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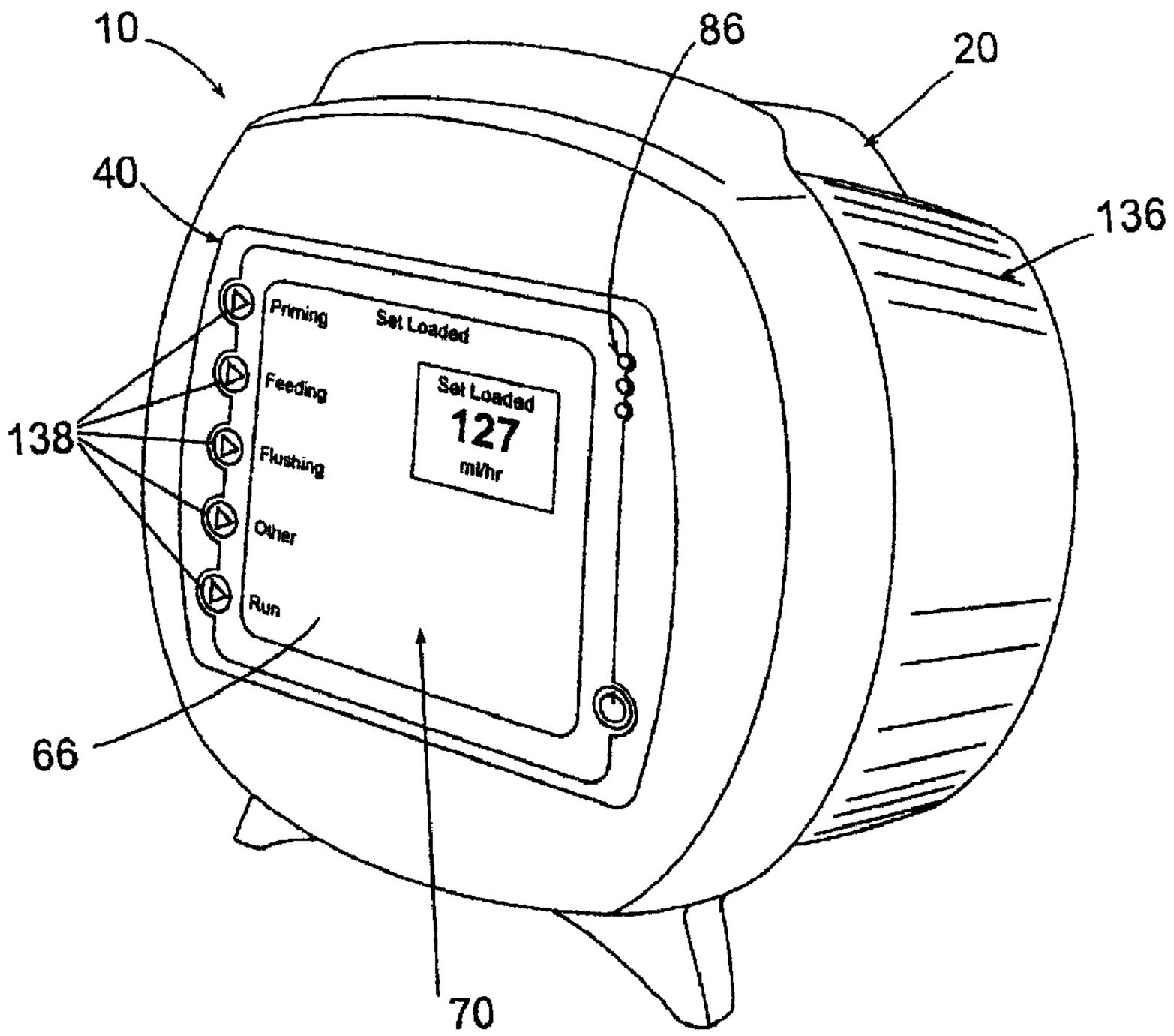
(54) Title: RE-CERTIFICATION SYSTEM FOR A FLOW CONTROL APPARATUS



(57) Abrégé/Abstract:
A flow control apparatus (10) adapted to load a re-certification feeding set (14) is disclosed. The flow control apparatus (10) comprises a sensor (30) for sensing the loading of the re-certification feeding set (14) to the flow control apparatus (10), and a

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(57) Abrégé(suite)/Abstract(continued):
software subsystem (36) in operative association with the sensor (30) that includes a re-certification procedure for verifying that at least one component of the flow control apparatus (10) is functioning within a predetermined operational range. Also disclosed is a method for verifying that at least one component of a flow control apparatus (10) is functioning within a predetermined operational range.

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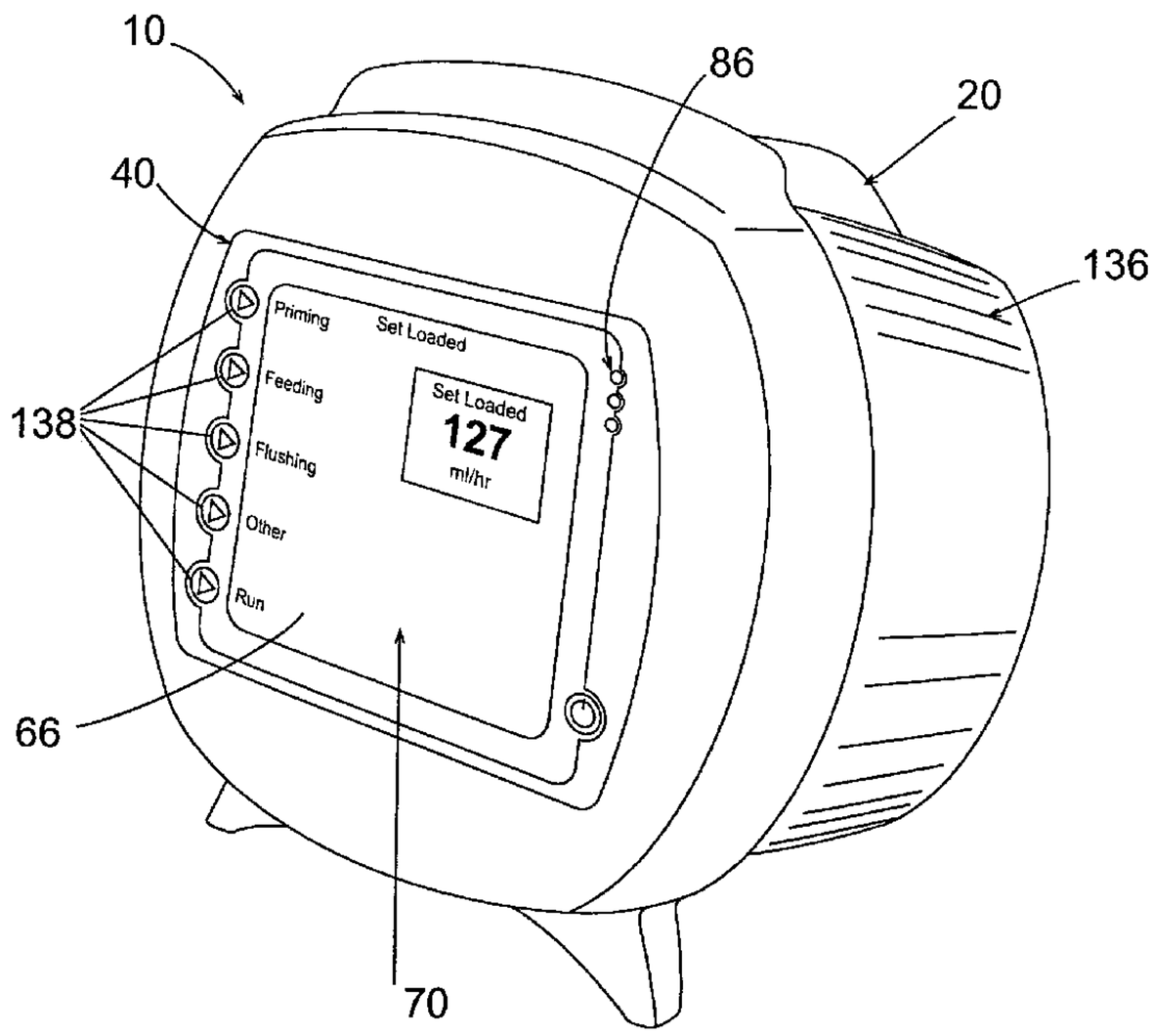
(54) Title: RE-CERTIFICATION SYSTEM FOR A FLOW CONTROL APPARATUS



(57) Abstract: A flow control apparatus (10) adapted to load a re-certification feeding set (14) is disclosed. The flow control apparatus (10) comprises a sensor (30) for sensing the loading of the re-certification feeding set (14) to the flow control apparatus (10), and a software subsystem (36) in operative association with the sensor (30) that includes a re-certification procedure for verifying that at least one component of the flow control apparatus (10) is functioning within a predetermined operational range. Also disclosed is a method for verifying that at least one component of a flow control apparatus (10) is functioning within a predetermined operational range.

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RE-CERTIFICATION SYSTEM FOR A FLOW CONTROL APPARATUS

Robert B. Gaines, Chris Knauper
and Jeffrey E. Price

FIELD OF THE INVENTION

The present invention relates to a flow control apparatus adapted to load with a re-certification feeding set.

BACKGROUND OF THE INVENTION

Administering fluids containing medicine or nutrition to a patient is generally well known in the art. Typically, fluid is delivered to the patient by a re-certification feeding set loaded to a flow control apparatus, such as a pump, connected to a source of fluid which delivers fluid to a patient at a controlled rate of delivery. However, there is a need in the art for an improved flow control apparatus having a re-certification procedure that verifies at least one component of the flow control apparatus is functioning within a predetermined operational range.

SUMMARY OF THE INVENTION

The present invention relates to a flow control apparatus comprising a flow control apparatus adapted to load with a re-certification feeding set, a sensor for sensing the loading of the re-certification feeding set to the flow control apparatus, and a software subsystem in operative association with the sensor, wherein the software subsystem comprises a re-certification procedure that is capable of verifying that at least one

component of the flow control apparatus is functioning within a predetermined operational range. Further, the software subsystem in cooperation with the sensed re-certification feeding set places the flow control apparatus in a non-medical delivery status.

The present invention also relates to a flow control apparatus comprising a flow control apparatus adapted to load with a re-certification feeding set, a sensor for sensing the loading of the re-certification feeding set to the flow control apparatus, and a software subsystem in operative association with the sensor, the software subsystem in cooperation with the sensed re-certification feeding set places the flow control apparatus in a non-medical delivery status, and wherein the software subsystem initiates a re-certification procedure that verifies at least one component of the flow control apparatus is functioning within a predetermined operation range upon sensing the re-certification feeding set loaded to the flow control apparatus by the sensor.

The present invention further relates to a method for verifying that at least one component of the flow control apparatus is functioning within a predetermined operational range comprising loading a re-certification feeding set to the flow control apparatus, sensing that the re-certification feeding set is loaded to the flow control apparatus, and utilizing a software subsystem that comprises a re-certification procedure that can verify at least one component of the flow control apparatus is functioning within a predetermined operation range.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an exemplary flow control apparatus according to the present invention;

FIG. 2 is a side view of the flow control apparatus having a re-certification feeding set loaded thereto according to the present invention;

FIG. 3 is a simplified block diagram illustrating the elements of the flow control apparatus according to the present invention;

FIG. 4 is a flow chart of a re-certification procedure according to the present invention;

FIG. 4A is a sub-routine of the flow chart shown in FIG. 4 according to the present invention;

FIG. 4B is another sub-routine of the flow chart shown in FIG. 4 according to the present invention; and

FIGS. 5A-I illustrate the sequence of screens shown to the user by the flow control apparatus to operate the re-certification procedure according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings, an embodiment of the flow control apparatus according to the present invention is illustrated and generally indicated as 10 in FIGS. 1-3. Flow control apparatus 10 comprises a re-certification procedure that is capable of verifying that at least one component of the flow control apparatus 10 is functioning within a predetermined operational range when a re-certification feeding set 14 is loaded to the flow control apparatus 10. The re-certification feeding set 14 includes tubing 56 engaged to a valve mechanism 28 and mounting member 74 that load the re-certification feeding set 14 to the flow control apparatus 10 for driving fluid through the tubing 56 for delivery to a patient. As used herein the term load means that the valve mechanism 28 and mounting member 74 are engaged to the flow control apparatus 10 and tubing 56 is in a stretched condition between valve mechanism 28 and mounting member 74 such that the re-certification feeding set 14 is ready for operation with flow control apparatus 10.

Referring to FIGS. 1 and 2, an exemplary flow control apparatus 10 according to the present invention comprises a housing 20 adapted for loading the re-certification feeding set 14 to the flow control apparatus 10. Flow control apparatus 10 comprises a main recess 21 covered by a main door 136 and includes first and second recesses 58 and 60 for providing sites that are adapted to load the re-certification feeding set 14 to the flow control apparatus 10. Preferably, a means for driving fluid, such as a rotor 26, is rotatably

engaged through housing 20 and adapted to engage tubing 56 such that tubing 56 is in a stretched condition between first and second recesses 58, 60 when the valve mechanism 28 and mounting member 74 are engaged to the flow control apparatus 10.

As used herein, the portion of tubing 56 of re-certification feeding set 14 leading to rotor 26 is termed upstream, while the portion of tubing 56 leading away from rotor 26 is termed downstream. Accordingly, rotation of rotor 26 compresses tubing 56 and provides a means for driving fluid from the upstream to the downstream side of the re-certification feeding set 14 for delivery to a patient. The present invention contemplates that any flow control apparatus having a means for driving fluid may be used, such as a linear peristaltic pump, bellows pump, turbine pump, rotary peristaltic pump, and displacement pump.

Referring to FIG. 1, flow control apparatus 10 further comprises a user interface 40 that assists the user to operatively interface with the flow control apparatus 10. A display 70, in operative association with a plurality of buttons 138 positioned along an overlay 66, provide the user a means to interact with a microprocessor 62 to operate the re-certification procedure of the present invention.

According to another aspect of the present invention, a software subsystem 36 operates the re-certification procedure that is capable of verifying that at least one component of flow control apparatus 10

is functioning within a predetermined operational range once a re-certification feeding set 14 (FIG. 3) is loaded thereto.

The re-certification feeding set 14 comprises a mounting member 74 having one or more identification members 76 attached thereto that designate the re-certification feeding set 14 as having a re-certification configuration to microprocessor 62 when sensed by flow control apparatus 10. Once the user loads the re-certification feeding set 14 to flow control apparatus 10, the sensor 30 senses the presence of the mounting member 74 engaged to the second recess 60 due to the location of one or more identification members 76 attached to the mounting member 74 and signals software subsystem 36 to initiate the re-certification procedure that verifies that at least one component of the flow control apparatus 10 is functioning within a predetermined operational range. Preferably identification members 76 are magnetic components, or in the alternative, magnetically-susceptible metallic components capable of being sensed by sensor 30 without requiring direct physical contact with sensor 30. Sensor 30 is preferably a Hall-effect sensor or other type of proximity sensor that is positioned near the second recess 60 such that sensor 30 can sense the presence of one or more identification members 76 when the mounting member 74 is engaged to second recess 60.

As shown in FIG. 3, the software subsystem 36 selects from three systems. The subsystem 36 can exit to a flow monitoring system 36a, an administration feeding set identifier system 36b or the re-certification system 12. The flow monitoring system 36a monitors flow through the flow control apparatus 10. The administration feeing set identifier system 36b identifies a feeding set, such as the re-certification set 14 described above. The re-certification system 12 is described more fully below. During re-certification system 12 operating the flow control apparatus is not operating in the flow control monitor 36a, thus, the flow control apparatus is not delivering medication (i.e. a non-medical delivery status). Referring to

FIGS. 1-3, software subsystem 36 directs flow control apparatus 10 to perform various manual and automatic tests related to verifying that at least one component of the flow control apparatus 10 is functioning within a predetermined operational range. For example, components of the flow control apparatus 10 that may be tested during the re-certification procedure can be the user interface 40, LED lights 86, sensor 30, rotor 26, valve mechanism 28, single motor source 44 and gear arrangement 34. In operation, the user loads a re-certification feeding set 14 to the flow control apparatus 10 in the manner as described above and illustrated in FIG. 2 in order to initiate the re-certification procedure.

Once the mounting member 74 is engaged to the second recess 60 and the presence of the mounting member 74 is sensed by the sensor 30, the software subsystem 36 initiates the re-certification procedure that instructs the microprocessor 62 to verify that at least one component of flow control apparatus 10 is functioning within a predetermined

As shown in FIGS. 5A-I the user will be instructed to follow a sequence of screens displayed on user interface 40 that controls the re-certification procedure. In addition, the software subsystem 36 performs a manual test for verifying that certain components are functioning properly and an automatic test that operates rotor 26 in order to drive a predetermined volume of fluid through the re-certification feeding set 14 to evaluate the performance of components of the flow control apparatus 10 that relate to the function of driving fluid through feeding set 14 by flow control apparatus 10. After these tests

have been successfully performed, the user interface 40 is provided with a determination whether the components tested by the flow control apparatus 10 are functioning within a predetermined operational range.

Software subsystem 36 in operative association with microprocessor 62 determines through a series of decision points and steps whether at least one component of the flow control apparatus 10 is functioning within a predetermined operational range.

Referring to the flow charts in FIGS. 4, 4A and 4B, the various decision points and steps executed by software subsystem 36 under the re-certification procedure are illustrated. Software subsystem 36 directs flow control apparatus 10 to initiate a re-certification procedure when the re-certification feeding set 14 is loaded to the flow control apparatus 10.

At step 302, the software subsystem 36 reads database 134 to determine whether prior automatic and manual tests have been recently performed on the flow control apparatus 10 to determine whether components are functioning within a predetermined operational range. After this determination is made, software subsystem 36 at decision point 304 determines whether the re-certification feeding set 14 has been loaded to flow control apparatus 10 and sensed by sensor 30 when the mounting member 74 is engaged to second recess 60. If no re-certification feeding set 14 is sensed, then at step

306 the software subsystem again determines whether the manual and automatic tests have been performed.

At step 308, if neither the manual nor automatic tests have been performed, then the user interface 40 displays screen 400 (FIG. 5A) instructing the user to load the re-certification feeding set 14 to the flow control apparatus 10. At step 310, the user loads the re-certification feeding set 14 in the same manner described above for re-certification feeding set 14. If both the automatic and manual tests have been performed as determined at decision point 306, then at step 312 the software subsystem 36 instructs the flow control apparatus 10 to enter normal operation.

If at decision point 304, the re-certification feeding set 14 is determined to be loaded, then at decision point 316, the software subsystem 36 re-confirms whether the re-certification feeding set 14 is actually loaded to the flow control apparatus 10. If the re-certification feeding set 14 is not loaded, then at step 318 screen 400 (FIG. 5A) is shown again instructing the user to load the re-certification feeding set 14 to the flow control apparatus 10. At step 320, the user loads the re-certification feeding set 14 as instructed. Once step 320 is completed, screen 402 (FIG. 5B) is shown to the user at step 322 for displaying the main screen for performing the manual test according to the present invention.

At decision point 324, the software subsystem 36 determines whether the manual test has been performed.

If not, then at step 326 button 510 for initiating the automatic test is hidden and disabled and software subsystem 36 proceeds to step 328. If the manual test has been performed, then at step 328, a re-iterative process subroutine B is executed at step 331 where the user is instructed to perform various manual tests for verifying that tested components of flow control apparatus 10 are functioning within a predetermined operational range by actuating buttons 500, 502, 506, and 508 at screen 402. These manual tests verify that the battery, LED light display, sound system, and sensor are functioning within a predetermined operational range as shall be discussed in greater detail below.

Referring to FIG. 4B the various decision points and steps executed by the software subsystem 36 when performing the various manual tests under subroutine B as well as the various screens and buttons presented to the user at user interface 40 for accomplishing the same are illustrated. At step 600, the user selects button 500 at screen 402 (FIG. 5B) which displays a buzzer test screen 404 (FIG. 5C) at step 602 which provides a means for verifying that the buzzer (not shown) or other sound system of flow control apparatus 10 is functioning within a predetermined operational range. The buzzer is then activated for the user to hear at step 604. At decision point 606, the user is queried whether the buzzer was heard and the user then presses either button 514 to signify YES or button 516 to signify NO or NOT SURE. At step 608, when the user presses button 514 software subsystem 36 verifies that button 514 is functional and also confirms the re-

certification of the buzzer. If button 516 is pressed, at step 330 software subsystem 36 determines whether all of the manual tests have been performed and passed at step 330. If the software subsystem 36 enters step 330 because other manual tests are yet to be performed a re-iterative process 331 is entered for performing the other manual tests under subroutine B.

At step 610, if the user selects button 502 at screen 402 then an LED Test screen 406 (FIG. 5D) is displayed at step 612 which provides a means for verifying that the LED lights 86 on user interface 40 are functioning within a predetermined operational range. The microprocessor 62 has LED lights 86 cycle through the red, yellow and green LED lights 86 at step 614. At decision point 616 the user is queried whether the LED lights 86 are actually cycling and the user presses either button 520 to signify YES or button 522 signifying NO. If the user presses button 520 then at step 618 the software subsystem 36 verifies that button 520 is operable and also re-certifies that LED lights 86 are functioning within a predetermined operational range. However, if the user presses button 522 then the software subsystem 36 at step 330 enters re-iterative process 331 for performing the other manual tests under subroutine B.

At step 622, if the user selects button 506 at screen 402 a screen 408 (FIG. 5E) is displayed at step 624 which provides step-by-step instructions to the user for performing a battery test on the battery (not shown) that provides power to the flow control apparatus 10.

These step-by-step instructions instruct the user to disconnect AC power to the flow control apparatus 10 which will cause the LED lights 86 to dim (step 626). At decision point 628 the software subsystem 36 determines whether the battery is dead, or in a minimal or critical charge based upon predetermined values stored in database 134. If the battery is dead, or in a minimal or critical charge the software subsystem 36 at step 632 activates an alarm. After the alarm has been activated, the user is then instructed to reconnect the AC power to the flow control apparatus 10 at step 620. However, if the battery is not dead, or in a minimal or critical charge then software subsystem 36 enters re-iterative process 331 for performing the other manual tests at step 328.

At step 634, if the user selects button 508 at screen 402 then a screen 410 (FIG. 5F) is displayed at step 636 which provides instructions to the user for performing a manual test which verifies that sensor 30 can sense the loading of the re-certification feeding set 14 to the second recess 60, and in particular sensing the engagement of the mounting member 74 to second recess 60. Screen 410 instructs the user to remove the re-certification feeding set 14 from the flow control apparatus 10 at step 638. Once the sensor 30 senses the removal of re-certification feeding set 14 from the flow control apparatus 10, the buzzer is sounded at step 642 by the software subsystem 36. At step 644, the user reloads the re-certification feeding set 14 to the flow control apparatus 10 as described above. Once the re-certification feeding set 14 is loaded, the software subsystem 36 activates the buzzer,

verifies that the sensor 30 can sense the engagement of the mounting member 74 to the second recess 60, and confirms that button 508 is operational. A button 530 is provided at screen 410 to cancel this procedure if so desired by the user.

Once it is confirmed that all of the manual tests have been performed at decision point 330, software subsystem 36 at step 332 displays and enables button 510 at screen 402 for allowing the user to start the automatic test during execution of a subroutine C at step 334.

At step 334 the automatic test is performed under subroutine C. The user first presses button 510 at screen 402 to begin the automatic test which provides a re-certification procedure that verifies that at least one component of the flow control apparatus 10 related to driving fluid through the re-certification feeding set 14, such as the rotor 26, gear arrangement 34 and single motor source 44, are functioning within a predetermined operational range. A screen 412 (FIG. 5G) is shown to the user that displays an "IN PROGRESS" message to the user signifying that the automatic test is being performed by software subsystem 36 at step 702. Once the automatic test is initiated, the software subsystem 36 determines at decision point 704 whether the automatic test has been successful.

If the automatic test is not successful, then at step 706, the software subsystem 36 transmits test data over a serial port (not shown) of the flow control

apparatus 10 to an external computer (not shown). At step 708, the software subsystem 36 displays a "RE-CERTIFICATION FAILURE" message to the user at screen 416 (FIG. 5I). After the message is displayed, at step 716 the user presses button 532 in order to power down the flow control apparatus 10 to complete subroutine C.

If the automatic test is successful, then at step 710, the software subsystem 36 saves the automatic test results to database 134. Once the automatic test results are saved, at step 712 the software subsystem 36 transmits test data over the serial port of the flow control apparatus 10 to the external computer.

After completion, a screen 414 (FIG. 5H) is shown to the user that displays a "RE-CERTIFICATION COMPLETE" message to the user at step 714. The software subsystem 36 at step 716 then instructs the user to power down the flow control apparatus 10 which completes the procedure of the re-certification system 12 according to the present invention.

It should be understood from the foregoing that, while particular embodiments of the invention have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the invention as will be apparent to those skilled in the art.

CLAIMS

What is claimed is:

1. A flow control apparatus comprising:

a) a flow control apparatus adapted to load with a re-certification feeding set thereto,

b) a sensor for sensing the loading of said re-certification feeding set to said flow control apparatus, and

c) a software subsystem in operative association with said sensor, wherein said software subsystem comprises a re-certification procedure that is capable of verifying that at least one component of said flow control apparatus is functioning within a predetermined operational range, and further wherein the software subsystem in cooperation with the sensed re-certification feeding set places the flow control apparatus in a non-medical delivery status.

2. The flow control apparatus according to claim 1, wherein said software subsystem initiates said re-certification procedure upon sensing by said sensor of said re-certification feeding set being loaded to said flow control apparatus.

3. The flow control apparatus according to claim 1, wherein said re-certification feeding set is in fluid flow communication with a fluid.

4. The flow control apparatus according to claim 2, wherein said re-certification feeding set comprises a mounting member.

5. The flow control apparatus according to claim 4, wherein said mounting member comprises at least one identification member.

6. A flow control apparatus comprising:

a) a flow control apparatus adapted to load with a re-certification feeding set thereto,

b) a sensor for sensing the loading of said re-certification feeding set to said flow control apparatus, and

c) a software subsystem in operative association with said sensor, the software subsystem in cooperation with the sensed re-certification feeding set places the flow control apparatus in a non-medical delivery status, and wherein said software subsystem initiates a re-certification procedure that verifies at least one component of said flow control apparatus is functioning within a predetermined operation range upon sensing said re-certification feeding set loaded to said flow control apparatus by said sensor.

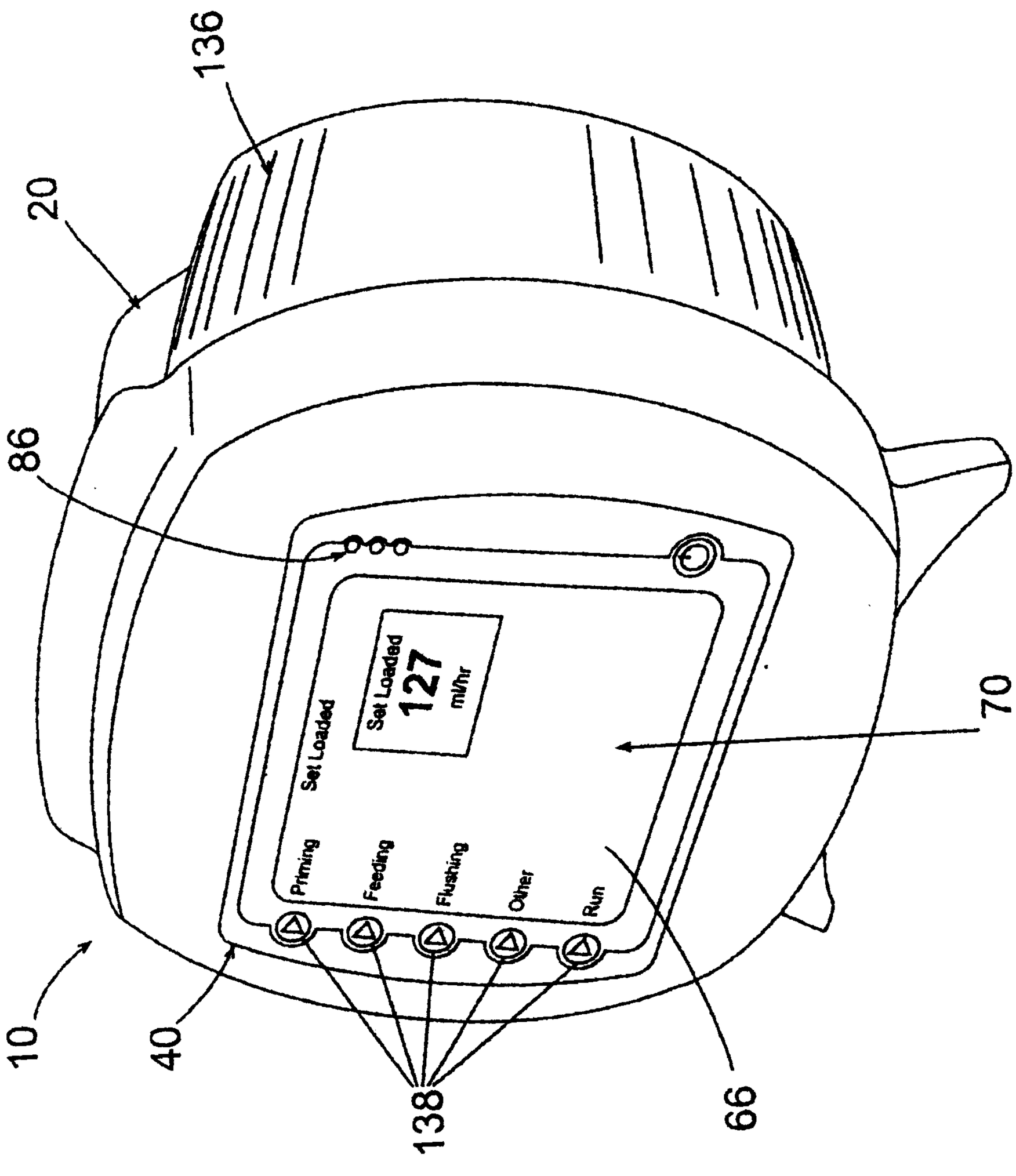

136
20
86
Set Loaded
127
ml/hr
Set Loaded
Priming
Feeding
Flushing
Other
Run
10
40
38
66
70

Fig. 1

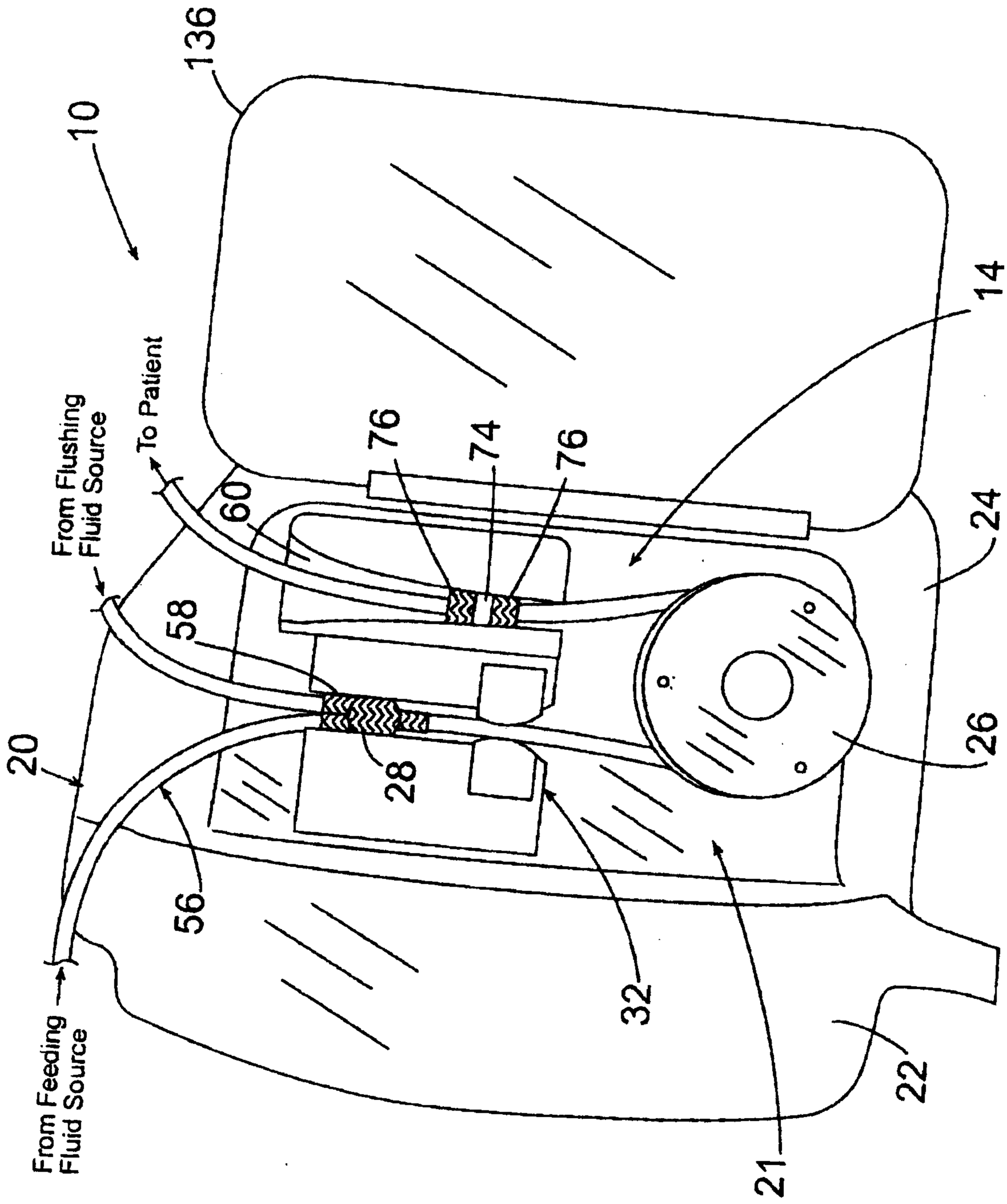
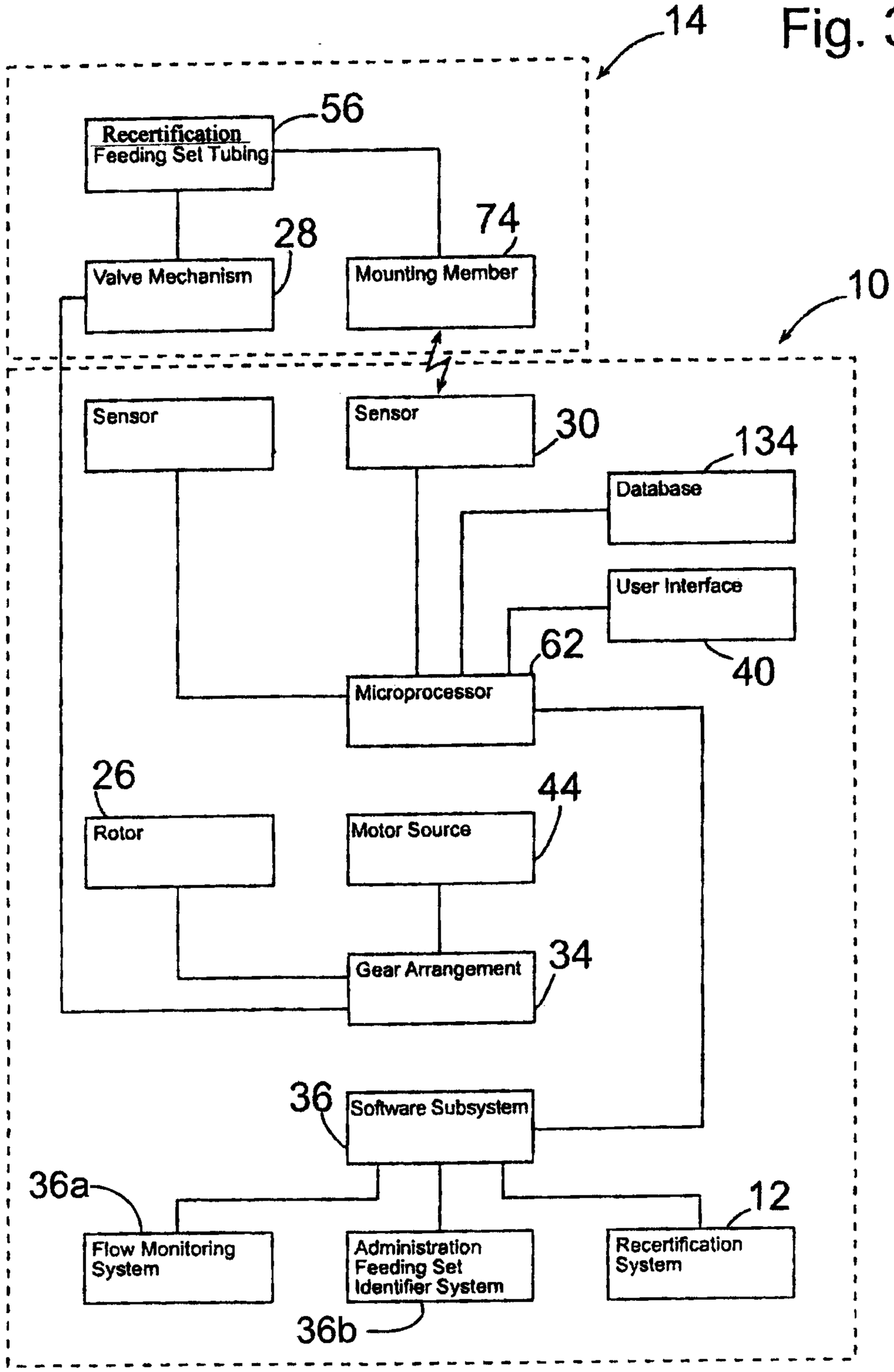

10
136
14
From Flushing Fluid Source
To Patient
76
74
76
60
58
24
20
28
26
56
32
From Feeding Fluid Source
1
22

Fig. 2

Fig. 3


14
Recertification
Feeding Set Tubing
56
28
74
Valve Mechanism
Mounting Member
10
Sensor
Sensor
30
134
Database
User Interface
62
40
Microprocessor
26
44
Rotor
Motor Source
34
Gear Arrangement
36
Software Subsystem
36a
12
Flow Monitoring System
Administration Feeding Set Identifier System
Recertification System
36b

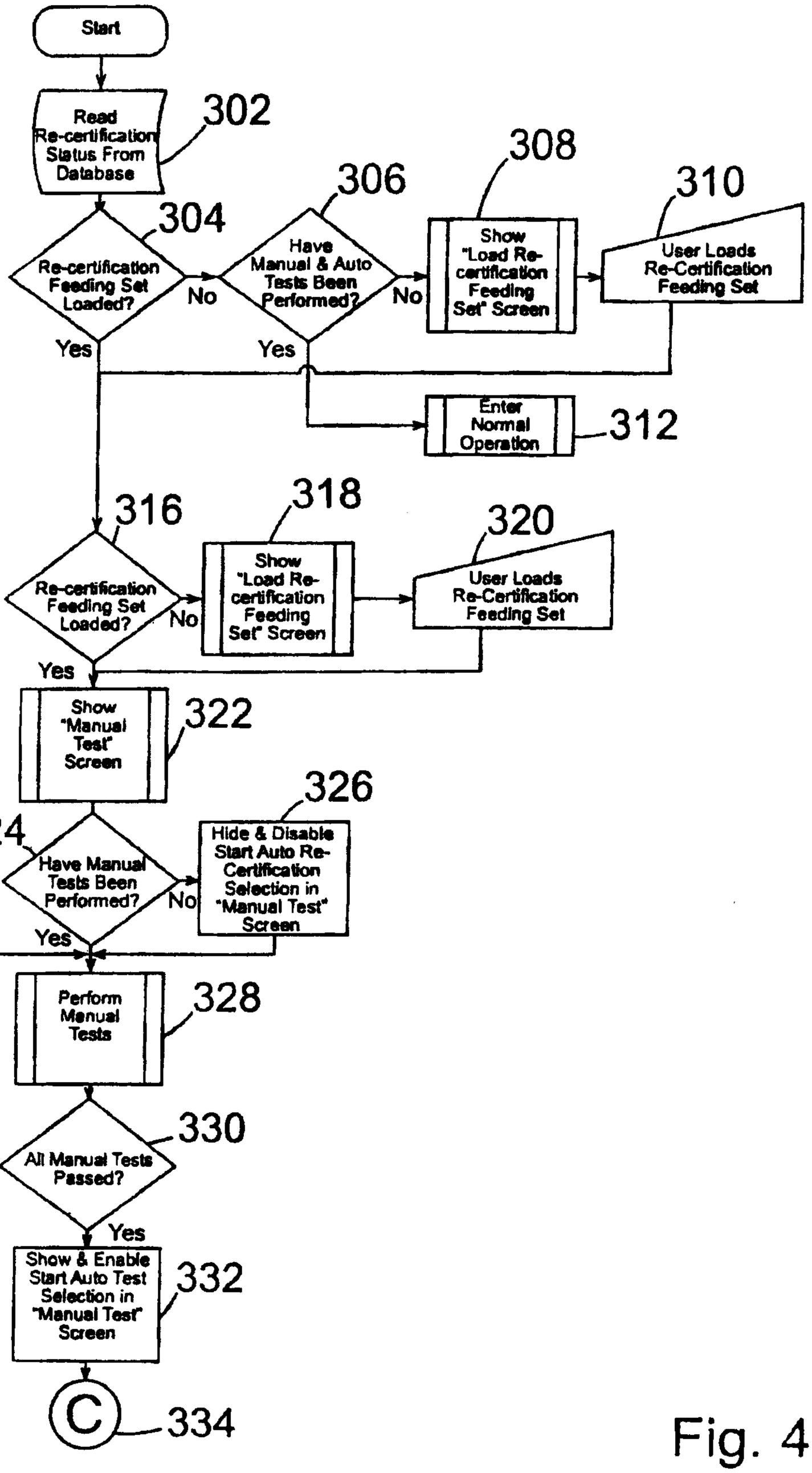

Start
Read Re-certification Status From Database
302
Re-certification Feeding Set Loaded?
304
No
Have Manual & Auto Tests Been Performed?
306
No
Show "Load Re-certification Feeding Set" Screen
308
User Loads Re-Certification Feeding Set
310
Yes
Yes
Enter Normal Operation
312
Re-certification Feeding Set Loaded?
316
No
Show "Load Re-certification Feeding Set" Screen
318
User Loads Re-Certification Feeding Set
320
Yes
Show "Manual Test" Screen
322
Have Manual Tests Been Performed?
324
No
Hide & Disable Start Auto Re-Certification Selection in "Manual Test" Screen
326
Yes
331
B
Perform Manual Tests
328
All Manual Tests Passed?
330
No
Yes
Show & Enable Start Auto Test Selection in "Manual Test" Screen
332
C
334

Fig. 4

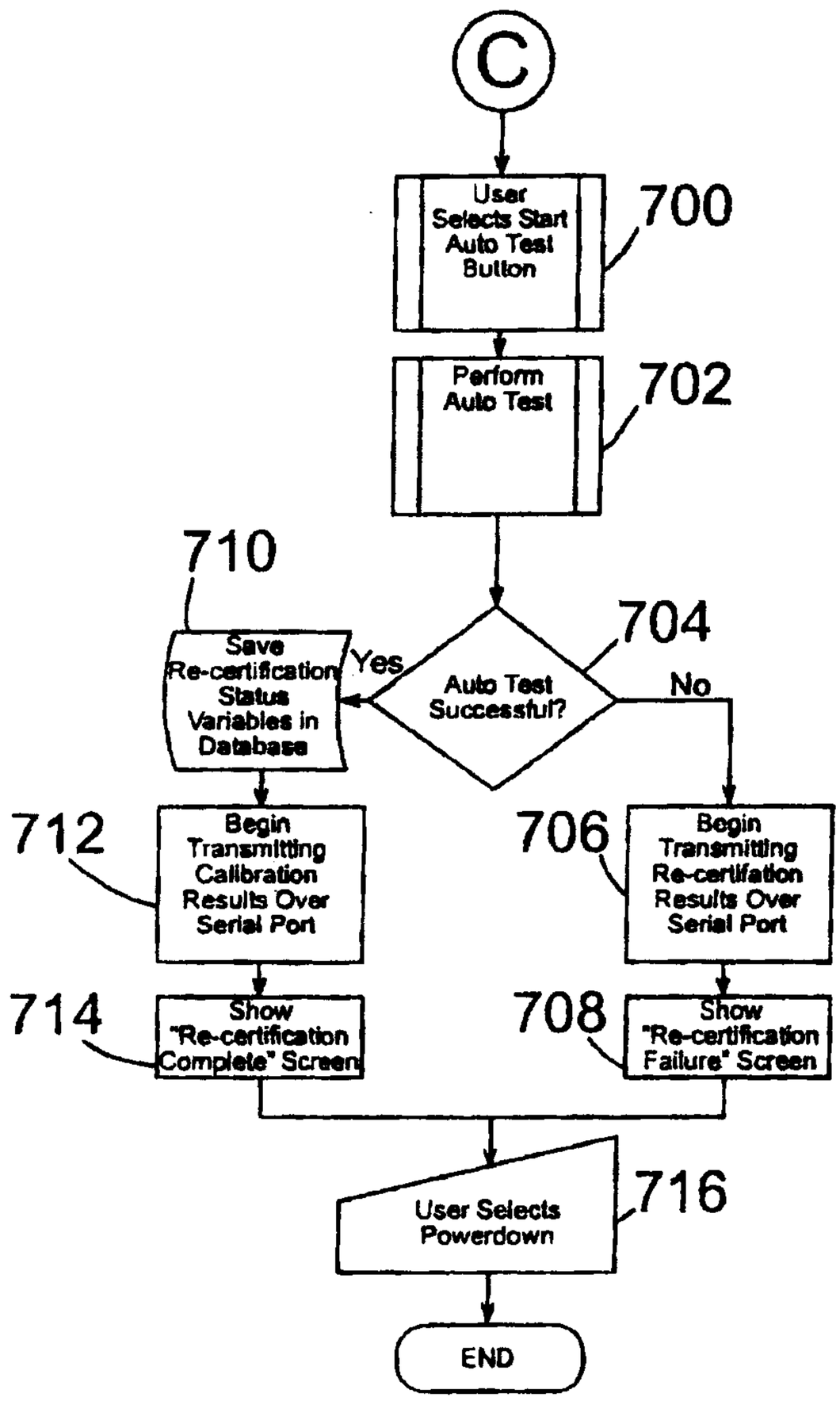
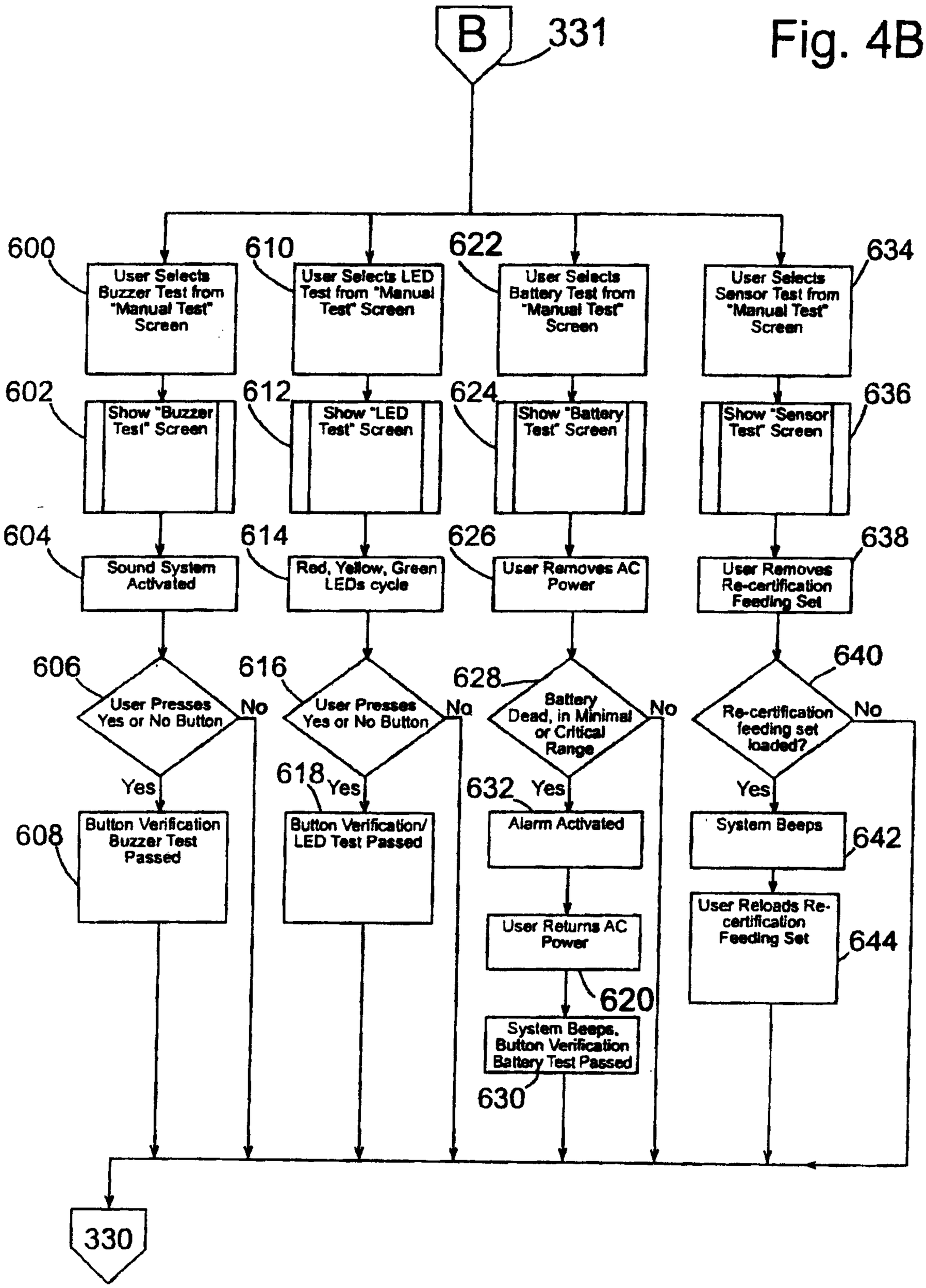

C
User Selects Start Auto Test Button
700
Perform Auto Test
702
710
Save Re-certification Status Variables in Database
Yes
Auto Test Successful?
704
No
712
Begin Transmitting Calibration Results Over Serial Port
706
Begin Transmitting Re-certifation Results Over Serial Port
714
Show "Re-certification Complete" Screen
708
Show "Re-certification Failure" Screen
User Selects Powerdown
716
END

Fig. 4A

Fig. 4B


B
331
600
User Selects Buzzer Test from "Manual Test" Screen
610
User Selects LED Test from "Manual Test" Screen
622
User Selects Battery Test from "Manual Test" Screen
634
User Selects Sensor Test from "Manual Test" Screen
602
Show "Buzzer Test" Screen
612
Show "LED Test" Screen
624
Show "Battery Test" Screen
636
Show "Sensor Test" Screen
604
Sound System Activated
614
Red, Yellow, Green LEDs cycle
626
User Removes AC Power
638
User Removes Re-certification Feeding Set
606
User Presses Yes or No Button
No
Yes
616
User Presses Yes or No Button
No
618
Yes
628
Battery Dead, in Minimal or Critical Range
No
632
Yes
640
Re-certification feeding set loaded?
No
Yes
608
Button Verification Buzzer Test Passed
Button Verification/ LED Test Passed
Alarm Activated
System Beeps
642
User Returns AC Power
620
User Reloads Re-certification Feeding Set
644
System Beeps, Button Verification Battery Test Passed
630
330

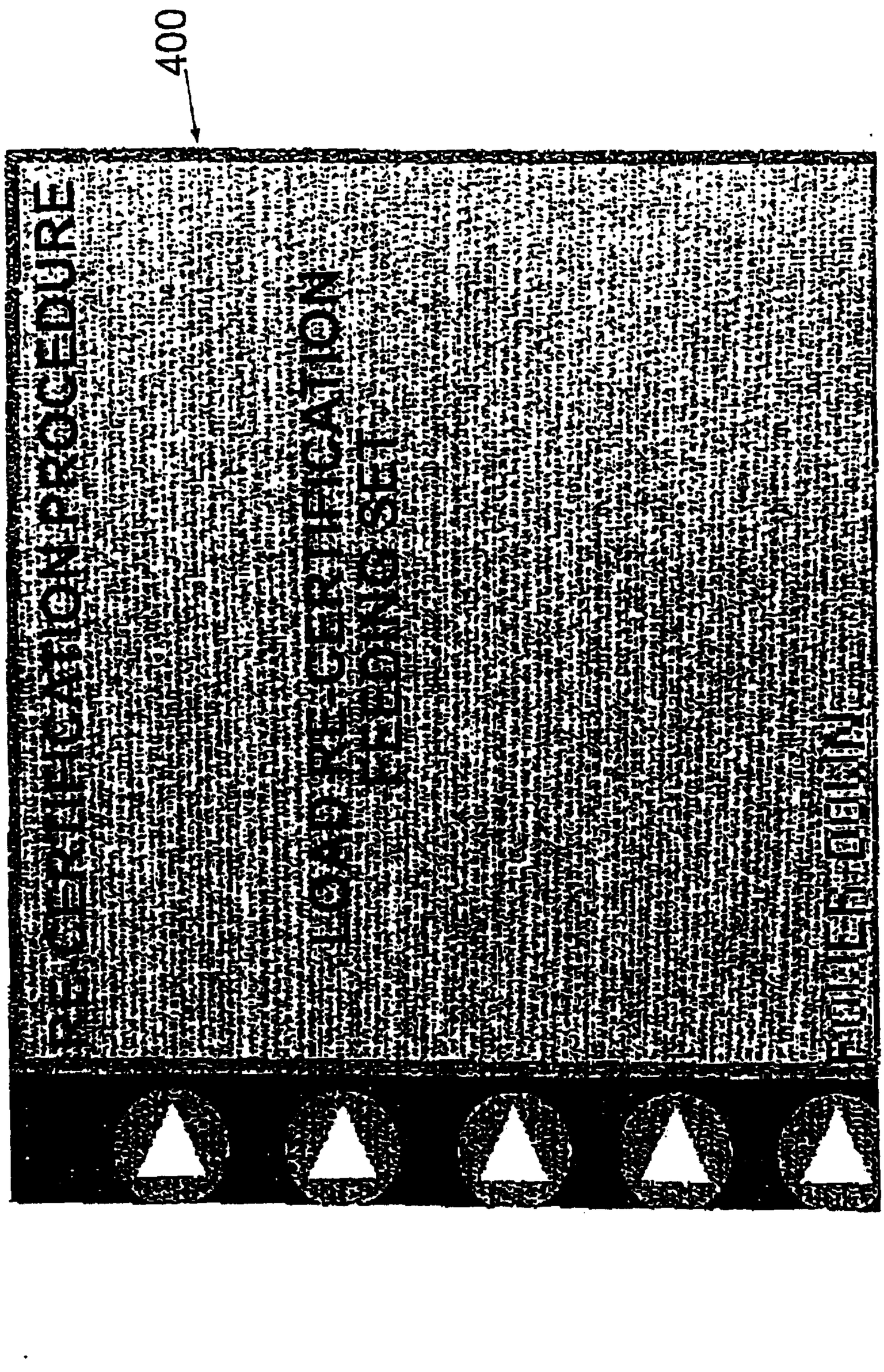


Fig. 5A

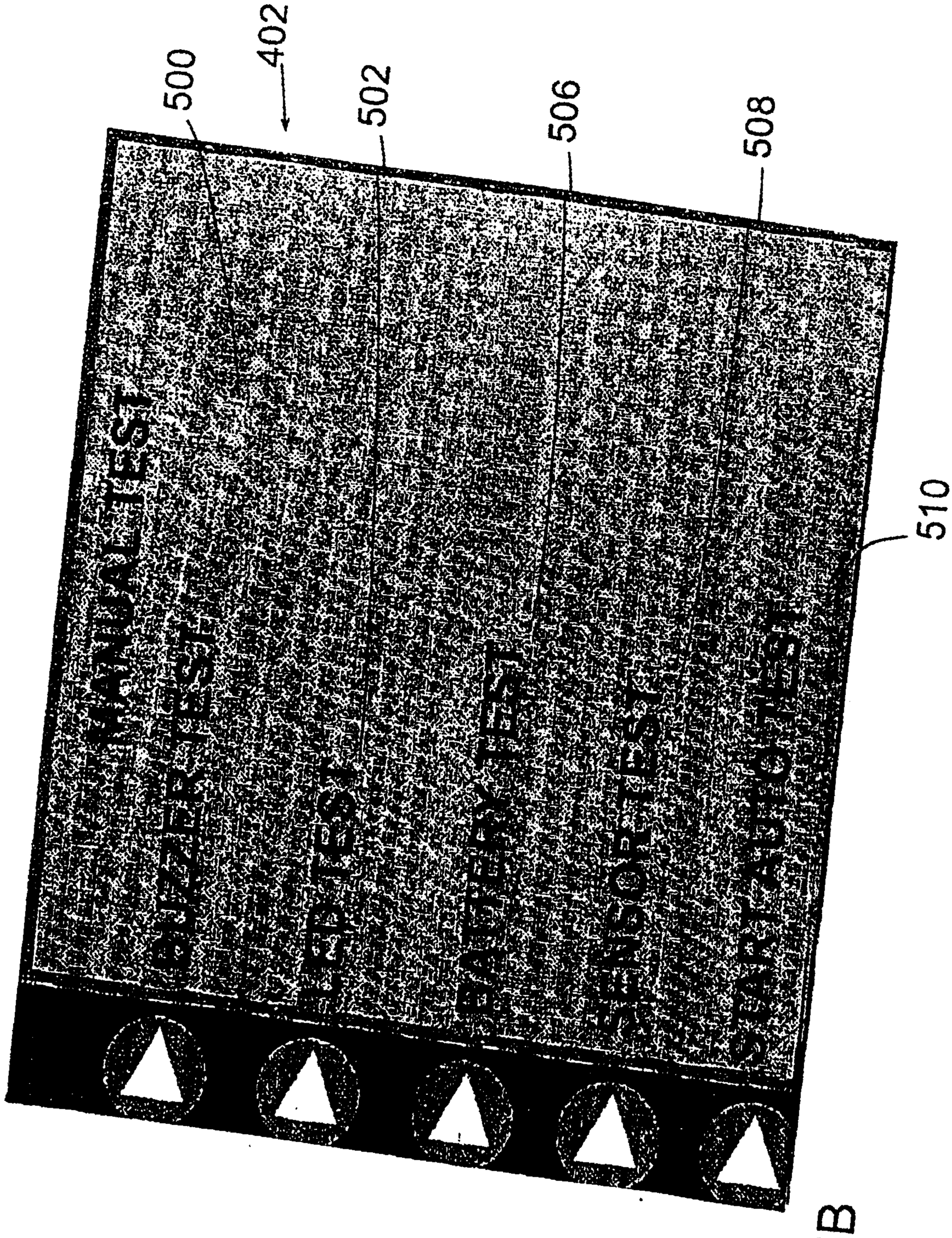


Fig. 5B

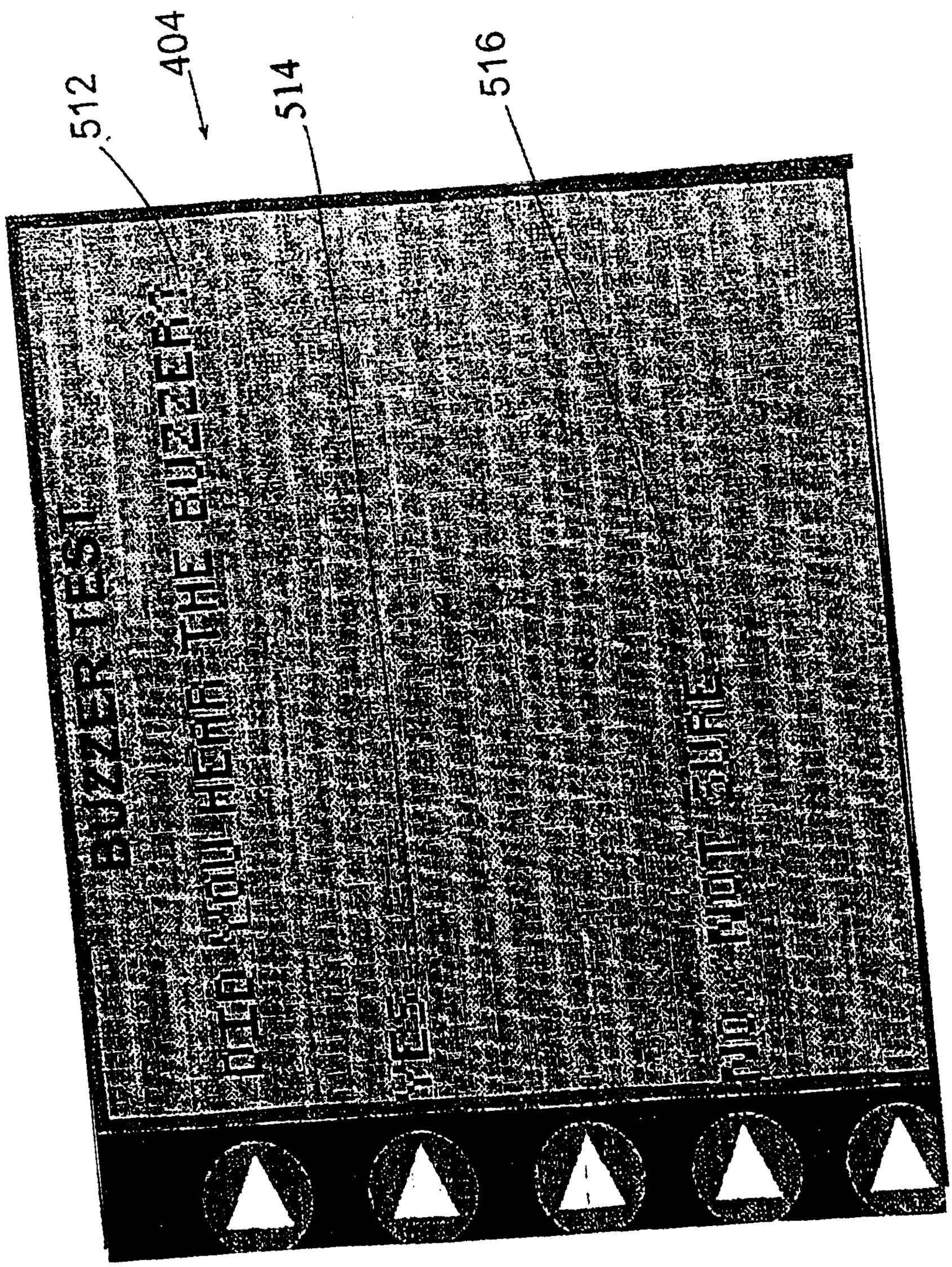


Fig. 5C

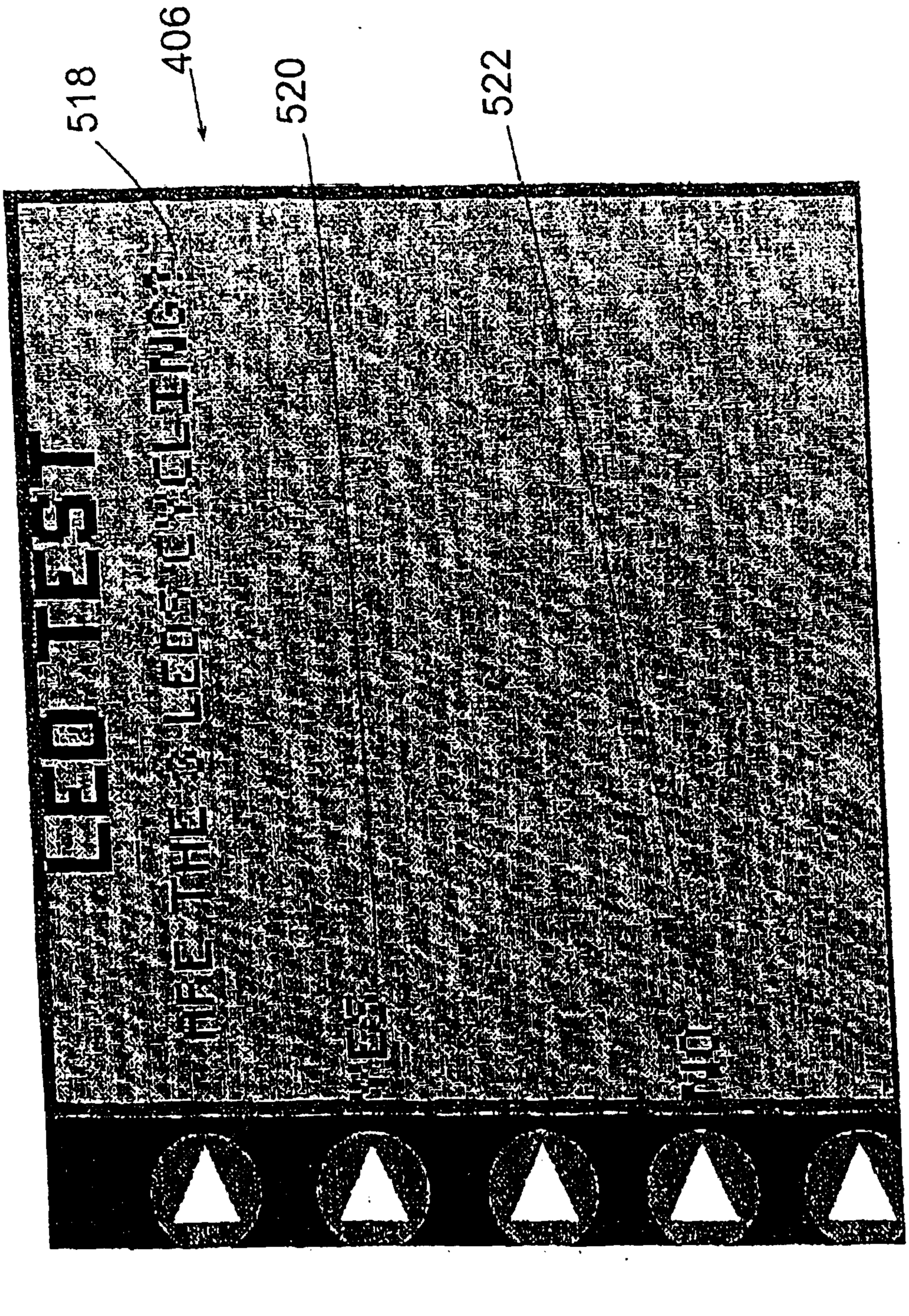


Fig. 5

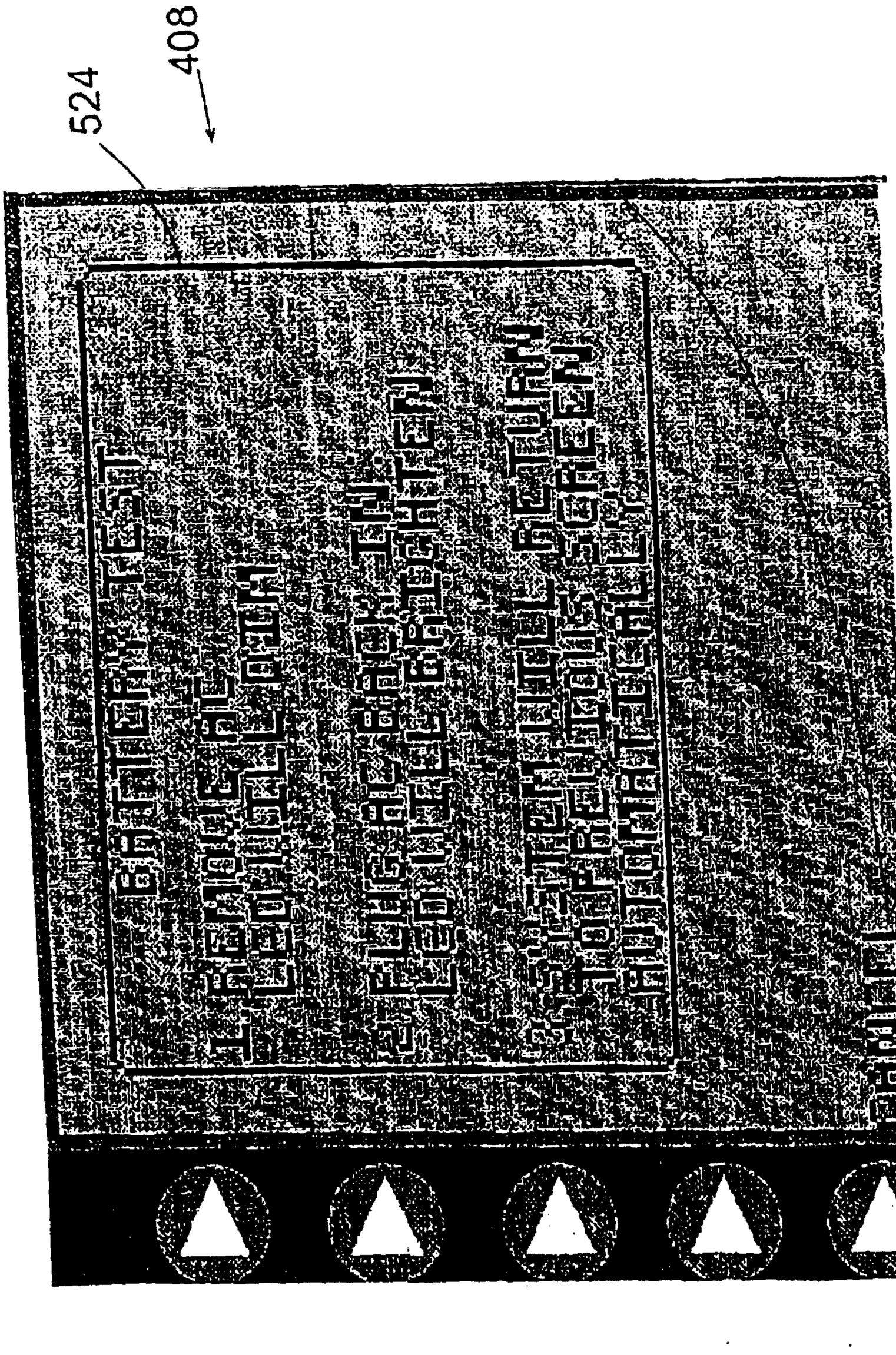


Fig. 5E

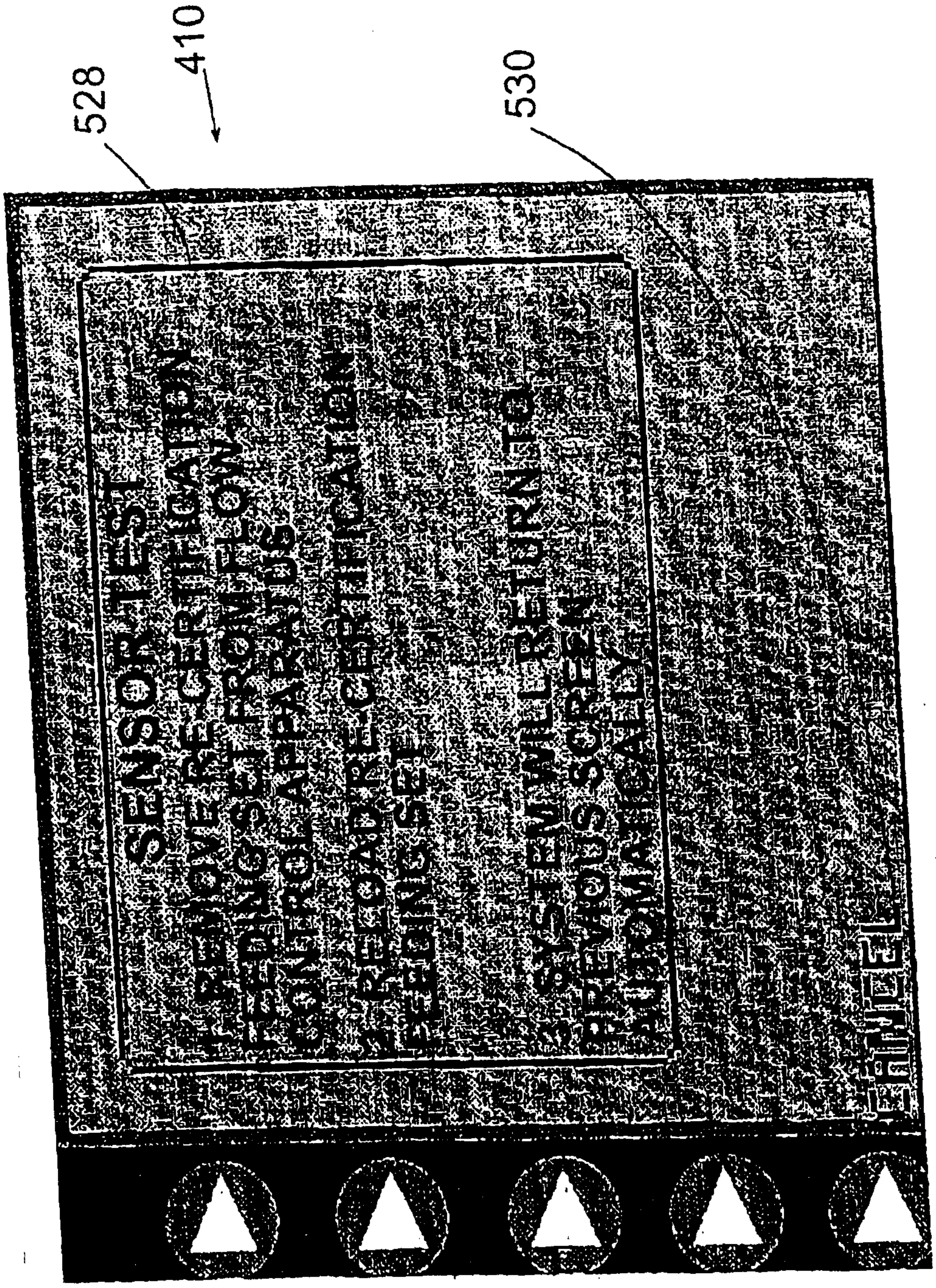

410
528
530
SENSOR TEST
REMOVE RE-CERTIFICATION
FEEDING SET FROM FLOW
CONTROL APPARATUS
RELOAD RE-CERTIFICATION
FEEDING SET
SYSTEM WILL RETURN TO
PREVIOUS SCREEN
AUTOMATICALLY

Fig. 5F

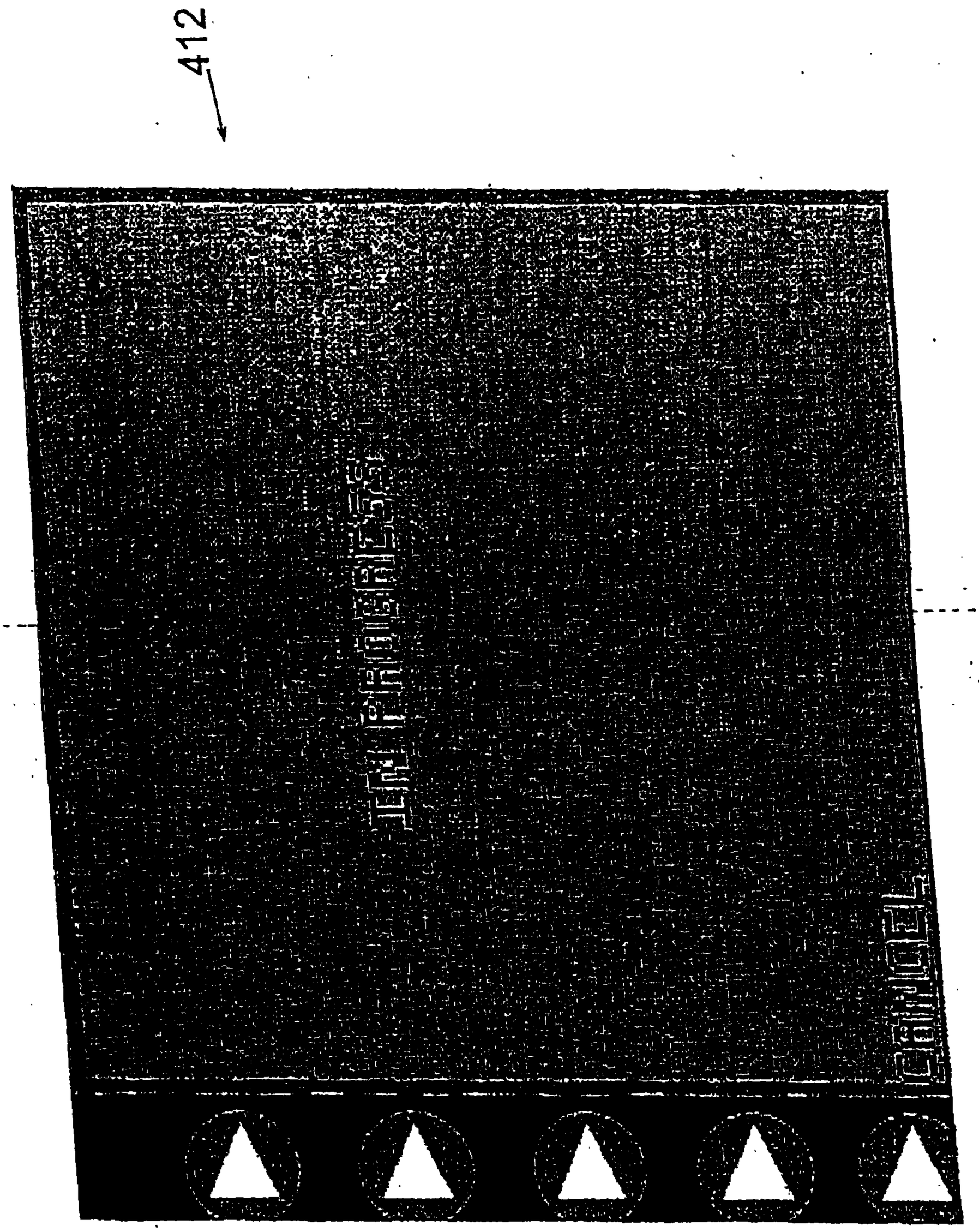


Fig. 5G

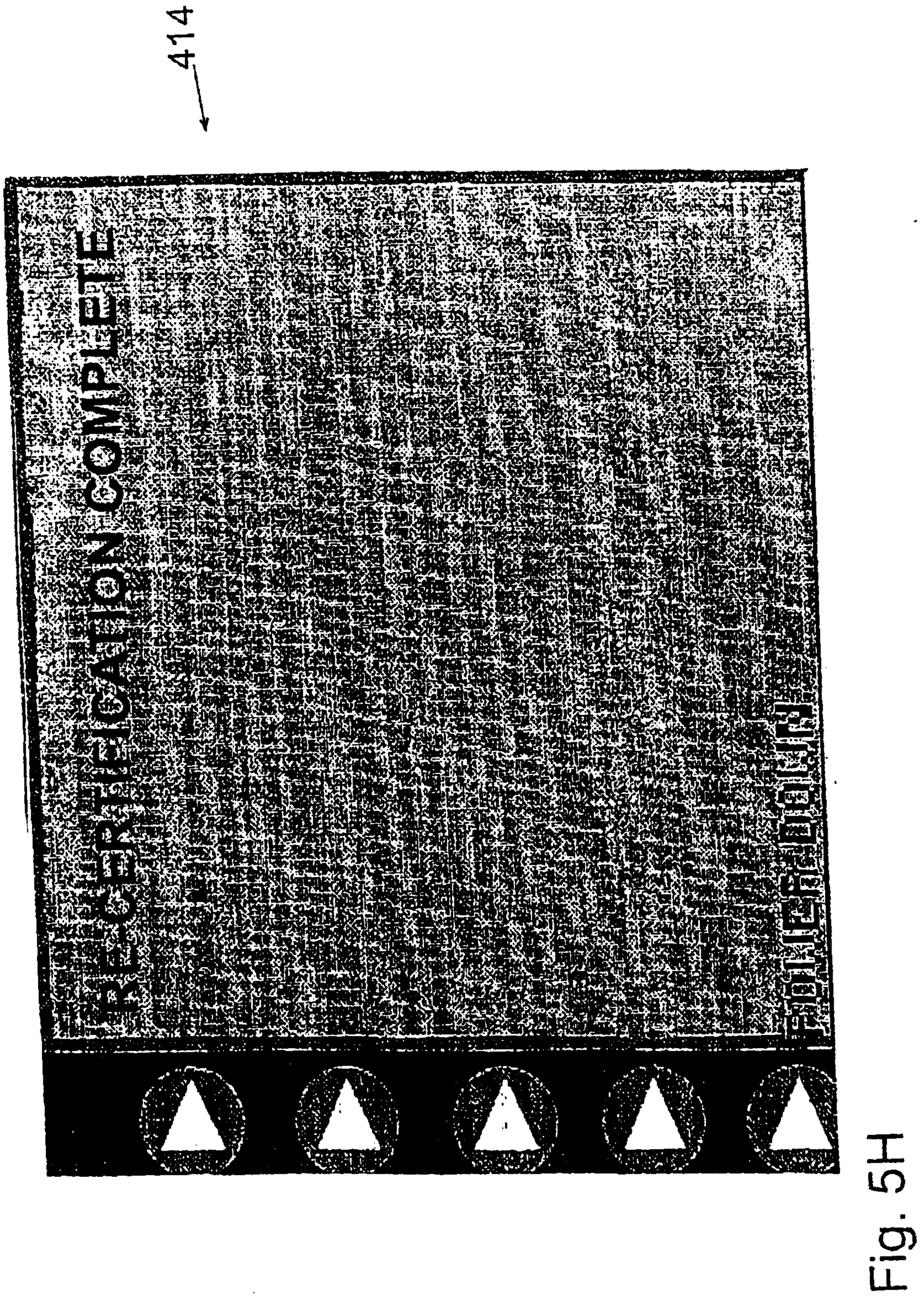


Fig. 5H

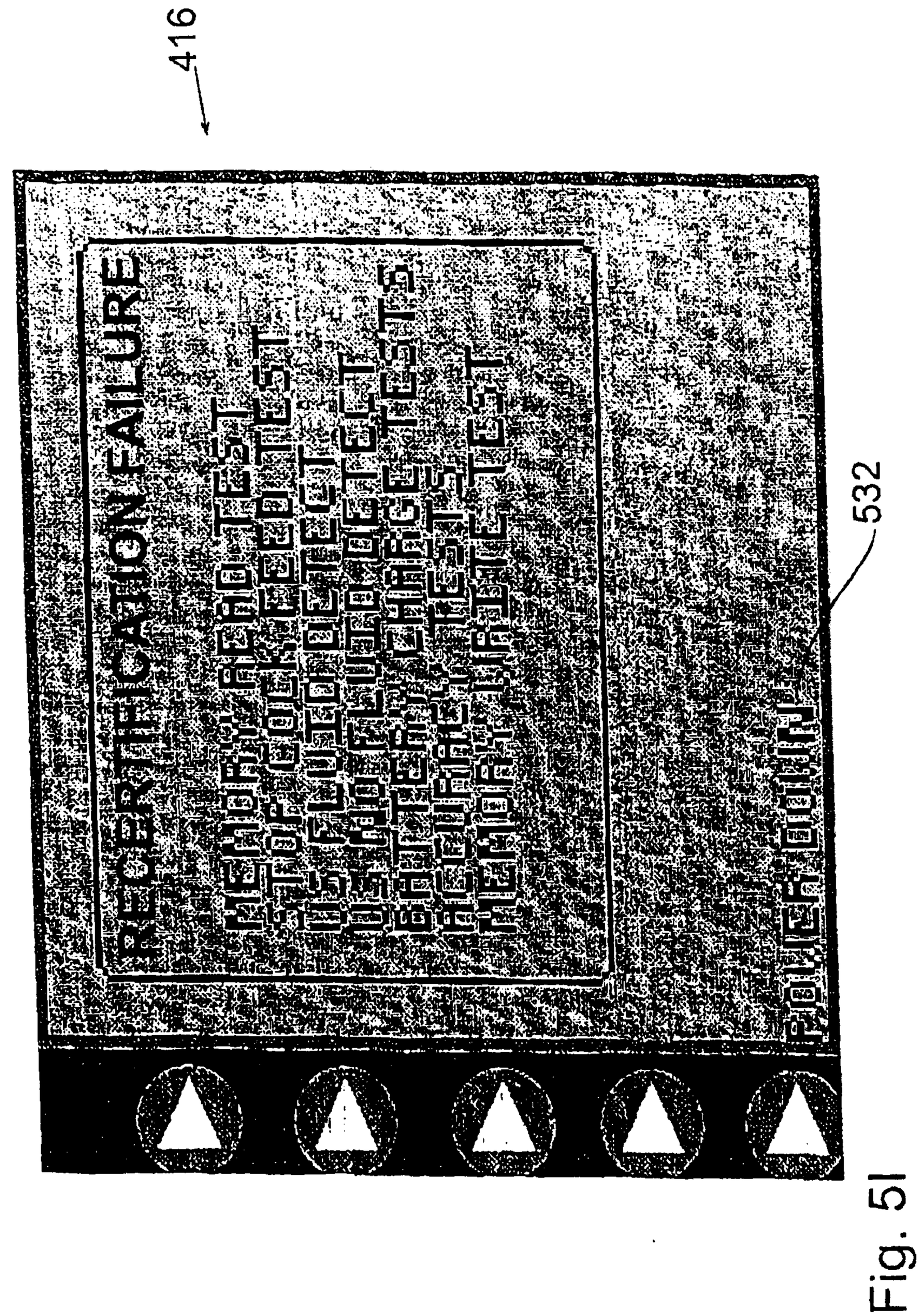
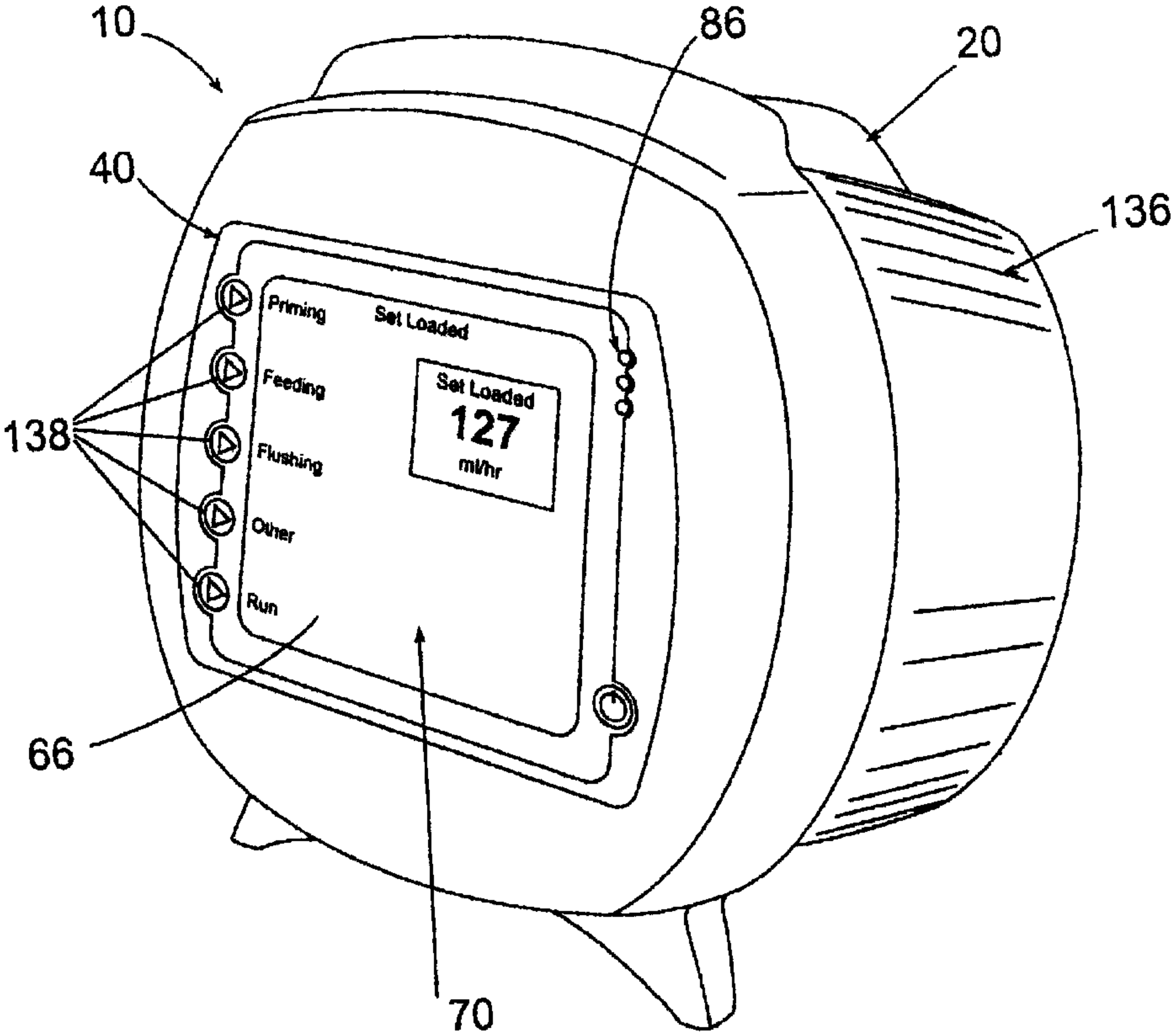


Fig. 5


10
86
20
40
136
138
Priming
Feeding
Flushing
Other
Run
Set Loaded
Set Loaded
127
ml/hr
66
70