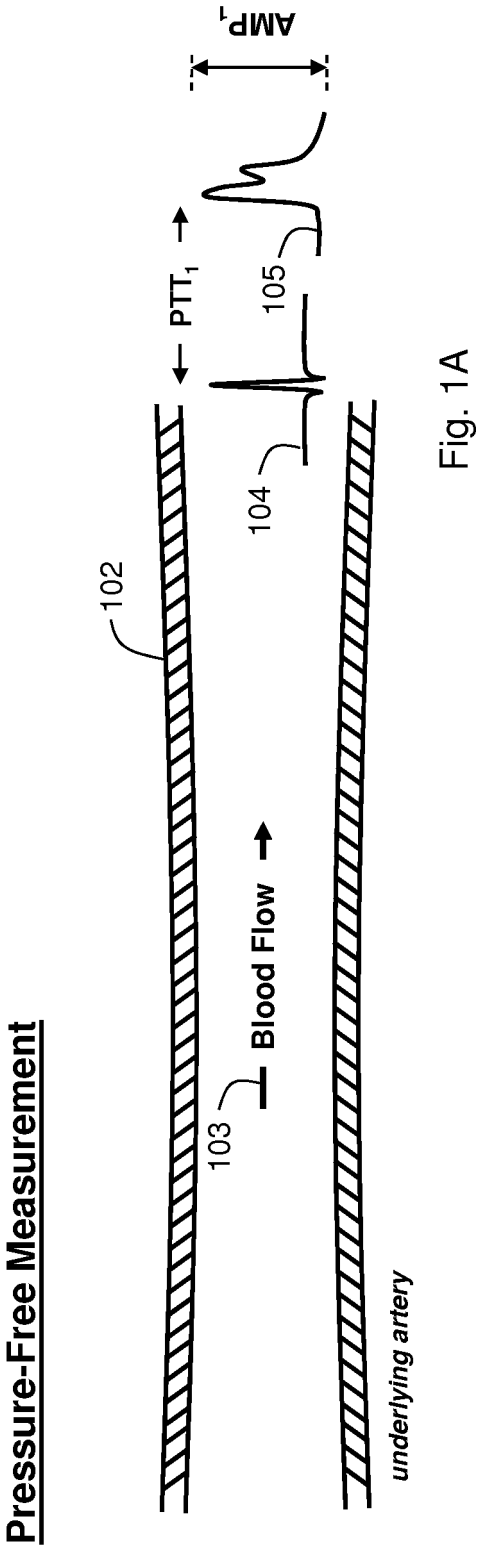

Pressure-Free Measurement
AMP1
PTT1
105
104
102
Blood Flow
103
underlying artery

Fig. 1A

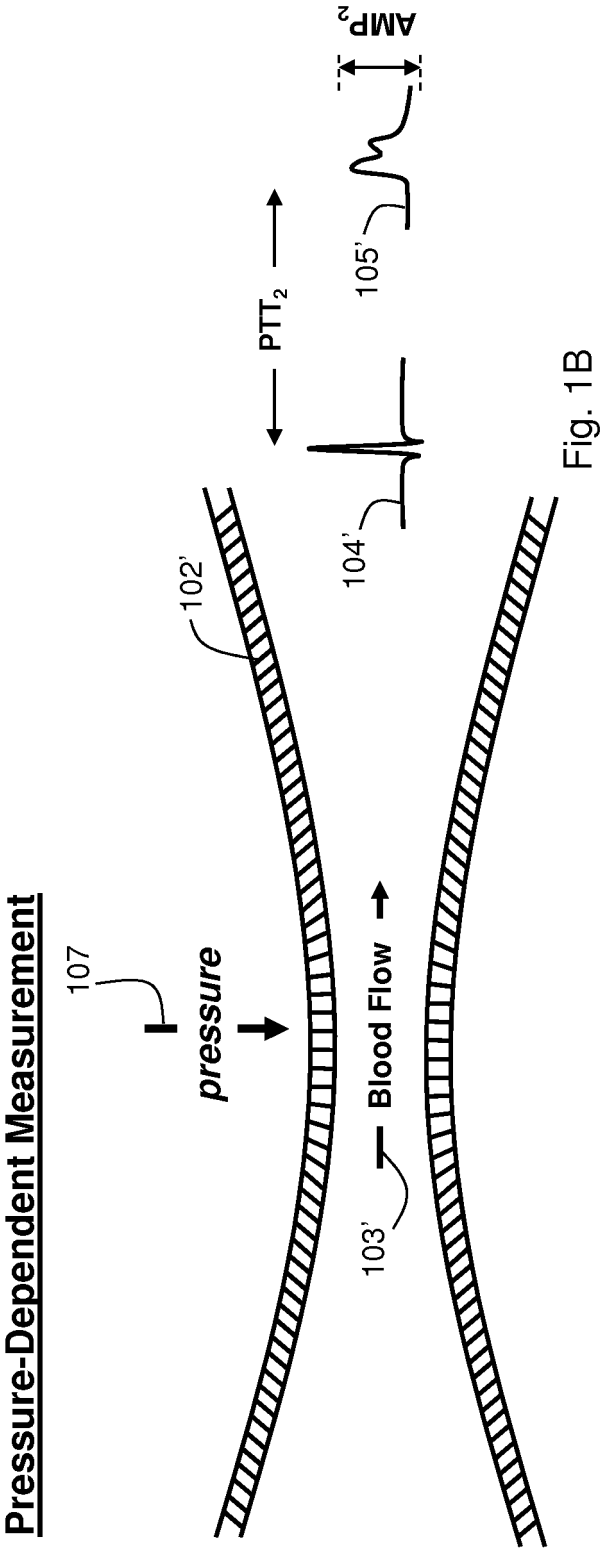

Pressure-Dependent Measurement
AMP2
PTT2
105'
104'
102'
107
pressure
Blood Flow
103'

Fig. 1B

Fig. 2A

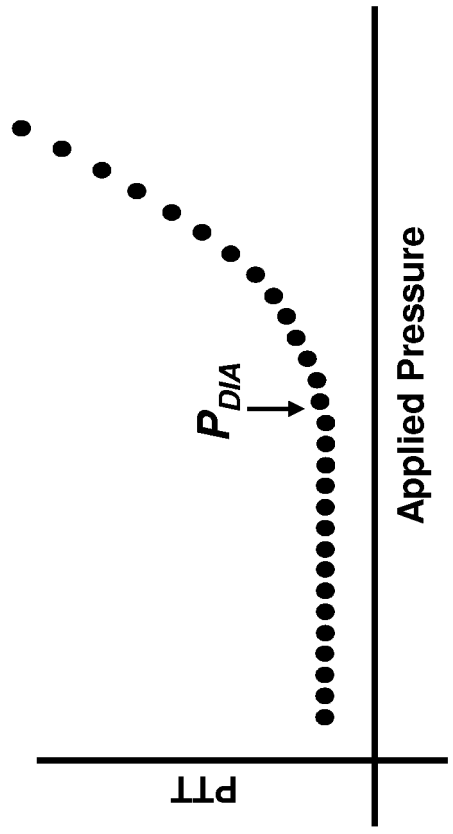

PTT
Applied Pressure
P_{DIA}

Fig. 2B

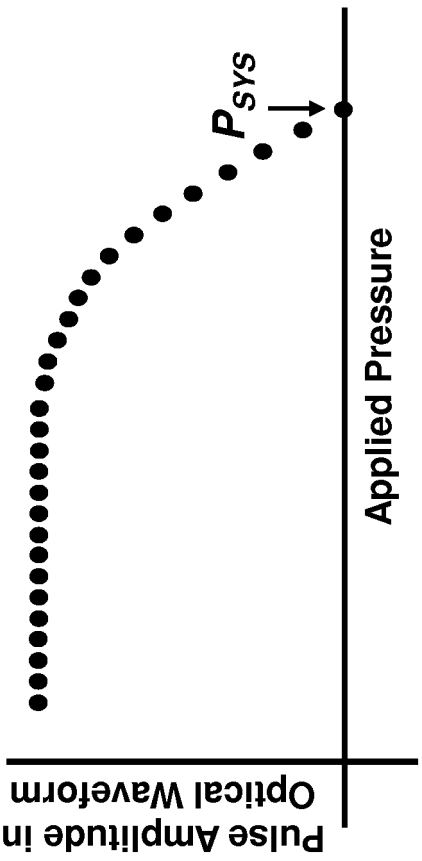

Pulse Amplitude in Optical Waveform
Applied Pressure
P_{SYS}

Fig. 3A

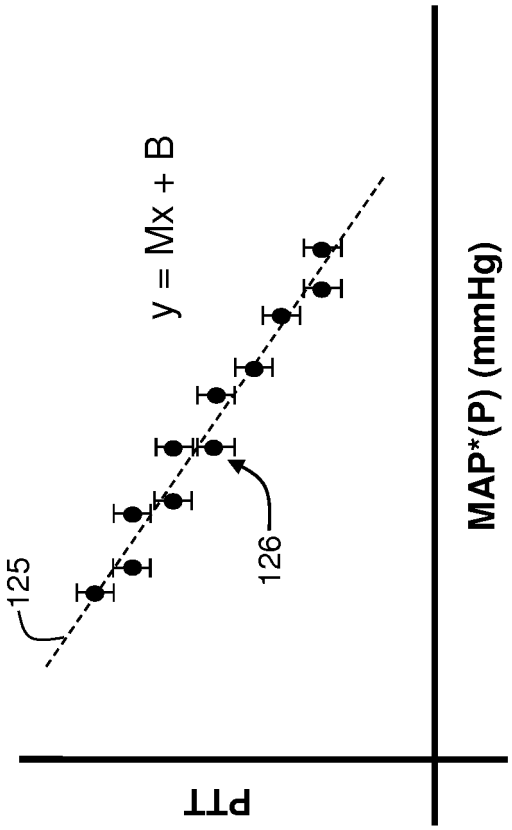
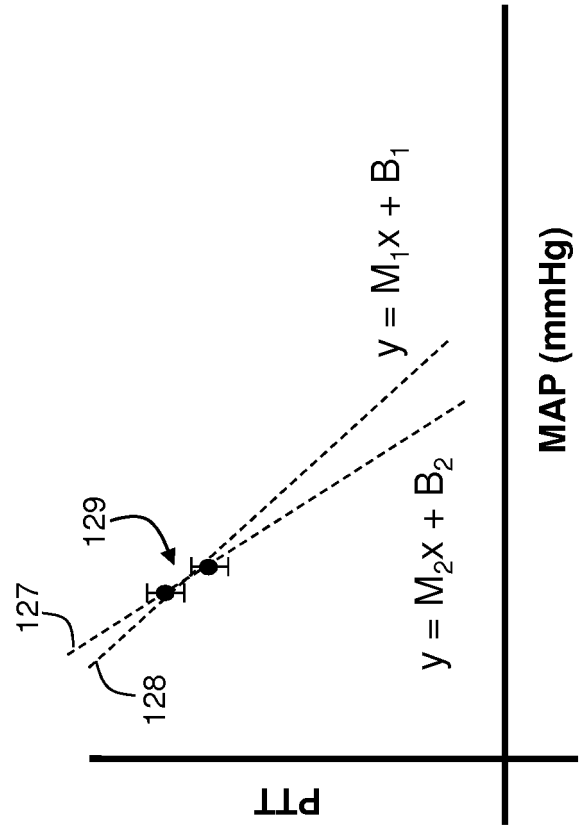

y = Mx + B
125
126
MAP*(P) (mmHg)
PTT

Fig. 3B


y = M1x + B1
y = M2x + B2
129
127
128
MAP (mmHg)
PTT

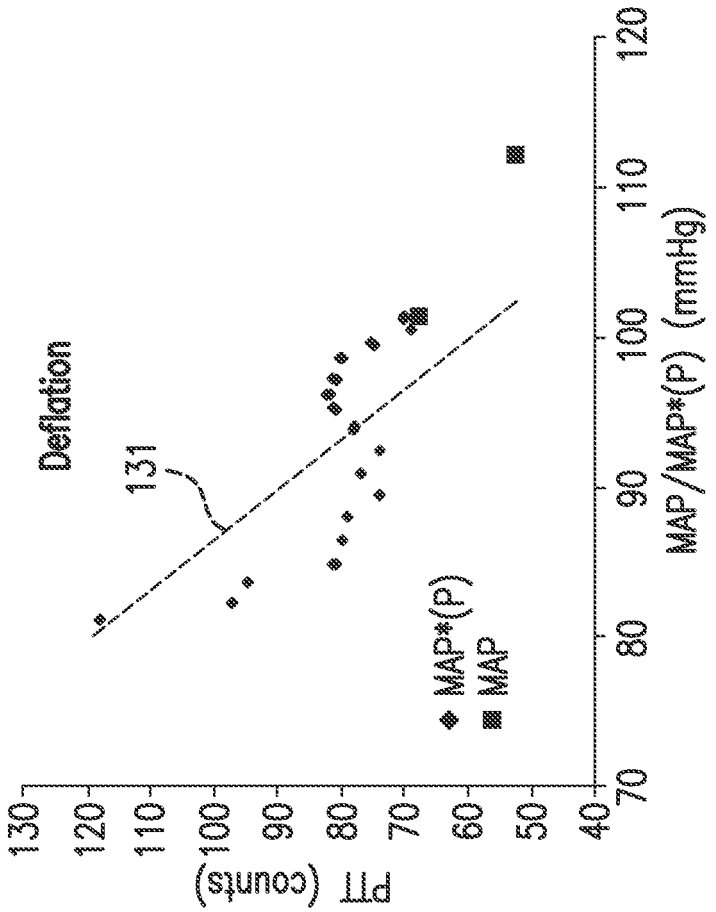

Deflation
131
MAP*(P)
MAP
PTT (counts)
MAP/MAP*(P) (mmHg)
130
120
110
100
90
80
70
60
50
40

FIG.4B

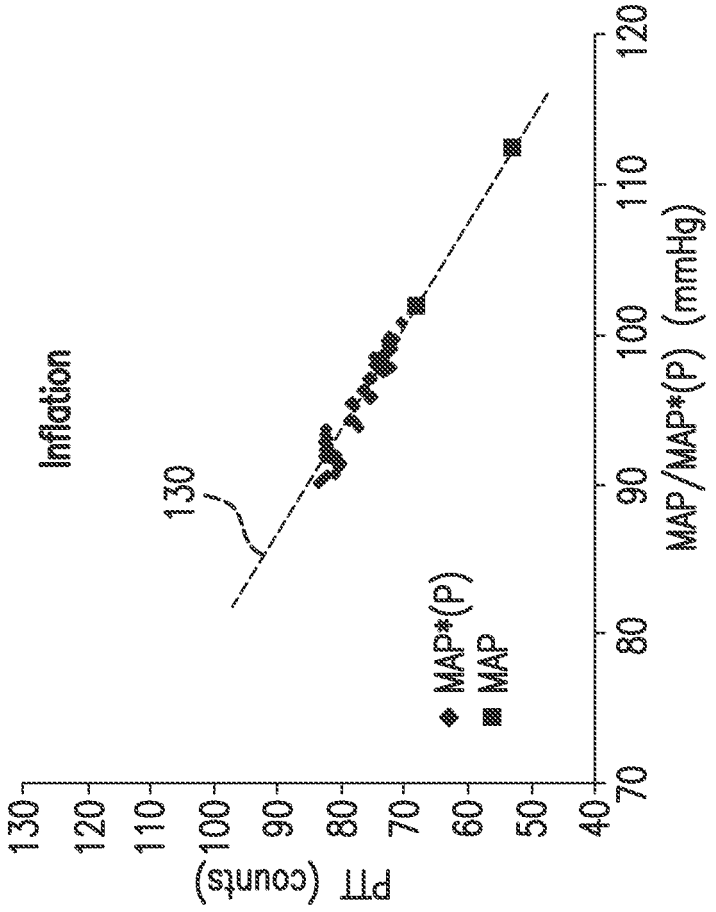
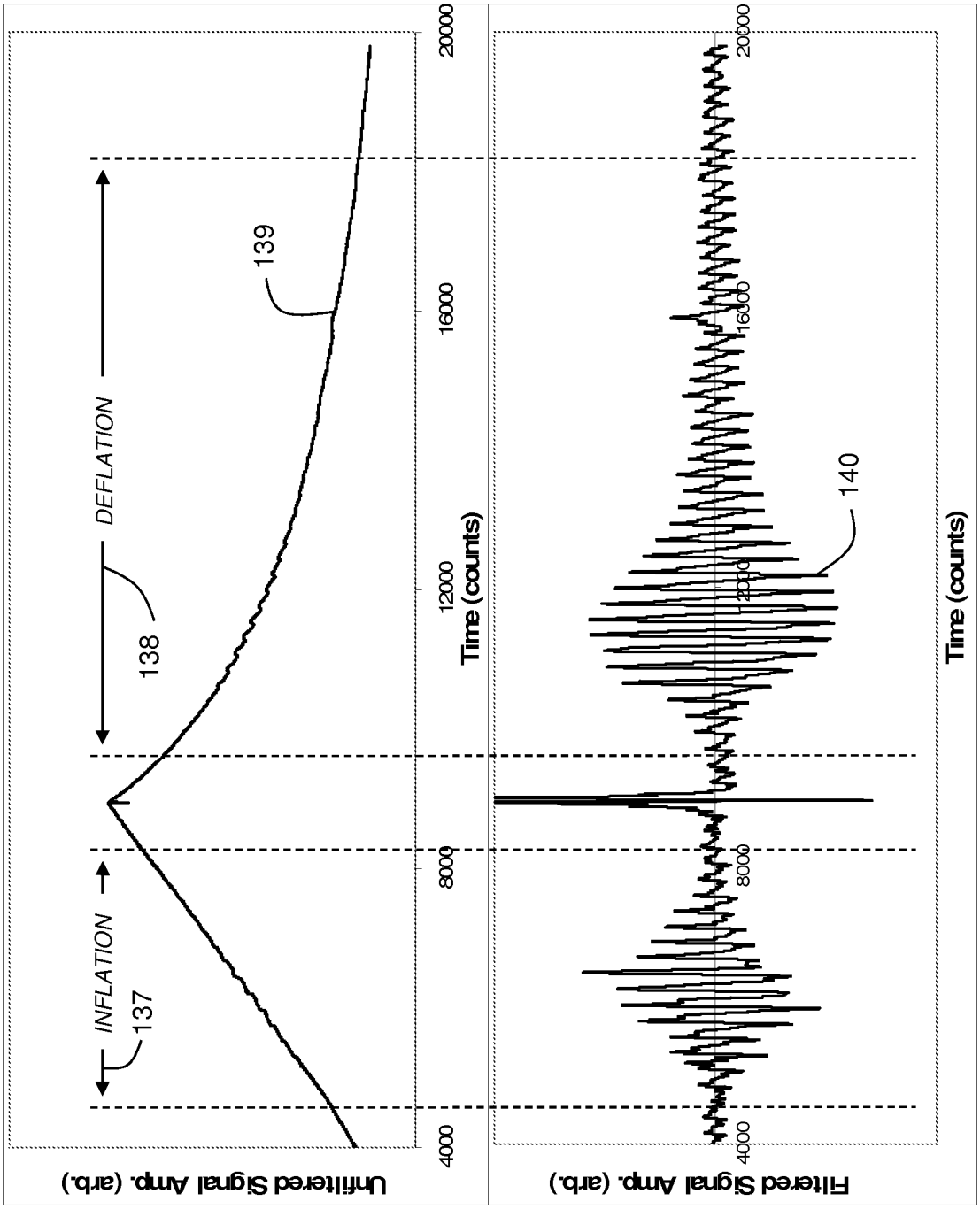

Inflation
130
MAP*(P)
MAP
PTT (counts)
MAP/MAP*(P) (mmHg)
130
120
110
100
90
80
70
60
50
40

FIG.4A

Fig. 5A

Fig. 5B


Unfiltered Signal Amp. (arb.)
Filtered Signal Amp. (arb.)
Time (counts)
4000
8000
12000
16000
20000
INFLATION
DEFLATION
137
138
139
140

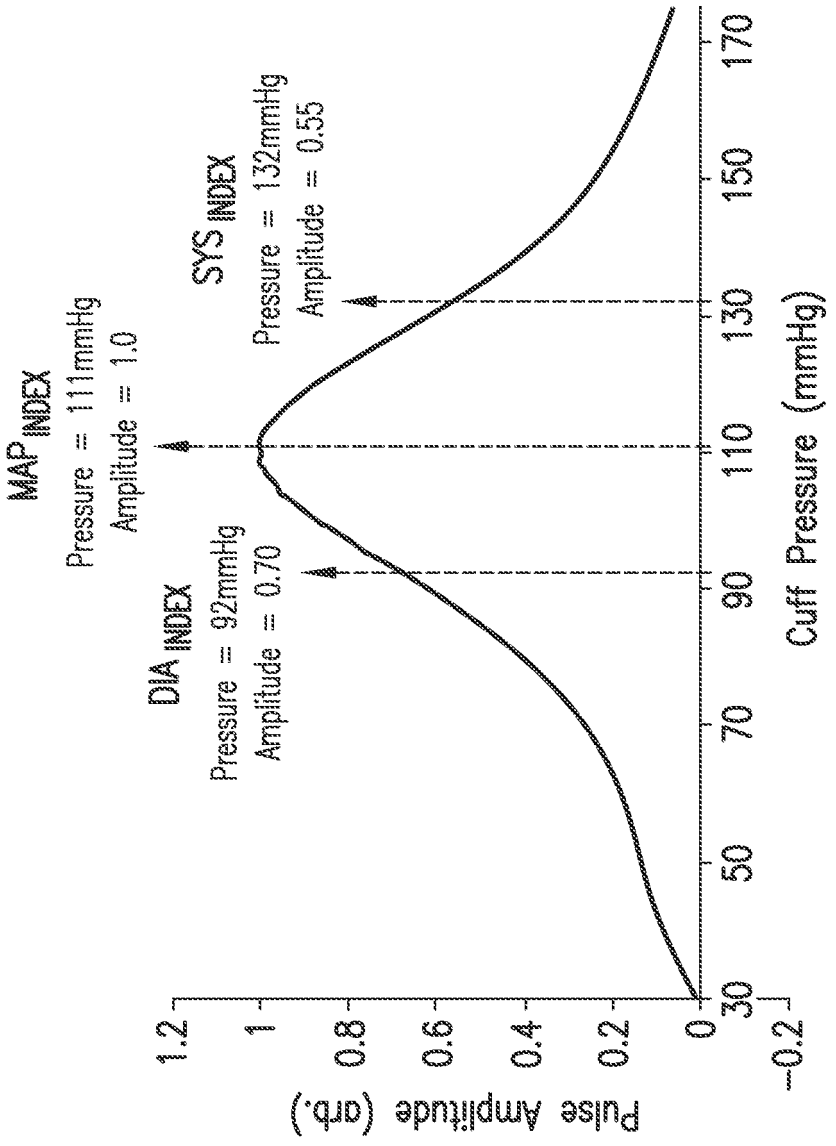

MAP INDEX
Pressure = 111mmHg
Amplitude = 1.0
SYS INDEX
Pressure = 132mmHg
Amplitude = 0.55
DIA INDEX
Pressure = 92mmHg
Amplitude = 0.70
Pulse Amplitude (arb.)
1.2
1
0.8
0.6
0.4
0.2
0
−0.2
30
50
70
90
110
130
150
170
Cuff Pressure (mmHg)

FIG.6

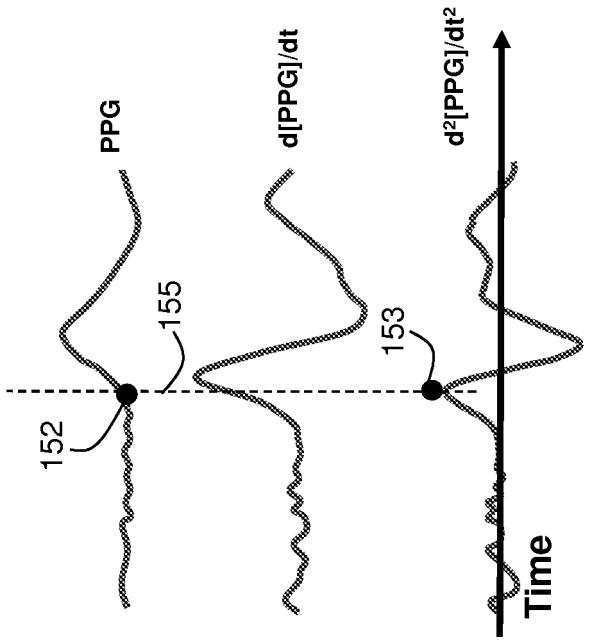


Fig. 7B

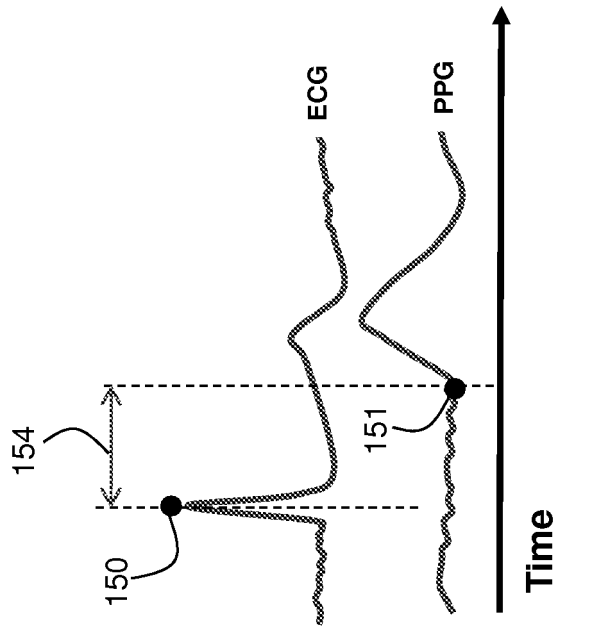


Fig. 7A

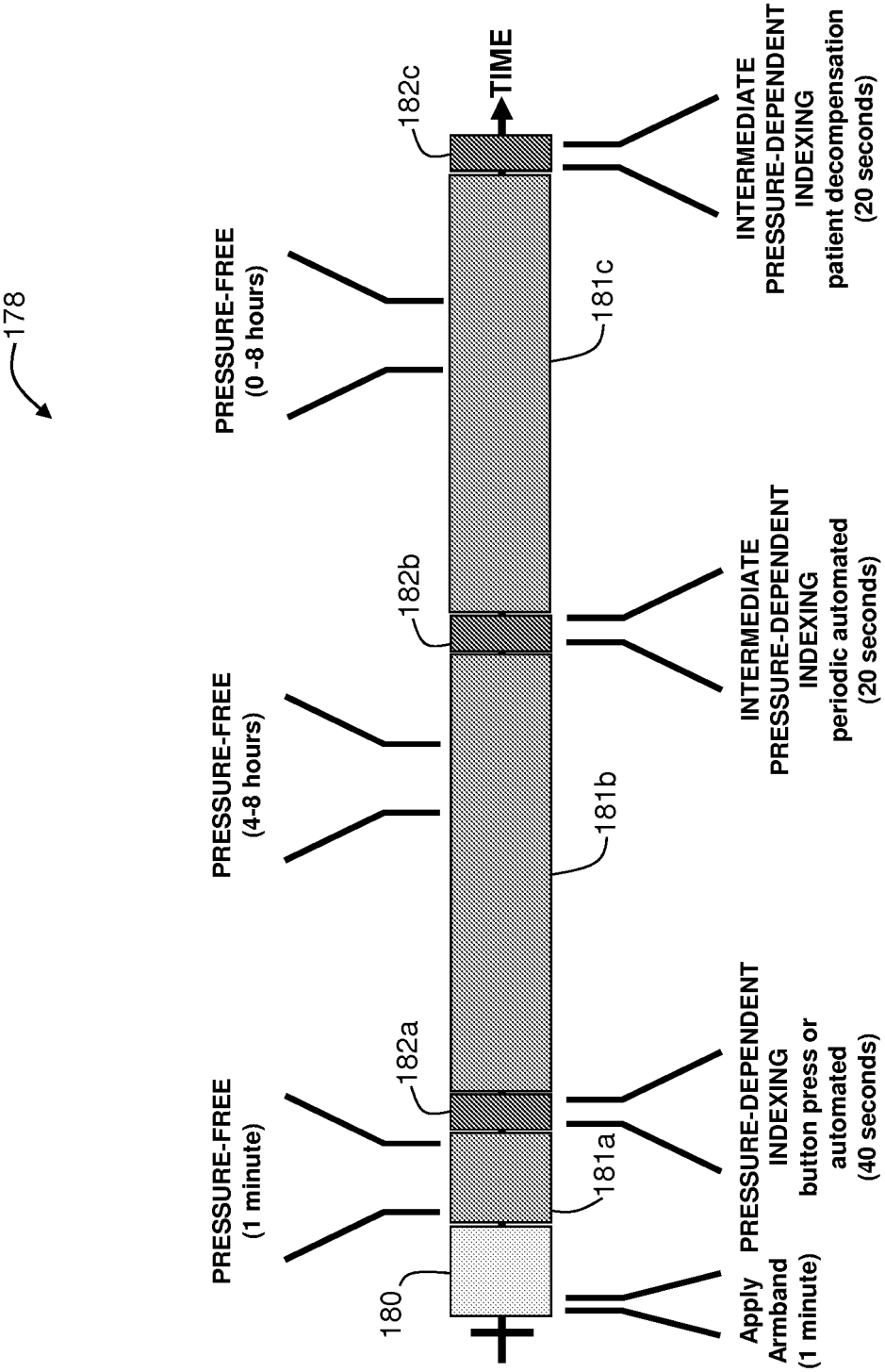

178
180
182a
182b
182c
181a
181b
181c
TIME
Apply Armband (1 minute)
PRESSURE-FREE (1 minute)
PRESSURE-DEPENDENT INDEXING button press or automated (40 seconds)
PRESSURE-FREE (4-8 hours)
INTERMEDIATE PRESSURE-DEPENDENT INDEXING periodic automated (20 seconds)
PRESSURE-FREE (0 -8 hours)
INTERMEDIATE PRESSURE-DEPENDENT INDEXING patient decompensation (20 seconds)

Fig. 8

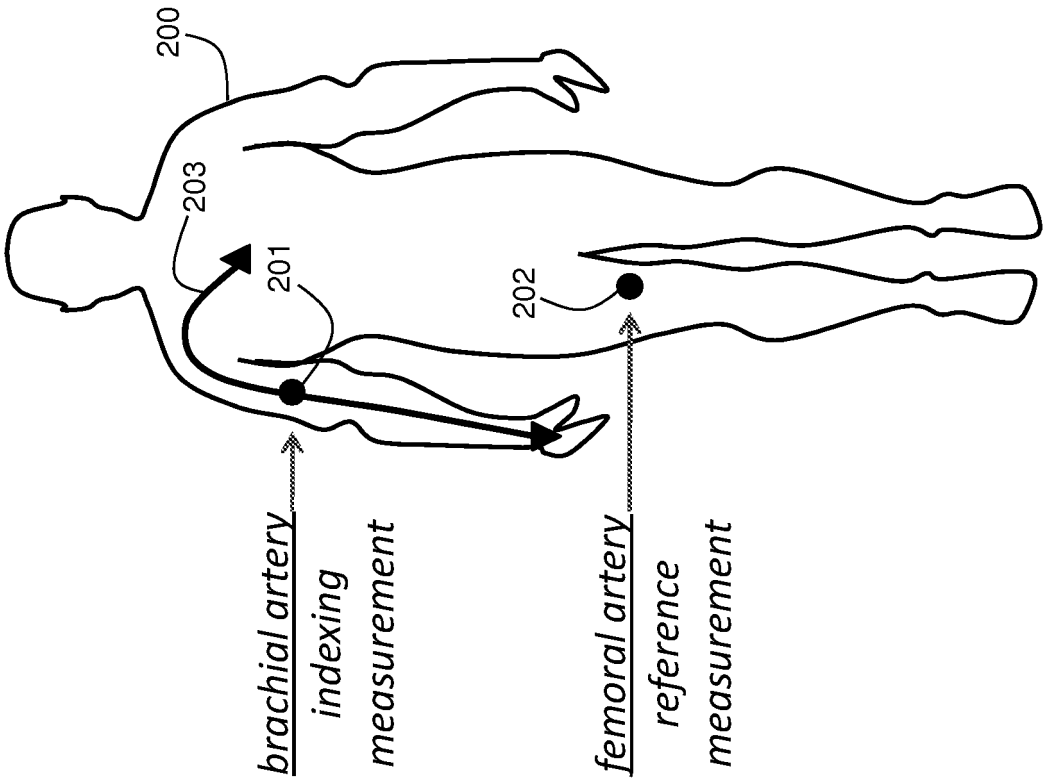

200
203
201
202
brachial artery
indexing
measurement
femoral artery
reference
measurement

Fig. 9

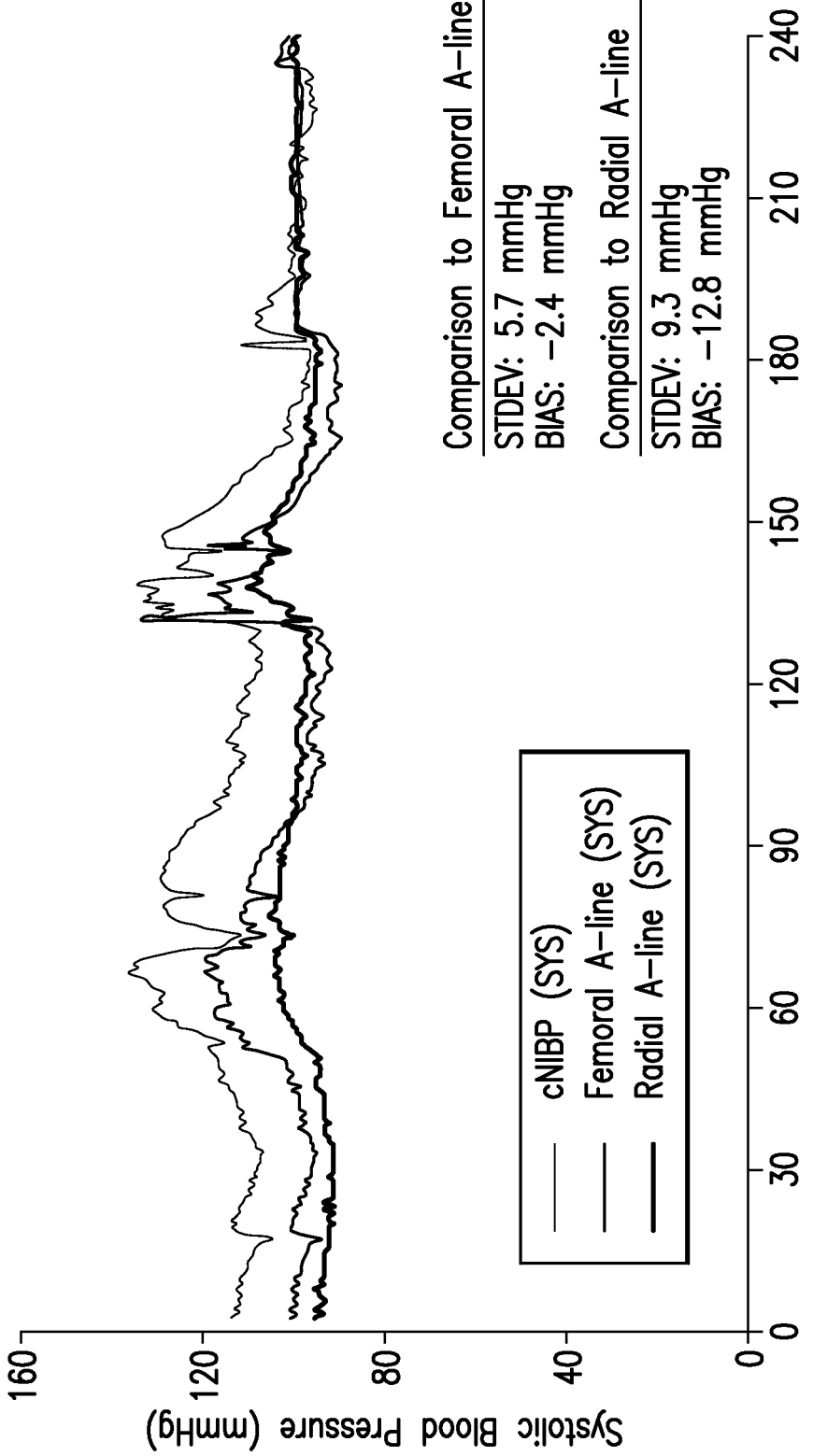

Systolic Blood Pressure (mmHg)
160
120
80
40
0
0
30
60
90
120
150
180
210
240
Time (minutes)
cNIBP (SYS)
Femoral A–line (SYS)
Radial A–line (SYS)
Comparison to Femoral A–line
STDEV: 5.7 mmHg
BIAS: –2.4 mmHg
Comparison to Radial A–line
STDEV: 9.3 mmHg
BIAS: –12.8 mmHg

FIG.1O

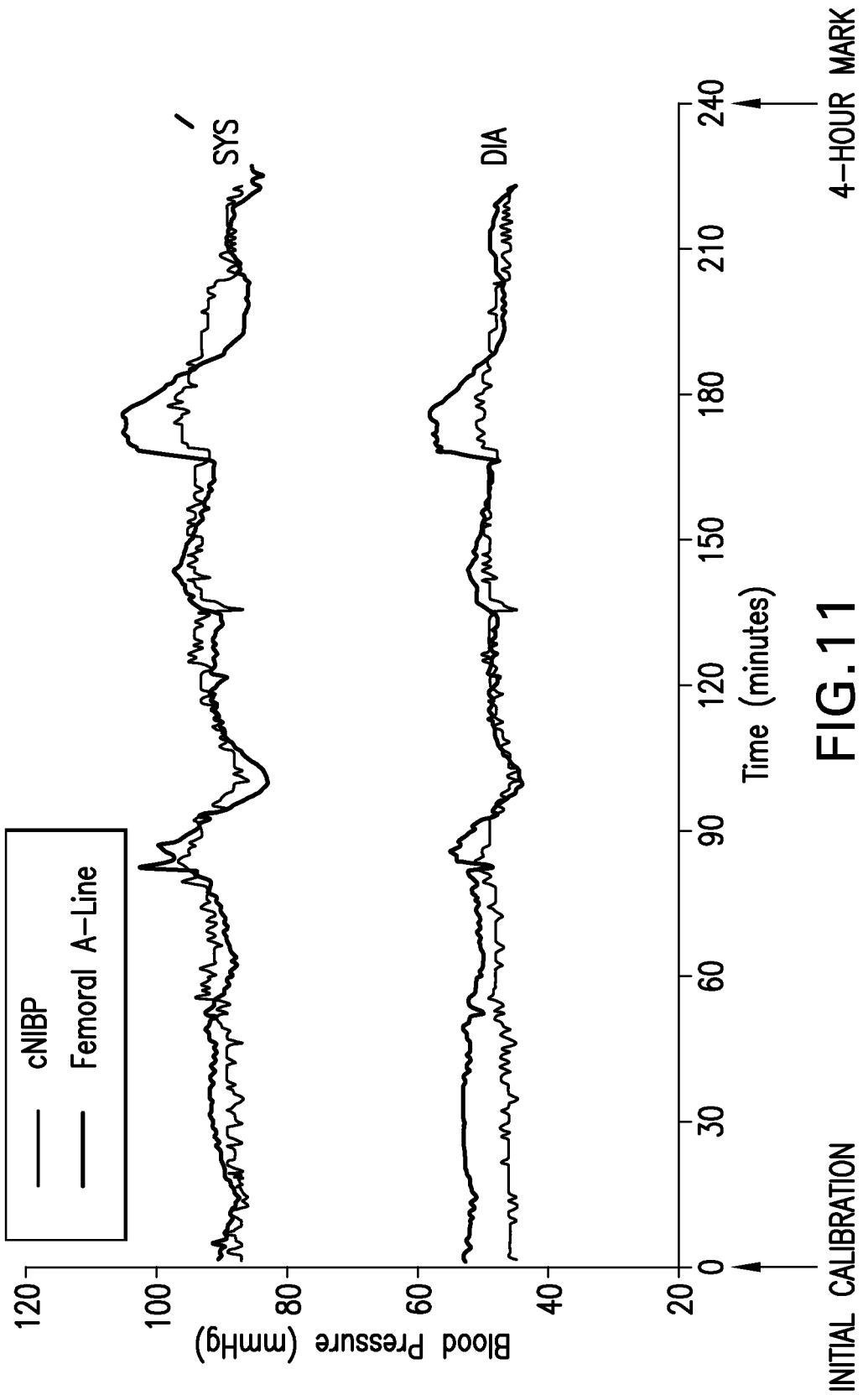

cNIBP
Femoral A-Line
SYS
DIA
Blood Pressure (mmHg)
120
100
80
60
40
20
0
30
60
90
120
150
180
210
240
Time (minutes)
INITIAL CALIBRATION
4-HOUR MARK

FIG. 11

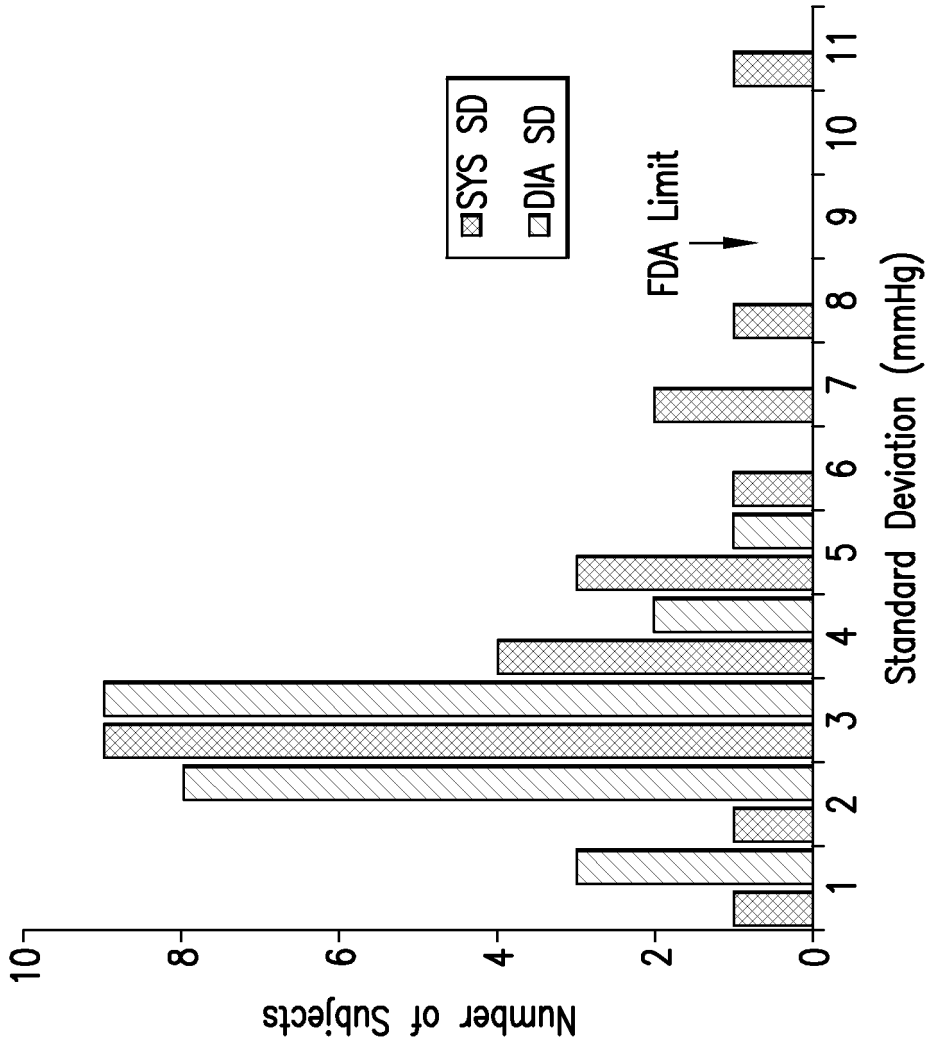

Number of Subjects
0
2
4
6
8
10
1
2
3
4
5
6
7
8
9
10
11
Standard Deviation (mmHg)
FDA Limit
SYS SD
DIA SD

FIG.12

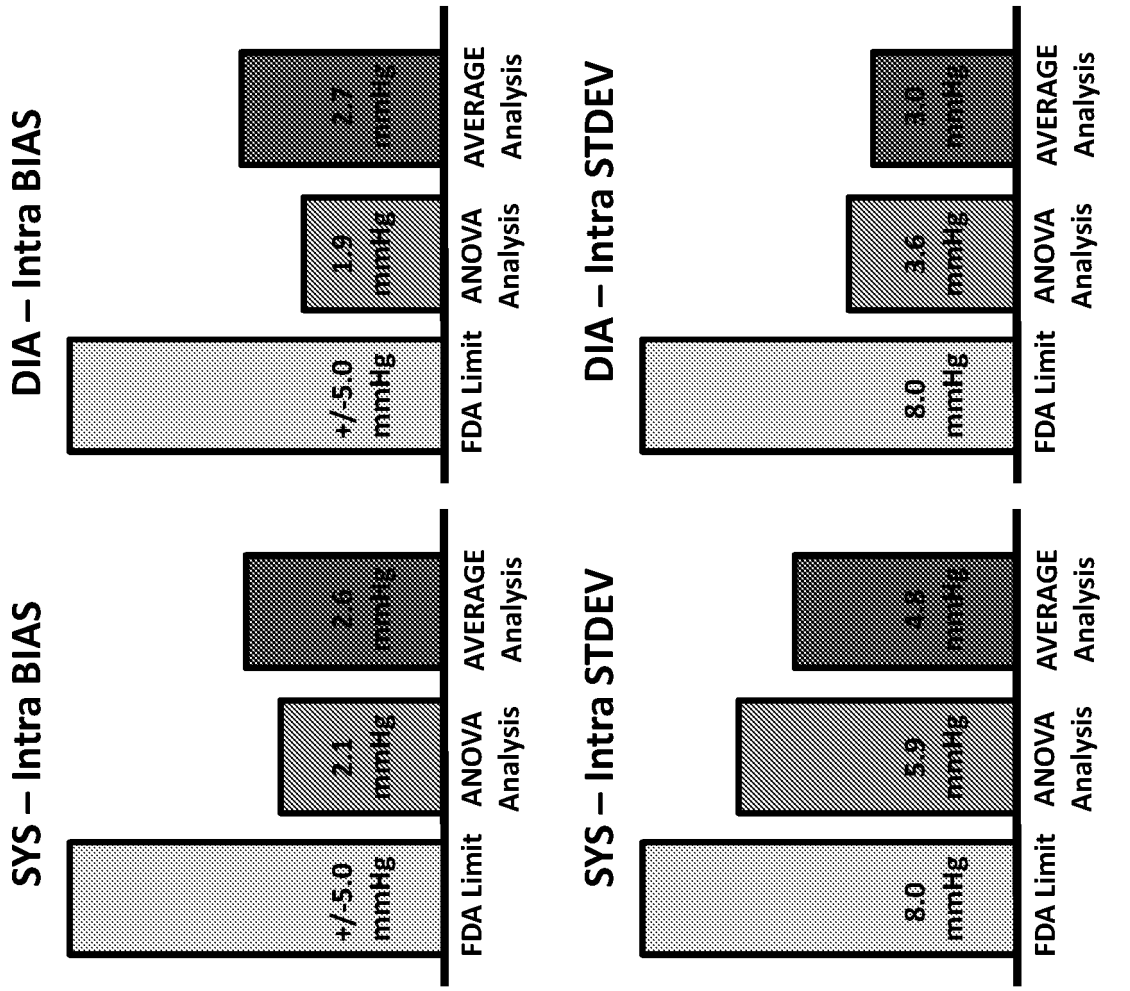

SYS – Intra BIAS
+/-5.0 mmHg
2.1 mmHg
2.6 mmHg
FDA Limit
ANOVA Analysis
AVERAGE Analysis
DIA – Intra BIAS
+/-5.0 mmHg
1.9 mmHg
2.7 mmHg
FDA Limit
ANOVA Analysis
AVERAGE Analysis
SYS – Intra STDEV
8.0 mmHg
5.9 mmHg
4.8 mmHg
FDA Limit
ANOVA Analysis
AVERAGE Analysis
DIA – Intra STDEV
8.0 mmHg
3.6 mmHg
3.0 mmHg
FDA Limit
ANOVA Analysis
AVERAGE Analysis

Fig. 13

Calibration Period	SYS DRIFT	DIA DRIFT
4 Hours *(N = 22)*	-0.07 mmHg/hour P = 0.03	-0.01 mmHg/hour not significant
8 Hours *(N = 6)*	-0.4 mmHg/hour P = 0.004	-0.3 mmHg/hour P = 0.0002

Fig. 14

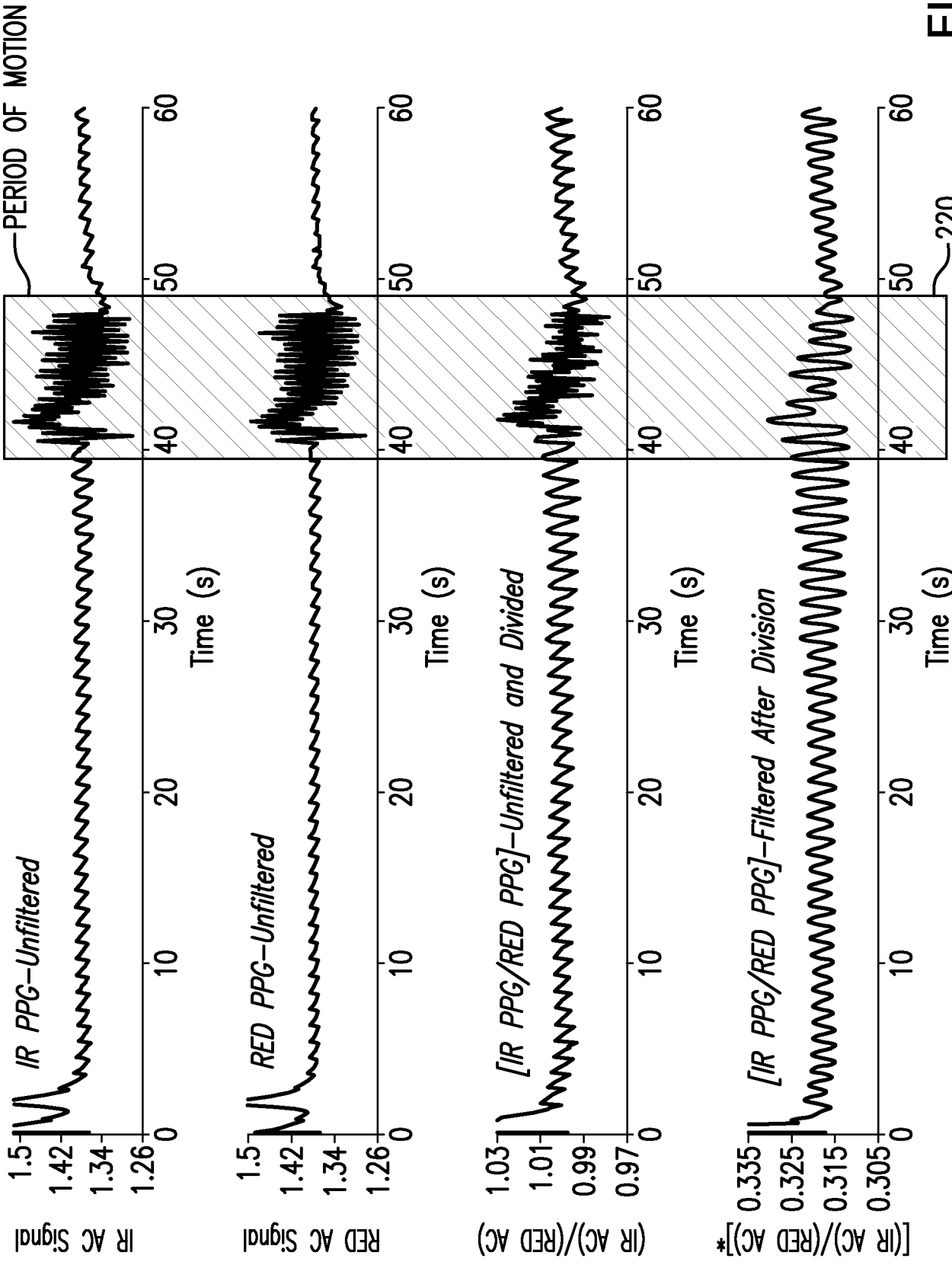

PERIOD OF MOTION
220
IR AC Signal
RED AC Signal
(IR AC)/(RED AC)
[(IR AC)/(RED AC)]*
IR PPG–Unfiltered
RED PPG–Unfiltered
[IR PPG/RED PPG]–Unfiltered and Divided
[IR PPG/RED PPG]–Filtered After Division
Time (s)
1.5
1.42
1.34
1.26
1.03
1.01
0.99
0.97
0.335
0.325
0.315
0.305
0
10
20
30
40
50
60

FIG. 15

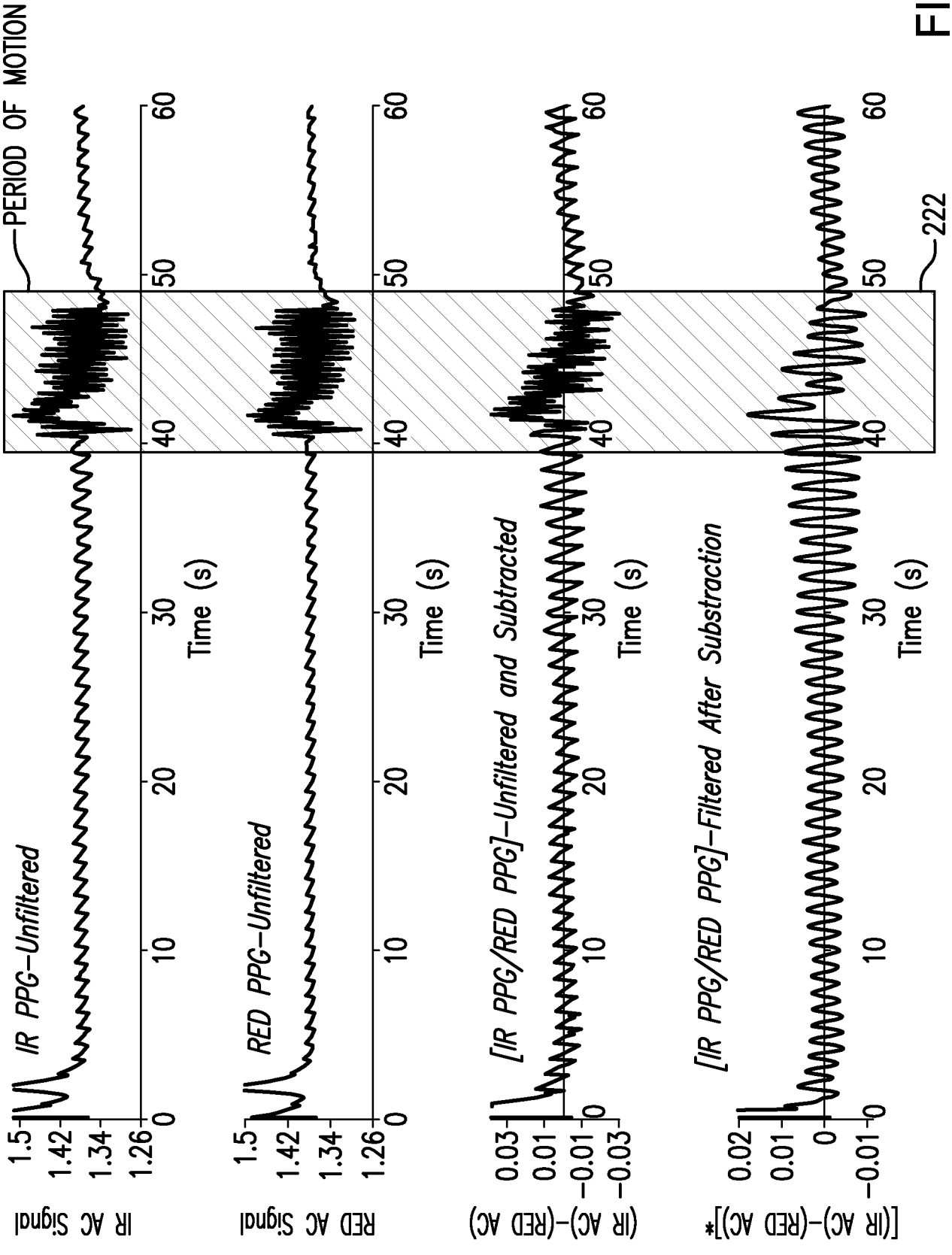

PERIOD OF MOTION
222
IR PPG–Unfiltered
RED PPG–Unfiltered
[IR PPG/RED PPG]–Unfiltered and Subtracted
[IR PPG/RED PPG]–Filtered After Substraction
IR AC Signal
RED AC Signal
(IR AC)–(RED AC)
[(IR AC)–(RED AC)]*
Time (s)
1.5
1.42
1.34
1.26
0.03
0.01
−0.01
−0.03
0.02
0
0
10
20
30
40
50
60

FIG.16

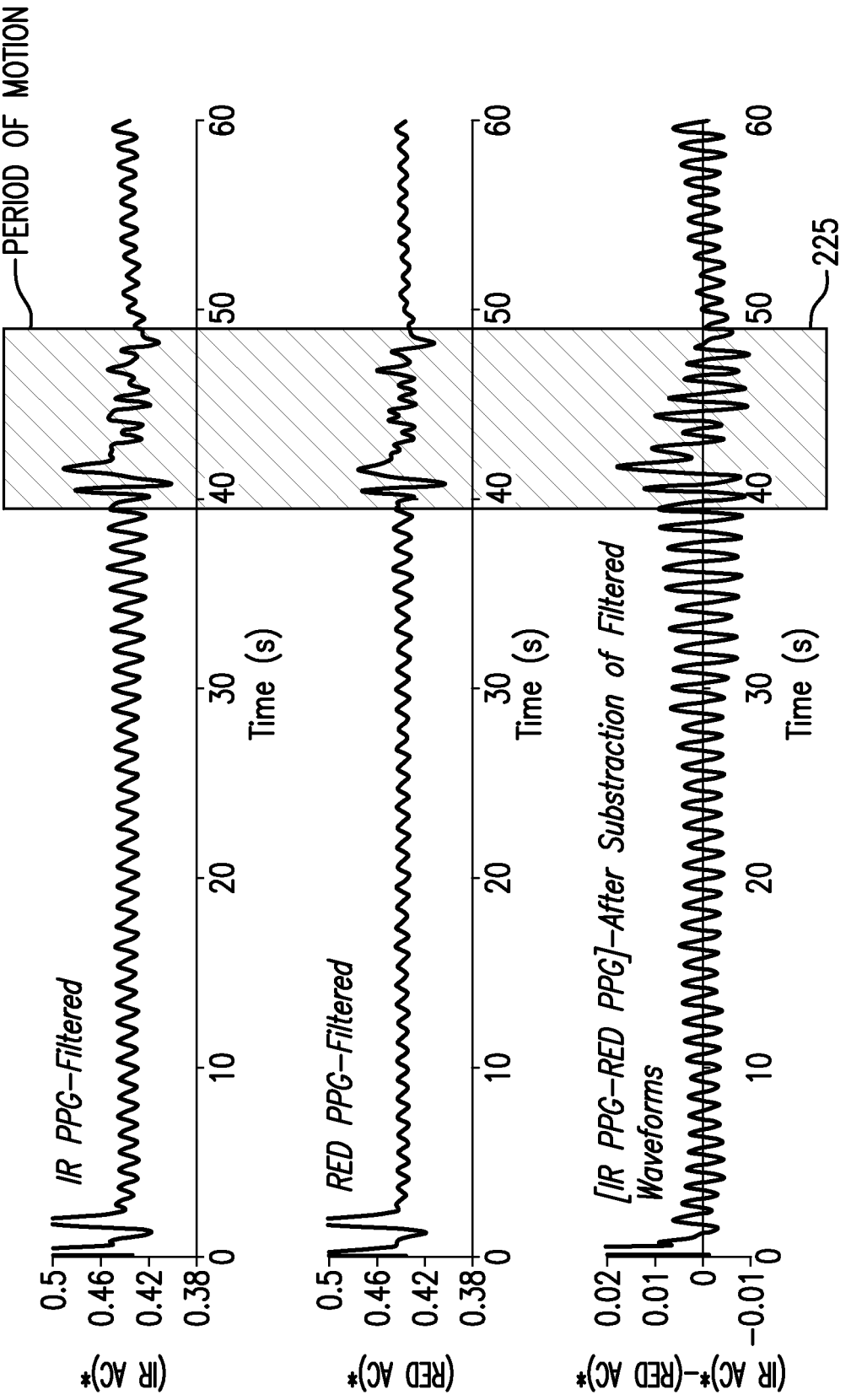

PERIOD OF MOTION
IR PPG–Filtered
RED PPG–Filtered
[IR PPG–RED PPG]–After Substraction of Filtered Waveforms
(IR AC)*
(RED AC)*
(IR AC)*–(RED AC)*
Time (s)
0.5
0.46
0.42
0.38
0.02
0.01
0
−0.01
0
10
20
30
40
50
60
225

FIG. 17

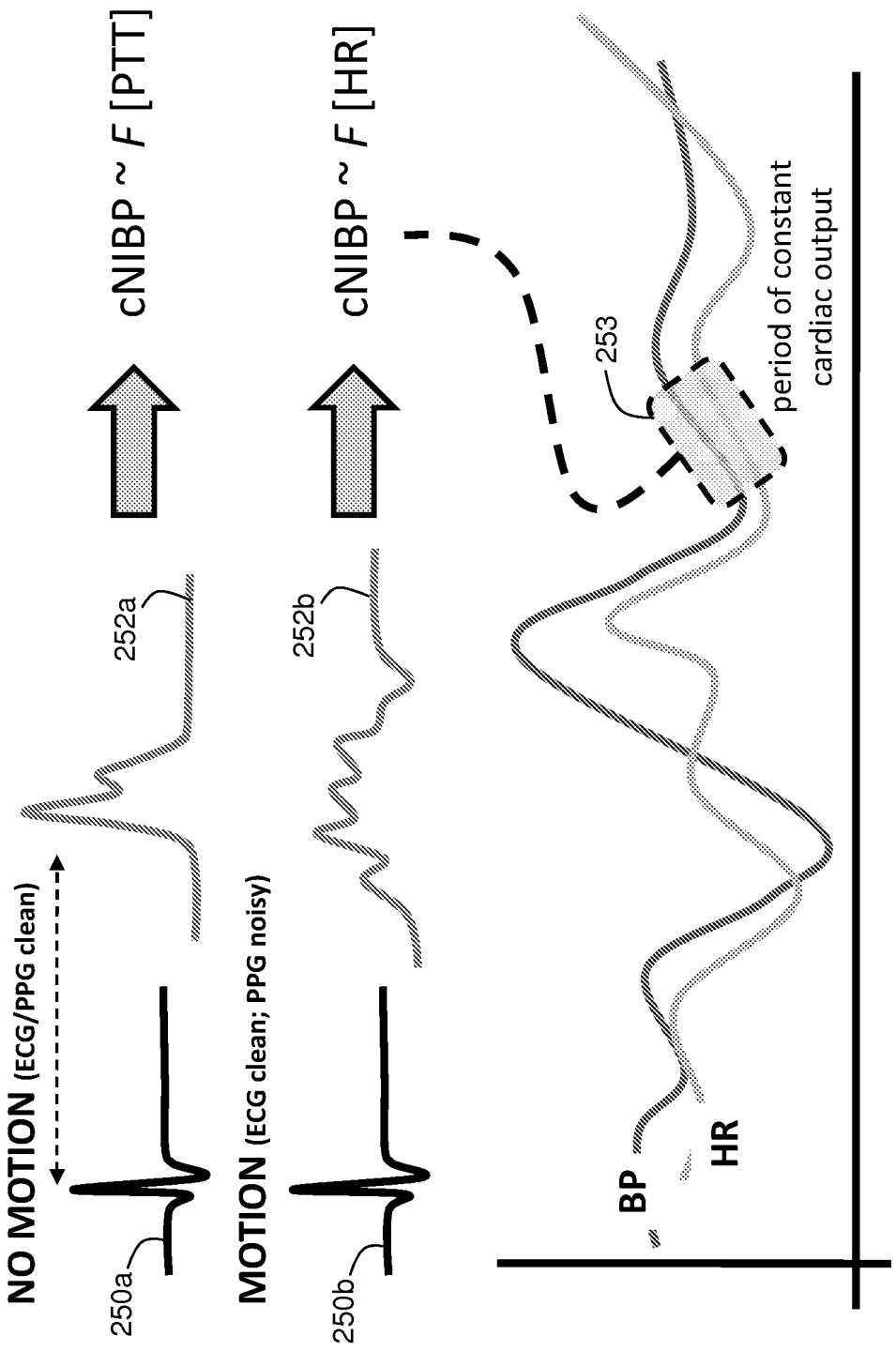

NO MOTION (ECG/PPG clean)
MOTION (ECG clean; PPG noisy)
250a
250b
252a
252b
cNIBP ~ F [PTT]
cNIBP ~ F [HR]
253
period of constant cardiac output
BP
HR

Fig. 18

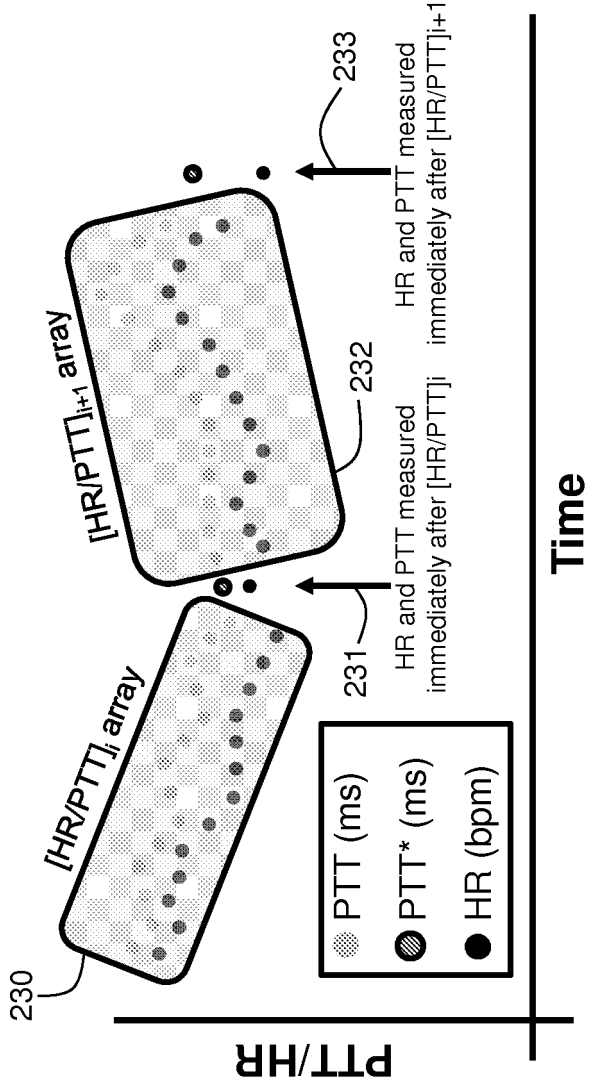

PTT/HR
Time
PTT (ms)
PTT* (ms)
HR (bpm)
230
231
HR and PTT measured immediately after [HR/PTT]i
232
HR and PTT measured immediately after [HR/PTT]i+1
233
[HR/PTT]i array
[HR/PTT]i+1 array

Fig. 19

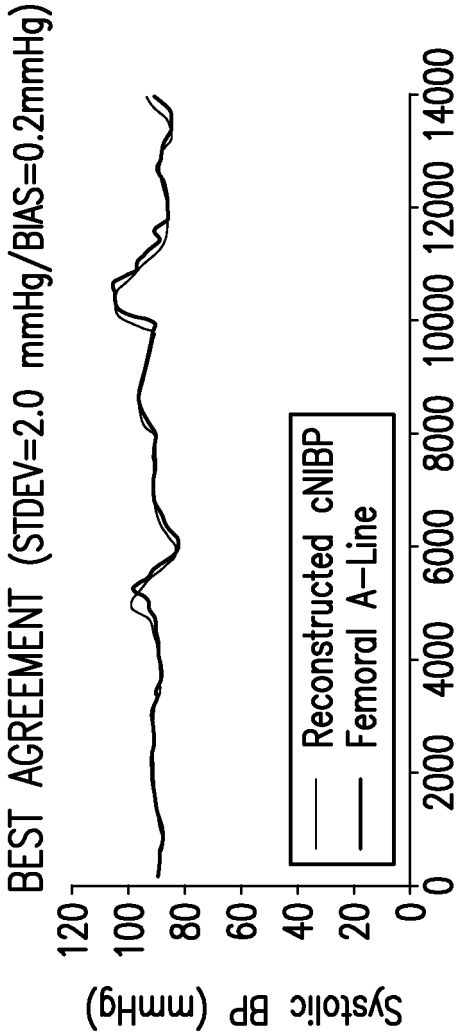


FIG.20A

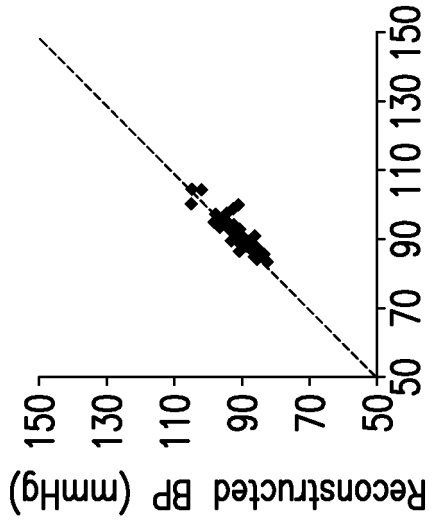


FIG.20B

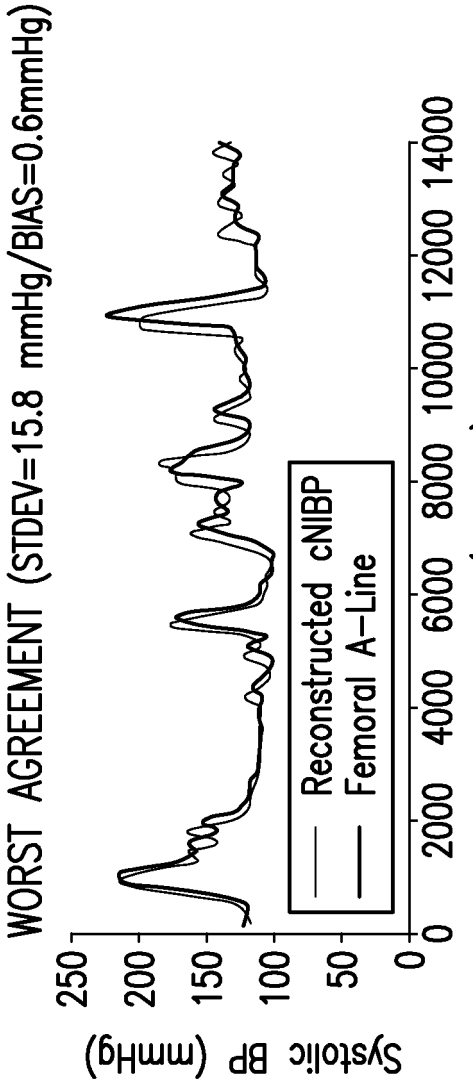


FIG.21A

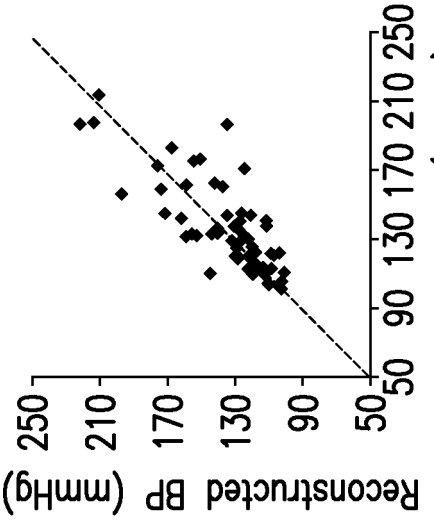


FIG.21B

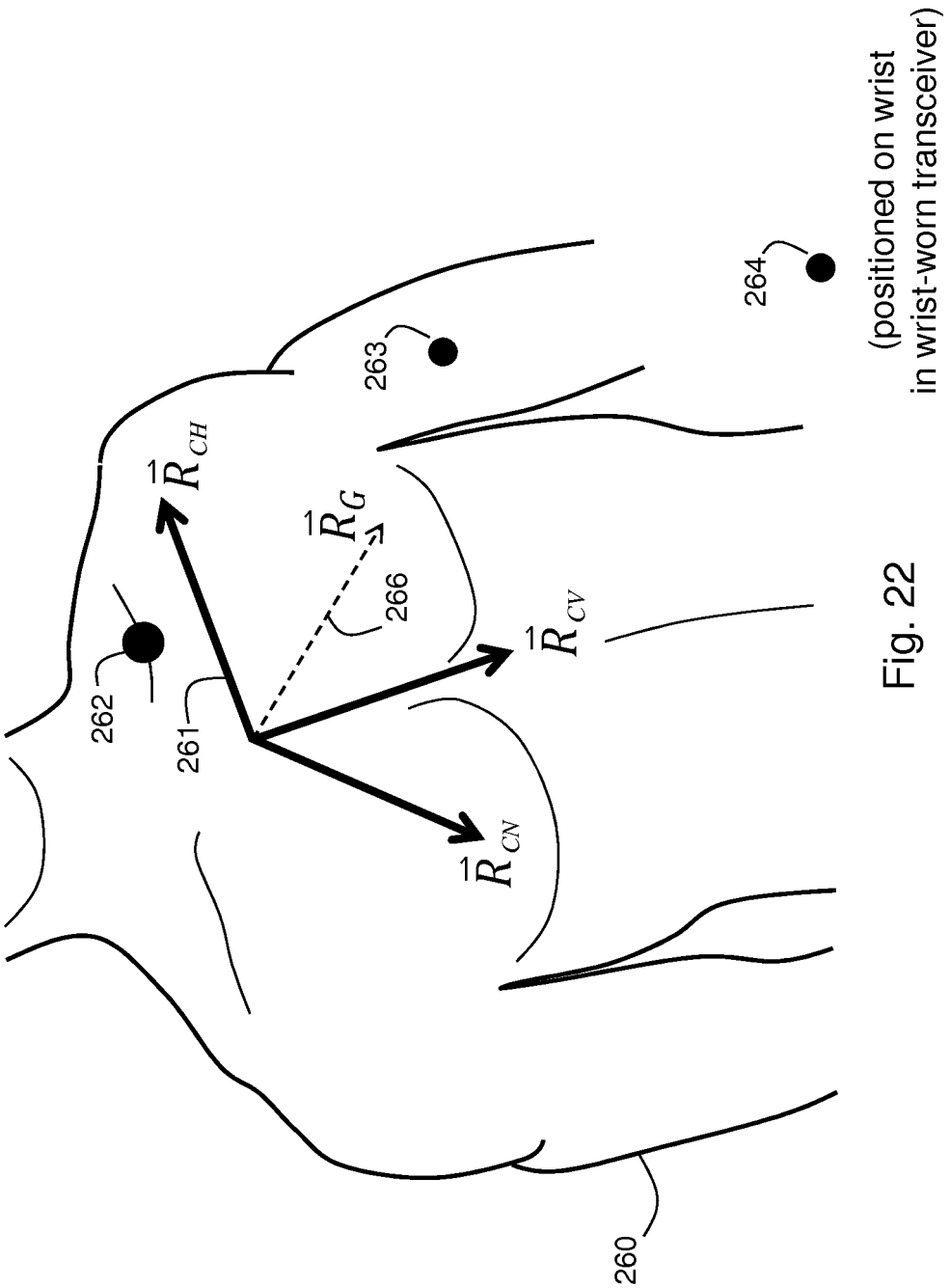

264
(positioned on wrist
in wrist-worn transceiver)
263
$^1\vec{R}_{CH}$
$^1\vec{R}_G$
266
$^1\vec{R}_{CV}$
262
261
$^1\vec{R}_{CN}$
260

Fig. 22

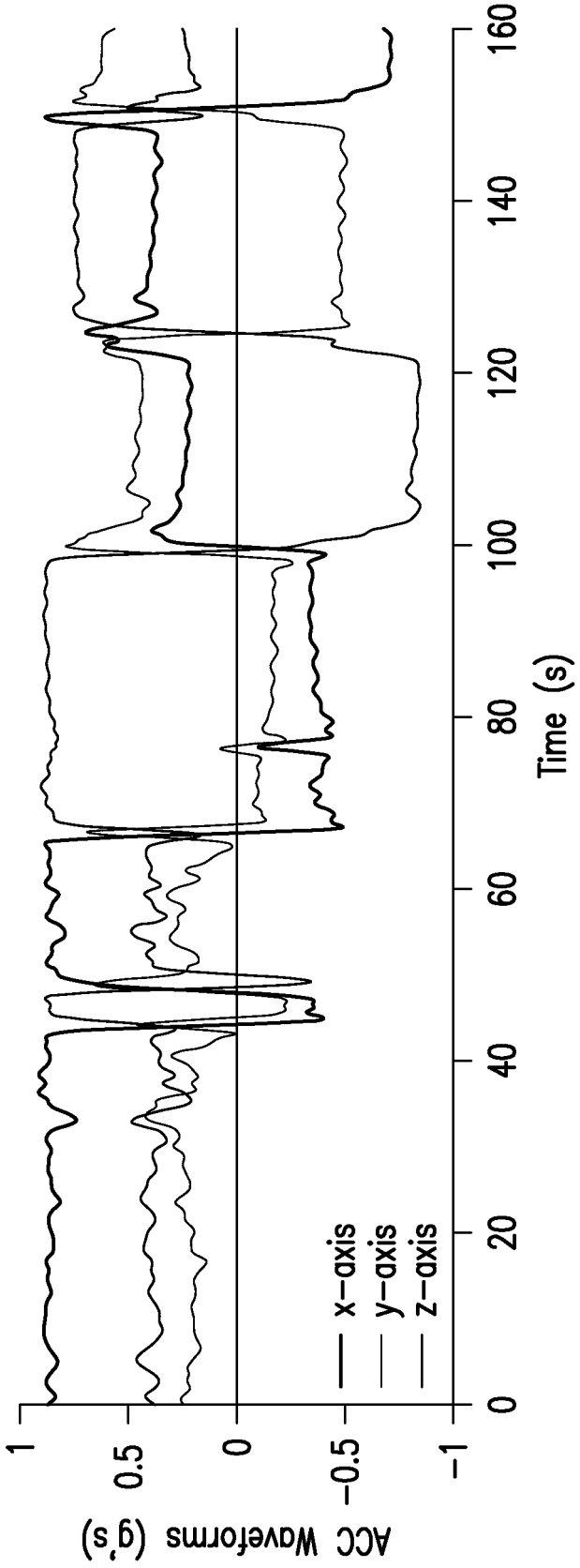


FIG.23A

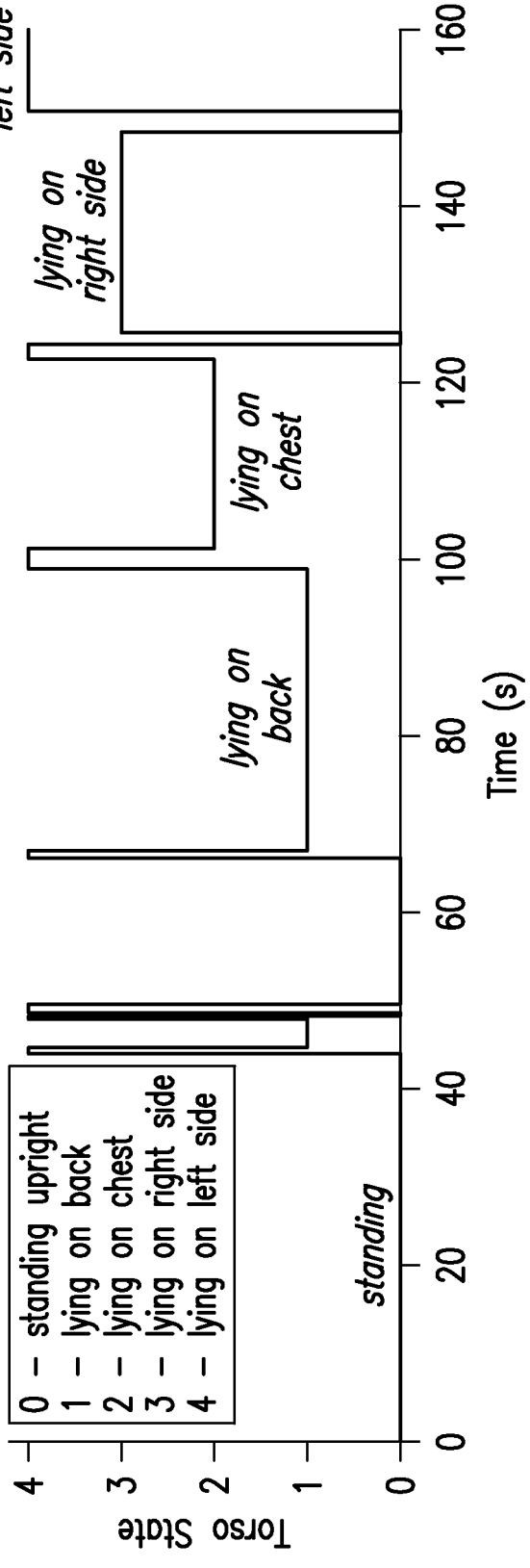


FIG.23B

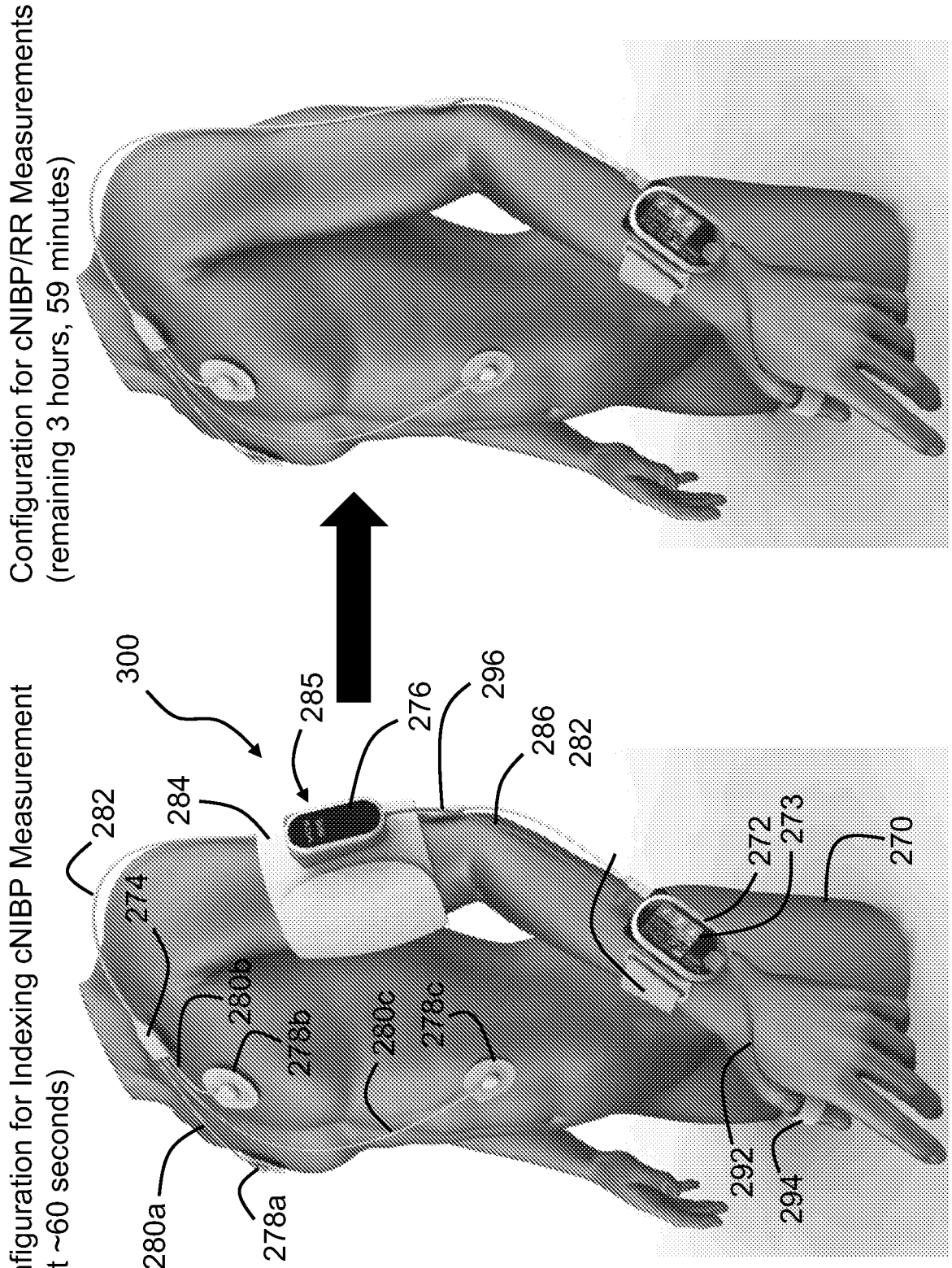


FIG.24A

FIG.24B

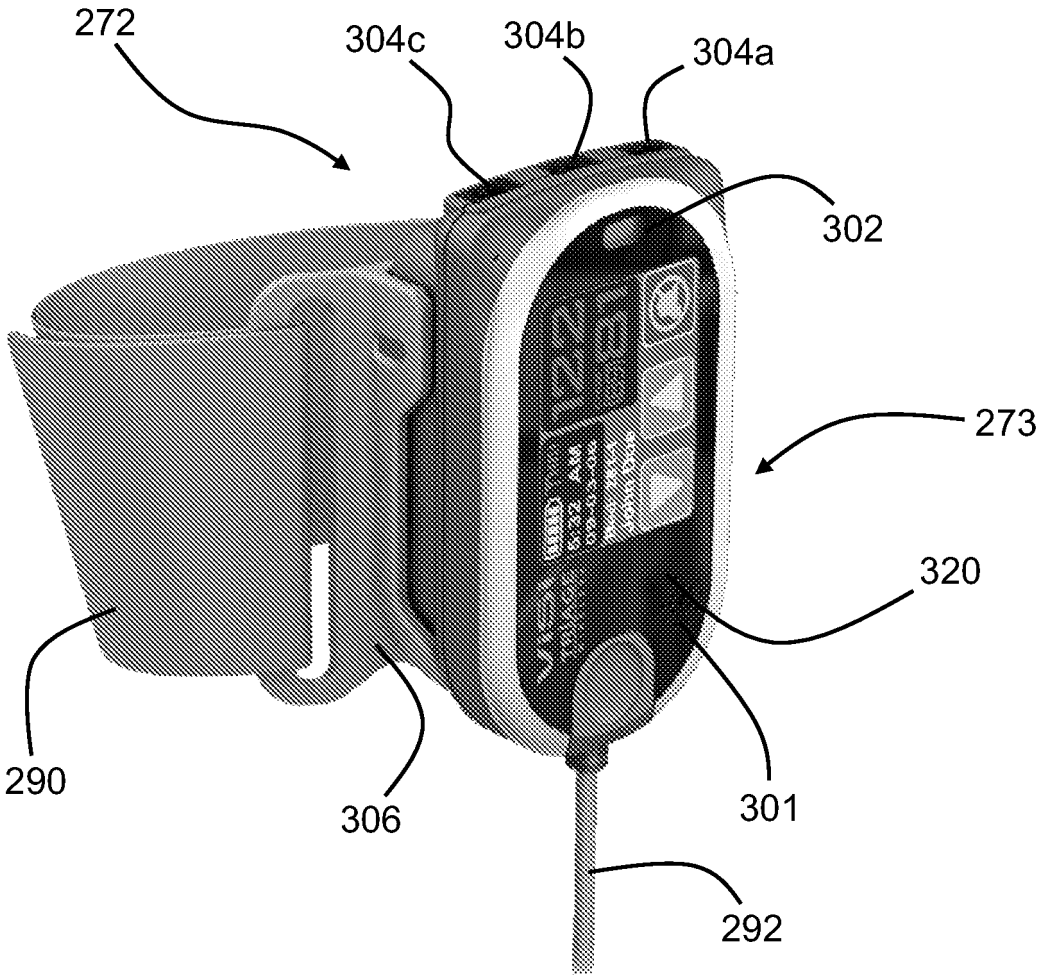


FIG.25

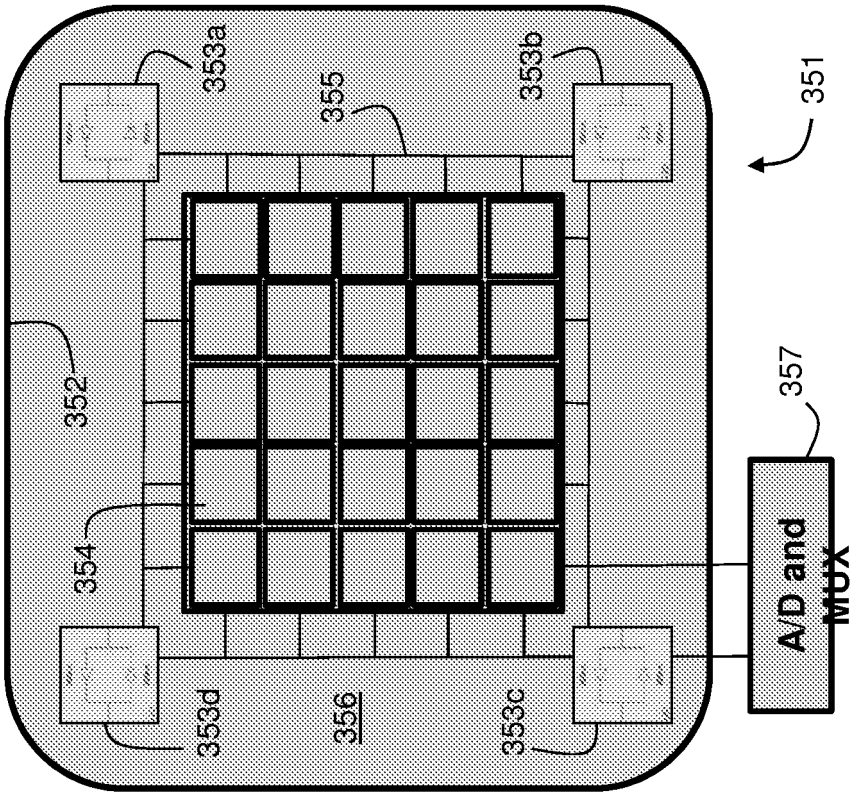

353a
355
353b
351
352
357
354
A/D and MUX
353d
356
353c

Fig. 27

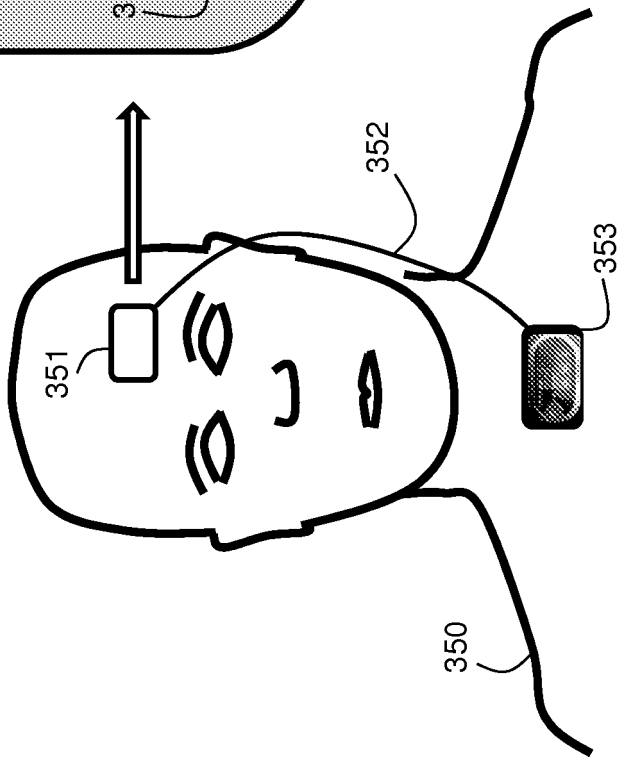

352
353
351
350

Fig. 26

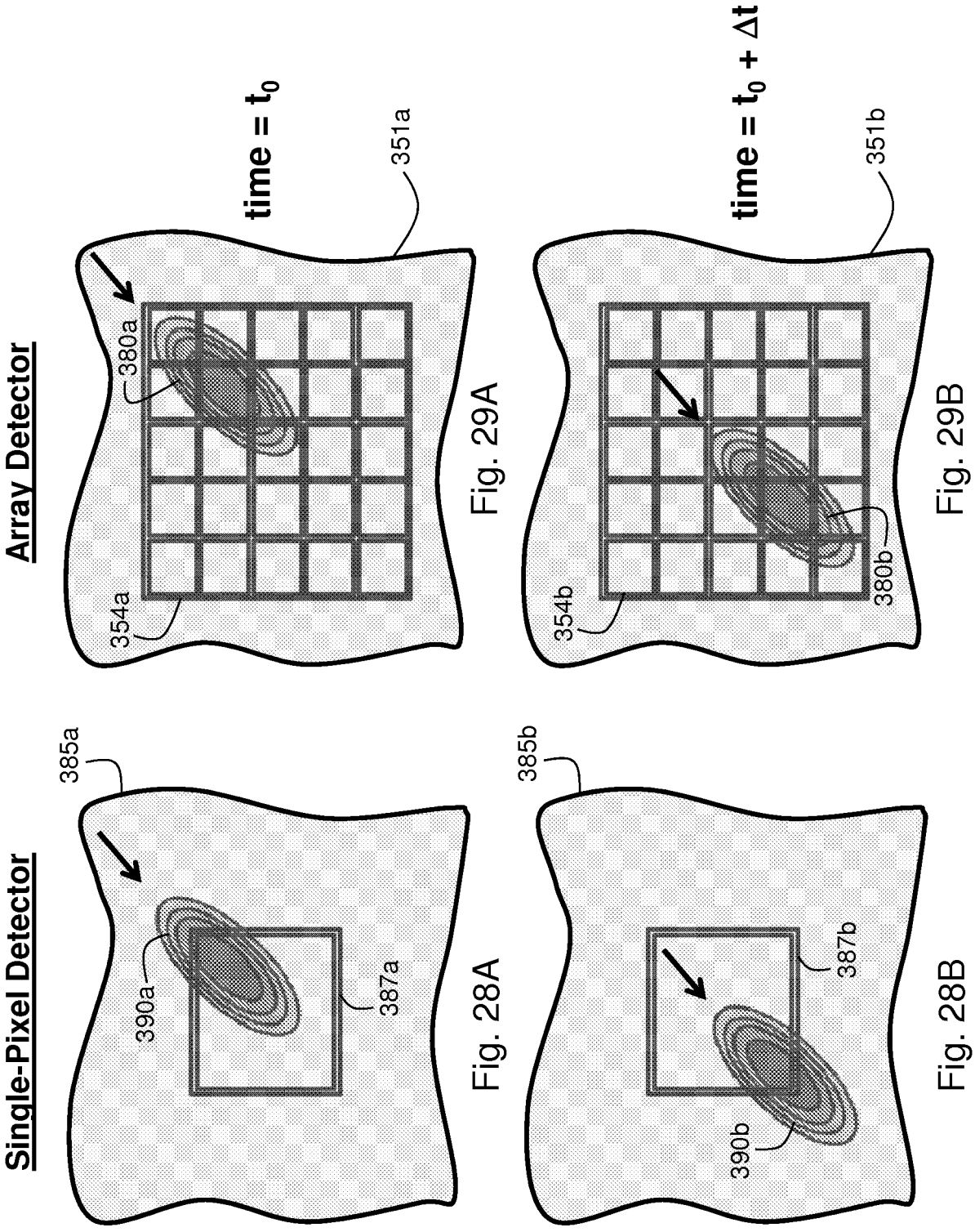


Fig. 28A Fig. 28B Fig. 29A Fig. 29B

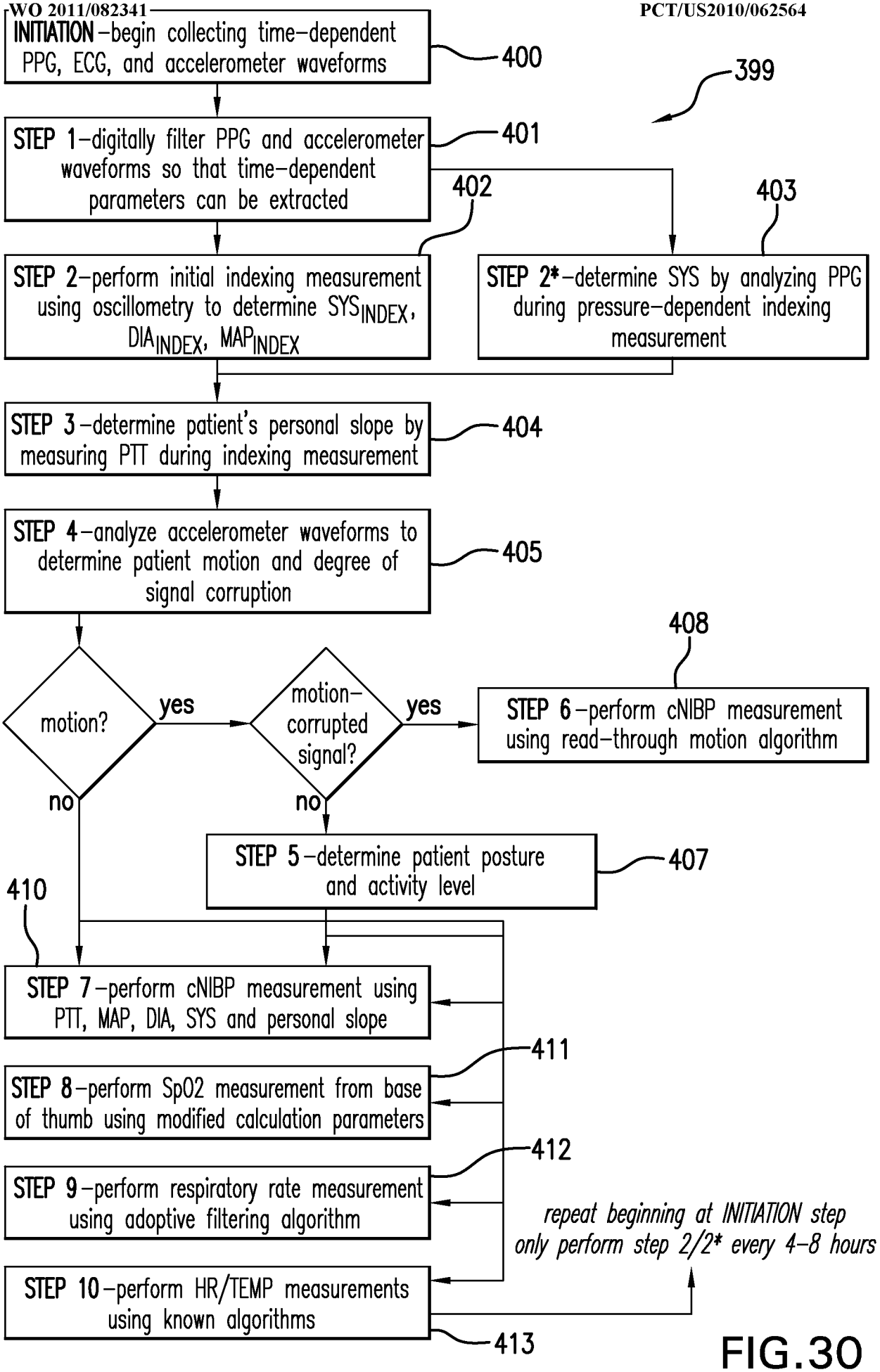

INITIATION–begin collecting time–dependent PPG, ECG, and accelerometer waveforms
400
399
STEP 1–digitally filter PPG and accelerometer waveforms so that time–dependent parameters can be extracted
401
402
403
STEP 2–perform initial indexing measurement using oscillometry to determine SYS$_{INDEX}$, DIA$_{INDEX}$, MAP$_{INDEX}$
STEP 2*–determine SYS by analyzing PPG during pressure–dependent indexing measurement
STEP 3–determine patient's personal slope by measuring PTT during indexing measurement
404
STEP 4–analyze accelerometer waveforms to determine patient motion and degree of signal corruption
405
408
motion?
yes
motion–corrupted signal?
yes
STEP 6–perform cNIBP measurement using read–through motion algorithm
no
no
STEP 5–determine patient posture and activity level
407
410
STEP 7–perform cNIBP measurement using PTT, MAP, DIA, SYS and personal slope
411
STEP 8–perform SpO2 measurement from base of thumb using modified calculation parameters
412
STEP 9–perform respiratory rate measurement using adoptive filtering algorithm
repeat beginning at INITIATION step
only perform step 2/2* every 4–8 hours
STEP 10–perform HR/TEMP measurements using known algorithms
413

FIG.30