26 JAN 2007

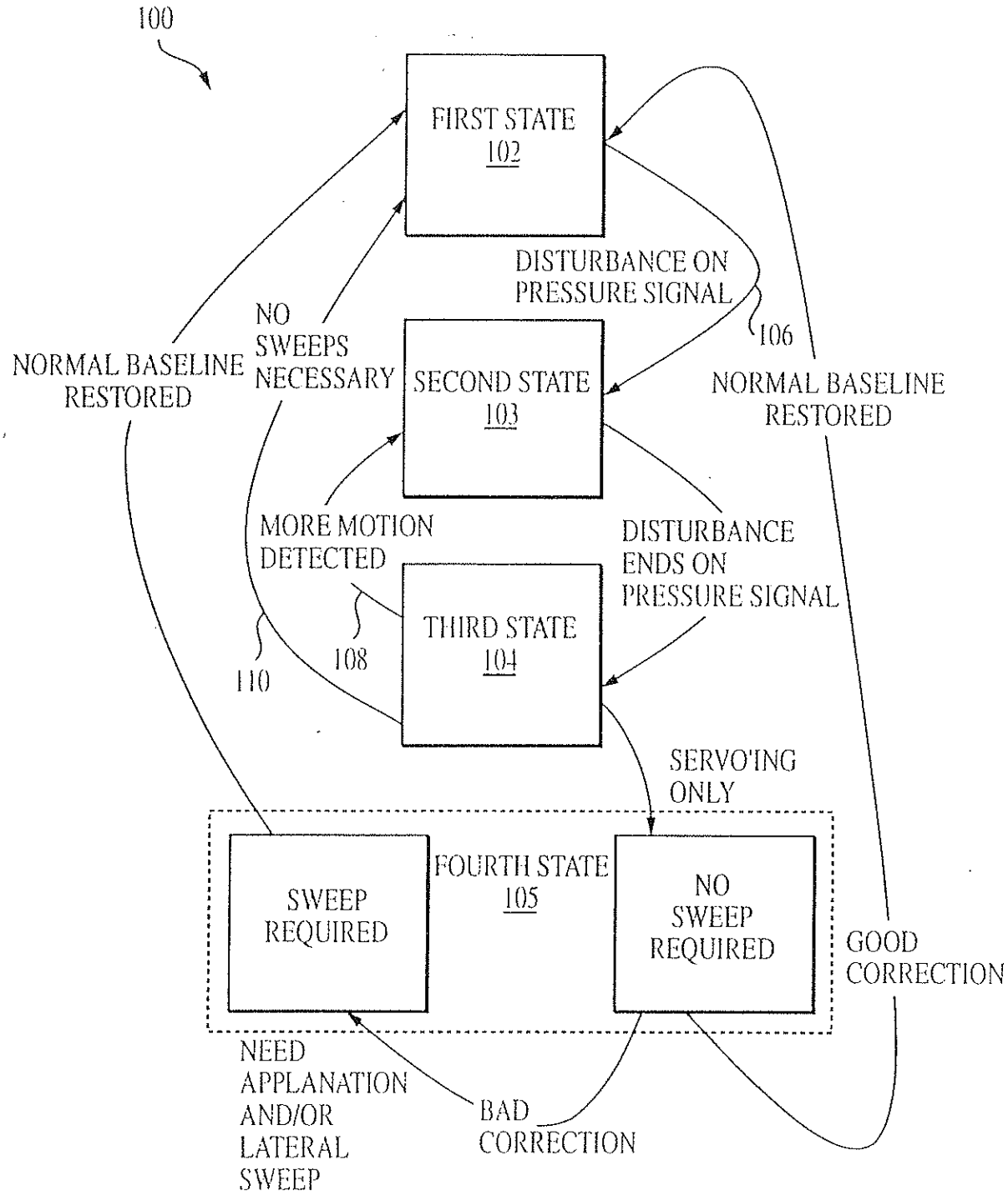


FIG. 1

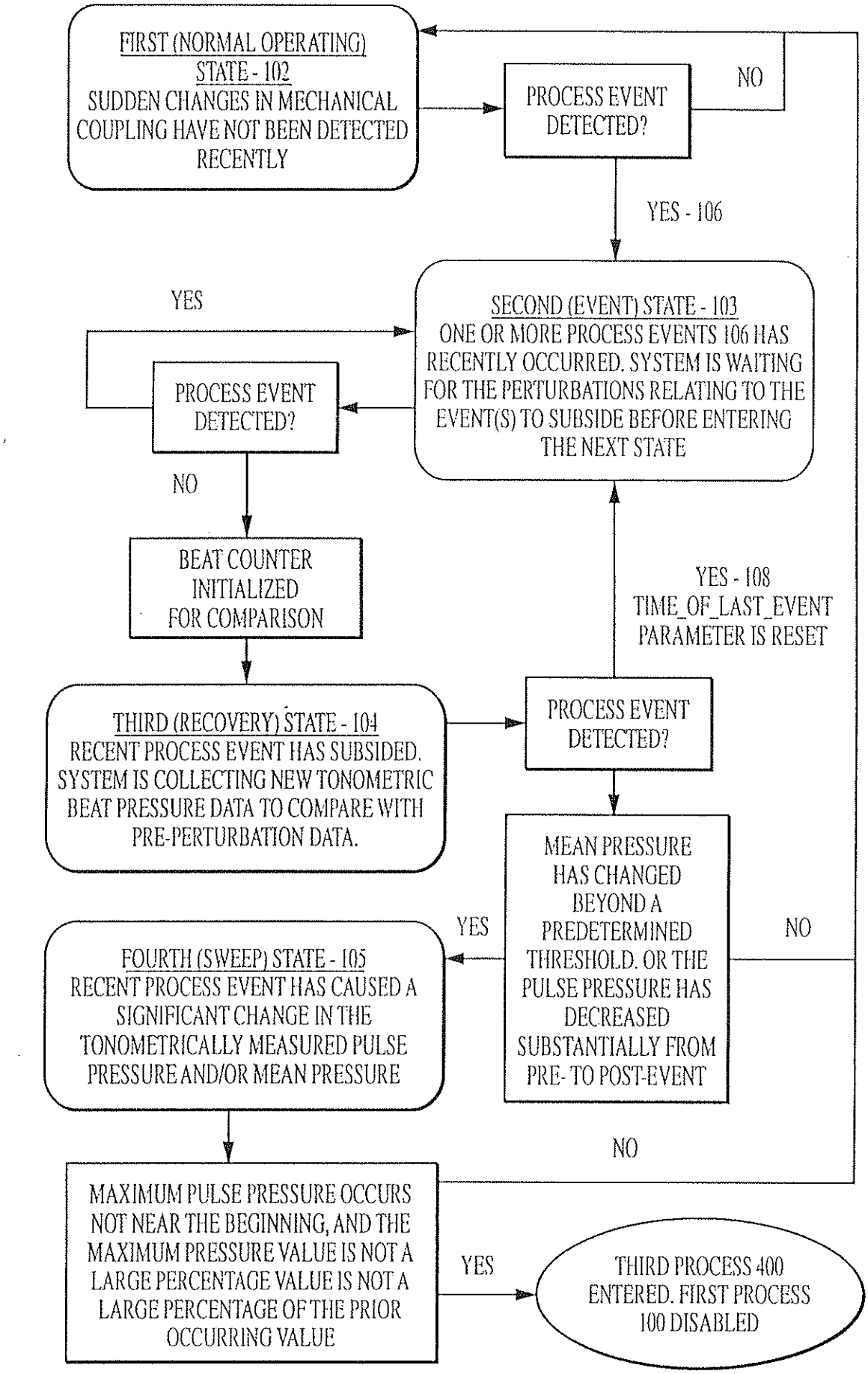

FIRST (NORMAL OPERATING) STATE - 102
SUDDEN CHANGES IN MECHANICAL COUPLING HAVE NOT BEEN DETECTED RECENTLY
PROCESS EVENT DETECTED?
NO
YES - 106
SECOND (EVENT) STATE - 103
ONE OR MORE PROCESS EVENTS 106 HAS RECENTLY OCCURRED. SYSTEM IS WAITING FOR THE PERTURBATIONS RELATING TO THE EVENT(S) TO SUBSIDE BEFORE ENTERING THE NEXT STATE
YES
PROCESS EVENT DETECTED?
NO
BEAT COUNTER INITIALIZED FOR COMPARISON
YES - 108
TIME_OF_LAST_EVENT PARAMETER IS RESET
THIRD (RECOVERY) STATE - 104
RECENT PROCESS EVENT HAS SUBSIDED. SYSTEM IS COLLECTING NEW TONOMETRIC BEAT PRESSURE DATA TO COMPARE WITH PRE-PERTURBATION DATA.
PROCESS EVENT DETECTED?
MEAN PRESSURE HAS CHANGED BEYOND A PREDETERMINED THRESHOLD. OR THE PULSE PRESSURE HAS DECREASED SUBSTANTIALLY FROM PRE- TO POST-EVENT
YES
NO
FOURTH (SWEEP) STATE - 105
RECENT PROCESS EVENT HAS CAUSED A SIGNIFICANT CHANGE IN THE TONOMETRICALLY MEASURED PULSE PRESSURE AND/OR MEAN PRESSURE
NO
MAXIMUM PULSE PRESSURE OCCURS NOT NEAR THE BEGINNING, AND THE MAXIMUM PRESSURE VALUE IS NOT A LARGE PERCENTAGE VALUE IS NOT A LARGE PERCENTAGE OF THE PRIOR OCCURRING VALUE
YES
THIRD PROCESS 400 ENTERED. FIRST PROCESS 100 DISABLED

FIG. 1a

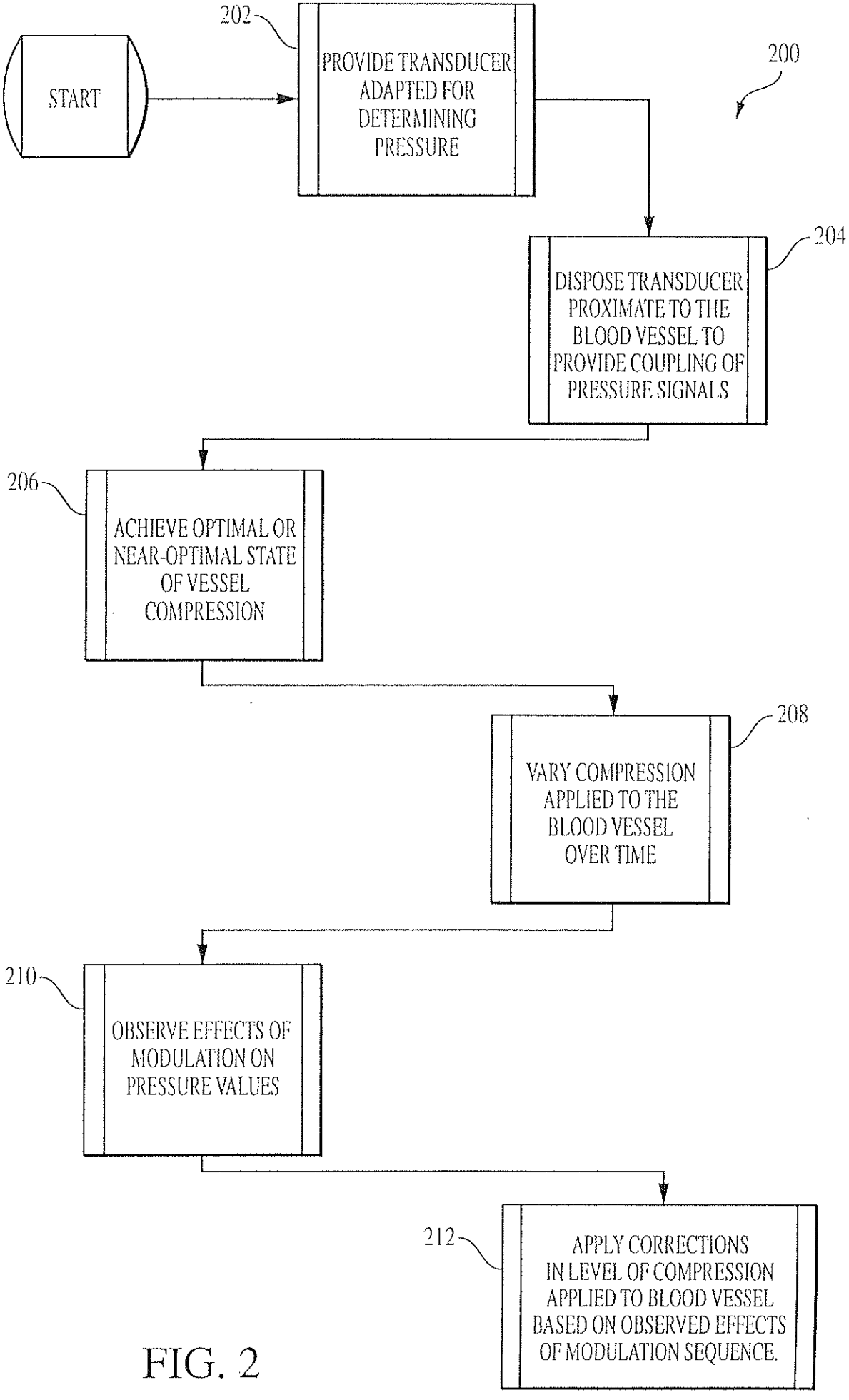

START
202
PROVIDE TRANSDUCER ADAPTED FOR DETERMINING PRESSURE
200
204
DISPOSE TRANSDUCER PROXIMATE TO THE BLOOD VESSEL TO PROVIDE COUPLING OF PRESSURE SIGNALS
206
ACHIEVE OPTIMAL OR NEAR-OPTIMAL STATE OF VESSEL COMPRESSION
208
VARY COMPRESSION APPLIED TO THE BLOOD VESSEL OVER TIME
210
OBSERVE EFFECTS OF MODULATION ON PRESSURE VALUES
212
APPLY CORRECTIONS IN LEVEL OF COMPRESSION APPLIED TO BLOOD VESSEL BASED ON OBSERVED EFFECTS OF MODULATION SEQUENCE.

FIG. 2

26 JAN 2007

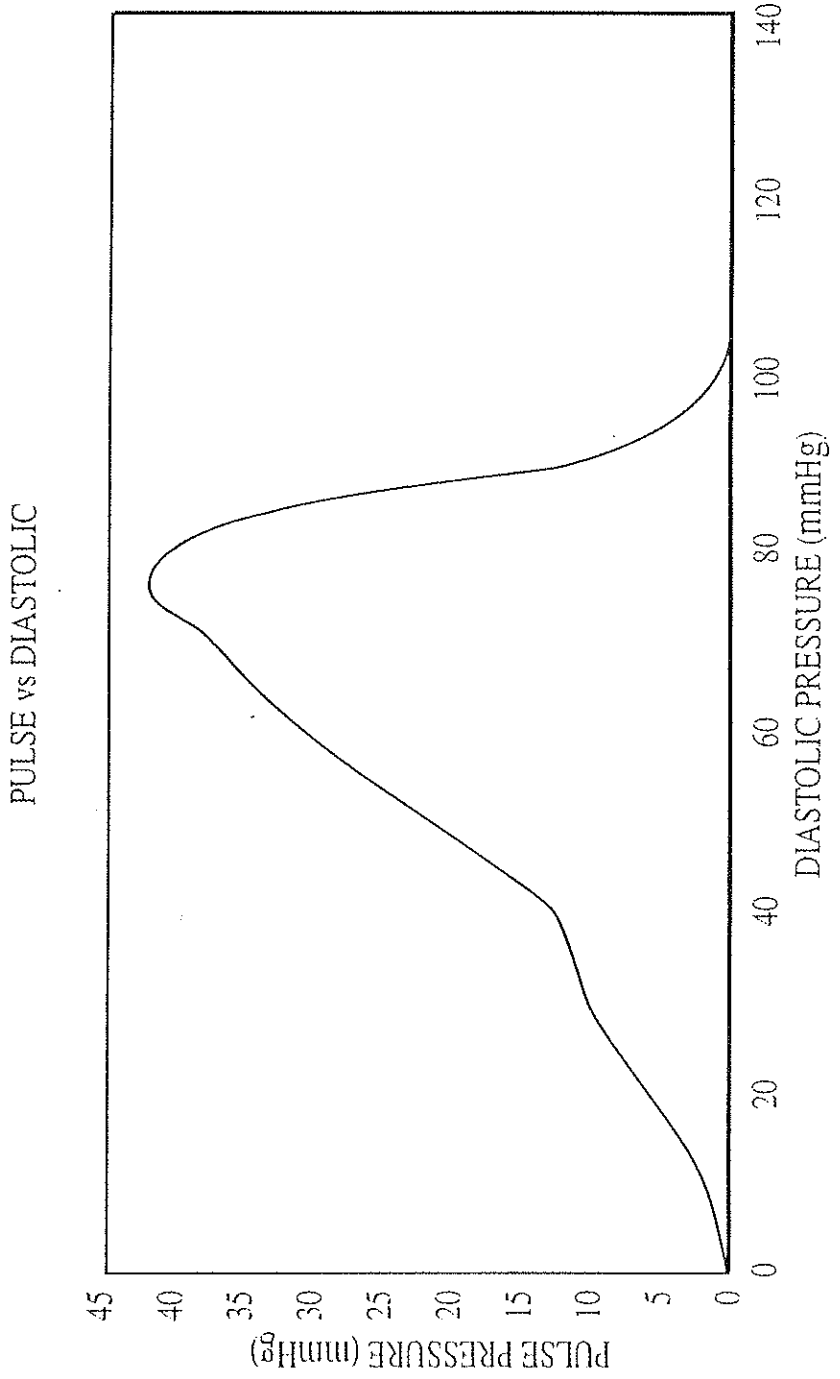


FIG. 2a

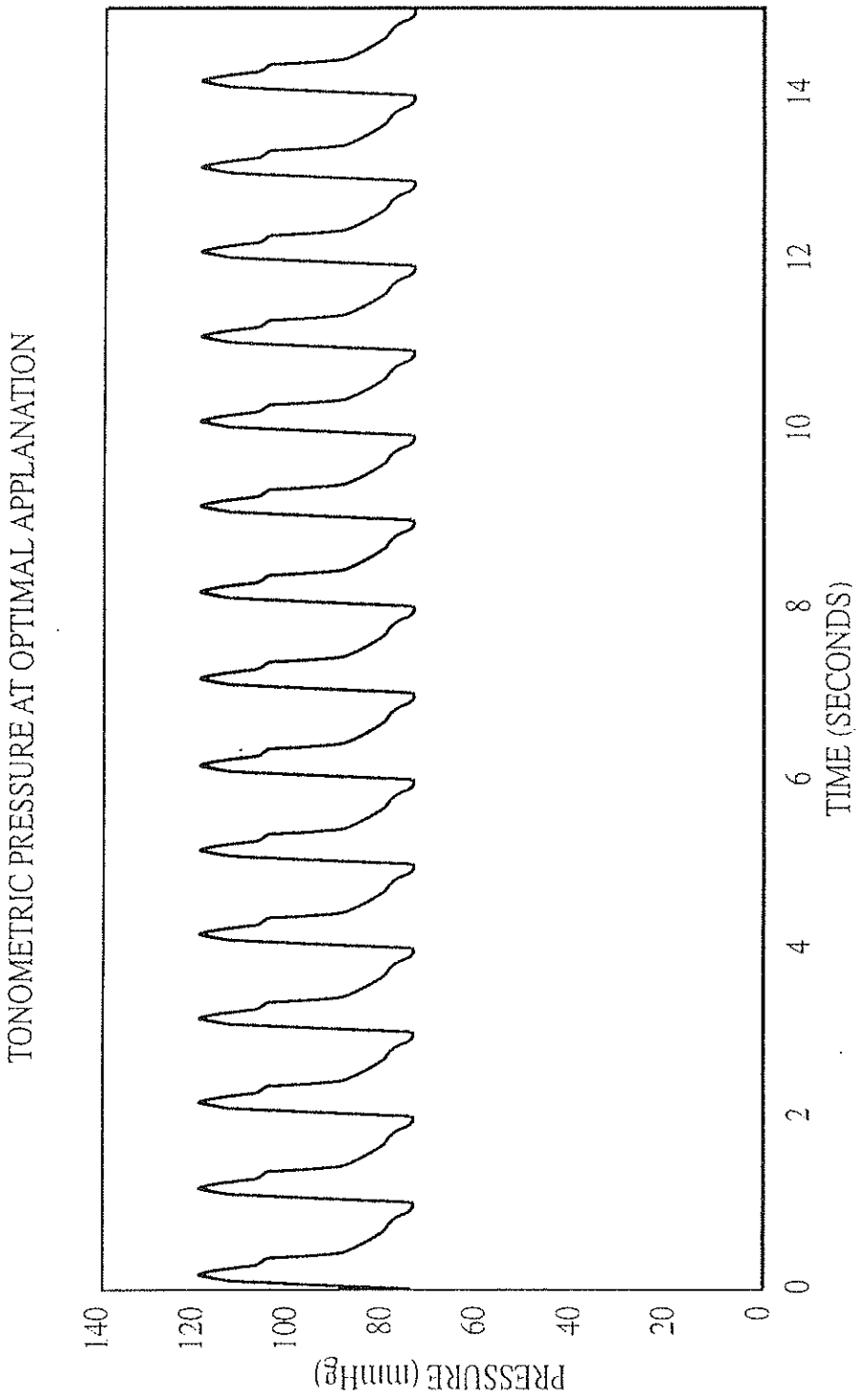

TONOMETRIC PRESSURE AT OPTIMAL APPLANATION
PRESSURE (mmHg)
140
120
100
80
60
40
20
0
0
2
4
6
8
10
12
14
TIME (SECONDS)

FIG. 2b

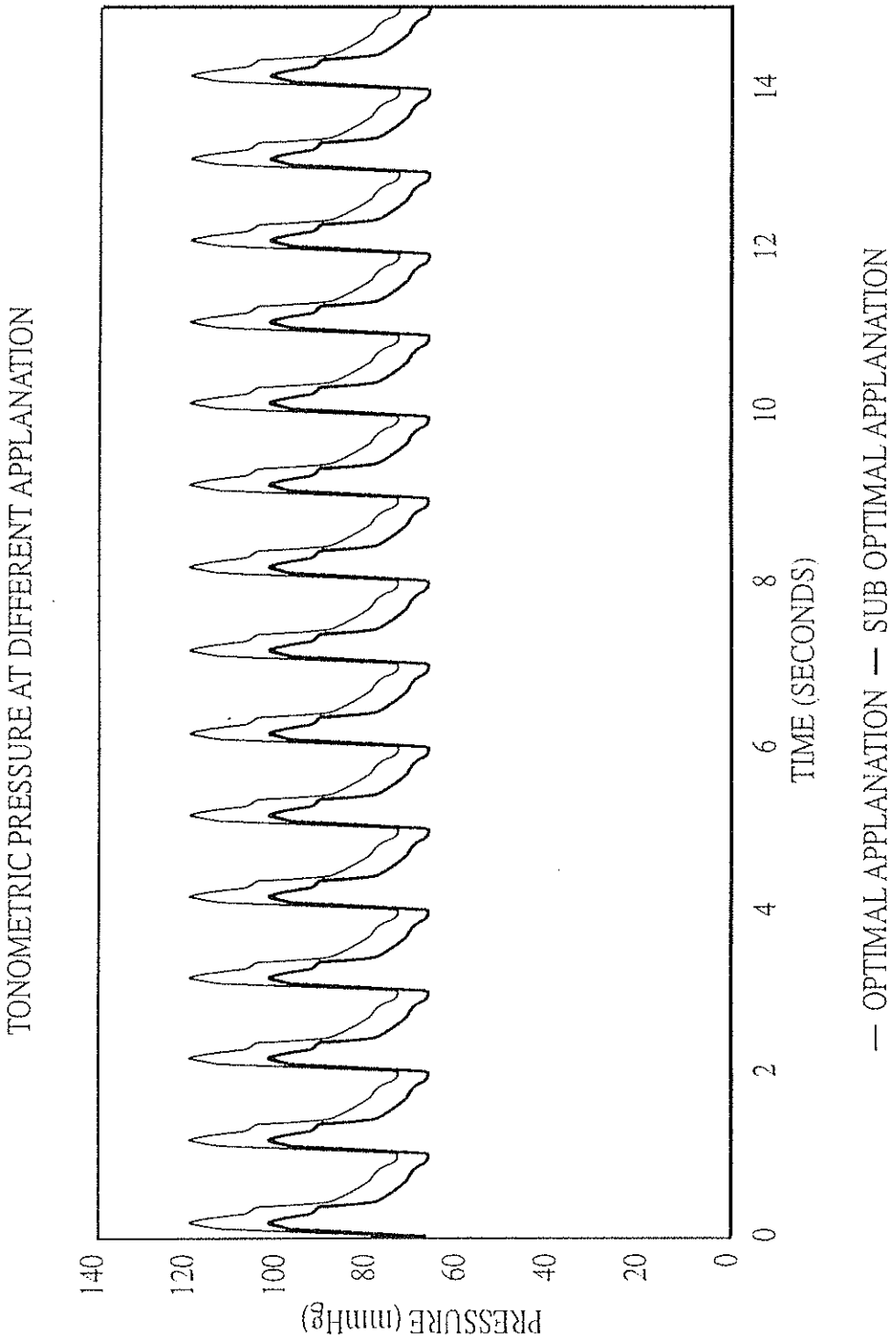

TONOMETRIC PRESSURE AT DIFFERENT APPLANATION
PRESSURE (mmHg)
140
120
100
80
60
40
20
0
0
2
4
6
8
10
12
14
TIME (SECONDS)
— OPTIMAL APPLANATION — SUB OPTIMAL APPLANATION

FIG. 2c

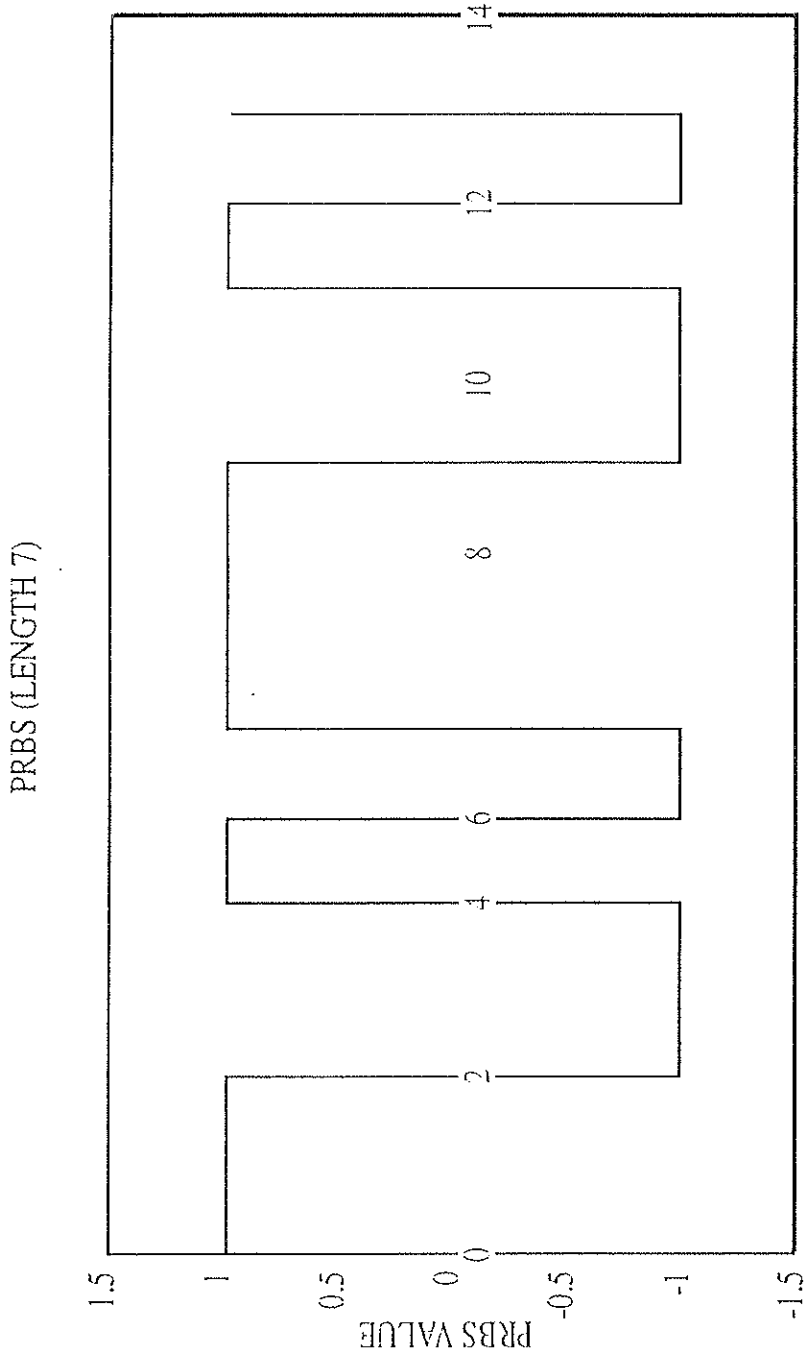


FIG. 2d

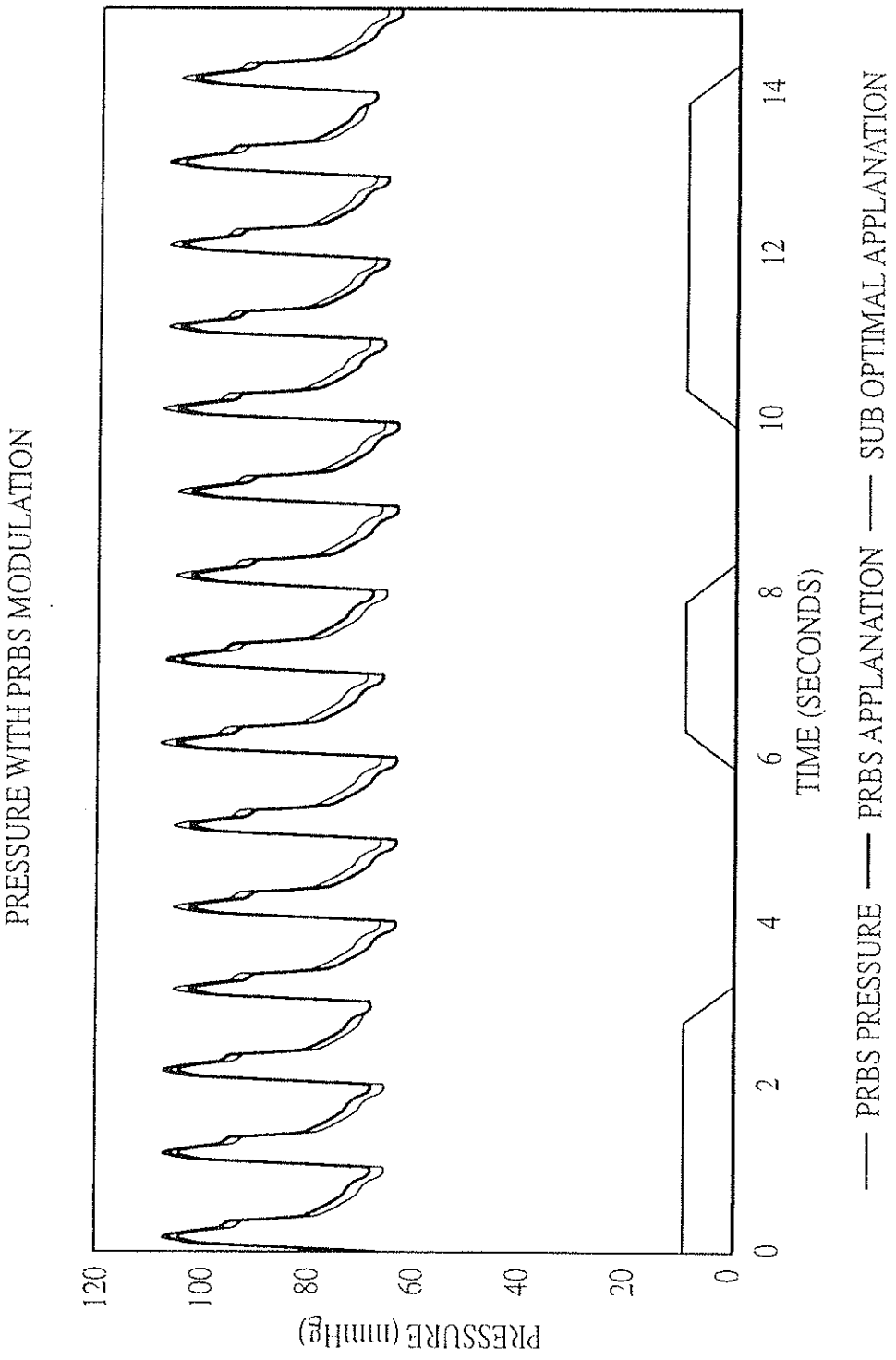

PRESSURE WITH PRBS MODULATION
PRESSURE (mmHg)
120
100
80
60
40
20
0
0
2
4
6
8
10
12
14
TIME (SECONDS)
PRBS PRESSURE
PRBS APPLANATION
SUB OPTIMAL APPLANATION

FIG. 2e

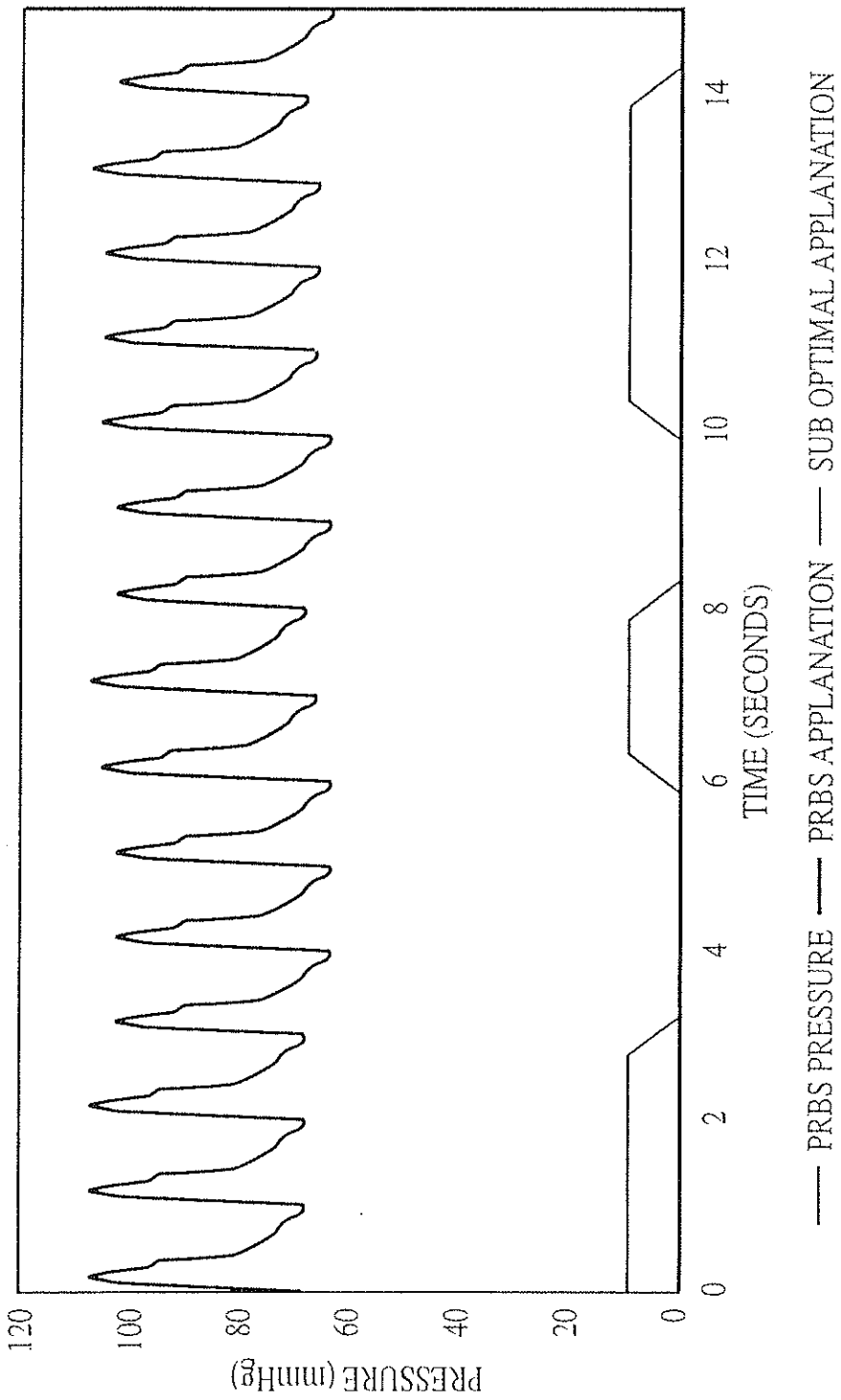

PRESSURE WITH PRBS MODULATION
PRESSURE (mmHg)
120
100
80
60
40
20
0
0
2
4
6
8
10
12
14
TIME (SECONDS)
PRBS PRESSURE
PRBS APPLANATION
SUB OPTIMAL APPLANATION

FIG. 2f

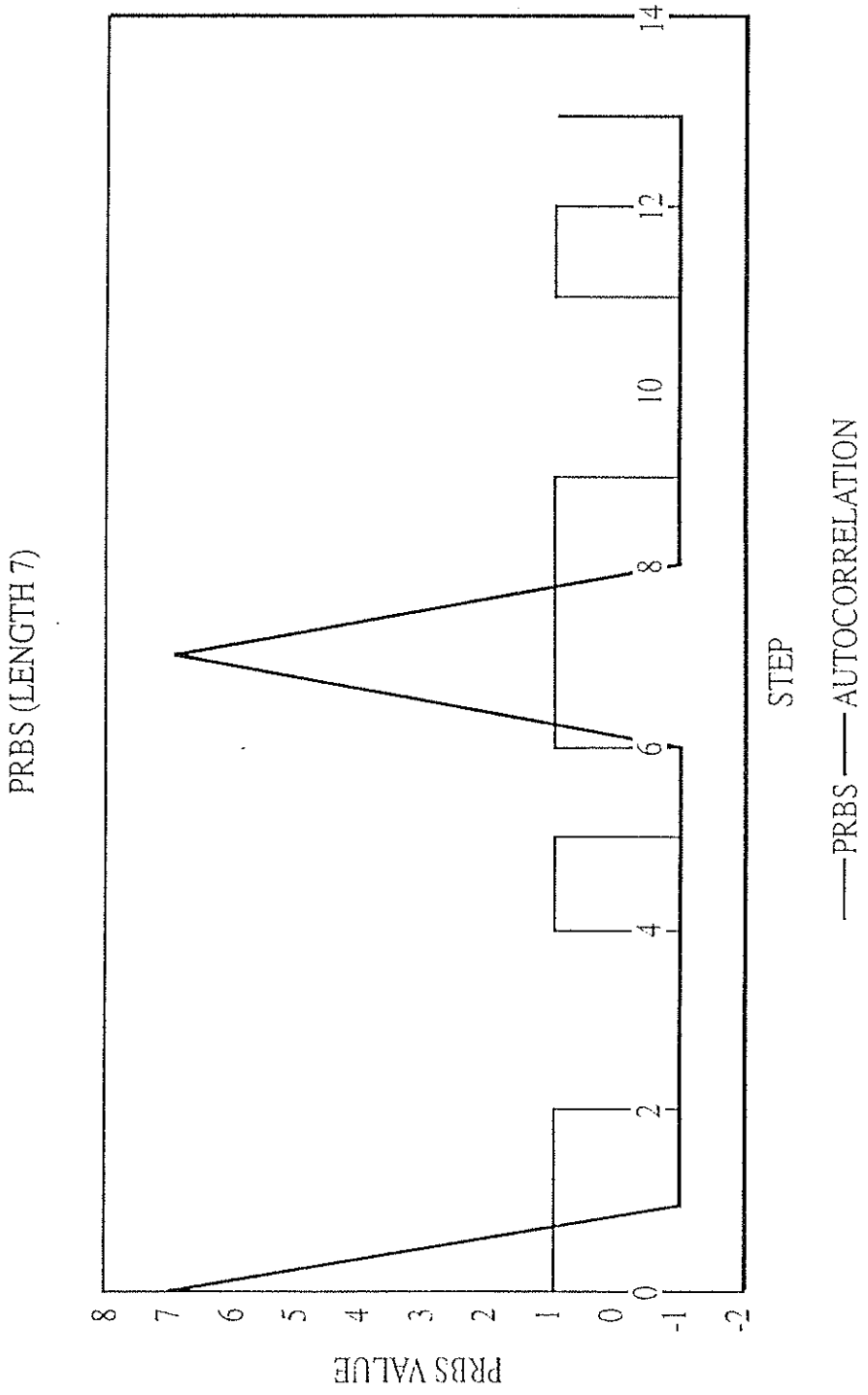

PRBS (LENGTH 7)
PRBS VALUE
8
7
6
5
4
3
2
1
0
-1
-2
0
2
4
6
8
10
12
14
STEP
PRBS
AUTOCORRELATION

FIG. 2g

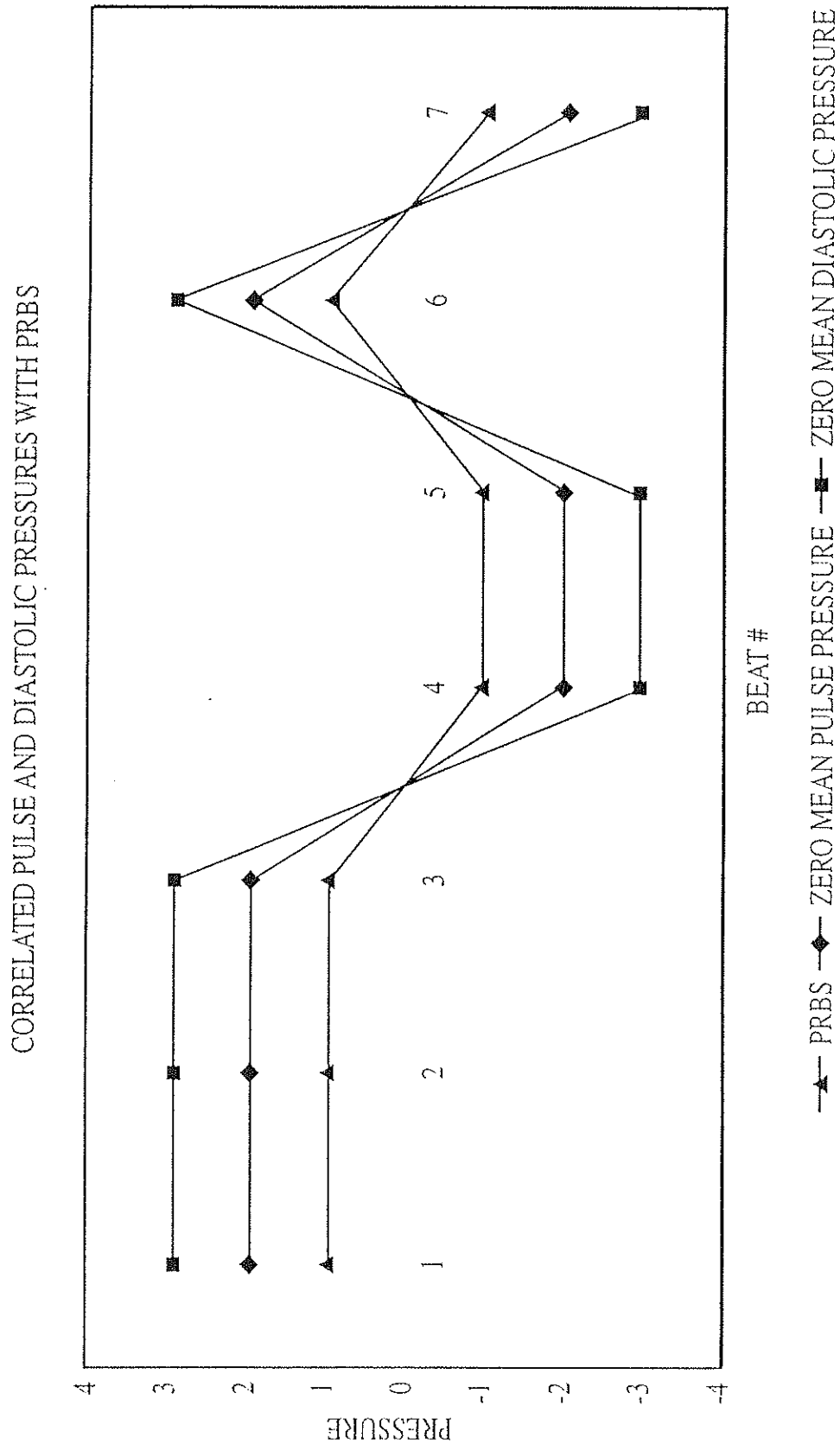

CORRELATED PULSE AND DIASTOLIC PRESSURES WITH PRBS
PRESSURE
4
3
2
1
0
-1
-2
-3
-4
1
2
3
4
5
6
7
BEAT #
PRBS
ZERO MEAN PULSE PRESSURE
ZERO MEAN DIASTOLIC PRESSURE

FIG. 2h

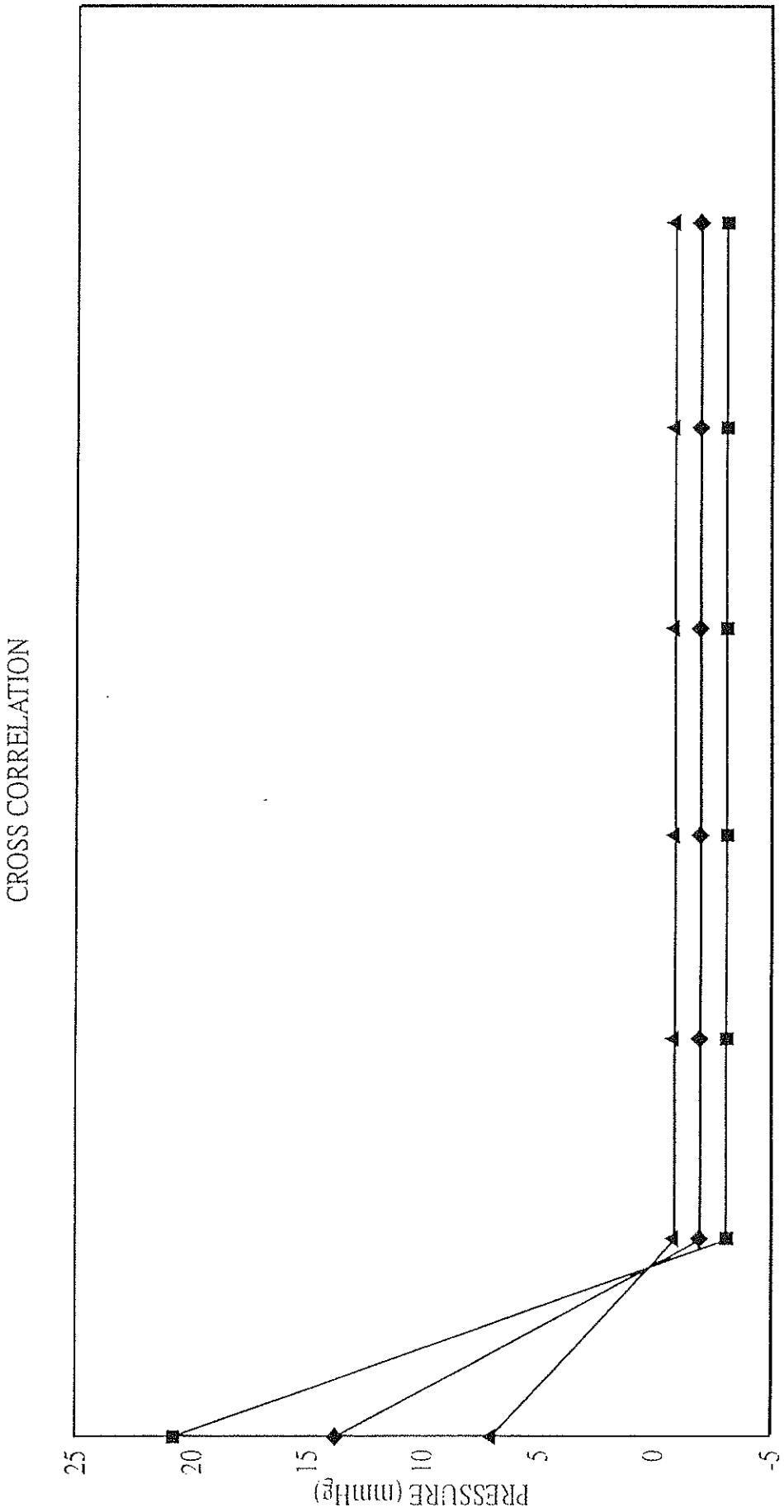

CROSS CORRELATION
PRESSURE (mmHg)
25
20
15
10
5
0
-5
PHASE DELAY
PRBS
PULSE PRESSURE
DIASTOLIC PRESSURE

FIG. 2i

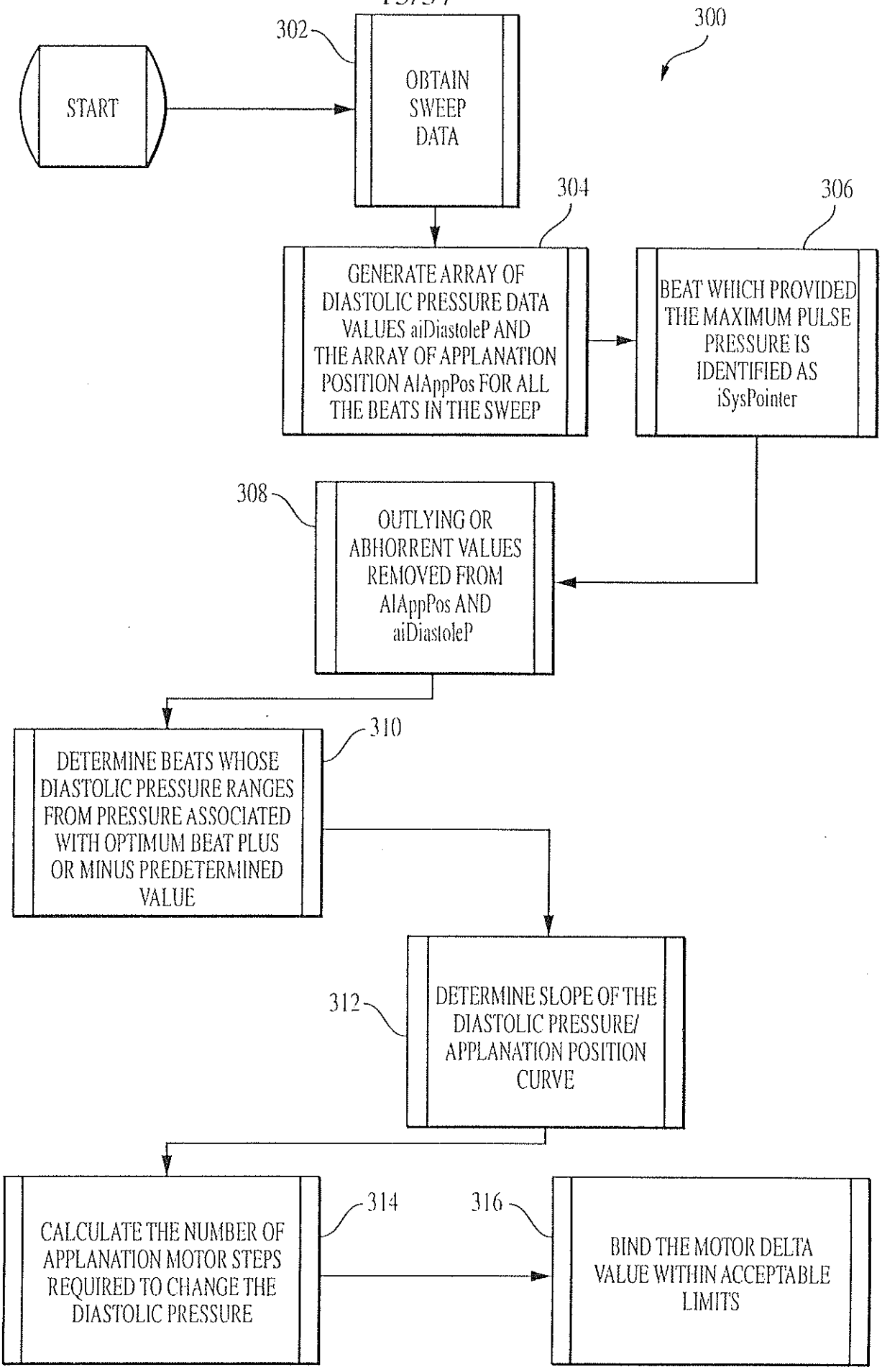

300
START
302
OBTAIN SWEEP DATA
304
GENERATE ARRAY OF DIASTOLIC PRESSURE DATA VALUES aiDiastoleP AND THE ARRAY OF APPLANATION POSITION AlAppPos FOR ALL THE BEATS IN THE SWEEP
306
BEAT WHICH PROVIDED THE MAXIMUM PULSE PRESSURE IS IDENTIFIED AS iSysPointer
308
OUTLYING OR ABHORRENT VALUES REMOVED FROM AlAppPos AND aiDiastoleP
310
DETERMINE BEATS WHOSE DIASTOLIC PRESSURE RANGES FROM PRESSURE ASSOCIATED WITH OPTIMUM BEAT PLUS OR MINUS PREDETERMINED VALUE
312
DETERMINE SLOPE OF THE DIASTOLIC PRESSURE/ APPLANATION POSITION CURVE
314
CALCULATE THE NUMBER OF APPLANATION MOTOR STEPS REQUIRED TO CHANGE THE DIASTOLIC PRESSURE
316
BIND THE MOTOR DELTA VALUE WITHIN ACCEPTABLE LIMITS

FIG. 3

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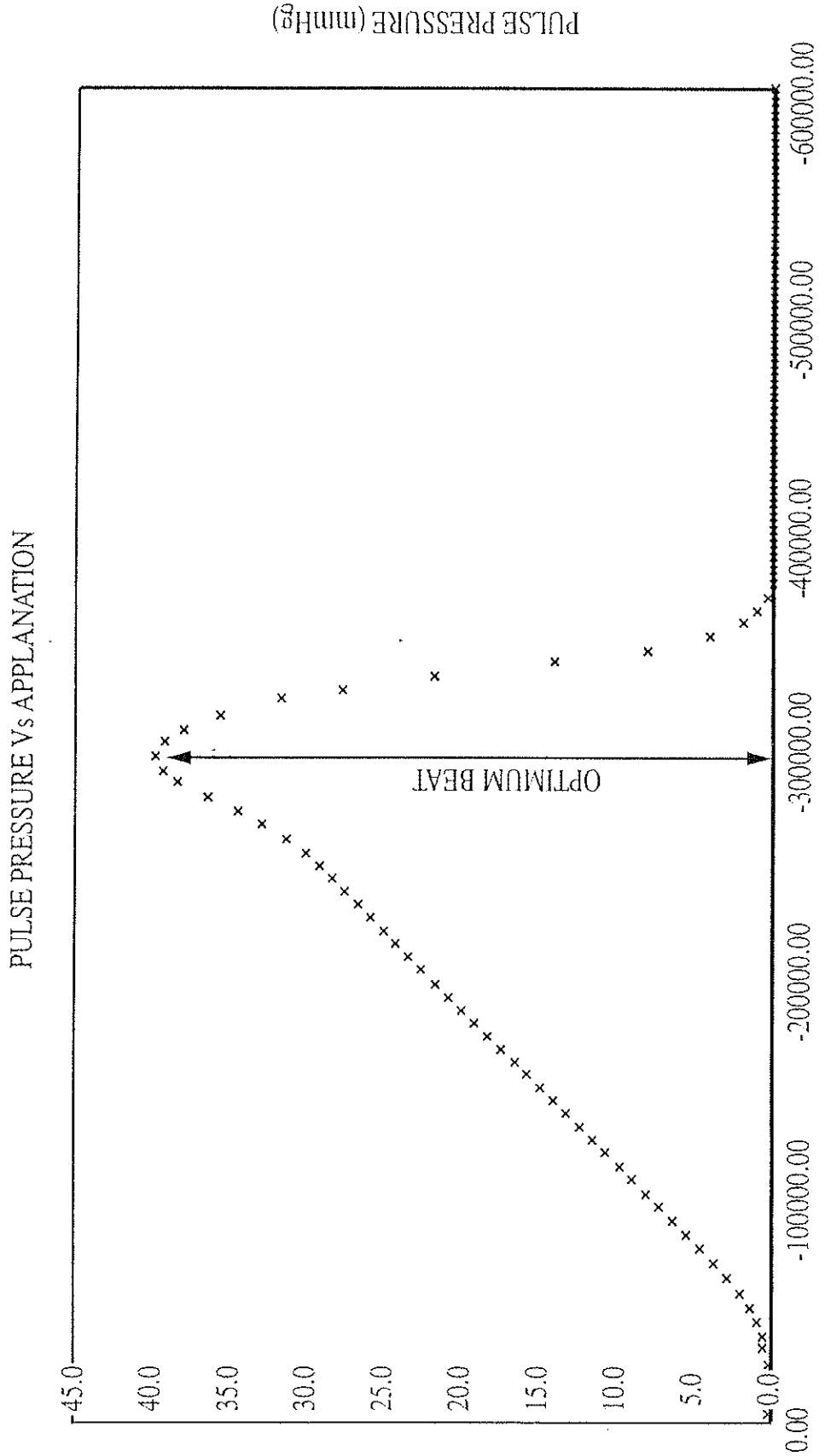


FIG. 3a

26 JAN 2007

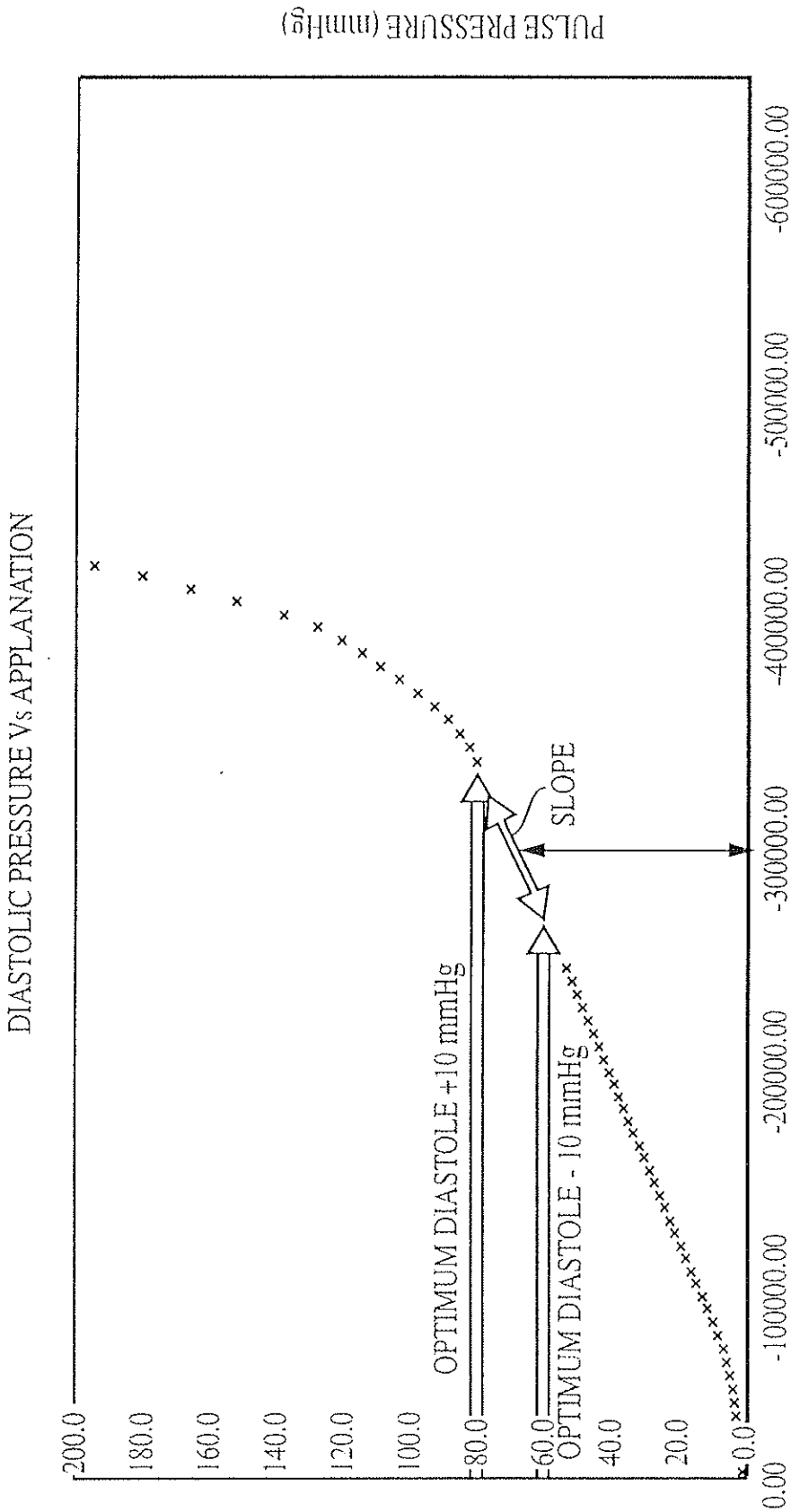


FIG. 3b

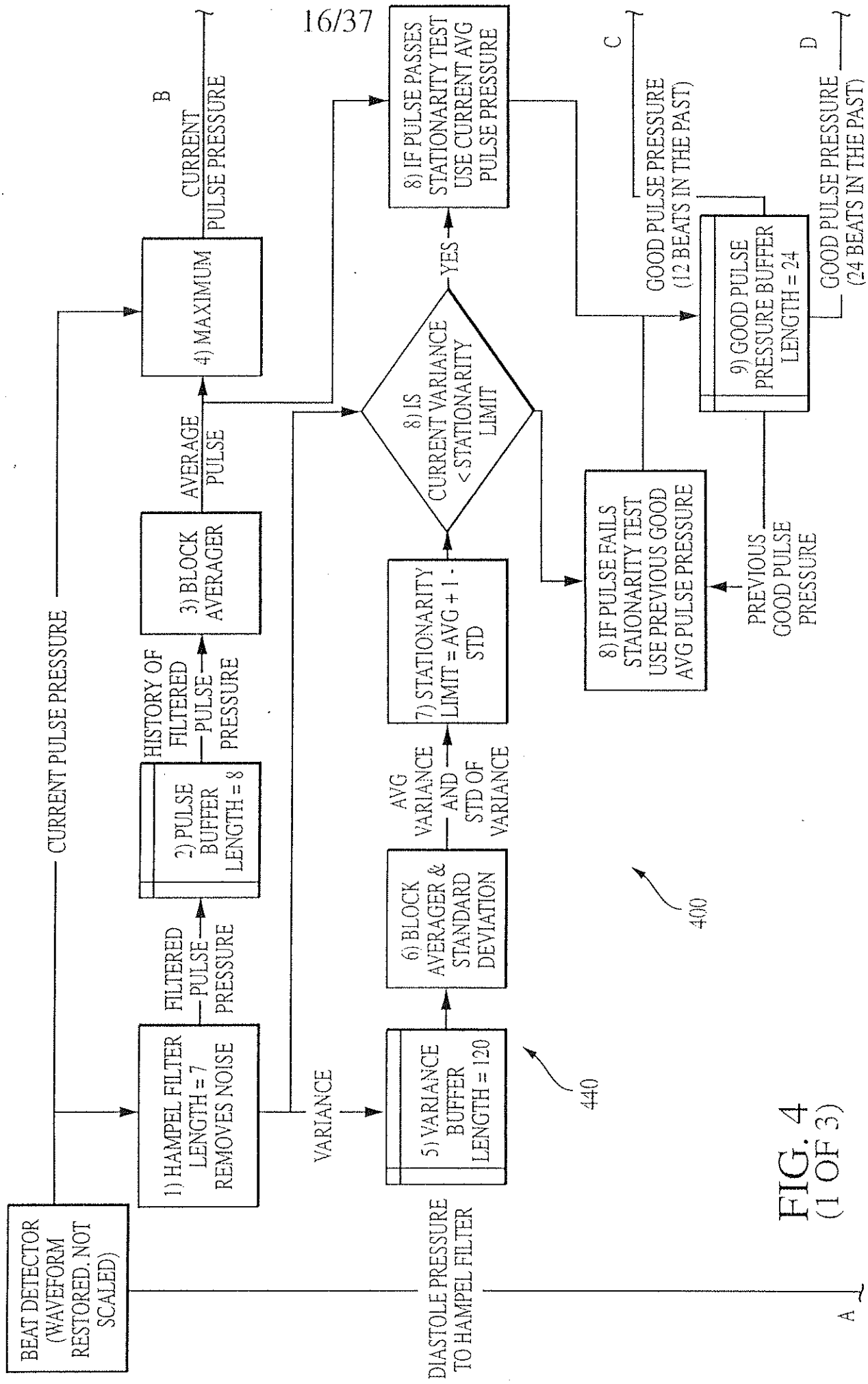

BEAT DETECTOR (WAVEFORM RESTORED. NOT SCALED)
DIASTOLE PRESSURE TO HAMPEL FILTER
A
CURRENT PULSE PRESSURE
1) HAMPEL FILTER LENGTH = 7 REMOVES NOISE
FILTERED PULSE PRESSURE
2) PULSE BUFFER LENGTH = 8
HISTORY OF FILTERED PULSE PRESSURE
3) BLOCK AVERAGER
AVERAGE PULSE
4) MAXIMUM
CURRENT PULSE PRESSURE
B
VARIANCE
5) VARIANCE BUFFER LENGTH = 120
440
6) BLOCK AVERAGER & STANDARD DEVIATION
AVG VARIANCE AND STD OF VARIANCE
7) STATIONARITY LIMIT = AVG + 1 - STD
8) IS CURRENT VARIANCE < STATIONARITY LIMIT
YES
8) IF PULSE PASSES STATIONARITY TEST USE CURRENT AVG PULSE PRESSURE
C
GOOD PULSE PRESSURE (12 BEATS IN THE PAST)
9) GOOD PULSE PRESSURE BUFFER LENGTH = 24
D
GOOD PULSE PRESSURE (24 BEATS IN THE PAST)
8) IF PULSE FAILS STAIONARITY TEST USE PREVIOUS GOOD AVG PULSE PRESSURE
PREVIOUS GOOD PULSE PRESSURE
400

FIG. 4
(1 OF 3)

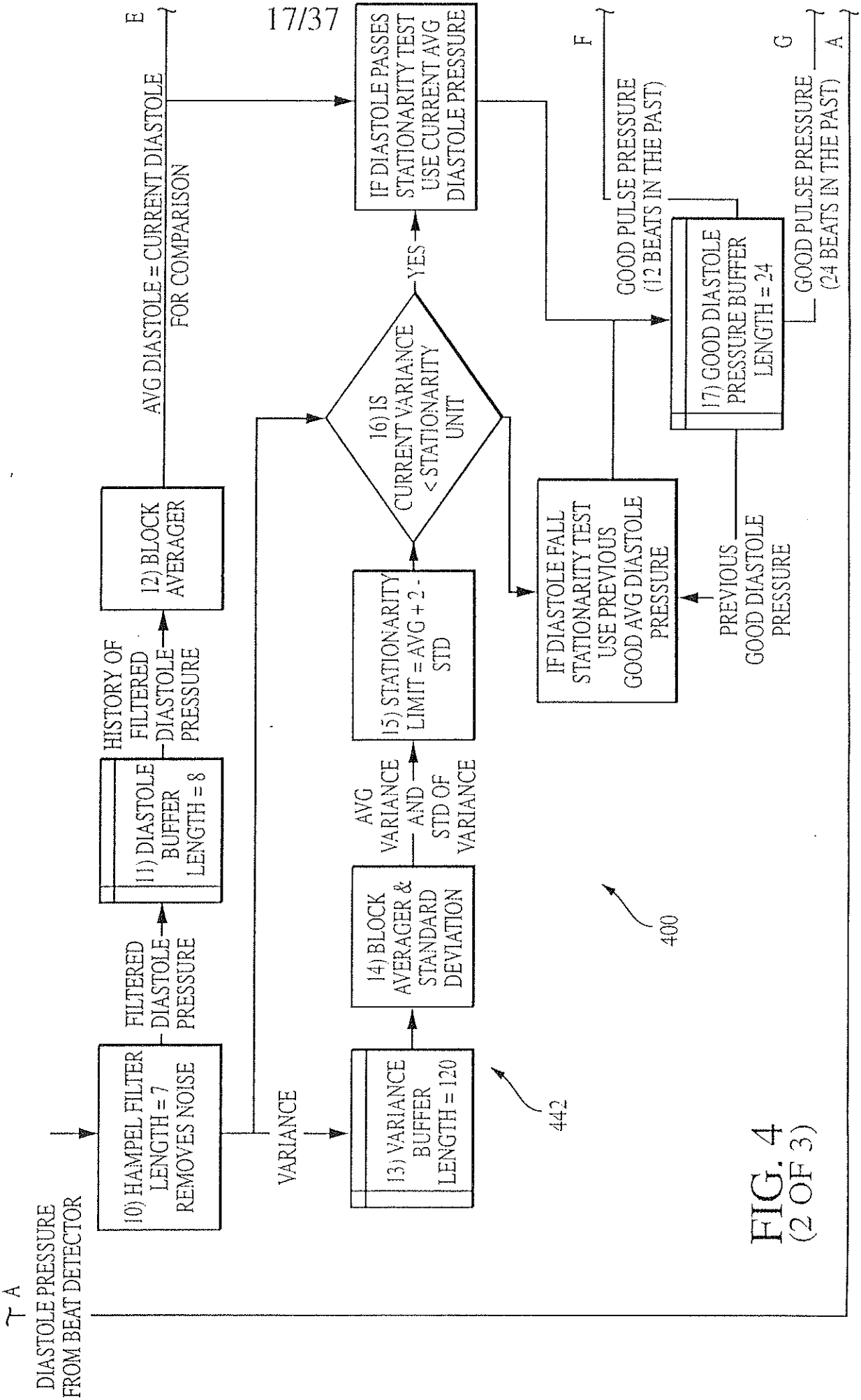

A
DIASTOLE PRESSURE FROM BEAT DETECTOR
10) HAMPEL FILTER LENGTH = 7 REMOVES NOISE
FILTERED DIASTOLE PRESSURE
11) DIASTOLE BUFFER LENGTH = 8
HISTORY OF FILTERED DIASTOLE PRESSURE
12) BLOCK AVERAGER
AVG DIASTOLE = CURRENT DIASTOLE FOR COMPARISON
E
VARIANCE
13) VARIANCE BUFFER LENGTH = 120
14) BLOCK AVERAGER & STANDARD DEVIATION
AVG VARIANCE AND STD OF VARIANCE
15) STATIONARITY LIMIT = AVG + 2 - STD
16) IS CURRENT VARIANCE < STATIONARITY UNIT
YES
IF DIASTOLE PASSES STATIONARITY TEST USE CURRENT AVG DIASTOLE PRESSURE
IF DIASTOLE FALL STATIONARITY TEST USE PREVIOUS GOOD AVG DIASTOLE PRESSURE
PREVIOUS GOOD DIASTOLE PRESSURE
F
GOOD PULSE PRESSURE (12 BEATS IN THE PAST)
17) GOOD DIASTOLE PRESSURE BUFFER LENGTH = 24
G
GOOD PULSE PRESSURE (24 BEATS IN THE PAST)
A
442
400

FIG. 4
(2 OF 3)

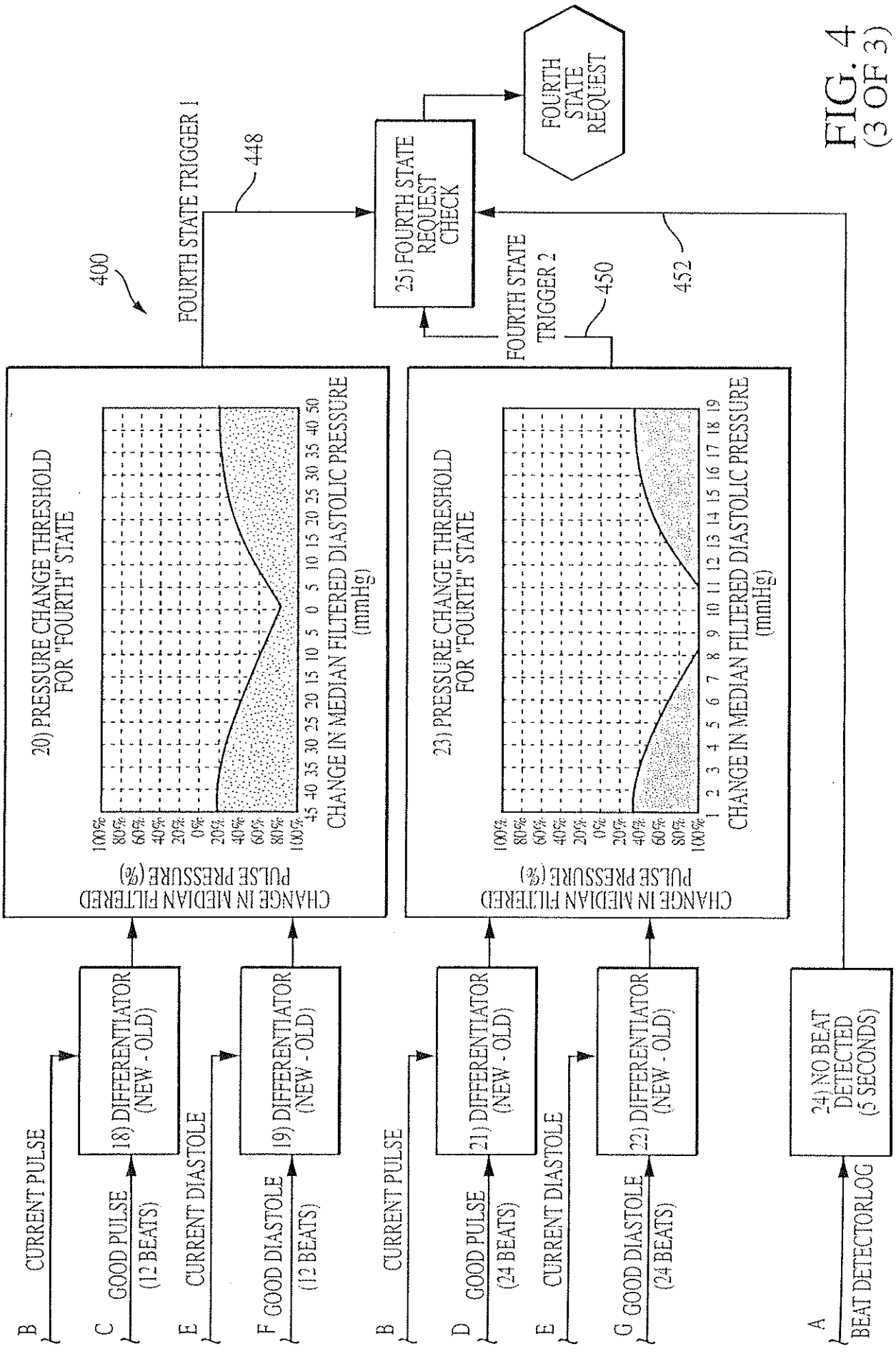

400
FOURTH STATE TRIGGER 1
448
25) FOURTH STATE REQUEST CHECK
FOURTH STATE REQUEST
FOURTH STATE TRIGGER 2
450
452
20) PRESSURE CHANGE THRESHOLD FOR "FOURTH" STATE
CHANGE IN MEDIAN FILTERED PULSE PRESSURE (%)
100% 80% 60% 40% 20% 0% 20% 40% 60% 80% 100%
45 40 35 30 25 20 15 10 5 0 5 10 15 20 25 30 35 40 50
CHANGE IN MEDIAN FILTERED DIASTOLIC PRESSURE (mmHg)
23) PRESSURE CHANGE THRESHOLD FOR "FOURTH" STATE
CHANGE IN MEDIAN FILTERED PULSE PRESSURE (%)
100% 80% 60% 40% 20% 0% 20% 40% 60% 80% 100%
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19
CHANGE IN MEDIAN FILTERED DIASTOLIC PRESSURE (mmHg)
B CURRENT PULSE
C GOOD PULSE (12 BEATS)
18) DIFFERENTIATOR (NEW - OLD)
E CURRENT DIASTOLE
F GOOD DIASTOLE (12 BEATS)
19) DIFFERENTIATOR (NEW - OLD)
B CURRENT PULSE
D GOOD PULSE (24 BEATS)
21) DIFFERENTIATOR (NEW - OLD)
E CURRENT DIASTOLE
G GOOD DIASTOLE (24 BEATS)
22) DIFFERENTIATOR (NEW - OLD)
A BEAT DETECTORLOG
24) NO BEAT DETECTED (5 SECONDS)

FIG. 4
(3 OF 3)

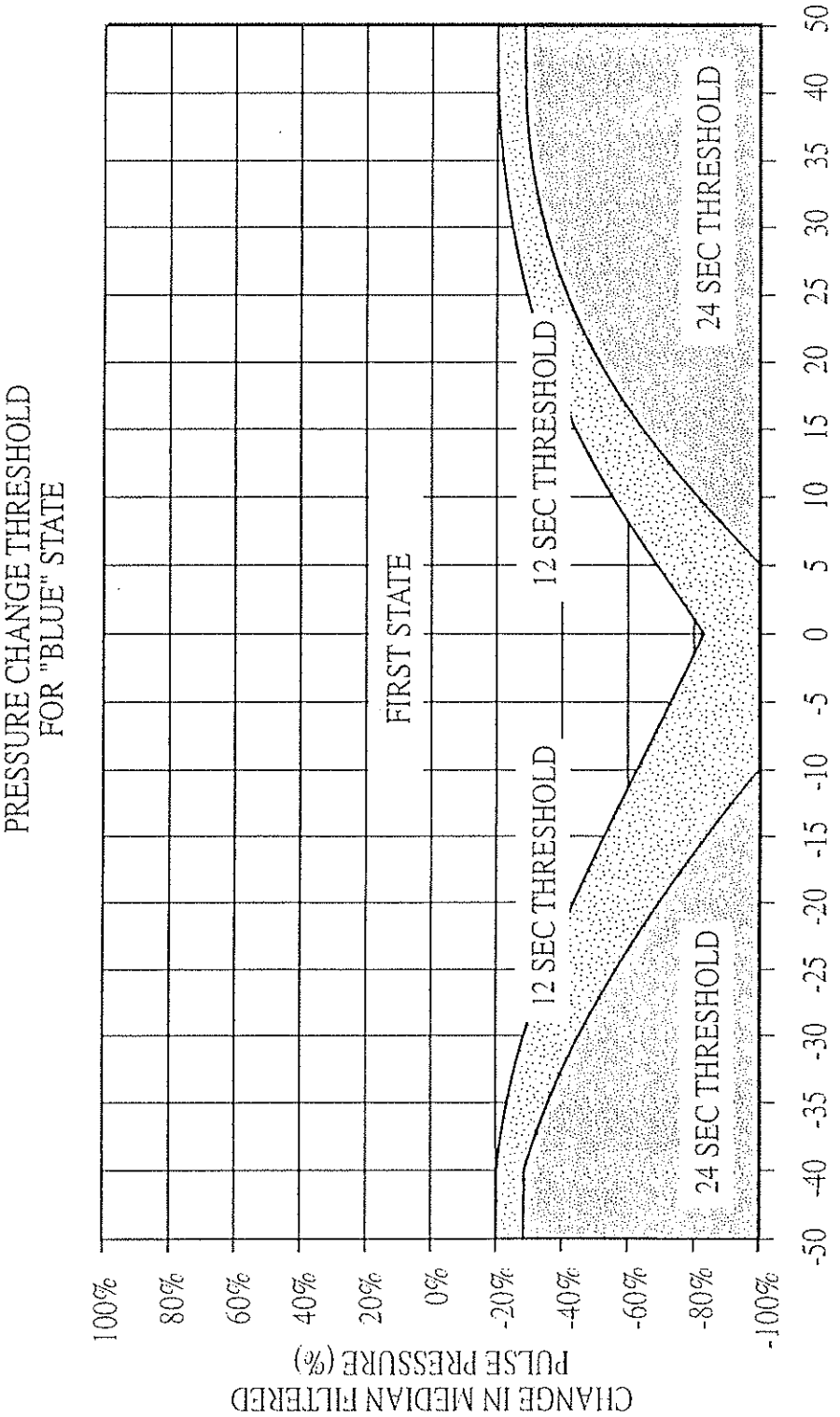

PRESSURE CHANGE THRESHOLD
FOR "BLUE" STATE
FIRST STATE
12 SEC THRESHOLD
12 SEC THRESHOLD
24 SEC THRESHOLD
24 SEC THRESHOLD
100%
80%
60%
40%
20%
0%
-20%
-40%
-60%
-80%
-100%
CHANGE IN MEDIAN FILTERED PULSE PRESSURE (%)
-50 -40 -35 -30 -25 -20 -15 -10 -5 0 5 10 15 20 25 30 35 40 50
CHANGE IN MEDIAN FILTERED DIASTOLIC PRESSURE (mmHg)

FIG. 4a

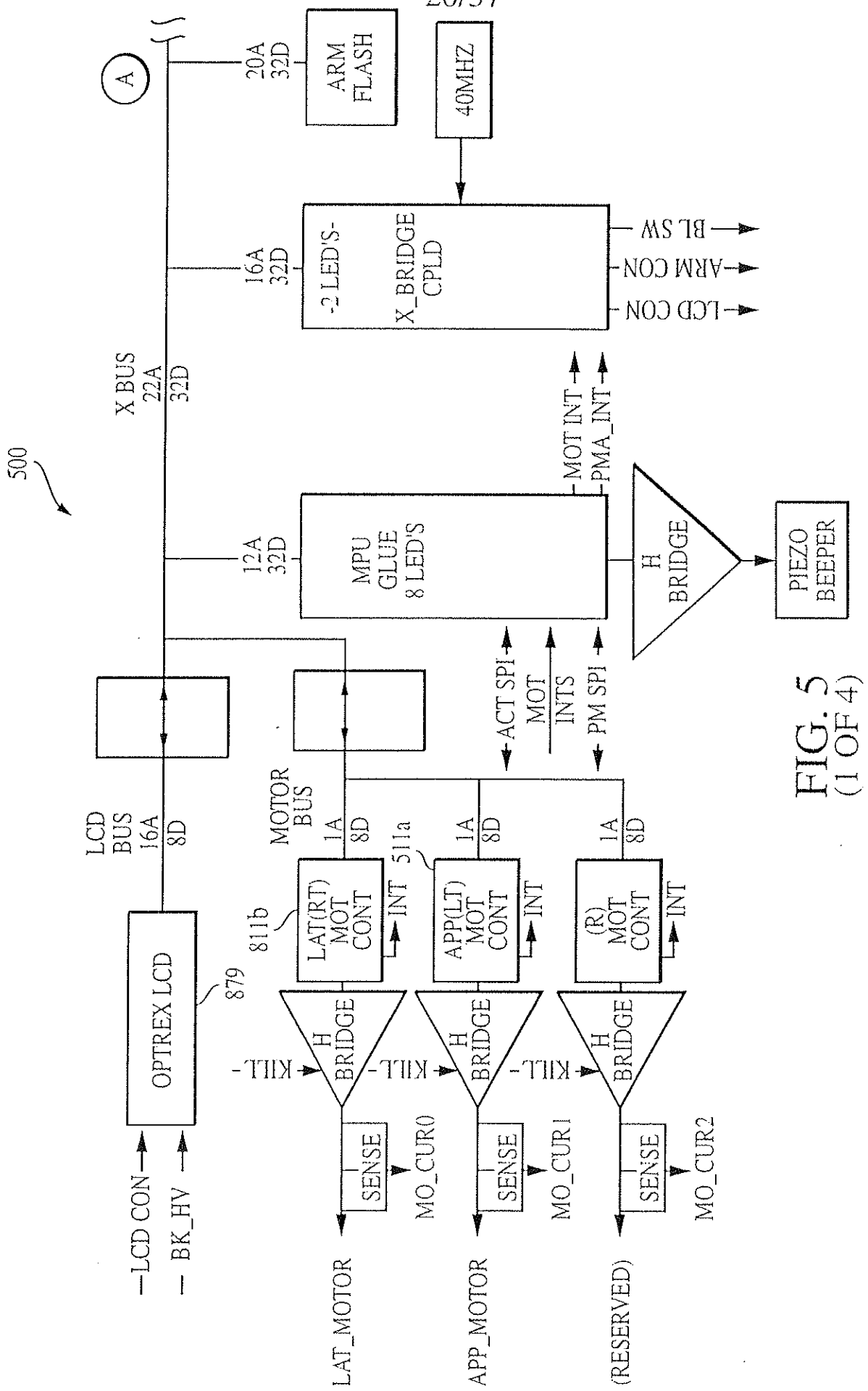

500
A
20A
32D
ARM FLASH
40MHZ
16A
32D
-2 LED'S-
X_BRIDGE CPLD
BL SW
ARM CON
LCD CON
X BUS
22A
32D
MOT INT
PMA_INT
12A
32D
MPU GLUE 8 LED'S
H BRIDGE
PIEZO BEEPER
ACT SPI
MOT INTS
PM SPI
LCD BUS
16A
8D
MOTOR BUS
1A
8D
511a
811b
LAT(RT) MOT CONT
APP(LT) MOT CONT
(R) MOT CONT
INT
879
OPTREX LCD
H BRIDGE
KILL-
SENSE
MO_CUR0
MO_CUR1
MO_CUR2
LCD CON
BK_HV
LAT_MOTOR
APP_MOTOR
(RESERVED)

FIG. 5
(1 OF 4)

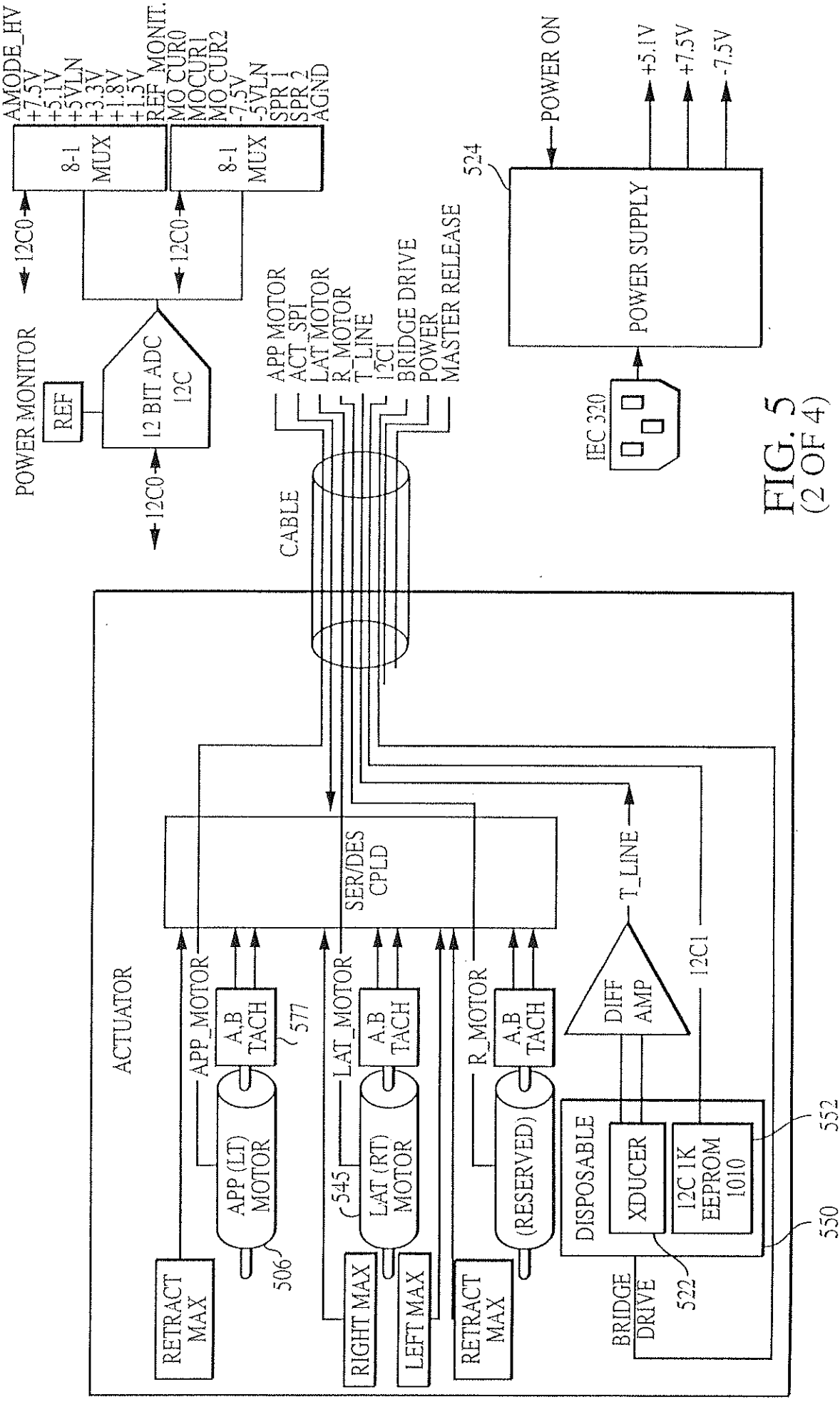

AMODE_HV
+7.5V
+5.1V
+5VLN
+3.3V
+1.8V
+1.5V
REF_MONIT.
MO_CUR0
MO_CUR1
MO_CUR2
-7.5V
-5VLN
SPR_1
SPR_2
AGND
8-1 MUX
8-1 MUX
12C0
12C0
12C0
POWER MONITOR
REF
12 BIT ADC 12C
APP MOTOR
ACT_SPI
LAT MOTOR
R_MOTOR
T_LINE
12C1
BRIDGE DRIVE
POWER
MASTER RELEASE
CABLE
524
POWER ON
+5.1V
+7.5V
-7.5V
POWER SUPPLY
IEC 320
ACTUATOR
SER/DES CPLD
T_LINE
12C1
APP_MOTOR
LAT_MOTOR
R_MOTOR
A,B TACH
A,B TACH
A,B TACH
577
DIFF AMP
APP (LT) MOTOR
LAT (RT) MOTOR
(RESERVED)
506
545
DISPOSABLE
XDUCER
12C 1K EEPROM 1010
552
550
RETRACT MAX
RIGHT MAX
LEFT MAX
RETRACT MAX
BRIDGE DRIVE
522

FIG. 5
(2 OF 4)

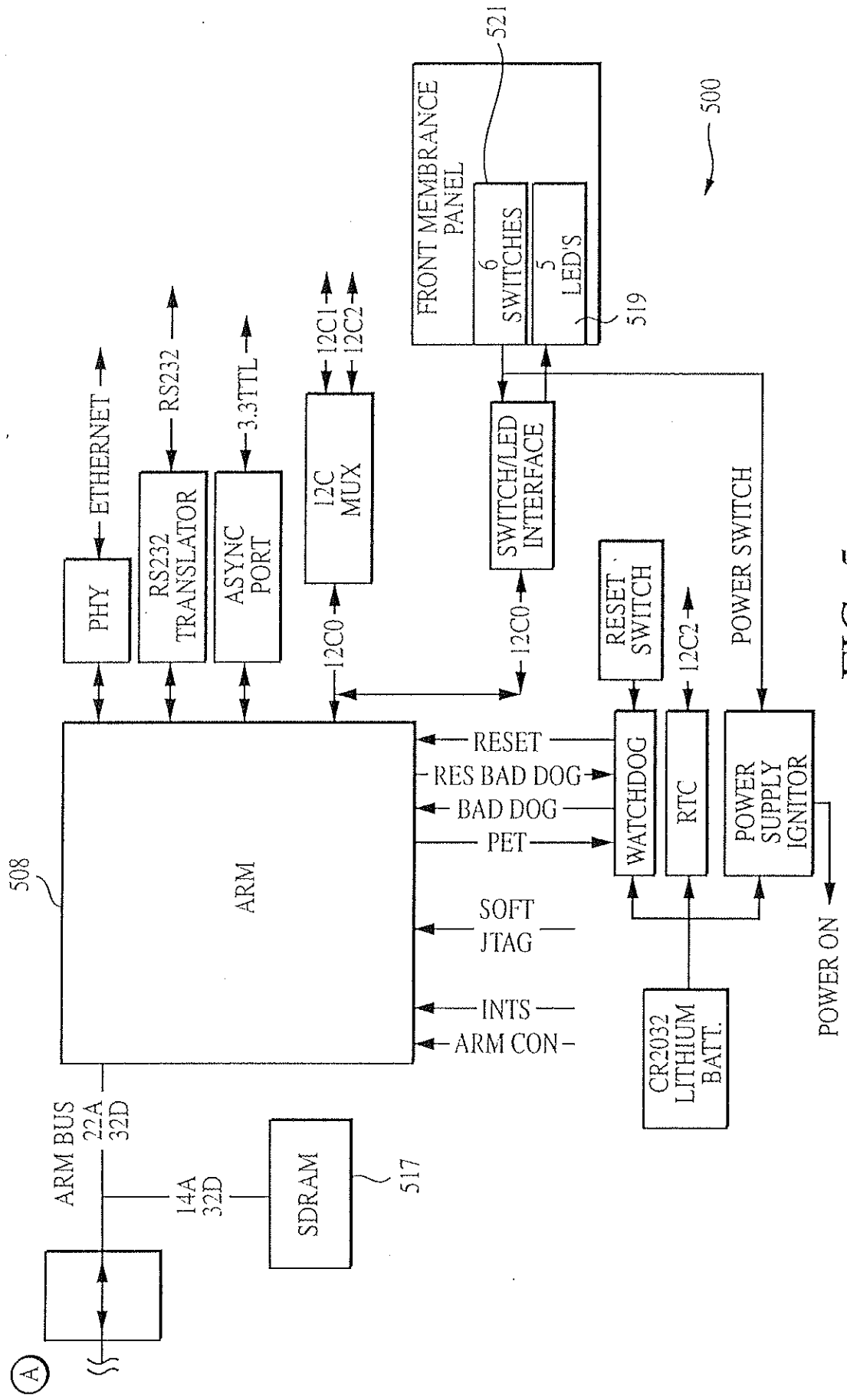

500
FRONT MEMBRANCE PANEL
521
6 SWITCHES
5 LED'S
519
ETHERNET
RS232
3.3TTL
12C1
12C2
PHY
RS232 TRANSLATOR
ASYNC PORT
12C MUX
SWITCH/LED INTERFACE
RESET SWITCH
POWER SWITCH
12C0
12C0
12C2
508
ARM
RESET
RES BAD DOG
BAD DOG
PET
SOFT
JTAG
INTS
ARM CON
WATCHDOG
RTC
POWER SUPPLY IGNITOR
POWER ON
CR2032 LITHIUM BATT.
ARM BUS 22A 32D
14A 32D
SDRAM
517
A

FIG. 5
(3 OF 4)

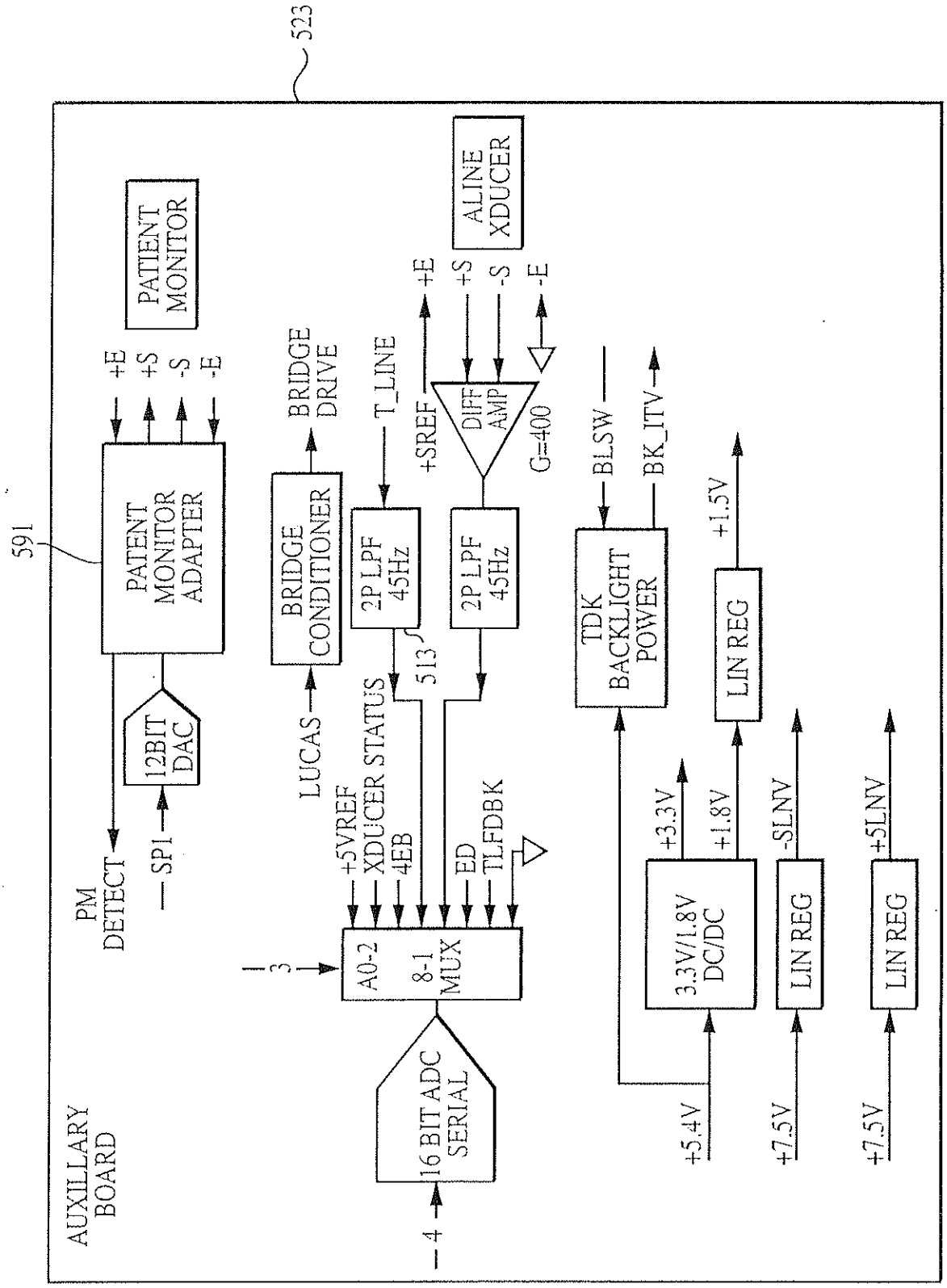

523
591
AUXILLARY BOARD
PATIENT MONITOR
PATIENT MONITOR ADAPTER
12BIT DAC
PM DETECT
SP1
+E
+S
-S
-E
BRIDGE CONDITIONER
BRIDGE DRIVE
LUCAS
2P LPF 45Hz
T_LINE
513
+5VREF
XDUCER STATUS
4EB
ED
TLFDBK
A0-2
8-1 MUX
3
16 BIT ADC SERIAL
4
ALINE XDUCER
+SREF
DIFF AMP
G=400
TDK BACKLIGHT POWER
BLSW
BK_ITV
+1.5V
LIN REG
+3.3V
+1.8V
3.3V/1.8V DC/DC
+5.4V
-5LNV
+7.5V
+5LNV

FIG. 5
(4 OF 4)

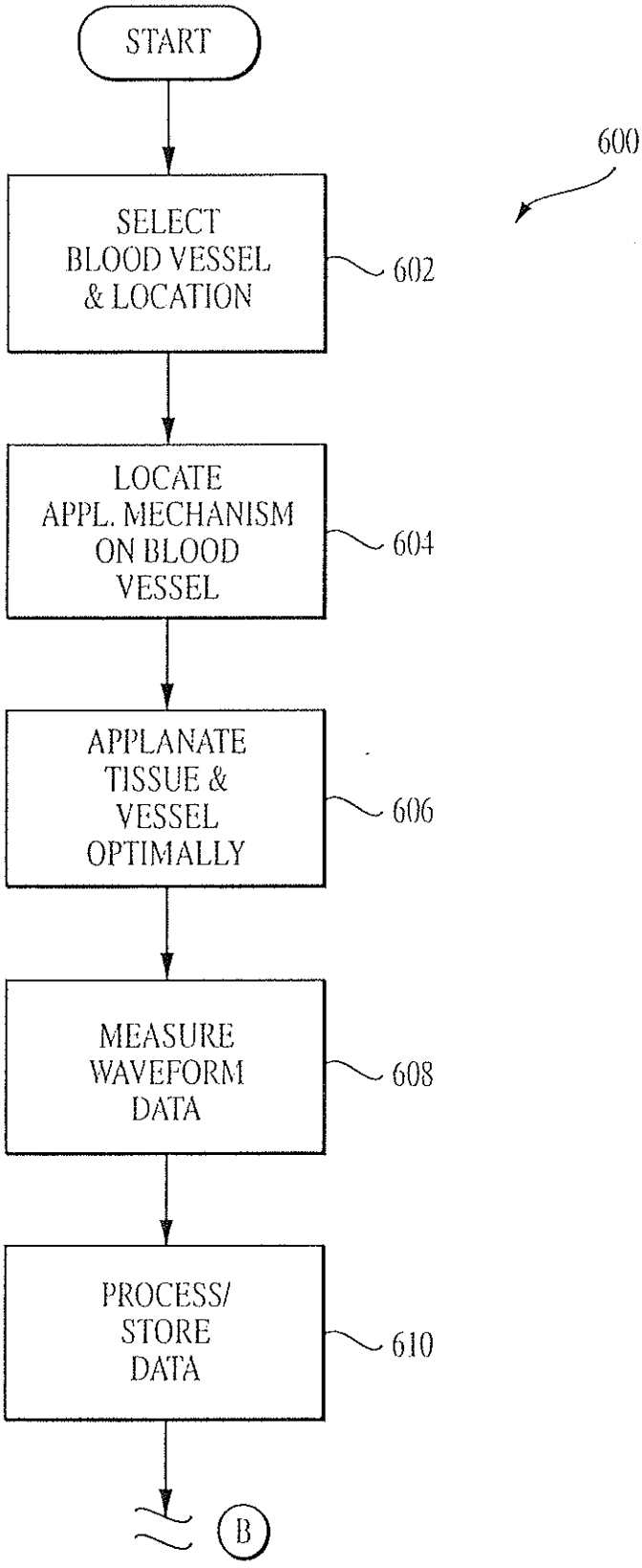

START
600
SELECT BLOOD VESSEL & LOCATION
602
LOCATE APPL. MECHANISM ON BLOOD VESSEL
604
APPLANATE TISSUE & VESSEL OPTIMALLY
606
MEASURE WAVEFORM DATA
608
PROCESS/ STORE DATA
610
B

FIG. 6
(1 OF 2)

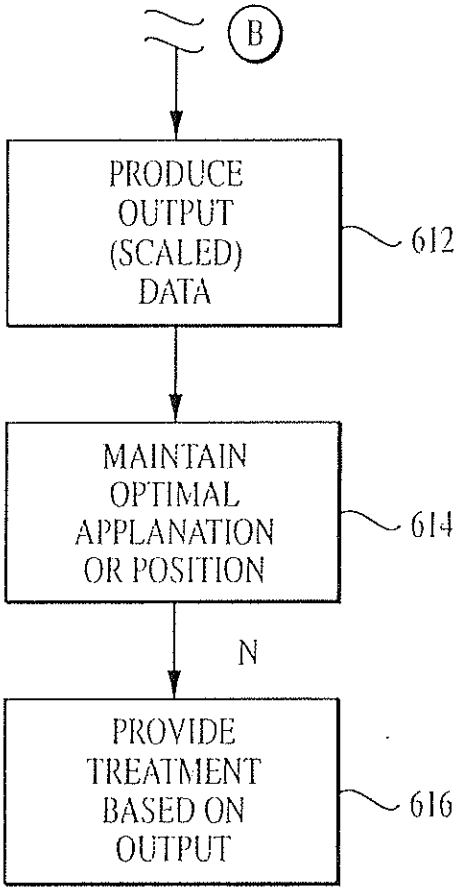

B
PRODUCE OUTPUT (SCALED) DATA
612
MAINTAIN OPTIMAL APPLANATION OR POSITION
614
N
PROVIDE TREATMENT BASED ON OUTPUT
616

FIG. 6
(2 OF 2)

26_JAN 2007

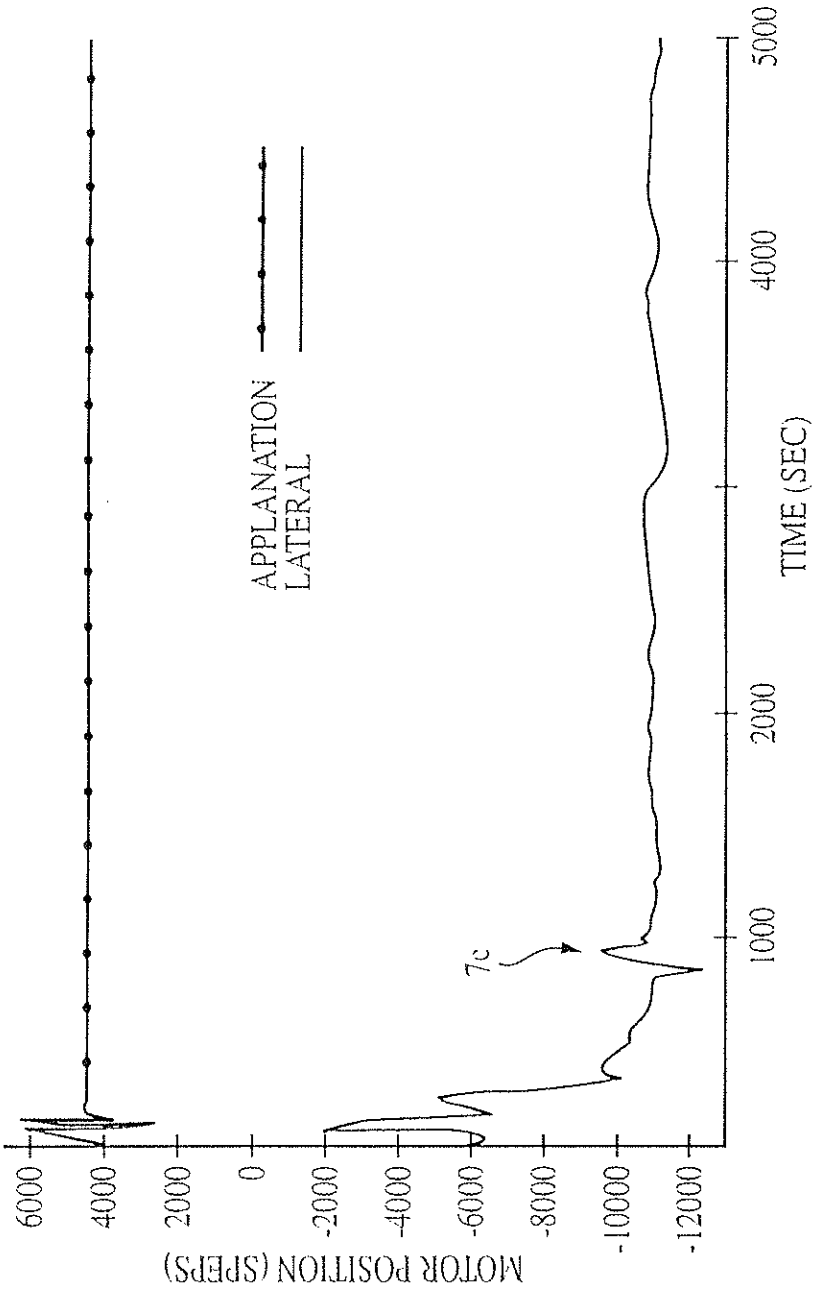


FIG. 7a

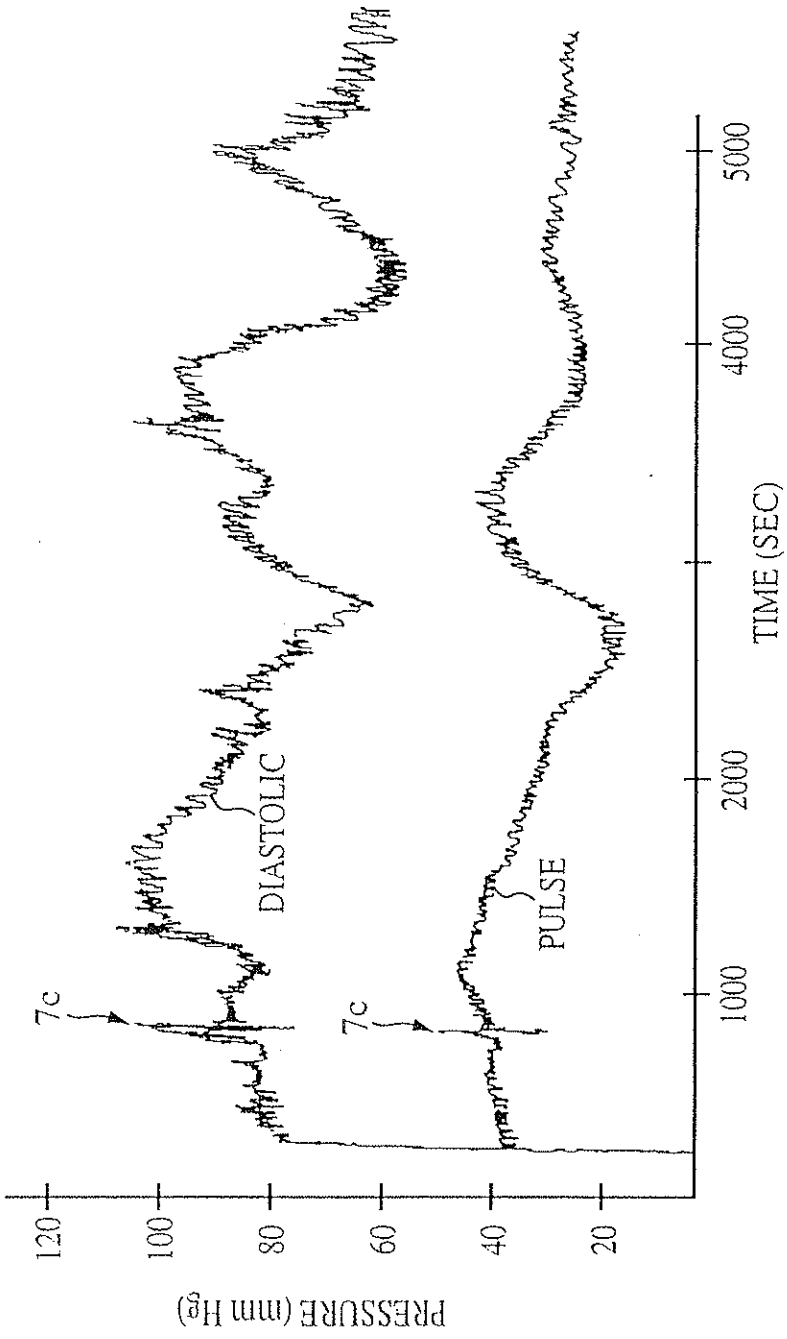

PRESSURE (mm Hg)
120
100
80
60
40
20
1000
2000
4000
5000
TIME (SEC)
DIASTOLIC
PULSE
7c
7c

FIG. 7b

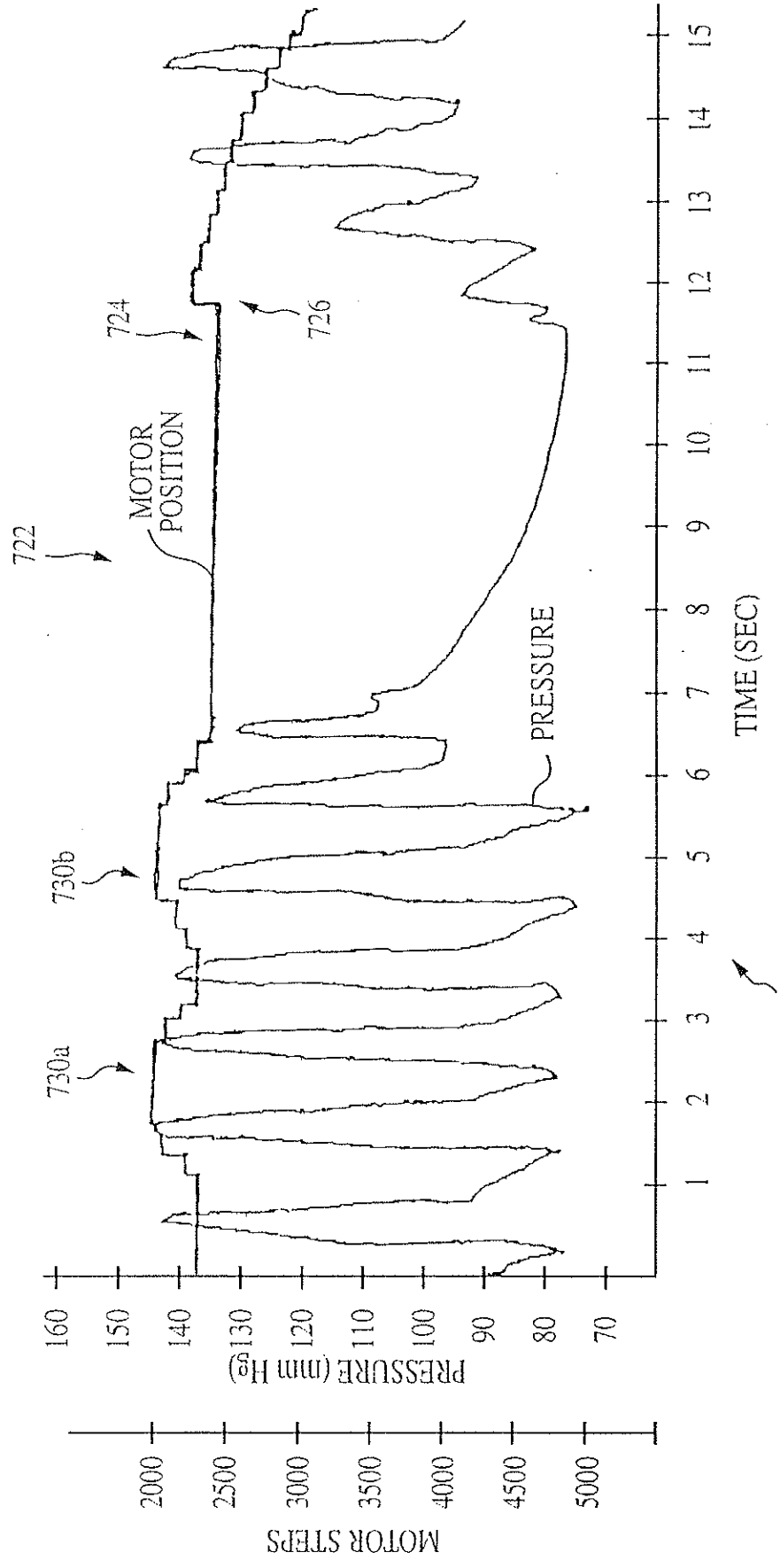

MOTOR STEPS
2000
2500
3000
3500
4000
4500
5000
PRESSURE (mm Hg)
160
150
140
130
120
110
100
90
80
70
TIME (SEC)
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
720
722
724
726
730a
730b
MOTOR POSITION
PRESSURE

FIG. 7c

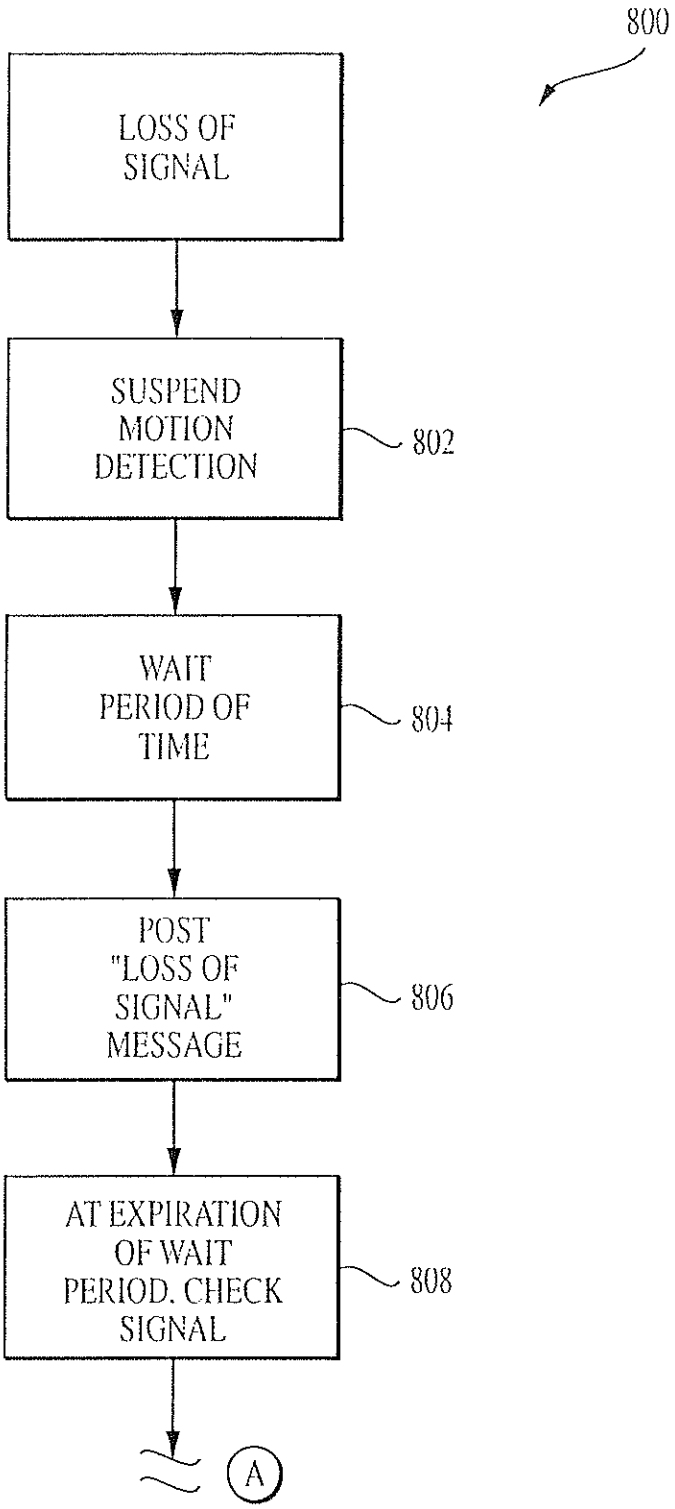

800
LOSS OF SIGNAL
SUSPEND MOTION DETECTION
802
WAIT PERIOD OF TIME
804
POST "LOSS OF SIGNAL" MESSAGE
806
AT EXPIRATION OF WAIT PERIOD. CHECK SIGNAL
808
A

FIG. 8
(1 OF 2)

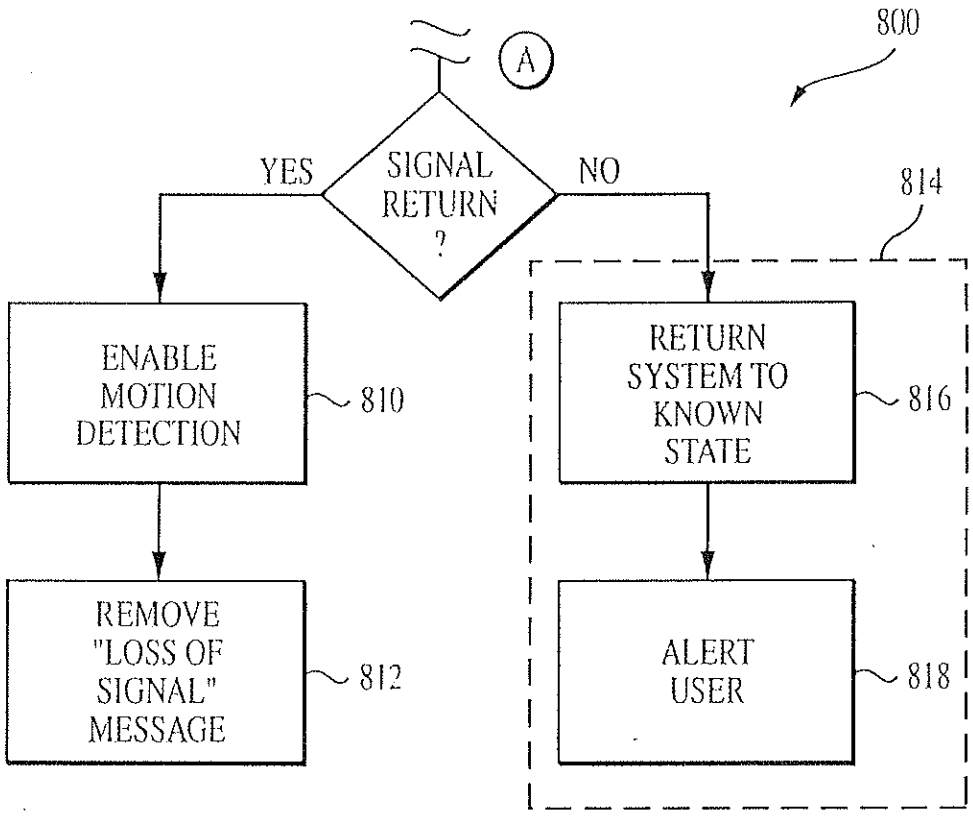

800
A
SIGNAL RETURN ?
YES
NO
814
ENABLE MOTION DETECTION
810
REMOVE "LOSS OF SIGNAL" MESSAGE
812
RETURN SYSTEM TO KNOWN STATE
816
ALERT USER
818

FIG. 8
(2 OF 2)

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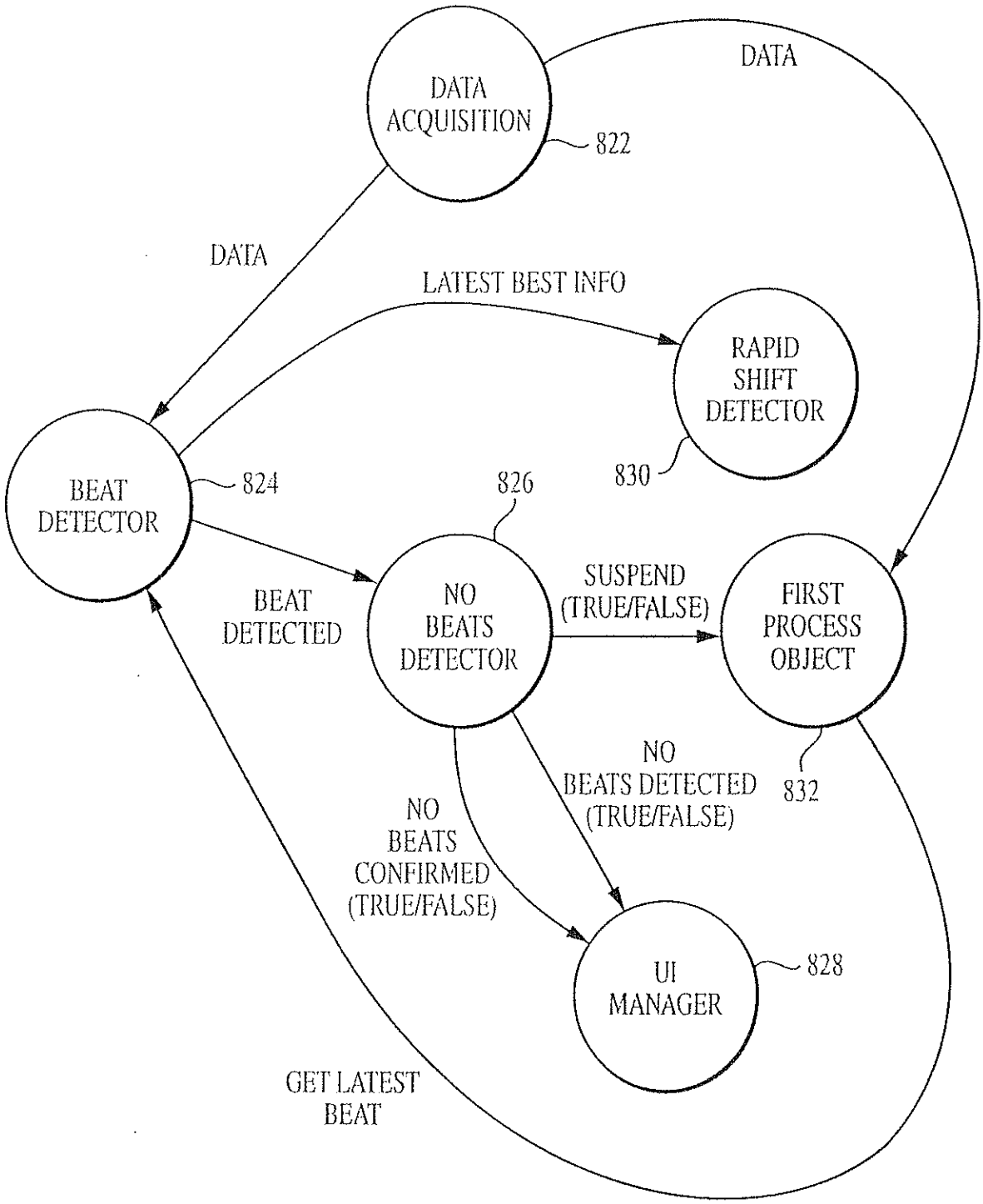


FIG. 8a

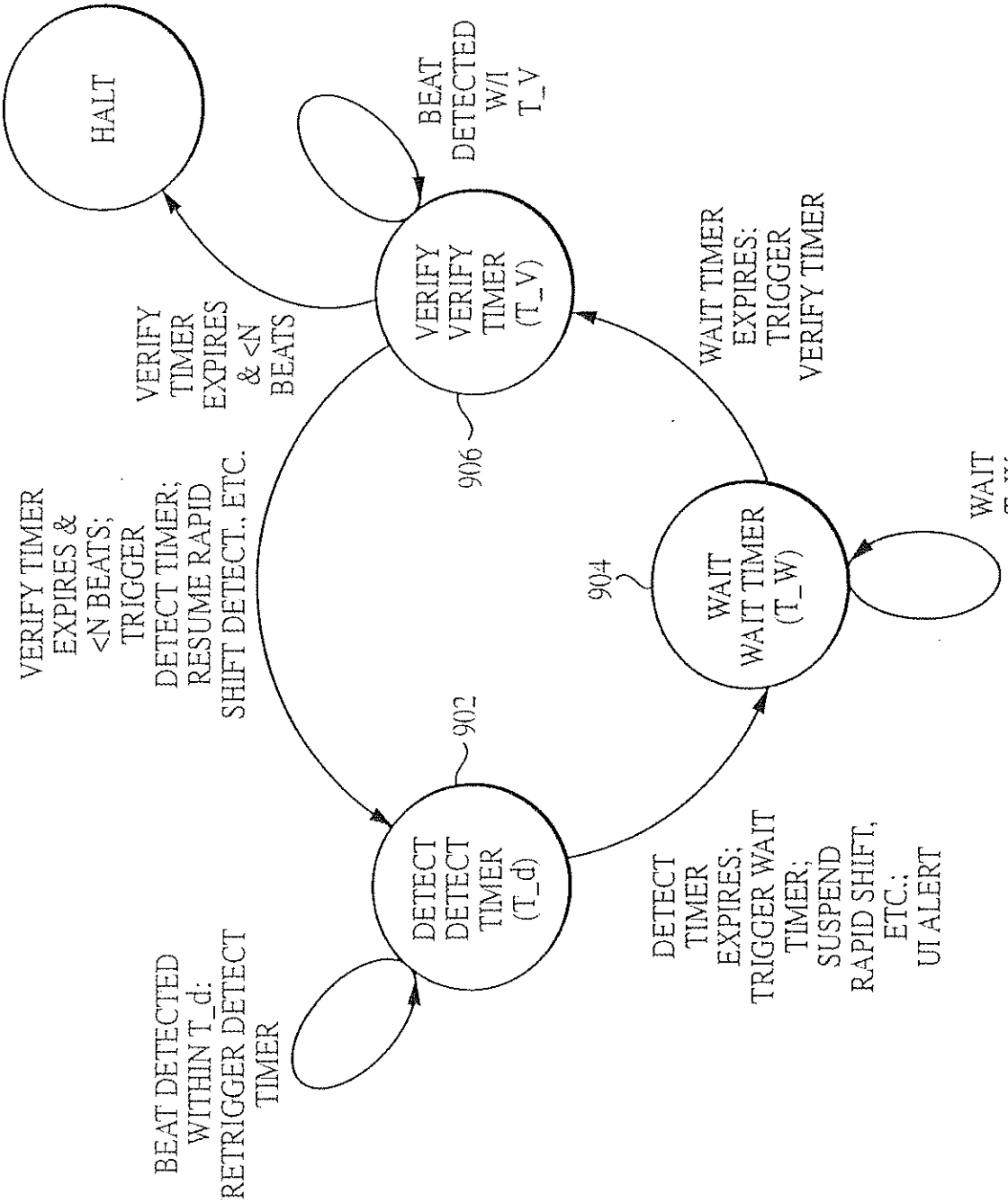

HALT
BEAT DETECTED W/I T_V
VERIFY TIMER EXPIRES & <N BEATS
VERIFY VERIFY TIMER (T_V)
906
WAIT TIMER EXPIRES: TRIGGER VERIFY TIMER
VERIFY TIMER EXPIRES & <N BEATS; TRIGGER DETECT TIMER; RESUME RAPID SHIFT DETECT., ETC.
902
904
WAIT WAIT TIMER (T_W)
WAIT T_W
BEAT DETECTED WITHIN T_d: RETRIGGER DETECT TIMER
DETECT DETECT TIMER (T_d)
DETECT TIMER EXPIRES; TRIGGER WAIT TIMER; SUSPEND RAPID SHIFT, ETC.; UI ALERT

FIG. 9

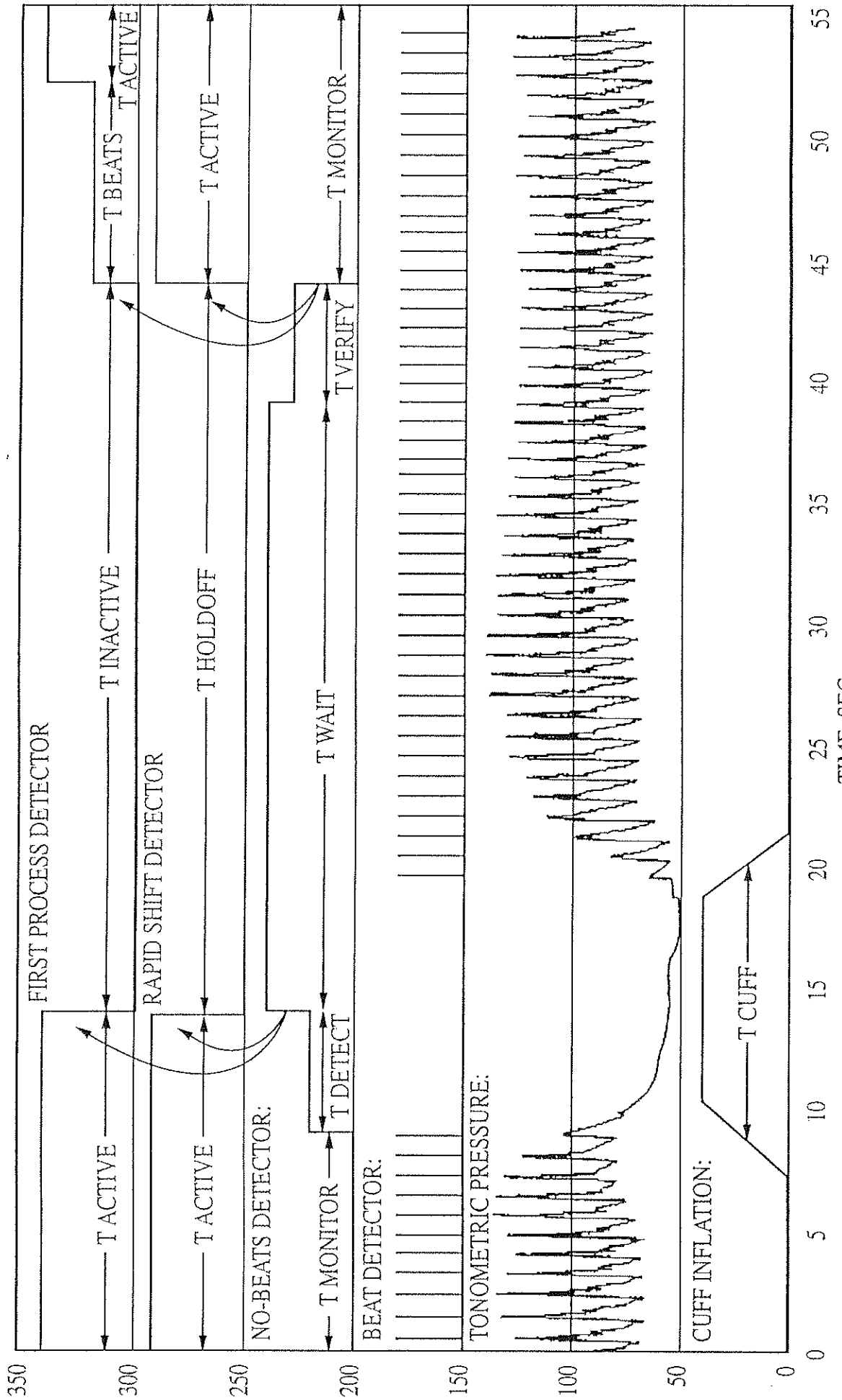

FIRST PROCESS DETECTOR
T ACTIVE
T INACTIVE
T BEATS
T ACTIVE
RAPID SHIFT DETECTOR
T ACTIVE
T HOLDOFF
T ACTIVE
NO-BEATS DETECTOR:
T MONITOR
T WAIT
T DETECT
T VERIFY
T MONITOR
BEAT DETECTOR:
TONOMETRIC PRESSURE:
CUFF INFLATION:
T CUFF
350
300
250
200
150
100
50
0
0
5
10
15
20
25
30
35
40
45
50
55
TIME, SEC

FIG. 10

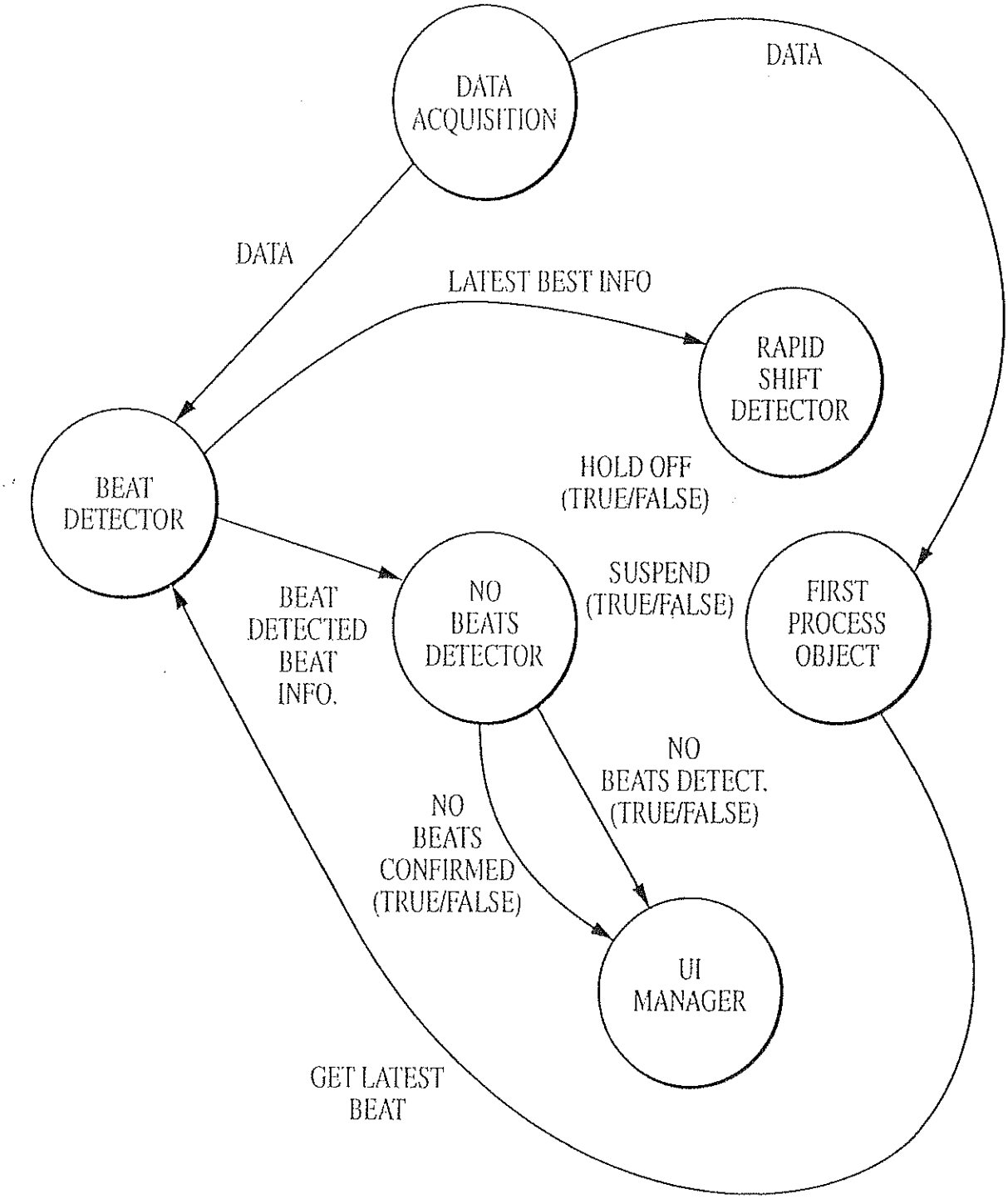

DATA ACQUISITION
DATA
DATA
LATEST BEST INFO
RAPID SHIFT DETECTOR
BEAT DETECTOR
HOLD OFF (TRUE/FALSE)
BEAT DETECTED BEAT INFO.
NO BEATS DETECTOR
SUSPEND (TRUE/FALSE)
FIRST PROCESS OBJECT
NO BEATS DETECT. (TRUE/FALSE)
NO BEATS CONFIRMED (TRUE/FALSE)
UI MANAGER
GET LATEST BEAT

FIG. 11

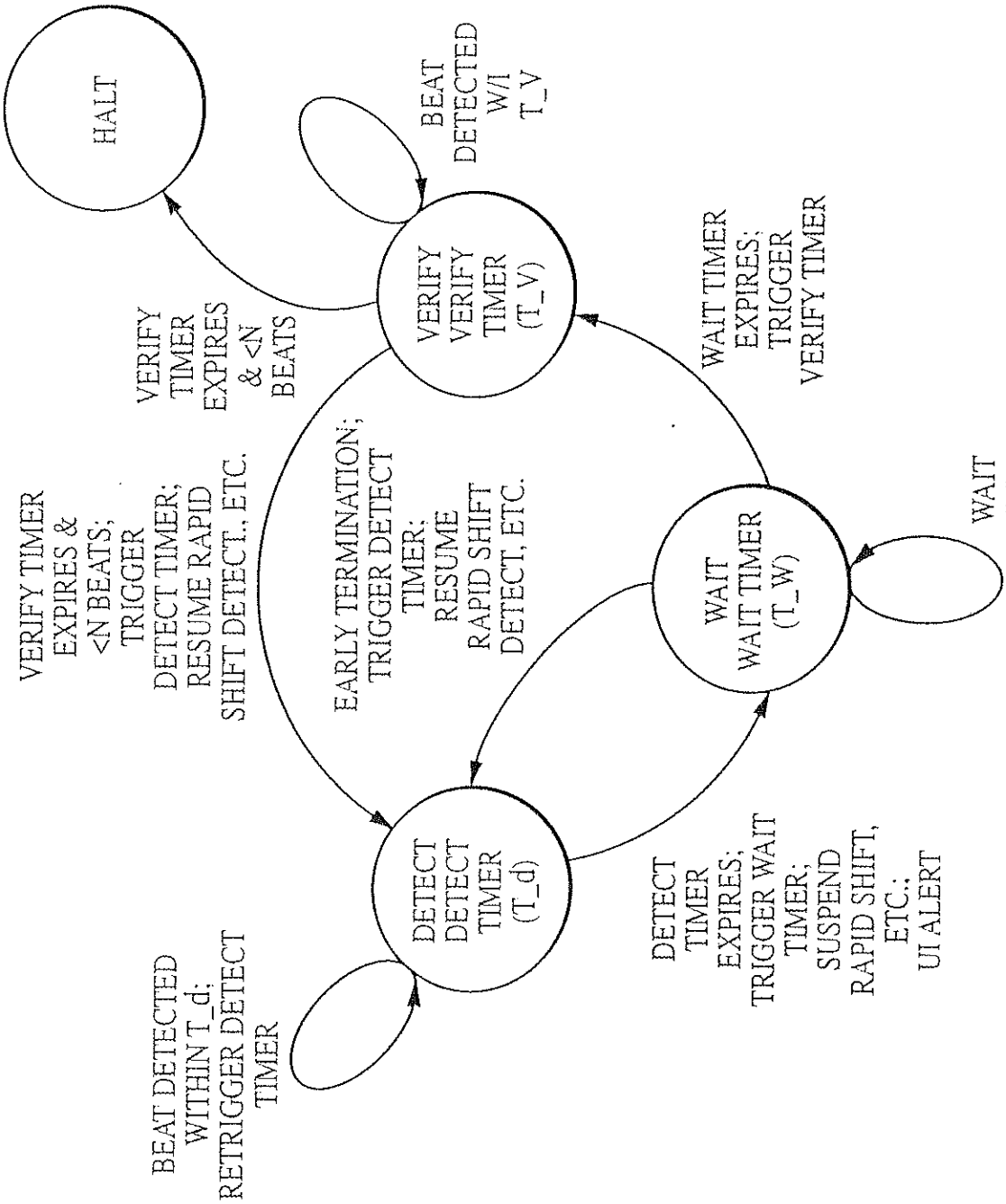

HALT
BEAT DETECTED W/I T_V
VERIFY TIMER EXPIRES & <N BEATS
VERIFY VERIFY TIMER (T_V)
WAIT TIMER EXPIRES; TRIGGER VERIFY TIMER
VERIFY TIMER EXPIRES & <N BEATS; TRIGGER DETECT TIMER; RESUME RAPID SHIFT DETECT., ETC.
EARLY TERMINATION; TRIGGER DETECT TIMER; RESUME RAPID SHIFT DETECT, ETC.
WAIT WAIT TIMER (T_W)
WAIT T_W
BEAT DETECTED WITHIN T_d; RETRIGGER DETECT TIMER
DETECT DETECT TIMER (T_d)
DETECT TIMER EXPIRES; TRIGGER WAIT TIMER; SUSPEND RAPID SHIFT, ETC.; UI ALERT

FIG. 12

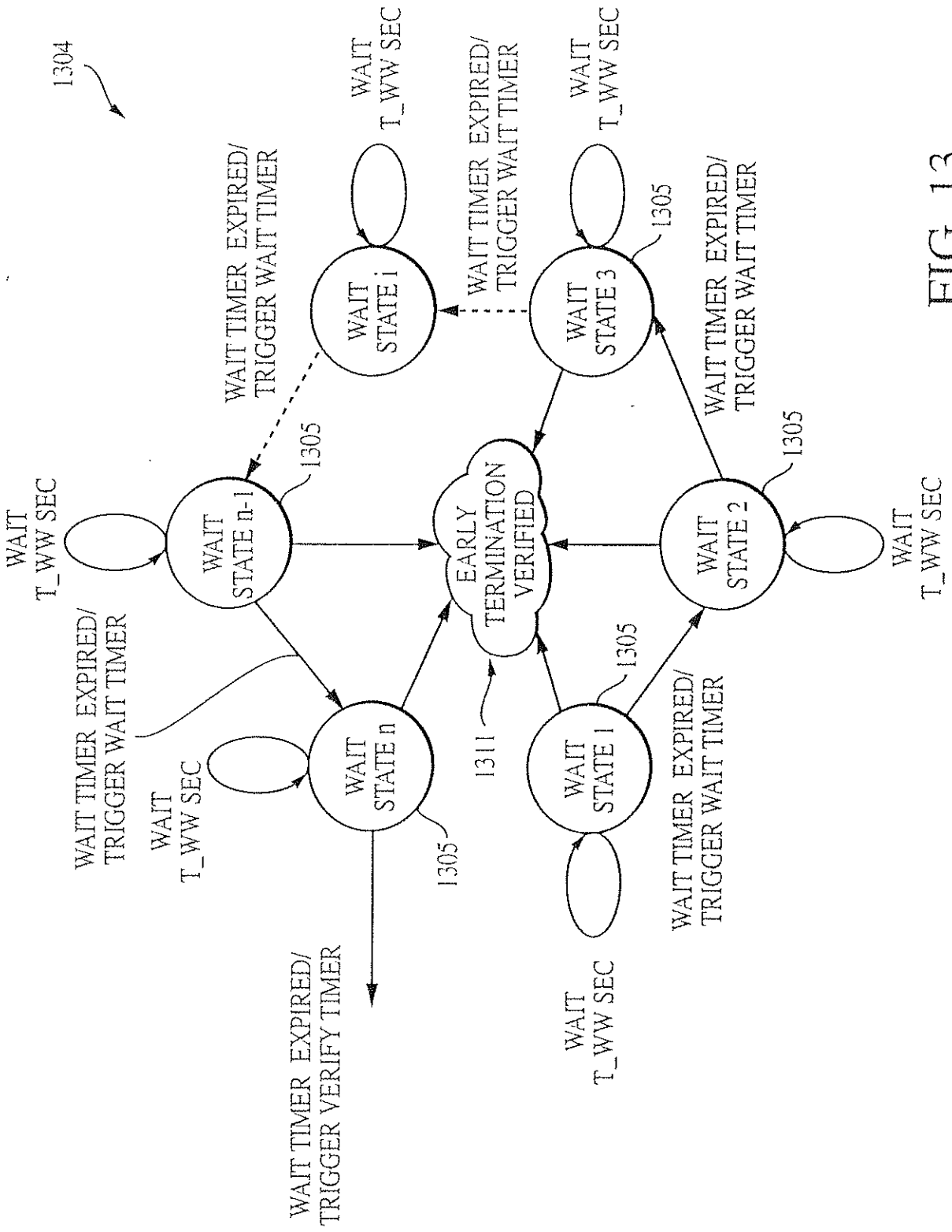

1304
WAIT STATE i
WAIT STATE 3
WAIT STATE n-1
EARLY TERMINATION VERIFIED
WAIT STATE n
WAIT STATE 1
WAIT STATE 2
1305
1311
WAIT T_WW SEC
WAIT TIMER EXPIRED/ TRIGGER WAIT TIMER
WAIT TIMER EXPIRED/ TRIGGER VERIFY TIMER

FIG. 13

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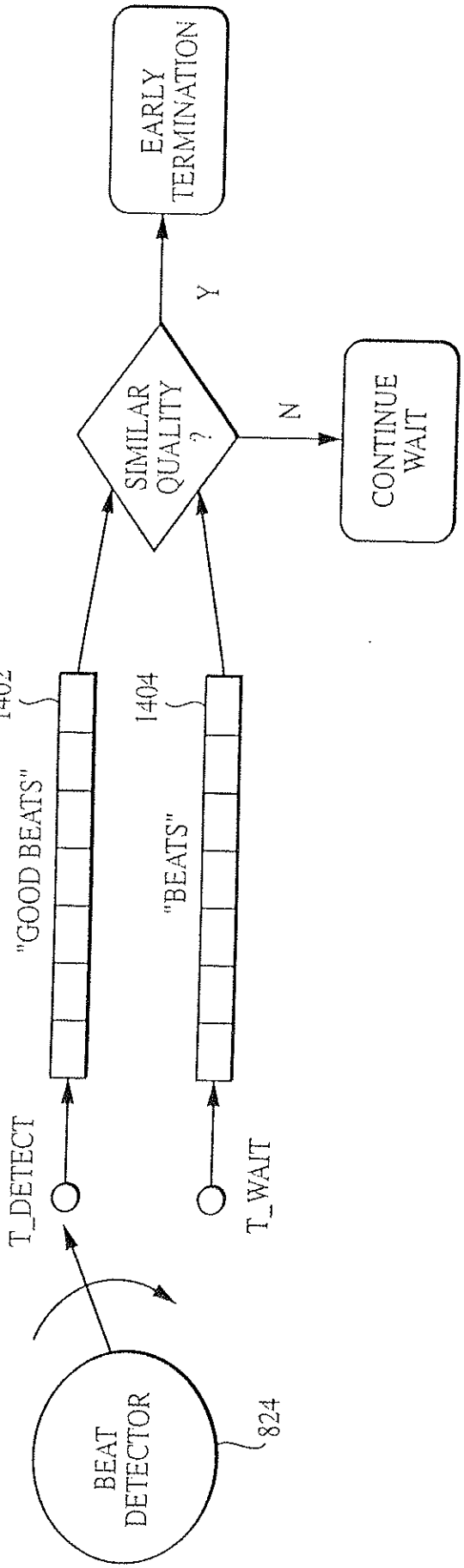


FIG. 14