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(54) **CONTROL SYSTEM FOR CRYOSURGERY**

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U.S. Applications:

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(51) **Int. Cl.**
A61B 18/18 (2006.01)

(52) **U.S. Cl.** **606/21**; 62/293; 606/22

(58) **Field of Classification Search** 606/20–26; 128/898
See application file for complete search history.

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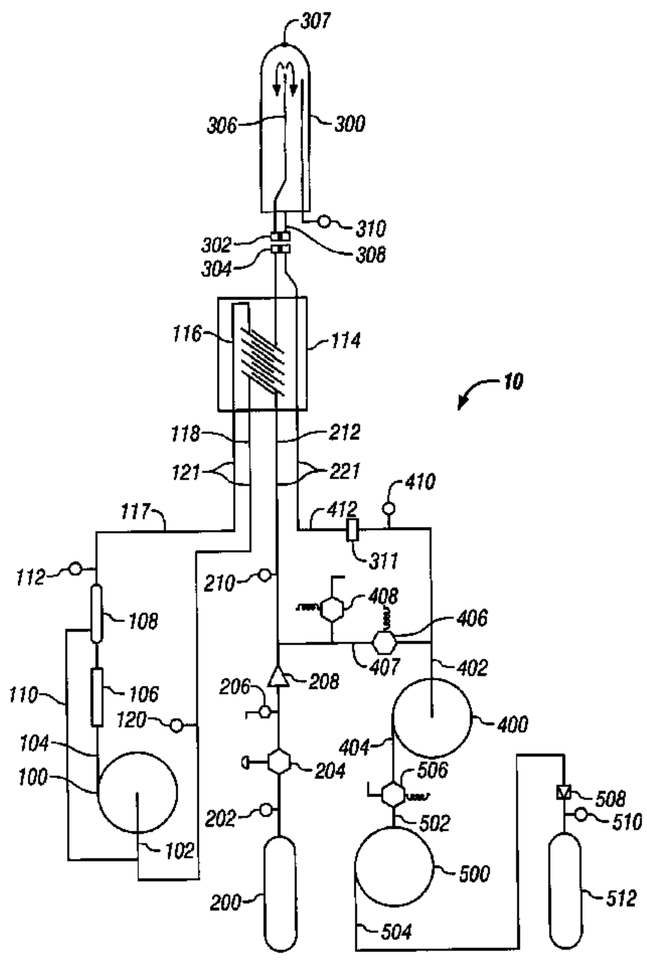
(57) **ABSTRACT**

An apparatus and method for automatic operation of a refrigeration system to provide refrigeration power to a catheter for tissue ablation or mapping. The primary refrigeration system can be open loop or closed loop, and a precool loop will typically be closed loop. Equipment and procedures are disclosed for bringing the system to the desired operational state, for controlling the operation by controlling refrigerant flow rate, for performing safety checks, and for achieving safe shutdown.

19 Claims, 8 Drawing Sheets



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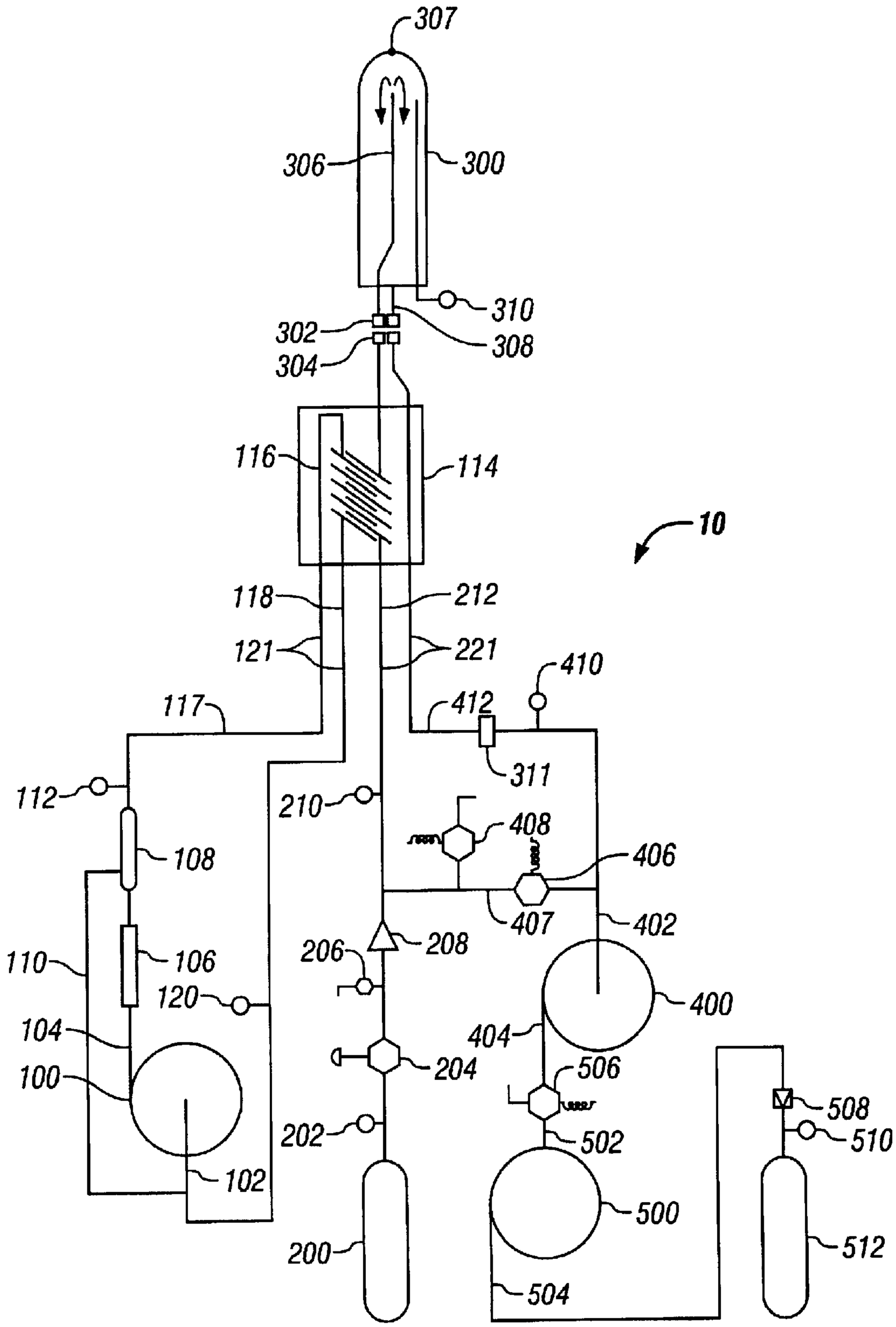
307
306
300
310
302
308
304
116
114
10
118
212
121
221
410
117
412
311
112
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408
108
406
407
402
206
208
110
106
120
400
104
204
404
506
100
508
202
502
510
102
500
200
512
504

FIG. 1

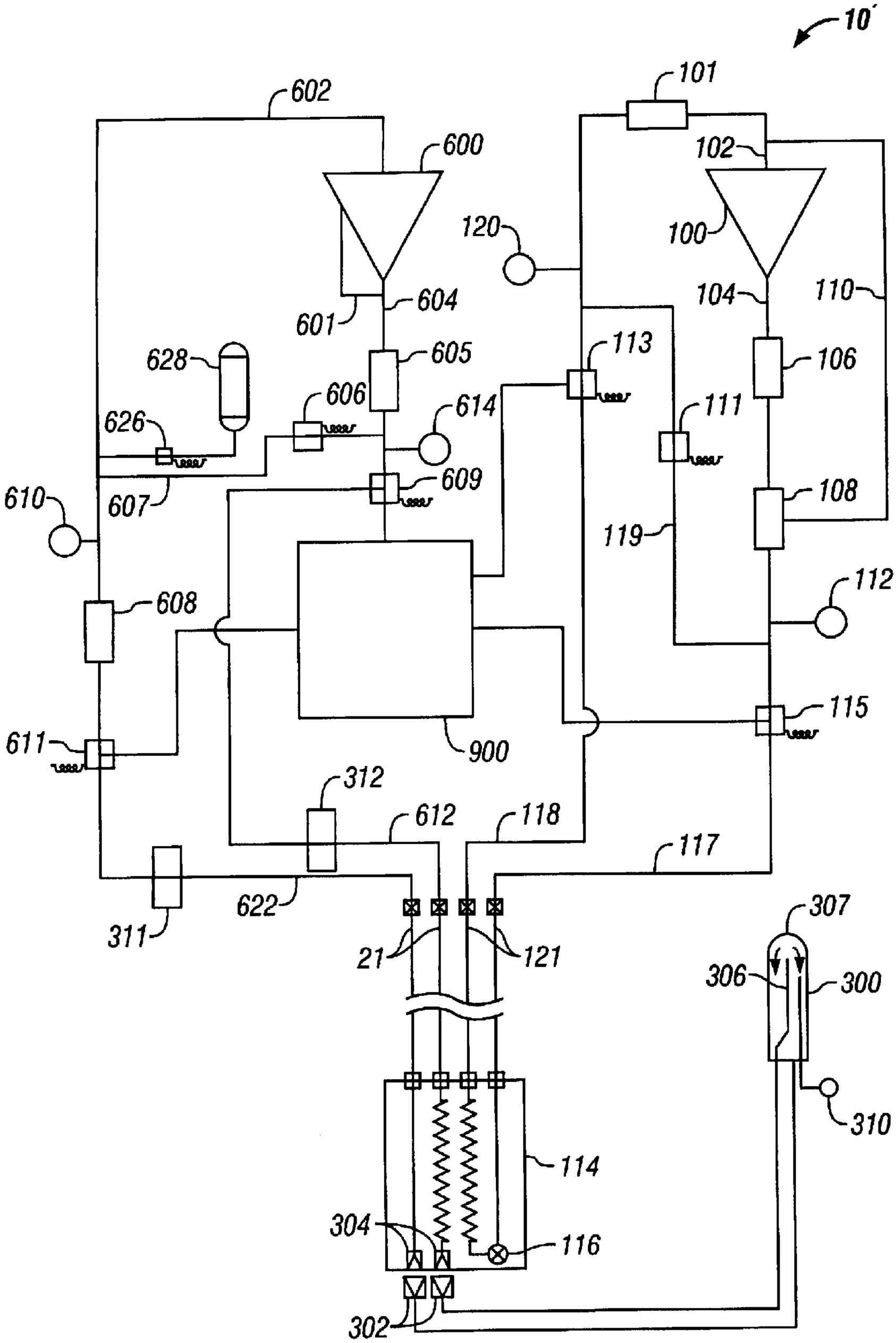

10'
101
602
600
102
120
100
601
604
104
110
628
605
113
106
606
614
626
111
609
610
607
108
119
608
112
900
115
611
312
612
118
117
622
307
311
21
121
306
300
310
114
304
116
302

FIG. 2

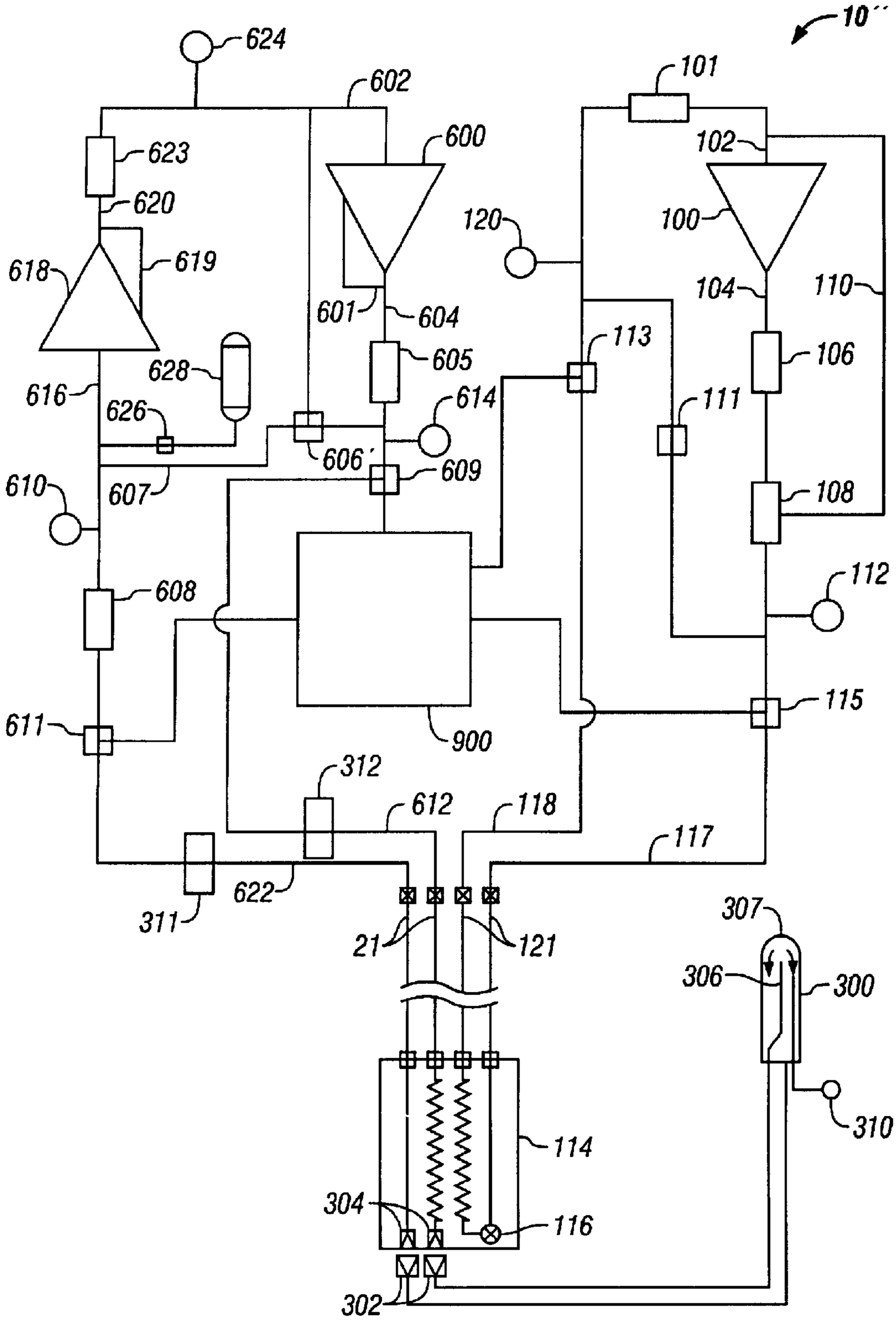

10''
624
602
623
600
620
618
619
601
604
605
628
616
626
614
606'
609
607
610
608
611
900
312
612
118
117
622
311
21
121
307
306
300
310
114
304
116
302
101
102
120
100
104
110
113
106
111
108
112
115

FIG. 3

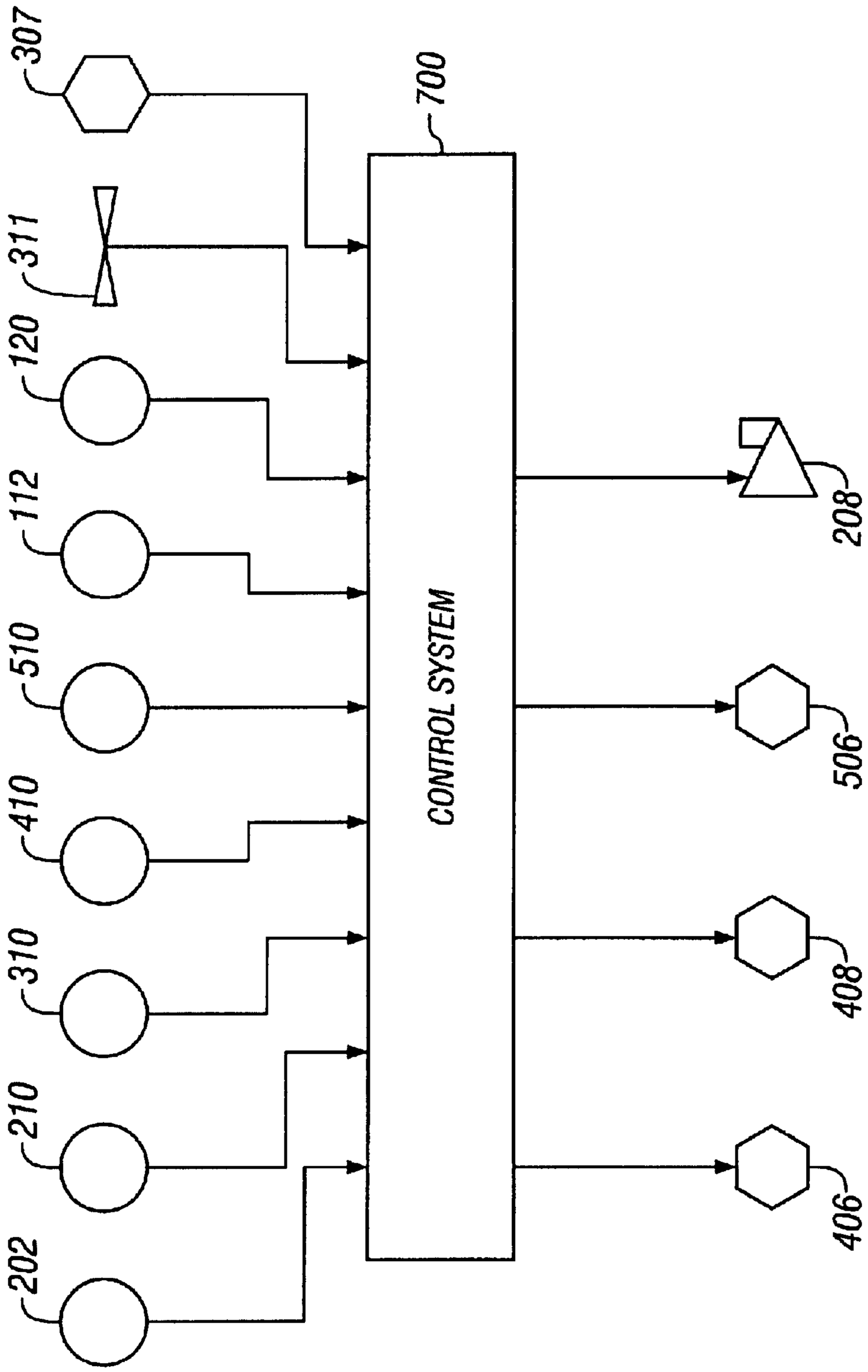

307
700
311
120
112
510
410
310
CONTROL SYSTEM
208
506
408
210
406
202

FIG. 4

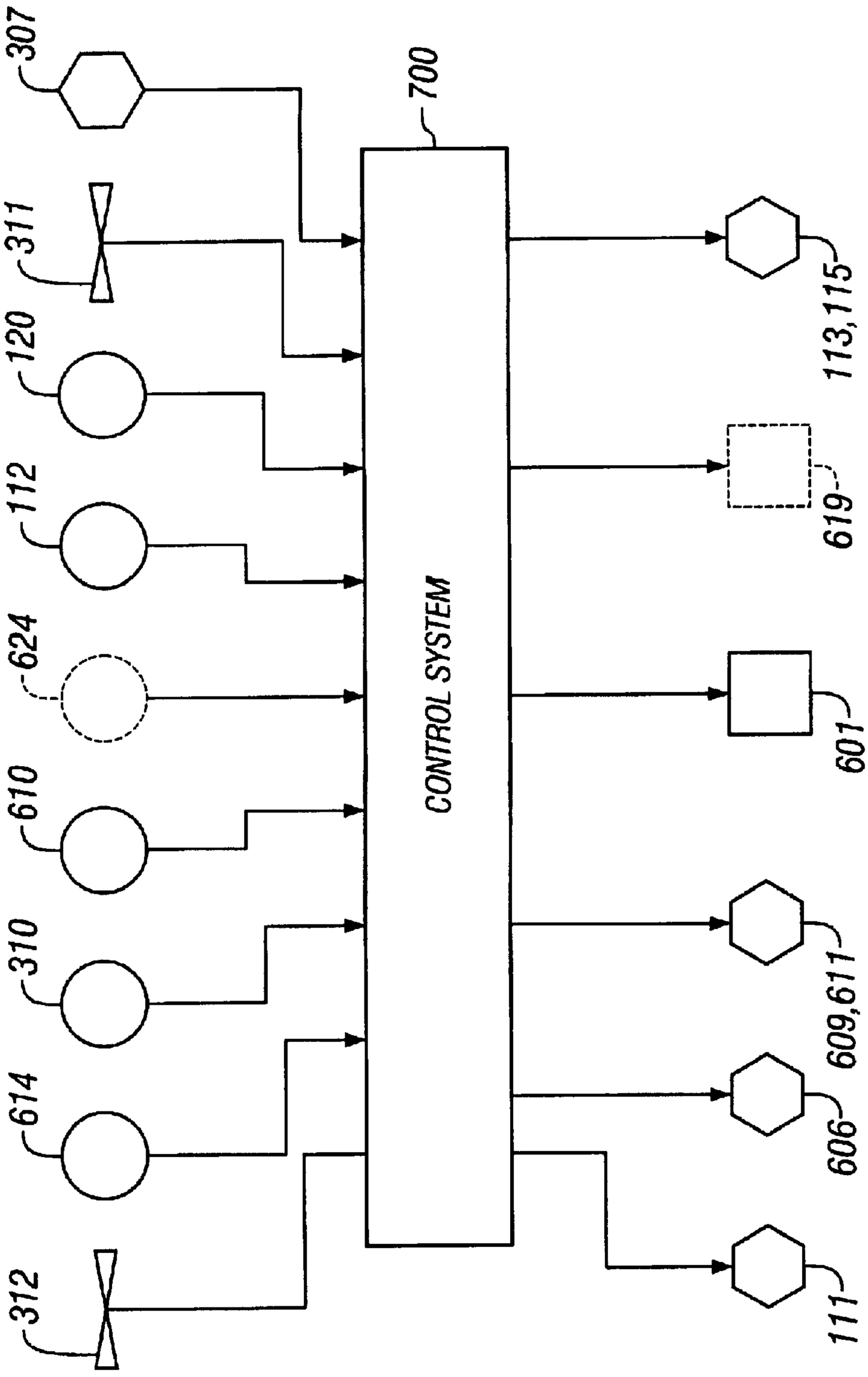
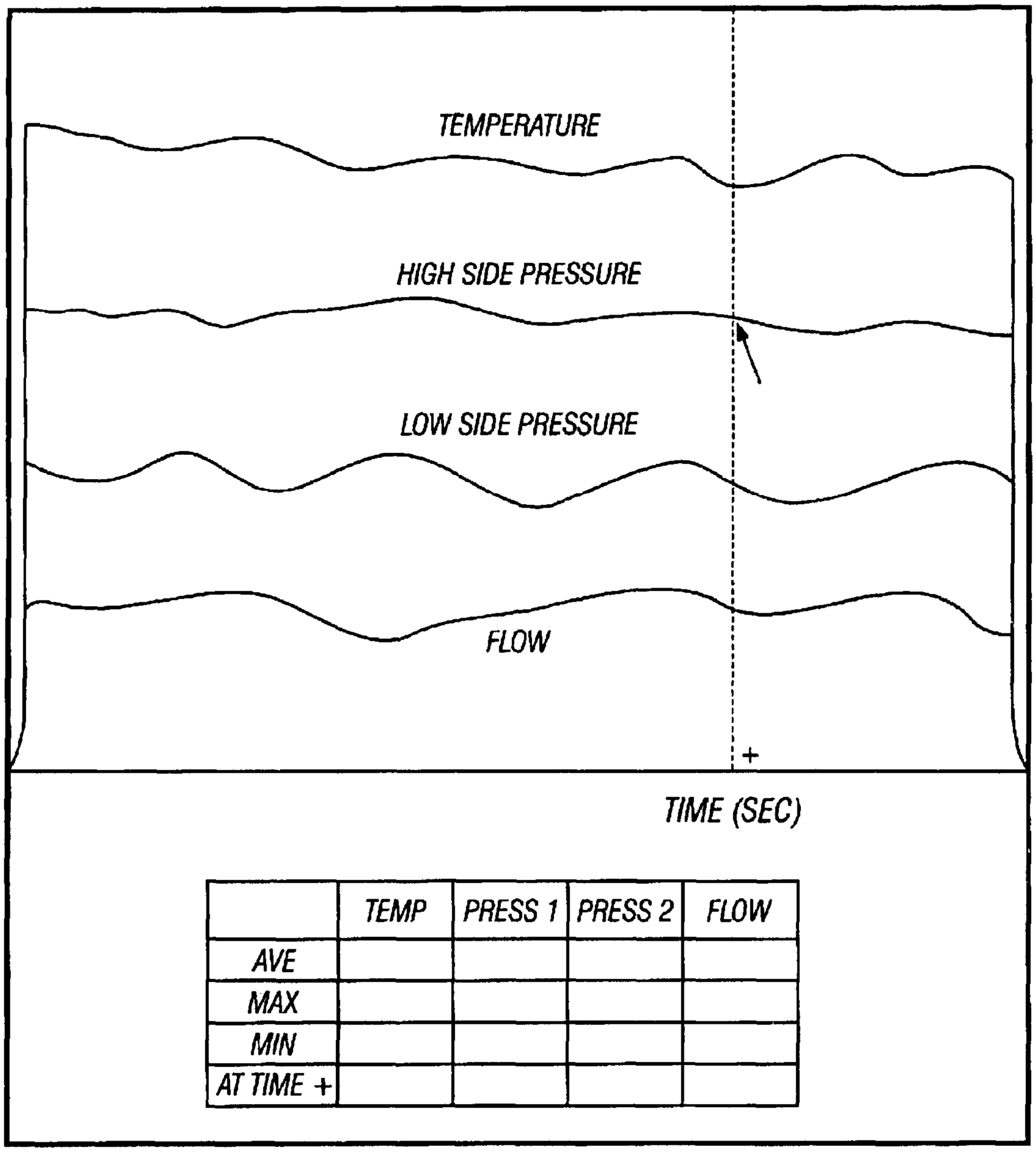

307
700
311
120
112
624
610
310
614
312
CONTROL SYSTEM
13,115
619
601
609,611
606
111

FIG. 5



	TEMP	PRESS 1	PRESS 2	FLOW
AVE				
MAX				
MIN				
AT TIME +				

FIG. 6

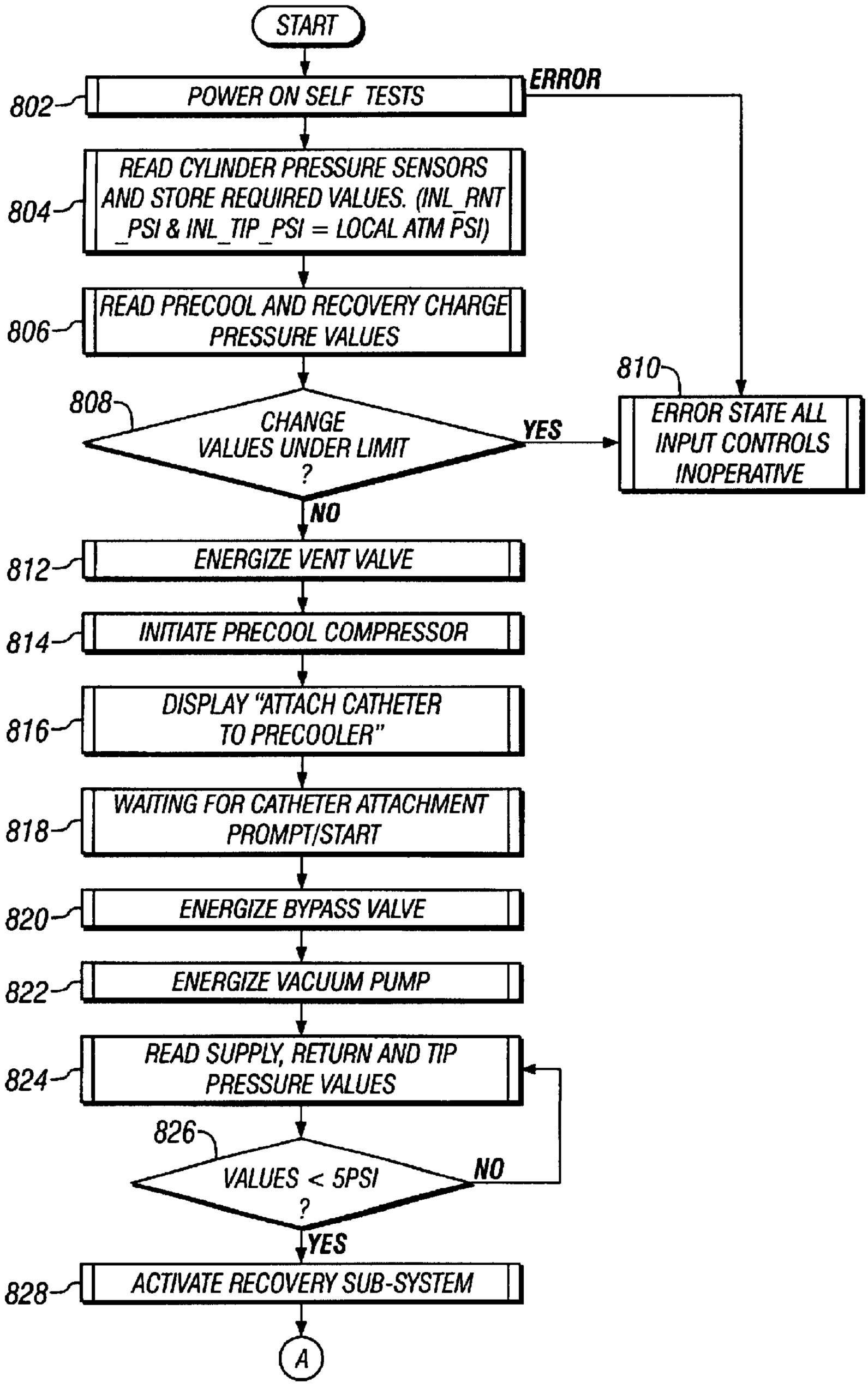

START
802
POWER ON SELF TESTS
ERROR
804
READ CYLINDER PRESSURE SENSORS AND STORE REQUIRED VALUES. (INL_RNT _PSI & INL_TIP_PSI = LOCAL ATM PSI)
806
READ PRECOOL AND RECOVERY CHARGE PRESSURE VALUES
808
CHANGE VALUES UNDER LIMIT ?
YES
810
ERROR STATE ALL INPUT CONTROLS INOPERATIVE
NO
812
ENERGIZE VENT VALVE
814
INITIATE PRECOOL COMPRESSOR
816
DISPLAY "ATTACH CATHETER TO PRECOOLER"
818
WAITING FOR CATHETER ATTACHMENT PROMPT/START
820
ENERGIZE BYPASS VALVE
822
ENERGIZE VACUUM PUMP
824
READ SUPPLY, RETURN AND TIP PRESSURE VALUES
826
VALUES < 5PSI ?
NO
YES
828
ACTIVATE RECOVERY SUB-SYSTEM
A

FIG. 7A

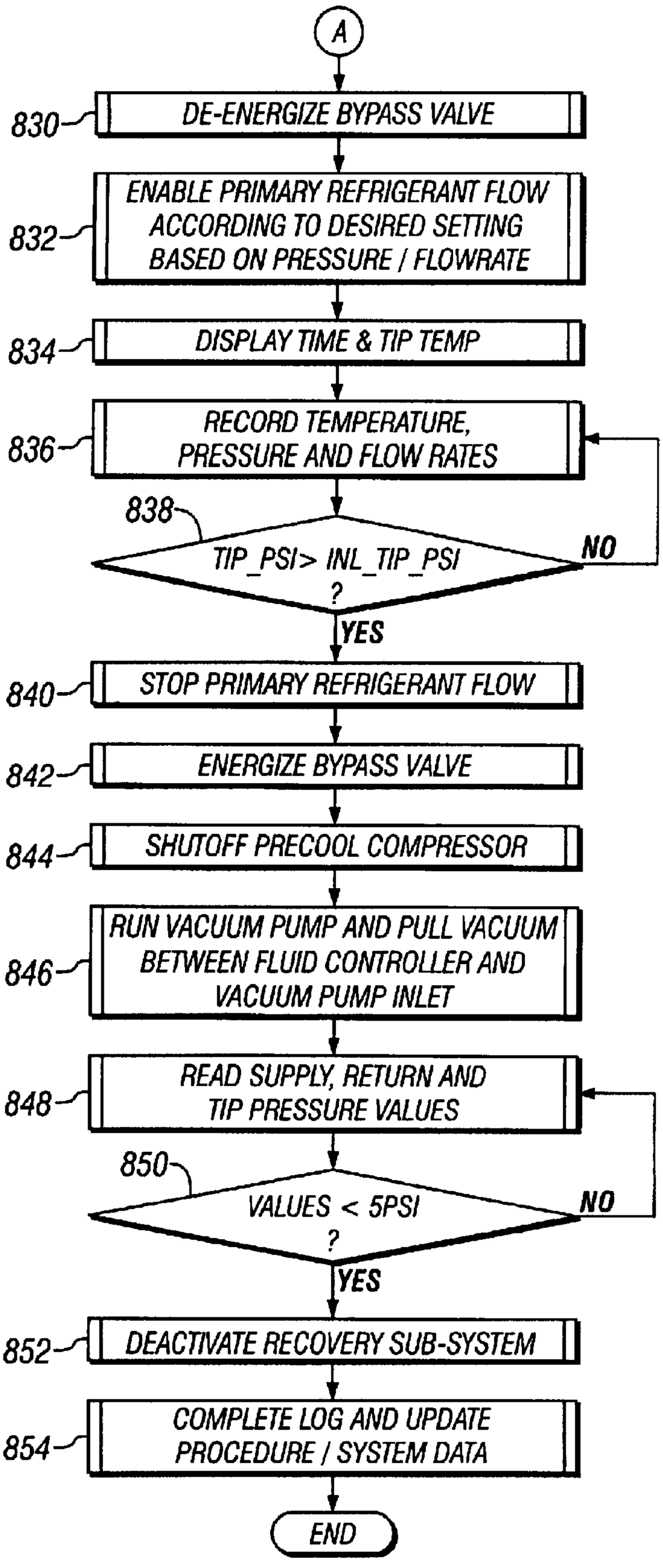

A
830
DE-ENERGIZE BYPASS VALVE
832
ENABLE PRIMARY REFRIGERANT FLOW ACCORDING TO DESIRED SETTING BASED ON PRESSURE / FLOWRATE
834
DISPLAY TIME & TIP TEMP
836
RECORD TEMPERATURE, PRESSURE AND FLOW RATES
838
TIP_PSI> INL_TIP_PSI ?
NO
YES
840
STOP PRIMARY REFRIGERANT FLOW
842
ENERGIZE BYPASS VALVE
844
SHUTOFF PRECOOL COMPRESSOR
846
RUN VACUUM PUMP AND PULL VACUUM BETWEEN FLUID CONTROLLER AND VACUUM PUMP INLET
848
READ SUPPLY, RETURN AND TIP PRESSURE VALUES
850
VALUES < 5PSI ?
NO
YES
852
DEACTIVATE RECOVERY SUB-SYSTEM
854
COMPLETE LOG AND UPDATE PROCEDURE / SYSTEM DATA
END

FIG. 7B

CONTROL SYSTEM FOR CRYOSURGERY

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

CROSS REFERENCE TO RELATED APPLICATIONS

[Not Applicable] *This application is a continuation-in-part of application Ser. No. 09/344,423 filed Jun. 25, 1999, now U.S. Pat. No. 6,237,355.*

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention is in the field of methods and apparatus used to generate and control the delivery of cryosurgical refrigeration power to a probe or catheter.

2. Background Information

In a cryosurgical system, contaminants such as oil, moisture, and other impurities are often deposited in the impedance tubing or other restriction through which the refrigerant is pumped. In the impedance tubing, the temperature is very low, and the flow diameter is very small. Deposit of these impurities can significantly restrict the flow of the cooling medium, thereby significantly reducing the cooling power.

BRIEF SUMMARY OF THE INVENTION

A cryosurgical catheter used in a cardiac tissue ablation process should be able to achieve and maintain a low, stable, temperature. Stability is even more preferable in a catheter used in a cardiac signal mapping process. When the working pressure in a cryosurgery system is fixed, the flow rate can vary significantly when contaminants are present, thereby varying the temperature to which the probe and its surrounding tissue can be cooled. For a given cryosurgery system, there is an optimum flow rate at which the lowest temperature can be achieved, with the highest possible cooling power. Therefore, maintaining the refrigerant flow rate at substantially this optimum level is beneficial.

In either the ablation process or the mapping process, it may be beneficial to monitor the flow rates, pressures, and temperatures, to achieve and maintain the optimum flow rate. Further, these parameters can be used to more safely control the operation of the system.

A cryosurgical system which is controlled based only upon monitoring of the refrigerant pressure and catheter temperature may be less effective at maintaining the optimum flow rate, especially when contaminants are present in the refrigerant. Further, a system in which only the refrigerant pressure is monitored may not have effective safety control, such as emergency shut down control.

It may also be more difficult to obtain the necessary performance in a cryosurgery catheter in which only a single compressor is used as a refrigeration source. This is because it can be difficult to control both the low and high side pressures at the most effective levels, with any known compressor. Therefore, it can be beneficial to have separate low side and high side pressure control in a cryosurgical system.

Finally, it is beneficial to have a system for monitoring various parameters of data in a cryosurgery system over a period of time. Such parameters would include catheter temperature, high side refrigerant pressure, low side refrigerant pressure, and refrigerant flow rate. Continuous historical and instantaneous display of these parameters, and display of their average values over a selected period of time, can be very helpful to the system operator.

The present invention provides methods and apparatus for controlling the operation of a cryosurgical catheter refrigeration system by monitoring pressures, temperature, and/or flow rate, in order to automatically maintain a stable refrigerant flow rate at or near an optimum level for the performance of cryosurgical tissue ablation or mapping. Different refrigerant flow rates can be selected as desired for ablation or mapping. Flow rate, pressures, and temperature can be used for automatic shut down control. Refrigerant sources which provide separate high side and low side pressure controls add to the performance of the system. Continuous displays of temperature, high side refrigerant pressure, low side refrigerant pressure, and refrigerant flow rate are provided to the operator on a single display, to enhance system efficiency and safety.

The novel features of this invention, as well as the invention itself, will be best understood from the attached drawings, taken along with the following description, in which similar reference characters refer to similar parts, and to which:

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. **1** is a schematic of a first embodiment of the apparatus of the present invention, using a pressure bottle as the primary refrigerant source;

FIG. **2** is a schematic of a second embodiment of the apparatus of the present invention, using a compressor as the primary refrigerant source;

FIG. **3** is a schematic of a third embodiment of the apparatus of the present invention, using two compressors connected in series as the primary refrigerant source;

FIG. **4** is a schematic of a first embodiment of a control system apparatus according to the present invention, for use with the apparatus shown in FIG. **1**;

FIG. **5** is a schematic of a second embodiment of a control system apparatus according to the present invention, for use with the apparatus shown in FIG. **2** or **3**;

FIG. **6** is a schematic of a parameter display for use with the control equipment of the present invention; and

FIG. **7** is a flow diagram showing one control sequence for use with the control apparatus of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

According to certain embodiments of the invention, the refrigeration system may be a two stage Joule-Thomson system with a closed loop precool circuit and either an open loop or a closed loop primary circuit. A typical refrigerant for the primary circuit would be R-508b, and a typical refrigerant for the precool circuit would be R-410a. In the ablation mode, the system may be capable of performing tissue ablation at or below minus 70° C. while in contact with the tissue and circulating blood. In the mapping mode, the system may be capable of mapping by stunning the tissue at a temperature between minus 10° C. and minus 18° C. while in contact with the tissue and circulating blood. These performance levels may be achieved while maintaining the catheter tip pressure at or below a sub-diastolic pressure of 14 psia.

As shown in FIG. **1**, one embodiment of the apparatus **10** of the present invention is an open loop system using a pressure bottle for the refrigerant source. Such a system can include a primary refrigerant supply bottle **200**, a primary refrigerant fluid controller **208**, a catheter **300**, a primary refrigerant recovery bottle **512**, a secondary refrigerant compressor **100**, a precool heat exchanger **114**, and various sensors. In certain embodiments, all but the catheter **300** and the precool heat exchanger **114** may be located in a cooling console housing. The precool heat exchanger **114** is connected to the console by flexible lines **121**, **221**. Pressure of the refrigerant in the primary refrigerant supply bottle **200** is monitored by a primary refrigerant supply pressure sensor **202**. Output of primary refrigerant from the supply bottle **200** is regulated by a pressure regulator **204**, which, in certain embodiments, can receive refrigerant from the bottle **200** at a pressure above 350 psia and regulate it to less than 350 psia. A primary refrigerant relief valve **206** is provided to prevent over pressurization of the primary system downstream of the pressure regulator **204**, for example, above 400 psia. The flow rate of primary refrigerant is controlled by the fluid controller **208**, which can be either a pressure controller or a flow controller. A feedback loop may be provided to control the operation of the fluid controller **208**. The feedback signal for the fluid controller **208** can come from a pressure sensor **310** or a flow sensor **311**, on the effluent side of the catheter **300**, discussed below.

A primary refrigerant high pressure sensor **210** is provided downstream of the fluid controller **208**, to monitor the primary refrigerant pressure applied to the precool heat exchanger **114**. The high pressure side **212** of the primary loop passes through the primary side of the cooling coil of the precool heat exchanger **114**, then connects to a quick connect fitting **304** on the precool heat exchanger **114**. Similarly, the low side quick connect fitting **304** on the precool heat exchanger **114** is connected to the low pressure side **412** of the primary loop, which passes back through the housing of the precool heat exchanger **114**, without passing through the cooling coil, and then through the flow sensor **311**. The catheter tip pressure sensor **310** monitors catheter effluent pressure in the tip of the catheter **300**. The control system maintains catheter tip pressure at a sub-diastolic level at all times.

The low pressure side **412** of the primary loop can be connected to the inlet **402** of a vacuum pump **400**. A primary refrigerant low pressure sensor **410** monitors pressure in the low side **412** of the primary loop downstream of the precool heat exchanger **114**. The outlet **404** of the vacuum pump **400** can be connected to the inlet **502** of a recovery pump **500**. A **3** way, solenoid operated, recovery valve **506** is located between the vacuum pump **400** and the recovery pump **500**. The outlet **504** of the recovery pump **500** is connected to the primary refrigerant recovery bottle **512** via a check valve **508**. A primary refrigerant recovery pressure sensor **510** monitors the pressure in the recovery bottle **512**. A 2 way, solenoid operated, bypass valve **406** is located in a bypass loop **407** between the low side **412** of the primary loop upstream of the vacuum pump **400** and the high side **212** of the primary loop downstream of the fluid controller **208**. A solenoid operated bypass loop vent valve **408** is connected to the bypass loop **407**.

In the catheter **300**, the high pressure primary refrigerant flows through an impedance device such as a capillary tube **306**, then expands into the distal portion of the catheter **300**, where the resultant cooling is applied to surrounding tissues. A catheter tip temperature sensor **307**, such as a thermocouple, monitors the temperature of the distal portion

of the catheter **300**. A catheter return line **308** returns the effluent refrigerant from the catheter **300** to the precool heat exchanger **114**. The high and low pressure sides of the catheter **300** are connected to the heat exchanger quick connects **304** by a pair of catheter quick connects **302**. As an alternative to pairs of quick connects **302**, **304**, coaxial quick connects can be used. In either case, the quick connects may carry both refrigerant flow and electrical signals.

In the precool loop, compressed secondary refrigerant is supplied by a precool compressor **100**. An after cooler **106** can be connected to the outlet **104** of the precool compressor **100** to cool and condense the secondary refrigerant. An oil separator **108** can be connected in the high side **117** of the precool loop, with an oil return line **110** returning oil to the precool compressor **100**. A high pressure precooler pressure sensor **112** senses pressure in the high side **117** of the precool loop. The high side **117** of the precool loop is connected to an impedance device such as a capillary tube **116** within the housing of the precool heat exchanger **114**. High pressure secondary refrigerant flows through the capillary tube **116**, then expands into the secondary side of the cooling coil of the precool heat exchanger **114**, where it cools the high pressure primary refrigerant. The effluent of the secondary side of the precool heat exchanger **114** returns via the low side **118** of the precool loop to the inlet **102** of the precool compressor **100**. A low pressure precooler pressure sensor **120** senses pressure in the low side **118** of the precool loop.

Instead of using primary refrigerant supply and return bottles, the apparatus can use one or more. primary compressors in a closed loop system. FIG. **2** shows a second embodiment of the apparatus of the present invention, with a single compressor system. This embodiment would be appropriate in applications where the high side and low side pressures can be adequately controlled with a single compressor. In the apparatus **10'** of this type of system, the low side **622** of the primary loop conducts the effluent of the catheter **300** to the inlet **602** of a primary refrigerant compressor **600**. The compressor **600** compresses the primary refrigerant, and returns it from the compressor outlet **604** via the high side **612** of the primary loop to the primary side of the precool heat exchanger **114**. A primary refrigerant high pressure sensor **614** is provided in the high side **612** of the primary loop, to monitor the primary refrigerant pressure applied to the precool heat exchanger **114**. A primary refrigerant high pressure flow sensor **312** can be provided in the high side **612** of the primary loop. A primary refrigerant low pressure sensor **610** monitors pressure in the low side **622** of the primary loop downstream of the precool heat exchanger **114**. A primary loop filter **608** can be provided in the low side **622** of the primary loop. A 2way, solenoid operated, primary refrigerant charge valve **626** and a primary refrigerant reservoir **628** can be provided in the low side **622** of the primary loop. A high pressure after-cooler **605** can be provided downstream of the primary refrigerant compressor **600**.

As further shown in FIG. **2**, a 2 way, solenoid operated, primary loop bypass valve **606** is located in a bypass loop **607** between the low side **622** of the primary loop upstream of the compressor **600** and the high side **612** of the primary loop downstream of the compressor **600**. Opening of the primary loop bypass valve **606** can facilitate startup of the primary compressor **600**. A precool loop filter **101** can be provided in the low side **118** of the precool loop. Further, a 2 way, solenoid operated, precool loop bypass valve **111** is located in a bypass loop **119** between the low side **118** of the precool loop upstream of the compressor **100** and the high side **117** of the precool loop downstream of the compressor **100**. Opening of the precool loop bypass valve **111** can facilitate startup of the precool compressor **100**.

A purification system **900** can be provided for removing contaminants from the primary refrigerant and the secondary refrigerant. Solenoid operated 3 way purification valves **609**, **611** are provided in the high side and low side, respectively, of the primary loop, for selectively directing the primary refrigerant through the purification system **900**. Similarly, solenoid operated 3 way purification valves **115**, **113** are provided in the high side and low side, respectively, of the precool loop, for selectively directing the secondary refrigerant through the purification system **900**.

The remainder of the precool loop, the precool heat exchanger **114**, and the catheter **300** are the same as discussed above for the first embodiment.

In applications where separate low side and high side pressure control is required, but where a closed loop system is desired, a two compressor primary system may be used. FIG. **3** shows a third embodiment of the apparatus of the present invention, with a dual compressor system. In the apparatus **10"** of this type of system, the low side **622** of the primary loop conducts the effluent of the catheter **300** to the inlet **616** of a low side primary refrigerant compressor **618**. The low side compressor **618** compresses the primary refrigerant, and provides it via its outlet **620** to the inlet **602** of a high side primary refrigerant compressor **600**. A low pressure after-cooler **623** can be provided downstream of the low side compressor **618**. The high side compressor **600** further compresses the primary refrigerant to a higher pressure and returns it via its outlet **604** and via the high side **612** of the primary loop to the primary side of the precool heat exchanger **114**. A primary refrigerant high pressure sensor **614** is provided in the high side **612** of the primary loop, to monitor the high side primary refrigerant pressure upstream of the precool heat exchanger **114**. A primary refrigerant low pressure sensor **610** monitors pressure in the low side **622** of the primary loop downstream of the precool heat exchanger **114**. A primary refrigerant intermediate pressure sensor **624** monitors pressure between the outlet **620** of the low side compressor **618** and the inlet **602** of the high side compressor **600**. The high side compressor **600** and the low side compressor **618** are separately controlled, using feedback from the catheter tip pressure sensor **310** and/or the flow sensors **311**, **312**.

As further shown in FIG. **3**, a 3 way, solenoid operated, bypass valve **606'** is located in a bypass loop **607** between the low side **622** of the primary loop upstream of the low side compressor **618** and the high side **612** of the primary loop downstream of the high side compressor **600**. A third port is connected between the high side and low side compressors. The precool loop, the precool heat exchanger **114**, and the catheter **300** are the same as discussed above for the first and second embodiments.

FIG. **4** shows a control diagram which would be suitable for use with the apparatus shown in FIG. **1**. A computerized automatic control system **700** is connected to the various sensors and control devices to sense and control the operation of the system, and to provide safety measures, such as shut down schemes. More specifically, on the sensing side, the low pressure precool sensor **120** inputs low side precool pressure PA, the high pressure precool sensor **112** inputs high side precool pressure PB, the primary supply pressure sensor **202** inputs supply bottle pressure P**1**, the primary recovery pressure sensor **510** inputs recovery bottle pressure P**2**, the high pressure primary sensor **210** inputs high side primary pressure P**3**, the low pressure primary sensor **410** inputs low side primary pressure P**4**, the catheter tip pressure sensor **310** inputs catheter tip pressure P**5**, the temperature sensor **307** inputs catheter tip temperature T, and the flow sensor **311** inputs primary refrigerant flow rate F. Further, on the control side, the control system **700** energizes the normally closed bypass valve **406** to open it, energizes the normally open vent valve **408** to close it, and energizes the recovery valve **506** to connect the vacuum pump outlet **404** to the recovery pump inlet **502**. Finally, the control system **700** provides a pressure set point SPP or flow rate set point SPF to the fluid controller **208**, depending upon whether it is a pressure controller or a flow controller.

FIG. **5** shows a control diagram which would be suitable for use with the apparatus shown in FIG. **2** or FIG. **3**. A computerized automatic control system **700** is connected to the various sensors and control devices to sense and control the operation of the system, and to provide safety measures, such as shut down schemes. More specifically, on the sensing side, the low pressure precool sensor **120** inputs low side precool pressure PA, the high pressure precool sensor **112** inputs high side precool pressure PB, the high pressure primary sensor **614** inputs high side primary pressure P**3**, the low pressure primary sensor **610** inputs low side primary pressure P**4**, the catheter tip pressure sensor **310** inputs catheter tip pressure P**5**, the temperature sensor **307** inputs catheter tip temperature T, and the flow sensors **311**, **312** input primary refrigerant flow rate F. Further, on the control side, the control system **700** energizes the normally closed primary loop bypass valve **606**, **606'** to open it, and the control system **700** energizes the normally closed precool loop bypass valve **111** to open it. The control system **700** also energizes the primary loop purification valves **609**, **611** to selectively purify the primary refrigerant, and the control system **700** energizes the precool loop purification valves **113**, **115** to selectively purify the secondary refrigerant. Finally, the control system **700** provides a minimum high side pressure set point PL**2** to the controller **601** of the primary compressor **600** in the system shown in FIG. **2**. Alternatively, in the system shown in FIG. **3**, the control system **700** provides a minimum high side pressure set point PL**2**B to the controller **601** of the high side primary compressor **600**, and the control system **700** provides a maximum low side pressure set point PL**2**A to the controller **619** of the low side primary compressor **618**.

A numeric digital display, or a graphical display similar to that shown in FIG. **6**, is provided on the cooling console to assist the operator in monitoring and operating the system. For example, on a single graphical display, graphs can be shown of catheter tip temperature T, high side primary pressure P**3**, low side primary pressure P**4**, and primary flow rate F, all versus time. Further, on the same display, the operator can position a vertical cursor at a selected time, resulting in the tabular display of the instantaneous values of T, P**3**, P**4**, and F, as well as the average, maximum, and minimum values of these parameters.

The present invention will now be further illustrated by describing a typical operational sequence of the open loop embodiment, showing how the control system **700** operates the remainder of the components to start up the system, to provide the desired refrigeration power, and to provide system safety. The system can be operated in the Mapping Mode, where the cold tip temperature might be maintained at minus 10 C., or in the Ablation Mode, where the cold tip temperature might be maintained at minus 65 C. Paragraphs are keyed to the corresponding blocks in the flow diagram shown in FIG. **7**. Suggested exemplary Pressure Limits used below could be PL**1**=160 psia; PL**2**=400 psia; PL**3**=500 psia; PL**4**=700 psia; PL**5**=600 psia; PL**6**=5 psia; PL**7**=diastolic pressure; PL**8**=375 psia; and PL**9**=5 psia. Temperature limits, flow limits, procedure times, and procedure types are set by the operator according to the procedure being performed.

Perform self tests (block **802**) of the control system circuitry and connecting circuitry to the sensors and controllers to insure circuit integrity.

Read and store supply cylinder pressure P**1**, primary low pressure P**4**, and catheter tip pressure P**5** (block **804**). At this time, P**4** and P**5** are at atmospheric pressure. If P**1** is less than Pressure Limit PL**2** (block **808**), display a message to replace the supply cylinder (block **810**), and prevent further operation. If P**1** is greater than PL**2**, but less than Pressure Limit PL**3**, display a message to replace the supply cylinder soon, but allow operation to continue.

Read precool charge pressure PB and recovery cylinder pressure P**2** (block **806**). If PB is less than Pressure Limit PL**1** (block **808**), display a message to service the precool loop (block **810**), and prevent further operation. If P**2** is greater than Pressure Limit PL**4** (block **808**), display a message to replace the recovery cylinder (block **810**), and prevent further operation. If P**2** is less than PL**4**, but greater than Pressure Limit PL**5**, display a message to replace the recovery cylinder soon, but allow operation to continue.

Energize the bypass loop vent valve **408** (block **812**). The vent valve **408** is a normally open two way solenoid valve open to the atmosphere. When energized, the vent valve **408** is closed.

Start the precool compressor **100** (block **814**). Display a message to attach the catheter **300** to the console quick connects **304** (block **816**). Wait for the physician to attach the catheter **300**, press either the Ablation Mode key or the Mapping Mode key, and press the Start key (block **818**). Read the catheter tip temperature T and the catheter tip pressure P**5**. At this time, T is the patient's body temperature and P**5** is atmospheric pressure.

Energize the bypass loop valve **406**, while leaving the recovery valve **506** deenergized (block **820**). The bypass valve **406** is a normally closed 2 way solenoid valve. Energizing the bypass valve **406** opens the bypass loop. The recovery valve **506** is a three way solenoid valve that, when not energized, opens the outlet of the vacuum pump **400** to atmosphere. Start the vacuum pump **400** (block **822**). These actions will put a vacuum in the piping between the outlet of the fluid controller **208** and the inlet of the vacuum pump **400**, including the high and low pressure sides of the catheter **300**. Monitor P**3**, P**4**, and P**5** (block **824**), until all three are less than Pressure Limit PL**6** (block **826**).

Energize the recovery valve **506** and the recovery pump **500** (block **828**). When energized, the recovery valve **506** connects the outlet of the vacuum pump **400** to the inlet of the recovery pump **500**. De-energize the bypass valve **406**, allowing it to close (block **830**). Send either a pressure set point SPP (if a pressure controller is used) or a flow rate set point SPF (if a flow controller is used) to the fluid controller **208** (block **832**). Where a pressure controller is used, the pressure set point SPP is at a pressure which will achieve the desired refrigerant flow rate, in the absence of plugs or leaks. The value of the set point is determined according to whether the physician has selected the mapping mode or the ablation mode. These actions start the flow of primary refrigerant through the catheter **300** and maintain the refrigerant flow rate at the desired level.

Continuously monitor and display procedure time and catheter tip temperature T (block **834**). Continuously monitor and display all pressures and flow rates F (block **836**). If catheter tip pressure P**5** exceeds Pressure Limit PL**7**, start the shutdown sequence (block **840**). Pressure Limit PL**7** is a pressure above which the low pressure side of the catheter **300** is not considered safe.

If F falls below Flow Limit FL**1**, and catheter tip temperature T is less than Temperature Limit TL**1**, start the shutdown sequence (block **840**). Flow Limit FL**1** is a minimum flow rate below which it is determined that a leak or a plug has occurred in the catheter **300**. FL**1** can be expressed as a percentage of the flow rate set point SPF. Temperature Limit TL**1** is a temperature limit factored into this decision step to prevent premature shutdowns before the catheter **300** reaches a steady state at the designed level of refrigeration power. So, if catheter tip temperature T has not yet gone below TL**1**, a low flow rate will not cause a shutdown.

If P**3** exceeds Pressure Limit PL**8**, and F is less than Flow Limit FL**2**, start the shutdown sequence (block **840**). PL**8** is a maximum safe pressure for the high side of the primary system. Flow Limit FL**2** is a minimum flow rate below which it is determined that a plug has occurred in the catheter **300**, when PL**8** is exceeded. FL**2** can be expressed as a percentage of the flow rate set point SPF.

If P**4** is less than Pressure Limit PL**9**, and F is less than Flow Limit FL**3**, start the shutdown sequence (block **840**). PL**9** is a pressure below which it is determined that a plug has occurred in the catheter **300**, when flow is below FL**3**. FL**3** can be expressed as a percentage of the flow rate set point SPF.

An exemplary shutdown sequence will now be described. Send a signal to the fluid controller **208** to stop the primary refrigerant flow (block **840**). Energize the bypass valve **406** to open the bypass loop (block **842**). Shut off the precool compressor **100** (block **844**). Continue running the vacuum pump **400** to pull a vacuum between the outlet of the fluid controller **208** and the inlet of the vacuum pump **400** (block **846**). Monitor primary high side pressure P**3**, primary low side pressure P**4**, and catheter tip pressure P**5** (block **848**) until all three are less than the original primary low side pressure which was read in block **804** at the beginning of the procedure (block **850**). Then, de-energize the recovery pump **500**, recovery valve **506**, vent valve **408**, bypass valve **406**, and vacuum pump **400** (block **852**). Display a message suggesting the removal of the catheter **300**, and update a log of all system data (block **854**).

Similar operational procedures, safety checks, and shutdown procedures would be used for the closed loop primary system shown in FIG. **2** or FIG. **3**, except that the primary compressor **600** or compressors **600**, **618** would provide the necessary primary refrigerant flow rate in place of the supply and recovery cylinders, the fluid controller, and the vacuum and recovery pumps. As with the open loop system, the closed loop system can be operated in the Mapping Mode, where the cold tip temperature might be maintained at minus 10 C., or in the Ablation Mode, where the cold tip temperature might be maintained at minus 65 C. As a first option to achieve the desired cold tip temperature, the precool bypass valve **111** can be adjusted to control the liquid fraction resulting after expansion of the secondary refrigerant, thereby adjusting the refrigeration capacity. Under this option, primary refrigerant high and low pressures are kept constant. As a second option, or in combination with the first option, primary refrigerant flow rate can be by means of operating controllers **601**, **619** on the primary compressors **600**, **618** to maintain a high pressure set point SPP which will achieve the desired flow rate, resulting in the desired cold tip temperature.

A Service Mode is possible, for purification of the primary and secondary refrigerants. In the Service Mode, the normally open bypass valves **111**, **606** are energized to close. The primary loop purification valves **609**, **611** are

selectively aligned with the purification system **900** to purify the primary refrigerant, or the precool loop purification valves **113**, **115** are selectively aligned with the purification system **900** to purify the secondary refrigerant.

In either the Mapping Mode or the Ablation Mode, the desired cold tip temperature control option is input into the control system **700**. Further, the type of catheter is input into the control system **700**. The normally closed charge valve **626** is energized as necessary to build up the primary loop charge pressure. If excessive charging is required, the operator is advised. Further, if precool loop charge pressure is below a desired level, the operator is advised.

When shutdown is required, the primary loop high side purification valve **609** is closed, and the primary loop compressors **600**, **618** continue to run, to draw a vacuum in the catheter **300**. When the desired vacuum is achieved, the primary loop low side purification valve **611** is closed. This isolates the primary loop from the catheter **300**, and the disposable catheter **300** can be removed.

While the particular invention as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages hereinbefore stated, it is to be understood that this disclosure is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended other than as described in the appended claims.

We claim:

1. Apparatus for performing cryosurgery, comprising:

a refrigerant supply source connectable to a high pressure duct;

a cryosurgery catheter having an inlet connectable to said high pressure duct, said catheter having a tip;

a refrigerant expansion element in said catheter;

a temperature sensor on said catheter;

a pressure sensor adapted to sense pressure inside said catheter tip;

a low pressure duct connectable to an outlet of said catheter;

a flow sensor in said low pressure duct downstream of said catheter; and

a control system connected and programmed to maintain a selected catheter temperature, in response to signals from said temperature sensor, said pressure sensor, and said flow sensor.

2. An apparatus as recited in claim **1**, further comprising:

a precool heat exchanger in said high pressure duct;

a precool compressor for compressing a secondary refrigerant; and

a precool expansion element connected to said precool compressor for expanding said secondary refrigerant to cool said precool heat exchanger.

3. An apparatus as recited in claim **2**, further comprising a bypass valve connected between an outlet of said precool compressor and an inlet of said precool compressor.

4. An apparatus as recited in claim **1**, wherein:

said refrigerant supply source comprises a pressure bottle; and

a fluid controller in said high pressure duct; and

further comprising a recovery bottle connected to said low pressure duct.

5. An apparatus as recited in claim **4**, wherein said fluid controller comprises a pressure controller.

6. An apparatus as recited in claim **4**, wherein said fluid controller comprises a flow controller.

7. An apparatus as recited in claim **4**, further comprising:

a vacuum pump having an inlet connected to said low pressure duct;

a recovery pump having an inlet connected to an outlet of said vacuum pump, said recovery pump having an outlet connected to said recovery bottle;

a bypass valve in a bypass duct connected between said high pressure duct and said low pressure duct; and

a vent valve connected to said bypass duct between said bypass valve and said high pressure duct.

8. An apparatus as recited in claim **1**, wherein:

said refrigerant supply source comprises a compressor;

said high pressure duct is connected to an outlet of said compressor;

a compressor controller; and

said control system operates said compressor controller to maintain refrigerant pressure above a selected level in said high pressure duct.

9. An apparatus as recited in claim **8**, further comprising a second compressor with a second compressor controller;

wherein:

said low pressure duct is connected to an inlet of said second compressor;

an outlet of said second compressor is connected to an inlet of said first compressor;

said control system operates said first compressor controller to maintain refrigerant pressure above a selected level in said high pressure duct; and

said control system operates said second compressor controller to maintain refrigerant pressure below a selected level in said low pressure duct.

10. An apparatus as recited in claim **8**, further comprising a bypass valve in a bypass duct connected between said high pressure duct and said low pressure duct.

11. An apparatus as recited in claim **1**, further comprising:

a precool heat exchanger in said high pressure duct;

a precool compressor for compressing a secondary refrigerant;

a precool expansion element connected to said precool compressor for expanding said secondary refrigerant to cool said precool heat exchanger; and

a bypass valve connected between an outlet of said precool compressor and an inlet of said precool compressor

wherein:

said refrigerant supply source comprises a primary compressor;

said high pressure duct is connected to an outlet of said primary compressor; and

said control system operates said bypass valve to maintain catheter temperature at a selected level.

12. Apparatus for performing cryosurgery, comprising:

a primary refrigerant pressure bottle connectable to a high pressure duct;

a fluid pressure controller in said high pressure duct;

a precool heat exchanger in said high pressure duct;

a precool compressor for compressing a secondary refrigerant;

a secondary expansion element connected to expand said secondary refrigerant to cool said precool heat exchanger;

a cryosurgery catheter having an inlet connectable to said high pressure duct;

a primary expansion element in said catheter connected to expand said primary refrigerant to cool a portion of said catheter;

a temperature sensor on said catheter;

a low pressure duct connectable to an outlet of said catheter;

a pressure sensor in said low pressure duct;

a flow sensor in said low pressure duct;

a vacuum pump having an inlet connected to said low pressure duct;

a recovery pump having an inlet connected to an outlet of said vacuum pump;

a recovery bottle connected to an outlet of said recovery pump;

a bypass valve in a bypass duct connected between said high pressure duct and said low pressure duct; and

a control system connected and programmed to operate said pressure controller to maintain a selected primary refrigerant flow rate, in response to signals from said temperature sensor, said pressure sensor, and said flow sensor.

13. A method for controlling a cryosurgical instrument, comprising:

providing a refrigerant supply, a cryosurgery catheter including an expansion element, a temperature sensor, a pressure sensor, a flow sensor, a precool loop, and a control system connected to said sensors;

flowing said refrigerant via a high pressure duct into said cryosurgery catheter;

precooling said refrigerant in said precool loop;

expanding said refrigerant in said catheter with said expansion element;

sensing the temperature of said catheter with said temperature sensor;

sensing the pressure of said expanded refrigerant with said pressure sensor;

sensing the flow rate of said refrigerant with said flow sensor; and

controlling said refrigerant with said control system, to maintain a selected catheter temperature, in response to signals from said temperature sensor, said pressure sensor, and said flow sensor.

14. A method as recited in claim **13**, wherein:

said refrigerant supply source comprises a pressure bottle; and

a fluid controller in said high pressure duct;

said method comprising operating said fluid controller to maintain a selected pressure at said pressure sensor.

15. A method as recited in claim **14**, wherein said fluid controller comprises a pressure controller, said method comprising modifying a pressure setpoint of said pressure controller to maintain a selected pressure at said pressure sensor.

16. A method as recited in claim **14**, wherein said fluid controller comprises a flow controller, said method comprising modifying a flow setpoint of said flow controller to maintain a selected pressure at said pressure sensor.

17. A method as recited in claim **13**, wherein:

said refrigerant supply source comprises a compressor; and

a compressor controller;

said method comprising operating said compressor controller to maintain a selected pressure at said pressure sensor.

18. A method as recited in claim **17**, further comprising:

providing a second compressor with a second compressor controller, wherein a low pressure duct is connected between said catheter and an inlet of said second compressor, and an outlet of said second compressor is connected to an inlet of said first compressor;

operating said control system and said first controller to maintain refrigerant pressure above a selected level in said high pressure duct; and

operating said control system and said second controller to maintain refrigerant pressure below a selected level in said low pressure duct.

19. A method as recited in claim **13**, wherein:

said refrigerant supply source comprises a compressor; and

a precool bypass valve in said precool loop;

said method comprising operating said precool bypass valve to maintain a selected catheter temperature.

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