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Placeholder Sheet for Supplemental Content

Application Number: 18927698 Document Date: 10/25/2024

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Samsung Ex. 1002
Samsung v. Omni
PGR2025-00063
Page 00001

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Placeholder Sheet for Supplemental Content

Application Number: 18927698 Document Date: 10/25/2024

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Form Revision Date: March 1, 2024

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PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/927,698	**10/25/2024 07:14:44 PM Z ET**	**OMNI0101PUSA13**

Title of Invention

WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9133	FILED BY	Sharon Kaiser
PATENT CENTER #	67724752	FILING DATE	-
CUSTOMER #	109543	FIRST NAMED INVENTOR	Mohammed N. ISLAM
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Kevin Heinl

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
ADS-aia0014_OMNI0101PUSA13.pdf	12	Application Data Sheet	1229 KB
Track1-Request_for_Prioritized_Examination_aia0424.pdf	2	Track One Request	180 KB
Application_OMNI0101PUSA13-APP.TEXT.docx	132	Application body structured text document	264 KB
Figures_OMNI0101PUSA13.pdf	100	Drawings-only black and white line drawings	14472 KB
POA_OMNI0101PUSA13.pdf	2	Power of Attorney	929 KB
Declaration-Assignment_OMNI0101PUS	1	Oath or Declaration filed	551 KB

A13.pdf			
Application_OMNI0101PUSA 13.pdf	132	Auxiliary PDF of Application	1483 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
ADS-aia0014_OMNI0101PUSA13.pdf	4DE26C60EF7FE226C0E739C66A43EC78DF3312D8A0228E75B6BBB44AA986A75BB4C78D832874CF02A03788114D0BE4973764E0C0A9FBAC5FCD57223AF7AB0616
Track1-Request_for_Prioritized_Examination_aia0424.pdf	B6D013E456BE1BD6627E583BC1F731089F47A732A258F83C821DB6831C0842B42648FA72947E62B972358F91AA679572773AF735E3A4984624064B553B9E32E5
Application_OMNI0101PUSA13-APP.TEXT.docx	5D58F79E24C9D44D96A5646D7ECAACCB0FD99DCCDF23C74754648EC51E9B8B36CA7D3F32A0587C4C9896CE96C5602DEADB2C2D908D8391CFDC86443B5834DC83
Figures_OMNI0101PUSA13.pdf	DA7E69AF29CA816C64A4C6FF9CBD397BCB1A797CC183BFE001D2D178C09820C41B6394B46D4DD65C650190A4A07E9DE034515AD842F01C2B1D95128AFE88C52E
POA_OMNI0101PUSA13.pdf	D4857F1401916700F38CD620192771F02BCDFD8D6E41E64E18F628A8EC03E5D94F01C107B27AE8B5983C9FD99CF0772812EF9C6AD32FBD5E87D940BC379CAB04
Declaration-Assignment_OMNI0101PUSA13.pdf	86EB02138F79B069ADD725A7930C1EF94343339F3D13AEDD42A377649DF1AA614F2E05335C6A9CDA978DD774B5D5BFBECD0C291AFE50A50D6FB503443D7961C2
Application_OMNI0101PUSA13.pdf	C43E75252082F45A527A0BF3C9FDC6F149FBB894F20DF09319BC1F77D7ADD82A1BE4B6E9B1FA1BB0E7597D002EA687221400103B5C3D99BB9174A9FAF553E4AD

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 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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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/927,698	**10/25/2024 07:14:44 PM Z ET**	**OMNI0101PUSA13**

Title of Invention

WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9133	FILED BY	Sharon Kaiser
PATENT CENTER #	67724752	AUTHORIZED BY	Kevin Heinl
CUSTOMER #	109543	FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Mohammed N. ISLAM

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 023978	**E20240OJ18028122**	**Sharon Kaiser**

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
023978	**37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.21 (Miscellaneous fees and charges)**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	56.00	1	56.00
2817	REQUEST FOR PRIORITIZED EXAMINATION	1680.00	1	1680.00
2111	UTILITY PATENT APPL. SEARCH FEE	280.00	1	280.00
4011	BASIC FILING FEE- UTILITY	64.00	1	64.00
2311	EXAMINATION OF ORIGINAL PATENT APPLICATION	320.00	1	320.00

2081	UTILITY APPL. SIZE FEE > THAN 100 PAGES (FEE X PAGES >= 101 IN 50 PAGE INCREMENTS)	168.00	2	336.00
			TOTAL AMOUNT:	**$2,736.00**

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 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.

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 or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.

Application Number	
Filing Date	
First Named Inventor	MOHAMMED N. ISLAM
Title	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI0101PUSA13

SIGNATURE of Applicant or Patent Practitioner

Signature	/Kevin J. Heinl/	Date (Optional)	2024-10-25
Name	Kevin J. Heinl	Registration Number	29,805
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 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.

PTO/AIA/82B(07-12)
Approved for use through 11/30/2014. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.

☒ I hereby appoint 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 equivalent):

109543

OR

☐ I hereby appoint Practitioner(s) named below 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 equivalent):

Name	Registration Number	Name	Registration Number

Please recognize or change the correspondence address for the application identified in the attached transmittal letter 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:

☐ Inventor or Joint Inventor

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign

☐ 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)

SIGNATURE of Applicant for Patent

Signature		Date	October 10, 2012
Name	Mohammed N. Islam	Telephone	734-647-8941
Title and Company	President - OMNI MEDSCI, INC.		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms for more than one signature, see below *.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

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
	Mohammed	N.	ISLAM	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Ann Arbor	State/Province	MI	Country of Residence	US

Mailing Address of Inventor:

Address 1	1718 Newport Creek Drive		
Address 2			
City	Ann Arbor	State/Province	MI
Postal Code	48103	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	109543		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW		
Attorney Docket Number	OMNI0101PUSA13	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	100	Suggested Figure for Publication (if any)	82

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

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

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

Representative Information:

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

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	109543		

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	18899012	2024-09-27

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
18899012	Continuation of	18891970	2024-09-20
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
18891970	Continuation of	18438144	2024-02-09
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
18438144	Continuation of	18103408	2023-01-30	11896346	2024-02-13

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
18103408	Continuation of	17514778	2021-10-29	11564577	2023-01-31

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17514778	Continuation of	17078771	2020-10-23	11160455	2021-11-02

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17078771	Continuation of	16/722188	2019-12-20	10820807	2020-11-03

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/722188	Continuation of	16/506885	2019-07-09	10517484	2019-12-31

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/506885	Continuation of	16/272069	2019-02-11
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/272069	Continuation of	16/029611	2018-07-08	10201283	2019-02-12

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/029611	Continuation of	15/888052	2018-02-04

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15/888052	Continuation of	15/212549	2016-07-18

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/212549	Continuation of	14/650897	2015-06-10	9494567	2016-11-15

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/650897	a 371 of international	PCT/US2013/075700	2013-12-17

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2013/075700	Claims benefit of provisional	61/747472	2012-12-31

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/506885	Continuation of	16/004359	2018-06-09	11109761	2021-09-07

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/004359	Continuation of	14/109007	2013-12-17	9993159	2018-06-12

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/109007	Claims benefit of provisional	61/747553	2012-12-31

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/506885	Continuation of	16/188194	2018-11-12

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/188194	Continuation of	16/004154	2018-06-08	10126283	2018-11-13

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/004154	Continuation of	15/855201	2017-12-27
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15/855201	Continuation of	15/711907	2017-09-21
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15/711907	Division of	15/357225	2016-11-21
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/357225	Continuation of	14/650981	2015-06-10	9500634	2016-11-22

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/650981	a 371 of international	PCT/US2013/07576	2013-12-17
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2013/075767	Claims benefit of provisional	61/747485	2012-12-31
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/506885	Continuation of	16/241628	2017-01-07	10441176	2019-10-15

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/241628	Continuation of	16/015737	2018-06-22
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/015737	Continuation of	15/594053	2017-05-12

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/594053	Continuation of	14/875709	2015-10-06	9651533	2017-05-16

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/875709	Continuation of	14/108986	2013-12-17

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/108986	Claims benefit of provisional	61/747487	2012-12-31

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/506885	Continuation of	16/284514	2019-02-25

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/284514	Continuation of	16/016649	2018-06-24

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/016649	Continuation of	15/860065	2018-01-02

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15/860065	Continuation of	15/686198	2017-08-25

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15/686198	Continuation of	15/357136	2016-11-21

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/357136	Continuation of	14/651367	2015-06-11	9500635	2016-11-22

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/651367	a 371 of international	PCT/US2013/075736	2013-12-17
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2013/075736	Claims benefit of provisional	61/747477	2012-12-31
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2013/075736	Claims benefit of provisional	61/754698	2013-01-21
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			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.			Add

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	OMNI MEDSCI, INC.		
Mailing Address Information For Applicant:			
Address 1	1718 Newport Creek Drive		
Address 2			
City	Ann Arbor	**State/Province**	MI
Country	US	Postal Code	48103
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country [i]		Postal Code	
Phone Number		Fax Number	
Email Address			

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

Signature:

Remove

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

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

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

Signature	/Kevin J. Heinl/			Date (YYYY-MM-DD)	2024-10-25
First Name	Kevin J.	Last Name	Heinl	Registration Number	29,805

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI0101PUSA13
	Application Number	
Title of Invention	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

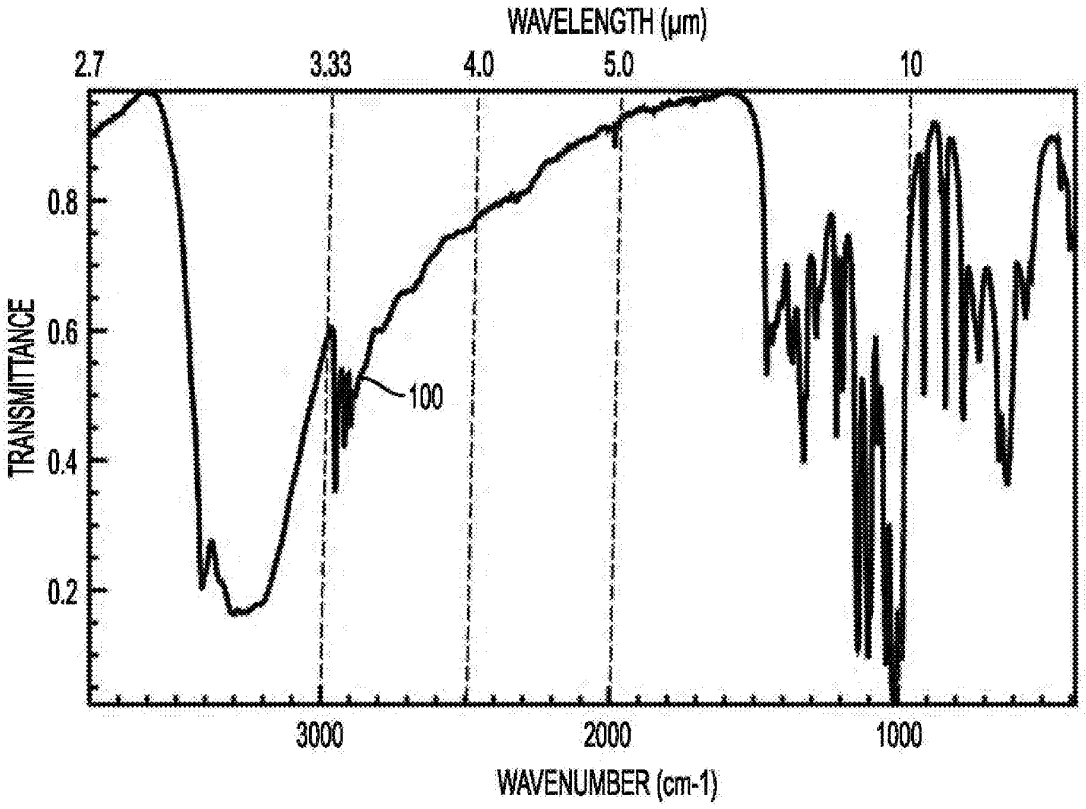

WAVELENGTH (μm)
2.7
3.33
4.0
5.0
10
TRANSMITTANCE
0.8
0.6
0.4
0.2
100
3000
2000
1000
WAVENUMBER (cm-1)

FIG. 1

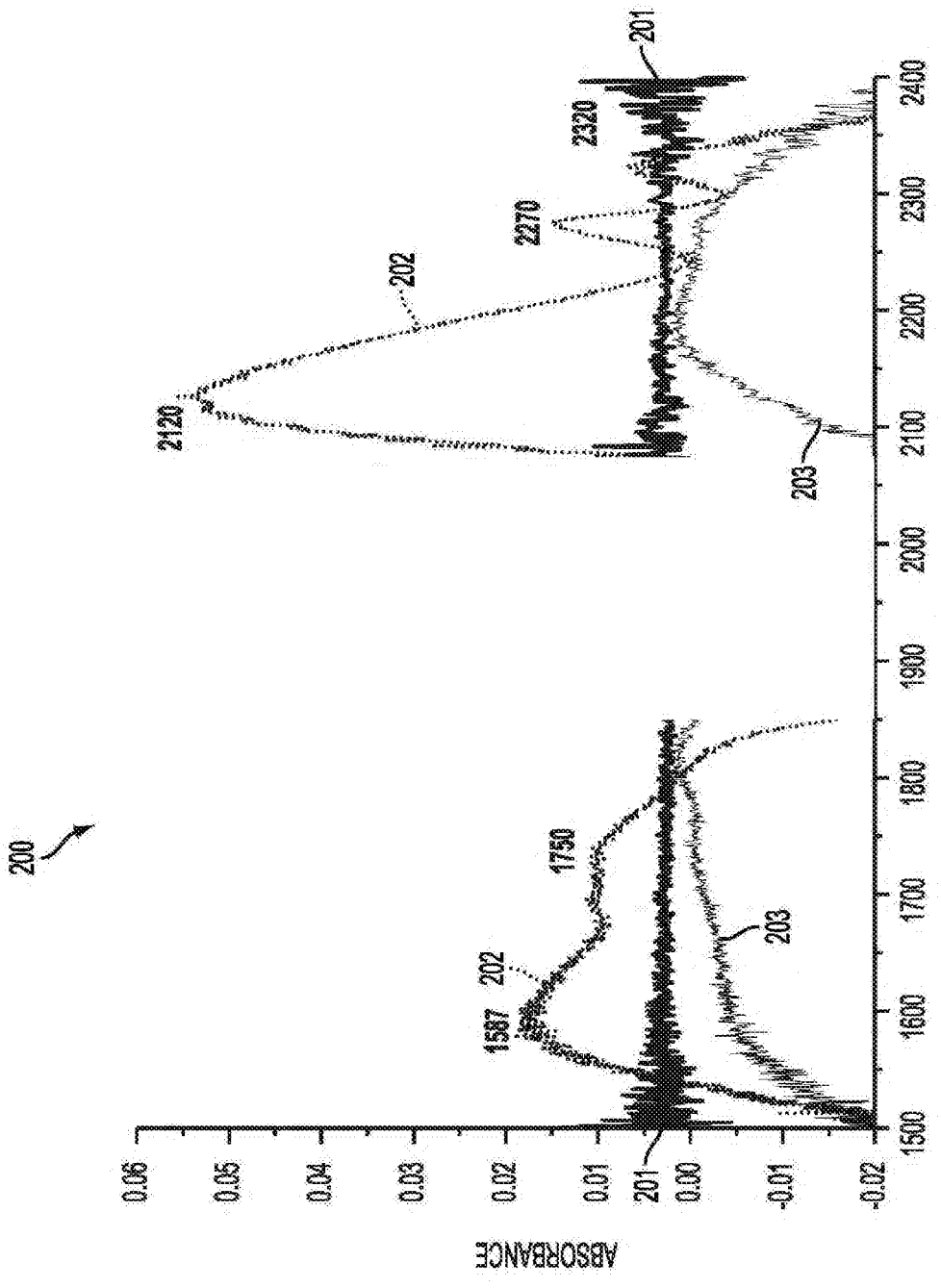

200
ABSORBANCE
0.06
0.05
0.04
0.03
0.02
0.01
0.00
-0.01
-0.02
1500
1600
1700
1800
1900
2000
2100
2200
2300
2400
WAVELENGTH (nm)
201
202
203
1587
1750
2120
2270
2320

FIG. 2

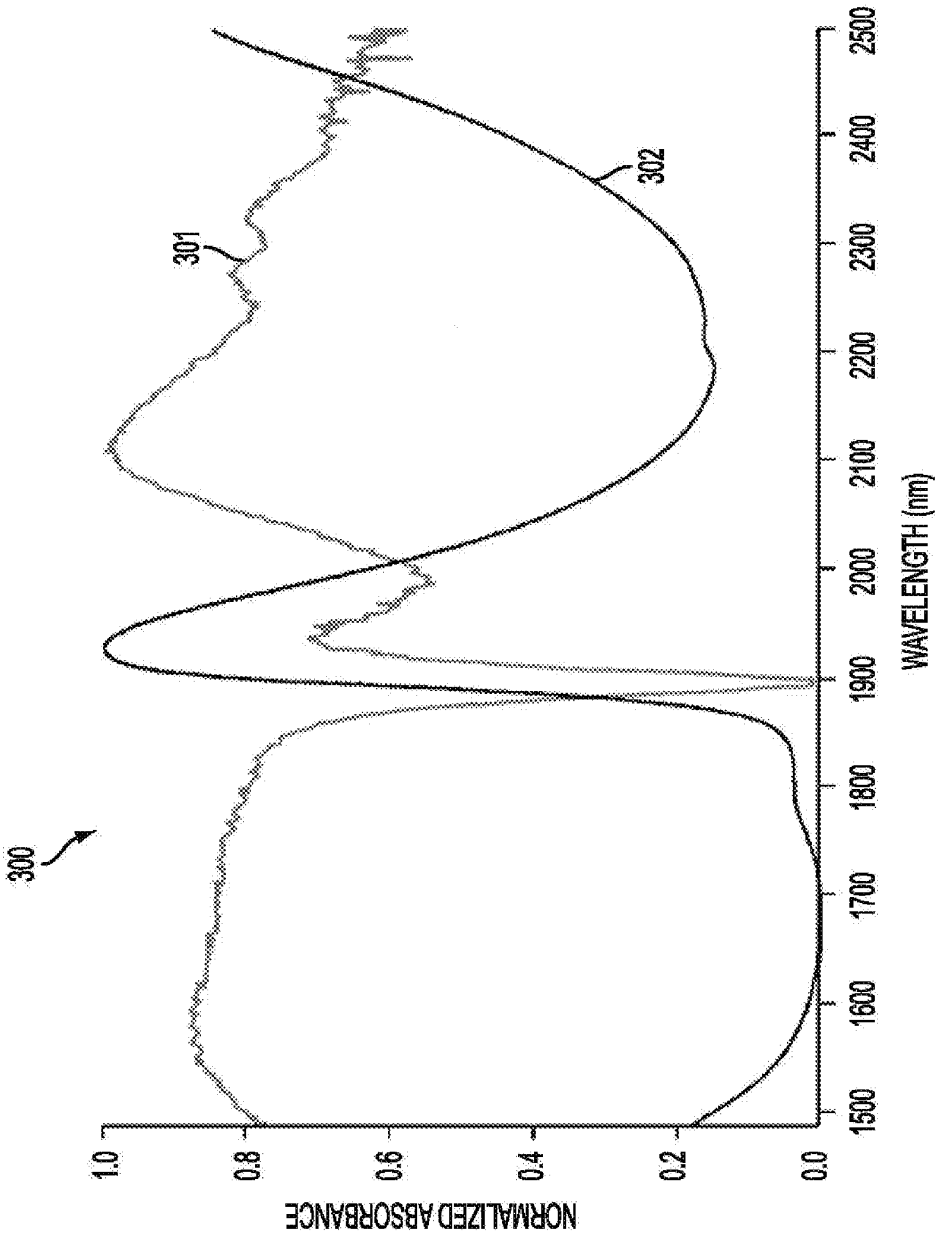

300
301
302
NORMALIZED ABSORBANCE
1.0
0.8
0.6
0.4
0.2
0.0
1500
1600
1700
1800
1900
2000
2100
2200
2300
2400
2500
WAVELENGTH (nm)

FIG. 3A

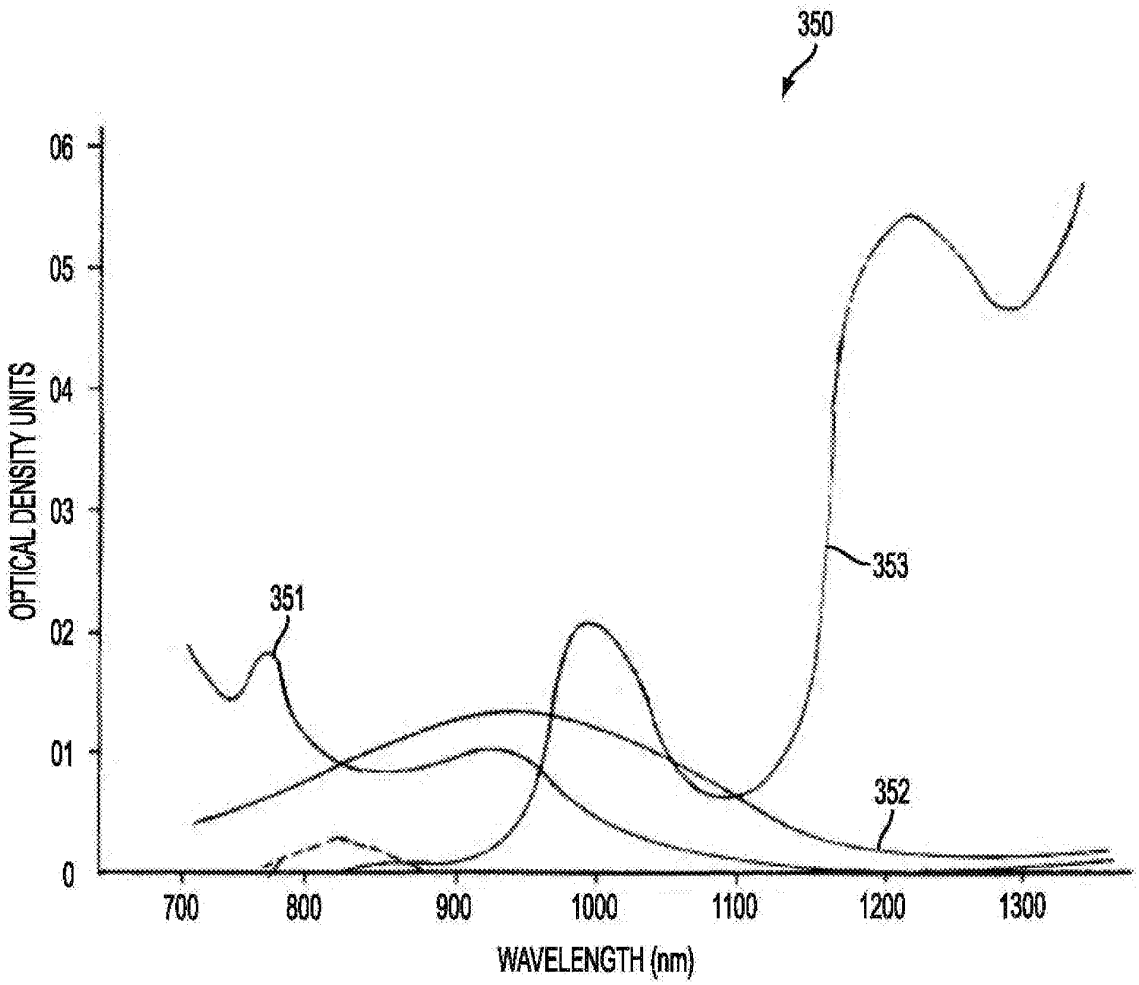

350
06
05
04
03
02
01
0
OPTICAL DENSITY UNITS
351
353
352
700
800
900
1000
1100
1200
1300
WAVELENGTH (nm)

FIG. 3B

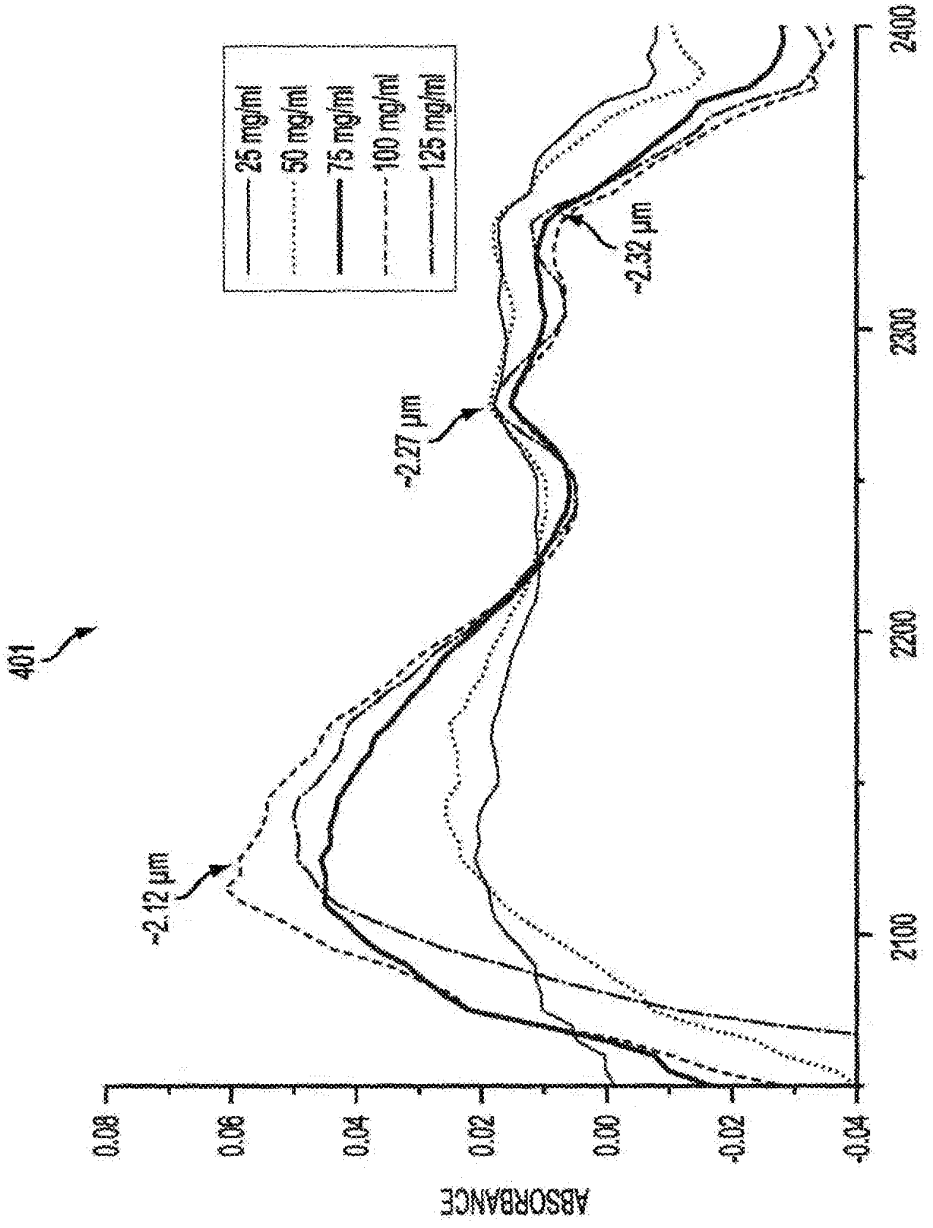

401
25 mg/ml
50 mg/ml
75 mg/ml
100 mg/ml
125 mg/ml
~2.12 µm
~2.27 µm
~2.32 µm
ABSORBANCE
0.08
0.06
0.04
0.02
0.00
-0.02
-0.04
2100
2200
2300
2400
WAVELENGTH (nm)

FIG. 4A

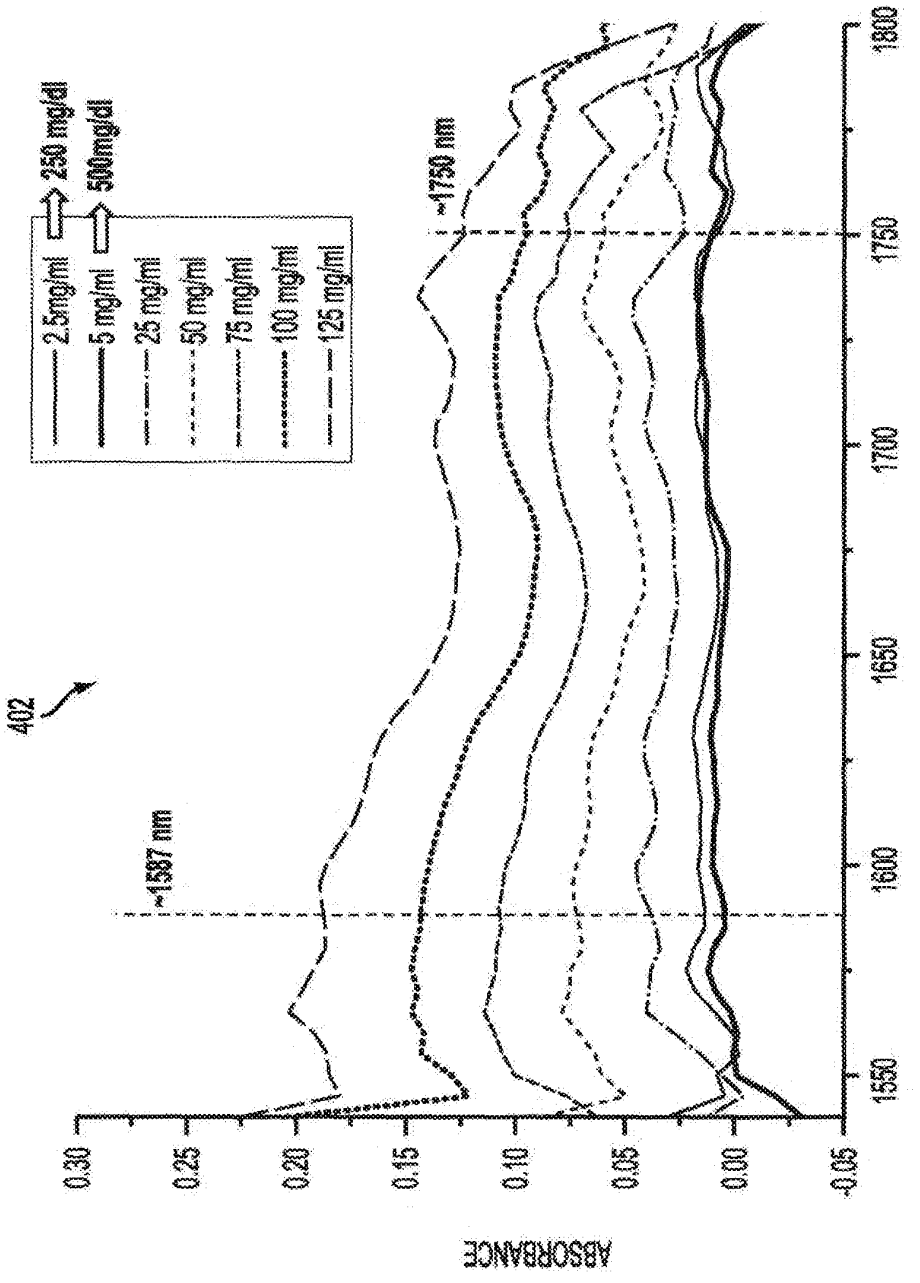

402
2.5mg/ml
5 mg/ml
25 mg/ml
50 mg/ml
75 mg/ml
100 mg/ml
125 mg/ml
250 mg/dl
500mg/dl
~1587 nm
~1750 nm
ABSORBANCE
0.30
0.25
0.20
0.15
0.10
0.05
0.00
-0.05
1550
1600
1650
1700
1750
1800
WAVELENGTH (nm)

FIG. 4B

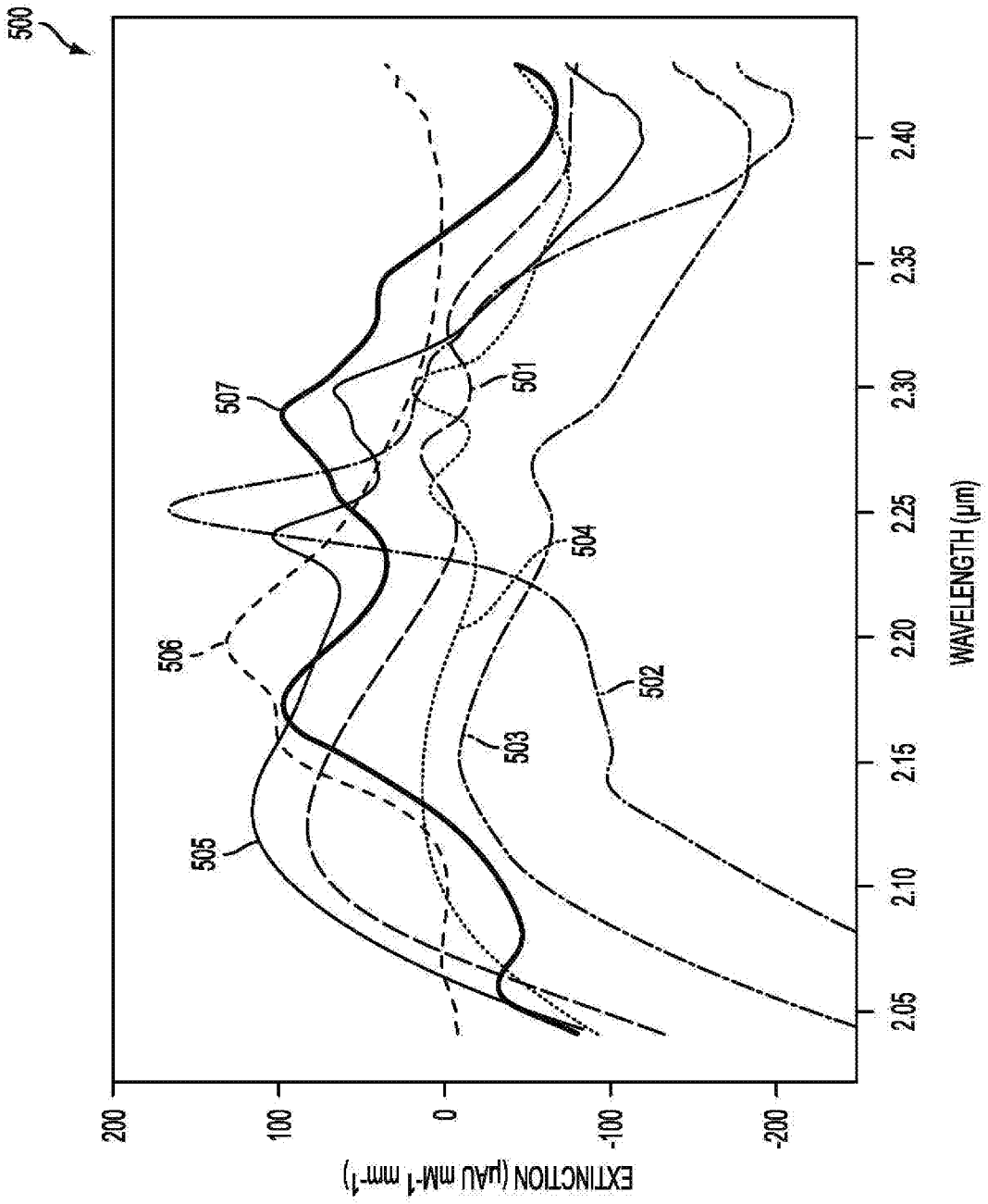

500
200
100
0
-100
-200
EXTINCTION (μAU mM-1 mm-1)
2.05
2.10
2.15
2.20
2.25
2.30
2.35
2.40
WAVELENGTH (μm)
501
502
503
504
505
506
507

FIG. 5

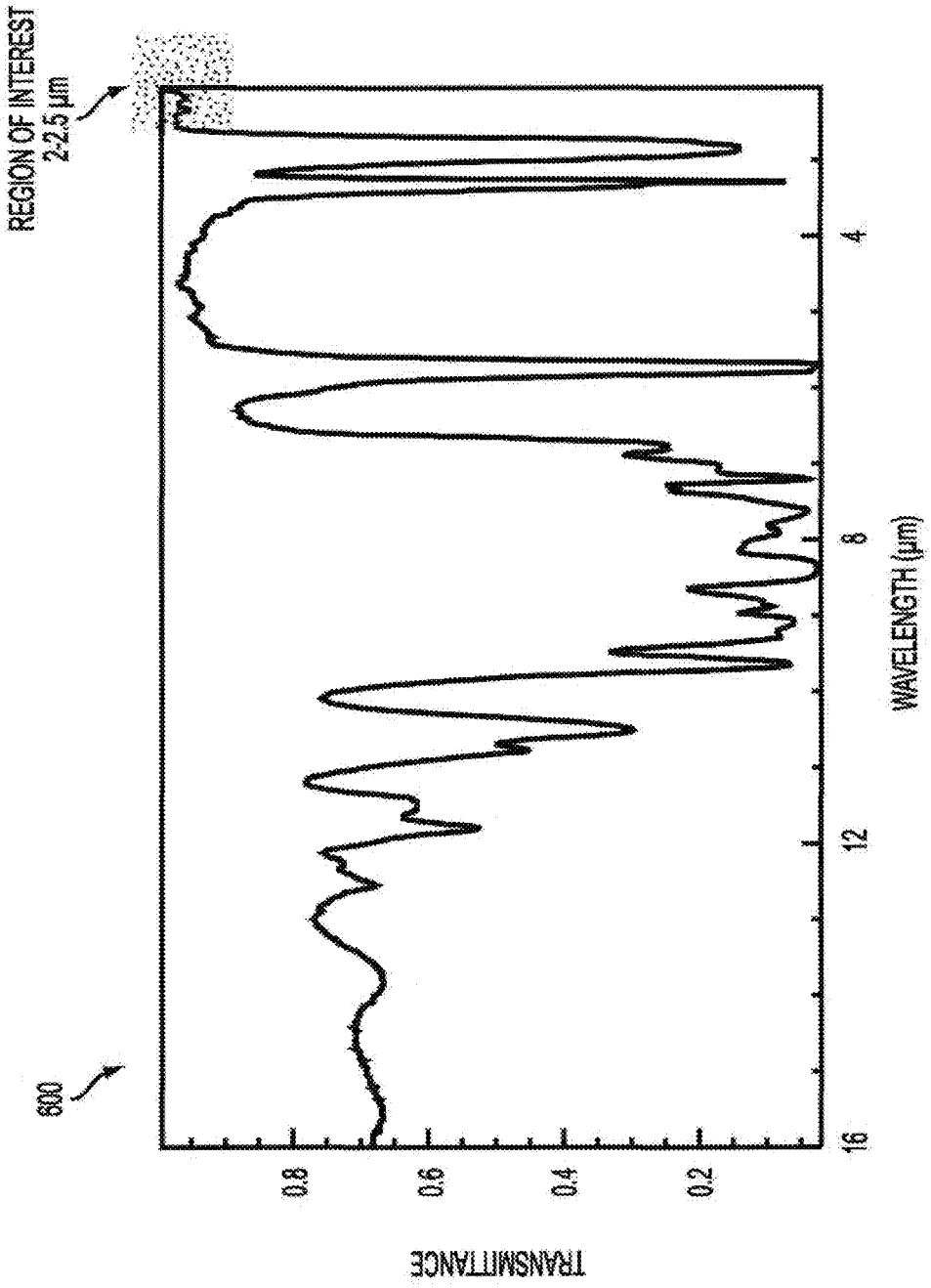

REGION OF INTEREST
2-2.5 µm
600
TRANSMITTANCE
0.8
0.6
0.4
0.2
4
8
12
16
WAVELENGTH (µm)

FIG. 6

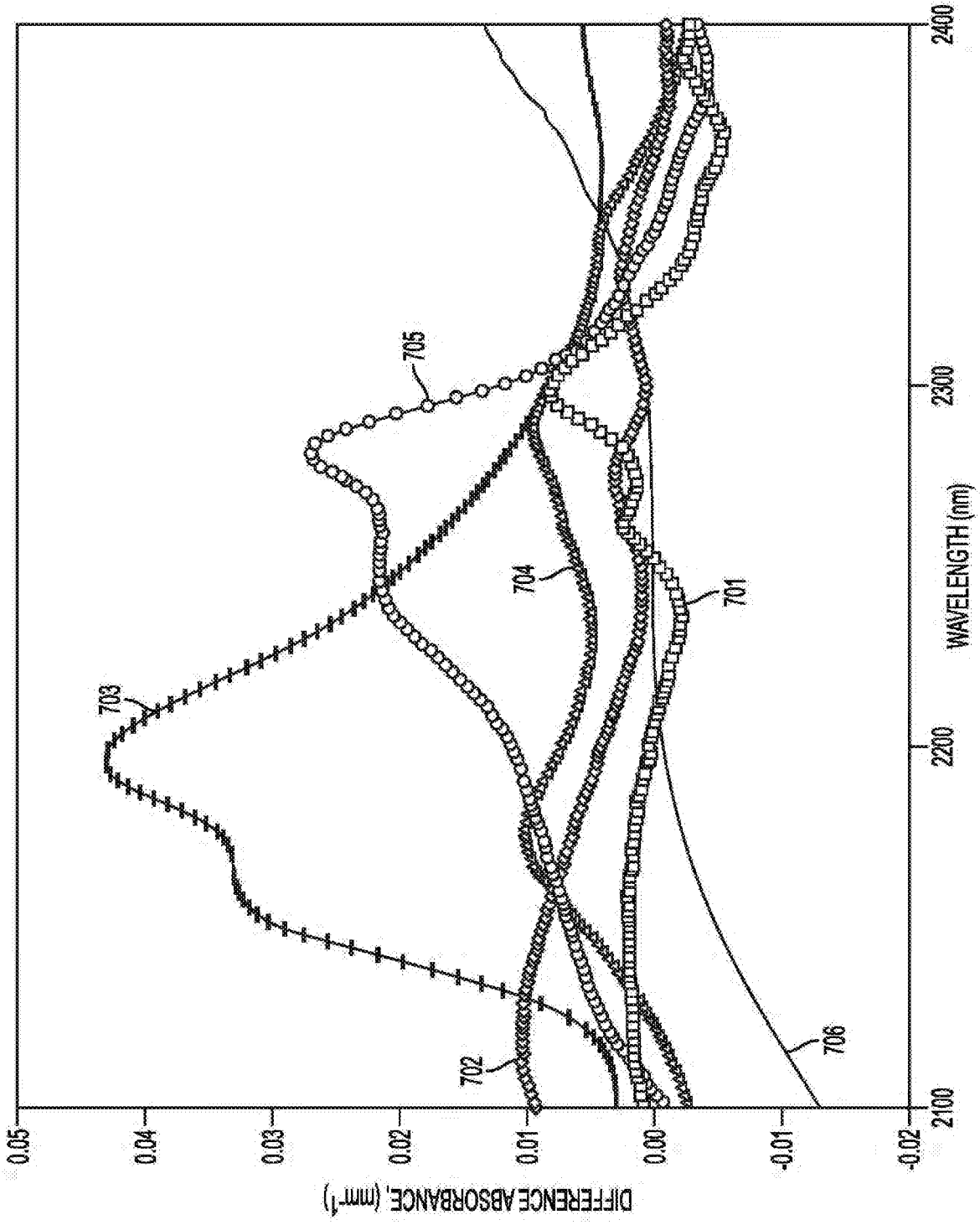

0.05
0.04
0.03
0.02
0.01
0.00
-0.01
-0.02
DIFFERENCE ABSORBANCE, (mm⁻¹)
2100
2200
2300
2400
WAVELENGTH (nm)
701
702
703
704
705
706

FIG. 7

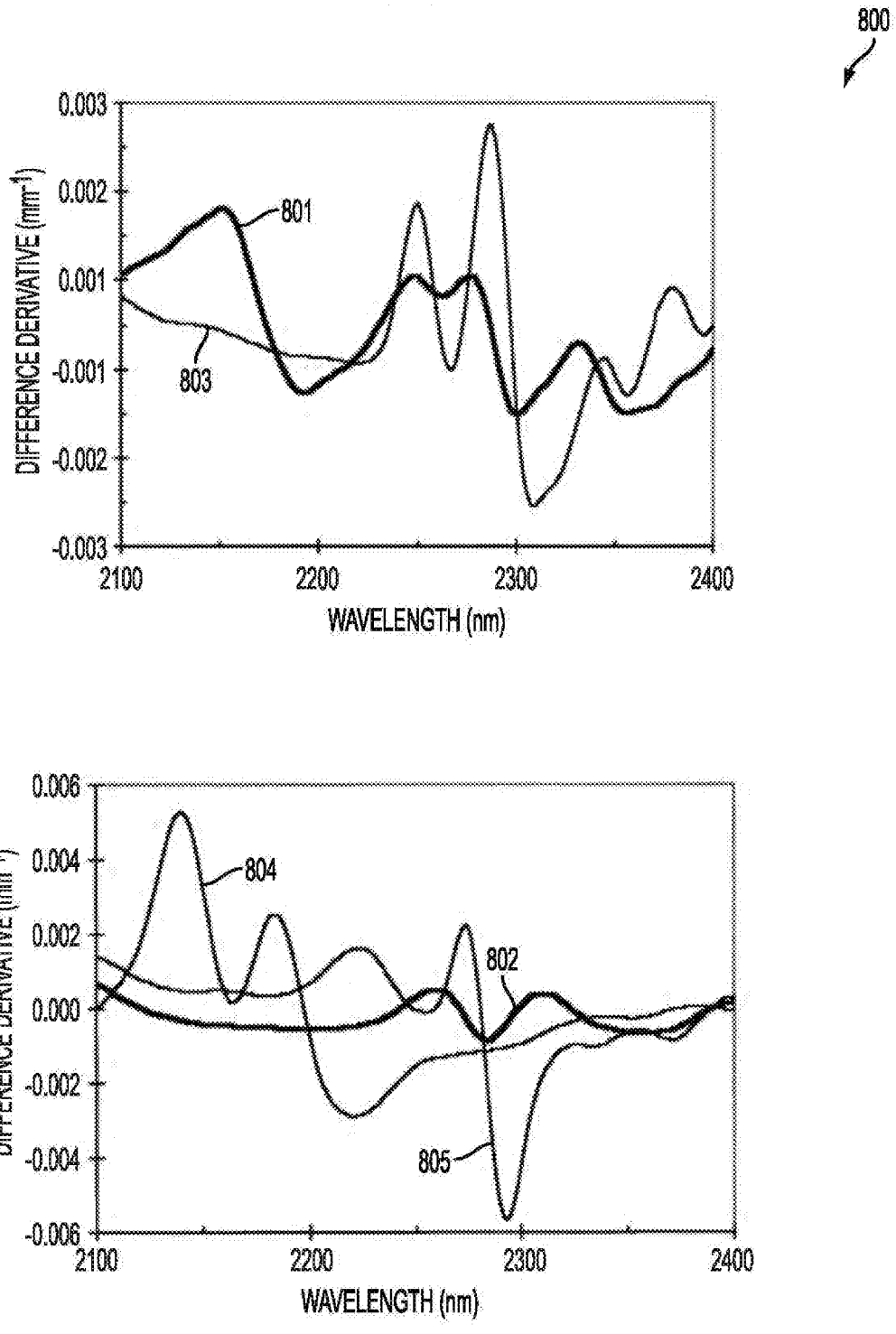

800
0.003
0.002
0.001
-0.001
-0.002
-0.003
DIFFERENCE DERIVATIVE (mm^{-1})
801
803
2100
2200
2300
2400
WAVELENGTH (nm)
0.006
0.004
0.002
0.000
-0.002
-0.004
-0.006
DIFFERENCE DERIVATIVE (mm^{-1})
804
802
805
2100
2200
2300
2400
WAVELENGTH (nm)

FIG. 8A

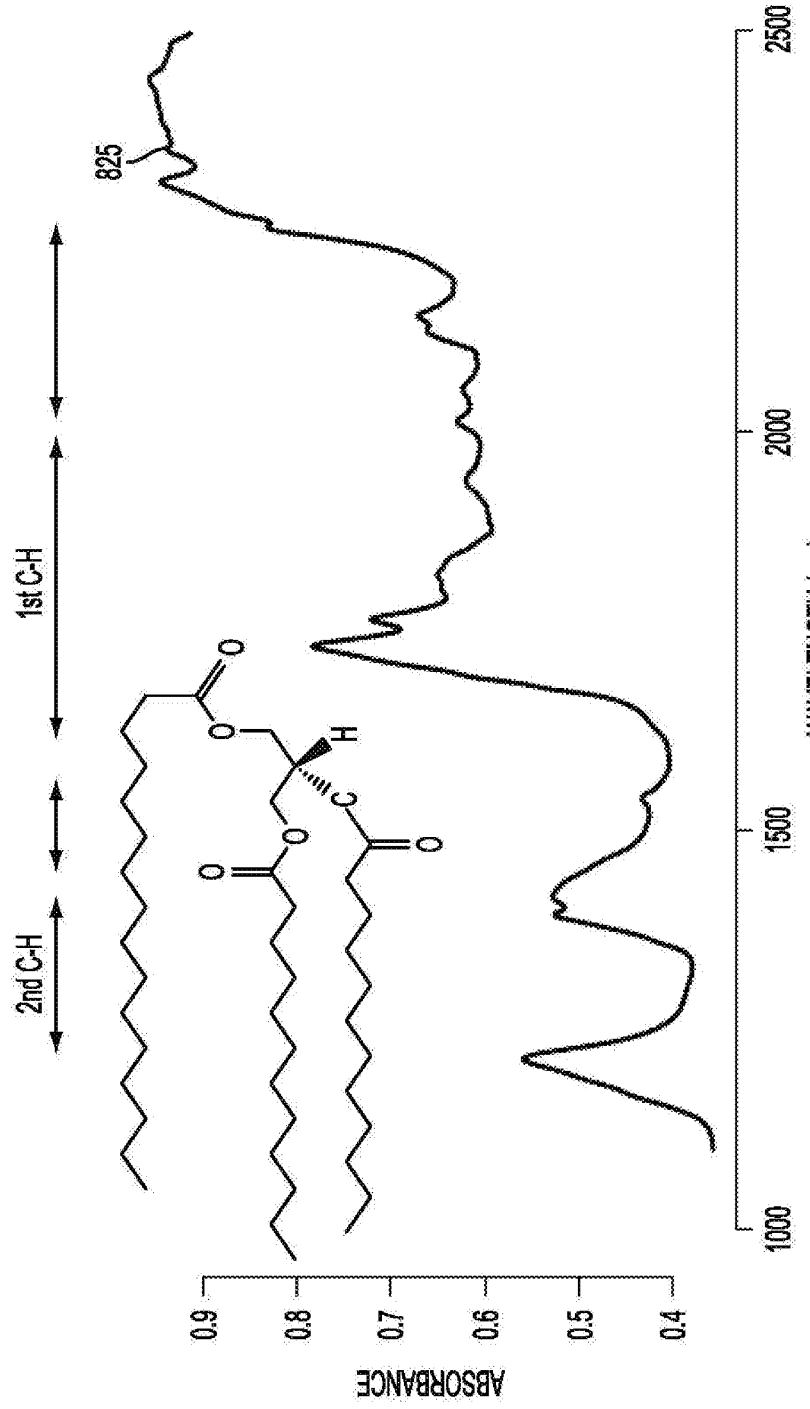

825
1st C-H
2nd C-H
O
O
O
O
H
C
O
0.9
0.8
0.7
0.6
0.5
0.4
ABSORBANCE
1000
1500
2000
2500
WAVELENGTH (nm)

FIG. 8B

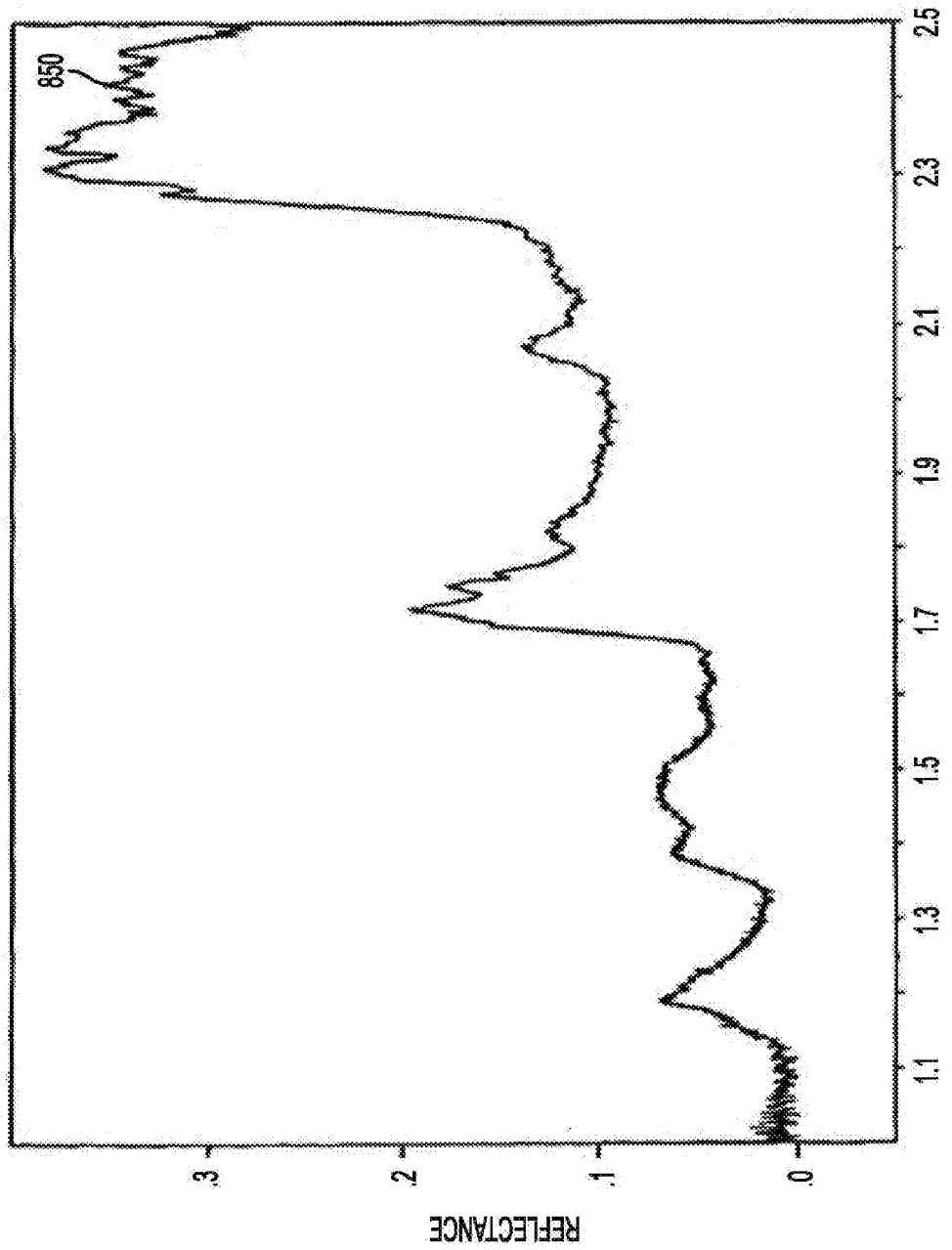


FIG. 8C

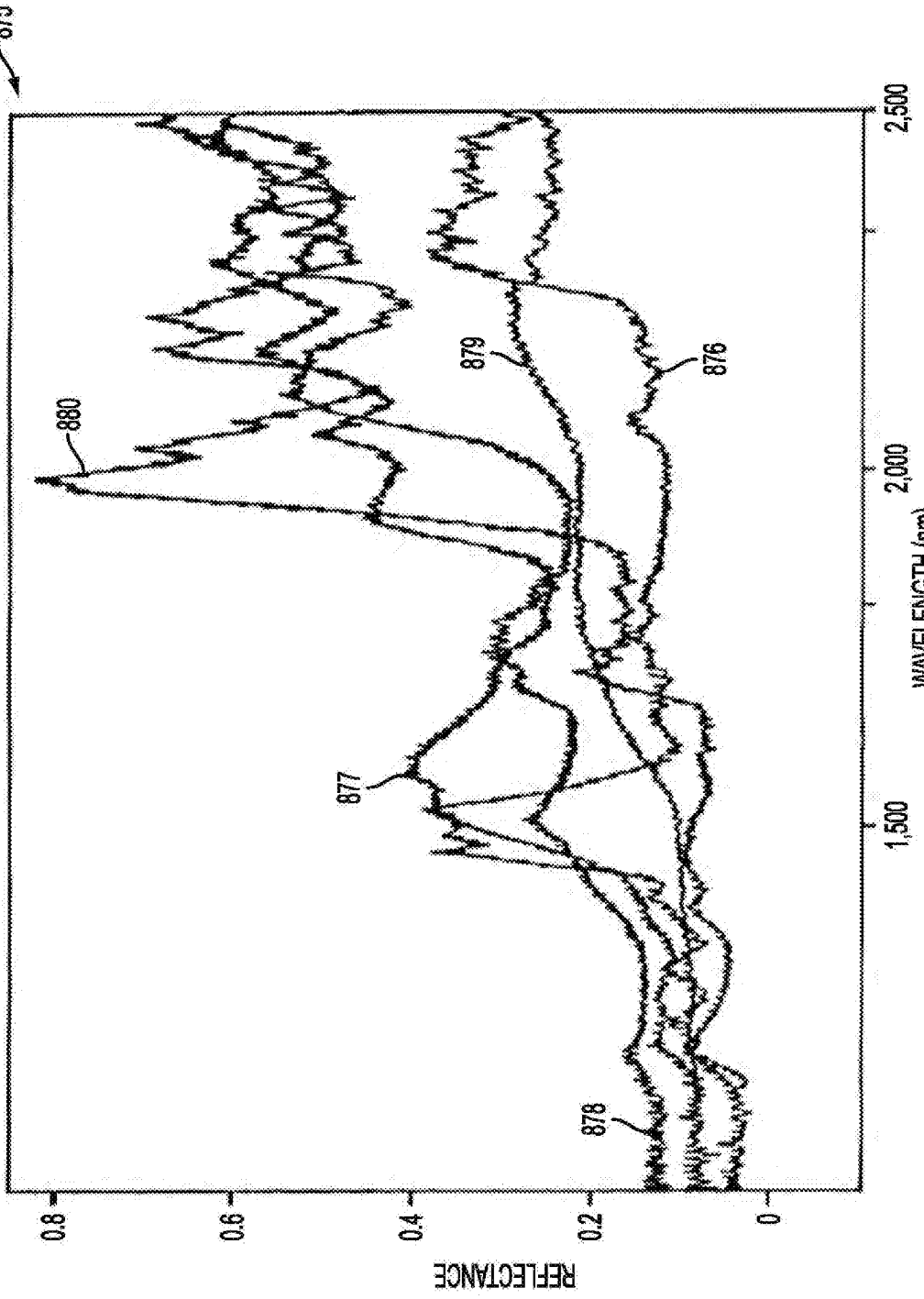

875
880
879
876
877
878
0.8
0.6
0.4
0.2
0
REFLECTANCE
1,500
2,000
2,500
WAVELENGTH (nm)

FIG. 8D

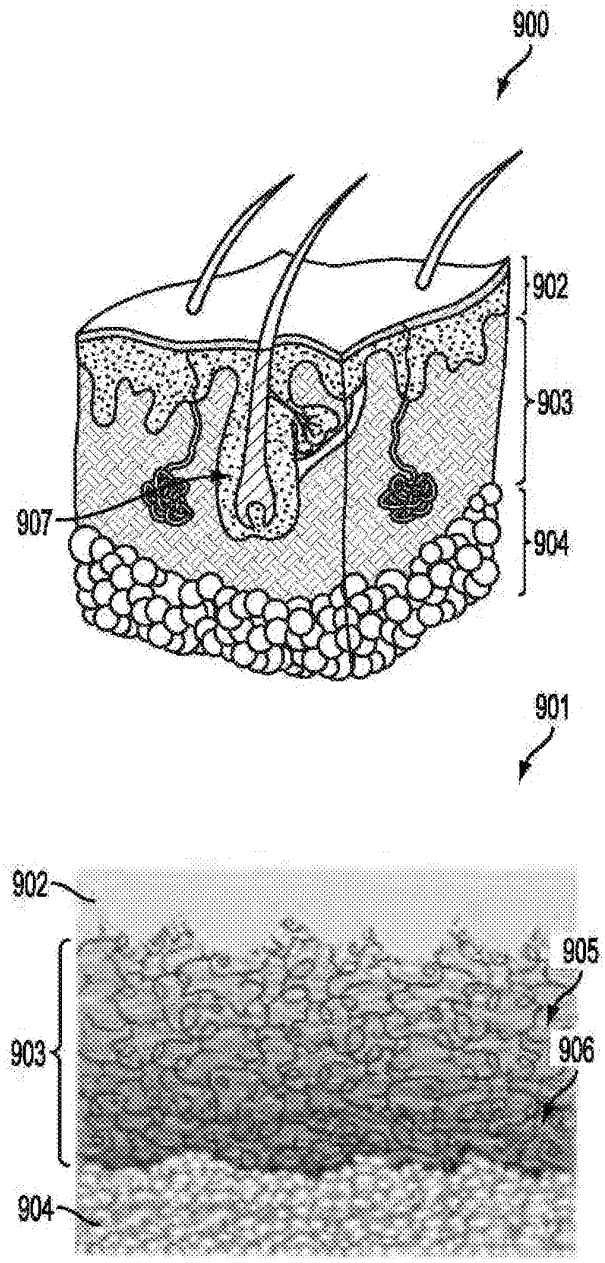


FIG. 9

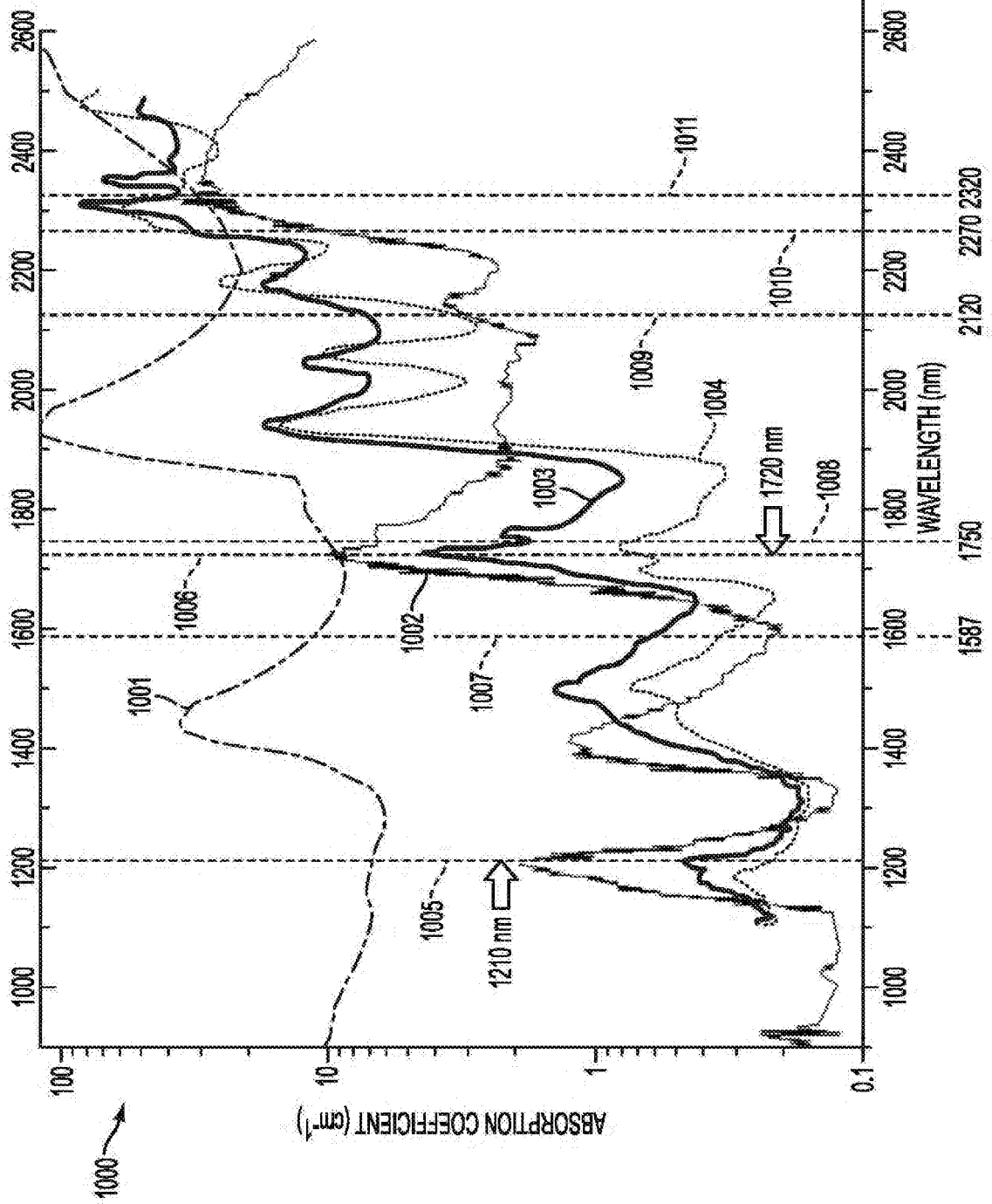

1000
100
10
1
0.1
ABSORPTION COEFFICIENT (cm⁻¹)
1000
1200
1400
1600
1800
2000
2200
2400
2600
WAVELENGTH (nm)
1587
1750
2120
2270
2320
1001
1002
1003
1004
1005
1006
1007
1008
1009
1010
1011
1210 nm
1720 nm

FIG. 10

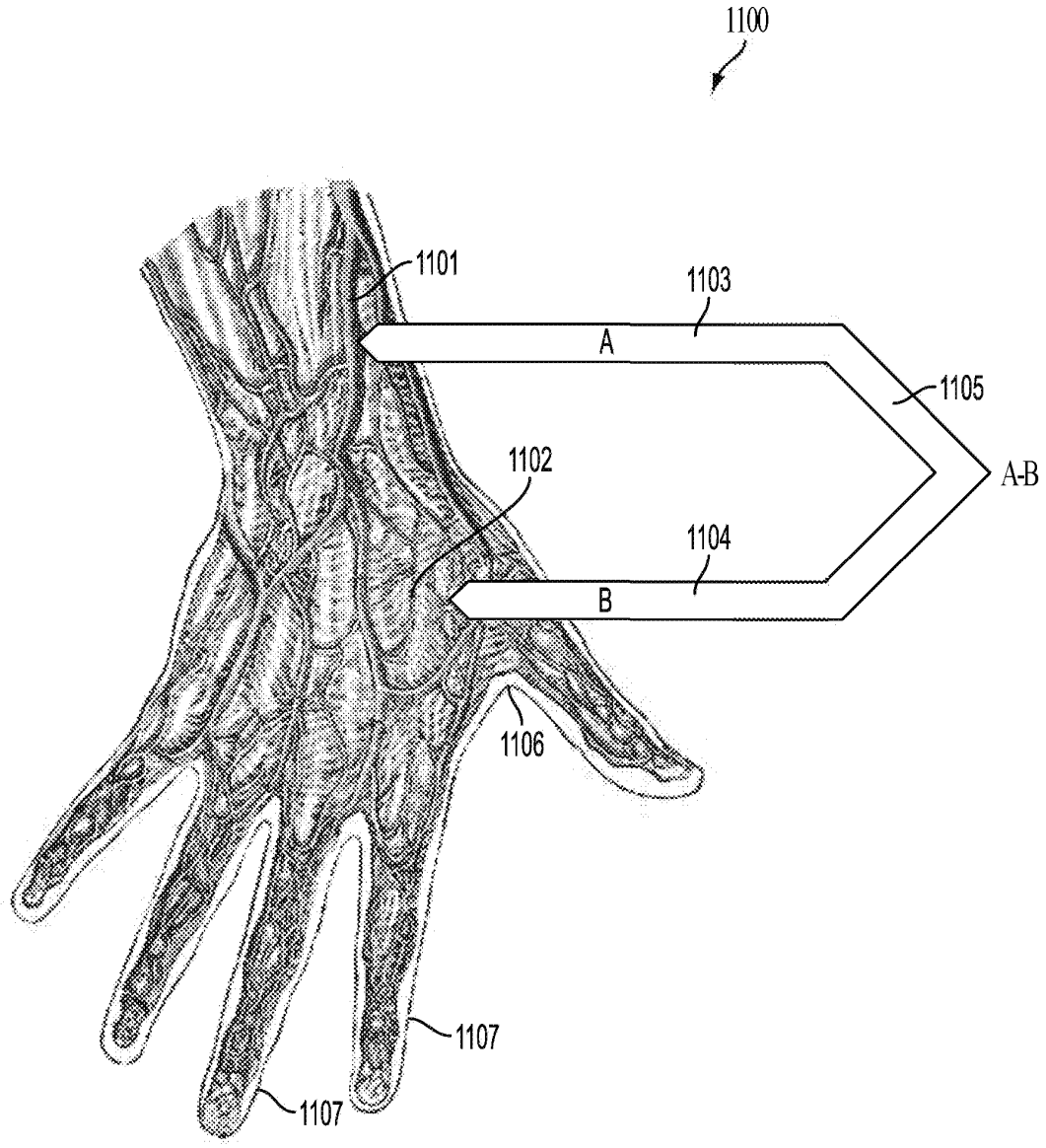


FIG. 11

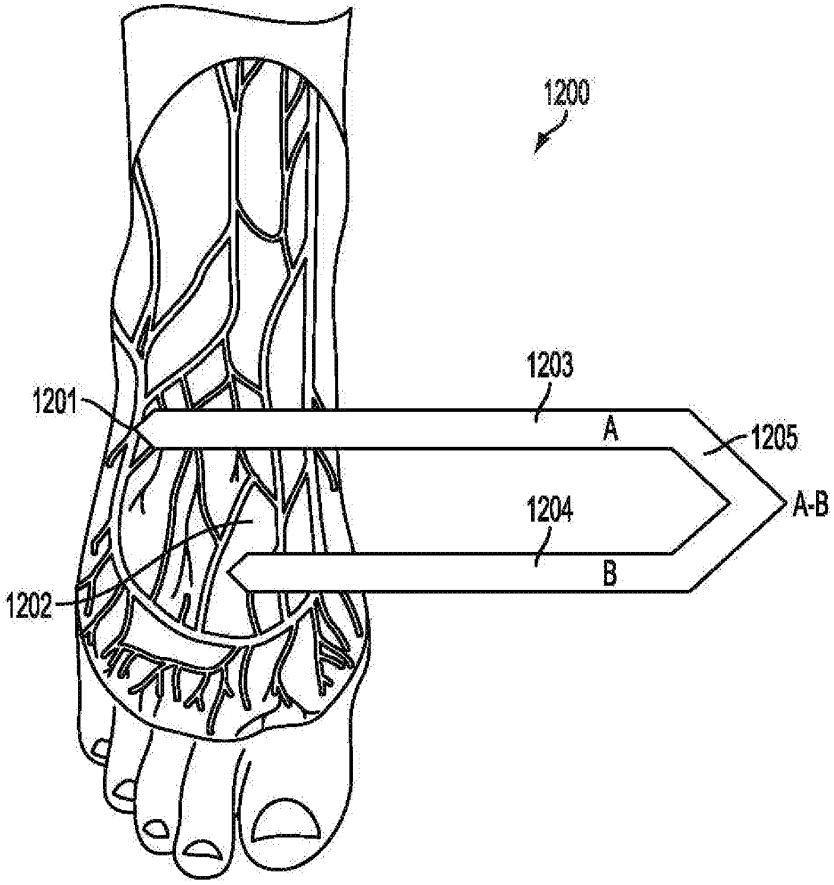


FIG. 12

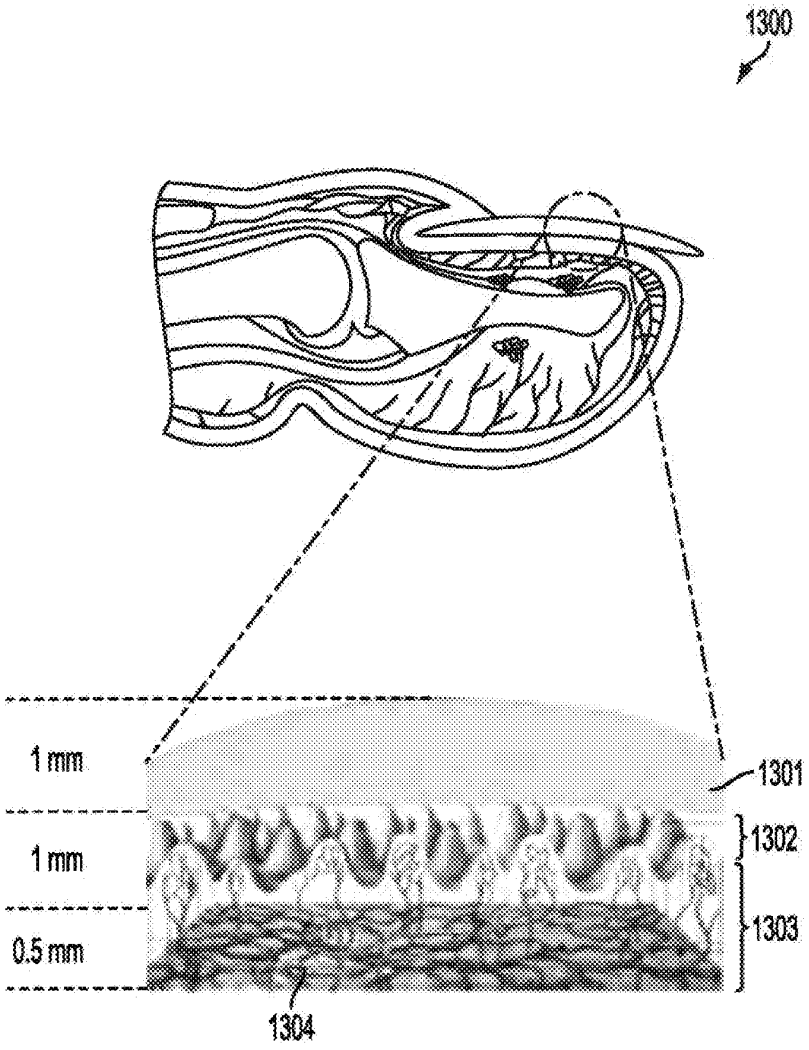


FIG. 13

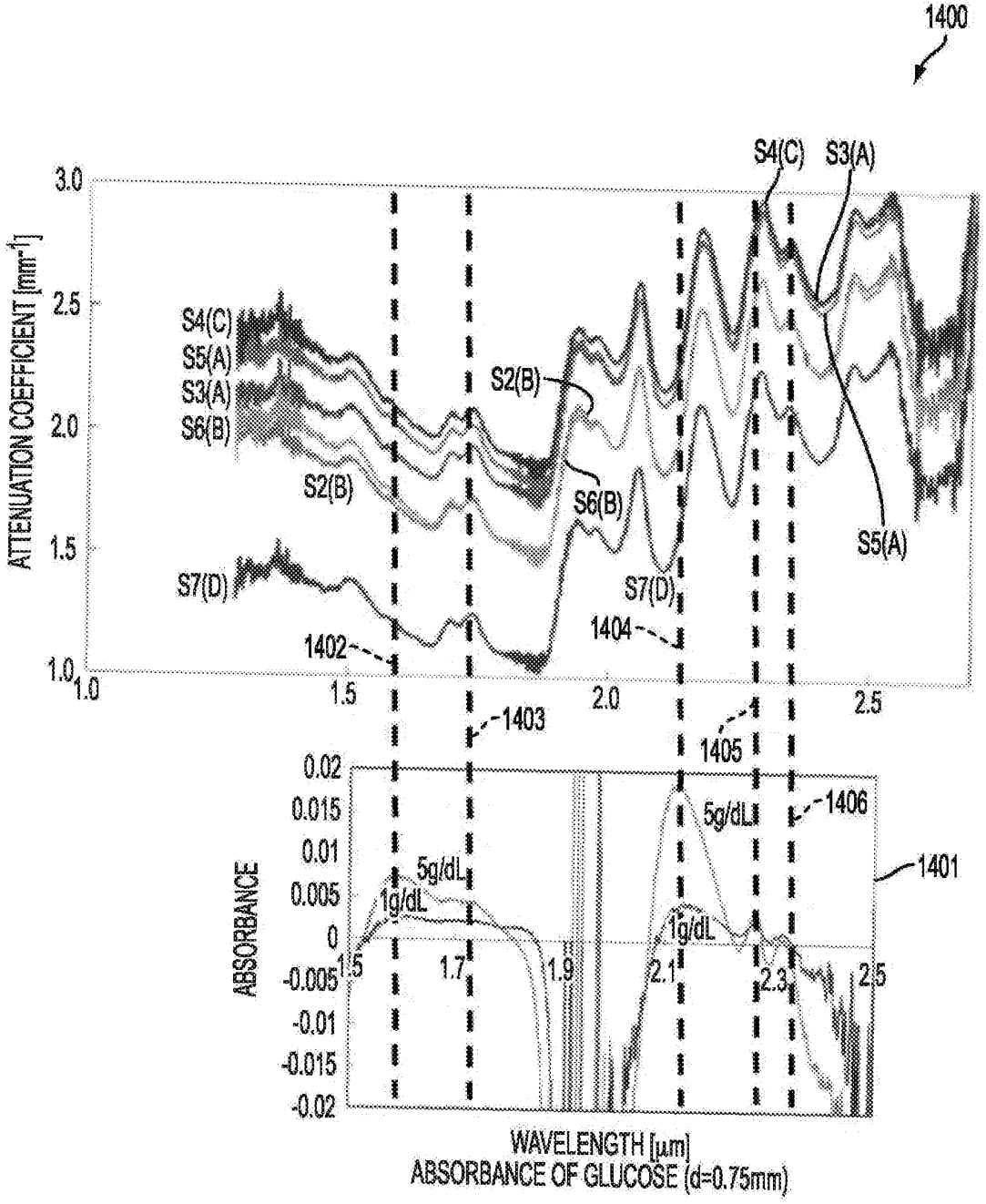

1400
ATTENUATION COEFFICIENT [mm⁻¹]
3.0
2.5
2.0
1.5
1.0
1.0
1.5
2.0
2.5
S4(C)
S3(A)
S4(C)
S5(A)
S3(A)
S6(B)
S2(B)
S2(B)
S6(B)
S5(A)
S7(D)
S7(D)
1402
1404
1403
1405
1406
1401
5g/dL
1g/dL
5g/dL
1g/dL
ABSORBANCE
0.02
0.015
0.01
0.005
0
-0.005
-0.01
-0.015
-0.02
1.5
1.7
1.9
2.1
2.3
2.5
WAVELENGTH [μm]
ABSORBANCE OF GLUCOSE (d=0.75mm)

FIG. 14

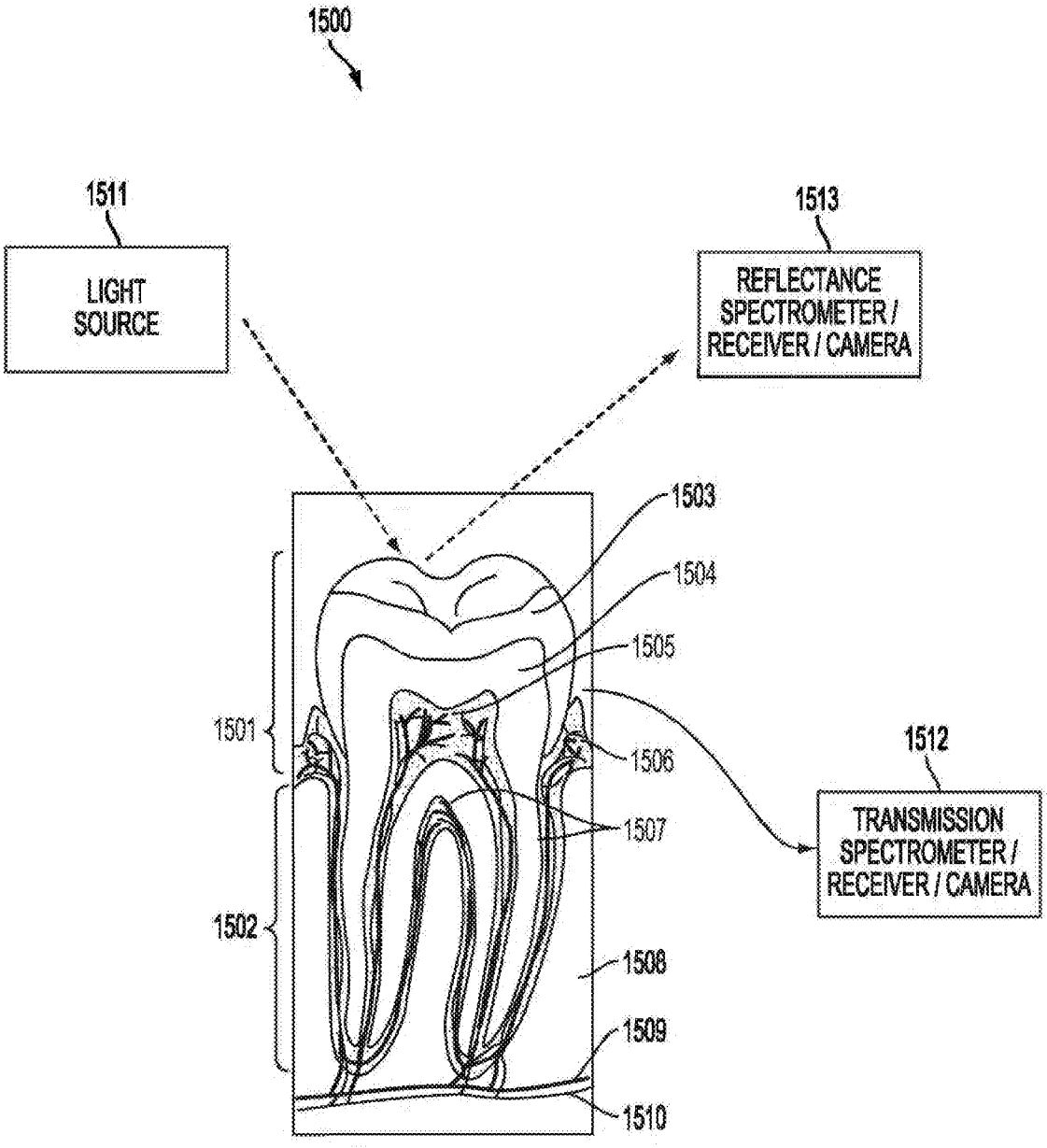

1500
1511
LIGHT SOURCE
1513
REFLECTANCE SPECTROMETER / RECEIVER / CAMERA
1503
1504
1505
1501
1506
1512
TRANSMISSION SPECTROMETER / RECEIVER / CAMERA
1507
1502
1508
1509
1510

FIG. 15

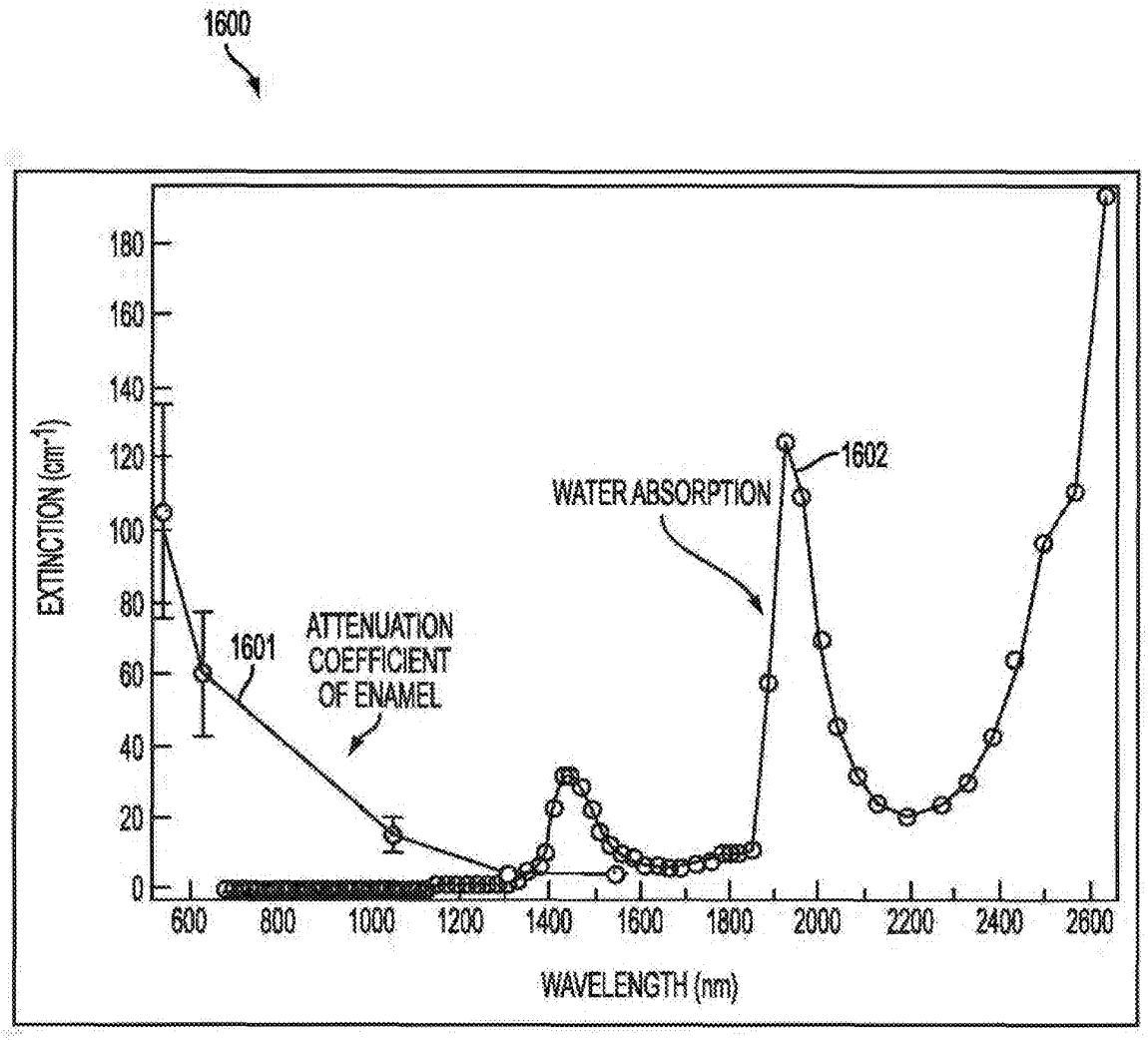

1600
EXTINCTION (cm⁻¹)
180
160
140
120
100
80
60
40
20
0
600
800
1000
1200
1400
1600
1800
2000
2200
2400
2600
WAVELENGTH (nm)
1601
ATTENUATION COEFFICIENT OF ENAMEL
WATER ABSORPTION
1602

FIG. 16A

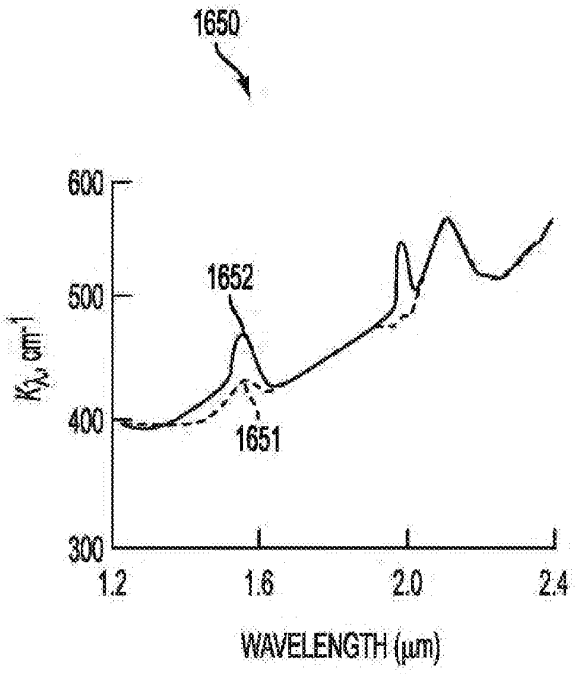

1650
600
500
400
300
1652
1651
K_λ, cm^{-1}
1.2
1.6
2.0
2.4
WAVELENGTH (μm)

FIG. 16B

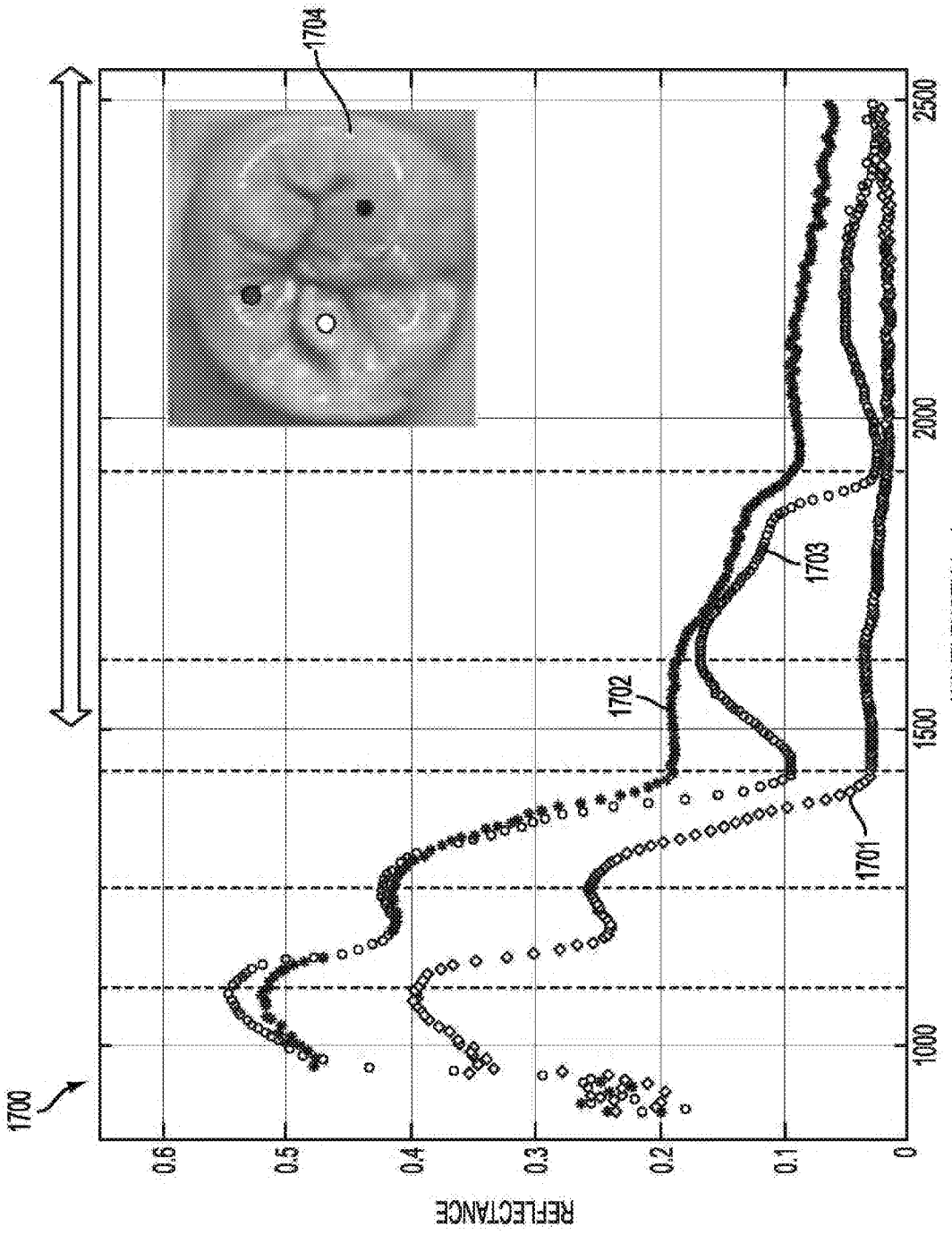

1704
1700
1703
1702
1701
REFLECTANCE
0.6
0.5
0.4
0.3
0.2
0.1
0
1000
1500
2000
2500
WAVELENGTH (nm)

FIG. 17

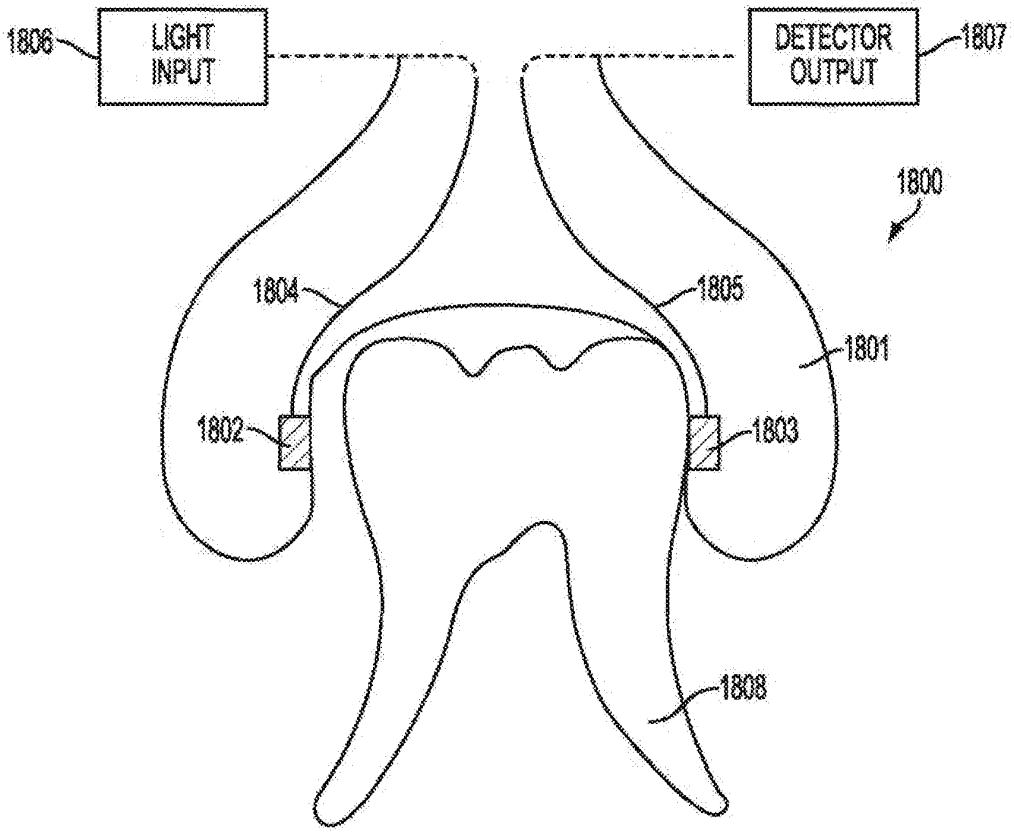

1806
LIGHT INPUT
DETECTOR OUTPUT
1807
1800
1804
1805
1801
1802
1803
1808

FIG. 18A

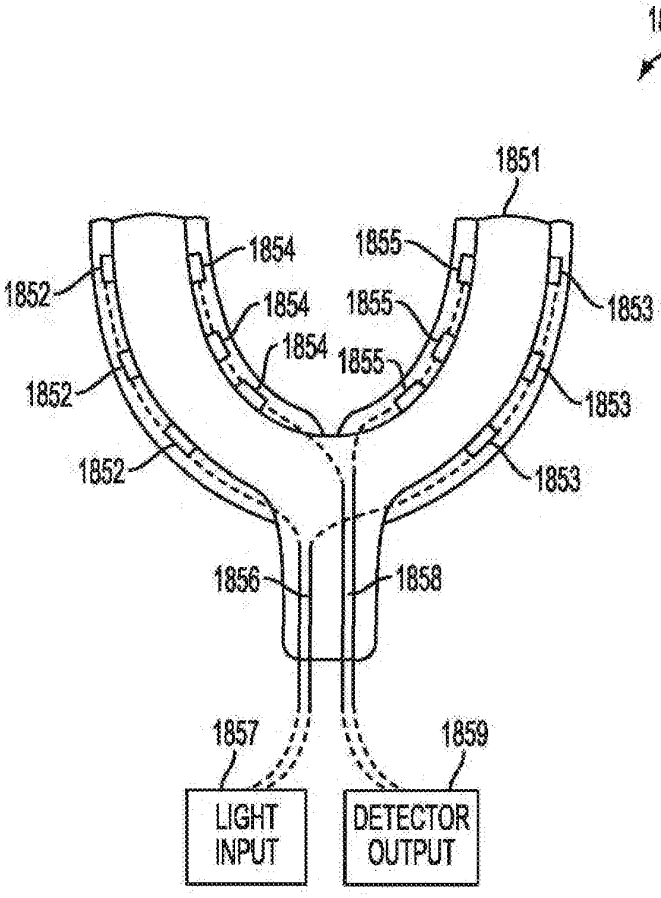

1850
1851
1852
1852
1852
1853
1853
1853
1854
1854
1854
1855
1855
1855
1856
1858
1857
1859
LIGHT INPUT
DETECTOR OUTPUT

FIG. 18B

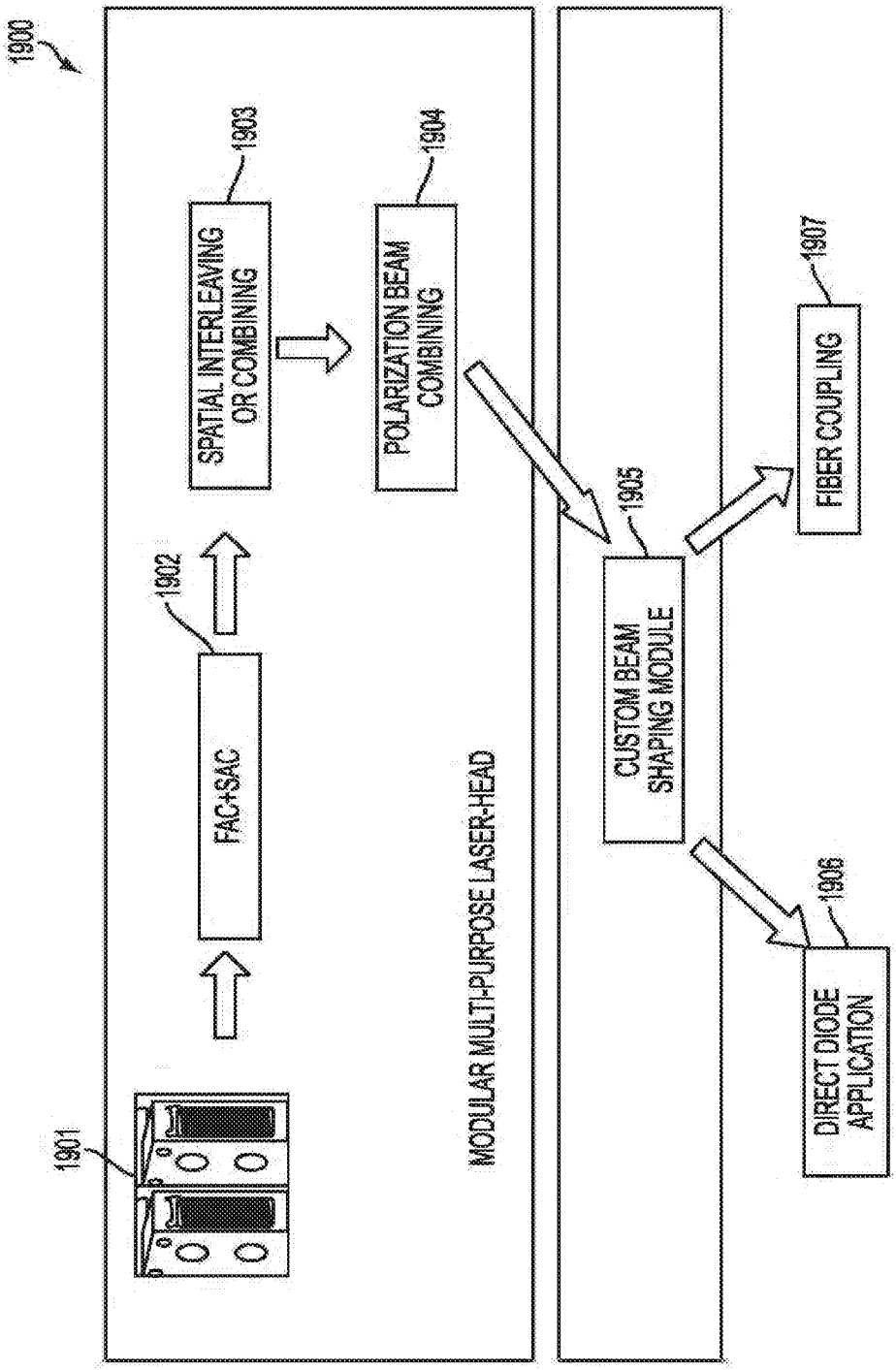

1900
1901
1902
FAC+SAC
1903
SPATIAL INTERLEAVING OR COMBINING
1904
POLARIZATION BEAM COMBINING
MODULAR MULTI-PURPOSE LASER-HEAD
1905
CUSTOM BEAM SHAPING MODULE
1906
DIRECT DIODE APPLICATION
1907
FIBER COUPLING

FIG. 19

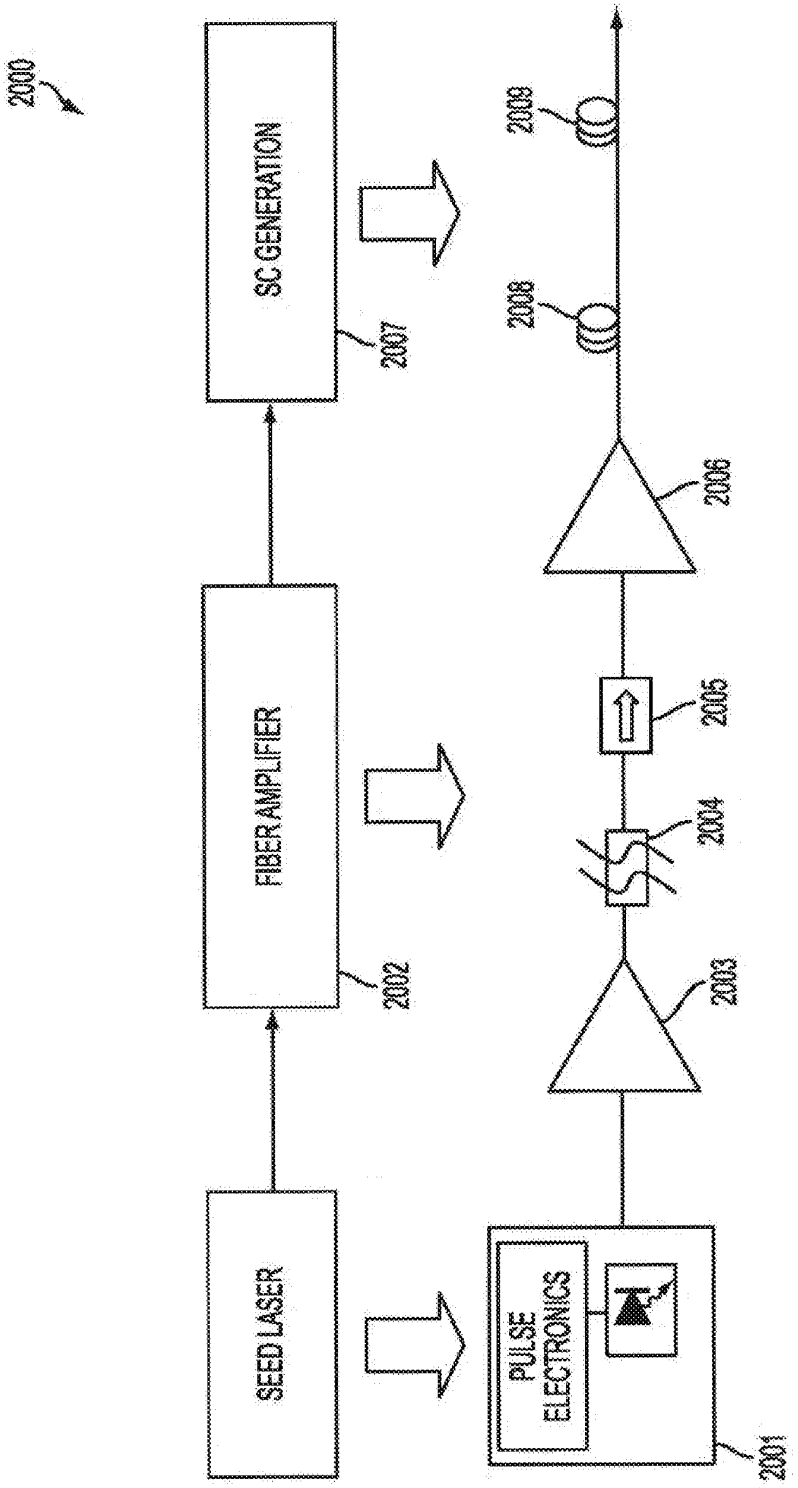

2000
SEED LASER
FIBER AMPLIFIER
SC GENERATION
PULSE ELECTRONICS
2001
2002
2003
2004
2005
2006
2007
2008
2009

FIG. 20

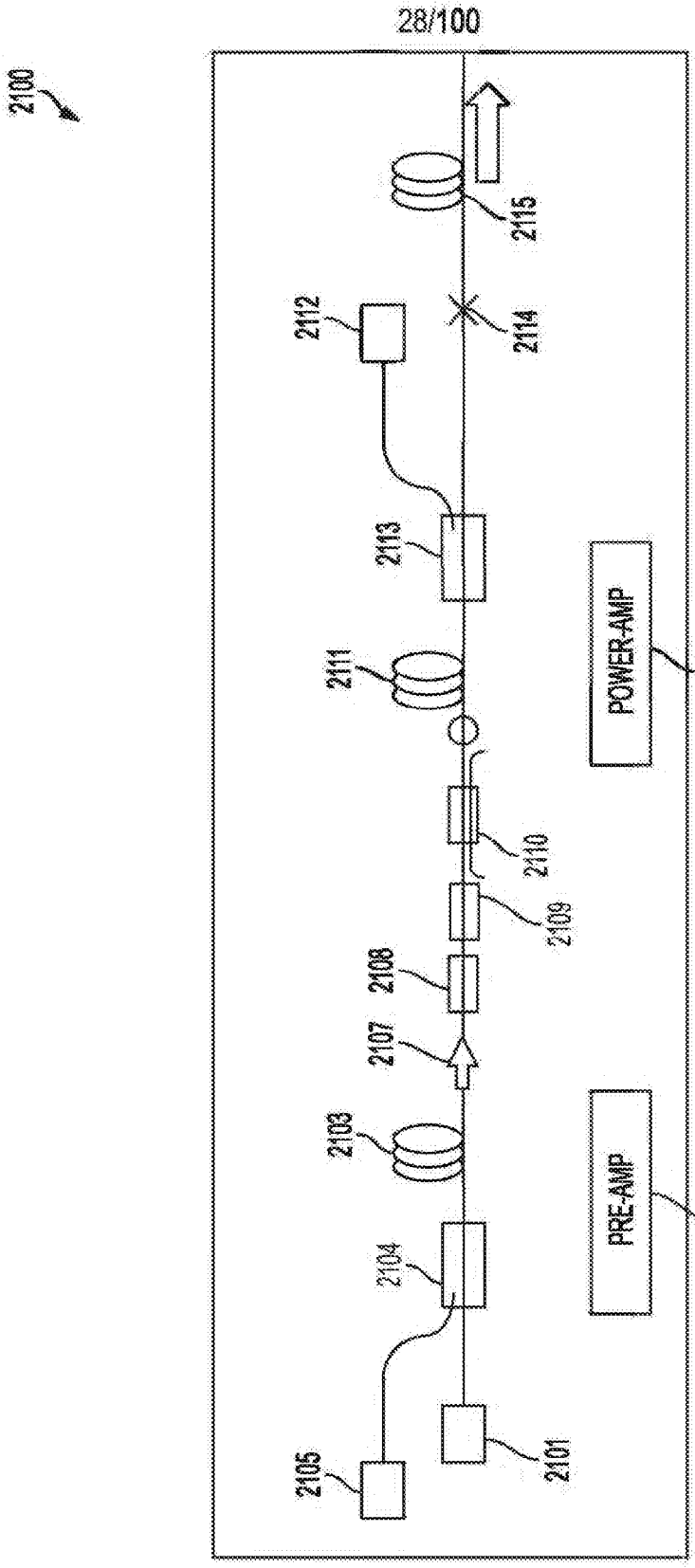

2100
2115
2114
2112
2113
2111
POWER-AMP
2106
2110
2109
2108
2107
2103
PRE-AMP
2102
2104
2101
2105

FIG. 21

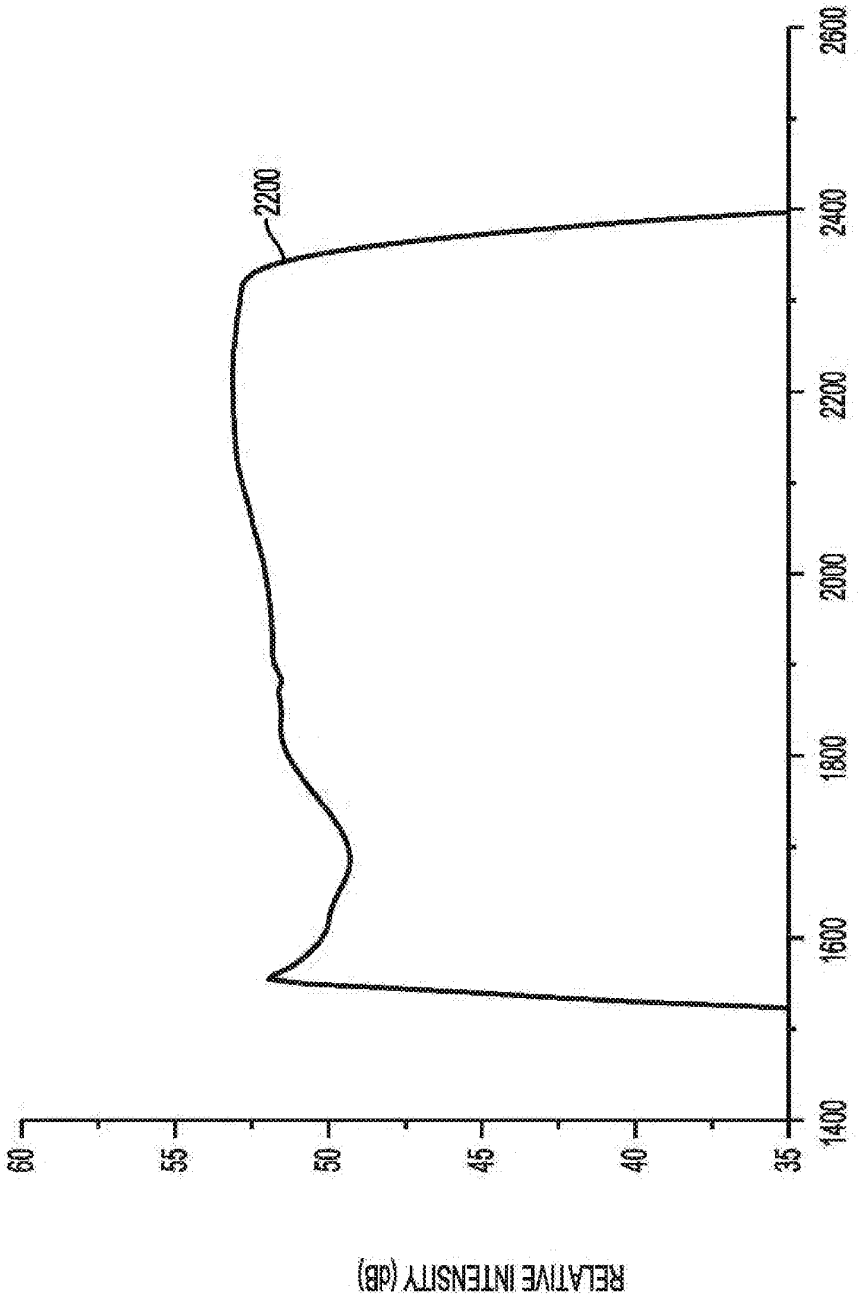

RELATIVE INTENSITY (dB)
60
55
50
45
40
35
1400
1600
1800
2000
2200
2400
2600
WAVELENGTH (nm)
2200

FIG. 22

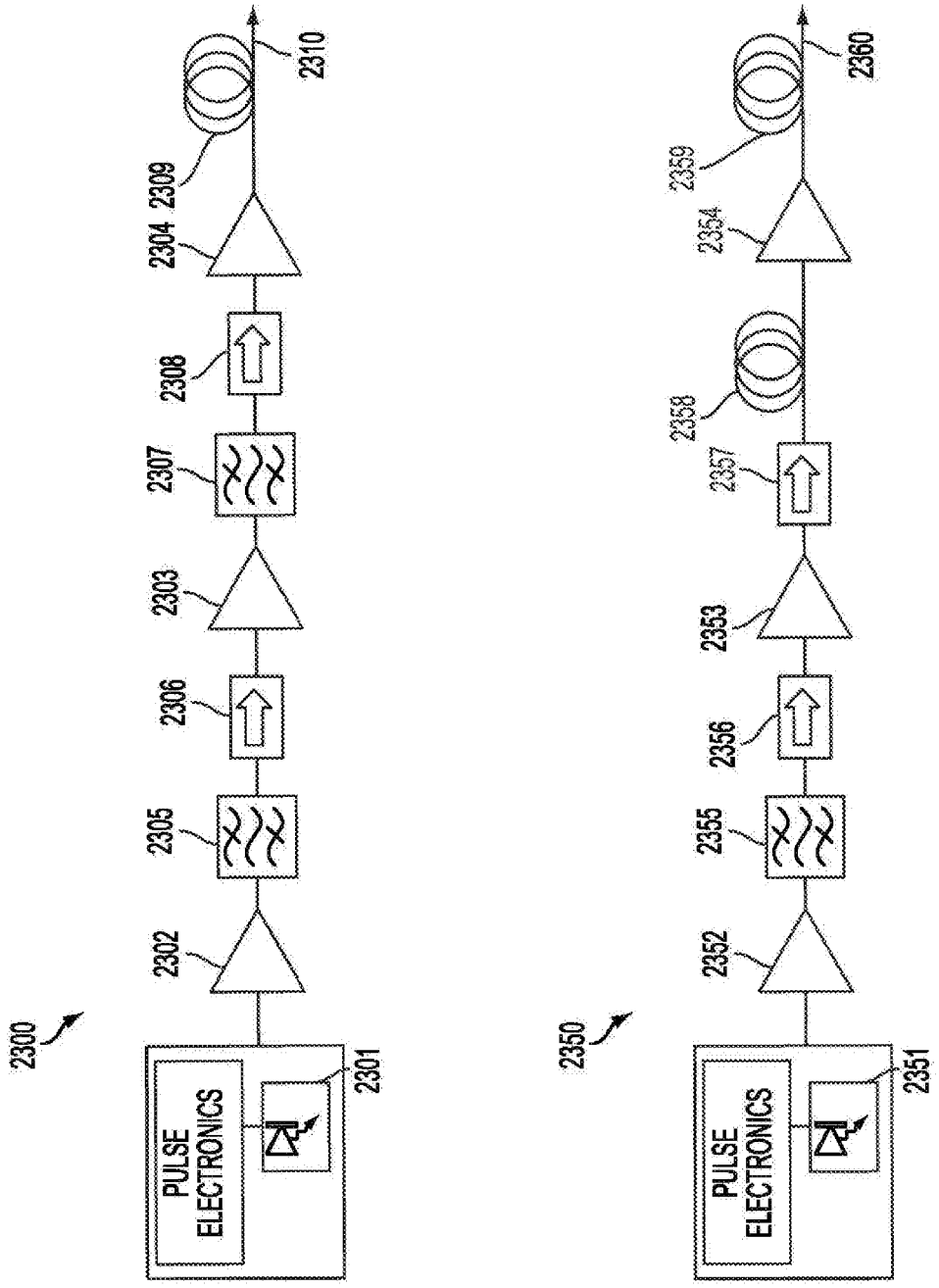

2300
PULSE ELECTRONICS
2301
2302
2305
2306
2303
2307
2308
2304
2309
2310
2350
PULSE ELECTRONICS
2351
2352
2355
2356
2353
2357
2358
2354
2359
2360

FIG. 23

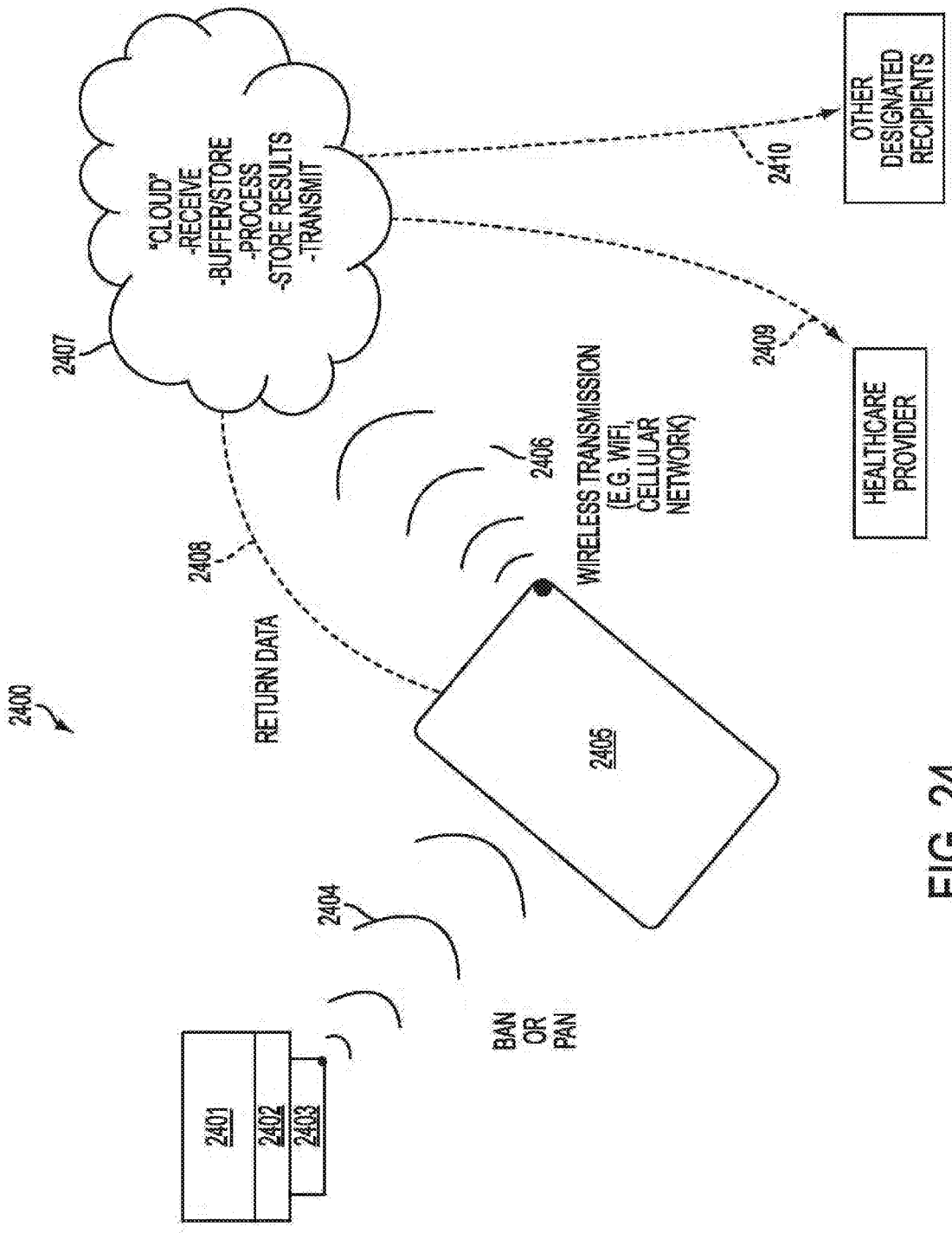

2400
2401
2402
2403
2404
BAN OR PAN
2405
2406
WIRELESS TRANSMISSION (E.G. WIFI, CELLULAR NETWORK)
2407
"CLOUD"
-RECEIVE
-BUFFER/STORE
-PROCESS
-STORE RESULTS
-TRANSMIT
2408
RETURN DATA
2409
HEALTHCARE PROVIDER
2410
OTHER DESIGNATED RECIPIENTS

FIG. 24

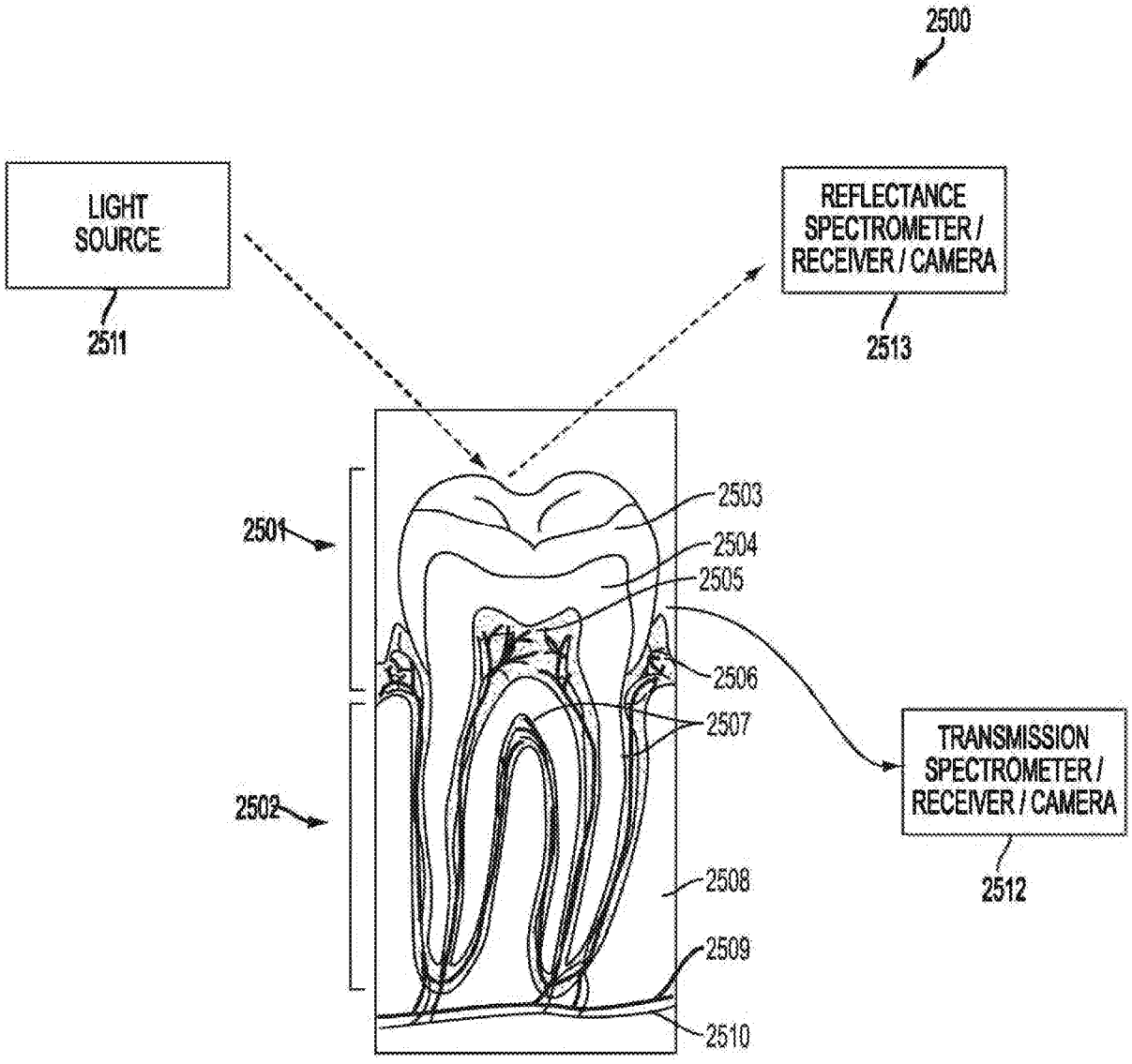

2500
LIGHT SOURCE
2511
REFLECTANCE SPECTROMETER / RECEIVER / CAMERA
2513
2501
2502
2503
2504
2505
2506
2507
2508
2509
2510
TRANSMISSION SPECTROMETER / RECEIVER / CAMERA
2512

FIG. 25

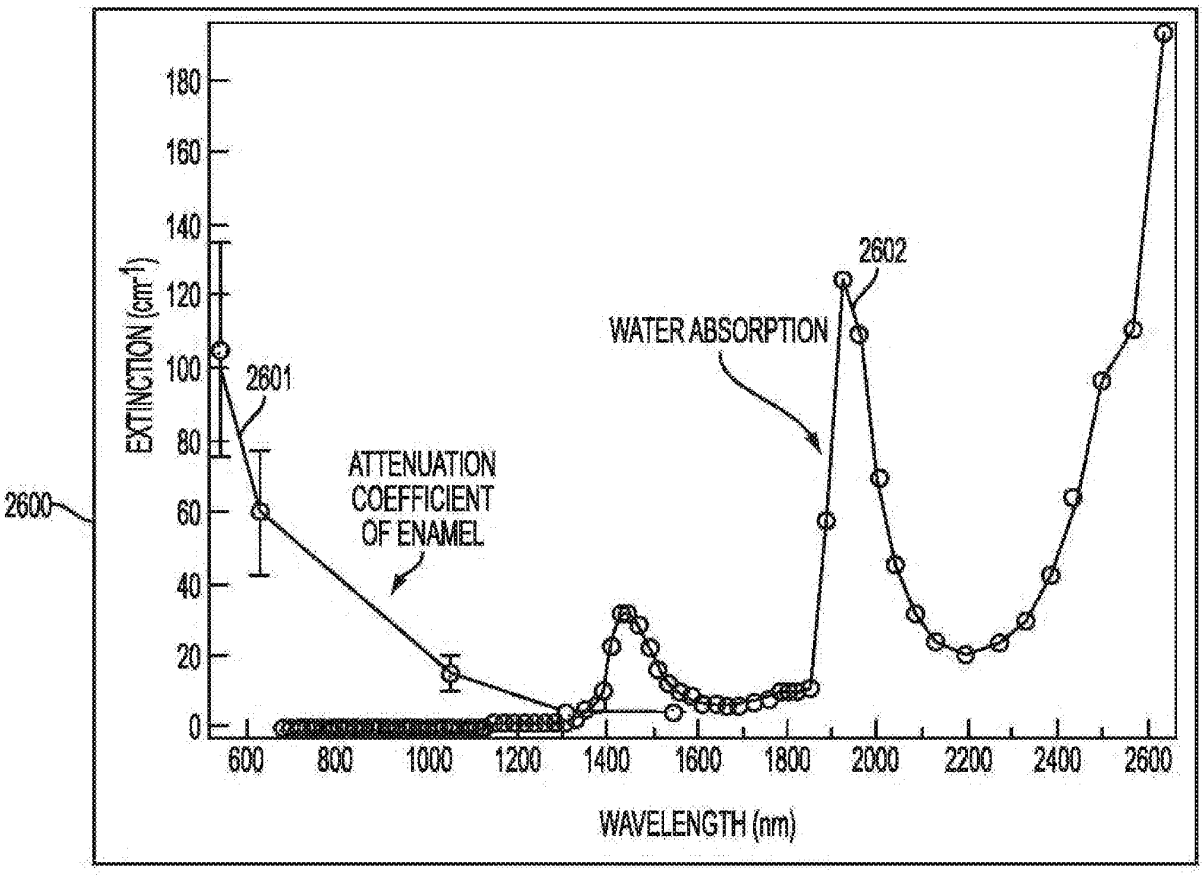

2600
EXTINCTION (cm^{-1})
180
160
140
120
100
80
60
40
20
0
2601
ATTENUATION COEFFICIENT OF ENAMEL
WATER ABSORPTION
2602
600
800
1000
1200
1400
1600
1800
2000
2200
2400
2600
WAVELENGTH (nm)

FIG. 26A

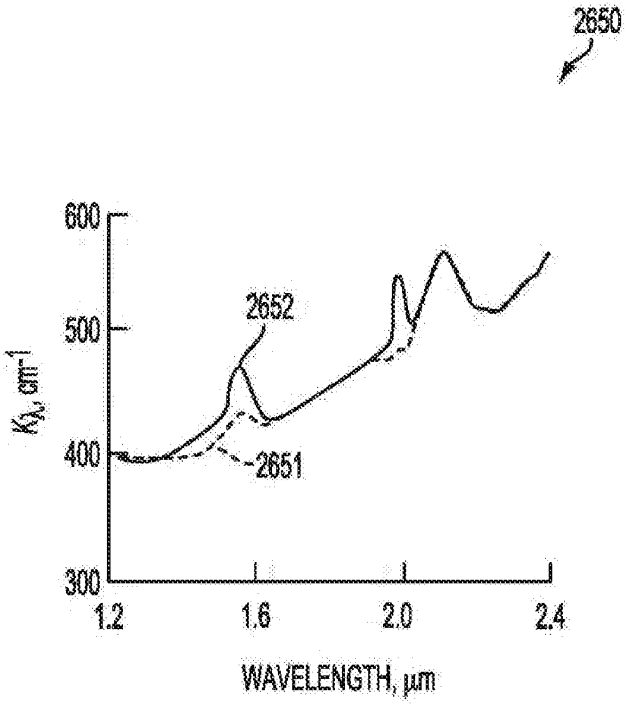

2650
600
500
400
300
K_λ, cm^{-1}
2652
2651
1.2
1.6
2.0
2.4
WAVELENGTH, μm

FIG. 26B

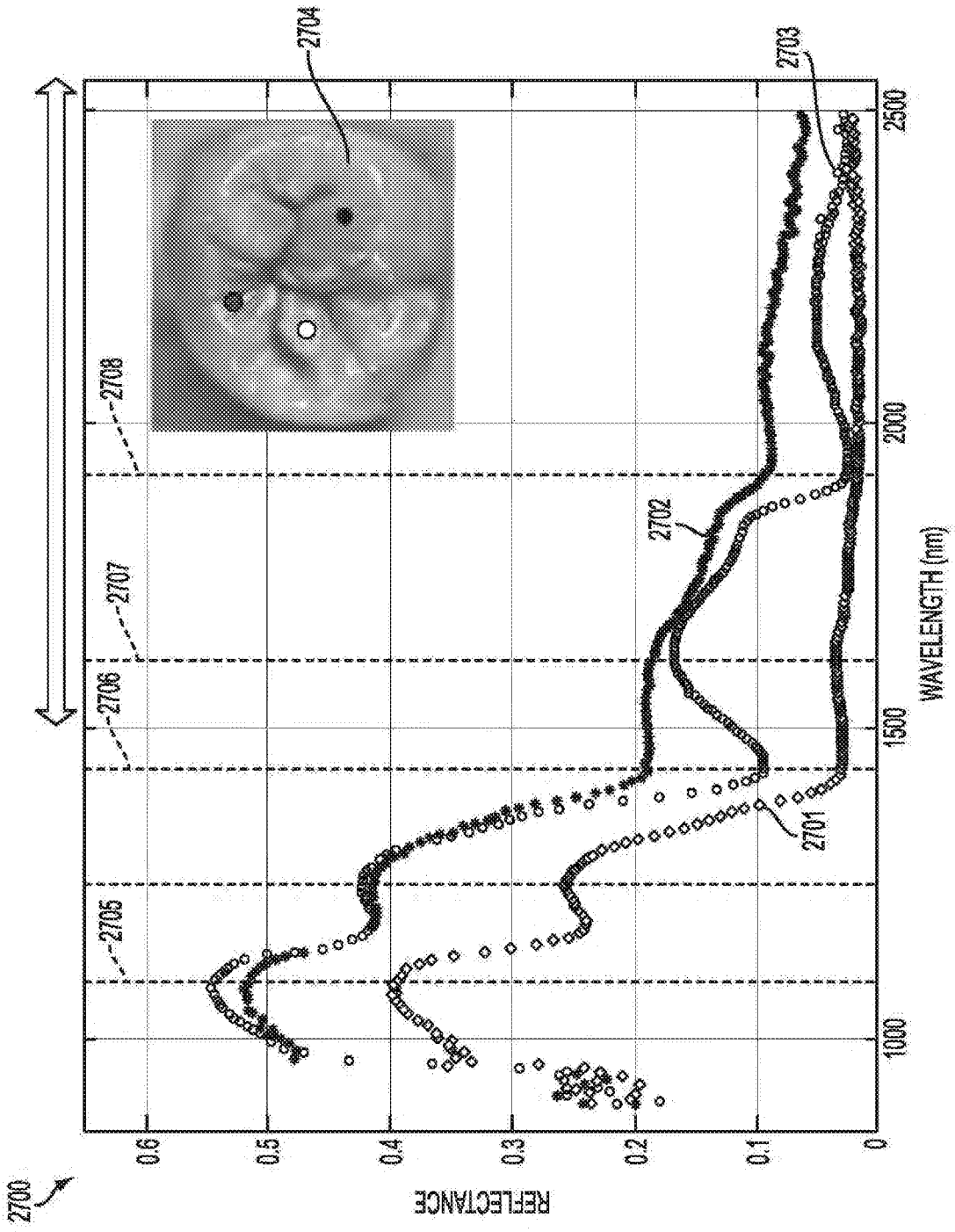

2700
2701
2702
2703
2704
2705
2706
2707
2708
REFLECTANCE
0
0.1
0.2
0.3
0.4
0.5
0.6
WAVELENGTH (nm)
1000
1500
2000
2500

FIG. 27

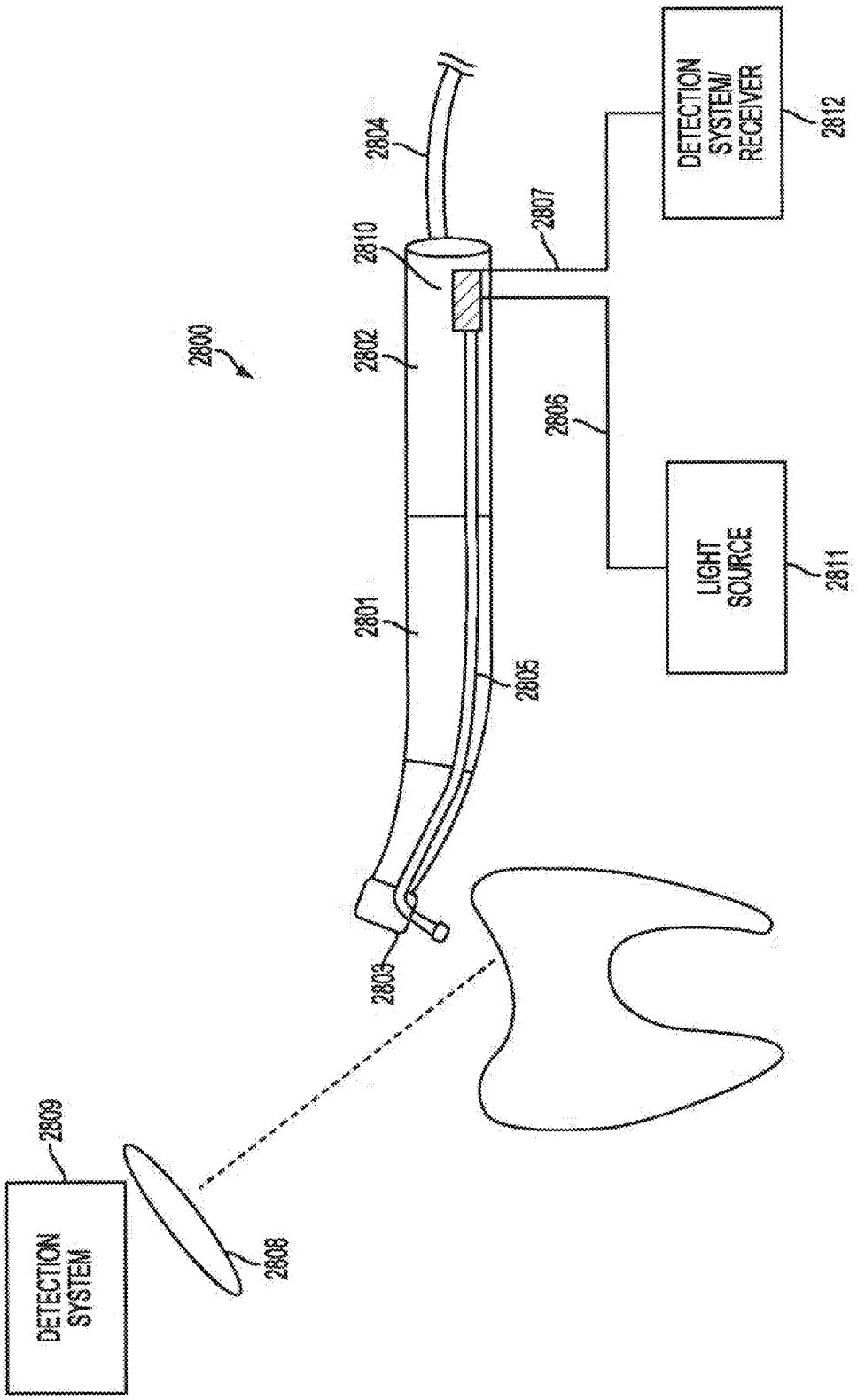

2800
2801
2802
2803
2804
2805
2806
2807
2808
2809
2810
2811
2812
DETECTION SYSTEM
DETECTION SYSTEM/ RECEIVER
LIGHT SOURCE

FIG. 28

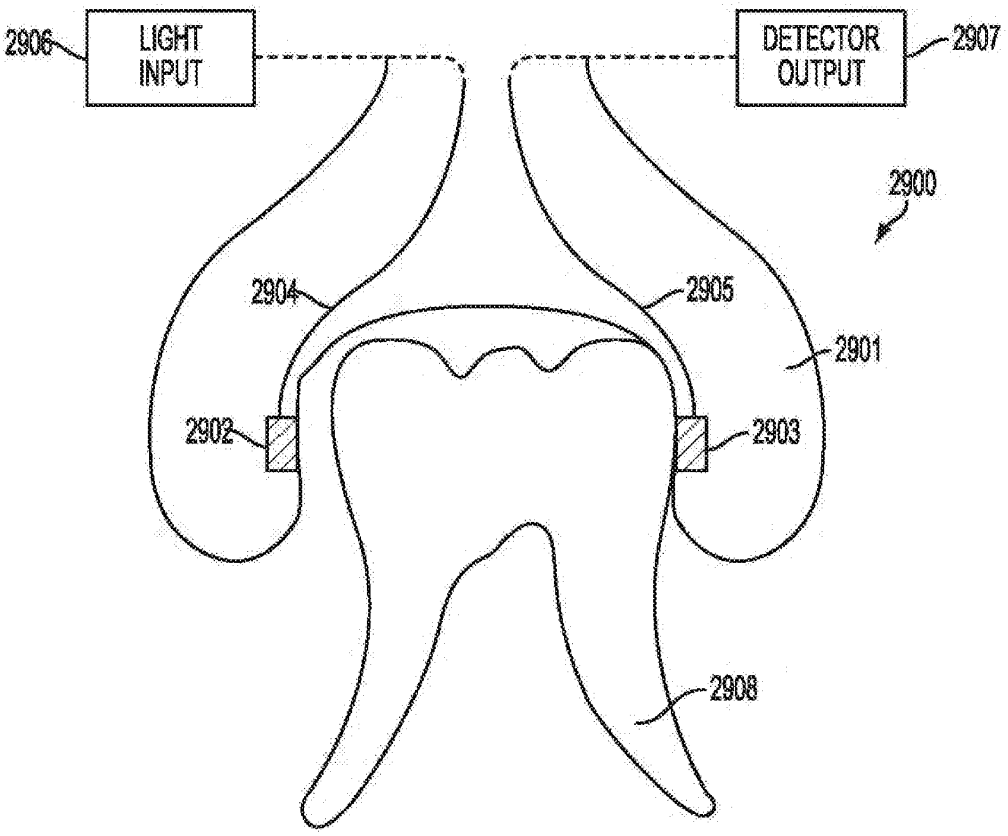

2906
LIGHT INPUT
DETECTOR OUTPUT
2907
2900
2904
2905
2901
2902
2903
2908

FIG. 29

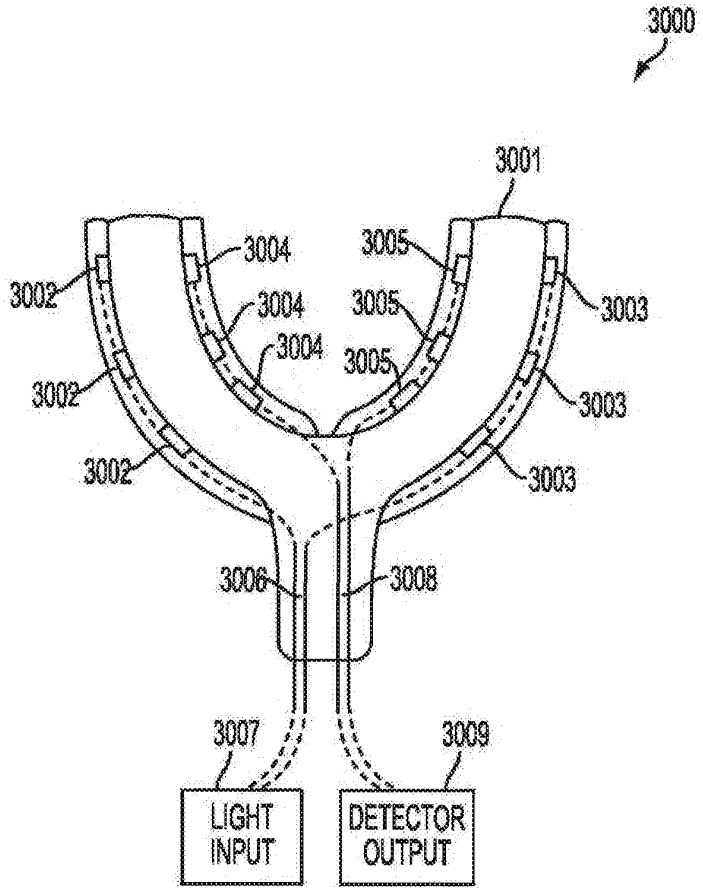

3000
3001
3002
3003
3004
3005
3006
3007
3008
3009
LIGHT INPUT
DETECTOR OUTPUT

FIG. 30

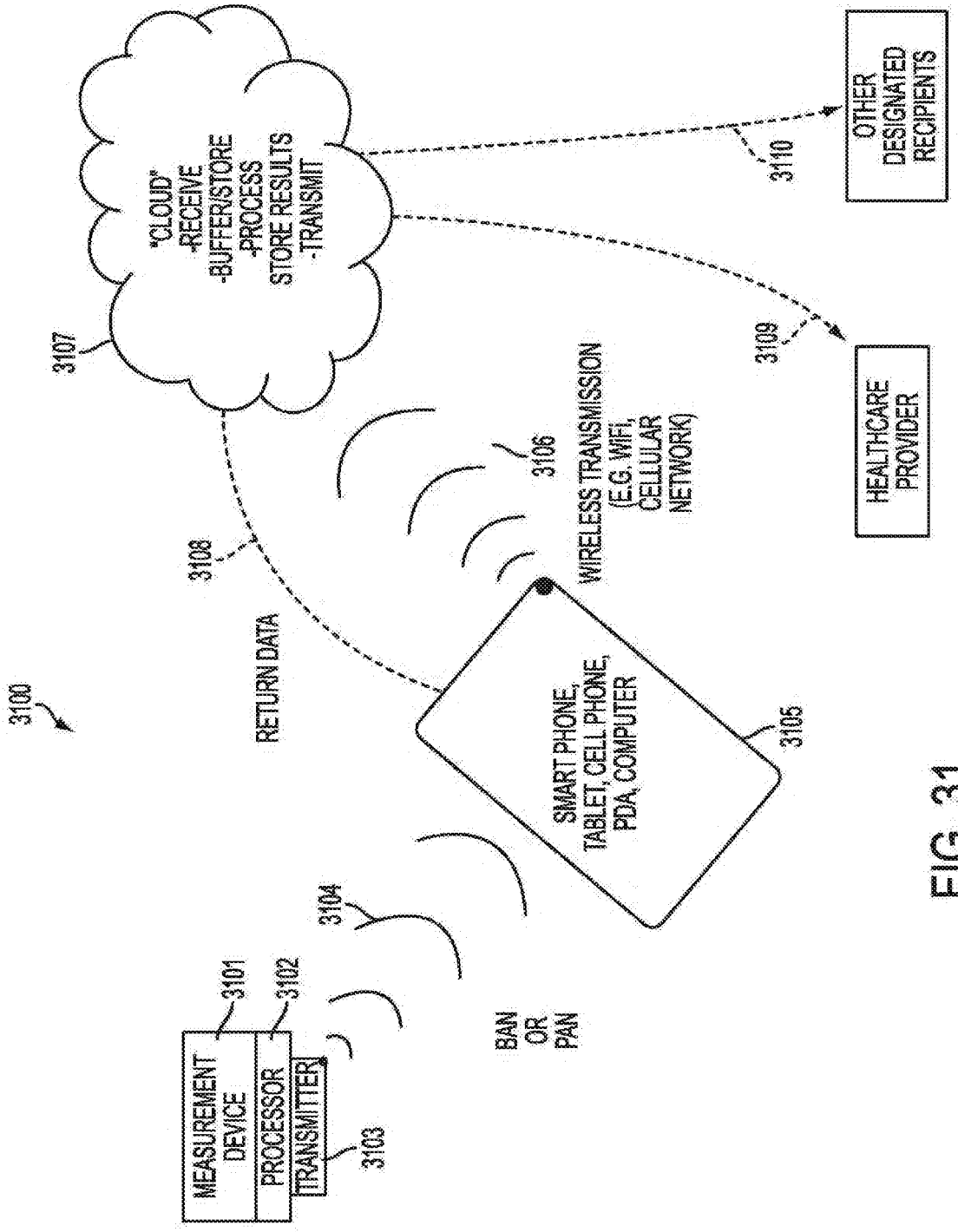

3100
MEASUREMENT DEVICE
PROCESSOR
TRANSMITTER
3101
3102
3103
3104
BAN OR PAN
SMART PHONE, TABLET, CELL PHONE, PDA, COMPUTER
3105
3106
WIRELESS TRANSMISSION (E.G. WIFI, CELLULAR NETWORK)
3107
"CLOUD" -RECEIVE -BUFFER/STORE -PROCESS STORE RESULTS -TRANSMIT
3108
RETURN DATA
3109
HEALTHCARE PROVIDER
3110
OTHER DESIGNATED RECIPIENTS

FIG. 31

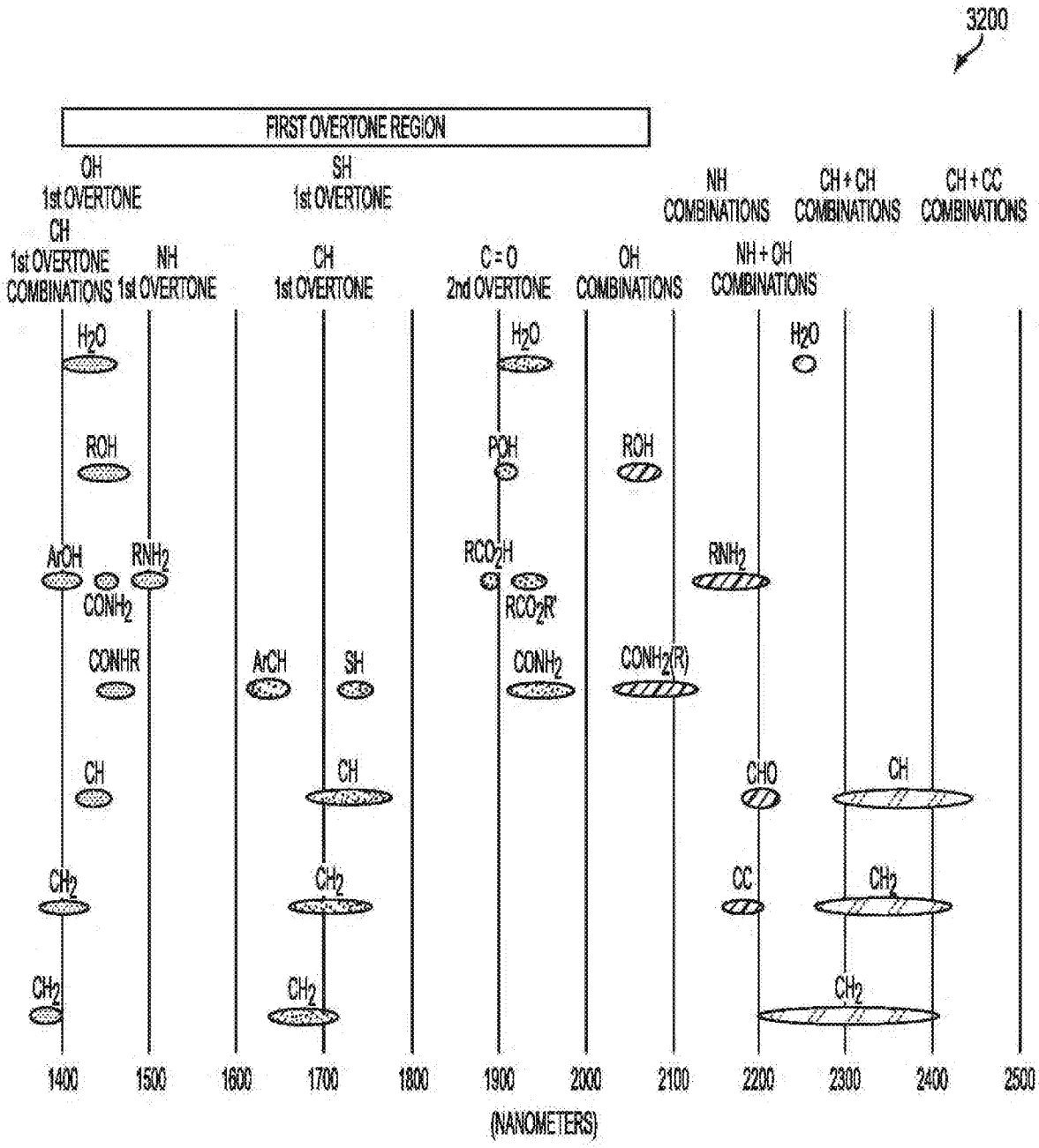

3200
FIRST OVERTONE REGION
OH 1st OVERTONE
SH 1st OVERTONE
NH COMBINATIONS
CH + CH COMBINATIONS
CH + CC COMBINATIONS
CH 1st OVERTONE COMBINATIONS
NH 1st OVERTONE
CH 1st OVERTONE
C = O 2nd OVERTONE
OH COMBINATIONS
NH + OH COMBINATIONS
H2O
ROH
ArOH
RNH2
CONH2
CONHR
ArCH
SH
RCO2H
RCO2R'
CONH2(R)
RNH2
CH
CHO
CC
CH2
1400
1500
1600
1700
1800
1900
2000
2100
2200
2300
2400
2500
(NANOMETERS)

FIG. 32

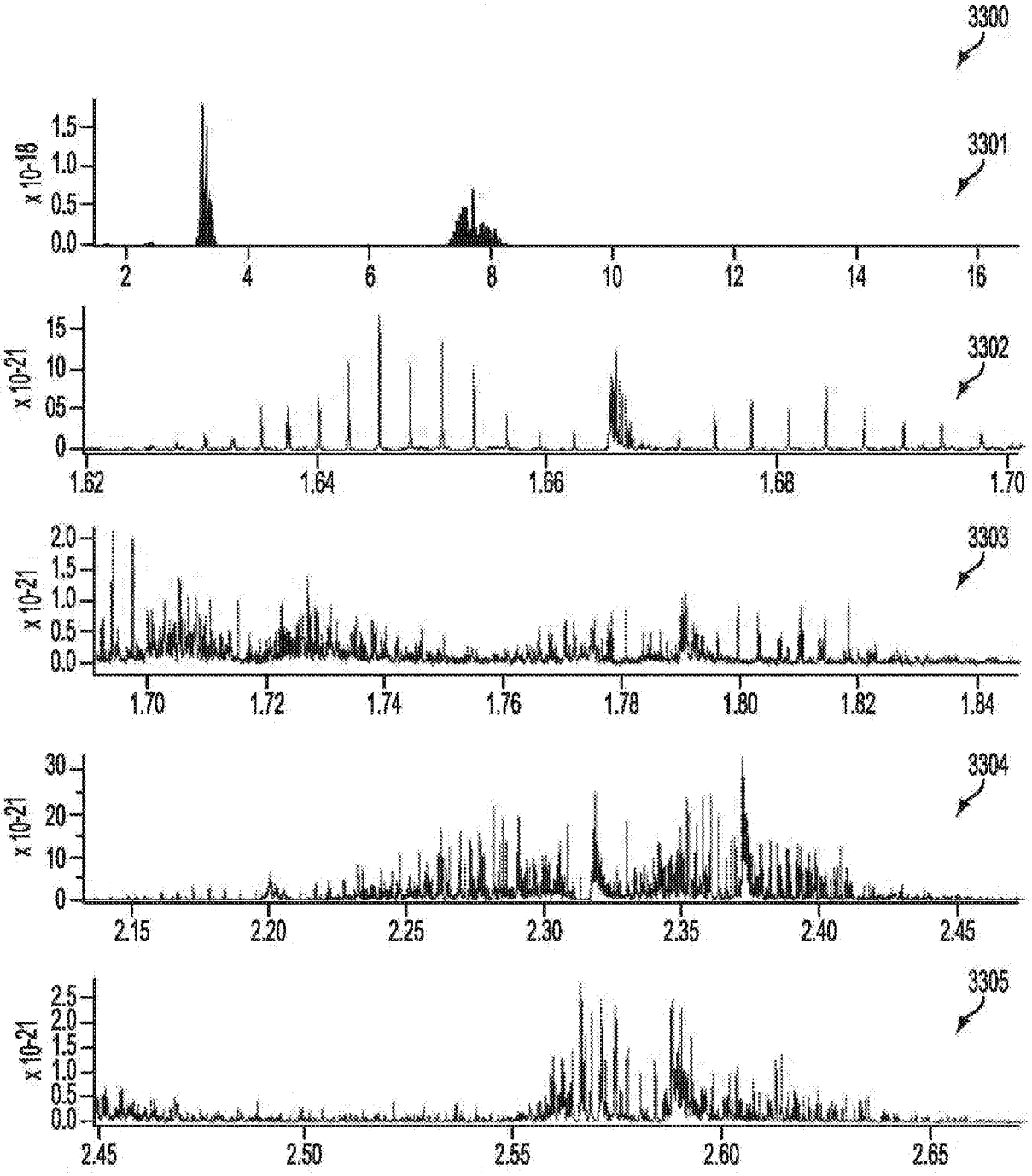

3300
3301
x 10-18
1.5
1.0
0.5
0.0
2
4
6
8
10
12
14
16
3302
x 10-21
15
10
05
0
1.62
1.64
1.66
1.68
1.70
3303
x 10-21
2.0
1.5
1.0
0.5
0.0
1.70
1.72
1.74
1.76
1.78
1.80
1.82
1.84
3304
x 10-21
30
20
10
0
2.15
2.20
2.25
2.30
2.35
2.40
2.45
3305
x 10-21
2.5
2.0
1.5
1.0
0.5
0.0
2.45
2.50
2.55
2.60
2.65

FIG. 33A

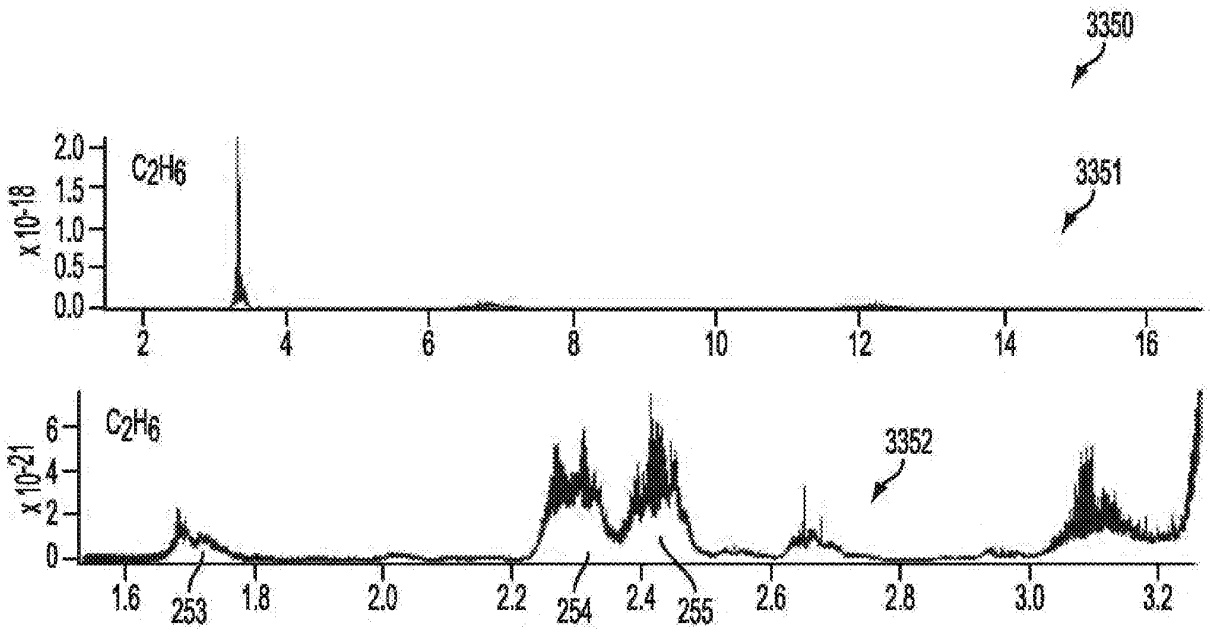

3350
3351
3352
C2H6
x 10-18
2.0
1.5
1.0
0.5
0.0
2
4
6
8
10
12
14
16
C2H6
x 10-21
6
4
2
0
1.6
253
1.8
2.0
2.2
254
2.4
255
2.6
2.8
3.0
3.2

FIG. 33B

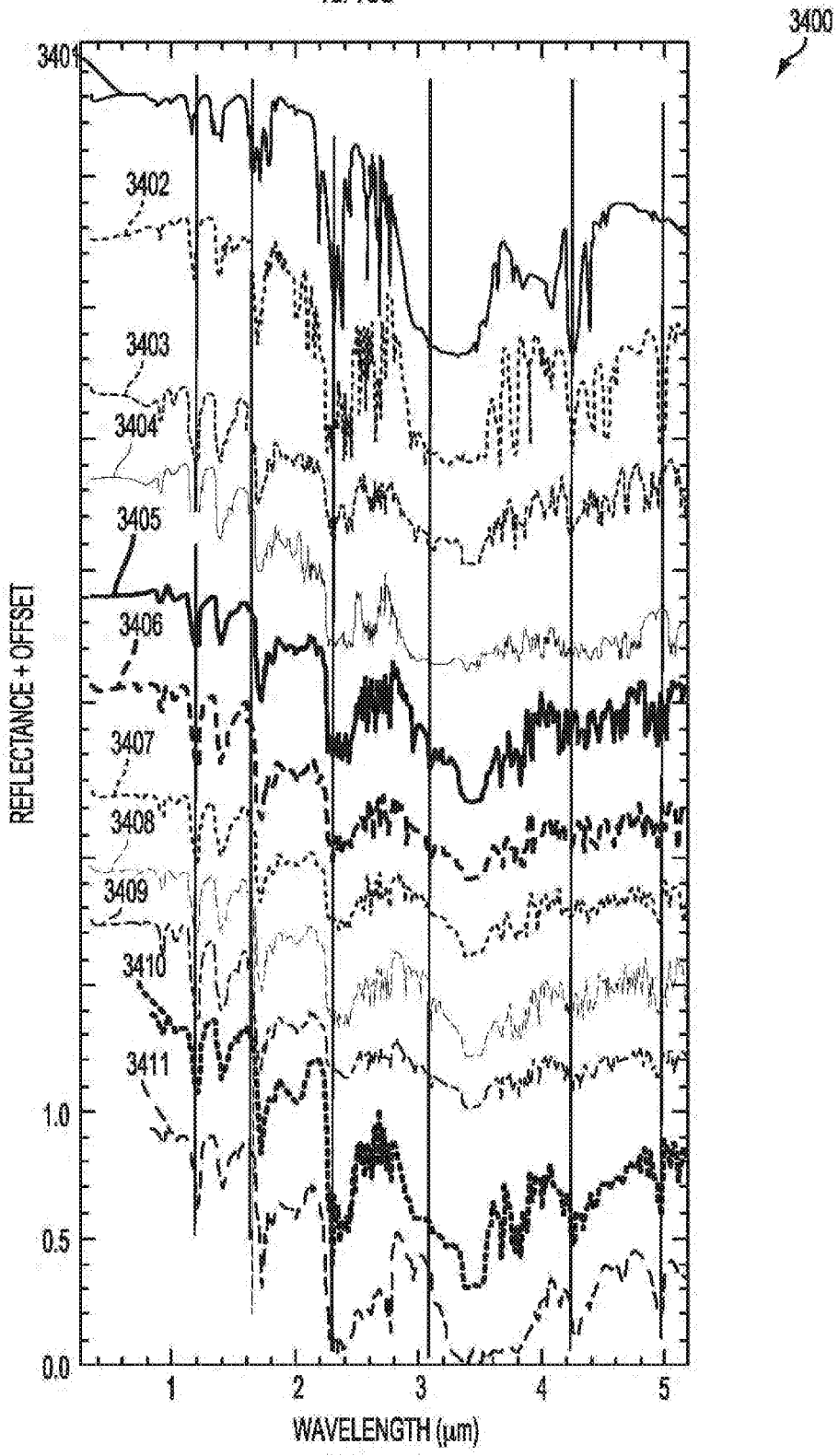

3400
3401
3402
3403
3404
3405
3406
3407
3408
3409
3410
3411
REFLECTANCE + OFFSET
0.0
0.5
1.0
1
2
3
4
5
WAVELENGTH (μm)

FIG.34

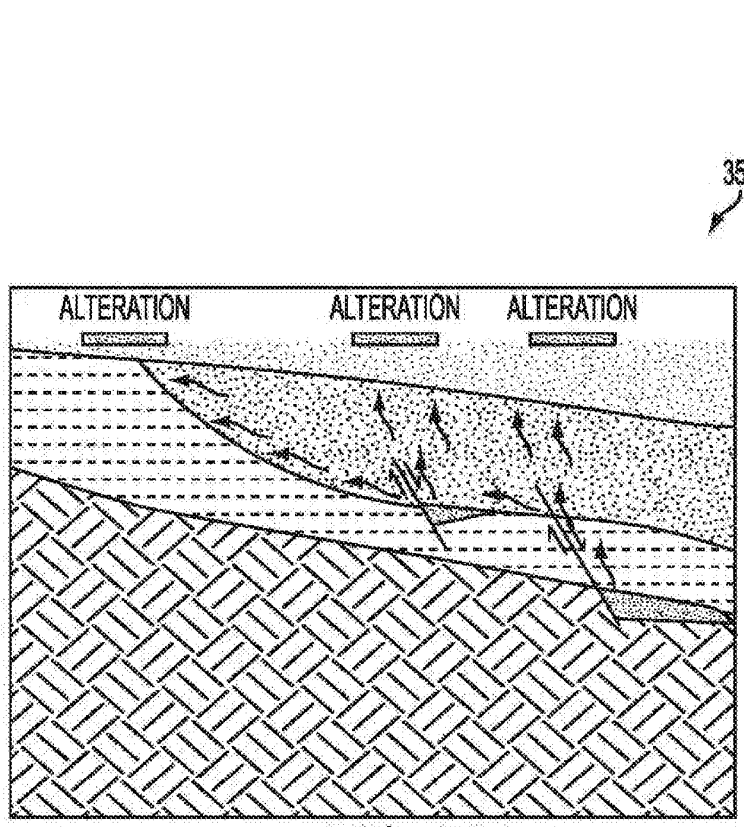


FIG. 35A

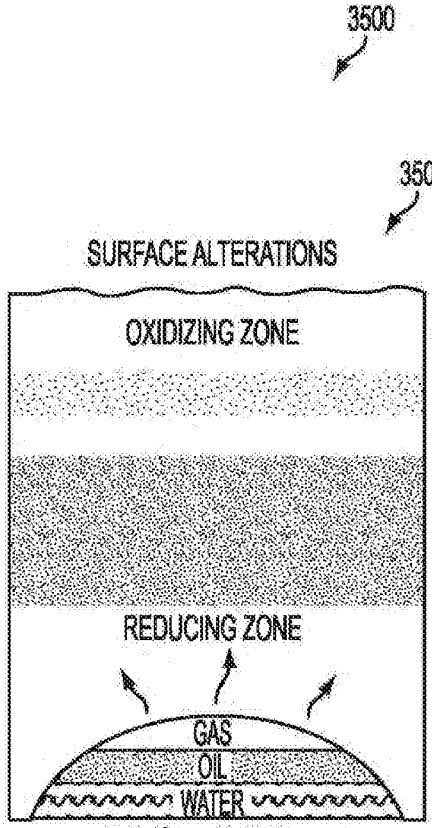


FIG. 35B

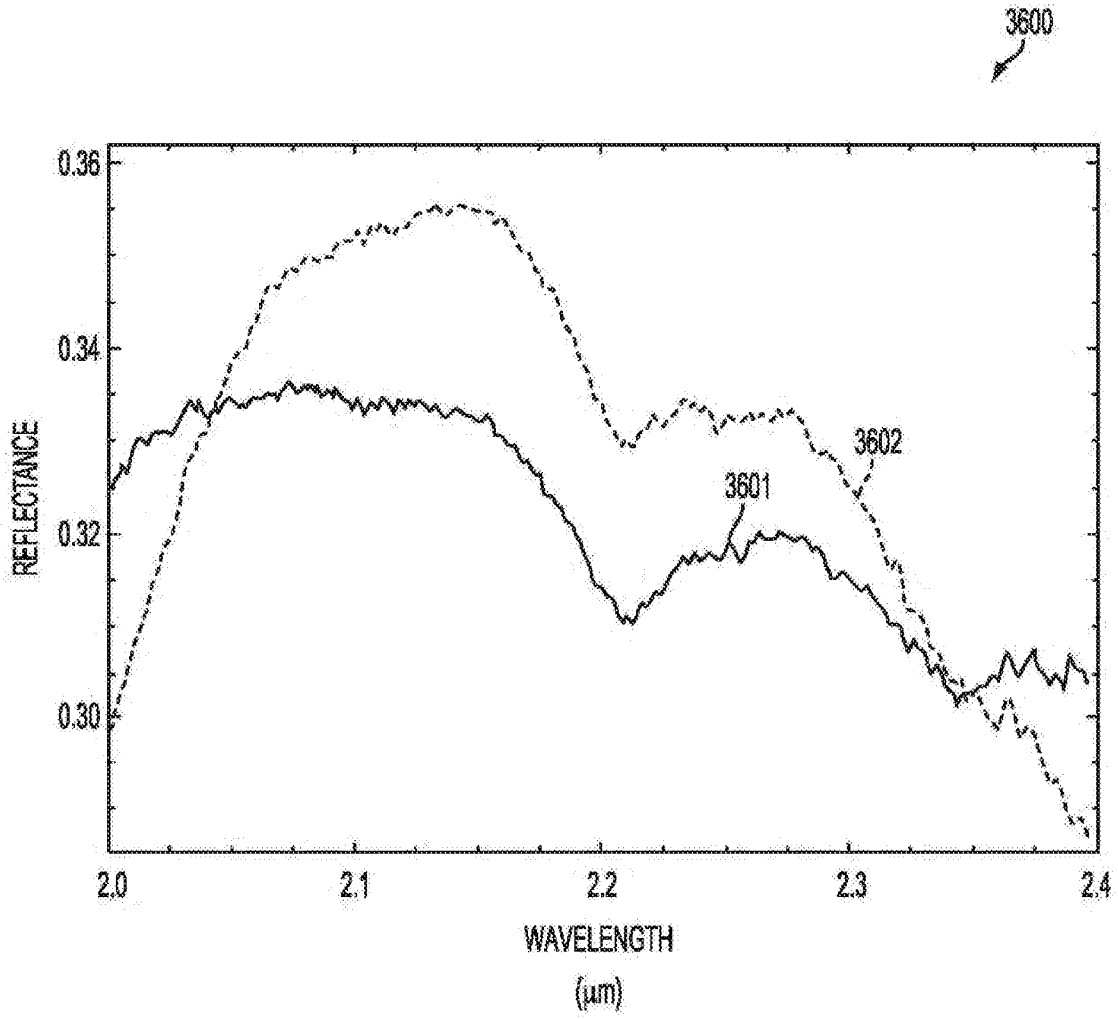

3600
0.36
0.34
0.32
0.30
REFLECTANCE
3602
3601
2.0
2.1
2.2
2.3
2.4
WAVELENGTH
(μm)

FIG. 36A

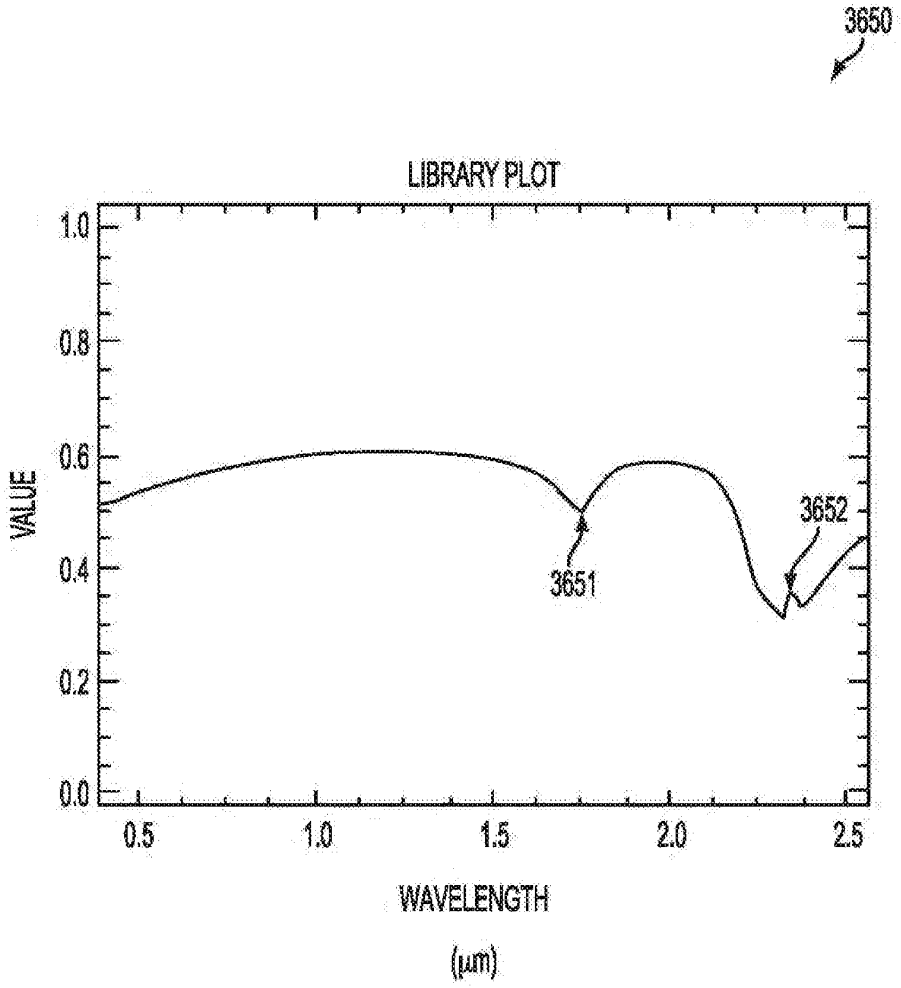

3650
LIBRARY PLOT
1.0
0.8
0.6
0.4
0.2
0.0
VALUE
3651
3652
0.5
1.0
1.5
2.0
2.5
WAVELENGTH
(μm)

FIG. 36B

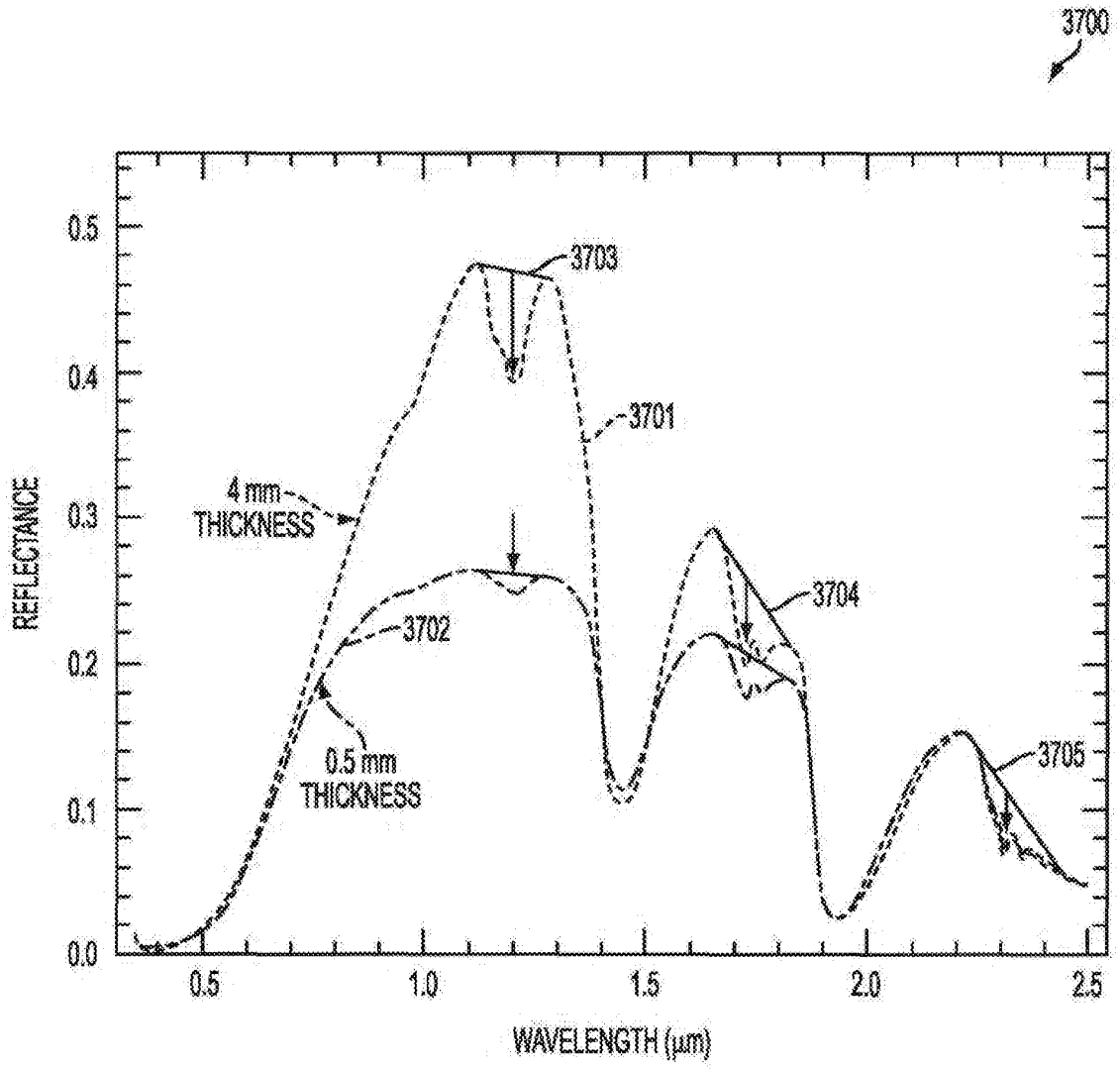

3700
0.5
0.4
0.3
0.2
0.1
0.0
REFLECTANCE
3703
3701
4 mm
THICKNESS
3704
3702
0.5 mm
THICKNESS
3705
0.5
1.0
1.5
2.0
2.5
WAVELENGTH (μm)

FIG. 37

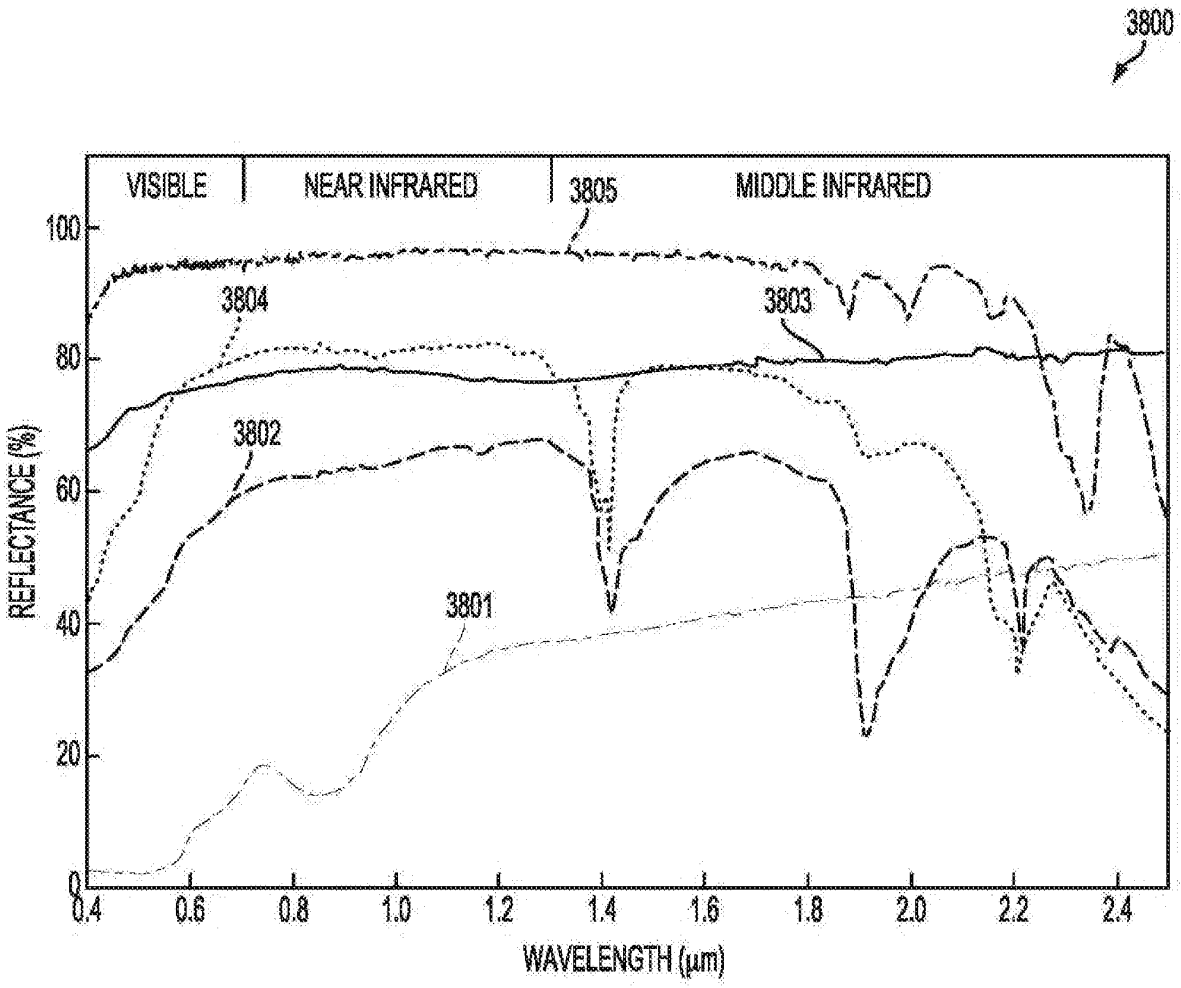

3800
VISIBLE
NEAR INFRARED
3805
MIDDLE INFRARED
100
80
60
40
20
0
3804
3803
3802
3801
REFLECTANCE (%)
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
WAVELENGTH (μm)

FIG. 38

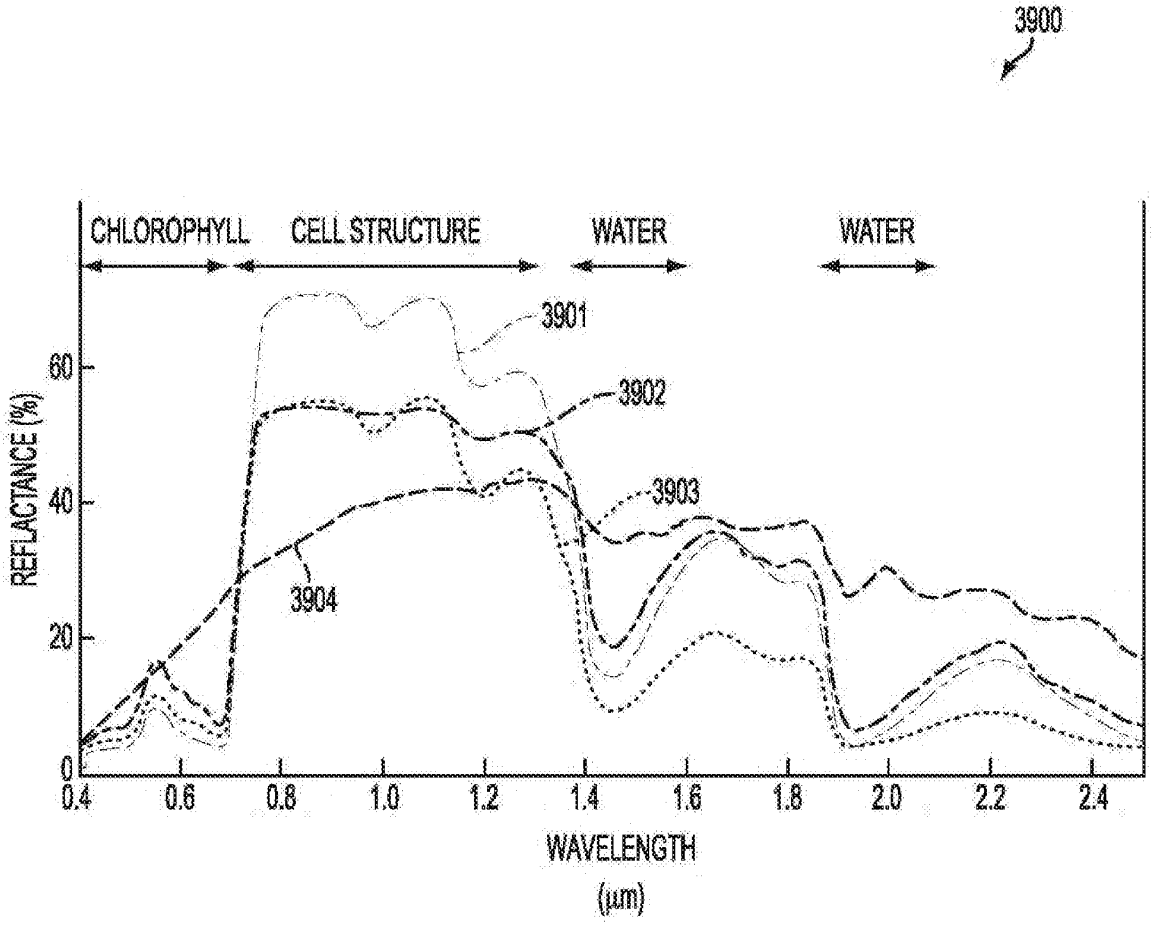

3900
CHLOROPHYLL
CELL STRUCTURE
WATER
WATER
3901
3902
3903
3904
REFLACTANCE (%)
0
20
40
60
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
WAVELENGTH
(μm)

FIG. 39

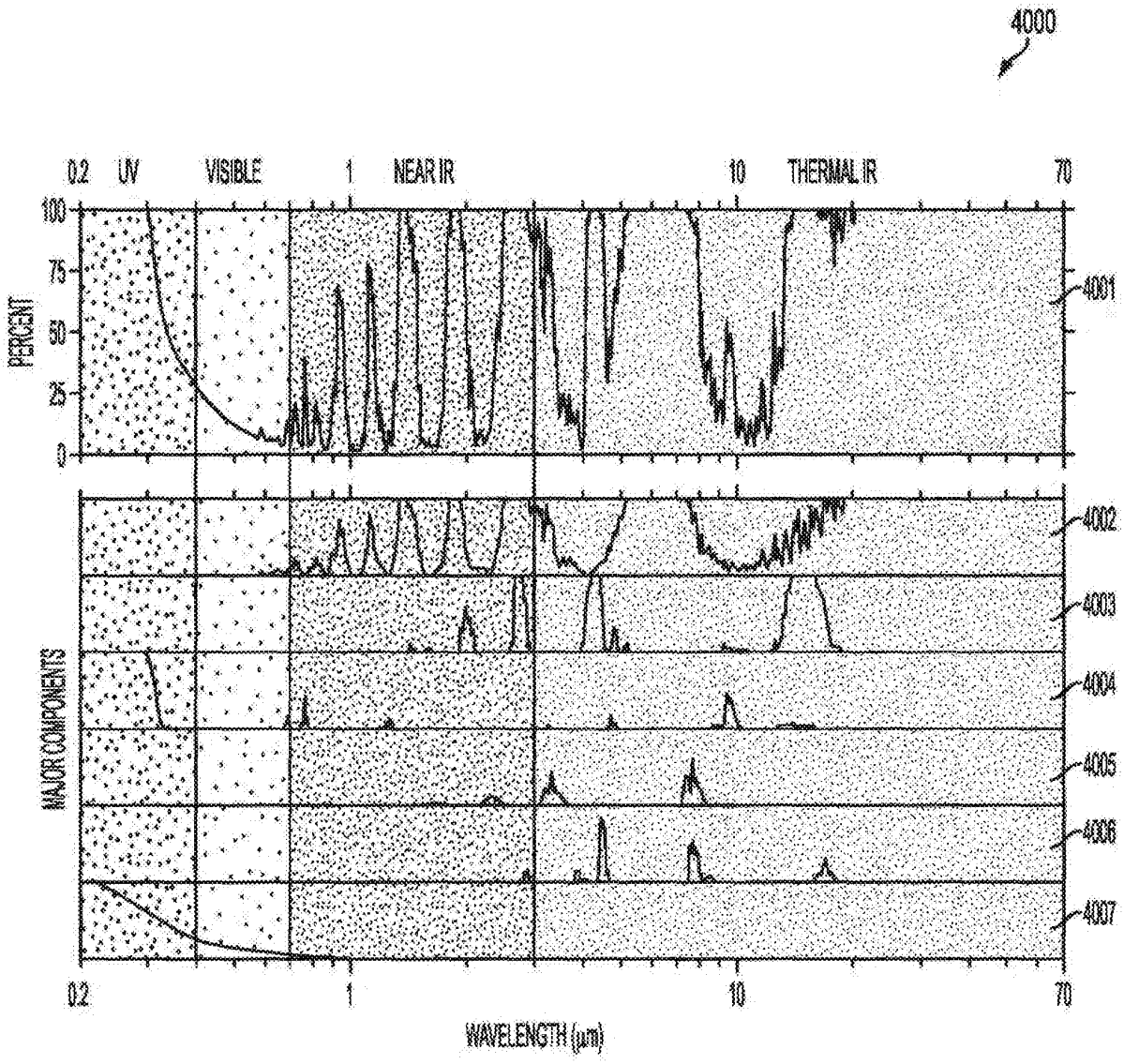

4000
0.2
UV
VISIBLE
1
NEAR IR
10
THERMAL IR
70
100
75
50
25
0
PERCENT
4001
4002
4003
4004
4005
4006
4007
MAJOR COMPONENTS
0.2
1
10
70
WAVELENGTH (μm)

FIG. 40

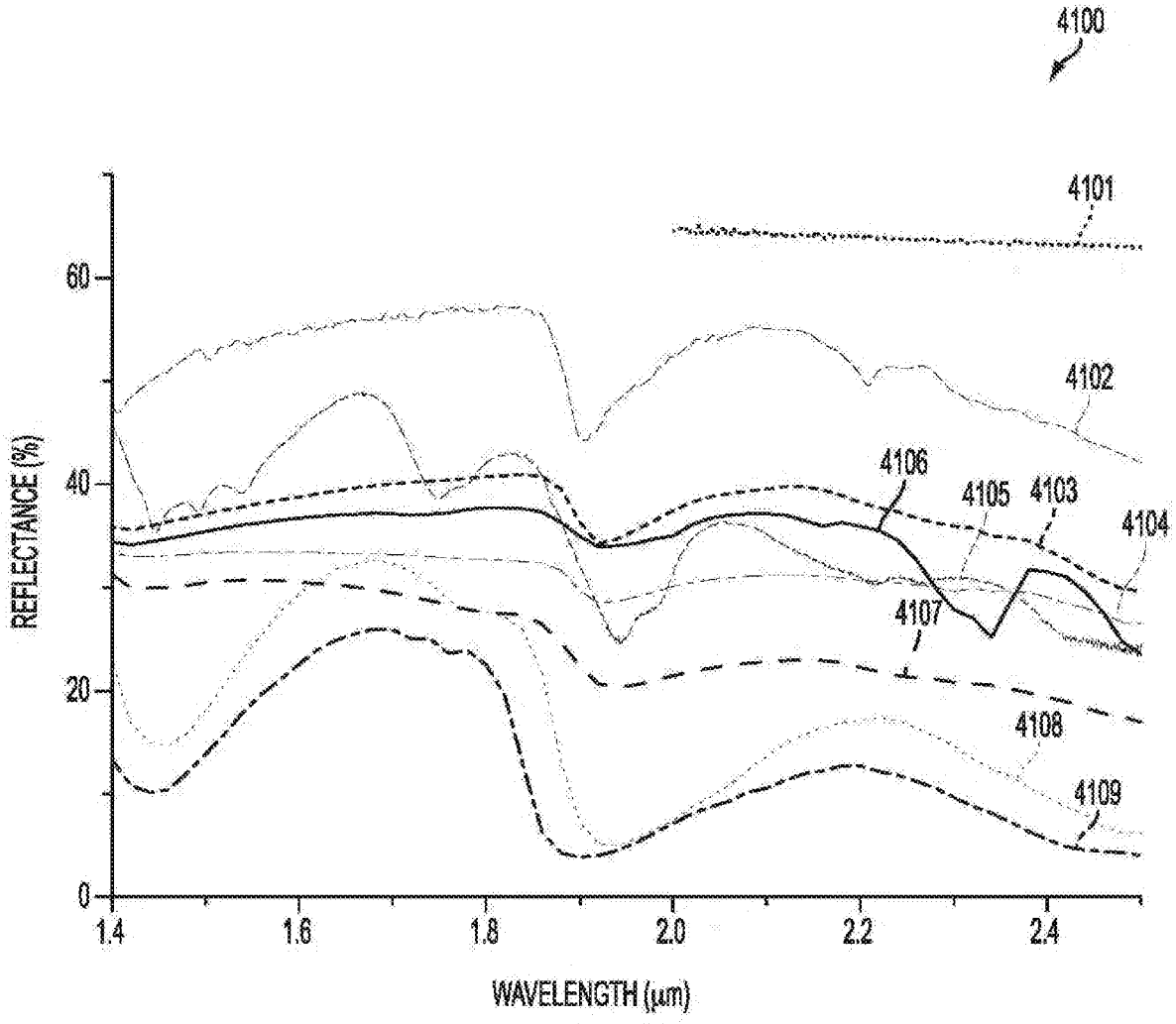

4100
4101
4102
4103
4104
4105
4106
4107
4108
4109
REFLECTANCE (%)
0
20
40
60
1.4
1.6
1.8
2.0
2.2
2.4
WAVELENGTH (μm)

FIG. 41

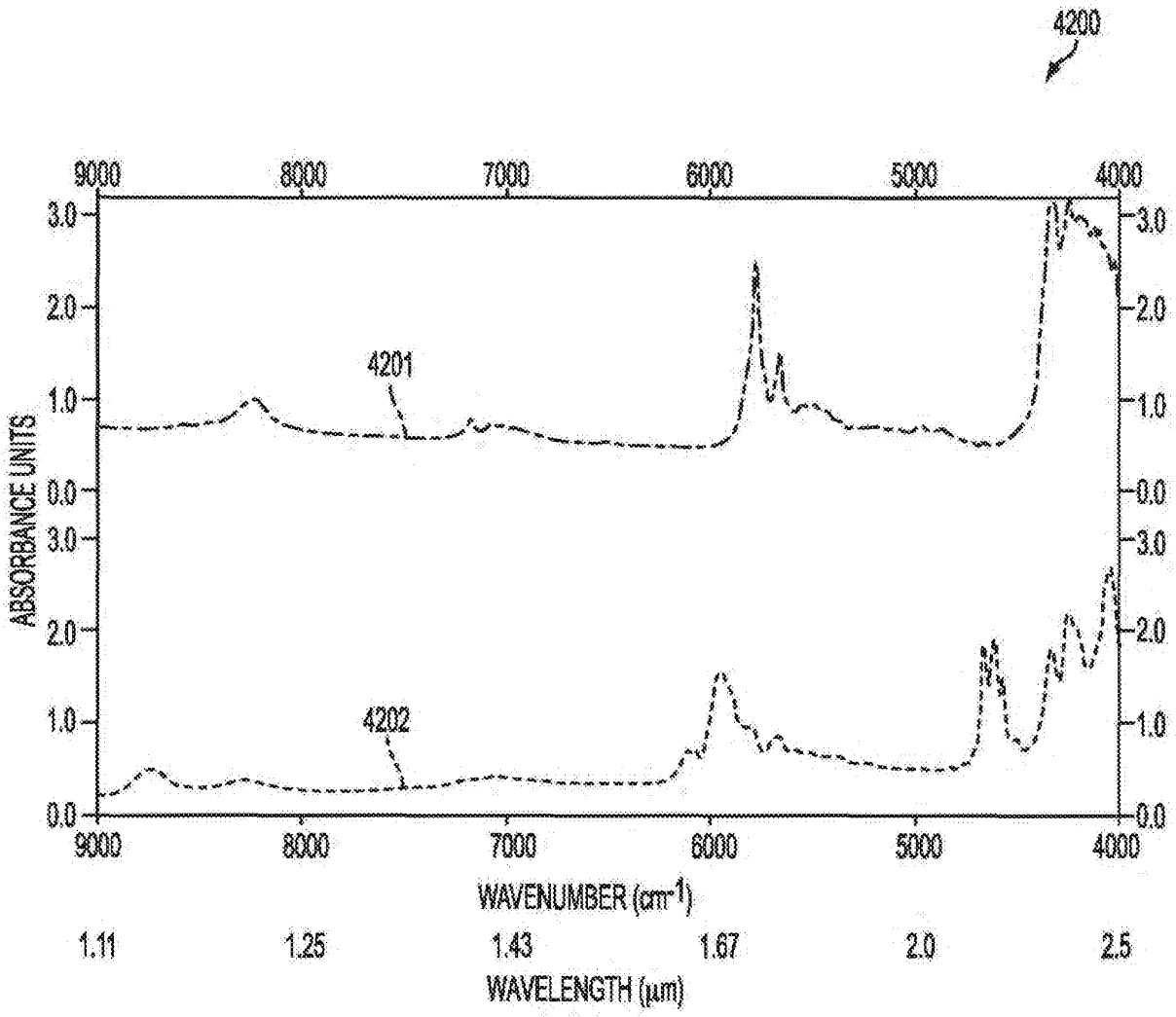

4200
9000
8000
7000
6000
5000
4000
3.0
2.0
1.0
0.0
4201
4202
ABSORBANCE UNITS
WAVENUMBER (cm-1)
1.11
1.25
1.43
1.67
2.0
2.5
WAVELENGTH (µm)

FIG. 42

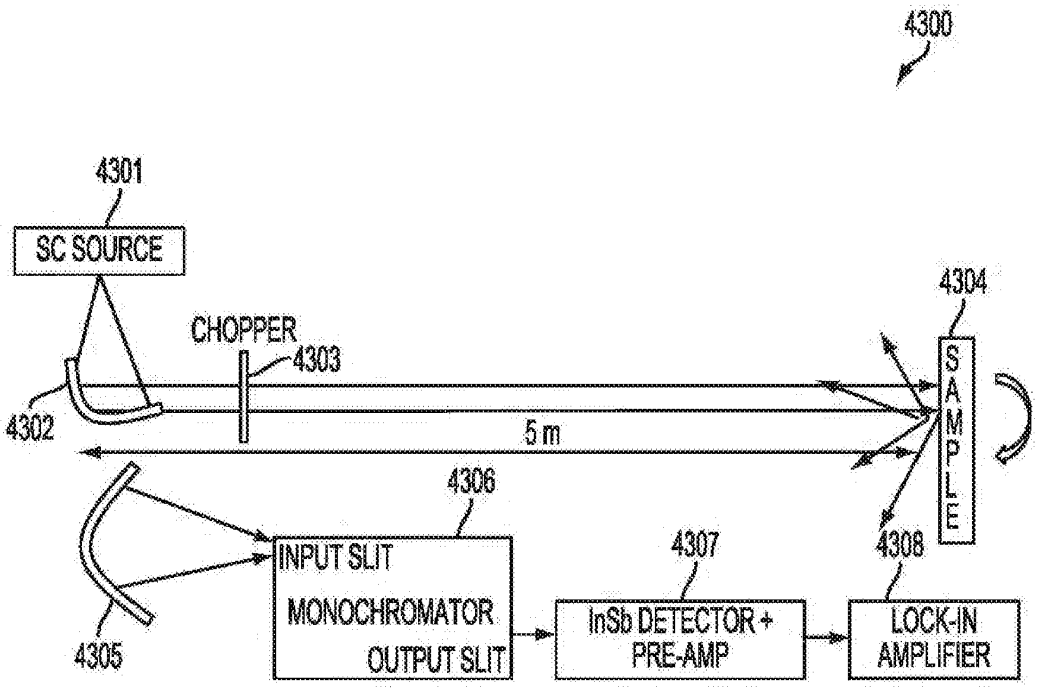

4300
4301
SC SOURCE
CHOPPER
4303
4304
4302
5 m
SAMPLE
4306
INPUT SLIT
MONOCHROMATOR
OUTPUT SLIT
4307
InSb DETECTOR +
PRE-AMP
4308
LOCK-IN
AMPLIFIER
4305

FIG. 43

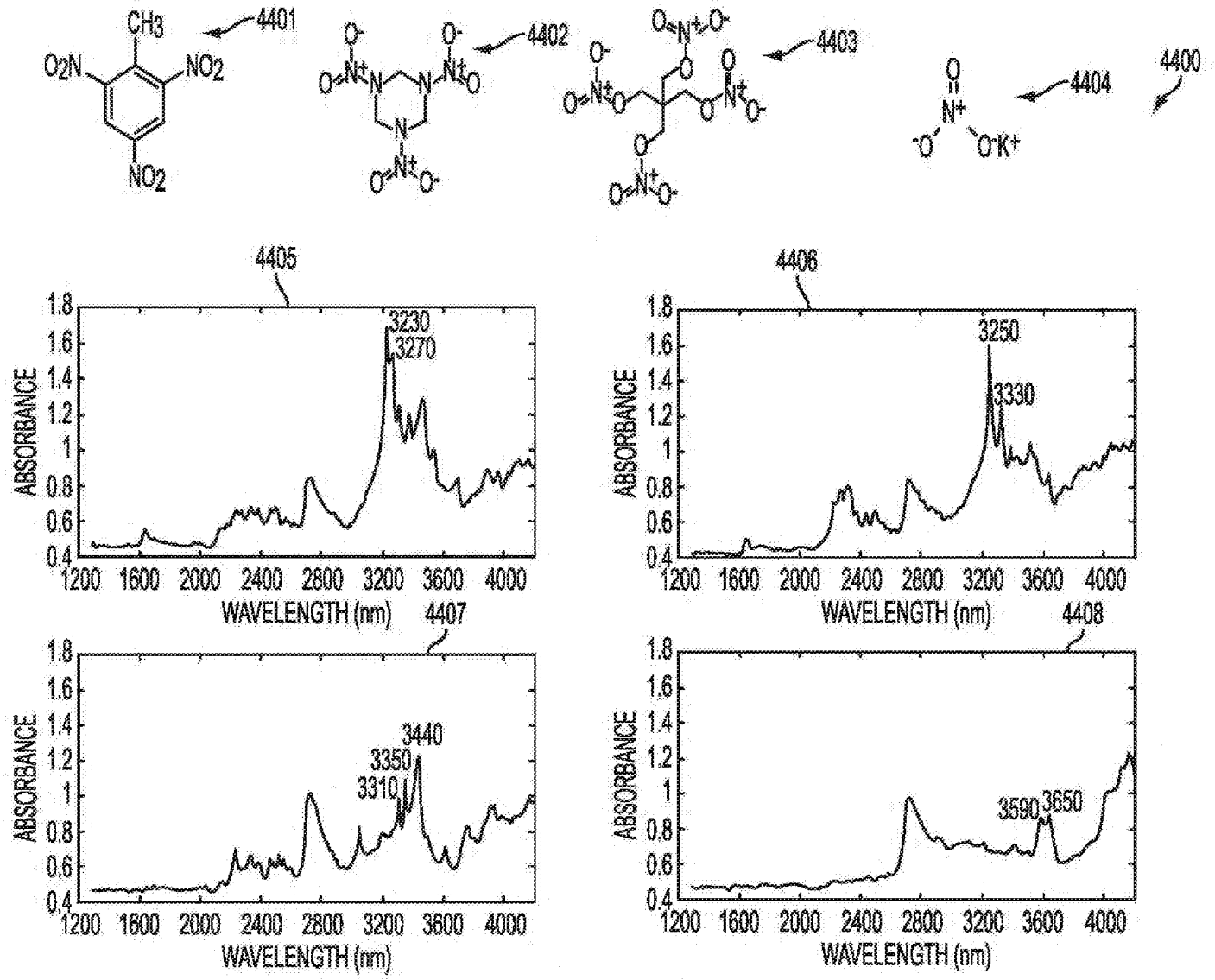


FIG. 44

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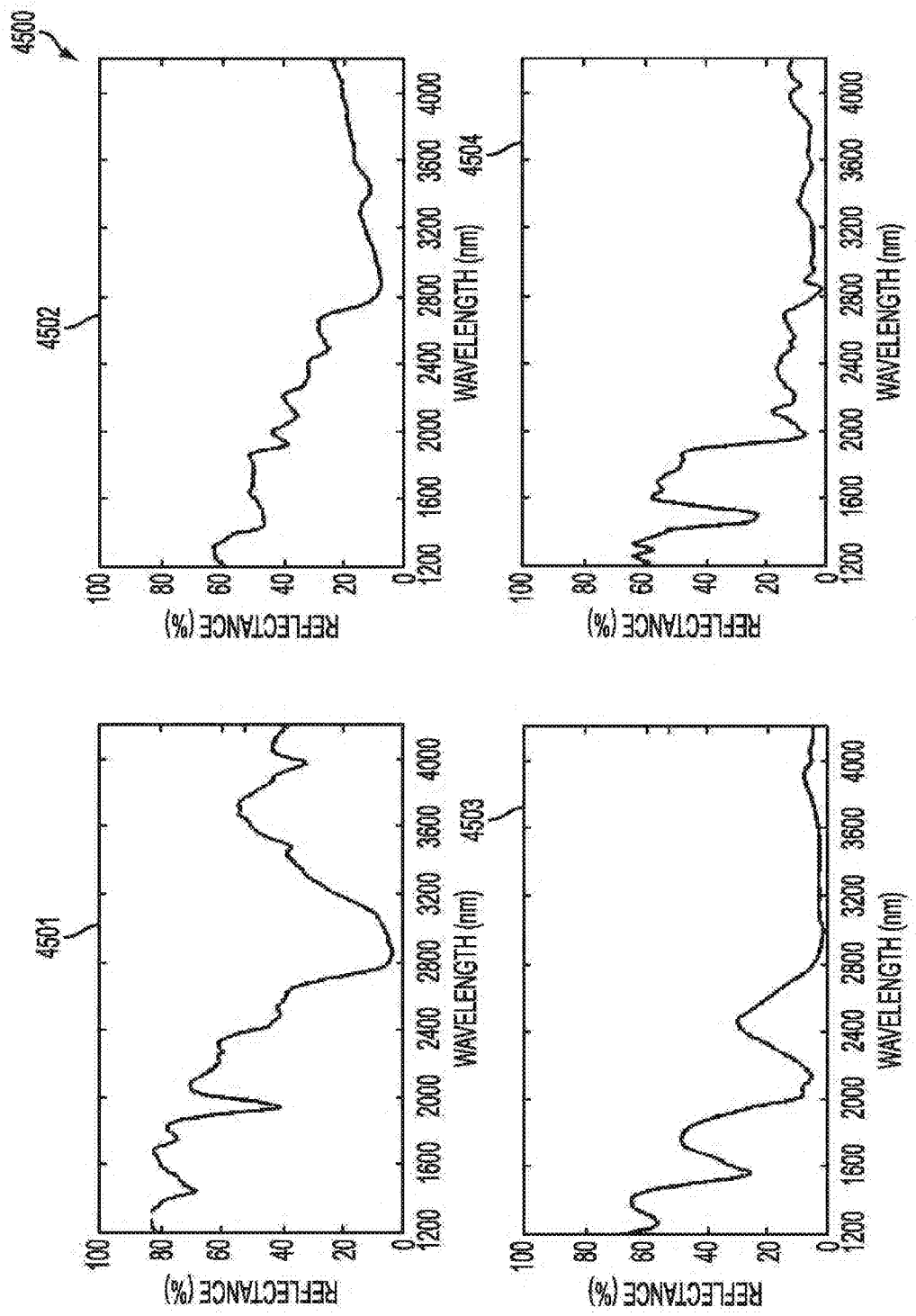

4500
4501
4502
4503
4504
REFLECTANCE (%)
WAVELENGTH (nm)
100
80
60
40
20
0
1200
1600
2000
2400
2800
3200
3600
4000

FIG. 45A

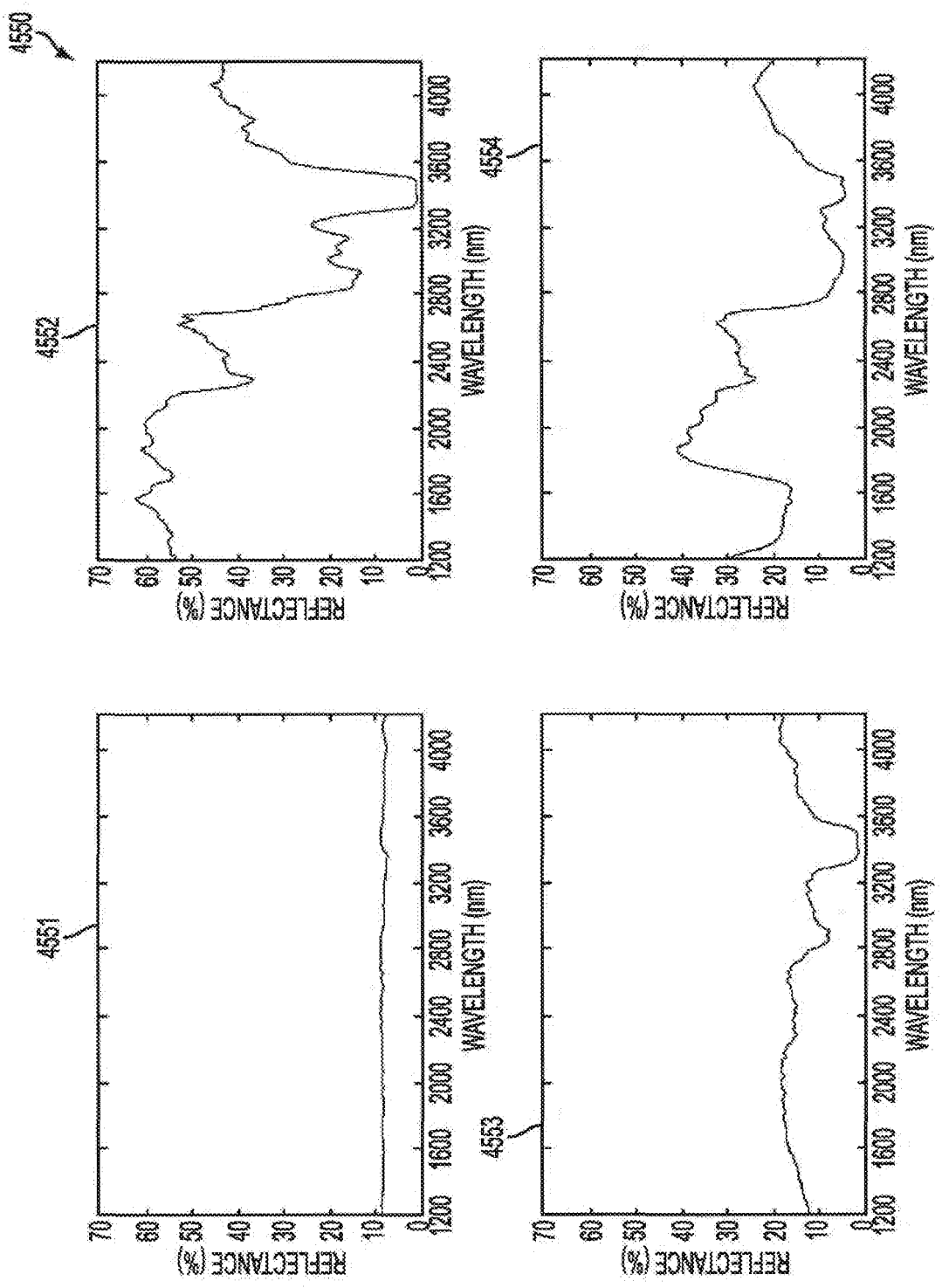

4550
4551
4552
4553
4554
REFLECTANCE (%)
WAVELENGTH (nm)
70
60
50
40
30
20
10
0
1200
1600
2000
2400
2800
3200
3600
4000

FIG. 45B

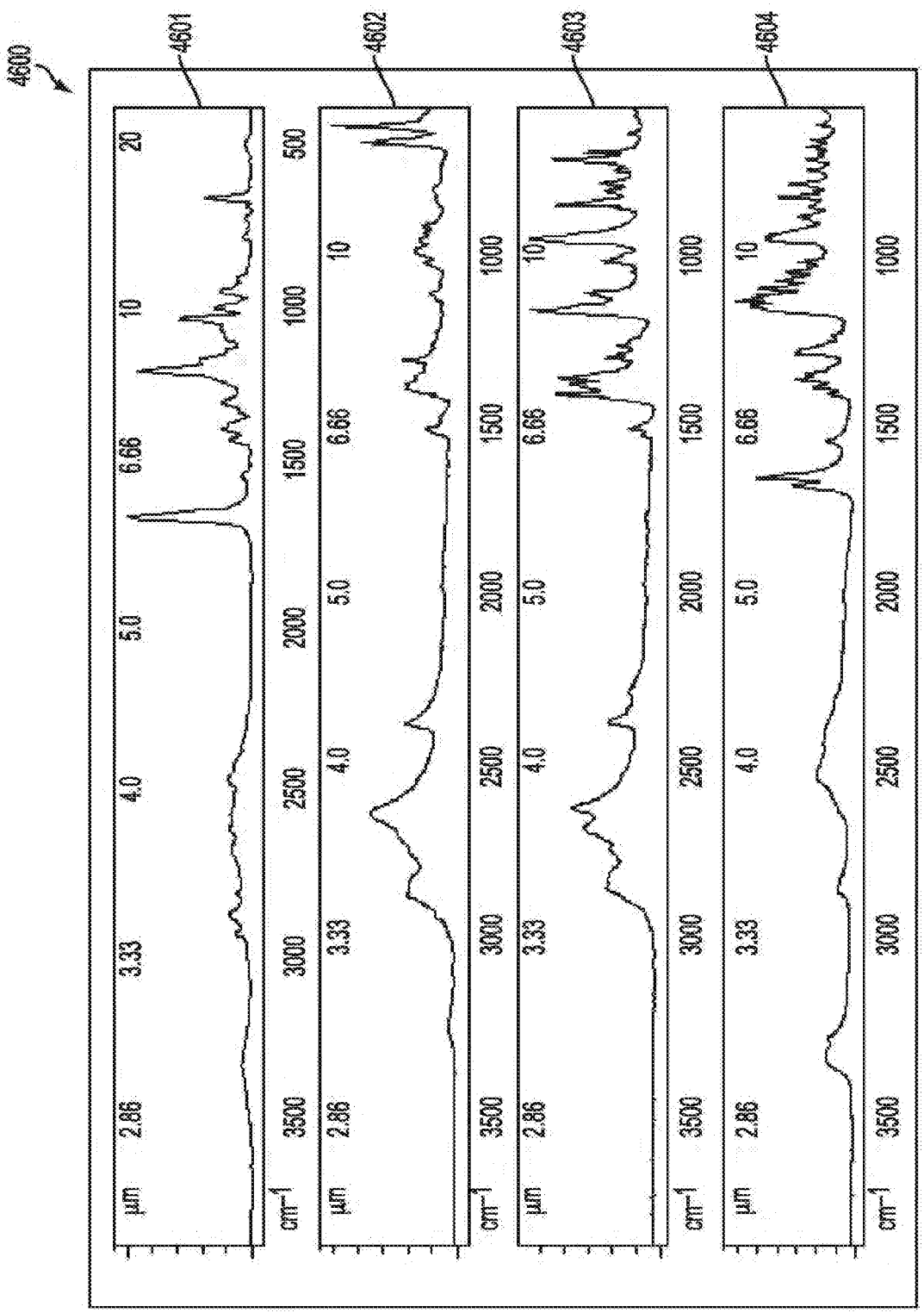

4600
4601
4602
4603
4604
μm
cm⁻¹
2.86
3.33
4.0
5.0
6.66
10
20
3500
3000
2500
2000
1500
1000
500

FIG. 46

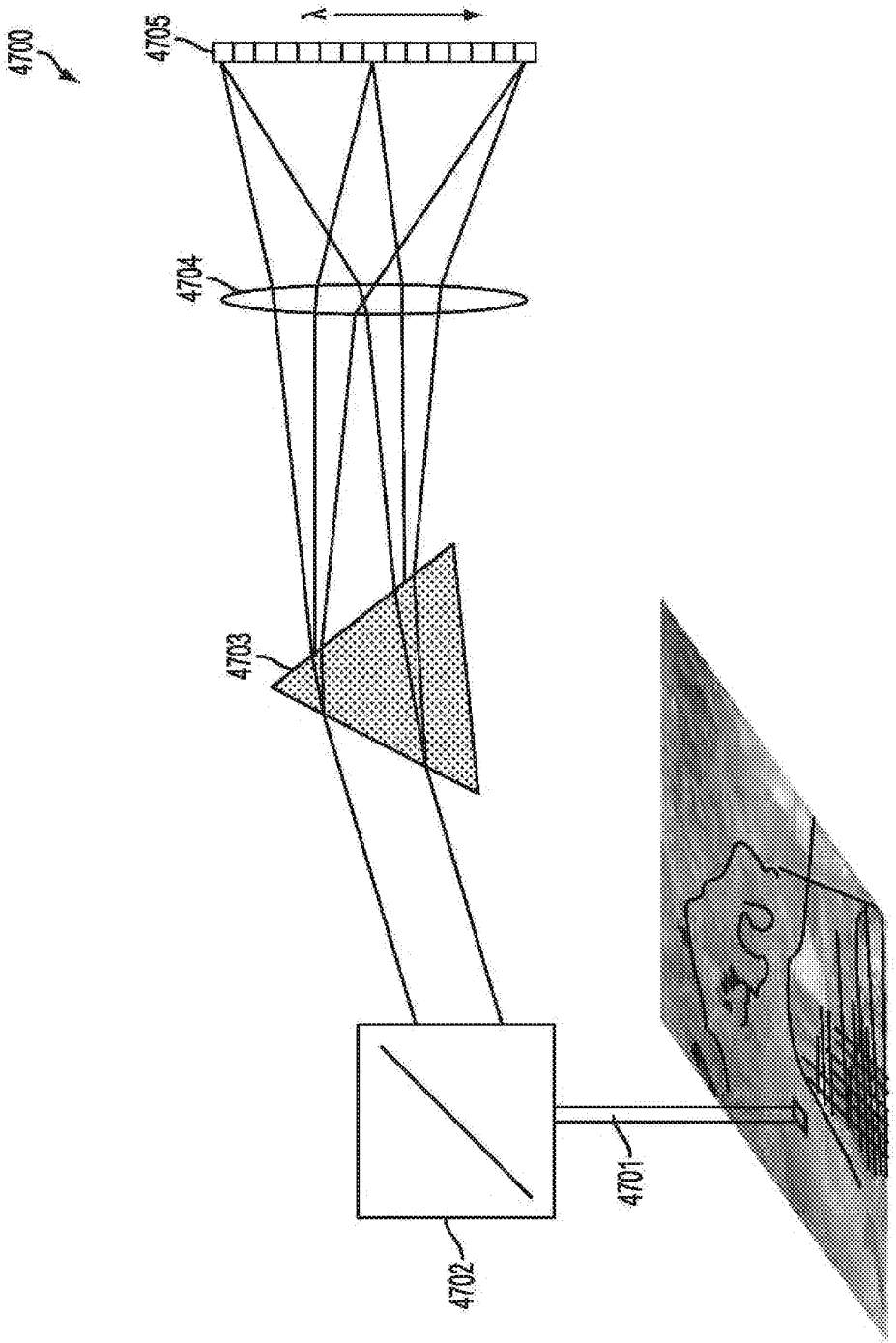


FIG. 47A

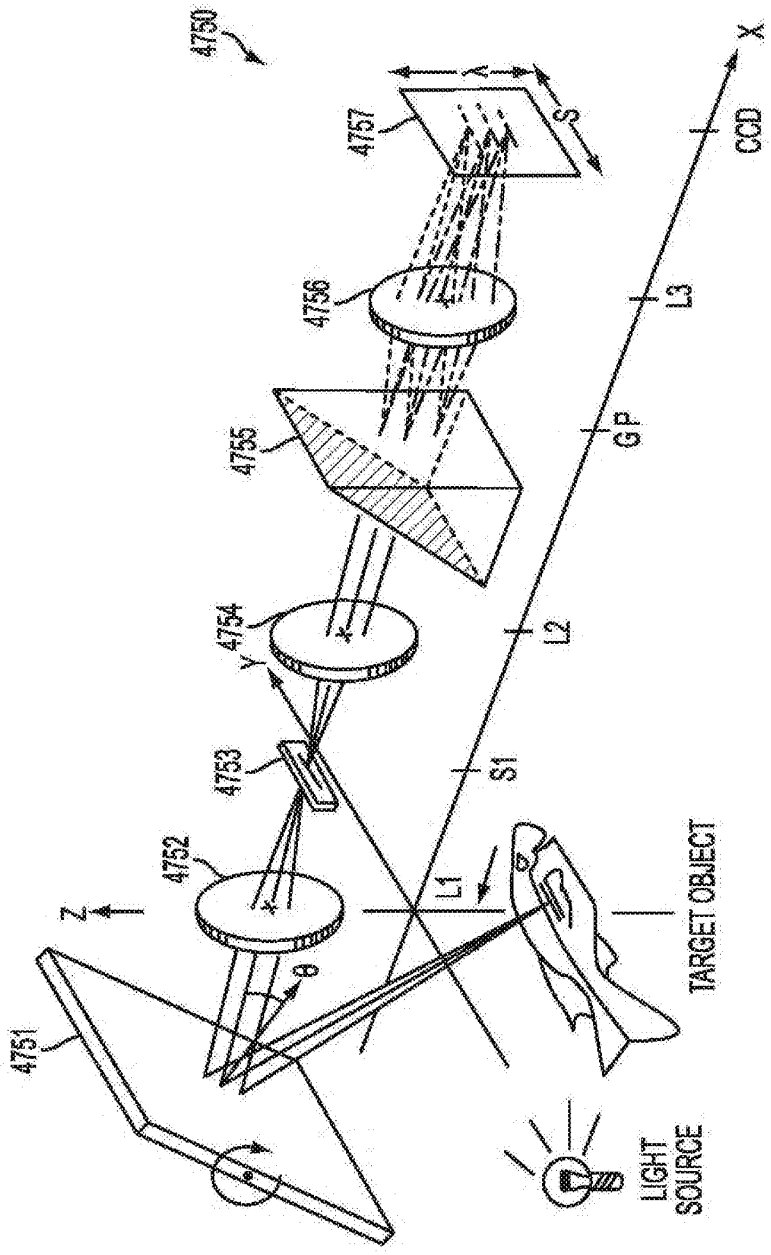

4750
4757
4756
4755
4754
4753
4752
4751
Z
θ
Y
X
L1
S1
L2
GP
L3
CCD
TARGET OBJECT
LIGHT SOURCE

FIG. 47B

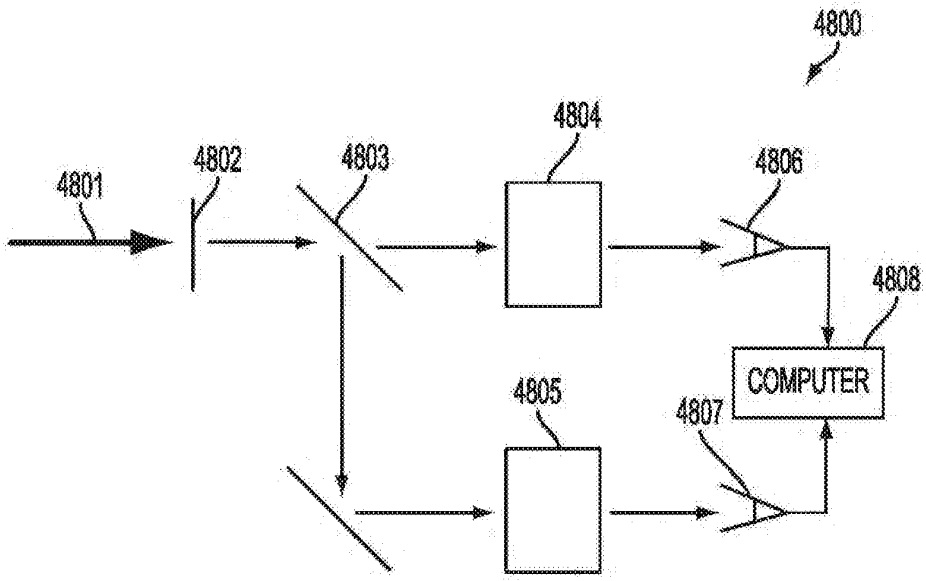


FIG. 48

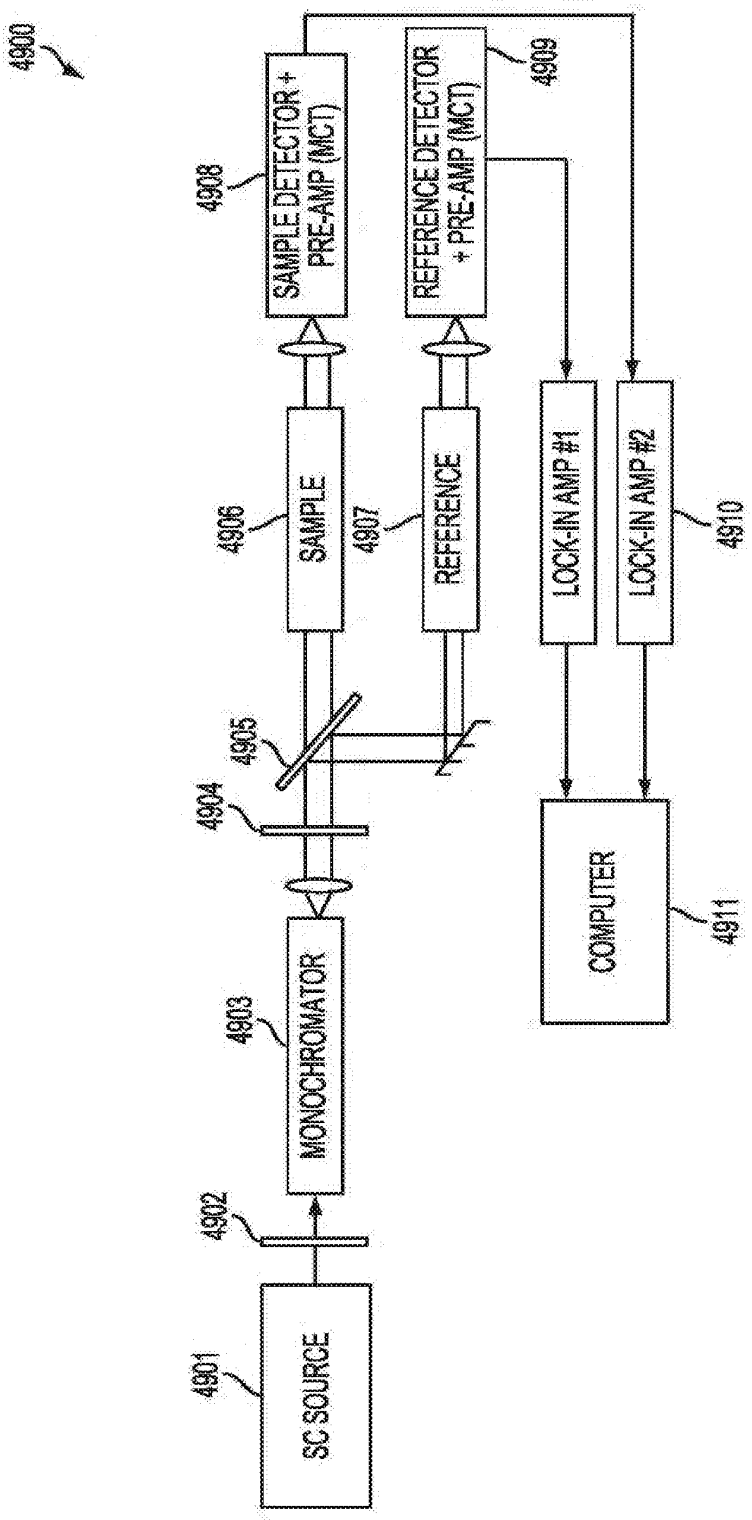

4900
4901
SC SOURCE
4902
4903
MONOCHROMATOR
4904
4905
4906
SAMPLE
4907
REFERENCE
4908
SAMPLE DETECTOR + PRE-AMP (MCT)
4909
REFERENCE DETECTOR + PRE-AMP (MCT)
LOCK-IN AMP #1
LOCK-IN AMP #2
4910
COMPUTER
4911

FIG. 49

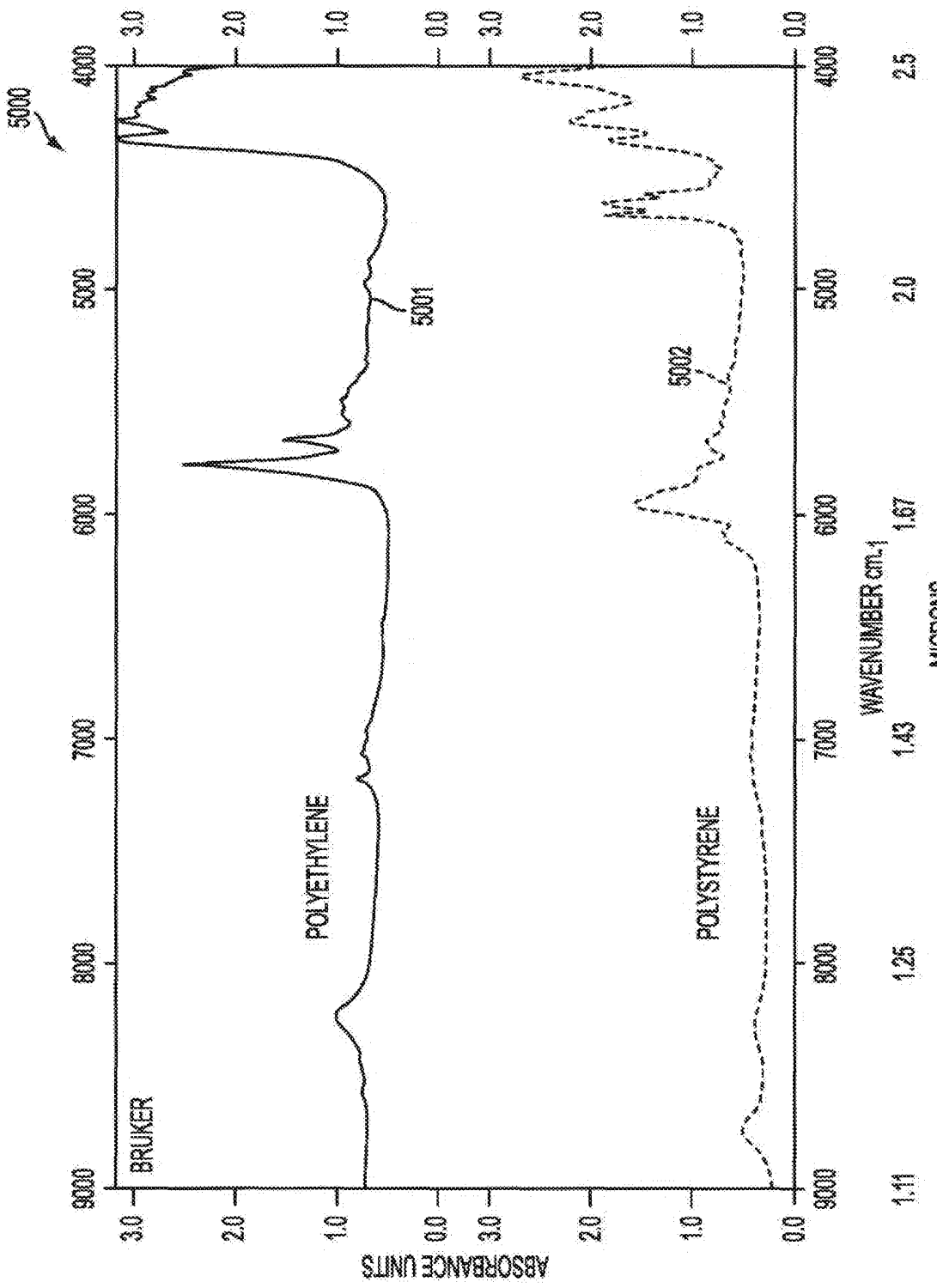

5000
BRUKER
POLYETHYLENE
5001
POLYSTYRENE
5002
ABSORBANCE UNITS
WAVENUMBER cm-1
MICRONS
9000
8000
7000
6000
5000
4000
3.0
2.0
1.0
0.0
1.11
1.25
1.43
1.67
2.0
2.5

FIG. 50

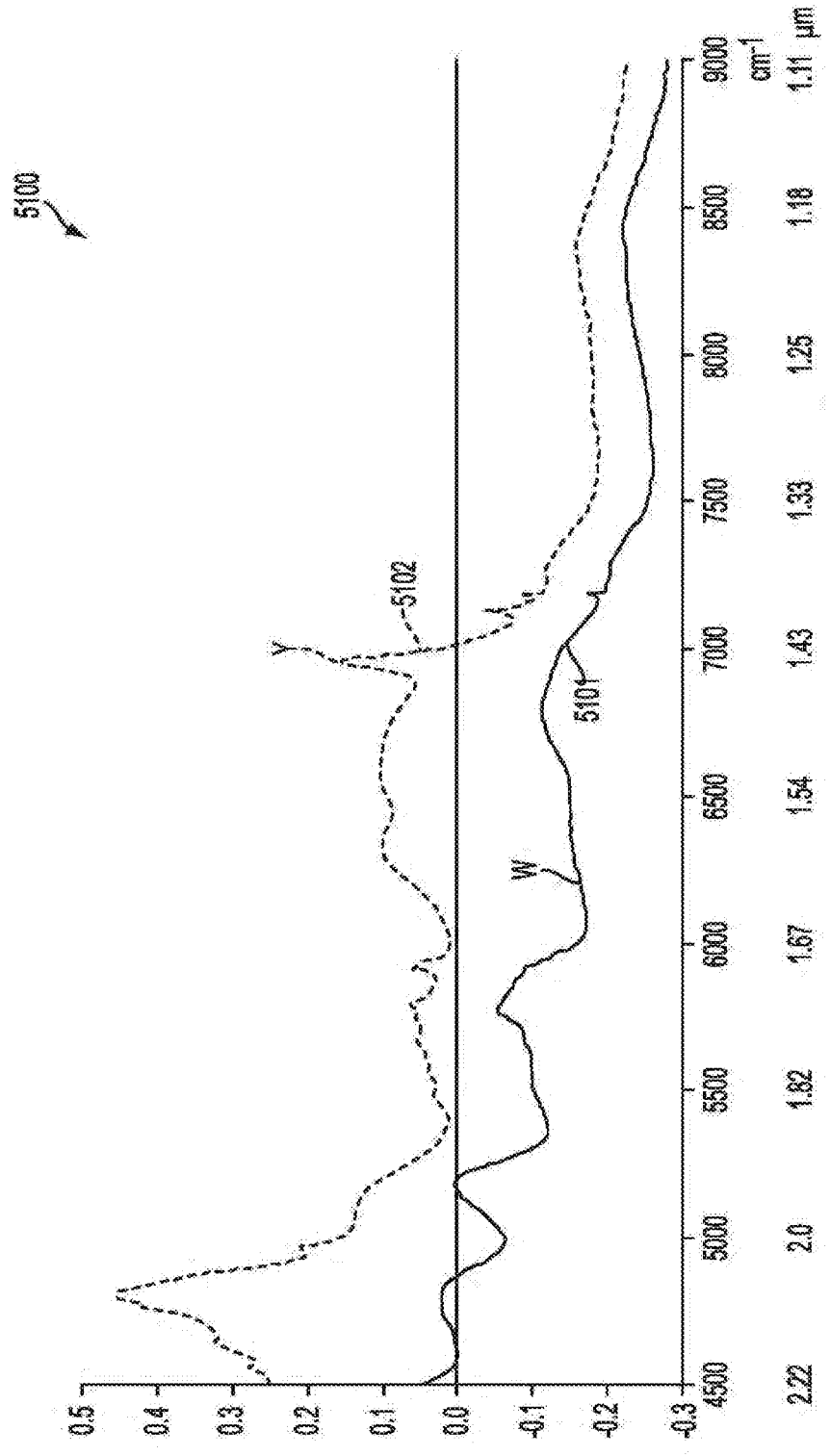

5100
5102
5101
Y
W
0.5
0.4
0.3
0.2
0.1
0.0
-0.1
-0.2
-0.3
4500
5000
5500
6000
6500
7000
7500
8000
8500
9000
cm-1
2.22
2.0
1.82
1.67
1.54
1.43
1.33
1.25
1.18
1.11
µm

FIG. 51

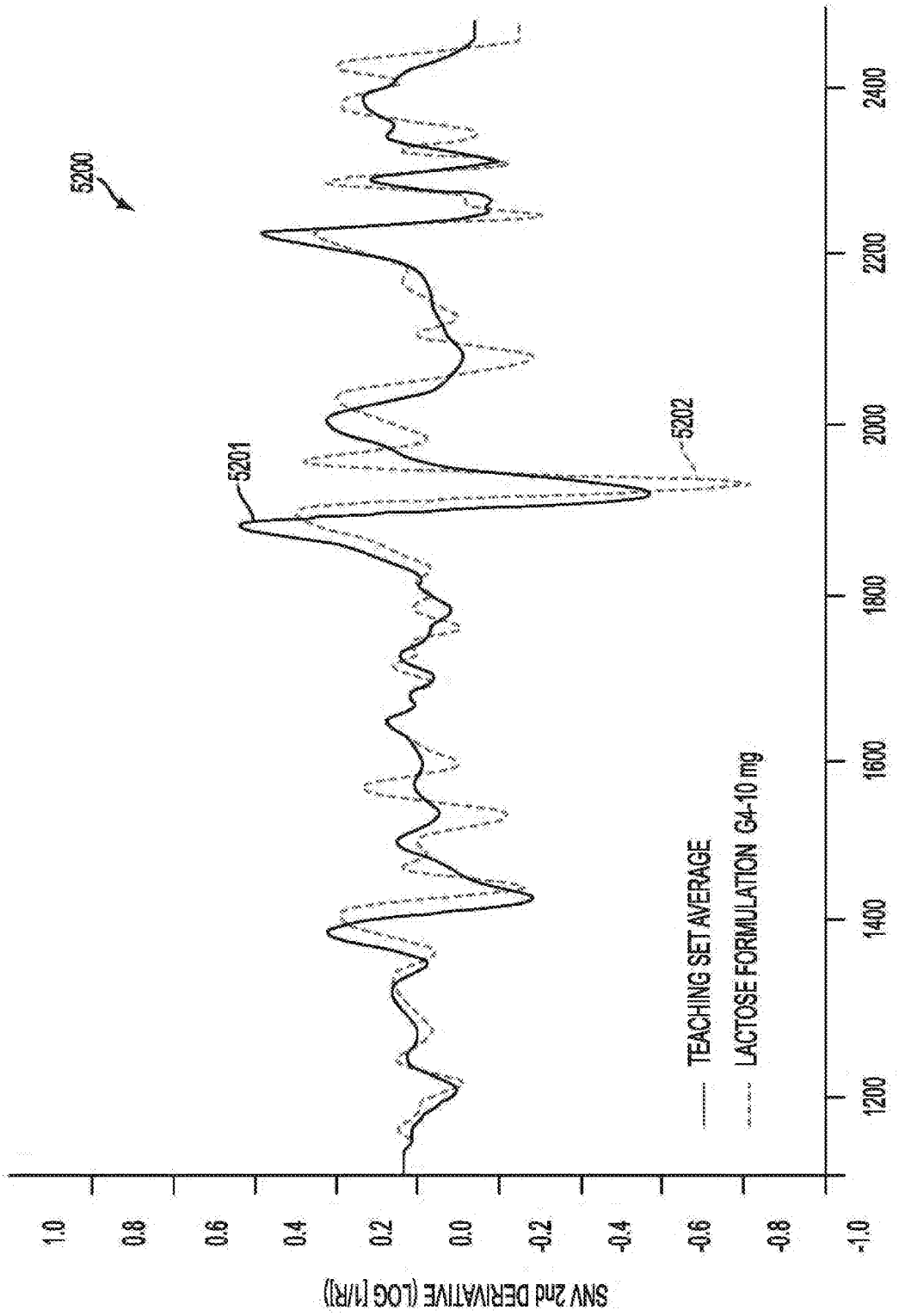

5200
5201
5202
SNV 2nd DERIVATIVE (LOG [1/R])
1.0
0.8
0.6
0.4
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
1200
1400
1600
1800
2000
2200
2400
WAVELENGTH
(nm)
TEACHING SET AVERAGE
LACTOSE FORMULATION G4-10 mg

FIG. 52

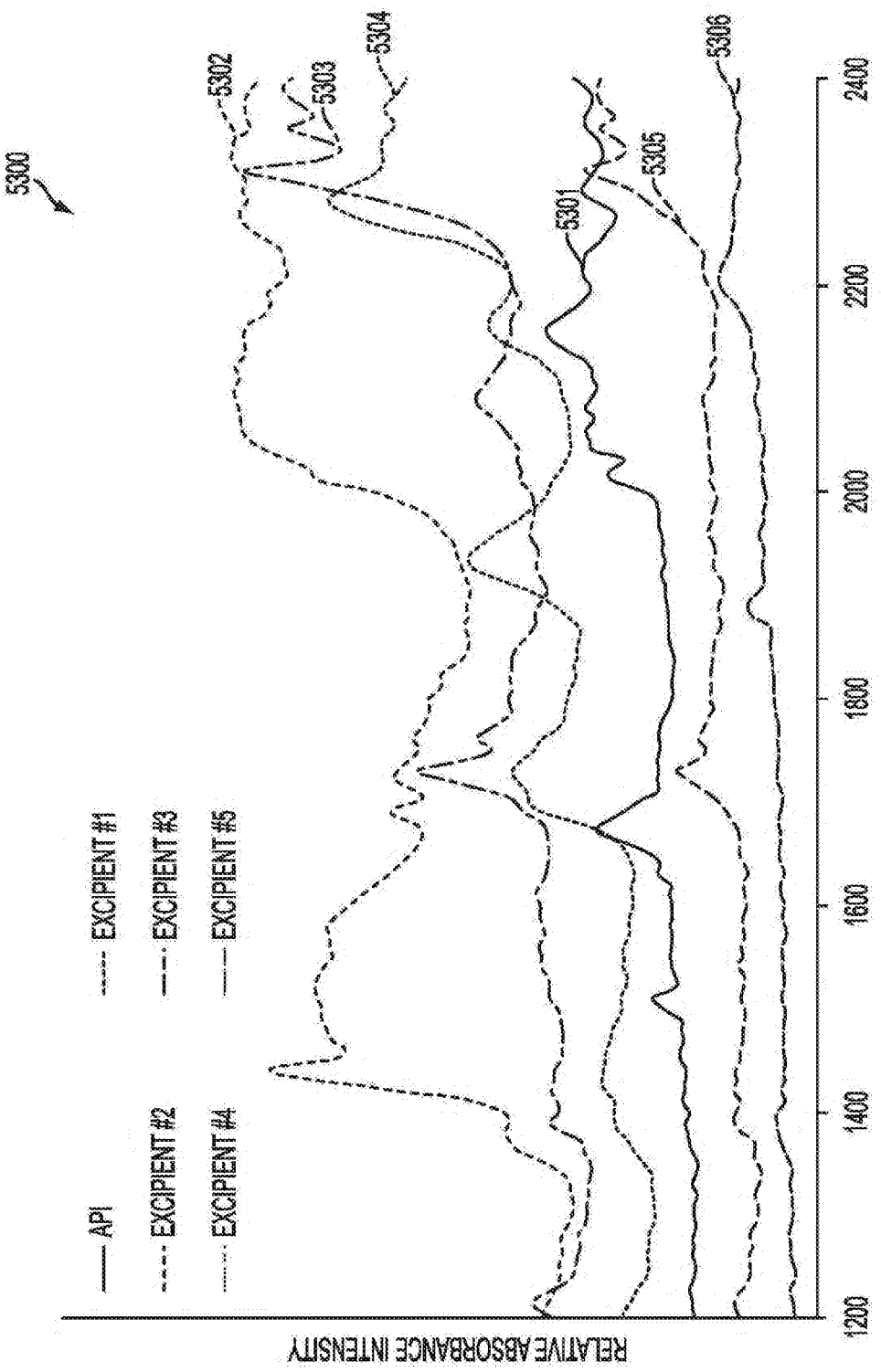

5300
API
EXCIPIENT #1
EXCIPIENT #2
EXCIPIENT #3
EXCIPIENT #4
EXCIPIENT #5
5301
5302
5303
5304
5305
5306
RELATIVE ABSORBANCE INTENSITY
1200
1400
1600
1800
2000
2200
2400
WAVELENGTH
(nm)

FIG. 53

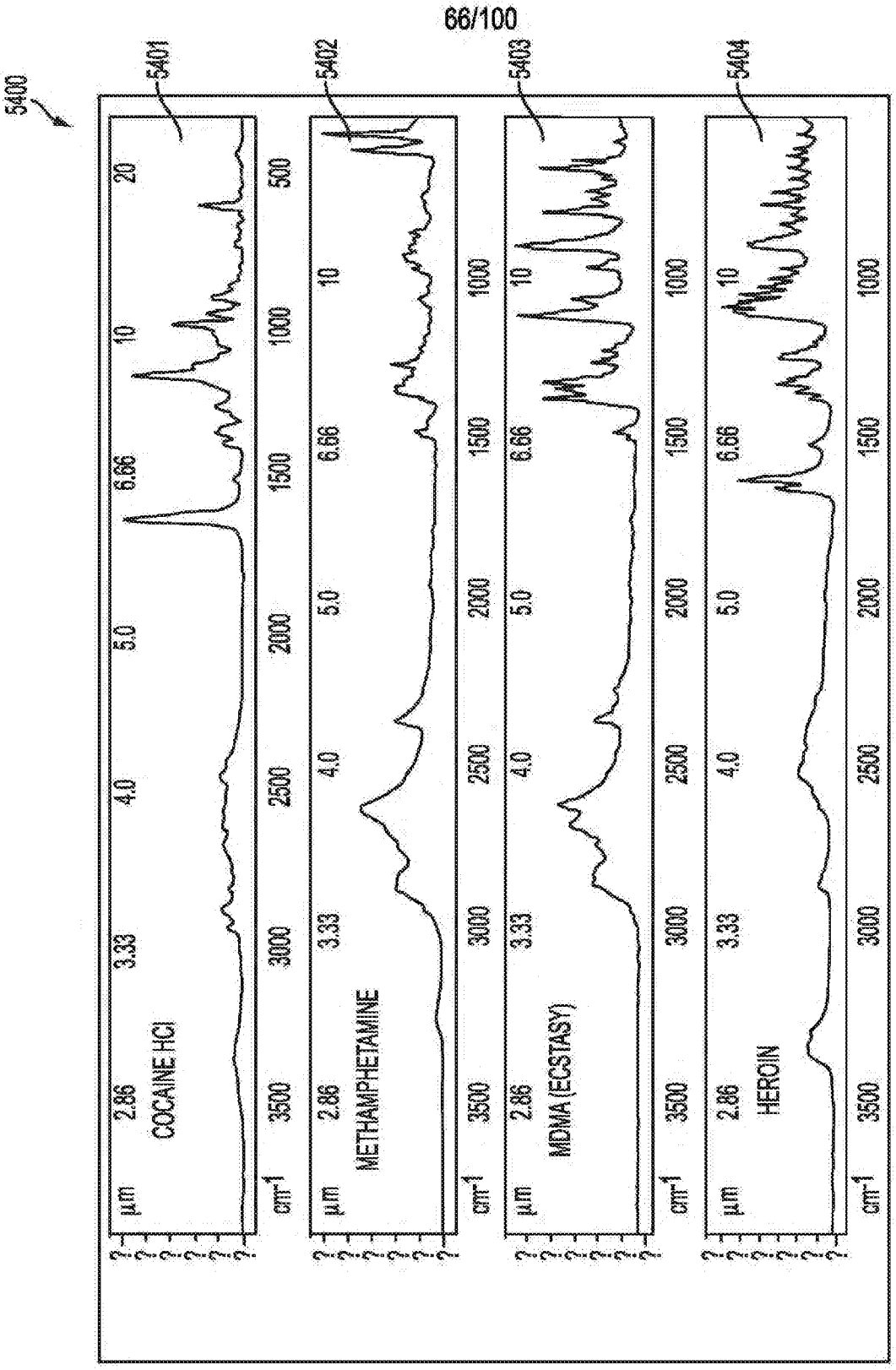

5400
5401
5402
5403
5404
COCAINE HCl
METHAMPHETAMINE
MDMA (ECSTASY)
HEROIN
µm
cm-1
2.86
3.33
4.0
5.0
6.66
10
20
3500
3000
2500
2000
1500
1000
500

FIG. 54

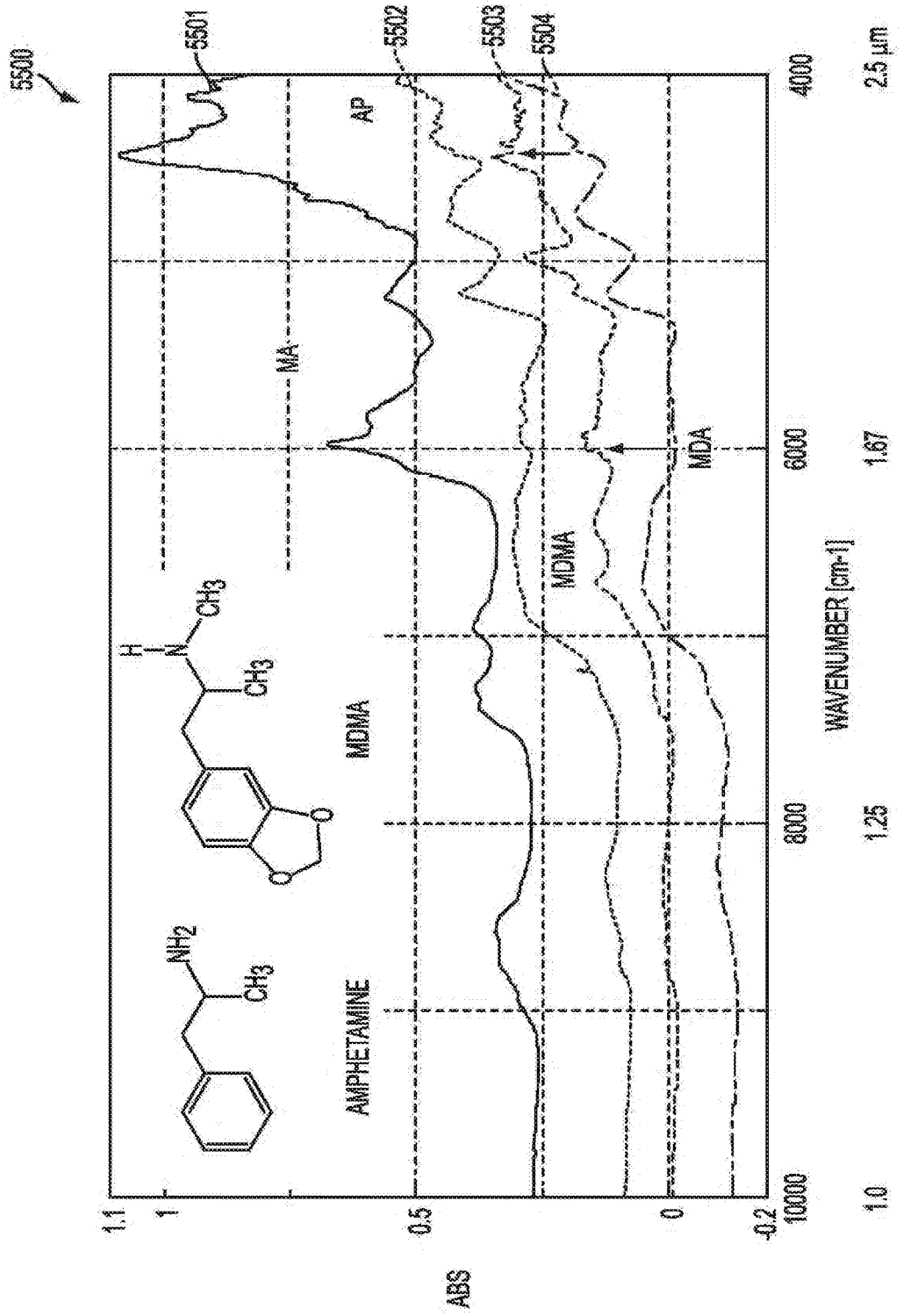

5500
5501
5502
5503
5504
AP
MA
MDMA
MDA
AMPHETAMINE
MDMA
ABS
1.1
1
0.5
0
-0.2
10000
8000
6000
4000
WAVENUMBER [cm-1]
1.0
1.25
1.67
2.5 µm

FIG. 55

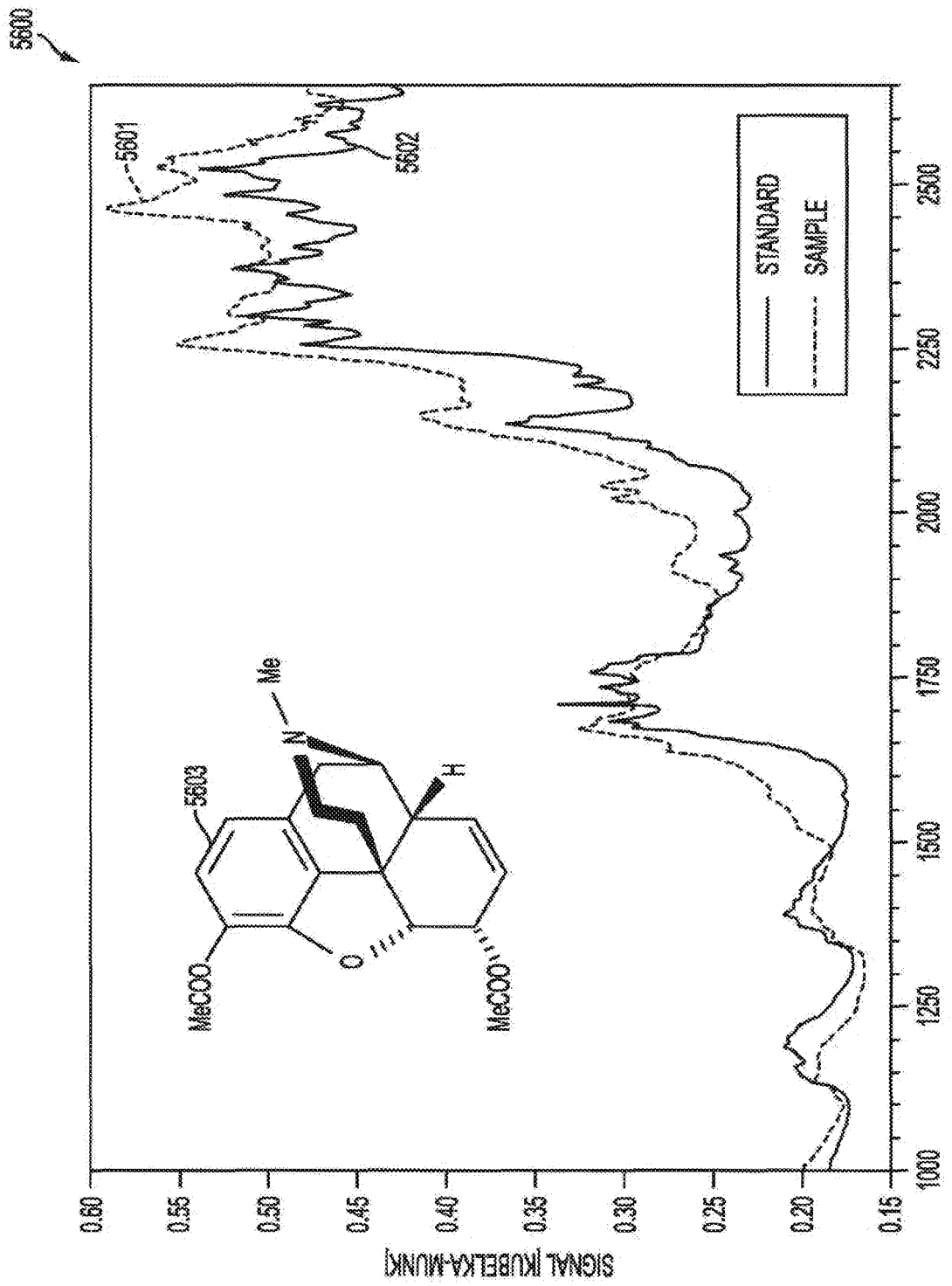

5600
5601
5602
5603
STANDARD
SAMPLE
SIGNAL [KUBELKA-MUNK]
FREQUENCY [nm]
0.60
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
1000
1250
1500
1750
2000
2250
2500
Me
N
H
O
MeCOO
MeCOO

FIG. 56

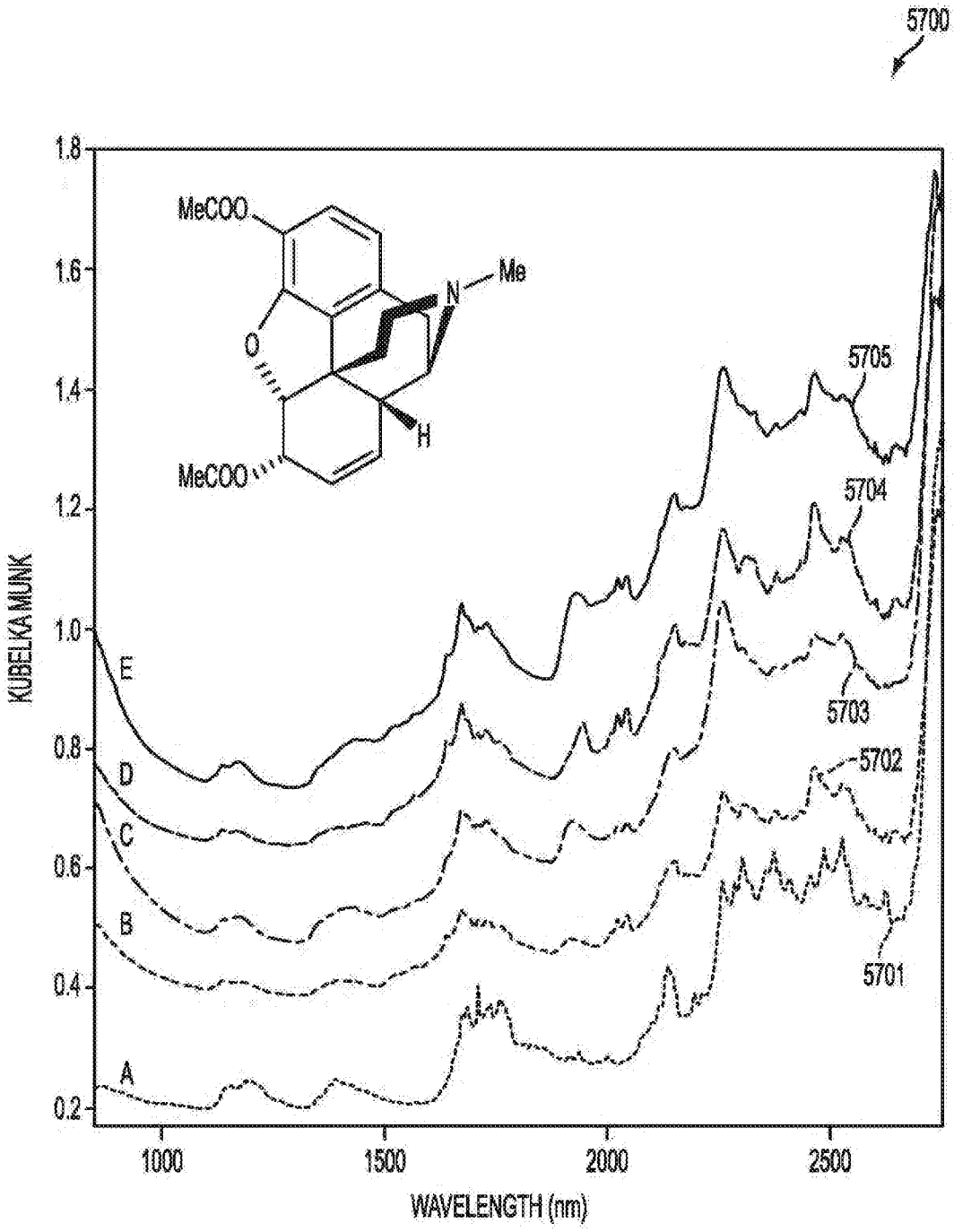

5700
1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
KUBELKA MUNK
MeCOO
N
Me
O
H
MeCOO
5705
5704
5703
5702
5701
E
D
C
B
A
1000
1500
2000
2500
WAVELENGTH (nm)

FIG. 57

5800

TENTATIVE FREQUENCIES OF HEROIN BANDS (nm)	ACTUALLY MEASURED PEAK FREQUENCIES (nm)	FORMS OF MODES OF VIBRATION ASSIGNMENT
1160	1157	C—O STRETCH FOURTH OVERTONE
1195	1190	C—H SECOND OVERTONE
	1200	C—H SECOND OVERTONE
1360	1357	C—H COMBINATION
1395	1391	C—H COMBINATION
1420	1425	O—H FIRST OVERTONE
1570	1570	N—H STRETCH FIRST OVERTONE
1685	1684	C—H STRETCH FIRST OVERTONE
1705	1709	C—H STRETCH FIRST OVERTONE
1725	1727	C—H STRETCH FIRST OVERTONE
1765	1767	C—H STRETCH FIRST OVERTONE
1780	1780	C—H STRETCH FIRST OVERTONE
1920	1914	C—O STRETCH SECOND OVERTONE
1950	1936	C—O STRETCH SECOND OVERTONE
1990	2000	N—H STRETCH/N—H BEND COMBINATION
2070	2074	N—H DEFORMATION OVERTONE
2090	2100	C—H COMBINATION
2140	2135	C—H STRETCH/C—O STRETCH COMBINATION OR SYM C—H DEFORMATION
	2144	C—H STRETCH/C—O STRETCH COMBINATION OR SYM C—H DEFORMATION

TO FIG. 58B

FIG. 58A

FROM FIG. 58A

2170	2172	ASYMMETRIC C—H STRETCH/C—H DEFORMATION COMBINATION
2180	2178	N—H BEND SECOND OVERTONE OR C—H STRETCH/C—O STRETCH COMBINATION, OR C—O STRETCH C—N STRETCH; N—H IN-PLANE BEND.
2200	2194	CH STRETCH/C—O STRETCH COMBINATION
2280	2284	C—H STRETCH/CH_2 DEFORMATION
2300	2300	C—H BEND SECOND OVERTONE
2325	2320	CH STRETCH/CH_2 DEFORMATION COMBINATION
2352	2352	CH_2 BEND SECOND OVERTONE
2380	2384	C—H STRETCH/C—C STRETCH COMBINATION
2470	2454	C—H COMBINATION OR SYM C—N—C STRETCH OVERTONE
2488	2485	C—H STRETCH/C—C STRETCH COMBINATION
2530	2524	ASYMMETRIC C—N—C STRETCH FIRST OVERTONE
2530	2537	ASYMMETRIC C—N—C STRETCH FIRST OVERTONE

FIG. 58B

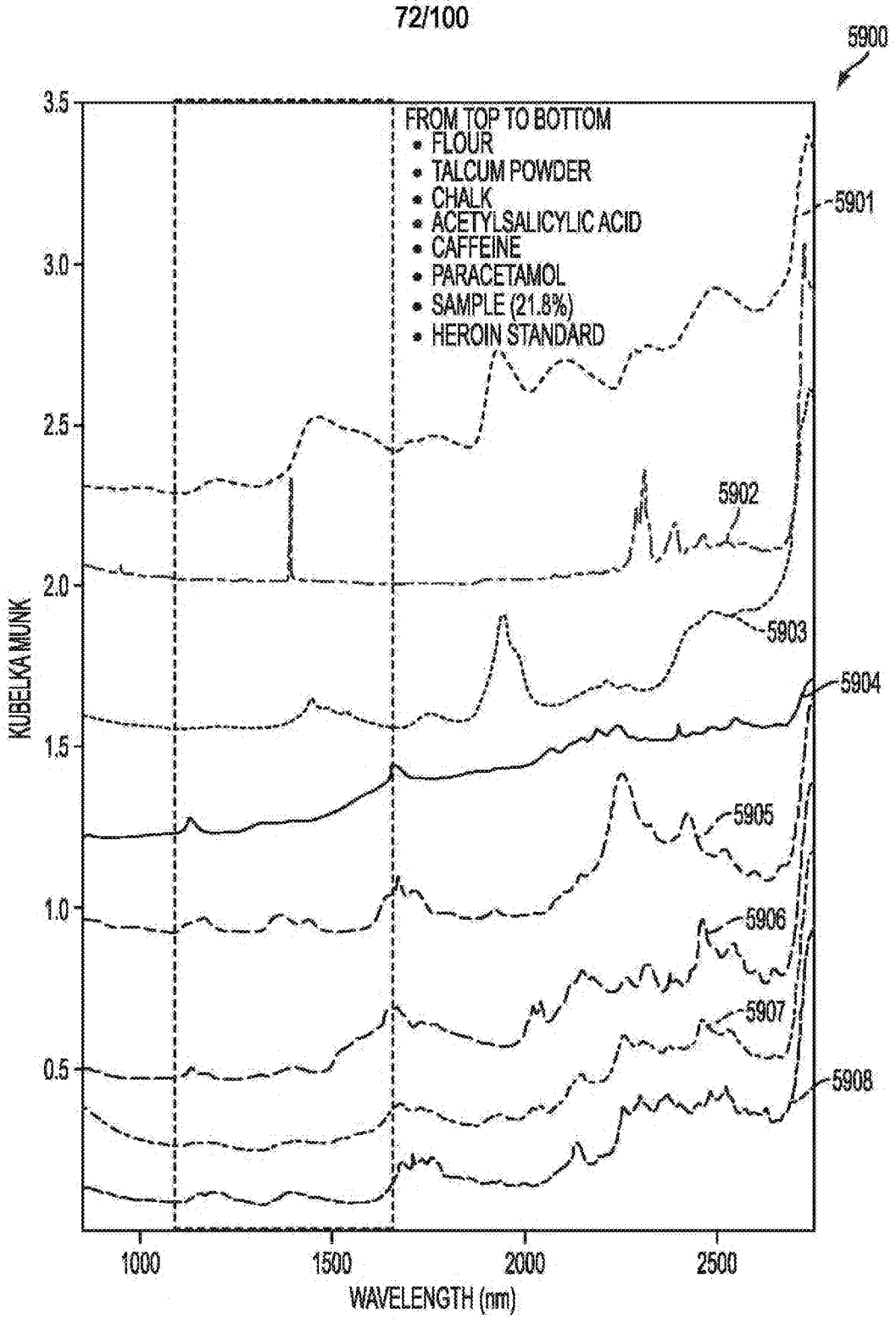

5900
FROM TOP TO BOTTOM
• FLOUR
• TALCUM POWDER
• CHALK
• ACETYLSALICYLIC ACID
• CAFFEINE
• PARACETAMOL
• SAMPLE (21.8%)
• HEROIN STANDARD
5901
5902
5903
5904
5905
5906
5907
5908
KUBELKA MUNK
3.5
3.0
2.5
2.0
1.5
1.0
0.5
1000
1500
2000
2500
WAVELENGTH (nm)

FIG. 59

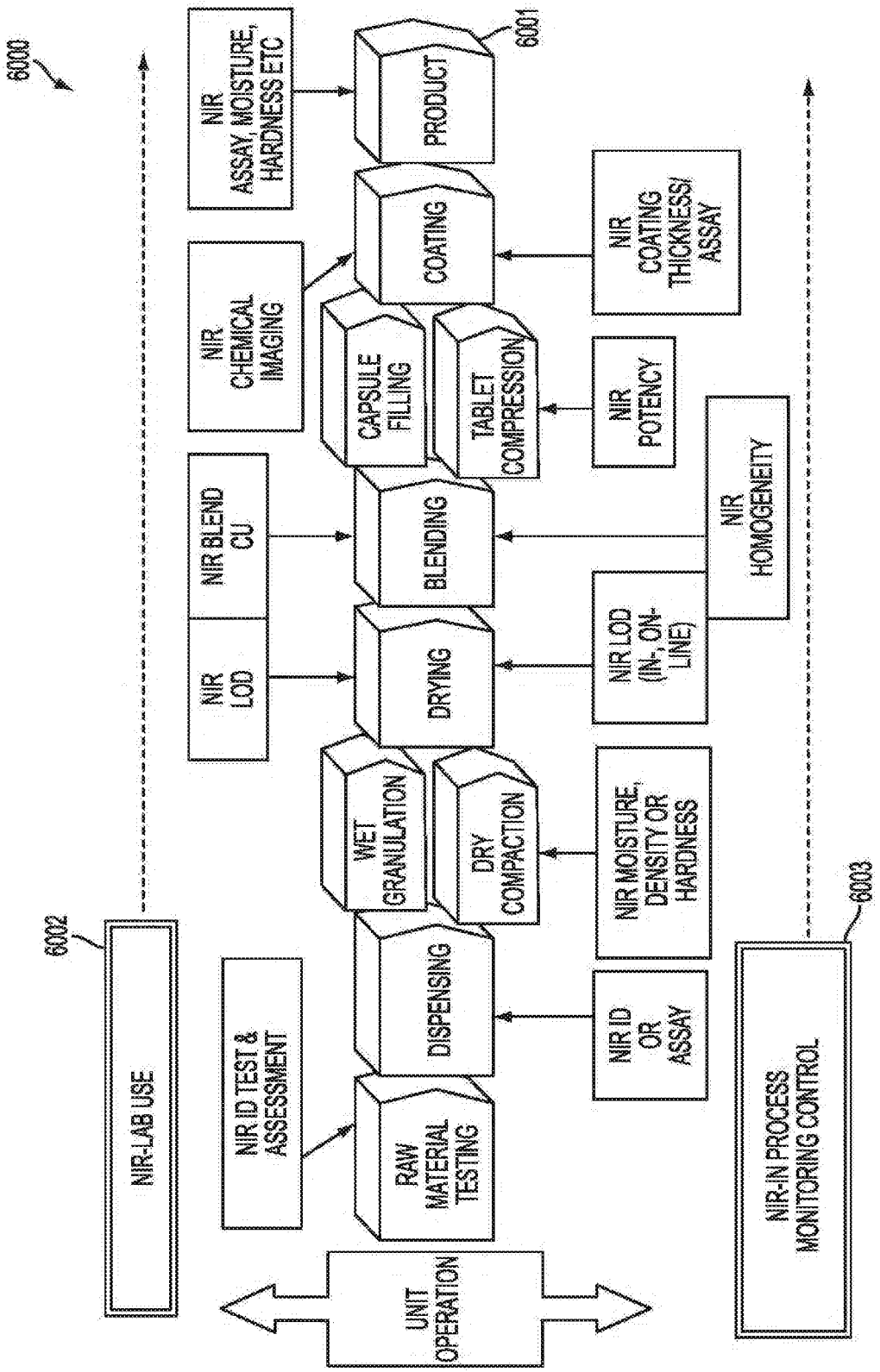

6000
6001
6002
6003
NIR-LAB USE
NIR-IN PROCESS MONITORING CONTROL
UNIT OPERATION
RAW MATERIAL TESTING
NIR ID TEST & ASSESSMENT
DISPENSING
NIR ID OR ASSAY
WET GRANULATION
DRY COMPACTION
NIR MOISTURE, DENSITY OR HARDNESS
DRYING
NIR LOD
NIR BLEND CU
NIR LOD (IN-, ON-LINE)
BLENDING
NIR HOMOGENEITY
CAPSULE FILLING
TABLET COMPRESSION
NIR CHEMICAL IMAGING
NIR POTENCY
COATING
NIR COATING THICKNESS/ ASSAY
PRODUCT
NIR ASSAY, MOISTURE, HARDNESS ETC

FIG. 60

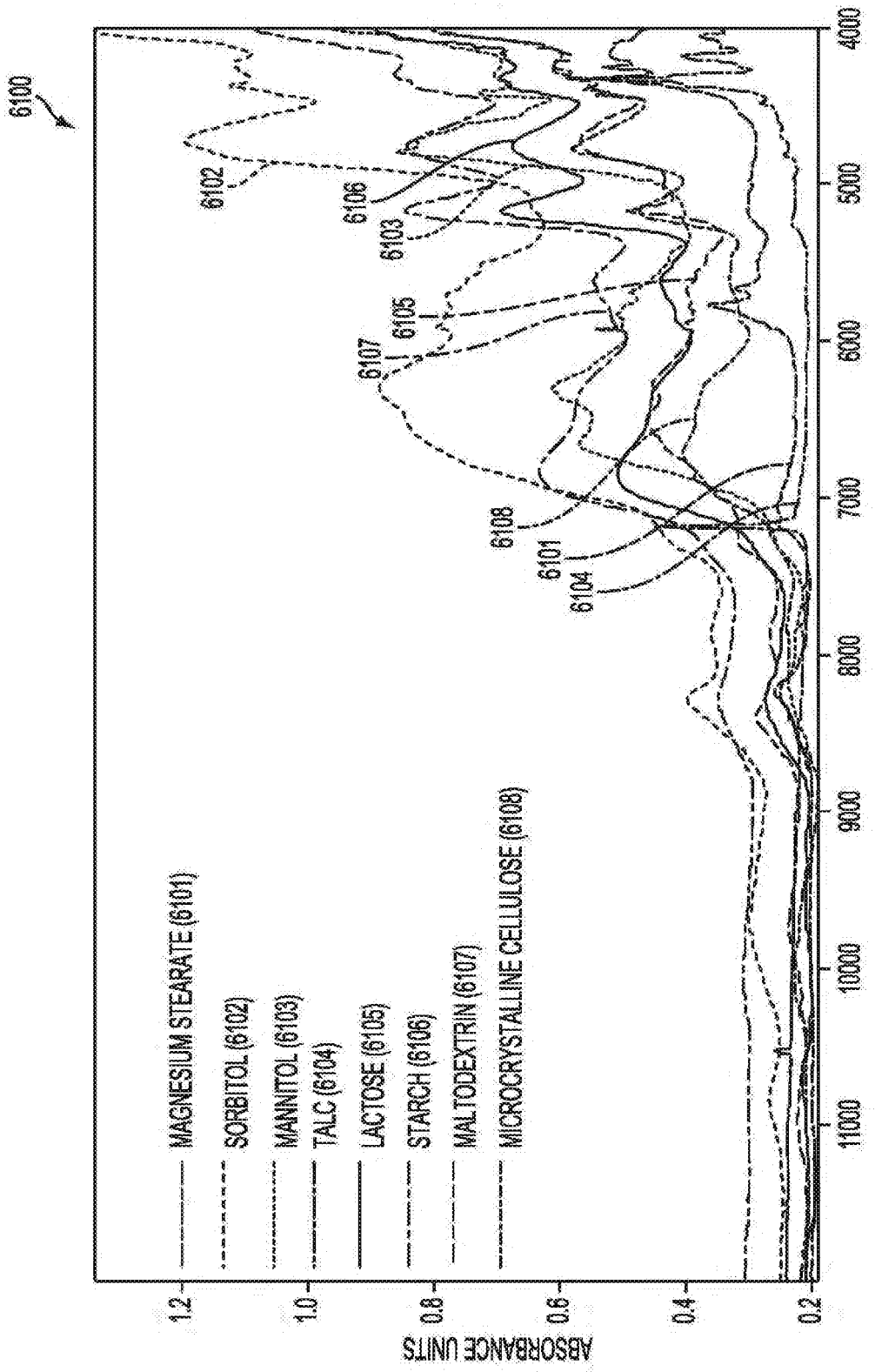

6100
MAGNESIUM STEARATE (6101)
SORBITOL (6102)
MANNITOL (6103)
TALC (6104)
LACTOSE (6105)
STARCH (6106)
MALTODEXTRIN (6107)
MICROCRYSTALLINE CELLULOSE (6108)
6102
6106
6103
6105
6107
6108
6101
6104
ABSORBANCE UNITS
1.2
1.0
0.8
0.6
0.4
0.2
11000
10000
9000
8000
7000
6000
5000
4000
WAVENUMBER
cm-1

FIG. 61

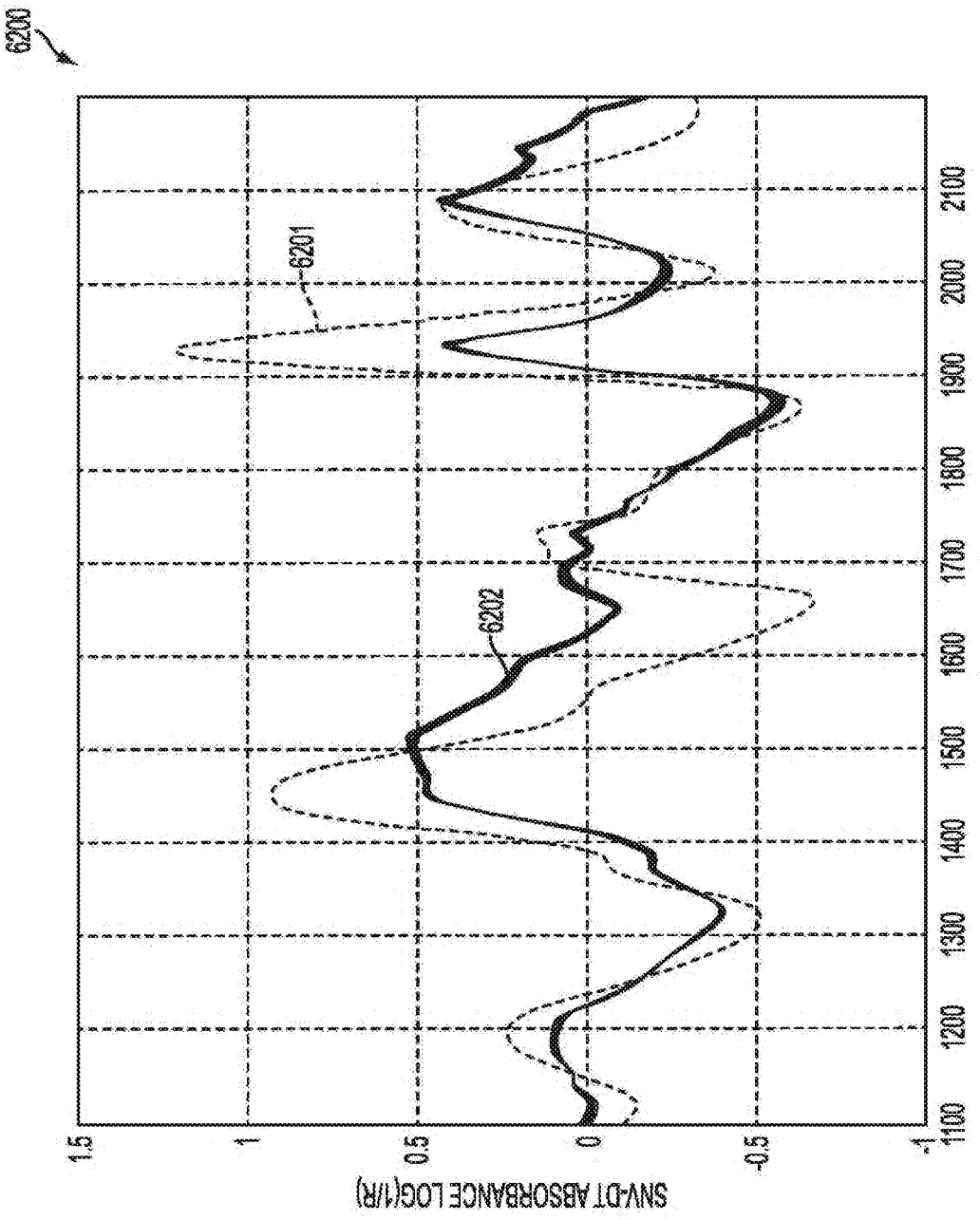

6200
6201
6202
SNV-DT ABSORBANCE LOG(1/R)
1.5
1
0.5
0
-0.5
-1
1100
1200
1300
1400
1500
1600
1700
1800
1900
2000
2100
WAVELENGTH
(nm)

FIG. 62

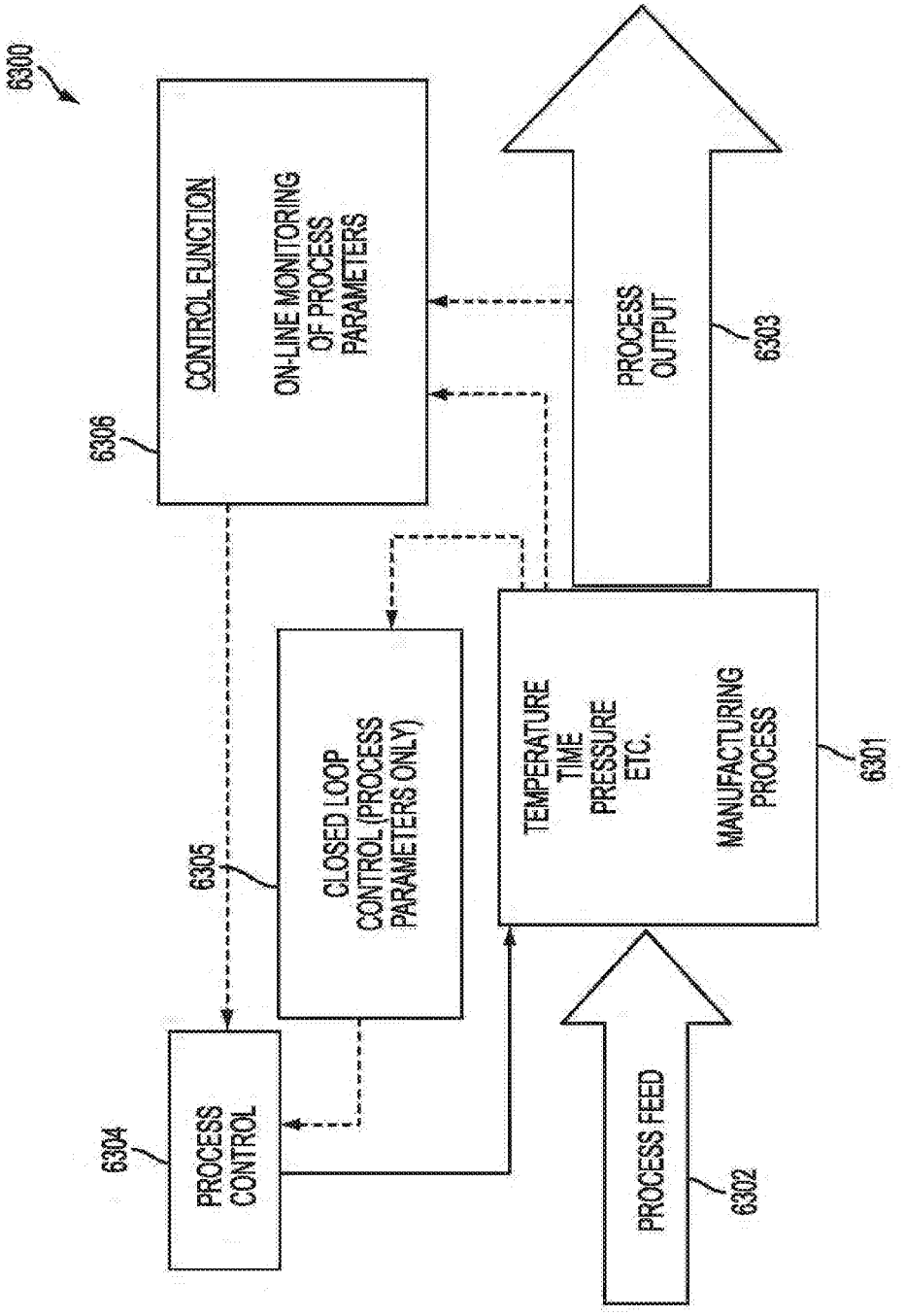

6300
CONTROL FUNCTION
ON-LINE MONITORING OF PROCESS PARAMETERS
6306
PROCESS OUTPUT
6303
6305
CLOSED LOOP CONTROL (PROCESS PARAMETERS ONLY)
TEMPERATURE
TIME
PRESSURE
ETC.
MANUFACTURING PROCESS
6301
6304
PROCESS CONTROL
PROCESS FEED
6302

FIG. 63

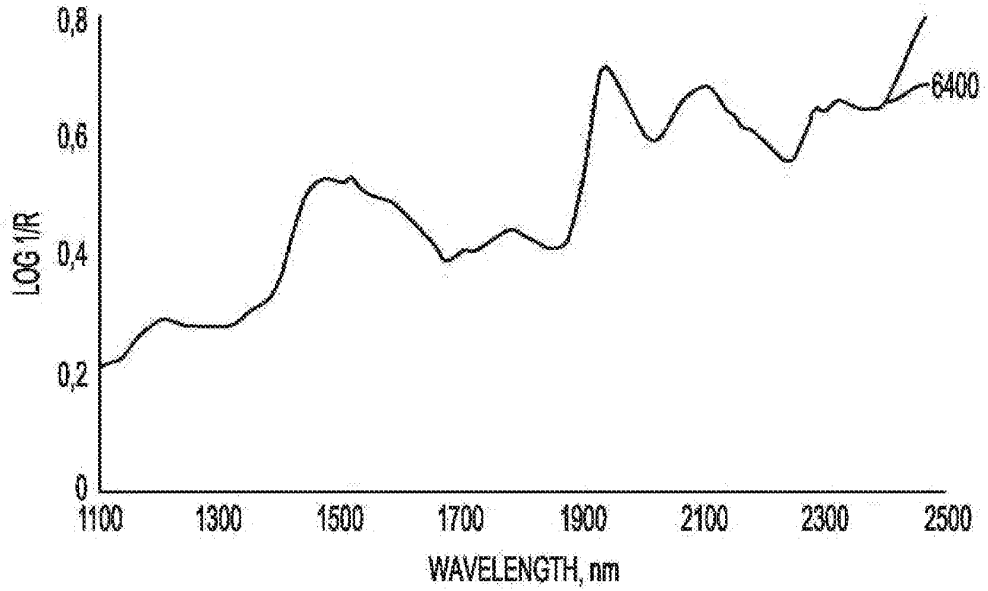


FIG. 64A

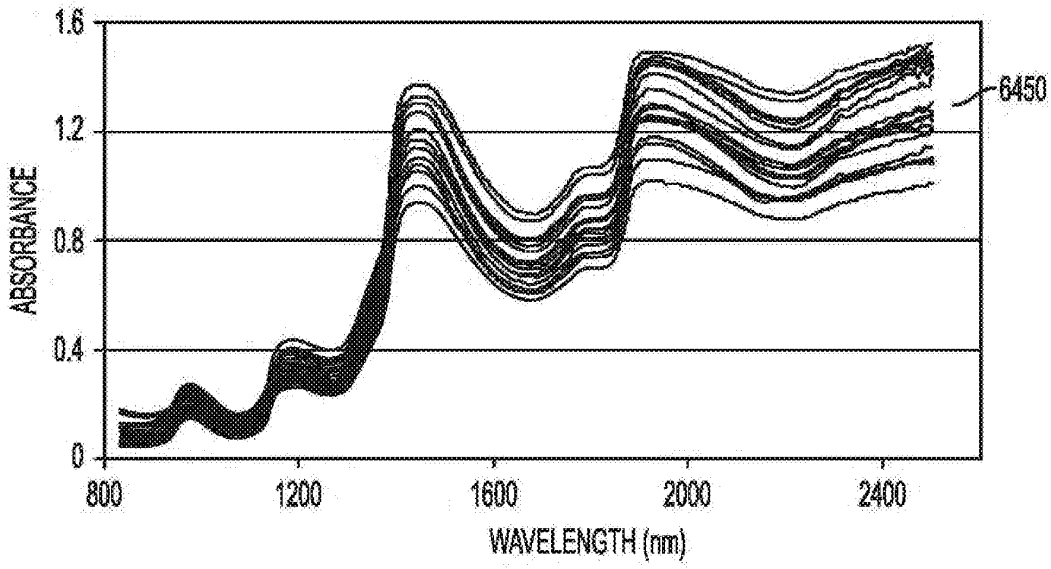


FIG. 64B

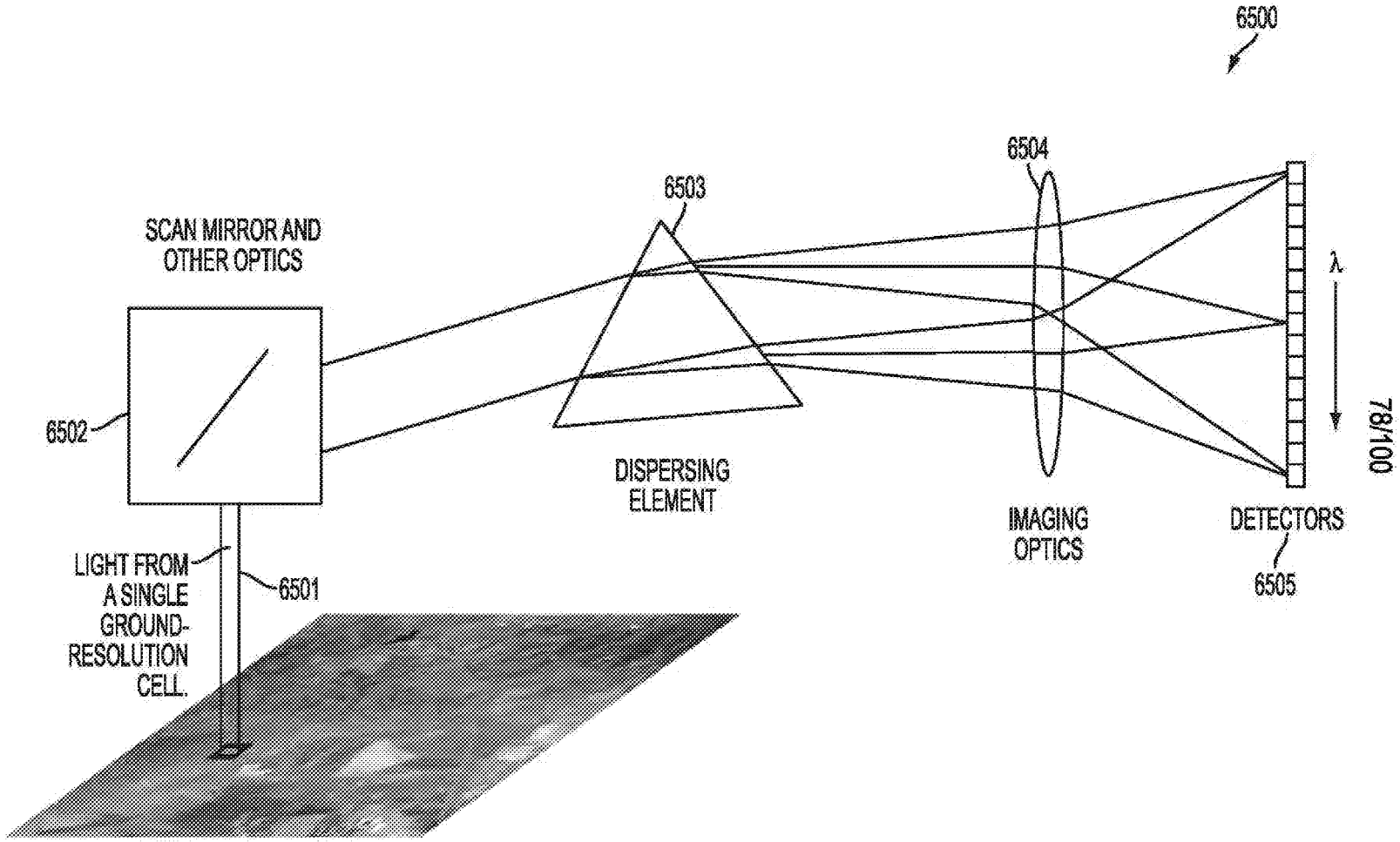


FIG. 65A

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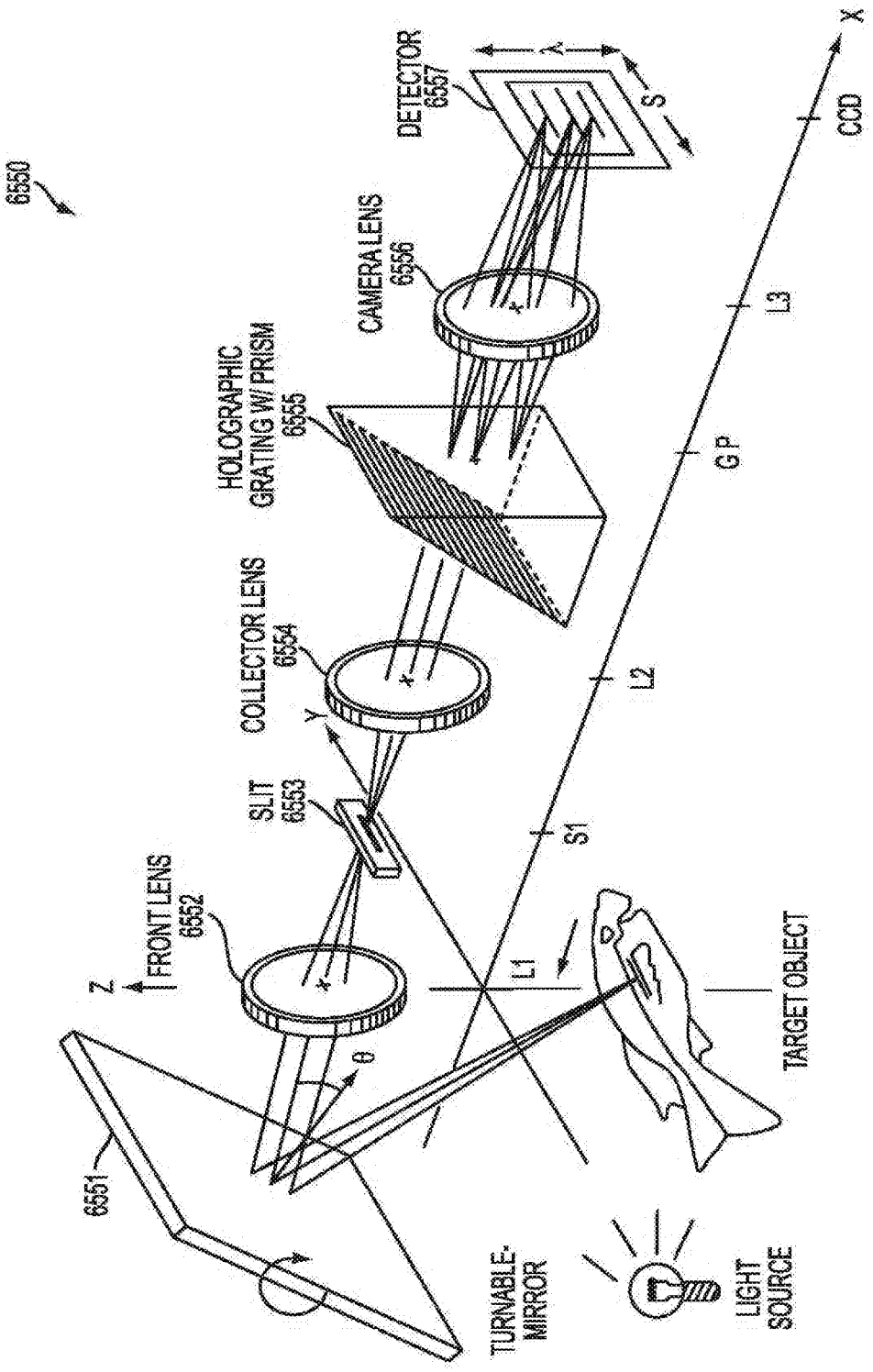

6550
DETECTOR
6557
CAMERA LENS
6556
HOLOGRAPHIC
GRATING W/ PRISM
6555
COLLECTOR LENS
6554
SLIT
6553
FRONT LENS
6552
6551
TURNABLE-
MIRROR
LIGHT
SOURCE
TARGET OBJECT
Z
Y
X
θ
L1
S1
L2
G P
L3
CCD
S

FIG. 65B

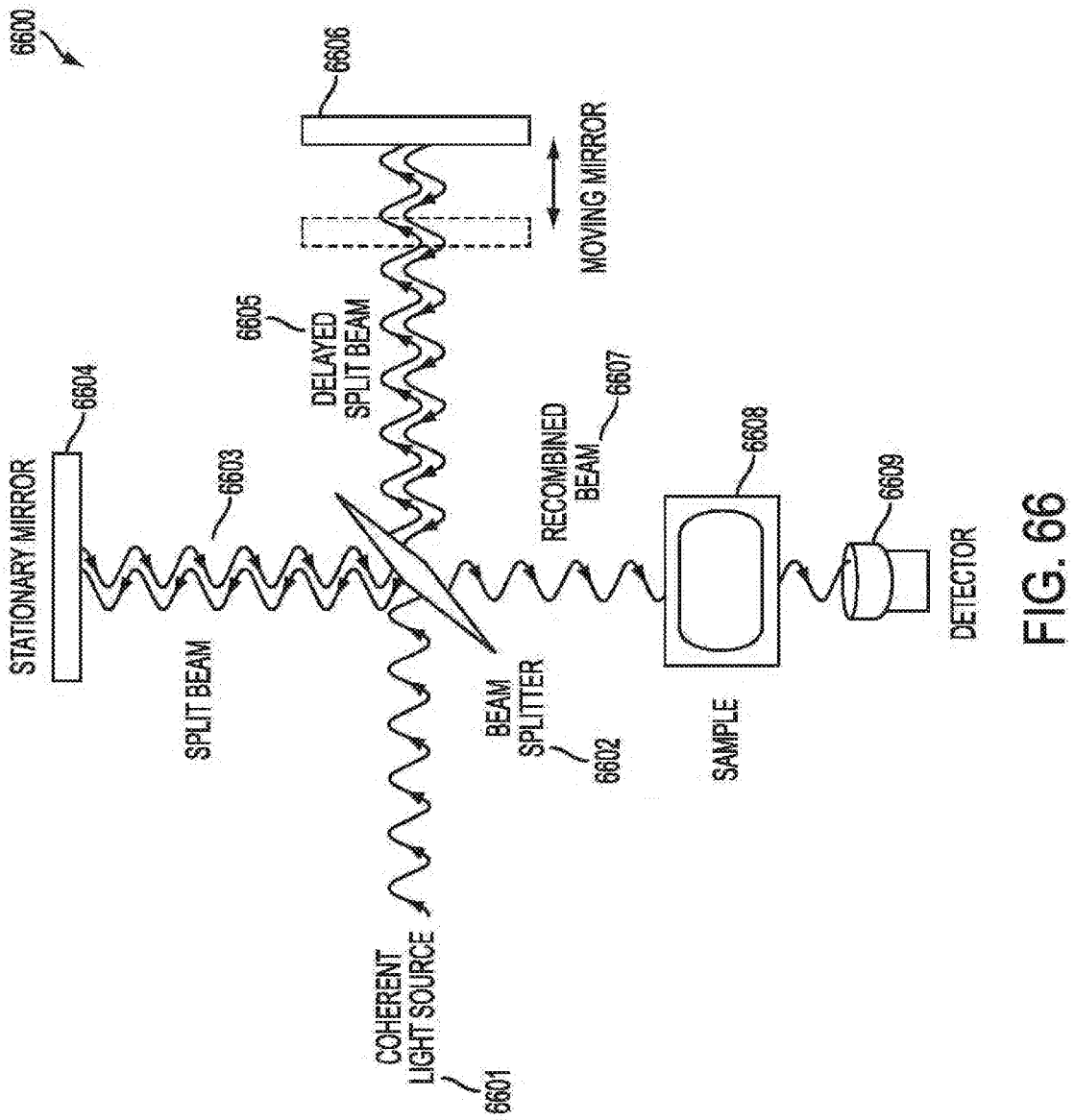

6600
6606
MOVING MIRROR
6605
DELAYED SPLIT BEAM
6604
STATIONARY MIRROR
6603
RECOMBINED BEAM
6607
6608
6609
DETECTOR
SPLIT BEAM
BEAM SPLITTER
6602
SAMPLE
COHERENT LIGHT SOURCE
6601

FIG. 66

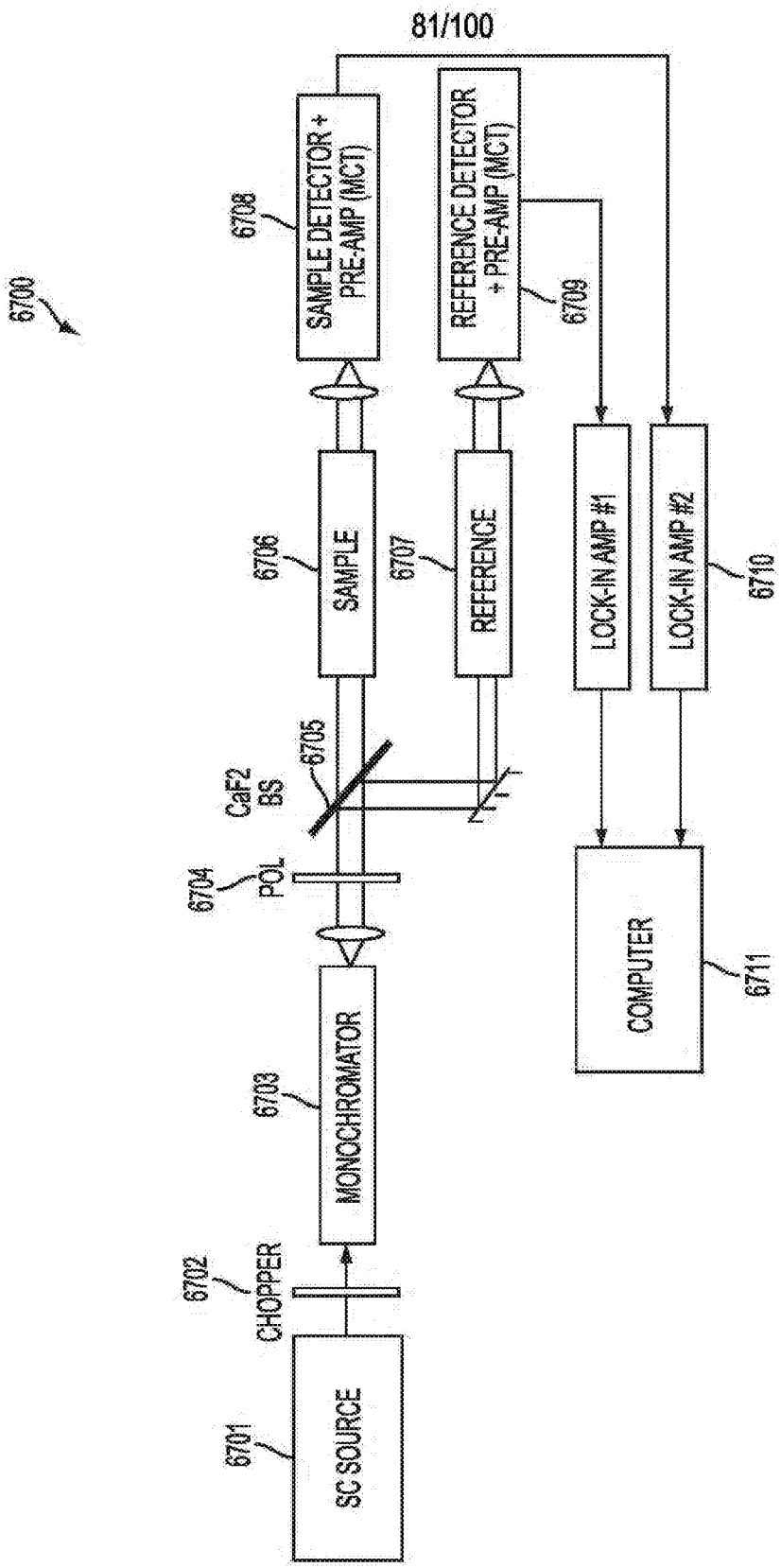

6700
6701
SC SOURCE
6702
CHOPPER
6703
MONOCHROMATOR
6704
POL
CaF2
BS
6705
6706
SAMPLE
6707
REFERENCE
6708
SAMPLE DETECTOR + PRE-AMP (MCT)
6709
REFERENCE DETECTOR + PRE-AMP (MCT)
6710
LOCK-IN AMP #1
LOCK-IN AMP #2
6711
COMPUTER

FIG. 67

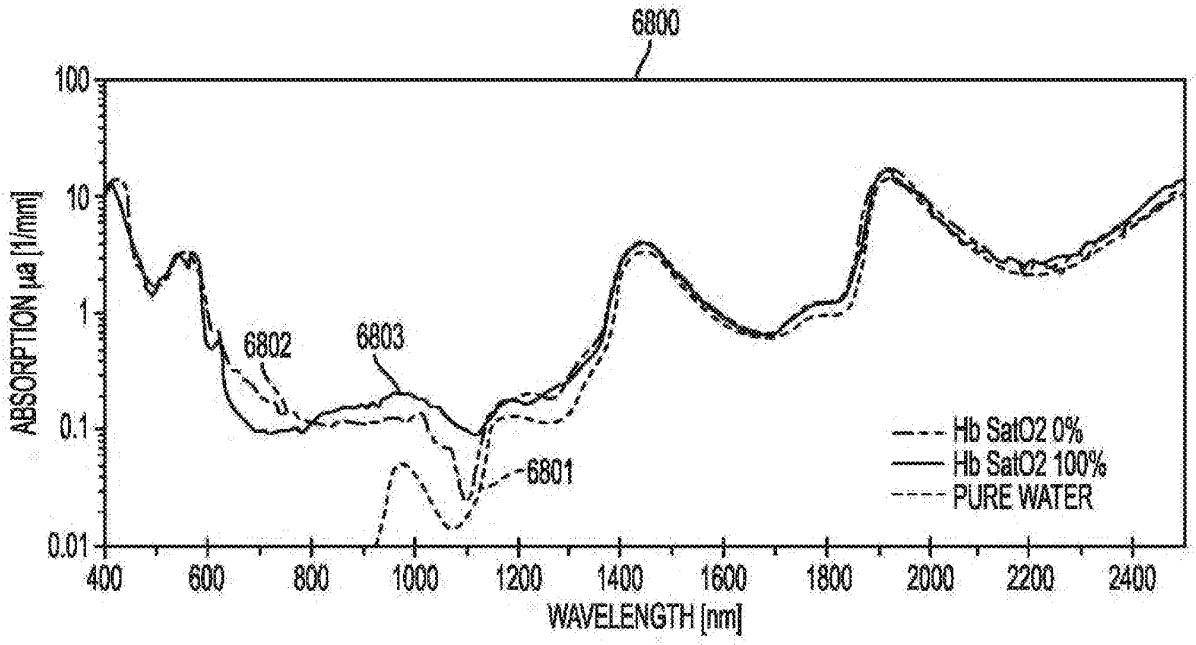

6800
100
10
1
0.1
0.01
ABSORPTION μa [1/mm]
6802
6803
6801
Hb SatO2 0%
Hb SatO2 100%
PURE WATER
400
600
800
1000
1200
1400
1600
1800
2000
2200
2400
WAVELENGTH [nm]

FIG. 68

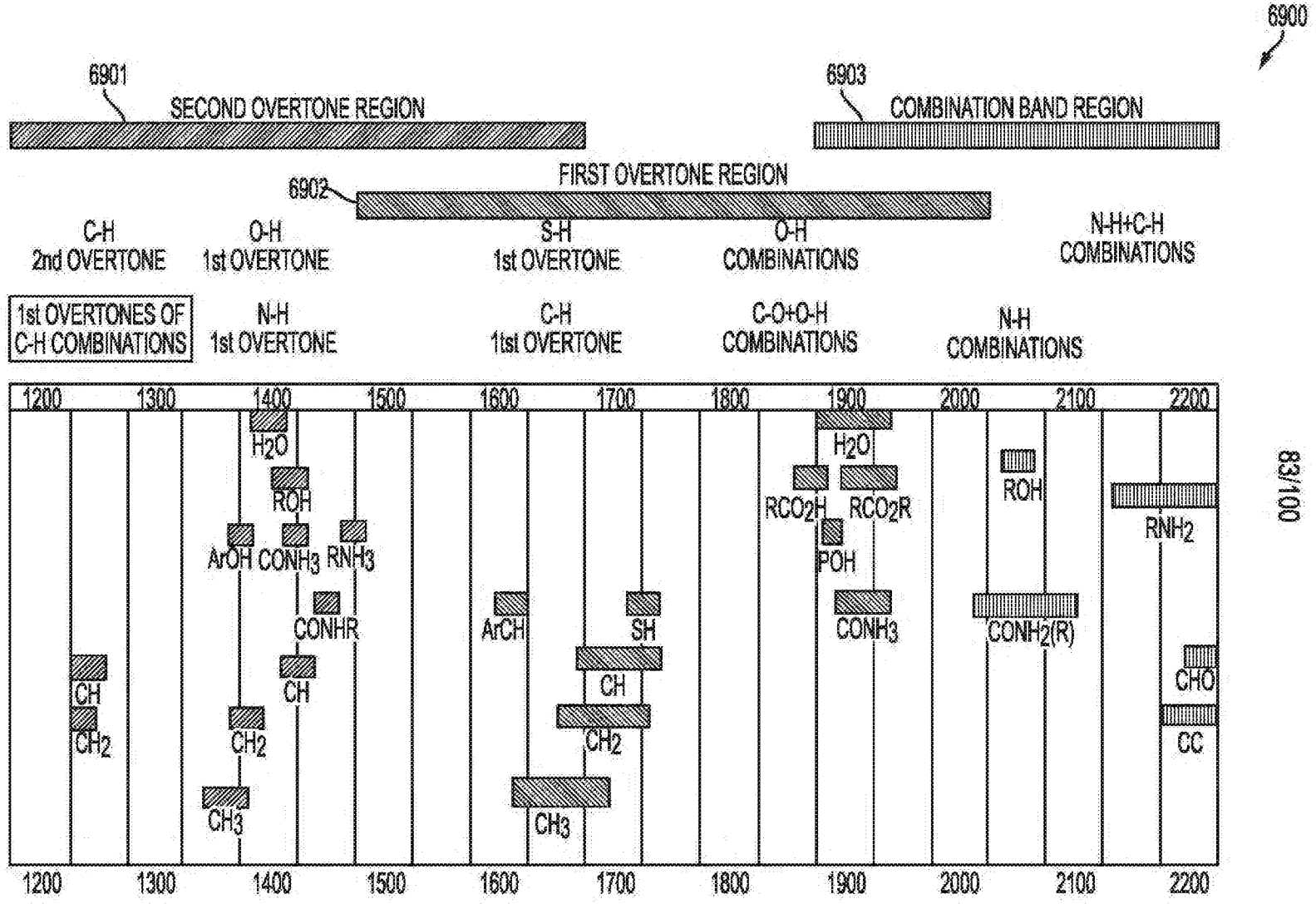


FIG. 69

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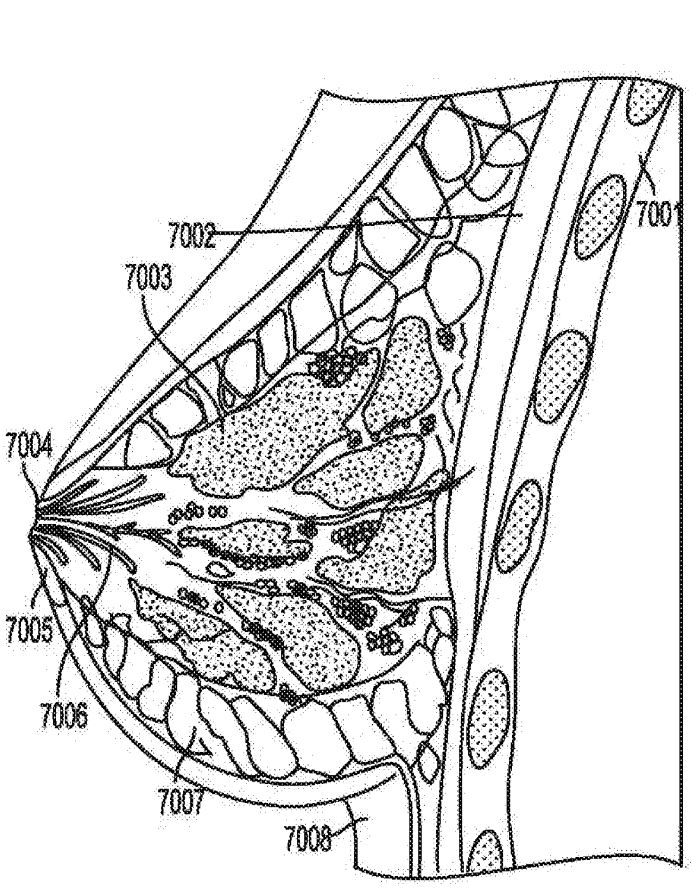

7000
7001
7002
7003
7004
7005
7006
7007
7008
THE BREAST: CROSS-SECTION
SCHEME OF THE MAMMARY GLAND.
1. CHEST WALL
2. PECTORALIS MUSCLES
3. LOBULES
4. NIPPLE
5. AREOLA
6. MILK DUCT
7. FATTY TISSUE
8. SKIN

FIG. 70

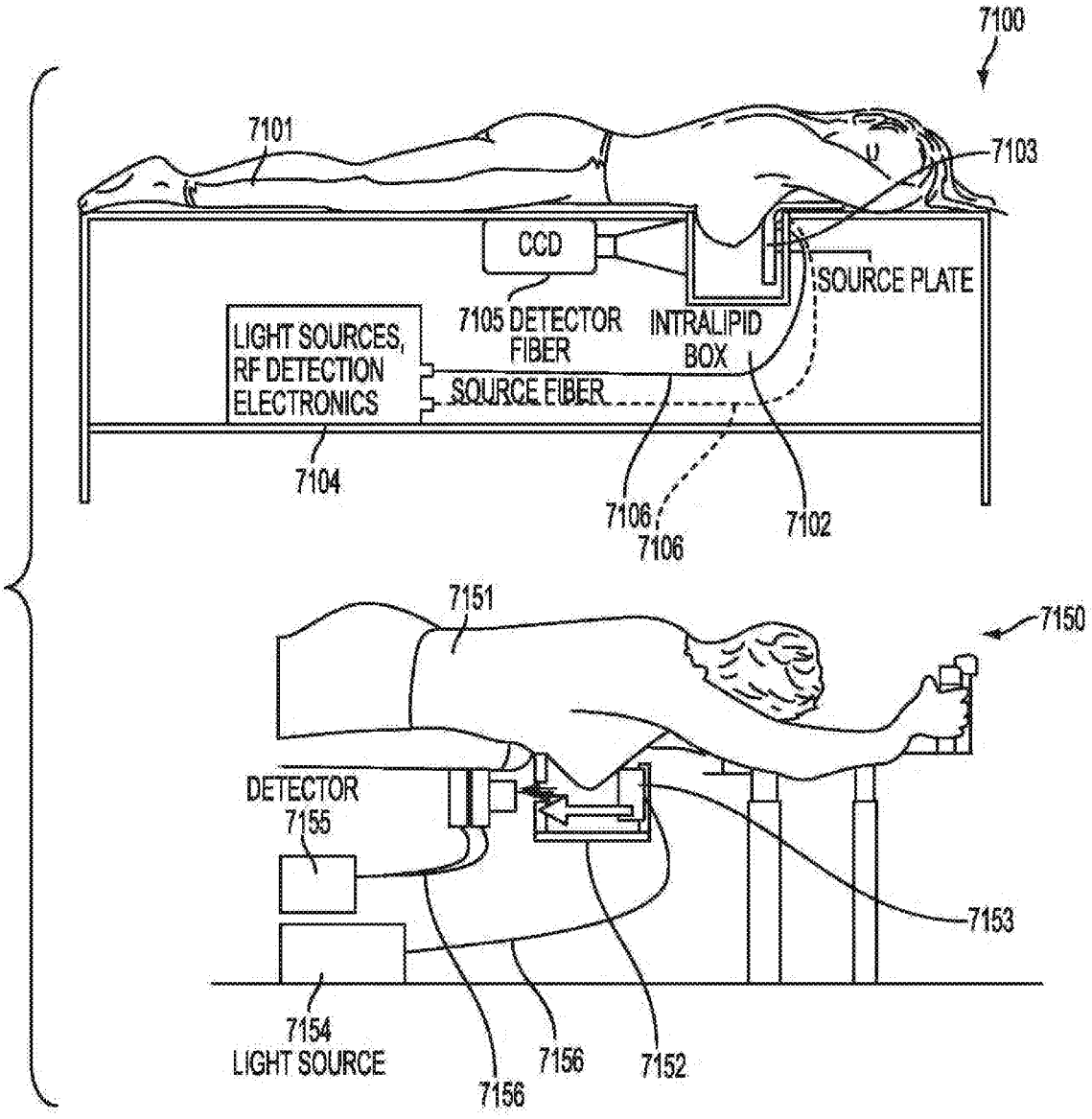

7100
7101
7103
CCD
SOURCE PLATE
7105 DETECTOR FIBER
INTRALIPID BOX
LIGHT SOURCES, RF DETECTION ELECTRONICS
SOURCE FIBER
7104
7106
7106
7102
7151
7150
DETECTOR 7155
7153
7154 LIGHT SOURCE
7156
7156
7152

FIG. 71

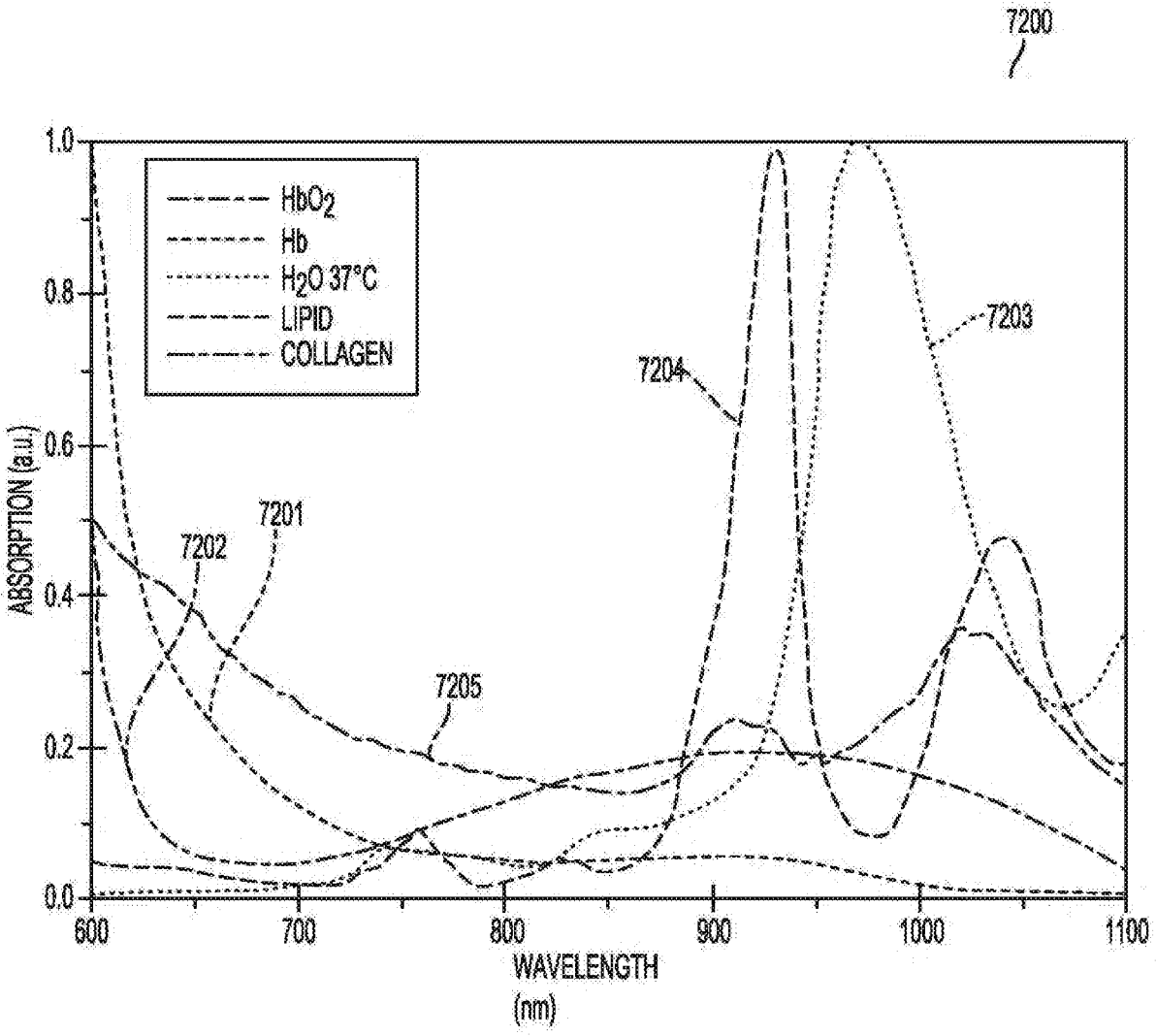

7200
1.0
0.8
0.6
0.4
0.2
0.0
ABSORPTION (a.u.)
HbO2
Hb
H2O 37°C
LIPID
COLLAGEN
7201
7202
7203
7204
7205
600
700
800
900
1000
1100
WAVELENGTH
(nm)

FIG. 72

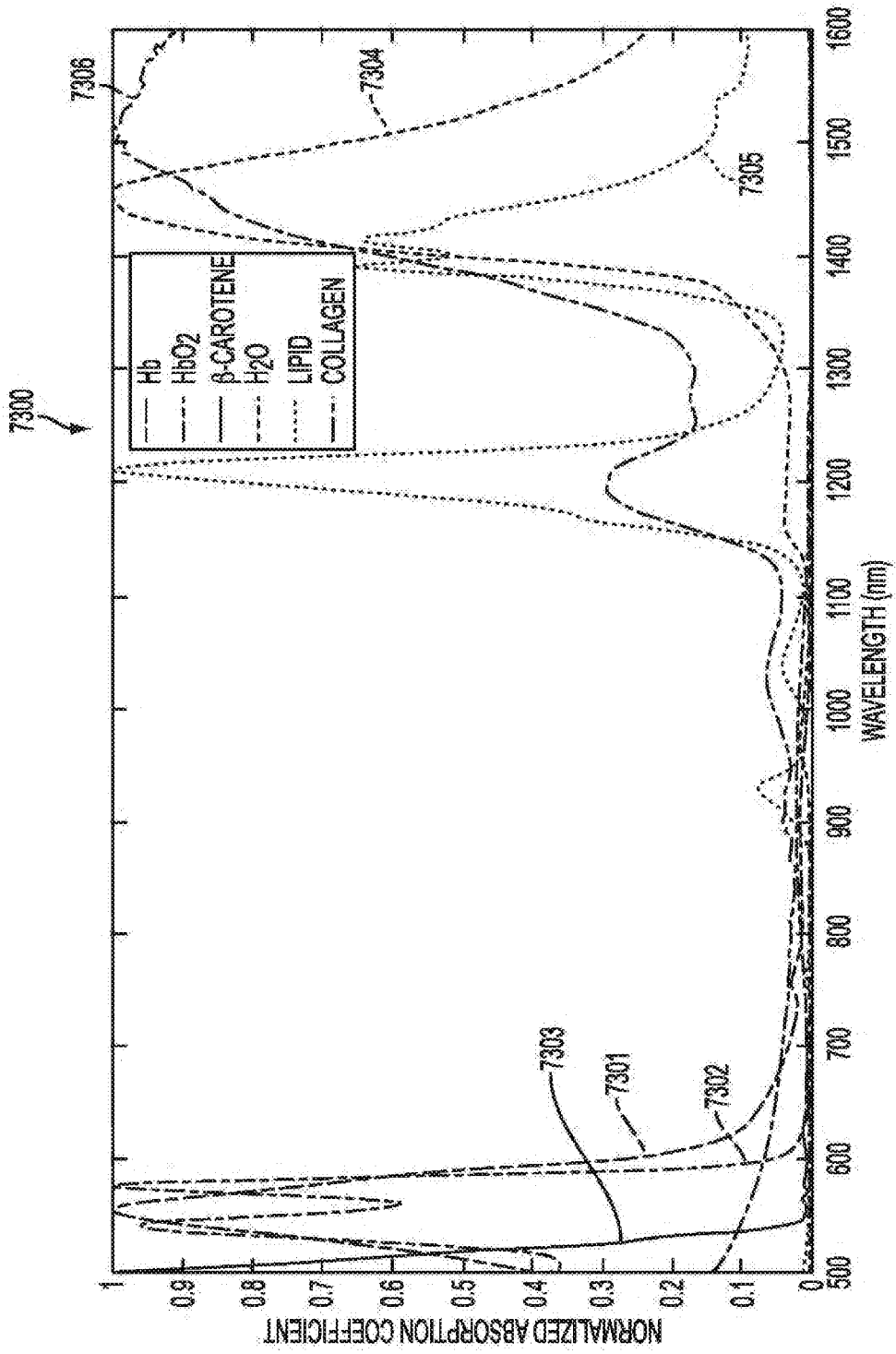

7300
7306
7304
7305
7303
7301
7302
Hb
HbO2
β-CAROTENE
H2O
LIPID
COLLAGEN
NORMALIZED ABSORPTION COEFFICIENT
WAVELENGTH (nm)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
500
600
700
800
900
1000
1100
1200
1300
1400
1500
1600

FIG. 73

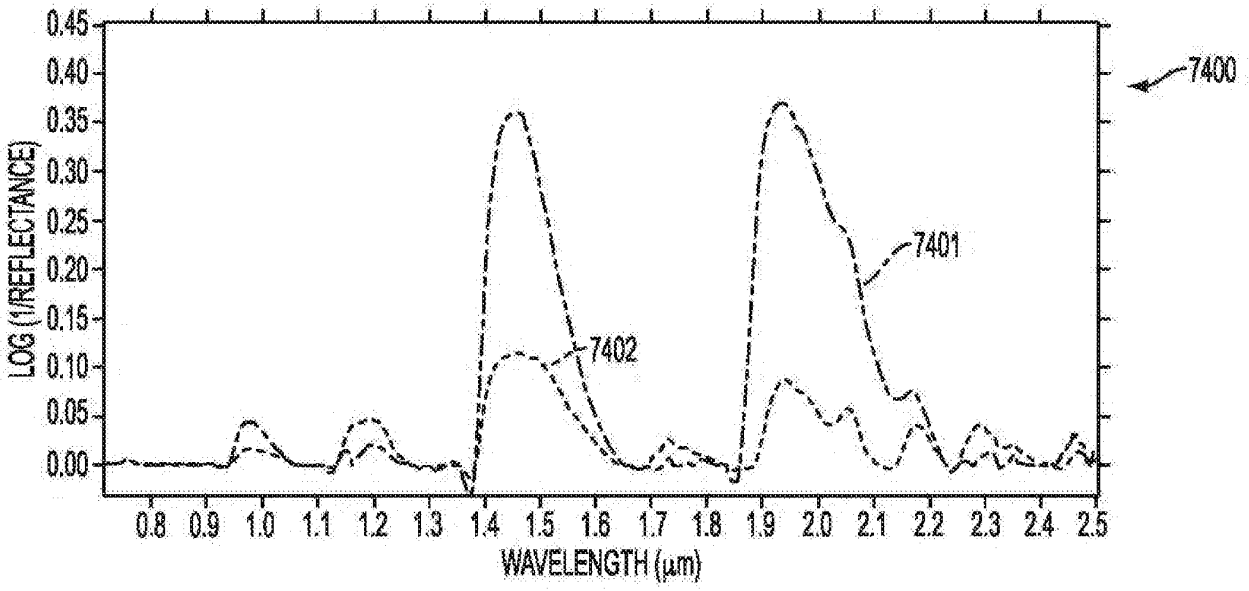


FIG. 74A

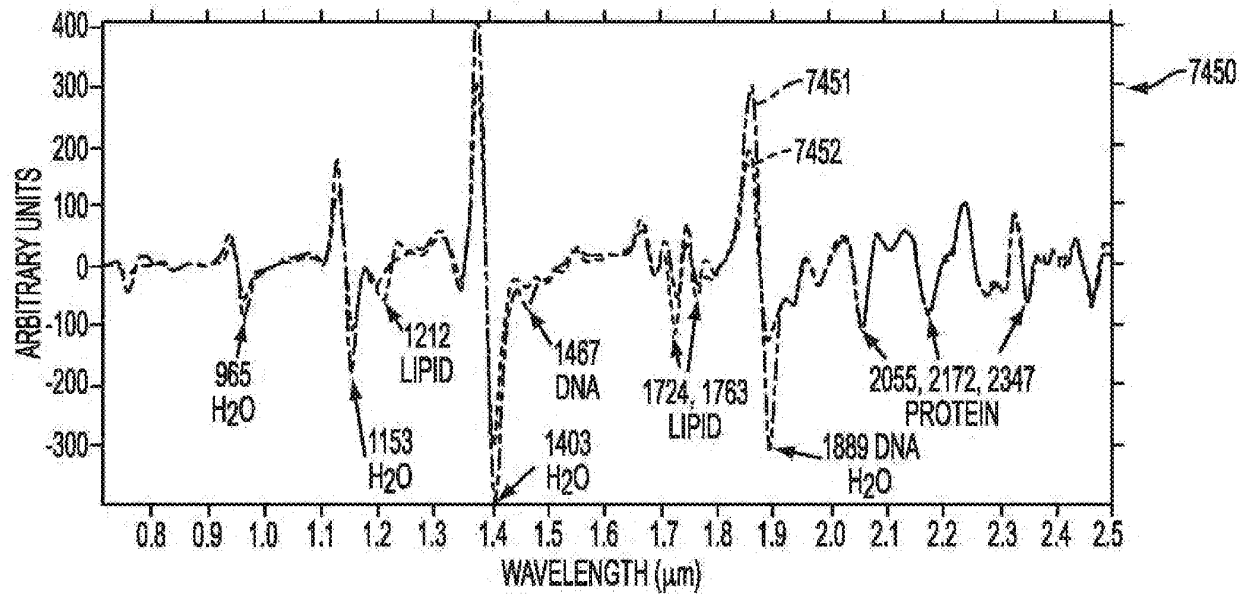


FIG. 74B

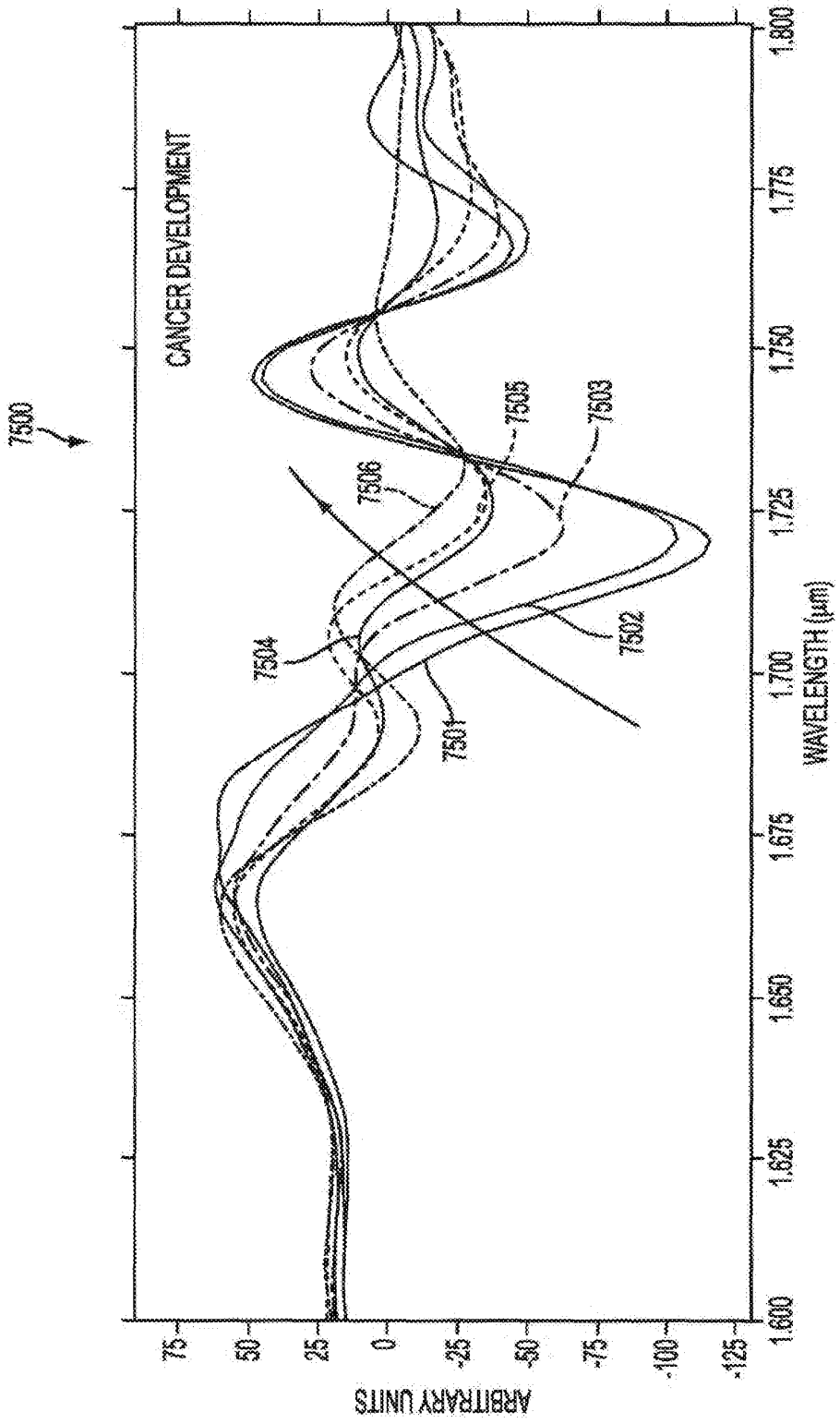

7500
CANCER DEVELOPMENT
7501
7502
7503
7504
7505
7506
ARBITRARY UNITS
75
50
25
0
-25
-50
-75
-100
-125
1.600
1.625
1.650
1.675
1.700
1.725
1.750
1.775
1.800
WAVELENGTH (μm)

FIG. 75

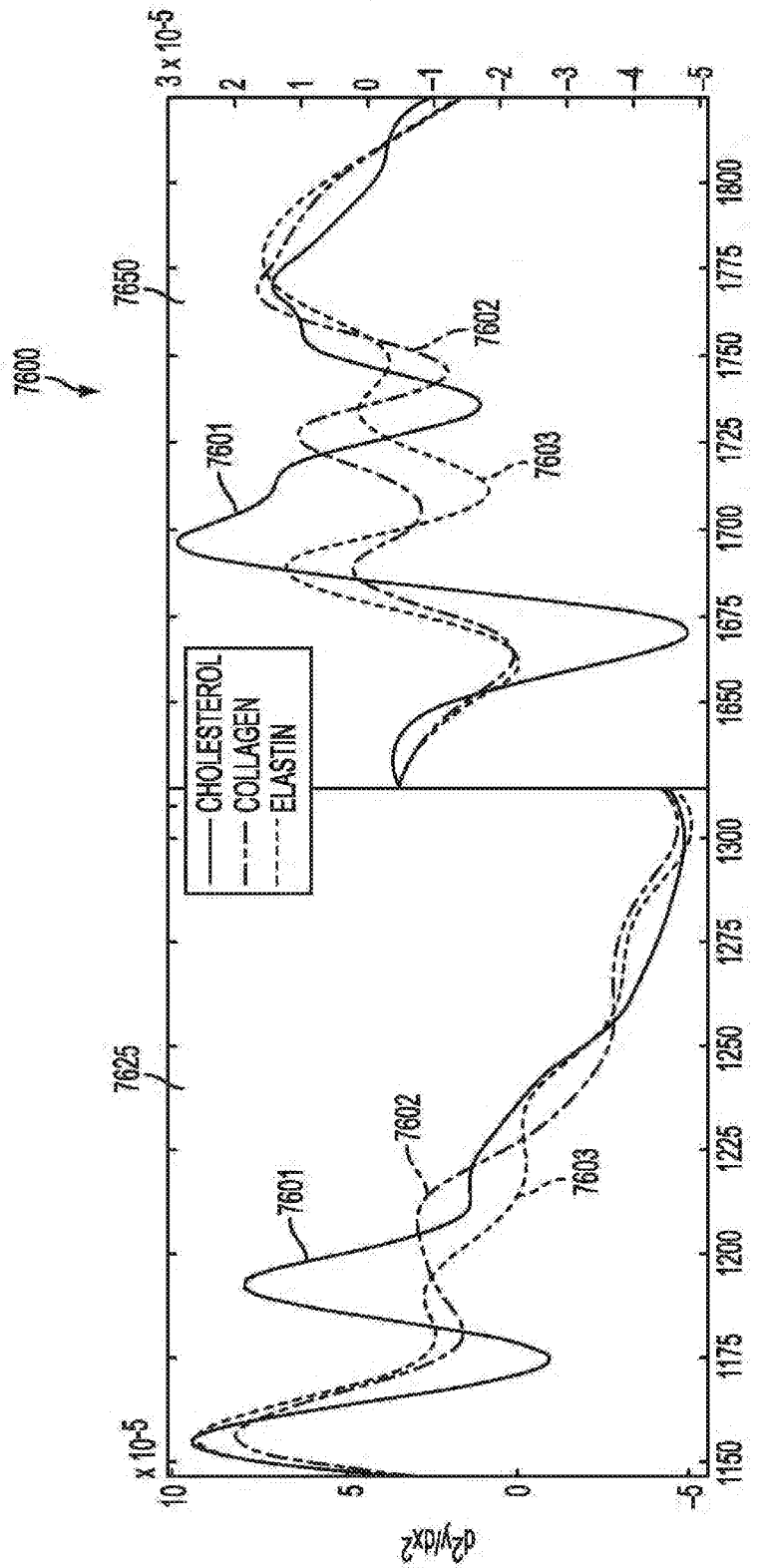

7600
7650
7625
7601
7602
7603
CHOLESTEROL
COLLAGEN
ELASTIN
3 x 10-5
x 10-5
d2y/dx2
WAVELENGTH (nm)
1150
1175
1200
1225
1250
1275
1300
1650
1675
1700
1725
1750
1775
1800

FIG. 76

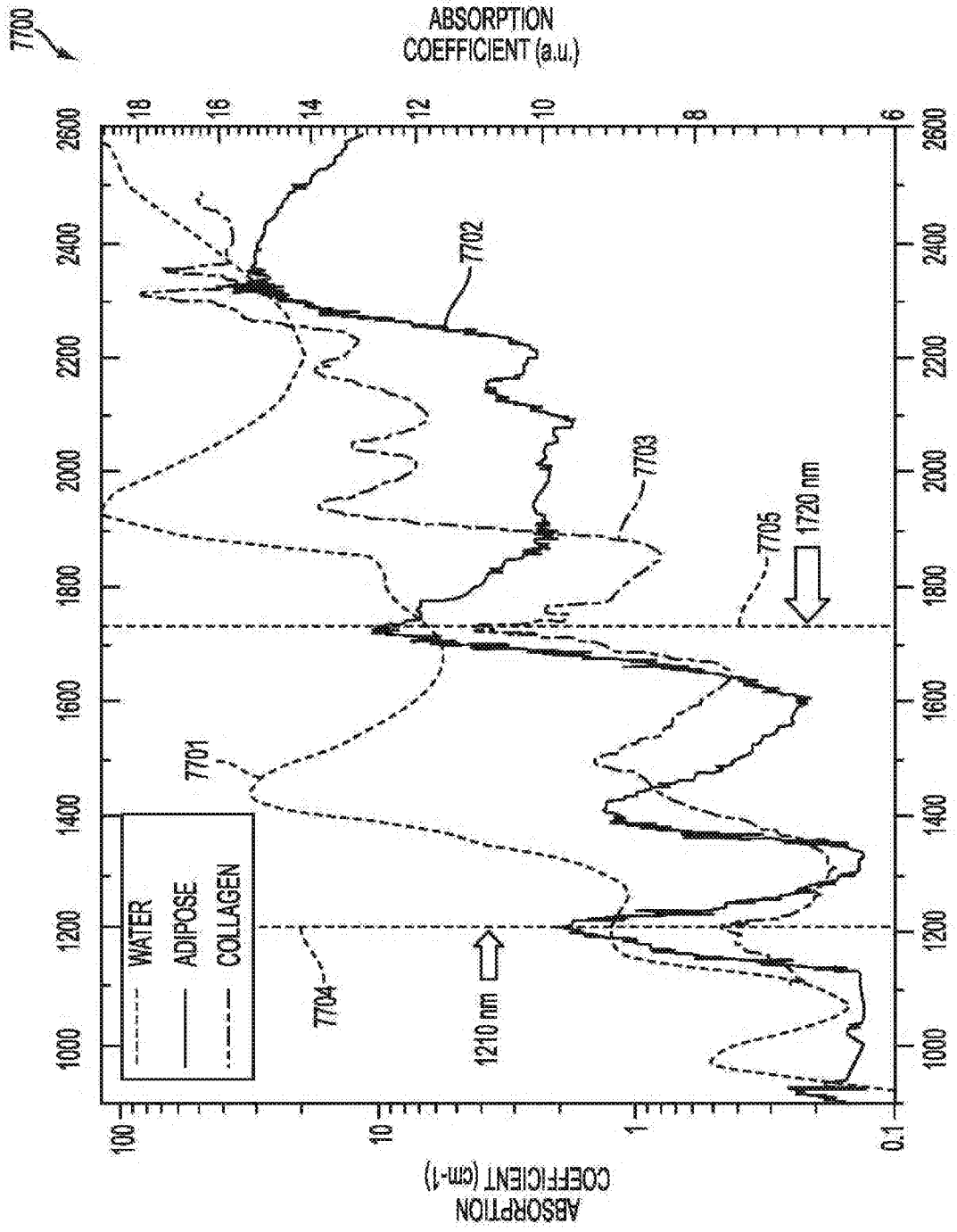

7700
ABSORPTION COEFFICIENT (a.u.)
18
16
14
12
10
8
6
2600
2400
2200
2000
1800
1600
1400
1200
1000
7702
7703
7705
1720 nm
7701
WATER
ADIPOSE
COLLAGEN
7704
1210 nm
100
10
1
0.1
ABSORPTION COEFFICIENT (cm-1)
WAVELENGTH nm

FIG. 77

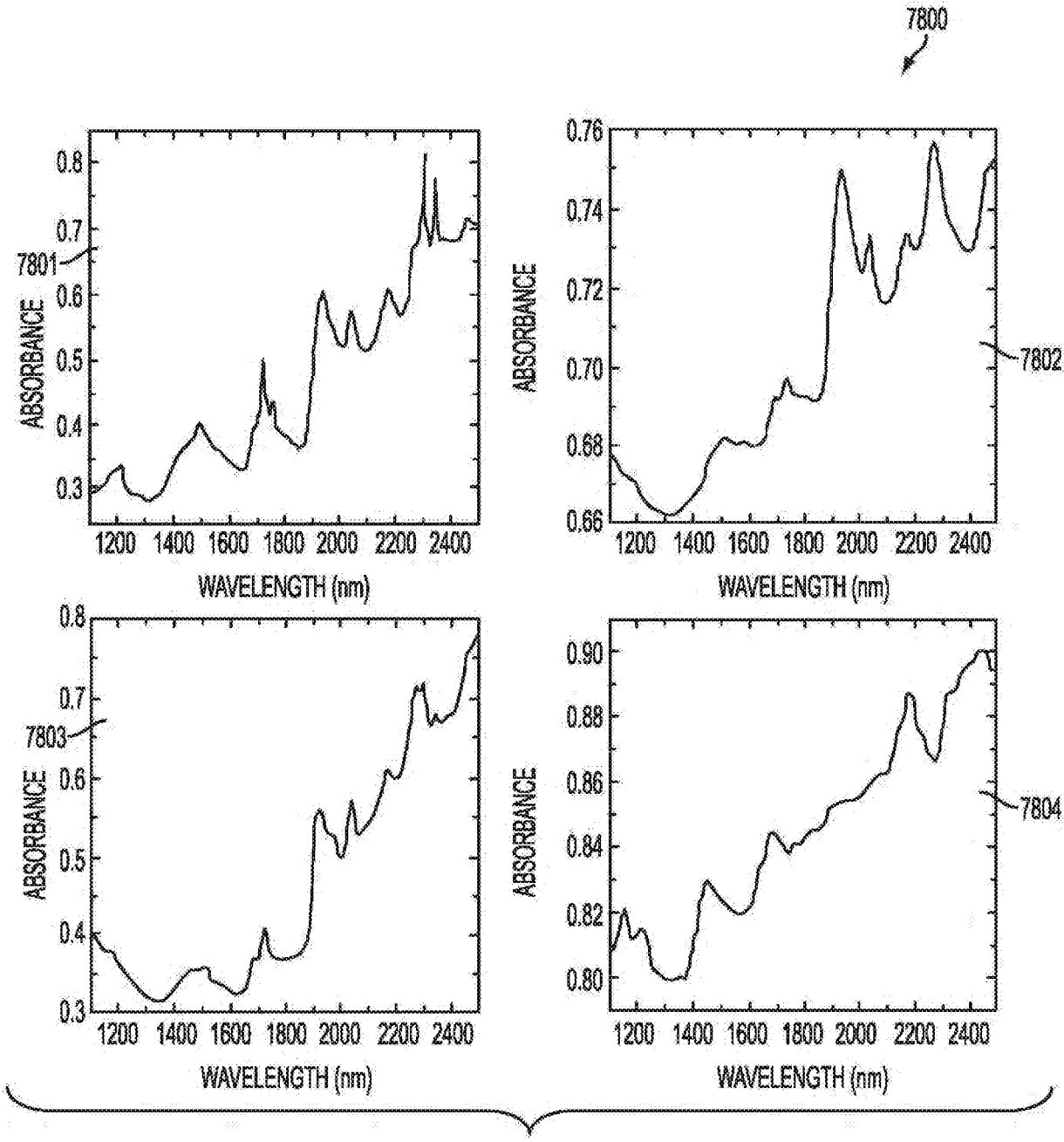

7800
7801
7802
7803
7804
ABSORBANCE
WAVELENGTH (nm)
0.8
0.7
0.6
0.5
0.4
0.3
0.76
0.74
0.72
0.70
0.68
0.66
0.90
0.88
0.86
0.84
0.82
0.80
1200 1400 1600 1800 2000 2200 2400

FIG. 78

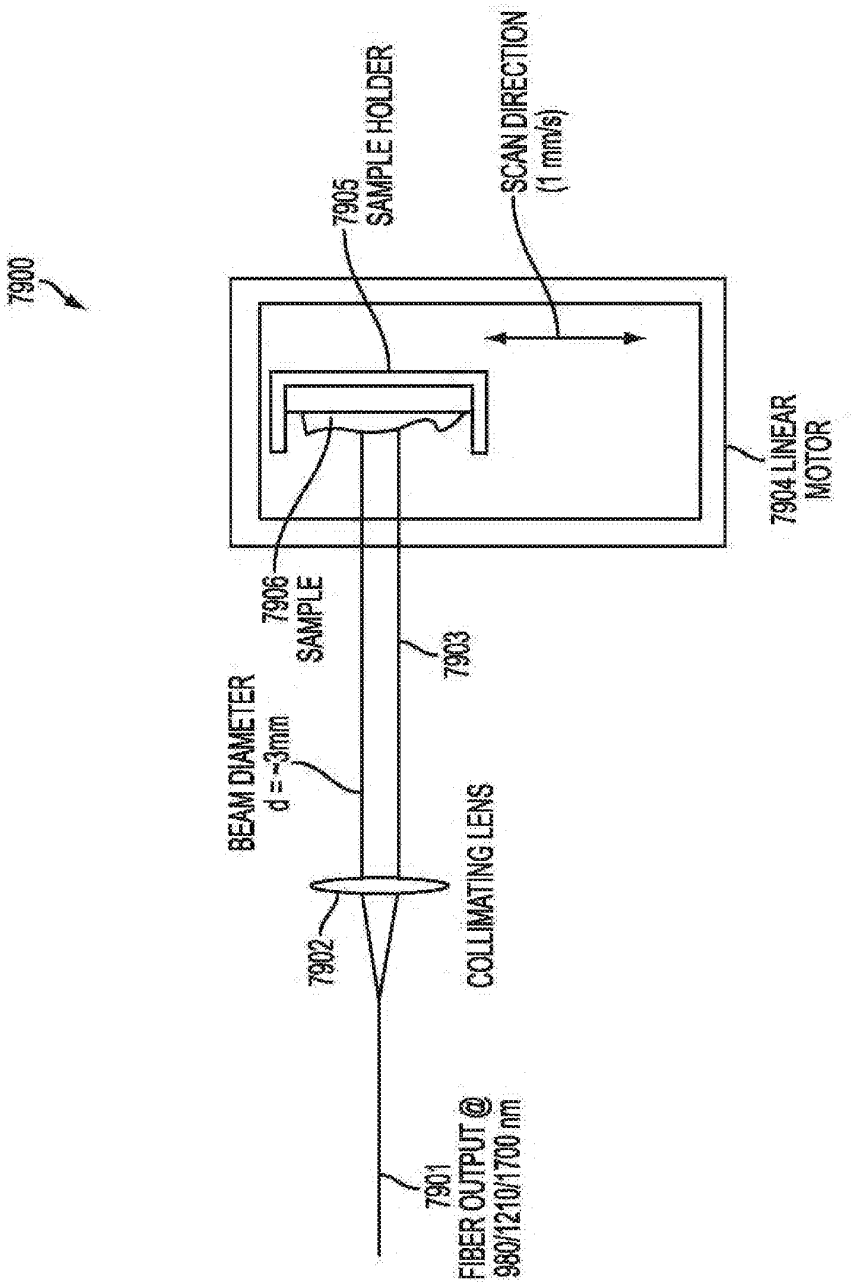

7900
7905
SAMPLE HOLDER
SCAN DIRECTION
(1 mm/s)
7904 LINEAR
MOTOR
7906
SAMPLE
7903
BEAM DIAMETER
d = ~3mm
7902
COLLIMATING LENS
7901
FIBER OUTPUT @
980/1210/1700 nm

FIG. 79

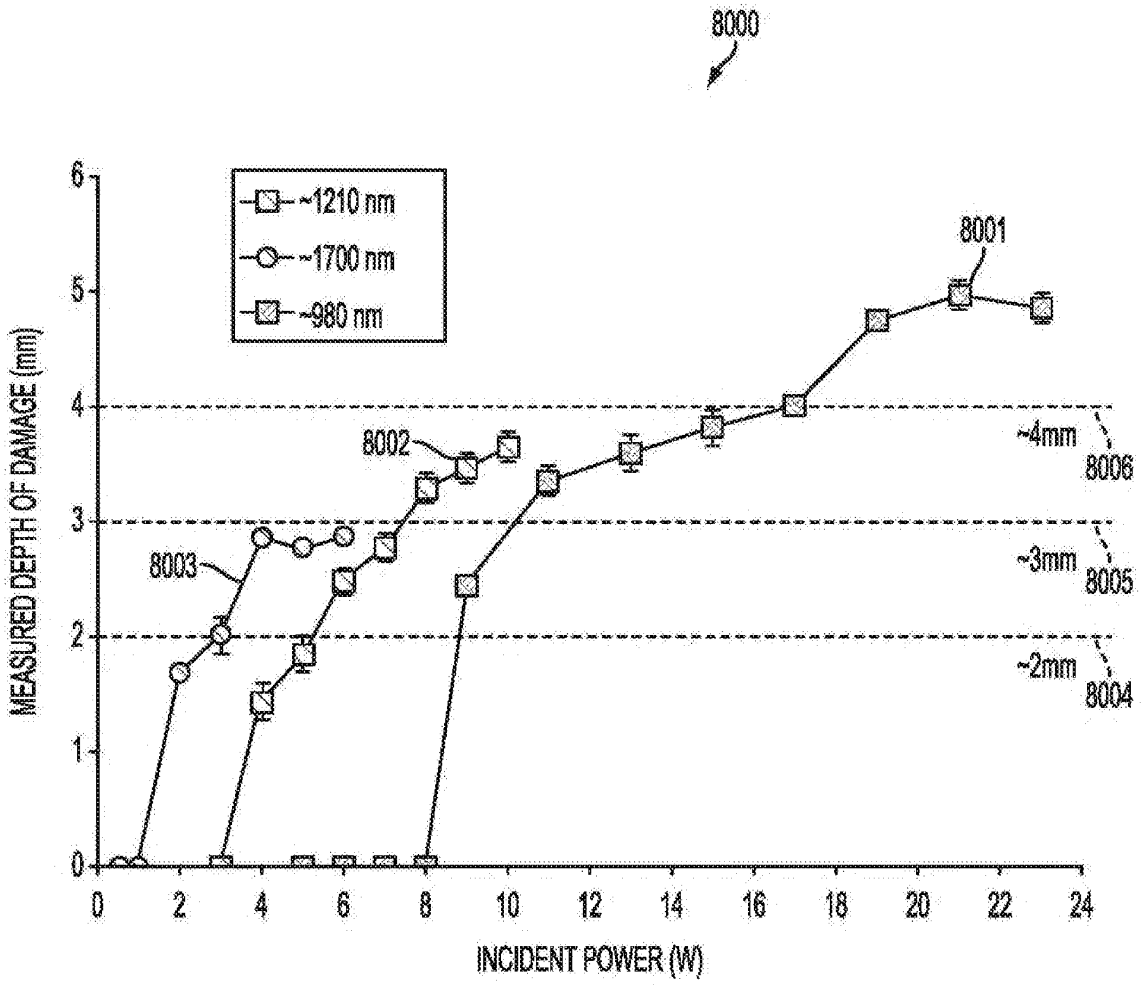

8000
~1210 nm
~1700 nm
~980 nm
8001
8002
8003
~4mm
8006
~3mm
8005
~2mm
8004
MEASURED DEPTH OF DAMAGE (mm)
INCIDENT POWER (W)
0
1
2
3
4
5
6
0
2
4
6
8
10
12
14
16
18
20
22
24

FIG. 80

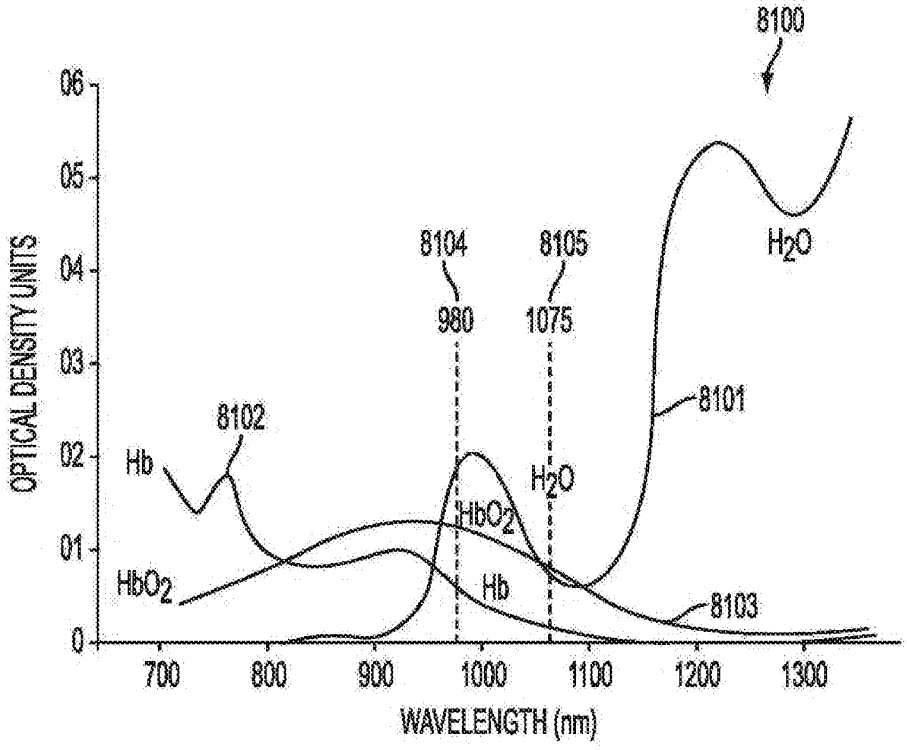

8100
06
05
04
03
02
01
0
OPTICAL DENSITY UNITS
8104
980
8105
1075
H_2O
8101
8102
Hb
H_2O
HbO_2
HbO_2
Hb
8103
700
800
900
1000
1100
1200
1300
WAVELENGTH (nm)

FIG. 81

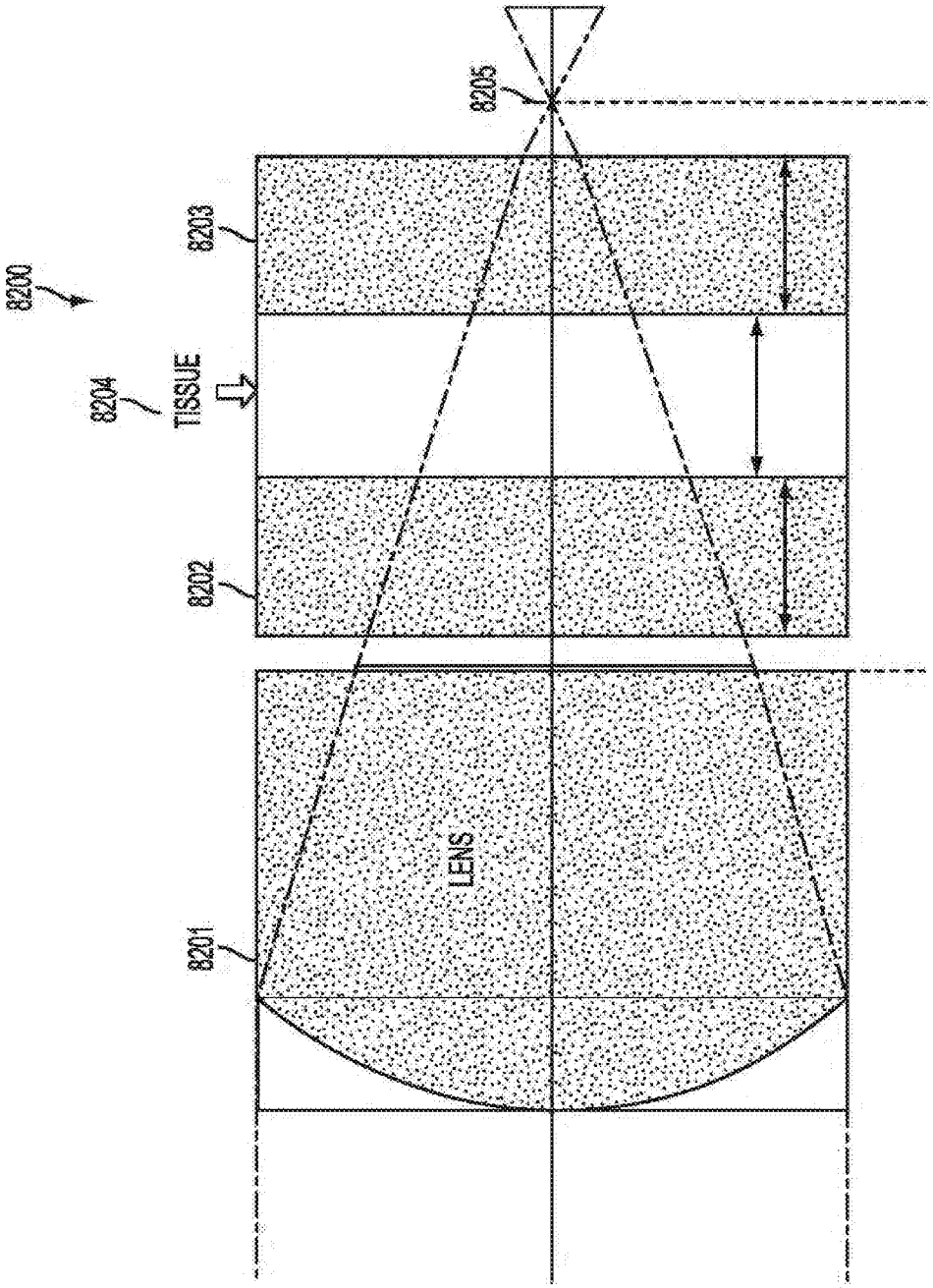


FIG. 82

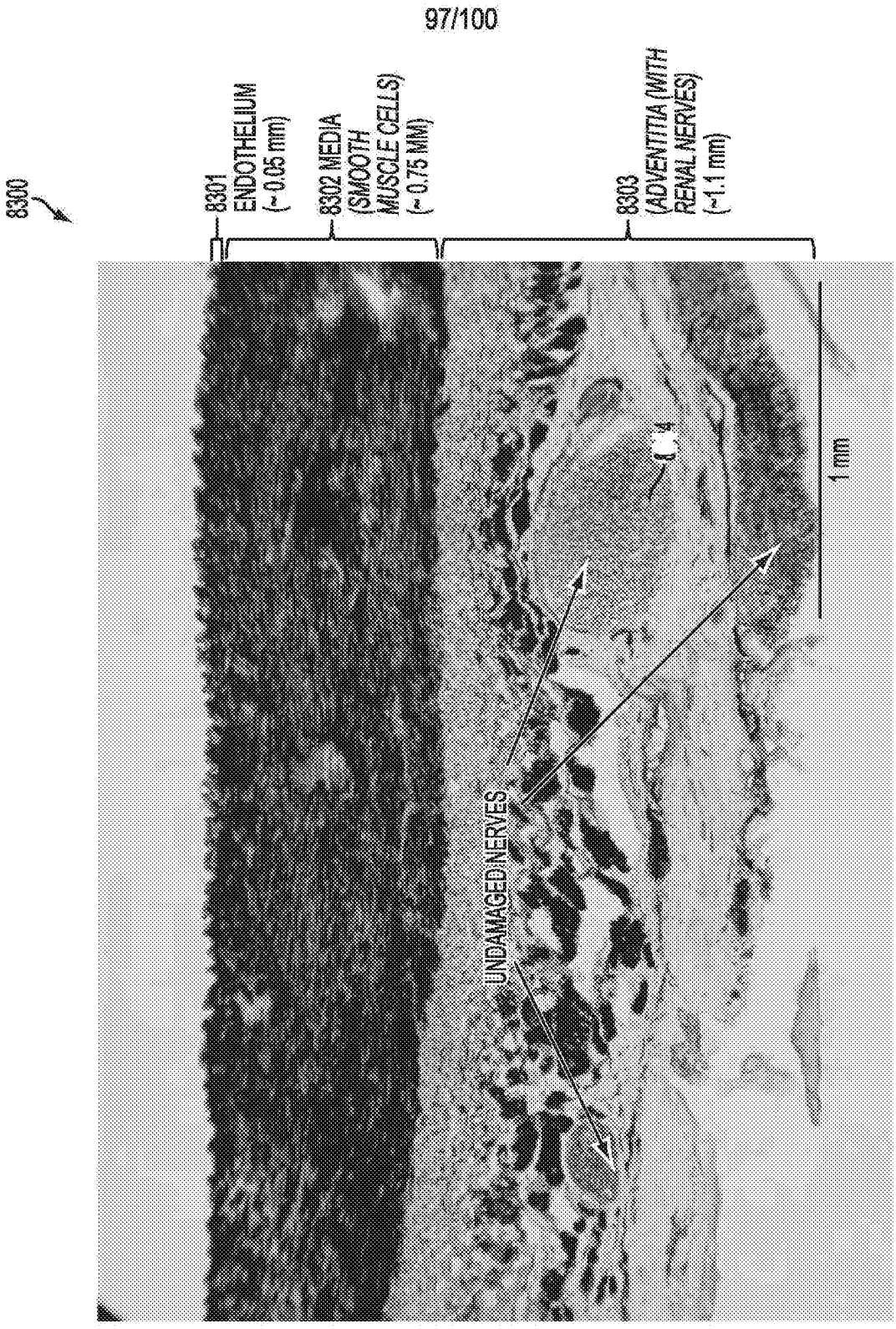

8300
8301
ENDOTHELIUM
(~ 0.05 mm)
8302 MEDIA
(SMOOTH
MUSCLE CELLS)
(~ 0.75 MM)
8303
(ADVENTITIA (WITH
RENAL NERVES)
(~1.1 mm)
UNDAMAGED NERVES
1 mm

FIG. 83A

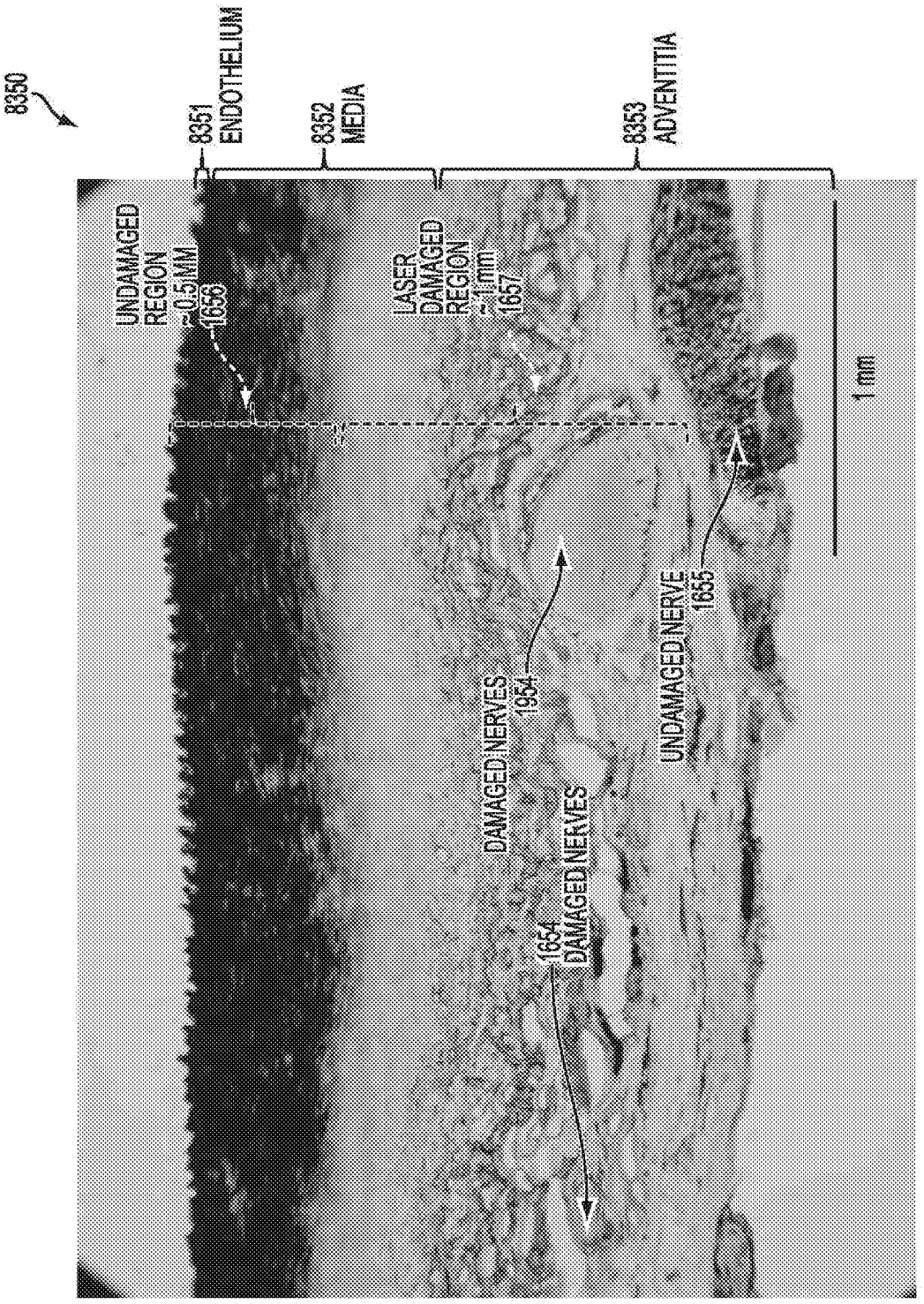

8350
8351
ENDOTHELIUM
8352
MEDIA
8353
ADVENTITIA
UNDAMAGED
REGION
~0.5MM
1658
LASER
DAMAGED
REGION
~1mm
1657
DAMAGED NERVES
1954
DAMAGED NERVES
1654
UNDAMAGED NERVE
1655
1 mm

FIG. 83B

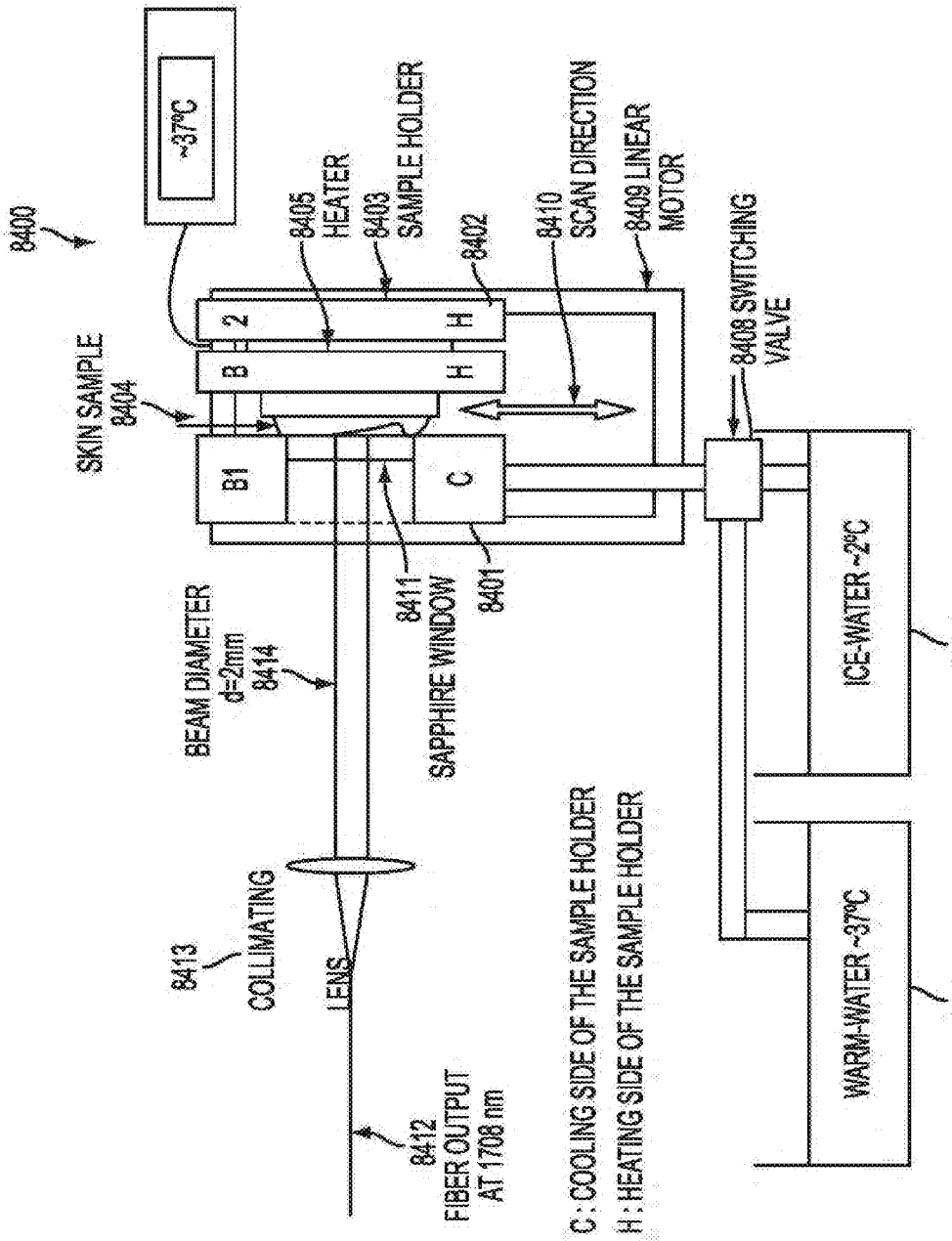

8400
~37°C
8405 HEATER
8403 SAMPLE HOLDER
8402
8410 SCAN DIRECTION
8409 LINEAR MOTOR
8408 SWITCHING VALVE
SKIN SAMPLE 8404
B2
BH
HH
B1
C
8411 SAPPHIRE WINDOW
8401
BEAM DIAMETER d=2mm 8414
8413 COLLIMATING LENS
8412 FIBER OUTPUT AT 1708 nm
C : COOLING SIDE OF THE SAMPLE HOLDER
H : HEATING SIDE OF THE SAMPLE HOLDER
ICE-WATER ~2°C
8407
WARM-WATER ~37°C
8406

FIG. 84

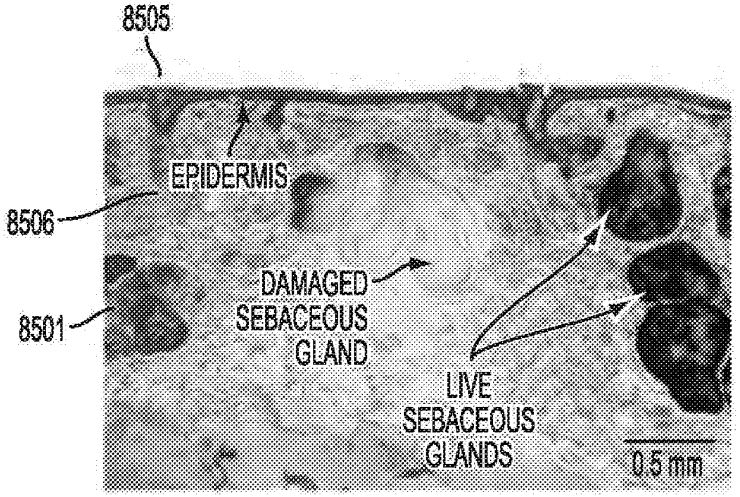


FIG. 85A

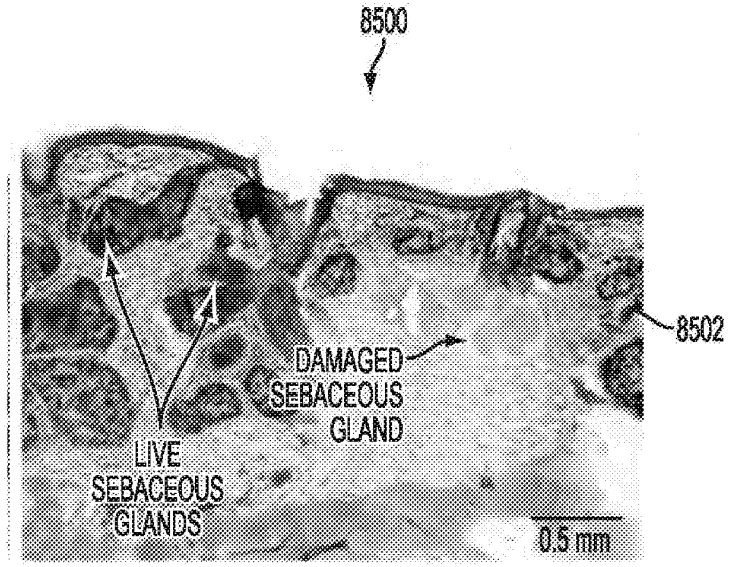


FIG. 85B

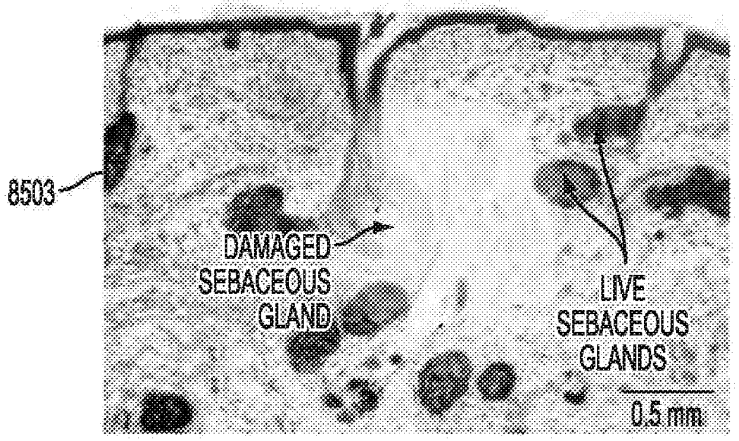


FIG. 85C

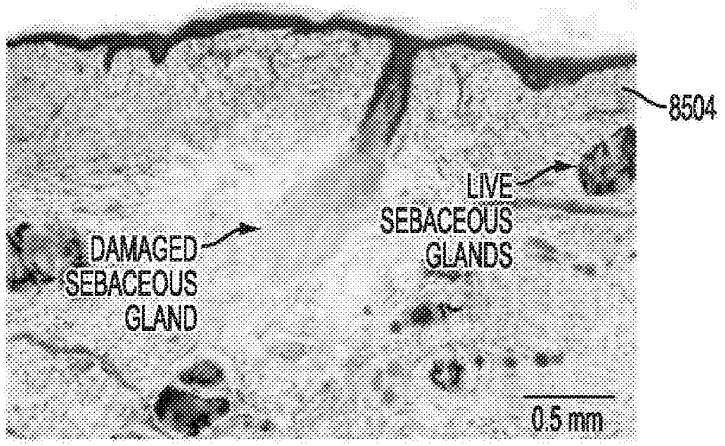


FIG. 85D

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WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Serial No. 18/899,012 filed September 27, 2024, which is a continuation of U.S. application Serial No. 18/891,970 filed September 20, 2024, which is a continuation of U.S. application Serial No. 18/438,144 filed February 9, 2024, which is a continuation of U.S. application Serial No. 18/103,408 filed January 30, 2023, now U.S. Patent No. 11,896,346, which is a continuation of U.S. application Serial No. 17/514,778 filed October 29, 2021, now U.S. Patent No. 11,564,577, which is a continuation of U.S. application Serial No. 17/078,771 filed October 23, 2020, now U.S. Patent No. 11,160,455, which is a continuation of U.S. application Serial No. 16/722188 filed December 20, 2019, now U.S. Patent No. 10,820,807, which is a continuation of U.S. application Serial No. 16/506,885 filed July 9, 2019, now U.S. Patent No. 10,517,484, which is a continuation of U.S. application Serial No. 16/272,069 filed February 11, 2019, now abandoned, which is a continuation of U.S. application Serial No. 16/029,611 filed July 8, 2018, now U.S. Patent No. 10,201,283, which is a continuation of U.S. application Serial No. 15/888,052 filed February 4, 2018 (U.S. Patent No. 10,136,819), now abandoned, which is a continuation of U.S. application Serial No. 15/212,549 filed July 18, 2016 (U.S. Patent No. 9,885,698), now abandoned, which is a continuation of U.S. application Serial No. 14/650,897 filed June 10, 2015, now U.S. Patent No. 9,494,567, which is a U.S. National Phase of PCT/US2013/075700 filed December 17, 2013, which claims the benefit of U.S. provisional application Serial No. 61/747,472 filed December 31, 2012, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

[0002] U.S. application Serial No. 16/506,885, now U.S. Patent No. 10,517,484, is also a continuation of U.S. application Serial No. 16/004,359 filed June 9, 2018, now U.S. Patent No. 11,109,761, which is a continuation of U.S. application Serial No. 14/109,007 filed December 17, 2013 (now U.S. Patent No. 9,993,159), which claims the benefit of U.S. provisional application Serial No. 61/747,553 filed December 31, 2012, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

[0003] U.S. application Serial No. 16/506,885, now U.S. Patent No. 10,517,484, is also a continuation of U.S. application Serial No.16/188,194 filed November 12, 2018 (U.S. Patent No. 10,386,230), now abandoned, which is a continuation of U.S. Application No. 16/004,154 filed June 8, 2018 (now U.S. Patent No. 10,126,283), which is a continuation of U.S. Application No. 15/855,201 filed December 27, 2017 (U.S. Patent No. 9,995,722), now abandoned, which is a continuation of U.S. Application No. 15/711,907 filed September 21, 2017 (U.S. Patent No. 9,897,584), now abandoned, which is a divisional of U.S. Application No. 15/357,225 filed November 21, 2016 (U.S. Patent No. 9,797,876), now abandoned, which is a continuation of U.S. Application No. 14/650,981 filed June 10, 2015 (now U.S. Patent No. 9,500,634), which is the U.S. national phase of PCT Application No. PCT/US2013/075767 filed December 17, 2013, which claims the benefit of U.S. provisional application Ser. No. 61/747,485 filed Dec. 31, 2012, the disclosures of all of which are hereby incorporated by reference in their entirety.

[0004] U.S. application Serial No. 16/506,885, now U.S. Patent No. 10,517,484, is also a continuation of U.S. application Serial No. 16/241,628 filed January 7, 2019, now U.S. Patent No. 10,441,176, which is a continuation of U.S. Serial No. 16/015,737 filed June 22, 2018 (U.S. Patent No. 10,172,523), now abandoned, which is a continuation of U.S. Serial No. 15/594,053 filed May 12, 2017 (U.S. Patent No. 10,188,299), now abandoned, which is a continuation of U.S. application Serial No. 14/875,709 filed October 6, 2015 (now U.S. Patent No. 9,651,533), which is a continuation of U.S. application Serial No. 14/108,986 filed December 17, 2013 (U.S. Patent No. 9,164,032), now abandoned, which claims the benefit of U.S. provisional application Serial No. 61/747,487 filed December 31, 2012, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

[0005] U.S. application Serial No. 16/506,885, now U.S. Patent No. 10,517,484, is also a continuation of U.S. Application Ser. No. 16/284,514 filed February 25, 2019, now abandoned, which is a continuation of U.S. Application Ser. No. 16/016,649 filed June 24, 2018 (U.S. Patent No. 10,213,113), now abandoned, which is a continuation of U.S. Application Ser. No. 15/860,065 filed January 2, 2018 (U.S. Patent No. 10,098,546), now abandoned, which is a continuation of U.S. Application Ser. No. 15/686,198 filed August 25, 2017 (U.S. Patent No. 9,861,286), now abandoned, which is a continuation of U.S. Application Ser. No. 15/357,136 filed November 21, 2016 (U.S. Patent. No. 9,757,040), now abandoned, which is a continuation of U.S. Application

Ser. No. 14/651,367 filed June 11, 2015 (now U.S. Patent No. 9,500,635), which is the U.S. national phase of PCT Application No. PCT/US2013/075736 filed December 17, 2013, which claims the benefit of U.S. provisional application Ser. No. 61/747,477 filed Dec. 31, 2012 and U.S. provisional application Ser. No. 61/754,698 filed Jan. 21, 2013, the disclosures of all of which are hereby incorporated by reference in their entirety.

[0006] This application is related to U.S. provisional application Serial Nos. 61/747,477 filed Dec. 31, 2012; Ser. No. 61/747,481 filed Dec. 31, 2012; Ser. No. 61/747,485 filed Dec. 31, 2012; Ser. No. 61/747,487 filed Dec. 31, 2012; Ser. No. 61/747,492 filed Dec. 31, 2012; Ser. No. 61/747,553 filed Dec. 31, 2012; and Ser. No. 61/754,698 filed Jan. 21, 2013, the disclosures of all of which are hereby incorporated in their entirety by reference herein.

[0007] This application is also related to International Application PCT/US2013/075736 entitled Short-Wave Infrared Super-Continuum Lasers For Early Detection Of Dental Caries; U.S. Application 14/108,995 filed December 17, 2013 entitled Focused Near-Infrared Lasers For Non-Invasive Vasectomy And Other Thermal Coagulation Or Occlusion Procedures (U.S. Pat. App. Pub. No. US2014/0188092A1); International Application PCT/US2013/075767 entitled Short-Wave Infrared Super-Continuum Lasers For Natural Gas Leak Detection, Exploration, And Other Active Remote Sensing Applications; U.S. Application 14/108,986 filed December 17, 2013 (U.S. Patent No. 9,164,032) entitled Short-Wave Infrared Super-Continuum Lasers For Detecting Counterfeit Or Illicit Drugs And Pharmaceutical Process Control; U.S. Application 14/108,974 filed December 17, 2013 entitled Non-Invasive Treatment Of Varicose Veins (U.S. Pat. App. Pub. No. US2014/018894A1); and U.S. Application 14/109,007 filed December 17, 2013 entitled Near-Infrared Super-Continuum Lasers For Early Detection Of Breast And Other Cancers (now U.S. Patent No. 9,993,159), the disclosures of all of which are hereby incorporated in their entirety by reference herein.

BACKGROUND

[0008] With the growing obesity epidemic, the number of individuals with diabetes is also increasing dramatically. For example, there are over 200 million people who have diabetes. Diabetes control requires monitoring of the glucose level, and most glucose measuring systems available commercially require drawing of blood. Depending on the severity of the diabetes, a

patient may have to draw blood and measure glucose four to six times a day. This may be extremely painful and inconvenient for many people. In addition, for some groups, such as soldiers in the battlefield, it may be dangerous to have to measure periodically their glucose level with finger pricks.

[0009] Thus, there is an unmet need for non-invasive glucose monitoring (e.g., monitoring glucose without drawing blood). The challenge has been that a non-invasive system requires adequate sensitivity and selectivity, along with repeatability of the results. Yet, this is a very large market, with an estimated annual market of over $10B in 2011 for self-monitoring of glucose levels.

[0010] One approach to non-invasive monitoring of blood constituents or blood analytes is to use near-infrared spectroscopy, such as absorption spectroscopy or near-infrared diffuse reflection or transmission spectroscopy. Some attempts have been made to use broadband light sources, such as tungsten lamps, to perform the spectroscopy. However, several challenges have arisen in these efforts. First, many other constituents in the blood also have signatures in the near-infrared, so spectroscopy and pattern matching, often called spectral fingerprinting, is required to distinguish the glucose with sufficient confidence. Second, the non-invasive procedures have often transmitted or reflected light through the skin, but skin has many spectral artifacts in the near-infrared that may mask the glucose signatures. Moreover, the skin may have significant water and blood content. These difficulties become particularly complicated when a weak light source is used, such as a lamp. More light intensity can help to increase the signal levels, and, hence, the signal-to-noise ratio.

[0011] As described in this disclosure, by using brighter light sources, such as fiber-based supercontinuum lasers, super-luminescent laser diodes, light-emitting diodes or a number of laser diodes, the near-infrared signal level from blood constituents may be increased. By shining light through the teeth, which have fewer spectral artifacts than skin in the near-infrared, the blood constituents may be measured with less interfering artifacts. Also, by using pattern matching in spectral fingerprinting and various software techniques, the signatures from different constituents in the blood may be identified. Moreover, value-add services may be provided by wirelessly communicating the monitored data to a handheld device such as a smart phone, and then wirelessly

communicating the processed data to the cloud for storing, processing, and transmitting to several locations.

[0012] Dental care and the prevention of dental decay or dental caries has changed in the United States over the past several decades, due to the introduction of fluoride to drinking water, the use of fluoride dentifrices and rinses, application of topical fluoride in the dental office, and improved dental hygiene. Despite these advances, dental decay continues to be the leading cause of tooth loss. With the improvements over the past several decades, the majority of newly discovered carious lesions tend to be localized to the occlusal pits and fissures of the posterior dentition and the proximal contact sites. These early carious lesions may be often obscured in the complex and convoluted topography of the pits and fissures or may be concealed by debris that frequently accumulates in those regions of the posterior teeth. Moreover, such lesions are difficult to detect in the early stages of development.

[0013] Dental caries may be a dynamic disease that is characterized by tooth demineralization leading to an increase in the porosity of the enamel surface. Leaving these lesions untreated may potentially lead to cavities reaching the dentine and pulp and perhaps eventually causing tooth loss. Occlusal surfaces (bite surfaces) and approximal surfaces (between the teeth) are among the most susceptible sites of demineralization due to acid attack from bacterial by-products in the biofilm. Therefore, there is a need for detection of lesions at an early stage, so that preventive agents may be used to inhibit or reverse the demineralization.

[0014] Traditional methods for caries detection include visual examination and tactile probing with a sharp dental exploration tool, often assisted by radiographic (x-ray) imaging. However, detection using these methods may be somewhat subjective; and, by the time that caries are evident under visual and tactile examination, the disease may have already progressed to an advanced stage. Also, because of the ionizing nature of x-rays, they are dangerous to use (limited use with adults, and even less used with children). Although x-ray methods are suitable for approximal surface lesion detection, they offer reduced utility for screening early caries in occlusal surfaces due to their lack of sensitivity at very early stages of the disease.

[0015] Some of the current imaging methods are based on the observation of the changes of the light transport within the tooth, namely absorption, scattering, transmission, reflection

and/or fluorescence of light. Porous media may scatter light more than uniform media. Taking advantage of this effect, the Fiber-optic trans-illumination is a qualitative method used to highlight the lesions within teeth by observing the patterns formed when white light, pumped from one side of the tooth, is scattered away and/or absorbed by the lesion. This technique may be difficult to quantify due to an uneven light distribution inside the tooth.

[0016] Another method called quantitative light-induced fluorescence – QLF – relies on different fluorescence from solid teeth and caries regions when excited with bright light in the visible. For example, when excited by relatively high intensity blue light, healthy tooth enamel yields a higher intensity of fluorescence than does demineralized enamel that has been damaged by caries infection or any other cause. On the other hand, for excitation by relatively high intensity of red light, the opposite magnitude change occurs, since this is the region of the spectrum for which bacteria and bacterial by-products in carious regions absorb and fluoresce more pronouncedly than do healthy areas. However, the image provided by QLF may be difficult to assess due to relatively poor contrast between healthy and infected areas. Moreover, QLF may have difficulty discriminating between white spots and stains because both produce similar effects. Stains on teeth are commonly observed in the occlusal sites of teeth, and this obscures the detection of caries using visible light.

[0017] As described in this disclosure, the near-infrared region of the spectrum offers a novel approach to imaging carious regions because scattering is reduced and absorption by stains is low. For example, it has been demonstrated that the scattering by enamel tissues reduces in the form of $1/(\text{wavelength})^3$, e.g., inversely as the cube of wavelength. By using a broadband light source in the short-wave infrared (SWIR) part of the spectrum, which corresponds approximately to 1400nm to 2500nm, lesions in the enamel and dentine may be observed. In one embodiment, intact teeth have low reflection over the SWIR wavelength range. In the presence of caries, the scattering increases, and the scattering is a function of wavelength; hence, the reflected signal decreases with increasing wavelength. Moreover, particularly when caries exist in the dentine region, water build up may occur, and dips in the SWIR spectrum corresponding to the water absorption lines may be observed. The scattering and water absorption as a function of wavelength may thus be used for early detection of caries and for quantifying the degree of demineralization.

[0018] SWIR light may be generated by light sources such as lamps, light emitting diodes, one or more laser diodes, super-luminescent laser diodes, and fiber-based super-continuum sources. The SWIR super-continuum light sources advantageously may produce high intensity and power, as well as being a nearly transform-limited beam that may also be modulated. Also, apparatuses for caries detection may include C-clamps over teeth, a handheld device with light input and light detection, which may also be attached to other dental equipment such as drills. Alternatively, a mouth-guard type apparatus may be used to simultaneously illuminate one or more teeth. Fiber optics may be conveniently used to guide the light to the patient as well as to transport the signal back to one or more detectors and receivers.

[0019] Remote sensing or hyper-spectral imaging often uses the sun for illumination, and the short-wave infrared (SWIR) windows of about 1.5-1.8 microns and about 2-2.5 microns may be attractive because the atmosphere transmits in these wavelength ranges. Although the sun can be a bright and stable light source, its illumination may be affected by the time-of-day variations in the sun angle as well as weather conditions. For example, the sun may be advantageously used for applications such as hyper-spectral imaging only between about 9am to 3pm, and it may be difficult to use the sun during cloudy days or during inclement weather. In one embodiment, the hyper-spectral sensors measure the reflected solar signal at hundreds (e.g., 100 to 200+) contiguous and narrow wavelength bands (e.g., bandwidth between 5nm and 10nm). Hyper-spectral images may provide spectral information to identify and distinguish between spectrally similar materials, providing the ability to make proper distinctions among materials with only subtle signature differences. In the SWIR wavelength range, numerous gases, liquids and solids have unique chemical signatures, particularly materials comprising hydro-carbon bonds, O-H bonds, N-H bonds, etc. Therefore, spectroscopy in the SWIR may be attractive for stand-off or remote sensing of materials based on their chemical signature, which may complement other imaging information.

[0020] A SWIR super-continuum (SC) source may be able to replace at least in part the sun as an illumination source for active remote sensing, spectroscopy, or hyper-spectral imaging. In one embodiment, reflected light spectroscopy may be implemented using the SWIR light source, where the spectral reflectance can be the ratio of reflected energy to incident energy as a function of wavelength. Reflectance varies with wavelength for most materials because energy at certain wavelengths may be scattered or absorbed to different degrees. Using a SWIR light source may

permit 24/7 detection of solids, liquids, or gases based on their chemical signatures. As an example, natural gas leak detection and exploration may require the detection of methane and ethane, whose primary constituents include hydro-carbons. In the SWIR, for instance, methane and ethane exhibit various overtone and combination bands for vibrational and rotational resonances of hydro-carbons. In one embodiment, diffuse reflection spectroscopy or absorption spectroscopy may be used to detect the presence of natural gas. The detection system may include a gas filter correlation radiometer, in a particular embodiment. Also, one embodiment of the SWIR light source may be an all-fiber integrated SWIR SC source, which leverages the mature technologies from the telecommunications and fiber optics industry. Beyond natural gas, active remote sensing in the SWIR may also be used to identify other materials such as vegetation, greenhouse gases or environmental pollutants, soils and rocks, plastics, illicit drugs, counterfeit drugs, firearms and explosives, paints, and various building materials.

[0021] Counterfeiting of pharmaceuticals is a significant issue in the healthcare community as well as for the pharmaceutical industry worldwide. For example, according to the World Health Organization, in 2006 the market for counterfeit drugs worldwide was estimated at around $43 Billion. Moreover, the use of counterfeit medicines may result in treatment failure or even death. For instance, in 1995 dozens of children in Haiti and Nigeria died after taking counterfeit medicinal syrups that contained diethylene glycol, an industrial solvent. As another example, in Asia one report estimated that 90% of Viagra sold in Shanghai, China, was counterfeit. With more pharmaceuticals being purchased through the internet, the problem of counterfeit drugs coming from across the borders into the United States has been growing rapidly.

[0022] A rapid, non-destructive, non-contact optical method for screening or identification of counterfeit pharmaceuticals is needed. Spectroscopy using near-infrared or short-wave infrared (SWIR) light may provide such a method, because most pharmaceuticals comprise organic compounds that have overtone or combination absorption bands in this wavelength range (e.g., between approximately 1-2.5 microns). Moreover, most drug packaging materials are at least partially transparent in the near-infrared or SWIR, so that drug compositions may be detected and identified through the packaging non-destructively. Also, using a near-infrared or SWIR light source with a spatially coherent beam permits screening at stand-off or remote distances. Beyond identifying counterfeit drugs, the near-infrared or SWIR spectroscopy may have many other

beneficial applications. For example, spectroscopy may be used for rapid screening of illicit drugs or to implement process analytical technology in pharmaceutical manufacturing. There are also a wide array of applications in assessment of quality in the food industry, including screening of fruit, vegetables, grains and meats.

[0023] In one embodiment, a near-infrared or SWIR super-continuum (SC) source may be used as the light source for spectroscopy, active remote sensing, or hyper-spectral imaging. One embodiment of the SWIR light source may be an all-fiber integrated SWIR SC source, which leverages the mature technologies from the telecommunications and fiber optics industry. Exemplary fiber-based super-continuum sources may emit light in the near-infrared or SWIR between approximately 1.4-1.8 microns, 2-2.5 microns, 1.4-2.4 microns, 1-1.8 microns, or any number of other bands. In particular embodiments, the detection system may be a dispersive spectrometer, a Fourier transform infrared spectrometer, or a hyper-spectral imaging detector or camera. In addition, reflection or diffuse reflection light spectroscopy may be implemented using the SWIR light source, where the spectral reflectance can be the ratio of reflected energy to incident energy as a function of wavelength.

[0024] Breast cancer is considered to be the most common cancer among women in industrialized countries. It is believed that early diagnosis and consequent therapy could significantly reduce mortality. Mammography is considered the gold standard among imaging techniques in diagnosing breast pathologies. However, the use of ionizing radiation in mammography may have adverse effects and lead to other complications. Moreover, screening x-ray mammography may be limited by false positives and negatives, leading to unnecessary physical and psychological morbidity. Although breast cancer is one of the focuses of this disclosure, the same techniques may also be applied to other cancer types, including, for example, skin, prostate, brain, pancreatic, and colorectal cancer.

[0025] Diagnostic methods for assessment and therapy follow-up of breast cancer include mammography, ultrasound, and magnetic resonance imaging. The most effective screening technique at this time is x-ray mammography, with an overall sensitivity for breast cancer detection around 75%, which is even further reduced in women with dense breasts to around 62%. Moreover, x-ray mammography has a 22% false positive rate in women under 50, and the method

cannot accurately distinguish between benign and malignant tumors. Magnetic resonance imaging and ultrasound are sometimes used to augment x-ray mammography, but they have limitations such as high cost, low throughput, limited specificity and low sensitivity. Thus, there is a continued need to detect cancers earlier for treatment, missed by mammography, and to add specificity to the procedures.

[0026] Optical breast imaging may be an attractive technique for breast cancer to screen early, augment with mammography, or use in follow-on treatments. Also, optical breast imaging may be performed by intrinsic tissue contrast alone (e.g., hemoglobin, water, collagen, and lipid content), or with the use of exogenous fluorescent probes that target specific molecules. For example, near-infrared (NIR) light may be used to assess optical properties, where the absorption and scattering by the tissue components may change with carcinoma. For most of the studies conducted to date, NIR light in the wavelength range of 600-1000nm has been used for sufficient tissue penetration; these wavelengths have permitted imaging up to several centimeters deep in soft tissue. Optical breast imaging using fluorescent contrast agents may improve lesion contrast and may potentially permit detection of changes in breast tissue earlier. In one embodiment, the fluorescent probes may either bind specifically to certain targets associated with cancer or may non-specifically accumulate at the tumor site.

[0027] Optical methods of imaging and spectroscopy can be non-invasive using non-ionizing electromagnetic radiation, and these techniques could be exploited for screening of wide populations and for therapy monitoring. "Optical mammography" may be a diffuse optical imaging technique that aims at detecting breast cancer, characterizing its physiological and pathological state, and possibly monitoring the efficacy of the therapeutic treatment. The main constituents of breast tissue may be lipid, collagen, water, blood, and other structural proteins. These constituents may exhibit marked and characteristic absorption features in the NIR wavelength range. Thus, diffuse optical imaging and spectroscopy in the NIR may be helpful for diagnosing and monitoring breast cancer. Another advantage of such imaging is that optical instruments tend to be portable and more cost effective as compared to other instrumentation that is conventionally used for medical diagnosis. This can be particularly true, if the mature technologies for telecommunications and fiber optics are exploited.

[0028] Spectroscopy using NIR or short-wave infrared (SWIR) light may be beneficial, because most tissue has organic compounds that have overtone or combination absorption bands in this wavelength range (e.g., between approximately 0.8-2.5 microns). In one embodiment, a NIR or SWIR super-continuum (SC) laser that is an all-fiber integrated source may be used as the light source for diagnosing cancerous tissue. Exemplary fiber-based super-continuum sources may emit light in the NIR or SWIR between approximately 1.4-1.8 microns, 2-2.5 microns, 1.4-2.4 microns, 1-1.8 microns, or any number of other bands. In particular embodiments, the detection system may be one or more photo-detectors, a dispersive spectrometer, a Fourier transform infrared spectrometer, or a hyper-spectral imaging detector or camera. In addition, reflection or diffuse reflection light spectroscopy may be implemented using the SWIR light source, where the spectral reflectance can be the ratio of reflected energy to incident energy as a function of wavelength.

[0029] For breast cancer, experiments have shown that with growing cancer the collagen content increases while the lipid content decreases. Therefore, early breast cancer detection may involve the monitoring of absorption or scattering features from collagen and lipids. In addition, NIR spectroscopy may be used to determine the concentrations of hemoglobin, water, as well as oxygen saturation of hemoglobin and optical scattering properties in normal and cancerous breast tissue. For optical imaging to be effective, it may also be desirable to select the wavelength range that leads to relatively high penetration depths into the tissue. In one embodiment, it may be advantageous to use optical wavelengths in the range of about 1000-1400nm. In another embodiment, it may be advantageous to use optical wavelengths in the range of about 1600-1800nm. Higher optical power densities may be used to increase the signal-to-noise ratio of the detected light through the diffuse scattering tissue, and surface cooling or focused light may be beneficial for preventing pain or damage to the skin and outer layer surrounding the breast tissue. Since optical energy may be non-ionizing, different exposure times may be used without danger or harmful radiation.

SUMMARY

[0030] According to one aspect of this disclosure, an apparatus is disclosed that is adapted to be worn by a user. The apparatus comprises one or more biosensors adapted to be placed on the

user, wherein one or more physiological parameters are measured, wherein measuring of the one or more physiological parameters comprises a differential measurement, and wherein the one or more physiological parameters comprises a pulse rate monitoring and a blood flow measurement. The apparatus also comprises a light source comprising a plurality of light emitting diodes that are configured to generate an output optical light having one or more optical wavelengths. The apparatus also comprises one or more lenses configured to receive at least a portion of the output optical light and to deliver a lens output light to tissue comprising skin. The apparatus further comprises a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal is indicative of the one or more physiological parameters that has a signal-to-noise ratio. The detection system is configured to be synchronized to the light source, comprises a plurality of detectors that are spatially separated from each other, and at least one analog to digital converter is coupled to at least one of the plurality of detectors. The apparatus is configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of light emitting diodes from an initial light intensity. The detection system further configured to generate a first signal responsive to light received while the light emitting diodes are off, generate a second signal responsive to light received while at least one of the light emitting diodes is on, and increase the signal-to-noise ratio by comparing the first signal and the second signal. The apparatus is at least in part configured to determine, based at least in part on the output signal, that the apparatus is being worn by the user.

[0031] According to another aspect of this disclosure, a wearable device configured to be worn by a user. The wearable device comprises a light source configured to be on or off, responsive to the light source being on, the light source generates an output light, a lens positioned to direct at least a portion of the output light towards a bodily tissue of the user. a detector; and

[0032] The processor is configured to be responsive to (1) the light source being on and the detector receiving at least a portion of the output light that is reflected from the bodily tissue of the user, generate a first output signal having a first signal-to-noise ratio; (2) responsive to the light source being off and the detector receiving ambient light, generate a second output signal having a second signal-to-noise ratio; (3) generate a third output signal using at least a portion of the first output signal and at least a portion of the second output signal, the third output signal having a third signal-to-noise ratio that is greater than the first signal-to-noise ratio and greater

than the second signal-to-noise ratio, the third output signal being associated with a physiological parameter of the user; and (4) determine, based at least in part on the third output signal, that the wearable device is being worn by the user.

[0033] According to a further aspect of this disclosure, a system is disclosed for a device worn by a user. The system comprises a light source comprising a plurality of light emitting diodes that are configured to generate an output optical light having one or more optical wavelengths. One or more lenses configured to receive at least a portion of the output optical light and to direct a lens output light towards a bodily tissue of the user. A detection system configured to receive at least a portion of the lens output light reflected from the bodily tissue and to generate an output signal having a signal-to-noise ratio. The detection system is configured to be synchronized to the light source. The signal-to-noise ratio of the output signal is increased by increasing light intensity of at least one of the plurality of light emitting diodes from an initial light intensity. The detection system comprises a plurality of detectors that are spatially separated from each other. At least one analog to digital converter is coupled to at least one of the plurality of detectors. The output signal is associated with one or more physiological parameters. The detection system is configured to generate a first signal responsive to light received while the light emitting diodes are off The detection system is configured to generate a second signal responsive to light received while at least one of the light emitting diodes is on. The detection system is configured to increase the signal-to-noise ratio by comparing the first signal and the second signal. The detection system is configured to measure the one or more physiological parameters when worn by the user. One or more physiological parameters change in response to stretching of a hand of the user, movement of a finger of the user, or movement of a thumb of the user, and wherein the device is at least in part configured to determine, based at least in part on the output signal, that the device is being worn by the user.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] For a more complete understanding of the present disclosure, and for further features and advantages thereof, reference is now made to the following description taken in conjunction with the accompanying drawings, in which:

[0035] FIGURE 1 plots the transmittance versus wavenumber for glucose in the mid-wave and long-wave infrared wavelengths between approximately 2.7 to 12 microns.

[0036] FIGURE 2 illustrates measurements of the absorbance of different blood constituents, such as glucose, hemoglobin, and hemoglobin A1c. The measurements are done using an FTIR spectrometer in samples with a 1mm path length.

[0037] FIGURE 3A shows the normalized absorbance of water and glucose (not drawn to scale). Water shows transmission windows between about 1500-1850nm and 2050-2500nm.

[0038] FIGURE 3B illustrates the absorbance of hemoglobin and oxygenated hemoglobin overlapped with water.

[0039] FIGURE 4A shows measured absorbance in different concentrations of glucose solution over the wavelength range of about 2000 to 2400nm. This data is collected using a SWIR super-continuum laser with the sample path length of about 1.1mm.

[0040] FIGURE 4B illustrates measured absorbance in different concentrations of glucose solution over the wavelength range of about 1550 to 1800nm. The data is collected using a SWIR super-continuum laser with a sample path length of about 10mm.

[0041] FIGURE 5 illustrates the spectrum for different blood constituents in the wavelength range of about 2 to 2.45 microns (2000 to 2450nm).

[0042] FIGURE 6 shows the transmittance versus wavelength in microns for the ketone 3-hydroxybutyrate. The wavelength range is approximately 2 to 16 microns.

[0043] FIGURE 7 illustrates the optical absorbance for ketones as well as some other blood constituents in the wavelength range of about 2100 to 2400nm.

[0044] FIGURE 8A shows the first derivative spectra of ketone and protein at concentrations of 10g/L (left). In addition, the first derivative spectra of urea, creatinine, and glucose are shown on the right at concentrations of 10g/L.

[0045] FIGURE 8B illustrates the near infrared absorbance for triglyceride.

[0046] FIGURE 8C shows the near-infrared reflectance spectrum for cholesterol.

[0047] FIGURE 8D illustrates the near-infrared reflectance versus wavelength for various blood constituents, including cholesterol, glucose, albumin, uric acid, and urea.

[0048] FIGURE 9 shows a schematic of the human skin. In particular, the dermis may comprise significant amounts of collagen, elastin, lipids, and water.

[0049] FIGURE 10 illustrates the absorption coefficients for water (including scattering), adipose, collagen, and elastin.

[0050] FIGURE 11 shows the dorsal of the hand, where a differential measurement may be made to at least partially compensate for or subtract out the skin interference.

[0051] FIGURE 12 shows the dorsal of the foot, where a differential measurement may be made to at least partially compensate for or subtract out the skin interference.

[0052] FIGURE 13 illustrates a typical human nail tissue structure and the capillary vessels below it.

[0053] FIGURE 14 shows the attenuation coefficient for seven nail samples that are allowed to stand in an environment with a humidity level of 14%. These coefficients are measured using an FTIR spectrometer over the near-infrared wavelength range of approximately 1 to 2.5 microns. Below is also included the spectrum of glucose.

[0054] FIGURE 15 illustrates the structure of a tooth.

[0055] FIGURE 16A shows the attenuation coefficient for dental enamel and water versus wavelength from approximately 600nm to 2600nm.

[0056] FIGURE 16B illustrates the absorption spectrum of intact enamel and dentine in the wavelength range of approximately 1.2 to 2.4 microns.

[0057] FIGURE 17 shows the near infrared spectral reflectance over the wavelength range of approximately 800nm to 2500nm from an occlusal tooth surface. The black diamonds

correspond to the reflectance from a sound, intact tooth section. The asterisks correspond to a tooth section with an enamel lesion. The circles correspond to a tooth section with a dentine lesion.

[0058] FIGURE 18A illustrates a clamp design of a human interface to cap over one or more teeth and perform a non-invasive measurement of blood constituents.

[0059] FIGURE 18B shows a mouth guard design of a human interface to perform a non-invasive measurement of blood constituents.

[0060] FIGURE 19 illustrates a block diagram or building blocks for constructing high power laser diode assemblies.

[0061] FIGURE 20 shows a platform architecture for different wavelength ranges for an all-fiber-integrated, high powered, super-continuum light source.

[0062] FIGURE 21 illustrates one embodiment of a short-wave infrared (SWIR) super-continuum (SC) light source.

[0063] FIGURE 22 shows the output spectrum from the SWIR SC laser of FIGURE 21 when ~10m length of fiber for SC generation is used. This fiber is a single-mode, non-dispersion shifted fiber that is optimized for operation near 1550nm.

[0064] FIGURE 23 illustrates high power SWIR-SC lasers that may generate light between approximately 1.4-1.8 microns (top) or approximately 2-2.5 microns (bottom).

[0065] FIGURE 24 schematically shows that the medical measurement device can be part of a personal or body area network that communicates with another device (e.g., smart phone or tablet) that communicates with the cloud. The cloud may in turn communicate information with the user, healthcare providers, or other designated recipients.

[0066] FIGURE 25 illustrates the structure of a tooth.

[0067] FIGURE 26A shows the attenuation coefficient for dental enamel and water versus wavelength from approximately 600nm to 2600nm.

[0068] FIGURE 26B illustrates the absorption spectrum of intact enamel and dentine in the wavelength range of approximately 1.2 to 2.4 microns.

[0069] FIGURE 27 shows the near infrared spectral reflectance over the wavelength range of approximately 800nm to 2500nm from an occlusal tooth surface. The black diamonds correspond to the reflectance from a sound, intact tooth section. The asterisks correspond to a tooth section with an enamel lesion. The circles correspond to a tooth section with a dentine lesion.

[0070] FIGURE 28 illustrates a hand-held dental tool design of a human interface that may also be coupled with other dental tools.

[0071] FIGURE 29 illustrates a clamp design of a human interface to cap over one or more teeth and perform a non-invasive measurement for dental caries.

[0072] FIGURE 30 shows a mouth guard design of a human interface to perform a non-invasive measurement for dental caries.

[0073] FIGURE 31 schematically shows that the medical measurement device can be part of a personal or body area network that communicates with another device (e.g., smart phone or tablet) that communicates with the cloud. The cloud may in turn communicate information with the user, dental or healthcare providers, or other designated recipients.

[0074] FIGURE 32 illustrates wavelength bands for different chemical compounds over the SWIR wavelength range of approximately 1400nm to 2500nm. Also indicated are whether the bands are overtone or combination bands.

[0075] FIGURE 33A shows the absorption spectra for methane.

[0076] FIGURE 33B shows the absorption spectra for ethane.

[0077] FIGURE 34 illustrates the reflectance spectra for some members of the alkane family plus paraffin.

[0078] FIGURE 35A depicts that micro-seepages may result from the vertical movement of hydro-carbons from their respective reservoirs to the surface. It is assumed that the rock column, including the seal rock, comprises interconnected fractures or micro-fracture systems.

[0079] FIGURE 35B illustrates that surface alterations may occur because leaking hydro-carbons set up near-surface oxidation and/or reduction zones that favor the development of a diverse array of chemical and mineralogical changes.

[0080] FIGURE 36A shows the reflectance spectra for locations with natural gas fields (3601) and locations without natural gas fields (3602).

[0081] FIGURE 36B illustrates spectra from field tests over regions with natural gas, which show two spectral features: one near 1.725 microns and another doublet between about 2.311 microns and 2.36 microns.

[0082] FIGURE 37 shows the reflectance spectra of a sample of oil emulsion from the Gulf of Mexico 2010 oil spill (different thicknesses of oil).

[0083] FIGURE 38 illustrates the reflectance spectra of some representative minerals that may be major components of rocks and soils.

[0084] FIGURE 39 shows the reflectance spectra of different types of green vegetation compared with dry, yellowed grass.

[0085] FIGURE 40 illustrates the atmospheric absorption and scattering of greenhouse gases at different wavelengths.

[0086] FIGURE 41 overlays the reflectance for different building materials from the ASTER spectra library.

[0087] FIGURE 42 shows the absorbance for two common plastics, polyethylene and polystyrene.

[0088] FIGURE 43 shows the experimental set-up for a reflection-spectroscopy based stand-off detection system.

[0089] FIGURE 44 illustrates the chemical structure and molecular formula for various explosives, along with the absorbance spectra obtained using a super-continuum source.

[0090] FIGURE 45A shows the reflection spectra for gypsum, pine wood, ammonium nitrate and urea.

[0091] FIGURE 45B illustrates the reflection spectra for three commercial automotive paints and military grade CARC paint (chemical agent resistant coating) (reflectance in this case are in arbitrary units).

[0092] FIGURE 46 shows the mid-wave infrared and long-wave infrared absorption spectra for various illicit drugs. It is expected that overtone and combination bands should be evident in the SWIR and near-infrared wavelength bands.

[0093] FIGURE 47A is a schematic diagram of the basic elements of an imaging spectrometer.

[0094] FIGURE 47B illustrates one example of a typical imaging spectrometer used in hyper-spectral imaging systems.

[0095] FIGURE 48 shows one example of a gas-filter correlation radiometer, which is a detection system that uses a sample of the gas of interest as a spectral filter for the gas.

[0096] FIGURE 49 exemplifies a dual-beam experimental set-up that may be used to subtract out (or at least minimize the adverse effects of) light source fluctuations.

[0097] FIGURE 50 shows the absorbance for two common plastics, polyethylene and polystyrene.

[0098] FIGURE 51 illustrates one example of the difference in near-infrared spectrum between an authentic tablet and a counterfeit tablet.

[0099] FIGURE 52 shows the second derivative of the spectral comparison of Prozac and a similarly formulated generic.

[0100] FIGURE 53 illustrates an example of the near infrared spectra for different pure components of a studied drug.

[0101] FIGURE 54 shows the mid-wave infrared and long-wave infrared absorption spectra for various illicit drugs.

[0102] FIGURE 55 shows the absorbance versus wavelength in the near-infrared region for four classes of illegal drugs.

[0103] FIGURE 56 illustrates the diffuse reflectance near-infrared spectrum of heroin samples.

[0104] FIGURE 57 illustrates the diffuse reflectance near-infrared spectra of different seized illicit drugs containing heroin of different concentrations, along with the spectrum for pure heroin.

[0105] FIGURE 58A lists possible band assignments for the various spectral features in pure heroin.

[0106] FIGURES 58B also lists possible band assignments for the various spectral features in pure heroin.

[0107] FIGURE 59 shows the diffuse reflectance near-infrared spectra of different compounds that may be frequently employed as cutting agents.

[0108] FIGURE 60 provides one example of a flow-chart in the process analytical technology for the pharmaceutical industry.

[0109] FIGURE 61 illustrates the typical near-infrared spectra of a variety of excipients.

[0110] FIGURE 62 exemplifies the absorbance from the blending process of a pharmaceutical compound.

[0111] FIGURE 63 shows what might be an eventual flow-chart of a smart manufacturing process.

[0112] FIGURE 64A illustrates the near-infrared reflectance spectrum of wheat flour.

[0113] FIGURE 64B shows the near-infrared absorbance spectra obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit.

[0114] FIGURE 65A is a schematic diagram of the basic elements of an imaging spectrometer.

[0115] FIGURE 65B illustrates one example of a typical imaging spectrometer used in hyper-spectral imaging systems.

[0116] FIGURE 66 shows one example of the Fourier transform infrared spectrometer.

[0117] FIGURE 67 exemplifies a dual-beam experimental set-up that may be used to subtract out (or at least minimize the adverse effects of) light source fluctuations.

[0118] FIGURE 68 illustrates the optical absorption of pure water, hemoglobin without oxygen, and hemoglobin saturated with oxygen.

[0119] FIGURE 69 shows examples of various absorption bands of chemical species in the wavelength range between about 1200-2200nm.

[0120] FIGURE 70 depicts the structure of a female breast.

[0121] FIGURE 71 illustrates particular embodiments of imaging systems for optically scanning a breast.

[0122] FIGURE 72 shows the normalized absorption spectra of main tissue absorbers in the NIR for breast cancer, between about 600-1100nm.

[0123] FIGURE 73 illustrates the normalized absorption coefficient in the wavelength range between about 500-1600nm for many of the components of breast tissue.

[0124] FIGURE 74A shows the typical spectra of the cancerous site of a treated rat and the corresponding site of a normal rat and illustrates the logarithm of the inverse of reflection spectra.

[0125] FIGURES 74B shows the typical spectra of the cancerous site of a treated rat and the corresponding site of a normal rat and illustrates second derivative spectra.

[0126] FIGURE 75 shows the second derivative of spectral changes over several weeks between about 1600-1800nm in rats with breast cancer.

[0127] FIGURE 76 illustrates the second derivative spectra for cholesterol, collagen and elastin.

[0128] FIGURE 77 shows the absorption coefficient as a function of wavelength between about 1000nm and 2600nm for water, adipose and collagen.

[0129] FIGURE 78 illustrates the absorbance for four types of collagen: collagen I, collagen II, collagen III, and collagen IV.

[0130] FIGURE 79 shows an experimental set-up for testing chicken breast samples using collimated light. In this experiment, the collimated light has a beam diameter of about 3mm.

[0131] FIGURE 80 plots the measured depth of damage (in millimeters) versus the time-averaged incident power (in Watts). Data is presented for laser wavelengths near 980nm, 1210nm and 1700nm, and lines are drawn corresponding to penetration depths of approximately 2mm, 3mm, and 4mm.

[0132] FIGURE 81 illustrates the optical absorption or density as a function of wavelength between approximately 700nm and 1300nm for water, hemoglobin and oxygenated hemoglobin.

[0133] FIGURE 82 shows a set-up used for in vitro damage experiments using focused infrared light. After a lens system, the tissue is placed between two microscope slides.

[0134] FIGURE 83A presents histology of renal arteries comprising endothelium, media and adventitia layers and some renal nerves in or below the adventitia and illustrates renal arteries with no laser exposure.

[0135] FIGURE 83B presents histology of renal arteries comprising endothelium, media and adventitia layers and some renal nerves in or below the adventitia and illustrates renal arteries after focused laser exposure, with the laser light near 1708nm.

[0136] FIGURE 84 illustrates the experimental set-up for ex vivo skin laser treatment with surface cooling to protect the epidermis and top layer of the dermis.

[0137] FIGURE 85A shows MTT histo-chemistry of ex vivo human skin treated with ~1708nm laser and cold window (5 seconds precool; 2mm diameter spot exposure for 3 seconds) at 725mW corresponding to ~70 J/cm2 average fluence.

[0138] FIGURE 85B also shows MTT histo-chemistry of ex vivo human skin treated with ~1708nm laser and cold window (5 seconds precool; 2mm diameter spot exposure for 3 seconds) at 725mW corresponding to ~70 J/cm2 average fluence.

[0139] FIGURE 85C shows MTT histo-chemistry of ex vivo human skin treated with ~1708nm laser and cold window (5 seconds precool; 2mm diameter spot exposure for 3 seconds) at 830mW corresponding to ~80 J/cm2 average fluence.

[0140] FIGURE 85D also shows MTT histo-chemistry of ex vivo human skin treated with ~1708nm laser and cold window (5 seconds precool; 2mm diameter spot exposure for 3 seconds) at 830mW corresponding to ~80 J/cm2 average fluence.

DETAILED DESCRIPTION

[0141] SECTION 1: NEAR-INFRARED LASERS FOR NON-INVASIVE MONITORING OF GLUCOSE, KETONES, HBA1C, AND OTHER BLOOD CONSTITUENTS

[0142] As required, detailed embodiments of the present disclosure are described herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the disclosure that may be embodied in various and alternative forms. The figures are not necessarily to scale; some features may be exaggerated or minimized to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as

limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the present disclosure.

[0143] Various ailments or diseases may require measurement of the concentration of one or more blood constituents. For example, diabetes may require measurement of the blood glucose and HbA1c levels. On the other hand, diseases or disorders characterized by impaired glucose metabolism may require the measurement of ketone bodies in the blood. Examples of impaired glucose metabolism diseases include Alzheimer's, Parkinson's, Huntington's, and Lou Gehrig's or amyotrophic lateral sclerosis (ALS). Techniques related to near-infrared spectroscopy or hyper-spectral imaging may be particularly advantageous for non-invasive monitoring of some of these blood constituents.

[0144] As used throughout this document, the term "couple" and or "coupled" refers to any direct or indirect communication between two or more elements, whether or not those elements are physically connected to one another. As used throughout this disclosure, the term "spectroscopy" means that a tissue or sample is inspected by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, refractive index, or opacity. In one embodiment, "spectroscopy" may mean that the wavelength of the light source is varied, and the transmission, absorption or reflectivity of the tissue or sample is measured as a function of wavelength. In another embodiment, "spectroscopy" may mean that the wavelength dependence of the transmission, absorption or reflectivity is compared between different spatial locations on a tissue or sample. As an illustration, the "spectroscopy" may be performed by varying the wavelength of the light source, or by using a broadband light source and analyzing the signal using a spectrometer, wavemeter, or optical spectrum analyzer.

[0145] As used throughout this document, the term "fiber laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein at least a part of the laser comprises an optical fiber. For instance, the fiber in the "fiber laser" may comprise one of or a combination of a single mode fiber, a multi-mode fiber, a mid-infrared fiber, a photonic crystal fiber, a doped fiber, a gain fiber, or, more generally, an approximately cylindrically shaped waveguide or light-pipe. In one embodiment, the gain fiber may be doped with rare earth material, such as ytterbium, erbium, and/or thulium. In another embodiment, the mid-infrared fiber may comprise one or a

combination of fluoride fiber, ZBLAN fiber, chalcogenide fiber, tellurite fiber, or germanium doped fiber. In yet another embodiment, the single mode fiber may include standard single-mode fiber, dispersion shifted fiber, non-zero dispersion shifted fiber, high-nonlinearity fiber, and small core size fibers.

[0146] As used throughout this disclosure, the term "pump laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein the output light or optical beam is coupled to a gain medium to excite the gain medium, which in turn may amplify another input optical signal or beam. In one particular example, the gain medium may be a doped fiber, such as a fiber doped with ytterbium, erbium or thulium. In one embodiment, the "pump laser" may be a fiber laser, a solid state laser, a laser involving a nonlinear crystal, an optical parametric oscillator, a semiconductor laser, or a plurality of semiconductor lasers that may be multiplexed together. In another embodiment, the "pump laser" may be coupled to the gain medium by using a fiber coupler, a dichroic mirror, a multiplexer, a wavelength division multiplexer, a grating, or a fused fiber coupler.

[0147] As used throughout this document, the term "super-continuum" and or "supercontinuum" and or "SC" refers to a broadband light beam or output that comprises a plurality of wavelengths. In a particular example, the plurality of wavelengths may be adjacent to one-another, so that the spectrum of the light beam or output appears as a continuous band when measured with a spectrometer. In one embodiment, the broadband light beam may have a bandwidth of at least 10nm. In another embodiment, the "super-continuum" may be generated through nonlinear optical interactions in a medium, such as an optical fiber or nonlinear crystal. For example, the "super-continuum" may be generated through one or a combination of nonlinear activities such as four-wave mixing, the Raman effect, modulational instability, and self-phase modulation.

[0148] As used throughout this disclosure, the terms "optical light" and or "optical beam" and or "light beam" refer to photons or light transmitted to a particular location in space. The "optical light" and or "optical beam" and or "light beam" may be modulated or unmodulated, which also means that they may or may not contain information. In one embodiment, the "optical

light" and or "optical beam" and or "light beam" may originate from a fiber, a fiber laser, a laser, a light emitting diode, a lamp, a pump laser, or a light source.

[0149] SPECTRUM FOR GLUCOSE

[0150] One molecule of interest is glucose. The glucose molecule has the chemical formula C6H12O6, so it has a number of hydro-carbon bonds. An example of the infrared transmittance of glucose 100 is illustrated in FIGURE 1. The vibrational spectroscopy shows that the strongest lines for bending and stretching modes of C-H and O-H bonds lie in the wavelength range of approximately 6-12 microns. However, light sources and detectors are more difficult in the mid-wave infrared and long-wave infrared, and there is also strongly increasing water absorption in the human body beyond about 2.5 microns. Although weaker, there are also non-linear combinations of stretching and bending modes between about 2 to 2.5 microns, and first overtone of C-H stretching modes between approximately 1.5-1.8 microns. These signatures may fall in valleys of water absorption, permitting non-invasive detection through the body. In addition, there are yet weaker features from the second overtones and higher-order combinations between about 0.8-1.2 microns; in addition to being weaker, these features may also be masked by absorption in the hemoglobin. Hence, the short-wave infrared (SWIR) wavelength range of approximately 1.4 to 2.5 microns may be an attractive window for near-infrared spectroscopy of blood constituents.

[0151] As an example, measurements of the optical absorbance 200 of hemoglobin, glucose and HbA1c have been performed using a Fourier-Transform Infrared Spectrometer – FTIR. As FIGURE 2 shows, in the SWIR wavelength range hemoglobin is nearly flat in spectrum 201 (the noise at the edges is due to the weaker light signal in the measurements). On the other hand, the glucose absorbance 202 has at least five distinct peaks near 1587nm, 1750nm, 2120nm, 2270nm and 2320nm.

[0152] FIGURE 3A overlaps 300 the normalized absorbance of glucose 301 with the absorbance of water 302 (not drawn to scale). It may be seen that water has an absorbance feature between approximately 1850nm and 2050nm, but water 302 also has a nice transmission window between approximately 1500-1850nm and 2050 to 2500nm. For wavelengths less than about 1100nm, the absorption of hemoglobin 351 and oxygenated hemoglobin 352 in FIGURE 3B has

a number of features 350, which may make it more difficult to measure blood constituents. Also, beyond 2500nm the water absorption becomes considerably stronger over a wide wavelength range. Therefore, an advantageous window for measuring glucose and other blood constituents may be in the SWIR between 1500 and 1850nm and 2050 to 2500nm. These are exemplary wavelength ranges, and other ranges can be used that would still fall within the scope of this disclosure.

[0153] One further consideration in choosing the laser wavelength is known as the "eye safe" window for wavelengths longer than about 1400nm. In particular, wavelengths in the eye safe window may not transmit down to the retina of the eye, and therefore, these wavelengths may be less likely to create permanent eye damage. The near-infrared wavelengths have the potential to be dangerous, because the eye cannot see the wavelengths (as it can in the visible), yet they can penetrate and cause damage to the eye. Even if a practitioner is not looking directly at the laser beam, the practitioner's eyes may receive stray light from a reflection or scattering from some surface. Hence, it can always be a good practice to use eye protection when working around lasers. Since wavelengths longer than about 1400nm are substantially not transmitted to the retina or substantially absorbed in the retina, this wavelength range is known as the eye safe window. For wavelengths longer than 1400nm, in general only the cornea of the eye may receive or absorb the light radiation.

[0154] Beyond measuring blood constituents such as glucose using FTIR spectrometers, measurements have also been conducted in another embodiment using super-continuum lasers, which will be described later in this disclosure. In this particular embodiment, some of the exemplary preliminary data for glucose absorbance are illustrated in FIGURES 4A and 4B. The optical spectra 401 in FIGURE 4A for different levels of glucose concentration in the wavelength range between 2000 and 2400nm show the three absorption peaks near 2120nm (2.12μm), 2270nm (2.27μm) and 2320nm (2.32μm). Moreover, the optical spectra 402 in FIGURE 4B for different levels of glucose concentration in the wavelength range between 1500 and 1800nm show the two broader absorption peaks near 1587nm and 1750nm. It should be appreciated that although data measured with FTIR spectrometers or super-continuum lasers have been illustrated, other light sources can also be used to obtain the data, such as super-luminescent laser diodes, light emitting

diodes, a plurality of laser diodes, or even bright lamp sources that generate adequate light in the SWIR.

[0155] Although glucose has a distinctive signature in the SWIR wavelength range, one problem of non-invasive glucose monitoring is that many other blood constituents also have hydrocarbon bonds. Consequently, there can be interfering signals from other constituents in the blood. As an example, FIGURE 5 illustrates the spectrum 500 for different blood constituents in the wavelength range of 2 to 2.45 microns. The glucose absorption spectrum 501 can be unique with its three peaks in this wavelength range. However, other blood constituents such as triacetin 502, ascorbate 503, lactate 504, alanine 505, urea 506, and BSA 507 also have spectral features in this wavelength range. To distinguish the glucose 501 from these overlapping spectra, it may be advantageous to have information at multiple wavelengths. In addition, it may be advantageous to use pattern matching algorithms and other software and mathematical methods to identify the blood constituents of interest. In one embodiment, the spectrum may be correlated with a library of known spectra to determine the overlap integrals, and a threshold function may be used to quantify the concentration of different constituents. This is just one way to perform the signal processing, and many other techniques, algorithms, and software may be used and would fall within the scope of this disclosure.

[0156] KETONE BODIES MONITORING

[0157] Beyond glucose, there are many other blood constituents that may also be of interest for health or disease monitoring. In another embodiment, it may be desirous to monitor the level of ketone bodies in the blood stream. Ketone bodies are three water-soluble compounds that are produced as by-products when fatty acids are broken down for energy in the liver. Two of the three are used as a source of energy in the heart and brain, while the third is a waste product excreted from the body. In particular, the three endogenous ketone bodies are acetone, acetoacetic acid, and beta-hydroxybutyrate or 3-hydroxybutyrate, and the waste product ketone body is acetone.

[0158] Ketone bodies may be used for energy, where they are transported from the liver to other tissues. The brain may utilize ketone bodies when sufficient glucose is not available for energy. For instance, this may occur during fasting, strenuous exercise, low carbohydrate,

ketogenic diet and in neonates. Unlike most other tissues that have additional energy sources such as fatty acids during periods of low blood glucose, the brain cannot break down fatty acids and relies instead on ketones. In one embodiment, these ketone bodies are detected.

[0159] Ketone bodies may also be used for reducing or eliminating symptoms of diseases or disorders characterized by impaired glucose metabolism. For example, diseases associated with reduced neuronal metabolism of glucose include Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis (ALS, also called Lou Gehrig's disease), Huntington's disease and epilepsy. In one embodiment, monitoring of alternate sources of ketone bodies that may be administered orally as a dietary supplement or in a nutritional composition to counteract some of the glucose metabolism impairments is performed. However, if ketone bodies supplements are provided, there is also a need to monitor the ketone level in the blood stream. For instance, if elevated levels of ketone bodies are present in the body, this may lead to ketosis; hyperketonemia is also an elevated level of ketone bodies in the blood. In addition, both acetoacetic acid and beta-hydroxybutyric acid are acidic, and, if levels of these ketone bodies are too high, the pH of the blood may drop, resulting in ketoacidosis.

[0160] The general formula for ketones is CnH2n0. In organic chemistry, a ketone is an organic compound with the structure RC(=O)R', where R and R' can be a variety of carbon-containing substituents. It features a carbonyl group (C=O) bonded to two other carbon atoms. Because the ketones contain the hydrocarbon bonds, there might be expected to be features in the SWIR, similar in structure to those found for glucose.

[0161] The infrared spectrum 600 for the ketone 3-hydroxybutyrate is illustrated in FIGURE 6. Just as in glucose, there are significant features in the mid- and long-wave infrared between 6 to 12 microns, but these may be difficult to observe non-invasively. On the other hand, there are some features in the SWIR that may be weaker, but they could potentially be observed non-invasively, perhaps through blood and water.

[0162] The optical spectra 700 for ketones as well as some other blood constituents are exemplified in FIGURE 7 in the wavelength range of 2100nm to 2400nm. In this embodiment, the absorbance for ketones is 701, while the absorbance for glucose is 702. However, there are also features in this wavelength range for other blood constituents, such as urea 703, albumin or

blood protein 704, creatinine 705, and nitrite 706. In this wavelength range of 2100 to 2400nm, the features for ketone 701 seem more spectrally pronounced than even glucose.

[0163] Different signal processing techniques can be used to enhance the spectral differences between different constituents. In one embodiment, the first or second derivatives of the spectra may enable better discrimination between substances. The first derivative may help remove any flat offset or background, while the second derivative may help to remove any sloped offset or background. In some instances, the first or second derivative may be applied after curve fitting or smoothing the reflectance, transmittance, or absorbance. For example, FIGURE 8A illustrates the derivative spectra for ketone 801 and glucose 802, which can be distinguished from the derivative spectra for protein 803, urea 804 and creatinine 805. Based on FIGURE 8A, it appears that ketones 801 may have a more pronounced difference than even glucose 802 in the wavelength range between 2100 and 2400nm. Therefore, ketone bodies should also be capable of being monitored using a non-invasive optical technique in the SWIR, and a different pattern matching library could be used for glucose and ketones.

[0164] HEMOGLOBIN A1C MONITORING

[0165] Another blood constituent that may be of interest for monitoring of health or diseases is hemoglobin A1c, also known as HbA1c or glycated hemoglobin (glycol-hemoglobin or glycosylated hemoglobin). HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. Thus, HbA1c may serve as a marker for average blood glucose levels over the previous months prior to the measurements.

[0166] In one embodiment, when a physician suspects that a patient may be diabetic, the measurement of HbA1c may be one of the first tests that are conducted. An HbA1c level less than approximately 6% may be considered normal. On the other hand, an HbA1c level greater than approximately 6.5% may be considered to be diabetic. In diabetes mellitus, higher amounts of HbA1c indicate poorer control of blood glucose levels. Thus, monitoring the HbA1c in diabetic patients may improve treatment. Current techniques for measuring HbA1c require drawing blood,

which may be inconvenient and painful. The point-of-care devices use immunoassay or boronate affinity chromatography, as an example. Thus, there is also an unmet need for non-invasive monitoring of HbA1c.

[0167] FIGURE 2 illustrates the FTIR measurements of HbA1c absorbance 203 over the wavelength range between 1500 and 2400nm for a concentration of approximately 1mg/ml. Whereas the absorbance of hemoglobin 201 over this wavelength range is approximately flat, the HbA1c absorbance 203 shows broad features and distinct curvature. Although the HbA1c absorbance 203 does not appear to exhibit as pronounced features as glucose 202, the non-invasive SWIR measurement should be able to detect HbA1c with appropriate pattern matching algorithms. Moreover, the spectrum for HbA1c may be further enhanced by using first or second derivative data, as seen for ketones in FIGURE 8A. Beyond absorption, reflectance, or transmission spectroscopy, it may also be possible to detect blood constituents such as HbA1c using Raman spectroscopy or surface-enhanced Raman spectroscopy. In general, Raman spectroscopy may require higher optical power levels.

[0168] As an illustration, non-invasive measurement of blood constituents such as glucose, ketone bodies, and HbA1c has been discussed thus far. However, other blood constituents can also be measured using similar techniques, and these are also intended to be covered by this disclosure. In other embodiments, blood constituents such as proteins, albumin, urea, creatinine or nitrites could also be measured. For instance, the same type of SWIR optical techniques might be used, but the pattern matching algorithms and software could use different library features or functions for the different constituents.

[0169] In yet another embodiment, the optical techniques described in this disclosure could also be used to measure levels of triglycerides. Triglycerides are bundles of fats that may be found in the blood stream, particularly after ingesting meals. The body manufactures triglycerides from carbohydrates and fatty foods that are eaten. In other words, triglycerides are the body's storage form of fat. Triglycerides are comprised of three fatty acids attached to a glycerol molecule, and measuring the level of triglycerides may be important for diabetics. The triglyceride levels or concentrations in blood may be rated as follows: desirable or normal may be less than 150 mg/dl; borderline high may be 150-199 mg/dl; high may be 200-499 mg/dl; and very high may be

500mg/dl or greater. FIGURE 8B illustrates one example of the near-infrared absorbance 825 for triglycerides. There are distinct absorbance peaks in the spectrum that should be measurable. The characteristic absorption bands may be assigned as follows: (a) the first overtones of C-H stretching vibrations (1600-1900nm); (b) the region of second overtones of C-H stretching vibrations (1100-1250nm); and, (c) two regions (2000-2200nm and 1350-1500nm) that comprise bands due to combinations of C-H stretching vibrations and other vibrational modes.

[0170] A further example of blood compositions that can be detected or measured using near-infrared light includes cholesterol monitoring. For example, FIGURE 8C shows the near-infrared reflectance spectrum for cholesterol 850 with wavelength in microns (μm). Distinct absorption peaks are observable near 1210nm (1.21 μm), 1720nm (1.72 μm), and between 2300-2500nm (2.3-2.5μm). Also, there are other features near 1450nm (1.45μm) and 2050nm (2.05μm). In FIGURE 8D the near-infrared reflectances 875 are displayed versus wavelength (nm) for various blood constituents. The spectrum for cholesterol 876 is overlaid with glucose 877, albumin 878, uric acid 879, and urea 880. As may be noted from FIGURE 8D, at about 1720nm and 2300nm, cholesterol 876 reaches approximate reflectance peaks, while some of the other analytes are in a more gradual mode. Various signal processing methods may be used to identify and quantify the concentration of cholesterol 876 and/or glucose 877, or some of the other blood constituents.

[0171] As illustrated by FIGURES 5 and 7, one of the issues in measuring a particular blood constituent is the interfering and overlapping signal from other blood constituents. The selection of the constituent of interest may be improved using a number of techniques. For example, a higher light level or intensity may improve the signal-to-noise ratio for the measurement. Second, mathematical modeling and signal processing methodologies may help to reduce the interference, such as multivariate techniques, multiple linear regression, and factor-based algorithms, for example. For instance, a number of mathematical approaches include multiple linear regression, partial least squares, and principal component regression (PCR). Also, as illustrated in FIGURE 8A, various mathematical derivatives, including the first and second derivatives, may help to accentuate differences between spectra. In addition, by using a wider wavelength range and using more sampling wavelengths may improve the ability to discriminate one signal from another. These are just examples of some of the methods of improving the ability

to discriminate between different constituents, but other techniques may also be used and are intended to be covered by this disclosure.

[0172] INTERFERENCE FROM SKIN

[0173] Several proposed non-invasive glucose monitoring techniques rely on transmission, absorption, and/or diffuse reflection through the skin to measure blood constituents or blood analytes in veins, arteries, capillaries or in the tissue itself. However, on top of the interference from other blood constituents or analytes, the skin also introduces significant interference. For example, chemical, structural, and physiological variations occur that may produce relatively large and nonlinear changes in the optical properties of the tissue sample. In one embodiment, the near-infrared reflectance or absorbance spectrum may be a complex combination of the tissue scattering properties that result from the concentration and characteristics of a multiplicity of tissue components including water, fat, protein, collagen, elastin, and/or glucose. Moreover, the optical properties of the skin may also change with environmental factors such as humidity, temperature and pressure. Physiological variation may also cause changes in the tissue measurement over time and may vary based on lifestyle, health, aging, etc. The structure and composition of skin may also vary widely among individuals, between different sites within an individual, and over time on the same individual. Thus, the skin introduces a dynamic interference signal that may have a wide variation due to a number of parameters.

[0174] FIGURE 9 shows a schematic cross-section of human skin 900, 901. The top layer of the skin is epidermis 902, followed by a layer of dermis 903 and then subcutaneous fat 904 below the dermis. The epidermis 902, with a thickness of approximately 10-150 microns, may provide a barrier to infection and loss of moisture and other body constituents. The dermis 903 ranges in thickness from approximately 0.5mm to 4mm (averages approximately 1.2mm over most of the body) and may provide the mechanical strength and elasticity of skin.

[0175] In the dermis 903, water may account for approximately 70% of the volume. The next most abundant constituent in the dermis 903 may be collagen 905, a fibrous protein comprising 70-75% of the dry weight of the dermis 903. Elastin fibers 906, also a protein, may also be plentiful in the dermis 903, although they constitute a smaller portion of the bulk. In addition, the dermis 903 may contain a variety of structures (e.g., sweat glands, hair follicles with

adipose rich sebaceous glands 907 near their roots, and blood vessels) and other cellular constituents.

[0176] Below the dermis 903 lies the subcutaneous layer 904 comprising mostly adipose tissue. The subcutaneous layer 904 may be by volume approximately 10% water and may be comprised primarily of cells rich in triglycerides or fat. With this complicated structure of the skin 900,901, the concentration of glucose may vary in each layer according to a variety of factors including the water content, the relative sizes of the fluid compartments, the distribution of capillaries, the perfusion of blood, the glucose uptake of cells, the concentration of glucose in blood, and the driving forces (e.g., osmotic pressure) behind diffusion.

[0177] To better understand the interference that the skin introduces when attempting to measure glucose, the absorption coefficient for the various skin constituents should be examined. For example, FIGURE 10 illustrates 1000 the absorption coefficients for water (including scattering) 1001, adipose 1002, collagen 1003 and elastin 1004. Note that the absorption curves for water 1001 and adipose 1002 are calibrated, whereas the absorption curves for collagen 1003 and elastin 1004 are in arbitrary units. Also shown are vertical lines demarcating the wavelengths near 1210nm 1005 and 1720nm 1006. In general, the water absorption increases with increasing wavelength. With the increasing absorption beyond about 2000nm, it may be difficult to achieve deeper penetration into biological tissue in the infrared wavelengths beyond approximately 2500nm.

[0178] Although the absorption coefficient may be useful for determining the material in which light of a certain infrared wavelength will be absorbed, to determine the penetration depth of the light of a certain wavelength may also require the addition of scattering loss to the curves. For example, the water curve 1001 includes the scattering loss curve in addition to the water absorption. In particular, the scattering loss can be significantly higher at shorter wavelengths. In one embodiment, near the wavelength of 1720nm (vertical line 1006 shown in FIGURE 10), the adipose absorption 1002 can still be higher than the water plus scattering loss 1001. For tissue that contains adipose, collagen and elastin, such as the dermis of the skin, the total absorption can exceed the light energy lost to water absorption and light scattering at 1720nm. On the other hand,

at 1210nm the adipose absorption 1002 can be considerably lower than the water plus scattering loss 1001, particularly since the scattering loss can be dominant at these shorter wavelengths.

[0179] The interference for glucose lines observed through skin may be illustrated by overlaying the glucose lines over the absorption curves 1000 for the skin constituents. For example, FIGURE 2 illustrated that the glucose absorption 202 included features centered around 1587nm, 1750nm, 2120nm, 2270nm and 2320nm. On FIGURE 10 vertical lines have been drawn at the glucose line wavelengths of 1587nm 1007, 1750nm 1008, 2120nm 1009, 2270nm 1010 and 2320nm 1011. In one embodiment, it may be difficult to detect the glucose lines near 1750nm 1008, 2270nm 1010 and 2320nm 1011 due to significant spectral interference from other skin constituents. On the other hand, the glucose line near 1587m 1007 may be more easily detected because it peaks while most of the other skin constituents are sloped downward toward an absorption valley. Moreover, the glucose line near 2120nm 1009 may also be detectable for similar reasons, although adipose may have conflicting behavior due to local absorption minimum and maximum nearby in wavelength.

[0180] Thus, beyond the problem of other blood constituents or analytes having overlapping spectral features (e.g., FIGURE 5), it may be difficult to observe glucose spectral signatures through the skin and its constituents of water, adipose, collagen and elastin. One approach to overcoming this difficulty may be to try to measure the blood constituents in veins that are located at relatively shallow distances below the skin. Veins may be more beneficial for the measurement than arteries, since arteries tend to be located at deeper levels below the skin. Also, in one embodiment it may be advantageous to use a differential measurement to subtract out some of the interfering absorption lines from the skin. For example, an instrument head may be designed to place one probe above a region of skin over a blood vein, while a second probe may be placed at a region of the skin without a noticeable blood vein below it. Then, by differencing the signals from the two probes, at least part of the skin interference may be cancelled out.

[0181] Two representative embodiments for performing such a differential measurement are illustrated in FIGURE 11 and FIGURE 12. In one embodiment shown in FIGURE 11, the dorsal of the hand 1100 may be used for measuring blood constituents or analytes. The dorsal of the hand 1100 may have regions that have distinct veins 1101 as well as regions where the veins

are not as shallow or pronounced 1102. By stretching the hand and leaning it backwards, the veins 1101 may be accentuated in some cases. A near-infrared diffuse reflectance measurement may be performed by placing one probe 1103 above the vein-rich region 1101. To turn this into a differential measurement, a second probe 1104 may be placed above a region without distinct veins 1102. Then, the outputs from the two probes may be subtracted 1105 to at least partially cancel out the features from the skin. The subtraction may be done preferably in the electrical domain, although it can also be performed in the optical domain or digitally/mathematically using sampled data based on the electrical and/or optical signals. Although one example of using the dorsal of the hand 1100 is shown, many other parts of the hand can be used within the scope of this disclosure. For example, alternate methods may use transmission through the webbing between the thumb and the fingers 1106, or transmission or diffuse reflection through the tips of the fingers 1107.

[0182] In another embodiment, the dorsal of the foot 1200 may be used instead of the hand. One advantage of such a configuration may be that for self-testing by a user, the foot may be easier to position the instrument using both hands. One probe 1203 may be placed over regions where there are more distinct veins 1201, and a near-infrared diffuse reflectance measurement may be made. For a differential measurement, a second probe 1204 may be placed over a region with less prominent veins 1202, and then the two probe signals may be subtracted, either electronically or optically, or may be digitized/sampled and processed mathematically depending on the particular application and implementation. As with the hand, the differential measurements may be intended to compensate for or subtract out (at least in part) the interference from the skin. Since two regions are used in close proximity on the same body part, this may also aid in removing some variability in the skin from environmental effects such as temperature, humidity, or pressure. In addition, it may be advantageous to first treat the skin before the measurement, by perhaps wiping with a cloth or treated cotton ball, applying some sort of cream, or placing an ice cube or chilled bag over the region of interest.

[0183] Although two embodiments have been described, many other locations on the body may be used using a single or differential probe within the scope of this disclosure. In yet another embodiment, the wrist may be advantageously used, particularly where a pulse rate is typically monitored. Since the pulse may be easily felt on the wrist, there is underlying the region a distinct

blood flow. Other embodiments may use other parts of the body, such as the ear lobes, the tongue, the inner lip, the nails, the eye, or the teeth. Some of these embodiments will be further described below. The ear lobes or the tip of the tongue may be advantageous because they are thinner skin regions, thus permitting transmission rather than diffuse reflection. However, the interference from the skin is still a problem in these embodiments. Other regions such as the inner lip or the bottom of the tongue may be contemplated because distinct veins are observable, but still the interference from the skin may be problematic in these embodiments. The eye may seem as a viable alternative because it is more transparent than skin. However, there are still issues with scattering in the eye. For example, the anterior chamber of the eye (the space between the cornea and the iris) comprises a fluid known as aqueous humor. However, the glucose level in the eye chamber may have a significant temporal lag on changes in the glucose level compared to the blood glucose level.

[0184] Because of the complexity of the interference from skin in non-invasive glucose monitoring (e.g., FIGURE 10), other parts of the body without skin above blood vessels or capillaries may be alternative candidates for measuring blood constituents. One embodiment may involve transmission or reflection through human nails. As an example, FIGURE 13 illustrates a typical human nail tissue structure 1300 and the capillary vessels below it. The fingernail 1301 is approximately 1mm thick, and below this resides a layer of epidermis 1302 with a thickness of approximately 1mm. The dermis 1304 is also shown, and within particularly the top about 0.5mm of dermis are a significant number of capillary vessels. To measure the blood constituents, the light exposed on the top of the fingernail must penetrate about 2-2.5mm or more, and the reflected light (round trip passage) should be sufficiently strong to measure. In one embodiment, the distance required to penetrate could be reduced by drilling a hole in the fingernail 1301.

[0185] In this alternative embodiment using the fingernail, there may still be interference from the nail's spectral features. For example, FIGURE 14 illustrates the attenuation coefficient 1400 for seven nail samples that are allowed to stand in an environment with a humidity level of 14%. These coefficients are measured using an FTIR spectrometer over the near-infrared wavelength range of approximately 1 to 2.5 microns. These spectra are believed to correspond to the spectra of keratin contained in the nail plate. The base lines for the different samples are believed to differ because of the influence of scattering. Several of the absorption peaks observed

correspond to peaks of keratin absorption, while other features may appear from the underlying epidermis and dermis. It should also be noted that the attenuation coefficients 1400 also vary considerably depending on humidity level or water content as well as temperature and other environmental factors. Moreover, the attenuation coefficient may also change in the presence of nail polish of various sorts.

[0186] Similar to skin, the large variations in attenuation coefficient for fingernails also may interfere with the absorption peaks of glucose. As an example, in FIGURE 14 below the fingernail spectrum is also shown the glucose spectrum 1401 for two different glucose concentrations. The vertical lines 1402, 1403, 1404, 1405 and 1406 are drawn to illustrate the glucose absorption peaks and where they lie on the fingernail spectra 1400. As is apparent, the nail has interfering features that may be similar to skin, particularly since both have spectra that vary not only in wavelength but also with environmental factors. In one embodiment, it may be possible to see the glucose peaks 1402 and 1404 through the fingernail, but it may be much more difficult to observe the glucose peaks near 1403, 1405 and 1406.

[0187] TRANSMISSION OR REFLECTION THROUGH TEETH

[0188] Yet another embodiment may observe the transmittance or reflectance through teeth to measure blood constituents or analytes. FIGURE 15 illustrates an exemplary structure of a tooth 1500. The tooth 1500 has a top layer called the crown 1501 and below that a root 1502 that reaches well into the gum 1506 and bone 1508 of the mouth. The exterior of the crown 1501 is an enamel layer 1503, and below the enamel is a layer of dentine 1504 that sits atop a layer of cementum 1507. Below the dentine 1504 is a pulp region 1505, which comprises within it blood vessels 1509 and nerves 1510. If the light can penetrate the enamel 1503 and dentine 1504, then the blood flow and blood constituents can be measured through the blood vessels in the dental pulp 1505. While it may be true that the amount of blood flow in the dental pulp 1505 may be less since it comprises capillaries, the smaller blood flow could still be advantageous if there is less interfering spectral features from the tooth.

[0189] The transmission, absorption and reflection from teeth has been studied in the near infrared, and, although there are some features, the enamel and dentine appear to be fairly transparent in the near infrared (particularly wavelengths between 1500 and 2500nm). For

example, the absorption or extinction ratio for light transmission has been studied. FIGURE 16A illustrates the attenuation coefficient 1600 for dental enamel 1601 (filled circles) and the absorption coefficient of water 1602 (open circles) versus wavelength. Near-infrared light may penetrate much further without scattering through all the tooth enamel, due to the reduced scattering coefficient in normal enamel. Scattering in enamel may be fairly strong in the visible, but decreases as approximately 1/(wavelength)3 [i.e., inverse of the cube of the wavelength] with increasing wavelength to a value of only 2-3 cm-1 at 1310nm and 1550nm in the near infrared. Therefore, enamel may be virtually transparent in the near infrared with optical attenuation 1-2 orders of magnitude less than in the visible range.

[0190] As another example, FIGURE 16B illustrates the absorption spectrum 1650 of intact enamel 1651 (dashed line) and dentine 1652 (solid line) in the wavelength range of approximately 1.2 to 2.4 microns. In the near infrared there are two absorption bands around 1.5 and 2 microns. The band with a peak around 1.57 microns may be attributed to the overtone of valent vibration of water present in both enamel and dentine. In this band, the absorption is greater for dentine than for enamel, which may be related to the large water content in this tissue. In the region of 2 microns, dentine may have two absorption bands, and enamel one. The band with a maximum near 2.1 microns may belong to the overtone of vibration of PO hydroxyapatite groups, which is the main substance of both enamel and dentine. Moreover, the band with a peak near 1.96 microns in dentine may correspond to water absorption (dentine may contain substantially higher water than enamel).

[0191] In addition to the absorption coefficient, the reflectance from intact teeth and teeth with dental caries (e.g., cavities) has been studied. In one embodiment, FIGURE 17 shows the near infrared spectral reflectance 1700 over the wavelength range of approximately 800nm to 2500nm from an occlusal (e.g., top/bottom) tooth surface 1704. The curve with black diamonds 1701 corresponds to the reflectance from a sound, intact tooth section. The curve with asterisks * 1702 corresponds to a tooth section with an enamel lesion. The curve with circles 1703 corresponds to a tooth section with a dentine lesion. Thus, when there is a lesion, more scattering occurs and there may be an increase in the reflected light.

[0192] For wavelengths shorter than approximately 1400nm, the shapes of the spectra remain similar, but the amplitude of the reflection changes with lesions. Between approximately 1400nm and 2500nm, an intact tooth 1701 has low reflectance (e.g., high transmission), and the reflectance appears to be more or less independent of wavelength. On the other hand, in the presence of lesions 1702 and 1703, there is increased scattering, and the scattering loss may be wavelength dependent. For example, the scattering loss may decrease as $1/(\text{wavelength})^3$ -- so, the scattering loss decreases with longer wavelengths. When there is a lesion in the dentine 1703, more water can accumulate in the area, so there is also increased water absorption. For example, the dips near 1450nm and 1900nm correspond to water absorption, and the reflectance dips are particularly pronounced in the dentine lesion 1703. One other benefit of the absorption, transmission or reflectance in the near infrared may be that stains and non-calcified plaque are not visible in this wavelength range, enabling better discrimination of defects, cracks, and demineralized areas.

[0193] Compared with the interference from skin 1000 in FIGURE 10 or fingernails 1400 in FIGURE 14, the teeth appear to introduce much less interference for non-invasive monitoring of blood constituents. The few features in FIGURES 16B or 17 may be calibrated out of the measurement. Also, using an intact tooth 1701 may further minimize any interfering signals. Furthermore, since the tooth comprises relatively hard tissue, higher power from the light sources in the near infrared may be used without damaging the tissue, such as with skin.

[0194] HUMAN INTERFACE FOR MEASUREMENT SYSTEM

[0195] A number of different types of measurements may be used to sample the blood in the dental pulp. The basic feature of the measurements should be that the optical properties are measured as a function of wavelength at a plurality of wavelengths. As further described below, the light source may output a plurality of wavelengths, or a continuous spectrum over a range of wavelengths. In a preferred embodiment, the light source may cover some or all of the wavelength range between approximately 1400nm and 2500nm. The signal may be received at a receiver, which may also comprise a spectrometer or filters to discriminate between different wavelengths. The signal may also be received at a camera, which may also comprise filters or a spectrometer. In an alternate embodiment, the spectral discrimination using filters or a spectrometer may be

placed after the light source rather than at the receiver. The receiver usually comprises one or more detectors (optical-to-electrical conversion element) and electrical circuitry. The receiver may also be coupled to analog to digital converters, particularly if the signal is to be fed to a digital device.

[0196] Referring to FIGURE 15, one or more light sources 1511 may be used for illumination. In one embodiment, a transmission measurement may be performed by directing the light source output 1511 to the region near the interface between the gum 1506 and dentine 1504. In one embodiment, the light may be directed using a light guide or a fiber optic. The light may then propagate through the dental pulp 1505 to the other side, where the light may be incident on one or more detectors or another light guide to transport the signal to a spectrometer, receiver or camera 1512. In another embodiment, the light source may be directed to one or more locations near the interface between the gum 1506 and dentine 1504 (in one example, could be from the two sides of the tooth). The transmitted light may then be detected in the occlusal surface above the tooth using a spectrometer, receiver, or camera 1512. In yet another embodiment, a reflectance measurement may be conducted by directing the light source output 1511 to, for example, the occlusal surface of the tooth, and then detecting the reflectance at a spectrometer, receiver or camera 1513. Although a few embodiments for measuring the blood constituents through a tooth are described, other embodiments and techniques may also be used and are intended to be covered by this disclosure.

[0197] The human interface for the non-invasive measurement of blood constituents may be of various forms. In one embodiment, a "clamp" design 1800 may be used to cap over one or more teeth, as illustrated in FIGURE 18A. The clamp design may be different for different types of teeth, or it may be flexible enough to fit over different types of teeth. For example, different types of teeth include the molars (toward the back of the mouth), the premolars, the canine, and the incisors (toward the front of the mouth). One embodiment of the clamp-type design is illustrated in FIGURE 18A for a molar tooth 1808. The C-clamp 1801 may be made of a plastic or rubber material, and it may comprise a light source input 1802 and a detector output 1803 on the front or back of the tooth.

[0198] The light source input 1802 may comprise a light source directly, or it may have light guided to it from an external light source. Also, the light source input 1802 may comprise a lens system to collimate or focus the light across the tooth. The detector output 1803 may comprise a detector directly, or it may have a light guide to transport the signal to an external detector element. The light source input 1802 may be coupled electrically or optically through 1804 to a light input 1806. For example, if the light source is external in 1806, then the coupling element 1804 may be a light guide, such as a fiber optic. Alternately, if the light source is contained in 1802, then the coupling element 1804 may be electrical wires connecting to a power supply in 1806. Similarly, the detector output 1803 may be coupled to a detector output unit 1807 with a coupling element 1805, which may be one or more electrical wires or a light guide, such as a fiber optic. This is just one example of a clamp over one or more teeth, but other embodiments may also be used and are intended to be covered by this disclosure.

[0199] In yet another embodiment, one or more light source ports and sensor ports may be used in a mouth-guard type design. For example, one embodiment of a dental mouth guard 1850 is illustrated in FIGURE 18B. The structure of the mouth guard 1851 may be similar to mouth guards used in sports (e.g., when playing football or boxing) or in dental trays used for applying fluoride treatment, and the mouth guard may be made from plastic or rubber materials, for example. As an example, the mouth guard may have one or more light source input ports 1852, 1853 and one or more detector output ports 1854, 1855. Although six input and output ports are illustrated, any number of ports may be used.

[0200] Similar to the clamp design describe above, the light source inputs 1852, 1853 may comprise one or more light sources directly, or they may have light guided to them from an external light source. Also, the light source inputs 1852, 1853 may comprise lens systems to collimate or focus the light across the teeth. The detector outputs 1854, 1855 may comprise one or more detectors directly, or they may have one or more light guides to transport the signals to an external detector element. The light source inputs 1852, 1853 may be coupled electrically or optically through 1856 to a light input 1857. For example, if the light source is external in 1857, then the one or more coupling elements 1856 may be one or more light guides, such as a fiber optic. Alternately, if the light sources are contained in 1852, 1853, then the coupling element 1856 may be one or more electrical wires connecting to a power supply in 1857. Similarly, the detector

outputs 1854, 1855 may be coupled to a detector output unit 1859 with one or more coupling elements 1858, which may be one or more electrical wires or one or more light guides, such as a fiber optic. This is just one example of a mouth guard design covering a plurality of teeth, but other embodiments may also be used and are intended to be covered by this disclosure. For instance, the position of the light source inputs and detector output ports could be exchanged, or some mixture of locations of light source inputs and detector output ports could be used.

[0201] Other elements may be added to the human interface designs of FIGURE 18 and are also intended to be covered by this disclosure. For instance, in one embodiment it may be desirable to have replaceable inserts that may be disposable. Particularly in a doctor's office or hospital setting, the same instrument may be used with a plurality of patients. Rather than disinfecting the human interface after each use, it may be preferable to have disposable inserts that can be thrown away after each use. In one embodiment, a thin plastic coating material may enclose the clamp design of FIGURE 18A or mouth guard design of FIGURE 18B. The coating material may be inserted before each use, and then after the measurement is exercised the coating material may be peeled off and replaced. Such a design may save the physician or user considerable time, while at the same time provide the business venture with a recurring cost revenue source. Any coating material or other disposable device may be constructed of a material having suitable optical properties that may be considered during processing of the signals used to detect any anomalies in the teeth.

[0202] LIGHT SOURCES FOR NEAR INFRARED

[0203] There are a number of light sources that may be used in the near infrared. To be more specific, the discussion below will consider light sources operating in the so-called short wave infrared (SWIR), which may cover the wavelength range of approximately 1400nm to 2500nm. Other wavelength ranges may also be used for the applications described in this disclosure, so the discussion below is merely provided for exemplary types of light sources. The SWIR wavelength range may be valuable for a number of reasons. First, the SWIR corresponds to a transmission window through water and the atmosphere. For example, 302 in FIGURE 3A and 1602 in FIGURE 16A illustrate the water transmission windows. Also, through the atmosphere, wavelengths in the SWIR have similar transmission windows due to water vapor in

the atmosphere. Second, the so-called "eye-safe" wavelengths are wavelengths longer than approximately 1400nm. Third, the SWIR covers the wavelength range for nonlinear combinations of stretching and bending modes as well as the first overtone of C-H stretching modes. Thus, for example, glucose and ketones among other substances may have unique signatures in the SWIR. Moreover, many solids have distinct spectral signatures in the SWIR, so particular solids may be identified using stand-off detection or remote sensing. For instance, many explosives have unique signatures in the SWIR.

[0204] Different light sources may be selected for the SWIR based on the needs of the application. Some of the features for selecting a particular light source include power or intensity, wavelength range or bandwidth, spatial or temporal coherence, spatial beam quality for focusing or transmission over long distance, and pulse width or pulse repetition rate. Depending on the application, lamps, light emitting diodes (LEDs), laser diodes (LD's), tunable LD's, super-luminescent laser diodes (SLDs), fiber lasers or super-continuum sources (SC) may be advantageously used. Also, different fibers may be used for transporting the light, such as fused silica fibers, plastic fibers, mid-infrared fibers (e.g., tellurite, chalcogenides, fluorides, ZBLAN, etc), or a hybrid of these fibers.

[0205] Lamps may be used if low power or intensity of light is required in the SWIR, and if an incoherent beam is suitable. In one embodiment, in the SWIR an incandescent lamp that can be used is based on tungsten and halogen, which have an emission wavelength between approximately 500nm to 2500nm. For low intensity applications, it may also be possible to use thermal sources, where the SWIR radiation is based on the black body radiation from the hot object. Although the thermal and lamp based sources are broadband and have low intensity fluctuations, it may be difficult to achieve a high signal-to-noise ratio in a non-invasive blood constituent measurement due to the low power levels. Also, the lamp based sources tend to be energy inefficient.

[0206] In another embodiment, LED's can be used that have a higher power level in the SWIR wavelength range. LED's also produce an incoherent beam, but the power level can be higher than a lamp and with higher energy efficiency. Also, the LED output may more easily be modulated, and the LED provides the option of continuous wave or pulsed mode of operation.

LED's are solid state components that emit a wavelength band that is of moderate width, typically between about 20nm to 40nm. There are also so-called super-luminescent LEDs that may even emit over a much wider wavelength range. In another embodiment, a wide band light source may be constructed by combining different LEDs that emit in different wavelength bands, some of which could preferably overlap in spectrum. One advantage of LEDs as well as other solid state components is the compact size that they may be packaged into.

[0207] In yet another embodiment, various types of laser diodes may be used in the SWIR wavelength range. Just as LEDs may be higher in power but narrower in wavelength emission than lamps and thermal sources, the LDs may be yet higher in power but yet narrower in wavelength emission than LEDs. Different kinds of LDs may be used, including Fabry-Perot LDs, distributed feedback (DFB) LDs, distributed Bragg reflector (DBR) LDs. Since the LDs have relatively narrow wavelength range (typically under 10nm), in one embodiment a plurality of LDs may be used that are at different wavelengths in the SWIR. For example, in a preferred embodiment for non-invasive glucose monitoring, it may be advantageous to use LDs having emission spectra near some or all of the glucose spectral peaks (e.g., near 1587nm, 1750nm, 2120nm, 2270nm, and 2320nm). The various LDs may be spatially multiplexed, polarization multiplexed, wavelength multiplexed, or a combination of these multiplexing methods. Also, the LDs may be fiber pig-tailed or have one or more lenses on the output to collimate or focus the light. Another advantage of LDs is that they may be packaged compactly and may have a spatially coherent beam output. Moreover, tunable LDs that can tune over a range of wavelengths are also available. The tuning may be done by varying the temperature, or electrical current may be used in particular structures, such as distributed Bragg reflector LDs. In another embodiment, external cavity LDs may be used that have a tuning element, such as a fiber grating or a bulk grating, in the external cavity.

[0208] In another embodiment, super-luminescent laser diodes may provide higher power as well as broad bandwidth. An SLD is typically an edge emitting semiconductor light source based on super-luminescence (e.g., this could be amplified spontaneous emission). SLDs combine the higher power and brightness of LDs with the low coherence of conventional LEDs, and the emission band for SLD's may be 5 to 100nm wide, preferably in the 60 to 100nm range. Although

currently SLDs are commercially available in the wavelength range of approximately 400nm to 1700nm, SLDs could and may in the future be made to cover a broader region of the SWIR.

[0209] In yet another embodiment, high power LDs for either direct excitation or to pump fiber lasers and SC light sources may be constructed using one or more laser diode bar stacks. As an example, FIGURE 19 shows an example of the block diagram 1900 or building blocks for constructing the high power LDs. In this embodiment, one or more diode bar stacks 1901 may be used, where the diode bar stack may be an array of several single emitter LDs. Since the fast axis (e.g., vertical direction) may be nearly diffraction limited while the slow-axis (e.g., horizontal axis) may be far from diffraction limited, different collimators 1902 may be used for the two axes.

[0210] Then, the brightness may be increased by spatially combining the beams from multiple stacks 1903. The combiner may include spatial interleaving, it may include wavelength multiplexing, or it may involve a combination of the two. Different spatial interleaving schemes may be used, such as using an array of prisms or mirrors with spacers to bend one array of beams into the beam path of the other. In another embodiment, segmented mirrors with alternate high-reflection and anti-reflection coatings may be used. Moreover, the brightness may be increased by polarization beam combining 1904 the two orthogonal polarizations, such as by using a polarization beam splitter. In one embodiment, the output may then be focused or coupled into a large diameter core fiber. As an example, typical dimensions for the large diameter core fiber range from approximately 100 microns in diameter to 400 microns or more. Alternatively or in addition, a custom beam shaping module 1905 may be used, depending on the particular application. For example, the output of the high power LD may be used directly 1906, or it may be fiber coupled 1907 to combine, integrate, or transport the high power LD energy. These high power LDs may grow in importance because the LD powers can rapidly scale up. For example, instead of the power being limited by the power available from a single emitter, the power may increase in multiples depending on the number of diodes multiplexed and the size of the large diameter fiber. Although FIGURE 19 is shown as one embodiment, some or all of the elements may be used in a high power LD, or additional elements may also be used.

[0211] SWIR SUPER-CONTINUUM LASERS

[0212] Each of the light sources described above have particular strengths, but they also may have limitations. For example, there is typically a trade-off between wavelength range and power output. Also, sources such as lamps, thermal sources, and LEDs produce incoherent beams that may be difficult to focus to a small area and may have difficulty propagating for long distances. An alternative source that may overcome some of these limitations is an SC light source. Some of the advantages of the SC source may include high power and intensity, wide bandwidth, spatially coherent beam that can propagate nearly transform limited over long distances, and easy compatibility with fiber delivery.

[0213] Supercontinuum lasers may combine the broadband attributes of lamps with the spatial coherence and high brightness of lasers. By exploiting a modulational instability initiated supercontinuum (SC) mechanism, an all-fiber-integrated SC laser with no moving parts may be built using commercial-off-the-shelf (COTS) components. Moreover, the fiber laser architecture may be a platform where SC in the visible, near-infrared / SWIR, or mid-IR can be generated by appropriate selection of the amplifier technology and the SC generation fiber. But until now, SC lasers were used primarily in laboratory settings since typically large, table-top, mode-locked lasers were used to pump nonlinear media such as optical fibers to generate SC light. However, those large pump lasers may now be replaced with diode lasers and fiber amplifiers that gained maturity in the telecommunications industry.

[0214] In one embodiment, an all-fiber-integrated, high-powered SC light source 2000 may be elegant for its simplicity (FIGURE 20). The light may be first generated from a seed laser diode 2001. For example, the seed LD 2001 may be a distributed feedback laser diode with a wavelength near 1542 or 1550 nm, with approximately 0.5–2.0 ns pulsed output, and with a pulse repetition rate between a kilohertz to about 100MHz or more. The output from the seed laser diode may then be amplified in a multiple-stage fiber amplifier 2002 comprising one or more gain fiber segments. In one embodiment, the first stage pre-amplifier 2003 may be designed for optimal noise performance. For example, the pre-amplifier 2003 may be a standard erbium-doped fiber amplifier or an erbium/ytterbium doped cladding pumped fiber amplifier. Between amplifier stages 2003 and 2006, it may be advantageous to use band-pass filters 2004 to block amplified spontaneous emission and isolators 2005 to prevent spurious reflections. Then, the power amplifier stage 2006 may use a cladding-pumped fiber amplifier that may be optimized to

minimize nonlinear distortion. The power amplifier fiber 2006 may also be an erbium-doped fiber amplifier, if only low or moderate power levels are to be generated.

[0215] The SC generation 2007 may occur in the relatively short lengths of fiber that follow the pump laser. In one exemplary embodiment, the SC fiber length may range from a few millimeters to 100m or more. In one embodiment, the SC generation may occur in a first fiber 2008 where the modulational-instability initiated pulse break-up primarily occurs, followed by a second fiber 2009 where the SC generation and spectral broadening primarily occurs.

[0216] In one embodiment, one or two meters of standard single-mode fiber (SMF) after the power amplifier stage may be followed by several meters of SC generation fiber. For this example, in the SMF the peak power may be several kilowatts and the pump light may fall in the anomalous group-velocity dispersion regime—often called the soliton regime. For high peak powers in the dispersion regime, the nanosecond pulses may be unstable due to a phenomenon known as modulational instability, which is basically parametric amplification in which the fiber nonlinearity helps to phase match the pulses. As a consequence, the nanosecond pump pulses may be broken into many shorter pulses as the modulational instability tries to form soliton pulses from the quasi-continuous-wave background. Although the laser diode and amplification process starts with approximately nanosecond-long pulses, modulational instability in the short length of SMF fiber may form approximately 0.5 ps to several-picosecond-long pulses with high intensity. Thus, the few meters of SMF fiber may result in an output similar to that produced by mode-locked lasers, except in a much simpler and cost-effective manner.

[0217] The short pulses created through modulational instability may then be coupled into a nonlinear fiber for SC generation. The nonlinear mechanisms leading to broadband SC may include four-wave mixing or self-phase modulation along with the optical Raman effect. Since the Raman effect is self-phase-matched and shifts light to longer wavelengths by emission of optical photons, the SC may spread to longer wavelengths very efficiently. The short-wavelength edge may arise from four-wave mixing, and often times the short wavelength edge may be limited by increasing group-velocity dispersion in the fiber. In many instances, if the particular fiber used has sufficient peak power and SC fiber length, the SC generation process may fill the long-wavelength edge up to the transmission window.

[0218] Mature fiber amplifiers for the power amplifier stage 2006 include ytterbium-doped fibers (near 1060 nm), erbium-doped fibers (near 1550nm), erbium/ytterbium-doped fibers (near 1550 nm), or thulium-doped fibers (near 2000 nm). In various embodiments, candidates for SC fiber 2009 include fused silica fibers (for generating SC between 0.8–2.7 μm), mid-IR fibers such as fluorides, chalcogenides, or tellurites (for generating SC out to 4.5 μm or longer), photonic crystal fibers (for generating SC between 0.4 and 1.7 μm), or combinations of these fibers. Therefore, by selecting the appropriate fiber-amplifier doping for 2006 and nonlinear fiber 2009, SC may be generated in the visible, near-IR / SWIR, or mid-IR wavelength region.

[0219] The configuration 2000 of FIGURE 20 is just one particular example, and other configurations can be used and are intended to be covered by this disclosure. For example, further gain stages may be used, and different types of lossy elements or fiber taps may be used between the amplifier stages. In another embodiment, the SC generation may occur partially in the amplifier fiber and in the pig-tails from the pump combiner or other elements. In yet another embodiment, polarization maintaining fibers may be used, and a polarizer may also be used to enhance the polarization contrast between amplifier stages. Also, not discussed in detail are many accessories that may accompany this set-up, such as driver electronics, pump laser diodes, safety shut-offs, and thermal management and packaging.

[0220] One example of an SC laser that operates in the SWIR used in one embodiment is illustrated in FIGURE 21. This SWIR SC source 2100 produces an output of up to approximately 5W over a spectral range of about 1.5 to 2.4 microns, and this particular laser is made out of polarization maintaining components. The seed laser 2101 is a distributed feedback (DFB) laser operating near 1542nm producing approximately 0.5nanosecond (ns) pulses at an about 8MHz repetition rate. The pre-amplifier 2102 is forward pumped and uses about 2m length of erbium/ytterbium cladding pumped fiber 2103 (often also called dual-core fiber) with an inner core diameter of 12 microns and outer core diameter of 130 microns. The pre-amplifier gain fiber 2103 is pumped using a 10W 940nm laser diode 2105 that is coupled in using a fiber combiner 2104.

[0221] In this particular 5W unit, the mid-stage between amplifier stages 2102 and 2106 comprises an isolator 2107, a band-pass filter 2108, a polarizer 2109 and a fiber tap 2110. The power amplifier 2106 uses a 4m length of the 12/130 micron erbium/ytterbium doped fiber 2111

that is counter-propagating pumped using one or more 30W 940nm laser diodes 2112 coupled in through a combiner 2113. An approximately 1-2 meter length of the combiner pig-tail helps to initiate the SC process, and then a length of PM-1550 fiber 2115 (polarization maintaining, single-mode, fused silica fiber optimized for 1550nm) is spliced 2114 to the combiner output.

[0222] If an output fiber of about 10m in length is used, then the resulting output spectrum 2200 is shown in FIGURE 22. The details of the output spectrum 2200 depend on the peak power into the fiber, the fiber length, and properties of the fiber such as length and core size, as well as the zero dispersion wavelength and the dispersion properties. For example, if a shorter length of fiber is used, then the spectrum actually reaches to longer wavelengths (e.g., a 2m length of SC fiber broadens the spectrum to ~2500nm). Also, if extra-dry fibers are used with less O-H content, then the wavelength edge may also reach to a longer wavelength. To generate more spectrum toward the shorter wavelengths, the pump wavelength (in this case ~1542nm) should be close to the zero dispersion wavelength in the fiber. For example, by using a dispersion shifted fiber or so-called non-zero dispersion shifted fiber, the short wavelength edge may shift to shorter wavelengths.

[0223] Although one particular example of a 5W SWIR-SC has been described, different components, different fibers, and different configurations may also be used consistent with this disclosure. For instance, another embodiment of the similar configuration 2100 in FIGURE 21 may be used to generate high powered SC between approximately 1060 and 1800nm. For this embodiment, the seed laser 2101 may be a 1064nm distributed feedback (DFB) laser diode, the pre-amplifier gain fiber 2103 may be a ytterbium-doped fiber amplifier with 10/125 microns dimensions, and the pump laser 2105 may be a 10W 915nm laser diode. In the mid-stage, a mode field adapter may be included in addition to the isolator 2107, band pass filter 2108, polarizer 2109 and tap 2110. The gain fiber 2111 in the power amplifier may be a 20m length of ytterbium-doped fiber with 25/400 microns dimension for example. The pump 2112 for the power amplifier may be up to six pump diodes providing 30W each near 915nm, for example. For this much pump power, the output power in the SC may be as high as 50W or more.

[0224] In another embodiment, it may be desirous to generate high power SWIR SC over 1.4-1.8 microns and separately 2-2.5 microns (the window between 1.8 and 2 microns may be less

important due to the strong water and atmospheric absorption). For example, the top SC source of FIGURE 23 can lead to bandwidths ranging from about 1400nm to 1800nm or broader, while the lower SC source of FIGURE 23 can lead to bandwidths ranging from about 1900nm to 2500nm or broader. Since these wavelength ranges are shorter than about 2500nm, the SC fiber can be based on fused silica fiber. Exemplary SC fibers include standard single-mode fiber SMF, high-nonlinearity fiber, high-NA fiber, dispersion shifted fiber, dispersion compensating fiber, and photonic crystal fibers. Non-fused-silica fibers can also be used for SC generation, including chalcogenides, fluorides, ZBLAN, tellurites, and germanium oxide fibers.

[0225] In one embodiment, the top of FIGURE 23 illustrates a block diagram for an SC source 2300 capable of generating light between approximately 1400 and 1800nm or broader. As an example, a pump fiber laser similar to FIGURE 21 can be used as the input to a SC fiber 2309. The seed laser diode 2301 can comprise a DFB laser that generates, for example, several milliwatts of power around 1542 or 1553nm. The fiber pre-amplifier 2302 can comprise an erbium-doped fiber amplifier or an erbium/ytterbium doped double clad fiber. In this example a mid-stage amplifier 2303 can be used, which can comprise an erbium/ytterbium doped double-clad fiber. A bandpass filter 2305 and isolator 2306 may be used between the pre-amplifier 2302 and mid-stage amplifier 2303. The power amplifier stage 2304 can comprise a larger core size erbium/ytterbium doped double-clad fiber, and another bandpass filter 2307 and isolator 2308 can be used before the power amplifier 2304. The output of the power amplifier can be coupled to the SC fiber 2309 to generate the SC output 2310. This is just one exemplary configuration for an SC source, and other configurations or elements may be used consistent with this disclosure.

[0226] In yet another embodiment, the bottom of FIGURE 23 illustrates a block diagram for an SC source 2350 capable of generating light between approximately 1900 and 2500nm or broader. As an example, the seed laser diode 2351 can comprise a DFB or DBR laser that generates, for example, several milliwatts of power around 1542 or 1553nm. The fiber pre-amplifier 2352 can comprise an erbium-doped fiber amplifier or an erbium/ytterbium doped double-clad fiber. In this example a mid-stage amplifier 2353 can be used, which can comprise an erbium/ytterbium doped double-clad fiber. A bandpass filter 2355 and isolator 2356 may be used between the pre-amplifier 2352 and mid-stage amplifier 2353. The power amplifier stage 2354 can comprise a thulium doped double-clad fiber, and another isolator 2357 can be used before

the power amplifier 2354. Note that the output of the mid-stage amplifier 2353 can be approximately near 1550nm, while the thulium-doped fiber amplifier 2354 can amplify wavelengths longer than approximately 1900nm and out to about 2100nm. Therefore, for this configuration wavelength shifting may be required between 2353 and 2354. In one embodiment, the wavelength shifting can be accomplished using a length of standard single-mode fiber 2358, which can have a length between approximately 5 and 50 meters, for example. The output of the power amplifier 2354 can be coupled to the SC fiber 2359 to generate the SC output 2360. This is just one exemplary configuration for an SC source, and other configurations or elements can be used consistent with this disclosure. For example, the various amplifier stages can comprise different amplifier types, such as erbium doped fibers, ytterbium doped fibers, erbium/ytterbium co-doped fibers and thulium doped fibers. One advantage of the SC lasers illustrated in FIGURES 20-23 are that they may use all-fiber components, so that the SC laser can be all-fiber, monolithically integrated with no moving parts. The all-integrated configuration can consequently be robust and reliable.

[0227] FIGURES 20-23 are examples of SC light sources that may be advantageously used for SWIR light generation in various medical diagnostic and therapeutic applications. However, many other versions of the SC light sources may also be made that are intended to also be covered by this disclosure. For example, the SC generation fiber could be pumped by a mode-locked laser, a gain-switched semiconductor laser, an optically pumped semiconductor laser, a solid state laser, other fiber lasers, or a combination of these types of lasers. Also, rather than using a fiber for SC generation, either a liquid or a gas cell might be used as the nonlinear medium in which the spectrum is to be broadened.

[0228] Even within the all-fiber versions illustrated such as in FIGURE 21, different configurations could be used consistent with the disclosure. In an alternate embodiment, it may be desirous to have a lower cost version of the SWIR SC laser of FIGURE 21. One way to lower the cost could be to use a single stage of optical amplification, rather than two stages, which may be feasible if lower output power is required or the gain fiber is optimized. For example, the pre-amplifier stage 2102 might be removed, along with at least some of the mid-stage elements. In yet another embodiment, the gain fiber could be double passed to emulate a two stage amplifier. In this example, the pre-amplifier stage 2102 might be removed, and perhaps also some of the mid-

stage elements. A mirror or fiber grating reflector could be placed after the power amplifier stage 2106 that may preferentially reflect light near the wavelength of the seed laser 2101. If the mirror or fiber grating reflector can transmit the pump light near 940nm, then this could also be used instead of the pump combiner 2113 to bring in the pump light 2112. The SC fiber 2115 could be placed between the seed laser 2101 and the power amplifier stage 2106 (SC is only generated after the second pass through the amplifier, since the power level may be sufficiently high at that time). In addition, an output coupler may be placed between the seed laser diode 2101 and the SC fiber, which now may be in front of the power amplifier 2106. In a particular embodiment, the output coupler could be a power coupler or divider, a dichroic coupler (e.g., passing seed laser wavelength but outputting the SC wavelengths), or a wavelength division multiplexer coupler. This is just one further example, but a myriad of other combinations of components and architectures could also be used for SC light sources to generate SWIR light that are intended to be covered by this disclosure.

[0229] WIRELESS LINK TO THE CLOUD

[0230] The non-invasive blood constituent or analytes measurement device may also benefit from communicating the data output to the "cloud" (e.g., data servers and processors in the web remotely connected) via wired and/or wireless communication strategies. The non-invasive devices may be part of a series of biosensors applied to the patient, and collectively these devices form what might be called a body area network or a personal area network. The biosensors and non-invasive devices may communicate to a smart phone, tablet, personal data assistant, computer, and/or other microprocessor-based device, which may in turn wirelessly or over wire and/or fiber optically transmit some or all of the signal or processed data to the internet or cloud. The cloud or internet may in turn send the data to doctors or health care providers as well as the patients themselves. Thus, it may be possible to have a panoramic, high-definition, relatively comprehensive view of a patient that doctors can use to assess and manage disease, and that patients can use to help maintain their health and direct their own care.

[0231] In a particular embodiment 2400, the physiological measurement device or non-invasive blood constituent measurement device 2401 may comprise a transmitter 2403 to communicate over a first communication link 2404 in the body area network or personal area

network to a receiver in a smart phone, tablet cell phone, PDA, or computer 2405. For the measurement device 2401, it may also be advantageous to have a processor 2402 to process some of the physiological data, since with processing the amount of data to transmit may be less (hence, more energy efficient). The first communication link 2404 may operate through the use of one of many wireless technologies such as Bluetooth, Zigbee, WiFi, IrDA (infrared data association), wireless USB, or Z-wave, to name a few. Alternatively, the communication link 2404 may occur in the wireless medical band between 2360 and 2390MHz, which the FCC allocated for medical body area network devices, or in other designated medical device or WMTS bands. These are examples of devices that can be used in the body area network and surroundings, but other devices could also be used and are included in the scope of this disclosure.

[0232] The personal device 2405 may store, process, display, and transmit some of the data from the measurement device 2401. The device 2405 may comprise a receiver, transmitter, display, voice control and speakers, and one or more control buttons or knobs and a touch screen. Examples of the device 2405 include smart phones such as the Apple iPhones® or phones operating on the Android or Microsoft systems. In one embodiment, the device 2405 may have an application, software program, or firmware to receive and process the data from the measurement device 2401. The device 2405 may then transmit some or all of the data or the processed data over a second communication link 2406 to the internet or "cloud" 2407. The second communication link 2406 may advantageously comprise at least one segment of a wireless transmission link, which may operate using WiFi or the cellular network. The second communication link 2406 may additionally comprise lengths of fiber optic and/or communication over copper wires or cables.

[0233] The internet or cloud 2407 may add value to the measurement device 2401 by providing services that augment the physiological data collected. In a particular embodiment, some of the functions performed by the cloud include: (a) receive at least a fraction of the data from the device 2405; (b) buffer or store the data received; (c) process the data using software stored on the cloud; (d) store the resulting processed data; and (e) transmit some or all of the data either upon request or based on an alarm. As an example, the data or processed data may be transmitted 2408 back to the originator (e.g., patient or user), it may be transmitted 2409 to a health care provider or doctor, or it may be transmitted 2410 to other designated recipients.

[0234] The cloud 2407 may provide a number of value-add services. For example, the cloud application may store and process the physiological data for future reference or during a visit with the healthcare provider. If a patient has some sort of medical mishap or emergency, the physician can obtain the history of the physiological parameters over a specified period of time. In another embodiment, if the physiological parameters fall out of acceptable range, alarms may be delivered to the user 2408, the healthcare provider 2409, or other designated recipients 2410. These are just some of the features that may be offered, but many others may be possible and are intended to be covered by this disclosure. As an example, the device 2405 may also have a GPS sensor, so the cloud 2407 may be able to provide time, data and position along with the physiological parameters. Thus, if there is a medical emergency, the cloud 2407 could provide the location of the patient to the healthcare provider 2409 or other designated recipients 2410. Moreover, the digitized data in the cloud 2407 may help to move toward what is often called "personalized medicine." Based on the physiological parameter data history, medication or medical therapies may be prescribed that are customized to the particular patient.

[0235] Beyond the above benefits, the cloud application 2407 and application on the device 2405 may also have financial value for companies developing measurement devices 2401 such as a non-invasive blood constituent monitor. In the case of glucose monitors, the companies make the majority of their revenue on the measurement strips. However, with a non-invasive monitor, there is no need for strips, so there is less of an opportunity for recurring costs (e.g., the razor/razor blade model does not work for non-invasive devices). On the other hand, people may be willing to pay a periodic fee for the value-add services provided on the cloud 2407. Diabetic patients, for example, would probably be willing to pay a periodic fee for monitoring their glucose levels, storing the history of the glucose levels, and having alarm warnings when the glucose level falls out of range. Similarly, patients taking ketone bodies supplement for treatment of disorders characterized by impaired glucose metabolism (e.g., Alzheimer's, Parkinson's, Huntington's or ALS) may need to monitor their ketone bodies level. These patients would also probably be willing to pay a periodic fee for the value-add services provided on the cloud 2407. Thus, by leveraging the advances in wireless connectivity and the widespread use of handheld devices such as smart phones that can wirelessly connect to the cloud, businesses can build a recurring cost business model even using non-invasive measurement devices.

[0236] Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for non-invasive monitoring of glucose, ketones, HbA1c and other blood constituents. However, many other medical procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure.

[0237] SECTION 2: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR EARLY DETECTION OF DENTAL CARIES

[0238] Near-infrared (NIR) and SWIR light may be preferred for caries detection compared to visible light imaging because the NIR/SWIR wavelengths generally have lower absorption by stains and deeper penetration into teeth. Hence, NIR/SWIR light may provide a caries detection method that can be non-invasive, non-contact and relatively stain insensitive. Broadband light may provide further advantages because carious regions may demonstrate spectral signatures from water absorption and the wavelength dependence of porosity in the scattering of light.

[0239] In general, the near-infrared region of the electromagnetic spectrum covers between approximately 0.7 microns (700nm) to about 2.5 microns (2500nm). However, it may also be advantageous to use just the short-wave infrared between approximately 1.4 microns (1400nm) and about 2.5 microns (2500nm). One reason for preferring the SWIR over the entire NIR may be to operate in the so-called "eye safe" window, which corresponds to wavelengths longer than about 1400nm. Therefore, for the remainder of the disclosure the SWIR will be used for illustrative purposes. However, it should be clear that the discussion that follows could also apply to using the NIR wavelength range, or other wavelength bands.

[0240] In particular, wavelengths in the eye safe window may not transmit down to the retina of the eye, and therefore, these wavelengths may be less likely to create permanent eye damage from inadvertent exposure. The near-infrared wavelengths have the potential to be dangerous, because the eye cannot see the wavelengths (as it can in the visible), yet they can penetrate and cause damage to the eye. Even if a practitioner is not looking directly at the laser beam, the practitioner's eyes may receive stray light from a reflection or scattering from some surface. Hence, it can always be a good practice to use eye protection when working around lasers. Since wavelengths longer than about 1400nm are substantially not transmitted to the retina or

substantially absorbed in the retina, this wavelength range is known as the eye safe window. For wavelengths longer than 1400nm, in general only the cornea of the eye may receive or absorb the light radiation.

[0241] FIGURE 25 illustrates the structure of an exemplary cross-section of a tooth 2500. The tooth 2500 has a top layer called the crown 2501 and below that a root 2502 that reaches well into the gum 2506 and bone 2508 of the mouth. The exterior of the crown 2501 is an enamel layer 2503, and below the enamel is a layer of dentine 2504 that sits atop a layer of cementum 2507. Below the dentine 2504 is a pulp region 2505, which comprises within it blood vessels 2509 and nerves 2510. If the light can penetrate the enamel 2503 and dentine 2504, then the blood flow and blood constituents may be measured through the blood vessels in the dental pulp 2505. While the amount of blood flow in the capillaries of the dental pulp 2505 may be less than an artery or vein, the smaller blood flow could still be advantageous for detecting or measuring blood constituents as compared to detection through the skin if there is less interfering spectral features from the tooth.

[0242] As used throughout this document, the term "couple" and or "coupled" refers to any direct or indirect communication between two or more elements, whether or not those elements are physically connected to one another. As used throughout this disclosure, the term "spectroscopy" means that a tissue or sample is inspected by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, refractive index, or opacity. In one embodiment, "spectroscopy" may mean that the wavelength of the light source is varied, and the transmission, absorption, or reflectivity of the tissue or sample is measured as a function of wavelength. In another embodiment, "spectroscopy" may mean that the wavelength dependence of the transmission, absorption or reflectivity is compared between different spatial locations on a tissue or sample. As an illustration, the "spectroscopy" may be performed by varying the wavelength of the light source, or by using a broadband light source and analyzing the signal using a spectrometer, wavemeter, or optical spectrum analyzer.

[0243] As used throughout this disclosure, the term "fiber laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein at least a part of the laser comprises an optical fiber. For instance, the fiber in the "fiber laser" may comprise one of or a combination

of a single mode fiber, a multi-mode fiber, a mid-infrared fiber, a photonic crystal fiber, a doped fiber, a gain fiber, or, more generally, an approximately cylindrically shaped waveguide or light-pipe. In one embodiment, the gain fiber may be doped with rare earth material, such as ytterbium, erbium, and/or thulium, for example. In another embodiment, the mid-infrared fiber may comprise one or a combination of fluoride fiber, ZBLAN fiber, chalcogenide fiber, tellurite fiber, or germanium doped fiber. In yet another embodiment, the single mode fiber may include standard single-mode fiber, dispersion shifted fiber, non-zero dispersion shifted fiber, high-nonlinearity fiber, and small core size fibers.

[0244] As used throughout this disclosure, the term "pump laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein the output light or optical beam is coupled to a gain medium to excite the gain medium, which in turn may amplify another input optical signal or beam. In one particular example, the gain medium may be a doped fiber, such as a fiber doped with ytterbium, erbium, and/or thulium. In one embodiment, the "pump laser" may be a fiber laser, a solid state laser, a laser involving a nonlinear crystal, an optical parametric oscillator, a semiconductor laser, or a plurality of semiconductor lasers that may be multiplexed together. In another embodiment, the "pump laser" may be coupled to the gain medium by using a fiber coupler, a dichroic mirror, a multiplexer, a wavelength division multiplexer, a grating, or a fused fiber coupler.

[0245] As used throughout this document, the term "super-continuum" and or "supercontinuum" and or "SC" refers to a broadband light beam or output that comprises a plurality of wavelengths. In a particular example, the plurality of wavelengths may be adjacent to one-another, so that the spectrum of the light beam or output appears as a continuous band when measured with a spectrometer. In one embodiment, the broadband light beam may have a bandwidth or at least 10nm. In another embodiment, the "super-continuum" may be generated through nonlinear optical interactions in a medium, such as an optical fiber or nonlinear crystal. For example, the "super-continuum" may be generated through one or a combination of nonlinear activities such as four-wave mixing, the Raman effect, modulational instability, and self-phase modulation.

[0246] As used throughout this disclosure, the terms "optical light" and or "optical beam" and or "light beam" refer to photons or light transmitted to a particular location in space. The "optical light" and or "optical beam" and or "light beam" may be modulated or unmodulated, which also means that they may or may not contain information. In one embodiment, the "optical light" and or "optical beam" and or "light beam" may originate from a fiber, a fiber laser, a laser, a light emitting diode, a lamp, a pump laser, or a light source.

[0247] TRANSMISSION OR REFLECTION THROUGH TEETH

[0248] The transmission, absorption and reflection from teeth has been studied in the near infrared, and, although there are some features, the enamel and dentine appear to be fairly transparent in the near infrared (particularly SWIR wavelengths between about 1400 and 2500nm). For example, the absorption or extinction ratio for light transmission has been studied. FIGURE 26A illustrates the attenuation coefficient 2600 for dental enamel 2601 (filled circles) and the absorption coefficient of water 2602 (open circles) versus wavelength. Near-infrared light may penetrate much further without scattering through all the tooth enamel, due to the reduced scattering coefficient in normal enamel. Scattering in enamel may be fairly strong in the visible, but decreases as approximately 1/(wavelength)3 [i.e., inverse of the cube of the wavelength] with increasing wavelength to a value of only 2-3 cm-1 at 1310nm and 1550nm in the near infrared. Therefore, enamel may be virtually transparent in the near infrared with optical attenuation 1-2 orders of magnitude less than in the visible range.

[0249] As another example, FIGURE 26B illustrates the absorption spectrum 2650 of intact enamel 2651 (dashed line) and dentine 2652 (solid line) in the wavelength range of approximately 1.2 to 2.4 microns. In the near infrared there are two absorption bands in the areas of about 1.5 and 2 microns. The band with a peak around 1.57 microns may be attributed to the overtone of valent vibration of water present in both enamel and dentine. In this band, the absorption is greater for dentine than for enamel, which may be related to the large water content in this tissue. In the region of 2 microns, dentine may have two absorption bands, and enamel one. The band with a maximum near 2.1 microns may belong to the overtone of vibration of PO hydroxyapatite groups, which is the main substance of both enamel and dentine. Moreover, the

band with a peak near 1.96 microns in dentine may correspond to water absorption (dentine may contain substantially higher water than enamel).

[0250] In addition to the absorption coefficient, the reflectance from intact teeth and teeth with dental caries (e.g., cavities) has been studied. In one embodiment, FIGURE 27 shows the near infrared spectral reflectance 2700 over the wavelength range of approximately 800nm to 2500nm from an occlusal (e.g., top) tooth surface 2704. The curve with black diamonds 2701 corresponds to the reflectance from a sound, intact tooth section. The curve with asterisks (*) 2702 corresponds to a tooth section with an enamel lesion. The curve with circles 2703 corresponds to a tooth section with a dentine lesion. Thus, when there is a lesion, more scattering occurs and there may be an increase in the reflected light.

[0251] For wavelengths shorter than approximately 1400nm, the shapes of the spectra remain similar, but the amplitude of the reflection changes with lesions. Between approximately 1400nm and 2500nm, an intact tooth 2701 has low reflectance (e.g., high transmission), and the reflectance appears to be more or less independent of wavelength. On the other hand, in the presence of lesions 2702 and 2703, there is increased scattering, and the scattering loss may be wavelength dependent. For example, the scattering loss may decrease as the inverse of some power of wavelength, such as 1/(wavelength)3 -- so, the scattering loss decreases with longer wavelengths. When there is a lesion in the dentine 2703, more water can accumulate in the area, so there is also increased water absorption. For example, the dips near 1450nm and 1900nm may correspond to water absorption, and the reflectance dips are particularly pronounced in the dentine lesion 2703.

[0252] FIGURE 27 may point to several novel techniques for early detection and quantification of carious regions. One method may be to use a relatively narrow wavelength range (for example, from a laser diode or super-luminescent laser diode) in the wavelength window below 1400nm. In one embodiment, wavelengths in the vicinity of 1310nm may be used, which is a standard telecommunications wavelength where appropriate light sources are available. Also, it may be advantageous to use a super-luminescent laser diode rather than a laser diode, because the broader bandwidth may avoid the production of laser speckle that can produce interference patterns due to light's scattering after striking irregular surfaces. As FIGURE 27 shows, the

amplitude of the reflected light (which may also be proportional to the inverse of the transmission) may increase with dental caries. Hence, comparing the reflected light from a known intact region with a suspect region may help identify carious regions. However, one difficulty with using a relatively narrow wavelength range and relying on amplitude changes may be the calibration of the measurement. For example, the amplitude of the reflected light may depend on many factors, such as irregularities in the dental surface, placement of the light source and detector, distance of the measurement instrument from the tooth, etc.

[0253] In one embodiment, use of a plurality of wavelengths can help to better calibrate the dental caries measurement. For example, a plurality of laser diodes or super-luminescent laser diodes may be used at different center wavelengths. Alternately, a lamp or alternate broadband light source may be used followed by appropriate filters, which may be placed after the light source or before the detectors. In one example, wavelengths near 1090nm, 1440nm and 1610nm may be employed. The reflection from the tooth 2705 appears to reach a local maximum near 1090nm in the representative embodiment illustrated. Also, the reflectance near 1440nm 2706 is higher for dental caries, with a distinct dip particularly for dentine caries 2703. Near 1610nm 2707, the reflection is also higher for carious regions. By using a plurality of wavelengths, the values at different wavelengths may help quantify a caries score. In one embodiment, the degree of enamel lesions may be proportional to the ratio of the reflectance near 1610nm divided by the reflectance near 1090nm. Also, the degree of dentine lesion may be proportional to the difference between the reflectance near 1610nm and 1440nm, with the difference then divided by the reflectance near 1090nm. Although one set of wavelengths has been described, other wavelengths may also be used and are intended to be covered by this disclosure.

[0254] In yet another embodiment, it may be further advantageous to use all of some fraction of the SWIR between approximately 1400 and 2500nm. For example, a SWIR super-continuum light source could be used, or a lamp source could be used. On the receiver side, a spectrometer and/or dispersive element could be used to discriminate the various wavelengths. As FIGURE 27 shows, an intact tooth 2701 has a relatively low and featureless reflectance over the SWIR. On the other hand, with a carious region there is more scattering, so the reflectance 2702, 2703 increases in amplitude. Since the scattering is inversely proportional to wavelength or some power of wavelength, the carious region reflectance 2702, 2703 also decreases with increasing

wavelength. Moreover, the carious region may contain more water, so there are dips in the reflectance near the water absorption lines 2706 and 2708. The degree of caries or caries score may be quantified by the shape of the spectrum over the SWIR, taking ratios of different parts of the spectrum, or some combination of this and other spectral processing methods.

[0255] Although several methods of early caries detection using spectral reflectance have been described, other techniques could also be used and are intended to be covered by this disclosure. For example, transmittance may be used rather than reflectance, or a combination of the two could be used. Moreover, the transmittance, reflectance and/or absorbance could also be combined with other techniques, such as quantitative light-induced fluorescence or fiber-optic trans-illumination. Also, the SWIR could be advantageous, but other parts of the infrared, near-infrared or visible wavelengths may also be used consistent with this disclosure.

[0256] One other benefit of the absorption, transmission or reflectance in the near infrared and SWIR may be that stains and non-calcified plaque are not visible in this wavelength range, enabling better discrimination of defects, cracks, and demineralized areas. For example, dental calculus, accumulated plaque, and organic stains and debris may interfere significantly with visual diagnosis and fluorescence-based caries detection schemes in occlusal surfaces. In the case of using quantitative light-induced fluorescence, such confounding factors typically may need to be removed by prophylaxis (abrasive cleaning) before reliable measurements can be taken. Surface staining at visible wavelengths may further complicate the problem, and it may be difficult to determine whether pits and fissures are simply stained or demineralized. On the other hand, staining and pigmentation generally interfere less with NIR or SWIR imaging. For example, NIR and SWIR light may not be absorbed by melanin and porphyrins produced by bacteria and those found in food dyes that accumulate in dental plaque and are responsible for the pigmentation.

[0257] HUMAN INTERFACE FOR MEASUREMENT SYSTEM

[0258] A number of different types of measurements may be used to image for dental caries, particularly early detection of dental caries. A basic feature of the measurements may be that the optical properties are measured as a function of wavelength at a plurality of wavelengths. As further described below, the light source may output a plurality of wavelengths, or a continuous spectrum over a range of wavelengths. In one embodiment, the light source may cover some or

all of the wavelength range between approximately 1400nm and 2500nm. The signal may be received at a receiver, which may also comprise a spectrometer or filters to discriminate between different wavelengths. The signal may also be received at a camera, which may also comprise filters or a spectrometer. In one embodiment, the spectral discrimination using filters or a spectrometer may be placed after the light source rather than at the receiver. The receiver usually comprises one or more detectors (optical-to-electrical conversion element) and electrical circuitry. The receiver may also be coupled to analog to digital converters, particularly if the signal is to be fed to a digital device.

[0259] Referring to FIGURE 25, one or more light sources 2511 may be used for illumination. In one embodiment, a transmission measurement may be performed by directing the light source output 2511 to the region near the interface between the gum 2506 and dentine 2504. In one embodiment, the light may be directed using a light guide or a fiber optic. The light may then propagate through the dental pulp 2505 to the other side, where the light may be incident on one or more detectors or another light guide to transport the signal to 2512 a spectrometer, receiver, and/or camera, for example. In one embodiment, the light source may be directed to one or more locations near the interface between the gum 2506 and dentine 2504 (in one example, could be from the two sides of the tooth). The transmitted light may then be detected in the occlusal surface above the tooth using a 2512 spectrometer, receiver, or camera, for example. In another embodiment, a reflectance measurement may be conducted by directing the light source output 2511 to, for example, the occlusal surface of the tooth, and then detecting the reflectance at a 2513 spectrometer, receiver or camera. Although a few embodiments for imaging the tooth are described, other embodiments and techniques may also be used and are intended to be covered by this disclosure. These optical techniques may measure optical properties such as reflectance, transmittance, absorption, or luminescence.

[0260] In one embodiment, FIGURE 28 shows that the light source and/or detection system may be integrated with a dental hand-piece 2800. The hand-piece 2800 may also include other dental equipment, such as a drill, pick, air spray or water cooling stream. The dental hand-piece 2800 may include a housing 2801 and a motor housing 2802 (in some embodiments such as with a drill, a motor may be placed in this section). The end of hand-piece 2803 that interfaces with the tooth may be detachable, and it may also have the light input and output end. The dental

hand-piece 2800 may also have an umbilical cord 2804 for connecting to power supplies, diagnostics, or other equipment, for example.

[0261] A light guide 2805 may be integrated with the hand-piece 2800, either inside the housing 2801, 2802 or adjacent to the housing. In one embodiment, a light source 2810 may be contained within the housing 2801, 2802. In an alternative embodiment, the hand-piece 2800 may have a coupler 2810 to couple to an external light source 2811 and/or detection system or receiver 2812. The light source 2811 may be coupled to the hand-piece 2800 using a light guide or fiber optic cable 2806. In addition, the detection system or receiver 2812 may be coupled to the hand-piece 2800 using one or more light guides, fiber optic cable or a bundle of fibers 2807.

[0262] The light incident on the tooth may exit the hand-piece 2800 through the end 2803. The end 2803 may also have a lens system or curved mirror system to collimate or focus the light. In one embodiment, if the light source is integrated with a tool such as a drill, then the light may reach the tooth at the same point as the tip of the drill. The reflected or transmitted light from the tooth may then be observed externally and/or guided back through the light guide 405 in the hand-piece 2800. If observed externally, there may be a lens system 408 for collecting the light and a detection system 2809 that may have one or more detectors and electronics. If the light is to be guided back through the hand-piece 2800, then the reflected light may transmit through the light guide 2805 back to the detection system or receiver 2812. In one embodiment, the incident light may be guided by a fiber optic through the light guide 2805, and the reflected light may be captured by a series of fibers forming a bundle adjacent to or surrounding the incident light fiber.

[0263] In another embodiment, a "clamp" design 2900 may be used as a cap over one or more teeth, as illustrated in FIGURE 29. The clamp design may be different for different types of teeth, or it may be flexible enough to fit over different types of teeth. For example, different types of teeth include the molars (toward the back of the mouth), the premolars, the canine, and the incisors (toward the front of the mouth). One embodiment of the clamp-type design is illustrated in FIGURE 29 for a molar tooth 2908. The C-clamp 2901 may be made of a plastic or rubber material, and it may comprise a light source input 2902 and a detector output 2903 on the front or back of the tooth, for example.

[0264] The light source input 2902 may comprise a light source directly, or it may have light guided to it from an external light source. Also, the light source input 2902 may comprise a lens system to collimate or focus the light across the tooth. The detector output 2903 may comprise a detector directly, or it may have a light guide to transport the signal to an external detector element. The light source input 2902 may be coupled electrically or optically through 2904 to a light input 2906. For example, if the light source is external in 2906, then the coupling element 2904 may be a light guide, such as a fiber optic. Alternately, if the light source is contained in 2902, then the coupling element 2904 may be electrical wires connecting to a power supply in 2906. Similarly, the detector output 2903 may be coupled to a detector output unit 2907 with a coupling element 2905, which may be one or more electrical wires or a light guide, such as a fiber optic. This is just one example of a clamp over one or more teeth, but other embodiments may also be used and are intended to be covered by this disclosure. For example, if reflectance from the teeth is to be used in the measurement, then the light input 2902 and detected light input 2903 may be on the same side of the tooth.

[0265] In yet another embodiment, one or more light source ports and sensor ports may be used in a mouth-guard type design. For example, one embodiment of a dental mouth guard 3000 is illustrated in FIGURE 30. The structure of the mouth guard 3001 may be similar to mouth guards used in sports (e.g., when playing football or boxing) or in dental trays used for applying fluoride treatment, and the mouth guard may be made from plastic, rubber, or any other suitable materials. As an example, the mouth guard may have one or more light source input ports 3002, 3003 and one or more detector output ports 3004, 3005. Although six input and output ports are illustrated, any number of ports may be used.

[0266] Similar to the clamp design described above, the light source inputs 3002, 3003 may comprise one or more light sources directly, or they may have light guided to them from an external light source. Also, the light source inputs 3002, 3003 may comprise lens systems to collimate or focus the light across the teeth. The detector outputs 3004, 3005 may comprise one or more detectors directly, or they may have one or more light guides to transport the signals to an external detector element. The light source inputs 3002, 3003 may be coupled electrically or optically through 3006 to a light input 3007. For example, if the light source is external in 3007, then the one or more coupling elements 3006 may be one or more light guides, such as a fiber

optic. Alternately, if the light sources are contained in 3002, 3003, then the coupling element 3006 may be one or more electrical wires connecting to a power supply in 3007. Similarly, the detector outputs 3004, 3005 may be coupled to a detector output unit 3009 with one or more coupling elements 3008, which may be one or more electrical wires or one or more light guides, such as a fiber optic. This is just one example of a mouth guard design covering a plurality of teeth, but other embodiments may also be used and are intended to be covered by this disclosure. For instance, the position of the light source inputs and detector output ports could be exchanged, or some mixture of locations of light source inputs and detector output ports could be used. Also, if reflectance from the teeth is to be measured, then the light sources and detectors may be on the same side of the tooth. Moreover, it may be advantageous to pulse the light source with a particular pulse width and pulse repetition rate, and then the detection system can measure the pulsed light returned from or transmitted through the tooth. Using a lock-in type technique (e.g., detecting at the same frequency as the pulsed light source and also possibly phase locked to the same signal), the detection system may be able to reject background or spurious signals and increase the signal-to-noise ratio of the measurement.

[0267] Other elements may be added to the human interface designs of FIGURES 28-30 and are also intended to be covered by this disclosure. For instance, in one embodiment it may be desirable to have replaceable inserts that may be disposable. Particularly in a dentist's or doctor's office or hospital setting, the same instrument may be used with a plurality of patients. Rather than disinfecting the human interface after each use, it may be preferable to have disposable inserts that can be thrown away after each use. In one embodiment, a thin plastic coating material may enclose the clamp design of FIGURE 29 or mouth guard design of FIGURE 30. The coating material may be inserted before each use, and then after the measurement is exercised the coating material may be peeled off and replaced. The coating or covering material may be selected based on suitable optical properties that do not affect the measurement, or known optical properties that can be calibrated or compensated for during measurement. Such a design may save the dentist or physician or user considerable time, while at the same time provide the business venture with a recurring cost revenue source.

[0268] WIRELESS LINK TO THE CLOUD

[0269] The non-invasive dental caries measurement device may also benefit from communicating the data output to the "cloud" (e.g., data servers and processors in the web remotely connected) via wireless means. The non-invasive devices may be part of a series of biosensors applied to the patient, and collectively these devices form what might be called a body area network or a personal area network. The biosensors and non-invasive devices may communicate to a smart phone, tablet, personal data assistant, computer and/or other microprocessor-based device, which may in turn wirelessly or over wire and/or fiber optic transmit some or all of the signal or processed data to the internet or cloud. The cloud or internet may in turn send the data to dentists, doctors or health care providers as well as the patients themselves. Thus, it may be possible to have a panoramic, high-definition, relatively comprehensive view of a patient that doctors and dentists can use to assess and manage disease, and that patients can use to help maintain their health and direct their own care.

[0270] In a particular embodiment 3100, the non-invasive measurement device 3101 may comprise a transmitter 3103 to communicate over a first communication link 3104 in the body area network or personal area network to a receiver in a smart phone, tablet, cell phone, PDA, and/or computer 3105, for example. For the measurement device 3101, it may also be advantageous to have a processor 3102 to process some of the measured data, since with processing the amount of data to transmit may be less (hence, more energy efficient). The first communication link 3104 may operate through the use of one of many wireless technologies such as Bluetooth, Zigbee, WiFi, IrDA (infrared data association), wireless USB, or Z-wave, to name a few. Alternatively, the communication link 3104 may occur in the wireless medical band between 2360MHz and 2390MHz, which the FCC allocated for medical body area network devices, or in other designated medical device or WMTS bands. These are examples of devices that can be used in the body area network and surroundings, but other devices could also be used and are included in the scope of this disclosure.

[0271] The personal device 3105 may store, process, display, and transmit some of the data from the measurement device 3101. The device 3105 may comprise a receiver, transmitter, display, voice control and speakers, and one or more control buttons or knobs and a touch screen. Examples of the device 3105 include smart phones such as the Apple iPhones® or phones operating on the Android or Microsoft systems. In one embodiment, the device 3105 may have

an application, software program, or firmware to receive and process the data from the measurement device 3101. The device 3105 may then transmit some or all of the data or the processed data over a second communication link 3106 to the internet or "cloud" 3107. The second communication link 3106 may advantageously comprise at least one segment of a wireless transmission link, which may operate using WiFi or the cellular network. The second communication link 3106 may additionally comprise lengths of fiber optic and/or communication over copper wires or cables.

[0272] The internet or cloud 3107 may add value to the measurement device 3101 by providing services that augment the measured data collected. In a particular embodiment, some of the functions performed by the cloud include: (a) receive at least a fraction of the data from the device 3105; (b) buffer or store the data received; (c) process the data using software stored on the cloud; (d) store the resulting processed data; and (e) transmit some or all of the data either upon request or based on an alarm. As an example, the data or processed data may be transmitted 3108 back to the originator (e.g., patient or user), it may be transmitted 3109 to a health care provider or doctor or dentist, or it may be transmitted 3110 to other designated recipients.

[0273] Service providers coupled to the cloud 3107 may provide a number of value-add services. For example, the cloud application may store and process the dental data for future reference or during a visit with the dentist or healthcare provider. If a patient has some sort of medical mishap or emergency, the physician can obtain the history of the dental or physiological parameters over a specified period of time. In another embodiment, alarms, warnings or reminders may be delivered to the user 3108, the healthcare provider 3109, or other designated recipients 3110. These are just some of the features that may be offered, but many others may be possible and are intended to be covered by this disclosure. As an example, the device 3105 may also have a GPS sensor, so the cloud 3107 may be able to provide time, date, and position along with the dental or physiological parameters. Thus, if there is a medical or dental emergency, the cloud 3107 could provide the location of the patient to the dental or healthcare provider 3109 or other designated recipients 3110. Moreover, the digitized data in the cloud 3107 may help to move toward what is often called "personalized medicine." Based on the dental or physiological parameter data history, medication or medical/dental therapies may be prescribed that are customized to the particular patient. Another advantage for commercial entities may be that by

leveraging the advances in wireless connectivity and the widespread use of handheld devices such as smart phones that can wirelessly connect to the cloud, businesses can build a recurring cost business model even using non-invasive measurement devices.

[0274] Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for non-invasive measurements of dental caries and early detection of carious regions. However, many other dental or medical procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure.

[0275] SECTION 3: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR NATURAL GAS LEAK DETECTION, EXPLORATION, AND OTHER ACTIVE REMOTE SENSING APPLICATIONS

[0276] One advantage of optical systems is that they can perform non-contact, stand-off or remote sensing distance spectroscopy of various materials. For remote sensing particularly, it may also be necessary to operate in atmospheric transmission windows. For example, two windows in the SWIR that transmit through the atmosphere are approximately 1.4-1.8 microns and 2-2.5 microns. In general, the near-infrared region of the electromagnetic spectrum covers between approximately 0.7 microns (700nm) to about 2.5 microns (2500nm). However, it may also be advantageous to use just the short-wave infrared between approximately 1.4 microns (1400nm) and about 2.5 microns (2500nm). One reason for preferring the SWIR over the entire NIR may be to operate in the so-called "eye safe" window, which corresponds to wavelengths longer than about 1400nm. Therefore, for the remainder of the disclosure the SWIR will be used for illustrative purposes. However, it should be clear that the discussion that follows could also apply to using the NIR wavelength range, or other wavelength bands.

[0277] In particular, wavelengths in the eye safe window may not transmit down to the retina of the eye, and therefore, these wavelengths may be less likely to create permanent eye damage from inadvertent exposure. The near-infrared wavelengths have the potential to be dangerous, because the eye cannot see the wavelengths (as it can in the visible), yet they can penetrate and cause damage to the eye. Even if a practitioner is not looking directly at the laser beam, the practitioner's eyes may receive stray light from a reflection or scattering from some surface. Hence, it can always be a good practice to use eye protection when working around lasers.

Since wavelengths longer than about 1400nm are substantially not transmitted to the retina or substantially absorbed in the retina, this wavelength range is known as the eye safe window. For wavelengths longer than 1400nm, in general only the cornea of the eye may receive or absorb the light radiation.

[0278] The SWIR wavelength range may be particularly valuable for identifying materials based on their chemical composition because the wavelength range comprises overtones and combination bands for numerous chemical bonds. As an example, FIGURE 32 illustrates some of the wavelength bands for different chemical compositions. In 100 is plotted wavelength ranges in the SWIR (between 1400 and 2500nm) for different chemical compounds that have vibrational or rotational resonances, along with whether the bands are overtone or combination bands. Numerous hydro-carbons are represented, along with oxygen-hydrogen and carbon-oxygen bonds. Thus, gases, liquids and solids that comprise these chemical compounds may exhibit spectral features in the SWIR wavelength range. In a particular embodiment, the spectra of organic compounds may be dominated by the C-H stretch. The C-H stretch fundamental occurs near 3.4 microns, the first overtone is near 1.7 microns, and a combination band occurs near 2.3 microns.

[0279] One embodiment of remote sensing that is used to identify and classify various materials is so-called "hyper-spectral imaging." Hyper-spectral sensors may collect information as a set of images, where each image represents a range of wavelengths over a spectral band. Hyper-spectral imaging may deal with imaging narrow spectral bands over an approximately continuous spectral range. As an example, in hyper-spectral imaging the sun may be used as the illumination source, and the daytime illumination may comprise direct solar illumination as well as scattered solar (skylight), which is caused by the presence of the atmosphere. However, the sun illumination changes with time of day, clouds or inclement weather may block the sun light, and the sun light is not accessible in the night time. Therefore, it would be advantageous to have a broadband light source covering the SWIR that may be used in place of the sun to identify or classify materials in remote sensing or stand-off detection applications.

[0280] As used throughout this document, the term "couple" and or "coupled" refers to any direct or indirect communication between two or more elements, whether or not those elements are physically connected to one another. As used throughout this disclosure, the term

"spectroscopy" means that a tissue or sample is inspected by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, refractive index, or opacity. In one embodiment, "spectroscopy" may mean that the wavelength of the light source is varied, and the transmission, absorption or reflectivity of the tissue or sample is measured as a function of wavelength. In another embodiment, "spectroscopy" may mean that the wavelength dependence of the transmission, absorption or reflectivity is compared between different spatial locations on a tissue or sample. As an illustration, the "spectroscopy" may be performed by varying the wavelength of the light source, or by using a broadband light source and analyzing the signal using a spectrometer, wavemeter, or optical spectrum analyzer.

[0281] As used throughout this document, the term "fiber laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein at least a part of the laser comprises an optical fiber. For instance, the fiber in the "fiber laser" may comprise one of or a combination of a single mode fiber, a multi-mode fiber, a mid-infrared fiber, a photonic crystal fiber, a doped fiber, a gain fiber, or, more generally, an approximately cylindrically shaped waveguide or light-pipe. In one embodiment, the gain fiber may be doped with rare earth material, such as ytterbium, erbium, and/or thulium. In another embodiment, the mid-infrared fiber may comprise one or a combination of fluoride fiber, ZBLAN fiber, chalcogenide fiber, tellurite fiber, or germanium doped fiber. In yet another embodiment, the single mode fiber may include standard single-mode fiber, dispersion shifted fiber, non-zero dispersion shifted fiber, high-nonlinearity fiber, and small core size fibers.

[0282] As used throughout this disclosure, the term "pump laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein the output light or optical beam is coupled to a gain medium to excite the gain medium, which in turn may amplify another input optical signal or beam. In one particular example, the gain medium may be a doped fiber, such as a fiber doped with ytterbium, erbium and/or thulium. In one embodiment, the "pump laser" may be a fiber laser, a solid state laser, a laser involving a nonlinear crystal, an optical parametric oscillator, a semiconductor laser, or a plurality of semiconductor lasers that may be multiplexed together. In another embodiment, the "pump laser" may be coupled to the gain medium by using a fiber coupler, a dichroic mirror, a multiplexer, a wavelength division multiplexer, a grating, or a fused fiber coupler.

[0283] As used throughout this document, the term "super-continuum" and or "supercontinuum" and or "SC" refers to a broadband light beam or output that comprises a plurality of wavelengths. In a particular example, the plurality of wavelengths may be adjacent to one-another, so that the spectrum of the light beam or output appears as a continuous band when measured with a spectrometer. In one embodiment, the broadband light beam may have a bandwidth of at least 10nm. In another embodiment, the "super-continuum" may be generated through nonlinear optical interactions in a medium, such as an optical fiber or nonlinear crystal. For example, the "super-continuum" may be generated through one or a combination of nonlinear activities such as four-wave mixing, parametric amplification, the Raman effect, modulational instability, and self-phase modulation.

[0284] As used throughout this disclosure, the terms "optical light" and or "optical beam" and or "light beam" refer to photons or light transmitted to a particular location in space. The "optical light" and or "optical beam" and or "light beam" may be modulated or unmodulated, which also means that they may or may not contain information. In one embodiment, the "optical light" and or "optical beam" and or "light beam" may originate from a fiber, a fiber laser, a laser, a light emitting diode, a lamp, a pump laser, or a light source.

[0285] As used throughout this disclosure, the term "remote sensing" may include the measuring of properties of an object from a distance, without physically sampling the object, for example by detection of the interactions of the object with an electromagnetic field. In one embodiment, the electromagnetic field may be in the optical wavelength range, including the infrared or SWIR. One particular form of remote sensing may be stand-off detection, which may range from non-contact up to hundreds of meters away, for example.

[0286] REMOTE SENSING OF NATURAL GAS LEAKS

[0287] Natural gas may be a hydro-carbon gas mixture comprising primarily methane, with other hydro-carbons, carbon dioxide, nitrogen and hydrogen sulfide. Natural gas is important because it is an important energy source to provide heating and electricity. Moreover, it may also be used as fuel for vehicles and as a chemical feedstock in the manufacture of plastics and other commercially important organic chemicals. Although methane is the primary component of natural gas, to uniquely identify natural gas through spectroscopy requires monitoring of both

methane and ethane. If only methane is used, then areas like cow pastures could be mistaken for natural gas fields or leaks. More specifically, the typical composition of natural gas is as follows:

Component	Range (mole %)
Methane	87.0-96.0
Ethane	1.5-5.1
Propane	0.1-1.5
Iso-butane	0.01-0.3
Normal-butane	0.01-0.3
Iso-pentane	Trace-0.14
Normal-pentane	Trace-0.04
Hexanes plus	Trace-0.06
Nitrogen	0.7-5.6
Carbon dioxide	0.1-1.0
Oxygen	0.01-0.1
Hydrogen	Trace-0.02

[0288] As one example of remote sensing of natural gas, a helicopter or aircraft may be flown at some elevation. The light source for remote sensing may direct the light beam toward the ground, and the diffuse reflected light may then be measured using a detection system on the aircraft. Thus, the helicopter or aircraft may be sampling a column area below it for natural gas, or whatever the material of interest is. In yet another embodiment, the column may sense aerosols of various sorts, as an example. Various kinds of SWIR light sources will be discussed later in this disclosure. The detection system may comprise, in one embodiment, a spectrometer followed by one or more detectors. In another embodiment, the detection system may be a dispersive element (examples include prisms, gratings, or other wavelength separators) followed by one or more detectors or detector arrays. In yet another embodiment, the detection system may comprise a gas-filter correlation radiometer. These are merely specific examples of the detection system, but combinations of these or other detection systems may also be used and are contemplated within the scope of this disclosure. Also, the use of aircraft is one particular example of a remote sensing system, but other system configurations may also be used and are included in the scope of this disclosure. For example, the light source and detection system may be placed in a fixed location, and for reflection the light source and detectors may be close to one another, while for transmission the light source and detectors may be at different locations. In yet another embodiment, the system

could be placed on a vehicle such as an automobile or a truck, or the light source could be placed on one vehicle, while the detection system is on another vehicle. If the light source and detection system are compact and lightweight, they might even be carried by a person in the field, either in their hands or in a backpack.

[0289] Both methane and ethane are hydro-carbons with unique spectral signatures. For example, ethane is C2H6, while methane is CH4. Also, methane and ethane have infrared absorption bands near 1.6 microns, 2.4 microns, 3.3 microns and 7 microns. It should be noted that the approximately 7 micron lines cannot be observed generally due to atmospheric absorption. Although the fundamental lines near 3.3 microns are stronger absorption features, the light sources and detectors in the mid-infrared may be more difficult to implement. Hence, the focus here is on observing the SWIR lines that fall in atmospheric transparency windows.

[0290] FIGURE 33 illustrates the absorption spectra for methane (FIGURE 33A) and ethane (FIGURE 33B) (from http://vpl.astro.washington.edu/spectra). The curves 3300 plot on a linear scale the absorption cross-section versus wavelength (in microns) for various methane lines. The curve 3301 covers the wavelength range between approximately 1.5-16 microns, while the curves below provide blown-up views of different wavelength ranges (3302 for approximately 1.62-1.7 microns, 3303 for approximately 1.7-1.84 microns, 3304 for approximately 2.15-2.45 microns, and 3305 for approximately 2.45-2.65 microns). The curves 3302 and 3303 fall within about the first SWIR atmospheric transmission window between approximately 1.4-1.8 microns, while the curves 3304 and 3305 fall within the second SWIR atmospheric transmission window between approximately 2-2.5 microns. As can be seen, there are numerous spectral features for identifying methane in the SWIR. In addition, there are even stronger features near 3.4-3.6 microns and around 7-8 microns, although these require different light sources and detection systems.

[0291] FIGURE 33B illustrates the absorption spectra for ethane. The curves 3350 plot on a linear scale the absorption cross-section versus wavelength (in microns) for various ethane lines. The curve 3351 covers the wavelength range between approximately 1.5-16 microns, while the curve 3352 expands the scale between about 1.6-3.2 microns. The features 3353 fall within about the first SWIR atmospheric transmission window between approximately 1.4-1.8 microns, while

the features 3354 and 3355 fall within the second SWIR atmospheric transmission window between approximately 2-2.5 microns. There are distinct spectral features for identifying ethane as well in the SWIR. In addition, there are even stronger features near 3.4-3.6 microns and around 7 microns.

[0292] For detecting natural gas leaks, a SWIR light source and a detection system could be used in transmission or reflection. The area surrounding the source or natural gas pipeline may be surveyed, and the detection system may monitor the methane and ethane concentration, or even the presence of these two gases. The region may be scanned to cover an area larger than the laser beam. Also, if a certain quantity of natural gas is detected, an alarm may be set-off to alert the operator or people nearby. This is just one example of the natural gas leak detection, but other configurations and techniques may be used and are intended to be covered by this disclosure.

[0293] Natural gas leak detection is one example where active remote sensing or hyper-spectral imaging can be used to detect hydro-carbons or organic compounds. However, there are many other examples where the technique may be used to perform reflectance spectroscopy of organic compounds, and these are also intended to be covered by this disclosure. In one particular embodiment, alkanes may be detected, where alkanes are hydro-carbon molecules comprising single carbon-carbon bonds. Alkanes have the general formula CnH2n+2 and are open chain, aliphatic or non-cyclic molecules. Below are examples of some of the alkanes, which include methane and ethane, as well as more complicated compounds.

	Formula
Methane	CH_4
Ethane	C_2H_6
Propane	C_3H_8
Butane	C_4H_{10}
Pentane	C_5H_{12}
Hexane	C_6H_{14}
Heptane	C_7H_{16}
Octane	C_8H_{18}
Nonane	C_9H_{20}
Decane	$C_{10}H_{22}$
Paraffin	$C_{20+}H_{42+}$
Polyethylene (LDPE, HDPE)	$(C_2H_4)_n$ or $(CH_2CH_2)_n$
Polyvinylchloride (PVC)	$(C_2H_3Cl)_n$ or $(CHClCH_2)_n$
Polypropylene	$(C_3H_6)_n$ or $\{CH(CH_3)CH_2\}_n$
Polyethylene terephthalate (PETE)	$C_{10}H_8O_4$ or $\{(CO_2)_2C_6H_4(CH_2)_2\}_n$
Nylon (polyamide)	$C_{12}H_{24}O_2N_2$ or $\{C_{10}H_{22}(CO)_2(NH)_2\}_n$

[0294] FIGURE 34 illustrates the reflectance spectra 3400 for some members of the alkane family plus paraffin. The vertical lines indicate positions of constant wavelength and are aligned with apparent absorptions in the methane spectrum at 1.19, 1.67, 2.32, 3.1, 4.23 and 4.99 microns. The spectra ore offset to enable easier viewing, and the offsets are of the following amounts: 3401 methane 4.1; 3402 ethane 3.6; 3403 propane 3.3; 3404 butane 2.8; 3405 pentane 2.3; 3406 hexane 2.0; 3407 heptane 1.5; 3408 octane 1.2; 3409 nonane 0.85; 3410 decane 0.4; and 3411 paraffin 0.05. The reflectance of alkanes in the near-infrared may be dominated by absorptions due to combinations and overtones of bands at longer wavelengths. Although this wavelength range is mostly unexplored by organic spectroscopists, the near-infrared may be valuable for terrestrial and planetary remote sensing studies. Alkanes may have the fundamental absorptions due to a variety of C-H stretches between approximately 3.3-3.5 microns. The first overtone may be a relatively deep triplet near 1.7 microns. This triplet appears in most of the series, but the exact wavelength position may move. Another absorption band may be present near 1.2 microns, and this is likely the second overtone of the C-H stretch. The third C-H stretch overtone is near 0.9 microns. There is yet another near-infrared feature near 1.396 microns, which may correspond to the combinations

of the first overtone of the C-H stretch with each of the two C-H band positions at approximately 1.35 microns and 1.37 microns. Moreover, there may be complex absorptions between 2.2-2.5 microns. For example, there may be a number of narrow individual absorption bands atop an overall absorption suite about 0.3 microns wide. A few absorption lines retain their location for most of the series 300, notably the 2.311 micron and 2.355 micron absorptions. This wavelength window may have multiple combinations and overtones, including contributions from the C-H stretch, CH3 asymmetric bend combination, and C-H stretch/CH3 symmetric bend combination.

[0295] REMOTE SENSING FOR NATURAL GAS EXPLORATION

[0296] In addition to remote sensing to detect natural gas leaks, the same or similar system could also be used to explore for natural gas fields, whether under land or under water. Whereas a natural gas leak from a pipeline or building may be above the ground or only a few meters below the ground, natural gas exploration may occur for gas and oil that are much further below the ground, or under the water in a bay, lake, sea or ocean. For example, the exploration for natural gas and oil may be performed by determining the reflectance spectra of surface anomalies. The surface manifestations of oil and gas reservoirs may be used to map the petroleum potential of an area, particularly related to the seepage of oil and gas to the surface along faults or imperfect reservoir seals. The visible products of such seepage (e.g., oil and tar deposits) are generally referred to as macro-seeps, whereas the invisible gaseous products may be referred to as micro-seeps.

[0297] As illustrated by 3500 in FIGURE 35, micro-seepages may result from the vertical movement of hydrocarbons 3501 from their respective reservoirs to the surface. These hydrocarbon micro-seepages involve buoyant, relatively rapid, vertical ascent of ultra-small bubbles of light hydrocarbons (primarily methane through the butanes) through a network of interconnected, groundwater-filled joints and bedding planes (3501). One of the assumptions required for micro-seepage to occur is that a rock column, including the seal rock, comprises extensive interconnected fractures or micro-fracture systems.

[0298] Direct detection methods may involve measurements of hydrocarbons, either in the form of oil accumulations or concentrations of escaping vapors, such as methane through butane. In addition, there are also indirect methods that may involve the measurement of secondary

alternations that arise from the seepage of the hydrocarbons. For instance, hydrocarbon-induced alterations may include microbial anomalies, mineralogical changes, bleaching of red beds, clay mineral alterations, and electrochemical changes. These alterations occur because leaking hydrocarbons set up near-surface oxidation and/or reduction zones that favor the development of a diverse array of chemical and mineralogical changes, c.f. 3502 in FIGURE 35. Such alterations 3502 may be distinct from adjacent rocks and, thus, may in some instance be detectable by various remote sensing techniques.

[0299] The diagnostic spectral features of methane and crude oil may comprise four distinct hydrocarbon absorption bands. For example, two bands near 1.18 microns and 1.38 microns may be narrow and sharply defined, although they may also be fairly weak. The other two spectral features may be near 1.68-1.72 microns and 2.3-2.45 microns; these bands may be broader, but they are also stronger than the previous two bands. The bands near 1.7 microns and 2.3 microns are spectral overtones or combinations of C-H vibrational modes. Moreover, hydrocarbon induced alterations associated with indirect detection may express themselves in a variety of spectral changes, such as mineralogical changes (calcium carbonate mineralization, near 2.35 microns), bleaching of red beds (near 1 micron), and clay minerals alterations (near 2.2 microns), among other changes.

[0300] Various field tests have been conducted that verify the spectral signatures associated with natural gas fields, either land-based or water-based (e.g., in bays). In one example shown in FIGURE 36A, the reflectance spectra 3600 was collected for different locations between approximately 2 microns and 2.4 microns. In 3601 the reflectance is plotted versus wavelength for locations with gas fields, while in 3602 the reflectance is plotted for locations without gas fields. The macroscopic features of the reflectance spectra of surface soils show two broad absorption bands near 2.2 microns and 2.33 microns with complex shapes. The slightly positive slope in the region of 2.3-2.4 microns with natural gas suggests that hydrocarbons are overriding the spectral signature of clays in this region.

[0301] In yet another embodiment, field tests were conducted over a wider spectra range from approximately 0.5 microns to 2.5 microns (FIGURE 36B). As the curve 3650 illustrates, two absorption features are found for the hydrocarbon spectral reflectance curve: one near 1.725

microns 3651 and a double absorption at approximately 2.311-2.36 microns 3652. Thus, in these two field trial examples, oil-gas reservoir areas were identifiable using feature bands of 1650-1750nm and 2000-2400nm. In addition, the remote sensing method may be used for off-shore oil and gas exploration and marine pollution investigation, to name just a few examples.

[0302] OTHER USES OF ACTIVE REMOTE SENSING OR HYPERSPECTRAL IMAGING

[0303] Active and/or hyper-spectral remote sensing may be used in a wide array of applications. Although originally developed for mining and geology (the ability of spectral imaging to identify various minerals may be ideal for the mining and oil industries, where it can be used to look for ore and oil), hyper-spectral remote sensing has spread to fields as diverse as ecology and surveillance. The table below illustrates some of the applications that can benefit from hyper-spectral remote sensing.

Atmosphere	Water vapor, cloud properties, aerosols
Ecology	Chlorophyll, leaf water, cellulose, pigments, lignin
Geology	Mineral and soil types
Coastal Waters	Chlorophyll, phytoplankton, dissolved organic materials, suspended sediments
Snow / Ice	Snow cover fraction, grainsize, melting
Biomass Burning	Subpixel temperatures, smoke
Commercial	Mineral (oil) exploration, agriculture and forest production

[0304] In one embodiment, near-infrared imaging spectroscopy data may be used to create qualitative images of thick oil or oil spills on water. This may provide a rapid remote sensing method to map the locations of thick parts of an oil spill. While color imagery may show locations

of thick oil, it is difficult to assess relative thickness or volume with just color imagery. As an example, FIGURE 37 illustrates the reflectance spectra 3700 of a sample of oil emulsion from the Gulf of Mexico 2010 oil spill. Curve 3701 is a 4mm thickness of oil, while curve 3702 is a 0.5mm thickness. Whereas the data in the visible hardly changes with oil thickness, in the near-infrared the change in reflectance spectra is much more dependent on the oil thickness. The data shows, for example, the C-H features near 1.2 microns 3703, 1.73 microns 3704, and 2.3 microns 3705. Thus, in the infrared wavelengths, both the reflectance levels and absorption features due to organic compounds may vary in strength with oil thickness.

[0305] Remote sensing may also be used for geology and mineralogy mapping or inspection. FIGURE 38 shows the reflectance spectra 3800 for some representative minerals that are major components of rocks and soils. In inorganic materials such as minerals, chemical composition and crystalline structure may control the shape of the spectral curve and the locations of absorption bands. Wavelength-specific absorption may arise from particular chemical elements or ions and the geometry of chemical bonds between elements, which is related to the crystal structure. In hematite 3801, the strong absorption in the visible may be caused by ferric iron. In calcite 3805, the carbonate ion may be responsible for the series of absorption bands between 1.8 and 2.4 microns. Kaolinite 3804 and montmorillonite 3802 are clay minerals common in soils. The strong absorption near 1.4 microns in both spectra, along with a weak 1.9 micron band in kaolinite arise from the hydroxide ions, while the stronger 1.9 micron band in montmorillonite may be caused by bound water molecules in the hydrous clay. In contrast to these spectra, orthoclase feldspar 3803, a dominant mineral in granite, shows very little absorption features in the visible or infrared.

[0306] Remote sensing or hyper-spectral imaging may also be used for agriculture as well as vegetation monitoring. For example, hyper-spectral data may be used to detect the chemical composition of plants, which can be used to detect the nutrient and water status of crops. FIGURE 39 illustrates the reflectance spectra 3900 of different types of green vegetation compared with dry, yellowed grass. In the visible spectra, the shape may be determined by absorption effects from chlorophyll and other leaf pigments. The reflectance rises rapidly across the boundary between red and infrared wavelengths, which may be due to interactions with the internal cellular structure of leaves. Leaf structure may vary significantly between plant species, as well as from

plant stress. Beyond 1.3 microns the reflectance decreases with increasing wavelength, except for two water absorption bands near 1.4 microns and 1.9 microns. Illustrated in FIGURE 39 are the reflectance for green grass 3901, walnut tree canopy 3902, fir tree 3903 and senescent 3904, which is dry, yellowed grass.

[0307] Active remote sensing may also be used to measure or monitor gases in the earth's atmosphere, including greenhouse gases, environmental pollutants and aerosols. For instance, greenhouse gases are those that can absorb and emit infrared radiation: In order, the most abundant greenhouse gasses in the Earth's atmosphere are: water vapor (H2O), carbon dioxide (CO2), methane (CH4), nitrous oxide (N2O) and ozone (O3). FIGURE 40 shows the atmospheric absorption and scattering of greenhouse gases 4000 at different wavelengths. Included in this figure are the total absorption and scattering 4001, along with the breakdown by major components: water vapor 4002, carbon dioxide 4003, oxygen and ozone 4004, methane 4005, and nitrous oxide 4006. Also shown is the Rayleigh scattering 4007 through the atmosphere, which dominates at shorter wavelengths, particularly wavelengths shorter than about 1 micron. In one embodiment, environmental concerns of climate change have led to the need to monitor the level of carbon dioxide in the atmosphere, and this may be achieved, for example, by performing spectroscopy in the vicinity of 1.6 microns and 2 microns.

[0308] In yet another embodiment, different building materials may be identified and distinguished from surrounding vegetation and forestry. FIGURE 41 overlays different reflectance data 4100 for samples cataloged in the ASTER spectra library (http://speclib.jpl.nasa.gov). This library has been made available by NASA as part of the Advanced Spaceborne Thermal Emission and Reflection Radiometer, ASTER, imaging instrumentation program. Included in this and other libraries are reflection spectra of natural and man-made materials, including minerals, rocks, soils, water and snow. In FIGURE 41 several spectra are included over the SWIR atmospheric transmission bands, and the water absorption between approximately 1.8 and 2 microns has been blocked out (features in there are either due to water or would be masked by the atmospheric moisture). Included in the graph are the spectra for silver metallic paint 4101, light brown loamy sand 4102, construction concrete-1 4103, construction concrete-cement 4104, gypsum 4105, asphaltic concrete 4106, construction concrete-bridges 4107, grass 4108 and conifer trees 4109. As an example, active remote sensing can be used to distinguish different concrete structures,

including roadways, buildings, and reinforced structures such as bridges. Also, building materials such as gypsum, painted structures, plywood, and concrete of various sorts, may be distinguished from plant life, soil and trees. Thus, beyond three dimensional imaging, this can add a fourth dimension – namely, identification of objects based on their chemical signature.

[0309] In a further embodiment, remote sensing or hyper-spectral imaging might be used for process control in a factory or manufacturing setting, particularly when the measurements are to be made at some stand-off or remote distance. As an example, plastics show distinct signatures in the SWIR, and process control may be used for monitoring the manufacture of plastics. Alternately, SWIR light could be used to see through plastics, since the signature for plastics can be subtracted off and there are large wavelength windows where the plastics are transparent. FIGURE 42 illustrates the absorbance 4200 for two common plastics: polyethylene 4201 and polystyrene 4202. Because of the hydro-carbon bonds, there are absorption features near 1.7 microns and 2.2-2.5 microns (c.f., discussion on alkanes). In general, the absorption bands in the near infrared are due to overtones and combination bands for various functional group vibrations, including signals from C-H, O-H, C=O, N-H, -COOH, and aromatic C-H groups. It may be difficult to assign an absorption band to a specific functional group due to overlapping of several combinations and overtones. However, with advancements in computational power and chemometrics or multivariate analysis methods, complex systems may be better analyzed. In one embodiment, using software analysis tools the absorption spectrum may be converted to its second derivative equivalent. The spectral differences may permit a fast, accurate, non-destructive and reliable identification of materials. Although particular derivatives are discussed, other mathematical manipulations may be used in the analysis, and these other techniques are also intended to be covered by this disclosure.

[0310] In another specific embodiment, experiments have been performed for stand-off detection of solid targets with diffuse reflection spectroscopy using a fiber-based super-continuum source (further described herein). In particular, the diffuse reflection spectrum of solid samples such as explosives (TNT, RDX, PETN), fertilizers (ammonium nitrate, urea), and paints (automotive and military grade) have been measured at stand-off distances of 5m. Although the measurements were done at 5m, calculations show that the distance could be anywhere from a few meters to over 150m. These are specific samples that have been tested, but more generally other

materials (particularly comprising hydro-carbons) could also be tested and identified using similar methods. The experimental set-up 4300 for the reflection-spectroscopy-based stand-off detection system is shown in FIGURE 43, while details of the SC source 4301 are described later in this disclosure (c.f. FIGURES 20,21, and 23). First, the diverging SC output is collimated to a 1 cm diameter beam using a 25 mm focal length, 90 degrees off-axis, gold coated, parabolic mirror 4302. To reduce the effects of chromatic aberration, refractive optics are avoided in the setup. All focusing and collimation is done using metallic mirrors that have almost constant reflectivity and focal length over the entire SC output spectrum. The sample 4304 is kept at a distance of 5m from the collimating mirror 4302, which corresponds to a total round trip path length of 10m before reaching the collection optics 4305. A 12cm diameter silver coated concave mirror 4305 with a 75cm focal length is kept 20cm to the side of the collimation mirror 4302. The mirror 4305 is used to collect a fraction of the diffusely reflected light from the sample, and focus it into the input slit of a monochromator 4306. Thus, the beam is incident normally on the sample 4304, but detected at a reflection angle of tan-1(0.2/5) or about 2.3 degrees. Appropriate long wavelength pass filters mounted in a motorized rotating filter wheel are placed in the beam path before the input slit 4306 to avoid contribution from higher wavelength orders from the grating (300 grooves/mm, 2μm blaze). The output slit width is set to 2mm corresponding to a spectral resolution of 10.8nm, and the light is detected by a 2mm x 2mm liquid nitrogen cooled (77K) indium antimonide (InSb) detector 4307. The detected output is amplified using a trans-impedance pre-amplifier 4307 with a gain of about 105V/A and connected to a lock-in amplifier 4308 setup for high sensitivity detection. The chopper frequency is 400Hz, and the lock-in time constant is set to 100ms corresponding to a noise bandwidth of about 1Hz. These are exemplary elements and parameter values, but other or different optical elements may be used consistent with this disclosure.

[0311] Three sets of solid samples are chosen to demonstrate the stand-off diffuse reflection spectra measurement in the laboratory. The first set comprises 'Non-hazardous Explosives for Security Training and Testing' (NESTT) manufactured by the XM Division of VanAken International. These samples contain small amounts of explosives deposited on an inert fused silica powder substrate. The experiments are conduced with the following samples – trinitrotoluene (TNT), research department explosive (RDX), Pentaerythritol tetranitrate (PETN),

and potassium nitrate. The TNT, RDX and potassium nitrate NESTT samples have 8% (by weight) explosives, while the PETN sample has 4%.

[0312] The second sample set consists of ammonium nitrate, urea, gypsum, and pinewood. Ammonium nitrate and urea are common fertilizers, but are also often used as explosives. These samples are ground to a fine powder in a mortar and pestle, and filled to a depth of about 5mm in a shallow glass container. We also measure the reflection spectrum of a 10cm diameter x 0.5cm thick Gypsum (CaSO4.2H2O) disk and a 5cm x 5cm x 0.5m piece of pine wood, since these samples are relevant for the remote sensing community (minerals and vegetation).

[0313] The final set of samples is selected to distinguish between commercial automotive and military vehicle paints based on their reflection signatures. Red, black, and green acrylic based spray paints are obtained from an auto supply store and sprayed 3 coats on different areas of a sanded Aluminum block to make the automotive paint samples. The sample of the military paint consisted of an Aluminum block coated with a chemical agent resistant coating (CARC) green paint.

[0314] The chemical structure and molecular formula of the 4 NESTT samples are shown in FIGURE 44 (4401, 4402, 4403, 4404), while the absorbance spectra obtained using the SC source are shown below in the same figure (4405, 4406, 4407, 4408). For each sample, the positions of the strongest/unique peaks have been labeled for clarity. TNT 4401, 4405 belongs to a class of compounds known as nitro-aromatics, in which the carbon directly attached to the nitro (NO2) group is part of an aromatic ring. The strongest peaks in the spectrum observed at 3230nm and 3270nm are due to the fundamental C-H stretching vibrations in the aromatic ring. There are also features between 2200-2600nm, which may arise from the combination between the C-H stretch and C-H bend vibrations. RDX 4402, 4406 belongs to the nitramines class containing the N-NO2 bond and also has multiple features in the 3200-3500nm band due to the C-H stretch vibrations. This spectrum also contains the C-H combination bands from 2200-2600nm. PETN 4403, 4407 is classified as a nitrate ester containing the C-O-NO2 bond, and its reflection spectrum is characterized by a triplet of peaks at 3310nm, 3350nm and 3440nm due to the C-H stretch vibration from the aliphatic groups. The C-H combination band is also present from 2200-2600nm. Potassium nitrate 4404, 4408 being an inorganic compound does not contain any absorption

features due to the C-H bond present in the other three samples. Instead, the unique spectral feature for this sample is a pair of peaks at 3590nm and 3650nm, which arise due to the first overtone of the asymmetric N-O stretching vibration of the nitrate ion (NO3-).

[0315] FIGURE 45A illustrates the reflection spectra 4500 for gypsum 4501, pinewood 4502, ammonium nitrate 4503 and urea 4504. The predominant spectral features in the gypsum 4501 (CaSO4.2H2O) reflectance occur due to the fundamental as well as combination bands of the water molecule near 1450nm, 1750nm, 1940nm and 2860nm. In addition, small dips in the spectrum at 2220, 2260 and 2480nm which arise due to the first overtone of the S-O bending vibration. Moreover, the valley at 3970nm occurs due to the first overtone of the –O-S-O stretching vibration of the sulfate (SO42-) ion. The pine wood spectrum 4502 comprises of bands due to its main constituents – cellulose, lignin and water. The valleys at 1450nm, 1920nm and 2860nm are attributed to water. The dip at 2100nm is due to the first overtone of the C-O asymmetric stretch, the one at 2270 nm due to the combination band of O-H and C-H, and the one at 2490nm due to combination band of C-H and C-O. Finally, the broad feature around 3450nm is due to the C-H stretching vibration. The ammonium nitrate (NH4NO3) spectrum 4503 has three prominent features in the near-IR region. The dip at 1270nm is due to the combination of N-H stretching and N-H bending vibrations, while the dip at 1570nm is due to the first overtone of N-H stretch. The doublet at 2050nm and 2140nm is possibly due to the second overtone of the N-H bending vibrations, while the fundamental N-H stretch appears as a broad feature around 3000 nm. Urea (NH2)2CO 4504 has two amide (-NH2) groups joined by a carbonyl (C=O) functional group. The absorption line at 1490nm occurs due to the third overtone of the C=O stretching vibration while the line at 1990nm is due to the second overtone of the same.

[0316] FIGURE 45B shows the reflection spectra 4550 for three commercial automotive paints 4551, 4552, 4553 and military grade CARC (chemical agent resistant coating) paint 4554. The paints consist of a complex mixture of many different chemicals, and, hence, it is very difficult to identify individual absorption lines. Since all four paints contain a variety of organic compounds, features are observed between 3200-3500nm from the C-H stretch and from 2200-2600nm due to the C-H stretch and C-H bond combination band. However, the primary difference between the automotive 45451, 4552, 4553 and CARC paint 4554 is the presence of a strong dip

between 1200-1850nm in the latter, which might be attributed to the absorption from Cobalt chromite - a green pigment found in CARC-green.

[0317] Thus, FIGURES 44 and 45 show that various materials, including explosives, fertilizers, vegetation, and paints have features in the near-infrared and SWIR that can be used to identify the various samples. Although stronger features are found in the mid-infrared, the near-infrared may be easier to measure due to higher quality detection systems, more mature fiber optics and light sources, and transmission through atmospheric transmission windows. Because of these distinct spectral signatures, these materials could also be detected using active remote sensing or hyper-spectral imaging, as described in this disclosure. These are just particular samples that have been tested at stand-off distances, but other materials and samples may also be identified using the SWIR remote sensing or hyper-spectral imaging methods, and these samples are also intended to be covered within this disclosure. As just another example, illicit drugs may be detectable using remote sensing or hyper-spectral imaging. FIGURE 46 shows the mid-wave infrared and long-wave infrared absorption spectra 1500 for various illicit drugs. The absorbance for cocaine 4601, methamphetamine 4602, MDMA (ecstasy) 4603, and heroin 4604 are plotted versus wavelength from approximately 2.5-20 microns. Although the fundamental resonances for these drugs may lie in the longer wavelength regions, there are corresponding overtones and combination bands in the SWIR and near-infrared wavelength range. Therefore, the active remote sensing or hyper-spectral imaging techniques described herein may also be applicable to detecting illicit drugs from aircraft, vehicles, or hand held devices.

[0318] DETECTION SYSTEMS

[0319] As discussed earlier, the active remote sensing system or hyper-spectral imaging system may be on an airborne platform, mounted on a vehicle, a stationary transmission or reflection set-up, or even held by a human for a compact system. For such a system, there are fundamentally two hardware parts: the transmitter or light source and the detection system. Between the two, perhaps in a transmission or reflection setting, may be the sample being tested or measured. Moreover, the output from the detection system may go to a computational system, comprising computers or other processing equipment. The output from the computational system may be displayed graphically as well as with numerical tables and perhaps an identification of the

material composition. These are just some of the parts of the systems, but other elements may be added or be eliminated, and these modified configurations are also intended to be covered by this disclosure.

[0320] By use of an active illuminator, a number of advantages may be achieved. First, the variations due to sunlight and time-of-day may be factored out. The effects of the weather, such as clouds and rain, might also be reduced. Also, higher signal-to-noise ratios may be achieved. For example, one way to improve the signal-to-noise ratio would be to use modulation and lock-in techniques. In one embodiment, the light source may be modulated, and then the detection system would be synchronized with the light source. In a particular embodiment, the techniques from lock-in detection may be used, where narrow band filtering around the modulation frequency may be used to reject noise outside the modulation frequency. In an alternate embodiment, change detection schemes may be used, where the detection system captures the signal with the light source on and with the light source off. Again, for this system the light source may be modulated. Then, the signal with and without the light source is differenced. This may enable the sun light changes to be subtracted out. In addition, change detection may help to identify objects that change in the field of view. In the following some exemplary detection systems are described.

[0321] In one embodiment, a SWIR camera or infrared camera system may be used to capture the images. The camera may include one or more lenses on the input, which may be adjustable. The focal plane assemblies may be made from mercury cadmium telluride material (HgCdTe), and the detectors may also include thermo-electric coolers. Alternately, the image sensors may be made from indium gallium arsenide (InGaAs), and CMOS transistors may be connected to each pixel of the InGaAs photodiode array. The camera may interface wirelessly or with a cable (e.g., USB, Ethernet cable, or fiber optics cable) to a computer or tablet or smart phone, where the images may be captured and processed. These are a few examples of infrared cameras, but other SWIR or infrared cameras may be used and are intended to be covered by this disclosure.

[0322] In another embodiment, an imaging spectrometer may be used to detect the light received from the sample. For example, FIGURE 47A shows a schematic diagram 4700 of the

basic elements of an imaging spectrometer. The input light 4701 from the sample may first be directed by a scanning mirror and/or other optics 4702. An optical dispersing element 4703, such as a grating or prism, in the spectrometer may split the light into many narrow, adjacent wavelength bands, which may then be passed through imaging optics 4704 onto one or more detectors or detector arrays 4705. Some sensors may use multiple detector arrays to measure hundreds of narrow wavelength bands.

[0323] An example of a typical imaging spectrometer 4750 used in hyper-spectral imaging systems is illustrated in FIGURE 47B. In this particular embodiment, the input light may be directed first by a tunable mirror 4751. A front lens 4752 may be placed before the entrance slit 4753 and the collector lens 4754. In this embodiment, the dispersing element is a holographic grating with a prism 4755, which separates the different wavelength bands. Then, a camera lens 4756 may be used to image the wavelengths onto a detector or camera 4757.

[0324] FIGURES 47A and 47B provide particular examples, but some of the elements may not be used, or other elements may be added, and these embodiments are also intended to be covered by this disclosure. For instance, a scanning spectrometer may be used before the detector, where a grating or dispersive element is scanned to vary the wavelength being measured by the detector. In yet another embodiment, filters may be used before one or more detectors to select the wavelengths or wavelength bands to be measured. This may be particularly useful if only a few bands or wavelengths are to be measured. The filters may be dielectric filters, Fabry-Perot filters, absorption or reflection filters, fiber gratings, or any other wavelength selective filter. In an alternate embodiment, a wavelength division multiplexer, WDM, may be used followed by one or more detectors or detector arrays. One example of a planar wavelength division multiplexer may be a waveguide grating router or an arrayed waveguide grating. The WDM may be fiber coupled, and detectors may be placed directly at the output or the detectors may be coupled through fibers to the WDM. Some of these components may also be combined with the configurations in FIGURES 47A and 47B.

[0325] While the above detection systems could be categorized as single path detection systems, it may be advantageous in some cases to use multi-path detection systems. In one embodiment, when the aim is to measure particular gases or material (rather than identify out of a

library of materials), it may be advantageous to use gas-filter correlation radiometry (GFCR), such as 4800 in FIGURE 48. A GFCR is a detection system that uses a sample of the gas of interest as a spectral filter for the gas. As shown in FIGURE 48, the incoming radiation 4801 may first be passed through a narrow band pass filter 4802. The beam may then be split by a beam splitter 4803 along two paths; one path comprising a gas cell filled with the gas of interest 4804 (known as the correlation cell) and the other path comprising no gas 4805. The light from each path may then be measured using two detectors 4806, 4807, and the signals may then be analyzed 4808. The difference in the transmission along the two paths may correspond primarily to the absorption of the gas along the correlation cell path. This GFCR configuration may be advantageous, for example, in the detection of natural gas. Since the goal is to measure methane and ethane, the correlation cells may contain these gases, either in combination or separately. Although a particular configuration for the GFCR has been described, variations of this configuration as well as addition of other components may also be used and are intended to be covered by this disclosure. For example, collection optics and lenses may be used with this configuration, and various modulation techniques may also be used to increase the signal to noise ratio.

[0326] In yet another example of multi-beam detection systems, a dual-beam set-up 4900 such as in FIGURE 49 may be used to subtract out (or at least minimize the adverse effects of) light source fluctuations. In one embodiment, the output from an SC source 4901 may be collimated using a calcium fluoride (CaF2) lens 4902 and then focused into the entrance slit of the monochromator 4903. At the exit slit, light at the selected wavelength is collimated again and may be passed through a polarizer 4904 before being incident on a calcium fluoride beam splitter 4905. After passing through the beam splitter 4905, the light is split into a sample 4906 and reference 4907 arm to enable ratiometric detection that may cancel out effects of intensity fluctuations in the SC source 4901. The light in the sample arm 4906 passes through the sample of interest and is then focused onto a HgCdTe detector 4908 connected to a pre-amp. A chopper 4902 and lock-in amplifier 4910 setup enable low noise detection of the sample arm signal. The light in the reference arm 4907 passes through an empty container (cuvette, gas cell etc.) of the same kind as used in the sample arm. A substantially identical detector 4909, pre-amp and lock-in amplifier 4910 is used for detection of the reference arm signal. The signal may then be analyzed using a computer system 4911. This is one particular example of a method to remove fluctuations from the light

source, but other components may be added and other configurations may be used, and these are also intended to be covered by this disclosure.

[0327] Although particular examples of detection systems have been described, combinations of these systems or other systems may also be used, and these are also within the scope of this disclosure. As one example, environmental fluctuations (such as turbulence or winds) may lead to fluctuations in the beam for active remote sensing or hyper-spectral imaging. A configuration such as illustrated in the representative embodiment of FIGURE 49 may be able to remove the effect of environmental fluctuations. Yet another technique may be to "wobble" the light beam after the light source using a vibrating mirror. The motion may lead to the beam moving enough to wash out spatial fluctuations within the beam waist at the sample or detection system. If the vibrating mirror is scanned faster than the integration time of the detectors, then the spatial fluctuations in the beam may be integrated out. Alternately, some sort of synchronous detection system may be used, where the detection is synchronized to the vibrating frequency.

[0328] Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for active remote sensing or hyper-spectral imaging. However, many other spectroscopy and identification procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure. As one example, the fiber-based super-continuum lasers may have a pulsed output with pulse durations of approximately 0.5-2nsec and pulse repetition rates of several Megahertz. Therefore, the active remote sensing or hyper-spectral imaging applications may also be combined with LIDAR-type applications. Namely, the distance or time axis can be added to the information based on time-of-flight measurements. For this type of information to be used, the detection system would also have to be time-gated to be able to measure the time difference between the pulses sent and the pulses received. By calculating the round-trip time for the signal, the distance of the object may be judged. In another embodiment, GPS (global positioning system) information may be added, so the active remote sensing or hyper-spectral imagery would also have a location tag on the data. Moreover, the active remote sensing or hyper-spectral imaging information could also be combined with two-dimensional or three-dimensional images to provide a physical picture as well as a chemical composition identification of the materials. These are just some modifications of the active remote sensing or hyper-spectral imaging system described in this disclosure, but other techniques may also be added or

combinations of these techniques may be added, and these are also intended to be covered by this disclosure.

[0329] SECTION 4: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

[0330] One advantage of optical systems is that they can perform non-contact, stand-off or remote sensing distance spectroscopy of various materials. As an example, optical systems can be used for identification of counterfeit drugs, detection of illicit drugs, or process control in the pharmaceutical industry, especially when the sensing is to be done at remote or stand-off distances in a non-contact, rapid manner. In general, the near-infrared region of the electromagnetic spectrum covers between approximately 0.7 microns (700nm) to about 2.5 microns (2500nm). However, it may also be advantageous to use just the short-wave infrared (SWIR) between approximately 1.4 microns (1400nm) and about 2.5 microns (2500nm). One reason for preferring the SWIR over the entire NIR may be to operate in the so-called "eye safe" window, which corresponds to wavelengths longer than about 1400nm. Therefore, for the remainder of the disclosure the SWIR will be used for illustrative purposes. However, it should be clear that the discussion that follows could also apply to using the near infrared – NIR -- wavelength range, or other wavelength bands.

[0331] In particular, wavelengths in the eye safe window may not transmit down to the retina of the eye, and therefore, these wavelengths may be less likely to create permanent eye damage from inadvertent exposure. The near-infrared wavelengths have the potential to be dangerous, because the eye cannot see the wavelengths (as it can in the visible), yet they can penetrate and cause damage to the eye. Even if a practitioner is not looking directly at the laser beam, the practitioner's eyes may receive stray light from a reflection or scattering some surface. Hence, it can always be a good practice to use eye protection when working around lasers. Since wavelengths longer than about 1400nm are substantially not transmitted to the retina or substantially absorbed in the retina, this wavelength range is known as the eye safe window. For wavelengths longer than 1400nm, in general only the cornea of the eye may receive or absorb the light radiation.

[0332] The SWIR wavelength range may be particularly valuable for identifying materials based on their chemical composition because the wavelength range comprises overtones and combination bands for numerous chemical bonds. For example, in the SWIR numerous hydro-carbon chemical compounds have overtone and combinational bands, along with oxygen-hydrogen and carbon-oxygen compounds. Thus, gases, liquids and solids that comprise these chemical compounds may exhibit spectral features in the SWIR wavelength range. In a particular embodiment, the spectra of organic compounds may be dominated by the C-H stretch. The C-H stretch fundamental occurs near 3.4 microns, the first overtone is near 1.7 microns, and a combination band occurs near 2.3 microns.

[0333] One embodiment of remote sensing that is used to identify and classify various materials is so-called "hyper-spectral imaging." Hyper-spectral sensors may collect information as a set of images, where each image represents a range of wavelengths over a spectral band. Hyper-spectral imaging may deal with imaging narrow spectral bands over an approximately continuous spectral range. As an example, in hyper-spectral imaging a lamp may be used as the light source. However, the incoherent light from a lamp may spatially diffract rapidly, thereby making it difficult to perform spectroscopy at stand-off distances or remote distances. Therefore, it would be advantageous to have a broadband light source covering the SWIR that may be used in place of a lamp to identify or classify materials in remote sensing or stand-off detection applications.

[0334] As used throughout this document, the term "couple" and or "coupled" refers to any direct or indirect communication between two or more elements, whether or not those elements are physically connected to one another. As used throughout this disclosure, the term "spectroscopy" means that a tissue or sample is inspected by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, fluorescence, refractive index, or opacity. In one embodiment, "spectroscopy" may mean that the wavelength of the light source is varied, and the transmission, absorption, fluorescence, or reflectivity of the tissue or sample is measured as a function of wavelength. In another embodiment, "spectroscopy" may mean that the wavelength dependence of the transmission, absorption, fluorescence or reflectivity is compared between different spatial locations on a tissue or sample. As an illustration, the "spectroscopy" may be performed by varying the wavelength of

the light source, or by using a broadband light source and analyzing the signal using a spectrometer, wavemeter, or optical spectrum analyzer.

[0335] As used throughout this document, the term "fiber laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein at least a part of the laser comprises an optical fiber. For instance, the fiber in the "fiber laser" may comprise one of or a combination of a single mode fiber, a multi-mode fiber, a mid-infrared fiber, a photonic crystal fiber, a doped fiber, a gain fiber, or, more generally, an approximately cylindrically shaped waveguide or light-pipe. In one embodiment, the gain fiber may be doped with rare earth material, such as ytterbium, erbium, and/or thulium. In another embodiment, the mid-infrared fiber may comprise one or a combination of fluoride fiber, ZBLAN fiber, chalcogenide fiber, tellurite fiber, or germanium doped fiber. In yet another embodiment, the single mode fiber may include standard single-mode fiber, dispersion shifted fiber, non-zero dispersion shifted fiber, high-nonlinearity fiber, and small core size fibers.

[0336] As used throughout this disclosure, the term "pump laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein the output light or optical beam is coupled to a gain medium to excite the gain medium, which in turn may amplify another input optical signal or beam. In one particular example, the gain medium may be a doped fiber, such as a fiber doped with ytterbium, erbium and/or thulium. In one embodiment, the "pump laser" may be a fiber laser, a solid state laser, a laser involving a nonlinear crystal, an optical parametric oscillator, a semiconductor laser, or a plurality of semiconductor lasers that may be multiplexed together. In another embodiment, the "pump laser" may be coupled to the gain medium by using a fiber coupler, a dichroic mirror, a multiplexer, a wavelength division multiplexer, a grating, or a fused fiber coupler.

[0337] As used throughout this document, the term "super-continuum" and or "supercontinuum" and or "SC" refers to a broadband light beam or output that comprises a plurality of wavelengths. In a particular example, the plurality of wavelengths may be adjacent to one-another, so that the spectrum of the light beam or output appears as a continuous band when measured with a spectrometer. In one embodiment, the broadband light beam may have a bandwidth of at least 10nm. In another embodiment, the "super-continuum" may be generated

through nonlinear optical interactions in a medium, such as an optical fiber or nonlinear crystal. For example, the "super-continuum" may be generated through one or a combination of nonlinear activities such as four-wave mixing, parametric amplification, the Raman effect, modulational instability, and self-phase modulation.

[0338] As used throughout this disclosure, the terms "optical light" and or "optical beam" and or "light beam" refer to photons or light transmitted to a particular location in space. The "optical light" and or "optical beam" and or "light beam" may be modulated or unmodulated, which also means that they may or may not contain information. In one embodiment, the "optical light" and or "optical beam" and or "light beam" may originate from a fiber, a fiber laser, a laser, a light emitting diode, a lamp, a pump laser, or a light source.

[0339] As used throughout this disclosure, the term "remote sensing" may include the measuring of properties of an object from a distance, without physically sampling the object, for example by detection of the interactions of the object with an electromagnetic field. In one embodiment, the electromagnetic field may be in the optical wavelength range, including the infrared or SWIR. One particular form of remote sensing may be stand-off detection, which may range exemplary from non-contact up to hundreds of meters away.

[0340] IDENTIFICATION OF COUNTERFEIT DRUGS

[0341] Pharmaceutical counterfeiting is a growing and significant issue for the healthcare community as well as the pharmaceutical industry worldwide. As a result of counterfeiting, users may be threatened by substandard drug quality or harmful ingredients, and legitimate companies may lose significant revenues. The definition for "counterfeit drug" by the World Health Organization was as follows: "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging." Later this definition was slightly modified, "Counterfeiting in relation to medicinal products means the deliberate and fraudulent mislabeling with respect to the identity, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product."

[0342] A rapid screening technique such as near-infrared or SWIR spectroscopy could aid in the search for and identification of counterfeit drugs. In particular, using a non-lamp based light source could lead to contact-free control and analysis of drugs. In a particular embodiment, remote sensing, stand-off detection, or hyper-spectral imaging may be used for process control or counterfeit drug identification in a factory or manufacturing setting, or in a retail, wholesale, or warehouse setting. In one embodiment, the light source for remote sensing may direct the light beam toward the region of interest (e.g., conveyor belt, stocking shelves, boxes or cartons, etc), and the diffuse reflected light may then be measured using a detection system. Various kinds of SWIR light sources will be discussed later in this disclosure. The detection system may comprise, in one embodiment, a spectrometer followed by one or more detectors. In another embodiment, the detection system may be a dispersive element (examples include prisms, gratings, or other wavelength separators) followed by one or more detectors or detector arrays. In yet another embodiment, the detection system may comprise a Fourier transform infrared spectrometer. These are merely specific examples of the detection system, but combinations of these or other detection systems may also be used and are contemplated within the scope of this disclosure.

[0343] For monitoring drugs, the SWIR light source and the detection system could be used in transmission, reflection, fluorescence, or diffuse reflection. Also, different system configurations may also be used and are included in the scope of this disclosure. For example, the light source and detection system may be placed in a fixed location, and for reflection the light source and detectors may be close to one another, while for transmission the light source and detectors may be at different locations. The region of interest may be surveyed, and the light beam may also be scanned to cover an area larger than the light source beam. In yet another embodiment, the system could be placed on a vehicle such as an automobile or a truck, or the light source could be placed on one vehicle, while the detection system is on another vehicle. If the light source and detection system are compact and lightweight, they might even be carried by a person in the field, either in their hands or in a backpack.

[0344] Another advantage of using the near-infrared or SWIR is that most drug packaging materials are at least partially transparent in this wavelength range, so that drug compositions may be detected and identified through the packaging non-destructively. As an example, SWIR light could be used to see through plastics, since the signature for plastics can be subtracted off and

there are large wavelength windows where the plastics are transparent. FIGURE 50 illustrates the absorbance 5000 for two common plastics: polyethylene 5001 and polystyrene 5002. Because of the hydro-carbon bonds, there are absorption features near 1.7 microns and 2.2-2.5 microns. In general, the absorption bands in the near infrared are due to overtones and combination bands for various functional group vibrations, including signals from C-H, O-H, C=O, N-H, -COOH, and aromatic C-H groups. It may be difficult to assign an absorption band to a specific functional group due to overlapping of several combinations and overtones. However, with advancements in computational power and chemometrics or multivariate analysis methods, complex systems may be better analyzed. In one embodiment, using software analysis tools the absorption spectrum may be converted to its second derivative equivalent. The spectral differences may permit a fast, accurate, non-destructive and reliable identification of materials. Although particular derivatives are discussed, other mathematical manipulations may be used in the analysis, and these other techniques are also intended to be covered by this disclosure.

[0345] Spectroscopy in the near-infrared or SWIR may be sensitive to both the chemical and physical nature of the sample composition and may be performed rapidly with minimal sample preparation. For example, near-infrared or SWIR spectroscopy may be used to study the homogeneity of powder samples, particle size determinations, product composition, the determination of the concentrations and distribution of components in solid tablets and content uniformity, among other applications. In yet other embodiments, applications include tablet identification, determination of moisture, residual solvents, active ingredient potency, the study of blending operations, and the detection of capsule tampering.

[0346] FIGURE 51 illustrates one example of the difference in near-infrared spectrum 5100 between an authentic tablet and a counterfeit tablet. Two grades of film coated tablets comprising drugs were investigated: curve 5101 is the genuine drug, while 5102 is a counterfeit drug. These two grades of capsules have noticeably different contents, and the differences are apparent in the near-infrared or SWIR spectra. In some cases the differences may not be as distinct. For these cases, more signal processing may be necessary to distinguish between samples.

[0347] In another embodiment, it may be advantageous to take a first, second or higher order derivative to elucidate the difference between real and counterfeit drugs. For example,

FIGURE 52 shows the second derivative 5200 of the spectral comparison of Prozac 5201 and a similarly formulated generic 5202, which had a fluoxetine hydrochloride (10mg). Although the reflectance curves from the two samples are close and, therefore, difficult to distinguish, the second derivative of the data helps to bring out the differences more clearly. Although a second derivative is used in this example, any number of signal processing algorithms and methods may be used, and these are also intended to be covered by this disclosure. For example, partial least square algorithms, multivariate data analysis, principal component analysis, or chemometric software may be implemented without departing from the scope of this disclosure.

[0348] In yet another embodiment, near-infrared or SWIR spectroscopy may be used to measure and calibrate various pharmaceutical formulations based on the active pharmaceutical ingredients and excipients. An excipient may be a pharmacologically inactive substance used as a carrier for the active ingredients of a medication. In some cases, the active substance may not be easily administered and/or absorbed by the human body; in such cases the active ingredient may be dissolved into or mixed with an excipient. Also, excipients are also sometimes used to bulk up formulations that contain very potent active ingredients, to allow for convenient and accurate dosage. In addition to their use in the single-dosage quantity, excipients can be used in the manufacturing process to aid in the handling of the active substance concerned.

[0349] FIGURE 53 shows an example of the near-infrared spectra 5300 for different pure components of a studied drug. The spectrum for the active pharmaceutical ingredient (API) 5301 is plotted, along with the spectra for five different excipients 5302, 5303, 5304, 5305 and 5306. Each spectrum has been baseline shifted to avoid overlapping. The near-infrared spectra have been obtained by averaging the spectra of each pixel of an area of a hyper-spectral image. As FIGURE 53 shows, each of the chemical compositions have a distinct spectrum, and the composition of a drug may be decomposed into its constitutive ingredients. These are just some examples of how near-infrared or SWIR spectroscopy may be applied to counterfeit drug detection, but other methods and analysis techniques may also be used without departing from the scope of this disclosure. As one other example, once the active pharmaceutical ingredient and the excipients spectral distribution of a drug formulation are understood, feedback may be provided of this information to the drug development stages.

[0350] RAPID SCREENING FOR ILLICIT DRUGS

[0351] Thus, FIGURES 51-53 show that near-infrared or SWIR spectroscopy may be used to identify counterfeit drugs. More generally, various materials including illicit drugs, explosives, fertilizers, vegetation, and paints have features in the near-infrared and SWIR that can be used to identify the various samples, and these applications are also intended to be within the scope of this disclosure. Although stronger features may be found in the mid-infrared, the near-infrared may be easier to measure due to higher quality detection systems, more mature fiber optics and light sources, and transmission through atmospheric transmission windows. Because of these distinct spectral signatures, these materials could also be detected using active remote sensing, hyper-spectral imaging, or near-infrared or SWIR spectroscopy. As just another example, illicit drugs may be detectable using remote sensing, hyper-spectral imaging, or near-infrared spectroscopy. FIGURE 54 shows the mid-wave infrared and long-wave infrared absorption spectra 5400 for various illicit drugs. The absorbance for cocaine 5401, methamphetamine 5402, MDMA (ecstasy) 5403, and heroin 5404 are plotted versus wavelength from approximately 2.5-20 microns. Although the fundamental resonances for these drugs may lie in the longer wavelength regions, there are corresponding overtones and combination bands in the SWIR and near-infrared wavelength range. Therefore, the active remote sensing, hyper-spectral imaging, or near-infrared or SWIR spectroscopy techniques described herein may also be applicable to detecting illicit drugs from aircraft, vehicles, or hand held devices.

[0352] The diffuse reflectance technique may be useful with near-infrared or SWIR spectroscopy for rapid identification of illegal drugs due to simple handling and simple use of a search data library created using near-infrared diffuse reflectance. For instance, FIGURE 55 illustrates the absorbance 5500 versus wavelength in the near-infrared region for four classes of illegal drugs. In particular, the spectra are shown for methamphetamine (MA) 5501, amphetamine (AP) 5502, MDMA (street name: ecstasy) 5503, and MDA (street name: the love drug) 5504. Each of the illegal drugs have unique spectral features in the near-infrared and SWIR. Also, comparing the mid-infrared spectrum for MDMA (5403 in FIGURE 54) with the near-infrared spectrum for MDMA (5503 in FIGURE 55), it seems clear that the near-infrared region shows overtones and combination bands that should be discernible. Referring to FIGURE 55, sample

identification may be accomplished by using the region (indicated by the arrows) where the spectral absorptions may provide specific peaks depending on the drug component.

[0353] In another embodiment, FIGURE 56 shows the diffuse reflectance near-infrared spectrum 5600 of heroin samples. Heroin, the 3,6-diacetyl derivative of morphine (hence diacetyl-morphine) is an opiate drug synthesized from morphine, which is usually a naturally occurring substance extracted from the seedpod of certain varieties of poppy plants. In particular, 5601 is the near-infrared spectrum for an illicit street drug sample, while 5602 is the spectra for a pure heroin standard. The difference between the spectra may arise at least in part from cutting agents. The inset 5603 shows the molecular structure for heroin. As in the other examples, the absorption in the near-infrared range is caused by overtone and combination vibrations of O-H, C-H, N-H and C=O groups, which exhibit their fundamental molecular stretching and bending absorption in the mid-infrared range (c.f., the mid-infrared spectrum for heroin is shown 5404 in FIGURE 54). These overtone and combination bands do not behave in a simple way, making the near-infrared spectra complex and harder to directly interpret. Also, although the near-infrared signatures may be weaker in magnitude, they are probably easier to detect in the near-infrared, and the sample preparation may also be much simpler in the near-infrared. Moreover, for remote sensing, the near-infrared may be preferable because of atmospheric transmission windows between approximately 1.4-1.8 microns and 2-2.5 microns.

[0354] Pure heroin may be a white powder with a bitter taste that is rarely sold on the streets, while illicit heroin may be a powder varying in color from white to dark brown due to impurities left from the manufacturing process or the presence of additives. The purity of street heroin may also vary widely, as the drug can be mixed with other white powders. The impurity of the drug may often make it difficult to gauge the strength of the dosage, which runs the risk of overdose. One nice feature of near-infrared or SWIR spectroscopy is that the technique may be used in a non-destructive, non-contact manner to determine rapidly the concentration of compounds present in complex samples at percentage levels with very little sample preparation. In a particular embodiment, FIGURE 57 illustrates the diffuse reflectance near-infrared spectra 5700 of different seized illicit drugs containing heroin (between 10.7 and 21.8%) compared with the spectrum of pure heroin 5701. Curve 5702 is for 21.8% by weight, curve 5703 is 13.2% by

weight, curve 5704 is 17% by weight, and curve 5705 is 10.7% by weight of heroin. The spectra have been shifted along the vertical axis to better illustrate the differences.

[0355] Although quite complex in the near-infrared, it may be possible to identify from the pure heroin near-infrared spectrum (5701 in FIGURE 57 or 5602 in FIGURE 56) the main wavelengths related to the most common functional groups in heroin. For example, FIGURE 58 lists possible band assignments 5800 for the various spectral features in pure heroin. As can be seen from FIGURE 58, the absorption in the near-infrared may be mainly due to overtone and combination bands associated with O-H, C-H, N-H and C=O groups.

[0356] As can be appreciated from FIGURE 57, there may be significant differences between the spectrum of pure heroin and sample spectra. These differences may be due to the presence of different compounds used as cutting agents, which can affect the shape and intensity of the near-infrared signals. FIGURE 59 illustrates the diffuse reflectance near-infrared spectra 5900 of different compounds that may be frequently employed as cutting agents. In the bottom of FIGURE 59 are shown the spectra 5908 for pure heroin and the spectra 5907 for a seized illicit street drug sample comprising 21.8% of heroin. The spectra for various cutting agents include: 5901 for flour, 5902 for talcum powder, 5903 for chalk, 5904 for acetylsalicylic acid, 5905 for caffeine, and 5906 for paracetamol. Thus, near-infrared or SWIR spectroscopy may be used to work back to the composition of an unknown drug. Although particular examples of counterfeit and illicit drugs have been described, the near-infrared or SWIR spectroscopy (including diffuse reflectance, reflectance, fluorescence or transmission) may also be applied to the identification of other drugs and substances without departing from the scope of this disclosure. This spectroscopy may be used non-destructively and non-contact over stand-off distances or in remote sensing distances, whether from an airborne, vehicle, hand-held, or stationary platform.

[0357] PROCESS ANALYTICAL TECHNOLOGY (PAT)

[0358] One definition of process analytical technology, PAT, is “a system for designing, analyzing and controlling manufacturing through timely evaluations (i.e., during processing) of significant quality and performance attributes of raw and in-process materials and processes, with

the goal of ensuring final product quality." Near-infrared or SWIR spectroscopy may have applications in the PAT of the pharmaceutical industry by providing, for example, quantitative analysis of multiple components in a sample and in pack quantification of drugs in formulation, as well as quality of a drug and quality control of complex excipients used in formulation. The PAT process may benefit from near-infrared or SWIR spectroscopy for some steps, such as: raw material identification, active pharmaceutical ingredient applications, drying, granulation, blend uniformity and content uniformity. Some of the strengths of near-infrared or SWIR spectroscopy include: radiation has good penetration properties, and, thus, minimal sample preparation may be required; measurement results may be obtained rapidly, and simultaneous measurements may be obtained for several parameters; non-destructive methods with little or no chemical waste; and organic chemicals that comprise most pharmaceutical products have unique spectra in the near-infrared and SWIR ranges, for example.

[0359] FIGURE 60 shows one example of a flow-chart 6000 in the PAT for the pharmaceutical industry. While the center shows the steps of the manufacturing process 6001, the top and bottom sides show where near-infrared spectroscopy could be applicable for lab use 6002 (top) or in process monitoring control 6003 (bottom). Indeed, near-infrared or SWIR spectroscopy has the potential to benefit almost every step in the manufacturing process. Just to provide a few examples of using near-infrared or SWIR spectroscopy in the PAT process, the raw material testing and blending process will be examined briefly.

[0360] At the commencement of manufacture of a drug product, it may be required to identify the correct material and grade of the pharmaceutical excipients to be used in the formulation. FIGURE 61 illustrates the typical near-infrared spectra 6100 for a variety of excipients. Included in the graph 6100 are spectra for: magnesium stearate 6101, sorbitol 6102, mannitol 6103, talc 6104, lactose 6105, starch 6106, maltodextrin 6107, and microcrystalline cellulose 6108. A suitable spectral database may be used to rapidly identify and qualify excipients. One nice aspect of the spectroscopy is that the near-infrared and SWIR are sensitive to both the physical and chemical characteristics of the samples.

[0361] One of the next steps in the manufacture of a dosage form is the blending together of the active component with the excipients to produce a homogeneous blend. In one embodiment,

the near-infrared or SWIR spectroscopy apparatus may comprise a fiber-optic probe, which may, for example, interface with the blending vessel. For such a fiber-optic probe, near infrared or SWIR spectra may be collected in real-time from a blending process. FIGURE 62 exemplifies the absorbance 6200 from the blending process. Although the initial spectra 6201 shows differences from the eventual spectra, as the process continues the blend converges to the final spectra 6202 and continues to overlap that spectra. Similar converging or overlapping spectra may also be used to check the product uniformity at the end of the process. The near-infrared spectra may be acquired in real-time; and, using appropriate data pre-processing and chemometric analysis, blend homogeneity plots may be derived, such as 6200.

[0362] One goal of the manufacturing process and PAT may be the concept of a "smart" manufacturing process, which may be a system or manufacturing operation responding to analytical data generated in real-time. Such a system may also have an in-built "artificial intelligence" as decisions may be made whether to continue a manufacturing operation. For example, with respect to the raw materials, integration of the quality measurement into smart manufacturing processes could be used to improve manufacturing operations by ensuring that the correct materials of the appropriate quality are used in the manufacture. Similarly, a smart blender would be under software control and would respond to the real-time spectral data collected.

[0363] FIGURE 63 illustrates what might be an eventual flow-chart 6300 of a smart manufacturing process. The manufacturing process 6301 may have as input the process feed 6302 and result in a process output 6303. A process controller 6304 may at least partially control the manufacturing process 6301, and the controller 6304 may receive inputs from the closed loop control (process parameters) 6305 as well as the on-line monitoring of process parameters 6306. The feedback loops in the process could refine the manufacturing process 6301 and improve the quality of the process output 6303. These are particular embodiments of the use of near-infrared or SWIR spectroscopy in the PAT of the pharmaceutical industry, but other variations, combinations, and methods may also be used and are intended to be covered by this disclosure.

[0364] The discussion thus far has centered on use of near-infrared or SWIR spectroscopy in applications such as identification of counterfeit drugs, detection of illicit drugs, and pharmaceutical process control. Although drugs and pharmaceuticals are one example, many other

fields and applications may also benefit from the use of near infrared or SWIR spectroscopy, and these may also be implemented without departing from the scope of this disclosure. As just another example, near-infrared or SWIR spectroscopy may also be used as an analytic tool for food quality and safety control. Applications in food safety and quality assessment include contaminant detection, defect identification, constituent analysis, and quality evaluation. The techniques described in this disclosure are particularly valuable when non-destructive testing is desired at stand-off or remote distances.

[0365] In one example, near-infrared or SWIR spectroscopy may be used in cereal breeding. The breeding purposes may require knowledge on both composition and functional properties of grain, while the functionality of wheat grain is an issue for wheat breeders. Most of the wheat functionality parameters depend on the protein-proteinase complex of wheat grain, as well as the condition of the carbohydrate complex. FIGURE 64A illustrates the near-infrared reflectance spectrum 6400 of wheat flour. Since these samples are complex in composition, several organic bonds involving hydrogen vibrate to produce overlapped spectral bands. Thus, the resulting spectrum 6400 appears like a wavy line without clearly defined features. Analytical methods based on this type of spectroscopy may have the potential to improve the quality of final cereal products by testing the products through the entire production process in the processing industry.

[0366] In yet another embodiment, near-infrared or SWIR spectroscopy may be used for the assessment of fruit and vegetable quality. Most commercial quality classification systems for fruit and vegetables are based on external features of the product, such as shape, color, size, weight and blemishes. However, the external appearance of most fruit is generally not an accurate guide to the internal eating quality of the fruit. As an example, for avocado fruit the external color is not a maturity characteristic, and its smell is too weak and appears later in its maturity stage. Analysis of the near-infrared or SWIR absorption spectra may provide qualitative and quantitative determination of many constituents and properties of horticulture produce, including oil, water, protein, pH, acidity, firmness, and soluble solids content or total soluble solids of fresh fruits. FIGURE 64B shows the near-infrared absorbance spectra 6450 obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit. Four oil absorption bands are near 2200-2400nm (CH2 stretch bend and combinations), with weaker absorption around 750nm, 1200nm, and 900-

930nm ranges. On the other hand, near 1300-1750nm range may be useful for determining the protein and oil content. The 900-920nm absorbance band may be useful for sugar determination. Although described in the context of grains, fruits, and vegetables, the near-infrared or SWIR spectroscopy may also be valuable for other food quality control and assessment, such as measuring the properties of meats. These and other applications also fall within the scope of this disclosure.

[0367] DETECTION SYSTEMS

[0368] The near-infrared or SWIR spectroscopy system, remote sensing system or hyper-spectral imaging system may be on an airborne platform, mounted on a vehicle, a stationary transmission or reflection set-up, or even held by a human for a compact system. For such a system, there are fundamentally two hardware parts: the transmitter or light source and the detection system. Between the two, perhaps in a transmission or reflection setting, may be the sample being tested or measured. Moreover, the output from the detection system may go to a computational system, comprising computers or other processing equipment. The output from the computational system may be displayed graphically as well as with numerical tables and perhaps an identification of the material composition. These are just some of the parts of the systems, but other elements may be added or be eliminated, and these modified configurations are also intended to be covered by this disclosure.

[0369] By use of an active illuminator, a number of advantages may be achieved. First, stand-off or remote distances may be achieved if a non-lamp system is used – i.e., if the beam does not rapidly diffract. Also, higher signal-to-noise ratios may be achieved. For example, one way to improve the signal-to-noise ratio would be to use modulation and lock-in techniques. In one embodiment, the light source may be modulated, and then the detection system would be synchronized with the light source. In a particular embodiment, the techniques from lock-in detection may be used, where narrow band filtering around the modulation frequency may be used to reject noise outside the modulation frequency. In another embodiment, change detection schemes may be used, where the detection system captures the signal with the light source on and with the light source off. Again, for this system the light source may be modulated. Then, the signal with and without the light source is differenced. Change detection may help to identify

objects that change in the field of view. In the following some exemplary detection systems are described.

[0370] In one embodiment, a SWIR camera or infrared camera system may be used to capture the images. The camera may include one or more lenses on the input, which may be adjustable. The focal plane assemblies may be made from mercury cadmium telluride material (HgCdTe), and the detectors may also include thermo-electric coolers. Alternately, the image sensors may be made from indium gallium arsenide (InGaAs), and CMOS transistors may be connected to each pixel of the InGaAs photodiode array. The camera may interface wirelessly or with a cable (e.g., USB, Ethernet cable, or fiber optics cable) to a computer or tablet or smart phone, where the images may be captured and processed. These are a few examples of infrared cameras, but other SWIR or infrared cameras may be used and are intended to be covered by this disclosure.

[0371] In another embodiment, an imaging spectrometer may be used to detect the light received from the sample. For example, FIGURE 65A shows a schematic diagram 6500 of the basic elements of an imaging spectrometer. The input light 6501 from the sample may first be directed by a scanning mirror and/or other optics 6502. An optical dispersing element 6503, such as a grating or prism, in the spectrometer may split the light into many narrow, adjacent wavelength bands, which may then be passed through imaging optics 6504 onto one or more detectors or detector arrays 6505. Some sensors may use multiple detector arrays to measure hundreds of narrow wavelength bands.

[0372] An example of a typical imaging spectrometer 6550 used in hyper-spectral imaging systems is illustrated in FIGURE 65B. In this particular embodiment, the input light may be directed first by a tunable mirror 6551. A front lens 6552 may be placed before the entrance slit 6553 and the collector lens 6554. In this embodiment, the dispersing element is a holographic grating with a prism 6555, which separates the different wavelength bands. Then, a camera lens 6556 may be used to image the wavelengths onto a detector or camera 6557.

[0373] FIGURES 65 provide particular examples, but some of the elements may not be used, or other elements may be added, and these are also intended to be covered by this disclosure. For instance, a scanning spectrometer may be used before the detector, where a grating or

dispersive element is scanned to vary the wavelength being measured by the detector. In yet another embodiment, filters may be used before one or more detectors to select the wavelengths or wavelength bands to be measured. This may be particularly useful if only a few bands or wavelengths are to be measured. The filters may be dielectric filters, Fabry-Perot filters, absorption or reflection filters, fiber gratings, or any other wavelength selective filter. In one embodiment, a wavelength division multiplexer, WDM, may be used followed by one or more detectors or detector arrays. One example of a planar wavelength division multiplexer may be a waveguide grating router or an arrayed waveguide grating. The WDM may be fiber coupled, and detectors may be placed directly at the output or the detectors may be coupled through fibers to the WDM. Some of these components may also be combined with the configurations in FIGURE 65.

[0374] While the above detection systems could be categorized as single path detection systems, it may be advantageous in some cases to use multi-path detection systems. In one embodiment, a detection system from a Fourier transform infrared spectrometer, FTIR, may be used. The received light may be incident on a particular configuration of mirrors, called a Michelson interferometer, that allows some wavelengths to pass through but blocks others due to wave interference. The beam may be modified for each new data point by moving one of the mirrors, which changes the set of wavelengths that pass through. This collected data is called an interferogram. The interferogram is then processed, typically on a computing system, using an algorithm called the Fourier transform. One advantageous feature of FTIR is that it may simultaneously collect spectral data in a wide spectral range.

[0375] FIGURE 66 illustrates one example of the FTIR spectrometer 6600. Light from the near-infrared or SWIR light source 6601 may be collimated and directed to a beam splitter 6602. In one embodiment, the beam splitter 6602 may be a 50:50 beam splitter. One portion of the beam 6603 may be reflected toward a stationary mirror 6604, while the other portion of the beam 6605 may be transmitted towards a moving mirror 6606. Light may be reflected from the two mirrors 6604, 6606 back to the beam splitter 6602, and then a portion of the recombined beam 6607 may be directed toward the sample 6608. The recombined beam 6607 may be focused onto the sample 6608, in one embodiment. On leaving the sample 6608, the light may be refocused or at least collected at a detector 6609. A background interferogram may be obtained by using the

set-up 6600 without a sample in the chamber 6608. When a sample is inserted into 6608, the background interferogram may be modulated by the presence of absorption bands in the sample. The FTIR spectrometer may have several advantages compared to a scanning (dispersive) spectrometer. Since all the wavelengths may be collected simultaneously, the FTIR may result in a higher signal-to-noise ratio for a given scan time or a shorter scan time for a given resolution. Moreover, unlike a spectrometer where a slit may limit the amount of the beam detected, the FTIR may accommodate the entire diameter of the beam coming from the light source 6601. The configuration 6600 is one example of an FTIR, but other configurations may also be used, and these are also intended to be covered by this disclosure.

[0376] In yet another example of multi-beam detection systems, a dual-beam set-up 6700 such as in FIGURE 67 may be used to subtract out (or at least minimize the adverse effects of) light source fluctuations. In one embodiment, the output from an SC source 6701 may be collimated using a CaF2 lens 6702 and then focused into the entrance slit of the monochromator 6703. At the exit slit, light at the selected wavelength is collimated again and may be passed through a polarizer 6704 before being incident on a calcium fluoride beam splitter 6705. After passing through the beam splitter 6705, the light is split into a sample 6706 and reference 6707 arm to enable ratiometric detection that may cancel out effects of intensity fluctuations in the SC source 6701. The light in the sample arm 6706 passes through the sample of interest and is then focused onto a HgCdTe detector 6708 connected to a pre-amp. A chopper 6702 and lock-in amplifier 6710 setup enable low noise detection of the sample arm signal. The light in the reference arm 6707 passes through an empty container (cuvette, gas cell etc.) of the same kind as used in the sample arm. A substantially identical detector 6709, pre-amp and lock-in amplifier 6710 is used for detection of the reference arm signal. The signal may then be analyzed using a computer system 6711. This is one particular example of a method to remove fluctuations from the light source, but other components may be added and other configurations may be used, and these are also intended to be covered by this disclosure.

[0377] Although particular examples of detection systems have been described, combinations of these systems or other systems may also be used, and these are also within the scope of this disclosure. As one example, environmental fluctuations (such as turbulence or winds) may lead to fluctuations in the beam for active remote sensing or hyper-spectral imaging. A

configuration such as FIGURE 67 may be able to remove the effect of environmental fluctuations. Yet another technique may be to "wobble" the light beam after the light source using a vibrating mirror. The motion may lead to the beam moving enough to wash out spatial fluctuations within the beam waist at the sample or detection system. If the vibrating mirror is scanned faster than the integration time of the detectors, then the spatial fluctuations in the beam may be integrated out. Alternately, some sort of synchronous detection system may be used, where the detection is synchronized to the vibrating frequency.

[0378] Described herein are just some examples of the beneficial use of near-infrared or SWIR lasers for spectroscopy, active remote sensing or hyper-spectral imaging. However, many other spectroscopy and identification procedures can use the near-infrared or SWIR light consistent with this disclosure and are intended to be covered by the disclosure. As one example, the fiber-based super-continuum lasers may have a pulsed output with pulse durations of approximately 0.5-2nsec and pulse repetition rates of several Megahertz. Therefore, the near-infrared or SWIR spectroscopy, active remote sensing or hyper-spectral imaging applications may also be combined with LIDAR-type applications. Namely, the distance or time axis can be added to the information based on time-of-flight measurements. For this type of information to be used, the detection system would also have to be time-gated to be able to measure the time difference between the pulses sent and the pulses received. By calculating the round-trip time for the signal, the distance of the object may be judged. In another embodiment, GPS (global positioning system) information may be added, so the near-infrared or SWIR spectroscopy, active remote sensing or hyper-spectral imagery would also have a location tag on the data. Moreover, the near-infrared or SWIR spectroscopy, active remote sensing or hyper-spectral imaging information could also be combined with two-dimensional or three-dimensional images to provide a physical picture as well as a chemical composition identification of the materials. These are just some modifications of the near-infrared or SWIR spectroscopy, active remote sensing or hyper-spectral imaging system described in this disclosure, but other techniques may also be added or combinations of these techniques may be added, and these are also intended to be covered by this disclosure.

[0379] SECTION 5: NEAR-INFRARED SUPER-CONTINUUM LASERS FOR EARLY DETECTION OF BREAST AND OTHER CANCERS

[0380] To perform non-invasive optical mammography, one desired attribute is that the light may penetrate as far as possible into the breast tissue. In diffuse reflection spectroscopy, a broadband light spectrum may be emitted into the tissue, and the spectrum of the reflected or transmitted light may depend on the absorption and scattering interactions within the target tissue. Since breast tissue has significant water and hemoglobin content, it is valuable to examine the wavelength range over which deep penetration of light is possible. FIGURE 68 illustrates the optical absorption 6800 of pure water (dotted line) 6801, hemoglobin without oxygen (thinner solid line) 6802, and hemoglobin saturated with oxygen (thicker solid line) 6803. It can be noted that above about 1100nm, the absorption of hemoglobin is almost the same as water absorption. The penetration depth may be proportional to the inverse of the optical absorption. Therefore, the highest penetration depth will be at the absorption valley, approximately in the wavelength range between about 900nm and about 1300nm. Although not as low in absorption compared to the first window, another absorption valley lies between about 1600nm and 1800nm. Thus, non-invasive imaging preferably should use wavelengths that fall in one of these two absorption valleys.

[0381] FIGURE 69 shows examples of various absorption bands of chemical species 6900 in the wavelength range between about 1200nm and 2200nm. Although the fundamental absorptions usually lie in the mid-infrared (e.g., wavelengths longer than about 3 microns), there are many absorption lines in the NIR corresponding to the second overtone region 6901 between about 1000nm and 1700nm, the first overtone region 6902 between about 1500nm and 2050nm, and the combination band region 6903 between about 1900nm and 2300nm. As an example, hydrocarbon bonds common in many biological substances have their fundamental absorption in the mid-IR near 3300-3600nm, but they also have many combination band lines between 2000-2500nm, and other lines at shorter wavelengths corresponding to the first and second overtones. Fortunately, there are spectral features of Figure 69 that overlap with the absorption valleys in Figure 68. These are likely to be the wavelengths of interest for spectroscopic analysis of cancerous regions.

[0382] In women, the breasts (FIGURE 70) 7000 overlay the pectoralis major muscles 7002 and cover much of the chest area and the chest walls 7001. The breast is an apocrine gland that produces milk to feed an infant child; the nipple 7004 of the breast is surrounded by an areola 7005, which has many sebaceous glands. The basic units of the breast are the terminal duct lobules

7003, which produce the fatty breast milk. They give the breast its function as a mammary gland. The lobules 7003 feed through the milk ducts 7006, and in turn these ducts drain to the nipple 7004. The superficial tissue layer (superficial fascia) may be separated from the skin 7008 by about 0.5-2.5cm of adipose of fatty tissue 7007.

[0383] Breast cancer is a type of cancer originating from breast tissue, most commonly from the inner lining of milk ducts 7006, the lobules 7003 that supply the ducts with milk, and/or the connective tissue between the lobules. Cancers originating from ducts 7006 are known as ductal carcinomas, while those originating from lobules 7003 or their connective tissue are known as lobular carcinomas. While the overwhelming majority of human cases occur in women, male breast cancer may also occur.

[0384] Several particular embodiments of imaging systems 7100, 7150 for optically scanning a breast are illustrated in FIGURE 71. In these particular embodiments, the patient 7101, 7151 may lie in a prone position with her breasts inside a box 7102, 7152 with probably a transparent window on the detector side. A compression plate 7103, 7153 may hold the breast in place against the viewing window by mildly compressing the breast to a thickness between about 5.5 and 7.5cm. The box 7102, 7152 may then be filled with a matching fluid with optical properties similar to human breast. In one instance, the matching fluid may comprise water, india ink for absorption, and a fat emulsion for scattering. The embodiments in FIGURE 71 may also have one or more detectors 7104, 7155, one or more light sources 7104, 7154, various electronics, and even an imaging system based on charge coupled devices 7105. As illustrated in FIGURE 71, the light sources 7104, 7154 and detectors 7104, 7155 may be coupled to the box 7102, 7152 through one or more fibers 7106, 7156. Also, the imaging may be in reflection mode (top of FIGURE 71), transmission mode (bottom of FIGURE 71), or some combination.

[0385] Beyond the geometry and apparatus of FIGURE 71, the optical imaging system may use one or more of three different illumination methods: continuous wave, time-domain photon migration, and frequency-domain photon migration. In one embodiment, continuous-wave systems emit light at approximately constant intensity or modulated at low frequencies, such as 0.1-100kHz. In another embodiment, the time-domain photon migration technique uses relatively short, such as 50-400psec, light pulses to assess the temporal distribution of photons. Since

scattering may increase the times of flight spent by photons migrating in tissues, the photons that arrive earliest at the detector probably encountered the fewest scattering events. In yet another embodiment, the frequency-domain photon migration devices modulate the amplitude of the light that may be continuously transmitted at relatively high frequencies, such as 10MHz to 1GHz. For example, by measuring the phase shift and amplitude decay of photons as compared to a reference signal, information may be acquired on the optical properties of tissue, and scattering and absorption may be distinguished. Beyond these three methods, other techniques or combinations of these methods may be used, and these other methods are also intended to fall within the scope of this disclosure.

[0386] Although particular embodiments of imaging architectures are illustrated in FIGURE 71, other system architectures may also be used and are also intended to be covered by this disclosure. For example, in one embodiment several couples of optical fibers for light delivery and collection may be arranged along one or more rings placed at different distances from the nipple 7004. In an alternate embodiment a "cap" with fiber leads for light sources and detectors may be used that fits over the breast. In yet another embodiment, imaging optics and light sources and detectors may surround the nipple 7004 and areola 7005 regions of the breast. As yet another alternative, a minimally invasive procedure may involve inserting needles with fiber enclosure (to light sources and detectors or receivers) into the breast, so as to probe regions such as the lobules 7003 and connective tissue. Both non-invasive and minimally invasive optical imaging methods are intended to be covered by this disclosure.

[0387] OPTICAL WAVELENGTH RANGES FOR CANCER DETECTION

[0388] Many of the diffuse optical tomography studies previously conducted have relied on using NIR in the wavelength range of about 600-1000nm, where light absorption at these wavelengths may be minimal, allowing for sufficient tissue penetration (up to 15cm). In these wavelength ranges, it has been claimed that concentrations of oxy- and deoxy-hemoglobin, water, and lipids can be determined. For example, FIGURE 72 shows the normalized absorption spectra 7200 of main tissue absorbers in the NIR between about 600nm and 1100nm: deoxy-hemoglobin, Hb, 7201, oxy-hemoglobin, HbO2, 7202, water 7203, lipids 7204 and collagen 7205. It is speculated that in a malignant tumor, hemoglobin concentration may be directly related to

angiogenesis, one of the main factors required for tumor growth and metastases. Moreover, the proportions of oxy- and deoxy-hemoglobin in a tumor may change due to its metabolism. Thus, by measuring concentrations of the breast components, discrimination of benign and malignant tumors may be possible with diffuse optical imaging. Experiment evidence suggests that cancerous tissue is associated with higher hemoglobin and water concentrations, and a lower lipid concentration with respect to normal breast tissue.

[0389] Based on FIGURE 68 and the dynamics of carcinoma, it may be advantageous to perform spectroscopy in longer wavelengths, such as windows between 1000-1400nm or 1600-1800nm. For example, looking at the absorption curves 6800 in FIGURE 68, the absorption between approximately 1000-1300nm may be comparable to the 600-1000nm window described in FIGURE 72. However, the loss through the soft tissue medium (penetration depth may be inversely related to the loss) will be due to absorption and scattering. In fact, the scattering properties of tissue may also contain valuable information for lesion diagnosis. Since the scattering is inversely proportional to some power of wavelength (for example, in some tissue scattering is inversely proportional to the wavelength cubed), the scattering contribution to the loss may decrease at longer wavelengths. Moreover, these longer wavelength windows may contain diagnostic information on content of collagen and adipose, both of which may be significant indicators for breast cancer.

[0390] Breast cancer spectroscopy may benefit from the use of wavelengths longer than about 1000nm for a number of reasons. As one example, the main absorbers in soft tissues of the visible spectrum of light may be oxy- and deoxygenated hemoglobin and beta-carotene. On the other hand, primary absorbers in the near-infrared spectrum of light may be water, adipose tissue and collagen. Particularly adipose and collagen content may be valuable for early detection of cancers. In one embodiment, increased levels of collagen in breast malignancies are thought to be due to increased vascularity of the tumors. Collagen type I may be an important component of artery walls. FIGURE 73 illustrates the normalized absorption coefficient 7300 in the wavelength range between about 500nm and 1600nm for Hb 7301, HbO2 7302, beta-carotene 7303, water 7304, lipid 7305 and collagen 7306.

[0391] COLLAGEN AND ADIPOSE SIGNATURES IN NEAR-IR

[0392] Examining the collagen content may be a valuable indicator for breast cancer detection. Collagen is one of the important extracellular matrix proteins, and fibrillar collagens help to determine stromal architecture. In turn, changes in the stromal architecture and composition are one of the aspects of both benign and malignant pathologies, and, therefore, may play an initial role in breast carcinogenesis. For example, collagen seems to be related to cancer development, because high mammographic density may be recognized as a risk factor for breast cancer. Moreover, collagen type in high-risk dense breasts may appear to be different from collagen in low-density breasts.

[0393] Experimental data also shows that malignant mammary gland tissues of animals and humans show a decrease in lipids when compared to normal tissues. The reduced amounts of lipids in the cancerous sites may be caused by a high metabolic demand of lipids in the malignant tumors. For example, due to the rapid proliferation of cancerous cells, there may be reduced lipid content in cancerous tissues. Thus, in addition to collagen, another valuable marker for breast cancer may be the lipid spectral features. It may also be possible to combine the markers from oxy- and deoxygenated hemoglobin and water with lipid and collagen lines to improve the diagnostics and/or therapeutics of optical imaging and/or treatment for breast and other types of cancer. Although specific examples of tissue constituents are discussed, other tissue constituents and related markers may also be associated with breast cancer and other cancers, and these other constituents are also intended to be covered by this disclosure.

[0394] As an example of the types of spectral signatures that may exist, in vivo investigations of progressive changes in rat mammary gland tumors were conducted using near-infrared spectroscopy with a Fourier-transform infrared spectrometer. In one embodiment, FIGURE 74 shows the typical spectra of the cancerous site of the treated rat and the corresponding site of the normal rat. FIGURE 74A shows the logarithm of the inverse of reflection spectra 7400, while FIGURE 74B shows their second derivative spectra 7450. The curves 7401, 7451 correspond to the spectra of the cancerous sites, while 7402, 7452 correspond to the spectra of the normal sites. Since the second derivative techniques may be useful in the analyses of NIR spectra to minimize baseline offsets and to resolve overlapping absorption without compromising signal-to-noise, FIGURE 74B may be used for interpretation of the spectral changes.

[0395] In FIGURE 74B identification may be made of several of the spectral features. In particular, there are DNA bands near 1471nm and 1911nm, while there are water bands near 967nm, 1154nm, 1402nm, and 1888nm. Moreover, there are lipid bands near 1209nm, 1721nm and 1764nm, and there are protein bands near 2055nm, 2172nm and 2347nm. The NIR spectra of FIGURE 74 show that the DNA and water contents in the cancerous tissue may be higher than those in normal tissues. On the other hand, the lipid content in the cancerous tissue may be less than the lipid content in normal tissues. With protein contents, however, little difference may be found between the normal and cancerous tissue.

[0396] These experiments on rats with breast cancer were also used to observe the temporal progression of the cancer. In this embodiment, as the cancer grew, the lipid band intensity decreased, and this band also shifted to higher wavelengths, and collagen peaks appeared in the tissues. In FIGURE 75, the second derivative spectral changes 7500 were investigated in the 1600nm to 1800nm wavelength range over several weeks. An early cancer was detected in the 5th week, and then it grew rapidly from the 6th 7501 to the 7th 7502 week. The cancer's temporal progression through the 8th 7503, 9th 7504, 10th 7505 and 11th 7506 week are shown in the various curves in FIGURE 75. With the cancer growth, the intensity of the lipid band in the vicinity of 1721nm decreased, and this band shifted to higher wavelengths by 7nm at the 11th week 7506 compared to the wavelength band at the 5th week. The higher wavelength shift may indicate that an order parameter of the lipids increases with progressive cancer growth.

[0397] Moreover, in the data of FIGURE 75 is seen that a new peak appeared as the cancer grew around 1690nm, which may be assigned to be a collagen absorption by comparison with the absorptions of standard collagen (c.f., FIGURE 78). The higher wavelength shift may be attributable to the formation of elastic fibers in the lipid layer with collagen induced in the cancer tissues, thus leading to an increased order parameter of the lipids. Thus, it can be seen that significant information about breast cancer tissue compared with normal tissue may be obtained by spectroscopy at the longer wavelengths in the near-infrared.

[0398] The second derivative spectra may also be insightful for observing and monitoring changes in tissue as well as characterizing tissue in the near-infrared wavelength range. As an example, FIGURE 76 illustrates the second derivative spectra 7600 for cholesterol (similar to one

embodiment of lipids) 7601, collagen 7602, and elastin 7603. The left curve 7625 shows the second derivative data over the wavelength range of about 1150nm to 1300nm, while the right curve 7650 shows the second derivative data over the wavelength range of about 1600nm to 1850nm. These wavelengths show numerous features for cholesterol/lipid 7601, collagen 7602, and elastin 7603, which again emphasizes the added value of using wavelengths longer than about 1000nm for cancer diagnostics.

[0399] To further illustrate the value of using longer wavelengths in the NIR or SWIR for observing changes in breast cancer and other cancer markers, the spectra of in water, lipids/adipose and collagen of different varieties may be studied. As one embodiment, the absorption coefficients 7700 are shown in FIGURE 77 as a function of wavelength between about 1000nm and 2600nm. FIGURE 77 overlaps the absorption coefficient for water 7701, adipose 7702 (forms of adipose include fatty tissue and acids, lipids, and cholesterol), and collagen type I 7703. One may note that particular absorption peaks for adipose 7702 and collagen type I 7703 align at wavelengths near 1210nm 7704 and 1720nm 7705, which also correspond to local minima in water absorption.

[0400] Moreover, the NIR spectra for collagen also depend on the type of collagen. As an example, FIGURE 78 illustrates the absorbance 7800 for four types of collagen: collagen I 7801, collagen II 7802, collagen III 7803, and collagen IV 7804. Collagen I, for instance, may be a major constituent of stroma. Also, collagen I and collagen III may be the principal collagens of the aorta. Since the spectra of the four collagens are distinctive, multicomponent analysis of collagens may possibly be used to distinguish the type of collagen involved.

[0401] The experimental results discussed thus far indicate that breast cancer detection may benefit from spectroscopy in the NIR and SWIR, particularly wavelengths between approximately 1000-1400nm and 1600-1800nm. These are wavelength windows that may have deep penetration into soft tissue, while still falling within lower absorption valleys of water. Moreover, the longer wavelengths lead to less scattering in tissue and water, again permitting deeper penetration of the light. In the NIR and SWIR wavelength range, the spectra of standard samples of cholesterol, protein, collagen, elastin and DNA were measured to obtain information on their characteristic bands in the spectra of mammary gland tissues. Absorption peaks in the standard samples occur at the following exemplary wavelengths:

Collagen: 1182nm, 1360nm, 1426nm, 1496nm, 1569nm, 1690nm, 1732nm;

Lipids: 1157nm, 1209nm, 1404nm, 1721nm, 1764nm;

Cholesterol: 918nm, 1195nm, 1376nm, 1585nm, 1711nm, 1757nm;

Protein: 910nm, 1143nm, 1186nm, 1279nm, 1420nm, 1503nm, 1579nm, 1690nm, 1739nm, 1799nm; and

DNA: 1414nm, 1471nm, 1626nm, 1728nm.

[0402] Comparing these absorption features with the data in FIGURES 73-78 shows that there are absorption features or signatures in the second derivatives that can be used to monitor changes in, for example, collagen and lipids. By using broadband light and performing spectroscopy in at least some part of the wavelength windows between about 1000-1400nm and/or 1600-1800nm, the collagen and lipid changes, or other constituent changes, may be monitored. In one embodiment, for breast cancer the decrease in lipid content, increase in collagen content, and possible shift in collagen peaks may be observed by performing broadband light spectroscopy and comparing normal regions to cancerous regions as well as the absorption strength as a function of wavelength. The spectroscopy may be in transmission, reflection, diffuse reflection, diffuse optical tomography, or some combination. Also, this spectroscopy may be augmented by fluorescence data, if particular tags or markers are added. Beyond looking at the absorbance, the data processing may involve also observing the first, second, or higher order derivatives.

[0403] Broadband spectroscopy is one example of the optical data that can be collected to study breast cancer and other types of cancer. However, other types of spectral analysis may also be performed to compare the collagen and lipid features between different wavelengths and different tissue regions (e.g., comparing normal regions to cancerous regions), and these methods also fall within the scope of this disclosure. For example, in one embodiment just a few discrete wavelengths may be monitored to see changes in lipid and collagen contents. In a particular embodiment, wavelengths near 1200nm may be monitored in the second derivative data of FIGURE 76 to measure the cholesterol/lipid peak below 1200nm in 7601 versus the collagen peak above 1200nm in 7602. In yet another embodiment, the absorption features in FIGURE 73 may

be relied upon to monitor the lipid content 7305 by measuring near 1200nm and the collagen content 7306 by measuring near 1300nm. Although these embodiments use only two wavelengths, any number of wavelengths may be used and are intended to be covered by this disclosure.

[0404] Thus, a breast cancer monitoring system, or a system to monitor different types of cancers, may comprise broadband light sources and detectors to permit spectroscopy in transmission, reflection, diffuse optical tomography, or some combination. In one particular embodiment, high signal-to-noise ratio may be achieved using a fiber-based super-continuum light source (described further herein). Other light sources may also be used, including a plurality of laser diodes, super-luminescent laser diodes, or fiber lasers.

[0405] Wavelength ranges that may be advantageous for cancer detection include the NIR and SWIR windows (or some part of these windows) between about 1000-1400nm and 1600-1800nm. These longer wavelengths fall within local minima of water absorption, and the scattering loss decreases with increasing wavelength. Thus, these wavelength windows may permit relatively high penetration depths. Moreover, these wavelength ranges contain information on the overtone and combination bands for various chemical bonds of interest, such as hydrocarbons.

[0406] These longer wavelength ranges may also permit monitoring levels and changes in levels of important cancer tissue constituents, such as lipids and collagen. Breast cancer tissue may be characterized by decreases in lipid content and increases in collagen content, possibly with a shift in the collagen peak wavelengths. The changes in collagen and lipids may also be augmented by monitoring the levels of oxy- and deoxy-hemoglobin and water, which are more traditionally monitored between 600-1000nm. Other optical techniques may also be used, such as fluorescent microscopy.

[0407] To permit higher signal-to-noise levels and higher penetration depths, higher intensity or brightness of light sources may be used. With the higher intensities and brightness, there may be a higher risk of pain or skin damage. At least some of these risks may be mitigated by using surface cooling and focused infrared light, as further described herein.

[0408] LASER EXPERIMENTS: PENETRATION DEPTH, FOCUSING, SKIN COOLING

[0409] Some preliminary experiments show the feasibility of using focused infrared light for non-invasive procedures, or other procedures where relatively shallow vessels below the skin are to be thermally coagulated or occluded with minimum damage to the skin upper layers. In one embodiment, the penetration depth and optically induced thermal damage has been studied in chicken breast samples. Chicken breast may be a reasonable optical model for smooth muscle tissue, comprising water, collagen and proteins. Commercially available chicken breast samples were kept in a warm bath (~32 degree Celsius) for about an hour, and then about half an hour at room temperature in preparation for the measurements.

[0410] An exemplary set-up 7900 for testing chicken breast samples using collimated light is illustrated in FIGURE 79. The laser light 7901 near 980nm, 1210nm, or 1700nm may be provided from one or more laser diodes or fiber lasers, as described further below. In this instance, laser diodes were used, which comprise a plurality of laser diode emitters that are combined using one or more multiplexers (particularly spatial multiplexers), and then the combined beam is coupled into a multi-mode fiber (typically 100 microns to 400 microns in diameter). The output from the laser diode fiber was then collimated using one or more lenses 7902. The resulting beam 7903 was approximately round with a beam diameter of about 3mm. The beam diameter was verified by blade measurements (i.e., translating a blade across the beam). Also, the time-averaged power was measured in the nearly collimated section after the lens using a large power meter. The chicken breast samples 7906 were mounted in a sample holder 7905, and the sampler holder 7905 was mounted in turn on a translation stage 7904 with a linear motor that could move perpendicular to the incoming laser beam. Although particular details of the experiment are described, other elements may be added or eliminated, and these alternate embodiments are also intended to be covered by this disclosure.

[0411] For these particular experiments, the measured depth of damage (in millimeters) versus the incident laser power (in Watts) is shown 8000 in FIGURE 80. In this embodiment, laser diodes were used at wavelengths near 980nm, 1210nm and 1700nm. The curve 8001 corresponds to about 980nm, the curve 8002 corresponds to about 1210nm, and the curve 8003

corresponds to about 1700nm. It may be noted that there is a threshold power, above which the damage depth increases relatively rapidly. For example, the threshold power for wavelengths around 980nm may be about 8W, the threshold power for wavelengths around 1210nm may be 3W, and the threshold power for wavelengths around 1700nm may be about 1W. The threshold powers may be different at the different wavelengths because of the difference in water absorption (e.g., 7701 in FIGURE 77). Part of the difference in threshold powers may also arise from the absorption of proteins such as collagen (e.g., 7703 in FIGURE 77). After a certain power level, the damage depth appears to saturate: i.e., the slope flattens out as a function of increasing pump power.

[0412] In one embodiment, if the penetration depth is defined as the depth where damage begins to approximately saturate, then for wavelengths of about 980nm 8001 the penetration depth 8006 may be defined as approximately 4mm, for wavelengths of about 1210nm 8002 the penetration depth 8005 may be defined as approximately 3mm, and for wavelengths of about 1700nm 8003 the penetration depth 8004 may be defined as approximately 2mm. These are only approximate values, and other values and criteria may be used to define the penetration depth. It may also be noted that the level of damage at the highest power points differs at the different wavelengths. For example, at the highest power point of 8003 near 1700nm, much more damage is observed, showing evidence of even boiling and cavitation. This may be due to the higher absorption level near 1700nm (e.g., 7701 in FIGURE 77). On the other hand, at the highest power point 8001 near 980nm, the damage is not as catastrophic, but the spot size appears larger. The larger spot size may be due to the increased scattering at the shorter wavelengths (e.g., 7701 in FIGURE 77). Based on data 8000 such as in FIGURE 80, it may be possible to select the particular wavelength for the laser beam to be used in the non-invasive procedure.

[0413] Even near wavelengths such as described in FIGURE 80, the particular wavelength selected may be more specifically defined based on the target tissue of interest. In one particular embodiment, the vessel lumen may be modeled as water, and for this example assume that wavelengths in the vicinity of 980nm are being selected to create thermal coagulation or occlusion. FIGURE 81 shows the optical absorption or density as a function of wavelength 8100 between approximately 700nm and 1300nm. Curves are shown for the water absorption 8101, hemoglobin Hb absorption 8102, and oxygenated hemoglobin HbO2 8103. In this example, two particular

wavelengths are compared: 980nm 8104 and 1075nm 8105. For instance, 980nm may be generated using one or more laser diodes, while 1075nm may be generated using an ytterbium-doped fiber laser. If maximizing the penetration depth is the significant problem, then 1075nm 8105 may be preferred, since it falls near a local minimum in water 8101, hemoglobin 8102, and oxygenated hemoglobin 8103 absorption. On the other hand, if the penetration depth at 980nm 8104 is adequate and the problem is to generate heat through water absorption, then 980nm 8104 may be a preferred wavelength for the light source because of the higher water absorption. This wavelength range is only meant to be exemplary, but other wavelength ranges and particular criteria for selecting the wavelength may be used and are intended to be covered by this disclosure.

[0414] In another embodiment, focused infrared light has been used to preserve the top layer of a tissue while damaging nerves at a deeper level. For instance, FIGURE 82 illustrates the set-up 8200 used for the focused infrared experiments. In this embodiment, a lens 8201 is used to focus the light. Although a single lens is shown, either multiple lenses, GRIN (gradient index) lenses, curved mirrors, or a combination of lenses and mirrors may be used. In this particular example, the tissue 8204 is placed between two microscope slides 8202 and 8203 for in vitro experiments. The tissue 8204 is renal artery wall either from porcine or bovine animals (about 1.2mm thick sample) – i.e., this is the artery leading to the kidneys, and it is the artery where typically renal denervation may be performed to treat hypertension. For this example, the minimum beam waist 8205 falls behind the tissue, and the intensity contrast from the front of the tissue (closest to the lens) to the back of the tissue (furthest from the lens) is about 4:1. These are particular ranges used for this experiment, but other values and locations of minimum beam waist may also be used and intended to be covered by this disclosure.

[0415] For a particular embodiment, histology of the renal artery is shown in FIGURE 83A for no laser exposure 8300 and shown in FIGURE 83B with focused infrared laser exposure 8350. In this experiment, the beam diameter incident on the lens was about 4mm, and the distance from the edge of the flat side of lens to the minimum beam waist was about 3.75mm. The beam diameter on the front side of the renal artery (i.e., the endothelium side) was about 1.6mm, and the beam diameter on the back side of the renal artery was about 0.8mm. In FIGURE 83A with no laser exposure, the layers of the artery wall may be identified: top layer of endothelium 8301 that is about 0.05mm thick, the media comprising smooth muscle cells or tissue 8302 that is about

0.75mm thick, and the adventitia 8303 comprising some of the renal nerves 8304 that is about 1.1mm thick. These are particular values for this experiment, and other layers and thicknesses may also be used and are intended to be covered by this disclosure.

[0416] The histology with focused infrared light exposure 8350 is illustrated in FIGURE 83B. The laser light used is near 1708nm from a cascaded Raman oscillator (described in greater detail herein), and the power incident on the tissue is about 0.8W and the beam is scanned across the tissue at a rate of approximately 0.4mm/sec. The various layers are still observable: the endothelium 8351, the media 8352, and the adventitia 8353. With this type of histology, the non-damaged regions remain darker (similar to FIGURE 83A), while the laser induced damaged regions turn lighter in color. In this example, the endothelium 8351 and top layer of the media 8352 remain undamaged – i.e., the top approximately 0.5mm is the undamaged region 8356. The laser damaged region 8357 extends for about 1mm, and it includes the bottom layer of the media 8352 and much of the adventitia 8353. The renal nerves 8354 that fall within the damage region 8357 are also damaged (i.e., lighter colored). On the other hand, the renal nerves beyond this depth, such as 8355, may remain undamaged.

[0417] Thus, by using focused infrared light near 1708nm in this example, the top approximately 0.5mm of the renal artery is spared from laser damage. It should be noted that when the same experiment is conducted with a collimated laser beam, the entire approximately 1.5mm is damaged (i.e., including regions 8356 and 8357). Therefore, the cone of light with the lower intensity at the top and the higher intensity toward the bottom may, in fact, help preserve the top layer from damage. There should be a Beer's Law attenuation of the light intensity as the light propagates into the tissue. For example, the light intensity should reduce exponentially at a rate determined by the absorption coefficient. In these experiments it appears that the focused light is able to overcome the Beer's law attenuation and still provide contrast in intensity between the front and back surfaces.

[0418] In another embodiment, experiments have also been conducted on dermatology samples with surface cooling, and surface cooling is shown to preserve the top layer of the skin during laser exposure. In this particular example, the experimental set-up 8400 is illustrated in FIGURE 84. The skin sample 8404, or more generally sample under test, is placed in a sample

holder 8403. The sample holder 8403 has a cooling side 8401 and a heating side 8402. The heating side 8402 comprises a heater 8405, which may be adjusted to operate around 37 degrees Celsius – i.e., close to body temperature. The cooling side 8401 is coupled to an ice-water bath 8407 (around 2 degrees Celsius) and a warm-water bath 8406 (around 37 degrees Celsius) through a switching valve 8408. The entire sample holder 8403 is mounted on a linear motor 8409, so the sample can be moved perpendicular 8410 to the incoming light beam.

[0419] In this embodiment, the light is incident on the sample 8404 through a sapphire window 8411. The sapphire material 8411 is selected because it is transparent to the infrared wavelengths, while also being a good thermal conductor. Thus, the top layer of the sample 8404 may be cooled by being approximately in contact with the sapphire window 8411. The laser light 8412 used is near 1708nm from a cascaded Raman oscillator (described in greater detail herein), and one or more collimating lenses 8413 are used to create a beam with a diameter 8414 of approximately 2mm. This is one particular embodiment of the sample surface cooling arrangement, but other apparatuses and methods may be used and are intended to be covered by this disclosure.

[0420] Experimental results obtained using the set-up of FIGURE 84 are included in FIGURE 18. In this example, FIGURE 85 shows the MTT histochemistry of human skin 8500 treated with ~1708 nm laser (5 seconds pre-cool; 2mm diameter spot exposure for 3 seconds) at 725 mW (A 8501, B 8502) corresponding to about 70 J/cm2 average fluence, and 830 mW (C 8503, D 8504) corresponding to about 80 J/cm2 average fluence. The images in FIGURE 85 show that the application of a cold window was effective in protecting the epidermis 8505 (darker top layer) and the top approximately 0.4 or 0.5mm of the dermis 8506. As before, the darker regions of the histology correspond to undamaged regions, while the lighter regions correspond to damaged regions. In contrast, when no surface cooling is applied, then thermal damage to the dermis occurs in the epidermis and dermis where the laser exposure occurs, and the thermal damage extends to about 1.3 or 1.4 mm or more from the skin surface. Thus, surface cooling applied to the skin may help to reduce or eliminate damage to the top layer of the skin under laser exposure.

[0421] In summary, experiments verify that infrared light, such as near 980nm, 1210nm, or 1700nm, may achieve penetration depths between approximately 2mm to 4mm or more. The top layer of skin or tissue may be spared damage under laser exposure by focusing the light beyond the top layer, applying surface cooling, or some combination of the two. These are particular experimental results, but other wavelengths, methods and apparatuses may be used for achieving the penetration and minimizing damage to the top layer and are intended to be covered by this disclosure. In an alternate embodiment, it may be beneficial to use wavelengths near 1310nm if the absorption from skin constituents (FIGURE 77), such as collagen 7703, adipose 7702 and elastin 7704, are to be minimized. The water absorption 7701 near 1310nm may still permit a penetration depth of approximately 1cm, or perhaps less. In yet another embodiment, wavelengths near 1210nm may be beneficial, if penetration depths on the order of 3mm are adequate and less scattering loss (e.g. 7701 in FIGURE 77) is desired. Any of FIGURES 68, 73, 75, 77, or 78 may be used to select these or other wavelengths to achieve the desired penetration depth and to also perhaps target particular tissue of interest, and these alternate embodiments are also intended to be covered by this disclosure.

[0422] LASER SYSTEMS FOR THERAPEUTICS OR DIAGNOSTICS

[0423] Infrared light sources can be used for diagnostics and therapeutics in a number of medical applications. For example, broadband light sources can advantageously be used for diagnostics, while narrower band light sources can advantageously be used for therapeutics. In one embodiment, selective absorption or damage can be achieved by choosing the laser wavelength to lie approximately at an absorption peak of particular tissue types. Also, by using infrared wavelengths that minimize water absorption peaks and longer wavelengths that have lower tissue scattering, larger penetration depths into the biological tissue can be obtained. In this disclosure, infrared wavelengths include wavelengths in the range of approximately 0.9 microns to 10 microns, with wavelengths between about 0.98 microns and 2.5 microns more suitable for certain applications.

[0424] As used throughout this document, the term "couple" and or "coupled" refers to any direct or indirect communication between two or more elements, whether or not those elements are physically connected to one another. In this disclosure, the term "damage" refers to affecting

a tissue or sample so as to render the tissue or sample inoperable. For instance, if a particular tissue normally emits certain signaling chemicals, then by "damaging" the tissue is meant that the tissue reduces or no longer emits that certain signaling chemical. The term "damage" and or "damaged" may include ablation, melting, charring, killing, or simply incapacitating the chemical emissions from the particular tissue or sample. In one embodiment, histology or histochemical analysis may be used to determine whether a tissue or sample has been damaged.

[0425] As used throughout this disclosure, the term "spectroscopy" means that a tissue or sample is inspected by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, refractive index, or opacity. In one embodiment, "spectroscopy" may mean that the wavelength of the light source is varied, and the transmission, absorption or reflectivity of the tissue or sample is measured as a function of wavelength. In another embodiment, "spectroscopy" may mean that the wavelength dependence of the transmission, absorption or reflectivity is compared between different spatial locations on a tissue or sample. As an illustration, the "spectroscopy" may be performed by varying the wavelength of the light source, or by using a broadband light source and analyzing the signal using a spectrometer, wavemeter, or optical spectrum analyzer.

[0426] As used throughout this document, the term "fiber laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein at least a part of the laser comprises an optical fiber. For instance, the fiber in the "fiber laser" may comprise one of or a combination of a single mode fiber, a multi-mode fiber, a mid-infrared fiber, a photonic crystal fiber, a doped fiber, a gain fiber, or, more generally, an approximately cylindrically shaped waveguide or light-pipe. In one embodiment, the gain fiber may be doped with rare earth material, such as ytterbium, erbium, and/or thulium. In another embodiment, the infrared fiber may comprise one or a combination of fluoride fiber, ZBLAN fiber, chalcogenide fiber, tellurite fiber, or germanium doped fiber. In yet another embodiment, the single mode fiber may include standard single-mode fiber, dispersion shifted fiber, non-zero dispersion shifted fiber, high-nonlinearity fiber, and small core size fibers.

[0427] As used throughout this disclosure, the term "pump laser" refers to a laser or oscillator that has as an output light or an optical beam, wherein the output light or optical beam

may be coupled to a gain medium to excite the gain medium, which in turn may amplify another input optical signal or beam. In one particular example, the gain medium may be a doped fiber, such as a fiber doped with ytterbium, erbium, and/or thulium. In another embodiment, the gain medium may be a fused silica fiber or a fiber with a Raman effect from the glass. In one embodiment, the "pump laser" may be a fiber laser, a solid state laser, a laser involving a nonlinear crystal, an optical parametric oscillator, a semiconductor laser, or a plurality of semiconductor lasers that may be multiplexed together. In another embodiment, the "pump laser" may be coupled to the gain medium by using a fiber coupler, a dichroic mirror, a multiplexer, a wavelength division multiplexer, a grating, or a fused fiber coupler.

[0428] As used throughout this document, the term "super-continuum" and/or "supercontinuum" and/or "SC" refers to a broadband light beam or output that comprises a plurality of wavelengths. In a particular example, the plurality of wavelengths may be adjacent to one-another, so that the spectrum of the light beam or output appears as a continuous band when measured with a spectrometer. In one embodiment, the broadband light beam may have a bandwidth of at least 10nm. In another embodiment, the "super-continuum" may be generated through nonlinear optical interactions in a medium, such as an optical fiber or nonlinear crystal. For example, the "super-continuum" may be generated through one or a combination of nonlinear activities such as four-wave mixing, the Raman effect, modulational instability, and self-phase modulation.

[0429] As used throughout this disclosure, the terms "optical light" and/or "optical beam" and or "light beam" refer to photons or light transmitted to a particular location in space. The "optical light" and or "optical beam" and/or "light beam" may be modulated or unmodulated, which also means that they may or may not contain information. In one embodiment, the "optical light" and/or "optical beam" and/or "light beam" may originate from a fiber, a fiber laser, a laser, a light emitting diode, a lamp, a pump laser, or a light source.

[0430] As used throughout this document, the terms "near" or "about" or the symbol "~" refer to one or more wavelengths of light with wavelengths around the stated wavelength to accomplish the function described. For example, "near 1720nm" may include wavelengths of between about 1680nm and 1760nm. In one embodiment, the term "near 1720nm" refers to one

or more wavelengths of light with a wavelength value anywhere between approximately 1700nm and 1740nm. Similarly, as used throughout this document, the term "near 1210nm" refers to one or wavelengths of light with a wavelength value anywhere between approximately 1170nm and 1250nm. In one embodiment, the term "near 1210nm" refers to one or more wavelengths of light with a wavelength value anywhere between approximately 1190nm and 1230nm.

[0431] While exemplary embodiments are described above, it is not intended that these embodiments describe all possible forms of the disclosure. Rather, the words used in the specification are words of description rather than limitation, and it is understood that various changes may be made without departing from the spirit and scope of the disclosure. Additionally, the features of various implementing embodiments may be combined to form further embodiments of the disclosure. While various embodiments may have been described as providing advantages or being preferred over other embodiments with respect to one or more desired characteristics, as one skilled in the art is aware, one or more characteristics may be compromised to achieve desired system attributes, which depend on the specific application and implementation. These attributes include, but are not limited to: cost, strength, durability, life cycle cost, marketability, appearance, packaging, size, serviceability, weight, manufacturability, ease of assembly, etc. The embodiments described herein that are described as less desirable than other embodiments or prior art implementations with respect to one or more characteristics are not outside the scope of the disclosure and may be desirable for particular applications.

WHAT IS CLAIMED IS:

1. An apparatus adapted to be worn by a user comprising:

one or more biosensors adapted to be placed on the user, wherein one or more physiological parameters are measured, wherein measuring of the one or more physiological parameters comprises a differential measurement, and wherein the one or more physiological parameters comprises a pulse rate monitoring and a blood flow measurement;

a light source comprising a plurality of light emitting diodes that are configured to generate an output optical light having one or more optical wavelengths;

one or more lenses configured to receive at least a portion of the output optical light and to deliver a lens output light to tissue comprising skin;

a detection system configured to receive at least a portion of the lens output light reflected from the tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source, wherein the detection system comprises a plurality of detectors that are spatially separated from each other, and wherein at least one analog to digital converter is coupled to at least one of the plurality of detectors;

wherein the output signal is indicative of the one or more physiological parameters;

the apparatus being configured to increase the signal-to-noise ratio by increasing light intensity of at least one of the plurality of light emitting diodes from an initial light intensity; and

the detection system further configured to:

generate a first signal responsive to light received while the light emitting diodes are off,

generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal; and

wherein the apparatus is at least in part configured to determine, based at least in part on the output signal, that the apparatus is being worn by the user.

2. The apparatus of Claim 1, wherein the tissue further comprises blood vessels and the one or more physiological parameters are related to hypertension, and wherein the blood flow measurement is affected by a temporal lag between different parts of the user.

3. The apparatus of Claim 1, wherein the tissue further comprises blood vessels and the one or more physiological parameters are related to hypertension, and wherein the differential measurement comprises a comparison of at least two separate spatial locations on the user.

4. The apparatus of Claim 1, wherein the one or more physiological parameters is configured to change in response to stretching of a hand of the user, movement of a finger of the user, or movement of a thumb of the user, and wherein the apparatus is further configured to combine at least a part of the output signal with data from at least some other of the one of more biosensors.

5. The apparatus of claim 1, wherein the apparatus further comprises a processor configured to be coupled to a non-transitory computer readable medium, and wherein the apparatus including the processor is configured to use artificial intelligence in making decisions associated with at least a portion of the output signal.

6. The apparatus of claim 1, wherein the plurality of light emitting diodes comprises six light emitting diodes, and wherein the detection system comprises the plurality of detectors arranged along an arc.

7. The apparatus of claim 6, wherein the apparatus is further configured to communicate with a smart phone or a tablet, the smart phone or the tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, one or more buttons or knobs, a microprocessor, and a touch screen.

8. A wearable device configured to be worn by a user, the wearable device comprising:

a light source configured to be on or off, responsive to the light source being on, the light source generates an output light;

a lens positioned to direct at least a portion of the output light towards a bodily tissue of the user;

a detector; and

a processor configured to:

(i) responsive to the light source being on and the detector receiving at least a portion of the output light that is reflected from the bodily tissue of the user, generate a first output signal having a first signal-to-noise ratio; and

(ii) responsive to the light source being off and the detector receiving ambient light, generate a second output signal having a second signal-to-noise ratio;

(iii) generate a third output signal using at least a portion of the first output signal and at least a portion of the second output signal, the third output signal having a third signal-to-noise ratio that is greater than the first signal-to-noise ratio and greater than the second signal-to-noise ratio, the third output signal being associated with a physiological parameter of the user; and

(iv) determine, based at least in part on the third output signal, that the wearable device is being worn by the user.

9. The wearable device of claim 8, wherein the generation of the third output signal is in response to movement of a thumb and a finger of the user.

10. The wearable device of claim 8, wherein the physiological parameter of the user changes in response to movement of a thumb and a finger of the user.

11. The wearable device of claim 8, wherein at least a portion of the output light has an optical wavelength between about 700 nanometers and about 2500 nanometers.

12. The wearable device of claim 8, wherein the physiological parameter of the user is associated with a blood constituent or a blood flow of the user.

13. The wearable device of claim 8, wherein the processor is further configured to modulate the light source with a modulation frequency.

14. The wearable device of claim 13, wherein the processor is further configured to cause the detector to apply narrow band filtering to the at least a portion of the output light that is reflected from the bodily tissue of the user around the modulation frequency.

15. A system for a device worn by a user comprising:

a light source comprising a plurality of light emitting diodes that are configured to generate an output optical light having one or more optical wavelengths;

one or more lenses configured to receive at least a portion of the output optical light and to direct a lens output light towards a bodily tissue of the user; and

a detection system configured to receive at least a portion of the lens output light reflected from the bodily tissue and to generate an output signal having a signal-to-noise ratio, wherein the detection system is configured to be synchronized to the light source, wherein the signal-to-noise ratio of the output signal is increased by increasing light intensity of at least one of the plurality of light emitting diodes from an initial light intensity, wherein the detection system comprises a plurality of detectors that are spatially separated from each other, and wherein at least one analog to digital converter is coupled to at least one of the plurality of detectors;

wherein the output signal is associated with one or more physiological parameters; and

wherein the detection system configured to:

generate a first signal responsive to light received while the light emitting diodes are off,

generate a second signal responsive to light received while at least one of the light emitting diodes is on, and

increase the signal-to-noise ratio by comparing the first signal and the second signal; and

measuring the one or more physiological parameters when worn by the user, wherein the one or more physiological parameters change in response to stretching of a hand of the user, movement of a finger of the user, or movement of a thumb of the user, and wherein the device is at least in part configured to determine, based at least in part on the output signal, that the device is being worn by the user.

16. The system of claim 15, wherein the plurality of light emitting diodes comprises six light emitting diodes, and wherein the detection system comprises the plurality of detectors arranged along an arc.

17. The system of claim 16, wherein the device is configured to use artificial intelligence in making decisions associated with at least a portion of the output signal.

18. The system of claim 17, wherein the device is further configured to combine at least a part of the output signal with data from other non-invasive devices or biosensors adapted to be placed on the user.

19. The system of claim 18, wherein the device is further configured to communicate with a smart phone or a tablet, the smart phone or the tablet comprising a wireless receiver, a wireless transmitter, a display, a speaker, a voice input module, a microprocessor, and a touch screen.

20. The system of claim 19, the device further configured to be coupled to an imaging system configured to remotely sense the user, the imaging system comprising:

a laser diode configured to be pulsed and to generate laser light having a laser wavelength, wherein the laser wavelength is a near-infrared wavelength between 700 nanometers and 2500 nanometers, and wherein the laser diode comprises one or more Bragg reflectors;

a beam splitter configured to receive at least part of received laser light from the laser diode and to split the received laser light into a sample arm light and a reference arm light, at least a portion of the sample arm light configured to be directed to the user;

the imaging system further comprising a second plurality of detectors; and

at least one of the second plurality of detectors configured to receive at least a portion of the reference arm light and configured to generate a reference detector output, and at least another of the second plurality of detectors configured to receive from the user at least a portion of reflected sample arm light and configured to generate a sample detector output; and

wherein the imaging system is configured to measure time-of-flight based at least in part on the sample detector output.

ABSTRACT

A wearable device to measure a user's physiological parameters comprising one or more biosensors, as well as a light source comprising light emitting diodes, lenses for directing light towards tissue of the user comprising blood vessels, and a detection system receiving reflected tissue light. The physiological parameters, for example hypertension, are measured with a differential measurement. For example, the physiological parameters may be associated with pulse rate and blood flow. The output signal is associated with the physiological parameters, and artificial intelligence may be used in making decisions regarding the output signal. Signal-to-noise ratio of the output signal may be improved by synchronizing the detection system to the light source, increasing light intensity, and detecting a change. The wearable device is configured to determine that is being worn by the user and may be configured to communicate with a smartphone or tablet.

Attorney Docket Number	OMNI0101PUSA13

ASSIGNMENT AND DECLARATION (37 C.F.R. 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. 1.76)

Title of Invention	WEARABLE DEVICES COMPRISING SEMICONDUCTOR DIODE LIGHT SOURCES WITH IMPROVED SIGNAL-TO-NOISE RATIO

As a below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application, or

☐ United States application or PCT international application number 18/891,970 filed on September 20, 2024. (I hereby authorize the insertion of the application filing date and number when they become known.)

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 state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I am aware of the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. § 1.56.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, I do hereby assign, sell and set over to OMNI MEDSCI, INC., a corporation organized and existing under the laws of the state of Michigan, and having a place of business at 1718 Newport Creek Drive, Ann Arbor, MI 48103, hereinafter referred to as the ASSIGNEE, its successors, assigns or other legal representatives, my entire right, title and interest, domestic and foreign, in and to the inventions and discoveries in the above-identified application including the right of said ASSIGNEE, its successors, assigns or other legal representatives to make applications and to receive Letters Patent for said inventions and discoveries in any and all foreign countries in its or their own name or names, or in my name, at its or their election, and I hereby assign, sell and set over to said ASSIGNEE, its successors, assigns or other legal representatives, all rights of priority, including any provisional applications, in and to said inventions and discoveries in all countries, including all applications claiming benefit of the filing date hereof, continuations, continuations-in-part, divisionals, reexaminations and reissue applications.

And I hereby agree for myself, my heirs, successors, assigns or other legal representatives to execute any and all papers, including applications for Letters Patent of any and all kinds and in any and all countries and to perform any and all acts which said ASSIGNEE, its successors, assigns or other legal representatives may deem necessary to secure thereto the rights herein assigned, sold and set over.

And I hereby represent and warrant that I have not granted any rights inconsistent with the rights granted herein.

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.

LEGAL NAME OF INVENTOR

Inventor: MOHAMMED N. ISLAM Date: 10/21/2020

Signature: 

Page 1 (Supplemental Sheet with Additional Joint Inventors is attached if necessary)

Note: An Application Data Sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Mohammed N. Islam	Nonprovisional Application Number (if known):	
Title of Invention:	WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via Patent Center or EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via Patent Center or EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Kevin J. Heinl/	Date 2024-10-25
Name (Print/Typed) Kevin J. Heinl	Practitioner Registration Number 29,805

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
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CONFIRMATION NO. 9133

109543
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FILING RECEIPT



Date Mailed: 11/06/2024

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Mohammed N. ISLAM, Ann Arbor, MI;

Applicant(s)

OMNI MEDSCI, INC., Ann Arbor, MI;

Power of Attorney: The patent practitioners associated with Customer Number 109543

Domestic Priority data as claimed by applicant

This application is a CON of 18/899,012 09/27/2024
which is a CON of 18/891,970 09/20/2024
which is a CON of 18/438,144 02/09/2024
which is a CON of 18/103,408 01/30/2023 PAT 11,896,346
which is a CON of 17/514,778 10/29/2021 PAT 11,564,577
which is a CON of 17/078,771 10/23/2020 PAT 11,160,455
which is a CON of 16/722,188 12/20/2019 PAT 10,820,807
which is a CON of 16/506,885 07/09/2019 PAT 10,517,484
which is a CON of 16/272,069 02/11/2019 ABN
which is a CON of 16/029,611 07/08/2018 PAT 10,201,283
which is a CON of 15/888,052 02/04/2018 PAT 10,136,819
which is a CON of 15/212,549 07/18/2016 PAT 9,885,698
which is a CON of 14/650,897 06/10/2015 PAT 9,494,567
which is a 371 of PCT/US2013/075700 12/17/2013
which claims benefit of 61/747,472 12/31/2012
and said 16/506,885 07/09/2019 is a CON of 16/004,359 06/09/2018 PAT 11,109,761

which is a CON of 14/109,007 12/17/2013 PAT 9,993,159
which claims benefit of 61/747,553 12/31/2012
and said 16/506,885 07/09/2019 is a CON of 16/188,194 11/12/2018 PAT 10,386,230
which is a CON of 16/004,154 06/08/2018 PAT 10,126,283
which is a CON of 15/855,201 12/27/2017 PAT 9,995,722
which is a CON of 15/711,907 09/21/2017 PAT 9,897,584
which is a DIV of 15/357,225 11/21/2016 PAT 9,797,876
which is a CON of 14/650,981 06/10/2015 PAT 9,500,634
and said 16/506,885 07/09/2019 is a CON of 16/241,628 01/07/2019 PAT 10,441,176
which is a CON of 16/015,737 06/22/2018 PAT 10,172,523
which is a CON of 15/594,053 05/12/2017 PAT 10,188,299
which is a CON of 14/875,709 10/06/2015 PAT 9,651,533
which is a CON of 14/108,986 12/17/2013 PAT 9,164,032
which claims benefit of 61/747,487 12/31/2012
and said 16/506,885 07/09/2019 is a CON of 16/284,514 02/25/2019 ABN
which is a CON of 16/016,649 06/24/2018 PAT 10,213,113
which is a CON of 15/860,065 01/02/2018 PAT 10,098,546
which is a CON of 15/686,198 08/25/2017 PAT 9,861,286
which is a CON of 15/357,136 11/21/2016 PAT 9,757,040
which is a CON of 14/651,367 06/11/2015 PAT 9,500,635
which is a 371 of PCT/US2013/075736 12/17/2013
which claims benefit of 61/747,477 12/31/2012
and claims benefit of 61/754,698 01/21/2013

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 11/05/2024
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/927,698**
Projected Publication Date: 02/13/2025
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes

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.

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 18/927,698

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	64		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	280		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	320		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	* 0	x =	0	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x =	0			
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).			336			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1000		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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Under Secretary of Commerce for Intellectual Property and
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Kathi Vidal

Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Derrick Brent
Deputy Under Secretary of Commerce for Intellectual Property and
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/927,698	10/25/2024	Mohammed N. ISLAM	OMNI0101PUSA13

CONFIRMATION NO. 9133

109543
Brooks, Kushman P.C./Cheetah Omni MedSci
150 W 2nd St., Suite 400N
Royal Oak, MI 48067

IMPROPER CFR REQUEST

OC000000080283542

Date Mailed: 11/06/2024

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Continuity, Priority Claims, Petitions, and Non-Publication Requests

In response to your request for a corrected Filing Receipt, the Office is unable to comply with your request because:

- The international (PCT) application number may only contain either a four-digit year with a six-digit sequence number (recommended) or a two-digit year with a five-digit sequence number.

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/ptnguyen/

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	18927698
	Filing Date	2024-10-25
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI0101PUSA13

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5408409		1995-04-18	Glassman et al.	
	2	5774213		1998-06-30	Trebino et al.	
	3	5957854		1999-09-28	Besson et al.	
	4	5970457		1999-10-19	Brant et al.	
	5	6044283		2000-03-28	Fein et al.	
	6	6278975		2001-08-21	Brant et al.	
	7	6289238		2001-09-11	Besson et al.	
	8	6441747		2002-08-27	Khair et al.	

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	9	6549702		2003-04-15	Islam et al.	
	10	6603910		2003-08-05	Islam et al.	
	11	6898451		2005-05-24	Wuori	
	12	7060061		2006-06-13	Altshuler et al.	
	13	7167300		2007-01-23	Fermann et al.	
	14	7263288		2007-08-28	Islam	
	15	7278966		2007-10-09	Hjelt et al.	
	16	7318909		2008-01-15	Lehmann et al.	
	17	7433116		2008-10-07	Islam	
	18	7519253		2009-04-14	Islam	
	19	7787924		2010-08-31	Acosta et al.	

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	Art Unit	
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	20	8198589		2012-06-12	Tolton et al.	
	21	8463576		2013-06-11	Yuen et al.	
	22	8472108		2013-06-25	Islam	
	23	8948832		2015-02-03	Hong et al.	
	24	9142117		2015-09-22	Muhsin et al.	
	25	9326712		2016-05-03	Kiani	
	26	9596990		2017-03-21	Park et al.	
	27	9757040		2017-09-12	Islam	
	28	9861286		2018-01-09	Islam	
	29	9885698		2018-02-06	Islam	
	30	6505133		2003-01-07	Hanna et al.	

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	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI0101PUSA13

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2024-10-25
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI0101PUSA13

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

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OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Kevin J. Heinl/	Date (YYYY-MM-DD)	2024-12-12
Name/Print	Kevin J. Heinl	Registration Number	29805

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18927698
Filing Date	2024-10-25
First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI0101PUSA13

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Kevin J. Heinl/	Date (YYYY-MM-DD)	2024-12-12
Name/Print	Kevin J. Heinl	Registration Number	29805

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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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.

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/927,698	**12/12/2024 02:25:08 PM Z ET**	**OMNI0101PUSA13**

Title of Invention

WEARABLE DEVICE FOR DIFFERENTIAL MEASUREMENT ON PULSE RATE AND BLOOD FLOW

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9133	FILED BY	Sharon Kaiser
PATENT CENTER #	68346235	FILING DATE	10/25/2024
CUSTOMER #	109543	FIRST NAMED INVENTOR	Mohammed N. ISLAM
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Kevin Heinl

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
OMNI0101PUSA13_IDS_1_US_patents.pdf	20	Information Disclosure Statement (IDS) Form (SB08)	1021 KB
OMNI0101PUSA13_IDS_1_b_US_patents.pdf	6	Information Disclosure Statement (IDS) Form (SB08)	1018 KB

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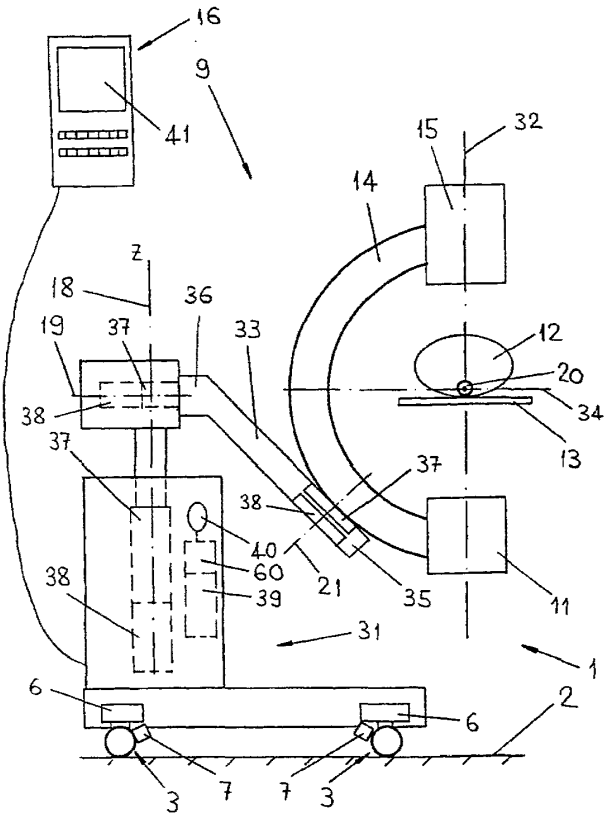
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[Fortsetzung auf der nächsten Seite]

(54) **Title:** DEVICE FOR MOVING A MEDICAL APPARATUS IN A CONTROLLED MANNER

(54) **Bezeichnung:** VORRICHTUNG ZUR KONTROLLIERTEN BEWEGUNG EINES MEDIZINISCHEN GERÄTS



(57) Abstract: The invention relates to a device for moving an X-ray apparatus in a controlled manner. The inventive apparatus is embodied as a C-bow (9) that can be displaced in parallel in relation to at least two axes (18; 19) and is mounted on a pedestal (31) in a rotatable manner in relation to three axes (18; 19; 21). Said pedestal comprises rollers (3) which can be driven by a motor. The direction of said rollers can be controlled. Each movement of the C-bow (9) is carried out in relation to a system of co-ordinates (29) and by means of controllable drive devices (6; 7; 37; 38). Said system is stationary in relation to the room. The drive devices (6; 7; 37; 38) are controlled by means of a computer (23) or a control device (39; 48) which can be controlled by means of a sterile control console or is voice-controlled. Adjusted positions or projections of the C-bow (9) can be stored in the computer (23) in such a way that a desired position or projection can be reproduced. The C-bow (9) can be combined with a surgical navigation system which comprises a position detection device (27). By measuring a reference base (51) that is provided with optical markers (28) and is applied to a patient (12) changes in the position of the patient (12) can thus be considered in such a way that an adjusted position and projection of the C-bow (9) can be reproduced after the patient (12) has changed position.

(57) Zusammenfassung: Vorrichtung zur kontrollierten Bewegung eines als C-Bogen (9) ausgeführten Röntgengerätes, wobei der C-Bogen (9) parallel bezüglich mindestens zweier Achsen (18; 19) verschiebbar und bezüglich dreier Achsen (18; 19; 21) rotierbar auf einem Sockel (31) mit motorisch antreibbaren und bezüglich ihrer Richtung steuerbaren

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— *mit internationalem Recherchenbericht*
— *mit geänderten Ansprüchen*

Zur Erklärung der Zweibuchstaben-Codes, und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

Rädern (3) montiert ist, wobei jede Bewegung des C-Bogens (9) relativ zu einem raumfesten Koordinatensystem (29) über steuerbare Antriebsvorrichtungen (6; 7; 37; 38) erfolgt. Die Steuerung dieser Antriebsvorrichtungen (6; 7; 37; 38) erfolgt entweder über eine Steuervorrichtung (39; 48), welche über eine sterile Steuerkonsole oder voice-controlled bedienbar ist, oder über einen Computer (23). Im Computer (23) sind einmal eingestellte Positionen und Projektionen des C-Bogens (9) speicherbar, so dass eine gewünschte Position und Projektion wieder reproduzierbar ist. Bei einer Kombination des C-Bogens (9) mit einem chirurgischen Navigationssystem, welches eine Positionserfassungsvorrichtung (27) umfasst, können mittels Vermessen einer an einem Patienten (12) angebrachten, mit optischen Markern (28) versehenen Referenzbasis (51) auch Lageänderungen des Patienten (12) so berücksichtigt werden, dass eine einmal eingestellte Position und Projektion des C-Bogens (9) auch nach einer Lageänderung des Patienten (12) wiederherstellbar ist.

Vorrichtung zur kontrollierten Bewegung eines medizinischen Geräts

Die Erfindung betrifft eine Vorrichtung zur kontrollierten Bewegung eines medizinischen Geräts gemäss dem Oberbegriff des Patentanspruchs 1 und ein Verfahren zur kontrollierten Bewegung eines medizinischen Gerätes gemäss dem Oberbegriff des Patentanspruchs 25.

Röntgengeräte, insbesondere solche, die auf einem C-förmigen Bogen an einem Ende eine Röntgenstrahlenquelle und am anderen Ende einen Röntgenstrahlen-empfänger (im folgenden kurz "C-Bogen" genannt) aufweisen, gehören zur Standardausstattung im unfallchirurgischen Operationssaal. Solche Geräte dienen der intraoperativen Bildgebung, um Repositionsmanöver bei den zu behandelnden Frakturen zu steuern und um das Einbringen von Implantaten für die Stabilisierung der Fraktur zu kontrollieren. Bei Anwendung des C-Bogens mit modernen chirurgischen Navigationssystemen werden intraoperativ erzeugte, in einem Computer speicherbare Fluoroskopiebilder benützt, um eine kontinuierliche Visualisierung des chirurgischen Verfahrens zu erlauben.

Da bei dem oben beschriebenen Vorgehen mit Röntgenstrahlen in Anwesenheit von Personen - Patient und OP Personal – gearbeitet wird, sollte die Positionierung des Röntgengerätes ohne lange Durchleuchtungszeit erfolgen und schon beim ersten Versuch richtig sein. Bislang wird aber der C-Bogen im Operationssaal nicht vom Operateur selbst, sondern durch einen OP Pfleger bewegt. Schon die Kommunikation zwischen dem Operateur und dem OP Pfleger über eine gewünschte, auszuführende Bewegung des Gerätes relativ zum Patienten beinhaltet zahlreiche Fehlermöglichkeiten. Oft wird der C-Bogen nach einem Operationsschritt benützt, um den Erfolg des Eingriffes zu kontrollieren und zu dokumentieren. Falls eine Korrektur des vorläufigen Ergebnisses erforderlich ist, muss der C-Bogen aus der mühsam gefundenen richtigen Position wieder entfernt werden, da das Gerät den Operateur sonst bei der Durchführung der Korrektur am Implantat oder am Knochenbruch behindert. Für die anschliessend notwendige Kontrolle muss der C-Bogen wiederum an die zuvor gefundene „richtige" Position dirigiert werden. Die Folge davon ist, dass oft lange Durchleuchtungszeiten entstehen, bis der Bildverstärker das richtige Bild

Bestätigungskopie

liefert. Ein C-Bogen mit „Gedächtnis" für eine einmal gefundene korrekte Einstellung würde eine deutliche Verbesserung bedeuten.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung zur kontrollierten Bewegung eines medizinischen Geräts, insbesondere eines Röntgengerätes zu schaffen.

Die Erfindung löst die gestellte Aufgabe mit einer Vorrichtung zur kontrollierten Bewegung eines medizinischen Geräts, insbesondere eines Röntgengerätes, welche die Merkmale des Anspruchs 1 aufweist, sowie mit einem Verfahren zur kontrollierten Bewegung eines medizinischen Gerätes, welches die Merkmale des Anspruchs 25 aufweist.

Variante ohne chirurgisches Navigationssystem (Basisversion)

Damit ist der Vorteil erzielbar, dass die Bewegung des Röntgengerätes durch den Operateur selbst erfolgt. Die vom Operateur gegebenen und in seinem eigenen Koordinatensystem gedachten Anweisungen müssen dann nicht mehr von einer zweiten Person interpretiert und umgesetzt werden.

Die erfindungsgemässe Vorrichtung zur kontrollierten Bewegung eines medizinischen Geräts dient zur steuerbaren Positionierung insbesondere eines Röntgengerätes in den zwei Dimensionen (x/y) einer Ebene, insbesondere einer parallel zum Boden eines Operationssaals liegenden Ebene. Die Vorrichtung umfasst mindestens drei, motorisch antreibbare Räder, welche über eine erste, zur Ebene parallel verlaufende, das Zentrum des Rades durchstossende Drehachse und eine zweite, senkrecht zur Ebene verlaufende, in der Ebene des Rades oder parallel zu dieser liegende Drehachse verfügen. Die Räder sind relativ zueinander fest positioniert. Jedes der Räder verfügt über eine erste Antriebsvorrichtung, mit welcher das Rad um die erste Drehachse rotierbar ist und über eine zweite Antriebsvorrichtung, mit welcher das Rad um die zweite Drehachse zur Änderung seiner Laufrichtung drehbar ist.

Die Räder können über ihre zweite Drehachse direkt am medizinischen Gerät befestigt sein, oder über ihre zweite Drehachse an einem als Plattform für das

medizinische Gerät bestimmten Rahmen befestigt sein. Die Ausführung mit Plattform eignet sich besonders zur Nachrüstung bereits existierender Geräte, während die Ausführung mit direkt am Gerät befestigten Rädern eher für Neugeräte in Betracht zu ziehen ist.

Als erste und zweite Antriebsvorrichtungen sind Schrittmotoren, insbesondere elektronisch steuerbare Schrittmotoren einsetzbar. Ebenfalls sind Schrittmotoren auf der Basis der digitalen Antriebstechnik möglich. Weiterführende Angaben zu solchen Schrittmotoren können beispielsweise aus

Dubbel; Taschenbuch für den Maschinenbau; Hrsg. W. Beitz und K.-H. Grote; Springer Verlag, 19. Auflage, 1997; Seiten: T9 und V29

entnommen werden.

Das erfindungsgemässe Röntgengerät ist vorzugsweise in Form eines C-Bogen mit einem Sockel auf der erfindungsgemässen Vorrichtung montiert. Bei C-Bogen kommen üblicherweise neben den oben erwähnten zwei Verfahrrichtungen in der Ebene parallel zum Boden des Operationsraumes weitere Bewegungsachsen für den C-Bogen relativ zum fahrbaren Sockel, welcher lediglich die Bewegungen des Gerätes parallel zum Boden ausführt, hinzu. Zur Handhabung des C-Bogens ist mindestens eine lineare Bewegung des C-Bogens parallel zu einer senkrecht auf dem Boden des Operationsraumes stehenden Achse (z-Achse) sowie Rotationbewegungen um mindestens zwei weitere Achsen notwendig. Auch diese Bewegungen des C-Bogens werden motorisiert ausgeführt. Der Antrieb dieser Bewegungen kann, wie vorangehend für die Räder der erfindungsgemässen Vorrichtung beschrieben, ebenfalls mittels Schrittmotoren erfolgen. Für lineare Bewegungen sind Linearmotoren, wie sie beispielsweise in

Dubbel; Taschenbuch für den Maschinenbau; Hrsg. W. Beitz und K.-H. Grote; Springer Verlag, 19. Auflage, 1997; Seiten: T9 und V31

ausführlich beschrieben werden, geeignet.

Die Steuerung aller oben erwähnten Antriebe kann einerseits durch den Operateur unter direkter visueller Kontrolle oder durch Aufrufen von gespeicherten Daten bezüglich einer zuvor eingenommenen Position und Projektion erfolgen:

1. Die erste Positionierung des C-Bogens erfolgt in dieser Ausführungsform des erfindungsgemässen Röntgengerätes durch den Operateur unter direkter Sichtkontrolle mittels:

a) Nutzen einer sterilisierbaren, vorzugsweise drahtlos arbeitenden Steuerkonsole; oder
b) Voice controlled (z.B. mit den Befehlen: vor, zurück, rechts, links, schnell, langsam, schwenke um Achse A,B,C).

2. Zur Positionierung des C-Bogens durch Aufrufen von gespeicherten Daten umfasst das erfindungsgemässe Röntgengerät zusätzlich einen Computer mit mindestens einem Datenspeicher, einem Bildschirm und einer Tastatur. Zur Wiederholung einer zuvor eingenommenen Projektion ergibt sich somit die Möglichkeit in Kombination mit dem Computer die bei der ersten Positionierung durchfahrenen Wege in ihrer zeitlichen Abfolge und Länge im Datenspeicher zu speichern und durch Aufruf einer im Computer gespeicherten Steuerfunktion zu reproduzieren. Der Aufruf dieser Steuerfunktion kann wiederum mittels einer Steuerkonsole oder „voice-controlled" (z.B. mit den Befehlen: Position 1, Position 2) erfolgen.

Mit dem erfindungsgemässen Röntgengerät ist der Vorteil erzielbar, dass vom C-Bogen eingenommene Positionen und Projektionen speicherbar sind und durch Abrufen der gespeicherten Daten automatisch aus einer beliebigen Position wieder eingenommen werden können. Dies ist beispielsweise für Kontrollen nach Korrekturen an einem Implantat oder Knochenbruch, wozu der C-Bogen zwecks Nichtbehinderung des Operateurs aus seiner Position entfernt wird, günstig. Die Steuerung des C-Bogens erhält somit eine „Gedächtnisfunktion" bezüglich vorgängig eingestellter Projektionen. Intraoperativ bestimmte Positionen und Projektionen des C-Bogens bezüglich des Patienten lassen sich daher vom Operateur nach Durchführung weiterer Operationsschritte beliebig oft wieder reproduzieren, ohne dass erneute Durchleuchtungskontrollen für die Positionierung notwendig sind. Die computergesteuerte Ausführungsform ermöglicht zudem eine Visualisierung des

geplanten Verfahrweges des C-Bogens auf dem Bildschirm des Computers, wodurch Kollisionen mit Gegenständen im Operationsraum beim automatischen Positionieren vermeidbar werden.

C-Bogen mit kombiniertem chirurgischen Navigationssystem

In einer weiteren Ausführungsform des erfindungsgemässen Röntgengerätes wird dieses kombiniert mit einem chirurgischen Navigationssystem betrieben. Solche chirurgische Navigationssysteme umfassen mindestens einen Computer mit Datenspeicher und entsprechenden Bedienungselementen sowie eine vorzugsweise optoelektronische Positionserfassungsvorrichtung zur Ermittlung der Lage von optischen Markern innerhalb eines drei-dimensionalen Koordinatensystem im Operationsraum. Als chirurgisches Navigationssystem kann beispielsweise ein auf dem Markt erhältliches Gerät „Surgigate", welches von der Firma MEDIVISION, Oberdorf, Schweiz vertrieben wird, eingesetzt werden. Häufig werden solche Navigationssysteme mit einer optoelektronischen Positionserfassungsvorrichtung, beispielsweise einem im Handel erhältlichen Gerät Optotrak 3020 (three-dimensional motion measurement system) von Northern Digital, Ontario, Canada betrieben. Die Aufgabe des Steuerungscomputers für die Antriebsvorrichtungen des C-Bogens kann hier durch den im Navigationssystem integrierten Computer übernommen werden. Zur Erfassung der Position und Projektion des C-Bogens sind am C-Bogen mindestens drei nicht kollinear angeordnete, optische Marker, vorzugsweise LED (Light Emitting Dioden) oder Infrarot-LED angebracht. Die Lage der optischen Marker innerhalb des dreidimensionalen Koordinatensystems im Operationsraum wird durch die optoelektronische Positionserfassungsvorrichtung vermessen und die sich daraus ergebenden Koordinaten im Datenspeicher des Computers abgespeichert. Aus der Lage aller Marker kann dann durch den Computer die Position und Projektion des C-Bogens im Operationsraum berechnet werden.

Um den C-Bogen erstmals in eine gewünschte Position zu bringen, kann neben der Steuerung durch den Computer eine weitere Steuerung (ähnlich zur Ausführungsform ohne Kombination mit einem chirurgischen Navigationssystem) für die jeweils erste Primärpositionierung des C-Bogens in das System integriert sein. Als Optionen für diese weitere Steuerung ergeben sich:

a) Steuerung des C-Bogens durch Spracheingabe mittels der Stimme;
b) Steuerung des C-Bogens über eine sterile Steuerkonsole (Virtual Keyboard), welche im chirurgischen Navigationssystem integrierbar ist; und
c) Steuerung des C-Bogens mittels eines mit optischen Markern versehenen Pointers.

Der Pointer gemäss c) umfasst mindestens drei optische, nicht kollinear angeordnete Marker, vorzugsweise LED (Light Emitting Dioden) oder Infrarot-LED, welche an einem Stab angebracht sind. Der Pointer wird vom Operateur bezüglich des Patienten so ausgerichtet, dass die Längsachse des Stabes den zentralen Röntgenstrahl des C-Bogens simuliert. Zur Erfassung der Position und Orientierung des Pointers werden mittels der Vermessungsvorrichtung die optischen Marker bezüglich ihrer räumlichen Lage vermessen und im Computer anschliessend die Lage und Orientierung des Pointers bestimmt. Ebenfalls durch den Computer lässt sich eine Ebene im Raum bestimmen, welche senkrecht zur Längsachse des Pointers steht. Diese Ebene definiert die gewünschte Projektionsebene für die Primärpositionierung des C-Bogens. Anschliessend wird dem Röntgengerät der Befehl erteilt, die so definierte Position und Projektion einzunehmen.

Auch in der hier beschriebenen Ausführungsform können vom C-Bogen eingenommene Positionen und Projektionen im Computer abgespeichert werden, so dass durch späteres Wiederaufrufen der entsprechenden Daten vom C-Bogen zuvor eingenommene Positionen und Projektionen reproduzierbar sind.

Beim Einsatz eines chirurgischen Navigationssystemes mit Positions-erfassungsvorrichtung besteht zusätzlich die Möglichkeit an einem Patienten eine Referenzbasis mit mindestens drei optischen, nicht kollinear angeordneten Markern zu befestigen. Dadurch können intraoperative Lageveränderungen des Patienten mittels Lagevermessung dieser Marker vermessen werden und die veränderte Position der Referenzbasis im Datenspeicher des Computers abgespeichert werden. Soll in der veränderten zweiten Position des Patienten im Operationsraum ein Röntgenbild aufgenommen werden, dessen Projektionsebene derjenigen eines in der ersten Position des Patienten aufgenommenen Röntgenbildes entspricht, kann mittels des Computers eine Koordinatentransformation durchgeführt werden und diejenige Position

und Projektion des C-Bogens berechnet und vom C-Bogen angefahren werden, welche in der zweiten Position des Patienten die Aufnahme eines Röntgenbildes mit der zum gewählten, in der ersten Position aufgenommen Röntgenbild übereinstimmenden Projektionsebene ermöglicht. Auf diese Art lässt sich trotz möglicher Bewegungen der Referenzbasen, z.B. bei der Frakturreposition, die identische Bildebene wieder herstellen. Das heisst, diese Ausführungsform des erfindungsgemässen Röntgengerätes berücksichtigt bei der Wiederherstellung gespeicherter Projektionen mögliche Patientenbewegungen.

Für Kontrollen soll die zur einer vorherigen Position und Projektion des C-Bogens identische Position und Projektion wiederherstellbar sein. Dies ist durch Kombination des Computers mit der oben erwähnten weiteren Steuerung des C-Bogens möglich. Als Optionen für Eingabe der Steuerbefehle für diese weitere Steuerung ergeben sich auch hier:

a) Steuerung des C-Bogens durch Spracheingabe;
b) Steuerung des C-Bogens über eine sterile Steuerkonsole (Virtual Keyboard), welche im chirurgischen Navigationssystem integrierbar ist; und
c) Steuerung des C-Bogens mittels eines mit optischen Markern versehenen Pointers.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass dank der erfindungsgemässen Vorrichtung der Bildverstärker im unfallchirurgischen Operationssaal wie bisher eingesetzt werden kann, dieser jedoch mit Hilfe der Steuerung solche Positionen einnimmt, die unmittelbar zur gewünschten Bildebene führen und diese z.B. nach Ausführen weiterer Operationsschritte aufgrund der Datenspeicherung beliebig oft für weitere Kontrollen wieder eingenommen werden kann.

Das erfindungsgemässe Verfahren zur kontrollierten Bewegung eines medizinischen Gerätes, insbesondere eines Röntgengerätes mit einer der oben beschriebenen Vorrichtungen umfasst die Verfahrensschritte:

A) Eingabe eines Befehls zur Bewegung des Gerätes in eine gewünschte Position durch den Bediener;
B) Verarbeiten dieses Befehls in Steuersignale durch eine Steuerungsvorrichtung;

C) Übertragen dieser Steuersignale an die an der Vorrichtung angebrachten Antriebsvorrichtungen;
D) Verfahren der bewegbaren Elemente in die gewünschte Position mittels der Antriebsvorrichtungen.

Die Eingabe des Befehls durch den Bediener kann mittels einer von Hand bedienbaren Steuerkonsole, als sprachliche Befehlseingabe oder über eine Tastatur oder eine Maus in einen Computer erfolgen.

Beim Einsatz eines Computers kann eine einmal eingenommene Position des Gerätes im Datenspeicher dieses Computers abgespeichert werden, wobei die Position des Gerätes durch Ermitteln der durchfahrenen Wege der bewegbaren Elemente in ihrer zeitlichen Abfolge und Länge im Computer berechenbar und im Datenspeicher abspeicherbar ist.

Anstelle der Berechnung der Position kann diese bei Anwendung einer optoelektronischen Positionserfassungsvorrichtung auch mittels Ausmessen der Lage von am Gerät angebrachten optischen Markern durch die optoelektronische Positionserfassungsvorrichtung im Datenspeicher abgespeichert werden.

Bei Kombination der Vorrichtung mit einem Computer ergibt sich somit der Vorteil, dass eine einmal eingenommene Position des Gerätes durch Aufruf einer Steuerfunktion und der im Datenspeicher abgespeicherten Daten wieder herstellbar ist.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine perspektivische Darstellung der erfindungsgemässen Vorrichtung in Form einer fahrbaren Plattform für ein medizinisches Röntgengerät;

Fig. 2 eine vergrösserte perspektivische Darstellung eines Rades der Vorrichtung nach Fig. 1;

Fig. 3 eine Darstellung einer Gesamtvorrichtung, welche die Plattform nach Fig. 1 und das darauf gestellte medizinische Röntgengerät umfasst;

Fig. 4 eine perspektivische Darstellung einer computergesteuerten Gesamtvorrichtung; und

Fig. 5 eine perspektivische Darstellung einer Gesamtvorrichtung mit integrierter Positionserfassungsvorrichtung.

Fig. 1 und 2 zeigen die erfindungsgemässe Vorrichtung zur kontrollierten Bewegung eines medizinischen Geräts in den zwei Dimensionen (x/y) einer Ebene 2, welche durch den Boden eines Operationssaals definiert ist. Ein ebener Rahmen 8 umfasst vier motorisch antreibbare Räder 3, welche über eine erste, zur Ebene 2 parallel verlaufende, das Zentrum des Rades 3 durchstossende Drehachse 4 und eine zweite, senkrecht zur Ebene 2 verlaufende, in der Ebene des Rades 3 liegende Drehachse 5 verfügen. Die Befestigung der Räder 3 am Rahmen 8 erfolgt über Winkelplatten 42, deren erster Plattenteil 43 am Rahmen 8 befestigt ist und in deren zweitem, rechtwinklig zum ersten Plattenteil 43 stehenden Plattenteil 44 die Radaufhängung 45 um die zweite Drehachse 5 rotierbar befestigt ist. An der Radaufhängung 45 sind die Radachsen 46 konzentrisch zur Drehachse 4 befestigt, so dass die mit den Radachsen 46 verbunden Räder 3 um die Drehachse 4 rotierbar sind. Die ersten Antriebsvorrichtungen 6, vorzugsweise Schrittmotoren, der Räder 3 sind radseitig und auf der Innenseite der Winkelplatte 42 mit den zweiten Plattenteilen 44 verbunden und ermöglichen eine Rotation der Räder 3 um deren erste Drehachse 4. Die zweiten Antriebsvorrichtungen 7, vorzugsweise Schrittmotoren, sind auf den von den Rädern 3 abgewandten Aussenseiten der Winkelplatten 42 mit den zweiten Plattenteilen 44 verbunden und ermöglichen eine Rotation der Radaufhängungen 45 und damit der Räder 3 um deren zweite Drehachse 5. An beiden Antriebsvorrichtungen 6;7 sind Empfänger 47 angebracht, welche die von einer Steuerung 48 ausgesendeten Steuersignale an die Antriebsvorrichtungen 6;7 übertragen. Die Steuerung 48 ist vorzugsweise fest programmierbar und über ein Mikrophon 40 voice-controlled

bedienbar. Die vom Mikrophon 40 empfangenen Sprachsignale werden durch eine Spracherkennungseinheit 60 (voice-coder od. voice recognition unit) in Analogsignale oder digitale Signale gewandelt und an die Steuerung 48 übertragen. Die Steuerung 48 verarbeitet diese von der Spracherkennungseinheit 60 erhaltenen Signale in entsprechende Steuersignale für die Antriebsvorrichtungen 6;7 und übermittelt diese Steuersignale drahtlos mittels eines Senders 62 an die an den Antriebsvorrichtungen 6;7 angebrachten Empfänger 47. Anstelle eines einzelnen Senders 62, welcher die Steuersignale an alle Empfänger 47 überträgt, können auch mehrere Sender verwendet werden, wobei jeweils ein Sender zur Steuersignalübertragung an einen ihm zugeordneten Empfänger dient. Die Zuordnung kann beispielsweise durch Verwendung bestimmter Frequenzen erfolgen. Vorzugsweise bei Neugeräten besteht die Möglichkeit, anstelle einer drahtlosen Steuersignalübermittlung die Steuerung 48 komplett in die Vorrichtung oder das medizinische Gerät zu integrieren, so dass auch eine Übermittlung der Steuersignale von der Steuerung 48 an die Antriebsvorrichtungen 6;7 mittels Kabeln möglich ist.

Fig. 3 zeigt eine Ausführungsform des erfindungsgemässen Röntgengerätes als C-Bogen 9 mit einem auf dem Boden des Operationsraumes fahrbaren Sockel 31, einer Röntgenstrahlenquelle 11 und einem Röntgenstrahlenempfänger 15, welche in einem Operationsraum um einen Operationstisch 13 angeordnet sind. Der fahrbare Sockel 31 ist in der Ebene 2, welche durch den Boden des Operationsraumes definiert ist, mittels der steuerbaren, am Sockel 31 über ihre zweite Drehachse 5 (Fig. 2) befestigten Räder 3 frei bewegbar, wodurch die Verschiebbarkeit des Röntgengerätes bezüglich zweier senkrecht zueinander stehender, in der Ebene 2 liegender Achsen (x;y) erzielt wird. Die Röntgenstrahlenquelle 11 und der Röntgenstrahlenempfänger 15 sind einander gegenüberliegend auf einer Zentralachse 32 angeordnet und mittels eines kreisbogenförmigen Trägers 14 fest verbunden und bilden den C-Bogen 9. Die Zentralachse 32 steht senkrecht zur Bildebene des aufzunehmenden Röntgenbildes und ebenso senkrecht zur Symmetrieachse 34 des Kreisbogens des Trägers 14. Der Träger 14 des C-Bogens 9 ist verschiebbar mit dem ersten Endstück 35 eines weiteren Verbindungsträgers 33 verbunden, wobei die Verschiebbarkeit zwischen Verbindungsträger 33 und dem C-förmigen Träger 14 entlang der äusseren Peripherie des C-förmigen Trägers 14 erfolgt und dadurch eine Rotation des C-Bogens 9 um eine Achse 20 ermöglicht wird, welche senkrecht auf einer durch die Symmetrieachse 34

und die Zentralachse 32 aufgespannten Ebene steht. Im Spezialfall der isozentrischen Bauweise liegt die Achse 20 im Zentrum des durch den Träger 14 definierten Halbkreises. Diese Bauweise weist zahlreiche Vorteile auf, u.a. dass ein einmal in den Bildmittelpunkt eingestelltes Objekt durch Rotationsbewegung um die Achse 20 nicht mehr aus dem Mittelpunkt herauswandert. Diese Bauform kommt jetzt mit neuen Geräten, beispielsweise bei dem Siremobil Iso-C von Siemens. Bei der nicht isozentrischen Bauweise liegt die Achse 20 auf der Symmetrieachse 34, jedoch ausserhalb des Mittelpunktes des Trägers 14, so dass die Strecke von der Achse 20 zum Träger 14 entlang der Symmetrieachse 34 länger ist als der Radius des Trägers 14. Dadurch ist der C-Bogen 9 austariert, d.h. er hat nicht die Tendenz, eine einmal eingestellte Projektion selbsttätig wieder zu verlassen durch Rotation des C-Bogens 9 um die Achse 20. Die Rotation des C-Bogens 9 relativ zum Verbindungsträger 33 ist ebenfalls nur bei einzelnen Bauformen vorhanden und erfolgt dann um eine bezüglich des Trägers 14 radiale, die Verbindung zwischen Verbindungsträger 33 und Träger 14 schneidende Achse 21. Der Verbindungsträger 33 ist mit seinem zweiten Endstück 36 mit dem fahrbaren Sockel 31 bewegbar verbunden. Die Bewegung des Verbindungsträgers 33 relativ zum fahrbaren Sockel 31 ist einerseits durch eine Verschiebbarkeit parallel zu einer senkrecht auf der Ebene 2 stehenden Achse 18 und eine Rotation um diese Achse 18 gegeben. Andererseits ist auch eine Verschiebbarkeit des Verbindungsträgers 33 parallel zu einer weiteren, parallel zur Ebene 2 verlaufenden Achse 19 sowie eine Rotation des Verbindungsträger 33 um diese Achse 19 möglich. Der Antrieb der bewegten Elemente erfolgt durch lineare Antriebsvorrichtungen 37 und rotative Antriebsvorrichtungen 6;7;38, welche über eine im Sockel 31 integrierte, vorzugsweise elektronische Steuerungsvorrichtung 39 steuerbar sind. Bedient wird die Steuerungsvorrichtung 39 voice-controlled über ein ebenfalls im Sockel 31 integriertes Mikrophon 40. Die Steuerungsvorrichtung 39 ist vorzugsweise fest programmierbar. Die vom Mikrophon 40 empfangenen Sprachsignale werden auch hier durch eine Spracherkennungseinheit 60 (voice-coder od. voice recognition unit) in Analogsignale oder digitale Signale gewandelt und an die Steuerungsvorrichtung 39 übertragen. Die Steuerungsvorrichtung 39 verarbeitet diese von der Spracherkennungseinheit 60 erhaltenen Signale in entsprechende Steuersignale für die Antriebsvorrichtungen 6;7;37;38 und übermittelt diese Steuersignale. Die Übertragung der Steuersignale von der Steuerungsvorrichtung 39 an die Antriebsvorrichtungen 6;7;37;38 erfolgt über Kabel. Das vom

Röntgenstrahlenempfänger 15 empfangene Röntgenbild wird auf dem Bildschirm 41 eines Bildverstärkers 16 angezeigt. Als Antriebsvorrichtungen 6;7;37;38 werden vorzugsweise Schrittmotoren eingesetzt.

Die in Fig. 4 dargestellte Ausführungsform des erfindungsgemässen Röntgengerätes unterscheidet sich von der in Fig. 3 dargestellten Ausführungsform lediglich darin, dass die Steuerung der Antriebsvorrichtungen 6;7;37;38 am Sockel 31 und am Verbindungsträger 33 zusätzlich durch einen externen Computer 23 übernommen werden kann. Die Eingabe der Steuerbefehle kann über die Tastatur 26 oder eine Maus (nicht gezeichnet) erfolgen. Die Speicherung einmal eingenommener Positionen und Projektionen des C-Bogens 9 erfolgt im Datenspeicher 25 des Computers 23, so dass diese Positionen und Projektionen beliebig reproduzierbar sind. Die Übertragung der Steuersignale vom Computer 23 an die Antriebsvorrichtungen 6;7;37;38 erfolgt in dieser Ausführungsform über ein Kabel 49, welches den Computer 23 mit dem Sockel 31 verbindet. Um mögliche Kollisionen mit Gegenständen im Operationsraum zu vermeiden, kann der gewünschte Verfahrweg des Röntgengerätes zuvor am Bildschirm 24 des Computers 23 angezeigt werden. Verbunden mit dem Computer 23 ist eine analog zur in Fig. 3 beschriebenen Ausführungsform des erfindungsgemässen Röntgengerätes im Sockel 31 integrierte, vorzugsweise elektronische Steuerungsvorrichtung 39, womit die linearen Antriebsvorrichtungen 37 und rotativen Antriebsvorrichtungen 6;7;38 bezüglich ihrer Bewegung steuerbar sind. Bedient wird die Steuerungsvorrichtung 39 entweder durch Dateneingabe in den Computer 23 oder „voice-controlled" über ein ebenfalls im Sockel 31 integriertes Mikrophon 40. Die Steuerungsvorrichtung 39 ist vorzugsweise fest programmierbar. Die vom Mikrophon 40 empfangenen Sprachsignale werden auch hier durch eine Spracherkennungseinheit 60 (voice-coder od. voice recognition unit) in Analogsignale oder digitale Signale gewandelt und an die Steuerungsvorrichtung 39 übertragen. Die Steuerungsvorrichtung 39 verarbeitet diese von der Spracherkennungseinheit 60 erhaltenen Signale in entsprechende Steuersignale für die Antriebsvorrichtungen 6;7;37;38 und übermittelt diese Steuersignale. Die Übertragung der Steuersignale von der Steuerungsvorrichtung 39 an die Antriebsvorrichtungen 6;7;37;38 erfolgt über Kabel. Die erste Positionierung des C-Bogens 9 kann in dieser Ausführungsform durch Dateneingabe in den Computer 23 oder durch Sprachbefehle an die Steuerungsvorrichtung 39 erfolgen. Die eingenommene Position und Projektion des C-Bogens 9 wird durch den Computer 23

durch Berechnung der durchfahrenen Wege aller Antriebsvorrichtungen 6;7;37;38 in ihrer zeitlichen Abfolge und Länge ermittelt und im Datenspeicher 25 abgespeichert. Eine solche einmal eingenommene und abgespeicherte Position und Projektion des C-Bogens 9 kann später durch Aufruf einer Steuerfunktion reproduziert werden. Die Steuerfunktion kann in der Steuerungsvorrichtung 39 oder im Computer 23 programmiert sein und kann mittels Dateneingabe in den Computer 23 oder auch „voice-controlled" über die Steuerung 39 aufgerufen werden. Durch Aufruf dieser Steuerfunktion werden die im Datenspeicher 25 abgespeicherten, die Position und Projektion des C-Bogens 9 definierenden Daten aufgerufen und an die Steuerungsvorrichtung 39 übertragen, wodurch die gewünschte Position und Projektion des C-Bogens 9 wieder herstellbar ist. Als Variante der hier beschriebenen Ausführungsform des erfindungsgemässen Röntgengerätes ist auch eine Steuerung aller Antriebsvorrichtungen 6;7;37;38 nur durch den Computer 23 denkbar. Ebenfalls möglich ist eine vollständige Integration der Steuerungsvorrichtung 39 inklusive Spracherkennungseinheit 60 in den Computer 23.

In Fig. 5 ist die mit einem chirurgischen Navigationssystem kombinierte Ausführungsform des erfindungsgemässen Röntgengerätes dargestellt. Die Unterschiede gegenüber der in Fig. 4 dargestellten Ausführungsform liegen lediglich darin, dass der C-Bogen 9 mit einer Referenzbasis 50 versehen ist. Eine weitere Referenzbasis 51 ist am Patienten 12 befestigt. Die Referenzbasen 50;51 umfassen je vier optische, nicht kollinear angeordnete Marker 28, welche durch LED ausgestaltet sind. Das chirurgische Navigationssystem umfasst eine optoelektronische Positionserfassungsvorrichtung 27, mittels welcher die Positionen der Marker 28 erfassbar und im Datenspeicher 25 die Lagekoordinaten der Marker 28 bezüglich eines dreidimensionalen Koordinatensystems 29 im Operationsraum speicherbar sind. Damit lassen sich Veränderungen der Position des Patienten 12 im Computer 23 erfassen. Durch den Computer 23 werden die gespeicherten Positionen und Projektionen des C-Bogens 9 so transformiert, dass in der veränderten zweiten Position des Patienten 12 diejenige Position und Projektion des C-Bogens berechnet und vom C-Bogen angefahren wird, welche die Aufnahme eines Röntgenbildes ermöglicht, dessen Projektionsebene mit derjenigen eines vorgängig in der ersten Position des Patienten 12 aufgenommenen Röntgenbildes übereinstimmt.

Patentansprüche

1. Vorrichtung zur kontrollierten Bewegung eines medizinischen Gerätes (1), insbesondere eines Röntgengerätes, in den zwei Dimensionen (x/y) einer Ebene (2), insbesondere einer parallel zum Boden eines Operationssaals liegenden Ebene, mittels mindestens drei, motorisch antreibbaren Rädern (3), welche über eine erste, zur Ebene (2) parallel verlaufende, das Zentrum des Rades (3) durchstossende Drehachse (4) und eine zweite, senkrecht zur Ebene (2) verlaufende, in der Ebene des Rades (3) oder parallel zu dieser liegende Drehachse (5) verfügen, und die Räder (3) zueinander in fester Relation positioniert sind,
dadurch gekennzeichnet, dass
A) jedes der Räder (3) über eine erste Antriebsvorrichtung (6) verfügt, mit welcher das Rad (3) um die erste Drehachse (4) rotierbar ist; und
B) jedes der Räder (3) über eine zweite Antriebsvorrichtung (7) verfügt, mit welcher das Rad (3) um die zweite Drehachse (5) zur Änderung seiner Laufrichtung drehbar ist.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Räder (3) über ihre zweite Drehachse (5) direkt am medizinischen Gerät (1) befestigt sind.

3. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Räder (3) über ihre zweite Drehachse (5) an einem als Plattform für das medizinischen Gerät (1) bestimmten Rahmen (8) befestigt sind.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die ersten und zweiten Antriebsvorrichtungen (6;7) drahtlos, vorzugsweise voice-controlled steuerbar sind.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass die ersten und zweiten Antriebsvorrichtungen (6;7) elektronisch steuerbare Schrittmotoren sind.

6. Fahrbares Röntgengerät mit einer Vorrichtung nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass es mindestens

A) einen fahrbaren Sockel (31) mit Rädern (3) und entsprechenden Antriebsvorrichtungen (6;7) zur translatorischen und rotativen Bewegung des Sockels (31) in den Achsrichtungen x und y des Koordinatensystems (2;29);

B) einen relativ zum Sockel (31) in den Achsrichtungen x, y und z des Koordinatensystemes (29) translatorisch und rotativ bewegbaren C-Bogen (9) mit einer Röntgenstrahlenquelle (22) und einem Röntgenstrahlenempfänger (15), welche mittels eines C-bogenförmigen Trägers (14) einander gegenüberliegend auf einer Zentralachse (32) angeordnet und fest verbunden sind, wobei die Zentralachse (32) senkrecht zur Bildebene des aufzunehmenden Röntgenbildes steht;

C) am Sockel (31) angebrachte Antriebsvorrichtungen (37;38) zur Bewegung des C-Bogens (9) relativ zum Sockel (31); und

D) eine Steuerungsvorrichtung (39) umfasst, mittels welcher vom Bediener eingebbare Steuerbefehle bezüglich einer durch den C-Bogen (9) einzunehmenden Position und Projektion in entsprechende Steuersignale für die Antriebsvorrichtungen (6;7;37;38) umsetzbar sind.

7. Röntgengerät nach Anspruch 6, dadurch gekennzeichnet, dass es einen Verbindungsträger (33) mit einem ersten Endstück (35) und einem longitudinal entgegengesetzten zweiten Endstück (36) umfasst, und das erste Endstück (35) bewegbar mit dem C-Bogen (9) und das zweite Endstück (36) bewegbar mit dem Sockel (31) verbunden ist.

8. Röntgengerät nach Anspruch 7, dadurch gekennzeichnet, dass am Sockel (31) Antriebsvorrichtungen (37;38) zur Bewegung des Verbindungsträgers (33) relativ zum Sockel (31) und am Verbindungsträger (33) mindestens eine Antriebsvorrichtung (37) zur Bewegung des C-Bogens (9) relativ zum Verbindungsträger (33) anbracht sind.

9. Röntgengerät nach Anspruch 7 oder 8, dadurch gekennzeichnet, dass die äussere Peripherie des Trägers (14) durch ein Gleitlager tangential gleitbar mit dem ersten Endstück (35) verbunden ist.

10. Röntgengerät nach einem der Ansprüche 7 bis 9, dadurch gekennzeichnet, dass das zweite Endstück (36) um eine senkrecht auf der Ebene (2) stehende Achse (18) verschiebbar und rotierbar sowie um eine senkrecht zur Achse (18) stehende Achse (19) verschiebbar und rotierbar mit dem Sockel (31) verbunden ist.

11. Röntgengerät nach einem der Ansprüche 6 bis 10, dadurch gekennzeichnet, dass es zusätzlich eine von Hand bedienbare Steuerkonsole zur Bedienung der Steuerungsvorrichtung (39) umfasst.

12. Röntgengerät nach einem der Ansprüche 6 bis 10, dadurch gekennzeichnet, dass es zusätzlich ein Mikrophon (40) und eine Spracherkennungseinheit (60) umfasst, womit die Steuerungsvorrichtung (39) „voice-controlled" bedienbar ist.

13. Röntgengerät nach einem der Ansprüche 6 bis 12, dadurch gekennzeichnet, dass es zusätzlich einen Computer (23) mit mindestens einem Datenspeicher (25), einem Bildschirm (24) und einer Tastatur (26) umfasst.

14. Röntgengerät nach Anspruch 13, dadurch gekennzeichnet, dass die Antriebsvorrichtungen (6;7;37;38) mittels Dateneingabe in den Computer (23) automatisch durch diesen steuerbar sind und somit der C-Bogen von einem Operateur durch Bedienung des Computers (23) kontrolliert verfahrbar ist.

15. Röntgengerät nach Anspruch 13 oder 14, dadurch gekennzeichnet, dass Position und Orientierung des C-Bogens (9) im Datenspeicher (25) des Computers (23) speicherbar sind.

16. Röntgengerät nach Anspruch 15, dadurch gekennzeichnet, dass im Datenspeicher (23) eine Steuerfunktion speicherbar ist, mittels welcher der C-Bogen (9) in eine im Datenspeicher (25) des Computers (23) gespeicherte Position und Orientierung des C-Bogens (9) reproduzierbar verfahrbar ist.

17. Röntgengerät nach Anspruch 16, dadurch gekennzeichnet, dass der Computer (23) mit der Steuerungsvorrichtung (39) verbunden ist und der Aufruf dieser Steuerfunktion mittels einer vom Operateur bedienbaren Steuerkonsole erfolgt.

18. Röntgengerät nach Anspruch 16, dadurch gekennzeichnet, dass Computer (23) mit der Steuerungsvorrichtung (39) verbunden ist und der Aufruf dieser Steuerfunktion „voice-controlled" erfolgt.

19. Röntgengerät nach einem der Ansprüche 6 bis 18, dadurch gekennzeichnet, dass es mit einem chirurgischen Navigationssystem kombiniert ist, welches eine optoelektronische Positionserfassungsvorrichtung (27) umfasst.

20. Röntgengerät (9) nach Anspruch 19, dadurch gekennzeichnet, dass zusätzlich mindestens drei, nicht kollinear angeordnete optische Marker (28) am C-Bogen (9) befestigt sind, so dass die Position der Marker (28) durch die optoelektronische Positionserfassungsvorrichtung (27) erfassbar und im Datenspeicher (25) die Lagekoordinaten der Marker (28) bezüglich eines dreidimensionalen Koordinatensystems (29) im Operationsraum speicherbar sind.

21. Röntgengerät nach Anspruch 19 oder 20, dadurch gekennzeichnet, dass es zusätzlich mindestens eine, an einem Patienten (12) befestigbare Referenzbasis (51) umfasst, welche mindestens drei optische, nicht kollinear angeordnete Marker (28) enthält, so dass die Position der Marker (28) durch die optoelektronische Positionserfassungsvorrichtung (27) erfassbar und im Datenspeicher (25) die Lagekoordinaten der Marker (28) bezüglich eines dreidimensionalen Koordinatensystems (29) im Operationsraum speicherbar ist.

22. Vorrichtung nach einem der Ansprüche 6 bis 21, dadurch gekennzeichnet, dass die Antriebsvorrichtungen (37) Linearschrittmotoren sind.

23. Vorrichtung nach einem der Ansprüche 6 bis 21, dadurch gekennzeichnet, dass die Antriebsvorrichtungen (38) Schrittmotoren sind.

24. Vorrichtung nach Anspruch 22 oder 23, dadurch gekennzeichnet, dass die Schrittmotoren digital ansteuerbar sind.

25. Verfahren zur kontrollierten Bewegung eines medizinischen Gerätes, inbesondere eines Röntgengerätes mit einer Vorrichtung gemäss einem der Ansprüche 1 bis 24, gekennzeichnet durch die Verfahrensschritte:

A) Eingabe eines Befehls zur Bewegung des Gerätes in eine gewünschte Position durch den Bediener;
B) Verarbeiten dieses Befehls in Steuersignale durch eine Steuerungsvorrichtung (39; 48);
C) Übertragen dieser Steuersignale an die an der Vorrichtung angebrachten Antriebsvorrichtungen (6;7;37;38);
D) Verfahren der bewegbaren Elemente in die gewünschte Position mittels der Antriebsvorrichtungen (6;7;37;38).

26. Verfahren nach Anspruch 25, dadurch gekennzeichnet, dass die Eingabe des Befehls durch den Bediener mittels einer von Hand bedienbaren Steuerkonsole erfolgt.

27. Verfahren nach Anspruch 25, dadurch gekennzeichnet, dass die Eingabe des Befehls durch den Bediener eine sprachliche Befehlseingabe ist.

28. Verfahren nach Anspruch 25, dadurch gekennzeichnet, dass die Eingabe des Befehls durch den Bediener über eine Tastatur (26) oder eine Maus in einen Computer (23) erfolgt.

29. Verfahren nach einem der Ansprüche 25 bis 28, dadurch gekennzeichnet, dass eine einmal eingenommene Position des Gerätes im Datenspeicher (25) eines Computers (23) abgespeichert wird.

30. Verfahren nach Anspruch 29, dadurch gekennzeichnet, dass die Position des Gerätes durch Erfassen der durchfahrenen Wege der bewegbaren Element in ihrer zeitlichen Abfolge und Länge im Computer (23) berechnet und im Datenspeicher (25) abgespeichert wird.

31. Vefahren nach Anspruch 29, dadurch gekennzeichnet, dass die Position des Gerätes mittels Ausmessen der Lage von am Gerät angebrachten optischen Markern (28) durch eine optoelektronische Positionserfassungsvorrichtung (27) und dem Computer (23) berechnet und im Datenspeicher (25) abgespeichert wird.

32. Verfahren nach einem der Ansprüche 29 bis 31, dadurch gekennzeichnet, dass eine einmal eingenommene Position des Gerätes durch Aufruf einer Steuerfunktion und der im Datenspeicher (25) abgespeicherten Daten wieder herstellbar ist.

GEÄNDERTE ANSPRÜCHE

[beim Internationalen Büro am 20. Dezember 2000 (20.12.00) eingegangen;
ursprüngliche Ansprüche 1,4 und 25 geandert;
alle weiteren Ansprüche unverandert (2 Seiten)]

1. Vorrichtung zur kontrollierten Bewegung eines medizinischen Gerätes (1), insbesondere eines Röntgengerätes, in den zwei Dimensionen (x/y) einer Ebene (2), insbesondere einer parallel zum Boden eines Operationssaals liegenden Ebene, mittels mindestens drei, motorisch antreibbaren Rädern (3), welche über eine erste, zur Ebene (2) parallel verlaufende, das Zentrum des Rades (3) durchstossende Drehachse (4) und eine zweite, senkrecht zur Ebene (2) verlaufende, in der Ebene des Rades (3) oder parallel zu dieser liegende Drehachse (5) verfügen, und die Räder (3) zueinander in fester Relation positioniert sind,
dadurch gekennzeichnet, dass
A) jedes der Räder (3) über eine erste Antriebsvorrichtung (6) verfügt, mit welcher das Rad (3) um die erste Drehachse (4) rotierbar ist; und
B) jedes der Räder (3) über eine zweite Antriebsvorrichtung (7) verfügt, mit welcher das Rad (3) um die zweite Drehachse (5) zur Änderung seiner Laufrichtung drehbar ist, wobei
C) die ersten und zweiten Antriebsvorrichtungen (6;7) drahtlos steuerbar sind.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Räder (3) über ihre zweite Drehachse (5) direkt am medizinischen Gerät (1) befestigt sind.

3. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Räder (3) über ihre zweite Drehachse (5) an einem als Plattform für das medizinischen Gerät (1) bestimmten Rahmen (8) befestigt sind.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die ersten und zweiten Antriebsvorrichtungen (6;7) voice-controlled steuerbar sind.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass die ersten und zweiten Antriebsvorrichtungen (6;7) elektronisch steuerbare Schrittmotoren sind.

24. Vorrichtung nach Anspruch 22 oder 23, dadurch gekennzeichnet, dass die Schrittmotoren digital ansteuerbar sind.

25. Verfahren zur kontrollierten Bewegung eines Röntgengerätes mit einer Vorrichtung gemäss einem der Ansprüche 1 bis 24, gekennzeichnet durch die Verfahrensschritte:

E) Eingabe eines Befehls zur Bewegung des Gerätes in eine gewünschte Position durch den Bediener;

F) Verarbeiten dieses Befehls in Steuersignale durch eine Steuerungsvorrichtung (39; 48);

G) Übertragen dieser Steuersignale an die an der Vorrichtung angebrachten Antriebsvorrichtungen (6;7;37;38);

H) Verfahren der bewegbaren Elemente in die gewünschte Position mittels der Antriebsvorrichtungen (6;7;37;38).

26. Verfahren nach Anspruch 25, dadurch gekennzeichnet, dass die Eingabe des Befehls durch den Bediener mittels einer von Hand bedienbaren Steuerkonsole erfolgt.

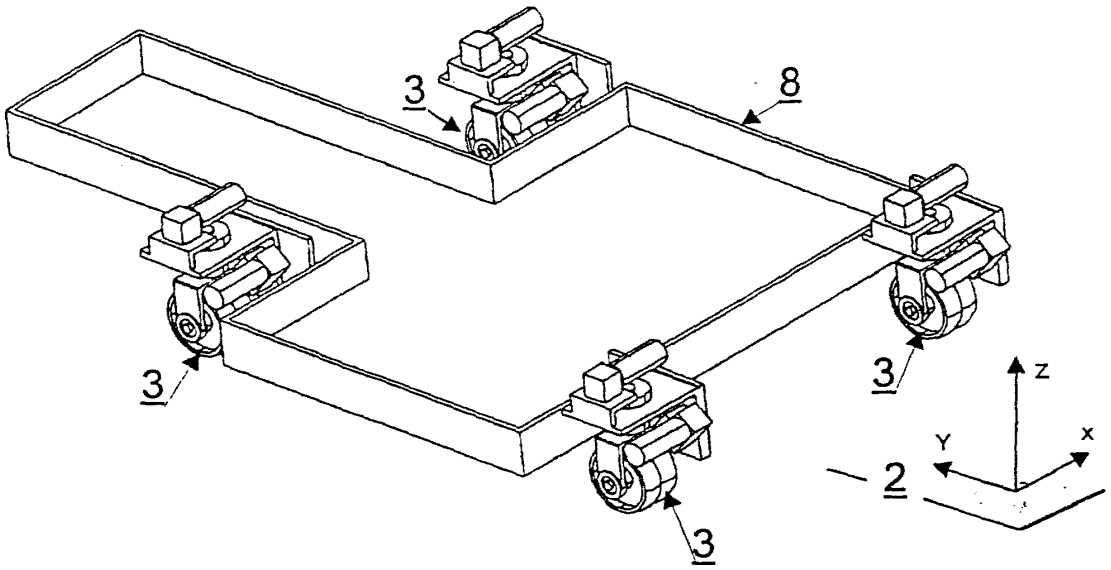
27. Verfahren nach Anspruch 25, dadurch gekennzeichnet, dass die Eingabe des Befehls durch den Bediener eine sprachliche Befehlseingabe ist.

28. Verfahren nach Anspruch 25, dadurch gekennzeichnet, dass die Eingabe des Befehls durch den Bediener über eine Tastatur (26) oder eine Maus in einen Computer (23) erfolgt.

29. Verfahren nach einem der Ansprüche 25 bis 28, dadurch gekennzeichnet, dass eine einmal eingenommene Position des Gerätes im Datenspeicher (25) eines Computers (23) abgespeichert wird.

30. Verfahren nach Anspruch 29, dadurch gekennzeichnet, dass die Position des Gerätes durch Erfassen der durchfahrenen Wege der bewegbaren Element in ihrer zeitlichen Abfolge und Länge im Computer (23) berechnet und im Datenspeicher (25) abgespeichert wird.

Fig. 1



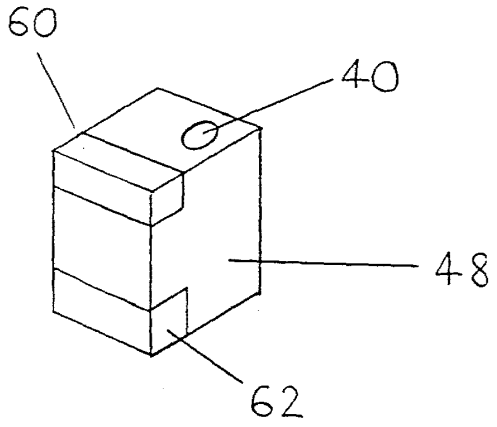
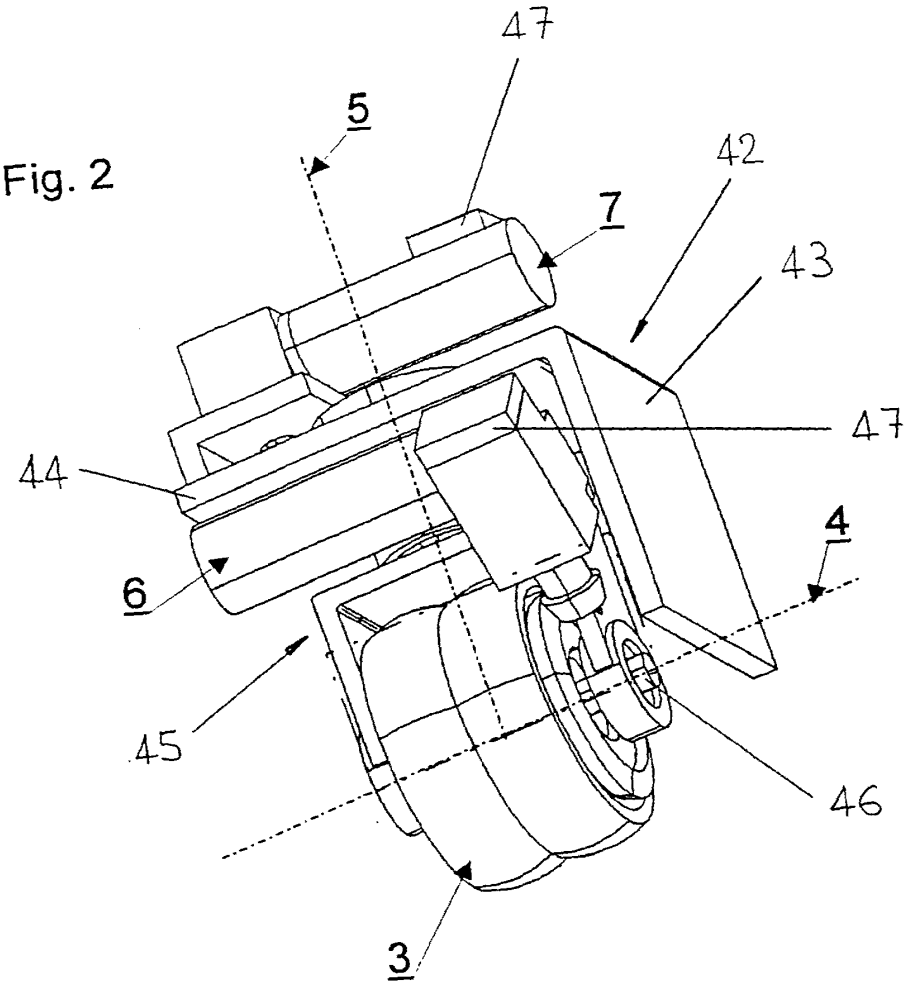


Fig. 2



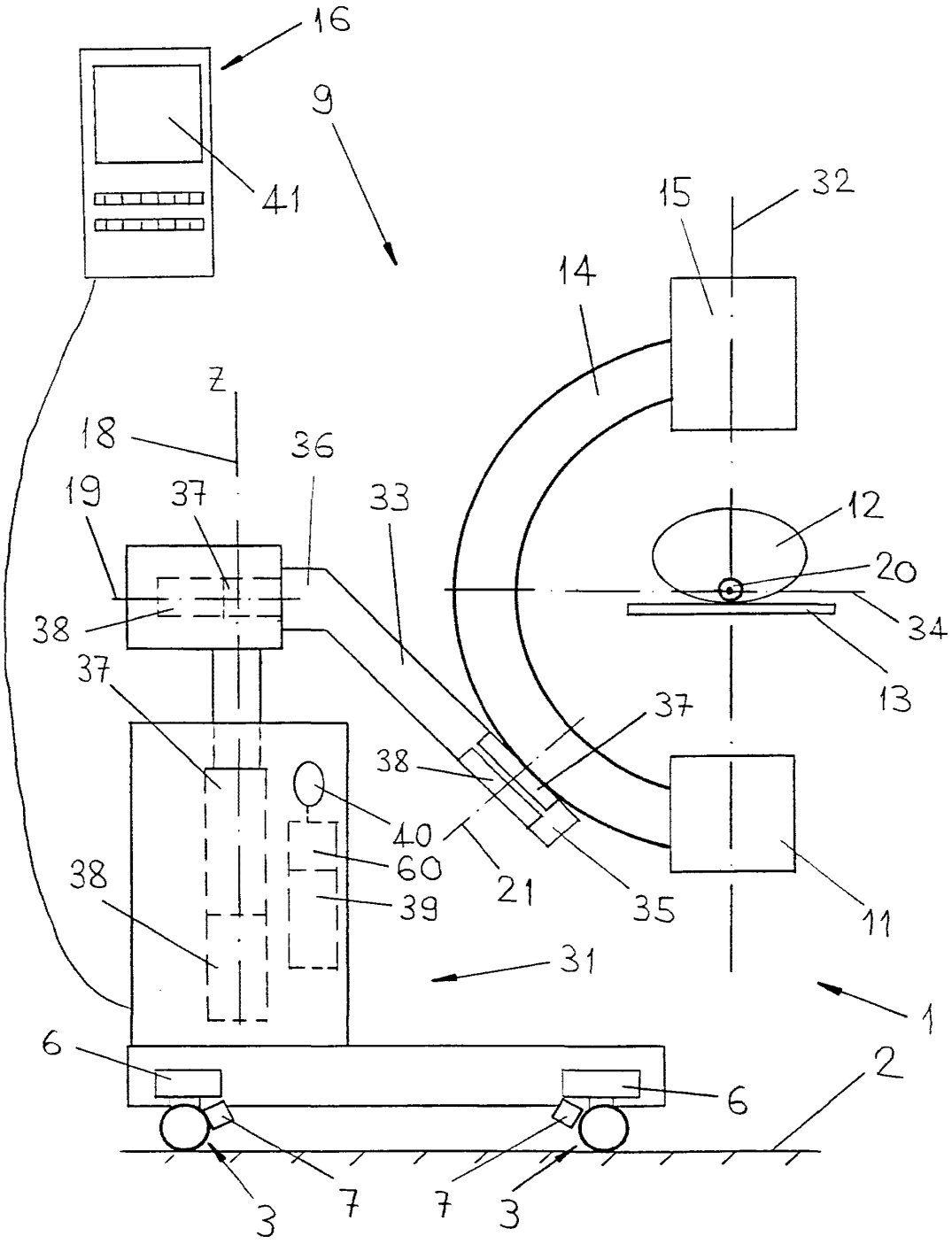

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Fig. 3

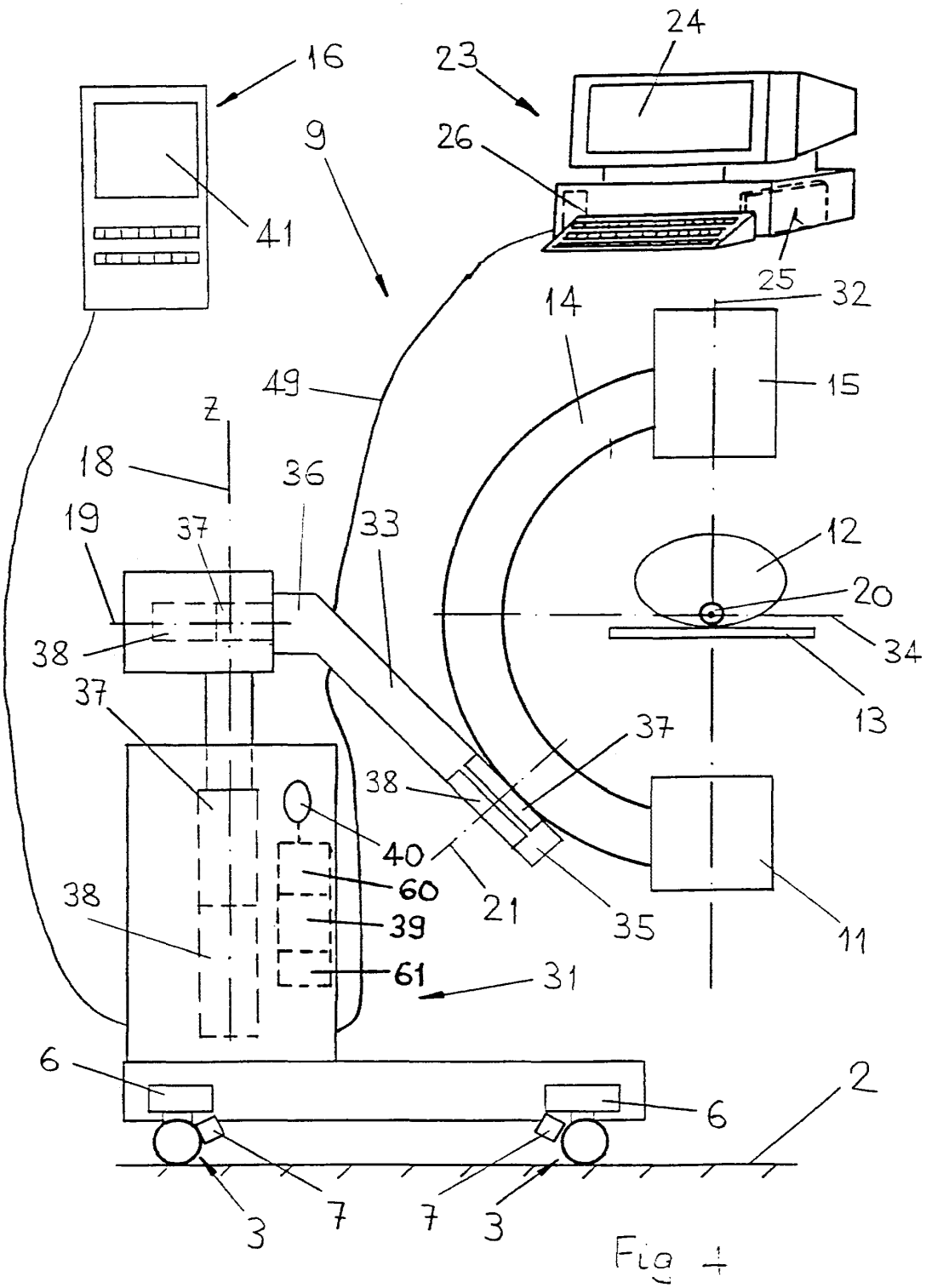

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Fig 1

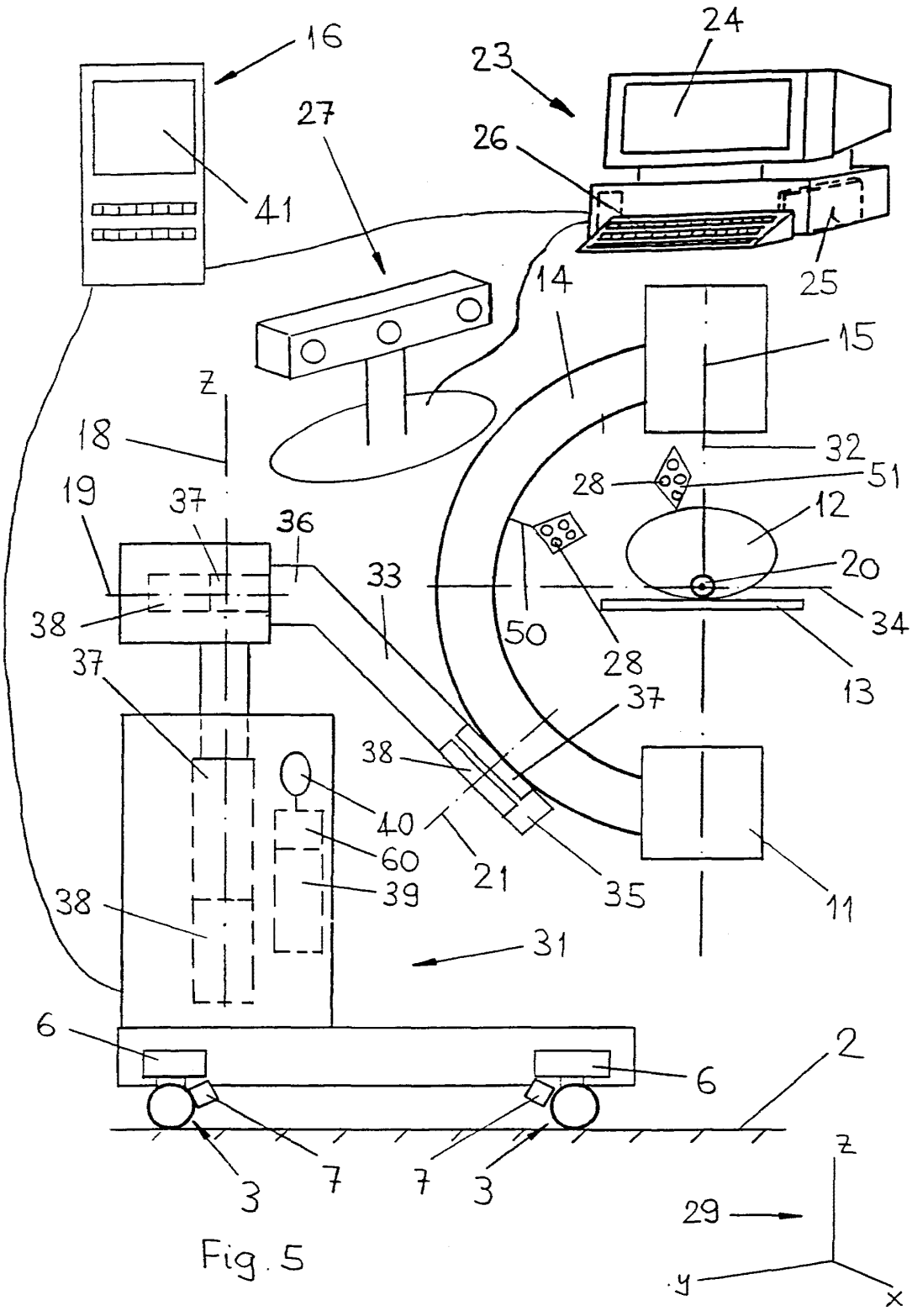

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Fig. 5

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/CH 00/00022

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B6/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B B62D B60K

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 00 32462 A (GRANT VERNON JOEL ;LI ZHENG DE (AU); GRANT BRENDAN JOEL (AU)) 8 June 2000 (2000-06-08) page 1, line 1-14 page 2, line 15-28; figures 1-3,6,7 ---	1-3,5
Y	WO 98 19875 A (GRANT VERNON JOEL ;GRANT BRENDAN JOEL (AU)) 14 May 1998 (1998-05-14) abstract; figure 2E page 8, line 16-18 --- -/--	1-3,5,6, 11, 13-17, 19,25, 26, 28-30,32

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 October 2000	27/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jonsson, P.O.

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INTERNATIONAL SEARCH REPORT

Intern: al Application No
PCT/CH 00/00022

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 297 138 A (YOKOGAWA MEDICAL SYST) 4 January 1989 (1989-01-04) page 3 page 7, line 12-18; figures 1-3	1-3,5
Y	DE 197 01 346 A (SIEMENS AG) 23 July 1998 (1998-07-23) column 2, line 54 -column 3, line 13 column 7, line 49 -column 8, line 13	6,11, 13-17, 19,25, 26, 28-30,32
X	US 4 589 126 A (AUGUSTSSON NILS E ET AL) 13 May 1986 (1986-05-13) column 3, line 17-53 column 4, line 3-36	25,29-32
A	US 4 341 279 A (WAERVE HANS) 27 July 1982 (1982-07-27) abstract; figure 2	1-5
A	EP 0 253 333 A (GEN ELECTRIC) 20 January 1988 (1988-01-20) abstract; figures 1-3 column 3, line 38-53	1-5
A	EP 0 910 990 A (SIEMENS AG) 28 April 1999 (1999-04-28) paragraph '0018!; figure 1	6-24
A	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 12, 29 October 1999 (1999-10-29) & JP 11 188027 A (HITACHI MEDICAL CORP), 13 July 1999 (1999-07-13) abstract	4,12,18, 27
A	PATENT ABSTRACTS OF JAPAN vol. 1997, no. 01, 31 January 1997 (1997-01-31) & JP 08 229028 A (HITACHI MEDICAL CORP), 10 September 1996 (1996-09-10) abstract	4,12,18, 27
A	US 5 762 608 A (DABROWSKI MICHAEL D ET AL) 9 June 1998 (1998-06-09) column 7, line 1-24	20,21, 30,31

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Information on patent family members

Internal Application No
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		US RE34511 E	18-01-1994

INTERNATIONALER RECHERCHENBERICHT

Interna ales Aktenzeichen
PCT/CH 00/00022

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61B6/00

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61B B62D B60K

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
E	WO 00 32462 A (GRANT VERNON JOEL ;LI ZHENG DE (AU); GRANT BRENDAN JOEL (AU)) 8. Juni 2000 (2000-06-08) Seite 1, Zeile 1-14 Seite 2, Zeile 15-28; Abbildungen 1-3,6,7 ---	1-3,5
Y	WO 98 19875 A (GRANT VERNON JOEL ;GRANT BRENDAN JOEL (AU)) 14. Mai 1998 (1998-05-14) Zusammenfassung; Abbildung 2E Seite 8, Zeile 16-18 --- -/--	1-3,5,6, 11, 13-17, 19,25, 26, 28-30,32

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
18. Oktober 2000	27/10/2000

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Jonsson, P.O.

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PGR2025-00063 Page 00323

INTERNATIONALER RECHERCHENBERICHT

Interna ıles Aktenzeichen
PCT/CH 00/00022

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	EP 0 297 138 A (YOKOGAWA MEDICAL SYST) 4. Januar 1989 (1989-01-04) Seite 3 Seite 7, Zeile 12-18; Abbildungen 1-3	1-3,5
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A	EP 0 910 990 A (SIEMENS AG) 28. April 1999 (1999-04-28) Absatz '0018!; Abbildung 1	6-24
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A	PATENT ABSTRACTS OF JAPAN vol. 1997, no. 01, 31. Januar 1997 (1997-01-31) & JP 08 229028 A (HITACHI MEDICAL CORP), 10. September 1996 (1996-09-10) Zusammenfassung	4,12,18, 27
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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Interna les Aktenzeichen
PCT/CH 00/00022

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		US RE34511 E	18-01-1994

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(51) International Patent Classification:
A63B 59/14 (2006.01)

(21) International Application Number:
PCT/US2006/044538

(22) International Filing Date:
17 November 2006 (17.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/737,768 18 November 2005 (18.11.2005) US

(71) Applicant *(for all designated States except US)*: **STX, LLC** [US/US]; 1500 BUSH STREET, SUITE 1, Baltimore, MD 21230 (US).

(72) Inventors: **BEDWELL, Katelyn**; 88 Buell Street, Apartment 2, Burlington, VT 05401 (US). **KOTULA, Joanna**; 908 SOUTH BAYLIS STREET, Baltimore, MD 21224 (US).

(74) Agents: **GOTTS, Lawrence, J.** et al.; Paul, Hastings, Janofsky & Walker LLP, 875 15th Street, N.W., Washington, DC 20005 (US).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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WO 2007/061772 A2

(54) Title: BOWED FIELD HOCKEY STICK

(57) Abstract: The present invention provides a field hockey stick having a substantially straight grip portion and a bowed hitting portion. In one embodiment, a stick has a substantially straight handle, a bowed throat, and a bowed head. In another embodiment, a stick has a substantially straight handle and a bowed throat, with at least a portion of the playing surface of the head in substantially the same plane or line as the front face of the handle. In another embodiment, a stick has a substantially straight handle and a bowed throat, with the playing surface of the head set back from the plane or line of the front face of the handle.

BOWED FIELD HOCKEY STICK

[0001] This application claims priority to U.S. Provisional Application No. 60/737,768, filed November 18, 2005, which is incorporated herein by reference in its entirety.

BACKGROUND

Field of the Invention

[0002] The present invention relates generally to field hockey sticks, and more particularly, to a field hockey stick having a substantially straight grip portion and a bowed hitting portion.

Background of the Invention

[0003] As shown in Figure 1, a field hockey stick 100 typically has a handle 102, a throat 104, and a head 106. The handle 102 starts at the top and extends through to the throat 104. The handle 102 and throat 104 together define the shaft of the stick 100. The stick 100 curves at the base of the throat 104 to form the head 106. A horizontal line (such as line 115) drawn through the point at which stick 100 begins to curve marks the end of throat 104 and the beginning of head 106. The head 106 is also considered the base of the stick 100. The head 106 includes a toe 108 and curves horizontally and upwardly to form toe 108. The front (or left hand side, as shown in Figure 1) of the stick 100 has a flat playing surface and the back is typically rounded and not playable in the game. The edges, disposed between the flat playing surface and the non-playing surface, are legal for play in the game. Generally, the flat playing surface (*i.e.*, hitting portion) includes all of head 106 and at least a portion of throat 104. All sticks are suitable for "right handed" play.

[0004] Traditionally, field hockey sticks have been constructed of relatively standard dimensions, due primarily to widely accepted rules of the game. These rules dictate aspects of the stick such as weight, length, shape, and cross-section. For example, these rules can require that the lower part of the stick's left-hand (playing side) be smooth and flat, that the back of the stick (right-hand side or non-playing side) be smooth and rounded, that the stick weigh not more than 737 grams, and that every cross-section of the stick be able to pass through a two-

inch ring. In meeting these rules, the traditional field hockey stick has typically featured a straight handle and straight hitting portion, a flat front face, and a curved back.

[0005] Recently, however, there has been a trend toward bowing or raking the entire length of a field hockey stick, from the end of the handle to the head. This bowing can enable players to increase the power with which they flick the ball, especially for shots on goal.

[0006] As players increase in skill level, they typically play lower to the ground and therefore can utilize more of the stick as a hitting surface, including the full hitting area of the stick from the end of the grip to the head. For example, in using full-length bowed sticks for push passes, a player typically sweeps the stick from a squatting position, causing the ball to travel down the stick and to whip off of the stick at a location near the head. However, because the full-length bow also shifts the hands behind the head, the full-length bowed sticks can impart an undesirable loft to the ball, especially as the bow increases the power of the shot. The setback position of the hands can also inhibit a player's feel for the ball during cradling and dribbling.

SUMMARY OF THE INVENTION

[0007] An embodiment of the present invention provides a field hockey stick having a substantially straight grip portion and a bowed hitting portion. In one embodiment, a stick has a substantially straight handle, a bowed throat, and a bowed head. In another embodiment, a stick has a substantially straight handle and a bowed throat, with at least a portion of the playing surface of the head in substantially the same plane as the front face of the handle. In another embodiment, a stick has a substantially straight handle and a bowed throat, with the playing surface of the head set back from the plane of the front face of the handle.

[0008] In comparison to conventional full-length bowed field hockey sticks, the field hockey stick of the present invention increases the whipping action of the stick and the resultant speed of the ball, while also improving ball control and minimizing loft. These performance benefits are especially apparent for skills such as dribbling or executing push passes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 is a schematic diagram of a conventional field hockey stick.

[0010] Figure 2 is a schematic diagram of an isometric view of the playing side of an exemplary field hockey stick having a substantially straight handle and a bowed throat, with at least a portion of the playing surface of the head in substantially the same plane as the front face of the handle, according to an embodiment of the present invention.

[0011] Figure 3 is a schematic diagram of the back edge of the field hockey stick shown in Figure 2.

[0012] Figure 4 is a schematic diagram of the playing side of the field hockey stick shown in Figure 2.

[0013] Figure 5 is a schematic diagram of the front edge of the field hockey stick shown in Figure 2.

[0014] Figure 6 is a schematic diagram of the front edge of an exemplary field hockey stick having a substantially straight handle and a bowed throat, with the playing surface of the head set back from the plane of the front face of the handle, according to an embodiment of the present invention.

[0015] Figure 7 is a schematic diagram of the front edge of an exemplary field hockey stick having a substantially straight handle and a bowed throat, with the playing surface of the head being generally flat and in substantially the same plane as the front face of the handle, according to an embodiment of the present invention.

[0016] Figure 8 is a schematic diagram of the front edge of an exemplary field hockey stick having a substantially straight handle and a bowed throat, with the playing surface of the head being generally flat and parallel to the plane of the front face of the handle, according to an embodiment of the present invention.

[0017] Figure 9 is a schematic cross-sectional view of a hitting portion of an exemplary field hockey stick having a V-shaped channel on a playing side, according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Figures 2-5 illustrate an exemplary field hockey stick 200 comprising a handle 202, a throat 204 adjacent to the handle 202, and a head 206 adjacent to the throat 204 on a side of the throat 204 opposite to the handle 202, according to an embodiment of the present invention. Handle 202 is substantially straight and throat 204 is bowed. At least a portion of the playing surface of the head 206 is in substantially the same plane as the front face 208 of the handle 202. Figures 3 and 5 best show the relative positions of the handle 202, throat 204, and head 206.

[0019] As shown in this embodiment, the hitting portion of the stick 200, comprised of the throat 204 and head 206, is bowed toward the non-playing side of the stick 200. The bow begins at a location proximate to the handle 202, reaches a maximum setback approximately halfway between the start of throat 204 (or the end of the handle 202) and the end of head 206, and returns such that at least a portion of head 206 is in substantially the same plane as the front face 208 of the handle 202. In this example, the bow continues through the head 206. Accordingly, when the field hockey stick is viewed from a direction facing the front edge (Figure 5), the playing side of the handle portion 202 lies substantially along a line and the bowed hitting portion bows away from the line in a direction toward the non-playing side of the field hockey stick. In the embodiment shown in Figures 2-5, the head portion 206 is bowed along with the throat 204 and has at least a portion lying in the aforementioned line.

[0020] In other embodiments, the bowed head 206 may extend across the aforementioned line such that at least a portion of the head 206 is in front of the front edge 208 of the field hockey stick. In still other embodiments, a top portion of the head 206 proximate to the throat 204 may be further frontward than a portion of the head 206 proximate to the end or bottom of the hockey stick 200. All or a portion of the head 206 in such embodiments may lie on the aforementioned line, be set back from the line, or be in front of the line. In this manner, the head 206 can be angled with respect to the aforementioned line, for example, to reduce or increase ball loft, as desired.

[0021] In an exemplary implementation of the invention, the maximum depth of the bow is approximately 25 mm. The maximum bow depth is measured as the shortest distance between a line in which the front edge of the handle portion lies to the front edge of the bowed hitting portion at its deepest location. Such a measurement in practice may be made by placing the field hockey stick on a tabletop or other flat surface with the playing side of the stick facing down. The maximum bow depth may then be measured as the largest distance the playing side surface is from the tabletop. As a skilled artisan would appreciate, however, the depth and shape of the bow could vary depending upon desired performance characteristics.

[0022] Figure 6 illustrates an exemplary field hockey stick 600 having a substantially straight handle 602 and a bowed throat 604, with the playing surface of the head 606 set back from the plane of the front face 608 of the handle 606, according to another embodiment of the present invention. In this embodiment, the hitting portion of the stick 600, comprised of the throat 604 and head 606, is bowed toward the non-playing side of the stick 600. The bow begins at a location proximate to the handle 602, reaches a maximum setback approximately halfway between the start of throat 604 and the end of head 606, and remains at a set back position such that the head 606 is set back from the plane of the front face 608 of the handle 602. The plane of the front face 608 is represented by the dashed line 610 in Figure 6. Line 610 also represents the line in which the playing side of the handle portion 602 lies when viewed from a direction facing the front edge of the hockey stick 600. Accordingly, the bowed hitting portion including the throat 604 and the head 606 is set back or offset from the line 610.

[0023] Figure 7 illustrates an exemplary field hockey stick 700 having a handle portion 702, a throat 704, and a head portion 706. In this embodiment, the bowed hitting portion including the throat 704 stops at the top of the head 706 such that substantially the full face or playing surface of the head 706 is flat and in the same plane as the front face of the handle 702. In other words, when viewed from a direction facing the front edge of the hockey stick, the playing side 708 of the handle portion 702 lies substantially along a line 710. In the

embodiment shown in Figure 7, the flat face of the head 706 also lies substantially on the line 710.

[0024] In another embodiment, shown in Figure 8, a field hockey stick 800 may include a handle portion 802, a throat 804, and a head portion 806. In this embodiment, as in the embodiment of Figure 7, the playing surface 812 of the head 806 is substantially flat. In Figure 8, however, the head 806 is set back or offset from a line 810 in which the playing side of the handle portion lies when viewed from a direction facing the front edge 808 of the field hockey stick. That is, the head 806 is set back from a line 810 or the plane of the front face of the handle 802. The flat front face 812 of the head 806 may be parallel or substantially parallel to the line 810 or the plane of the front face of the handle 802. Alternatively, the front face of head 806 may be angled with respect to line 810 to accommodate a desired loft, as described above.

[0025] Figure 9 is a cross-sectional view of a hitting portion of a field hockey stick according to an embodiment of the present invention. A portion of a throat 204 is shown having a generally V-shaped playing side surface (downward facing surface in Figure 9), or channel, and a generally rounded non-playing side surface (upward facing surface in Figure 9). The V-shaped channel in accordance with the present invention reduces friction as compared to a curved playing surface by providing at most two contact points with a ball. By contrast, a curved playing surface may contact a ball along a continuous line or surface area, thereby increasing friction. The depth of the channel of the present invention may vary along the throat and may continue through the head portion 206. In another embodiment, the channel is only in the throat portion 204. The depth of the channel may, for example, be greatest in a region around the midpoint of the throat portion 204 and may decrease gradually as it moves toward the head 206 and/or toward the handle portion 202, though one of skill in the art would appreciate that the depth of the channel may be as varied or consistent as desired. In a preferred embodiment, the maximum depth of the channel is approximately 4 mm.

[0026] In providing a substantially straight handle and a bowed hitting portion, the present invention creates an offset between the grip portion of the stick and

the hitting portion, so that a player's hands are more forward of most, if not all, of the hitting surface. In addition, in comparison to prior art sticks, the bow is more pronounced over a shorter distance, while still complying with widely accepted rules of field hockey stick construction (*e.g.*, limiting the depth of the bow to 25 mm). The forwardly positioned hands and more pronounced bow in the hitting portion provide significant unexpected benefits over full-length bowed sticks. For example, having the hitting portion offset from the more forward grip allows a player to cradle the ball better when dribbling. The forward shift in hand placement also increases the power of drives and helps keep the ball from being lofted into the air. In addition, the forward position of the hand can increase the speed of a sweep or push pass off the bow because the ball can stay in contact with the stick longer and be subjected to an increased whip off the end of the stick.

[0027] The field hockey stick of the present invention can be made of, for example, wood or composites. As used herein, composites refer to field hockey sticks made by bladder molding or by wrapping sheets of uncured fiber-reinforced thermosetting resin around a mandrel, which is then withdrawn to form a hollow tubular lay-up. Examples of the materials used in the resin include fiberglass, carbon, and aramid. Composite sticks have been available on the market for several years and have been approved for use in international play.

[0028] The foregoing disclosure of embodiments of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure. The scope of the invention is to be defined only by the claims, and by their equivalents.

WHAT IS CLAIMED IS:

1. A field hockey stick comprising:

a substantially straight handle portion; and

a bowed hitting portion.

2. The field hockey stick of claim 1, further comprising:

a playing side;

a non-playing side;

a front edge; and

a back edge,

wherein, when viewed from a direction facing the front edge, a playing side of the handle portion lies substantially along a line, and wherein the bowed hitting portion bows away from the line in a direction toward the non-playing side of the field hockey stick.

3. The field hockey stick of claim 2, wherein the bowed hitting portion comprises a throat portion and a head portion, at least a portion of the head portion lying on the line when viewed in a direction facing the front edge of the field hockey stick.

4. The field hockey stick of claim 2, wherein the bowed hitting portion comprises a throat portion and a head portion, and wherein no portion of the head portion lies on the line when viewed in a direction facing the front edge of the field hockey stick.

5. The field hockey stick of claim 2, wherein the bowed hitting portion comprises a throat portion, the field hockey stick further comprising a head portion having a substantially flat face that lies substantially along the line when viewed in a direction facing the front edge of the field hockey stick.

6. The field hockey stick of claim 2, wherein the bowed hitting portion comprises a throat portion, the field hockey stick further comprising a head portion having a substantially flat face that is offset from the line in a direction toward the non-playing side of the field hockey stick when viewed in a direction facing the front edge of the field hockey stick.

7. The field hockey stick of claim 6, wherein the line is a first line and the substantially flat face of the head portion lies substantially along a second line that is parallel to the first line when viewed in a direction facing the front edge of the field hockey stick.

8. The field hockey stick of claim 6, wherein the head portion comprises an upper portion and a lower portion, the upper portion being closer to the throat portion than the lower portion, and wherein the upper portion is closer to the line than the lower portion.

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9. The field hockey stick of claim 2, wherein the bowed hitting portion reaches a maximum distance from the line at approximately half the length of the hitting portion.

10. The field hockey stick of claim 9, wherein the maximum distance from the line is 25 mm.

11. The field hockey stick of claim 1, wherein the field hockey stick is hollow.

12. The field hockey stick of claim 1, wherein the bowed hitting portion comprises a playing side surface having a substantially V-shaped channel.

13. A field hockey stick comprising:

a substantially straight handle portion;

a throat portion; and

a head portion,

wherein, with respect to a perspective moving from the handle portion of the field hockey stick to the head portion of the field hockey stick, a portion of the throat portion proximate to the handle portion curves toward a non-playing side of the field hockey stick and a portion of the throat portion proximate to the head portion curves toward a playing side of the field hockey stick.

14. The field hockey stick of claim 13, wherein the head portion curves toward a playing side of the field hockey stick with respect to a perspective moving from the handle portion of the field hockey stick to the head portion of the field hockey stick.

15. The field hockey stick of claim 13, wherein the head portion is offset with respect to the handle portion.

16. The field hockey stick of claim 14, wherein the head portion is offset with respect to the handle portion.

17. The field hockey stick of claim 13, wherein the head portion has a substantially flat front face that is substantially coplanar with a front face of the handle portion.

18. The field hockey stick of claim 13, wherein the head portion has a substantially flat front face that is offset with respect to the handle portion.

19. The field hockey stick of claim 13, wherein a front face of the handle portion lies substantially along a first line and wherein the head portion has a substantially flat front face that lies substantially along a second line, wherein the second line is at an angle to the first line.

20. The field hockey stick of claim 13, wherein the field hockey stick is hollow.

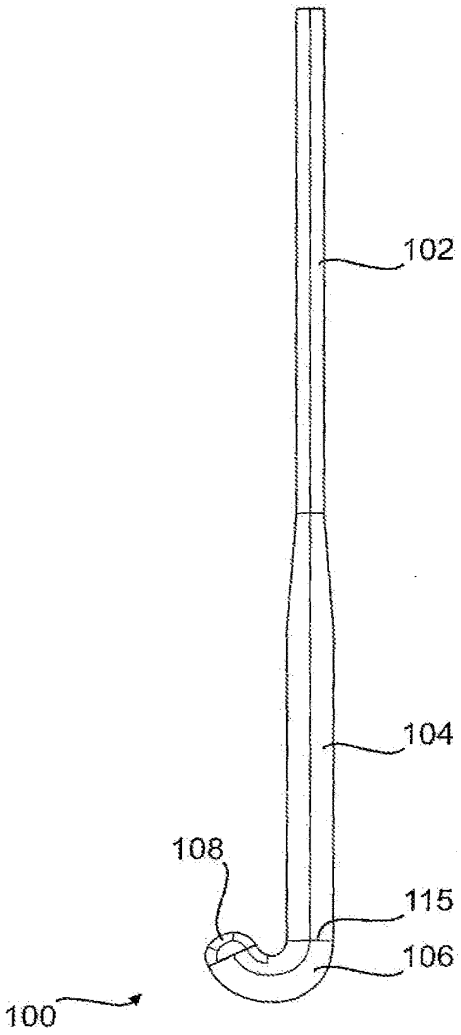


FIG. 1

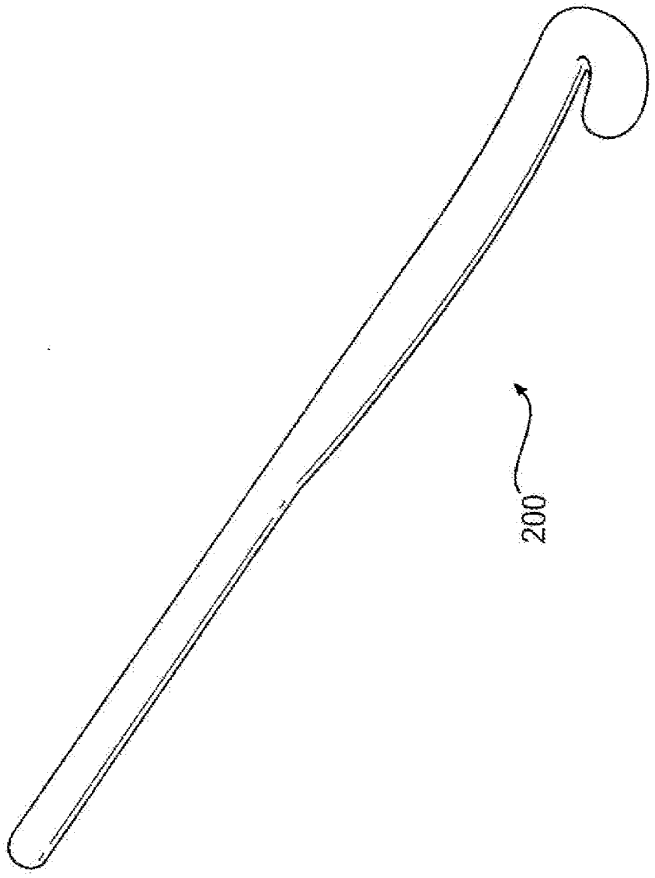


FIG. 2

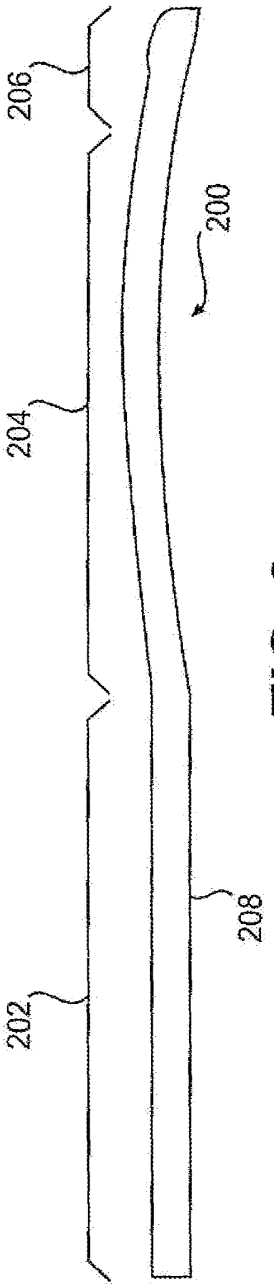


FIG. 3



FIG. 4



FIG. 5

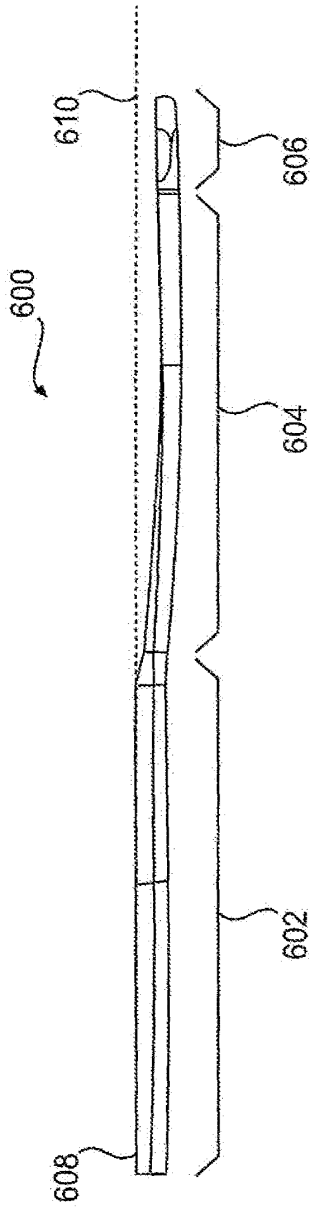


FIG. 6

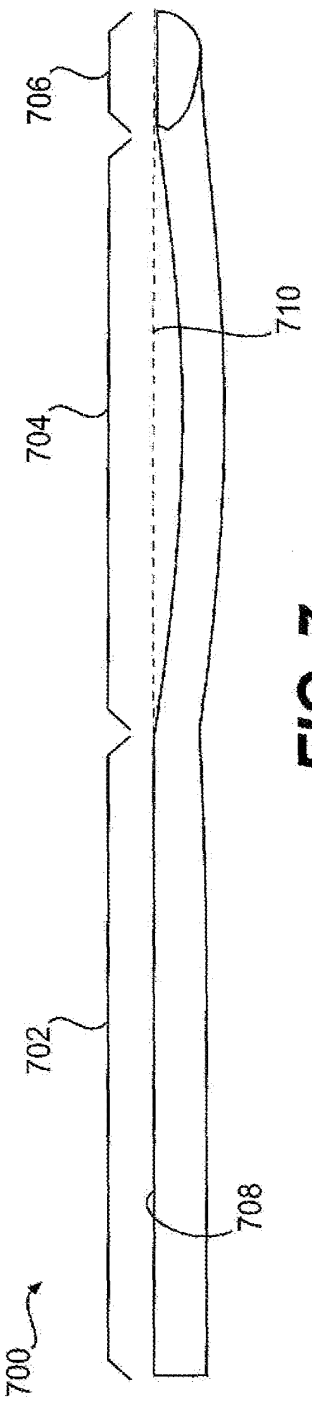


FIG. 7

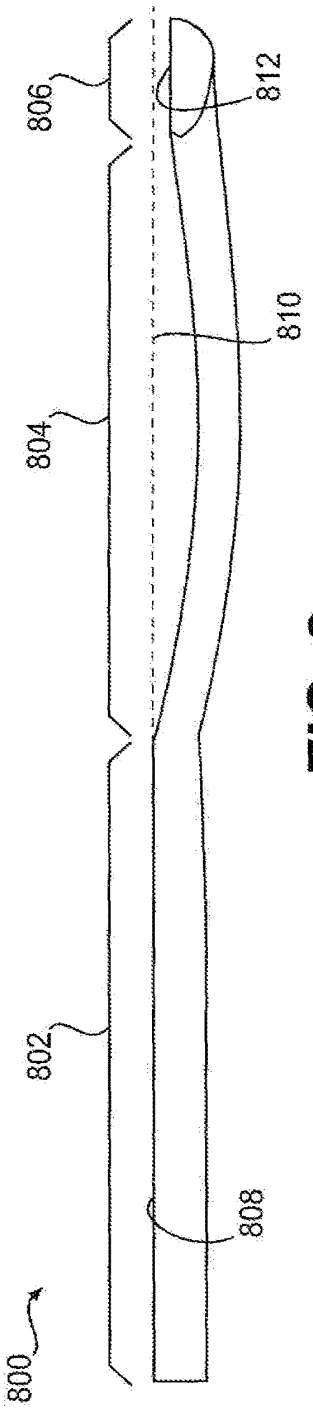


FIG. 8

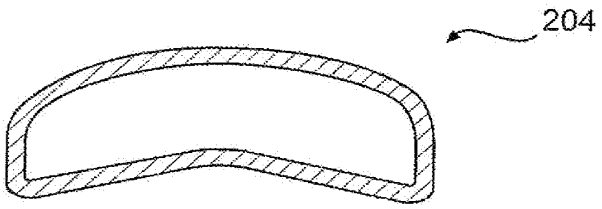


FIG. 9

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First Named Inventor	Mohammed N. ISLAM
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Examiner Name	
Attorney Docket Number	OMNI0101PUSA13

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18927698
	Filing Date	2025-10-24
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI0101PUSA13

	13	2009130464	WO	A1	2009-10-29	Zakian et al.		☐
	14	2012135952	WO	A1	2012-10-11	Mandelis, et al.		☐
	15	2013012938	WO	A1	2013-01-24	Raskin et al.		☐
	16	2015084376	WO	A1	2015-06-11	Han et al.		☐

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI0101PUSA13

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Kevin J. Heinl/	Date (YYYY-MM-DD)	2024-12-12
Name/Print	Kevin J. Heinl	Registration Number	29805

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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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.

Espacenet

Bibliographic data: JP2005270544 (A) — 2005-10-06

BIOLOGICAL INFORMATION MEASURING DEVICE

Inventor(s): MAEKAWA KAZUYA; NAKAMURA TAKASHI; MORIYA KOICHI; MIYAHARA SHINICHIRO ± (MAEKAWA KAZUYA, ; NAKAMURA TAKASHI, ; MORIYA KOICHI, ; MIYAHARA SHINICHIRO)

Applicant(s): SEIKO INSTR INC ± (SEIKO INSTRUMENTS INC)

Classification: **- international:** ***A61B5/024; A61B5/0245;*** (IPC1-7): A61B5/0245
- cooperative: **A61B5/02427 (EP); A61B5/02438 (EP)**

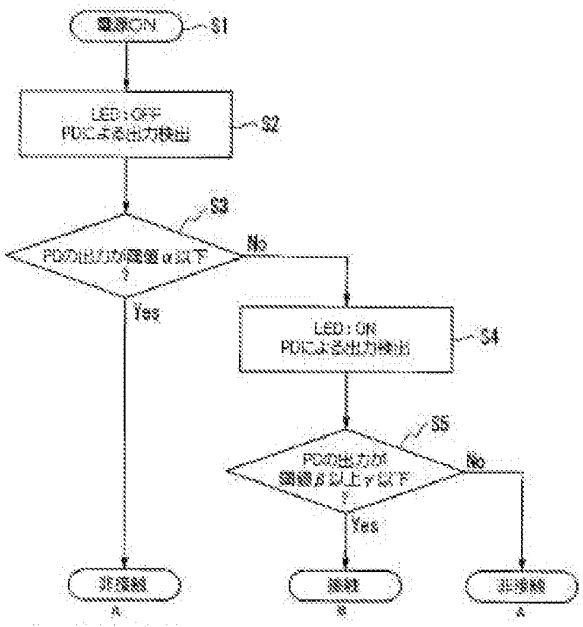
Application number: JP20040091943 20040326 Global Dossier

Priority number(s): JP20040091943 20040326

Also published as: JP4476664 (B2) WO2005092179 (A1)

Abstract of JP2005270544 (A)

PROBLEM TO BE SOLVED: To provide a biological information measuring device which attains to miniaturization by a simple constitution and prevents incorrect detection even when exterior light enters. ;SOLUTION: The biological information measuring device 1 is equipped with a light emitting part 4 in which a detection part detects whether or not a biosensor part 6 is brought into contact with the surface of a living body emits light onto the living body, a cover glass 23 which is arranged on the lower face of a body 2, lets the light emitted from the light emitting part 4 penetrate through and reflect, and lets the light backscattered at the living body penetrate through, a light receiving part 5 for receiving the light penetrated through the cover glass 23, and a judging part 7a for judging whether or not the living body is in contact with the biosensor part 6 based on the reception signal received by the light receiving part 5. ;COPYRIGHT: (C)2006,JPO&NCIPI



S1 : TURN ON POWER
S2 : LED OFF, DETECT OUTPUT BY PD
S3 : IS OUTPUT FROM PD EQUAL TO OR LOWER THAN THRESHOLD VALUE α?
S4 : LED ON, DETECT OUTPUT BY PD
S5 : IS OUTPUT FROM PD BETWEEN THRESHOLD VALUES α AND γ?
A : NON-CONTACT
B : CONTACT

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	A61B	5/02	320B	

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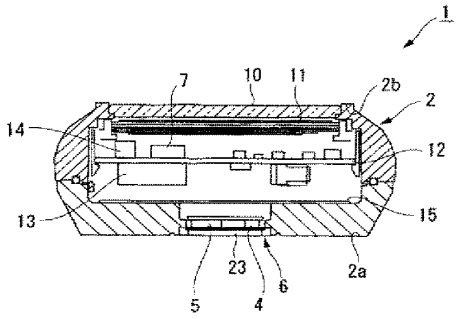
（特許庁注：以下のものは登録商標）
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最終頁に続く

(54)【発明の名称】生体情報計測装置

(57)【要約】
【課題】　簡易な構成で小型化を図るとともに、外光が入ったとしても誤検出することがない生体情報計測装置を提供すること。
【解決手段】　生体センサ部６が生体の表面に接触したか否かを検出する検出部が、生体に光を照射する光発光部４と、本体２の下面に配されて、光発光部４により照射した光を透過及び反射させるとともに、生体において後方散乱した光を透過させるカバーガラス２３と、カバーガラス２３を透過した光を受光する光受光部５と、該光受光部５により受光された受光信号に基づいて生体と生体センサ部６とが接触しているか否かを判断する判断部７ａとを備える生体情報計測装置１を提供する。
【選択図】　図６



【特許請求の範囲】
【請求項1】
本体と、
該本体に設けられると共に生体に向けて光を照射し前記生体からの後方散乱光の光量に応じた生体情報信号を生成する生体センサ部と、
前記本体に設けられると共に前記生体情報信号に基づいて生体情報を演算する生体情報演算部と、
前記本体の下面側に配され、前記生体センサ部が前記生体の表面に接触したか否かを検出する検出部とを備え、
該検出部が、前記生体に光を照射する光発光部と、
前記本体の下面に配されて、前記光発光部により照射した光を透過及び反射させるとともに、前記生体において後方散乱した光を透過させるカバーガラスと、
前記カバーガラスを透過した光を受光する光受光部と、
該光受光部により受光された受光信号に基づいて前記生体と前記生体センサ部とが接触しているか否かを判断する判断部とを備えることを特徴とする生体情報計測装置。
【請求項2】
前記光受光部が、前記カバーガラスを透過した前記生体からの後方散乱光を受光すると共に後方散乱光の光量に応じた生体情報信号を生成することを特徴とする請求項１に記載の生体情報計測装置。
【請求項3】
前記カバーガラスに、前記光発光部と前記光受光部との間に配され前記カバーガラス内を伝搬する光の一部を反射させる反射面を備えることを特徴とする請求項２に記載の生体情報計測装置。
【請求項4】
一端が前記カバーガラスに、他端が前記光受光部の受光面にそれぞれ近接して配設されたバンドル状の光ファイバを備えることを特徴とする請求項２に記載の生体情報計測装置。
【請求項5】
前記カバーガラスの前記光受光部の対向面に、前記生体からの後方散乱光を集光させる集光部を備えることを特徴とする請求項１または請求項２に記載の生体情報計測装置。

【発明の詳細な説明】
【技術分野】
【0001】
本発明は、手首（腕）に装着した状態で脈拍等の生体情報を測定することができる生体情報計測装置に関するものである。
【背景技術】
【0002】
近年の健康管理への関心の高まりにより、手首（腕）等に装着したまま脈拍等の様々な生体情報を計測することができる生体情報計測装置が各種提供されている（例えば、特許文献１参照）。
【0003】
この特許文献１に記載の脈拍計（生体情報計測装置）は、皮膚接触側に２つの電極を備えている。そして、この２つの電極がともに皮膚に触れると、皮膚を通して微少電流が流れ、両電極間の電圧が低下するため、脈拍センサが皮膚に接触しているものと判断する。したがって、この２つの電極の電位差によって皮膚との接触の有無を検出することができる。
【0004】
また、発光ダイオード（光発光部）及び受光素子（光受光部）により脈拍測定システムを有する脈拍測定器（生体情報計測装置）も提案されている（例えば、特許文献２参照）。この特許文献２に記載の脈拍測定器は、明暗測定用の受光素子を配置し、この受光素子

の出力に応じて接触の有無を検出するものである。
【特許文献1】特開２００３－７０７５７号公報（段落番号００２１－００２９、図２等）
【特許文献2】特開昭６０－２４６７３６号公報
【発明の開示】
【発明が解決しようとする課題】
【0005】
しかしながら、上述した特許文献１に記載の生体情報計測装置は、電極がある程度大きい場合は精度良く生体の接触を検出することが可能であるが、電極が小さい場合は誤検出が多く、例えば、腕時計型のような小型の端末で用いることが難しいという問題がある。また、特許文献２に記載の生体情報計測装置は、単に受光素子からの出力から明暗を判断し、接触の有無を判断しているので、外光の程度によっては誤検出してしまうおそれがある。
【0006】
本発明は上述した事情に鑑みてなされたものであって、簡易な構成で小型化を図るとともに、外光が入ったとしても誤検出することがない生体情報計測装置を提供することを目的とする。
【課題を解決するための手段】
【0007】
本発明は、前記課題を解決するために以下の手段を提供する。
【0008】
本発明の生体情報計測装置は、本体と、該本体に設けられると共に生体に向けて光を照射し前記生体からの後方散乱光の光量に応じた生体情報信号を生成する生体センサ部と、前記本体に設けられると共に前記生体情報信号に基づいて生体情報を演算する生体情報演算部と、前記本体の下面側に配され、前記生体センサ部が前記生体の表面に接触したか否かを検出する検出部とを備え、該検出部が、前記生体に光を照射する光発光部と、前記本体の下面に配されて、前記光発光部により照射した光を透過及び反射させるとともに、前記生体において後方散乱した光を透過させるカバーガラスと、前記カバーガラスを透過する光を受光する光受光部と、該光受光部により受光された受光信号に基づいて前記生体と前記生体センサ部とが接触しているか否かを判断する判断部とを備えることを特徴とする。
【0009】
本発明に係る生体情報計測装置においては、光発光部から生体に向けて光を照射する。照射された光はカバーガラス表面での反射やカバーガラス内での伝搬、生体での後方散乱などにより、光受光部により受光される。検出部に備えられた判断部は、光発光部が発光している状態及び発光していない状態で、光受光部により受光された受光信号に基づいて生体表面と生体センサ部とが接触しているか否かを判断する。判断部により生体表面と生体センサ部とが接触していると判断、すなわち、本体を手首（腕等）に装着していると判断し、生体センサ部により、生体に向けて光を照射し生体からの後方散乱光の光量に応じた生体情報信号を生成する。さらに、生体情報検出部において、生体情報信号を所定の演算をして脈拍等の生体情報の算出を行う。また、光受光部に外光が入ったとしても、生体表面と生体センサ部との接触を誤検出することがなくなる。
【0010】
また、本発明の生体情報計測装置は、前記光受光部が、前記カバーガラスを透過した前記生体からの後方散乱光を受光すると共に後方散乱光の光量に応じた生体情報信号を生成することが好ましい。
【0011】
本発明に係る生体情報計測装置においては、光受光部において、受光された光に基づいて生体表面と生体センサ部との接触と、生体情報信号の生成との両方を行うため、部品点数の少量化を図ることができ、さらに、生体情報計測装置全体の小型化を図るができる。

【0012】
また、本発明の生体情報計測装置は、前記カバーガラスに、前記光発光部と前記光受光部との間に配され前記カバーガラス内を伝搬する光の一部を反射させる反射面を備えることが好ましい。
【0013】
本発明に係る生体情報計測装置においては、光照射部により照射された光のうちカバーガラス内部を伝搬した光を、反射面により生体表面側に反射させることになる。このため、生体情報を測定する際、生体情報を含んでいないカバーガラス内を伝搬する光を遮断することができるため、精度よく生体情報を測定することが可能になる。
【0014】
また、本発明の生体情報計測装置は、一端が前記カバーガラスに、他端が前記光受光部の受光面にそれぞれ近接して配設されたバンドル状の光ファイバを備えることが好ましい。
【0015】
本発明に係る生体情報計測装置においては、光ファイバが配されているため、生体の表皮などの表面部分を通ってきた光が光ファイバの外周面で反射されることになる。生体の表皮などの表面部分のみを通ってきた光は生体情報をあまり含んでいないため、この光を遮断することにより、光ファイバに入射して光ファイバ内を伝搬し光受光部に導かれる光の大部分は真皮部分以下の生体の深部を通ってきた光、すなわち生体情報を多く含んだ光となる。
【0016】
また、本発明の生体情報計測装置は、前記カバーガラスの前記光受光部の対向面に、前記生体からの後方散乱光を集光させる集光部を備えることが好ましい。
【0017】
本発明に係る生体情報計測装置においては、光受光部により照射され生体において後方散乱した光が、集光部によって光受光部の受光面に効率良く集光されることになる。したがって、脈拍信号等の生体情報信号を生成する際、光受光部の面積を小さくすることができるため、生体情報計測装置全体の小型化を図ることが可能になる。
【発明の効果】
【0018】
本発明に係る生体情報計測装置によれば、光発光部の発光状態を変えた際の光受光部によって受光された光に基づいて接触の有無を検知しているため、簡易な構成で生体との接触を検知することができる。したがって、外光が光受光部に入る場合においても、正確に生体との接触を認識することができるため、高精度に生体情報の算出を行うことが可能となる。
【発明を実施するための最良の形態】
【0019】
以下、本発明に係る生体情報計測装置の一実施形態を、図１から図１１を参照して説明する。
【0020】
本実施形態の生体情報計測装置１は、図１から図８に示すように、腕時計型であって手首（腕）Ａに装着した状態で、生体情報である脈拍数を算出するものである。
【0021】
この生体情報計測装置１は、各種の電気部品及び電子部品を内蔵したハウジング（本体）２と、このハウジング２の下面２ａを生体表面Ｂ側に向けた状態でハウジング２を手首Ａに装着する固定手段３と、ハウジング２に設けられると共に生体表面（生体）Ｂに向けて光を照射するＬＥＤ（Light Emitting Diode）４と生体からの後方散乱光を受光するＰＤ（Photo－Diode）５とを有する生体センサ部６と、ハウジング２に設けられると共に生体センサ部６により受光した光量に応じた脈拍信号（生体情報信号）を生成し生成された脈拍信号を演算し脈拍数を算出するデータ処理部（生体情報演算部）７とを備えている

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【0022】
生体センサ部６は、生体センサ部（ハウジング２の下面２ａ側）が生体表面Ｂに接触したか否かを検出する検出部を兼ねている。すなわち、生体センサ部６が、生体表面Ｂに接触したか否かを検出すると共に脈拍信号を生成するための生体からの光の検出を行う機能を有するＬＥＤ４とＰＤ５とを備えていることになる。
【0023】
また、生体情報計測装置１は、図７に示すように、ハウジング２の下面２ａ側に配されて、ＬＥＤ４により照射した光を透過及び反射させるとともに、生体において後方散乱した光を透過させるカバーガラス２３を備えている。また、ＰＤ５がこのカバーガラス２３を伝搬する光及びカバーガラス２３を透過した生体からの後方散乱光を受光するようになっている。
【0024】
また、データ処理部７には、ＰＤ５により受光された受光信号に基づいて生体と生体センサ部６とが接触しているか否かを判断する判断部７ａとを備えている。
【0025】
上記ハウジング２は、プラスチックやアルミニウム等の金属材料からなり、所定の厚みをもって、例えば、上面視略長方形状に形成されている。ハウジング２の上面２ｂの中央部分には、略正方形状のガラス板１０が嵌め込まれており、該ガラス板１０の内側には演算された上記脈拍数やその他各種の情報を表示する表示部１１が配されている。
【0026】
また、ハウジング２内には、図５及び図６に示すように、メイン基板１２が設けられており、該メイン基板１２に上記データ処理部７、上記表示部１１、充電可能な充電池１３、脈拍数を記録するメモリ１４、サブ基板１５及びその他各種の電子部品が実装又は配線等により電気的に接続されている。
【0027】
上記データ処理部７は、ＣＰＵ等のＩＣ部品を含むものであり、ＰＤ５により生成された脈拍信号を一旦アンプ等により増幅した後に、高速フーリエ変換処理（ＦＦＴ処理）等の所定処理を行い、その処理結果を解析することにより脈拍数を算出する機能を有している。また、データ処理部７は、算出した脈拍数をメモリ１４に記録すると共に、後述する各ボタン２０からの入力に基づいて表示部１１に表示させるようになっている。更に、データ処理部７は、他の構成品を総合的に制御する機能も有している。
【0028】
上記表示部１１は、例えば、ＬＣＤ（Liquid Crystal Display）等の液晶表示器であり、上述した脈拍数以外に、例えば、図示しない水晶振動子によりカウントされた時刻を表示する時刻表示機能やその他の各種情報を表示する機能を有している。例えば、時刻、日付、曜日や充電池１３の残電力量等を表示できるようになっている。
【0029】
また、ハウジング２には、図１及び図２に示すように、複数のボタン２０、例えば、ハウジング２の上面２ｂであって表示部１１の下側に配された３つのボタン２０及びハウジング２の側面に配された１つのボタン２０が設けられている。これら各ボタン２０を押下することで、各種操作ができるようになっている。例えば、脈拍の計測開始、計測停止や、脈拍数と時刻との表示切替や、メモリ１４内に記録されている脈拍数データを外部の機器にデータ送信する等の操作ができるようになっている。
【0030】
更に、ハウジング２の側面には、上記充電池１３に充電器等の外部から電力を供給して充電させる外部接続端子（充電手段）２１が設けられている。なお、外部接続端子２１を覆うようにカバー等を取り付けて、外部接続端子２１を保護しても構わない。こうすることで、外部接続端子２１を水滴や埃等から保護することが可能となり、より好適である。また、外部接続端子２１に限らず、充電器及びハウジング２内にそれぞれ電力を供給する

ためのトランス等を設け、非接触状態で充電池１３の充電を行うように構成しても構わない。

【0031】

また、ＰＤ５により生成された脈拍信号は、フレキシブル基板２４、サブ基板１５及びメイン基板１２を介して、上記データ処理部７に送られるようになっている。また、カバーガラス２３内を伝搬してＰＤ５により受光された光は、判断部７ａに送られるようになっている。

【0032】

判断部７ａは、ＰＤ５により検出された受光信号を電圧として受けて、この電圧値とあらかじめ設定されている閾値電圧αＶとを常に比較している。ＬＥＤ４がＯＦＦ状態において、検出された受光信号が閾値電圧αＶ以下であればＬＥＤ４及びＰＤ５が生体表面Ｂと非接触状態であると判断するようになっている。一方、ＰＤ５により検出された受光信号が閾値電圧αＶ以上であれば、ＬＥＤ４をＯＮ状態にする。そして、ＰＤ５により検出された受光信号が閾値電圧βＶ以上であればＬＥＤ４及びＰＤ５が生体表面Ｂに非接触状態であると判断するようになっている。一方、ＰＤ５により検出された受光信号が閾値電圧βＶ以下であればＬＥＤ４及びＰＤ５が生体表面Ｂと接触状態であると判断するようになっている。すなわち、データ処理部７は、この検出結果に基いて、ＬＥＤ４から光を照射するようにＬＥＤ４の作動を制御するように設定されている。なお、この場合だけに限らず、例えば、生体表面Ｂに接触していないことが検出されたときに、ＦＦＴ処理を行なわないように設定しても構わない。

【0033】

上記固定手段３は、ハウジング２に基端側が取り付けられて手首Ａに装着可能な第１のバンド３０及び第２のバンド３１を有している。第１のバンド３０及び第２のバンド３１は、ハウジング２の長手方向に、該ハウジング２を挟んで対向するように設けられている。また、両バンド３０、３１は、伸縮自在な弾性材料により形成されている。

【0034】

上記第１のバンド３０には、先端にバックル３０ａ及びタング３０ｂが取り付けられている。また、第２のバンド３１には、上記タング３０ｂが挿入される挿入孔３１ａが該第２のバンド３１の長手方向に沿って複数形成されている。これにより、使用者の手首Ａの太さに応じて第１のバンド３０及び第２のバンド３１の長さを調整することができるようになっている。

【0035】

このように構成された生体情報計測装置１により、手首Ａに装着した状態で脈拍数を算出する場合について説明する。

【0036】

まず、図８のフローチャート図に示すように、ボタン２０を押下し、脈拍の計測モードに切り替えることによって、ＰＤ５の電源がＯＮ状態になる（ステップＳ１）。ここで、まず、ＬＥＤ４をＯＦＦ状態のまま、ＰＤ５により受光される受光信号の電圧を検出する（ステップＳ２）。ＰＤ５により受光された光が電圧としてデータ処理部７の判断部７ａに出力される。この場合において、判断部７ａは、検出された電圧値と閾値電圧αＶとを常に比較しており（ステップＳ３）、検出された電圧値が閾値電圧α以上である場合（ステップＳ３「ＮＯ」）、ＬＥＤ４をＯＮ状態にする（ステップＳ４）。再び、データ処理部７の判断部７ａは、検出された電圧値と閾値電圧βＶ及びγＶとを常に比較しており（ステップＳ５）、検出された電圧値が閾値電圧「β以上γ以下」となった場合（ステップＳ５「ＹＥＳ」）、ＬＥＤ４及びＰＤ５が生体表面Ｂに接触していることを判断する。

【0037】

一方、ＬＥＤ４がＯＦＦ状態において、ＰＤ５により検出された電圧値が閾値電圧α以下であれば（ステップＳ３「ＹＥＳ」）、ＬＥＤ４及びＰＤ５が生体表面Ｂと非接触であると判断する。また、ＬＥＤ４がＯＮ状態において、ＰＤ５により検出された電圧値が閾値電圧「β以上γ以下」でない場合（ステップＳ５「ＮＯ」）、ＬＥＤ４及びＰＤ５が生

体表面Ｂと非接触であると判断する。すなわち、データ処理部７は、ＬＥＤ４及びＰＤ５が確実に生体表面Ｂに接触しているかの検出を行う。

【0038】

本実施例では、データ処理部は常に検出された電圧値と閾値電圧を比較しているが、例えば脈拍を計測する前にのみ比較するものや、脈拍を計測する前後に比較するものであっても構わない。

【0039】

判断部７ａにより、図２及び図３に示すように、使用者の手首Ａを巻回するよう両バンド３０、３１を巻き、手首Ａの大きさに応じて第１のバンド３０のタング３０ｂを第２のバンド３１の挿入孔３１ａに挿入し、ハウジング２を手首Ａに装着していると判断すると、データ処理部７は、ＬＥＤ４から生体に向けて光を照射させる。照射された光は、生体内で脂肪や筋といった組織や血液により吸収および散乱され、照射された光の一部が後方散乱光としてＰＤ５で検出される。検出される光は、脈動による血液量の変化に伴い変動する。ＰＤ５は、この後方散乱光を受光すると共に受光量の変化に応じた脈拍信号（生体情報信号）を生成して、データ処理部７に出力する。つまり、手首Ａ（生体）内部の動脈及び細動脈内の血流変動に応じて、ＬＥＤ４から照射された光の後方散乱光の光量が変動するので、ＰＤ５は、動脈の脈動、即ち、脈波に応じた後方散乱光の受光が行える。これにより、ＰＤ５は、脈拍信号の生成が行える。

【0040】

データ処理部７は、送られてきた脈拍信号を増幅した後に、ＦＦＴ処理等の所定処理をした後、解析を行なって脈拍数を算出する。そして、データ処理部７は、算出した脈拍数をメモリ１４に記録すると共に各ボタン２０操作に基づいて表示部１１に表示させる。

【0041】

使用者は、必要時に各ボタン２０を押下することで、容易に算出された脈拍数を表示部１１に表示させて確認が行えるので、使用に関して簡便である。また、使用者は、各ボタン２０の操作により、脈拍数以外のその他の情報、例えば、時刻や充電池１３の残電力等についても表示部１１により確認することができるので使い易い。

【0042】

また、上述したように、使用者は、ハウジング２を両バンド３０、３１により所定の力で締め付けて手首Ａに装着しているので、長時間装着したとしても圧迫感を感じることがないので、不快に感じることがない。

【0043】

ＬＥＤ４及びＰＤ５は、フレキシブル基板２４の弾性によって、ハウジング２の下面２ａ側に向けて押圧されて生体表面Ｂに出来るだけ近接していることから、脈拍数を高精度に算出することができる。

【0044】

また、充電池１３に電力を充電する場合には、例えば、充電器に接続されている充電コード等を外部接続端子２１に接続することで充電を行うことができ、通常の電池を別個に用意する必要はない。従って、維持経費の削減を図ることができる。なお、ハウジング２内に音声を出力するブザー等の音声出力手段を設けて、充電池１３の充電量が“０”に近くなるまで減少した場合に、音声を出力させて充電時期（充電タイミング）を知らせるように構成しても構わない。

【0045】

以上説明したように、本実施形態の生体情報計測装置１によれば、ＬＥＤ４の発光状態を変えた際のＰＤ５によって受光された光に基づいて、ＬＥＤ４及びＰＤ５が生体表面Ｂに接触しているか否かを検知しているため、簡易な構成で生体表面Ｂとの接触を検知することができる。したがって、外光がＰＤ５に入る場合においても、正確に生体表面Ｂとの接触を認識することができるため、高精度に生体情報の検出を行うことが可能となる。

【0046】

なお、本発明の技術範囲は上記実施の形態に限定されるものではなく、本発明の趣旨を

逸脱しない範囲において種々の変更を加えることが可能である。

【0047】

例えば、図９に示すように、カバーガラス２３に、ＬＥＤ４とＰＤ５との間に配されカバーガラス２３内を伝搬する光の一部を反射させる反射面２３ａを設けても良い。この構成の場合には、ＬＥＤ４により照射された光のうちカバーガラス２３内部を伝搬する光を、反射面２３ａにより生体表面Ｂ側に反射させることになる。このため、生体情報を測定する際、ノイズ光となるカバーガラス２３内を伝搬する光を遮断することができるため、脈拍信号を生成する際のＳＮ比を向上することが可能になる。

【0048】

あるいは、図１０に示すように、ＰＤ５とカバーガラス２３とが離間して配設され、一端４０ａがカバーガラス２３に、他端４０ｂがＰＤ５の受光面５ａにそれぞれ近接しては配設されたバンドル状の光ファイバ４０を備えていても良い。この構成の場合には、ＰＤ５とカバーガラス２３との隙間部に光ファイバ４０が配されているため、生体表面Ｂの表皮などの表面部分を通ってきた光が光ファイバ４０の外周面で反射される。生体表面Ｂの表皮などの表面部分のみを通ってきた光は生体情報をあまり含んでいないため、この光を遮断することにより、光ファイバ４０に入射して光ファイバ４０内を伝搬しＰＤ５に導かれる光の大部分は真皮部分以下の生体の深部を通ってきた光、すなわち生体情報を多く含んだ光となる。

【0049】

さらに、図１１に示すように、カバーガラス２３のＰＤ５の対向面に、生体からの後方散乱光を集光させる凹部（集光部）４１が形成されていても良い。この構成の場合には、ＰＤ５により照射され生体において後方散乱した光が、凹部４１によってＰＤ５の受光面５ａに効率良く集光されることになる。したがって、ＰＤ５により脈拍信号を生成する際、ＰＤ５の受光面積を小さくすることができるため、生体情報計測装置全体の小型化を図ることが可能になる。なお、集光部としてはＰＤ５の集光面５ａに光が集光すれば良いため、凸形状であっても良い。

【0050】

また、さらに、ＬＥＤ４とＰＤ５とが生体表面Ｂとの接触の検知に用いられると共に、脈拍信号を生成するための生体からの後方散乱光の受光とを兼ねる構成としたが、これに代えて、図１２に示すように、もう一対のＬＥＤ５１とＰＤ５２とを有する検出部５３と、ＬＥＤ４，ＰＤ５とＬＥＤ５１，ＰＤ５２とを遮蔽する光遮蔽板５４とを設けている生体情報計測装置５０であっても良い。この構成の場合には、ＬＥＤ４とＰＤ５とが生体表面Ｂとの接触の検知を行い、ＬＥＤ５１とＰＤ５２とが脈拍信号を生成するための生体からの後方散乱光の受光を行うため、脈拍信号を生成するのに必要な後方散乱光をＰＤ５２により受光する。

【0051】

また、ＬＥＤ４とＰＤ５の間隔に制約を設けることで、ＬＥＤ４より発せられた光がカバーガラス２３の表面で反射しＰＤ５に入射することがないようにすることが可能である。カバーガラスの材料として屈折率１．５のアクリルを用いたときのＬＥＤ４とＰＤ５との位置関係の例を図１３および表１に示す。

【0052】

【表1】

データ	X	Y	Z_1	Z2	Z3
a	0.1	0.5	0.7	2.211083	2.911083
b	0.5	0.5	3.5	2.211083	5.711083
c	1	0.5	7	2.211083	9.211083
d	0.1	1	0.7	4.422166	5.122166
e	0.5	1	3.5	4.422166	7.922166
f	1	1	7	4.422166	11.42217

ＰＤ５は受光面５ａがパッケージ５ｂの上面よりも一段下がった構造をしている。ＬＥＤ４とＰＤ５とは面一に配されており、ここで、これらとカバーガラス２３との距離をＸとし、カバーガラス２３の厚さをＹとしたとき、ＬＥＤ４で発せられた光のうちカバーガラス２３の下面２３ｂでの反射光が受光面５ａに入射しないための距離Ｚ１およびカバーガラス２３内部で一度反射した光が受光面５ａに入射しないための距離Ｚ３はＸ、Ｙによって異なる。Ｘ，Ｙが長くなるとＺ１，Ｚ３も長くなり、逆にＸ，Ｙが短くなるとＺ１、Ｚ３は短くなる。このように、どの領域で反射した光を遮断するかにより、上記表１に示した設計値に設定することも可能である。

【0053】

また、上記実施形態においては、生体情報として脈拍数を例にして説明したが、脈拍数に限らず、生体情報であれば構わない。

【0054】

また、ハウジングに、他の電子機器との間で無線通信可能な無線通信手段等の機能を付加しても良い。こうすることで、Ｂｌｕｅｔｏｏｔｈ等の無線通信により、メモリに記録した脈拍数を外部の電子機器にデータ送信したり、各種情報をメモリに入手させることができる。

【実施例】

【0055】

上記一実施形態に係る生体情報計測装置１を用いたときのＰＤ５により検出された出力結果について説明する。

【0056】

また、本実施形態においては、ＬＥＤ４がＯＦＦ状態における電圧閾値αは１．９Ｖであり、ＬＥＤ４がＯＮ状態における電圧閾値β及び電圧閾値γはそれぞれ０．４Ｖ、１．８Ｖとする。ここで用いるＰＤ５は、入射する光強度が増加するにしたがって、ＰＤ５により出力される電圧値が減少するものとして説明する。すなわち、測定電圧がα以下であるということは１．９Ｖ以下であり、測定電圧がβ以上γ以下であるということは０．４Ｖ以上１．８Ｖ以下であることを示す。

【0057】

図１４に示すように、状態１では、外光がない暗い状態で生体情報計測装置１が手首Ａに装着されていない状態を示す。まず、ＬＥＤ４がＯＦＦ状態であるときには、外光及びＬＥＤ４光がないため、ＰＤ５に光が入射しないのでＰＤ５からの出力電圧（測定値）は約２Ｖとなる。次いで、ＬＥＤ４がＯＮ状態にすると、外光はないが、ＬＥＤ４により照

射され、カバーガラス２３表面で反射した光および内部を伝搬した光がＰＤ５に入射するので、ＰＤ５からの出力電圧（測定値）は１．８Ｖを少し超えた値となる。

【0058】

次に、状態２では、外光がない暗い状態で生体情報計測装置１が手首Ａに装着されている状態を示す。まず、ＬＥＤ４がＯＦＦ状態であるときには、外光及びＬＥＤ４光がないため、ＰＤ５に光が入射しないのでＰＤ５からの出力電圧（測定値）は約２Ｖとなる。次いで、ＬＥＤ４をＯＮ状態にすると、外光はないが、ＬＥＤ４により照射され、カバーガラス２３内を伝搬した光及び生体内で後方散乱した光がＰＤ５に入射するので、ＰＤ５からの出力電圧（測定値）は約１．４Ｖとなる。

【0059】

次に、状態３では、外光の強度が約６００Ｌｘで生体情報計測装置１が装着されていない状態を示す。

【0060】

まず、ＬＥＤ４がＯＦＦ状態であるときには、外光及びＬＥＤ４光がないが、外光があるため、ＰＤ５からの出力電圧（測定値）は約０．１２Ｖとなる。次いで、ＬＥＤ４がＯＮ状態にすると、外光及びＬＥＤ４により照射され、カバーガラス２３内を伝搬した光がＰＤ５に入射するので、ＰＤ５からの出力電圧（測定値）は約０．１１Ｖとなる。これらの結果は外光の強度や生体表面の状態、ＬＥＤ４とＰＤ５の距離などで若干異なるが、これらの結果よりＬＥＤ４がＯＦＦ状態であるとき、ＰＤ５の測定値が１．９Ｖを下回っていれば、ＰＤ５に外光が入射しているものとしてＬＥＤ４及びＰＤ５と生体表面Ｂとが非接触状態であると判断できる。また、ＬＥＤ４がＯＦＦ状態でＰＤ５の測定値が１．９Ｖを上回っている場合で、ＬＥＤ４をＯＮ状態としＰＤ５の測定値が１．８Ｖを上回っている場合は、ＰＤ５に生体からの後方散乱光が入射していないものとしてＬＥＤ４及びＰＤ５と生体表面Ｂとが非接触状態であると判断し、ＬＥＤ４をＯＮ状態としＰＤ５の測定値が０．４Ｖを下回っている場合はＰＤ５に生体以外の物体からの反射光が入射しているものとしてＬＥＤ４及びＰＤ５と生体表面Ｂとが非接触状態であると判断できる。

【0061】

本実施例では閾値をそれぞれ１．９Ｖ、１．８Ｖ、０．４Ｖとしているが閾値の設定値はこの限りではない。

【図面の簡単な説明】

【0062】

【図1】本発明に係る生体情報計測装置の一実施形態を示す正面図である。

【図2】図１に示す生体情報計測装置の背面図である。

【図3】図１に示す生体情報計測装置を手首に装着した状態を示す側面図であり、図２に示す方向とは逆方向から見た図である。

【図4】図１に示す生体情報計測装置を斜め上方から見た状態を示す斜視図である。

【図5】図３に示す生体情報計測装置の断面矢視Ｃ－Ｃ図である。

【図6】図１に示す生体情報計測装置の断面矢視Ｄ－Ｄ図である。

【図7】図１に示す生体情報計測装置の生体センサ部を示す断面図である。

【図8】図５に示す生体情報計測装置のデータ処理部で行われる接触検知を示すフローチャート図である。

【図9】図７に示す生体情報計測装置の生体センサ部の他の変形例を示す断面図である。

【図10】図７に示す生体情報計測装置の生体センサ部の他の変形例を示す断面図である。

【図11】図７に示す生体情報計測装置の生体センサ部の他の変形例を示す断面図である。

【図12】図１に示す生体情報計測装置の他の変形例を示す平面図である。

【図13】図７に示す生体情報計測装置のＬＥＤとＰＤとの位置関係を示す断面図である。

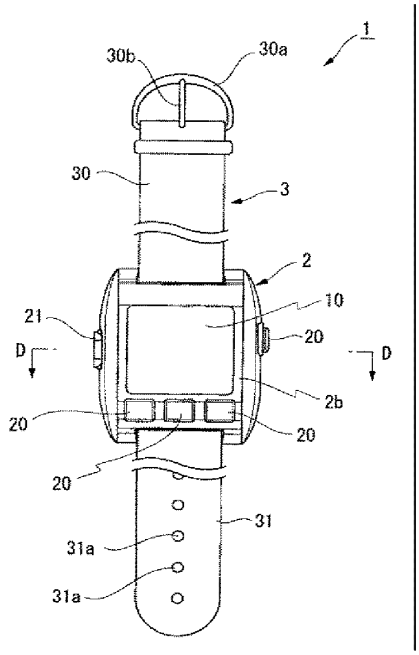
【図14】本発明における実施例において、生体センサ部と生体との接触状態によりＰＤにより出力される電圧値を示すグラフである。

【符号の説明】

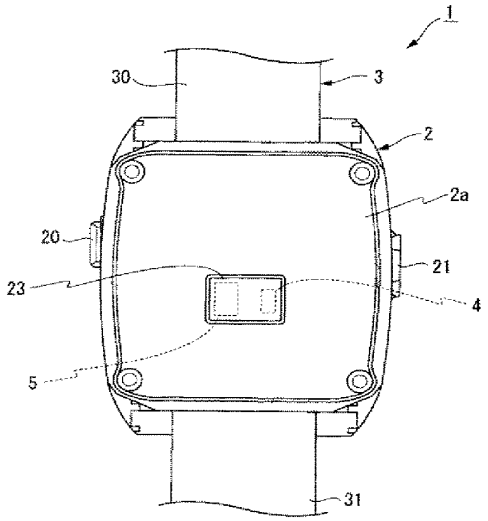
【0063】

Ｂ　　生体表面（生体）
１，５０　　生体情報計測装置
２　　ハウジング（本体）
２ａ　　本体の下面
４　　ＬＥＤ（光発光部）
５　　ＰＤ（光受光部）
７　　データ処理部（生体情報検出部）
７ａ　判断部
８　　生体センサ部
２３　カバーガラス
２３ａ　反射面
４０　光ファイバ
４０ａ　光ファイバの一端
４０ｂ　光ファイバの他端
４１　凹部（集光部）

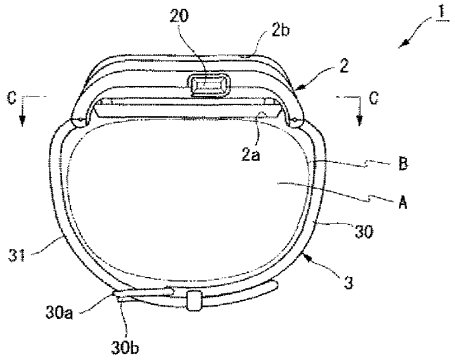
【図1】



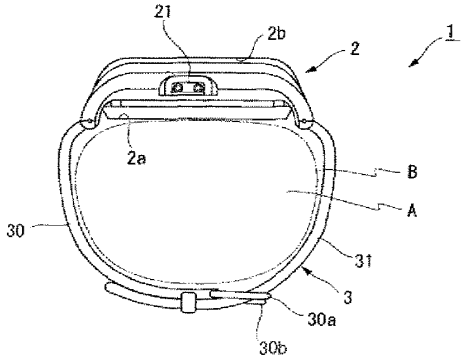
【図2】



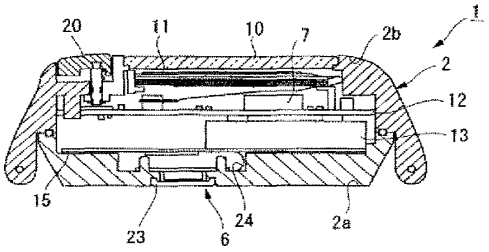
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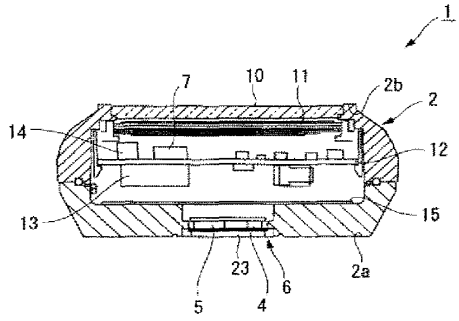
【図4】



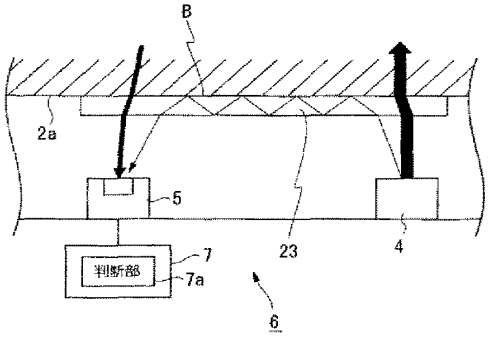
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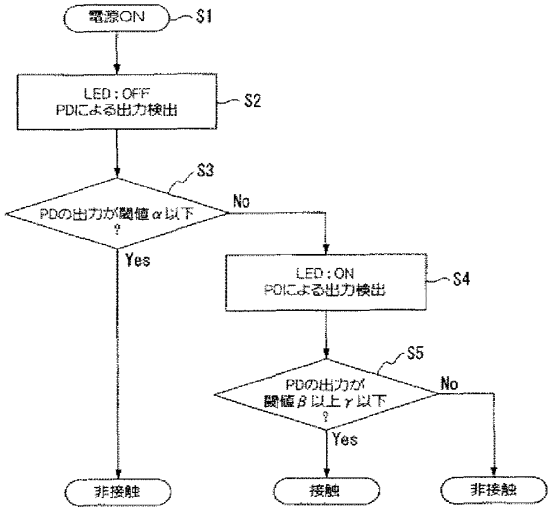
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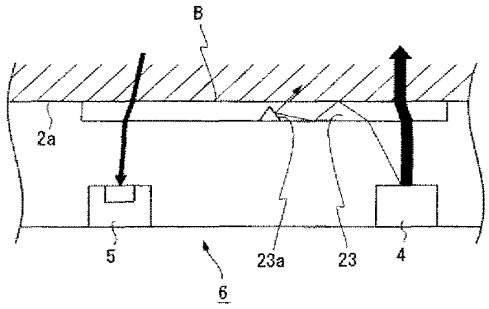
【図7】



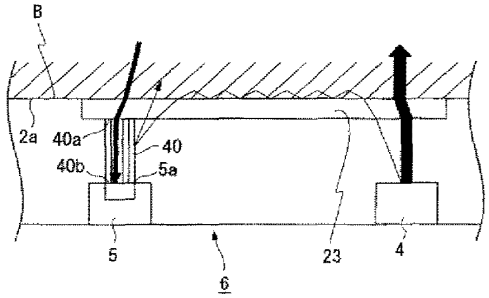
【図8】



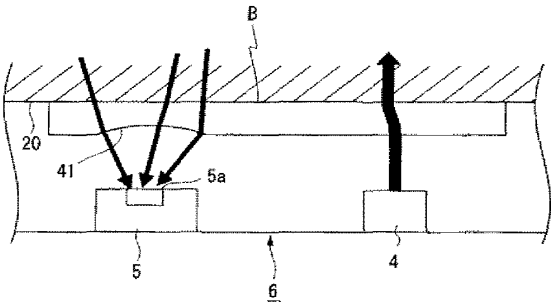
【図9】



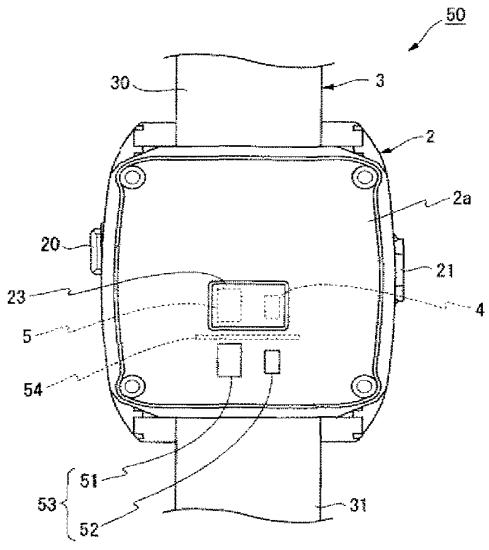
【図10】



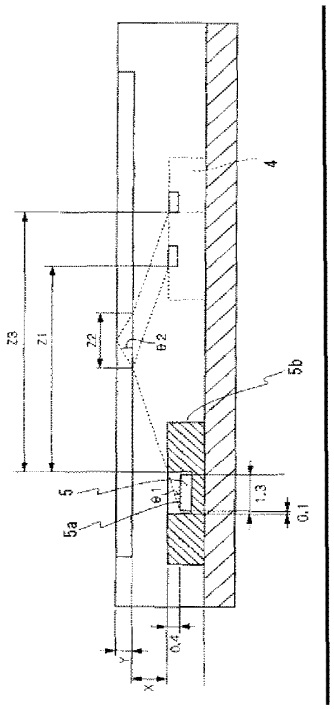
【図11】



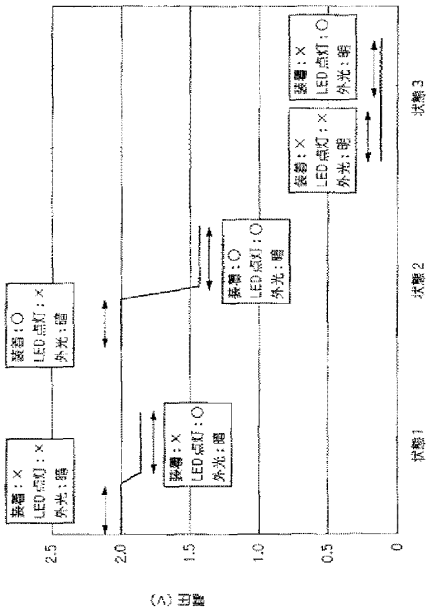
【図12】



【図13】



【図14】


装着：×
LED点灯：×
外光：暗
装着：○
LED点灯：×
外光：暗
装着：×
LED点灯：○
外光：暗
装着：○
LED点灯：○
外光：暗
装着：×
LED点灯：×
外光：明
装着：×
LED点灯：○
外光：明
状態1
状態2
状態3
2.5
2.0
1.5
1.0
0.5
0
(x) 出力

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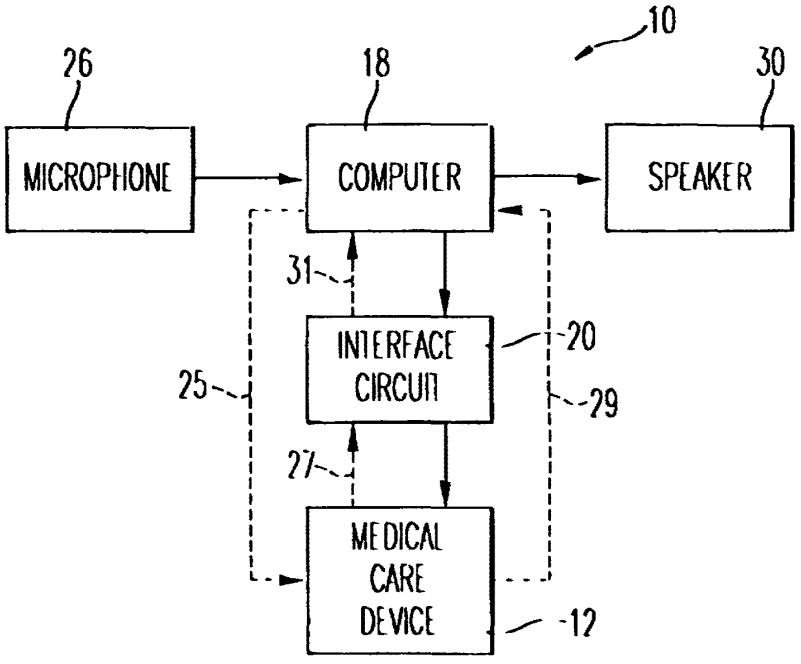
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(54) Title: VOICE COMMAND AND CONTROL MEDICAL CARE SYSTEM

(57) Abstract

A voice command and control medical care system is provided which comprises a processor (18) having a continuous speech recognition capability. The processor (18) is programmed to process a user's conversational speech to identify valid commands therein and to generate control signals for operating medical equipment (12) such as surgical tools in accordance with the commands. The processor is programmed to generate audio messages (30) reporting status information when requested, and to generate confirmation messages and await acknowledgement before executing a command. The system is configurational to interface with and control via voice activation essentially any piece of medical equipment having instruments and control switches that can be controlled via electrical or electromagnetic signals.



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VOICE COMMAND AND CONTROL MEDICAL CARE SYSTEM

This application claims the benefit of U.S. Provisional Application No. 60/006,107, filed October 25, 1995.

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Field of the Invention

The invention relates to a voice command and control system for controlling medical equipment.

Background of the Invention

A number of voice assisted machine control applications have been developed due to recent advancements in speech recognition software. Examples of these applications include input and storage of electronic patient records, assistance in clinical diagnosis, generation and manipulation of medical images, and manipulation of surgical devices such as microscopes.

Voice activated control of surgical instruments for vitreo-retinal surgery, for example, appears to be a good application for voice actuation technology. Intraocular surgery frequently requires simultaneous use of elaborate and sophisticated pieces of equipment by the surgeon, and coordination and integration of such equipment in an operating room with assistants and one or more nurses. A nurse is typically required to manipulate equipment controls in response to a surgeon's commands. Delays can occur when the nurse is busy setting up or adjusting other parameters when the surgeon's command is received. Delays associated with the human interface between a surgeon and a nurse can increase complexity of the surgery, particularly when conditions inside the patient's eye change rapidly and unexpectedly.

U.S. Patent No. 4,989,253 discloses a voice control system for moving and focusing a microscope. The system is disadvantageous, however, because it employs a discrete speech recognition algorithm. An operator must therefore give simple verbal commands, which are typically only one or two words, and speak them clearly and slowly. During procedures such as intraocular eye surgery, it is difficult to expect a surgeon to speak in the slow, halting manner required for accurate word identification using a discrete speech recognition algorithm.

U.S. Patent No. 5,303,148 discloses a voice activated image display controller which requires each operator to speak every command in order to create a stored user-specific pronunciation list. The controller compares received digitized audio signals with the list to determine if a spoken word is a valid command. The controller is disadvantageous because it requires operators to undergo time-consuming training in order to use it.

A need exists, therefore, for a voice command and control system for medical equipment which allows a surgeon to render voice commands using natural, conversational speech and which does not require the surgeon to participate in extensive training of the speech recognition engine. Further, a need exists for a voice command and control system which allows a surgeon to effectively handle volatile and quickly changing patient conditions (e.g., intraocular pressure), and to decrease surgery time without compromising the safety of the surgical procedure.

Summary of the Invention

In accordance with an aspect of the present invention, a voice command and control system is provided which can process audio signals from a microphone to identify an operator's verbal commands contained within conversational speech using speech recognition software. The commands are then converted to digital control signals which can be applied to a medical care device. The system is configured to continuously monitor the audio signals such that the operator does not have to speak in a slow, deliberate and unnatural manner.

In accordance with another aspect of the invention, the system is configured to automatically generate a request for confirmation of a command signal, and to await

acknowledgement from the operator before executing the command.

In accordance with yet another aspect of the invention, the system is configured to provide audible status data relating to a parameter or function of the medical care device in response to an operator's query command.

In accordance with still yet another aspect of the invention, the system is programmed to define functions and parameters of the medical care device and corresponding commands which are valid when that function or parameter is active, and to store them in files. The files facilitate the speech recognition process, as well as increase safety and efficiency with which the voice controlled medical care device is used.

In accordance with an embodiment of the present invention, a voice controlled medical care system is provided which comprises (1) a medical care device to be controlled in accordance with commands spoken by an operator, the spoken commands being selected from the group consisting of a single command word, a command phrase comprising a plurality of the command words, and a mixed phrase comprising at least one command word and at least one non-command word; (2) a microphone for transducing the spoken commands and generating corresponding audio output signals; (3) a processor comprising a first port connected to the microphone for receiving the audio output signals, the processor being programmable to substantially continuously monitor the first port for the audio output signals, to process the audio output signals to identify the command words therein, and to generate corresponding control signals for transmission to the medical care device; and (4) an interface circuit connected to the processor and the medical care device and operable to

provide the control signals from the processor to the medical care device.

Brief Description of the Drawings

These and other features and advantages of the present invention will be more readily apprehended from the following detailed description when read in connection with the appended drawings, which form a part of this original disclosure, and wherein:

Fig. 1 depicts a voice command and control medical care system constructed in accordance with an embodiment of the present invention and in use with an intraocular microsurgical system in an operating room;

Fig. 2 is a schematic block diagram of a voice command and control medical care system in accordance with an embodiment of the invention;

Figs. 3 and 4 depict an exemplary and known medical care device;

Fig. 5 is flowchart depicting the sequence of operations for processing an operator's verbal command to generate digital control signals for controlling a medical care device in accordance with an embodiment of the present invention;

Fig. 6 depicts a computer screen generated by a voice command and control medical care system in accordance with an embodiment of the present invention;

Figs. 7, 8, 9 and 10 illustrate computer screens generated by a voice command and control system in accordance with another embodiment of the present invention; and

Fig. 11 is a schematic block diagram of a hardware interface for connecting a computer with a medical care device in accordance with an embodiment of the present invention.

Detailed Description of the Preferred Embodiment

Fig. 1 depicts an operating room environment in which a voice command and control medical care system 10 is being used, in accordance with an embodiment of the present invention. The system 10 shall be described for illustrative purposes herein in connection with a Premiere® microsurgical system, which is commercially available from Storz Instrument Company, St. Louis, Missouri. The system 10 processes verbal commands to effect a desired change in a piece of equipment (e.g., a microsurgical system) via digital or analog circuit means. It is to be understood, however, that the system 10 can be used with other devices besides the Premiere® microsurgical system in accordance with the present invention. These other devices can include, but are not limited to, a laser, a microscope, surgical tools such as remote-controlled scissors, medical imaging devices, devices for assisting patients such as electromechanical prosthetic and mobilization tools, devices for controlling medical care environments including room lighting and air quality, patent monitoring devices such as sensors for patient vital signs, among others.

The Premiere® microsurgical system regulates speed, suction and other variables for intraocular surgical instruments which an ophthalmic surgeon holds in his or her hand during a surgical procedure. In accordance with the illustrated embodiment, a surgeon 14 or other operator of the voice command and control medical care system 10 can speak verbal commands into a headset 16 while performing surgery, as shown in Fig. 1. The system 10 comprises a computer 18, which is preferably a personal computer or a portable, laptop computer, and which is connected to the Premiere® microsurgical system 12 by an interface circuit 20 (Fig. 2). The system 10, therefore, eliminates the need to perform certain functions such as manipulating

instrument panel controls (indicated generally at 22) manually, thereby allowing the surgeon 14 and any other attending medical personnel 24 freedom to manipulate devices such as hand-held surgical tools and foot pedals and other operating room equipment. The system 10 can reduce burdens placed on a surgeon 14 and other medical attendants 24 during a surgical or other medical procedure, and can reduce the number of personnel required in the operating room. For example, a vitreo-retinal surgical suite is a complicated environment requiring several components of sophisticated medical equipment that are used simultaneously. A nurse is typically required to manually press buttons on the Premiere® microsurgical system 12 in response to requests from the surgeon to, for example, increase the vitrectomy cut rate. In addition to the surgeon, two nurses are required throughout an operation. The system 10 is cost effective in that it can transform this environment into an operating room requiring only one nurse and the surgeon. By eliminating the human interface between the surgeon and the nurse to adjust the Premiere® microsurgical system 12, the voice command and control system 10 provides a faster and more accurate response which, in addition to the cost effectiveness of reducing personnel, optimizes surgical outcome.

Fig. 2 is a schematic block diagram of the voice command and control medical care system 10. Operator voice commands are provided to a microphone 26 which is connected to the computer 18. The transduced audio signals received from the microphone 26 are processed in accordance with speech recognition software. The system 10 preferably uses Listen® for Windows® version 2.0 by Verbex Voice Systems, Inc., Edison, New Jersey. The Listen® for Windows® software is user-independent to accommodate many surgeons or operators, without requiring extensive voice training

prior to use. The accuracy without training is approximately 80% to 90% for all users. The accuracy can be improved to approximately 100% when operators undergo training for less than one half hour to build an individual vocal profile. The refined operator specific grammar is saved in the memory of the computer or on magnetic disc or other storage device (e.g., a nonvolatile random access memory device) and can be utilized whenever that particular operator is using the system 10.

Listen® for Windows® provides a continuous versus discrete speech recognition algorithm. The software therefore allows an operator 14 to speak to the computer 18 in a natural and continuous manner, e.g., as a surgeon would normally speak to a nurse. Discrete algorithms for speech recognition are less effective than continuous speech recognition algorithms because they require users to speak more slowly and in a hesitant manner. Further, users typically speak only one or two words at a time. Surgeons may not be able to speak in the unnatural and discrete manner required for accurate recognition by discrete voice recognition algorithms during stressful situations encountered in an operation.

With continued reference to Fig. 2, the microphone 26 is preferably a unidirectional, noise canceling microphone Model P\N 42446-02-00 available from CTI Audio, Inc., Conneaut, Ohio. This microphone is preferred because it can specifically amplify the operator's commands only and is designed to reduce noise. The microphone 26 can be worn as a headset microphone 16, or can be permanently mounted on an operating room microscope 28 as shown in Fig. 1. The computer 18 is preferably an IBM Think Pad laptop computer because it is portable, has multimedia capabilities allowing it to receive microphone input signals, and has an Intel 486 DX33 processor which provides for efficient

execution of both speech recognition and digital conversion programs. The output from the microphone is connected to the microphone jack on the multimedia laptop computer 18.

As shown in Fig. 2, the computer 18 comprises or is connected to a speaker 30 to provide the surgeon with audible feedback and confirmation requests during the surgical procedure. The computer 18 provides control signals corresponding to an operator's verbal requests to a medical care device 12 via an interface circuit 20. In accordance with one embodiment of the present invention, the interface circuit 20 can be a hardware interface, as will be described in connection with Fig. 11. Alternatively, the computer 18 can provide control signals directly to the medical care device 12 via a serial or parallel port on the computer, as indicated by the phantom line 25. In accordance with other embodiments of the invention, the medical care device 12 can provide feedback signals to the interface circuit 20 or directly to the computer 18, as indicated by phantom lines 27 and 29, respectively, or the interface circuit can provide feedback signals to the computer 18, as indicated by phantom line 31.

With reference to Fig. 3, the Premiere® microsurgical system 12 controls a number of instruments that are placed inside the eye during vitreo-retinal surgery. These instruments can include, but are not limited to, a vitrectomy cutter 32, a fragmentation handpiece 34 and a needle 36. The microsurgical system 12 comprises a main console 38 having a display 40, a number of control buttons indicated generally at 42, and connectors for connecting an electrical line 46, an air line 48, an aspiration line 50, and an irrigation line 52, among others, to different surgical instruments. The microsurgical system 12 further comprises a remote controller 54 that can be connected to

the main console 38 via a single plug connector 56. The remote controller has a display 58 that is similar to the main console display 40.

As indicated in Fig. 4, the main console display 40 comprises function select switches 60, 62, 64, 66, 68, and 70 for operating the microsurgical system 12 in a number of modes, including Vitrectomy, Fragmentation, Scissors, Bipolar, Illumination and Intraocular Pressure (IOP) Control modes, respectively. The main console also has a number of input switches (e.g., ten input switches) 72 for controlling levels of variable functions such as aspiration and cut rate. The functions of these ten switches is determined by software used to control the microsurgical system 12. The functions of the switches changes with each screen 74 presentation.

With continued reference to Fig. 3, essentially any mode or feature can be selected, or any parameter level adjusted, using either the main console 38 or the remote controller 54. When a mode (e.g., Vitrectomy mode) is selected from either the console 38 or the remote controller 54, the mode is highlighted on the console screen, as indicated in Fig. 4, and flashes on the remote controller display. The operational modes of the microsurgical system 12 associated with normal posterior eye surgery will now be described for illustrative purposes. In the Vitrectomy mode, the microsurgical system 12 allows for vitreous cutting via the cutter 32 and for linear control over aspiration. In the Fragmentation mode, the microsurgical system 12 provides for phacofragmentation with linear control of aspiration for posterior segment procedures. The Scissors mode allows a surgeon to employ a pneumatically driven intraocular scissor instrument in single-cut, variable rate and proportional control modes. In single-cut control mode, scissors close rapidly when

actuated and remain closed until deactivated. In variable rate control mode, scissors open and close automatically at a cyclical rate established by a cut-rate display on display 40. In proportional control mode, scissors open and close in proportion to the level of actuation (e.g., the position of a foot pedal, or length or magnitude of an actuating control signal).

As stated previously, the main console 38 comprises push buttons or switches 42 (Fig. 3) for selecting operational modes and various parameters, and for increasing or decreasing the value of parameters. The remote controller 54 can facilitate activation of these buttons 42 via the computer 18. In the past, a surgeon mentally decides on a value for each parameter such as bipolar power, cutting rate or maximum aspiration rate and conveys this selection verbally to a scrub nurse. The scrub nurse then interprets the verbal command and pushes the appropriate button on the main console 38 to select the desired parameter or to change the value of a given parameter. The surgeon does not manually make the parameter or value change because he or she does not want to direct attention away from the microscope and the operation, while holding surgical instruments inside a patient's eye. The voice command and control of the medical care system of the present invention is advantageous because it allows the surgeon to actuate appropriate buttons on the medical care device 12 without the nurse and by using only his voice, thereby reducing any delays in carrying out the verbal command as the command is interpreted and executed by a human being. This system 10 can therefore reduce personnel required in the operating room and the duration of the surgery.

The computer 18 preferably operates in a MicroSoft Windows® environment and has Listen® for Windows® software

stored in its digital memory. In accordance with an embodiment of the present invention, the computer 18 is also provided with a custom executable program, which is written, for example, using Visual C++ developmental software, to process command words identified by the speech recognition software and to manipulate the medical care device 12 accordingly. The custom software code is provided in Appendices A and B. The overall operation of the system will be described with reference to the flowchart in Fig. 5.

As shown in Fig. 5, the computer is programmed to essentially continuously monitor its microphone input for audio output signals from the microphone 26, which transduces utterances of the operator (block 80). Because the speech recognition software has a continuous speech recognition algorithm, the verbal commands of the operator need not be as discretely or precisely stated as with a discrete speech recognition algorithm. In other words, the surgeon can intermingle actual command words with unintended words such as hesitations (e.g., "uh").

With reference to block 82 of Fig. 5, the computer analyzes the audio output signals of the microphone 26 using the speech recognition software to identify command words therein. When the voice command and control medical care system 10 is being configured for use with a particular type of medical care device 12, the functional modes of that device 12 are identified and defined, along with parameters which can or cannot be changed within those modes and restrictions, if any, on changing to different modes. Commands are subsequently defined to allow a user to initiate a particular function of the device 12, change a parameter setting or functional mode. These commands are then stored in corresponding grammar files. Appendix A

contains several grammar files for using the system 10 with the Premiere® microsurgical device 12.

By way of example, Fig. 6 depicts a window screen on the monitor 40 of the computer 18. Against a Windows® environment background, a pop-up menu 84 is generated by the computer which lists available commands a surgeon can speak into the microphone while in the Vitrectomy mode selected and highlighted in Fig. 4. When any of these listed commands is spoken into the microphone, the computer 18 is programmed via the custom software program of the present invention to compare the audio output signal with the phrases listed in the grammar file labeled Posterior Vitrectomy Grammar in Appendix A. If the surgeon requests a change in the level of illumination (e.g., "Premiere®, set illumination high"), the computer 18 will ignore the command because it does not locate the word "illumination" in the Posterior Vitrectomy Grammar File, as indicated in blocks 90 and 91. Once a valid command is identified, the computer 18 is programmed to generate a pop-up menu corresponding to that command. This is illustrated in Figs. 7 and 8. The Premiere® microsurgical system 12 can also be used in an anterior versus posterior surgical mode to perform cataract surgery. The computer 18 is programmed to identify commands, generate screens and control medical instruments specific to the Premiere® microsurgical system when operating in the anterior surgical mode, as well as the posterior surgical mode.

Fig. 7 provides another example of a Vitrectomy mode screen. The box 86 on the left side of the screen provides status information for the selected instrument or mode (e.g., posterior vitrectomy). The computer 18 generates the status screen in accordance with data received from the medical care device 12. The computer 18 also generates the pop-up menu 88 on the right side of the screen which

corresponds to the current mode or instrument function in use by the operator. The pop-up menu 88 lists commands with can be used to operate an instrument in that particular mode, to change to another mode, to request status information regarding a system function such as aspiration rate, to set a parameter level such as "Premiere® set power high" or to issue a system command such as "stop listening". If the operator gives a verbal command such as "Premiere® go to fragmentation", the computer 18 is programmed to generate the screen depicted in Fig. 8.

The status screen 86 on the left hand side of the screen in Fig. 8 gives different status information from that of Fig. 7, that is, information pertaining to posterior fragmentation. In addition, the commands for operating an instrument, setting a parameter value, inquiring about the status of certain parameters such as power, as well as auxiliary commands, change from those of the pop-up menu for the posterior vitrectomy mode in Fig. 7. For example, the parameter values for setting power or switching the pulse on or off cannot be changed when in the Vitrectomy mode. Similarly, cut rate cannot be set in the Fragmentation mode. While in the Fragmentation mode, verbal commands given by the operator are processed by the computer 18 in accordance with the speech recognition software using the grammar file for fragmentation, which is also provided in Appendix A. Thus, the speech recognition software preferably accomplishes voice controlled navigation through the various modes and parameter value changes of the medical care device 12 during a surgical procedure using a library of context-dependent command definitions stored in various grammar files.

With continued reference to the flowchart in Fig. 5, once the computer 18 identifies a valid command in an audio

output signal from the microphone 26, the computer 18 is programmed to generate a confirmation message before executing the identified command, as shown in block 94, unless the command is a request for status information, as indicated in blocks 92 and 93. The confirmation messages are generated by the computer using prerecorded messages. Alternatively, synthesized speech messages can be generated by the computer 18 using appropriate software. The computer 18 is programmed to wait for acknowledgment from the operator before executing the command. Thus, the confirmation/acknowledgment feature of the system 10 increases the safety of the system, particularly in surgery, because the surgeon can cancel a verbal command, as described below.

The confirmation function of the present invention is illustrated in Fig. 9. The computer 18 generates a Confirm dialogue box 95. The pop-up menu 88 on the right hand side of Fig. 9 lists valid confirmation responses or commands which can be spoken by the operator and recognized by the computer 18. If the operator responds with "yes" or "OK", the computer 18 is programmed to execute the command, as shown in blocks 96 and 98. As shown in the status screens 86 in Figs. 8 and 10, the maximum power has been increased from 5% to 80%. The manner by which this is done will be described below in connection with Fig. 11. If the user responds with "no" or "cancel", the computer 18 is programmed to continue monitoring its microphone input for audio output signals from the microphone 26, as indicated by the negative branch of decision block 96. With reference to decision block 100, if the operator speaks the command "stop listening", the computer 18 ceases to identify commands, if any, in the surgeons conversation via speech recognition until it is commanded to resume listening, as indicated in blocks 101 and 102.

The manner in which commands are executed by computer 18 will now be described. As stated previously, when the system 10 is to be used with a particular medical care device 12, the modes of operation and possibilities for affecting changes to different parameters throughout the modes is defined (e.g., using grammar files). The method by which modes are selected and parameter values are changed within the medical care unit 12 is also analyzed. In the case of the remote controller 54 of the Premiere® microsurgical system, it was determined that pushing any of thirty buttons on the controller could be simulated electronically by shorting together various pairs of 16 wires contained within the controller 54. To enable the computer 18 to control the remote controller 54, a hardware interface 103 was designed and fabricated as shown in Fig. 11. The hardware interface 103 was placed in a black box connected to a parallel port of the computer 18 by a standard printer cable, and connected to the Premiere® remote controller 54 by a 16-pin ribbon cable. The buttons 42 on the Premiere® microsurgical system are essentially soft keys which are programmed to have multiple functions, depending on the mode in which the microsurgical system 12 is operating when a valid command is identified in the audio output signals from microphone 26. For example, one of the input switches 72 in Fig. 4 can be depressed one time in the Scissor mode to increase scissor cut rate by 30%. The same button can be depressed one time in the Phacofragmentation mode to increase ultrasound power by 1%. Each command for a particular function is assigned a digital code which is stored in the digital memory of the computer 18. The codes can be used to affect a change to a parameter value, instrument setting or change an operational mode (e.g., selecting a different instrument).

In accordance with the illustrated embodiment of the present invention, the computer 18 is programmed to generate an 8-bit binary number corresponding to the command to be executed by the medical care device 12. The least significant bits (LSB) D0 through D3 and the most significant bits (MSB) D4 through D7 are provided to decoders 104 and 106, respectively. The decoders are connected to the inputs of four quad bi-lateral switches 108, 110, 112 and 114 via NAND gates on four quad 2-input NAND gate components 116, 118, 120 and 122, respectively. As shown in Fig. 11, each switch 108, 110, 112 and 114 has four outputs connected to the 16-pin ribbon cable and four outputs which are connected to ground.

By way of example, if a verbal command is given to set cut rate high while in the Vitrectomy mode, the computer 18 is programmed in accordance with the invention to map the command to an appropriate digital code. The code can correspond to a signal for operating one of the sixteen switches corresponding to outputs P0 through P16, for example. When activated, the switch allows an electrical signal to be applied to one of the sixteen internal wires in the controller 54 for simulating the activation of a push button on the main console 38. For example, if the button for increasing cut rate on the main console can be activated remotely by shorting together the fourth and eighth wires of the sixteen internal wires of the remote controller 54 via their corresponding switches 110 and 112, the computer 18 can output 0100B and 1000B at its parallel port. Accordingly, all of the outputs of the decoder 104 are high, except for pin number 4, which is set low. Similarly, all of the outputs of the decoder 106 are high, except for output number 8, which is set low. Each NAND gate receives a high value from the decoder outputs, except for pin numbers 4 and 8 on decoders 104 and 106,

respectively. The NAND gates produce a low value at the input of their corresponding switches, resulting in the switches staying open. However, switches corresponding to pins P4 and P8 of decoders 110 and 112, respectively, close since their corresponding NAND gates have one high and one low input, thus the internal wires of the controller 52 connected to pins P4 and P8 receive an electrical signal to emulate the pushing of a button on the main console 38.

It is to be understood that the number of buttons on a device 12 and the number of possible functions is arbitrary. For example, the computer 18 can be programmed to output digital signals in accordance with a matrix such that activating combinations of switches can effect different functions of the medical care device 12. In addition to providing data on a parallel port, the computer 18 can generate serial output signals which can be decoded by an interface circuit or the device 12 itself to affect desired parameter and mode changes, or other functions requested verbally by the operator. The control signals generated by the computer 18 to execute the operator's commands can be output via a parallel or serial port, can be conducted along an electrical wire or other communication link such as optical fiber. In addition, wireless communication can be used between the computer 18 and the device 12 to be controlled, such as ultrasonic signals, infrared signals, radio frequency signals or other electromagnetic signals.

The degree to which the parameters are changed can also be implemented in a number of different ways in accordance with various embodiments of the present invention. In the illustrated embodiment (Fig. 11), the closing of one of the switches corresponding to lines P0 through P15 simulates activation of a push button on the main console 38. The degree of change in the parameter

variable requested by the operator is programmed and stored in the digital memory of the computer 18. Changes to parameter values are incremented such that each time a manual console button is depressed (i.e., one of the switches P0 through P15 is activated), the parameter increases or decreases from its current state by a predetermined amount. For example, if the computer 18 identifies the command "Premiere® set power high", the computer 18 is programmed to generate a control signal at the parallel port which closes appropriate switches P0 through P15 to simulate a single depression of a control button to take the medical care device 12 to the next power level, which could be an increase of 1% or 10%. Alternatively, the rate at which parameters are incremented or decremented can be done continuously, as opposed to discretely.

In addition to discrete or incremental control, the amount by which parameters can be changed can also be implemented via proportional and derivative control. For example, a parameter can increased or decreased in value in proportion to the duration of the signal being sent to the medical care device by the computer 18 or interface circuit 20. Further, feedback data can be provided to the computer 18 or other processor (e.g., a processor in the interface circuit) from the medical care device 12 for monitoring purposes. The control signal is continuously applied, or increased or decreased in magnitude, until the parameter reaches a desired threshold or another condition in the program code has been satisfied. The change in parameter value can be accomplished numerically. For example, the operator can state "Microscope, increase power thirty percent" or "Microscope, increase power three zero percent" or "three, 'oh' percent". Using the speech recognition software, the computer 18 can identify the desired level or

value of a parameter from a verbal command, and then determine the amount of change required based on the current value of the parameter. The computer 18 subsequently generates and transmits one or more control signals to the medical care device 12 in order to manipulate the instrument or control button thereon and automatically jump to the desired level. Alternatively, the computer 18 can generate control signals to continuously or discretely increase or decrease the current parameter level of the instrument or control button to achieve the desired parameter level.

The interface between the computer 18 and the medical care device 12 can be implemented a number of ways such as a separate digital circuit (e.g., the circuit depicted in Fig. 11), or as components on a peripheral board inserted into a slot in a personal computer. The interface circuit can be implemented using digital or analog components or both. Further, the interface between the computer 18 and the medical care device 12 can be implemented completely using software run by the computer 18. In accordance with the present invention, the system 10 can be used to interface with essentially any type of variable input or output device that can be switched or actuated by an electrical or electromagnetic signal.

As stated previously, the system 10 can be used to control a number of different devices such as medical imaging devices, surgical instruments, and environmental control equipment in operating rooms, patients' rooms and laboratories. The device to be controlled is analyzed to ascertain those functions and tools that are to be voice actuated. A vocabulary of commands is defined to control each function or tool while the tool or function is active. The tool or function-specific commands are stored in a file (e.g., a grammar file) that is accessed by the computer

when processing an output signal from a microphone. The file for a particular function or tool can be defined to restrict the initiation of certain functional modes, the use of certain tools or the amount a parameter can be changed while that function or tool is active. When executing a command in a file, the computer 18 facilitates the initiation of another mode by deactivating the instrument in current use and activating relevant parameters in the new mode. The computer 18 can be programmed via the content of the files and the order with which the files and their corresponding screens (e.g., the Posterior Vitrectomy Grammar file and the active screen depicted in Fig. 7) are generated to anticipate commands (i.e., to more efficiently process audio signals to identify valid commands therein), as well as to guide operator command choices, in accordance with an optimal sequence for using a medical care device 12 or performing a particular procedure such as intraocular surgery. The degree to which parameters can be changed, and the manner in which the device 12 is manipulated to affect the desired change, is defined and appropriate control signals are stored for subsequent retrieval or generation and transmission to the device 12.

The system 10 is advantageous for medical procedures such as intraocular surgery, for example, because parameters such as IOP may need to be adjusted quickly and unexpectedly during surgery. Unfortunately, the scrub nurse, who typically manipulates control buttons on medical care equipment, can be too busy setting up and adjusting other instrumentation to quickly respond to a new command, resulting in a delay in changing the parameter as needed. This can reduce the response time of the surgeon to changing conditions inside the eye and hence adversely affect the outcome of the surgery. Using the system 10 of

the present invention allows changes to be made in chosen parameters directly by the surgeon, while allowing him or her to continue holding surgical instruments inside the eye. Further, the surgeon does not have to direct attention away from the patient and the microscope view to ascertain the value of a parameter. Following a query command, the computer 18 automatically generates a status report, using pre-recorded or synthesized messages and pronunciations of numerical values, which is broadcast over the speaker 30 (Fig. 2). The above-described features increase the safety of the medical procedure being performed using the voice controlled medical care system 10 of the present invention.

While certain advantageous embodiments have been chosen to illustrate the invention, it will be understood by those skilled in the art that various changes and modifications can be made herein without departing from the scope of the invention as defined in the appended claims.

APPENDIX A

```
;;** START OF LISTEN.INI UPDATES **
;; [EXECUTE]
Premier = C:\MSVC\BIN\PREMIER\PREMIER.EXE
;;**END OF LISTEN.INI UPDATES **
;;-----------Speech Interface File--------------------
#application "Premier"  ; Application Name
#include "setup.inc"       ; Required Listen include file
#include "prompt.inc"   ; Required Listen include file
#vocabulary "Premier"     ; Vocabulary Name
;;-------------------------------------------------


;;-------------Grammar Common Section----------------------
;;COMMON.VSN - Listen 2.0 Common User Interface
;;-------------------------------------------------


  #list %END
  #description " "
   end "end"
   exit "end"
  #end_list


  #list %DIGIT
  #description "Any digit from 0 to 9"
      0
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end_list

  #list %DIGIT-OH
  #description "Any digit, including oh(0)"
      oh "0"
      0
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end_list

  #list %DIGIT1-9
```

```
#description "Any digit from 1 to 9"
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list

#list %DIGIT1-8
#description "Any digit from 1 to 8"
    1
    2
    3
    4
    5
    6
    7
    8
#end_list

#list %DIGIT1-7
#description "Any digit from 1 to 7"
    1
    2
    3
    4
    5
    6
    7
#end_list

#list %DIGIT1-6
#description "Any digit from 1 to 6"
    1
    2
    3
    4
    5
    6
#end_lst

#list %DIGIT1-5
#description "Any digit from 1 to 5"
    1
    2
    3
    4
    5
#end_list

#list %DIGIT1-4
#description "Any digit from 1 to 4"
```

```
    1
    2
    3
    4
#end list

#list %DIGIT1-3
#description "Any digit from 1 to 3"
    1
    2
    3
#end_list

#list %DIGIT1-2
#description "Only the digits 1 or 2"
    1
    2
#end_list

#list %ZERO
#description "Either 0 or oh"
    oh "0"
    0
#end_list

#list %1-2DIGITS,,,1,2
#description "A series of 1 to 2 digits, including oh(0)"
    oh "0"
    0
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list

#list %1-3DIGITS,,,1,3
#description "A series of 1 to 3 digits, including oh(0)"
    oh "0"
    0
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list

#list %1-4DIGITS,,,1,4
```

```
#description "A series of 1 to 4 digits, including oh(0)"
    oh "0"
    0
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list

#list %1-5DIGITS,,,1,5
#description "A series of 1 to 5 digits, including oh(0)"
    oh "O"
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list

#list %1-6DIGITS,,,1,6
#description "A series of 1 to 6 digits, including oh(0)"
    oh "0"
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list

#list %1-NDIGITS,,,*
#description "A series of any number of digits, including oh(0)"
    oh "0"
    0
    1
    2
    3
    4
    5
    6
    7
    8
    9
#end_list
```

```
  #list %0-NDIGITS,,,'
  #description "A series of any number of digits, including oh(0), all
optional"
      oh "0"
      0
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end_list

  #list %0-DIGIT-OH,,,0,1
  #description "Any digit, including oh(0), all optional"
      oh "0"
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end_lst

  #list %DIRECTION1-9,\NO_MOD_ALL
  #description "Any digit from 1 to 9, used with the move command"
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end_list

  #list %3DIGITS-DT1\NO_MOD_ALL,,3,3
  #description "Three digits, without oh(0), used for Digit Training."
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end_list
```

```
  #list %3DIGITS-DT2,\NO_MOD_ALL,,3,3
  #description "Three digits, without 0(zero), used for Digit Training."
      oh "0"
      1
      2
      3
      4
      5
      6
      7
      8
      9
  #end list

  #list %NEGATIVE,,,0,1
  #list_phrase modify negative word list
      negative "-"
      minus "-"
  #end_list

  #list %SWITCH TO_LIST,\NO_MOD_ALL
  #list_phrase modify switch to list
  #description "The SWITCH_TO_LIST can only be modified from within the
Listen Command Editors by selecting the 'Switch to list...'command, under
the 'Edit' menu
      "program manager"
      "task list"
  #include "switchto.inc"
  #end_list

: ------------------------------------------------
:     Vocabulary level Host response templates and translations
: ------------------------------------------------

  #host_response
      #translations
         #initiator ""
         #separator ""
         #terminator ""

  #templates
      move up 1 > "<UP>"
      move up 2 > "<UP><UP>"
      move up 3 > "<UP><UP><UP>"
      move up 4 > "<UP><UP><UP><UP>"
      move up 5 > "<UP><UP><UP><UP><UP>"
      move up 6 > "<UP><UP><UP><UP><UP><UP>"
      move up 7 > "<UP><UP><UP><UP><UP><UP><UP>"
      move up 8 > "<UP><UP><UP><UP><UP><UP><UP><UP>"
      move up 9 > "<UP><UP><UP><UP><UP><UP><UP><UP><UP>"
      move down 1 > "<DOWN>"
      move down 2 > "<DOWN><DOWN>"
      move down 3 > "<DOWN><DOWN><DOWN>"
      move down 4 > "<DOWN><DOWN><DOWN><DOWN>"
      move down 5 > "<DOWN><DoWN><DOWN><DOWN><DOWN>"
```

```
    move down 6 > "<DOWN><DOWN><DOWN><DOWN><DOWN><DOWN>"
    move down 7 > "<DOWN><DOWN><DOWN><DOWN><DOWN><DOWN><DOWN>"
    move down 8 > "<DOWN><DOWN><DOWN><DOWN><DOWN><DOWN><DOWN><DOWN>"
    move down 9 > "<DOWN><DOWN><DOWN><DOWN><DOWN><DOWN><DOWN><DOWN
    move left 1 > "<LEFT>"
    move left 2 > "<LEFT><LEFT>"
    move left 3 > "<LEFT><LEFT><LEFT>"
    move left 4 > "<LEFT><LEFT><LEFT><LEFT>"
    move left S > "<LEFT><LEFT><LEFT><LEFT><LEFT>"
    move left 6 > "<LEFT><LEFT><LEFT><LEFT><LEFT><LEFT>"
    move left 7 > "<LEFT><LEFT><LEFT><LEFT><LEFT><LEFT><LEFT>"
    move left 8 > "<LEFT><LEFT><LEFT><LEFT><LEFT><LEFT><LEFT><LEFT>"
    move left 9 > "<LEFT><LEFT><LEFT><LEFT><LEFT><LEFT><LEFT><LEFT
    move right 1 > "<RIGHT>"
    move right 2 > "<RIGHT><RIGHT>"
    move right 3 > "<RIGHT><RIGHT><RIGHT>"
    move right 4 > "<RIGHT><RIGHT><RIGHT><RIGHT>"
    move right 5 > "<RIGHT><RIGHT><RIGHT><RIGHT><RIGHT>"
    move right 6 > "'RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIGHT>"
    move right 7 > "<RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIGHT>"
    move right 8 > "<RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIG
    move right 9 > "<RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIGHT><RIG

#control_response
    sample noise >\RECALIBRATE

    #grammar "Top/Menu"
    #context
       "CONTEXT= PREMIER.EXE,*,**
    #end_context
    #phrase !SHOW_RUN_MENU_O,\INACTIVE,1
       #spoken show run menu
       #response "<ALT+R>"
    #end_phrase
       #phrase !RUN_ANTERIOR_1
          #spoken run anterior
          #response "<ALT+R>A"
       #end_phrase
       #phrase !RUN POSTERIOR_2
          #spoken run posterior
          #response "<ALT+R>P"
       #end_phrase


#phrase !SELECT_MENU_ITEM_ADD2MENU_3,\INACTIVE,1
#spoken select menu item
#response "<ENTER>"
#end_phrase

#phrase !HIDE_MENU_ADD2MENU_4,\1NACTIVE,1
    #spoken hide menu
    #response "<ESC><ESC>"
#end_phrase

#phrase !SWITCH_TO_SWITCH_TO_LIST_ADD2MENU_5,\NO_MOD_RESPONSE|\IN
    #spoken switch to %SWITCH_TO_LIST
    #response "$E" %SWITCH TO_LIST "$"
```

```
#end_phrase

#phrase !BEGIN_PHRASE_TRAINING_PLEASE_ADD2MENU_6,\NO_MOD_RESPONSE
    #spoken begin phrase training please
    #response "$W$"
#end_phrase

#phrase !BEGIN_ADVANCED_TRAINING_PLEASE_ADD2MENU_7,\NO_MOD_RESPON
    #spoken begin advanced training please
    #response "$T$"
#end_phrase

#phrase !MOVE_UP_DIRECTION1-9_ADD2MENU_8,\1NACTIVE,1
    #spoken move up %DIRECTION1-9
#end_phrase

#phrase !MOVE_DOWN_DIRECTION1-9_ADD2MENU_9,\INACTIVE,1
    #spoken move down %DIRECTION1-9
#end_phrase

#phrase !MOVE_LEFT_DIRECTION1-9_ADD2MENU_10,\1NACTIVE,1
    #spoken move left %DIRECTION1 9
#end _phrase

#phrase !MOVE_RIGHT_DIRECTION1-9_ADD2MENU_11,\INACTIVF 1
#spoken move right %DIRECTION1 9
#end_phrase

#phrase !NEXT_FIELD_ADD2MENU_12,\INACTIVE,1
    #spoken next field
    #response "<TAB>"
#end_phrase

#phrase !PREVIOUS_FIELD_ADD2MENU_13,\1NACTIVE,1
    #spoken previous field
    #response "<SHIFT+TAB>"
#end_phrase

#phrase !CLOSE_WINDOW_PLEASE_ADD2MENU_14,\INACTIVE,1
    #spoken close window please
    #response "<ALT+F4>
#end_phrase

#phrase !MAXIMIZE_WINDOW_ADD2MENU_15,INACTIVE,1
    #spoken maximize window
    #response "<ALT+SPACE>x"
#end_phrase

#phrase !MINIMIZE_WINDOW_ADD2MENU_16,\1NACTIVE,1
    #spoken minimize window
    #response "<ALT+SPACE>n"
#end_phrase

#phrase !RESTORE_W1NDOW_ADD2MENU_17,INACTIVE,1
    #spoken restore window
    #response "<ALT+SPACE>r"
#end_phrase
```

```
#phrase !SAMPLE_NOISE_ADD2MENU_18,\NO_MOD_ALL,1
    #spoken sample noise
    #response ""
#end_phrase

#phrase !SHOW_PHRASE_WINDOW_ADD2MENU_19,\NO_MOD_RESPONSE|INACTIVE,1
    #spoken show phrase window
    #response "$H$"
#end_phrase

#phrase !HIDE_PHRASE_WINDOW_ADD2MENU_20,\NO_MOD_RESPONSE|INACTIVE,1
    #spoken hide phrase window
    #response "$h$"
#end_phrase

#phrase !SHOW_RECOGNIZED_TEXT_ADD2MENU_21,\NO_MOD_RESPONSE|\INACTIVE,1
    #spoken show recognized text
    #response "$R$"
#end_phrase

#phrase !HIDE RECOGNIZED_TEXT_ADD2MENU_22,\NO_MOD_RESPONSE|\INACTIVE,1
    #spoken hide recognized text
    #response "$r$"
#end_phrase

#phrase !RECORD_VOICE_ADD2MENU_23,\NO_MOD_RESPONSE|\INACTIVE,1
    #spoken record voice macro
    #response "$S$"
#end_phrase

#phrase !STOP_RECORDING_ADD2MENU_24,\NO_MOD_RESPONSE|\INACTIVE,1
    #spoken stop recording voice macro
    #response "$s$"
#end_phrase

#phrase !PLAYBACK_ADD2MENU_25,\NO_MOD_RESPONSE|\INACTIVE,1
    #spoken playback voice macro
    #response "$M$"
#end_phrase

#phrase !STOP_LISTEN1NG_ADD2MENU_26,\NO_MOD_RESPONSE
    #spoken stop listening
    #response "$I$"
#end_phrase

#main_structure
#end_structure

#end_grammar


;; ------------------------------------------------
;;                Premier - Untitled Grammar
;; ------------------------------------------------
```

```
#grammar "Premier- Untitled"

#context
"CONTEXT=*,#32770,Premier - Untitled"
  #end_context

  #phrase !SAMPLE_NOISE_DIALOG_BOX_D0003_041,\NO_MOD_ALL,1
      #spoken sample noise
      #response
  #end_phrase
  #phrase !STOP_LISTENING_PROGRAM_MANAGER_334_467,\NO_MOD_RESPONSE,1
      #spoken stop listening
      #response "$I$"
  #end_phrase
  #phrase !RUN_POSTERIOR
      #spoken run posterior
      #response "<ALT+R> p"
  #end_phrase
  #phrase !RUN_ANTERIOR
      #spoken run anterior
      #response "<ALT+R>a"
  #end_phrase

#main_structure
#end_structure

#end_grammar



;; ------------------------------------------
;;                Confirm Grammar
;; ------------------------------------------

#grammar "Confirm"

#context
"CONTEXT=*,#32770,Confirm"
  #end_context

  #phrase !NO_169
      #spoken no
      #response "\e"
  #end_phrase
  #phrase !CANCEL_724
      #spoken cancel
      #response "\e"
  #end_phrase
  #phrase !YES_041
      #spoken yes
      #response "\r"
  #end_phrase
  #phrase !OK_041
      #spoken oh kay
```

```
      #response "\r"
   #end_phrase

#main_structure
#end_structure

#end_grammar


;; ------------------------------------
;;             Dialog Box Grammar
;; ------------------------------------

#grammar "Dialog Box"

#context
      "CONTEXT=*,#32770,*"
#end_context

      #phrase !TOGGLE_CHECKBOX_DIALOG_BOX_103
         #spoken toggle checkbox
         #response "<SPACE>"
   #end_phrase

   #phrase !CANCEL_DIALOG_BOX_104
      #spoken cancel
      #response "<ESC>"
   #end_phrase

   #phrase !YES_DIALOG_BOX_105
      #spoken yes
      #response "y"
   #end_phrase

   #phrase !NO_DIALOG_BOX_106
      #spoken no
      #response "n"
   #end_phrase

   #phrase !OH_KAY_DIALOG_BOX_107
      #spoken oh kay
      #response "<ENTER>"
   #end_phrase

   #phrase !NEXT_FIELD_DIALOG_BOX_108
      #spoken next field
      #response "<TAB>"
   #end_phrase

   #phrase !MOVE_UP_DIRECTION1-9_DIALOG_BOX_109,\NO_MOD_ALL
      #spoken move up %DIRECTION1-9
   #end_phrase

   #phrase !MOVE_DOWN_DIRECTION1-9_DIALOG_BOX_110,\NO_MOD_ALL
      #spoken move down %DIRECTION1-9
```

```
#end_phrase

#phrase !MOVE_LEFT_DIRECTION1-9_DIALOG_BOX_111,\NO_MOD_ALL
    #spoken move left %DIRECTION1-9
#end_phrase

#phrase !MOVE_RIGHT_DIRECTION1-9_DIALOG_BOX_112,\NO_MOD_ALL
    #spoken move right %DIRECTION1-9
#end_phrase

#phrase !SAMPLE_NOISE_DIALOG_BOX_113,\NO_MOD_ALL
    #spoken sample noise
    #response ""
#end_phrase

#phrase !STOP_LISTENING_DIALOG_BOX_114,\NO_MOD_RESPONSE
    #spoken stop listening
    #response ^$I$"
#end_phrase

#phrase !SHOW_PHRASE_WINDOW_DIALOG_BOX_115,\NO_MOD_RESPONSE
    #spoken show phrase window
    #response "$H$"
#end_phrase

#phrase !HIDE_PHRASE_WINDOW_DIALOG_BOX_116,\NO_MOD_RESPONSE
    #spoken hide phrase window
    #response "$h$"
#end_phrase

#phrase !SHOW_RECOGNIZED_TEXT_DIALOG_BOX_117,\NO_MOD_RESPONSE
    #spoken show recognized text
    #response "$R$"
#end_phrase

#phrase !HIDE_RECOGNIZED_TEXT_DIALOG_B0X_118,\NO_MOD_RESPONSE
    #spoken hide recognized text
    #response "$r$"
#end_phrase

#phrase !TRAIN_PHRASES_DIALOG_BOX_119,\NO_MOD_RESPONSE
    #spoken begin phrase training please
    #response "$W$"
#end_phrase

#phrase !TRAIN_ADVANCED_DIALOG_BOX_120,\NO_MOD_RESPONSE
    #spoken begin advanced training please
    #response "$T$"
#end_phrase
#phrase !RECORD_VOICE_DIALOG_BOX_121,\NO_MOD_RESPONSE
    #spoken record voice macro
    #response "$S$"
#end_phrase

#phrase !STOP_RECORDING_DIALOG_BOX_122,\NO_MOD_RESPONSE
    #spoken stop recording voice macro
```

```
      #response "$s$"
  #end_phrase

  #phrase !PLAYBACK_DIALOG_BOX_123,\NO_MOD_RESPONSE
      #spoken playback voice macro
      #response "$M$"
  #end_phrase


#main_structure
#end_structure

#end_grammar



;; ------------------------------------------
;;          Anterior Vitrectomy Grammar
;; ------------------------------------------

#grammar "Anterior Vitrectomy"

#context
"CONTEXT=",#32770,Anterior Vitrectomy"
#end_context
  #phrase !PREMIER_GO_TO_I_A_467_169_358_500
      #spoken premier go to IA
      #response "premier goto IA/r"
  #end_phrase
  #phrase "PREMIER_END_VITRECTOMY_334_724_962_467
      #spoken premier %END vitrectomy
      #response "premier "%END" vitrectomy\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478_464_334
      #spoken premier go to phaco
      #response "premier goto phaco\r"
  #end_phrase
  #phrase !PREMIER_SET_CUTRATE_LOW_467_D0000
      #spoken premier set cut rate low
      #response "premier set cutrate low\r"
  #end_phrase
  #phrase !PREMIER_SET_CUTRATE_HIGH_467_DOOO0
      #spoken premier set cut rate high
      #response "premier set cutrate high\r"
  #end_phrase
  #phrase !PREMIER_SET_ASPIRATION_LOW_334_D0000
      #spoken premier set aspiration low
      #response "premier set aspiration low\r"
  #end _phrase
  #phrase !PREMIER_SET_ASPIRATION_HIGH_334_D0000
      #spoken premier set aspiration high
      #response "premier set aspiration high\r"
  #end_phrase
  #phrase !PREMIER_REPORT_ASPIRATION_467
      #spoken premier report aspiration
      #response "premier report aspiration\r"
```

```
   #end_phrase
   #phrase !PREMIER_REPORT_CUTRATE_467
       #spoken premier report cut rate
       #response "premier report cut rate\r"
   #end_phrase


   #phrase !SAMPLE_NOISE_DIALOG_BOX_D0000,\NO_MOD_ALL
       #spoken sample noise
       #response ""
   #end_phrase

   #phrase !STOP_LISTENING_DIALOG_BOX_D0000,\NO_MOD_RESPONSE,1
       #spoken stop listening
       #response "$I$"
   #end_phrase



#main_structure
#end_structure

#end_grammar


;; ----------------------------------------
;;            Posterior Vitrectomy Grammar
;; ----------------------------------------

#grammar "Posterior Vitrectomy"

#context
"CONTEXT=*,#32770,Posterior Vitrectomy"
   #end_context


   #phrase !STOP_LISTENING_PROGRAM_MANAGER_500,\NO_MOD_RESPONSE,1
       #spoken stop listening
       #response "$I$"
   #end_phrase
   #phrase !PREMIER_REPORT_GAS_041
       #spoken premier report gas
       #response "premier report gas\r"
       #end_phrase
   phrase !PREMIER_SET_BIPOLAR_HIGH 478
       #spoken premier set bipolar high
       #response "premier set bipolar high\r"
   #end_phrase
   #phrase !PREMIER_SET_BIPOLAR_LOW_358
       #spoken premier set bipolar low
       #response "premier set bipolar low\r"
   #end_phrase
   #phrase !PREMIER_REPORT_BIPOLAR_705
       #spoken premier report bipolar
       #response "premier report bipolar\r"
   #end_phrase
```

```
#phrase !PREMIER_GAS_ON_962
    #spoken premier gas on
    #response "premier gas on\r"
#end_phrase
#phrase !PREMIER_GAS_OFF_464
    #spoken premier gas off
    #response "premier gas off\r"
#end_phrase
#phrase !PREMIER_REPORT_ASPIRATION_467_041
    #spoken premier report aspiration
    #response "premier report aspiration\r"
#end_phrase
#phrase !PREMIER_REPORT_CUTRATE_467_467
    #spoken premier report cut rate
    #response "premier report cut rate\r"
#end_phrase
#phrase !PREMIER_SET_CUTRATE_HIGH_467_D0000_334
    #spoken premier set cut rate high
    #response "premier set cutrate high\r"
#end_phrase
#phrase !PREMIER_END_VITRECTOMY_334_724_962_467_169
    #spoken premier %END vitrectomy
    #response "premier "%END" vitrectomy\r"
#end_phrase
#phrase !PREMIER_GO_TO_PHACO_D0000_724
    #spoken premier go to scissors
    #response "premier goto scissors\r"
#end_phrase
#phrase !PREMIER_GO_TO_PHACO_D0000_478
    #spoken premier go to fragmentation
    #response "premier goto fragmentation\r"
#end_phrase
#phrase !PREMIER_SET_CUTRATE_LOW_467_D0001
    #spoken premier set cut rate low
    #response "premier set cutrate low\r"
#end_phrase
#phrase !PREMIER_SET_ASPIRATION_LOW_334_D0001
    #spoken premier set aspiration low
    #response "premier set aspiration low\r"
#end_phrase
#phrase !PREMIER_SET_ASPIRATION_HIGH_334_D0001
    #spoken premier set aspiration high
    #response "premier set aspiration high\r"
#end_phrase


#phrase !SAMPLE_NOISE_DIALOG_BOX_D0001\NO_MOD_ALL
    #spoken sample noise
    #response
#end_phrase


#main_structure
#end_structure
```

```
#end_grammar


;; ----------------------------------------
;;              Post Main Grammar
;; ----------------------------------------

#grammar "Post Main"

#context
"CONTEXT=*,#32770,Posterior Main Menu"
  #end_context

  #phrase !STOP_LISTENING_PROGRAM_MANAGER_334,\NO_MOD_RESPONSE,1
      #spoken stop listening
      #response "$I$"
  #end_phrase
  #phrase !PREMIER_GO_TO_PHACO_041_500
      #spoken premier go to fragmentation
      #response "premier goto fragmentation\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_1_A_467_169
      #spoken premier go to scissors
      #response "premier goto scissors\r"
  #end_phrase
  #phrase !PREMIER_END_VITRECTOMY_334_724
      #spoken premier %END posterior
      #response "premier "%END" program\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478
      #spoken premier go to vitrectomy
      #response "premier goto vitrectomy\r"
  #end_phrase


  #phrase !SAMPLE_NOISE_DIALOG_BOX_D0003,\NO_MOD_ALL
      #spoken sample noise
      #response ""
  #end_phrase



#main_structure
#end_structure

#end_grammar



;; ----------------------------------------
;;                 Ant Main Grammar
;; ----------------------------------------
```

```
#grammar "Ant Main"


#context
"CONTEXT=*,#32770,Anterior Main Menu"
  #end_context



  #phrase !PREMIER_GO_TO_PHACO_041_500_D0000
      #spoken premier go to phaco
      #response "premier goto phaco\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_I_A 467_169_D0000
      #spoken premier go to IA
      #response "premier goto IA"
  #end_phrase
  #phrase !PREMIER_END_VITRECTOMY_334_724_D0000
      #spoken premier %END anterior
      #response "premier "%END" program\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478_D0000
      #spoken premier go to vitrectomy
      #response "premier goto vitrectomy\r'
  #end_phrase



  #phrase !SAMPLE_NOISE_DIALOG_BOX_D0004,\NO_MOD_ALL
      #spoken sample noise
      #response ""
  #end_phrase

  #phrase !STOP LISTENING_DIALOG_BOX_D0004,\NO_MOD_RESPONSE,1
      #spoken stop listening
      #response "$I$"
  #end_phrase




#main_structure
#end_structure

#end_grammar


;; ----------------------------------------
;;                Phaco Grammar
;; ----------------------------------------

#grammar "Phaco"

#context
```

```
"CONTEXT=*,#32770,Phaco"
  #end_context


  #phrase !PREMIER_SET_PULSE_RATE_OFF_041
      #spoken premier set pulse rate off
      #response "premier set pulserate off\r"
  #end_phrase
  #phrase !PREMIER_SET_PULSE_RATE_LOW_041
      #spoken premier set pulse rate low
      #response "premier set pulserate low\r"
  #end_phrase
  #phrase !PREMIER_REPORT_MIN_PHACO_041
      #spoken premier report min phaco
      #response "premier report min phaco\r"
  #end_phrase
  #phrase !PREMIER_REPORT_MAX_PHACO_467
      #spoken premier report max phaco
      #response "premier report max phaco\r"
  #end_phrase
  #phrase !PREMIER REPORT PULSERAIE 334
      #spoken premier report pulse rate
      #response "premier report pulse rate\r"
  #end_phrase
  #phrase !PREMIER_REPORT_ASPIRATION_500
      #spoken premier report aspiration
      #response "premier report aspiration\r"
  #end_phrase
  #phrase !PREMIER_SET_PULSE_RATE_HIGH_491
      #spoken premier set pulse rate high
      #response "premier set pulserate high\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_1_A_467_169_358
      #spoken premier go to IA
      #response "premier goto IA"
  #end_phrase
  #phrase !PREMIER_END_VITRECTOMY_334_724_962
      #spoken premier %END phaco
      #response "premier "%END" phaco\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478_464
      #spoken premier go to vitrectomy
      #response "premier goto vitrectomy\r"
  #end_phrase
  #phrase !PREMIER_SET_MAX_PHACO_LOW_705
      #spoken premier set max phaco low
      #response "premier set maxphaco low\r"
  #end_phrase
  #phrase !PREMIER_SET_MAX_PHACO_HIGH_145
      #spoken premier set max phaco high
      #response "premier set maxphaco high\r"
  #end _phrase
  #phrase !PREMIER_SET_MIN_PHACO_HIGH_281
      #spoken premier set min phaco high
      #response "premier set minphaco high\r"
  #end_phrase
```

```
  #phrase !PREMIER_SET_ASPIRATION_LOW_827
      #spoken premier set aspiration low
      #response "premier set aspiration low\r"
  #end_phrase
  #phrase !PREMIER_SET_CUTRATE_LOW_467_D0003
      #spoken premier set min phaco low
      #response "premier set minphaco low\r"
  #end_phrase
  #phrase !PREMIER_SET_ASPIRATION_HIGH_334_D0003
      #spoken premier set aspiration high
      #response "premier set aspiration high\r"
  #end_phrase


  #phrase !SAMPLE_NOISE_DIALOG_BOX_D0005,\NO_MOO_ALL
      #spoken sample noise
      #response ""
  #end_phrase

  #phrase !STOP_LISTENING_DIALOG_BOX_D0005,\NO_MOD_RESPONSE,1
      #spoken stop listening
      #response "$I$"
  #end_phrase




#main_structure
#end_structure

#end_grammar




;; ----------------------------------------
;;                 Irr/Asp Grammar
;; ----------------------------------------

#grammar "IA"

#context
"CONTEXT=*,#32770,Irrigation-Aspiration"
  #end_context


  #phrase !PREMIER_GO_TO_PHACO
      #spoken premier go to phaco
      #response "premier goto phaco\r"
  #end_phrase
  #phrase !PREMIER_END_VITRECTOMY_334_724_436
      #spoken premier %END IA
      #response "premier "%END" IA\r"
```

```
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478_391
      #spoken premier go to vitrectomy
      #response "premier goto vitrectomy\r"
  #end_phrase


  #phrase !SAMPLE_NOISE_DIALOG_BOX_D0006,\NO_MOD_ALL
      #spoken sample noise
      #response ""
  #end _phrase

  #phrase !STOP_LISTENING_DIALOG_BOX_D0006,\NO_MOD_RESPONSE,1 _
      #spoken stop listening
      #response "$I$"
  #end_phrase




#main_structure
#end_structure

#end_grammar



;; ----------------------------------------
;;             Scissors Grammar
;; ----------------------------------------

#grammar "Scissors"

#context
"CONTEXT=*,#32770,Scissors"
  #end_context

  #phrase !STOP_LISTENING_PROGRAM_MANAGER_467,\NO_MOD_RESPONSE,1
      #spoken stop listening
      #response "$I$"
  #end_phrase
  #phrase !PREMIER_SET_CUTRATE_HIGH_467_D0000_334_041
      #spoken premier set cut rate high
      #response "premier set cutrate high\r"
  #end_phrase
  #phrase !PREMIER_SET_CUTRATE_LOW_467_D0001_467
      #spoken premier set cut rate low
      #response "premier set cutrate low\r"
  #end_phrase
  #phrase !PREMIER_REPORT_CUT_RATE_724
      #spoken premier report cut rate
      #response "premier report cut rate\r"
  #end_phrase
```

```
  #phrase !PREMIER_SET_BIPOLAR_HIGH_478_D0000
      #spoken premier set bipolar high
      #response "premier set bipolar high\r"
  #end_phrase
  #phrase !PREMIER_SET_BIPOLAR_LOW_358_D0000
      #spoken premier set bipolar low
      #response "premier set bipolar low\r"
  #end_phrase
  #phrase !PREMIER_REPORT_BIPOLAR_705_D0000
      #spoken premier report bipolar
      #response "premier report bipolar\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_FRAG
      #spoken premier go to fragmentation
      #response "premier goto fragmentation\r"
  #end_phrase
  #phrase !PREMIER_END_VITRECTOMY_334_724_436_D0000
      #spoken premier %END scissors
      #response "premier "%END" scissors\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478_391_D0000
      #spoken premier go to vitrectomy
      #response "premier goto vitrectomy\r"
  #end_phrase


  #phrase !SAMPLE_NOISE_DIALOG_B0X_D0007,\NO_MOD_ALL
      #spoken sample noise
      #response ""
  #end_phrase




#main structure
#end structure

#end grammar


;; ----------------------------------------
;;          Fragmentation Grammar
;; ----------------------------------------

#grammar "Frag"

#context
"CONTEXT=*,#32770,Fragmentation"
  #end_context


  #phrase !STOP_LISTENING_PROGRAM_MANAGER_041,\NO_MOD_RESPONSE,1
      #spoken stop listening
```

```
    #response "$I$"
#end_phrase
#phrase !PREMIER_SET_BIPOLAR_HIGH_041,\INACTIVE,1
    #spoken premier set bipolar high
    #response "premier set bipolar high\r"
#end_phrase
#phrase !PREMIER_SET_POWER_LOW_145
    #spoken premier set power low
    #response "premier set power low\r"
#end_phrase
#phrase !PREMIER_SET_POWER_HIGH_281
    #spoken premier set power high
    #response "premier set power high\r"
#end_phrase
#phrase !PREMIER_SET_PULSE_RATE_HIGH_961
    #spoken premier pulse on
    #response "premier set pulse rate high\r"
#end_phrase
#phrase !PREMIER_SET_PULSE_RATE_LOW_961
    #spoken premier pulse off
    #response "premier set pulse rate low\r"
#end_phrase
#phrase !PREMIER_SET_ASPIRATION_LOW_334_D0001_491
    #spoken premier set aspiration low
    #response "premier set aspiration low\r"
#end_phrase
#phrase !PREMIER_SET_ASPIRATION_HIGH_334_D0001_995
    #spoken premier set aspiration high
    #response "premier set aspiration high\r"
#end_phrase
#phrase !PREMIER_REPORT_ASPIRATION_467_041_942
    #spoken premier report aspiration
    #response "premier report aspiration\r"
#end_phrase
#phrase !PREMIER_REPORT_PULSE_RATE_827
    #spoken premier report pulse rate
    #response "premier report pulse rate\r"
#end_phrase
#phrase !PREMIER_REPORT_POWER_436
    #spoken premier report power
    #response "premier report power\r"
#end_phrase
#phrase !PREMIER_SET_BIPOLAR_LOW_358_D0001,\INACTIVE,1
    #spoken premier set bipolar low
    #response "premier set bipolar low\r"
#end_phrase
#phrase !PREMIER_REPORT_BIPOLAR_705_D0001,\INACTIVE,1
    #spoken premier report bipolar
    #response "premier report bipolar\r"
#end_phrase
#phrase !PREMIER_GO_TO_PHACO_D0001
    #spoken premier go to scissors
    #response "premier goto scissors\r"
#end_phrase
#phrase !PREMIER_END_VITRECTOMY_334_724_436_D0001
    #spoken premier %END fragmentation
```

```
    #response "premier "%END" fragmentation\r"
  #end_phrase
  #phrase !PREMIER_GO_TO_VITRECTOMY_478_391_D0001
    #spoken premier go to vitrectomy
    #response "premier goto vitrectomy\r"
  #end_phrase


  #phrase !SAMPLE_NOISE_DIALOG_BOX_D0008,\NO_MOD_ALL
    #spoken sample noise
    #response ""
  #end_phrase


#main structure
#end_structure

#end grammar


#include "global.inc"                    ; Required Listen include file


#end vocabulary
#end_application
```

APPENDIX B

```
// premier.cpp : Defines the class behaviors for the application.
//

#include "stdafx.h"
#include "premier.h"
#include "mydialog h"
#include "mainfrm.h"
#include "premidoc.h"
#include "premivw.h"
#include <skeleton.hpp>


#ifdef _DEBUG
#undef THIS_FILE
static char BASED_CODE THIS_FILE[] = __ FILE __;
#endif


extern "C"
{
      #include "c:\msvc\bin\pushbttn.c"
}


/////////////////////////////////////////////////////////////////////////////
///
// CPremierApp

BEGIN_MESSAGE_MAP(CPremierApp, CWinApp)
      //{{AFX_MSG_MAP(CPremierApp)
      ON_COMMAND (ID_APP_ABOUT, OnAppAbout)
      ON_COMMAND (ID_RUN_ANT, OnRunAnt)
      ON_COMMAND (ID_RUN_POST, OnRunPost)
      ON_COMMAND (ID_UTIL_BUTTON_PRESS, OnUtilButtonPress)
      //}}AFX_MSG_MAP
      // Standard file based document commands
      ON_COMMAND (ID_FILE_NEW, CWinApp::OnFileNew)
      ON_COMMAND (ID_FILE_OPEN, CWinApp::OnFileOpen)

END_MESSAGE_MAP()

/////////////////////////////////////////////////////////////////////////////
///
// CPremierApp construction

CPremierApp::CPremierApp()
{

    // TODO: add construction code here,
    // Place all significant initialization in InitInstance
}

/////////////////////////////////////////////////////////////////////////////
///
// The one and only CPremierApp object
```

```
CPremierApp NEAR theApp;

/////////////////////////////////////////////////////////////////////////////
///
// CPremierApp initialization

BOOL CPremierApp::InitInstance()
{
    // Standard initialization
    // If you are not using these features and wish to reduce the size
    //  of your final executable, you should remove from the following
    //  the specific initialization routines you do not need.

    SetDialogBkColor();              // set dialog background color to gray
      LoadStdProfileSettings();      // Load standard INI file options
(including MRU)

      // Register the application's document templates.  Document
templates
      //  serve as the connection between documents, frame windows and
views.

AddDocTemplate(new CSingleDocTemplate(IDR_MENU1,
         RUNTIME_CLASS(CPremierDoc),
         RUNTIME_CLASS(CMainFrame),       // main SDI frame window
         RUNTIME_CLASS(CPremierView)));


      // create a new (empty) document
      OnFileNew();

if (m_lpCmdLine[0] != '\o')
{
// TODO: add command line processing here
}

return TRUE;
}

/////////////////////////////////////////////////////////////////////////////
//
// CAboutDlg dialog used for App About

class CAboutDlg : public CDialog
(
public:
      CAboutDlg();

// Dialog Data
      //{{AFX_DATA(CAboutDlg)
      enum { IDD = IDD_ABOUTBOX };
      //}}AFX_DATA

// Implementation
protected:
```

```
        virtual void DoDataExchange(CDataExchange* pDX); // DDX/DDV support
        //{{AFX_MSG(CAboutDlg)
            // No message handlers
        //}}AFX_MSG
        DECLARE_MESSAGE MAP()
};

CAboutDlg::CAboutDlg() : CDialog(CAboutDlg::IDD)
{
        //{{AFX_DATA_INIT(CAboutDlg)
        //}}AFX_DATA_INIT
}

void CAboutDlg::DoDataExchange(CDataExchange* pDX)
}
        CDialog::DoDataExchange(pDX);
        //{{AFX_DATA MAP(CAboutDlg)
        //}}AFX_DATA_MAP
)

BEGIN_MESSAGE_MAP(CAboutDlg, CDialog)
        //{{AFX_MSG_MAP(CAboutDlg)
            // No message handlers
        //}}AFX_MSG_MAP
END_MESSAGE MAP()

// App command to run the dialog
void CPremierApp::OnAppAbout()
{
        CAboutDlg aboutDlg;
        aboutDlg.DoModal();
}


/////////////////////////////////////////////////////////////////////////////
///
// CPremierApp commands


//Procedure to play a sound
void FAR PASCAL CppSndPlaySound (LPSTR sndName, UINT sndType) {

        BOOL (FAR PASCAL *lpPlaySound) (LPCSTR sndIs, UINT flags);

        lpPlaySound =
(lpSndCall)GetProcAddress(GetModuleHandle("MMSYSTEM"),"SNDPLAYSOUBD");

        if (lpPlaySound) (*lpPlaySound) (sndName,sndType);
}

void push_button(int button, DWORD ptime) {
        DWORD start_time;
            press(button);
            start_time=GetCurrentTime();
            while ((GetCurrentTime()-start_time)< ptime) {}
            release();
```

```
void pause(DWORD ptime) {
      DWORD start_time;
         start_time=GetCurrentTime();
         while ((GetCurrentTime()-start_time)< ptime) {}
}


void initialize_anterior() {
      push_button(3,1000);        // Goto Phaco Mode
      pause(250);
      push_button(3,1000);
      pause(250);
      push_button(19,2050);      // Set Max Phaco to 50
      pause(250);
      push button(4,1000);      // Goto Vitr Mode
      pause(250);
      push_button(23,4300);    // Set Max Asp to 150
      pause(250);
      push button(4,1000);     // Leave Vitr Mode
}


//  Procedure to bring up dialog box on command "Run:Begin"
void CPremierApp::OnRunAnt()
{
  CMyDialog2 MsgBox;
  CIntroDialog IntroBox;
  CVitrDialog VitBox;
  CAntMainDialog NoModeBox;
  CIrrAspDialog IrrAspBox;
  CPhacoDialog PhacoBox;
  CMydialog4 ButtonBox;
  CString Reply,Caption;
  DWORD start_time,difftime;
  CStringArray WordList;
  int nleft,nright,i,num,diff;
  int cutrate, aspiration;


Caption = "Confirm";
CppSndPlaySound("c:\\msvc\\bin\\premier\\befant.wav",0x0001);
MessageBox(NULL,"Ready to begin ?",Caption,MB_OK);
CppSndPlaySound("c:\\msvc\\bin\\premier\\befinit.Wav",0x0001);
initialize_anterior();
while (NoModeBox entry!="premier end program") {
      if (NoModeBox.entry=="premier goto vitrectomy") {
         VitBox.entry="";
         push_button(4,1000);
         CppSndPlaySound("c:\\msvc\\bin\\premier\\invimode.wav",0x0001);
      }
      else {
         if (NoModeBox.entry=="premier goto phaco") {
            PhacoBox.entry="";
            push_button(3,1000);
            pause(250);
         push button(3,1000);
```

```
            CppSndPlaySound("c:\\msvc\\ban\\premier"\inphmode.wav",0x0001,);
            }
            else {
               if (NoModeBox.entry=="premier goto IA") {
                     IrrAspBox.entry="";
                     push_button(2,1000);

         CppSndPlaySound(ec:\\msvc\\bin\\premier\\iniamode.wav",0x0001);
               }
               else {
                  NoModeBox.entry="";
                  CppSndPlaySound("-
c:\\msvc\\bin\\premier\\selmode.wav",0x0001);
                  NoModeBox.DoModal();
            }
         }
}
while (VitBox.entry!="premier end vitrectomy") {
            VitBox.entry="";
            VitBox.DoModal();
            if (VitBox.entry!="premier end vitrectomy") {
               if (Vitbox.entry=="premier set cutrate high") {
                  CppSndPlaySound ("c
\\msvc\\bin\\premier\\set_cuth.wav",0x0001);
                  if (MessageBox(NULL,VitBox.entry,Caption,MB
OKCANCEL)==IDOK) {
                     if (VitBox.cutrate==300) {

         CppSndPlaySound("C:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                        push_button(21,2200);
                     VitBox.cutrate=600;
               }
               CppSndPlaySound("c:\\msvc\\bin\\premier\\rcuth.wav",0x0001);
            }
         }
         if (VitBox.entry=="premier set cutrate low) {
            CppSndPlaySound('c:\\msvc\\bin\\premier\\set_cutl.wav",0x0001);
            if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
               if (VitBox.cutrate==600) {

         CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                  push_button(22,2200);
                  VitBox.cutrate=300;
               }
               CppSndPlaySound("c:\\msvc\\bin\\premier\\rcutl.wav",0x0001);
            }
         }
         if (VitBox.entry=="premier set aspiration high") {
            CppSndPlaySound("c:\\msvc\\bin\\premier\\set_asph.wav",0x0001);
            if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                  if (VitBox.aspiration==150) {

         CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",Ox0001);
                  push_button{23,5200);
                  VitBox.aspiration=300;
               }
```

```
            CppSndPlaySound("c:\\msvc\\bin\\premier\\rvasph.wav",0x0001);
         }
      }
      if (VitBox.entry=="premier set aspiration low") {
         CppSndPlaySound("c:\\msvc\\bin\\premier\\set_aspl.wav",0x0001);
         if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (VitBox.aspiration==300) {

      CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                push_button(24,5200);
            VitBox.aspiration=150;
            }
            CppSndPlaySound("c:\\msvc\\bin\\premier\\rvaspl.wav",0x0001);
         }
      }
      if (VitBox,entry=="premier report aspiration") {
            if (VitBox.aspiration==300)

      CppSndPlaySound("c:\\msvc\\bin\\premier\\rvasph.wav",0x0001);
            else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rvaspl.wav",0x0001);
      }
      if (VitBox.entry=="premier report cut rate") {
            if (VitBox.cutrate==600)

      CppSndPlaySound("c:\\msvc\\bin\\premier\\rcuth.wav",0x0001);
            else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rcutl.wav",0x0001);
      }
      if ((VitBox.entry=="premier goto phaco")||(VitBox.entry=="premier
goto IA"))  {
         NoModeBox.entry=VitBox.entry;
         VitBox.entry="premier end vitrectomy";
      }
      }
      else {
         push_button(4,1000);
         NoMode.Box.entry="";
      )


      if (VitBox.entry=="pb")
         if (ButtonBox,DoModal()) {
            difftime=ButtonBox.time_msec;
            press(ButtonBox button);
            start_time=GetCurrentTime();
            while (GetCurrentTime()-start time_difftime) {}
            release();
         }
}
while (PhacoBox.entry!="premier end phaco") {
      PhacoBox entry="";
      PhacoBox DoModal();
      if (PhacoBox.entry!="premier end phaco") {
         if (PhacoBox.entry=="premier set maxphaco high") {
```

```
CppSndPlaySound("c:\\msvc\\bin\\premier\\smaxphhwi.wav",0x0001);
            if (MessageBox
(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
               if (PhacoBox.maxphaco==50) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                  push button (19,2200):
                  PhacoBox.maxphaco=100;
               }
               else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rmxphhi.wav",0x0001);
            }
      }
      if (PhacoBox.entry=="premier set maxphaco low ") {

      CppSndPlaySound("c:\\msvc\\bin\\premier\\smaxphlo.wav",0xO001);
         if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
               if (PhacoBox maxphaco==100) {
               CppSndPlaySound("c:
\\msvc\\bin\\premier\\plswait.wav",0x0001);
      push_button(20,2200);
               PhacoBox maxphaco=50;
            }
            CppSndPlaySound
("c:\\msvc\\bin\\premier\\rmxphlo.wav",0x0001);
            }
      }
      if (PhacoBox.entry=="premier set minphaco high") {
         CppSndPlaySound("c:\\msvc\\bin\\premier\\sminphhi.wav",0x0001);
         if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (PhacoBox.minphaco==5) {

      CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0X0001);
               push_button (17, 1450);
               PhacoBox.minphaco=30;
               }
            CppSndPlaySound("c:\\msvc\\bin\\premier\\rmnphhi.wav",0x0001);
         }
      }
      if (PhacoBox.entry=="premier set minphaco low") {
         CppSndPlaySound ("c:\\msvc\\bin\\premier\\sminphlo.wav",0x0001);
         if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (PhacoBox.minphaco==30) {

      CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                  push_button(18,1450);
                  PhacoBox.minphaco=5;
            }
            CppSndPlaySound("c:\\msvc\\bin\\premier\\rmnphlo.wav",0x0001);
         }
      }
      if (PhacoBox.entry=="premier set aspiration low") {
         CppSndPlaySound("c:\\msvc\\bin\\premier\\set_aspl.wav",0x0001);
         if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (PhacoBox.fixedasp==60) {
```

```
CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
            push_button (24,1650);
            PhacoBox.fixedasp=30;
      }
      CppSndPlaySound("c:\\msvc\\bin\\premier\\rasplo.wav",OxO001);
   }
}
if (PhacoBox.entry=="premier set aspiration high") {

CppSndPlaySound("c:\\msvc\\bin\\premier\\set_asph.wav",0x0001);
   if (MessageBox(NULL,PhacoBox,entry,Caption,MB_OKCANCEL)==IDOK) {
      if (PhacoBox.fixedasp==30) }

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
            push_button(23,1650);
            PhacoBox.fixedasp=60;
      }
      CppSndPlaySound("c:\\msvc\\bin\\premier\\rasphi.wav",0x0001);
   }
}
if (PhacoBox.entry=="premier set pulserate low") {
   CppSndPlaySound("c:\\msvc\\bin\\premier\\spulselo.wav",OxO001);
   if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
      if (PhacoBox.pulserate==0) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
            push_button(21,1300);
            PhacoBox.pulserate=4;
      }
      else {
            if (PhacoBox.pulserate==8) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
            push_button(22,1300);
            PhacoBox.pulserate=4;
         }
      }
      CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
   }
}
if (PhacoBox.entry=="premier set pulserate high") {
   CppSndPlaySound("c:\\msvc\\bin\\premier\\spulsehi.wav",0x0001);
   if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
      if (PhacoBox.pulserate==0) {

CppSndPlaySound("c\\msvc\\bin\\premier\\plswait.wav",0x0001);
            push_button(21,1900);
            PhacoBox.pulserate=8;
      }
      else {
            if (PhacoBox.pulserate==4) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                        push_button(21,1300);
                        PhacoBox.pulserate=8;
```

```
                }
            }
            CppSndPlaySound("c:\\msvc\\bin\\premier\\rpulshi.wav",0x0001);
        }
    }
    if (PhacoBox.entry=="premier set pulserate off") {
        CppSndPlaySound("c:\\msvc\\bin\\premier\\spulseze.wav",0x0001);
        if (MessageBox(NULL,PhacoBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (PhacoBox.pulserate==8) {

    CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                        push_button(22,1900);
                        PhacoBox.pulserate=0;
                }
                else {
                    if (PhacoBox.pulserate==4) {

    CppSndPlaySound("c:\\msvc\\bin\\premier\\plswaitwav",0x0001);
                                push_button(22,1300);
                                PhacoBox.pulserate=0;
                        }
                }

    CppSndPlaySound("c:\\msvc\\bin\\premier\\rpulsze.wav",0x0001);
            }
        }
        if (PhacoBox.entry.="premier report pulse rate") {
            if (PhacoBox.pulserate==8)

    CppSndPlaySound("c:\\msvc\\bin\\premier\\rpulslo.wav",0x0001);
            else {
                if (PhacoBox pulserate==4)

    CppSndPlaySound("c:\\msvc\\bin\\premier\\rpulslo.wav",0x0001);
                else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rpulsze.wav",0x0001);

            }
        }
        if (PhacoBox.entry=="premier report aspiration") {
                if (PhacoBox.fixedasp==60)

    CppSndPlaySound("c:\\msvc\\bin\\premier\\rasphi.wav",0x0001);
                else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rasplo.wav",0x0001);
        }
        if (PhacoBox.entry=="premier report max phaco") {
                if (PhacoBox.maxphaco==100)

    CppSndPlaySound("c:\\msvc\\bin\\premier\\rmxphhi.wav",0x0001);
                else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rmxphlo.wav",0x0001);
        }
        if (PhacoBox.entry=="premier report min phaco") {
                if (PhacoBox.minphaco==30)
        CppSndPlaySound("c.\\msvc\\bin\\premier\\rmnphhi.wav",0x0001);
                else CppSndPlaySound("c:\\msvc\\bin\\premier\\rmnphlo.wav",0x0001);
```

```
            }
            if ((PhacoBox.entry=="premier goto vitrectomy")||(PhacoBox.
               NoModeBox.entry=PhacoBox.entry;
               PhacoBox.entry="premier end phaco";
            }
         }
         else {
            push_button(3,1000);
            NoModeBox.entry="";
         }
   }
   while (IrrAspBox entry!="premier end IA") {
         IrrAspBox.entry="";
         IrrAspBox DoModal();
         if (IrrAspBox.entry=="premier end IA") {
            push_button(2,1000);
            pause(250);
            push_button(2,1000);
            NoModeBox.entry="";
         }
         if ((IrrAspBox.entry=="premier goto
   phaco")||(IrrAspBox.entry=="premier goto vitrectomy")){

                     NoModeBox.entry=IrrAspBox.entry;
                     IrrAspBox.entry,"premier end IA";
                  }
               }
            }
            push_button(14,1000);
         }

         void initialize_posterior() {
            /*push_button(1,1000);                    //Goto Vitr Mode
            pause(250);
            push_button(23,4300);                    // Set Max Asp to 150
            pause(250);
            push_button(6,1000);                     // Turn on IOP
            pause(250);
            push_button(15,3700);                    // Set IOP to 40
            pause(250);
            push_button(6,1000);                     // Turn off IOP
            pause(250);    */
            push_button(2,1000);                     // Goto Frag Mode
            pause(250);
            /*push_button(19,1200);                  // Set Frag Power to 8
            pause(250);    */
            push_button(24,2200);                    // Set Max Asp to 150
            pause(250);
            push_button(3,1000);                  // Goto Scissors : Variable Rate
            pause(250);
            push button(3,1000);
            pause(2S0);
            push button(21,1900);                    // Set cut rate to 120
            pause(250);
            push button(3,1000);                     // Leave Scissors
            pause(250);
            push button(3,1000);
```

```
   pause(250);
   /*
   push button(4,1000);                    // Turn on Bipolar ~
   pause(250);
   push button(19,2850);                   // Set Bipolar to 16
   pause(250);    */
}

void CPremierApp::OnRunPost()
{
   CFragmentDialog FragBox;
   CPostVitrDialog VitBox;
   CScissorDialog SBox;
   CPostMainDialog NoModeBox;
   CMydialog4 ButtonBox;
   CString Caption;
   DWORD start_time,difftime;
   int bip;

   Caption = "Confirm";
   CppSndPlaySound("c:\\msvc\\bin\\premier\\befpost.wav",0x0001);
   MessageBox(NULL,"Ready to begin ?",Caption,MB_OK);
   CppSndPlaySound("c:\\msvc\\bin\\premier\\befinit.wav",0x0001);
   initialize_posterior();
   bip = 16;
   while (NoModeBox.entry!=premier end program") {
      if (NoModeBox.entry=="premier goto vitrectomy") {
         VitBox.entry="";
         push_button(1,1000);                    // Vitr button
         pause(250);
         push_button(4,1000);              // Turn on Bipolar


CppSndPlaySound("c:\\msvc\\bin\\premier\\invimode.wav",0x0001);
}
else{
      if (NoModeBox.entry=="premier goto fragmentation") {
         FragBox.entry="";
         push_button(2,1000);

CppSndPlaySound("c:\\msvc\\bin\\premier\\infrmode.wav",0x0001);
      }
      else {
         if (NoModeBox.entry=="premier goto scissors") {
            SBox.entry="";
            push button(1,1000);
            pause(250);
            push_button(3,1000);
            pause(250);
            push_button(4,1000);          // Turn on Bipolar


CppSndPlaySound("c:\\msvc\\bin\\premier\\inscmode.wave"0x0001);
      }
      else{
            NoModeBox.entry="";
```

```
            CppSndPlaySound("c:\\msvc\\bin\\premier\\selmode.wav",0x0001);
                        NoModeBox.DoModal();
                }
            }
        }
    while (VitBox.entry!="premier end vitrectomy") {
        VitBox.entry="";
        VitBox.bipolar=bip;
        VitBox.DoModal();
        if (VitBox entry!="premier end vitrectomy") {
            if (VitBox.entry=="premier set cutrate high") {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\set_cuth.wav",OxO001);
              if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                if (VitBox.cutrate==300) {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wavw,0x0001);
                    push_button(21,2200);
                    VitBox.cutrate=600;

                }

        CppSndPlaySound("c:\\msvc\\bin\\premier\\rcuth.wav",OxO001);
            }
        }
        if (VitBox.entry=="premier set cutrate low") {
            CppSndPlaySound("c:\\msvc\\bin\\premier\\set_cutl.wav",OxO001);
            if (MessageBox(NULL,VitBox.entry,Caption,MB OKCANCEL)==IDOK) {
                if (VitBox.cutrate==600) {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                    push_button(22,2200);
                    VitBox.cutrate=300;
                }
                CppSndPlaySound("c\\msvc\\bin\\premier\\rcutl.wav,0x0001);
            }
        }
        if (VitBox.entry=="premier set aspiration high") {
            CppSndPlaySound("c:\\msvc\\bin\\premier\\set_asph.wav",0x0001);
            if (MessageBox(NULL,VitBox.entry,Caption,MB OKCANCEL)==IDOK) {
                if (VitBox aspiration==150) {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",OxO001);
                    push_button(23,5200);
                    VitBox.aspiration=300;
                }

        CppSndPlaySound("c:\\msvc\\bin\\premier\\rvasph.wav",OxO001);
            }
        }
        if (VitBox.entry=="premier set aspiration low") {
            CppSndPlaySound("c:\\msvc\\bin\\premier\\set_aspl.wav",0x0001);
            if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                if (VitBox.aspiration==300) {

        CppSndPlaySound("c\\msvc\\bin\\premier\\plswait.wav",0x0001);
```

```
                push_button(24,5200);
                VitBox.aspiration=150;
            }

CppSndPlaySound("c:\\msvc\\bin\\premier\\rvaspl.wav",0x0001);
    }
}
if (VitBox.entry=="premier set bipolar low") {
    CppSndPlaySound("c:\\msvc\\bin\\premier\\setbiplo.wav",OxO001);
    if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (bip==22) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                push_button(20,1150);
                bip=16;
            }

CppSndPlaySound("c\\msvc\\bin\\premier\\repbiplo.wav",0x0001);
    }
}
if (VitBox.entry=="premier set bipolar high") {
    CppSndPlaySound("c:\\msvc\\bin\\"premier\\setbiphi.wav",0x0001);
    if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (bip==16) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x000I);
                push_button(19,1150);
                bip=22;
            }
CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiphi.wav",0x0001);
    }
}
if (VitBox.entry=="premier gas on") {
    CppSndPlaySound("c:\\msvc\\bin\\premier\\setgason.wav",OxO001);
    if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) (
            if (VitBox.iopstatus=="OFF"} {
                push_button(6,1000);
                VitBox.iopstatus="ON";
            }

CppSndPlaySound("c:\\msvc\\bin\\premier\\repgason.wav",0x0001);
    }
}
if (VitBox.entry=="premier gas off") {

CppSndPlaySound("c:\\msvc\\bin\\premier\\setgasof.wav",OxO001);
    if (MessageBox(NULL,VitBox.entry,Caption,MB_OKCANCEL)==IDOK) {
            if (VitBox.iopstatus=="ON") {
                push_button(6,1000);
                VitBox.iopstatus="OFF";
            }

CppSndPlaySound("c:\\msvc\\bin\\premier\\repgasof.wav",OxO001);
    }
}
if (VitBox.entry=="premier report aspiration") {
```

```
            if (VitBox.aspiration==300)

      CppSndPlaySound("c:\\msvc\\bin\\premier\\rvasph.wav",OxO001);
            else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rvaspl.wav",0x0001);
      }
      if (VitBox.entry=="premier report gas") {
            if (VitBox.iopstatus=="ON")

      CppSndPlaySound("c:\\msvc\\bin\\premier\\repgason.wav",0x0001);
            else
CppSndPlaySound("c:\\msvc\\bin\\premier\\repgasof.wav",0x0001);
      }
      if (VitBox.entry=="premier report bipolar") {
            if (bip==22)

      CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiphi.wav",0x0001);
            else
CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiplo.wav",0x0001);
      }
      if (VitBox.entry==-premier report cut rate")  {
            if (VitBox.cutrate==600)

      CppSndPlaySound("c:\\msvc\\bin\\premier\\rcuth.wav",0x0001);
            else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rcutl.wav",OxO001);
      }
      if ((VitBox.entry=="premier goto
fragmentation")||(VitBox.entry=="premier goto scissors"))  {
         NoModeBox.entry=VitBox.entry;
         VitBox.entry="premier end vitrectomy";
         if (VitBox.iopstatus=="ON") {
            VitBox.iopstatus="OFF";
            push_button(6,1000);
         )
         pause(250);
         push_button(4,1000);              // Turn off Bipolar
      }
      if (VitBox.entry=="pb")
         if (ButtonBox.DoModal()) {
            difftime=ButtonBox.time_msec;
            press(ButtonBox.button);
            start_time=GetCurrentTime();
            while (GetCurrentTime()-start_time<difftime)  {}
            release();
         }
      }
      else {
         if (VitBox.iopstatus=="ON") {
            VitBox.iopstatus="OFF";
            push_button(6,1000);
         }
         push_button(1,1000);
         pause(250);
         push_button(4,1000);                          // Turn off Bipolar
         NoModeBox.entry="";
```

```
        )
    }
    while (FragBox.entry!="premier end fragmentation")  {
            FragBox.entry="";
            FragBox.bipolar=bip;
            FragBox.DoModal();
            if (FlagBox.entry=="premier set bipolar low:)  {

           CppSndPlaySound("c:\\msvc\\bin\\premier\\setbipol.wav",0x0001);
              if (MessageBox (NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                 if (bip==22) (

           CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",OxO001);
                    push_button (18,1450);
                    bip=16;
                 }

           CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiplo.wav",0x0001);
              }
           }
           if (FragBox.entry=="premier set bipolar high") (

           CppSndPlaySound("c:\\msvc\\bin\\premier\\setbiphi.wav",0x0001);
              if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                 if (bip==16) {

           CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                    push_button(17,1450);
                    bip=22;
                 }

           CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiphi.wav",0x0001);
              )
           }
           if (FragBox.entry=="premier set power high") {
              CppSndPlaySound("c:\\msvc\\bin\\premier\\setpowhi.wav",OxO001);
              if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK) (
                       if (FragBox.fragpower==5) {

           CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",Ox0001);
                    push_button(19,1150);
                    FragBox.fragpower=20;
                 }

           CppSndPlaySound("c:\\msvc\\bin\\premier\\reppowhi.wav",OxO001);
              }
           }
           if (FragBox.entry=="premier see power low") {

           CppSndPlaySound("c:\\msvc\\bin\\premier\\setpowlo.wav",OxO001);
              if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                 if (FragBox.fragpower==20) {

           CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",OxO001);
                    push_button(20,1150);
                    FragBox.fragpower= 5;
```

```
      }

CppSndPlaySound("c:\\msvc\\bin\\premier\\reppowlo.wav",OxO001);
   }
)
if (FragBox.entry=="premier set aspiration high")  {
   CppSndPlaySound("c:\\msvc\\bin\\premier\\set_asph.wav",0x0001);
   if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK) {
      if (FragBox.aspiration==150) {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",OxO001);
         push_button(23,5200);
         FragBox.aspiration=300;
      }
      CppSndPlaySound("c:\\msvc\\bin\\premier\\rfasphi.wav",OxO001);
   }
}
if (FragBox.entry=="premier set aspiration low") {
   CppSndPlaySound("c:\\msvc\\bin\\premier\\set_aspl.wav",0x0001);
   if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK) {
      if (FragBox.aspiration==300)   {

CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
         push_button (24,5200);
         FragBox.aspiration=150;
      }
      CppSndPlaySound("c:\\msvc\\bin\\premier\\rtasplo.wav",OxO001);
   }
}
if (FragBox.entry=="premier set pulse rate high") {
   CppSndPlaySound("c:\\msvc\\bin\\premier\\spulseon.wav",0X0001);
   if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK)  {
      if (FragBox.pulserate==0)   {

CppSndPlaySound("c\\msvc\\bin\\premier\\plswait.wav",0x0001);
         push_button(21,1500);
         FragBox.pulserate=5;
      }

CppSndPlaySound("c:\\msvc\\bin\\premier\\repplson.wav",0x0001);
   )
)
if {FragBox.entry=="premier set pulse rate low")   {
   CppSndPlaySound("c:\\msvc\\bin\\premier\\spulseof.wav",0x0001);
   if (MessageBox(NULL,FragBox.entry,Caption,MB_OKCANCEL)==IDOK)   {
      if (FragBox.pulserate==5)   {

CppSndPlaySound("c\\msvc\\bin\\premier\\plswait.wav",0x0001);
         push_button(22,1500);
            FragBox.pulserate=O;
         }

CppSndPlaySound("c:\\msvc\\bin\\premier\\repplsof.wav",0x0001);
      }
   )
   if (FragBox.entry=="premier report aspiration")   {
```

```
                if (FragBox.aspiration==300)

        CppSndPlaySound("c:\\msvc\\bin\\premier\\rfasphi.wav",0x0001);
                else
    CppSndPlaySound("c:\\msvc\\bin\\premier\\rfasplo.wav",0x0001);
            }
            if (FragBox.entry=="premier report pulse rate")   {
                if (FragBox.pulserate==5)

        CppSndPlaySound("c:\\msvc\\bin\\premier\\repplson.wav",0x0001);
                else
    CppSndPlaySound("c:\\msvc\\bin\\premier\\repplsof.wav",0x0001);
            }
            if (FragBox.entry=="premier report power") {
                if (FragBox.fragpower==20)

        CppSndPlaySound("c:\\msvc\\bin\\premier\\reppowhi.wav",0x0001);
                else
    CppSndPlaySound("c:\\msvc\\bin\\premier\\reppowlo.wav",0x0001);
            )
            if (FragBox.entry=="premier report bipolar") (
                if (bip==22)

        CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiphi.wav",0x0001);
                else
    CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiplo.wav",0x0001);
            }
            if (FragBox.entry=="premier end fragmentation") (
               push_button(2,1000);
               NoModeBox.entry="";
            }
            if ((FragBox.entry=="premier goto
    vitrectomy")||(FragBox.entry=="premier goto scissors")) {
               NoModeBox.entry=FragBox.entry;
               FragBox.entry="premier end fragmentation";
            }
    }
    while (SBox.entry!="premier end scissors")  {
          SBox.entry="";
          SBox.bipolar=bip;
          SBox.DoModal();
          if (SBox.entry=="premier set cutrate low") {
                CppSndPlaySound(c:\\msvc\\bin\\premier\\set_cut1.wav",0x0001);
                if (MessageBox(NULL,SBox.entry,Caption,MB_OKCANCEL)==IDOK) {
                   if (SBox.cutrate==200) {

          CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                      push_button(22,1900);
                      SBox.cutrate=120;
                   }

          CppSndPlaySound("c:\\msvc\\bin\\premier\\rscut1.wav",0x0001);
                }
          }
          if (SBox.entry=="premier set cutrate high") {
```

```
        CppSndPlaySound("c:\\msvc\\bin\\premier\\set_cuth.wav",0x0001);
              if (MessageBox(NULL,SBox.entry,Caption,MB_OKCANCEL)==IDOK)   {
                 if (SBox.cutrate==120)  {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                    push_button(21,1900);
                    SBox.cutrate=200;
              }

        CppSndPlaySound("c:\\msvc\\bin\\premier\\rscuth.wav",0x0001);
              }
        }
        if (SBox.entry=="premier set bipolar low") {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\setbiplo.wav",0x0001);
              if (MessageBox(NULL,SBox.entry,Caption,MB_OKCANCEL)==IDOK)  (
                 if (bip==22) {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                    push_button(20,1150);
                    bip=16;
                 }

        CppSndPlaySound("c:\\msvc\\bin\\premier\\rephiplo.wav",0x0001);
           }
        }
        if (SBox.entry=="premier set bipolar high") {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\setbiphi.wav",0x0001);
              if (MessageBox(NULL,SBox.entry,Caption,MB_OKCANCEL)==IDOK)  (
                 if (bip==16) {

        CppSndPlaySound("c:\\msvc\\bin\\premier\\plswait.wav",0x0001);
                    push_button(19,1150);
                    bip=22;
                 }

        CppSndPlaySound("c\\msvc\\bin\\premier\\repbiphi.wav",0x0001);
        }

)
        if (SBox.entry=="premier report bipolar")  (
                 if (bip==22)

        CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiphi.wav",0x0001);
                    else
CppSndPlaySound("c:\\msvc\\bin\\premier\\repbiplo.wav",0x0001);
        }
        if (SBox.entry=="premier report cut rate")  {
                 if (SBox.cutrate==200)

        CppSndPlaySound("c:\\msvc\\bin\\premier\\rscuth.wav",0x0001);
                 else
CppSndPlaySound("c:\\msvc\\bin\\premier\\rscutl.wav",0x0001);
        }
```

```
        if (SBox.entry=="premier end scissors") {
           push_button(3,1000);
           pause(250);
           push_button(3,1000);
           pause(250);
           push_button(4,1000);                    // Turn off Bipolar
           NoModeBox.entry="";
        }
        if ((SBox.entry=="premier goto vitrectomy")||(SBox.entry=="premier
goto fragmentation")) (
           NoModeBox.entry=SBox.entry;
           SBox.entry="premier end scissors";
           push_button(4,1000);                    // Turn off Bipolar
        )
     }
    }

    push_button(14,1000);
)

void CPremierApp::OnUtilButtonPress()
{
        CButtonDialog ButtonBox;
        DWORD start_time, difftime;

        while (ButtonBox.DoModal()==IDOK)
              {
                 difftime=ButtonBox.ptime;
                 press(ButtonBox.button);
                 start_time=GetCurrentTime();
                 while (GetCurrentTime()-start_time<difftime) {}
                 release();
              }
}
```

What Is Claimed Is

1. A voice controlled medical care system comprising:

a medical care device to be controlled in accordance with commands spoken by an operator, said spoken commands being selected from the group consisting of one of a number of different command words, a command phrase comprising a plurality of said command words, and a mixed phrase comprising at least one of said command words and at least one non-command word;

a microphone for transducing said spoken commands and generating corresponding audio output signals; and

a processor comprising a first port connected to said microphone for receiving said audio output signals, said processor being programmable to substantially continuously monitor said first port for said audio output signals, to process said audio output signals to identify said command words therein, and to generate corresponding control signals for transmission to said medical care device.

2. A voice controlled medical care system as claimed in claim 1, wherein said processor comprises at least one port selected from the group consisting of a serial port and a parallel port, and said medical care device is connected to said processor via said port to receive said control signals.

3. A voice controlled medical care system as claimed in claim 1, wherein said processor is operable to generate said control signals in a signal type selected from the group consisting of an electrical signal, an infrared signal, an ultrasonic signal, a radio frequency signal, and an electromagnetic signal.

4. A voice controlled medical care system as claimed in claim 1, wherein said medical care device comprises at least one controllable device selected from the group consisting of a variable input device and a variable output device, and further comprising an interface circuit connected to said processor and said medical care device for operating said controllable device in accordance with said control signals.

5. A voice controlled medical care system as claimed in claim 4, wherein at least one of said processor and said interface circuit is operable to generate said control signals in a signal type selected from the group consisting of an electrical signal, an infrared signal, an ultrasonic signal, a radio frequency signal, and an electromagnetic signal.

6. A voice controlled medical care system as claimed in claim 1, wherein said spoken commands each comprise identification of said medical care device followed by a function of said medical care device that is being requested by said operator.

7. A voice controlled medical care system as claimed in claim 1, wherein said medical care device is an active surgical instrument, said processor being programmable to generate said control signals to control said surgical instrument during a surgical procedure.

8. A voice controlled medical care system as claimed in claim 1, wherein said medical care device is selected from the group consisting of a laser, an environmental control system, a surgical tool, an imaging device, a microscope,

patient prosthetic device, a patient mobilization device, and a patient monitoring device.

9. A voice controlled medical care system comprising:

a medical care device to be controlled in accordance with commands spoken by an operator, said spoken commands comprising at least one of a number of different command words, said medical care device having a plurality of controllable devices selected from the group consisting of a variable input device and a variable output device and being configured to operate in a plurality of functional modes by controlling selected ones of said controllable devices;

a microphone for transducing said spoken commands and generating corresponding audio output signals; and

a processor connected to said microphone for receiving said audio output signals, said processor being programmable to process said audio output signals to identify said command words therein, and to generate corresponding control signals for transmission to said medical care device, said control signals comprising data to configure said medical care device to perform an operation selected from the group consisting of changing from one to another one of said plurality of modes, and changing the setting of at least one of said plurality of controllable devices, as requested by said operator in said spoken commands.

10. A voice controlled medical care system as claimed in claim 9, wherein said processor is programmed to change settings of selected ones of said plurality of controllable devices and to restrict said operator from changing settings on other ones of said plurality of controllable

devices, depending on which of a particular one of said plurality of modes has been selected.

11. A voice controlled medical care system as claimed in claim 10, further comprising at least one output device selected from the group consisting of a display device and a speaker, said processor being programmable to operate said at least one output device to indicate when said operator is restricted from changing settings on different ones of said plurality of controllable devices.

12. A voice controlled medical care system as claimed in claim 9, wherein said processor is programmable to increase and decrease the settings of said plurality of controllable devices in increments.

13. A voice controlled medical care system as claimed in claim 12, wherein a characteristic of said control signals selected from the group consisting of duration, magnitude and number of said control signals corresponds to the amount the settings of said plurality of controllable devices are incremented and decremented.

14. A voice controlled medical care system as claimed in claim 12, wherein at least one of said plurality of controllable devices is nonlinear, said processor having stored data relating a characteristic of said control signals selected from the group consisting of duration, magnitude and number of said control signals to different settings of said nonlinear controllable device.

15. A voice controlled medical care system as claimed in claim 9, wherein said processor is programmable to

continuously increase and decrease the settings of said plurality of controllable devices.

16. A voice controlled medical care system as claimed in claim 15, wherein a characteristic of said control signals selected from the group consisting of duration, magnitude and number of said control signals corresponds to the amount the settings of said plurality of controllable devices are incremented and decremented.

17. A voice controlled medical care system as claimed in claim 15, wherein at least one of said plurality of controllable devices is nonlinear, said processor having stored data relating a characteristic of said control signals selected from the group consisting of duration, magnitude, and number of said control signals to different settings of said nonlinear controllable device.

18. A voice controlled medical care system as claimed in claim 9, wherein said processor is programmable to change the settings of said plurality of controllable devices from a current value to a value specified in said command words.

19. A voice controlled medical care system comprising:

a medical care device to be controlled in accordance with commands spoken by an operator, said spoken commands comprising at least one of a number of different command words, said medical care device having a plurality of controllable devices selected from the group consisting of a variable input device and a variable output device;

a microphone for transducing said spoken commands and generating corresponding audio output signals;

a processor connected to said microphone for receiving said audio output signals, said processor being

programmable to process said audio output signals to identify said command words therein, and to generate corresponding control signals for transmission to said medical care device, said control signals comprising data to change the settings of said plurality of controllable devices as requested by said operator in said spoken commands; and

a speaker connected to said processor;

wherein said spoken commands comprise a status query relating to a selected one of said plurality of controllable devices, said processor being programmable to identify said status query and to provide status data relating to said selected controllable device to said operator via said speaker.

20. A voice controlled medical care system as claimed in claim 19, wherein said processor generates messages comprising said status data using a method selected from the group consisting of playing pre-recorded messages, and synthesizing voice messages using synthesized speech program code.

21. A voice controlled medical care system comprising:

a medical care device to be controlled in accordance with commands spoken by an operator, said spoken commands comprising at least one of a number of different command words, said medical care device having a plurality of controllable devices selected from the group consisting of a variable input device and a variable output device;

a microphone for transducing said spoken commands and generating corresponding audio output signals;

a processor connected to said microphone for receiving said audio output signals, said processor being programmable to process said audio output signals to

identify said command words therein, and to generate corresponding control signals for transmission to said medical care device, said control signals comprising data to change the settings of said plurality of controllable devices as requested by said operator in said spoken commands; and

a speaker connected to said processor;

wherein said processor is programmable to provide a confirmation request to change the settings of said plurality of controllable devices as requested by said operator in said spoken commands to said operator via said speaker, and to suspend transmission of said corresponding control signals to said medical care device until said operator provides an acknowledgement command signal via said microphone and said processor identifies said acknowledgement command signal.

22. A voice controlled medical care system as claimed in claim 21, wherein said processor generates said confirmation request using a method selected from the group consisting of playing pre-recorded messages, and synthesizing voice messages using synthesized speech program code.

23. A voice controlled medical care system comprising:

at least one surgical tool to be controlled in accordance with commands spoken by an operator, said spoken commands comprising at least one of a number of different command words, said surgical tool having a plurality of controllable devices selected from the group consisting of a variable input device and a variable output device;

a microphone for transducing said spoken commands and generating corresponding audio output signals; and

a processor connected to said microphone for receiving said audio output signals, said processor being programmable in accordance with program code to process said audio output signals to identify said command words therein, and to generate corresponding control signals for transmission to said surgical tool, said control signals comprising data to change the setting of at least one of said plurality of controllable devices as requested by said operator in said spoken commands, said program code comprising a plurality of files corresponding, respectively, to a plurality of modes for operating said surgical tool, said plurality of files each comprising lists of selected ones of said command words which are valid for said surgical tool when operating in a corresponding one of said plurality of modes, said processor being programmable to use one of said plurality of files corresponding to the present one of said plurality of modes in which said surgical instrument is operating to identify said command words in said audio output signals.

24. A voice controlled medical care system as claimed in claim 23, wherein said processor is programmable to access said plurality of files in accordance with a logical sequence set forth in said program code, said logical sequence corresponding to a particular surgical procedure using said surgical tool.

25. A voice controlled medical care system as claimed in claim 23, wherein said plurality of files each comprise data allowing said operator to change settings of selected ones of said plurality of controllable devices and to restrict said operator from changing settings of other ones of said plurality of controllable devices, depending on

which of a particular one of said plurality of modes has been selected.

26. A voice controlled medical care system as claimed in claim 23, wherein said plurality of files each comprise data allowing said operator to go to selected ones of said plurality of modes, while restricting said operator from changing to certain other ones of said plurality of modes, depending on the particular one of said plurality of modes in which said surgical tool is operating.

27. A voice controlled medical care system as claimed in claim 23, further comprising a plurality of surgical tools, wherein said program code comprises at least one file for each of said plurality of surgical tools, said file comprising a list of selected ones of said command words which are valid for said surgical tool when said surgical tool is in use.

28. A voice controlled medical care system as claimed in claim 27, wherein said processor is programmable to use said file corresponding to an active one of said plurality of surgical tools to identify said command words in said audio output signals.

29. A method of controlling a medical care system, comprising the steps of:

receiving audio signals corresponding to commands spoken by an operator, said spoken commands being selected from the group consisting of one of a number of different command words, a command phrase comprising a plurality of said command words, and a mixed phrase comprising at least one of said command words and at least one non-command word;

identifying said command words in said audio signals; and

controlling a medical care device in accordance with said command words.

30. A method of controlling a medical care system as claimed in claim 29, wherein said controlling step comprises the step of generating a control signal for transmission to said medical care device, said control signal selected from the group consisting of an electrical signal, an infrared signal, an ultrasonic signal, a radio frequency signal, and an electromagnetic signal.

31. A method of controlling a medical care system as claimed in claim 29, wherein said medical care device comprises a plurality of controllable devices selected from the group consisting of a variable input device and a variable output device and is configured to operate in a plurality of functional modes by controlling selected ones of said plurality of controllable devices, and said controlling step comprises the step of generating data to configure said medical care device to perform an operation selected from the group consisting of changing from one to another one of said plurality of modes, and changing the setting of at least one of said plurality of controllable devices, as requested by said operator in said spoken commands.

32. A method of controlling a medical care system as claimed in claim 31, wherein said controlling step further comprises the step of restricting said operator from changing the setting of selected ones of said plurality of controllable devices, depending on the particular one of

said plurality of modes in which said medical care device is operating.

33. A method of controlling a medical care system as claimed in claim 31, wherein said controlling step comprises the steps of increasing and decreasing the setting of a selected one of said plurality of controllable devices in increments in accordance with said spoken commands.

34. A method of controlling a medical care system as claimed in claim 31, wherein said controlling step comprises the steps of increasing and decreasing the setting of a selected one of said plurality of controllable devices continuously in accordance with said spoken commands.

35. A method of controlling a medical care system as claimed in claim 31, wherein at least one of said plurality of controllable devices is nonlinear, said controlling step comprising the steps of:

defining a relationship between different settings of said nonlinear controllable device and a characteristic of said control signals selected from the group consisting of duration, magnitude, and number of said control signals;

storing data relating to said relationship; and

accessing said data to operate said nonlinear controllable device in accordance with said spoken commands.

36. A method of controlling a medical care system as claimed in claim 31, wherein said controlling step further comprises the step of restricting said operator from changing to certain other ones of said plurality of modes,

depending on the particular one of said plurality of modes in which said medical care device is operating.

37. A method of controlling a medical care system as claimed in claim 29, wherein said spoken commands comprise a status query command, said controlling step comprising the step of generating a message reporting a condition of said medical care device in accordance with said status query command.

38. A method of controlling a medical care system as claimed in claim 37, wherein said generating step comprises the step of retrieving prerecorded messages from a memory device using a processor.

39. A method of controlling a medical care system as claimed in claim 37, wherein said generating step comprises the step of creating synthesized messages using a speech synthesizer.

40. A method of controlling a medical care system as claimed in claim 29, wherein said identifying step further comprises the step of generating a confirmation message.

41. A method of controlling a medical care system as claimed in claim 40, wherein said identifying step further comprises the steps of:

suspending said controlling step;

receiving additional ones of said audio signals;

determining if said spoken commands corresponding to said additional ones of said audio signals comprise an acknowledgment command;

commencing said controlling step if said acknowledgement is identified in said spoken words and is affirmative; and

canceling said controlling step if said acknowledgement is identified in said spoken words and is negative.

42. A method of controlling a medical care system as claimed in claim 41, wherein said identifying step further comprises the step of canceling said controlling step if said acknowledgement is not received.

43. A method of controlling a medical care system as claimed in claim 29, wherein said medical care device is a surgical tool, and said identifying step comprises the step of accessing a file corresponding to said surgical tool, said file comprising a list of valid commands for operating said surgical tool.

44. A method of controlling a medical care system as claimed in claim 29, wherein said medical care device is a surgical tool, and said identifying step comprises the step of accessing a plurality of files corresponding to said surgical tool, said files corresponding, respectively, to different modes of operating said surgical tool, each of said files comprising a list of valid commands for operating said surgical tool in said corresponding mode, said list of valid commands restricting access to selected ones of said plurality of files while an active one of said plurality of files is accessed in accordance with a logical sequence for performing a surgical procedure using said surgical tool.

45. A method of controlling a medical care system as claimed in claim 29, wherein said medical device comprises a plurality of surgical tools, and said identifying step comprises the step of accessing a file selected from a plurality of files corresponding, respectively, to a plurality of surgical tools, said selected file comprising a list of selected ones of said command words which are valid for a selected one of said plurality of surgical tools when said selected surgical tool is in use.

46. A voice controlled medical care system as claimed in claim 45, wherein said identifying step further comprises the step of using said file corresponding to said selected surgical tool to identify said command words in said audio output signals.

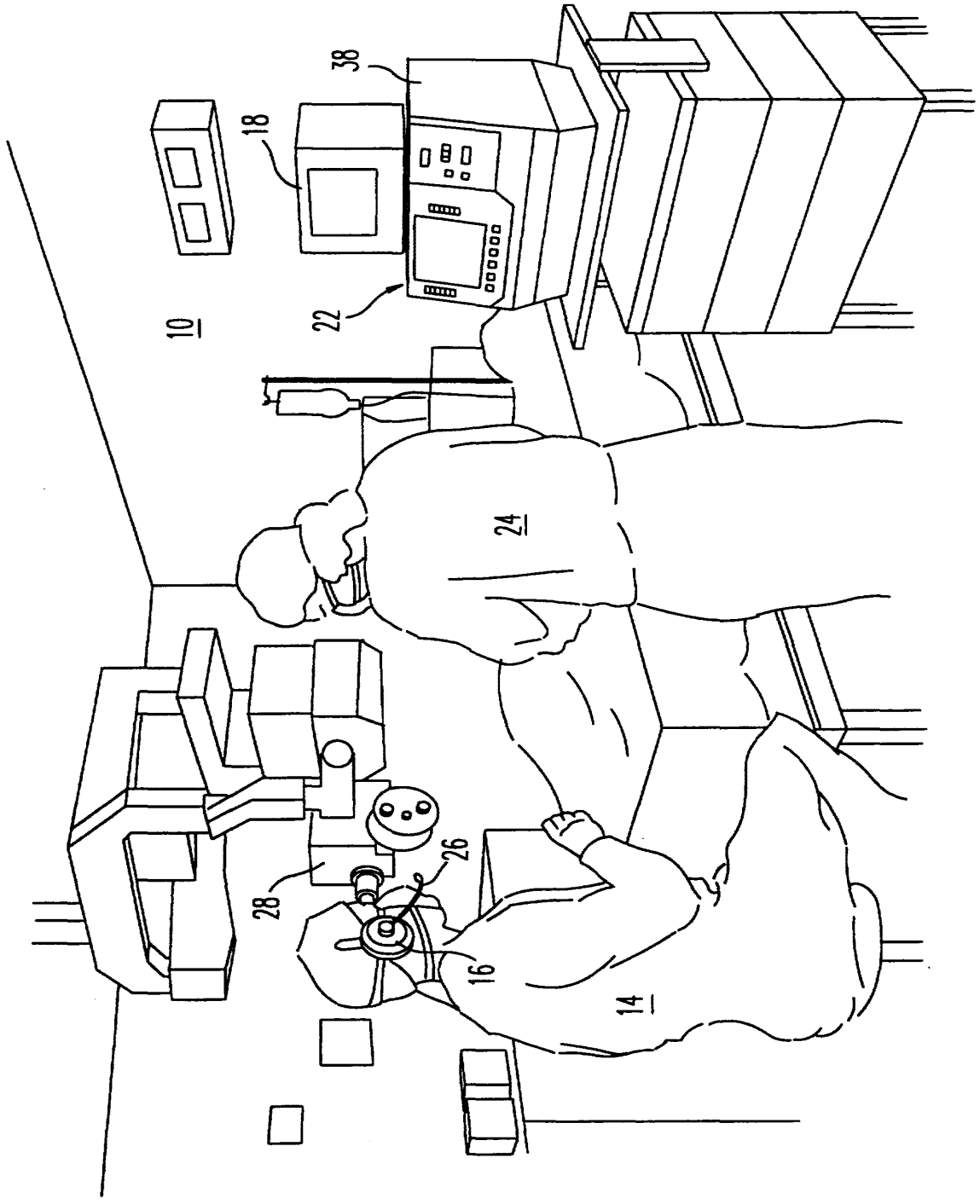


FIG. 1

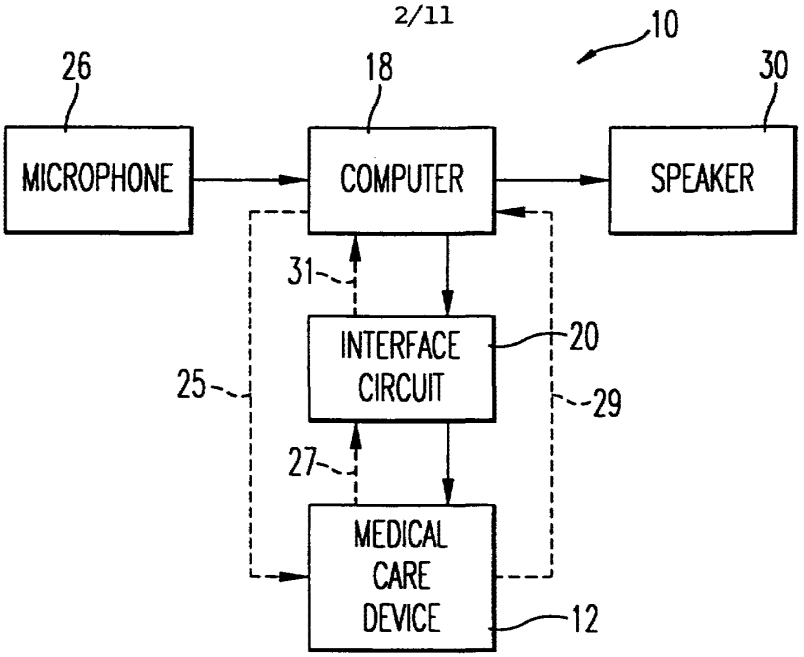


FIG. 2

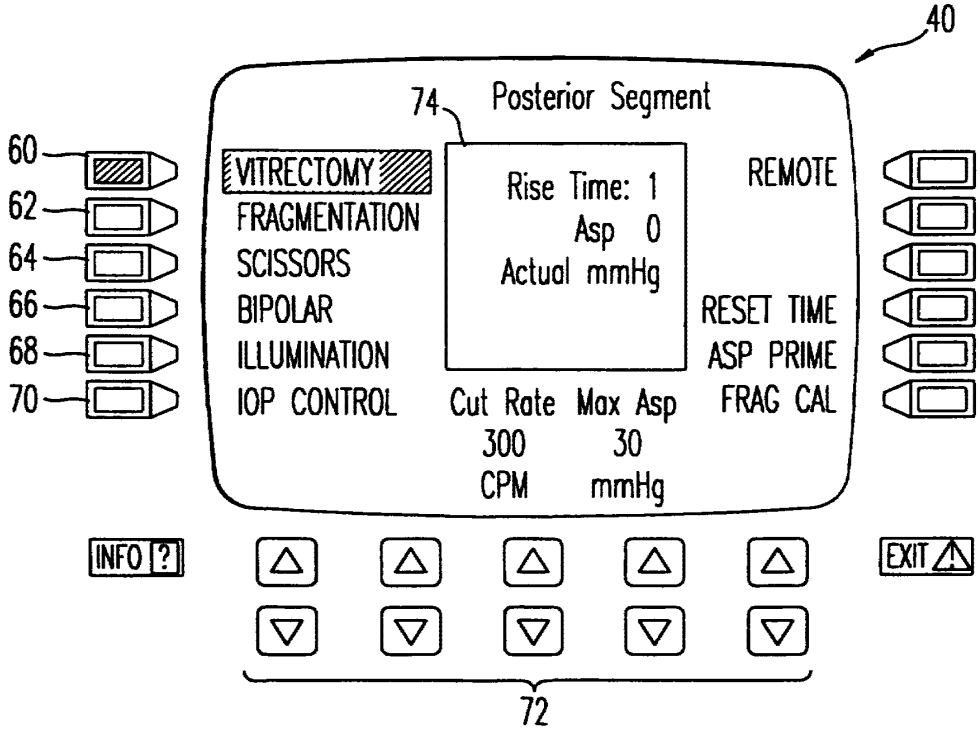


FIG. 4
PRIOR ART

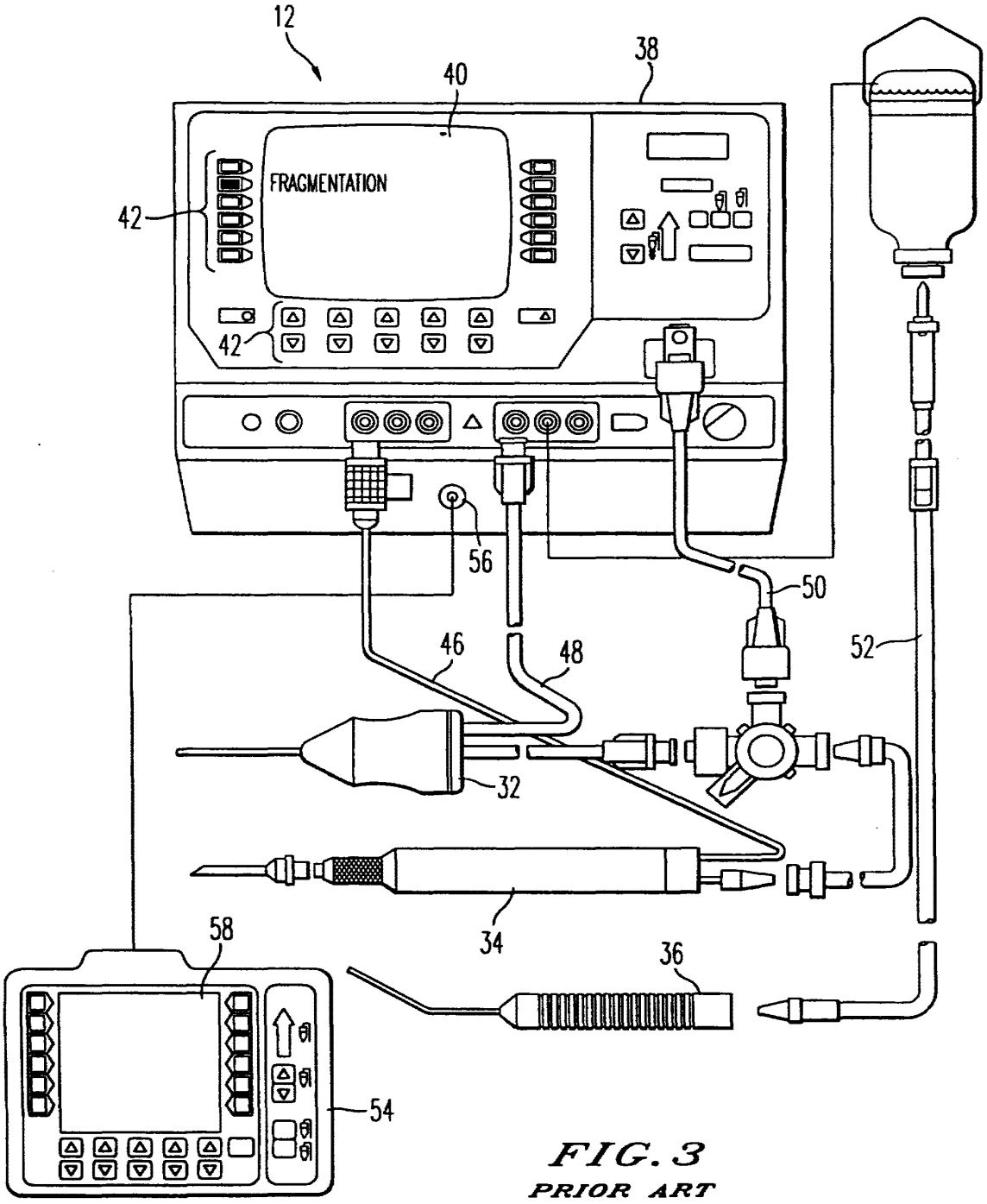
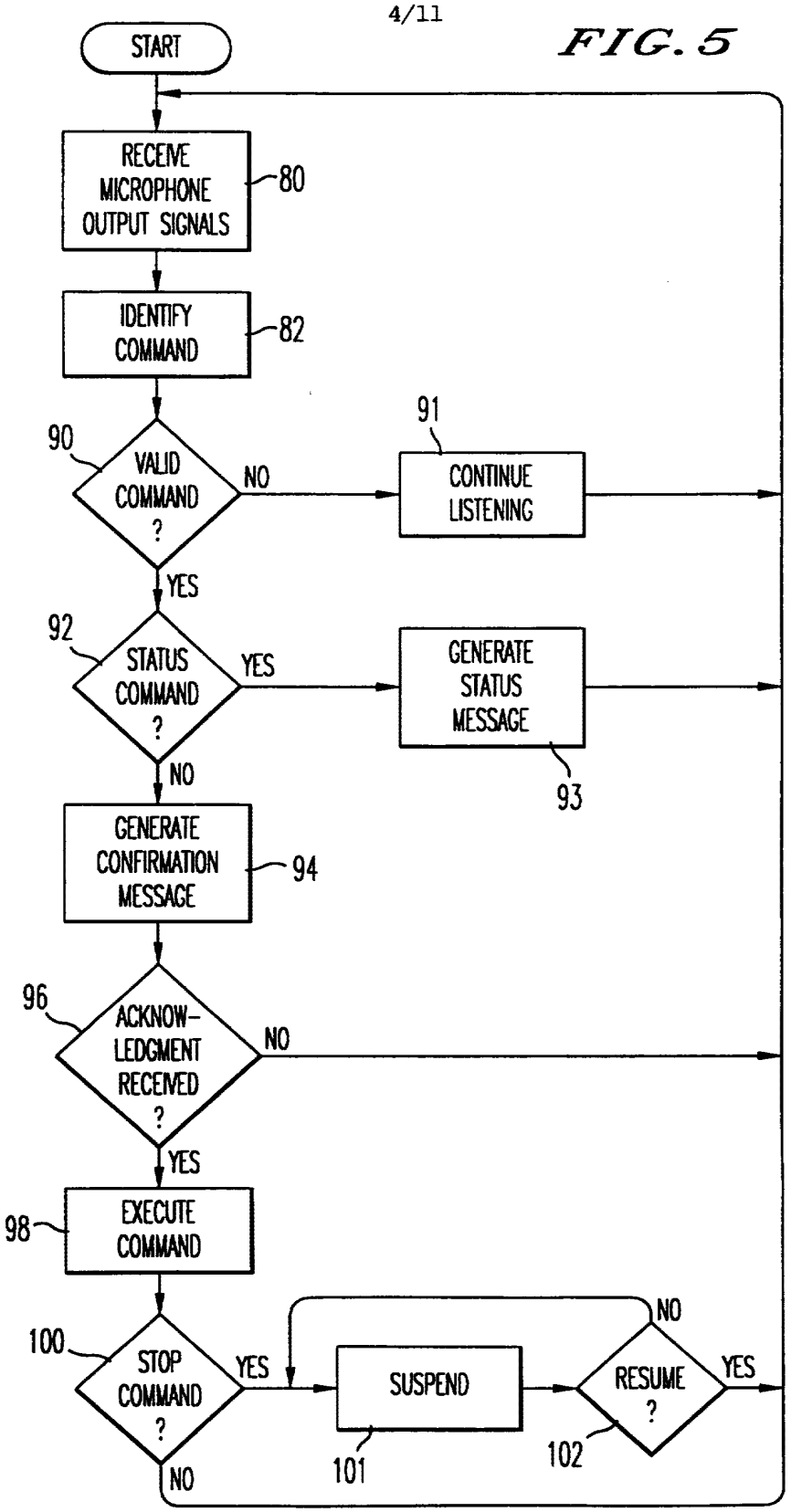


FIG. 3
PRIOR ART

FIG. 5


START
RECEIVE MICROPHONE OUTPUT SIGNALS
80
IDENTIFY COMMAND
82
90
VALID COMMAND ?
NO
91
CONTINUE LISTENING
YES
92
STATUS COMMAND ?
YES
GENERATE STATUS MESSAGE
93
NO
GENERATE CONFIRMATION MESSAGE
94
96
ACKNOW-LEDGMENT RECEIVED ?
NO
YES
98
EXECUTE COMMAND
100
STOP COMMAND ?
YES
SUSPEND
101
RESUME ?
102
NO
YES
NO

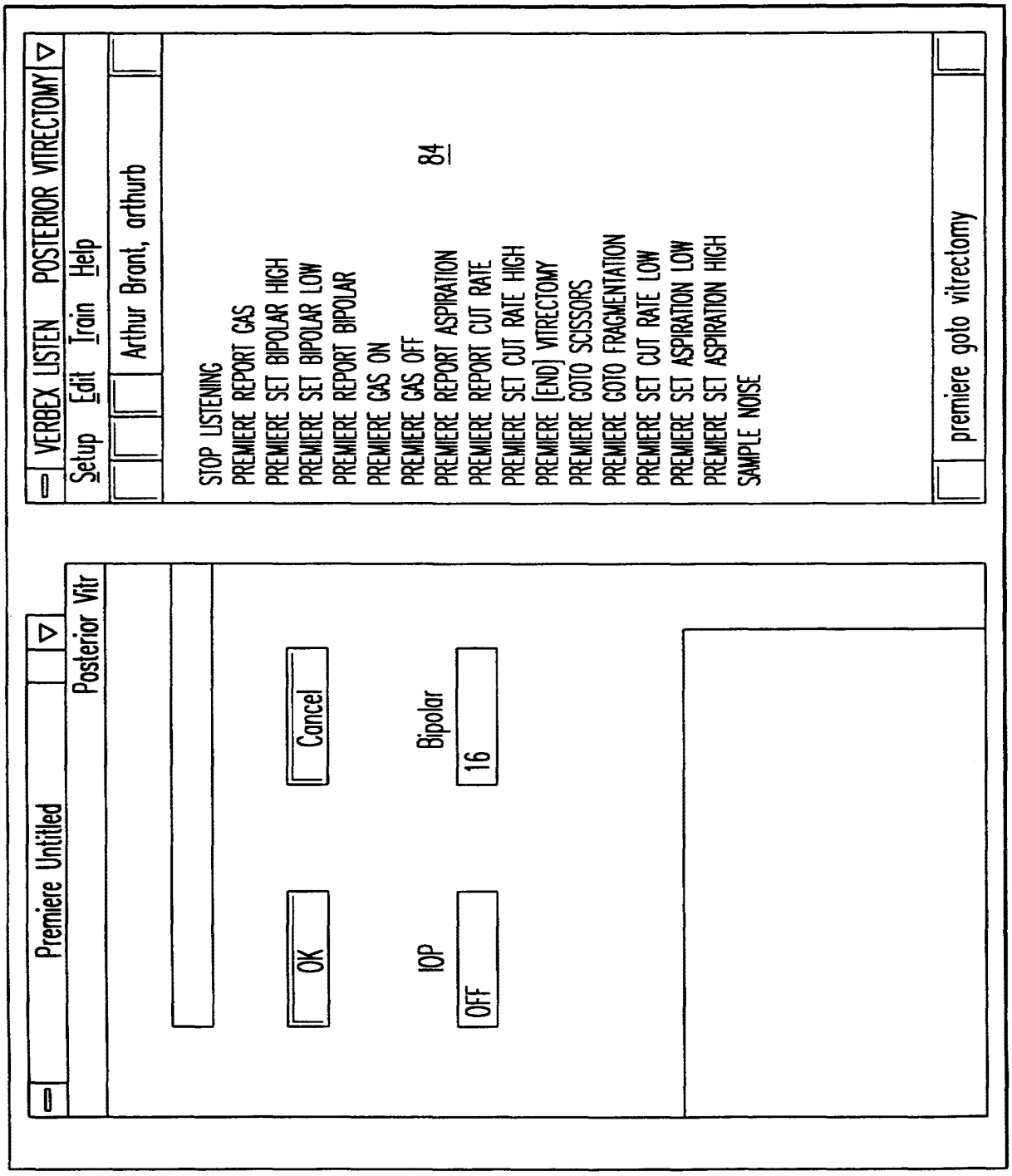

VERBEX LISTEN POSTERIOR VITRECTOMY
Setup Edit Train Help
Arthur Brant, arthurb
STOP LISTENING
PREMIERE REPORT GAS
PREMIERE SET BIPOLAR HIGH
PREMIERE SET BIPOLAR LOW
PREMIERE REPORT BIPOLAR
PREMIERE GAS ON
PREMIERE GAS OFF
84
PREMIERE REPORT ASPIRATION
PREMIERE REPORT CUT RATE
PREMIERE SET CUT RATE HIGH
PREMIERE [END] VITRECTOMY
PREMIERE GOTO SCISSORS
PREMIERE GOTO FRAGMENTATION
PREMIERE SET CUT RATE LOW
PREMIERE SET ASPIRATION LOW
PREMIERE SET ASPIRATION HIGH
SAMPLE NOISE
premiere goto vitrectomy
Premiere Untitled
Posterior Vitr
OK
Cancel
IOP
OFF
Bipolar
16

FIG. 6

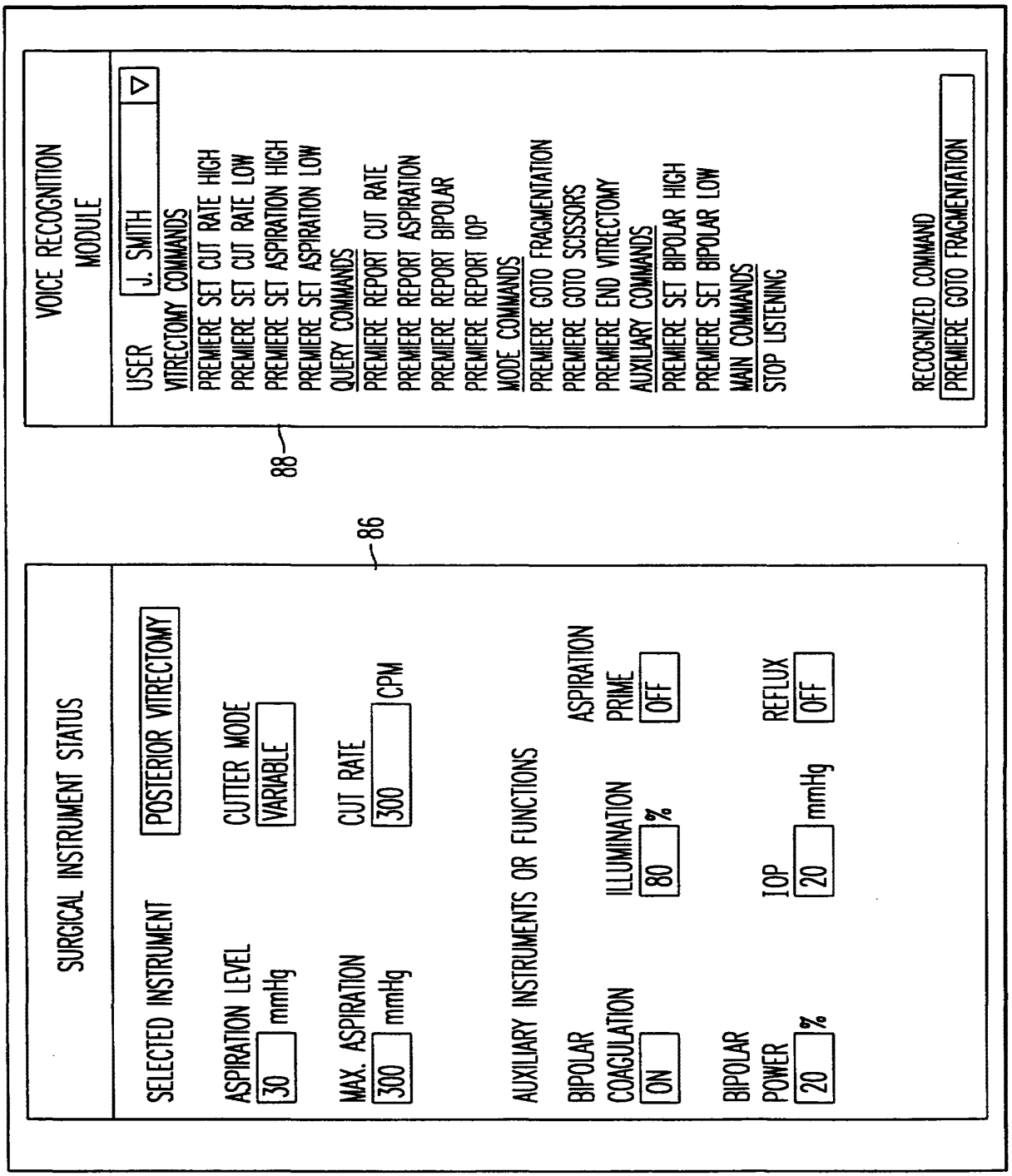

SURGICAL INSTRUMENT STATUS
SELECTED INSTRUMENT
POSTERIOR VITRECTOMY
ASPIRATION LEVEL
30 mmHg
CUTTER MODE
VARIABLE
MAX. ASPIRATION
300 mmHg
CUT RATE
300 CPM
AUXILIARY INSTRUMENTS OR FUNCTIONS
BIPOLAR COAGULATION
ON
ILLUMINATION
80 %
ASPIRATION PRIME
OFF
BIPOLAR POWER
20 %
IOP
20 mmHg
REFLUX
OFF
86
VOICE RECOGNITION MODULE
USER
J. SMITH
VITRECTOMY COMMANDS
PREMIERE SET CUT RATE HIGH
PREMIERE SET CUT RATE LOW
PREMIERE SET ASPIRATION HIGH
PREMIERE SET ASPIRATION LOW
QUERY COMMANDS
PREMIERE REPORT CUT RATE
PREMIERE REPORT ASPIRATION
PREMIERE REPORT BIPOLAR
PREMIERE REPORT IOP
MODE COMMANDS
PREMIERE GOTO FRAGMENTATION
PREMIERE GOTO SCISSORS
PREMIERE END VITRECTOMY
AUXILIARY COMMANDS
PREMIERE SET BIPOLAR HIGH
PREMIERE SET BIPOLAR LOW
MAIN COMMANDS
STOP LISTENING
RECOGNIZED COMMAND
PREMIERE GOTO FRAGMENTATION
88

FIG. 7

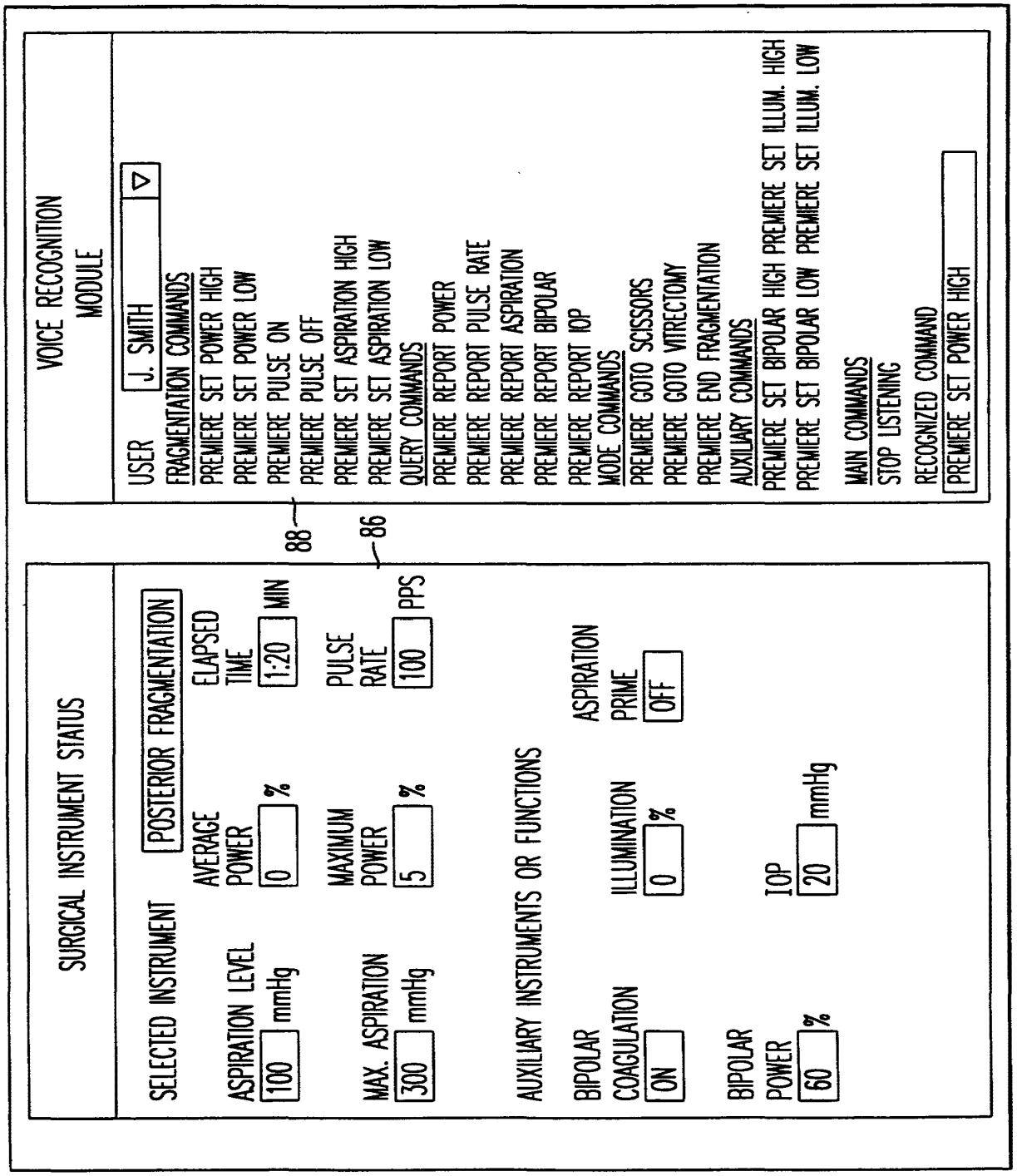

SURGICAL INSTRUMENT STATUS
SELECTED INSTRUMENT
POSTERIOR FRAGMENTATION
AVERAGE POWER
0 %
ELAPSED TIME
1:20 MIN
ASPIRATION LEVEL
100 mmHg
MAXIMUM POWER
5 %
PULSE RATE
100 PPS
MAX. ASPIRATION
300 mmHg
AUXILIARY INSTRUMENTS OR FUNCTIONS
ASPIRATION PRIME
OFF
BIPOLAR COAGULATION
ON
ILLUMINATION
0 %
IOP
20 mmHg
BIPOLAR POWER
60 %
88
86
VOICE RECOGNITION MODULE
USER
J. SMITH
FRAGMENTATION COMMANDS
PREMIERE SET POWER HIGH
PREMIERE SET POWER LOW
PREMIERE PULSE ON
PREMIERE PULSE OFF
PREMIERE SET ASPIRATION HIGH
PREMIERE SET ASPIRATION LOW
QUERY COMMANDS
PREMIERE REPORT POWER
PREMIERE REPORT PULSE RATE
PREMIERE REPORT ASPIRATION
PREMIERE REPORT BIPOLAR
PREMIERE REPORT IOP
MODE COMMANDS
PREMIERE GOTO SCISSORS
PREMIERE GOTO VITRECTOMY
PREMIERE END FRAGMENTATION
AUXILIARY COMMANDS
PREMIERE SET BIPOLAR HIGH PREMIERE SET ILLUM. HIGH
PREMIERE SET BIPOLAR LOW PREMIERE SET ILLUM. LOW
MAIN COMMANDS
STOP LISTENING
RECOGNIZED COMMAND
PREMIERE SET POWER HIGH

FIG. 8

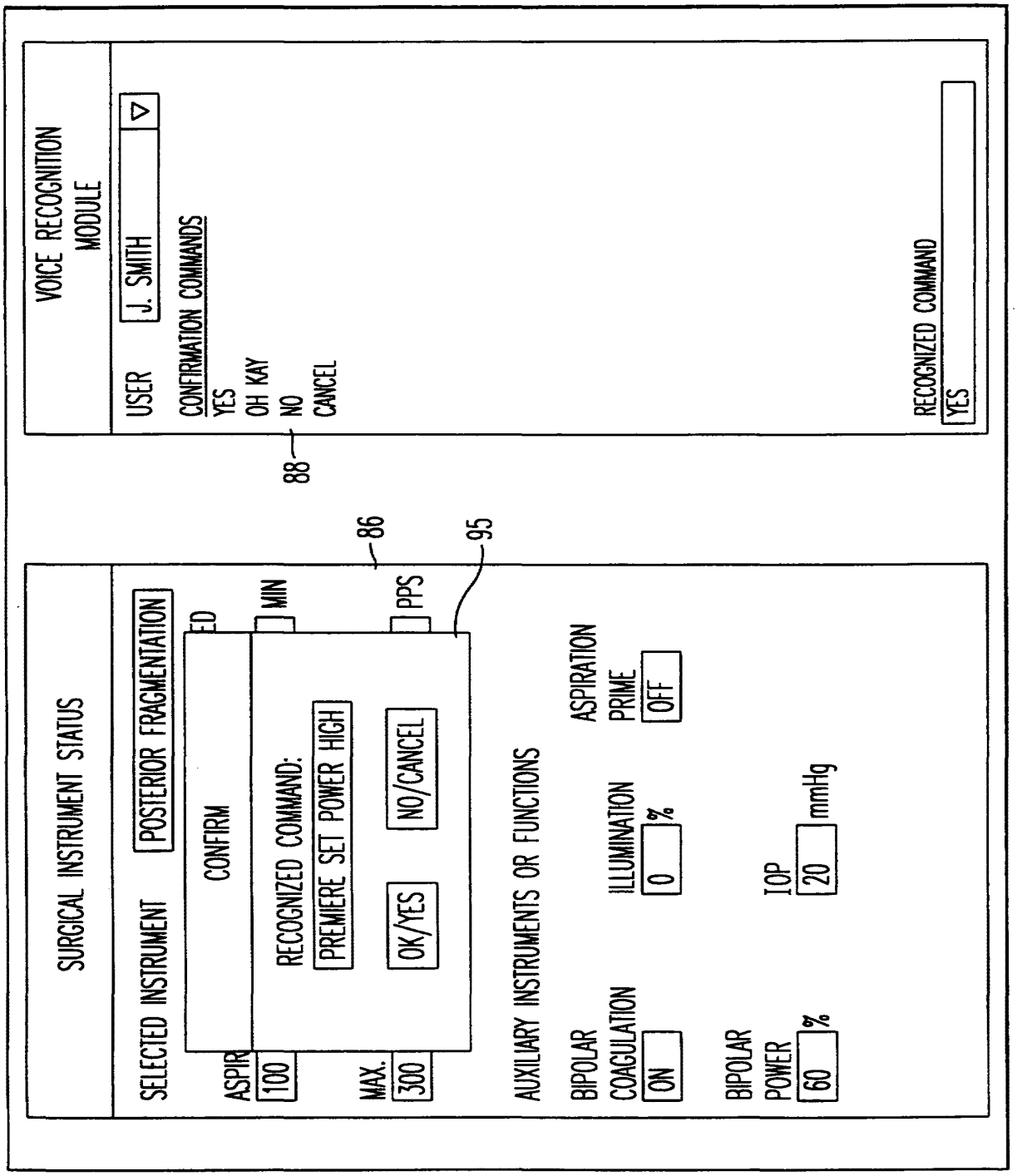

SURGICAL INSTRUMENT STATUS
SELECTED INSTRUMENT
POSTERIOR FRAGMENTATION
CONFIRM
ED
MIN
PPS
86
95
ASPIR
100
MAX.
300
RECOGNIZED COMMAND:
PREMIERE SET POWER HIGH
OK/YES
NO/CANCEL
AUXILIARY INSTRUMENTS OR FUNCTIONS
BIPOLAR COAGULATION
ON
ILLUMINATION
0
%
ASPIRATION PRIME
OFF
BIPOLAR POWER
60
%
IOP
20
mmHg
VOICE RECOGNITION MODULE
USER
J. SMITH
CONFIRMATION COMMANDS
YES
OH KAY
NO
CANCEL
88
RECOGNIZED COMMAND
YES

FIG. 9

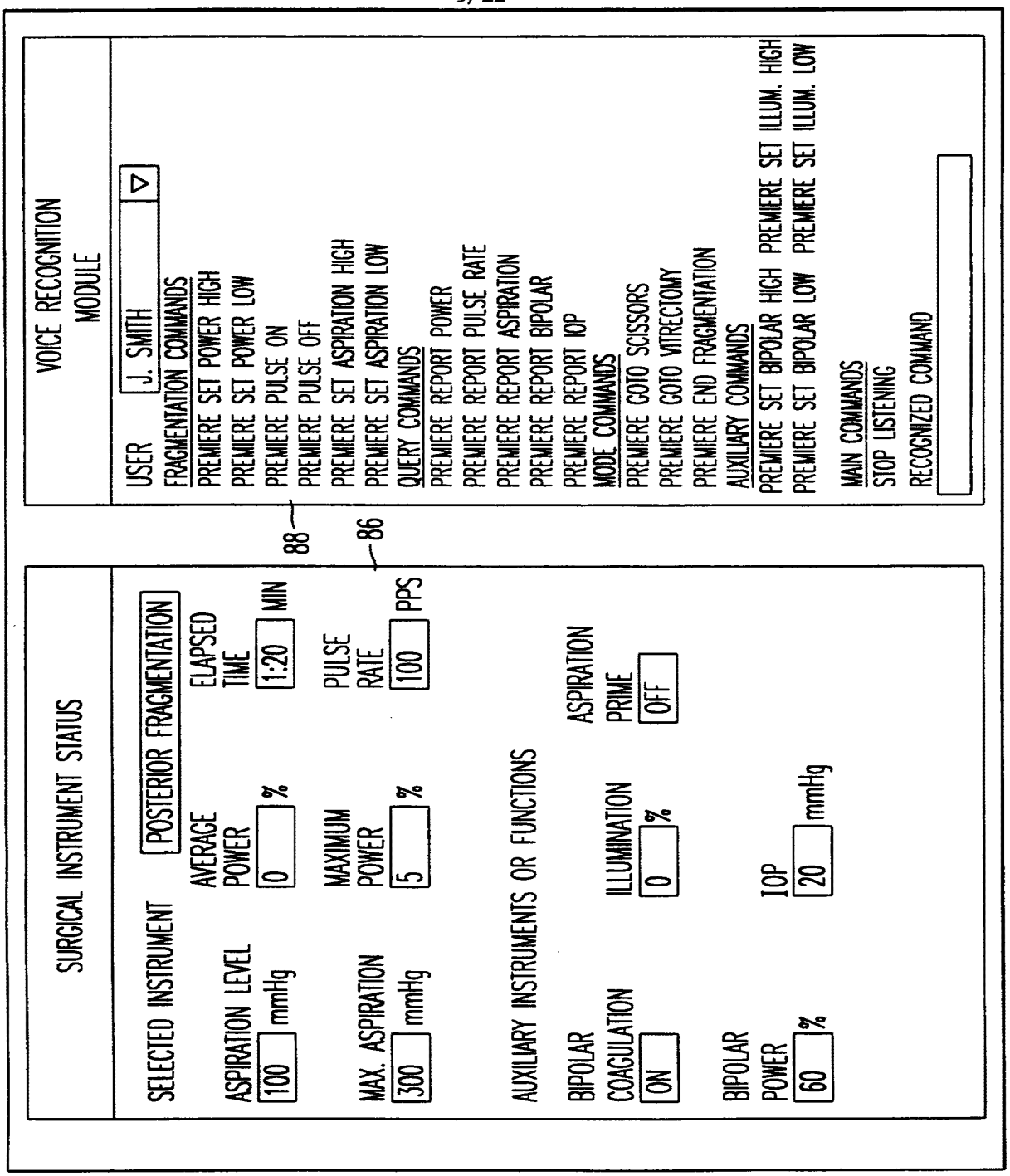

SURGICAL INSTRUMENT STATUS
SELECTED INSTRUMENT
POSTERIOR FRAGMENTATION
ASPIRATION LEVEL
100 mmHg
AVERAGE POWER
0 %
ELAPSED TIME
1:20 MIN
MAX. ASPIRATION
300 mmHg
MAXIMUM POWER
5 %
PULSE RATE
100 PPS
AUXILIARY INSTRUMENTS OR FUNCTIONS
BIPOLAR COAGULATION
ON
ILLUMINATION
0 %
ASPIRATION PRIME
OFF
BIPOLAR POWER
60 %
IOP
20 mmHg
88
86
VOICE RECOGNITION MODULE
USER
J. SMITH
FRAGMENTATION COMMANDS
PREMIERE SET POWER HIGH
PREMIERE SET POWER LOW
PREMIERE PULSE ON
PREMIERE PULSE OFF
PREMIERE SET ASPIRATION HIGH
PREMIERE SET ASPIRATION LOW
QUERY COMMANDS
PREMIERE REPORT POWER
PREMIERE REPORT PULSE RATE
PREMIERE REPORT ASPIRATION
PREMIERE REPORT BIPOLAR
PREMIERE REPORT IOP
MODE COMMANDS
PREMIERE GOTO SCISSORS
PREMIERE GOTO VITRECTOMY
PREMIERE END FRAGMENTATION
AUXILIARY COMMANDS
PREMIERE SET BIPOLAR HIGH PREMIERE SET ILLUM. HIGH
PREMIERE SET BIPOLAR LOW PREMIERE SET ILLUM. LOW
MAIN COMMANDS
STOP LISTENING
RECOGNIZED COMMAND

FIG. 10

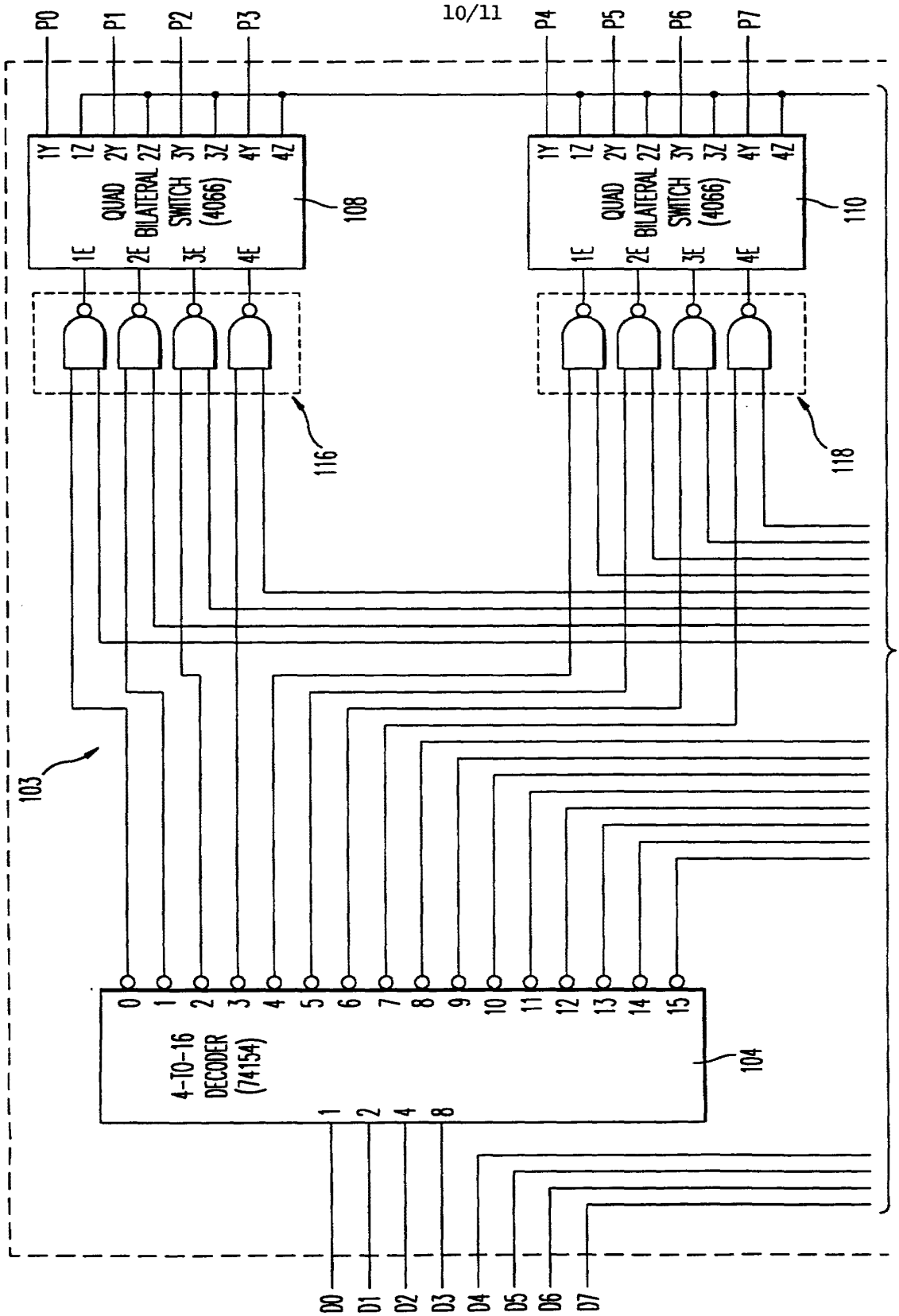

P0
P1
P2
P3
P4
P5
P6
P7
1Y
1Z
2Y
2Z
3Y
3Z
4Y
4Z
QUAD BILATERAL SWITCH (4066)
108
110
1E
2E
3E
4E
116
118
103
TO FIG.11B
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
4-TO-16 DECODER (74154)
104
1
2
4
8
D0
D1
D2
D3
D4
D5
D6
D7

FIG. 11A

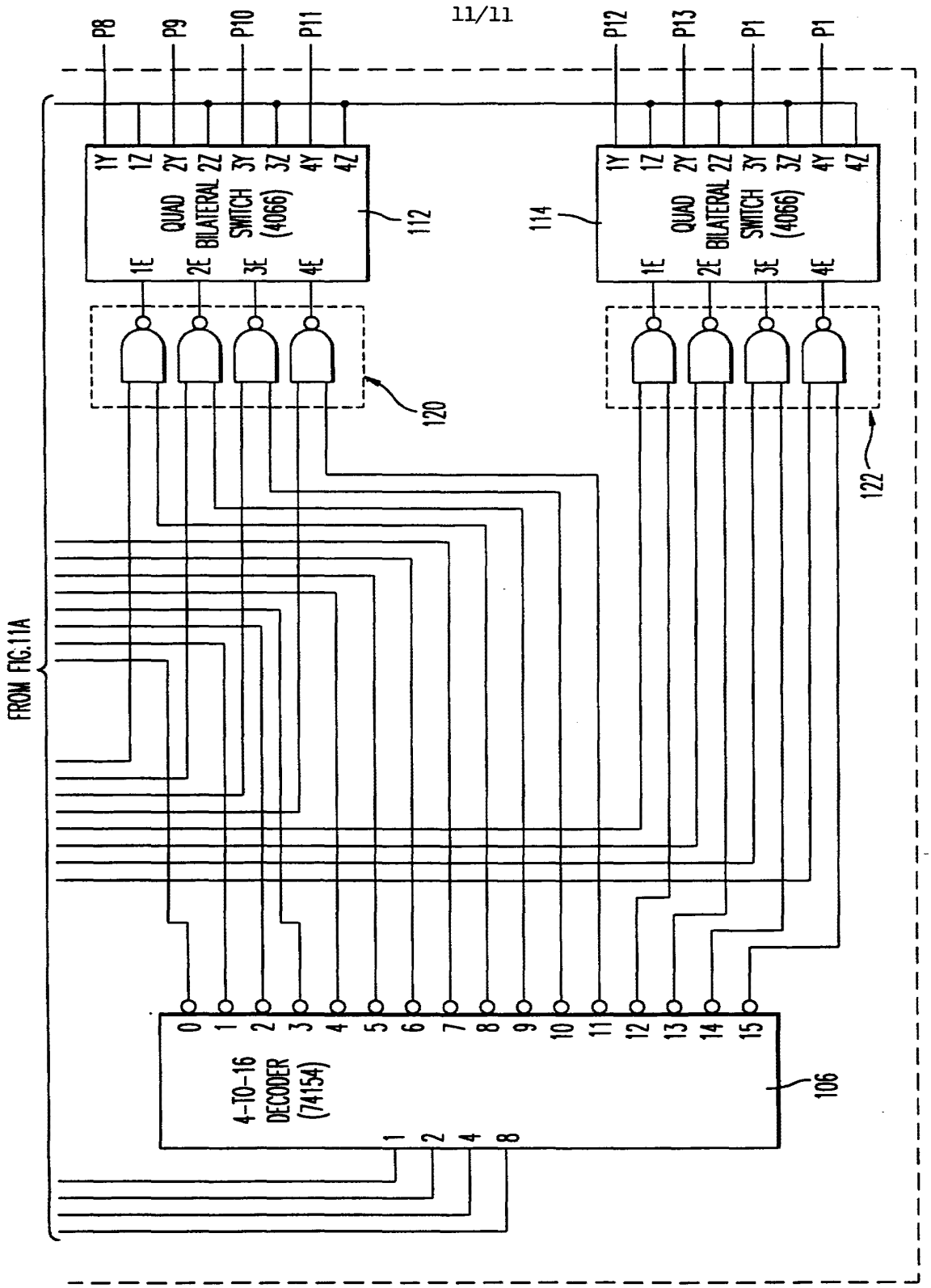

P8
P9
P10
P11
P12
P13
P1
P1
1Y
1Z
2Y
2Z
3Y
3Z
4Y
4Z
QUAD BILATERAL SWITCH (4066)
112
114
1E
2E
3E
4E
120
122
FROM FIG.11A
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
4-TO-16 DECODER (74154)
106
1
2
4
8

FIG. 11B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17320

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 19/00
US CL :606/2

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/736, 897, 898; 604/19-22; 606/2, 3-52

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,181,521 A (LEMELSON) 26 January 1993, entire document.	1-46 --- 1-46

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

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"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 10 FEBRUARY 1997	Date of mailing of the international search report 25 FEB 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer DAVID SHAY Telephone No. (703) 308-2215

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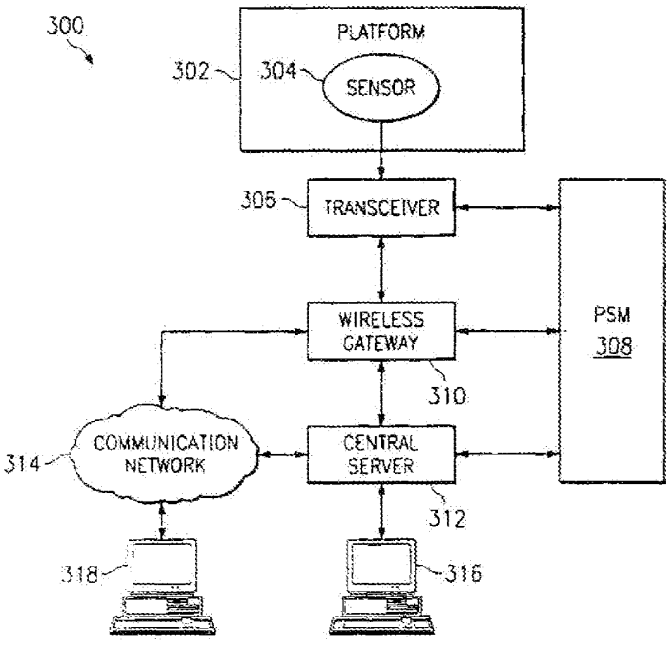
(74) Agents: **TANNENBAUM, David, H.** et al.; Fulbright & Jaworski L.L.P., 2200 Ross Avenue, Suite 2800, Dallas, TX 75201 (US).

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[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR WIRELESS COMMUNICATION OF SENSED DATA TO A CENTRAL SERVER



(57) Abstract: A system and method are disclosed which enable sensed data to be communicated to a central server for processing thereon. In a preferred embodiment, the system includes at least one sensor capable of sensing a physical characteristic and outputting data representing such physical characteristic to a transmitter (or transceiver). The transmitter communicates the data in a first wireless protocol to a wireless gateway, which is capable of communicating in a plurality of different wireless protocols. For example, the wireless gateway may be capable of communicating in a plurality of the following wireless protocols: short-range radio protocol (e.g., Bluetooth), WLAN protocol (e.g., 802.11 or wireless medical transmission standard (WMTS)), and cellular protocols (e.g., CDPD, EDGE, HDR, CDMA, or WCDMA). The wireless gateway translates the data from the first wireless protocol to at least a second wireless protocol, and communicates the data either directly or indirectly to a central server using the at least a second wireless protocol. For example, the transmitter may communicate the sensed data in Bluetooth protocol, and the wireless gateway may translate the sensed data into another protocol, such as cellular, for further communication thereof. One or more intermediaries may be included for receiving data from the wireless gateway and communicating such data to the central server. Such an intermediary may receive the data from the wireless gateway in a particular wireless protocol, and may communicate the data to the central server in a different protocol, such as Internet Protocol. The central server receives and processes the data.

WO 02/27640 A2

Published:

----- *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEM AND METHOD FOR WIRELESS COMMUNICATION OF SENSED DATA TO A CENTRAL SERVER

RELATED APPLICATIONS

This application is related to concurrently filed and commonly assigned U.S. Patent Application Serial Number 09/676,382 entitled "WIRELESS GATEWAY CAPABLE OF COMMUNICATING ACCORDING TO A PLURALITY OF PROTOCOLS," the disclosure of which is hereby incorporated herein by reference. This application is also related to co-pending U.S. Patent Application Serial Numbers 09/157,607, filed September 21, 1998, entitled "Full-Fashioned Weaving Process for Production of a Woven Garment with Intelligence Capability," and 09/273,175, filed March 19, 1999, entitled "Fabric or Garment with Integrated Flexible Information Infrastructure," the disclosures of which are hereby incorporated herein by reference. This application is also related to co-pending U.S. Provisional Application Serial Number 60/142,360, filed July 6, 2000, entitled "Fabric or Garment with Integrated Flexible Information Infrastructure for Monitoring Vital Signs of Infants," the disclosure of which is hereby incorporated herein by reference.

TECHNICAL FIELD

The present invention relates in general to a system and method for communicating data to a central server, and in specific to a system and method which utilize a multi-protocol wireless gateway to enable communication of sensed data to a central server for processing thereon.

BACKGROUND

Sensors are available in the prior art for detecting various physical characteristics of a person, animal, or an environment and outputting data about such physical characteristics. For example, sensors are available for outputting vital sign data or other data relating to a person, such as heart rate or EKG, pulse, voice, temperature, blood oxygen levels, atmospheric exposure, such as chemical and biological exposure, atmospheric smoke and oxygen levels, and radiation exposure. Sensors typically communicate such sensed data to a monitoring device, which interprets the sensed data, stores the sensed data, and/or analyzes the sensed data. A monitoring device may analyze the sensed data and output the data in an understandable format (e.g., in line graph form), and may also output, for example, warnings about a detected characteristic.

Sensors for detecting physical conditions are commonly utilized in the health care arena, such as within a care giver's facility (e.g., a hospital, clinic, or nursing home). Turning to Fig. 1, a typical environment commonly implemented in a care giver's facility of the prior art is shown. As shown, care giver facility 100 may include various patients, such as $Patient_1$ and $Patient_2$. Each patient may have one or more sensors, such as sensors 102_A, 102_B, and 102_C, for detecting and outputting personal data (e.g., vital sign data) to an associated monitoring device, such as monitoring devices 104_A, 104_B, and 104_C. Thus, for example, monitoring devices 104_A and 104_B may be heart monitors that receive heart rate data from sensors 102_A and 102_B respectively, and monitoring device 104_C may be a blood pressure monitor that receives blood pressure data from sensor 102_C. As further shown in Fig. 1, the monitoring devices generally include a software application program (e.g., application programs 110_A, 110_B, and 110_C), and a processor for executing such software application programs (e.g., processors 108_A, 108_B, and 108_C). Additionally, the monitoring devices typically include some type of input/output device (e.g., input/output devices 106_A, 106_B, and 106_C), such as keypads for inputting information and displays, printers, and speakers for outputting information. Furthermore, the monitoring devices typically include memory (e.g., memory 112_A, 112_B, and 112_C) for storing data, such memory may include any suitable type of data storage device, such as random access memory (RAM), a tape drive, a hard drive, a floppy disk, a writeable CD-ROM drive, etcetera.

Within the monitoring devices, the software application programs are typically executable to receive the sensed data and interpret such sensed data. The software

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application programs are also typically executable to analyze the sensed data and output a representation of the sensed data and/or warnings via the input/output devices of the monitoring equipment. For example, a heart monitor may execute an application program to monitor the sensed heart rate data and display the heart rate on a display, and the application program may, upon determining that the heart rate is at a dangerous level, sound a warning to notify care givers of the detected condition. The monitoring devices commonly store sensed data to its memory (e.g., to its data storage device), and often a care giver will access the stored sensed data to evaluate the patient's condition based on such collected data.

It should be recognized that the monitoring devices of the prior art are typically stand-alone devices, which are each assigned/dedicated to a particular patient. For example, suppose monitoring devices 104_A and 104_B are heart monitors, and further suppose that $Patient_1$ and $Patient_2$ require having their heart rates monitored. The monitoring devices are patient-dependent, in that one heart monitor (e.g., monitor 104_A) is dedicated specifically for monitoring $Patient_1$ and another heart monitor (e.g., monitor 104_B) is dedicated specifically for monitoring $Patient_2$. Accordingly, prior art systems typically require that a monitoring device, including the software for interpreting/analyzing received sensed data and input/output devices for communicating relevant information about the sensed data, be dedicated to an individual patient.

Turning to Fig. 2, a further environment that may be implemented in the prior art is shown. As in Fig. 1, a care giver's facility 100 includes one or more patients, such as $Patient_1$ having sensor 102_A for detecting and outputting personal data (e.g., vital sign data) to an associated monitoring device 104_A. Again, monitoring device 104_A generally includes application program 110_A executing on processor 108_A to interpret/analyze received sensed data, as well as input/output devices 106_A and memory 112_A. In this implementation of Fig. 2, a transmitter 202, which may transmit data via wireless protocol, is coupled to monitoring device 104_A and communicates data from monitoring device 104_A to a local server 204 within the care giver's facility 100. Accordingly, local server 204 may collect data from various monitoring devices to allow care givers to monitor the vital statistics of patients within the care giver's facility 100 from a central monitoring station coupled to local server 204, such as personal computer (PC) 205. Additionally, care givers may use

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handheld wireless devices, such as handheld monitor 206, that are capable of receiving data from transmitter 202 and/or local server 204 to monitor the status of one or more patients.

As further shown in Fig. 2, local server 204 of facility 100 may be communicatively coupled to a communication network 208, such as a public switched telephone network (PSTN), wide area network (WAN), or the Internet, as examples. Accordingly, care givers external to facility 100 may monitor the status of patients within facility 100 via communication network 208. That is, care givers may access the data available on local server 204 from a remote location via communication network 208. As one example, another health care facility 200 may include a server 212 that is remote from server 204, and remote server 212 may be capable of accessing information on local server 204 via communication network 208 and vice-versa. Thus, for instance, a number of hospitals (e.g., facilities 100 and 200) may be communicatively networked together to allow care givers in each hospital to access data from the other hospitals within the network. As another example, a care giver may utilize PC 210 (or other processor-based device) to access data contained on local server 204 or on remote server 212 via communication network 208.

It should be recognized that the system of Fig. 2 aids in allowing care givers to be mobile and still monitor the status of patients. For example, handheld device 206 allows a care giver to be mobile within facility 100, while still having continuous access to the status of $Patient_1$. Additionally, such prior art system enables a care giver to be mobile between various facilities. For instance, a care giver may use remote server 212 of 200 to monitor the status of $Patient_1$ residing within facility 100. Furthermore, such prior art system enables a care giver to monitor the status of $Patient_1$ from other locations outside of facility 100 and facility 200. For instance, a care giver can use PC 210 to monitor the status of $Patient_1$ from the care giver's home, office, or other location.

However, various problems and/or shortcomings exist in such prior art systems. First, while the prior art systems assist in mobilizing care givers, such systems typically do not allow for mobilizing patients. For example, in most prior art systems, a patient is relatively immobile with respect to monitoring devices and/or the care giver's facility. For instance, in Fig. 2, $Patient_1$ is typically confined to monitoring device 104_A. While monitoring device 104_A may be relatively mobile (e.g., relatively small and/or implemented on wheels or other transportable base), $Patient_1$ is required to remain confined to relative

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close proximity of monitoring device 104_A. Furthermore, $Patient_1$ is typically confined to facility 100 for monitoring. For example, transmitter 202 typically transmits data to local server 204 only from within facility 100. Thus, a desire exists for a system and method that enable increased mobility of patients while still allowing personal data of the patients to be monitored.

Additionally, in typical prior art systems, monitoring devices that each include input/output, processor, application software, and memory are dedicated to each patient. Accordingly, because a separate monitoring device is required for each patient, such monitoring devices are not cost effective to implement or to update. For example, if an update is made for the software executing on a monitoring device, the update is required to be made at each monitoring device. Additionally, periodic maintenance and troubleshooting is typically required for the various components of each monitoring device to ensure proper operation. Furthermore, such monitoring devices of the prior art typically require that the care giver use the software programs provided by the manufacturer of such monitoring devices. Thus, a care giver may have little or no option in selecting a desired software program for interpreting/analyzing sensed data. Accordingly, a desire exists for a system and method in which a central server receives the sensed data and executes application program(s) to analyze and/or store the data for monitoring patients. Thus, dedicated monitoring devices each including software, memory, and other complexity, may be eliminated, and instead their functionality may be provided by a central server.

Typically, in prior art monitoring systems, the sensed data (e.g., the data output by sensor 102_A of Fig. 2) is communicated to a monitoring device (e.g., monitoring device 104_A of Fig. 2) for processing, and resulting processed data is then communicated to a local server. Thus, processed data, rather than the raw sensed data, is communicated to the local server. Accordingly, the capability of local server 204 in further processing (e.g., further monitoring/analyzing) the received data may be limited and/or skewed because the received data is the result of the processing of monitor 104_A, rather than the actual raw sensed data from sensor 102_A. As one example, suppose sensor 102_A in Fig. 2 senses a patient's heartbeat, and outputs data indicating each sensed heartbeat to monitor 104_A. Monitor 104_A may interpret the sensed heartbeat data to determine a heart rate, and may further determine whether the determined heart rate is normal. This processed data (e.g., the determined heart rate and/or the determination of whether the heart rate is normal) is then communicated to

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local server 204. Thus, local server 204 is limited in the amount of further processing that it can perform because it does not receive the actual raw sensed heartbeat data. For instance, local server 204 may not utilize a software program that is superior to the program executing on monitor device 104_A in order to more accurately determine the heart rate, because local server 204 receives pre-processed data, rather than the raw sensed data. Accordingly, a desire exists for a system and method that enable raw sensed data to be communicated to a central server for processing thereon.

Furthermore, typical prior art monitoring systems do not utilize bi-directional communication. For instance, in the system of Fig. 2, while monitoring device 104_A utilizes transmitter 202 to communicate information to local server 204, information is typically not communicated from local server 204 to monitoring device 104_A. Thus, for example, a user typically cannot control the operation of monitoring device 104_A from local server 204 because local server 204 is not capable of communicating information/instructions to monitoring device 104_A. Accordingly, a desire exists for a system and method that enable bi-directional communication between monitoring devices and/or sensors and a central server.

Furthermore, the prior art system is inflexible in the manner in which sensed data may be communicated to a server. For example, wireless transmitters, such as transmitter 202 of Fig. 2, for transmitting data to a server, such as local server 204 of Fig. 2, typically utilize one wireless communication protocol and provide no flexibility for communicating via other protocols. Thus, the compatibility of transmitter 202 with a particular server is limited to the particular protocol utilized by transmitter 202. Also, should the wireless communication network utilized by transmitter 202 become unavailable for some reason, transmitter 202 has no ability to communicate information (e.g., via an available protocol) to the server. Thus, a desire exists for a system and method that provide flexibility in the communication of data.

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SUMMARY OF THE INVENTION

The present invention is directed to a system and method which enable sensed data to be communicated to a central server for processing thereon. A preferred embodiment provides a system that includes at least one sensor capable of sensing a physical characteristic and outputting data representing such physical characteristic to a transmitter. The transmitter communicates the data in a first wireless protocol to a wireless gateway, which is preferably capable of communicating in a plurality of different wireless protocols. For example, the wireless gateway of a preferred embodiment may be capable of communicating in a plurality of the following wireless protocols: short-range radio protocol (e.g., Bluetooth), WLAN protocol (e.g., 802.11 or wireless medical transmission standard (WMTS)), and cellular protocol (e.g., CDPD, EDGE, HDR, CDMA, or WCDMA). In a most preferred embodiment, such transmitter is actually implemented as a transceiver that is capable of not only transmitting sensed data, but is further capable of receiving data, thereby enabling bi-directional communication.

The wireless gateway translates the data from the first wireless protocol to at least a second wireless protocol, and communicates the data either directly or indirectly to a central server using such second wireless protocol. Accordingly, in a most preferred embodiment, the wireless gateway is capable of translating the sensed data from one communication protocol to another. As one example, the transmitter may communicate the sensed data in Bluetooth protocol (or other short-range radio protocol), and the wireless gateway may translate the sensed data into another protocol for further communication thereof, such as WLAN protocol (e.g., 802.11 or WMTS) or cellular protocol. Most preferably, the wireless gateway may be implemented as disclosed more fully in concurrently filed and commonly assigned U.S. Patent Application Serial Number 09/676,382 entitled "WIRELESS GATEWAY CAPABLE OF COMMUNICATING ACCORDING TO A PLURALITY OF PROTOCOLS," the disclosure of which is hereby incorporated herein by reference. The central server receives and processes (as well as stores) the data.

In a preferred embodiment, a platform may be included on which one or more sensors is coupled. In a most preferred embodiment, such platform is fabric having an information infrastructure integrated therein. Furthermore, in a most preferred embodiment, the fabric is fashioned into a wearable garment, thereby enabling one or more

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sensors coupled to the garment's information infrastructure to sense physical characteristics of the wearer of such garment.

A preferred embodiment may be implemented to include at least one intermediary for receiving data from the wireless gateway and communicating such data to the central server. Such an intermediary may receive the data from the wireless gateway in a wireless protocol, and may communicate the data to the central server in a different protocol, such as Internet Protocol. The intermediary may be implemented to communicate the data to the central server via a communication network, such as a public switched telephone network (PSTN), wireless communication network, general purpose processor-based information network, dedicated communication lines, cable system, digital subscriber line (DSL), direct PC to PC connection, local area network (LAN), wide area network (WAN), modem to modem connection, the Internet, an Intranet, an Extranet, or any combination thereof suitable for providing information communication between such intermediary and central server. As an example, a base unit may be located at a nurses station in a hospital to receive sensed data for the patients in a hospital from the wireless gateway(s), and the base unit may communicate such data to a central server via the hospital's Intranet. As another example, a base unit may be located in a patient's home to receive sensed data for the patient in the patient's home from the wireless gateway, and the base unit may communicate such data to a central server via the Internet.

While a most preferred embodiment is implemented within the health care arena to communicate sensed data from a patient (e.g., vital sign data) to a central server, it should be understood that the present invention may be implemented in various other arenas. As one example, a preferred embodiment may be implemented to enable communication of sensed data (e.g., temperature data) to a temperature control system or air conditioning system (central server) responsible for controlling the temperature of a particular facility. As another example, a preferred embodiment may be implemented within a robot to detect hazardous conditions in an environment and communicate the sensed data acquired in such an environment to a central server. Additionally, any type of physical characteristic capable of being sensed is intended to be within the scope of the present invention. For example, in a preferred embodiment, one or more sensors are implemented to sense physical characteristics, such as vital sign characteristics or environmental characteristics. Examples of such vital sign characteristics include heart rate, breathing rate, blood pressure,

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pulse, body temperature, and blood oxygen level, and examples of such environmental characteristics include temperature, audio, atmospheric smoke and oxygen levels, gas level, light level (e.g., light brightness or intensity), air flow, and radiation level.

Most preferably, the raw sensed data is communicated to a central server for processing. That is, in a most preferred embodiment, the actual sensed data is communicated to a central server, rather than communicating to the central server information resulting from processing of the actual sensed data. Additionally, in a preferred embodiment, the communicated data includes information in addition to the actual sensed data. For example, the communicated data may also include such information as physical characteristic type, source identification, time stamp, and location information.

It should be appreciated that a technical advantage of one aspect of a preferred embodiment is that it enables increased mobility of patients (or other "source") while still allowing personal data of the patients to be monitored. Another technical advantage of one aspect of a preferred embodiment is that it enables a central server to receive sensed data, thereby enabling the central server to execute software program(s) to analyze and/or store the data. Accordingly, dedicated monitoring devices that each include software, memory, and other complexity, may be eliminated, and instead their functionality may be provided by the central server of a preferred embodiment.

It should also be appreciated that a further technical advantage of one aspect of a preferred embodiment is that it enables raw sensed data to be communicated to a central server for processing thereon. Accordingly, analysis of such sensed data may be made at the central server, rather than receiving at the central server an analysis of the sensed data performed by another device. Yet a further technical advantage of one aspect of a preferred embodiment is that it enables bi-directional communication between the source of the sensed data and a central server. Still a further technical advantage of one aspect of a preferred embodiment is that it provides flexibility in the communication of data to a central server. For example, a wireless gateway capable of communicating in a plurality of wireless protocols is preferably utilized to enable flexibility in the communication of sensed data to a central server.

The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may

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be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

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BRIEF DESCRIPTION OF THE DRAWING

For a more complete understanding of the present invention, reference is now made to the following descriptions taken in conjunction with the accompanying drawing, in which:

Fig. 1 shows a typical environment commonly implemented in a care giver's facility of the prior art;

Fig. 2 shows a further environment that may be implemented in the prior art for communicating sensed data within a care giver's communication network;

Fig. 3 shows an exemplary environment in which a preferred embodiment of the present invention may be implemented;

Fig. 4 shows an exemplary environment in which a most preferred embodiment may be implemented;

Fig. 5 shows an exemplary implementation of a preferred embodiment within a hospital environment for communication of sensed data within the hospital environment;

Fig. 6 shows an exemplary implementation that enables communication of sensed data from a particular base location, such as a patient's home, to a central server;

Fig. 7 shows an exemplary implementation that further enables communication of sensed data to a central server not only from a particular base location, but also from a wide area; and

Fig. 8 shows an exemplary implementation that enables communication of sensed data to a central server from within a wide area of communication.

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DETAILED DESCRIPTION

Various embodiments of the present invention are now described with reference to the above Figs., wherein like reference numerals represent like parts throughout the several views. Turning to Fig. 3, an exemplary environment 300 in which a preferred embodiment of the present invention may be implemented is shown. As shown, a platform 302 may be provided, which includes one or more sensors 304. As will be described in greater detail hereafter, sensors 304 preferably detect a physical condition (or physical characteristic) and outputs data representing the physical condition. Most preferably, sensors 304 detect personal data, such as vital sign data for a person, and communicate the detected information to a transceiver 306. However, sensors 304 may detect other physical characteristics, such as environmental data (e.g., temperature, gas level, light level, air flow, radiation level, or other hazardous level of an environment). As will also be described in greater detail hereafter, platform 302 preferably provides an infrastructure that enables various sensors 304 to be added thereto and removed therefrom to easily modify the "sensing system" provided by platform 302. In a preferred embodiment, transceiver 306 receives sensed data from the one or more sensors 304, digitizes the sensed data, and communicates the received data via wireless communication. In a most preferred embodiment transceiver 306 is capable of both transmitting and receiving data. However, in alternative embodiments, a transmitter may be implemented in place of transceiver 306, enabling wireless transmission of data received from the one or more sensors 304. Transceiver 306 may use, for example, short-range personal area network (PAN), short-range radio, or WLAN to communicate data, or transceiver 306 may be implemented as an optical transceiver capable of communicating via infrared, as examples.

Preferably, environment 300 includes a wireless gateway 310, which is most preferably a multi-protocol gateway that is capable of communicating in a plurality of different wireless protocols. For example, wireless gateway 310 may be capable of communicating in a plurality of the following wireless protocols: short-range radio protocol (e.g., Bluetooth), WLAN protocol (e.g., 802.11 or WMTS), and cellular protocols (e.g., CDPD, EDGE, HDR, CDMA, or WCDMA). Such protocols are well-known in the art, and therefore will not be described in great detail herein. Additionally, it should be recognized that wireless gateway 310 may be implemented with the capability of communicating in any desired wireless protocol now known or developed in the future, and any such

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implementation in intended to be within the scope of the present invention. In a most preferred embodiment, wireless gateway 310 is capable of translating the sensed data from one communication protocol to another. As one example, transceiver 306 may communicate the sensed data in Bluetooth protocol (or other short-range radio protocol), and wireless gateway 310 may translate the sensed data into another protocol for further communication thereof, such as WLAN protocol (e.g., 802.11 or WMTS) or cellular protocol. Most preferably, wireless gateway 310 may be implemented as disclosed more fully in concurrently filed and commonly assigned U.S. Patent Application Serial Number 09/676,382 entitled "WIRELESS GATEWAY CAPABLE OF COMMUNICATING ACCORDING TO A PLURALITY OF PROTOCOLS," the disclosure of which is hereby incorporated herein by reference.

From wireless gateway 310, the sensed data is communicated, either directly or indirectly, to central server 312. In a most preferred embodiment, wireless gateway 310 communicates with transceiver 306 via a first wireless protocol (e.g., Bluetooth), and communicates, either directly or indirectly, with central server 312 via a different wireless protocol. In a preferred embodiment, wireless gateway 310 communicates with central server 312 via a communication path, at least a portion of which is via a wireless protocol. For example, wireless gateway 310 may communicate via a wireless protocol directly with central server 312. Thus, the entire communication path between wireless gateway 310 and central server 312 may be a wireless communication path using such wireless protocol. As a further example, wireless gateway 310 may communicate indirectly via a wireless protocol with central server 312. For instance, wireless gateway may communicate via a wireless protocol to an intermediary, which may forward the communication to central server 312 via a different wireless or wireline protocol. For example, an intermediary may forward the communication to central server 312 via the Internet. Thus, only a portion of the communication path between wireless gateway 310 and central server 312 may be via a wireless protocol utilized by wireless gateway 310.

In a most preferred embodiment, central server 312 processes the data that it receives (either directly or indirectly) from wireless gateway 310. For example, the data received at central server 312 may be processed by one or more software programs operating thereon. That is, various software programs may be operating on central server 312 to receive, interpret, analyze, monitor, and/or store the sensed data communicated

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thereto. Central server 312 may be any suitable processor-based device for receiving and processing the sensed data including without limitation a personal computer (PC) or mainframe computer. Furthermore, it should be understood that central server 312 may actually comprise a plurality of processor-based devices communicatively coupled together; and gateway may be communicated from wireless gateway 310 to all of such plurality of processor-based devices simultaneously, and/or such data may be communicated from one of such processor-based devices to the next of such devices. Additionally, while only one platform 302 is shown in Fig. 3, it should be understood that in a preferred embodiment, many such platforms may be implemented, and central server 312 may receive data sensed by all of such platforms. Further, each platform may have associated therewith its own transceiver 306, as well as its own wireless gateway 310 in order to communicate sensed data to central server 312. Alternatively, multiple platforms may share a single transceiver 306 and/or a single wireless gateway 310. Thus, in some embodiments, wireless gateway 310 may be utilized to communicate sensed data from a plurality of platforms, each having one or more sensors, to central server 312. Furthermore, each platform may include one or more various sensors 304.

Because a preferred embodiment enables sensed data to be communicated from various different sensors 304 to a central server 312, rather than each sensor communicating data to a separate, dedicated monitoring device, the quality, efficiency and cost effectiveness of processing such data can be improved at central server 312 to improve the overall processing (e.g., monitoring/analysis) of the sensed data. Thus, for example, in a most preferred embodiment the functionality of the monitoring devices of the prior art (e.g., monitoring devices 104_A, 104_B, and 104_B of Figs. 1 and 2) may be provided by central server 312, thereby eliminating the requirement of providing monitoring devices that are dedicated solely to a particular sensor or platform (e.g., dedicated to a particular patient). As will be discussed in greater detail hereafter, in some implementations transceiver 306 and/or wireless gateway 310 may include data processing (e.g., monitoring/analysis) functionality. However, in a most preferred embodiment, central server 312 provides the primary processing functionality.

In a preferred embodiment, a user can select the most desirable software program(s) to be utilized at central server 312 for processing (e.g., monitoring/analyzing) the sensed data. Thus, for example, a user is not limited specifically to software provided by the

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manufacturer of a monitoring device, but may instead choose one or more of various different software program(s) to be utilized at central server 312 for processing the sensed data. Additionally, software programs may be utilized to process data received from multiple sensors on platform 302 in order to more fully monitor/analyze the overall condition of platform 302 or some entity (e.g., a patient) associated with platform 302. Using a software program to monitor data collected from various different sensors is typically not available in the prior art. For example, in the prior art the output of a heart sensor is generally monitored by a heart rate monitoring device, and the output of a blood pressure sensor is generally monitored by a blood pressure device. However, a system that allows for data from a heart sensor, data from a blood pressure sensor, as well as data from various other sensors, to be collectively processed by such system to monitor/analyze the overall condition of a patient is typically not available. Thus, a preferred embodiment is advantageous in that it enables data from various different sensors to be collectively processed to evaluate the condition of platform 302 or an entity (e.g., a patient) associated with platform 302.

As further shown in Fig. 3, in a preferred embodiment a user, such as a care giver (e.g., a physician or nurse), may access data from central server 312 via a suitable processor-based device, such as devices 316, 318 and 308. For example, processor-based device 316, which may be any suitable processor-based device including without limitation a personal PC or laptop computer, may be communicatively coupled to central server 312 to enable a user to access data from central server 312. Similarly, processor-based device 318, which may also be any suitable processor-based device including without limitation a PC or laptop computer, may be communicatively coupled to central server 312 via communication network 314 to enable a user to access data from central server 312. Communication network 314 may be any suitable communication network, including without limitation a public switched telephone network (PSTN), wireless communication network, a general purpose processor-based information network, dedicated communication lines, a cable system, digital subscriber line (DSL), direct PC to PC connection, a local area network (LAN), a wide area network (WAN), modem to modem connection, the Internet, an Intranet, an Extranet, or any combination thereof suitable for providing information communication between processor-based device 318 and central server 312.

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Additionally, a handheld device 308, such as a personal digital assistant (PDA), pager, or 3G cellular telephone, may be capable of communicating with one or more of central server 312, wireless gateway 310, and transceiver 306. Handheld device 308 may be referred to herein as a "personal status monitor" ("PSM"), and may enable an entity associated with platform 302 (e.g., a patient) to monitor sensed data and/or receive warnings/instructions. For example, a warning (e.g., an audible alarm) may be provided by PSM 308 upon detection by PSM 308 or central server 312 of a dangerous condition based on the sensed data, and/or instructions may be provided from central server 312 to PSM 308 to educate the entity associated with platform 302 as to appropriate actions to take. Additionally, PSM 308 may be a device used by an entity not associated with platform 302, such as a care giver responsible for a patient being monitored by platform 302. In this manner, for example, a nurse, physician, or other care giver may use PSM 308 to monitor the status of one or more patients. Preferably, PSM 308 is a wireless device capable of receiving data via a wireless protocol, such as Bluetooth.

A most preferred embodiment of the present invention has particularly desired application within the health care arena to communicate sensed personal data (e.g., vital sign data) from one or more patients to a central server. However, as will be recognized by one of ordinary skill in the art, various embodiments of the present invention may be implemented within many other arenas. Thus, the present invention, therefore, is not intended to be limited solely to application within the health care arena or solely to the communication of personal data of patients to a central server, but instead may be implemented within various other arenas (some of which are briefly mentioned herein) and may be implemented to communicate various other types of sensed data to a central server.

Turning to Fig. 4, an exemplary environment 400 in which a most preferred embodiment may be implemented is shown. As shown, a platform 402 is provided, which includes one or more sensors 403. As illustrated in Fig. 4, in a most preferred embodiment, platform 402 is implemented as fabric that includes an integrated infrastructure in which sensors 403 may be implemented. Most preferably, such fabric is fashioned into a wearable garment such that sensors 403 may detect physical characteristics (e.g., personal data) from the person wearing the garment and/or about the physical characteristics of the environmental surroundings of such person. Such a fabric platform may be implemented in the manner described in greater detail in co-pending U.S. Patent Application Serial

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Numbers 09/157,607, filed September 21, 1998, entitled "Full-Fashioned Weaving Process for Production of a Woven Garment with Intelligence Capability," and 09/273,175, filed March 19, 1999, entitled "Fabric or Garment with Integrated Flexible Information Infrastructure;" and also as in co-pending U.S. Provisional Application Serial Number 60/142,360, filed July 6, 2000, entitled "Fabric or Garment with Integrated Flexible Information Infrastructure for Monitoring Vital Signs of Infants," the disclosures all of which are hereby incorporated herein by reference. Thus, for instance, as shown in the example of Fig. 4, platform 402 may be a wearable fabric garment (e.g., a shirt, a vest, pants, shorts, a cap, etcetera). In alternative embodiments, platform 402 may be implemented as fabric having an integrated infrastructure that is fashioned into something other than a wearable garment (e.g., fabric for a chair or other furnishing, fabric for curtains, fabric for carpeting, etcetera). In still other alternatives, platform 402 may be implemented as a non-fabric platform that includes an infrastructure in which one or more sensors 403 may be implemented.

Transceiver 306 is communicatively coupled to the infrastructure of platform 402 to receive sensed data from the one or more sensors 403. Thus, transceiver 306 may be integrated within the infrastructure of platform 402, or otherwise communicatively coupled to such infrastructure. Wireless gateway 310_A is included within environment 400 to receive the sensed data from transceiver 306 and communicate such data, either directly or indirectly, to a central server, which in this exemplary implementation is a web-based server 406. More specifically, in this exemplary implementation, wireless gateway 310_A communicates the sensed data to a base unit 404, which in turn communicates the sensed data to web-based server 406 via fixed transmission facility (e.g., the Internet, PSTN, private data network, or other suitable communication network). Transceiver 306 may communicate the sensed data to wireless gateway 310_A via a first wireless protocol (e.g., via short-range radio protocol, such as Bluetooth), and wireless gateway 310_A translates the data to a second wireless protocol (e.g., WLAN, infrared, PAN, cellular, or other wireless protocol) that is suitable for communicating with base unit 404. Base unit 404 communicates the sensed data in a suitable protocol (e.g., Internet Protocol) to web-based server 406.

Web-based server 406 may include one or more software application programs 408 executing thereon to process the received sensed data. Additionally, a processor-based

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device 316 (e.g., workstation, PC, or laptop) may be communicatively coupled to web-based server 406 to enable a user to input information to web-based server 406 and/or to receive output of information from web-based server 406. For example, a user may utilize processor-based device 316 to monitor and/or analyze the received sensed data. For instance, a user may interact with application programs 408 to monitor/analyze the physical characteristics represented by the sensed data (e.g., a patient's vital signs). As further shown in Fig. 4, a data storage device 407 may be communicatively coupled to central server 406 to enable central server 406 to store the sensed data thereto. Such data storage device 407 may be implemented as any suitable data storage device, including without limitation RAM, a hard drive, floppy disk, or writeable CD-ROM. Furthermore, sensed data and/or data output by application programs 408 may be stored to data storage device 407 as one or more databases. Accordingly, in a preferred embodiment, a user may utilize processor-based device 316, for example, to query the data collected by the central server 406 in data storage device 407. For instance, a user may utilize Standard Query Language (SQL) or may otherwise interact with an application program 408 to query data for one or more patients collected in data storage device 407. As a result, reports including data from data storage device 407 may be generated, for instance, in hypertext markup language (HTML), Dynamic hypertext markup language (DHTML), extensible markup language (XML), extensible hypertext markup language (XHTML), standard generalized markup language (SGML), or other appropriate format for displaying to the user on processor-based device 316.

Furthermore, a processor-based handheld device 308 (e.g., PDA or PSM) may be communicatively coupled to transceiver 306 and/or wireless gateway 310_A. Thus, a user may receive sensed data from transceiver 306 and/or wireless gateway 310_A, and the user may then analyze/monitor the sensed data using handheld device 308. Handheld device 308 may execute one or more application programs, such as application programs 408, to aid a user in evaluating the received sensed data information. Most preferably, handheld device 308 communicates in the same protocol in which transceiver 306 communicates to enable handheld device 308 to receive information directly from such transceiver 306. Of course, wireless gateway 310_A may be utilized to forward sensed data to handheld device 308 if, for example, handheld device 308 is not within communication range of transceiver 306.

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Additionally, handheld device 308 may provide redundancy or backup in the event of communication failure with web-based server 406. For instance, within the health care arena, a patient may have personal data (e.g., vital sign data) communicated from transceiver 306 to wireless gateway 310_A, which communicates the data to base unit 404, which communicates the data to web-based server 406. A physician, nurse, or other care giver may utilize handheld device 308 to receive sensed data for one or more patients for which such care giver is responsible in order to monitor the patients. More specifically, wireless gateway 310_A may communicate sensed data to handheld device 308 in substantially real-time. However, handheld device 308 is most preferably implemented to enable communication directly with transceiver 306, such that if a failure occurs, for example, with wireless gateway 310_A, a care giver has the ability to monitor a patient with handheld device 308. Furthermore, such a handheld device 308 may be utilized by a patient being monitored to provide information (e.g., monitoring information and/or instructions) to the patient. For example, software may execute on handheld device 308 to analyze the patient's sensed data, and provide information/instructions to the patient based on the sensed data. Additionally, a patient may receive via handheld device 308 instructions from a care giver, which the care giver may communicate, for example, from another handheld device 308 and/or via web-based server 406 using workstation 316.

Fig. 5 shows an exemplary implementation of a preferred embodiment within a hospital environment 500 for communication of sensed data within the hospital environment. As shown, platform 402 is again provided, which includes one or more sensors 403. As described in conjunction with Fig. 4, in a most preferred embodiment, platform 402 may be implemented as fabric that includes an integrated infrastructure in which sensors 403 may be implemented, and such fabric may be fashioned into a wearable garment, which may be worn by a patient to enable sensors 403 to sense personal data (e.g., vital sign data) for such patient. Also shown is transceiver 306, which is communicatively coupled to the infrastructure of platform 402 to receive sensed data from the one or more sensors 403. Thus, transceiver 306 may be integrated within the infrastructure of platform 402, or otherwise communicatively coupled to such infrastructure.

Wireless gateway 310_B is included within environment 500 to receive the sensed data from transceiver 306 and communicate such data, either directly or indirectly, to a central server, which in this exemplary implementation is again shown as web-based server

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406. More specifically, in this exemplary implementation, wireless gateway 310_B communicates the sensed data to base unit 404_A, which in turn communicates the sensed data to web-based server 406. Transceiver 306 may communicate the sensed data to wireless gateway 310_B via a first wireless protocol, and wireless gateway 310_B translates the data to a second wireless protocol that is suitable for communicating with base unit 404_A within the hospital environment 500. For instance, transceiver 306 may communicate the sensed data to wireless gateway 310_B via Bluetooth protocol, and wireless gateway 310_B may translate the data to WMTS, which is a suitable protocol for transmission within hospital environment 500. Thus, wireless gateway 310_B may communicate the sensed data to base unit 404_A using WMTS protocol, and base unit 404_A may then communicate the sensed data in a suitable protocol (e.g., Internet Protocol) to web-based server 406 via the hospital's Intranet 502 or other communication network.

In this exemplary implementation, a patient may have data sensed by sensors 403, which may, for instance, be communicatively coupled to an infrastructure of a wearable garment, and the sensed data is received from the sensors 403 at transceiver 306, which in turn transmits the sensed data using Bluetooth protocol to wireless gateway 310_B. It should be recognized that transceiver 306 may be capable of communicating the data only a limited distance, shown as D_1. For example, to save on power consumption, transceiver 306 may be capable of communicating at only a relatively short distance. Thus, for instance the distance D_1 within which transceiver 306 is capable of communicating the sensed data may be approximately 30 feet. Accordingly, wireless gateway 310_B is preferably maintained within relative close proximity of transceiver 306 to enable wireless gateway 310_B to receive the sensed data from transceiver 306. For instance, wireless gateway 310_B may be placed beside the bed of a patient within hospital 500, or the wireless gateway 310_B may be clipped to the clothing of such patient, as examples.

Wireless gateway 310_B is preferably capable of communicating at a further distance than transceiver 306, shown as distance D_2. Thus, for instance, distance D_2 within which wireless gateway transceiver is capable of communicating the sensed data may be approximately 300 feet. Accordingly, base unit 404_A is preferably maintained within range of wireless gateway 310_B (e.g., within distance D_2) to enable base unit 404_A to receive the sensed data from wireless gateway 310_B. For instance, base unit 404_A may be placed at a

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nurses station on the floor of hospital 500 on which a patient being monitored is located, as an example.

In a most preferred embodiment, wireless gateway 310_B includes the capability of communicating via a wireline protocol. For example, wireless gateway 310_B preferably includes a connector for being communicatively coupled to communication network 502 via a wireline connection 503. For example, wireless gateway 310_B may include a telephone jack connection (e.g., an RJ-11 connector) or an RJ-45 connector with a standard modem for communicating with network 502. Accordingly, wireless gateway 310_B may provide further flexibility by enabling not only wireless communication, but also wireline communication. Thus, for example, if wireless communication with base unit 404_A is interrupted (e.g., base unit 404_A fails), wireless gateway 310_B may utilize wireline connection 503 to maintain communication with central server 406.

Fig. 6 shows an exemplary implementation that enables communication of sensed data from a particular base location 600, such as a patient's home, to a central server. As shown, platform 402 including one or more sensors 403, transceiver 306, wireless gateway 310_C, and base unit 404_B may be implemented within a base location (e.g., a patient's home) 600. In this exemplary implementation, wireless gateway 310_C receives sensed data from transceiver 306 and communicates the sensed data to base unit 404_B, which in turn communicates the sensed data to web-based server 406. Thus, for example, transceiver 306 may communicate the sensed data to wireless gateway 310_C via a first wireless protocol, and wireless gateway 310_C translates the data to a second wireless protocol that is suitable for communicating with base unit 404_B within the base location (e.g., patient's home) 600. For instance, transceiver 306 may communicate the sensed data to wireless gateway 310_C via Bluetooth protocol, and wireless gateway 310_C may translate the data to 802.11, which is a suitable protocol for communication with base unit 404_B. Thus, wireless gateway 310_C may communicate the sensed data to base unit 404_B using 802.11 protocol, and base unit 404_B may then communicate the sensed data in a suitable protocol (e.g., Internet Protocol) to web-based server 406 via the Internet 602 or other communication network. As examples, base unit 404_B may access Internet 602 via a cable modem or DSL connection, or base unit 404_B may access an Internet Service Provider (ISP) 604 via an analog or ISDN dial-up modem in order to communicate the sensed data over Internet 602.

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In this exemplary implementation, a patient may have physical characteristics sensed by sensors 403, which may, for instance, be communicatively coupled to an infrastructure of a wearable garment, and the sensed data is received from the sensors 403 at transceiver 306, which in turn transmits the sensed data using Bluetooth protocol to wireless gateway 310_C. As described above, transceiver 306 may be capable of communicating the data only a limited distance D_1 (e.g., 30 feet). Accordingly, wireless gateway 310_C is preferably maintained within relative close proximity of transceiver 306 to enable wireless gateway 310_C to receive the sensed data from transceiver 306. For instance, wireless gateway 310_C may be clipped to the clothing of such patient, carried in a purse (or other handbag, such as a diaper bag), arranged within room(s) of the patient's house, or may actually be implemented within (or coupled to) handheld device 308, which the patient keeps with him/her, as examples.

Wireless gateway 310_C is preferably capable of communicating at a further distance than transceiver 306, shown as distance D_2 (e.g., 300 feet). Accordingly, base unit 404_B is preferably maintained within range of wireless gateway 310_C (e.g., within distance D_2) to enable base unit 404_B to receive the sensed data from wireless gateway 310_C. For instance, one or more base unit(s) 404_B may be strategically placed within the base location 600 to enable such one or more base unit(s) 404_B to be within communication range of wireless gateway 310_C within base location 600. For example, one or more base units 404_B may be strategically placed within a patient's home (base location 600) to enable communication between wireless gateway 310_C and base unit(s) 404_B within the patient's home. Accordingly, this exemplary implementation enables a patient to be monitored by central server 406 from the patient's home. Again, wireless gateway 310_C most preferably includes the capability of communicating via a wireline protocol. For example, wireless gateway 310_C most preferably includes a connector for being communicatively coupled to Internet 602 (or ISP 604) via a wireline connection 603 (e.g., a telephone jack connection with a standard modem for communicating with Internet 602).

Fig. 7 shows an exemplary implementation that further enables communication of sensed data from a wide area to a central server. That is, Fig. 7 shows an exemplary implementation that enables communication of sensed data from areas outside of the base location 600 (e.g., outside the patient's home). As shown, platform 402 including one or more sensors 403, transceiver 306, wireless gateway 310_D, and base unit 404_B may be

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implemented within a base location (e.g., a patient's home) 600. In this exemplary implementation, wireless gateway 310_D receives sensed data from transceiver 306 and communicates the sensed data to base unit 404_B, which in turn communicates the sensed data to web-based server 406, in the manner described above in conjunction with Fig. 6. However, in this exemplary implementation, wireless gateway 310_D is further capable of communicating sensed data to web-based server 406 from within base location 600 or outside of base location 600. More specifically, in this exemplary implementation, wireless gateway 310_D is capable of communicating via one or more cellular protocols, such as CDPD, EDGE, HDR, CDMA, or WCDMA. Thus, for example, transceiver 306 may communicate the sensed data to wireless gateway 310_D via a first wireless protocol, and wireless gateway 310_D may translate the data to a second wireless protocol that is suitable for communicating via cellular network 702, which may in turn be communicatively coupled to Internet 602 for communicating data to web-based server 406. For instance, transceiver 306 may communicate the sensed data to wireless gateway 310_D via Bluetooth protocol, and wireless gateway 310_D may translate the data to a cellular protocol for communication central server 406 via cellular network 702 (which may be communicatively coupled to Internet 602). Thus, wireless gateway 310_D may communicate the sensed data to cellular network 702 using an appropriate cellular protocol, and the cellular network may then communicate the sensed data in a suitable protocol (e.g., Internet Protocol) to web-based server 406 via the Internet 602 or other communication network. As an example, as is well-known in the art, a packet data gateway within the cellular network may be utilized to communicate the sensed data in a suitable protocol to web-based server 406.

In this exemplary implementation, a patient may have data sensed by sensors 403, which may, for instance, be communicatively coupled to an infrastructure of a wearable garment, and the sensed data is received from the sensors 403 at transceiver 306, which in turn transmits the sensed data using Bluetooth protocol to wireless gateway 310_D. As described above, transceiver 306 may be capable of communicating the data only a limited distance D_1 (e.g., 30 feet). Accordingly, wireless gateway 310_D is preferably maintained within relative close proximity of transceiver 306 to enable wireless gateway 310_D to receive the sensed data from transceiver 306. For instance, wireless gateway 310_D clipped to the clothing of such patient, carried in a purse (or other handbag, such as a diaper bag),

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or may actually be implemented within (or coupled to) handheld device 308, which the patient keeps with him/her, as examples

Because wireless gateway 310_D is capable of communicating via cellular communication in this exemplary implementation, such wireless gateway 310_D is capable of communicating at a much further distance than transceiver 306. In this implementation, if wireless gateway 310_D is within range of base unit 404_B, then base unit 404_B is preferably used to communicate with central server 406. However, if communication between base unit 404_B and wireless gateway 310_D is interrupted (e.g., wireless gateway 310_D is not within range for communication with base unit 404_B, or the communication there between is otherwise interrupted), wireless gateway 310_D may utilize cellular network 702 to communicate with central server 406, as well as other suitable third parties 703, such as a 911 operator. As will be described in greater detail hereafter, in a most preferred embodiment, wireless gateway 310_D may be implemented with an amount of intelligence for analyzing sensed data received from transceiver 306. For example, wireless gateway 310_D may be capable of recognizing critical conditions indicated by the sensed data, and may utilize cellular network 702 to contact 911, central server 406, or otherwise make an emergency call to notify appropriate personnel of the critical condition.

Turning to Fig. 8, an exemplary implementation that enables communication of sensed data within a wide area of communication is shown. In this exemplary implementation, a particular base area (e.g., a patient's home) may not be defined for a user, and a base unit is not included for use within such a particular base area, but instead a wide area communication, such as cellular communication, may be utilized for communicating sensed data to central server 406. That is, Fig. 8 shows an exemplary implementation that enables communication of sensed data within a wide area utilizing wide area communication, such as cellular communication. In this exemplary implementation, wireless gateway 310_E receives sensed data from transceiver 306 and communicates the sensed data to central server 406 via cellular network 702. More specifically, in this exemplary implementation, wireless gateway 310_E is capable of communicating via one or more cellular protocols, such as CDPD, EDGE, HDR, CDMA, or WCDMA. Thus, for example, transceiver 306 may communicate the sensed data to wireless gateway 310_E via a first wireless protocol, and wireless gateway 310_E may translate the data to a second wireless protocol that is suitable for communicating via

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cellular network 702, which may in turn be communicatively coupled to Internet 602 for communicating data to web-based server 406. For instance, transceiver 306 may communicate the sensed data to wireless gateway 310_E via Bluetooth protocol, and wireless gateway 310_E may translate the data to a cellular protocol for communication to central server 406 via cellular network 702 (which may be communicatively coupled to Internet 602). Thus, wireless gateway 310_E may communicate the sensed data to cellular network 702 using an appropriate cellular protocol, and the cellular network may then communicate the sensed data in a suitable protocol (e.g., Internet Protocol) to web-based server 406 via the Internet 602 or other communication network.

In this exemplary implementation, a patient may have physical characteristics sensed by sensors 403, which may, for instance, be communicatively coupled to an infrastructure of a wearable garment, and the sensed data is received from the sensors 403 at transceiver 306, which in turn transmits the sensed data using Bluetooth protocol to wireless gateway 310_E. As described above, transceiver 306 may be capable of communicating the data only a limited distance D_1 (e.g., 30 feet). Accordingly, wireless gateway 310_E is preferably maintained within relative close proximity of transceiver 306 to enable wireless gateway 310_E to receive the sensed data from transceiver 306. For instance, wireless gateway 310_E may be clipped to the clothing of such patient, carried in a purse (or other handbag, such as a diaper bag), or may actually be implemented within (or coupled to) handheld device 308, which the patient keeps with him/her, as examples.

Because wireless gateway 310_E is capable of communicating via cellular communication in this exemplary implementation, such wireless gateway 310_E is capable of communicating at a much further distance than transceiver 306. In this implementation, wireless gateway 310_E utilizes cellular network 702 to communicate with central server 406, as well as other suitable third parties 703, such as a 911 operator. Wireless gateway 310_E may only periodically communicate data to central server 406 via cellular network 702. For example, wireless gateway 310_E may only access central server 406 via cellular network 702 periodically or upon detection of particular conditions of the sensed data. For instance, wireless gateway 310_E may store an hour's worth of sensed data, and only access central server 406 via cellular network 702 once an hour for transmission of the data. As will be described in greater detail hereafter, in a most preferred embodiment, wireless gateway 310_E may be implemented with an amount of intelligence for analyzing sensed

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data received from transceiver 306. Accordingly, wireless gateway 310_E may be capable of recognizing critical conditions indicated by the sensed data, and may utilize cellular network 702 to contact 911, central server 406, or otherwise make an emergency call to notify appropriate personnel of the critical condition.

An exemplary implementation of transceiver 306 that may be utilized in a preferred embodiment is shown in Fig. 9. Of course, it should be recognized that any other suitable implementation of such transceiver 306 now known or later developed may be utilized, and any such implementation is intended to be within the scope of the present invention.

In a most preferred embodiment, sensed data communicated to wireless gateway 310 includes information in addition to the actual sensed data. For example, in a most preferred embodiment, the sensed data includes physical characteristic type, source identification, time stamp, and location information. Of course, additional information may also be included. The physical characteristic type information identifies the type of physical characteristic that the sensed data represents. For instance, the physical characteristic type information may identify certain sensed data as representing heart rate data and other sensed data as representing body temperature information. Source identification information identifies the source of the physical characteristic, such as a particular patient or a particular platform from which the physical characteristic was obtained. For instance, source identification information may identify a particular patient from which the sensed data was obtained, such as the patient's name, social security number, or other identifier. Such source identification may further include contact information for quickly reaching the source, such as a patient's room number within a hospital, a patient's address, and the patient's telephone number. Time stamp information identifies the specific date and time at which the sensed data was actually obtained. Location information identifies the location of the source of such sensed data. For instance, location information may identify the exact location (e.g., address) at which a patient is located at the time of obtaining the sensed data (e.g., such information may be acquired using a global positioning system for instance).

In a preferred embodiment, data may be temporarily stored in any suitable data storage device, such as a hard drive, floppy disk, or writeable CD-ROM, that is communicatively coupled to wireless gateway 310, and wireless gateway 310 may periodically communicate such data to the central server. Thus, wireless gateway 310 may

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not be required to maintain a constant communication connection with the central server, but may instead only periodically establish such a connection to communicate the data. Furthermore, as described in greater detail in concurrently filed and commonly assigned U.S. Patent Application Serial Number 09/676,382 entitled "WIRELESS GATEWAY CAPABLE OF COMMUNICATING ACCORDING TO A PLURALITY OF PROTOCOLS," the disclosure of which is hereby incorporated herein by reference, wireless gateway 310 of a most preferred embodiment may be capable of performing at least a limited amount of analysis of the sensed data. Accordingly, wireless gateway 310 may, based on the sensed data, determine that communication with the central server (or an appropriate third party) should be initiated. For example, wireless gateway 310 may determine that heart rate data it receives is at a critical (or dangerous) level or is otherwise abnormal, and may in response to receiving such data initiate communication with the central server to immediately communicate the data to such central server in order to alert a monitoring care giver. Alternatively (or in addition thereto), wireless gateway 310 may initiate a call to 911 (or other emergency personnel) to request immediate medical attention for the monitored patient. As described above, the data most preferably includes information identifying the monitored patients name, location (e.g., address), and other information, which wireless gateway 310 may use to properly notify emergency personnel of the situation.

Furthermore, in a preferred embodiment, wireless gateway 310 may determine an appropriate communication method or protocol to use based on the sensed data. For example, in the exemplary implementation of Fig. 7, wireless gateway 310_D may based upon the sensed data determine to use either protocol 802.11 (or other suitable protocol) to communicate to central server 406 via base unit 404_B or cellular network 702 to communicate to central server 406 or a suitable third party 703. For instance, wireless gateway 310_D may receive heart rate data, and upon determining that the heart rate data is not at a critical or otherwise abnormal level, wireless gateway 310_D may communicate the sensed data to central server 406 via base unit 404_B. On the other hand, wireless gateway 310_D may determine that heart rate data it receives is at a critical (or dangerous) level or is otherwise abnormal, and may in response to receiving such data initiate communication with central server 406 or a third party 703 via cellular network 702 (or via a wireline network, such as PSTN). Additionally, if no communication path is available, wireless

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gateway 310 may be implemented to sound an audible alarm and/or present a visual alarm (e.g., on a display that may be implemented within such wireless gateway 310).

While the various embodiments have been described above as being implemented within the health care arena (e.g., for communicating vital sign data from a patient to a central server), it should be understood that the present invention may be implemented in various other arenas. As one example, a preferred embodiment may be implemented to enable communication of sensed data (e.g., temperature data) to a temperature control system or air conditioning system (central server) responsible for controlling the temperature of a particular facility. As another example, a preferred embodiment may be implemented within a robot to detect hazardous conditions in an environment and communicate the sensed data acquired in such an environment to a central server.

Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

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WHAT IS CLAIMED IS:

1. A system for communicating data to a central server for processing thereon, said system comprising:

at least one sensor, each of said at least one sensor for sensing a physical characteristic and outputting data representing said physical characteristic to a transmitter;

said transmitter for communicating said data via a first wireless protocol to a wireless gateway;

said wireless gateway for translating said data from said first wireless protocol to at least a second wireless protocol and for communicating said data either directly or indirectly to a central server via said at least a second wireless protocol; and

said central server for receiving said data and processing said data.

2. The system of claim 1 further comprising:

at least one platform on which one or more of said at least one sensor is coupled.

3. The system of claim 2 wherein said at least one platform comprises fabric having an information infrastructure integrated therein.

4. The system of claim 3 wherein said fabric is fashioned into a wearable garment.

5. The system of claim 2 wherein said at least one platform provides an information infrastructure to which said at least one sensor can be removably coupled.

6. The system of claim 2 wherein said at least one platform provides an information infrastructure to which said at least one sensor is permanently coupled.

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7. The system of claim 1 wherein said transmitter is a transceiver that is further capable of receiving data.

8. The system of claim 1 wherein said central server comprises a plurality of processor-based devices communicatively coupled together.

9. The system of claim 1 wherein said central server is a web-based server.

10. The system of claim 1 further comprising:

at least one intermediary for receiving data from said wireless gateway and communicating said data to said central server.

11. The system of claim 10 wherein said at least one intermediary receives said data from said wireless gateway in said at least a second wireless protocol, and wherein said at least one intermediary communicates said data to said central server in a protocol different from said at least a second wireless protocol.

12. The system of claim 11 wherein said at least a second wireless protocol is selected from the group consisting of WLAN, infrared, PAN, and cellular protocol.

13. The system of claim 11 wherein said WLAN protocol includes 802.11 and WMTS protocol.

14. The system of claim 11 wherein said at least one intermediary communicates said data to said central server using a wireline protocol.

15. The system of claim 11 wherein said at least one intermediary communicates said data to said central server using Internet Protocol.

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16. The system of claim 10 herein said at least one intermediary communicates said data to said central server via a communication network.

17. The system of claim 16 wherein said communication network is selected from the group consisting of:

public switched telephone network (PSTN), wireless communication network, general purpose processor-based information network, dedicated communication lines, cable system, digital subscriber line (DSL), direct PC to PC connection, local area network (LAN), wide area network (WAN), modem to modem connection, the Internet, an Intranet, an Extranet, or any combination thereof suitable for providing information communication between said at least one intermediary and said central server.

18. The system of claim 10 wherein said intermediary comprises a processor-based device.

19. The system of claim 10 wherein said intermediary comprises a device selected from the group consisting of:

base unit and a packet data gateway within a cellular network.

20. The system of claim 1 wherein said physical characteristic is selected from the group consisting of vital sign characteristic and environmental characteristic.

21. The system of claim 20 wherein said vital sign characteristic includes heart rate, breathing rate, blood pressure, pulse, body temperature, and blood oxygen level.

22. The system of claim 20 wherein said environmental characteristic includes temperature, audio, atmospheric smoke and oxygen levels, gas level, light level, air flow, and radiation level.

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23. The system of claim 1 wherein said data includes information selected from the group consisting of:

physical characteristic type, source identification, time stamp, and location information.

24. The system of claim 1 further comprising:

at least one handheld device arranged to receive said data from at least one of said transmitter, said wireless gateway, and said central server.

25. The system of claim 1 further comprising:

at least one software program executing on said central server for interpreting said data to enable a user to monitor said physical characteristic.

26. The system of claim 1 wherein said first wireless protocol and said at least a second wireless protocol are selected from the group consisting of: short-range radio protocols, WLAN protocols, infrared, PAN protocols, and cellular protocols.

27. The system of claim 26 wherein said short-range radio protocols include Bluetooth protocol, said WLAN protocols include 802.11 and wireless medical transmission standard (WMTS) protocols, and said cellular protocols include CDPD, EDGE, HDR, CDMA, and WCDMA protocols.

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28. A method for communicating data to a central server for processing thereon, said method comprising:

sensing at least one physical characteristic;

generating data representing said at least one physical characteristic;

communicating said data in a first wireless protocol to a wireless gateway;

translating by said wireless gateway from said first wireless protocol to at least a second wireless protocol; and

communicating said data from said wireless gateway to a central server via a communication path, wherein at least a portion of said communication path is in said at least a second wireless protocol.

29. The method of claim 28 further comprising:

using at least one sensor to perform said sensing and said generating steps.

30. The method of claim 29 further comprising:

communicatively coupling said at least one sensor to at least one platform.

31. The method of claim 30 wherein said at least one platform comprises fabric having an information infrastructure integrated therein.

32. The method of claim 31 wherein said fabric is fashioned into a wearable garment.

33. The method of claim 30 wherein said communicatively coupling includes removably coupling said at least one sensor to said at least one platform.

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34. The method of claim 28 further comprising:

using a transmitter to perform said communicating said data to said wireless gateway.

35. The method of claim 28 further comprising:

using a transceiver to perform said communicating said data to said wireless gateway.

36. The method of claim 35 further comprising:

receiving data from said wireless gateway at said transceiver.

37 . The method of claim 28 wherein said central server comprises a plurality of processor-based devices communicatively coupled together.

38 . The method of claim 28 wherein said central server is a web-based server.

39 . The method of claim 28 wherein said communicating said data from said wireless gateway to said central server via a communication path further comprises:

communicating said data from said wireless gateway to at least one intermediary; and

communicating said data from said at least one intermediary to said central server.

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40. The method of claim 39 further comprising:

communicating said data from said wireless gateway to said at least one intermediary in said at least a second wireless protocol; and

communicating said data from said at least one intermediary to said central server in a protocol different from said at least a second wireless protocol.

41. The method of claim 40 wherein said at least a second wireless protocol is selected from the group consisting of WLAN, infrared, PAN, WLAN, and cellular protocol.

42. The method of claim 40 wherein said protocol different from said at least a second wireless protocol is a wireline protocol.

43. The method of claim 40 wherein said protocol different from said at least a second wireless protocol is Internet Protocol.

44. The method of claim 39 further comprising:

said at least one intermediary communicating said data to said central server via a communication network.

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45. The method of claim 44 wherein said communication network is selected from the group consisting of:

public switched telephone network (PSTN), wireless communication network, general purpose processor-based information network, dedicated communication lines, cable system, digital subscriber line (DSL), direct PC to PC connection, local area network (LAN), wide area network (WAN), modem to modem connection, the Internet, an Intranet, an Extranet, or any combination thereof suitable for providing information communication between said at least one intermediary and said central server.

46. The system of claim 39 wherein said at least one intermediary comprises a processor-based device.

47. The method of claim 39 wherein said at least one intermediary comprises a device selected from the group consisting of:

base unit and a packet data gateway within a cellular network.

48. The method of claim 28 wherein said at least one physical characteristic is a characteristic selected from the group consisting of vital sign characteristic and environmental characteristic.

49. The method of claim 48 wherein said vital sign characteristic includes heart rate, breathing rate, blood pressure, pulse, body temperature, and blood oxygen level.

50. The method of claim 48 wherein said environmental characteristic includes temperature, audio, atmospheric smoke and oxygen levels, gas level, light level, air flow, and radiation level.

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51. The method of claim 28 wherein said communicating said data from said wireless gateway to said central server via a communication path comprises:

periodically communicating said data from said wireless gateway to said central server.

52. The method of claim 51 further comprising:

storing said data to a data storage device communicatively coupled to said wireless gateway until said data is communicated from said wireless gateway to said central server.

53. The method of claim 28 further comprising:

determining from said data whether to immediately communicate said data to said central server; and

upon determining to immediately communicate said data, performing said step of communicating said data from said wireless gateway to said central server.

54. The method of claim 53 wherein said determining step comprises:

determining that said data represents a critical physical characteristic.

55. The method of claim 53 wherein said determining step comprises:

determining an abnormality in said data.

56. The method of claim 53 further comprising:

performing said determining step by said wireless gateway.

57. The method of claim 28 further comprising:

selecting said at least a second wireless protocol from a plurality of wireless protocols.

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58. The method of claim 57 further comprising:

performing said selecting step by said wireless gateway.

59. The method of claim 57 wherein said selecting step further comprises:

selecting a wireless protocol that is available for communicating with said central server.

60. The method of claim 57 wherein said selecting step further comprises:

selecting a wireless protocol based on said data.

61. The method of claim 60 wherein said selecting step further comprises:

selecting one wireless protocol if determined that said data represents a critical physical characteristic, and selecting a different wireless protocol if determined that said data represents a non-critical physical characteristic.

62. The method of claim 28 wherein said first wireless protocol and said at least a second wireless protocol are selected from the group consisting of: short-range radio protocols, WLAN protocols, infrared, PAN protocols, and cellular protocols.

63. The method of claim 62 wherein said short-range radio protocols include Bluetooth protocol, said WLAN protocols include 802.11 and wireless medical transmission standard (WMTS) protocols, and said cellular protocols include CDPD, EDGE, HDR, CDMA, and WCDMA protocols.

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64. A system for sensing at least one physical characteristic and communicating data representing said at least one physical characteristic to a central server for processing thereon, said system comprising:

at least one sensor for sensing at least one physical characteristic and outputting data representing said at least one physical characteristic to at least one wireless communication device;

said at least one wireless communication device arranged to communicate said data in at least a first wireless protocol to a wireless gateway that is operable to communicate in a plurality of wireless protocols;

said wireless gateway for translating said data from said first wireless protocol to at least a second wireless protocol and for communicating said data to a central server via a communication path, wherein for at least a portion of said communication path said data is in said at least a second wireless protocol; and

said central server for receiving said data and processing said data.

65. The system of claim 64 further comprising:

at least one platform on which one or more of said at least one sensor is coupled.

66. The system of claim 65 wherein said at least one platform comprises fabric having an information infrastructure integrated therein.

67. The system of claim 66 wherein said fabric is fashioned into a wearable garment.

68. The system of claim 65 wherein said at least one platform provides an information infrastructure to which said at least one sensor can be removably coupled.

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69. The system of claim 65 wherein said at least one platform provides an information infrastructure to which said at least one sensor is permanently coupled.

70. The system of claim 64 wherein said at least one wireless communication device is a transmitter.

71. The system of claim 64 wherein said at least one wireless communication device is a transceiver that is further capable of receiving data.

72. The system of claim 64 wherein said central server comprises a plurality of processor-based devices communicatively coupled together.

73. The system of claim 64 wherein said central server is a web-based server.

74. The system of claim 64 further comprising:

at least one intermediary for receiving data from said wireless gateway and communicating said data to said central server.

75. The system of claim 74 wherein said at least one intermediary is arranged to receive said data from said wireless gateway in said at least a second wireless protocol and communicate said data to said central server in a protocol different from said at least a second wireless protocol.

76. The system of claim 75 wherein said at least a second wireless protocol is selected from the group consisting of WLAN, infrared, PAN, and cellular protocol.

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77. The system of claim 75 wherein said at least one intermediary communicates said data to said central server using a wireline protocol.

78. The system of claim 75 wherein said at least one intermediary communicates said data to said central server using Internet Protocol.

79. The system of claim 74 wherein said at least one intermediary communicates said data to said central server via a communication network.

80. The system of claim 79 wherein said communication network is selected from the group consisting of:

public switched telephone network (PSTN), wireless communication network, general purpose processor-based information network, dedicated communication lines, cable system, digital subscriber line (DSL), direct PC to PC connection, local area network (LAN), wide area network (WAN), modem to modem connection, the Internet, an Intranet, an Extranet, or any combination thereof suitable for providing information communication between said at least one intermediary and said central server.

81. The system of claim 74 wherein said at least one intermediary comprises a processor-based device.

82. The system of claim 74 wherein said at least one intermediary comprises a device selected from the group consisting of:

base unit and a packet data gateway within a cellular network.

83. The system of claim 64 wherein said at least one physical characteristic includes a characteristic selected from the group consisting of vital sign characteristic and environmental characteristic.

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84. The system of claim 83 wherein said vital sign characteristic includes heart rate, breathing rate, blood pressure, pulse, body temperature, and blood oxygen level.

85. The system of claim 83 wherein said environmental characteristic includes temperature, audio, atmospheric smoke and oxygen levels, gas level, light level, air flow, and radiation level.

86. The system of claim 64 wherein said at least a first wireless protocol and said at least a second wireless protocol are selected from the group consisting of: short-range radio protocols, WLAN protocols, infrared, PAN protocols, and cellular protocols.

87. The system of claim 86 wherein said short-range radio protocols include Bluetooth protocol, said WLAN protocols include 802.11 and wireless medical transmission standard (WMTS) protocols, and said cellular protocols include CDPD, EDGE, HDR, CDMA, and WCDMA protocols.

FIG. 1
(PRIOR ART)

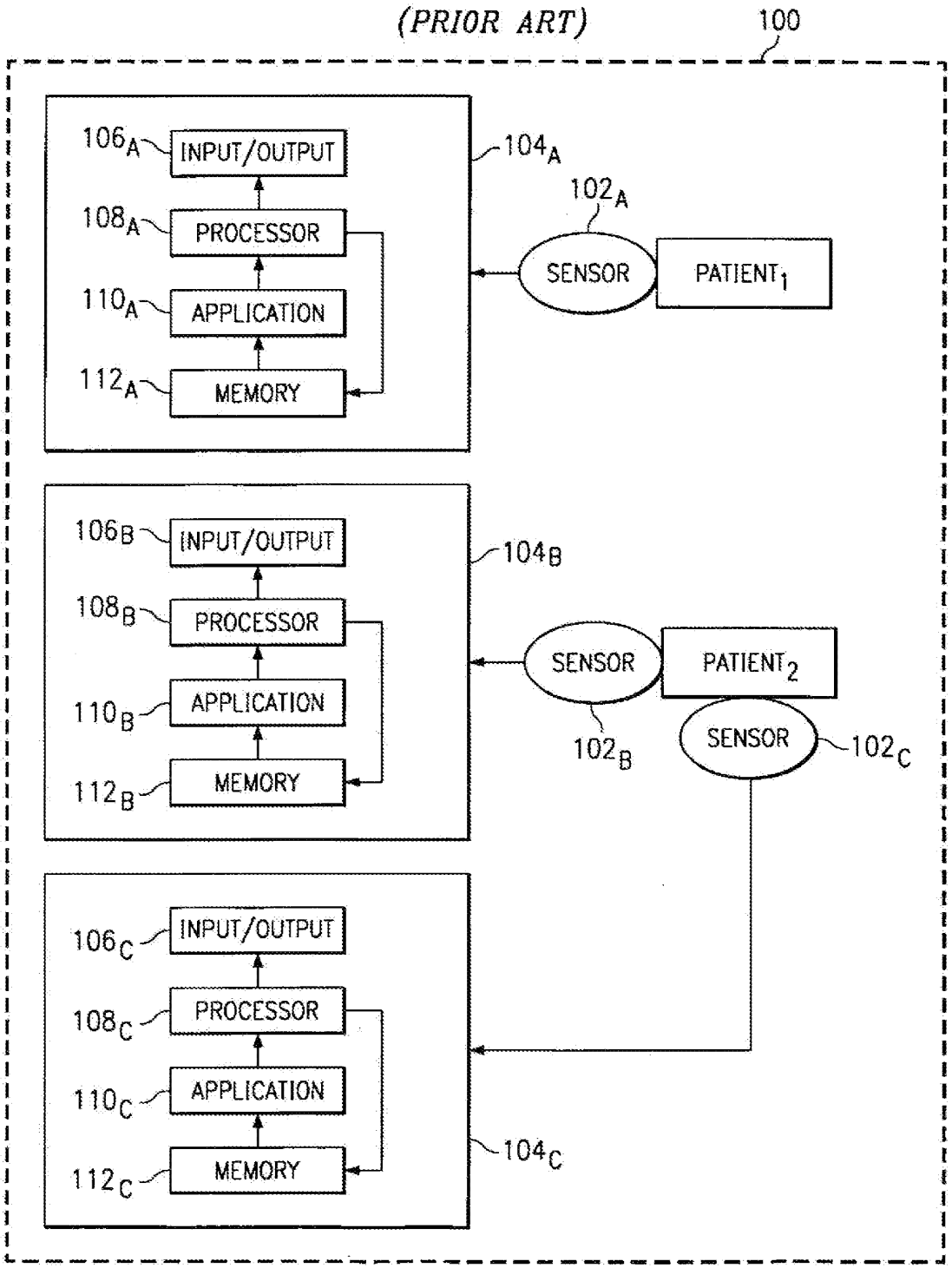


FIG. 2
(PRIOR ART)

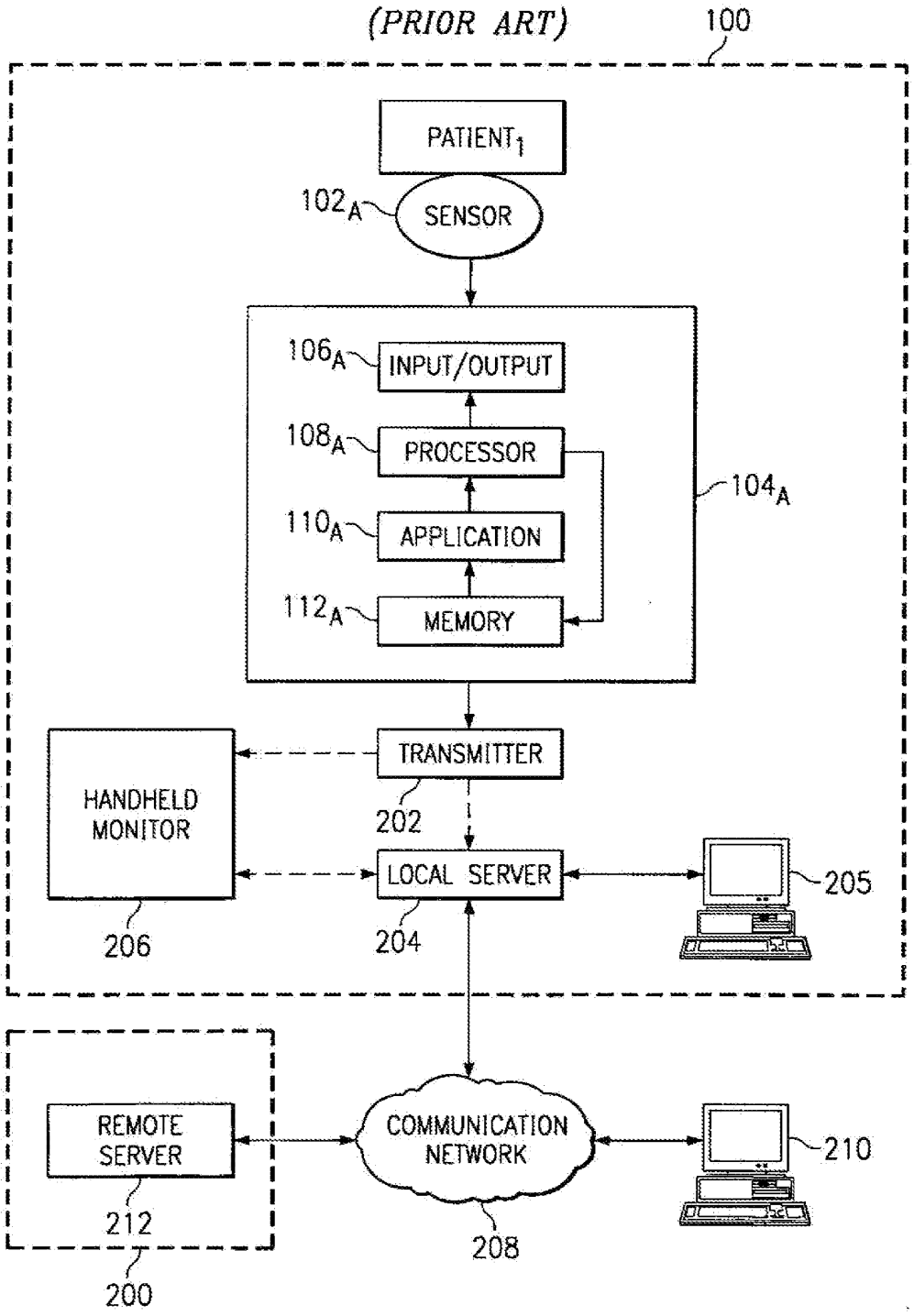


FIG. 3

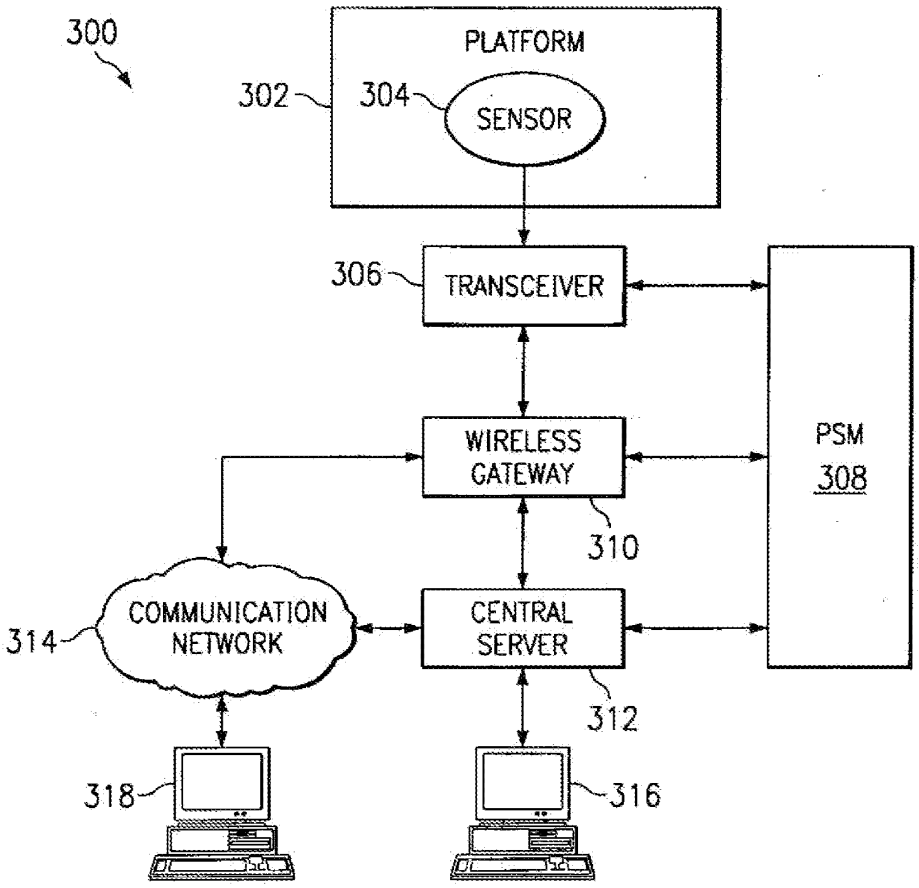

300
PLATFORM
302
304
SENSOR
306
TRANSCEIVER
WIRELESS GATEWAY
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PSM
308
COMMUNICATION NETWORK
314
CENTRAL SERVER
312
318
316

FIG. 4

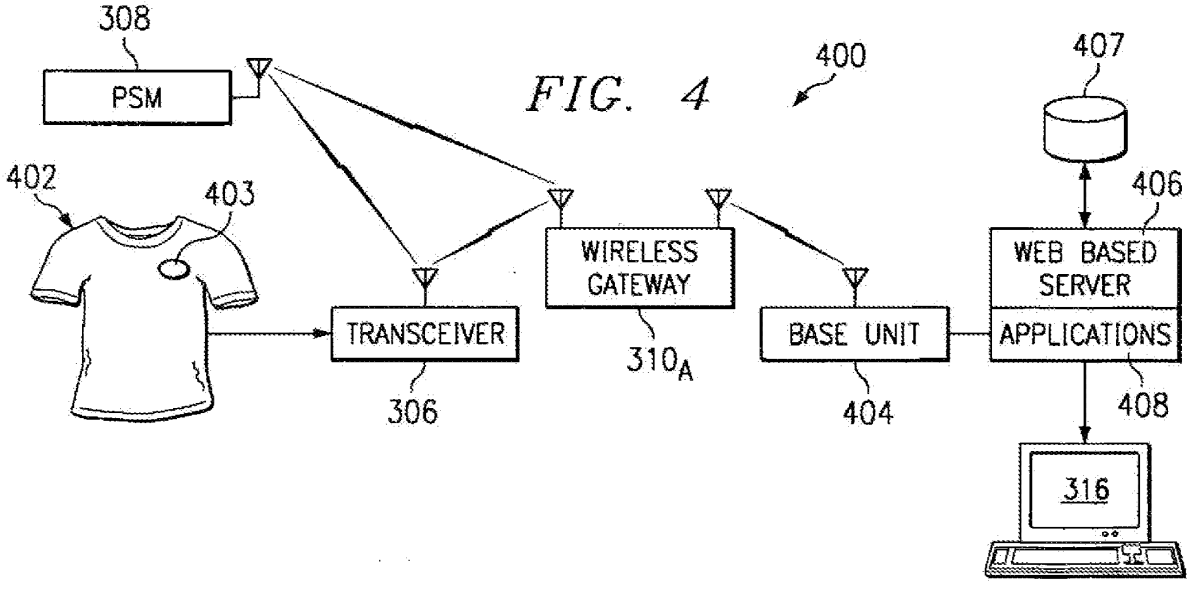

308
PSM
400
407
402
403
406
WIRELESS GATEWAY
WEB BASED SERVER
TRANSCEIVER
BASE UNIT
APPLICATIONS
310A
306
404
408
316

FIG. 5

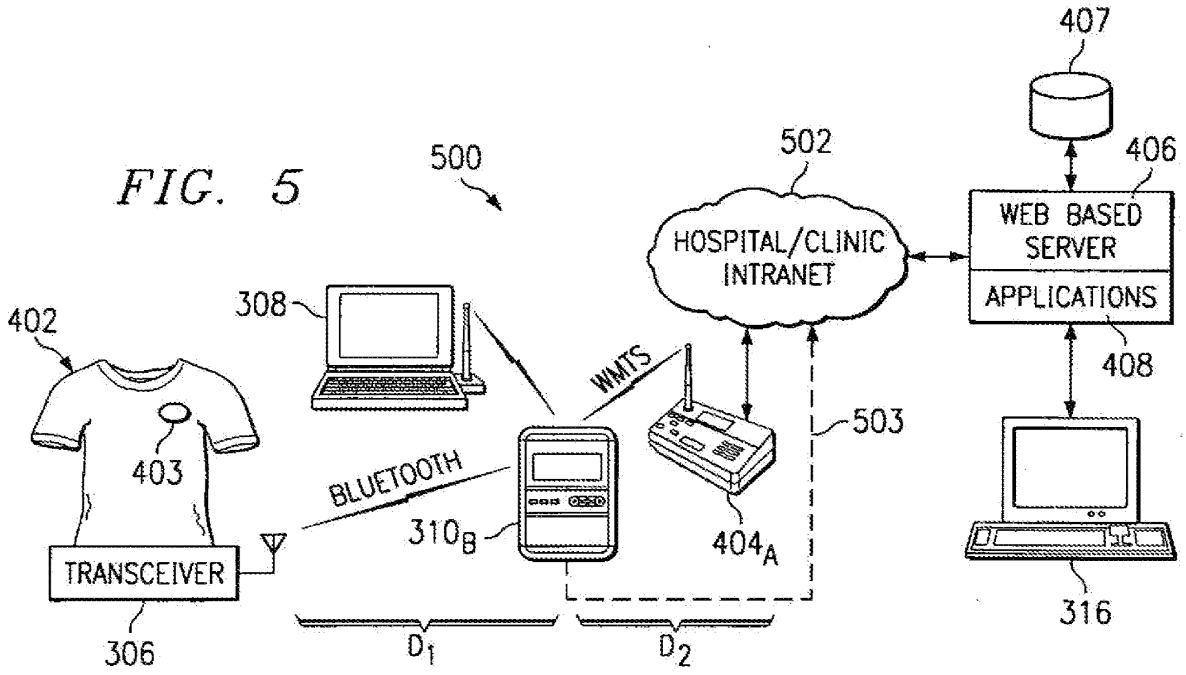

500
502
407
406
HOSPITAL/CLINIC INTRANET
WEB BASED SERVER
APPLICATIONS
408
308
402
WMTS
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403
BLUETOOTH
310_B
404_A
TRANSCEIVER
306
D_1
D_2
316

FIG. 6

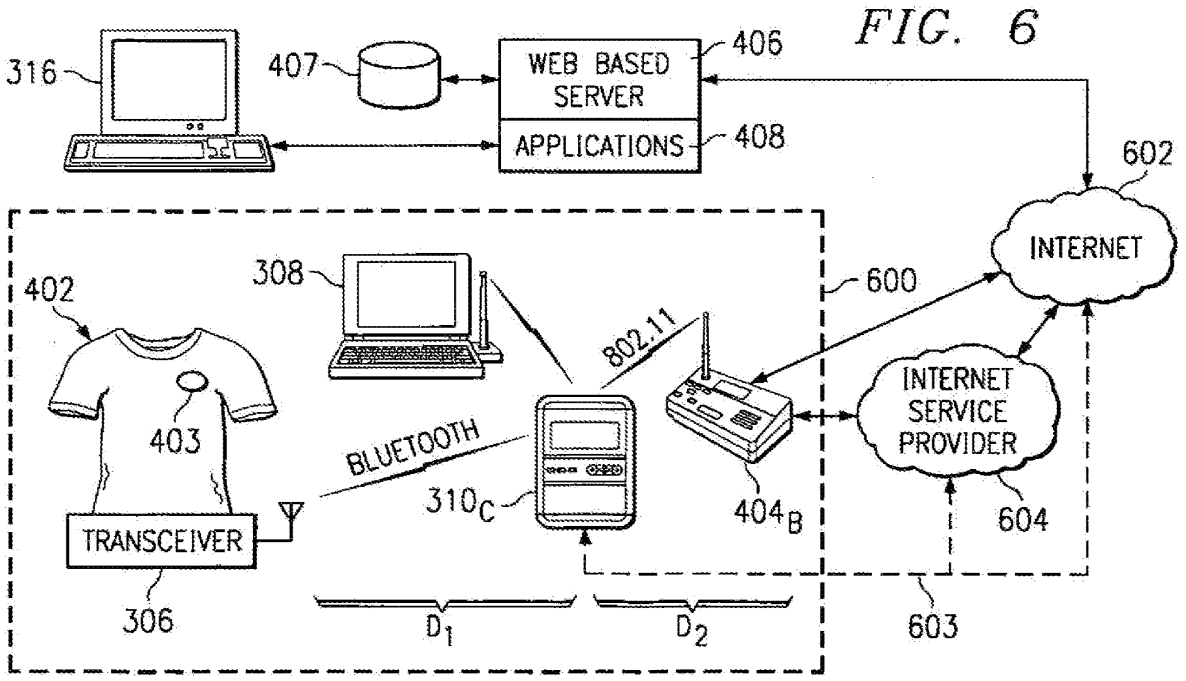

316
407
WEB BASED SERVER
406
APPLICATIONS
408
602
INTERNET
600
308
402
802.11
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BLUETOOTH
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604
TRANSCEIVER
306
D_1
D_2
603

FIG. 7

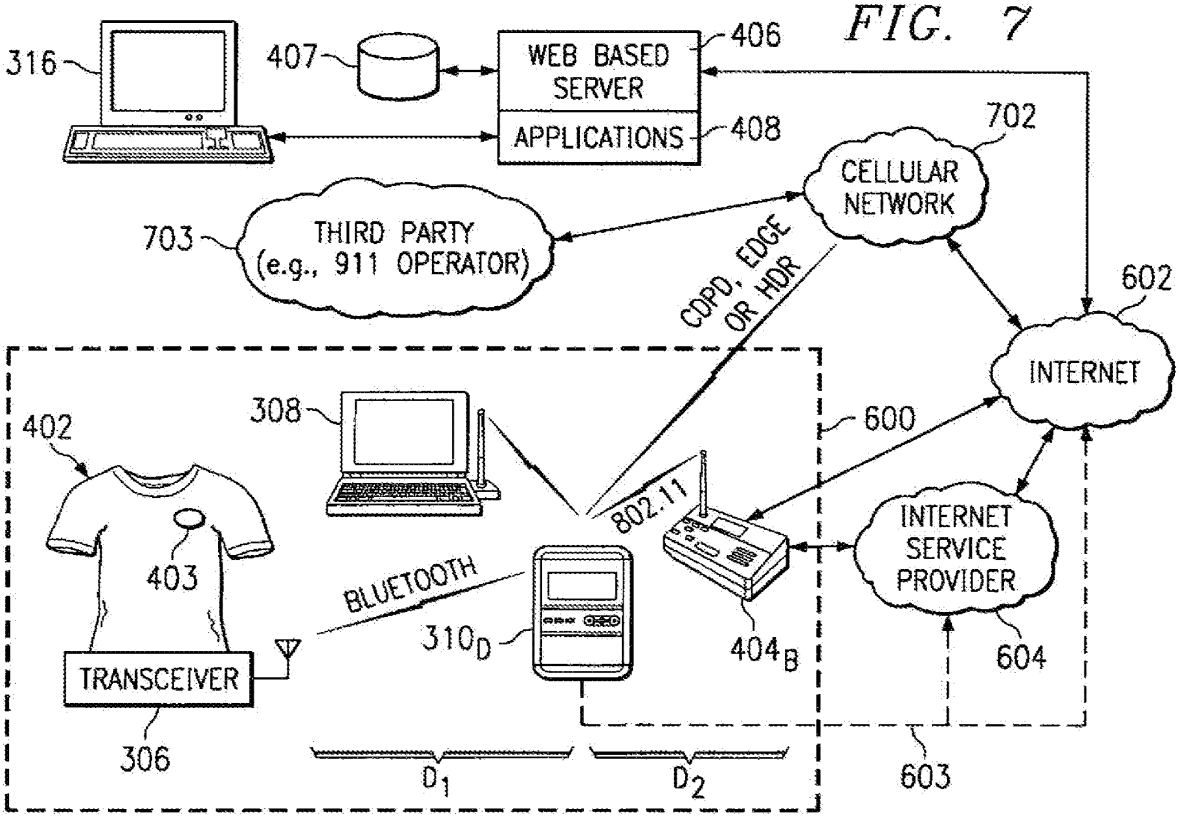
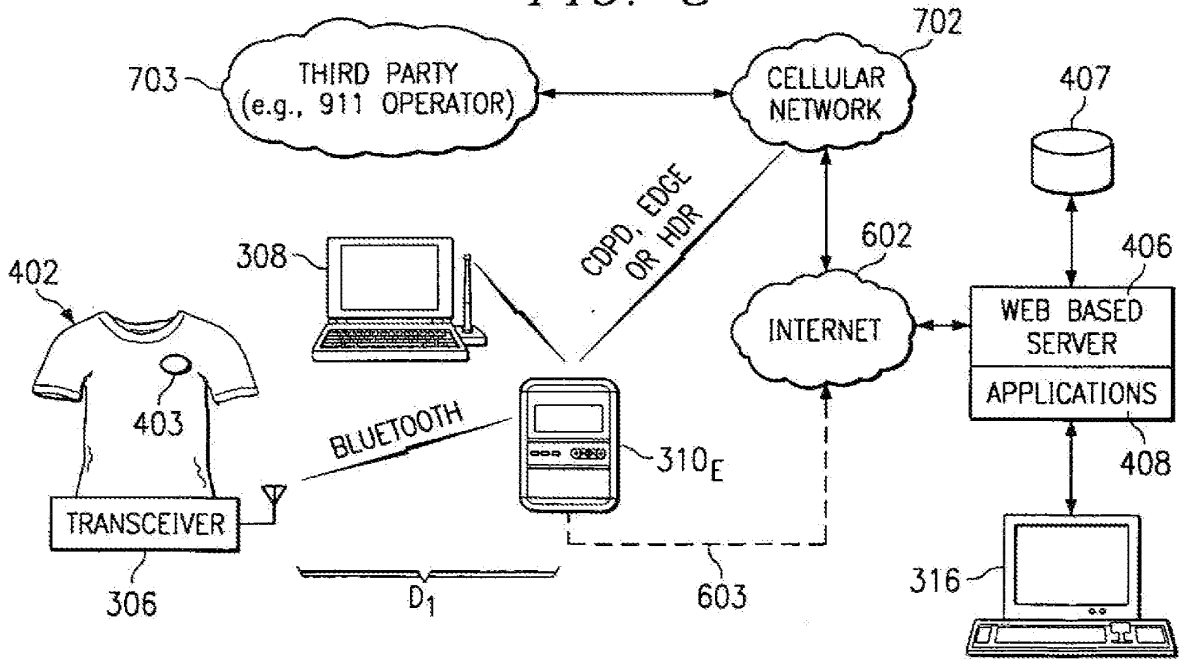

316
407
WEB BASED SERVER
406
APPLICATIONS
408
702
CELLULAR NETWORK
703
THIRD PARTY (e.g., 911 OPERATOR)
CDPD, EDGE OR HDR
602
INTERNET
308
402
600
802.11
403
BLUETOOTH
INTERNET SERVICE PROVIDER
310_D
404_B
604
TRANSCEIVER
306
D_1
D_2
603

FIG. 8


703
THIRD PARTY (e.g., 911 OPERATOR)
702
CELLULAR NETWORK
407
CDPD, EDGE OR HDR
602
406
308
402
INTERNET
WEB BASED SERVER
APPLICATIONS
403
BLUETOOTH
310_E
408
TRANSCEIVER
316
306
D_1
603

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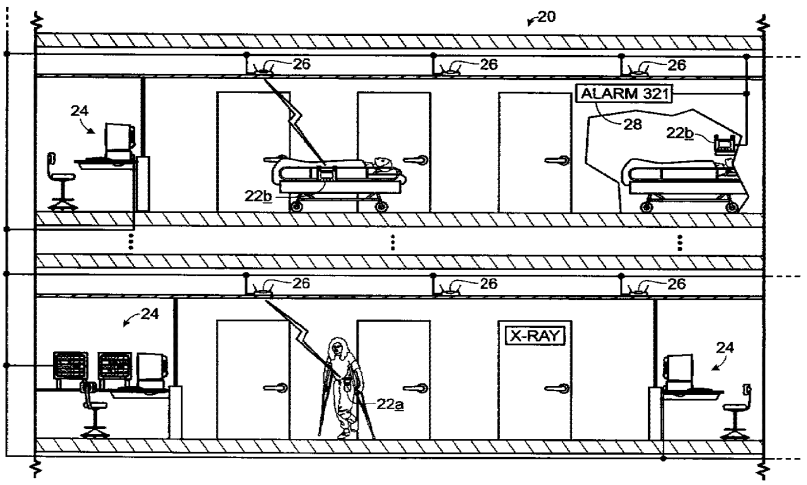
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[Continued on next page]

(54) Title: PATIENT MONITORING SYSTEM



(57) Abstract: A wireless patient monitor is adapted to communicate with any one of plural medical telemetry networks, each having one or more central stations, where each network is configured to communicate via wireless communications using one of multiple different communications settings. The monitor includes one or more sensor inputs for receiving vital signs data from a patient, a wireless transceiver; and a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver. The monitor also includes a display device and is controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station. There is also a method of monitoring a patient and a wireless medical telemetry system.

WO 01/89362 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PATIENT MONITORING SYSTEM

Cross-Reference to Related Applications

This application claims priority to U.S. Provisional Patent Application Serial No. 60/205,412, filed May 19, 2000 and entitled PATIENT MONITORING SYSTEM. The subject matter of this application is incorporated herein by this reference.

Field of the Invention

The present invention relates generally to monitoring the vital signs of one or more patients, and more particularly to a system and method for monitoring patients via wireless communications.

Background

Devices for measuring various physiological parameters, or "vital signs," of a patient such as temperature, blood pressure, heart rate, heart activity, etc., have been a standard part of medical care for many years. Indeed, the vital signs of some patients (e.g., those undergoing relatively moderate to high levels of care) typically are measured on a substantially continuous basis to enable physicians, nurses and other health care providers to detect sudden changes in a patient's condition and evaluate a patient's condition over an extended period of time. However, since most hospitals and other medical facilities care for numerous patients assigned to numerous different rooms, it can be difficult for a finite number of clinicians to monitor multiple patients on a continuous basis. In an effort to alleviate this problem, some medical monitoring systems have been developed to enable the vital signs data collected from patients to be conveyed to a central location, thereby allowing one or a few clinicians to simultaneously monitor multiple patients in different locations. However, many of

such prior systems have not allowed the monitored patients to move about the hospital. Although a few "mobile" monitoring systems have been attempted, such systems are difficult to use and prone to failure resulting in the loss of a patient's vital signs data.

Summary

A wireless patient monitor is adapted to communicate with any one of plural medical telemetry networks, each having one or more central stations, where each network is configured to communicate via wireless communications using one of multiple different communications settings. The monitor includes one or more sensor inputs for receiving vital signs data from a patient, a wireless transceiver configured to transmit and receive wireless communications; and a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver. The controller is configured, upon initial power-up, to automatically transmit a signal to a local one of the plural networks via the transceiver to request the communications settings used by the local network, and to establish communications with at least one of the central stations on the local network using the communications settings received from the local network without intervention from a user of the patient monitor.

Another version of the invention is a wireless, patient vital signs monitor adapted to communicate with a medical telemetry network having at least one central station. The monitor includes one or more sensor input ports for receiving patient vital signs data, a controller coupled to receive the vital signs data via the one or more input ports, and a wireless transceiver controllable by the controller to communicate

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with the at least one central station. The controller is configured, when not in communication with the at least one central station, to repeatedly attempt to establish communications with the at least one central station via the wireless transceiver. A display device is also included and is controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station.

Yet other versions of the invention include a wireless, patient vital signs monitor, a method of monitoring a patient and a wireless medical telemetry system. The advantages of the present invention will be understood more readily after a consideration of the drawings and the Detailed Description.

Brief Description of the Drawings

Fig. 1 is a fragmentary, schematic illustration of an exemplary medical telemetry network according to the present invention in the context of a hospital.

Fig. 2 is a fragmentary, schematic diagram of a system for monitoring a plurality of patients in accordance with the present invention.

Fig. 3 is a front elevation view of an exemplary central monitoring station according to the present invention.

Fig. 4 is a schematic diagram of an exemplary system for monitoring patients according to the present invention.

Fig. 5 is a front isometric view of an exemplary patient monitor according to the present invention.

Fig. 6 is a front isometric view of another exemplary patient monitor according to the present invention.

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Fig. 7 is a schematic, functional block diagram of an exemplary patient monitor according to the present invention.

Fig. 8 is an exemplary image for display on a display screen according to the present invention.

Fig. 9 is similar to the image of Fig. 8 but modified to include a message region for display on a display screen according to the present invention.

Fig. 10 is similar to the image of Fig. 8 but modified to include a user-interface for display on a display screen according to the present invention.

Fig. 11 is a flowchart illustrating an exemplary rendezvous process according to the present invention.

Fig. 12 is a flowchart illustrating an exemplary communications configuration process according to the present invention.

Fig. 13 is an exemplary image for display on a display screen, and including a user-interface operable to select a primary central station in accordance with the present invention.

Fig. 14 is an exemplary image for display on a display screen, and including a user-interface operable to confirm a monitoring configuration in accordance with the present invention.

Fig. 15 is an exemplary image for display on a display screen, and including a user-interface operable to identify a patient being monitored in accordance with the present invention.

Fig. 16 is an exemplary image for display on a display screen, and including a user-interface operable to select a primary central station in accordance with the present invention.

Fig. 17 is an exemplary image for display on a display screen, and including a user-interface operable to change alarm condition parameters in accordance with the present invention.

Fig. 18 is an exemplary image representing ECG data from a single electrode for display on a display screen according to the present invention.

Fig. 19 is an exemplary image representing ECG data from plural electrodes for display on a display screen according to the present invention.

Fig. 20 is an exemplary image indicating an alarm condition for display on a display screen according to the present invention.

Fig. 21 is a schematic illustration of a system for monitoring a patient at plural central stations according to the present invention.

Fig. 22 is a flowchart diagram of an exemplary method for monitoring a patient at a central location in accordance with the present invention.

Fig. 23 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

Fig. 24 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

Fig. 25 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

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Fig. 26 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

Detailed Description

From an overview, and as will be described in detail below, a system and method for monitoring patients is described that affords communication between plural patient monitors and plural central monitoring stations. The system and method is designed to allow the patient monitors to communicate with the central monitoring stations by using any known communication connection (such as to-be-described access points) located anywhere using any known communications technology (such as the IEEE 802.11 standard for wireless communication) that provides a communication channel. The to-be-described system and method also makes it possible for a clinician to view patient data on a display component of the patient monitor via any known communication channel such as the Internet. For example, the clinician could view patient data using known web browsers.

The to-be described system and method also includes a so-called "rendezvous process" of establishing communications with one or more central stations. As will be shown in connection with the description of Fig. 11, the rendezvous process may be carried out in any of a variety of different ways, and may vary depending on whether wireless or wired communications are used, as well as on whether the patient monitor is establishing a new communications connection or reestablishing prior communications which were lost or terminated.

The patient monitors of the to-be-described system are also constructed to function both as part of a network of patient monitors and central stations, as well as stand-alone patient monitors.

Turning now to details, a system for monitoring patients according to the present invention is indicated generally at 20 in Fig 1. System 20 includes one or more patient monitors 22, each adapted to collect vital signs data from a patient. System 20 also includes one or more central monitoring stations 24 adapted to communicate with the patient monitors and receive, process and store the vital signs data. Thus, physicians, nurses and other health-care personnel (hereinafter referred to collectively as clinicians) are able to monitor a plurality of patients simultaneously and continuously from one or more central locations. As will be described in more detail below, patient monitors 22 and central stations 24 are coupled to communicate using wireless transmissions within a medical telemetry network, thereby allowing a patient to move about inside or outside a monitoring facility without loss of central monitoring.

In the exemplary embodiments shown and described herein, system 20 is configured for use in a hospital. However, it will be appreciated that system 20 also may be used in a variety of other environments including: (i) other types of medical facilities, research facilities, senior-care facilities, hospices, field hospitals, etc.; and (ii) types of non-medical facilities and environments such as patient residences, retail stores, or patient locations outdoors. Therefore, it will be understood that the description herein encompasses medical telemetry systems for use in all such environments.

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System 20 may be configured to provide patient monitoring within selected regions of a facility or throughout the facility. In the exemplary embodiment depicted in Fig. 1, system 20 is configured with patient monitors and central stations on multiple floors of a hospital. System 20 includes one or more wireless transceivers 26 disposed within the facility and configured to communicate with patient monitors 22 via wireless transmissions. The wireless transceivers are configured to convey communications between the patient monitors and the central stations. As a result, centralized patient monitoring will extend wherever wireless transceivers 26 are disposed within a facility.

Transceivers 26 may be also be characterized as transmitter/receivers 26, i.e. any device capable of transmitting and sending communication signals, whether it be a device operable for a wired application or a device operable for a wireless application. However, for purposes of the remainder of the description of the exemplary embodiment, the term transceivers will be used to describe for the wireless application being described.

Each floor may include a single central station (as shown on the upper floor in Fig. 1) or plural central stations (as shown on the lower floor). Alternatively, a single central station may be configured to monitor patients on multiple floors. In many hospitals, central stations 24 are assigned to sections within the hospital that perform different functions rather than to particular floors. For example, one or more central stations may be configured to monitor patients admitted to the Intensive Care Ward, one or more different central stations may be configured to monitor patients admitted to the Emergency Room, while one or more other central stations may be configured

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to monitor patients admitted to the Maternity Ward, etc. Regardless of how the central stations are arranged or assigned, system 20 may be configured to allow any patient monitor 22 to be monitored by any central station 24.

In addition to allowing multiple remote patients to be monitored at a central location, system 20 may also be configured to allow clinicians to view information about a patient's condition from various locations inside and/or outside the hospital. For example, in the embodiment depicted in Fig. 1, system 20 includes one or more annunciating devices 28, each having a display adapted to identify a particular patient (e.g., by name, room number, etc.) and to provide some information concerning the patient's condition. Typically, annunciating devices 28 are used to indicate alarm conditions for a monitored patient. Alternatively, the annunciating devices may be configured to indicate the condition of selected patients regardless of whether an alarm condition exists. In addition to annunciator devices 28, system 20 may also include other devices configured to enable clinicians to monitor a patient's condition at a location remote from either the patient or the central station. These other devices will be described in more detail below.

System 20 may be implemented in many different forms and configurations using various types and combinations of components to provide a variety of features and functions within the scope of the invention. For clarity, the invention will be described below primarily in the context of one particular exemplary embodiment. However, it will be understood that the scope of the invention is not limited to the particular embodiment described, but rather extends to all such embodiments, forms, configurations, types and combinations.

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Turning attention to Fig. 2, a schematic representation of exemplary system 20 is shown. The system includes a medical telemetry network 30 adapted to monitor a plurality of patients. In the exemplary embodiment, network 30 includes a physical data transport structure 32 (also referred to herein as a network) such as an Ethernet Local Area Network (LAN) system. Alternatively, network 30 may be any of the electrical and/or optical network communications structures known to those of skill in the art. Alternatively, physical data transport structure 32 may include any other suitable network structure, including a wireless structure, whether now known or later developed. In any event, physical data transport structure 32 is adapted to interconnect a plurality of network components, and to transmit data communications between the components.

Although not shown in Fig. 2, it will be appreciated by those of skill in the art that physical data transport structure 32 typically will include one or more devices adapted to connect the physical transmission lines together and route communications within the communications structure. Examples of such devices include switches, hubs, bridges, routers, and the like. Thus, as used her herein physical data transport structure 32 includes all such devices which may be necessary and/or beneficial to a particular implementation as well as the physical communication lines.

Communications transmitted within network 30 typically comply with one or more standard data communication protocols which are known to those of skill in the art. As will be described in more detail below, the components of exemplary network 30 use a variety of standard communication protocols including the Transmission Control Protocol/Internet Protocol (TCP/IP) suite, User Datagram Protocol (UDP),

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etc. Use of standard communication protocols allows a variety of different components to be connected to communicate over the network. Furthermore, use of standard communication protocols enables the use of standard routers, switches and other network devices as mentioned above. Alternatively or additionally, the components may communicate using one or more non-standardized protocols adapted for medical telemetry or a particular application.

Network 30 includes one or more central stations 24, each connected to communicate via physical data transport structure 32 and configured to monitor a plurality of patients. It will be appreciated that central stations 24 may take any one or more of a variety of different forms. In the exemplary embodiment, each central station takes the form of a computer workstation configured to communicate via physical data transport structure 32 and monitor a plurality of patients. Central stations 24 may be any suitable type of central station such as the ACUITY® central station available from Welch Allyn Protocol, Inc. of Beaverton, Oregon. The ACUITY® central station is a version of the invention claimed in U.S. Patent No. 5,319,313 to Welch et al.

One example of a central station in accordance with the present invention is shown in Fig. 3. Exemplary central station 24 includes a processing module 34 having at least one processor (not shown) and at least one data storage unit (not shown). The processor is adapted to execute software stored in the data storage unit to communicate with patient monitors, analyze patient data, etc. Central station 24 also includes a plurality of display devices such as display monitors 36. Alternatively, central station 24 may include a single display monitor. In any event, display

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monitors 36 are connected to processing module 34 and adapted to display vital signs data collected from a plurality of patients. Typically, central station 24 also includes one or more input devices 38 (e.g. keyboard, cursor control, mouse, remote control, touch-screen, etc.) operable by a user to control the central station. Central station 24 may also include one or more audio input/output (i/o) devices such as speakers, microphones, sirens, buzzers, etc., adapted to produce an audible message to a user of the central station n. Those of skill in the art will appreciate that central stations 24 may have a variety of different configurations within the scope of the invention.

Central stations 24 are typically disposed at selected centralized locations within the hospital such as at nursing stations, etc. Each central station is adapted to receive patient vital signs data from one or more patient monitors via physical data transport structure 32. The central stations are controllable by a user to display selected information concerning each monitored patient on the display monitor. This allows clinicians to view the information collected by a patient monitor at the centralized location. Additionally, central stations 24 may be configured to simultaneously display data from a plurality of patients, thereby enabling a single clinician to watch over several patients at different locations. In addition to communicating with patient monitors, central stations 24 may also be configured to communicate with other central stations within the network. Thus, for example, patient data received at one central station may be forwarded to a different central station. This allows two or more clinicians at different locations to simultaneously monitor a single patient. Communications among different central stations will be described in more detail below.

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Turning attention back to Fig. 2, network 30 may also include one or more database systems 40 configured to store patient information. Database system 40 is connected to physical data transport structure 32 and accessible by central stations 24 to store and retrieve data. Patient information stored on database system 40 may include a variety of information concerning each patient including personal information, medical history, room location, etc. Typically, the central stations are configured to access database system 40 to identify patients who are admitted to the hospital and display a list of the patients on display monitor 36. This allows a clinician to associate vital signs data received from a particular patient monitor with the corresponding patient. The central station also may be configured to store on database system 40 some or all of the vital signs data received from the patient monitors. While database system 40 is depicted in Fig. 2 as a single, separate system connected to physical data transport structure 32, it will be appreciated that other configurations are also within the scope of the invention. For example, database system 40 may be multiple databases distributed around network 30. Alternatively, database system 40 may be contained within some or all of the central stations. Typically, database system 40 is a system or network of data storage devices, some of which are contained within the central stations and others existing separately in network 30. In any event, it will be appreciated that database system 40 may be any of the various database systems or structures such as are known to those of skill in the art.

As discussed above, central stations 24 are configured to communicate with a plurality of patient monitors via physical data transport structure 32. Communications

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between the central stations and patient monitors may be via wire (i.e., transmitted over a physical line adapted to convey electrical or optical signals), or may be wireless communications. Considering first the wire communications, one or more patient monitors 22 may be connected to physical data transport structure 32 either directly (e.g., through an Ethernet connection), or indirectly through a terminal server 42 or similar device. Terminal server 42 includes a plurality of ports adapted to receive connections from the patient monitors. In addition, the terminal server is also connected to physical data transport structure 32. The terminal server is configured to receive communications from the patient monitors and forward the communications to the appropriate central station via physical data transport structure 32. Similarly, the terminal server also is configured to receive communications from the central stations via physical data transport structure 32 and convey the communications to the appropriate patient monitor. Terminal server 42 may be any of a variety of terminal servers such as are known to those of skill in the art. Any known wire or wireless communication technologies may be used to perform the functions described above.

In TCP/IP based networks, communications between central stations and patient monitors are directed to the appropriate component using network addresses such as IP addresses as well as hardware addresses. Typically, each central station is assigned a unique IP address and all communications to and from a particular central station will include the particular station's IP address. Similarly, all patient monitors which are directly connected to physical data transport structure 32 are assigned a unique IP address. In contrast, patient monitors which are connected to physical data transport structure 32 through a terminal server typically do not have a unique IP

address. Instead, the terminal server has an IP address with which to communicate with the other components connected to physical data transport structure 32. Communications from a patient monitor are transmitted to the terminal server with the IP address of the destination component (e.g., a central station). The terminal server appends its own IP address to each communication and then forwards the communication to the appropriate component. Similarly, communications to a patient monitor are transmitted with the terminal server's address as the destination address. Upon receipt, the terminal server forwards the communications to the appropriate patient monitor.

As shown in Fig. 2, network 30 also includes one or more wireless transceivers 26, which are hereinafter referred to as access points 26. Each access point is connected to physical data transport structure 32 and configured to communicate with the other components connected to physical data transport structure 32. Each access point includes the software necessary to communicate via physical data transport structure 32 using the selected communications protocols of network 30 (e.g., TCP/IP, UDP, etc.). In the exemplary embodiment, each access point has a unique IP address that may be permanently coded into the access point, or may be assigned by a server such as described below. The access points also are configured to communicate, via wireless transmissions, with components which are not directly connected to physical data transport structure 32. Each access point includes a wireless receiver to receive wireless communications, and a wireless transmitter to transmit wireless communications.

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It will be appreciated that access points 26 may be configured to communicate using any of a variety of different wireless transmission technologies depending on the application, environment, governmental regulations, etc. In the exemplary implementation, the access points are configured to communicate with the patient monitors (described in more detail below) as well as other devices under the IEEE 802.11 standard using Frequency Hopping Spread Spectrum (FHSS) technology in the 2.4 GHz ISM (Industrial, Scientific, and Medical) band. The IEEE 802.11 communications standard is well known to those of skill in the art. Access points 26 essentially act as network bridges between the wireless components of network 30 and wired network physical data transport structure 32. Other wireless transmission, or communication, technologies known to those skilled in the art may be used including IEEE 802.11a, IEEE 802.11b, and IEEE 802.15.

Exemplary access points 26 may be any wireless transceivers adapted to communicate using the IEEE 802.11 FHSS technology. One example of a suitable access point is the SPECTRUM24 AP 3021 available from Symbol Technologies of Holtsville, New York. In other implementations and embodiments, access points 26 may be selected which are configured to communicate using other technologies. In any event, the access points usually are configured to simultaneously communicate with a plurality of patient monitors and/or other wireless devices. For example, the AP 3021 access points are adapted to simultaneously communicate with up to approximately 15 patient monitors.

Each access point typically has a range within which it can communicate with wireless devices. The range will vary depending on the power of the wireless

transmitter, environmental conditions, etc. Typically, the access points are arranged within the hospital so that at least one access point is able to communicate with a patient monitor at any point within a defined region of the hospital. For example, if it is desired that wireless patient monitors be used on a particular floor of the hospital, then sufficient access points are provided and positioned so that every location on the particular floor is within the range of one or more access points. This ensures that a patient associated with a patient monitor can move about the hospital floor without loss of central monitoring. It will be understood that the access points may be arranged to provide wireless coverage within a defined region that is less than an entire floor of the hospital. Alternatively, the access points may be arranged to provide coverage for regions that span multiple floors (whether or not adjacent) and/or multiple buildings.

As will be discussed in more detail below, patient monitors and other wireless devices communicate over physical data transport structure 32 by first associating with an access point. Once a patient monitor has associated with a particular access point, communications between the patient monitor and components on physical data transport structure 32 are conveyed by the particular access point. However, as the patient monitor moves out of range of the particular access point and into the range of another access point, the patient monitor associates with the other access point and subsequent communications between the patient monitor and components on physical data transport structure 32 are conveyed by the other access point.

Use of FHSS technology allows access points to be positioned so that the ranges of the access points overlap. Such an arrangement provides for geographic

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redundancy in the event an access point fails. In addition, overlapping the access point ranges increases the monitoring capacity within the defined region or selected portions of the defined region. The access points typically are configured to communicate with one another to minimize or prevent interference. The access points may also be configured to manage and balance the communication loads experienced by each access point. In addition, one or more of the central stations may be configured to control the access points to balance communication loads.

It will be appreciated that in many implementations the communication of patient information by wireless transmission must be secure and confidential. These security needs may be met in any of a variety of ways known to those of skill in the art. For example, the 802.11 standard provides WEP (Wired Equivalent Privacy) which encrypts the wireless transmissions. In addition, some implementations may utilize additional security measures such as end-to-end data encryption, etc.

In the exemplary embodiment, network 30 also includes a router 44 or similar device connected to physical data transport structure 32 between a first portion 46 and a second portion 48 of physical data transport structure 32. Components connected to the first portion are assigned IP addresses corresponding to a first subnet, while components connected to the second portion are assigned IP addresses corresponding to a second subnet. First portion 46 is connected to central stations 24, database system 40, terminal server 42 and the other components of network 30 which are configured for wired communications via physical data transport structure 32. Second portion 48 is connected to access points 26. Thus, first portion 46 may be seen as a wired portion of network 30, while second portion 48 may be seen as a wireless

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portion of network 30. Use of router 44 between wired portion 46 and wireless portion 48 allows the wireless portion of the network to be isolated from the communication traffic on the wired portion of the network. Communications between patient monitors and central stations are passed by router 44 from wired portion 46 to wireless portion 48 and vice versa. However, communications between central stations and/or other components connected to wired portion 46 are not passed to wireless portion 48. Alternatively, wired portion 46 and wireless portion 48 may be directly connected to the same subnet, eliminating the need for a router.

In the exemplary embodiment, network 30 also includes at least one server system 50 connected to the wireless portion of the network. As will be discussed in more detail below, server system 50 is adapted to assign IP addresses to the patient monitors once the patient monitors associate with an access point. Server system 50 may be configured to assign IP addresses according to any suitable protocol such as the Dynamic Host Configuration Protocol (DHCP), the Bootstrap Protocol (BOOTP), etc. It will be appreciated that server system 50 is connected on the wireless portion of physical data transport structure 32 relative to router 44 to ensure that requests for IP addresses from the patient monitors are received at server system 50. Alternatively, router 44 may be configured to convey the requests for IP addresses between the wireless and wired portions, in which case server system 50 may be connected on the wired portion of the network.

Server system 50 may be a separate computer system adapted to manage and assign IP addresses only, or it may be configured to perform other functions including network management, etc. In alternative embodiments, one of central stations 24 is

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configured to perform the functions of server system 50, thereby alleviating the need for a separate server system 50. In such embodiments, the central station which is configured to assign IP addresses in the alternative embodiment should be connected to the wireless portion of network 30 unless router 44 is adapted to pass requests for an IP address to the wired portion of the network.

Network 30 may also include one or more wireless communication devices referred to herein as clinician terminals 52. The wireless clinician terminals may take any one of a variety of different forms including Personal Digital Assistants (PDA's), Internet Protocol (IP) telephones, portable computers, etc. Clinician terminals 52 include wireless transceivers (e.g., RF network cards) that are configured to associate with access points 26. The clinician terminals also include suitable software executable by the terminals to communicate with the central stations via access points 26. The clinician terminals may also be configured to perform a variety of functions such as receiving and displaying patient vital signs data from the central station, transmitting control instructions to the central station to control a selected aspect of the central station, transmitting control instructions to the central station for forwarding to a patient monitor to control selected aspects of the patient monitor, sending and receiving textual messages, receiving and acknowledging alarm signals, etc. In the exemplary embodiment, clinician terminals 52 are configured to function as quasi-central stations, by displaying patient vital signs data and providing a user-interface operable by the clinician to control the patient monitor.

Clinician terminals 52 enable physicians, nurses and others to obtain information concerning a patient from any location within the defined region of

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network 30, rather than only at the patient's location or at a central station. Thus, for example, a clinician several floors away from a patient can receive a notification of an alarm at the patient monitor associated with the patient. Further, the clinician can evaluate the patient's condition from the vital signs data without going to the patient's location. The clinician may then take appropriate action depending on the patient's condition. It will be appreciated that clinician terminals 52 enable clinicians to work more efficiently and effectively, and to care for a larger number of patients than would otherwise be possible. Furthermore, while the clinician terminals may include paging functions, the clinician terminals provide substantially more information to the clinicians than pagers.

Exemplary telemetry network 30 also is connected to the main computer network 54 of the hospital, referred to hereinafter as the secondary or non-telemetry network. Secondary network 54 typically includes a plurality of computer terminals 56, database systems 58, etc. The secondary network interconnects the hospital's administrative computers and other non-telemetry components. Typically, secondary network 54 is connected to telemetry network 30 through router 44. This isolates the telemetry network from non-telemetry communication traffic, while allowing devices connected to the non-telemetry network to access patient vital signs data. Similarly, users of central stations 24 are able to access information on the secondary network as needed. In some implementations it may be desirable to provide security measures to ensure that only authorized users of secondary network 54 are able to access telemetry network 30. Any of a variety of suitable security measures may be employed as are known to those of skill in the art.

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Network 30 may also be connected to a communications network external to the hospital such as an extranet, virtual private network, Wide Area Network (WAN), etc. In the exemplary implementation, network 30 is connected to the Internet 60. Typically, network 30 is connected to the Internet via a firewall 62 or other suitable security device to restrict access to patient data and other confidential information.

As shown in Fig. 4, the telemetry network of one hospital 64 may be connected to the telemetry network and/or the secondary network of one or more other hospitals 66 in remote locations. The telemetry network may be connected to the remote hospitals via Internet 60 or via a direct, non-public network 68 such as is known to those of skill in the art. Central stations 24 of hospital 64 may be configured to transmit patient information including vital signs data to central stations or other computers in remote hospital 66. Similarly, the central stations of hospital 64 may be configured to request and receive patient information including vital signs data from remote hospitals 66. It will be appreciated that communication of patient information between remote hospitals allows clinicians to participate in consultations with their remote colleagues more effectively and efficiently.

In the implementation described above, access points 26 were arranged within the hospital to provide wireless monitoring in a defined region of the hospital. In alternative implementations, the defined region may extend outside the hospital. For example, system 20 may include one or more access points 26 which are positioned outside of the hospital, as shown in Fig. 4. The access points are connected to Internet 60 and configured to transmit the patient vital signs data to network 30 and one or more central stations 24. This allows patients to move outside of the hospital without

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loss of continuous central monitoring. So long as the patient remains within the range of at least one access point, the patient's vital signs data may be displayed on a central station as if the patient was still in the hospital. Similarly, emergency response workers could connect a patient monitor to an accident victim so that the hospital can monitor the victim's condition while the victim is transported to the hospital.

It will be appreciated that placement of access points outside of the hospital also allows clinicians to access patient data when outside the hospital. As shown in Fig. 4, one or more clinician terminals 52 may associate with the external access points to view patient information and control the patient monitor connected to a patient. This provides clinicians with more flexibility to leave the hospital while continuing to monitor their patients at the hospital (or patients outside the hospital). Alternatively, clinicians may monitor patients using personal computers 70 or similar devices configured to connect to Internet 60 and communicate with central stations at the hospital. Computers 70 may be located anywhere a connection is available that provides a communication channel using any communication technology. For example, computers 70 may be located anywhere a connection to the Internet is available. Alternatively, computers 70 may be configured to associate with an external access point and communicate via wireless transmissions.

As discussed above, the defined region of monitoring will extend outside the hospital wherever access points 26 are positioned. In areas where the external network of access points is undeveloped, patient monitors 22 and/or clinician terminals 52 may be configured to communicate using other wireless communication technologies. For example, the implementation depicted in Fig. 4 includes a Cellular

Digital Packet Data (CDPD) network 72, such as is currently used for cellular telephone and other communications. Patient monitors 22 and/or clinician terminals 52 may be configured to communicate with central stations in hospital 64 via CDPD network 72. Thus, for example, a patient might be discharged to go home while continuing to be monitored. It will be appreciated that this alleviates the need to have new wireless networks installed throughout a geographic region, since the components of system 20 are configured to communicate using preexisting networks. An alternate implementation (undepicted) would be to use what is known as a Global System Mobile (GSM), or any other available wide-reaching communication system.

Considering patient monitors 22 in more detail, it will be appreciated that there are a variety of different patient monitors available and suitable for use with system 20. System 20 may include one or more patient monitors of a single type, or may include multiple types of patient monitors, each configured to communicate with one or more central stations. For example, the exemplary embodiment of system 20 depicted in Figs. 1 and 2 includes a first type of patient monitor 22a adapted to be carried or worn by a patient, and a second type of patient monitor 22b adapted to be mounted on a bed, wheelchair, etc, as well as being carried. Patient monitors 22a and 22b may be configured to perform the same monitoring functions or may be configured to perform different monitoring functions. In any event, each type of patient monitor 22 is configured to collect vital signs data from a patient and communicate at least a portion of the vital signs data to a central station via physical data transport structure 32. Suitable patient monitors are available from several

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manufacturers, including the MICROPAQ and PROPAQ patient monitors available from Welch Allyn Protocol, Inc. of Beaverton, Oregon.

Turning attention now to Fig. 5, exemplary patient monitor 22a is shown in more detail. The monitor includes a portable housing 80 having one or more sensor input ports 82. The housing is sized to be held by a clinician or patient, or to be worn by the patient using a strap, belt, or similar device. Sensor input ports 82 are adapted to receive and connect to sensor cables 83. Each cable 83 is attached to one or more sensor assemblies (not shown). The sensor assemblies may include any vital signs sensor assembly adapted to detect and/or measure selected vital signs data from a patient and transmit the vital signs data via cables 83. Examples, of suitable sensor assemblies include electrocardiogram (ECG) sensor assemblies, non-invasive blood pressure sensor assemblies, invasive blood pressure sensor assemblies, temperature sensor assemblies, pulse oximetry sensor assemblies, respiration sensor assemblies, carbon dioxide sensor assemblies, etc. Suitable sensor assemblies are available from Welch Allyn Protocol, Inc. of Beaverton, Oregon. In any event, each sensor input port is adapted to receive patient vital signs data from the sensor assembly attached thereto.

Patient monitor 22a also includes a display device such as display screen 84 adapted to display the vital signs data or an image representative of the vital signs data. Exemplary display screen 84 is in the form of a liquid crystal display (LCD) device. Alternatively or additionally to display screen 84, patient monitor 22a may include any other suitable display device such as a printer, one or more indicator lights, light-emitting diodes, etc. The patient monitor also includes one or more input

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devices such as buttons 86 disposed on housing 80. Buttons 86 are operable by a user to input information into patient monitor 22a, as will be discussed in more detail below. In addition to, or in place of buttons 86, the patient monitor may include other types of input devices including switches, knobs, etc. As a further alternative, display screen 84 may be a touch-screen adapted to input information in response to contact by the user at selected locations on the screen. While the exemplary embodiment will be described below as having input devices in the form of buttons, it will be understood that any type of input device may be used.

Exemplary patient monitor 22a further includes a battery assembly 88 having one or more batteries. Battery assembly 88 is mountable in a battery compartment within housing 80. The batteries typically are rechargeable, however non-rechargeable batteries may also be used. Although not shown in Fig. 5, patient monitor 22a also includes a controller, a memory device, and an on-board wireless transceiver, all operably disposed within portable housing 80. An internal antenna 90 is mounted within the housing and coupled to the wireless transceiver. Alternatively, antenna 90 may be disposed externally to housing 80. An audio input/output device 92, (e.g., speaker, microphone, buzzer, siren, etc.) is also disposed within the housing and adapted to produce an audible notification to a clinician, patient, or other user of the monitor. An alternative to the input/output device would be a bi-directional audio device.

As shown in Fig. 6, exemplary patient monitor 22b includes a portable housing 94 adapted to attach to a bed, wheelchair or other support structure. Housing 94 includes one or more sensor input ports 82 adapted to connect to sensor cables 83 and

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receive vital signs data from one or more sensor assemblies (not shown). Similar to patient monitor 22a, patient monitor 22b includes a display device such as display screen 84 and one or more input devices such as buttons 86. Although not shown in Fig. 6, patient monitor 22b also includes a battery assembly 88, an antenna 90, and an audio output device 92. As will be described in more detail below, patient monitor 22b also includes a controller, a memory device and an on-board wireless transceiver, all operably disposed in housing 94.

Unlike patient monitor 22a, patient monitor 22b includes an output port 96 adapted to receive a hard-wired network connection cable 98 such as an Ethernet, RS-232, modem line, or similar network communications cable for connection to physical data transport structure 32 or terminal server 42. Thus, patient monitor 22b is configured to communicate with central stations 24 using either wireless communications via its on-board wireless transceiver, or wire communications via output port 96. As will be discussed in more detail below, patient monitor 22b may be configured to automatically switch between wire and wireless communications in various situations.

As mentioned above, each patient monitor 22 includes a controller disposed within the portable housing. It will be appreciated that any of a variety of different computer controllers, micro-controllers, or processors, such as are known to those of skill in the art, may be used. The controller, indicated at 100 in Fig. 7, is operably coupled to receive power from battery assembly 88. The controller may also be configured to receive power from other sources (e.g., AC line current through a wall socket, DC current through photovoltaic cells, etc.).

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Controller 100 is also connected to memory device 102. It will be appreciated that memory device 102 may be any one or a combination of devices adapted to store electronic information such as RAM, ROM, PROM, EPROM, etc. Memory device 102 may also include removable storage media such as magnetic discs and tapes, optical discs, etc. In addition to storing patient vital signs data, memory device 102 may be configured to store one or more software control programs executable by controller 100 to perform its various functions including receiving and analyzing vital signs data, presenting information to a user, etc. In addition, the software will include the necessary programs for communicating with central stations 24 (e.g., TCP/IP, DHCP, etc.) While memory device 102 has been depicted as a single device, those of skill in the art will appreciate that memory device 102 may be a plurality of either similar or different memory devices.

Controller 100 is also coupled to sensor ports 82 and configured to receive vital signs data from the sensor assemblies via the sensor ports. In addition, controller 100 may be configured to supply power and/or suitable drive signals onto one or more of the sensor ports to drive the sensor assemblies attached to the ports. In any event, vital signs data received at controller 100 may be stored in memory device 102, processed, discarded, and/or communicated immediately to a central station.

The controller is connected to control wireless transceiver 104 and communicate with central stations 24 via the transceiver. Wireless transceiver 104 may be any of a variety of wireless transceivers which are known to those of skill in the art. One example of a suitable wireless transceiver is the SPECTRUM24 LA 3021 PC card, available from Symbol Technologies of Holtsville, New York.

Alternatively, other wireless transceivers may be used. In any event, wireless transceiver 104 is configured to communicate with access points 26 using the appropriate communications protocol of network 30. The wireless transceiver is connected to antenna 90 and transmits data received from controller 100 to access points 26. Similarly, the wireless transceiver receives transmissions from one or more access points and forwards the communications to the controller. The wireless communications between patient monitor 22 and the central stations will be discussed in more detail below.

In the case of patient monitor 22b, controller 100 is also connected to output port 96 and configured to communicate with central stations 24 via the output port rather than via wireless transceiver 104. Controller 100 may also include a network card or similar device (not shown) adapted to transmit and receive communications via output port 96. For clarity, the description below assumes that patient monitor 22 communicates with central stations 24 via wireless transceiver 104. However, it will be understood that, unless stated otherwise, and for purposes of this description, communications via output port 96 are viewed as identical to communications via the wireless transceiver, and therefore both types of communications are included within the description. A distinction between wireless and hard-wired communication is that patient location (room) is known with hard-wired communication (via the network jack to which the monitor is connected) and not known with wireless communication. However, for purposes of this description, that distinction is not seen as pertinent and that is why communications via output port 96 are viewed as identical to communications via the wireless transceiver.

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Controller 100 is also connected to receive inputs from buttons 86. The buttons are operable by a user of the patient monitor to input information to the controller, as well as to control the controller. Each button may have a single function or may have a variety of functions depending on such factors as the operating condition of the controller, status of the sensor assemblies, communications with a central station, screen displays, etc. In the exemplary embodiment, controller 100 is configured to control the function of buttons 86 and to disable the buttons under defined conditions.

Controller 100 is configured to control display screen 84 to display an image representing the vital signs data. It will be appreciated that the image displayed on display screen 84 will vary depending on the vital signs data collected by the patient monitor. Additionally, exemplary controller 100 is configured to change the display based on instructions received from the user via buttons 86. For example, the user might select between displaying a single ECG signal from a single electrode, or multiple ECG signals from multiple electrodes. Fig. 8 shows an exemplary display screen 84 on which vital signs data is being displayed. A waveform region 106 of the display shows an image representing the signal data received from an ECG sensor assembly. A numeric region 108 of the display shows images that provide numerical representations of the vital signs data (e.g., heart rate, oxygen saturation in the patient's blood, etc.). The display may also include a patient identifier 110 that uniquely identifies the patient, such as the patient's name, etc. Fig. 9 shows another exemplary display screen 84 similar to the one in Fig. 8. However, the display screen shown in Fig. 9 has been changed to include a message region 112 for displaying messages to a user. Similarly, Fig. 10 shows another exemplary display screen 84 in

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which the image has been changed to include a user-interface region 114. The user-interface region allows a user to enter information and control the patient monitor by operating buttons 86. Control of the display screen will be described in further detail below.

Controller 100 is also connected to control audio output device 92 and/or other audible indicator devices to produce audible messages or signals. The controller may be configured to control the audio output device to produce audible signals under any one or more of a variety of conditions. For example, controller 100 is typically configured to analyze at least some of the vital signs data and produce an audible alarm if the vital signs data is outside a selected nominal range. The analysis of vital signs data and detection of alarm conditions will be described in further detail below.

While one exemplary functional embodiment of patient monitors 22 has been depicted in Fig. 7 and described above, it will be appreciated that many other configurations are possible. Thus, the invention is not limited to the exemplary embodiment described, but includes any patient monitor configuration adapted to collect vital signs data from a patient and communicate the vital signs data to one or more central stations.

Typically, patient monitors 22 are configured to function as stand-alone devices capable of providing local patient monitoring regardless of whether the patient monitor is in communication with a central station. The patient monitor may be configured to begin monitoring immediately upon power-up and attachment of at least one sensor assembly. Alternatively, the patient monitor may be configured to begin monitoring upon receipt of an actuation signal.

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Patient monitors 22 are also configured to attempt to establish communications with one or more central stations and communicate the vital signs data to the central stations. In the exemplary embodiment, the patient monitors are configured to attempt to establish communications immediately at power-up and to continue the attempt until communications are established. Alternatively, one or more of the patient monitors may be configured to attempt to establish communications only in response to an instruction by a user and/or the occurrence of selected conditions. Those of skill in the art will appreciate that the process of establishing communications with one or more central stations, also referred to herein as the rendezvous process, may be carried out in any of a variety of different ways. In addition, the rendezvous process may vary depending on whether the patient monitor is communicating through wireless or wire communications, as well as on whether the patient monitor is establishing a new communications connection or reestablishing prior communications which were lost or terminated.

The rendezvous process of the exemplary embodiment is schematically illustrated in Fig. 11. The process begins with establishing a connection to physical data transport structure 32 by any one of several methods. Where patient monitor 22 is configured to communicate using only wireless communications, the patient monitor establishes a connection to physical data transport structure 32 by associating with an access point, as indicated at 200. It will be appreciated that the process of associating with an access point may vary with varying configurations of the access point and/or varying configurations of the patient monitor. In the exemplary embodiment, wireless transceiver 104 associates with a patient monitor according to

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the IEEE 802.11 standard, and the details of that standard are known to those skilled in the art. Certain features of the exemplary embodiment include that (i) the patient monitors can be used in any telemetry network described herein (such as the 802.11-standard telemetry network) without user-adjustment of the communications frequency, and (ii) the patient monitors automatically scan for access points and detect access-point configuration and synchronization information.

In addition, the wireless transceiver determines which access points are within range of the patient monitor, and the current communications load on the in-range access points. Using this information, the patient monitor selects one of the in-range access points with which to communicate, and begins the authentication process which is followed by the association process. Once the authentication and association processes are complete, the connection between the patient monitor and physical data transport structure 32 is established.

In the exemplary embodiment where communications over network 30 conform to the IP protocol, each device must have an associated IP address with which to send and receive communications. In some embodiments, patient monitor 22 may have a permanently assigned IP address stored in memory device 102. Alternatively, patient monitor 22 may not have an assigned IP address, and instead may be configured to request an IP address upon establishing a connection with physical data transport structure 32, as indicated at 202 and 204. Typically, patient monitor 22 requests an IP address by transmitting a broadcast request to server 50 using the appropriate protocol (e.g., DHCP, BOOTP, etc.). The request is answered by server 50, which responds by assigning the patient monitor an IP address from a

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store of available IP addresses, and then transmitting a notification of the assignment to the patient monitor. Alternatively, server 50 may store a pre-assigned IP address for each device, and respond with the corresponding pre-assigned IP address. Upon receiving the assigned IP address, the patient monitor is prepared to broadcast a request for communications to one or more central stations, as will be described in more detail below.

Where patient monitor 22 is adapted to communicate using either wireless or wire communications, the process for establishing a connection to physical data transport structure 32 will vary depending on whether a wireless or wire connection is established. In the former case, the process may occur as described above, i.e., first associating with an access point, and then requesting an IP address if necessary. Alternatively, if a wire connection is to be established, the patient monitor may be physically connected to a terminal server which is connected to the network, as indicated at 206. It will be appreciated that the connection indicated at 206 may alternatively take other forms, such as a modem connection to a modem server, etc. In any case, once the connection is established and any necessary hand-shaking between the patient monitor and the terminal server is completed, the patient monitor is prepared to broadcast a request for communications to one or more central stations. Patient monitor 22 will communicate using the IP address of the server, and therefore is not required to have its own IP address.

As a further alternative, the patient monitor may be directly connected to a hard-wired connection on physical data transport structure 32 with an Ethernet or similar connection technology, as indicated at 208. As with a patient monitor that is

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connected to communicate using wireless communications, a patient monitor directly connected to physical data transport structure 32 may have a permanently assigned IP address, or may request the assignment of an IP address once the physical connection is established. In any event, in the hard-wired implementation, the terminal server is then prepared to initiate a request for communications to one or more central stations.

Regardless of how a patient monitor establishes a connection with physical data transport structure 32, the patient monitor must then establish communications with a central station by broadcasting a request for communications to the central station, as indicated at 210. It will be appreciated by those of skill in the art that a patient monitor may broadcast a request for communications in any of a variety of ways. In the exemplary embodiment, the patient monitor transmits the request as a UDP broadcast to all central stations. Alternatively, other communication protocols may be used.

The UDP communications request may include a variety of parameters adapted to inform the central station about the patient monitor. For example, communications requests typically include such information as the identity, type, and/or capabilities of the patient monitor, the IP and MAC (Media Access Control) addresses of the patient monitor, the version of software installed on the patient monitor, etc. The request may also include an indicator of the type of communications desired. For example, the patient monitor may request communications to establish central monitoring of a patient, download newer versions of the patient monitoring software (discussed in more detail below), or perform network maintenance, etc. This information allows the central station to determine how to respond to the request. Unless stated otherwise,

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the description below will assume that the patient monitor's communications request is for the purposes of establishing centralized monitoring of a patient.

In the exemplary embodiment, the communications request is passed to, and received by, all central stations of network 30, as indicated at 212. Any routers or other network devices connected to physical data transport structure 32 are configured to pass on the request to the central stations as necessary. Alternatively, the request may be conveyed to fewer than all of the central stations, or to a single central station. Each central station is configured to respond to the communications request when received. Upon receiving the first response the patient monitor transmits an acknowledgement to the central station that sent the first response. The patient monitor is configured to reject subsequent responses by transmitting a "reject" message to any central station that sends a subsequent response. The central stations are configured to cease sending responses to the communications request after receiving a "reject" message, unless a new request for communications is received.

In some embodiments, the central stations may be configured to ensure that a preferred central station responds to the communications request. For example, the central stations may be configured to recognize a patient monitor that has communicated with network 30 in the past (e.g., based upon information transmitted in the communications request), and to allow the particular central station that was previously in communication with the patient monitor to respond first. Thus, in the exemplary embodiment the central stations are configured to determine if a communications request was sent by a patient monitor which was previously in communication with a particular central station within a predefined time period. If so,

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the particular central station is configured to respond to the request immediately, while the remaining central stations will wait for a relatively short period of time (e.g., 10, 15, 20, 25, or 30 seconds, etc.) before responding. This priority is based on the assumption that the patient monitor is likely still connected to the same patient as during the previous communications, and that the patient is likely to be monitored at the same central station as during the previous communications. In any event, once the patient monitor receives a first response to its communications request, the patient monitor and the central station which sent the first response (hereinafter referred to as the "provisional central station") begin communicating to configure the centralized monitoring session, as indicated at 214.

As will be described in more detail below, the particular central station which serves as the provisional central station begins the process of configuring the monitoring session. However, before the centralized monitoring begins, one of the central stations of network 30 is selected to complete the configuration process and perform the central monitoring. This selected central station is referred to herein as the "primary central station." If the provisional central station is selected to be the primary central station, then no change in communications is needed, and the provisional central station assumes the role of the primary central station. Conversely, if a different central station is selected to be the primary central station, communications with the patient monitor are transferred from the provisional central station to the selected central station, which then assumes the role of primary central station.

As is known to those of skill in the art, wireless communications which have been established between a patient monitor and a primary central station may be lost or "dropped" for any of a variety of reasons. For example, the wireless transmissions may not be received by the access point and/or the wireless transceiver of the patient monitor because the patient monitor is moved out of the defined range of network 30 (i.e., out of range of any access point). Similarly, the transmissions may have been blocked by structures between the patient monitor and the access point, such as when the patient monitor is taken into an elevator or similar enclosure. Alternatively, a portion or device of network 30 may have failed, causing the communications to be dropped. As a further alternative, the battery in the patient monitor may have been replaced or discharged, causing the patient monitor to lose communications.

The response by patient monitor 22 and central stations 24 to communications dropouts may vary depending on the length and/or cause of the dropout. In the exemplary embodiment for example, a relatively brief dropout (e.g., less than approximately 10, 20, or 30 seconds, etc.), is treated as an interruption rather than as an actual loss of communications. Lost or incomplete transmissions due to such interruptions may be resent, discarded, or ignored according to the communications protocols used by the patient monitor and central stations. Once the interruption ends, the patient monitor and primary central station resume communicating as before.

In the event of a loss of communications that extends beyond a brief interruption, exemplary patient monitor 22 is configured to detect the loss and automatically attempt to restore the communications. If the patient monitor is no longer associated with an access point, the patient monitor attempts to establish an

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association as described in the 802.11 standard, and continues to attempt to establish an association until association with an access point is regained. Once the patient monitor re-associates with an access point (or if the patient monitor never lost the association), the patient monitor broadcasts a request for communications to the central stations, and the rendezvous process proceeds as described above. Once the patient monitor is in communication with a provisional central station, the patient monitor and provisional central station begin the process of configuring the monitoring session, as indicated at 214.

It will be appreciated that the session configuration process may proceed in any of a variety of different ways to configure a variety of different monitoring parameters. For example, the configuration process may identify which patient is being monitored, which central station will monitor the patient, which central station will control the patient monitor, what types of vital signs data should be monitored, how the vital signs data should be analyzed, what alarm conditions should be detected, how the patient monitor should function, etc. An exemplary session configuration process is indicated generally at 216 in Fig. 12. During process 216 a primary central station is selected, the monitored patient is identified, and the patient's room or other location is specified.

Referring to Fig. 12, the provisional central station first determines whether the patient monitor is still connected to the same patient as before the communications dropout. If such is the case, then the provisional central station assumes that the patient monitor is attempting to restore communications which were lost, and prior values for patient identity, etc., may be used. Alternatively, if the request is to

establish new communications, then the central station determines the information needed to complete the configuration by querying a user of the patient monitor, as will be described in more detail below.

The provisional central station may be configured to employ a variety of different methods or mechanisms to determine whether the patient monitor is still connected to the same patient. In the exemplary embodiment for example, the provisional central station first sends a request to the patient monitor for an indication of whether the patient monitor was continuously monitoring the patient during the period the communications were lost, as indicated at 218. If the patient monitor responds affirmatively, then the patient currently being monitored is necessarily the same patient that was previously monitored.

Patient monitor 22 is configured to receive the request and detect whether it continuously monitored the same patient during the communication dropout. Typically, the patient monitor is configured to detect continuous monitoring by detecting whether the patient monitor was operational during the communications dropout, and whether vital signs data was continuously received via at least one of the sensor assemblies. For example, one exemplary ECG sensor assembly connectable to a patient is adapted to continuously send ECG vital signs data to patient monitor controller 100. If the patient monitor is disconnected from the patient during the dropout, the ECG signal will lapse. Any lapse in the ECG vital signs data is detected by the controller. Alternatively, the ECG sensor assembly, or other types of sensor assemblies, may be configured to detect actual contact with the patient. In any event, the patient monitor responds to the request by informing the provisional central station

of whether the patient monitor has continuously monitored the same patient. It should be noted that the patient monitor may be monitoring the patient through sensor assemblies that do not continuously send vital signs data to the controller, and that do not detect contact with the patient. In which case, the patient monitor will be unable to confirm that it has continuously monitored the same patient, and will respond to the request from the central station accordingly.

If, at step 218, the patient monitor responds that it has continuously monitored the same patient, the provisional central station proceeds to perform a reconnect process, as indicated at 220 and as described below. Alternatively, if the patient monitor responds that it has not continuously monitored the same patient, the provisional central station then determines whether the patient monitor was recently connected to network 30, as indicated at 222. In other words, if the time period during which communications between the patient monitor and the primary central station were lost is less than a predetermined length of time, then the provisional central station concludes that the patient monitor is attempting to restore a recent connection, and proceeds to perform reconnect process 220. Otherwise, the provisional monitor concludes that the patient monitor is attempting to establish a new communications session. It should be noted that if the patient monitor was continuously monitoring the same patient during the communications dropout, then the provisional central station may safely assume the patient monitor is still connected to the same patient regardless of the length of the dropout.

The predetermined length of time that defines a recent connection may be set to any desired length of time as appropriate for a particular application. In the

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exemplary embodiment, the predetermined length of time is selected to be less than the minimum time period (e.g., 1, 2, 3, 4, or 5 minutes, etc.) normally needed to disconnect a patient monitor from one patient and reconnect the patient monitor to another patient. Thus, if the patient monitor was out of communication for any period of time less than that minimum disconnection/reconnection time, the provisional central station concludes that the patient monitor is still connected to the same patient. Alternatively, other time periods may be used.

The provisional central station may determine whether the patient monitor was recently connected in various ways. Typically, each central station is adapted to store patient vital signs data in database system 40. The vital signs data includes the time of collection by the patient monitor and/or receipt by the central station. Thus, the provisional central station may be configured to access database system 40 to determine the time that the last vital signs data was received from the patient monitor. Alternatively, the patient monitor may be configured to determine the length of the dropout and to inform the provisional central station, either automatically or in response to a query from the provisional central station.

In addition to the length of time during which communications were lost, the provisional central station may be configured also to evaluate other conditions at step 222. For example, if the prior communications were dropped intentionally, i.e., in response to a command by a user, the provisional central station may be configured to assume that a new patient has been connected to the patient monitor. In which case, the patient monitor is not attempting to restore a recent connection, but instead is attempting to establish a new communications connection.

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As mentioned above, the provisional central station proceeds to perform a reconnect process, indicated at 220, if the provisional central station determines either that the patient monitor continuously monitored the same patient during the dropout, or that the patient monitor was recently connected to communicate with a primary central station. During reconnect process 220 the provisional central station automatically determines which patient is being monitored by the patient monitor, and which central station served as the primary central station before the communications dropout. Typically, this information is stored by the patient monitor in memory device 102, and is communicated to the provisional central station by the patient monitor. Alternatively, the information may be stored in database system 40 and read by the provisional central station via physical data transport structure 32.

In any event, if the provisional central station is not the primary central station, then the provisional central station conveys a message to the primary central station to take over the remainder of the rendezvous process. If the primary central station is available, it begins communicating with the patient monitor via physical data transport structure 32 and conducts the remainder of the configuration process as described below. Likewise, the patient monitor transmits all subsequent communications to the primary central station, and the provisional central station ends further communications with the patient monitor.

Alternatively, if the primary central station does not respond to the provisional central station or is otherwise unavailable, the provisional central station may be configured to transmit a message to the patient monitor that the primary central station is unavailable. In the exemplary embodiment, the patient monitor controller causes

display screen 84 to display a user-interface 114, such as shown in Fig. 13, including a message that the primary central station is unavailable. The user-interface may also include instruction elements 116 which are selectable by a user to instruct the central station to recheck the availability of the primary central station, or to try a new primary central station. The clinician or other user of the patient monitor may use buttons 86 to select the desired instruction, which the patient monitor then communicates to the provisional central station. Depending on the user's instructions, the provisional central station either sends another message to the primary central station to take over the communications, or transmits a list of central stations to the patient monitor. In the latter case, controller 100 causes the display device to display a list of central stations, from which the user may select using buttons 86. The patient monitor transmits the user's selection to the provisional central station, which sends a message to the selected central station to take over the communications. If the selected central station is not available, the provisional central station informs the patient monitor and the user either selects a different central station, or instructs the provisional central station to retry the selected central station. This process may be repeated until an available central station is selected to act as the primary central station. The selected central station then begins communicating with the patient monitor and conducts the remainder of the configuration process.

Once the primary central station takes over the communications with the patient monitor, the primary central station is configured to determine the patient identity (patient ID) of the particular patient being monitored by the patient monitor. In general, either or both the primary central station and the patient monitor may be

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configured to be involved with the determination of patient ID. For example, the primary central station may determine the patient ID by transmitting a request for the patient ID to the patient monitor. If the patient monitor cannot provide the patient ID, the primary central station then accesses database system 40 to obtain the patient ID which was stored during the patient monitor's last communication session. Once the primary central station determines the identification of the particular patient being monitored by the patient monitor, the primary central station thereafter associates all vital signs data received from the patient monitor with the particular patient. In addition, the vital signs data along with other patient information may be stored on database system 40, and then retrieved for viewing and analysis at a later time.

After the primary central station has assumed the communications with the patient monitor and determined the identity of the patient being monitored, the primary central station then determines whether the patient has been assigned to a particular location, such as a room number, bed, ward, floor, etc., as indicated at 224 in Fig. 12. This information may then be displayed on central station monitor 36 to inform the clinician of the patient's assigned location. However, in view of the portability of patient monitors 22, a particular patient may be temporarily absent from his or her assigned location even though the patient is continuously monitored at the central station. In any event, the primary central station determines whether the patient has been assigned to a particular location by sending a request for the information to the patient monitor. If the patient monitor is unable to provide an assigned location, the primary central station may be configured to search database system 40 for the information.

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If the primary central station is unable to determine the assigned location, the central station is configured to query the user of the patient monitor for the patient's assigned location, as will be described in more detail below. Otherwise, the rendezvous and configuration processes are complete, and the primary central station proceeds to confirm that no other patient monitor is monitoring the same patient, as indicated at 226. In addition to checking the other patient monitors in communication with the primary central station, the primary central station also communicates with other central stations in network 30 to ensure that the same patient is not being monitored by a different central station. In the event the primary central station determines that another patient monitor is monitoring the same patient, an alarm or other indication may be displayed at the primary central station and/or the patient monitor so that a different patient ID may be selected.

As described above, the patient monitor is adapted to automatically attempt to restore communications with its primary central station in the event the communications are lost. Upon reestablishing communication, the primary central station (or a provisional central station, if different than the primary central station) is configured to automatically determine whether the patient monitor is still connected to the same patient. The central station may use a variety of mechanisms and methods to determine whether the patient monitor is still connected to the same patient, including measuring the length of time of the communications dropout, and determining whether the patient monitor disconnected from the patient data during the dropout. If the patient monitor is still connected to the same patient, the central station then associates the patient monitor with the patient so that any vital signs data received

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from the patient monitor is also associated with the patient. It will be appreciated that the capability to automatically identify the monitored patient at the central station after a communications dropout, enables the central station to monitor a large number of patients without constant intervention by a clinician to reconfigure a patient monitor each time a dropout occurs. Furthermore, the automatic configuration ensures that centralized monitoring of the patient resumes as soon as the patient monitor restores communication with the central station.

Turning attention back to Fig. 12, if the provisional central station determines that the patient monitor is not attempting to restore lost communications, the provisional central station proceeds to configure a new monitoring session by determining the identity of the patient being monitored, the primary central station which will monitor the patient, and the patient's assigned location. When the patient monitor establishes a new communications connection with the provisional central station, the patient monitor automatically displays a notification to a user of the patient monitor on display screen 84. As will be described below, the notification typically includes a user-interface operable by a user of the patient monitor to configure the communications session.

It will be appreciated that the provisional central station may determine the identity of the monitored patient in various ways. For example, even where the patient monitor has not recently been in communication with a central station and has not been monitoring the patient continuously since its last communication with a central station, it nevertheless may be more likely than not that the patient monitor has been reconnected to monitor the same patient. In the exemplary embodiment

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therefore, the provisional central station first determines whether the identity of the previous patient monitored by the patient monitor is available, as indicated at 228.

To determine whether the patient ID of the previous patient is available, the provisional central station may be configured first to query the patient monitor. Exemplary patient monitor 22 is configured to store the ID of the previous patient in memory device 102, unless the patient ID is cleared by the user. Thus, the exemplary provisional central station transmits a request to the patient monitor for the previous patient ID. If the previous patient ID is available at the patient monitor, the patient monitor communicates the previous patient ID to the provisional central station. Otherwise, the patient monitor responds that no patient ID is available.

If the patient ID is not available at the patient monitor, the provisional central station may be configured to search database system 40 for the previous patient ID associated with the patient monitor. Alternatively, if the patient monitor is connected to physical data transport structure 32 via a hard-wired connection, the provisional central station may be configured to search the database system for the previous patient ID associated with the particular location of the hard-wired connection. This strategy is based on the likelihood that the patient who was previously in the room with the hard-wired connection has not been moved since the last communications session. In the exemplary embodiment, the provisional central station is configured to search for the patient ID associated with the patient monitor if the patient monitor is communicating via wireless transmissions, and to search for the patient ID associated with the particular location of the hardwired connection if the patient monitor is communicating via wire.

If the previous patient ID is available (either from the patient monitor or the database system), the provisional central station communicates an instruction to the patient monitor to confirm whether the patient currently being monitored is the same as the last patient monitored, as indicated at 230. In response, controller 100 automatically causes display screen 84 to display a user-interface 114, such as illustrated in Fig. 14. The user-interface displays the previous patient's identity (i.e., the patient's name, identifying number, and/or other identifying designation) and asks the user to confirm that the patient monitor is connected to the previous patient. Exemplary user-interface 114 also includes instruction elements 116 which are selectable by the user to indicate that the patient monitor is or is not connected to the previous patient. In the exemplary embodiment, the user-interface also displays the patient's assigned location, indicated at 118, and the central station that previously monitored the patient, indicated at 120. Thus, the clinician or other user is prompted by user-interface 114 to confirm that the same patient is being monitored, and is assigned to the same location, and is to be monitored by the same central station. Alternatively, the user may indicate that a new patient is being monitored, or that the patient has been assigned to a new location, or that the patient should be monitored by a different central station. The user's selection is communicated by the patient monitor to the provisional central station.

As shown in Fig. 12, if the user confirms the previous patient, location and primary central station (i.e., by selecting the instruction element labeled "YES"), the rendezvous and configuration processes are complete, and the primary central station proceeds to confirm that no other patient monitor is monitoring the same patient, as

indicated at 226 and as discussed above. It should be noted that if the provisional central station is not the primary central station, then the provisional central station sends a request to the primary central station to take over the communications and complete the configuration process, as described above.

Alternatively, if the user responds by selecting a different one of the instruction elements, the provisional central station proceeds to determine the necessary configuration information. For example, if the user indicates that the patient currently being monitored is not the previous patient (i.e., by selecting the instruction element labeled "NO"), the provisional central station determines whether the patient monitor is configured to display a list of patients, as indicated at 232. The provisional central station may determine whether the patient monitor is configured to display a list of patients in various ways, including by sending a query to the patient monitor for its capabilities, or by accessing database system 40 to ascertain the capabilities of the patient monitor based on the type of patient monitor. As mentioned above, the type of the patient monitor may be transmitted to the provisional central station during the initial portion of the rendezvous process.

If the patient monitor is not configured to display a list of patients, then the patient ID confirmation process is passed to the central station, as indicated at 226. The central station typically is configured to display a user-interface allowing a clinician to specify the patient ID and the patient's assigned location. In addition, the clinician may instruct the central station to transfer communications with the patient monitor to a different central station, as will be described in more detail below. If, on the other hand, the patient monitor is configured to display a list of patients, the

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central station accesses database system 40 to identify at least some of the patients admitted to the hospital, and transmits a list of those patients to the patient monitor.

As indicated at 234, exemplary controller 100 displays the list of patients on display screen 84. An exemplary display screen presenting a list of patients is illustrated in Fig. 15. Rather than identifying the patient at the patient monitor, the clinician may operate buttons 86 to instruct that the patient's ID be selected at the central station, as indicated at 236. In which case the patient ID confirmation process is passed to the central station, as indicated at 226 and as discussed above. Alternatively, the clinician may select the ID of the monitored-patient from the patient list. The patient's ID is then communicated to the central station by the patient monitor. Next, the central station transmits a list of locations to the patient monitor controller, which displays the list to the user, as indicated at 238. Once the user selects the patient's assigned location from the list, the controller communicates the information to the central station. Finally, the central station confirms the patient is not being monitored by a different patient monitor, as indicated at 226, at which point the rendezvous and configuration processes are complete.

If, at step 230, the clinician indicates that the patient has been assigned to a different location (i.e., by selecting the instruction element labeled "NEW ROOM"), the patient monitor communicates this information to the central station, which responds by sending a list of locations to the patient monitor, as described above. The clinician then selects the patient's assigned location from the list, as indicated at 238. The location assignment is communicated to the central station, which then completes

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the rendezvous and configuration processes by confirming that the patient is not being monitored by a different patient monitor.

Returning attention briefly to Fig. 14, if the central station that monitored the previous patient will not be the primary central station, the clinician requests communications with a different central station (e.g., by selecting the control element labeled "NEW UNIT"). The clinician's instruction is then communicated to the provisional central station, which responds by transmitting a list of central stations in network 30. Controller 100 displays the list of central stations on display screen 84, as indicated at 240 in Fig. 12. Figure 16 illustrates an exemplary user-interface on display screen 84, including a list of user-selectable central stations. Once the clinician selects the desired central station from the list, the selection is communicated to the provisional central station. If the provisional central station is not the selected central station, the provisional central station sends a request to the selected central station to take over the communications and configuration process. If the selected central station is available, it takes over the communications with the patient monitor and completes the configuration process. Otherwise, the provisional central station causes the patient monitor to notify the clinician that the selected central station is unavailable, as described above.

Once the a central station is selected to be the primary central station and assumes the communications with the patient monitor, the primary central station proceeds to determine the identity of the patient and the patient's assigned location. As described above, the identity of the patient and the patient's assigned location may be entered by the clinician at the patient monitor and then communicated to the

primary central station. Alternatively, the patient ID and assigned location may be specified at the primary central station. In any event, once the primary central station has confirmed the identity and the assigned location of the patient, as indicated at 226, the rendezvous and configuration processes are complete.

As described above, exemplary configuration process 216 is adapted to automatically determine the patient's identity, etc., whenever possible. This tends to minimize the amount of effort required by the clinician to configure the patient monitor for centralized monitoring. However, it will be appreciated that the provisional central station may be configured also to determine the patient identity, primary central station, and assigned location in other ways. For example, if the patient ID is not available at step 228, then the exemplary provisional central station is configured to determine whether a list of central stations should be presented to the clinician, as indicated at 232. Typically, a list of central stations is presented whenever network 30 includes more than one central station. As indicated at 240 and described above, the provisional central station transmits the list of central stations to the patient monitor for display to the clinician. The clinician selects a desired central station to serve as the primary central station. The patient monitor communicates the selection to the provisional central station, which sends a message to the selected central station to take over the communications. If the selected central station is not available, the clinician is informed to make another selection, as described above. If, at step 242, the provisional central station determines that a list of central stations should not be presented to the user, the provisional central station becomes the primary central station and completes the remainder of the configuration process.

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Once the primary central station is in communication with the patient monitor, the primary central station queries the clinician for the patient ID and assigned location. Alternatively, the patient ID and assigned location may be specified at the primary central station. In any event, the primary central station then confirms that no other patient monitors are monitoring the same patient, thereby completing the rendezvous and configuration processes.

It will be appreciated by those of skill in the art that the exemplary rendezvous and configuration processes illustrated in Figs. 11 and 12 and described above, provide a variety of capabilities for monitoring patients via medical telemetry network 30. For example, a clinician may select which central station will monitor the patient by entering instructions at the patient monitor. The clinician's instructions are communicated to the provisional central station, which then sends a request to the selected central station to take over the communications. Alternatively, the patient monitor may send a request for communications directly to the selected central station in response to the clinician's instructions. In any event, the clinician is not required to configure the patient monitor at the central station, but instead may configure and initiate the central monitoring process without leaving the patient's location.

Furthermore, exemplary patient monitor 22 is configured to automatically attempt to establish communications with a central station beginning at power-up. The patient monitor determines, without user intervention, the communications settings needed to establish a connection and to communicate with network 30 such as transmission frequency, IP addresses, synchronization, etc. Thus, a patient monitor may be shipped from its manufacturing site to any location in the world and the

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patient monitor will automatically configure itself to begin communications with a local medical telemetry network according to the present invention. Similarly, a patient monitor used in a network at one location may be taken to a different location, where the patient monitor will configure itself to communicate with the local medical telemetry network at the different location. As a result, patient monitors 22 may be operated without specialized training or knowledge in network communications. Instead, clinicians may place a new patient monitor in immediate use simply by powering-up the patient monitor.

If communications between a patient monitor and central station are lost, the patient monitor automatically attempts to restore the communications without requiring reconfiguration. However, if the patient monitor is attempting to establish a new communications connection, the clinician or other user of the patient monitor is automatically notified once a communications connection (either wire or wireless) is established to allow the monitoring session to be configured. A user-interface for configuring the monitoring session is automatically displayed on the patient monitor display screen. The user-interface is at least partially defined by instructions received from the central station, and is operable by a user of the patient monitor to identify the monitored patient, and to select a primary central station to perform the central monitoring, etc. After a primary central station is identified and assumes communications with, and control of, the patient monitor, the patient is continuously monitored at the primary central station. In view of the capability of the patient monitors and central stations to automatically initiate and configure the centralized

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monitoring process, system 20 represents a substantial advancement in patient monitoring.

It will be appreciated by those of skill in the art that the rendezvous and configuration processes described above are just one of the many ways in which the central stations and patient monitors may be configured to establish new communications and/or restore lost communications. Many variations and modifications to the rendezvous and configuration processes are possible within the scope of the invention. Therefore, it will be understood that the invention is not limited to the particular exemplary processes described above, but includes all such processes, variations, and modifications suitable for establishing communications between a patient monitor and a central monitoring station via a communications network structure.

Once patient monitor 22 has established (or restored) communications with the primary central station, the patient monitor is configured to continuously communicate the vital signs data it collects to the central station. In the exemplary embodiment, patient monitor 22 is configured to communicate all vital signs data that is collected. Alternatively, the patient monitor may be configured to communicate only a portion of the vital signs data collected. In any event, the central station is configured to receive the vital signs data and associate it with the patient being monitored. As mentioned above, the central station typically is configured to communicate simultaneously with a plurality of patient monitors, in which case the vital signs data received from each patient monitor is associated with the particular patient connected to that patient monitor.

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Although patient monitor 22 is adapted to communicate with one or more central stations to establish central monitoring, the patient monitor is also configured to provide patient monitoring at the patient's location. As mentioned above, exemplary controller 100 is adapted to receive the vital signs data via sensor ports 82, and to display an image on display screen 84 that represents at least a portion of the vital signs data. It will be appreciated that the image may take any of a variety of different forms which will vary depending on the type of vital signs data collected. Thus, exemplary patient monitor 22 provides continuous local monitoring regardless of whether the patient monitor is in communication with a central station. Buttons 86 enable a clinician or other user to control a variety of functions including the information displayed on display screen 84, the format of the displayed image, the vital signs data collected, analysis of the vital signs data, alarm conditions, etc. For example, controller 100 may be controllable to display signals from selected sensor assemblies such as an ECG sensor assembly, or from a selected electrode of the ECG sensor assembly. In addition, the controller may be configured to analyze at least some of the collected vital signs data using one or more user-selectable parameters to provide additional information.

Similarly, controller 100 may be configured to analyze the vital signs data to detect whether the data is within certain defined nominal ranges, and to indicate an alarm condition if the controller detects that a portion of the data is not within the defined ranges. For example, if the upper and lower parameter values for heart rate are 120 and 50 beats per minute, respectively, the patient monitor will indicate an alarm if the detected heart rate is either greater than 120 or less than 50 beats per

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minute. Alternatively, any other portion of the collected vital signs data may be analyzed for alarm conditions, such as blood pressure, temperature, oxygen saturation in the patient's blood (SpO2), etc. Further, the defined nominal ranges typically are variable parameters and selectable by the user to specify particular alarm conditions for a particular patient. Fig. 17 illustrates an exemplary user-interface displayable on display screen 84, and operable by a clinician to specify the parameter values used by controller 100 to analyze the vital signs data. Alarm indications may include warning messages on display screen 84 and/or warning sounds from audio output device 92, etc.

Patient monitor 22 may also be configured to detect equipment or communications problems and provide an indication of the problem to the user. For example, controller 100 may be configured to detect a low power level in battery assembly 88, a sensor assembly that has become disconnected from the patient, a malfunction in buttons 86, lost communications, etc. The indication provided to the user may be the same as or different than the indication provided in response to the alarm conditions.

When patient monitor 22 is in communication with network 30, the primary central station may be configured to control some or all of the functions of the patient monitor. This enables a clinician to control a plurality of remotely distributed patient monitors from a single location. In addition, a central station may be configured to enable a clinician to control all patient monitors in communication with the central station to function identically. Alternatively, the clinician may control each patient monitor to function differently.

In the exemplary embodiment, the primary central station is configured and operable to change the variable parameter values which define nominal data ranges. Thus, the clinician can set or change the detection of alarm conditions at the primary central station. Instructions entered by the clinician at the primary central station are communicated to controller 100. The controller is configured to change the specified variable value in response to the instruction, and to analyze the vital signs data using the new value. Similarly, the primary central station may be configured to communicate instructions to controller 100 specifying what portions of the vital signs data should be analyzed. For example, it is known to those of skill in the art that a patient's heart rate may be determined from ECG data or from SpO2 data. Thus, where the patient monitor is collecting both ECG data and SpO2 data from a patient, a clinician at the central station may specify which type of data the controller analyzes to determine heart rate.

In addition, since the central stations typically have greater data processing capability than the patient monitors, the primary central station may be configured to analyze the vital signs data received from the patient monitor to determine additional information. For example, the primary central station may be configured to perform ST and/or arrhythmia analysis on the ECG waveform data, whereas controller 100 may analyze the ECG waveform to determine only the patient's heart rate. If the primary central station detects an alarm condition as a result of the analysis, the alarm condition may be displayed on central station monitor 36. In addition, the primary central station may communicate the alarm condition to the patient monitor and instruct controller 100 to present an indication of the alarm condition at the patient

monitor. By varying where the vital signs data analysis occurs (at the central station or at the patient monitor), the patient monitor's resources may be concentrated on collecting the vital signs data and presenting information to a clinician attending the patient.

The primary central station may also be configured to control both the types of information and the image displayed on display screen 84. For example, where the ECG sensor assembly includes a plurality of electrodes, the clinician at the primary central station may instruct the patient monitor to display the waveform from a particular one of the electrodes, as shown in Fig. 18. Alternatively, the clinician may instruct the patient monitor to display the waveforms from a plurality of the electrodes, as shown in Fig. 19. It will be appreciated that controller 100 may be configured to control display screen 84 to display any desired information or image format in response to instructions received from the primary central station. Alternatively, the controller may be configured to turn off a portion or all of the display screen in response to instructions from the central station.

As described above, the patient monitor and/or the primary central station may be configured to indicate an alarm condition, equipment problem, etc., with at least one of a visible indicator or an audible indicator. For example, Fig. 20 illustrates an exemplary image displayable on display screen 84 which indicates an alarm condition. Typically, the user-interface will include an icon or other indicia to specify the cause of the alarm or problem (e.g., high heart rate, high temperature, etc.).

The patient monitor and primary central station may be configured to continue presenting the indicator for a predetermined time period, or for as long as the

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condition or problem persists. Alternatively, the indicator may be terminated after a specified period of time, even if the condition or problem has not ended. In the exemplary embodiment, the indicator also may be terminated (or suspended for a defined time period) if the clinician acknowledges the indication at the patient monitor and/or the primary central station. Thus, an alarm condition detected at the primary central station and communicated to the patient monitor may be acknowledged at the patient monitor. The acknowledgement is communicated to the primary central station, which then terminates the indication. As a result, a clinician attending the patient need not leave the patient's location to return to the primary central station and acknowledge the alarm.

Once communications are established between a patient monitor and a primary central station of the exemplary embodiment, the patient monitor communicates all vital signs data to the primary central station and is controlled by the primary central station. While other central stations also may receive the vital signs data and send instructions for the patient monitor (as will be described in more detail below), the primary central station maintains control of the patient monitor and is responsible for providing the central monitoring. However, control and central monitoring of the patient monitor may be transferred to a different central station, in which case the different central station is configured to take over communications with the patient monitor and assume control of the central station.

In the exemplary embodiment, a clinician may transfer control of the patient monitor to a different central station by entering a transfer instruction at the patient monitor or at the primary central station. If the clinician is at the patient monitor,

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controller 100 transmits the transfer instruction to the primary central station, which responds by sending a list of central stations to the patient monitor. The controller displays the list on display screen 84 to allow the clinician to select the desired central station. Once the clinician makes a selection, the patient monitor communicates the selection to the primary central station, which sends a request to the selected central station to take over the communications. If the selected central station is unavailable, the primary central station sends a notification to the patient monitor so that the clinician can make another selection. Alternatively, the patient monitor may communicate with the selected central station directly. However, if the clinician is at the primary central station when transferring control, the primary central station sends a request to the selected central station to take over the communications, as described above. Once the selected central station takes over as the new primary central station, the patient monitor communicates all subsequent vital signs data to the new primary central station.

As mentioned above, communications dropouts between the patient monitor and the primary central station may occur for a variety of reasons. Once a dropout occurs, the patient monitor begins attempting to restore the communications. However, during the dropout, the patient is not monitored at the central station. Therefore, the patient monitor may be configured to detect when central monitoring has ended, and to take additional steps to minimize any disruption due to the dropout.

In the exemplary embodiment, the patient monitor is configured to function differently when out of communication with a central station. For example, controller 100 may disable buttons 86 (e.g., by disregarding inputs at the buttons) when the

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controller is in communication with a central station so that the functions of the patient monitor can only be changed at the central station. Alternatively, the controller may suppress alarm indications at the patient monitor when in communication with a central station. Similarly, the controller may turn off the display when in communication with a central station to conserve battery power. The controller may be configured to perform the above steps either automatically, or in response to an instruction from the central station. However, the controller typically is configured to activate the buttons, the display and the alarm indications when not in communication with a central station.

Furthermore, some embodiments of patient monitor 22 include a button 86 operable by the patient to request clincian assistance (i.e., a "Nurse Call" button). In such case, the patient monitor may be configured to respond differently to activation of the button depending on whether the patient monitor is in communication with a central station. For example, the patient monitor may be configured to sound an audible alarm if the patient monitor is not in communication with a central station, or to forward the request for assistance to a central station without sounding an audible alarm if the patient monitor is in communication with a central station.

Similarly, when communications between the patient monitor and central station are lost, the patient monitor may be configured to automatically switch from a centrally-monitored mode, in which the vital signs data is communicated to a central station that at least partially controls the patient monitor, to a stand-alone mode, in which the vital signs data are not communicated to a central station. Typically, the patient monitor also is configured to automatically switch from the stand-alone mode

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to the centrally-monitored mode when the communications are restored. In other words, the patient monitor may be configured to automatically relinquish at least partial control of the patient monitoring process when in communication with a central station, but to resume full control in the event communications are lost.

In addition to automatically switching between a stand-alone mode and a centrally-monitored mode, the patient monitor may also be configured to take any one or more of a variety of steps to return to the centrally-monitored mode with minimal disruption. As described above for example, the exemplary patient monitor is configured to automatically and continuously attempt to restore the communications during the dropout. Upon restoring a connection to physical data transport structure 32, the patient monitor is configured to reestablish communications with a primary central station and, where possible, to configure the monitoring session without intervention by a clinician.

Nevertheless, the vital signs data are not communicated to the central station during the dropout. As a result, further analysis at the central station of the vital signs data received during the dropout cannot be conducted, and the vital signs data cannot be stored on database system 40 for later access. Therefore, exemplary patient monitor 22 could be configured to store at least a portion of the vital signs data collected during the dropout, and then communicate the stored vital signs data to the central station once the communications are restored. The vital signs data may be stored in memory device 102 and/or some other data storage buffer. In any event, the data collected during a dropout period would not be lost.

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It will be appreciated that, depending on the length of the dropout, the vital signs data collected may exceed the patient monitor's storage capacity. Therefore, the patient monitor may be configured to store only a portion of the vital signs data collected once it detects the dropout. For example, the patient monitor may be configured to begin storing the data immediately after detecting the dropout, and then cease storing new data once the memory device is full. Alternatively, the patient monitor may be configured to begin storing the data immediately, and once the memory storage is full, to begin storing subsequent data in place of the oldest stored data. As a further alternative, the patient monitor may be configured to store only data from selected sensor assemblies rather than all sensor assemblies.

As another alternative, the patient monitor may be configured to store portions of the vital signs data which meet defined criteria. In the exemplary embodiment for example, controller 100 is configured to analyze the vital signs data received during a dropout, and to detect the occurrence of a medically-significant event based on the vital signs data. The controller only stores data that corresponds to the occurrence of a medically-significant event. Examples of typical medically-significant events include alarm conditions, arrhythmia, activation of the Nurse-Call button, etc. The amount of data stored may vary depending on the event. Typically, a continuous sequence of data is stored from a point in time several seconds or minutes before the event is detected to several seconds or minutes after the event ends. Thus, several running seconds or minutes of prior data are continuously buffered until an event is detected, at which point all or a portion of the data is stored until the event ends.

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It will be appreciated that the criteria defining a medically-significant event may vary depending on the type of event, the type of sensor assembly that collects the data, the condition of the patient, the clinician's judgment, etc. The patient monitor may be pre-programmed with the criteria defining medically-significant events. Alternatively, the criteria for medically-significant events may be programmed into the patient monitor by the clinician or received from the central station. In any event, by storing only data corresponding to the occurrence of medically-significant events, the patient monitor is able to conserve data storage capacity while ensuring that communication dropouts do not prevent the primary central station from receiving the most important vital signs data.

Alternatively, or additionally, exemplary patient monitor 22 may be configured to selectively store data under other conditions. For example, controller 100 may store data at selected time intervals, or in response to an instruction from a clinician via buttons 86, etc. Thus, it will be appreciated that the patient monitor may be configured to selectively store data under any conditions as desired for a particular application.

In the embodiments described above, patient monitor 22 communicates collected vital signs data to a single central station, referred to herein as the primary central station. Likewise, the patient monitor is controlled by the primary central station. However, in other embodiments, the patient monitor may be configured to broadcast the vital signs data it collects to a plurality of central stations, and to receive and execute instructions from a plurality of central stations. As a further alternative,

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the primary central station may be configured to convey vital signs data received from a patient monitor to one or more other central stations.

As shown in Fig. 21, exemplary primary central station 24a is configured to receive vital signs data from patient monitor 22, and to forward the vital signs data to one or more secondary central stations 24b. The vital signs data received from the patient monitor may then be displayed at the secondary central station(s) as well as at the primary central station. Typically, the secondary central station communicates a request to the primary central station to receive a particular patient's vital signs data. In response to the request, the primary central station is configured to continuously forward all vital signs data it receives that is associated with the particular patient. In addition, instructions entered at a secondary central station are communicated to the primary central station, which forwards the instructions to the patient monitor for execution. Thus, from the point of view of a clinician monitoring the patient, a secondary central station provides the same capabilities as the primary central station. However, some functions are performed only at the primary central station, such as storing or archiving the vital signs data to database system 40, performing arrhythmia analysis, etc.

It will be appreciated that communicating the vital signs data to one or more secondary central stations allows the patient's data to be monitored by clinicians at plural locations within the hospital. Thus, there is no need for a clinician to travel to a different floor, or care unit, etc., of the hospital to view the data from a particular patient. Similarly, a clinician endeavoring to monitor a particular patient is not

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restricted to a single location, but instead can monitor the patient from a variety of different locations.

In addition to providing central monitoring from multiple locations, secondary central stations 24b may also be configured to provide a failsafe in the event of a failure involving the primary central station. Thus, in the exemplary embodiment, at least one of the secondary central stations is configured to automatically attempt to take over communications with the patient monitor if communications between primary central station 24a and the patient monitor are lost. The secondary central station may be configured to detect the loss of communications from the primary central station in a variety of ways. In the exemplary embodiment, the secondary central station is configured to detect a loss of communications with the primary central station(even a sudden, catastrophic one such as loss of power). In response to the message, the secondary central station would then attempt to establish communications with the patient monitor. Additionally, the secondary central station is configured to monitor the communications it receives from the primary central station, and if the primary central station suddenly stops communicating (e.g., due to loss of power, malfunction, etc.) for a defined period of time, the secondary central station is configured to attempt to establish communications with the patient monitor. Alternatively, the patient monitor may be configured to transmit a request for communications to the secondary central station in the event the primary central station stops communicating.

Once the secondary central station establishes communications with the patient monitor, the secondary central station takes over the functions of the primary central

station. Alternatively, the clinician may be prompted to select a new primary central station for further monitoring. Where plural secondary central stations are monitoring the patient monitor, the first secondary central station to establish communications with the patient monitor takes over as the primary central station. The new primary central station then begins forwarding the vital signs data received from the patient monitor to the remaining secondary central stations. Thus, the patient continues to be monitored at a central location staffed by clinicians, and the vital signs data collected from the patient continues to be stored for later retrieval.

As described above, patient monitor 22 and central stations 24 are configured to automatically establish and maintain communications while the patient monitor is monitoring a patient. However, patient monitor 22 may also be operable to end the communications with the central station(s). This provides an intentional and controlled termination of communications so that the patient monitor and/or the central stations do not automatically attempt to restore communications. In the exemplary embodiment, the patient monitor is operable by a clinician (e.g., using buttons 86) to transmit an end-communications signal to the primary central station. The primary central station is configured to send a confirmation of the end-communications signal to the patient monitor, which is displayed to the clinician at the patient monitor. The primary central station may also send a notification to the secondary central stations, if any.

Once the end-communications signal has been received and confirmed, the patient monitor may be powered down by the clinician without causing the primary central station to report a loss of communications. The primary central station will of

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course detect the loss of communication, but will be configured not to report this type of loss because it is expected. Alternatively, the primary central station will terminate the communications after a defined delay period even though vital signs data were still being received. If the patient monitor is still operating and collecting data after the communications are terminated, the patient monitor would be required to initiate the rendezvous process described above to resume centralized monitoring of the patient. Any monitoring parameters, alarm conditions, etc., that were changed at the patient monitor in response to an instruction from the central station would be reset to the nominal default values stored by the patient monitor. Likewise, any monitoring parameters, alarm conditions, etc., that were changed at the central station in response to an instruction from the clinician at the patient monitor, would be reset to the nominal default values stored by the central station.

As shown in Figs. 1 and 2 and described above, patient monitor 22b is configured to establish communications with a central station and communicate vital signs data via either one of output port 96 or wireless transceiver 104 (illustrated in Fig. 7). In addition, exemplary patient monitor 22b is configured to detect whether output port 96 is connected to physical data transport structure 32 (either directly or through terminal server 42), and to switch automatically between wireless communications and wire communications depending on whether the output port is connected to the network structure. For example, where patient monitor 22b is initially in communications with a central station via output port 96 and the output port is disconnected from physical data transport structure 32, then controller 100 is configured to automatically associate with an access point and continue the

communications with the central station via wireless transceiver 104. Similarly, where patient monitor 22b is in wireless communications with a central station when output port 96 is connected to physical data transport structure 32, controller 100 is configured to automatically cease communicating via wireless transceiver 104, and instead to communicate with the central station via the output port. Thus, the clinician can select whether patient monitor 22b communicates using wire or wireless communications by connecting and disconnecting, respectively, output port 96 to physical data transport structure 32.

As mentioned above, patient monitor 22 may also be configured to establish communications with a central station to download newer versions of the control software stored in memory device 102 and executable by controller 100. It will be appreciated that the download process may be carried out in any of a variety of different ways within the scope of the invention. It should also be understood that the control software could be for any component of the patient monitor, such as by way of examples, computer cards associated with any/all of the sensor assemblies (e.g. a pulse oximetry card, an NIBP card, etc.), computer cards associated with radio telemetry, etc.

In the exemplary embodiment, patient monitor 22 is operable by a user to request a software update. In response to the user's instructions, the patient monitor attempts to establish communications with one or more central stations, and transmits a query for new versions of the software to the central stations. The query is included as a part of the request for communications which the patient monitor broadcasts to the central stations during the rendezvous process. Each central station responding to

the request indicates the version of the software stored at the central station. The patient monitor waits a defined period (e.g., 10 seconds) to receive responses from the central stations, and then selects a central station with the newest version of the software. Thus, even where the central stations have multiple versions of the software, the patient monitor is configured to determine which central station(s) has the newest version and to download the software from the central station with the newest version. This allows a system administrator to store new versions of the software on just one or a few of the central stations, and then operate the patient monitors to automatically find and download the newest software.

Once a central station with the newest version of the software is selected, the patient monitor transmits a request to the selected central station to download the new software. The selected central station responds by transmitting the new software via either wire or wireless communications, depending on whether the patient monitor is communicating via output port 96 or wireless transceiver 104. The software download may be carried out using any of a variety of methods or protocols, such as Trivial File Transfer Protocol (TFTP), etc. Typically, the patient monitor and selected central station verify that the software was accurately received at the patient monitor using one or more of a variety of error-checking methods known to those of skill in the art. Once the patient monitor receives the new software, controller 100 updates the control software by installing the new software. The controller may carry out this updating process for control software of any of components of the patient monitor as described above.

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As described above, the invention provides a system for continuously monitoring a plurality of patients at one or more central stations using a plurality of portable patient monitors. The invention also provides a method for monitoring a patient at a central location, as indicated generally at 300 in Fig. 22. The method is implemented by software running on patient monitors 22, central stations 24, and/or other components of system 20. The method includes, at step 310 establishing wireless communications between a patient monitor and a communications network having at least one wireless transceiver and a plurality of central stations. Then communicating a list of the plural central stations to the patient monitor via the wireless transceiver, as indicated at step 320. Alternatively, the list of the plural central stations may be provided to, or stored on, the patient monitor in other ways. In any event, method 300 proceeds with selecting, at the patient monitor, one of the plural central stations, as indicated at 330. Then collecting, at the patient monitor, vital signs data from a patient, as indicated at step 340. The vital signs data are communicated to the wireless transceiver, at step 350, and then communicated from the wireless transceiver to the selected central station, at step 360.

A further method for monitoring patients according to the present invention is indicated generally at 400 in Fig. 23. Method 400 includes, at step 410, establishing communications between a wireless patient monitor and a central station adapted to receive vital signs data from a plurality of patients. Configuring the patient monitor to collect vital signs data from a particular one of the plural patients, at step 420. Communicating a list of the plural patients from the central station to the patient monitor, as indicated at step 430. Alternatively, the list of patients may be provided

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to, or stored on, the patient monitor in other ways. In any event, method 400 continues at step 440 with identifying, at the patient monitor, the particular patient. Communicating the identity of the particular patient to the central station, at step 450. Communicating the vital signs data collected from the particular patient to the central station, as indicated at step 460. Finally, associating, at the central station, the vital signs data with the particular patient, as indicated at step 470.

Another method for monitoring patients according to the present invention is indicated generally at 500 in Fig. 24. Method 500 includes, at step 510, establishing wireless communications between a patient monitor and a central station. Collecting vital signs data from a patient at the patient monitor, at step 520. Communicating the vital signs data from the patient monitor to the central station, at step 530. In the event that communications between the patient monitor and the central station are lost, detecting that loss of communications, at step 540. Storing at least a portion of the vital signs data at the patient monitor while the patient monitor is out of communications with the central station, as indicated at step 550. Restoring wireless communications between the patient monitor and the central station, at step 560. Then, communicating at least a portion of the stored vital signs data from the patient monitor to the central station, as indicated at step 570.

Another method for monitoring patients according to the present invention is indicated generally at 600 in Fig. 25, and includes establishing wireless communications between a patient monitor and a first central station, as indicated at step 610. Collecting vital signs data from a patient at the patient monitor, at step 620. Communicating the vital signs data from the patient monitor to the first central station,

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at step 630. So long as communications between the patient monitor and the first central station are maintained, the patient monitor continues to communicate the vital signs data to the first central station, as indicated at 640. However, in the event communications between the patient monitor and the first central station are lost, then wireless communications are automatically established between the patient monitor and a second central station, as indicated at step 650. Finally, communicating the vital signs data from the patient monitor to the second central station, at step 660. It should also be noted that when a clinician using the patient monitor transfers communication to a different central station, there is a transition time (presently that duration is in the range of about 5-10 seconds). During that transition time, the patient monitor could be configured to store data for later uploading to the different central station chosen by the clinician.

Another method for monitoring patients according to the present invention is indicated generally at 700 in Fig. 26. Method 700 includes, at step 710, establishing wireless communications between a patient monitor connected to a particular one of plural patients and a central station. Communicating the identity of the particular patient from the patient monitor to the central station, at step 720. As noted above in connection with the determination of patient ID, either or both the central station and the patient monitor may be involved with this determination. The patient monitor may be adapted to detect the disconnection of the particular patient from the patient monitor, and also adapted to send a patient-disconnection signal to the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost. The central station could then determine patient

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ID by associating the patient-disconnection signal with the patient monitor and received patient vital signs data from that patient monitor. Alternatively, the patient monitor could be adapted to detect the identity of the particular patient and inform the central station of the identity of that particular patient.

Collecting vital signs data from the particular patient at the patient monitor, as indicated at 730. Then, communicating the vital signs data to the central station, at step 740, and associating, at the central station, the patient monitor with the particular patient, as indicated at step 750. So long as communications between the patient monitor and the central station are maintained, the patient monitor continues to communicate the vital signs data to the central station, which associates the vital signs data with the particular patient, as indicated at 760. In the event communications between the patient monitor and the central station are lost for a period of time, reestablishing the communications between the patient monitor and the central station, at step 770. Then, automatically determining, at the central station, whether the patient monitor is still connected to the particular patient, as indicated at step 780. Finally, if the patient monitor is still connected to the particular patient, then associating the patient monitor with the particular patient.

In addition to the exemplary methods for monitoring patients described above, it will be appreciated that the configuration and operation of system 20 is not limited to the exemplary methods as many variations and modifications are possible within the scope of the invention. Further, system 20 may be configured and operated to monitor patients according to a variety of other methods within the scope of the

invention. Therefore, it will be understood that all such methods, variations and modifications are within the scope of the invention.

It is believed that the disclosure set forth above encompasses multiple distinct inventions with independent utility. While each of these inventions has been disclosed in its preferred form, the specific embodiments thereof as disclosed and illustrated herein are not to be considered in a limiting sense as numerous variations are possible. The subject matter of the inventions includes all novel and non-obvious combinations and subcombinations of the various elements, features, functions and/or properties disclosed herein. No single feature, function, element or property of the disclosed embodiments is essential to all of the disclosed inventions. Similarly, where the claims recite "a" or "a first" element or the equivalent thereof, such claims should be understood to include incorporation of one or more such elements, neither requiring nor excluding two or more such elements.

It is believed that the following claims particularly point out certain combinations and subcombinations that are directed to one of the disclosed inventions and are novel and non-obvious. Inventions embodied in other combinations and subcombinations of features, functions, elements and/or properties may be claimed through amendment of the present claims or presentation of new claims in this or a related application. Such amended or new claims, whether they are directed to a different invention or directed to the same invention, whether different, broader, narrower or equal in scope to the original claims, are also regarded as included within the subject matter of the inventions of the present disclosure.

WE CLAIM

1. A wireless patient monitor adapted to communicate with any one of plural medical telemetry networks, each having one or more central stations, where each network is configured to communicate via wireless communications using one of multiple different communications settings, the monitor comprising:

one or more sensor inputs for receiving vital signs data from a patient;

a wireless transceiver configured to transmit and receive wireless communications; and

a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver;

where the controller is configured, upon initial power-up, to automatically transmit a signal to a local one of the plural networks via the transceiver to request the communications settings used by the local network, and to establish communications with at least one of the central stations on the local network using the communications settings received from the local network without intervention from a user of the patient monitor.

2. The monitor of claim 1, where the controller is configured to transmit the vital signs data to the at least one central station using the selected communications settings.

3. The monitor of claim 2, where the controller is configured to transmit the vital signs data to the at least one central station without intervention from the user.

4. The monitor of claim 1, where the communications settings include a communications address for the monitor.

5. The monitor of claim 1, where the communications settings include a communications address for the at least one central station.

6. A wireless, patient vital signs monitor adapted to communicate with a medical telemetry network having at least one central station, the monitor comprising:

one or more sensor input ports for receiving patient vital signs data;

a controller coupled to receive the vital signs data via the one or more input ports;

a wireless transceiver controllable by the controller to communicate with the at least one central station;

where the controller is configured, when not in communication with the at least one central station, to repeatedly attempt to establish communications with the at least one central station via the wireless transceiver; and

a display device controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station.

7. The monitor of claim 6, further comprising one or more user-operable input devices, and where the controller is adapted to control the display device to display a user-interface adapted to request inputs from a user via the one or more input devices.

8. The monitor of claim 7, where the controller is adapted to receive instructions from the at least one central station via the wireless transceiver, and where the user-interface is at least partially defined by the instructions.

9. The monitor of claim 8, where the medical telemetry network includes plural central stations, and where the instructions identify at least two of the plural central stations, and where the user-interface is adapted to allow a user to select one of the identified central stations via the one or more input devices.

10. The monitor of claim 9, where the controller is adapted, if not in communication with the selected central station, to attempt to establish communications with the selected central station and transmit the vital signs data to the selected central station.

11. The monitor of claim 9, where the controller is adapted to control the display device to display a notification to the user if the controller cannot establish communications with the selected central station.

12. A wireless, patient vital signs monitor adapted to communicate with a central station, comprising:

a wireless transceiver;

a controller coupled to the wireless transceiver and configured to establish communications with the central station via the wireless transceiver; and

one or more sensor input ports for receiving patient vital signs data;

where the controller is coupled to receive the vital signs data via the one or more input ports and communicate the vital signs data to the central station via the wireless transceiver;

where the controller includes a data storage buffer for storage of the vital signs data, and where the controller is configured to automatically detect a loss of communications with the central station, and to store, in the data storage buffer, at least a portion of the vital signs data received while out of communications with the central station; and

where the controller is configured to communicate the stored vital signs data to the central station via the wireless transceiver if communications with the central station are restored.

13. The monitor of claim 12, where the controller is adapted to store only the portions of the vital signs data that meet one or more defined criteria.

14. The monitor of claim 12, where the controller is adapted to analyze the vital signs data received while out of communications with the central station, and to detect the occurrence of a medically-significant event based on the vital signs data.

15. The monitor of claim 14, where the controller is adapted to store only those portions of the vital signs data which correspond to the occurrence of medically-significant events.

16. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a central station;

collecting vital signs data from a patient at the patient monitor;

communicating the vital signs data from the patient monitor to the central station;

detecting a loss of communications between the patient monitor and the central station;

storing at least a portion of the vital signs data at the patient monitor while the patient monitor is out of communications with the central station;

restoring wireless communications between the patient monitor and the central station; and

communicating at least a portion of the stored vital signs data from the patient monitor to the central station.

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17. The method of claim 16, further comprising analyzing the vital signs data at the patient monitor while the patient monitor is out of communications with the central station to detect the occurrence of a medically-significant event, and where the step of storing includes storing only portions of the vital signs data which correspond to the occurrence of medically-significant events.

18. A wireless, patient vital signs monitor adapted to communicate with a medical telemetry network having at least one central station, the monitor comprising:

one or more sensor input ports for receiving patient vital signs data;

a wireless transceiver; and

a controller coupled to receive the vital signs data via the one or more input ports, and configured to control the wireless transceiver to establish and maintain communications with the at least one central station;

where the controller is configured to detect a loss of communications with the at least one central station, and if a loss of communications is detected, to automatically switch from a first operating mode in which the controller transmits the received vital signs data to the at least one central station, to a second operating mode in which the controller does not transmit the received vital signs data to the at least one central station.

19. The monitor of claim 18, where the controller is adapted to attempt to reestablish communications with the at least one central station, and to automatically switch back to the first operating mode if the communications are reestablished.

20. The monitor of claim 18, further comprising an output device controllable by the controller to indicate an alarm if the vital signs data is outside one or more defined ranges, and where the controller is adapted to control the output device not to indicate the alarm when the controller is in the first operating mode.

21. The monitor of claim 18, further comprising one or more input devices operable by a user to input information to the controller, and where the controller is adapted to disregard at least some inputs by the user when the controller is in the first operating mode.

22. The monitor of claim 18, further comprising a display device controllable by the controller to display information to a user, and where the controller is adapted to control the display device not to display any information when the controller is in the first operating mode.

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23. The monitor of claim 18, further comprising an output device controllable by the controller to indicate an alarm, and an input device operable by a user to input a request for assistance to the controller, and where, if the user inputs a request for assistance, the controller is configured to communicate the request to the at least one central station if in the first operating mode, and to control the output device to indicate an alarm if in the second operating mode.

24. A wireless, patient vital signs monitor adapted to communicate with at least one central station connected to receive vital signs data via a communications network, where the communications network includes one or more hard-wired ports and one or more network transceivers, the monitor comprising:

one or more sensor input ports for receiving patient vital signs data;

an output port connectable to a hard-wired port on the network;

a wireless transceiver adapted to transmit information to, and receive information from, at least one of the one or more network transceivers; and

a controller coupled to receive the vital signs data via the one or more input ports, and configured to communicate the vital signs data to the at least one central station via a selected one of the output port or the wireless transceiver.

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25. The monitor of claim 24, where the controller is configured to communicate the vital signs data to the at least one central station via the output port if the output port is connected to a hard-wired port, and to communicate the vital signs data to the at least one central station via the wireless transceiver if the output port is not connected to a hard-wired port.

26. The monitor of claim 25, where the controller is configured to automatically switch from communicating the vital signs data via the output port to communicating the vital signs data via the wireless transceiver upon the disconnection of the output port from a hard-wired port.

27. The monitor of claim 25, where the controller is configured to automatically switch from communicating the vital signs data via the wireless transceiver to communicating the vital signs data via the output port upon the connection of the output port to a hard-wired port.

28. A method for monitoring a patient, comprising:

providing a medical telemetry network having at least one central station connected to one or more wireless transceivers and to one or more hard-wired ports;

collecting vital signs data from a patient at a patient monitor;

automatically detecting whether the patient monitor is connected to one of the one or more hard-wired ports;

communicating the vital signs data to the central station via the wireless transceiver if the patient monitor is not connected to one of the one or more hard-wired ports.

29. The method of claim 28, further comprising, if the patient monitor is connected to one of the one or more hard-wired ports, then communicating the vital signs data to the central station via the connected hard-wired port.

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30. A wireless medical telemetry system, comprising:

a central station adapted to receive vital signs data associated with a plurality of patients; and

at least one wireless patient monitor including a controller and a wireless transceiver, where the patient monitor also includes control software executable by the controller to

monitor a particular one of the plurality of patients by collecting vital signs data from the particular patient, and

transmit the collected vital signs data to the central station via the wireless transceiver;

where the controller is adapted to receive new control software via the wireless transceiver, and to update the control software with new control software.

31. The system of claim 30, where the controller is adapted to receive the new control software from the central station.

32. The system of claim 31 wherein the at least one patient monitor includes plural components, and the controller is adapted to receive the new control software for use with any of the components.

33. The system of claim 32, where the controller is adapted to transmit a query to the central station to determine whether the new control software is available for transmission to the patient monitor.

34. The system of claim 33, further comprising a second central station, and where the controller is adapted to transmit the query to both central stations, and where each central station is adapted to respond to the query.

35. The system of claim 34, where each of the central station and the second central station are adapted to store a different one of multiple versions of the new control software, and where each central station is adapted to inform the patient monitor of the version of the new control software it stores in response to the query, and

where the controller is adapted to determine which central station is storing a latest version of the new control software and to transmit a download request to the central station that is storing the latest version.

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36. A wireless medical telemetry system, comprising:

at least one wireless patient monitor configured to collect patient vital signs data; and

at least one central station adapted to establish communications with the at least one patient monitor via a wireless transceiver, and to receive the patient vital signs data from the at least one patient monitor;

where the at least one patient monitor is operable by a user to transmit an end-communications signal to the at least one central station; and

where the at least one central station is configured to terminate the communications with the at least one patient monitor in response to the end-communications signal.

37. The system of claim 36, where the at least one central station is configured to communicate a confirmation of the end-communications signal to the patient monitor.

38. The system of claim 37, where the at least one patient monitor includes a display device adapted to display a message to the user in response to the confirmation.

39. The system of claim 36, where the at least one central station is configured to continue receiving the vital signs data until the communications with the at least one patient monitor are terminated.

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40. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a wireless transceiver connected to a remote central station;

collecting, at the patient monitor, vital signs data from a patient and communicating the vital signs data to the central station via the wireless transceiver;

communicating an end-communications signal from the patient monitor to the central station; and

terminating the communications by the central station in response to the end-communications signal.

41. The method of claim 40, further comprising communicating a confirmation of the end-communications signal from the central station to the patient monitor.

42. The method of claim 41, further comprising displaying a message to a user of the patient monitor in response to the confirmation.

43. The method of claim 40, further comprising discontinuing the step of collecting and communicating the vital signs data.

44. The method of claim 43, where the step of terminating is performed before the discontinuing.

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45. The method of claim 43, where the step of terminating is performed after the discontinuing.

46. A system for monitoring the vital signs of a patient from a selected remote location, the system comprising:

at least one wireless patient monitor adapted to collect vital signs data from a patient;

a medical telemetry network including a plurality of central stations adapted to receive vital signs data, and one or more wireless transceivers adapted to communicate with the at least one patient monitor;

where the at least one patient monitor is operable by a user to select one of the plural central stations, and to transmit a request to establish communications to the selected central station via the one or more wireless transceivers.

47. The system of claim 46, where the selected central station is adapted to establish communications with the at least one patient monitor in response to the request, and to receive the vital signs data via the one or more wireless transceivers.

48. The system of claim 46, where at least one of the plural central stations is configured to communicate a list of the plural central stations to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list of plural central stations to the user.

49. The system of claim 48, where the at least one patient monitor includes one or more input devices operable by the user to select one of the plural central stations on the list.

50. The system of claim 46, where the at least one patient monitor is operable by the user to select a different one of the plural central stations, and to transmit, to the selected central station, a request to change communications from the selected central station to the different central station.

51. The system of claim 50, where the selected central station is configured to terminate communications with the at least one patient monitor in response to the request to change communications.

52. The system of claim 51, where the different central station is configured to establish communications with the at least one patient monitor in response to the request to change communications, and to receive the vital signs data via the one or more wireless transceivers.

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53. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a communications network having at least one wireless transceiver and a plurality of central stations;

selecting, at the patient monitor, one of the plural central stations;

collecting, at the patient monitor, vital signs data from a patient and communicating the vital signs data to the wireless transceiver; and

communicating the vital signs data from the wireless transceiver to the selected central station via the communications network.

54. The method of claim 53, further comprising:

communicating a list of the plural central stations to the patient monitor via the wireless transceiver; and

displaying the list to a user of the patient monitor.

55. The method of claim 54, further comprising receiving an input from the user selecting one of the plural central stations on the list.

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56. The method of claim 55, further comprising:

receiving a subsequent input from the user selecting a different one of the plural central stations;

communicating subsequently collected vital signs data to the wireless transceiver; and

communicating the subsequently collected vital signs data from the wireless transceiver to the different central station via the communications network.

57. A medical monitoring system, comprising:

a central station adapted to receive vital signs data concerning a plurality of patients;

one or more transmitter/receivers associated with the central station; and

at least one patient monitor configured to monitor a particular one of the plurality of patients by collecting vital signs data from the particular patient, and configured to establish communications with the central station and communicate the collected vital signs data to the central station via the one or more transmitter/receivers;

where the at least one patient monitor is operable by a user to identify the particular patient from the plurality of patients, and to inform the central station of the identity of the particular patient; and

where the central station is configured to associate the vital signs data received from the at least one patient monitor with the particular patient.

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58. The system of claim 57, where the central station is configured to transmit a list of the plurality of patients to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list to the user.

59. The system of claim 57, where the central station is adapted to store the identity of the particular patient and, in the event that the communications with the central station are lost and then restored, to transmit a request to the at least one patient monitor for a confirmation that the at least one patient monitor is still configured to monitor the particular patient.

60. The system of claim 57, where the system, the one or more transmitter/receivers, and the at least one patient monitor is wireless.

61. The system of claim 60, where the central station is configured to transmit a list of the plurality of patients to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list to the user.

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62. The system of claim 61, where the central station is adapted to store the identity of the particular patient and, in the event that the communications with the central station are lost and then restored, to transmit a request to the at least one patient monitor for a confirmation that the at least one patient monitor is still configured to monitor the particular patient.

63. A method for monitoring a patient, comprising:

establishing communications between a patient monitor and a central station via a transmitter/receiver associated with the central station, where the central station is adapted to receive vital signs data from a plurality of patients;

configuring the patient monitor to collect vital signs data from a particular one of the plural patients;

identifying, at the patient monitor, the particular patient;

communicating the identity of the particular patient to the central station;

communicating the vital signs data to the central station; and

associating, at the central station, the vital signs data with the particular patient.

64. The method of claim 63, further comprising:

communicating a list of the plural patients from the central station to the patient monitor; and

displaying the list to a user of the monitor.

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65. The method of claim 63, further comprising,

if the communications between the patient monitor and the central station are lost, then:

restoring the communications between the patient monitor and the central station;

communicating a request for confirmation from the central station to the patient monitor that the patient monitor is still configured to monitor the particular patient; and

communicating the confirmation from the patient monitor to the central station.

66. The method of claim 63, where the step of establishing communications is between a wireless patient monitor and a central station via a wireless transmitter/receiver associated with the central station, where the central station is adapted to receive vital signs data from a plurality of patients.

67. The method of claim 66, further comprising:

communicating a list of the plural patients from the central station to the patient monitor; and

displaying the list to a user of the monitor.

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68. The method of claim 66, further comprising,

if the communications between the patient monitor and the central station are lost, then:

restoring the communications between the patient monitor and the central station;

communicating a request for confirmation from the central station to the patient monitor that the patient monitor is still configured to monitor the particular patient; and

communicating the confirmation from the patient monitor to the central station.

69. A medical monitoring system, comprising:

a central station associated with one or more transmitter/receivers, and adapted to receive vital signs data concerning a plurality of patients; and

a patient monitor having a transmitter/receiver, the patient monitor being adapted to establish communications with the central station and transmit an identity of a particular one of the plural patients, and adapted to collect vital signs data from the particular patient when connected to the particular patient and to transmit the vital signs data to the central station;

where the central station is configured to receive the identity of the particular patient and the vital signs data, and to associate the vital signs data with the particular patient when the communications are established; and

where, in the event that the communications between the patient monitor and central station are lost for a period of time and then restored, the central station is configured to automatically determine whether the patient monitor is still connected to the particular patient, and to associate the vital signs data with the particular patient if the patient monitor is still connected to the particular patient.

70. The system of claim 69, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

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71. The system of claim 69, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to inform the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

72. The system of claim 69, where the central station is configured to transmit a request to the patient monitor for a patient identity if the central station does not determine that the patient monitor is still connected to the particular patient.

73. The system of claim 69, where the system and the one or more transmitter/receivers are wireless.

74. The system of claim 73, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

75. The system of claim 73, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to inform the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

76. The system of claim 73, where the central station is configured to transmit a request to the patient monitor for a patient identity if the central station does not determine that the patient monitor is still connected to the particular patient.

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77. A method for monitoring a patient from a central station configured to monitor a plurality of patients, where each of the plural patients has an identity, the method comprising:

establishing communications between a patient monitor connected to a particular one of the plural patients and the central station;

communicating the identity of the particular patient from the patient monitor to the central station;

collecting vital signs data from the particular patient at the patient monitor;

communicating the vital signs data to the central station;

associating, at the central station, the vital signs data with the particular patient; and

in the event communications between the patient monitor and the central station are lost for a period of time:

reestablishing the communications between the patient monitor and the central station,

automatically determining, at the central station, whether the patient monitor is still connected to the particular patient, and

if the patient monitor is still connected to the particular patient, then associating the vital signs data with the particular patient.

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78. The method of claim 77, where the step of determining includes determining that the patient monitor is still connected to the particular patient if the period of time when the communications between the patient monitor and the central station were lost was less than a predetermined length of time.

79. The method of claim 77, where the step of determining includes

detecting, at the patient monitor, if the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost; and

informing the central station whether the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost.

80. The method of claim 77, where the step of establishing communications involves wireless communications between a patient monitor connected to a particular one of the plural patients and the central station.

81. The method of claim 80, where the step of determining includes determining that the patient monitor is still connected to the particular patient if the period of time when the communications between the patient monitor and the central station were lost was less than a predetermined length of time.

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82. The method of claim 80, where the step of determining includes

detecting, at the patient monitor, if the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost; and

informing the central station whether the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost.

83. A method for monitoring a patient, comprising:

collecting, by a patient monitor, vital signs data from the patient;

establishing communications between the patient monitor and a central station;

communicating the vital signs data from the patient monitor to the central station;

analyzing the vital signs data to detect an alarm condition;

indicating the alarm condition at both the patient monitor and the central station;

receiving, at the patient monitor, an acknowledgement from a user of the patient monitor;

communicating the acknowledgement from the patient monitor to the central station; and

terminating the indication of the alarm condition at the central station in response to the acknowledgement.

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84. The method of claim 84, where the step of indicating includes indicating the alarm condition at the patient monitor, and further comprising terminating the indication of the alarm condition at the patient monitor in response to the acknowledgement.

85. The method of claim 84, where the step of indicating includes producing an audible signal at the central station, and where the step of terminating includes terminating the audible signal.

86. The method of claim 84, where the step of indicating includes producing a visible signal at the central station, and where the step of terminating includes terminating the visible signal.

87. The method of claim 84, where the step of analyzing is performed by the central station.

88. The method of claim 84, where the step of analyzing is performed by the patient monitor.

89. The method of claim 84, where the step of establishing communications involves wireless communications between the patient monitor and a central station.

90. The method of claim 89, where the step of indicating includes indicating the alarm condition at the patient monitor, and further comprising terminating the indication of the alarm condition at the patient monitor in response to the acknowledgement.

91. The method of claim 89, where the step of indicating includes producing an audible signal at the central station, and where the step of terminating includes terminating the audible signal.

92. The method of claim 89, where the step of indicating includes producing a visible signal at the central station, and where the step of terminating includes terminating the visible signal.

93. The method of claim 89, where the step of analyzing is performed by the central station.

94. The method of claim 89, where the step of analyzing is performed by the patient monitor.

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95. A medical monitoring system, comprising:

at least one patient monitor adapted to collect vital signs data from a patient; and

a central station adapted to communicate with the at least one patient monitor via transmissions;

where the at least one patient monitor includes a controller configured to analyze the vital signs data based on one or more variable parameter values; and

where the central station is configured to communicate an instruction to the at least one patient monitor to change the value of at least one of the one or more variables to a new value, and where the controller is configured to analyze the vital signs data based on the new value in response to the instruction.

96. The system of claim 95, where the one or more variable parameter values includes a nominal data range, and where the controller is configured to analyze the vital signs data to determine whether the vital signs data is within the nominal data range and to indicate an alarm condition to a user if the vital signs data is outside the nominal data range.

97. The system of claim 96, where the vital signs data includes data indicating a heart-rate of the patient, and where the one or more variable parameter values includes a nominal range of heart-rate data.

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98. The system of claim 96, where the vital signs data includes data chosen from the group consisting of the oxygen saturation of the patient's arterial blood, the patient's blood pressure, and the amount of carbon dioxide in the patient's breath, and where the one or more variable parameter values is respectively chosen from the group consisting of a nominal range of oxygen saturation data, blood pressure data, and carbon dioxide data.

99. The system of claim 95, where the system and the at least one patient monitor are wireless, and the central station is adapted to communicate with the at least one patient monitor via wireless transmissions.

100. The system of claim 99, where the one or more variable parameter values includes a nominal data range, and where the controller is configured to analyze the vital signs data to determine whether the vital signs data is within the nominal data range and to indicate an alarm condition to a user if the vital signs data is outside the nominal data range.

101. The system of claim 100, where the vital signs data includes data indicating a heart-rate of the patient, and where the one or more variable parameter values includes a nominal range of heart-rate data.

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102. The system of claim 100, where the vital signs data includes data chosen from the group consisting of the oxygen saturation of the patient's arterial blood, the patient's blood pressure, and the amount of carbon dioxide in the patient's breath, and where the one or more variable parameter values is respectively chosen from the group consisting of a nominal range of oxygen saturation data, blood pressure data, and carbon dioxide data.

103. A medical monitoring system, comprising:

a central station adapted to receive vital signs data concerning a plurality of patients;

one or more transmitter/receivers associated with the central station; and

at least one patient monitor configured to monitor a particular one of the plurality of patients by collecting vital signs data from the particular patient, and configured to establish communications with the central station and communicate the collected vital signs data to the central station via the one or more transmitter/receivers;

where the system is operable by plural users to identify the particular patient from the plurality of patients, and to inform the user of the identity of the particular patient; and

where the system is configured to associate the vital signs data received from the at least one patient monitor with the particular patient.

104. The system of claim 103, where the central station is operable by a first user to identify the particular patient from the plurality of patients, and to inform a second user of the identity of the particular patient.

105. The system of claim 103, where the at least one patient monitor is operable by the second user to identify the particular patient from the plurality of patients, and to inform a second user of the identity of the particular patient.

106. The system of claim 104, where the central station is configured to maintain a list of the plurality of patients being monitored by the system.

107. The system of claim 104, where the central station is configured to transmit a list of the plurality of patients to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list to the second user.

108. The system of claim 107, where the central station is adapted to store the identity of the particular patient and, in the event that the communications with the central station are lost and then restored, to transmit a request to the at least one patient monitor for a confirmation that the at least one patient monitor is still configured to monitor the particular patient.

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109. A medical monitoring system, comprising:

a central station associated with one or more transmitter/receivers, and adapted to receive vital signs data concerning a plurality of patients; and

a patient monitor having a transmitter/receiver, the patient monitor being adapted to establish communications with the central station and adapted to collect vital signs data from a particular one of the plural patients when connected to the particular patient and to transmit the vital signs data to the central station;

where the central station is configured to receive the vital signs data, and to associate the vital signs data with the particular patient when the communications are established; and

where, in the event that the communications between the patient monitor and central station are lost for a period of time and then restored, the central station is configured to automatically determine whether the patient monitor is still connected to the particular patient, and to associate the vital signs data with the particular patient if the patient monitor is still connected to the particular patient.

110. The system of claim 109, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

111. The system of claim 109, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to send a patient-disconnection signal to the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

112. The system of claim 111, wherein the patient monitor is adapted to detect the identity of the particular patient and inform the central station of the identity.

113. The system of claim 109, where the central station is configured to transmit a request to the patient monitor for a patient identity if the central station does not determine that the patient monitor is still connected to the particular patient.

114. The system of claim 109, where the system and the one or more transmitter/receivers are wireless.

115. The system of claim 114, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

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116. The system of claim 114, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to send a patient-disconnection signal to the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

117. The system of claim 116, wherein the patient monitor is adapted to detect the identity of the particular patient and inform the central station of the identity.

118. A wireless medical telemetry system, comprising:

at least one wireless patient monitor configured to monitor a patient by collecting vital signs data from the patient;

a first central station associated with one or more wireless transceivers, and adapted to establish communications with the at least one patient monitor and receive the vital signs data via the one or more wireless transceivers; and

a second central station associated with the one or more wireless transceivers, and adapted to receive vital signs data via the one or more wireless transceivers;

where the second central station is configured to automatically attempt to establish communications with the at least one patient monitor and receive the vital signs data in place of the first central station in the event the communications between the first central station and the at least one patient monitor are lost.

119. The system of claim 118, where the second central station is configured to monitor the communications between the first central station and the at least one patient monitor.

120. The system of claim 119, where the second central station is configured to monitor the communications between the first central station and the at least one patient monitor by receiving the vital signs data from the first central station, and to automatically attempt to establish communications with the at least one patient monitor if the second central station stops receiving the vital signs data from the first central station.

121. The system of claim 118, where the at least one patient monitor is configured to transmit a request to establish communications to the second central station via the one or more wireless transceivers in the event the communications with the first central station are lost.

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122. The system of claim 118, further comprising a third central station associated with the one or more wireless transceivers, and adapted to receive vital signs data via the one or more wireless transceivers, and where both the second and third central stations are configured to automatically attempt to establish communications with the at least one patient monitor and receive the vital signs data in place of the first central station in the event the communications between the first central station and the at least one patient monitor are lost.

123. The system of claim 118, where the first central station is configured to communicate instructions to the at least one patient monitor to control the patient monitor, and where the second central station is configured to automatically attempt to assume control of the at least one patient monitor in the event the communications between the first central station and the at least one patient monitor are lost.

124. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a first central station;

collecting vital signs data from a patient at the patient monitor;

communicating the vital signs data from the patient monitor to the first central station; and

if communications between the patient monitor and the first central station are lost, automatically establishing wireless communications between the patient monitor and a second central station, and communicating the vital signs data from the patient monitor to the second central station.

125. The method of claim 124, further comprising monitoring, at the second central station, the communications between the patient monitor and the first central station.

126. The method of claim 125, where the step of monitoring includes receiving, at the second central station, the vital signs data from the first central station.

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127. The method of claim 124, where the step of establishing wireless communications between the patient monitor and the second central station includes detecting, at the patient monitor, a loss of communications with the first central station, and transmitting a request to establish communications from the patient monitor to the second central station.

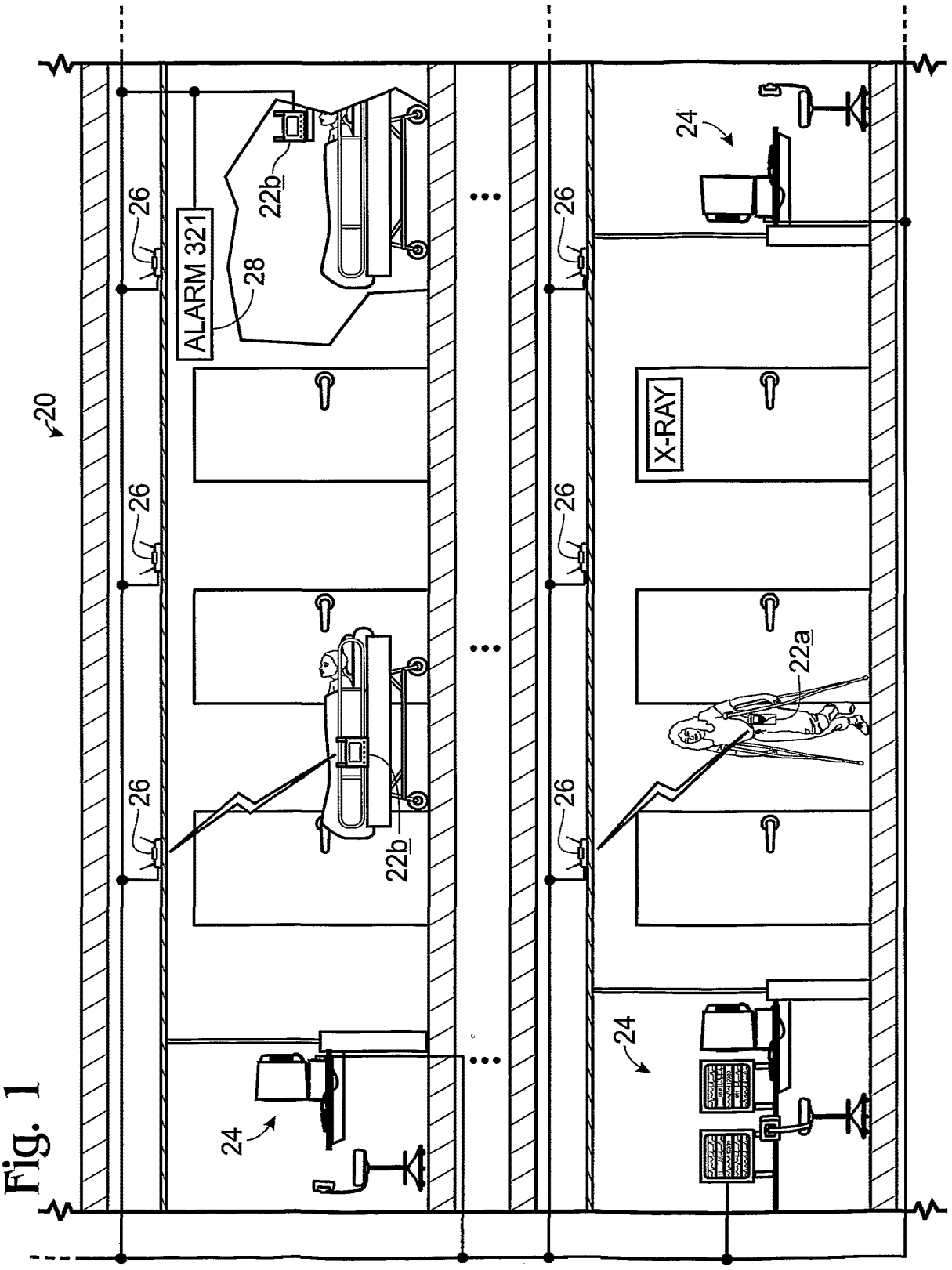


Fig. 1

Fig. 2

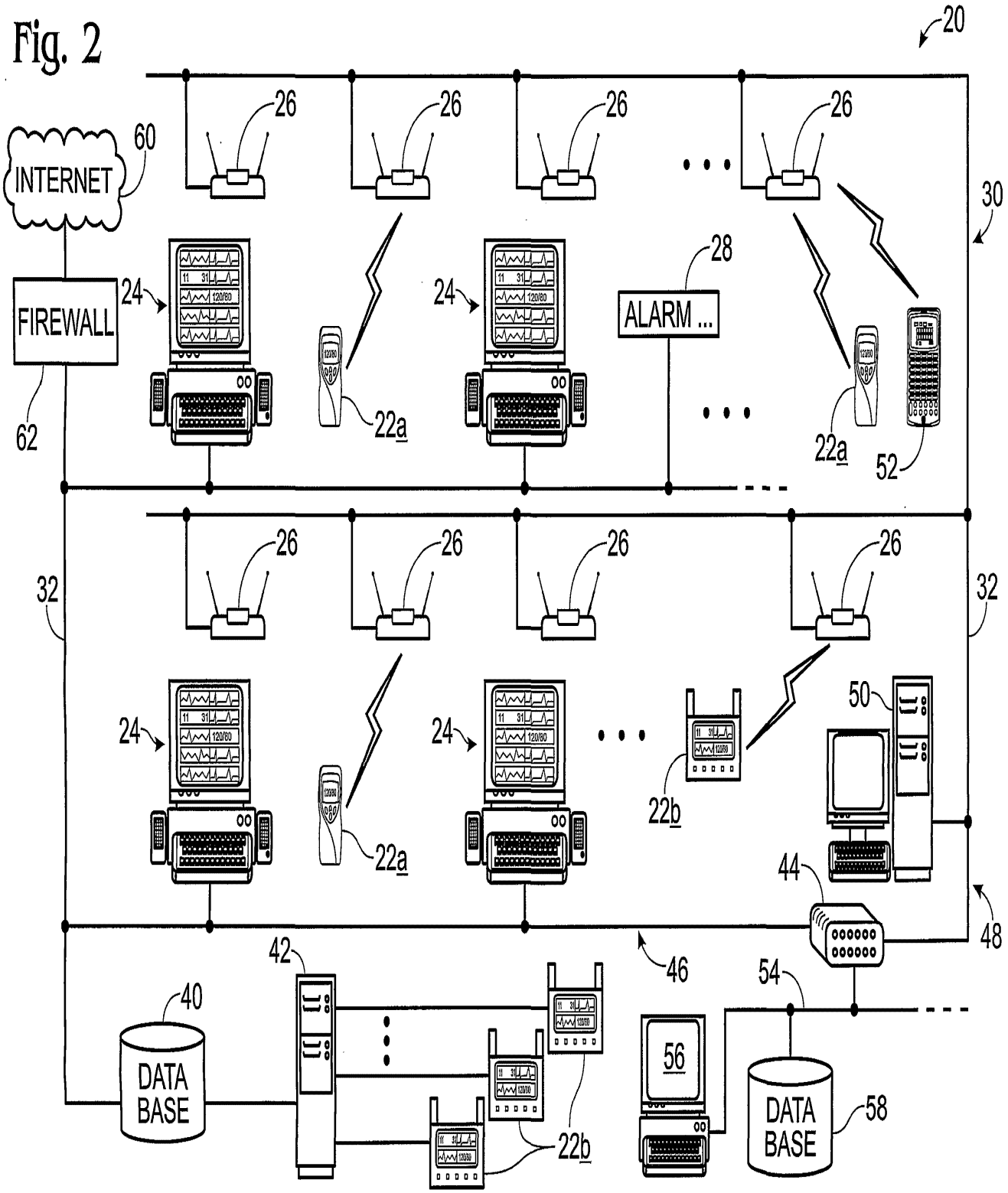

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DATA BASE
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Fig. 3

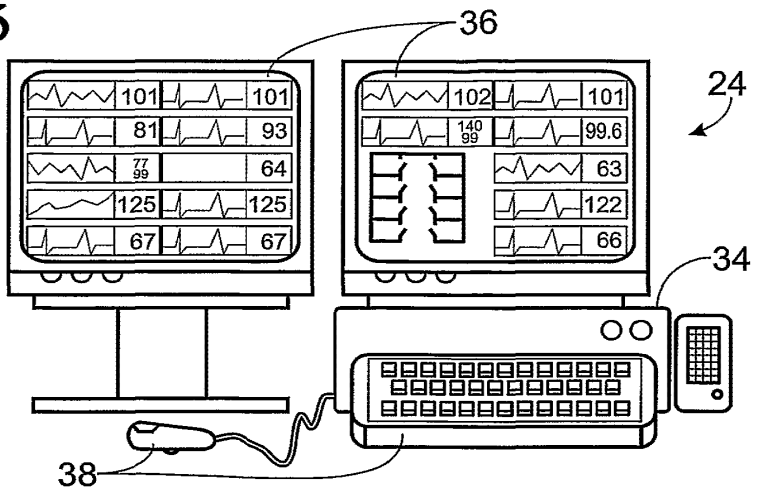

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Fig. 4

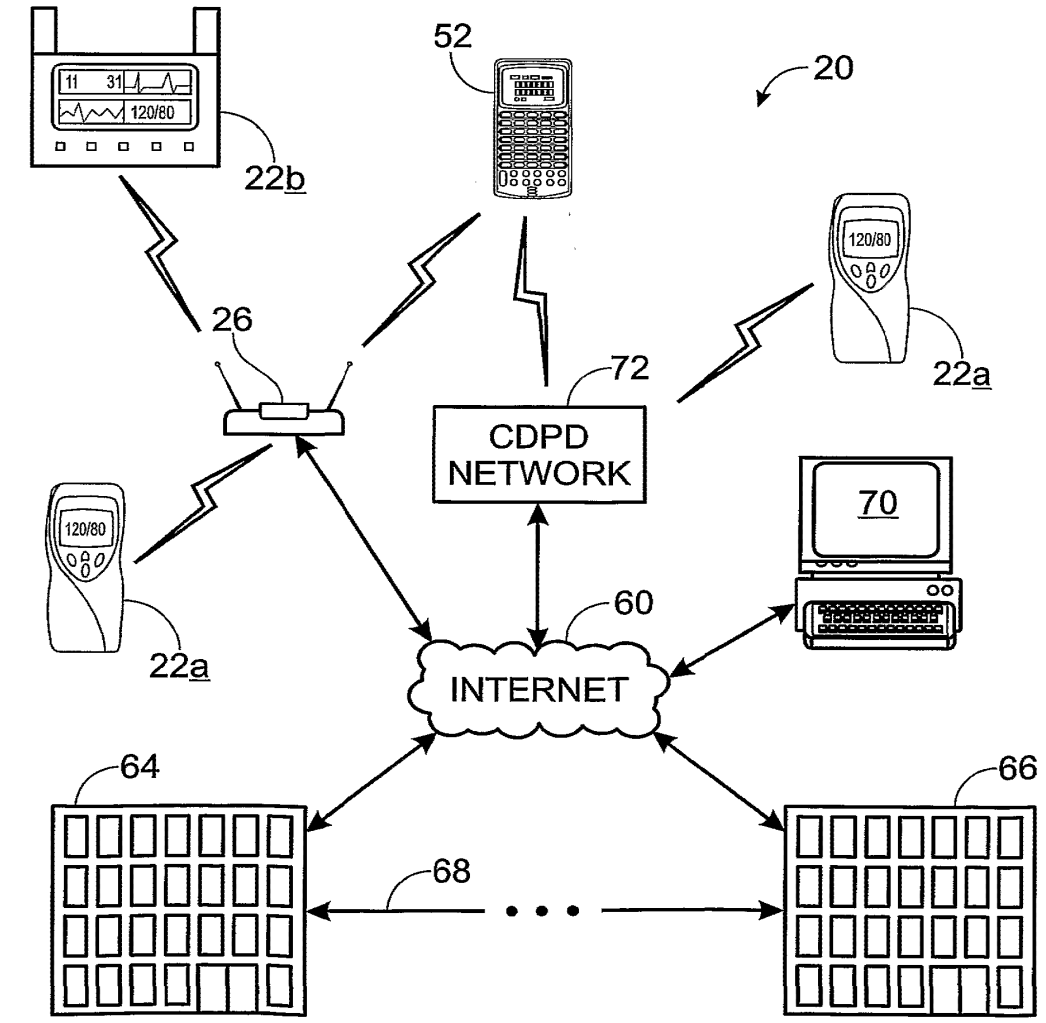

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NETWORK
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Fig. 5

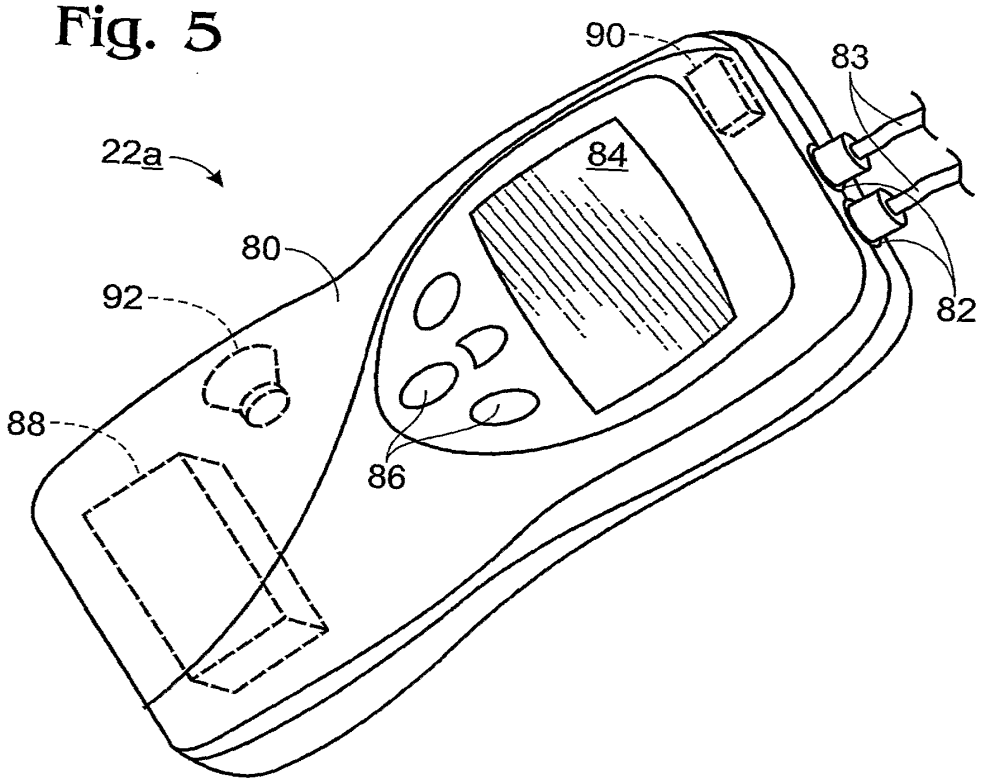


Fig. 6

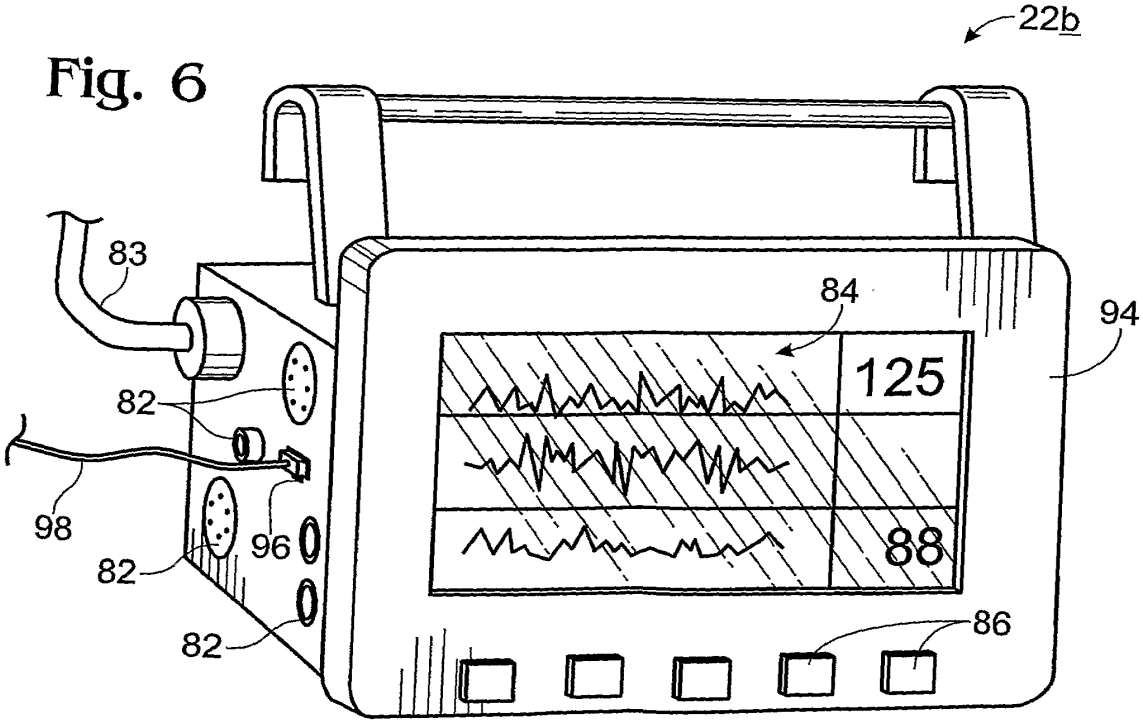


Fig. 7

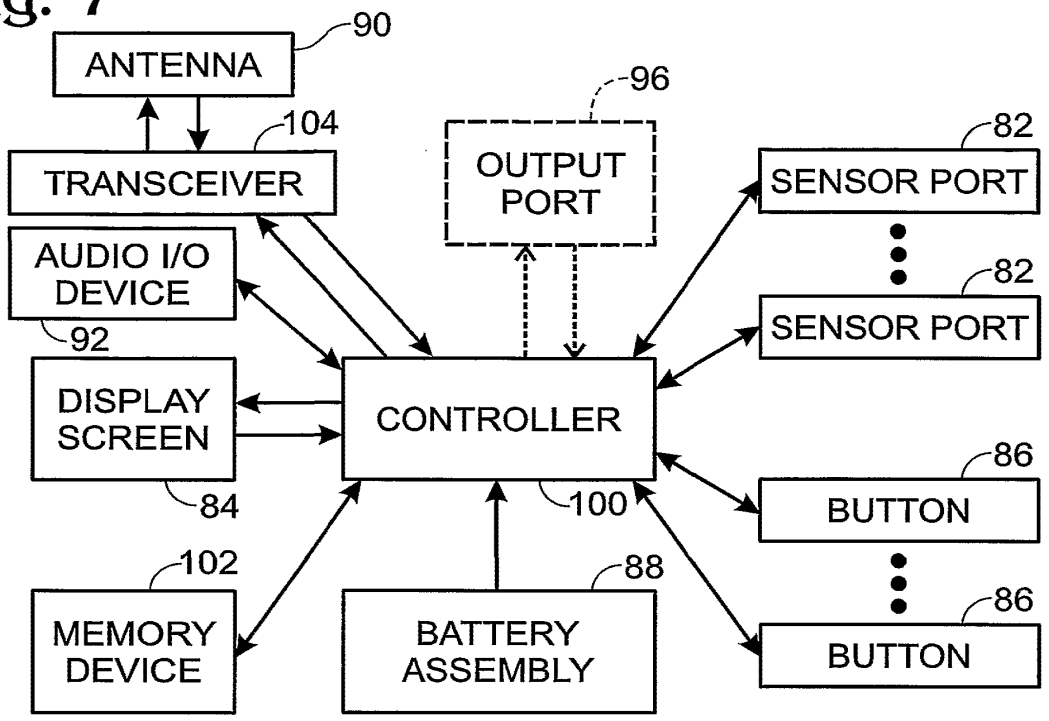

ANTENNA
90
TRANSCEIVER
104
OUTPUT PORT
96
SENSOR PORT
82
SENSOR PORT
82
AUDIO I/O DEVICE
92
DISPLAY SCREEN
84
CONTROLLER
100
BUTTON
86
BUTTON
86
MEMORY DEVICE
102
BATTERY ASSEMBLY
88

Fig. 8

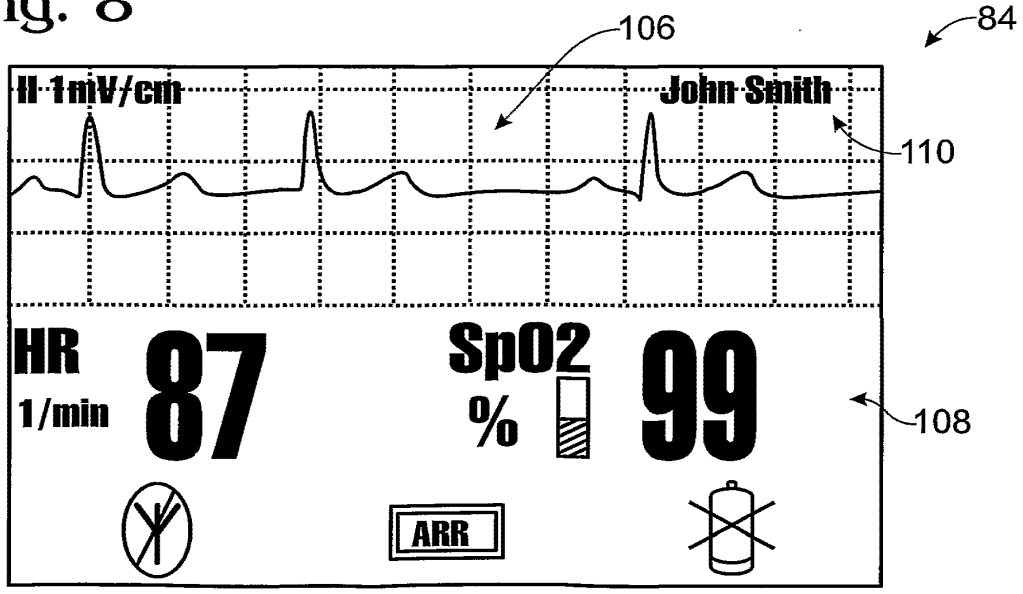

84
106
II 1mV/cm
John Smith
110
HR
1/min
87
SpO2
%
99
108
ARR

Fig. 9

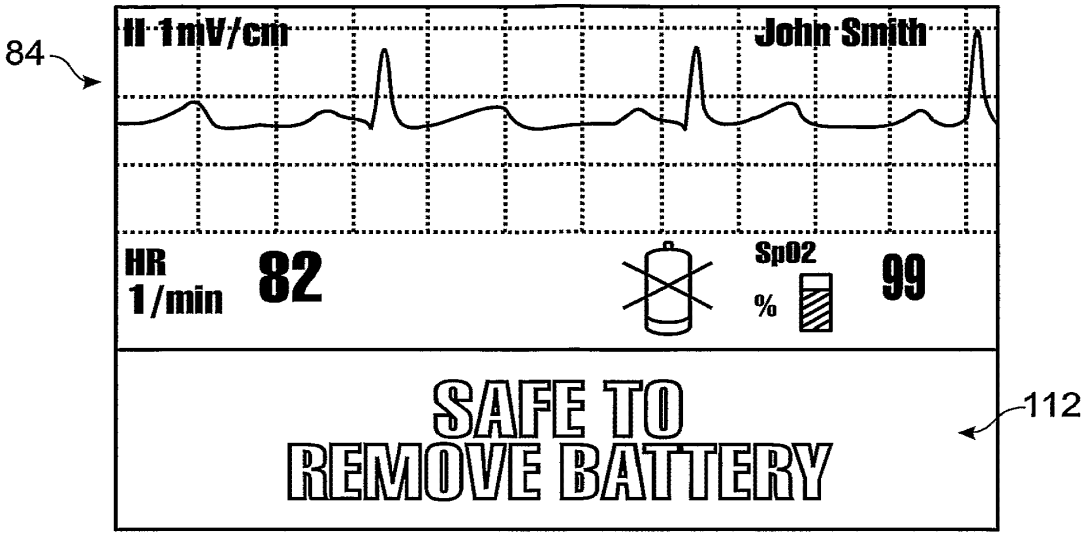

84
II 1mV/cm
John Smith
HR
1/min
82
SpO2
%
99
SAFE TO
REMOVE BATTERY
112

Fig. 10

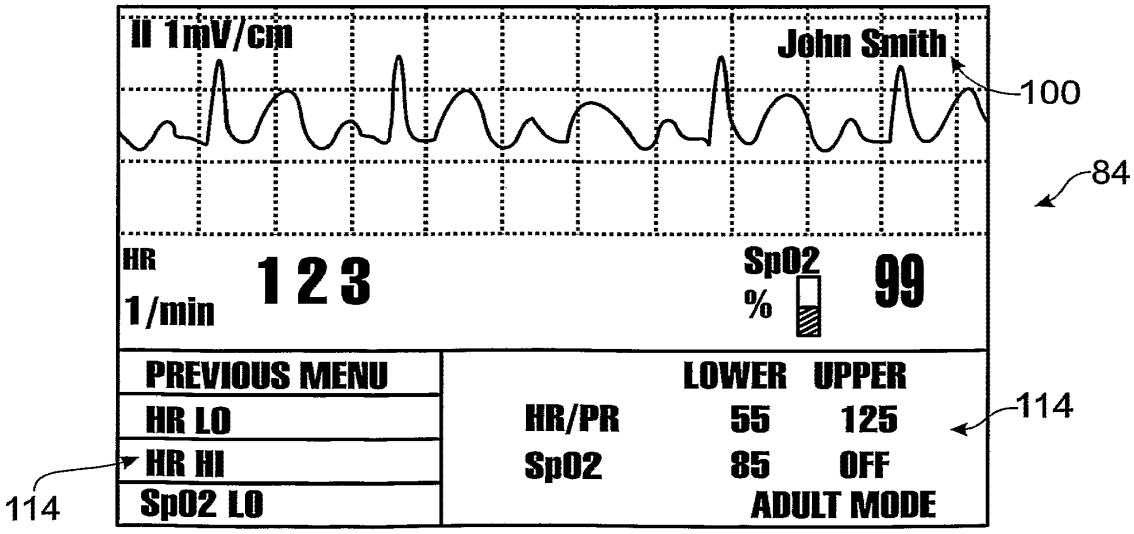

II 1mV/cm
John Smith
100
84
HR
1/min
123
SpO2
%
99
PREVIOUS MENU
HR LO
HR HI
SpO2 LO
114
LOWER UPPER
HR/PR 55 125
SpO2 85 OFF
ADULT MODE
114

Fig. 11

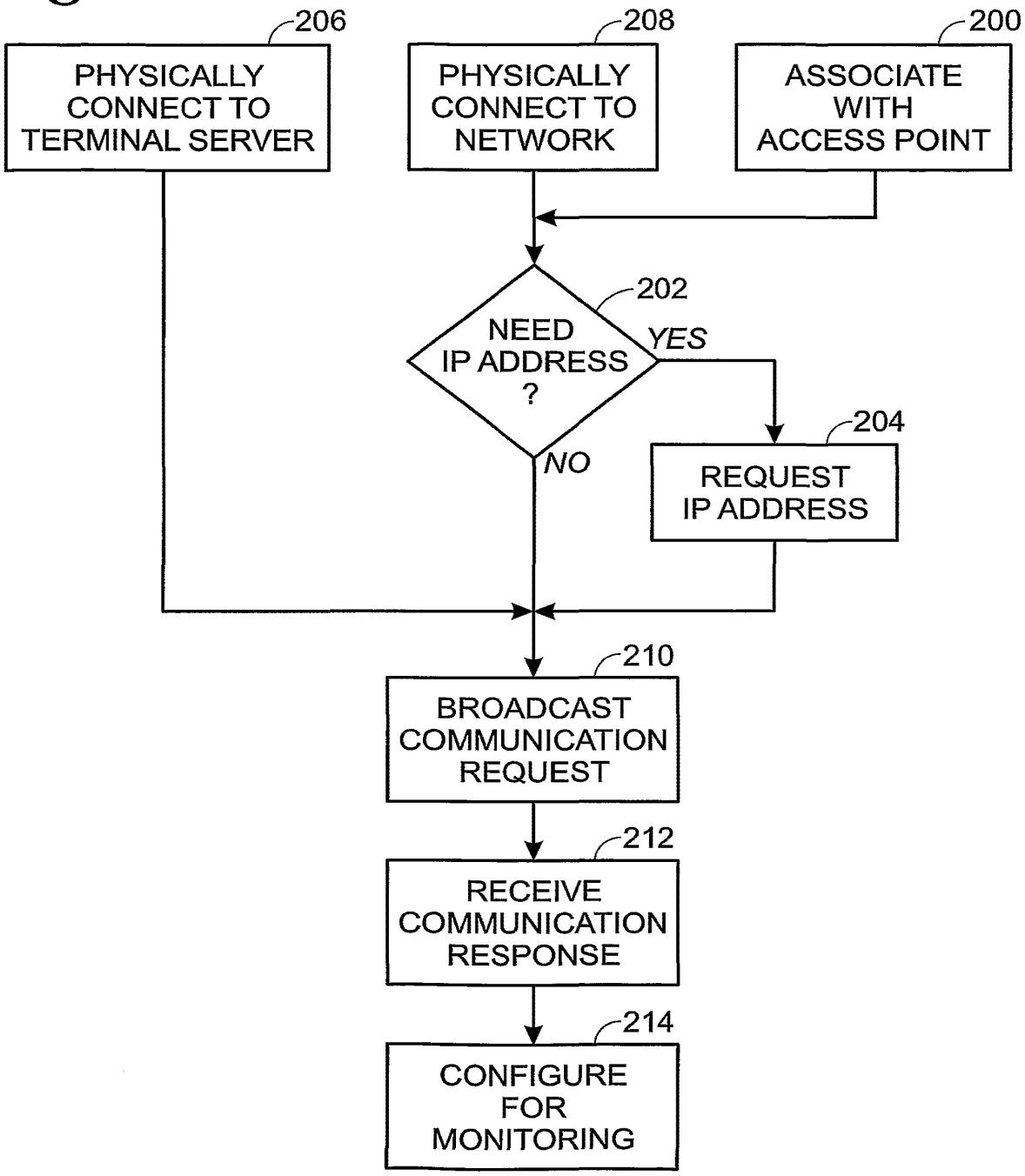

206
PHYSICALLY CONNECT TO TERMINAL SERVER
208
PHYSICALLY CONNECT TO NETWORK
200
ASSOCIATE WITH ACCESS POINT
202
NEED IP ADDRESS ?
YES
NO
204
REQUEST IP ADDRESS
210
BROADCAST COMMUNICATION REQUEST
212
RECEIVE COMMUNICATION RESPONSE
214
CONFIGURE FOR MONITORING

Fig. 12

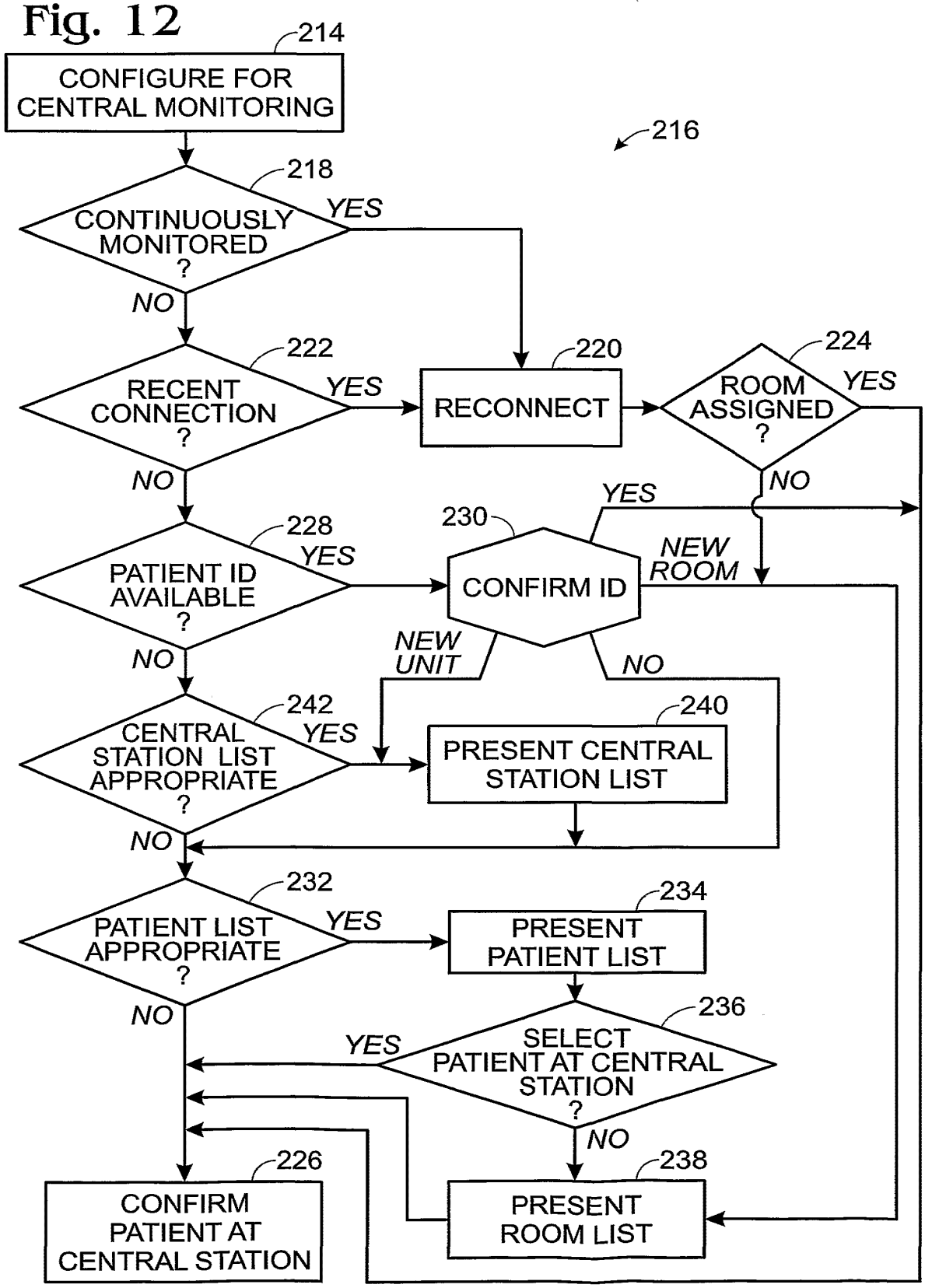

214
CONFIGURE FOR CENTRAL MONITORING
216
218
CONTINUOUSLY MONITORED ?
YES
NO
222
RECENT CONNECTION ?
YES
NO
220
RECONNECT
224
ROOM ASSIGNED ?
YES
NO
228
PATIENT ID AVAILABLE ?
YES
NO
230
CONFIRM ID
YES
NEW ROOM
NEW UNIT
NO
242
CENTRAL STATION LIST APPROPRIATE ?
YES
NO
240
PRESENT CENTRAL STATION LIST
232
PATIENT LIST APPROPRIATE ?
YES
NO
234
PRESENT PATIENT LIST
236
SELECT PATIENT AT CENTRAL STATION ?
YES
NO
226
CONFIRM PATIENT AT CENTRAL STATION
238
PRESENT ROOM LIST

Fig. 13

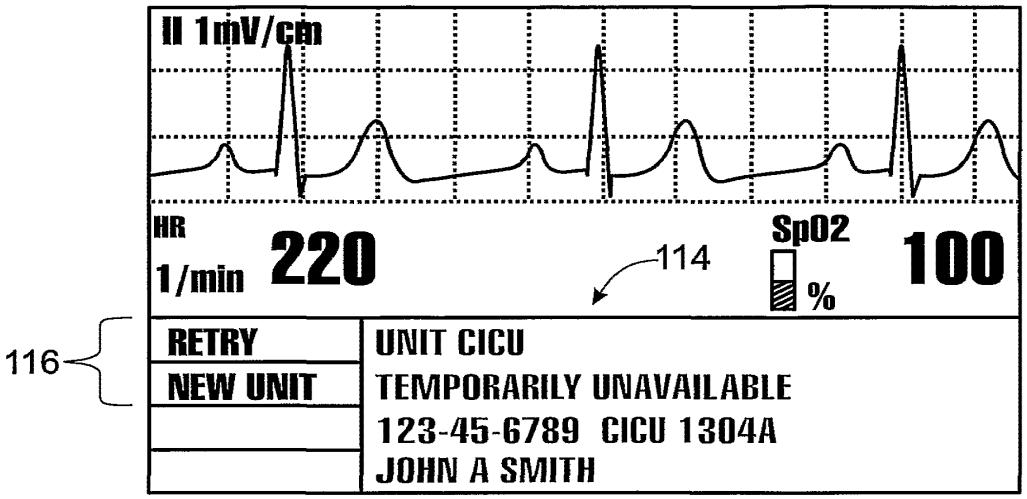

II 1mV/cm
HR
1/min
220
114
SpO2
%
100
116
RETRY
NEW UNIT
UNIT CICU
TEMPORARILY UNAVAILABLE
123-45-6789 CICU 1304A
JOHN A SMITH

Fig. 14

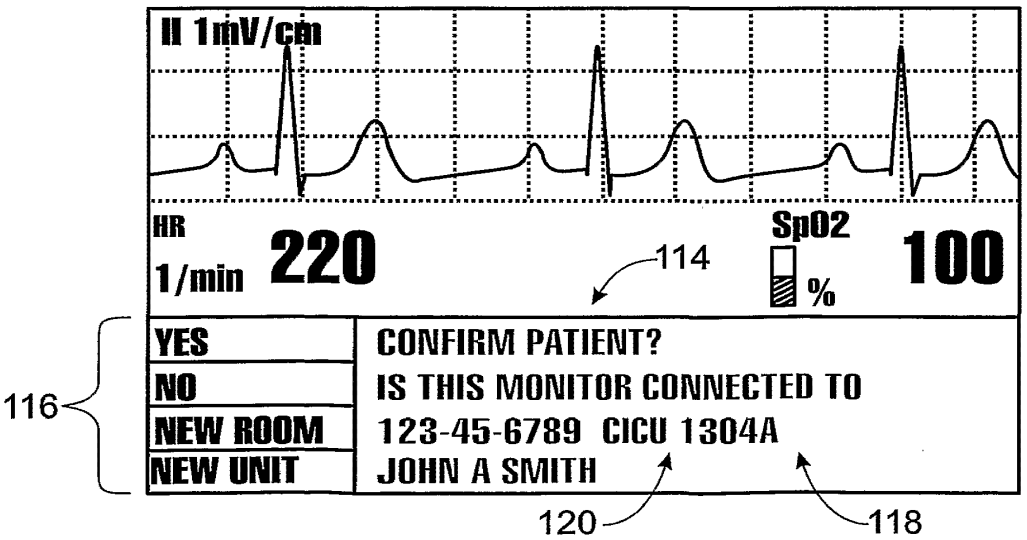

II 1mV/cm
HR
1/min
220
114
SpO2
%
100
116
YES
NO
NEW ROOM
NEW UNIT
CONFIRM PATIENT?
IS THIS MONITOR CONNECTED TO
123-45-6789 CICU 1304A
JOHN A SMITH
120
118

Fig. 15

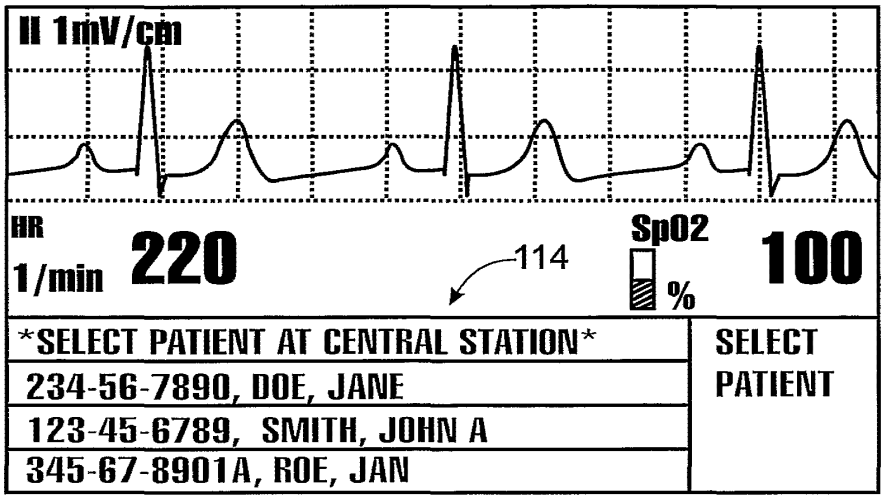

II 1mV/cm
HR
1/min 220
114
SpO2
%
100
SELECT PATIENT AT CENTRAL STATION
234-56-7890, DOE, JANE
123-45-6789, SMITH, JOHN A
345-67-8901A, ROE, JAN
SELECT
PATIENT

Fig. 16

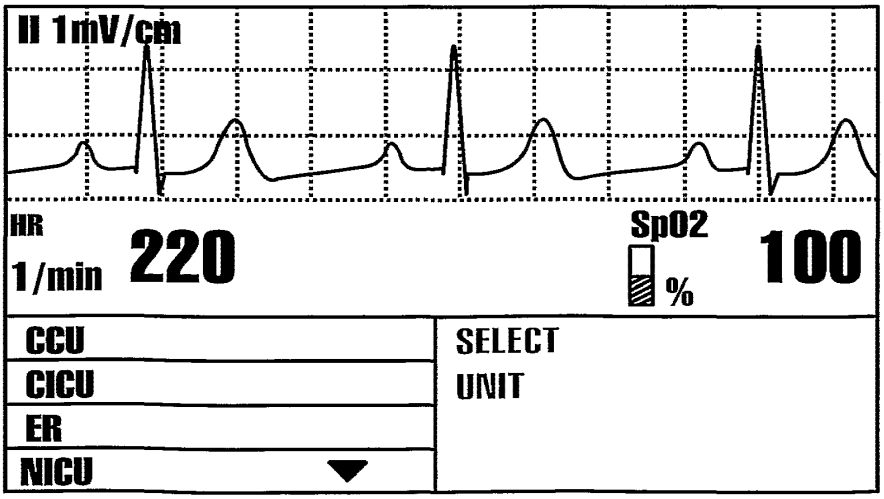

II 1mV/cm
HR
1/min 220
SpO2
%
100
CCU
CICU
ER
NICU
SELECT
UNIT

Fig. 17

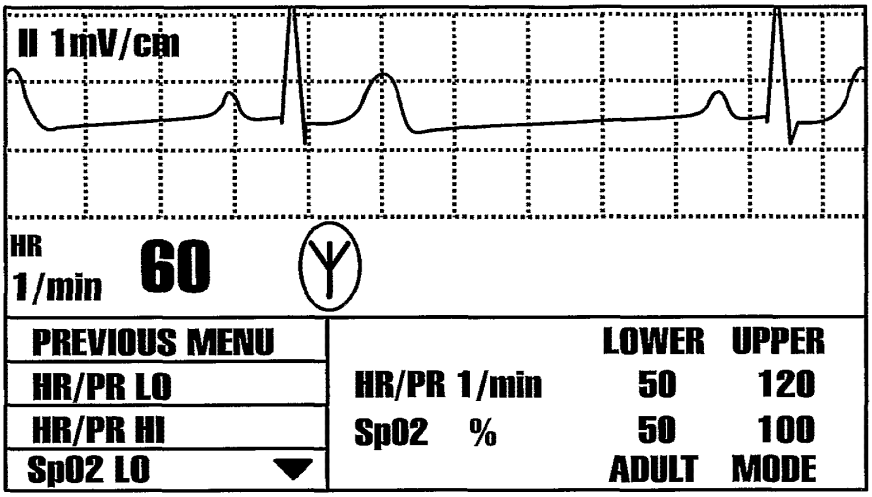

II 1mV/cm
HR
1/min
60
PREVIOUS MENU
HR/PR LO
HR/PR HI
SpO2 LO
LOWER
UPPER
HR/PR 1/min
50
120
SpO2 %
50
100
ADULT MODE

Fig. 18

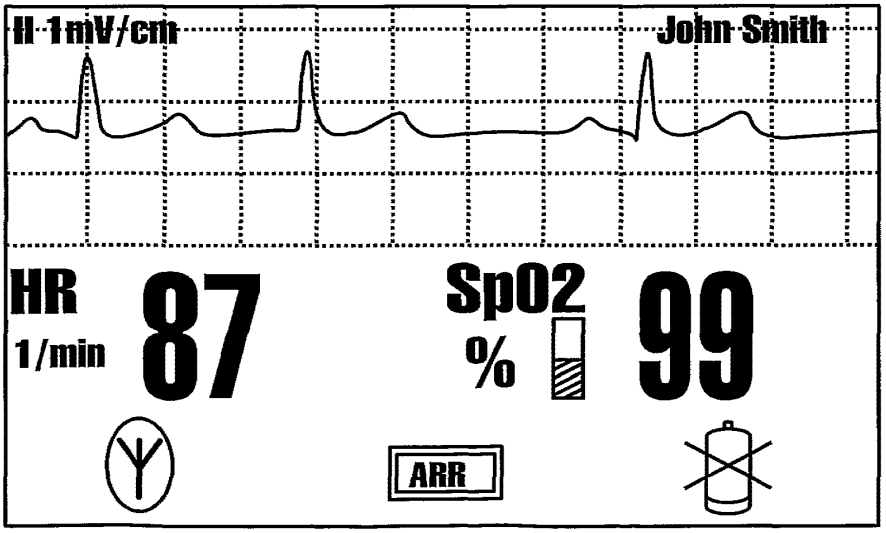

II 1mV/cm
John Smith
HR
1/min
87
SpO2
%
99
ARR

Fig. 19

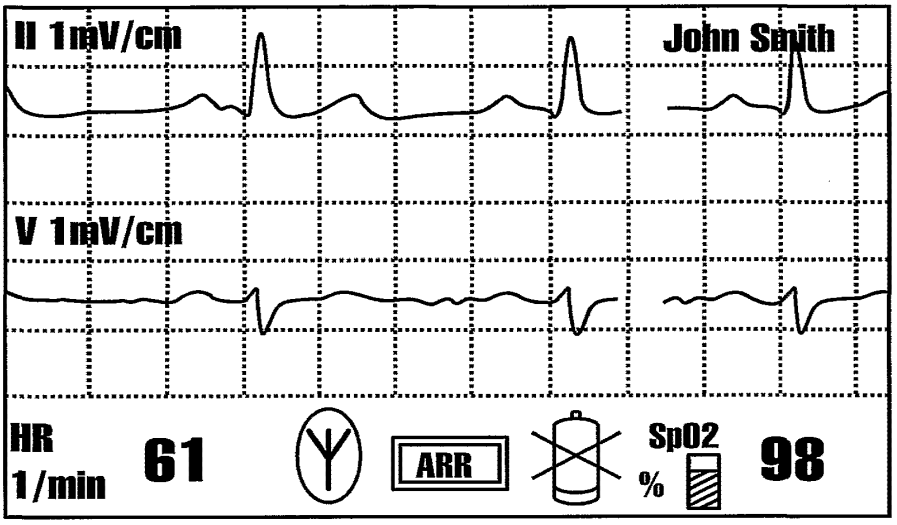

II 1mV/cm
John Smith
V 1mV/cm
HR
1/min
61
ARR
SpO2
%
98

Fig. 20

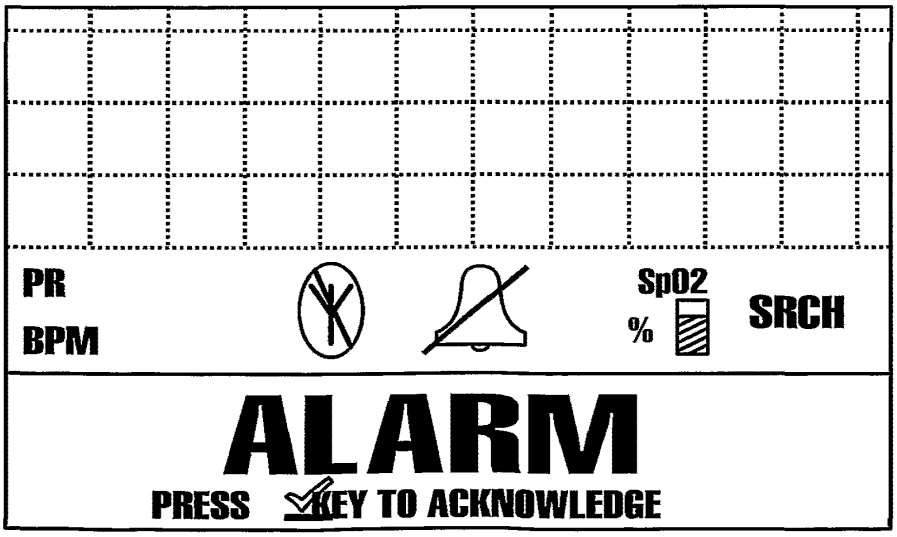

PR
BPM
SpO2
%
SRCH
ALARM
PRESS KEY TO ACKNOWLEDGE

Fig. 21

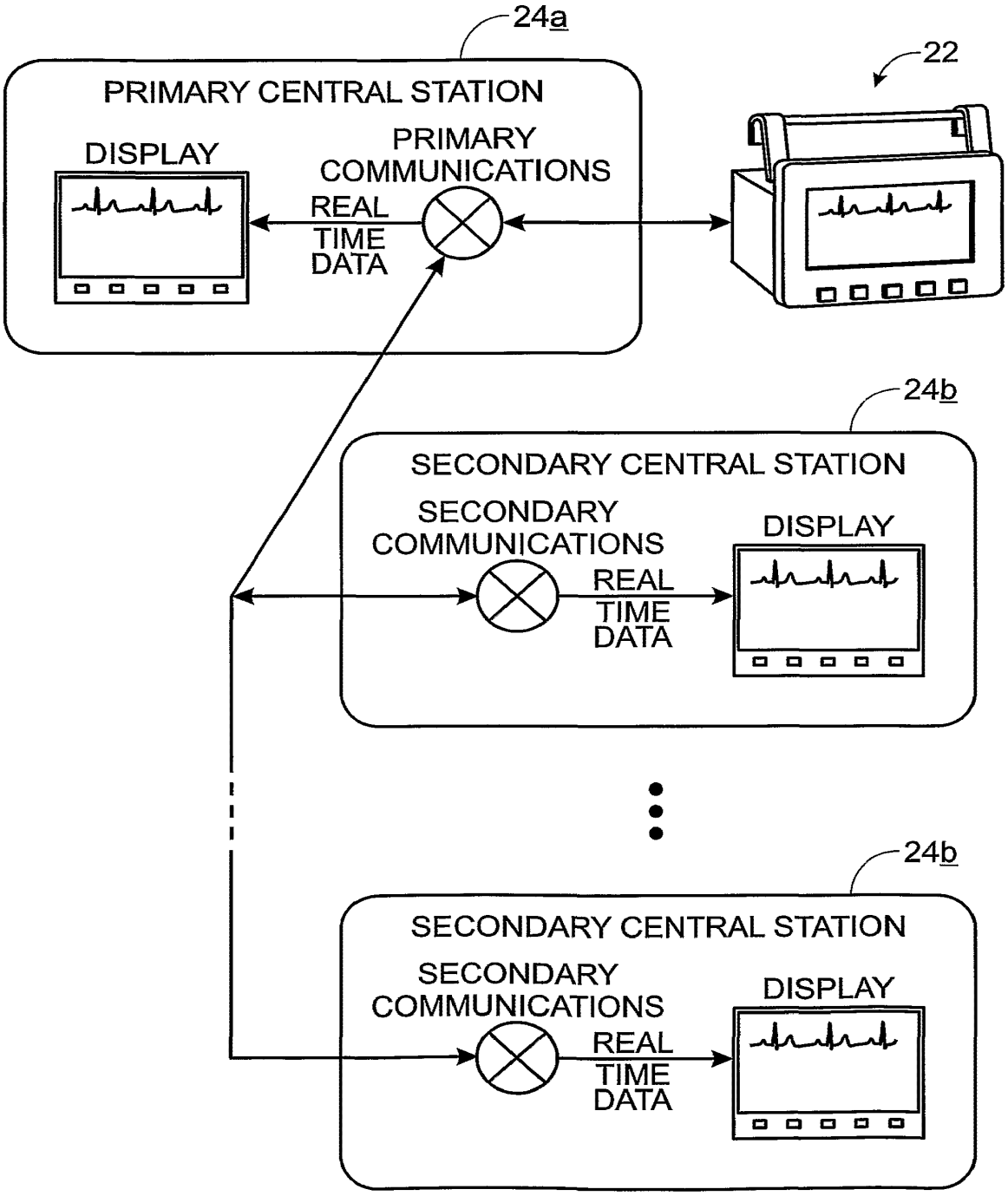

24a
22
PRIMARY CENTRAL STATION
DISPLAY
PRIMARY COMMUNICATIONS
REAL TIME DATA
24b
SECONDARY CENTRAL STATION
SECONDARY COMMUNICATIONS
DISPLAY
REAL TIME DATA
24b
SECONDARY CENTRAL STATION
SECONDARY COMMUNICATIONS
DISPLAY
REAL TIME DATA

Fig. 22

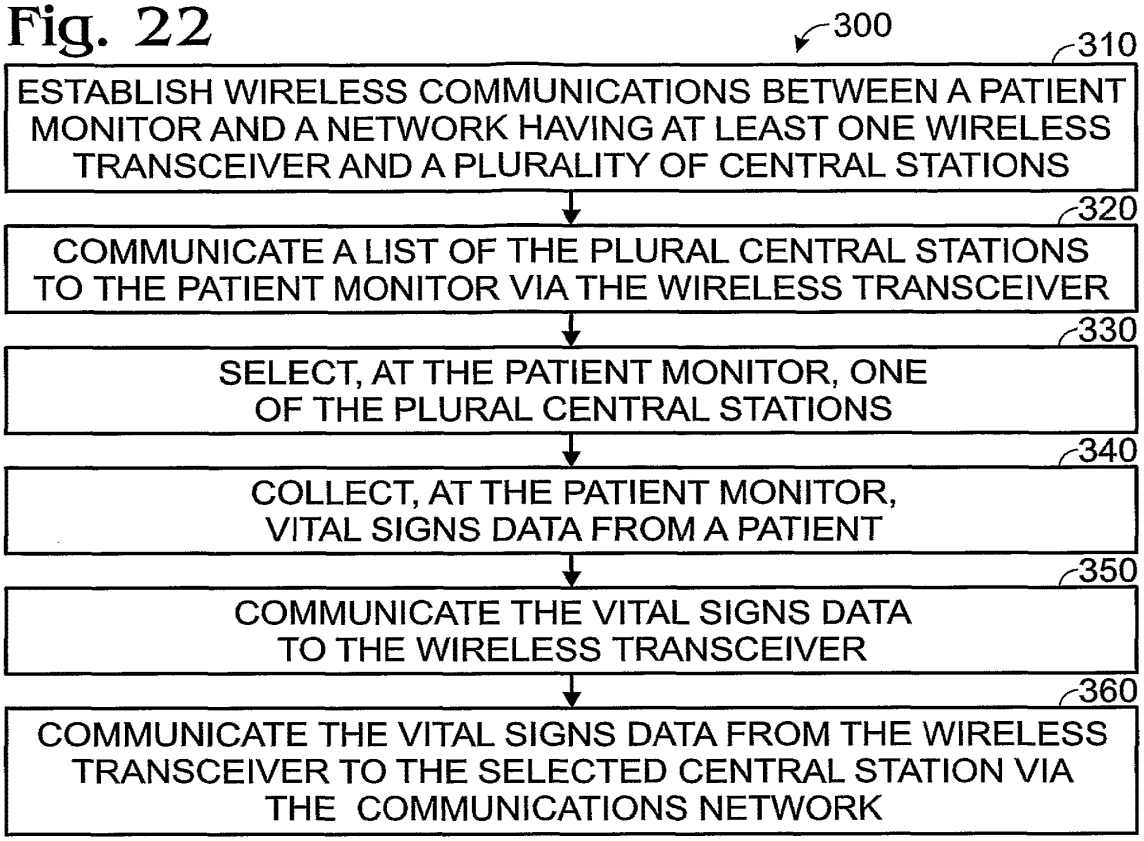

300
310
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A NETWORK HAVING AT LEAST ONE WIRELESS TRANSCEIVER AND A PLURALITY OF CENTRAL STATIONS
320
COMMUNICATE A LIST OF THE PLURAL CENTRAL STATIONS TO THE PATIENT MONITOR VIA THE WIRELESS TRANSCEIVER
330
SELECT, AT THE PATIENT MONITOR, ONE OF THE PLURAL CENTRAL STATIONS
340
COLLECT, AT THE PATIENT MONITOR, VITAL SIGNS DATA FROM A PATIENT
350
COMMUNICATE THE VITAL SIGNS DATA TO THE WIRELESS TRANSCEIVER
360
COMMUNICATE THE VITAL SIGNS DATA FROM THE WIRELESS TRANSCEIVER TO THE SELECTED CENTRAL STATION VIA THE COMMUNICATIONS NETWORK

Fig. 23

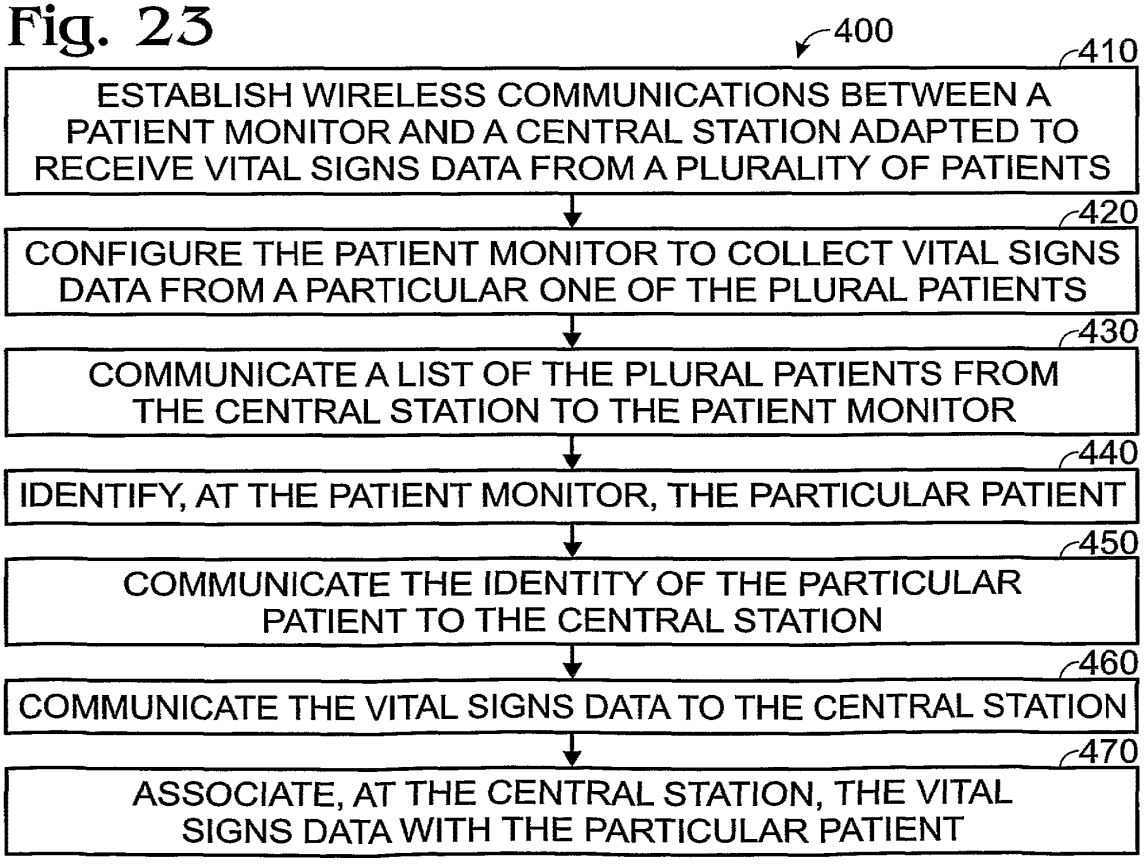

400
410
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A CENTRAL STATION ADAPTED TO RECEIVE VITAL SIGNS DATA FROM A PLURALITY OF PATIENTS
420
CONFIGURE THE PATIENT MONITOR TO COLLECT VITAL SIGNS DATA FROM A PARTICULAR ONE OF THE PLURAL PATIENTS
430
COMMUNICATE A LIST OF THE PLURAL PATIENTS FROM THE CENTRAL STATION TO THE PATIENT MONITOR
440
IDENTIFY, AT THE PATIENT MONITOR, THE PARTICULAR PATIENT
450
COMMUNICATE THE IDENTITY OF THE PARTICULAR PATIENT TO THE CENTRAL STATION
460
COMMUNICATE THE VITAL SIGNS DATA TO THE CENTRAL STATION
470
ASSOCIATE, AT THE CENTRAL STATION, THE VITAL SIGNS DATA WITH THE PARTICULAR PATIENT

Fig. 24

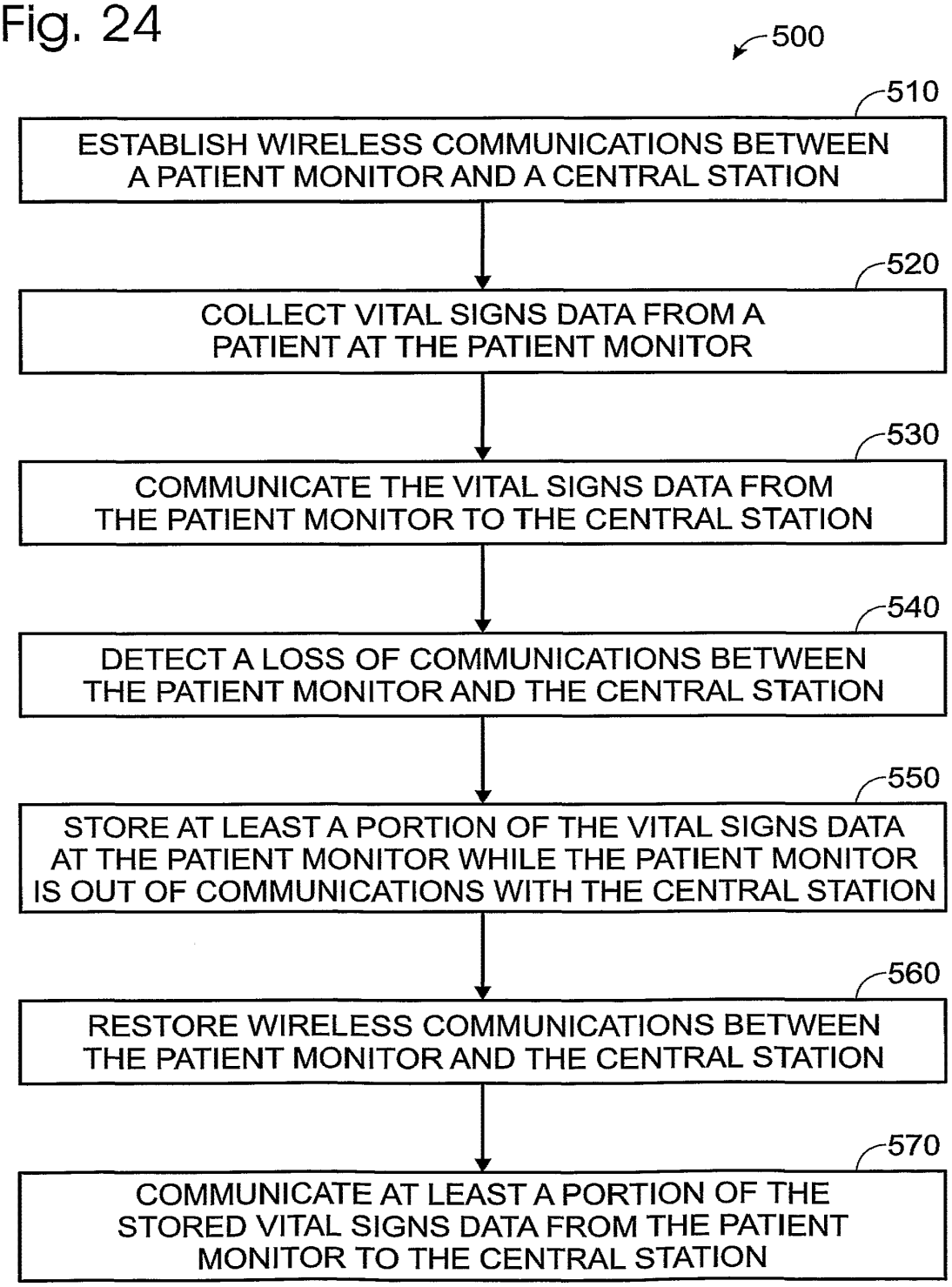

500
510
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A CENTRAL STATION
520
COLLECT VITAL SIGNS DATA FROM A PATIENT AT THE PATIENT MONITOR
530
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE CENTRAL STATION
540
DETECT A LOSS OF COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION
550
STORE AT LEAST A PORTION OF THE VITAL SIGNS DATA AT THE PATIENT MONITOR WHILE THE PATIENT MONITOR IS OUT OF COMMUNICATIONS WITH THE CENTRAL STATION
560
RESTORE WIRELESS COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION
570
COMMUNICATE AT LEAST A PORTION OF THE STORED VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE CENTRAL STATION

Fig. 25

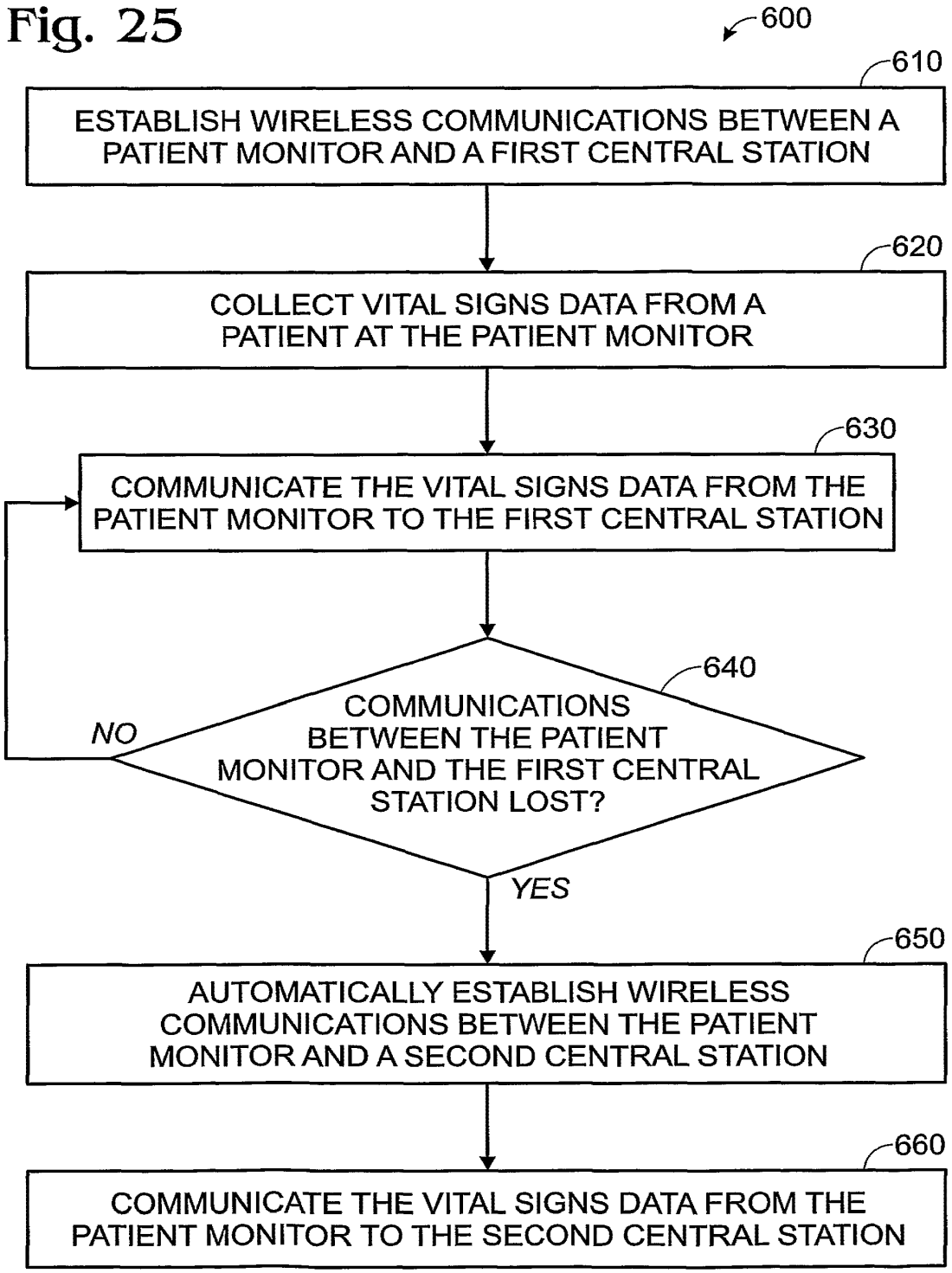
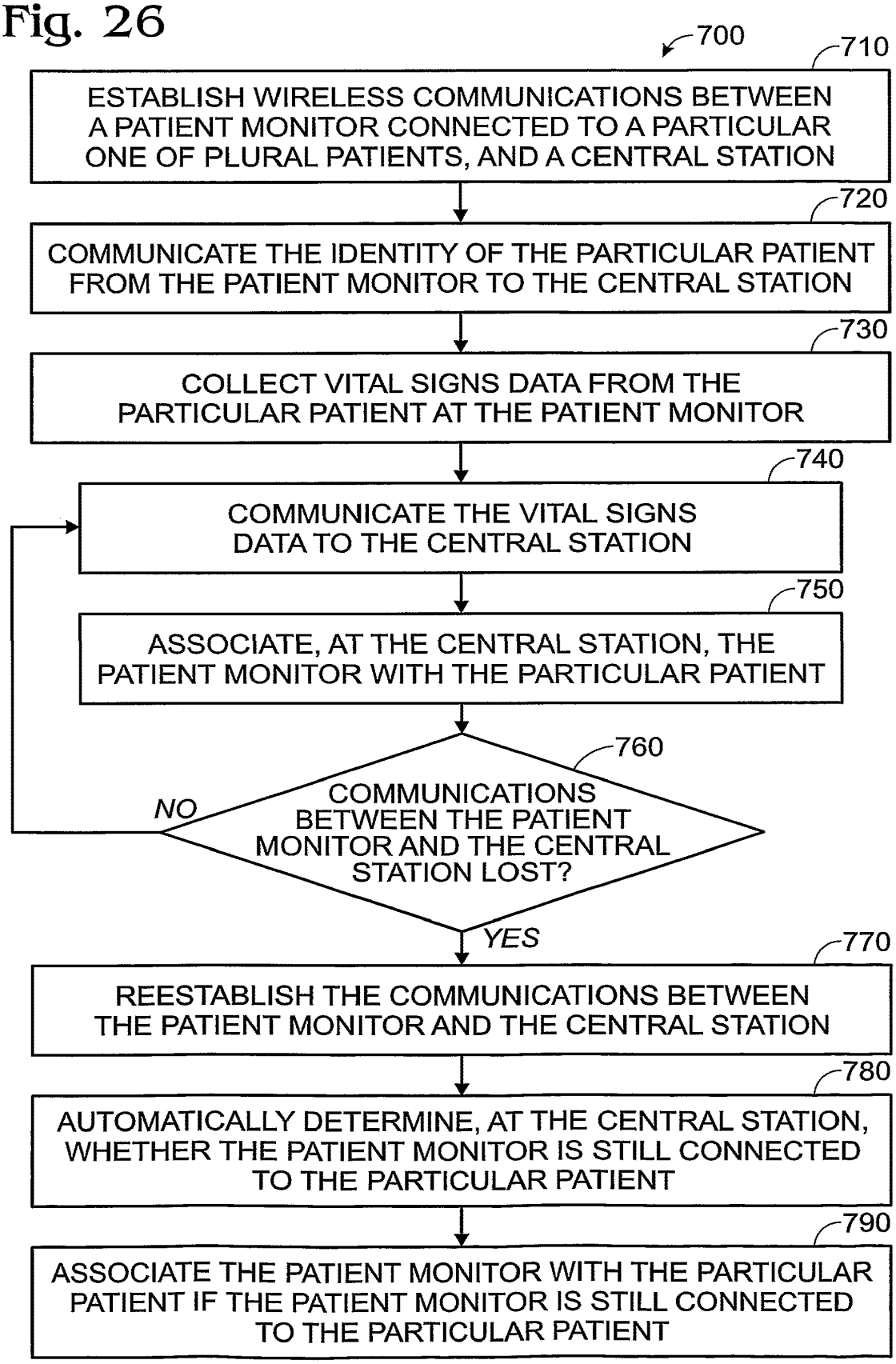

600
610
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A FIRST CENTRAL STATION
620
COLLECT VITAL SIGNS DATA FROM A PATIENT AT THE PATIENT MONITOR
630
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE FIRST CENTRAL STATION
640
COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE FIRST CENTRAL STATION LOST?
NO
YES
650
AUTOMATICALLY ESTABLISH WIRELESS COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND A SECOND CENTRAL STATION
660
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE SECOND CENTRAL STATION

Fig. 26


700
710
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR CONNECTED TO A PARTICULAR ONE OF PLURAL PATIENTS, AND A CENTRAL STATION
720
COMMUNICATE THE IDENTITY OF THE PARTICULAR PATIENT FROM THE PATIENT MONITOR TO THE CENTRAL STATION
730
COLLECT VITAL SIGNS DATA FROM THE PARTICULAR PATIENT AT THE PATIENT MONITOR
740
COMMUNICATE THE VITAL SIGNS DATA TO THE CENTRAL STATION
750
ASSOCIATE, AT THE CENTRAL STATION, THE PATIENT MONITOR WITH THE PARTICULAR PATIENT
760
COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION LOST?
NO
YES
770
REESTABLISH THE COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION
780
AUTOMATICALLY DETERMINE, AT THE CENTRAL STATION, WHETHER THE PATIENT MONITOR IS STILL CONNECTED TO THE PARTICULAR PATIENT
790
ASSOCIATE THE PATIENT MONITOR WITH THE PARTICULAR PATIENT IF THE PATIENT MONITOR IS STILL CONNECTED TO THE PARTICULAR PATIENT

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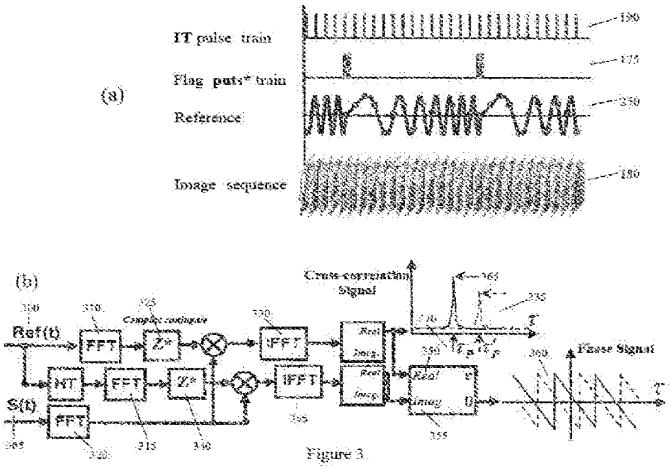


Figure 3

(57) Abstract: Systems and methods for improved thermophotonic imaging are provided in which both amplitude and phase image information is obtained with a high signal to noise ratio and depth-resolved capabilities. Image data obtained from an imaging camera is dynamically averaged and subsequently processed to extract amplitude and/or phase image data. The system may be configured for a wide range of imaging modalities, including single frequency modulation (thermophotonic lock-in imaging), Thermal-Wave Radar imaging or Thermophotonic Radar imaging involving chirp modulation, and Binary Phase Coded Modulation. Such imaging modalities may find application in many diverse areas, including non-destructive testing and biomedical diagnostic imaging including the imaging of teeth and monitoring changes in the tooth over time which are due to pathology such as dental caries or erosion.

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SYSTEMS AND METHODS FOR THERMOPHOTONIC DYNAMIC IMAGING

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Application No. 61/471,772, titled "SYSTEMS AND METHODS FOR THERMOPHOTONIC DYNAMIC IMAGING" and filed on April 5, 2011, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to systems and methods of non-destructive subsurface imaging. More particularly, this invention relates to systems and methods for thermophotonic imaging.

Thermographic and thermophotonic imaging methods have found widespread use in applications such as non-destructive testing of various materials and biomedical diagnostic imaging. While numerous methods have been developed and described in the literature, most solutions proposed to date have relied on methods involving single frequency analysis of amplitude and phase images. Such methods, while well suited for some specific applications, often fail in applications that demand higher sensitivity. Another disadvantage of known thermographic and thermophotonic imaging methods is the use of low speed imaging techniques, which can place significant limitations on depth and/or spatial resolution.

Accordingly, despite the existence of a number of thermographic and thermophotonic imaging modalities, there remains a need for imaging solutions that deliver higher sensitivity, lower detection limit, increased speed, and improved depth

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resolution. In industrial quality control, there is a need for fast and reliable monitoring of substrate integrity and process-induced defects during manufacturing and component reliability testing, for example in identifying subsurface cracks and delaminations in automotive and aerospace components and surface coatings, respectively. In oral health care, there is a need to have an imaging system that can image an entire tooth surface or group of teeth so as to provide the oral health care provider with the location of dental caries or defects in teeth and or dental materials.

As compared to conventional thermographic imaging, which monitors contrast due to thermal and/or mechanical property inhomogeneities of materials (thermographic contrast), thermophotonic imaging, in addition to thermographic contrast, involves amplified contrast due to optical property inhomogeneities. Both modalities are based on the generation and detection of (photo)thermal waves in a sample.

SUMMARY

Systems and methods for improved thermophotonic imaging are provided in which both amplitude and phase image information is obtained with a high signal to noise ratio and depth-resolved capabilities. Image data obtained from an imaging camera is dynamically averaged and subsequently processed to extract amplitude and/or phase image data. The system may be configured for a wide range of imaging modalities, including single frequency modulation (thermophotonic lock-in imaging), Thermal-Wave Radar imaging or Thermophotonic Radar imaging involving chirp modulation, and Binary Phase Coded Modulation. Such imaging modalities may find application in many diverse areas, including non-destructive testing and biomedical diagnostic imaging including the imaging of teeth and monitoring changes in the tooth

PGR2025-00063 Page 00651

over time which are due to pathology such as dental caries or erosion.

In a first aspect, there is provided a method of performing thermophotonic imaging, the method comprising the steps of: providing a sample; providing an optical source having a wavelength selected to generate photothermal radiation within the sample; providing an imaging camera with an optical bandwidth selected for detection of the photothermal radiation; generating a reference waveform comprising a plurality of modulation cycles; producing a modulated optical beam by modulating an intensity of an optical beam emitted by the optical source according to the reference waveform; illuminating the sample with the modulated optical beam;

imaging the photothermal radiation with the imaging camera; recording a plurality of dynamically averaged image frames at time offsets corresponding to different values of the reference waveform; and processing the dynamically averaged image frames and the reference waveform to obtain an image relating to the photothermal radiation.

The dynamically averaged image frames may be obtained according to the following steps: recording a plurality of image frames at times corresponding to different values of the reference waveform; repeating, one or more times, the step of recording the image frames at times corresponding to different values of the reference waveform, and dynamically averaging the recorded images for each the different value of the reference waveform, thereby obtaining dynamically averaged image frames.

The step of recording the plurality of image frames at different values of the reference waveform may comprise recording the plurality of image frames over a single modulation cycle/correlation period, and may be obtained over more than one modulation cycle, where a frame acquisition rate of the imaging camera may less than

a modulation frequency of the reference waveform.

The method may further comprise the step of recording, for each image frame of the plurality of image frames, a substantially instantaneous value of the reference waveform, and may further comprise generating a quadrature waveform based on the reference waveform, and recording, for each image frame of the plurality of image frames, a substantially instantaneous value of the quadrature waveform.

An integration pulse train may be generated comprising a series of pulses, wherein each pulse is generated at a time at which an image frame is acquired by the imaging camera, wherein the step of generating of the reference waveform is triggered according to the integration pulse train. The integration pulse train may be generated by the imaging camera.

A flag pulse train may be generated comprising a series of pulses, wherein each pulse is generated at a commencement of a given modulation cycle/correlation period, and identifying one or both of a beginning and an end of the given modulation cycle/correlation period according to the flag pulse train. A modulation frequency of the reference waveform may be greater than approximately 0.01 Hz.

The reference waveform may comprise a single frequency and wherein the image is obtained by lock-in processing, and the step of processing the dynamically averaged image frames and the reference waveform may comprise, for each pixel in the image frame, performing the steps of: multiplying the dynamically averaged image frames by the reference waveform to obtain in-phase product values; and summing the in-phase product values to obtain an in-phase sum; generating a quadrature waveform based on the reference waveform; multiplying the dynamically averaged image frames by the quadrature waveform to obtain phase-shifted product values; and summing the phase-shifted product values to obtain a phase-shifted sum.

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The image may be an amplitude image, and wherein the processing further comprises calculating a magnitude of a complex quantity based on the in-phase sum and the phase-shifted sum. The image may be a phase image wherein the processing further comprises: calculating a phase angle of a complex quantity based on the in-phase sum and the phase-shifted sum.

The reference waveform may comprise multiple frequency components, and the reference waveform may comprise a frequency chirp and may be a binary phase coded waveform.

The image may be a cross-correlation peak amplitude image obtained by the steps of: obtaining a complex cross-correlation signal of the reference waveform and each pixel of the dynamically averaged image frames; and determining, for each the pixel, a peak amplitude value of a peak in a real part of the cross-correlation signal.

The image may be a cross-correlation peak delay image obtained by the steps of: obtaining a complex cross-correlation signal of the reference waveform and each pixel of the dynamically averaged image frames; and determining, for each the pixel, a delay of a peak in a real part of the complex cross-correlation signal.

The image may be a cross-correlation phase image obtained by the steps of: obtaining a first complex cross-correlation signal of the reference waveform and each pixel of the dynamically averaged image frames; obtaining a second complex cross-correlation signal of a quadrature waveform and each pixel of the dynamically averaged image frames, wherein the quadrature waveform is based on the reference waveform; forming a complex quantity comprising a real portion of first complex cross-correlation signal and a real portion of the second complex cross-correlation signal; and obtaining the phase image by determining, for each pixel, a phase angle of the complex quantity at a pre-selected time delay.

The sample may be selected from the group consisting of automotive components, aerospace components, an optical material, a laser material, a biomedical material, and a biological tissue.

The sample may be a material comprising one or more of a subsurface crack and a delamination. The sample may be an unsintered component in a green state.

The method may further comprise the step of determining a case hardness depth.

The sample may be a dental sample, tooth sample or whole groups of teeth. The method may further comprise the step of analyzing the image to determine one or more of a presence and a location of demineralization, erosion or dental caries in the dental or tooth sample. The method may further comprise the step of monitoring an evolution of one or more of demineralization, erosion and dental caries by comparing the image to one or more other images. The sample may be a dental or medical instrument and may be selected from the group consisting of endodontic instruments, catheters and other indwelling instruments.

The wavelength may be selected to lie within a range of approximately 600 nm to 2000 nm. The imaging camera may be selected to have a spectral response overlapping with at least a portion of the mid-infrared spectrum.

In another aspect, there is provided a system for performing thermophotonic imaging, the system comprising: an optical source having a wavelength selected to generate photothermal radiation within a sample; an imaging camera with an optical bandwidth selected for detection of the photothermal radiation, wherein the imaging camera is configured to acquire image frames a given frame rate and output an integration pulse train comprising a series of pulses, each pulse corresponding to a time at which an image frame is acquired by the imaging camera; a waveform

generating system for generating a reference waveform, wherein an output of the waveform generating system is connected to an input of the optical source for modulating an intensity of an optical beam emitted by the optical source; a processor programmed to dynamically average image frames obtained by the imaging camera, and to process the dynamically averaged image frames, the reference waveform and a quadrature waveform based on the reference waveform, to provide one or more of an amplitude image and a phase image; and a memory for storing dynamically averaged image frames.

A modulation frequency of the reference waveform may be greater than approximately 0.01 Hz. The imaging camera may comprise a frame acquisition rate that is less than a modulation frequency of the reference waveform. The wavelength may lie within approximately 600 nm to 2000 nm. A spectral response of the imaging camera may overlap at least a portion of the mid-infrared spectrum.

A further understanding of the functional and advantageous aspects of the disclosure can be realized by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments will now be described, by way of example only, with reference to the drawings, in which:

Figure 1 shows of a system that may be employed for thermophotonic imaging.

Figure 2 illustrates a method of thermophotonic lock-in imaging.

Figure 3 illustrates thermal-wave radar imaging, where (a) shows the waveforms and frames captured, and (b) provides a flow chart illustrating the method.

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Figure 4 (a) illustrates a method of binary phase code imaging. Theoretical simulation of CC signals using frequency (dashed) and phase (solid) modulation for absorbers at depths (b) 50 μm and (c) 1 mm below the surface using thermal and optical properties of dental enamel. Chirp: 0.1-4.9 Hz, 6.4 s; BPC: 2.5 Hz, 16 bit, 6.4 s.

Figure 5 shows (a) an optical image, (b) front (F) and side (S) dental radiographs of sample A1(human bicuspid tooth) before treatment; and (c) front (F) and side (S) dental radiographs (d) optical image of sample A1 after 10 days of demineralization treatment with an artificial caries solution within the treatment window; thermophotonic lock-in phase images of sample A1 (e) before treatment and after (f) 2, (g) 4, (h) 8, and (i) 10 days of demineralization with an artificial caries solution within the treatment window; (j) phase profiles along the dashed line shown in figure 5i for samples at several demineralization stages (dashed vertical lines show the location of the treatment window); and (k) Transverse micro-radiographic mineral profile along the center of the treatment window of the 10-day demineralized sample.

Figure 6 shows (a) an optical image of sample A2, the occlusal surface of a maxillary molar with stained pits and fissures; thermophotonic (b) amplitude and (c) phase images of sample A2 obtained at 10 Hz; thermophotonic (d) amplitude and (e) phase images of sample A2 obtained at 100 Hz; and (f)-(i) transverse micro-radiographic mineral profiles of points f-i, respectively, as indicated in (e).

Figure 7 provides images of (a) sample B1, (left) the plastic step wedge (right) inside the scattering medium, (b) sample B2, strip pattern left to right: green, transparent, black, and (c) sample B3, where the squares in (c) indicate the locations of two demineralization (artificial caries) treatment windows.

Figure 8 plots thermal wave radar and phase lock-in (LI) imaging of sample

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B2 , with LI thermography phase images at (a) 0.01Hz and (b) IHz; (c) Cross-correlation (CC) amplitude image (chirp frequency bandwidth: 0.01-1 Hz in 6s); (d) mean horizontal LI phase profile of figure (a); and distribution of (e) LI phase and (f) CC amplitude values over the steps.

Figure 9 plots thermal wave radar imaging of sample B2 using (a) CC amplitude, (b) CC peak delay time, (c) CC phase and their mean horizontal profiles (d), (e), and (f), respectively (chirp frequency bandwidth: 0.01-1 Hz in 6s).

Figure 10 plots thermal wave radar and thermophotonic lock-in imaging of sample B3, showing (a) CC amplitude image, (b) CC peak delay time image, (c) CC phase image (chirp frequency bandwidth: 0.01-1 Hz in 6s); thermophotonic lock-in phase images at (d) 0.01 Hz and (e) 1 Hz; and (f) transverse micro-radiographic mineral profiles at points 1-3 indicated in figure (c)

Figure 11 plots (a) binary phase code and (b) phase LI imaging of sample Bl, and distribution of (c) binary phase code image and (d) phase LI image values over the steps of sample B2.

Figure 12 provides thermophotonic lock-in and binary phase code images of sample B3, with thermophotonic lock-in (a) amplitude and (b) phase images 1 Hz; and binary phase code (c) amplitude image (d) peak delay time image and (e) phase image.

Figure 13 (a) Exploded view of the cross-shaped sample simulating two absorbers at different depths. Conventional LIT (b) Amplitude and (c) phase image. binary phase code peak delay time image matched to the camera temporal data of (d) point 1 and (e) point 2, as indicated in part (b), using a 3-bit [1 1 -1] code.

Figure 14 (a) Teeth matrix with hidden inter-proximal early caries. The rectangle shows the imaged area. (b) Conventional LIT and (c) binary phase code

phase images of teeth matrix. (d-f) thermal coherence tomographic images obtained as several delay times differentiating between the defective (e) and healthy (f) regions.

Figure 15 (a) Optical image of goat bone. The rectangle shows the images area. (b) binary phase code phase images at 1 Hz using a 7 bit binary code.

Figure 16 illustrates the method of asynchronous undersampling for lower frame acquisition rate imaging cameras.

DETAILED DESCRIPTION

Various embodiments and aspects of the disclosure will be described with reference to details discussed below. The following description and drawings are illustrative of the disclosure and are not to be construed as limiting the disclosure. Numerous specific details are described to provide a thorough understanding of various embodiments of the present disclosure. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of embodiments of the present disclosure. It should be understood that the order of the steps of the methods disclosed herein is immaterial so long as the methods remain operable. Moreover, two or more steps may be conducted simultaneously or in a different order than recited herein unless otherwise specified.

As used herein, the terms, "comprises" and "comprising" are to be construed as being inclusive and open ended, and not exclusive. Specifically, when used in the specification and claims, the terms, "comprises" and "comprising" and variations thereof mean the specified features, steps or components are included. These terms are not to be interpreted to exclude the presence of other features, steps or components.

As used herein, the term "exemplary" means "serving as an example, instance,

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or illustration," and should not be construed as preferred or advantageous over other configurations disclosed herein.

As used herein, the terms "about" and "approximately", when used in conjunction with ranges of dimensions of particles, compositions of mixtures or other physical properties or characteristics, are meant to cover slight variations that may exist in the upper and lower limits of the ranges of dimensions so as to not exclude embodiments where on average most of the dimensions are satisfied but where statistically dimensions may exist outside this region. It is not the intention to exclude embodiments such as these from the present disclosure.

As used herein, the term "thermophotonic imaging" relates to the generation of images based on thermal infrared photons emitted from surface and subsurface regions of opaque or non-opaque matter, resulting from photothermal excitation of a sample with a light source such as a laser. The emitted infrared photons carry optical absorption information at the excitation wavelength as well as at the detection spectral band determined by the spectral response of the infrared imaging detector. The case of optically opaque samples, conventionally known as "infrared thermographic imaging", which involves only thermal properties, is understood to be incorporated by implication in the opaque limit of thermophotonic imaging. As compared to conventional thermographic imaging which monitors contrast due to thermal and/or mechanical property inhomogeneities of materials (thermographic contrast), thermophotonic imaging, in addition to thermographic contrast, involves amplified contrast due to optical property inhomogeneities. Both modalities are based on the generation and detection of (photo)thermal waves in a sample.

Embodiments described below provide systems and methods for improved thermophotonic imaging. In a first embodiment, a system and method is provided in

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which photothermal image data are dynamically averaged and subsequently processed to determine both amplitude and phase image information with high signal to noise ratio. The system may be configured for a wide range of imaging modalities, including, but not limited to, single frequency modulation (thermophotonic lock-in imaging or thermophotonic lock-in imaging), chirp modulation (thermal-wave radar imaging or thermal wave radar imaging), and binary phase coded modulation (Binary Phase Coding imaging or binary phase code imaging).

Figure 1 shows a schematic of a thermophotonic imaging system 100 that may be utilized for a number of different imaging modalities. System 100 includes imaging camera 110 for detecting and imaging thermophotonic radiation, laser 120 for exciting a photothermal response in a sample 130, data acquisition system 140, and computing system 150 that is interfaced to camera 110 and/or data acquisition system 140 (in the example embodiment shown in Figure 1, computing system 150 is directly interfaced to camera 110 for reading both image data and data acquisition header data in image frames, as described further below). Sample 130 may be positioned using a sample positioning device, such as a 3-axis (XYZ) sample positioning system (not shown).

Laser 120 is modulated to produce a modulated optical beam that is directed onto the surface of an extracted sample tooth 130, which in turn leads to the generation of photothermal radiation from sample 130 that is subsequently detected by imaging camera 110. In order to obtain high signal-to-noise ratio (SNR) via phase-sensitive detection, a synchronous driving and data acquisition approach is employed, in which frames outputted by imaging camera 110 are synchronized with the modulation of laser 110 for further processing.

Referring now to Figure 2, system 100 is further described in the context of a

thermophotonic imaging modality involving thermophotonic lock-in detection, which represents an illustrative yet non-limiting embodiment of an imaging modality compatible with system 100. Data acquisition system 140 generates analog in-phase reference waveform 160 and analog quadrature reference waveform 165, where quadrature waveform 165 is phase shifted by 90° relative to in-phase waveform 160. Alternatively, the quadrature reference waveform may be computed from the Hilbert Transform of the in-phase reference signal.

In-phase waveform 160 is provided to the modulation input 170 of laser system 120, (shown in Figure 1). In response to in-phase waveform 160, the intensity of the emitted laser light is modulated, where the modulation profile of the laser intensity follows that of in-phase waveform 160 plus a DC offset.

Imaging camera 110 obtains image frames at a defined frequency as shown by integration pulse train (IT pulse train) 190 in Figure 2. Integration pulse train 190 is provided (e.g. as a TTL pulse train) from imaging camera 110 to data acquisition system 140 to trigger the generation of in-phase waveform 160 and quadrature waveform 165 by data acquisition system 140. Integration pulse train 190 also triggers the generation of flag pulse train 175 by data acquisition system 140, where flag pulse train 175 provides a "high" pulse at the beginning of each modulation cycle, as shown in Figure 2.

In the embodiment shown in Figure 1, imaging camera 110 is capable of providing a header for each recorded image frame, where the header includes the measurement of two values that are measured at a time that is substantially instantaneous with the detection of an image frame. The two values are obtained from two analog signals corresponding to instantaneous values of waveforms 160 and 165. Data acquisition system 140 provides these waveforms to imaging camera 110 for

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inclusion of the two values in the frame header, thereby providing a measurement of their values at a time that is substantially simultaneous to the instant that the frame is captured. Values from flag pulse train 175 are also stored in the frame header to allow for the determination of the beginning of each waveform period, which is used for averaging purposes as further described below. It is to be understood that the direct interfacing of computing system 150 to camera 110, as shown in Figure 1, is but one of many different possible system implementations. In other embodiments, computing system may be interfaced to camera 110 and/or data acquisition system 140 for synchronous acquisition of both image and modulation waveform instantaneous data, as further described below.

During image acquisition, computing system 150 reads image frames from imaging camera 110 via image sequence 180, and queries the frame headers until it finds a frame whose flag pulse train is "high" (the beginning of a modulation cycle). After a "high" pulse is detected, computing system 150 reads a sequence of frames that correspond to one complete modulation cycle, where the number of frames and delay between frame acquisition events is determined based on the frame rate of imaging camera 110 and the modulation frequency of the in-phase waveform 160. The frames are stored in a buffer (e.g. a 3D buffer) in a memory (such as computer RAM). By performing these steps, system 100 obtains a series of individual imaging frames corresponding to one modulation cycle.

To obtain an improved SNR of the acquired image frames, the above steps are repeated and the values for each frame of one complete modulation cycle are averaged in the buffer to reduce the stochastic noise. Most averaging algorithms read the signal corresponding to all recorded cycles and then initiate the averaging processes. Unfortunately, due to the huge flow of data needed to meet the bandwidth

demands of the image frames, such an averaging methodology fails at high frame rates, such as those that are preferably used in the present embodiment.

Accordingly, in a one embodiment, the image frames are dynamically averaged, where the frames corresponding to one modulation cycle are collected and dynamically processed to determine a running average. Initially, a first set of image frames corresponding to a first modulation cycle are collected and stored in a memory location. Subsequently, image frames are obtained for a second modulation cycle, and the recorded image frame values are dynamically averaged. This process is repeated for subsequent modulation cycles, with the averaging based on the number of modulation cycles that have been processed, with the result that an averaged set of image frames with improved SNR is obtained. This provides a dramatic improvement in memory management and speed, and requires significantly less sophisticated computer hardware.

After having obtained an averaged set of image frames over a modulation cycle, the averaged frame sequence, shown at 180 as f(t) in Figure 2, corresponding to averaged image frames, is processed to obtain amplitude and phase images. This is performed by weighting each pixel in the image for each frame obtained, where the pixel value is weighted once by the in-phase reference signal 160 and once by the quadrature reference signal 165 in two separate channels. The weighted sequences are then separately summed to get the S^{0} and S^{90} images, as shown in steps 200 and 210 of Figure 2, respectively. Finally, using equation 1 for each pixel the amplitude and phase images are calculated:

$$A = \sqrt{(S^{0})^{2} + (S^{90})^{2}} \quad \text{and} \quad \Phi = \arctan(S^{90} / S^{0}) \quad (1)$$

Computing system 150 may be programmed with a signal acquisition and/or processing program for processing the data received from imaging camera 110 and/or

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data acquisition device 140, and for performing the aforementioned averaging steps and calculation of the amplitude and phase images. For example, generic data processing programs may be provided commercially or created for specific applications associated with the thermophotonic imaging modalities disclosed herein. A suitable programming medium for the creation of such a program is the LabView environment. This environment provides a flexible platform for adapting the imaging software to non-destructive / diagnostic groups of equipment (set-ups) for application specific to particular materials and configurations (e.g. engineering materials NDT, biomaterials diagnostics, dental caries imaging).

Unlike lock-in thermography, which is mostly used in non-destructive testing of metals and other opaque structural materials at very low modulation frequencies (on the order of 0.01Hz or so), and in which low camera frame rates (usually 20 fps), and high optical excitation power (high SNR signal) are used without averaging, in thermophotonic imaging of biological samples and industrial materials with defects very close to surface, one may need high frequency thermal waves and low optical excitation power (poor SNR signal) to meet safety criteria. Therefore, in such cases, it can be advantageous to employ very high camera frame rates and a real-time averaging methodology, as provided, according to the present embodiment.

While the above embodiments provide exemplary systems and methods for obtaining thermophotonic images, it is to be understood that the systems and methods may be varied without departing from the spirit and scope of the aforementioned embodiments. For example, referring now to Figure 1, although system 100 is shown as comprising computing system 150 and data acquisition system 140, these elements of the apparatus may be provided in a number of different formats. Computing system 150, which comprises a processor and a memory, may be directly integrated with data

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acquisition system 140. For example, data acquisition system 140 may reside in total or in part on a hardware card housed within an apparatus that also comprises a processor and a memory.

Laser system 120 may further comprise additional sub-components or subsystems such as, but not limited to, a laser diode emitter, laser driver, fiber coupled output, collimator, and thermoelectric cooler and controller. In one exemplary embodiment, laser system 120 has two laser diodes so as to provide improved optical contrast of a type of sample through large differential absorption (for example, 808 nm and 1120 nm). Typically, laser diodes are mounted on thermoelectric coolers and the diode assembly is fixed on an air cooled heat sink through a heat conductive thermal pad. The laser light may be delivered to the sample through an optical fiber and a collimator. A collimator and/or spatial filter may be provided to maintain a relatively uniform optical intensity on the interrogated surface. The thermoelectric controller provides the cooling power to the thermoelectric coolers and controls the temperature of the laser diode. The laser driver may be employed to provide the electrical power needed to operate the laser diode and can modulate the laser light intensity according to the analog modulation signal it receives at its "mod in" terminal.

Furthermore, it is to be understood that optical source need not be a coherent light source such as a laser, but may instead be an incoherent source such as a LED, provided that sufficient optical intensity is achieved to obtain a measurable thermophotonic image signal. With the advent of high-power LEDs, one may employ a high-power infrared LED or LED array in place of a laser source. LED arrays are significantly less expensive than laser sources and generally do not require complicated cooling systems. This strategy can be used because in the proposed

methodologies it is the thermal (conductive and radiative) response from the sample that is investigated, and not the purely optical response.

As noted in the example embodiment provided above, data acquisition system 140 is capable of generating and/or providing waveforms 160 and 165 in response to the integration pulse train 175 generated by the imaging camera. In a non-limiting example, data acquisition system may be a DAQ board such as National Instrument Multi Data acquisition device (NI USB-6229 BNC), and the like, which may be directly integrated with or housed within computing system 150. Such a multifunction data acquisition (multiDAQ) system can generate and acquire analog signals simultaneously and has two independent counters and 48 digital I/O channels for synchronization applications. The data acquisition system may be connected to the computer with a USB port and may be configured to communicate with other devices through BNC connections.

Computing system 150 may be interfaced to imaging camera 110 through an interfacing device such as a networking card. For example, the GigE network PCI card may be employed to provide a suitable interface between the camera and the computer for rapidly transferring image frames to the memory of the computing system 150 according to the GigE standard.

As noted above, the sample 130 and/or laser source may be positionable relative to one another. For example, a sample positioning system may be provided that consists of one or more single axis translation stages mounted to move the sample relative to the incident laser beam in X, and optionally Y and Z directions. A rotational stage may be added to this assembly to assist in the placement of the sample in the focal plane of the camera.

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While system 100 as disclosed above is capable of averaging numerous modulation cycles of the signals before processing them, it is also possible to perform that averaging based on the computed amplitude and phase images as opposed to the image frames.

Such an embodiment may be achieved by reading, at a given point in time, a sequence of frames corresponding to one or more modulation cycles, processing the image frames as outlined above, and calculating the desired diagnostic images (i.e. amplitude, phase) and then repeating these steps and averaging the amplitude and phase images. While this "processing, then averaging" mode is less effective in eliminating the stochastic noise than the "averaging, then processing" strategy, it requires less sophisticated triggering/synchronization equipment. For example, this embodiment involves the simplification of the control section of the camera and signal processing system with respect to triggering. This approach will yield non-triggered, yet synchronized, data arrays resulting in an image of somewhat compromised quality.

Furthermore, although system 100 is shown in Figure 1 in which the waveforms 160, 165 and 175 are provided by data acquisition system 140 to imaging camera 110 for incorporation of the substantially instantaneously measured values into the frame header, it is to be understood that the values may be provided according to alternative system implementations. Such embodiments may be useful in cases where imaging camera 110 is not equipped or configured for the incorporation of a header in each image frame. For example, in one non-limiting embodiment, the waveforms 160, 165 and 175 may be directly provided to computing system 150 by data acquisition system 140, optionally along with integration pulse train 190 from imaging camera 110 for triggering. Provided that the relative time delay between the

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reception of the waveforms and the generation and/or reception of image frames may be determined (for example, by measuring a delay between system components), the appropriate values of the waveforms corresponding to the measurement of image frames may be determined.

Alternatively, the waveforms 160, 165 and 175 may be generated directly by computing system 150 (optionally triggered by integration pulse train 190 provided by imaging camera 110), and the correlation between the appropriate values of the waveforms and the acquisition of image frames may be determined based on a known system delay. These embodiments may be applied to the system shown in Figure 1, or in the system described above in which the synchronization of triggering is not necessary.

In one embodiment, imaging camera 110 is an infrared imaging camera that is sensitive in the infrared spectrum. Imaging camera 110 may incorporate the necessary optical components for the collection and detection of photothermal radiation, or one or more of the optical components may be externally mounted or otherwise provided. For example, imaging camera may include an extension tube supporting an objective lens.

In one exemplary embodiment, imaging camera 110 is a focal plane array (FPA) mid-infrared camera. A suitable but non-limiting example of such a camera is the Cedip Titanium 520M (France), which has a spectral range of 3.6 - 5.1 μm and maximum frame rate of 175 Hz at full frame. The camera's detector array consists of 320x256 Indium Antimonide (InSb) elements with element size of 30x30 μm^2. An extension tube and a objective lens (such as Cedip MW50 L0106, a 50-mm-focal-length lens) may be employed to obtain a magnification of (for example, of unity) relative to the interrogated surface of sample 130.

While the mid-infrared camera may be preferred for obtaining optimum results for some sample types, one may also employ less expensive near- or far-infrared cameras, generally with the performance trade-off of a reduced signal-to-noise ratio. However, the low signal to noise ratio can be mitigated, at least in part, by a number of methods such as, for example, increasing the number of averages, using matched filtering signal processing methods (thermal wave radar and binary phase code) described above, increasing the optical source intensity, increasing the camera integration time, and/or improving the optical collection efficiency. It is expected to be more effective to employ a far infrared camera to capture thermal infrared photons due to the peak of the blackbody radiation being located in that spectral range, although the spectral transmissivity of the interrogated material must also be considered in determining the thermal infrared photon emission flux to the camera following self-absorption.

Furthermore, in selected embodiments, uncooled imaging cameras may be employed to simplify the system and/or reduce cost. The cooling system of a camera is one of the factors that make the camera expensive. Uncooled cameras are significantly less expensive but at the same time less sensitive. This problem can be solved by increasing compensation for a reduced performance by using one of the mitigating methods described above.

In another embodiment, a camera with a lower frame acquisition rate may be employed. While lowering the frame rate does not significantly affect the performance of thermophotonic lock-in imaging, the sampling period can be critical in matched filtering methodologies (thermal wave radar and binary phase code) as it determines the depth resolution. Two strategies can be followed to overcome the depth resolution limitation while using a low-grade (low frame rate) camera.

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In a first method, synchronous/asynchronous undersampling may be employed, whereby the frame rate is chosen such that the data are captured from many modulation cycles instead of just one. This embodiment is illustrated in Figure 16. Although this sampling strategy increases the total sampling duration, this alternative implementation enables the use of a lower-grade camera to access image depth resolution commensurate with that of the foregoing high-grade camera. The combination of critical undersampling determination with the desired thermal-wave depth penetration, and their software implementation thus provide a unique and important benefit to system performance.

The undersampling frequency (f_s) can be determined as follows:

$$f_s = f_{lock\text{-}in} / [m+(l/n)] \qquad (1a)$$

where f_s is the undersampling frequency, $f_{lock\text{-}in}$ is the desired lock-in frequency (or alternatively, chirp/binary phase code repetition rate), m is an integer number and is called the order of undersampling, and n is the number of frames per correlation period. In Figure 13, m=1 and n=12, that is one frame is captured in every m=1 modulation cycle and at the end of the process the sampled modulation cycle (i.e. correlation period) consists of n=12 frames[8].

In a second method, artificial oversampling is performed as per the sampling theorem, which states that if the Fourier transform of a function $h(t)$ is zero for all frequencies above a certain frequency f_c, then the continuous function $h(t)$ can be uniquely determined from a knowledge of the sampled values. So, if the function is sampled at $T= 1/2f_c$, then one can use the expression below to reconstruct the waveform at any sampling/frame rate:

$$h(t) = T \sum_{n=-\infty}^{\infty} h(nT) \frac{\sin(2\pi f_c (t - nT))}{\pi (t - nT)} \qquad (2)$$

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The methodology is also known as "Sine interpolation". Therefore, one can use a low frame rate camera and then use Sine interpolation to improve the sampling resolution. The determination of cut off frequency, f_c, satisfying the requirement of a predetermined thermal diffusion length (depth resolution) may be performed according to equation 5, as further described below.

An alternative option for an infrared camera for use with system 100 may be provided by modifying a digital visible spectrum camera such as a commercial digital camera or a webcam. Such cameras may be modified to be sensitive in the near-infrared spectral region by removing the infrared filter and then inserting an infrared band pass filter in the optical path of the detector array. The performance degradation that is likely based on use of such a camera may be mitigated, at least in part, by the methods listed above.

An alternative option for an infrared camera for use with system 100 may be provided by modifying a digital visible spectrum camera as noted above and using methods listed above to handle performance degradation. The output from this camera would be in color with color linked to the status of the specimen under examination. In another embodiment, the camera may be a monochrome camera, and the defect region may be displayed in a unique false colour. The defect may be identified automatically by image processing (for example, using known methods to identify regions of an image based on intensity and/or the presence of a border feature). Alternatively, the defect may be identified in response to input from a user or operator viewing the image.

In one example embodiment, the defect size may be correlated with its displayed colour. For example, an area where there is a large defect may be displayed (and optionally imaged) in red while an area which is sound or healthy may be

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displayed (and optionally imaged) in green. An area where the defect is small can be displayed (and optionally imaged) in yellow. This gradation from green to yellow to red would help the operator visually understand the relative size of the defect, and in the case of dental imaging, would assist in visually assessing the severity of any detected defects.

Another imaging modality that is suitable with system 100 employs thermal-wave radar imaging. In thermal wave radar imaging chirp modulation is used instead of the aforementioned method of single frequency modulation (thermophotonic lock-in) modality and the matched filtering signal processing method is employed to increase the SNR. For non-opaque targets, this method is referred to "thermophotonic radar imaging". It should be noted that this methodology is completely different from thermophotonic lock-in imaging and is a depth selective method as opposed to a depth integrated method in thermophotonic lock-in imaging. As a result, thermal wave radar not only probes deeper into a sample, but also provides improved resolution of details and faster image acquisition due to its high SNR (i.e. requires less averaging).

Figure 3(a) explains the thermal wave radar imaging method graphically. As in the thermophotonic lock-in method, a sequence of image frames are acquired in combination with the values indicating the values of the waveforms 160, 165 and 175. The role of the flag pulse train 175, the integration pulse train 190, and the averaging method, are the same as in the thermophotonic lock-in method described above. However, unlike the case of thermophotonic lock-in in which one modulation cycle is being averaged, it is one chirp cycle of the chirped reference signal 250 that is averaged in the thermal wave radar imaging or the thermophotonic radar imaging method.

Figure 3(b) depicts the signal processing block diagram of thermal wave radar