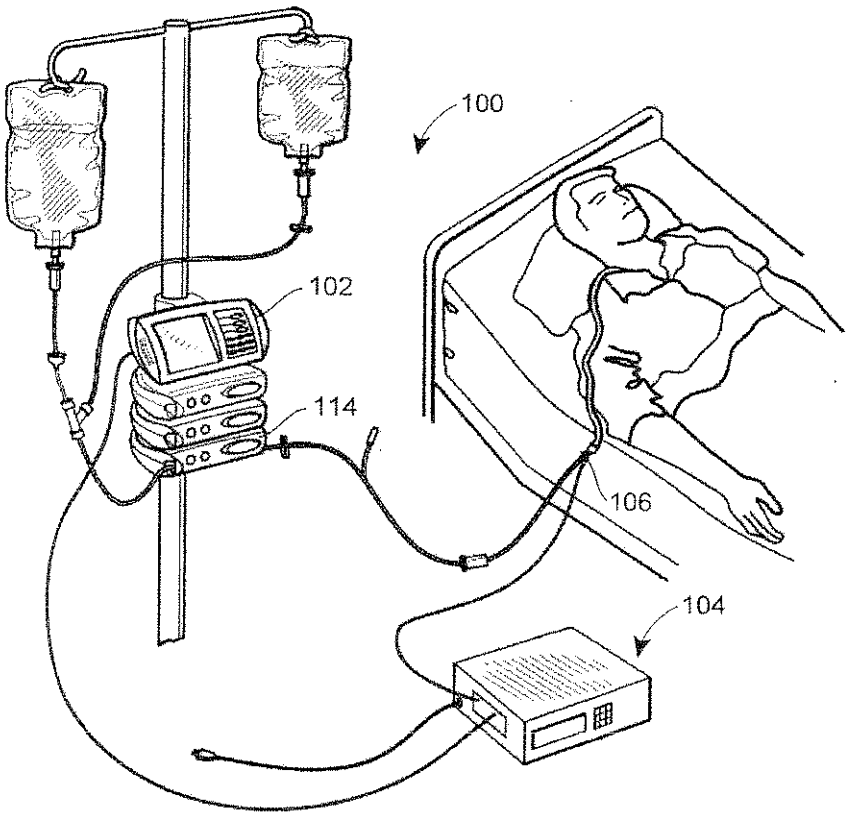

FIG. 1

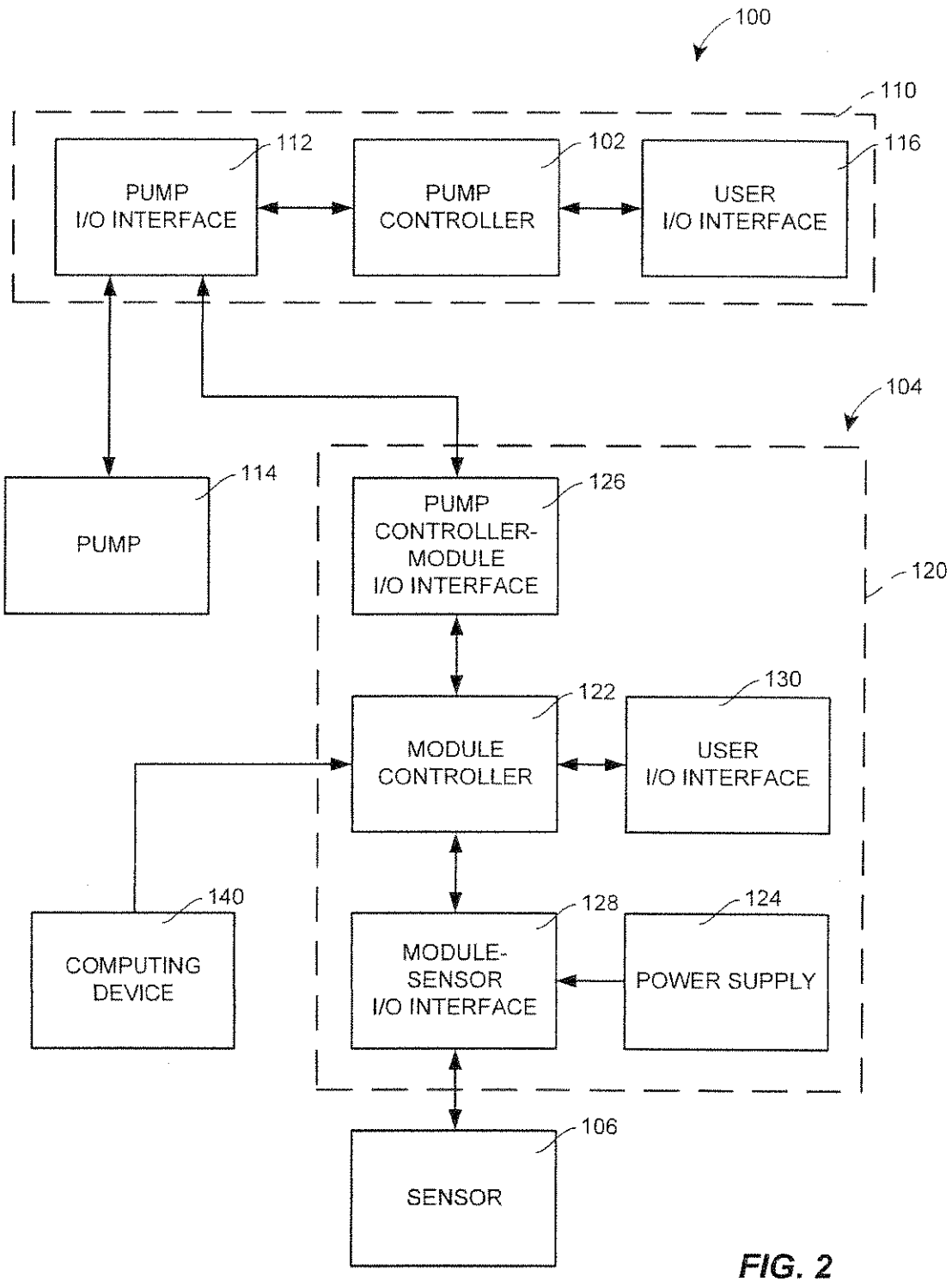
100
110
112
102
116
PUMP I/O INTERFACE
PUMP CONTROLLER
USER I/O INTERFACE
104
114
126
PUMP
PUMP CONTROLLER-MODULE I/O INTERFACE
120
122
130
MODULE CONTROLLER
USER I/O INTERFACE
140
128
124
COMPUTING DEVICE
MODULE-SENSOR I/O INTERFACE
POWER SUPPLY
106
SENSOR

FIG. 2

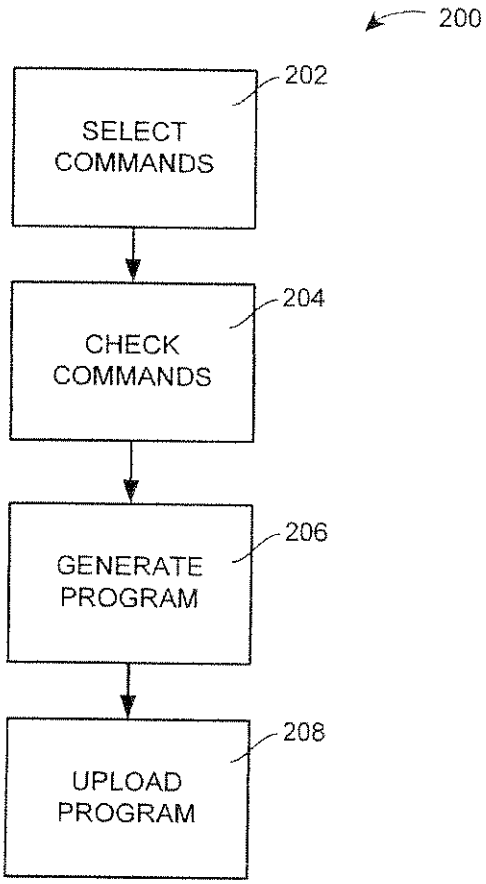
200
202
SELECT COMMANDS
204
CHECK COMMANDS
206
GENERATE PROGRAM
208
UPLOAD PROGRAM

FIG. 3

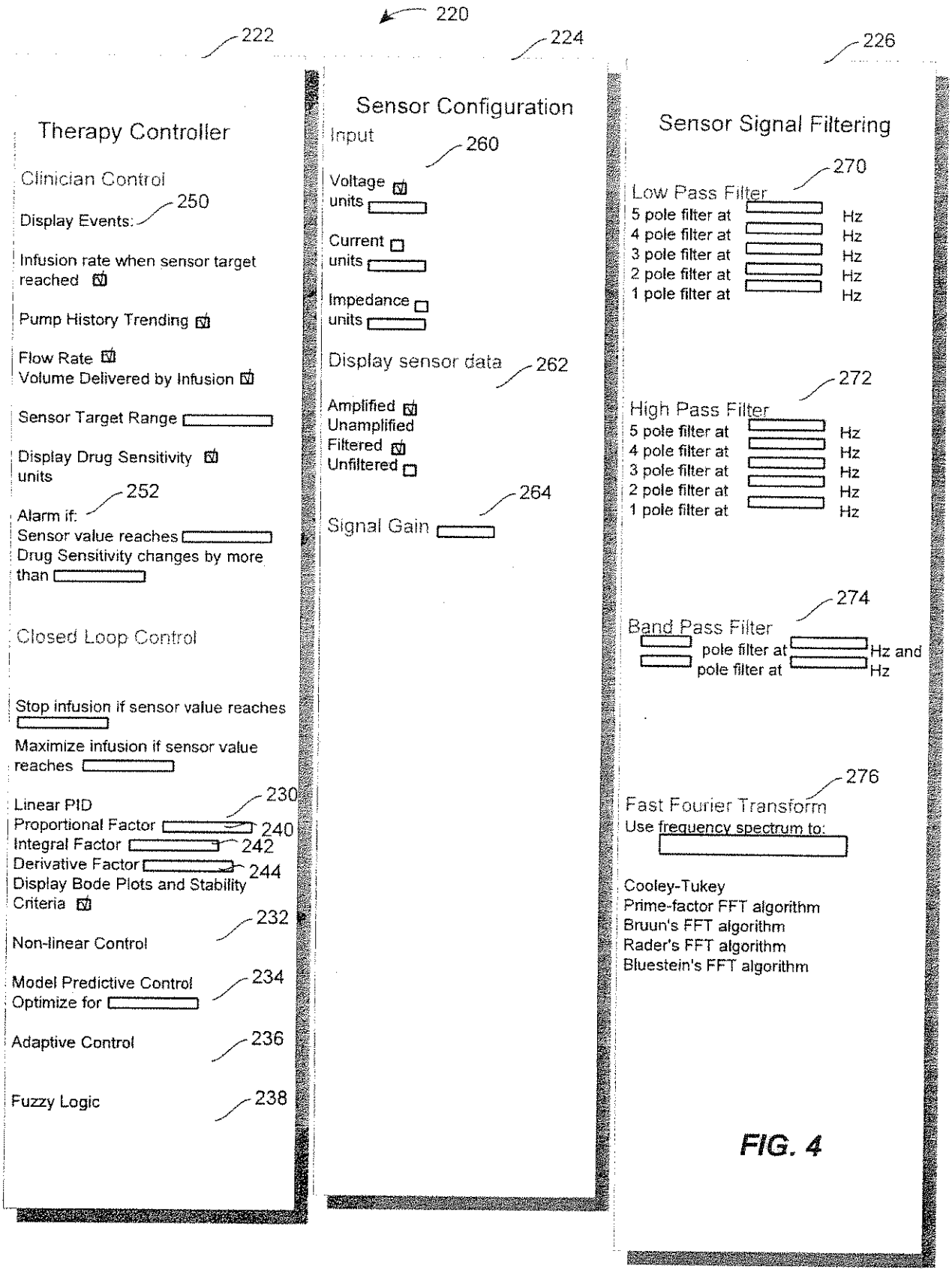
220
222
224
226
Therapy Controller
Clinician Control
Display Events:
250
Infusion rate when sensor target reached
Pump History Trending
Flow Rate
Volume Delivered by Infusion
Sensor Target Range
Display Drug Sensitivity
units
Alarm if:
252
Sensor value reaches
Drug Sensitivity changes by more than
Closed Loop Control
Stop infusion if sensor value reaches
Maximize infusion if sensor value reaches
Linear PID
230
Proportional Factor
240
Integral Factor
242
Derivative Factor
244
Display Bode Plots and Stability Criteria
232
Non-linear Control
Model Predictive Control
234
Optimize for
Adaptive Control
236
Fuzzy Logic
238
Sensor Configuration
Input
260
Voltage
units
Current
units
Impedance
units
Display sensor data
262
Amplified
Unamplified
Filtered
Unfiltered
Signal Gain
264
Sensor Signal Filtering
Low Pass Filter
270
5 pole filter at Hz
4 pole filter at Hz
3 pole filter at Hz
2 pole filter at Hz
1 pole filter at Hz
High Pass Filter
272
5 pole filter at Hz
4 pole filter at Hz
3 pole filter at Hz
2 pole filter at Hz
1 pole filter at Hz
Band Pass Filter
274
pole filter at Hz and
pole filter at Hz
Fast Fourier Transform
276
Use frequency spectrum to:
Cooley-Tukey
Prime-factor FFT algorithm
Bruun's FFT algorithm
Rader's FFT algorithm
Bluestein's FFT algorithm

FIG. 4

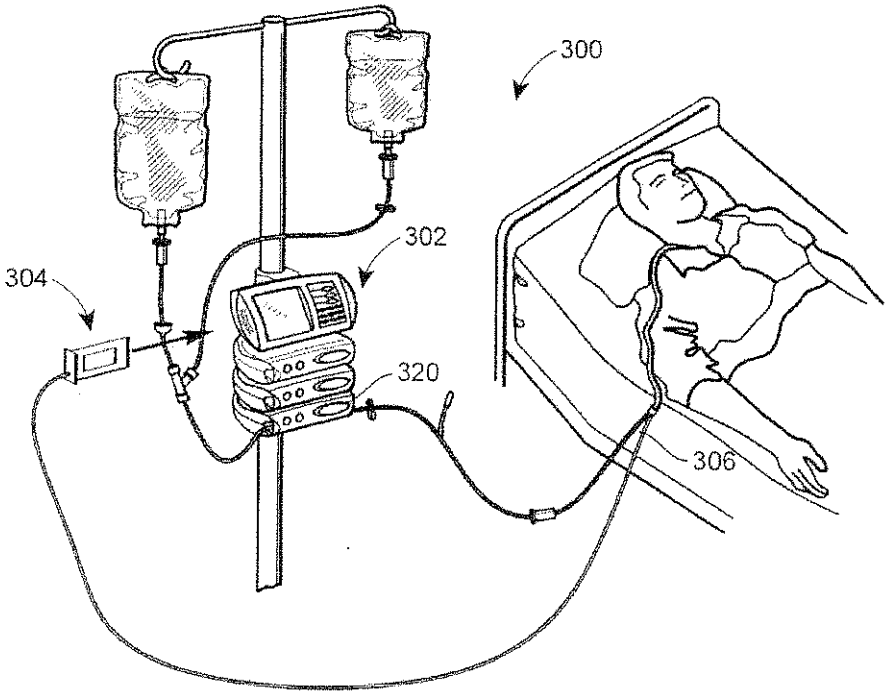

FIG. 5

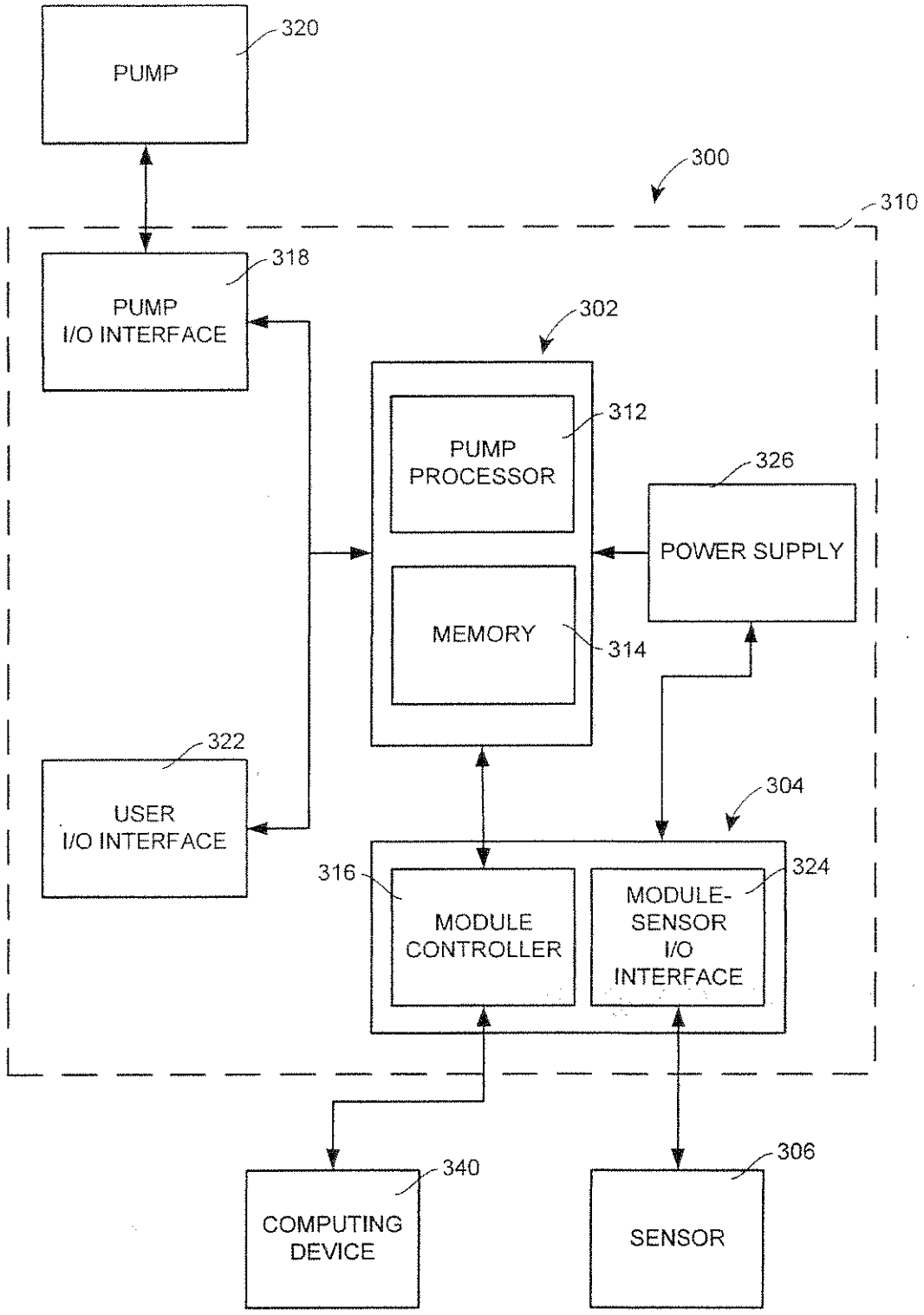
PUMP
320
300
310
PUMP
I/O INTERFACE
318
302
PUMP
PROCESSOR
312
326
POWER SUPPLY
MEMORY
314
322
USER
I/O INTERFACE
304
316
MODULE
CONTROLLER
MODULE-
SENSOR
I/O
INTERFACE
324
COMPUTING
DEVICE
340
SENSOR
306

FIG. 6

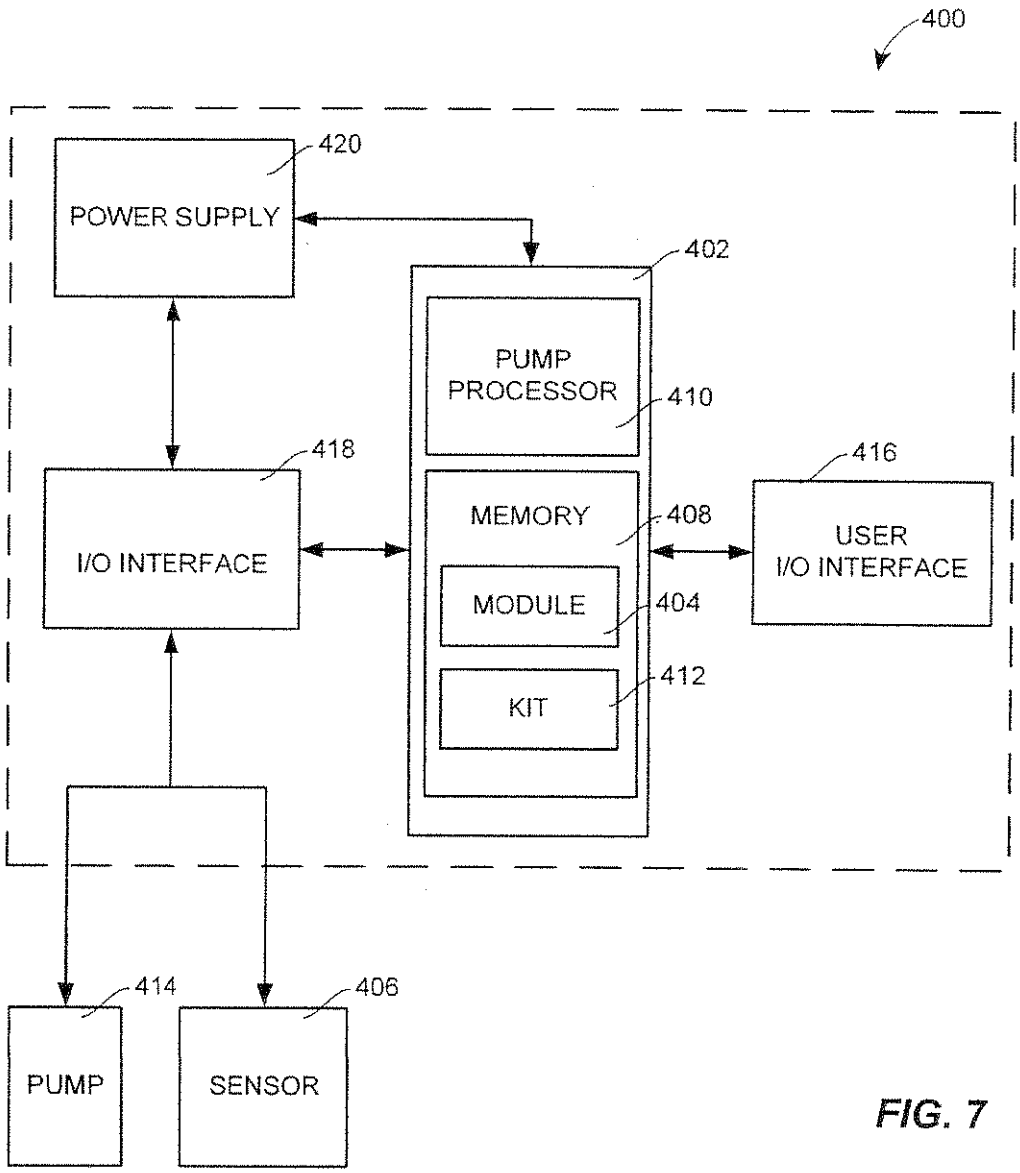
400
420
POWER SUPPLY
402
PUMP PROCESSOR
410
418
I/O INTERFACE
MEMORY
408
416
USER I/O INTERFACE
MODULE
404
412
KIT
414
406
PUMP
SENSOR

FIG. 7

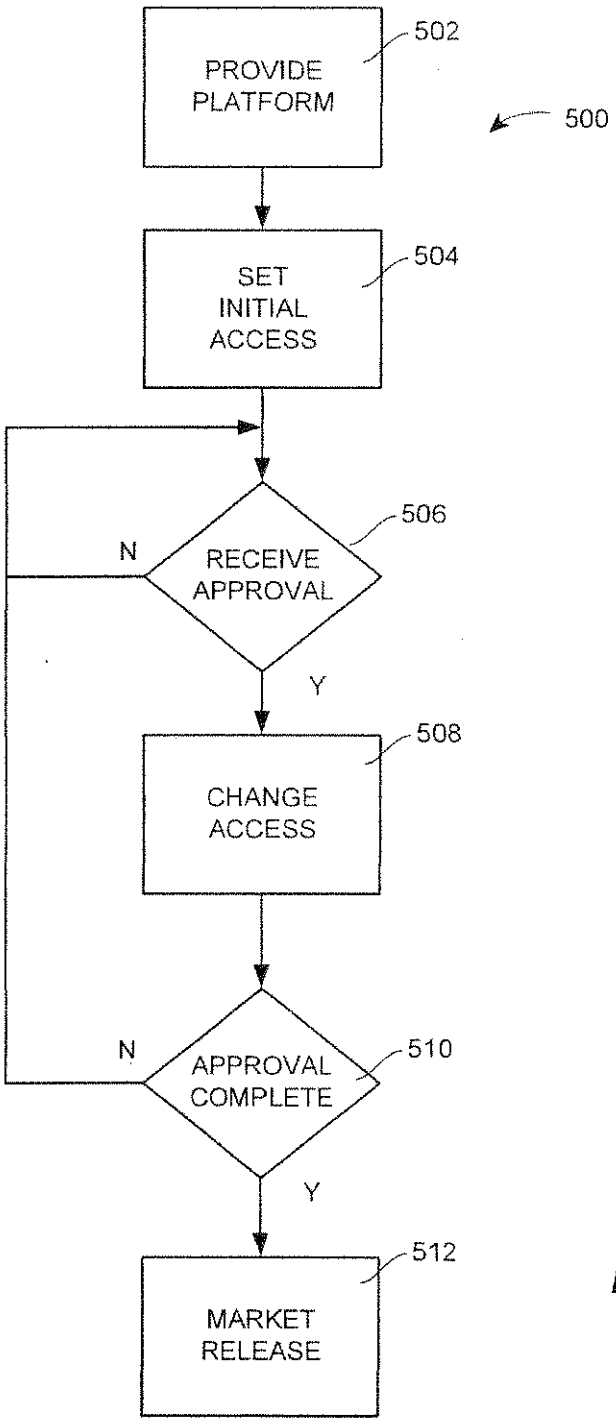
PROVIDE PLATFORM
502
500
SET INITIAL ACCESS
504
RECEIVE APPROVAL
506
N
Y
CHANGE ACCESS
508
APPROVAL COMPLETE
510
N
Y
MARKET RELEASE
512

FIG. 8

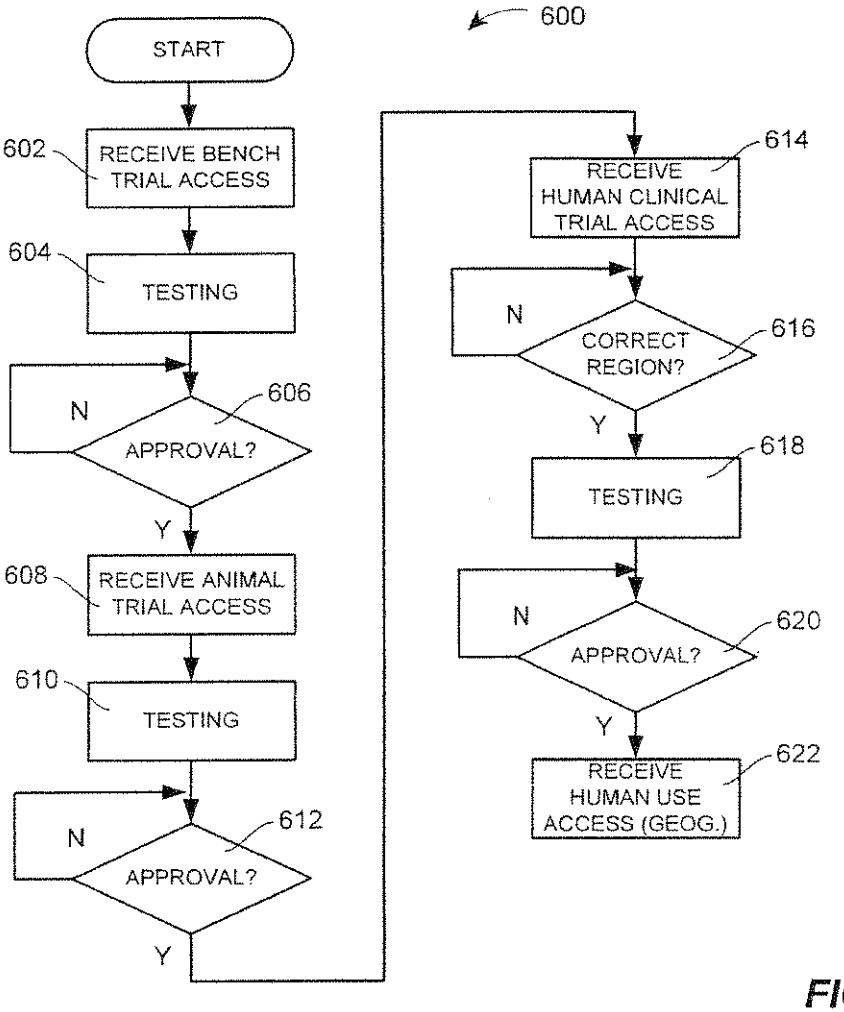
600
START
602
RECEIVE BENCH TRIAL ACCESS
604
TESTING
606
N
APPROVAL?
Y
608
RECEIVE ANIMAL TRIAL ACCESS
610
TESTING
612
N
APPROVAL?
Y
614
RECEIVE HUMAN CLINICAL TRIAL ACCESS
N
616
CORRECT REGION?
Y
618
TESTING
N
620
APPROVAL?
Y
622
RECEIVE HUMAN USE ACCESS (GEOG.)

FIG. 9

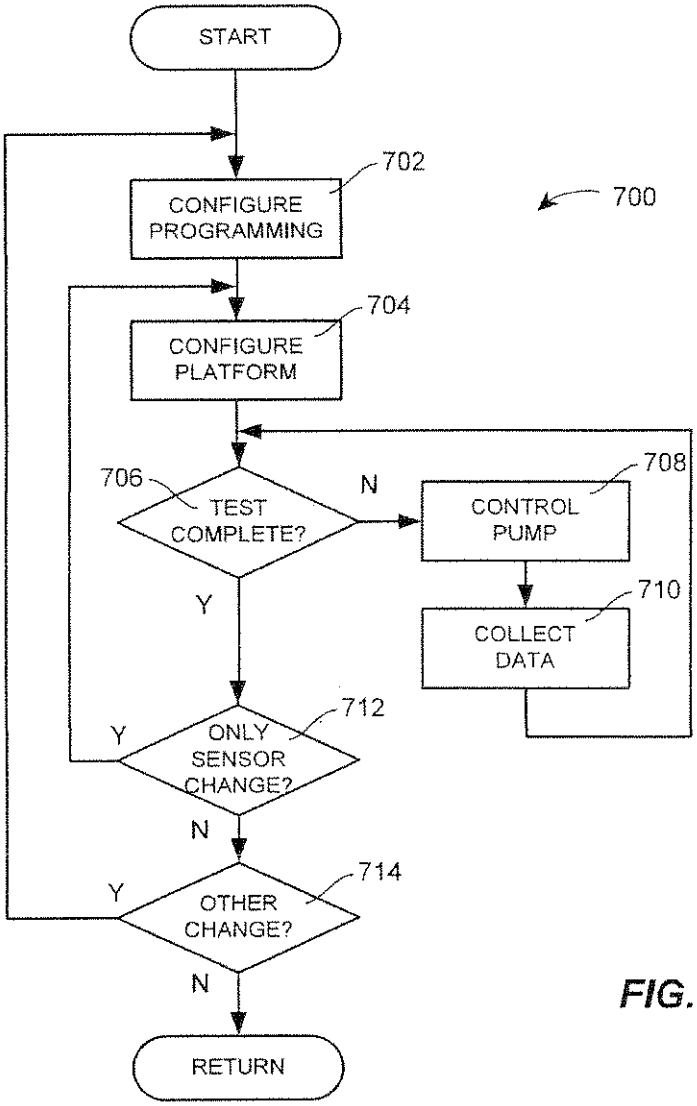
START
CONFIGURE PROGRAMMING
702
700
CONFIGURE PLATFORM
704
TEST COMPLETE?
706
N
CONTROL PUMP
708
Y
COLLECT DATA
710
ONLY SENSOR CHANGE?
712
Y
N
OTHER CHANGE?
714
Y
N
RETURN

FIG. 10

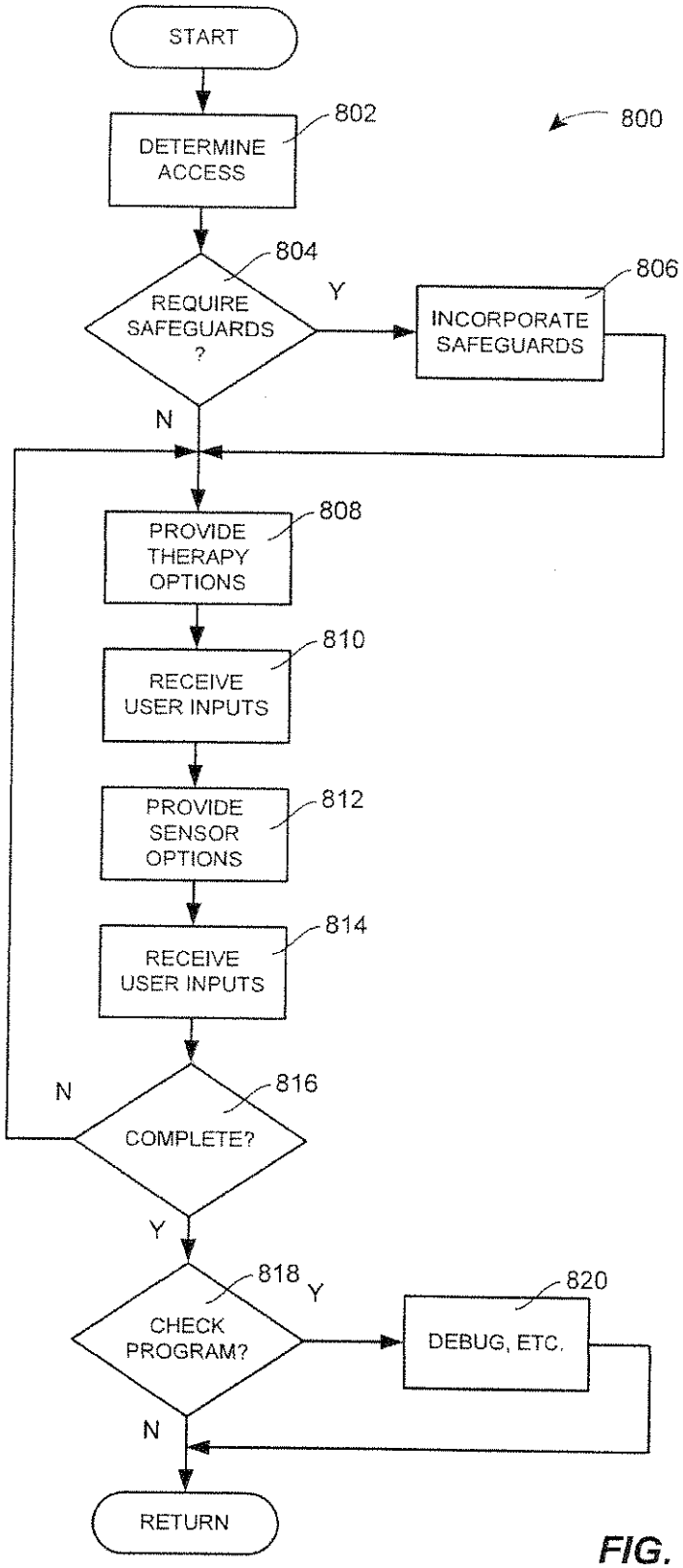
START
DETERMINE ACCESS
802
800
REQUIRE SAFEGUARDS ?
804
Y
INCORPORATE SAFEGUARDS
806
N
PROVIDE THERAPY OPTIONS
808
RECEIVE USER INPUTS
810
PROVIDE SENSOR OPTIONS
812
RECEIVE USER INPUTS
814
N
COMPLETE?
816
Y
CHECK PROGRAM?
818
Y
DEBUG, ETC.
820
N
RETURN

FIG. 11