

[54] **AUTOMATIC SYSTEM WITH
PERFUSION PROTECTION AGAINST
MALFUNCTION**

[72] Inventors: **Ion Mogos; Cormel I. Muscel; Nicolae Du-
mitrescu**, all of Bucharest, Romania

[73] Assignee: **Institutul Oncologic Bucharest, Bucharest,
Romania**

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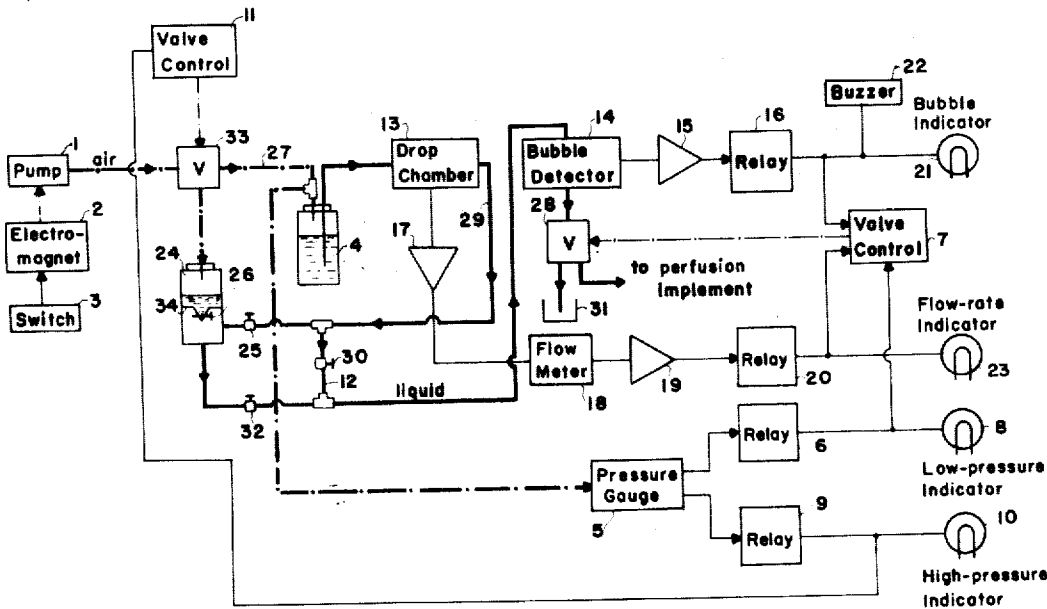
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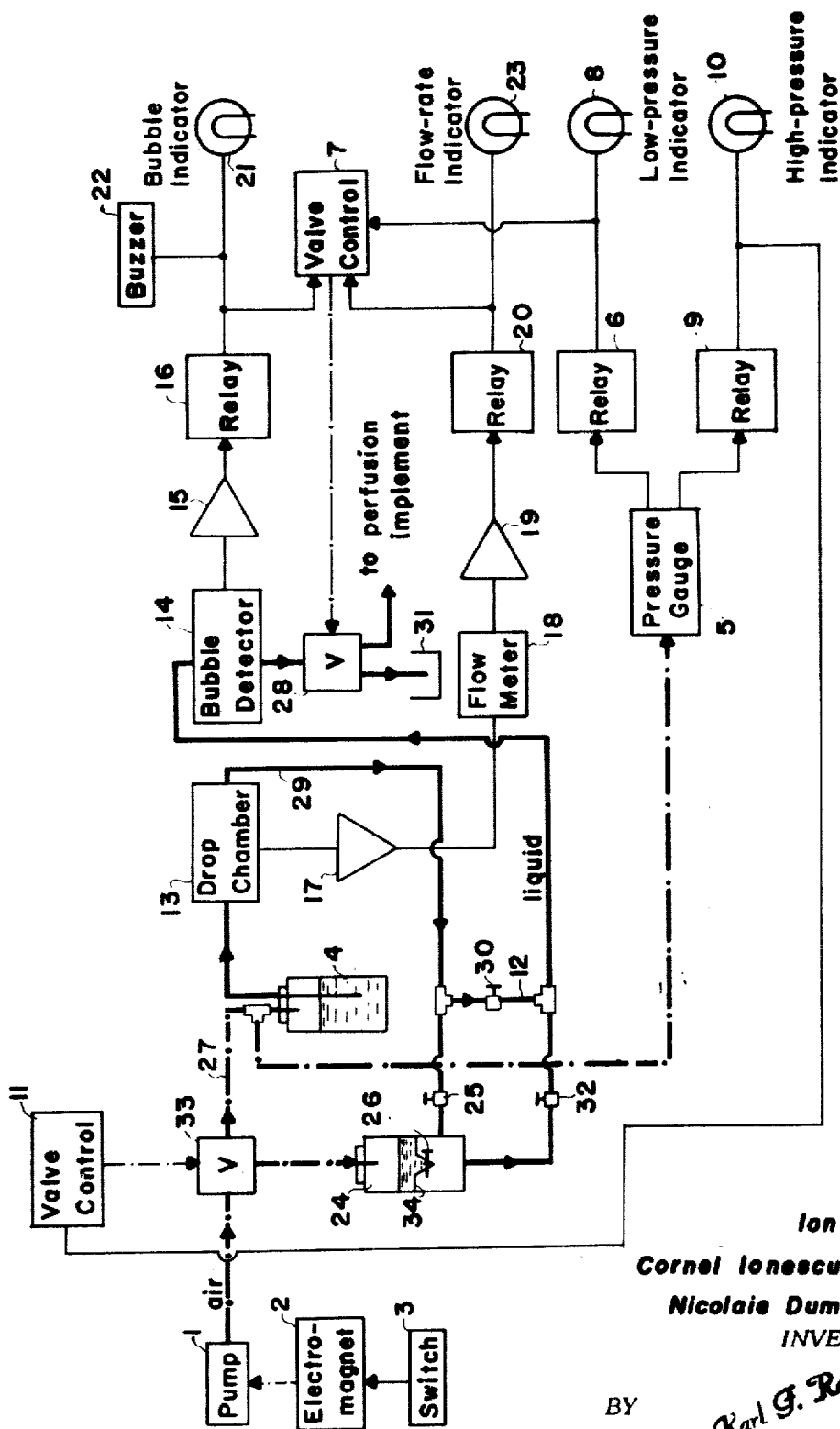
Primary Examiner—Dalton L. Truluck
Attorney—Karl F. Ross

[57] **ABSTRACT**

A system for performing intravenous perfusions of a treatment liquid propelled by gas under pressure includes a gauge which vents the gas line in the event of excessive gas pressure. In the event of insufficient gas pressure, the gauge actuates a controller for switching a valve to divert the liquid flow from the perfusion implement to a drain, the controller also responding in like manner to gas occlusions sensed by a bubble detector and to a slowdown in the flow rate as measured by a drop counter.

6 Claims, 2 Drawing Figures





Ion Mogos
Cornel Ionescu Muscel
Nicolaie Dumitrescu
INVENTOR.

BY

Karl G. Rau
Attorney

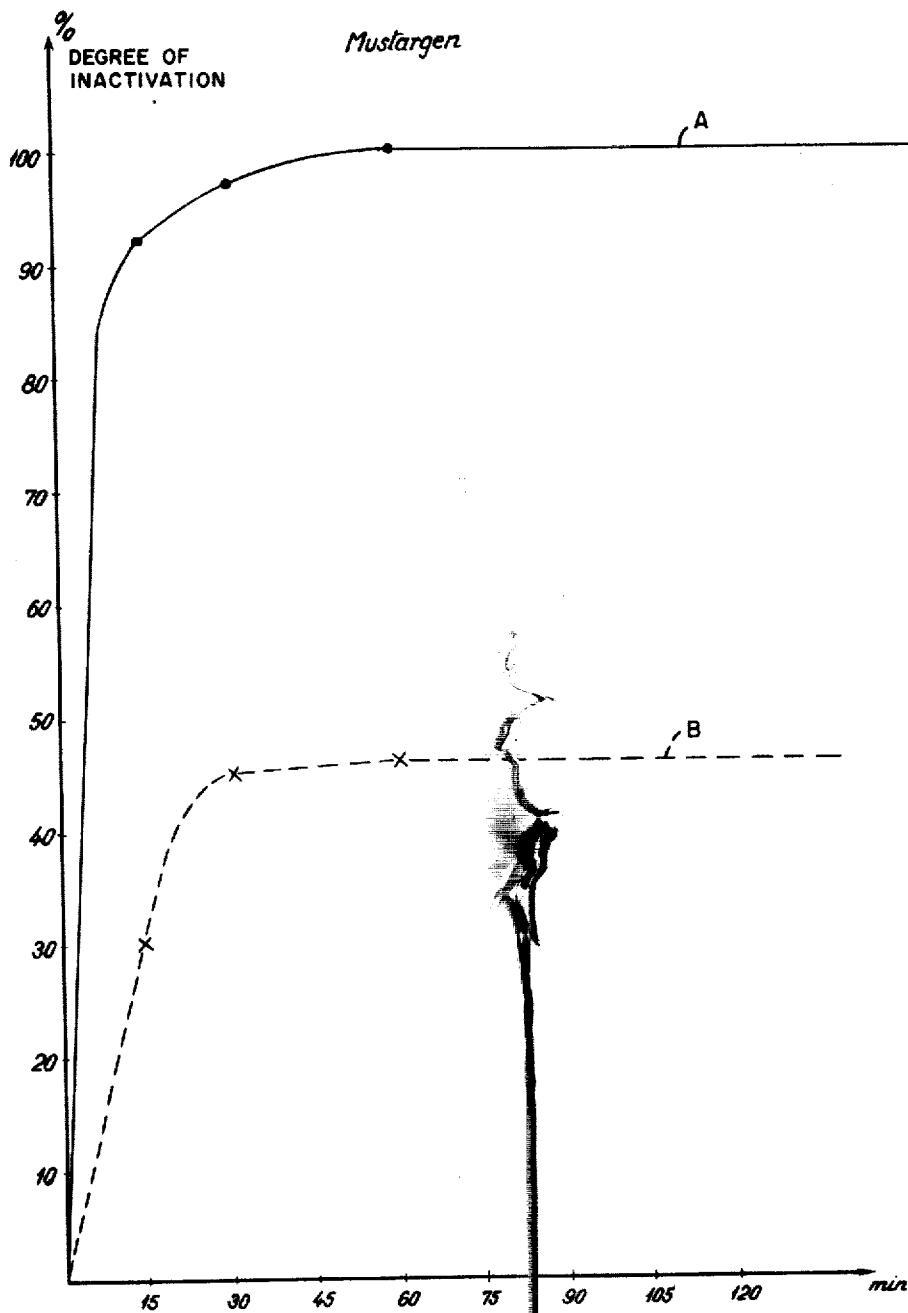


Fig. 2

Ion MOGOS
Cornel IONESCU MUSCEL
Nicolae DUMITRASCU

INVENTOR

BY

Karl F. Ross

AUTOMATIC SYSTEM WITH PERFUSION PROTECTION AGAINST MALFUNCTION

The present invention relates to automatic equipment for continuous perfusion with protective electronic circuits designed to prevent accidents that could endanger a patient treated with an intravenously administered liquid.

The object of our invention is to provide means for indicating malfunctions and avoiding accidents during transfusion, such as gas emboly, thrombosis, rupture of bloodvessel or detachment of the needle from the vein.

More specifically, our invention aims at arresting the flow of serum towards the patient and diverting the liquid to a drain under any of the following conditions:

a. when an air bubble appears in the perfusion line, removal of the bubble to the drain and reappearance of the treatment liquid in the circuit returning the valve to its normal operating position;

b. when the pressure of the treatment liquid increases or decreases beyond predetermined limits;

c. when the flow rate of the liquid decreases, owing to thrombosis, conduit clogging or loss of pressure in the perfusion line.

In accordance with this invention, we provide a normally closed first valve for venting a gas line leading from a source of high-pressure gas to a container for the liquid to be intravenously administered, a second valve being disposed in a fluid line originating at that container for normally conveying the treatment liquid to a perfusion implement but for diverting this liquid to a drain, via a line branching off the main fluid line, under potentially dangerous circumstances. Thus, a pressure gauge responsive to the gas pressure in the container generates a first alarm signal whenever this gas pressure rises above an upper limit of a predetermined range, at the same time actuating a controller for the first valve to vent the gas line; when the gas pressure falls beneath a lower limit of that range, a second alarm signal is generated by the gauge which simultaneously actuates a controller for the second valve to divert the liquid flow from the perfusion implement to the drain.

In accordance with other features of our invention, the controller for the second valve responds also to the output of a drop counter, connected to a drop chamber in series with the main fluid line, and to the output of a bubble detector, also inserted in the main fluid line, for similarly diverting the liquid flow upon a substantial decrease of the flow rate from a predetermined level and in the presence of gas occlusions.

If an additive, such as a short-lived cytostatic agent or cell-growth inhibitor known as Mustargen (N_2H), is to be admixed with the treatment liquid, a vessel containing this additive may be connected to the gas line in parallel with the container for the treatment liquid and may be inserted in the main fluid line so that the liquid continuously entrains some additive which is under the same gas pressure; advantageously, the fluid line may be provided with a conduit bypassing this vessel and with valves selectively operable to divide the flow between the vessel and the bypass.

The invention will be further described hereinafter with reference to the accompanying drawing in which:

FIG. 1 is a block diagram of a perfusion system embodying our invention; and

FIG. 2 is a graph showing the degree of inactivation of a cytostatic (Mustargen) in a conventional system and in a system according to the invention.

From a diaphragm-type miniature pump 1, actuated by an electromagnet 2 whose supply voltage may be varied by means of a switch 3, air under a pressure of 80-200 mm. Hg. (adjustable through manipulation of the switch 1) is introduced into a vessel 4 containing the treatment fluid. The existing pressure in vessel 4 may be read on a mercury pressure gauge 5, provided with contacts at every scale graduation of 10 mm. Hg.

When the pressure in gas line 27 decreases below a predetermined value related to the patient's arterial pressure,

the mercury in pressure gauge 5 energizes a relay 6 which actuates an electromagnetic controller 7 and a signal lamp 8. Controller 7 thereupon operates a safety valve 28 in fluid line 29 to block the fluid flow to the patient, via a perfusion implement not shown, until the pressure again exceeds the established lower limit (adjustable between 80 and 180 mm. Hg.).

In the same manner, when the pressure in vessel 4 exceeds the predetermined upper limit (adjustable between 100 and 200 mm. Hg.), pressure gauge 5 energizes a relay 9 activating a signal lamp 10 and an electromagnetic controller 11 which opens a safety valve 33 to vent the gas line 27 whereby the gas pressure drops again to its normal range.

The treatment liquid from vessel 4 is thus driven with an adjustable pressure, sensed by means of pressure gauge 5, through line 29 at a rate that is adjustable by a valve 30 in a bypass tube 12; line 29 traverses a drop chamber 13 and a bubble detector 14.

Detector 14 is provided with two platinum contacts between which the treatment fluid flows. When the fluid column is interrupted by the presence of an air bubble in the line 29, a transistor amplifier 15 energizes a relay 16 to actuate the controller 7 for operating the valve 28 to divert the liquid flow to a drain flask 31.

When the fluid column is reestablished between the contacts of detector 14 and the air bubble has been discharged to the drainage flask 31, controller 7 restores the valve 28 to its working position. The appearance of an air bubble in the perfusion line 29 is indicated by means of a lamp 21 and a buzzer 22 also energized by relay 16.

Drop chamber 13 is also provided with two platinum contacts so arranged that every drop of liquid bridging the two contacts produces an electric pulse fed to a transistor amplifier 17. The amplified pulses are applied via a shaping circuit, not shown, to a flow meter 18 provided with an instrument counting the number of drops per minute so that the transfusion rate can be read at any time. When the rate is less than two drops per minute, an amplifier 19 controlled by timer 18 actuates a relay 20 which, by means of controller 7 and valve 28, again blocks the circuit leading to the perfusion implement while signaling the condition by means of a lamp 23.

The complete equipment, mounted on a carrier for transporting the patients, is fed from an accumulator battery on a shock-absorbing support. In this manner the system may operate either from the mains or independently thereof.

If a cytostatic subject to rapid inactivation is used in vessel 24, tube 12 is partially closed by clamp-type valve 30 and the fluid is admitted into a vessel 24 in parallel therewith, the cytostatic dropping through a retaining device 34 to the bottom of vessel 24 wherefrom it is entrained by the treatment liquid at a rate adjusted by means of valves 25, 26 and 32.

Curve A of FIG. 2 shows the normal deactivation of Mustargen, in N/100 HCl solution, whereas curve B indicates the same upon administration by the system according to the invention, as measured in terms of rate of hydrolysis.

If an accidental supply-voltage breakdown occurs, the electromagnetic controller 7 for valve 28, which normally is held open, is no longer energized so that the valve cuts off the perfusion circuit leading toward the patient.

The system according to the invention presents the following advantages as compared with conventional equipment:

It prevents and warns of the danger of gas emboly and pressure increase with possible rupture of the blood vessel or dislodgement of the needle;

it indicates the occurrence of thrombosis, pressure loss, or reduction in the flow rate;

it allows safe and controlled treatment, with constant pressure and flow-rate, with massive doses of cytostatics and other medications administered intraarterially, interstitially, intralymphatically and intraperitoneally;

it optically and acoustically signals the presence of a failure in the operation of the equipment or trouble with the patient, so that the medical attendants can intervene promptly and efficiently;

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it allows perfusion to be performed on both bed and ambulatory patients, without unduly restricting their movements;

finally, it affords efficient utilization of short-lived cytostatics, avoids the waste of treatment fluids and; guards against the danger of harm during perfusion in case of accidental failure of a power supply.

What is claimed is:

1. A perfusion system for intravenously administering a liquid to a patient, comprising a container for said liquid; a source of gas under pressure; a gas line connecting said source to said container for subjecting the liquid therein to the pressure of the gas; a fluid line originating at said container for conveying said liquid to a perfusion implement; normally closed first valve means connected with said gas line; gauge means responsive to the gas pressure in said container for generating a first alarm signal upon said gas pressure rising above an upper limit of a predetermined range and for generating a second alarm signal upon said gas pressure falling beneath a lower limit of said range; drain means branching off said fluid line; second valve means at the junction of said fluid line with said drain means for normally directing said liquid to said perfusion implement; first control means for said first valve means responsive to said first alarm signal for venting said gas line; and second control means for said second valve means responsive to said second alarm signal for diverting said liquid from said perfusion implement to said drain means.

2. A perfusion system as defined in claim 1, further comprising a drop chamber in series with said fluid line upstream of said junction and counting means connected to said drop

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chamber for measuring the rate of liquid flow therethrough, said counting means having an output connected to said second control means for operating said second valve means to divert said liquid to said drain means upon a substantial decrease of said rate from a predetermined level.

3. A perfusion system as defined in claim 1, further comprising a bubble detector in series with said fluid line upstream of said junction for ascertaining the presence of gas occlusions in the liquid flow, said bubble detector having an output connected to said second control means for operating said second valve means to divert said liquid to said drain means in the presence of such gas occlusions.

4. A perfusion system as defined in claim 1, further comprising a vessel for the storage of an additive to be admixed with said liquid, said vessel being connected to said gas line in parallel with said container for placing said additive under the pressure of said gas, said fluid line passing through said vessel ahead of said junction.

5. A perfusion system as defined in claim 4, further comprising conduit means bypassing said vessel and further valve means for selectively dividing the flow of said liquid between said vessel and said conduit means.

6. A perfusion system as defined in claim 1 wherein said second control means is an electromagnetic device effective in a deenergized condition to maintain said second valve means in an off-normal position cutting off the flow of said liquid to said perfusion implement.

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