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	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

SIGNATURE of Applicant or Patent Practitioner

Signature	/David S. Bir/	Date (Optional)	2015-10-01
Name	David S. Bir	Registration Number	38,383
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)
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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):

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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 *.

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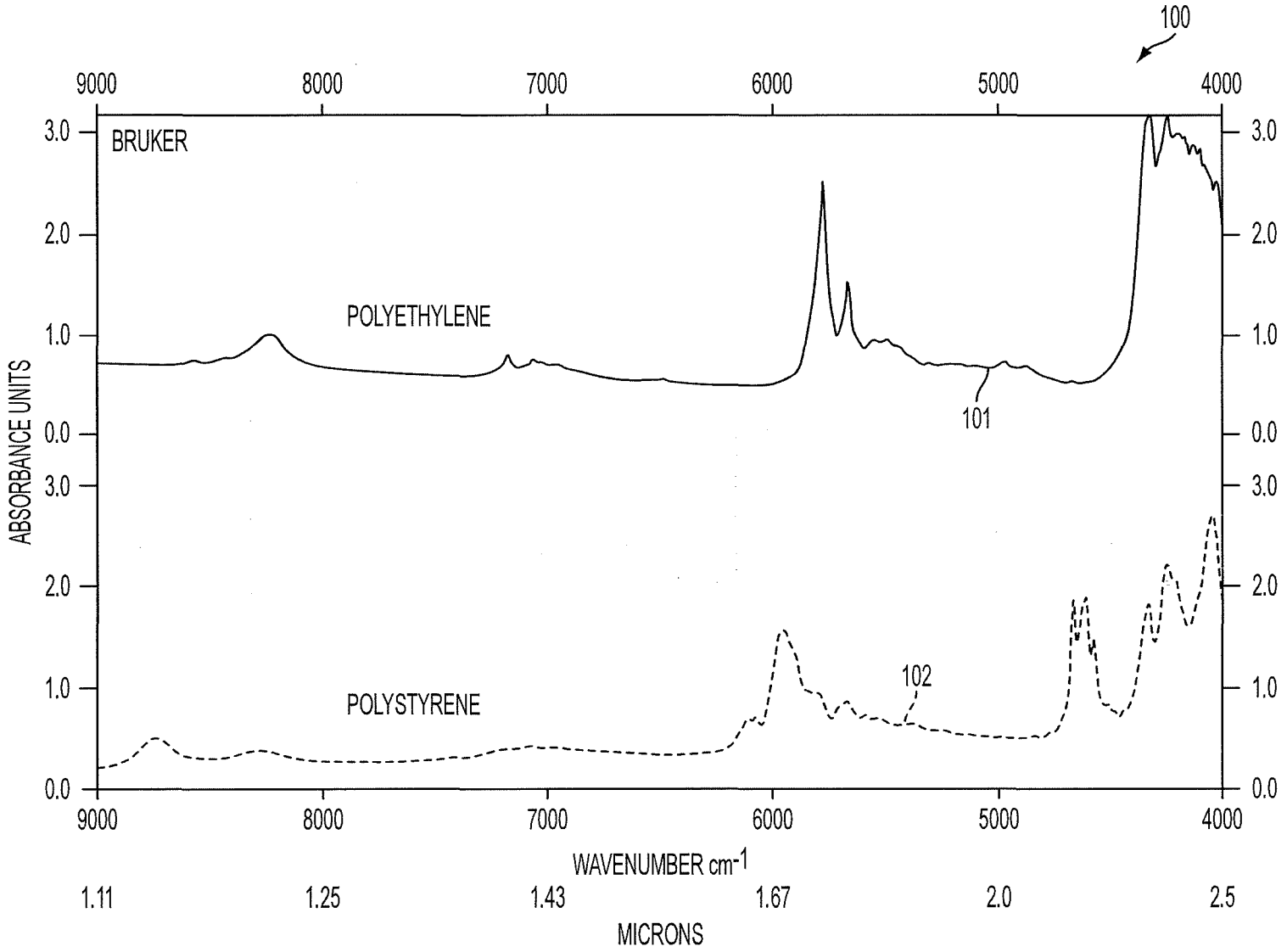

100
9000
8000
7000
6000
5000
4000
BRUKER
POLYETHYLENE
101
POLYSTYRENE
102
ABSORBANCE UNITS
3.0
2.0
1.0
0.0
WAVENUMBER cm-1
1.11
1.25
1.43
1.67
2.0
2.5
MICRONS

FIG. 1

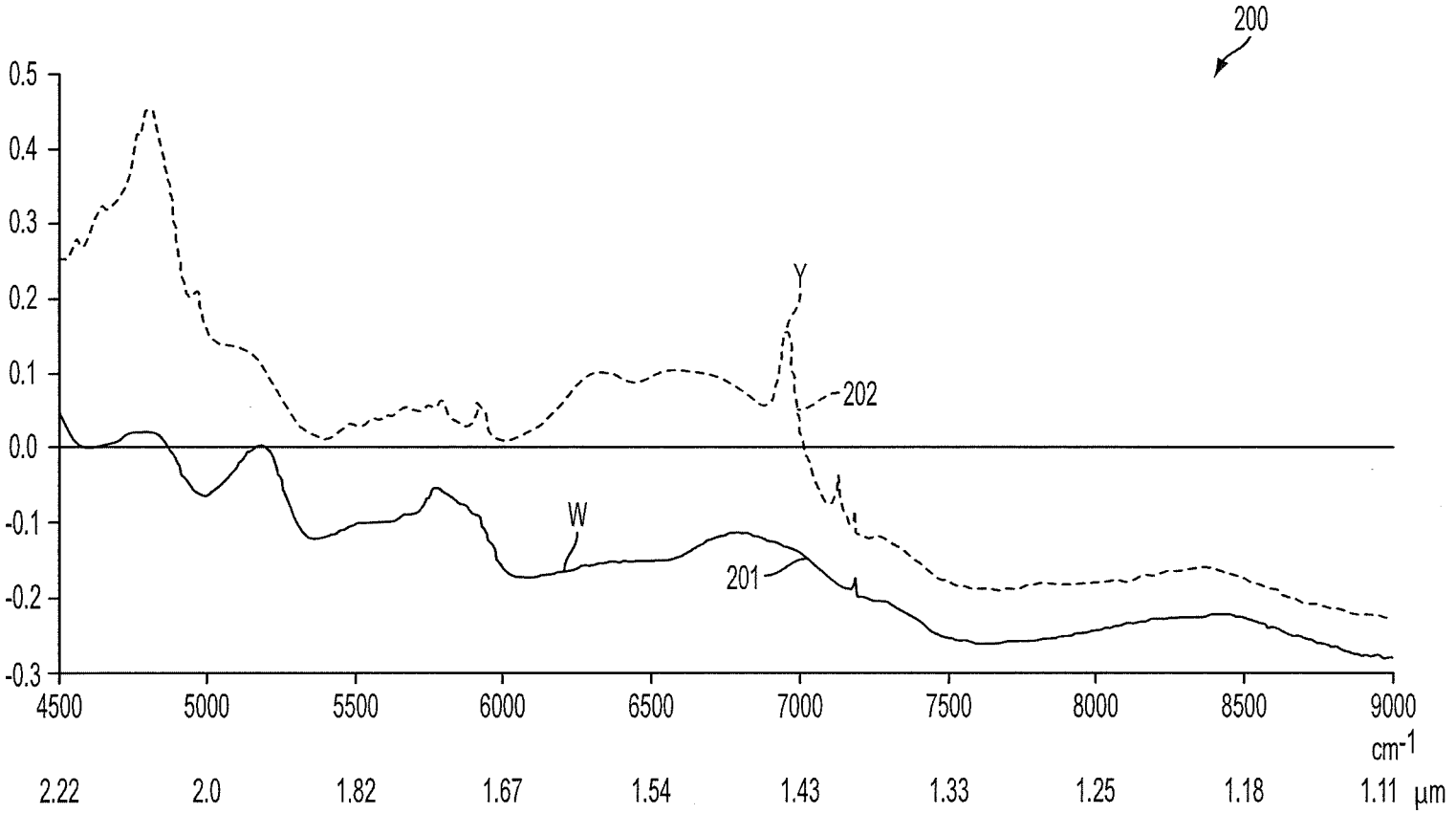

200
0.5
0.4
0.3
0.2
0.1
0.0
-0.1
-0.2
-0.3
Y
202
W
201
4500
5000
5500
6000
6500
7000
7500
8000
8500
9000
cm-1
2.22
2.0
1.82
1.67
1.54
1.43
1.33
1.25
1.18
1.11 µm

FIG. 2

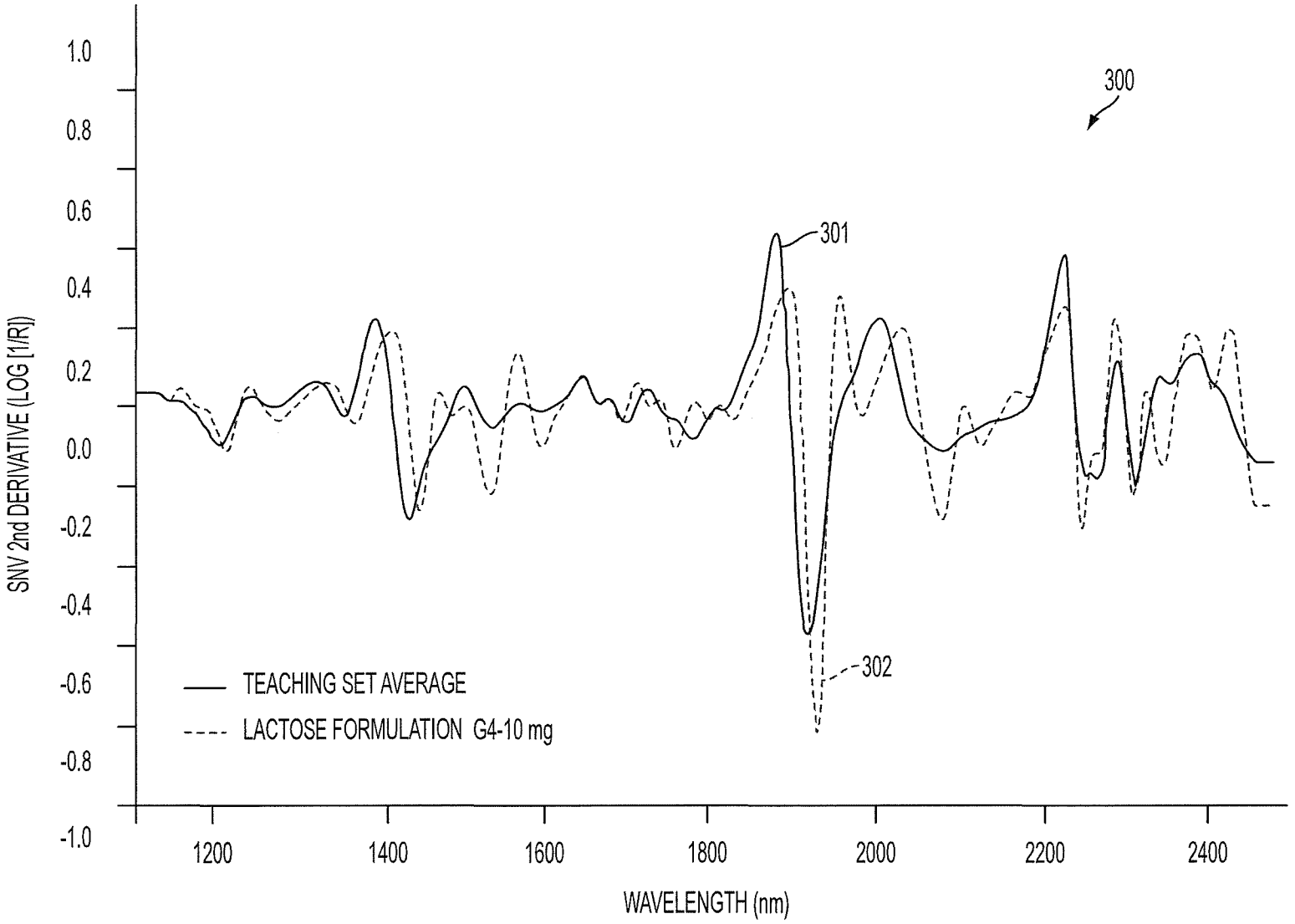

300
301
302
1.0
0.8
0.6
0.4
0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
SNV 2nd DERIVATIVE (LOG [1/R])
TEACHING SET AVERAGE
LACTOSE FORMULATION G4-10 mg
1200
1400
1600
1800
2000
2200
2400
WAVELENGTH (nm)

FIG. 3

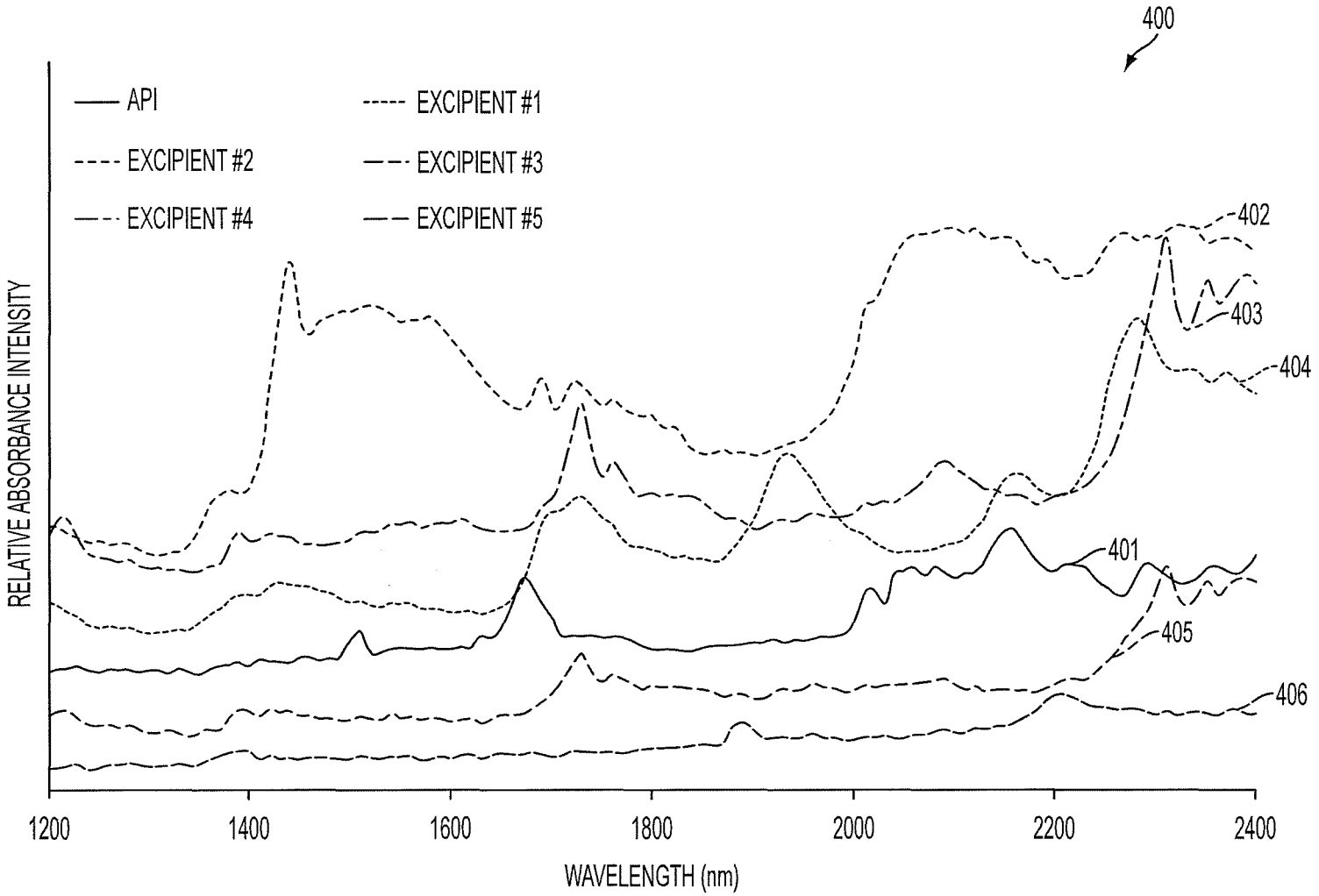

400
API
EXCIPIENT #1
EXCIPIENT #2
EXCIPIENT #3
EXCIPIENT #4
EXCIPIENT #5
RELATIVE ABSORBANCE INTENSITY
402
403
404
401
405
406
1200
1400
1600
1800
2000
2200
2400
WAVELENGTH (nm)

FIG. 4

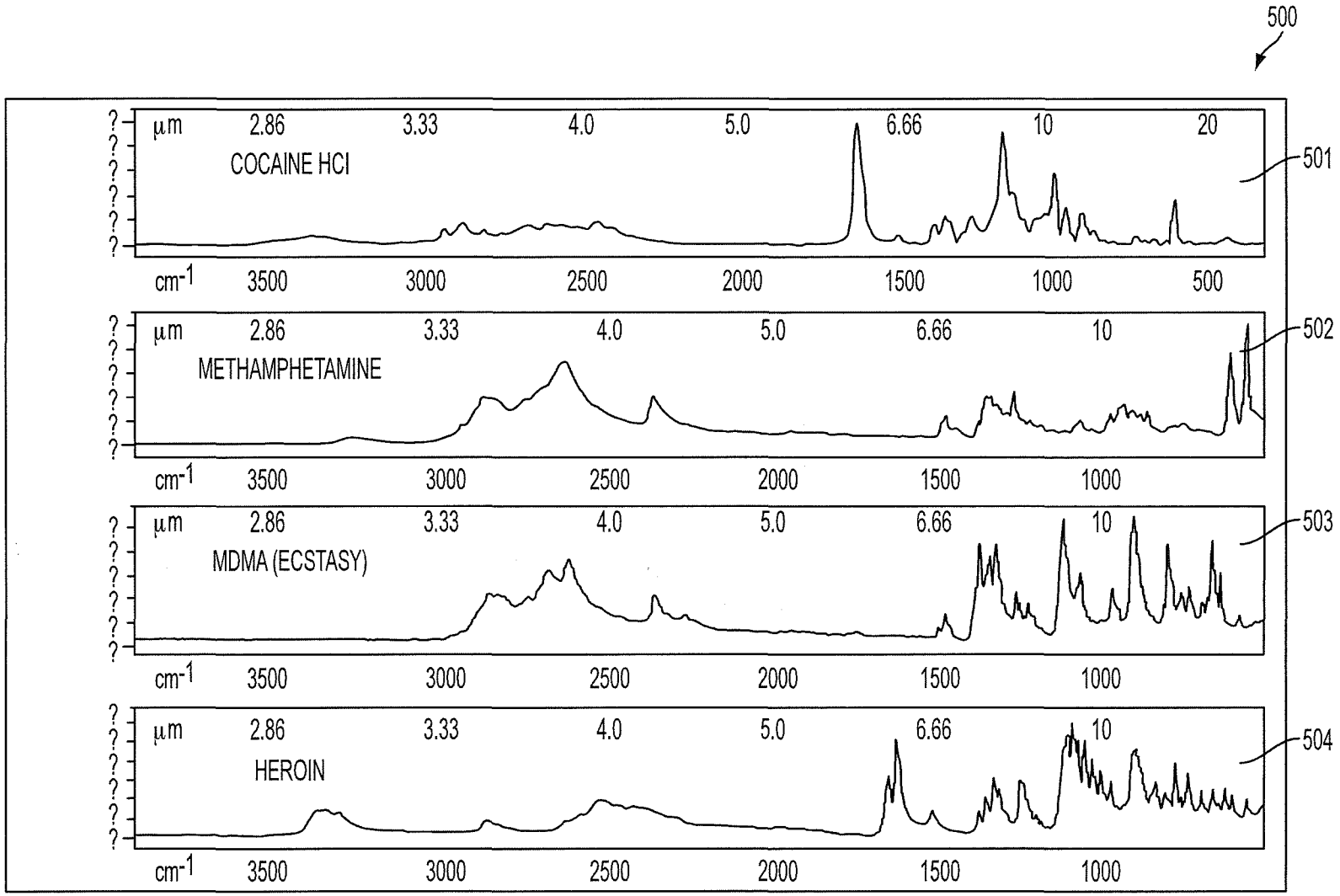

500
μm 2.86 3.33 4.0 5.0 6.66 10 20
COCAINE HCl
501
cm-1 3500 3000 2500 2000 1500 1000 500
μm 2.86 3.33 4.0 5.0 6.66 10
METHAMPHETAMINE
502
cm-1 3500 3000 2500 2000 1500 1000
μm 2.86 3.33 4.0 5.0 6.66 10
MDMA (ECSTASY)
503
cm-1 3500 3000 2500 2000 1500 1000
μm 2.86 3.33 4.0 5.0 6.66 10
HEROIN
504
cm-1 3500 3000 2500 2000 1500 1000

FIG. 5

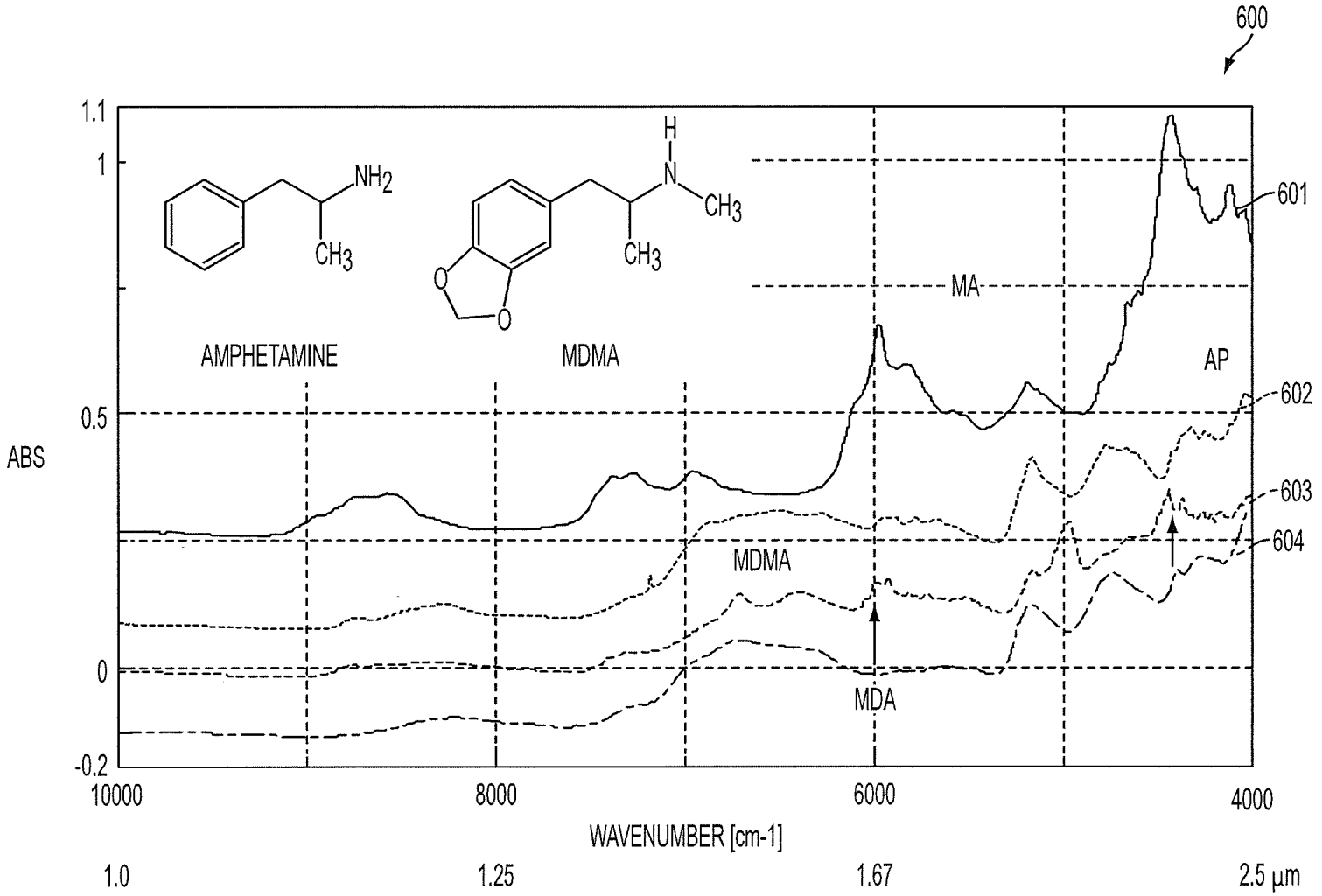

600
1.1
1
0.5
0
-0.2
ABS
NH2
CH3
AMPHETAMINE
H
N
CH3
CH3
O
O
MDMA
MA
AP
601
602
603
604
MDMA
MDA
10000
8000
6000
4000
WAVENUMBER [cm-1]
1.0
1.25
1.67
2.5 µm

FIG. 6

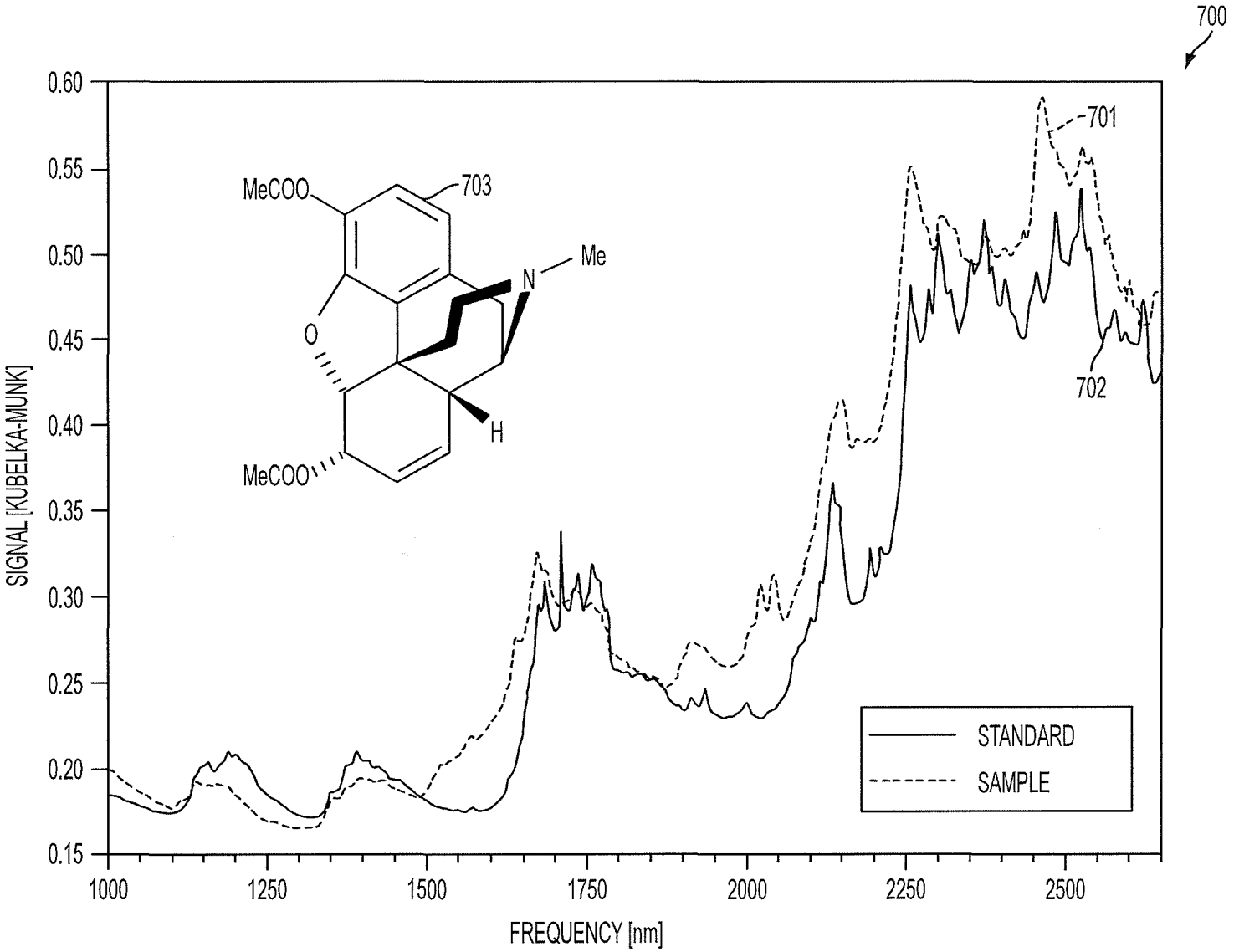

700
701
702
703
MeCOO
N
Me
O
H
MeCOO
SIGNAL [KUBELKA-MUNK]
FREQUENCY [nm]
0.60
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
1000
1250
1500
1750
2000
2250
2500
STANDARD
SAMPLE

FIG. 7

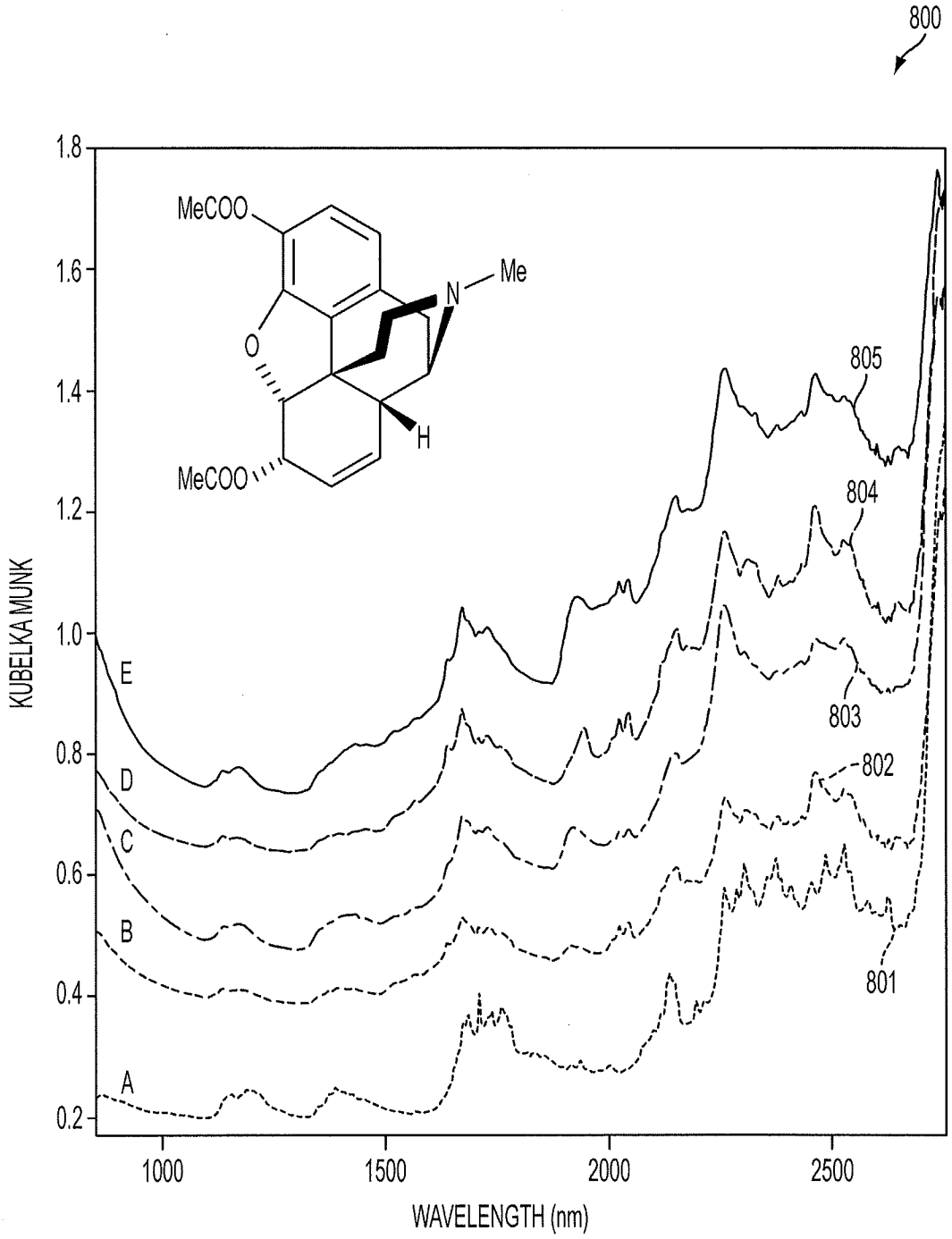

800
1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
KUBELKA MUNK
1000
1500
2000
2500
WAVELENGTH (nm)
MeCOO
Me
N
O
H
MeCOO
805
804
803
802
801
E
D
C
B
A

FIG. 8

900

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. 9B

FIG. 9A

FROM FIG. 9A

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. 9B

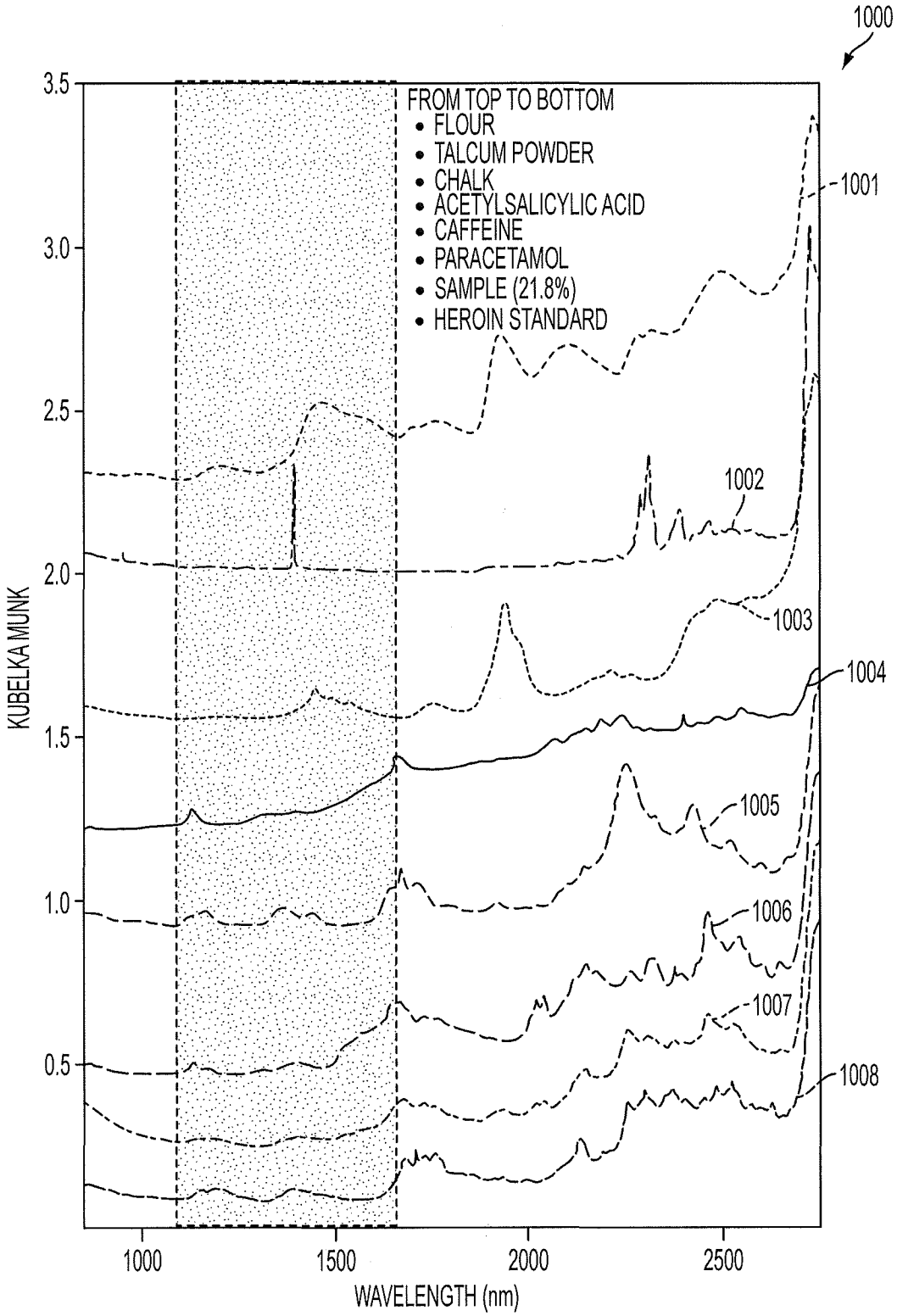

1000
FROM TOP TO BOTTOM
• FLOUR
• TALCUM POWDER
• CHALK
• ACETYLSALICYLIC ACID
• CAFFEINE
• PARACETAMOL
• SAMPLE (21.8%)
• HEROIN STANDARD
1001
1002
1003
1004
1005
1006
1007
1008
KUBELKA MUNK
3.5
3.0
2.5
2.0
1.5
1.0
0.5
1000
1500
2000
2500
WAVELENGTH (nm)

FIG. 10

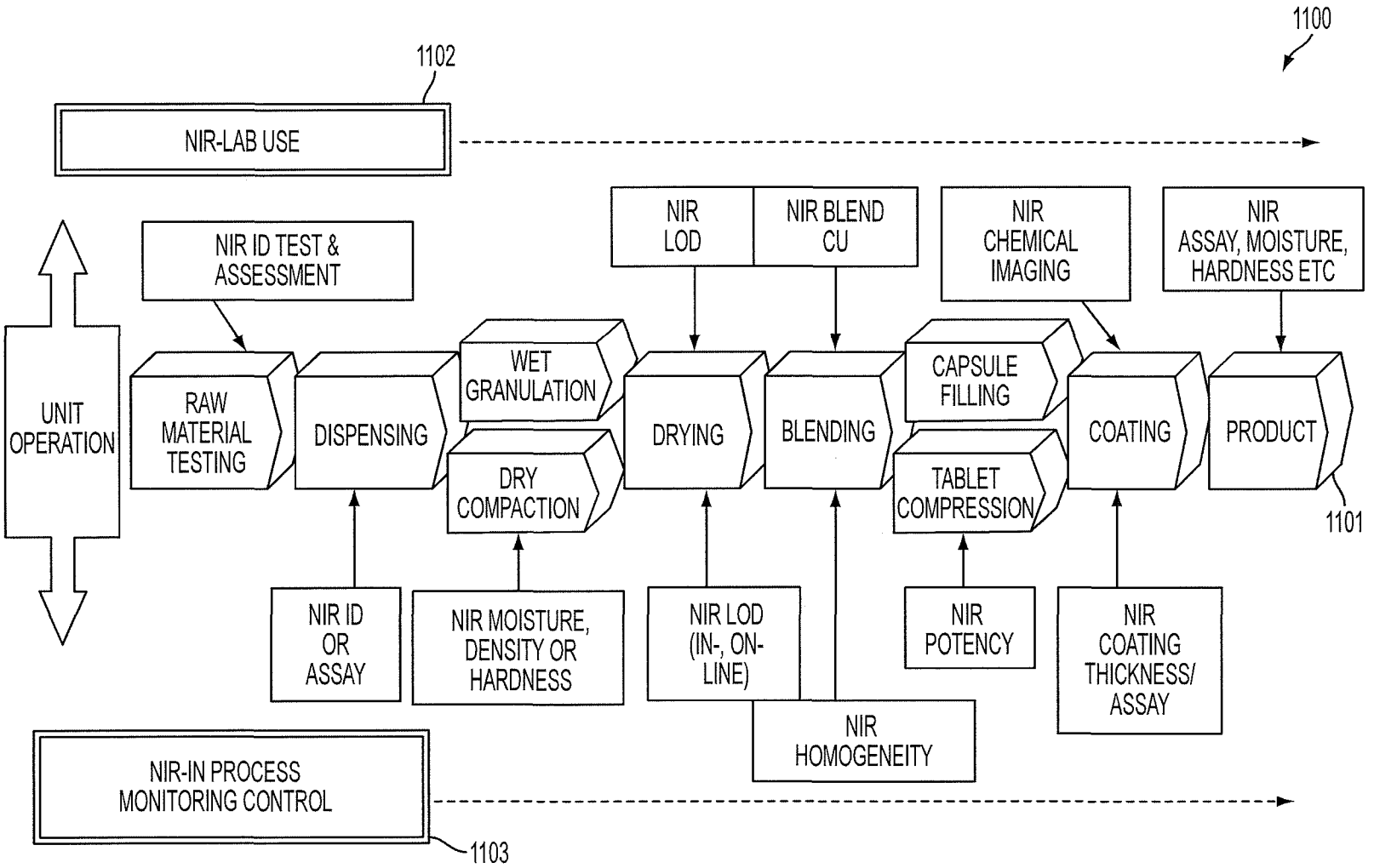

1100
1102
NIR-LAB USE
NIR ID TEST & ASSESSMENT
NIR LOD
NIR BLEND CU
NIR CHEMICAL IMAGING
NIR ASSAY, MOISTURE, HARDNESS ETC
UNIT OPERATION
RAW MATERIAL TESTING
DISPENSING
WET GRANULATION
DRY COMPACTION
DRYING
BLENDING
CAPSULE FILLING
TABLET COMPRESSION
COATING
PRODUCT
1101
NIR ID OR ASSAY
NIR MOISTURE, DENSITY OR HARDNESS
NIR LOD (IN-, ON-LINE)
NIR HOMOGENEITY
NIR POTENCY
NIR COATING THICKNESS/ ASSAY
NIR-IN PROCESS MONITORING CONTROL
1103

FIG. 11

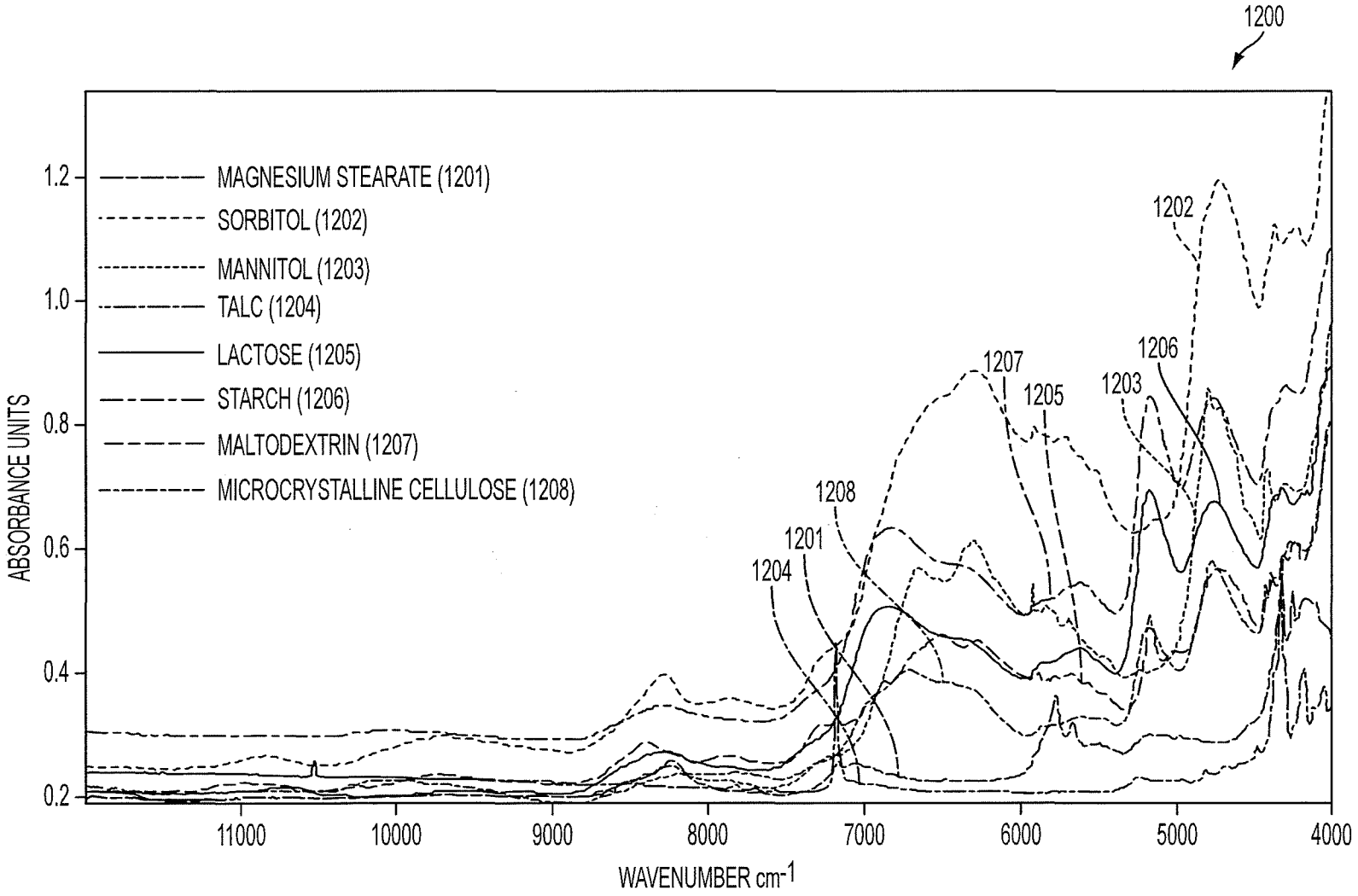

1200
MAGNESIUM STEARATE (1201)
SORBITOL (1202)
MANNITOL (1203)
TALC (1204)
LACTOSE (1205)
STARCH (1206)
MALTODEXTRIN (1207)
MICROCRYSTALLINE CELLULOSE (1208)
ABSORBANCE UNITS
1.2
1.0
0.8
0.6
0.4
0.2
11000
10000
9000
8000
7000
6000
5000
4000
WAVENUMBER cm-1
1202
1207
1206
1205
1203
1208
1201
1204

FIG. 12

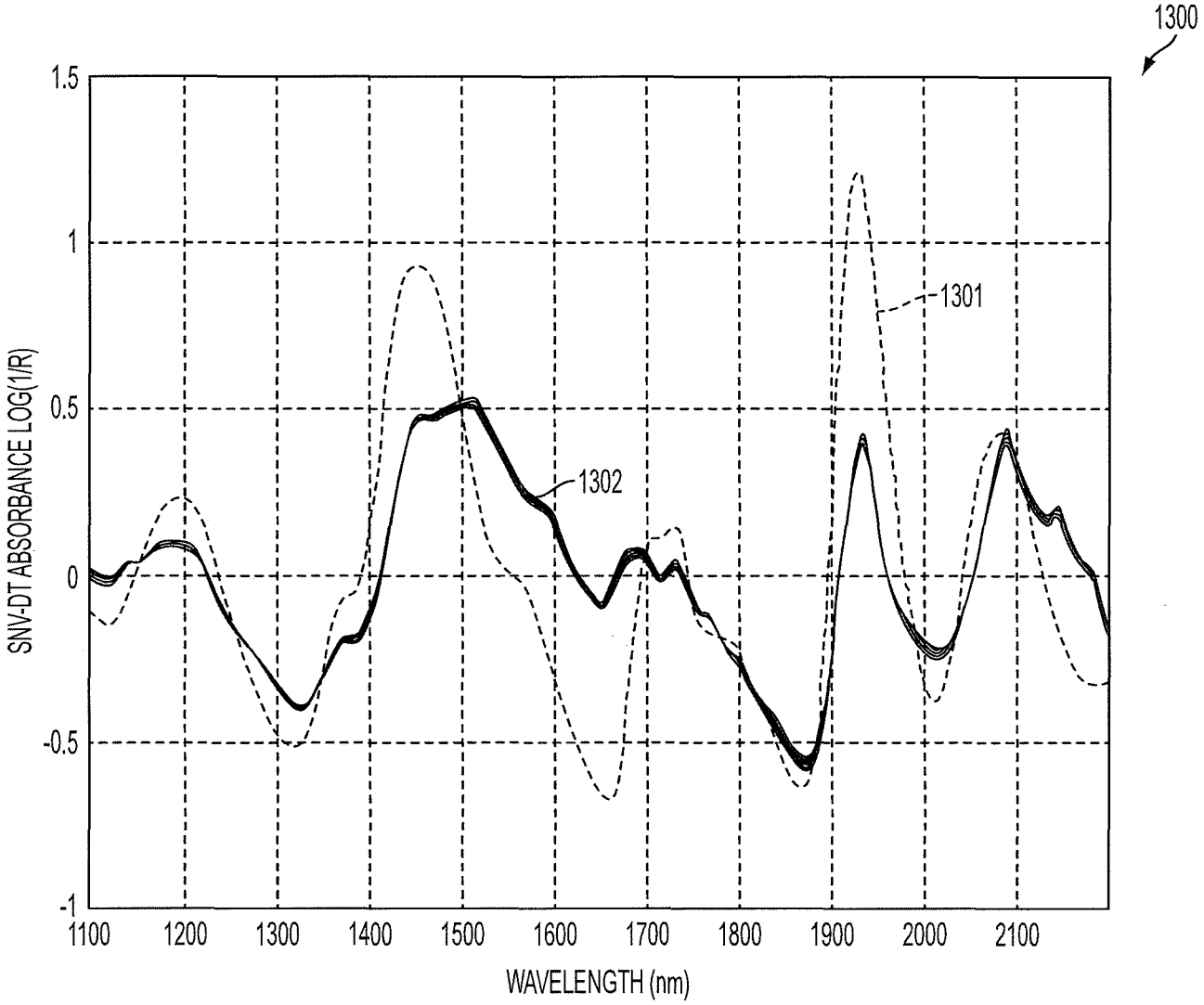

1300
1.5
1
0.5
0
-0.5
-1
SNV-DT ABSORBANCE LOG(1/R)
1301
1302
1100
1200
1300
1400
1500
1600
1700
1800
1900
2000
2100
WAVELENGTH (nm)

FIG. 13

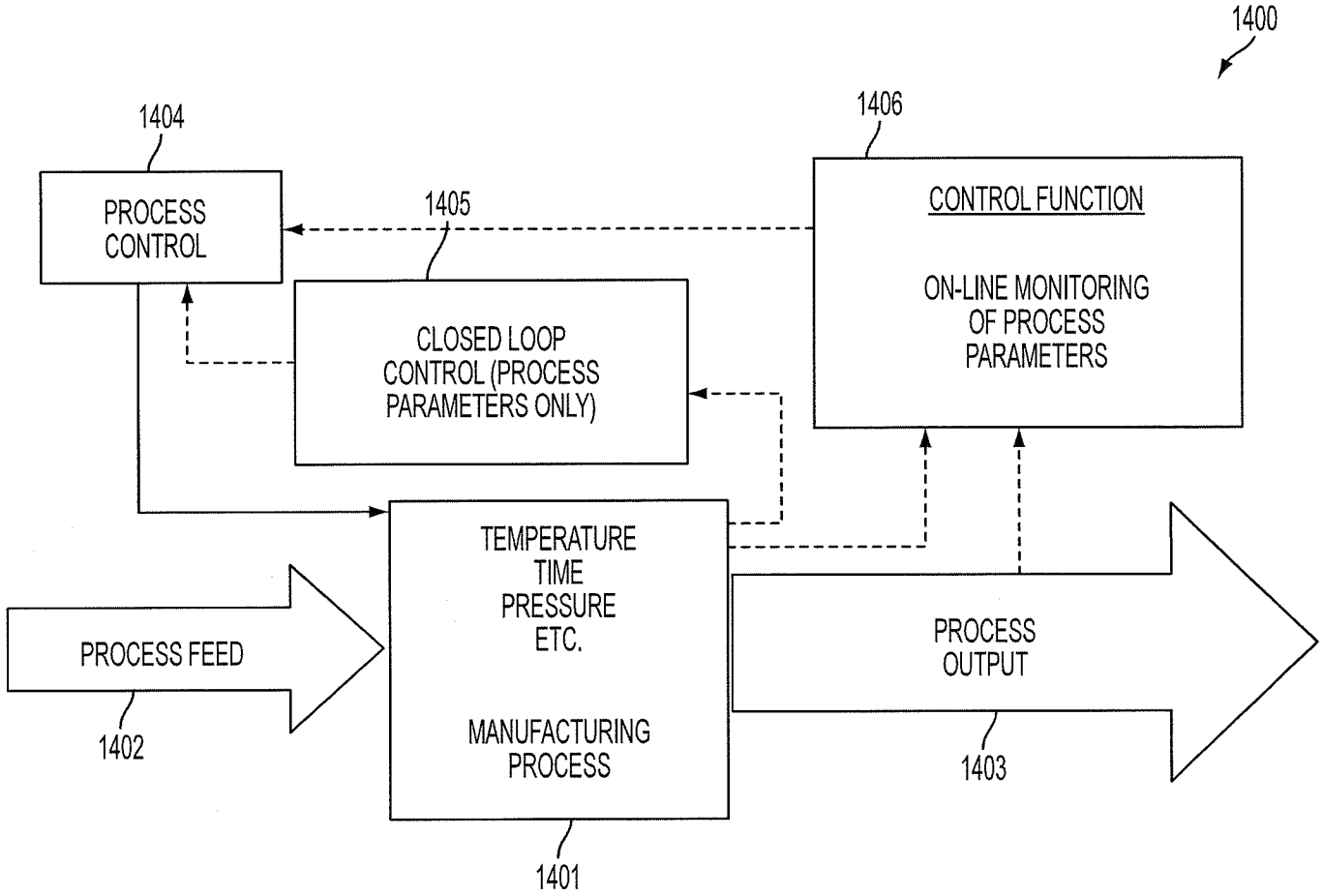

1400
1404
PROCESS CONTROL
1405
1406
CONTROL FUNCTION
ON-LINE MONITORING OF PROCESS PARAMETERS
CLOSED LOOP CONTROL (PROCESS PARAMETERS ONLY)
TEMPERATURE
TIME
PRESSURE
ETC.
MANUFACTURING PROCESS
PROCESS FEED
1402
PROCESS OUTPUT
1403
1401

FIG. 14

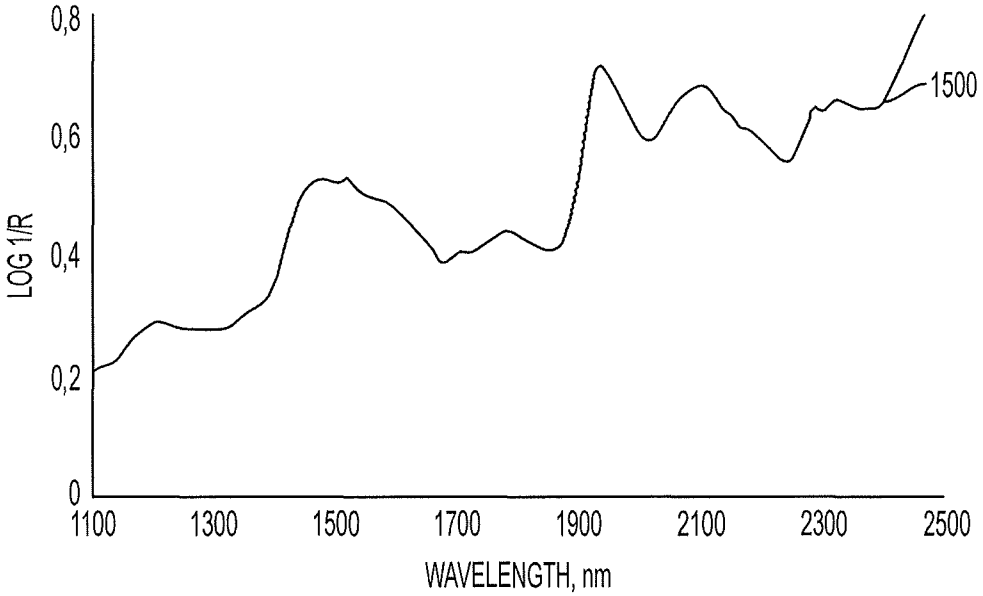


FIG. 15A

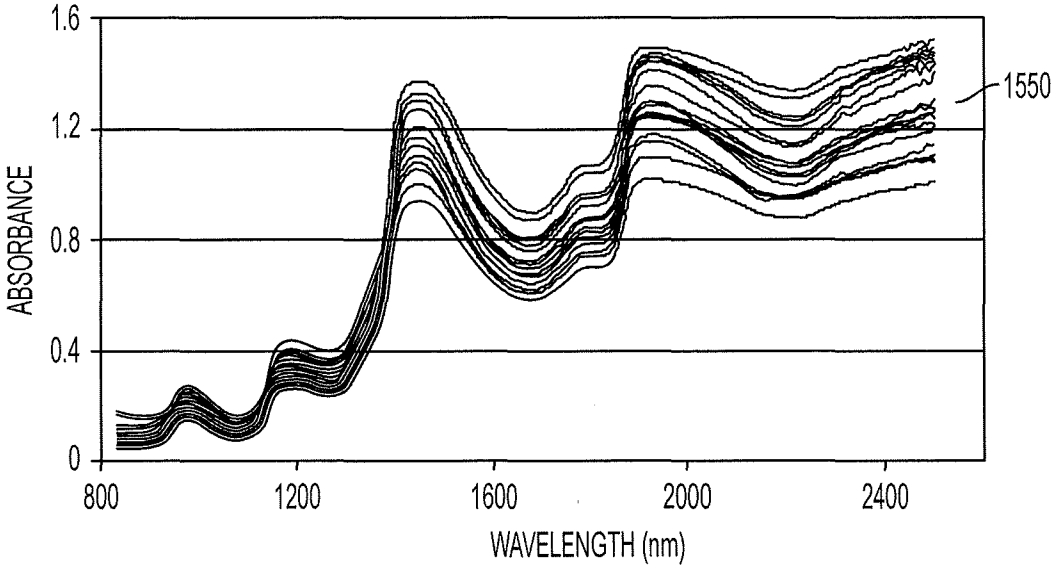


FIG. 15B

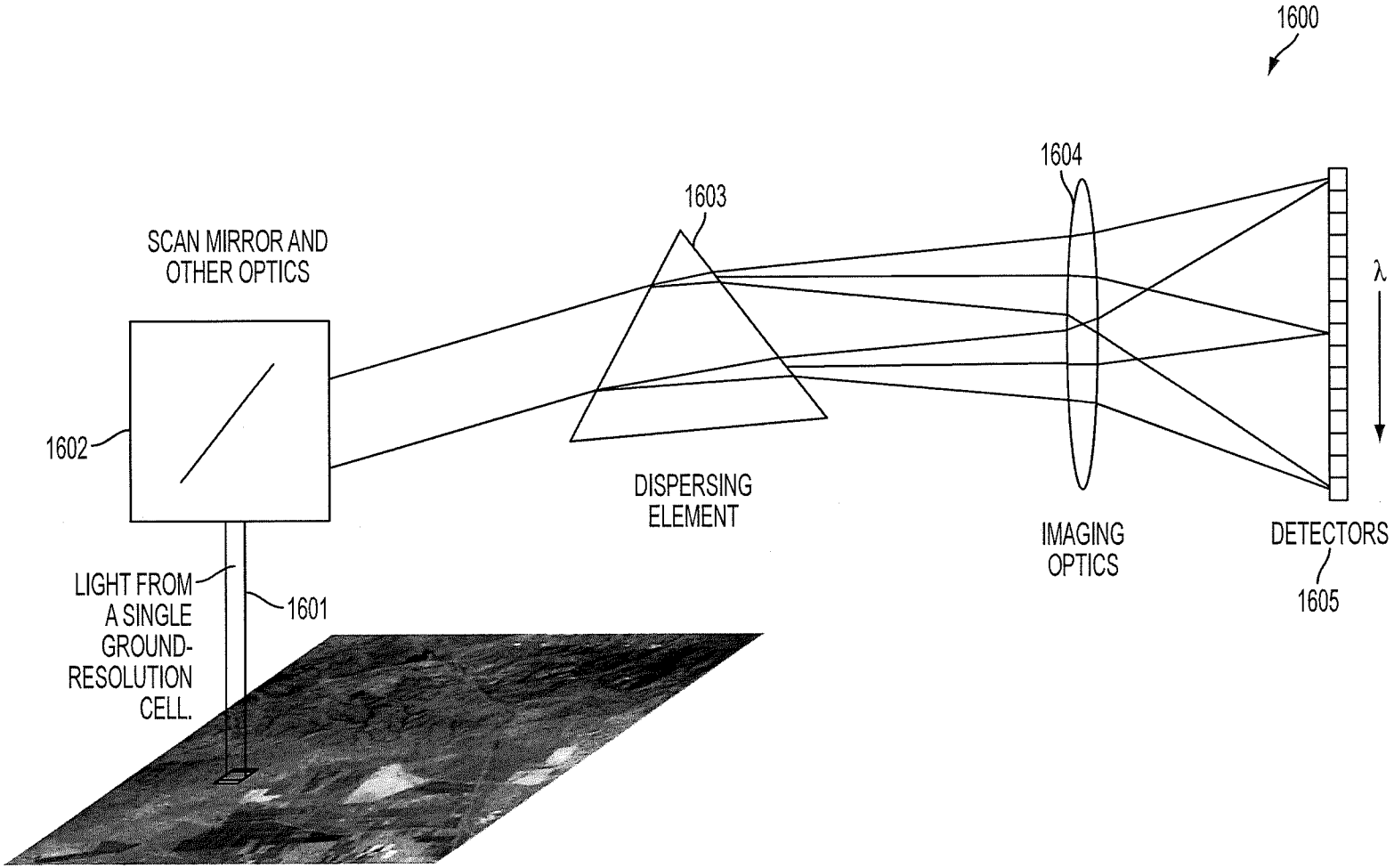

1600
1604
1603
SCAN MIRROR AND
OTHER OPTICS
λ
1602
DISPERSING
ELEMENT
IMAGING
OPTICS
DETECTORS
1605
LIGHT FROM
A SINGLE
GROUND-
RESOLUTION
CELL.
1601

FIG. 16A

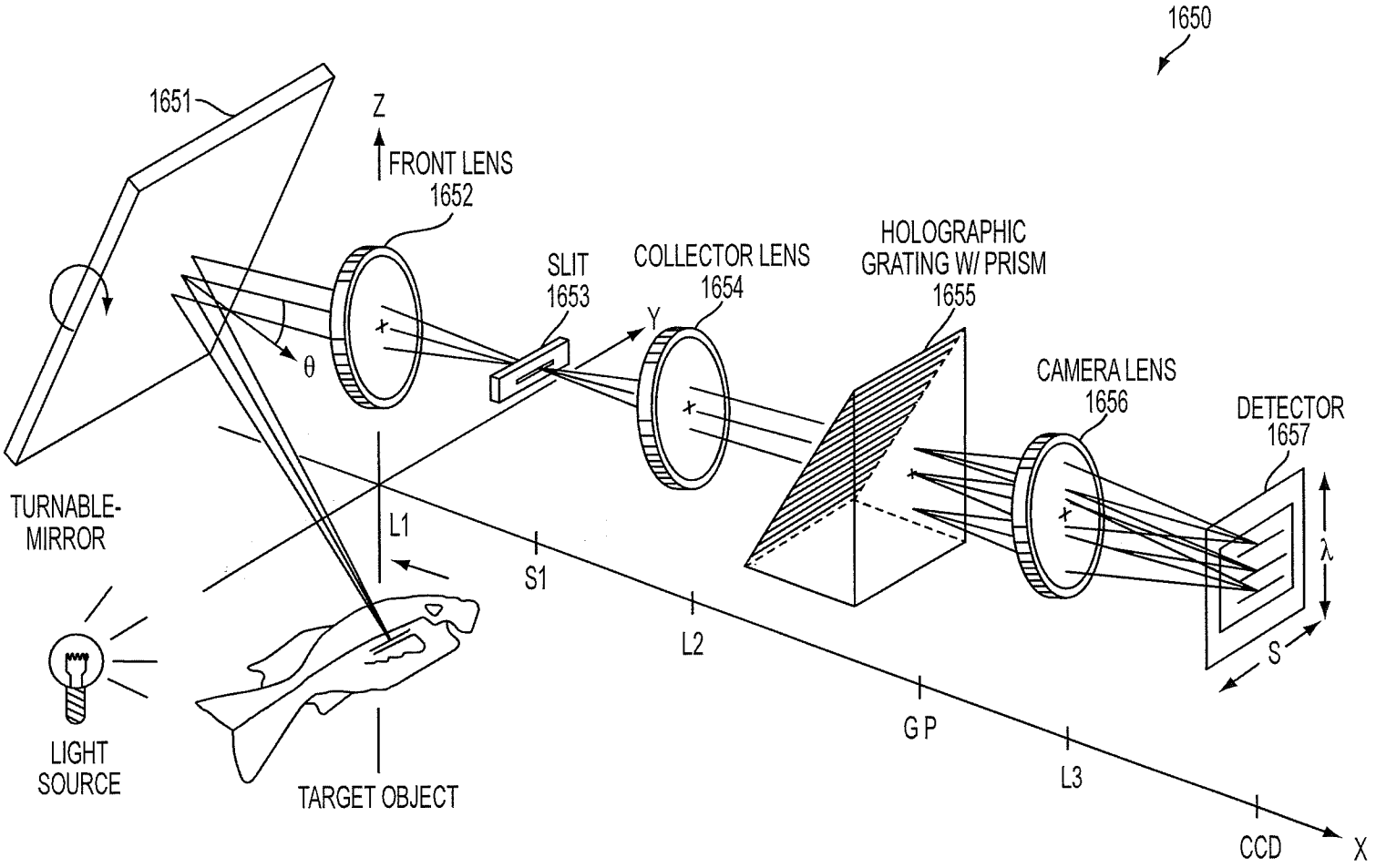

1650
1651
Z
FRONT LENS
1652
SLIT
1653
COLLECTOR LENS
1654
HOLOGRAPHIC
GRATING W/ PRISM
1655
CAMERA LENS
1656
DETECTOR
1657
θ
Y
TURNABLE-
MIRROR
L1
S1
L2
G P
L3
CCD
X
λ
S
LIGHT
SOURCE
TARGET OBJECT

FIG. 16B

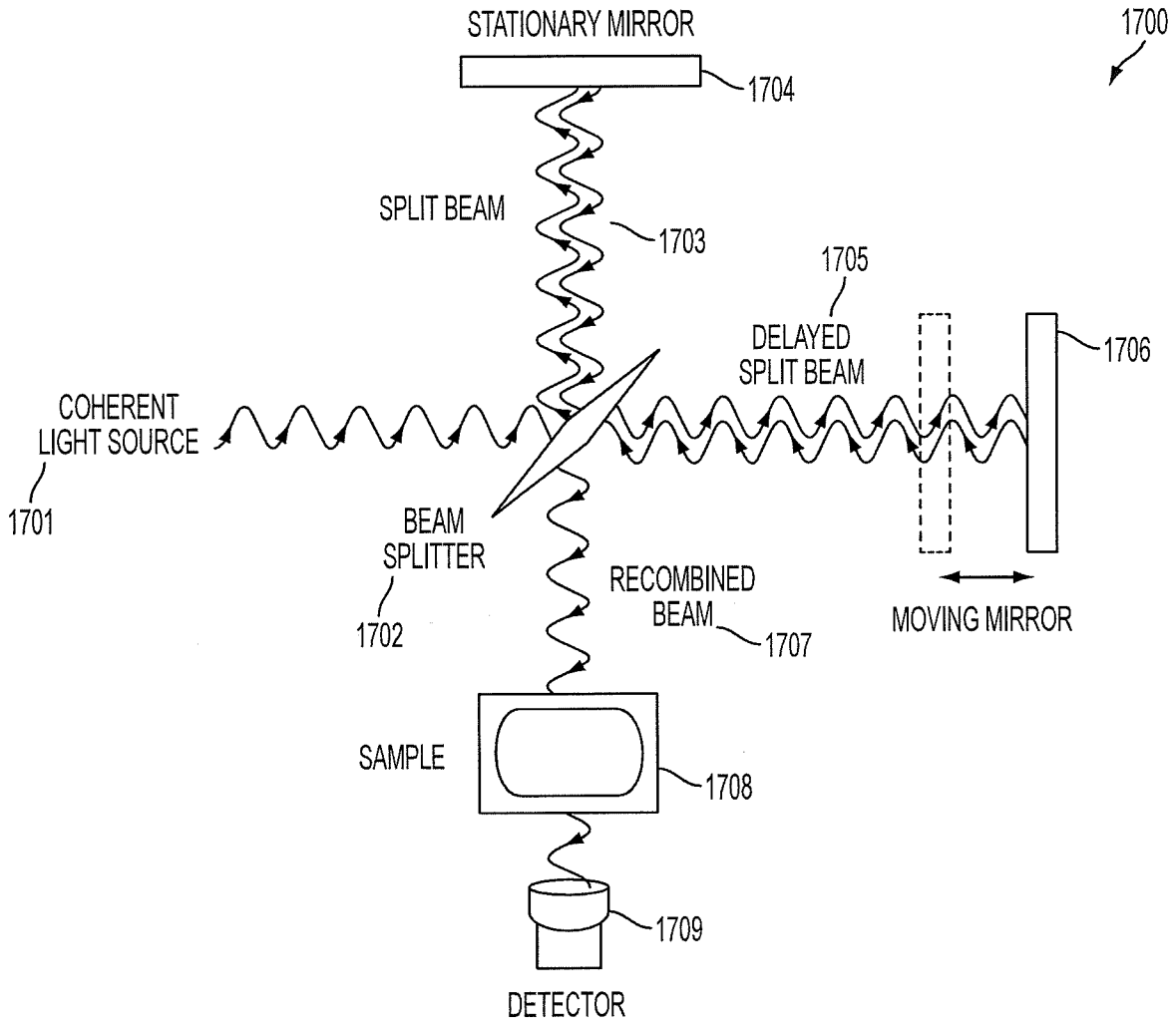

STATIONARY MIRROR
1700
1704
SPLIT BEAM
1703
1705
DELAYED
SPLIT BEAM
1706
COHERENT
LIGHT SOURCE
1701
BEAM
SPLITTER
1702
RECOMBINED
BEAM
1707
MOVING MIRROR
SAMPLE
1708
1709
DETECTOR

FIG. 17

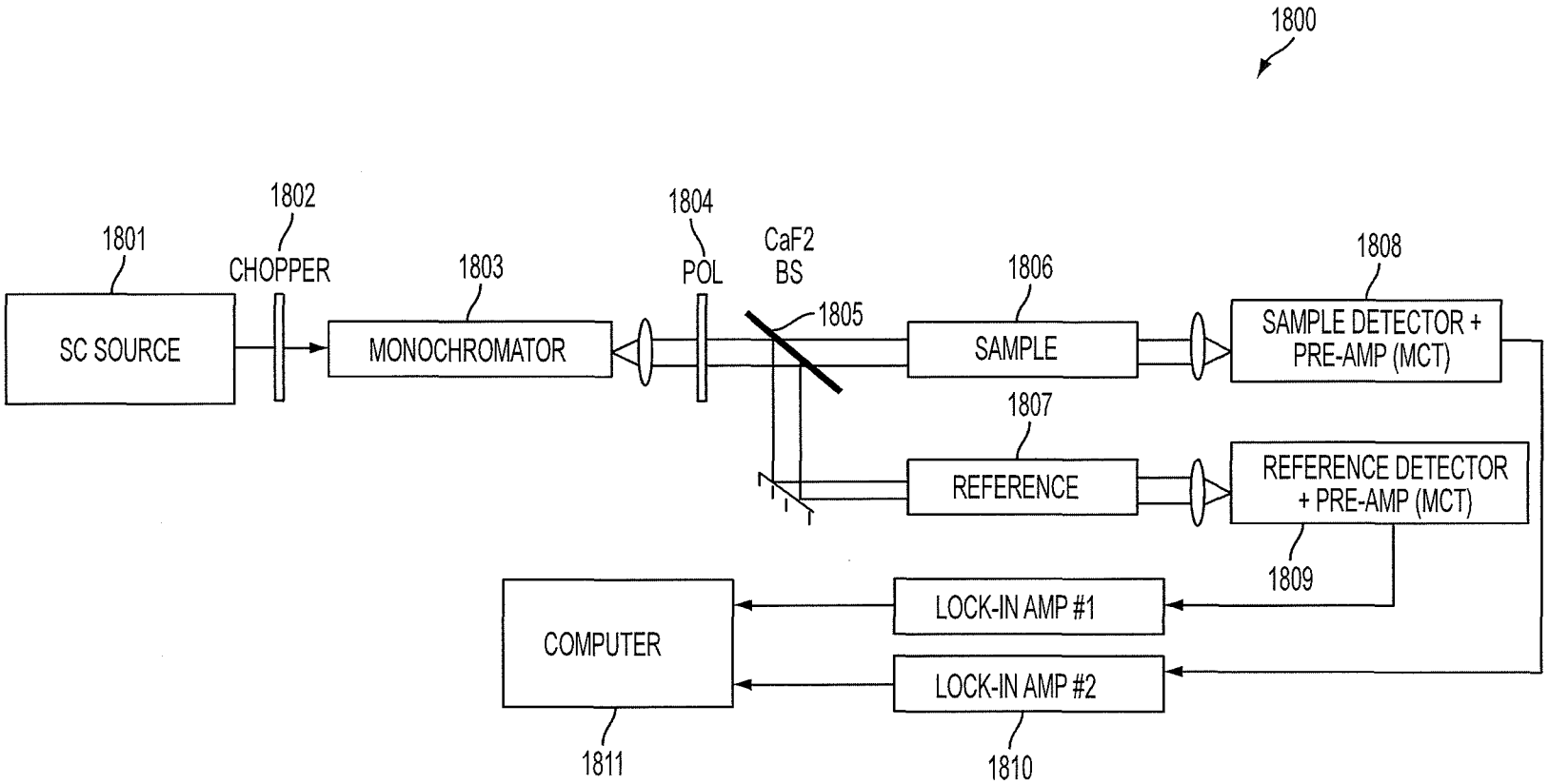

1800
1801
SC SOURCE
1802
CHOPPER
1803
MONOCHROMATOR
1804
POL
CaF2
BS
1805
1806
SAMPLE
1807
REFERENCE
1808
SAMPLE DETECTOR +
PRE-AMP (MCT)
REFERENCE DETECTOR
+ PRE-AMP (MCT)
1809
LOCK-IN AMP #1
LOCK-IN AMP #2
COMPUTER
1810
1811

FIG. 18

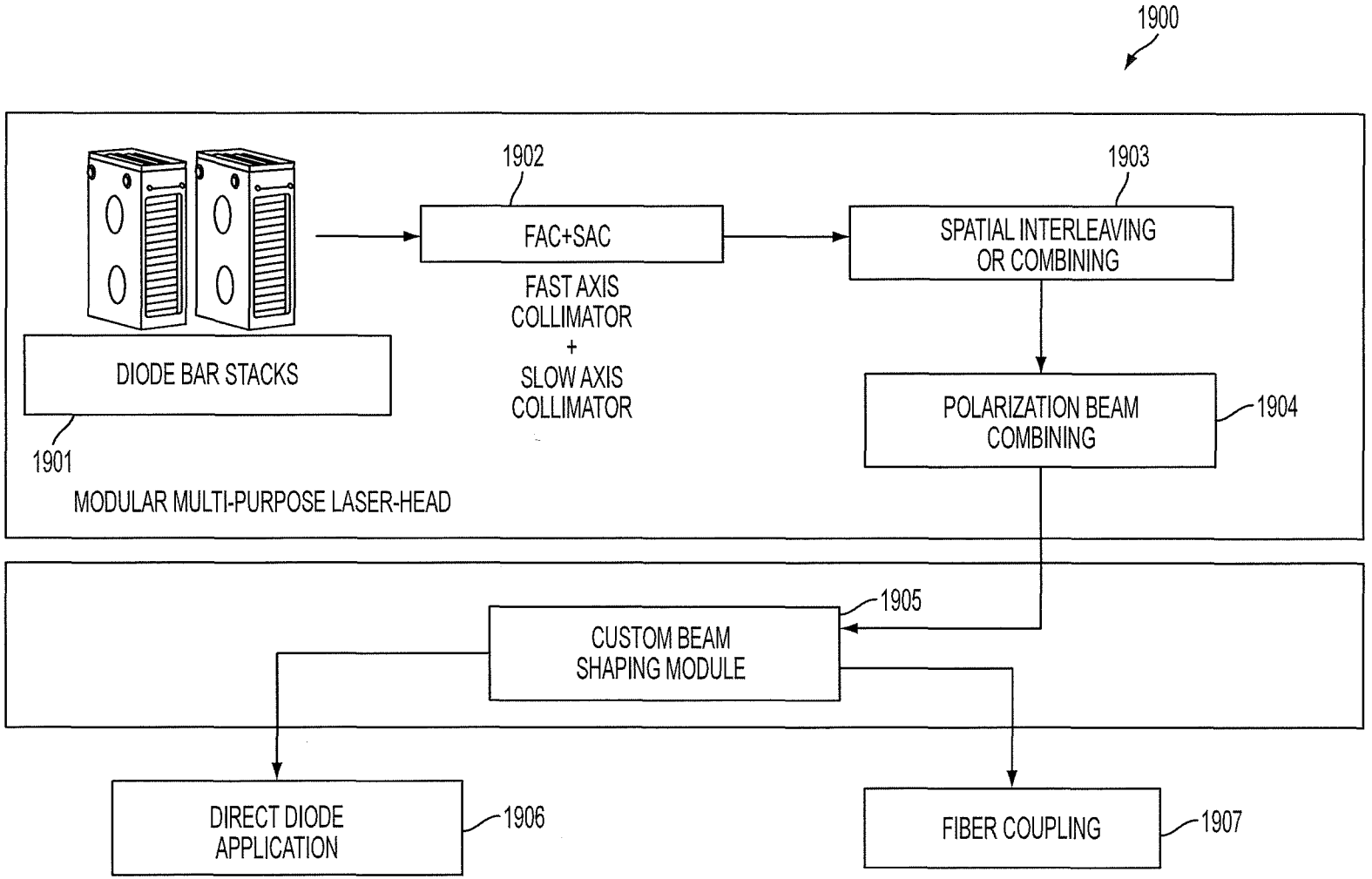


FIG. 19

Petitioner WHOOP, Inc. Ex1002
Page 23 of 1089

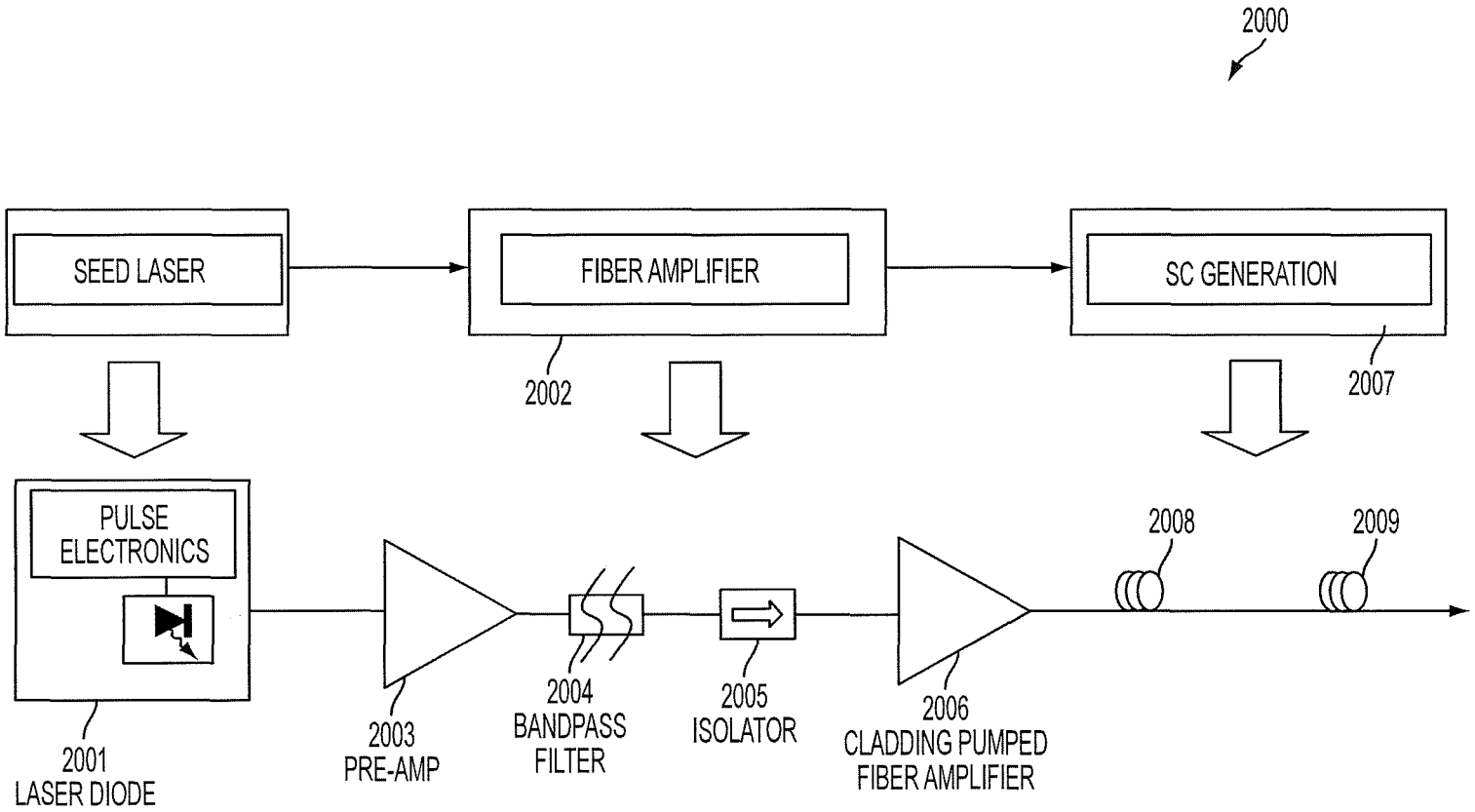

2000
SEED LASER
FIBER AMPLIFIER
SC GENERATION
2002
2007
PULSE ELECTRONICS
2008
2009
2001
LASER DIODE
2003
PRE-AMP
2004
BANDPASS FILTER
2005
ISOLATOR
2006
CLADDING PUMPED FIBER AMPLIFIER

FIG. 20

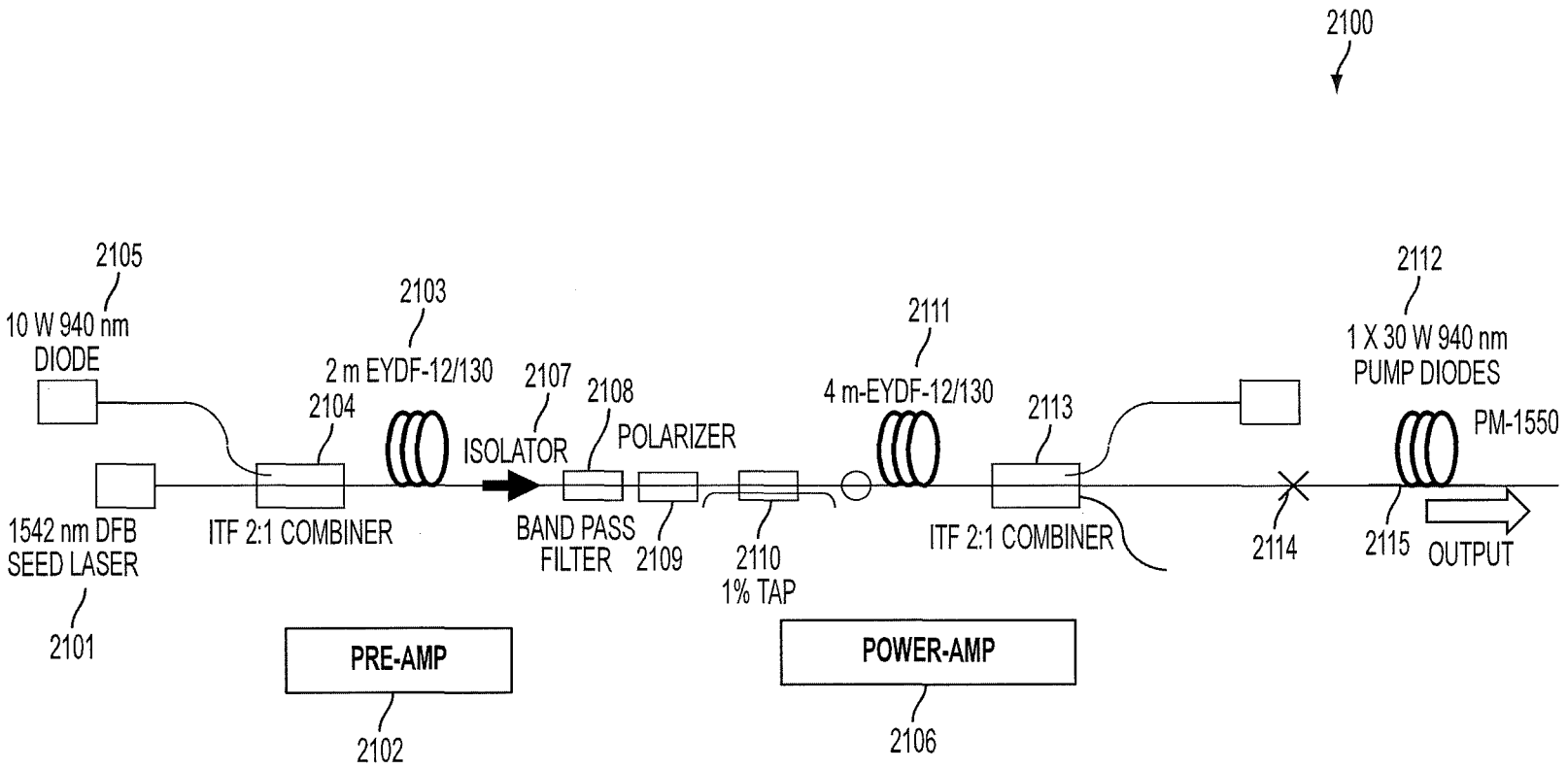

2100
2105
10 W 940 nm
DIODE
2103
2 m EYDF-12/130
2104
2107
ISOLATOR
2108
POLARIZER
2111
4 m-EYDF-12/130
2113
2112
1 X 30 W 940 nm
PUMP DIODES
PM-1550
1542 nm DFB
SEED LASER
2101
ITF 2:1 COMBINER
BAND PASS
FILTER
2109
2110
1% TAP
ITF 2:1 COMBINER
2114
2115
OUTPUT
PRE-AMP
2102
POWER-AMP
2106

FIG. 21

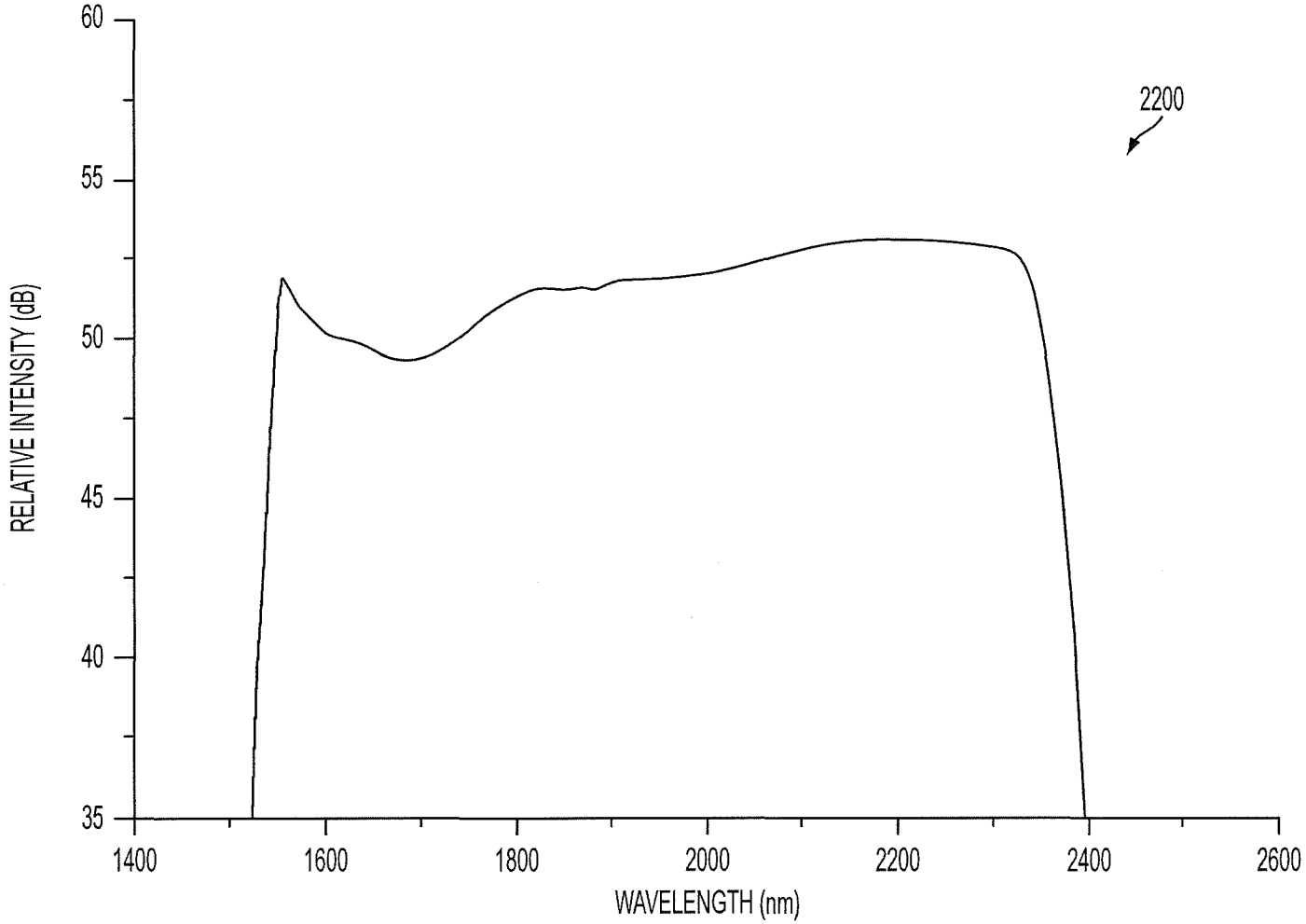

60
55
50
45
40
35
RELATIVE INTENSITY (dB)
1400
1600
1800
2000
2200
2400
2600
WAVELENGTH (nm)
2200

FIG. 22

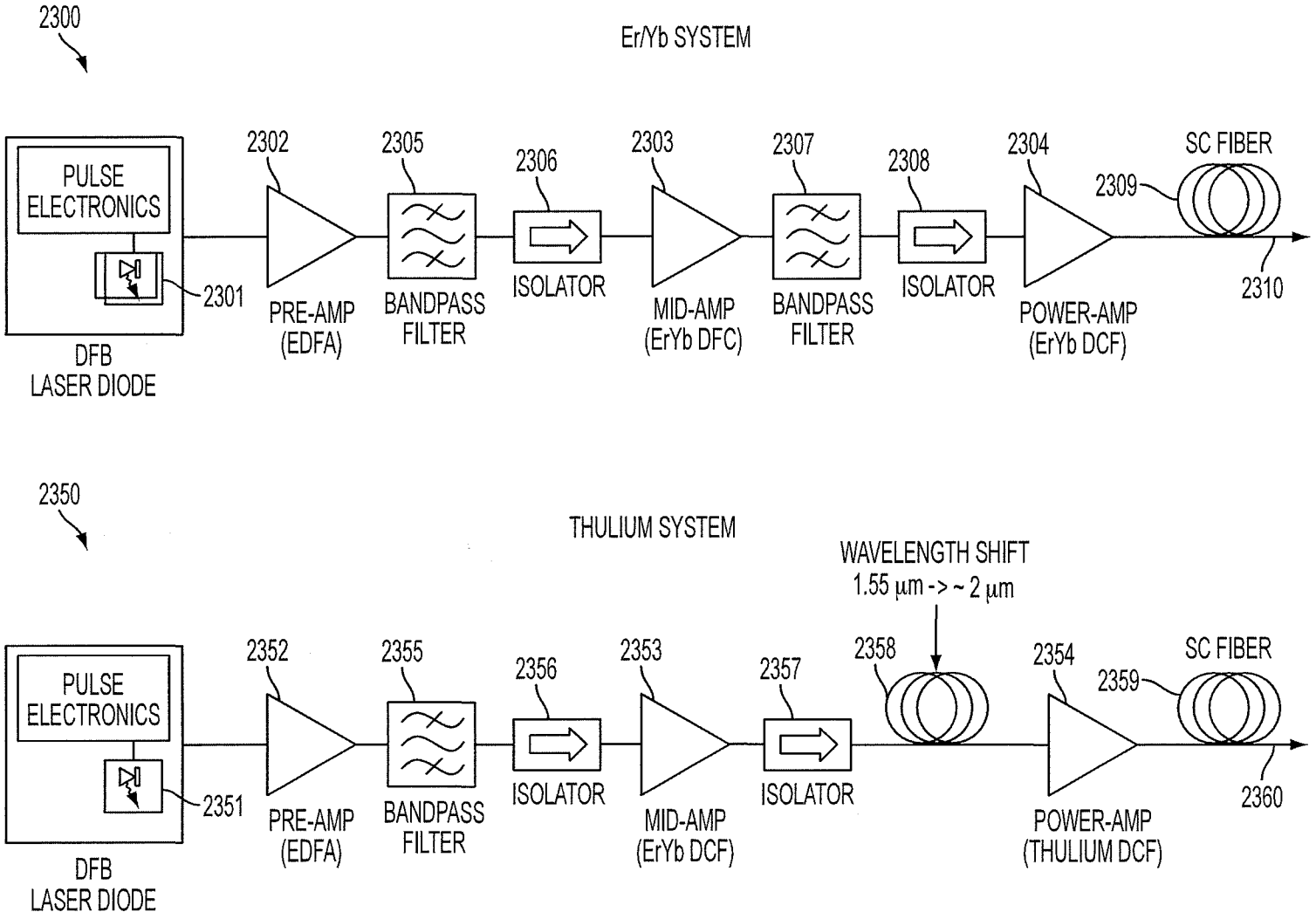

2300
Er/Yb SYSTEM
PULSE ELECTRONICS
2301
DFB LASER DIODE
2302
PRE-AMP (EDFA)
2305
BANDPASS FILTER
2306
ISOLATOR
2303
MID-AMP (ErYb DFC)
2307
BANDPASS FILTER
2308
ISOLATOR
2304
POWER-AMP (ErYb DCF)
2309
SC FIBER
2310
2350
THULIUM SYSTEM
WAVELENGTH SHIFT
1.55 μm -> ~ 2 μm
PULSE ELECTRONICS
2351
DFB LASER DIODE
2352
PRE-AMP (EDFA)
2355
BANDPASS FILTER
2356
ISOLATOR
2353
MID-AMP (ErYb DCF)
2357
ISOLATOR
2358
2354
POWER-AMP (THULIUM DCF)
2359
SC FIBER
2360

FIG. 23

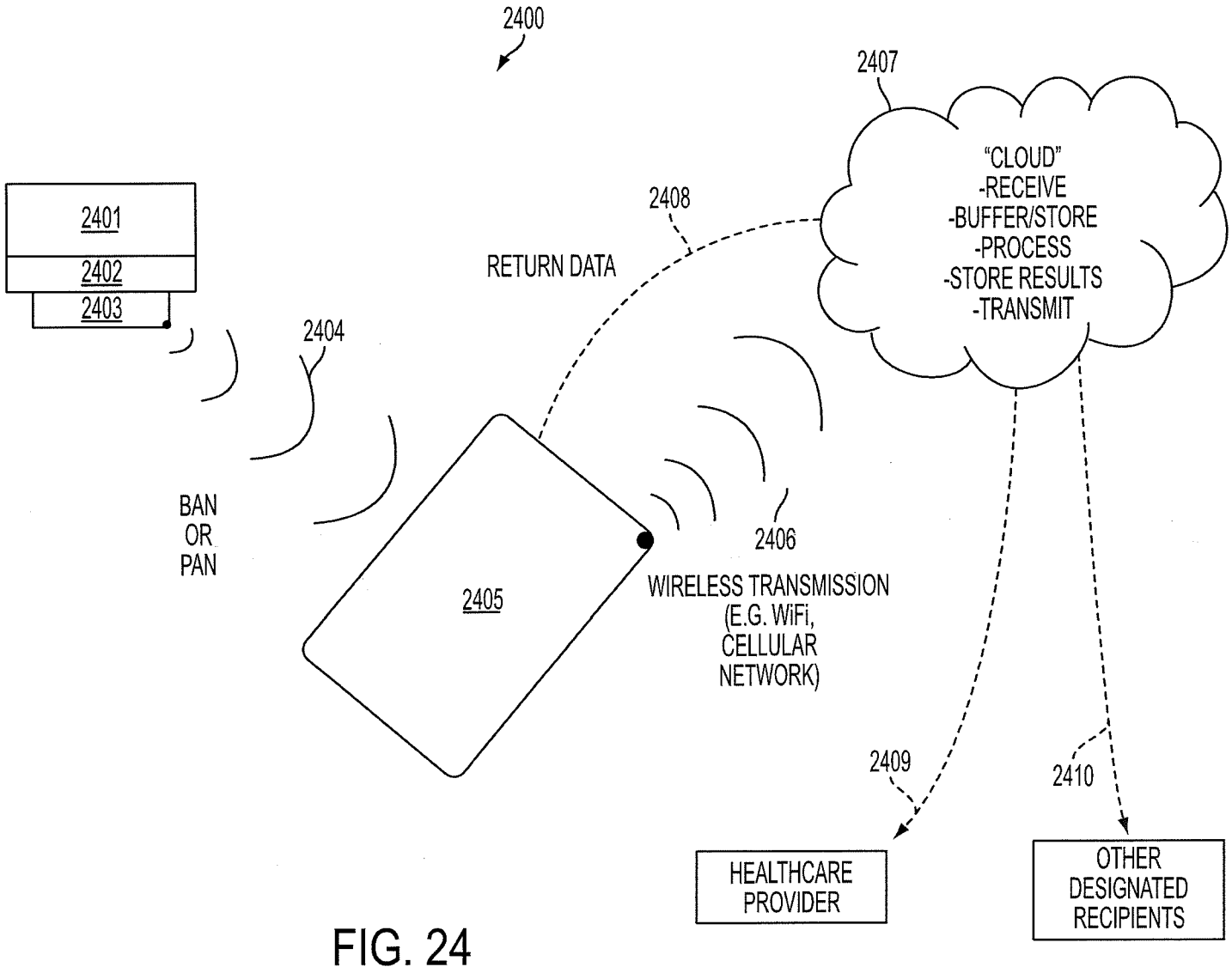

2400
2407
"CLOUD"
-RECEIVE
-BUFFER/STORE
-PROCESS
-STORE RESULTS
-TRANSMIT
2408
RETURN DATA
2401
2402
2403
2404
BAN
OR
PAN
2405
2406
WIRELESS TRANSMISSION
(E.G. WiFi,
CELLULAR
NETWORK)
2409
2410
HEALTHCARE
PROVIDER
OTHER
DESIGNATED
RECIPIENTS

FIG. 24

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Group Art Unit:

Mohammed N. ISLAM

Examiner:

Serial No.:

Filed:

For: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Attorney Docket No.: OMNI 0105 PUSP1

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)(1)

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

Commissioner:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and §§ 1.97-1.98, the references listed and identified on the attached Form PTO/SB/08a are being submitted herewith for consideration by the Examiner. This Statement is being filed in accordance with 37 C.F.R. § 1.97(b)(1).

While this Statement is being filed in compliance with the duty of disclosure, citation of the listed references is not to be construed as an admission that any of the references are "material" as defined under 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.98(d), copies of the listed references are not being provided since the references were previously cited by or submitted to the Patent and Trademark

Office in prior application Serial No. 14/108,986, filed December 17, 2013 (pending), of which the present application is a continuation.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

Mohammed N. ISLAM

By: /David S. Bir/
David S. Bir
Reg. No. 38,383
Attorney/Agent for Applicant

Date: October 1, 2015

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Southfield, MI 48075-1238
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Fax: 248-358-3351

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First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4063106		1977-12-13	Ashkin, et al.	
	2	4158750		1979-06-19	Sakoe, et al.	
	3	4221997		1980-09-09	Flemming	
	4	4275266		1981-06-23	Lasar	
	5	4374618		1983-02-22	Howard	
	6	4403605		1983-09-13	Tanikawa	
	7	4462080		1984-07-24	Johnstone, et al.	
	8	4516207		1985-05-07	Moriyama, et al.	

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	First Named Inventor	Mohammed N. ISLAM
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	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	9	4523884		1985-06-18	Clement, et al.	
	10	4605080		1986-08-12	Lemelson	
	11	4641292		1987-02-03	Tunnell, et al.	
	12	4704696		1987-11-03	Reimer, et al.	
	13	4728974		1988-03-01	Nio, et al.	
	14	4762455		1988-08-09	Coughlan, et al.	
	15	4776016		1988-10-04	Hansen	
	16	4958910		1990-09-25	Taylor, et al.	
	17	4989253		1991-01-29	Liang, et al.	
	18	5078140		1992-01-07	Kwoh	
	19	5084880		1992-01-28	Esterowitz, et al.	

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	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	20	5086401		1992-02-04	Glassman, et al.	
	21	5134620		1992-07-28	Huber	
	22	5142930		1992-09-01	Allen, et al.	
	23	5180378		1993-01-19	Kung, et al.	
	24	5191628		1993-03-02	Byron	
	25	5218655		1993-06-08	Mizrahi	
	26	5230023		1993-07-20	Nakano	
	27	5267256		1993-11-30	Saruwatari, et al.	
	28	5267323		1993-11-30	Kimura	
	29	5300097		1994-04-05	Lerner, et al.	
	30	5303148		1994-04-12	Mattson, et al.	

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	Attorney Docket Number	OMNI 0105 PUSP1

	31	5305427		1994-04-19	Nagata	
	32	5313306		1994-05-17	Kuban, et al.	
	33	5323404		1994-06-21	Grubb	
	34	5345538		1994-09-06	Narayannan, et al.	
	35	5408409		1995-04-18	Glassman, et al.	
	36	5544654		1996-08-13	Murphy, et al.	
	37	5572999		1996-11-12	Funda, et al.	
	38	5695493		1997-12-09	Nakajima, et al.	
	39	5696778		1997-12-09	MacPherson	
	40	5792204		1998-08-11	Snell	
	41	5812978		1998-09-22	Nolan	

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	42	5950629		1999-09-14	Taylor, et al.	
	43	5970457		1999-10-19	Brant, et al.	
	44	6014249		2000-01-11	Fermann, et al.	
	45	6185535		2001-02-06	Hedin, et al.	
	46	6200309		2001-03-13	Rice, et al.	
	47	6224542		2001-05-01	Chang, et al.	
	48	6246707		2001-06-12	Yin, et al.	
	49	6273858		2001-08-14	Fox, et al.	
	50	6278975		2001-08-21	Brant, et al.	
	51	6301273		2001-10-09	Sanders, et al.	
	52	6337462		2002-01-08	Smart	

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	53	6340806		2002-01-22	Smart, et al.	
	54	6350261		2002-02-26	Domankevitz, et al.	
	55	6374006		2002-04-16	Islam, et al.	
	56	6407853		2002-06-18	Samson, et al.	
	57	6436107		2002-08-20	Wang, et al.	
	58	6442430		2002-08-27	Ferek-Petric	
	59	6450172		2002-09-17	Hartlaub, et al.	
	60	6453201		2002-09-17	Daum, et al.	
	61	6458120		2002-10-01	Shen, et al.	
	62	6462500		2002-10-08	L'Hegarat, et al.	
	63	6463361		2002-10-08	Wang, et al.	

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	64	6567431		2003-05-20	Tabirian, et al.	
	65	6605080		2003-08-12	Altshuler, et al.	
	66	6625180		2003-09-23	Bufetov, et al.	
	67	6631025		2003-10-07	Islam, et al.	
	68	6659999		2003-12-09	Anderson, et al.	
	69	6760148		2004-07-06	Islam	
	70	6885498		2005-04-26	Islam	
	71	6885683		2005-04-26	Fermann, et al.	
	72	6943936		2005-09-13	Islam, et al.	
	73	7027467		2006-04-11	Baev, et al.	
	74	7060061		2006-06-13	Altshuler, et al.	

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	75	7167300		2007-01-23	Fermann, et al.	
	76	7259906		2007-08-21	Islam	
	77	7433116		2008-10-07	Islam	

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	1	20020032468		2002-03-14	Hill, Michael R.S. ; et al.	
	2	20020082612		2002-06-27	Moll, Frederic H. ; et al.	
	3	20020128846		2002-09-12	Miller, Steven C.	
	4	20020178003		2002-11-28	Gehrke, James K. ; et al.	
	5	20040174914		2004-09-09	Fukatsu, Susumu	

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	1	EP1148666	EP		2001-10-24	Grant Andrew R et al.		☐
	2	WO01150959	WO		2001-07-19	SUHM		☐
	3	WO09715240	WO		1997-05-01	BRANT		☐
	4	WO97049340	WO		1997-12-31	WANG		☐

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	1		☐

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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.

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

☒ None

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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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First Named Inventor	Mohammed N. ISLAM
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	1	5084880		1992-01-28	Esterowitz, et al.	
	2	5180378		1993-01-19	Kung, et al.	
	3	5400165		1995-03-21	Gnauck, et al.	
	4	5458122		1995-10-17	Hethuin	
	5	5617871		1997-04-08	Burrows	
	6	5631758		1997-05-20	Knox, et al.	
	7	5687734		1997-11-18	Dempsey, et al.	
	8	5696778		1997-12-09	MacPherson	

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	Attorney Docket Number	OMNI 0105 PUSP1

	9	5704351		1998-01-06	Mortara, et al.	
	10	5718234		1998-02-17	Warden, et al.	
	11	5748103		1998-05-05	Flach, et al.	
	12	5855550		1999-01-05	Lai, et al.	
	13	5862803		1999-01-26	Besson, et al.	
	14	5867305		1999-02-02	Waarts, et al.	
	15	5912749		1999-06-15	Harstead, et al.	
	16	5944659		1999-08-31	Flach, et al.	
	17	5957854		1999-09-28	Besson, et al.	
	18	6014249		2000-01-11	Fermann, et al.	
	19	6043927		2000-03-28	Islam	

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	First Named Inventor	Mohammed N. ISLAM
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	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	20	6289238		2001-09-11	Besson, et al.	
	21	6333803		2001-12-25	Kurotori, et al.	
	22	6364834		2002-04-02	Reuss, et al.	
	23	6381391		2002-04-30	Islam, et al.	
	24	6402691		2002-06-11	Peddicord, et al.	
	25	6407853		2002-06-18	Samson, et al.	
	26	6441747		2002-08-27	Khair, et al.	
	27	6443890		2002-09-03	Schulze, et al.	
	28	6454705		2002-09-24	Cosentino, et al.	
	29	6480656		2002-11-12	Islam, et al.	
	30	6549702		2003-04-15	Islam, et al.	

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	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	31	6603910		2003-08-05	Islam, et al.	
	32	6659947		2003-12-09	Carter, et al.	
	33	6802811		2004-10-12	Slepian	
	34	7167300		2007-01-23	Fermann, et al.	
	35	7209657		2007-04-24	Islam	
	36	7263288		2007-08-28	Islam	
	37	7519253		2009-04-14	Islam	

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	1	20020013518		2002-01-31	West, Kenneth G. ; et al.	
	2	20020019584		2002-02-14	Schulze, Arthur E. ; et al.	

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	Examiner Name	
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	3	20020032468		2002-03-14	Hill, Michael R.S. ; et al.	
	4	20020082612		2002-06-27	Moll, Frederic H. ; et al.	
	5	20020109621		2002-08-15	Khair, Mohammad ; et al.	
	6	20020115914		2002-08-22	Russ, Tomas	
	7	20020178003		2002-11-28	Gehrke, James K. ; et al.	
	8	20040174914		2004-09-09	Fukatsu, Susumu	
	9	20040240037		2004-12-02	Harter, Donald J.	
	10	20050111500		2005-05-26	Harter, Donald J. ; et al.	
	11	20060245461		2006-11-02	Islam; Mohammed N.	
	12	20060268393		2006-11-30	Islam; Mohammed N.	
	13	20070078348		2007-04-05	Holman; Hoi-Ying N.	

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	Examiner Name	
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	14	20090028193		2009-01-29	Islam; Mohammed N.	
	15	20090204110		2009-08-13	Islam; Mohammed N.	

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	2	200227640	WO		2002-04-04	Whittington Charles Lynn et al.		☐
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	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
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Name/Print	David S. Bir	Registration Number	38383

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	1	6246896	B1	2001-06-12	DUMOULIN	
	2	6285897	B1	2001-09-04	KILCOYNE	
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	1	Pan, Yingtian, et al., "Hand-held arthroscopic optical coherence tomography for in vivo high-resolution imaging of articular cartilage", Journal of Biomedical Optics 8(4), October 2003, pages 648-654.	☐
	2	Xie, Tuqiang, et al., "Endoscopic optical coherence tomography with a modified microelectromechanical systems mirror for detection of bladder cancers", APPLIED OPTICS, Vol. 42, No. 31, November1, 2003, pages 6422-6426.	☐
	3	Dubois, A., et al., "Three-dimensional cellular-level imaging using full-field optical coherence tomography", Physics in Medicine and Biology, Phys. Med. Biol. 49, 2004, pages 1227-1234.	☐
	4	Park, Jesung, et al., "Analysis of birefringent image in the retinal nerve fiber layer by polarization sensitive optical coherence tomography", Ophthalmic Technologies XIV, Proceedings of SPIE, Vol. 5314, 2004, pages 188-194.	☐
	5	Unterhuber, A., et al., "Advances in broad bandwidth light sources for ultrahigh resolution optical coherence tomography", Physics in Medicine and Biology, Phys. Med. Biol. 49, 2004, pages 1235-1246.	☐
	6	Drexler, Wolfgang, "Ultrahigh-resolution optical coherence tomography", Journal of Biomedical Optics, Vol. 9, No. 1, January/February 2004, pages 47-74.	☐
	7	Schmitt, Joseph, et al., "Intravascular Optical Coherence Tomography Opens a Window Onto Coronary Artery Disease", Optics & Photonics News, February 2004, pages 20-25.	☐
	8	Nassif, N.A., et al., "In vivo high-resolution video-rate spectral-domain optical coherence tomography of the human retina and optic nerve", OPTICS EXPRESS, Vol. 12, No. 3, February 9, 2004, pages 367-376.	☐
	9	Choi, Seung-Ho, et al., "Observation of Optical Precursors in Water", Physical Review Letters, Volume 92, Number 19, May 14, 2004, pages 193903-1-193903-.3.	☐
	10	Pierce, Mark C., et al., "Advances in Optical Coherence Tomography imaging for Dermatology", Optical Coherence Tomography Advances, The Journal of Investigative Dermatology, September 3, 2004, pages 458-463.	☐
	11	"State-Specific Trends in Chronic Kidney Failure - United States, 1990-2001", Morbidity and Mortality Weekly Report, Department of Health and Human Services Centers for Disease Control and Prevention, Vol. 53, No. 39, copied from intemet: file://C:\Documents and Settings\eturlo\Desktop\State-Speciflc Trends in Chronic Kidney ... 2/12/10, October 8, 2004, pages 918-920.	☐

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	12	I.B. Ads, A.A.E. Wagie, N.B. Mariun, A.B.E. Jammal, "An Internet-based blood pressure monitoring system for patients," Journal of Telemedicine and Telecare, 2001, pp. 51-53	☐
	13	R.H. Istepanian, B. Woodward, P.A. Bales, S. Chen, B. Luk, "The comparative performance of mobile telemediCal systems based on the IS-54 and GSM cellular telephone standards," Journal of Telemedicine and Telecare, 1999, pp. 97-104	☐
	14	Shaw, et al, IR Supercontinuum Generation in As-Se Photonic Crystal Fiber, Optical Society of America, Copyright 2005, 3 pages	☐
	15	PCT/US06/44451, Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration, November 29, 2007, 12 pages	☐
	16	G.S. Edwards et al., "Free-electron-laser-based biophysical and biomedical instrumentation," American Institute of Physics, Vol. 74, No. 7, July 2003, pp. 3207-3245	☐
	17	Computer Motion, Inc., "501(k) Summary -ZEUS® MicroWrist™ Surgical System and Accessories," September 24, 2002, 6 pages	☐
	18	Computer Motion, Inc. "HERMES™ O.R. Control Center - 510(k) Summary of Safety and Effectiveness," October 11, 2002, 5 pages	☐
	19	K.M. Joos, et al. "Optic Nerve Sheath Fenestration with a Novel Wavelength Produced by the Free Electron Laser (FEL)," Lasers in Surgery and Medicine, 27: 2000,191-205	☐
	20	J. Sanghera, I. Aggarwal, "IR Fiber Optics at NRL," undated, 10 pages	☐
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	22	B. Rigas, P.T.T. Wong, "Human Colon Adenocarcinoma Cell Lines Display Infrared Spectroscopic Features," Cancer Research, January 1, 1992, pp. 84-88	☐

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	23	G. Edwards, et al., "Comparison of OPA and Mark-III FEL for Tissue Ablation at 6.45 Microns," Department of Physics and Free Electron Laser Laboratory, Duke University, 2002, 7 pages	☐
	24	Glenn Edwards, "Biomedical and potential clinical applications for pulsed lasers operating near 6.45 um," Society of Photo-Optical Instrumentation Engineers, 1995, 2 pages	☐
	25	PASSAT, "Solid-State Lasers and Optical Components," July 14, 2003, 5 pages	☐
	26	P.A. Thielen and L.B. Shaw, et al., "Small-core As-Se fiber for Raman amplification," OPTICS LETI-ERS, Vol. 28, No. 16, August 15, 2003, 3 pages	☐
	27	R.Rox Anderson, et al., "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation," Department of Dermatology, Harvard Medical School, Science, Vol. 220, April 29, 1983, 4 pages	☐
	28	U.S. Appln. Serial No. 10/652,276, "System and Method for Voice Control of Medical devices," by Mohammed N. Islam, abandoned (074036.0129) Date filed: August 29, 2003	☐
	29	U.S. Appln. Serial No. 10/757,341, "System and Method for Voice Control of Medical devices," by Mohammed N. Islam, issued (074036.0132) Date filed: January 13, 2004	☐
	30	U.S. Appln. Serial No. 12/206432, "System and Method for Voice Control of Medical Devices," by Mohammed N. Islam, pending (074036.0154) Date filed: September 8, 2008	☐
	31	U.S. Patent and Trademark Office, Office Action for USSN 12/206,432, filed 09/08/2008, Mohammed N, Islam, Attorney Docket No. 074036.0154, Date filed: March 12, 2009	☐
	32	U.S. Patent and Trademark Office, Notice of Allowance and Fee(s) Due for USSN 12/206,432, filed 09/08/2008, Mohammed N. Islam, Attorney Docket No. 074036.0154, Date filed: August 28, 2009	☐
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(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6181414		2001-01-30	Raz et al.	
	2	7105823		2006-09-12	Abrahamsson et al.	
	3	8472108		2013-06-25	Islam	

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	1	20060283931		2006-12-21	Polli et al.	
	2	20120239013		2012-09-20	Islam	
	3	20130274569		2013-10-17	Islam	

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	4	20140236021		2014-08-21	Islam	

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	1	"Application Brief AB-070: The role of infrared microprobe analysis in forensic drug analysis," www.smithsdetection.com, June 27, 2005.	☐
	2	Jasco Application Note No. 200DR0188-E, "Rapid Identification of illegal drug using NIR (identification of MDMA tablet)", September 4, 2008.	☐
	3	PALOU, A. J. CRUZ, M. BLANCO, J. TOMAS, J. DE LOS RIOS, M. ALCALA, "Determination of drug, excipients and coating distribution in pharmaceutical tablets using NIR-CI," Journal of Pharmaceutical Analysis, Vol. 2, no. 2, pp. 90-97 (2012).	☐
	4	ARNOLD, T., M. De BIASIO, R. LEITNER, "Near-Infrared Imaging Spectroscopy for Counterfeit Drug Detection," Next Generation Spectroscopic Technologies IV, edited by M. A. Druy, R.A. Crocombe, Proceedings of SPIE, Vol. 8032, 80320Y-1 to 7, (2011).	☐
	5	WEDDING, B.B., C. WRIGHT, S. GRAUF, R.D. WHITE, "The application of near infrared spectroscopy for the assessment of avocado quality attributes," Infrared Spectroscopy -- Life and Biomedical Sciences, pp. 211-230 (2011).	☐

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	6	MICHAELS, C.A., T. MASIELLO, P.M. CHU, "Fourier transform spectrometry with a near infrared supercontinuum source," Optical Society of America, CLEO/IQEC Conference, paper CMDD6 (2009).	☐
	7	MICHAELS, C.A., T. MASIELLO, P.M. CHU, "Fourier transform spectrometry with a near-infrared supercontinuum source," Applied Spectroscopy, Vol. 63, no. 5, pp. 538-543 (2009).	☐
	8	MOROS,J., J. KULIGOWSKI, G. QUINTAS, S. GARRIGUES, M. DeLa GUARDIA, "New cut-off criterion for uninformative variable elimination in multivariate calibration of near-infrared spectra for the determination of heroin in illicit street drugs," Analytica Chimica Acta, Vol. 630, pp. 150-160 (2008).	☐
	9	MOROS, J. N. GALLPIENSO, R. VILCHES, S. GARRIGUES, M. DeLa GUARDIA, "Nondestructive direct determination of heroin in seized illicit street drugs by diffuse reflectance near-infrared spectroscopy," Analytical Chemistry, Vol. 80, no. 19, pp. 7257-7265 (October 1, 2008).	☐
	10	ROGGO, Y. P. CHALUS, L. MAURER, C. LEMA-MARTINEZ, A. EDMOND, N. JENT, "A review of near infrared spectroscopy and chemometrics in pharmaceutical technologies," Journal of Pharmaceutical and Biomedical Analysis, Vol. 44, pp. 683-700 (2007).	☐
	11	POJIC, M. J. MASTILOVIC, N. MAJCEN, "The application of near infrared spectroscopy in wheat quality control," Infrared Spectroscopy - Life and Biomedical Sciences, pp. 167-184 (2012).	☐
	12	REICH, G. "Near-infrared spectroscopy and imaging: basic principles and pharmaceutical applications," Advanced Drug Delivery Reviews, vol. 57, pp. 1109-1143 (2005).	☐
	13	RODIONOVA, O.Y., L.P. HOUMOLLER, A.L. POMERANTSEV, P. GELADI, J. BURGER, V.L. DOROFEYEV, A.P. ARZAMASTSEV, "NIR spectrometry for counterfeit drug detection: a feasibility study," Analytica Chimica Acta, vol. 549, pp. 151-158 (2005).	☐
	14	SCHNEIDER, R.C., K.A. KOVAR, "Analysis of ecstasy tablets: comparison of reflectance and transmittance near infrared spectroscopy," Forensic Science International, vol. 134, pp. 187-195 (2003).	☐
	15	OLSEN, B.A., M.W. BORER, F.M. PERRY, R.A. FORBES, "Screening for counterfeit drugs using near-infrared spectroscopy," Pharmaceutical Technology, pp. 62-71 (June 2002).	☐
	16	SCAFI, S.H.F., C. PASQUINI, "Identification of counterfeit drugs using near-infrared spectroscopy," Analyst, vol. 126, pp. 2218-2224 (2001).	☐

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	17	SONDERMANN, N., K.A. KOVAR, "Identification of ecstasy in complex matrices using near-infrared spectroscopy," Forensic Science International, vol. 102, pp. 133-147 (1999).	☐
	18	RAMBLA, F.J., S. GARRIGUES, M. DeLa GUARDIA, "PLS-NIR determination of total sugar, glucose, fructose and sucrose in aqueous solutions of fruit juices," Analytica Chimica Acta, vol. 344, pp. 41-53 (1997).	☐

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☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

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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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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Attorney Docket Number	POWM 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8157730	B2	2012-04-17	LeBoeuf, et al.	
	2	8430310	B1	2013-04-30	Ho, et al.	
	3	8509882	B2	2013-08-13	Albert, et al.	
	4	8788002	B2	2014-07-22	LeBoeuf, et al.	
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	1	20080086318	A1	2008-04-10	Gilley, et al.	

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	2	20090287067	A1	2009-11-19	Dorogusker, et al.	
	3	20130281795	A1	2013-10-24	Varadan	
	4	20140081100	A1	2014-03-20	Muhsin, et al.	
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	1	WO2013012938		A1	2013-01-24	Raskin, et al.		☐
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SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Serial No. 14/108,986 filed December 17, 2013, which claims the benefit of U.S. provisional application Serial No. 61/747,487 filed December 31, 2012, the disclosures of which are hereby incorporated in their entirety by reference herein.

[0002] This application is related to U.S. provisional applications Serial Nos. 61/747,477 filed December 31, 2012; Serial No. 61/747,481 filed December 31, 2012; Serial No. 61/747,485 filed December 31, 2012; Serial No. 61/747,472 filed December 31, 2012; Serial No. 61/747,492 filed December 31, 2012; Serial No. 61/747,553 filed December 31, 2012; and Serial No. 61/754,698 filed January 21, 2013, the disclosures of which are hereby incorporated in their entirety by reference herein.

[0003] This application is also related to International Application No. PCT/US2013/075700 (Publication No. WO/2014/105520) entitled Near-Infrared Lasers For Non-Invasive Monitoring Of Glucose, Ketones, HBA1C, And Other Blood Constituents; International Application PCT/US2013/075736 (Publication No. WO/2014/105521) entitled Short-Wave Infrared Super-Continuum Lasers For Early Detection Of Dental Caries; U.S. Application 14/108,995 (Publication No. 2014/0188092) entitled Focused Near-Infrared Lasers For Non-Invasive Vasectomy And Other Thermal Coagulation Or Occlusion Procedures; International Application PCT/US2013/075767 (Publication No. WO/2014/143276) entitled Short-Wave Infrared Super-Continuum Lasers For Natural Gas Leak Detection, Exploration, And Other Active Remote Sensing Applications; U.S. Application 14/108,974 (Publication No. 2014/0188094) entitled Non-Invasive Treatment Of Varicose Veins; and U.S. Application 14/109,007 (Publication No. 2014/0236021) entitled Near-Infrared Super-Continuum Lasers For Early Detection Of Breast And Other Cancers, the disclosures of which are hereby incorporated in their entirety by reference herein.

BACKGROUND AND SUMMARY

[0004] 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.

[0005] 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.

[0006] 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.

[0007] In one embodiment, a measurement system includes a light source configured to generate an output optical beam comprising one or more semiconductor sources configured to generate an input beam, one or more optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the one or more optical amplifiers, and one or more optical fibers configured to receive at least a portion of the intermediate beam and to deliver at least the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam. A nonlinear element is configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum, wherein at least a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 1400 nanometers and approximately 2500 nanometers, and wherein at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample for a non-destructive and non-contact measurement, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample. A receiver is configured to receive at least a portion of the spectroscopy output beam having a bandwidth of at least 10 nanometers and to process the portion of the spectroscopy output beam to generate an output signal, and wherein at least a part of the delivered portion of the output optical beam is at least partially transmitting through a packaging material covering at least a part of the sample, and wherein the output signal is based on a chemical composition of the sample.

[0008] In another embodiment, a measurement system includes a light source configured to generate an output optical beam comprising a plurality of semiconductor sources configured to generate an input optical beam, a multiplexer configured to receive at least a portion of the input optical beam and to form an intermediate optical beam, and one or more fibers configured to receive at least a portion of the intermediate optical beam and to form the output optical beam, wherein the output optical beam comprises one or more optical wavelengths. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample. A receiver is configured to receive at least a portion of the spectroscopy output beam and to process the portion of the spectroscopy output beam to generate an output signal, wherein the receiver comprises a Fourier transform infrared (FTIR) spectrometer or a dispersive spectrometer, and wherein at least a part of the delivered portion of the output optical beam is at least partially transmitting through a packaging material covering at least a part of the sample.

[0009] In yet another embodiment, a method of measuring includes generating an output optical beam comprising generating an input optical beam from a plurality of semiconductor sources, multiplexing at least a portion of the input optical beam and forming an intermediate optical beam, and guiding at least a portion of the intermediate optical beam and forming the output optical beam, wherein the output optical beam comprises one or more optical wavelengths. The method may also include receiving a received portion of the output optical beam and delivering a delivered portion of the output optical beam to a sample, wherein the sample comprises an organic compound with an overtone or combinational absorption band in the wavelength range between approximately 1 micron and approximately 2.5 microns. The method may further include generating a spectroscopy output beam having a bandwidth of at least 10 nanometers from the sample using a Fourier transform infrared (FTIR) spectrometer or a dispersive spectrometer, receiving at least a portion of the spectroscopy output beam, and processing the portion of the spectroscopy output beam and generating an output signal.

[0010] With the growing obesity epidemic, the number of individuals with diabetes is 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.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] In various embodiments, a measurement system includes a light source configured to generate an output optical beam that includes one or more semiconductor sources configured to generate an input beam, one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers; and one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam. The light source may also include a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum. The at least a portion of the output beam broadened spectrum comprises a near-infrared wavelength between approximately 700nm and approximately 2500nm, and at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns. The system may also include a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam, and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample having a bandwidth of at least 10 nanometers and to generate an output signal. In addition, a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen may be configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.

[0015] In another embodiment, a measurement system includes a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more

optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam; and a receiver is configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link, and a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

[0016] Other embodiments may include a measurement system comprising a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. The wearable measurement device is configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam. The wearable measurement device further comprises a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system also includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link and a remote device configured to receive over the

wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] 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:

[0018] FIGURE 1 shows the absorbance for two common plastics, polyethylene and polystyrene.

[0019] FIGURE 2 illustrates one example of the difference in near-infrared spectrum between an authentic tablet and a counterfeit tablet.

[0020] FIGURE 3 shows the second derivative of the spectral comparison of Prozac and a similarly formulated generic.

[0021] FIGURE 4 illustrates an example of the near infrared spectra for different pure components of a studied drug.

[0022] FIGURE 5 shows the mid-wave infrared and long-wave infrared absorption spectra for various illicit drugs.

[0023] FIGURE 6 shows the absorbance versus wavelength in the near-infrared region for four classes of illegal drugs.

[0024] FIGURE 7 illustrates the diffuse reflectance near-infrared spectrum of heroin samples.

[0025] FIGURE 8 illustrates the diffuse reflectance near-infrared spectra of different seized illicit drugs containing heroin of different concentrations, along with the spectrum for pure heroin.

[0026] FIGURE 9 lists possible band assignments for the various spectral features in pure heroin.

[0027] FIGURE 10 shows the diffuse reflectance near-infrared spectra of different compounds that may be frequently employed as cutting agents.

[0028] FIGURE 11 provides one example of a flow-chart in the process analytical technology for the pharmaceutical industry.

[0029] FIGURE 12 illustrates the typical near-infrared spectra of a variety of excipients.

[0030] FIGURE 13 exemplifies the absorbance from the blending process of a pharmaceutical compound.

[0031] FIGURE 14 shows what might be an eventual flow-chart of a smart manufacturing process.

[0032] FIGURE 15A illustrates the near-infrared reflectance spectrum of wheat flour.

[0033] FIGURE 15B shows the near-infrared absorbance spectra obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit.

[0034] FIGURE 16A is a schematic diagram of the basic elements of an imaging spectrometer.

[0035] FIGURE 16B illustrates one example of a typical imaging spectrometer used in hyper-spectral imaging systems.

[0036] FIGURE 17 shows one example of the Fourier transform infrared spectrometer.

[0037] FIGURE 18 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.

[0038] FIGURE 19 illustrates a block diagram or building blocks for constructing high power laser diode assemblies.

[0039] FIGURE 20 shows a platform architecture for different wavelength ranges for an all-fiber-integrated, high powered, super-continuum light source.

[0040] FIGURE 21 illustrates one embodiment for a short-wave infrared super-continuum light source.

[0041] FIGURE 22 shows the output spectrum from the SWIR SC laser of FIGURE 21 when about a 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.

[0042] 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).

[0043] FIGURE 24 schematically shows a medical measurement device as 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.

DETAILED DESCRIPTION

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

IDENTIFICATION OF COUNTERFEIT DRUGS

[0055] 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."

[0056] 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.

[0057] 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.

[0058] 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 1 illustrates the absorbance 100 for two common plastics: polyethylene 101 and polystyrene 102. 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.

[0059] 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.

[0060] FIGURE 2 illustrates one example of the difference in near-infrared spectrum 200 between an authentic tablet and a counterfeit tablet. Two grades of film coated tablets comprising drugs were investigated: curve 201 is the genuine drug, while 202 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.

[0061] 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 3 shows the second derivative 300 of the spectral comparison of Prozac 301 and a similarly formulated generic 302, 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.

[0062] 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.

[0063] FIGURE 4 shows an example of the near-infrared spectra 400 for different pure components of a studied drug. The spectrum for the active pharmaceutical ingredient (API) 401 is plotted, along with the spectra for five different excipients 402, 403, 404, 405 and 406. 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 4 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.

RAPID SCREENING FOR ILLICIT DRUGS

[0064] Thus, FIGURES 2-4 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 5 shows the mid-wave infrared and long-wave infrared absorption spectra 500 for various illicit drugs. The absorbance for cocaine 501, methamphetamine 502, MDMA (ecstasy) 503, and heroin 504 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.

[0065] 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 6 illustrates the absorbance 600 versus wavelength in the near-infrared region for four classes of illegal drugs. In particular, the spectra are shown for methamphetamine (MA) 601, amphetamine (AP) 602, MDMA (street name: ecstasy) 603, and MDA (street name: the love drug) 604. Each of the illegal drugs have unique spectral features in the near-infrared and SWIR. Also, comparing the mid-infrared spectrum for MDMA (503 in FIGURE 5) with the near-infrared spectrum for MDMA (603 in FIGURE 6), it seems clear that the near-infrared region shows overtones and combination bands that should be discernible. Referring to FIGURE 6, 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.

[0066] In another embodiment, FIGURE 7 shows the diffuse reflectance near-infrared spectrum 700 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, 701 is the near-infrared spectrum for an illicit street drug sample, while 702 is the spectra for a pure heroin

standard. The difference between the spectra may arise at least in part from cutting agents. The inset 703 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 504 in FIGURE 5). 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.

[0067] 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 8 illustrates the diffuse reflectance near-infrared spectra 800 of different seized illicit drugs containing heroin (between 10.7 and 21.8%) compared with the spectrum of pure heroin 801. Curve 802 is for 21.8% by weight, curve 803 is 13.2% by weight, curve 804 is 17% by weight, and curve 805 is 10.7% by weight of heroin. The spectra have been shifted along the vertical axis to better illustrate the differences.

[0068] Although quite complex in the near-infrared, it may be possible to identify from the pure heroin near-infrared spectrum (801 in FIGURE 8 or 702 in FIGURE 7) the main wavelengths related to the most common functional groups in heroin. For example, FIGURE 9 lists possible band assignments 900 for the various spectral features in pure heroin. As can be seen from FIGURE 9,

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.

[0069] As can be appreciated from FIGURE 8, 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 10 illustrates the diffuse reflectance near-infrared spectra 1000 of different compounds that may be frequently employed as cutting agents. In the bottom of FIGURE 10 are shown the spectra 1008 for pure heroin and the spectra 1007 for a seized illicit street drug sample comprising 21.8% of heroin. The spectra for various cutting agents include: 1001 for flour, 1002 for talcum powder, 1003 for chalk, 1004 for acetylsalicylic acid, 1005 for caffeine, and 1006 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.

PROCESS ANALYTICAL TECHNOLOGY (PAT)

[0070] 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.

[0071] FIGURE 11 shows one example of a flow-chart 1100 in the PAT for the pharmaceutical industry. While the center shows the steps of the manufacturing process 1101, the top and bottom sides show where near-infrared spectroscopy could be applicable for lab use 1102 (top) or in process monitoring control 1103 (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.

[0072] 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 12 illustrates the typical near-infrared spectra 1200 for a variety of excipients. Included in the graph 1200 are spectra for: magnesium stearate 1201, sorbitol 1202, mannitol 1203, talc 1204, lactose 1205, starch 1206, maltodextrin 1207, and microcrystalline cellulose 1208. 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.

[0073] 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 13 exemplifies the absorbance 1300 from the blending process. Although the initial spectra 1301 shows differences from the eventual spectra, as the process continues the blend converges to the final spectra 1302 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 1300.

[0074] 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.

[0075] FIGURE 14 illustrates what might be an eventual flow-chart 1400 of a smart manufacturing process. The manufacturing process 1401 may have as input the process feed 1402 and result in a process output 1403. A process controller 1404 may at least partially control the manufacturing process 1401, and the controller 1404 may receive inputs from the closed loop control (process parameters) 1405 as well as the on-line monitoring of process parameters 1406. The feedback loops in the process could refine the manufacturing process 1401 and improve the quality of the process output 1403. 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.

[0076] 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.

[0077] 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 15A illustrates the near-infrared reflectance spectrum 1500 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 1500 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.

[0078] 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 15B shows the near-infrared absorbance spectra 1550 obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit. Four oil absorption bands are near 2200-2400nm (CH_2 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.

DETECTION SYSTEMS

[0079] 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.

[0080] 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.

[0081] 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.

[0082] In another embodiment, an imaging spectrometer may be used to detect the light received from the sample. For example, FIGURE 16A shows a schematic diagram 1600 of the basic elements of an imaging spectrometer. The input light 1601 from the sample may first be directed by a scanning mirror and/or other optics 1602. An optical dispersing element 1603, 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 1604 onto one or more detectors or detector arrays 1605. Some sensors may use multiple detector arrays to measure hundreds of narrow wavelength bands.

[0083] An example of a typical imaging spectrometer 1650 used in hyper-spectral imaging systems is illustrated in FIGURE 16B. In this particular embodiment, the input light may be directed first by a tunable mirror 1651. A front lens 1652 may be placed before the entrance slit 1653 and the collector lens 1654. In this embodiment, the dispersing element is a holographic grating with a prism 1655, which separates the different wavelength bands. Then, a camera lens 1656 may be used to image the wavelengths onto a detector or camera 1657.

[0084] FIGURES 16 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 16.

[0085] 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.

[0086] FIGURE 17 illustrates one example of the FTIR spectrometer 1700. Light from the near-infrared or SWIR light source 1701 may be collimated and directed to a beam splitter 1702. In one embodiment, the beam splitter 1702 may be a 50:50 beam splitter. One portion of the beam 1703 may be reflected toward a stationary mirror 1704, while the other portion of the beam 1705 may be transmitted towards a moving mirror 1706. Light may be reflected from the two mirrors 1704, 1706 back to the beam splitter 1702, and then a portion of the recombined beam 1707 may be directed toward the sample 1708. The recombined beam 1707 may be focused onto the sample 1708, in one embodiment. On leaving the sample 1708, the light may be refocused or at least collected at a detector 1709. A background interferogram may be obtained by using the set-up 1700 without a sample in the chamber 1708. When a sample is inserted into 1708, 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 1701. The configuration 1700 is one

example of an FTIR, but other configurations may also be used, and these are also intended to be covered by this disclosure.

[0087] In yet another example of multi-beam detection systems, a dual-beam set-up 1800 such as in FIGURE 18 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 1801 may be collimated using a CaF_2 lens 1802 and then focused into the entrance slit of the monochromator 1803. At the exit slit, light at the selected wavelength is collimated again and may be passed through a polarizer 1804 before being incident on a calcium fluoride beam splitter 1805. After passing through the beam splitter 1805, the light is split into a sample 1806 and reference 1807 arm to enable ratiometric detection that may cancel out effects of intensity fluctuations in the SC source 1801. The light in the sample arm 1806 passes through the sample of interest and is then focused onto a HgCdTe detector 1808 connected to a pre-amp. A chopper 1802 and lock-in amplifier 1810 setup enable low noise detection of the sample arm signal. The light in the reference arm 1807 passes through an empty container (cuvette, gas cell etc.) of the same kind as used in the sample arm. A substantially identical detector 1809, pre-amp and lock-in amplifier 1810 is used for detection of the reference arm signal. The signal may then be analyzed using a computer system 1811. 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.

[0088] 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 18 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.

LIGHT SOURCES FOR SWIR AND NEAR INFRARED

[0089] 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 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. The SWIR corresponds to a transmission window through water and the atmosphere. Also, the so-called "eye-safe" wavelengths are wavelengths longer than approximately 1400nm as previously described.

[0090] 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.

[0091] 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 due to the low power levels. Also, the lamp based sources tend to be energy inefficient.

[0092] 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.

[0093] 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. 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.

[0094] 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 5nm to 100nm wide, preferably in the 60nm 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 that cover a broader region of the SWIR.

[0095] 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. FIGURE 19 shows an example block diagram 1900 with 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.

[0096] The brightness may be increased by spatially combining the beams from multiple stacks 1903. The combiner may include spatial interleaving, wavelength multiplexing, or 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 a particular 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 diameters of approximately 100 microns 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.

SWIR SUPER-CONTINUUM LASERS

[0097] 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.

[0098] 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 recently, 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.

[0099] 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 (DFB) laser diode with a wavelength near 1542nm or 1550 nm, with approximately 0.5–2.0ns pulsed output, and with a pulse repetition rate between one 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 a particular 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.

[0100] The SC generation 2007 may occur in the relatively short lengths of fiber that follow the pump laser. Exemplary SC fiber lengths 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 occurs primarily, followed by a second fiber 2009 where the SC generation and spectral broadening occurs primarily.

[0101] 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 anomalous 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 0.5ps 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.

[0102] 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.

[0103] 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 1550nm), or thulium-doped fibers (near 2000nm). In various embodiments, candidates for SC fiber 2009 include fused silica fibers (for generating SC between 0.8–2.7μm), mid-IR fibers such as fluorides, chalcogenides, or tellurites (for generating SC out to 4.5μm or longer), photonic crystal fibers (for generating SC between 0.4-1.7μm), 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.

[0104] 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.

[0105] In one embodiment, one example of the SC laser that operates in the SWIR is illustrated in FIGURE 21. This SWIR SC source 2100 produces an output of up to approximately 5W over a spectral range of about 1.5-2.4 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 0.5nsec 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 laser diode near 940nm 2105 that is coupled in using a fiber combiner 2104.

[0106] 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 an approximately 4m length of the 12/130 micron erbium/ytterbium doped fiber 2111 that is counter-propagating pumped using one or more 30W laser diodes near 940nm 2112 coupled in through a combiner 2113. An approximately 1-2m 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.

[0107] 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 about 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 around 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.

[0108] 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 1060nm and 1800nm. For this embodiment, the seed laser 2101 may be a distributed feedback laser diode around 1064nm, 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 laser diode near 915nm. A mode field adapter may be included in the mid-stage, 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 an about 20m length of ytterbium-doped fiber with 25/400 microns dimension. The pump 2112 for the power amplifier may be up to six pump diodes providing 30W each near 915nm. For this much pump power, the output power in the SC may be as high as 50W or more.

[0109] In one 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.

[0110] In one embodiment, the top of FIGURE 23 illustrates an exemplary block diagram for an SC source 2300 capable of generating light between approximately 1400nm 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 1542nm 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.

[0111] In yet another embodiment, the bottom of FIGURE 23 illustrates a block diagram for an exemplary SC source 2350 capable of generating light between approximately 1900nm 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 1542nm 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 1542nm, 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 5m and 50m, 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, 21,and 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.

[0112] FIGURES 20, 21 and 23 are examples of SC light sources that may advantageously be used for near-infrared or SWIR light generation in various spectroscopy, active remote sensing and hyper-spectral imaging 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.

[0113] Even within the all-fiber versions illustrated such as in FIGURE 21, different configurations could be used consistent with the disclosure. In one 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 near-infrared or SWIR light that are intended to be covered by this disclosure.

[0114] 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.

WIRELESS LINK TO THE CLOUD

[0115] 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.

[0116] In a particular embodiment 2400 illustrated in Figure 24, 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.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] Although the present disclosure has been described in several embodiments, a myriad of changes, variations, alterations, transformations, and modifications may be suggested to one skilled in the art, and it is intended that the present disclosure encompass such changes, variations, alterations, transformations, and modifications as falling within the spirit and scope of the appended claims.

[0123] 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. A measurement system comprising:

a light source configured to generate an output optical beam, comprising:

one or more semiconductor sources configured to generate an input beam;

one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers; and

one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam;

a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum; and

wherein at least a portion of the output beam broadened spectrum comprises a near-infrared wavelength between approximately 700nm and approximately 2500nm, and wherein at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns;

a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam;

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample having a bandwidth of at least 10 nanometers and to generate an output signal; and

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the

personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.

2. The system of Claim 1, wherein the personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor-based device.

3. The system of Claim 1, wherein the output signal comprises one or more physiological parameters.

4. The system of Claim 1, further comprising a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

5. A measurement system comprising:

a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;

a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam; and

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a

portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

6. The system of Claim 5, wherein the semiconductor sources are light emitting diodes operating in pulsed mode.

7. The system of Claim 5, wherein the wireless transmission link is configured to operate at least in part on Bluetooth or WiFi.

8. The system of Claim 5, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data.

9. The system of Claim 5, wherein the personal device is a separate device from the measurement apparatus and the light source.

10. The system of Claim 5, wherein the output signal comprises one or more physiological parameters, and the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time.

11. The system of Claim 10, wherein the remote device is capable of generating an alarm when at least one of the one or more physiological parameters falls out of an acceptable range.

12. The system of Claim 5, wherein the personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor-based device.

13. The system of Claim 5, wherein the measurement system is capable of performing a non-invasive blood measurement.

14. A measurement system comprising:

a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;

the wearable measurement device configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam;

the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link;

a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

15. The system of Claim 14, wherein the semiconductor sources are light emitting diodes operating in pulsed mode.

16. The system of Claim 14, wherein the personal device is a separate device from the wearable measurement device.

17. The system of Claim 14, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data.

18. The system of Claim 14, wherein the remote device is capable of generating an alarm when at least one of the one or more physiological parameters falls out of an acceptable range.

19. The system of Claim 14, wherein the measurement system is capable of performing a non-invasive blood measurement.

20. The system of Claim 14, wherein the personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor-based device.

ABSTRACT

A measurement system includes a light source generating an output optical beam using semiconductor sources generating an input beam, optical amplifiers outputting an intermediate beam, and optical fibers receiving the intermediate beam and forming a first optical beam. A nonlinear element broadens the output beam spectrum to at least 10nm, the spectrum comprising a near-infrared wavelength of 700-2500nm. A measurement apparatus receives the output optical beam and delivers to a sample an analysis output beam. A receiver receives and processes the analysis output beam reflected or transmitted from the sample.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. ISLAM
Filer:	David S. Bir/Pamela Demos
Attorney Docket Number:	OMNI 0105 PUSP1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	70	70
Utility Search Fee	2111	1	300	300
Utility Examination Fee	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
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First Named Inventor/Applicant Name:	Mohammed N. ISLAM
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Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	AssignmentDeclaration.pdf	90610 f1093ab5bdca4392cc78c17c168d7534ae720ff5	no	1
Warnings:					
Information:					
2	Foreign Reference	WO2013012938A1.pdf	1524053 33f291e44365e56db1cfbb9ce04e57dee0e0fdfb	no	35
Warnings:					
Information:					
3	Foreign Reference	WO2015084376A1.pdf	1500669 4cd6ddf8cdf5ead44488e07b7b0ed3fdc38b311c	no	35
Warnings:					
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4	Application Data Sheet	ADS.pdf	1505257 c6b04c62215e3d0067fd06c1ec7d08449d7d6da8	no	6
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5	Power of Attorney	POA.pdf	211428 300c99d100eb68df2bc1da87a77b5a33c5c264af	no	2
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7	Transmittal Letter	IDS_Transmittal.pdf	19796 3a9437b0d23325141071f9d3b8cd36d9e474f7c6	no	2
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19		Continuation_Application.pdf	254705 b71b510fb1b0e62e7d2cf112701c53bfed1717dc	yes	47

Multipart Description/PDF files in .zip description

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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.

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Attorney Docket Number	OMNI0105PUSP

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	**SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL**

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 _____ filed on _____. (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, Michigan 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.

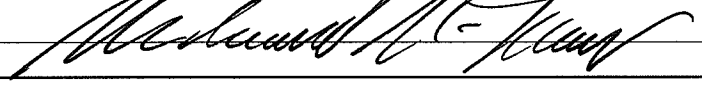
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LEGAL NAME OF INVENTOR

Inventor: MOHAMMED N. ISLAM Date: 12/17/2013

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.

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(54) Title: HEALTH METER

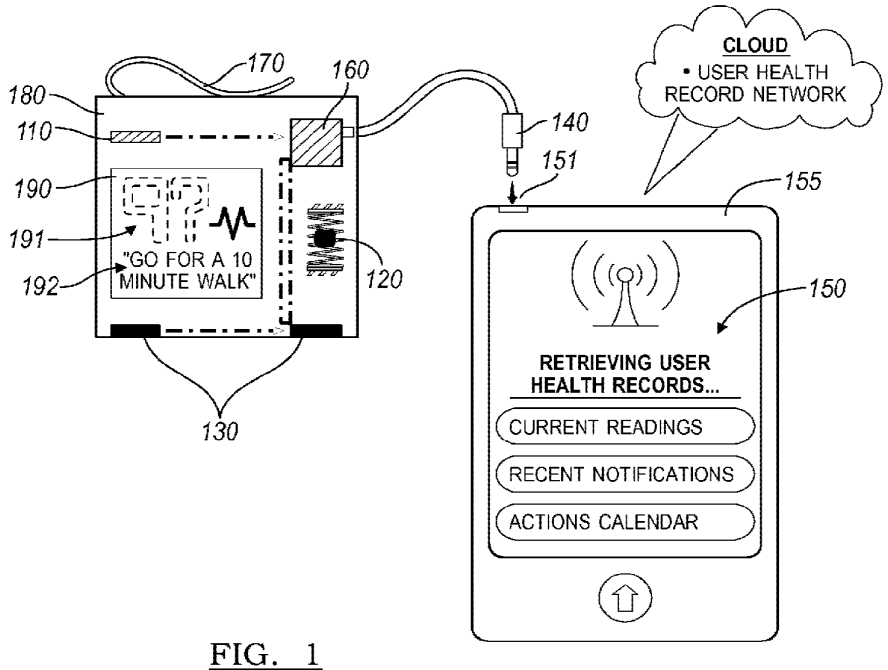


FIG. 1

(57) Abstract: One variation of a preferred health meter includes: a housing configured to be worn by a user; a glucose meter coupled to the housing; a pedometer coupled to the housing; a processor arranged within the housing and configured to generate a directive for a user action in response to a measured glucose level and an output of the pedometer; and a display arranged within the housing and configured to display the directive for the user.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

HEALTH METER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/509,075, filed 18 JUL 2011, U.S. Provisional Application No. 61/527,730, filed 26 AUG 2011, and U.S. Provisional Application No. 61/531,858, filed 07 SEP 2011, all of which are incorporated in their entirety by this reference.

TECHNICAL FIELD

[0002] This invention relates generally to the health care field, and more specifically to a new and useful health meter in the health care field.

BACKGROUND

[0003] Blood glucose meters are commonly used, particularly by individuals diagnosed with diabetes, to monitor glucose levels in the blood stream. Conventional blood glucose meters typically measure blood glucose levels in users and provide analyses of blood samples to users, but conventionally blood glucose meters fail to convey such information in valuable ways that are tailored to the needs of each user and that promote health improvements rather than just health maintenance. Thus, there is a need in the health care field for a new and useful health meter for testing the blood glucose level of a user.

BRIEF DESCRIPTION OF THE FIGURES

[0004] FIGURE 1 is a schematic representation of a health meter of a preferred embodiment;

[0005] FIGURE 2 is a schematic representation of a variation of the preferred health meter;

[0006] FIGURE 3 is a flowchart representation of one variation in accordance with the preferred health meter;

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[0007] FIGURE 4 is a flowchart representation of one variation in accordance with the preferred health meter; and

[0008] FIGURE 5 is a schematic representation of a variation of the preferred health meter.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0009] The following description of the preferred embodiments of the invention is not intended to limit the invention to these preferred embodiments, but rather to enable any person skilled in the art to make and use this invention.

1. Health Meter

[0010] As shown in FIGURES 1 and 2, the health meter 100 of the preferred embodiment for providing a health-related notification to a user includes: a blood glucose meter 110 that generates an output based upon the level of glucose in the blood of the user; a pedometer 120 that detects a footstep taken by the user and generates an output based upon the detected footstep; a heart rate monitor 130 that detects the heart rate of the user and generates an output based upon the heart rate of the user; a data link 140 that conveys the output of at least one of the blood glucose meter 110, pedometer 120, and heart rate monitor 130 to a digital multimedia device 155; a software module 150 that evaluates the output of at least one of the blood glucose meter 110, pedometer 120, and heart rate monitor 130 and generates a health report of the user based upon the evaluation; and a processor 160 that accesses the health report and controls the conveyance of the health-related notification 192, based upon the health report, to the user. The preferred health meter 100 may further include a clip 170 and a housing 180. The preferred health meter 100 may also include a display 190 that renders a form of the health-related notification 192. Finally, the preferred health meter 100 may further include a data storage device that stores the health report such that the processor 160 may access the health report and convey the health-related notification 192 to the user when the data link 140 is not in communication with the digital multimedia device 155.

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[0011] The preferred health meter 100 preferably captures current biological and/or physiological metrics of the user to enable generation of directives for the user to improve the current and/or long-term health of the user. The preferred health meter 100 preferably interfaces with a digital multimedia device 155, via the data link 140, to analyze user physiological data, to display the directive, and/or to track and maintain user physiological data over time. The digital multimedia device 155 is preferably a cellular phone, a smartphone, a tablet, a desktop computer, or a laptop computer, though the digital multimedia device 155 may be any other suitable external electronic device. The preferred health meter 100 may additionally or alternatively communicate with a remote server, such as through the digital multimedia device 155 connected via the data link 140, to enable these or any additional functions.

[0012] The blood glucose meter 110 of the preferred health meter 100 functions to analyze the blood of the user and to generate an output based upon the analysis of the blood. In a first example implementation, the blood glucose meter 110 includes a glucose test strip slot configured to receive a test strip, as shown in FIGURE 1. In this example implementation, the user may dispense a blood sample onto the glucose test strip, such as by pricking a finger to induce the finger to bleed, then swiping blood from the finger onto the glucose test strip. The user may then insert the glucose test strip into the glucose test strip slot of the blood glucose meter 110, at which point the blood glucose meter 110 analyzes the blood sample, determines the glucose level in the blood sample, and then generates the output. In another example implementation, as shown in FIGURE 2, the blood glucose meter includes a recess configured to receive a finger of the user and a spike configured to prick the finger. In this example implementation, the user may insert a finger into the recess, wherein the spike pierces the skin of the finger to obtain a blood sample. The blood glucose meter 110 may then analyze the blood sample. In this example implementation, the user may activate the spike, such as by engaging a button, switch, or lever. Alternatively, the processor 160 may activate the spike, such as by triggering a linear actuator or solenoid.

[0013] In another example implementation shown in FIGURE 2, the blood glucose meter 110 is a bloodless glucose meter. For example, the blood glucose meter

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110 may be an infrared glucose meter including an optical emitter and an optical receiver and implementing near-infrared spectroscopy to estimate the level of glucose in the blood of the user, such as disclosed in U.S. Patent No. 7,310,542, issued 18 DEC 2007 and which is incorporated herein in its entirety by this reference. Alternatively, the blood glucose meter 110 may use acoustic waves to analyze the glucose level in the blood under the skin. In this example implementation, the blood glucose meter 110 preferably analyzes intracorporeal blood under the skin of the finger, though the blood glucose meter 100 may additionally or alternatively analyze intracorporeal or intravascular blood under the skin of the palm, forearm, neck, or any other part of the body of the user. In this example implementation, the blood glucose meter 100 preferably measures the glucose level of the user whenever the user contacts the blood glucose meter for any suitable period of time, such as when the user attaches the housing to an article of clothing. In a further example implementation, the blood glucose meter 110 includes a first element that is a glucose sensor placed substantially beneath the skin of the user and in communication with a second element that analyzes the blood sensed by the first element. The communication link between the first and second elements of this fourth example may be a wired connection or a wireless connection, such as a Bluetooth connection. In this fourth example implementation, the blood glucose meter 110 may be a continuous blood glucose meter that measures the glucose level in the blood of the user at specified intervals (i.e. every five minutes). However, the blood glucose meter 110 may access a blood sample by any other method and estimate the glucose level in the blood of the user in any other way.

[0014] The blood glucose meter 110 may be activated directly by any number of inputs or actions. For example, insertion of a glucose test strip into a test strip slot of the blood glucose meter 110 may initiate the process of analyzing the blood sample and generating the output based upon the glucose in the blood sample. In this example, the insertion of the blood glucose test strip (or any other step of acquiring a blood sample, such as the first and second examples above) may activate the blood glucose meter 110 and may further activate one or more other elements of the heath meter, such as the data link 140 to transmit and/or receive data, the software module 150 to analyze the

output of the blood glucose meter 110, or the processor 160 to convey a message to the user. Alternatively, the blood glucose meter 110 may be a passive element or indirectly activated such that the function of the blood glucose meter 110 is initiated by another element of the preferred health meter 100, such as by the processor 160 when the processor 160 receives a notification from an digital multimedia device 155 (e.g., a computer executing a native health maintenance application) indicating that the user should take test blood glucose. In this example, the processor 160 may control the blood glucose meter 110 such that the processor 160 sends commands to the blood glucose meter 110 and receives data from the blood glucose meter 110 based upon those commands. The processor 160 may further analyze the data to generate the directive that is based upon the blood glucose level. The processor 160 may further transmit the directive to a digital multimedia device 155 when connected via the data link 140. The directive is preferably related to the glucose level in the blood of the user but may also be related to additional information such as white blood cell count or cholesterol level of the user, any of which may be input by the user, received from the digital multimedia device 155, or measured by an additional biological or physiological sensor. The blood glucose meter 110, however, may function in any other way and may be activated by any other device or element to measure glucose level in the blood of the user.

[0015] The pedometer 120 of the preferred health meter 100 preferably detects a footstep taken by the user and generates an output based upon the detected footsteps. In a first example implementation, the pedometer 120 includes an accelerometer, such as a mass-spring accelerometer, a piezoelectric accelerometer, a null-balance accelerometer, a shear mode accelerometer, or any other type of accelerometer, wherein the pedometer associates an output of the accelerometer with a footstep taken by the user. In a second example implementation, the pedometer includes a Global Positioning System (GPS) sensor, a near-field communication (NFC) tag, or any other type of sensor and/or communication device that communicates with an external electronic device or transmitter to detect user motion or change of user location. For example, the pedometer 120 may sense NFC tags arranged along a walkway and estimate, based upon the distance between a NFC tags, the number of step taken by the user as the user

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traverses the walkway. Furthermore, the time taken by the user to pass from a first to a second NFC tag may be used to determine if the user is walking, jogging, or running. A demographic of the user (i.e. age, height, race, gender, etc., a combination thereof) may suggest an average step length of the user in this example implementation. In another example implementation, the pedometer 120 may interface with the digital multimedia device 155 to retrieve a signal from the digital multimedia device 155 and to determine a footstep taken by the user based upon the signal. The signal could include a location measurement, an accelerometer measurement, a distance calculation, or any other suitable measurement or calculation. The pedometer 120 preferably actively monitors for footsteps and may add the detected footstep to a log of footsteps taken by the user. Alternatively, the processer 160 and/or software module 150 may log or track user footsteps. Furthermore, the processor 160 and/or software module 150 may activate the pedometer 120 by indicating when the pedometer 120 should and should not monitor for footsteps. However, the pedometer 120 may function in any other way and include any other type of sensor.

[0016] The heart rate monitor 130 of the preferred health meter 100 functions to detect the heart rate of the user. The heart rate monitor 130 preferably includes two conductive pads (or electrodes) that contact the skin of the patient and sense electrical signals within the body that control heart function, as shown in FIGURES 1, 2, and 5. The electrodes of the heart rate monitor 130 are preferably integrated into opposing legs of the clip 170, but may alternatively be located on the housing 180. In one example implementation, a first conductive pad is arranged on a surface of the clip 170 and a second conductive pad is arranged on the housing 180 such that the heart rate monitor 130 measures the heart rate of a user when the user contacts the first and second conductive pads to arrange the clip 140 on an article of clothing or to remove the clip 140 from the article of clothing. In another example implementation, a first conductive pad is arranged on a first section of the clip 140 and a second conductive pad is arranged on a second section of the clip 140, wherein the data link 140 that extends from an end of the first section and the second section encases the data link 140 when the first and second sections are assembled. In this example implementation, the heart rate monitor

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preferably measures the heart rate of a user when the user engages the clip to separate the first and second sections to access the data link 140. The heart rate monitor 130 may alternatively include an infrared or RF transmitter and receiver that implement infrared or acoustic energy to detect blood flow through blood vessels in a particular region of the body of the user. In another example implementation, the heart rate monitor 130 includes a microphone that detects the sound of a mechanical disturbance in the body of the user consistent with a heartbeat. The heart rate monitor 130 may be active and consistently monitoring for heart beats of the user, such as whenever the user touches the heart rate monitor 130. The heart rate monitor may alternatively be passive and attempt to measure user heart rate only when instructed by the processor 160 or initiated by the user.

[0017] The heart rate monitor preferably incorporates a timer such that the heart rate monitor 130 may determine the heart rate of the user based upon the elapsed time between two or more heartbeats or based upon the number of heartbeats in a given period of time. However, the heart rate monitor 130 may rather interface with another element of the health monitor that does include a timer, such as the processor 160, in order to calculate the user heart rate. The heart rate monitor 130, however, may function in any other way and may be activated by any other device or element.

[0018] The data link 140 of the preferred health meter 100 functions to transmit the output of at least one of the blood glucose meter 110, the pedometer 120, and the heart rate monitor 130 to the digital multimedia device 155, as shown in FIGURES 3 and 4. The data link 140 is preferably a wired connection, as shown in FIGURES 1 and 2, wherein the data link includes a wired jack connector (e.g., a 1/8" headphone jack) such that the preferred health meter 100 may communicate with the digital multimedia device 155 through an audio jack of the digital multimedia device 155. In one example implementation of the data link 140 that is a wired jack, the data link 140 is configured only to transmit data (or outputs) from the blood glucose meter 110, the pedometer 120, the heart rate monitor 130, the processor 160, etc. In another example implementation, the data link 140 is configured to transmit data to and from at least one element of the preferred health meter 100 and the digital multimedia device 155. In this example

implementation, the data link 140 may transmit data into the digital multimedia device 155 through the microphone input of the audio jack of the digital multimedia device 151 and may retrieve data from the audio output of the audio jack of the digital multimedia device 151. In this example implementation, the data link 140 may communicate with the digital multimedia device 155 via inter-integrated circuit communication (I2C), one-wire, master-slave, or any other suitable communication protocol. However, the data link 140 may transmit data in any other way and may include any other type of wired connection (such as a USB wired connection) that supports data transfer between the preferred health meter 100 and the digital multimedia device 155.

[0019] Alternatively, the data link 140 may be a wireless connection. For example, the data link 140 may include a Bluetooth module that interfaces with a second Bluetooth module included in the digital multimedia device, wherein data (e.g., sensor outputs) are transmitted from the preferred health meter 100 to the digital multimedia device over Bluetooth communications. The data link 140 may implement other types of wireless communications, such as 3G, 4G, radio, or Wi-Fi communication. In this example implementation, data is preferably encrypted before being transmitted by the data link 140. For example, cryptographic protocols such as Diffie–Hellman key exchange, Wireless Transport Layer Security (WTLS), or any other suitable type of protocol may be used. The data encryption may also comply with standards such as the Data Encryption Standard (DES), Triple Data Encryption Standard (3-DES), or Advanced Encryption Standard (AES).

[0020] The data link 140 that is a wired connection may further serve as a power and/or charging connector for the preferred health meter 100. The data link 140 may transmit the outputs of the blood glucose meter 110, the pedometer 120, and the heart rate monitor 130 directly from these components to the digital multimedia device, as shown in FIGURE 4. Alternatively and as shown in FIGURE 3, the outputs of the blood glucose meter 110, the pedometer 120, and the heart rate monitor 130 may first pass to the processor 160 (and be subsequently modified) and/or pass to the data storage module 200 before transmission by the data link 140. However, the data link 140 may

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include any other type of connector or connection, function via any other method, and/or complete any other function.

[0021] The software module 150 of the preferred health meter 100 functions to evaluate the output of at least one of the blood glucose meter 110, the pedometer 120, and the heart rate monitor 130 and to generate a health report of the user based upon the evaluation. Preferably, the software module 150 evaluates at least one of the blood glucose level, motion or activity, and heart rate of the user in order to determine the current health risk of the user. For example, the software module 150 may determine that the blood sugar of the user is too low or less than ideal (hypoglycemia), which increases short-term risk of diabetic crash. The software module 150 may additionally or alternatively determine that the blood sugar level of the user is within a proper range but recent activity (e.g., running) and a high heart rate indicate that the blood sugar level of the user will drop within a predicted period of time, which also increases risk of diabetic crash. The software module 150 may additionally or alternatively determine that the blood sugar level of the user is too high (hyperglycemia) and is not associated with an appropriate level of user activity, which increases long-term risk of worsening diabetic condition. The software module 150 preferably incorporates at least one of user goals, user health condition, user demographic, previous user activity, and previous user compliance in evaluating health risk and generating the health report for the user. For example, if the user, such as in consultation with a doctor, sets a specific acceptable blood glucose level range which is entered into the software module 150, the software module 150 may not only include short-term risks like diabetic crash or long-term risks like worsening diabetic condition in the health report, but may also include risk of moving outside of the acceptable glucose level range defined by the user as a user goal. In another example, the software module 150 may determine the user to be in poor health, such as suffering from a second disease, and therefore increase the evaluated health risk of certain measured biosignals. For example, the software module 150 may note that the user has cancer or bronchitis and therefore associate a greater health risk for the user with a heart rate outside a narrower range of acceptable heart rates. Furthermore, the software module may notify a physician, hospital, paramedic, etc. if

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the health risk of the user is substantially high or above a preset threshold. For example, the software module 150 may contact a 9-1-1 service, send an email to a physician, or alert a family member of the user via a SMS message. The software module 150 may additionally or alternatively generate a health report that includes any other health- and/or user-related information that may be useful in treating, maintaining, improving, or generating a diagnosis of the user.

[0022] A shown in FIGURE 1, the software module 150 is preferably an application (or 'app') that executes on the digital multimedia device 155. As described above, the digital multimedia device is preferably a smartphone but may also be a tablet, laptop computer, desktop computer, PDA, e-book reader, or any other digital multimedia device. The software module 150 preferably includes an interface that accepts inputs from the user, such as user goals, user health condition, user demographic, etc., and uses these inputs to evaluate the health risk of the user. The software module 150 also or alternatively accesses a remote network (or database) that contains health information (health records) of the user. The remote network may be a server associated with a hospital or a network of hospitals (such as where a primary care physician of the user is employed), a server associated with a health insurance agency or network of health insurance agencies (such as a health insurance company that insures the user), a server associated with a third party that manages health records, or any other user- or heath-related server or entity. Physicians and/or staff associated with the health care of the user may add to, update, or otherwise modify the user health record on the remote network such that the software module 150 may access current user health information and evaluate appropriate risk levels based upon the user health information, biosignals, and/or physiological data. The software module 150 may further add the health report generated by the software module 150 to the user health records on the remote network. In the variation of the preferred health meter 100 in which the software module 150 retrieves and/or transmits user health data from and/or to the remote network, the data is preferably encrypted with cryptographic protocols such as those described above. Alternatively, the user, physician, and/or staff may add, update, or otherwise modify user health information from directly within the software

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module 150, such as by entering information into a user interface displayed on a screen of the digital multimedia device 155 that couples to the preferred health meter 100 via the data link 140.

[0023] The software module 150 may also execute fully or in part on a remote server. For example, the software module 150 may be a cloud-computing-based application that performs data analysis, calculations, and other actions remotely from the digital multimedia device 155. In this example, the digital multimedia device 155 may receive an output of the preferred health meter 100 via the data link 140 and then transfer the output to the remote server upon which the software module 150 executes. The data are preferably transferred via a wireless connection, such as a 3G or 4G cellular connection or via a Wi-Fi internet connection. In this variation, the digital multimedia device 155 performs the primary function of transmitting data to and/or receiving data from the software module 150. The software module 155 may include a first software component that executes on the digital multimedia device 155, such as an app that manages the collection, transmission, retrieval, and/or display of data. The software module 150 may thus further include a second software component that executes on the remote server to retrieve the data, analyze the data, generate the health report, and/or manage the transmission of the health report back to the digital multimedia device 155, wherein the first software component manages retrieval of data sent from the second software component, transmits a form of the health report back to the preferred health meter 100 through the data link 140, and/or renders of a form of the health report on the display of the digital multimedia device 155 and or display 190 of the health meter 100. However, the software module 150 may include any number of software components that execute on any digital multimedia device 155, health meter, or server and that perform any other function or combination of functions.

[0024] The processor 160 of the preferred health meter 100 functions to access the health report and to control conveyance of the health-related notification 192 (e.g., directive) to the user. The health-related notification 192 is preferably based upon the health report generated by the software module 150. In one example implementation, the processor 160 receives the health report and generates the health-related

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notification 192 based upon the health report. In this example implementation, a form of the health report is preferably transmitted from the digital multimedia device 155 to the processor 160 via the data link 140, wherein the digital multimedia device 155 accesses the health report either from the software module 150 executing on the digital multimedia device 155 or from the software module 150 executing on a remote server and in communication with the digital multimedia device 155. In another example implementation, the software module 150 generates both the health report and the health-related notification 192 based upon the health report. In this example implementation, the health-related notification 192 is preferably transmitted to the processor 160 via the data link 140. The processor 160 preferably controls conveyance of the health-related notification 192 to the user, such as by triggering the display 190 to depict the directive or notification, by triggering a display of the digital multimedia device 155 to display the directive or notification, or by generating and/or transmitting an email, SMS, voicemail, Facebook or Twitter message, or any other message accessible by the user and which contains the health-related notification 192. The processor 160 may also convey the health-related notification 192 by altering the state (i.e. ON or OFF) of one or more lamps (e.g. LEDs) that comprise the display 190. For example, each of a series of lamps may be labeled one of 'Eat', 'Walk', 'Run', 'Rest', 'Test', 'Medicate', etc., wherein the processor 160 toggles the state of each lamp to indicate which action the user should take to minimize health risk associated with at least one of the blood glucose level, heart rate, and activity of the user. However, the processor 160 may manage the conveyance of any other information and function in any other way.

[0025] The health-related notification 192 preferably contains information relevant to the health of the user and specifically to minimizing the health risk of the user based upon at least a portion of the health report, such as the blood glucose level, the heart rate, and/or the activity level of the user. The health-related notification 192 preferably includes an explicit directive for the user to perform a certain action, such as to eat, rest, or exercise. Therefore, the health-related notification 192 preferably systematically and repeatably analyzes a health condition of the user and provides medical consultation to manage and/or improve user health (or substantially minimize

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user health risk) substantially in real time. For example, the health-related notification 192 may indicate that the user should eat, walk, run, rest, test, or medicate. The notification may further include information related to what or how much to eat, how much protein or carbohydrate to consume, where and how long to run, level of exertion, how to rest and for how long, when to test blood glucose level or heart rate, when to schedule a future test, what and how much medication to consume or inject, and/or any other relevant information. The health-related notification 192 is preferably displayed to the user through the preferred health meter 100, such as with a series of labeled idiot lights or on the display 190. Alternatively, the health-related notification may be provided to the user through an email, voicemail, SMS, calendar, Facebook, or Twitter message, or any other message. Furthermore, the health-related notification provided through the digital multimedia device 155 or any other external electronic device, such as a phone, smartphone, tablet, PDA, e-book, MP3 player, laptop computer, or desktop computer. In one example, the processor 160 generates the health-related notification 192 and the display 190 renders the health-related notification 192. The data link 140 then manages an SMS message (or other type of message) that is sent to a cellular phone number associated with the user. The data link 140 may additionally or alternatively add to or modify a calendar of the user to include the directive of the health-related notification 192, such as by adding an exercise event to an opening in the user's schedule.

[0026] The preferred health meter 100 may further include an alarm or buzzer that alerts the user when a new health-related notification 192 is available. Alternatively, the preferred health meter 100 may communicate with the digital multimedia device that includes an alarm or buzzer to notify the user that a new health-related notification 192 is available. However, the health-related notification 192 may include any other information and/or directive and may be conveyed to the user in any other way or combination of ways.

[0027] As shown in FIGURES 1 and 2, the preferred health meter 100 may further include a display 190 that functions to depict the health-related notification 192. The display is preferably an e-ink display that requires power substantially only when

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changing rendered content. However, the display 190 may include any other type of digital display, such as an LCD display with a LED, PDP, OLED, or SED backlight, a segment display, or any other type of display. The display may render content, such as the health-related notification 192, the number of steps taken by the user, or the heart rate of the user in black and white, in color, or in any other form, and the display may update at specific time intervals (such as every minute or every hour) or in conjunction with certain events. Such events may include a user request for updated information, a new blood glucose test, a certain heart rate of the user, a sufficient period of user inactivity, completion of the health-related notification 192 and/or health report, or immediacy of a health-related event scheduled in the user's calendar of the user. The processor 160 preferably controls the display 190, though the display 190 may be controlled by any other component of the preferred health meter 100 and in any other way.

[0028] One variation of the preferred health meter 100 further includes a data storage module 200 that retains health-related data such as the health report, the health-related notification, results of one or more blood glucose tests, one or more heart rates of the user, footsteps taken by the user, and/or any other output of any other physiological and/or biological sensor incorporated into the preferred health meter 100. The data storage module 200 is preferably arranged within the housing 180 and is preferably coupled to processor such that data stored on the data storage module 200 remains accessible to the processor 160. Alternatively, the data storage module 200 may be integral with the digital multimedia device 155 or otherwise substantially remote from the processor 160, such as connected to the remote server or a remote network. Data generated by the blood glucose meter 110, the pedometer 120, the heart rate monitor 130, or any other element connected to the data storage module 200, are preferably stored on the data storage module 200 when the data link 140 is not in communication with the digital multimedia device 155. Furthermore, data are preferably transmitted to the digital multimedia device 155 when a communication link is established via the data link 140. However the data storage module 200 may store these or any other data.

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[0029] Another variation of the preferred health meter 100 further includes a housing 180 that substantially encases at least one of the blood glucose meter 110, the pedometer 120, the heart rate monitor 130, the data link 140, the processor 150, the display 190, and the data storage module 200. Generally, the housing 180 is preferably of a clamshell configuration, including a front element and a back element that fasten together to form a vessel that contains one or more components of the preferred health meter 100. The housing 180 preferably manufactured from medical-grade materials such as antimicrobial plastics, 316L stainless steel, or medical-grade silicone rubbers. Alternatively, the housing 180 may be manufactured of non-medical-grade materials but include a medical-grade coating, such as overmolded medical-grade silicone rubber. The housing 180 is also preferably waterproof and dustproof, such as with an Ingress Protection rating of 25 or greater. Implementation of medical-grade materials, a dustproof housing, and/or a waterproof housing may promote longevity of the preferred health meter 100 by reducing susceptibility to damage by cleaning agents, bodily fluids, misuse, etc. However, the housing 180 may be of any other form and may encase any other element.

[0030] Yet another variation of the preferred health meter 100 further includes a clip 170 that couples the housing to an article of clothing worn by the user, such as a belt, belt loop, purse, pocket, armband, or any other article of clothing, accessory, or wearable article worn by the user. Furthermore, the clip 170 may couple the preferred health meter 100 to other features or items proximal the user, such as to a seat belt of a car driven by the user or to the digital multimedia device 155 that is a cellular phone carried by the user. However, the clip 170 may couple the preferred health meter 100 to any other suitable object. In the variation of the preferred health meter 100 in which the data link 140 includes a wired connection, the clip 170 is preferably physically coextensive with the data link 140, as shown in FIGURES 2 and 5. In one example implementation, the data link 140 includes a wired jack that is separable from (i.e. transiently or removably coupled to) the clip 170 such that the wired jack may be inserted into the digital multimedia device 155 to enable communication therebetween. In another example implementation shown in FIGURE 2 and 5, clip includes a first

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section 170a and a second section 170b, wherein the data link 140 extends from the second section 170b and the first section 170a transiently couples to the second section 170b to encase the wired jack and is separable from the second section 170b to enable access to the data link 140. In the foregoing example implementation, the first section 170a of the clip 170 is preferably sprung (i.e. coupled to a spring) and the second section of the clip 170 that includes the data link 140 is preferably not sprung to permit substantially free manipulation of the data link 140, such as when the user plugs the data link 140 into a port of the digital multimedia device 155. Generally, the data link 140 preferably slides out of the first section 170a of the clip 170, thus freeing the second section to pivot and to enable access to the wired jack of the data link 140.

[0031] As shown in FIGURES 2 and 5, the clip 170 preferably defines a circular cross-section swept along a U-shaped profile. Alternatively, the clip 170 may be an alligator-, carabineer-, snap-, French barrette-, plunger-type, or any other type of clip. The clip 170 is preferably arranged on the housing 180, such as glued, bonded, or fastened with one or more screws. However, a portion of the clip 170 may also be physically coextensive with the housing 180. For example, the housing 180 may include features that include one side or section of the clip 170. The clip 170 is preferably sprung against the housing 180 such that the clip 170 retains the housing 180 on an article of clothing by pinching (e.g., biasing against) a portion of the article of clothing between the housing 180 and a portion of the clip 170. At least one side or section of the clip 170 may therefore be coupled to a return spring that provides a clamping force between (at least one section of) the clip 170 and the housing 180. However, the clip 170 and data link 140 may be of any other physically coextensive or distinct configuration, and the clip 170 may be arranged within or on the preferred health meter 100 in any other way.

[0032] One variation of the preferred health meter 100 shown in FIGURE 1 includes: a housing 180 configured to be worn by a user; a glucose meter 110 coupled to the housing 180; a pedometer 120 coupled to the housing 180; a processor 160 arranged within the housing 180 and configured to generate a directive for a user action in response to a measured glucose level and an output of the pedometer 120; and a display 190 arranged within the housing 180 and configured to display the directive for the user.

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[0033] As shown in FIGURE 5, another variation of the preferred health meter 100 configured to be worn by a user includes: a physiological sensor 109; a clip 170 coupled to the physiological sensor and including a sprung loop configured bias against (or pinch) an article of clothing worn by the user to couple the physiological sensor to the article of clothing; and a data link 140 comprising a wired jack physically coextensive with the clip 170 and configured to transmit a form of an output of the physiological sensor. In this variation, the wired jack of the data link 140 preferably includes a stereo jack that communicates data to and from an external electronic device via inter-integrated circuit communication protocol. The physiological sensor 109 is preferably a blood glucose meter 110 that analyzes intracorporeal blood of the user (i.e. a bloodless blood glucose meter). However, the physiological sensor 109 may be a pedometer 120, a heart rate monitor 130, or any other type of biological sensor. The physiological sensor 109 preferably measures a biological status of the user at a specified interval and the data link 140 preferably transmits a form of a plurality of outputs of the physiological sensor 109 when coupled to an external electronic device. As shown in FIGURE 5, the clip 170 may further include a first section 170a and a second section 170b, wherein the first section 170a transiently couples to the second section 170b to encase the wired jack that extends from the second section 170b. For example, the second section 170b of the clip 170 may translate linearly relative the first section 170a such that the wired jack may be exposed. Furthermore, the first section 170a may be sprung against the housing 180 while the second section 170b is not sprung but rather pivotable relative the first section 170a when the datalink 140 is exposed.

[0034] As shown in FIGURE 5, a further variation of the preferred health meter 100 includes: a housing 180; a clip 170 arranged on the housing 180 and including a sprung loop configured to bias against a portion of a wearable article to couple the housing 180 to the wearable article; and a heart rate monitor 130 comprising a first conductive pad 121 and a second conductive pad 122 configured to engage an extremity of a user, wherein the first conductive pad 121 is arranged on a surface of the clip 170. In this variation, the wearable article is preferably a shirt, a pair of pants, a belt, a jacket, a vest, a coat, a glove, a shoe, a hat, an armband, or any other suitable article of clothing

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or accessory. However, the wearable article may be any other suitable item, article, or object, such as a seatbelt or medical diagnostic equipment or instrumentation. The second conductive pad 122 may be arranged on the housing 180 such that the heart rate monitor 120 measures the heart rate of a user when the user contacts the first and second conductive pads 121, 122 while arranging the clip 170 on an article of clothing. As shown in FIGURE 5, the clip 170 may define a circular cross-section swept along a U-shaped profile, though the clip 170 may be of any other cross section or profile. Furthermore, the clip 170 may include a first section 170a and a second section 170b separable from the first section 170a, wherein the first section is preferably sprung against the housing, as shown in FIGURE 5. The first conductive pad 121 is preferably arranged on the first section 170a and the second conductive pad 122 is preferably arranged on the second section 170b of the clip 170. The preferred health meter 100 may further include a data link 140 including a wired jack extending from the second section 170b, wherein the data link 140 transmits a form of an output of the heart rate monitor 120. The first section 170a of the clip 170 may also be removably coupled to the second section 170b to encase the data link 140, as described above. This variation of the preferred health meter 100 may further include a switch that triggers the heart rate monitor to measures the heart rate of a user when the user moves the second section 170b of the clip 170 relative to the first section 170a, such as to clip the preferred health meter 100 to the wearable article or to remove the preferred health meter 100 from the wearable article. In this and the foregoing variations in which the physiological sensor 109 and/or heart rate monitor 120 includes one or more conductive pads arranged on the clip 170, the clip is preferably electrically non-conductive such that the first and second conductive pads 121, 122 are electrically isolated via the clip 170. For example, the clip 170 may be nylon, polyethylene, ABS, or any other suitable type or polymer or plastic. However, the preferred health meter 100 can be of any other form or configuration and can function in any other way.

2. Example Implementations

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[0035] In a first example implementation of the preferred health meter 100, the preferred health meter 100 includes a housing 180 that substantially encapsulates the blood glucose meter 110, the pedometer 120, and the processor 160; the clip 170, the heart rate monitor 130, and the display 190 are arranged on the housing 180. The blood glucose meter 110 includes a test strip slot into which the user inserts a blood sample on a glucose test strip. The pedometer 120 is a two-axis accelerometer and the heart rate monitor 130 includes two conductive pads, each arranged on separate sections of the clip 170. The data link 140 is a wired connection comprising 1/8" headphone jack connector and is physically coextensive with the clip 170 such that the data link 140 may separate from a portion of the clip 170 to enable insertion into a portion of the digital multimedia device 155. The digital multimedia device 155 is a smartphone with a 1/8" headphone jack 151 and the software module 150 is an application configured to execute on the smartphone. The software module 150: receives data from the blood glucose meter 110, the pedometer 120 and heart rate monitor 130 through the data link 140; assesses the data in conjunction with user goals, user health condition, user demographic, previous user activity, and previous user compliance to generate the health report; dispatches the health report to a remote network configured to store the health record of the patient and wherein the health record of the patient is available to a primary-care physician of the user; transmits the health report to the processor 160 via the data link 140; and/or modifies a calendar of the user on the smartphone to reflect explicit directives relevant to the health of the user (such as scheduling a walk). The processor 160 accesses the health report; generates the health-related notification 152 or directive, and renders the health-related notification 152 on the display 190.

[0036] In a second example implementation of the preferred health meter 100, the housing 180 encapsulates the blood glucose meter 110 and the data link 140 and is implanted into the body of the user such that the data link transmits the glucose level of the blood, as measured by the implanted blood glucose meter 110, to the digital multimedia device. The data link 140 includes a low-power, short-range wireless communication module that transmits and receives data to and from the digital multimedia device 155 that is a smartphone. The heart rate monitor 130 is a microphone

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arranged on the smartphone and senses the heart rate of the user when the user places a finger over the microphone. The pedometer 120 is an accelerometer arranged within the smartphone and detects motion of the smartphone carried by the user. The software module 150 is a cloud-based application operating on a remote server that: receives data from the blood glucose meter 110, the pedometer 120 and heart rate monitor 130 through a wireless connection established with server by the smartphone; assesses the data in conjunction with user goals, user health condition, user demographic, previous user activity, and previous user compliance to generate the health report; stores the health report on a remote network configured to store the health record of the patient and wherein the health record of the patient is available to a primary-care physician of the user; and dispatches the health report to the smartphone via the wireless connection with the smartphone. The processor 160 is arranged within the smartphone and receives the health report from the software module 150 and renders a form of the health report (such as compliance with set user goals) on the display 190 integral with the smartphone. The processor 160 further suggests specific directives to the user, such as to go for a run with a second user substantially proximal the user and who has substantially similar heath-related goals and has a substantially similar recent health report as the user.

[0037] In a third example implementation, the preferred health meter 100 functions much as the first example implementation above, but in place of (or in addition to) a blood glucose meter 110, the preferred health meter 100 includes elements of a polysomnography test kit, such as an lung airflow sensor, an eye movement sensor, and a chest wall movement meter, wherein the polysomnography sensors detect sleep patterns of the user. Data collected by the polysomnography sensors are preferably transmitted to the digital multimedia device 155 via the data link 140 and then accessed by the software module 150. The software module 150 uses the data to detect sleep apnea in the patient and to generate a health report incorporating a diagnosis thereof. The health report is then used to provide directives to the user for improving sleep, and the processor 160 manages generation and distribution of the directives to alter and improve the user sleep, such as to change the position of an

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adjustable bed in which the user sleeps, to increase the level of white noise proximal to the user at night, or to increase oxygen flow through a face mask worn by the user.

[0038] In a fourth example implementation, the preferred health meter 100 functions much as the second example implementation above, aside from the housing 180 that encapsulates the blood glucose meter 110 and data link 140, wherein the data link 140 is a proprietary connector configured to plug into a data port of a digital multimedia device 155 that is a smartphone, and wherein the blood glucose meter 110 is a bloodless glucose meter.

[0039] As a person skilled in the art will recognize from the previous detailed description and from the figures and claims, modifications and changes can be made to the preferred embodiments of the invention without departing from the scope of this invention as defined in the following claims.

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CLAIMS

We Claim:

1. A health meter comprising:
- a housing configured to be worn by a user;
- a glucose meter coupled to the housing;
- a pedometer coupled to the housing;
- a processor arranged within the housing and configured to generate a directive for a user action in response to a measured glucose level and an output of the pedometer; and
- a display arranged within the housing and configured to display the directive for the user.

2. The health meter of Claim 1, wherein the processor is further configured to estimate an activity of the user based upon footsteps taken by the user and detected by the pedometer.

3. The health meter of Claim 1, further comprising a heart rate monitor, wherein the processor generates the directive in further response to a measured heart rate of the user.

4. The health meter of Claim 1, wherein the glucose meter comprises an optical emitter and an optical detector configured to detect a glucose level in intracorporeal blood of the user.

5. The health meter of Claim 1, wherein the display comprises a set of indicator lamps, wherein each lamp is assigned a distinct directive for a user action, and wherein the processor sets a state of each indicator lamp according to the generated directive for the user action.

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6. The health meter of Claim 1, wherein the processor generates the directive for a user action that is one of to eat, to rest, and to exercise.

7. A health meter configured to be worn by a user, the health meter comprising:
- a physiological sensor;
- a clip coupled to the physiological sensor and comprising a sprung loop configured to bias against an article of clothing worn by the user to couple the physiological sensor to the article of clothing; and
- a data link comprising a wired jack physically coextensive with the clip and configured to transmit a form of an output of the physiological sensor.

8. The health meter of Claim 7, wherein the wired jack of the data link comprises a stereo jack configured to communicate data between an external electronic device via inter-integrated circuit communication protocol.

9. The health meter of Claim 7, wherein the clip further comprises a first section and a second section, wherein the first section transiently couples to the second section to encase the wired jack that extends from the second section.

10. The health meter of Claim 9, wherein the first section of the clip is sprung against the housing, and wherein the second section is pivotable relative the first section.

11. The health meter of Claim 9, wherein the second section of the clip is configured to translate linearly relative the first section to expose the wired jack.

12. The health meter of Claim 7, wherein the physiological sensor measures a biological status of the user at a specified interval, and wherein the data link transmits a form of a plurality of outputs of the physiological sensor when coupled to an external electronic device.

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13. The health meter of Claim 12, wherein the physiological sensor comprises a blood glucose meter configured analyze intracorporeal blood of the user.

14. A health meter comprising:

- a housing;
- a clip arranged on the housing and comprising a sprung loop configured to bias against a portion of a wearable object to couple the housing to the wearable object; and
- a heart rate monitor comprising a first conductive pad and a second conductive pad configured to engage an extremity of a user, wherein the first conductive pad is arranged on a surface of the clip.

15. The health meter of Claim 14, wherein the second conductive pad is arranged on the housing, and wherein the heart rate monitor measures the heart rate of a user when the user contacts the first and second conductive pads.

16. The health meter of Claim 14, wherein the clip defines a circular cross-section swept along a U-shaped profile.

17. The health meter of Claim 14, wherein the clip further comprises a first section and a second section separable from the first section, wherein the first section is sprung against the housing and wherein the first conductive pad is arranged on the first section.

18. The health meter of Claim 17, further comprising a data link comprising a wired jack extending from the second section and configured to transmit a form of an output of the heart rate monitor, wherein the first section is removably coupled to the second section to encase the data link.

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19. The health meter of Claim 17, further comprising a switch, wherein the second conductive pad is arranged on the second section, and wherein the switch is configured to trigger the heart rate monitor to measures the heart rate of a user when the user moves the second section relative to the first section.

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FIG. 1

SUBSTITUTE SHEET (RULE 26)

FIG. 2

SUBSTITUTE SHEET (RULE 26)

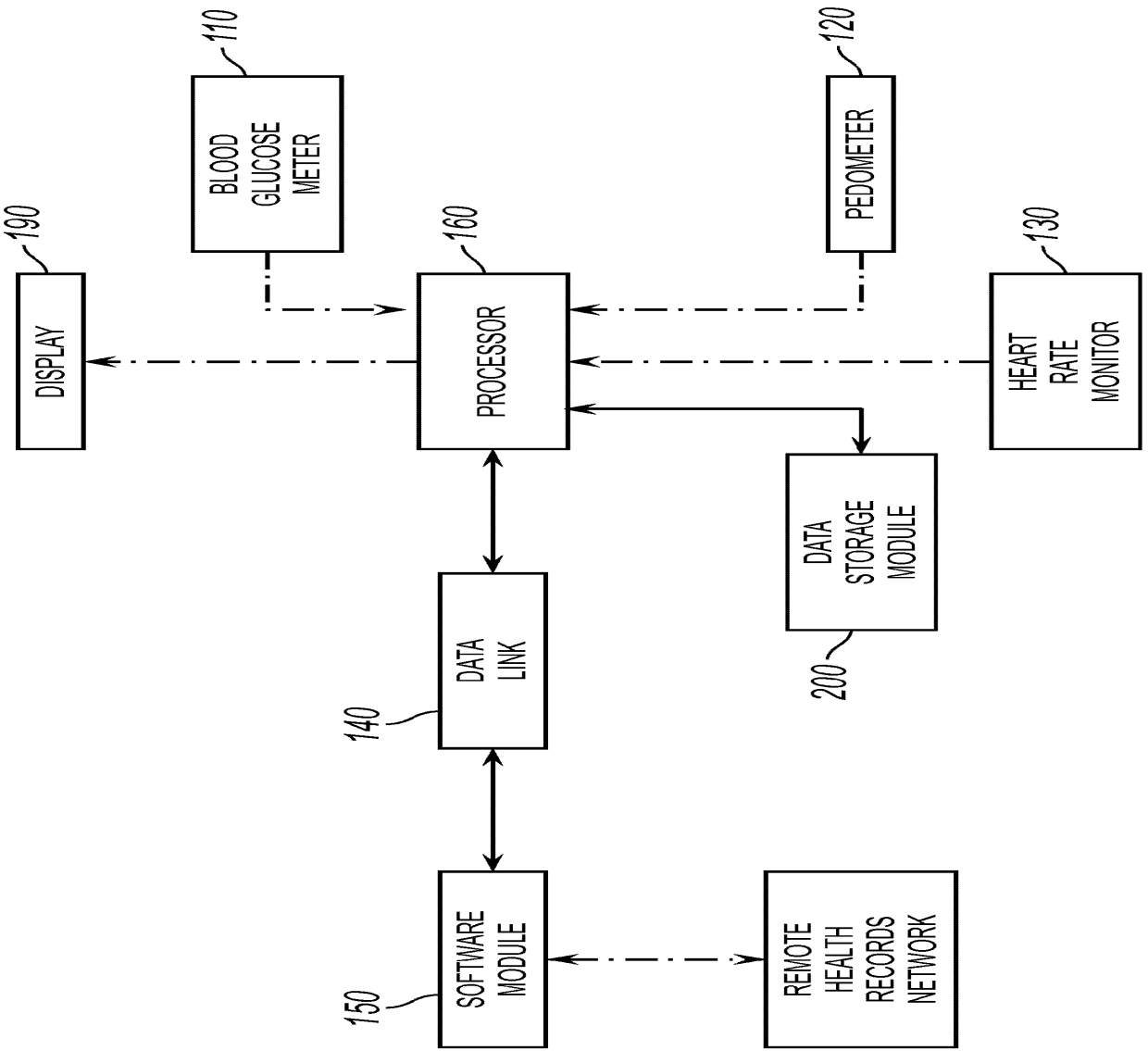


FIG. 3

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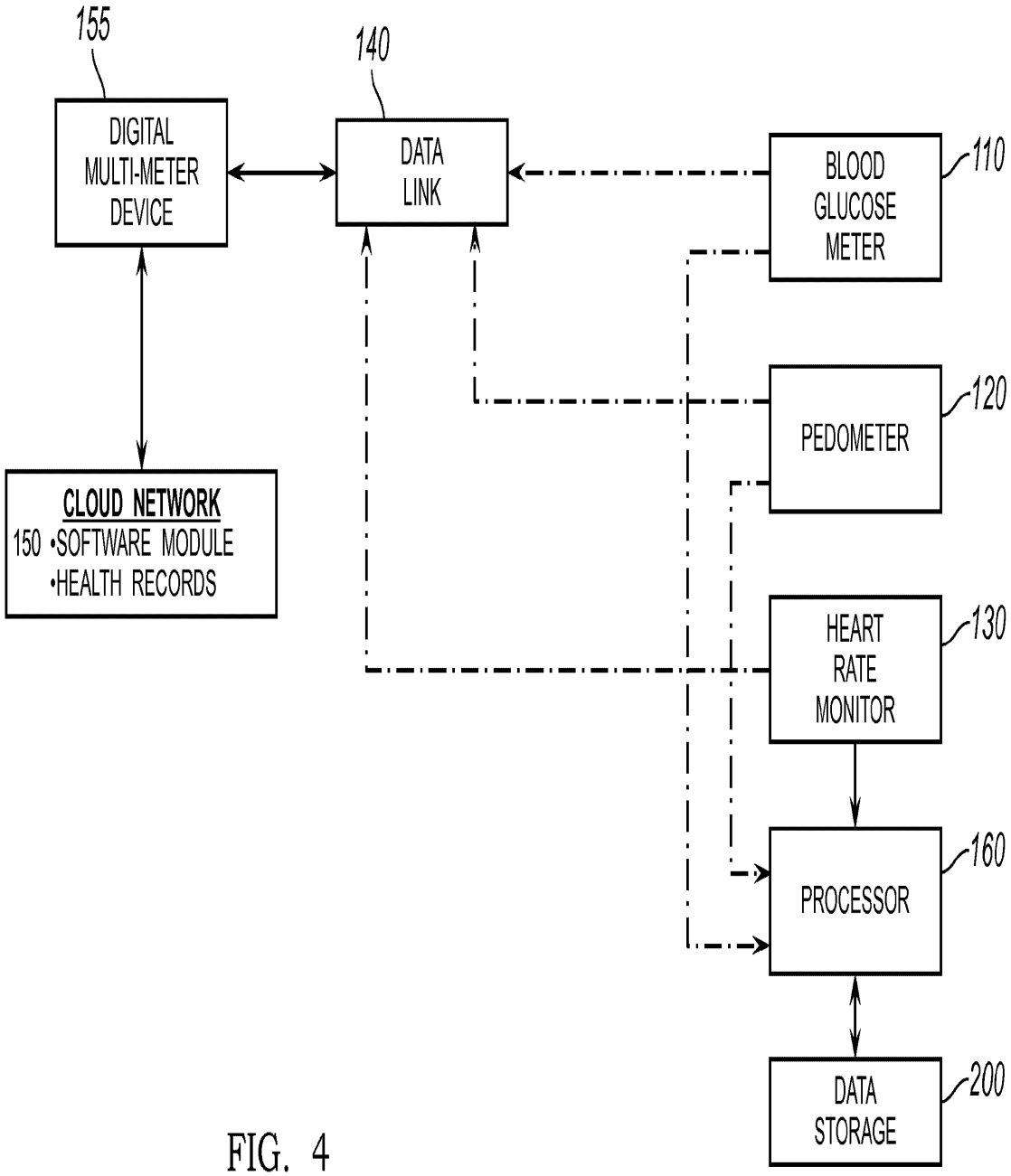


FIG. 4

SUBSTITUTE SHEET (RULE 26)

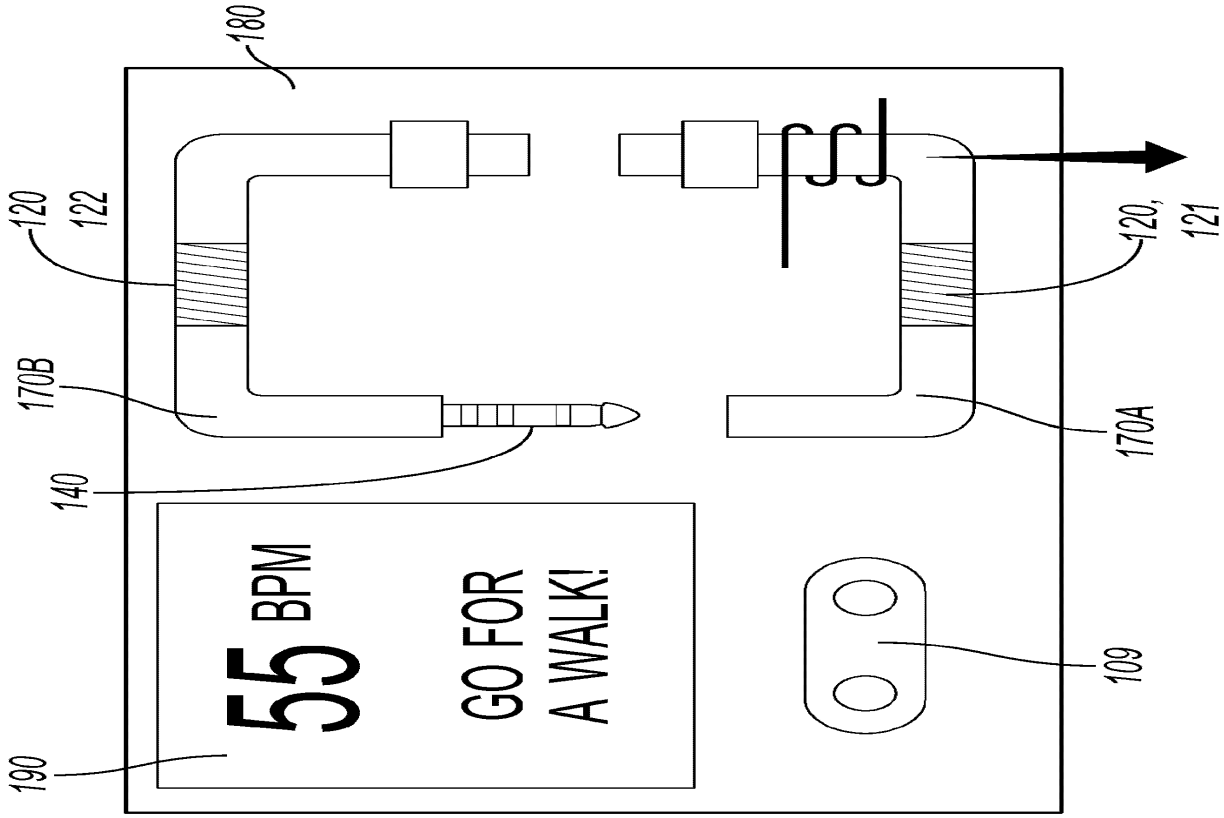


FIG. 5

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/47229

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/04 (2012.01)
USPC - 600/365, 587; 702/160
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(8) - A61B 5/04 (2012.01)
USPC - 600/365, 587; 702/160

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
600/301, 347, 520
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google
Search Terms: Glucose meter, sensor, measure, insulin pump, diabetes, health monitor, health meter, pedometer, exercise meter, exercise monitor, activity monitor, activity meter

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0191075 A1 (ANGELIDES) 29 July 2010 (29.07.2010) Entire document, especially Abstract, para[0019]- para[0021], para[0024]- para[0031], para[0035], Claims 2-4 and FIG. 1.	1-3
X	US 2003/0208113 A1 (MAULT et al.) 06 November 2003 (06.11.2003) Entire document, especially Abstract, para[0062], para[0069]- para[0075], para[0105], para[0132], para[0137], para[0148]- para[0149] and FIGS. 1, 16.	1-2, 4-6
X	US 2009/0264337 A1 (ANGELIDES) 22 October 2009 (22.10.2009) Entire document, especially Abstract, para[0007]-[0009].	1-2
X	US 2009/0240128 A1 (MENSINGER et al.) 24 September 2009 (24.09.2009) Entire document, especially Abstract, para[0097], Claims 11, 18, 19.	1-2
X	US 2008/0139910 A1 (MASTRÓTOTARO et al.) 12 June 2008 (12.06.2008) Entire document, especially Abstract, para[0033].	1-2
A	US 2011/0124996 A1 (REINKE et al.) 26 May 2011 (26.05.2011) Entire document.	1-6
A	US 2009/0240193 A1 (MENSINGER et al.) 24 September 2009 (24.09.2009) Entire document.	1-6

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
28 November 2012 (28.11.2012)	04 DEC 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/47229

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
-- see extra sheet --

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/47229

Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-6 describing a combination pedometer and glucose meter health monitor to generate a directive for a user action in response to a measured glucose level and an output of the pedometer

Group II: claims 7-19 describing a health monitor comprising a clip to bias a physiological sensor against cloting, a data link and a heart rate monitor or glucose sensor

The inventions listed as Groups I - IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The commonality between the groups comprises a health monitor which comprises a generic glucose sensor, however, glucose sensors in general are well known in the art to monitor health (see US 2007/0276294 A1 to Gupta et al., who describes health monitors that monitor both glucose and heart rate (Abstract, para[0007]), therefore such monitors in general do not constitute an advancement over existing art.
Thus the remaining features are, group I: directive generation device for monitoring health in response to glucose and a pedometer, and group II: a clipping arrangement for physiological sensors (in general) and a data link for use therewith. None of the groups share a technical feature with another group. Thus, unity is lacking.

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(54) Title: WEARABLE MULTI-MODAL PHYSIOLOGICAL SENSING SYSEM

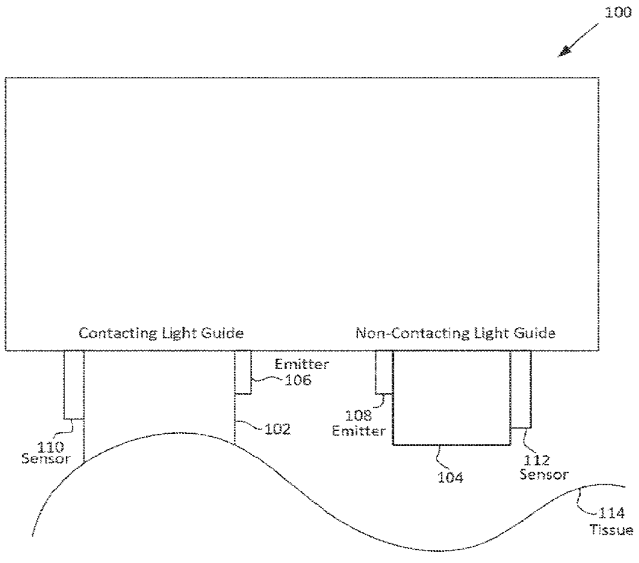


FIG. 1

(57) Abstract: A PPG signal may be obtained from a pulse oximeter, which employs a light emitter and a light sensor to measure the perfusion of blood to the skin of a user. However, the signal may be compromised by noise due to motion artifacts. To address the presence of motion artifacts, examples of the present disclosure can receive light information from each of two light guides, one in contact with the tissue of the user and one not in contact with the tissue of the user. First light information can be obtained from the first light guide, and second light information can be obtained from the second light guide. A heart rate signal can then be computed from the first and second light information, for example, by using blind source separation and/or cross-correlation.

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WEARABLE MULTI-MODAL PHYSIOLOGICAL SENSING SYSTEM

Field of the Disclosure

[0001] This relates generally to reducing motion artifacts from a physiological signal.

Background of the Disclosure

[0002] A photoplethysmogram (PPG) signal may be obtained from a pulse oximeter, which employs a light emitter and a light sensor to measure the perfusion of blood to the skin of a user. However, the signal may be compromised by noise due to motion artifacts. That is, movement of the body of a user may cause the skin and vasculature to expand and contract, introducing noise to the signal. Further, the device itself may move with respect to the body of the user, introducing further noise. To address the presence of motion artifacts, examples of the present disclosure can receive light information from each of two light guides, one in contact with the tissue of the user and one not in contact with the tissue of the user. First light information can be obtained from the first light guide, and second light information can be obtained from the second light guide. A heart rate signal can then be computed from the first and second light information, for example, by using blind source separation and/or cross-correlation.

Summary of the Disclosure

[0003] A photoplethysmogram (PPG) signal may be obtained from a pulse oximeter, which employs a light emitter and a light sensor to measure the perfusion of blood to the skin of a user. However, the signal may be compromised by noise due to motion artifacts. That is, movement of the body of a user may cause the skin and vasculature to expand and contract, introducing noise to the signal. Further, the device itself may move with respect to the body of the user, introducing further noise. To address the presence of motion artifacts, examples of the present disclosure can receive light information from each of two light guides, one in contact with the tissue of the user

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and one not in contact with the tissue of the user. First light information can be obtained from the first light guide, and second light information can be obtained from the second light guide. A heart rate signal can then be computed from the first and second light information, for example, by using blind source separation and/or cross-correlation.

Brief Description of the Drawings

[0004] FIG. 1 illustrates an electronic device having light sensors for determining a heart rate signal according to examples of the disclosure.

[0005] FIG. 2 illustrates a method of computing a heart rate signal according to examples of the disclosure.

[0006] FIG. 3 illustrates a method of computing a heart rate signal according to examples of the disclosure.

[0007] FIG. 4 is a block diagram illustrating an exemplary API architecture, which may be used in some examples of the disclosure.

[0008] FIG. 5 illustrates an exemplary software stack of an API according to examples of the disclosure.

[0009] FIG. 6 is a block diagram illustrating exemplary interactions between the touch screen and other components of the device according to examples of the disclosure.

[0010] FIG. 7 is a block diagram illustrating an example of a system architecture that may be embodied within any portable or non-portable device according to examples of the disclosure.

Detailed Description

[0011] In the following description of examples, reference is made to the accompanying drawings which form a part hereof, and in which it is shown by way of illustration specific examples that can be practiced. It is to be understood that other examples can be used and structural changes can be made without departing from the scope of the disclosed examples.

[0012] A photoplethysmogram (PPG) signal may be obtained from a pulse oximeter, which employs a light emitter and a light sensor to measure the perfusion of

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blood to the skin of a user. However, the signal may be compromised by noise due to motion artifacts. That is, movement of the body of a user may cause the skin and vasculature to expand and contract, introducing noise to the signal. Further, the device itself may move with respect to the body of the user, introducing further noise. To address the presence of motion artifacts, examples of the present disclosure can receive light information from each of two light guides, one in contact with the tissue of the user and one not in contact with the tissue of the user. First light information can be obtained from the first light guide, and second light information can be obtained from the second light guide. A heart rate signal can then be computed from the first and second light information, for example, by using blind source separation and/or cross-correlation.

[0013] Although examples disclosed herein may be described and illustrated herein primarily in terms of two sensors, emitters, and light guides, it should be understood that the examples are not so limited, but are additionally applicable to devices including any number and configuration of sensors, emitters, and light guides.

[0014] Examples of the disclosure are directed to a system for sensing and measurement of physiological signals that enables a signal decomposition approach to physiological measurements. That is, multiple signals may be obtained, and each signal may contain a physiological signal of interest (e.g., a heart rate signal)—each signal may also contain different noise components, and thus signal decomposition methods may be used to filter the noise and compute the signal of interest. Multiple sensing modalities optimized for the signal decomposition approach may provide robustness against non-signal artifacts commonly induced in wearable sensors, such as motion- or biologically-induced artifacts. Sensing modalities may include detection of physiological signals from optical sensors, force and pressure sensors, temperature sensors, accelerometers, proximity detectors, and/or impedance sensors, among other possibilities. In some examples, sensing modalities may include optical sensors including light guides in contact and not in contact with tissue of a user. Because the signal of interest may be compromised by noise due to motion of the device with respect to the tissue and also by noise due to motion of the tissue itself (e.g., the expansion and contraction of tissue and vasculature), different noise may be captured by sensors corresponding to each of contacting and non-contacting light guides, and signal decomposition methods (e.g., blind source separation) may be employed to separate the signal of interest from the noise.

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[0015] FIG. 1 illustrates an electronic device 100 having light sensors for determining a heart rate signal according to examples of the disclosure. A first light sensor 110 may be co-located with a contacting light guide 102 and a first light emitter 106. The contacting light guide 102 may be configured so as to be in contact with tissue 114 of a user, such as skin. For example, the contacting light guide 102 may be curved such that the surface is configured to contact tissue 114 of the user. In some examples, the contacting light guide 102 may jut out from the body of the electronic device 100 such that it is configured to contact tissue 114 of the user. A second light sensor 112 may be co-located with a non-contacting light guide 104 and a second light emitter 108. The non-contacting light guide 104 may be configured so as to not be in contact with tissue 114 of the user. In some examples, the non-contacting light guide 104 may be recessed with respect to the body of the electronic device 100 such that it is configured not to contact tissue 114 of the user.

[0016] The electronic device 100 may be situated such that the sensors 110 and 112, the emitters 106 and 108, and the light guides 102 and 104 are proximate the tissue 114 of the user, so that light from a light emitter may be directed through a light guide and be incident on the tissue. For example, the electronic device 100 may be held in a user's hand or strapped to a user's wrist, among other possibilities. A portion of the light from a light emitter may be absorbed by the skin, vasculature, and/or blood, among other possibilities, and a portion may be reflected back to a light sensor co-located with the light emitter. In some examples, light guides may direct light to tissue and/or back to a light sensor, and some emitters and sensors may direct light to and from tissue without a light guide.

[0017] FIG. 2 illustrates a method of computing a heart rate signal. Light may be emitted from a first light emitter through a contacting light guide (200). First light information may be received at a first light sensor through the contacting light guide (202). Similarly, light may be emitted from a second light emitter through a non-contacting light guide (204), and second light information may be received at a second light sensor through the non-contacting light guide (206). In some examples, a light emitter may emit light, the light may travel to the tissue of a user, and a portion of the light may reflect to a co-located light sensor, and some or all of the travel of the light may be directed by a light guide. Accordingly, the first light information may indicate an

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amount of light from a first light emitter that has been reflected by the skin, blood, and/or vasculature of the user, among other possibilities. In some examples, the first light information may indicate an amount of light from the first light emitter that has been absorbed by the skin, blood, and/or vasculature of the user.

[0018] The light emitters may produce light in ranges corresponding to infrared (IR), green, amber, blue, and/or red light, among other possibilities. Additionally, the light sensors may be configured to sense light having certain wavelengths more easily than light having other wavelengths. For example, if the first light emitter emits light having a wavelength in the IR range, then the first light sensor may be configured to sense light in the IR range more powerfully than light in the green range. That is, the incidence of light in the IR range may produce a stronger response in the first light sensor than the incidence of light in the green range. In this way, the first light sensor can be configured so as to sense the light produced by the first light emitter more powerfully than the light produced by the second light emitter, for example. In some examples, each light emitter may produce light in the same wavelength.

[0019] In some examples, a light emitter may be a light emitting diode (LED) and a light sensor may be a photodiode. The light information may include information produced by the photodiode. For example, the light information may include a voltage reading that corresponds to light absorbed by the photodiode. In some examples, the light information may include some transformation of raw signal produced by the photodiode, such as through filtering, scaling, or other signal processing.

[0020] Based on the first and second light information, a heart rate signal may be computed (206). For example, the first and second light information may be processed through blind source separation and/or cross-correlation methods. For example, the first and second light information may be processed with principal component analysis (one example method of blind source separation), to separate out a plurality of linearly uncorrelated component signals. Those components may then be further processed with a cross-correlation method, serving as a second filter, to compute a heart rate signal. In some examples, the first light information may include light information of red, green, and blue wavelengths, and the second light information may also include light information of red, green, and blue wavelengths, although any number and combination of wavelengths is possible. In some examples, the computed heart rate signal may

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include one or more additional signals, such as residual noise and/or a signal corresponding to a respiratory rate of a user, among other possibilities.

[0021] FIG. 3 illustrates a method of computing a heart rate signal based on multiple wavelengths of contacting and non-contacting light information. Red, green, and blue contacting light information (300) may be processed with blind source separation (e.g., principal component analysis, among other possibilities) (304). Further, red, green, and blue non-contacting light information (302) may be processed with blind source separation (306). The results of the contacting and non-contacting blind source separation processes may be cross-correlated (308), and the result may be a heart rate signal with reduced noise (310).

[0022] The examples discussed above can be implemented in one or more Application Programming Interfaces (APIs). An API is an interface implemented by a program code component or hardware component (hereinafter "API-implementing component") that allows a different program code component or hardware component (hereinafter "API-calling component") to access and use one or more functions, methods, procedures, data structures, classes, and/or other services provided by the API-implementing component. An API can define one or more parameters that are passed between the API-calling component and the API-implementing component.

[0023] The above-described features can be implemented as part of an application program interface (API) that can allow it to be incorporated into different applications (*e.g.*, spreadsheet apps) utilizing touch input as an input mechanism. An API can allow a developer of an API-calling component (which may be a third party developer) to leverage specified features, such as those described above, provided by an API-implementing component. There may be one API-calling component or there may be more than one such component. An API can be a source code interface that a computer system or program library provides in order to support requests for services from an application. An operating system (OS) can have multiple APIs to allow applications running on the OS to call one or more of those APIs, and a service (such as a program library) can have multiple APIs to allow an application that uses the service to call one or more of those APIs. An API can be specified in terms of a programming language that can be interpreted or compiled when an application is built.

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[0024] In some examples, the API-implementing component may provide more than one API, each providing a different view of the functionality implemented by the API-implementing component, or with different aspects that access different aspects of the functionality implemented by the API-implementing component. For example, one API of an API-implementing component can provide a first set of functions and can be exposed to third party developers, and another API of the API-implementing component can be hidden (not exposed) and provide a subset of the first set of functions and also provide another set of functions, such as testing or debugging functions which are not in the first set of functions. In other examples the API-implementing component may itself call one or more other components via an underlying API and thus be both an API-calling component and an API-implementing component.

[0025] An API defines the language and parameters that API-calling components use when accessing and using specified features of the API-implementing component. For example, an API-calling component accesses the specified features of the API-implementing component through one or more API calls or invocations (embodied for example by function or method calls) exposed by the API and passes data and control information using parameters via the API calls or invocations. The API-implementing component may return a value through the API in response to an API call from an API-calling component. While the API defines the syntax and result of an API call (e.g., how to invoke the API call and what the API call does), the API may not reveal how the API call accomplishes the function specified by the API call. Various API calls are transferred via the one or more application programming interfaces between the calling (API-calling component) and an API-implementing component. Transferring the API calls may include issuing, initiating, invoking, calling, receiving, returning, or responding to the function calls or messages; in other words, transferring can describe actions by either of the API-calling component or the API-implementing component. The function calls or other invocations of the API may send or receive one or more parameters through a parameter list or other structure. A parameter can be a constant, key, data structure, object, object class, variable, data type, pointer, array, list or a pointer to a function or method or another way to reference a data or other item to be passed via the API.

[0026] Furthermore, data types or classes may be provided by the API and implemented by the API-implementing component. Thus, the API-calling component

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may declare variables, use pointers to, use or instantiate constant values of such types or classes by using definitions provided in the API.

[0027] Generally, an API can be used to access a service or data provided by the API-implementing component or to initiate performance of an operation or computation provided by the API-implementing component. By way of example, the API-implementing component and the API-calling component may each be any one of an operating system, a library, a device driver, an API, an application program, or other module (it should be understood that the API-implementing component and the API-calling component may be the same or different type of module from each other). API-implementing components may in some cases be embodied at least in part in firmware, microcode, or other hardware logic. In some examples, an API may allow a client program to use the services provided by a Software Development Kit (SDK) library. In other examples an application or other client program may use an API provided by an Application Framework. In these examples the application or client program may incorporate calls to functions or methods provided by the SDK and provided by the API or use data types or objects defined in the SDK and provided by the API. An Application Framework may in these examples provide a main event loop for a program that responds to various events defined by the Framework. The API allows the application to specify the events and the responses to the events using the Application Framework. In some implementations, an API call can report to an application the capabilities or state of a hardware device, including those related to aspects such as input capabilities and state, output capabilities and state, processing capability, power state, storage capacity and state, communications capability, etc., and the API may be implemented in part by firmware, microcode, or other low level logic that executes in part on the hardware component.

[0028] The API-calling component may be a local component (i.e., on the same data processing system as the API-implementing component) or a remote component (i.e., on a different data processing system from the API-implementing component) that communicates with the API-implementing component through the API over a network. It should be understood that an API-implementing component may also act as an API-calling component (i.e., it may make API calls to an API exposed by a different API-implementing component) and an API-calling component may also act as an API-

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implementing component by implementing an API that is exposed to a different API-calling component.

[0029] The API may allow multiple API-calling components written in different programming languages to communicate with the API-implementing component (thus the API may include features for translating calls and returns between the API-implementing component and the API-calling component); however the API may be implemented in terms of a specific programming language. An API-calling component can, in one example, call APIs from different providers such as a set of APIs from an OS provider and another set of APIs from a plug-in provider and another set of APIs from another provider (e.g. the provider of a software library) or creator of the another set of APIs.

[0030] FIG. 4 is a block diagram illustrating an exemplary API architecture, which may be used in some examples of the disclosure. As shown in FIG. 4, the API architecture 600 includes the API-implementing component 610 (e.g., an operating system, a library, a device driver, an API, an application program, software or other module) that implements the API 620. The API 620 specifies one or more functions, methods, classes, objects, protocols, data structures, formats and/or other features of the API-implementing component that may be used by the API-calling component 630. The API 620 can specify at least one calling convention that specifies how a function in the API-implementing component receives parameters from the API-calling component and how the function returns a result to the API-calling component. The API-calling component 630 (e.g., an operating system, a library, a device driver, an API, an application program, software or other module), makes API calls through the API 620 to access and use the features of the API-implementing component 610 that are specified by the API 620. The API-implementing component 610 may return a value through the API 620 to the API-calling component 630 in response to an API call.

[0031] It will be appreciated that the API-implementing component 610 may include additional functions, methods, classes, data structures, and/or other features that are not specified through the API 620 and are not available to the API-calling component 630. It should be understood that the API-calling component 630 may be on the same system as the API-implementing component 610 or may be located remotely and accesses the API-implementing component 610 using the API 620 over a network. While FIG. 4 illustrates a single API-calling component 630 interacting with the API 620, it should be

understood that other API-calling components, which may be written in different languages (or the same language) than the API-calling component 630, may use the API 620.

[0032] The API-implementing component 610, the API 620, and the API-calling component 630 may be stored in a non-transitory machine-readable storage medium, which includes any mechanism for storing information in a form readable by a machine (e.g., a computer or other data processing system). For example, a machine-readable medium includes magnetic disks, optical disks, random access memory; read only memory, flash memory devices, etc.

[0033] In the exemplary software stack shown in FIG. 5, applications can make calls to Services A or B using several Service APIs and to Operating System (OS) using several OS APIs. Services A and B can make calls to OS using several OS APIs.

[0034] Note that the Service 2 has two APIs, one of which (Service 2 API 1) receives calls from and returns values to Application 1 and the other (Service 2 API 2) receives calls from and returns values to Application 2. Service 1 (which can be, for example, a software library) makes calls to and receives returned values from OS API 1, and Service 2 (which can be, for example, a software library) makes calls to and receives returned values from both OS API 1 and OS API 2. Application 2 makes calls to and receives returned values from OS API 2.

[0035] FIG. 6 is a block diagram illustrating exemplary interactions between the touch screen and the other components of the device. Described examples may include touch I/O device 1001 that can receive touch input for interacting with computing system 1003 via wired or wireless communication channel 1002. Touch I/O device 1001 may be used to provide user input to computing system 1003 in lieu of or in combination with other input devices such as a keyboard, mouse, etc. One or more touch I/O devices 1001 may be used for providing user input to computing system 1003. Touch I/O device 1001 may be an integral part of computing system 1003 (e.g., touch screen on a smartphone or a tablet PC) or may be separate from computing system 1003.

[0036] Touch I/O device 1001 may include a touch sensing panel which is wholly or partially transparent, semitransparent, non-transparent, opaque or any combination thereof. Touch I/O device 1001 may be embodied as a touch screen, touch pad, a touch

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screen functioning as a touch pad (e.g., a touch screen replacing the touchpad of a laptop), a touch screen or touchpad combined or incorporated with any other input device (e.g., a touch screen or touchpad disposed on a keyboard) or any multi-dimensional object having a touch sensing surface for receiving touch input.

[0037] In one example, touch I/O device 1001 embodied as a touch screen may include a transparent and/or semitransparent touch sensing panel partially or wholly positioned over at least a portion of a display. According to this example, touch I/O device 1001 functions to display graphical data transmitted from computing system 1003 (and/or another source) and also functions to receive user input. In other examples, touch I/O device 1001 may be embodied as an integrated touch screen where touch sensing components/devices are integral with display components/devices. In still other examples a touch screen may be used as a supplemental or additional display screen for displaying supplemental or the same graphical data as a primary display and to receive touch input.

[0038] Touch I/O device 1001 may be configured to detect the location of one or more touches or near touches on device 1001 based on capacitive, resistive, optical, acoustic, inductive, mechanical, chemical measurements, or any phenomena that can be measured with respect to the occurrences of the one or more touches or near touches in proximity to device 1001. Software, hardware, firmware or any combination thereof may be used to process the measurements of the detected touches to identify and track one or more gestures. A gesture may correspond to stationary or non-stationary, single or multiple, touches or near touches on touch I/O device 1001. A gesture may be performed by moving one or more fingers or other objects in a particular manner on touch I/O device 1001 such as tapping, pressing, rocking, scrubbing, twisting, changing orientation, pressing with varying pressure and the like at essentially the same time, contiguously, or consecutively. A gesture may be characterized by, but is not limited to a pinching, sliding, swiping, rotating, flexing, dragging, or tapping motion between or with any other finger or fingers. A single gesture may be performed with one or more hands, by one or more users, or any combination thereof.

[0039] Computing system 1003 may drive a display with graphical data to display a graphical user interface (GUI). The GUI may be configured to receive touch input via touch I/O device 1001. Embodied as a touch screen, touch I/O device 1001 may display the GUI. Alternatively, the GUI may be displayed on a display separate from touch I/O

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device 1001. The GUI may include graphical elements displayed at particular locations within the interface. Graphical elements may include but are not limited to a variety of displayed virtual input devices including virtual scroll wheels, a virtual keyboard, virtual knobs, virtual buttons, any virtual UI, and the like. A user may perform gestures at one or more particular locations on touch I/O device 1001 which may be associated with the graphical elements of the GUI. In other examples, the user may perform gestures at one or more locations that are independent of the locations of graphical elements of the GUI. Gestures performed on touch I/O device 1001 may directly or indirectly manipulate, control, modify, move, actuate, initiate or generally affect graphical elements such as cursors, icons, media files, lists, text, all or portions of images, or the like within the GUI. For instance, in the case of a touch screen, a user may directly interact with a graphical element by performing a gesture over the graphical element on the touch screen. Alternatively, a touch pad generally provides indirect interaction. Gestures may also affect non-displayed GUI elements (e.g., causing user interfaces to appear) or may affect other actions within computing system 1003 (e.g., affect a state or mode of a GUI, application, or operating system). Gestures may or may not be performed on touch I/O device 1001 in conjunction with a displayed cursor. For instance, in the case in which gestures are performed on a touchpad, a cursor (or pointer) may be displayed on a display screen or touch screen and the cursor may be controlled via touch input on the touchpad to interact with graphical objects on the display screen. In other examples in which gestures are performed directly on a touch screen, a user may interact directly with objects on the touch screen, with or without a cursor or pointer being displayed on the touch screen.

[0040] Feedback may be provided to the user via communication channel 1002 in response to or based on the touch or near touches on touch I/O device 1001. Feedback may be transmitted optically, mechanically, electrically, olfactory, acoustically, or the like or any combination thereof and in a variable or non-variable manner.

[0041] Attention is now directed towards examples of a system architecture that may be embodied within any portable or non-portable device including but not limited to a communication device (e.g. mobile phone, smart phone), a multi-media device (e.g., MP3 player, TV, radio), a portable or handheld computer (e.g., tablet, netbook, laptop), a desktop computer, an All-In-One desktop, a peripheral device, or any other system or

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device adaptable to the inclusion of system architecture 2000, including combinations of two or more of these types of devices. FIG. 7 is a block diagram of one example of system 2000 that generally includes one or more computer-readable mediums 2001, processing system 2004, I/O subsystem 2006, radio frequency (RF) circuitry 2008, audio circuitry 2010, and sensors circuitry 2011. These components may be coupled by one or more communication buses or signal lines 2003.

[0042] It should be apparent that the architecture shown in FIG. 7 is only one example architecture of system 2000, and that system 2000 could have more or fewer components than shown, or a different configuration of components. The various components shown in FIG. 7 can be implemented in hardware, software, firmware or any combination thereof, including one or more signal processing and/or application specific integrated circuits.

[0043] RF circuitry 2008 can be used to send and receive information over a wireless link or network to one or more other devices and includes well-known circuitry for performing this function. RF circuitry 2008 and audio circuitry 2010 can be coupled to processing system 2004 via peripherals interface 2016. Interface 2016 can include various known components for establishing and maintaining communication between peripherals and processing system 2004. Audio circuitry 2010 can be coupled to audio speaker 2050 and microphone 2052 and can include known circuitry for processing voice signals received from interface 2016 to enable a user to communicate in real-time with other users. In some examples, audio circuitry 2010 can include a headphone jack (not shown). Sensors circuitry 2011 can be coupled to various sensors including, but not limited to, one or more Light Emitting Diodes (LEDs) or other light emitters, one or more photodiodes or other light sensors, one or more photothermal sensors, a magnetometer, an accelerometer, a gyroscope, a barometer, a compass, a proximity sensor, a camera, an ambient light sensor, a thermometer, a GPS sensor, and various system sensors which can sense remaining battery life, power consumption, processor speed, CPU load, and the like.

[0044] Peripherals interface 2016 can couple the input and output peripherals of the system to processor 2018 and computer-readable medium 2001. One or more processors 2018 communicate with one or more computer-readable mediums 2001 via controller 2020. Computer-readable medium 2001 can be any device or medium that can

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store code and/or data for use by one or more processors 2018. In some examples, medium 2001 can be a non-transitory computer-readable storage medium. Medium 2001 can include a memory hierarchy, including but not limited to cache, main memory and secondary memory. The memory hierarchy can be implemented using any combination of RAM (*e.g.*, SRAM, DRAM, DDRAM), ROM, FLASH, magnetic and/or optical storage devices, such as disk drives, magnetic tape, CDs (compact disks) and DVDs (digital video discs). Medium 2001 may also include a transmission medium for carrying information-bearing signals indicative of computer instructions or data (with or without a carrier wave upon which the signals are modulated). For example, the transmission medium may include a communications network, including but not limited to the Internet (also referred to as the World Wide Web), intranet(s), Local Area Networks (LANs), Wide Local Area Networks (WLANs), Storage Area Networks (SANs), Metropolitan Area Networks (MAN) and the like.

[0045] One or more processors 2018 can run various software components stored in medium 2001 to perform various functions for system 2000. In some examples, the software components can include operating system 2022, communication module (or set of instructions) 2024, touch processing module (or set of instructions) 2026, graphics module (or set of instructions) 2028, and one or more applications (or set of instructions) 2030. Each of these modules and above noted applications can correspond to a set of instructions for performing one or more functions described above and the methods described in this application (e.g., the computer-implemented methods and other information processing methods described herein). These modules (i.e., sets of instructions) need not be implemented as separate software programs, procedures or modules, and thus various subsets of these modules may be combined or otherwise re-arranged in various examples. In some examples, medium 2001 may store a subset of the modules and data structures identified above. Furthermore, medium 2001 may store additional modules and data structures not described above.

[0046] Operating system 2022 can include various procedures, sets of instructions, software components and/or drivers for controlling and managing general system tasks (*e.g.*, memory management, storage device control, power management, *etc.*) and facilitates communication between various hardware and software components.

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[0047] Communication module 2024 can facilitate communication with other devices over one or more external ports 2036 or via RF circuitry 2008 and can include various software components for handling data received from RF circuitry 2008 and/or external port 2036.

[0048] Graphics module 2028 can include various known software components for rendering, animating and displaying graphical objects on a display surface. In examples in which touch I/O device 2012 is a touch sensing display (e.g., touch screen), graphics module 2028 can include components for rendering, displaying, and animating objects on the touch sensing display.

[0049] One or more applications 2030 can include any applications installed on system 2000, including without limitation, a browser, address book, contact list, email, instant messaging, word processing, keyboard emulation, widgets, JAVA-enabled applications, encryption, digital rights management, voice recognition, voice replication, location determination capability (such as that provided by the global positioning system (GPS)), a music player, *etc*.

[0050] Touch processing module 2026 can include various software components for performing various tasks associated with touch I/O device 2012 including but not limited to receiving and processing touch input received from I/O device 2012 via touch I/O device controller 2032.

[0051] I/O subsystem 2006 can be coupled to touch I/O device 2012 and one or more other I/O devices 2014 for controlling or performing various functions. Touch I/O device 2012 can communicate with processing system 2004 via touch I/O device controller 2032, which can include various components for processing user touch input (*e.g.*, scanning hardware). One or more other input controllers 2034 can receive/send electrical signals from/to other I/O devices 2014. Other I/O devices 2014 may include physical buttons, dials, slider switches, sticks, keyboards, touch pads, additional display screens, or any combination thereof.

[0052] If embodied as a touch screen, touch I/O device 2012 can display visual output to the user in a GUI. The visual output may include text, graphics, video, and any combination thereof. Some or all of the visual output may correspond to user-interface objects. Touch I/O device 2012 can form a touch sensing surface that accepts touch input

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from the user. Touch I/O device 2012 and touch screen controller 2032 (along with any associated modules and/or sets of instructions in medium 2001) can detect and track touches or near touches (and any movement or release of the touch) on touch I/O device 2012 and can convert the detected touch input into interaction with graphical objects, such as one or more user-interface objects. In the case in which device 2012 is embodied as a touch screen, the user can directly interact with graphical objects that are displayed on the touch screen. Alternatively, in the case in which device 2012 is embodied as a touch device other than a touch screen (e.g., a touch pad), the user may indirectly interact with graphical objects that are displayed on a separate display screen embodied as I/O device 2014.

[0053] Touch I/O device 2012 may be analogous to the multi-touch sensing surface described in the following U.S. Patents: 6,323,846 (Westerman et al.), 6,570,557 (Westerman et al.), and/or 6,677,932 (Westerman), and/or U.S. Patent Publication 2002/0015024A1, each of which is hereby incorporated by reference.

[0054] In examples for which touch I/O device 2012 is a touch screen, the touch screen may use LCD (liquid crystal display) technology, LPD (light emitting polymer display) technology, OLED (organic LED), or OEL (organic electro luminescence), although other display technologies may be used in other examples.

[0055] Feedback may be provided by touch I/O device 2012 based on the user's touch input as well as a state or states of what is being displayed and/or of the computing system. Feedback may be transmitted optically (e.g., light signal or displayed image), mechanically (e.g., haptic feedback, touch feedback, force feedback, or the like), electrically (e.g., electrical stimulation), olfactory, acoustically (e.g., beep or the like), or the like or any combination thereof and in a variable or non-variable manner.

[0056] System 2000 can also include power system 2044 for powering the various hardware components and may include a power management system, one or more power sources, a recharging system, a power failure detection circuit, a power converter or inverter, a power status indicator and any other components typically associated with the generation, management and distribution of power in portable devices.

[0057] In some examples, peripherals interface 2016, one or more processors 2018, and memory controller 2020 may be implemented on a single chip, such as

processing system 2004. In some other examples, they may be implemented on separate chips.

[0058] Examples of the disclosure can be advantageous in allowing for an electronic device to obtain a heart rate signal with reduced noise due to motion artifacts, making for a more accurate reading of heart rate.

[0059] In some examples, a method of an electronic device including a plurality of light emitters, a plurality of light sensors, and a plurality of light guides is disclosed. The method may include: emitting light from each of the plurality of light emitters through respective light guides, wherein a contacting light guide may be configured to contact tissue of a user and a non-contacting light may be configured not to contact tissue of the user; receiving first light information from the contacting light guide; receiving second light information from the non-contacting light guide; and computing a heart rate signal based on the first and second light information. Additionally or alternatively to one or more of the above examples, a surface of the contacting light guide may be curved such that the surface is configured to contact tissue of the user. Additionally or alternatively to one or more of the above examples, the non-contacting light guide may be recessed with respect to the electronic device such that the non-contacting light guide may be configured not to contact tissue of the user. Additionally or alternatively to one or more of the above examples, computing the heart rate signal based on the first and second light information may include performing blind source separation on the first and second light information. Additionally or alternatively to one or more of the above examples, computing the heart rate signal based on the first and second light information may include performing cross-correlation on the first and second light information. Additionally or alternatively to one or more of the above examples, emitting light through the contacting light guide may include emitting light of a plurality of wavelengths through the contacting light guide; and wherein computing the heart rate signal may include performing blind source separation on light information of the plurality of wavelengths. Additionally or alternatively to one or more of the above examples, the plurality of wavelengths may include wavelengths of red, green, and blue light. Additionally or alternatively to one or more of the above examples, one or more of the plurality of light sensors may be in contact with respective light guides through which

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light is sensed, and one or more of the plurality of light sensors may be not in contact with respective light guides through which light is sensed.

[0060] In some examples, a non-transitory computer readable medium is disclosed. The non-transitory computer readable medium may contain instructions that, when executed, perform a method of an electronic device including a plurality of light emitters, a plurality of light sensors, and a plurality of light guides. The method may include: emitting light from each of the plurality of light emitters through respective light guides, wherein a contacting light guide may be configured to contact tissue of a user and a non-contacting light may be configured not to contact tissue of the user; receiving first light information from the contacting light guide; receiving second light information from the non-contacting light guide; and computing a heart rate signal based on the first and second light information. Additionally or alternatively to one or more of the above examples, a surface of the contacting light guide may be curved such that the surface is configured to contact tissue of the user. Additionally or alternatively to one or more of the above examples, the non-contacting light guide may be recessed with respect to the electronic device such that the non-contacting light guide may be configured not to contact tissue of the user. Additionally or alternatively to one or more of the above examples, computing the heart rate signal based on the first and second light information may include performing blind source separation on the first and second light information. Additionally or alternatively to one or more of the above examples, computing the heart rate signal based on the first and second light information may include performing cross-correlation on the first and second light information. Additionally or alternatively to one or more of the above examples, emitting light through the contacting light guide may include emitting light of a plurality of wavelengths through the contacting light guide; and wherein computing the heart rate signal may include performing blind source separation on light information of the plurality of wavelengths. Additionally or alternatively to one or more of the above examples, the plurality of wavelengths may include wavelengths of red, green, and blue light. Additionally or alternatively to one or more of the above examples, one or more of the plurality of light sensors may be in contact with respective light guides through which light is sensed, and one or more of the plurality of light sensors may be not in contact with respective light guides through which light is sensed.

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[0061] In some examples, an electronic device is disclosed. The electronic device may include: a processor to execute instructions; a plurality of light emitters; a plurality of light sensors; a plurality of light guides; and a memory coupled with the processor to store instructions, which when executed by the processor, may cause the processor to perform operations to generate an application programming interface (API) that allows an API-calling component to perform a method. The method may include: emitting light from each of the plurality of light emitters through respective light guides, wherein a contacting light guide may be configured to contact tissue of a user and a non-contacting light may be configured not to contact tissue of the user; receiving first light information from the contacting light guide; receiving second light information from the non-contacting light guide; and computing a heart rate signal based on the first and second light information. Additionally or alternatively to one or more of the above examples, a surface of the contacting light guide may be curved such that the surface is configured to contact tissue of the user. Additionally or alternatively to one or more of the above examples, the non-contacting light guide may be recessed with respect to the electronic device such that the non-contacting light guide may be configured not to contact tissue of the user. Additionally or alternatively to one or more of the above examples, computing the heart rate signal based on the first and second light information may include performing blind source separation on the first and second light information. Additionally or alternatively to one or more of the above examples, computing the heart rate signal based on the first and second light information may include performing cross-correlation on the first and second light information. Additionally or alternatively to one or more of the above examples, emitting light through the contacting light guide may include emitting light of a plurality of wavelengths through the contacting light guide; and wherein computing the heart rate signal may include performing blind source separation on light information of the plurality of wavelengths. Additionally or alternatively to one or more of the above examples, the plurality of wavelengths may include wavelengths of red, green, and blue light. Additionally or alternatively to one or more of the above examples, one or more of the plurality of light sensors may be in contact with respective light guides through which light is sensed, and one or more of the plurality of light sensors may be not in contact with respective light guides through which light is sensed.

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[0062] Although the disclosed examples have been fully described with reference to the accompanying drawings, it is to be noted that various changes and modifications will become apparent to those skilled in the art. Such changes and modifications are to be understood as being included within the scope of the disclosed examples as defined by the appended claims.

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WHAT IS CLAIMED IS:

1. A method of an electronic device including a plurality of light emitters, a plurality of light sensors, and a plurality of light guides, the method comprising:

emitting light from each of the plurality of light emitters through respective light guides, wherein a contacting light guide is configured to contact tissue of a user and a non-contacting light is configured not to contact tissue of the user;

receiving first light information from the contacting light guide;

receiving second light information from the non-contacting light guide; and

computing a heart rate signal based on the first and second light information.

2. The method of claim 1, wherein a surface of the contacting light guide is curved such that the surface is configured to contact tissue of the user.

3. The method of claim 1, wherein the non-contacting light guide is recessed with respect to the electronic device such that the non-contacting light guide is configured not to contact tissue of the user.

4. The method of claim 1, wherein computing the heart rate signal based on the first and second light information includes performing blind source separation on the first and second light information.

5. The method of claim 1, wherein computing the heart rate signal based on the first and second light information includes performing cross-correlation on the first and second light information.

6. The method of claim 1, wherein emitting light through the contacting light guide includes emitting light of a plurality of wavelengths through the contacting light guide; and

wherein computing the heart rate signal includes performing blind source separation on light information of the plurality of wavelengths.

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7. The method of claim 6, wherein the plurality of wavelengths include wavelengths of red, green, and blue light.

8. The method of claim 1, wherein one or more of the plurality of light sensors are in contact with respective light guides through which light is sensed, and one or more of the plurality of light sensors are not in contact with respective light guides through which light is sensed.

9. A non-transitory computer readable medium, the computer readable medium containing instructions that, when executed, perform a method of an electronic device including a plurality of light emitters, a plurality of light sensors, and a plurality of light guides, the method comprising:

emitting light from each of the plurality of light emitters through respective light guides, wherein a contacting light guide is configured to contact tissue of a user and a non-contacting light is configured not to contact tissue of the user;

receiving first light information from the contacting light guide;

receiving second light information from the non-contacting light guide; and

computing a heart rate signal based on the first and second light information.

10. The non-transitory computer readable medium of claim 9, wherein a surface of the contacting light guide is curved such that the surface is configured to contact tissue of the user.

11. The non-transitory computer readable medium of claim 9, wherein the non-contacting light guide is recessed with respect to the electronic device such that the non-contacting light guide is configured not to contact tissue of the user.

12. The non-transitory computer readable medium of claim 9, wherein computing the heart rate signal based on the first and second light information includes performing blind source separation on the first and second light information.

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13. The non-transitory computer readable medium of claim 9, wherein computing the heart rate signal based on the first and second light information includes performing cross-correlation on the first and second light information.

14. The non-transitory computer readable medium of claim 9, wherein emitting light through the contacting light guide includes emitting light of a plurality of wavelengths through the contacting light guide; and

wherein computing the heart rate signal includes performing blind source separation on light information of the plurality of wavelengths.

15. The non-transitory computer readable medium of claim 14, wherein the plurality of wavelengths include wavelengths of red, green, and blue light.

16. The non-transitory computer readable medium of claim 9, wherein one or more of the plurality of light sensors are in contact with respective light guides through which light is sensed, and one or more of the plurality of light sensors are not in contact with respective light guides through which light is sensed.

17. An electronic device, comprising:

a processor to execute instructions;

a plurality of light emitters;

a plurality of light sensors;

a plurality of light guides; and

a memory coupled with the processor to store instructions, which when executed by the processor, cause the processor to perform operations to generate an application programming interface (API) that allows an API-calling component to perform a method comprising:

emitting light from each of the plurality of light emitters through respective light guides, wherein a contacting light guide is configured to contact tissue of a user and a non-contacting light is configured not to contact tissue of the user;

receiving first light information from the contacting light guide;

receiving second light information from the non-contacting light guide; and

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computing a heart rate signal based on the first and second light information.

18. The electronic device of claim 17, wherein a surface of the contacting light guide is curved such that the surface is configured to contact tissue of the user.

19. The electronic device of claim 17, wherein the non-contacting light guide is recessed with respect to the electronic device such that the non-contacting light guide is configured not to contact tissue of the user.

20. The electronic device of claim 17, wherein computing the heart rate signal based on the first and second light information includes performing blind source separation on the first and second light information.

21. The electronic device of claim 17, wherein computing the heart rate signal based on the first and second light information includes performing cross-correlation on the first and second light information.

22. The electronic device of claim 17, wherein emitting light through the contacting light guide includes emitting light of a plurality of wavelengths through the contacting light guide; and

wherein computing the heart rate signal includes performing blind source separation on light information of the plurality of wavelengths.

23. The electronic device of claim 22, wherein the plurality of wavelengths include wavelengths of red, green, and blue light.

24. The electronic device of claim 17, wherein one or more of the plurality of light sensors are in contact with respective light guides through which light is sensed, and one or more of the plurality of light sensors are not in contact with respective light guides through which light is sensed.

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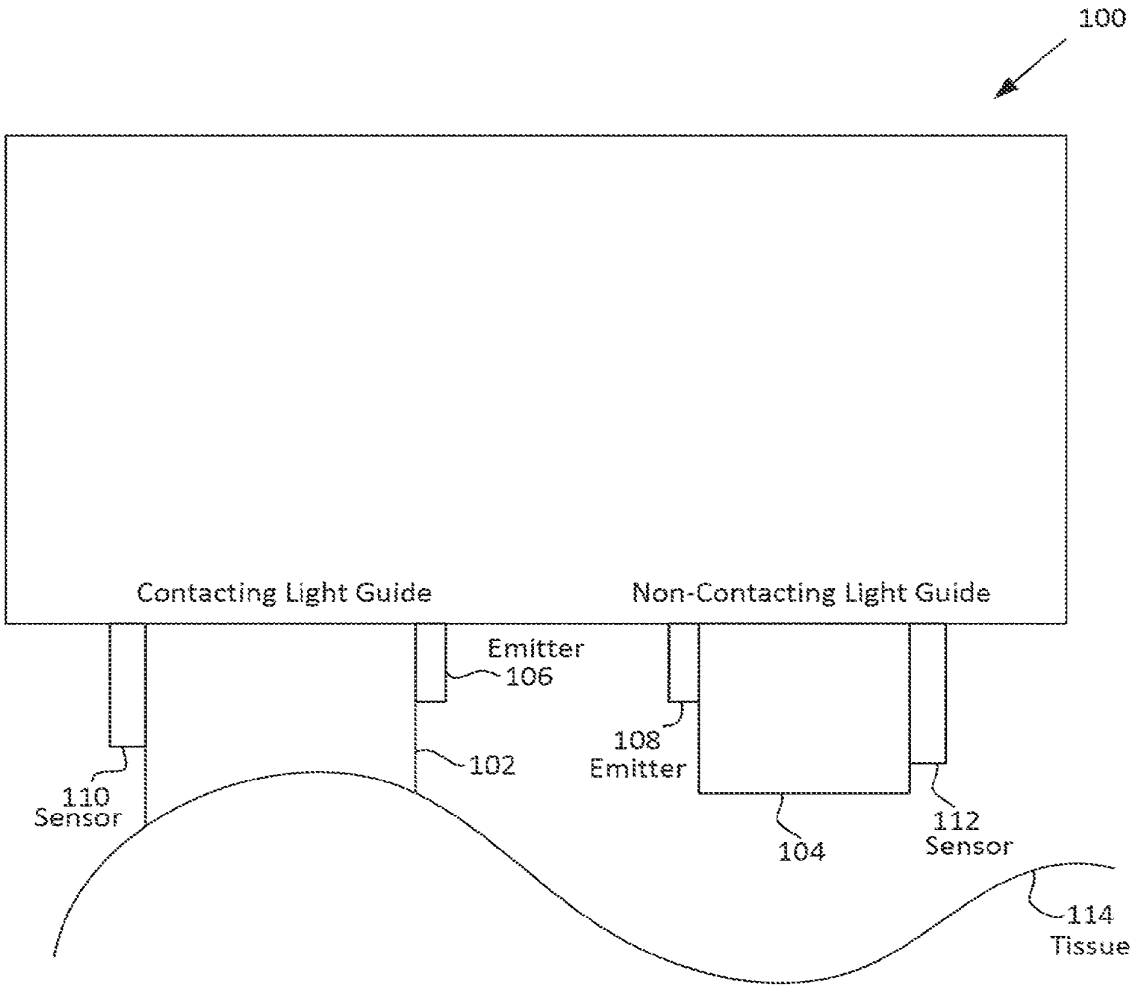

100
Contacting Light Guide
Non-Contacting Light Guide
Emitter
106
102
108
Emitter
110
Sensor
104
112
Sensor
114
Tissue

FIG. 1

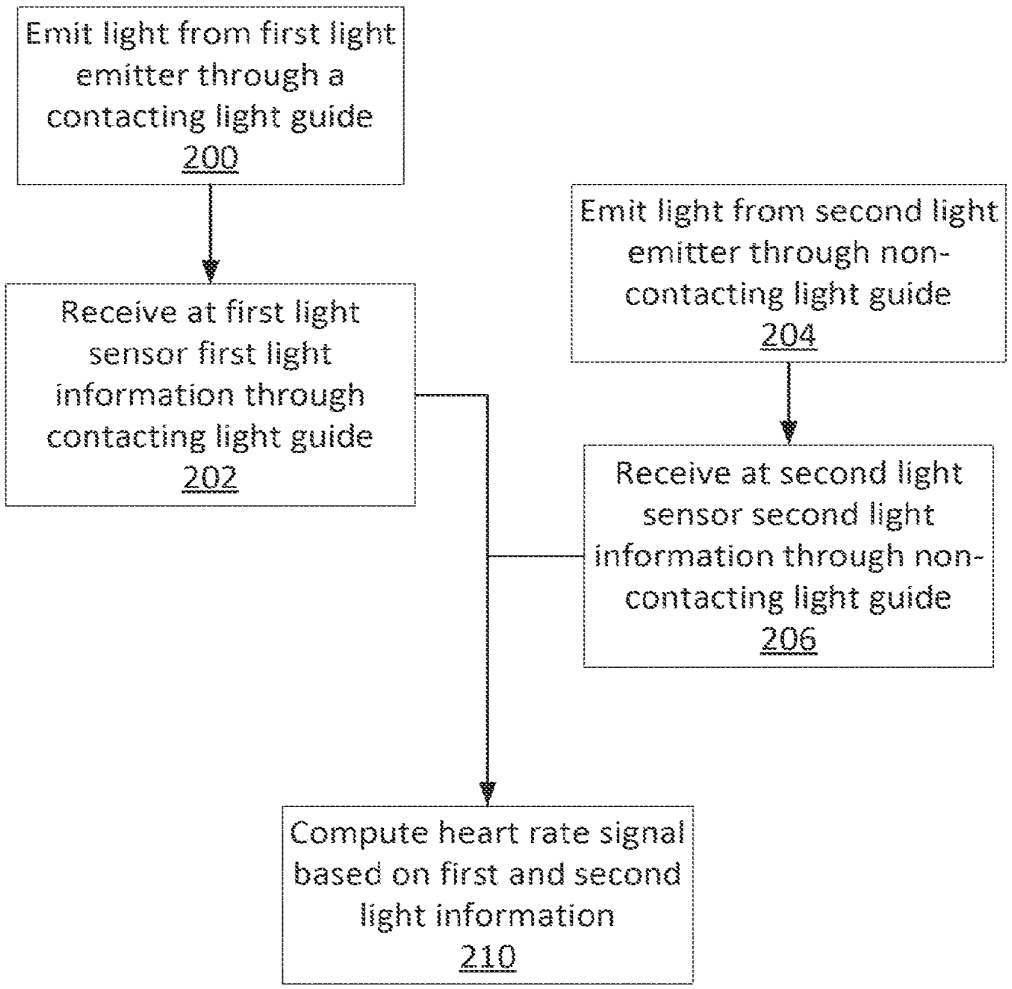

Emit light from first light emitter through a contacting light guide
200
Receive at first light sensor first light information through contacting light guide
202
Emit light from second light emitter through non-contacting light guide
204
Receive at second light sensor second light information through non-contacting light guide
206
Compute heart rate signal based on first and second light information
210

FIG. 2

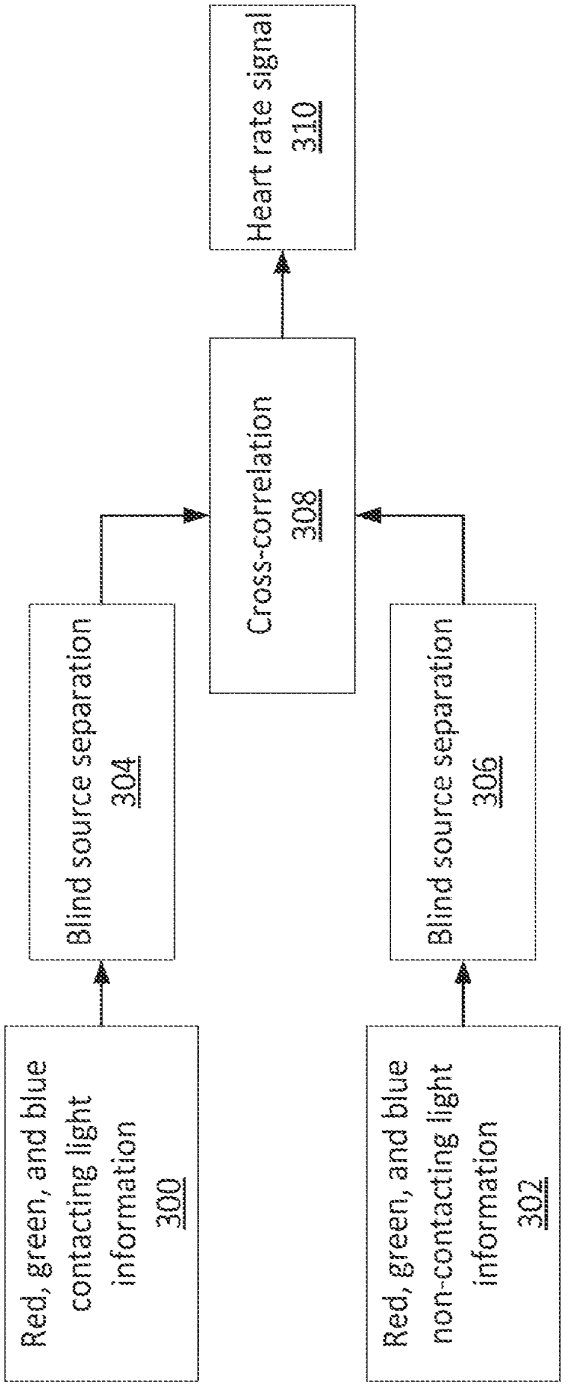


FIG. 3

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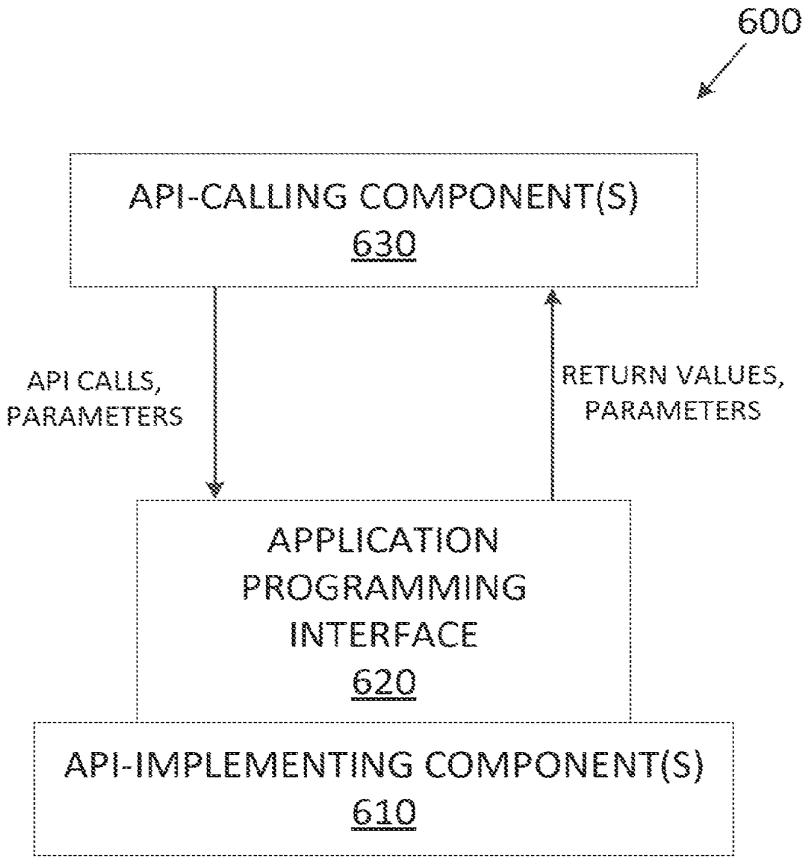

600
API-CALLING COMPONENT(S)
630
API CALLS,
PARAMETERS
RETURN VALUES,
PARAMETERS
APPLICATION
PROGRAMMING
INTERFACE
620
API-IMPLEMENTING COMPONENT(S)
610

FIG. 4

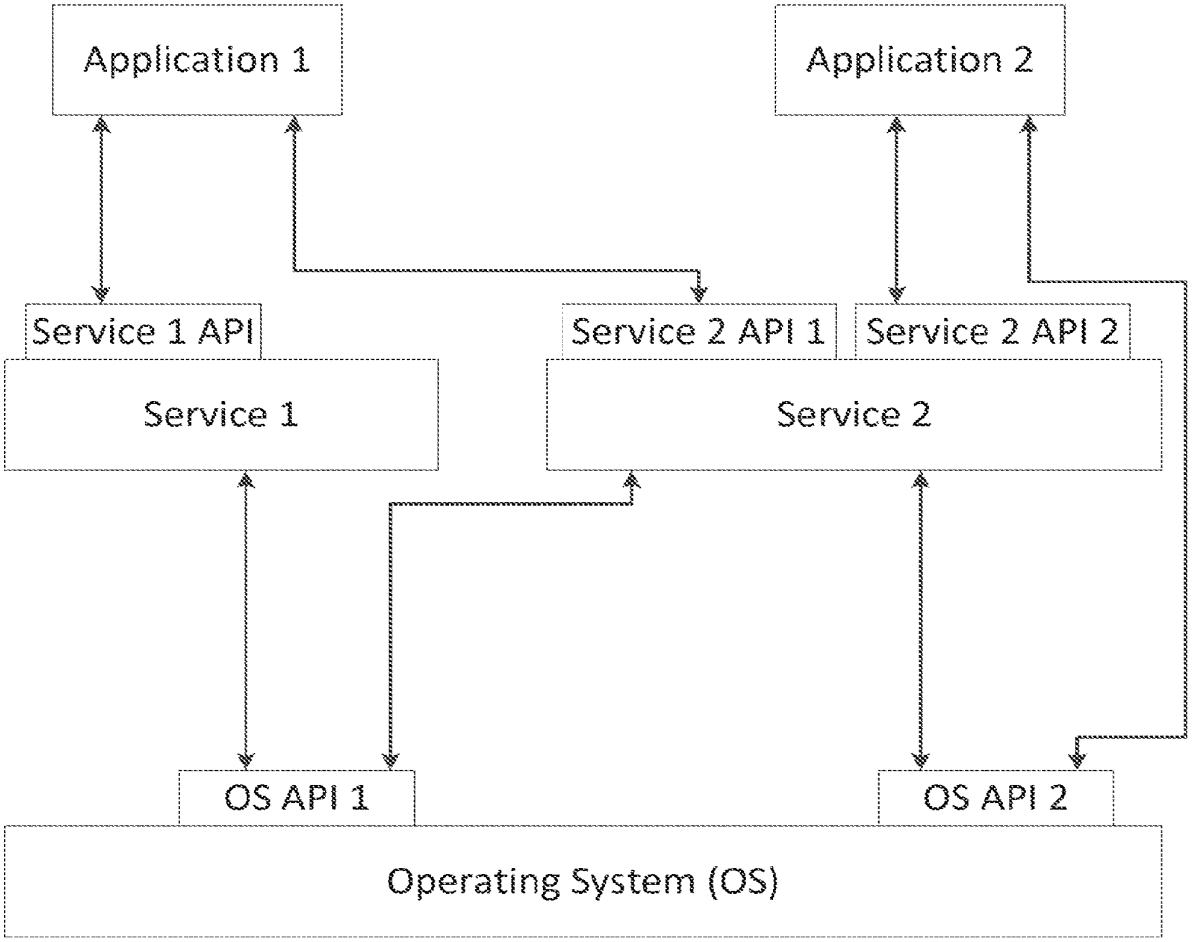

Application 1
Application 2
Service 1 API
Service 2 API 1
Service 2 API 2
Service 1
Service 2
OS API 1
OS API 2
Operating System (OS)

FIG. 5

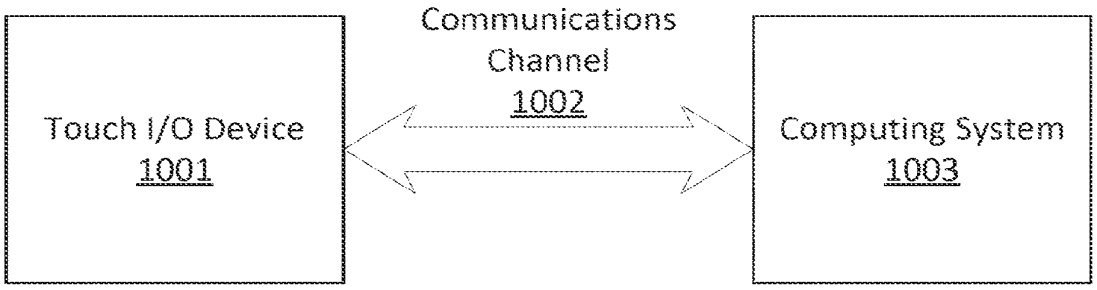

Communications
Channel
1002
Touch I/O Device
1001
Computing System
1003

FIG. 6

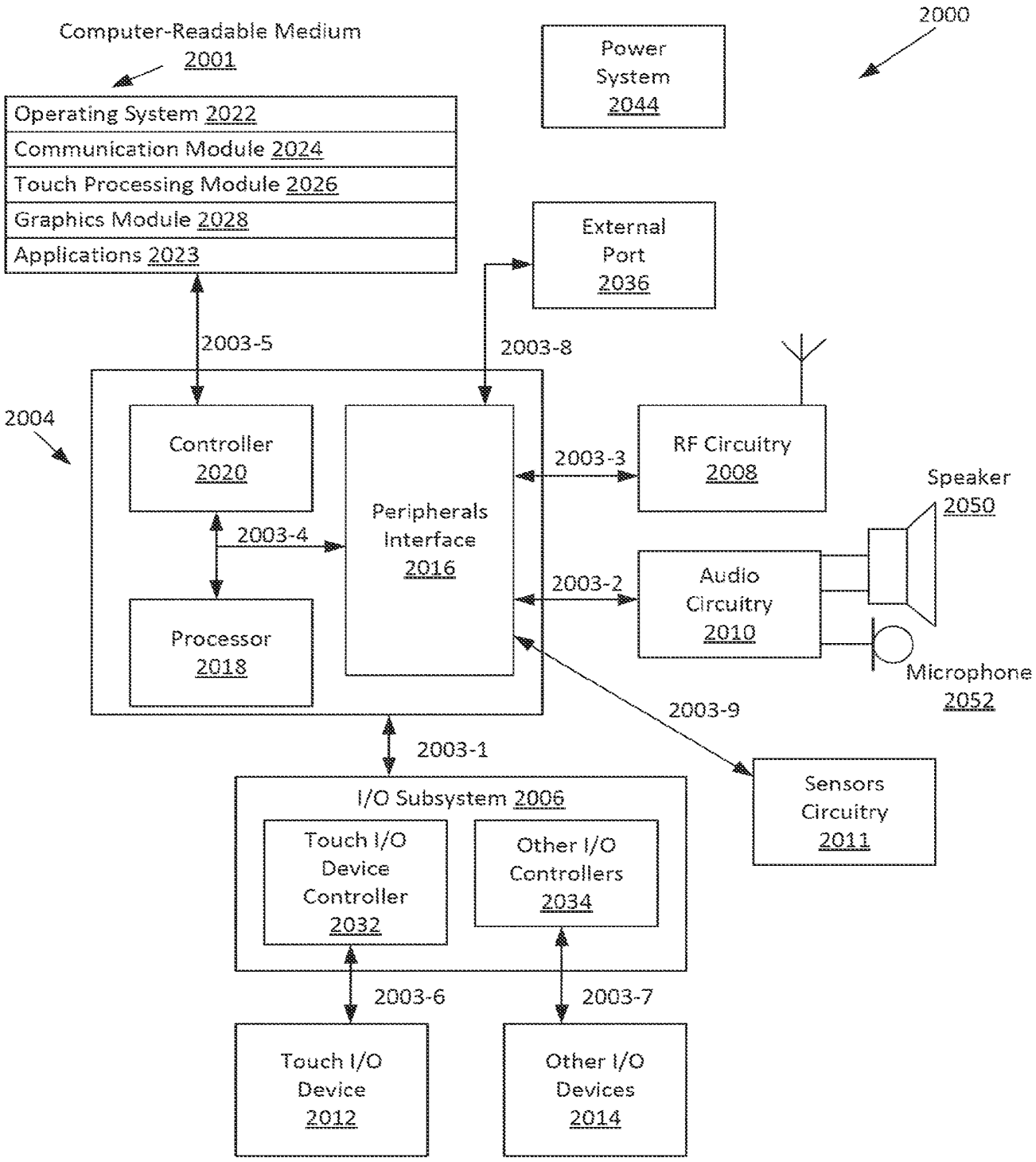

2000
Computer-Readable Medium
2001
Power System
2044
Operating System 2022
Communication Module 2024
Touch Processing Module 2026
Graphics Module 2028
Applications 2023
External Port
2036
2003-5
2003-8
2004
Controller
2020
Peripherals Interface
2016
2003-3
RF Circuitry
2008
Speaker
2050
2003-4
2003-2
Audio Circuitry
2010
Processor
2018
Microphone
2052
2003-9
2003-1
Sensors Circuitry
2011
I/O Subsystem 2006
Touch I/O Device Controller
2032
Other I/O Controllers
2034
2003-6
2003-7
Touch I/O Device
2012
Other I/O Devices
2014

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/073405

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/024 A61B5/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data, BIOSIS, COMPENDEX, EMBASE, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/131519 A1 (LEBOEUF STEVEN FRANCIS [US] ET AL) 23 May 2013 (2013-05-23)	1-3, 7-11, 15-19, 23,24
Y	paragraph [0145] - paragraph [0151] paragraph [0182] - paragraph [0191] paragraph [0194] - paragraph [0196] figures 1-6,13-15,20,21	4-6, 12-14, 20-22
Y	US 2013/131474 A1 (GU REN-HAU [TW] ET AL) 23 May 2013 (2013-05-23) paragraph [0065] paragraph [0070]	4,6,12, 14,20,22
Y	US 2008/033266 A1 (DIAB MOHAMED K [US] ET AL) 7 February 2008 (2008-02-07) paragraph [0273] - paragraph [0277] paragraph [0315] - paragraph [0324]	5,13,21

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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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
15 August 2014	22/08/2014

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

1

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Page 195 of 1089

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/073405

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/088651 A1 (SHUROS ALLAN CHARLES [US] ET AL) 2 April 2009 (2009-04-02) paragraph [0052] paragraph [0064] - paragraph [0071] figures 3A-5 -----	1-24

1

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Petitioner WHOOP, Inc. Ex1002
Page 196 of 1089

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/073405

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013131519 A1	23-05-2013	NONE	
US 2013131474 A1	23-05-2013	TW 201322056 A	01-06-2013
		US 2013131474 A1	23-05-2013
US 2008033266 A1	07-02-2008	US 2008033266 A1	07-02-2008
		US 2009076400 A1	19-03-2009
		US 2009182211 A1	16-07-2009
		US 2012165624 A1	28-06-2012
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		US 2013345523 A1	26-12-2013
US 2009088651 A1	02-04-2009	EP 2211699 A1	04-08-2010
		JP 5043193 B2	10-10-2012
		JP 2010540102 A	24-12-2010
		US 2009088651 A1	02-04-2009
		WO 2009045811 A1	09-04-2009

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI 0105 PUSP1
	Application Number	
Title of Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL	

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 i	US

Mailing Address of Inventor:

Address 1	1718 Newport Creek Drive		
Address 2			
City	Ann Arbor	State/Province	MI
Postal Code	48103	Country i	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.
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☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	109543		
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Application Information:

Title of the Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL		
Attorney Docket Number	OMNI 0105 PUSP1	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	26	Suggested Figure for Publication (if any)	1

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	Application Number	
Title of Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL	

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.

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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, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	14108986	2013-12-17
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
14108986	non provisional of	61747487	2012-12-31

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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(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(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).

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI 0105 PUSP1
	Application Number	
Title of Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL	

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Remove Access Code[i] (if applicable)

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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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☒ Authorization to Permit Access to the Instant Application by the Participating Offices

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In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI 0105 PUSP1
	Application Number	
Title of Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL	

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. [X]

Organization Name	OMNI MEDSCI, INC.		
Mailing Address Information:			
Address 1	1718 Newport Creek Drive		
Address 2			
City	Ann Arbor	**State/Province**	MI
Country [i]	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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	OMNI 0105 PUSP1
	Application Number	
Title of Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL	

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Country i		Postal Code	
Phone Number		Fax Number	
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Signature:

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Signature	/David S. Bir/			Date (YYYY-MM-DD)	2015-10-01
First Name	David	Last Name	Bir	Registration Number	38383

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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.

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

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

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

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

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(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	1	Hori, Takashi, et al., "Flatly broadened, wideband and low noise supercontinuum generation in highly nonlinear hybrid fiber", OPTICS EXPRESS, Vol. 12, No. 2, January 26, 2004, pages 317-324.	☐
	2	Wadsworth, W. J., et al., "Supercontinuum and four-wave mixing with Q-switched pulses in endlessly single-mode photonic crystal fibres", OPTICS EXPRESS, Vol. 12, No. 2, January 26, 2004, pages 299-309.	☐
	3	Hilligsoe, Karen Marie, et al., "Supercontinuum generation in a photonic crystal fiber with two zero dispersion wavelengths", OPTICS EXPRESS, Vol. 12, No. 6, March 22, 2004, pages 1045-1054.	☐
	4	Venugopalan, V., "Optical Society of America BIOMED Topical Meeting Tutorial on Tissue Optics", April 27, 2004, pages 1-32.	☐
	5	Slusher, Richart E., et al., "Large Raman gain and nonlinear phase shifts in high-purity As2So3 chalcogenide fibers", J. Opt. Soc. Am. B, Vol. 21, No. 6, June 2004, pages 1146-1155.	☐
	6	Leon-Saval, S. G., et al., "Supercontinuum generation in submicron fibre waveguides", OPTICS EXPRESS, Vol. 12, No. 13, June 28, 2004, pages 2864-2869.	☐
	7	Nicholson, J. W., et al., "High power, single mode, all-fiber source of femtosecond pulses at 1550 nm and its use in supercontinuum generation", OPTICS EXPRESS, Vol. 12, No. 13, June 28, 2004, pages 3025-3034.	☐
	8	Genty, G., et al., "Enhanced bandwidth of supercontinuum generated m microstructured fibers", OPTICS EXPRESS, Vol. 12, No. 15, July 26, 2004, pages 3471-3480.	☐
	9	Champert, Pierre-Alain, et al., "White-light supercontinuum generation in normally dispersive optical fiber using original multi-wavelength pumping system", OPTICS EXPRESS, Vol. 12, No. 19, September 20, 2004, pages 4366-4371.	☐
	10	Nicholson, J. W., "Supercontinuum generation in ultraviolet-irradiated fibers", OPTICS LETTERS, Vol. 29, No. 20, October 15, 2004, pages 2363-2365.	☐
	11	Hori, Takashi, et al., "Experimental and numerical analysis of widely broadened supercontinuum generation in highly nonlinear dispersion-shifted fiber with a femtosecond pulse", J. Opt. Soc. Am. B, Vol. 21, No. 11, November 2004, pages 1969-1980.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	12	Demircan, Ayhan, et al., "Supercontinuum generation by the modulation instability", Optics Communications 244, 2005, pages 181-185.	☐
	13	Papernyi, S. B., et al., "Sixth-Order Cascaded Raman Amplification", OFC/NFOEC, 2005, 3 pages.	☐
	14	Tanaka, Keiji, "Optical nonlinearity in photonic glasses", Journal of Materials Science: Materials in Electronics 16, 2005, pages 633-643.	☐
	15	Westbrook, Paul S., "Improved Supercontinuum Generation Through UV Processing of Highly Nonlinear Fibers", Journal of Lightwave Technology, Vol. 23, No. 1, January 2005, pages 13-18.	☐
	16	Abeeluck, Akheelesh K., et al., "Continuous-wave pumping in the anomalous- and normal dispersion regimes of nonlinear fibers for supercontinuum generatfon", OPTICS LETTERS, Vol. 30, No. 1, January 1, 2005, pages 61-63.	☐
	17	Kutz, J. Nathan, et al., "Enhanced Supercontinuum Generation through Dispersion-Management', OPTICS EXPRESS, Vol. 13, No. 11, May 30, 2005, pages 3989-3998.	☐
	18	Lee, Ju Han, et al., "Experimental performance comparison for various continuous-wave supercontinuum schemes: ring cavity and single pass structures", OPTICS EXPRESS, Vol. 13, No. 13, June 27, 2005, pages 4848-4853.	☐
	19	Saliminia, A., et al., "Ultra-broad and coherent white light generation in silica glass by focused femtosecond pulses at 1.5pm", OPTICS EXPRESS, Vol. 13, No. 15, July 25, 2005, pages 5731-5738.	☐
	20	Takushima, Yuichi, "High average power, depolarized super-continuum generation using a 1.55-um ASE noise source, OPTICS EXPRESS, Vol. 13, No. 15, July 25, 2005, pages 5871.-5877.	☐
	21	Travers, J. C., et al., "Extended continuous-wave supercontinuum generation in a low-water-loss holey fiber", OPTICS LETTERS, Vol. 30, No. 15, August 1, 2005, pages 1938-1940.	☐
	22	Kobtsev, Serguei M., et al., "Modelling of high-power supercontinuum generation in highly nonlinear, dispersion shifted fibers at CW pump", OPTICS EXPRESS, Vol. 13, No. 18, September 5, 2005, pages 6912-6918.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	23	Falk, Peter, et al., "Supercontinuum generation in a photonic crystal fiber with two zero-dispersion wavelengths tapered to normal dispersion at all wavelengths", OPTICS EXPRESS, Vol. 13, No. 19, September 19, 2005, pages 7535-7540.	☐
	24	Tombelaine, Vincent, et al., "Ultra wide band supercontinuum generation in air-silica holey fibers by SHG-induced modulation instabilities", OPTICS EXPRESS, Vol. 13, No. 19, September 19, 2005, pages 7399-7404.	☐
	25	Lee, Ju Han, et al., "Continuous-wave supercontinuum laser based on an erbium-doped fiber ring cavity incorporating a highly nonlinear optical fiber", OPTICS LETTERS, Vol. 30, No. 19, October 1, 2005, pages 2599-2601.	☐
	26	Genty, G., et al., "Supercontinuum generation in large mode-area microstructured fibers", OPTICS EXPRESS, Vol. 13, No. 21, October 17, 2005, pages 8625-8633.	☐
	27	Schreiber, T., et al., "Supercontinuum generation by femtosecond single and dual wavelength pumping in photonic crystal fibers with two zero dispersion wavelengths", OPTICS EXPRESS, Vol. 13, No. 23, November 14, 2005, pages 9556-9569.	☐
	28	Travers, J. C., et al., "Extended blue supercontinuum generation in cascaded holey fibers", OPTICS LETTERS, Vol. 30, No. 23, December 1, 2005, pages 3132-3134.	☐
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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	1	Islam, M. N., et al., "Broad bandwidths from frequency-shifting solitons in fibers", OPTICS LETTERS, Vol. 14, No. 7, April 1, 1989, pages 370-372.	☐
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	41	Edwards, Glenn S., et al., "Advantage of the Mark-III FEL for biophysical research and biomedical applications", J. Synchrotron Rad. Volume 10, 2003, pages 354-357.	☐
	42	Nicholson, J. W., et al., "Pulsed and continuous-wave supercontinuum generation in highly nonlinear, dispersion-shifted fibers", Applied Physics B 77, 2003, pages 211-218.	☐
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	44	Nicholson, J. W., et al., "All-fiber, octave-spanning supercontinuum", OPTICS LETTERS, Vol. 28, No. 8, April 15, 2003, pages 643-645.	☐

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	45	Faralli, S., et al., "Impact of Double Rayleigh Scattering Noise in Distributed Higher Order Raman Pumping Schemes", IEEE Photonics Technology Letters, Vol. 15, No. 6, June 2003, pages 804-806.	☐
	46	"New and Emerging Techniques - Surgical, Rapid Review, Laser Discectomy", Australian Safety and Efficacy Register of New Interventional Procedures - Surgical, June 2003, 12 pages.	☐
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Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5747806		1998-05-05	Khalil	
	2	6115673		2000-09-05	Malin	
	3	6512936	B1	2003-01-28	MONFRE	
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	9	6587702	B1	2003-07-01	RUCHTI	
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	1	20100331637	A1	2010-12-30	Ting	
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	1	HAZEN, K.H., M.A. Arnold, G.W. Small, "Measurement of glucose and other analytes in undiluted human serum with near-infrared transmission spectroscopy," Analytica Chimica Acta, vol, 371, pp. 255-267 (1998).	☐
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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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	1	6885683		2005-04-26	FERMANN ET AL.	
	2	6281471	B1	2001-08-28	SMART	
	3	6340806		2002-01-22	SMART ET AL.	
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	1	20100046067	A1	2010-02-25	FERMANN ET AL.	

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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	7787503	B2	2010-08-31	WADSWORTH	
	2	7800818	B2	2010-09-21	MATTSSON	
	3	8000574	B2	2011-08-16	BUCHTER	
	4	6611643	B2	2003-08-26	BIRK	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	SUN, Y., C.F. Booker, S. Kumari, R.N. Day, M. Davidson, A. Periasamy, "Characterization of an orange acceptor fluorescent protein for sensitized spectral fluorescence resonant energy transfer microscopy using a white-light laser," Journal of Biomedical Optics, Vol. 14, no. 5, paper 054009 (2009).	☐
	2	BORLINGHAUS, R., "Colours Count: how the challenge of fluorescence was solved in confocal microscopy," in Modern Research and Educational Topics in Microscopy, A. Mendez-Vilas and J. Diaz, eds, pp. 890-899, Formatex (2007)	☐
	3	BORLINGHAUS, R., "The White Confocal: Continuous Spectral Tuning in Excitation and Emission," in Optical Fluorescence Microscopy, A. Diaspro (Ed), Chapter 2, pp. 37-54, ISBN 978-3-642-15174-3, Springer-Verlag, Berlin (2011).	☐
	4	BORLINGHAUS, R.T., L. Kuschel, "White Light Laser: The Ultimate Source for Confocal Microscopy," http://www.leica-microsystems.com/science-lab/white-light-laser (June 27, 2012).	☐
	5	ZIEGLER, U., A.G. Bittermann, M. Hoechli, "Introduction to Confocal Laser Scanning Microscopy (LEICA)," www.zmb.unizh.ch, May 29, 2013.	☐
	6		☐

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

[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)		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/875,709	10/06/2015	2688	730	OMNI 0105 PUSP1	20	3

CONFIRMATION NO. 7496

FILING RECEIPT

109543
Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075



Date Mailed: 10/26/2015

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

Inventor(s)

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 14/108,986 12/17/2013 PAT 9164032
which claims benefit of 61/747,487 12/31/2012

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 - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 10/22/2015
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/875,709**
Projected Publication Date: To Be Determined - pending completion of Corrected Papers
Non-Publication Request: No
Early Publication Request: No
** **SMALL ENTITY** **

Title

SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Preliminary Class

369

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/875,709

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE($)	FEE($)		RATE($)	FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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)		(Column 2)	(Column 3)					
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1

CONFIRMATION NO. 7496

109543
Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

FORMALITIES LETTER

OC000000078218858

Date Mailed: 10/26/2015

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. The substitute specification must be submitted with markings and be accompanied by a clean version (without markings) as set forth in 37 CFR 1.125(c) and a statement that the substitute specification contains no new matter (see 37 CFR 1.125(b)). The specification, claims, and/or abstract page(s) submitted is not acceptable and cannot be scanned or properly stored because:
  - The application contains drawings, but the specification does not contain a brief description of the several views of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(9).
- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - More than one figure is present and each figure is not labeled "Fig." with a consecutive Arabic numeral (1, 2, etc.) or an Arabic numeral and capital letter in the English alphabet (A, B, etc.)(see 37 CFR 1.84(u)(1)). See Figure(s) 9. A brief description of the several views of the drawings (see 37 CFR 1.74) should be added or amended to correspond to the corrected numbering of the figures. See also 37 CFR 1.77(b)(9).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

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Commissioner for Patents
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/tnnguyen/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Mohammed N. ISLAM

Serial No.: 14/875,709

Filed: October 6, 2015

For: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Group Art Unit: 2688

Examiner:

Attorney Docket No.: OMNI 0105 PUSP1

RESPONSE TO NOTICE TO FILE CORRECTED PAPERS

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In response to the Notice to File Corrected Application Papers mailed October 26, 2015, Applicant submits herewith a substitute specification with markings accompanied by a clean version (without markings) so that the Brief Description of the Drawings identifies Figures 9A and 9B. The previously submitted drawings have been reviewed and are believed to meet the requirements with respect to each figure being labeled "Fig." with a consecutive Arabic numeral and capital letter in the English alphabet. No new matter has been added.

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Respectfully submitted,

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Application Number:	14875709
International Application Number:	
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Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
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1	Specification	Specification_Marked_Up_Copy.pdf	233167 1e354df1fb9fa0a4e2f57d541436234f9aa8dea6	no	41

Warnings:	
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2	Specification	Specification_Clean_Copy.pdf	233069 99462ab6a858d8c0f7781b2796318fc6a3a727c5	no	41
Warnings:					
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SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Serial No. 14/108,986 filed December 17, 2013, which claims the benefit of U.S. provisional application Serial No. 61/747,487 filed December 31, 2012, the disclosures of which are hereby incorporated in their entirety by reference herein.

[0002] This application is related to U.S. provisional applications Serial Nos. 61/747,477 filed December 31, 2012; Serial No. 61/747,481 filed December 31, 2012; Serial No. 61/747,485 filed December 31, 2012; Serial No. 61/747,472 filed December 31, 2012; Serial No. 61/747,492 filed December 31, 2012; Serial No. 61/747,553 filed December 31, 2012; and Serial No. 61/754,698 filed January 21, 2013, the disclosures of which are hereby incorporated in their entirety by reference herein.

[0003] This application is also related to International Application No. PCT/US2013/075700 (Publication No. WO/2014/105520) entitled Near-Infrared Lasers For Non-Invasive Monitoring Of Glucose, Ketones, HBA1C, And Other Blood Constituents; International Application PCT/US2013/075736 (Publication No. WO/2014/105521) entitled Short-Wave Infrared Super-Continuum Lasers For Early Detection Of Dental Caries; U.S. Application 14/108,995 (Publication No. 2014/0188092) entitled Focused Near-Infrared Lasers For Non-Invasive Vasectomy And Other Thermal Coagulation Or Occlusion Procedures; International Application PCT/US2013/075767 (Publication No. WO/2014/143276) entitled Short-Wave Infrared Super-Continuum Lasers For Natural Gas Leak Detection, Exploration, And Other Active Remote Sensing Applications; U.S. Application 14/108,974 (Publication No. 2014/0188094) entitled Non-Invasive Treatment Of Varicose Veins; and U.S. Application 14/109,007 (Publication No. 2014/0236021) entitled Near-Infrared Super-Continuum Lasers For Early Detection Of Breast And Other Cancers, the disclosures of which are hereby incorporated in their entirety by reference herein.

BACKGROUND AND SUMMARY

[0004] 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.

[0005] 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.

[0006] 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.

[0007] In one embodiment, a measurement system includes a light source configured to generate an output optical beam comprising one or more semiconductor sources configured to generate an input beam, one or more optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the one or more optical amplifiers, and one or more optical fibers configured to receive at least a portion of the intermediate beam and to deliver at least the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam. A nonlinear element is configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum, wherein at least a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 1400 nanometers and approximately 2500 nanometers, and wherein at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample for a non-destructive and non-contact measurement, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample. A receiver is configured to receive at least a portion of the spectroscopy output beam having a bandwidth of at least 10 nanometers and to process the portion of the spectroscopy output beam to generate an output signal, and wherein at least a part of the delivered portion of the output optical beam is at least partially transmitting through a packaging material covering at least a part of the sample, and wherein the output signal is based on a chemical composition of the sample.

[0008] In another embodiment, a measurement system includes a light source configured to generate an output optical beam comprising a plurality of semiconductor sources configured to generate an input optical beam, a multiplexer configured to receive at least a portion of the input optical beam and to form an intermediate optical beam, and one or more fibers configured to receive at least a portion of the intermediate optical beam and to form the output optical beam, wherein the output optical beam comprises one or more optical wavelengths. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample. A receiver is configured to receive at least a portion of the spectroscopy output beam and to process the portion of the spectroscopy output beam to generate an output signal, wherein the receiver comprises a Fourier transform infrared (FTIR) spectrometer or a dispersive spectrometer, and wherein at least a part of the delivered portion of the output optical beam is at least partially transmitting through a packaging material covering at least a part of the sample.

[0009] In yet another embodiment, a method of measuring includes generating an output optical beam comprising generating an input optical beam from a plurality of semiconductor sources, multiplexing at least a portion of the input optical beam and forming an intermediate optical beam, and guiding at least a portion of the intermediate optical beam and forming the output optical beam, wherein the output optical beam comprises one or more optical wavelengths. The method may also include receiving a received portion of the output optical beam and delivering a delivered portion of the output optical beam to a sample, wherein the sample comprises an organic compound with an overtone or combinational absorption band in the wavelength range between approximately 1 micron and approximately 2.5 microns. The method may further include generating a spectroscopy output beam having a bandwidth of at least 10 nanometers from the sample using a Fourier transform infrared (FTIR) spectrometer or a dispersive spectrometer, receiving at least a portion of the spectroscopy output beam, and processing the portion of the spectroscopy output beam and generating an output signal.

[0010] With the growing obesity epidemic, the number of individuals with diabetes is 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.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] In various embodiments, a measurement system includes a light source configured to generate an output optical beam that includes one or more semiconductor sources configured to generate an input beam, one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers; and one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam. The light source may also include a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum. The at least a portion of the output beam broadened spectrum comprises a near-infrared wavelength between approximately 700nm and approximately 2500nm, and at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns. The system may also include a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam, and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample having a bandwidth of at least 10 nanometers and to generate an output signal. In addition, a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen may be configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.

[0015] In another embodiment, a measurement system includes a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more

optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam; and a receiver is configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link, and a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

[0016] Other embodiments may include a measurement system comprising a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. The wearable measurement device is configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam. The wearable measurement device further comprises a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system also includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link and a remote device configured to receive over the

wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] 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:

[0018] FIGURE 1 shows the absorbance for two common plastics, polyethylene and polystyrene.

[0019] FIGURE 2 illustrates one example of the difference in near-infrared spectrum between an authentic tablet and a counterfeit tablet.

[0020] FIGURE 3 shows the second derivative of the spectral comparison of Prozac and a similarly formulated generic.

[0021] FIGURE 4 illustrates an example of the near infrared spectra for different pure components of a studied drug.

[0022] FIGURE 5 shows the mid-wave infrared and long-wave infrared absorption spectra for various illicit drugs.

[0023] FIGURE 6 shows the absorbance versus wavelength in the near-infrared region for four classes of illegal drugs.

[0024] FIGURE 7 illustrates the diffuse reflectance near-infrared spectrum of heroin samples.

[0025] FIGURE 8 illustrates the diffuse reflectance near-infrared spectra of different seized illicit drugs containing heroin of different concentrations, along with the spectrum for pure heroin.

[0026] ~~FIGURE 9 lists~~FIGURES 9A and 9B list possible band assignments for the various spectral features in pure heroin.

[0027] FIGURE 10 shows the diffuse reflectance near-infrared spectra of different compounds that may be frequently employed as cutting agents.

[0028] FIGURE 11 provides one example of a flow-chart in the process analytical technology for the pharmaceutical industry.

[0029] FIGURE 12 illustrates the typical near-infrared spectra of a variety of excipients.

[0030] FIGURE 13 exemplifies the absorbance from the blending process of a pharmaceutical compound.

[0031] FIGURE 14 shows what might be an eventual flow-chart of a smart manufacturing process.

[0032] FIGURE 15A illustrates the near-infrared reflectance spectrum of wheat flour.

[0033] FIGURE 15B shows the near-infrared absorbance spectra obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit.

[0034] FIGURE 16A is a schematic diagram of the basic elements of an imaging spectrometer.

[0035] FIGURE 16B illustrates one example of a typical imaging spectrometer used in hyper-spectral imaging systems.

[0036] FIGURE 17 shows one example of the Fourier transform infrared spectrometer.

[0037] FIGURE 18 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.

[0038] FIGURE 19 illustrates a block diagram or building blocks for constructing high power laser diode assemblies.

[0039] FIGURE 20 shows a platform architecture for different wavelength ranges for an all-fiber-integrated, high powered, super-continuum light source.

[0040] FIGURE 21 illustrates one embodiment for a short-wave infrared super-continuum light source.

[0041] FIGURE 22 shows the output spectrum from the SWIR SC laser of FIGURE 21 when about a 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.

[0042] 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).

[0043] FIGURE 24 schematically shows a medical measurement device as 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.

DETAILED DESCRIPTION

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

IDENTIFICATION OF COUNTERFEIT DRUGS

[0055] 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."

[0056] 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.

[0057] 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.

[0058] 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 1 illustrates the absorbance 100 for two common plastics: polyethylene 101 and polystyrene 102. 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.

[0059] 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.

[0060] FIGURE 2 illustrates one example of the difference in near-infrared spectrum 200 between an authentic tablet and a counterfeit tablet. Two grades of film coated tablets comprising drugs were investigated: curve 201 is the genuine drug, while 202 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.

[0061] 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 3 shows the second derivative 300 of the spectral comparison of Prozac 301 and a similarly formulated generic 302, 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.

[0062] 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.

[0063] FIGURE 4 shows an example of the near-infrared spectra 400 for different pure components of a studied drug. The spectrum for the active pharmaceutical ingredient (API) 401 is plotted, along with the spectra for five different excipients 402, 403, 404, 405 and 406. 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 4 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.

RAPID SCREENING FOR ILLICIT DRUGS

[0064] Thus, FIGURES 2-4 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 5 shows the mid-wave infrared and long-wave infrared absorption spectra 500 for various illicit drugs. The absorbance for cocaine 501, methamphetamine 502, MDMA (ecstasy) 503, and heroin 504 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.

[0065] 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 6 illustrates the absorbance 600 versus wavelength in the near-infrared region for four classes of illegal drugs. In particular, the spectra are shown for methamphetamine (MA) 601, amphetamine (AP) 602, MDMA (street name: ecstasy) 603, and MDA (street name: the love drug) 604. Each of the illegal drugs have unique spectral features in the near-infrared and SWIR. Also, comparing the mid-infrared spectrum for MDMA (503 in FIGURE 5) with the near-infrared spectrum for MDMA (603 in FIGURE 6), it seems clear that the near-infrared region shows overtones and combination bands that should be discernible. Referring to FIGURE 6, 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.

[0066] In another embodiment, FIGURE 7 shows the diffuse reflectance near-infrared spectrum 700 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, 701 is the near-infrared spectrum for an illicit street drug sample, while 702 is the spectra for a pure heroin

standard. The difference between the spectra may arise at least in part from cutting agents. The inset 703 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 504 in FIGURE 5). 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.

[0067] 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 8 illustrates the diffuse reflectance near-infrared spectra 800 of different seized illicit drugs containing heroin (between 10.7 and 21.8%) compared with the spectrum of pure heroin 801. Curve 802 is for 21.8% by weight, curve 803 is 13.2% by weight, curve 804 is 17% by weight, and curve 805 is 10.7% by weight of heroin. The spectra have been shifted along the vertical axis to better illustrate the differences.

[0068] Although quite complex in the near-infrared, it may be possible to identify from the pure heroin near-infrared spectrum (801 in FIGURE 8 or 702 in FIGURE 7) the main wavelengths related to the most common functional groups in heroin. For example, FIGURE 9 lists possible band assignments 900 for the various spectral features in pure heroin. As can be seen from FIGURE 9,

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.

[0069] As can be appreciated from FIGURE 8, 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 10 illustrates the diffuse reflectance near-infrared spectra 1000 of different compounds that may be frequently employed as cutting agents. In the bottom of FIGURE 10 are shown the spectra 1008 for pure heroin and the spectra 1007 for a seized illicit street drug sample comprising 21.8% of heroin. The spectra for various cutting agents include: 1001 for flour, 1002 for talcum powder, 1003 for chalk, 1004 for acetylsalicylic acid, 1005 for caffeine, and 1006 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.

PROCESS ANALYTICAL TECHNOLOGY (PAT)

[0070] 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.

[0071] FIGURE 11 shows one example of a flow-chart 1100 in the PAT for the pharmaceutical industry. While the center shows the steps of the manufacturing process 1101, the top and bottom sides show where near-infrared spectroscopy could be applicable for lab use 1102 (top) or in process monitoring control 1103 (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.

[0072] 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 12 illustrates the typical near-infrared spectra 1200 for a variety of excipients. Included in the graph 1200 are spectra for: magnesium stearate 1201, sorbitol 1202, mannitol 1203, talc 1204, lactose 1205, starch 1206, maltodextrin 1207, and microcrystalline cellulose 1208. 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.

[0073] 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 13 exemplifies the absorbance 1300 from the blending process. Although the initial spectra 1301 shows differences from the eventual spectra, as the process continues the blend converges to the final spectra 1302 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 1300.

[0074] 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.

[0075] FIGURE 14 illustrates what might be an eventual flow-chart 1400 of a smart manufacturing process. The manufacturing process 1401 may have as input the process feed 1402 and result in a process output 1403. A process controller 1404 may at least partially control the manufacturing process 1401, and the controller 1404 may receive inputs from the closed loop control (process parameters) 1405 as well as the on-line monitoring of process parameters 1406. The feedback loops in the process could refine the manufacturing process 1401 and improve the quality of the process output 1403. 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.

[0076] 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.

[0077] 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 15A illustrates the near-infrared reflectance spectrum 1500 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 1500 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.

[0078] 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 15B shows the near-infrared absorbance spectra 1550 obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit. Four oil absorption bands are near 2200-2400nm (CH_2 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.

DETECTION SYSTEMS

[0079] 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.

[0080] 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.

[0081] 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.

[0082] In another embodiment, an imaging spectrometer may be used to detect the light received from the sample. For example, FIGURE 16A shows a schematic diagram 1600 of the basic elements of an imaging spectrometer. The input light 1601 from the sample may first be directed by a scanning mirror and/or other optics 1602. An optical dispersing element 1603, 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 1604 onto one or more detectors or detector arrays 1605. Some sensors may use multiple detector arrays to measure hundreds of narrow wavelength bands.

[0083] An example of a typical imaging spectrometer 1650 used in hyper-spectral imaging systems is illustrated in FIGURE 16B. In this particular embodiment, the input light may be directed first by a tunable mirror 1651. A front lens 1652 may be placed before the entrance slit 1653 and the collector lens 1654. In this embodiment, the dispersing element is a holographic grating with a prism 1655, which separates the different wavelength bands. Then, a camera lens 1656 may be used to image the wavelengths onto a detector or camera 1657.

[0084] FIGURES 16 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 16.

[0085] 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.

[0086] FIGURE 17 illustrates one example of the FTIR spectrometer 1700. Light from the near-infrared or SWIR light source 1701 may be collimated and directed to a beam splitter 1702. In one embodiment, the beam splitter 1702 may be a 50:50 beam splitter. One portion of the beam 1703 may be reflected toward a stationary mirror 1704, while the other portion of the beam 1705 may be transmitted towards a moving mirror 1706. Light may be reflected from the two mirrors 1704, 1706 back to the beam splitter 1702, and then a portion of the recombined beam 1707 may be directed toward the sample 1708. The recombined beam 1707 may be focused onto the sample 1708, in one embodiment. On leaving the sample 1708, the light may be refocused or at least collected at a detector 1709. A background interferogram may be obtained by using the set-up 1700 without a sample in the chamber 1708. When a sample is inserted into 1708, 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 1701. The configuration 1700 is one

example of an FTIR, but other configurations may also be used, and these are also intended to be covered by this disclosure.

[0087] In yet another example of multi-beam detection systems, a dual-beam set-up 1800 such as in FIGURE 18 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 1801 may be collimated using a CaF_2 lens 1802 and then focused into the entrance slit of the monochromator 1803. At the exit slit, light at the selected wavelength is collimated again and may be passed through a polarizer 1804 before being incident on a calcium fluoride beam splitter 1805. After passing through the beam splitter 1805, the light is split into a sample 1806 and reference 1807 arm to enable ratiometric detection that may cancel out effects of intensity fluctuations in the SC source 1801. The light in the sample arm 1806 passes through the sample of interest and is then focused onto a HgCdTe detector 1808 connected to a pre-amp. A chopper 1802 and lock-in amplifier 1810 setup enable low noise detection of the sample arm signal. The light in the reference arm 1807 passes through an empty container (cuvette, gas cell etc.) of the same kind as used in the sample arm. A substantially identical detector 1809, pre-amp and lock-in amplifier 1810 is used for detection of the reference arm signal. The signal may then be analyzed using a computer system 1811. 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.

[0088] 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 18 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.

LIGHT SOURCES FOR SWIR AND NEAR INFRARED

[0089] 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 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. The SWIR corresponds to a transmission window through water and the atmosphere. Also, the so-called "eye-safe" wavelengths are wavelengths longer than approximately 1400nm as previously described.

[0090] 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.

[0091] 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 due to the low power levels. Also, the lamp based sources tend to be energy inefficient.

[0092] 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.

[0093] 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. 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.

[0094] 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 5nm to 100nm wide, preferably in the 60nm 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 that cover a broader region of the SWIR.

[0095] 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. FIGURE 19 shows an example block diagram 1900 with 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.

[0096] The brightness may be increased by spatially combining the beams from multiple stacks 1903. The combiner may include spatial interleaving, wavelength multiplexing, or 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 a particular 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 diameters of approximately 100 microns 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.

SWIR SUPER-CONTINUUM LASERS

[0097] 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.

[0098] 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 recently, 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.

[0099] 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 (DFB) laser diode with a wavelength near 1542nm or 1550 nm, with approximately 0.5–2.0ns pulsed output, and with a pulse repetition rate between one 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 a particular 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.

[0100] The SC generation 2007 may occur in the relatively short lengths of fiber that follow the pump laser. Exemplary SC fiber lengths 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 occurs primarily, followed by a second fiber 2009 where the SC generation and spectral broadening occurs primarily.

[0101] 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 anomalous 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 0.5ps 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.

[0102] 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.

[0103] 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 1550nm), or thulium-doped fibers (near 2000nm). In various embodiments, candidates for SC fiber 2009 include fused silica fibers (for generating SC between 0.8–2.7μm), mid-IR fibers such as fluorides, chalcogenides, or tellurites (for generating SC out to 4.5μm or longer), photonic crystal fibers (for generating SC between 0.4-1.7μm), 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.

[0104] 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.

[0105] In one embodiment, one example of the SC laser that operates in the SWIR is illustrated in FIGURE 21. This SWIR SC source 2100 produces an output of up to approximately 5W over a spectral range of about 1.5-2.4 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 0.5nsec 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 laser diode near 940nm 2105 that is coupled in using a fiber combiner 2104.

[0106] 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 an approximately 4m length of the 12/130 micron erbium/ytterbium doped fiber 2111 that is counter-propagating pumped using one or more 30W laser diodes near 940nm 2112 coupled in through a combiner 2113. An approximately 1-2m 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.

[0107] 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 about 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 around 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.

[0108] 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 1060nm and 1800nm. For this embodiment, the seed laser 2101 may be a distributed feedback laser diode around 1064nm, 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 laser diode near 915nm. A mode field adapter may be included in the mid-stage, 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 an about 20m length of ytterbium-doped fiber with 25/400 microns dimension. The pump 2112 for the power amplifier may be up to six pump diodes providing 30W each near 915nm. For this much pump power, the output power in the SC may be as high as 50W or more.

[0109] In one 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.

[0110] In one embodiment, the top of FIGURE 23 illustrates an exemplary block diagram for an SC source 2300 capable of generating light between approximately 1400nm 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 1542nm 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.

[0111] In yet another embodiment, the bottom of FIGURE 23 illustrates a block diagram for an exemplary SC source 2350 capable of generating light between approximately 1900nm 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 1542nm 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 1542nm, 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 5m and 50m, 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, 21,and 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.

[0112] FIGURES 20, 21 and 23 are examples of SC light sources that may advantageously be used for near-infrared or SWIR light generation in various spectroscopy, active remote sensing and hyper-spectral imaging 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.

[0113] Even within the all-fiber versions illustrated such as in FIGURE 21, different configurations could be used consistent with the disclosure. In one 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 near-infrared or SWIR light that are intended to be covered by this disclosure.

[0114] 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.

WIRELESS LINK TO THE CLOUD

[0115] 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.

[0116] In a particular embodiment 2400 illustrated in Figure 24, 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.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] Although the present disclosure has been described in several embodiments, a myriad of changes, variations, alterations, transformations, and modifications may be suggested to one skilled in the art, and it is intended that the present disclosure encompass such changes, variations, alterations, transformations, and modifications as falling within the spirit and scope of the appended claims.

[0123] 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.

SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Serial No. 14/108,986 filed December 17, 2013, which claims the benefit of U.S. provisional application Serial No. 61/747,487 filed December 31, 2012, the disclosures of which are hereby incorporated in their entirety by reference herein.

[0002] This application is related to U.S. provisional applications Serial Nos. 61/747,477 filed December 31, 2012; Serial No. 61/747,481 filed December 31, 2012; Serial No. 61/747,485 filed December 31, 2012; Serial No. 61/747,472 filed December 31, 2012; Serial No. 61/747,492 filed December 31, 2012; Serial No. 61/747,553 filed December 31, 2012; and Serial No. 61/754,698 filed January 21, 2013, the disclosures of which are hereby incorporated in their entirety by reference herein.

[0003] This application is also related to International Application No. PCT/US2013/075700 (Publication No. WO/2014/105520) entitled Near-Infrared Lasers For Non-Invasive Monitoring Of Glucose, Ketones, HBA1C, And Other Blood Constituents; International Application PCT/US2013/075736 (Publication No. WO/2014/105521) entitled Short-Wave Infrared Super-Continuum Lasers For Early Detection Of Dental Caries; U.S. Application 14/108,995 (Publication No. 2014/0188092) entitled Focused Near-Infrared Lasers For Non-Invasive Vasectomy And Other Thermal Coagulation Or Occlusion Procedures; International Application PCT/US2013/075767 (Publication No. WO/2014/143276) entitled Short-Wave Infrared Super-Continuum Lasers For Natural Gas Leak Detection, Exploration, And Other Active Remote Sensing Applications; U.S. Application 14/108,974 (Publication No. 2014/0188094) entitled Non-Invasive Treatment Of Varicose Veins; and U.S. Application 14/109,007 (Publication No. 2014/0236021) entitled Near-Infrared Super-Continuum Lasers For Early Detection Of Breast And Other Cancers, the disclosures of which are hereby incorporated in their entirety by reference herein.

BACKGROUND AND SUMMARY

[0004] 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.

[0005] 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.

[0006] 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.

[0007] In one embodiment, a measurement system includes a light source configured to generate an output optical beam comprising one or more semiconductor sources configured to generate an input beam, one or more optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the one or more optical amplifiers, and one or more optical fibers configured to receive at least a portion of the intermediate beam and to deliver at least the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam. A nonlinear element is configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum, wherein at least a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 1400 nanometers and approximately 2500 nanometers, and wherein at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample for a non-destructive and non-contact measurement, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample. A receiver is configured to receive at least a portion of the spectroscopy output beam having a bandwidth of at least 10 nanometers and to process the portion of the spectroscopy output beam to generate an output signal, and wherein at least a part of the delivered portion of the output optical beam is at least partially transmitting through a packaging material covering at least a part of the sample, and wherein the output signal is based on a chemical composition of the sample.

[0008] In another embodiment, a measurement system includes a light source configured to generate an output optical beam comprising a plurality of semiconductor sources configured to generate an input optical beam, a multiplexer configured to receive at least a portion of the input optical beam and to form an intermediate optical beam, and one or more fibers configured to receive at least a portion of the intermediate optical beam and to form the output optical beam, wherein the output optical beam comprises one or more optical wavelengths. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample. A receiver is configured to receive at least a portion of the spectroscopy output beam and to process the portion of the spectroscopy output beam to generate an output signal, wherein the receiver comprises a Fourier transform infrared (FTIR) spectrometer or a dispersive spectrometer, and wherein at least a part of the delivered portion of the output optical beam is at least partially transmitting through a packaging material covering at least a part of the sample.

[0009] In yet another embodiment, a method of measuring includes generating an output optical beam comprising generating an input optical beam from a plurality of semiconductor sources, multiplexing at least a portion of the input optical beam and forming an intermediate optical beam, and guiding at least a portion of the intermediate optical beam and forming the output optical beam, wherein the output optical beam comprises one or more optical wavelengths. The method may also include receiving a received portion of the output optical beam and delivering a delivered portion of the output optical beam to a sample, wherein the sample comprises an organic compound with an overtone or combinational absorption band in the wavelength range between approximately 1 micron and approximately 2.5 microns. The method may further include generating a spectroscopy output beam having a bandwidth of at least 10 nanometers from the sample using a Fourier transform infrared (FTIR) spectrometer or a dispersive spectrometer, receiving at least a portion of the spectroscopy output beam, and processing the portion of the spectroscopy output beam and generating an output signal.

[0010] With the growing obesity epidemic, the number of individuals with diabetes is 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.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] In various embodiments, a measurement system includes a light source configured to generate an output optical beam that includes one or more semiconductor sources configured to generate an input beam, one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers; and one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam. The light source may also include a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum. The at least a portion of the output beam broadened spectrum comprises a near-infrared wavelength between approximately 700nm and approximately 2500nm, and at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns. The system may also include a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam, and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample having a bandwidth of at least 10 nanometers and to generate an output signal. In addition, a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen may be configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.

[0015] In another embodiment, a measurement system includes a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more

optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. A measurement apparatus is configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam; and a receiver is configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link, and a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

[0016] Other embodiments may include a measurement system comprising a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. The wearable measurement device is configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam. The wearable measurement device further comprises a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system also includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link and a remote device configured to receive over the

wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] 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:

[0018] FIGURE 1 shows the absorbance for two common plastics, polyethylene and polystyrene.

[0019] FIGURE 2 illustrates one example of the difference in near-infrared spectrum between an authentic tablet and a counterfeit tablet.

[0020] FIGURE 3 shows the second derivative of the spectral comparison of Prozac and a similarly formulated generic.

[0021] FIGURE 4 illustrates an example of the near infrared spectra for different pure components of a studied drug.

[0022] FIGURE 5 shows the mid-wave infrared and long-wave infrared absorption spectra for various illicit drugs.

[0023] FIGURE 6 shows the absorbance versus wavelength in the near-infrared region for four classes of illegal drugs.

[0024] FIGURE 7 illustrates the diffuse reflectance near-infrared spectrum of heroin samples.

[0025] FIGURE 8 illustrates the diffuse reflectance near-infrared spectra of different seized illicit drugs containing heroin of different concentrations, along with the spectrum for pure heroin.

[0026] FIGURES 9A and 9B list possible band assignments for the various spectral features in pure heroin.

[0027] FIGURE 10 shows the diffuse reflectance near-infrared spectra of different compounds that may be frequently employed as cutting agents.

[0028] FIGURE 11 provides one example of a flow-chart in the process analytical technology for the pharmaceutical industry.

[0029] FIGURE 12 illustrates the typical near-infrared spectra of a variety of excipients.

[0030] FIGURE 13 exemplifies the absorbance from the blending process of a pharmaceutical compound.

[0031] FIGURE 14 shows what might be an eventual flow-chart of a smart manufacturing process.

[0032] FIGURE 15A illustrates the near-infrared reflectance spectrum of wheat flour.

[0033] FIGURE 15B shows the near-infrared absorbance spectra obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit.

[0034] FIGURE 16A is a schematic diagram of the basic elements of an imaging spectrometer.

[0035] FIGURE 16B illustrates one example of a typical imaging spectrometer used in hyper-spectral imaging systems.

[0036] FIGURE 17 shows one example of the Fourier transform infrared spectrometer.

[0037] FIGURE 18 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.

[0038] FIGURE 19 illustrates a block diagram or building blocks for constructing high power laser diode assemblies.

[0039] FIGURE 20 shows a platform architecture for different wavelength ranges for an all-fiber-integrated, high powered, super-continuum light source.

[0040] FIGURE 21 illustrates one embodiment for a short-wave infrared super-continuum light source.

[0041] FIGURE 22 shows the output spectrum from the SWIR SC laser of FIGURE 21 when about a 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.

[0042] 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).

[0043] FIGURE 24 schematically shows a medical measurement device as 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.

DETAILED DESCRIPTION

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

IDENTIFICATION OF COUNTERFEIT DRUGS

[0055] 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."

[0056] 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.

[0057] 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.

[0058] 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 1 illustrates the absorbance 100 for two common plastics: polyethylene 101 and polystyrene 102. 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.

[0059] 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.

[0060] FIGURE 2 illustrates one example of the difference in near-infrared spectrum 200 between an authentic tablet and a counterfeit tablet. Two grades of film coated tablets comprising drugs were investigated: curve 201 is the genuine drug, while 202 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.

[0061] 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 3 shows the second derivative 300 of the spectral comparison of Prozac 301 and a similarly formulated generic 302, 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.

[0062] 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.

[0063] FIGURE 4 shows an example of the near-infrared spectra 400 for different pure components of a studied drug. The spectrum for the active pharmaceutical ingredient (API) 401 is plotted, along with the spectra for five different excipients 402, 403, 404, 405 and 406. 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 4 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.

RAPID SCREENING FOR ILLICIT DRUGS

[0064] Thus, FIGURES 2-4 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 5 shows the mid-wave infrared and long-wave infrared absorption spectra 500 for various illicit drugs. The absorbance for cocaine 501, methamphetamine 502, MDMA (ecstasy) 503, and heroin 504 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.

[0065] 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 6 illustrates the absorbance 600 versus wavelength in the near-infrared region for four classes of illegal drugs. In particular, the spectra are shown for methamphetamine (MA) 601, amphetamine (AP) 602, MDMA (street name: ecstasy) 603, and MDA (street name: the love drug) 604. Each of the illegal drugs have unique spectral features in the near-infrared and SWIR. Also, comparing the mid-infrared spectrum for MDMA (503 in FIGURE 5) with the near-infrared spectrum for MDMA (603 in FIGURE 6), it seems clear that the near-infrared region shows overtones and combination bands that should be discernible. Referring to FIGURE 6, 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.

[0066] In another embodiment, FIGURE 7 shows the diffuse reflectance near-infrared spectrum 700 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, 701 is the near-infrared spectrum for an illicit street drug sample, while 702 is the spectra for a pure heroin

standard. The difference between the spectra may arise at least in part from cutting agents. The inset 703 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 504 in FIGURE 5). 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.

[0067] 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 8 illustrates the diffuse reflectance near-infrared spectra 800 of different seized illicit drugs containing heroin (between 10.7 and 21.8%) compared with the spectrum of pure heroin 801. Curve 802 is for 21.8% by weight, curve 803 is 13.2% by weight, curve 804 is 17% by weight, and curve 805 is 10.7% by weight of heroin. The spectra have been shifted along the vertical axis to better illustrate the differences.

[0068] Although quite complex in the near-infrared, it may be possible to identify from the pure heroin near-infrared spectrum (801 in FIGURE 8 or 702 in FIGURE 7) the main wavelengths related to the most common functional groups in heroin. For example, FIGURE 9 lists possible band assignments 900 for the various spectral features in pure heroin. As can be seen from FIGURE 9,

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.

[0069] As can be appreciated from FIGURE 8, 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 10 illustrates the diffuse reflectance near-infrared spectra 1000 of different compounds that may be frequently employed as cutting agents. In the bottom of FIGURE 10 are shown the spectra 1008 for pure heroin and the spectra 1007 for a seized illicit street drug sample comprising 21.8% of heroin. The spectra for various cutting agents include: 1001 for flour, 1002 for talcum powder, 1003 for chalk, 1004 for acetylsalicylic acid, 1005 for caffeine, and 1006 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.

PROCESS ANALYTICAL TECHNOLOGY (PAT)

[0070] 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.

[0071] FIGURE 11 shows one example of a flow-chart 1100 in the PAT for the pharmaceutical industry. While the center shows the steps of the manufacturing process 1101, the top and bottom sides show where near-infrared spectroscopy could be applicable for lab use 1102 (top) or in process monitoring control 1103 (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.

[0072] 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 12 illustrates the typical near-infrared spectra 1200 for a variety of excipients. Included in the graph 1200 are spectra for: magnesium stearate 1201, sorbitol 1202, mannitol 1203, talc 1204, lactose 1205, starch 1206, maltodextrin 1207, and microcrystalline cellulose 1208. 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.

[0073] 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 13 exemplifies the absorbance 1300 from the blending process. Although the initial spectra 1301 shows differences from the eventual spectra, as the process continues the blend converges to the final spectra 1302 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 1300.

[0074] 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.

[0075] FIGURE 14 illustrates what might be an eventual flow-chart 1400 of a smart manufacturing process. The manufacturing process 1401 may have as input the process feed 1402 and result in a process output 1403. A process controller 1404 may at least partially control the manufacturing process 1401, and the controller 1404 may receive inputs from the closed loop control (process parameters) 1405 as well as the on-line monitoring of process parameters 1406. The feedback loops in the process could refine the manufacturing process 1401 and improve the quality of the process output 1403. 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.

[0076] 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.

[0077] 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 15A illustrates the near-infrared reflectance spectrum 1500 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 1500 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.

[0078] 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 15B shows the near-infrared absorbance spectra 1550 obtained in diffusion reflectance mode for a series of whole 'Hass' avocado fruit. Four oil absorption bands are near 2200-2400nm (CH_2 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.

DETECTION SYSTEMS

[0079] 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.

[0080] 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.

[0081] 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.

[0082] In another embodiment, an imaging spectrometer may be used to detect the light received from the sample. For example, FIGURE 16A shows a schematic diagram 1600 of the basic elements of an imaging spectrometer. The input light 1601 from the sample may first be directed by a scanning mirror and/or other optics 1602. An optical dispersing element 1603, 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 1604 onto one or more detectors or detector arrays 1605. Some sensors may use multiple detector arrays to measure hundreds of narrow wavelength bands.

[0083] An example of a typical imaging spectrometer 1650 used in hyper-spectral imaging systems is illustrated in FIGURE 16B. In this particular embodiment, the input light may be directed first by a tunable mirror 1651. A front lens 1652 may be placed before the entrance slit 1653 and the collector lens 1654. In this embodiment, the dispersing element is a holographic grating with a prism 1655, which separates the different wavelength bands. Then, a camera lens 1656 may be used to image the wavelengths onto a detector or camera 1657.

[0084] FIGURES 16 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 16.

[0085] 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.

[0086] FIGURE 17 illustrates one example of the FTIR spectrometer 1700. Light from the near-infrared or SWIR light source 1701 may be collimated and directed to a beam splitter 1702. In one embodiment, the beam splitter 1702 may be a 50:50 beam splitter. One portion of the beam 1703 may be reflected toward a stationary mirror 1704, while the other portion of the beam 1705 may be transmitted towards a moving mirror 1706. Light may be reflected from the two mirrors 1704, 1706 back to the beam splitter 1702, and then a portion of the recombined beam 1707 may be directed toward the sample 1708. The recombined beam 1707 may be focused onto the sample 1708, in one embodiment. On leaving the sample 1708, the light may be refocused or at least collected at a detector 1709. A background interferogram may be obtained by using the set-up 1700 without a sample in the chamber 1708. When a sample is inserted into 1708, 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 1701. The configuration 1700 is one

example of an FTIR, but other configurations may also be used, and these are also intended to be covered by this disclosure.

[0087] In yet another example of multi-beam detection systems, a dual-beam set-up 1800 such as in FIGURE 18 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 1801 may be collimated using a CaF_2 lens 1802 and then focused into the entrance slit of the monochromator 1803. At the exit slit, light at the selected wavelength is collimated again and may be passed through a polarizer 1804 before being incident on a calcium fluoride beam splitter 1805. After passing through the beam splitter 1805, the light is split into a sample 1806 and reference 1807 arm to enable ratiometric detection that may cancel out effects of intensity fluctuations in the SC source 1801. The light in the sample arm 1806 passes through the sample of interest and is then focused onto a HgCdTe detector 1808 connected to a pre-amp. A chopper 1802 and lock-in amplifier 1810 setup enable low noise detection of the sample arm signal. The light in the reference arm 1807 passes through an empty container (cuvette, gas cell etc.) of the same kind as used in the sample arm. A substantially identical detector 1809, pre-amp and lock-in amplifier 1810 is used for detection of the reference arm signal. The signal may then be analyzed using a computer system 1811. 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.

[0088] 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 18 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.

LIGHT SOURCES FOR SWIR AND NEAR INFRARED

[0089] 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 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. The SWIR corresponds to a transmission window through water and the atmosphere. Also, the so-called "eye-safe" wavelengths are wavelengths longer than approximately 1400nm as previously described.

[0090] 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.

[0091] 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 due to the low power levels. Also, the lamp based sources tend to be energy inefficient.

[0092] 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.

[0093] 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. 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.

[0094] 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 5nm to 100nm wide, preferably in the 60nm 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 that cover a broader region of the SWIR.

[0095] 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. FIGURE 19 shows an example block diagram 1900 with 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.

[0096] The brightness may be increased by spatially combining the beams from multiple stacks 1903. The combiner may include spatial interleaving, wavelength multiplexing, or 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 a particular 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 diameters of approximately 100 microns 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.

SWIR SUPER-CONTINUUM LASERS

[0097] 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.

[0098] 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 recently, 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.

[0099] 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 (DFB) laser diode with a wavelength near 1542nm or 1550 nm, with approximately 0.5–2.0ns pulsed output, and with a pulse repetition rate between one 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 a particular 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.

[0100] The SC generation 2007 may occur in the relatively short lengths of fiber that follow the pump laser. Exemplary SC fiber lengths 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 occurs primarily, followed by a second fiber 2009 where the SC generation and spectral broadening occurs primarily.

[0101] 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 anomalous 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 0.5ps 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.

[0102] 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.

[0103] 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 1550nm), or thulium-doped fibers (near 2000nm). In various embodiments, candidates for SC fiber 2009 include fused silica fibers (for generating SC between 0.8–2.7μm), mid-IR fibers such as fluorides, chalcogenides, or tellurites (for generating SC out to 4.5μm or longer), photonic crystal fibers (for generating SC between 0.4-1.7μm), 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.

[0104] 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.

[0105] In one embodiment, one example of the SC laser that operates in the SWIR is illustrated in FIGURE 21. This SWIR SC source 2100 produces an output of up to approximately 5W over a spectral range of about 1.5-2.4 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 0.5nsec 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 laser diode near 940nm 2105 that is coupled in using a fiber combiner 2104.

[0106] 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 an approximately 4m length of the 12/130 micron erbium/ytterbium doped fiber 2111 that is counter-propagating pumped using one or more 30W laser diodes near 940nm 2112 coupled in through a combiner 2113. An approximately 1-2m 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.

[0107] 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 about 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 around 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.

[0108] 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 1060nm and 1800nm. For this embodiment, the seed laser 2101 may be a distributed feedback laser diode around 1064nm, 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 laser diode near 915nm. A mode field adapter may be included in the mid-stage, 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 an about 20m length of ytterbium-doped fiber with 25/400 microns dimension. The pump 2112 for the power amplifier may be up to six pump diodes providing 30W each near 915nm. For this much pump power, the output power in the SC may be as high as 50W or more.

[0109] In one 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.

[0110] In one embodiment, the top of FIGURE 23 illustrates an exemplary block diagram for an SC source 2300 capable of generating light between approximately 1400nm 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 1542nm 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.

[0111] In yet another embodiment, the bottom of FIGURE 23 illustrates a block diagram for an exemplary SC source 2350 capable of generating light between approximately 1900nm 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 1542nm 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 1542nm, 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 5m and 50m, 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, 21,and 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.

[0112] FIGURES 20, 21 and 23 are examples of SC light sources that may advantageously be used for near-infrared or SWIR light generation in various spectroscopy, active remote sensing and hyper-spectral imaging 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.

[0113] Even within the all-fiber versions illustrated such as in FIGURE 21, different configurations could be used consistent with the disclosure. In one 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 near-infrared or SWIR light that are intended to be covered by this disclosure.

[0114] 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.

WIRELESS LINK TO THE CLOUD

[0115] 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.

[0116] In a particular embodiment 2400 illustrated in Figure 24, 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.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] Although the present disclosure has been described in several embodiments, a myriad of changes, variations, alterations, transformations, and modifications may be suggested to one skilled in the art, and it is intended that the present disclosure encompass such changes, variations, alterations, transformations, and modifications as falling within the spirit and scope of the appended claims.

[0123] 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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/875,709

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE($)	FEE($)		RATE($)	FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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)		(Column 2)	(Column 3)					
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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".
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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
14/875,709	10/06/2015	2688	730	OMNI 0105 PUSP1	20	3

CONFIRMATION NO. 7496

UPDATED FILING RECEIPT

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Date Mailed: 11/10/2015

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

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

Domestic Priority data as claimed by applicant

This application is a CON of 14/108,986 12/17/2013 PAT 9164032
which claims benefit of 61/747,487 12/31/2012

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.

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/875,709**
Projected Publication Date: 02/18/2016
Non-Publication Request: No
Early Publication Request: No
** **SMALL ENTITY** **

Title

SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Preliminary Class

369

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1

CONFIRMATION NO. 7496

109543
Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

PUBLICATION NOTICE

OC000000080707126

Title:SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Publication No.US-2016-0047787-A1
Publication Date:02/18/2016

NOTICE OF PUBLICATION OF APPLICATION

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

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	POWM 0105 PUSP1

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	6212310	B1	2001-04-03	Waarts, et al.	
	2	7890158	B2	2011-02-15	Rowe, et al.	
	3	8213007	B2	2012-07-03	Wang, et al.	
	4	7848605	B2	2010-12-07	Ridder, et al.	
	5	8158493	B2	2012-04-17	Shah, et al.	

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	1	20060198397	A1	2006-09-07	Korolev, et al.	

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	Attorney Docket Number	POWM 0105 PUSP1

	2	20090105605	A1	2009-04-23	Abreu	
	3	20100160794	A1	2010-06-24	Banet, et al.	
	4	20110292376	A1	2011-12-01	Kukushkin, et al.	

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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]
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	POWM 0105 PUSP1

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	/David S. Bir/	Date (YYYY-MM-DD)	2016-03-08
Name/Print	David S. Bir	Registration Number	38383

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

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

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

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

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

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

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	25135402
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	09-MAR-2016
Filing Date:	06-OCT-2015
Time Stamp:	14:38:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Supplemental_IDS.pdf	612404 eaa136e7bcc7c79ffdf860efd93175dd09e5fd20	no	5

Warnings:	
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Total Files Size (in bytes):	612404

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

109543 7590 05/26/2016

Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

EXAMINER
FEIN, ABRA S

ART UNIT	PAPER NUMBER
2884	

NOTIFICATION DATE	DELIVERY MODE
05/26/2016	ELECTRONIC

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

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

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

docketing@brookskushman.com

Office Action Summary	Application No. 14/875,709	Applicant(s) ISLAM, MOHAMMED N.	
	Examiner Abra Fein	Art Unit 2884	AIA (First Inventor to File) Status No

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *5/13/2016*.

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

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

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

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

Disposition of Claims*

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

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

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

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

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

Application Papers

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

11)☒ The drawing(s) filed on *10/06/2015* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *3/09/2016, 10/06/2015 (x 11)*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Petitioner WHOOP, Inc. Ex1002
Page 343 of 1089

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Double Patenting

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

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/forms/. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal

Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

3. **Claims 1-4** are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 9,164,032 in view of Banet et al. (US 2010/0160798, hereinafter Banet; pub. Jun. 24, 2010).

4. Regarding **Claim 1,** claim 1 of U.S. Patent No. 9,164,032 sets forth the elements of claim 1 of the instant application with the exception the system further comprises a personal device. Banet teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link [0005]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as claimed by U.S. Patent No. 9,164,032, with a personal device, as taught by Banet, for the benefit of transmitting and displaying information generated.

6. Regarding **Claim 2**, claim 1 of U.S. Patent No. 9,164,032 sets forth the elements of claim 1 of the instant application but does not teach the elements of claim 2. Banet teaches the personal device is a tablet [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to use a tablet for a personal device, since it has been held to be within the general skill of a working in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

7. Regarding **Claim 3**, claim 1 of U.S. Patent No. 9,164,032 sets forth the elements of claim 1 of the instant application but does not teach the elements of claim 3. Banet teaches the output signal comprises one or more physiological parameters (blood pressure) [0005]. Banet further teaches the benefit of showing changes in values of the physiological parameters over periods of time [0080]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as claimed by U.S. Patent No. 9,164,032, with the output signal comprising one or more physiological

parameters, as taught by Banet, for the benefit of showing changes in values of the physiological parameters over periods of time.

8. Regarding **Claim 4**, claim 1 of U.S. Patent No. 9,164,032 sets forth the elements of claim 1 of the instant application but does not teach the elements of claim 4. Banet teaches a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data [0005]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as claimed by U.S. Patent No. 9,164,032, with a remote device, as taught by Banet, for the benefit of transmitting and displaying information generated.

4. These modifications of the primary reference in light of the secondary reference is proper because the applied references are so related that the appearance of features shown in one would suggest the application of those features to the other. See *In re Rosen*, 673 F.2d 388, 213 USPQ 347 (CCPA 1982); *In re Carter*, 673 F.2d 1378, 213 USPQ 625 (CCPA 1982), and *In re Glavas*, 230 F.2d 447, 109 USPQ 50 (CCPA 1956). Further, it is noted that case law has held that a designer skilled in the art is charged with knowledge of the related art; therefore, the combination of old elements, herein, would have been well within the level of ordinary skill. See *In re Antle*, 444 F.2d 1168,170 USPQ 285 (CCPA 1971) and *In re Naibandian*, 661 F.2d 1214, 211 USPQ 782 (CCPA 1981).

Specification

6. The use of the trademarks Bluetooth, Zigbee, Wifi, IrDA, USB, and iPhone [0116-0117] has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might

adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

5. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claim 7** contains the trademark/trade names Bluetooth and Wifi. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe Bluetooth Special Interest Group and Wi-Fi Alliance, and, accordingly, the identification/description is indefinite.

10. **Claim 18** is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

11. **Claim 18** recites the limitation "the one or more physiological parameters" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

12. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 5, 7-14, and 16-20** are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Polli et al. (US 2006/0283931, hereinafter Polli) in view of Banet.

15. Regarding **Claim 5**, Polli teaches a measurement system comprising: a light source comprising: a plurality of semiconductor sources configured to generate an output optical beam; a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers [0076; 0013, Polli inherently teaches wavelengths between 700 nanometers and 2500 nanometers since that is the definition of near-infrared]. Polli does not explicitly a personal device and a remote device.

Banet teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the

personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link; a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data [0005]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with a personal device and remote device, as taught by Banet, for the benefit of transmitting and displaying information generated.

16. Regarding **Claim 7**, Polli as adapted above teaches the system of claim 5. Polli does not teach the wireless transmission link is configured to operate at least in part on Bluetooth or Wifi. Banet teaches the wireless transmission link is configured to operate at least in part on Bluetooth or Wifi [0108] for the benefit of transmitting information [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as taught by Polli as adapted above, with the wireless transmission link being configured to operate at least in part on Bluetooth or Wifi, as taught by Banet, for the benefit of transmitting information.

17. Regarding **Claim 14**, Polli teaches a measurement system comprising: a light source comprising a plurality of semiconductor sources configured to generate an output optical beam; a measurement apparatus configured to receive a received portion of the output optical beam with one or more optical wavelengths, and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal [0076; 0013, Polli inherently teaches wavelengths between 700 nanometers and 2500 nanometers since that is the definition of near-infrared].

Banet teaches wearable measurement device further comprising a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link; a remote device configured to

receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data [0005]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with a personal device and remote device, as taught by Banet, for the benefit of transmitting and displaying information generated. Additionally, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make the measurement system wearable, since it has been held that making an old device portable or movable without producing any new and unexpected results involves only routine skill in the art. *In re Lindberg,* 93 USPQ 23 (CCPA 1952).

18. Regarding **Claim 10-11 and 18**, Polli as adapted above teaches the systems of claims 5 and 14. Polli does not teach the output signal comprises physiological parameters. Banet teaches the output signal comprises one or more physiological parameters, and the remove device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time [0063; 0080], and wherein the remote device is capable of generating an alarm when at least one of the one or more physiological parameters falls out of an acceptable range [0117]. Banet further teaches the benefit of showing changes in values of the physiological parameters over periods of time [0080]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as taught by Polli as adapted above, with the output signal comprising one or more physiological parameters, wherein the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time, wherein the remote device is capable of generating an alarm when at least one of the one or more physiological parameters falls out of an acceptable range, as taught by Banet, for the benefit of showing changes in values of the physiological parameters over periods of time.

19. Regarding **Claims 8 and 17**, Polli as adapted above teaches the systems of claims 5 and 14, but does not teach specifics of the remote device. Banet teaches the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more

other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server, and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data [0152]. Banet further teaches the benefit of providing medical diagnostic information to medical professionals [0152]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as taught by Polli as adapted above, with having the remote device configured to transmit at least a portion of the processed data to other location, as taught by Banet, for the benefit of providing medical diagnostic information to medical professionals.

20. Regarding **Claims 9 and 16**, Polli as adapted above teaches the systems of claims 5 and 14, but does not teach the personal device is separate from the measurement apparatus and the light source. Banet teaches the personal device is separate from the measurement apparatus and the light source [0005]. Banet further teaches the benefit of using the personal device to monitor information transmitted from the measurement apparatus. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli as adapted above, with the personal device being separate from the measurement apparatus and light source, as taught by Banet, for the benefit of the personal device being used to monitor information transmitted from the measurement apparatus using a separate display panel.

21. Regarding **Claims 12 and 20**, Polli as adapted above teaches the systems of claims 5 and 14. Polli does not teach the person al device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, a microprocessor-based device. Banet teaches the personal device is a tablet [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to use a tablet for a personal device, since it has been held to be within the general skill of a working in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

22. Regarding **Claims 13 and 19**, Polli as adapted above teaches the systems of claims 5 and 14. Polli does not teach the measurement system is capable of performing a non-invasive blood measurement. Banet teaches the measurement system is capable of performing a non-invasive blood

measurement (Abstract) for the benefit of continuous measurement of blood pressure that does not require any external calibration (Abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli as adapted above, with being capable of performing a non-invasive blood measurement, as taught by Banet, for the benefit of continuous measurement of blood pressure that does not require any external calibration.

23. **Claims 6 and 15** are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Polli and Banet as applied to claims 5 and 14 above, and further in view of Fujimoto et al. (US 2009/0244288, hereinafter Fujimoto; pub. Oct. 1, 2009).

24. Regarding **Claims 6 and 15**, Polli as adapted above teaches the systems of claims 5 and 14. Polli does not teach the semiconductor sources are light emitting diodes operating in pulsed mode. Fujimoto teaches a measurement system wherein semiconductor sources are light emitting diodes operating in pulsed mode [0079]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to use a light emitting diode operating in pulsed mode, since it has been held to be within the general skill of a working in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Allowable Subject Matter

25. **Claims 1-4** would be allowable if rewritten or amended to overcome the nonstatutory double patenting rejection set forth in this Office action.

26. The following is an examiner's statement of reasons for allowance:

27. Regarding **Claim 1**, Polli teaches a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductor sources configured to generate an input beam; a measurement apparatus configured to receive a received portion of the output optical beam, which is a delivered portion of the output optical beam; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal wherein at least a portion of the output beam broadened spectrum comprises a

short-wave infrared wavelength between approximately 700 nm and approximately 2500 nm [0076; 0013].

Islam (US 2009/0028193, hereinafter Islam) teaches the use of optical amplifiers configured to receive at least a portion of an input beam and to output an intermediate beam from at least one of the one or more optical amplifiers (Abstract). Buchter et al. (US 8,000,574, hereinafter Buchter) teaches one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least the portion of the intermediate beam to form a first optical beam (col. 8, lines 18-20). Islam (US 2006/0268393, hereinafter Islam 2) teaches a nonlinear element configured to receive at least a portion of an optical beam and to broaden a spectrum associated with at least a portion of that optical beam through a nonlinear effect in the nonlinear element to form an output optical beam with an output beam broadened spectrum [0039]. Banet teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link [0005].

Islam (US 2012/0239013, hereinafter Islam 3) teaches a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductor sources configured to generate an input beam; one or more optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the one or more optical amplifiers; and one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to form a first optical beam; a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum (Abstract); and wherein at least a portion of the one or more fibers is a fused silica fiber [0004], a measurement apparatus configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample (Fig. 20); and a receiver [0138]. Liu (US 2014/0249427, hereinafter Liu; PCT filed Dec. 15, 2011) teaches a fused silica fiber with a core diameter

less than approximately 400 microns [0027].

The prior art of record does not disclose or reasonably suggest, along with the other claim limitations, a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductors sources, one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers, one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam, and a nonlinear element configured to receive at least a portion of a first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 700 nm and approximately 2500 nm; a measurement apparatus; and a receiver, **comprising: namely**, wherein the delivered portion of the output optical beam is a spatially coherent beam.

28. **Claims 2-4** would be allowable due to dependency.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abra Fein whose telephone number is (571)272-0552. The examiner can normally be reached on Monday-Friday 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/DAVID PORTA/
Supervisory Patent Examiner, Art Unit 2884

/A. F./
Examiner, Art Unit 2884

Notice of References Cited	Application/Control No. 14/875,709	Applicant(s)/Patent Under Reexamination ISLAM, MOHAMMED N.	
	Examiner Abra Fein	Art Unit 2884	Page 1 of 1

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	D	US-				
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(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	POWM 0105 PUSP1

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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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	3	8213007	B2	2012-07-03	Wang, et al.	
	4	7848605	B2	2010-12-07	Ridder, et al.	
	5	8158493	B2	2012-04-17	Shah, et al.	

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Receipt date: 03/09/2016	Application Number	14875709	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2015-10-06	
	First Named Inventor	Mohammed N. ISLAM	
	Art Unit	2884	
	Examiner Name	Abra S. Fein	
	Attorney Docket Number	POWM 0105 PUSP1	

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Examiner Name	Abra S. Fein
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The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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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	/David S. Bir/	Date (YYYY-MM-DD)	2016-03-08
Name/Print	David S. Bir	Registration Number	38383

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Petitioner WHOOP, Inc. Ex1002

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Application Number	
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First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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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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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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	43	5970457		1999-10-19	Brant, et al.	
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	53	6340806		2002-01-22	Smart, et al.	
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	1	20020032468		2002-03-14	Hill, Michael R.S. ; et al.	
	2	20020082612		2002-06-27	Moll, Frederic H. ; et al.	
	3	20020128846		2002-09-12	Miller, Steven C.	
	4	20020178003		2002-11-28	Gehrke, James K. ; et al.	
	5	20040174914		2004-09-09	Fukatsu, Susumu	

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	1	EP1148666	EP		2001-10-24	Grant Andrew R et al.		☐
	2	WO01150959	WO		2001-07-19	SUHM		☐
	3	WO09715240	WO		1997-05-01	BRANT		☐
	4	WO97049340	WO		1997-12-31	WANG		☐

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☐ See attached certification statement.

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

☒ None

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Signature	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
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Attorney Docket Number	OMNI 0105 PUSP1

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	1	6885683		2005-04-26	FERMANN ET AL.	
	2	6281471	B1	2001-08-28	SMART	
	3	6340806		2002-01-22	SMART ET AL.	
	4	6301271	B1	2001-10-09	SANDERS ET AL.	
	5	7294105	B1	2007-11-13	ISLAM	

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	1	20100046067	A1	2010-02-25	FERMANN ET AL.	

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	2	20080105665	A1	2008-05-08	KONDO	

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	1	ISTEPANIAN, ROBERT H., "The Comparative Performance of Mobile Telemedical Systems based on the IS-54 and GSM Cellular Telephone Standards"; Journal of Telemedicine and Telecare 1999; pp 97-104	☐
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	1	6181414		2001-01-30	Raz et al.	
	2	7105823		2006-09-12	Abrahamsson et al.	
	3	8472108		2013-06-25	Islam	

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	2	20120239013		2012-09-20	Islam	
	3	20130274569		2013-10-17	Islam	

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	4	20140236021		2014-08-21	Islam	

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	1	"Application Brief AB-070: The role of infrared microprobe analysis in forensic drug analysis," www.smithsdetection.com, June 27, 2005.	☐
	2	Jasco Application Note No. 200DR0188-E, "Rapid Identification of illegal drug using NIR (identification of MDMA tablet)", September 4, 2008.	☐
	3	PALOU, A. J. CRUZ, M. BLANCO, J. TOMAS, J. DE LOS RIOS, M. ALCALA, "Determination of drug, excipients and coating distribution in pharmaceutical tablets using NIR-CI," Journal of Pharmaceutical Analysis, Vol. 2, no. 2, pp. 90-97 (2012).	☐
	4	ARNOLD, T., M. De BIASIO, R. LEITNER, "Near-Infrared Imaging Spectroscopy for Counterfeit Drug Detection," Next Generation Spectroscopic Technologies IV, edited by M. A. Druy, R.A. Crocombe, Proceedings of SPIE, Vol. 8032, 80320Y-1 to 7, (2011).	☐
	5	WEDDING, B.B., C. WRIGHT, S. GRAUF, R.D. WHITE, "The application of near infrared spectroscopy for the assessment of avocado quality attributes," Infrared Spectroscopy -- Life and Biomedical Sciences, pp. 211-230 (2011).	☐

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	6	MICHAELS, C.A., T. MASIELLO, P.M. CHU, "Fourier transform spectrometry with a near infrared supercontinuum source," Optical Society of America, CLEO/IQEC Conference, paper CMDD6 (2009).	☐
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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.

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	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
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	Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5747806		1998-05-05	Khalil	
	2	6115673		2000-09-05	Malin	
	3	6512936	B1	2003-01-28	MONFRE	
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	8	6738652	B2	2004-05-18	MATTU	

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
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	Attorney Docket Number	OMNI 0105 PUSP1

	9	6587702	B1	2003-07-01	RUCHTI	
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	11	6990364		2006-01-24	Ruchti	
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	17	7395158	B2	2008-07-01	Monfre	
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	20	7697966	B2	2010-04-13	MONFRE	
	21	7787924		2010-08-31	Acosta	
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	1	20100331637	A1	2010-12-30	Ting	
	2	20110143364	A1	2011-06-16	KIM	
	3	20030022126	A1	2003-01-30	BUCHALLA	
	4	20060223032	A1	2006-10-05	FRIED	

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	5	20100322490	A1	2010-12-23	PAN	
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	1	HAZEN, K.H., M.A. Arnold, G.W. Small, "Measurement of glucose and other analytes in undiluted human serum with near-infrared transmission spectroscopy," Analytica Chimica Acta, vol, 371, pp. 255-267 (1998).	☐
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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
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Exs Wed Feb 17

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Petitioner WHOOP, Inc. Ex1002

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	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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☐ 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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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	1	SUN, Y., C.F. Booker, S. Kumari, R.N. Day, M. Davidson, A. Periasamy, "Characterization of an orange acceptor fluorescent protein for sensitized spectral fluorescence resonant energy transfer microscopy using a white-light laser," Journal of Biomedical Optics, Vol. 14, no. 5, paper 054009 (2009).	☐
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☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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Petitioner WHOOP, Inc. Ex1002

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	Art Unit
	ABRA FEIN	2884

CPC- SEARCHED		
Symbol	Date	Examiner
G01N33/15, G01N21/359, G01N33/49	5/13/2016	/A.F./

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
250	338.4	5/13/2016	/A.F./

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search	5/13/2016	/A.F./
EAST text search	5/13/2016	/A.F./
Class 250 text search	5/13/2016	/A.F./
Consultation with Yara Green (class 250)	5/17/2016	/A.F./

INTERFERENCE SEARCH			
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CONFIRMATION NO. 7496

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/875,709	10/06/2015	250	2884	OMNI 0105 PUSP1

APPLICANTS
OMNI MEDSCI, INC., Ann Arbor, MI;

INVENTORS
Mohammed N. Islam, Ann Arbor, MI;

**** CONTINUING DATA ************************
This application is a CON of 14/108,986 12/17/2013 PAT 9164032
which claims benefit of 61/747,487 12/31/2012

**** FOREIGN APPLICATIONS ************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
10/22/2015

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ABRA S FEIN/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MI	26	20	3

ADDRESS

Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075
UNITED STATES

TITLE

SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

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(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
Art Unit	
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Attorney Docket Number	OMNI 0105 PUSP1

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
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	Attorney Docket Number	OMNI 0105 PUSP1

	1	Pan, Yingtian, et al., "Hand-held arthroscopic optical coherence tomography for in vivo high-resolution imaging of articular cartilage", Journal of Biomedical Optics 8(4), October 2003, pages 648-654.	☐
	2	Xie, Tuqiang, et al., "Endoscopic optical coherence tomography with a modified microelectromechanical systems mirror for detection of bladder cancers", APPLIED OPTICS, Vol. 42, No. 31, November1, 2003, pages 6422-6426.	☐
	3	Dubois, A., et al., "Three-dimensional cellular-level imaging using full-field optical coherence tomography", Physics in Medicine and Biology, Phys. Med. Biol. 49, 2004, pages 1227-1234.	☐
	4	Park, Jesung, et al., "Analysis of birefringent image in the retinal nerve fiber layer by polarization sensitive optical coherence tomography", Ophthalmic Technologies XIV, Proceedings of SPIE, Vol. 5314, 2004, pages 188-194.	☐
	5	Unterhuber, A., et al., "Advances in broad bandwidth light sources for ultrahigh resolution optical coherence tomography", Physics in Medicine and Biology, Phys. Med. Biol. 49, 2004, pages 1235-1246.	☐
	6	Drexler, Wolfgang, "Ultrahigh-resolution optical coherence tomography", Journal of Biomedical Optics, Vol. 9, No. 1, January/February 2004, pages 47-74.	☐
	7	Schmitt, Joseph, et al., "Intravascular Optical Coherence Tomography Opens a Window Onto Coronary Artery Disease", Optics & Photonics News, February 2004, pages 20-25.	☐
	8	Nassif, N.A., et al., "In vivo high-resolution video-rate spectral-domain optical coherence tomography of the human retina and optic nerve", OPTICS EXPRESS, Vol. 12, No. 3, February 9, 2004, pages 367-376.	☐
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	11	"State-Specific Trends in Chronic Kidney Failure - United States, 1990-2001", Morbidity and Mortality Weekly Report, Department of Health and Human Services Centers for Disease Control and Prevention, Vol. 53, No. 39, copied from intemet: file://C:\Documents and Settings\eturlo\Desktop\State-Specific Trends in Chronic Kidney ... 2/12/10, October 8, 2004, pages 918-920.	☐

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	12	I.B. Ads, A.A.E. Wagie, N.B. Mariun, A.B.E. Jammal, "An Internet-based blood pressure monitoring system for patients," Journal of Telemedicine and Telecare, 2001, pp. 51-53	☐
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	14	Shaw, et al, IR Supercontinuum Generation in As-Se Photonic Crystal Fiber, Optical Society of America, Copyright 2005, 3 pages	☐
	15	PCT/US06/44451, Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration, November 29, 2007, 12 pages	☐
	16	G.S. Edwards et al., "Free-electron-laser-based biophysical and biomedical instrumentation," American Institute of Physics, Vol. 74, No. 7, July 2003, pp. 3207-3245	☐
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	18	Computer Motion, Inc. "HERMES™ O.R. Control Center - 510(k) Summary of Safety and Effectiveness," October 11, 2002, 5 pages	☐
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Petitioner WHOOP, Inc. Ex1002
Page 409 of 1089

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	23	G. Edwards, et al., "Comparison of OPA and Mark-III FEL for Tissue Ablation at 6.45 Microns," Department of Physics and Free Electron Laser Laboratory, Duke University, 2002, 7 pages	☐
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	29	U.S. Appln. Serial No. 10/757,341, "System and Method for Voice Control of Medical devices," by Mohammed N. Islam, issued (074036.0132) Date filed: January 13, 2004	☐
	30	U.S. Appln. Serial No. 12/206432, "System and Method for Voice Control of Medical Devices," by Mohammed N. Islam, pending (074036.0154) Date filed: September 8, 2008	☐
	31	U.S. Patent and Trademark Office, Office Action for USSN 12/206,432, filed 09/08/2008, Mohammed N, Islam, Attorney Docket No. 074036.0154, Date filed: March 12, 2009	☐
	32	U.S. Patent and Trademark Office, Notice of Allowance and Fee(s) Due for USSN 12/206,432, filed 09/08/2008, Mohammed N. Islam, Attorney Docket No. 074036.0154, Date filed: August 28, 2009	☐

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	1	8157730	B2	2012-04-17	LeBoeuf, et al.	
	2	8430310	B1	2013-04-30	Ho, et al.	
	3	8509882	B2	2013-08-13	Albert, et al.	
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	1	20080086318	A1	2008-04-10	Gilley, et al.	

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	Examiner Name	
	Attorney Docket Number	POWM 0105 PUSP1

	2	20090287067	A1	2009-11-19	Dorogusker, et al.	
	3	20130281795	A1	2013-10-24	Varadan	
	4	20140081100	A1	2014-03-20	Muhsin, et al.	
	5	20150011851	A1	2015-01-08	Mehta, et al.	

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	1	WO2013012938		A1	2013-01-24	Raskin, et al.		☐
	2	WO2015084376		A1	2015-06-11	Han, et al.		☐

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	POWM 0105 PUSP1

CERTIFICATION STATEMENT

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

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

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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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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Application Number	
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First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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	First Named Inventor	Mohammed N. ISLAM
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	1	Islam, M. N., et al., "Broad bandwidths from frequency-shifting solitons in fibers", OPTICS LETTERS, Vol. 14, No. 7, April 1, 1989, pages 370-372.	☐
	2	Islam, M. N., et al., "Femtosecond distributed soliton spectrum in fibers", J. Opt. Soc. Am. B, Vol. 6, No. 6, June 1989, pages 1149-1158.	☐
	3	Busse, Lynda E., et al., "Design Parameters for Fluoride Multimode Fibers", Journal of Lightwave Technology, Vol. 9, No. 7, July 1991, pages 828-831.	☐
	4	Wuthrich, Stefan, et al., "Optical damage thresholds at 2.94 um in fluoride glass fibers", APPLIED OPTICS, Vol. 31, No. 27, September 20, 1992, pages 5833-5837.	☐
	5	Inoue, H., et al., "Computer simulation of the vibrational spectra and properties of fluoride glasses based on ZrF4", Journal of Non-Crystalline Solids, Vol. 161, 1993, pages 118-122.	☐
	6	Mizunami, Toru, et al., "Gain saturation characteristics of Raman amplification in silica and fluoride glass optical fibers", Optics Communications 97, 1993, pages 74-78.	☐
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	12	Iatridis, James C., et al., "Is the Nucleus Pulposus a Solid or a Fluid? Mechanical Behaviors of the Nucleus Pulposus of the Human Intervertebral Disc", Spine, Volume 21(10), May 15, 1996, pages 1174-1184.	☐
	13	Asobe, Masaki, "Nonlinear Optical Properties of Chalcogenide Glass Fibers and Their Application to All-Optical Switching", Optical Fiber Technology, Volume 3, Article No. OF970214, 1997, pages 142-148.	☐
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	15	Hamilton, James D., et al., "High Frequency Ultrasound Imaging with Optical Arrays", IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 45, No. 1, January 1998, pages 216-235.	☐
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	17	Nowak, G. A., et al., "Low-power high-efficiency wavelength conversion based on modulational instability in high-nonlinearity fiber," OPTICS LETTERS, Vol. 23, No. 12, June 15, 1998, pages 936-938.	☐
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	19	Lucas, Jacques, "Infrared glasses", Current Opinion in Solid State & Materials Science 4, 1999. pages 181-187.	☐
	20	Sanghera, J. S., et al., "Active and passive chalcogenide glass optical fibers for IR applications: a review', Journal of Non-Crystalline Solids 256 & 257, 1999, pages 6-16.	☐
	21	Nishida, Yoshiki, et al., "Reliability of Fluoride Fiber Module for Optical Amplifier Use", IEEE Photonics Technology Letters, Vol. 11, No. 12, December 1999, pages 1596-1598.	☐
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	23	Urban, J. P. G., et al., "The Nucleus of the Intervertebral Disc from Development to Degeneration" Amer. Zool., Volume 40, 2000, pages 53-61.	☐
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	26	Boult, Maggi, et al., "Systematic Review of Percutaneous Endoscopic Laser Discectomy: Update and Re-appraisal", Australian Safety and Efficacy Register of New Interventional Procedures - Surgical Report No. 5, February, 2000, 49 pages.	☐
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	31	Jackson, Stuart D., et al., "Theory and numerical simulation of nth-order cascaded Raman fiber lasers", J. Opt. Soc. Am. B, Vol. 18, No. 9, September 2001, pages 1297-1306.	☐
	32	Werle, Peter, et al., "Near- and mid-infrared laser-optical sensors for gas analysis", Optics and Lasers in Engineering 37, 2002, pages 101-114.	☐
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	34	Harbold, J. M., et al., "Highly nonlinear As-S-Se glasses for all-optical switching", OPTICS LETTERS, Vol. 27, No. 2, January 15, 2002, pages 119-121.	☐
	35	Coen, Stephane, et al., "Supercontinuum generation by stimulated Raman scattering and parametric four-wave mixing in photonic crystal fibers", J. Opt. Soc. Am. B, Vol. 19, No. 4, April 2002, pages 753-764.	☐
	36	Dudley, John M., et al., "Supercontinuum generation in air-silica microstructured fibers with nanosecond and femtosecond pulse pumping", J. Opt. Soc. Am. B, Vol. 19, No. 4, April 2002, pages 765-771.	☐
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	41	Edwards, Glenn S., et al., "Advantage of the Mark-III FEL for biophysical research and biomedical applications", J. Synchrotron Rad. Volume 10, 2003, pages 354-357.	☐
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	43	Sobol, Emil, et al., "Time-resolved, light scattering measurements of cartilage and cornea denaturation due to free electron laser radiation", Journal of Biomedical Optics, Vol. 8, No. 2, April 2003, pages 216-222.	☐
	44	Nicholson, J. W., et al., "All-fiber, octave-spanning supercontinuum", OPTICS LETTERS, Vol. 28, No. 8, April 15, 2003, pages 643-645.	☐

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Exs Wed 1 of 2

Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	45	Faralli, S., et al., "Impact of Double Rayleigh Scattering Noise in Distributed Higher Order Raman Pumping Schemes", IEEE Photonics Technology Letters, Vol. 15, No. 6, June 2003, pages 804-806.	☐
	46	"New and Emerging Techniques - Surgical, Rapid Review, Laser Discectomy", Australian Safety and Efficacy Register of New Interventional Procedures - Surgical, June 2003, 12 pages.	☐
	47	Avdokhin, A. V., et al, "Continuous-wave, high-power, Raman continuum generation in holey fibers", OPTICS LETTERS, Vol. 28, No. 15, August 1, 2003, pages 1353-1355.	☐
	48	Mussot, Arnaud, et al., "Generation of a broadband single-mode supercontinuum in a conventional dispersion-shifted fiber by use of a subnanosecond microchip laser", OPTICS LETTERS, Vol. 28, No. 19, October 1, 2003, pages 1820-1822.	☐
	49	Slusher, Richard, et al., "Highly nonlinear composite chalcogenide/polymer fibers", OSA 2004, 1 page.	☐
	50	Thongtrangan, Issada, et al., "Minimally invasive spinal surgery: a historical perspective", Neurosurg. Focus, Volume 16, Article 13, January 2004, pages 1-10.	☐

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

EXAMINER SIGNATURE

Examiner Signature	/Abra Fein/	Date Considered	05/13/2016

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

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

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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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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 record s.

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

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

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

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

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

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

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

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

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Petitioner WHOOP, Inc. Ex1002

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	Art Unit
	ABRA FEIN	2884

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/13/2016								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	(14/108986).APP.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:07
S2	1029	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:07
S3	269	((Mohammed) near2 (Islam)).INV.	US-PGPUB; USPAT	OR	ON	2015/06/15 12:07
S4	7	(("6885683") or ("6281471") or ("6340806") or ("6301271") or ("7294105") or ("20100046067") or ("20080105665")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:08
S5	52	(("5084880") or ("5180378") or ("5400165") or ("5458122") or ("5617871") or ("5631758") or ("5687734") or ("5696778") or ("5704351") or ("5718234") or ("5748103") or ("5855550") or ("5862803") or ("5847305") or ("5912749") or ("5944659") or ("5957854") or ("6014249") or ("6043927") or ("6289238") or ("6333803") or ("6364834") or ("6381391") or ("6402691") or ("6407853") or ("6441747") or ("6443890") or ("6454705") or ("6480656") or ("6549702") or ("6603910") or ("6659947") or ("6802811") or ("7167300") or ("7209657") or ("7263288") or ("7519253") or ("20020013518") or ("20020019584") or ("20020032468") or ("20020082612") or ("20020109621") or ("20020115914") or ("20020178003") or ("20040174914") or ("20040240037") or ("20050111511") or ("20060245461") or ("20060268393") or ("20070078348") or ("20090028193") or ("20090204110")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:12
S6	4	(("7787503") or ("7800818") or ("8000574") or ("6611643")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:13
S7	82	(("4063106") or ("4158750") or ("4221997") or ("4275266") or ("4374618") or ("4403605") or ("4462080") or ("4516207") or ("4523884") or ("4605080") or ("4641292") or ("4704696") or ("4728974") or ("4762455") or ("4776016") or ("4958910") or	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:19

		("4989253") or ("5078140") or ("5084880") or ("5086401") or ("5134620") or ("5142930") or ("5180378") or ("5191628") or ("5218655") or ("5230023") or ("5267256") or ("5267323") or ("5300097") or ("5303148") or ("5305427") or ("5313306") or ("5323404") or ("5345538") or ("5408409") or ("5544654") or ("5572999") or ("5695493") or ("5696778") or ("5792204") or ("5812978") or ("5950629") or ("5970457") or ("6014249") or ("6185535") or ("6200309") or ("6224542") or ("6246707") or ("6273858") or ("6278975") or ("6301273") or ("6337462") or ("6340806") or ("6350261") or ("6374006") or ("6407853") or ("6436107") or ("6442430") or ("6450172") or ("6453201") or ("6458120") or ("6462500") or ("6463361") or ("6567431") or ("6605080") or ("6625180") or ("6631025") or ("6659999") or ("6760148") or ("6885498") or ("6885683") or ("6943936") or ("7027467") or ("7060061") or ("7167300") or ("7259906") or ("7433116") or ("20020032468") or ("20020082612") or ("20020128846") or ("20020178003") or ("20040174914")).PN.				
S8	3	(("6246896") or ("6285897") or ("6847336")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:21
S9	30	(("5747806") or ("5115673") or ("6512936") or ("6534012") or ("6640117") or ("6788965") or ("6816241") or ("6738652") or ("6587702") or ("6864978") or ("6990364") or ("7010336") or ("7133710") or ("7233816") or ("7299080") or ("7317938") or ("7395158") or ("7519406") or ("7620674") or ("7697966") or ("7787924") or ("8145286") or ("6773922") or ("7807718") or ("20100331637") or ("20110143364") or ("20030022126") or ("20060223032") or ("20100322490") or ("20120013722")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:54
S10	2	(("8472108") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:54
S11	168	S4 S5 S6 S7 S8 S9 S10	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/15 13:07
S12	2	((12/206432) or (10/652276) or	US-	OR	OFF	2015/06/15

		(10/757341)).APP.	PGPUB; USPAT			14:48
S13	5	(("WOadj2014105520") or ("WOadj2014143276A9") or ("WOadj2014143276") or ("WOadj2013148656") or ("EPadj2831566") or ("WOadj2013148666") or ("EPadj2831565") or ("20130265568") or ("WOadj2014105521") or ("8859969") or ("20130256534") or ("20140236021") or ("CAadj2648549") or ("WOadj2007117867") or ("20060283931") or ("EPadj2011047") or ("EPadj1671094") or ("WOadj2005031302")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 14:51
S14	16	WO adj "2014105520" WO adj 2014143276A9 WO adj "2014143276" WO adj "2013148656" EP adj "2831566" WO adj "2013148666" EP adj "2831565" "20130265568" WO adj "2014105521" "8859969" "20130256534" "20140236021" CA adj "2648549" WO adj "2007117867" "20060283931" EP adj "2011047" EP adj "1671094" WO adj "2005031302"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/15 14:51
S15	7	(("6885683") or ("6281471") or ("6340806") or ("6301271") or ("7294105") or ("20100046067") or ("20080105665")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S16	52	(("5084880") or ("5180378") or ("5400165") or ("5458122") or ("5617871") or ("5631758") or ("5687734") or ("5696778") or ("5704351") or ("5718234") or ("5748103") or ("5855550") or ("5862803") or ("5847305") or ("5912749") or ("5944659") or ("5957854") or ("6014249") or ("6043927") or ("6289238") or ("6333803") or ("6364834") or ("6381391") or ("6402691") or ("6407853") or ("6441747") or ("6443890") or ("6454705") or ("6480656") or ("6549702") or ("6603910") or ("6659947") or ("6802811") or ("7167300") or ("7209657") or ("7263288") or ("7519253") or ("20020013518") or ("20020019584") or ("20020032468") or ("20020082612") or ("20020109621") or ("20020115914") or ("20020178003") or ("20040174914") or ("20040240037") or ("20050111511") or ("20060245461") or ("20060268393") or ("20070078348") or ("20090028193") or ("20090204110")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S17	4	(("7787503") or ("7800818") or ("8000574") or ("6611643")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S18	82	(("4063106") or ("4158750") or ("4221997") or ("4275266") or ("4374618") or ("4403605") or ("4462080") or ("4516207") or	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37

		("4523884") or ("4605080") or ("4641292") or ("4704696") or ("4728974") or ("4762455") or ("4776016") or ("4958910") or ("4989253") or ("5078140") or ("5084880") or ("5086401") or ("5134620") or ("5142930") or ("5180378") or ("5191628") or ("5218655") or ("5230023") or ("5267256") or ("5267323") or ("5300097") or ("5303148") or ("5305427") or ("5313306") or ("5323404") or ("5345538") or ("5408409") or ("5544654") or ("5572999") or ("5695493") or ("5696778") or ("5792204") or ("5812978") or ("5950629") or ("5970457") or ("6014249") or ("6185535") or ("6200309") or ("6224542") or ("6246707") or ("6273858") or ("6278975") or ("6301273") or ("6337462") or ("6340806") or ("6350261") or ("6374006") or ("6407853") or ("6436107") or ("6442430") or ("6450172") or ("6453201") or ("6458120") or ("6462500") or ("6463361") or ("6567431") or ("6605080") or ("6625180") or ("6631025") or ("6659999") or ("6760148") or ("6885498") or ("6885683") or ("6943936") or ("7027467") or ("7060061") or ("7167300") or ("7259906") or ("7433116") or ("20020032468") or ("20020082612") or ("20020128846") or ("20020178003") or ("20040174914")).PN.				
S19	3	(("6246896") or ("6285897") or ("6847336")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S20	30	(("5747806") or ("5115673") or ("6512936") or ("6534012") or ("6640117") or ("6788965") or ("6816241") or ("6738652") or ("6587702") or ("6864978") or ("6990364") or ("7010336") or ("7133710") or ("7233816") or ("7299080") or ("7317938") or ("7395158") or ("7519406") or ("7620674") or ("7697966") or ("7787924") or ("8145286") or ("6773922") or ("7807718") or ("20100331637") or ("20110143364") or ("20030022126") or ("20060223032") or ("20100322490") or ("20120013722")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S21	2	(("8472108") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S22	168	S15 S16 S17 S18 S19 S20 S21	US-PGPUB; USPAT;	OR	ON	2015/06/16 09:37

			EPO; JPO; DERWENT			
S23	2	((12/206432) or (10/652276) or (10/757341)).APP.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S24	5	(("WOadj2014105520") or ("WOadj2014143276A9") or ("WOadj2014143276") or ("WOadj2013148656") or ("EPadj2831566") or ("WOadj2013148666") or ("EPadj2831565") or ("20130265568") or ("WOadj2014105521") or ("8859969") or ("20130256534") or ("20140236021") or ("CAadj2648549") or ("WOadj2007117867") or ("20060283931") or ("EPadj2011047") or ("EPadj1671094") or ("WOadj2005031302")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S25	16	WO adj "2014105520" WO adj 2014143276A9 WO adj "2014143276" WO adj "2013148656" EP adj "2831566" WO adj "2013148666" EP adj "2831565" "20130265568" WO adj "2014105521" "8859969" "20130256534" "20140236021" CA adj "2648549" WO adj "2007117867" "20060283931" EP adj "2011047" EP adj "1671094" WO adj "2005031302"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:37
S26	185	S22 S23 S24 S25	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:37
S27	126	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:44
S28	1	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same semiconductor same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:46
S29	24	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconductor and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:47
S30	24	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconduct$5 and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:47
S31	21	S26 and ((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC	US-PGPUB; USPAT;	OR	ON	2015/06/16 09:48

		(short near wave near infrared)(short near wave near IR)) and semiconduct$5 and(multiplexer multiplexor)	EPO; JPO; DERWENT			
S32	648	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same semiconduct$5 same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:05
S33	123	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:08
S34	5	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:37
S35	6	S25 and (semiconduct$5 multiplex$5)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:50
S36	2	S25 and (multiplex$5)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:50
S37	6	S25 and (semiconduct$5 multiplex$5 mux)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:51
S38	8	S25 and (laser (super near luminesc$5 near diode)LED (light near emit$5 near diode))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:53
S39	9	S25 and (fiber)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:54
S40	1	S25 and (FTIR)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:56
S41	4	S25 and (fourier)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:59
S42	4	S25 and (fourier with (IR infrared infra-red))	US-PGPUB;	OR	ON	2015/06/16 10:59

			USPAT; EPO; JPO; DERWENT			
S43	4	S25 and (fourier near4 (IR infrared infra-red))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:59
S44	575	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:21
S45	8428	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:21
S46	3	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:22
S47	59	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:07
S48	4	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:08
S49	23	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S50	2	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S51	23	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S52	7	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)same fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S53	115	S26 and fiber	US-PGPUB; USPAT; EPO; JPO;	OR	ON	2015/06/16 13:14

			DERWENT			
S54	43	S26 and(fiber with beam)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S55	2	S26 and(fiber with beam)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S56	9	S26 and(FTIR FT-IR ("fourier transform infrared"))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:20
S57	270	((Mohammed) near2 (Islam)).INV.	US-PGPUB; USPAT	OR	ON	2015/06/16 13:22
S58	67	S57 and multiplexer.clm.	US-PGPUB; USPAT	OR	ON	2015/06/16 13:22
S59	21	S57 and ((multiplexer and semiconductor and fibers).clm.)	US-PGPUB; USPAT	OR	ON	2015/06/16 13:23
S60	2	S57 and ((multiplexer and semiconductor and fibers and FTIR).clm.)	US-PGPUB; USPAT	OR	ON	2015/06/16 13:23
S61	125	S57 and (broaden$5)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S62	64	S57 and (broaden$5 with (nonlinear non-linear))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S63	29	S57 and (broaden$5 with (nonlinear non-linear) with spectrum)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S64	9	S57 and (broaden$5 near4(nonlinear non-linear) with spectrum)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S65	2	S57 and (organic with (overtone (combination$5 absor%8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:31
S66	2	S57 and (organic with (overtone (combination$5 near absor$8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:32
S67	206	(organic with (overtone (combination$5 near absor$8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:32
S68	62	(organic with (overtone))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:40
S69	14	(organic with (overtone))and "250".clas.	US-PGPUB; USPAT	OR	ON	2015/06/16 16:40
S70	1	("6105823").PN.	US-PGPUB; USPAT	OR	OFF	2015/06/17 16:05

S71	320	abrahamsson.in.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/17 16:05
S72	4	abrahamsson.in. and multiplexer	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/17 16:06
S73	1034	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2015/07/23 13:49
S74	5	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:49
S75	2	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S76	125	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S77	8	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)same fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S78	14	(organic with (overtone))and "250".clas.	US-PGPUB; USPAT	OR	ON	2015/07/23 13:50
S79	1	(sample) with (overtone or "combinational absorption band") with(wavelength near range) .clm.	US-PGPUB; USPAT	OR	ON	2015/07/23 13:53
S81	7	250/338.4 and @pd>"20150625"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/24 11:51
S89	1	("20100161794").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/13 11:39
S90	606	banet.in.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:40
S91	5	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/05/13 11:58

S92	0	S91 and (LED light near emit$7 near diode) with puls$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:58
S93	93	(near-infrared near-IR)with(LED light near emit$7 near diode) with puls$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:59
S94	8	(near-infrared near-IR)with(LED light near emit$7 near diode) with puls$5 and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:59
S95	1059	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/05/13 13:56

5/13/2016 2:05:13 PM
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(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Mohammed N. ISLAM
Art Unit	
Examiner Name	
Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5084880		1992-01-28	Esterowitz, et al.	
	2	5180378		1993-01-19	Kung, et al.	
	3	5400165		1995-03-21	Gnauck, et al.	
	4	5458122		1995-10-17	Hethuin	
	5	5617871		1997-04-08	Burrows	
	6	5631758		1997-05-20	Knox, et al.	
	7	5687734		1997-11-18	Dempsey, et al.	
	8	5696778		1997-12-09	MacPherson	

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	9	5704351		1998-01-06	Mortara, et al.	
	10	5718234		1998-02-17	Warden, et al.	
	11	5748103		1998-05-05	Flach, et al.	
	12	5855550		1999-01-05	Lai, et al.	
	13	5862803		1999-01-26	Besson, et al.	
	14	5867305		1999-02-02	Waarts, et al.	
	15	5912749		1999-06-15	Harstead, et al.	
	16	5944659		1999-08-31	Flach, et al.	
	17	5957854		1999-09-28	Besson, et al.	
	18	6014249		2000-01-11	Fermann, et al.	
	19	6043927		2000-03-28	Islam	

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	20	6289238		2001-09-11	Besson, et al.	
	21	6333803		2001-12-25	Kurotori, et al.	
	22	6364834		2002-04-02	Reuss, et al.	
	23	6381391		2002-04-30	Islam, et al.	
	24	6402691		2002-06-11	Peddicord, et al.	
	25	6407853		2002-06-18	Samson, et al.	
	26	6441747		2002-08-27	Khair, et al.	
	27	6443890		2002-09-03	Schulze, et al.	
	28	6454705		2002-09-24	Cosentino, et al.	
	29	6480656		2002-11-12	Islam, et al.	
	30	6549702		2003-04-15	Islam, et al.	

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
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	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	31	6603910		2003-08-05	Islam, et al.	
	32	6659947		2003-12-09	Carter, et al.	
	33	6802811		2004-10-12	Slepian	
	34	7167300		2007-01-23	Fermann, et al.	
	35	7209657		2007-04-24	Islam	
	36	7263288		2007-08-28	Islam	
	37	7519253		2009-04-14	Islam	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020013518		2002-01-31	West, Kenneth G. ; et al.	
	2	20020019584		2002-02-14	Schulze, Arthur E. ; et al.	

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Petitioner WHOOP, Inc. Ex1002

Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	3	20020032468		2002-03-14	Hill, Michael R.S. ; et al.	
	4	20020082612		2002-06-27	Moll, Frederic H. ; et al.	
	5	20020109621		2002-08-15	Khair, Mohammad ; et al.	
	6	20020115914		2002-08-22	Russ, Tomas	
	7	20020178003		2002-11-28	Gehrke, James K. ; et al.	
	8	20040174914		2004-09-09	Fukatsu, Susumu	
	9	20040240037		2004-12-02	Harter, Donald J.	
	10	20050111500		2005-05-26	Harter, Donald J. ; et al.	
	11	20060245461		2006-11-02	Islam; Mohammed N.	
	12	20060268393		2006-11-30	Islam; Mohammed N.	
	13	20070078348		2007-04-05	Holman; Hoi-Ying N.	

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Petitioner WHOOP, Inc. Ex1002

Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

	14	20090028193		2009-01-29	Islam; Mohammed N.	
	15	20090204110		2009-08-13	Islam; Mohammed N.	

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	1	200189362	WO		2001-11-29	West Kenneth G et al.		☐
	2	200227640	WO		2002-04-04	Whittington Charles Lynn et al.		☐
	3	200228123	WO		2002-04-04	Whittington Charles Lynn		☐

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Examiner Signature	/Abra Fein/	Date Considered	05/13/2016

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

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

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

OR

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

☐ See attached certification statement.

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

☒ None

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	/David S. Bir/	Date (YYYY-MM-DD)	2015-10-01
Name/Print	David S. Bir	Registration Number	38383

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

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Petitioner WHOOP, Inc. Ex1002

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7771320	B2	2010-08-10	Riley, et al.	
	2	6619835	B2	2003-09-16	Kita	
	3	9326712	B1	2016-05-03	Kiani	
	4	5267152	A	1993-11-30	Yang et al.	
	5	7356364	B1	2008-04-08	Bullock et al.	
	6	5246004		1993-09-21	Clarke, et al.	
	7	8472108		2013-06-25	Islam	

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Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20100217102	A1	2010-08-26	LeBoeuf, et al.	
	2	20120310062	A1	2012-12-06	Li, et al.	
	3	20120316455	A1	2012-12-13	Rahman, et al.	
	4	20140275854	A1	2014-09-18	Venkatraman, et al.	
	5	20140275852	A1	2014-09-18	Hong, et al.	
	6	20160045118	A1	2016-02-18	Kiani	
	7	20110208015	A1	2011-08-25	Welch, et al.	
	8	20110040197	A1	2011-02-17	Welch et al.	
	9	20070021670	A1	2007-01-25	Mandelis et al.	
	10	20110282167	A1	2011-11-17	Ridder et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

	11	20130274569		2013-10-17	Islam			

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	1	U.S. Provisional Application No. 61/350,673; titled: OPTICOUSTIC SENSOR; Inventor: Massi Joe E. Kiani; filed on June 2, 2010.	
	2	International Search Report and Written Opinion for International Application No. PCT/US2013/075700 dated April 24, 2014	
	3	International Preliminary Report on Patentability for International Application No. PCT/US2013/075700 dated July 9, 2015	
	4	Ooi ET, Zhang XQ, Chen JH, Soh PH, Ng K, Yeo JH, "Non-invasive glucose measurement using multiple laser diodes," Optical Diagnostic and Sensing VII, edited by Gerard L. Cote, Alexander V. Priezzhev, Proc. of SPIE Vol. 6445, 64450K , (2007).	
	5	Schulz, I., J. Putzger, A. Niklas, M. Brandt, A. Jager, A. Hardt, S. Knorzer, K.A. Hiller, S. Loffler, G. Schmalz, S.N. Danilov, S. Giglberger, M. Hirmer, S.D. Ganichev, G. Monkman, "PPG signal acquisition and analysis on in vitro tooth model for dental pulp vitality assessment," ARC Submission 16, (2012).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

	6	Drexler, C., Hirmer, M., Danilov, S., Giglberger, S., Putzger, J., Niklas, A., Jager, A., Hiller, K., Loffler, S., Schmalz, G., Redlich, B., Schulz, I., Monkman, G., Ganichev, S. "Infrared spectroscopy for clinical diagnosis of dental pulp vitality." Infrared, Millimeter, and Terahertz Waves (IRMMW-THz), 2012 37th International Conference on. IEEE (2012).
	7	Hirmer, Marion, Danilov, Sergey, Giglberger, Stephan, Putzger, Jurgen, Niklas, Andreas, Jager, Andreas, Hiller, Karl-Anton, Loffler, Susanne, Schmalz, Gottfried, Redlich, Britta, Schulz, Irene, Monkman, Gareth, Ganichev, Sergey. "Spectroscopic Study of Human Teeth and Blood from Visible to Terahertz Frequencies for Clinical Diagnosis of Dental Pulp Vitality." Journal of Infrared, Millimeter, and Terahertz Waves 33.3 (2012): 366-375.
	8	Na, J, J.H. Baek, S.Y. Ryu, C. Lee, B.H. Lee, "Tomographic imaging of incipient dental-caries using optical coherence tomography and comparison with various modalities," Optical Review, vol. 16, no. 4, pp. 426-431 (2009).

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

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	/David S. Bir/	Date (YYYY-MM-DD)	2016-06-22
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	14875709
Filing Date:	06-Oct-2015
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Filer:	David S. Bir/Pamela Demos
Attorney Docket Number:	OMNI 0105 PUSP1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	26136687
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	22-JUN-2016
Filing Date:	06-OCT-2015
Time Stamp:	17:29:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$90
RAM confirmation Number	4396
Deposit Account	023978
Authorized User	BIR, DAVID S.

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

Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	ISR_and_WO.pdf	2432619 7d24707f10549aff20794fba6af5aa2b455db702	no	15
Warnings:					
Information:					
2	Non Patent Literature	IPRP.pdf	2048361 886f28553ff80f85158927da96fe5a2994810146	no	10
Warnings:					
Information:					
3	Non Patent Literature	Provisional_Application_61350673.pdf	3855731 8c99530daa6b316f5ff7b72b409523d8456756b5	no	22
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	Supplemental_IDS.pdf	613766 52fb660c832fbca63601a090bf6d14666858105b	no	6
Warnings:					
Information:					
5	Non Patent Literature	2007-Ooi-GlucoSTATS.pdf	492976 5b44216c10b13f2bc2a67589ba2201693f4d79ff	no	14
Warnings:					
Information:					
6	Non Patent Literature	2009-Na-Tomographic_Imaging_and_comparisons.pdf	1199064 413a9d31fb2524de77569a8ca4556c6a326c4382	no	12
Warnings:					
Information:					
7	Non Patent Literature	2012-Drexler-Infrared_Spectroscopy_Pulp_Vitalit.pdf	346446 52c37eb2ebc63dc535eeaa08259ac9098b48a888	no	1
Warnings:					
Information:					

8	Non Patent Literature	2012-Hirmer-Spectroscopy_study_of_teeth.pdf	814060 39d86dd593cbbfb9affc43f9b985f4203c388664	no	10
Warnings:					
Information:					
9	Non Patent Literature	2012-Schulz-PPG_Signal.pdf	544826 15ad6e46b3b0cef66e3d18c2d42b11a07bb8d224	no	5
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	30678 c0045a6f5eec952dec580512b85536d714f1d569	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	12378527	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
BIR, DAVID S.

BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD MI 48075 USA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 24 April 2014 (24.04.2014)
Applicant's or agent's file reference OMNI0101PCT	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. **PCT/US2013/075700**	International filing date *(day/month/year)* **17 December 2013 (17.12.2013)**
Applicant **OMNI MEDSCI, INC.**	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:

   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 . 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the PCT Applicant's Guide, National Chapters.

Name and mailing address of the ISA/KR International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer COMMISSIONER Telephone No. 82-42-481-8754

Form PCT/ISA/220 (July 2010)

* Attention

Copies of the documents cited in the international search report can be searched in the following Korean Intellectual Property Office English website for six months(expire date : **2014.10.24**) from the date of mailing of the international search report.

http://www.kipo.go.kr/en/ => PCT Services => PCT Services

ID : PCT international application number
PW : **Z92JGD54**

Inquiries related to PCT International Search Report or Written Opinion prepared by KIPO as an International Searching Authority can be answered not only by KIPO but also through IPKC (Intellectual Property Korea Center), located in Vienna, VA, which functions as a PCT Help Desk for PCT applicants.

Homepage: http://www.ipkcenter.com

Email: ipkc@ipkcenter.com

Notes to Form PCT/ISA/220 (July 2010)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference OMNI0101PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. **PCT/US2013/075700**	International filing date *(day/month/year)* **17 December 2013 (17.12.2013)**	(Earliest) Priority Date *(day/month/year)* 31 December 2012 (31.12.2012)

Applicant

OMNI MEDSCI, INC.

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/075700

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/1477(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/1477; G06F 15/42; A61B 18/22; A61B 6/00; A61B 5/1455; A61B 5/00

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: near-infrared, laser, diagnosis, non-invasive, tooth, glucose and blood

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012-0239013 A1 (ISLAM, MOHAMMED N.) 20 September 2012 See abstract, paragraphs [0004]-[0015], [0059], [0136]-[0139], claims 30-40, and figures 7, 19-20.	1-20
A	US 2007-0021670 A1 (MANDELIS, ANDREAS et al.) 25 January 2007 See abstract, claims 1-28, and figure 1.	1-20
A	US 2011-0282167 A1 (RIDDER, TRENT et al.) 17 November 2011 See abstract, and claims 1-18.	1-20
A	US 5267152 A (YANG, WON S. et al.) 30 November 1993 See abstract, claim 1-3, and figure 1.	1-20
A	US 7356364 B1 (BULLOCK, AUDRA M. et al.) 08 April 2008 See abstract, and claims 14-20.	1-20

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

☒ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
23 April 2014 (23.04.2014)	**24 April 2014 (24.04.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
CHOI, Sang Won
Telephone No. +82-42-481-8291

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/075700

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012-0239013 A1	20/09/2012	CA 2623380 A1	31/05/2007
		CA 2623380 C	11/02/2014
		EP 1949151 A2	30/07/2008
		EP 1949151 A4	06/11/2013
		US 2009-0028193 A1	29/01/2009
		US 2009-0204110 A1	13/08/2009
		US 2014-0001364 A1	02/01/2014
		US 7519253 B2	14/04/2009
		US 8055108 B2	08/11/2011
		US 8391660 B2	05/03/2013
		WO 2007-061732 A2	31/05/2007
		WO 2007-061732 A3	28/02/2008
US 2007-0021670 A1	25/01/2007	AU 2006-272332 A1	25/01/2007
		AU 2006-272332 B2	01/11/2012
		BR PI0613428 A2	30/10/2012
		CA 2615017 A1	25/01/2007
		CN 101262822 A	10/09/2008
		CN 101262822 B	20/11/2013
		EP 1906835 A1	09/04/2008
		EP 1906835 A4	31/07/2013
		IL 188747 D0	07/08/2008
		JP 2009-501579 A	22/01/2009
		JP 2013-172975 A	05/09/2013
		KR 10-2008-0051129 A	10/06/2008
		NZ 565509 A	26/08/2011
		US 8306608 B2	06/11/2012
		WO 2007-009234 A1	25/01/2007
		ZA 200801139 A	31/12/2008
US 2011-0282167 A1	17/11/2011	CN 102365047 A	29/02/2012
		EP 2389100 A1	30/11/2011
		EP 2389100 A4	22/05/2013
		JP 2012-515630 A	12/07/2012
		US 2010-0010325 A1	14/01/2010
		US 8174394 B2	08/05/2012
		WO 2010-085716 A1	29/07/2010
US 5267152 A	30/11/1993	CN 1025410 C	13/07/1994
		CN 1051297 A	15/05/1991
		CN 1051297 C0	01/05/1994
		EP 0426358 A1	08/05/1991
		EP 0426358 B1	12/05/1999
		JP 03-146032 A	21/06/1991
		JP 05-081253 B	12/11/1993
		JP 10-000181 U	25/08/1998
		JP 2588468 Y2	30/10/1998
		KR 10-1992-0002091 A	28/02/1992
		KR 10-1993-0011586 B1	13/12/1993

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/075700

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 7356364 B1	08/04/2008	None	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
BIR, DAVID S.

BROOKS KUSHMAN P.C. 1000 TOWN CENTER
TWENTY-SECOND FLOOR SOUTHFIELD MI 48075 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**24 April 2014 (24.04.2014)**
Applicant's or agent's file reference: OMNI0101PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2013/075700	**17 December 2013 (17.12.2013)**	31 December 2012 (31.12.2012)

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

A61B 5/1477(2006.01)i

Applicant

OMNI MEDSCI, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. +82-42-472-7140	23 April 2014 (23.04.2014)	CHOI, Sang Won Telephone No. +82-42-481-8291

Form PCT/ISA/237 (cover sheet) (July 2011)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2013/075700

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)
   - ☐ on paper
   - ☐ in electronic form

   b. (time)
   - ☐ in the international application as filed.
   - ☐ together with the international application in electronic form.
   - ☐ subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2013/075700

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following document:

D1: US 2012-0239013 A1 (ISLAM, MOHAMMED N.) 20 September 2012

1. Novelty and Inventive Step

1.1. Claim 1

The subject-matter of claim 1 relates to a diagnostic system comprising:
(a) a light source configured to generate an output optical beam, comprising: (a-1) semiconductor sources configured to generate an input beam; (a-2) optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the optical fibers; (a-3) optical fibers configured to receive at least a portion of the intermediate beam and to deliver the portion of the intermediate beam to a distal end of the optical fibers to form a first optical beam; and (a-4) a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum, wherein a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength approximately 1400-2500 nm, and wherein a portion of the one of more fibers is a fused silica fiber with a core diameter less than approximately 400 microns; (b) an interface device configured to receive a received portion of the output optical beam and to deliver portion of the output optical beam to a sample, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample; and (c) a receiver configured to receive at least a portion of the spectroscopy output beam having a bandwidth of 10nm and to process the portion of the spectroscopy output beam to generate an output signal representing at least in part a property of hydro-carbon bonds.

D1, which is considered to be the closest prior art to the subject matter of claim 1, discloses an optical system for use in a medical procedure, the system comprising: (a-1') a plurality of semiconductor laser diodes, each of the diodes

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Box No. V

being capable of generating an optical beam that is optically coupled to a beam combiner; (a-3') a first stage optical fiber optically coupled to the beam combiner and (a-2') optical amplifiers, wherein the first stage optical fiber receives the optical beams and forms a corresponding pump beam having a wavelength range between approximately 1700 nm and 1750 nm; (a-3') a second stage light guide optically coupled to the first stage optical fiber, the second stage light guide adapted to propagate the pump beam; and (b') a lens subsystem adapted to receive and deliver at least a portion of the pump beam to target portions of tissue (see claims 35 and 39 and paragraph [0007]). D1 further discloses that the optical system can be chemical sensing systems comprising (c') a detection system collecting at least a fraction of the light and being coupled to the detector and a receiver for sensing characteristic of specific types of chemical bonds (see paragraphs [0136]-[0137]) and that the first fiber can be made fused silica (see paragraph [0011]) and is coupled to (a-4') a nonlinear element which is capable of broadening the pump optical spectral width to at least 100 nm through a nonlinear effect in the element (see paragraph [0007]).

Claim 1 differs from D1 in that the optical fibers are the fused silica fiber with the core diameter 400 microns. However, the diameter of the fiber can be easily optimized by repeated experiments practiced by a person skilled in the art. Accordingly, a person skilled in the art would easily conceive the idea of employing the feature of claim 1. Therefore, claim 1 lacks an inventive step under PCT Article 33(3).

1.2. Claims 2-5
Claims 2-5 are dependent on claim 1.

Claim 2 further comprises the interface device further comprising a replaceable insert. The additional feature of claim 2 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 2 would have been obvious over D1. Therefore, claim 2 lacks an inventive step under PCT Article 33(3).

Claim 3 further comprises the sample comprising at least in part enamel, dentine and blood and the output signal representing at least in part a property of the blood. The additional feature of claim 3 is considered to be a minor difference over the disclosure of D1 that the target portions of tissue comprise protein, amino acids, or amide groups, which falls under the general knowledge of a person skilled in the art (see claim 36). Accordingly, claim 3 would have been obvious over D1. Therefore, claim 3 lacks an inventive step under PCT Article 33(3).

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In case the space in any of the preceding boxes is not sufficient.
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Claim 4 further comprises the input beam comprising a repetition rate approximately 1kHz-100MHz. The additional feature of claim 4 can be easily optimized by repeated experiments practiced by a person skilled in the art, considering that at least the portion of the pump beam has a repetition rate between continuous wave and several Megahertz (see claim 35 in D1). Accordingly, claim 4 would have been obvious over D1. Therefore, claim 4 lacks an inventive step under PCT Article 33(3).

Claim 5 further comprises the receiver further comprising a wireless transmitter configured to communicate a wireless signal associated with the output signal to a network. The additional feature of claim 5 is considered to be a minor difference over the disclosure of D1 in that the optical fibers include super-continuum (SC) generation (see paragraph [0004]) and that a chemical sensing system using an SC light source may lead remote detection of chemical species (see paragraphs [0138]-[0139]), which falls under the general knowledge of a person skilled in the art. Accordingly, a person skilled in the art would easily conceive the idea of employing the feature of claim 5. Therefore, claim 5 lacks an inventive step under PCT Article 33(3).

1.3. Claim 6
Claim 6 relates to a measurement system comprising: (a) a light source generating an output optical beam, comprising (a-1) a plurality of semiconductor sources generating an input optical beam, (a-2) a multiplexer configured to receive at least a portion of the input optical beam and to form an intermediate optical beam, and (a-3) one or more fibers configured to receive at least a portion of the intermediate optical beam and to form the output optical beam, wherein the output optical beam comprises one or more optical wavelengths; (b) an interface device configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample comprising at least in part enamel, dentine and pulp, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample; and (c) a receiver configured to receive at least a portion of the spectroscopy output beam and to process the portion of the spectroscopy output beam to generate an output signal representing at least in part a property of blood contained within the pulp.

D1, which is considered to be the closest prior art to the subject matter of claim 6, discloses an optical system for use in a medical procedure, the system comprising: (a-1') a plurality of semiconductor laser diodes, each of the diodes being capable of generating an optical beam that is optically coupled to a beam combiner; (a-3') a first stage optical fiber optically coupled to the beam combiner and (a-2') optical amplifiers capable of amplifying the pump signal, wherein the first stage optical fiber receives the optical beams and forms a corresponding pump

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beam having a wavelength range between approximately 1700 nm and 1750 nm; (a-3'') a second stage light guide optically coupled to the first stage optical fiber, the second stage light guide adapted to propagate the pump beam; and (b') a lens subsystem adapted to receive and deliver at least a portion of the pump beam to target portions of tissue (see claims 35 and 39 and paragraph [0007]). D1 further discloses that the optical system can be a chemical sensing systems comprising (c') a detection system collecting at least a fraction of the light and being coupled to the detector and receiver for sensing characteristic of specific types of chemical bonds (see paragraphs [0136]-[0137]).

Claim 6 differs from D1 in that the light source comprises the multiplexer, that the sample comprises at least in part enamel, dentine and pulp and that the output signal represents at least in part a property of blood contained within the pulp. However, considering that amplified spontaneous emission (ASE) from the amplifier is controlled by an add/drop multiplexer (see paragraph [0059]) and that the target portions of tissue comprise protein, amino acids, or amide groups (see claim 36), such a slight constructional change in the system of D1 comes within the scope of the customary practice followed by a person skilled in the art. Accordingly, a person skilled in the art would easily conceive the idea of employing the feature of claim 6. Therefore, claim 6 lacks an inventive step under PCT Article 33(3).

1.4. Claims 7-11 and 14-16
Claims 7-11, 14-16 are dependent on claim 6.

Claim 7 further comprises the light source comprising a super-continuum laser. The additional feature of claim 7 is a minor difference over the disclosure of D1 in that super-continuum (SC) light source could be used in chemical sensing (see paragraph [0015]), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 7 would have been obvious over D1. Therefore, claim 7 lacks an inventive step under PCT Article 33(3).

Claim 8 further comprises the light source comprising a super-luminescent diode. The additional feature of claim 8 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 8 would have been obvious over D1. Therefore, claim 8 lacks an inventive step under PCT Article 33(3).

Claim 9 further comprises the light source comprising a light emitting diode. The additional feature of claim 9 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 9 would have been obvious over D1. Therefore, claim 9 lacks an inventive step under PCT

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In case the space in any of the preceding boxes is not sufficient.
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Article 33(3).

Claim 10 further comprises at least a portion of the one of more optical wavelengths comprising a short-wave infrared wavelength approximately 1400-2500nm. The additional feature of claim 10 is a minor difference over the disclosure of D1 in that the pump beam wavelength is in a wavelength range between approximately 1700 nm and 1750 nm, which falls under the general knowledge of a person skilled in the art (see claim 39). Accordingly, claim 10 would have been obvious over D1. Therefore, claim 10 lacks an inventive step under PCT Article 33(3).

Claim 11 further comprises the property of the blood comprising a glucose level. The additional feature of claim 11 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 11 would have been obvious over D1. Therefore, claim 11 lacks an inventive step under PCT Article 33(3).

Claim 14 further comprises the delivered portion of the output optical beam transmitted through the sample. The additional feature of claim 14 is a minor difference over the disclosure of D1 in that the pump beam wavelength is selected to obtain a desired penetration depth (see claim 35), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 14 would have been obvious over D1. Therefore, claim 14 lacks an inventive step under PCT Article 33(3).

Claim 15 further comprises the interface device further comprising a replaceable insert. The additional feature of claim 15 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 15 would have been obvious over D1. Therefore, claim 15 lacks an inventive step under PCT Article 33(3).

Claim 16 further comprises the receiver configured to process the portion of the spectroscopy output beam using a pattern matching methodology. The additional feature of claim 16 is a minor difference over the disclosure of D1 in that super-continuum (SC) broadband source could be particularly useful for spectral fingerprinting and that the relative magnitudes at different wavelengths or a particular spectral pattern of absorption or reflection can be pattern matched to identify the chemical of interest (see paragraph [0137]), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 16 would have been obvious over D1. Therefore, claim 16 lacks an inventive step under PCT Article 33(3).

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1.5. Claims 12-13
Claims 12-13 are dependent on claim 11.

Claims 12-13 further comprise at least a portion of the one or more optical wavelengths which comprises a short-wave infrared wavelength approximately 1587-1750nm (claim 12) and near 2120nm, 2270nm or 2320 nm (claim 13). Claims 12-13 differ from D1 in the wavelength. However, the selection of the wavelength can be easily optimized by repeated experiments practiced by a person skilled in the art. Accordingly, claims 12-13 would have been obvious over D1. Therefore, claims 12-13 lack an inventive step under PCT Article 33(3).

1.6. Claim 17
Claim 17 relates to a method of measuring comprising: (a) generating an output optical beam, comprising (a-1) generating an input optical beam from a plurality of semiconductor sources, (a-2) multiplexing at least a portion of the input optical beam and forming an intermediate optical beam and (a-3) guiding at least a portion of the intermediate optical beam and forming the output optical beam, wherein the output optical beam comprises one or more optical wavelengths; (b) receiving a received portion of the output optical beam and delivering a delivered portion of the output optical beam to a sample, wherein the sample comprises at least in part enamel, dentine and pulp; (c) generating a spectroscopy output beam from the sample; (d) receiving at least a portion of the spectroscopy output beam; and (e) processing the portion of the spectroscopy output beam and generating an output signal representing at least in part a property of blood contained within the pulp.

D1, which is considered to be the closest prior art to the subject matter of claim 17, discloses a method for performing a medical procedure, the method comprising the steps of: (a') generating one or more optical beams utilizing a plurality of semiconductor laser diodes; (a-1') optically coupling the one or more optical beams to a beam combiner; (a-2') receiving at a first stage optical fiber the one or more optical beams and forming a corresponding pump beam having at least one wavelength; (a-3') propagating the pump beam in a second stage light guide optically coupled to the first stage optical fiber; and (b') receiving and delivering at least a portion of the pump beam with a lens subsystem to target portions of tissue (see claim 30). D1 further discloses that a method of generating broadband light by (c') generating a pump signal comprises broadening the pump optical spectral width to at least 100 nm using a nonlinear effect (see paragraph [0009]).

Claim 17 differs from D1 in the steps of (d) receiving the spectroscopy output beam and (e) processing the portion of the spectroscopy output beam and generating the output signal. Furthermore, claim 17 differs from D1 in that the sample comprises

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In case **the space in any of the preceding boxes is not sufficient.**
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enamel, dentine and pulp. However, the steps of (d) receiving and (e) processing are merely matters of design option when the general technical knowledge about the state of the art is used. And the sample comprising at least in part enamel, dentine and plup is a minor difference over the disclosure of D1 in that the target portions of tissue comprise protein, amino acids, or amide groups (see claim 36), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 17 would have been obvious over D1. Therefore, claim 17 lacks an inventive step under PCT Article 33(3).

1.7. Claims 18-20
Claims 18-20 are dependent on claim 17.

Claim 18 further comprises the one or more optical wavelengths comprising a short-wave infrared wavelength approximately 1400-2500nm. The additional feature of claim 18 is a minor difference over the disclosure of D1 in that the pump beam wavelength is in a wavelength range between approximately 1700 nm and 1750 nm, which falls under the general knowledge of a person skilled in the art (see claim 31). Accordingly, claim 18 would have been obvious over D1. Therefore, claim 18 lacks an inventive step under PCT Article 33(3).

Claim 19 further comprises the property of the blood comprising a glucose level. The additional feature of claim 19 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 19 would have been obvious over D1. Therefore, claim 19 lacks an inventive step under PCT Article 33(3).

Claim 20 further comprises communicating a wireless signal associated with the output signal to a network. The additional feature of claim 20 is considered to be a minor difference over the disclosure of D1 in that the optical fibers include super-continuum (SC) generation (see paragraph [0004]) and that a chemical sensing system using a SC light source may lead remote detection of chemical species (see paragraphs [0138]-[0139]), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 20 would have been obvious over D1. Therefore, claim 20 lacks an inventive step under PCT Article 33(3).

2. Industrial Applicability
Claims 1-20 are industrially applicable under PCT Article 33(4).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference OMNI0101PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2013/075700	International filing date *(day/month/year)* 17 December 2013 (17.12.2013)	Priority date *(day/month/year)* 31 December 2012 (31.12.2012)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant OMNI MEDSCI, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 30 June 2015 (30.06.2015)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Kihwan Moon e-mail: pt01.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
BIR, DAVID S.

BROOKS KUSHMAN P.C. 1000 TOWN CENTER
TWENTY-SECOND FLOOR SOUTHFIELD MI 48075 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)* **24 April 2014 (24.04.2014)**

Applicant's or agent's file reference
OMNI0101PCT

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2013/075700	**17 December 2013 (17.12.2013)**	31 December 2012 (31.12.2012)

International Patent Classification (IPC) or both national classification and IPC
A61B 5/1477(2006.01)i

Applicant
OMNI MEDSCI, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. +82-42-472-7140	23 April 2014 (23.04.2014)	CHOI, Sang Won Telephone No. +82-42-481-8291

Form PCT/ISA/237 (cover sheet) (July 2011)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2013/075700

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

   ☐ on paper

   ☐ in electronic form

   b. (time)

   ☐ in the international application as filed.

   ☐ together with the international application in electronic form.

   ☐ subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2013/075700

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following document:

D1: US 2012-0239013 A1 (ISLAM, MOHAMMED N.) 20 September 2012

1. Novelty and Inventive Step

1.1. Claim 1

The subject-matter of claim 1 relates to a diagnostic system comprising:
(a) a light source configured to generate an output optical beam, comprising: (a-1) semiconductor sources configured to generate an input beam; (a-2) optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the optical fibers; (a-3) optical fibers configured to receive at least a portion of the intermediate beam and to deliver the portion of the intermediate beam to a distal end of the optical fibers to form a first optical beam; and (a-4) a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum, wherein a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength approximately 1400-2500 nm, and wherein a portion of the one of more fibers is a fused silica fiber with a core diameter less than approximately 400 microns; (b) an interface device configured to receive a received portion of the output optical beam and to deliver portion of the output optical beam to a sample, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample; and (c) a receiver configured to receive at least a portion of the spectroscopy output beam having a bandwidth of 10nm and to process the portion of the spectroscopy output beam to generate an output signal representing at least in part a property of hydro-carbon bonds.

D1, which is considered to be the closest prior art to the subject matter of claim 1, discloses an optical system for use in a medical procedure, the system comprising: (a-1') a plurality of semiconductor laser diodes, each of the diodes

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of : Box No. V

being capable of generating an optical beam that is optically coupled to a beam combiner; (a-3') a first stage optical fiber optically coupled to the beam combiner and (a-2') optical amplifiers, wherein the first stage optical fiber receives the optical beams and forms a corresponding pump beam having a wavelength range between approximately 1700 nm and 1750 nm; (a-3') a second stage light guide optically coupled to the first stage optical fiber, the second stage light guide adapted to propagate the pump beam; and (b') a lens subsystem adapted to receive and deliver at least a portion of the pump beam to target portions of tissue (see claims 35 and 39 and paragraph [0007]). D1 further discloses that the optical system can be chemical sensing systems comprising (c') a detection system collecting at least a fraction of the light and being coupled to the detector and a receiver for sensing characteristic of specific types of chemical bonds (see paragraphs [0136]-[0137]) and that the first fiber can be made fused silica (see paragraph [0011]) and is coupled to (a-4') a nonlinear element which is capable of broadening the pump optical spectral width to at least 100 nm through a nonlinear effect in the element (see paragraph [0007]).

Claim 1 differs from D1 in that the optical fibers are the fused silica fiber with the core diameter 400 microns. However, the diameter of the fiber can be easily optimized by repeated experiments practiced by a person skilled in the art. Accordingly, a person skilled in the art would easily conceive the idea of employing the feature of claim 1. Therefore, claim 1 lacks an inventive step under PCT Article 33(3).

1.2. Claims 2-5
Claims 2-5 are dependent on claim 1.

Claim 2 further comprises the interface device further comprising a replaceable insert. The additional feature of claim 2 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 2 would have been obvious over D1. Therefore, claim 2 lacks an inventive step under PCT Article 33(3).

Claim 3 further comprises the sample comprising at least in part enamel, dentine and blood and the output signal representing at least in part a property of the blood. The additional feature of claim 3 is considered to be a minor difference over the disclosure of D1 that the target portions of tissue comprise protein, amino acids, or amide groups, which falls under the general knowledge of a person skilled in the art (see claim 36). Accordingly, claim 3 would have been obvious over D1. Therefore, claim 3 lacks an inventive step under PCT Article 33(3).

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In case **the space in any of the preceding boxes is not sufficient.**
Continuation of : Previous Page

Claim 4 further comprises the input beam comprising a repetition rate approximately 1kHz-100MHz. The additional feature of claim 4 can be easily optimized by repeated experiments practiced by a person skilled in the art, considering that at least the portion of the pump beam has a repetition rate between continuous wave and several Megahertz (see claim 35 in D1). Accordingly, claim 4 would have been obvious over D1. Therefore, claim 4 lacks an inventive step under PCT Article 33(3).

Claim 5 further comprises the receiver further comprising a wireless transmitter configured to communicate a wireless signal associated with the output signal to a network. The additional feature of claim 5 is considered to be a minor difference over the disclosure of D1 in that the optical fibers include super-continuum (SC) generation (see paragraph [0004]) and that a chemical sensing system using an SC light source may lead remote detection of chemical species (see paragraphs [0138]-[0139]), which falls under the general knowledge of a person skilled in the art. Accordingly, a person skilled in the art would easily conceive the idea of employing the feature of claim 5. Therefore, claim 5 lacks an inventive step under PCT Article 33(3).

1.3. Claim 6
Claim 6 relates to a measurement system comprising: (a) a light source generating an output optical beam, comprising (a-1) a plurality of semiconductor sources generating an input optical beam, (a-2) a multiplexer configured to receive at least a portion of the input optical beam and to form an intermediate optical beam, and (a-3) one or more fibers configured to receive at least a portion of the intermediate optical beam and to form the output optical beam, wherein the output optical beam comprises one or more optical wavelengths; (b) an interface device configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample comprising at least in part enamel, dentine and pulp, wherein the delivered portion of the output optical beam is configured to generate a spectroscopy output beam from the sample; and (c) a receiver configured to receive at least a portion of the spectroscopy output beam and to process the portion of the spectroscopy output beam to generate an output signal representing at least in part a property of blood contained within the pulp.

D1, which is considered to be the closest prior art to the subject matter of claim 6, discloses an optical system for use in a medical procedure, the system comprising: (a-1') a plurality of semiconductor laser diodes, each of the diodes being capable of generating an optical beam that is optically coupled to a beam combiner; (a-3') a first stage optical fiber optically coupled to the beam combiner and (a-2') optical amplifiers capable of amplifying the pump signal, wherein the first stage optical fiber receives the optical beams and forms a corresponding pump

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beam having a wavelength range between approximately 1700 nm and 1750 nm; (a-3'') a second stage light guide optically coupled to the first stage optical fiber, the second stage light guide adapted to propagate the pump beam; and (b') a lens subsystem adapted to receive and deliver at least a portion of the pump beam to target portions of tissue (see claims 35 and 39 and paragraph [0007]). D1 further discloses that the optical system can be a chemical sensing systems comprising (c') a detection system collecting at least a fraction of the light and being coupled to the detector and receiver for sensing characteristic of specific types of chemical bonds (see paragraphs [0136]-[0137]).

Claim 6 differs from D1 in that the light source comprises the multiplexer, that the sample comprises at least in part enamel, dentine and pulp and that the output signal represents at least in part a property of blood contained within the pulp. However, considering that amplified spontaneous emission (ASE) from the amplifier is controlled by an add/drop multiplexer (see paragraph [0059]) and that the target portions of tissue comprise protein, amino acids, or amide groups (see claim 36), such a slight constructional change in the system of D1 comes within the scope of the customary practice followed by a person skilled in the art. Accordingly, a person skilled in the art would easily conceive the idea of employing the feature of claim 6. Therefore, claim 6 lacks an inventive step under PCT Article 33(3).

1.4. Claims 7-11 and 14-16
Claims 7-11, 14-16 are dependent on claim 6.

Claim 7 further comprises the light source comprising a super-continuum laser. The additional feature of claim 7 is a minor difference over the disclosure of D1 in that super-continuum (SC) light source could be used in chemical sensing (see paragraph [0015]), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 7 would have been obvious over D1. Therefore, claim 7 lacks an inventive step under PCT Article 33(3).

Claim 8 further comprises the light source comprising a super-luminescent diode. The additional feature of claim 8 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 8 would have been obvious over D1. Therefore, claim 8 lacks an inventive step under PCT Article 33(3).

Claim 9 further comprises the light source comprising a light emitting diode. The additional feature of claim 9 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 9 would have been obvious over D1. Therefore, claim 9 lacks an inventive step under PCT

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Article 33(3).

Claim 10 further comprises at least a portion of the one of more optical wavelengths comprising a short-wave infrared wavelength approximately 1400-2500nm. The additional feature of claim 10 is a minor difference over the disclosure of D1 in that the pump beam wavelength is in a wavelength range between approximately 1700 nm and 1750 nm, which falls under the general knowledge of a person skilled in the art (see claim 39). Accordingly, claim 10 would have been obvious over D1. Therefore, claim 10 lacks an inventive step under PCT Article 33(3).

Claim 11 further comprises the property of the blood comprising a glucose level. The additional feature of claim 11 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 11 would have been obvious over D1. Therefore, claim 11 lacks an inventive step under PCT Article 33(3).

Claim 14 further comprises the delivered portion of the output optical beam transmitted through the sample. The additional feature of claim 14 is a minor difference over the disclosure of D1 in that the pump beam wavelength is selected to obtain a desired penetration depth (see claim 35), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 14 would have been obvious over D1. Therefore, claim 14 lacks an inventive step under PCT Article 33(3).

Claim 15 further comprises the interface device further comprising a replaceable insert. The additional feature of claim 15 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 15 would have been obvious over D1. Therefore, claim 15 lacks an inventive step under PCT Article 33(3).

Claim 16 further comprises the receiver configured to process the portion of the spectroscopy output beam using a pattern matching methodology. The additional feature of claim 16 is a minor difference over the disclosure of D1 in that super-continuum (SC) broadband source could be particularly useful for spectral fingerprinting and that the relative magnitudes at different wavelengths or a particular spectral pattern of absorption or reflection can be pattern matched to identify the chemical of interest (see paragraph [0137]), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 16 would have been obvious over D1. Therefore, claim 16 lacks an inventive step under PCT Article 33(3).

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1.5. Claims 12-13
Claims 12-13 are dependent on claim 11.

Claims 12-13 further comprise at least a portion of the one or more optical wavelengths which comprises a short-wave infrared wavelength approximately 1587-1750nm (claim 12) and near 2120nm, 2270nm or 2320 nm (claim 13). Claims 12-13 differ from D1 in the wavelength. However, the selection of the wavelength can be easily optimized by repeated experiments practiced by a person skilled in the art. Accordingly, claims 12-13 would have been obvious over D1. Therefore, claims 12-13 lack an inventive step under PCT Article 33(3).

1.6. Claim 17
Claim 17 relates to a method of measuring comprising: (a) generating an output optical beam, comprising (a-1) generating an input optical beam from a plurality of semiconductor sources, (a-2) multiplexing at least a portion of the input optical beam and forming an intermediate optical beam and (a-3) guiding at least a portion of the intermediate optical beam and forming the output optical beam, wherein the output optical beam comprises one or more optical wavelengths; (b) receiving a received portion of the output optical beam and delivering a delivered portion of the output optical beam to a sample, wherein the sample comprises at least in part enamel, dentine and pulp; (c) generating a spectroscopy output beam from the sample; (d) receiving at least a portion of the spectroscopy output beam; and (e) processing the portion of the spectroscopy output beam and generating an output signal representing at least in part a property of blood contained within the pulp.

D1, which is considered to be the closest prior art to the subject matter of claim 17, discloses a method for performing a medical procedure, the method comprising the steps of: (a') generating one or more optical beams utilizing a plurality of semiconductor laser diodes; (a-1') optically coupling the one or more optical beams to a beam combiner; (a-2') receiving at a first stage optical fiber the one or more optical beams and forming a corresponding pump beam having at least one wavelength; (a-3') propagating the pump beam in a second stage light guide optically coupled to the first stage optical fiber; and (b') receiving and delivering at least a portion of the pump beam with a lens subsystem to target portions of tissue (see claim 30). D1 further discloses that a method of generating broadband light by (c') generating a pump signal comprises broadening the pump optical spectral width to at least 100 nm using a nonlinear effect (see paragraph [0009]).

Claim 17 differs from D1 in the steps of (d) receiving the spectroscopy output beam and (e) processing the portion of the spectroscopy output beam and generating the output signal. Furthermore, claim 17 differs from D1 in that the sample comprises

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enamel, dentine and pulp. However, the steps of (d) receiving and (e) processing are merely matters of design option when the general technical knowledge about the state of the art is used. And the sample comprising at least in part enamel, dentine and plup is a minor difference over the disclosure of D1 in that the target portions of tissue comprise protein, amino acids, or amide groups (see claim 36), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 17 would have been obvious over D1. Therefore, claim 17 lacks an inventive step under PCT Article 33(3).

1.7. Claims 18-20
Claims 18-20 are dependent on claim 17.

Claim 18 further comprises the one or more optical wavelengths comprising a short-wave infrared wavelength approximately 1400-2500nm. The additional feature of claim 18 is a minor difference over the disclosure of D1 in that the pump beam wavelength is in a wavelength range between approximately 1700 nm and 1750 nm, which falls under the general knowledge of a person skilled in the art (see claim 31). Accordingly, claim 18 would have been obvious over D1. Therefore, claim 18 lacks an inventive step under PCT Article 33(3).

Claim 19 further comprises the property of the blood comprising a glucose level. The additional feature of claim 19 is merely a matter of design option when the general technical knowledge about the state of the art is used. Accordingly, claim 19 would have been obvious over D1. Therefore, claim 19 lacks an inventive step under PCT Article 33(3).

Claim 20 further comprises communicating a wireless signal associated with the output signal to a network. The additional feature of claim 20 is considered to be a minor difference over the disclosure of D1 in that the optical fibers include super-continuum (SC) generation (see paragraph [0004]) and that a chemical sensing system using a SC light source may lead remote detection of chemical species (see paragraphs [0138]-[0139]), which falls under the general knowledge of a person skilled in the art. Accordingly, claim 20 would have been obvious over D1. Therefore, claim 20 lacks an inventive step under PCT Article 33(3).

2. Industrial Applicability
Claims 1-20 are industrially applicable under PCT Article 33(4).

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	14875709
Filing Date	06-Oct-2015
First Named Inventor	Mohammed Islam
Attorney Docket Number	OMNI 0105 PUSP1
Title of Invention	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
OMNI MEDSCI, INC.	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
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◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○	I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

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Registration Number 38383

○ A sole inventor

○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

○ A joint inventor; all of whom are signing this request

Signature	/David S. Bir/
Name	David S. Bir

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

Electronic Patent Application Fee Transmittal

Application Number:	14875709
Filing Date:	06-Oct-2015
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Filer:	David S. Bir
Attorney Docket Number:	OMNI 0105 PUSP1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Statutory or Terminal Disclaimer	2814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 14875709

Filing Date: 06-Oct-2015

Applicant/Patent under Reexamination: Islam et al.

Electronic Terminal Disclaimer filed on July 6, 2016

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

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

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	26267267
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	06-JUL-2016
Filing Date:	06-OCT-2015
Time Stamp:	13:43:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$160
RAM confirmation Number	11144
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	33577 7b8826c29299fc83a86b8bd69b3996dc48212488	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30467 9f9ec3fdce950455489d277615dbcdeb1a241c78	no	2
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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.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Mohammed N. ISLAM

Group Art Unit: 2884

Examiner: Fein, Abra S.

Serial No.: 14/875,709

Filed: October 06, 2015

For: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Attorney Docket No.: OMNI 0105 PUSP1

AMENDMENT UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Office Action mailed May 26, 2016, please amend the above-identified application as follows:

Amendments to the Specification:

Please amend Paragraphs [0015] – [0016] as shown below:

[0015] In another embodiment, a measurement system includes a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. The light source is configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources. ~~A measurement~~ An apparatus comprising a plurality of lenses is configured to receive a ~~received~~ portion of the output optical beam and to deliver ~~to a sample~~ an analysis output beam to a sample.~~, which is a delivered portion of the output optical beam; and a~~ A receiver is configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link, and a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, ~~to buffer the received output status,~~ to process the received output status to generate processed data and to store the processed data.

[0016] Other embodiments may include a measurement system comprising a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers. The light source is configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of

semiconductor sources. The wearable measurement device comprises a plurality of lenses~~is~~ configured to receive a ~~received~~ portion of the output optical beam and to deliver ~~to a sample~~ an analysis output beam to a sample~~, which is a delivered portion of the output optical beam~~. The wearable measurement device further comprises a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal. The system also includes a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission ~~link~~ link.~~and~~ The system also includes ~~a~~ remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, ~~to buffer the received output status,~~ to process the received output status to generate processed data and to store the processed data,~~ and~~ wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

Please amend Paragraphs [0116]- [0117] as shown below:

[0116] In a particular embodiment 2400 illustrated in Figure 24, 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~~ BLUETOOTH, ZIGBEE, WI-FI, 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.

[0117] 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 IPHONE ~~iPhones®~~ or phones operating on the ~~Android~~ 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~~ WI-FI or the cellular network. The second communication link 2406 may additionally comprise lengths of fiber optic and/or communication over copper wires or cables.

Please delete the Abstract and replace with the attached abstract provided on a separate sheet of paper pursuant to 37 C.F.R. § 1.72(b).

ABSTRACT

A measurement system includes a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of light emitting diodes (LEDs) configured to generate an output optical beam with a near-infrared wavelength between 700 nanometers and 2500 nanometers. The light source is configured to increase signal-to-noise ratio by increasing a light intensity and pulse rate of the LEDs. The system includes a plurality of lenses configured to receive the output optical beam and to deliver an analysis output beam to a sample. The wearable measurement device includes a receiver configured to process the analysis output beam reflected or transmitted from the sample and to generate an output signal that may be transmitted to a remote device configured to process the received output status to generate processed data and to store the processed data.

Petitioner WHOOP, Inc. Ex1002
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Amendments to the Claims:

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

1. (Original) A measurement system comprising:

a light source configured to generate an output optical beam, comprising:

one or more semiconductor sources configured to generate an input beam;

one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers; and

one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam;

a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum; and

wherein at least a portion of the output beam broadened spectrum comprises a near-infrared wavelength between approximately 700nm and approximately 2500nm, and wherein at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns;

a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam;

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample having a bandwidth of at least 10 nanometers and to generate an output signal; and

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.

2. (Original) The system of Claim 1, wherein the personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor-based device.

3. (Original) The system of Claim 1, wherein the output signal comprises one or more physiological parameters.

4. (Original) The system of Claim 1, further comprising a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

5. (Currently Amended) A measurement system comprising:

a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 ~~nanometers;~~nanometers,

the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;

~~a measurement~~ an apparatus comprising a plurality of lenses configured to receive a ~~received~~ portion of the output optical beam and to deliver ~~to a sample~~ an analysis output beam to a sample~~, which is a delivered portion of the output optical beam; and~~

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and

a remote device configured to receive over the wireless transmission link ~~a received~~ an output status comprising the at least a portion of the processed output signal, ~~to buffer the received output status,~~ to process the received output status to generate processed data and to store the processed data.

6. (Currently Amended) The system of Claim 5, wherein the ~~semiconductor sources are light emitting diodes operating in pulsed mode~~receiver is configured to be synchronized to the light source.

7. (Currently Amended) The system of Claim 5, wherein ~~the wireless transmission link is configured to operate at least in part on Bluetooth or WiFi~~at least one of the light emitting diodes emits light with a bandwidth between 20 nanometers to 40 nanometers.

8. (Original) The system of Claim 5, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data.

9. (Currently Amended) The system of Claim 5, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode~~personal device is a separate device from the measurement apparatus and the light source~~.

10. (Original) The system of Claim 5, wherein the output signal comprises one or more physiological parameters, and the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time.

11. (Currently Amended) The system of ~~Claim 10~~Claim 9, wherein the output signal is generated in part by comparing the first and second signals~~remote device is capable of generating an alarm when at least one of the one or more physiological parameters falls out of an acceptable range~~.

12. (Currently Amended) The system of Claim 5, wherein the receiver further comprises one or more filters in front of one of more detectors to select a fraction of the one or more optical wavelengths~~personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor based device~~.

13. (Currently Amended) The system of Claim 5, wherein the output optical beam comprises a plurality of optical wavelengths, and the output signal is generated in part by comparing signals at different optical wavelengths~~measurement system is capable of performing a non-invasive blood measurement~~.

14. (Currently Amended) A measurement system comprising:

a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical

wavelengths is a near-infrared wavelength between 700 nanometers and 2500 ~~nanometers;~~nanometers,

the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;

the wearable measurement device comprising a plurality of lenses configured to receive a ~~received~~ portion of the output optical beam and to deliver ~~to a sample~~ an analysis output beam to a sample~~, which is a delivered portion of the output optical beam~~;

the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and

a remote device configured to receive over the wireless transmission link ~~a received~~an output status comprising the at least a portion of the processed output signal, ~~to buffer the received output status,~~ to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

15. (Currently Amended) The system of Claim 14, wherein the receiver is configured to be synchronized to pulses of the light source~~semiconductor sources are light emitting diodes operating in pulsed mode~~.

16. (Currently Amended) The system of Claim 14, wherein at least one of the light emitting diodes emits light with a bandwidth between approximately 20 nanometers to approximately 40 nanometers.~~the personal device is a separate device from the wearable measurement device.~~

17. (Original) The system of Claim 14, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data.

18. (Currently Amended) The system of Claim 14, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode~~remote device is capable of generating an alarm when at least one of the one or more physiological parameters falls out of an acceptable range~~.

19. (Currently Amended) The system of ~~Claim 14~~Claim 18, wherein the output signal is generated in part by comparing the first and second signals~~measurement system is capable of performing a non-invasive blood measurement~~.

20. (Currently Amended) The system of Claim 14, wherein the receiver further comprises one or more filters in front of one of more detectors to select a fraction of the one or more optical wavelengths~~personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor-based device~~.

Remarks

In the Office Action mailed May 26, 2016, claims 1-4 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 9,164,032 in view of Banet et al. (US 2010/0160798 A1). Claim 18 was rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as having insufficient antecedent basis. Claims 5, 7-14, and 16-20 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli et al. (US 2006/0283931 A1) in view of Banet. Claims 6 and 15 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli and Banet, and further in view of Fujimoto et al. (US 2009/0244288 A1).

Claims 1-20 are pending, with claims 1, 5, and 14 being independent. Claims 5-7, 9, 11-16, and 18-20 have been amended. No new subject matter has been added.

Reconsideration and re-examination of the application as amended is respectfully requested.

Specification

The rejection noted that the specification contained references to various trademarks. Applicant has amended the specification accordingly pursuant to MPEP §608.01(v).

Double Patenting Rejection

Claims 1-4 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 9,164,032 in view of Banet et al. (US 2010/0160798 A1).

Applicant will submit a Terminal Disclaimer to obviate the rejection.

Rejection Under 35 U.S.C. § 112

Claims 7 and 18 were rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as being indefinite. Claims 7 and 18 have been amended such that the rejection has been obviated.

Rejection Under 35 U.S.C. § 103(a)

Claims 5, 7-14, and 16-20 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli et al. (US 2006/0283931 A1) in view of Banet. Claims 6 and 15 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli and Banet, and further in view of Fujimoto et al. (US 2009/0244288 A1). Applicant respectfully disagrees and traverses the rejection. However, independent claims 5 and 14 have been amended to more particularly point out the claimed subject matter.

Applicant respectfully submits that the proposed combination of Polli et al. and Banet taken as a whole fails to disclose or suggest all of the features of amended independent claims 5 and 14 such as a light source configured to increase signal-to-noise ratio as disclosed and claimed by Applicant, for example. As such, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Summary

Applicant has made a genuine effort to respond to the rejections and advance prosecution of this application. Applicant respectfully submits that all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested.

The Examiner is requested to telephone the undersigned to discuss resolution of any remaining issues.

No additional fee is believed be due as a result of filing this paper. However, please charge any fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 02-3978.

Respectfully submitted,

Mohammed N. ISLAM

By: /David S. Bir/
David S. Bir
Reg. No. 38,383
Attorney/Agent for Applicant

Date: July 6, 2016

BROOKS KUSHMAN P.C.
1000 Town Center, 22nd Floor
Southfield, MI 48075-1238
Phone: 248-358-4400
Fax: 248-358-3351

Electronic Acknowledgement Receipt

EFS ID:	26268183
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	06-JUL-2016
Filing Date:	06-OCT-2015
Time Stamp:	15:06:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response_to_OA_dtd_5_26_16.pdf	85915 4f15a174a203c2fe639430a44c6546201e468166	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	4
	Abstract	5	5
	Claims	6	11
	Applicant Arguments/Remarks Made in an Amendment	12	14
Warnings:			
Information:			
	Total Files Size (in bytes):	85915	

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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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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/875,709	Filing Date 10/06/2015	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	**140**
☒ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	**300**
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	**360**
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	* 0	x $40 =	**0**
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	* 0	x $210 =	**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).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	**800**

APPLICATION AS AMENDED – PART II

AMENDMENT **07/06/2016**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x $40 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	**0**

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
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This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

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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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	1	102010012987	DE	A1	2010-10-07	FRAUNHOFER GES FORSCHUNG		
	2	2005013843	WO	A2	2005-02-17	The Regents of the University of California		
	3	2007061772	WO	A2	2007-05-31	OMNI SCIENCES, INC.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

	4	2009130464	WO	A1	2009-10-29	UNIVERSITY OF MANCHESTER		

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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]
	1	VINAY V. ALEXANDER ET AL.; Modulation Instability High Power All-Fiber Supercontinuum Lasers And Their Applications; Optical Fiber Technology 18; 2012; pages 349-374.	
	2	ROBERT S. JONES ET AL.; Near-Infrared Transillumination At 1310-nm For The Imaging Of Early Dental Decay; Volume 11, No. 18; Optics Express 2259; September 8, 2003	
	3	Extended European Search Report for European Application No. 13867874.3 dated July 15, 2016	
	4	Extended European Search Report for European Application No. 13867892.5 dated July 22, 2016	

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

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	/David S. Bir/	Date (YYYY-MM-DD)	2016-07-21
Name/Print	David S. Bir	Registration Number	38383

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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.

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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.

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.

Electronic Acknowledgement Receipt

EFS ID:	26415939
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	21-JUL-2016
Filing Date:	06-OCT-2015
Time Stamp:	19:43:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	DE102010012987_w_English_Abstract.pdf	2308892 19a13bcfd1f90066341fc61d3872cf49f9ecf99b	no	18

Warnings:

Information:					
2	Foreign Reference	WO2005013843A2I.pdf	1823144 d0f26f4dfa27ba56005e4b853c676efb32bb60b4	no	38
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Information:					
3	Foreign Reference	WO2007061732A2I.pdf	3281087 244aee080f51028c732f98646f80712be6da9344	no	66
Warnings:					
Information:					
4	Foreign Reference	WO2009130464A1I.pdf	3470704 6dd8b21777a346ab09fa106e24bb268a8312b2cc	no	76
Warnings:					
Information:					
5	Non Patent Literature	7_15_16_Extended_EP_Search_Report.pdf	215929 efb9e67dba62b2dbdd534b8e980cea139aed67c6	no	7
Warnings:					
Information:					
6	Non Patent Literature	7_22_16_Extended_EP_Search_Report.pdf	302860 0f6974bf4daac07487859da4be4359d2c040fbee	no	8
Warnings:					
Information:					
7	Non Patent Literature	Jones_et_al_Near_Infrared_transillumination.pdf	1755277 59fbb6e4b86ff9091b27deff3ab10847a00b6e5e	no	7
Warnings:					
Information:					
8	Non Patent Literature	Vinay_v_Alexander_Modulation_instability_initiated_high_power.pdf	2561554 7105a4b8acaa1c8377f01c8ef10ce6e3ef8e7416	no	26
Warnings:					
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9	Information Disclosure Statement (IDS) Form (SB08)	Supplemental_IDS.pdf	612885 24897f42631ad0a3e5a25e4511ba58a84d62b65f	no	4

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New International Application Filed with the USPTO as a Receiving Office

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Espacenet

Bibliographic data: DE102010012987 (A1) — 2010-10-07

Method for attaching optical transmission element on e.g. finger nail, of body of sportsman for determining e.g. glucose content of blood, involves attaching optical transmission element and optical detector element to parts of body

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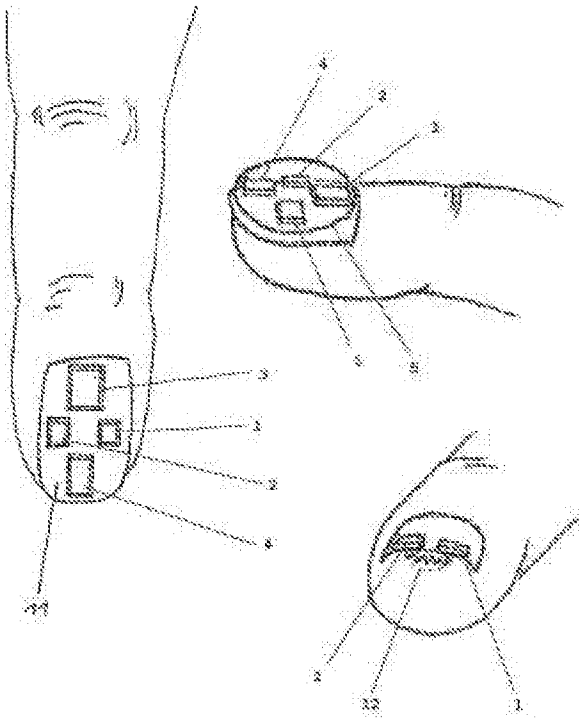
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Abstract of DE102010012987 (A1)

The method involves irradiating light of predetermined wavelength in a measuring volume (12) within a human or animal body. A scattered part of the light irradiated in the measuring volume is detected by an optical detector element (2). An optical transmission element (1) and the optical detector element are attached to multiple parts of the body, where the parts are mechanically fixed and accessible without surgical interferences. The optical transmission element and the optical detector element are fastened next to each other. An independent claim is also included for an arrangement for attaching an optical transmission element.



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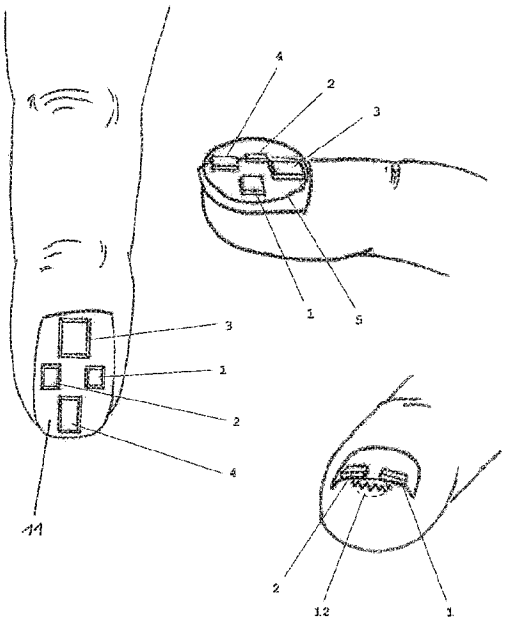
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Prüfungsantrag gemäß § 44 PatG ist gestellt.

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Bezeichnung: **Verfahren zum Anbringen und eine Anordnung eines optischen Sende- bzw. Detektorelements**

(57) Zusammenfassung: Die vorliegende Erfindung betrifft ein Verfahren und eine Anordnung zur Erfassung von Daten eines menschlichen oder tierischen Körpers. Hierbei wird mit wenigstens einem optischen Sendeelement Licht mindestens einer vorgegebenen Wellenlänge in ein Messvolumen innerhalb des menschlichen oder tierischen Körpers eingestrahlt und mit wenigstens einem optischen Detektorelement wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des in das Messvolumen eingestrahlten Lichts detektiert. Die Befestigung des wenigstens einen optischen Sendeelements und des wenigstens einen optischen Detektorelements erfolgt mit wenigstens einem Befestigungsmittel ausschließlich an einem oder mehreren mechanisch festen und ohne chirurgische Eingriffe zugänglichen Körperteilen. Dadurch können die Messdaten mit erhöhter Verlässlichkeit, insbesondere weitgehend ohne Bewegungsartefakte, erfasst werden.



Beschreibung

Technisches Anwendungsgebiet

[0001] Die Erfindung bezieht sich auf ein Verfahren zum Anbringen und eine Anordnung eines optischen Sende- bzw. Detektorelements eines Messgerätes.

Stand der Technik

[0002] Mit optischen Verfahren können beispielsweise der Glukosegehalt des Blutes oder die Herzfrequenz (Puls) und/oder die Sauerstoffsättigung des Blutes (Pulsoximetrie) erfasst werden.

[0003] Bei der Pulsoximetrie wird gut durchblutetes Gewebe mit Licht von zwei oder mehr verschiedenen Wellenlängen durchstrahlt und von einem dem Sender gegenüberliegenden Detektor empfangen. Das Spektrum des empfangenen Lichtes enthält die Informationen über Herzfrequenz und Sauerstoffsättigung. Die Signalauswertung basiert auf dem Lambert-Beer'schen Gesetz, nach dem die Konzentration eines Stoffes aus der Absorption in einer Losung bestimmt werden kann. In der praktischen Anwendung sind die strengen Randbedingungen des Lambert-Beer'schen Gesetzes jedoch nicht vollständig erfüllt. Es existieren viele andere Substanzen im Blut, die neben den wichtigen Absorbern Oxi-Hämoglobin und Hämoglobin ebenfalls Licht absorbieren, wie z. B. Carboxihämoglobin und Methämoglobin. Deren Beitrag zur Absorption kann nur durch Messung bei zusätzlichen Wellenlängen bestimmt werden, d. h. falls nur bei zwei Wellenlängen gemessen wird, bewirken diese Substanzen einen durch das Messprinzip bedingten Messfehler.

[0004] Darüber hinaus erreicht ein Teil des Lichts, welches in das Gewebe eingestrahlt wird, aufgrund von Reflexionen nicht den Detektor.

[0005] Weitere wichtige Fehlerquellen sind Bewegungsartefakte, wobei externe und interne Bewegungsartefakte unterschieden werden. Externe Bewegungsartefakte beruhen im Wesentlichen auf einer Relativbewegung zwischen Sensor und Patient. Insbesondere genügen bei herkömmlichen Fingerclipsensoren bereits kleine Handbewegungen, Zittern oder Erschütterungen, bspw. während des Krankentransports, um Bewegungsartefakte hervorzurufen. Unter Umständen können diese zu so großen Störungen führen, dass nur noch ein ungenügendes Signal-Rausch-Verhältnis gegeben ist. Interne Bewegungsartefakte entstehen durch Umlagerungen venösen Blutes im Applikationsort.

[0006] Insgesamt führen kleinste Bewegungen zu einer Veränderung des Messvolumens. Ein Ansatz, Bewegungsartefakte zu unterdrücken bzw. ein durch Bewegungen beeinträchtigtes Signal-Rausch-Verhältnis zu verbessern, besteht darin, eine statistische Auswertung der Messwerte vorzunehmen. Insbesondere können bei Vorliegen einer hohen Anzahl von Messwerten regellos auftretende, unkorrekte Messwerte durch eine Mittelwertbildung geringer bewertet werden.

[0007] Kommerzielle Pulsoximeter arbeiten mit zwei oder mehr Wellenlängen, elektronischen Filtern und speziellen Kalibrieralgorithmen, um die Verlässlichkeit der Messung zu erhöhen. Speziell die Unterdrückung der Bewegungsartefakte ist ein großes Problem, vor allem im Wellnessbereich, wenn beispielsweise die Herzfrequenz während körperlicher Aktivitäten wie Laufen oder Radfahren gemessen werden soll. Die Adaption an den Patienten muss praktikabel und tolerabel sein. Deshalb verwenden bestehende Geräte relativ lockere Applikationen in Form von Finger- bzw. Ohrclipsen oder Finger- bzw. Zehenbändern.

[0008] Neben dem vorstehend beschriebenen Verfahren, das auf einer Messung von transmittiertem Licht beruht, gibt es auch Pulsoximeter, bei denen Sender und Detektor nebeneinander angeordnet sind und bei denen die Sauerstoffsättigung und die Herzfrequenz über ein sog. Reflexionsverfahren ermittelt werden. Die Messsonden werden beispielsweise mittels Bändern auf der Stirn, auf der Brust, am Oberarm oder am Finger fixiert oder aber auch über eine Art Haken in der Haut verankert, wie der WO 2007/012931 zu entnehmen ist.

[0009] Die Aufgabe der vorliegenden Erfindung besteht darin, ein Verfahren und eine Anordnung anzugeben, mit denen Messdaten eines menschlichen oder tierischen Körpers nicht-invasiv, einfach, kostengünstig und mit erhöhter Verlässlichkeit erfasst werden können. Insbesondere sollen Bewegungsartefakte weitgehend unterdrückt werden.

Darstellung der Erfindung

[0010] Die vorstehende Aufgabe wird mit dem Verfahren gemäß Patentanspruch 1 und den Anordnungen gemäß den Patentansprüchen 6 und 8 gelöst. Vorteilhafte Ausgestaltungen des Verfahrens sowie der Anordnungen sind Gegenstand der abhängigen Patentansprüche oder lassen sich der nachfolgenden Beschreibung sowie den Ausführungsbeispielen entnehmen.

[0011] Das vorgeschlagene Verfahren bezieht sich auf das Anbringen wenigstens eines optischen Sendeelements, mit dem Licht mindestens einer vorgegebenen Wellenlänge in ein Messvolumen innerhalb eines menschlichen oder tierischen Körpers einstrahlbar ist, und wenigstens eines optischen Detektorelements, mit dem wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des

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in das Messvolumen eingestrahlten Lichts detektierbar ist. Das Verfahren zeichnet sich dadurch aus, dass die Befestigung des wenigstens einen optischen Sendeelements und des wenigstens einen optischen Detektorelements ausschließlich an einem oder mehreren mechanisch festen und ohne chirurgische Eingriffe zugänglichen Körperteilen erfolgt. Insbesondere erfolgt die Befestigung also ohne Einbeziehung von mechanisch weichem Gewebe, wie bspw. Haut mit darunterliegendem Muskel-, Fett- oder sonstigem Weichgewebe, das das oder die mechanisch festen Körperteile umgibt.

[0012] Durch die ausschließliche Befestigung an mechanisch festen Körperteilen werden Bewegungsartefakte oder Fehler durch ein sich änderndes Messvolumen wie sie beispielweise bei den oben genannten Pulsoximetrieverfahren auftreten, unterdrückt.

[0013] Besonders bevorzugt werden das wenigstens eine optische Sendeelement, insbesondere eine oder mehrere lichtemittierende Dioden (LED), und das wenigstens eine optische Detektorelement (optischer Sensor), insbesondere eine oder mehrere Photodioden, nebeneinander an einem Fingernagel oder einem Fußnagel befestigt. Das Licht einer oder mehrerer unterschiedlicher Wellenlängen wird in ein durchblutetes Gewebe enthaltendes Messvolumen unterhalb des Fingernagels oder des Fußnagels eingestrahlt. Die Messung erfolgt im sog. Reflexionsverfahren, d. h. mittels des optischen Sensors wird das durch das Messvolumen reflektierte, remittierte und/oder diffus in Richtung des optischen Detektorelements gestreute Licht detektiert. Der optische Sensor und das optische Sendeelement können insbesondere in einer miniaturisierten Einheit integriert sein oder aber einzeln nebeneinander auf dem Fingernagel oder Fußnagel angebracht sein. Durch die ausschließliche Befestigung der Sensoren bzw. der miniaturisierten Einheit am Nagel, beispielsweise durch Ankleben ausschließlich auf dem Nagel oder durch mechanische Befestigung (z. B. mit einer Art Klammer), kommt es bei Bewegung des Fingers oder der Zehe weder zu einer relativen Verschiebung zwischen optischem Sendeelement und optischem Detektorelement noch verändern sich Kräfte, die auf die Anordnung wirken.

[0014] In einer bevorzugten Ausführungsform erfolgt die Befestigung mittels Ankleben, wobei Klebstoffe auf anorganischer oder organischer Basis oder auch Lacke eingesetzt werden. Besonders bevorzugt sind dabei Klebstoffe oder Lacke, die einerseits einen festen, verschiebefreien Sitz des wenigstens einen optischen Sendeelements bzw. des wenigstens einen optischen Detektorelements oder der miniaturisierten Einheit gewährleisten, die jedoch unter bestimmten Bedingungen wieder ablösbar sind. Dies können beispielsweise Klebstoffe sein, die unter ultraviolettem Licht ablösbar sind. Solche Klebstoffe kommen beispielsweise bei „UV-Tapes for Wafer Dicing" der japanischen Firma FURUKAWA ELECTRIC CO., LTD. zum Einsatz. Alternativ können Lacke oder Klebstoffe eingesetzt werden, die mit geeigneten chemischen Lösemitteln ablösbar sind.

[0015] In einer weiteren bevorzugten Ausführungsform erfolgt die Befestigung mit einer oder mehreren Klammern, die am Finger- oder Zehennagel befestigt werden. Insgesamt sind alle Befestigungsarten bevorzugt, die ein „Wackeln" des befestigten Sensors unterbinden.

[0016] In einer weiteren bevorzugten Ausführungsform werden das wenigstens eine optische Sendeelement und das optische Detektorelement an einem oder mehreren Zähnen derart befestigt, dass das wenigstens eine optische Sendeelement palatinal und das wenigstens eine optische Detektorelement labial oder das wenigstens eine optische Sendeelement labial und das wenigstens eine optische Detektorelement palatinal angeordnet sind und dass ein zwischen dem wenigstens einen optischen Sendeelement und dem wenigstens einen optischen Detektorelement befindliches Zahnfleisch, insbesondere die sog. Interdentalpapille, durchstrahlt wird. Die Messung erfolgt im Transmissionsverfahren, d. h. das wenigstens eine optische Sendelement und das wenigstens eine optische Detektorelement sind auf gegenüberliegenden Seiten des Messvolumens angeordnet und es wird das durch das (durchblutetes Gewebe enthaltende) Messvolumen transmittierte Licht erfasst.

[0017] In einer alternativen, bevorzugten Ausführungsform wird das wenigstens eine optische Sendeelement an einem ersten Zahn und das wenigstens eine optische Detektorelement an demselben Zahn oder an einem zum ersten Zahn benachbarten zweiten Zahn angebracht und ein zwischen dem wenigstens einen optischen Sendeelement und dem wenigstens einen optischen Detektorelement befindliches Zahnfleisch durchstrahlt. Hierbei kann das optische Sendelement und/oder das optische Detektorelement in einer Zahnfleischtasche des betreffenden Zahns angeordnet werden. Die Anordnung in einer Zahnfleischtasche ist vor allem dann vorteilhaft, wenn das wenigstens eine optische Sendeelement und das wenigstens eine optische Detektorelement an demselben Zahn angebracht sind. Die Messung erfolgt im Transmissionsverfahren, d. h. das wenigstens eine optische Sendelement und das wenigstens eine optische Detektorelement sind auf gegenüberliegenden Seiten des Messvolumens angeordnet und es wird das durch das (durchblutetes Gewebe enthaltende) Messvolumen transmittierte Licht erfasst.

[0018] Unabhängig vom Ort der Befestigung und der Art des Messverfahrens (Reflexions- oder Transmissionsverfahren) ist bevorzugt, dass eine Ansteu-

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ereinheit das wenigstens eine optische Sendeelement so ansteuert, dass dieses das Licht bei mindestens einer vorgegebenen Wellenlänge in das Messvolumen einstrahlt, dass ein Signal des wenigstens einen optischen Detektorelements an eine Verarbeitungs- und/oder Auswerteeinheit weitergeleitet wird und dass ein verarbeitetes und/oder ausgewertetes Signal an eine Speichereinheit weitergeleitet und/oder an einer Anzeigeeinheit angezeigt wird.

[0019] Des Weiteren ist eine Alarmfunktion bevorzugt, die im Falle einer Unter- oder Überschreitung von für die erfassten Daten vorgegebenen Grenzwerten ein Alarmsignal ausgibt, beispielsweise in Form eines akustischen, mechanischen (z. B. Vibration), elektrischen (z. B. Kribbelgefühl als Folge einer schwachen Elektrostimulation), biochemischen (Duft) oder optischen Alarmsignals.

[0020] Die Weiterleitung des Signals des wenigstens einen optischen Detektorelements erfolgt bevorzugt drahtgebunden oder drahtlos über ein optisches, elektromagnetisches oder akustisches Übertragungsverfahren. Insbesondere können die Signale hierzu analog oder digital aufbereitet werden.

[0021] Besonders bevorzugt ist, Licht mehrerer unterschiedlicher Wellenlängen einzustrahlen, wobei unter Licht elektromagnetische Strahlung in einem Wellenlängenbereich von 300 nm bis 1500 nm verstanden wird. Die Einstrahlung erfolgt vorzugsweise mittels mehrerer Laserdioden, die ausreichend schmalbandig sind. Die Einstrahlung mindestens zweier Messsignale unterschiedlicher Wellenlängen kann insbesondere gleichzeitig oder bevorzugt nacheinander in zeitlichem Abstand erfolgen. Besonders bevorzugt erfolgt die Einstrahlung des Lichts bei einer ersten Wellenlänge von 660 nm und bei einer zweiten Wellenlänge von 940 nm.

[0022] Insbesondere werden bei einer gleichzeitigen Einstrahlung der mindestens zwei Messsignale unterschiedlicher Wellenlänge mittels mindestens zweier Laserdioden mehrere verschiedene Detektoren vorgesehen, die jeweils schmalbandig genug sind, um die Intensität der empfangenen Messsignale bei den einzelnen Wellenlängen getrennt zu ermitteln und so eine Auswertung zu ermöglichen.

[0023] In einer bevorzugten Ausführungsform wird das Licht bei jeder Wellenlänge in Form von Lichtpulsen abgegeben, wobei die Wiederholrate der Lichtpulse im Bereich von 500 Hz bis 100 kHz liegen kann. Insbesondere können die Pulse der verschiedenen Wellenlänge zeitlich zueinander verschoben erfolgen, so dass zu jedem Zeitpunkt nur das Licht bei einer Wellenlänge ausgestrahlt wird. Vorteilhaft ist hierbei, dass zur Detektion lediglich ein breitbandiger Detektor eingesetzt werden muss. Zu beachten ist, dass der zeitliche Abstand zwischen den ausgesandten Messsignalen unterschiedlicher Wellenlänge sehr kurz im Vergleich zur Periodendauer des Pulsschlags sein muss, z. B. kleiner 50 Millisekunden. Im Falle längerer Verzögerungszeiten könnte man nicht mehr von identischen Proben- bzw. Messvolumen für die verschiedenen Wellenlängen ausgehen, da allein der Pulsschlag schon das Probevolumen verändert. Andererseits muss der zeitliche Abstand so groß sein, dass der Detektor in der Lage ist, die Pulse zu trennen. Sonst sind die Intensitäten der unterschiedlichen Wellenlängen nicht einzeln ermittelbar.

[0024] Insbesondere eignet sich das erfindungsgemäße Verfahren zur Anbringung von Teilen eines mobilen Messgerätes, mit dem Daten eines menschlichen oder tierischen Körpers erfasst werden können. Derartige mobile Messgeräte können beispielsweise von einer zu untersuchenden bzw. zu überwachenden Person bzw. einem Sportler mitgeführt werden.

[0025] Eine erfindungsgemäße Anordnung mit wenigstens einem optischen Sendeelement, mit dem Licht mindestens einer vorgebbaren Wellenlänge in ein Messvolumen innerhalb eines menschlichen oder tierischen Körpers einstrahlbar ist, mit wenigstens einem optischen Detektorelement, mit dem wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des in das Messvolumen eingestrahlten Lichts detektierbar ist, mit einer Ansteuereinheit zur Ansteuerung des wenigstens einen optischen Sendeelements, mit einer Verarbeitungs- und/oder Auswerteeinheit sowie mit einer Speichereinheit und/oder einer Anzeigeeinheit, zeichnet sich dadurch aus, dass sie wenigstens ein Befestigungsmittel aufweist, mit dem das wenigstens eine optische Sendeelement und das wenigstens eine optische Detektorelement ausschließlich an einem oder mehreren mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteilen befestigbar ist.

[0026] Unter der ausschließlichen Befestigung an einem oder mehreren mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteilen ist zu verstehen, dass keine den oder die mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteile umgebenden Weichgewebe mit in die Befestigung einbezogen werden. Selbstverständlich kann die Befestigung des wenigstens einen optischen Sendeelements und des wenigstens einen optischen Detektorelements dabei direkt oder indirekt, beispielsweise über einen Träger, erfolgen.

[0027] Besonders bevorzugt ist, dass als Befestigungsmittel eine Klammer vorgesehen ist, die an den einen oder die mehreren mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteile, insbesondere einen Finger- oder Fußnagel oder ein oder mehrere Zähne, angepasst ist. Alternativ ist bevorzugt, dass als Befestigungsmittel selbstklebende Klebeflächen an den zu befestigenden Elementen

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vorgesehen sind, die ein Ankleben am Applikationsort, z. B. an einem Finger- oder Fußnagel oder an einem oder mehreren Zähnen ermöglichen. Unter den zu befestigenden Elementen sind insbesondere diskrete optische Sendeelemente, diskrete optische Empfangselemente, elektronischen Baugruppen, die zumindest Teile der Ansteuer- und/oder Verarbeitungs- und/oder Auswerte- und/oder Speichereinheit enthalten, integrierte Einheiten aus den vorstehend genannten Bauelementen/Baugruppen oder zugehörige Träger zu verstehen.

[0028] Die erfindungsgemäße Anordnung mit wenigstens einem optischen Sendeelement, mit dem Licht mindestens einer vorgebbaren Wellenlänge in ein Messvolumen innerhalb des menschlichen oder tierischen Körpers einstrahlbar ist, mit wenigstens einem optischen Detektorelement, mit dem wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des in das Messvolumen eingestrahlten Lichts detektierbar ist, mit einer Ansteuereinheit zur Ansteuerung des wenigstens einen optischen Sendeelements, mit einer Verarbeitungs- und/oder Auswerteeinheit sowie mit einer Speichereinheit und/oder einer Anzeigeeinheit, zeichnet sich dadurch aus, dass das wenigstens eine optische Sendeelement und das wenigstens eine optische Detektorelement ausschließlich an einem mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteil befestigt sind.

[0029] In einer bevorzugten Ausführungsform ist das wenigstens eine optische Sendeelement und das wenigstens eine optische Detektorelement nebeneinander an einem Fingernagel oder einem Fußnagel befestigt.

[0030] In einer weiteren bevorzugten Ausführungsform sind das wenigstens eine optische Sendeelement und das wenigstens eine optische Detektorelement an einem oder mehreren Zähnen derart befestigt, dass das wenigstens eine optische Sendeelement palatinal und das wenigstens eine optische Detektorelement labial oder das wenigstens eine optische Sendeelement labial und das wenigstens eine optische Detektorelement palatinal angeordnet ist und ein zwischen dem wenigstens einen optischen Sendeelement und dem wenigstens einen optischen Detektorelement befindlicher Raum enthält zumindest teilweise Zahnfleisch.

[0031] In einer weiteren bevorzugten Anordnung ist das wenigstens eine optische Sendeelement an einem ersten Zahn angebracht und das wenigstens eine optische Detektorelement an einem zum ersten Zahn benachbarten zweiten Zahn angebracht und ein zwischen dem wenigstens einen optischen Sendeelement und dem wenigstens einen optischen Detektorelement befindlicher Raum enthält zumindest teilweise Zahnfleisch.

[0032] Desweiteren ist bevorzugt, dass eine Ansteuereinheit zur Ansteuerung des optischen Sendeelementes vorgesehen ist, mit der Licht einer oder mehrerer unterschiedlicher Wellenlängen gleichzeitig oder zeitversetzt erzeugt werden kann. Insbesondere kann das Licht jeder Wellenlänge in Form von Lichtpulsen abgegeben werden, wobei die Wiederholrate der Lichtpulse im Bereich von 500 Hz bis 100 kHz liegen kann. Insbesondere können die Pulse der verschiedenen Wellenlänge zeitlich zueinander verschoben erfolgen, so dass zu jedem Zeitpunkt nur das Licht einer Wellenlänge ausgestrahlt wird. Die Ansteuereinheit übernimmt bevorzugt auch die zeitliche Koordination des wenigstens einen optischen Sendeelements und des wenigstens einen optischen Detektorelements. Dies kann eine mit einem Taktgeber und entsprechenden Teilern ausgestattete finite Zustandsmaschine sein, die als festverdrahteter Schaltkreis, vorzugsweise als anwendungsspezifischer integrierter Schaltkreis (ASIC), oder als ein programmierbarer Schaltkreis ausgeführt ist (z. B. FPGA). Eine Realisierung mit Hilfe eines Mikrocontrollers, der die zeitliche Abfolge der Lichtpulse und/oder die Auswertung der Empfangssignale vornimmt, ist ebenfalls möglich. In einer alternativen Ausgestaltung sind die Pulse der verschiedenen Wellenlängen unterschiedlich lang. Obwohl das optische Detektorelement nur eine Intensität eines Lichtsignals erfasst, kann anhand der zeitlichen Dauer des gemessenen Pulses mittels der Auswerteeinheit auf die gesendete Wellenlänge zurückgeschlossen werden. Die Detektoreinheit detektiert bzw. misst bevorzugt im Dauerbetrieb. Eine aktive zeitliche Koordination zwischen optischem Sender und Empfänger ist in diesem Falle nicht erforderlich.

[0033] In einer bevorzugten Ausführungsform erfolgt in der Verarbeitungseinheit eine digitale oder analoge Aufbereitung oder Vorverarbeitung der Signale des wenigstens einen optischen Detektorelements, wie z. B. Verstärkung, Filterung, A/D-Wandlung und evtl. auch Zwischenspeicherung. Des Weiteren weist die Anordnung bevorzugt eine Auswerteeinrichtung auf, in der die Signale des wenigstens einen optischen Detektorelements oder die verarbeiteten Signale ausgewertet und eventuell auch zwischengespeichert werden, insbesondere hinsichtlich Pulsfrequenz und/oder Sauerstoffsättigung. Bevorzugt erfolgt eine Übermittlung der verarbeiteten Signale drahtlos an die Auswerteeinrichtung, die beispielsweise in einer Armbanduhr untergebracht ist.

[0034] Als Energieversorgungseinheit ist bevorzugt eine Batterie vorgesehen. Alternativ können beispielsweise auch Solarzellen oder Thermogeneratoren vorgesehen werden. Insbesondere können auch mehrere Energieversorgungseinheiten vorgesehen sein. Eine weitere Möglichkeit der Energieversorgung besteht darin, die erforderliche Energie induktiv drahtlos bereitzustellen. Hierfür muss ein Feldgene-

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rator ein ausreichend starkes magnetisches Wechselfeld erzeugen, welches das hier betrachtete Messgerät mit Hilfe einer Empfangsspule zur Energiegewinnung „anzapft".

[0035] Besonders bevorzugt ist eine Zusammenfassung von Systemkomponenten in Einheiten, die jeweils in eine Kapselung integriert sind. Beispielsweise können das wenigstens eine optische Sendeelement, die Ansteuereinheit und eine erste Energieversorgungseinheit in einer ersten Einheit integriert und das wenigstens eine optische Detektorelement, eine zweite Energieversorgung und die Verarbeitungseinheit und/oder eine Auswerteeinheit und/oder ein Sendemodul zur drahtlosen Kommunikation in einer zweiten Einheit integriert sein, wobei die einzelnen Komponenten innerhalb der ersten und zweiten Einheit bevorzugt jeweils drahtgebunden verbunden sind.

[0036] Alternativ können das wenigstens eine optische Sendeelement, das wenigstens eine optische Detektorelement, die Ansteuereinheit, eine Energieversorgung, eine Verarbeitungseinheit und/oder eine Auswerteeinheit und/oder ein Sendemodul zur drahtlosen Kommunikation in einer verkapselten Einheit integriert sein, wobei die einzelnen Komponenten innerhalb der verkapselten Einheit bevorzugt drahtgebunden verbunden sind.

[0037] Besonders bevorzugt ist, dass die Fläche der integrierten Einheiten kleiner oder höchstens gleich der Fläche des oder der mechanisch festen Körperteile ist, an denen sie befestigt sind.

[0038] In einer bevorzugten Anordnung ist das wenigstens eine optische Detektorelement drahtgebunden mit einer Verarbeitungseinheit und diese drahtgebunden oder drahtlos mit einer Auswerteeinheit verbunden.

[0039] In einer weiteren bevorzugten Anordnung ist die Auswerteeinheit in einer Armbanduhr oder in einem Kopfhörer integriert, die bzw. der mit einem Detektormodul für die drahtlose Kommunikation mit dem zugeordneten Sendemodul ausgestattet sind. Alternativ ist in der Armbanduhr oder in dem Kopfhörer lediglich das Detektormodul für die drahtlose Kommunikation mit dem Sendemodul integriert und die eigentliche Auswertung erfolgt in einer Auswerteeinheit, die in einem Mobiltelefon oder in einem PDA (Personal Digital Assistent), also einem Minicomputer/Organizer, integriert ist und die drahtgebunden mit dem in der Armbanduhr oder dem Kopfhörer integrierten Detektormodul verbunden ist.

[0040] Die Anordnung lässt sich besonders vorteilhaft zur Ermittlung einer Sauerstoffsättigung des Blutes und/oder der Herzfrequenz oder des Pulses einsetzen. Des Weiteren lässt sich die Anordnung vorteilhaft zur Ermittlung des Glukosegehalts des Blutes einsetzen. Weiterhin lässt sich die Anordnung vorteilhaft zur Bestimmung des Wassergehalts des Blutes einsetzen, um beispielsweise eine Dehydrierung zu detektieren.

[0041] In einer weiteren Ausgestaltung ist die erfindungsgemäße, im Mund angeordnete Vorrichtung vorteilhaft mit einem Temperatursensor und einer entsprechend weitergebildeten Signalverarbeitung/Auswerteeinheit kombiniert. Die Temperaturerfassung kann vorteilhaft optisch, wie in üblichen im Ohr messenden Thermometern, oder elektrisch mittels elektrischer Temperatursensoren, erfolgen.

Kurze Beschreibung der Zeichnungen

[0042] Fig. 1 zeigt auf einem Fingernagel angeordnete Systemkomponenten

[0043] Fig. 2 zeigt ein erstes Ausführungsbeispiel von an benachbarten Zähnen angeordneten Systemkomponenten

[0044] Fig. 3 zeigt ein zweites Ausführungsbeispiel von an benachbarten Zähnen angeordneten Systemkomponenten

[0045] Fig. 4 zeigt in einer Kapselung angeordnete Systemkomponenten

[0046] Fig. 5 zeigt eine Kapselung mit einer Klammer

[0047] Fig. 6 zeigt ein Blockschaltbild eines erfindungsgemäßen Gesamtsystems

Wege zur Ausführung der Erfindung

[0048] Die der Erfindung zugrunde liegende Idee der Anordnung optischer Sende- und Detektorelemente auf mechanisch festen und leicht zugänglichen Körperteilen ist besonders dann vorteilhaft einsetzbar, wenn diese bei Platzierung auf weichem Untergrund kein zuverlässiges Signal geben. Die Unzuverlässigkeit der Signale kann beispielsweise darin begründet sein, dass bei Körperbewegungen Bewegungsartefakte auftreten. Am Beispiel eines auf einem Fingernagel (Fig. 1) bzw. an benachbarten Zähnen (Fig. 2 und Fig. 3) platzierten Systems aus optischem Sendeelement **1** und optischem Detektorelement **2** soll im Folgenden beschrieben werden, wie sich die Erfindung vorteilhaft zur Messung der Sauerstoffsättigung und/oder Pulsfrequenz einsetzen lässt. Diese Beispiele sollen die Erfindung lediglich erläutern, nicht aber einschränken.

[0049] Die Fig. 1 zeigt in vereinfachender schematischer Weise einen Fingernagel **11**, auf den eine miniaturisierte Einheit aus wenigstens einem optischen

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Detektorelement (Sensor) **2** und wenigstens einem optischen Sendeelement **1** auf dem Fingernagel **11** so aufgeklebt werden, dass auch über längere Zeiträume, z. B. Stunden, keine Verschiebung möglich ist. Die miniaturisiere Einheit kann dabei beispielsweise die Erscheinungsform eines künstlichen Fingernagels aufweisen, der bei Bedarf entfernt bzw. ausgetauscht werden kann. Durch die miniaturisierte Einheit werden die gewöhnlichen Lebensabläufe nicht beeinträchtigt. Die von dem mindestens einen optischen Sendeelement **1** ausgestrahlten Lichtsignale einer oder mehrerer unterschiedlicher Wellenlängen werden in dem durchbluteten Gewebe **12** reflektiert, remittiert oder diffus gestreut. Die reflektierten, remittierten oder diffus gestreuten Lichtsignale werden durch das mindestens eine optische Detektorelement **2** detektiert. Neben der oben beschriebenen Anordnung kannten einzelne Komponenten, z. B. das wenigstens eine optische Detektorelement **2**, das wenigstens eine optische Sendeelement **1**, eine Verarbeitungseinheit **3** und eine Energieversorgungseinheit **4**, auch diskret, d. h. nicht in einem gemeinsamen Gehäuse/Kapselung **5** angeordnet sein. Dann sollten die diskret angeordneten Komponenten aber drahtgebunden verbunden sein.

[0050] Die Sensorsignale werden nach einer Vorverarbeitung in der Verarbeitungseinheit **3**, dazu zählen Filterung, Verstärkung, möglicherweise Differenzbildung, gegebenenfalls Digitalisierung, drahtgebunden oder ggf. drahtlos an einen Empfänger (beispielsweise in Form einer nicht dargestellten Armbanduhr oder eines nicht dargestellten Kopfhörers) übermittelt, der die Sensorsignale auswertet. Alternativ wertet der Empfänger die Signale nicht aus, sondern sendet sie an eine Auswerteeinheit weiter, die beispielsweise in einem nicht dargestellten Mobiltelefon oder in einen nicht dargestellten PDA (Personal Digital Assistant) integriert ist. Aus den bei bestimmten Wellenlängen bzw. Wellenlängenkombinationen erfassten Sensorsignalen lässt sich unter Heranziehung von individuellen Kalibrierungen beispielsweise die prozentuale Sauerstoffsättigung oder aber auch der Blutzuckergehalt des Blutes ermitteln, das in dem untersuchten Gewebe zirkuliert. Aus dem zeitlichen Verlauf der Sensorsignale lässt sich insbesondere die Herzfrequenz (Puls) ermitteln. Die individuellen Kalibrierungen berücksichtigen den Einfluss des einzelnen Individuums als auch den Messort und können eine empirische Kalibration durch invasive arterielle O_2-Messung umfassen.

[0051] In Fig. 2 ist eine Anordnung dargestellt, bei der die Einheiten **8** und **9** an zwei benachbarten Zähnen labial, d. h. lippenseitig, befestigt sind. Dabei umfasst die Einheit **8** den optischen Detektor **2**, d. h. das mindestens eine optische Detektorelement, die Verarbeitungseinheit **3**, in der die Signal(vor)verarbeitung erfolgt, eine Einheit **13** zur drahtlosen Kommunikation zwischen Verarbeitungseinheit **3** und Auswerteeinheit **14** sowie eine Energieversorgungseinheit **4**. Die Einheit **9** umfasst dagegen den optischen Sender **1** mit mindestens einem optischen Sendeelement, die Ansteuereinheit **15** sowie eine zweite Energieversorgungseinheit **17** (vgl. Fig. 6).

[0052] Alternativ dazu können die Einheiten **8** und **9** auch palatinal, d. h. gaumenseitig, angeordnet sein. Sender und Empfänger sind dabei so platziert, dass ein Teil des Zahnfleischs zwischen den Zähnen durchstrahlt wird. Dabei empfängt der Detektor **2**, d. h. das optische Detektorelement, das durch das Zahnfleisch **12** diffus gestreute Licht.

[0053] In einer bevorzugten Ausgestaltung des erfindungsgemäßen Messsystems sind die beiden Einheiten **8** und **9** separat gekapselt. Dabei dienen entweder die Kapselungen **5** selbst oder eine zusätzlich verwendete und bevorzugt mit der jeweiligen Kapselung fest verbundene Klammer **10** als Mittel zur Befestigung des Systems an einem Zahn bzw. an mehreren benachbarten Zähnen (vgl. Fig. 4/Fig. 5). Die verarbeiteten Sensorsignale werden analog zu obigem Ausführungsbeispiel verarbeitet und drahtgebunden oder ggf. drahtlos an einen Empfänger (beispielsweise in Form einer Armbanduhr oder eines Kopfhörers) übermittelt, der die verarbeiteten Sensorsignale auswertet. Alternativ wertet der Empfänger die Signale nicht aus, sondern sendet sie an eine Auswerteeinheit weiter, die beispielsweise in ein Mobiltelefon oder in einen PDA (Personal Digital Assistant) integriert ist.

[0054] Aufgrund der notwendigen Miniaturisierung ist das System vorteilhafter so gestaltet, dass der Anwender es nach Belieben ein- und ausschalten kann. Bei einer induktiven Energieversorgung kann dies einfach durch (De-)Aktivieren eines hierfür notwendigen Generators geschehen, der beispielsweise wie die Auswerteeinheit in einer Armbanduhr, einem Kopfhörer, einem Mobiltelefon oder einem PDA untergebracht ist. In einem batteriebetriebenen Fall sollte das An- und Abschalten des Systems vorteilhafterweise über eine Bedienschnittstelle erfolgen, die auch beispielsweise in einer Armbanduhr, einem Kopfhörer, einem Mobiltelefon oder einem PDA untergebracht ist.

[0055] In Fig. 3 ist eine Anordnung dargestellt, bei der sich die in der Einheit **9** integrierten Sendekomponenten und die in der Einheit **8** integrierten Detektorkomponenten auf verschiedenen Seiten der Zähne **6**, **7** befinden (Sender palatinal und Empfänger labial oder Sender labial und Empfänger palatinal (bevorzugt)). In einer ersten Ausgestaltung sind dabei die Einheiten **8** und **9** von je einer Kapselung umgeben. Bei dieser Anordnung wird die sog. Interdentalpapille durchstrahlt. Die gekapselten Einheiten werden bevorzugt an den Zähnen **6**, **7** festgeklammert, da im Vergleich zu einer Klebung das Anbringen und

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Entfernen problemloser möglich ist. Die Weiterverarbeitung und Weiterleitung der Sensorsignale kann wie im vorangehenden Ausführungsbeispiel beschrieben erfolgen.

[0056] In einer weiteren Ausgestaltung (Fig. 4) sind alle Komponenten so wie in Fig. 3 angeordnet, jedoch von einer einzigen Kapselung **5** umgeben. Dies hat den Vorteil, dass das System einfacher anzubringen und zu entfernen ist. Überdies weist die Kapselung **5** dann eine kleinere Oberfläche auf, wodurch sich eine geringere Gefahr für das Eindringen von Feuchtigkeit ergibt.

[0057] In Fig. 5 ist nur die Kapselung **5**, jedoch nicht die Systemkomponenten dargestellt. Dabei dient entweder die Kapselung **5** selbst oder eine zusätzlich verwendete und bevorzugt mit der Kapselung fest verbundene Klammer **10** als Mittel zur Befestigung des Systems an den Zähnen **6**, **7**. Die in Fig. 5 skizzierte Methode der Befestigung ist auch dann einsetzbar, wenn sich alle Systemkomponenten auf einer Seite der Zähne (palatinal oder labial) befinden.

[0058] Die erfindungsgemäße Anordnung kann selbstverständlich nicht nur wie abgebildet an den Oberkieferzähnen realisiert werden, sondern selbstverständlich auch an den Unterkieferzähnen.

[0059] Fig. 6 zeigt eine bevorzugte Zusammenfassung von Systemkomponenten in Einheiten, die jeweils in eine Kapselung integriert sind. Gemäß Fig. 6 sind das wenigstens eine optische Sendeelement **1**, die Ansteuereinheit **15** und eine erste Energieversorgungseinheit **4** in einer ersten Einheit **9** integriert. Das wenigstens eine optische Detektorelement **2**, eine zweite Energieversorgung **16**, die Verarbeitungseinheit **3** und ein Sendemodul zur drahtlosen Kommunikation **13'** sind in einer zweiten Einheit **9** integriert. Dabei sind die einzelnen Komponenten innerhalb der ersten und zweiten Einheit **8**, **9** bevorzugt jeweils drahtgebunden verbunden. Beide Einheiten **8**, **9** sind beispielsweise auf einem Finger- oder Zehennagel **11** oder an Zähnen **6**, **7** befestigt.

[0060] Das Detektormodul **13"** für die drahtlose Kommunikation, eine Auswerteeinheit **14**, eine Speichereinheit **18**, eine weitere Energieversorgungseinheit **17** sowie eine Anzeige **19** bilden eine dritte Einheit. Diese kann beispielsweise in einem Kopfhörer, einer Armbanduhr oder einem Mobiltelefon oder PDA untergebracht sein.

[0061] Das erfindungsgemäße Verfahren und die erfindungsgemäße Anordnung mit der ausschließlichen Befestigung des wenigstens einen optischen Sendeelements und des wenigstens einen optischen Detektorelements an einem oder mehreren mechanisch festen und ohne chirurgische Eingriffe zugänglichen Körperteilen ermöglicht es beispielsweise auch, dass einem Freizeitsportler während der Ausübung seines Sportes Informationen über Puls und Sauerstoffsättigung mit Hilfe eines transportablen bzw. mobilen Messgerätes angezeigt werden.

Bezugszeichenliste

1	Optischer Sender, optisches Sendeelement
2	Optischer Detektor, optisches Detektorelement
3	Verarbeitungseinheit
4, 16, 17	Energieversorgungseinheit
5	Kapselung
6	Erster Zahn im Querschnitt (Draufsicht)
7	Zweiter Zahn im Querschnitt (Draufsicht)
8	Einheit, welche folgende Systemkomponenten enthält: optischer Detektor, Verarbeitungseinheit, Sendeeinheit für drahtlose Kommunikation, Energieversorgungseinheit
9	Einheit, welche folgende Systemkomponenten enthält: Optischer Sender, Ansteuereinheit, Energieversorgungseinheit
10	Befestigungsmittel, Klammer
11	Fingernagel, Fußnagel
12	Durchstrahlter Raum (Messvolumen)
13', 13"	Sende-, Empfangsmodul zur drahtlosen Kommunikation
14	Auswerteeinheit
15	Ansteuereinheit
18	Speichereinheit
19	Anzeigeeinheit

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ZITATE ENTHALTEN IN DER BESCHREIBUNG

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Zitierte Patentliteratur

- WO 2007/012931 **[0008]**

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Patentansprüche

1. Verfahren zum Anbringen wenigstens eines optischen Sendeelements (**1**), mit dem Licht mindestens einer vorgegebenen Wellenlänge in ein Messvolumen (**12**) innerhalb eines menschlichen oder tierischen Körpers einstrahlbar ist, und wenigstens eines optischen Detektorelements (**2**), mit dem wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des in das Messvolumen (**12**) eingestrahlten Lichts detektierbar ist, **dadurch gekennzeichnet**, dass die Befestigung des wenigstens einen optischen Sendeelements (**1**) und des wenigstens einen optischen Detektorelements (**2**) ausschließlich an einem oder mehreren mechanisch festen und ohne chirurgische Eingriffe zugänglichen Körperteilen erfolgt.

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) und das optische Detektorelement (**2**) nebeneinander an einem Fingernagel oder einem Fußnagel (**11**) befestigt werden und dass die Einstrahlung des Lichts in ein Messvolumen (**12**) unter dem Fingernagel oder Fußnagel (**11**) erfolgt.

3. Verfahren nach Anspruch 1,
dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) und das optische Detektorelement (**2**) an einem oder mehreren Zähnen (**6**, **7**) derart befestigt werden,
dass das wenigstens eine optische Sendeelement (**1**) palatinal und das wenigstens eine optische Detektorelement (**2**) labial oder das wenigstens eine optische Sendeelement (**1**) labial und das wenigstens eine optische Detektorelement (**2**) palatinal angeordnet werden und
dass ein zwischen dem wenigstens einen optischen Sendeelement (**1**) und dem wenigstens einen optischen Detektorelement (**2**) befindliches Zahnfleisch durchstrahlt wird.

4. Verfahren nach Anspruch 1, dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) an einem ersten Zahn (**6**) angebracht wird und das wenigstens eine optische Detektorelement (**2**) an demselben Zahn (**6**) oder an einem zum ersten Zahn (**6**) benachbarten zweiten Zahn (**7**) angebracht wird und dass ein zwischen dem wenigstens einen optischen Sendeelement (**1**) und dem wenigstens einen optischen Detektorelement (**2**) befindliches Zahnfleisch durchstrahlt wird.

5. Verfahren nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass eine Ansteuereinheit (**15**) das wenigstens eine optische Sendeelement (**1**) so ansteuert, dass dieses das Licht mindestens einer vorgegebenen Wellenlänge in das Messvolumen (**12**) einstrahlt, dass ein Signal des wenigstens einen optischen Detektorelements (**2**) an eine Verarbeitungs- (**3**) und/oder Auswerteeinheit (**14**) weitergeleitet wird und dass ein verarbeitetes und/oder ausgewertetes Signal an eine Speichereinheit (**18**) weitergeleitet und/oder an einer Anzeigeeinheit (**19**) angezeigt wird.

6. Anordnung mit wenigstens einem optischen Sendeelement (**1**), mit dem Licht mindestens einer vorgebbaren Wellenlänge in ein Messvolumen (**12**) innerhalb eines menschlichen oder tierischen Körpers einstrahlbar ist, mit wenigstens einem optischen Detektorelement (**1**), mit dem wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des in das Messvolumen (**12**) eingestrahlten Lichts detektierbar ist, mit einer Ansteuereinheit (**15**) zur Ansteuerung des wenigstens einen optischen Sendeelements (**1**), mit einer Verarbeitungs- (**3**) und/oder Auswerteeinheit (**14**) sowie mit einer Speichereinheit (**18**) und/oder einer Anzeigeeinheit (**19**), dadurch gekennzeichnet, dass die Anordnung wenigstens ein Befestigungsmittel (**10**) aufweist, mit dem das wenigstens eine optische Sendeelement (**1**) und das wenigstens eine optische Detektorelement (**2**) ausschließlich an einem oder mehreren mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteilen befestigbar ist.

7. Anordnung nach Anspruch 6, dadurch gekennzeichnet, dass als Befestigungsmittel (**10**) eine Klammer vorgesehen ist, die an den einen oder die mehreren mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteile, insbesondere einen Finger- oder Fussnagel (**11**) oder ein oder mehrere Zähne (**6**, **7**), angepasst ist.

8. Anordnung mit wenigstens einem optischen Sendeelement (**1**), mit dem Licht mindestens einer vorgebbaren Wellenlänge in ein Messvolumen (**12**) innerhalb eines menschlichen oder tierischen Körpers einstrahlbar ist, mit wenigstens einem optischen Detektorelement (**2**), mit dem wenigstens ein transmittierter, reflektierter, remittierter oder diffus gestreuter Teil des in das Messvolumen (**12**) eingestrahlten Lichts detektierbar ist, mit einer Ansteuereinheit (**15**) zur Ansteuerung des wenigstens einen optischen Sendeelements (**1**), mit einer Verarbeitungs- (**3**) und/oder Auswerteeinheit (**14**) sowie mit einer Speichereinheit (**18**) und/oder einer Anzeigeeinheit (**19**), dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) und das wenigstens eine optische Detektorelement (**2**) ausschließlich an einem oder mehreren mechanisch festen und ohne chirurgischen Eingriff zugänglichen Körperteilen befestigt sind.

9. Anordnung nach Anspruch 8, dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) und das wenigstens eine optische Detektorelement (**2**) nebeneinander an einem Fingernagel oder einem Fußnagel (**11**) befestigt sind.

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10. Anordnung nach Anspruch 8, dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) und das wenigstens eine optische Detektorelement (**2**) an einem oder mehreren Zähnen (**6**, **7**) derart befestigt sind, dass das wenigstens eine optische Sendeelement (**1**) palatinal und das wenigstens eine optische Detektorelement (**2**) labial oder das wenigstens eine optische Sendeelement (**1**) labial und das wenigstens eine optische Detektorelement (**2**) palatinal angeordnet ist und dass ein zwischen dem wenigstens einen optischen Sendeelement (**1**) und dem wenigstens einen optischen Detektorelement (**2**) befindlicher Raum zumindest teilweise Zahnfleisch enthält.

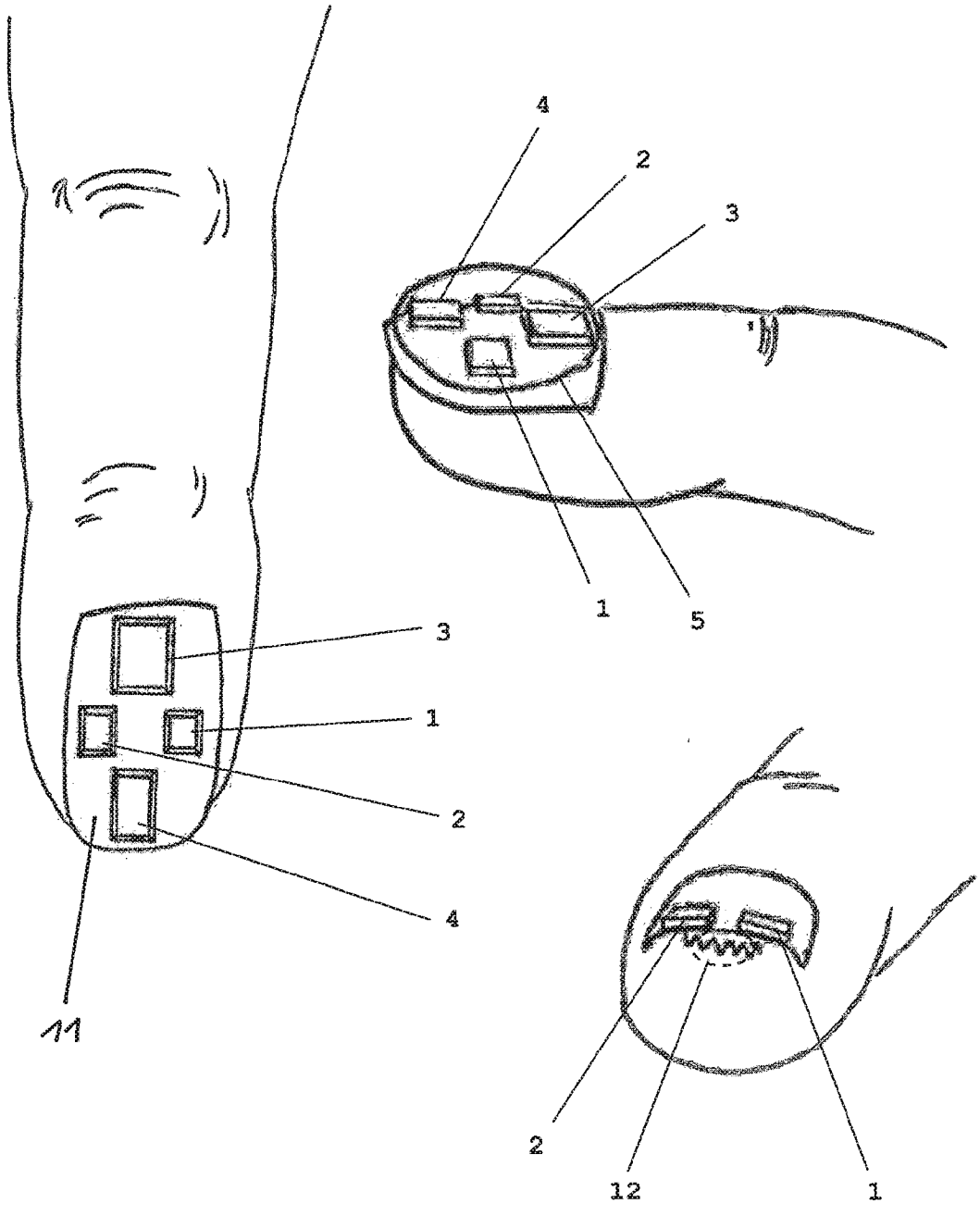
11. Anordnung nach Anspruch 8, dadurch gekennzeichnet, dass das wenigstens eine optische Sendeelement (**1**) an einem ersten Zahn (**6**) angebracht ist und das wenigstens eine optische Detektorelement (**2**) an demselben Zahn (**6**) oder an einem zum ersten Zahn (**6**) benachbarten zweiten Zahn (**7**) angebracht ist und dass ein zwischen dem wenigstens einen optischen Sendeelement (**1**) und dem wenigstens einen optischen Detektorelement (**2**) befindlicher Raum zumindest teilweise Zahnfleisch enthält.

Es folgen 5 Blatt Zeichnungen

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Anhängende Zeichnungen

Fig 1



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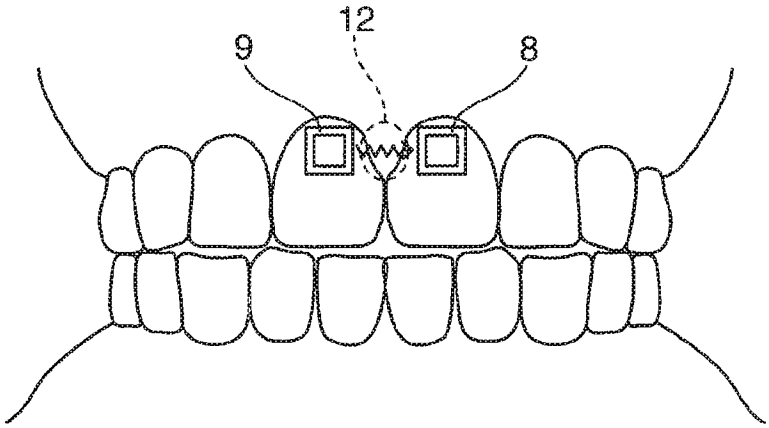


Fig. 2

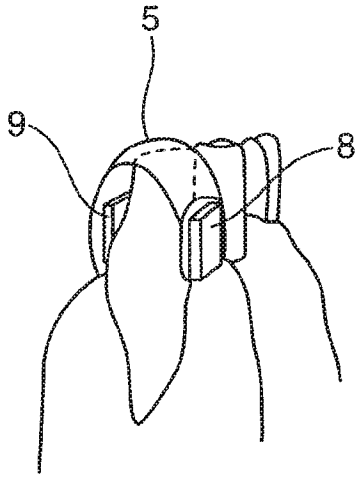


Fig. 4

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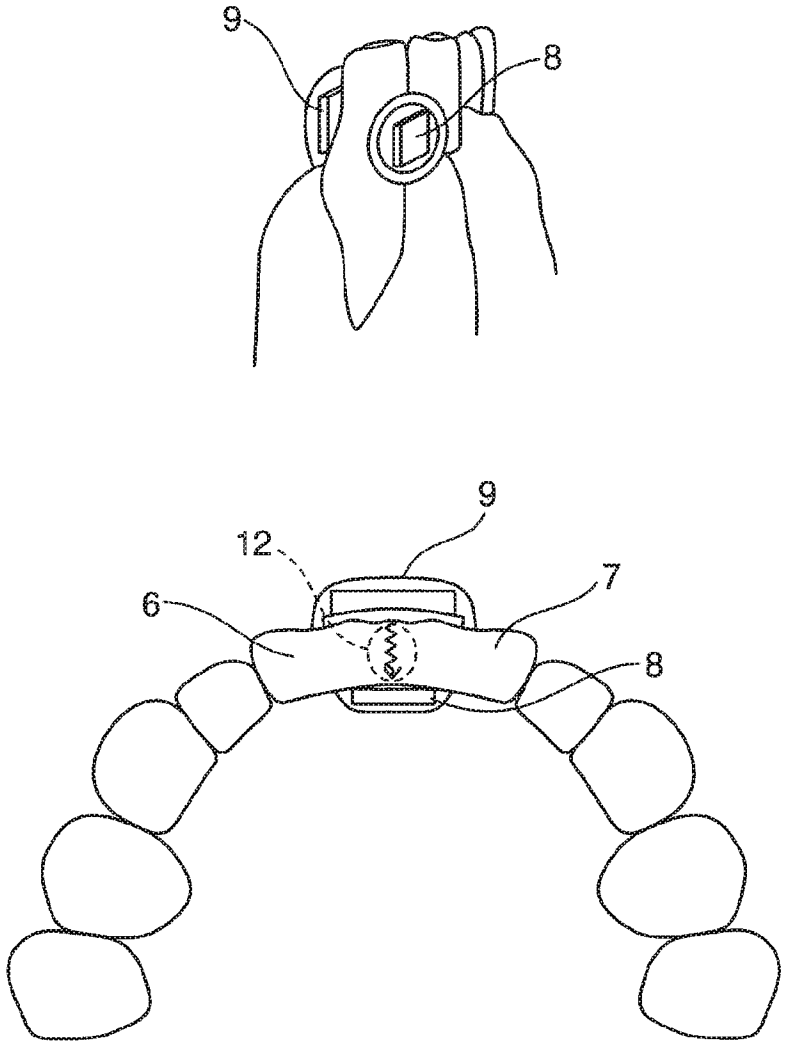
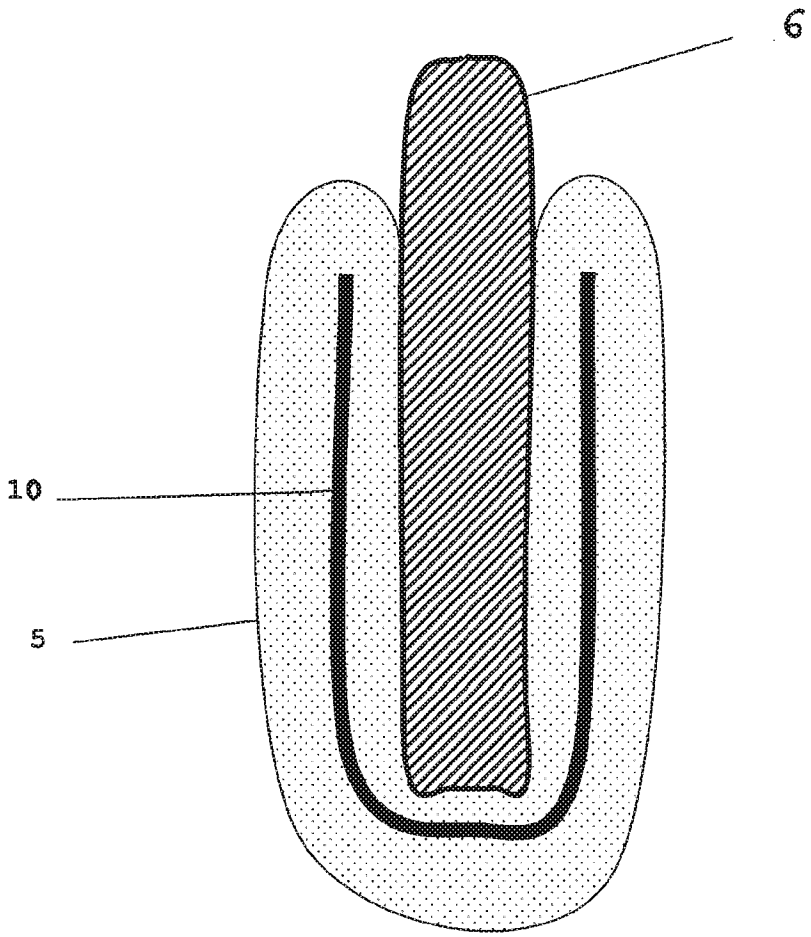


Fig. 3

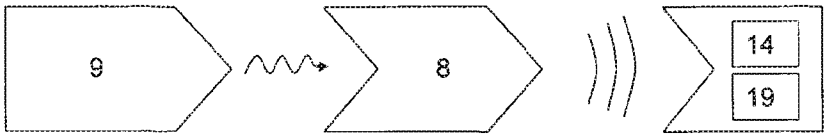
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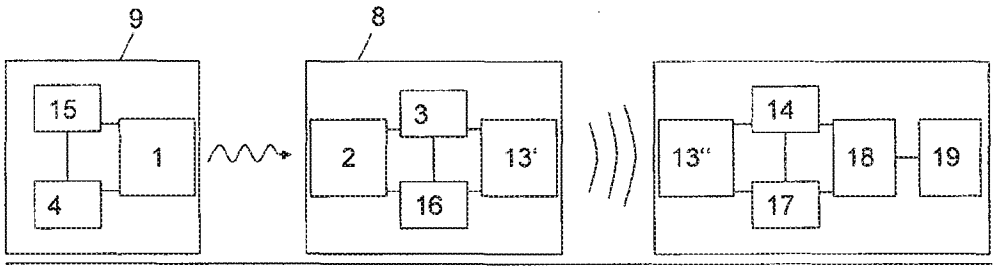
Fig 5



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Fig 6





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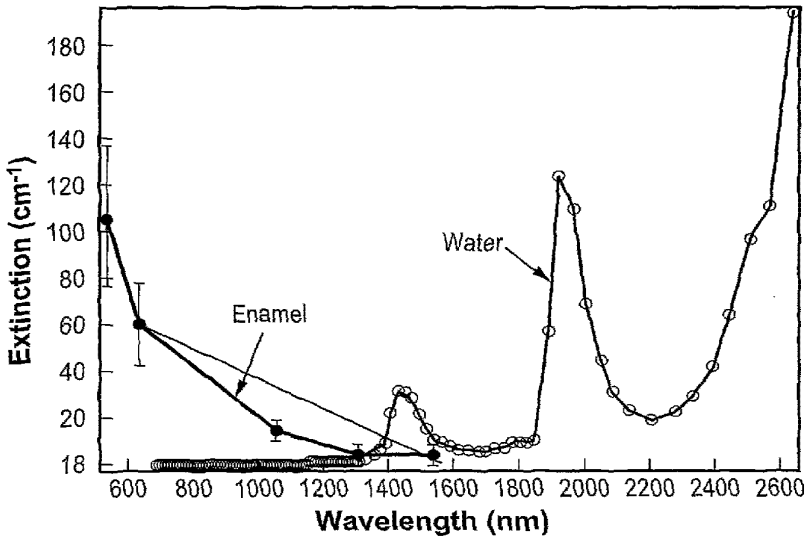
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[Continued on next page]

(54) **Title:** NEAR-INFRARED TRANSILLUMINATION FOR THE IMAGING OF EARLY DENTAL DECAY



(57) **Abstract:** A method for detecting tooth decay and other tooth anomalies wherein a tooth is transilluminated with a near-infrared light source preferably in the range from approximately 795-nm to approximately 1600-nm, more preferably in the range from approximately 830-nm to approximately 1550-nm, more preferably in the range from approximately 1285-nm to approximately 1335-nm, and more preferably at a wavelength of approximately 1310-nm, and the light passing through the tooth is imaged for determining an area of decay in the tooth. The light source is a fiber optic bundle coupled to a halogen lamp or more preferably a superluminescent diode, and the imaging device is preferably a CCD camera or a focal plane array (FPA).

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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.

TITLE OF THE INVENTION

NEAR-INFRARED TRANSILLUMINATION FOR THE IMAGING OF EARLY DENTAL DECAY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. provisional application serial number 60/493,569 filed on August 8, 2003, the entirety of which is herein incorporated by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made with Government support under Grant No. 1-R01 DE14698 and Grant No. T32 DE07306-07 awarded by NIH/NICDR. The Government has certain rights in this invention.

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC

[0003] Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0004] This invention pertains generally to detection of dental caries by transillumination of a tooth, and more particularly to transillumination at wavelengths that are not subject to scattering by sound tooth enamel and identification of dental caries in interproximal sites between teeth.

2. Incorporation by Reference of Publications

[0005] The following publications are incorporated by reference herein in their entirety:

[0006] J. D. B. Featherstone and D. Young, "The need for new caries detection methods," Lasers in Dentistry V, San Jose, CA, Proc. SPIE **3593,** 134-140 (1999).

[0007] J. Peltola and J. Wolf, " Fiber optics transillumination in caries

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diagnosis," Proc Finn Dent Soc, **77**, 240-244 (1981).

[0008] J. Barenie, G. Leske, and L. W. Ripa, "The use of fiber optic transillumination for the detection of proximal caries," Oral Surg, **36**, 891-897 (1973).

[0009] R. D. Holt and M. R. Azeevedo, "Fiber optic transillumination and radiographs in diagnosis of approximal caries in primary teeth," Community Dent Health, **6**, 239-247 (1989).

[0010] C. M. Mitropoulis, "The use of fiber optic transillumination in the diagnosis of posterior approximal caries in clinical trials," Caries Res, **19**, 379-384, (1985).

[0011] A. Peers, F. J. Hill, C. M. Mitropoulos, and P. J. Holloway, "Validity and reproducibility of clinical examination, fibre-optic transillumination, and bite-wing radiology for the diagnosis of small approximal carious lesions." Caries Res., **27**, 307-311 (1993).

[0012] C. M. Pine, "Fiber-Optic Transillumination (FOTI) in Caries Diagnosis," in *Early Detection of Dental Caries*, G. S. Stookey, ed., (Indiana Press, Indianapolis, Ind. 1996).

[0013] J. Vaarkamp, J. J. t. Bosch, E. H. Verdonschot, and E. M. Bronkhorst, "The real performance of bitewing radiography and fiber-optic transillumination for approximal caries diagnosis," J Dent Res, **79**, 1747-1751 (2000).

[0014] A. Schneiderman, M. Elbaum, T. Schultz, S. Keem, M. Greenebaum, and J. Driller, "Assessment of Dental caries with Digital Imaging Fiber-Optic Transillumination (DIFOTI):In vitro Study," Caries Res., **31**, 103-110 (1997).

[0015] D. Fried, J. D. B. Featherstone, R. E. Glena, and W. Seka, "The nature of light scattering in dental enamel and dentin at visible and near-IR wavelengths," Appl. Optics, **34**, 1278-1285 (1995).

[0016] R. Jones and D. Fried, "Attenuation of 1310 and 1550-nm laser light through dental enamel," in Lasers in Dentistry VIII, San Jose, Proc. SPIE **4610,** 187-190 (June 2002).

[0017] G. M. Hale and M. R. Querry, "Optical constants of water in the 200-nm to 200-μm wavelength region.," Appl. Optics, **12**, 555-563 (1973).

[0018] D. Spitzer and J. J. ten Bosch, "The absorption and scattering of light in

bovine and human dental enamel," Calcif. Tiss. Res., **17**, 129-137 (1975).

[0019] S. Keem and M. Elbaum, "Wavelet representations for monitoring changes in teeth imaged with digital imaging fiber-optic transillumination," IEEE Trans Med Imaging, **16**, 653-63 (1997).

3. Incorporation by Reference of Patents

[0020] The following U.S. patents which describe transillumination techniques and devices are incorporated by reference herein in their entirety:

[0021] U.S. No. 6,341,957

[0022] U.S. No. 6,243,601

[0023] U.S. No. 6,201,880

4. Description of Related Art

[0024] During the past century, the nature of dental decay or dental caries has changed dramatically due to the addition of fluoride to the drinking water, the widespread use of fluoride dentifrices and rinses, and improved dental hygiene. Despite these advances, however, dental decay continues to be the leading cause of tooth loss in the United States. By age 17, 80% of children have experienced at least one cavity. In addition, two-thirds of adults in the age range of 35 to 44 have lost at least one permanent tooth to caries. Older adults suffer tooth loss due to the problem of root caries.

[0025] Today, almost all new decay occurs in the occlusal pits and fissures of the posterior dentition and the interproximal contact sites between teeth. These early carious lesions are often obscured or "hidden" in the complex and convoluted topography of the pits and fissures or are concealed by debris that frequently accumulates in those regions of the posterior teeth. Such decay, particularly in the early stages, is difficult to detect using the dentist's existing armamentarium of dental x-rays and the dental explorer (a metal mechanical probe). Therefore, new imaging technologies are needed for the early detection of such lesions.

[0026] Moreover, the treatment for early dental decay or caries is shifting away from aggressive cavity preparations that attempt to completely remove demineralized tooth structure toward non-surgical or minimally invasive restorative techniques. In non-surgical therapy, a clinician prescribes

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antibacterial rinses, fluoride treatments, and dietary changes in attempt to naturally remineralize the decay before it becomes irreversible. The success of this type of therapy is contingent on early caries detection and also requires imaging modalities that can safely and accurately monitor the success of such treatment. Conventional x-rays do not precisely measure the lesion depth of early dental decay, and due to ionizing radiation exposure are not indicated for regular monitoring. These constraints and limitations are the impetus for investigating optical imaging systems that could detect early dental decay, while providing the biologically compatible wavelengths that facilitate frequent screening.

[0027] Before the advent of x-rays, dentists used light for the detection of caries lesions. In the past 30 years, the development of high intensity fiber-optic illumination sources has resurrected this method for caries detection. Previous groups pursuing visible light transillumination, have used or proposed more advanced imaging techniques like temporal or coherence gating and sophisticated image processing algorithms to enhance the imaging and detection of dental decay.

[0028] Fiber-optic transillumination (FOTI) is one technology being developed for the detection of interproximal lesions. One digital-based system, DIFOTITM (Digital Imaging Fiber-Optic Transillumination) from Electro-Optical Sciences, Inc., that utilizes visible light, has recently received FDA approval. During FOTI a carious lesion appears dark upon transillumination because of decreased transmission due to increased scattering and absorption by the lesion. However, the strong light scattering of sound dental enamel at visible wavelengths, 400-nm to 700-nm, inhibits imaging through the tooth.

BRIEF SUMMARY OF THE INVENTION

[0029] The present invention is directed to the detection, diagnosis, and imaging of carious dental tissue. The invention resolves changes in the state of mineralization of dental hard tissues with sufficient depth resolution to be useful for the clinical diagnosis and longitudinal monitoring of lesion progression. One aspect of the invention is to provide system and method for the detection, diagnosis, and imaging of early caries lesions and/or for the

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monitoring of lesion progression. Another aspect of the invention is to provide a near-infrared transillumination system and method for the detection and imaging of early interproximal caries lesions. A further aspect of the invention is to provide a near-infrared transillumination system and method for the detection of cracks and imaging the areas around composite restorations.

[0030] In one mode, near-IR light at 1310-nm is used for the detection and imaging of interproximal caries lesions where a high contrast between sound enamel and simulated lesions is exhibited. In addition, occlusal lesions, root caries, secondary decay around composite restorations, and cracks and defects in the tooth enamel can be seen.

[0031] In accordance with one aspect of the invention, a method for detecting tooth anomalies comprises transilluminating a tooth with light having a wavelength in the range from approximately 795-nm to approximately 1600-nm, and the step of imaging light passing through said tooth for determining an anomaly or area of decay in said tooth. In accordance with other aspects of the present invention, a tooth is transilluminated with near-infrared light at a wavelength more preferably in the range from approximately 830-nm to approximately 1550-nm, more preferably in the range from approximately 1285-nm to approximately 1335-nm, and more preferably at a wavelength of approximately 1310-nm.

[0032] In another mode, the light is filtered to remove extraneous light. The light may be polarized with one or more polarizing filters to remove light not passing through said tooth. The polarizing filters are preferably crossed high-extinction polarizing filters. The method may also comprise filtering said light with a bandpass filter to remove light outside a specified bandwidth.

[0033] Generally, transilluminating a tooth comprises directing light from a near-infrared light source at a surface of said tooth. The light source may be a fiber-optic bundle coupled to a halogen lamp, a superluminescent laser diode, or similar IR source.

[0034] In one mode of the invention, the light source may be manipulated behind the tooth to direct said light at a lingual surface of the tooth. Alternatively, the light source may be manipulated in front of said tooth to

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direct said light at a facial surface of the tooth.

[0035] In one embodiment, the step of imaging light passing through the tooth comprises detecting intensity of light passing through the tooth at a plurality of spatial positions, developing a spatial profile of the detected light intensity, using the spatial intensity profile to identify an area in said tooth exhibiting intensity gradients, designating said area of said tooth exhibiting intensity gradients as an area of tooth decay. In another embodiment, detected light intensity is compared over at least a portion of said spatial positions for determining an area of decay in said tooth and an area of the tooth exhibiting a lower detected light intensity than an at least partially surrounding area is designated as an area of tooth decay.

[0036] In one aspect of the invention, the step of detecting the intensity of light passing through said tooth comprises directing a first detector at an aspect of the tooth, such as a facial aspect of the tooth, an occlusal aspect of the tooth, an opposite aspect of the tooth from the light source, or the same aspect of the tooth as the light source.

[0037] According to another embodiment of the invention, a second detector a second detector may at a different aspect of the tooth than the first detector. For example, the second detector may be directed at an occlusal aspect of the tooth while the first detector is directed at a facial aspect of the tooth. The detector may comprise a focal plane array, near-infrared CCD camera, or the like.

[0038] The method may be used to determine anomalies such as an area of decay, a crack, a composite restoration, and dental caries in an occlusal site or interproximal contact site between said tooth and an adjacent tooth of said tooth.

[0039] According to another aspect of the invention, a system for detecting tooth decay comprises a near-infrared light source emitting light having a wavelength in the range from approximately 785-nm to approximately 1600-nm wherein the light source is configured to transilluminate a tooth, and means for imaging light passing through said tooth and determining an area of decay in said tooth. In accordance with other aspects of the present

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invention, a light source has a wavelength more preferably in the range from approximately 830-nm to approximately 1550-nm, more preferably in the range from approximately 1285-nm to approximately 1335-nm, and more preferably at a wavelength of approximately 1310-nm. In one mode, the light source comprises a polarized light source. In another mode, the light source comprises an unpolarized light source. In one embodiment, the light source comprises a fiber-optic bundle coupled to a halogen lamp. In another embodiment, the light source comprises a superluminescent diode (SLD). In still another embodiment, the imaging means comprises a CCD camera. In another embodiment, the imaging means comprises a focal plane array (FPA).

[0040] According to yet another aspect of the invention, a system for detecting a tooth anomaly comprises a near-infrared light source having a wavelength in the range from approximately 795-nm to approximately 1600-nm, wherein the light source is configured to transilluminate a tooth. The system further includes an imaging device configured to detect intensity of light from said light source passing through said tooth, whereby an anomaly in said tooth can be determined from intensity of light detected by said imaging device.

[0041] Further aspects of the invention will be brought out in the following portions of the specification, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0042] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[0043] FIG. 1 is graph comparing the attenuation coefficient of dental enamel and water as a function of wavelength.

[0044] FIG. 2 is a flowchart of an embodiment of a method for detecting dental caries by near-infrared transillumination according to the present invention.

[0045] FIG. 3 is a schematic diagram of a system for Near-Infrared Transillumination of whole teeth and tooth sections according to the present invention.

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[0046] FIG. 4 is a schematic diagram of another system for Near-Infrared Transillumination of whole teeth and tooth sections according to the present invention using two light sources.

[0047] FIGS. 5A-5D are views of a tooth with a simulated lesion. FIG. 5A is a side view of a 3-mm thick tooth section with a simulated lesion. FIG. 5B illustrates that the lesion cannot be seen using transillumination with visible light and a CCD camera. FIG. 5C illustrates that the lesion is clearly visible under NIR. FIG. 5D is an x-ray of the section using D-speed film indicates the small contrast difference between the simulated lesion and sound enamel.

[0048] FIGS. 6A-6F are NIR transillumination images of tooth sections with simulated lesions are shown for sample thicknesses of 2-mm, 3-mm, 4-mm, 5-mm, 6-mm and 6.75-mm, respectively. The corresponding spatial line profiles are shown on the inset in the lower right of each image, and the measured lesion contrast is shown in the lower left. The left axis represents the pixel intensity ranging from 0 to 4096, and the bottom axis the pixel position through the lesion.

[0049] FIG. 7 is a graph showing the mean ±s.d lesion contrast plotted versus thickness of plano-parallel enamel samples, n=5.

[0050] FIG. 8 is an NIR image of a whole tooth sample. A natural carious lesion and a composite restoration are seen on the left and right, respectively. The tooth is slightly rotated to present different viewing angles. A crack is also visible in the center of the tooth.

DETAILED DESCRIPTION OF THE INVENTION

[0051] Referring more specifically to the drawings, for illustrative purposes the present invention is embodied in the system(s) and method(s) generally shown in FIG. 2 through FIG. 8. It will be appreciated that the apparatus may vary as to configuration and as to details of the parts, and that the method may vary as to the specific steps and sequence, without departing from the basic concepts as disclosed herein.

[0052] A principal limiting factor of light in the visible wavelength range from approximately 400-nm to 700-nm being transmitted through a tooth is light scattering in sound enamel and dentin. The present invention overcomes that

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limiting factor by employing near-infrared (NIR) for transillumination of a tooth. The magnitude of light scattering in dental enamel decreases as $1/\lambda^3$, where λ is the wavelength, due to the size of the principal scatterers in the enamel. The attenuation coefficients of dental enamel measured at 1310-nm and 1550-nm were 3.1 cm^{-1} and 3.8 cm^{-1}, respectively. As shown in FIG. 1, the magnitude of scattering at those wavelengths is more than a factor of 30 times lower than in the visible range. This translates to a mean free path of 3.2 mm for 1310-nm photons, indicating that enamel is transparent in the near-infrared (NIR). At longer wavelengths past 1550-nm, the attenuation coefficient is not expected to decrease any further due to the increasing absorption coefficient of water, 12% by volume, in dental enamel.

[0053] As indicated above, at shorter wavelengths the light is subject to scattering. On the other hand, at longer wavelengths, absorption of water in the tissue increases and thereby reduces the penetration of infrared light.

[0054] Note also that, during the caries process, micropores are formed in the lesion due to partial dissolution of the individual mineral crystals. Such small pores can behave as scattering centers smaller than the wavelength of the light. Accordingly, there can be an increase in both the magnitude of light scattering and the contribution of large angle scattering to the scattering phase function in caries lesions due to the increased microporosity. Changes in the optical constants and scattering phase function of enamel and dentin result in more rapid depolarization of incident polarized light. Accordingly, polarized light (e.g., via linear or circular polarization) will provide a greater image contract than unpolarized light and can be exploited to aid in the near-infrared optical detection of carious lesions.

[0055] The present invention is particularly useful in detecting occlusal caries (biting surfaces) and interproximal caries or lesions located at interproximal contact sites between adjacent teeth. The present invention is also useful in detecting other anomalies such as root caries, cracks, and imaging around composite restorations.

[0056] Referring to FIG. 2, an exemplary method for detecting tooth anomalies

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such as dental decay or caries according to the invention is illustrated. First, a near-infrared light source is positioned adjacent to a tooth to be examined, as shown at block 20. Next, the tooth is transilluminated with the near-infrared light, as shown at block 22. The wavelength of the light is preferably in the range from approximately 795-nm to approximately 1600-nm, more preferably in the range from approximately 830-nm to approximately 1550-nm, more preferably in the range from approximately 1285-nm to approximately 1335-nm, and more preferably at a wavelength of approximately 1310-nm. Use of near-infrared light in these ranges provides deeper depth resolution and improved contrast between sound and carious enamel as compared to light at other wavelengths.

[0057] Once the tooth is transilluminated, the intensity of the light passing through the tooth at a plurality of spatial positions is detected, thereby forming an image of the tooth structure, as shown at block 24. The detected light intensity over at least a portion of the spatial positions is then compared so that an area of tooth decay can be identified, as shown at block 26. This is preferably accomplished by developing a spatial profile so that intensity gradients can be seen. An area of the tooth that exhibits a lower detected light intensity than an at least partially surrounding area is indicative of an area of tooth decay. While contrast alone can be used as an indicator of tooth decay, more preferably the existence of a defined boundary or edge between areas exhibiting intensity gradients is a more accurate indicator. It will be appreciated, of course, that a dentist or trained clinician will review and evaluate the images to distinguish lesions from, for example, areas containing fillings, composite restorations, or other non-dental caries areas that effect intensity gradients in the image. Note that the incident light is preferably linearly polarized and, preferably, only light in the orthogonal polarization state is measured.

[0058] An exemplary NIR imaging device 30 is shown schematically in FIG 3. Light 50 is emitted from a light source 32, through polarizer 38 and aperture 34 toward tooth or series of teeth 36. Light source 32 preferably comprises a broadband light source, such as fiber-optic bundle coupled to a halogen lamp,

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or a superluminescent laser diode (SLD). It was found that the speckle of conventional narrow bandwidth diode lasers such as a 50-mW 1310-nm source, Model QLD-1300-50 (Qphotonics Inc., Chesapeake, VA) interfered significantly with image resolution and were not optimal for the present invention.

[0059] Crossed near-IR polarizers, 38, 40 are used to remove light that directly illuminated the array without passing through the tooth. In a clinical situation, the light passing between the teeth will saturate the image preventing detection. Dental enamel is birefringent and, therefore, the polarization state of the light passing through the tooth may be altered to reduce extinction. Polarization gating using crossed high extinction polarizers 38, 40 removes extraneous light that does not pass through the tooth and exploits the native birefringence of the tooth enamel to rotate the plane of polarization so that only light that passes through the tooth is measured. Caries lesions depolarize light which provides better image contrast between sound and carious tissue

[0060] Light passing through tooth 36 and polarizer 40 is further filtered with bandpass filter 42 to remove all light outside the spectral region of interest.

[0061] The light is then focused with lens 44 and picked up with detector 46 to acquire images of tooth or teeth 36. In a preferred embodiment, detector 46 comprises a near-infrared (NIR) InGaAs focal plane array (FPA).

[0062] The illuminating light intensity of light source 32, the diameter of aperture 34, and the distance of the light source to tooth 36, may all be adjusted to obtain the maximum contrast between the lesion and the surrounding enamel without saturation of the InGaAs FPA around the lesion area.

[0063] Alternatively, detector 46 may comprise a CCD camera with the IR filter 42 and a 70-nm bandpass filter centered at approximately 830-nm. Alternatively, the bandpass filter may be removed. Imaging with a near-IR CCD camera is less expensive with an InGaAs detector, but does not perform as well as an InGaAs detector. As another alternative, transillumination can also be conducted using a CCD camera with a near-infrared phosphor in the

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range of approximately 1000-nm to approximately 1600-nm.

[0064] In yet another alternative embodiment, image quality may be improved by utilizing biocompatible index matching fluids and gels and/or solid materials of high refractive index to reduce reflection, total internal reflection, and refraction at the tooth entrance and exit surfaces. Such materials would be placed on the end of the illumination source 32 and/or the detector 46 and would make physical contact with the tooth surface

[0065] Now referring to Figure 4, an alternative embodiment of NIR imaging device 60 is shown schematically for imaging tooth 36. This device 60 may be used for the near-IR imaging of occlusal and pit and fissure lesions by placing light source 62 on the facial aspect 68 or lingual aspect 70 of the tooth and placing a second imaging source 66 above the occlusal surface 72 of the tooth 36 in addition to the first imaging source 68 either the facial or lingual aspects, 68, 70. Detection of light 50 along different axes may be achieved with a combination of prisms, mirrors or optical fiber components. For example, the imaging fiber optic bundle 62 could be fitted with a 90° prism (not shown) and connected to a near-IR imaging camera. Alternatively, the light source may also be placed in any combination of these viewing angles, including having the light source and imager on the same aspect of the tooth.

EXAMPLE 1

(Sample Preparation)

[0066] Thirty plano-parallel sections of enamel of various thicknesses (2-mm, 3-mm, 4-mm, 5-mm, 6-mm, and 6.75-mm) were prepared from non-carious human teeth. These sections were stored in a moist environment to preserve tissue hydration with 0.1% thymol added to prevent bacterial growth. Uniform scattering phantoms simulating dental decay were produced midway through each section by drilling 1-mm diameter x 1.2-mm deep cavities in the proximal region of each sample and filling the cavities with hydroxyapatite paste. A thin layer of unfilled composite resin was applied to the outside of the filled cavity to seal the hydroxyapatite within the prepared tooth cavity.

(NIR Imaging)

[0067] Both a 150-watt halogen lamp, Visar™ (Den-Mat, Santa Maria, CA),

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and a 1310-nm superluminescent diode (SLD) with an output power of 3.5 mW and a bandwidth of 25-30 nm, Model QSDM-1300-5 (Qphotonics Inc., Chesapeake, VA) were separately used as the illumination source.

[0068] Model K46-252 (Edmund Scientific, Barrington, NJ) crossed near-IR polarizers were used to remove light that directly illuminated the array without passing through the tooth. A 50-nm bandpass filter centered at 1310-nm Model BP-1300-090B (Spectrogon US, Parsippany, NJ) was used to remove all light outside the spectral region of interest.

[0069] A near-infrared (NIR) InGaAs focal plane array (FPA) having a resolution of 318 x 252 pixels was used to acquire all of the images. The particular FPA used was an Alpha NIRTM (Indigo Systems, Goleta, Ca) with an Infinimite™ lens (Infinity, Boulder, Co).

[0070] The acquired 12-bit digital images were analyzed using IRVista™ software (Indigo Systems, Goleta, Ca).

[0071] The illuminating light intensity, source to sample distance, and the aperture diameter were adjusted for each sample to obtain the maximum contrast between the lesion and the surrounding enamel.

[0072] Although the 3.5-mW SLD source provided similar image quality to the halogen lamp source, all the images illustrated herein were acquired using the fiber-optic illuminator. Due to the natural tooth contours, the sides near the simulated lesions in the tooth sections were masked with putty to ensure that light traveled the full width of the sample. This masking is not applicable in a clinical situation and was not necessary to acquire images of whole teeth.

[0073] In addition, good images of teeth were obtained using the 3.5 mW SLD operating at 1310-nm. This is important because this illumination source is very compact and can be easily placed in the oral cavity. Furthermore, the SLD is much more compact than the illumination source used for DiFOTI and can be integrated into a small dental explorer and manipulated behind the teeth for collection of images using the camera.

(Visible and X-ray Imaging)

[0074] A tooth section of minimal sample thickness, 3-mm, was chosen for comparison of the NIR transillumination system with conventional visible light

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FOTI and x-ray transillumination. For visible light transillumination, the same fiber-optic illuminator was used to illuminate the section and a color 1/3" CCD camera with a resolution of 450 lines, Model DFK 5002/N, (Imaging Source, Charlotte, NC) equipped with the same Infinimite™ lens recorded the projection image. The corresponding x-ray image was acquired by placing the section directly on Ultra-Speed™ D-speed film (Kodak, Rochester, NY) using 75 kVp, 15 mA, and 12 impulses.

(Image Analysis)

[0075] The coordinates of each simulated lesion were known prior to analyzing the contrast of each lesion. The mean pixel intensity of the lesion and the enamel above and below the lesion was measured using the IRvista™ software. Lesion contrast was calculated for each sample as follows:

$$\text{Lesion Contrast (C)} = (I_E - I_L)/ I_E,$$

where I_E is the mean intensity of the enamel bordering the lesion and I_L is the mean intensity of the lesion. Lesion contrast is defined as a ratio that will vary from zero (0) to one (1). For each of the six sample thicknesses measured, the mean lesion contrast was calculated and plotted versus sample thickness.

[0076] Although contrast is important, the boundary or edge between the lesion and the sound tooth structure is central to detection of the lesion. Therefore, the spatial intensity profile of a lesion with its surrounding enamel was analyzed. An intensity profile was mapped from a (1) distinct line in six sample images representing each thickness.

RESULTS

[0077] Visible light, NIR and X-ray images of a simulated lesion placed in one of the 3-mm thick tooth sections are shown in FIG. 5A-5D. The lesion 80 cannot be seen using visible light transillumination, however the lesion is clearly visible with high contrast using NIR light transillumination. A radiographic image of the tooth section using D-speed film shows a low lesion contrast, or a small contrast difference between the lesion and the surrounding enamel.

[0078] The lesion contrast was calculated for all thirty of the enamel sections under NIR illumination. Representative spatial intensity profiles from six of the

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samples of each thickness and the corresponding images are shown in FIG. 6A-6F. From these profiles, the edge or boundary between the sound enamel and the lesion is clearly demarcated in all six of the sections. The image contrast plotted vs. section thickness is shown in FIG. 7. A lesion contrast of greater than 0.35 was seen in all the sections with the exception of the 6-mm samples. A 0.35 lesion contrast is equivalent to a lesion intensity that is 65% of the surrounding enamel.

[0079] For 6-mm samples, a mean lesion contrast of 0.16 was calculated. A steep intensity gradient is visible between the surrounding enamel and the lesion. This gradient is less pronounced for sections greater than 4-mm thick, especially on the lower border of the lesion. A NIR image of a whole tooth sample with a natural lesion 84, depicted in FIG. 8, illustrates that a natural lesion 84 can be resolved with the same success as the simulated lesions placed in plano-parallel sections. A composite filling 86 is also visible on the opposite side of the tooth in FIG. 8, indicating that there is also high contrast between composite filling materials and sound tooth structure.

DISCUSSION OF EXPERIMENTAL RESULTS

[0080] The high contrast and intensity profiles of the simulated lesions with the surrounding enamel indicate the significant potential of NIR transillumination for imaging dental caries. Since the clinical use of transillumination is to detect interproximal lesions, it is important to note that forty of the sixty-four interproximal surfaces in the mouth would require imaging through less than 5-mm of enamel. This study suggests that resolving caries lesions through 5-mm of enamel is clinically feasible. This is further demonstrated by the NIR imaging of whole teeth with natural decay.

[0081] During the transillumination of whole tooth samples, polarization gating with crossed polarizers was critical for preventing the illuminating light from saturating the InGaAs array near the area of the lesion "shadow". This technique will also be important in a clinical setting where adjacent tooth surfaces will reflect, but not depolarize the light, and could interfere with the accuracy of the projection image.

[0082] During demineralization of enamel in the caries process, preferential

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dissolution of the mineral phase creates pores that highly scatter light. The simulated lesions in our study are primarily made up of isotropic scatterers, with scattering occurring at the grain boundaries in the hydroxyapatite powder. Therefore, such simulated lesions may possibly overestimate the magnitude of scattering in natural caries lesions; however, creating more accurate optical simulated lesions requires an intimate understanding of the fundamental optical properties of carious tissue that has yet to be determined.

[0083] It was found that 1310-nm is optimal for both high transmission through sound dental enamel and for achieving high contrast between caries lesions and sound enamel.

[0084] Simulated lesions composed of an unorganized paste of hydroxyapatite, strongly scatter the 1310-nm light, which provides high contrast with the transparent sound enamel. Optical transillumination is similar to other projection imaging modalities like conventional x-rays, however the image contrast arises from changes in tissue scattering as opposed to variations in tissue density. Therefore, this method can be more sensitive than x-rays for resolving early caries lesions. Clinicians are trained to diagnose at the low lesion contrast depicted in the radiograph of FIG. 5D, but the high contrast in the NIR image suggests that the simulated lesions are more sensitive to optical detection. This is due to the fact that the simulated lesions have only slightly lower density than the sound enamel but strongly scatter NIR light.

[0085] In addition, favorable images to a depth of 4-mm to 5-mm were obtained using a CCD camera with the IR filter removed operating at approximately 830-nm.

[0086] As can be seen, therefore, there are several advantages between the present invention and known systems that use DiFOTI or other FOTI techniques. These include:

[0087] (a) Illumination

[0088] The DiFOTI system and other FOTI systems utilize an unfiltered fiber-optic illuminator with most intensity in the visible range, as opposed to the broadband near-IR illumination sources of the present invention. Tests

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revealed that narrow band sources such as conventional laser diodes generate too much laser speckle for imaging. Successful results were achieved with a fiber-optic illuminator having either a 50-nm bandpass filter centered at 1310-nm or a 70-nm bandpass filter centered at 830-nm. Test results were also favorable (speckle-free) with a low cost 3.5 mW, single mode fiber pigtailed, superluminescent laser diode operating at 1310-nm with a bandwidth of 25-nm to 30-nm.

[0089] (b) Image processing

[0090] DiFOTI utilizes proprietary image processing techniques to improve image quality. Although imaging processing techniques may be used in conjunction with the current invention, post imaging digital processing methods is generally not required to improve performance.

[0091] (c) Performance

[0092] The images collected with FOTI and DiFOTI are not true projection or transillumination images, since the penetration of visible light or the mean-free path is less than 100-μm in enamel. The way these systems work is that light migrates through the enamel of the tooth, backlighting the lesion for better contrast. That means that these systems must have a direct line of sight to the lesion surface. Therefore, they cannot be used to determine how far a lesion has penetrated through the enamel since they can only view the lesion surface.

[0093] The present invention acquires true projection images similar to x-rays by imaging through the full thickness of the enamel. In those images, the camera does not have a direct line of site to the lesion surface. This is possible because of the increase in the mean free path of enamel, that is optimum at 1310-nm - 3.3 mm.

[0094] Although the description above contains many details, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Therefore, it will be appreciated that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be

limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more." All structural, chemical, and functional equivalents to the elements of the above-described preferred embodiment that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase "means for."

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CLAIMS

What is claimed is:

1. A method for detecting tooth anomalies, comprising:

transilluminating a tooth with light having a wavelength in the range from approximately 795-nm to approximately 1600-nm; and

imaging light passing through said tooth for determining an anomaly in said tooth.

2. A method as recited in claim 1, wherein said light has a wavelength in the range from approximately 830-nm to approximately 1550-nm.

3. A method as recited in claim 1, wherein said light has a wavelength in the range from approximately 1285-nm to approximately 1335-nm.

4. A method as recited in claim 1, wherein said light has a wavelength of approximately 1310-nm.

5. A method as recited in claim 1, further comprising:

filtering said light to remove extraneous light.

6. A method as recited in claim 5, wherein filtering said light comprises polarizing said light with one or more polarizing filters to remove light not passing through said tooth.

7. A method as recited in claim 6, wherein said one or more polarizing filters comprises crossed high-extinction polarizing filters.

8. A method as recited in claim 5, further comprising:

filtering said light with a bandpass filter to remove light outside a specified bandwidth.

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9. A method as recited in claim 1, wherein transilluminating a tooth comprises directing light from a near-infrared light source at a surface of said tooth.

10. A method as recited in claim 9, wherein the light source comprises a fiber-optic bundle coupled to a halogen lamp.

11. A method as recited in claim 9, wherein the light source comprises a superluminescent laser diode.

12. A method as recited in claim 9, wherein directing light from a light source comprises manipulating the light source behind said tooth to direct said light at a lingual surface of the tooth.

13. A method as recited in claim 10, wherein directing light from a light source comprises manipulating the light source in front of said tooth to direct said light at a facial surface of the tooth.

14. A method as in claim 1, wherein transilluminating a tooth comprises simultaneously directing light from a near-infrared light source at a surface of a plurality of teeth.

15. A method as recited in claim 9, wherein said step of imaging light passing through said tooth, comprises:

detecting intensity of light passing through said tooth at a plurality of spatial positions;

developing a spatial profile of said detected light intensity;

using said spatial intensity profile, identifying an area in said tooth exhibiting intensity gradients; and

designating said area of said tooth exhibiting intensity gradients as an area of tooth decay.

16. A method as recited in claim 15, wherein the step of detecting intensity

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of light passing through said tooth comprises directing a first detector at an aspect of the tooth.

17. A method as in claim 16, wherein the first detector is directed at a facial aspect of the tooth.

18. A method as in claim 16, wherein the first detector is directed at an occlusal aspect of the tooth.

19. A method as in claim 16, wherein the first detector is directed at an opposite aspect of the tooth from the light source.

20. A method as in claim 16, wherein the first detector is directed at the same aspect of the tooth as the light source.

21. A method as in claim 16, further comprising directing a second detector at a different aspect of the tooth than the first detector.

22. A method as in claim 21, wherein the second detector is directed at an occlusal aspect of the tooth and the first detector is directed at a facial aspect of the tooth.

23. A method as in claim 16, wherein the detector comprises a focal plane array.

24. A method as in claim 16, wherein the detector comprises a near-infrared CCD camera.

25. A method as in claim 24, wherein said light has a wavelength of 830-nm.

26. A method as in claim 1, wherein imaging light passing through said

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tooth comprises determining an area of decay in said tooth.

27. A method as in claim 1, wherein imaging light passing through said tooth comprises determining a crack in said tooth.

28. A method as in claim 1, wherein imaging light passing through said tooth comprises determining an anomaly around a composite restoration in said tooth.

29. A method as in claim 26, further comprising identifying dental caries in an occlusal site of said tooth.

30. A method as in claim 26, further comprising identifying dental caries in an interproximal contact site between said tooth and an adjacent tooth.

31. A method of detecting tooth decay, comprising:

transilluminating a tooth with a near-infrared light source having a wavelength in the range from approximately 795-nm to approximately 1600-nm;

detecting intensity of light passing through said tooth at a plurality of spatial positions;

comparing detected light intensity for at least a portion of said spatial positions; and

designating an area of said tooth exhibiting a lower detected light intensity than an at least partially surrounding area as an area of tooth decay.

32. A method of detecting tooth decay, comprising:

transilluminating a tooth with a near-infrared light source having a wavelength in the range from approximately 795-nm to approximately 1600-nm;

detecting intensity of light passing through said tooth at a plurality of spatial positions;

developing a spatial profile of said detected light intensity;

using said spatial intensity profile, identifying areas in said tooth exhibiting

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intensity gradients; and

designating said area of said tooth exhibiting intensity gradients as an area of tooth decay.

33. A method of detecting dental caries in interproximal contact sites between adjacent teeth, comprising:

positioning a near-infrared light source having a wavelength in the range from approximately 795-nm to approximately 1600-nm adjacent to a tooth;

transilluminating said tooth with said light source;

detecting intensity of light passing through said tooth at a plurality of spatial positions;

developing a spatial profile of said detected light intensity;

using said spatial intensity profile, identifying areas in said tooth exhibiting intensity gradients; and

designating said area of said tooth exhibiting intensity gradients as an area of tooth decay.

34. A method as in any one of claims 1, 31, 32, and 33, wherein said light has a wavelength in the range from approximately 830-nm to approximately 1550-nm.

35. A method as in any one of claims 1, 31, 32, and 33, wherein said light has a wavelength in the range from approximately 1285-nm to approximately 1335-nm.

36. A method as in any one of claims 1, 31, 32, and 33, wherein said light has a wavelength of approximately 1310-nm.

37. A method as in any one of claims 31, 32, and 33, further comprising:

filtering said light with one or more polarizing filters to remove extraneous light not passing through said tooth.

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38. A method as in any one of claims 31, 32, and 33, wherein transilluminating a tooth comprises directing light from a near-infrared light source at a surface of said tooth.

39. A method as recited in claim 38, wherein the light source comprises a fiber-optic bundle coupled to a halogen lamp.

40. A method as recited in claim 38, wherein the light source comprises a superluminescent laser diode.

41. A system for detecting tooth decay, comprising:

a near-infrared light source emitting light having a wavelength in the range from approximately 795-nm to approximately 1600-nm;

said light source configured to transilluminate a tooth; and

means for imaging light passing through said tooth and determining an area of decay in said tooth.

42. A system as recited in claim 41, wherein the means for imaging light comprises a focal plane array.

43. A system as recited in claim 41, wherein the means for imaging light comprises a near-infrared CCD camera.

44. A system for detecting a tooth anomaly, the system comprising:

a near-infrared light source having a wavelength in the range from approximately 795-nm to approximately 1600-nm;

said light source configured to transilluminate a tooth; and

an imaging device configured to detect intensity of light from said light source passing through said tooth;

whereby an anomaly in said tooth can be determined from intensity of light detected by said imaging device.

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45. A system as in either of claims 41 or 44, wherein said light has a wavelength in the range from approximately 830-nm to approximately 1550-nm

46. A system as in either of claims 41 or 44, wherein said light has a wavelength in the range from approximately 1285-nm to approximately 1335-nm.

47. A system as in either of claims 41 or 44, wherein said light has a wavelength of approximately 1310-nm.

48. A system as in either of claims 41 or 44, further comprising:
one or more polarizing filters to remove light not passing through said tooth.

49. A system as recited in claim 48, wherein said one or more polarizing filters comprises crossed high-extinction polarizing filters.

50. A system as in either of claims 41 or 44, further comprising:
a bandpass filter to remove light outside a specified bandwidth.

51. A system as in either of claims 41 or 44, wherein the light source comprises a fiber-optic bundle coupled to a halogen lamp.

52. A system as in either of claims 41 or 44, wherein the light source comprises a superluminescent laser diode.

53. A system as in either of claims 41 or 44, wherein the light source is configured to be positioned behind said tooth to direct said light at a lingual surface of the tooth.

54. A system as in either of claims 41 or 44, wherein the light source is configured to be positioned in front of said tooth to direct said light at a facial surface of the tooth.

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55. A system as recited in claim 44, wherein the imaging device comprises a first detector.

56. A system as recited in claim 55, wherein the first detector is configured to be directed at a facial aspect of the tooth.

57. A system as in claim 55, wherein the first detector is directed at an occlusal aspect of the tooth.

58. A system as in claim 55, wherein the first detector is directed at an opposite aspect of the tooth from the light source.

59. A system as in claim 55, wherein the first detector is directed at the same aspect of the tooth as the light source.

60. A system as in claim 59, wherein the imaging device further comprises a second detector directed at a different aspect of the tooth than the first detector.

61. A system as in claim 59, wherein the second detector is directed at an occlusal aspect of the tooth and the first detector is directed at a facial aspect of the tooth.

62. A system as in claim 55, wherein the detector comprises a focal plane array.

63. A system as in claim 55, wherein the detector comprises a near-infrared CCD camera.

64. A system as in claim 63, wherein said light has a wavelength of 830-nm.

65. A method as in claim 44, wherein imaging light passing through said

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tooth comprises determining an area of decay in said tooth.

66. A method as in claim 65, wherein said area of decay comprises decay in an occlusal site of said tooth.

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67. A method as in claim 65, wherein said area of decay comprises decay in an interproximal contact site between said tooth and an adjacent tooth.

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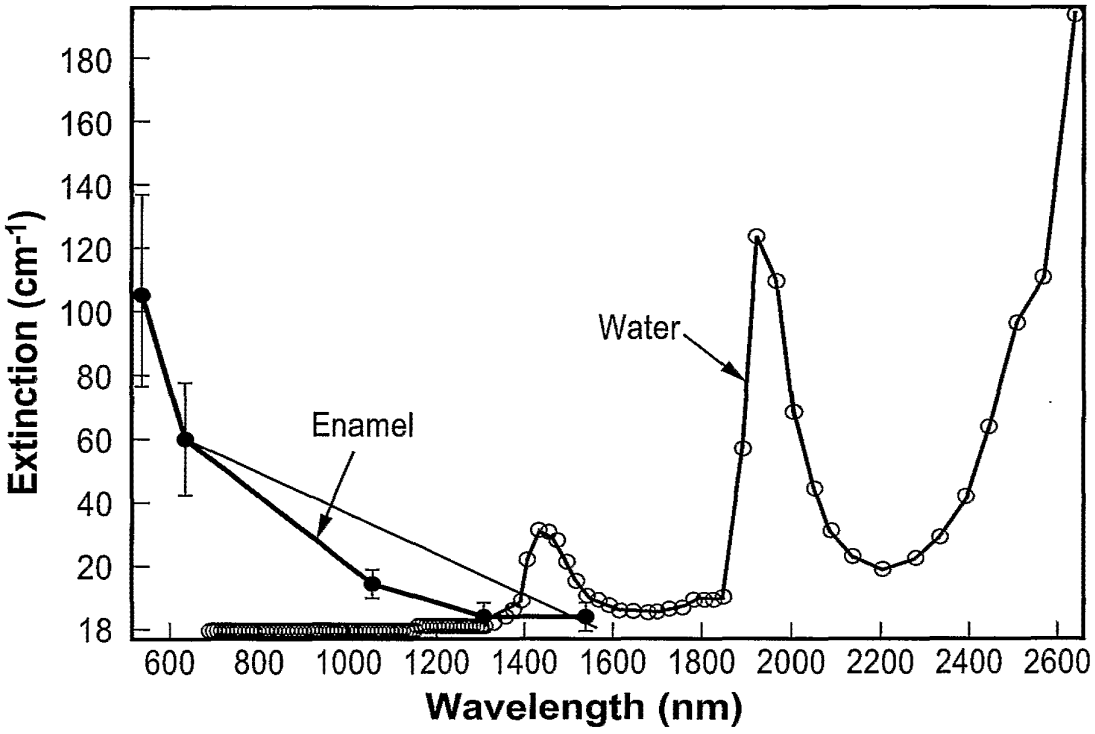

Extinction (cm-1)
180
160
140
120
100
80
60
40
20
18
600
800
1000
1200
1400
1600
1800
2000
2200
2400
2600
Wavelength (nm)
Water
Enamel

FIG. 1

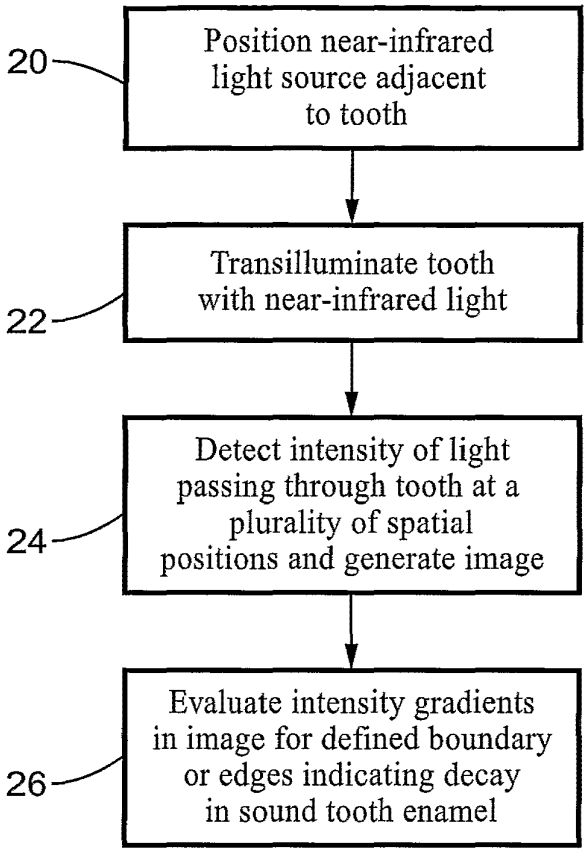

20
Position near-infrared light source adjacent to tooth
22
Transilluminate tooth with near-infrared light
24
Detect intensity of light passing through tooth at a plurality of spatial positions and generate image
26
Evaluate intensity gradients in image for defined boundary or edges indicating decay in sound tooth enamel

FIG. 2

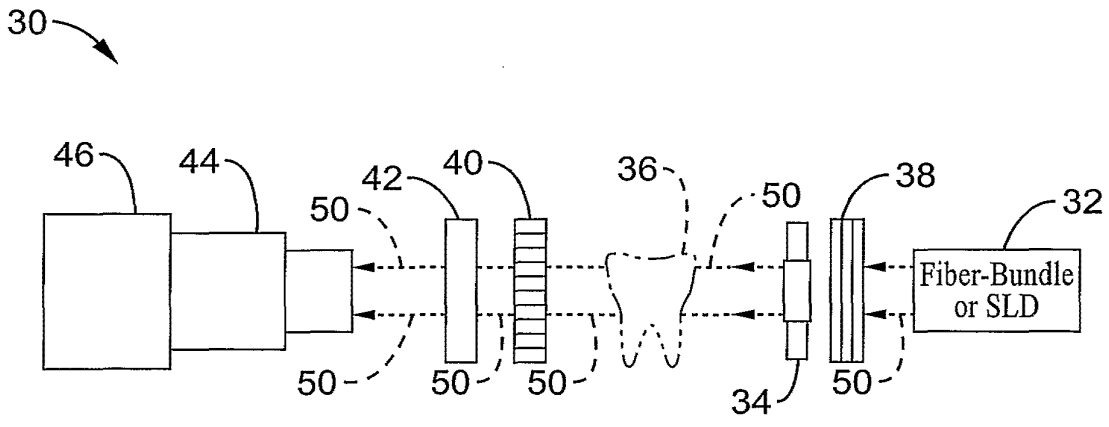

30
46
44
42
40
36
50
38
32
Fiber-Bundle or SLD
50
50
50
50
34
50

FIG. 3

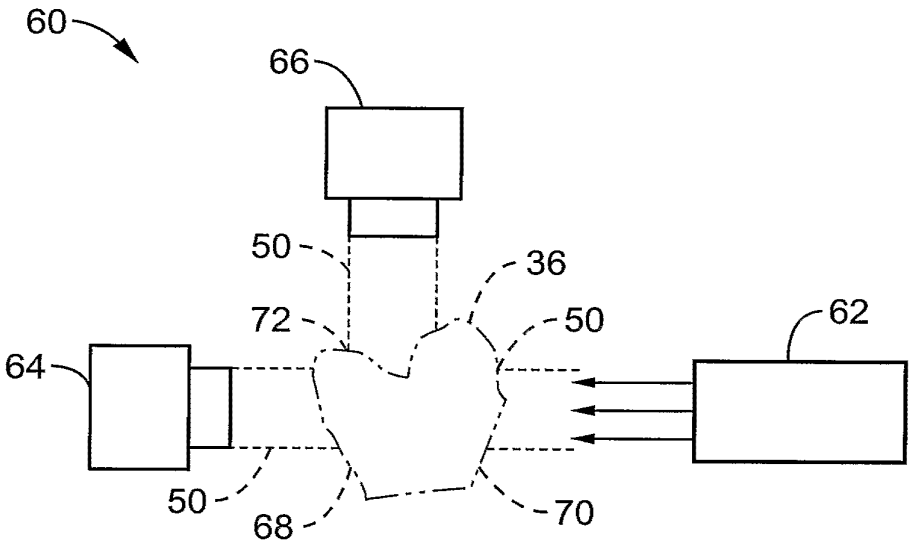


FIG. 4

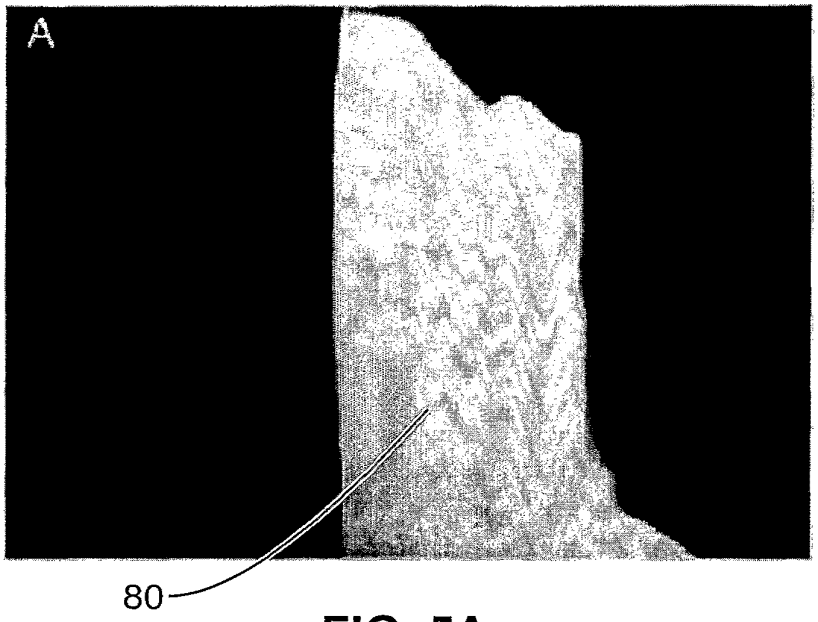


FIG. 5A

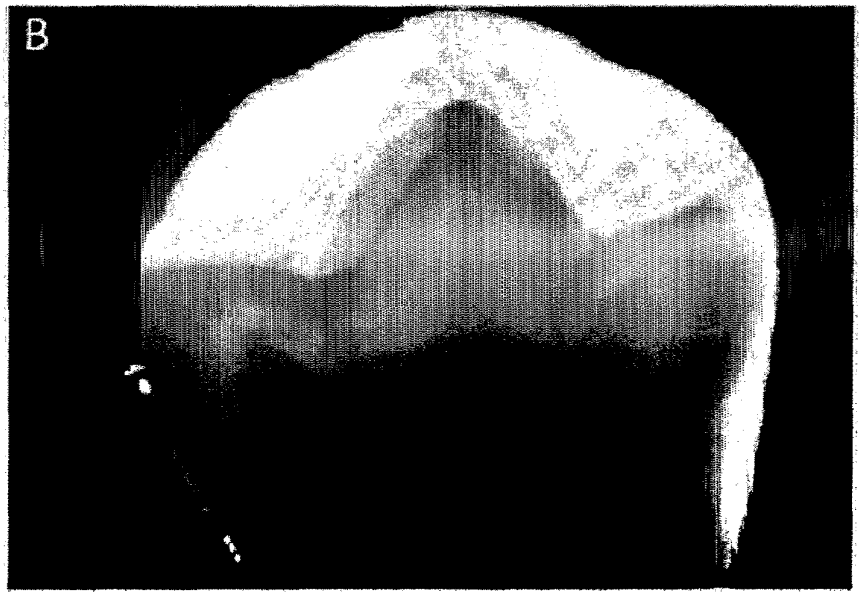


FIG. 5B

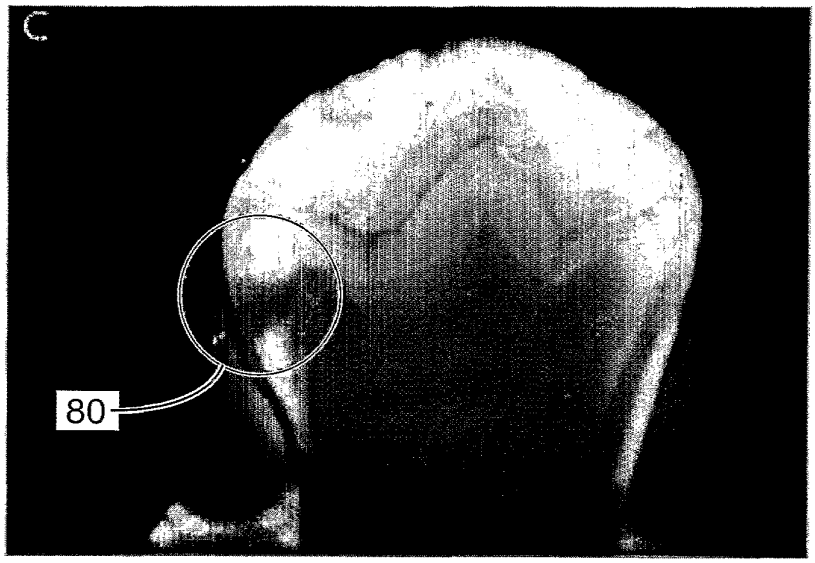


FIG. 5C

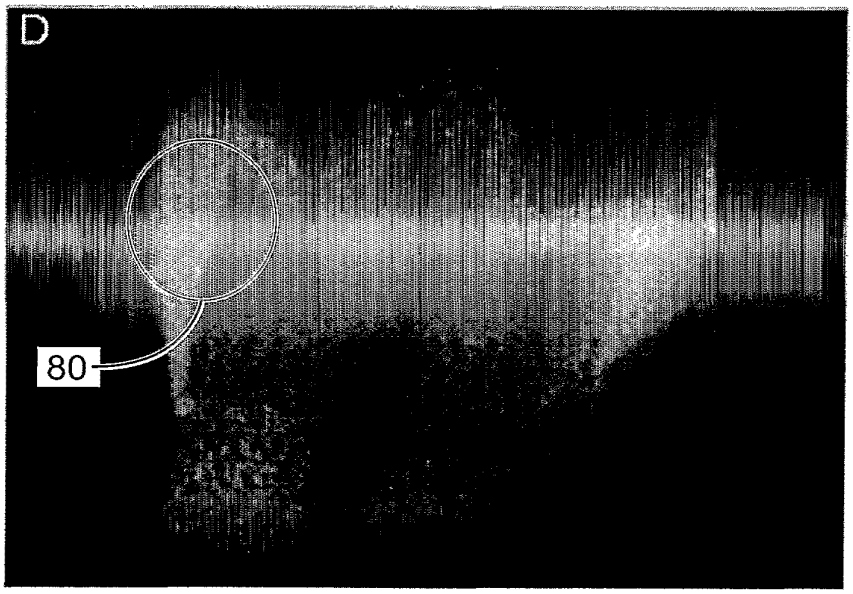


FIG. 5D

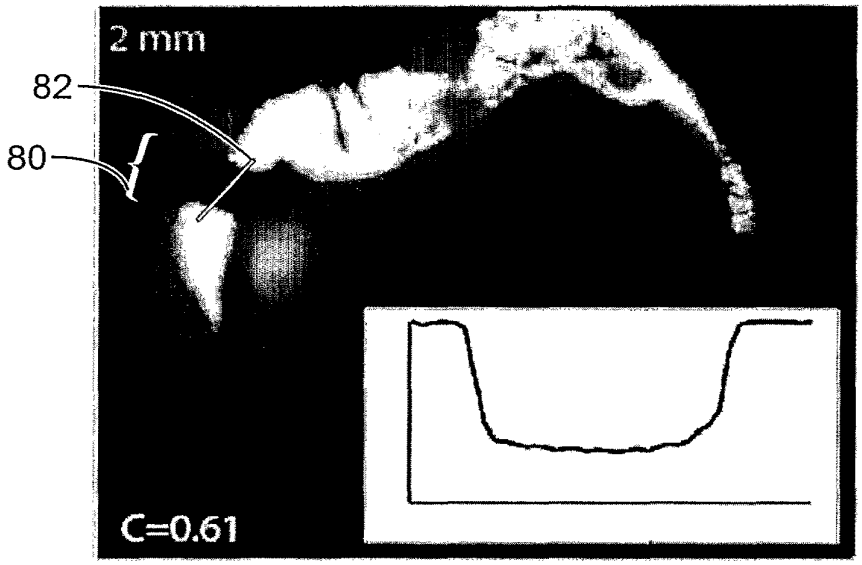


FIG. 6A

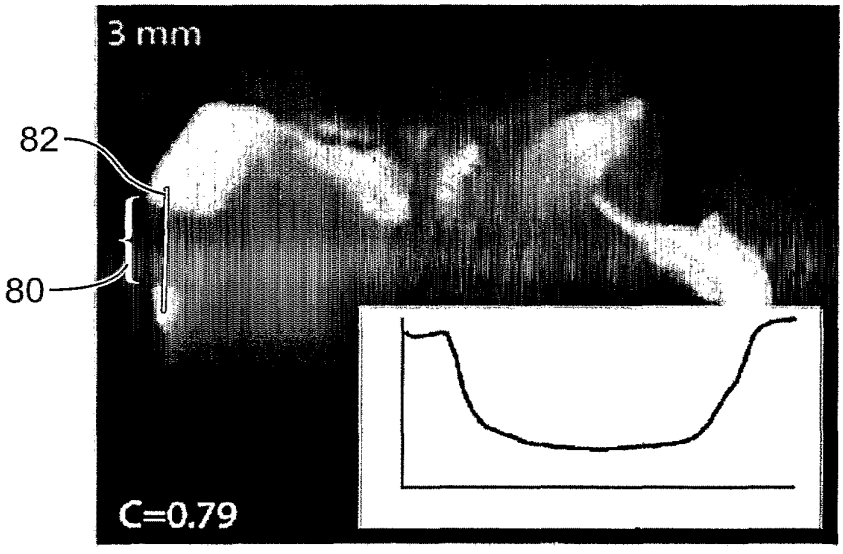


FIG. 6B

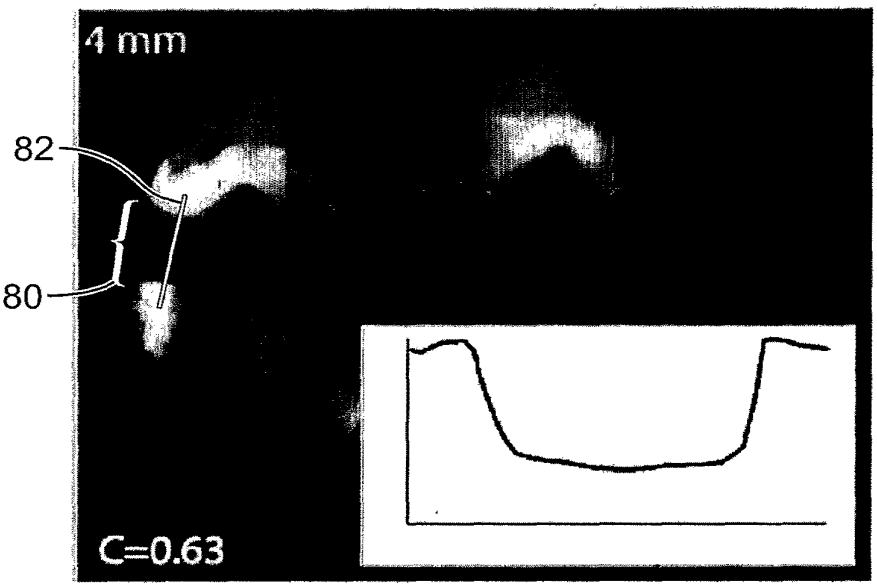


FIG. 6C

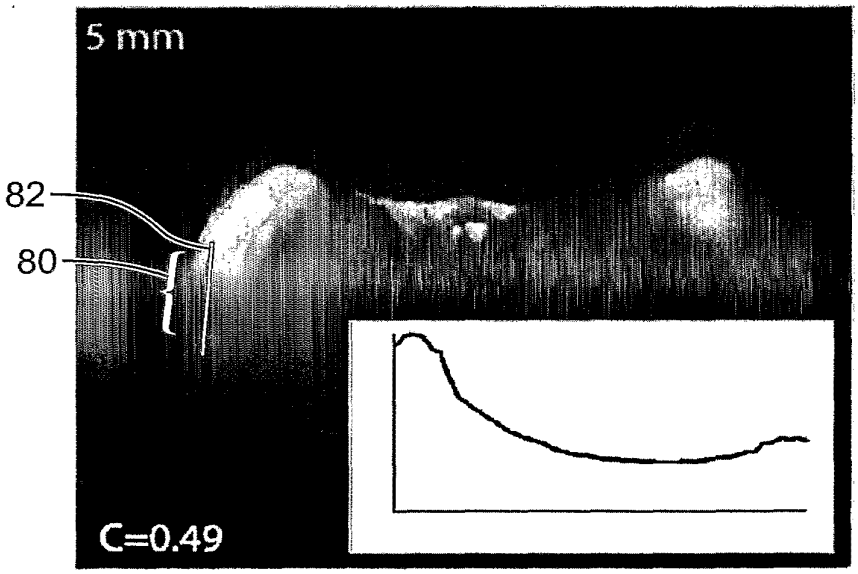


FIG. 6D

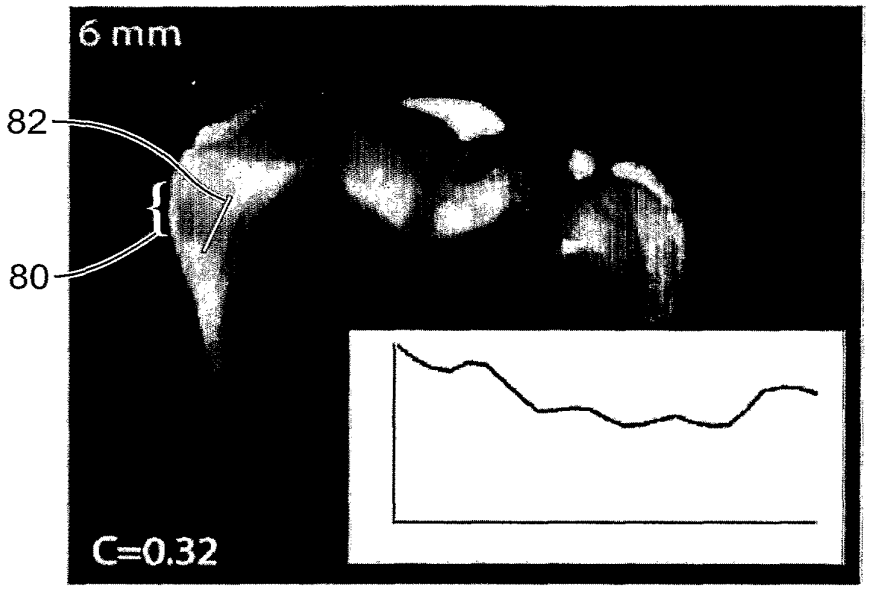


FIG. 6E

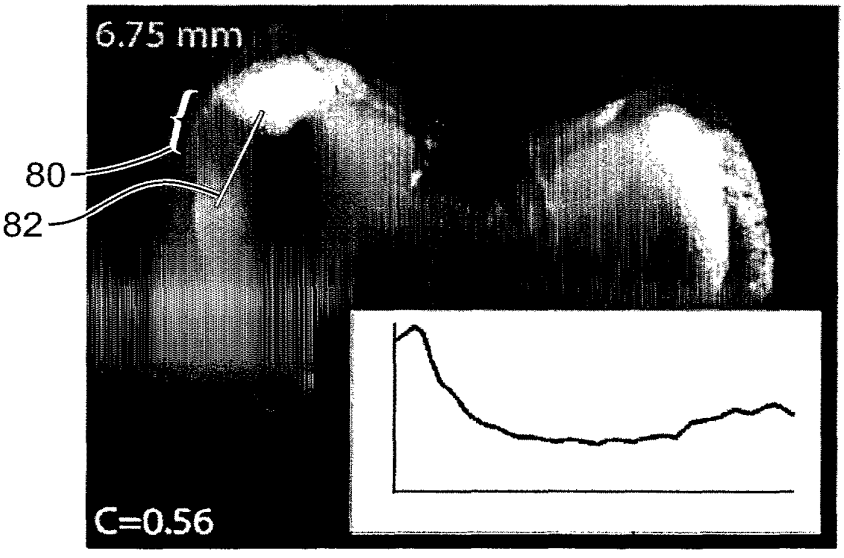


FIG. 6F

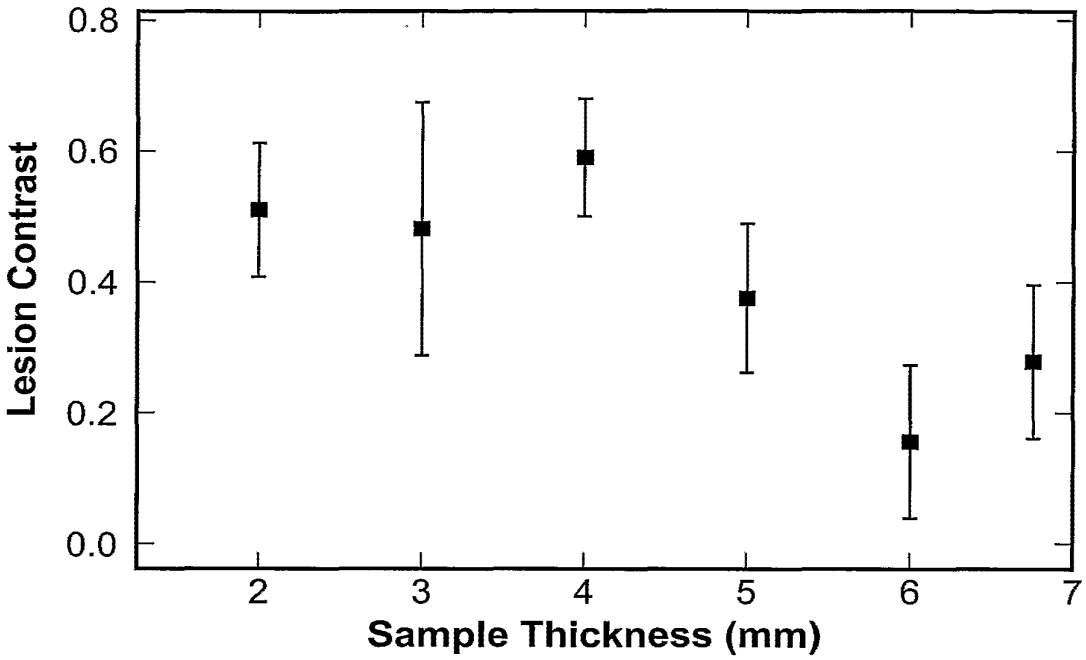

0.8
0.6
0.4
0.2
0.0
Lesion Contrast
2
3
4
5
6
7
Sample Thickness (mm)

FIG. 7

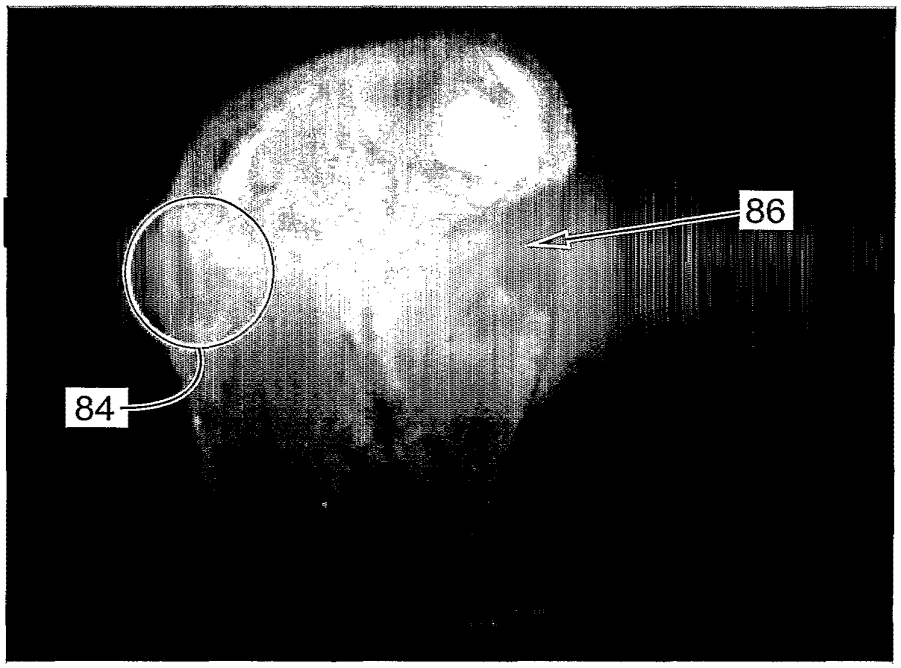

86
84

FIG. 8