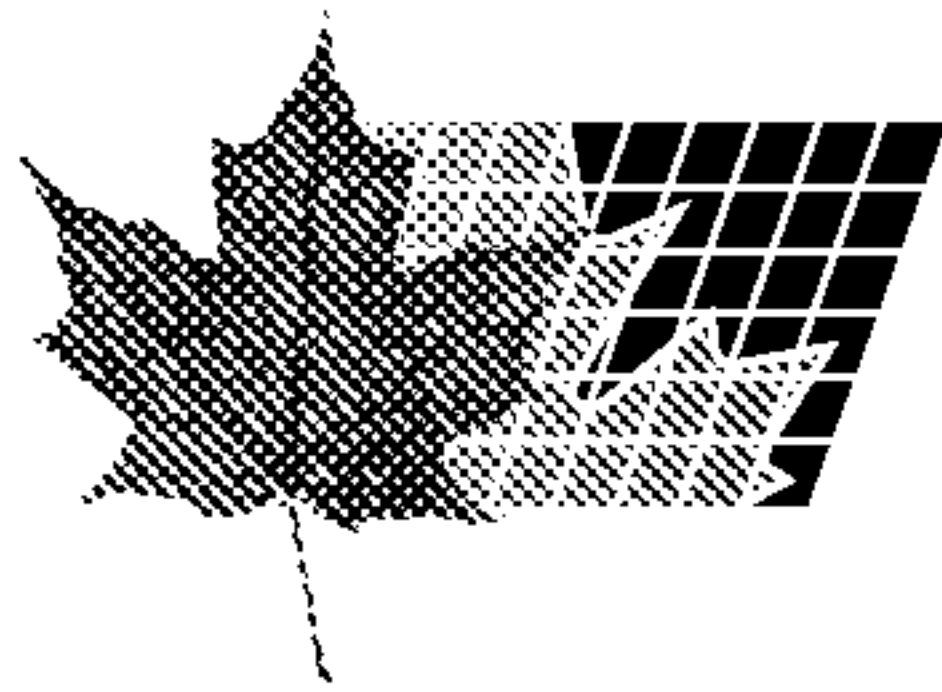


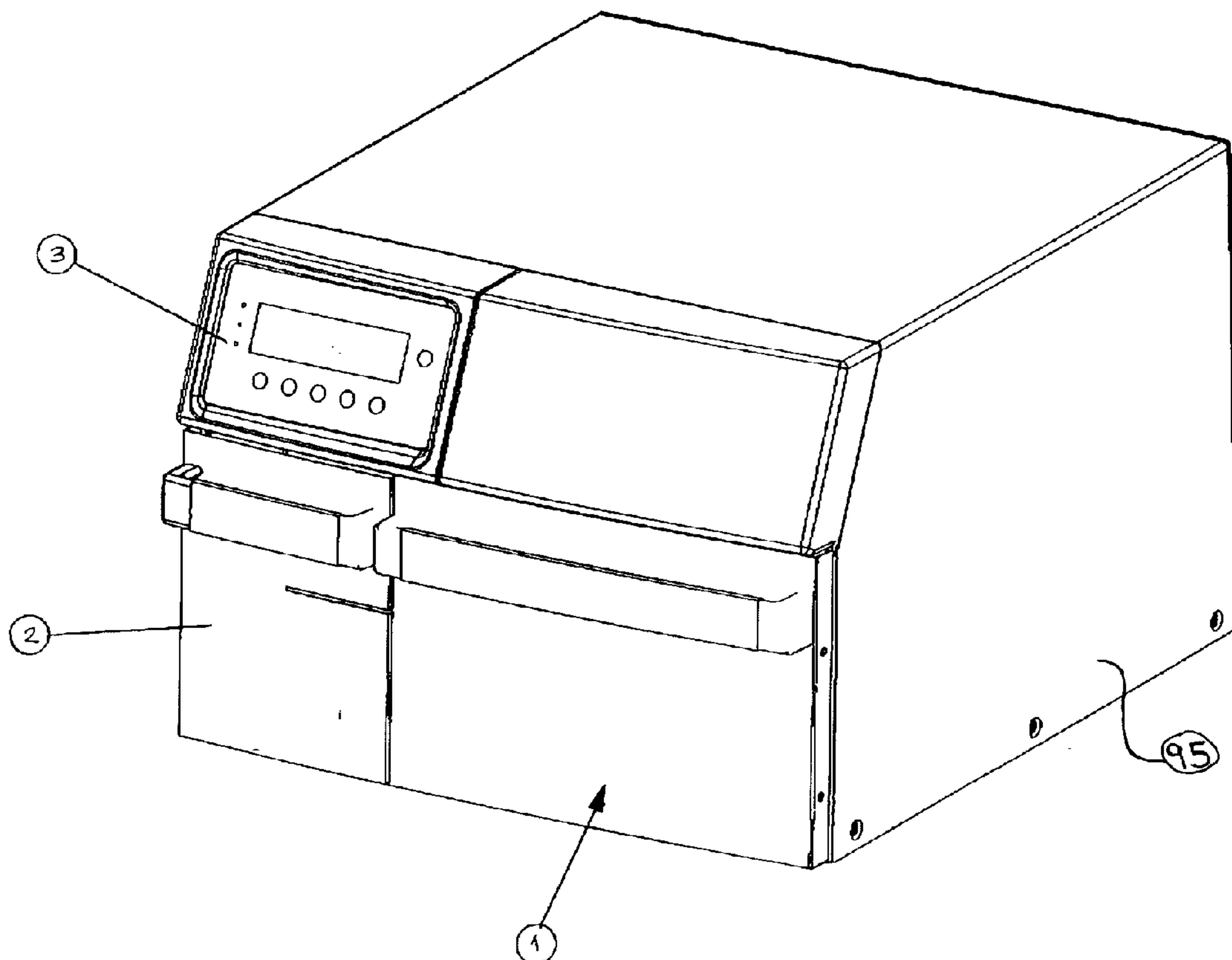


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(54) **APPAREIL ET METHODE POUR LA STERILISATION A LA
VAPEUR DES INSTRUMENTS MEDICAUX ET DENTAIRES**

(54) **APPARATUS AND METHOD FOR STEAM STERILIZATION OF
MEDICAL AND DENTAL INSTRUMENTS**



APPARATUS AND METHOD FOR STEAM STERILIZATION OF MEDICAL AND DENTAL INSTRUMENTS

BACKGROUND OF THE INVENTION

5 Field of the Invention

This invention relates to an apparatus and method for steam sterilization of medical instruments, dental instruments or the like, as well as a control system for same.

SUMMARY OF THE INVENTION

10 It is an object of the invention to provide a portable and less expensive apparatus for steam sterilization of medical or dental instruments which can sterilize the instruments in less time than the prior art devices.

Further features of the invention will be described or will become apparent in the course of the following detailed description.

15

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be more clearly understood, the preferred embodiment thereof will now be described in detail by way of example, with reference to the accompanying drawings, in which:

20 Fig. 1 is a perspective view of the apparatus for sterilization of dental and medical instruments, according to a preferred embodiment of the present invention;

Fig. 2 is a perspective view of the preferred embodiment with the access door in the open position and the cassette removed;

Fig. 3 is a perspective view of a cassette according to the preferred embodiment
25 of the present invention;

Fig. 4 is a perspective view of a preferred locking assembly for the cassette;

Fig. 5 is a perspective view of the cassette showing the rear of the cassette;

Fig. 6 is a perspective view of the interior portion of the cassette lid;

Fig. 7 is a cross-sectional view of the sealing assembly for the cassette lid;

Fig. 7A is a cross-sectional view of the sealing assembly for the cassette lid

5 showing the lid in the sealed position;

Fig. 8 is a perspective view of a preferred armature for the sterilization apparatus;

Fig. 9 is an elevational view of the armature;

Fig. 10 is a perspective view of a preferred steam generator assembly;

10 Fig. 11 is a perspective view of the heating element for the steam generator assembly;

Fig. 12 is a cross-sectional view of a preferred atomizing nozzle assembly;

Fig. 13 is a cut-away perspective view showing the cassette received within the sterilization apparatus;

15 Fig. 14 is an elevational view showing a preferred reed switch for the sterilization apparatus;

Fig. 15 is a cross-sectional view showing a preferred steam coupling assembly for the sterilization apparatus;

Fig. 16 is a chart showing the pressure of a sample sterilization cycle over time;

20 Fig. 17 is a schematic view of the preferred embodiment;

Fig. 21 is a schematic view of a control system according to a preferred embodiment of the invention;

Fig. 22 is a schematic view of a logic board for the control system;

Fig. 23 is a schematic view of a input/output board for the control system; and
Fig. 24 is a flowchart of the control system functions.

DESCRIPTION OF THE PREFERRED EMBODIMENT

5 Apparatus

Figure 1 shows the apparatus for sterilizing medical and dental instruments according to a preferred embodiment of the present invention. The apparatus includes a housing, such as a box-like preferably aluminium armature (95) having an open front and rear portion. The main user interface areas of the apparatus are connected to the front portion of
10 the armature and consist of an access door (1), shown in its closed position, a control panel (3) with a graphic display (3), and a printer door (2) where the printer, printer paper, water filter, air filter and drain tube are located. The access and printer doors are pivotably connected to the armature by conventional hinges.

Figure 2 shows the access door (1) in the open position, where its surface is
15 aligned with a lower heating plate (43) (shown in Fig. 13) in a chamber (5) to facilitate the insertion of the cassette (described in detail below). Inside the chamber (5) there are two side isoplates for thermal insulation and support for the cassette, two upper and lower heating plates for the pre-heating and drying part of the sterilization cycle, and a rear isoplate for thermal insulation and support (all described in detail below). The access door (1) seals the front end of
20 the chamber by a door seal (5a).

Figure 3 shows a preferred cassette (100) for storing dental instruments, medical instruments, or the like. The cassette includes an auxiliary handle (9) shown in its carrying position and a front handle (8) shown in its closed position. The cassette consists of two parts.

A tray (6), on which the instruments to be sterilized are placed, remains stationary throughout the entire sterilization cycle. A pivotable lid (7), which moves up or down depending of the pressure inside the cassette, covers the tray.

Figure 4 shows a preferred anti-tampering assembly adapted to prevent
5 tampering with the instruments. A self adhesive thermal paper label (not shown) is inserted in a slot (12) in such a way that it covers the front part of a preferably metal bracket. During the sterilization cycle, the colour of the thermal paper is changed to black by the heat generated by the heating plates, indicating that the cassette has been placed in the chamber for sterilization. When the operator opens the cassette to retrieve the instruments, an opening handle (10) is
10 lifted and a crossbar (13) tears the label indicating that the cassette has been opened. A label retainer (11) stores the label with relevant information. The lid (7) could also include a conventional bar-code identification system to organise and identify the cassette contents.

Figure 5 shows the rear of the cassette with couplings (15) and the auxiliary handle (9) in its resting position. The cassette is in its sealed position. When the operator opens
15 the cassette, the lid (7) pivots around a conventional hinge (14).

Figure 6 shows the interior (16) portion of the lid (7) and the seal gland (17), where a bi-directional seal (described in detail below) is installed.

Figure 7 shows a cross-section of the bi-directional seal (96), which is an important part of the present invention. When the lid (7) is in the open position, a vacuum lip (19) is covered by an edge (21a) of the lid (7) preventing an incorrect closing of the lid. When
20 the cassette is in the closed position (see Fig. 7A), the tray (6) touches a pressure lip (18) first, forcing the seal to rotate around the pivot point (20) and causing the vacuum lip (19) to touch the tray wall. As the cycle progresses, the lid (7) separates from the tray (6) when the cassette

is pressurised, but the pressure lip (18) seals against the tray to prevent any leakage to the exterior. At the end of the cycle, as the cassette cools down, the vacuum lip (19) seals against the tray to maintain vacuum. The interior portion (16) of the lid travels back to the position shown on Figure 7A, forcing a seal tail (21) to be compressed by the tray wall to create the vacuum seal.

Figure 8 shows the armature (95), which is able to withstand the load exerted by the cassette during the sterilization cycle, but is also sufficiently light to provide portability of the whole unit. The armature is preferably extruded from aluminium. The extrusion process must be free of imperfections to prevent any vacuum leakage during the sterilization cycle. The armature walls include a web structure (101) which minimizes wall thickness and armature weight, while maintaining the structural strength required to withstand pressure forces. The web structure is also positioned in such a way so as to interact with other parts of the apparatus mounted thereon.

Figure 9 shows holes (22) for mounting of the access door (1). Two spring-loaded rods (not shown) connected to the door, are inserted into the holes (22) and kept inside the armature by a front plate which also has the mounting features for the door seal (5a). This plate is fastened to the armature by means of screws.

Figure 10 shows a preferred steam generator assembly (97), which is a boiler with a deep drawn cap (98). The boiler is mounted on the armature (95) by any conventional means, such as screws through holes (23) on the steam generator base. The water is atomised by a spray nozzle located at the top of the boiler (24). The nozzle breaks down the water droplets into a mist, increasing the surface area of the water and reducing the time required to bring the fluid to a state of saturated steam. The exhaust of this steam is conducted to the

system through a port (25). A conventional pressure relieve valve is located at port (26) as a safety device to prevent catastrophic failure of the boiler assembly.

Figure 11 shows the boiler base (99) with a boiler gasket (31a) where a seal may be maintained between the base and the cap by any suitable means. A heating element (27) is free to translate in the Boiler base, avoiding any stress caused by thermal expansion. A rod (29) is secured by a nut and bolt arrangement (30), which clamps the heating element (27) against the base. The temperature of the boiler is monitored by a thermocouple fastened through the compression fitting located at (31) and inserted on a thermocouple housing (28) allowing easy replacement of the component in the field.

Figure 12 shows a preferred spray nozzle assembly. It consists of two parts threadably secured to each other at (34) and sealed to the atmosphere by an o-ring located on a gland (35). The water is pumped into an upper part (33) through a hole (38). The water travels down through the upper part and exits into a lower part (32) of the spray nozzle assembly through a cross-hole 36. It then swirls around an acme thread (37) gaining angular momentum and accelerates as it moves down through a conical feature at the bottom of the lower part (32) until it reaches an opening (39). The sudden expansion together with the centrifugal force causes the water to separate in the desired conical shape, such that the spray covers substantially the entire heating element (27) (shown in Fig. 11), providing uniform cooling and, therefore, reducing the induced thermal stresses in the heating element. The size of the opening (39) is configured to prevent possible clogging of the nozzle which could lead to cycle interruption.

Referring to Figure 13, the cassette is shown inserted within the armature (95) in the sealed position. The cassette locates on top of the lower heating plate (43) and is

supported by a side isoplate (40) and a rear isoplate (41). The rear isoplate is supported by a rear plate (42).

Figure 14 shows a reed switch (46). The main purpose of the reed switch is to indicate whether the cassette is present inside the chamber in order to determine whether the sterilization cycle should commence. As the cassette is inserted into the chamber (5), the rear end of the cassette (100) displaces a magnet (47) located inside a plug (44) which is urged against the cassette by any suitable biasing means, such as a spring (45). The reed switch (46) located on the outer surface of the rear plate (42) is activated by the magnetic field exerted by the magnet. The main advantage of the reed switch is to prevent any further leak path in the chamber and to calibrate the cassette final resting position inside the armature (95).

Figure 15 shows a preferred coupling assembly (48) and a preferred probe assembly (49). The couplings (15) are mounted in an opening on the rear wall (50) of the cassette and are sealed by a seal (53). The seal is compressed against the rear wall by means of a wave spring (54) located outside the cassette. This arrangement permits the couplings to float and adjust themselves to any tolerance scenario on the probes (49), thereby allowing interchangeability between cassettes and probe assemblies. The probes (49) are assembled in an opening on the rear plate (52), supporting the rear isoplate (51) by a nut (58). The probes are sealed to the rear plate by a seal (59). When the cassette is inserted into the armature (95), the coupling is penetrated by the probe (49), connecting the cassette to the valve system. A probe tip (63) locates within the coupling (48) and depresses the poppet (56), breaking the contact with a coupling seal (55). The steam can travel in and out of the system through the port (60) after being filtered against any debris by a probe filter (61). The filter is a preferably stainless steel wire mesh rolled in a cylinder shape to fit inside the probe chamber and held in

place by the fitting at the rear of the probe. When the cassette is removed, the sealing of its contents is re-established by the poppet (56) seated against the coupling seal (55). Before the poppet (56) is seated against the coupling seal (55), air is prevented from entering the cassette by an outer seal (57) which seals against probe wall (62), ensuring the sterility of the instruments, as the cassette is removed from the chamber.

Process

For convenience, the description below refers to a process for achieving fast sterilization cycles for solid unwrapped instruments. However, the process according to the present invention can be varied by altering the sequence of the sterilization cycle or by altering the number of cycle stages in order to sterilize different types of instruments (such as rubber, plastics, hollow, etc), which may be wrapped in various wrapping materials such as cloth, paper, or plastic film. However, the strategy adopted for each stage of the sterilization cycle remains the same, and it will be understood by those skilled in the art that such variations are within the scope of this invention.

Figure 16 shows a chart of a generic sterilization cycle and figure 17 shows the valve schematics.

The sterilization process includes the steps set out below.

1. Insertion of the Cassette inside the sterilization chamber

The cassette (100) is placed over the access door (4) and inserted in the chamber (5) in such a way that it contacts the side isoplates (40) and the rear isoplate (41) at the rear end of the armature (95). These isoplates provide the required support against the

pressure loads during sterilization as well as thermal insulation.

The insertion is facilitated by the clearance between the cassette (100) and the side isoplates (40). The insertion motion is completed when the cassette contacts the rear isoplate (41). At that time, the reed switch (46) located outside the chamber is activated by the magnet (47) located inside the rear isoplate (42). The reed switch (46) is activated when the magnet (47), which is mounted in the spring-loaded housing (44)/(45), is displaced rearwardly by the insertion of the cassette. The cassette is sealably connected to the valve system when the probes (49) penetrate the cassette coupling (15)/(48). At this point, the sterilization cycle is ready to start. The access door (4) is then closed and the cycle may commence only if the door switch (74) mounted on the front plate and activated by the door (1) and the reed switch (46) are triggered indicating the presence of the cassette and that the access door is in the closed position, respectively.

2. Heating Plates up to the sterilization temperature (64).

The two aluminium casting heating plates (43) located immediately above and below the cassette, are powered. Their temperature is monitored via a thermocouple (75) located inside each heating plate. They are isolated from the armature (95) so that substantially all of the heat generated is transferred to the cassette (100) by thermal conduction. The temperature is controlled in order to ensure that it remains within 5°C of the sterilization temperature relevant to the type of instruments to be sterilized. If the temperature is too low, the steam will condense inside the cassette. If it is too high, there is a risk of damaging the instruments or components located inside the cassette.

As the cassette warms up, the air pressure inside the cassette increases and the

lid (7) is displaced until it touches the upper heating plate. The cassette is locked in position due to the pressure load against the heating plates. The temperature of the heating plates increases to close to the sterilization temperature and the next stage starts.

5 3. Air vacuum draw (air removal) (65)

A two stage, diaphragm vacuum pump (77) connected to the system by any suitable flexible tubing, such as Norprene™, as shown schematically in Fig. 17 is activated and the air vacuum draw commences. The vacuum is drawn from both, inside and outside the cassette to equalize the pressure acting on the cassette. The reduced pressure acting on the
10 cassette the construction of the cassette to be greatly simplified and, therefore, its costs of construction are greatly reduced. Although some additional time is required to evacuate the volume outside the cassette, the volume of air evacuated is still smaller than the amount required to be evacuated by the prior art autoclaves, having a cylindrical chamber. This is achieved by the chamber (5) having a shape which closely corresponds with the cassette
15 shape.

Consequently, the pressure inside the cassette is always higher then the pressure outside the cassette (i.e. inside the vacuum chamber defined by the armature). This is accomplished by:

i) Evacuating air from the chamber in which the cassette is located every time a
20 vacuum draw process takes place inside the cassette.

ii) Preferably, an additional armature pressure sensor (76), for monitoring the pressure inside the chamber, is mounted in the chamber. If this sensor detects a leak that causes the pressure outside cassette to be higher then inside, the cycle is immediately aborted

and air is allowed inside the cassette.

iii) Preferably, the system allows for vacuum draws in the chamber (5) only, in order to test the integrity of the cassette seal (17), probe seal (49), and vacuum valve (78).

The air removal part of the cycle preferably starts with a low vacuum draw in the chamber only, for the reasons described at (iii) above.

Air from the steam generator assembly (97) is removed by opening momentarily the boiler valve (80). Any residual water located inside the doubled circuit tube-fin heat exchanger (79) and recirculation heat exchanger (82) (located at the back of the apparatus and connected to the valve system) is evacuated, as schematically shown in Fig. 17. The recirculating heat exchanger (82) and its tubing are also evacuated by opening momentarily the recirculation valve (81). The vacuum valve (78) is then opened and air is removed from the cassette. Preferably, the majority of the air from the entire system is removed. However, even though the level of vacuum reached is high, some residual air still exists in the system. As soon as the vacuum level detected by the cassette pressure transducer (83) reaches the target vacuum level of 10 Kpa, the cycle proceeds to the next stage.

4. Pressurization with steam for air removal (66)

The steam generator assembly (97) is activated and starts to generate steam. The boiler valve (80) opens allowing steam to flow into the cassette (100), and the pressure inside the cassette gradually increases. Saturated steam starts to fill the voids created by the vacuum draw. There is still a mixture of saturated steam and residual air inside the chamber. The pressure increases to a level slightly above the atmospheric pressure and the air is purged out of the system by the opening of the exhaust valve (83).

Since air is more dense than saturated steam, it tends to be pushed out to the exhaust valve ahead of the steam. As soon as the pressure reaches atmospheric level, the venting terminates and the cycle proceeds to the next stage.

5 5. Vacuum draw (Recirculation) (67)

At this stage, the system is almost entirely filled with saturated steam and a simple vacuum draw would be very slow. In order to increase the speed of the vacuum draw, the boiler is isolated from the system by closing the boiler valve (80). This step reduces the volume to be evacuated, and causes the boiler to act as a steam reservoir, in order to assist
10 with a later part of the cycle (described in detail below).

The speed of vacuum draw is increased by forcing the circulation of the saturated steam through the coils of the heat exchangers (79) and (82), which are, at this point, being cooled by fans (85) and (86) located at the back of the apparatus, mounted between the vacuum pump and the heat exchanger. As the saturated steam travels through that cooler
15 region, it condenses and this change of phase reduces the pressure drastically, greatly accelerating the speed of vacuum draw. The steam displacement is accomplished with the proper valve arrangement in the two stages of the vacuum pump (77). The pump starts by first opening the bleed valve (87) in order to relieve the vacuum which is still resident in that part of the system. The steam is circulated through the coils of the heat exchangers (79) and (82) by
20 opening the vacuum valve (78) and the recirculation valve (81). The condensation is purged out of the system to the exhaust bottle (not shown). When this stage is complete, all of the air is extracted from the system and the instruments inside the cassette are ready to be sterilized. The increased speed of the vacuum draw allows the present invention to reduce the sterilization

cycle time required by prior art autoclaves.

6. Pressurization for sterilization (68)

5 The pressure and temperature inside the cassette are increased to the levels required for sterilization. The levels are mandated by regulations, which may vary from country to country. The apparatus and process according to the present invention may be varied to accommodate these standards using the controls and program disclosed, and it will be understood by those skilled in the art that such variations are within the scope of this invention.

10 The boiler valve (80) opens, allowing the boiler, in which steam is being stored under pressure, to purge the steam inside the cassette, reducing the time required to reach the sterilization level. When the predetermined pressure level required for sterilization is reached, the next cycle stage starts

7. Sterilization (69)

15 The duration of this cycle depends on the applicable standard. During sterilization, the correlation between steam pressure and temperature is closely monitored by the control system. The sterilization pressure control may be achieved either by switching the electrical power supplied to the boiler cyclically on and off, or by maintaining the boiler in the on position. If the pressure increases above the tolerance specified by the applicable standard,
20 the exhaust valve may be opened for the time required to relieve the excess pressure. This process is referred to as the PID (proportional integral derivative) control of the steam generator duty cycle.

Throughout the pressurization and sterilization phases, steam is generated on

demand by pumping water when the temperature of the boiler increases rapidly above the temperature of the saturated steam present in the chamber by a predetermined amount (this condition is referred to as " dt_{on} "). The pumping is stopped when the gradient of the boiler temperature changes sign and the temperature reaches a predetermined threshold (this condition is referred to as " dt_{off} ") above the temperature of the saturated steam present in the chamber. The values of dt_{on} and dt_{off} may vary with the stage of the cycle and the value of the pressure inside the cassette.

8. Vent (70)

The pressure is released from the cassette (100) by opening the exhaust valve (84) allowing the exhaust water evacuate to the exhaust bottle. The rate of pressure release is controlled and regulated by the control system to a value determined by the appropriated standards. The heating plates (43) are turned on and maintained at a temperature above the boiling point inside the chamber, in order to prepare the apparatus for the next stage. When the pressure measured by the pressure transducer (83) inside the chamber approaches atmospheric pressure, the bleed valve (87) opens and vacuum pump (77) is activated.

9. Vacuum draw (drying) (71)

The preparation for the end of the process is commenced by ensuring that the instruments in the cassette (100) are dry and ready for storage. The bleed valve (87) is opened and the vacuum pump (77) is activated. The vacuum valve (78) is opened in order to evacuate any steam still resident in the cassette. The recirculation valve (81) remains closed in order to avoid the contamination of the instruments already sterilized. The temperature of the heating

plates (43) is maintained above boiling point of water, and any water that is inside the cassette is boiled off and evacuated. The duration of this cycle is dependent of the load inside the cassette (type of sterilization cycle selected).

5 10. Vacuum draw with air (72)

The remainder of steam generated by the heating plates (43) is exhausted. The air valve (89) is opened in order to allow the filtered air from the microbial filter (90) to enter. The air heater (88) pre-warms the air to avoid further condensation inside the cassette and proceeds with the cooling and drying of the instruments. The duration of this cycle is dependent
10 of the load inside the cassette (type of sterilization cycle selected).

11. End of Cycle (73)

The cycle is terminated and the armature valve (91) opened in order to allow air to pass through the armature (95). The pressure increases to atmospheric pressure and the
15 access door (1) can now be opened. The cassette (100) is ready to be removed from the chamber.

12. Cassette Removal From The Chamber

As the temperature inside the cassette (100) falls, a small vacuum is created
20 inside the cassette. The lid (16) returns to its original position separating from the upper heating plate. The removal of the cassette is then established in such a way that the poppet (56) on the coupling (48) is closed against the seal (55) before the cassette is disconnected from the probes (49), ensuring that the cassette content is isolated from the ambient air. Sterility is

therefore ensured for the entire storage period. The cassette storage can also take place at atmospheric pressure. In this case, the cassette remains coupled with the valve system until it reaches the ambient temperature and then removed from the armature.

5 Electronic Control System

Hardware

The control system according to a preferred embodiment of the present invention comprises a multiprocessor control system to perform the complex operations required for executing and validating a selected sterilization cycle. The automatic control system is made of
10 two main components:

- The Input/Output Board
- The Logic Board

The input/output board ("I/O Board") is the part of the control system that is in
15 direct contact with the electromechanical components of the sterilizing apparatus described above. The I/O Board is in receives information from the sensors and switches, and translates captured data into engineering units. The I/O Board performs the following functions:

- reads boiler temperature sensor - (Fig.21-13)
- reads cassette temperature sensor - (Fig.21-8)
- 20 • reads upper heater temperature sensor - (Fig.21-6)
- reads lower heater temperature sensor - (Fig.21-7)
- reads cassette pressure sensor - (Fig.21-9)
- reads armature pressure sensor - (Fig.21-11)

- controls water pump - (Fig.21-12)
- controls vacuum pump - (Fig.21-22)
- controls steam generator - (Fig.21-14)
- controls air heater - (Fig.21-15)
- 5 • controls upper and lower heaters (Fig.21-6,7)
- controls fans (Fig.21-27)
- controls the following valves: boiler valve (Fig.21-24), air valve (Fig.21-17), armature valve (Fig.21-18), recirculation valve (Fig.21-19), vacuum valve (Fig.21-20), exhaust valve (Fig.21-21), and bleed valve (Fig.21-23).

10 The I/O Board includes a microcontroller (Fig.23-1) which has a ROM (Fig.23-2), where the I/O software resides, and a RAM (Fig.23-3), where data and variables are stored. The microcontroller receives information from the pressure sensors (Fig.21-9, 11) through an Analog to Digital Converter (Fig.23-10), the temperature sensors (Fig.21-6,7,8,13) through another Analog to Digital Converter (Fig.23-12), and controls the valves, pumps, steam
15 generator assembly, heaters and fans through solid state relays (Fig.23-6,7,4,5,8,11).

The main function of the I/O board is serial communication with a logic board, a second electronic component of the control system according to the present invention. The I/O Board communicates with the logic board through the Serial Communication Interface (Fig.23-9).

20 The Logic Board interfaces with the Graphics Display(Fig.21-16), the Keyboard(Fig.21-10), the Sound Generator(Fig.21-2) and the Printer (Fig.21-3). The main components of the Logic Board are:

- Microcontroller (Fig.22-1)
- Flash memory (Fig.22-2)
- RAM (Fig.22-3)
- Real Time Clock (Fig.22-4)
- 5 • Two serial communication drivers (one for communicating with the I/O board (Fig.22-6), the other for communicating with a serial printer or a remote PC (Fig.22-7))
- Graphics Display adapter (Fig.22-5)
- Keyboard adapter (Fig.22-8)
- Sound generator adapter (Fig.22-9)

10 The Logic Board Software is responsible for the execution and validation of a selected sterilization cycle. The Logic Board Software also communicates with the user through the graphics display, keyboard and sounds.

 The I/O Board Software is a collection of software drivers that translate commands received from the Logic Board into signals for valves, pumps, heaters and steam
15 generator assembly. The I/O Board Software is also responsible for receiving information from the pressure and temperature sensors, translating these readings into engineering data, and supplying it to the Logic Board on request. The algorithms implemented in the Logic Board Software are set out below.

20 Software

 A flow-chart for the operation of the system in Fig.22-1 is shown in Fig.24. The sequence of steps carried out in a sterilization process is shown in Fig.24 page 1.

Reading Sensors

A common part for all the steps carried out in a sterilization process is the ability to monitor the temperature and pressure inside the chamber (Fig.21-10) when it is under vacuum, or is pressurized, or is being held at the desired steam sterilization condition.

- 5 • As seen in Fig. 21, a pressure transducer (9) is connected with the chamber volume and a thermocouple or thermistor (8) extends into the chamber. This operation is identified as "Read Chamber Temperature Sensor" and "Read Cassette Pressure Sensor".
- 10 • Another important parameter is the temperature of the boiler (Fig.21-14), monitored with a thermocouple or thermistor (Fig.21-13). This operation is identified as "Read Boiler Temperature Sensor".
- The pressure inside the armature (Fig.21-25) is measured with a vacuum pressure sensor (Fig.21-11). This operation is identified as "Read Armature Pressure Sensor".
- 15 • The temperature of the heating plates (Fig.21 – 6,7) is monitored with two thermocouples or thermistors (Fig.21-6,7). This operation is identified as "Read Upper Heater Temperature Sensor" and as "Read Lower Heater Temperature Sensor".

Displaying Cycle Progress

20 A common part for all the steps carried out in a sterilization process is the ability to communicate to the user the evolution of the cycle. This is accomplished through a graphics display which shows as dotted lines a graph of the cycle to be performed and fills in the gaps as the cycle progresses. The temperature and pressure inside chamber are also displayed, as are the cycle stages and the time elapsed. This operation is identified as "Display graph: evolution

of the cycle” and “Display Cycle Parameters”. During the evolution of the cycle the cycle parameters are saved for printing on completion of the cycle or for servicing in case of a fault condition.

Device Configuration

5 A common element for all the control system steps described is the device status. Each step has a specific device configuration, as follows:

- Upper Heater: ON or OFF
- Lower Heater: ON or OFF
- Boiler: ON or OFF
- 10 • Water Pump: ON or OFF
- Vacuum Pump: ON or OFF
- Air Heater: ON or OFF
- Boiler Valve: Open or Closed
- Air Valve: Open or Closed
- 15 • Armature Valve: Open or Closed
- Recirculation Valve: Open or Closed
- Exhaust Valve: Open or Closed
- Vacuum Valve: Open or Closed
- Bleed Valve: Open or Closed

20 *Armature Vacuum Draw*

The operation identified as “Armature vacuum draw” (see Fig.24-page 2) relates to the step of turning on the vacuum pump (Fig.21-22) and heating up the cassette (Fig.21-10) by turning on the heating plates (Fig.21-6,7). Everything else is off, as seen in the device

configuration on Fig.24 (page 2). This step ensures that there is a good insulation between the cassette and armature (good cassette seal and good vacuum valve) by monitoring closely the pressure inside the chamber and inside the armature. If the pressure inside the chamber follows the pressure in the armature, the cycle is aborted with a fault indication.

5 *Turn Vacuum Pump On*

This operation is described in Fig.24 (page 13). The vacuum pump (Fig.1-22) does not start if the pressure at its input [the side of the pump that is connected to Vacuum valve (Fig.1-20), Armature (Fig.1-25), Heat Exchanger (Fig.1-26), and Bleed Valve (Fig.1-23)] is different from the atmospheric pressure by 5kPa (plus or minus). In order to start the vacuum pump in any condition the Bleed valve (Fig.21-23) was introduced in the circuit. Every time the vacuum pump is turned on the Bleed valve is open for 2 seconds and on confirmation of it being closed the vacuum valve (Fig,1-20), if required, is turned on.

Upper and Lower Heater Control

This operation is described in Fig.24-page 4. The upper (Fig.21-6) and lower (Fig.21-7) heaters are required to heat the sterilization chamber (cassette – Fig.21-10) to a temperature close to the sterilization temperature, to minimize the duration of the cycle (shorter pressurization time), and to reduce the distilled water consumption. The heating plates are also an important part of the drying stage of the cycle. During drying, the heating plates are maintained at a temperature of 10°C above the boiling temperature inside the cassette, in conjunction with a deep vacuum draw. The temperature threshold for turning on the heating plates is greater by 1°C than the temperature threshold for turning off the heating plates. Also, the temperature threshold varies with the cycle stage, where heating plate control is required. During the venting stage (Fig.24-page11) and drying stage (Fig.24-page12), the temperature threshold for both heating plates

follows the boiling temperature inside the chamber plus 10°C.

Vacuum Draw (simple with steam generation)

This operation is described in Fig.24-page 3. The purpose of this stage is to remove the air from the cassette and boiler in order to check for leaks in the cassette (100) and
5 chamber (5). The vacuum pump is turned on and a very deep vacuum is drawn from both, inside and outside the cassette. The pressure inside the cassette is always higher than the pressure in the chamber. This is accomplished by forcing air removal outside the cassette (in the chamber) every time a vacuum draw process takes place inside the cassette. The armature pressure sensor (Fig.21-11) monitors the pressure of the chamber. If this sensor
10 detects a leak which causes the chamber pressure to be higher than cassette pressure, the cycle is immediately aborted and air is allowed inside the cassette through the air Valve (Fig.21-17). This safety check takes place throughout the entire duration of the cycle, and it is done in the background anytime when a cassette present condition is detected.

The majority of the air from the whole system including the boiler is removed and
15 any residual water located inside the heat exchanger tubing is evacuated. However, even though the level of vacuum reached is deep, some residual air still exists in the system.

This process (air removal) may be unnecessarily extended if water is left in the boiler from a previous cycle which ended before the drying stage was completed. To avoid this delay, the boiler valve (Fig.21-24) is closed when the level of the vacuum brings the boiling
20 temperature inside chamber close to the steam generator temperature.

As soon as the vacuum level detected by the cassette pressure transducer reaches the target, the cycle proceeds to the next stage.

Relieving Vacuum with Steam

This operation is described in Fig.24-page 5. During this stage, the steam generator (boiler – Fig.21-14) is turned on full power and the boiler valve (Fig.21-24) is open. The boiler starts to generate steam and the pressure in the cassette gradually increases. The saturated steam in the cassette starts to fill the voids created by the vacuum draw. There is still a mixture of saturated steam and residual air inside the chamber. When the pressure increases above the atmospheric pressure (by aprox.10kPa), this stage is complete.

Water Pump Control

This operation is described in Fig.24-page 6. Throughout relieving vacuum with steam stage, pressurization and sterilization phases, steam is generated on demand by pumping water into the boiler when the temperature of the boiler (Fig.21-14) rises rapidly above the temperature of the saturated steam present in the chamber (Fig.21-10) with a fixed amount (dt_{on}). The pumping stops when the gradient of the boiler temperature changes sign and the boiler temperature reaches a determined threshold (dt_{off}) above the temperature of the saturated steam present in the chamber. The values of dt_{on} and dt_{off} may vary with the stage of the cycle and the pressure inside the cassette.

Purging

This operation is described in Fig.24-page 7. During this stage of the cycle, the exhaust valve (Fig.21-21) is open and the condensate together with steam and residual air is removed from the chamber. During this stage, the heating plates are maintained at sterilization temperature. This stage ends either when the pressure inside cassette is above the atmospheric pressure or when the time allowed for this stage expires.

An important part of this stage is boiler control through “Water Pump Control”.

Even though the steam generator is turned off in accordance with the device configuration for this phase, the boiler continues to produce steam due to thermal inertia. The steam is trapped inside the boiler because the boiler valve (Fig.21-24) is closed. This operation mode is identified as "Using boiler as a Steam Reservoir".

5 *Vacuum Draw Recirculation*

This operation is described in Fig.24-page 8. This stage of the cycle is similar to "Vacuum Draw – Simple" with the difference that the boiler valve (Fig.21-24) is closed and the recirculation valve (Fig.21-19) is open. Because the boiler valve is closed the boiler is accumulating steam. The steam stored in the boiler will be used on the next stage of the cycle.

10 During this phase the heating plates are maintained at sterilization temperature.

An important part of this stage is the recirculation of steam through the heat exchanger (Fig.21-26), which is cooled by fans (Fig.21-27). As the saturated steam travels through that cold region, it condenses and this change of phase reduces the pressure drastically, greatly accelerating the speed of the vacuum draw. This operation is identified as

15 "Vacuum Draw Recirculation".

Pressurizing

This operation is described in Fig.24-page 9. During this stage, the steam generator (boiler – Fig.21-14) is turned on full power and the boiler valve (Fig.21-24) is open.

The boiler starts to generate steam and the Cassette gradually increases its pressure and
20 temperature to the levels required for sterilization. When the sterilization pressure is reached, the next cycle stage starts. An important operation during this stage of the cycle is identified as "Water Pump Control".

Sterilizing

This operation is described in Fig.24-page 10. The duration of this stage depends on the desired sterility assurance level, load configuration and types, the initial bioburden level, and the selection made by user. During sterilization, the correlation between steam pressure and temperature is closely monitored by the control system. The sterilization pressure control may be achieved either by switching the electrical power supplied to the steam generator assembly cyclically on and off, or, by turning the boiler power full on and controlling the pressure by opening and closing the exhaust valve, as needed, to relieve the extra pressure. This process is referred to as the PID (proportional integral derivative) control of the steam generator assembly duty cycle. An important operation during this stage of the cycle is identified as "Water Pump Control".

Venting

This operation is described in Fig.24-page 11. This stage is simply the release of the pressure from the sterilization chamber. The rate of pressure relieve is controlled and regulated by the control system to a value determined by the appropriated standards. The heating plates are turned on and kept at a temperature above the boiling point inside the chamber, to get ready for the next stage. When the pressure inside the chamber approaches the atmospheric pressure this stage ends. Two operations are performed during this stage: "Water Pump Control" and "Upper and Lower Heater Control".

Drying

This operation is described in Fig.24-page 12. During this stage the temperature of the heating plates is above the water boiling point temperature, and any water that is inside the Cassette is boiled and evacuated. The duration of this cycle is dependent of the load inside

the Cassette (type of sterilization cycle selected). Three operations are performed during this stage: "Water Pump Control", "Upper and Lower Heater Control" and "Turn Vacuum Pump On".

Air Drying

5 This operation is described in Fig.24-page14. During this stage air (which may first be pre-warmed and/or passed through a suitable bacteria-retentive filter) is introduced inside the Cassette proceeding with the cooling and drying of the instruments. The duration of this cycle is dependent of the load inside the Cassette. The main operation performed during this stage is "Upper and Lower Heater Control".

Relieving Vacuum with Air

10 This operation is described in Fig.24-page15. This stage ends the cycle by bringing air inside the cassette and armature, and unlocking the door.

It will be appreciated that the above description relates to the preferred embodiment by way of example only. Many variations on the invention will be obvious to those knowledgeable in the field, and such obvious variations are within the scope of the invention as described and claimed, whether or not expressly described.

15

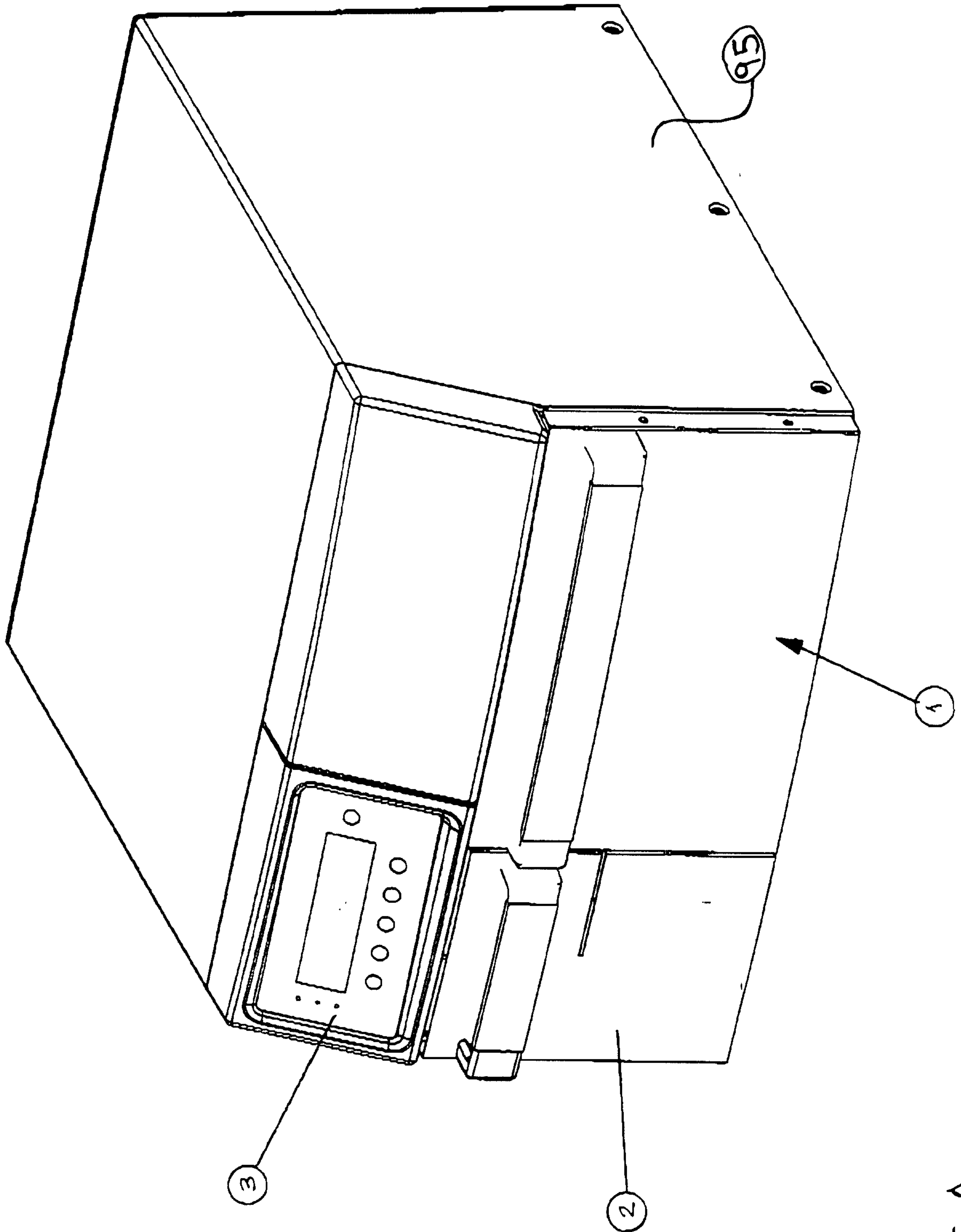


FIGURE 1

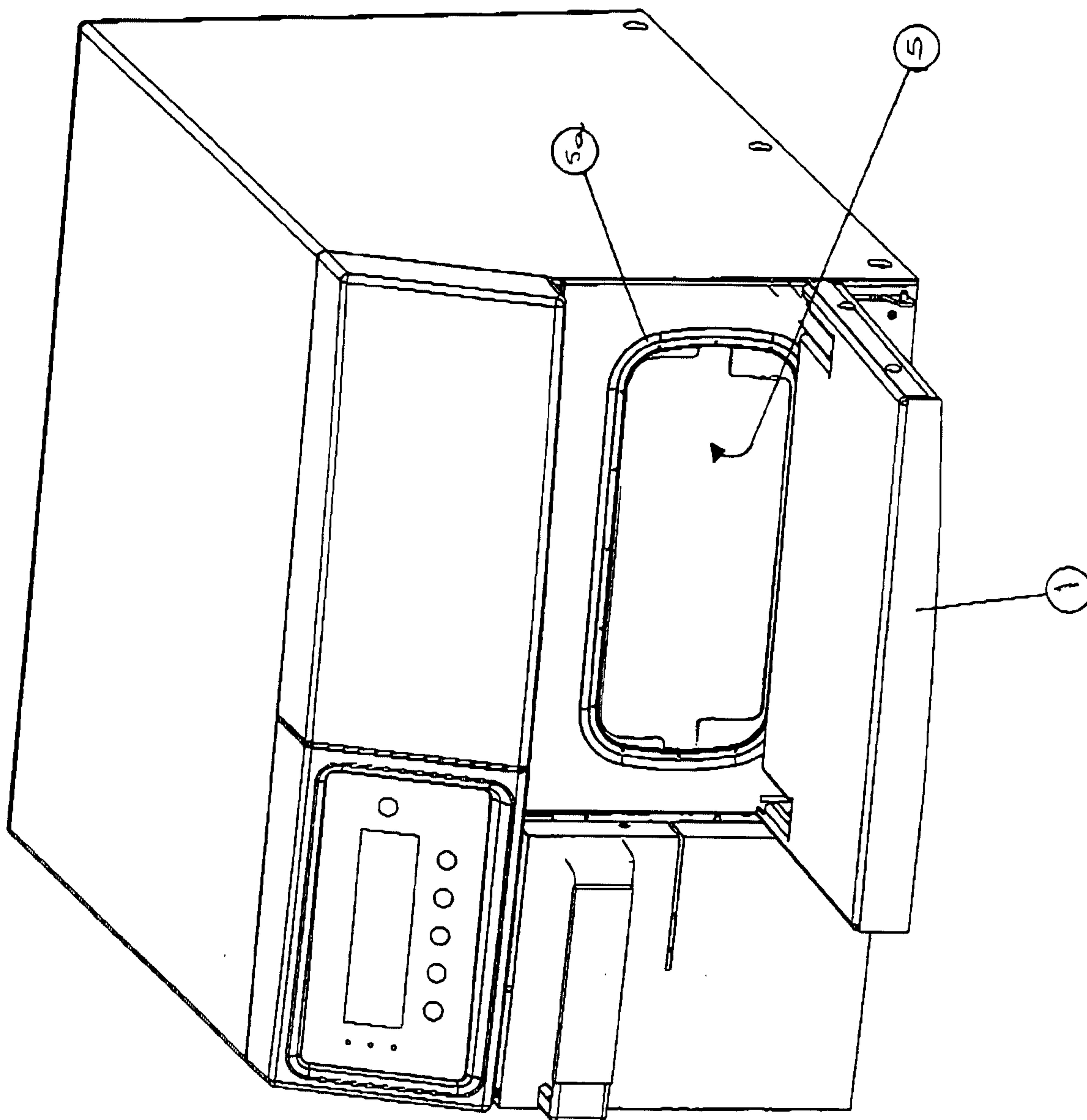


Figure 2

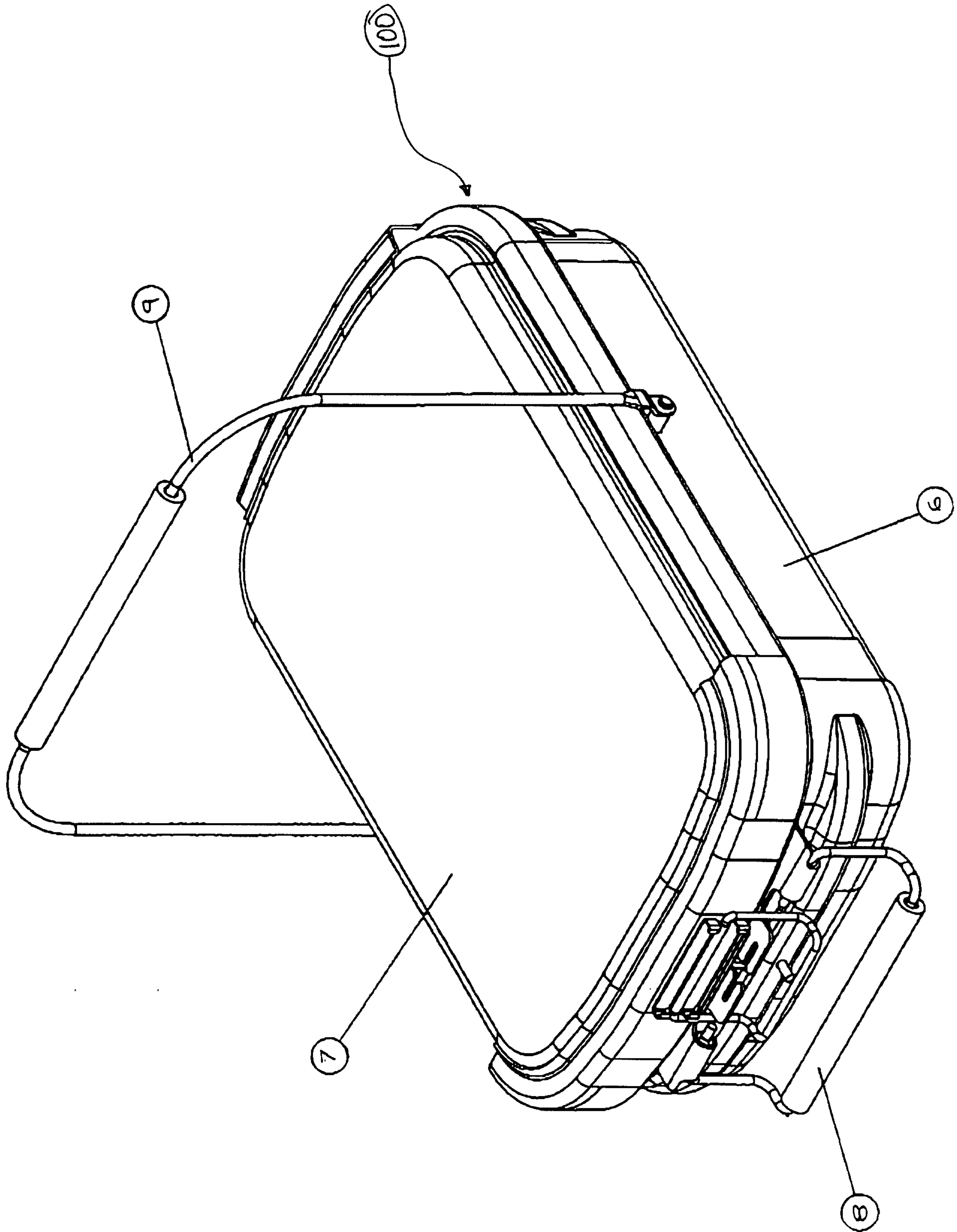
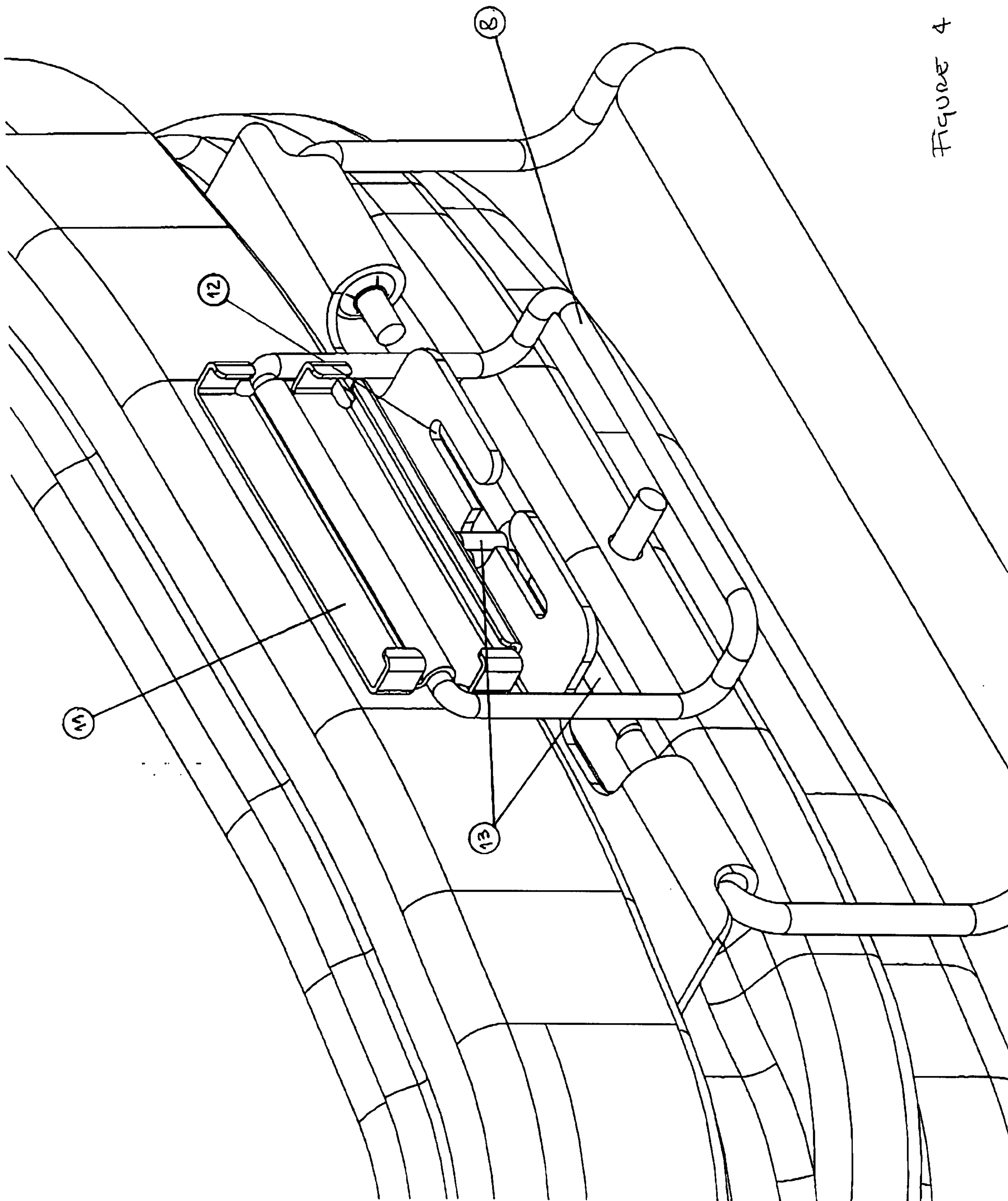


Figure 3

Figure 4



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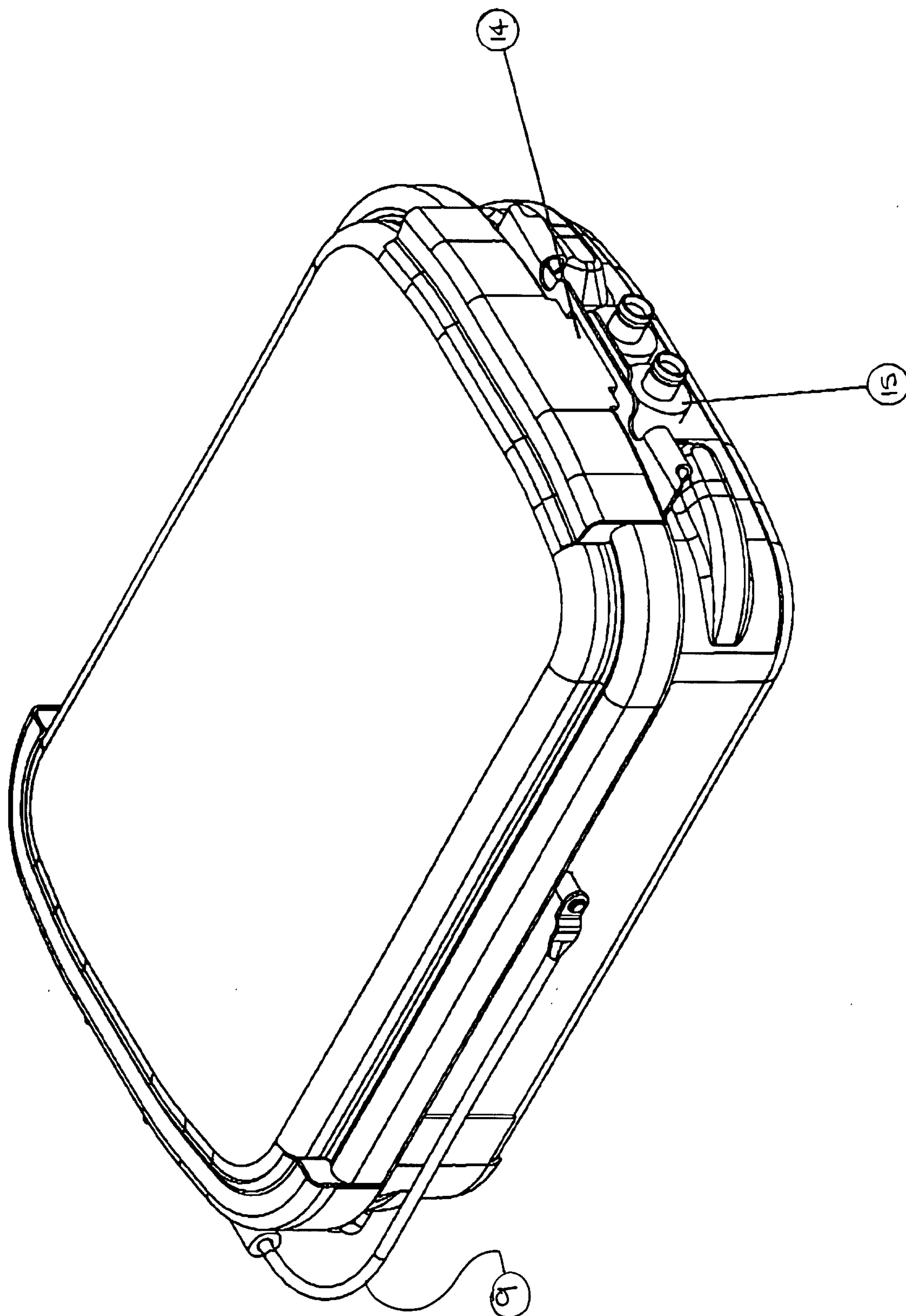


FIGURE 3

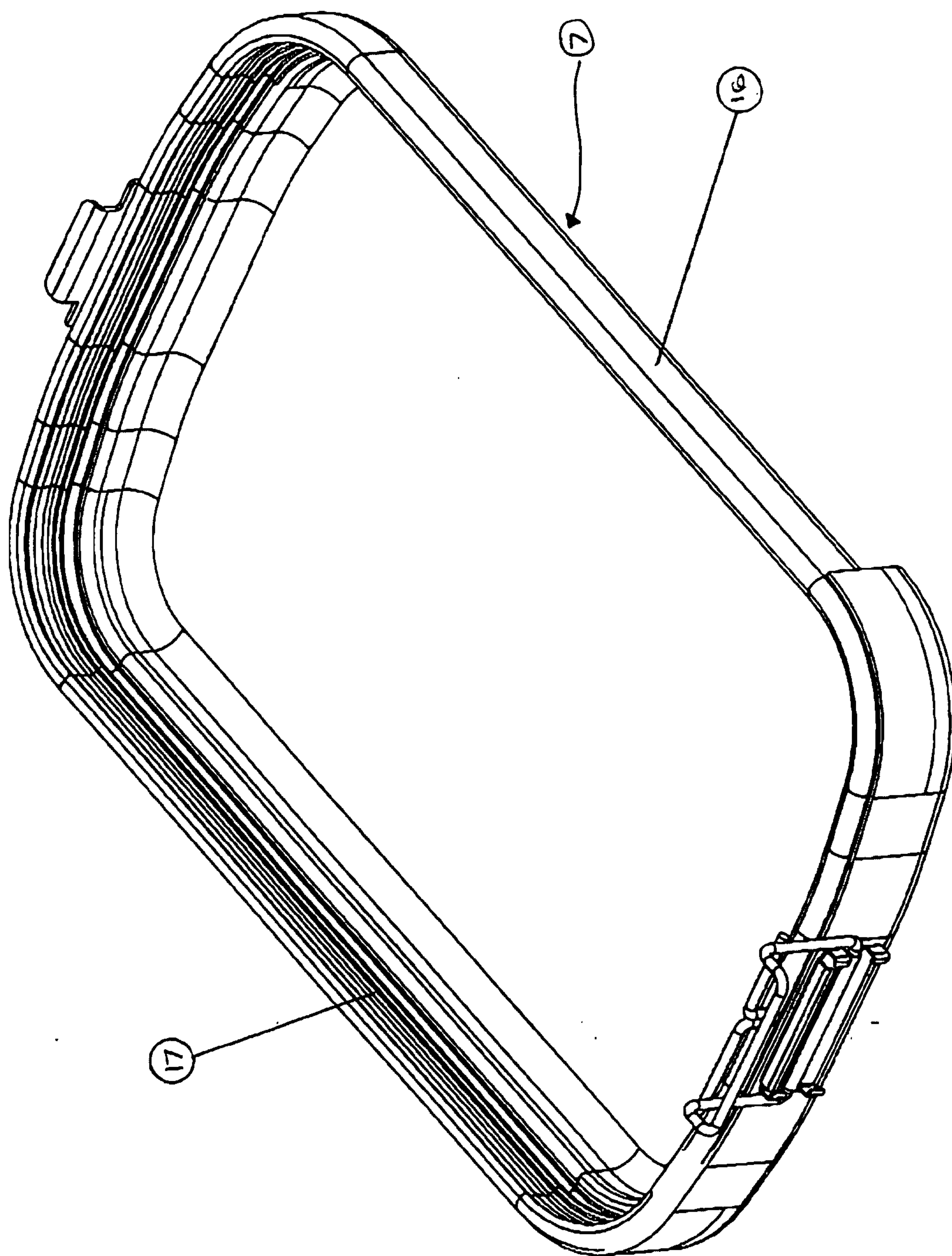
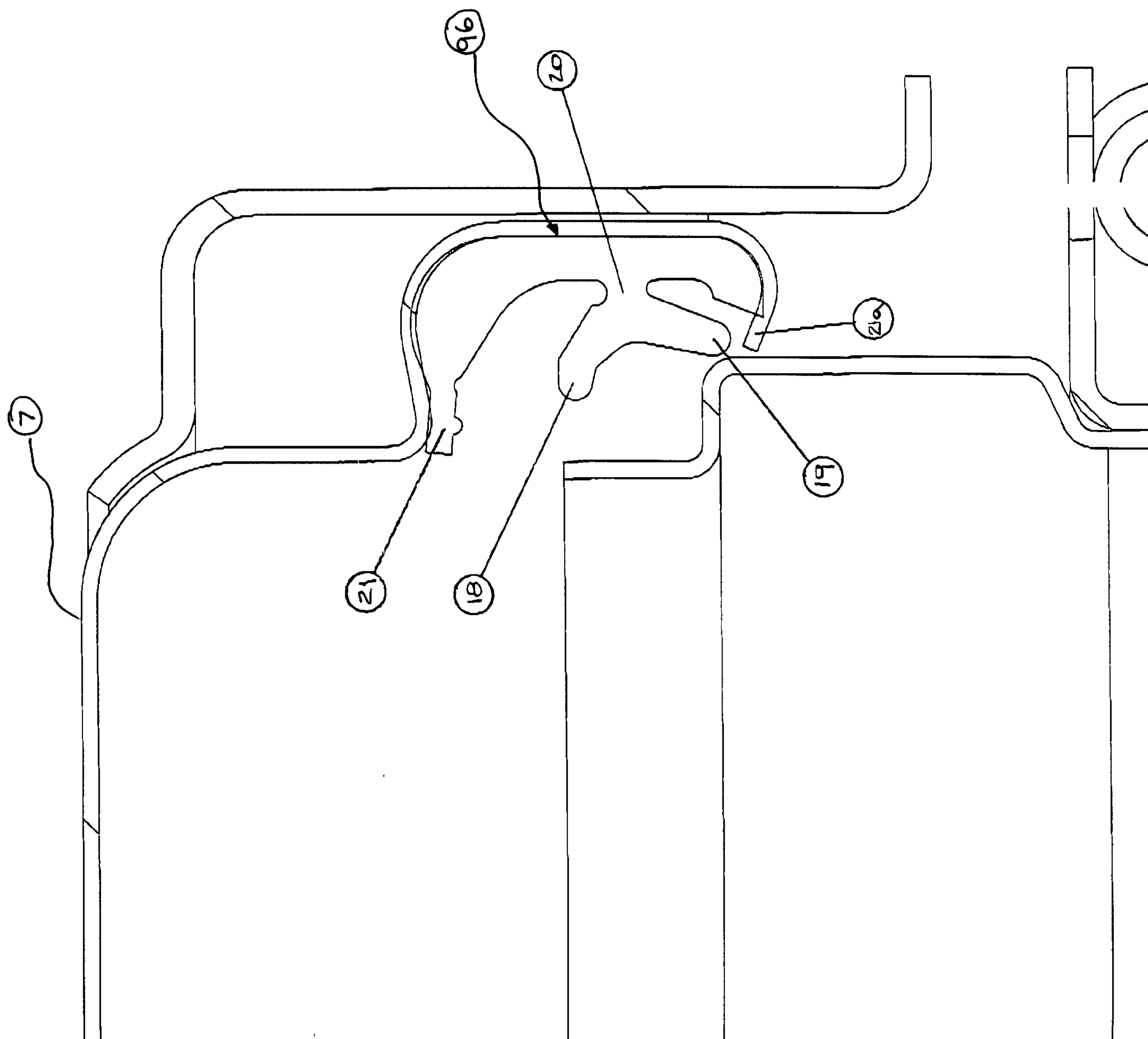


Figure 6

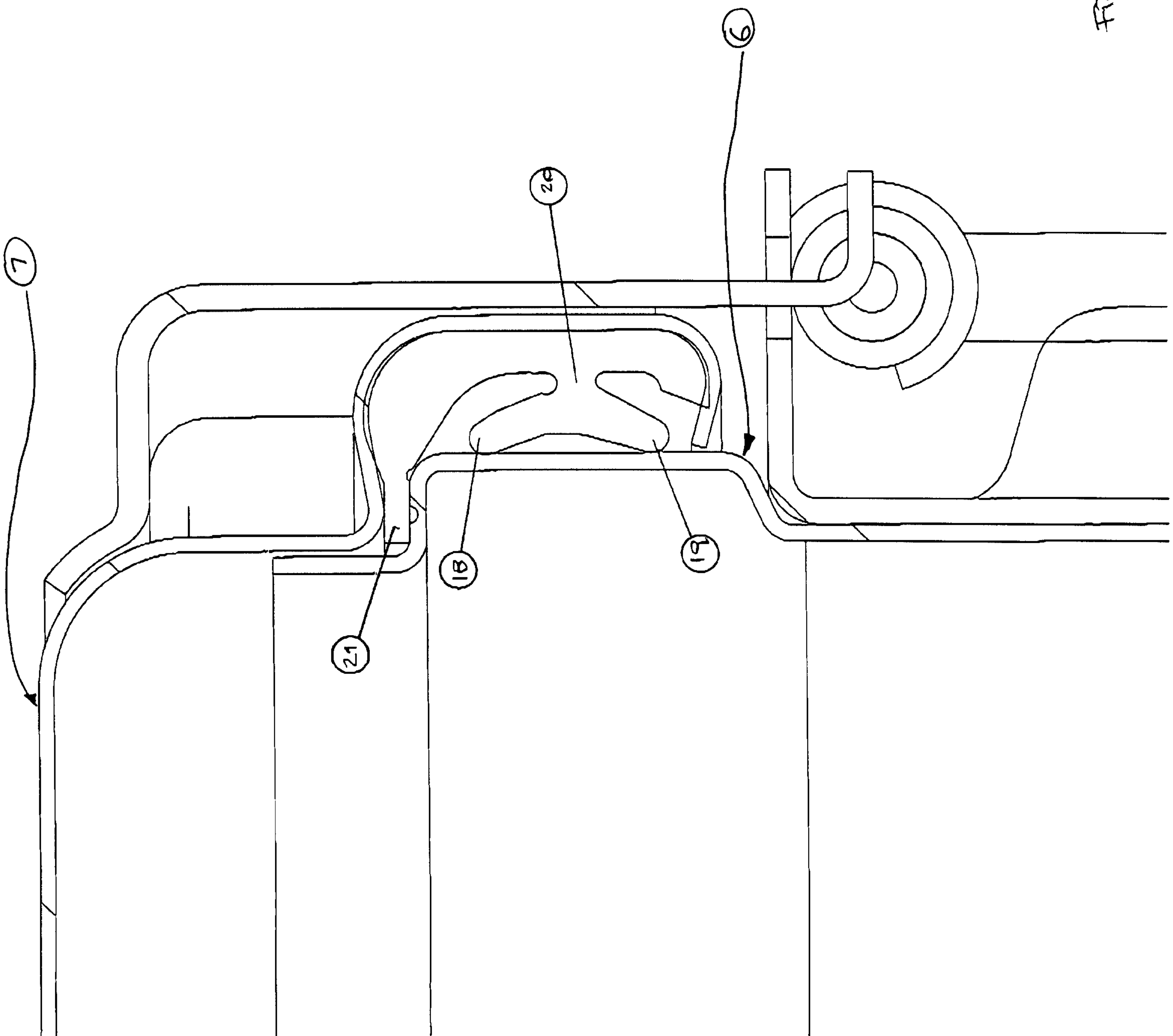
FIGURE 7



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Figure 7a



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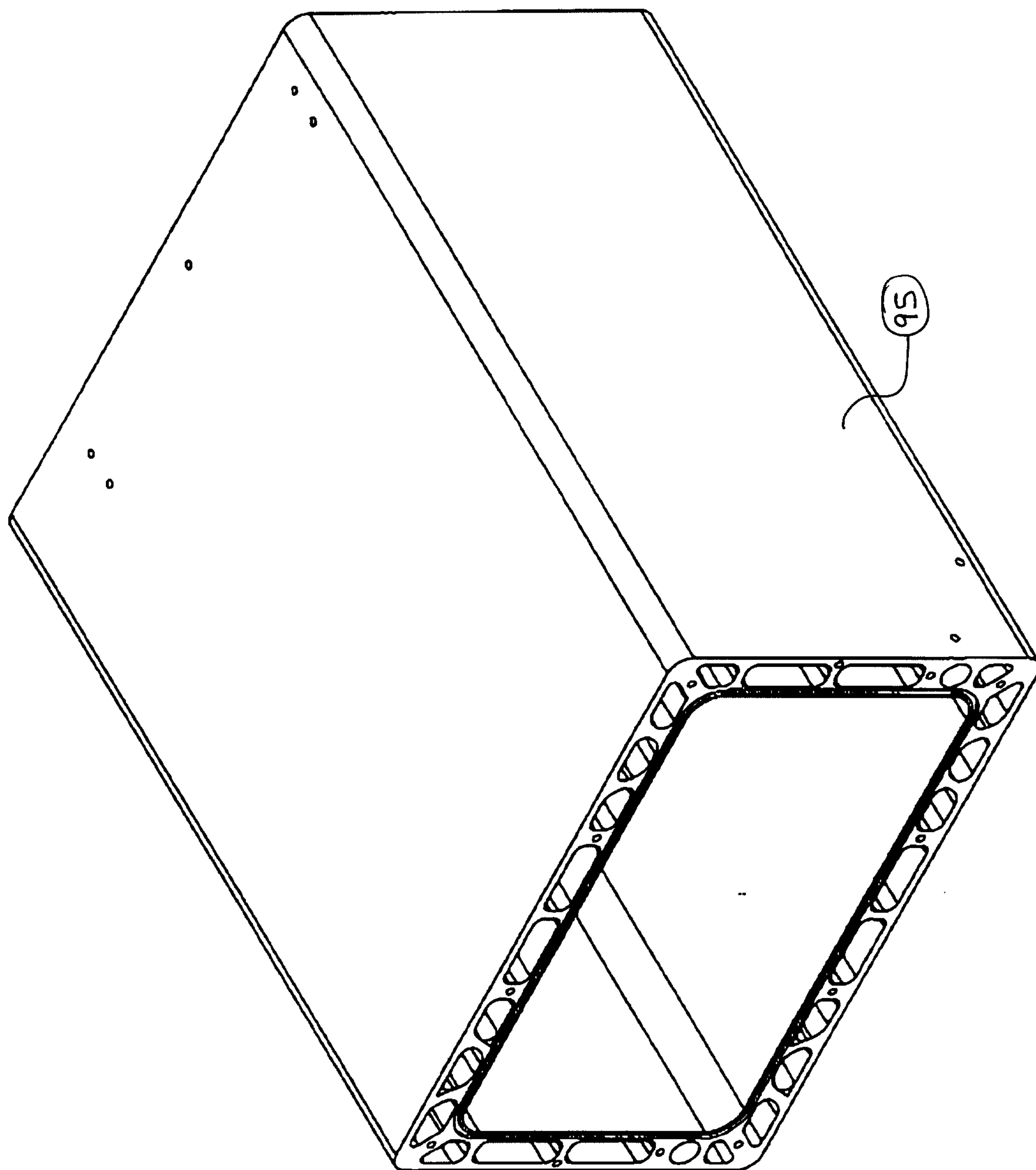


FIGURE B

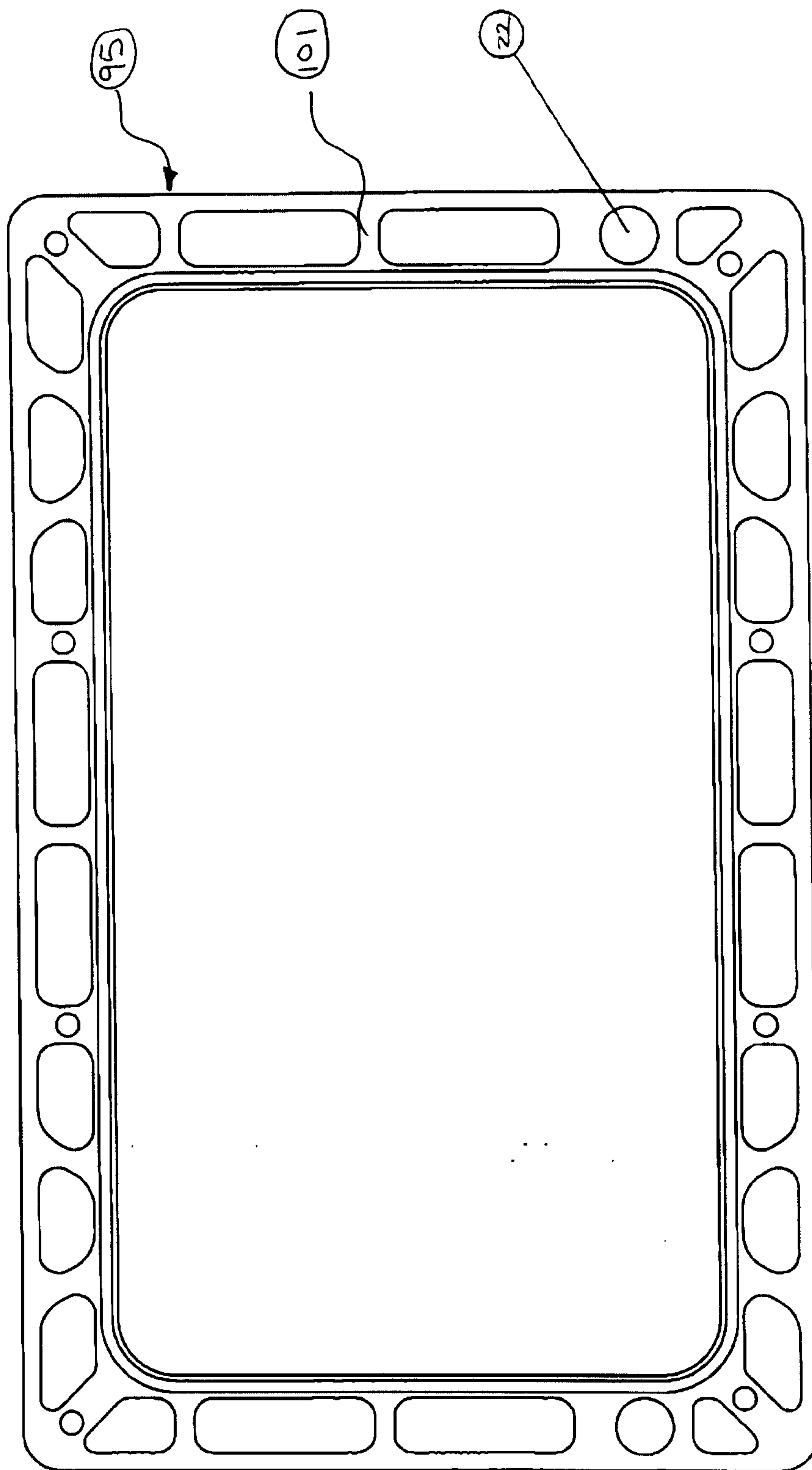


FIGURE 9

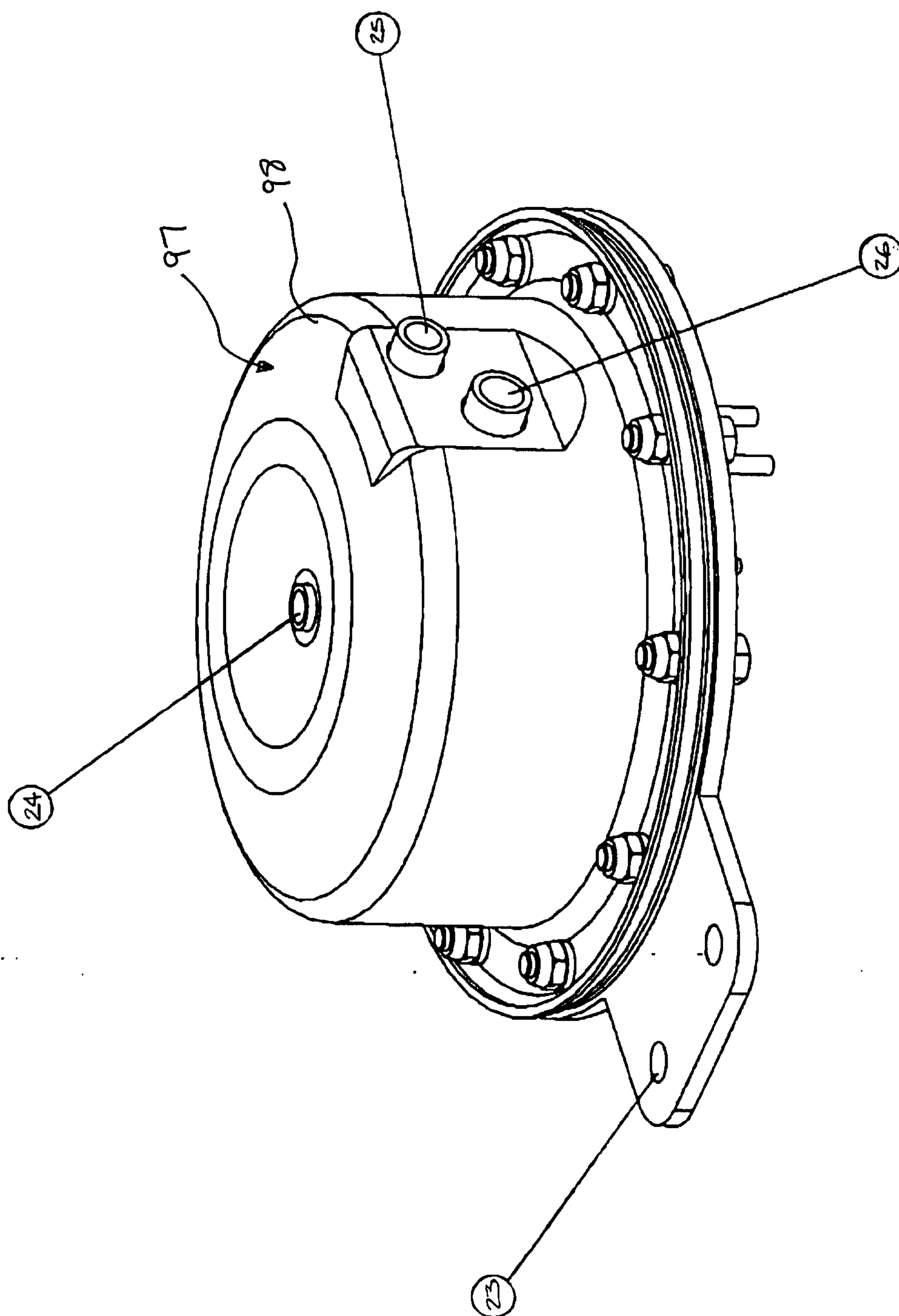


Figure 10

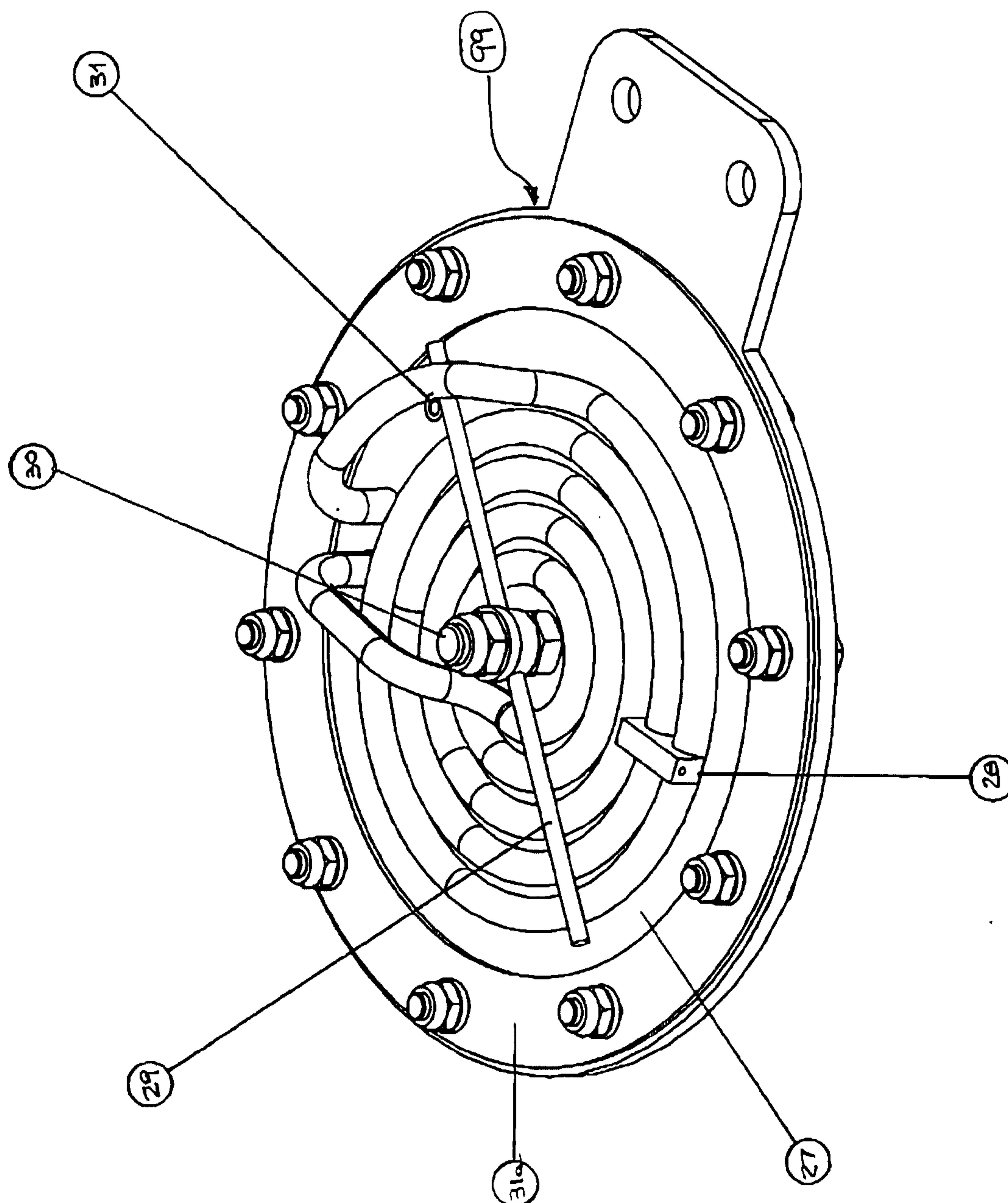


FIGURE 11

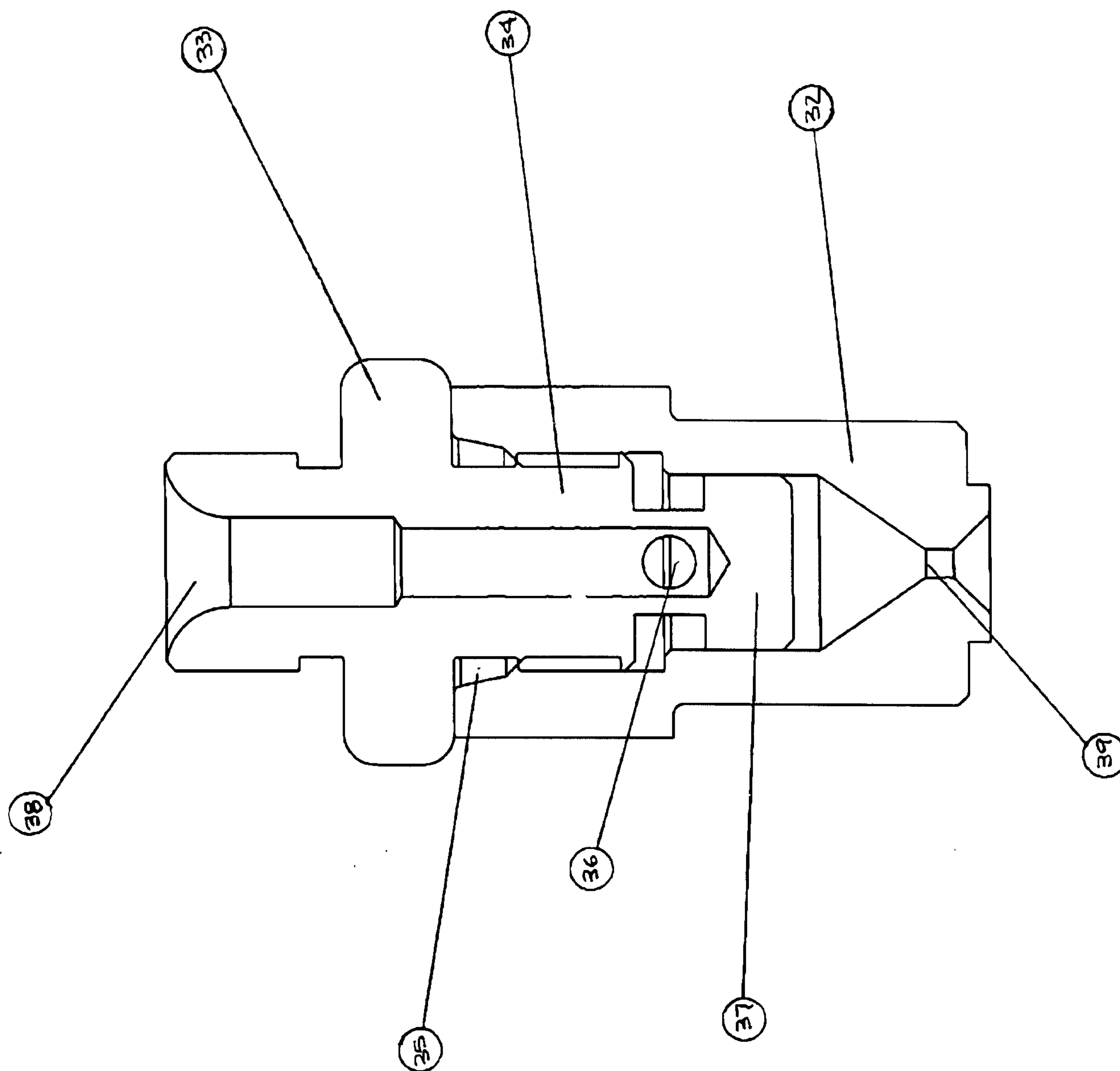


FIGURE 12

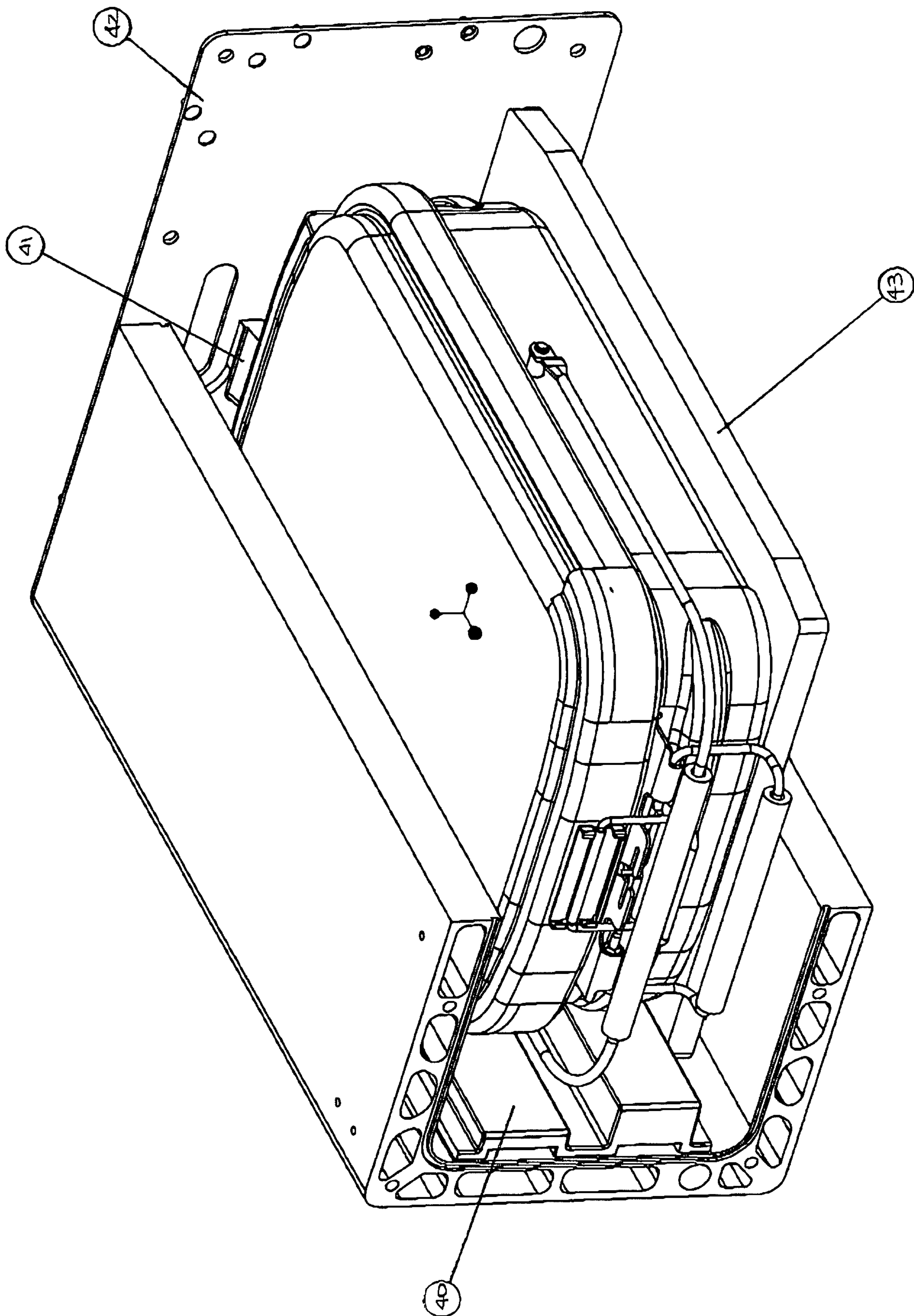
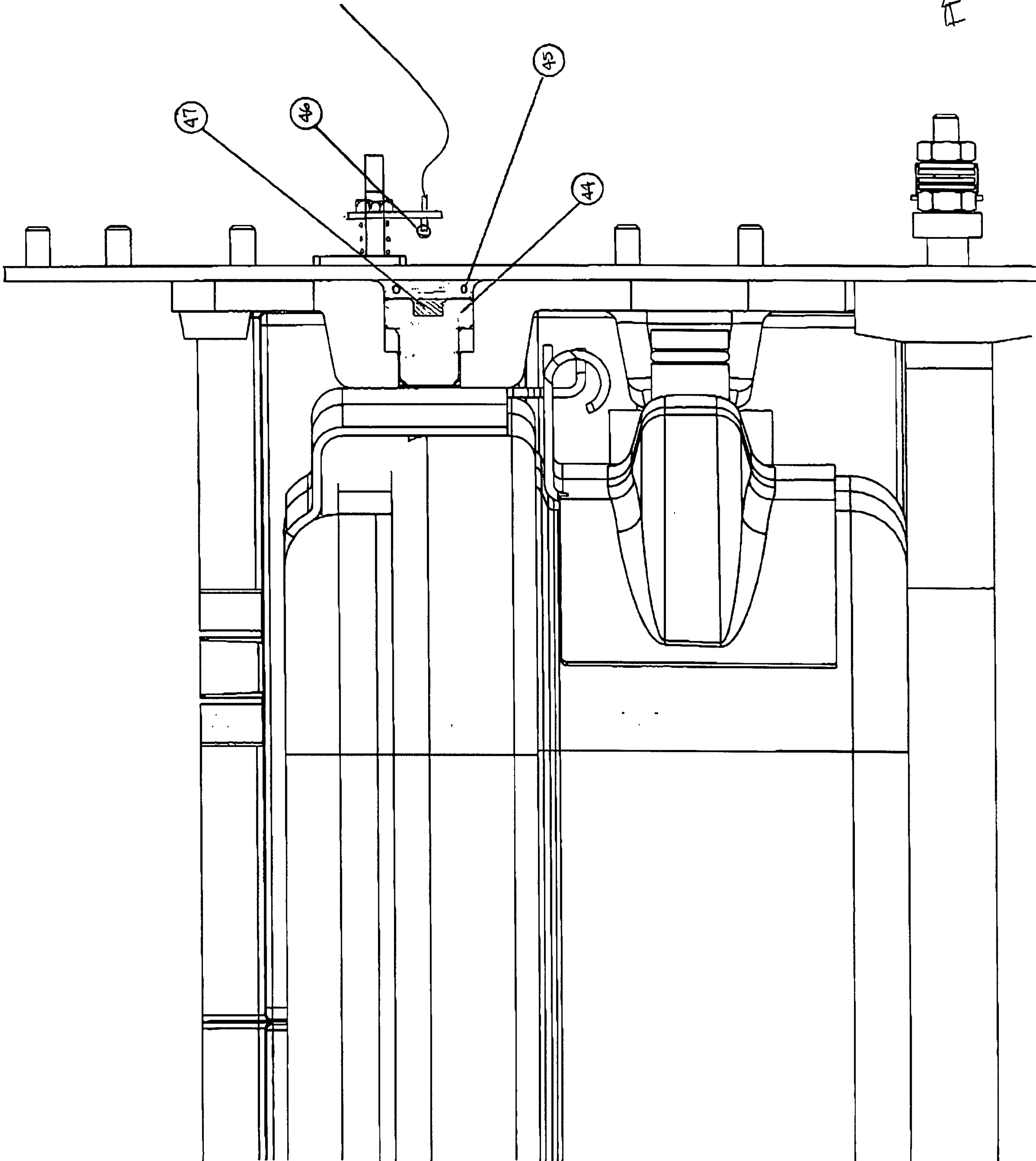
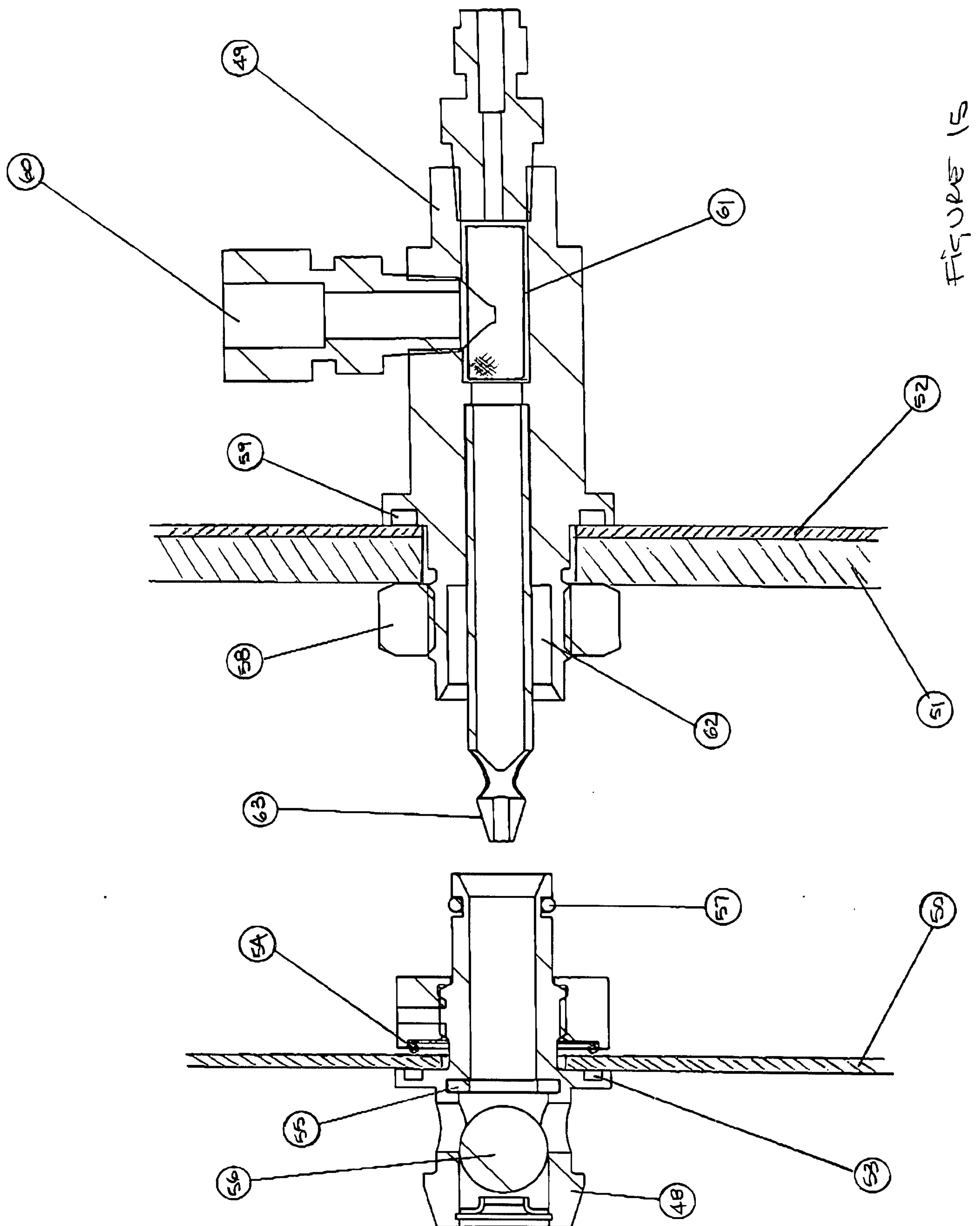


Figure 13

Figure 14





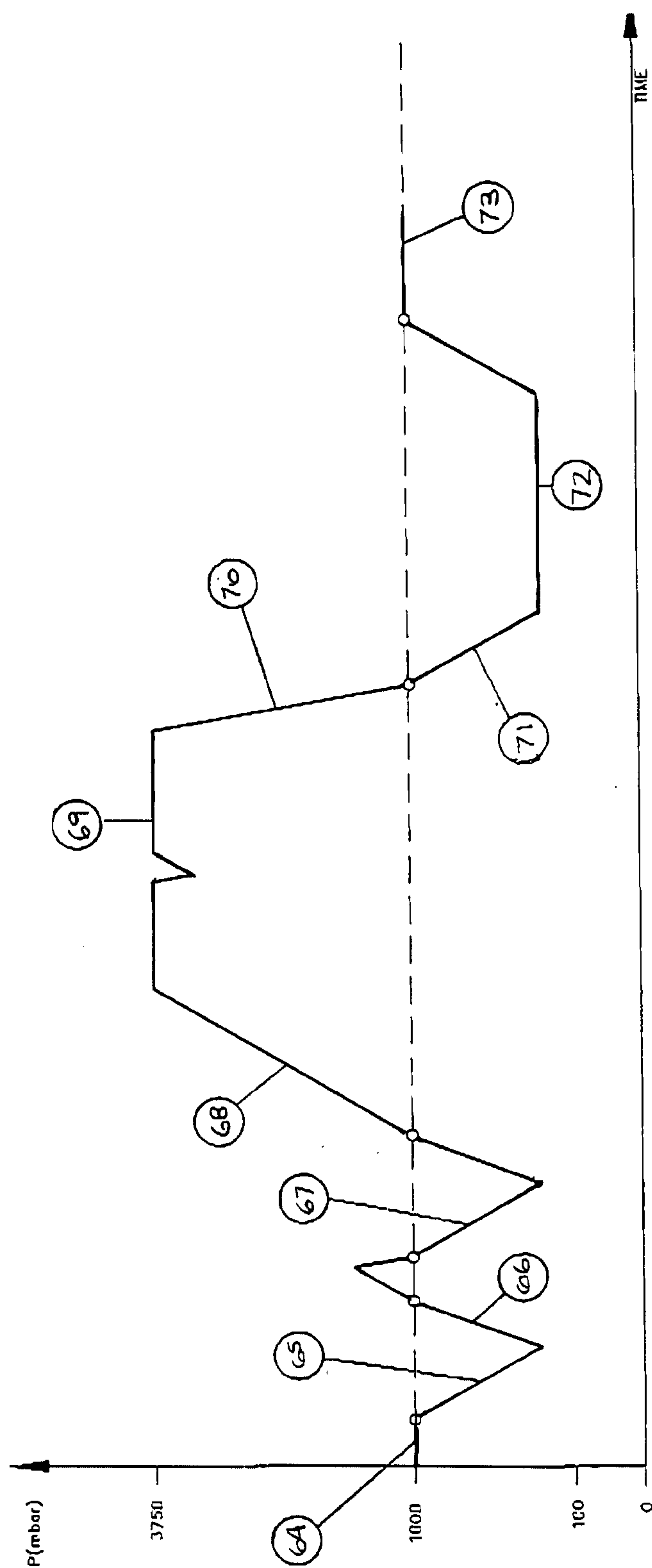


FIGURE 16

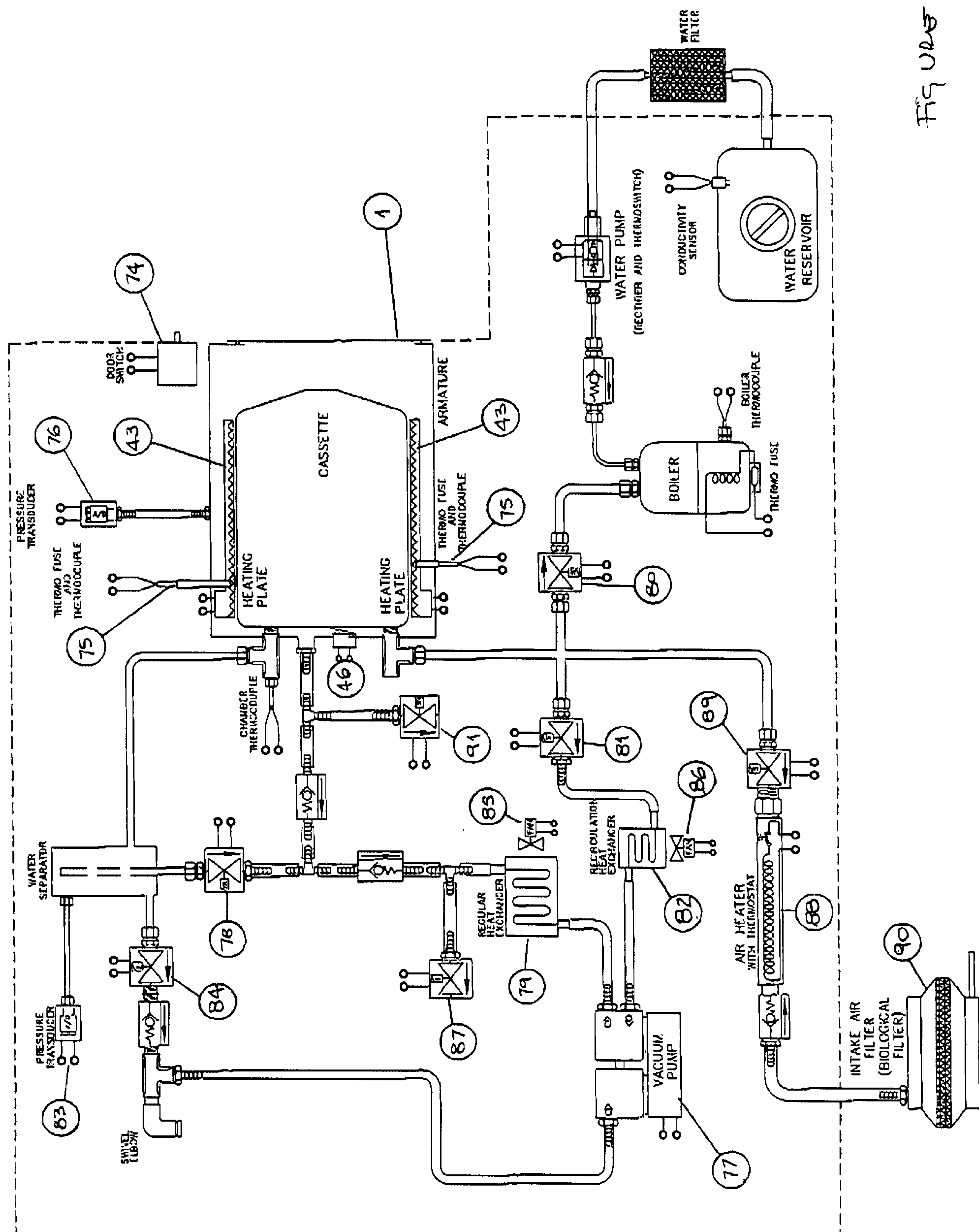


Fig 17

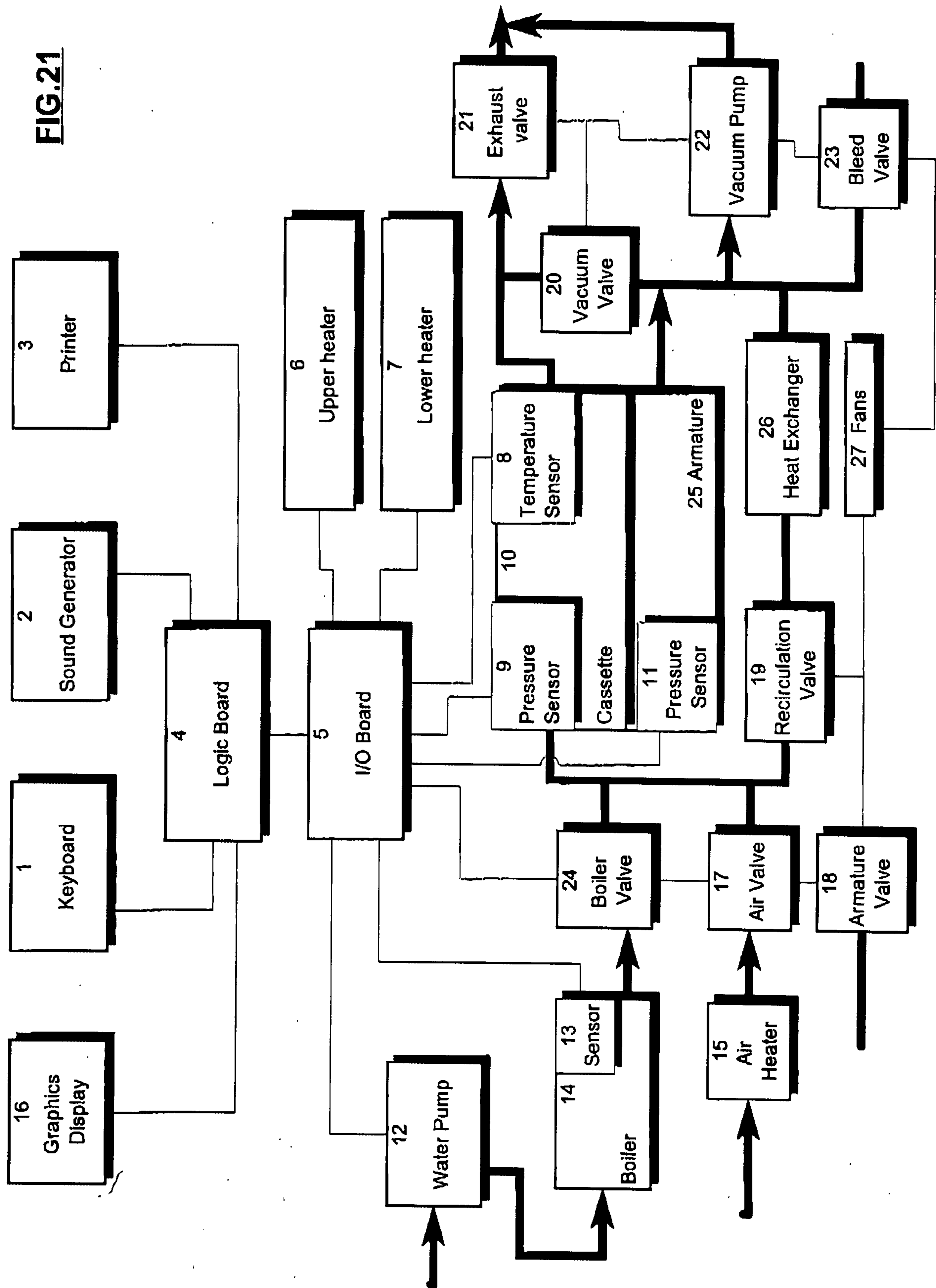
FIG.21

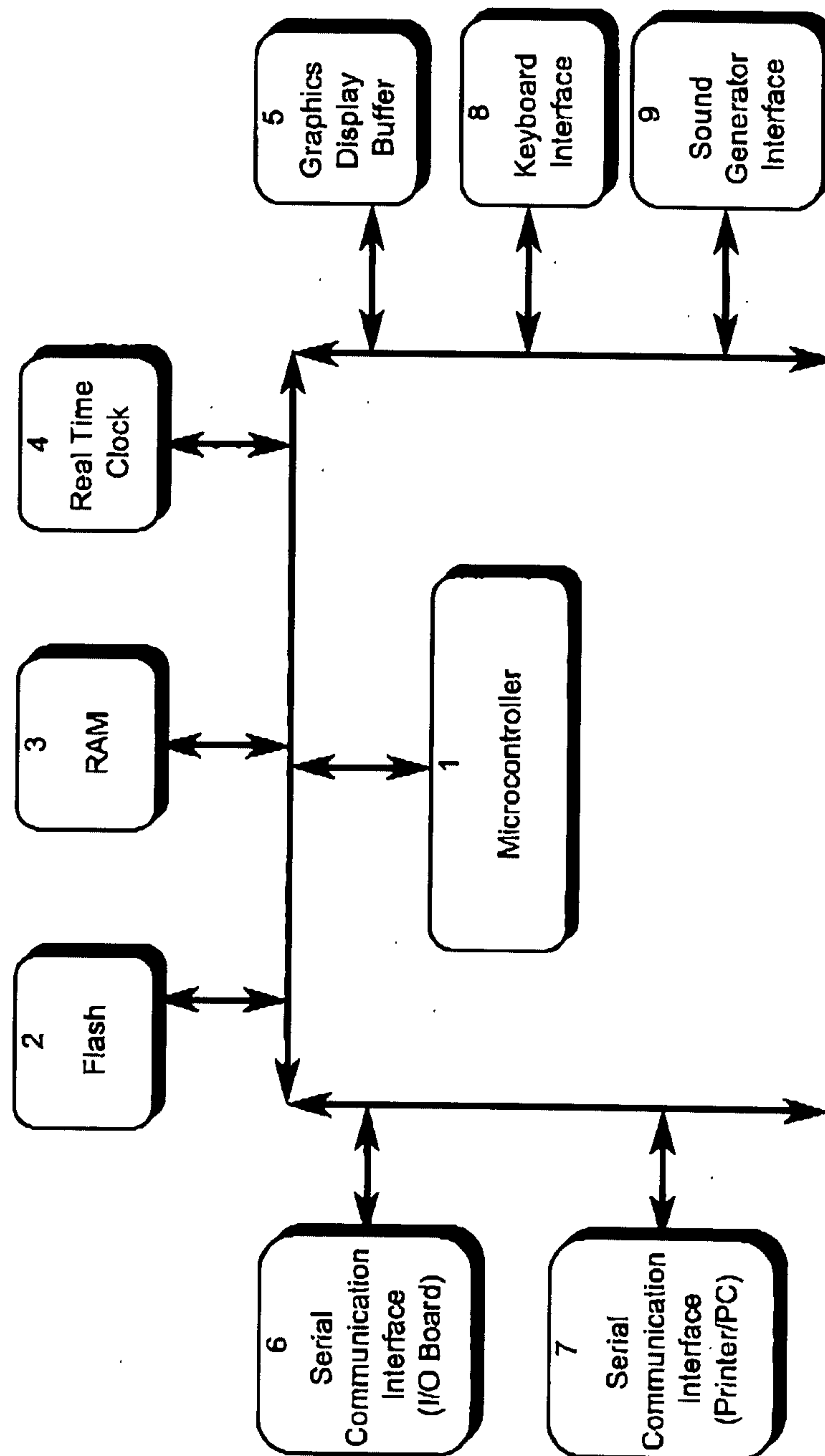
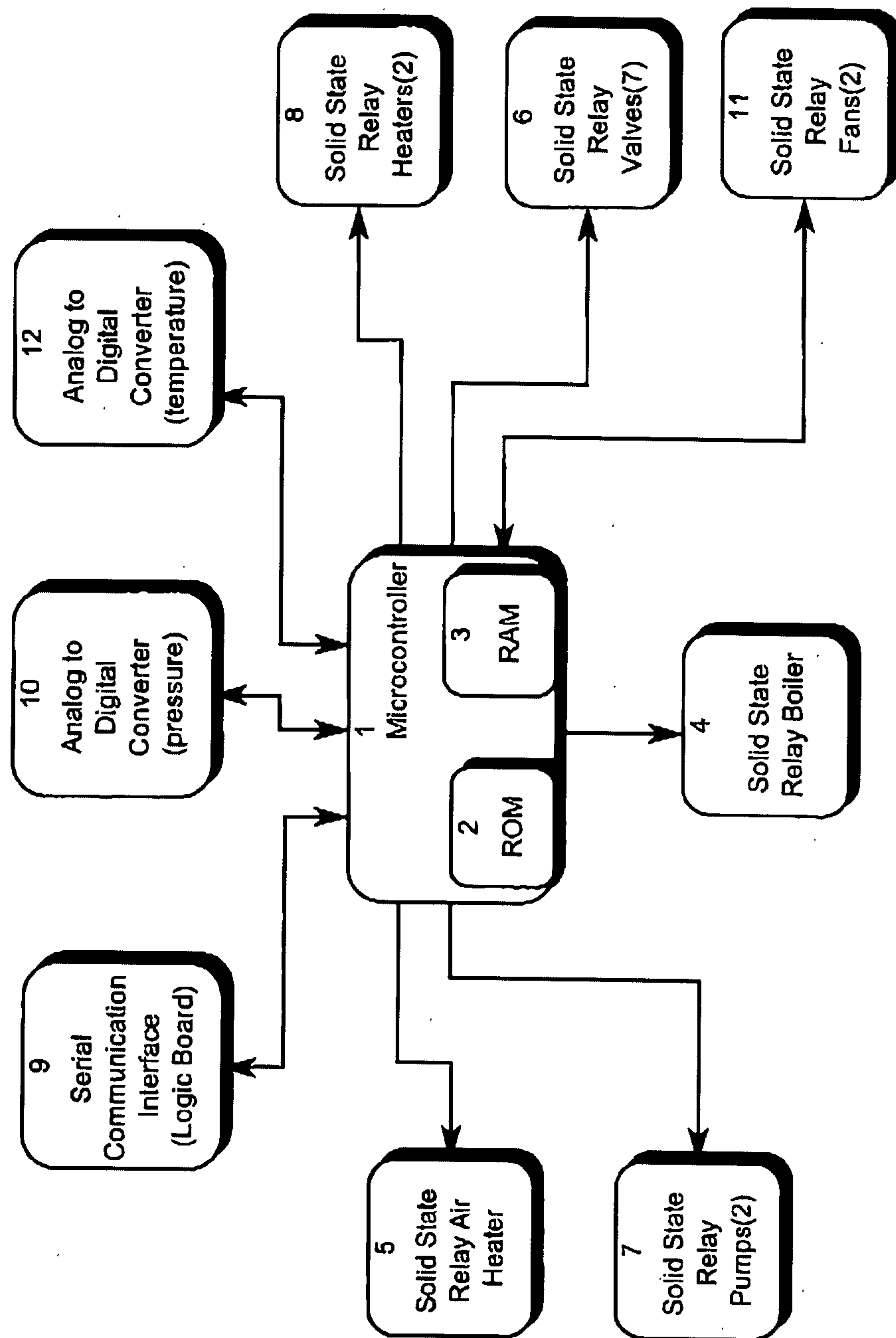
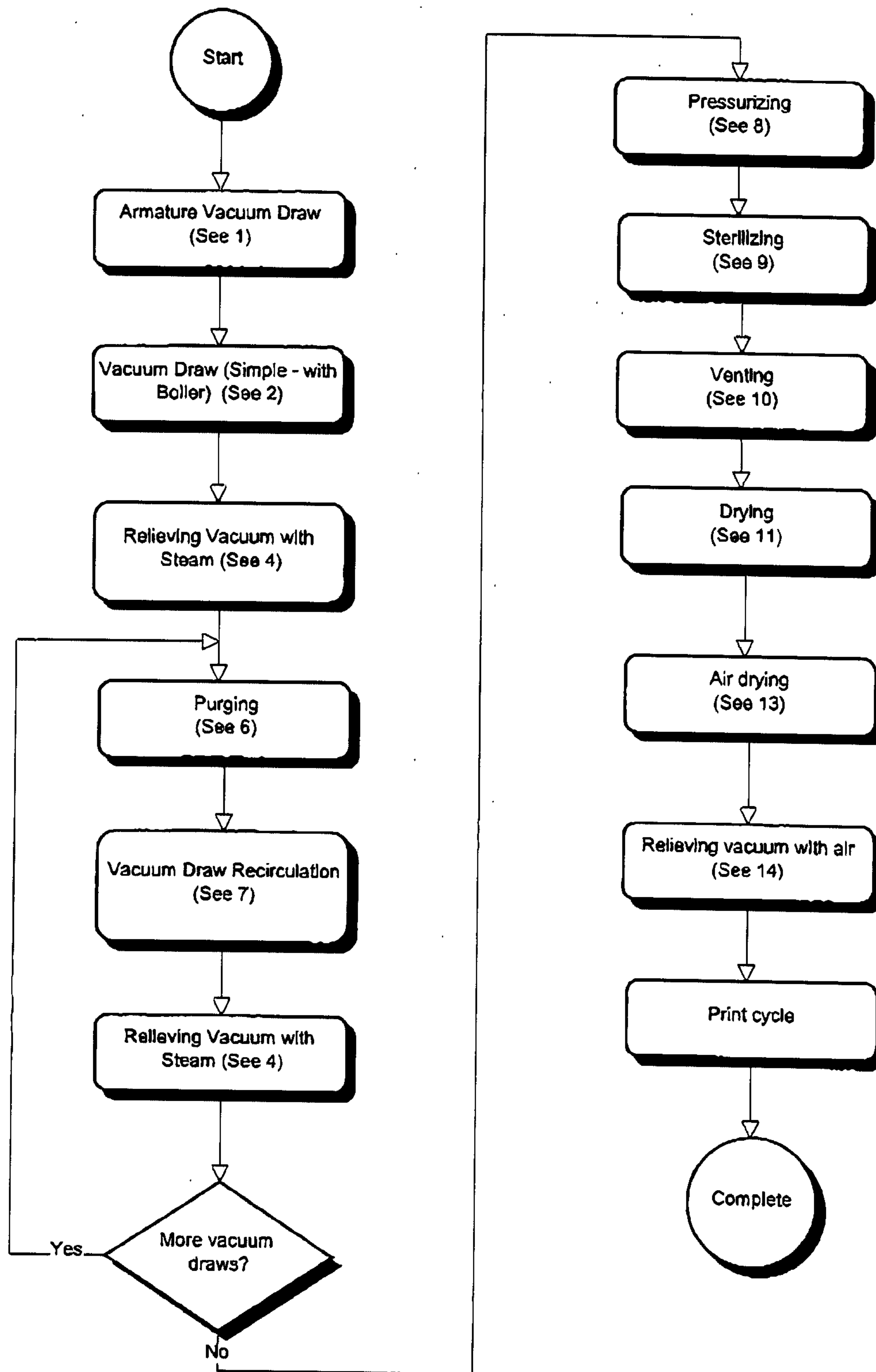
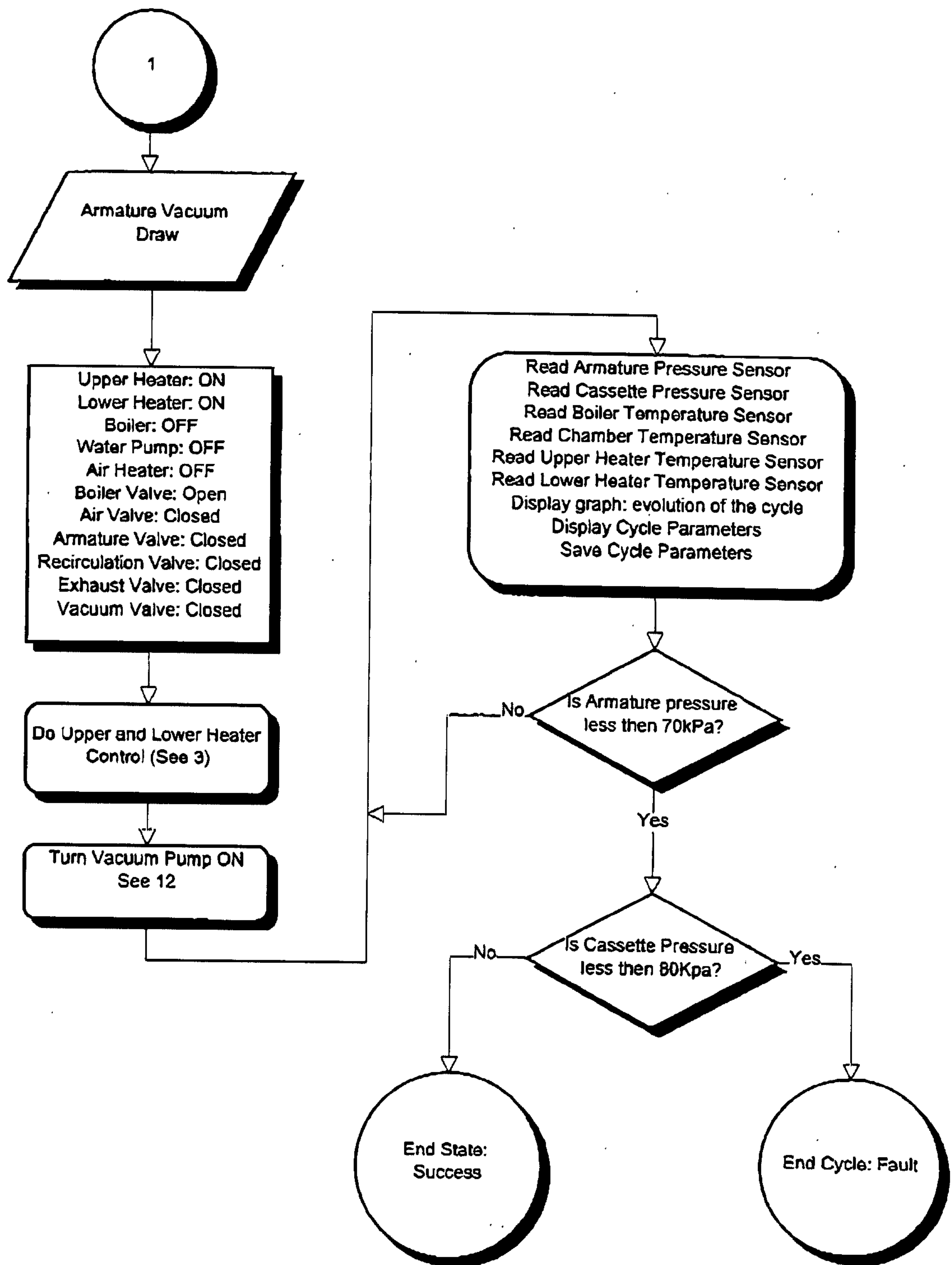
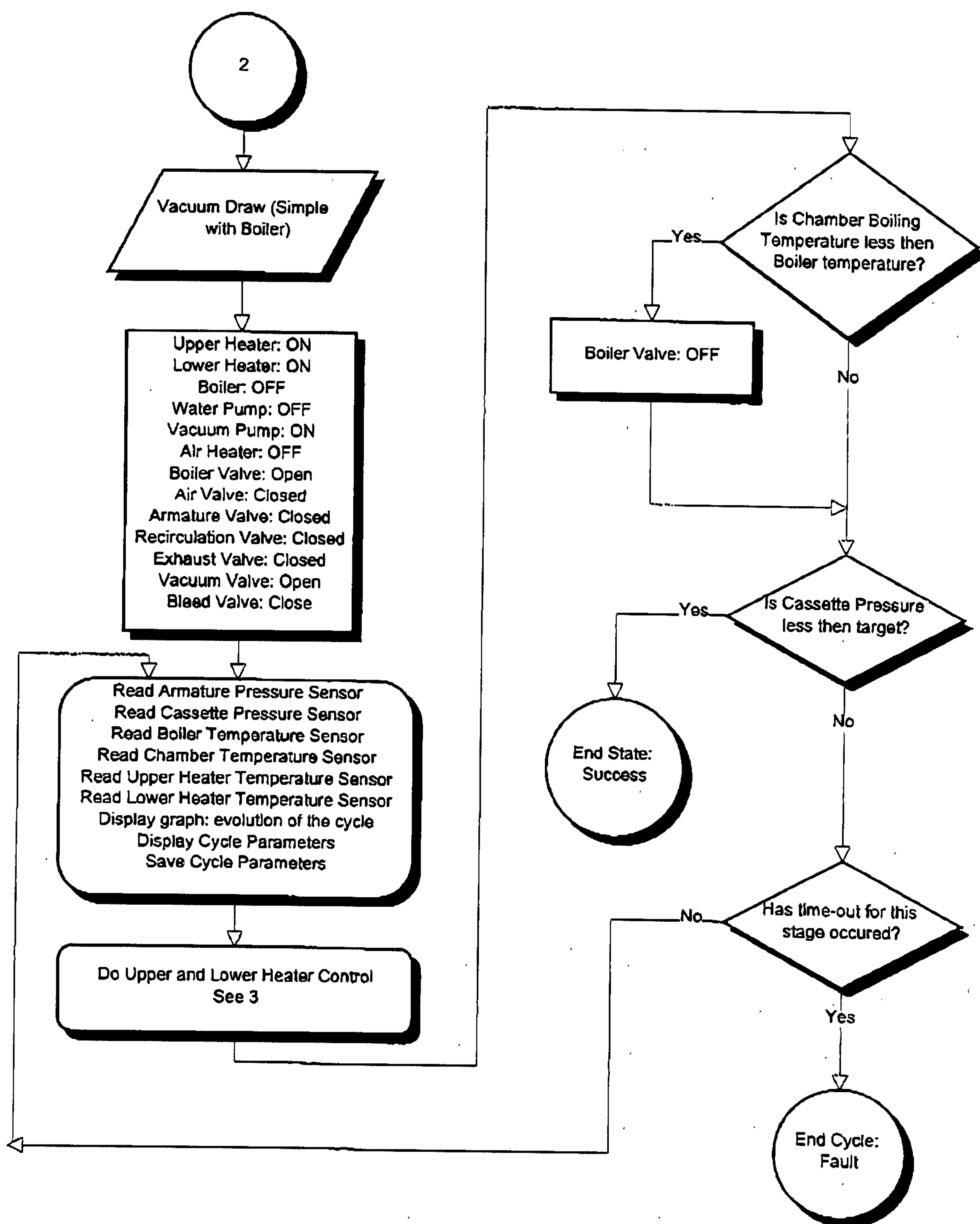
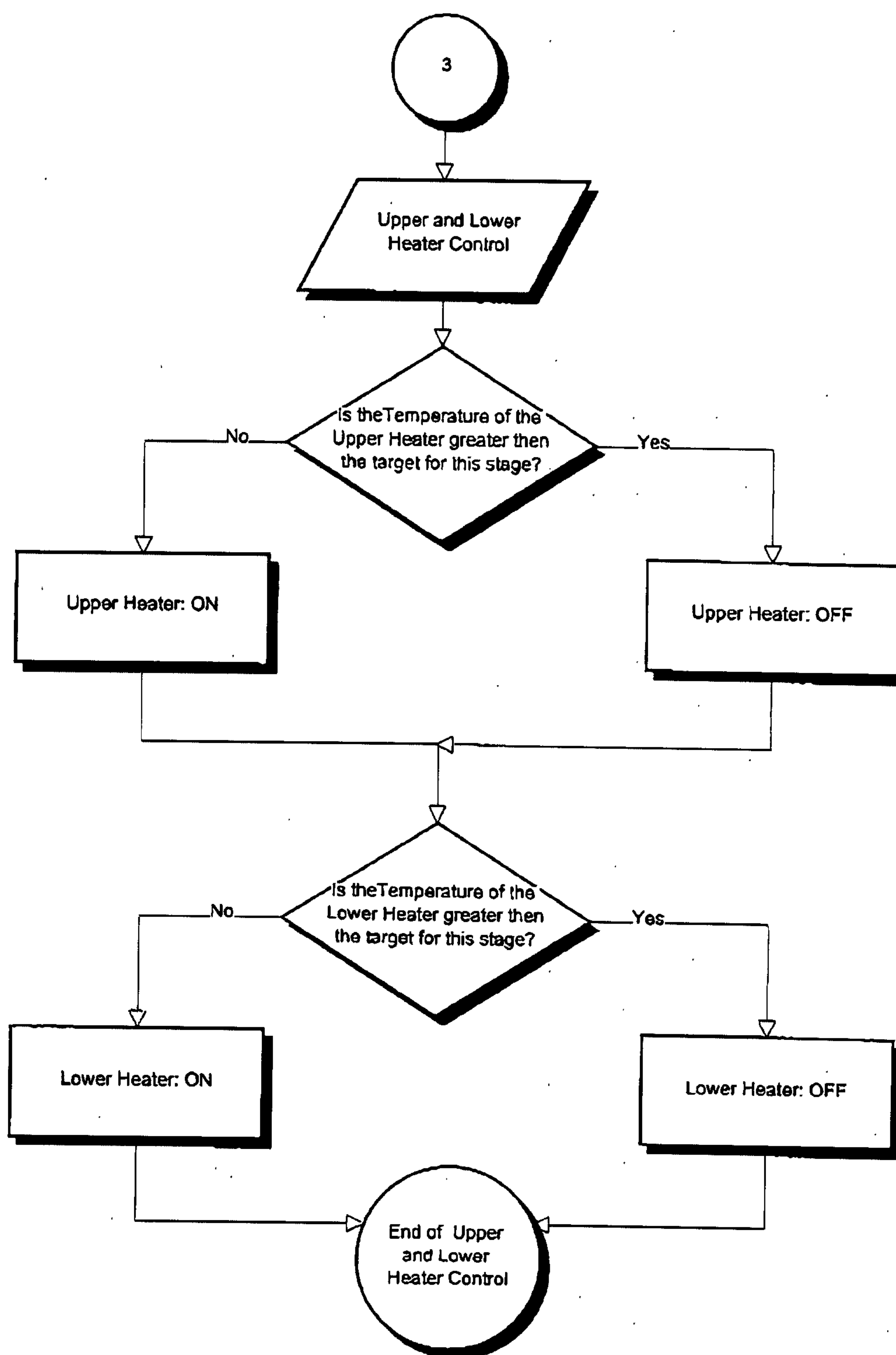
FIG.22 - Logic Board

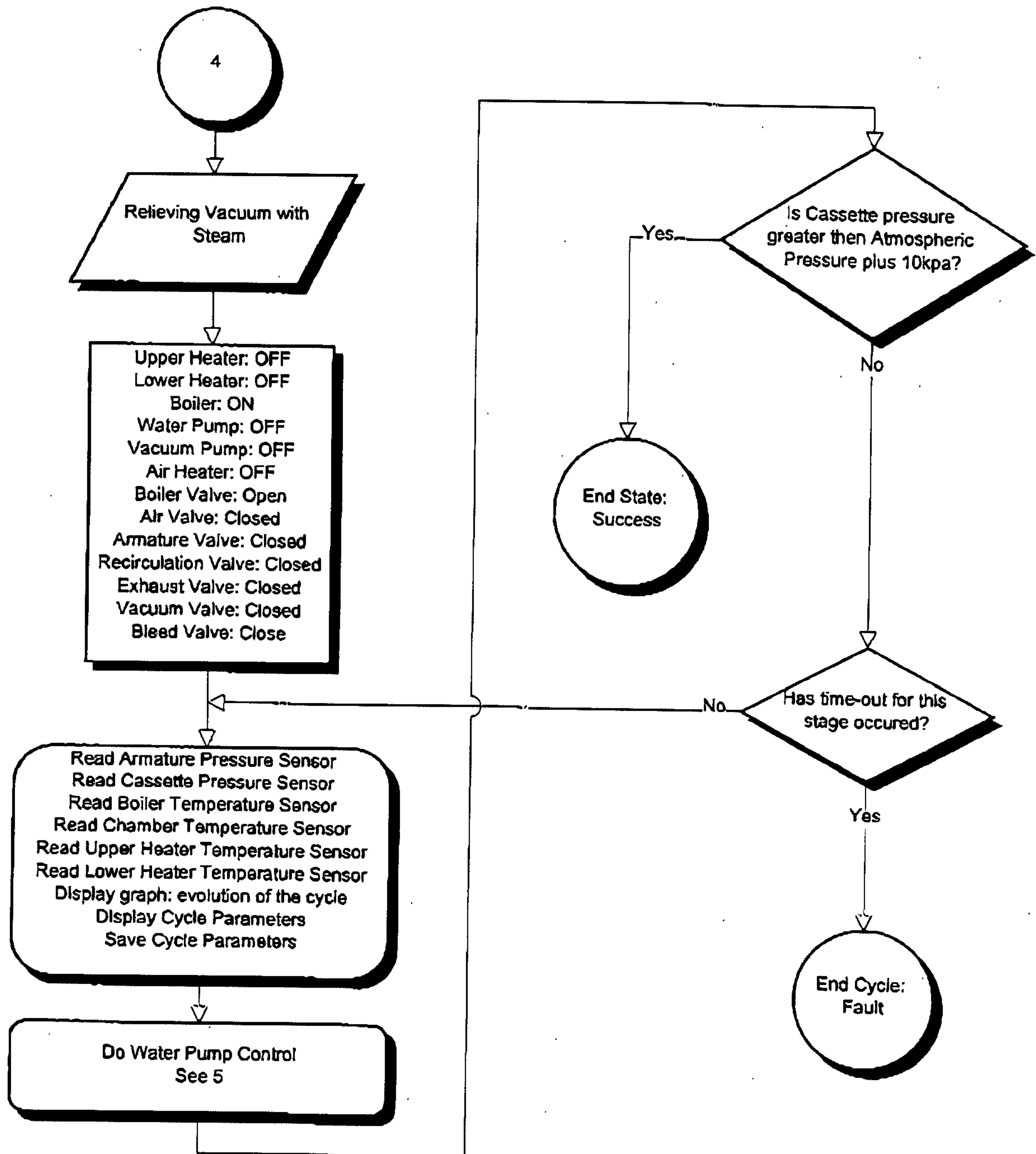
FIG.23 - Input/Output Board

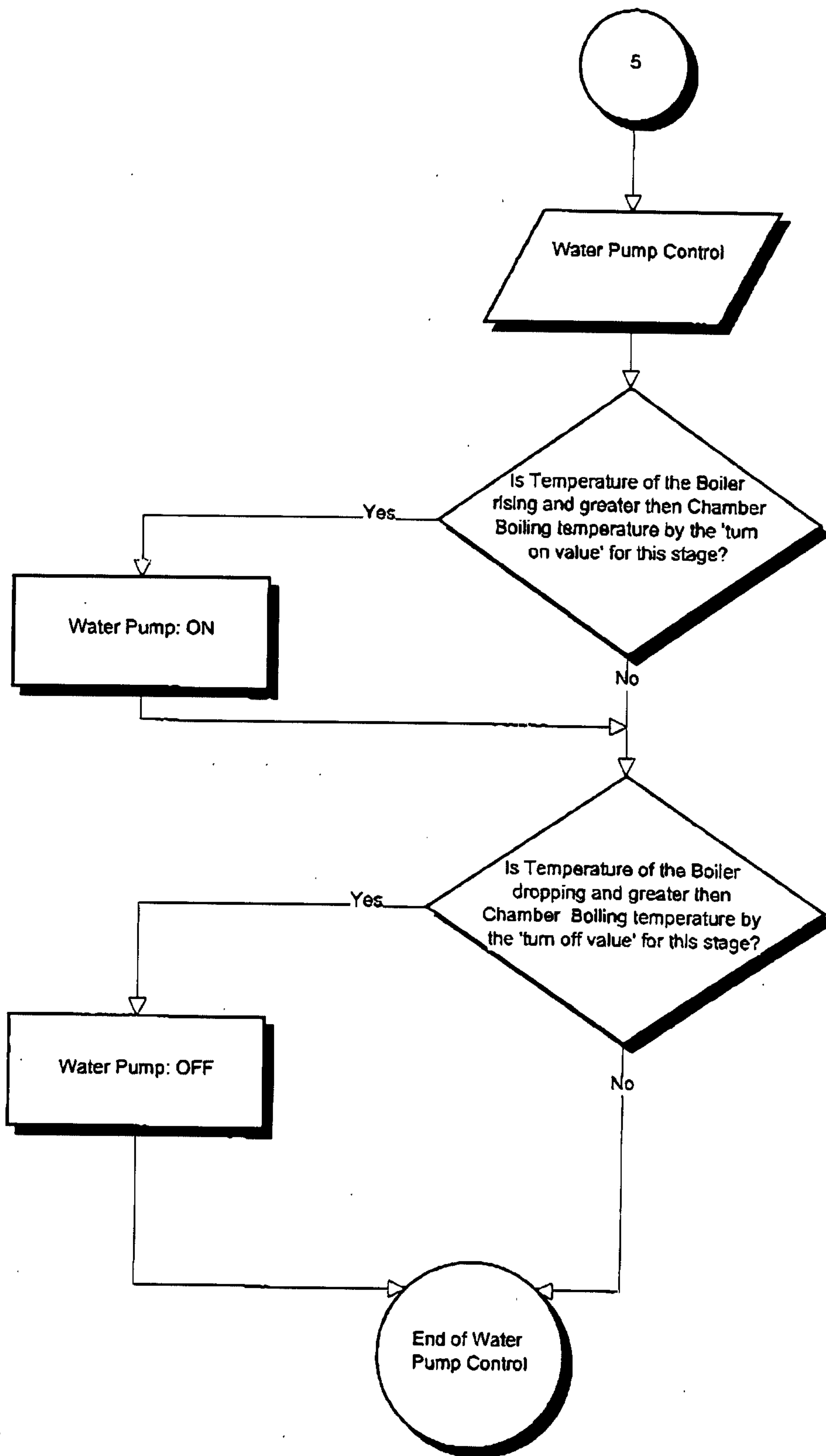


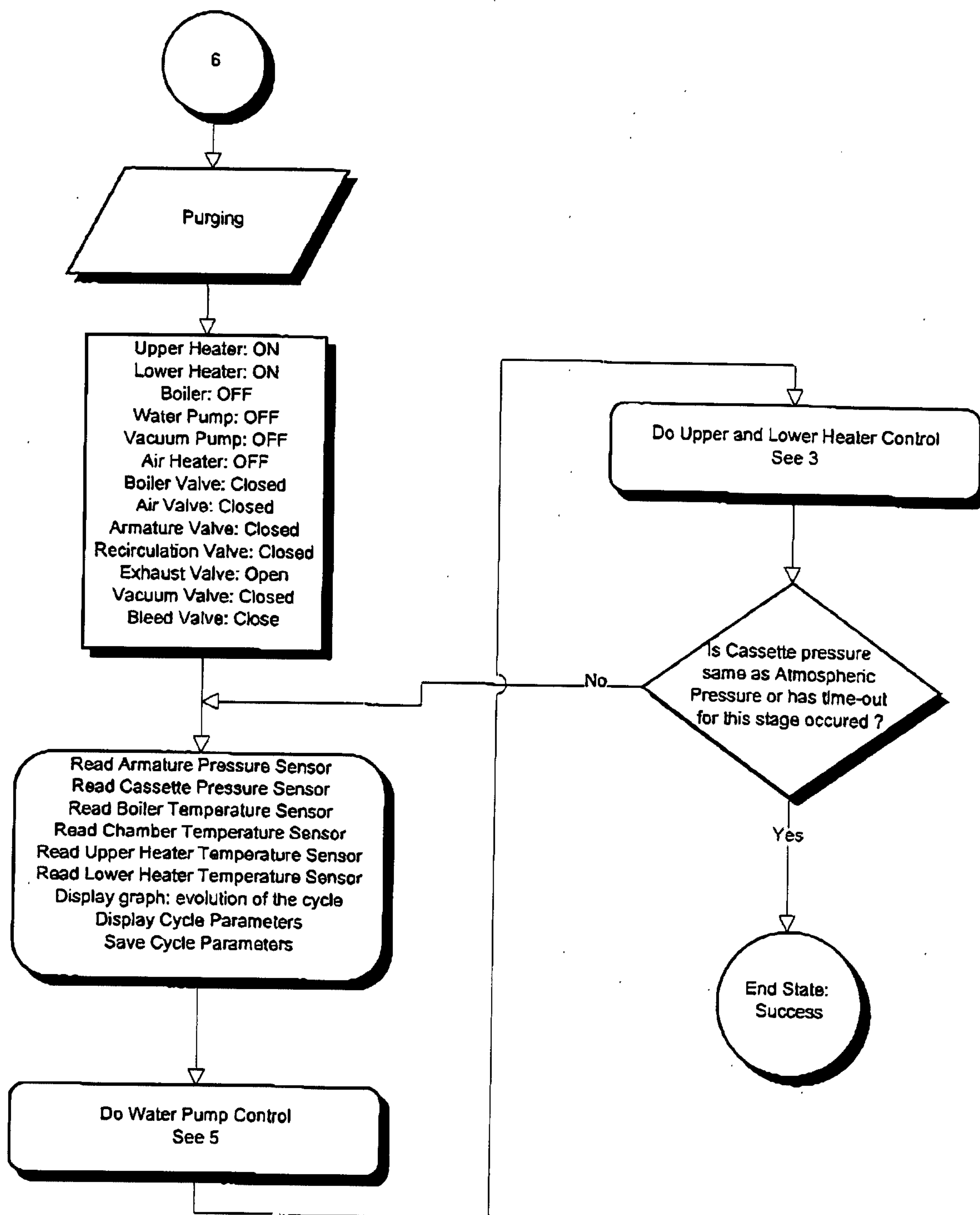


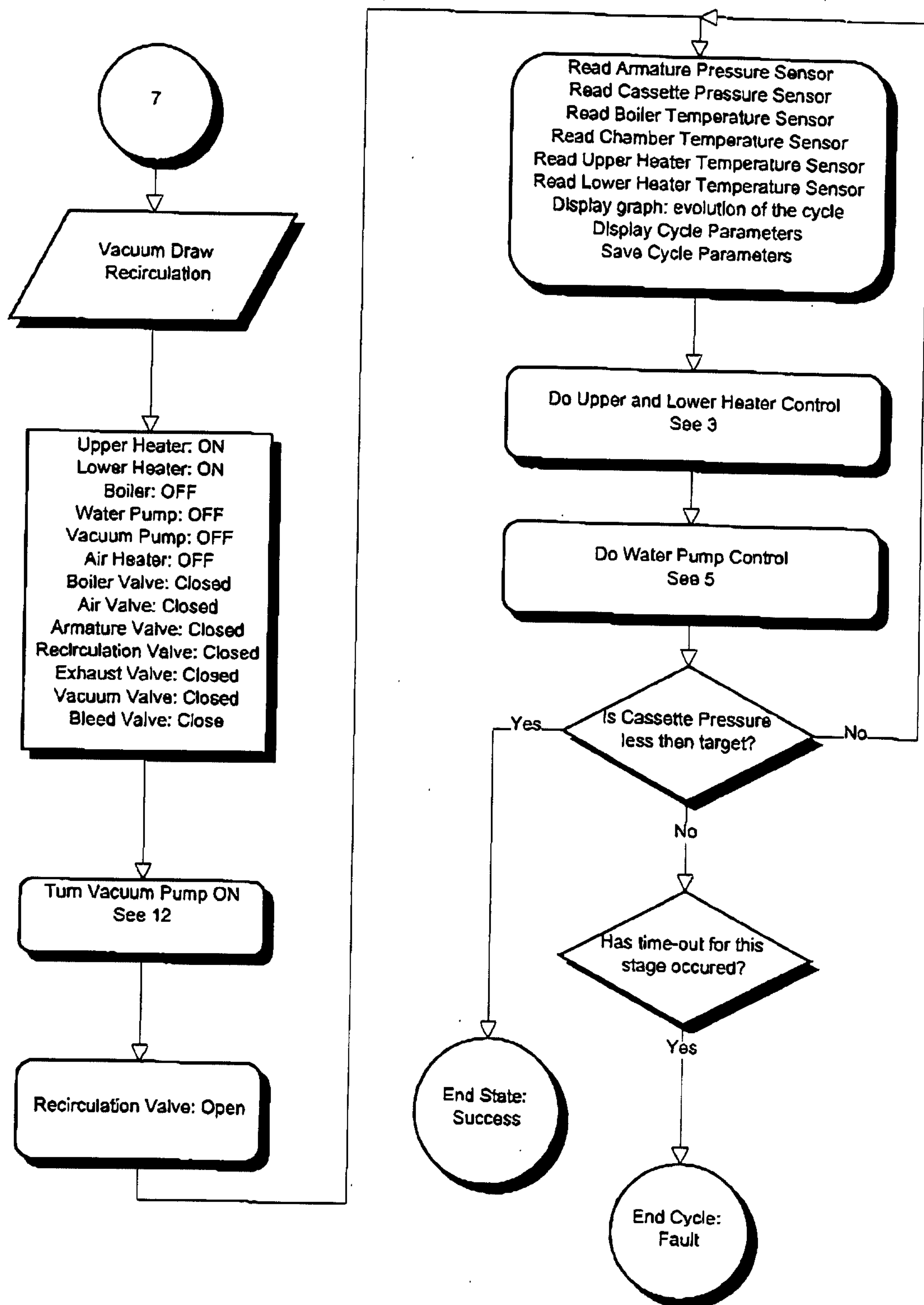


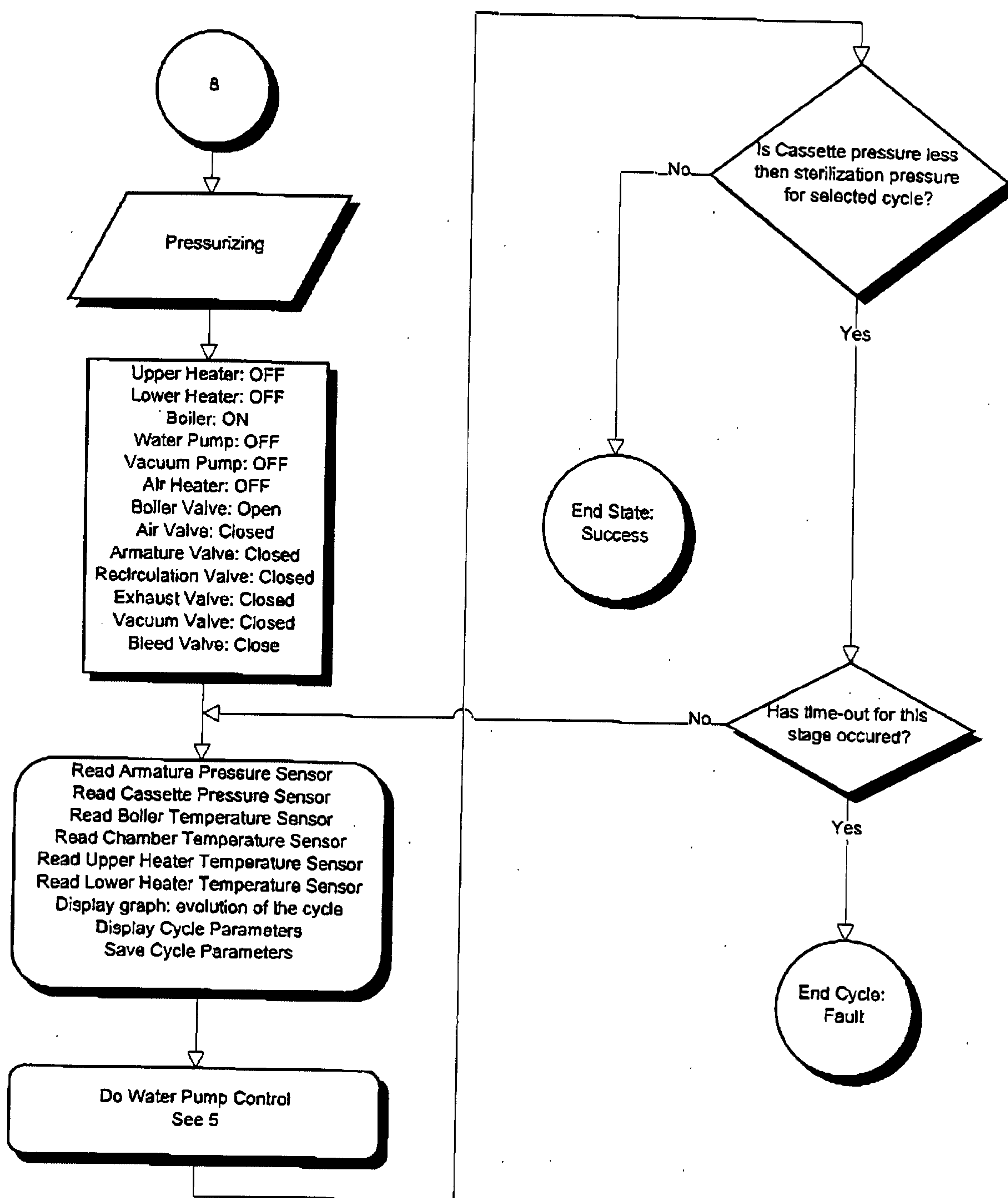


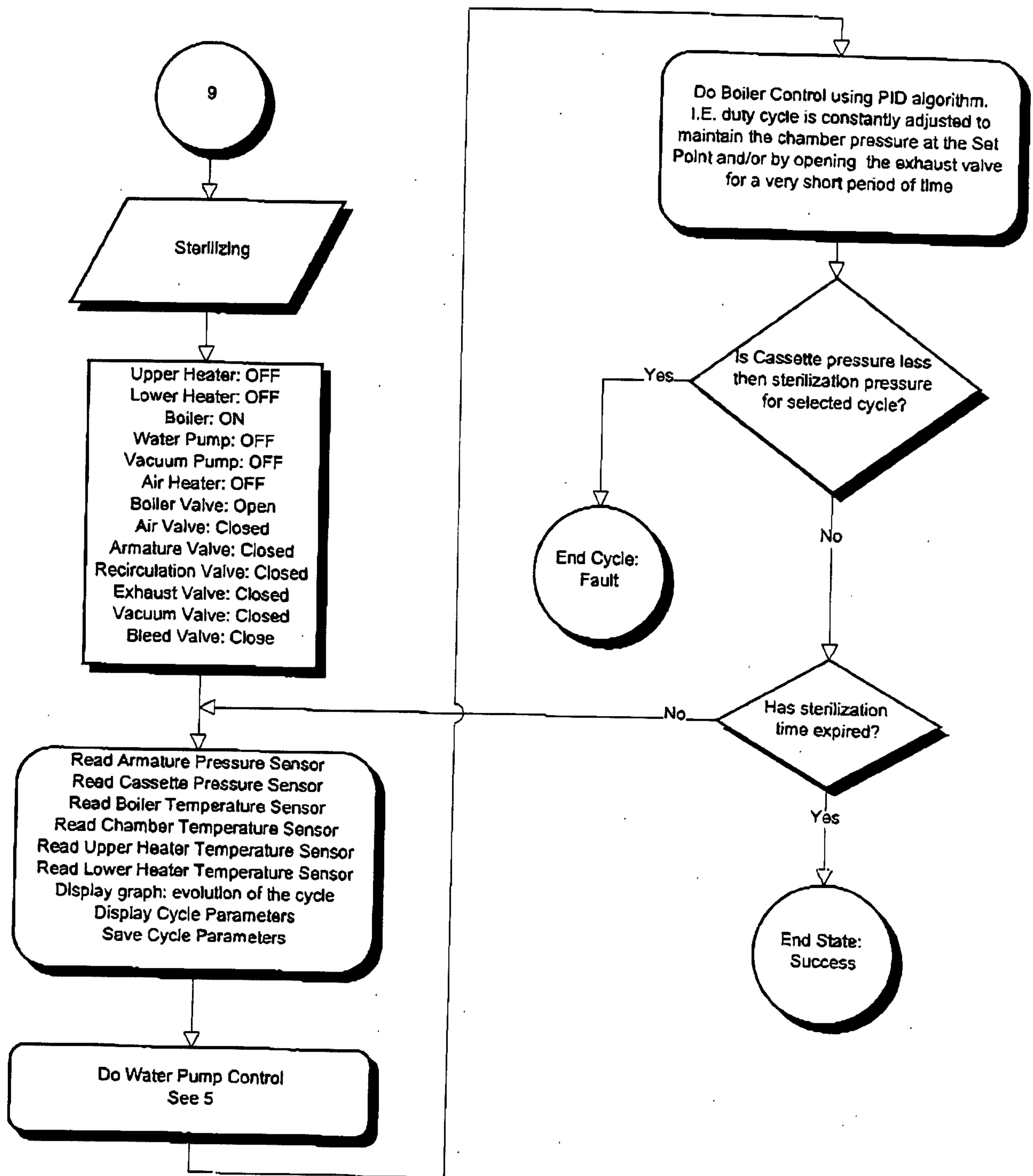


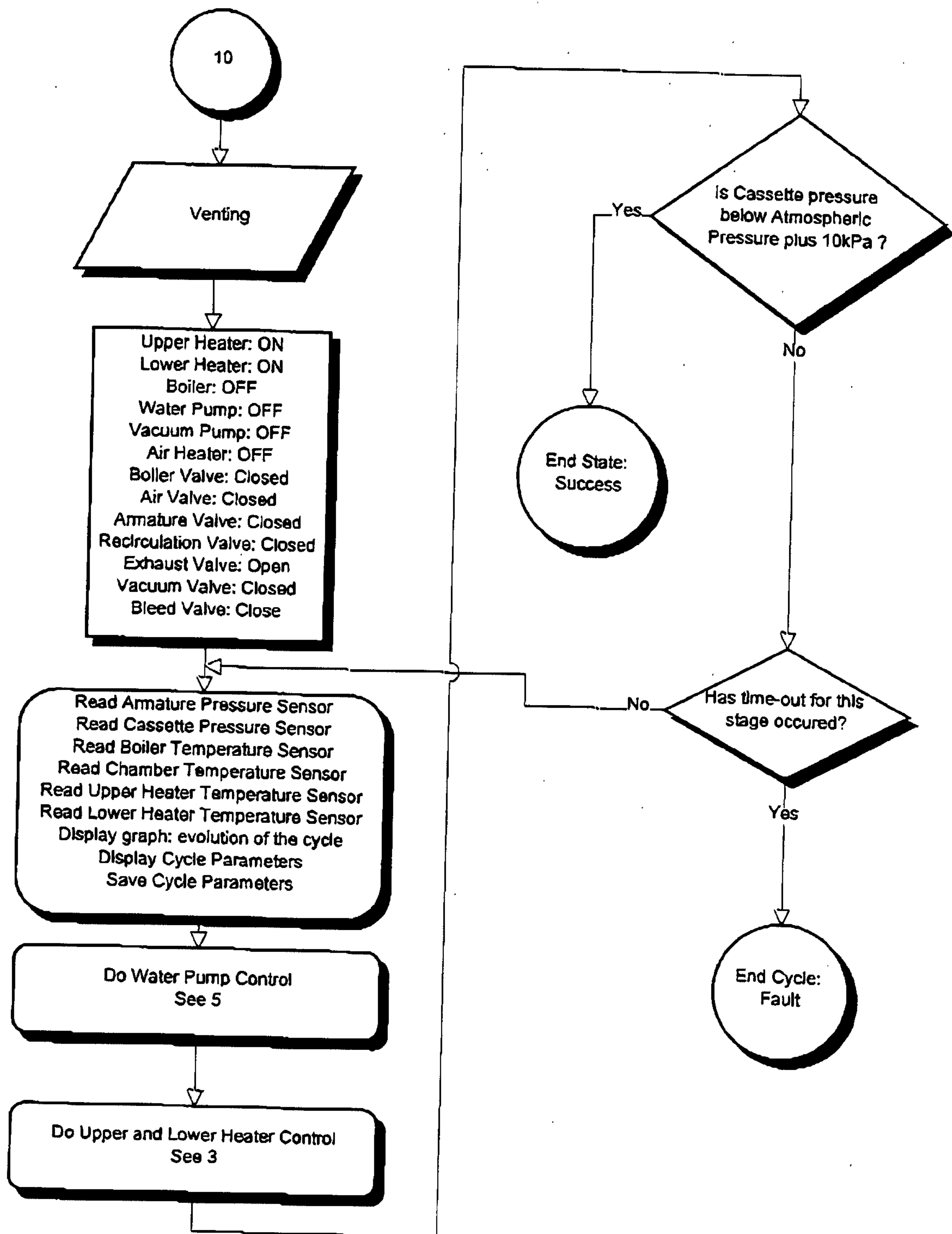


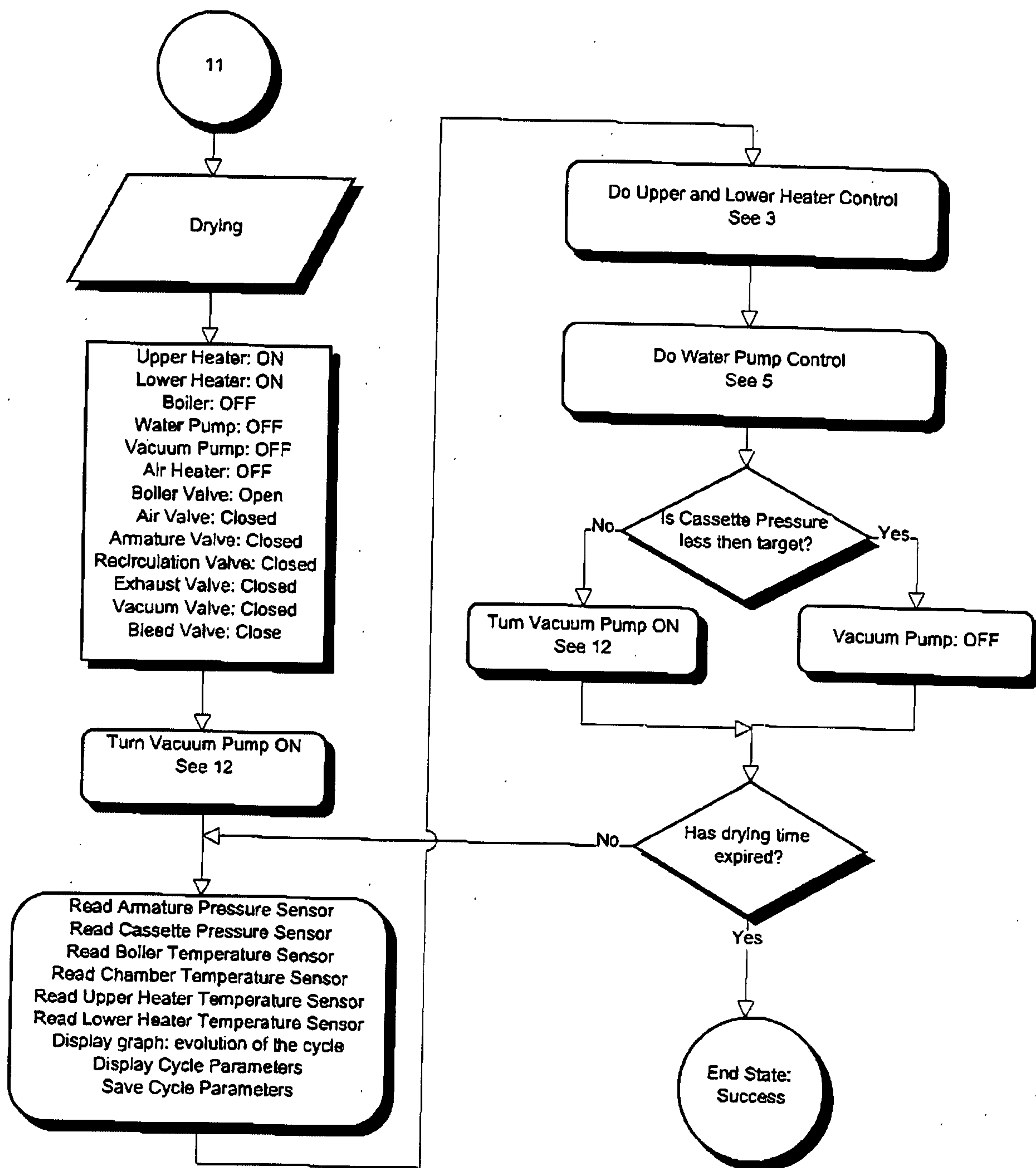


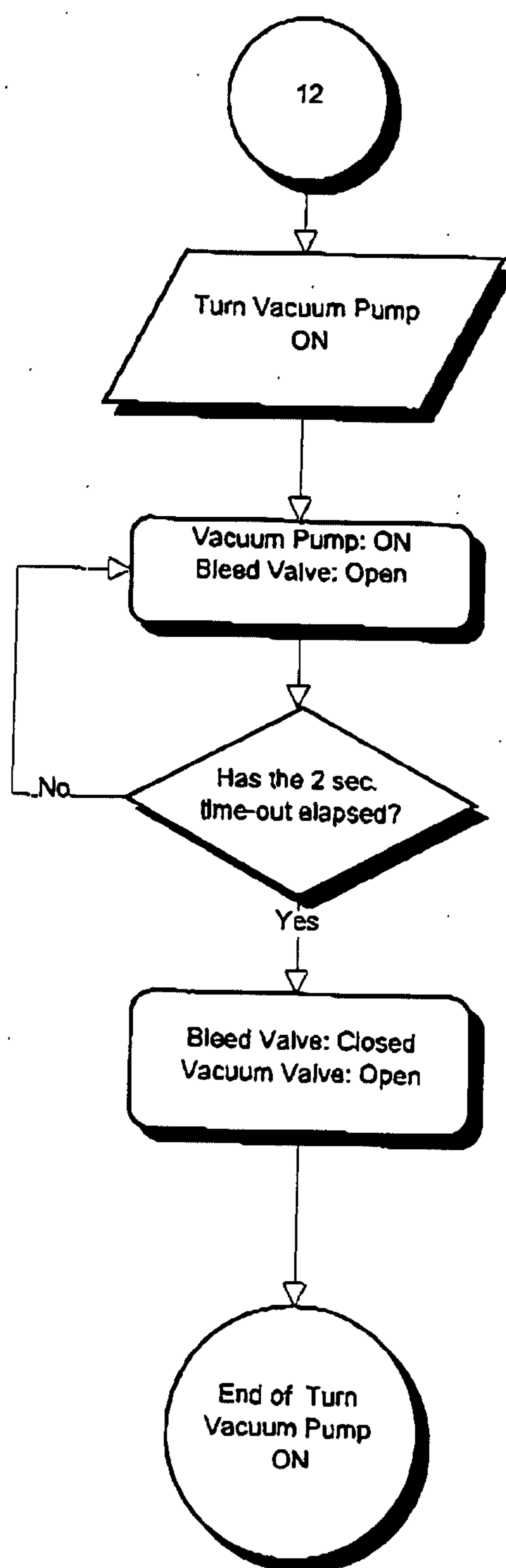


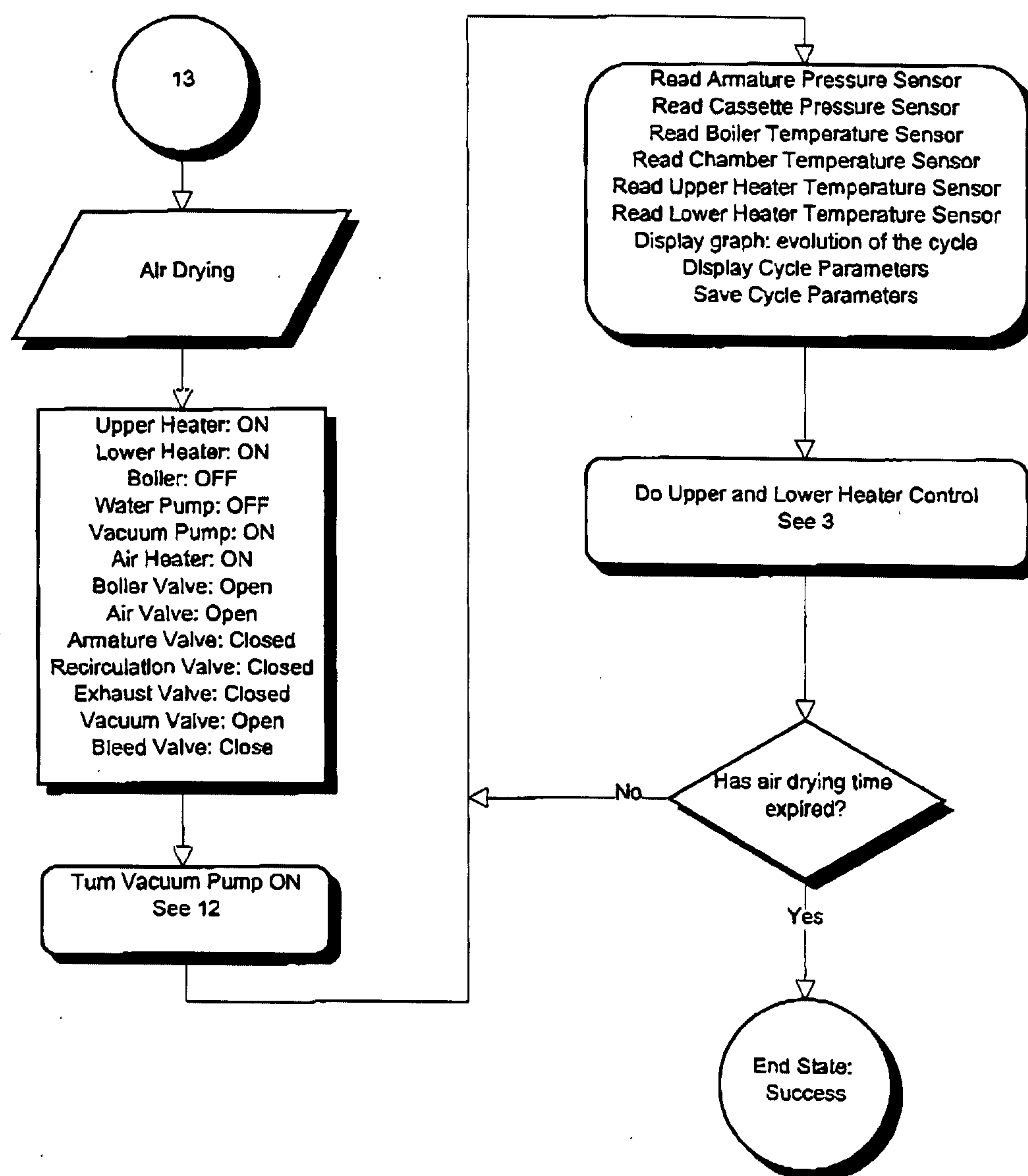












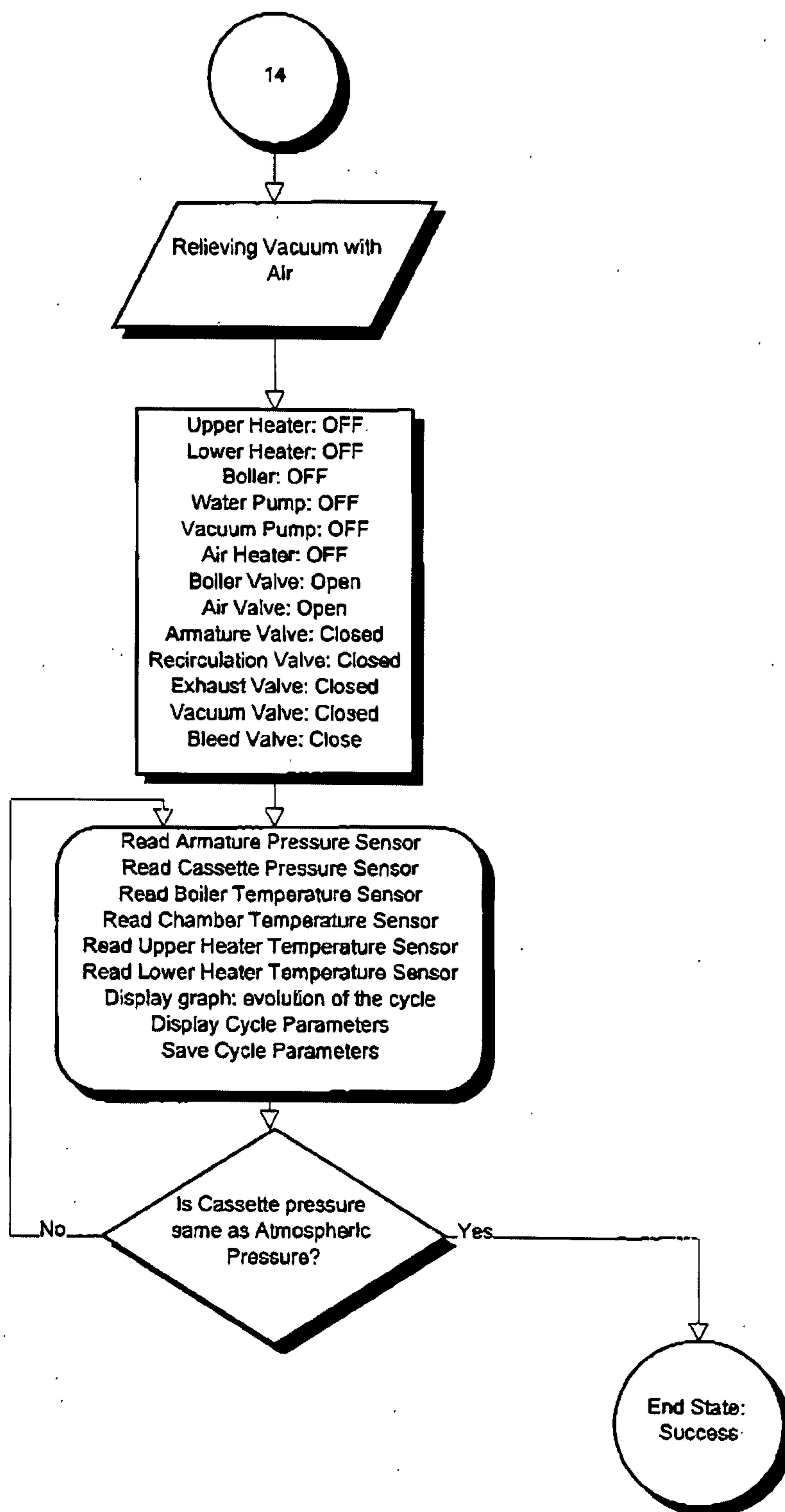


FIG.24

