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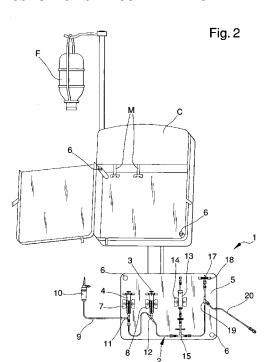
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(54) Title: HYDRAULIC CIRCUIT FOR THE INJECTION OF FLUIDS FOR APPLICATIONS FOR RADIOACTIVE DIAG-NOSTIC FLUIDS IN NUCLEAR MEDICINE



(57) Abstract: The hydraulic circuit for the injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine, comprises an infusion line associable with a patient, introduction means for introducing a preset volume of a fluid for applications in medicine associated with the infusion line, and a support element for supporting the introduction means having fastening/release means for fastening to/releasing from the frame of an appliance for nuclear medicine, for the association of the introduction means with automatic injection means of the appliance.



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HYDRAULIC CIRCUIT FOR THE INJECTION OF FLUIDS FOR APPLICATIONS FOR RADIOACTIVE DIAGNOSTIC FLUIDS IN NUCLEAR MEDICINE

Technical Field

5 The present invention relates to a hydraulic circuit for the injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine.

Background Art

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As is known, nuclear medicine is a method which, by means of radiology image diagnostics, allows detecting organic, anatomic or biological molecular alterations in the body of a patient.

Such method requires, to start with, the peripheral injection of a radiopharmaceutical product into a patient.

By means of tomographic acquisitions, such as positron emission tomography (PET), it is then possible to make the three-dimensional study of an organ or of a patient body area.

In particular, tomography appliances are able to detect the radiation emitted by a radiopharmaceutical product and subsequently transform it into a digital signal for computerised analysis.

It is known that the infusion of the radiopharmaceutical product into the patient is traditionally done manually by an operator, by means of specific pre-filled syringes that are screened against the radiations.

Despite the screening and despite the fact that the operator, during infusion, positions the syringe so as to reduce to the utmost the exposure of his/her body to radioactive emissions, such manual operation does in fact have considerable drawbacks.

During infusion in fact, the operator must necessarily press on the syringe piston, using his/her thumb which, consequently, is exposed to the radiations that filter between the radiopharmaceutical product containment cylinder and the piston itself.

This involves a high risk for the health of the operator, whose level of exposure to the radioactive emissions must be continuously monitored by means of

special detectors.

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Furthermore, the operator remains alongside the patient for all the time needed to make the infusion of the radiopharmaceutical product and during any subsequent operations, such as the post-hydration of the patient and, consequently, is exposed to the radioactive emissions produced by the injected radiopharmaceutical product.

To overcome this drawback automatic appliances are known for injecting the radiopharmaceutical product into a patient.

Generally speaking, the known appliances have a housing suitable for accommodating a syringe pre-filled with the radiopharmaceutical product and have automatic injection means suitable for moving the syringe piston.

These known machines are not however without drawbacks as well.

In particular, in the case of the radiopharmaceutical product escaping as a result of a breakage of the syringe or of the hydraulic circuit connecting it to the patient, it is necessary to carefully clean the appliance.

Such cleaning operation however is not easy to perform due to the presence of elements inside the housing, such as the elements making up the hydraulic circuit, the syringe lock means or, again, the shape of the housing itself.

Another drawback is represented by the fact that the operator is in any case obliged to intervene manually before and after the injection of the radiopharmaceutical product, in particular to perform a preliminary cycle of prehydration of the patient by means of the injection of a physiological salt solution, to prepare the injection of the radiopharmaceutical product and, if necessary, to perform a cycle of post-hydration of the patient after the injection.

After the infusion cycle, furthermore, it is necessary to completely wash the hydraulic circuit of the appliance with physiological salt solution in order to ensure the total removal of the radiopharmaceutical product, for a greater safety of the operators and of whosoever comes into contact with hospital waste, and for the purpose of completely infusing the radioactive diagnostic fluid into the patient.

Object of the Invention

The main aim of the present invention is to provide a hydraulic circuit for the

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injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine, which facilitates cleaning operations, thus providing the utmost protection of the appointed operators from radioactive emissions.

Another object of the present invention is to provide a hydraulic circuit for the injection of fluids that permits performing a complete infusion cycle on the patient: from the preparation of the hydraulic circuit for the injection, to the subsequent pre-hydration of the patient, to the injection of the radioactive diagnostic fluid, up to the washing of the hydraulic circuit and the post-10 hydration of the patient.

Another object of the invention is to provide a hydraulic circuit for the injection of fluids that ensures utmost safety for the patient.

Another object of the invention is to provide a hydraulic circuit for the injection of fluids that is simple to use.

Another object of the invention is to provide a hydraulic circuit for the injection of fluids that allows speeding up the overall injection cycle of the radioactive diagnostic fluid into a patient.

The above objects are achieved by the present hydraulic circuit for the injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine, comprising at least an infusion line associable with a patient, and introduction means for introducing a preset volume of a fluid for applications in medicine associated with said infusion line, characterized in that it comprises at least a support element for supporting said introduction means having fastening/release means for fastening to/releasing from the frame of an appliance for nuclear medicine, for the association of said introduction means with automatic injection means of said appliance.

Brief Description of the Drawings

Other characteristics and advantages of the present invention will become more evident from the description of a form of preferred, but not sole, embodiment, of a hydraulic circuit for the injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine, illustrated purely as an example but not limited to the annexed drawings in which:

Figure 1 is an axonometric view of the hydraulic circuit according to the invention applied to an appliance for the injection of fluids;

Figure 2 is an axonometric view of the hydraulic circuit according to the invention extracted from the appliance of figure 1;

5 Figure 3 is a schematic view of the hydraulic circuit according to the invention. Embodiments of the Invention

With particular reference to such illustrations, a hydraulic circuit for the injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine has been globally indicated by 1.

In particular, in the following description reference is made to the field of application of the nuclear medicine and, therefore, to the injection of radioactive diagnostic fluids, before the carrying out of diagnostic exams such as tomographic acquisitions or the like. Different applications of the hydraulic circuit 1 cannot however be ruled out.

As shown in the figures 1 and 2, the hydraulic circuit 1 is installable on the frame T of an appliance A, inside a special housing container C. The appliance A is of the type usable in nuclear medicine for the automated introduction of the radioactive diagnostic fluid into a patient.

The hydraulic circuit 1 comprises an infusion line 2 associable with the patient and with which are associated introduction means 3 for introducing a preset volume of a radioactive diagnostic fluid, of the type commonly used for diagnostic exams in nuclear medicine.

Advantageously, the hydraulic circuit 1 comprises auxiliary introduction means 4 for introducing a physiological salt solution or the like, these too associated with the infusion line 2.

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The introduction means 3 and the auxiliary introduction means 4 are both associable with automatic injection means of the appliance A, generically indicated in the figures 1 and 2 with the reference M.

The automatic injection means M are controlled by the appliance A for the controlled introduction into the patient of the physiological salt solution and of the radioactive diagnostic fluid.

The presence of the introduction means 3 and of the auxiliary introduction

means 4, operatively associable with the automatic injection means M, allows, after the prearrangement of the appliance A and the connection of the hydraulic circuit 1 to the patient, to perform a complete introduction cycle of the physiological salt solution and of the radioactive diagnostic fluid without any further intervention on the part of the appointed operators.

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As shown in the above illustrations, all the elements of the hydraulic circuit 1 are fastened to a support element 5, substantially plate-shaped and made of polymer material. Different shapes of the support element 5 and the use of different materials cannot however be ruled out.

The support element 5 has rapid type fastening/release means for fastening to / release from one of the inner walls of the container C, generically indicated with the reference 6, which allow the fast installation and removal of the entire hydraulic circuit 1 onto/from the appliance A. The fastening/release means 6 can, e.g., be of the clip type, but alternative embodiments are not however to be ruled out.

Usefully, in case of the breakage of the hydraulic circuit 1 with escape of the radioactive diagnostic fluid, the presence of the support element 5 and of the fastening/release means 6 allows the fast removal of the entire hydraulic circuit 1 and facilitates the cleaning operations of the container C, which consists of smooth and easy-to-wash surfaces.

The auxiliary introduction means 4 consist of an auxiliary piston device, of the type of a conventional syringe for injections, fixed to the support element 5 by means of suitable first retention means 7, of the clip type or the like.

The introduction means 3 consist of a piston device, of the type of a syringe for injections conventionally used for the injection of the radioactive diagnostic fluid, fixed to the support element 5 by means of suitable second retention means 8, of the clip type or the like, and associated with the infusion line 2 downstream with respect to the auxiliary piston device 4.

Usefully, the piston device 3 comprises a containment chamber having outer screening from radiations and filled beforehand with a preset volume of radioactive diagnostic fluid to be injected into a patient.

The automatic injection means M of the appliance A may have, e.g., two

distinct electromechanical linear actuators associable with the auxiliary piston device 4 and the piston device 3 respectively.

The hydraulic circuit 1 comprises an inlet line 9 of the physiological salt solution which has, at one extremity, a first connector 10 associable with an external bottle F if necessary supported by the frame T of the appliance A and which is associated, at the opposite extremity, with a valve 11.

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In particular, the valve 11 is of the type of a three-way valve having an inlet mouth 11a associated with the inlet line 9, an inlet/outlet mouth 11b associated with the dispensing/suction mouth of the auxiliary piston device 4 and an outlet mouth 11c associated with the infusion line 2.

Along the infusion line 2 is a second connector 12, of the type of a T connector, arranged downstream with respect to the valve 11 and having an inlet mouth 12a associated with the dispensing mouth of the piston device 3.

The hydraulic circuit 1 comprises a pressure detector 13 suitable for reading any abnormal pressures inside the infusion line 2, fixed to the support element 5 by means of suitable third retention means 14, of the clip type or the like.

For example, high pressure values can be caused by an out-of-vein injection potentially dangerous for the patient, while low pressure values can be caused by a breakage of the infusion line 2.

20 In particular, along the infusion line 2 is a third connector 15, of the type of a T connector, arranged downstream of the second connector 12 and having a mouth 15a associated with the pressure detector 13.

Advantageously, between the mouth 15a and the pressure detector 13 a solenoid valve can be placed, schematised in figure 3 and indicated with the reference 16, suitable for isolating the pressure detector 13 from the rest of the hydraulic circuit 1 and usable, in particular, during the preparation operations of the appliance 1, before the infusion cycle.

The hydraulic circuit 1 also comprises a hydrophobic filter 17 suitable for expelling the air present inside the infusion line 2 and fastened to the support element 5 by means of suitable fourth retention means 18, of the clip type or the like.

In particular, at an end section of the infusion line 2 a fourth connector 19 is

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present of the type of a T connector, arranged downstream of the third connector 15, having a mouth 19a for the outflow of the air associated with the hydrophobic filter 17 and a mouth 19b for the outflow of the fluid introduced by the piston device 3 or by the auxiliary piston device 4, associated with an outlet line 20 towards the patient.

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Before use, the hydraulic circuit 1 is first of all arranged by an operator inside the container C, and the support element 5 is fastened to the inner wall of the container C by means of the fastening/release means 6.

The container C is then closed and the outlet line 20 of the hydraulic circuit 1 is connected to a venous catheter on the patient.

During use, the physiological salt solution is introduced into the infusion line 2 towards the patient, by means of the automatic injection means M.

In particular, the auxiliary piston device 4 aspirates the physiological salt solution from the bottle F, through the inlet line 9 and through the mouth 11a and the mouth 11b of the valve 11 and, afterwards, introduces the physiological salt solution into the infusion line 2, through the mouth 11b and the mouth 11c of the valve 11.

The introduction of the physiological salt solution allows eliminating the air present inside the infusion line 2, with the patient connected to the circuit and, therefore, without the need for any manual intervention by the operator. In particular, the entire infusion line 2 is filled with the physiological salt solution and the air is expelled through the hydrophobic filter 17.

A patient pre-hydration phase can also be envisaged, in which the physiological salt solution is injected into the patient according to predefined volume and flow.

Subsequently, the radioactive diagnostic fluid is introduced into the infusion line 2 towards the patient, by means of the piston device 3.

In particular, during such introduction, the piston device 3 introduces the radioactive diagnostic fluid already present inside the containment chamber in the infusion line 2, through the mouth 12a of the second connector 12.

Subsequently, a further introduction can be made of the physiological salt solution into the infusion line 2 towards the patient, by means of the auxiliary

piston device 4.

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During such further introduction the entire infusion line 2 is filled with the physiological salt solution, so as to empty the infusion line 2 of the radioactive diagnostic fluid residues, and so as to allow the introduction into the patient of all the radioactive diagnostic fluid.

A patient post-hydration phase can also be envisaged in which the physiological salt solution is injected into the patient according to predefined volume and flow.

It has in fact been ascertained how the described invention achieves the proposed objects and in particular the fact is underlined that the hydraulic circuit facilitates the appliance cleaning operations, thus providing the utmost protection of the appointed operators from radioactive emissions.

The presence of the support in fact, together with the presence of the fastening/release means, makes it possible to perform, in a simple and quick way, the installation and removal operations of the hydraulic circuit on/from the frame of an appliance for nuclear medicine.

Another advantage stems from the fact that the presence of the supplementary introduction means for introducing the physiological salt solution allows automating a complete patient infusion cycle, comprising both the introduction of the radioactive diagnostic fluid and any patient pre-hydration and post-hydration phases, thus reducing to the utmost the manual intervention of the appointed operators.

The almost total absence of manual intervention also involves faster execution times of the complete infusion cycle.

25 Furthermore, the described hydraulic circuit ensures utmost safety for the patient, in particular thanks to the presence of the pressure detector inside the hydraulic circuit.

The invention thus conceived is susceptible to numerous modifications and variations, all of which falling within the scope of the inventive concept.

Furthermore all the details can be replaced with others that are technically equivalent.

In practice, the materials used, as well as the contingent shapes and dimensions.

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may be any according to requirements without because of this moving outside the protection scope of the following claims.

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CLAIMS

- 1) Hydraulic circuit for the injection of fluids for applications in medicine, particularly radioactive diagnostic fluids in nuclear medicine, comprising at least an infusion line associable with a patient, and introduction means for introducing a preset volume of a fluid for applications in medicine associated with said infusion line, characterized in that it comprises at least a support element for supporting said introduction means having fastening/release means for fastening to/releasing from the frame of an appliance for nuclear medicine, for the association of said introduction means with automatic injection means of said appliance.
- 2) Hydraulic circuit according to claim 1, characterized in that it comprises auxiliary introduction means for introducing a physiological salt solution or the like integrally associated with said support element and associated with said infusion line.

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- 15 3) Hydraulic circuit according to one or more of the preceding claims, characterized in that said auxiliary introduction means are associable with said automatic injection means of said appliance.
 - 4) Hydraulic circuit according to one or more of the preceding claims, characterized in that said introduction means comprise at least a piston device having a containment chamber of a preset volume of said fluid and associated with said infusion line.
 - 5) Hydraulic circuit according to one or more of the preceding claims, characterized in that said auxiliary introduction means comprise at least an auxiliary piston device, associable with at least a bottle containing said physiological salt solution and associated with said infusion line, upstream of said piston device.
 - 6) Hydraulic circuit according to one or more of the preceding claims, characterized in that at least one between said piston device and said auxiliary piston device is of the type of a syringe or the like.
- 30 7) Hydraulic circuit according to one or more of the preceding claims, characterized in that said piston device comprises at least a portion screened against radiations.

8) Hydraulic circuit according to one or more of the preceding claims, characterized in that said support element is substantially plate-shaped.

9) Hydraulic circuit according to one or more of the preceding claims, characterized in that said support element is at least in part made of polymer material.

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- 10) Hydraulic circuit according to one or more of the preceding claims, characterized in that said fastening/release means are of the clip type or the like.
- 11) Hydraulic circuit according to one or more of the preceding claims, characterized in that said support element is associable, by interposition of said fastening/release means, with at least an inner wall of a container on said frame.
- 12) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least an inlet line of said physiological salt solution, associated with said auxiliary piston device and associable with said bottle containing physiological salt solution.
- 13) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a first connector associated with a free end of said inlet line and associable with said bottle.
 - 14) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a valve, of the type of a three-way valve, associated with said inlet line, with said auxiliary piston device and with said infusion line.
 - 15) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a second connector, of the type of a T connector, associated with said piston device and with said infusion line.
- 25 16) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a pressure detector associated with said infusion line, downstream of said piston device.
 - 17) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a third connector, of the type of a T connector, associated with said pressure detector and with said infusion line.
 - 18) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a hydrophobic filter or the like

associated with said infusion line, downstream of said piston device.

19) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises at least a fourth connector, of the type of a T connector, associated with said hydrophobic filter, with said infusion line and with an outlet line associable with said patient.

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20) Hydraulic circuit according to one or more of the preceding claims, characterized in that it comprises retention means on said support element for retaining at least one between said piston device, said auxiliary piston device, said pressure detector and said hydrophobic filter.

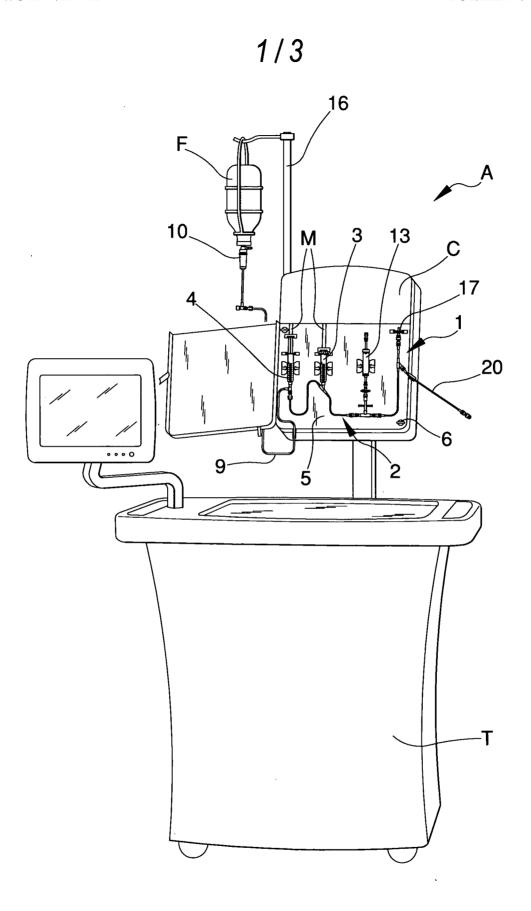
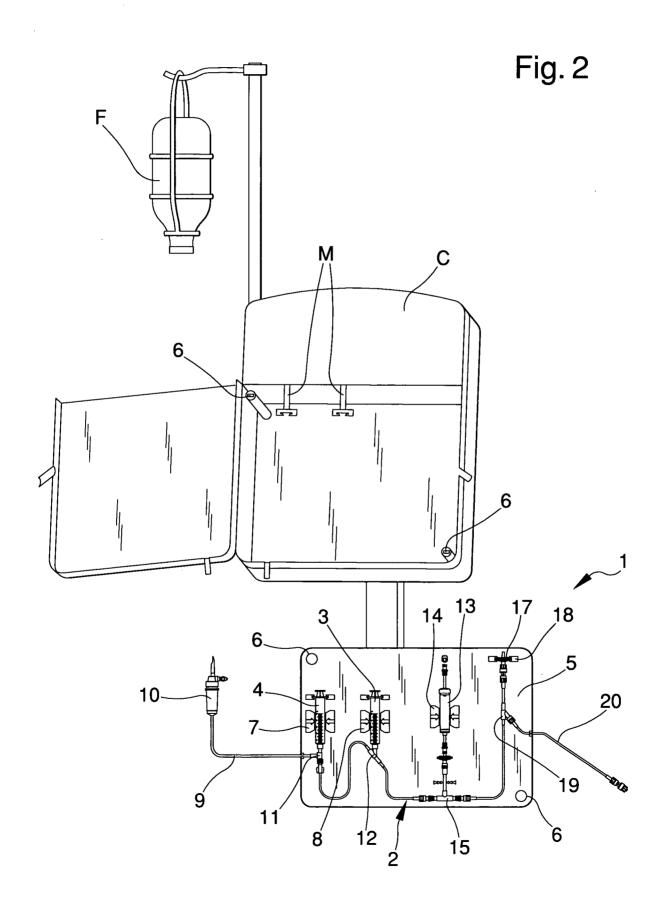
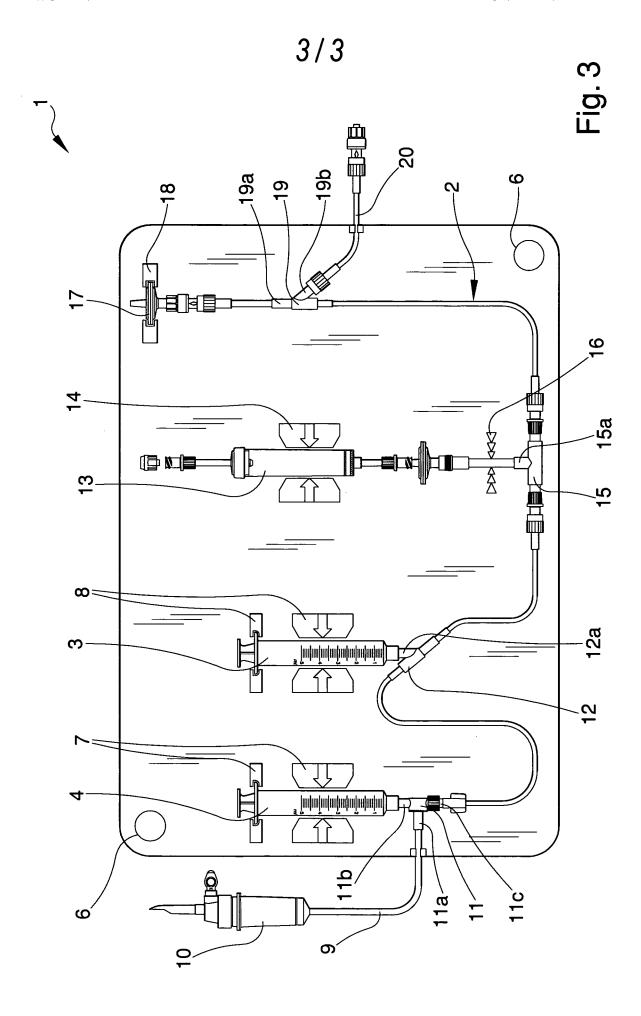


Fig. 1





INTERNATIONAL SEARCH REPORT

International application No PCT/IB2009/000356

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/14 ADD. A61M5/00 A61M36/00 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X US 2005/203329 A1 (MUTO AKIO [JP] ET AL) 1 - 2015 September 2005 (2005-09-15) figures 1-14 paragraph [0032] - paragraph [0060] X PALMER ET AL: "An automated [<15>0]H20 1-8. 11-20 production and injection system for PET imaging" NUCLEAR MEDICINE AND BIOLOGY, ELSEVIER, NY, US, vol. 22, no. 2. 1 February 1995 (1995-02-01), pages 241-249, XP022382231 ISSN: 0969-8051 the whole document X X Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-"O" document referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 9 July 2009 20/07/2009 Name and mailing address of the ISA/ Authorized officer European Patent Office, P.B. 5818.Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 Reinbold, Sylvie

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/000356

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INTERNATIONAL SEARCH REPORT

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