ORIGINAL

DEVICE FOR INJECTING CONTRAST MEDIA

ABSTRACT

The invention relates to a medical device for injecting contrast media including at least two separate vessels and immiscible contents inside one and/or both of the vessels, an injector and a distributor arranged such as to establish alternating communication between said vessels and said injector, said medical device being characterised in that it includes a means for providing said alternating communication at a frequency of 0.2 to 5 Hz.

We Claim:

1. A medical device for injecting contrast media and comprising at least two separate reservoirs the respective contents of which cannot mix with one another in either one of said reservoirs, an injector and a directional control valve arranged in such a way as to place said reservoirs alternately in communication with said injector, which medical device is characterized in that it comprises means for bringing about said alternating communication at a frequency of between 0.2 and 5 Hz for a minimum of two consecutive cycles.

2. The medical device as claimed in claim 1, in which the frequency is around 1 Hz.

3. The medical device as claimed in claim 1, in which the frequency can vary over time.

4. The medical device as claimed in claims 1 to 3 and designed to allow continuous flow of between 0.1 and 5 ml with the same reservoir.

5. The medical device as claimed in one of the preceding claims, in which one reservoir contains a contrast medium and the other reservoir contains a saline solution.

6. The medical device as claimed in one of the preceding claims 1 to 4, in which each reservoir contains a contrast medium at a concentration specific to it.

7. The use of a medical device as claimed in one of the preceding claims, characterized in that the communication of the reservoirs with the injector is alternated at a frequency of between 0.2 and 5 Hz.

8. The use as claimed in claim 7, in which said frequency is around 1 Hz.

9. The use as claimed in claim 7 or 8, in which a continuous flow of between 0.1 and 5 ml is allowed with the same reservoir.

10. The use as claimed in one of the preceding claims 7 to 9, in which a volume of less than 5 ml is injected from one reservoir on each alternation.

11. The use as claimed in one of the preceding claims 7 to 10 for injecting contrast media into the heart.

12. The use as claimed in one of the preceding claims 7 to 11 for amplifying an extravasion detection signal.

13. The use as claimed in one of the preceding claims 7 to 12 to vary the concentration of a contrast medium at a specific moment in an injection, characterized in that just one injector is used.

Dated this 12th day of April 2012

Rohit Singh

IN/PA-1224

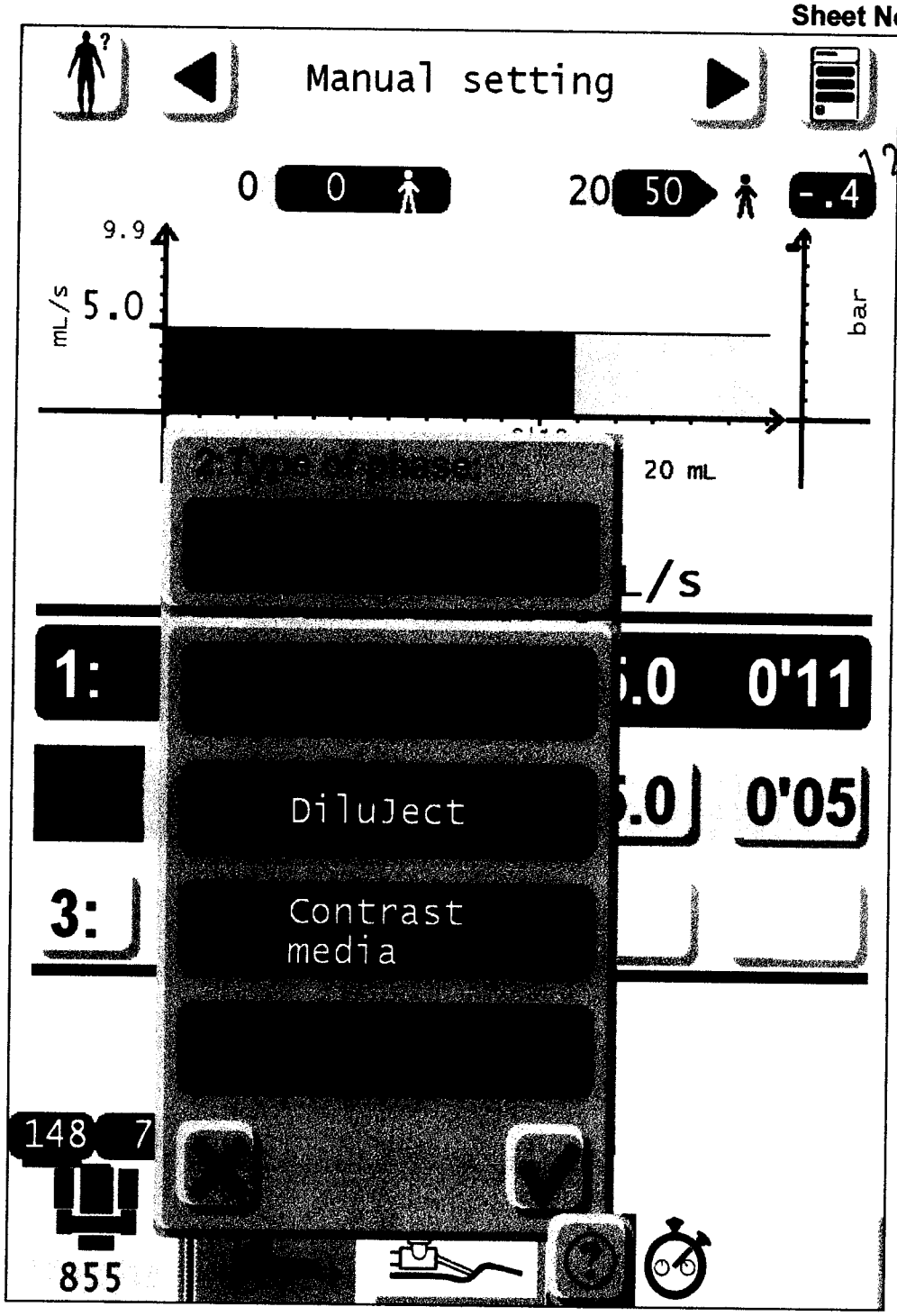

Figure 1A

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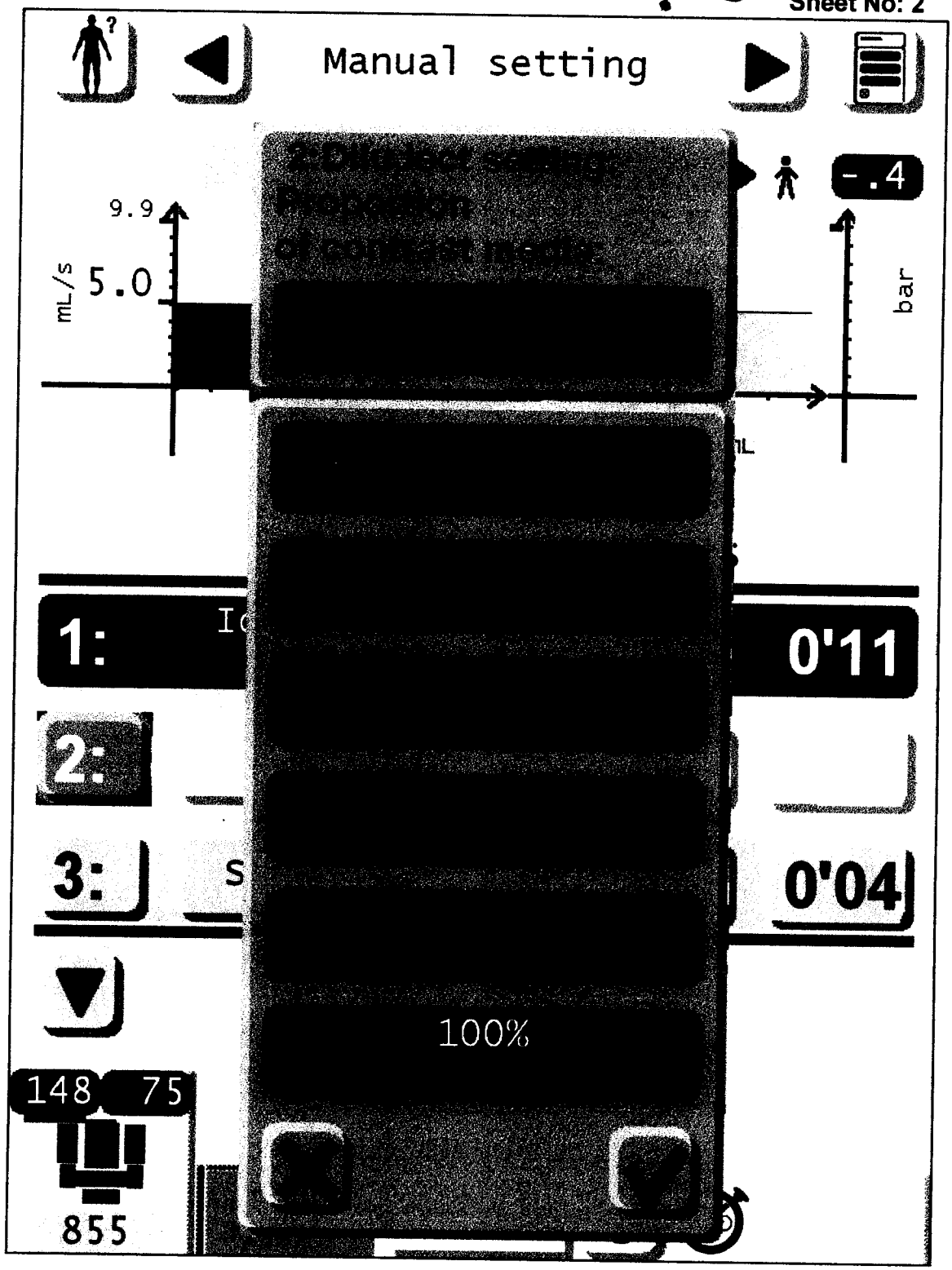

Figure 1B

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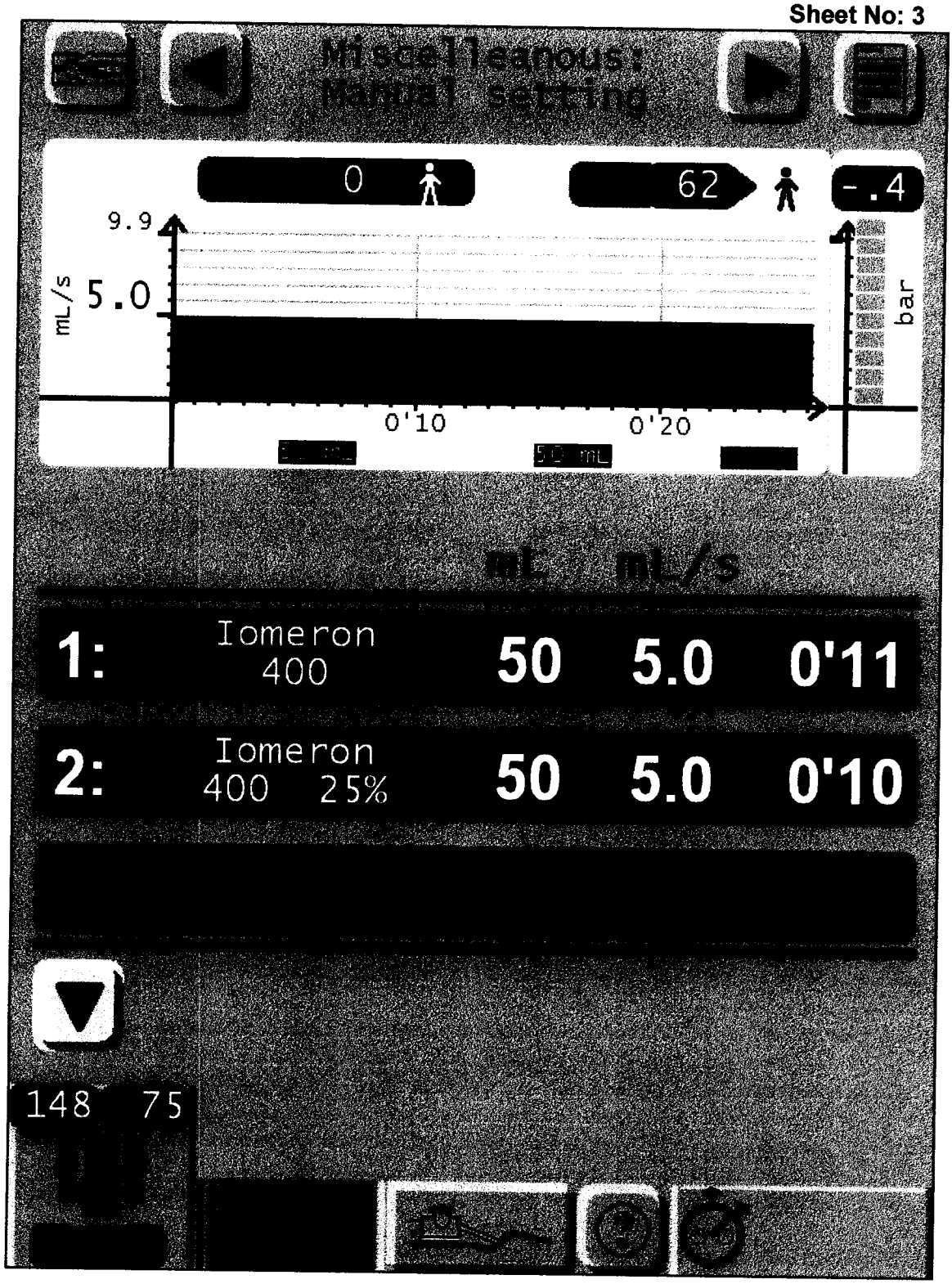

Figure 1C

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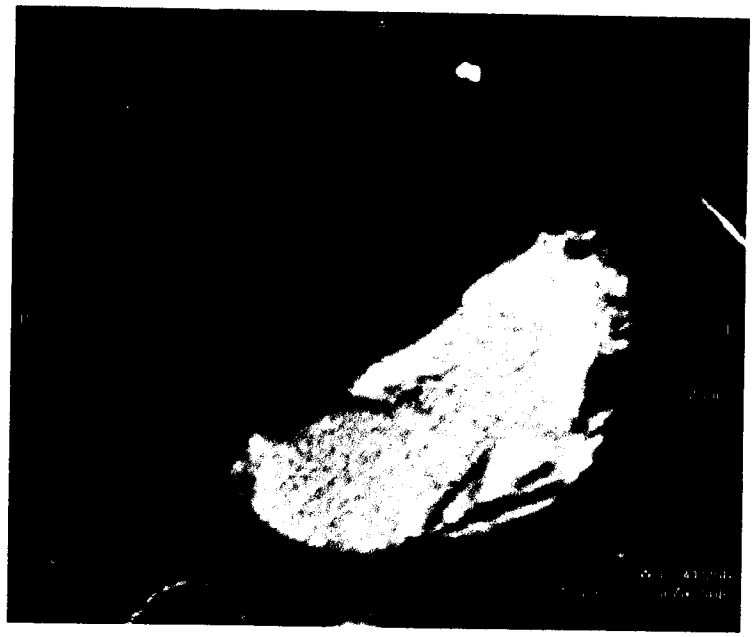

Figure 2A

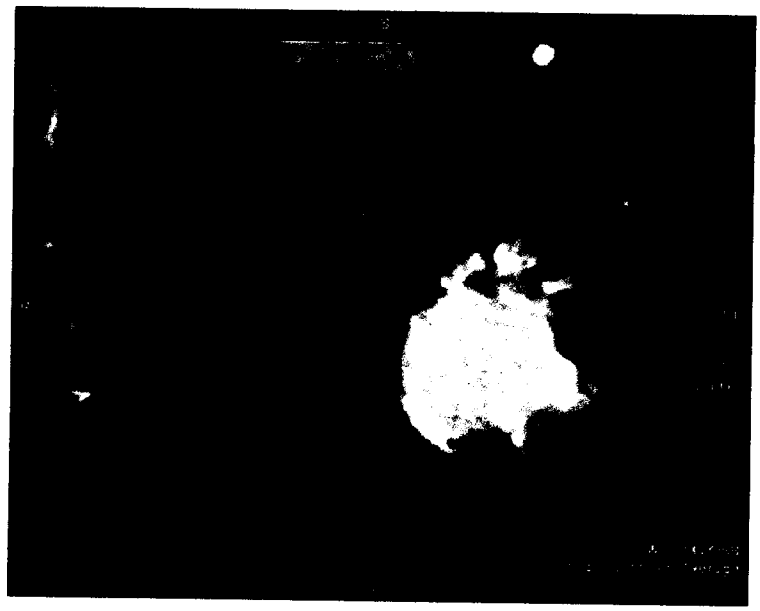

Figure 2B

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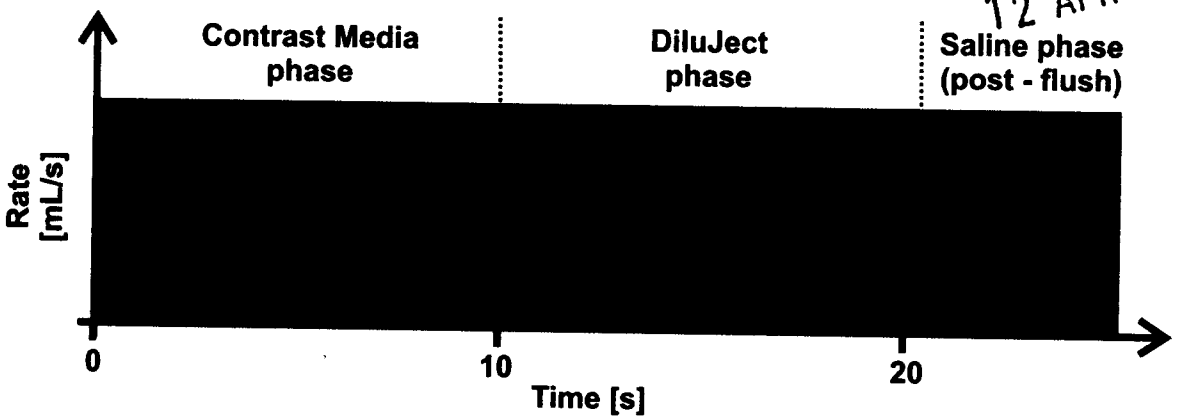

Figure 3A

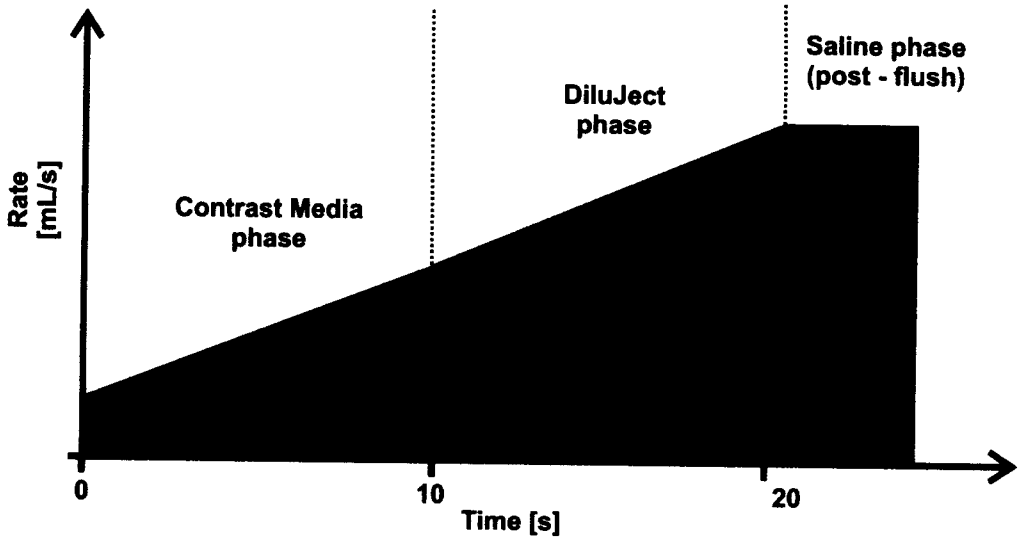

Figure 3B

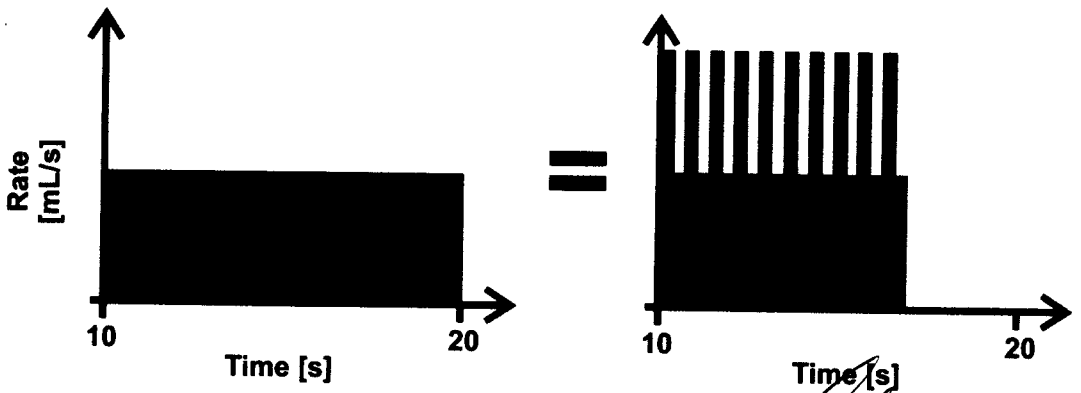

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Figure 3C

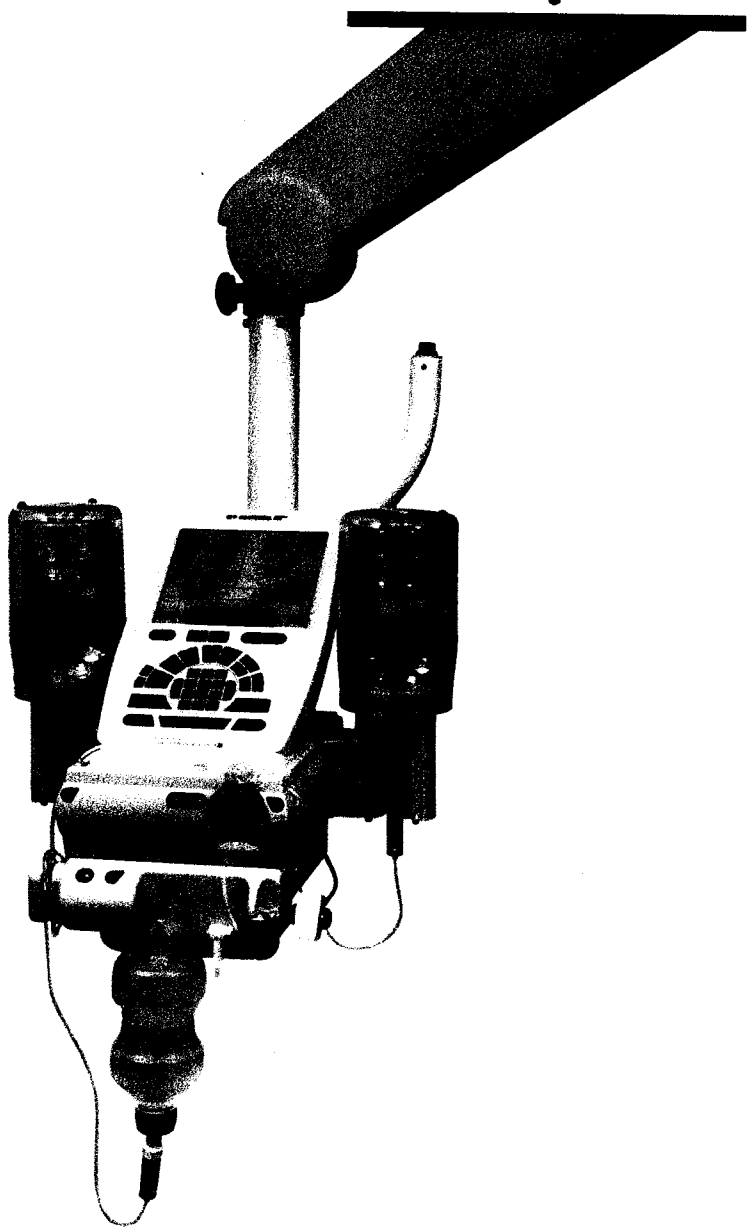

Figure 4A

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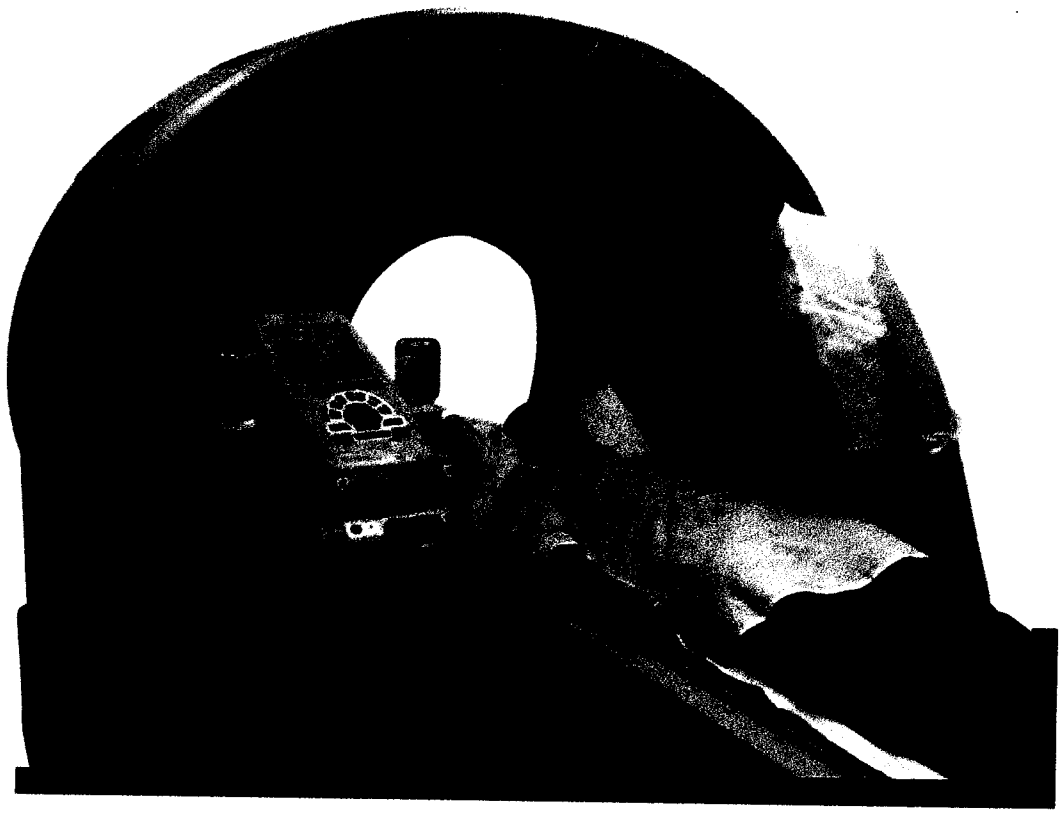

Figure 4B

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Field of the invention

The field of the invention is that of medical imaging, obtained by injecting contrast media and, more specifically, that of the injection of more or less dilute contrast media such as for X-ray imaging, CT scanners or MRI imaging.

Prior art

The use of syringe driving injectors capable, from two syringes in parallel, of injecting a contrast medium at the same time as a saline solution, the purpose of this being to dilute the contrast medium, are already known at the present time.
Patents US 7267667 and US 5911252 describe such devices. US 2007/213848 describes a mechanism (on/off valve) for the alternating injection of a radioactive compound into a saline solution. This mechanism therefore covers a method of eluting (rather than of diluting) the radioactive compound in a saline solution. This elution method - more specifically elution control method - provides control over the activity of the radioactive compound. If this activity is too weak at the detector, the saline solution enters the reservoir containing the radioactive compound and takes up a certain quantity thereof by elution. As soon as the activity measured by the detector returns to the desired value, the valve closes and the saline solution passes only through the "bypass" line.

General overview of the invention

In the invention, the solution to the aforementioned problem is to inject contrast medium into an organ that

is to be analyzed in such a way that the concentrations of such contrast medium vary over the course of time and/or with the region of the organ being analyzed at the moment of image acquisition.

The present invention offers several advantages, particularly the ability to make such concentration modifications inside the organ at a precise moment corresponding to image acquisition, without having to resort to two injectors used in parallel, at lower cost and with a lower risk (notably of error and/or of contamination) to the patient.

It should be noted that the present invention differs from the teaching of US 2007/213848 in that the concentration of the contrast medium is varied by alternating the injections of "saline solution/contrast medium" in such a way that the mixing - and therefore the desired concentration - is obtained before it reaches the heart.

The invention can also be applied to the amplification of an extravasion detection signal, for example using ultrasound, situated downstream of the point of injection into the patient as a result of the change in the nature or concentration of the injected liquid. Thus it is possible to make sure that the liquid has indeed been injected into the vessels concerned thereby excluding any potential extravasion if the injection needle is withdrawn from the patient's vein during said injection. If use is being made of an extravasion detector, because the signal is more or less constant, it is sometimes no longer possible to ensure that the signal is measuring correctly (false positive, or even false negative). By modifying the nature of the liquid

during the course of injection (which corresponds to a change in the measured signal), and using any correspondence there might be between this measured change and the injection sequence, it is possible to ensure that the extravasion detector is operating correctly and from this deduce that the injection flow is normal, excluding any extravasion. In the event of failure to measure this signal which is variable as a function of the frequency of injection of the two alternating liquids, it is possible from this to deduce either that the measurement probe is incorrectly positioned or that extravasion is taking place and, in both instances, to interrupt injection.

Detailed description of the invention

The invention is described in greater detail below through examples illustrated by the following figures:

Figures 1A, 1B and 1C give an example of an injector programming interface, featuring the various possible combinations with, in figure 1A, the option to choose between the injection of contrast, saline or dilution "dilujject"; in figure 1B the dilution options (15%, 20%, 25% or 30%); and in figure 1C, the dilution phase in a diagram.

Figures 2A and 2B depict images obtained with a dilution of 15% and a flow rate of 4 ml/s (2A and 2B) and show an optimum dilution in the heart with a difference, in this example, between the concentration in the right side of the heart and the left side of the heart.

Figures 3A-3C (3A fixed dilution, 3B dilution at variable flow rate and frequency, 3C two examples of dilutions at different flow rates) depict examples of injection cycles with different dilution modes.

Figures 4A and 4B depict an injector that can be used to carry out the invention.

One of the objectives of the present invention is to obtain a contrast medium dilution (either by using two different contrast media or by using one contrast medium and a saline solution or any other solution that has no effect on the contrast during the examination, such as a non-iodized pharmaceutical solution) before it reaches the target organ (for example, the right side of the patient's heart), in order to be able to improve the acquisition of data relating to the anatomy and operation of the organ being analyzed (in the case of the heart: to view the septum, the coronary blood vessels, better calculate the ejection fraction of the heart; knowing that in order to do this the left-hand side of the heart is preferably filled with contrast while the right-hand side of the heart is filled with a dilute contrast solution) either at the same time or at the respective moment when images are acquired respectively in the organ concerned (first the left side of the heart then the right side).
To do this, the invention preferably involves successively injecting into the patient's vein phases of contrast medium alternating with phases of injection of saline solution or of a more weakly concentrated contrast medium, the purpose of this being to obtain a mixing of the various phases which can take place within the patient's cardiovascular system before it reaches the heart or the organ that is to be analyzed.

The invention may advantageously be used in CT scanning or in MRI. In order to obtain effective dilution it is necessary for the frequency to be high enough that mixing can take place in the patient's cardiovascular system before it reaches the target organ. In the case of the heart, it is desirable to have a frequency quite close to cardiac frequency, typically of the order of 1 Hz, but that can also be effective between 5 Hz and 0.2 Hz.

Thus it is possible to dispense with a double injector and perform the dilution directly inside the patient's body using one single injector connected to two types of solutions of different concentrations (or one contrast solution and one saline solution) at a lower cost and involving fewer connections and manipulations which always represent a risk in terms of asepsis and of errors.

Typically, the desired percentage dilution to be obtained in the heart can be chosen (e.g. 15%, 20%, 25% or 30% dilution, which means that for 25% there will be just 25% contrast medium and 75% saline solution). In the case of a 25% dilution, it is possible for example to choose a phase of 1 ml of contrast followed by a phase of 3 ml of saline, the two phases representing a cycle which is repeated according to the total volume that is to be injected (e.g. for 20 ml injected 5 successive cycles will be carried out in the example described). The flow rate in this case is the same for the saline solution and the contrast solution (e.g. 4 ml/s). Alternatively, it is also possible to vary the flow rate in order to obtain the same dilution effect but with a modified volume. Thus, in the example described above, the 3 ml of the saline solution phase can be replaced by a 1.5 ml phase with a flow rate

reduced by half (in the example 2 ml/s instead of 4 ml/s). It is also possible to elect to vary the flow rate of the contrast solution and perform other combinations that have the effect of modifying the contrast ratios in the target organ. It is also possible to elect to vary the respective flow rates and/or volumes of saline and of contrast in each cycle, for example progressively, in order to obtain dynamic images with concentrations that vary during the examination and/or image acquisition period, using algorithms that can adopt any suitable mathematical form.

In order to produce such a device, use is preferably made of a processor capable of managing the alternation between the two reservoirs, for example by commanding the opening and closing of clamps situated between each of the reservoirs and the injection device (for example a peristaltic cassette).