

[54] **PROCESS AND APPARATUS FOR
CRYOSTATIC PRE-OPERATIVE
TREATMENT OF GANGRENOUS
EXTREMITIES**

[76] Inventor: **Howard J. Nethery**, 200
Pennsylvania Ave., Louisville, Ky.
40206

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[58] **Field of Search** 128/399, 400, 402, 68.1,
128/379, 382

[56] **References Cited**

UNITED STATES PATENTS

1,991,784	2/1935	Bohemier et al.	128/400
2,110,022	3/1938	Kliesrath	128/400

2,260,134	10/1941	Ballman	128/400
2,726,658	12/1955	Chessey	128/400
2,825,338	3/1958	Schnepf et al.	128/402

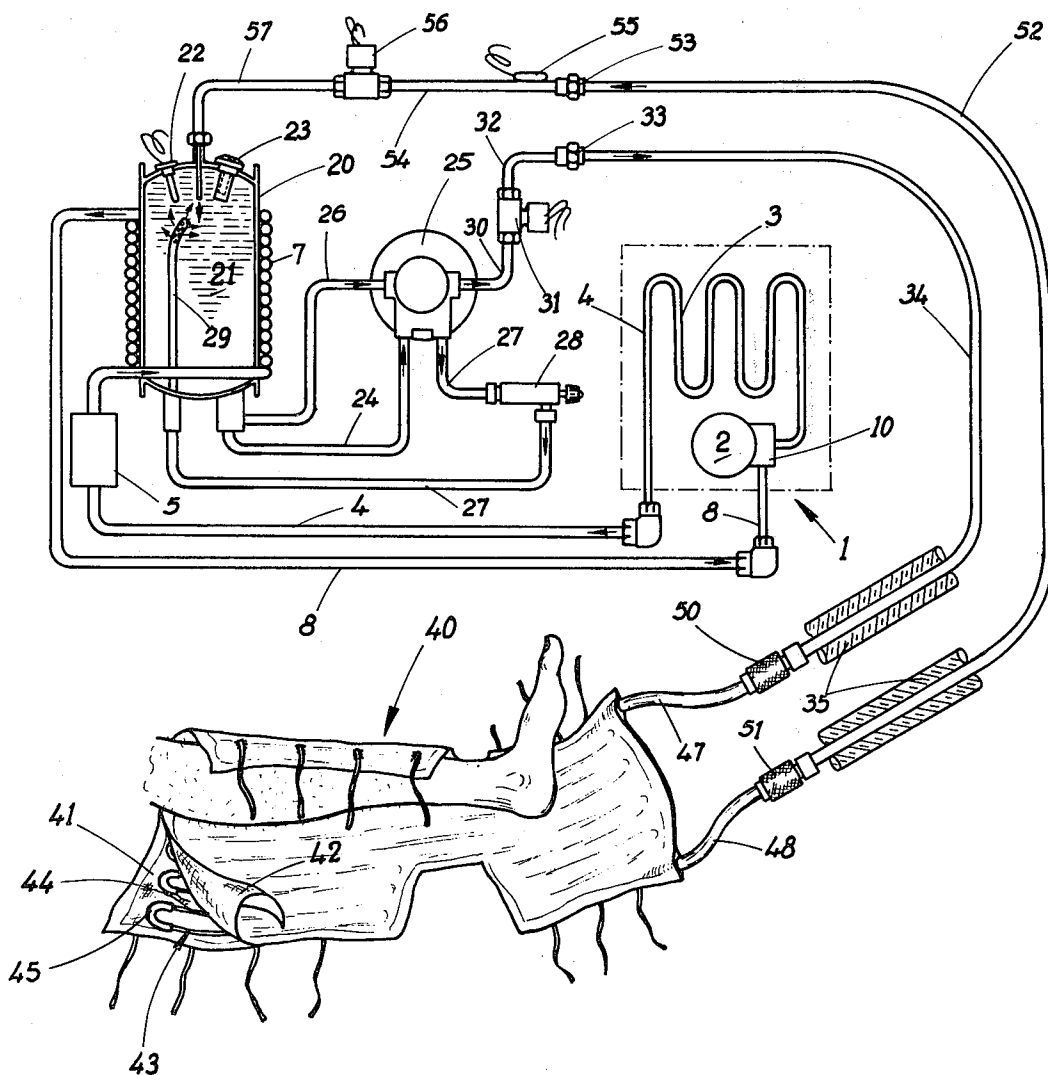
Primary Examiner—Lawrence W. Trapp
Attorney, Agent, or Firm—Wm. R. Price

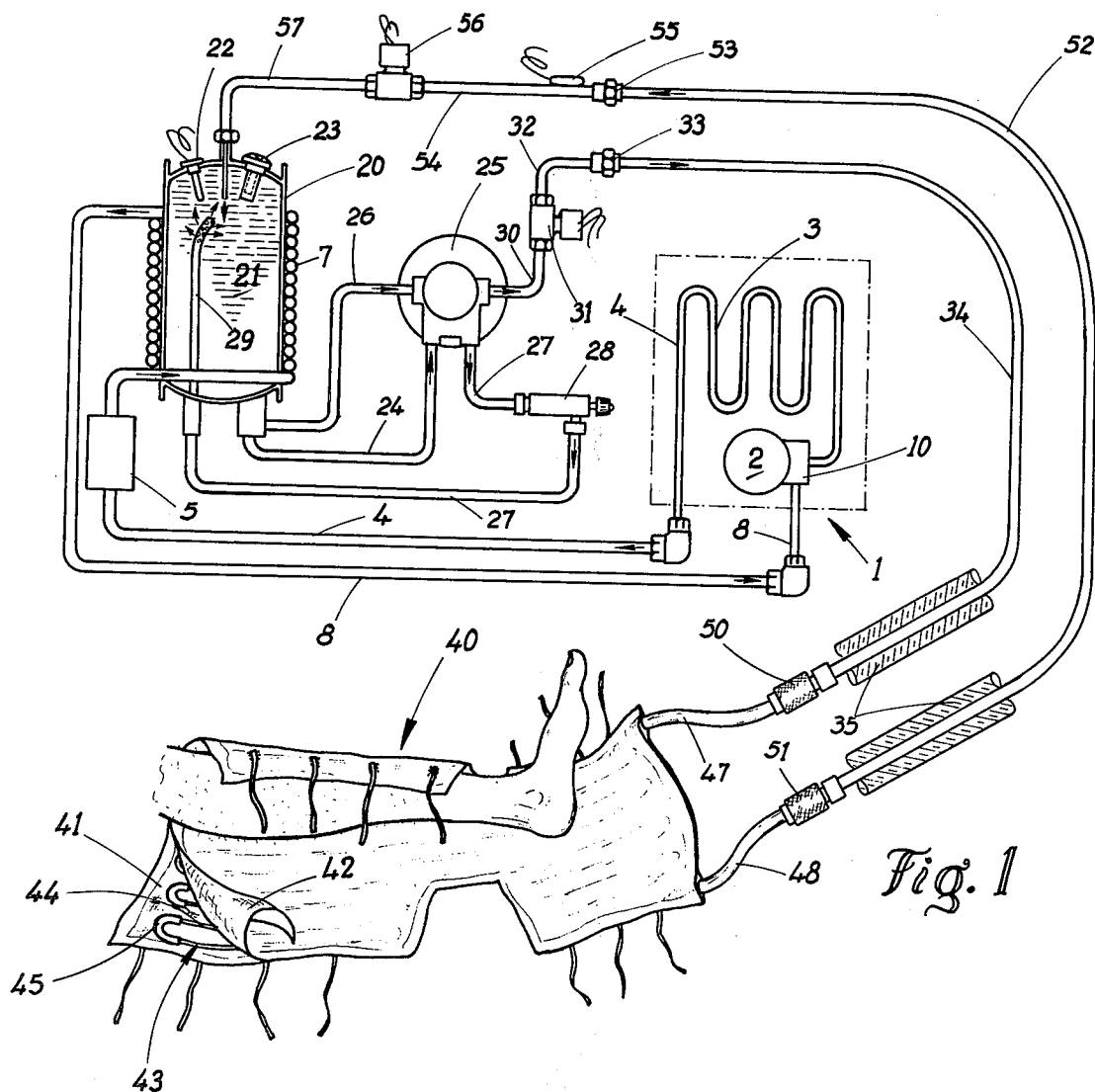
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ABSTRACT

A new technique and new apparatus has been developed to facilitate the physiologic amputation of poor risk patients having gangrene of the leg. This process involves the controlled application of refrigeration through a freezing pad wrapped around the affected portion of the extremity to completely freeze the extremity. The refrigerant circulating throughout the freezing pad is supplied through flexible tubes from a refrigeration unit thus allowing freedom of movement to the patient, limited ambulation and movement of the extremity during the pre-operative period of treatment.

8 Claims, 1 Drawing Figure





PROCESS AND APPARATUS FOR CRYOSTATIC PRE-OPERATIVE TREATMENT OF GANGRENOUS EXTREMITIES

FIELD OF THE INVENTION

This invention relates to a freezing pad for making cold application to the body in medical treatment. An object of the invention is to provide electrical and mechanical means for producing a continuous supply of refrigerant and for circulating said refrigerant through a freezing pad applied to the body by means of flexible tubes or hoses.

DESCRIPTION OF THE PRIOR ART

Freezing of an extremity has been accepted by the medical profession as an effective method of controlling wet gangrene of an extremity with its infectious and toxic complications. After circulation between the affected portion of the extremity is completely cut off from the rest of the body, the surgeon can then initiate supportive procedures to improve the general condition of the patient and perform the surgical amputation as an elective procedure. Previously, however, freezing of the extremity has involved inefficient messy and cumbersome methods of applying ice or dry ice to an extremity or by actually inserting the extremity into a large and cumbersome refrigeration unit. In the latter case, the extremity is completely immobilized and movement of the patient is severely limited. This is unsatisfactory since, in many cases, the patient is in such poor condition that pneumonia and other complications can set in, which complications are exacerbated, as a result of the patient being unable to move. Refrigeration apparatus has long been known for applying cooling application to the body. Thus, as early as 1933, Hassell in U.S. Pat. No. 1,896,953, disclosed an electric ice cap consisting of a sinuous tube interspersed between two covers through which a secondary refrigerant was circulated. Barnes, in U.S. Pat. No. 2,397,232, in 1946, disclosed a flexible applicator which could be connected to a source of refrigerant for effecting refrigeration anesthesia. Again, Barnes, et al. in U.S. Pat. No. 2,415,455, disclosed a splint-like apparatus for refrigeration anesthesia consisting of movable and flexible metal plates cooled on one side by circulating refrigerant in a series of tubular conduits. Chessey, in U.S. Pat. No. 2,726,658, disclosed flexible pads suitable for attachment to the body which were cooled by circulating a secondary refrigerant or brine solution cooled in a refrigeration unit.

SUMMARY OF THE INVENTION

Insofar as I am aware, the concept of providing a secondary or primary refrigerant at subfreezing temperatures to a flexible pad or applicator which can be applied to a gangrenous extremity has not been disclosed. According to this invention, there is provided a freezing pad through which refrigerant, primary or secondary, is circulated at subfreezing temperatures for a sufficient time to completely freeze the gangrenous portion of the extremity and thus effectuate complete physiologic amputation of said extremity prior to surgical amputation. Due to the fact that the refrigerant is supplied from a refrigeration source through elongated flexible tubes, the patient is provided with a certain limited ambulation, is allowed freedom of movement in bed from either sitting, lying or prostrate position, or is

even allowed to get out of bed and sit in a chair if desired. Further, after the limb has been completely frozen, the temperature can be set to a holding temperature in the freezing range and the patient maintained in this condition for periods of as long as a week or more, while supportive procedures are initiated to put the patient into condition for surgical procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings,

FIG. 1 is a schematic illustration of a refrigeration unit utilized to cool a secondary refrigerant to a preselected freezing temperature which refrigerant is then circulated through a pump to the freezing pad or boot of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings in detail, the refrigeration unit is schematically illustrated as indicated by numeral 1. It consists of a motor compressor 2, a condenser coil 3, a high pressure line 4 leading from the condenser coil to an expansion valve 5. The evaporation coil 7 which surrounds tank 20 leads to low pressure or suction line 8 through suction port 10 back to motor compressor 2. As previously indicated, the tank 20 for the secondary refrigerant 21 contains, in this instance, 95 percent alcohol although other secondary refrigerants can be used. A thermometer 22 is inserted into the tank 20 at the top as is a liquid level probe 23. The liquid refrigerant 21 is discharged from the tank 20, via line 24, to pump 25, and is recycled back through recycle line 27 which operates in conjunction with thermostat 28 and terminates in vertical discharge leg 29 in the tank 20. The outlet line 30 from the pump 25 is supplied by line 26 and goes to solenoid valve 31 which, if opened, supplies the subfreezing alcohol solution refrigerant 21 through line 32 to the flexible tube 34 joined together by quick disconnect coupling 33. The flexible tube 34, of course is outside of the refrigeration unit and is therefore preferably covered with a flexible, low-temperature insulation 35 such as an expanded NEOPRENE, known in the trade as ARMOFLEX. The flexible tube 34, is connected to the freezer pad 40 by means of quick disconnect coupling 50 to the inlet opening 47 of the sinuous tubing, 43 forming the refrigeration or cooling portion of the freezing pad. As will be noted, the freezing pad 40 consists of an outer layer 41 of waterproof material and an inner layer 42 of waterproof material which in the drawing has been pulled away to illustrate its construction. The sinuous tubing 43 consists of a series of parallel lengths 44 running the length of freezing pad 40 which are reinforced at the right 45. The outlet opening 48 is connected via quick disconnect coupling 51 to return flexible tubing 52 which in turn is connected through quick disconnect coupling 53 to return line 54. A thermometer 55, is illustrated next to the return line 54 and solenoid valve 56 controls the flow of the returning liquid through line 57 back to the secondary refrigerant tank 20. It will thus be seen that there is provided a refrigeration apparatus suitable for use for cooling a tank of secondary refrigerant to subfreezing temperatures so as to allow freezing of selected portions of the patient's extremity.

OPERATION

As will be noted, the patient's foot and leg is placed into the freezing pad 40 and the pad is pulled up around

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the foot and leg and tied by means of tying straps. Additional insulation in the form of polyurethane foam or other materials can be wrapped around the pad 40 to prevent loss of freezing capacity. The apparatus is then set at a freezing temperature in the range of between 25 to 40°C. and the refrigeration unit is turned on. As soon as the unit provides sufficient refrigeration to anesthetize the extremity, a tourniquet is applied above the upper portion of the freezing pad 40. Thus, through the use of the tourniquet and through the complete freezing of the extremity, the circulation between the extremity and the rest of the body is completely cut off. Thus, there is affected a complete physiologic amputation of that portion of the leg. Thereafter, the temperature of the liquid circulating through the freezing pad can be raised to a holding temperature of somewhere in the range of between 0 to 10°C. and the apparatus will proceed automatically without further nursing care. It is only necessary then to check the apparatus from time to time and to begin supportive procedure for the patient so as to provide him strength for the subsequent surgical amputation. In many instances, the patient gains sufficient strength, as soon as the circulation of toxins from the gangrenous area is cut off, that within several hours an operation can be scheduled. Nevertheless, it is possible to maintain the patient in this condition for up to a week or longer while he is allowed to regain strength through supplemental therapy. During this time, the patient can sit up, can roll over, can move around, can get out of bed, can perform his own toilet and can sit in a chair without any particular nursing care.

It will be apparent to those skilled in the art that I have provided an efficient, almost completely automatic method of freezing gangrenous extremities as a preoperative treatment for surgical amputation. The method eliminates wet and messy dressings with the constant nursing care previously experienced through the use of ice packing. Since the tubes supplying refrigerant to the freezing pad are flexible, the patient is allowed considerable mobility and even limited ambulation during the pre-operative period of treatment.

Many modifications will occur to those skilled in the art from the detailed description hereinabove given and such description is meant to be exemplary in nature and non-limiting except so as to be comensurate in scope with the appended claims.

I claim:

1. In a process of cryostatic pre-operative treatment of a gangrenous extremity in preparation for the subsequent surgical amputation of said extremity,

- a. the improvement of lowering the temperature of the affected portion of the extremity and providing refrigeration anesthesia to the patient and ultimately providing physiologic amputation of said portion of said extremity while providing to said

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patient movement of said extremity and limited ambulation during the period of said pre-operative treatment and simultaneously reducing nursing care to a minimum during said period of said pre-operative treatment, which comprises the steps of:

- b. wrapping the affected part of the extremity with a flexible freezing pad, having inner and outer layers and containing sinuous tubing interposed between said layers which covers most of the area of said pad and
- c. supplying refrigerant to said sinuous tubing and removing refrigerant from said sinuous tubing from a from some distance from said pad through flexible tubing extending from said source to said pad and from said pad to said source and which forms a closed circuit with said source and said pad;
- d. circulating said refrigerant through said sinuous tubing at subfreezing temperatures for sufficient time to completely freeze the wrapped gangrenous extremity and to effect physiologic amputation of said extremity by completely cutting off circulation between the affected part of said extremity and the rest of the body;
- e. thereafter, raising the temperature of the circulating refrigerant to a freezing holding temperature for sufficient time to maintain the extremity in frozen condition until the patient gains sufficient strength to undergo surgical amputation.

2. The process of claim 1, the further step of applying a tourniquet to said extremity above said pad simultaneously with the step of circulating said refrigerant through said sinuous tube.

3. The process of claim 1, in which the refrigerant, circulated through said sinuous tubing, is at a temperature in the range of 20 to 40°C.

4. The process of claim 1, in which the holding freezing temperature of said refrigerant is in the range of from 0 to 10°C.

5. The process of claim 1, the further improvement of wrapping a layer of low temperature insulation around said pad after it is wrapped onto the affected extremity.

6. The process of claim 1, the further improvement in circulating refrigerant through said sinuous tubing at subfreezing temperatures, which comprises the step of expanding compressed and liquid refrigerant into said sinuous tubing forming the refrigeration portion of said freezing pad.

7. The process of claim 6, in which the compressed and liquid refrigerant, which is expanded into said sinuous tubing, has been compressed and liquified by a motor compressor in said source.

8. The process of claim 1, in which said refrigerant, circulated through said sinuous tubing, is a secondary liquid refrigerant, cooled by the evaporation of a primary refrigerant in said source.

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