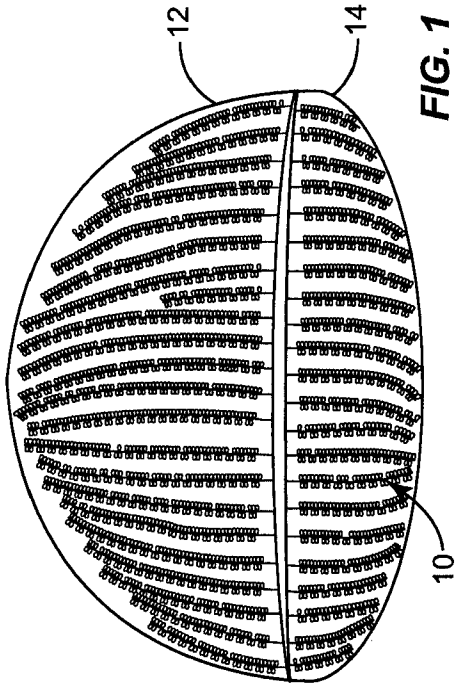


FIG. 1

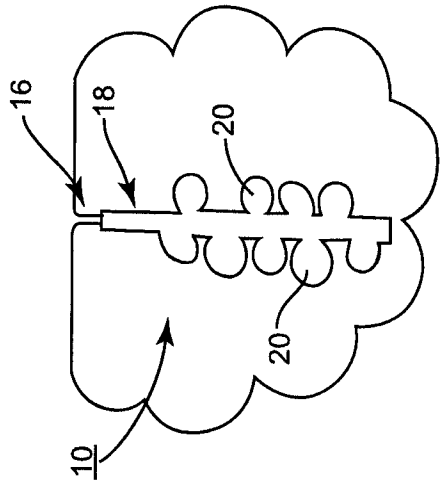


FIG. 2

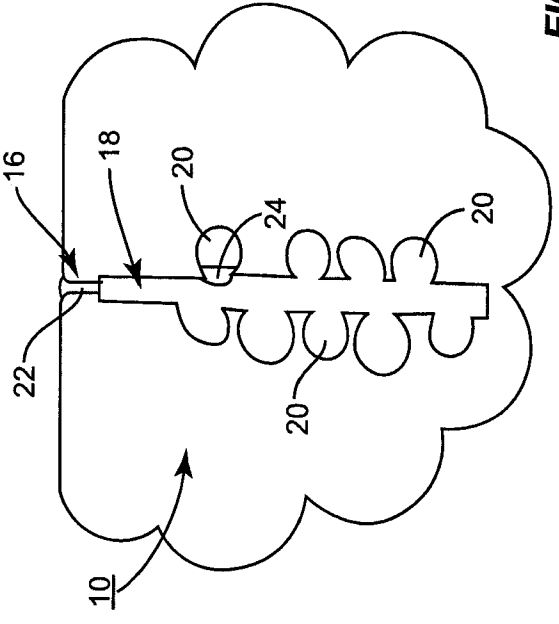


FIG. 3

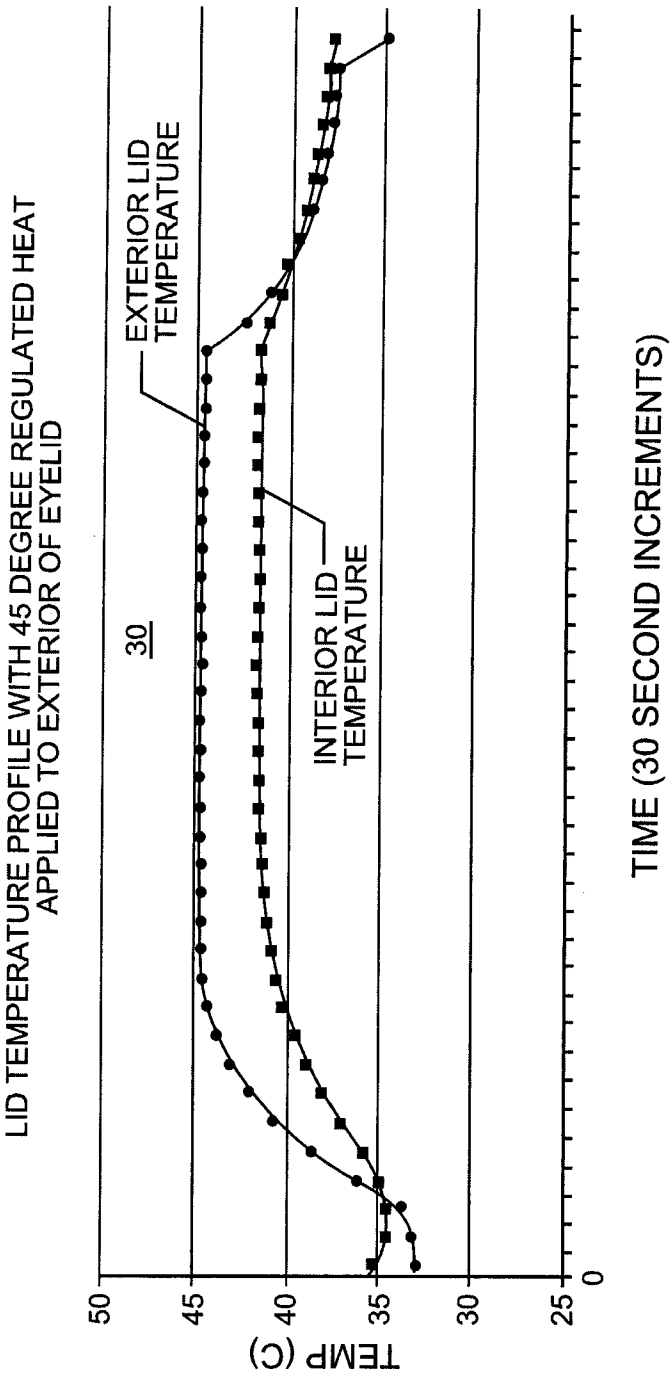

LID TEMPERATURE PROFILE WITH 45 DEGREE REGULATED HEAT APPLIED TO EXTERIOR OF EYELID
30
EXTERIOR LID TEMPERATURE
INTERIOR LID TEMPERATURE
TEMP (C)
50
45
40
35
30
25
0
TIME (30 SECOND INCREMENTS)

FIG. 4

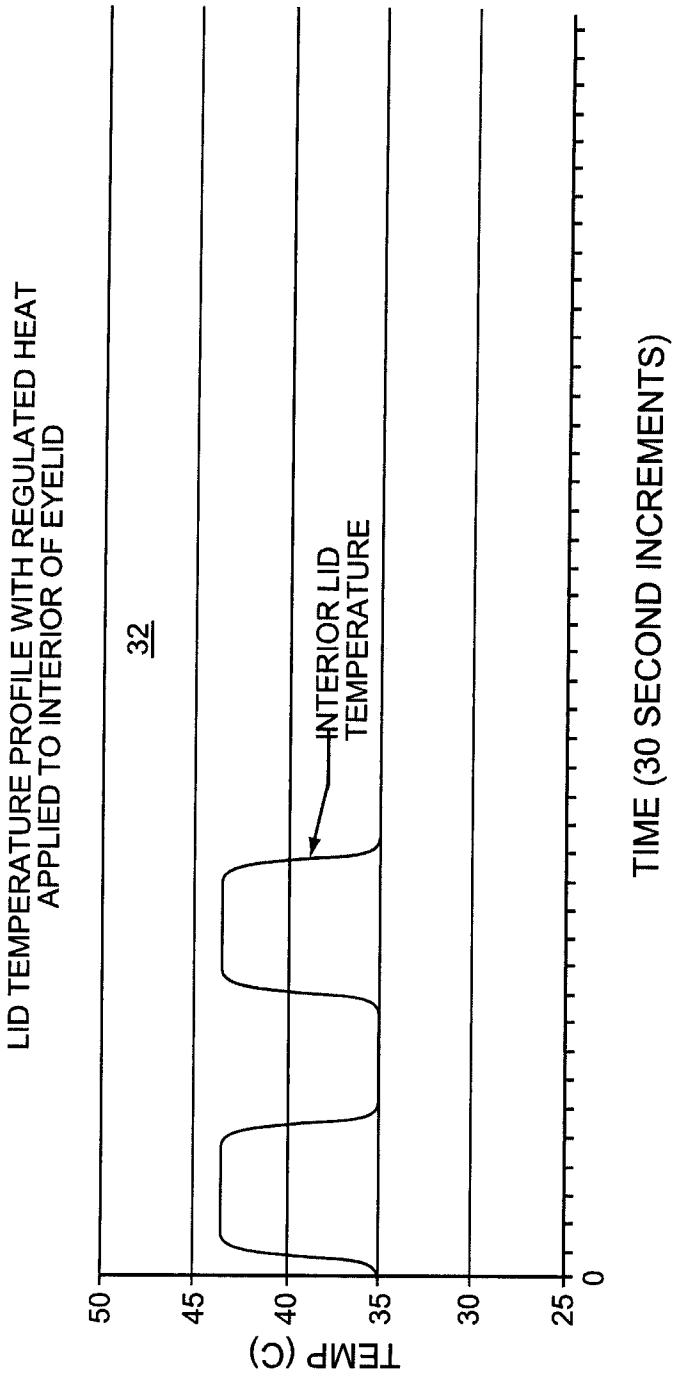

LID TEMPERATURE PROFILE WITH REGULATED HEAT APPLIED TO INTERIOR OF EYELID
32
INTERIOR LID TEMPERATURE
TEMP (C)
50
45
40
35
30
25
0
TIME (30 SECOND INCREMENTS)

FIG. 5

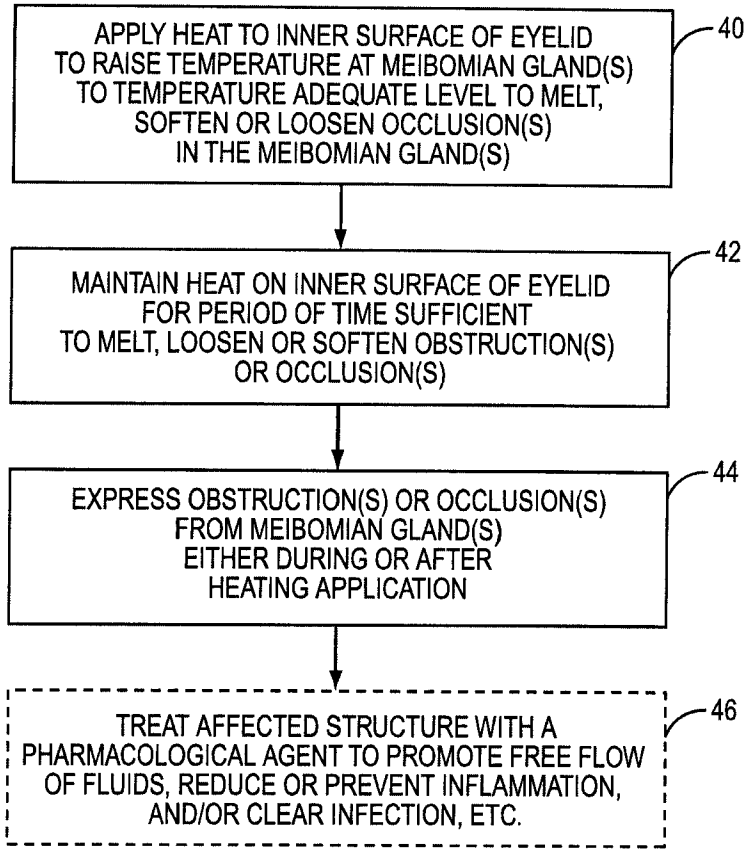

APPLY HEAT TO INNER SURFACE OF EYELID TO RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) TO TEMPERATURE ADEQUATE LEVEL TO MELT, SOFTEN OR LOOSEN OCCLUSION(S) IN THE MEIBOMIAN GLAND(S)
40
MAINTAIN HEAT ON INNER SURFACE OF EYELID FOR PERIOD OF TIME SUFFICIENT TO MELT, LOOSEN OR SOFTEN OBSTRUCTION(S) OR OCCLUSION(S)
42
EXPRESS OBSTRUCTION(S) OR OCCLUSION(S) FROM MEIBOMIAN GLAND(S) EITHER DURING OR AFTER HEATING APPLICATION
44
TREAT AFFECTED STRUCTURE WITH A PHARMACOLOGICAL AGENT TO PROMOTE FREE FLOW OF FLUIDS, REDUCE OR PREVENT INFLAMMATION, AND/OR CLEAR INFECTION, ETC.
46

FIG. 6

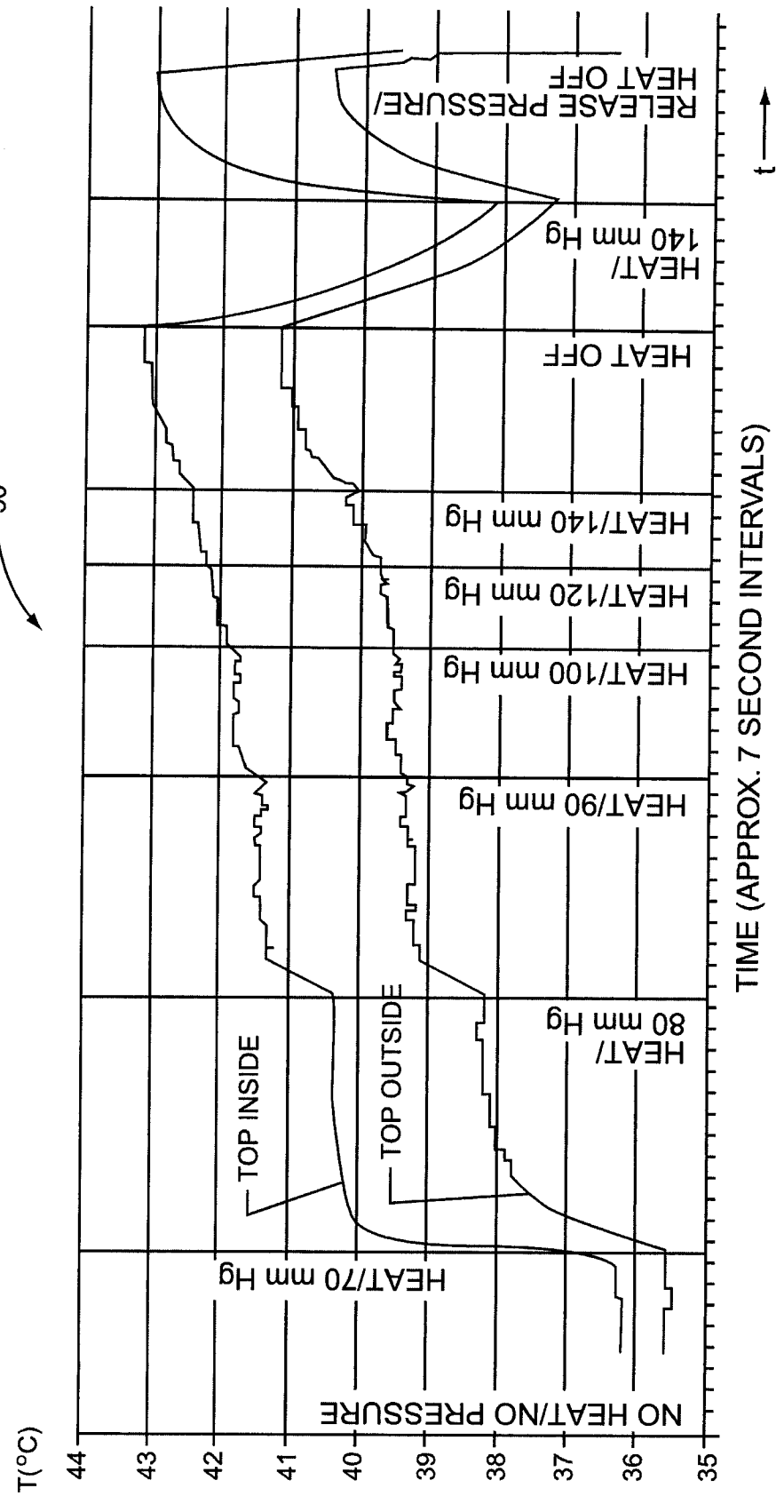

50
T(°C)
44
43
42
41
40
39
38
37
36
35
NO HEAT/NO PRESSURE
HEAT/70 mm Hg
HEAT/
80 mm Hg
HEAT/90 mm Hg
HEAT/100 mm Hg
HEAT/120 mm Hg
HEAT/140 mm Hg
HEAT OFF
HEAT/
140 mm Hg
RELEASE PRESSURE/
HEAT OFF
TOP INSIDE
TOP OUTSIDE
TIME (APPROX. 7 SECOND INTERVALS)
t

FIG. 7

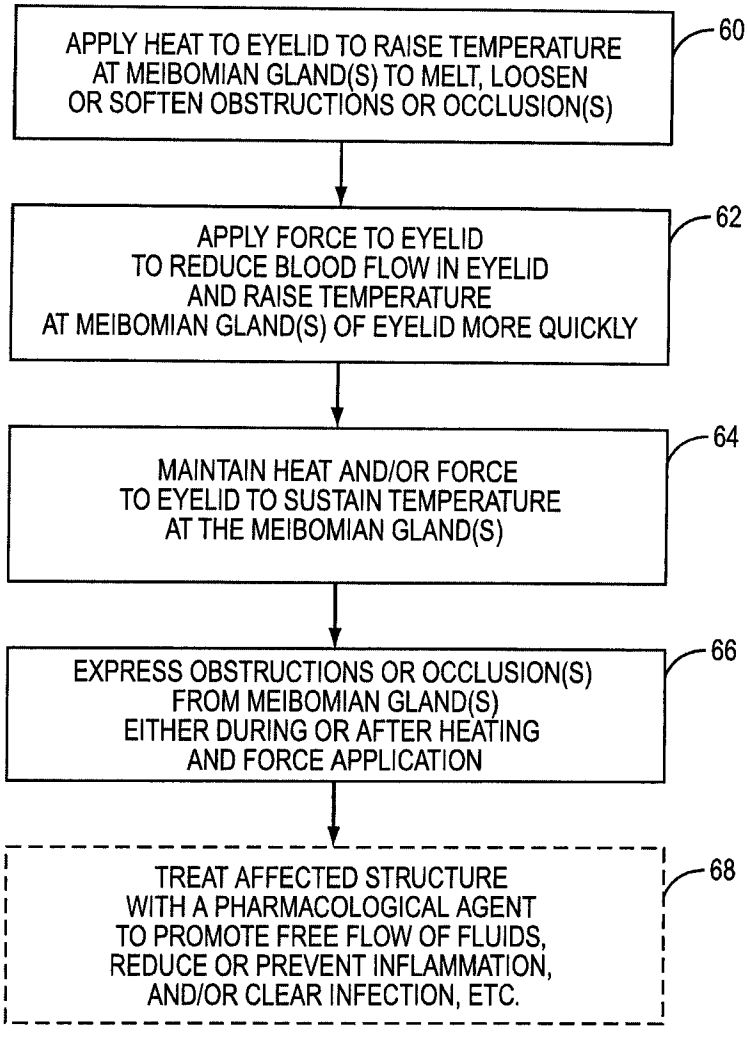

APPLY HEAT TO EYELID TO RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) TO MELT, LOOSEN OR SOFTEN OBSTRUCTIONS OR OCCLUSION(S)
60
APPLY FORCE TO EYELID TO REDUCE BLOOD FLOW IN EYELID AND RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) OF EYELID MORE QUICKLY
62
MAINTAIN HEAT AND/OR FORCE TO EYELID TO SUSTAIN TEMPERATURE AT THE MEIBOMIAN GLAND(S)
64
EXPRESS OBSTRUCTIONS OR OCCLUSION(S) FROM MEIBOMIAN GLAND(S) EITHER DURING OR AFTER HEATING AND FORCE APPLICATION
66
TREAT AFFECTED STRUCTURE WITH A PHARMACOLOGICAL AGENT TO PROMOTE FREE FLOW OF FLUIDS, REDUCE OR PREVENT INFLAMMATION, AND/OR CLEAR INFECTION, ETC.
68

FIG. 8

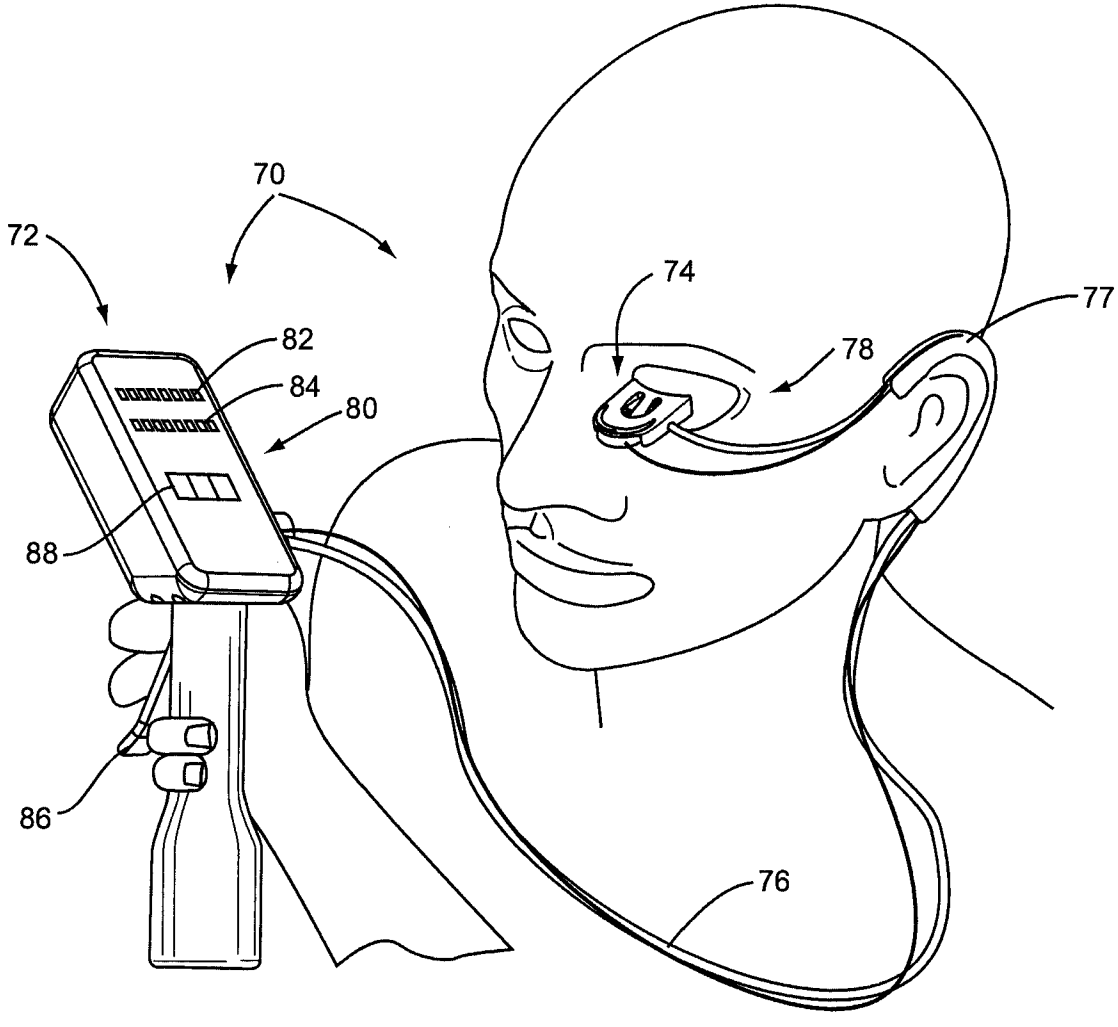


FIG. 9

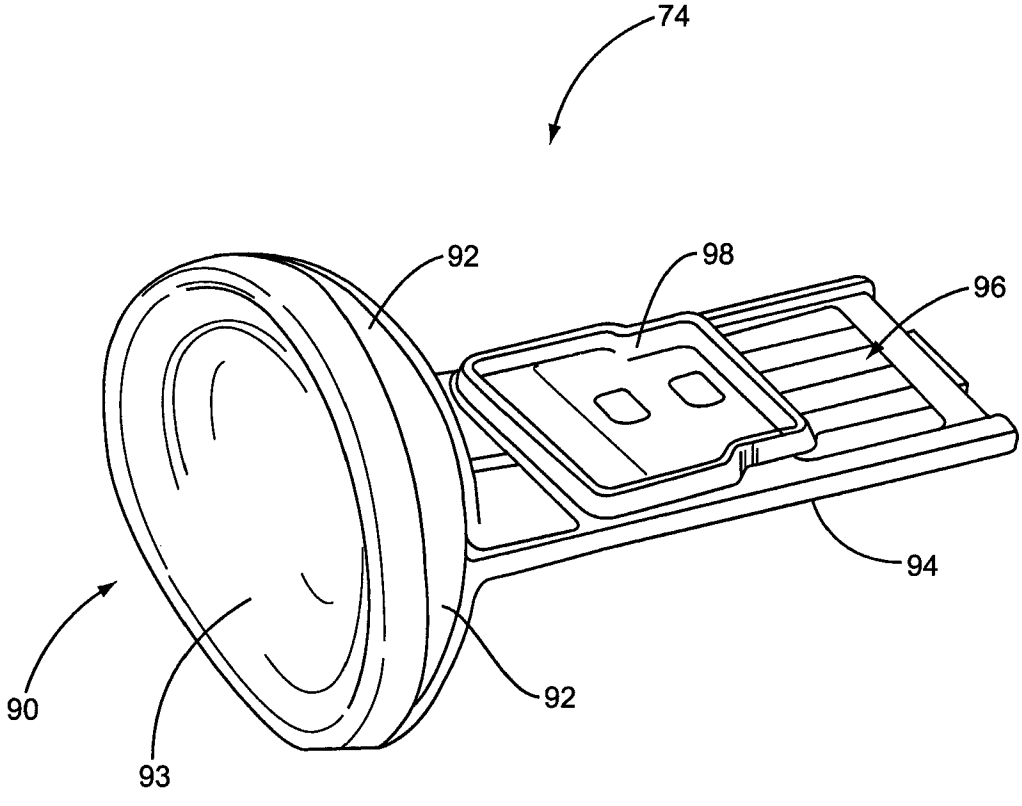


FIG. 10

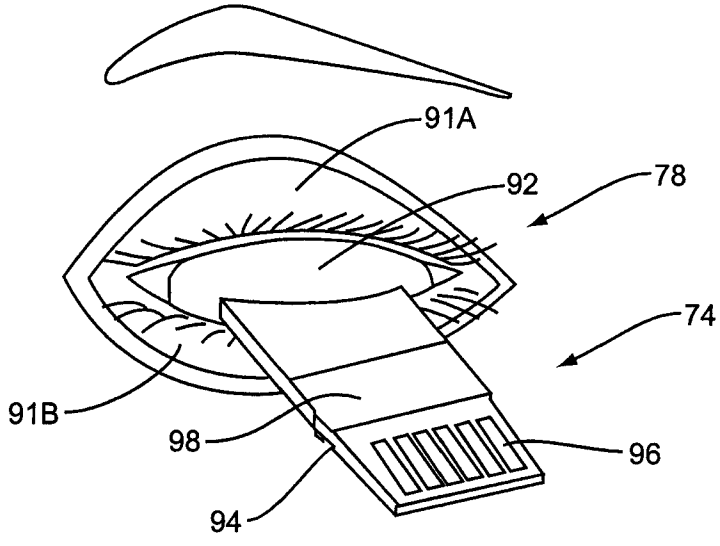


FIG. 11

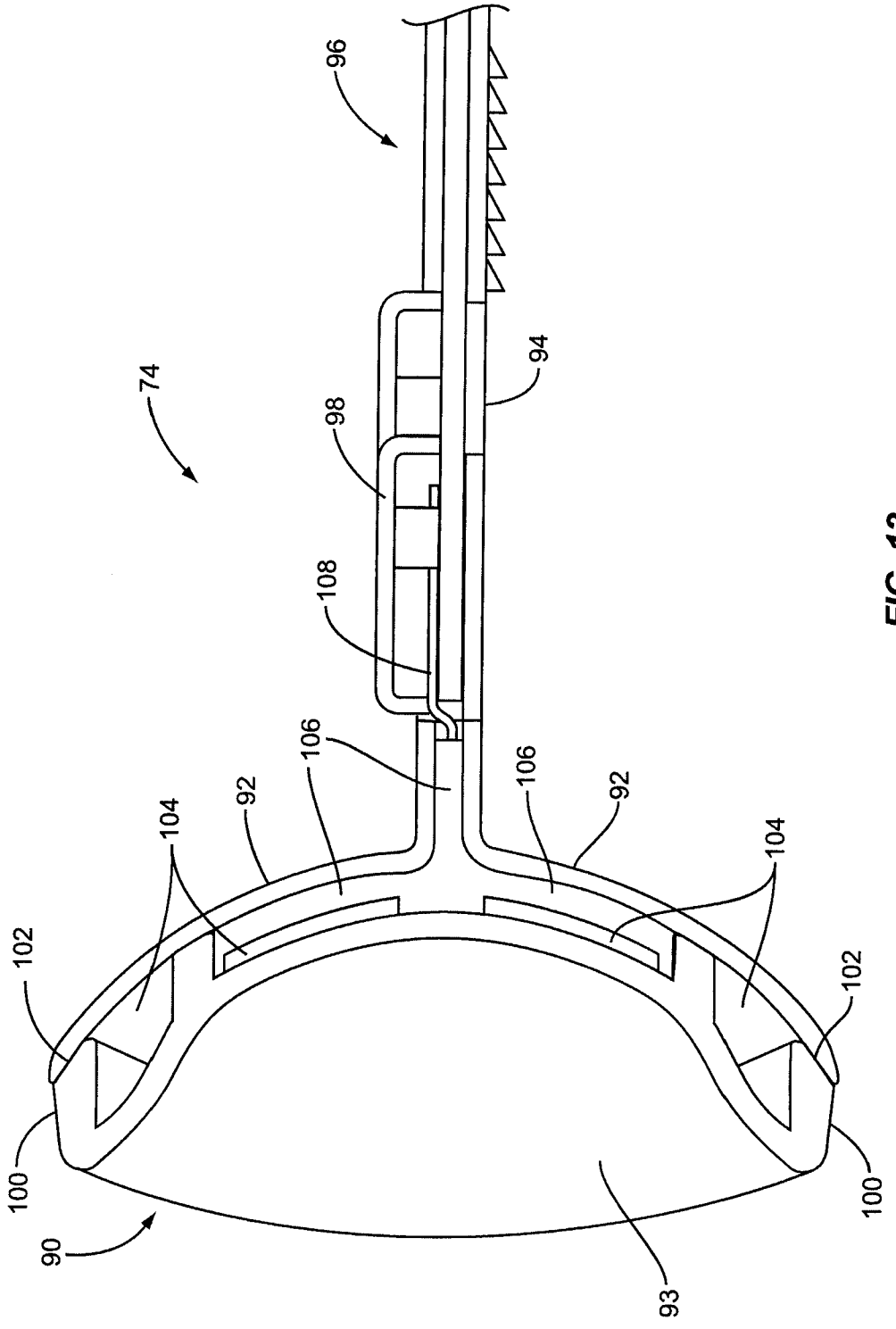


FIG. 12

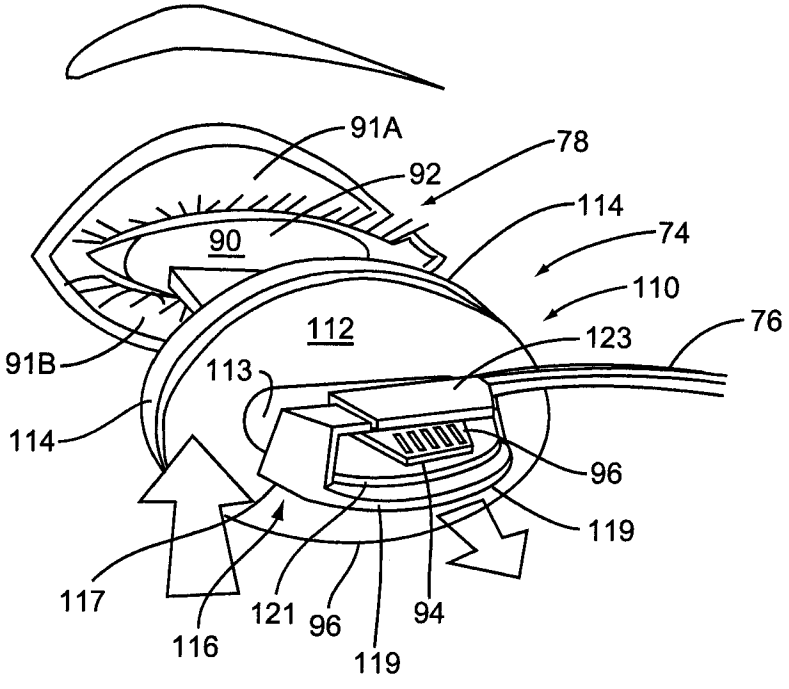


FIG. 13A

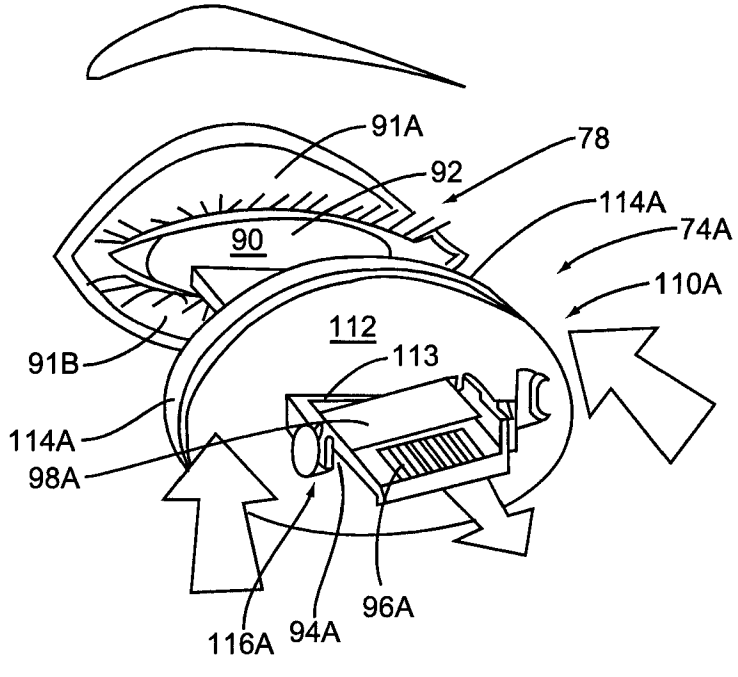


FIG. 13B

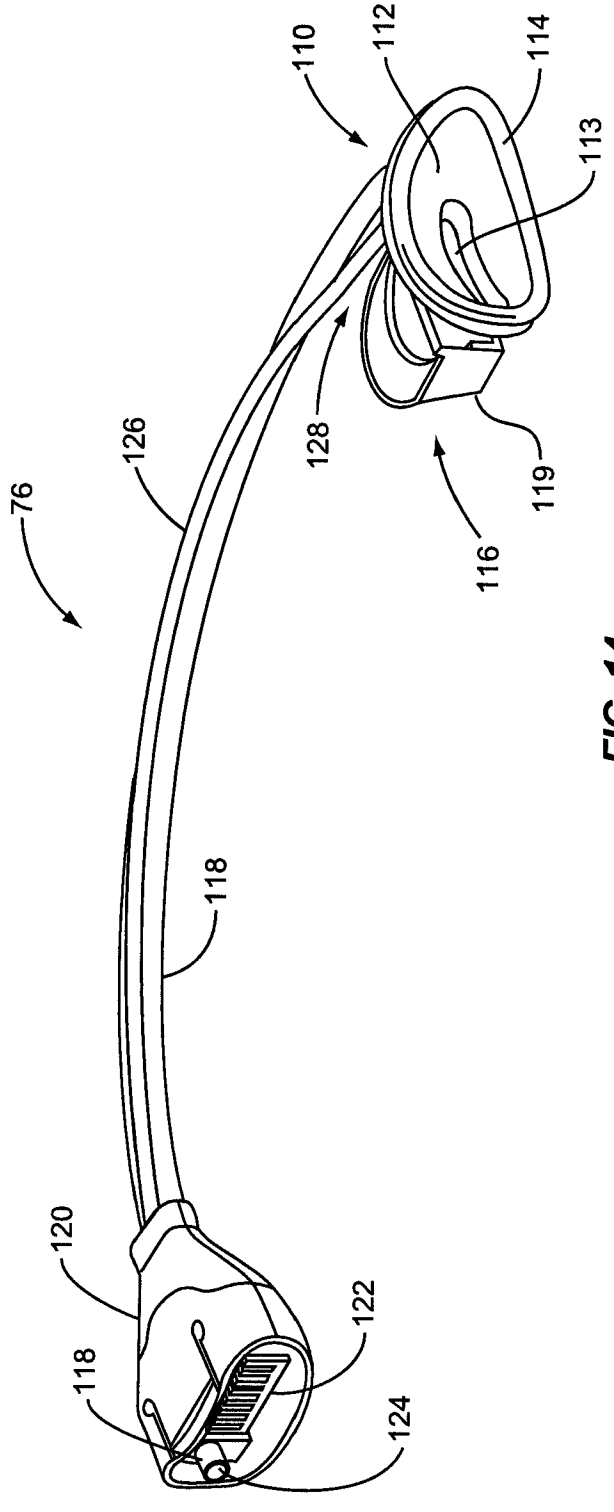


FIG. 14

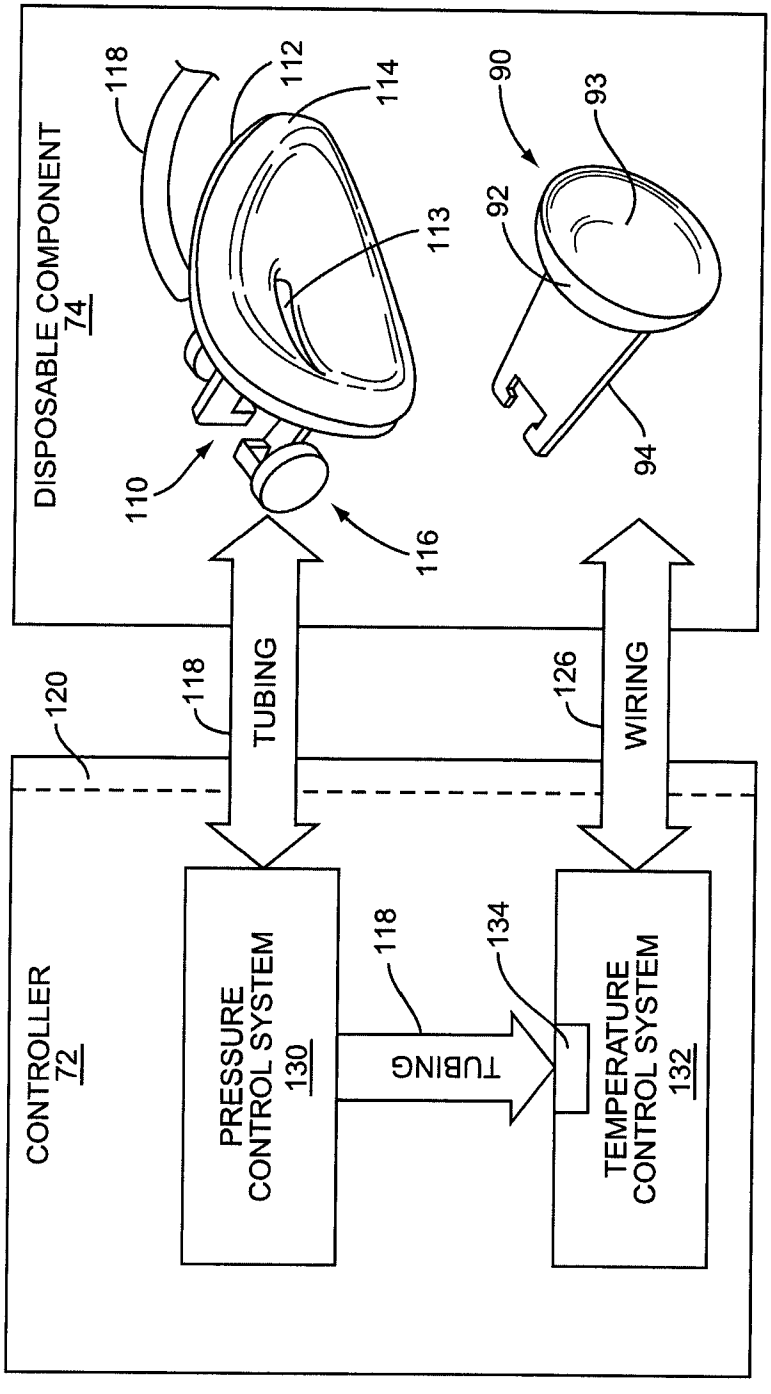

DISPOSABLE COMPONENT
74
118
112
114
113
110
116
90
93
92
94
120
118
TUBING
126
WIRING
CONTROLLER
72
PRESSURE
CONTROL SYSTEM
130
118
134
TUBING
TEMPERATURE
CONTROL SYSTEM
132

FIG. 15

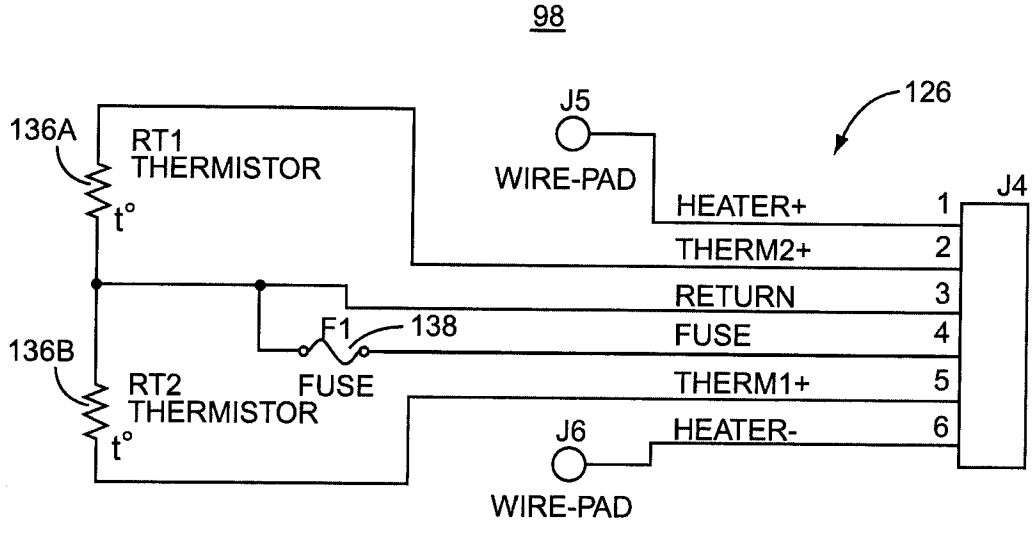

98
136A
RT1
THERMISTOR
t°
136B
RT2
THERMISTOR
t°
F1
138
FUSE
J5
WIRE-PAD
J6
WIRE-PAD
126
J4
HEATER+ 1
THERM2+ 2
RETURN 3
FUSE 4
THERM1+ 5
HEATER- 6

FIG. 16

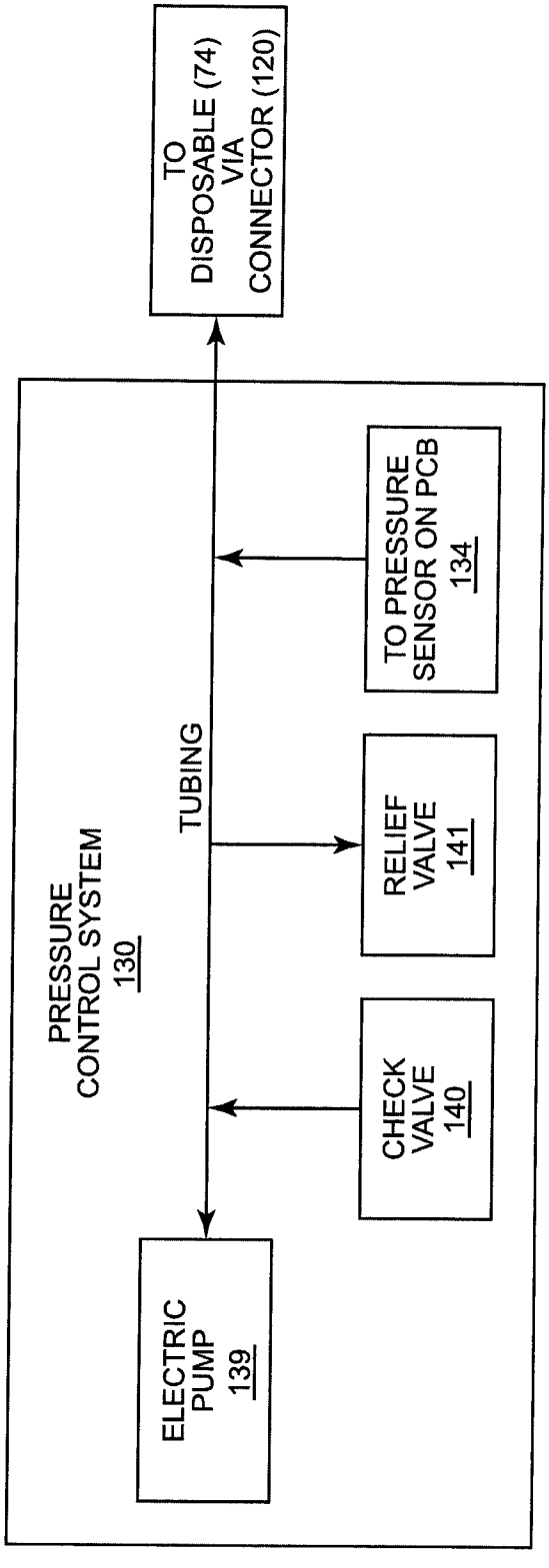

TO DISPOSABLE (74) VIA CONNECTOR (120)
PRESSURE CONTROL SYSTEM 130
TUBING
TO PRESSURE SENSOR ON PCB 134
RELIEF VALVE 141
CHECK VALVE 140
ELECTRIC PUMP 139

FIG. 17

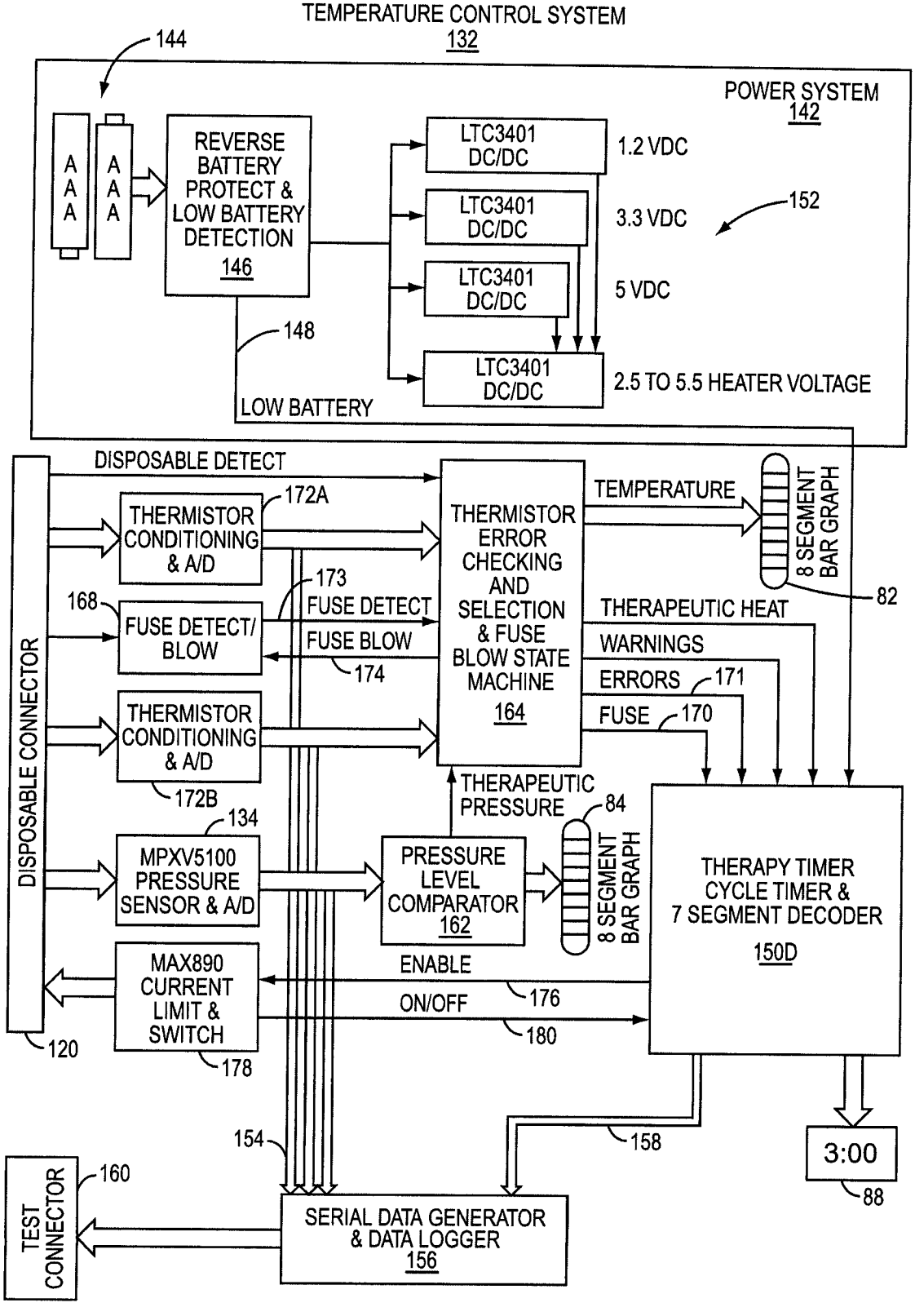

TEMPERATURE CONTROL SYSTEM
132
144
POWER SYSTEM
142
AAA
AAA
REVERSE BATTERY PROTECT & LOW BATTERY DETECTION
146
LTC3401 DC/DC
1.2 VDC
LTC3401 DC/DC
3.3 VDC
152
LTC3401 DC/DC
5 VDC
LTC3401 DC/DC
2.5 TO 5.5 HEATER VOLTAGE
148
LOW BATTERY
DISPOSABLE DETECT
DISPOSABLE CONNECTOR
THERMISTOR CONDITIONING & A/D
172A
THERMISTOR CONDITIONING & A/D
172B
FUSE DETECT/ BLOW
168
173
FUSE DETECT
FUSE BLOW
174
THERMISTOR ERROR CHECKING AND SELECTION & FUSE BLOW STATE MACHINE
164
TEMPERATURE
8 SEGMENT BAR GRAPH
82
THERAPEUTIC HEAT
WARNINGS
ERRORS
171
FUSE
170
THERAPEUTIC PRESSURE
84
MPXV5100 PRESSURE SENSOR & A/D
134
PRESSURE LEVEL COMPARATOR
162
8 SEGMENT BAR GRAPH
THERAPY TIMER CYCLE TIMER & 7 SEGMENT DECODER
150D
MAX890 CURRENT LIMIT & SWITCH
178
ENABLE
176
ON/OFF
180
120
154
158
3:00
88
TEST CONNECTOR
160
SERIAL DATA GENERATOR & DATA LOGGER
156

FIG. 18

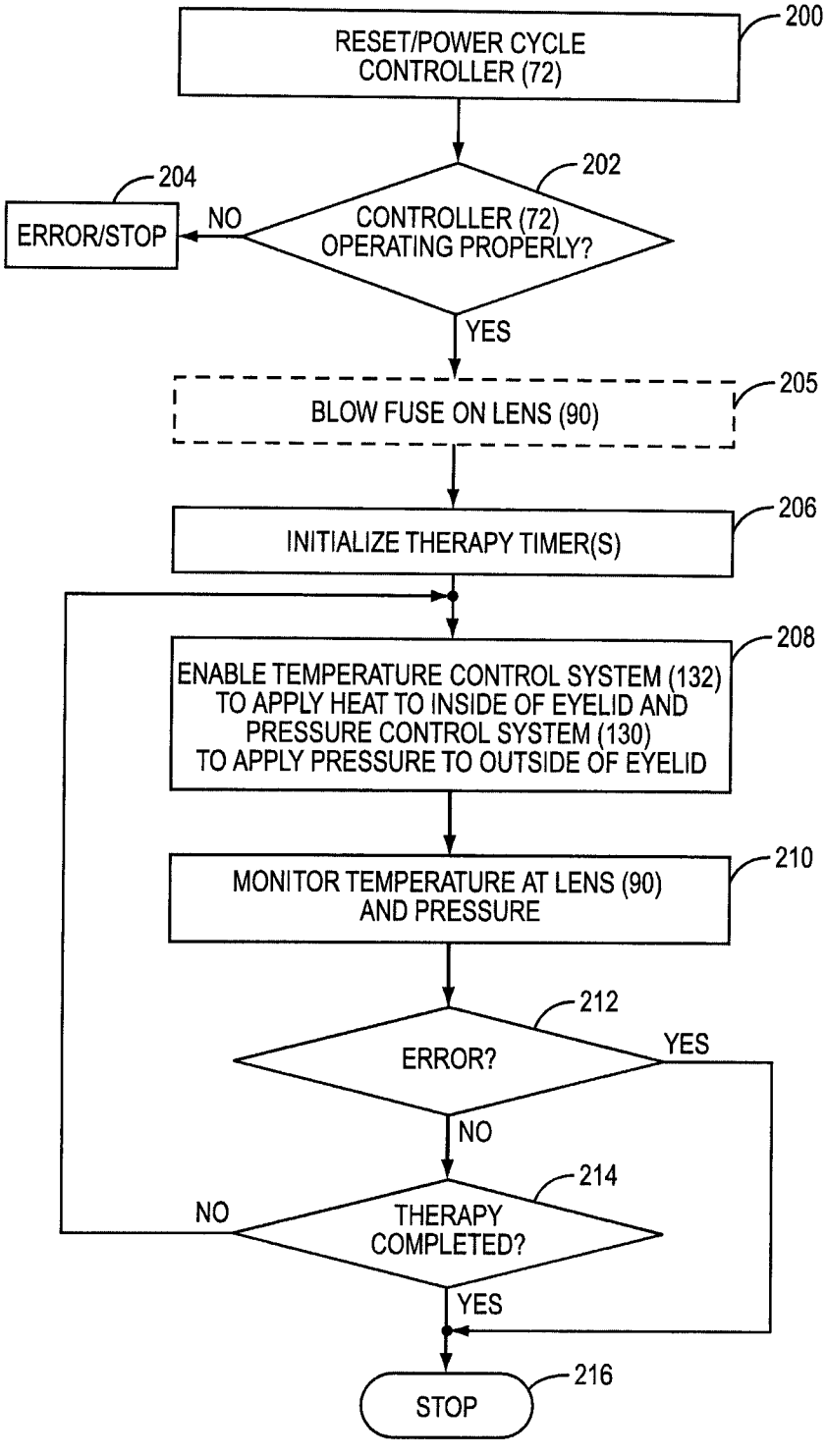

RESET/POWER CYCLE CONTROLLER (72)
200
CONTROLLER (72) OPERATING PROPERLY?
202
NO
ERROR/STOP
204
YES
BLOW FUSE ON LENS (90)
205
INITIALIZE THERAPY TIMER(S)
206
ENABLE TEMPERATURE CONTROL SYSTEM (132) TO APPLY HEAT TO INSIDE OF EYELID AND PRESSURE CONTROL SYSTEM (130) TO APPLY PRESSURE TO OUTSIDE OF EYELID
208
MONITOR TEMPERATURE AT LENS (90) AND PRESSURE
210
ERROR?
212
YES
NO
THERAPY COMPLETED?
214
NO
YES
STOP
216

FIG. 19

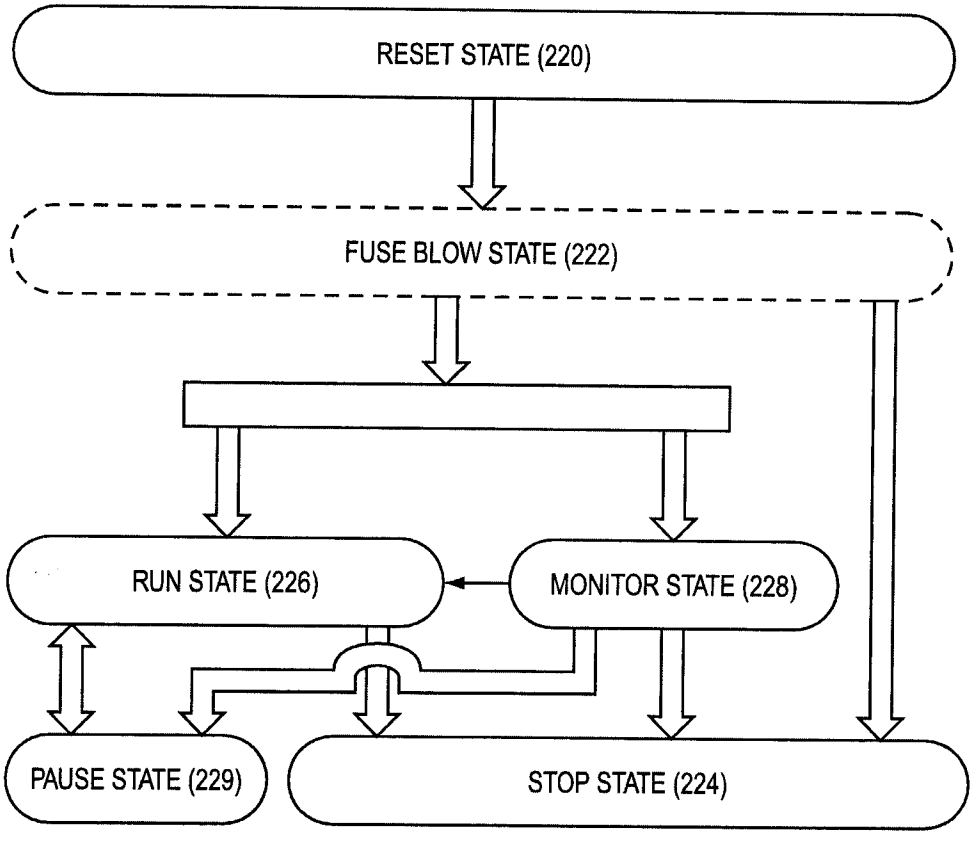

RESET STATE (220)
FUSE BLOW STATE (222)
RUN STATE (226)
MONITOR STATE (228)
PAUSE STATE (229)
STOP STATE (224)

FIG. 20

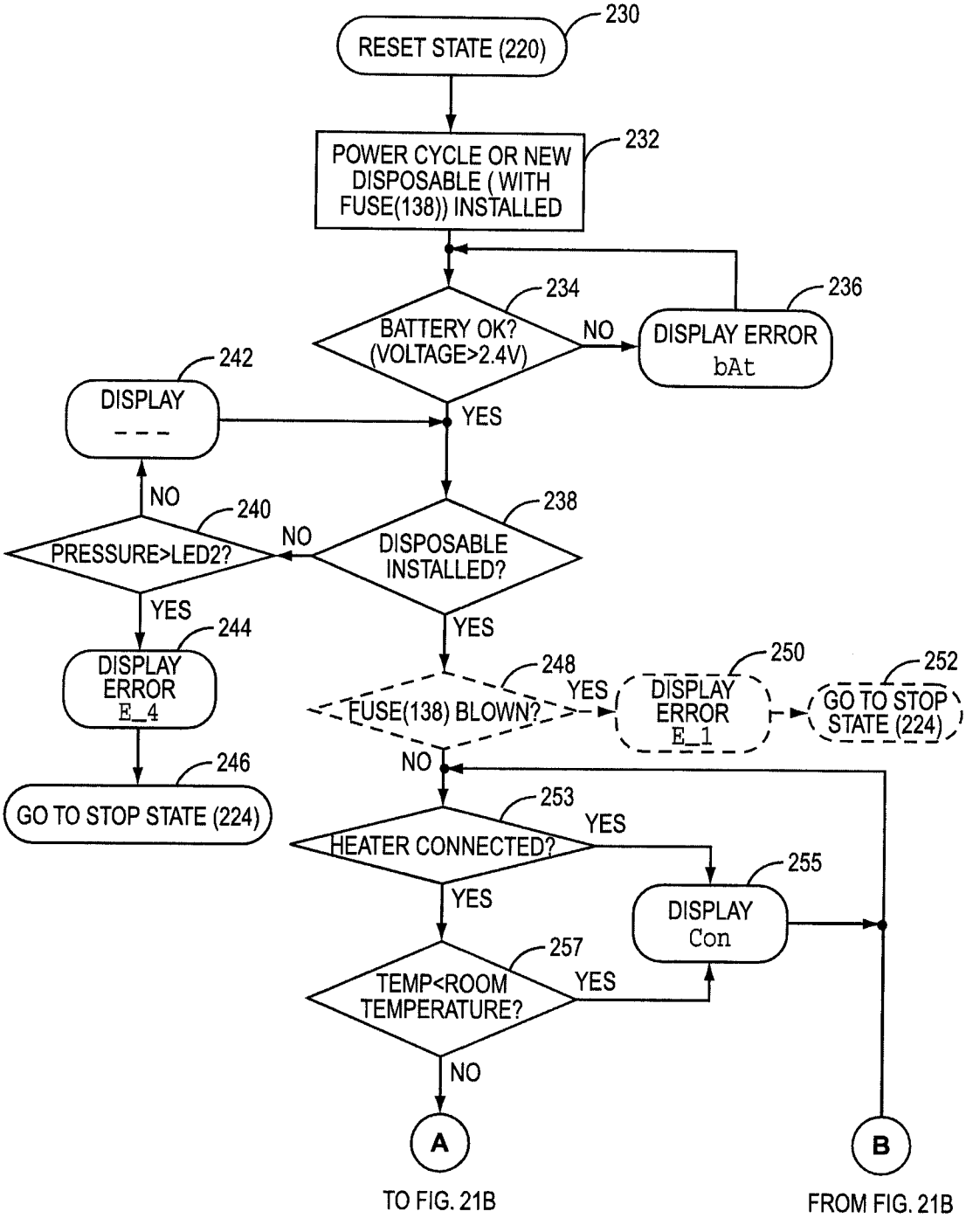

RESET STATE (220)
230
POWER CYCLE OR NEW DISPOSABLE (WITH FUSE(138)) INSTALLED
232
BATTERY OK? (VOLTAGE>2.4V)
234
NO
DISPLAY ERROR bAt
236
YES
DISPLAY - - -
242
NO
PRESSURE>LED2?
240
NO
DISPOSABLE INSTALLED?
238
YES
YES
DISPLAY ERROR E_4
244
FUSE(138) BLOWN?
248
YES
DISPLAY ERROR E_1
250
GO TO STOP STATE (224)
252
NO
GO TO STOP STATE (224)
246
HEATER CONNECTED?
253
YES
YES
DISPLAY Con
255
TEMP<ROOM TEMPERATURE?
257
YES
NO
A
B
TO FIG. 21B
FROM FIG. 21B

FIG. 21A

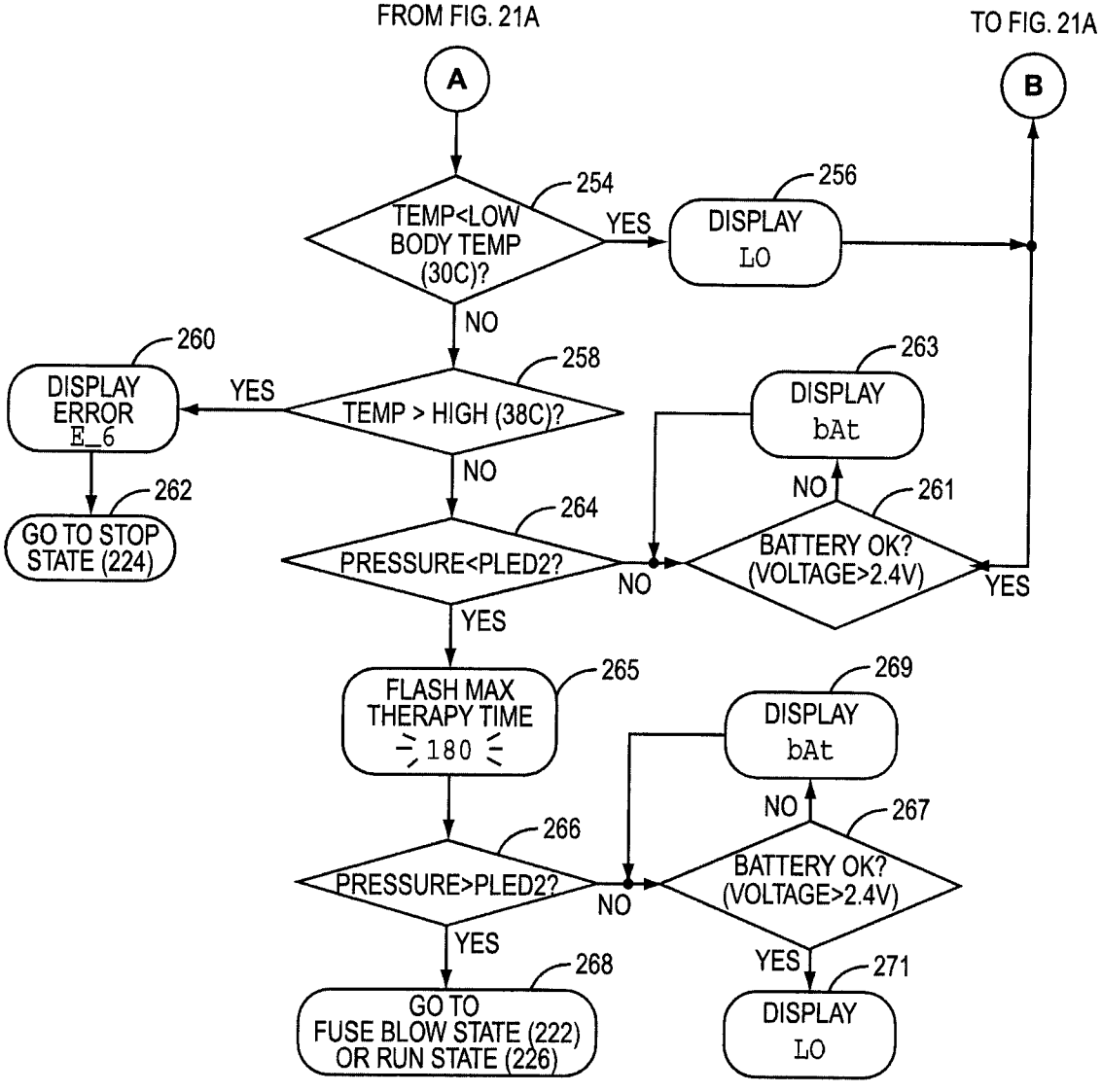

FROM FIG. 21A
TO FIG. 21A
A
B
254
TEMP<LOW BODY TEMP (30C)?
YES
256
DISPLAY LO
NO
260
DISPLAY ERROR E_6
YES
258
TEMP > HIGH (38C)?
263
DISPLAY bAt
NO
NO
261
262
GO TO STOP STATE (224)
264
PRESSURE<PLED2?
NO
BATTERY OK? (VOLTAGE>2.4V)
YES
YES
265
FLASH MAX THERAPY TIME 180
269
DISPLAY bAt
NO
267
266
PRESSURE>PLED2?
NO
BATTERY OK? (VOLTAGE>2.4V)
YES
YES
268
GO TO FUSE BLOW STATE (222) OR RUN STATE (226)
271
DISPLAY LO

FIG. 21B

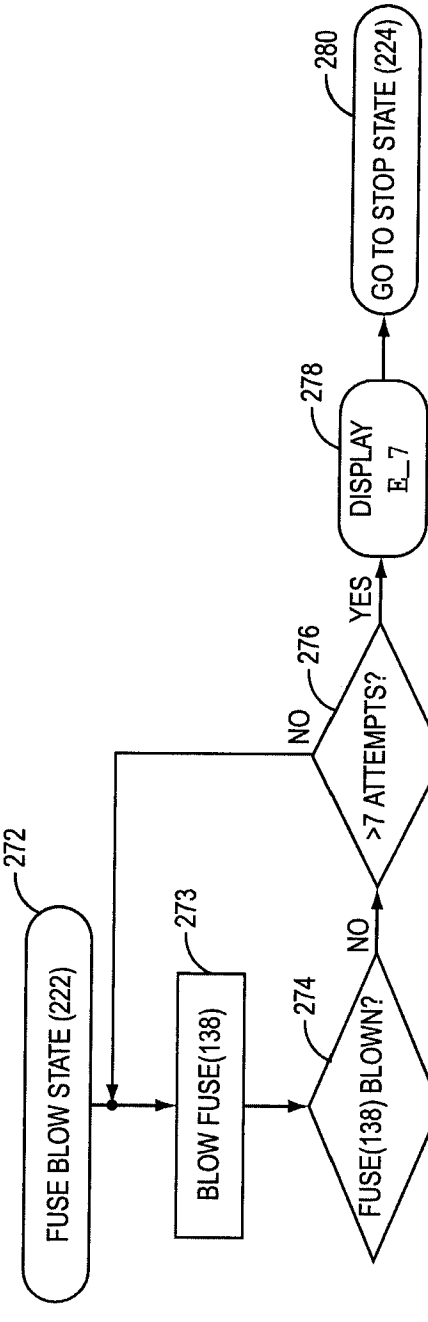

FUSE BLOW STATE (222)
272
BLOW FUSE(138)
273
FUSE(138) BLOWN?
274
NO
YES
>7 ATTEMPTS?
276
NO
YES
DISPLAY E_7
278
GO TO STOP STATE (224)
280
GO TO RUN STATE (226)
GO TO MONITOR STATE (228)
282

FIG. 22

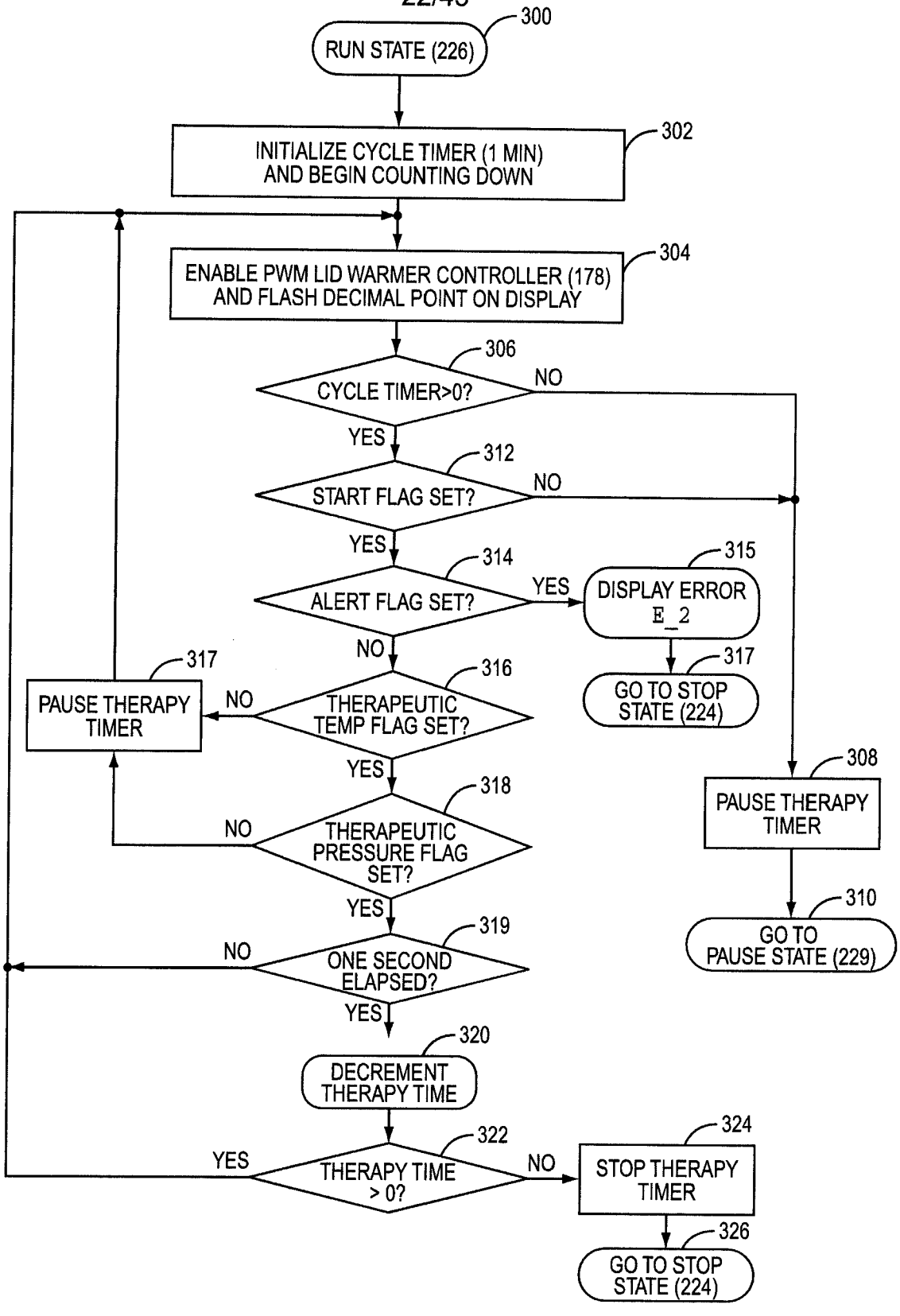

300
RUN STATE (226)
302
INITIALIZE CYCLE TIMER (1 MIN) AND BEGIN COUNTING DOWN
304
ENABLE PWM LID WARMER CONTROLLER (178) AND FLASH DECIMAL POINT ON DISPLAY
306
CYCLE TIMER>0?
NO
YES
312
START FLAG SET?
NO
YES
314
ALERT FLAG SET?
YES
315
DISPLAY ERROR E_2
317
GO TO STOP STATE (224)
NO
316
THERAPEUTIC TEMP FLAG SET?
NO
317
PAUSE THERAPY TIMER
YES
318
THERAPEUTIC PRESSURE FLAG SET?
NO
YES
319
ONE SECOND ELAPSED?
NO
YES
320
DECREMENT THERAPY TIME
322
THERAPY TIME > 0?
YES
NO
324
STOP THERAPY TIMER
326
GO TO STOP STATE (224)
308
PAUSE THERAPY TIMER
310
GO TO PAUSE STATE (229)

FIG. 23

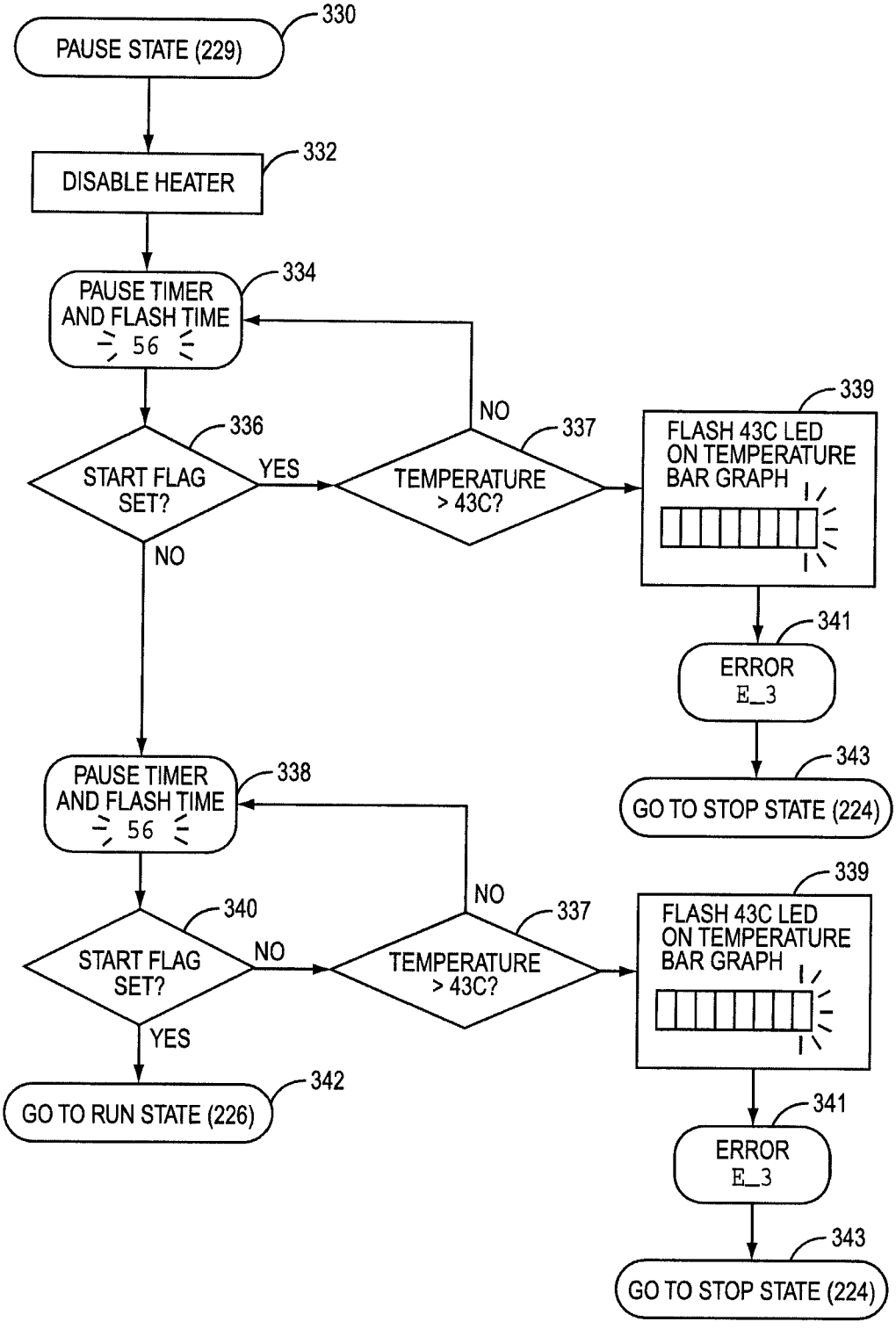

330
PAUSE STATE (229)
332
DISABLE HEATER
334
PAUSE TIMER AND FLASH TIME
56
336
START FLAG SET?
YES
NO
337
TEMPERATURE > 43C?
NO
339
FLASH 43C LED ON TEMPERATURE BAR GRAPH
341
ERROR E_3
343
GO TO STOP STATE (224)
338
PAUSE TIMER AND FLASH TIME
56
340
START FLAG SET?
NO
YES
337
TEMPERATURE > 43C?
NO
339
FLASH 43C LED ON TEMPERATURE BAR GRAPH
342
GO TO RUN STATE (226)
341
ERROR E_3
343
GO TO STOP STATE (224)

FIG. 24

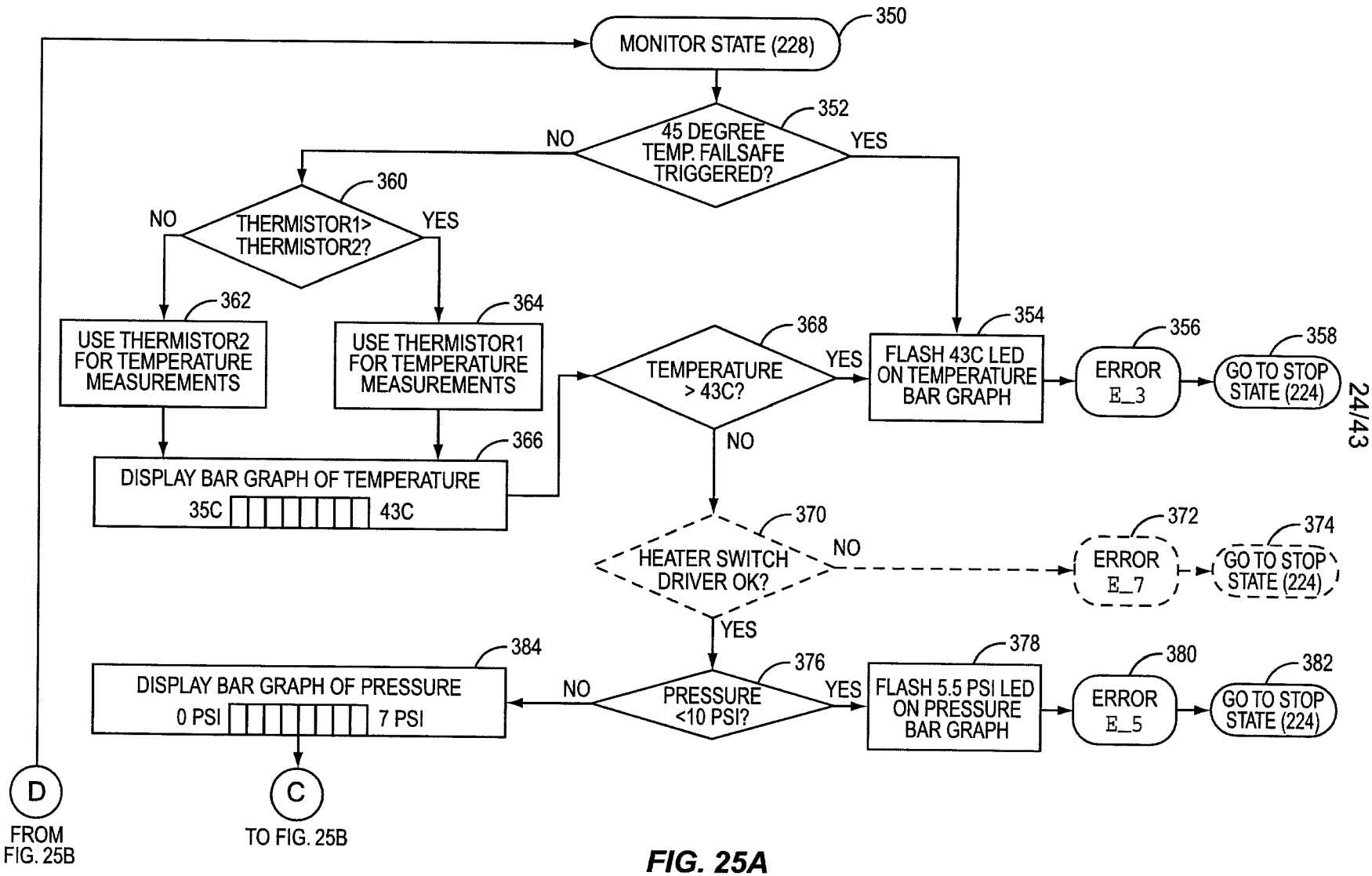

MONITOR STATE (228)
350
45 DEGREE TEMP. FAILSAFE TRIGGERED?
352
NO
YES
THERMISTOR1> THERMISTOR2?
360
NO
YES
USE THERMISTOR2 FOR TEMPERATURE MEASUREMENTS
362
USE THERMISTOR1 FOR TEMPERATURE MEASUREMENTS
364
DISPLAY BAR GRAPH OF TEMPERATURE
35C
43C
366
TEMPERATURE > 43C?
368
YES
NO
FLASH 43C LED ON TEMPERATURE BAR GRAPH
354
ERROR E_3
356
GO TO STOP STATE (224)
358
HEATER SWITCH DRIVER OK?
370
NO
YES
ERROR E_7
372
GO TO STOP STATE (224)
374
PRESSURE <10 PSI?
376
NO
YES
DISPLAY BAR GRAPH OF PRESSURE
0 PSI
7 PSI
384
FLASH 5.5 PSI LED ON PRESSURE BAR GRAPH
378
ERROR E_5
380
GO TO STOP STATE (224)
382
D
FROM FIG. 25B
C
TO FIG. 25B

FIG. 25A

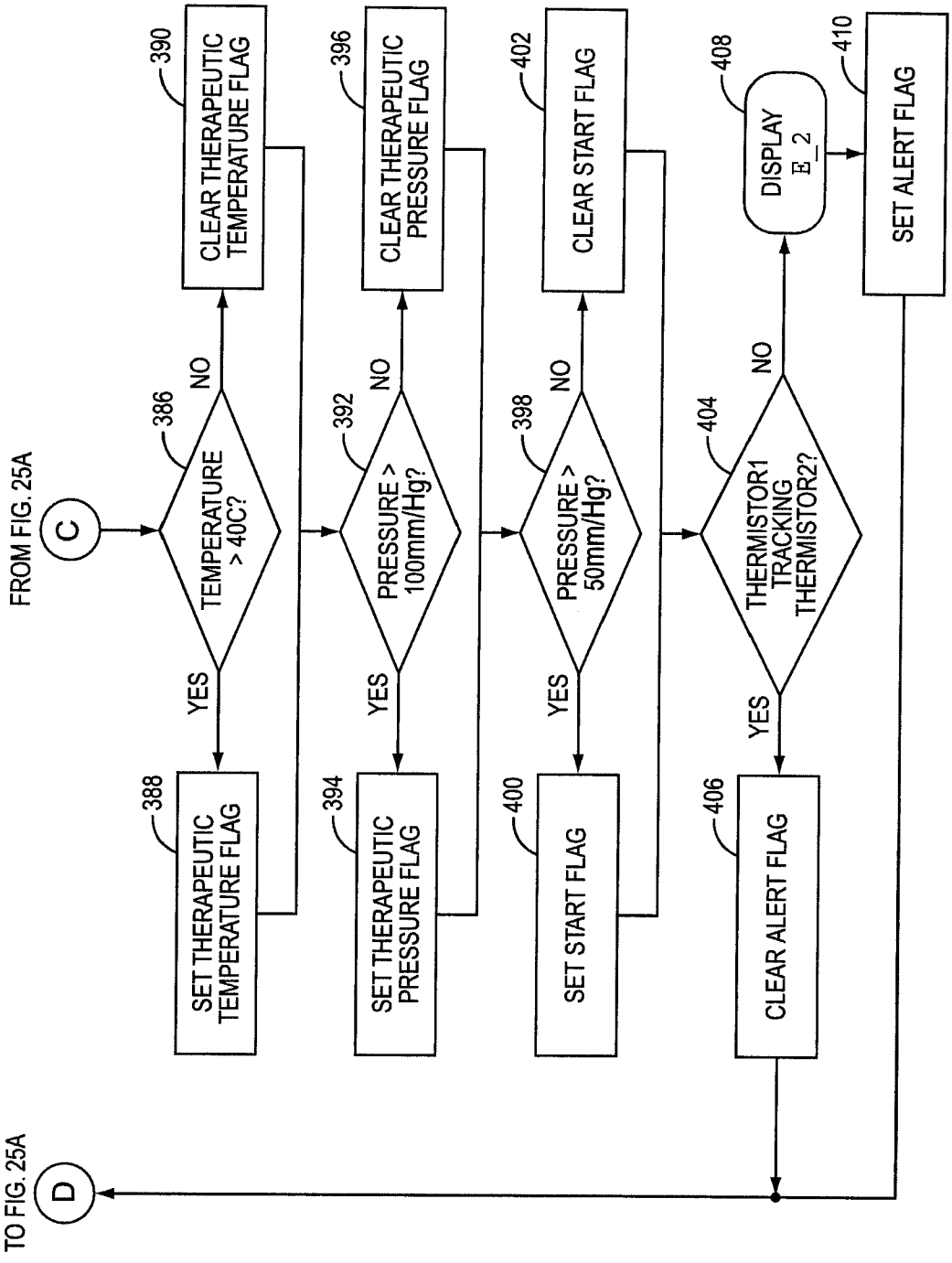

FROM FIG. 25A
C
386
TEMPERATURE > 40C?
NO
YES
390
CLEAR THERAPEUTIC TEMPERATURE FLAG
388
SET THERAPEUTIC TEMPERATURE FLAG
392
PRESSURE > 100mm/Hg?
NO
YES
396
CLEAR THERAPEUTIC PRESSURE FLAG
394
SET THERAPEUTIC PRESSURE FLAG
398
PRESSURE > 50mm/Hg?
NO
YES
402
CLEAR START FLAG
400
SET START FLAG
404
THERMISTOR1 TRACKING THERMISTOR2?
NO
YES
408
DISPLAY E_2
410
SET ALERT FLAG
406
CLEAR ALERT FLAG
D
TO FIG. 25A

FIG. 25B

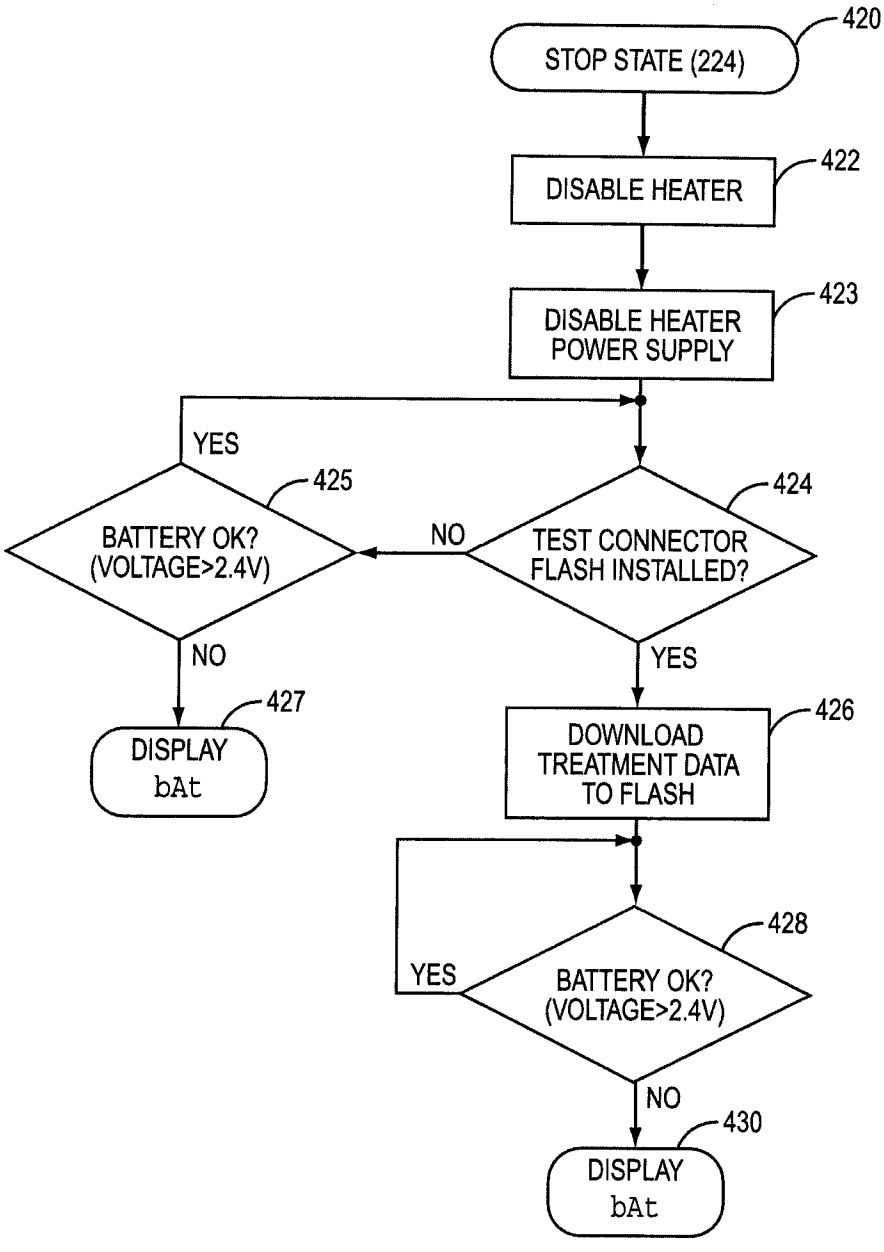

420
STOP STATE (224)
422
DISABLE HEATER
423
DISABLE HEATER POWER SUPPLY
YES
425
BATTERY OK? (VOLTAGE>2.4V)
NO
424
TEST CONNECTOR FLASH INSTALLED?
NO
YES
427
DISPLAY bAt
426
DOWNLOAD TREATMENT DATA TO FLASH
428
YES
BATTERY OK? (VOLTAGE>2.4V)
NO
430
DISPLAY bAt

FIG. 26

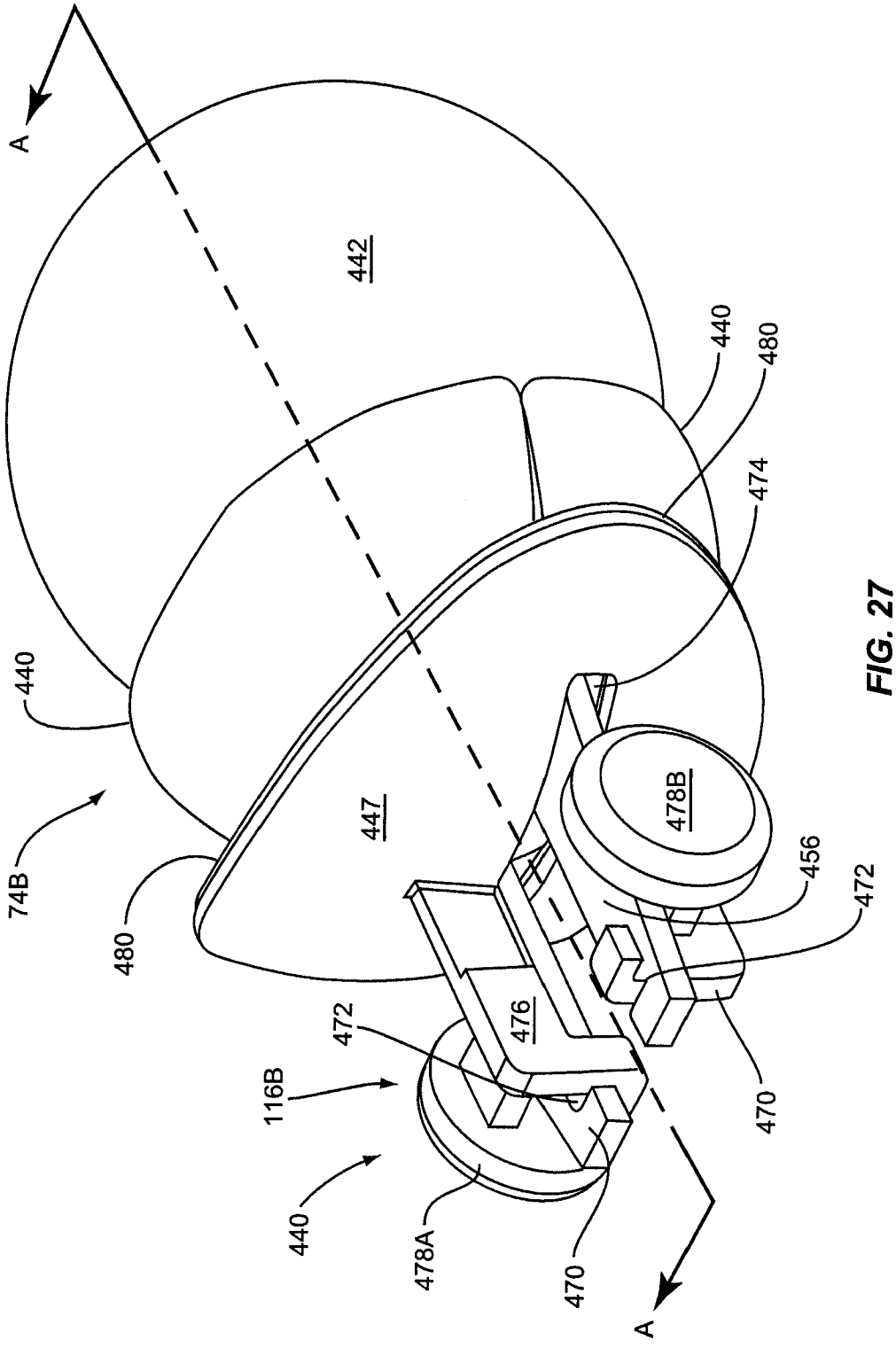

A
442
440
480
474
440
74B
480
447
478B
456
472
476
472
116B
470
440
478A
470
A

FIG. 27

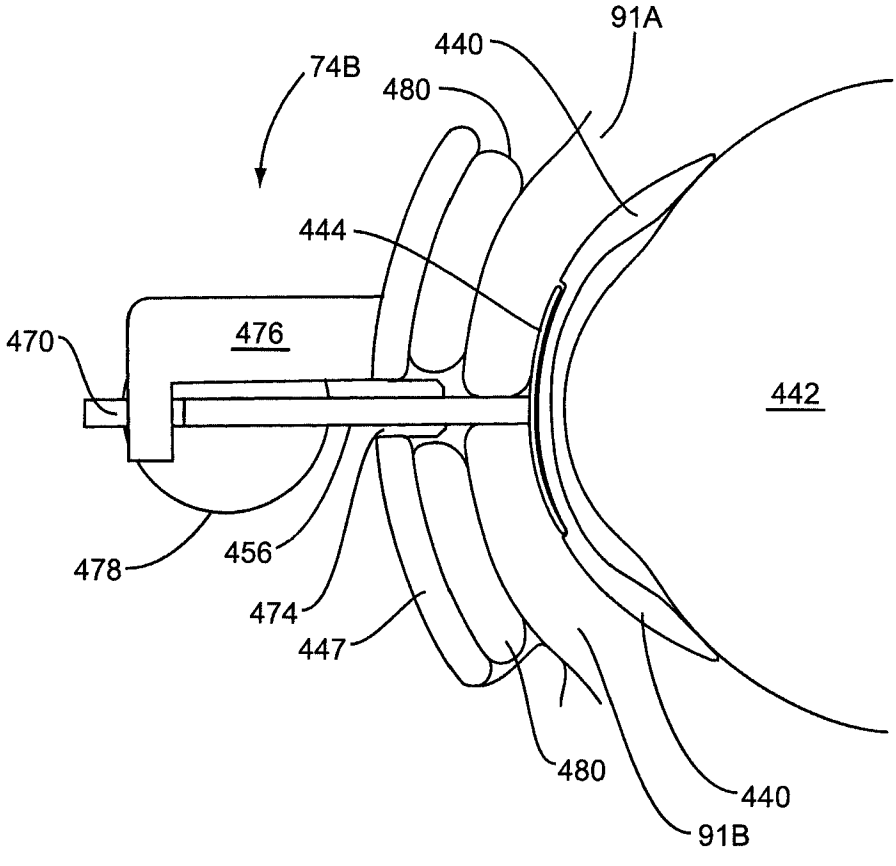


FIG. 28

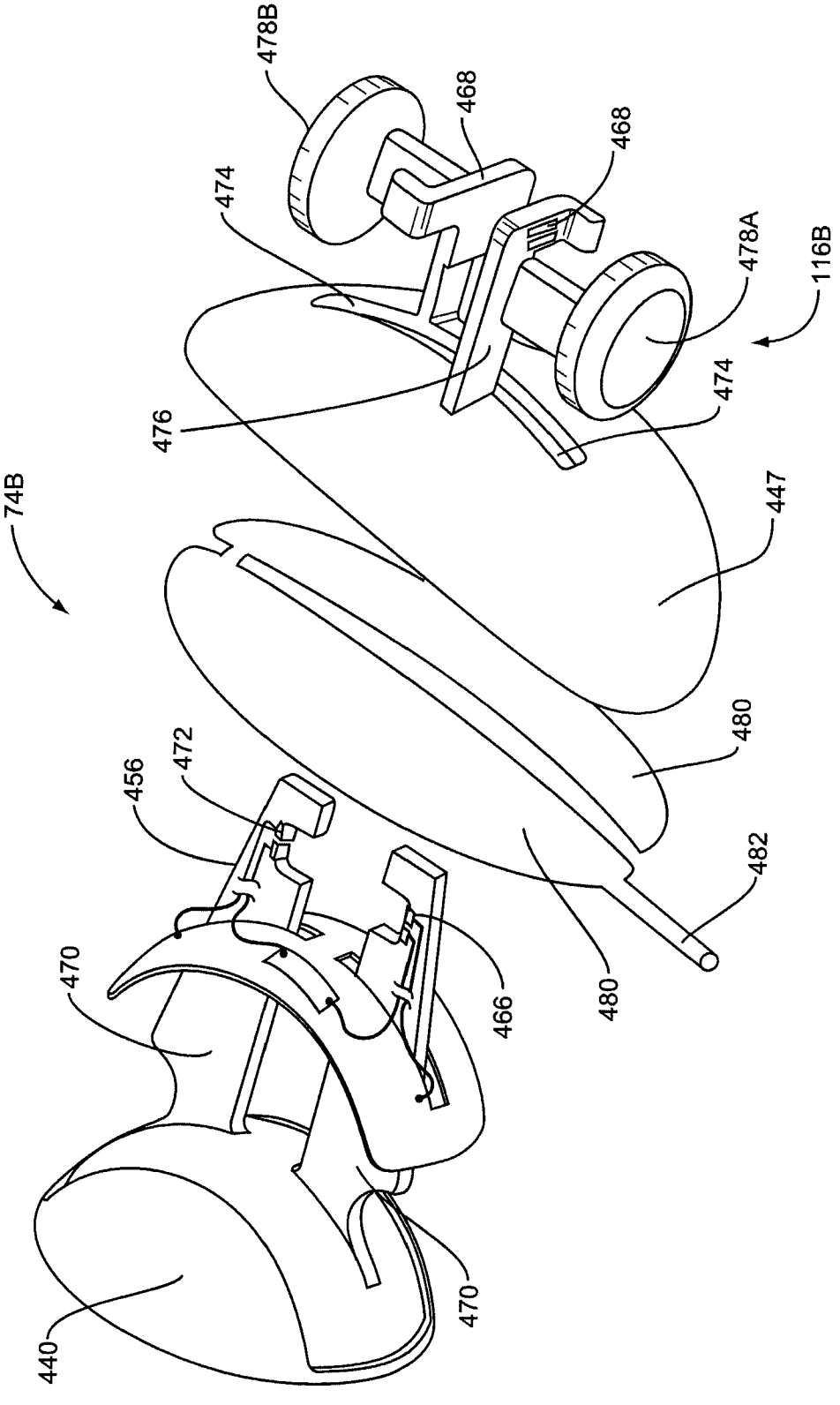

478B
468
468
474
478A
116B
474
476
74B
447
480
472
456
482
470
466
480
470
440

FIG. 29

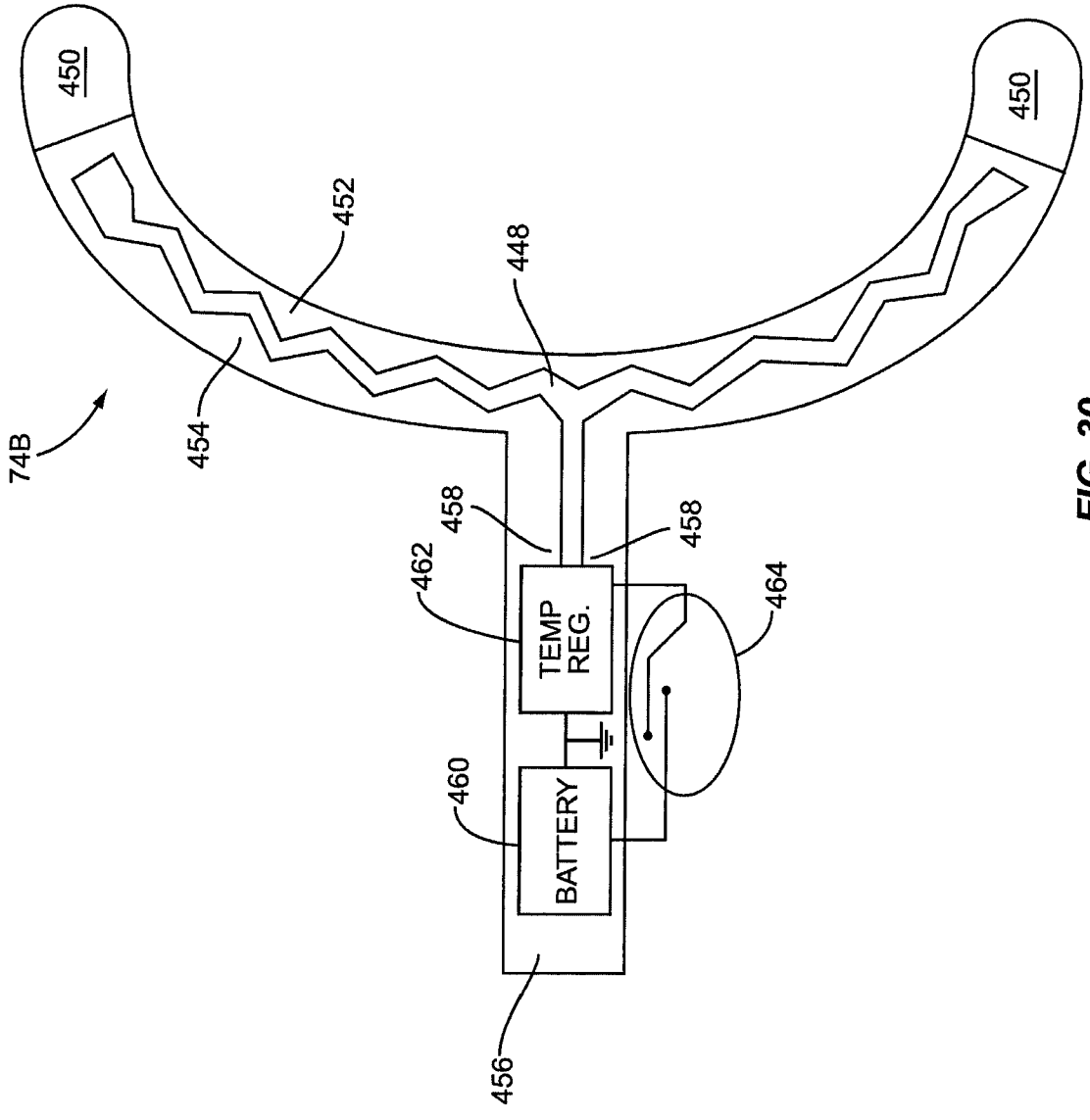

74B
450
450
452
448
454
458
458
462
464
TEMP REG.
460
BATTERY
456

FIG. 30

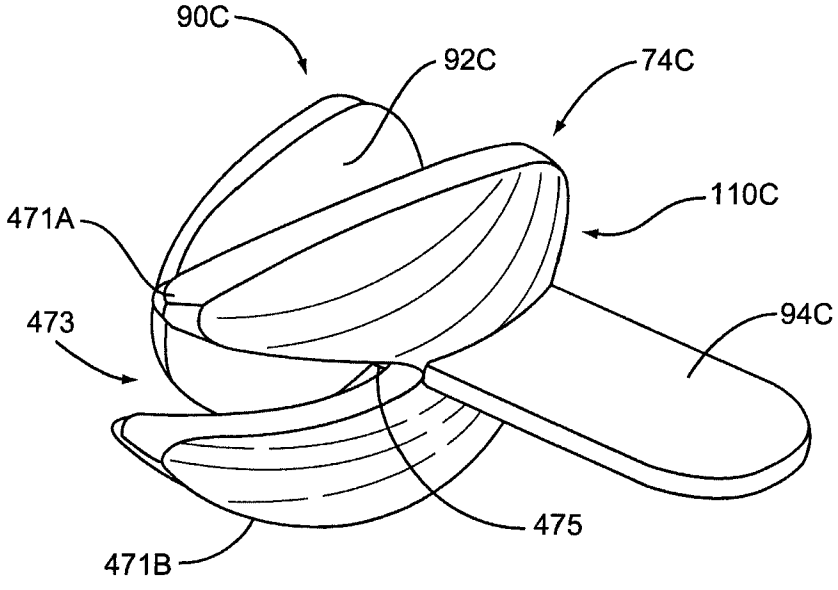


FIG. 31A

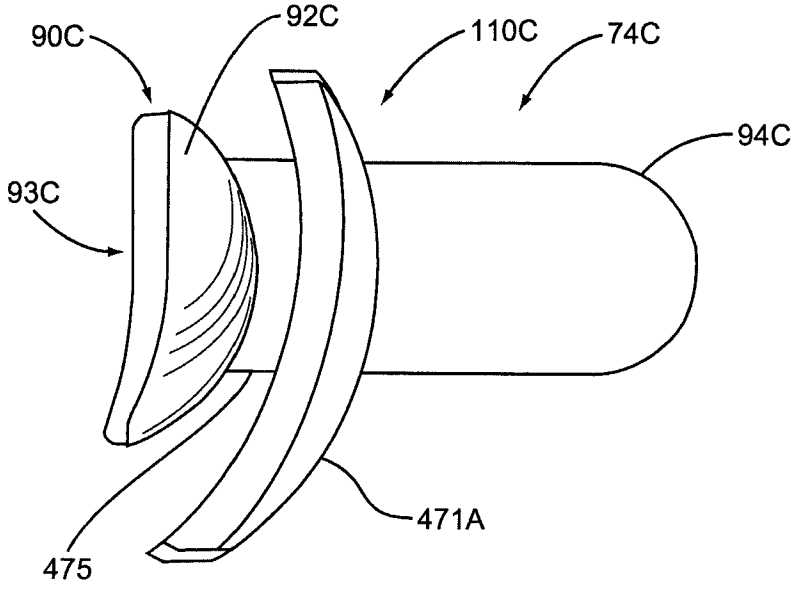


FIG. 31B

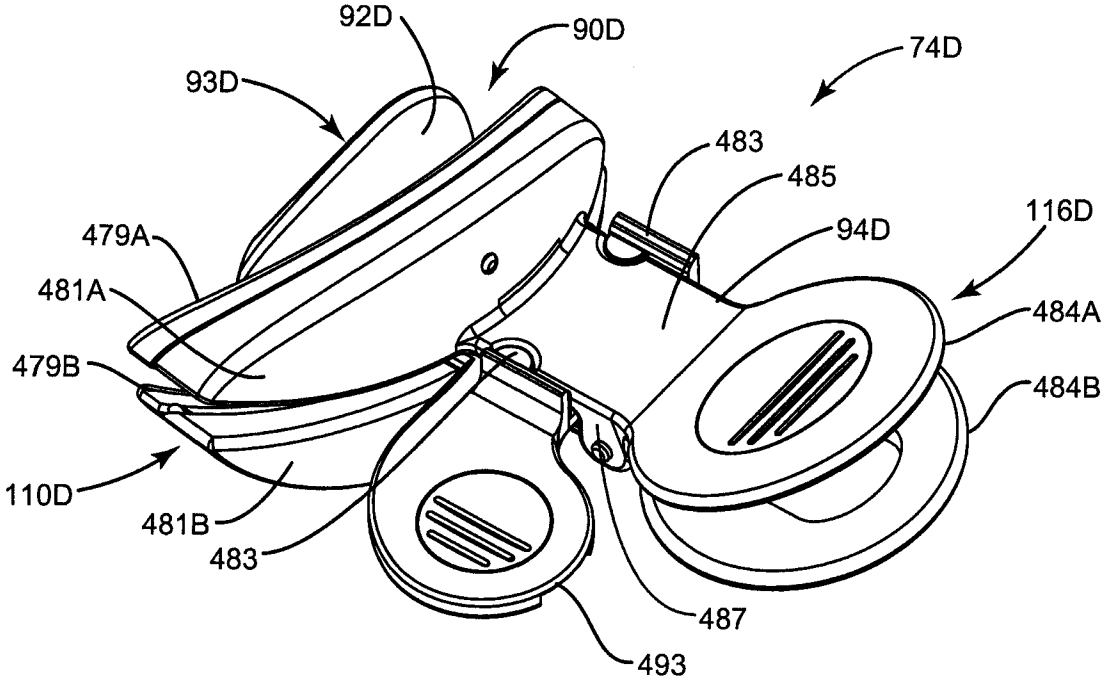

92D
90D
74D
93D
483
485
116D
479A
94D
481A
484A
479B
484B
110D
481B
483
487
493

FIG. 32

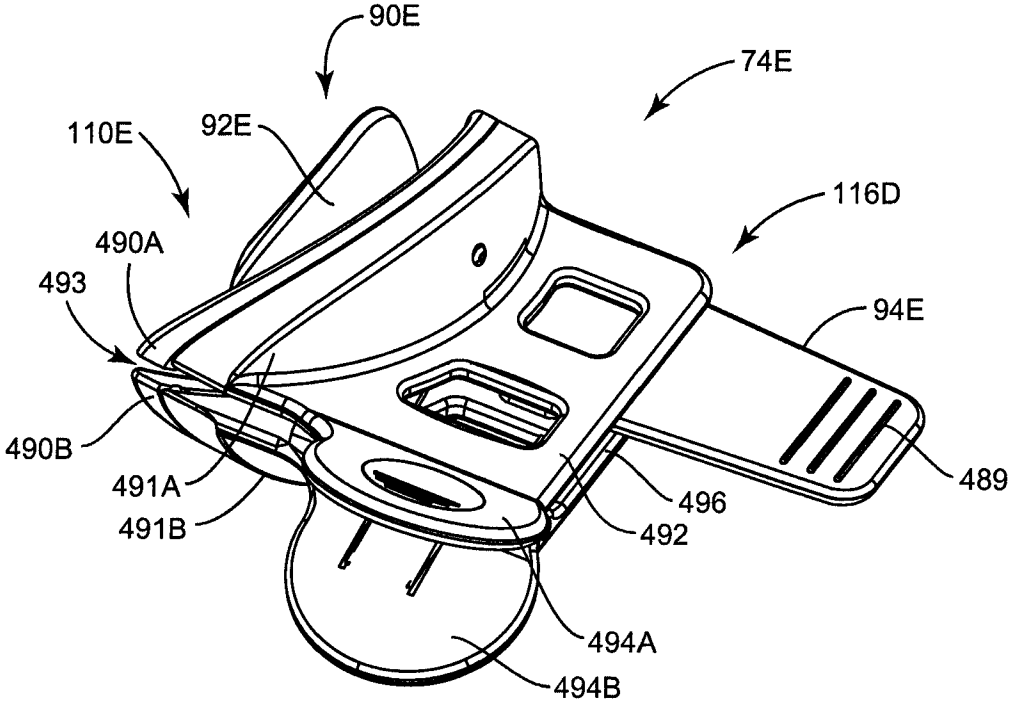

90E
74E
110E
92E
116D
490A
493
94E
490B
491A
496
489
491B
492
494A
494B

FIG. 33

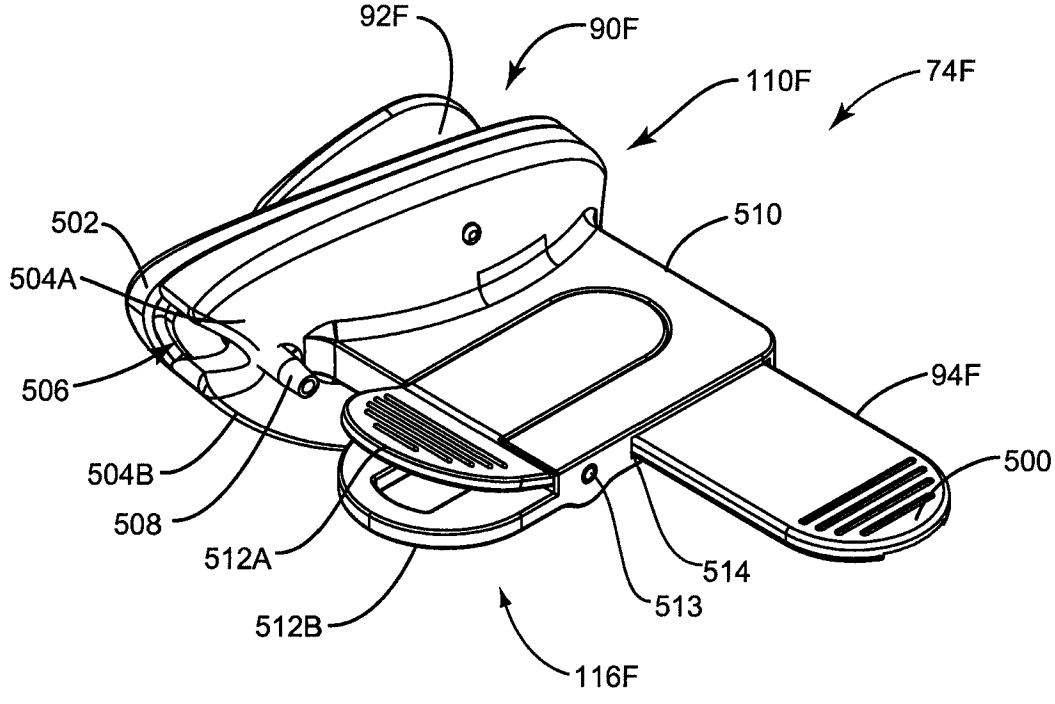

92F
90F
110F
74F
502
504A
506
504B
508
512A
512B
510
94F
500
514
513
116F

FIG. 34

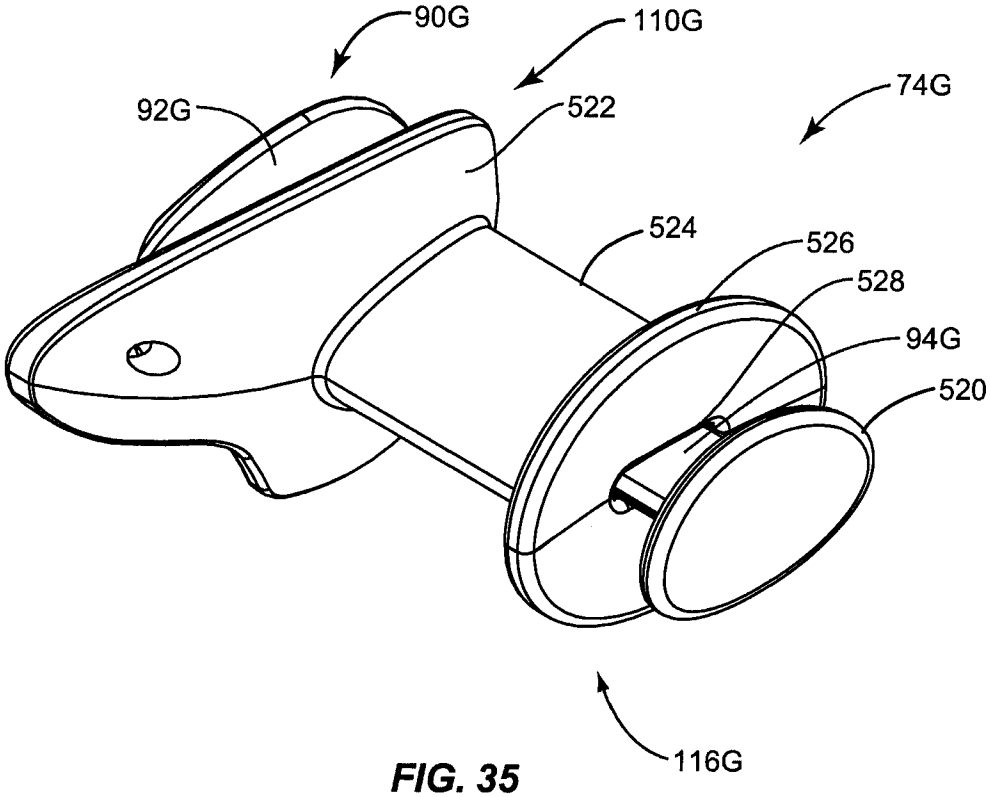


FIG. 35

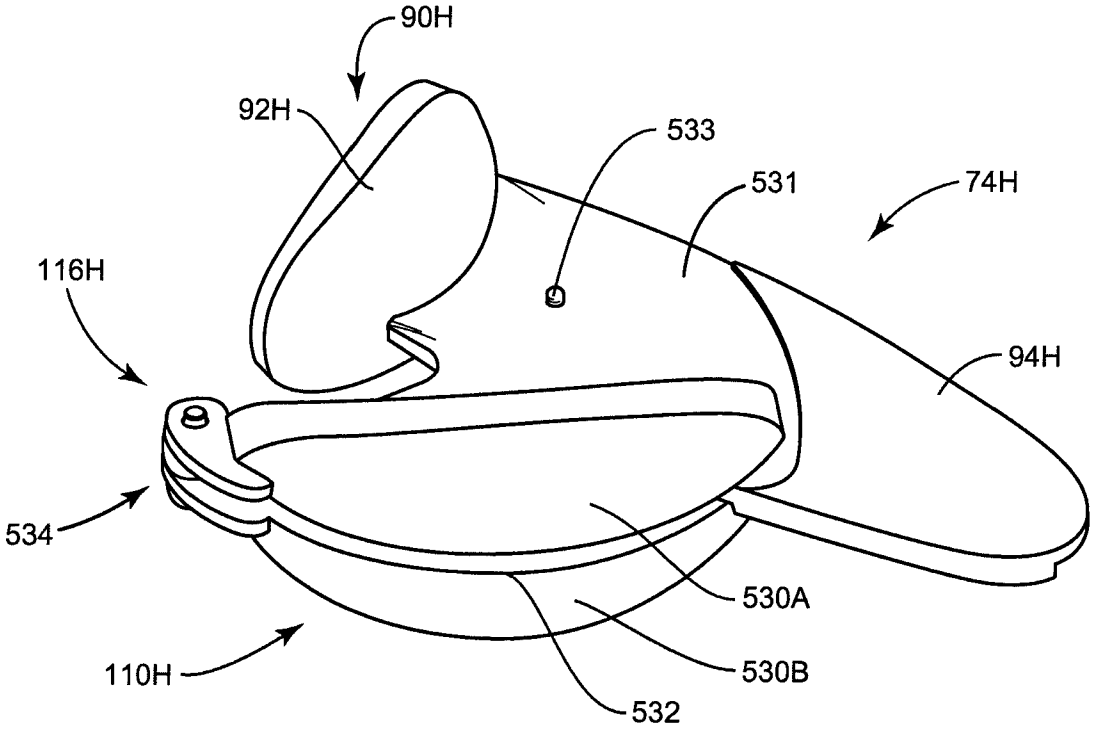


FIG. 36A

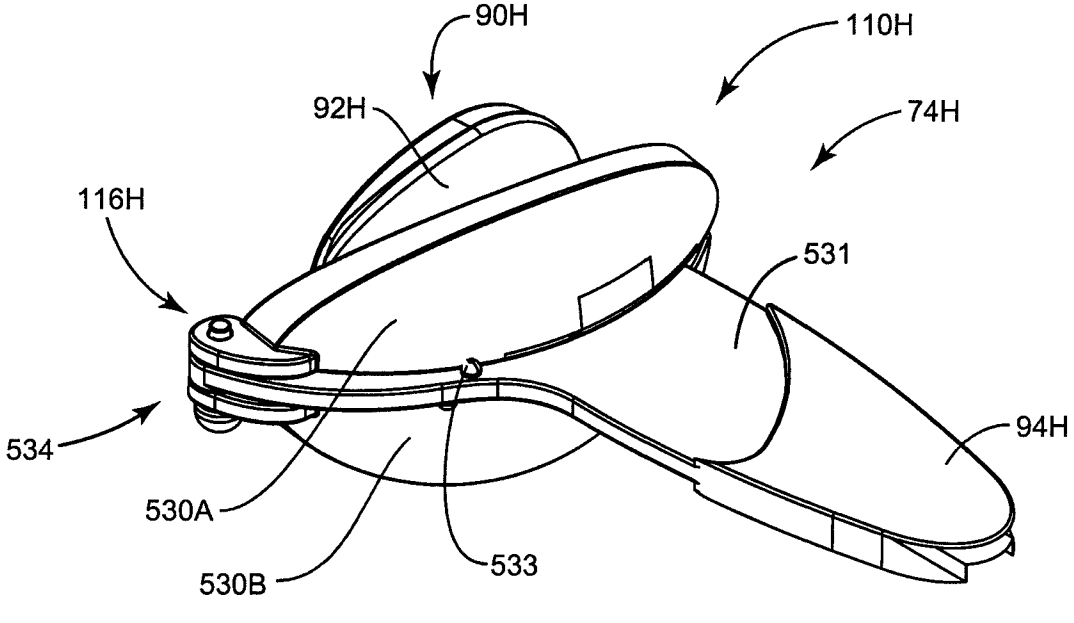


FIG. 36B

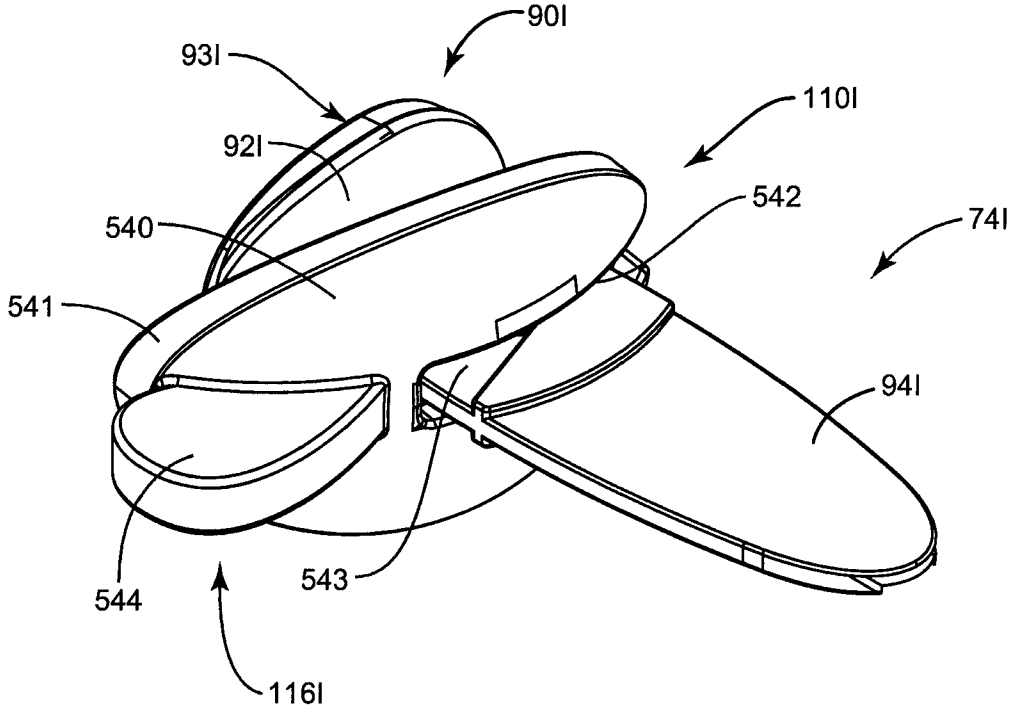


FIG. 37

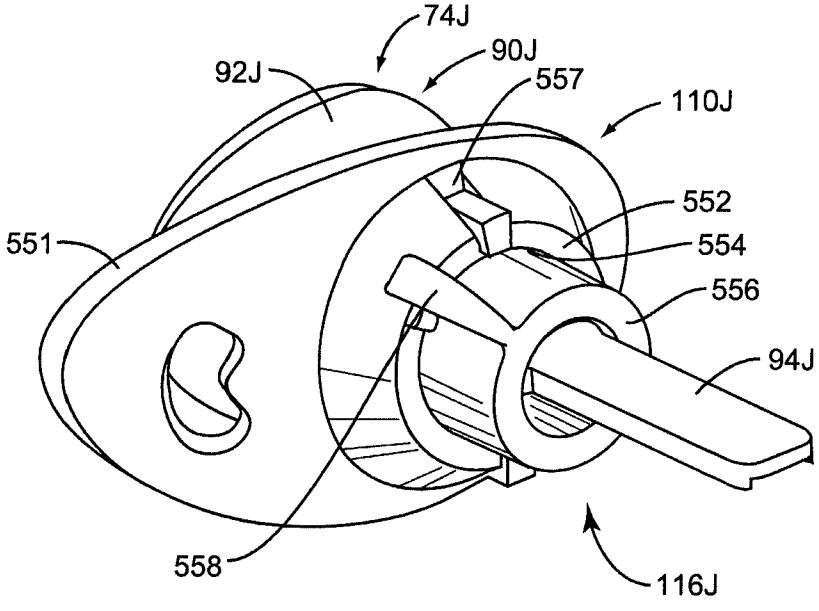


FIG. 38A

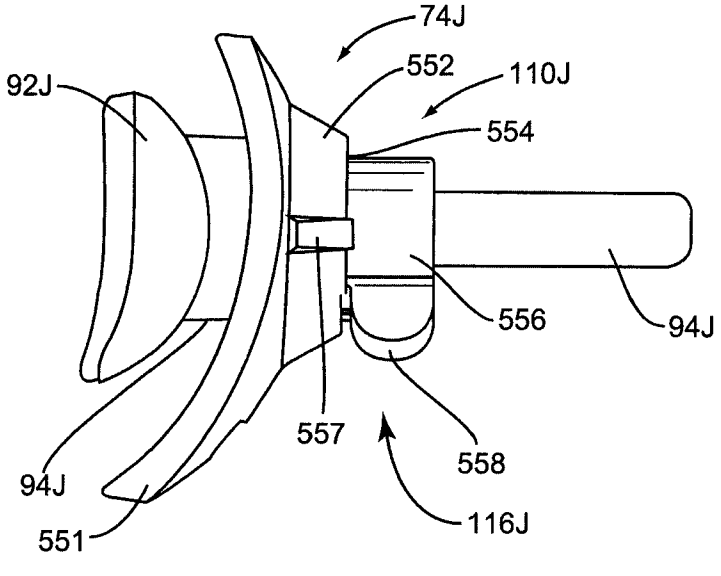


FIG. 38B

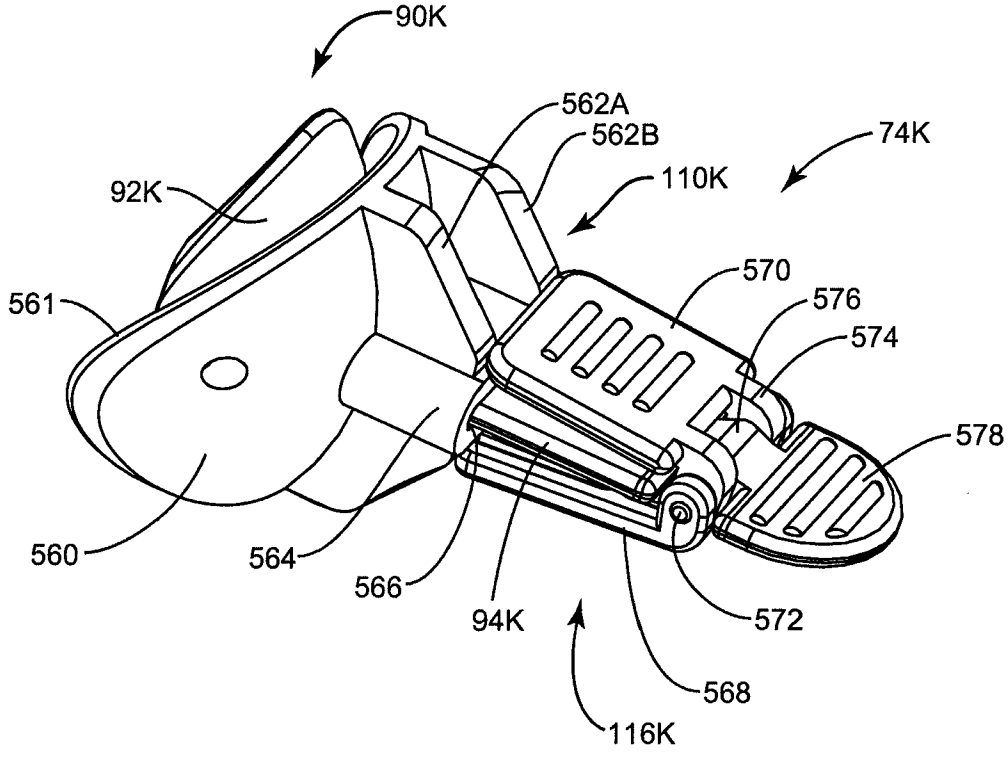

90K
562A
562B
74K
110K
92K
570
561
576
574
578
560
564
566
94K
572
568
116K

FIG. 39

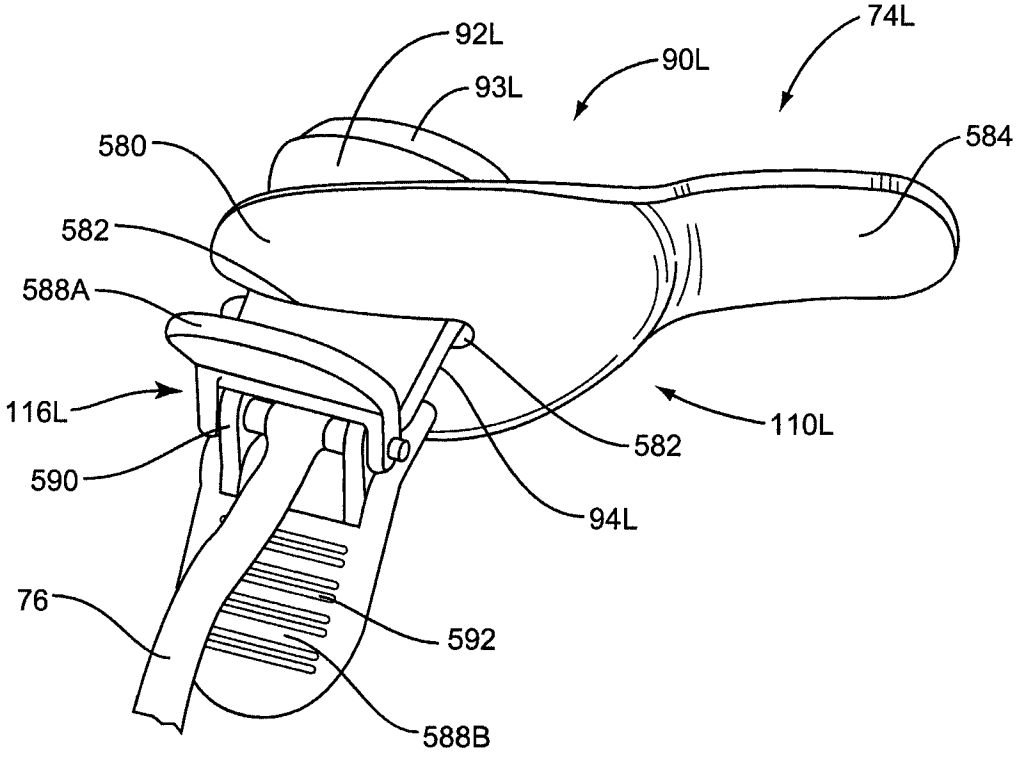

92L
74L
90L
93L
580
584
582
588A
116L
110L
582
590
94L
76
592
588B

FIG. 40

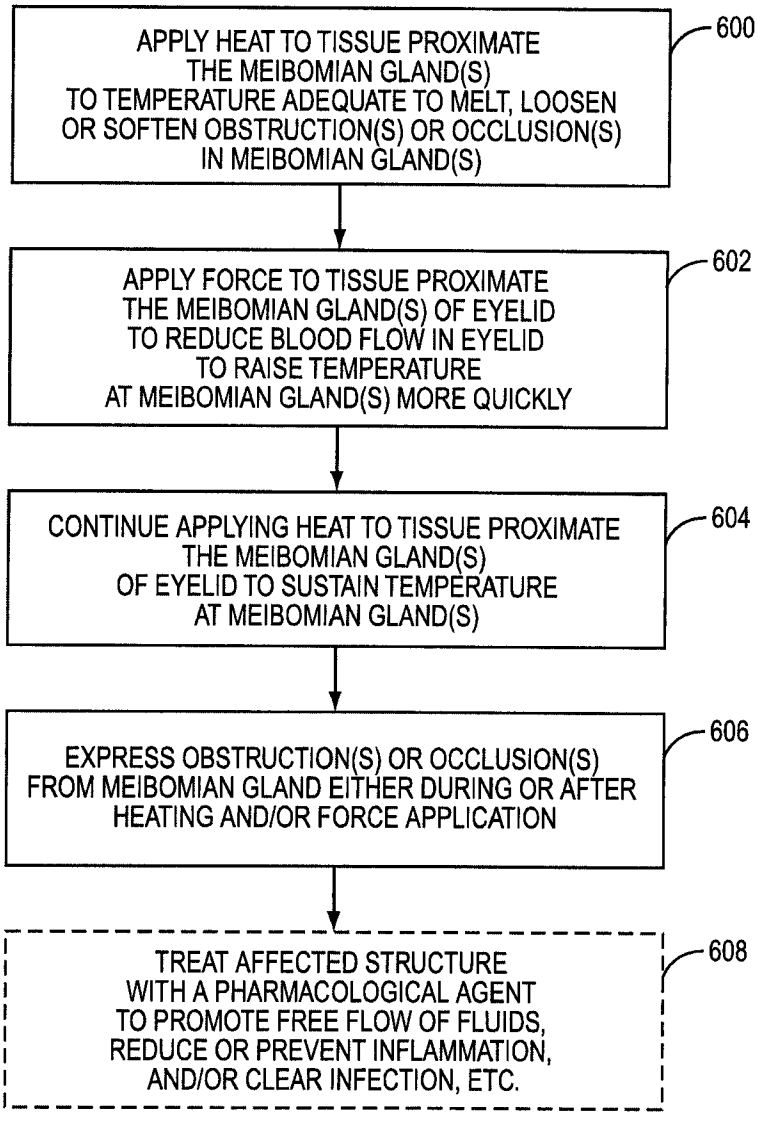

APPLY HEAT TO TISSUE PROXIMATE THE MEIBOMIAN GLAND(S) TO TEMPERATURE ADEQUATE TO MELT, LOOSEN OR SOFTEN OBSTRUCTION(S) OR OCCLUSION(S) IN MEIBOMIAN GLAND(S)
600
APPLY FORCE TO TISSUE PROXIMATE THE MEIBOMIAN GLAND(S) OF EYELID TO REDUCE BLOOD FLOW IN EYELID TO RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) MORE QUICKLY
602
CONTINUE APPLYING HEAT TO TISSUE PROXIMATE THE MEIBOMIAN GLAND(S) OF EYELID TO SUSTAIN TEMPERATURE AT MEIBOMIAN GLAND(S)
604
EXPRESS OBSTRUCTION(S) OR OCCLUSION(S) FROM MEIBOMIAN GLAND EITHER DURING OR AFTER HEATING AND/OR FORCE APPLICATION
606
TREAT AFFECTED STRUCTURE WITH A PHARMACOLOGICAL AGENT TO PROMOTE FREE FLOW OF FLUIDS, REDUCE OR PREVENT INFLAMMATION, AND/OR CLEAR INFECTION, ETC.
608

FIG. 41

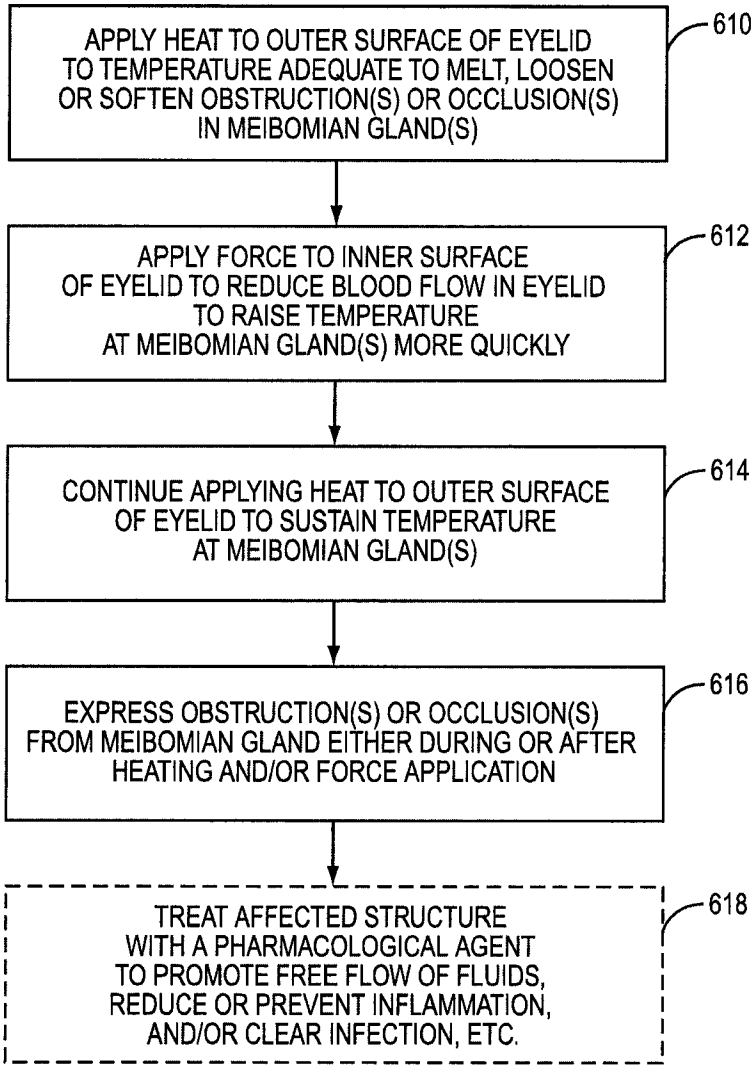

APPLY HEAT TO OUTER SURFACE OF EYELID TO TEMPERATURE ADEQUATE TO MELT, LOOSEN OR SOFTEN OBSTRUCTION(S) OR OCCLUSION(S) IN MEIBOMIAN GLAND(S)
610
APPLY FORCE TO INNER SURFACE OF EYELID TO REDUCE BLOOD FLOW IN EYELID TO RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) MORE QUICKLY
612
CONTINUE APPLYING HEAT TO OUTER SURFACE OF EYELID TO SUSTAIN TEMPERATURE AT MEIBOMIAN GLAND(S)
614
EXPRESS OBSTRUCTION(S) OR OCCLUSION(S) FROM MEIBOMIAN GLAND EITHER DURING OR AFTER HEATING AND/OR FORCE APPLICATION
616
TREAT AFFECTED STRUCTURE WITH A PHARMACOLOGICAL AGENT TO PROMOTE FREE FLOW OF FLUIDS, REDUCE OR PREVENT INFLAMMATION, AND/OR CLEAR INFECTION, ETC.
618

FIG. 42

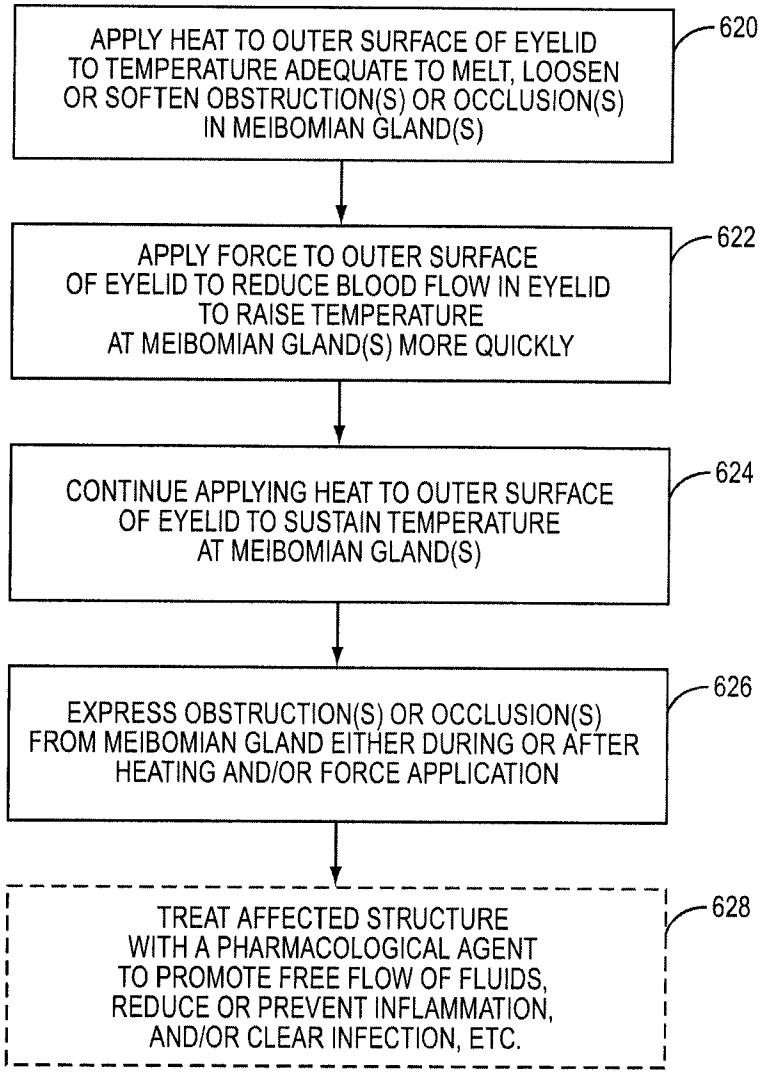

APPLY HEAT TO OUTER SURFACE OF EYELID TO TEMPERATURE ADEQUATE TO MELT, LOOSEN OR SOFTEN OBSTRUCTION(S) OR OCCLUSION(S) IN MEIBOMIAN GLAND(S)
620
APPLY FORCE TO OUTER SURFACE OF EYELID TO REDUCE BLOOD FLOW IN EYELID TO RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) MORE QUICKLY
622
CONTINUE APPLYING HEAT TO OUTER SURFACE OF EYELID TO SUSTAIN TEMPERATURE AT MEIBOMIAN GLAND(S)
624
EXPRESS OBSTRUCTION(S) OR OCCLUSION(S) FROM MEIBOMIAN GLAND EITHER DURING OR AFTER HEATING AND/OR FORCE APPLICATION
626
TREAT AFFECTED STRUCTURE WITH A PHARMACOLOGICAL AGENT TO PROMOTE FREE FLOW OF FLUIDS, REDUCE OR PREVENT INFLAMMATION, AND/OR CLEAR INFECTION, ETC.
628

FIG. 43

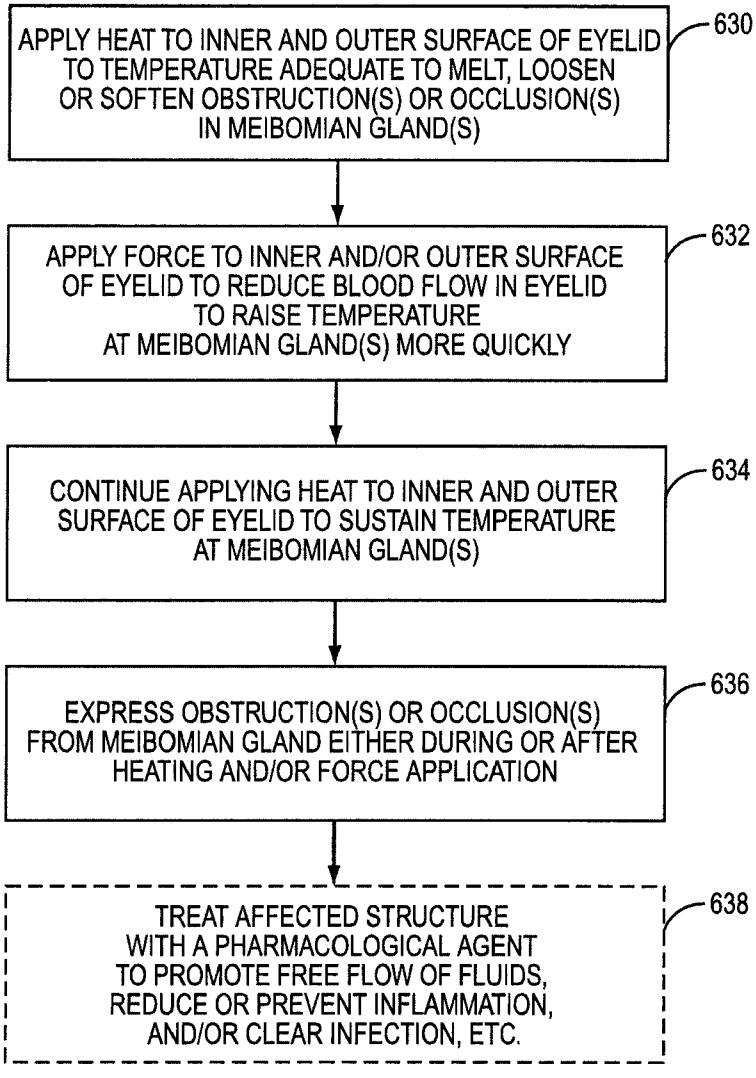

APPLY HEAT TO INNER AND OUTER SURFACE OF EYELID TO TEMPERATURE ADEQUATE TO MELT, LOOSEN OR SOFTEN OBSTRUCTION(S) OR OCCLUSION(S) IN MEIBOMIAN GLAND(S)
630
APPLY FORCE TO INNER AND/OR OUTER SURFACE OF EYELID TO REDUCE BLOOD FLOW IN EYELID TO RAISE TEMPERATURE AT MEIBOMIAN GLAND(S) MORE QUICKLY
632
CONTINUE APPLYING HEAT TO INNER AND OUTER SURFACE OF EYELID TO SUSTAIN TEMPERATURE AT MEIBOMIAN GLAND(S)
634
EXPRESS OBSTRUCTION(S) OR OCCLUSION(S) FROM MEIBOMIAN GLAND EITHER DURING OR AFTER HEATING AND/OR FORCE APPLICATION
636
TREAT AFFECTED STRUCTURE WITH A PHARMACOLOGICAL AGENT TO PROMOTE FREE FLOW OF FLUIDS, REDUCE OR PREVENT INFLAMMATION, AND/OR CLEAR INFECTION, ETC.
638

FIG. 44