(12) PATENT **(11)** Application No. **AU 200028930 B2**
(19) AUSTRALIAN PATENT OFFICE **(10)** Patent No. **726636**

(54) Title
Method and apparatus for producing sterile surgical media

(51)[7] International Patent Classification(s)
A61B 019/02 **A61B 019/00**

(21) Application No: **200028930** (22) Application Date: **2000.04.20**

(43) Publication Date : **2000.08.03**
(43) Publication Journal Date : **2000.08.03**
(44) Accepted Journal Date : **2000.11.16**

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(56) Related Art
US 4934152
US 5163299
US 5457962

ABSTRACT

A sterile drape (51) for use in surgical procedures to cover and conform to a basin to define a drape receptacle for containing a sterile medium that is thermally treated by controlling the temperature of the basin, and drape being characterized by having a centering indicium (52, 53) to guide proper positioning of said drape in said basin.

AUSTRALIA

Patents Act 1990

COMPLETE SPECIFICATION

STANDARD PATENT

Applicant(s):

O.R. SOLUTIONS, INC.

Invention Title:

METHOD AND APPARATUS FOR PRODUCING STERILE SURGICAL MEDIA

The following statement is a full description of this invention, including the best method of performing it known to me/us:

METHOD AND APPARATUS FOR PRODUCING STERILE SURGICAL MEDIA

The present application is a divisional application of application no. 81880/98 which is, in turn, application no. 22013/95. The disclosures of both of these applications are incorporated herein by reference.

The present invention pertains to improvements in methods and apparatus for producing surgical sterile fluid media. In particular, the invention is an improvement of the methods and apparatus disclosed in U.S. Patent Nos. 4,393,659 (Keyes et al), 4,934,152 (Templeton) and 5,402,644 (Faries, et al). The disclosures in those patents are expressly incorporated herein in their entireties by this reference. These patents are examples of prior art methods and apparatus and should not be considered as representative of the common general knowledge.

Discussion of the Prior Art

The Keyes et al patent discloses a surgical slush producing system having a cabinet with a heat transfer basin at its top surface. A refrigeration mechanism in the cabinet takes the form of a closed refrigeration loop including: an evaporator in heat exchange relation to the exterior of the heat transfer basin; a compressor; a condenser; and a refrigeration expansion control, all located within the cabinet. A separate product basin is configured to be removably received in the heat transfer basin. Spacers, in the form of short cylindrical stubs or buttons are arranged in three groups spaced about the heat transfer basin and projecting into the heat transfer basin interior to maintain a prescribed space between the two

basins. During use, that space contains a thermal transfer liquid, such as alcohol or glycol, serving as a thermal transfer medium between the two basins. A sterile sheet of material, impervious to the thermal transfer medium, is disposed between the product basin exterior and the liquid thermal transfer medium to preserve the sterile nature of the product basin. Surgically sterile liquid, such as sodium chloride solution, is placed in the product basin and congeals on the side of that basin when the refrigeration unit is activated. A scraping tool is utilized to remove congealed sterile material from the product basin side to thereby form a slush of desired consistency in the product basin.

As noted in the Templeton patent, the above-described system has a number of disadvantages. In particular, the separate product basin must be removed and re-sterilized after each use. Additionally, the glycol or other thermal transfer medium is typically highly flammable or toxic and, in any event, complicates the procedure. The Templeton patent discloses a solution to these problems by constructing an entirely new apparatus whereby the product basin is eliminated in favor of a sterilized drape impervious to the sterile surgical liquid, the drape being made to conform to the basin and directly receive the sterile liquid. Congealed liquid is scraped off the sides of the conformed drape receptacle to form the desired slush.

In addition, Templeton also provides an electrical heater disposed at the bottom of the basin to convert the sterile slush to warmed liquid, or to heat additional sterile liquid added to the basin. Templeton describes the need for such warmed sterile liquid as occurring after a surgical procedure is completed to facilitate raising the body cavity of the surgery patient back to its normal temperature by contact with the warmed liquid. However, there are a number of instances during a surgical procedure when it is desirable to have simultaneous access to both the sterile warmed liquid and the sterile surgical slush, and,

on occasion, a supply of near-freezing liquid-state sterile fluid. For example, if the surgical slush is not at the desired consistency (e.g., too thick), the availability of warmed sterile liquid to be added to the slush permits rapid adjustability of the slush consistency. Likewise, maintaining instruments at or near body temperature during surgery is a desirable feature permitted by warmed sterile liquid. Of course, if the warmed sterile liquid is simultaneously available with the surgical slush, there is no need to wait for the slush to melt at the end of the surgical procedure. Finally, the simultaneous and separate provision of slush and warm and near-freezing liquid permits different sterile media to be used as is sometimes necessary for various surgical procedures.

OBJECTS AND SUMMARY OF THE INVENTION

The invention provides a sterile drape for use in surgical procedures to cover and conform to a basin to define a drape receptacle for containing a sterile medium that is thermally treated by controlling the temperature of the basin, and drape being characterized by having a centering indicium secured thereto guide proper positioning of said drape in said basin.

The above and still further objects, features and advantages of the present invention will be apparent upon consideration of the following detailed description of the specific embodiments thereof, particularly when taken in conjunction with the accompanying drawings wherein like components are designated by like reference numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a view in perspective of a surgical slush unit and warming unit combination provided in accordance with the present invention.

Fig. 2 is a view in perspective of a surgical slush unit and warming unit having a different means for attaching the units together.

Fig. 3 is a view in perspective of a single unit containing adjacent separate heating and cooling basins pursuant to the present invention.

Fig. 4 is a view in perspective of a pedestal mounted double unit containing separate adjacent heating and cooling units pursuant to the present invention.

Fig. 5 is a view in perspective of a pedestal mounted triple unit containing separate successively adjacent heating, chilling and slush forming units pursuant to the present invention.

Fig. 6 is a plan view of a surgical drape suitable for use with the embodiments illustrated in Figs. 1, 2 and 3.

Fig. 7 is a view in perspective showing the surgical drape of Fig. 4 positioned over the unit illustrated in Fig. 3.

Fig. 8 is a partial view in perspective of a surgical drape with receptacle covers positioned over the unit illustrated in Fig. 3.

Fig. 9 is an electrical schematic diagram of the heating unit employed in the present invention.

Fig. 10 is a schematic diagram of the cooling system employed in the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1 of the accompanying drawings, a surgical slush unit 10 has a heating unit 20 secured thereto. Surgical slush unit 10 may, for example, be configured as the type described and illustrated in the aforementioned Templeton patent, although other configurations are suitable within the scope of the present invention. Surgical slush unit 10 has a top surface 11 with a slush basin 12 recessed therein. A power switch 13 is disposed on the sidewall of the cabinet in the Templeton unit. An additional cooling unit temperature controller/indicator switch 14 is shown disposed on the unit top surface 11. In the manner described in the Templeton patent, a suitable sterile liquid, such as a saline solution, is cooled in basin 12 to form surgical slush. In use, the top surface 11 and basin 12 are covered with a sterile liquid impervious drape (not shown in Fig. 1) that

can be recessed into the basin. As contemplated by Templeton, ice formed on the sides of the drape is scraped off the drape surface to form slush. In the system described in U.S. Patent No. 5,163,299 (Faries et al), the formed ice is removed from the drape by gently lifting the drape and shaking it slightly. In either event, surgical slush at the desired consistency may be formed in the receptacle provided by the drape in the slush basin.

Heating unit 20 may be secured to a sidewall of a cooling unit cabinet such that the top surface 21 of the heating unit is a substantially coplanar extension of the slush unit top surface 11. Attachment of the heating unit 20 to the surgical slush unit cabinet may be by bolts, brackets or other suitable means. A warming basin 22 is recessed into top surface 21. A heater power switch 23 and a temperature controller/indicator 24 are provided on top surface 21 adjacent the warming basin to maintain the temperature of the sterile medium at a temperature somewhat above normal operating room temperature.

Another technique for securing heater unit 20 to pre-existing surgical slush machine 10 is illustrated in Fig. 2. Specifically, a separate wheeled stand 26 has a horizontal support surface for heater unit 20. The thusly supported heater unit has its top surface 21 substantially coplanar with top surface 11 of the surgical slush unit. A belt or strap 27 extends from stand 26 to circumscribe the cabinet of the surgical slush unit 10, thereby preventing inadvertent separation of the slush forming and heating units.

In Fig. 3 there is illustrated an integral assembly 30 wherein a slush basin 12 for slush phase medium and a warming basin 22 for heated liquid phase medium are recessed into the top surface 31 of a common cabinet. Also disposed on top surface 31 are a cooling unit power switch 13, a cooling unit temperature controller/indicator 14, a heater power switch 23 and a heater unit temperature controller/indicator 24.

Figs. 4 and 5 show a two and a three basin coplanar assembly, respectively, each covered by a drape. Fig. 4 illustrates a surgical slush unit 10' attached to and adjacent a heater unit 20' and jointly supported by a unitary pedestal base 25. Fig. 5 shows a near-freezing chilled liquid unit 40 mounted adjacently between the slush and heater units, 10' and 20', respectively, all supported by pedestal 25. The chiller unit 40 is provided for those procedures requiring ready access to a liquid state chilled surgical liquid and is included with a basin 42, a separate power switch 43 and controller/indicator 44. A sterile drape 51, described hereinafter, is shown overlaying the basin assemblies of both Fig. 4 and Fig. 5. The number and order of close adjacency of the sterile fluid basins is selectable in accordance with the preferences of the surgeon and/or the demands of the particular procedure and includes the option of more than one basin containing media maintained at the same thermal state.

A sterile drape 51, suitable for covering the top surfaces of the combinations of surgical slush units, heater units and chilled liquid units described above (i.e., in Figs. 1 - 5), is illustrated in Fig. 6. The drape is made of a material that is impervious to the liquid and slush, and is sufficiently soft and flexible to conform to the basin walls. The thickness of the drape is preferably minimized to render thermal transfer therethrough most efficient, yet sufficiently thick to resist tearing and puncturing of the drape during whisking of slush and other normal use. Typically, by way of example only, the drape is made of materials commonly used in hospitals for surgical drapes and has a thickness in the range of 4.5 to 6.0 mils. The drape 51 may also be made of polyurethane film as disclosed for the drape in the aforementioned Templeton patent. Such drapes are sufficiently transparent to permit power controls and controller/indicators to be observed and operated therethrough. Drape 51 is designed to be disposable after a single use and is provided pre-sterilized

and pre-packaged in a leak-proof plastic bag or other sealed container to preserve the sterile nature of the drape during storage.

An advantageous feature of drape 51 is the provision of centering marks or indicia 52, 53, as shown in Fig. 6 for a two basin application, adapted to be placed over the centers of the basins during installation of the drape. Specifically, the centering indicia are thusly positioned when the drape is pushed down into the basins until it conforms to the basin shapes and forms drape receptacles 54 for the sterile medium. Alternatively, basin-like recesses or receptacles may be formed in the drape and configured to fit directly into the basins. The installed drape, used in conjunction with the embodiment of Fig. 3, is illustrated in Fig. 7. Similarly drapes provided with three or more centering marks appropriately positioned are used for any number and combination of basin units. Of course, individual drapes may be provided, as desired for each individual heater, chiller or slush maker.

As an added enhancement for use with drape 51, flap-like covers 55 may be removably extended to cover medium-containing receptacles 54. A roller 56 is shown in Fig. 8 affixed near one of two drape receptacles. A sheet of drape-like material 57, attached at one end to the roller is selectively unrolled and rolled to cover and uncover the corresponding drape receptacle to provide thermal insulation for the contained sterile medium between periods of required accessibility, and to expose the medium as needed. Also illustrated in Fig. 8, a cover 55 can be a foldaway flap or slidable sheet of material extendable over the receptacle from one side and can be provided with hold-down attachments 58 to interact with corresponding fixtures on the drape 59 to position and secure the cover in place. Alternatively, a peel off adhesive strip affixed to the drape near the edge of the drape receptacle opposite the flap attachment can be used to removably secure the flap across the receptacle.

In addition to providing thermal insulation, cover 55 acts to reduce the unnecessary exposure of the sterile medium to airborne pathogens and, in this regard, can be electrostatically charged to more effectively attract and capture such pathogens.

The manner of heating sterile liquid in a heating basin (e.g., heating basin 22 of Fig. 3) is illustrated schematically in Fig. 9. Specifically, an electrical circuit includes a power source 61 connected in series with a temperature control unit 62, a heater element 60 and power control switch 23. Heater 60 is typically a thin wafer-like member disposed along the bottom surface of heating basin 22, secured to the basin by a suitable pressure sensitive adhesive having efficient heat transfer characteristics. Heater 60, may, for example, be of the type described in the aforementioned Templeton patent. Temperature control unit 62 includes a device for adjusting the current passing through the heating element 60 so as to permit selective adjustment of the heat applied to the liquid in basin 22. The power switch 23 permits selective application and removal of current flow with respect to the heater 60.

A temperature sensor 64 is disposed adjacent basin 22 to sense the temperature of the liquid therein. Sensor 64 is connected in series with a voltage source 65 and an indicator 66. Voltage source 65 and power source 61 may be the same source, or the voltage for one may be derived from the other. Indicator 66 measures the current through temperature sensor 64, that current being proportional to the sensed temperature. Indicator 66 and temperature controller 62 may correspond, for example, to the temperature controller/indicators 24 described above.

The refrigeration components used to produce and maintain both slush and near-freezing chilled liquid are illustrated schematically in Fig. 10 and include a compressor 71 selectively actuable by means of an electrical power source 72 and an on-off power switch 13. Power source 72 may be the same source as power source 61, but separate

power switches are provided for heating and cooling. The compressor 71 causes a suitable refrigerant fluid to flow through a series circuit including a condenser 73, an evaporator 74 and a suitable thermal expansion valve 75. The evaporator 74 is disposed about the sides of slush basin 12 to permit cooling of the basin to a desired temperature. A temperature sensor 76 is disposed along the outside surface of the bottom of basin 12 to monitor the temperature of the chilled liquid or slush formed therein. Sensor 76 is connected in series with a voltage source 77, preferably derived from power source 72, and indicator 78. Indicator 78 measures the current passing through sensor 76 which, in turn, is proportional to the temperature sensed in basin 12.

From the foregoing description it will be appreciated that the invention makes available a novel method and apparatus for permitting combinations of surgical slush and chilled and warmed sterile liquid to be made simultaneously and adjacently available at a surgical procedure.

Having described preferred embodiments of a new and improved method and apparatus for producing surgical slush and chilled and heated sterile liquid in accordance with the present invention, it is believed that other modifications, variations and changes will be suggested to persons skilled in the art after having access to the teachings set forth herein. It is therefore to be understood that all such variations, modifications and changes are believed to fall within the scope of the present invention as defined by the appended claims.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A sterile drape for use in surgical procedures to cover and conform to a basin to define a drape receptacle for containing a sterile medium that is thermally treated by controlling the temperature of the basin, and drape being characterized by having a centering indicium to guide proper positioning of said drape in said basin.

2. A sterile drape as claimed in claim 1, wherein said centering indicium corresponds substantially to the center of said basin.

3. A sterile drape as claimed in claim 1 and which is adapted to cover and conform to a plurality of basins and wherein said drape has a plurality of centering indicia corresponding to respective ones of said plurality of basins to guide proper positioning of said drape in said basins.

4. A sterile drape as claimed in claim 1 and substantially as herein described with reference to the accompanying drawings.

Dated this 20th day of April 2000
O. R. SOLUTIONS, INC
By their Patent Attorneys
GRIFFITH HACK
Fellows Institute of Patent Attorneys of Australia

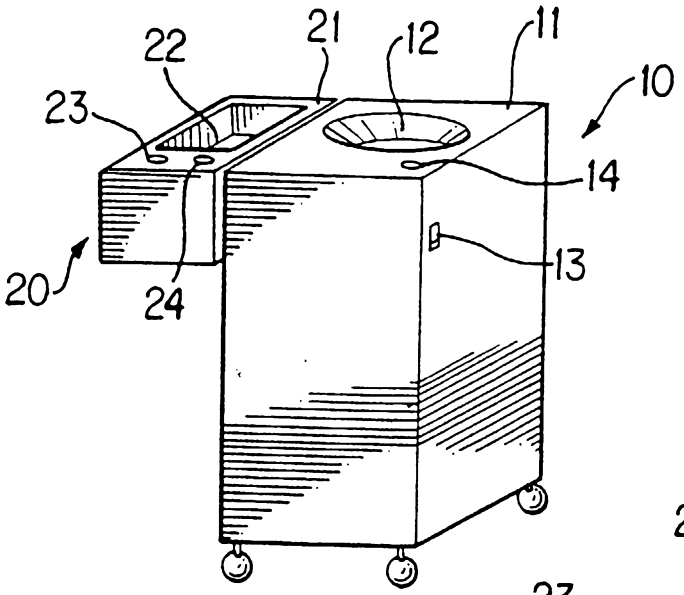

FIG. 1

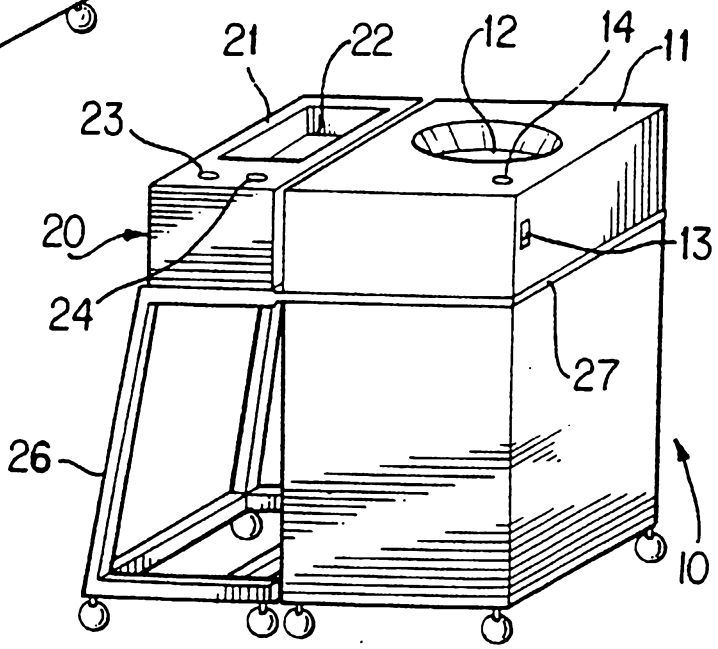

FIG. 2

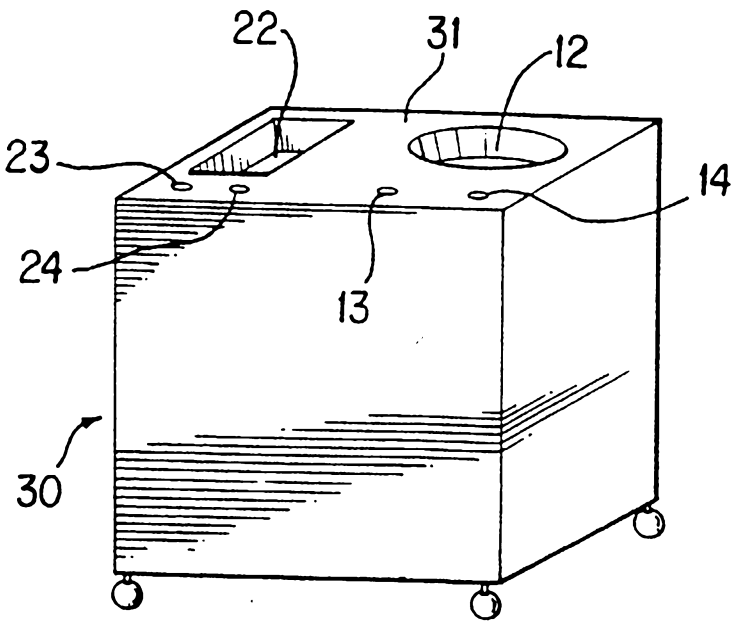

FIG. 3

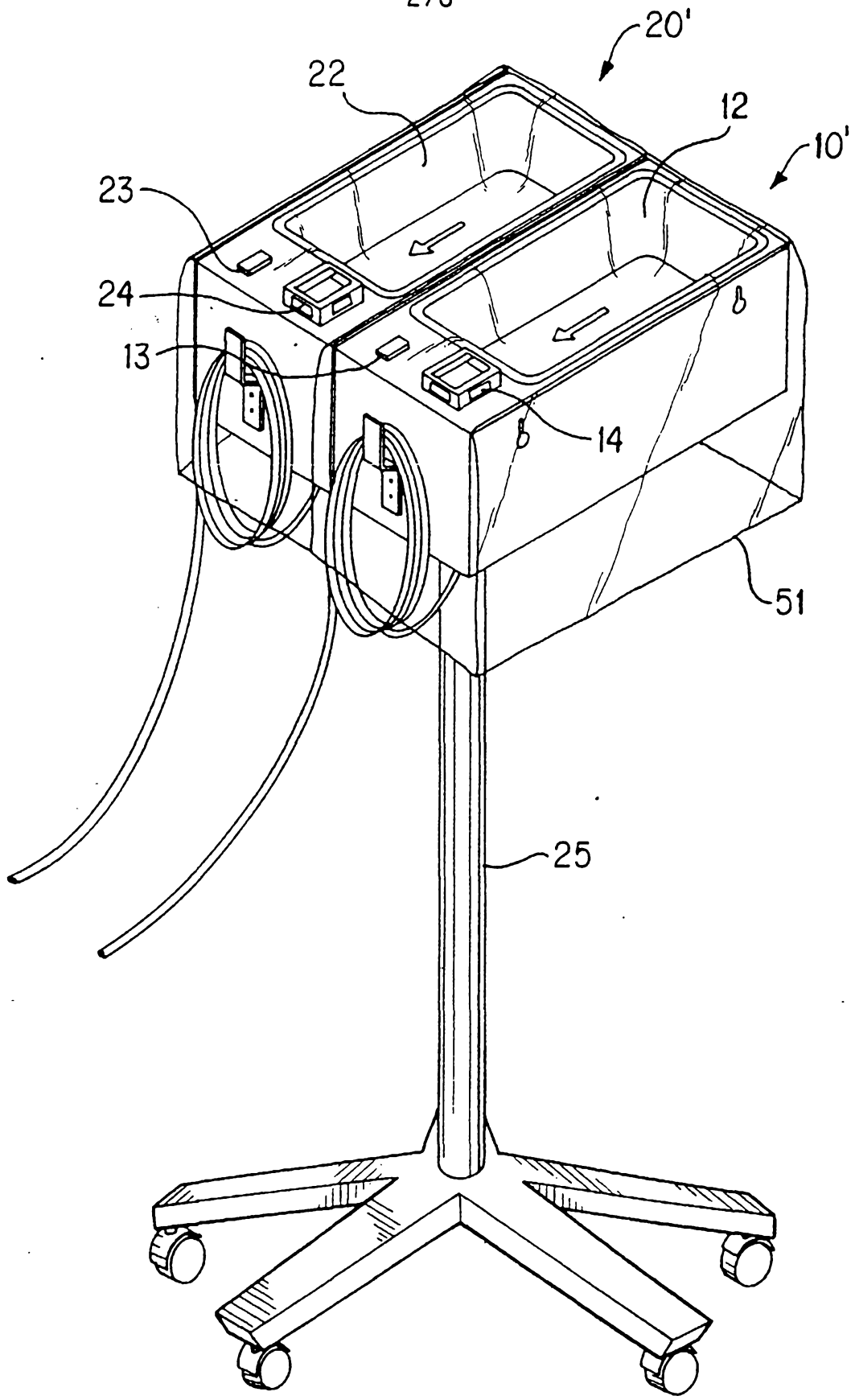

FIG. 4

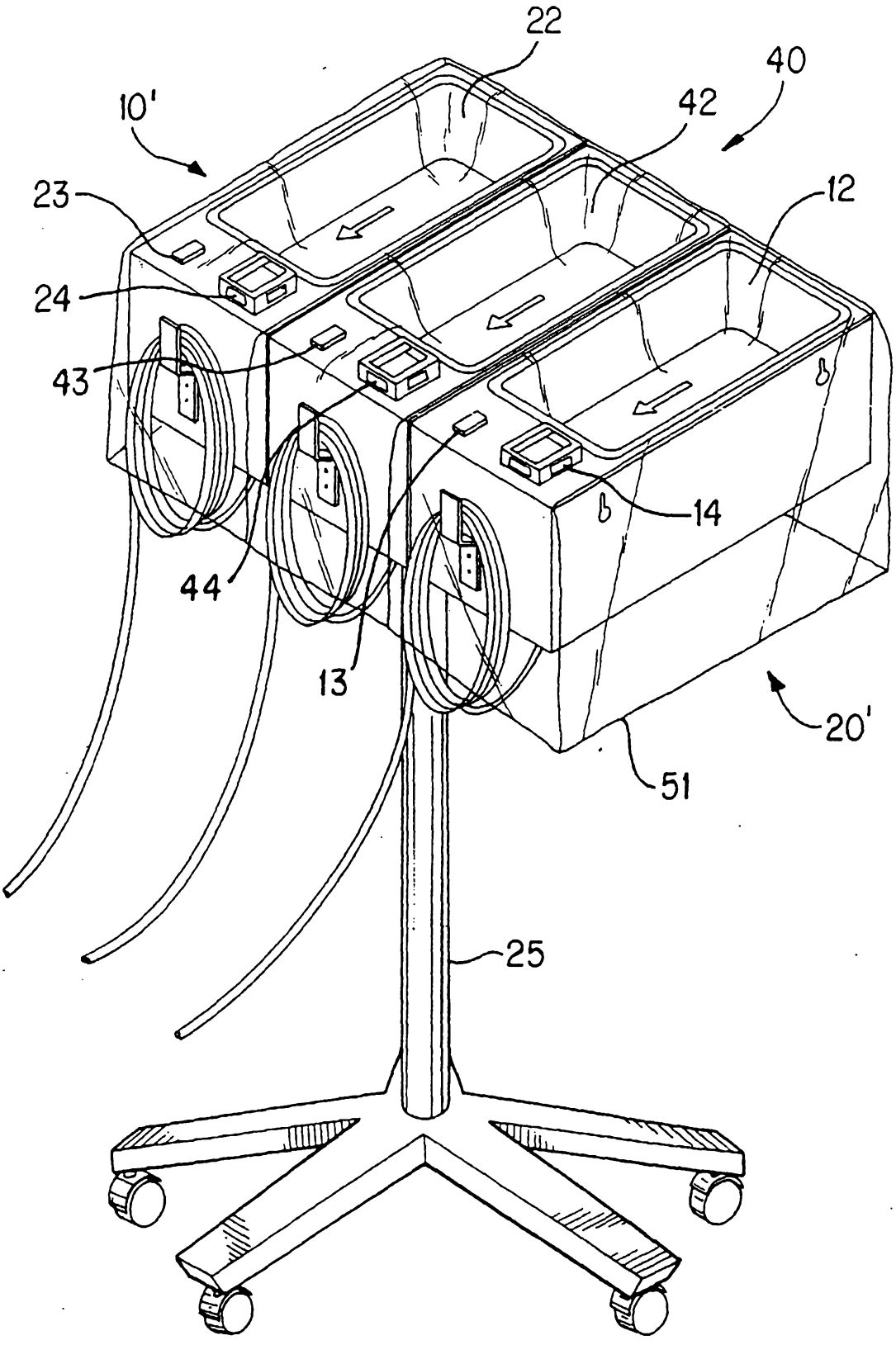

FIG. 5

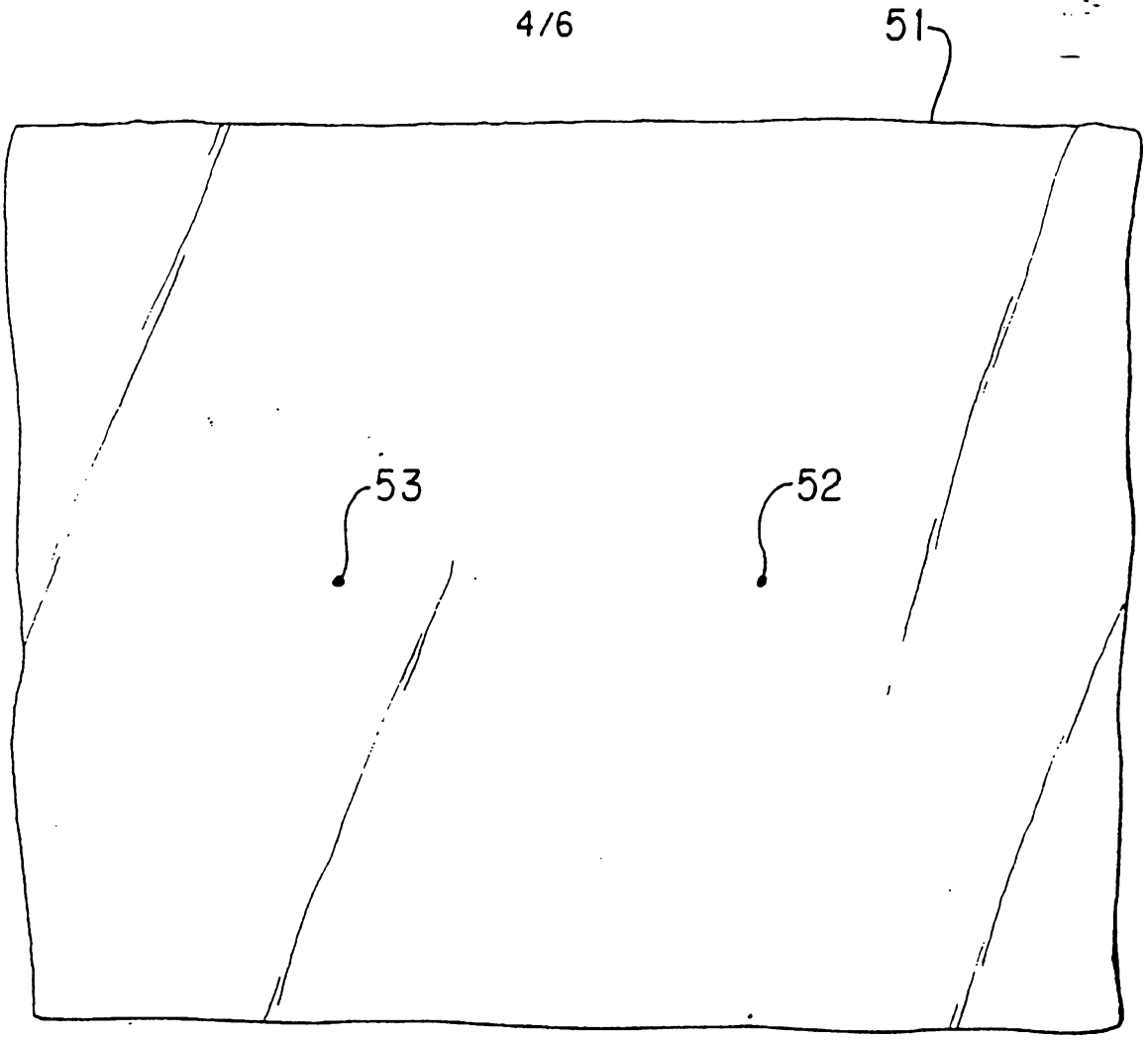

FIG. 6

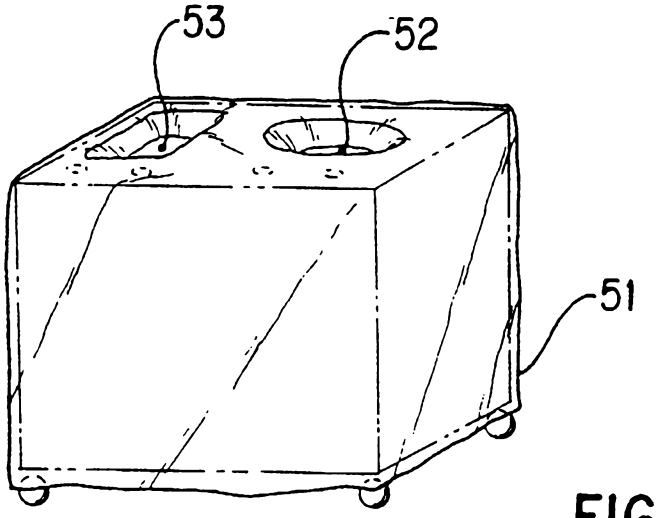

FIG. 7

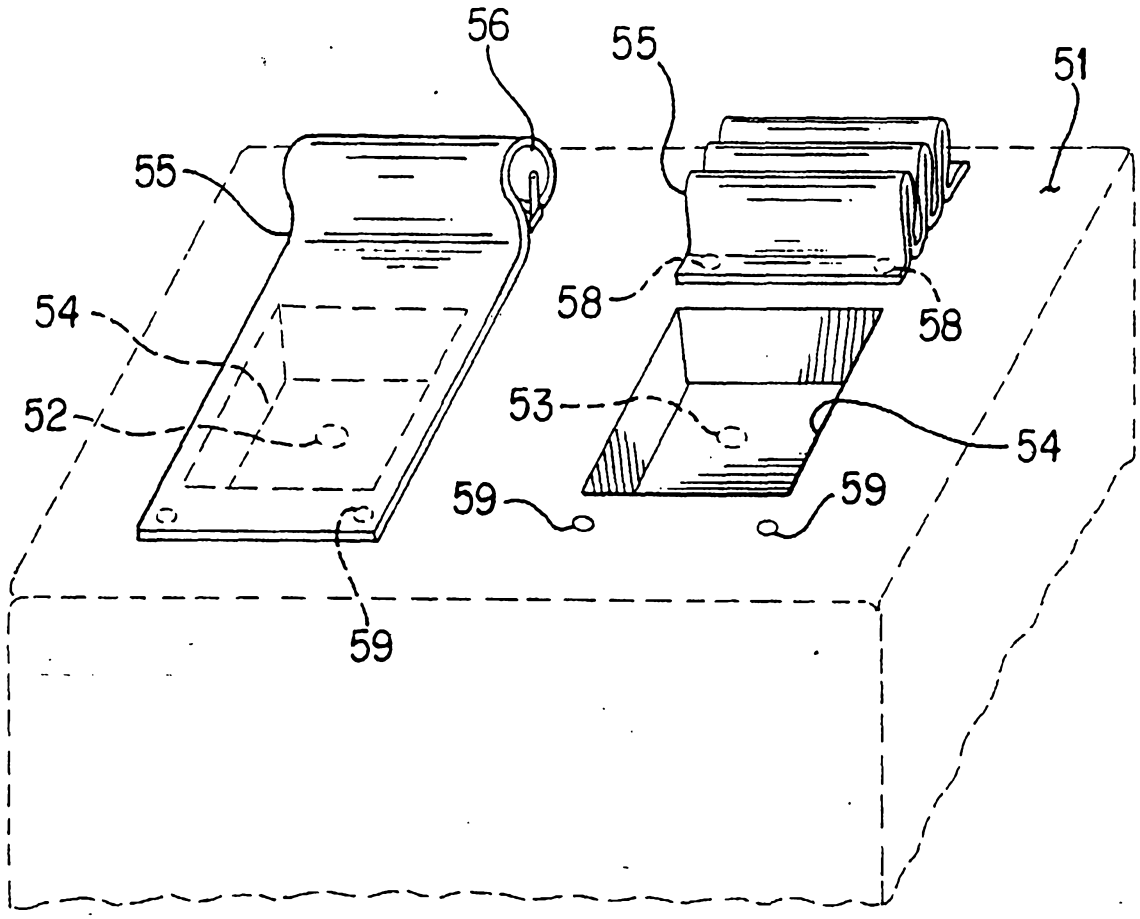

FIG. 8

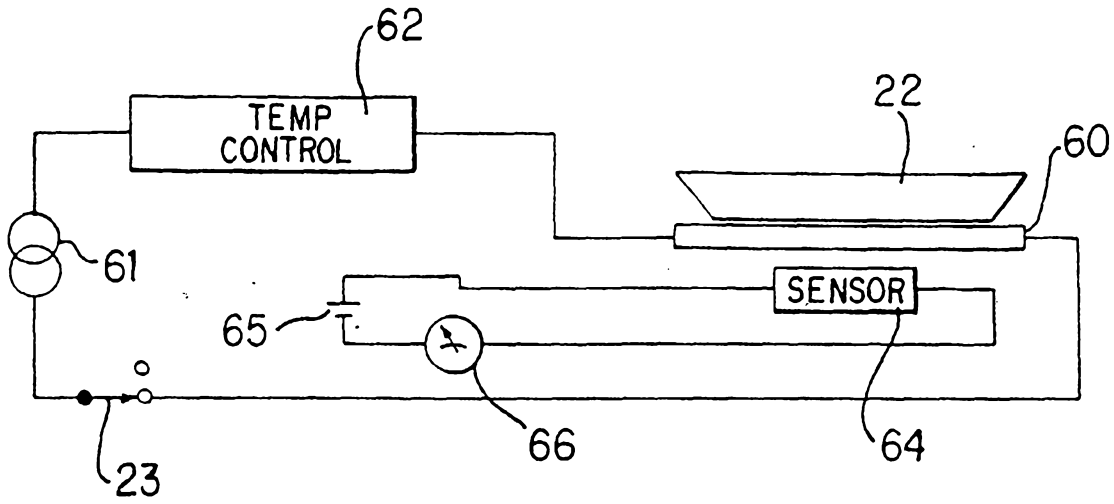
62
TEMP CONTROL
22
60
61
SENSOR
65
66
64
23

FIG. 9

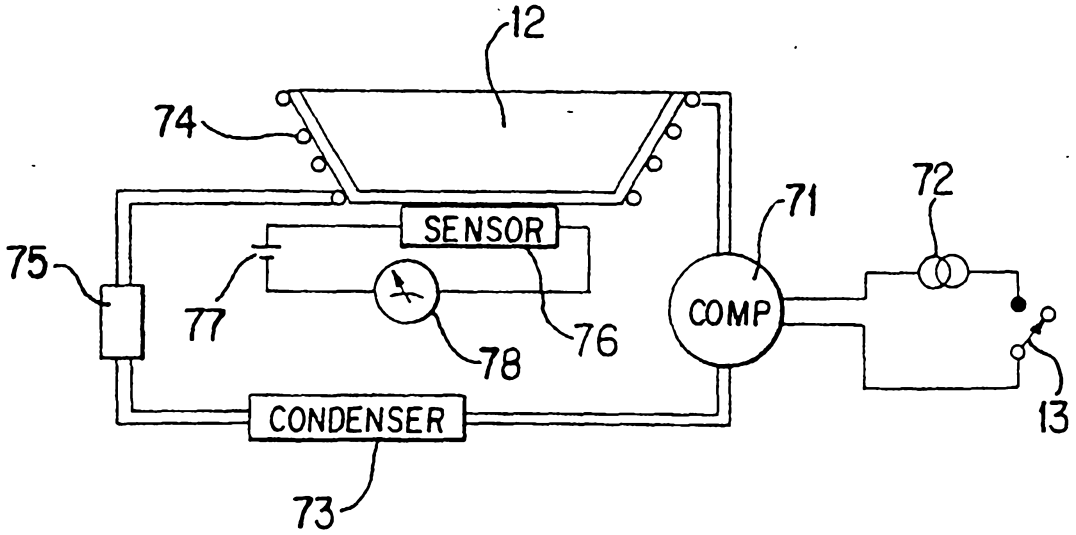
12
74
71
72
SENSOR
75
77
78
76
COMP
13
CONDENSER
73

FIG. 10