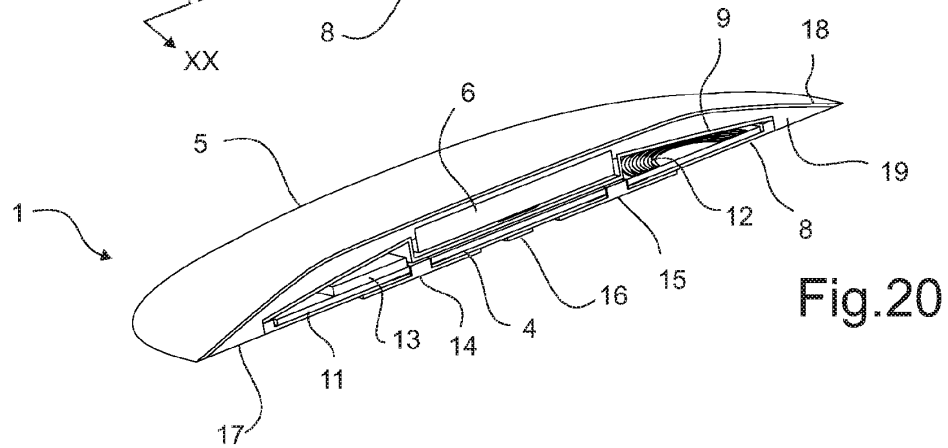
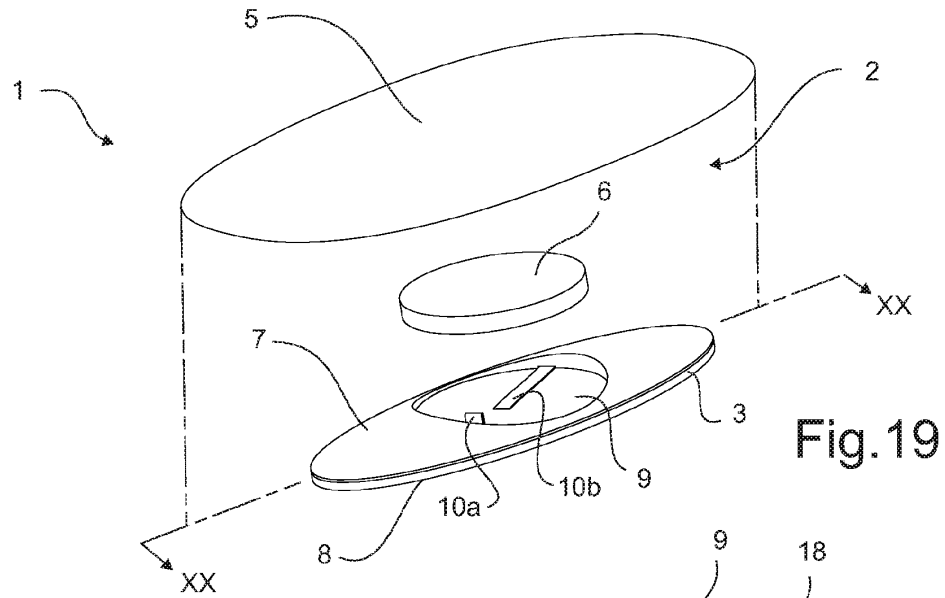
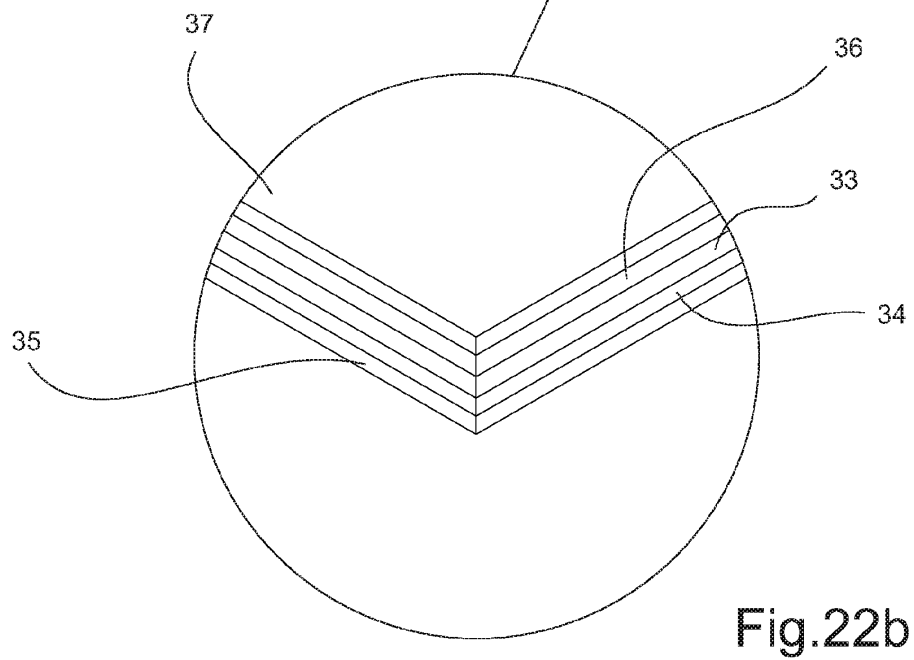
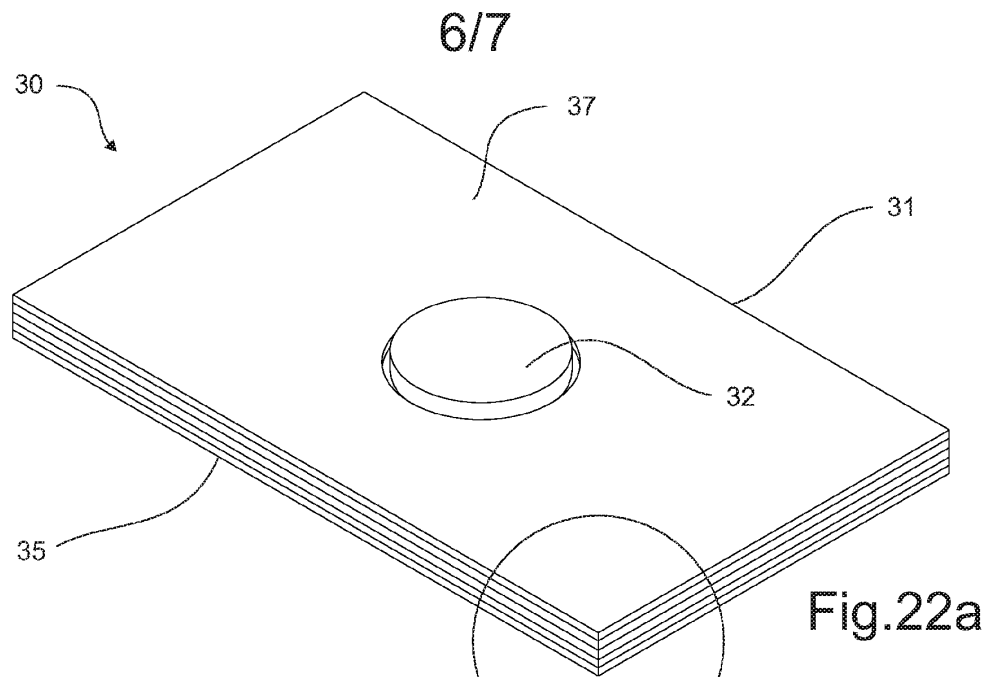
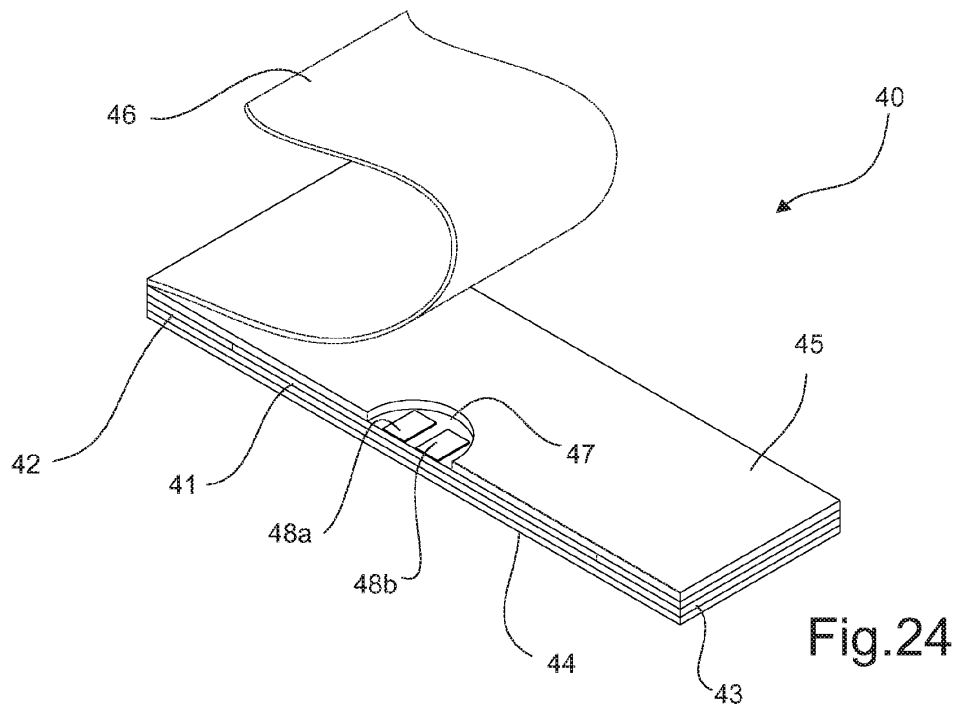
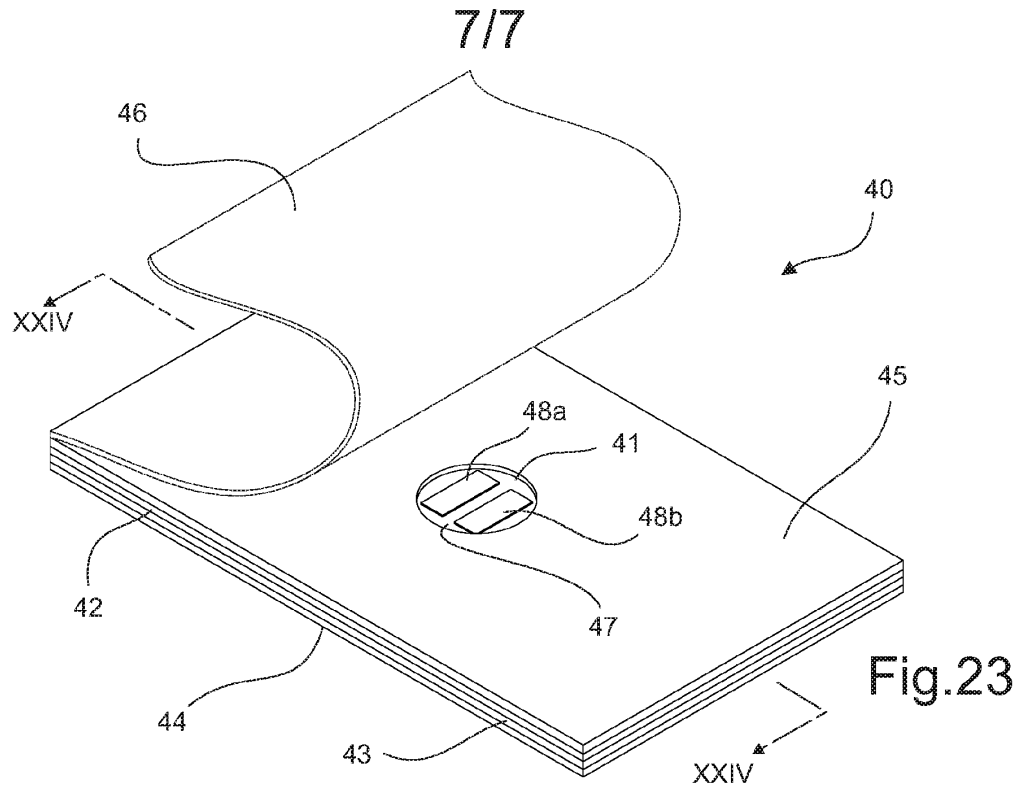


Fig.18

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	15/880,712
	Filing Date	January 26, 2018
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Johnson, Nicole F.
	Attorney Docket Number	3022036 US08

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):			
☒ That each item from a foreign patent information disclosure of information contained in the information disclosure statement was first cited in any communication office in a counterpart foreign application not more than three months prior to the filing of the 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 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	/Peter J. Bilinski/	Date (YYYY-MM-DD)	2018-07-20
Name/Print	Peter J. Bilinski	Registration Number	35,067
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.			

Electronic Acknowledgement Receipt	
EFS ID:	33234900
Application Number:	15880712
International Application Number:	
Confirmation Number:	9503
Title of Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	88750
Filer:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US08
Receipt Date:	20-JUL-2018
Filing Date:	26-JAN-2018
Time Stamp:	09:32:02
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	Miscellaneous Incoming Letter	2018-07-20-Transmittal-Form. pdf	72058	no	1
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Warnings:					

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	2018-07-20-PTO-SB-08a-b.pdf	173639 95e203a1969ee9da57135e55369ccd69c6cb1a6a	no	2
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3	Foreign Reference	WO-2006-094513-A2.pdf	3362616 7f6dd0697d7651cc2ecf48fd73dcb2fb67064a6b	no	76
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4	Non Patent Literature	European-Examination-Report-for-EP-07844766-1.pdf	2052678 282965b8892b963d2007c90a79b856ca40d81e88	no	4
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5	Miscellaneous Incoming Letter	2018-07-20-Certification-Statement.pdf	78251 57f9537bdf8b5afa6e51571e355117503adf1de13	no	1
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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	15/880,712	
	Filing Date	January 26, 2018	
	First Named Inventor	Steven D. Baker	
	Art Unit	3762	
	Examiner Name	Johnson, Nicole F.	
Total Number of Pages in This Submission	84	Attorney Docket Number	3022036 US08

ENCLOSURES <i>(Check all that apply)</i>		
☐ Fee Transmittal Form ☐ Fee Attached ☐ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☒ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ Incomplete Application ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☐ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC <i>(Appeal Notice, Brief, Reply Brief)</i> ☐ Proprietary Information ☐ Status Letter ☒ Other Enclosure(s) (please identify below): PTO/SB/08a/b (2 pgs); Certification Statement (1 pg); One (1) Foreign Patent Document (76 pgs) and One (1) NPL Document (4 pgs)
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Barclay Damon, LLP		
Signature	/Peter J. Bilinski/		
Printed name	Peter J. Bilinski		
Date	July 20, 2018	Reg. No.	35,067

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Application Number 	Application/Control No. 15/880,712	Applicant(s)/Patent under Reexamination BAKER ET AL.	
Document Code - DISQ		Internal Document – DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 7/3/18	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Lawana Hixon

U.S. Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 15/880,712
First Inventor : Baker, Steven D.
Filed : January 26, 2018
Art Unit : 3762
Examiner : Johnson, Nicole F.
Docket No. : 3022036 US08
Customer No. : 88,750
Confirmation No. : 9503
Title: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A
DISPOSABLE ELECTRODE MODULE

Mailstop: Amendment
Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Sir:

In response to the non-final Office Action, dated June 29, 2018, and having a three (3) month response deadline of September 29, 2018, Applicant herein responds, as follows:

Amendments to the Claims are reflected in the Listing of Claims, which begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Claims:

Please replace all prior and current listing of claims in the above-captioned application, with the following Listing of Claims:

Listing of Claims

1. (Original) A method for manufacturing a body-worn physiological sensor, the method comprising:
 - providing a disposable substrate made from an insulating material, said substrate comprising:
 - a flexible printed circuit board layer made from the insulating material;
 - at least two electrodes disposed on the disposable substrate; and
 - conductive traces defined between the at least two electrodes;
 - providing a computation-communication module, said module comprising:
 - a housing;
 - a processor disposed in the housing; and
 - attaching the computation-communication module to the disposable substrate.
2. (Original) The method of claim 1, further comprising:
 - providing conductive traces in the flexible circuit layer.
3. (Original) The method of claim 2, in which the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module.
4. (Original) The method of claim 1, further comprising:
 - providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels.

5. (Original) The method of claim 1, in which the computation-communication module is releasably attached to the disposable substrate.
6. (Original) The method of claim 1, further comprising:
providing a radio circuit in the computation-communication module.
7. (Original) The method of claim 3, further comprising:
at least partially covering the conductive traces with an insulating covering.
8. (Original) The method of claim 7, in which the insulating covering is a fabric.
9. (Original) The method of claim 1, further comprising:
integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.
10. (Original) The method of claim 3, further comprising:
screening the conductive traces onto the flexible printed circuit board layer.
11. (Original) The method of claim 9, in which each electrode includes an electrode gel and a conductive surface defining a half cell.
12. (Original) The method of claim 11, in which the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient.
13. (Original) The method of claim 3, further comprising:
providing a pacer circuit in the flexible printed circuit board layer of the disposable substrate.

14. (Original) A body-worn physiological sensor made by the process of:
 - providing a disposable substrate made from an insulating material, said substrate comprising:
 - a flexible printed circuit board layer made from an insulating material;
 - at least two electrodes disposed on the disposable substrate; and
 - conductive traces defined between the at least two electrodes;
 - providing a computation-communication module, said module comprising:
 - a housing;
 - a processor disposed in the housing; and
 - attaching the computation-communication module to the disposable substrate.
15. (Original) The body-worn physiological sensor of claim 14, wherein the process further comprises:
 - providing the conductive traces in the flexible printed circuit board layer.
16. (Original) The body-worn physiological sensor of claim 15, in which the process further comprises:
 - configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module.
17. (Original) The body-worn physiological sensor of claim 14, in which the computation-communication module is releasably attached to the disposable substrate.
18. (Original) The body-worn physiological sensor of claim 14, wherein the process further comprises:
 - providing the computation-communication module with a radio circuit.
19. (Original) The body-worn physiological sensor of claim 16, in which the process further comprises:
 - at least partially covering the conductive traces with an insulating covering.

20. (Original) The body-worn physiological sensor of claim 14, in which the process further comprises:

integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.

Remarks

This paper is timely filed in response to the non-final Office Action, dated June 29, 2018, in regard to the above-captioned application.

Status of Claims

Claims 1-20 were pending. The only outstanding issue in the Office Action is an obviousness-type double patenting rejection of the pending claims. With this paper, Applicant concurrently files a properly executed Terminal Disclaimer pursuant to relevant portions of 37 CFR §1.321 and MPEP §1490. Withdrawal of this rejection is respectfully requested.

Applicant gratefully acknowledges the allowability of all pending claims 1-20 over the prior art of record.

Conclusion

In summary, the above-captioned application is in an allowable condition and an expedited Notice of Allowance is earnestly solicited.

To further expedite disposition of this matter, the Examiner is invited to contact Applicant's representative at the telephone number listed below. The Examiner is further authorized to contact Applicant via electronic transmission, if needed, using the noted e-mail address below.

USSN 15/880,712
Response to Office Action, dated June 29, 2018
Response Dated: July 3, 2018

Other than the fee for filing the Terminal Disclaimer, no additional fees are due and owing for the timely filing of this paper. However and in the event that additional fees, extensions of time or additional extensions of time are needed, Applicant herein authorizes use of Applicant's Deposit Account 50-3010.

Respectfully submitted,
BARCLAY DAMON, LLP

/Peter J. Bilinski/

Date: July 3, 2018

Peter J. Bilinski
Registration No. 35,067
Attorney for Applicant
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pbilinski@barclaydamon.com

TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 3022036 US08
In re Application of: Steven D. Baker et al. Application No.: 15/880,712 Filed: January 26, 2018 For: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE The applicant, <u>Welch Allyn, Inc.</u>, owner of <u>100</u> percent interest 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 No. <u>9,433,366</u> as the term of said prior patent is presently shortened by any terminal disclaimer. The applicant 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 applicant 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. Check either box 1 or 2 below, if appropriate. 1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee. I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. 2. ☒ The undersigned is an attorney or agent of record. Reg. No. <u>35,067</u> <u>/Peter J. Bilinski/</u> Signature <u>July 3, 2018</u> Date <u>Peter J. Bilinski</u> Typed or printed name <u>Attorney for Applicant</u> Title <u>315-425-2700</u> Telephone Number ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.	

This collection of information is required by 37 CFR 1.321. 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.

TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	15/880,712	
	Filing Date	January 26, 2018	
	First Named Inventor	Steven D. Baker	
	Art Unit	3762	
	Examiner Name	Johnson, Nicole F.	
Total Number of Pages in This Submission	10	Attorney Docket Number	3022036 US08

ENCLOSURES <i>(Check all that apply)</i>		
☒ Fee Transmittal Form ☒ Fee Attached ☒ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☐ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation ☐ Change of Correspondence Address ☒ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC <i>(Appeal Notice, Brief, Reply Brief)</i> ☐ Proprietary Information ☐ Status Letter ☐ Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Barclay Damon, LLP		
Signature	/Peter J. Bilinski/		
Printed name	Peter J. Bilinski		
Date	July 3, 2018	Reg. No.	35,067

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. 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 2 hours 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.

Electronic Patent Application Fee Transmittal				
Application Number:		15880712		
Filing Date:		26-Jan-2018		
Title of Invention:		BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		
First Named Inventor/Applicant Name:		Steven D. Baker		
Filer:		Peter J Bilinski/Susanne Pelose		
Attorney Docket Number:		3022036 US08		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	160	160
Total in USD (\$)				160

Electronic Acknowledgement Receipt	
EFS ID:	33081401
Application Number:	15880712
International Application Number:	
Confirmation Number:	9503
Title of Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	88750
Filer:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US08
Receipt Date:	03-JUL-2018
Filing Date:	26-JAN-2018
Time Stamp:	14:23:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	070518INTEFSW00002957503010
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	Miscellaneous Incoming Letter	2018-07-03-Fee-Transmittal.pdf	72342	no	1
			efc84f3e788039d605aa654e6b08debcfa0a3f09		
Warnings:					
Information:					
2		2018-07-03-Amendment.pdf	118924	yes	7
			5563d78f028529004860046b80c80df9c075741d		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	7	
Warnings:					
Information:					
3	Terminal Disclaimer Filed	2018-07-03-Terminal-Disclaimer.pdf	76513	no	1
			33aaf4f0963542814e27ea4054b898ab4c38fdcc8		
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	2018-07-03-Transmittal-Form.pdf	69447	no	1
			9586221ca1dd4220c559ade41854300b7ec2663f		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30509	no	2
			afe7f164ef647c1bc7624e01bc9759415c948a36		

Warnings:	
Information:	
Total Files Size (in bytes):	367735
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.	

FEE TRANSMITTAL**Complete if known**

☐ Applicant asserts small entity status. See 37 CFR 1.27.	Application Number	15/880,712
☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.	Filing Date	January 26, 2018
	First Named Inventor	Steven D. Baker
	Examiner Name	Johnson, Nicole F.
	Art Unit	3762
TOTAL AMOUNT OF PAYMENT (\$)	160.00	Practitioner Docket No. 3022036 US08

METHOD OF PAYMENT (check all that apply)
☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-3010 Deposit Account Name: Barclay Damon, LLP

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**
☒ Charge any additional fee(s) or underpayment of fee(s) ☐ Credit any overpayment of fee(s) under 37 CFR 1.16 and 1.17

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES** (U = undiscounted fee; S = small entity fee; M = micro entity fee)

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	300	150*	75	660	330	165	760	380	190	
Design	200	100	50	160	80	40	600	300	150	
Plant	200	100	50	420	210	105	620	310	155	
Reissue	300	150	75	660	330	165	2,200	1,100	550	
Provisional	280	140	70	0	0	0	0	0	0	

* The \$150 small entity status filing fee for a utility application is further reduced to \$75 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	100	50	25
Each independent claim over 3 (including Reissues)	460	230	115
Multiple dependent claims	820	410	205
Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
-20 or HP = _____ x _____ = _____			
HP = highest number of total claims paid for, if greater than 20.			
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
-3 or HP = _____ x _____ = _____			
HP = highest number of independent claims paid for, if greater than 3.			

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

4. OTHER FEE(S)

Non-English specification, \$130 fee (no small or micro entity discount)

Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)

Other (e.g., late filing surcharge): Terminal Disclaimer (\$160.00) \$160.00

SUBMITTED BY

Signature	/Peter J. Bilinski/	Registration No. (Attorney/Agent) 35,067	Telephone 315-425-2700
Name (Print/Type)	Peter J. Bilinski		Date July 3, 2018

This collection of information is required by 37 CFR 1.136. 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, 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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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 15/880,712		Filing Date 01/26/2018		☐ 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), (j), 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 \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*			X \$	=			
☐ 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	07/03/2018	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 \$100 =		0	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X \$460 =		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 \$		=	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$		=	
	☐ 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. ** 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 number found in the appropriate box in column 1.									

LIE
ANNETTE COWAN

This collection of information is required by 37 CFR 1.16. 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 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.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/880,712	01/26/2018	Steven D. Baker	3022036 US08	9503
88750	7590	06/29/2018		
Barclay Damon, LLP Barclay Damon Tower 125 East Jefferson Street SYRACUSE, NY 13202			EXAMINER JOHNSON, NICOLE F	
			ART UNIT 3762	PAPER NUMBER
			NOTIFICATION DATE 06/29/2018	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@hblaw.com

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Double Patenting

2. 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 §§ 706.02(l)(1) - 706.02(l)(3) 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.

3. Claim 14 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 9,433,366. Although the claims at issue are not identical, they are not patentably distinct from each other because both claimed sets are directed towards a body-worn physiological sensor comprising a disposable substrate/module comprising a flexible printed layer, conductive/resistive traces and a computer-communication module.

Allowable Subject Matter

4. Claims 1-13 are allowed.

5. Claims 15-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is an examiner's statement of reasons for allowance: The closest prior art, Harry (as cited in 14/880613), fails to disclose, suggest and/or teach the claimed invention since the reference is silent in regards to a monitoring device having a disposable electrode module comprising a flexible circuit layer an insulating member having an opening on opposing sides of the module, each opening sized to receive an electrode gel, in combination with the other claimed elements (e.g., see 'Arguments'.)

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. JOHNSON whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Koharski can be reached on 571-272-7230. 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.

/NICOLE F. JOHNSON/
Primary Examiner, Art Unit 3762

Notice of References Cited	Application/Control No. 15/880,712	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	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-2002/0099277 A1	07-2002	Harry, Andrea	A61B5/0002	600/301
*	B	US-2004/0030258 A1	02-2004	Williams, Christopher Edward	A61B5/0478	600/544
*	C	US-2008/0139953 A1	06-2008	Baker; Steven D.	A61B5/0006	600/509
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

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

Search Notes 	Application/Control No. 15880712	Applicant(s)/Patent Under Reexamination BAKER ET AL.
	Examiner NICOLE F JOHNSON	Art Unit 3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner
A61B5/0484	6/25/2018	NFJ

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	372 & 508-509	6/25/2018	NFJ

* 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
Inventor Search (PE2E)	6/25/2018	NFJ
EAST Search (see attachment)		
Consulted search notes from 14/880413 (same patent family)		

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	3202	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:54
L2	5514	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:54
L3	918	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:57
L4	1413	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:58
L5	2395	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/06/25 08:58
S1	1534	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:14
S2	2846	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:16
S3	717	600/372.ccls.	US-PGPUB;	OR	OFF	2013/05/11

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			12:25
S4	38520	(eck or eckg or cardiac or heart) same monitor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S5	3417	S4 and (electrical same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S6	1847	S5 and (power same source)\	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S7	53826	(current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S8	33	S6 and (current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S9	33	S6 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S10	23	S9 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:27
S11	4727	(external) same ((heart or EKG or EOG) same monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2013/05/11 12:38

			IBM_TDB			
S12	2815	S11 and @py<="2009"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
S13	11	S12 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:39
S14	351	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:52
S15	3	"20030171743"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/07/16 10:50
S16	1	S15 and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/07/16 10:51
S17	1758	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:02
S18	3249	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:02
S19	829	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:03
S23	1956	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2014/01/13 11:56

			JPO; DERWENT; IBM_TDB			
S24	3618	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 11:59
S25	59931	(substrate same resistivity)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:03
S26	7022177	S25 and ((print same pattern) same thickness)"0"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:04
S27	502	S25 and ((print same pattern) same thickness)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:04
S28	5	S27 and (medical same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:04
S29	925	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/01/13 12:09
S33	2367	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/09/30 15:21
S34	4254	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/09/30 15:24
S35	1095	600/372.ccls.	US-PGPUB; USPAT;	OR	OFF	2014/09/30 15:25

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S36	2559	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/21 16:08
S37	4544	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/21 16:12
S38	2559	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:27
S39	4544	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:46
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S41	735	S40 and adhesive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:51
S42	398	S41 and (conductors or trace\$2)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 08:51
S44	1190	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 09:00

S45	2049	(external same sensor) same (flexible same circuit)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
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S47	398	S46 and (conductors or trace\$2)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
S48	7	S47 and (electrode\$2 same gel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:02
S49	6137	h05k3/361.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:06
S50	0	A61B5/04084.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:10
S51	1544	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/02/23 12:10
S52	1231	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:32
S53	2686	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2015/05/30 11:33

			DERWENT; IBM_TDB			
S54	4711	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:37
S55	0	h05k3/361.cpc ". "	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:37
S56	1580	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/30 11:37
S62	2781	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/14 19:17
S63	4863	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/14 19:17
S64	2	"20080139953" and (current same limit\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/15 11:23
S65	20	("2008/0139953").URPN.	USPAT	OR	OFF	2015/11/15 11:36
S66	23	("20020099277" "20030055478" "20030069510" "20030073915" "20050154325" "20060224072" "20080139953" "20080275327" "4082086" "4779630" "5042481" "5224479" "5343869" "5458124" "5622168" "5645063" "5921925" "6115638" "6161036" "6453186" "6572636" "6585707" "6730025").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:36
S67	1907	600/508.CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:37
S68	3569	600/509.ccls.	US-PGPUB;	OR	OFF	2015/11/15

			USPAT; USOCR			11:37
S69	3950	600/301.ccls.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/15 11:38
S70	1716	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/15 11:38
S72	1	"20020099277" and trace\$2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/11/15 11:55
S73	4968	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/15 15:25
S74	2864	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/15 15:25
S75	1286	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/15 15:25
S76	789	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/15 15:25
S77	4972	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S78	2870	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10

S79	1286	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S80	789	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:10
S81	1784	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/17 11:16
S82	2892	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 08:59
S83	4999	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 08:59
S84	1289	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 08:59
S85	1800	A61B5/0484.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/05/02 09:01

6/25/2018 9:10:31 AM

C:\Users\nlavert\Documents\EAST\Workspaces\15880712.wsp

Bibliographic Data

Application No: 15/880,712

Foreign Priority claimed: ☐ Yes ☒ No

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

Verified and Acknowledged:

/NICOLE F JOHNSON/

NFJ

Examiner's Signature

Initials

Title:

BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
01/26/2018	600	3762	3022036 US08
RULE			

APPLICANTS

Welch Allyn, Inc., Skaneateles Falls, NY, UNITED STATES

INVENTORS

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Eric T. McAdams Whitehead, UNITED KINGDOM

James P. Welch Mission Viejo, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15237719 08/16/2016 PAT 9877663

15237719 is a CON of 14880413 10/12/2015 PAT 9433366

14880413 is a CON of 14595815 01/13/2015 PAT 9155484

14595815 is a CON of 14268666 05/02/2014 PAT 8965492

14268666 is a CON of 14103219 12/11/2013 PAT 8750974

14103219 is a DIV of 13488520 06/05/2012 PAT 8630699

13488520 is a CON of 11591619 11/01/2006 PAT 8214007

FOREIGN APPLICATIONS

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SYRACUSE, NY 13202

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	15/237,719
				Filing Date	August 16, 2016
				First Named Inventor	Steven D. Baker
				Art Unit	3762
				Examiner Name	Johnson, Nicole F.
				Attorney Docket Number	3022036 US07
Sheet	1	of	2		

[illegible][illegible]

Examiner Signature	/NICOLE F LAVERT/	Date Considered	06/25/2018
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 806. Draw line through citation if not in conformance and not considered. Include copy of the form with lead communication to applicant. * CITE NO. Those applications which are marked with a single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.95a(2)(4)(g)) because that application was filed after June 30, 2003 or is available in the IFW. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov/mpep/801.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.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. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. * Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	15/237,719
		Filing Date	August 16, 2016
		First Named Inventor	Steven D. Baker
		Art Unit	3762
		Examiner Name	Johnson, Nicole F.
		Attorney Docket Number	3022036 US07
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AE	Supplementary European Search Report for EP 07 844 786.1; Dated: May 31, 2017; 10 pages	

Examiner Signature	/NICOLE F LAVERT/	Date Considered	06/25/2018
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¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	15/237,719
				Filing Date	August 16, 2016
				First Named Inventor	Steven D. Baker
				Art Unit	3762
				Examiner Name	Johnson, Nicole F.
Sheet	1	of	2	Attorney Docket Number	3022036 US07

[illegible][illegible]

Examiner Signature	/NICOLE F LAVERT/	Date Considered	06/25/2018
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iRhythm, Inc. / Welch Allyn, Inc.

Exhibit 1008

Page 155

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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	15/237,719
		Filing Date	August 16, 2016
		First Named Inventor	Steven D. Baker
		Art Unit	3762
		Examiner Name	Johnson, Nicole F.
		Attorney Docket Number	3022036 US07
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AE	European Supplementary Partial Search Report for EP 07 84 4766.1; Dated: February 24, 2017; 7 pages	

Examiner Signature	/NICOLE F LAVERT/	Date Considered	06/25/2018
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FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number:	Application Number:
	3622636 (US92)	130488,720
	Applicant: Steven G. Traker et al.	Confirmation No.: 9661
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,141,067 A	02/27/1979	Ferreira			
	4,791,938	12/20/1988	Asai et al.			
	4,800,894 A	01/31/1989	Milani			
	4,857,109	09/18/1990	Groeger et al.			
	4,958,845	09/25/1990	Cadell et al.			
	4,974,807	12/04/1990	Miwa			
	5,257,831	11/02/1993	Wik			
	5,294,928 A	03/15/1994	Cocper et al.			
	5,309,918 A	05/10/1994	Schraag			
	5,319,383	06/07/1994	Weich et al.			
	5,458,122	10/17/1995	Heithuin			
	5,515,738	05/14/1996	Sarhan			
	5,538,007	07/23/1996	Gorman			
	5,544,661	03/13/1996	Davis et al.			
	5,579,001	11/26/1996	Dempsey et al.			
	5,579,776	12/03/1996	Dempsey et al.			
	5,600,071	02/04/1997	Soorlakumar et al.			
	5,682,803	11/04/1997	Gideon et al.			
	5,687,734	11/18/1997	Dempsey et al.			
	5,694,940	12/09/1997	Unger et al.			
	5,743,289	04/28/1998	Okipami et al.			
	5,748,103	05/05/1998	Flach et al.			
	5,767,791	06/16/1998	Stoop et al.			
	5,808,331	09/15/1998	Zhang et al.			
	5,832,480	11/03/1998	Riley			
	5,871,451	02/16/1999	Unger et al.			

EXAMINER /NICOLE F LAVERT/	DATE CONSIDERED 06/25/2018
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* Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Dossier Number: W2226 L002	Application Number: 13488,530
	Applicant: Steven D. Risken et al	Confirmation No.: 9591
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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EXAMINER: /NICOLE F LAVERT/	DATE CONSIDERED: /NICOLE F LAVERT/
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Date: June 7, 2012

Sheet 3 of 6

Customer Ref: 89759

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number:	Application Number:
	3022635 (US02)	13488,320
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group An Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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EXAMINER: /NICOLE F LAVERT/	DATE CONSIDERED: 06/25/2018
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iRhythm, Inc. / Welch Allyn, Inc.

Exhibit 1008

Page 159

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 2012016 USPTO	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 8661
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2002/0106799 A1	08/08/2002	Potts et al.			
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Date: June 1, 2017

Sheet 3 of 6

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Document Number:	Application Number:
	102036-11502	11488529
	Applicant: Steven D. Baker et al.	Confirmation No.: 9001
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2010/0145202	08/10/2010	McLaughlin et al.			
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
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	11088546	03/30/1999	JP			✓	
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EXAMINER /NICOLE F LAVERT/	DATE CONSIDERED 06/25/2018
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Date: June 7, 2012

Sheet 6 of 6

Customer No.: 88758

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use separate sheets if necessary)	Locket Number: 3022036 US02	Application Number: 137485,920
	Applicant: Steven D. Baker et al.	Confirmation No.: 9891
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

OTHER DOCUMENTS (Including Author, Title, Date, Page(s), etc.)		
		Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2008-507455 (5 pages).
		International Search Report/Written Opinion for PCT/US07/83156 dated May 15, 2008 (16 pages).

EXAMINER	/NICOLE F. LAVERT/	DATE CONSIDERED	06/25/2018
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Date: May 23, 2011

Sheet 2 of 2

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Doc. of Number:	Application Number:
	1122036/11801	11/501,618
	Applicant: Steven F. Baker et al.	Confirmation No.: 7975
	Filing Date: November 1, 2006	Class. Act (601): 3162

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 2009/142385	11/27/2008	WO				
	WO 2009/056859	5/7/2009	WO				

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Notice of References Cited	Application/Control No. 15/237,719	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	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-2007/0219588 A1	09-2007	Freeman; Gary A.	A61H31/005	607/5
*	B	US-2009/0018409 A1	01-2009	Benet; Matthew J.	A61B5/0408	600/301
	C	US-				
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Notice of References Cited

Part of Paper No. 20170106

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Notice of References Cited	Application/Control No. 15/237,719	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art. Unit 3762	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-2003/0135125 A1	07-2003	Lu, Steven N.	A61B5/0008	600/510
	B	US-				
	C	US-				
	D	US-				
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FOREIGN PATENT DOCUMENTS

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Notice of References Cited

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Notice of References Cited	Application/Control No. 11/551,519	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERGT	Art Unit 3762	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,294,925 A	03-1994	Cooper et al.	341/142
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*	G	US-2005/0117489 A1	06-2005	Jackson et al.	600/516
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*	I	US-2006/0074284 A1	04-2006	Juola et al.	600/372
*	J	US-2006/0136001 A1	06-2006	Onaga et al.	607/009
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Notice of References Cited	Application/Control No. 18/488,520	Applicant(s)/Patent Under Reexamination BAKER ET AL	
	Examiner NICOLE F. LAVERT	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

* A	Document Number Country Code Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-2008/0134963 A1	06-2008	Baker et al.	600/509
B	US-			
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I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

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U.S. Patent and Trademark Office
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Part of Paper No. 20130511

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Notice of References Cited	Application/Control No. 14/595,815	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3782	Page 1 of 1

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*	A	US-2004/0030258 A1	02-2004	Williams et al.	600/544
	B	US-			
	C	US-			
	D	US-			
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	F	US-			
	G	US-			
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	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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Notice of References Cited

Part of Paper No. 20150223

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Notice of References Cited	Application/Control No. 14/860,413	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	Page 1 of 1

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*		Document Number Country Code Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2002/0099277 A1	07-2002	Harry, Andrea	A61B5/0002	600/301
	B	US-				
	C	US-				
	D	US-				
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	M	US-				

FOREIGN PATENT DOCUMENTS

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/880,712	01/26/2018	Steven D. Baker	3022036 US08

CONFIRMATION NO. 9503

PUBLICATION NOTICE



88750
Barclay Damon, LLP
Barclay Damon Tower
125 East Jefferson Street
SYRACUSE, NY 13202

Title:BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Publication No.US-2018-0146877-A1

Publication Date:05/31/2018

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

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

PATENT APPLICATION FEE DETERMINATION RECORD						Application or Docket Number 15/880,712				
Substitute for Form PTO-875										
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR 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			N/A	300			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	660			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760			
TOTAL CLAIMS (37 CFR 1.16(i))	20	minus 20 = *				x 100 =	0.00			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *				x 460 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00			
			TOTAL			TOTAL	1720			
* 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		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			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.										



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
15/880,712	01/26/2018	3735	1720	3022036 US08	20	2

CONFIRMATION NO. 9503

FILING RECEIPT



000000097506800

88750
Barclay Damon, LLP
Barclay Damon Tower
125 East Jefferson Street
SYRACUSE, NY 13202

Date Mailed: 02/22/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Steven D. Baker, Beaverton, OR;
Eric T. McAdams, Whitehead, UNITED KINGDOM;
James P. Welch, Mission Viejo, CA;

Applicant(s)

Welch Allyn, Inc., Skaneateles Falls, NY;

Power of Attorney: The patent practitioners associated with Customer Number 88750

Domestic Priority data as claimed by applicant

This application is a CON of 15/237,719 08/16/2016 PAT 9877663
which is a CON of 14/880,413 10/12/2015 PAT 9433366
which is a CON of 14/595,815 01/13/2015 PAT 9155484
which is a CON of 14/268,666 05/02/2014 PAT 8965492
which is a CON of 14/103,219 12/11/2013 PAT 8750974
which is a DIV of 13/488,520 06/05/2012 PAT 8630699
which is a CON of 11/591,619 11/01/2006 PAT 8214007

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: 02/20/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/880,712**

Projected Publication Date: 05/31/2018

Non-Publication Request: No

Early Publication Request: No

Title

BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE
MODULE

Preliminary Class

600

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

page 2 of 4

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

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

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).

SelectUSA

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 U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor 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.

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UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	3022036 US08
	First Named Inventor	Steven D. Baker
	Title	Body Worn Physiological Sensor Device Having...
	Priority Mail Express® Label No.	N/A

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>32</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>14</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: _____ _____ _____ _____ _____
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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>88,750</u> OR ☐ Correspondence address below				
Name				
Address				
City	State	Zip Code		
Country	Telephone	Email		
Signature	/Peter J. Bilinski/		Date	January 26, 2018
Name (Print/Type)	Peter J. Bilinski		Registration No. (Attorney/Agent)	35,067

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.

FEE TRANSMITTAL**Complete if known**

☐ Applicant asserts small entity status. See 37 CFR 1.27.	Application Number	Not Yet Assigned
☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.	Filing Date	Concurrently Herewith
	First Named Inventor	Steven D. Baker
	Examiner Name	Not Yet Assigned
	Art Unit	Not Yet Assigned
TOTAL AMOUNT OF PAYMENT (\$)	Practitioner Docket No.	3022036 US08

METHOD OF PAYMENT (check all that apply)
☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-3010 Deposit Account Name: Barclay Damon, LLP

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**
☒ Charge any additional fee(s) or underpayment of fee(s) ☐ Credit any overpayment of fee(s) under 37 CFR 1.16 and 1.17

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)**

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	300	150*	75	660	330	165	760	380	190	1,720.00
Design	200	100	50	160	80	40	600	300	150	
Plant	200	100	50	420	210	105	620	310	155	
Reissue	300	150	75	660	330	165	2,200	1,100	550	
Provisional	280	140	70	0	0	0	0	0	0	

* The \$150 small entity status filing fee for a utility application is further reduced to \$75 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	100	50	25
Each independent claim over 3 (including Reissues)	460	230	115
Multiple dependent claims	820	410	205
Total Claims			
20	-20 or HP = 0	x	0
HP = highest number of total claims paid for, if greater than 20.			
Indep. Claims			
2	-3 or HP = 0	x	0
HP = highest number of independent claims paid for, if greater than 3.			

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
46	- 100 = 0	/ 50 = 0 (round up to a whole number)	x	0

4. OTHER FEE(S)

Non-English specification, \$130 fee (no small or micro entity discount)

Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)

Other (e.g., late filing surcharge): _____

SUBMITTED BY

Signature	/Peter J. Bilinski/	Registration No. (Attorney/Agent) 35,067	Telephone 315-425-2700
Name (Print/Type)	Peter J. Bilinski	Date January 26, 2018	

This collection of information is required by 37 CFR 1.136. 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, 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.

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	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		
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		
	Steven	D.	Baker			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Beaverton	State/Province	OR	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	c/o Welch Allyn, Inc., Attn: Legal Dept.					
Address 2	4341 State Street Road					
City	Skaneateles Falls	State/Province	NY			
Postal Code	13153-0220	Country	US			
Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Eric	T.	McAdams			
Residence Information (Select One) ☐ US Residency ☒ Non US Residency ☐ Active US Military Service						
City	Whitehead	Country of Residence	UK			
Mailing Address of Inventor:						
Address 1	c/o Welch Allyn, Inc., Attn: Legal Dept.					
Address 2	4341 State Street Road					
City	Skaneateles Falls	State/Province	NY			
Postal Code	13153-0220	Country	US			
Inventor 3					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	James	P.	Welch			

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Mission Viejo	State/Province	CA	Country of Residence	US
Mailing Address of Inventor:					
Address 1	c/o Welch Allyn, Inc., Attn: Legal Dept.				
Address 2	4341 State Street Road				
City	Skaneateles Falls	State/Province			
Postal Code	13153-0220	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	88750
Email Address	ipdocket@barclaydamon.com Add Email Remove Email

Application Information:

Title of the Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		
Attorney Docket Number	3022036 US08	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	14	Suggested Figure for Publication (if any)	6

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

Publication Information:
☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	88750		

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	15237719	2016-08-16		
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15237719	Continuation of	14880413	2015-10-12	9433366	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)
14880413	Continuation of	14595815	2015-01-13	9155484	2015-10-13
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14595815	Continuation of	14268666	2014-05-02	8965492	2015-02-24

Application Data Sheet 37 CFR 1.76			Attorney Docket Number		3022036 US08
			Application Number		
Title of Invention		BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE			

Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14268666	Continuation of	14103219	2013-12-11	8750974	2014-06-10

Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14103219	Division of	13488520	2012-06-05	8630699	2014-01-14

Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13488520	Continuation of	11591619	2006-11-01	8214007	2012-07-03

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	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

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).

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

Applicant Information:

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Applicant 1			
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:			
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

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.

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:

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This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Peter J. Bilinski/		Date (YYYY-MM-DD)	2018-01-26
First Name	Peter J.	Last Name	Bilinski	Registration Number 35067

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3022036 US08
		Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

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.**

**BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE
ELECTRODE MODULE**

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application is a continuation application of, and claims priority and benefit to co-pending U.S. Patent Application Serial Number 15/237,719, filed August 16, 2016 and entitled: “Body Worn Physiological Sensor Device Having a Disposable Electrode Module”, which is a continuation of U.S. Patent Application Serial Number 14/880,413, filed October 12, 2015 and entitled: “Body Worn Physiological Sensor Device Having a Disposable Electrode Module”, now issued U.S. Patent No. 9,433,366 B2, which is a continuation of U.S. Patent Application Serial Number 14/595,815, filed January 13, 2015 and entitled: “Body Worn Physiological Sensor Device Having a Disposable Electrode Module”, now issued U.S. Patent No. 9,155,484 B2, which is a continuation of U.S. Patent Application Serial Number 14/268,666, filed May 2, 2014, and entitled: “Body Worn Physiological Sensor Device Having a Disposable Electrode Module”, now issued U.S. Patent No. 8,965,492 B2, which is a continuation application of U.S. Patent Application Serial Number 14/103,219, filed December 11, 2013, and entitled “Body Worn Physiological Sensor Device Having a Disposable Electrode Module”, now issued U.S. Patent No. 8,750,974 B2, which is a divisional application of, and claims priority and benefit to, U.S. Patent Application Serial Number 13/488,520, filed June 5, 2012, and entitled “Body Worn Physiological Sensor Device Having a Disposable Electrode Module”, and now issued U.S. Patent No. 8,630,699, which is a continuation application of U.S. Patent Application Serial Number 11/591,619, filed November 1, 2006, and entitled “Body Worn Physiological Sensor Device Having a Disposable Electrode Module” and now issued U.S. Patent No. 8,214,007. All of the aforementioned patent(s) and patent application(s) are herein incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] This invention relates generally to a physiological monitor and more particularly to a body worn physiological monitor.

BACKGROUND OF THE INVENTION

[0003] Measurements of various physiological parameters are important to the study of the human condition. Physiological measurements can be particularly important in a health care setting, such as in a hospital. One of the more important physiological measurements performed on a patient is the electrocardiogram (ECG), showing the condition of the human heart.

[0004] Portable patient monitors have evolved that allow patients to enjoy at least some mobility. Typically a battery operated monitor can be hung on a belt, shoulder strap, or carried by a patient using some other similar hanging arrangement. Sensors, such as ECG electrodes, are affixed to the patient's body, such as with tape, and connected to the battery operated monitor by wires. After a fixed interval of time, or at a low battery indication, the batteries can be replaced or recharged. One example of a portable patient monitor is the Micropaq wireless patient monitor, manufactured by Welch Allyn, Inc., that permits multi-parameter monitoring and patient alarm capabilities built in a small, rugged, lightweight, patient-wearable device.

[0005] Another version of a portable physiological monitor is the heart rate monitor typically used by individuals engaged in an athletic activity. The monitor includes a sensor, which generally makes direct or indirect contact with an individual's chest to monitor heart beats and then by wires, or by wireless techniques, the sensor transmits the sensed heart beat to a nearby microcomputer based monitor and display. Such units generally measure only heart beat and are not capable of doing any of the traditional ECG analysis functions.

[0006] A recurrent problem with the portable monitors typically used in healthcare applications is the need for wires from sensors situated on the patient's body to the portable unit. These wires can become tangled and cause discomfort or become unplugged when inadvertently pulled or tugged on. In addition, wire motion can increase ECG noise due to the triboelectric effect. Muscle movement can also increase ECG noise, due to the typical placement of ECG electrodes over major muscles. Moreover, portable monitor battery maintenance (e.g. battery recharging or replacement) can be time consuming and costly.

[0007] Another problem is related to the requirement that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules. Conventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor. The problem is that the physical volume of conventional power resistors is too large for use in a compact monitor application.

[0008] Another shortcoming of small sensor devices is that these devices lack the intelligence to vary the amount and type of data transmitted, depending on patient condition. Exercise heart monitors do not transmit a full patient waveform for clinical analysis while medical monitors measure and transmit the full patient waveform, even when the patient is healthy. While transmitting the full patient waveform is the preferred solution from a purely clinical standpoint, such transmission requires significant power to transmit large amounts of data and restricts the design from being small and inexpensive.

[0009] Yet another problem is that arrhythmia analysis is a computationally intensive operation not well-suited to existing small portable monitors that presently have no ability to perform arrhythmia analysis.

[0010] Therefore, there is a need for a body worn combined physiological sensor and monitor having a disposable sensor, but used and worn by a patient as a single unit directly and non-permanently affixed to a patient's body. Also, what is needed is a physically compact resistive element for protecting a body worn device from damage caused by multiple defibrillation cycles. Also, what is needed is a medical-grade monitor that can intelligently measure and transmit data only as required to alert clinicians that the patient needs additional attention. What is also needed is a body-worn device capable of running arrhythmia analysis through computationally efficient algorithms.

SUMMARY OF THE INVENTION

[0011] According to one aspect, a body worn patient monitoring device comprises at least one disposable module including a plurality of electrical connections to the body. The electrical connections are coupled to a skin surface of the patient to measure physiological signals of the patient. The at least one disposable module includes a disposable module connector. The body worn patient monitoring device includes at least one internal or external power source to power the body worn patient monitoring device. The body worn patient monitoring device also includes at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector. The communication-computation module also includes at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate a raw physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a

predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module. The body worn patient monitoring device, including the at least one disposable module and the at least one communication-computation module, is directly non-permanently affixed to the skin surface of the patient.

[0012] According to another aspect, a method of providing high voltage circuit protection for a body worn monitor comprises the steps of: providing a substrate that supports one or more electrical connections to a patient's body; determining a print pattern and thickness of a first material having a first resistivity to be printed on the substrate; determining a print pattern and thickness of a second material having a second resistivity to be printed on the substrate; printing the first material onto the substrate; and printing the second material onto the substrate wherein at least part of the second material overlays the first material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] For a further understanding of these and objects of the invention, reference will be made to the following Detailed Description which is to be read in connection with the accompanying drawings, in which:

[0014] FIG. 1A shows an exemplary body worn physiological monitor having a disposable electrode module;

[0015] FIG. 1B shows a partially unassembled side view of the body worn physiological monitor of FIG. 1A;

[0016] FIG. 1C shows an assembled side view of the body worn physiological monitor of FIG. 1A;

[0017] FIG. 1D shows a bottom view of the body worn physiological monitor of FIG. 1A;

[0018] FIG. 2 shows an exploded perspective view of an exemplary body worn physiological monitor;

[0019] FIG. 3 shows an exploded perspective view of an exemplary computation and communication module;

[0020] FIG. 4A shows an exemplary disposable unit flexible circuit board;

[0021] FIG. 4B shows a partial enlarged view of a portion of the flexible circuit board of FIG. 4A, further showing an exemplary resistive trace having a fillet;

- [0022] FIG. 4C shows a partial side elevated view of a portion of the flexible circuit board of FIG. 4A, further showing an exemplary conductive surface overlaying a resistive material;
- [0023] FIG. 4D shows a partial side elevational view of the circuit board of FIG. 4A, further showing an exemplary conductive surface having a snap receptacle;
- [0024] FIG. 5 shows a block diagram of one embodiment of a body worn physiological monitor having a power source in a disposable unit;
- [0025] FIG. 6 shows a block diagram of one embodiment of a body worn physiological monitor having a power source in or connected to the computation and communication module;
- [0026] FIG. 7A shows a schematic diagram of a direct connected reference electrode used in conjunction with a body worn physiological monitor;
- [0027] FIG. 7B shows a schematic diagram of a virtual reference electrode as used in conjunction with a body worn physiological monitor;
- [0028] FIG. 8 shows a schematic diagram depicting one embodiment of an analog switching arrangement provided on a body worn physiological monitor to select a reference electrode configuration;
- [0029] FIG. 8A shows an exemplary driven lead circuit topology for use with electrodes of a body worn physiological monitor;
- [0030] FIG. 9 shows an exemplary ESIS filter circuit topology with circuit protection;
- [0031] FIG. 10 shows an alternative circuit protection to that depicted in FIG. 9;
- [0032] FIG. 11 shows a flow chart for an algorithm utilized by a body worn physiological monitor to detect whether a patient has a pace maker;
- [0033] FIG. 12 shows a circuit topology of a high pass filter useful for baseline restoration;
- [0034] FIG. 13 shows seven graphs of amplitudes plotted versus frequency to illustrate exemplary operation of the circuit of FIG. 12;
- [0035] FIG. 14 shows two exemplary positions for a body worn ECG monitor to be non-permanently affixed directly to a patient's body;
- [0036] FIG. 15 shows a block diagram of a setup for simulating the effect of patient defibrillation on resistive traces;
- [0037] FIG. 16A symbolically shows resistive dots silk screened on a tray;
- [0038] FIG. 16B shows a histogram of an exemplary resistive distribution of baked resistive dots; and

[0039] FIG. 17 shows an exemplary ECG waveform.

[0040] Package styling varies slightly between the drawings. Such minor differences, e.g. the case styling of computation and communication module 102, illustrate minor variations in mechanical packaging suitable for use as body worn monitors. Drawings are not necessarily shown to scale.

DETAILED DESCRIPTION

[0041] A "body worn" device is described herein with regard to certain exemplary embodiments. A "body worn" device is defined herein as a device that is directly, but non-permanently, affixed to a patient's body. A "body worn monitor" is a device that can be directly "worn" on the patient's body as a single unit, including one or more physiological sensors and a communications and computation module to perform at least initial processing of one or more physiological measurements made using one or more physiological sensors. Unlike prior art patient-wearable devices, at least one sensor can be incorporated into the device that makes a direct or indirect (such as by capacitive coupling) electrical connection with the patient's body without the use of external wires from sensors to the device. In addition and unlike athletic heart monitors, a "body worn" monitor can be a full functioning medical grade monitor, e.g. meeting the requirements of European Unions' Medical Device Directive and other applicable industry standards, such as EC-13 for an electrocardiograph. The body worn medical-grade monitor can include a device, for example, such as a pulse oximeter, CO₂ monitor, respiration monitor, or can function as an ECG monitor, incorporating physiological sensors, front end analog electronic signal conditioning circuits, and a microcomputer based computation unit with wireless reporting of measured physiological data, all contained within in a "body worn" package that can be non-permanently affixed directly to a patient's body. A body-worn medical-grade monitor can also include additional measurement capabilities beyond those mentioned here.

[0042] FIGS. 1A-1D depict various views of an exemplary body worn physiological monitor 100 having a communication and computation module 102 and a disposable electrode module 110. In this exemplary embodiment, physiological monitor 100 is designed for use as an electrocardiogram (ECG) monitor for obtaining and recording and/or transmitting ECG information, including ECG waveforms and alarms for a person, such as a patient, wearing body worn physiological monitor 100.

[0043] FIG. 1A shows an exemplary top view of body worn physiological monitor 100. A crescent shape allows the body worn physiological monitor 100 to be placed on the chest of a patient, and more specifically around the pectoralis major, to allow measurement of lead configuration I, II, or III, or to be placed on the patient's side allowing measurement using a V-lead configuration. Though not shown, multiple body worn physiological monitor 100 units can be used to effectively provide multiple leads. By placing electrodes around the body so that they are not situated directly atop major muscles, both motion noise artifacts and muscle noise artifacts can be prevented. Moreover, by eliminating cables, noise due to cable motion or compression (i.e. triboelectric effect) can be eliminated.

[0044] FIG. 1B shows a side elevated view of physiological monitor 100 having an exemplary attachment mechanism, such as a retention clip 104, to mechanically attach communications and computation module 102 to the top surface of the disposable electrode module 110. Flexible printed circuit layer 101 can be made from a thin insulating material, such as according to this embodiment, a 75 micron thick layer of Mylar®. Typically electrical traces (not shown in FIGS. 1A-1D) on flexible printed circuit layer 101 can be further protected by an insulating covering, analogous to a conformal coating. A formed plastic layer or a cloth with adhesive on one side thereof can be used to cover and protect flexible printed circuit layer 101, as well as to provide an aesthetic outer layer to make the body worn monitor 100 visually appealing.

[0045] FIG. 1C shows a side view of physiological monitor 100 in which the communications and computation module 102 has been affixed to disposable electrode module 110. FIG. 1D depicts a view of the underside of exemplary physiological monitor 100 showing one embodiment of disposable electrode module 110 having electrodes 109. In this embodiment, each electrode 109 comprises electrode gel 103 and conductive surface 404 (FIG. 4). Together, electrode gel 103 and conductive surface 404 create a half cell, such as, for example, a Silver/Silver Chloride half cell. Also and according to this embodiment, conductive surface 404 can directly accept the electrode gel 103.

[0046] FIG. 2 shows an exploded assembly view of the exemplary body worn physiological monitor 100. As noted with regard to FIGS. 1A-1D, the body worn physiological monitor 100 includes a removable and reusable communications and computation module 102 and a disposable electrode module 110, the later including electrode gels 103 for ECG monitoring and

batteries 204 to power communications and computation module 102. A flat planar insulating/adhesive member 105 includes a plurality of openings that are each sized to receive electrode gels 103. The insulating member 105 provides a bottom side cover for the flexible printed circuit layer 101 and augments adhesion to the human body. Electrode gel 103, when attached to an appropriate substrate such as silver-silver-chloride or other substrate, can be used to establish a relatively low impedance electrical connection between conductive surface 404 (FIG. 4) and the patient's skin.

[0047] Electrode gels 103 can adhere to a patient's skin. While electrode gel 103 is typically an adhesive electrode gel, the adhesion offered by electrode gels 103 alone might not give a sufficient holding force for non-permanently affixing body worn physiological monitor 100 to a patient. To achieve a better adhesion of body worn monitor 100 to a patient's skin, insulating/adhesive member 105 can be used to non-permanently affix body worn physiological monitor 100 to a patient. Thus, body worn monitor 100 can be applied to a patient in the same way an adhesive strip is applied, such as for example, those adhesive strips sold under the brand name "BAND-AID®". One exemplary type of foam adhesive suitable for affixing a flexible circuit board to a patient is 1.6 mm adhesive foam from Scapa Medical of Bedfordshire, UK. As shown in FIGS. 1B and 1C (although not to scale), each of the electrode gels 103 extend sufficiently below adhesive layer 105 in order to ensure good electrical connection with a patient's skin surface (not shown). Tab 106, FIG. 1A, allows for easy removal of a protective backing 111 from adhesive layer 105.

[0048] Flexible printed circuit layer 101 can include contacts, such as battery clips (not shown), to receive and connect to batteries 204. (It is contemplated that in some future embodiments, a single battery can provide sufficient electrical power.) In the exemplary embodiment, as shown in FIG. 2, batteries 204 can be mounted under respective battery flaps 205 arranged on opposite sides of the flexible printed circuit layer 101. Alternatively, battery clips (not shown) or battery holders (not shown) can be used to provide both mechanical support and electrical connections for each of the batteries 204. One type of battery holder suitable for such use, for example, is the model 2990 battery holder, manufactured by the Keystone Electronics Corp. of Astoria, N.Y. Battery cover 107 provides protection for batteries 204 as well as a surface to press upon when applying electrodes 103 to conductive surface 404. Retention clips 104 can comprise, for example, a plurality of spring fingers with latching clips.

Retention clip 104, affixed to disposable electrode module 110, can be used to secure reusable communications and computation module 102 to disposable package 110. Reusable communications and computation module 102 is herein illustrated in a simplified representation, including cover 201, communications and computation printed circuit board assembly 202, and base 203.

[0049] FIG. 3 shows a mechanical view of an exemplary reusable communications and computation module 102, as well as a preferred method for making an electrical connection between flexible printed circuit layer 101 in disposable electrical module 110 and communications and computation printed circuit board assembly 202 situated in reusable communications and computation module 102. In this exemplary embodiment, communications and computation printed circuit board assembly 202 can include a plurality of press fit and/or soldered conductive sockets 301 for receiving electrical plug 302, the plug having a corresponding plurality of conductive pins. Each conductive pin shown in plug 302 can correspond to an electrical connection pad on flexible printed circuit layer 101. A row of mechanical sockets 303 can receive the multi-pin row of plug 302. Thus, an electrical connection can be made between each pad of flexible printed circuit layer 101 having a conductive post on plug 302 and each corresponding conductive socket 301 on communications and computation printed circuit board assembly 202. Posts 304 can align and secure each of the cover 201, communications and computation printed circuit board assembly 202, and base 203. Note that in FIG. 3, a simplified drawing of cover 201 omits slots to receive retention clip 104 to affix communications and computation module 102 to disposable package 110. A body worn monitor 100 would typically also include retention clip 104 FIG. 2, or other suitable type of mechanical clip(s), in order to provide a secure mechanical connection between communications and computation module 102 and disposable electrode module 110.

[0050] FIG. 4A shows one embodiment of flexible circuit board 101 in an expanded (e.g. unassembled) view. Flexible circuit board 101 is formed on a substrate 406. Substrate 406 can be cut, for example, from a Mylar sheet of suitable thickness. In this embodiment, one battery 204 can be mounted adjacent to a conductive surface 404. Conductive gel 103 (not shown in FIG. 4) can be mounted on the exposed conductive side of a conductive surface 404.

[0051] Conductive surface 404 can also be viewed as the electrode portion of a half cell and electrode gel 103 can be considered to be the electrolyte portion of a half cell. In conventional terms of art, the combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell. For example, the combination of a conductive surface 404 and an electrolyte layer (e.g., electrode gel 103) forms a half cell. For convenient quick reference to a half cell structure, the term "electrode" (assigned reference designator "109") is used interchangeably with "half cell" herein. It is understood that in typical embodiments, electrode 109 comprises conductive surface 404 and electrode gel 103.

[0052] Typically, electrodes make use of a circular or square conductive surface. Increasing the ratio of the perimeter of the surface to the area of the surface affects current density distribution and defibrillation recovery.

[0053] For convenience, we define the term "annulus" herein and throughout as the region between two simple curves. A simple curve is a closed curve that does not cross itself. Under this definition, an annulus can include substantially square shapes, substantially rectangular shapes, substantially circular shapes, substantially oval shapes, as well as substantially rectangular shapes with rounded corners. Further we include in the definition of annulus, the case of a substantially "U" shaped surface as described by a single closed curve.

[0054] One exemplary electrode gel 103 suitable for such use on a body worn monitor is type LT00063 hydrogel supplied by Tyco Healthcare of Prague, Czech Republic. Typically, a conductive surface 404 creates the electrode portion of the half cell. By increasing the ratio of perimeter to area of the circular electrode portion of the half cell, the signal to noise ratio of the input ECG signal can be increased.

[0055] As depicted herein on the exemplary circuit layout, two batteries 304 can be connected in series, with one polarity being made available at connection pad 407 from battery connection 402, battery connection 401 creating the series connection between the two batteries, and connection pad 410 providing the second polarity of the series connected batteries. Note that in some embodiments, a single battery alternatively may be used in lieu of the exemplary arrangement or two batteries can be also wired in parallel, depending on the voltage requirements of a particular communications and computation module 102.

[0056] Connection pads 408 and 409 electrically couple the signals from electrode gels 103 (not shown in FIGS. 4A-4D) via conductive surface 404 and resistive traces 412 to electrical plug 302 (not shown in FIGS. 4A-4D). Electrode contact pad 405 can be connected via resistive trace 413 to connection pad 411 to provide a direct-connected reference electrode (not shown in FIGS. 4A-4D). Traces 412 extending between conductive surface 404 and connection pads 408 and 409 and trace 413 extending between conductive surface 405 and connection pad 411 can be made from resistive materials including resistive metals, carbon, silver ink, powders, paints, or other material of determinable electrical resistance.

[0057] Resistive traces on flexible circuit board layer 101 replace the bulky power resistors needed by prior art monitors, having electrodes or sensors connected by wires or leads. These resistive traces should survive multiple defibrillation cycles such that body worn monitor 100 remains functional even after one or more attempts to re-start a patient's heart. In order to survive defibrillation, the resistive traces should dissipate that portion of the potentially damaging defibrillation energy that is coupled into the monitor. This fractional portion of the defibrillation energy typically enters body worn monitor 100 from electrodes 109, FIG. 1D (electrodes 109 including conductive surface 404 and electrode gel 103).

[0058] It is desirable that the resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms. Below 1 kilo ohm, depending on the resistive material used, it can be more likely that the resistance of the resistive traces 412 and 413 will increase with each successive defibrillation pulse. Above 10 kilo ohms, a high resistance impairs the signal to noise ratio, specifically due to thermal noise, which has a mean square value of $4 \cdot k \cdot T \cdot R \cdot BW$, where "k" is Boltzmann's constant, "T" is temperature measured in degrees Kelvin, "R" is resistance in ohms, and "BW" is bandwidth, in Hz, which becomes significant relative to the EC-13 requirement that the noise referred to input be less than 30 μ V peak-to-valley.

[0059] Power dissipation in the herein described traces can be calculated by E^2/R , in which E refers to the potential across the trace and R is the resistance of the trace. R can be calculated by $\rho \cdot L/A$, where ρ is the resistivity of the material used to form the trace, L is the length of the trace, and A is the cross-sectional area of the trace.

[0060] In developing resistive traces for use on a flexible printed circuit layer 101, typically formed on a Mylar substrate 406, such as shown in FIG. 4A, various materials were tested. Silver, including silver inks, while useable, was found to be less desirable, because it was difficult to achieve sufficiently thin silver traces on Mylar to achieve high enough resistances. Carbon, including carbon pastes and carbon inks, was also tried and found to be suitable. In order to use carbon however, several additional problems had to be solved. At 1 kilo ohm, the power dissipated by the resistors caused them to degrade across multiple defibrillation cycles. The solution was to make carbon traces in the range of about 8 to 10 kilo ohms. 10 kilo ohm resistances proved to be a good compromise between noise levels, power dissipation by the resistors, and manufacturing tolerances for depositing carbon ink on a Mylar substrate to dissipate the power from multiple defibrillation cycles. To achieve the desired resistance of about 10 kilo ohms (interchangeably represented herein as "10 k" or "10 k Ω "), for a given resistivity of the carbon paste, and given trace width and thickness (height), the length of the trace is then defined. In some cases, such as for traces 412, the length needed for a trace run, as between conductive surface 404 and connection point 409, might be longer than the length defined for a particular trace resistance (typically 10 k). In this case, traces can be extended by lengths of silver conductive traces. There can be a short overlay distance, on the order of 5 to 10 mm, in which a silver trace overlaps the carbon trace to provide a more robust connection between the resistive and conductive portions of the traces. Where overlap is used, the overall length of the resistive portion can be adjusted slightly to maintain the desired overall resistance.

[0061] Another problem associated with carbon traces was arcing at the interface between the carbon and conductive traces. Arcing was particularly problematic at the abrupt connection between the carbon trace and conductive surface 404. Arcing was also observed to occur between the end section of the carbon trace and conductive surface 404. (Electrode gels 103 create the conductive path to the patient through conductive surface 404 and a layer of conductive gel.)

[0062] According to one solution to the above noted arcing problem, as shown in FIG. 4B, a rounded (fillet) section 430 of carbon trace can be added at the interface to conductive surface 404. A fillet or "tear drop" shape causes the carbon trace to become gradually wider as it connects to conductive surface 404 and relieves the electrical potential stress at the interface.

[0063] An alternative solution to the arcing problem is shown in FIG. 4C, wherein carbon can be laid down beyond the trace (412) to include a pattern of conductive surface 404 formed from carbon. A carbon annulus pattern can be deposited before the conductive surface 404 is deposited. Conductive surface 404 can then be deposited as an overlay over the earlier formed carbon annulus shape. Finally, conductive gel 103 can be attached to the conductive surface layer (the carbon layer residing between conductive surface 404 and the Mylar substrate used as flexible circuit board 101). Both of the aforementioned arcing solutions can be used together. It should also be noted that conductive surface 404 can be formed from suitable materials other than silver, including, for example, materials such as silver chloride.

[0064] Arcing can also occur between the resistive traces and other (typically silver) conductive traces on the flexible circuit board 101. Trace to trace arcing can be suppressed by allowing sufficient spacing between the traces. Generally a minimum spacing of about 3 mm/kV, as required by ASNI/AAMI DF80:2003 57.10 BB, has been found to be sufficient to prevent trace to trace arcing from a defibrillation event. Closer trace spacing, as close as 0.01 mm/kV, can be employed successfully by first applying an insulating dielectric layer, similar to a conformal coating, over the surface of flexible circuit board 101 that covers most of the substrate and traces. The insulating dielectric layer can be prevented from forming or adhering to conductive surface 404, such as by use of a mask during application of the insulating layer.

[0065] In an alternate embodiment, as depicted in FIG. 4D, a snap device can be added to conductive surface 404 to accept a manufacture snap-on electrode (not shown), such as, for example, the ConMed Cleartrace line of ECG electrodes including the model 1700 Cleartrace electrode manufactured by the ConMed Corp. of Utica, N.Y. or similar type electrodes made by the 3M Corp. of St. Paul, Minn. When designed to accept a snap-on electrode, the conductive surface 404 is typically smaller than in the previous embodiment. A receptacle snap 432 for receiving the commercial snap-on electrode can be inserted by any suitable method, such as by press fitting or other fastening method, into conductive surface 404, typically also penetrating through substrate 406. In this embodiment, arcing can be similarly suppressed in this embodiment by adding a fillet to the carbon-conductive surface interface and/or depositing a conductive surface 404 over a carbon layer as previously described.

[0066] Example: Resistive traces and an annulus were tested on a substrate formed from CT3 heat stabilized treated polyester (75 microns thick), such as manufactured by the MacDermid Autotype Corp. of Schaumburg, Ill. Resistive traces were silk screened onto the substrate using 7102 carbon paste conductor from the DuPont Corporation of Wilmington, Del. The carbon paste conductor was deposited through a 43T silk screen mesh. The substrate containing the paste deposit was then cured inside a fan assisted air circulated oven at 120°C for a period of 5 minutes. The traces formed were about 55 mm long and 2 mm wide, having an overall thickness of about 7.5 microns. The initial measured resistance of each trace was about 14 kilo ohms. After each trace was subjected to 3 defibrillation cycles, the measured resistance increased to about 15 kilo ohms. Over a 3 mm length, the trace widens to about 5 mm, terminating into a carbon annulus with an outer diameter of about 20 mm and an inner diameter of about 10 mm. A silver layer of PF-410 silver ink from the Norcote Corp. of Eastleigh Hampshire, UK was then deposited over the carbon annulus, also to an overall thickness of about 7.5 microns. The deposition of the silver layer was via the silk screen printing method, in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120°C for a period of 15 minutes. A third dielectric insulating layer comprising SD2460, components A & B (dielectric and hardener), manufactured by Lackwerke Peters GmbH + Co KG of Kempen, Germany, and having a thickness of approximately 13 microns was then deposited over the traces and substrate, but not over the annulus. (The electrodes were formed by attaching a conductive gel to the annulus. The conductive gel used was LT00063 hydrogel from Tyco Healthcare of Prague, Czech Republic.) Again, the silk screen printing process was used to deposit the dielectric layer through a 90T screen mesh. The substrate was placed again into a fan assisted air circulated oven at 120°C for a period of 30 minutes.

[0067] Example: Silver traces for use as conductive (not resistive) traces on a body worn monitor circuit substrate were formed from a silver paste that was silk screened onto a Mylar substrate. 45 mm long traces had a measured resistance in a range of 3.5 to 6 ohms, 75 mm traces had a measured resistance in a range of 6.5 to 13 ohms, and 105 mm traces had a measured resistance in a range of 10 to 16 ohms. The deposition of the silver layer was performed via the silk screen printing method in which a 90T silk screen mesh was used. The

substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120°C for a period of 15 minutes.

[0068] FIG. 15 diagrammatically depicts an exemplary test setup used to simulate the effect of a patient defibrillation on resistive traces. Defibrillator 1501 was used to apply multiple defibrillation shocks of 360 Joules each to the 100 ohm resistor 1502. The 100 ohm resistor according to this setup simulated a patient's body. Note that most of the defibrillation energy goes into the patient's body by design, to restart the patient's heart. Resistive traces 1503 and 1504 were wired across resistor 1502, also as shown in FIG. 15, in order to simulate the electrical circuit that would be formed between the resistive traces in a body worn monitor situated on a patient undergoing defibrillation. Neon bulbs 1506 were used as part of the protection circuitry that can be used with resistive traces in a body worn monitor. 400 ohm safety resistor 1505 was present as a precaution to limit short circuit current in the event of a test setup failure. Both the 100 ohm resistor (simulating human skin resistance) and the 400 ohm safety resistor were used in accordance with medical specification AAMI EC-13. Following 3 defibrillation shocks of 360 Joules each, the measured resistance of the 10 k carbon track changed from 10 k to 11 k following the first shock, to 13.1 k following the second shock, and to 13.2 k following the third shock. The measured resistance of the 9.7 k trace changed from 9.7 k to 11.6 k following the first shock, to 13.0 k following the second shock, and finally to 13.2 k, following the third shock. In a subsequent related test, the 100 ohm resistor was replaced by a closer simulation in the form of a fresh (dead) chicken. The setup otherwise remained the same as shown in FIG. 15. In this case, the resistance as measured on each of the test resistive traces changed from 10.7 k to 10.25 k, and from 8.5 k to 9.4 k, following multiple defibrillations. During testing, it was also noted that the change in measured resistance of the resistive traces was generally consistent. It was also noted that as a given resistive trace was increased, the $(\Delta R \text{ \{caused by defibrillation\}} / R \text{ \{net trace resistance\}})$ can be minimized.

[0069] The screen printing technique for laying down resistive traces was further investigated by printing a plurality of small carbon resistive dots 1601 of about 20 mm in diameter using a 7102 carbon ink applied by a screen printer (not shown). The carbon dots 1601 were laid out on a tray 1602 as shown in FIG. 16A, for baking in an oven. A manually operated squeegee (not shown) was used to apply the resistive dots 1601 to the tray 1602 through a mask (not shown). It was determined that control of thickness during application was one important factor for

controlling the distribution of resistance. It was noted that during manual application, the variation of resistance depended upon the distance between the plurality of dots 1601 and the person applying the resistive paste, and that the pressure applied using the squeegee could also affect the final resistance by a factor of two. It was further noted that "even" heating across the tray 1602 was advantageous during oven drying, although this factor was found to have less effect on the final dot resistance distribution. A resistance distribution of the baked and measured dots 1601 is shown in the histogram of FIG. 16B. This testing indicated that production traces laid down on a substrate, such as Mylar, for use in a body worn monitor should preferably be printed using a semi-automatic screen print process, such as by a screen printing mechanical roller process. A digital multimeter ("DMM") with probes placed at each edge of a dot 1601 was used to measure the resistance from one edge of the dot to the other. It was found that uniform application of ink was important to keeping a tight distribution of resistance, with even heating having a smaller influence on the distribution of the resistance of the test dots. Since a trace with too low a resistance has a greater $\Delta R/R$, and higher probability of failing and very high resistance traces result in worse S/N ratio, it is important to have a reasonably tight tolerance on the trace resistance.

[0070] FIG. 5 shows a block diagram representative of one embodiment of the body worn physiological monitor 100. Physiological sensors 501 (such as electrodes 109 in FIG. 1D) can be electrically coupled to electromechanical connector 502 (as by the resistive traces 412 shown in FIG. 4). Connector 502 serves to electrically couple communications and computation module 102 to a disposable electrode module 110 (FIG. 2). Secondary connector 503 can also electrically couple one or more additional sensors, which can be situated both on and off of disposable electrode module 110, to electromechanical connector 502 for electrical coupling along with physiological sensor signals 501 to communications and computation module 102 (shown in FIG. 1) via electromechanical connector 505. Signals received by the communications and computation module 102 can be electrically coupled into communications and computation module 102 via electronic protection circuits 506 and/or filters, such as ESIS filters 507.

[0071] Signals can be limited or clipped in amplitude, as needed, by protection circuit 506, and filtered by filter 507. One or more analog amplifiers 508 can be used to amplify the amplitude limited and filtered signals. In the exemplary body worn ECG monitor, amplifiers 508 can advantageously be differential amplifiers to amplify the difference signal (e.g. the ECG "vector") between two ECG electrodes. The electrical output of amplifiers 508 can be electrically coupled to both PACER circuits 509 and ECG circuits 510. PACER circuits 509 are described further below. ECG circuits 510 perform several functions, including "trace restore", low pass filtering (anti-aliasing), high pass filtering, and amplification (gain). Low pass filtering filters signals according to the Nyquist criterion to avoid aliasing later when the signals are digitized by analog to digital converter (ADC) 516. The high pass filter causes the input to be AC coupled from a roll off frequency of about 0.05 Hz, as specified by industry ECG standards. Gain is required to cause the small pre-amplified potentials from physiological sensors (such as electrodes 109) to more closely match the available dynamic range of the digitizing ADC 516. Note that ADC 516 can be a dedicated ADC chip or can be included in a microcomputer integrated circuit, such as a microcomputer serving as microprocessor 512.

[0072] A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms "microcomputer", "microcontroller", and "microprocessor". Such microprocessors are also interchangeably represented herein as " μ P" or " μ C". Further, any microprocessor disclosed herein can be replaced by any integrated device that can perform the function of a microprocessor, such as, but not limited to, a field programmable gate array ("FPGA") programmed to perform the functions of a microprocessor.

[0073] Typically, one or more differential amplifiers can be dedicated to particular difference voltages associated with physiological sensors 501 or 504, but it should be noted that one or more amplifiers 508 can also be multiplexed by techniques as known in the art, to serve multiple physiological sensors using a lesser number of amplifiers. Similarly, one or more ADCs 516 can serve two or more signals from physiological sensors 501 or 504 using techniques such as multiplexing in time that is digitizing one physiological sensor difference signal at a time sending a digital result to a next stage one after the other. ECG circuits 510 and PACER circuits 509 are referred to in the plural, since there can be individual circuits for each measured physiological signal, such as for each measured ECG vector.

[0074] Electrical power from power source 515 can be regulated by regulator 514 and distributed as regulated voltage 517 to most function blocks (as represented herein by the label "POWER"). Each of these function blocks also has a control ("CTRL") input 511 from microprocessor 512, allowing these circuits to be disabled, when not needed, in order to save battery power. When viewed over time, most of the ECG waveform does not contain useful information since there is significant "dead time" between heart beats. Therefore, for example, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heartbeat, circuits can be powered down (in a device "sleep mode") to save on the order of 60% of the energy stored in the power source that would have otherwise been used during this dead time.

[0075] FIG. 17 shows an exemplary ECG waveform. In brief, the P wave can be related to the electrical current causing atrial contraction. The QRS complex can be related to ventricular contraction of the left and right ventricles. The Q wave can be related to electrical current traveling through the intraventricular septum, while the R and S waves can be related to the ventricles contracting. The T-wave is due to the re-polarization of the ventricles. Usually, atrial re-polarization occurs atop the QRS complex, and being much smaller than the QRS complex, is not seen. The ST segment connects the QRS complex to the T-wave. Irregular or missing waves may be indicators of cardiac issues including: ischemic tissue, e.g. due to myocardial infarction, bundle branch block, atrial problems (specifically P-wave abnormalities), pericarditis, and electrolyte disturbance.

[0076] Generally, power source 515 can include one or more "button" cells typically disposed on disposable electrode module 110; however, the block diagram of FIG. 6 shows an embodiment of a body worn physiological monitor 100 where power is supplied by a power source located on, or connected to communications and computation module 102 instead of residing within disposable electrode module 110.

[0077] Beyond power saving considerations, it can also be desirable in some embodiments of body worn physiological monitor 100 to put the microcontroller and/or other circuits, including particularly digital circuits, into a sleep mode during an ADC conversion cycle to minimize pickup of self generated electrical noise and to minimize power use. Preferably, the A/D circuit can acquire multiple samples and buffer the samples, before awakening the microprocessor,

which then can batch-process the data. Buffering can be set to match the patient's heart rate, as there is no significant clinical benefit to analyzing every sample as it is taken.

[0078] Turning back to the input circuits, typically amplifiers 508 are differential or instrumentation amplifiers useful to selectively amplify desired difference signals between connector terminals (such as an ECG vector), while rejecting common mode signals (such as interfering signals that appear simultaneously on both connector terminals). Beyond using a differential amplifier, other techniques can be advantageously used to further reduce common mode pickup (CMR) and thus to improve the common mode rejection ratio (CMRR) of the input amplifier stages of body worn physiological monitor 100. CMR is of particular concern with regard to body worn physiological monitor 100 because of the proliferation of potentially interfering electromagnetic fields, such as from 50 Hz or 60 Hz AC power line distribution throughout a hospital. For example, many fluorescent ceiling lamp fixtures generate strong 60 Hz alternating current (AC) electromagnetic fields that can appear as common mode signals on physiological sensors 501, such as ECG electrodes 109.

[0079] FIG. 7A shows one embodiment in which body worn physiological sensor 501 comprises a plurality of ECG electrodes 109 and 701. Two electrodes 109 generate an ECG difference potential for patient 703. A third electrode, reference electrode 701 can be electrically coupled to electronics common 704 (or other potential level) and can be used to improve CMR. In this embodiment, the electronics common 704 (shown as the negative terminal of the battery in FIG. 7A) can be directly tied to the patient in the vicinity of electrodes 109. Thus, the electronics common of the electronic circuits in communications and computation module 102 can be made to more closely follow any change in potential in the vicinity of electrodes 109. Reference electrode 701 can be particularly helpful to ensure that inputs 109 remain within a reasonably narrow common mode range, such as by reducing a 60 Hz potential that would otherwise appear to move the electronics common 704 at 60 Hz with respect to electrodes 109.

[0080] In another embodiment as shown in FIG. 7B, virtual electrode 702 performs a similar function as previously described with regard to reference electrode 701. In this embodiment, instead of creating a DC-coupled reference electrode, electrode 701 is replaced by the capacitive coupling between flexible printed circuit layer 101 and the patient 703, resulting in a virtual electrode 702 with an AC coupled common. Such AC coupling increases with decreased

distance between flexible printed circuit layer 101 and the patient and can advantageously reduce 60 Hz common mode signals (AC signals).

[0081] In yet another version of a directly connected electrode 701, as shown in FIG. 8A, electrode 701 can be actively driven by an electrical output from communications and computation module 102. Typically, an operational amplifier (OpAmp) or other type of amplifier can be used to create a "driven lead". Driven lead circuits can be used to further improve CMR over passive electrodes 701 as shown in FIG. 7A. An exemplary circuit suitable for use to drive an electrode 701 is shown in FIG. 8A. Amplifiers (OpAmps) 810 and 811 buffer the high impedance signals from electrode 1 and 2 (exemplary electrodes 109). Difference amplifier 508 conveys the difference signal (such as an ECG vector) as previously described. The two 10 kilo ohm resistors provide an average of the common mode signals appearing simultaneously at the inputs of buffer amplifiers 810 and 811. The inverting low pass filter built around OpAmp 812 inverts the averaged common mode pickup signal (at electrodes 1 and 2) and applies that signal out of phase (180° phase shifted) to a directly connected driven electrode (such as electrode 701). By applying the average common mode signal to the driven electrode, amplifier 812 effectively suppresses common mode signals at electrodes 1 and 2 within the effective bandwidth of the negative feedback loop by active noise cancellation. In theory, a virtual electrode 702 could be similarly driven, but the voltage requirements to drive a capacitively coupled common electrode are high enough to make a "driven virtual electrode" a less practical option. Thus, it can be seen that a reference electrode can be a passive connection or an actively driven connection.

[0082] It can also be desirable to have more than one CMR technique available. For example, in a low noise environment, a lower power reference electrode might be used for CMR. Then if the noise increases to a level where the reference electrode provides insufficient CMR, the body worn monitor can switch to a driven lead more suitable for CMR in a high noise environment. In this embodiment, a particular CMR configuration can be selected by electronic switching. FIG. 8 shows one such exemplary switching block represented as reference electrode switch 801. Microprocessor μ P) 512 can control reference electrode switch 801 to select direct connected electrode 701, virtual electrode 702, or directly connected electrode 701 additionally driven by a driven lead circuit 802. It should also be noted that in the embodiment of FIG. 8, when virtual

electrode 702 provides sufficient CMR, electrode 701 can be used as a third electrode, thus allowing body worn monitor 100 to simultaneously measure two different heart vectors.

[0083] FIG. 9 shows one embodiment of an exemplary defibrillation protection circuit (506) and ESIS filter 507. As shown in FIG. 9, electrodes 109 can be connected via input resistors R91 and R92. Gas discharge tubes, such as neon bulbs L1 and L2, can be used for over voltage protection by firing at a designed voltage to prevent large potentials from appearing at the input leads to amplifier 508. The gas discharge tubes can be disposed on either disposable electrode module 110 or on the communication and computation module 102. Defibrillation protection resistors R91 and R92 can further reside in disposable electrode module 110, such as in the form of the resistance of traces 412.

[0084] ESIS filters 507 can be used to satisfy AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS). Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used. Without such suppression, the high RF output of an electrosurgical device can render ECG monitoring impossible and or render the monitor unusable. Resistors R93 to R98 and capacitors C91 to C96 form cascaded low pass filter sections (e.g. R93-C1). Three cascaded single pole filters are shown on each input leg of amplifier 508 as an example; more or less stages can also be used. It is also not necessary for each section of the cascaded filter to have identical values or roll off points in the frequency domain to create a specific response, e.g., Bessel, Chebychev, or other filter response known to those skilled in the art. Also, ESIS filters are not limited to cascaded single pole filters and can take other forms as known in the art.

[0085] Test circuit 906 can provide a relatively sharp transient signal for testing the PACER circuit described below as part of a body worn monitor 100 "power on self test ". Resistors R99 and R100 can pull the output of the differential amplifier 508 allowing the microcontroller (512) to detect which electrode, if any, has detached, much as a "lead failed" detection is accomplished by ECG monitors having leads. Body worn monitor 100 does not use leads, but it is still possible for one or both of the physiological sensors to move free of a patient's body. Such disconnects can occur in situations in which body worn monitor 100 partially moves away from the body to which it is non-permanently affixed. The input impedance at one or both of the electrodes 109 changes in a sensor off (sensor disconnect) event. When a patient is attached, amplifier 508

typically has an output voltage of near zero volts. However, if one of the electrodes 109 comes off, resistors R99 or R100 cause the output of amplifier 508 to move to a most positive output ("positive rail") or to a most negative output ("negative rail"). Note that the negative rail can be a small voltage near zero, in the case of single supply circuit operation, and that both inputs could be pulled to the same rail. Lead-fail detection can also be analyzed to determine when the device is attached to the patient and then to automatically enter full operational mode. Such analysis can be done at a low frequency.

[0086] The ESIS filter 507 also can cause a stretching in the time domain of a pacer pulse so that the event is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the ADC sample rate and the pacer pulse is likely to occur between samples.

[0087] FIG. 10 shows an alternative circuit to accomplish over voltage protection, such as is required during defibrillation. In FIG. 10, diodes 1001 prevent the electrode potentials from going much more than one diode voltage drop above Vcc or below ground and resistors R91 and R92 limit current. Using circuit protection, such as gas discharge tubes L1 and L2 (FIG. 9) and/or diodes 1001 (FIG. 10) combined with resistances R91 and R92, typically in the form of resistive traces 412, a body worn device can survive multiple defibrillation cycles of at least 360 joules.

[0088] PACER circuit 509 detects pacemaker pulses. One reason to detect a pacemaker is to prevent the ECG circuitry from inadvertently registering the regular pulses from a pacemaker as an actual heart rhythm. Separation of a pacemaker signal from signals generated by the heart is important both to generate accurate ECG analysis results as well as to correctly detect the absence of an actual heart rhythm. For example, a pacemaker continues to function even where a human heart has completely failed.

[0089] A pacer event (pacemaker signal) is typically a narrow pulse typically less than 100 microseconds wide. Because of the capacitance between the pacer in a patient and an ECG circuit, an otherwise relatively square pacer pulse as administered at the patient's heart by a pacemaker, can appear to an ECG monitor as a pulse with a negative undershoot and an exponential return to zero that could inadvertently mimic a QRS signal. A pacer signal, however, can be recognized by an analog differentiator and alert microprocessor 512 to the presence of a pacer and to disregard the refractory period of the corresponding R-C recovery due

to the pacer signal. The pacer detection circuit or PACER circuit can generate a microprocessor interrupt to inform the microprocessor that a pacer event occurred and to mark a corresponding physiological signal in time as related to a pacer event. PACER circuit 509 can also cause one or more pacer related circuits to automatically power down for power saving, where it is determined that a patient is not using a pacemaker.

[0090] FIG. 11 shows an algorithm useful to determine if the pacer circuit should be enabled. A typical PACER detection circuit uses a significant percentage of the energy available from a power source such as batteries 204. If a PACER signal is not detected, such as at power up of body worn monitor 100, the pacer circuit can be automatically disabled allowing for a longer battery life. Since typical PACER circuits can use several amplifiers (OpAmps), they can consume up to one third of the analog power, therefore securing the PACER circuits when they are not needed (i.e. the patient does not have a pace maker) can cause a significant improvement in battery life. The algorithm also can also provide checks to determine if a demand type pace maker begins operation (which might be inactive at power up of body worn monitor 100) by analyzing beat variability. While it can be advantageous to have the body worn device automatically sense the presence of a pacemaker and to enable the PACER detection circuit, the choice as to whether to enable or disable the PACER circuit can also be done by externally configuring the body worn device. Such external configuration can be done through a hardwired communication connection cable or via communications and computation module 102, in which communications and computation module 102 is a two-way radio transceiver communication device capable of receiving a configuration command sent for a remote radio transceiver. The radio could be 802.11 compliant, but generally would use a lighter-weight (simpler) protocol that can be more energy efficient. A suitable lighter weight protocol could be proprietary, or standards-based, such as ZigBee or Bluetooth. A body worn physiological monitor 100 is particularly well suited for use in hospital environment as part of an integrated wireless monitoring network. The details of such monitoring networks are disclosed in U.S. patent application Ser. No. 11/031,736 entitled, "Personal Status Physiological Monitor System and Architecture and Related Monitoring Methods", which is incorporated by reference herein in its entirety.

[0091] FIG. 12 shows a high pass filter (HPF) suitable for use in ECG circuits block 510. An advantage of a 0.5 Hz HPF is faster recovery from DC offsets due to patient movement, defibrillation, electrocautery, etc. However ST segment analysis is negatively impacted if HPF cutoff is greater than about 0.05 Hz. Thus, it is preferable to have the ability to change between a 0.5 and 0.05 Hz cutoff frequency. The high pass filter of FIG. 12 is implemented by a low pass filter configured as an inverting amplifier in a negative feedback circuit to give a net effective high pass transfer function from circuit input to output. The corner frequency of the composite filter can be adjusted by switching in resistor R2'. Alternatively, S1 can be switched at a periodic rate to place a duty cycle on C. Note that the frequency of switching of S1 should be fast with respect to the corner frequency of the anti-aliasing low pass filter. The graphs A-D of FIG. 13 further illustrate the performance of the exemplary filter of FIG. 12. These graphs show normalized amplitude on the vertical axis plotted against frequency on the horizontal axis. FIG. 13, graph A represents a raw input signal. FIG. 13, graphs B and C are Bode Plots representing the high and low-pass filter sections. After applying filter responses B & C to input Data A, filtered data D is the result. The HPF cutoff can be 0.5 Hz or some lower value depending on whether R2' is switching in or if C is duty cycled.

[0092] Another method to achieve this frequency change is to use digital filters implemented on Microprocessor 512 to reverse the effects of the 0.5 Hz HPF, then implement a digital HPF at a lower cutoff frequency, 0.05 Hz, for example. The response of the 0.5 Hz filter should be known to implement the inverse filter. This response can be measured using microprocessor 512 to trigger the test circuit 906 to create an impulse, $H(s)$. The inverse response is the $[1-H(s)]$ (FIG. 13, graph E) and this inverse filter can be digitally implemented by methods familiar to those skilled in the art. $H'(s)$ is the frequency response of the new HPF with lower cutoff frequency, nominally 0.05 Hz. The digital filter for $H'(s)$ is digitally generated (F) and applied along with $[1-H(s)]$ (FIG. 13, graph E), resulting in the frequency response displayed in FIG. 13, graph G. A high pass filter suitable for use in ECG circuits block 510 can be implemented in full or in part by software that can run on microprocessor 512.

[0093] FIG. 14 shows how a body worn monitor 100 configured as an ECG monitor can be situated on a patient in at least two different orientations to measure different heart vectors. A primary heart vector is measured by orientation from the patient's right shoulder to the left hip, as shown by position 1401. An alternative position 1402 can be more suitable where there is injury

or where patient anatomy is such that it causes the preferred position 1401 to be less desirable. Also, body worn monitor 100 can be affixed to the side of patient 703 (similar to a measurement made by a conventional ECG "V" lead) or back of a patient 703 (such as where a patient needs to sleep on their stomach) to monitor still other ECG vectors (not shown). In effect, a body worn monitor 100 can be placed to pick a particular vector that can be traversed by the electrodes 109. For example at least the first three primary heart vectors, i.e. I, II, and III, can be made conveniently available in this manner.

[0094] While illustrated with an internal battery, it is important to note that a body worn physiological monitor 100 can be powered by either an internal power source only, an external power source only, or by an internal or an external power source. An internal power source can be a renewable power source, such as a rechargeable battery.

[0095] Another type of internal power source is a Peltier device operated in reverse, also called a Seebeck device. Seebeck discovered that a conductor generates a voltage when subjected to a temperature gradient. Thermoelectric couples are solid-state devices capable of generating electrical power from a temperature gradient, known as the Seebeck effect. (By contrast, the Peltier effect refers to the situation where electrical energy is converted into a temperature gradient.) A Seebeck device "couple" consists of one N-type and one P-type semiconductor pellet. The temperature differential causes electron flow from hot to cold in the N-type couple and hole flow from hot to cold in the P-type couple. To create an electromotive force (EMF), the following connections are made: On the cold side (i.e. the side that is exposed to room temperature) the pellets are joined and on the hot side (i.e. the patient side), the pellets are connected to a load, such as the computation and communication module 102. The open circuit voltage of a Seebeck device is given by $V = S \Delta T$, in which S is the Seebeck coefficient in volts/°K and ΔT is the temperature difference between the hot and cold sides. It is a challenge today to completely power the computation and communication module 102 from a Seebeck device that is of the same size as the computation and communication module 102. Presently, a Seebeck device may only provide supplementary power, but as electronics migrate toward lower power and Seebeck coefficients and thermocouple densities improve, a Seebeck device can be a viable long-term power solution for a patient-worn monitor. Other methods of generating energy, such as mechanical (as is used in some wrist watches) and solar, can also be viable methods for providing a renewable self-contained power source for a body worn monitor.

[0096] Turning to analysis routines suitable for use on a body worn monitor, typically, ECG beat picking, such as by using wavelet or Fourier transforms and/or matched filter analysis in the time domain can be computationally expensive. Modeling the QRS pulse as three triangles with alternating polarities creates a rough matched filter for the QRS pulse. Taking the second derivative results in impulse functions at the peaks of the triangles (where the first derivative is discontinuous), and all other points are zero. The second derivative method also makes the convolution with incoming data extremely efficient as most of the multiplies have a 0 as the multiplicand and requires minimal computation. The result can then be integrated twice to produce a matched-filter output, which can be fed into the beat-picking algorithm that provides fiducial marks. Using a second matched filter that is sinusoidal in shape and with appropriate discriminators, the system can provide indications of Life Threatening Arrhythmias (LTA); that is, Asystole, Vfib, and Vtach. While the accuracy of this system is less competitive with a high-end Arrhythmia solutions such as those provided, for example, by Mortara, the filters can be tuned to err toward false positives and upon a positive LTA response, activate transmission of full waveforms.

[0097] Research has also shown that analysis of the R-R portion of the ECG waveform interval statistics can provide a method to predict atrial flutter. Applying this and other low-computational cost methods can allow a body worn monitor device to begin transmitting full waveforms for either clinical or algorithmic analysis by a more powerful engine, when the probability of other arrhythmias is high. Transmitting only the R-R intervals of ECG waveforms is an example of a lossy data compression method. R-R intervals comprise a string of data and the string of data can also be compressed. Lossless or lossy data compression of the entire waveform can be implemented to save battery life, including not transmitting (or perhaps not even sampling) data between the T and the P wave. Because data compression results in less data to transmit, the power saved may offset the computation cost of the data compression.

[0098] While we have referred often to ECG applications herein, the application of low-intensity computational methods as a power saving measure apply equally well to other types of low power-sensors, including, but not limited to EEG, SPO₂, temperature, and invasive or non-invasive blood pressure measurements. Whether the body-worn medical-grade monitor performs complex analysis or simply compares a single numeric value to a single numeric limit, the device can function in a low-power radio state until a predetermined threshold is exceeded. A body

worn monitor can also periodically send data or send data upon external request. Additionally, external devices can send commands to modify the operating parameters and thresholds.

[0099] Turning to other communication matters, it may be that adverse events occur in which no uplink is available. In a case of no uplink (failed communications), the body worn monitor can buffer time-stamped waveforms corresponding to any adverse events. The buffers can also store waveforms for later analysis in which this storage is triggered by the patient when the patient recognizes a condition, such as chest pain. In the case of an alarm that occurs when there is no uplink, alarms can be configured to be latched until confirmed by a clinician. Preferably, non-continuous data are marked (time stamp, sample number) to allow correlation of non-continuous data with continuous data and data are also marked to indicate when an alarm was initiated for later data analysis, including algorithm performance analysis.

[00100] In those instances in which many body worn monitor devices are used in close proximity to one another, there can be concern that the reports from one body worn monitor might be interchanged with reports from another body worn monitor. The body worn monitor presented herein, can be configured with a patient context (i.e. name, room number, patient ID, age, etc) and can maintain that context for as long as the monitor is connected to the patient to avoid such problems. The body worn monitor can determine the status of its connection to the patient via a continuous vital signs monitor, pressure, temperature, galvanic response, or similar input. Upon detection of a loss of connection with a patient, the device can, depending upon different variable settings, either erase the patient context or when re-connected to the patient, require the care giver to confirm the patient context. When the body worn monitor is initially powered up or connected to a patient, it can have a time holdoff for alarms to prevent false alarms (e.g. low heart rate, lead-fail detection) while the system stabilizes.

[00101] Regarding firmware updates, where there are large numbers of body worn monitors in a hospital, it can be problematic to keep them all updated with the latest version of firmware. One solution to this problem is to provide a wireless update ability for downloading and installing new firmware and/or configurations into all of the body worn monitors.

[00102] While the present invention has been particularly shown and described with reference to the preferred mode as illustrated in the drawings, it will be understood by one skilled in the art that various changes in detail may be effected therein without departing from the spirit and scope of the invention as defined by the following claims. It is further understood that several aspects of the invention, including, but not limited to, defibrillation protection resistors, pacer detect circuit disabling, methods for ECG signal high pass filtering, and various other low power modes are not limited to body worn monitors, and can be used in ECG monitors of any type.

What is claimed is:

1. A method for manufacturing a body-worn physiological sensor, the method comprising:
providing a disposable substrate made from an insulating material, said substrate comprising:
a flexible printed circuit board layer made from the insulating material;
at least two electrodes disposed on the disposable substrate; and
conductive traces defined between the at least two electrodes;
providing a computation-communication module, said module comprising:
a housing;
a processor disposed in the housing; and
attaching the computation-communication module to the disposable substrate.
2. The method of claim 1, further comprising:
providing conductive traces in the flexible circuit layer.
3. The method of claim 2, in which the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module.
4. The method of claim 1, further comprising:
providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels.
5. The method of claim 1, in which the computation-communication module is releasably attached to the disposable substrate.
6. The method of claim 1, further comprising:
providing a radio circuit in the computation-communication module.

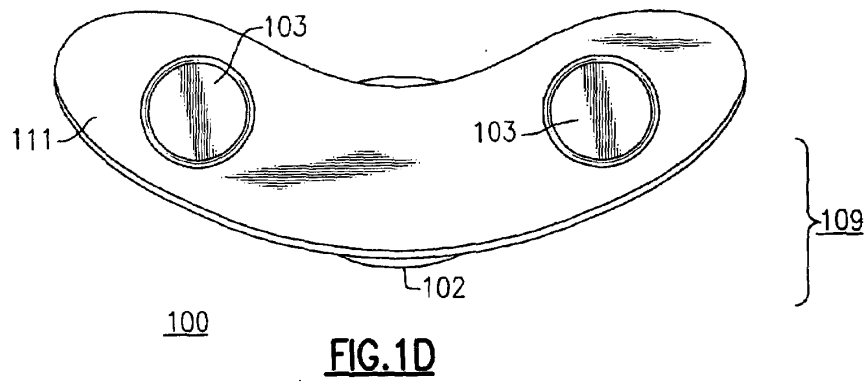
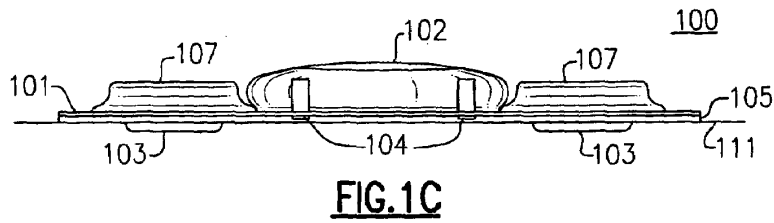
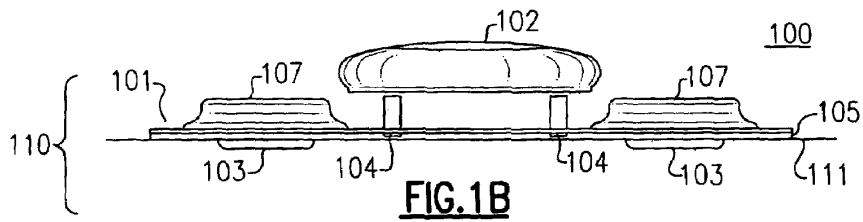
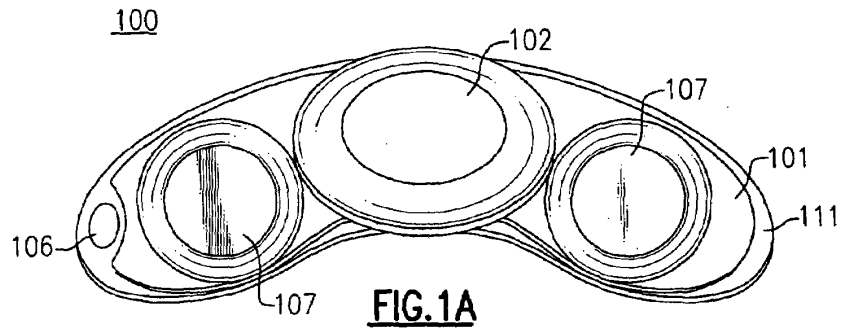
7. The method of claim 3, further comprising:
at least partially covering the conductive traces with an insulating covering.
8. The method of claim 7, in which the insulating covering is a fabric.
9. The method of claim 1, further comprising:
integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.
10. The method of claim 3, further comprising:
screening the conductive traces onto the flexible printed circuit board layer.
11. The method of claim 9, in which each electrode includes an electrode gel and a conductive surface defining a half cell.
12. The method of claim 11, in which the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient.
13. The method of claim 3, further comprising:
providing a pacer circuit in the flexible printed circuit board layer of the disposable substrate.
14. A body-worn physiological sensor made by the process of:
providing a disposable substrate made from an insulating material, said substrate comprising:
a flexible printed circuit board layer made from an insulating material;
at least two electrodes disposed on the disposable substrate; and
conductive traces defined between the at least two electrodes;
providing a computation-communication module, said module comprising:
a housing;

a processor disposed in the housing; and
attaching the computation-communication module to the disposable substrate.

15. The body-worn physiological sensor of claim 14, wherein the process further comprises:
providing the conductive traces in the flexible printed circuit board layer.
16. The body-worn physiological sensor of claim 15, in which the process further comprises:
configuring the conductive traces in the flexible printed circuit board layer to
electrically couple with the attached computation-communication module.
17. The body-worn physiological sensor of claim 14, in which the computation-
communication module is releasably attached to the disposable substrate.
18. The body-worn physiological sensor of claim 14, wherein the process further comprises:
providing the computation-communication module with a radio circuit.
19. The body-worn physiological sensor of claim 16, in which the process further comprises:
at least partially covering the conductive traces with an insulating covering.
20. The body-worn physiological sensor of claim 14, in which the process further comprises:
integrating at least two electrodes into the flexible printed circuit board layer of
the disposable substrate.

ABSTRACT

A body worn patient monitoring device includes a flexible substrate having a plurality of electrical connections adapted to be coupled to a skin surface to measure physiological signals. The flexible substrate is adapted to be directly and non-permanently affixed to a skin surface of a patient and configured for single patient use. A communication-computation module, removably attached to an upper surface of the flexible substrate, is configured to receive physiological signals from the flexible substrate and includes a microprocessor that is configured to process and analyze the physiological signals. A series of resistive traces screened onto the flexible substrate are configured as at least one series current-limiting resistor to protect the communication-computation module.



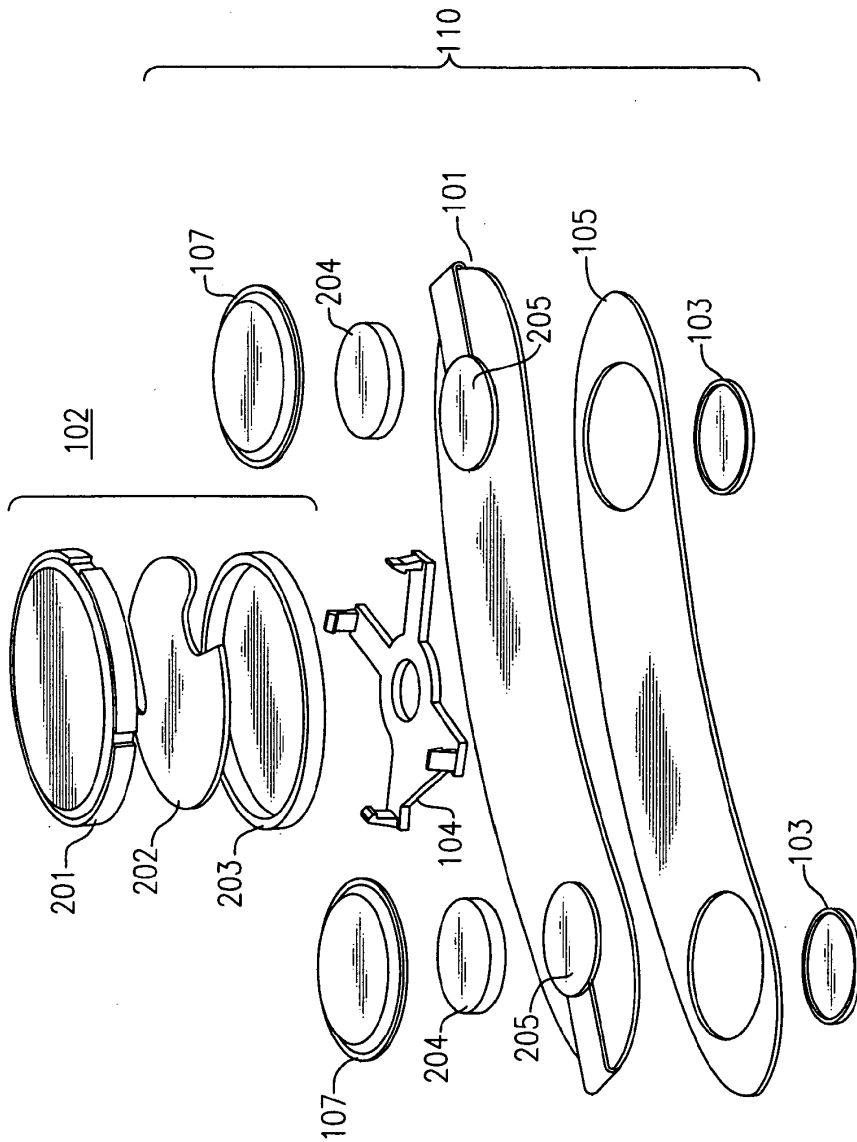
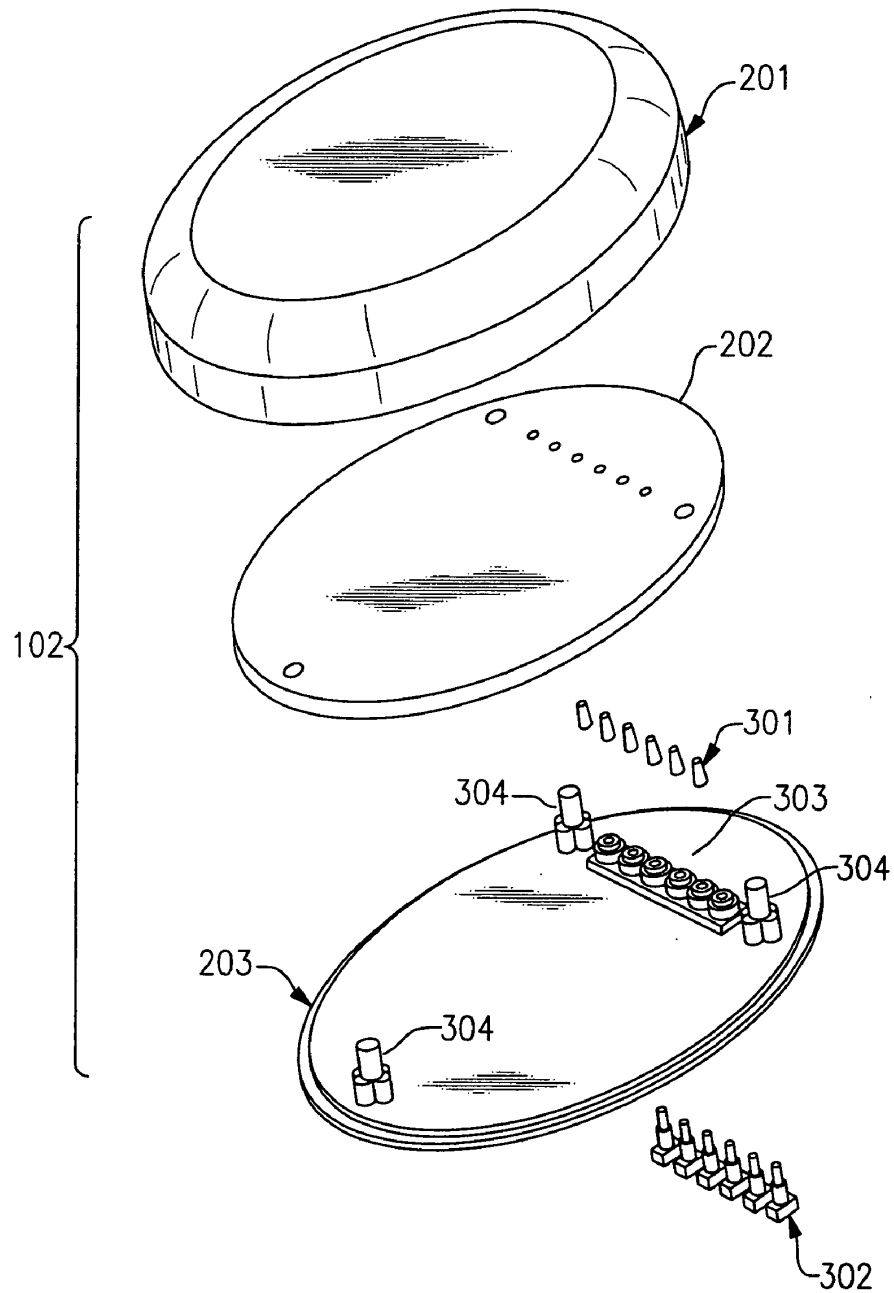


FIG. 2

**FIG.3**

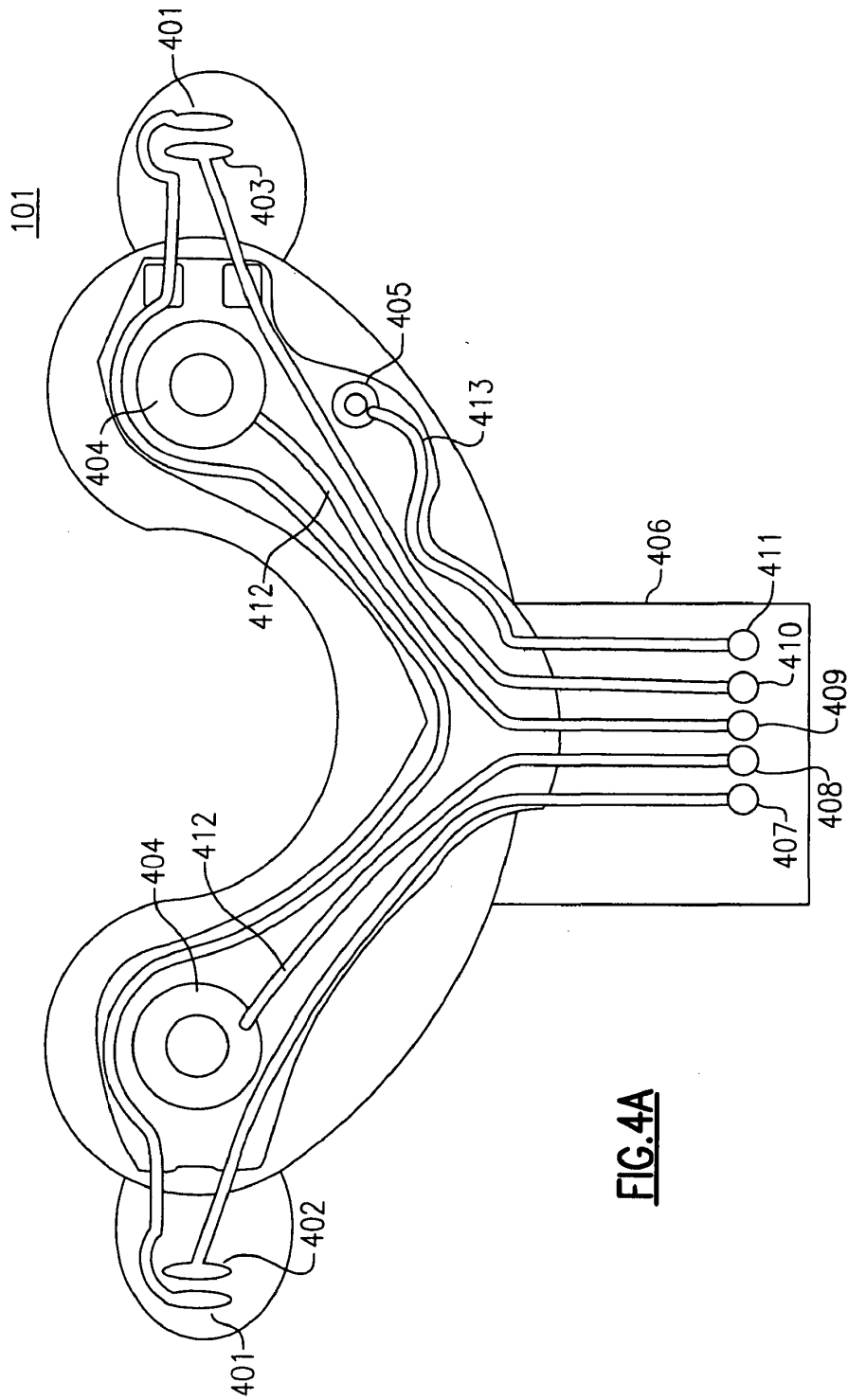


FIG. 4A

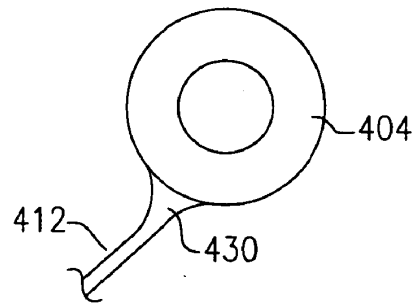


FIG. 4B

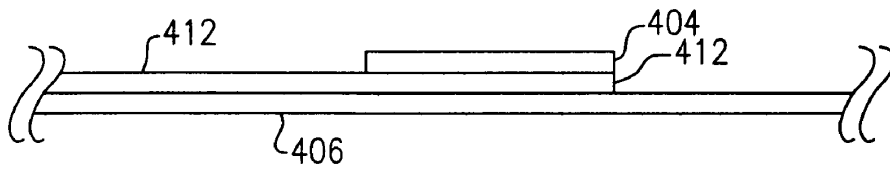


FIG. 4C

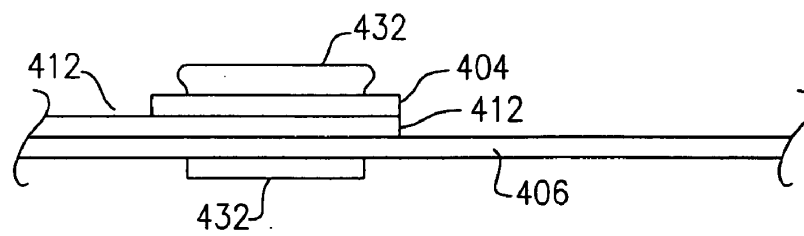


FIG. 4D

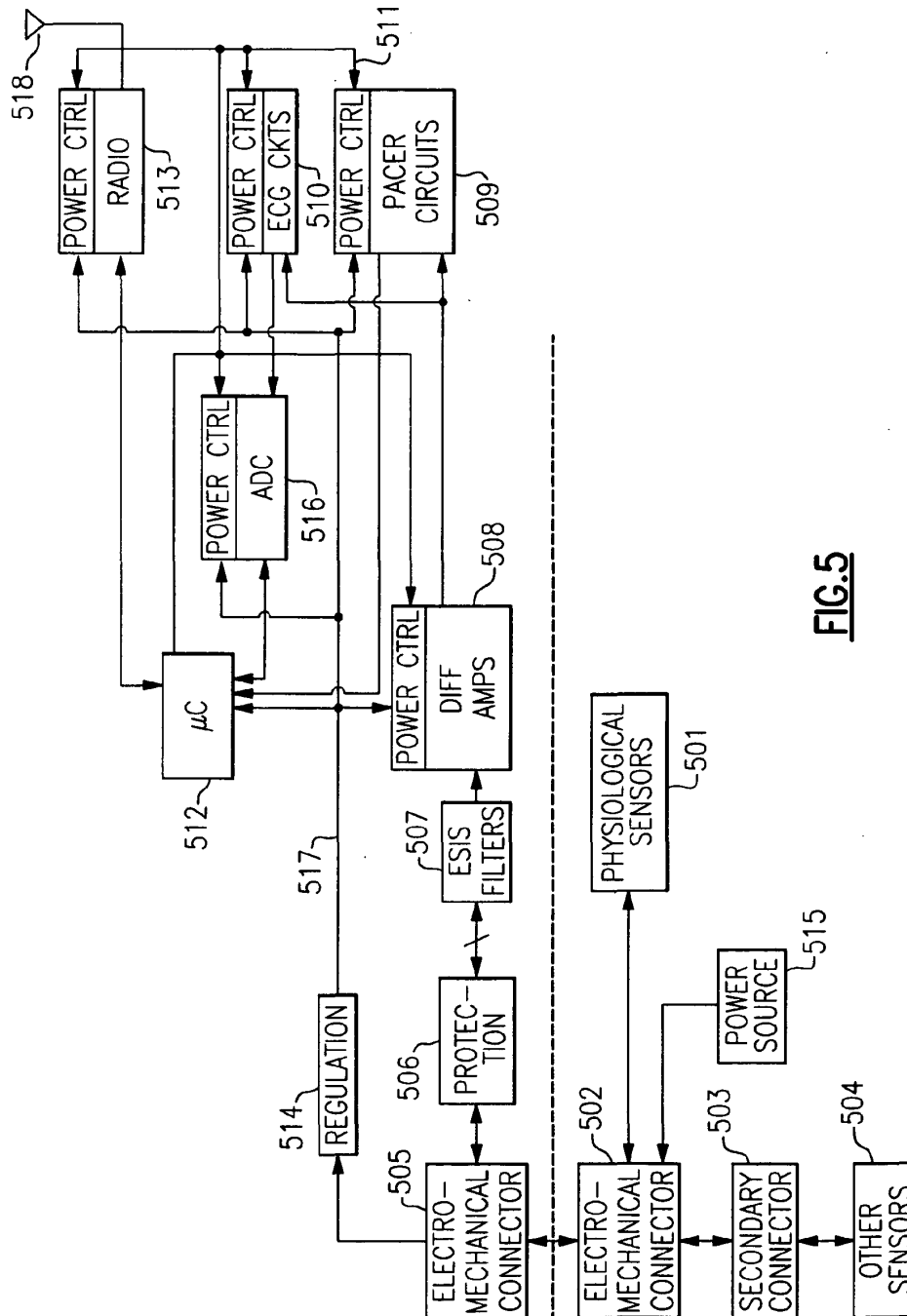
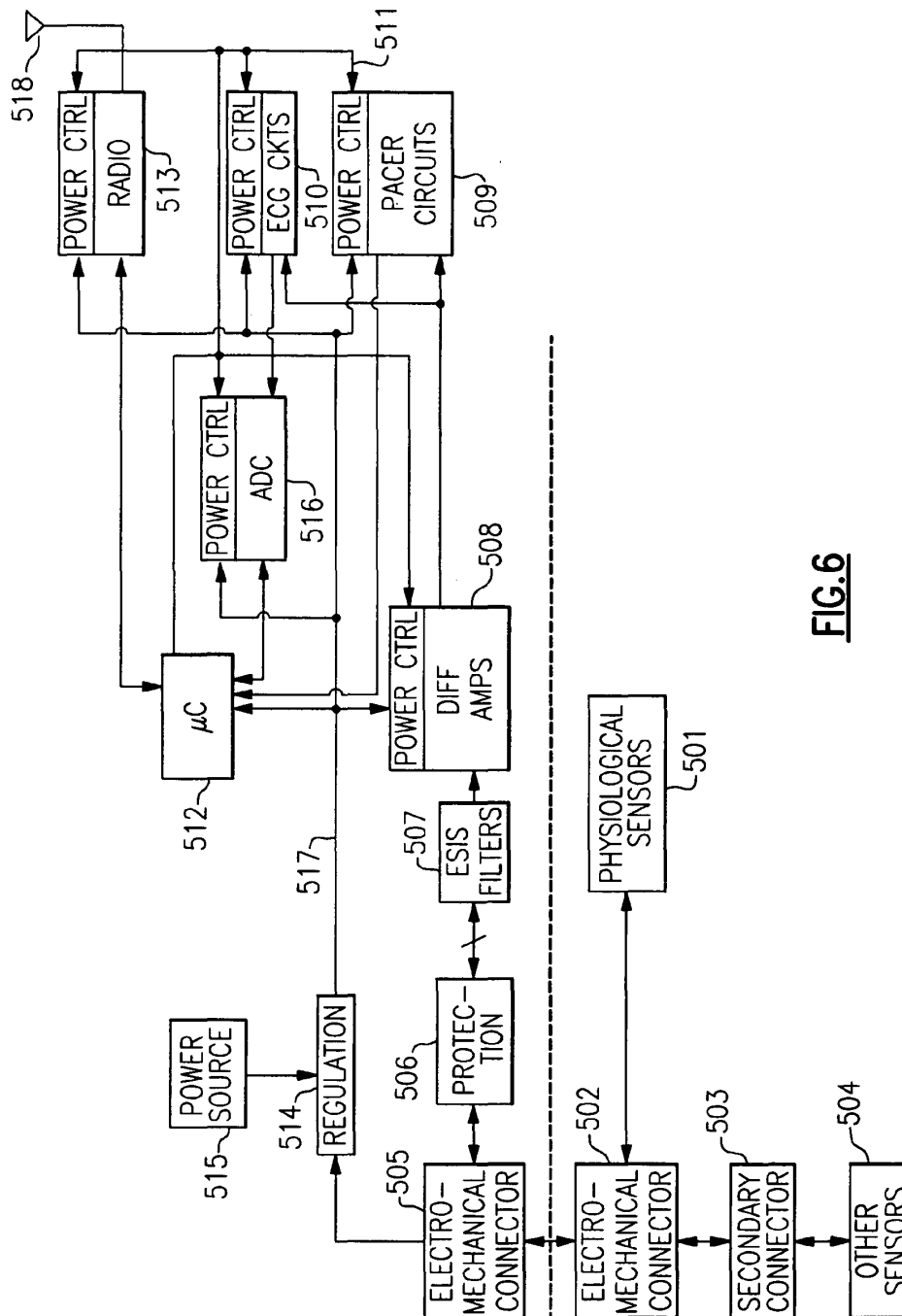
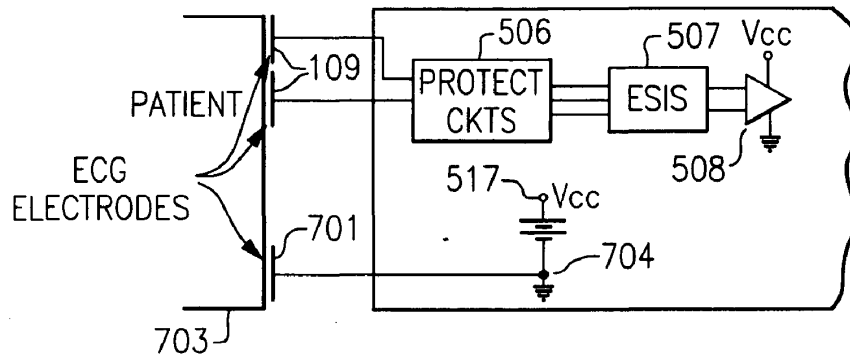
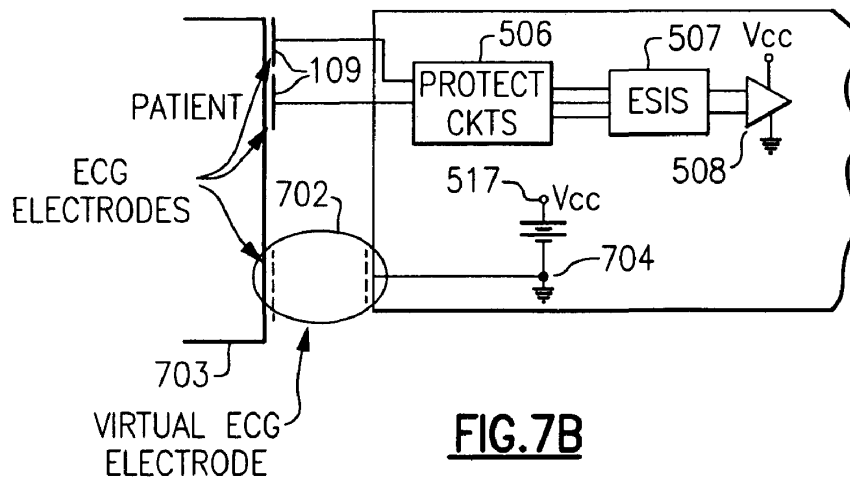
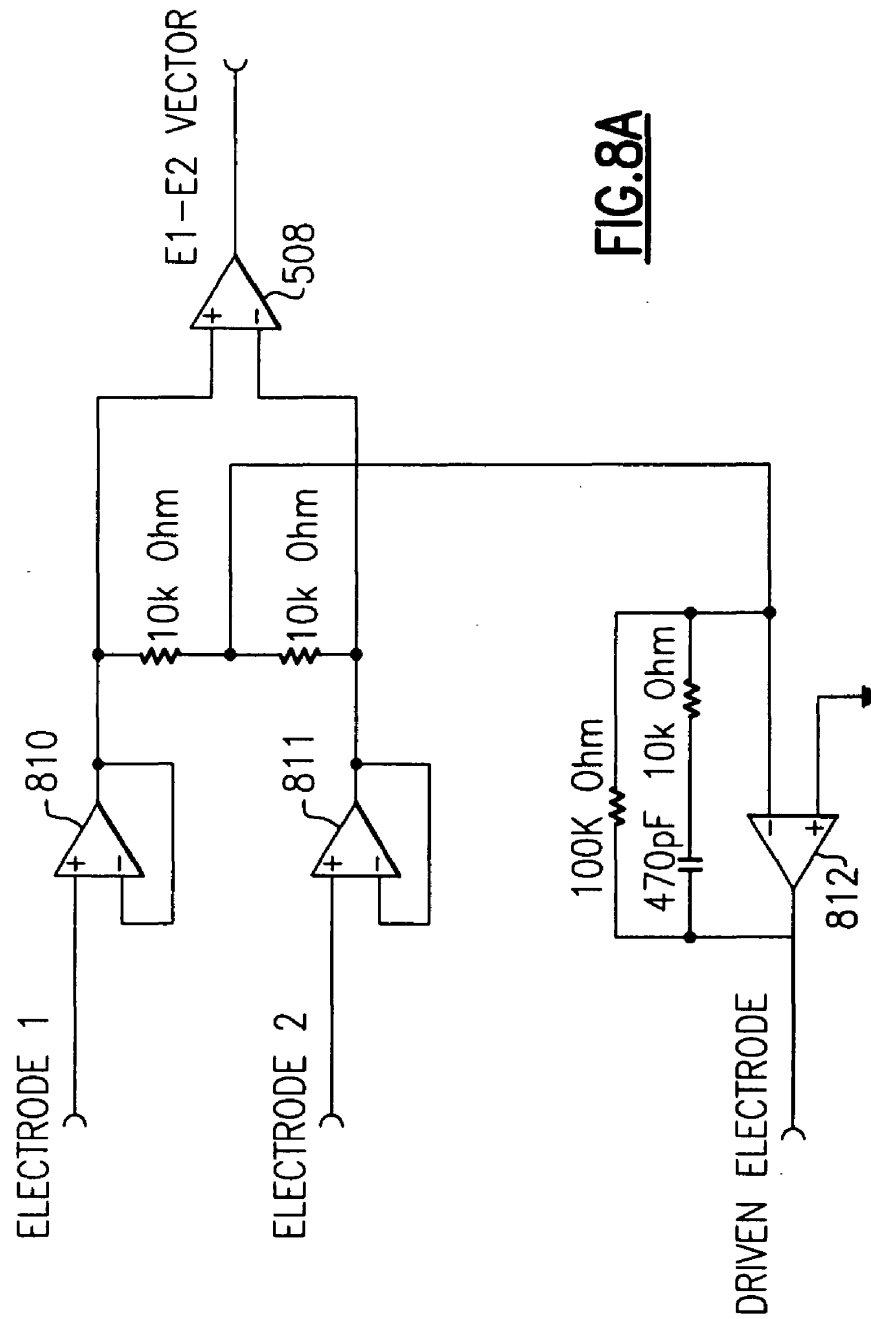


FIG. 5

**FIG. 6**

**FIG. 7A****FIG. 7B**



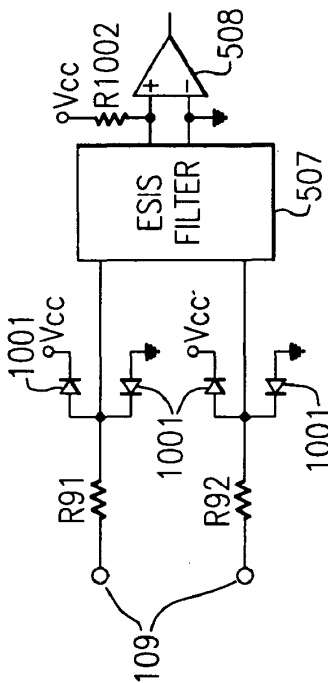
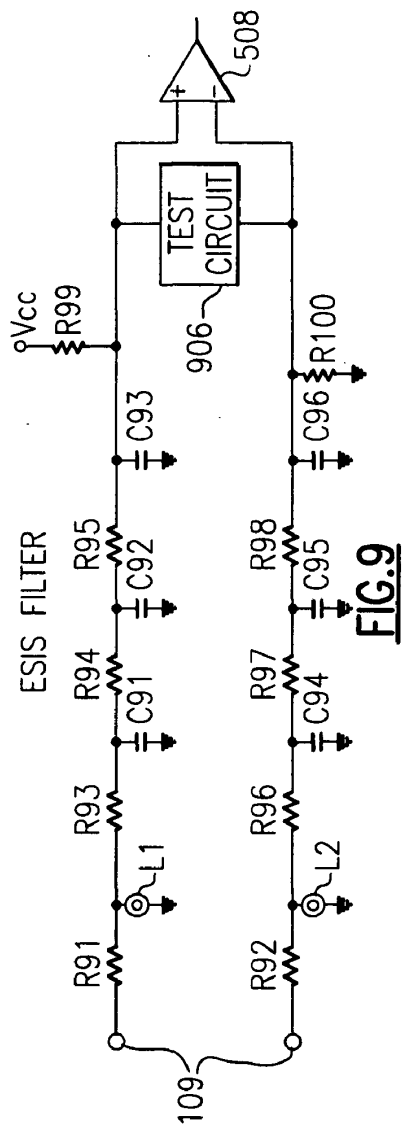
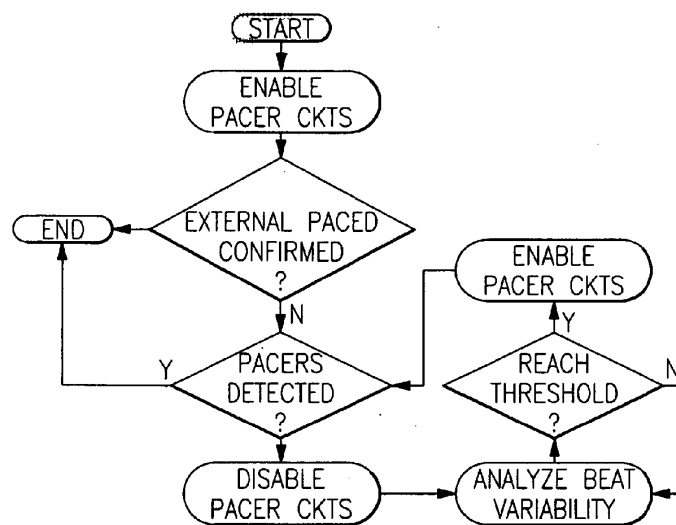
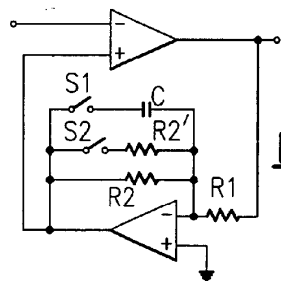
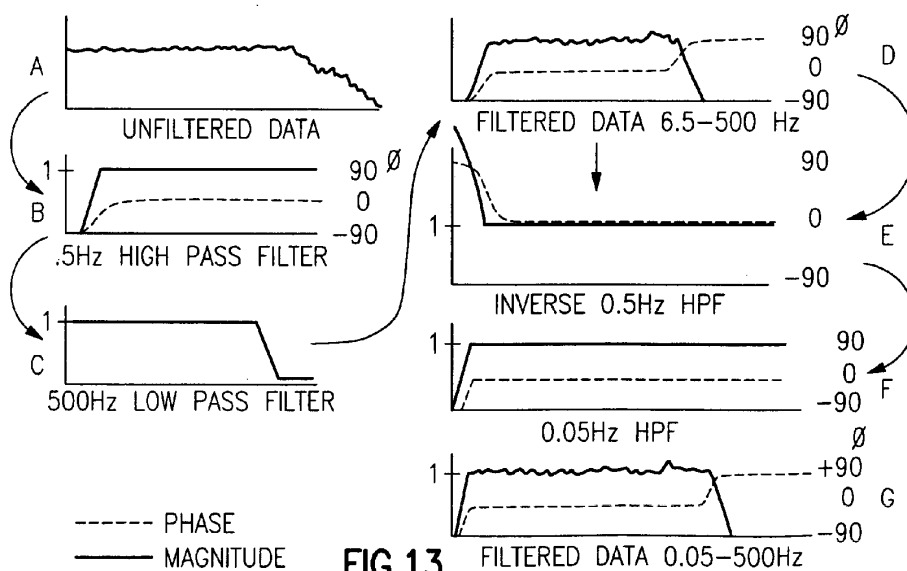


FIG. 10

**FIG. 11****FIG. 12****FIG. 13**

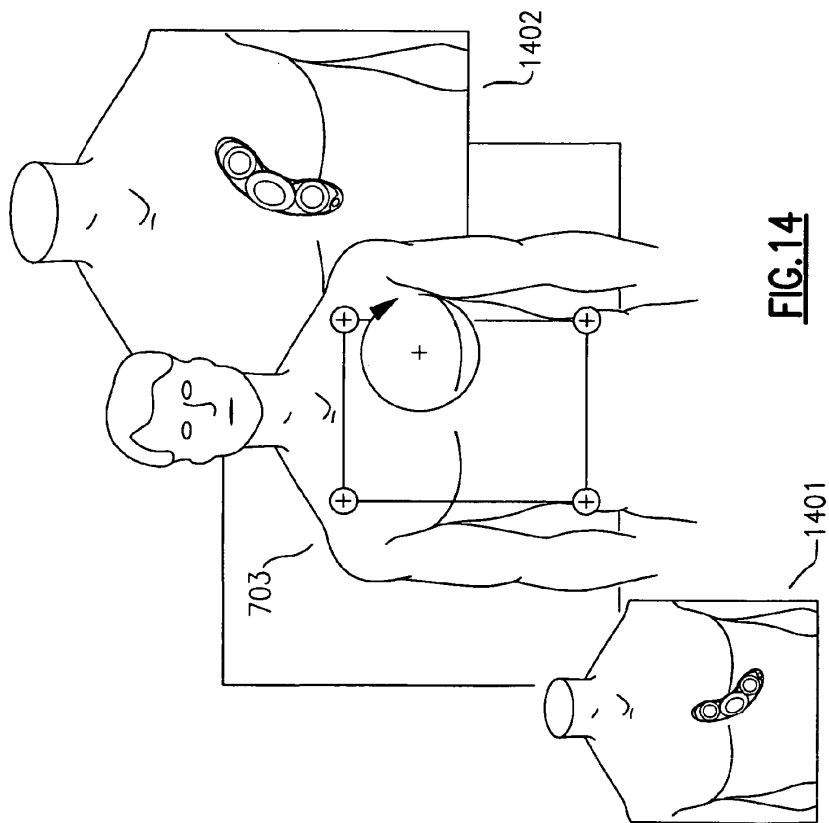


FIG. 14

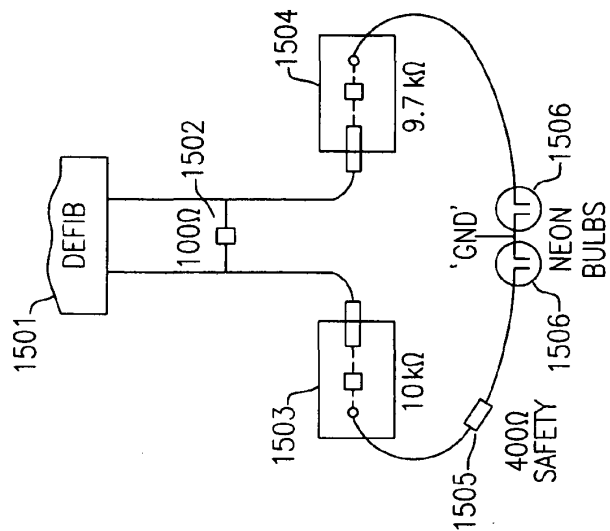
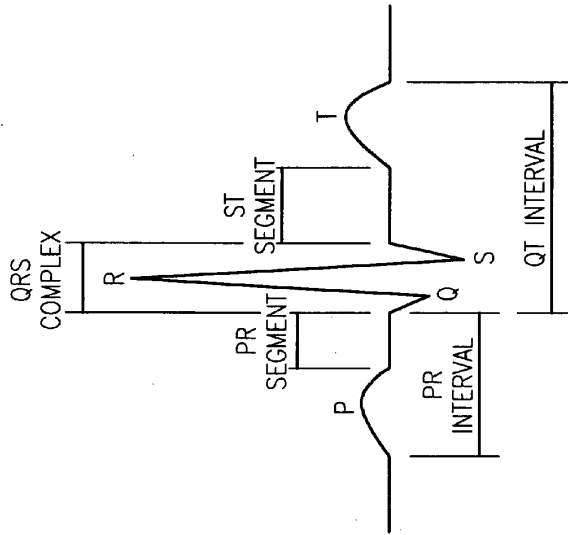
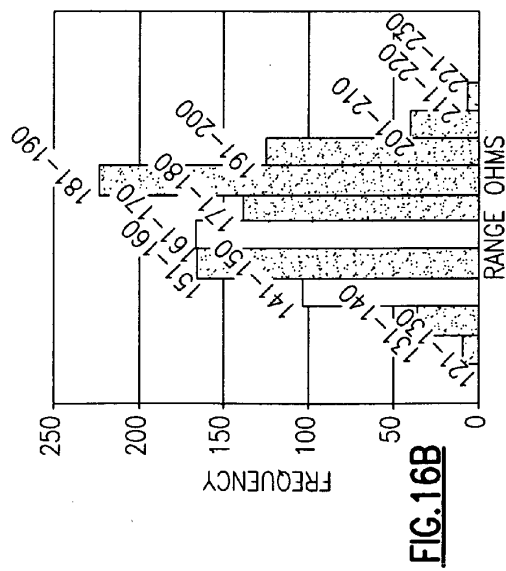
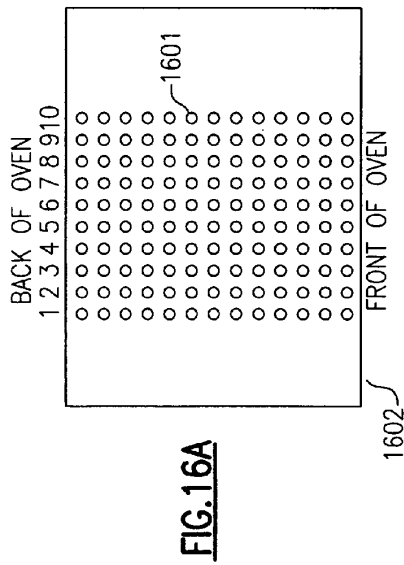


FIG. 15



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker et al.	Art Unit:	Not Yet Assigned
Serial No.:	Not Yet Assigned	Examiner:	Not Yet Assigned
Filing Date:	Concurrently Herewith		
Title:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

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

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.97, Applicants and their legal representatives hereby make of record the references on the attached PTO/SB/08A Form which are known by them and considered warranting disclosure under 37 C.F.R. §1.56. Also, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Forms (PTO/SB/08a/b, PTO-1449 and PTO-892). These references were cited during prosecution of parent applications U.S. Serial Nos. 15/237,719, 14/880,413, 14/595,815, 14/268,666, 14/103,219, 13/488,520 and 11/591,619, copies of each of the references can be found in the PTO file for the parent application.

The above information is presented so that the Patent and Trademark Office may, in the first instance, determine any materiality thereof to the claimed invention. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that these listed references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed (1) no later than three months from the application's filing date or (2) before the mailing date of the first Office Action on the merits and is therefore submitted as both timely and proper. Therefore, no fees are due and owing.

It is believed no fees are due. However, in the event of a fee deficiency, the Director is authorized to charge any underpayment or credit any overpayment to our Deposit Account No. 50-3010.

Respectfully submitted,

BARCLAY DAMON, LLP

/Peter J. Bilinski/

January 26, 2018
Date

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	15/237,719
				Filing Date	August 16, 2016
				First Named Inventor	Steven D. Baker
				Art Unit	3762
				Examiner Name	Johnson, Nicole F.
				Attorney Docket Number	3022036 US07
Sheet	1	of	2		

[illegible][illegible]

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		Filing Date	August 16, 2016
		First Named Inventor	Steven D. Baker
		Art Unit	3762
		Examiner Name	Johnson, Nicole F.
		Attorney Docket Number	3022036 US07
Sheet	2	of	2

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	AE	Supplementary European Search Report for EP 07 844 786.1; Dated: May 31, 2017; 10 pages	

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Substitute for form 1449/PTO				Complete if Known Application Number 15/237,719 Filing Date August 16, 2016 First Named Inventor Steven D. Baker Art Unit 3762 Examiner Name Johnson, Nicole F. Attorney Docket Number 3022036 US07	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)					
Sheet	1	of	2		

[illegible][illegible]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	15/237,719
		Filing Date	August 16, 2016
		First Named Inventor	Steven D. Baker
		Art Unit	3762
		Examiner Name	Johnson, Nicole F.
		Attorney Docket Number	3022036 US07
Sheet	2	of	2

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	AE	European Supplementary Partial Search Report for EP 07 84 4766.1; Dated: February 24, 2017; 7 pages	

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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1008
Page 238

Date: June 7, 2012

Sheet 1 of 6

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number:	Application Number:
	3622636 US92	130488,720
	Applicant: Steven G. Traker et al.	Confirmation No.: 9661
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	5,832,480	11/03/1998	Riley			
	5,871,451	02/16/1999	Unger et al.			

EXAMINER	DATE CONSIDERED
EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

* Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Dossier Number: W2226 L002	Application Number: 13488,530
	Applicant: Steven D. Risken et al	Confirmation No.: 9891
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

* Substitute Disclosure Statement Form (PTO-1449)

Date: June 7, 2012

Sheet 3 of 6

Customer Ref: 89759

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number:	Application Number:
	3022635 US02	13488,320
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group An Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,296,314 B1	10/02/2001	Blackadar et al.			
	6,331,444	12/18/2001	Ferrari et al.			
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609, draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number:	Application Number:
	3922036 US02	17488 S20
	Applicant: Steven D. Baker et al.	Confirmation No.: 8661
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2002/0106799 A1	08/08/2002	Potts et al.			
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

*Substitute Disclosure Statement Form (PTO-1449)

Date: June 1, 2012

Sheet 3 of 6

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Document Number: 102036-11502	Application Number: 11488529
	Applicant: Steven D. Baker et al.	Confirmation No.: 9001
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2010/0145202	08/10/2010	McLaughlin et al.			
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
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Date: June 7, 2012

Sheet 6 of 6

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use separate sheets if necessary)	Locket Number: 3022036 US02	Application Number: 137485,920
	Applicant: Steven D. Baker et al.	Confirmation No.: 9691
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

OTHER DOCUMENTS (Including Author, Title, Date, Page(s), etc.)		
		Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2008-507455 (5 pages).
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

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Date: May 23, 2011

Sheet 2 of 2

Customer No.: 88750

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Doc. of Number:	Application Number:
	us2006/01801	11/001,618
	Applicant: Steven D. Baker et al.	Confirmation No.: 7975
	Filing Date: November 1, 2006	Group Art Unit: 3162

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 2009/142385	11/27/2008	WO				
	WO 2009/056859	5/7/2009	WO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		

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Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Notice of References Cited	Application/Control No. 15/237,719	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20170106

Notice of References Cited	Application/Control No. 15/237,719	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art. Unit 3762	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-2003/0135125 A1	07-2003	Lu, Steven N.	A61B5/0008	600/510
	B	US-				
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U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20170528

Notice of References Cited	Application/Control No. 11/551,519	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERGT	Art Unit 3762	Page 1 of 1

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U.S. Patent and Trademark Office
PTO-0552 (Rev. 01-2007)

Notice of References Cited

Part of Paper No. 20100303

Notice of References Cited	Application/Control No. 13/488,520	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

* A	Document Number Country Code Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-2008/0134963 A1	06-2008	Baker et al.	600/599
B	US-			
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FOREIGN PATENT DOCUMENTS

* N	Document Number Country Code Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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U.S. Patent and Trademark Office
 PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20130511

Notice of References Cited	Application/Control No. 14/595,815	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3782	Page 1 of 1

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*	A	US-2004/0030258 A1	02-2004	Williams et al.	600/544
	B	US-			
	C	US-			
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FOREIGN PATENT DOCUMENTS

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U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20150223

Notice of References Cited	Application/Control No. 14/860,413	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	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-2002/0099277 A1	07-2002	Harry, Andrea	A61B5/0002	600/301
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FOREIGN PATENT DOCUMENTS

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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

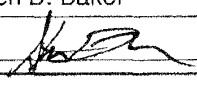
Notice of References Cited

Part of Paper No. 20151115

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	Not Yet Assigned
	Filing Date	Concurrently Herewith
	First Named Inventor	Steven D. Baker
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	3022036 US08

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):			
☐ That each item from a foreign patent information disclosure of information contained in the information disclosure statement was first cited in any communication office in a counterpart foreign application not more than three months prior to the filing of the 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 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	/Peter J. Bilinski/	Date (YYYY-MM-DD)	2018-01-26
Name/Print	Peter J. Bilinski	Registration Number	35,067
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.			

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

Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
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 <u>14/103,219</u> filed on <u>December 11, 2013</u>. The above-identified application was made or authorized to be made by me. I believe that I am the original inventor or an original joint inventor of a claimed invention in the application. I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. LEGAL NAME OF INVENTOR Inventor: <u>Steven D. Baker</u> Date (Optional): <u>16 Dec 2013</u> Signature:  Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

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

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

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

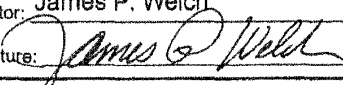
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
As the below named inventor, I hereby declare that: This declaration is directed to: ☐ The attached application, or ☒ United States application or PCT international application number <u>14/103,219</u> filed on <u>December 11, 2013</u> The above-identified application was made or authorized to be made by me. I believe that I am the original inventor or an original joint inventor of a claimed invention in the application. I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.	
LEGAL NAME OF INVENTOR Inventor: <u>Eric T. McAdams</u> Date (Optional): <u>18 December 2013</u> Signature: <u>/Eric T. McAdams/</u>	
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	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
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 <u>14/103,219</u> filed on <u>December 11, 2013</u> The above-identified application was made or authorized to be made by me. I believe that I am the original inventor or an original joint inventor of a claimed invention in the application. I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. LEGAL NAME OF INVENTOR Inventor: <u>James P. Welch</u> Date (Optional): <u>1/28/2014</u> Signature: <u></u> 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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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Steven D. Baker
Title	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	3022036 US08

SIGNATURE of Applicant or Patent Practitioner

Signature	/Peter J. Bilinski/	Date (Optional)	January 26, 2018
Name	Peter J. Bilinski	Registration Number	35,067
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			
NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.			
☒ *Total of <u> 1 </u> forms are submitted.			

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number

Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)



I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

88,750

OR



I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:



The address associated with the above-mentioned Customer Number

OR



The address associated with Customer Number:

OR

Firm or
Individual Name

Address

City

State

Zip

Country

Telephone

Email

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

Welch Allyn, 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

Chris Horacek

Title

Vice President - Deputy General Counsel

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.



Total of

1

forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		
First Named Inventor/Applicant Name:		Steven D. Baker		
Filer:		Peter J Bilinski/Susanne Pelose		
Attorney Docket Number:		3022036 US08		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1720

Electronic Acknowledgement Receipt	
EFS ID:	31614517
Application Number:	15880712
International Application Number:	
Confirmation Number:	9503
Title of Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	88750
Filer:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US08
Receipt Date:	26-JAN-2018
Filing Date:	
Time Stamp:	11:33:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$1720
RAM confirmation Number	012618INTEFSW00016828503010
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	Transmittal of New Application	2018-01-26-Application-Transmittal.pdf	87725	no	1
			e6aca894a49f8f460483e683f9723e8f8e33f331		
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	2018-01-26-Fee-Transmittal.pdf	74303	no	1
			726a5c56d3c4b75c593e5c37512e615e01be1bd9		
Warnings:					
Information:					
3	Application Data Sheet	2018-01-26-ADS.pdf	101245	no	8
			0e40051531835fbc2891e30968c9b7da24480003		
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
4		2018-01-26-Specification.pdf	262199	yes	32
			c5047eec13681ed25efa7e51cc499196203a0dd1		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	28	
	Claims		29	31	
	Abstract		32	32	
Warnings:					
Information:					

5	Drawings-only black and white line drawings	2018-01-26-Drawings.pdf	226326	no	14
			0f3a03da51900a43d28f499e2d6146817ed62cfd		
Warnings:					
Information:					
6	Transmittal Letter	2018-01-26-IDS.pdf	80791	no	1
			2980b470db0f9fb4f6260dfe7d93b926c20932a4		
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	2018-01-26-PTO-SB-08a-b-PTO-1449-and-PTO-892.pdf	9793216	no	19
			e65baea55b07ed3a3d6e3e10f2b5622c94de8b6eb		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
8	Miscellaneous Incoming Letter	2018-01-26-Certification-Statement.pdf	78244	no	1
			d67f75701bb4e78698f9a5f997d99fdd3eab6548		
Warnings:					
Information:					
9	Oath or Declaration filed	2018-01-26-Declaration.pdf	323412	no	3
			404015f098cff15e44edfa80c77599040384b388		
Warnings:					
Information:					
10	Power of Attorney	2018-01-26-POA.pdf	135475	no	2
			cd577060b57c9e801dfd1e465b03b6819bee3a3e		
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	34954	no	2
			ba98dc394d360c2def9d4a8e1faac437bed23482		
Warnings:					
Information:					
Total Files Size (in bytes):			11197890		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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