



(22) **Date de dépôt/Filing Date:** 2008/10/10

(41) **Mise à la disp. pub./Open to Public Insp.:** 2009/04/23

(62) **Demande originale/Original Application:** 2 702 385

(30) **Priorités/Priorities:** 2007/10/12 (US11/871,787);
2007/10/12 (US11/871,712); 2007/10/12 (US11/871,680);
2007/10/12 (US11/871,793); 2008/02/27 (US12/038,474);
2008/02/27 (US12/038,648); 2008/08/27 (US12/199,068);
2008/08/27 (US12/199,176); 2008/08/27 (US12/199,166);
2008/08/27 (US12/199,062); 2008/08/27 (US12/199,055);
2008/08/27 (US12/199,077); 2008/08/27 (US12/198,947);
2008/08/27 (US12/199,196)

(51) **Cl.Int./Int.Cl. A61M 1/16** (2006.01),
A61M 39/10 (2006.01)

(71) **Demandeur/Applicant:**
DEKA PRODUCTS LIMITED PARTNERSHIP, US

(72) **Inventeurs/Inventors:**
KAMEN, DEAN, US;
GRANT, KEVIN L., US;
DEMERS, JASON A., US;
DALE, JAMES D., US;
COLLINS, DAVID E., US;
WILT, MICHAEL J., US;
PRESCOTT, SHANNON, US;
...

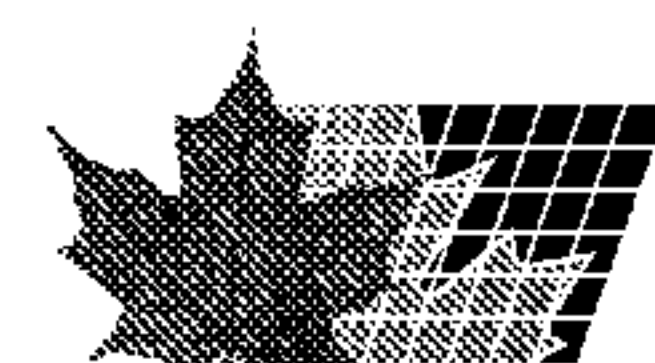
(74) **Agent:** CASSAN MACLEAN

(54) **Titre : APPAREIL ET PROCEDES D'HEMODIALYSE**

(54) **Title: APPARATUS AND METHODS FOR HEMODIALYSIS**

(57) **Abrégé/Abstract:**

An enclosure for containing a hemodialysis unit includes a housing (51) suitable to support components for performing hemodialysis including a dialyzer (14), one or more pumps to circulate blood through the dialyzer, a source of dialysate, and one or more pumps to circulate the dialysate through the dialyzer. The housing may have a front panel (511) at which blood circuit connections and dialysate fluidic connections are located, e.g., blood line connections for patient blood access, connections for a reagent supply, dialyzer connections for both blood flow and dialysate, etc. The enclosure may also include a pair of vertical, side-by-side doors (53) hingedly mounted to the housing. With the doors in the closed position, access to the patient access and dialysate fluidic connections may be blocked, and the doors may allow for the retention of heat in the housing suitable for disinfection during a disinfection cycle.



(72) **Inventeurs(suite)/Inventors(continued):** MARCEK, GEOFFREY A., US; BODWELL, JESSE T., US;
CHAWAN, ARUN D., US

Abstract

An enclosure for containing a hemodialysis unit includes a housing (51) suitable to support components for performing hemodialysis including a dialyzer (14), one or more pumps to circulate blood through the dialyzer, a source of dialysate, and one or more pumps to circulate the dialysate through the dialyzer. The housing may have a front panel (511) at which blood circuit connections and dialysate fluidic connections are located, e.g., blood line connections for patient blood access, connections for a reagent supply, dialyzer connections for both blood flow and dialysate, etc. The enclosure may also include a pair of vertical, side-by-side doors (53) hingedly mounted to the housing. With the doors in the closed position, access to the patient access and dialysate fluidic connections may be blocked, and the doors may allow for the retention of heat in the housing suitable for disinfection during a disinfection cycle.

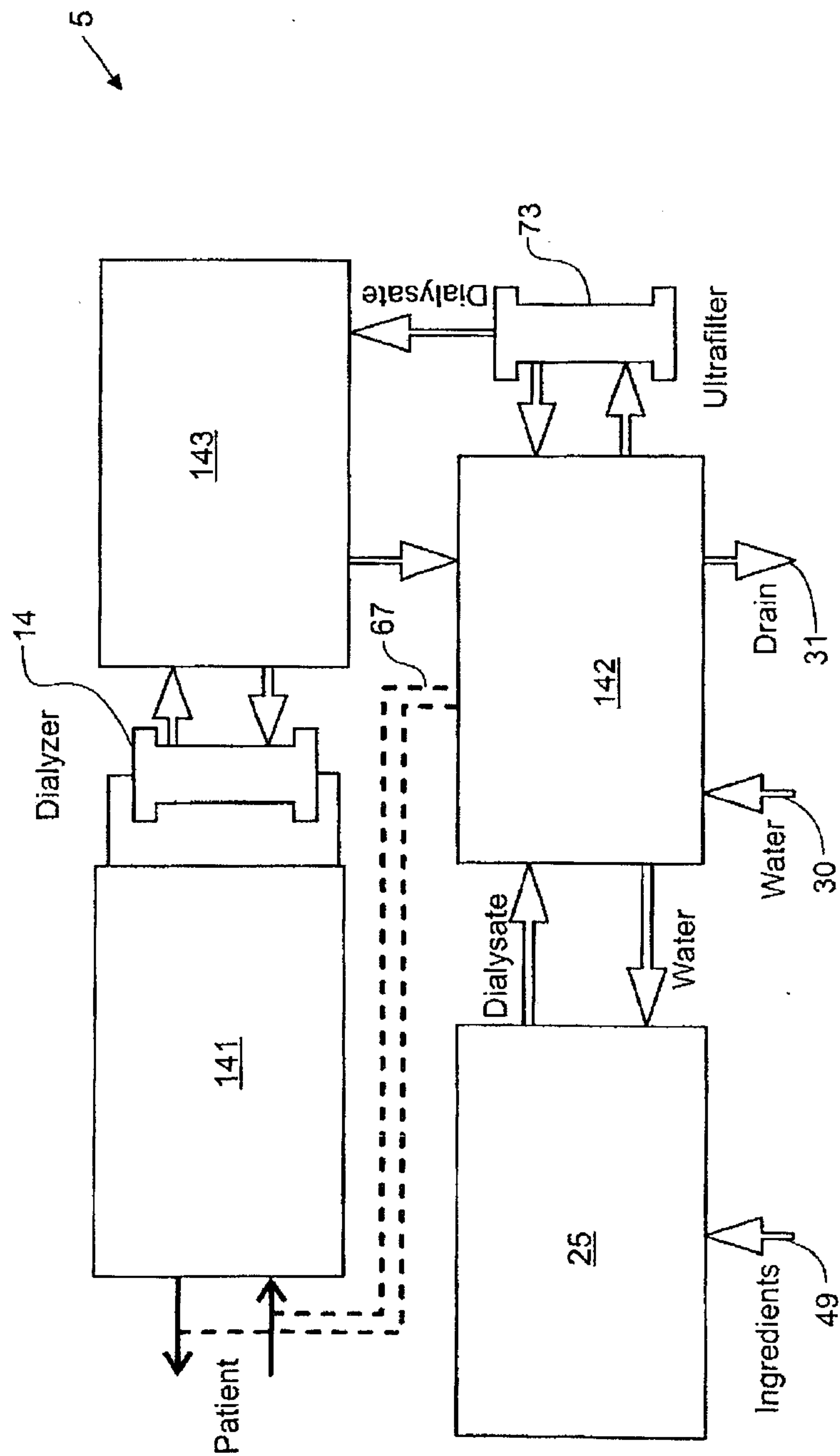


FIG.1

SUBSTITUTE SHEET (RULE 26)

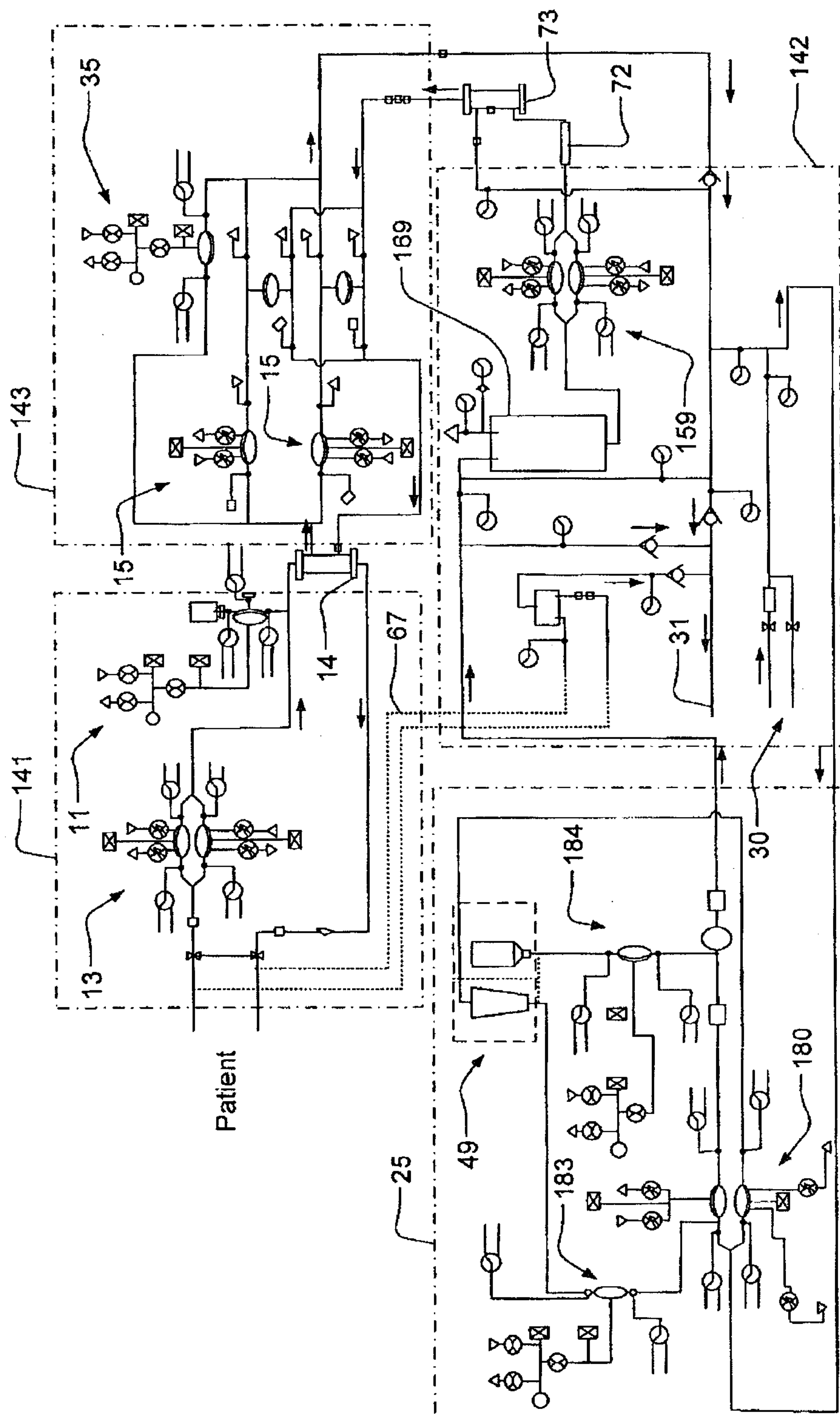


FIG. 2

SUBSTITUTE SHEET (RULE 26)

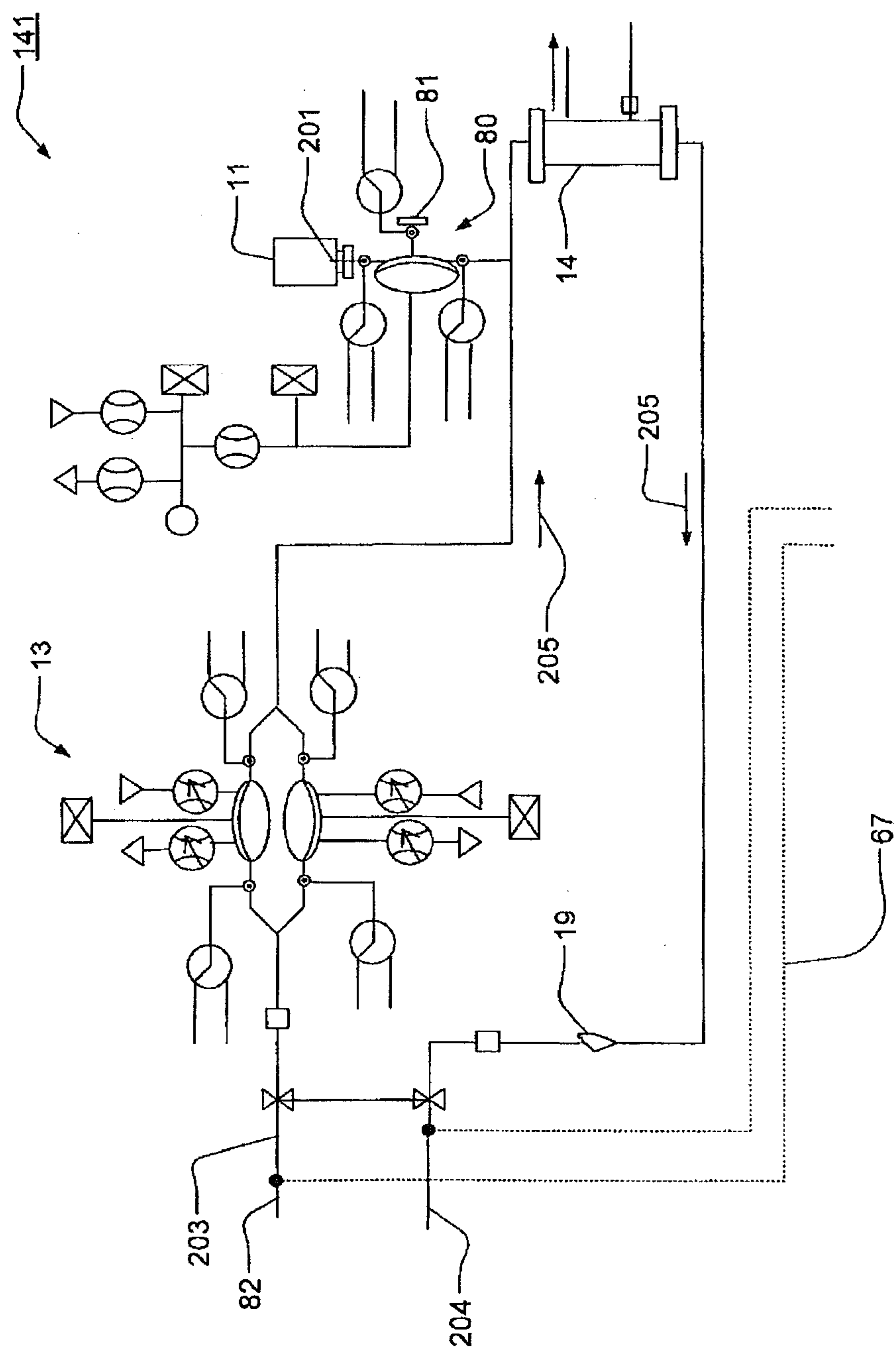


FIG. 3

SUBSTITUTE SHEET (RULE 26)

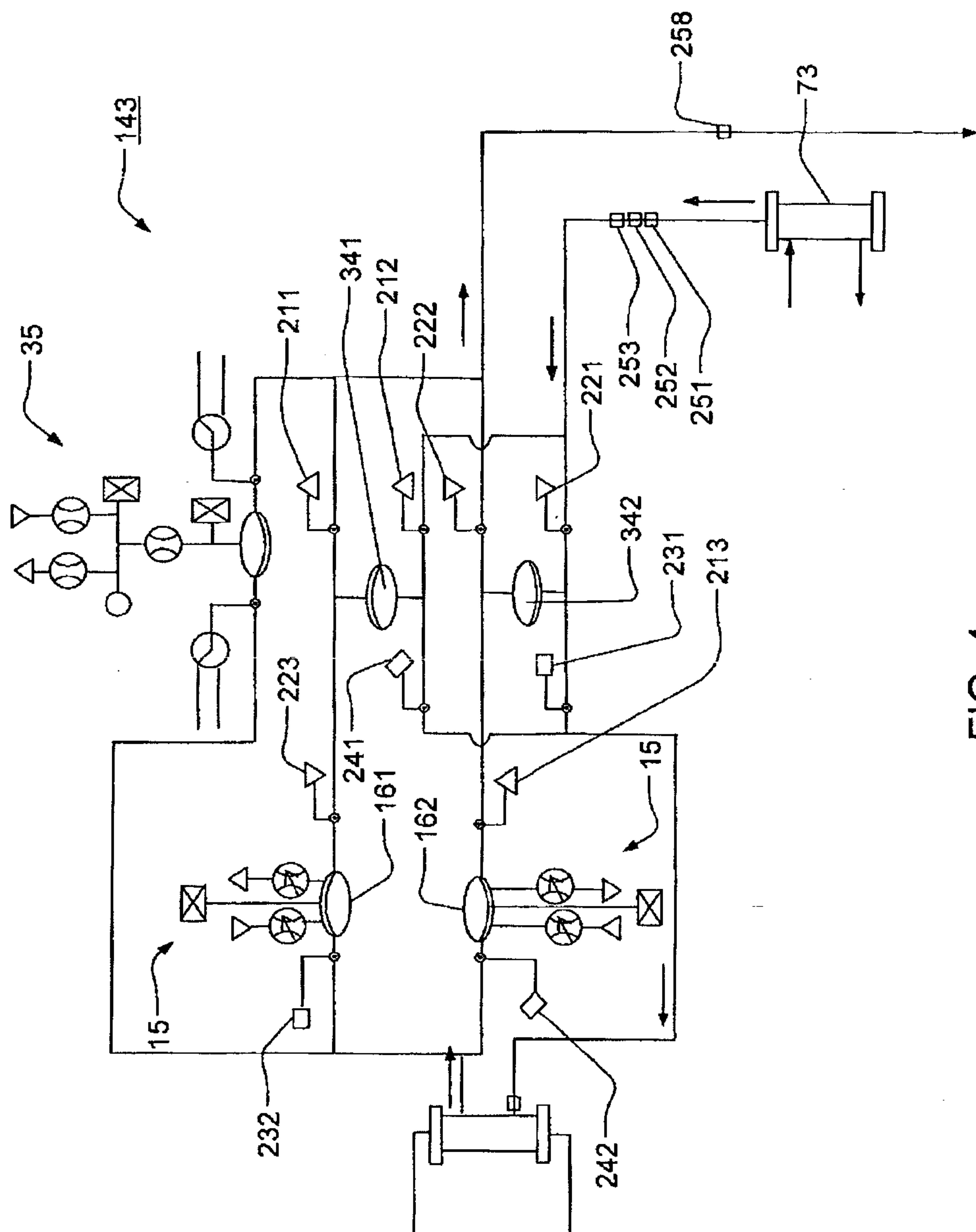


FIG. 4

SUBSTITUTE SHEET (RULE 26)

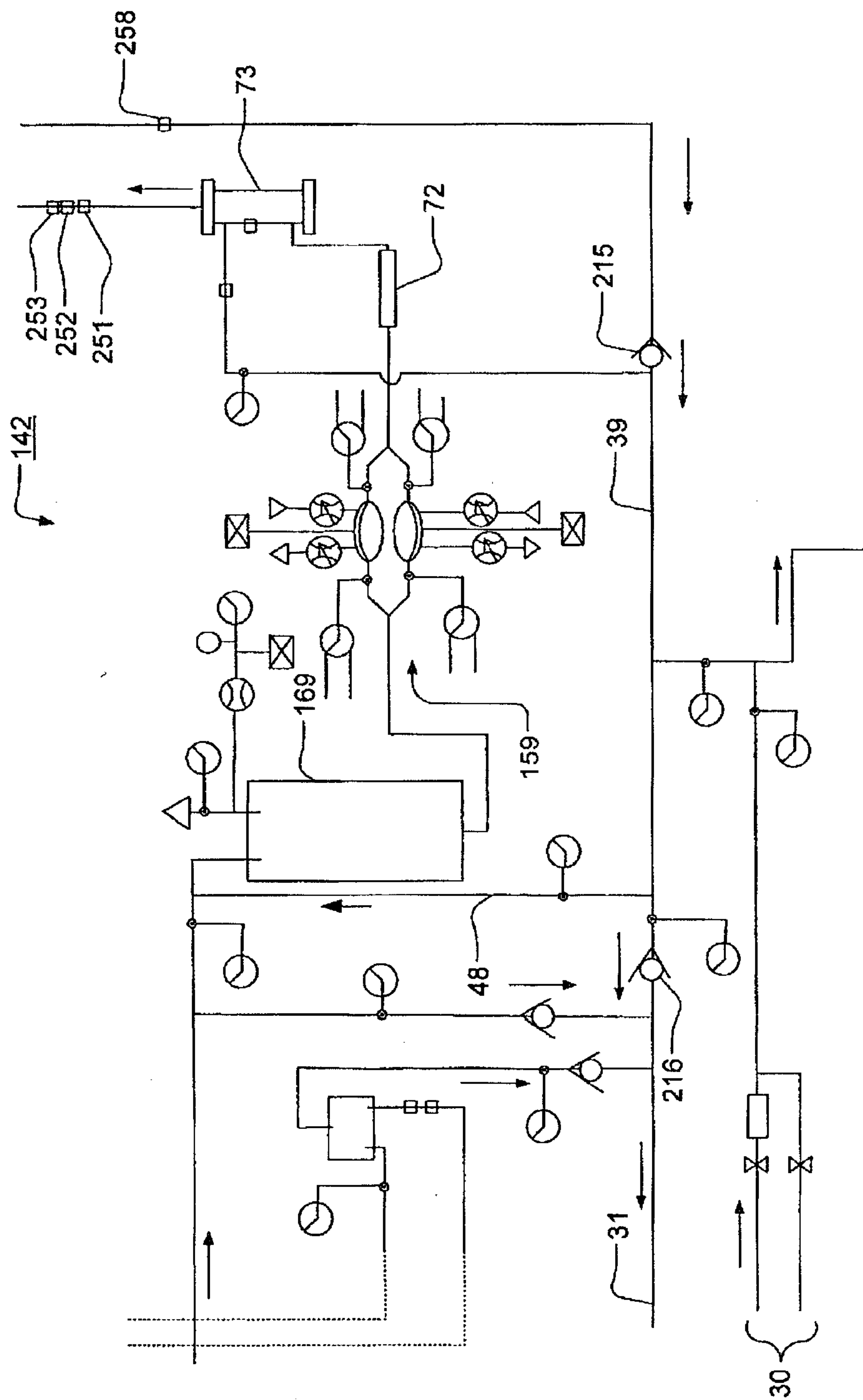


FIG. 5

SUBSTITUTE SHEET (RULE 26)

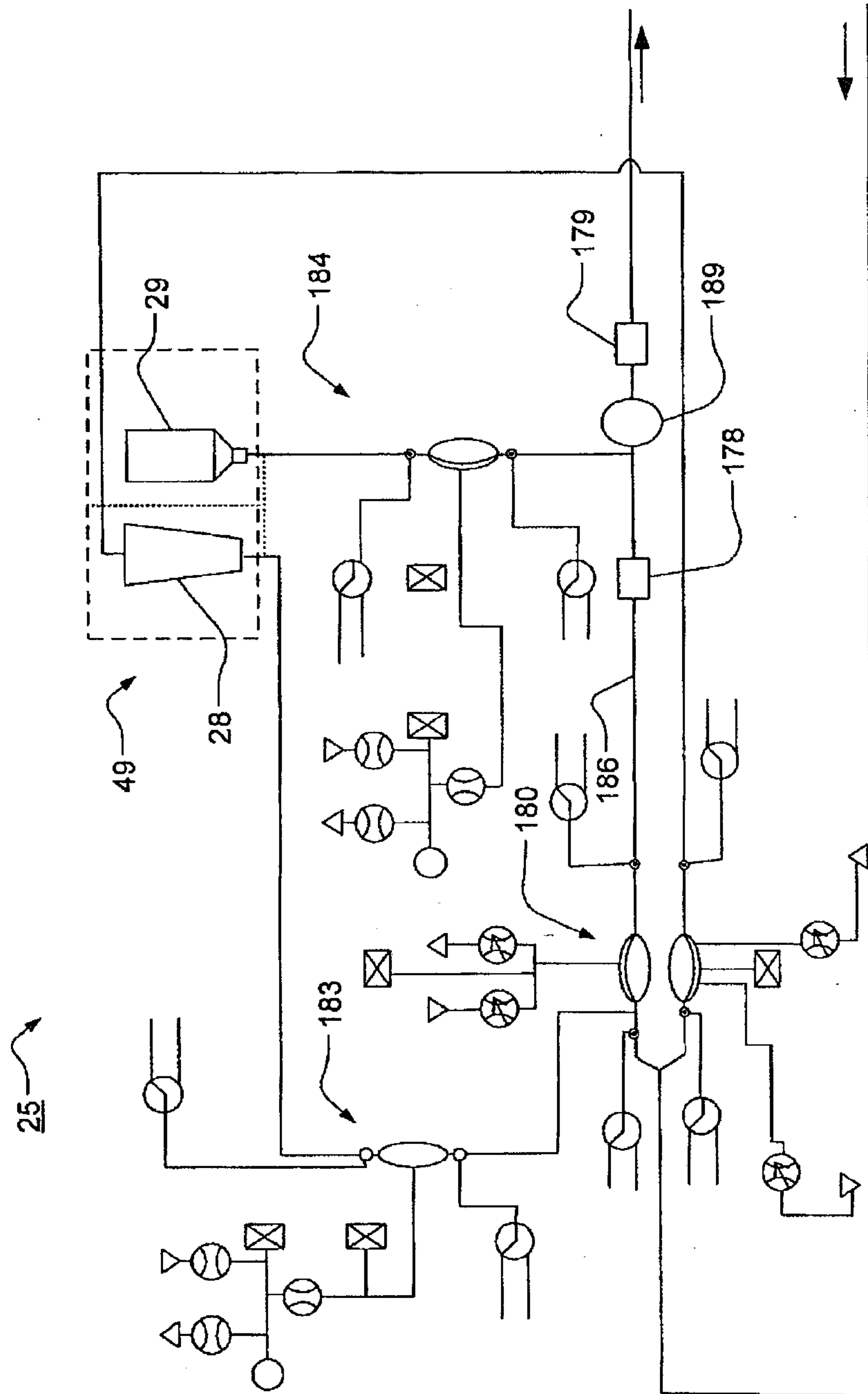


FIG. 6

SUBSTITUTE SHEET (RULE 26)

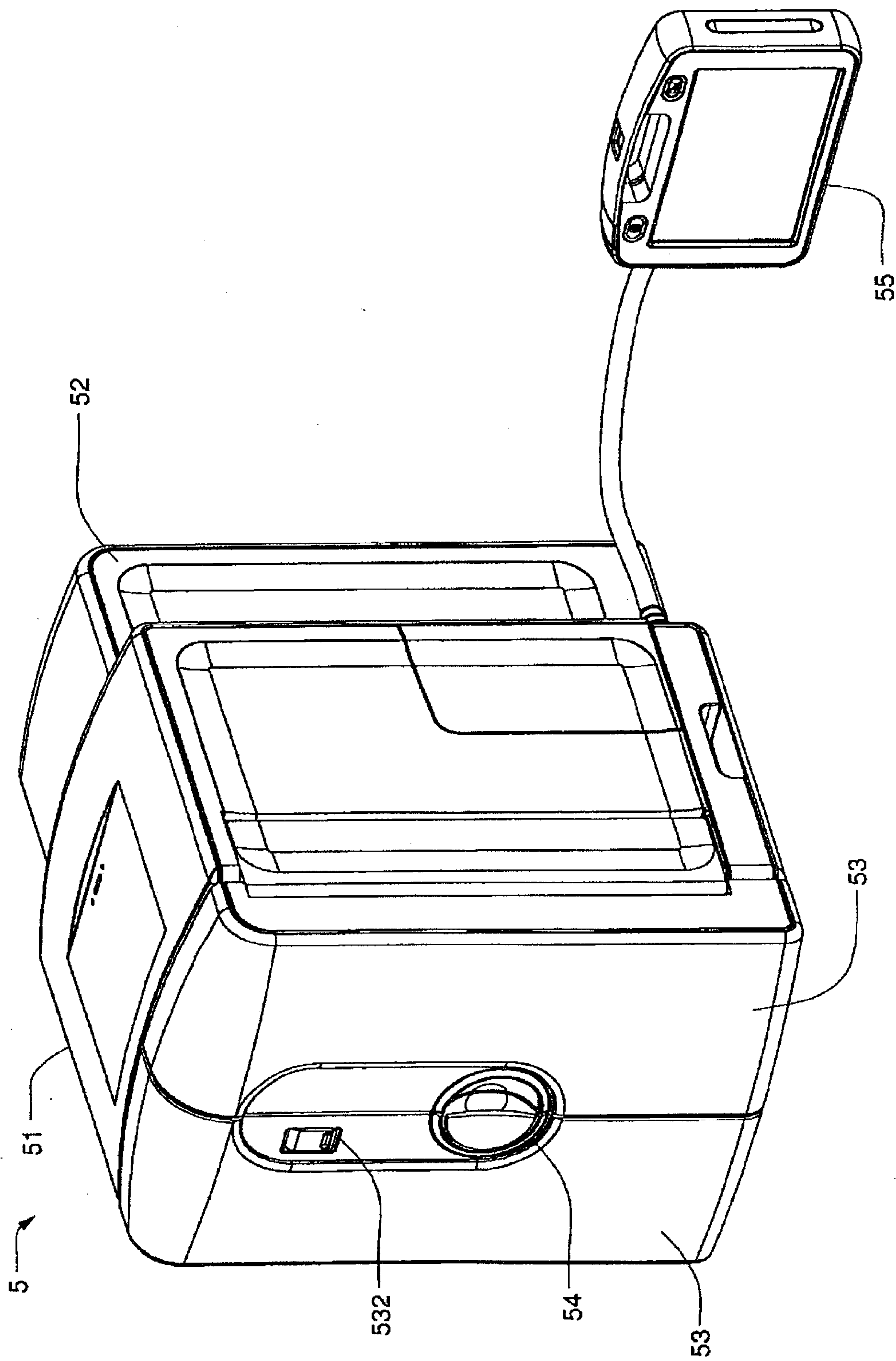


FIG. 7

SUBSTITUTE SHEET (RULE 26)

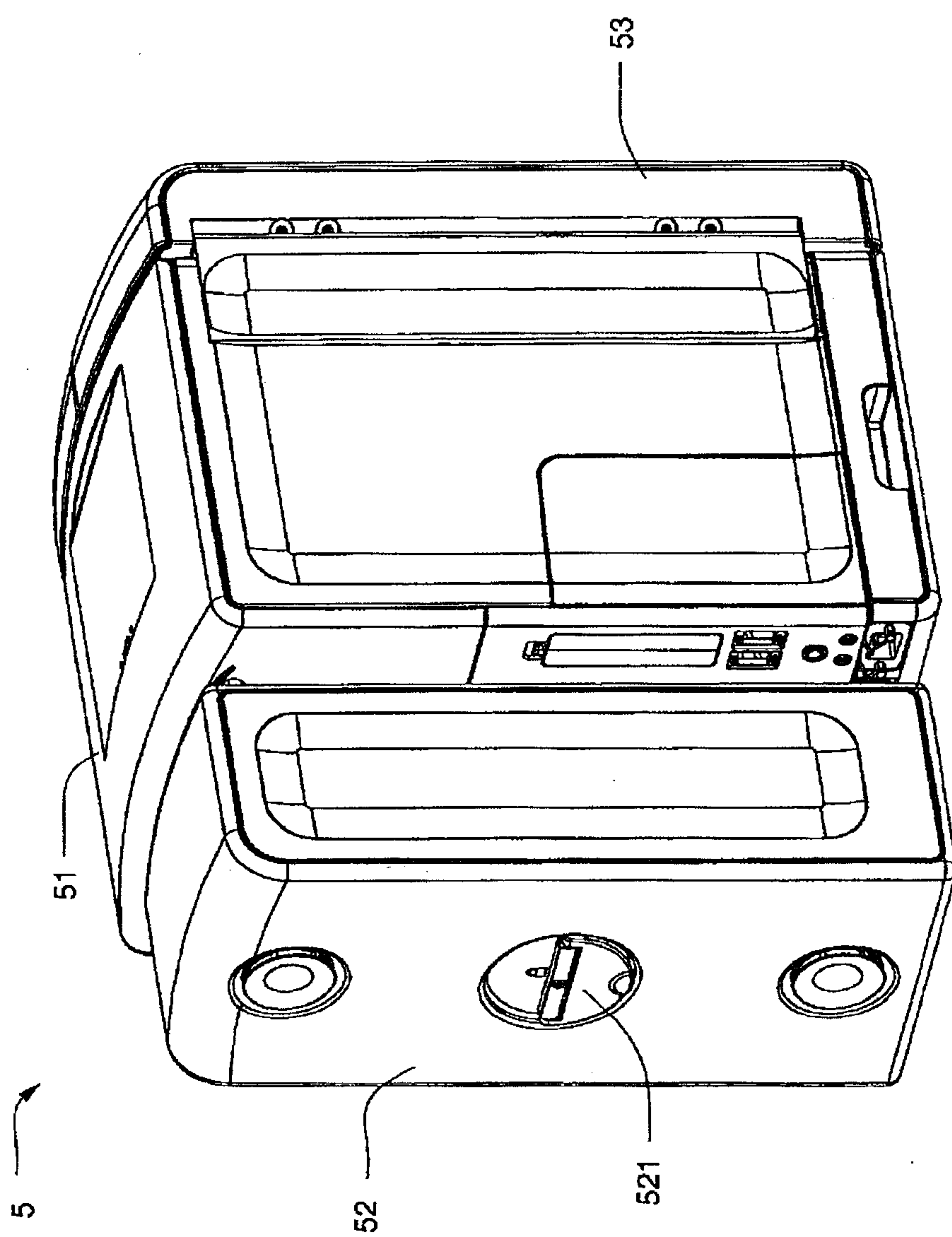


FIG. 8

SUBSTITUTE SHEET (RULE 26)

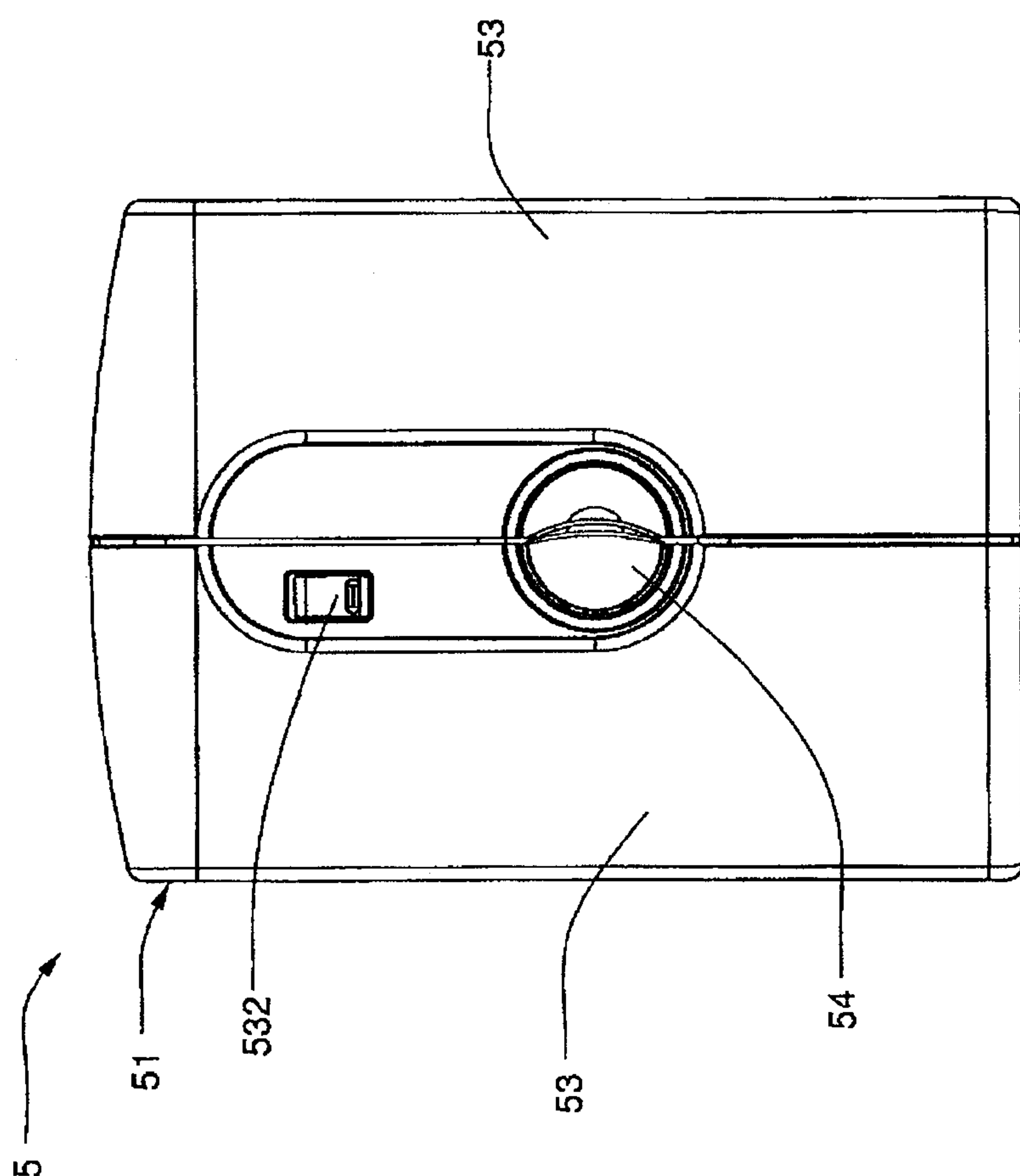


FIG. 9

SUBSTITUTE SHEET (RULE 26)

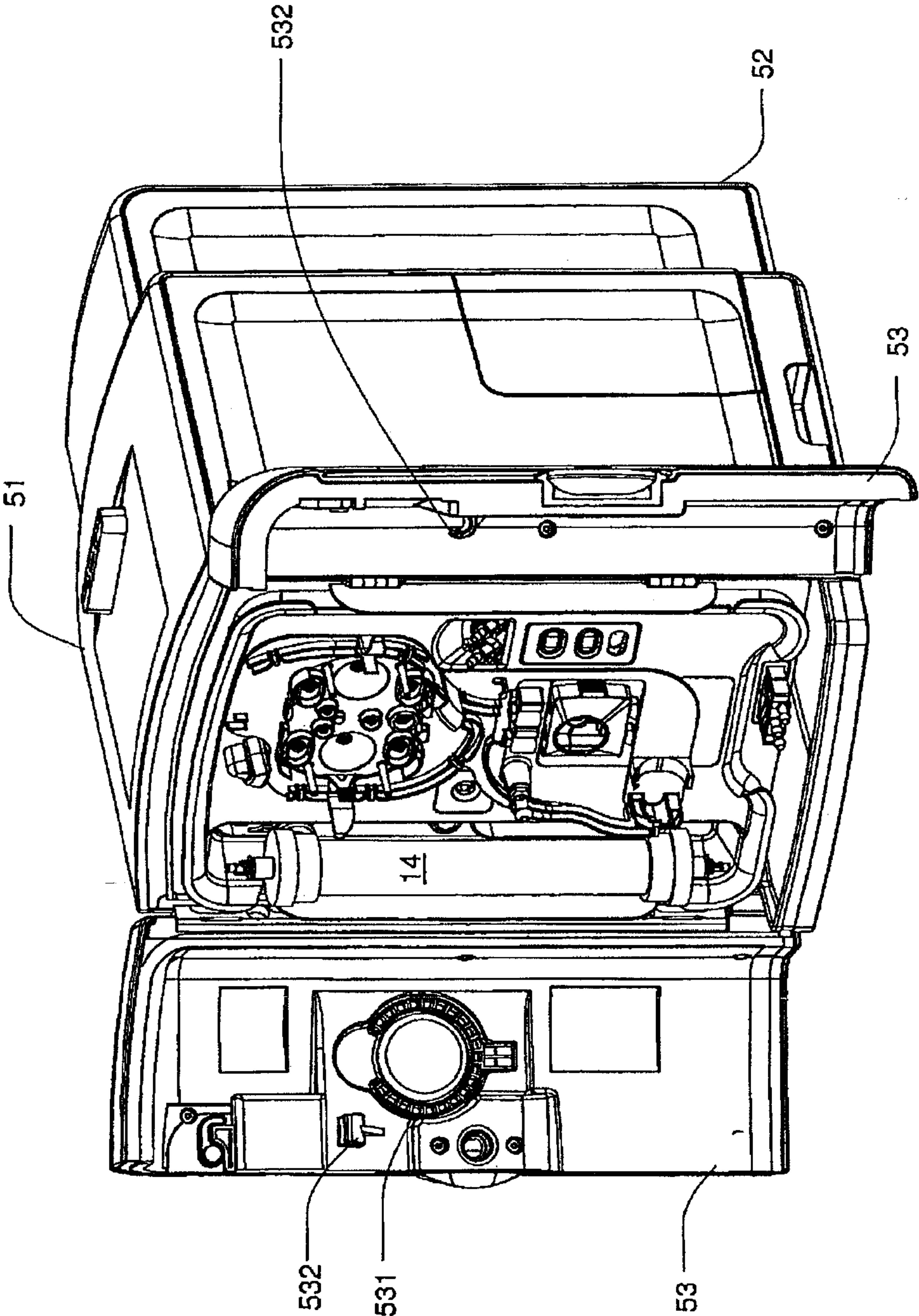
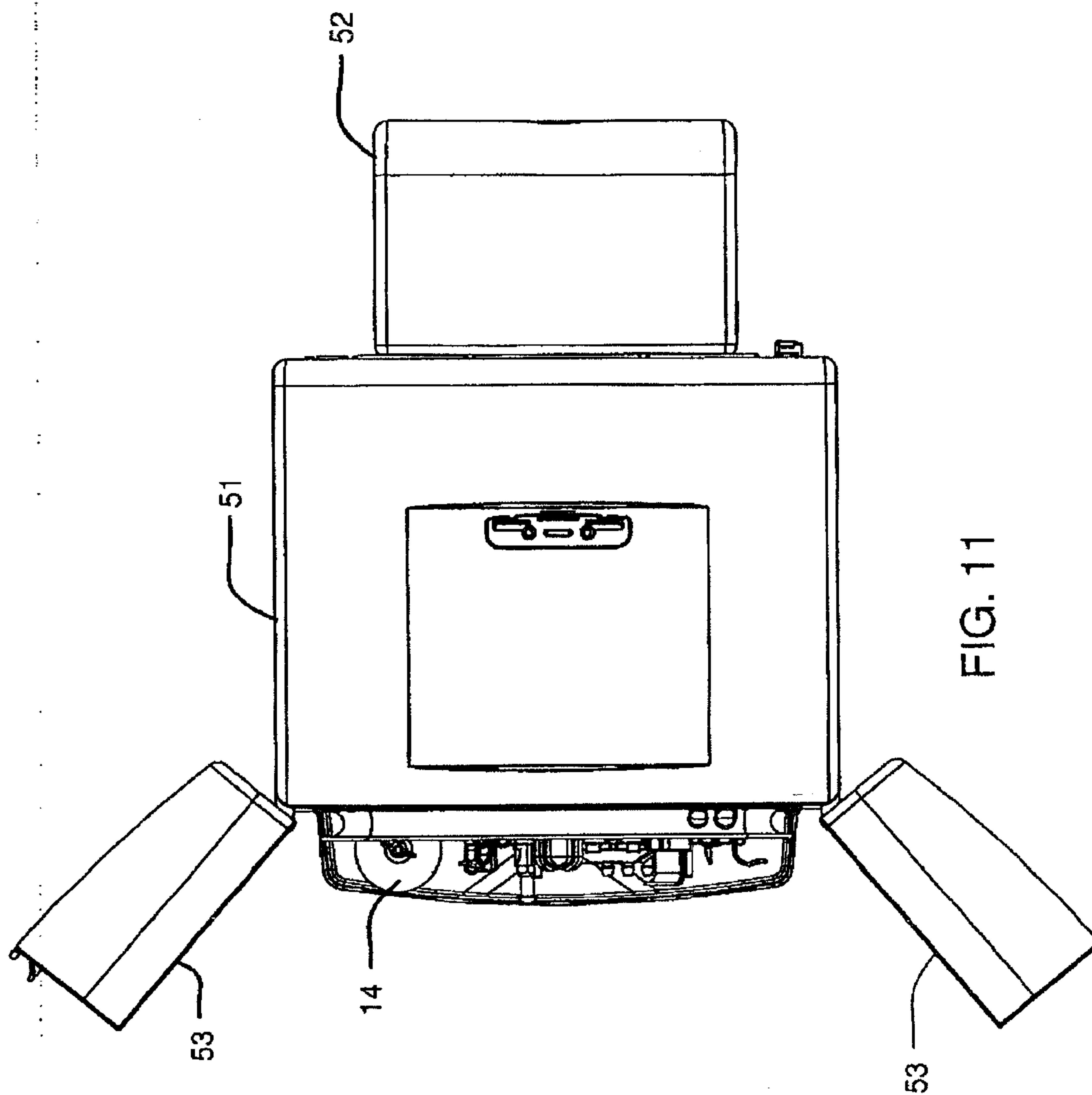


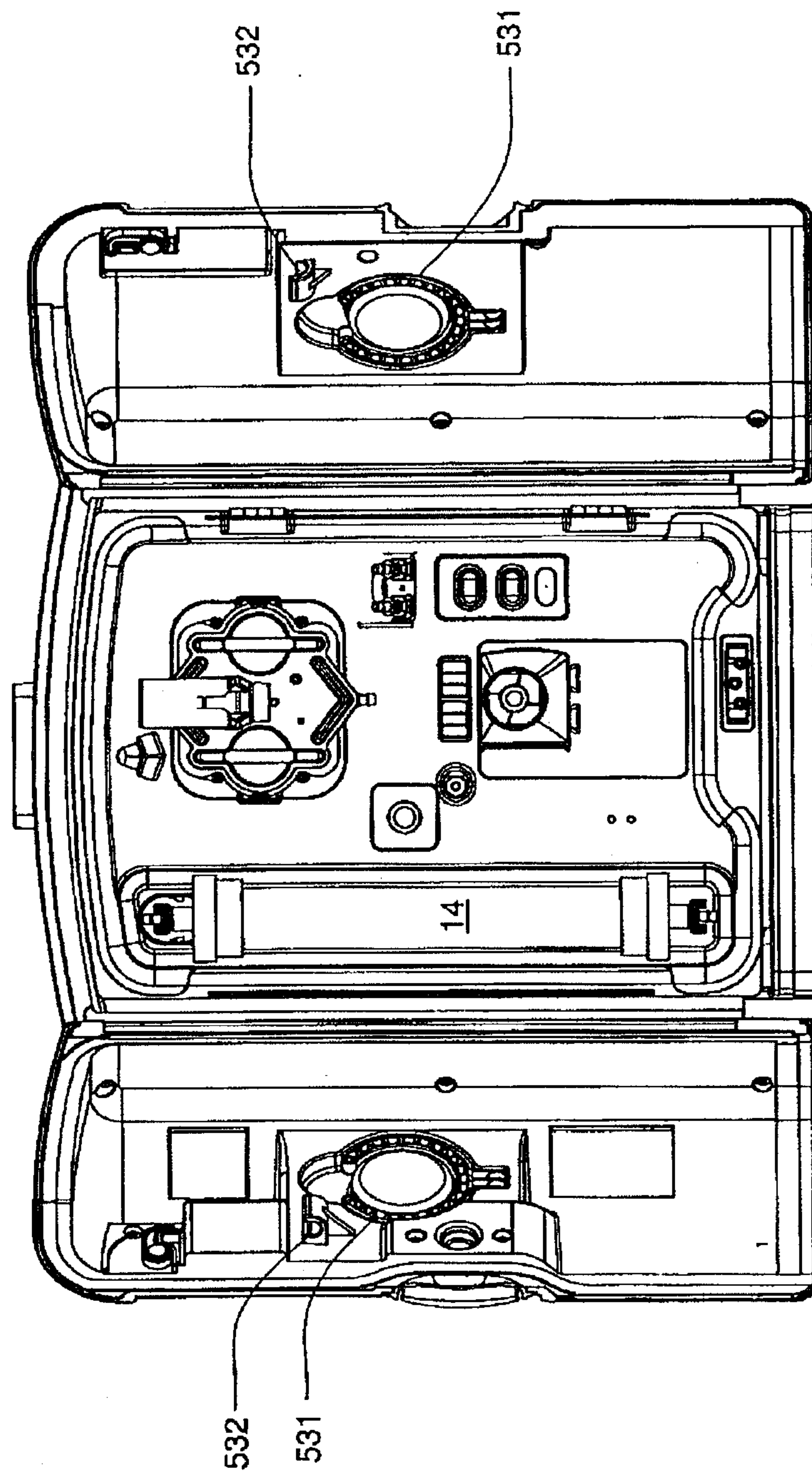
FIG. 10

SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

12/50



SUBSTITUTE SHEET (RULE 26)

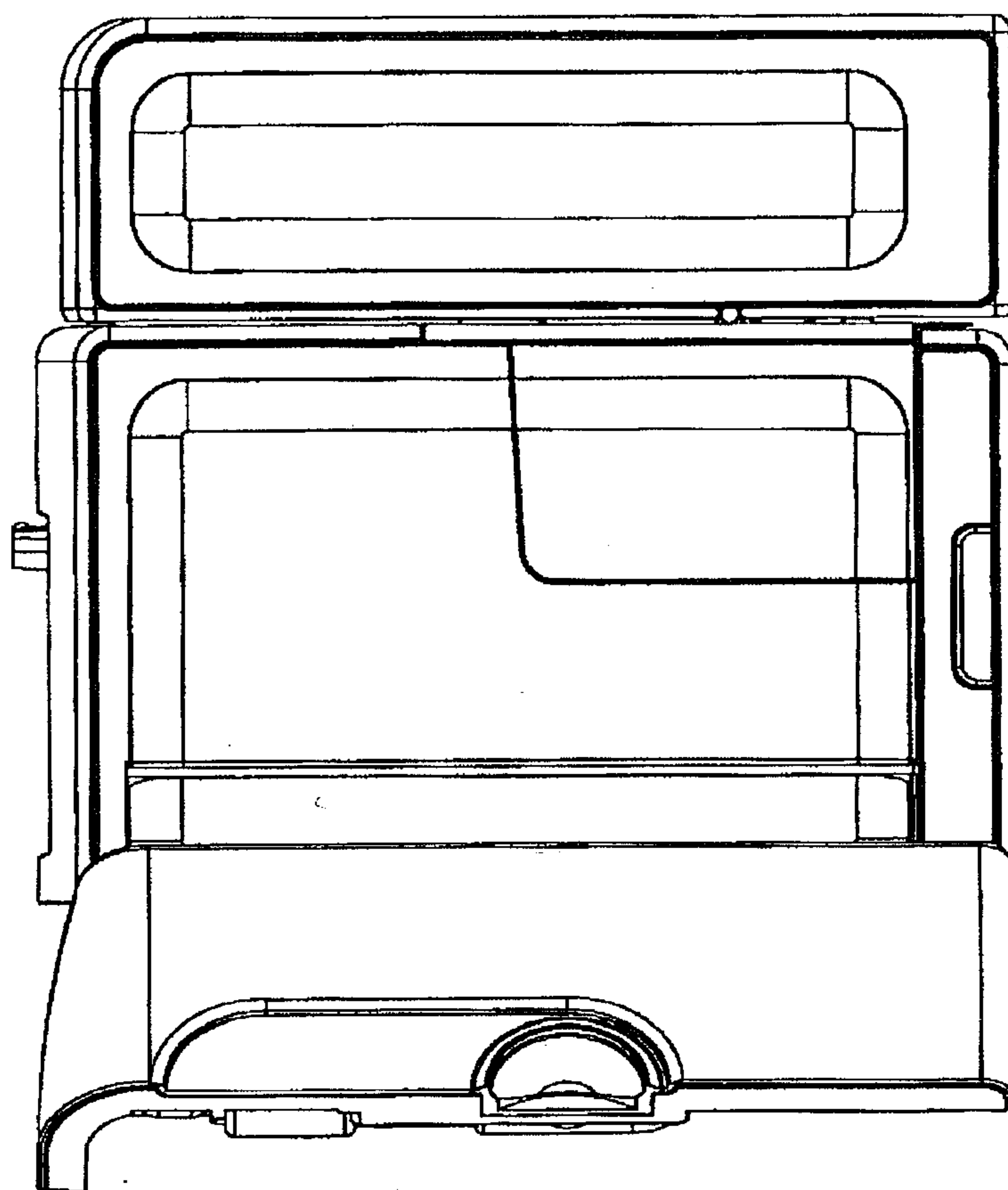
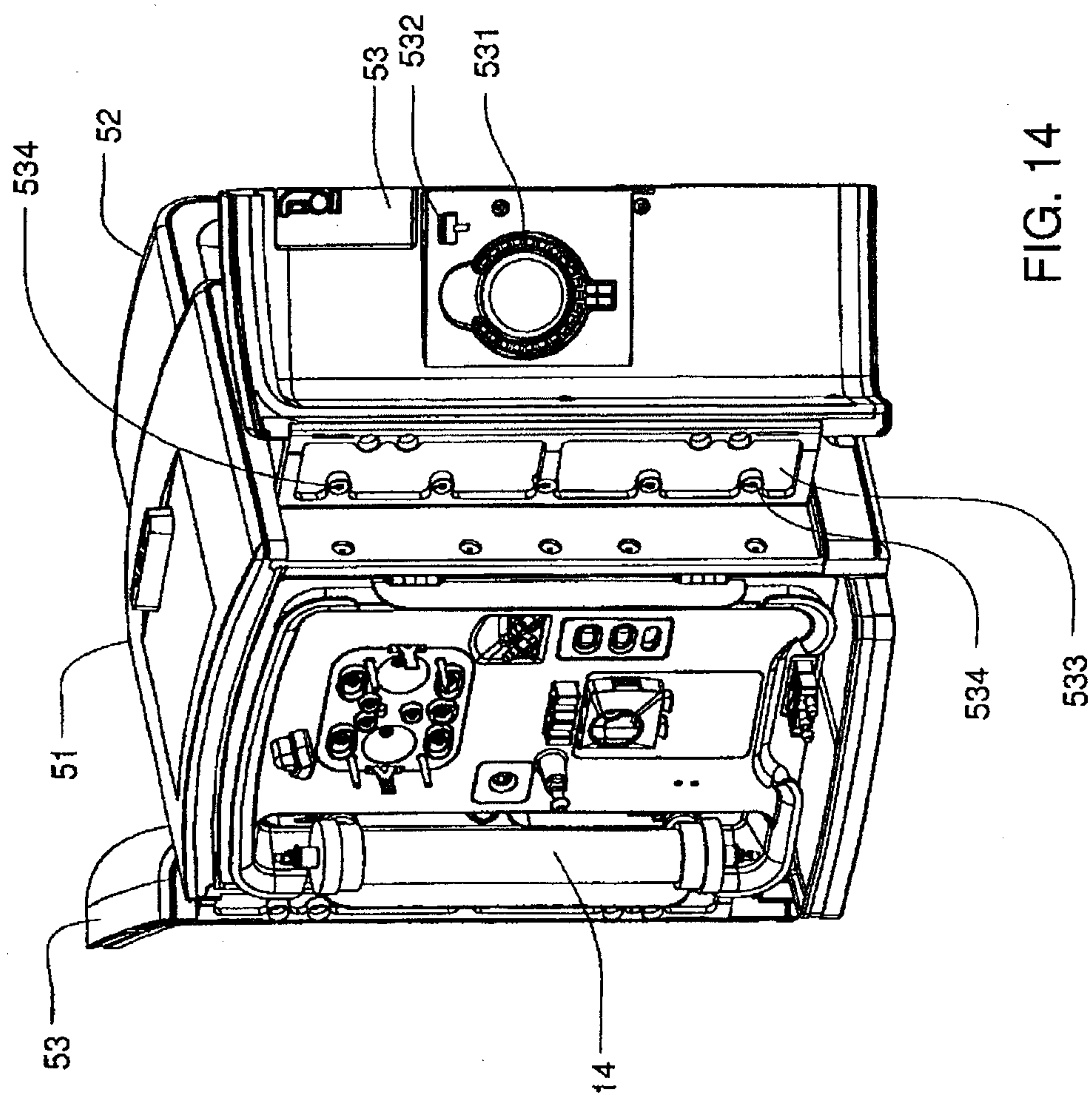


FIG. 13

SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

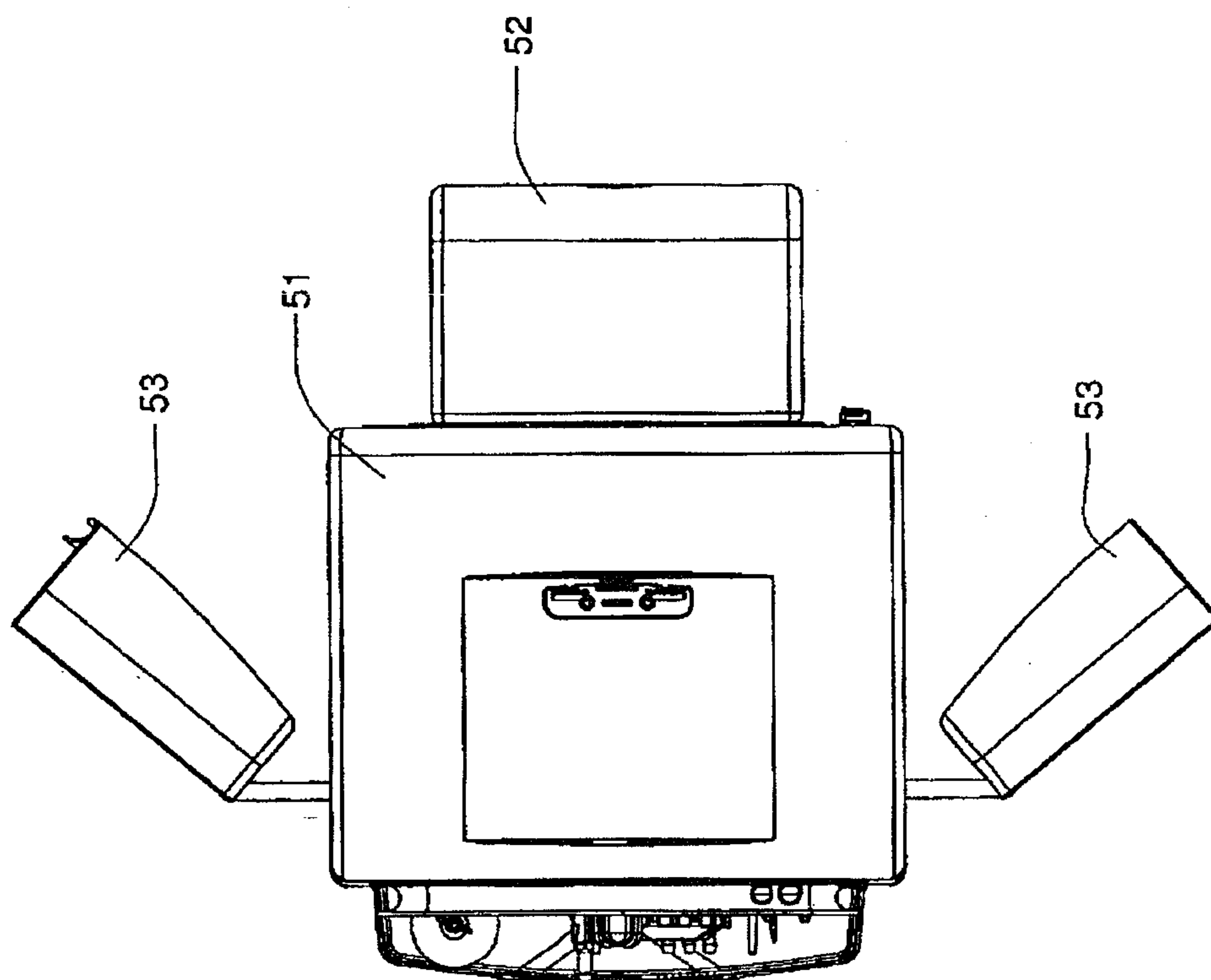


FIG. 15

SUBSTITUTE SHEET (RULE 26)

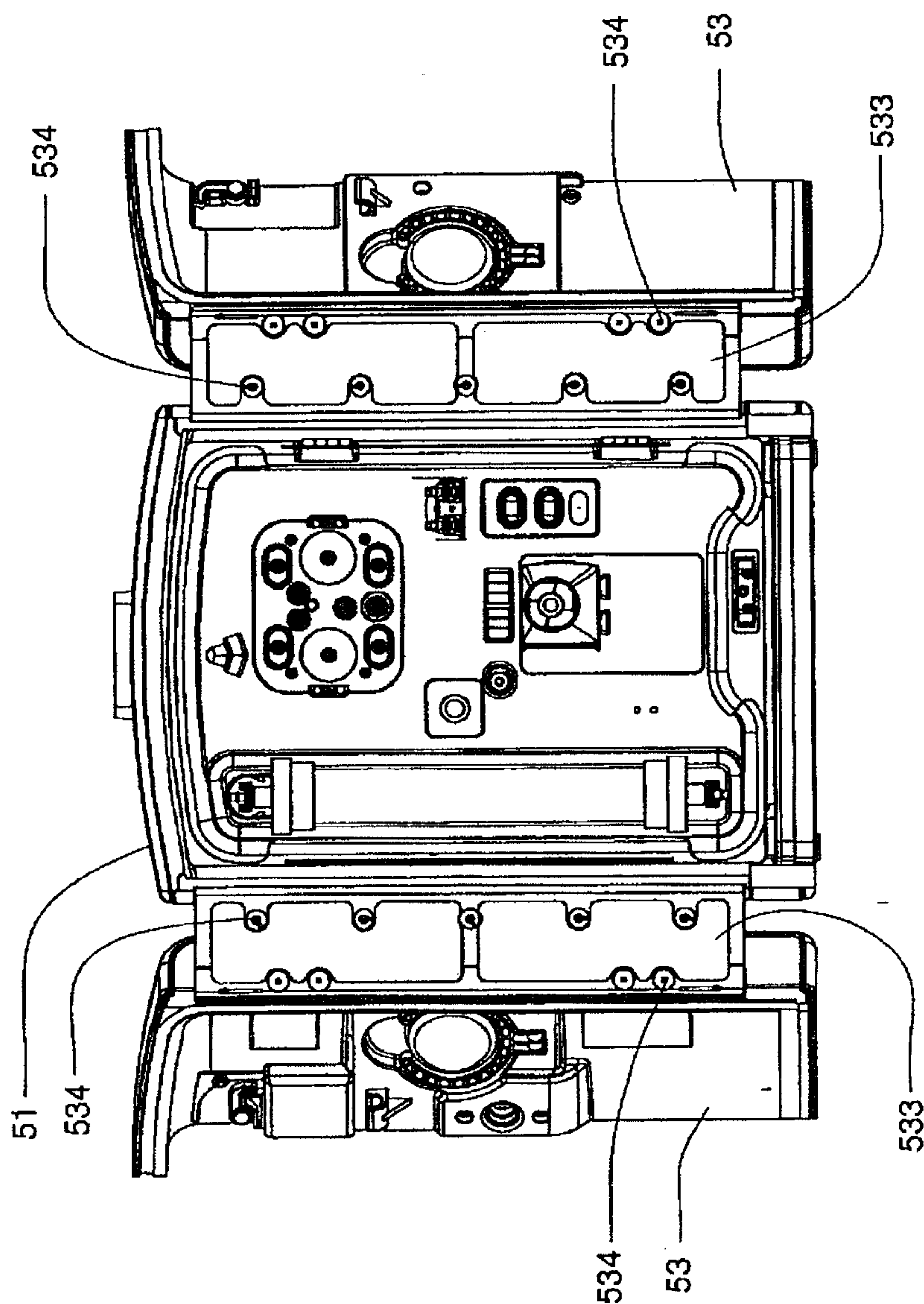


FIG. 16

SUBSTITUTE SHEET (RULE 26)

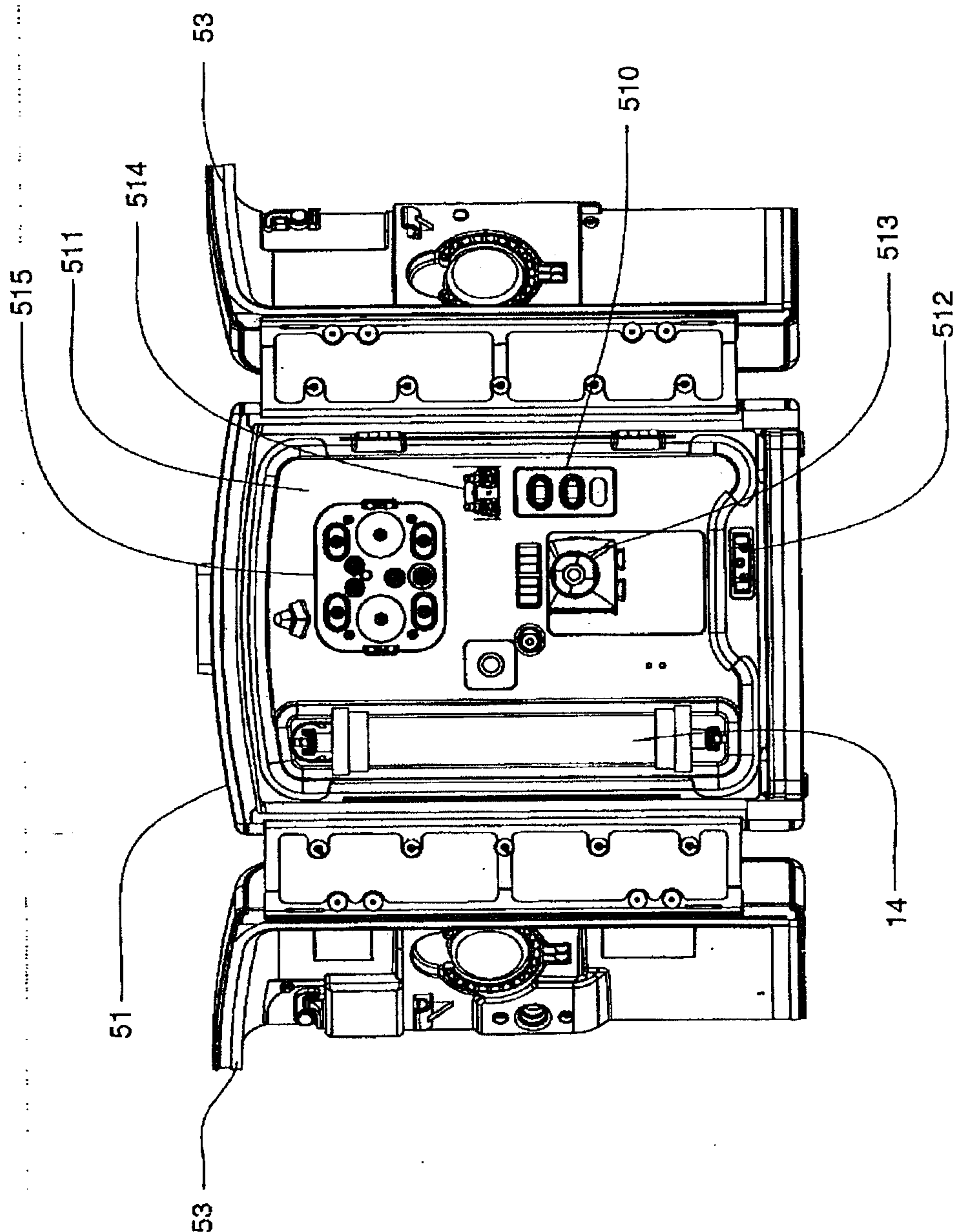


FIG. 17

SUBSTITUTE SHEET (RULE 26)

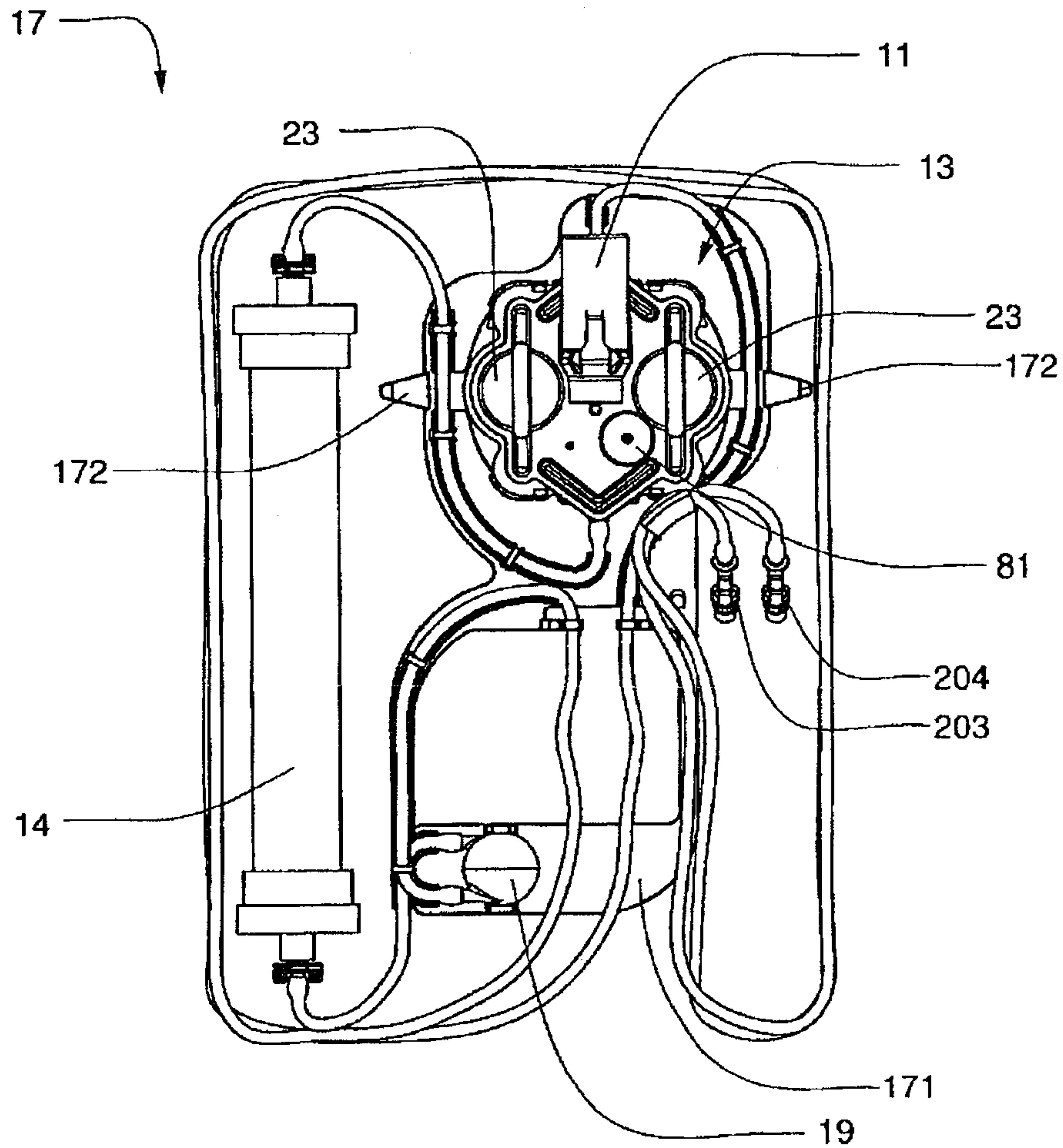


FIG. 18

SUBSTITUTE SHEET (RULE 26)

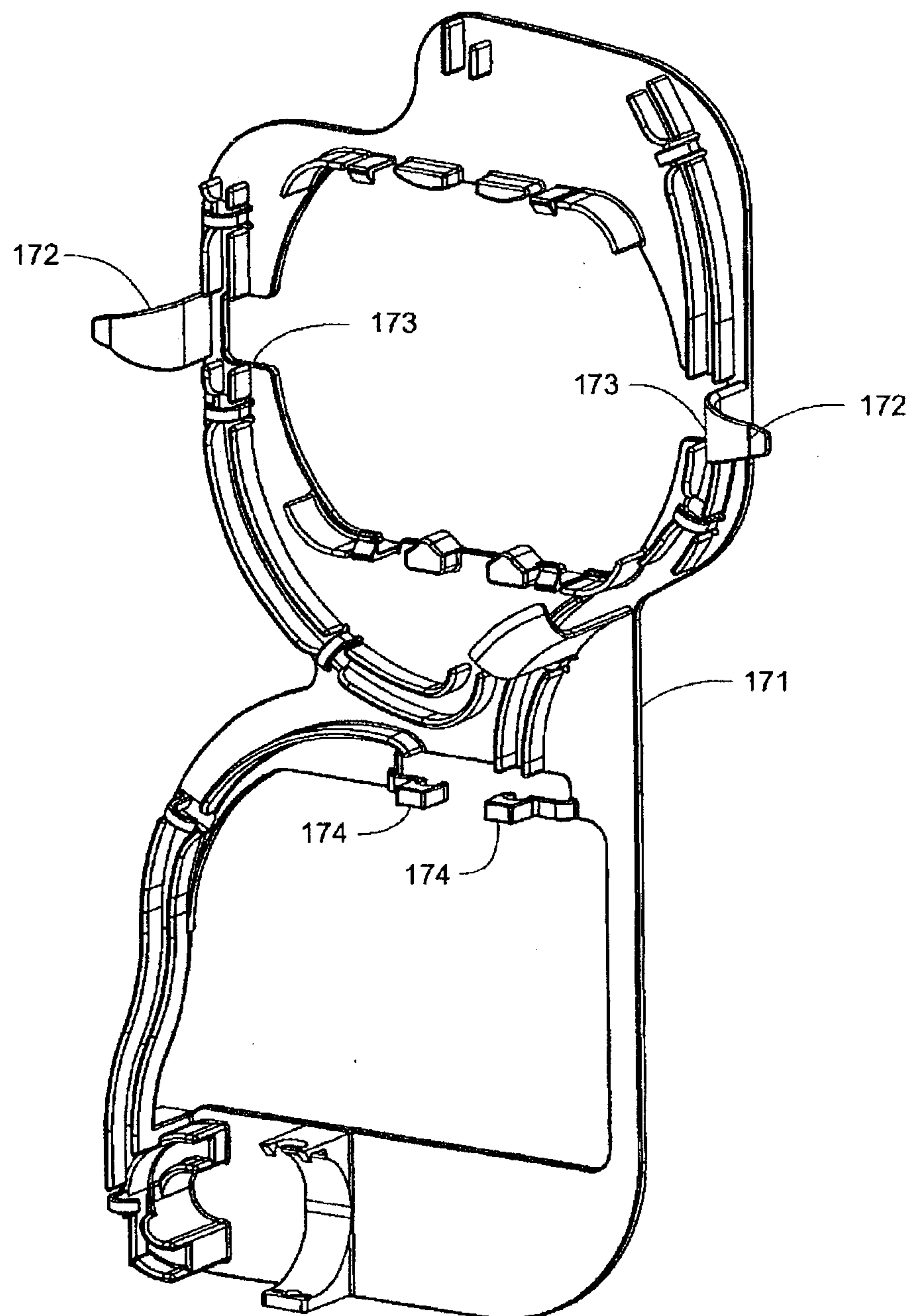


FIG. 19

SUBSTITUTE SHEET (RULE 26)

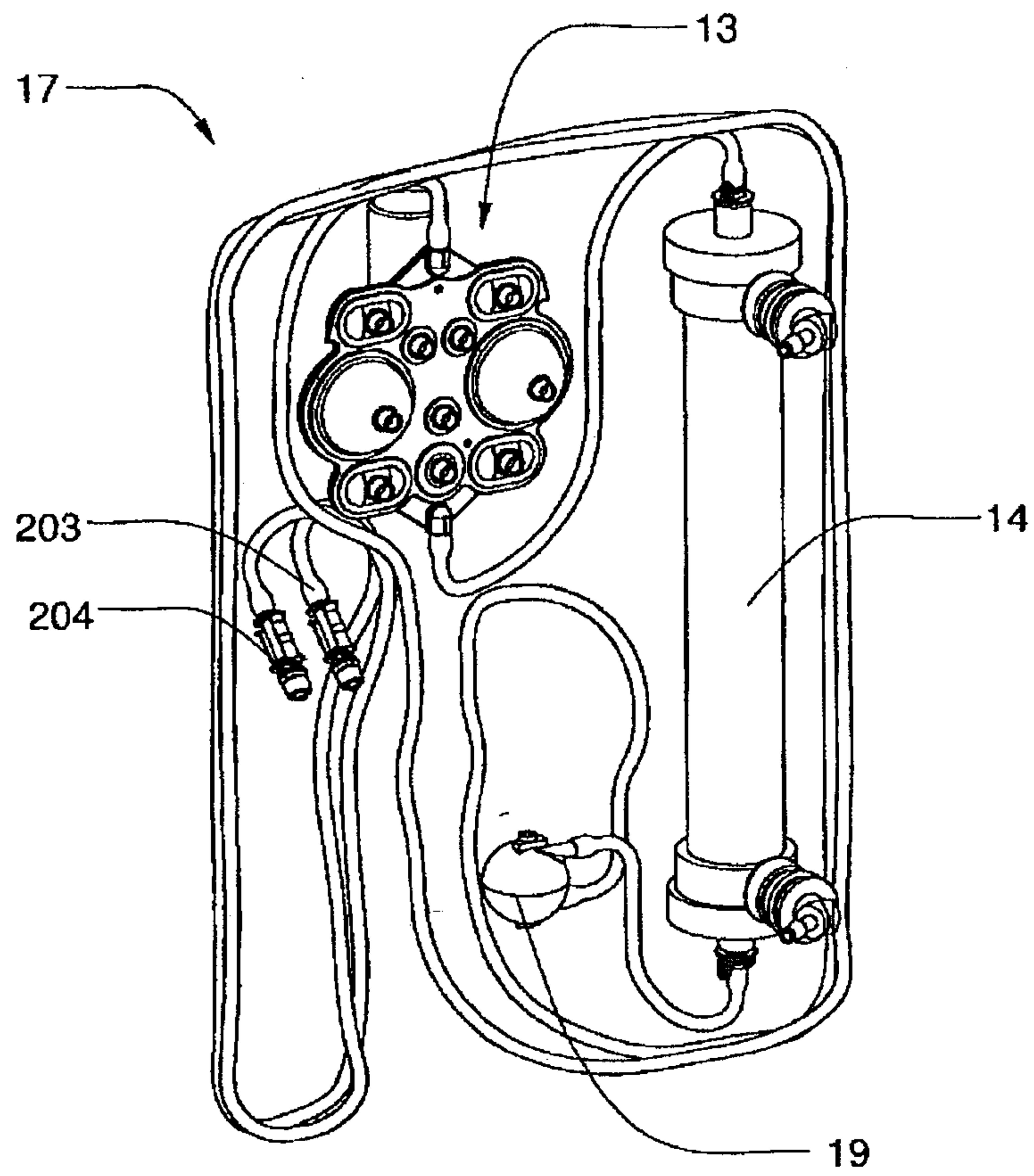


FIG. 20

SUBSTITUTE SHEET (RULE 26)

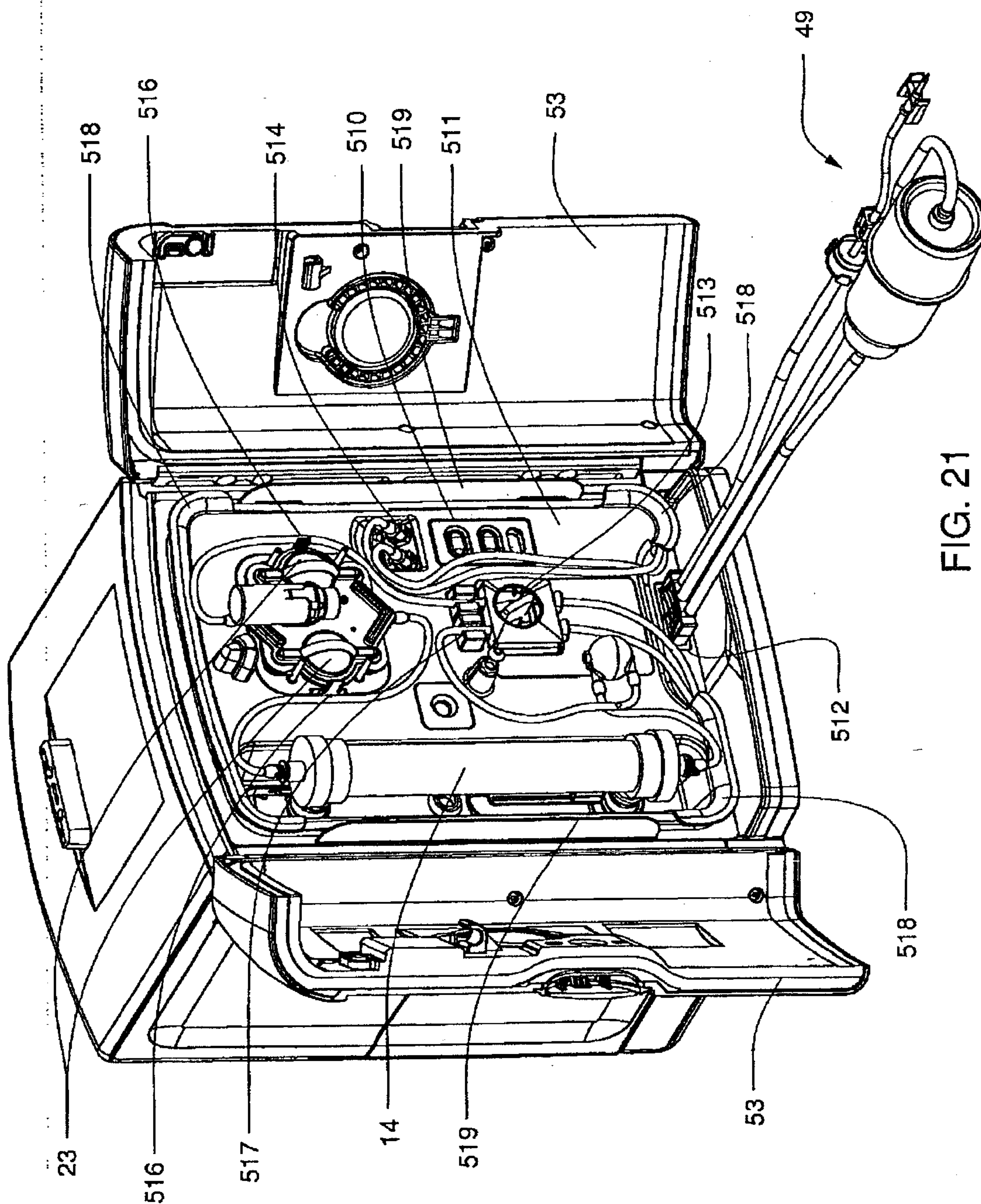


FIG. 21

SUBSTITUTE SHEET (RULE 26)

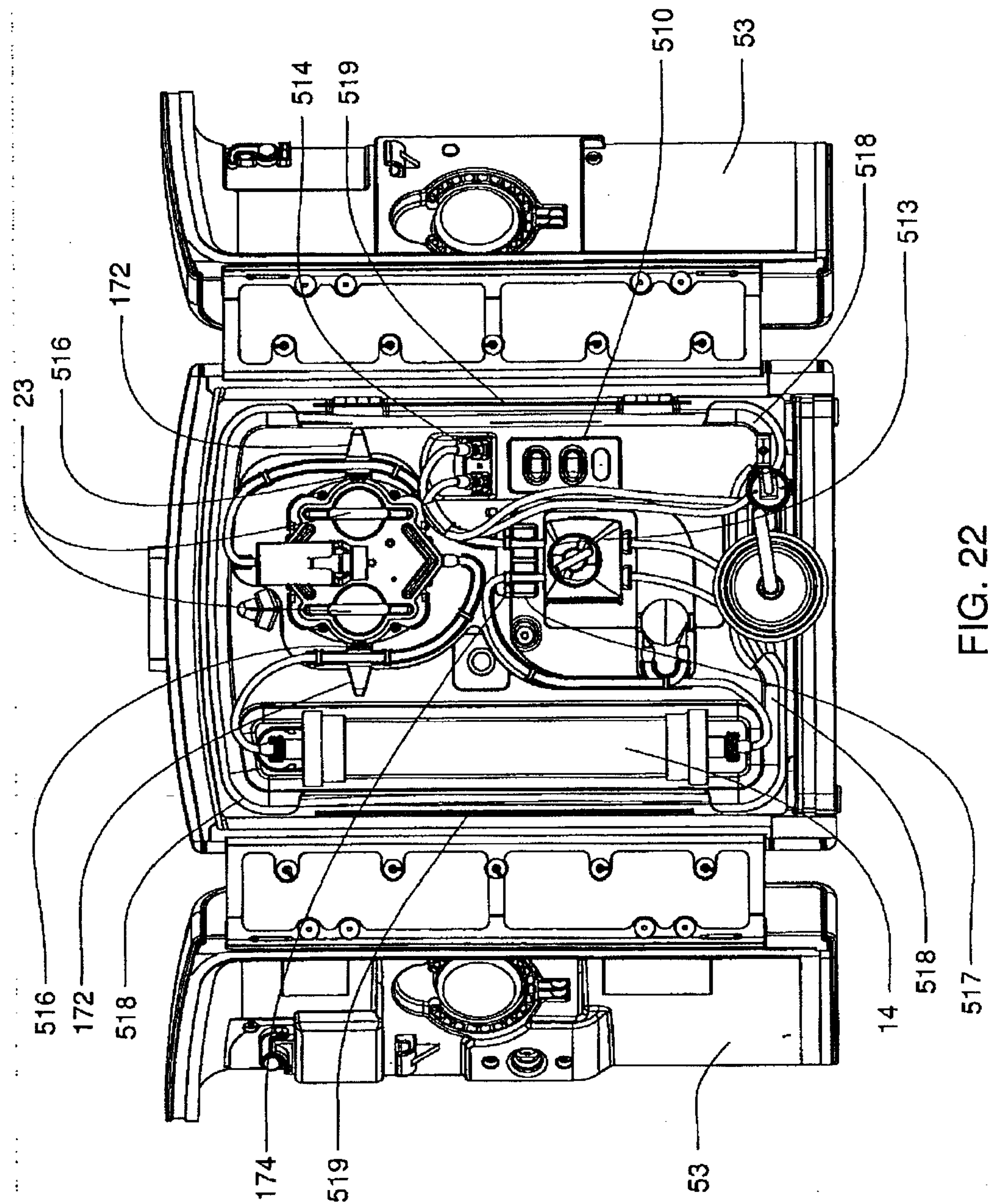


FIG. 22

SUBSTITUTE SHEET (RULE 26)

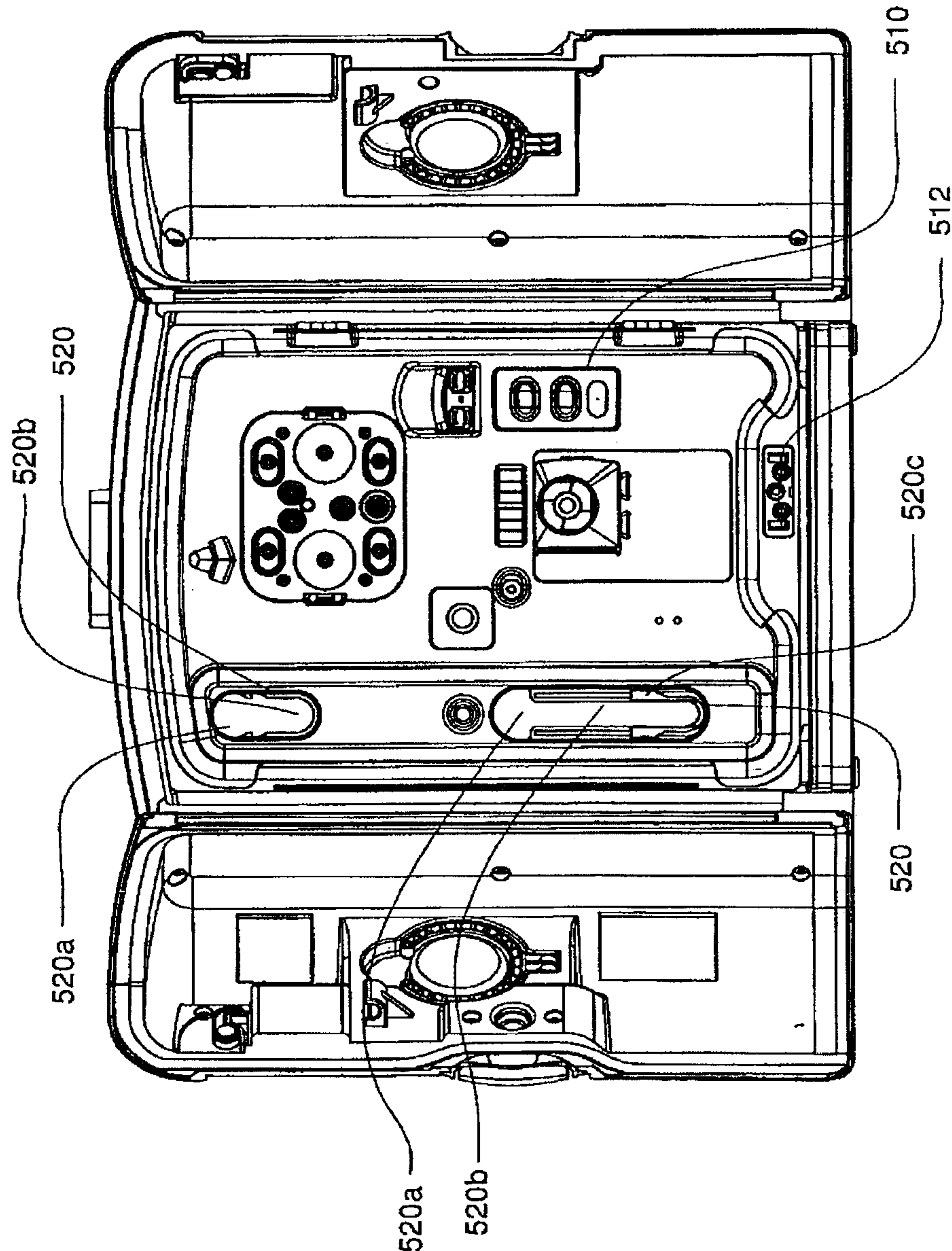


FIG. 23

SUBSTITUTE SHEET (RULE 26)

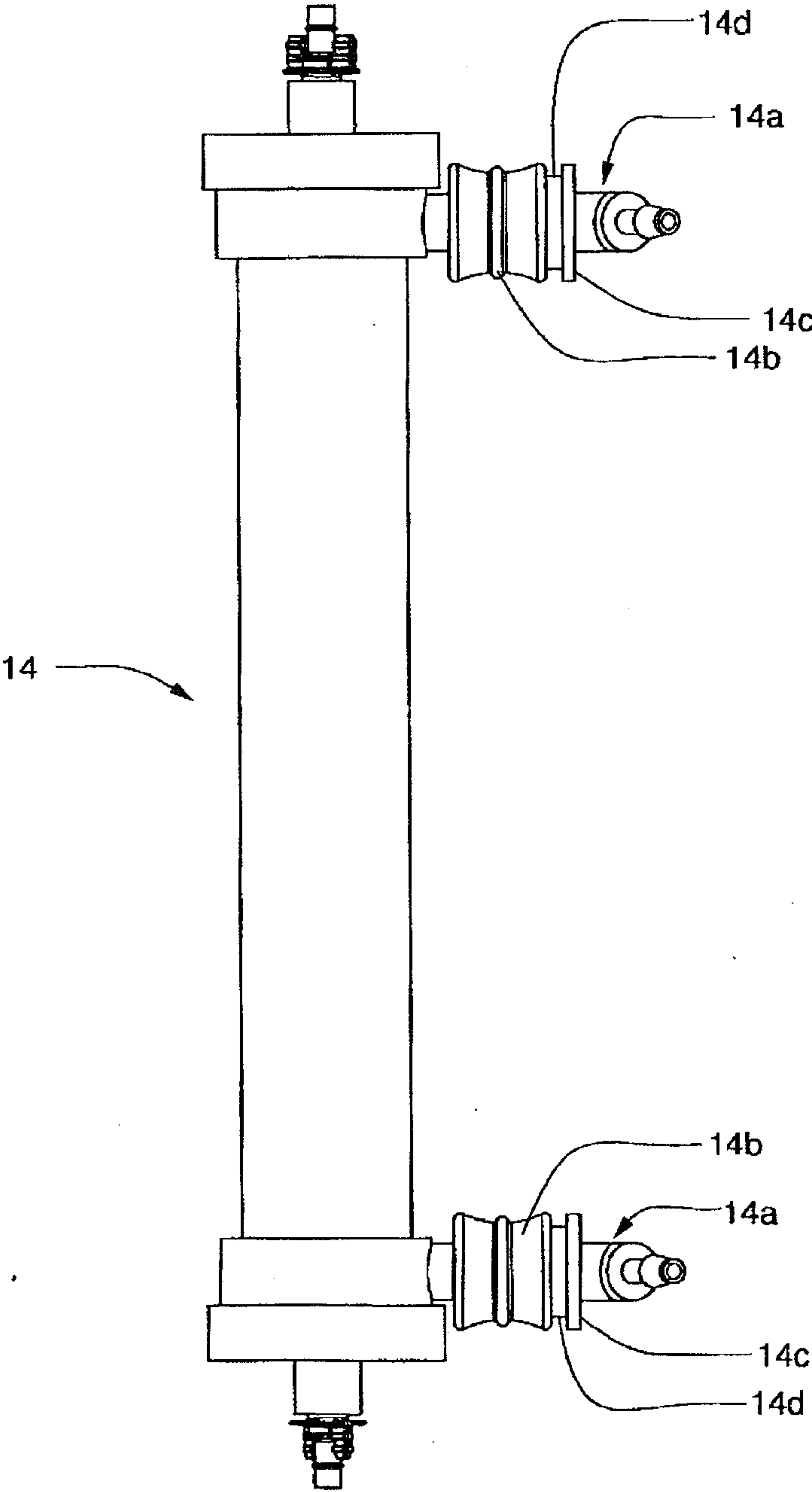


FIG. 24

SUBSTITUTE SHEET (RULE 26)

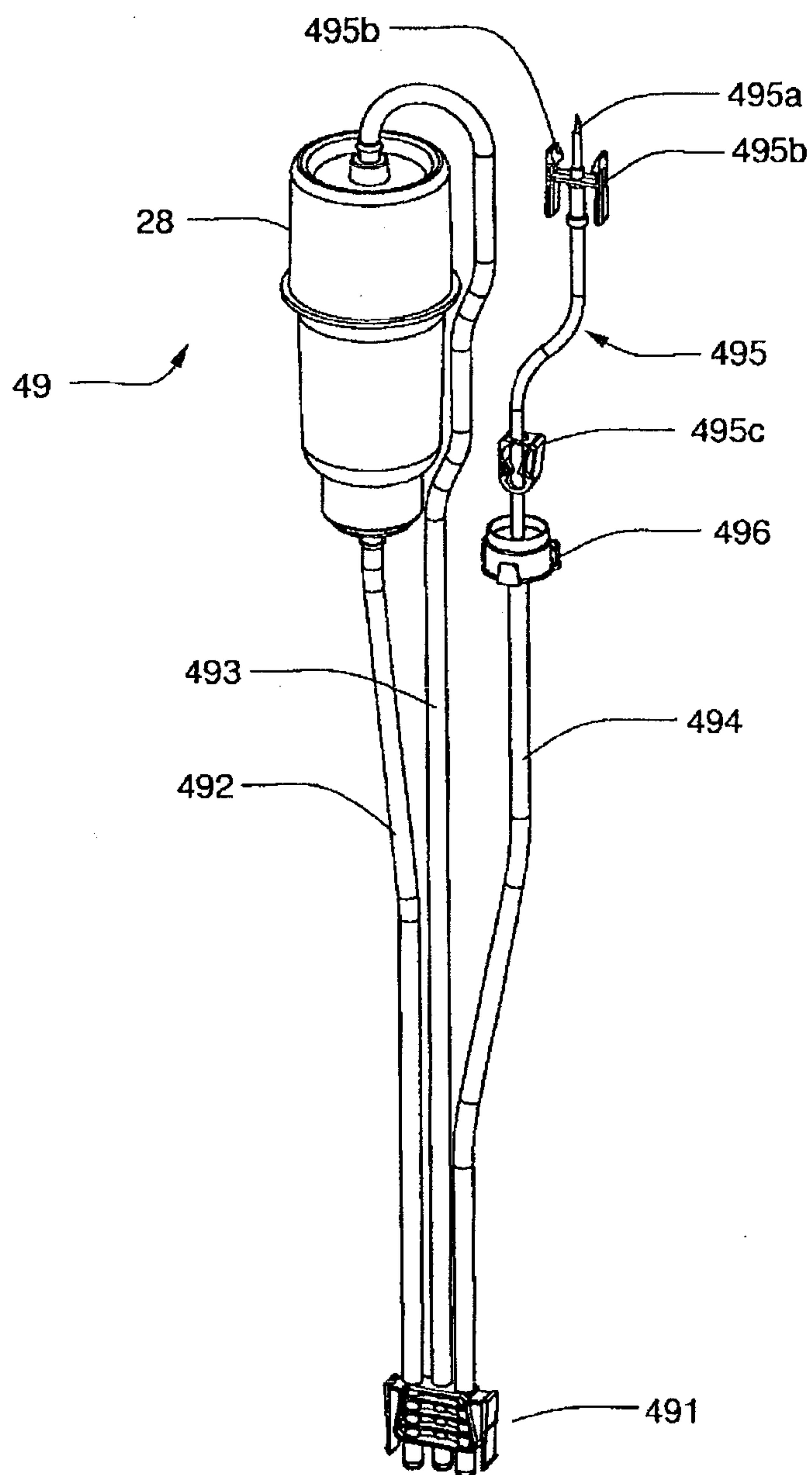


FIG. 25

SUBSTITUTE SHEET (RULE 26)

26/50

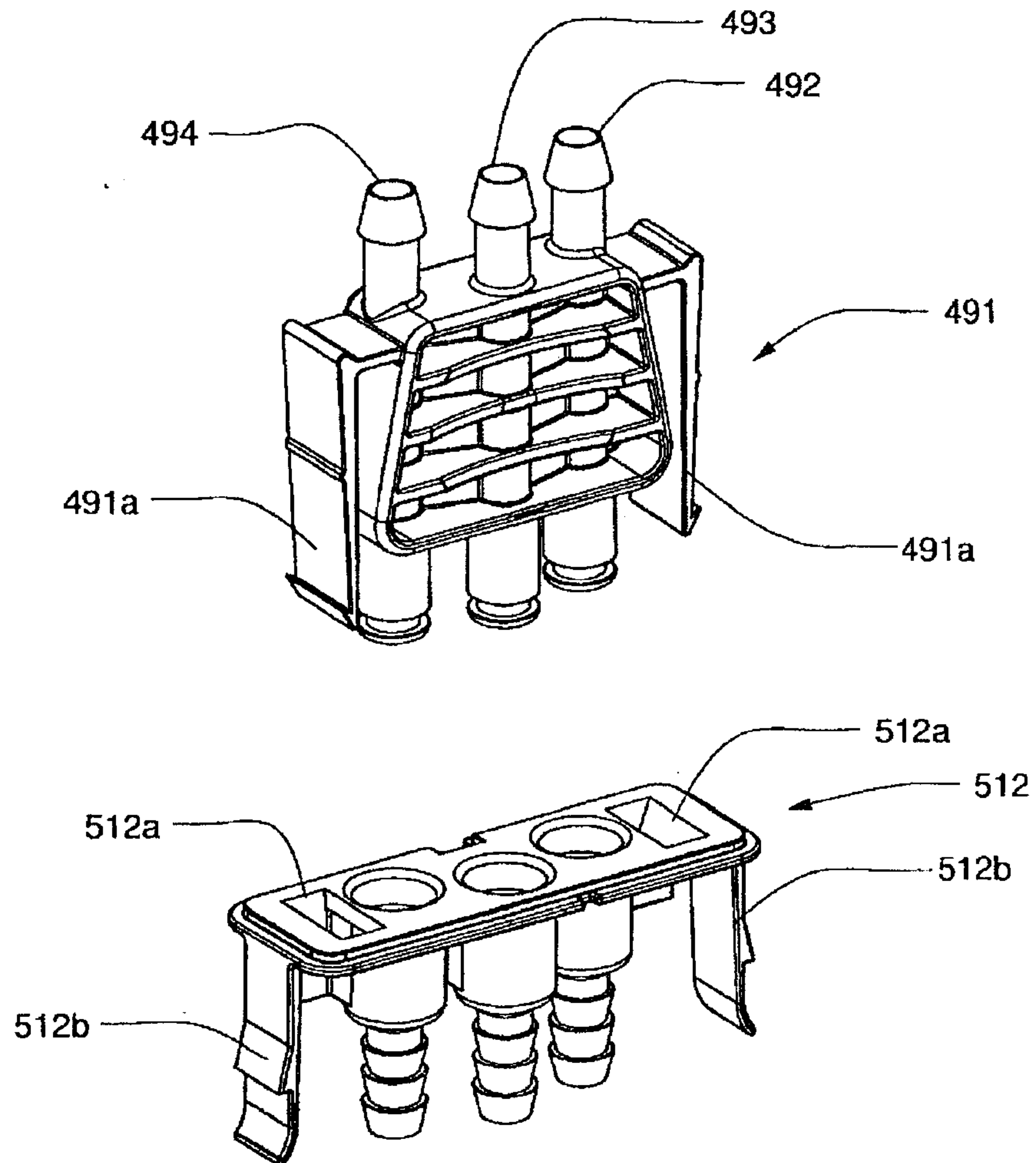


FIG. 26

SUBSTITUTE SHEET (RULE 26)

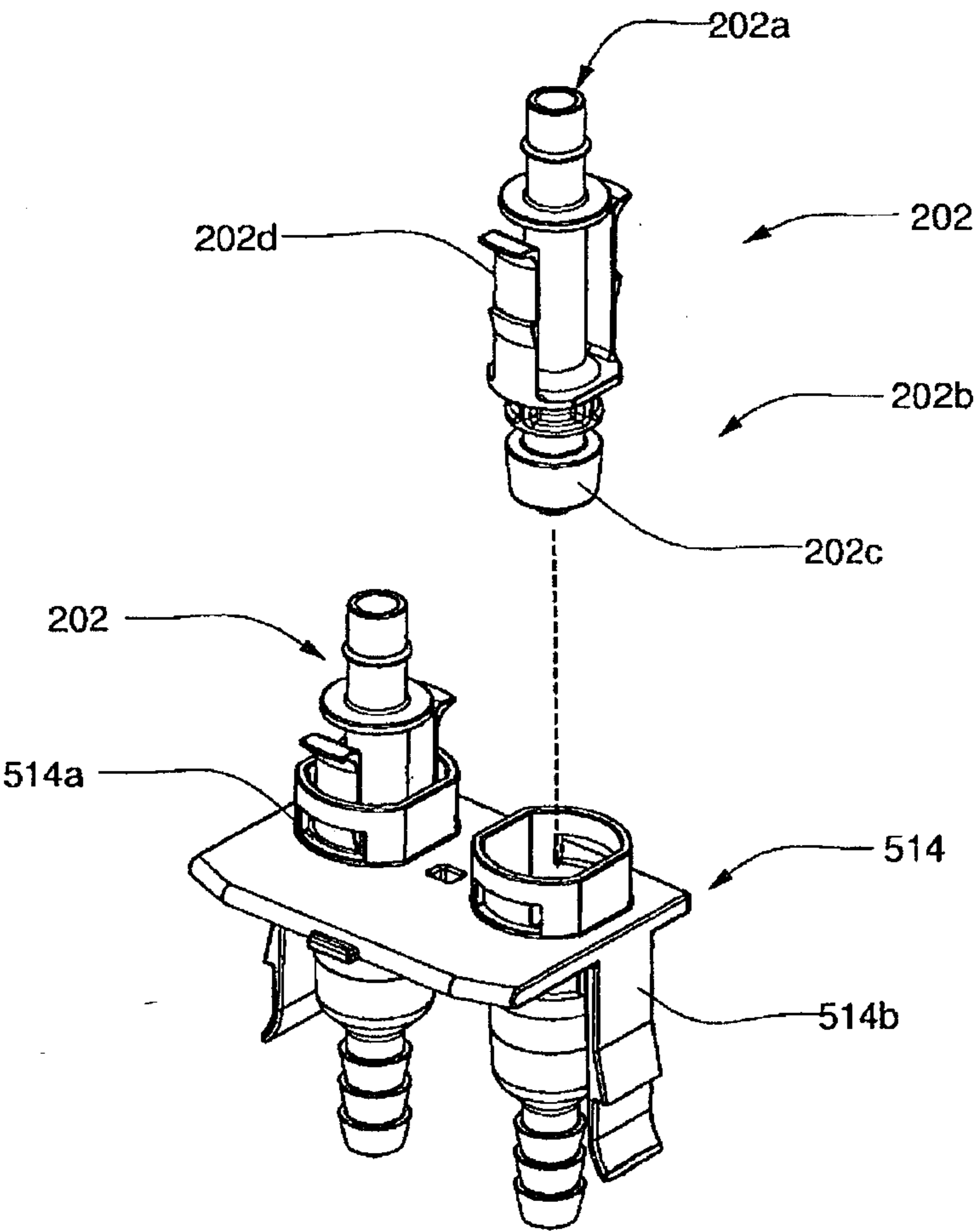


FIG. 27

SUBSTITUTE SHEET (RULE 26)

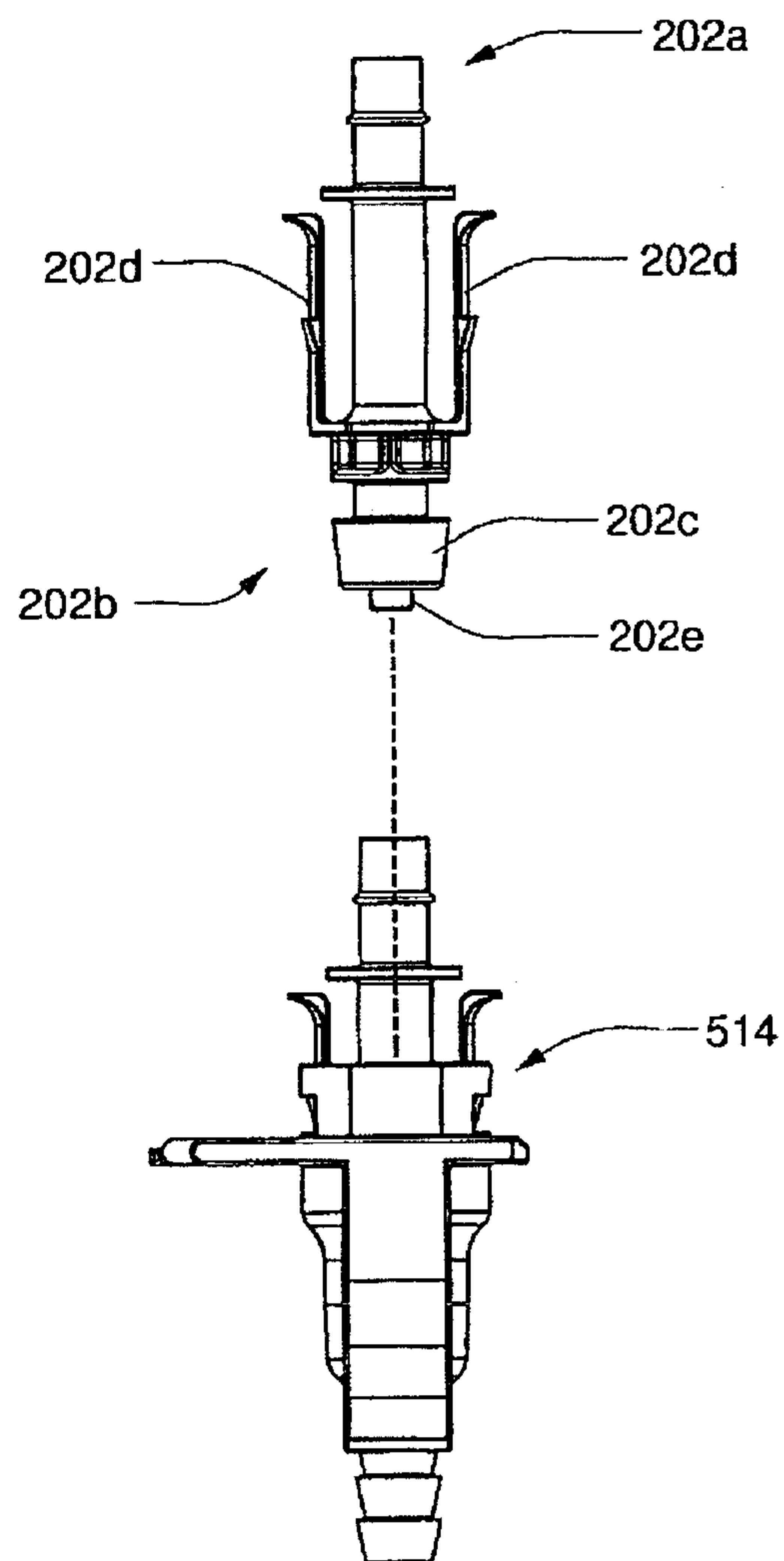


FIG. 28

SUBSTITUTE SHEET (RULE 26)

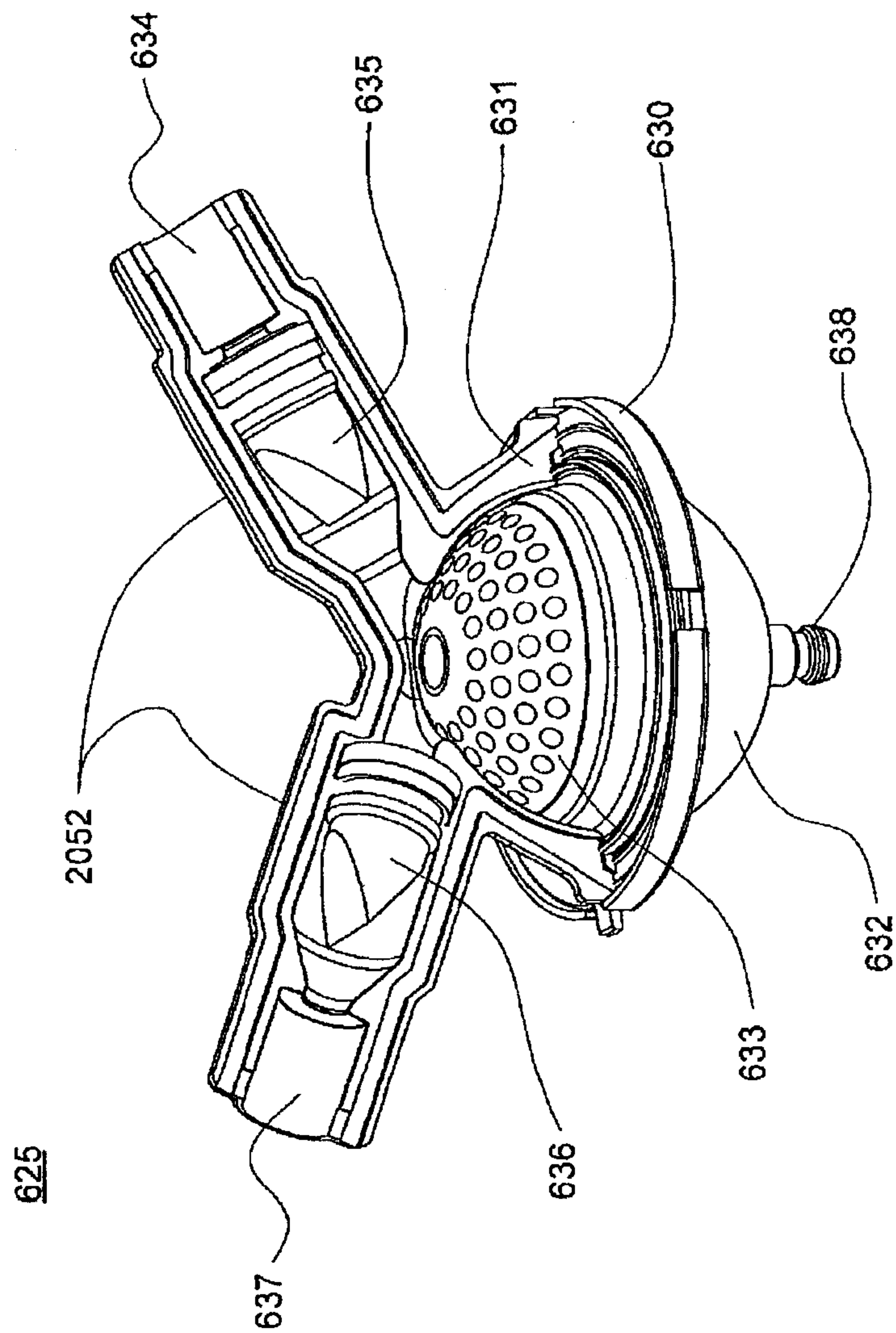


FIG. 29

SUBSTITUTE SHEET (RULE 26)

+

2025

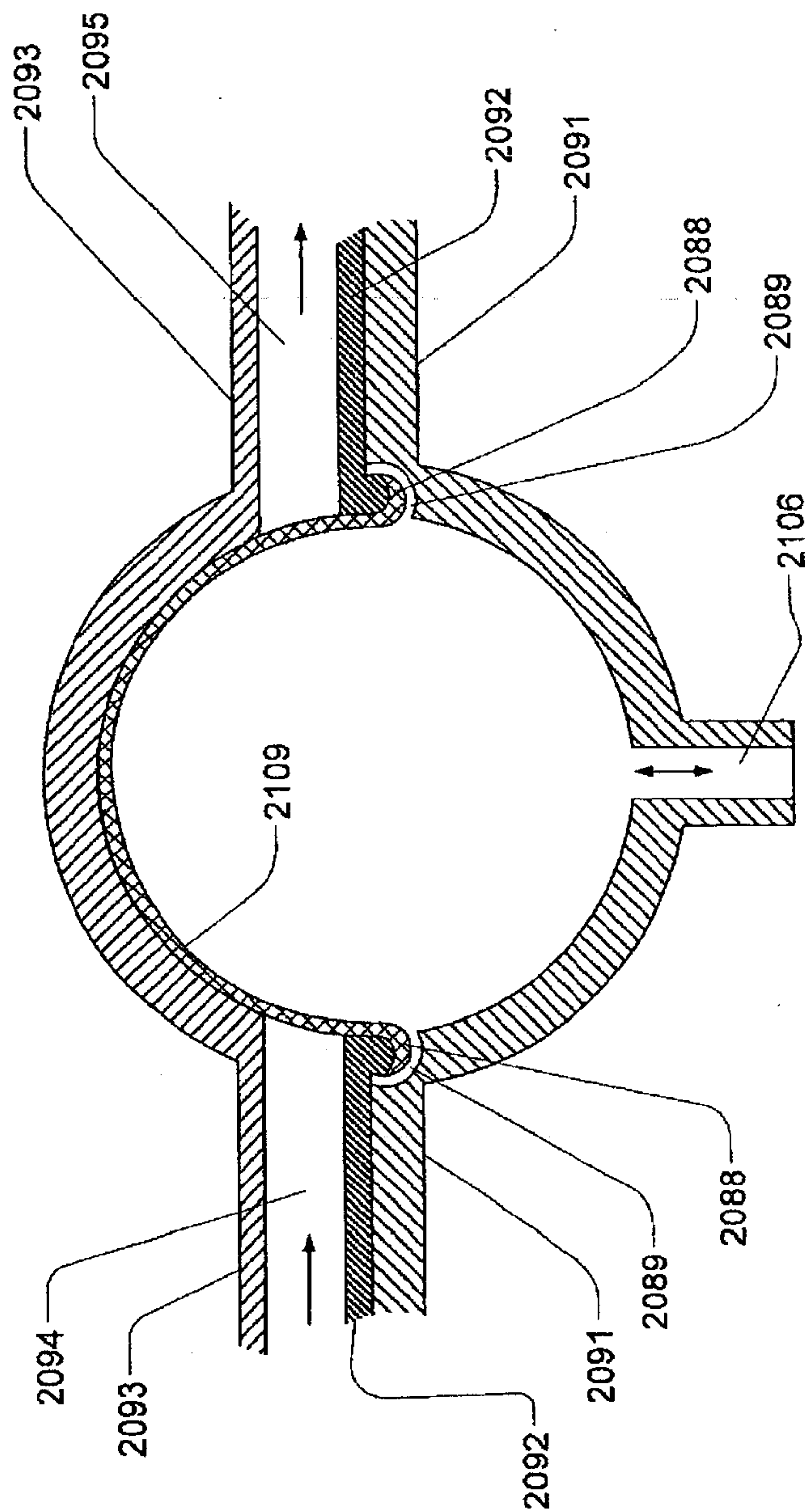


FIG. 30

SUBSTITUTE SHEET (RULE 26)

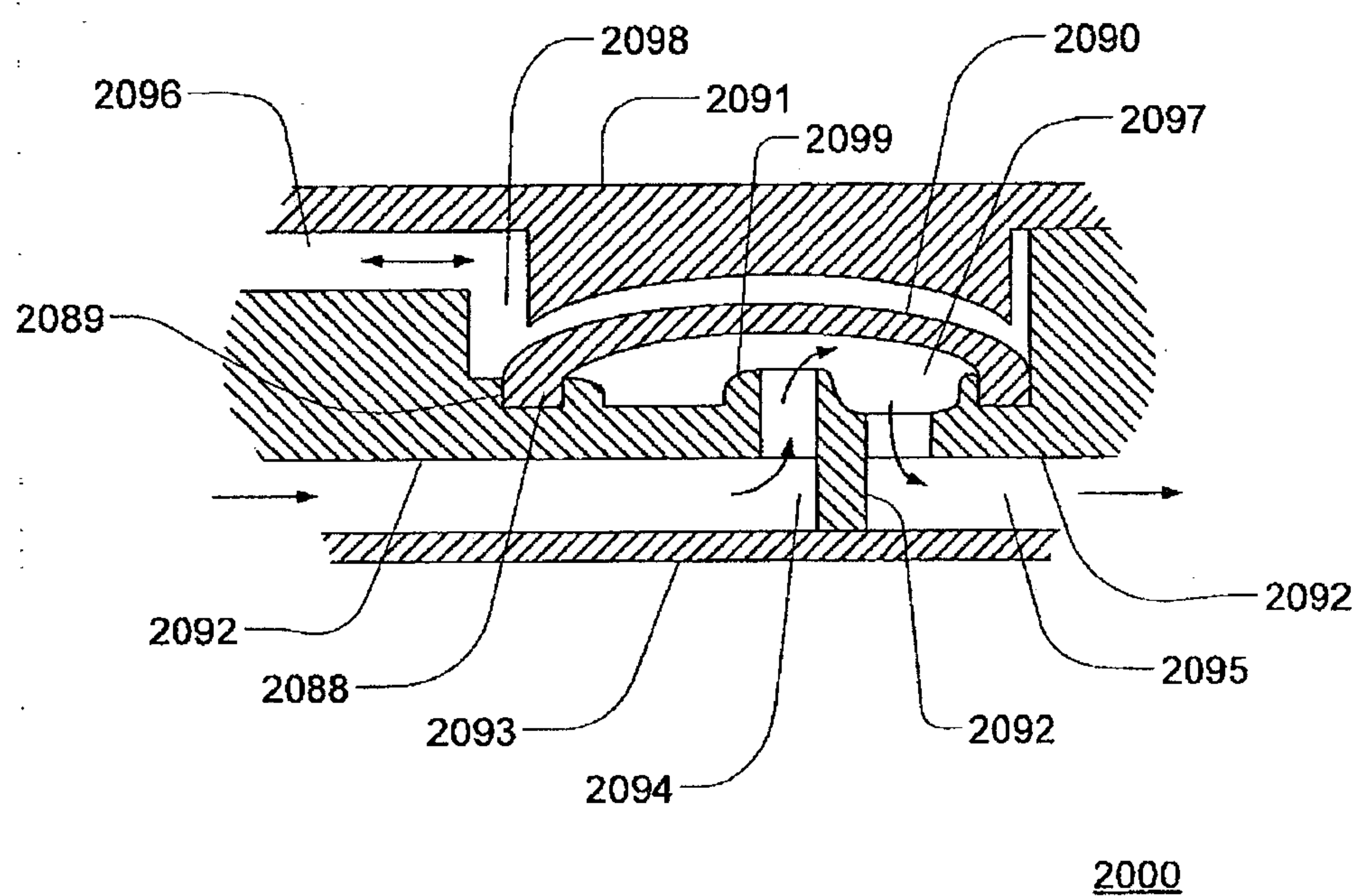


FIG. 31

SUBSTITUTE SHEET (RULE 26)

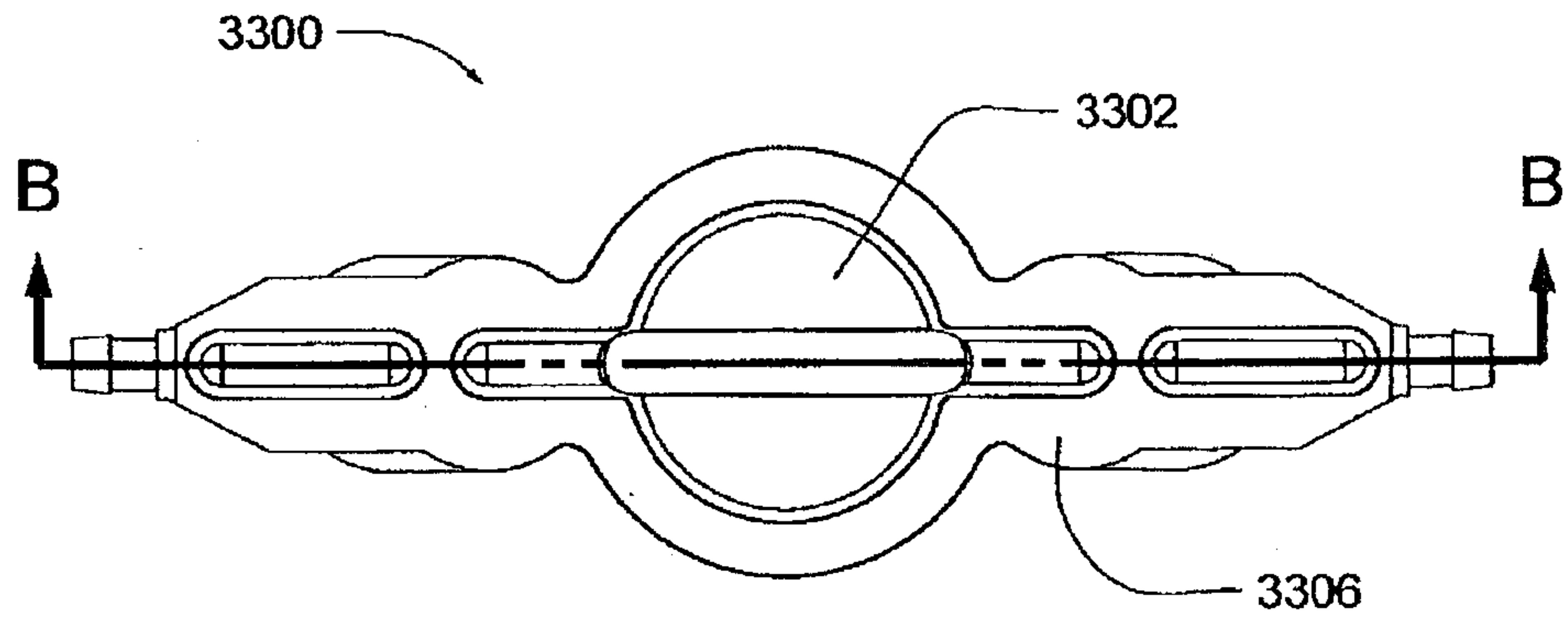


FIG. 32A

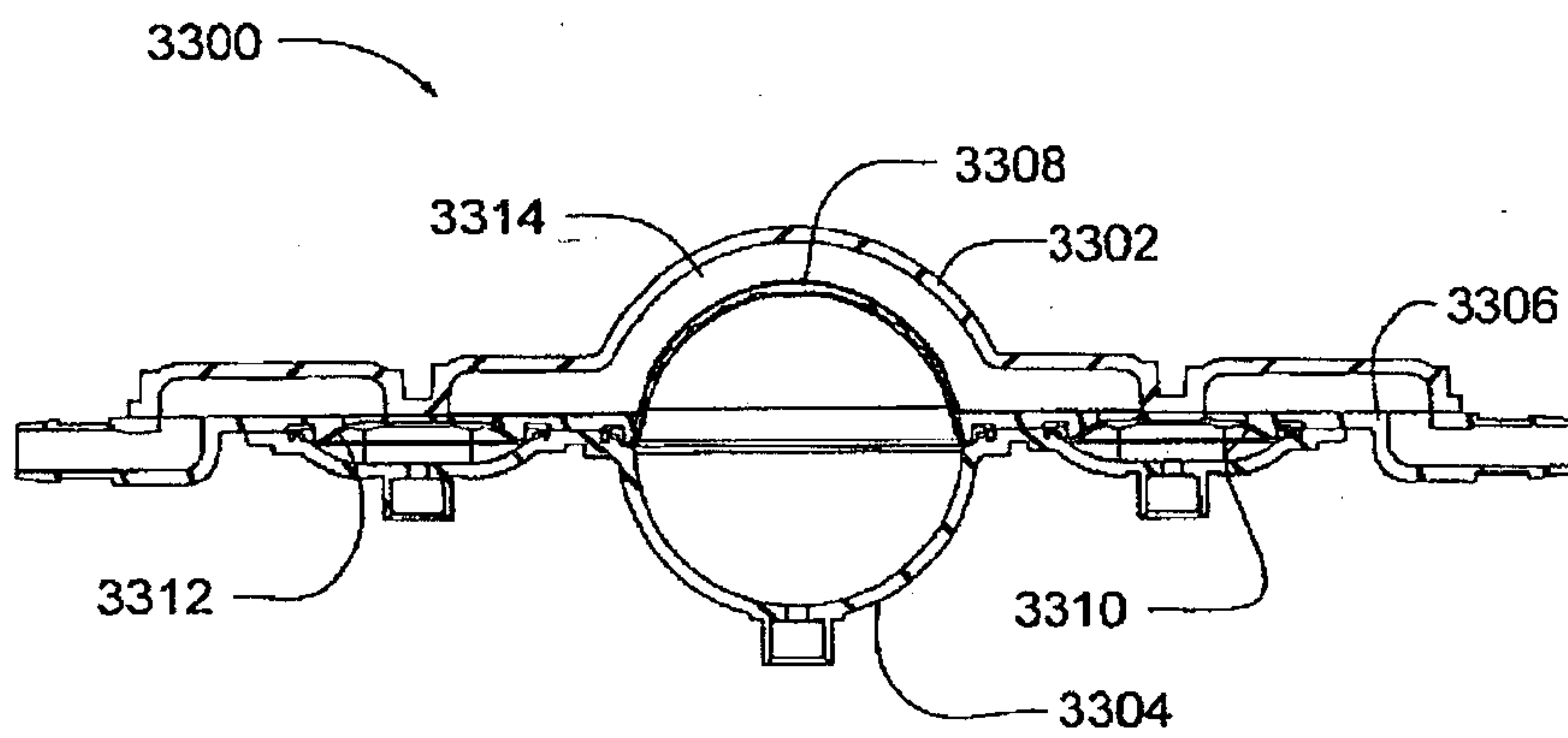


FIG. 32B

SUBSTITUTE SHEET (RULE 26)

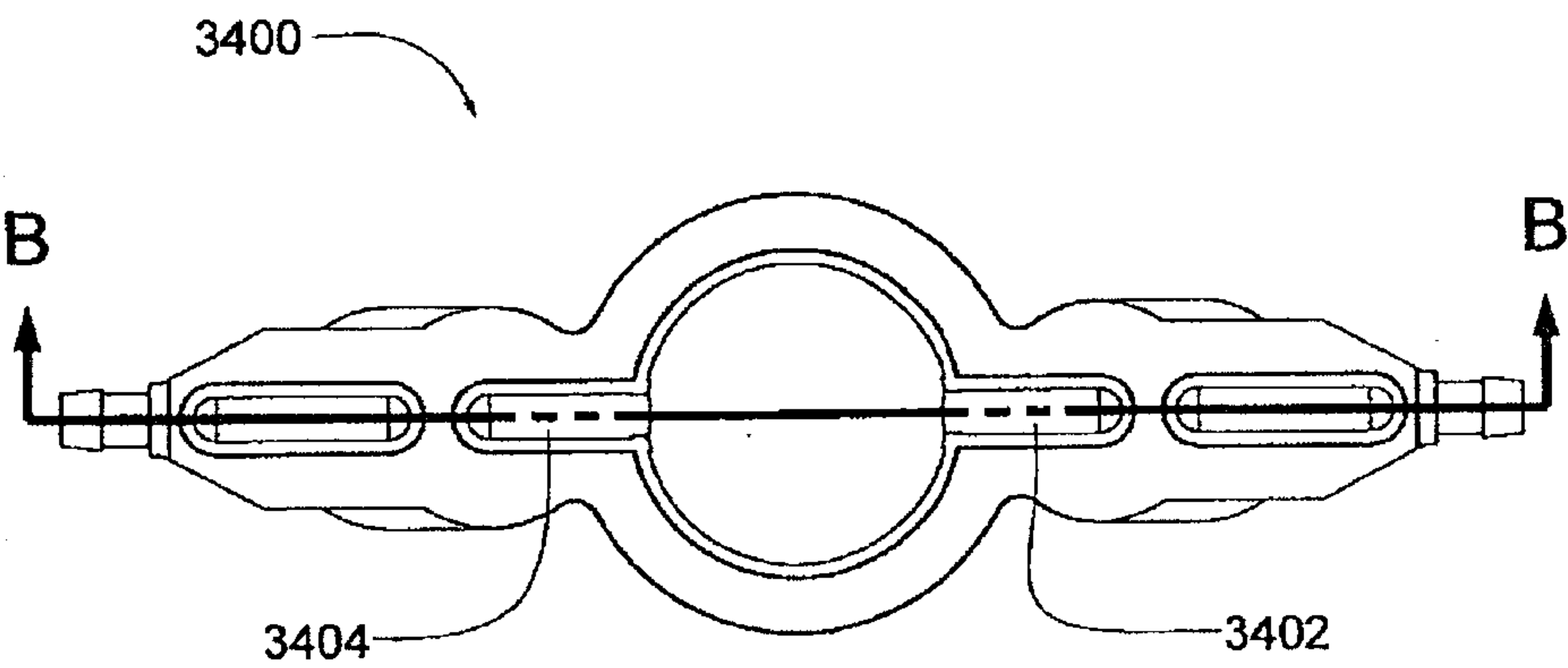


FIG. 33A

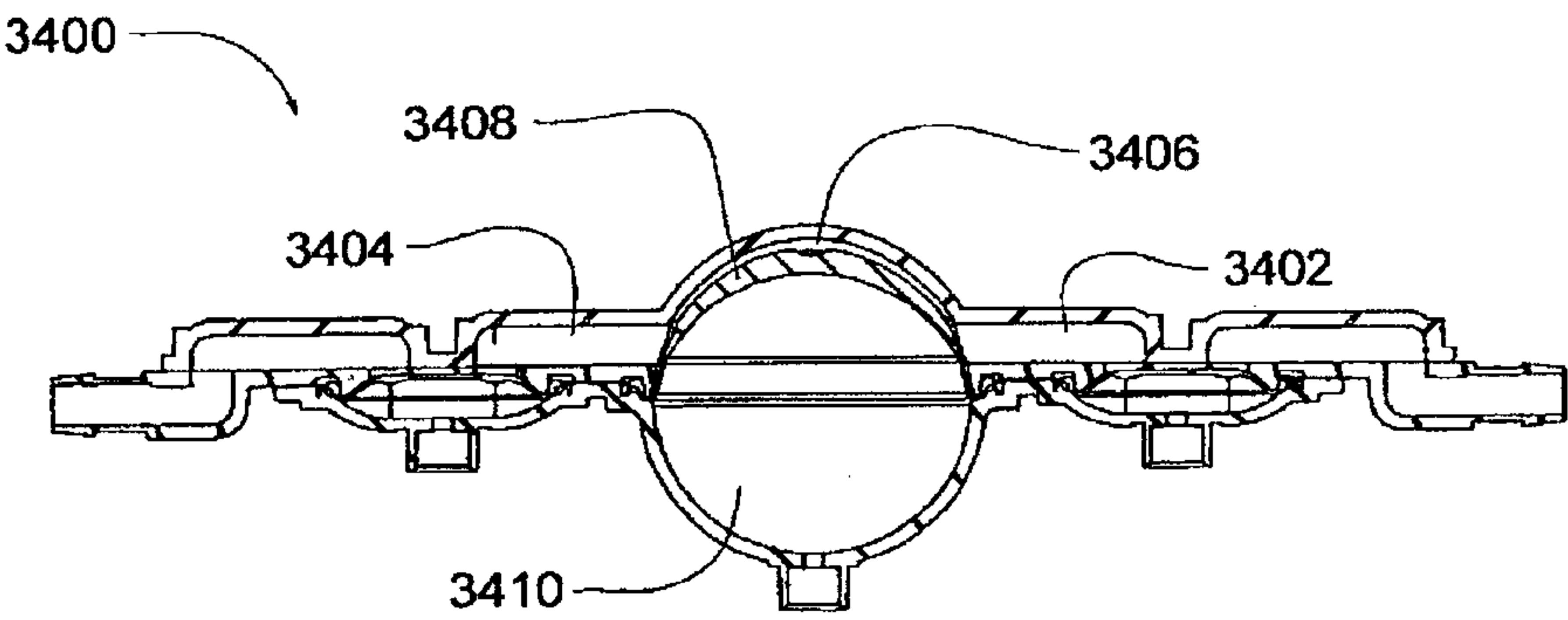


FIG. 33B

SUBSTITUTE SHEET (RULE 26)

34/50

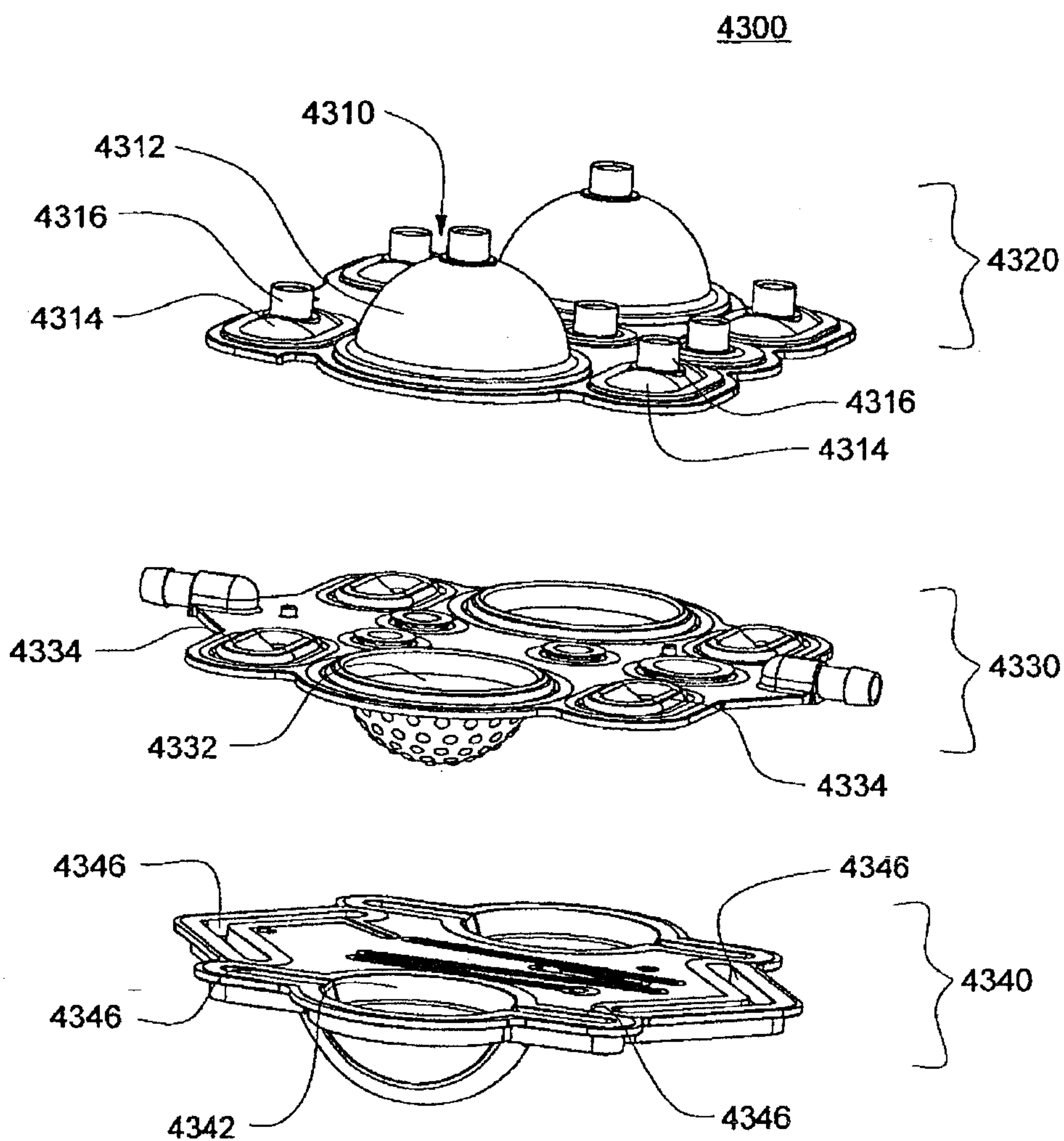


FIG. 34A

SUBSTITUTE SHEET (RULE 26)

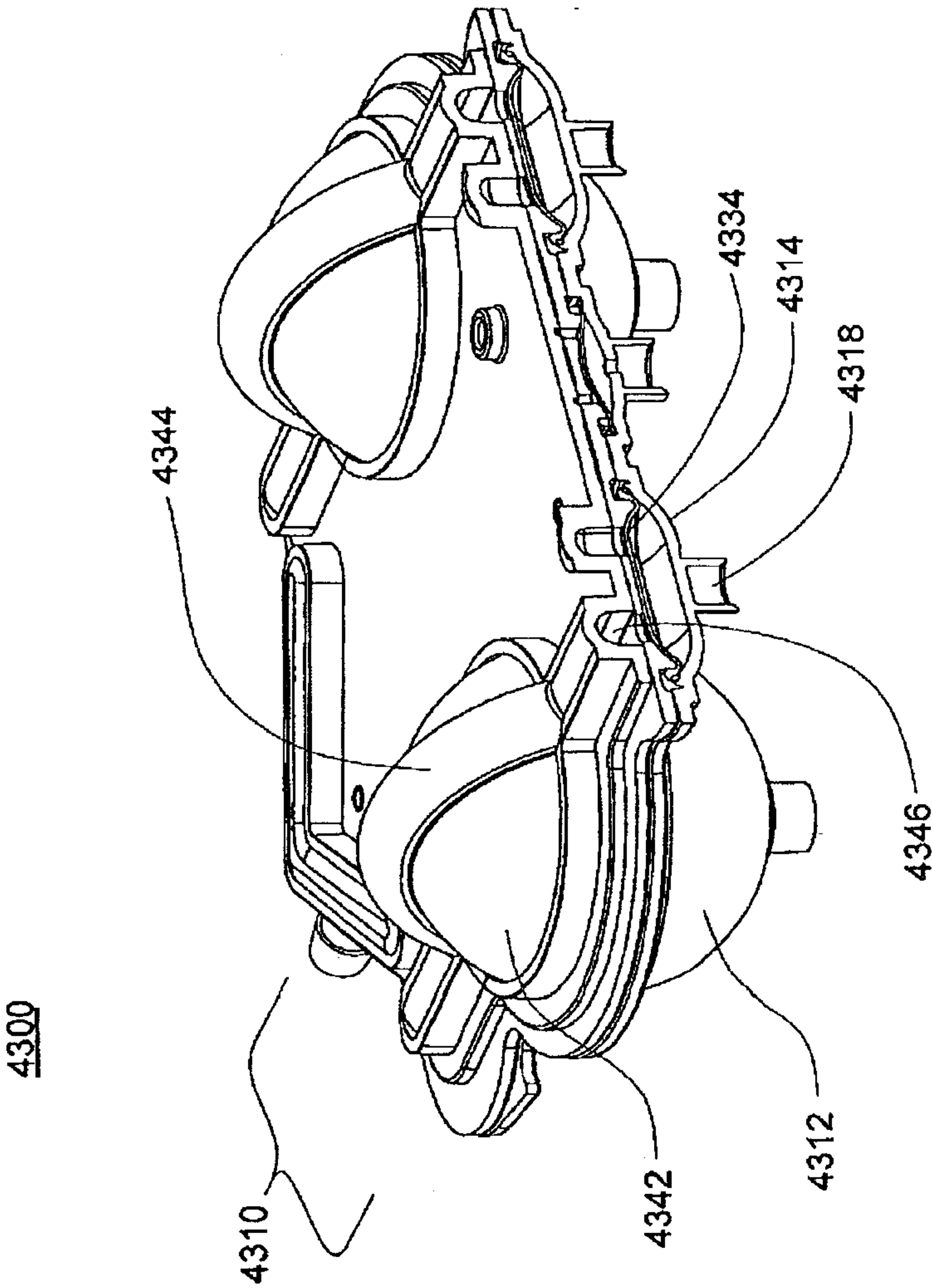


FIG. 34B

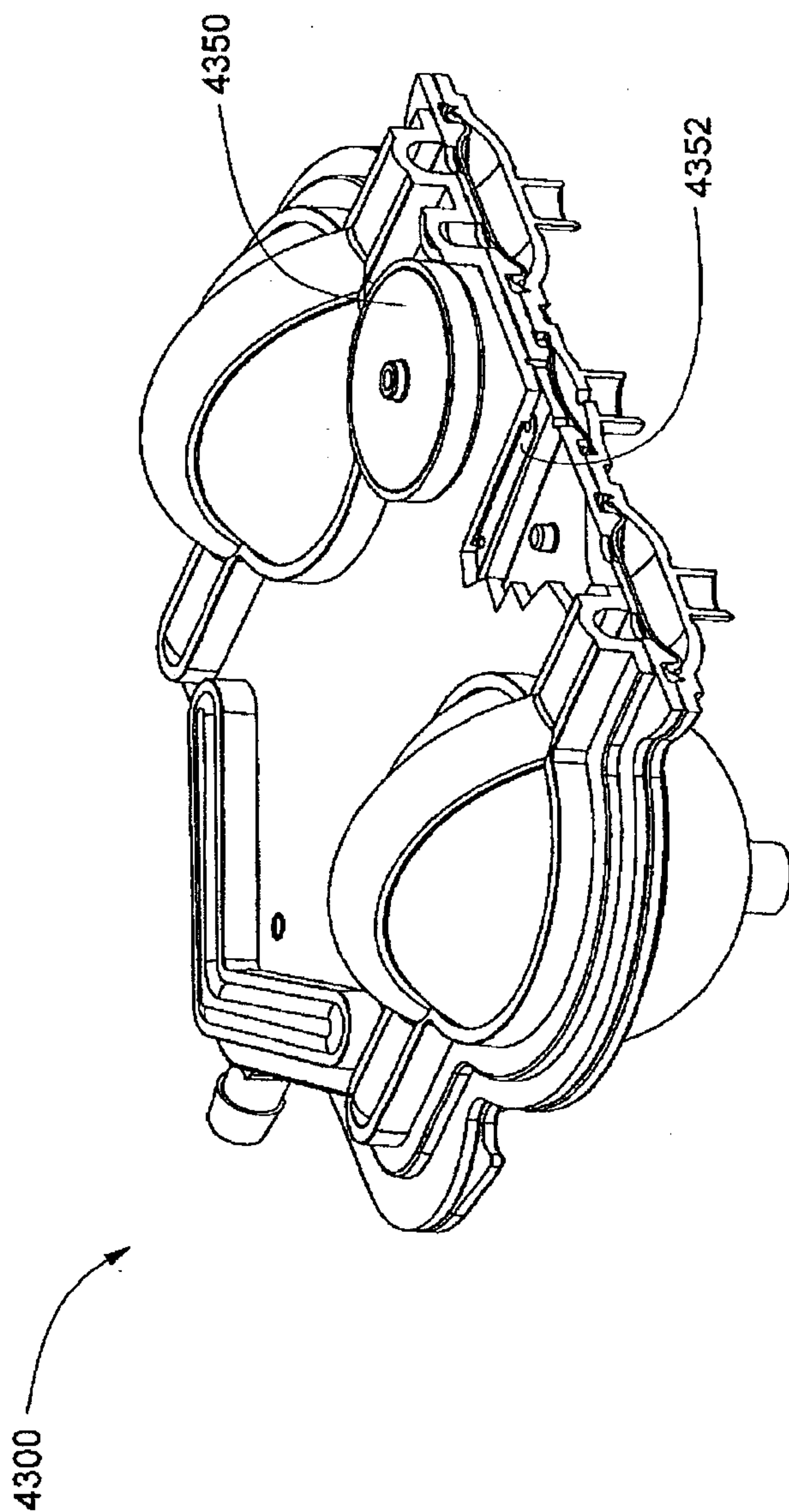


FIG. 34C

SUBSTITUTE SHEET (RULE 26)

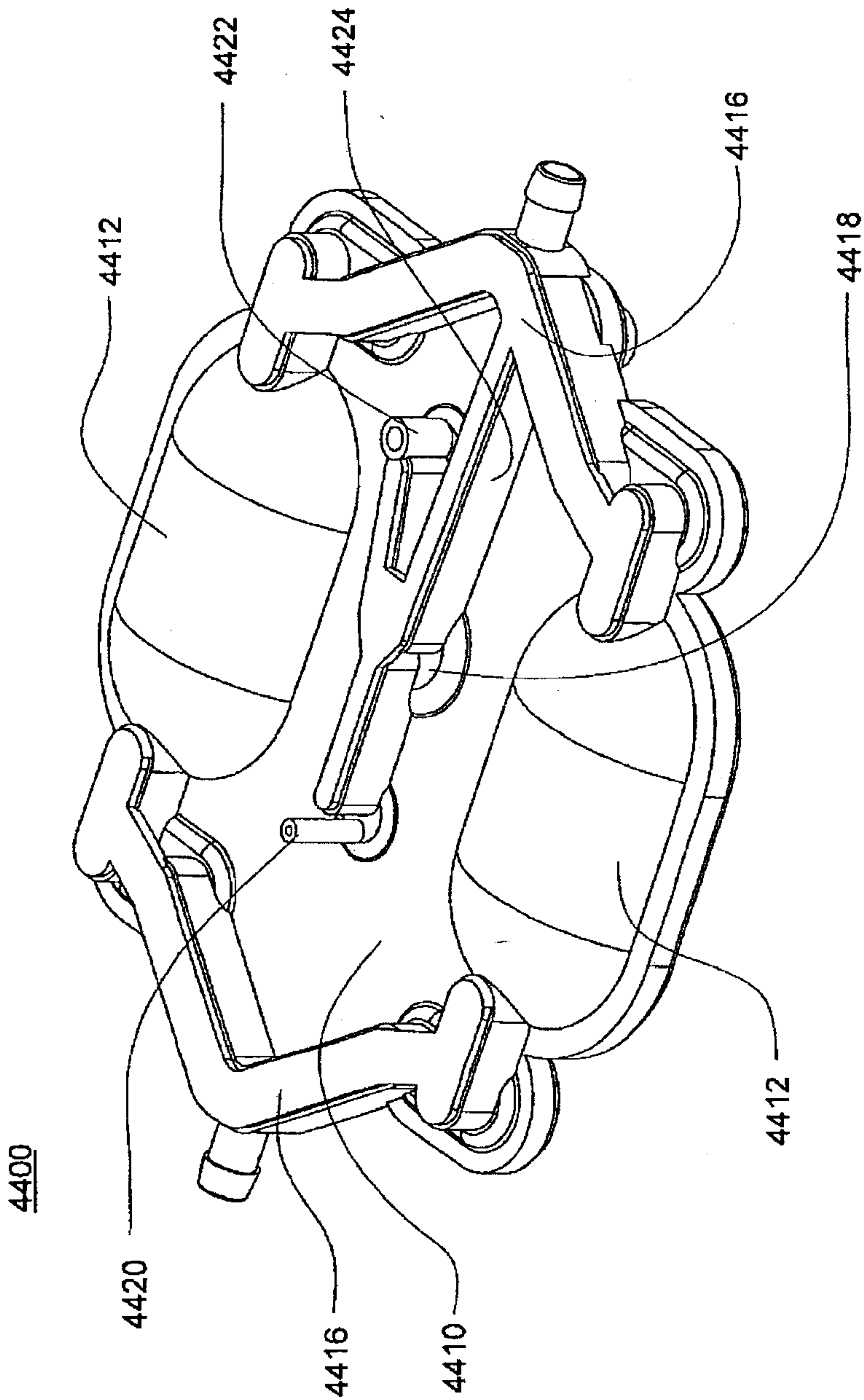


FIG. 35A

SUBSTITUTE SHEET (RULE 26)

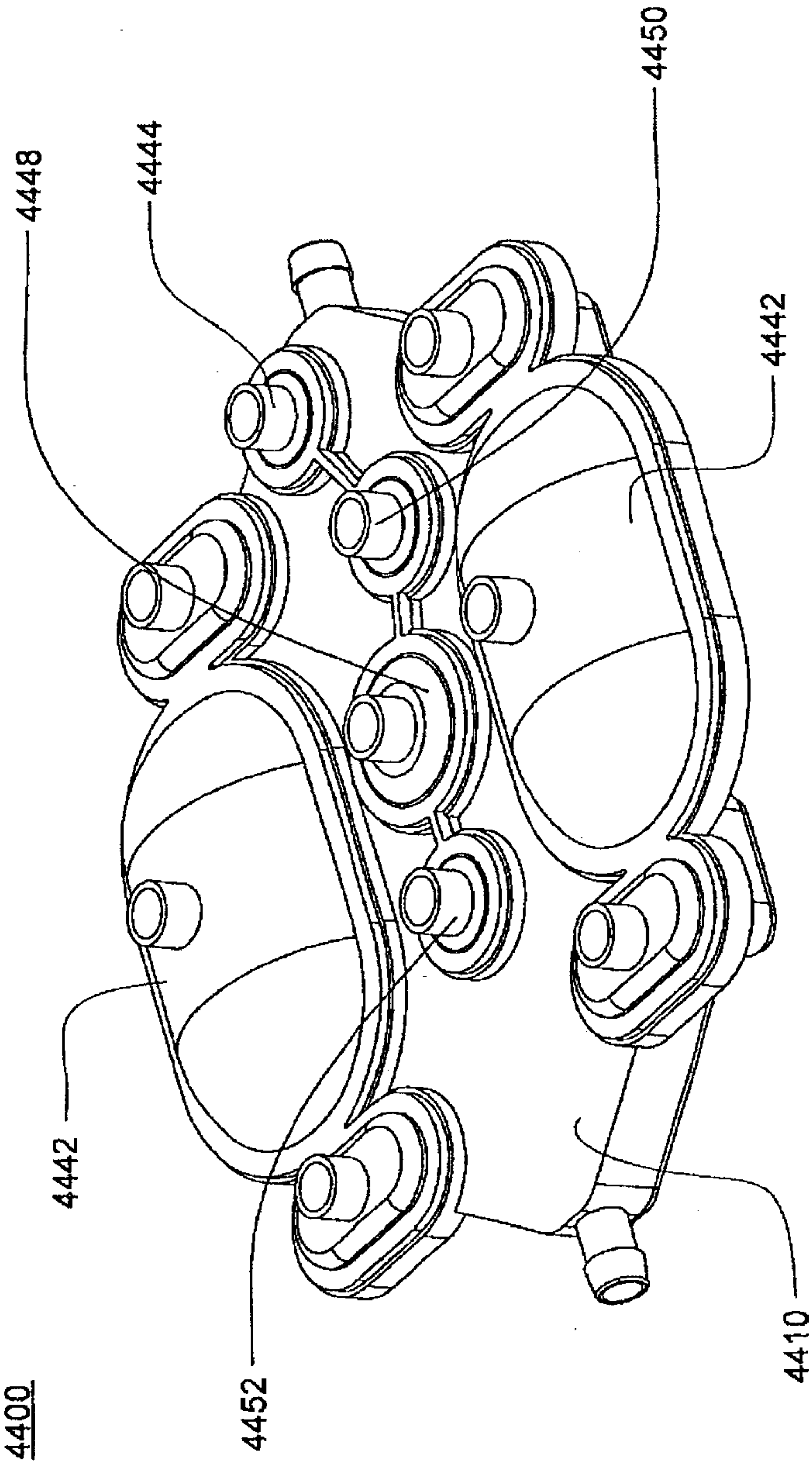


FIG. 35B

SUBSTITUTE SHEET (RULE 26)

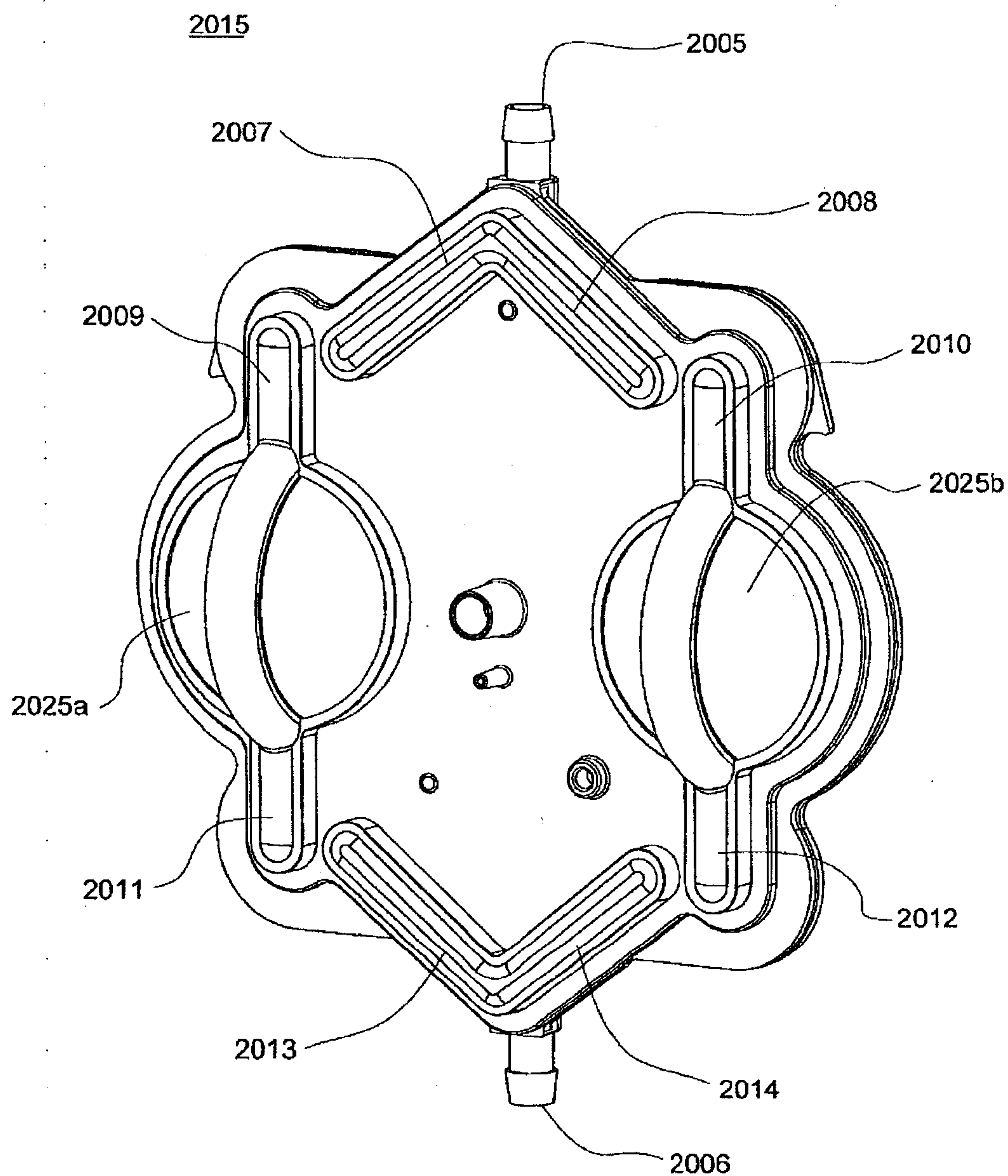


FIG. 36A

SUBSTITUTE SHEET (RULE 26)

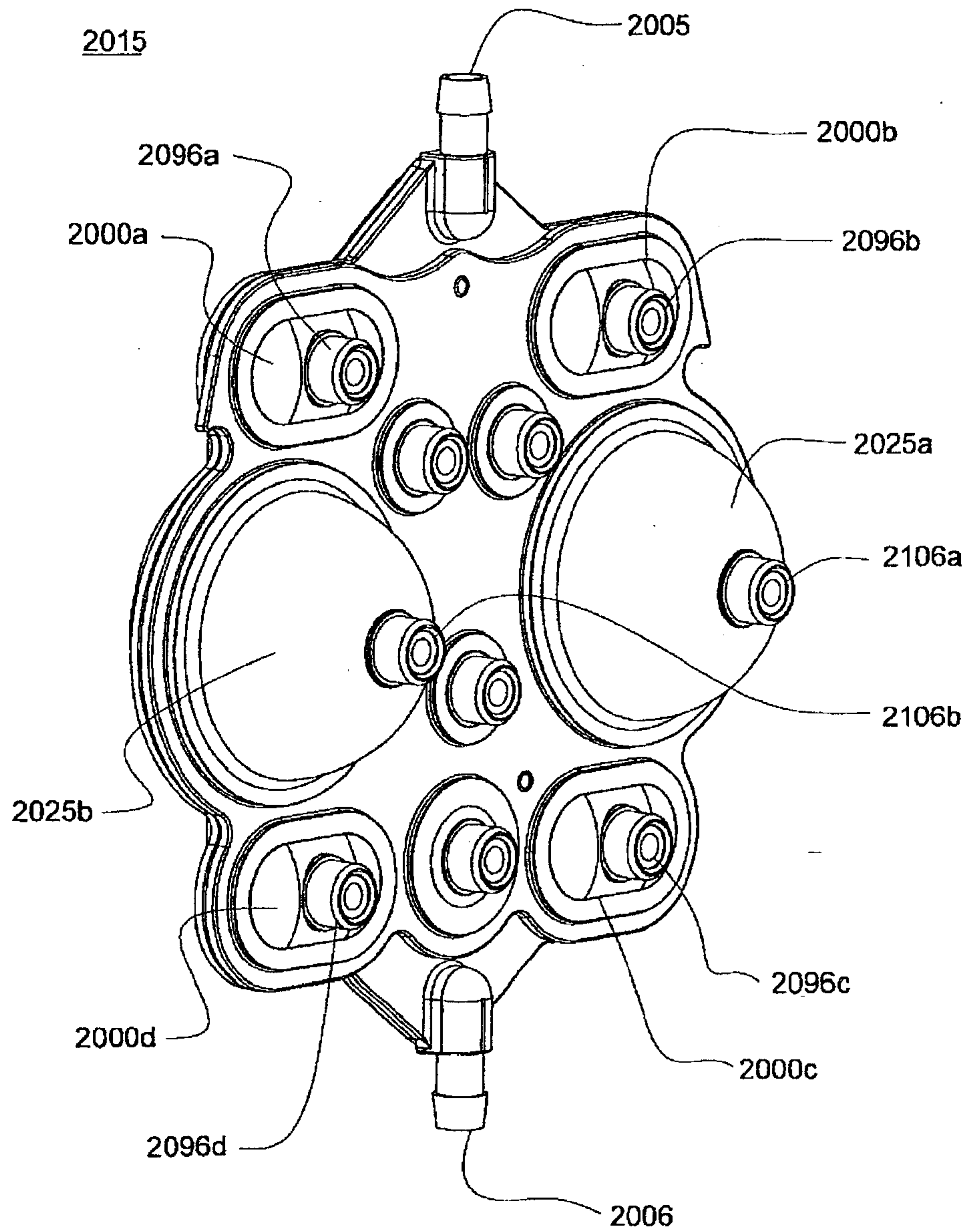
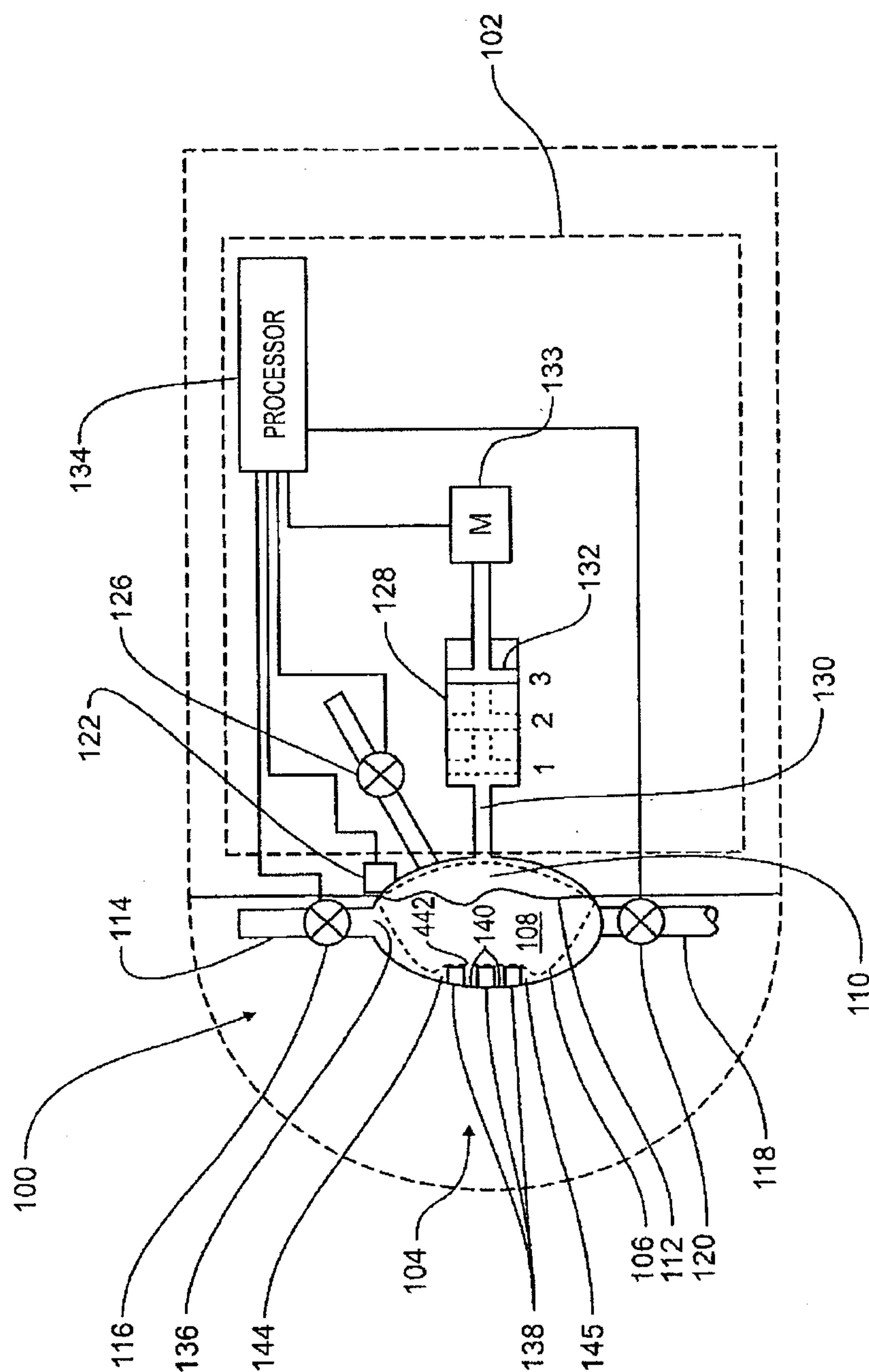


FIG. 36B

SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

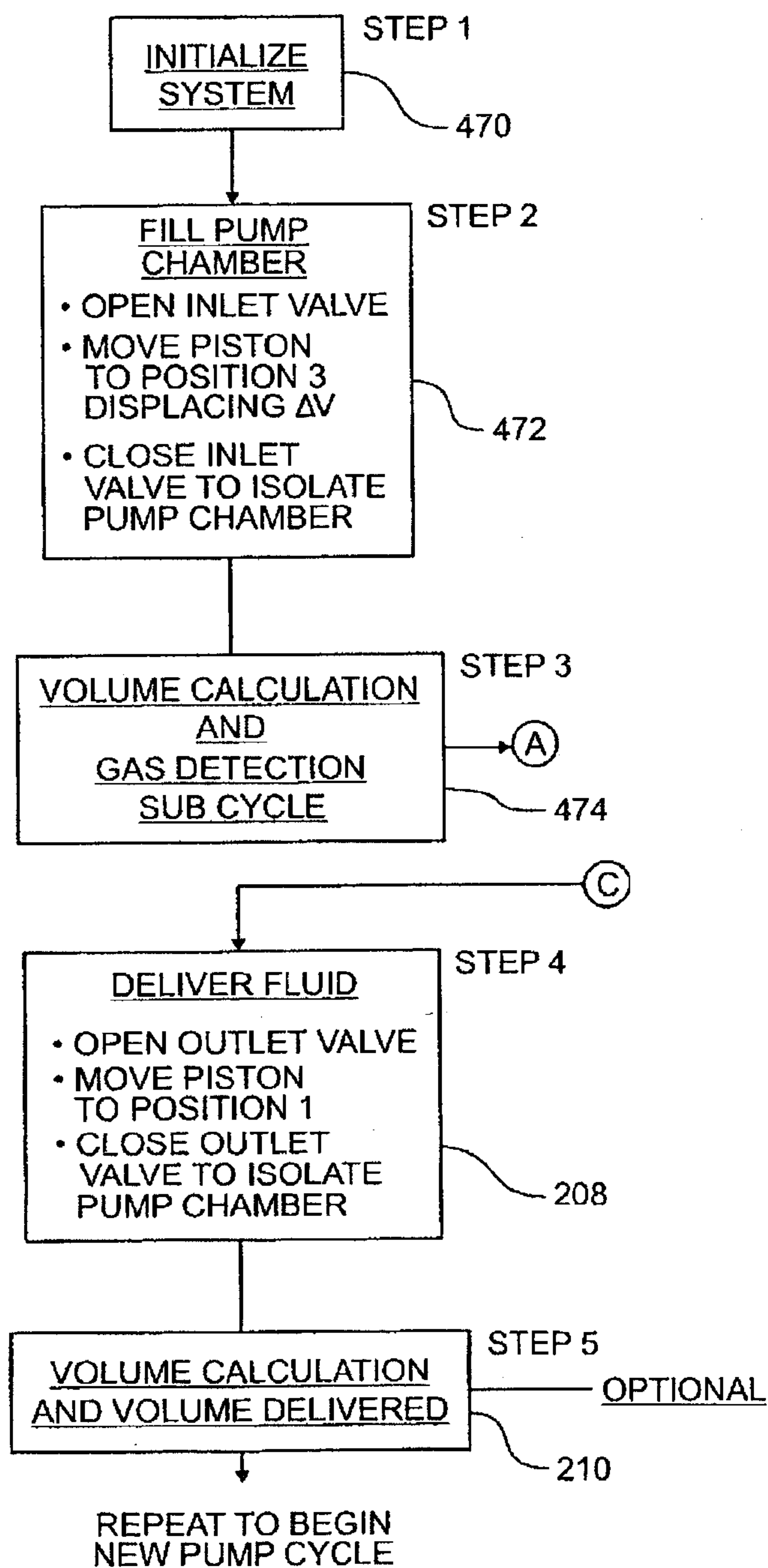


FIG. 38A

SUBSTITUTE SHEET (RULE 26)

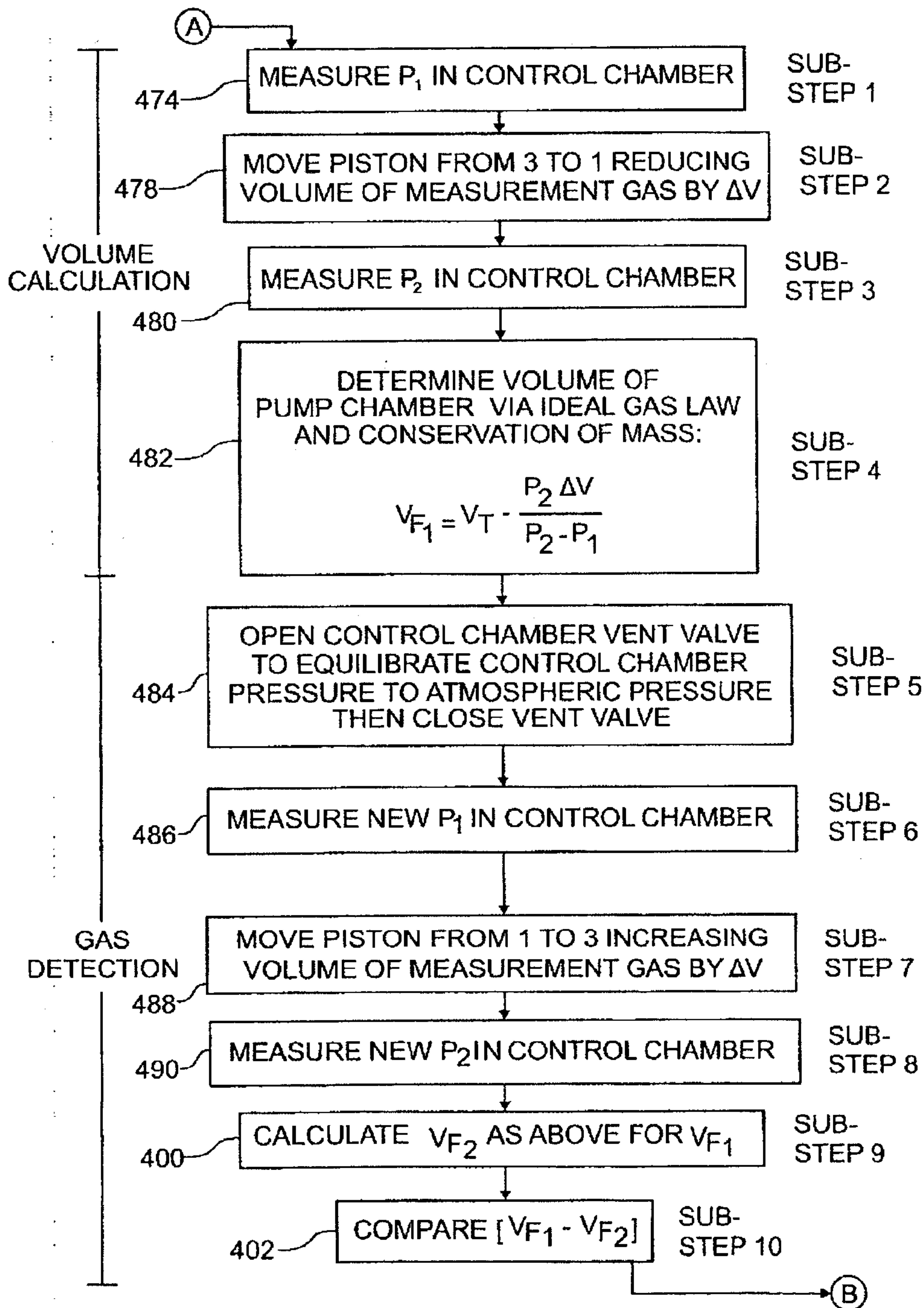


FIG. 38B

SUBSTITUTE SHEET (RULE 26)

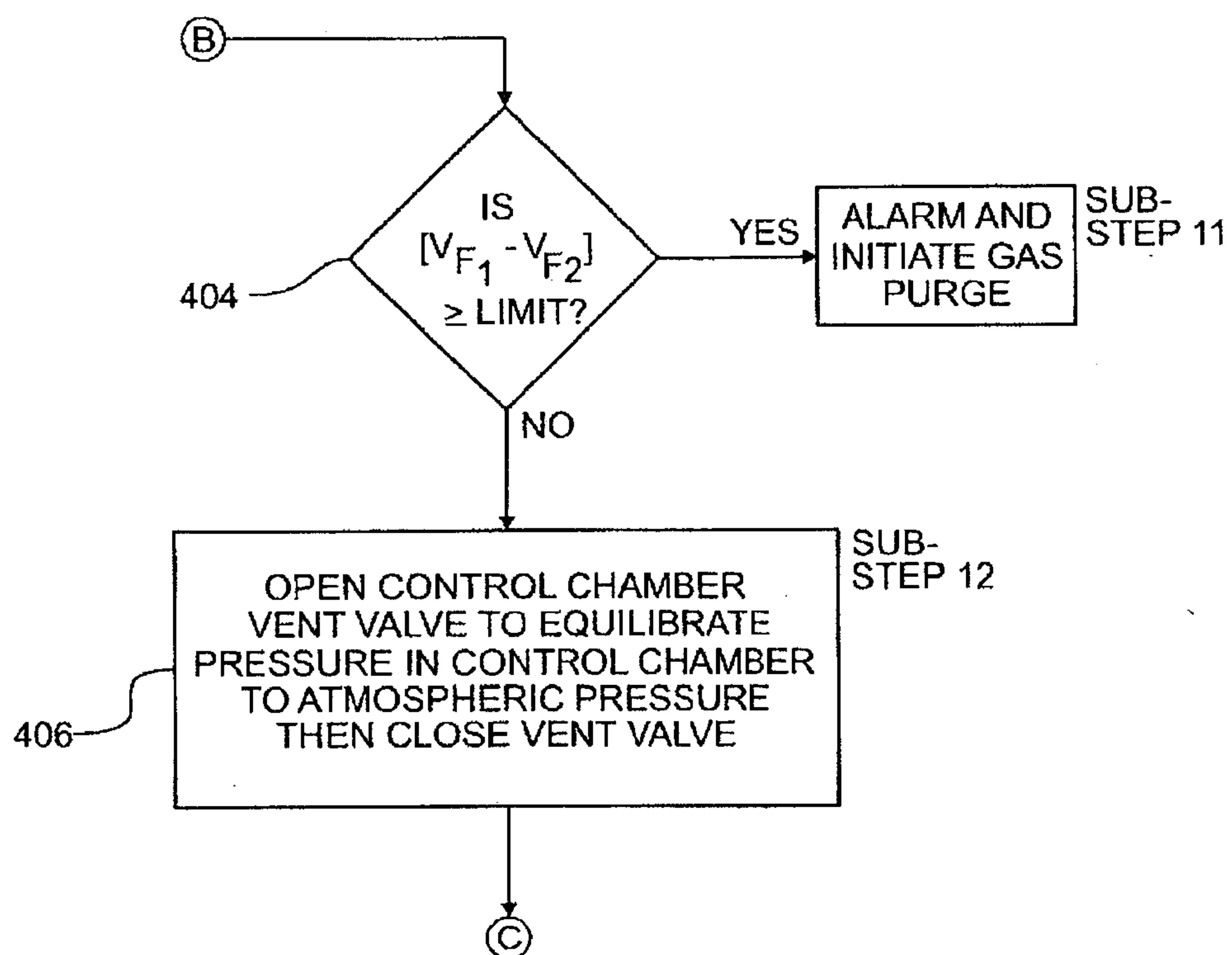


FIG. 38C

SUBSTITUTE SHEET (RULE 26)

45/50

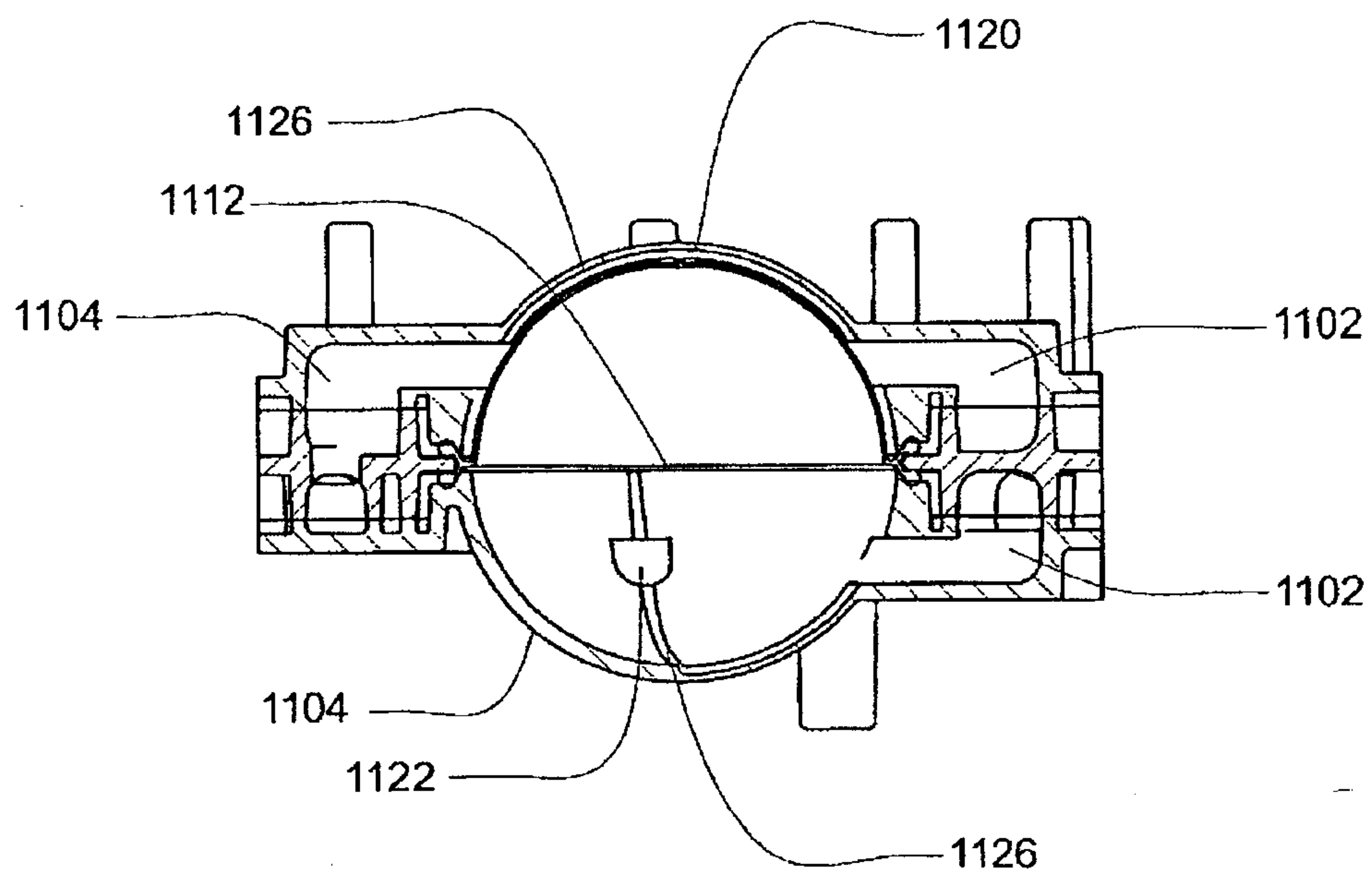


FIG. 39

SUBSTITUTE SHEET (RULE 26)

46/50

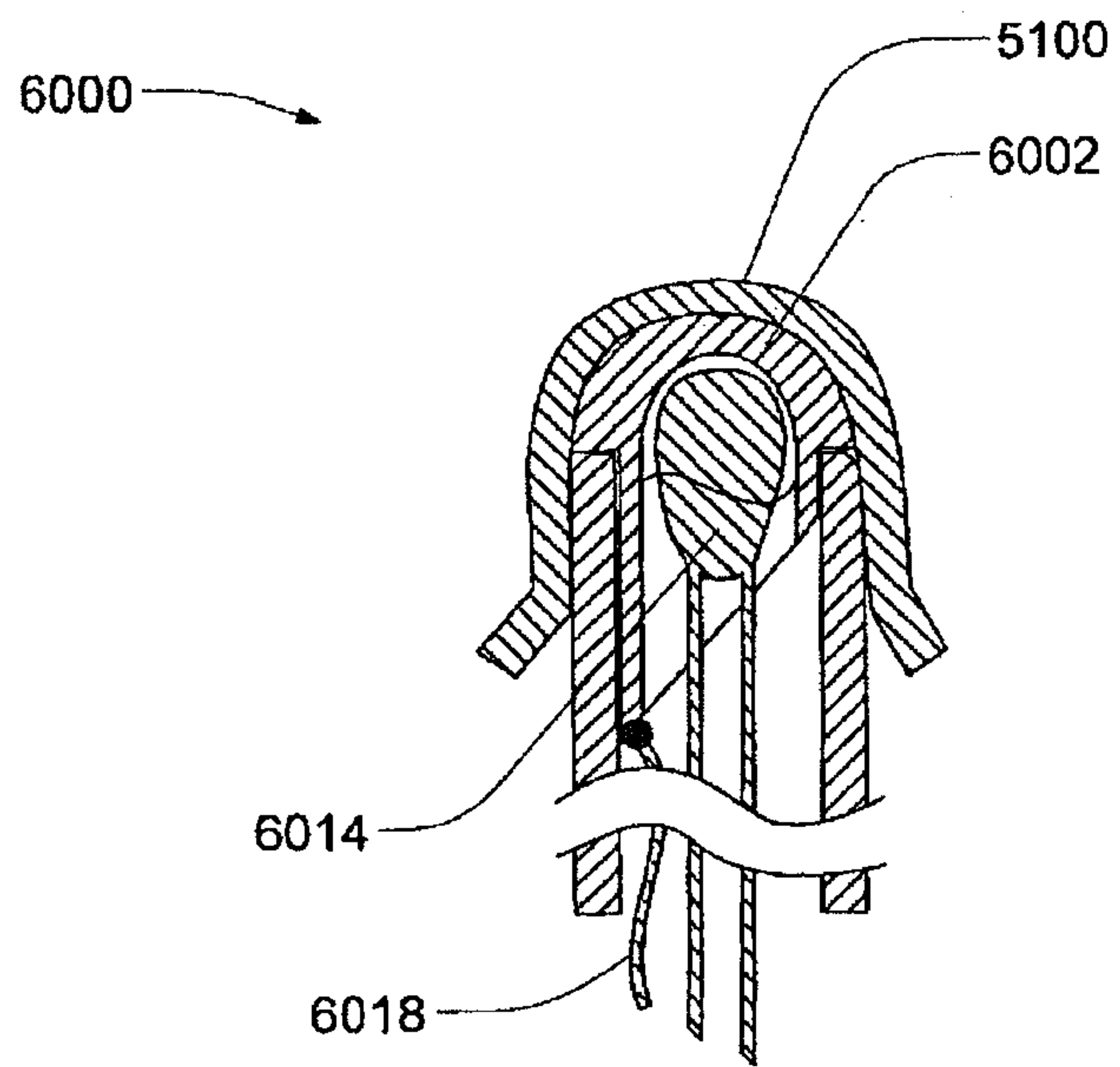


FIG. 40

SUBSTITUTE SHEET (RULE 26)

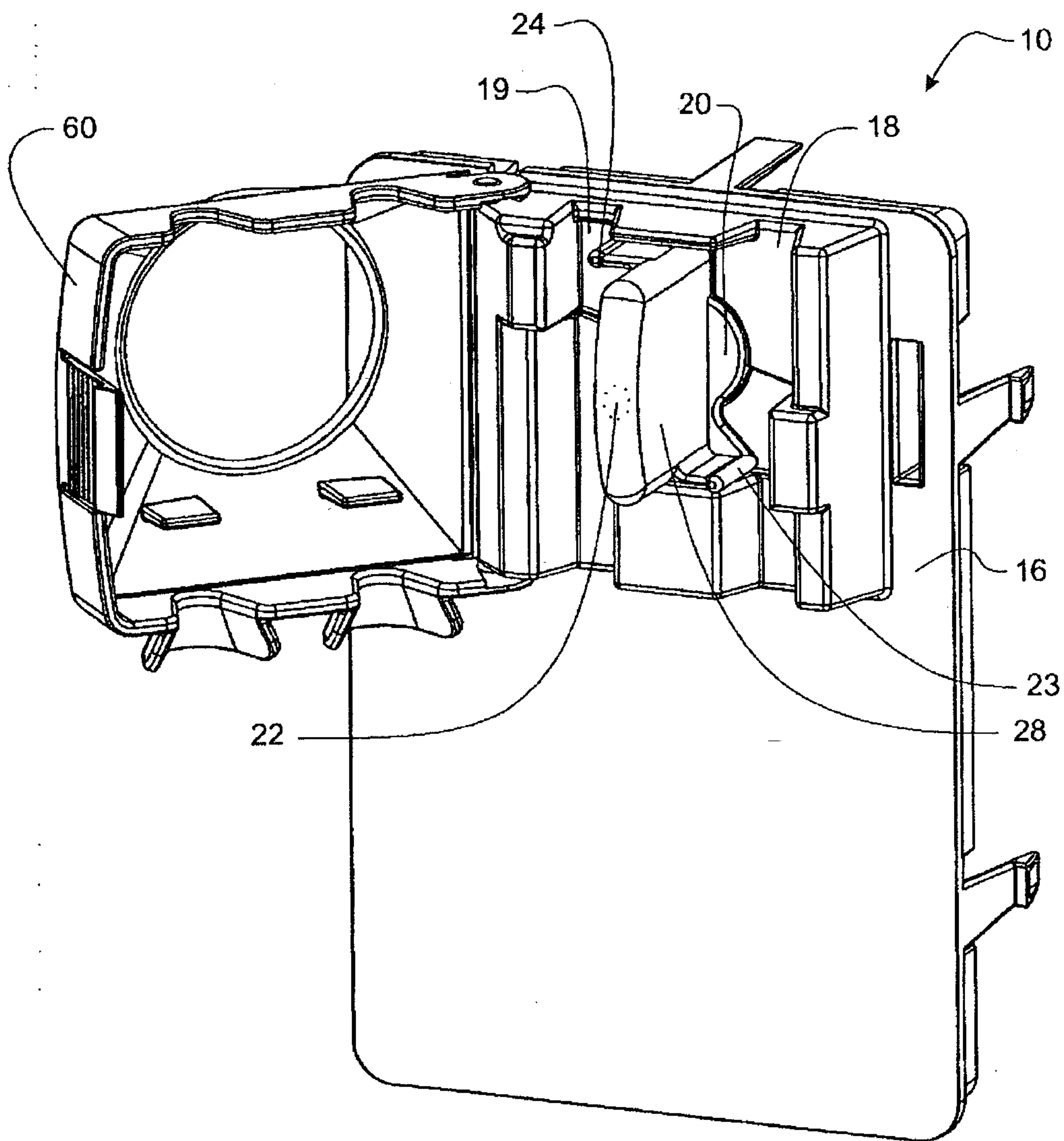


FIG. 41

SUBSTITUTE SHEET (RULE 26)

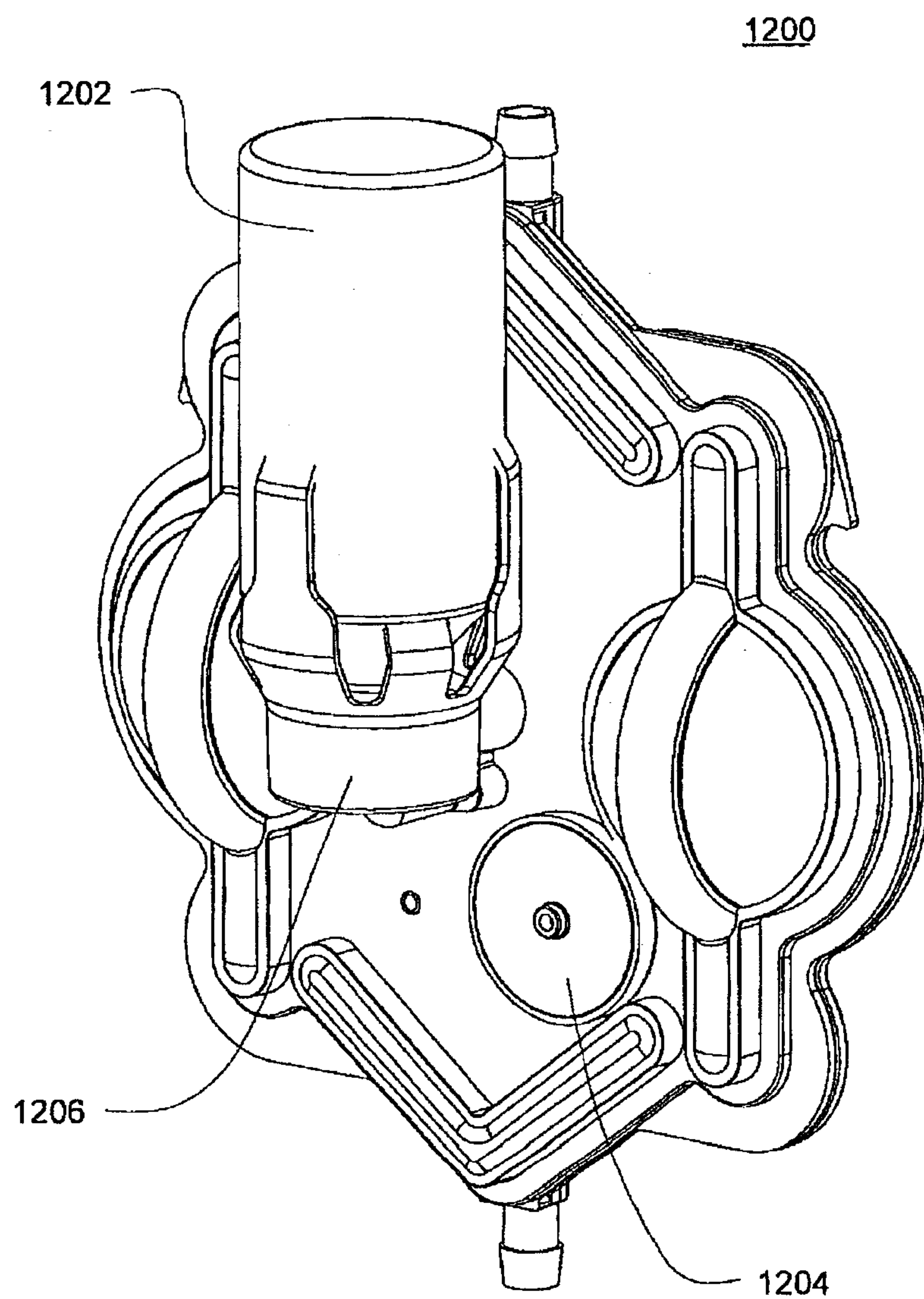


FIG. 42

SUBSTITUTE SHEET (RULE 26)

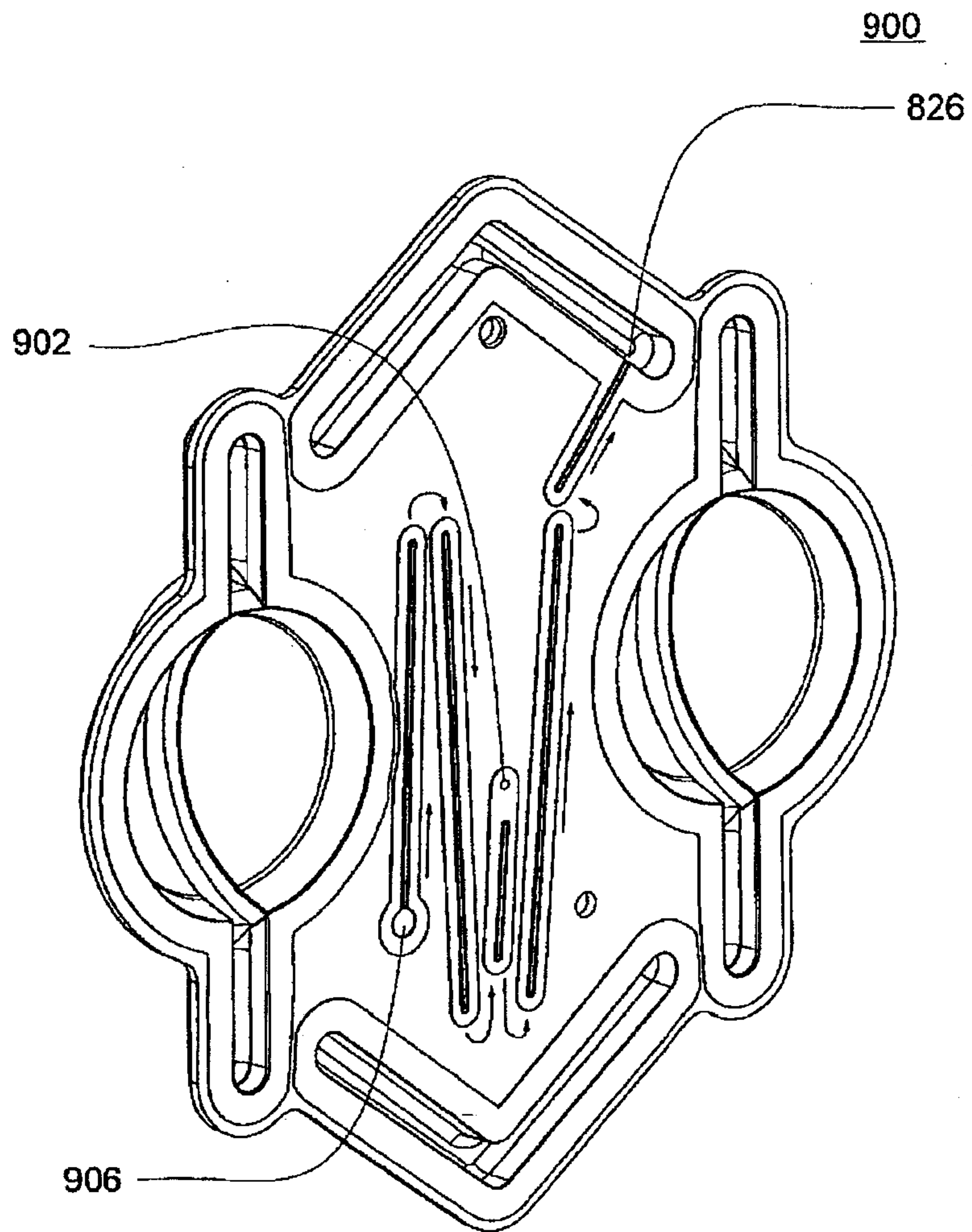


FIG. 43

SUBSTITUTE SHEET (RULE 26)

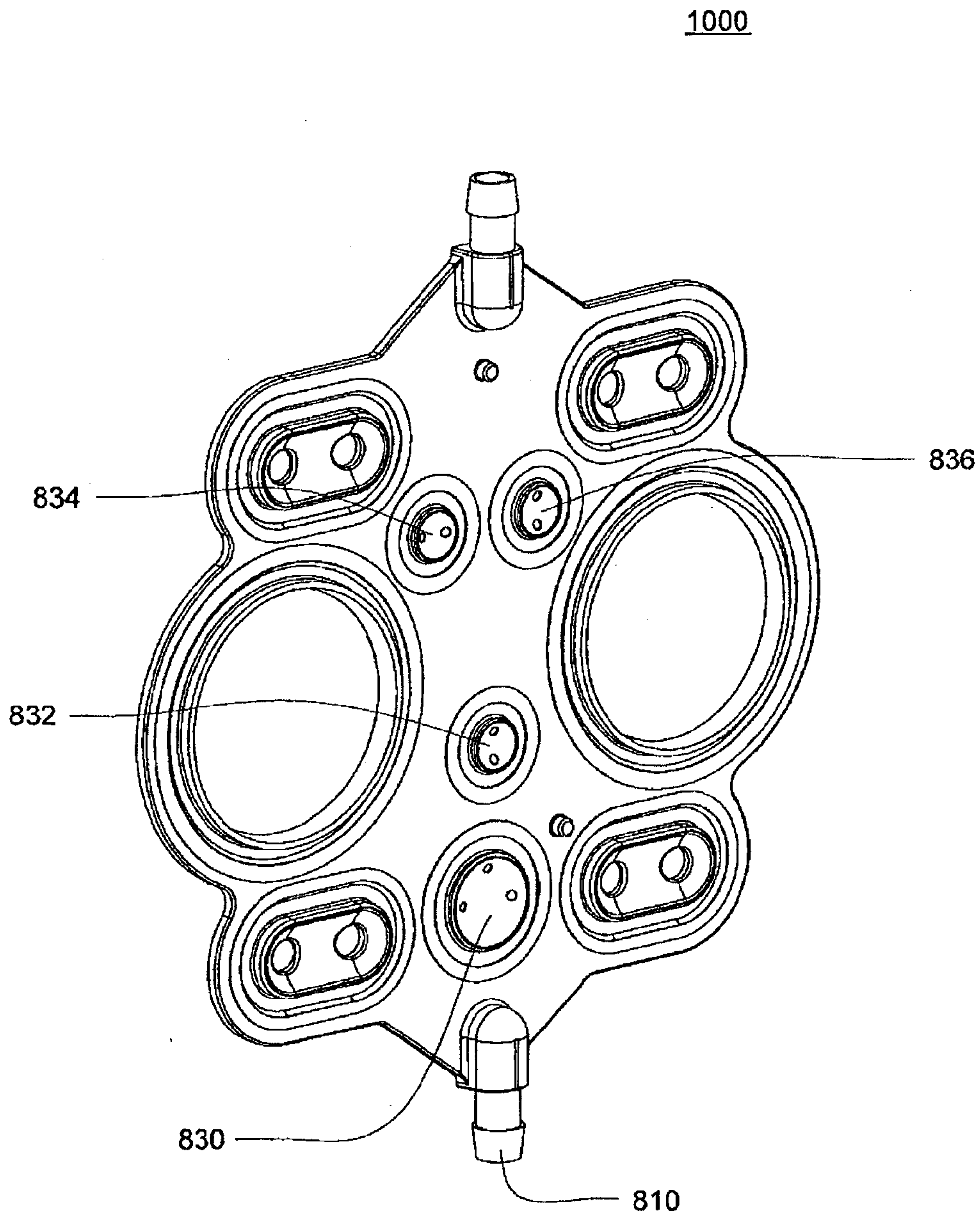


FIG. 44

SUBSTITUTE SHEET (RULE 26)

What is claimed is:

1. A modular assembly system for a portable hemodialysis unit, comprising:

a dialysis unit including a dialysis unit housing that contains components for performing hemodialysis, including a dialyzer, one or more pumps to circulate blood through the dialyzer, an apparatus for preparing and storing dialysate, an electronics section including electronic components for controlling operation of components of the dialysis unit, a heater controllable to heat liquid-contacting components of the dialysis unit to disinfect the liquid-contacting components, and one or more pumps to circulate the dialysate through the dialyzer, the housing having a front opening at which blood circuit connections and dialysate fluidic connections are located, and a disinfection section within the dialysis unit housing that includes liquid-contacting components and is heated by the heater to disinfect the liquid-contacting components;

wherein the electronics section is located within the dialysis unit housing and is separated and thermally insulated from heat in the disinfection section used to disinfect liquid-contacting components of the dialysis unit.

2. The system of claim 1, further comprising a power unit within a power unit housing, the power unit housing being selectively connectable to the dialysis unit housing, wherein the pumps are pneumatic pumps and the power unit provides pneumatic power to the dialysis unit.

3. The system of claim 2, wherein power unit and dialysis unit electrical power requirements are provided by standard residential electrical power.

4. The system of claim 3, wherein the power unit and dialysis unit electrical power requirements are provided by approximately 110V, 15 amp electrical power.

5. The system of claim 2, wherein the dialysis unit provides electrical power to the power unit, and the power unit uses the electrical power to generate operating power for the pumps.

6. The system of claim 2, wherein the dialysis unit provides control signals to the power unit.
7. The system of claim 2, wherein the power unit is selectively connectable to and disconnectable from the dialysis unit by operation of a single handle.
8. The system of claim 2, wherein the power unit has a volume that is smaller than a volume of the dialysis unit.
9. The system of claim 2, wherein the dialysis unit and the power unit are sized and weighted to each be carried by hand by a human.
10. The system of claim 2, wherein the power unit provides air pressure and vacuum to the dialysis unit to power the pumps.
11. The system of claim 2, wherein the dialysis unit housing has a rear side opposite the front opening, and the power unit is connectable to the rear side of the dialysis unit housing.
12. The system of claim 2, wherein the pumps are pneumatic pumps and the power unit provides pneumatic power to the dialysis unit, and wherein the dialysis unit includes a plurality of valves to control application of pneumatic power to the pumps.
13. The system of claim 12, wherein pneumatic controls or the plurality of valves are located in the electronics section.
14. The system of claim 2, wherein the power unit includes a pressure pump and a vacuum pump to provide suitable pressure and vacuum to the dialysis unit.

15. The system of claim 1, wherein the blood circuit connections at the front opening include arterial and venous blood line connectors, and the dialysate fluidic connections at the front opening include a connection point for an acid or bicarbonate source, connection points for dialyzer dialysate connections, and a blood line connection point for connecting the arterial and venous blood line connectors to a drain circuit of the dialysis unit.
16. The system of claim 1, further comprising a control interface that is connected to the dialysis unit housing by a flexible cable, the control interface being arranged to allow a user to receive information from and provide information to the hemodialysis unit.
17. The system of claim 16, wherein the dialysis unit housing includes a control interface mounting area at a top of the housing where the control interface is mountable.
18. The system of claim 16, wherein the dialysis unit housing includes at least one door that is movable to expose the front opening.
19. The system of claim 18, wherein the at least one door includes a hook to support the control interface.
20. The system of claim 18, wherein the dialysis unit housing includes a pair of vertical, side-by-side doors.
21. The system of claim 20, wherein at least one of the doors includes a seal to resist air exchange between an interior and an exterior of dialysis unit housing when the doors are in a closed position.
22. The system of claim 1, wherein the electronics section includes pneumatic controls for controlling flow of control fluid for the one or more pumps of the dialysis unit.

23. A modular assembly system for a portable hemodialysis unit, comprising:
- a dialysis unit including a first housing that contains suitable components for performing hemodialysis and that has a front panel at which blood circuit connections and dialysate fluidic connections are located, the front panel including an occluder for tubes of a blood flow circuit and being configured to removably mount components including a dialyzer, and a blood circuit assembly having one or more pneumatically operated pumps to circulate blood through the dialyzer, the first housing containing one or more pneumatically operated pumps to circulate the dialysate through the dialyzer, a controller to control flow of control fluid, a heater, and sensors; and
- a power unit including a second housing that contains suitable components for providing pneumatic power to the pneumatically operated pumps, the second housing of the power unit being selectively connectable to the first housing of the dialysis unit, the power unit providing pneumatic power to the dialysis unit for the pneumatically operated pumps when connected to the dialysis unit through an interface.
24. The system of claim 23, wherein power unit and dialysis unit electrical power requirements are provided by standard residential electrical power.
25. The system of claim 24, wherein the power unit and dialysis unit electrical power requirements are provided by approximately 1 IOV, 15amp electrical power.
26. The system of claim 23, wherein the dialysis unit provides electrical power to the power unit, and the power unit uses the electrical power to generate pneumatic power for the pumps.

27. The system of claim 23, wherein the dialysis unit provides control signals to the power unit.
28. The system of claim 23, wherein the power unit is selectively connectable to and disconnectable from the dialysis unit by operation of a single handle.
29. The system of claim 23, wherein the power unit has a volume that is smaller than a volume of the dialysis unit.
30. The system of claim 23, wherein the dialysis unit and the power unit are sized and weighted to each be carried by hand by a human.
31. The system of claim 23, wherein the power unit comprises one or more electrical pumps supplying pneumatic pressure to one or more air tanks, said one or more air tanks configured to provide air pressure and vacuum to the dialysis unit to power the pumps.
32. The system of claim 23, wherein the dialysis unit housing has a rear side opposite the front panel, and the power unit is connectable to the rear side of the dialysis unit housing.
33. The system of claim 23, wherein the blood circuit connections at the front panel include arterial and venous blood line connectors, and the dialysate fluidic connections at the front panel include a connection point for an acid/bicarbonate source, dialyzer blood and dialysate connections, and a blood line connection point for connecting the arterial and venous blood line connectors to a directing circuit of the dialysis unit.
34. The system of claim 23, further comprising a control interface that is connected to the dialysis unit housing by a flexible cable, the control interface being arranged to allow a user to receive information from and provide information to the hemodialysis unit.

35. The system of claim 34, wherein the dialysis unit housing includes a control interface mounting area at a top of the housing where the control interface is mountable.
36. The system of claim 35, wherein the dialysis unit housing includes at least one door that is movable to expose the front panel.
37. The system of claim 36, wherein the at least one door includes a hook to support the control interface.
38. The system of claim 37, wherein the dialysis unit housing includes a pair of vertical, side-by-side doors.
39. The system of claim 38, wherein at least one of the doors includes a seal to resist air exchange between an interior and an exterior of dialysis unit housing when the doors are in a closed position.
40. The system of claim 23, wherein the dialysis unit housing includes an electronics section that is separated and insulated from a disinfection section that is heated to disinfect components of the hemodialysis unit.
41. The system of claim 23, wherein the dialysis unit includes a plurality of valves to control application of pneumatic power to the pumps.
42. The system of claim 23, wherein the power unit includes one or more air or vacuum storage tanks to provide stored pneumatic pressure and vacuum to the dialysis unit.
43. The system of claim 23, further comprising the dialyzer and the blood circuit assembly mounted to the front panel.