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(54) Title: APPARATUS, SYSTEM AND METHOD FOR THE REMOVAL OF BODY FLUIDS

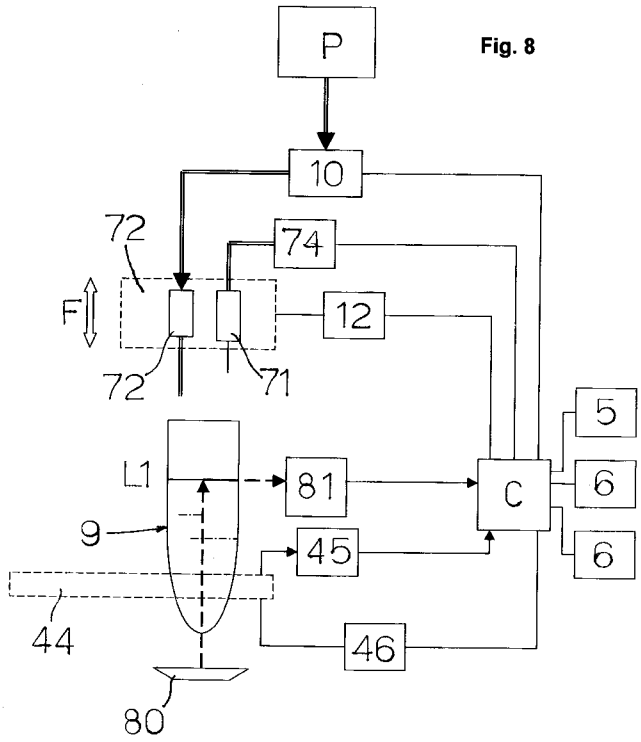

Fig. 8

(57) Abstract: The invention relates to an apparatus (1) for collecting organic liquids, usable, in particular, for collecting follicular liquid and the relevant oocytes or other organic liquids in the human or animal field by means of a suction pump; the apparatus comprises: - a tray (4) provided with a plurality of seats (40) for housing a corresponding plurality of test tubes (9) to be filled with an organic liquid; - handling means for said test tubes which cause said test tubes to move along a given path; a filling station (72, 70, 71) disposed on the path followed by said test tubes; - sensor means (80, 81) for controlling the filling of the test tubes, means which are disposed and acting in correspondence of said filling station; -control means (C) connected to the handling means of said tray, to said filling station and to said sensor means.

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TITLE

APPARATUS, SYSTEM AND METHOD FOR THE REMOVAL OF BODY FLUIDS.

* * * *

DESCRIPTION

The present invention relates to an apparatus, a system and a method for collecting organic liquids.

The invention can be applied in the process for the removal of oocytes and it can be used for collecting different liquids in the human and animal field.

To exemplify this process and with reference to human procreation, the collection of follicular liquid and of its respective oocytes can be carried out by using a vacuum pump which acts on a duct connected to the patient and allows the filling of a series of test tubes positioned in succession.

A drawback of the current collection techniques arises from the fact that the evaluation of a correct filling of the test tubes depends on the operator and is connected with the experience and with the skills of the same operator.

A further drawback of the known techniques arises from the fact that they require two operators for removing and filling the test tubes.

Further drawback are due to the following causes: variability of the physical parameters of the pumps used for aspirating; variability due to the operator; regularity of the depression.

A further drawback is connected with the thermal stress to which the liquid is submitted when it changes from 37° C (human body temperature) to ambient temperature present inside the test tube.

Even in the field of veterinary, the MAP procedure (medically assisted procreation) is widely used.

Infertility problems in animals belonging to a superior breed used for producing meat and for other activities (race horses, animals belonging to valuable breeds and so on), sex selection and the possibility of rapidly creating a high genealogy stall are some of the motivations which lead to the use of such techniques. The MAP procedure does not require large quantities of sperm which can be used for a higher number of females. This procedure is similar to the procedure adopted for the human species, comprising the removal of oocytes. However, the relatively limited use of the MAP techniques for animals is probably due to its costs which are still high and to the

difficulty of carrying out certain procedures such as the removal of oocytes which, more than for the women, requires skills and experience to achieve a high percentage of satisfactory results.

The aim of the present invention is to overcome said drawbacks.

According to the invention, these results have been achieved by adopting the idea of an apparatus having the features described in claim 1. Further features are described in the other claims. One of the advantages of the present invention is that it is possible to collect organic liquids in a safe, effective and relatively rapid way; that the operation can be carried out by a single operator; that the filling of the test tubes takes place automatically and with extremely high precision; that the system is closed, that is the liquid that has been removed never comes into contact with the environment as happens in the well-known technique when changing the test tubes; that the risk of contamination is basically completely eliminated or at least reduced; that the temperature of the liquid that has been collected is kept unchanged; the apparatus of the present invention is easy and simple to use and its features remain unchanged even after it has been used for a long time.

The present invention can advantageously be applied to the field of Reproductive Medicine for the removal of oocytes, as well as in the field of Obstetrics and Gynaecology in general for the aspiration of any other type of liquid such as cystic liquids, peritoneal effusions and any liquid that can be reached with a needle in an echo-guided manner, including the removal of amniotic fluid.

Every technician who works in this field will better understand these advantages and further advantages and features of the present invention thanks to the following description and to the enclosed drawings as a practical exemplification which should not be considered in a limitative sense wherein:

-Fig. 1 is a schematic perspective view of a possible embodiment of apparatus according to the present invention which is represented in an open configuration;

- Figs 2, 3, 4 represent the embodiment of Fig. 1 respectively in a front, lateral and top plan view;

- Figs 5, 6 and 7 are section views according to line B-B of Fig.2, to line A-A of Fig. 2 and respectively to line C-C of Fig. 4.

- Fig. 8 is a block diagram representing the apparatus according to the invention;

- Figs 9, 10 and 11 are block diagrams which relate to systems for removing organic

liquids of well-known types (Fig.9 - prior art) and according to two innovative forms according to the invention (Figs. 10 and 11).

With reference to the example in the enclosed drawings, the apparatus 1 consists of a structure 2 provided with an end which is closed by means of a hinged cover 3. A rotary tray 4, destined to contain a plurality of test tubes, is disposed in that part of the apparatus 1 closed by means of the cover 3.

In particular, the test tubes 9 can be housed in corresponding seats 40 which are disposed angularly equidistant from one another along a drum-shaped structure 44 which is rotatable around its vertical axis under the action of corresponding motion means (schematically represented by block 45 in Fig. 8). In practice, the test tubes (which can be of the type called "Falcon type") are handled in such a manner that they are positioned in a filling station which is provided with two needles 70 and 71.

The structure 44 can be formed in plastic material, for example PVC, and it can have a shaped portion which defines a toothed crown engageable with a corresponding belt connected to said motion means for the tray 4. Lowerly, in correspondence of each seat 40 for the test tubes, the structure of the tray 44 has holes for allowing the sensor means for filling the test tubes, described below, to act.

The motion means for the tray allow its step- by -step rotation. For this purpose, it is possible to insert permanent magnets on the external side of the structure 44 so as to determine the position of a single test tube with its corresponding zero and intermedium positions, thanks to the interaction with a Hall effect sensor (the sensor means for the positions of the test tubes are schematically represented by block 46 in Fig. 8).

Moreover, on the tray, can be disposed means for adjusting the temperature consisting, for example, of one or more resistors and a thermostat.

The needles 70 and 71 are fixed to a support arm 72 which can be moved vertically in the direction indicated by arrow F in Fig. 7. In practice, there is a motion unit 12, kinematically connected to the arm 72, which causes the arm to move vertically; the connection between the support 72 (which is slidable along vertical guides between an upper waiting position and a lower active position or aspirating/suction position) and the motion unit 12 (which can be a step by step unit) can be of the type with a screw-female screw unit. Moreover, support 72 can be provided with a permanent magnet, which, in combination with two Hall effect sensors, which are vertically distanced,

provides a signal for its vertical position.

Support arm 72 is provided with the first needle 70 which is destined to the passage of the liquid and the second needle 71 (which, in the drawings, is shorter than the first needle) destined to the passage of air so as to determine a depression inside the test tube to be filled, test tube which is closed by a liquid tight plug 91. The needle 70 is connected to one end of the suction tube 73 which, at the opposite end, receives the entry liquid for filling the test tubes. An electro-valve 10 is disposed and acts on the aspiration tube which, on command, closes and blocks the liquid flow. The needle 71 is connected to the aspiration pump represented by block 74 in Fig.8.

The filling station is provided with sensors for the filling of the test tubes. Said sensors comprise an emitter 80 which is disposed lowerly so that it can send a luminous beam upwards according to the vertical direction corresponding to the test tube axis and photoreceiver 81 disposed laterally to the test tube at an height which corresponds to the filling level of the test tube itself. The emitter 80 and the receiver 81 can be of the infrared type. During the filling phase, the light beam sent by the emitter 80 doesn't arrive to the receiver 81 till the correct filling level is reached, i.e. when the beams laterally diverted arrived on the receiver 81. During the filling of the tube, the luminous intensity present on the receiver increases proportionally and the maximum intensity level is reached when the level of the liquid inside the test tube reaches the height of the photoreceiver 81 (height L1 in Fig. 8).

The sensor means 80 and 81 can be used to detect the presence of test tubes in the seat 40 and the filling, even if it is a partial filling, of the test tubes themselves.

The apparatus comprises a processing unit C which is also connected to the motion means 45 of the tray 4, to the motion means 12 of the support 72 for the needles, to the electro-valve 10 which acts on the suction tube connectable to the patient P, to the vacuum pump 74 and to the sensors 80, 81 of the filling of the test tubes.

If an obstruction of the aspiration tube occur (due to blood clots, mucus or similar organic material which may hinder the passage) it is possible to advantageously foresee an "OverBoost" function (aspiration with a higher depression) in which the depression is increased for a limited time, time which can be set by means of control software. This function can be enabled while the machine is carrying out the aspiration cycle by simply pressing a function key.

Moreover, the processing unit C is connected to a video screen 5 and to a series of

control pushbuttons 6. The writings present on the screen are just exemplificative.

During operation of the apparatus, an empty test tube is positioned in the filling station and the support arm 72 for the needles is lowered until it reaches the aspiration position in which the two needles 70 and 71 pass through the plug 91 of the test tube 9.

The action of the pump 74 through the needle 71 determines a depression inside the test tube and the liquid to be collected flows through the needle inside the test tube itself.

When the desired filling level, which corresponds to height (L1) (where the photoreceiver 81 is positioned), is reached, a signal from said photoreceiver determines the closing of the electro-valve 10, the disabling of the pump and the subsequent lifting of the needles into their rest position. At this point, the tray rotates and takes an empty test tube to the filling station in order to carry out another filling cycle.

According to a further embodiment of the apparatus, it is foreseen to use the apparatus with double filling needles (special needles consisting of concentric tubes); according to this methodic, the follicular liquid is aspirated into the tube with a smaller internal diameter until the follicle has been emptied. At this point, the operator can decide to wash the follicle by using the larger external tube. Said tube is connected to a sterile container provided with a suitable washing fluid. By pressing a suitable pushbutton on the display (when this function is enabled) the operator operates a pump which aspirates the liquid and sends it into the follicle through this tube; the apparatus aspirates this liquid by means of the external tube according to the procedures described above.

The flow of washing liquid can be released in two ways: by aspiration using a pump for liquids or by means of a peristaltic pump. When the operator blocks the cycle, aspiration and the flow of washing liquid automatically break (as previously described). Therefore, it is foreseen to introduce a further pump into the tool which is schematically represented by block 11 in Fig. 7, in which the connection tubes have not been illustrated.

In conventional procedures, schematically shown by the blocks of Fig. 9 the doctor A1 who is carrying out a removal is working under sterile conditions helped by a sterile assistant A4 and by a non-sterile operating room assistant A3 who is carrying out all

the other operations; an anaesthetist A2 is also present. In the drawing of Fig. 9, the blocks indicate the following parts: 120 operating bed, 121 echograph, 123 table for the aspirator, 124 sterile table.

The removal process of oocytes represents an example of a process to be optimized.

In a woman, this process takes place as follows: after preparing the necessary material in a sterile manner, the needle is suitably connected to the test tube and from the test tube it is connected to aspiration system. After a deep sedation (carried out by the anaesthetist A2) the operator A1 introduces the probe and the needle into the ovaries and aspirates the follicles in succession. The sterile operating room assistant A4 changes the test tube manually whenever it is full, replaces it with an empty test tube and automatically interrupts aspiration. The test tube is passed to the operating room staff A3 and placed in a thermostat at 37 ° C or handed to the lab staff if the oocytes search is carried out contextually to the removal process. The process proceeds in this way until the end of the operation. The condition changes to which the oocyte is submitted are evident in this situation.

The new system allows the elimination of both the sterile operating room assistant A4 and the non-sterile operating room assistant A3 since all the operations they usually carry out can be controlled by means of a remote control automatic system run by an operator (changing of test tubes, enabling/ interrupting aspiration and so on).

In this case, as shown in Fig. 10, a system for removing organic liquids consists of removal apparatus according to the invention and of an echograph 121.

According to a further embodiment of the invention, which is schematically shown in Fig. 11, the removal apparatus 1' is also provided with a trans-vaginal probe (which is not shown) and uses its own video screen 5 for a corresponding display. In other words, the procedure and the means necessary for carrying out the removal have undoubtedly been simplified. In practice, it is foreseen to use single apparatus capable of carrying out aspiration as well as an echographic display. Said apparatus can remarkably be simplified because operations such as the removal of oocytes do not require complex echographic apparatus but a simplified instrument provided with a trans-vaginal probe, with a digital monitor and with a good definition; said apparatus provides the possibility of altering the grey tones, image magnification and biopsy guides.

As a final result, a single operator can carry out the removal of oocytes together with

the anaesthetist if necessary, by using a single machine whose functions are those of collecting and of maintaining follicular liquids under controlled conditions and which is provided with an echographic display system for the follicles to be aspirated.

The command and control organs for the elements described above and illustrated in the enclosed drawings are well-known to the technicians who work in this field so they have not been described in detail for simplicity's sake.

Moreover, the execution details may equally vary as regards shape, size , disposition of elements and kind of material used within the solution idea that has been adopted and within the limits of the protection offered by the present patent.

CLAIMS

1) Apparatus for collecting organic liquids, usable, in particular, for collecting follicular liquid and the relevant oocytes or other organic liquids in the human or animal field by means of a suction pump, characterised in that the apparatus comprises:

- a tray (4) provided with a plurality of seats (40) for housing a corresponding plurality of test tubes (9) to be filled with an organic liquid;
- handling means for said test tubes which cause said test tubes to move along a given path;
- a filling station (72, 70, 71) disposed on the path followed by said test tubes;
- sensor means (80, 81) for controlling the filling of the test tubes, means which are disposed and acting in correspondence of said filling station;
-control means (C) connected to the handling means of said tray, to said filling station and to said sensor means.

2) Apparatus according to claim 1 characterised in that said control means (C) are connected to an electro-valve (10) disposed on a suction tube which is connected to said pump.

3) Apparatus according to claim 1 characterised in that said sensor means comprise a light emitter (80) and a corresponding receiver (81) which are respectively disposed underneath the test tubes during the filling phase and laterally to it at a height which corresponds to a predetermined filling level.

4) Apparatus according to claim 1 characterised in that said filling station comprises a first needle (70) connected to a suction tube which carries the liquid to be collected and a second needle (71) which is connected to the suction pump and destined to determine a depression inside the test tube.

5) Apparatus according to claim 1 characterised in that said tray (4) is provided with thermal adjustment means.

6) Apparatus according to claim 4 characterised in that said needles (70, 71) are fixable to a support arm (72) which is vertically movable so as to displace said needles into an upper or waiting position and into a lower or filling position, in said later position the needles passing through a plug (91) of the test tube (9) to be filled.

7) Apparatus according to claim 1 characterised in that it is provided with a second pump (11) and with a double needle device with a double coaxial tube for washing the

follicle.

8) Apparatus according to claim 1 characterised in that the structure (44) of said tray (4) has a shaped portion defining a toothed crown engageable with motion transmitting means connected to corresponding motion means for the tray (4).

9) Apparatus according to claim 1 characterised in that the structure (44) of said tray (4), in correspondence of each seat (40) for the test tubes, is provided with holes so as to allow sensor means (80) for the filling of the test tubes (9) to act.

10) Apparatus according to one of the previous claims characterised in that it is provided with an echographic probe and with a video screen (5).

11) System for collecting organic liquids in the human field characterised in that it consists of an apparatus (1) according to one or more claims from 1 to 9 and of an echographic device.

12) System for collecting organic liquids in the human field characterised in that it consists of an apparatus (1) according to one of the claims from 1 to 9 and of an echographic device which comprises an echographic probe and an echographic monitor.

13) Method for collecting organic liquids usable for collecting follicular liquid and the relevant oocytes or other organic liquids in the human or animal field by means of a suction pump characterised in that it uses an apparatus according to one or more claims from 1 to 10.

14) Method for collecting organic liquids usable for collecting follicular liquid and the relevant oocytes or other organic liquids in the human or animal field by means of a suction pump characterised in that it uses a system according to claims 11 or 12.

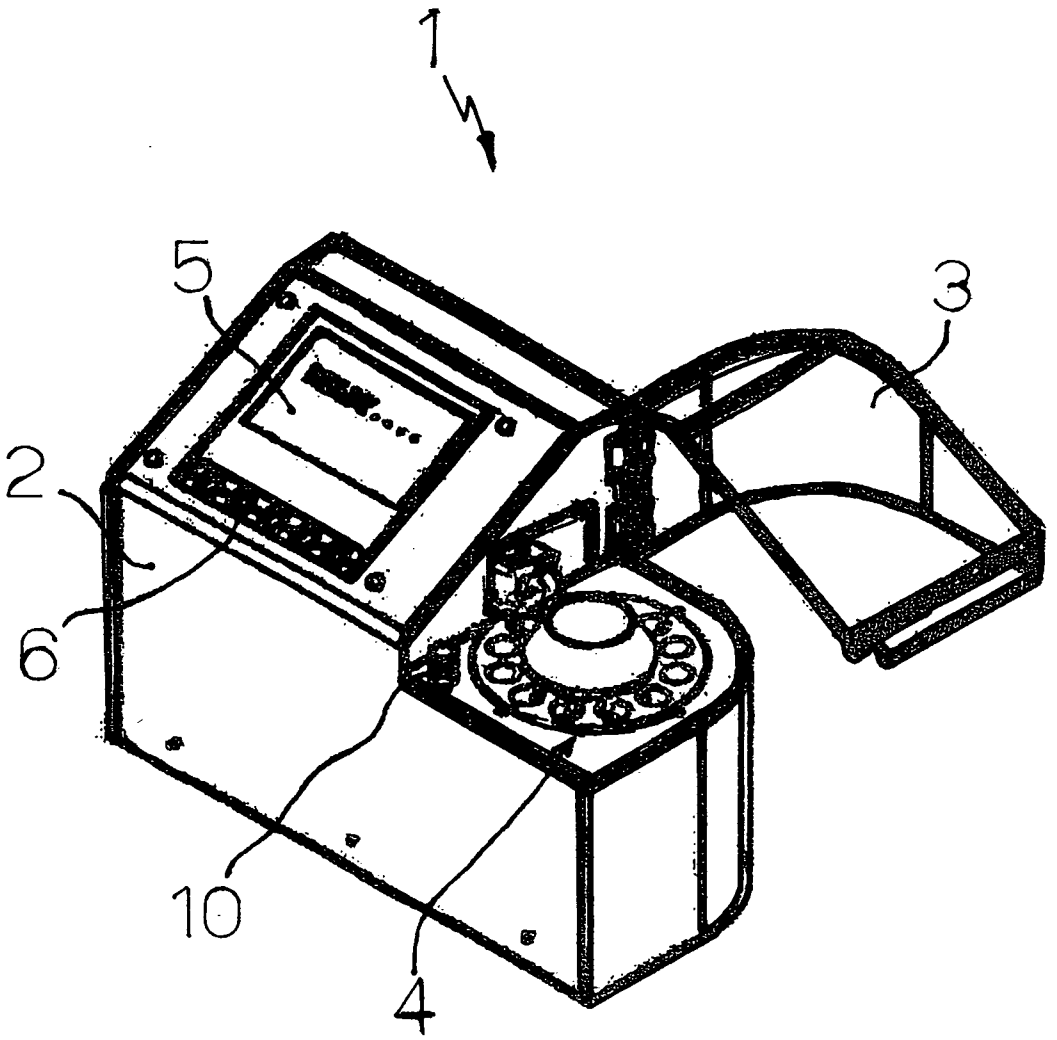
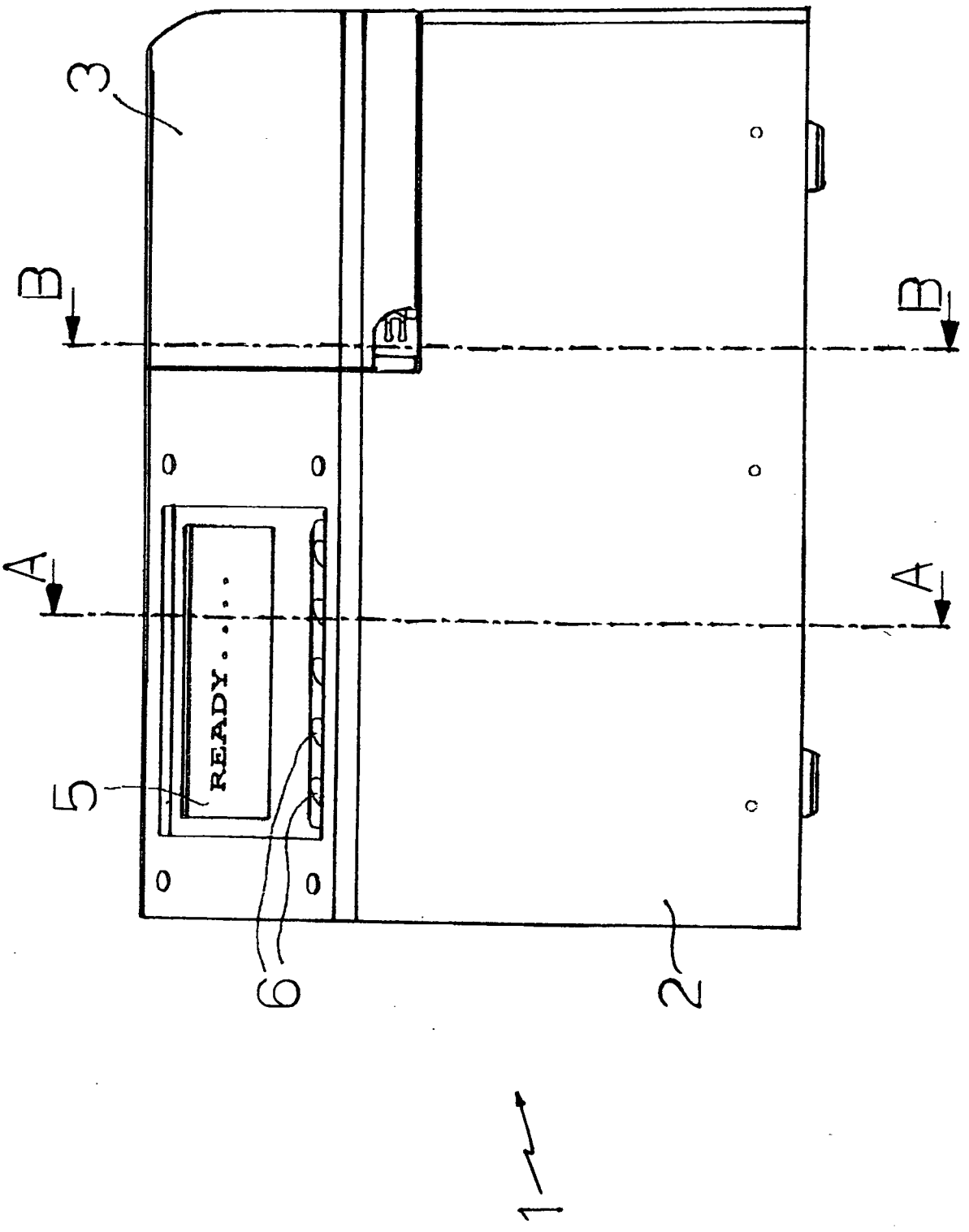


Fig. 1

Fig. 2



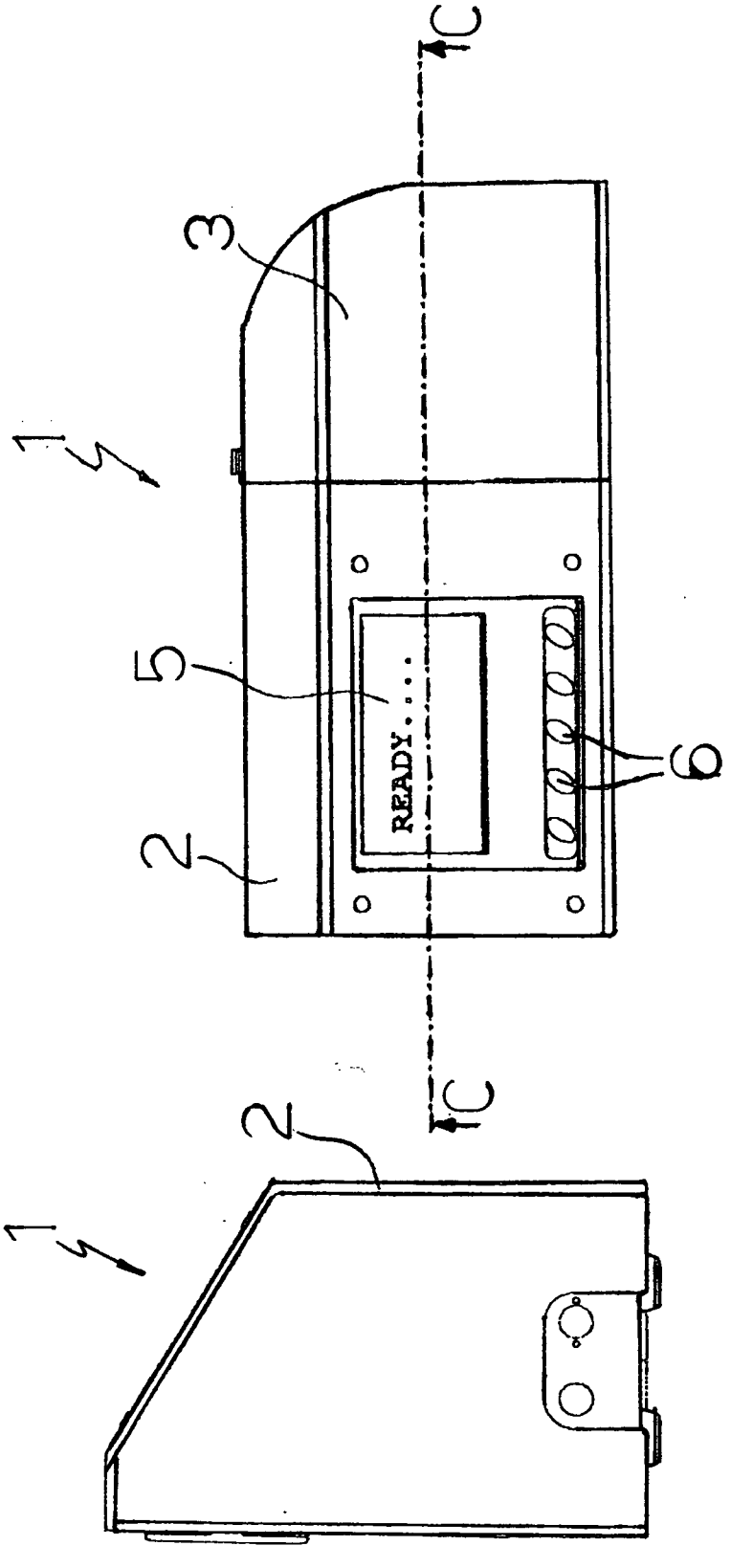


Fig. 4

Fig. 3

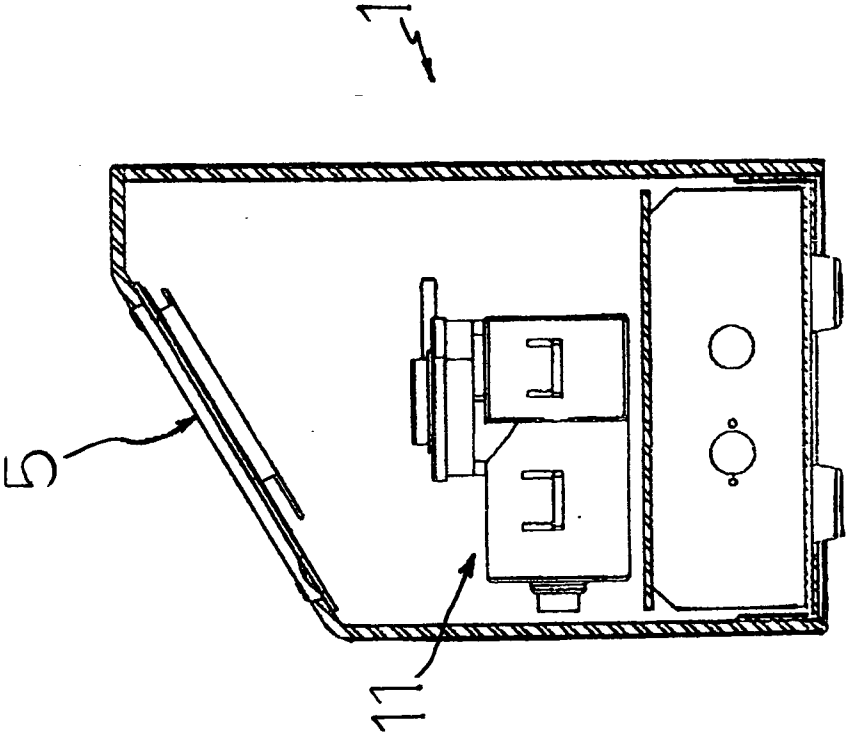


Fig. 6

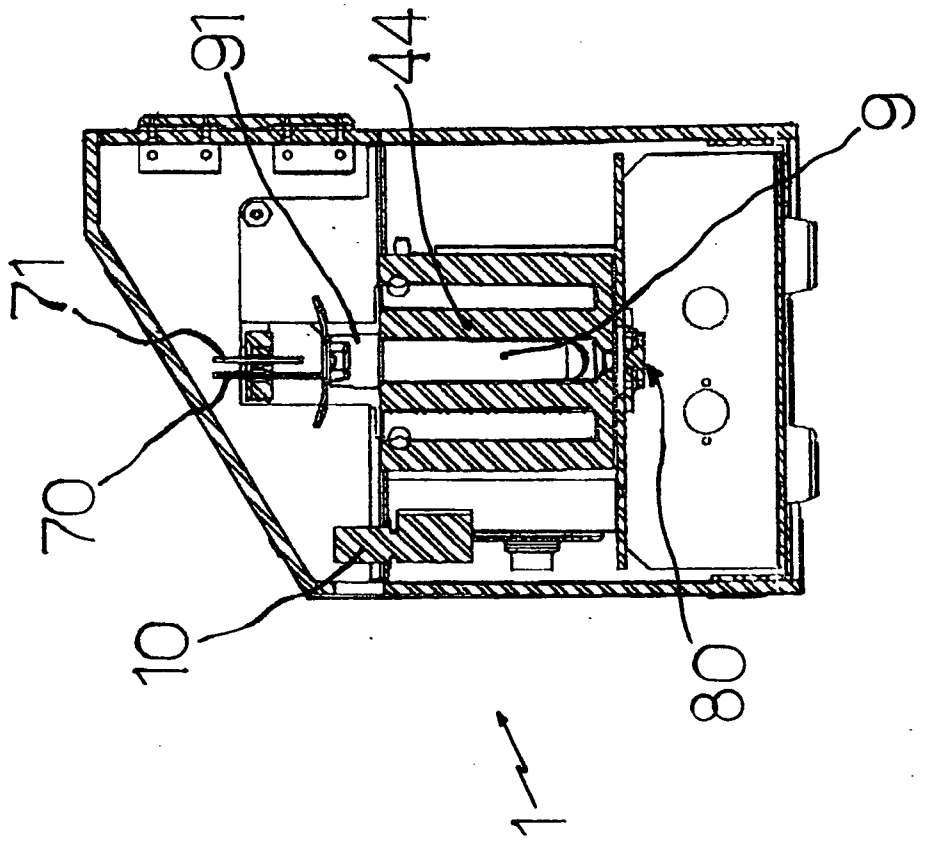


Fig. 5

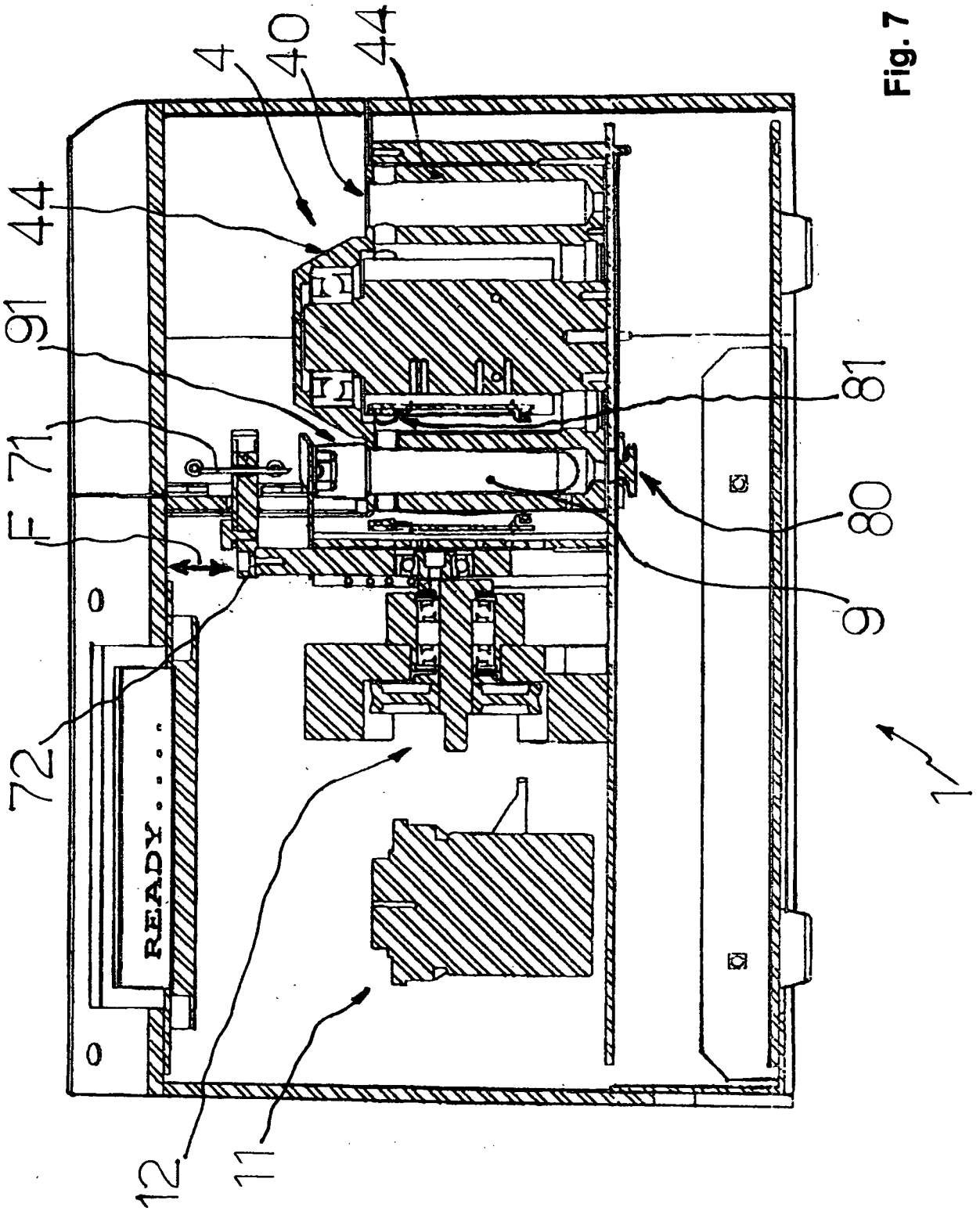


Fig. 7

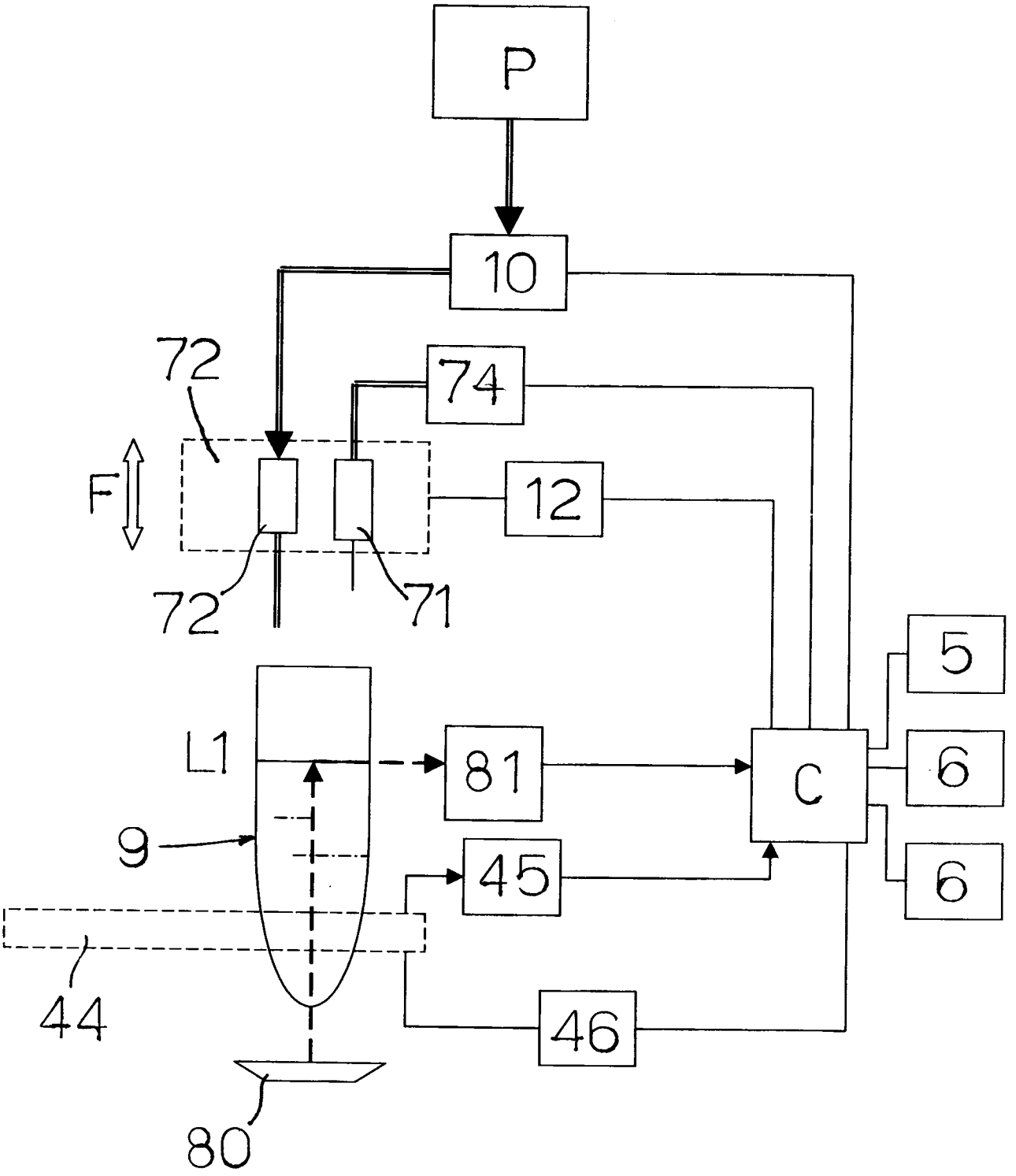


Fig. 8

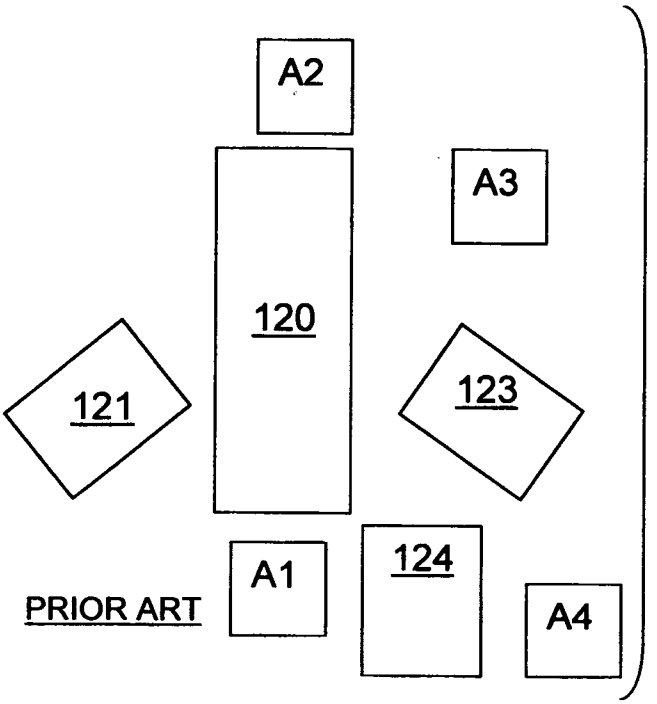


Fig. 9

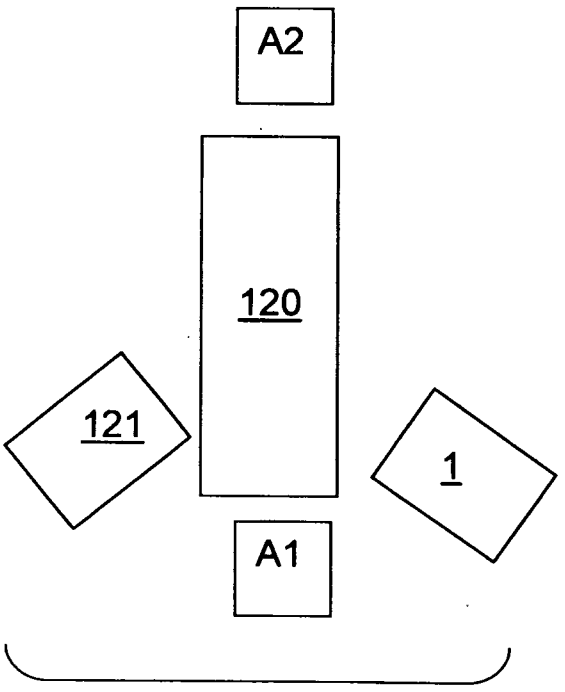


Fig. 10

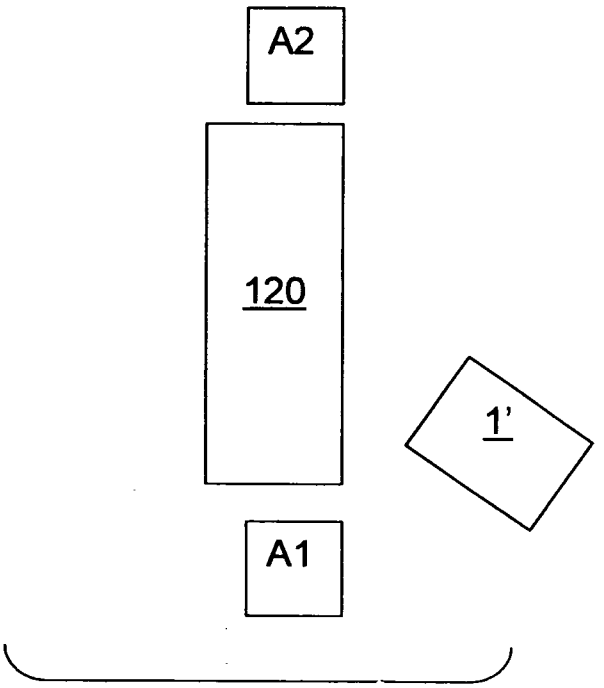


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2008/000402

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N35/02 B01L11/00
ADD. A61B5/00 A61B10/00

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)
A61B G01N A61M B01L A61D G01F

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

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
6 April 2009	21/04/2009

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	Ruchaud, Nicolas

INTERNATIONAL SEARCH REPORT

International application No
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