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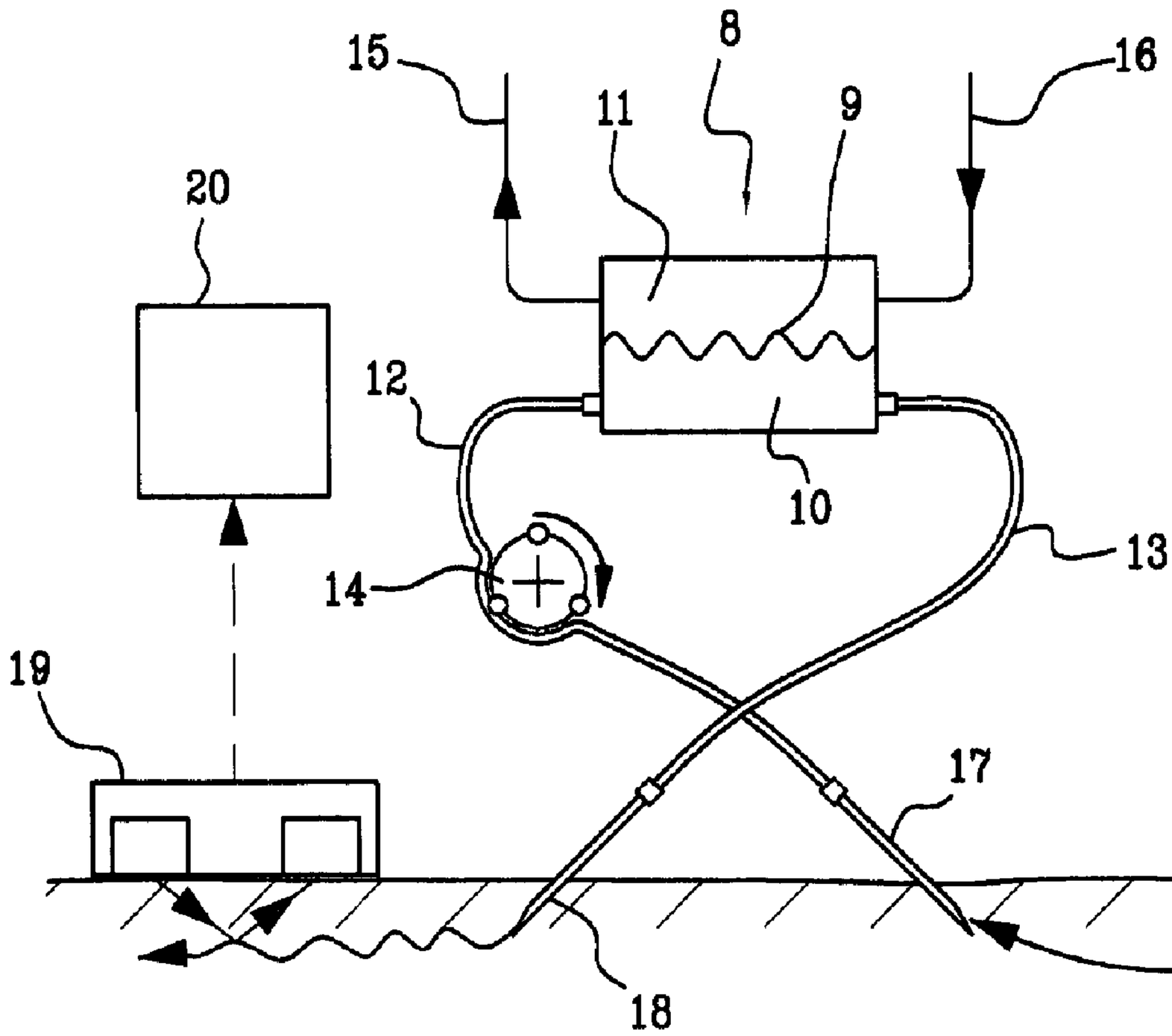
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(72) Inventeurs/Inventors:
STEFANI, DAVID, IT;
LODI, CARLO ALBERTO, IT;
SANNA, SALVATORE, IT

(73) Propriétaire/Owner:
GAMBRO LUNDIA AB, SE

(74) Agent: ROBIC

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An apparatus for monitoring a vascular access comprises a dialysis circuit having a venous needle (18) and a blood pump (14) of a peristaltic type which generates oscillatory perturbations in the circuit. An optical sensor (19), arranged on a patient's body by the venous needle, perceives the perturbations transmitted through the needle and sends a pulsating signal to an analysis device (20), absence of which pulsating signal provides an indication of a detachment of the needle.

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(71) Applicant *(for all designated States except US)*: **GAMBRO LUNDIA AB** [SE/SE]; P.O. Box 10101, S-22010 Lund (SE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **STEFANI, David** [IT/IT]; No. 10, Via Nenni, I-41100 Modena (IT). **LODI, Carlo Alberto** [IT/IT]; No. 28, via Dallari, I-41012 Carpi (IT). **SANNA, Salvatore** [IT/IT]; No. 64, via Curiel, I-41037 Mirandola (IT).

(74) Agent: **KRONBORG PETTERSSON, Niklas**; Gambro Lundia AB, P.O. Box 10101, SE-220 10 Lund (SE).

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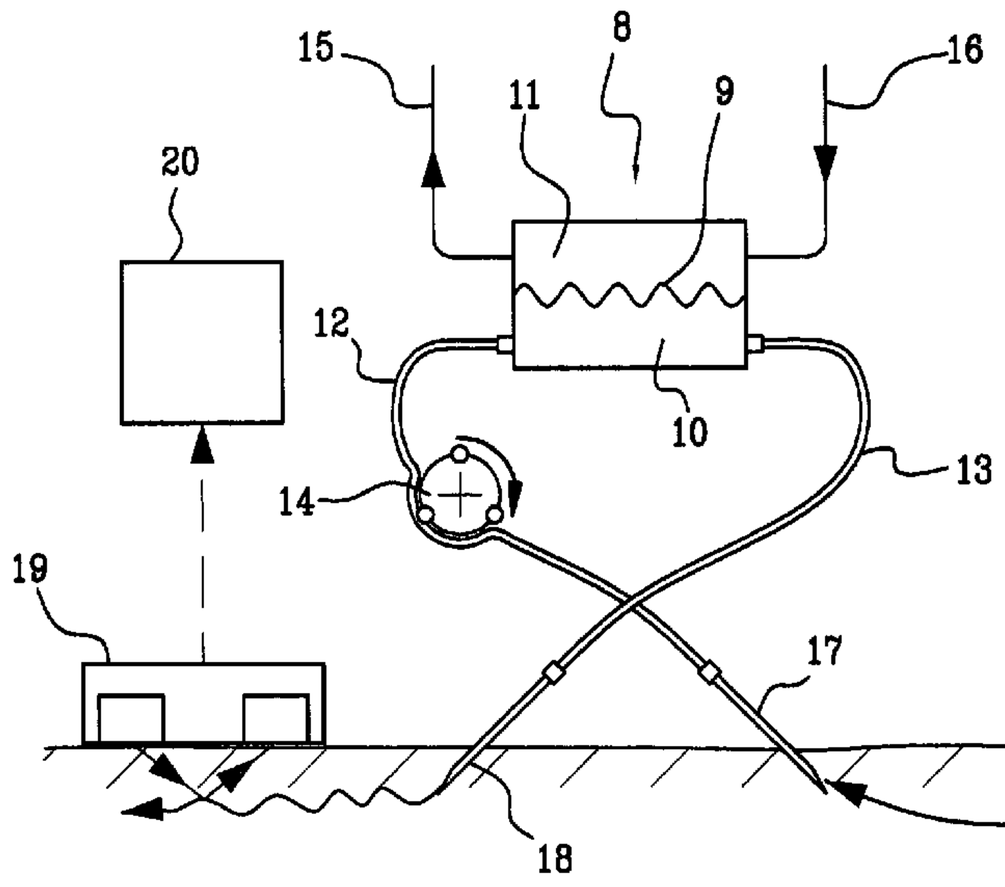


FIG 2

(57) **Abstract**: An apparatus for monitoring a vascular access comprises a dialysis circuit having a venous needle (18) and a blood pump (14) of a peristaltic type which generates oscillatory perturbations in the circuit. An optical sensor (19), arranged on a patient's body by the venous needle, perceives the perturbations transmitted through the needle and sends a pulsating signal to an analysis device (20), absence of which pulsating signal provides an indication of a detachment of the needle.

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DESCRIPTION

"An Apparatus and a Method for Monitoring a Vascular Access"

BACKGROUND OF THE INVENTION

[0001] The invention relates to an apparatus and a method for monitoring a vascular access.

[0002] Specifically, though not exclusively, the invention can be usefully applied in detection of detachment of a needle in an extracorporeal blood circuit, such as for example an extracorporeal circuit used in a dialysis treatment.

[0003] The prior art comprises various systems for monitoring a needle, typically a needle (generally called a venous needle) via which extracorporeal blood is returned to the body of the individual.

[0004] Some known systems for detecting a detachment of the needle from the patient are based on detection of the presence of blood that has exited from the detached needle and/or the vascular access and spilled onto the patient's body. These systems can be based on a monitoring performed with a sensor of an electrical parameter (such as for example in US 2002/0198483, WO 99/24145, FR 2737124, US 7276041), or an optical parameter (such as for example WO 2006/001759 and US 2006/0130591), or both (such as for example EP 1736185 and EP 1263488).

[0005] Other known systems (see for example US 6663585, WO 02/102441, WO 01/47581, WO 03/086504, WO 2006/138359, US 2006/0081517, DE 102006041265) are based on monitoring the state of an electrical circuit formed at least partly by at least a tract of blood circuit, exploiting blood's characteristic of being electrically conductive.

[0006] A further known system is described in US 2007/0118064, in which an apparatus guides the blood in the venous line in an inverse direction, using an ultrafiltration pump, and detects a detachment of the venous needle on the basis of recognition of a presence of air bubbles in the venous line itself.

[0007] There also exist systems based on the monitoring of the pressure in the extracorporeal circuit, such as for example US 4898576, EP 328162, US 2005/0010118, US 6077443, US 6221040, WO 03/002174, US 6090048.

[0008] US 4898576 describes an infusion system in which the infusion flow has a periodic variation and in which the state of the vascular axis is determined on the basis of the flow resistance, which is calculated on the

basis of the variation in pressure in relation to the flow variation.

[0009] EP 328162 describes an infusion system in which the pressure signal measured in the infusion line downstream of the infusion pump is filtered by a high-pass filter and the filtered signal is evaluated in order to calculate the correct communication with the vascular access.

[0010] US 2005/0010118 describes a dialysis apparatus in which the disconnection of the needle from the vascular access is detected when the frequency component, caused by the heartbeat of the patient, disappears from the pressure signal measured in the extracorporeal circuit.

[0011] US 6077443 shows a dialysis apparatus in which a series of pressure pulses are generated in the dialysis circuit and the detachment of the needle is detected by the monitoring of the pressure pulses induced in the extracorporeal blood circuit of the series of pulses.

[0012] US 6221040 shows a dialysis apparatus in which the detachment of the venous needle is detected by analyzing both the venous pressure and the arterial pressure of the extracorporeal circuit.

[0013] WO 03/002174 describes a dialysis apparatus in which the detachment of the venous needle is detected if both the venous pressure and the arterial pressure are reduced and, during the same period of time, the extracorporeal blood flow stays constant.

[0014] US 6090048 describes a dialysis apparatus in which the detachment of the venous needle from the patient is determined by verifying whether a pressure wave, generated by the blood pump or the heartbeat, passes through the needle and reaches the pressure sensor on the venous line.

[0015] The prior art also comprises WO 2007/033025 which describes an apparatus infusion control in which the infusion fluid flow rate is controlled in response to patient parameter values measured, such as for example pulse oximetry and blood pressure.

SUMMARY OF THE INVENTION

[0016] An aim of the present invention is to provide a way of determining a detachment of a needle from the vascular access of an individual.

[0017] An advantage of the invention is to realize a simple, economical and reliable system for detecting, in good time, a detachment of a needle, in particular the venous needle in an extracorporeal blood circuit.

[0018] A further advantage of the invention is to provide a method and an

apparatus for detecting detachment of a needle by means of a relatively low-cost simple instrumentation.

[0019] A further advantage is to make available a method and an apparatus which can discriminate between the effective detachment of the needle and the occurrence of other non-alarming facts, such as for example displacement of the individual (perhaps during a dialysis treatment a patient might move his or her arm which the vascular access is realised in), variations of velocity/frequency of the blood pump, etc.

[0020] According to the present invention, there is provided an apparatus for monitoring a vascular access, comprising:

a fluid transport system for moving a fluid;

at least a needle connected to the fluid transport system and to a vascular access of an individual for supplying and/or removing the fluid to and/or from the vascular access via the at least a needle;

a perturbation generator configured for generating variations of at least a parameter in the fluid transport system and/or for generating variations of at least a parameter in the needle, wherein the parameter comprises one or more chemical and/or physical characteristics of the fluid;

a sensor configured for application to the individual's body, the sensor emitting a signal indicating the variations of the at least a parameter transmitted through the needle;

an analysis device for recognising a detachment of the at least a needle, on a basis of said signal, c h a r a c t e r i z e d i n that the sensor comprises at least an emitter of light radiations and a receiver of radiations, the emitter of light radiations and the receiver of radiations being configured to be operatively associated to at least a tissue of the individual's body.

[0020a] According to the present invention, there is also provided a method for monitoring a vascular access, comprising the following steps:

providing a fluid transport system;

providing at least a needle adapted to be connected to the fluid transport system, and adapted to be connected to a vascular access of an individual; and

generating variations of at least a parameter in the fluid transport system and/or generating variations of at least a parameter in the at least a needle, wherein the parameter comprises one or more chemical and/or physical characteristics of the fluid;

monitoring an individual's body in order to identify the variations of the at least a parameter transmitted through the at least a needle;

recognising a detachment of the at least a needle on a basis of the monitoring, c h a r a c t e r i z e d i n that the step of monitoring comprises at least an emission of light radiation on at least a tissue of the individual's body, and at least a receiving of the radiation.

[0021 In a specific embodiment of the invention, the detachment of the needle from the vascular access is determined by means of a method and/or an apparatus configured to perform the monitoring of the power spectrum of the vascular pulsation of the individual in proximity of the needle. In particular this monitoring comprises verifying, either continuously or periodically, the presence or not, in the vascular pulsation of the individual, of the contribution due to the pulsation which is induced in the extracorporeal system by an actuator predisposed to generate pulses (such as for example a peristaltic pump which generates pulses during normal functioning thereof).

[0022] In a specific embodiment of the invention, an apparatus and/or a method for determining the detachment of a needle comprises means for and/or a step of monitoring the energy of a signal deriving from the vascular pulsation in proximity of the needle, and control means for and/or a step of verifying a variation of the energy.

[0023] In a specific embodiment of the invention, an apparatus and/or a method for determining detachment of a needle comprises means for and/or a step of monitoring a signal indicating the vascular pulsation in proximity of the needle, and control means for and/or a step of verifying a variation of the signal.

[0024] In particular the control means can comprise means for filtering the signal which filter the signal in a range (of predetermined entity) around the - known - frequency of a pulse generator operating in the extracorporeal fluid

system. The control means can be predisposed to perform a frequency analysis of the signal received from the means for monitoring.

[0025] In particular the above-cited means for monitoring can comprise a radiation sensor (for example optical or sound radiations) which is operatively associated to the body of the individual in proximity of the

needle. The sensor can be, for example, configured for detection of radiation absorbed and/or reflected. The sensor can be, in particular, a pulse oximeter predisposed in proximity of the needle, for example a pulse oximeter applied to a fingertip of a hand of the arm the vascular access is realised in.

[0026] In particular the above-cited means for monitoring and controlling operate on the basis of the monitoring and processing of signals by frequency analysis of the signals themselves. This makes an accurate measuring of the absolute value of the signals themselves not strictly necessary.

[0027] In particular the means for monitoring and controlling perform a verification of the absence (or reduction below a predetermined threshold) of a certain component of the monitored signal, in particular a pulsating or undulating component of known frequency.

[0028] Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of at least an embodiment of the invention, illustrated by way of non-limiting example in the accompanying figures of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] The following description will be made with reference to the accompanying figures of the drawings, provided by way of non-limiting example.

[0030] Figure 1 is a schematic representation of a first embodiment of a monitoring apparatus according to the present invention, in which the monitoring apparatus is operatively associated to a fluid infusion system (for example a medical fluid or a corporeal fluid) into the vascular system of an individual.

[0031] Figure 2 shows a second embodiment of a monitoring apparatus of the present invention, in which the monitoring apparatus is operatively associated to an extracorporeal treatment system of the blood of an individual (a patient or a donor) with an extracorporeal circuit of the double-needle type.

[0032] Figure 3 shows a third embodiment of the invention, in which the monitoring apparatus sensor comprises a finger pulsimeter of a type that absorbs radiation, which is arranged such as to be very highly sensitive to pulsations induced by the blood pump on the arterial branch of a double-needle extracorporeal circuit.

[0033] Figure 4 is a diagram representing the functioning of an

absorption pulsimeter

[0034] Figure 5 is a diagram showing the functioning of a reflection pulsimeter.

[0035] Figure 6 is a diagram showing time progress of the radiations detected by the receiver of the pulsimeter of figure 4 (absorbed radiations) or figure 5 (reflected radiations).

[0036] Figure 7 schematically shows the time progress of the signal emitted by the sensor of figure 4 or figure 5.

DETAILED DESCRIPTION

[0037] With reference to figure 1, 1 denotes in its entirety an apparatus for monitoring a vascular access, 2 denotes a fluid transport system for moving a fluid, 3 a needle connected at an end thereof to the fluid transport system and an opposite end thereof to a vascular access of an individual, 4 the body of the individual, 5 a perturbation generator for generating perturbations in the fluid transport system, 6 a sensor configured to be operatively associated to the body 4 of the individual for emitting a signal indicating the perturnbations which are induced in the transport system 2 by the generator 5 and which are transmitted into the body 4 of the individual via the needle 3, 7 an analysis device configured to recognise a determined situation, which can be traced to the detachment of the needle 3 from the vascular access, on the basis of the signal received from the sensor 6. The determined situation can be, for example, the absence or drastic reduction of the perturbations originating from the generator 5.

[0038] Optionally the generator 5 can be predisposed to generate variations of at least a parameter in the fluid transport system 2. The generator 5 can optionally be predisposed to generate variations of at least a parameter associated to the needle 3 (in particular a characteristic parameter of the fluid path defined internally of the needle). The generator 5 can optionally be predisposed to generate variations of at least a parameter both in the fluid transport system 2 and in the needle 3.

[0039] The generator 5 can be predisposed to operate directly on the fluid transport system 2, having at least a part associated directly to the system 2 (for example in direct contact with a part of the system 2, the part possibly comprising, for example, a wall delimiting a fluid path internal of the system 2). The generator 5 can be, alternatively or in addition to the aforementioned, predisposed to operate directly on the needle 3, having at least a part thereof associated directly to the needle 3 or to the fluid path defined internally of the needle 3.

[0040] The analysis device 7 can optionally be connected to the fluid transport system 2 (for example to a control unit which governs the system itself) for receiving and/or supplying the system 2 such that, from an analysis of the data available both to the analysis device 7 and to the transport system 2, it is possible to calculate, with a relatively greater certainty, if the needle 3 has effectively become detached. By way of example, the analysis device 7 and the transport system 2 can be connected such as to determine whether, coincidentally with the recognition of a determined and potentially faulty situation on the part of the analysis device 7, there is also present at least a further situation under the control of the transport system 2 such as, for example, the operativity of the perturbation generator 5. In this case, if both the conditions are shown to exist, one being potentially faulty signalled by the device 7 and the other of the generator 5 activity, an alarm situation can be set off (for example by the analysis device 7 and/or by the transport system 2). There can also be other situations under the control of the transport system 2 which are used, in combination with what is detected by the analysis device 7, to determine an alarm situation or in any case a faulty situation, such as for example reaching of a determined pressure level (or hematocrit level in the case of blood transport, or concentration level of a determined substance, or particle, or element in the transported fluid) in a determined zone of the transport system 2, the halting of the fluid movement along the system etc. All the above-mentioned various situations controlled by the transport system 2 can be used (in combination with the potentially faulty system detected by the device 7) by themselves or in combination with one another.

[0041] With reference to figure 2, 8 denotes a membrane exchanger for extracorporeal blood treatment, provided with a semipermeable membrane 9 which separates a blood chamber 10 from a fluid chamber 11, 12 being a blood removal line (arterial line) for transport of blood from a vascular access of an individual to an inlet of the blood chamber 10, 13 denoting a blood return line (venous line) for returning the treated blood from an outlet of the blood chamber 10 to the vascular access of the individual, 14 denoting a blood pump (in the present embodiment a rotary peristaltic pump) for blood circulation in the extracorporeal circuit, 15 denoting a discharge line for fluid drainage from the fluid chamber 11, 16 denoting a treatment fluid (dialysate) supply line to the fluid chamber 11, 17 a blood removal needle (arterial needle) connected to the removal line 12, 18 a blood return needle (venous needle) connected to the blood return line 13, 19 a sensor (in the present case a radiation reflecting type, for example light or sound radiation) configured for emitting a signal indicating the perturbations which are

induced in the extracorporeal blood circuit by the blood pump 14 and which are transmitted into the body of the individual via the venous needle 18, 20 being a control unit which is predisposed to govern the functioning of the apparatus for the treatment of the extracorporeal blood and which is provided with an analysis device for recognising detachment of the venous needle 18 on the evidence of the signal received from the sensor 19.

[0042] With reference to figure 3, 21 denotes a fistula (a known type of vascular access) to which the extracorporeal circuit of figure 2 is connected (figure 3 illustrates only a part of the extracorporeal blood apparatus of figure 2, keeping the same numbering as in figure 2), 22 denotes a radiation-absorbing sensor (in the specific case an optical sensor, for example a finger pulsimeter) connected to the control unit 20 having the above-mentioned needle-detachment sensing device.

[0043] With reference to figure 4, 23 denotes a radiation emitter (for example emitting light radiation) which is part of the sensor 22, 24 denotes a radiation receiver coupled to the emitter 23 for receiving a part of the radiations emitted by the emitter 23 which is absorbed by the tissue of the individual's body, 25 denotes the individual's body (in particular a finger) having the tissue thereof interposed between the emitter 23 and the receiver 24. In the specific case the sensor 22 comprises a pulse oximeter, of known type, in which the emitter 23 comprises, for example, a LED and the receiver 24 comprises, for example, a photo-detector. The above-mentioned pulse oximeter, in use, illuminates the individual's tissue. The light crosses the individual's body, encountering tissues, bone, skin, arterial blood and venous blood, and is thus attenuated. It is known that some elements of the individual's body (for example bone, tissue and venous blood) can absorb the light constantly, while other elements (arterial blood) can absorb the light variably according to a certain frequency. The overall signal detected by the receiver 24 is therefore a time-variable signal (pletismographic signal, see figures 6 and 7). By analysing the frequency of the signal detected by the receiver 24 and sent on to the analysis device, it is possible (for example by knowing the frequency of the signal induced by the peristaltic pump or other perturbation generator and using frequency filters of known type) to recognise the contribution provided by the above-mentioned perturbation generator to the overall signal. This enables identification of any absence, or sharp reduction, in the contribution provided by the perturbation generator, and thus enables a deduction in the existence of a faulty situation (needle detachment) in the vascular access.

[0044] With reference to figure 5, 26 denotes in its entirety a radiation sensor of the reflection type (usable in any one of the systems described in

figures from 1 to 3 and located in operative connection with the analysis device 7 or with the control unit 20), 27 denotes a radiation emitter (for example light or sound radiation, 28 a receiver of reflected radiation coming from the the emitter 27, 29 a tissue (for example epidermic or dermic tissue) to which the sensor 26 is frontally applied, 30 denotes the whole of the radiations which are emitted by the emitter 27 and captured by the receiver 28.

[0045] With reference to figure 6, 31 denotes a graph (pletismographic signal) representing the size, in function of the time, of the absorbed radiations received by the receiver 24 of figure 4, 32 denotes the variable part of the absorbed radiations due to the pulsating or oscillating progress of the perturbation transmitted through the needle 17 (the undulating component of pressure and/or flow in the arterial blood), 33 denotes the part (substantially constant in time) of the radiations due to the absorption of the venous blood, 34 the part (substantially constant in time) of radiation due to the absorption of the venous blood, 35 the part (substantially constant) due to the absorption of other tissues (bone, skin, muscles etc). Figure 7 illustrates the same graph as in figure 6, in greater detail. The graph is substantially of the reflective type rather than of the absorption type.

[0046] In general, the monitoring apparatus of the invention comprises a fluid transport system for moving a fluid. The fluid can be, for example, a medical fluid – such as for example a medication, a buffer solution or an anticoagulant in an extracorporeal blood treatment, a replacement fluid in a hemo(dia)filtration treatment - or a corporeal fluid, such as for example the blood removed to be treated in an extracorporeal treatment device and/or the blood returned after the treatment. This fluid transport system can comprise, for example, an infusion circuit in the vascular system of a patient, a circuit for processing blood from a donor, a circuit for an extracorporeal blood treatment of a patient, an extracorporeal blood circuit for treatment of kidney failure and/or hepatic insufficiency (for example a blood circuit for dialysis, hemo(dia)filtration, pure ultrafiltration, therapeutic plasma exchange, hemoperfusion, etc.). In particular the extracorporeal blood circuit of figure 2 can comprise any one of the known-type circuits used in hemodialysis, hemodiafiltration, hemofiltration and hemoperfusion treatments, in treatment of hepatic insufficiency, etc. In figure 2, for the sake of simplicity, the various elements with which a known circuit of the above-mentioned type is provided have not been illustrated.

[0047] The monitoring apparatus of the invention can comprise, as in the above examples, at least a needle connected to the fluid transport system and to a vascular access of an individual. The needle can be configured to

introduce and/or remove a fluid into/from the vascular system of the individual. The vascular access can be of any kind of vascular access of known type. The connection between the fluid transport system and the vascular access can be a single-needle type (for example the system of figure 1 or even a single-needle dialysis system or another single-needle system for processing the extracorporeal blood) or a double-needle type. The fluid transport system and the vascular access are connected to one another and/or removed from the vascular access by passing through the above-mentioned needle or needles.

[0048] The monitoring apparatus of the invention can comprise, as in the above-mentioned examples, a perturbation generator configured for generating variations of at least a parameter (in particular a chemical/physical parameter of the fluid) in the above-cited fluid transport system and/or in the needle (or needles). The perturbation generator comprises, optionally, at least an actuator arranged in the fluid transport system. The perturbation generator optionally comprises at least an actuator arranged in the fluid transport system. The perturbation generator is optionally configured to generate variations of the parameter, of the pulsating or undulating type. The parameter can comprise one or more chemical/physical characteristics of the fluid.

[0049] The parameter can comprise, for example, one of the following fluid characteristics or a known function of one or more of these characteristics: pressure, flow (in volume or mass), temperature, viscosity, hematocrit, conductivity, concentration of a substance in the fluid, optical properties (for example reflections or absorption of the light), speed of propagation of the sound.

[0050] The perturbation generator can comprise, for example, a pressure and/or flow variation generator in the fluid transport system. The pressure and/or flow variation generator comprises, optionally, a flexible-wall deformation pump configured for fluid transport, such as for example a rotary-type peristaltic pump (as in figure 2), or any other type of pump used in the prior art for movement of fluids in the medical field which can generate variations (of a pulsating or undulating type) of pressure and/or flow. In the case of a peristaltic pump the generation of pressure and/or flow waves is determined by the normal functioning of the pump. In the specific case of figure 2, the perturbation generator is a blood pump (for example of the type used in a dialysis circuit).

[0051] Other types of perturbation generators can be used, as can other ways of generating the perturbations such as, for example, by means of

oscillating variation of the set value of the fluid supply pump flow rate, and/or by means of the introduction (for example with an oscillating flow) of a second fluid (having at least a different characteristic, such as temperature, concentration, viscosity etc., with respect to the main fluid) into the main flow of the fluid transport system, and/or by means of removing (for example with an oscillating flow or a variable flow according to a prefixed regime) of a part of the fluid (for example the liquid part of a fluid also containing solid parts in suspension; reference in particular is made to a plasmatic liqiuid present in the blood which can be ultrafiltered through a sempermeable membrane, such as for example the membrane 9).

[0052] As has been seen, the monitoring apparatus of the invention comprises a sensor configured for application (direct or indirect) to the body of an individual. In the specific embodiment of figure 1, the sensor is applied to the skin of the individual. The sensor can optionally be of the type configured for direct application in contact with the body of the individual. In use, a determined perturbation (for example oscillatory) induced in a zone of the fluid transport system propagates along the system and reaches the vascular access zone. Here the perturbation passes through the needle and form here propagates, at least partially, internally of the body of the individual, in particular along a part of the vascular system, in particular at least the part which faces and is most closely interested by the fluid flow passing through the needle (entering or exiting from the extracorporeal fluid transport system). The perturbation, which originates in the extracorporeal system and which – passing through the needle – propagates within the body of the individual, can be detected by the sensor which is operatively associated to the individual's body. The sensor is configured to emit a signal indicating the above-mentioned variations of the parameter which are transmitted through the needle (or needles).

[0053] The sensor comprises at least an active part which can assume at least an operative configuration in which it interacts, for example contactingly, with the individual's body and in which it is not rigidly constrained to the needle. The active part of the sensor optionally constitutes an independent unit with respect to the needle. Overall the sensor too can constitute an independent unit with respect to the needle. The sensor can, in substance, form a structurally and functionally isolated unit with respect to the needle itself. By virtue of the structure and functionality of the sensor, the application of the sensor itself to the individual's body can be performed independently with respect to application of the needle. The two applications (of the needle and the sensor) to the patient can be done at different times, since the needle and the sensor form two distinct units. The

connection between the two units consists, essentially, of the fact that the sensor is predisposed to receive a signal which, originating from the fluid transport system, can pass through the needle and a part of the tissues of the individual's body which, with the needle correctly positioned, are interposed between the needle and the sensor. The needle and the active part of the sensor are optionally not solidly constrained to one another, so that the movement of the needle does not necessarily lead to the movement of the sensor.

[0054] The needle has a proximal end which is configured to penetrate, in a known way, a vascular access, and a distal end which is connected, in a known way, to the fluid transport system. When the proximal end is in a normal operative configuration, in which it penetrates into the vascular access, the proximal end is optionally arranged in an intermediate zone between the distal end and the active part of the sensor (as illustrated in figures 1, 2 and 3). In other words, the sensor is arranged such as to be operatively associated to the part of the body of the individual which is most greatly interested by the flow which exits from (or enters) the needle. Normally the needle, in the correct position, assumes an oblique orientation with respect to the surface of the body. The sensor can operate, in other words, on a zone of the surface of the body which is close to the needle and which forms, with the needle itself (which needle, as mentioned is in an oblique position), obtuse angles (such as in figures from 1 to 3). In this way the zone in which the sensor operates is the zone of the individual's body where the greater part of the fluid which passed or will pass through the needle flows. This enables the sensor to operate on a signal of greater intensity. It is however possible to have it so that the sensor is configured to operate in the zone of the body that forms an acute angle with the needle arranged obliquely, i.e. in other words with the sensor arranged substantially below the needle, i.e. "internally" of the extension and/or the straight prolongation of the oblique needle, out of the individual's body (and not "externally" to the extension and/or prolongation, as happens in the above-described case).

[0055] The active part of the sensor can optionally assume at least an operative configuration in which it interacts contactingly or nearly contactingly with a surface of the individual's body. The sensor can comprise a physiological sensor for detecting at least a physiological parameter of the individual. In a specific embodiment (as has already been seen) the sensor can comprise at least an emitter of radiation and a receiver of radation. The emitter and the receiver of radiation can be configured to be operatively associated to at least a tissue of the individual's body. The

radiation emitter can comprise, for example, at least an emitter of light radiations. The emitter and the receiver of radiation are configured to be arranged on two opposite sides of the tissue and/or a same side of the tissue. The radiation receiver can comprise at least a receiver of radiations reflected from the tissue and/or at least a receiver of radiations absorbed by the tissue. It is however possible to include the use of a plurality of sensors, which can be different from each other.

[0056] In the embodiment illustrated in the accompanying figures of the drawings, in particular figures from 2 to 5, the sensor can comprise a pulsimeter, such as for example a finger pulsimeter or a frontal pulsimeter. A pulse oximetry sensor is configured, as is known, to perform a trans-illumination of a portion of the body crossed by the blood and to measure the extinction of the light (due to reflection and/or absorption) during the trans-illumination. The sensor can be mounted on a finger, in particular a finger-tip, or on other parts of the body (arm, leg etc.), in proximity of the vascular access. In particular the sensor is mounted, optionally, such as to trans-illuminate a portion of the body crossed by the blood just returned through the venous needle (or just before entering the arterial needle). As is known, a pulse oximeter is able to provide a progress chart of the vascular pulsation (pletismographic curve, see figure 7), as well as other data, such as cardiac frequency, oxygen saturation and perfusion index.

[0057] Other types of sensors can be used, such as for example an intracorporeal blood pressure sensor, of a type which measures the systolic pressure of the individual and/or the diastolic pressure and/or the mean arterial pressure. It is further possible to use a temperature sensor, a viscosity sensor, a hematocrit sensor, a conductivity sensor, a substance or element concentration sensor or a sensor of a type of particle, an ultrasound sensor (or other type of acoustic sensor), an infrared sensor (or other type of optical sensor), etc.

[0058] The monitoring apparatus comprises an analysis device for recognising the detachment of the at least a needle on the basis of the signal. The analysis device is configured for discriminating, in the signal provided by the sensor, the above-mentioned variations of the parameter transmitted through the vascular access, and for comparing the transmitted variations with at least a threshold value. The analysis device can comprise, for example, at least a filter for processing the signal emitted by the sensor such as to identify the above-mentioned variations pased through the vascular access. In particular the analysis device is programmed to identify, in the signal provided by the sensor, the component of the signal which is due to the pulsating or oscillating progress of the perturbation.

[0059] In a further embodiment, the perturbation generator 5 can comprise a sound energy generator (for example an ultrasound generator), and the sensor 6 can comprise an acoustic sensor configured for detecting the above-mentioned sound energy. The perturbation generator 5, in this as in the preceding cases, can be configured to generate an isolated pulsation (a momentary change in a determined parameter), such as for example a sound pulse, or in order to generate variations of a pulsating type of at least a parameter, such as for example periodical oscillating or undulating variations of a determined parameter, for example a sound wave, or for generating a series of pulsations with a determined frequency or period.

CLAIMS

1. An apparatus for monitoring a vascular access, comprising:

a fluid transport system for moving a fluid;

at least a needle connected to the fluid transport system and to a vascular access of an individual for supplying and/or removing the fluid to and/or from the vascular access via the at least a needle;

a perturbation generator configured for generating variations of at least a parameter in the fluid transport system and/or for generating variations of at least a parameter in the needle, wherein the parameter comprises one or more chemical and/or physical characteristics of the fluid;

a sensor configured for application to the individual's body, the sensor emitting a signal indicating the variations of the at least a parameter transmitted through the needle;

an analysis device for recognising a detachment of the at least a needle, on a basis of said signal, c h a r a c t e r i z e d i n that the sensor comprises at least an emitter of light radiations and a receiver of radiations, the emitter of light radiations and the receiver of radiations being configured to be operatively associated to at least a tissue of the individual's body.

2. The apparatus of claim 1, wherein the perturbation generator is operatively directly associated to the fluid transport system.

3. The apparatus of claim 1 or 2, wherein the perturbation generator comprises at least an actuator arranged in the fluid transport system.

4. The apparatus of any one of claims 1 to 3, wherein the fluid transport system comprises at least an actuator, the perturbation generator comprising the actuator.

5. The apparatus of any one of claims 1 to 4, wherein the sensor comprises at least an active part which is configured to assume at least an operative configuration in which the sensor interacts with the individual's body and is not constrained rigidly to the needle.

6. The apparatus of any one of claims 1 to 5, wherein:

the at least a needle has a proximal end which is configured for penetrating a vascular access at a point of penetration and a distal end which is connected to the fluid transport system;

the sensor comprises at least an active part which is configured to assume at least an operative configuration in which the sensor interacts with the individual's body such that, when the proximal end is in a normal operative configuration in which the proximal end penetrates into the vascular access, said penetration point is arranged in an intermediate zone between the distal end and the active part.

7. The apparatus of any one of claims 1 to 6, wherein the sensor comprises at least an active part which can assume at least an operative configuration in which it interacts contactingly or nearly contactingly with a surface of the individual's body.

8. The apparatus of any one of claims 1 to 7, wherein the sensor comprises a physiological sensor for detecting at least a physiological parameter of the individual.

9. The apparatus of any one of claims 1 to 8, wherein the emitter of light radiations and the receiver of radiations are configured to be arranged on two opposite sides of the tissue.

10. The apparatus of any one of claims 1 to 9, wherein the emitter of light radiations and the receiver of radiations are configured to be arranged on a same side of the tissue.

11. The apparatus of any one of claims 1 to 10, wherein the receiver of radiations comprises at least a receiver of radiations reflected by the tissue and/or at least a receiver of radiations absorbed by the tissue.

12. The apparatus of any one of claims 1 to 11, wherein the sensor comprises one or more sensors selected from the group of sensors including: a pulsimeter, an optic sensor.

13. The apparatus of claim 12, wherein the pulsimeter comprises a finger pulsimeter.

14. The apparatus of any one of claims 1 to 13, wherein the analysis device is configured to discriminate, in the signal provided by the sensor, the variations of the at least a parameter transmitted through the vascular access, and to compare the variations with at least a threshold value.

15. The apparatus of any one of claims 1 to 14, wherein the analysis device comprises at least a filter for processing the signal emitted by the sensor such as to identify the variations of the at least a parameter transmitted through the vascular access.

16. The apparatus of any one of claims 1 to 15, wherein the fluid transport

system comprises an extracorporeal blood circuit configured for removal and return of blood from and to the individual's body, the needle being the blood return needle.

17. The apparatus of claim 16, wherein the fluid transport system comprises a membrane exchanger having a blood chamber and a fluid chamber which are separated from one another by a semipermeable membrane, the extracorporeal blood circuit having a blood removal line which is connected to an inlet of the blood chamber and a blood return line connected to an exit of the blood chamber.

18. The apparatus of any one of claims 1 to 17, wherein the perturbation generator is configured to generate pulsating-type variations of the at least a parameter.

19. The apparatus of any one of claims 1 to 18, wherein the perturbation generator is operatively associated in contact with a flexible wall delimiting a fluid path of the fluid transport system.

20. The apparatus of any one of claims 1 to 19, wherein the at least a parameter comprises at least a parameter of the fluid selected from a group comprising: pressure, flow, hematocrit, concentration of a substance in the fluid, optical properties, optical absorption, optical reflection, acoustic properties, acoustic impedance, velocity of sound propagation.

21. The apparatus of any one of claims 1 to 20, wherein the perturbation generator comprises at least a generator of variations of pressure and/or flow in the fluid transport system.

22. The apparatus of claim 21, wherein the generator of variations of pressure and/or flow comprises a flexible-wall deformation pump configured for fluid transport.

23. The apparatus of claim 22, wherein the flexible-wall deformation pump comprises a peristaltic pump.

24. The apparatus of any one of claims 21, 22 and 23, wherein the flexible-wall deformation pump is a rotary pump.

25. A method for monitoring a vascular access, comprising the following steps:

providing a fluid transport system;

providing at least a needle adapted to be connected to the fluid transport system, and adapted to be connected to a vascular access of an individual; and

generating variations of at least a parameter in the fluid transport system and/or generating variations of at least a parameter in the at least a needle, wherein the parameter comprises one or more chemical and/or physical characteristics of the fluid;

monitoring an individual's body in order to identify the variations of the at least a parameter transmitted through the at least a needle;

recognising a detachment of the at least a needle on a basis of the monitoring, characterized in that the step of monitoring comprises at least an emission of light radiation on at least a tissue of the individual's body, and at least a receiving of the radiation.

26. The method of claim 25, wherein the variations of at least a parameter are generated directly in the fluid transport system.

27. The method of claim 25 or 26, comprising a stage of connecting an actuator to the fluid transport system, the variations of the at least a parameter being generated by the actuator.

28. The method of any one of claims from 25 to 27, wherein the variations of the at least a parameter are generated by an actuator of the fluid transport system.

29. The method of any one of claims from 25 to 28, comprising stages of positioning a sensor for the monitoring on the individual's body, and positioning the at least a needle on the individual's body, the positioning stages being performed independently from one another.

30. The method of any one of claims from 25 to 29, wherein:

the at least a needle has a proximal end which is configured to penetrate a vascular access and a distal end connected to the fluid transport system;

the method comprises a stage of positioning a sensor for monitoring on the individual's body such that when the proximal end is in a normal operating configuration in which the proximal end is penetrating the vascular access, the proximal end is arranged in an intermediate zone between the distal end and an active part of the sensor which interacts with the individual's body.

31. The method of any one of claims from 25 to 30, comprising a stage of positioning a sensor for monitoring such that the sensor has an active part

which interacts in contact or nearly in contact with a surface of the individual's body.

32. The method of any one of claims from 25 to 31, wherein the stage of monitoring comprises detecting at least a physiological parameter of the individual.

33. The method of any one of claims from 25 to 32, wherein the emission and reception of radiation are performed on two opposite sides of the tissue.

34. The method of any one of claims from 25 to 33, wherein the emission and reception of radiation are performed on a same side of the tissue.

35. The method of any one of claims from 25 to 34, wherein the radiation received comprises reflected radiation from the tissue and/or radiation absorbed by the tissue.

36. The method of any one of claims from 25 to 35, wherein the monitoring comprises measuring pulse oximetry and/or an optical characteristic.

37. The method of claim 36, wherein the pulse oximetry is measured at a finger of the individual.

38. The method of any one of claims from 25 to 37, wherein the stage of recognising the detachment of the needle comprises: detecting a signal indicating a characteristic of the individual's body; discriminating, in the signal, a part due to the variations of the at least a parameter transmitted through the vascular access; and comparing the variations with at least a threshold value.

39. The method of any one of claims from 25 to 38, comprising at least a filtering stage for processing a signal indicating a characteristic of the individual's body such as to identify, in the signal, the part thereof which is due to the variations of the at least a parameter transmitted through the vascular access.

40.The method of any one of claims from 25 to 39, wherein the fluid transport system comprises an extracorporeal blood circuit configured for removing and returning blood from and to the individual's body, the needle being the blood return needle.

41. The method of claim 40, wherein the fluid transport system comprises a membrane exchanger having a blood chamber and a fluid chamber which are separated from one another by a semipermeable membrane, the extracorporeal blood circuit having a blood removal line connected to an inlet of the blood chamber and a blood return line connected to an outlet of the blood chamber.

42. The method of any one of claims from 25 to 41, wherein the variations of the at least a parameter comprises a variation of the parameter of a pulsating type.

43. The method of any one of claims from 25 to 42, comprising a stage of connecting a perturbation generator contactingly with a flexible wall delimiting a fluid path in the fluid transport system, the variations of the at least a parameter being generated by the perturbation generator.

44. The method of any one of claims from 25 to 43, wherein the at least a parameter comprises at least a parameter of the fluid selected from a group

comprising: pressure, flow, hematocrit, concentration of a substance in the fluid, optical properties, optical absorption, optical reflection, acoustic properties, acoustic impedance, velocity of sound propagation.

45. The method of any one of claims from 25 to 44, wherein the stage of generating the variations of the at least a parameter comprises varying pressure and/or flow in the fluid transport system.

46. The method of claim 45, wherein the stage of generating the variations of the at least a parameter comprises activating a flexible-wall deformation pump configured for fluid transport.

47. The method of claim 46, wherein the flexible-wall deformation pump comprises a peristaltic pump.

48. The method of claim 45 or 46, wherein the flexible-wall deformation pump is a rotary pump.

49. Use of the apparatus according to any one of claims 1 to 24.

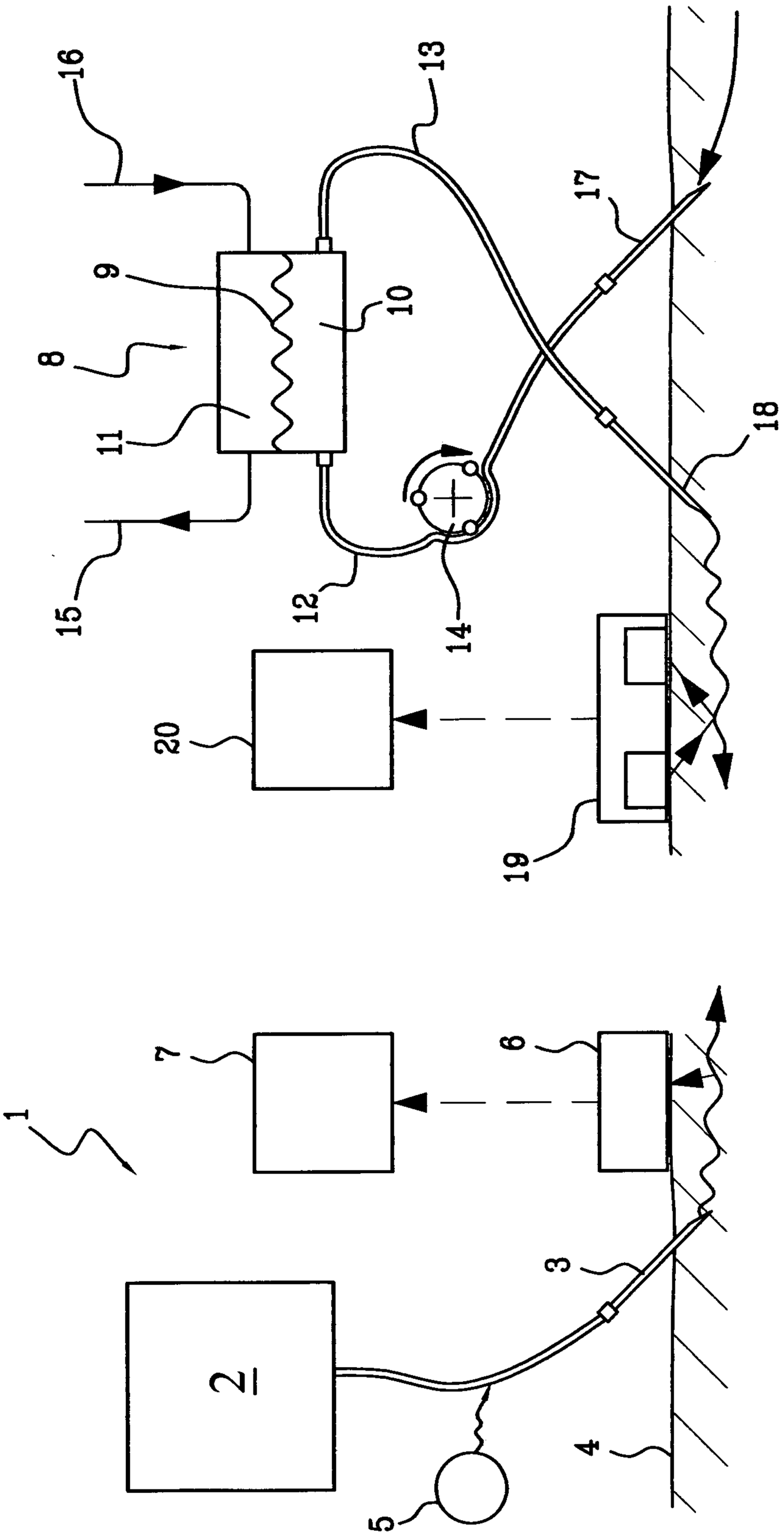


FIG 1

FIG 2

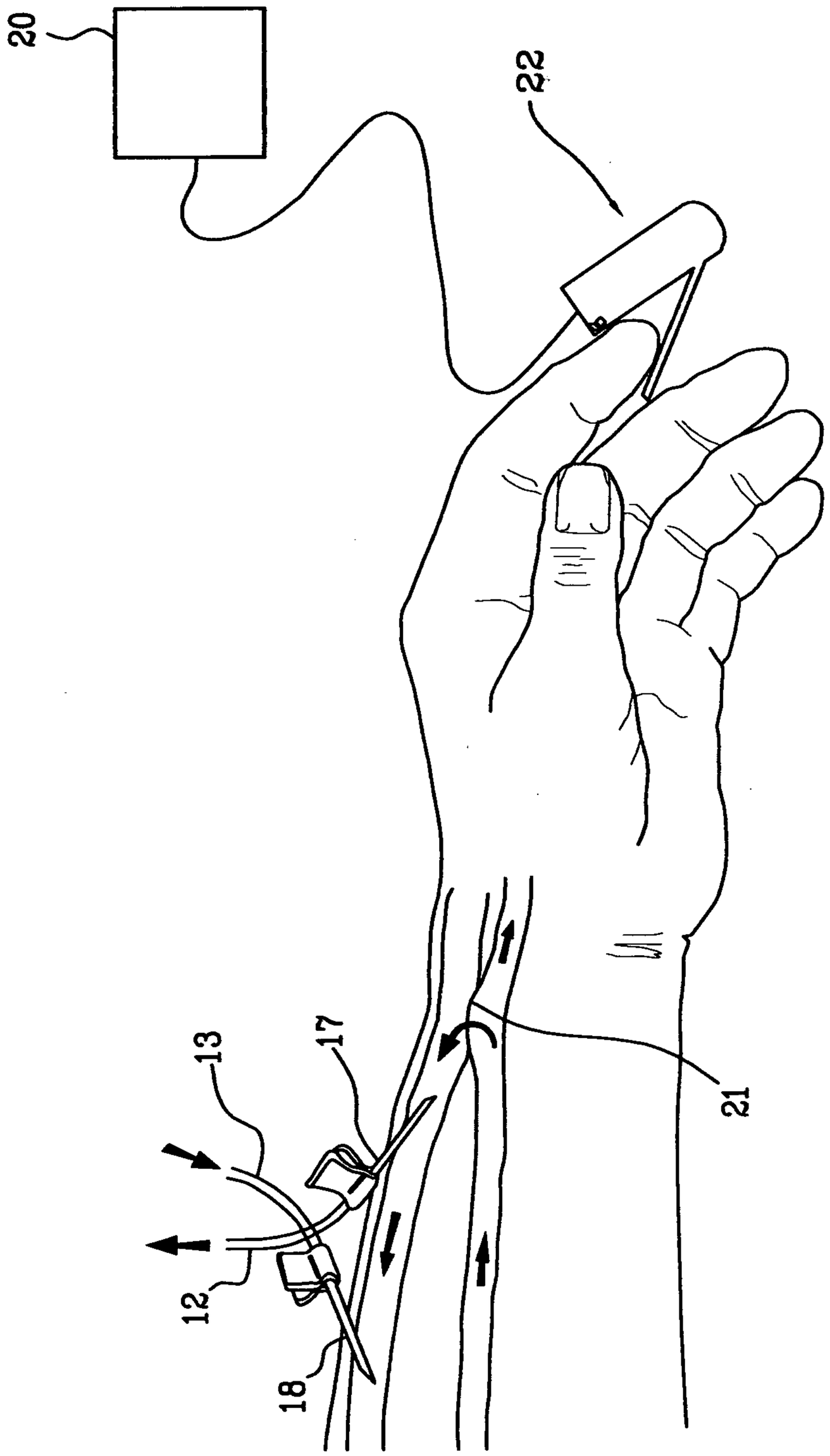


FIG 3

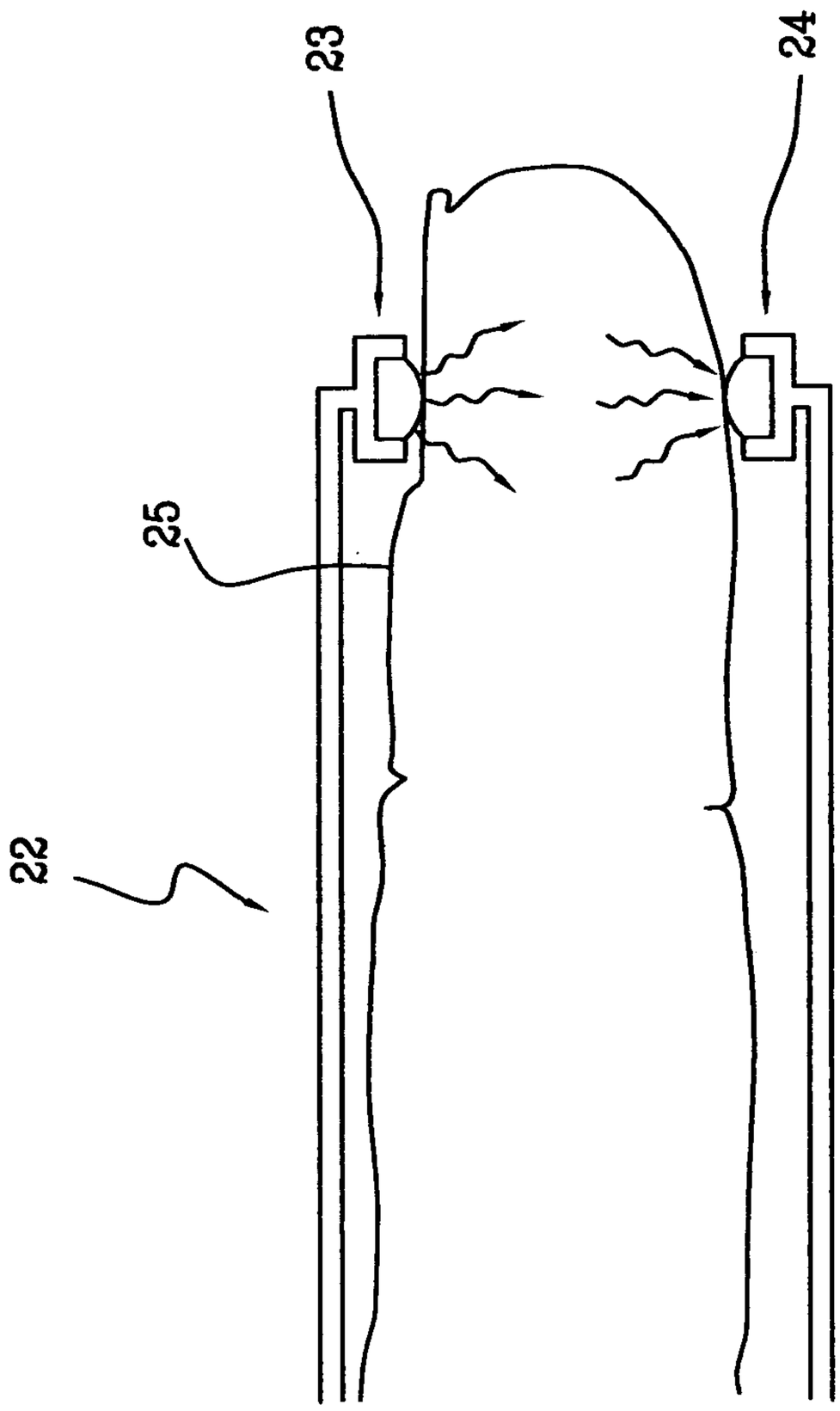


FIG 4

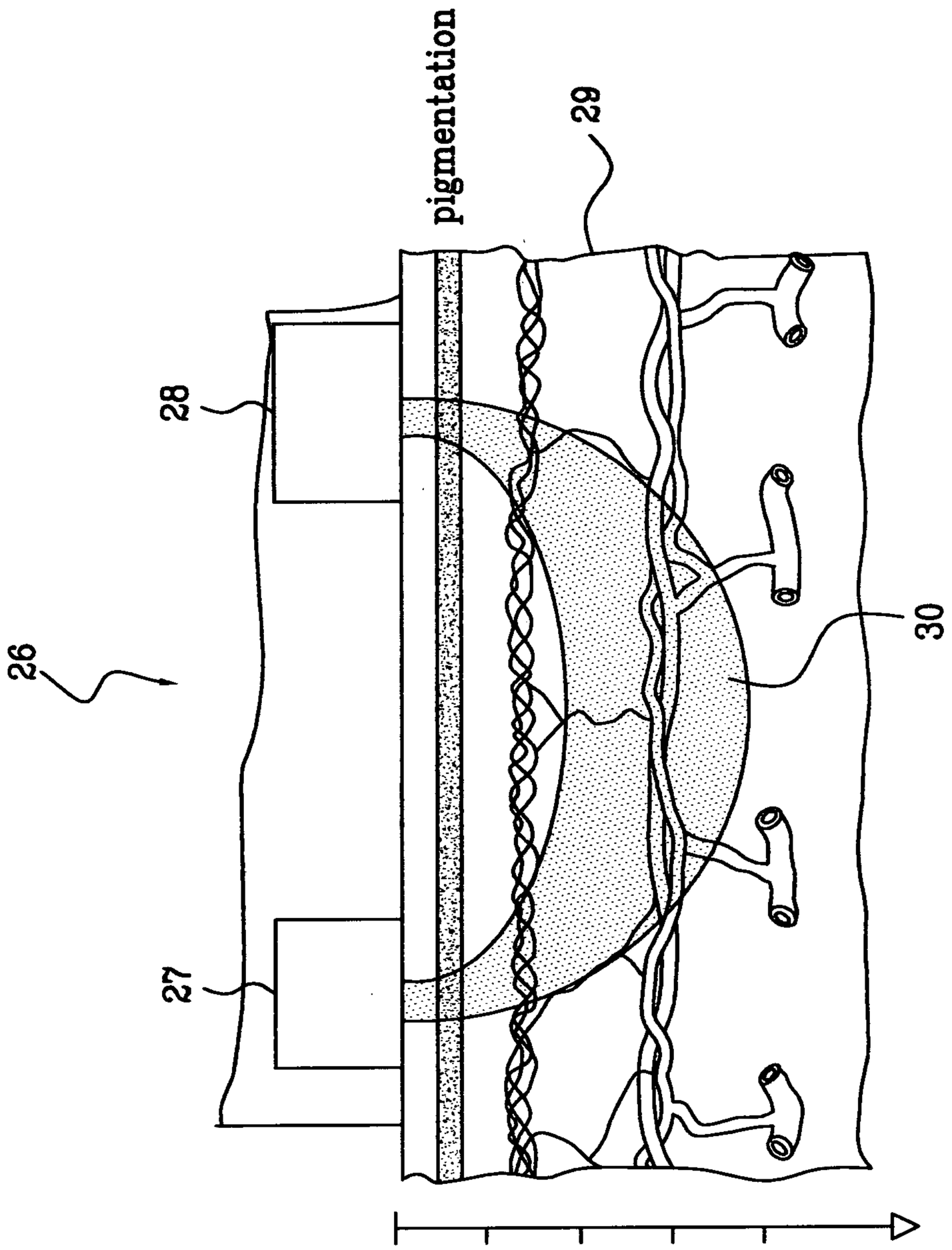


FIG 5

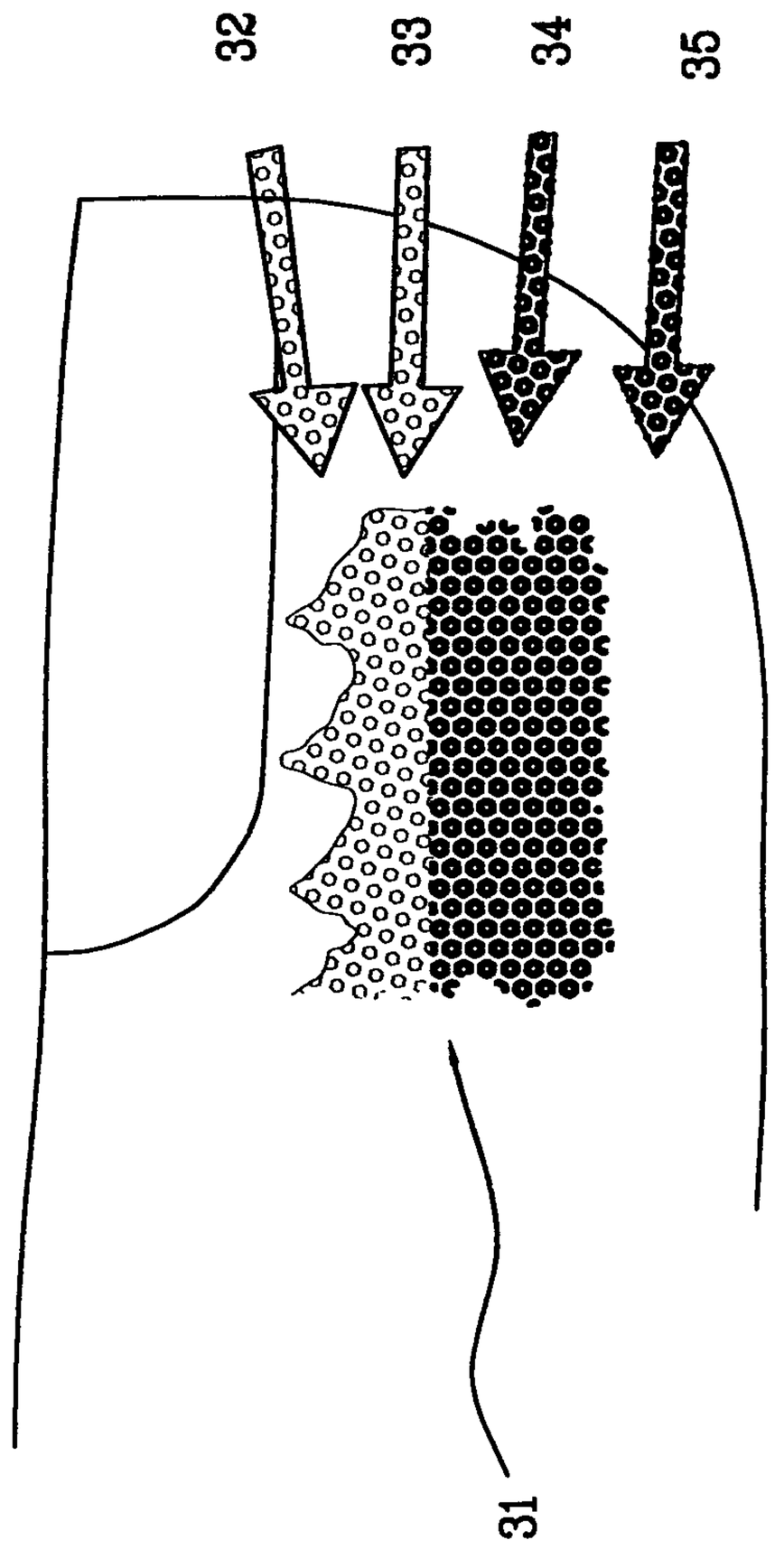


FIG 6

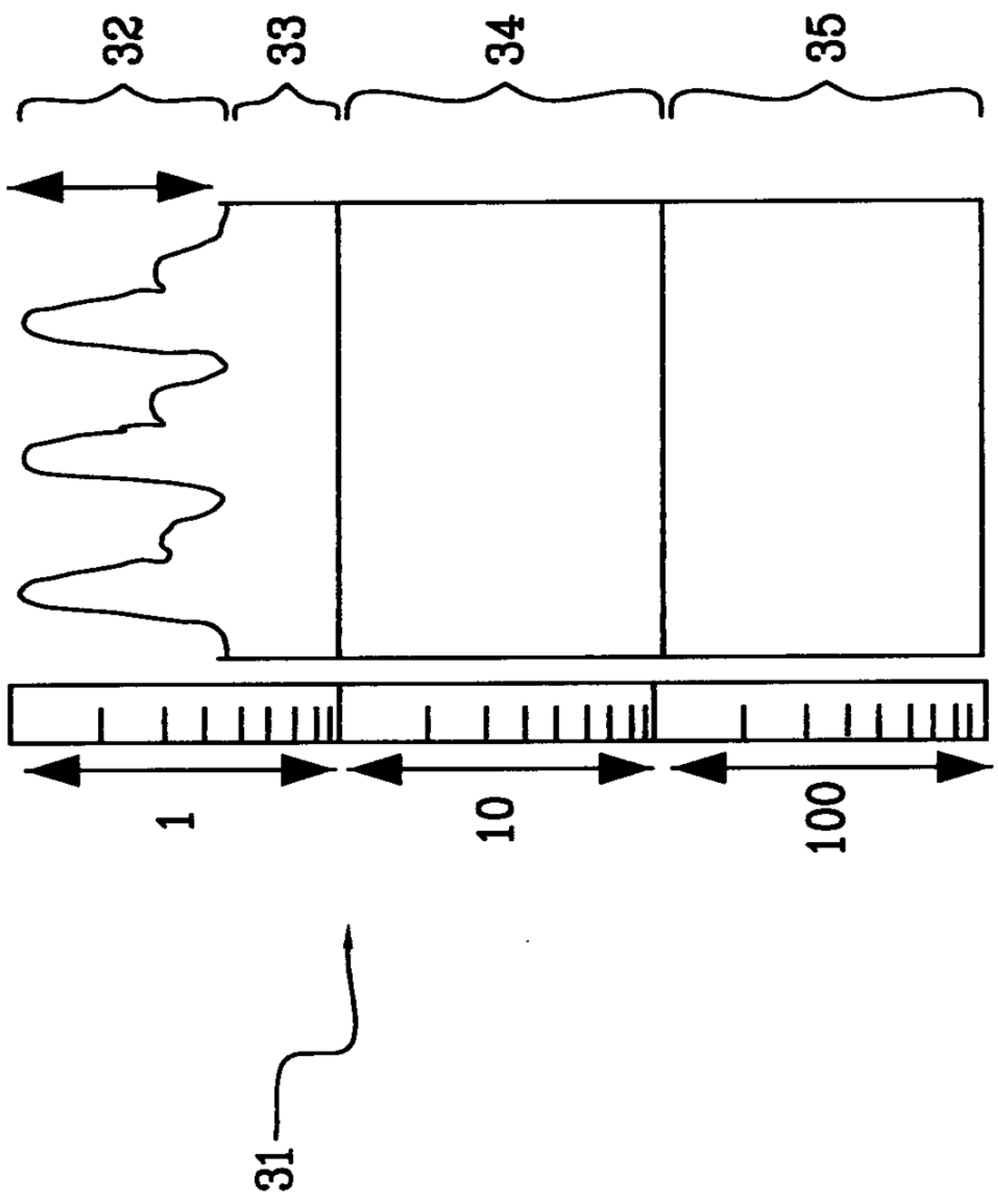
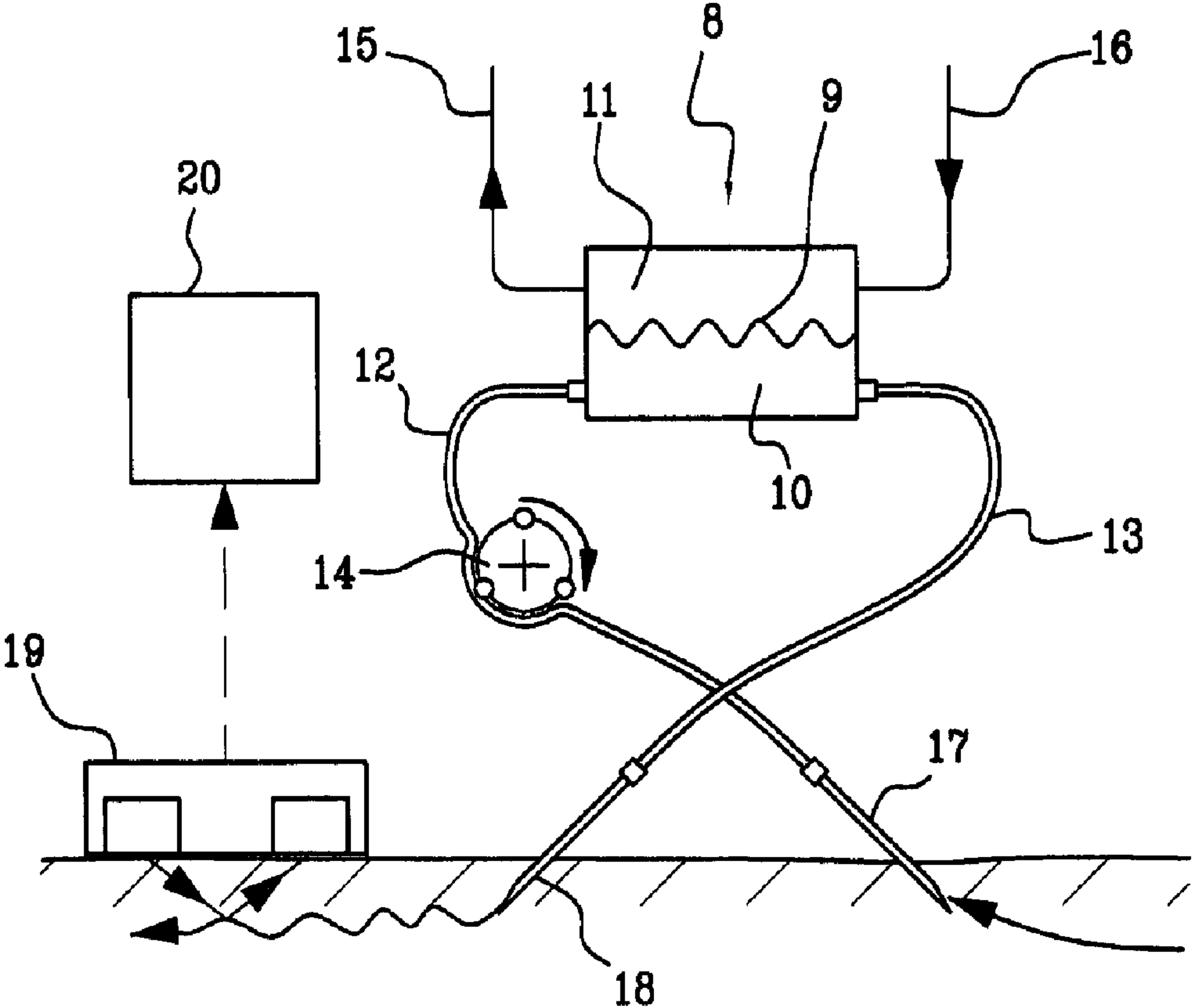


FIG 7


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