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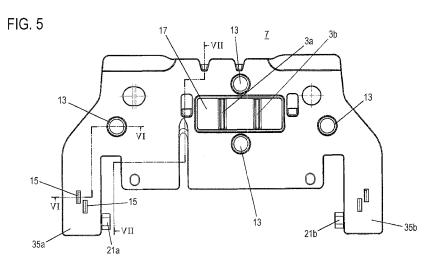
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(54) Title: CASSETTE AND SYSTEM COMPONENT INSERTABLE INTO A CENTRIFUGE IN COOPERATION WITH THE CASSETTE



(57) Abstract: The invention pertains to a cassette (2) comprising a product conveying path (1, 1a, 1b) and a positioning means (3a, 3b) engageable with a counter-piece on a centrifuge having a rotor for separating blood components or on a system component (4) arranged in a centrifuge. The positioning is effected such that a section of the product conveying path (1, 1a, 1b) is aligned with a section of the centrifuge or the system component arranged in the centrifuge. Furthermore, a tube connected with bags is accommodated in the product conveying path (1, 1a, 1b).



# CASSETTE AND SYSTEM COMPONENT INSERTABLE INTO A CENTRIFUGE IN COOPERATION WITH THE CASSETTE

# Description

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The invention relates to a cassette used as cover for accommodating blood bags for a cartridge of a centrifuge for separating blood components, and a system component insertable into such a centrifuge in cooperation with the cassette.

In transfusion medicine, the so-called blood component therapy has established itself since the beginning of the nineties. This means that, instead of a whole blood conserve, only those blood components required by the individual patient are administered to said patient. This separate administering of the individual blood components makes it possible that one single blood conserve optimally helps an average of 1.8 patients.

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The essential blood components are

the red blood cells in the so-called erythrocyte concentrate, which are transfused in order to maintain the oxygen supply after severe loss of blood,

the blood platelets in the thrombocyte concentrate, which are administered in cases of coagulation disturbances (haemophilia), and

the blood plasma, which is administered in cases of coagulation disturbances and volume deficits.

30 Apart therefrom, blood plasma is an essential basic component for the production of many medicaments.

The separation of the individual blood components, which is defined as cell separation/isolation, is known to be effected by treating the blood in a centrifuge. By means of

centrifuging, the individual blood components are separated from each other, and can then be separately filled into the respective containers for further use.

5 Documents DE 10 2007 000 308 A1, DE 10 2007 000 309 A1 and DE 10 2007 000 310 Al already reveal a cartridge for use in a centrifuge for separating blood components and a respective centrifuge as well as a respective method. According to these documents, a cartridge comprises an 10 intermediate wall and a cover. The intermediate wall separates a blood bag area disposed radially inside from a product area disposed radially outside. In an installation position of the cartridge, the cover is located above the blood bag area. The cover is connected to the intermediate wall pivotally at one point, and detachably at a second 15 point. In this way, the blood bag area is freely accessible by a lateral turning away of the cover. For loading the cartridge with a blood bag, the cover is opened, a blood bag and a product bag are inserted into the respective 20 chambers, and a connecting tube is inserted along a product conveying path. Moreover, photosensitive sensors are arranged along the product conveying path and are used to establish the composition of the product while the product is obtained; when a specific composition is reached, 25 measures are taken for terminating the obtaining of the product. However, loading of the cartridge may only be effected manually, which renders it time- and costconsuming. Besides, there is the possibility that the product is destroyed upon a faulty insertion of the connecting tube, since the sensors do not react timely. 30

Therefore, the known means need to be improved such that, on the one hand, faulty loading is avoided and, on the other hand, time is saved.

According to the invention, a cassette is provided, comprising a product conveying path in the form of a passage and a positioning means engageable with a counterpiece on a centrifuge or on a system component arranged in a centrifuge such that a section of the product conveying path is aligned with a section of the centrifuge or the system component arranged in the centrifuge. A tube connected with bags is accommodated in the product-conveying path.

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Thus, according to the invention, cassettes with the already inserted tube and two or more bags (one blood bag and at least one product bag) attached to the tube can be supplied to a user in the form of a kit. Thus, after a blood collecting process, the cassette comprising the tube and the bags can be inserted into a system component of a centrifuge, or directly into the centrifuge to perform a centrifugation process in which the blood in the one bag is separated and at least one of the separated blood components is transferred into the second bag.

After this centrifugation process has been completed, it is merely necessary to replace the cassette present in the centrifuge by a new one and to subject the old cassette to further processing. In this respect it is noted that, in general, any number of cassettes can be subjected to the centrifugation process. Preferably a number of six cassettes is processed simultaneously in the centrifuge.

30 Since the tubes and bags are replaced together with their related cassette, a remarkable reduction of dead time is achieved.

The exact alignment of the connecting means with the counter-piece makes it possible to reach an exact alignment

of the product conveying path with the respective section of the centrifuge or the system component. This ensures that photosensitive sensors arranged in the section of the system component can detect the product flowing through the product conveying path anytime. Thus, appropriate reactions, e.g. for terminating the production process are promptly possible, without delay. In particular, the section of the product-conveying path and/or tube arranged directly adjacent to the positioning means can be exactly positioned to be directly adjacent to the counter piece where the sensors are provided. Furthermore, due to the positioning means, it is ensured that an axis of the sensors substantially intersects a central axis of the product conveying path at a right angle.

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Advantageously, the cassette may consist of a lower part and an upper part which are connected to each other by snap elements or other means. It is also possible that the positioning means is only formed in the lower part, only in the upper part, or in both. Other means in terms of the invention may e.g. be screw joints and/or rivet joints or bonded joints.

Preferably, the positioning means is provided in the form of one or plural bars arranged in the direction of one or plural sections of the product conveying path. The bars can be arranged in a window. Such an arrangement can be easily manufactured, and can easily establish a form-fit connection with an appropriately formed counter-piece.

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Advantageously, at least one shut-off device for interrupting a product flow can additionally be provided at one or plural sections of the product conveying path. The shut-off device makes an abrupt termination of the production process possible. The maximally possible portion

of the desired product, e.g. thrombocytes, can be gained before the product is contaminated by undesired blood components.

Advantageously, the at least one shut-off device can be integrated into the lower part or into the upper part of the cassette, and can be operated directly from outside the cassette. This allows a quick and safe operation of the shut-off device without the danger of a failure, which may otherwise occur by a faulty insertion of the shut-off device. The operation of the shut-off device can be effected manually or mechanically, e.g. by means of actuating members operated pneumatically, hydraulically or electronically.

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- Advantageously, the at least one shut-off device can be provided in the form of one or two tube clamps, which can be operated separately from each other.
- Besides, the cassette may comprise connecting means for being connected to a cartridge, which can be accommodated in the centrifuge or the system component arranged in the centrifuge. Accordingly, the cassette fulfills a function as cover of the cartridge.
- Advantageously, the cassette according to the invention is accommodated in a system component for arrangement in a centrifuge for separating blood components, with a rotor rotatable around a hub. The system component comprises a counter-piece which can be engaged with a positioning means of the cassette. In this way, an exact positioning of a section of the product conveying path to a section of the system component is ensured.

The counter-piece may be provided in the form of an elevation having one or plural grooves in the wall sections

of which one or plural sensors are arranged. Preferably, these are photosensitive sensors/photosensors.

Additionally, the system component can comprise an operating means for operating a lock-off device disposed in the cassette. The operating means can preferably be provided in the form of a centrally arranged, long lever having two ends and two short, L-shaped levers arranged at the ends of the long lever. Each end of the long lever is directly operable by a first piston, or indirectly by a second piston and a leg of the short, L-shaped lever.

Preferably, the cassette and the system component can be used in a centrifuge for separating blood components, having a rotor of a centrifuge rotatable around a hub. The system component is accommodated in the rotor, or integrated into the same. Moreover, a cartridge can be incorporated into the system component, and this cartridge can be provided with a cassette loaded with a blood bag and a product bag. The cassette is used as cover for a blood bag area of the cartridge.

The use of a cassette according to the invention and the system component according to the invention allows to obtain one or also plural blood products, such as plasma, erythrocytes, or thrombocytes. This may be obtained particularly in that a microprocessor can be provided in the system component to be used for controlling and monitoring the product extraction process.

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Then, by means of the microprocessor, particularly the detection results of the sensors can be processed and the operations of the shut-off devices can be carried out accordingly. Advantageously, the microprocessor in the system component can furthermore be connected to another

microprocessor accommodated in the rotor of the centrifuge, which is adapted to carry out the control and the monitoring of the entire product extraction process.

- 5 Further advantages of the invention can be seen from the description of a currently preferred embodiment and the Figures attached. Referring to the Figures,
- Fig. 1 shows a top view of a lower part of a cassette according to the invention;
  - Fig. 2 shows a sectional view along a line II-II in Fig. 1;
- Figs. 3a and 3b show a top view and a view of a detail III from Fig. 1, respectively;
  - Fig. 4 shows a sectional view along a line IV-IV in Fig. 1,
- Fig. 5 shows a top view of an upper part of a cassette according to the invention;
  - Fig. 6 shows a sectional view along a line VI-VI in Fig. 5;
- Fig. 7 shows a sectional view along a line VII-VII in Fig. 25 5;

Fig 8 shows a view of a cassette according to the invention, said cassette being provided in a system component according to the invention.

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A currently preferred embodiment of the invention is described by means of Figures 1 to 8.

A cassette 2 according to the embodiment is composed of a lower part 5 and an upper part 7 which are connected to

each other by means of snap elements 9 and 13, and 11 and 15, respectively. The upper part is made of a transparent material. Besides, as can be seen from the Figures, the cassette 2 is provided approximately in the form of a rectangle having two arms 35a, 35b.

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The lower part 5 as well as the upper part 7 of the cassette 2 comprises a window 17 in a central area of the rectangle. Moreover, in the upper part 7, two bars 3a, 3b are formed to be used as positioning means according to the invention. The bars 3a, 3b extend along a partial section of a product-conveying path 1.

A channel-type passage 1 is formed as product-conveying

path 1 in the lower part 5. The passage 1 is divided into
two sections 1a and 1b. At one edge of the lower part 5
opposite the arms 35a, 35b, two tube clamps 19a, 19b are
integrated into the lower part 5.

A tube (not shown in the Figures) provided with a blood bag, a filter and a product bag is laid in the product-conveying path 1 such that the tube is conducted from the blood bag disposed between the arms 35a, 35b to the first section 1a, along the bar 3a, through the tube clamp 19a arranged in the first section 1a further to the arm 35a. The tube then emerges from the arm 35a, leads to the filter, and enters via the second arm 35b the second section 1b of the passage 1. Then, the tube is led along the bar 3b, through the tube clamp 19b and again the arm 35b, in order to emerge from the same towards the product bag.

At each of its arms 35a, 35b, the cassette 2 comprises a projection 21a, 21b disposed inside, which is used to detachably fix the cassette to a non-represented cartridge

similar to the one in documents DE 10 2007 000 308 A1, DE 10 2007 000 309 A1 and DE 10 2007 000 310 A1. The blood bag, the filter and the product bag are then accommodated in appropriate chambers of the cartridge. The cassette 2 replaces a cover in the said applications.

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Together with the cassette 2, the loaded cartridge is inserted into a system component 4 that is arranged in a centrifuge. An elevation 25 in which two grooves are formed is provided in a section of the system component 4. Photosensitive sensors 23a, 23b are inserted into the inner walls of each groove.

If the cassette 2 is disposed in the system component 4, the elevation 25 is engaged in a form-fit connection with 15 the window 17, and the bars 3a and 3b with the grooves formed in the elevation 25. The sections of the tube extending along the bars 3a, 3b are disposed directly below the bars 3a, 3b, whereby the contents of the tube can be 20 exactly registered by the photosensitive sensors 23a, 23b. The first photosensitive sensor 23a is assigned to the first section 1a of the product-conveying path 1, whereas the second photosensitive sensor 23b is assigned to the second section 1b of the product-conveying path 1. The 25 optical axes of the photosensitive sensors 23a and 23b substantially intersect the central axis of the product conveying path (the tube) at a right angle.

Since the tube does not have to be inserted into the

cassette 2 any more, but the cassette is already delivered together with the readily laid tube including blood bag, filter and product bag, a faulty insertion of the tube or a displacement of the tube that would lead to a faulty registration by the sensors can be reliably excluded.

Thus, it is possible, due to the interaction of the cassette according to the invention with the system component, to obtain a blood product by means of the method disclosed in document DE 10 2007 000 309 A.

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According to the embodiment, the rotor of the centrifuge is designed for six system components 4 having one cartridge each. After all cartridges loaded with cassettes 2 have been inserted, the centrifuge is started. By means of the centrifugal force, the desired separation of the blood components is effected. Since the "buffy coat" diluted by an additive solution is in the blood bag, the lighter components of it will remain radially inside, whereas its heavier components, i.e. the red blood cells, collect outside.

In order to transport the desired blood component according to the embodiment, these are the platelets
(thrombocytes) - in high quality, i.e. without the

20 admixture of other blood cells, from the blood bag, the
separation of the components will be followed by a slight
pressure being applied onto the blood bag by means of a
pressure pad, so that, after the previously closed tube
clamps 19a, 19b have been opened, the solution rich in

25 platelets begins to rise into the tube disposed in the
passage 1. The solution rich in platelets is led through
the tube into the filter designed as a leukocyte filter,
and is further conducted therethrough.

In the leukocyte filter, the undesired leukocytes, i.e. the white blood cells, are removed. Due to the arrangement of the tube with the filter, the filtration is effected against the centrifugal force. Thus, heavier blood components, such as unintentionally transported red blood

cells, are trapped in a filter-inlet chamber positioned radially outside.

After having passed the leukocyte filter, the solution rich in platelets continues flowing through the tube laid in the second section 1b of the passage 1 into a product bag, in which it is collected. Preferably, the product bag is already formed as final storage bag for the product.

In order to remove any air that might be present in the filter, the flow speed is kept low for a certain volume quantity at the beginning of the product transfer, thereby enabling the filter to fill with the blood product reliably and completely. After the transfer of this specific volume quantity, the conveying speed for a specific second volume quantity is increased by means of an appropriate control of the pressure pad. While this second volume is transported, there is hardly any risk that red blood cells contaminate the blood product (here: the thrombocyte concentrate).

20 Should this nevertheless happen, this small number of red blood cells are collected in the lower and outer area of the filter, due to the tube being guided from radially outside and below into the filter, and due to the effect of the centrifugal force.

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After the second volume has been transferred, the first photosensor 23a is activated and the flow speed of the blood product in the tube is reduced.

30 When the first photosensor 23a detects a predetermined proportion of red blood cells in the thrombocyte-rich solution, it outputs a signal by means of which the flow speed is again reduced. Furthermore, the second photosensor 23b disposed behind the filter is activated.

During this phase, also a rather large number of red blood cells can enter the filter and even pass therethrough until the second photosensor 23b detects a predetermined proportion of red blood cells in the blood product and outputs a signal for terminating the cell separation process. By this signal, the tube clamps 19a, 19b are closed by operation of the ends 29a, 29b of a long lever 29 by means of pistons 31a, 31b, so that the red blood cells in the filter are reliably separated from the thrombocyte concentrate in the product bag.

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As an alternative to the termination by the second photosensor 23b, the cell separation process can also be terminated after a certain period of time has elapsed after the activation of the second photosensor 23b.

In the embodiment, altogether six cartridges are provided in the centrifuge. The above-described control of the cell separation process in a cartridge 1 by means of a pressure pad, the opening and closing of the tube clamps 19a, 19b, and the process control by means of the two photosensors 23a, 23b enables a continued cell separation in the cartridges of the other system components, since the described process control takes place individually for each combination of cartridge and system component.

The control of the process is effected by a microprocessor provided in the system component, said microprocessor processing the detection/registration results of the sensors 23a, 23b and accordingly controlling the opening and closing of the tube clamps 19a, 19b by operating the levers 31a, 31b and 33a, 33b, respectively. Besides, the microprocessor is connected to a microprocessor arranged in the hub of the rotor for controlling the centrifuge and

monitoring the microprocessors in the individual system components.

When the above-mentioned process is carried out, a precise operation of the tube clamps 19a, 19b is required for ensuring an optimum yield while simultaneously avoiding a contamination of the product. For operating the tube clamps 19a and 19b integrated in the lower part 5 of the cassette 2, the invention provides, in the system component, an arrangement having a centrally arranged long lever 29 and L-shaped, short levers 27a, 27b arranged at the two ends 29a and 29b of the long lever 29. The ends 29a, 29b of the long lever are disposed between a leg of the short lever 27a, 27b and a closing arm 191 of the tube clamp 19a and 19b, respectively.

At its central section, the long lever 29 is fixed to the system component 4. The short levers 27a, 27b are pivotally supported around the intersection of the two legs of the "L". The entire lever arrangement is disposed along the edge of the cassette 2, on which the tube clamps 19a, 19b are arranged when the cassette is inserted into the system component.

Pistons 31a, 31b, 33a, 33b, which are suitably arranged in the system component 4, are used for operating the levers 27a, 27b and 29. The pistons 31a, 31b directly act on the respective end 29a, 29b of the long lever. The pistons 33a, 33b directly act on a leg of the short levers 27a and 27b, respectively, said leg being disposed between the pistons 33a and 33b and the respective ends 29a, 29b of the long lever 29.

Since the ends 29a, 29b of the long lever 29 are disposed directly opposite the closing arm 191 of the tube clamps

19a and 19b when the cassette is inserted, an operation of the piston 31a or 31b leads to the closing of the respective tube clamp 19a or 19b. Since, in turn, an operation of the pistons 33a, 33b acts on the one leg of 5 the rotatably supported, short levers 27a and 27b, respectively, this operation leads to a twisting of the levers 27a and 27b, respectively. The leg disposed between the pistons 33a and 33b acts on the end 29a or 29b of the long lever 29, whereas the other leg of the short lever 27a or 27b acts on an opening arm 192 of the tube clamp 19a or 10 19b, thereby opening the same. The indirect operation of the ends 29a, 29b of the long lever serves to exclude that the tube clamp bursts open too suddenly or too wide, so that problems e.g. due to the tube clamps getting jammed can be avoided. 15

The invention has been described by means of a currently preferred embodiment, but is not restricted thereto in any way, but only defined by the scope of the claims attached.

### Claims

- 1. A cassette (2) comprising
- a product conveying path (1, 1a, 1b) and a positioning

  means (3a, 3b) engageable with a counter-piece on a
  centrifuge having a rotor for separating blood components
  or on a system component (4) arranged in a centrifuge such
  that a section of the product conveying path (1, 1a, 1b) is
  aligned with a section of the centrifuge or the system

  component arranged in the centrifuge, wherein a tube
  connected with bags is accommodated in the product
  conveying path (1, 1a, 1b).
- A cassette (2) according to claim 1, consisting of a
   lower part (5) and an upper part (7), wherein
   the positioning means (3a, 3b) is formed in the lower
   part (5) or in the upper part (7), or in both.
  - 3. A cassette (2) according to claim 2,
- wherein the lower part (5) and the upper part (7) are connectable to each other by a connecting means (9, 11, 13, 15) and the product conveying path (1, 1a, 1b) is provided in the form of a passage.
- 25 4. A cassette (2) according to any of the preceding claims, wherein

the positioning means (3a, 3b) is provided in the form of one or plural bars (3a, 3b) arranged in the direction of one or plural sections of the product conveying path (1,

- 30 la, 1b), and the bars are arranged in a window (17).
  - 5. A cassette (2) according to any of the preceding claims, wherein

at least one shut-off device (19a, 19b) for

interrupting a product flow is provided at one or plural sections of the product conveying path (1, 1a, 1b).

6. A cassette (2) according to claim 5, wherein the at least one shut-off device (19a, 19b) is integrated into the lower part (5) or into the upper part (7) of the cassette.

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7. A cassette (2) according to claim 5 or 6, wherein the shut-off device (19a, 19b) is provided at a rim of the cassette and is directly operable from outside the cassette.

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8. A cassette (2) according to any of claims 5 to 7, wherein

the at least one shut-off device (19a, 19b) is provided in the form of one or two tube clamps (19a, 19b), which can be operated separately from each other.

9. A cassette (2) according to any of the preceding claims, wherein

the cassette comprises connecting means (21a, 21b) for establishing a connection with a cartridge accommodating the cassette, said cartridge being adapted to be accommodated in the centrifuge or in the system component arranged in the centrifuge.

25 10. A system component (4) for being arranged in a centrifuge for separating blood components, the centrifuge comprising a rotor rotatable around a hub, wherein

the system component (4) comprises a counter-piece (25) which can be engaged with a positioning means (3a, 3b) of a cassette according to any one of claims 1 to 9.

11. A system component (4) according to claim 10, wherein the counter-piece (25) is provided in the form of an elevation (25) having one or plural grooves in the wall sections of which one or plural sensors (23a, 23b) are arranged.

- 12. A system component (4) according to claim 10 or 11, further comprising an operating means (27, 29, 29a, 29b, 31, 33) for operating a lock-off device (19a, 19b) disposed in the cassette (2).
- 13. A system component according to claim 12, wherein the operating means is provided in the form of a centrally arranged, long lever (29) having two ends (29a, 29b) and two short, L-shaped levers (27a, 27b) arranged at the ends (29a, 29b) of the long lever, each end (29a, 29b) of the long lever (29) being directly operable by a first piston (31a, 31b), or indirectly by a second piston (33a, 33b) and a leg of the short, L-shaped lever (27a, 27b).

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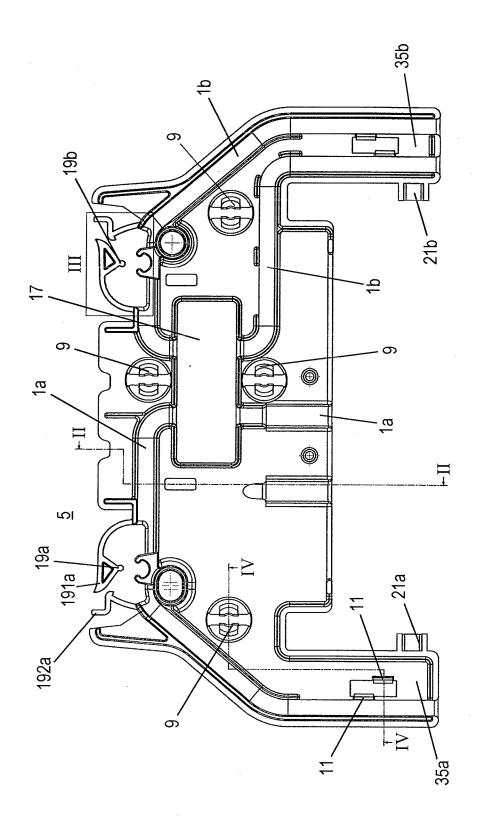
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14. A system component according to any of claims 11 to 13, wherein the one sensor or the plural sensors are formed as light sensitive sensors (23a, 23b), and by engaging the positioning means (3a, 3b) of the cassette (2) with the counter-piece (25), a central axis of a tube accommodated in the product conveying path (1, 1a, 1b) of the cassette (2) is exactly aligned to the optical axis or optical axes of the light sensitive sensor (23a, 23b) or of the light sensitive sensors (23a, 23b).

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- 15. A centrifuge for separating blood components, comprising
  - a rotor rotatable around a hub,
- at least one system component (4) according to any one of claims 10 to 13, accommodated in the rotor, or integrated into the same,
  - a cartridge accommodated in the system component (4), and a cassette loaded with a blood bag and a product bag according to any one of claims 1 to 9, wherein the cassette is used as cover for a blood bag area of the cartridge.



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FIG. 2

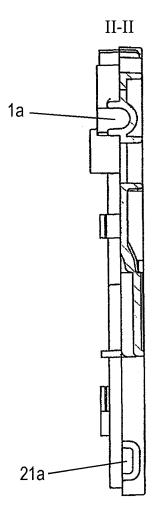


FIG. 3A

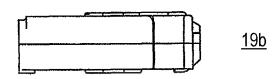


FIG. 3B

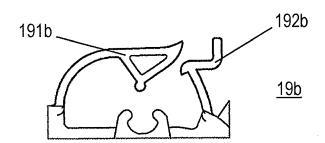
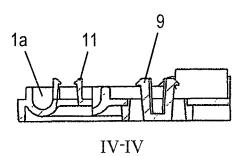


FIG. 4



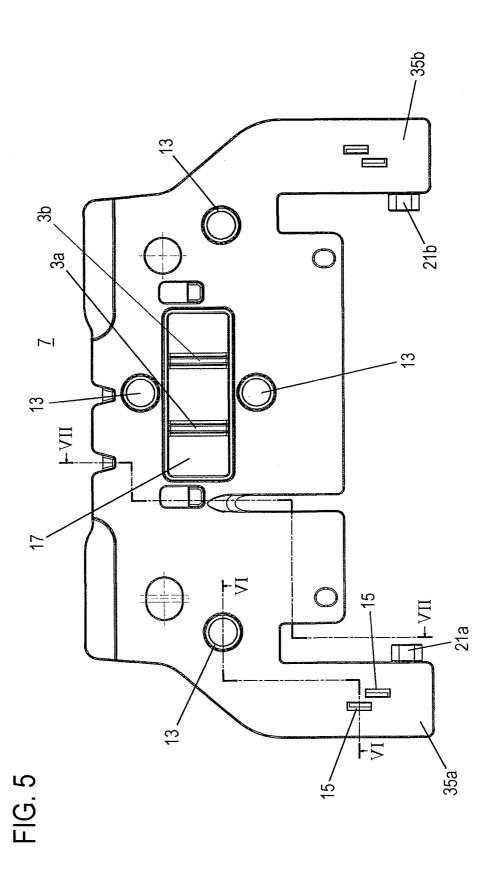


FIG. 6

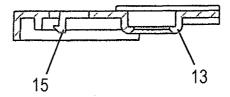
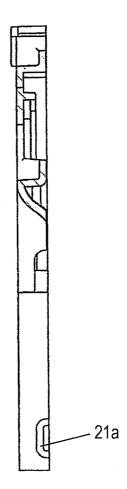
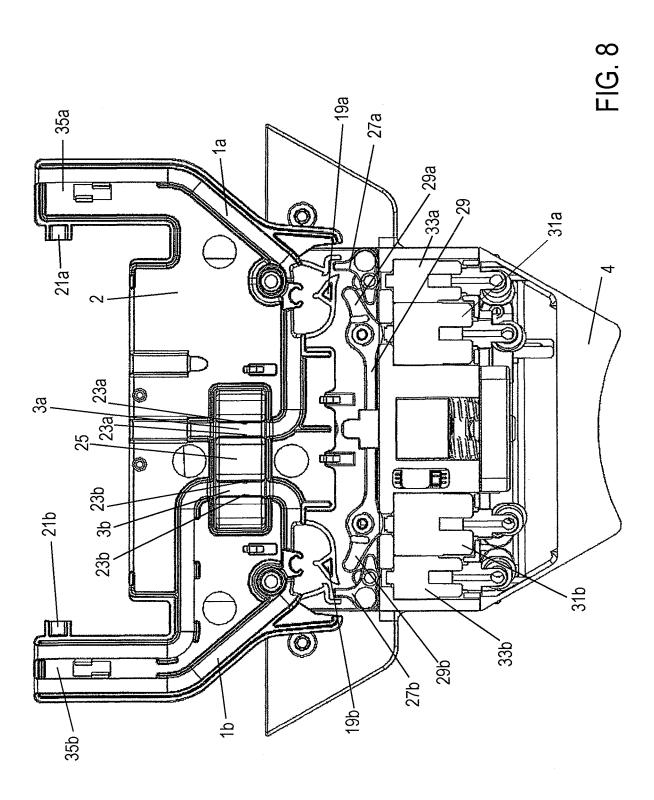


FIG. 7





### INTERNATIONAL SEARCH REPORT

International application No PCT/EP2011/050094

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M1/02 A61M1/36 B04B5/04 ADD. 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 B04B 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 C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Category' Citation of document, with indication, where appropriate, of the relevant passages US 5 795 317 A (BRIERTON MARK J [US] ET 1,2,9,10 Χ AL) 18 August 1998 (1998-08-18) column 16, lines 1-36 column 24, lines 14-22; figures 2A, 2B, 3 3,5-8,12.13 EP 1 557 187 A1 (TOP KK [JP]) 3,5-827 July 2005 (2005-07-27) paragraphs [0020], [0022] - [0027]; figures 1-6 DE 10 2007 000309 A1 (ANDREAS HETTICH GMBH γ 12,13 & CO KG [DE]; TERUMO ÈUROP N V [BE]) 11 December 2008 (2008-12-11) cited in the application paragraphs [0044], [0053]; figures 2,7 Α 14,15 Х 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 "A" document defining the general state of the art which is not considered to be of particular relevance cited to understand the principle or theory underlying the invention "E" 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 involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention citation or other special reason (as specified) 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 in the art. "P" 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 20 April 2011 02/05/2011 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 Böttcher, Stephanie

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