



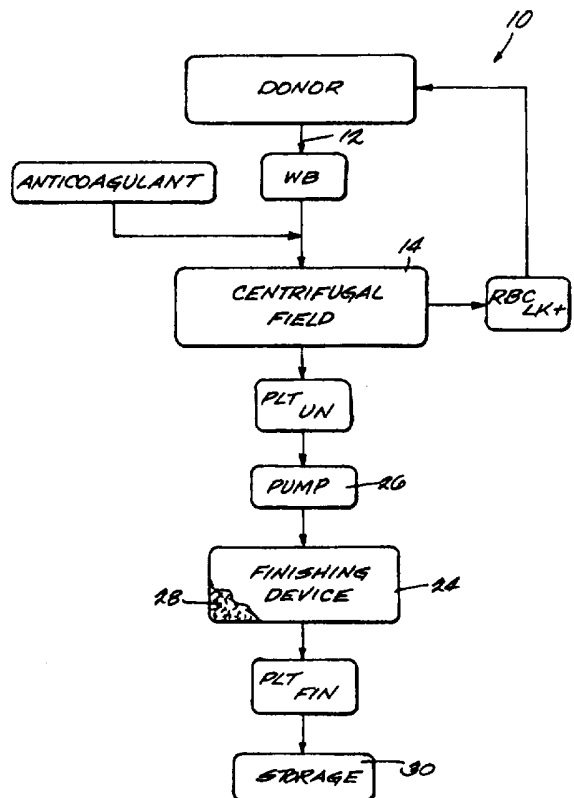
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(54) Title: SYSTEMS AND METHODS FOR ON-LINE FINISHING OF CELLULAR BLOOD PRODUCTS LIKE PLATELETS HARVESTED FOR THERAPEUTIC PURPOSES

(57) Abstract

Blood processing systems and methods establish on-line communication between a container and a source of blood containing leukocytes and platelets, such as a human donor. The systems and methods create a centrifugal field between the source of blood and the container that separates from the blood an unfinished suspension of platelets having a first physiologic characteristic different than the desired physiologic characteristic. The systems and methods pump the unfinished platelet suspension outside the centrifugal field through a finishing device (24). The finishing device (24) changes the first physiologic characteristic to the desired physiological characteristic, thereby creating the finished platelet suspension. The system and methods convey the finished platelet suspension from the finishing device directly into the container. The systems and methods function without interrupting the on-line communication between the container and the source of blood.



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**SYSTEMS AND METHODS****FOR ON-LINE FINISHING OF CELLULAR BLOOD PRODUCTS  
LIKE PLATELETS HARVESTED FOR THERAPEUTIC PURPOSES****Field of the Invention**

5           The invention generally relates to blood processing systems and methods. In a more specific sense, the invention relates to systems and methods for removing leukocytes from blood components collected for therapeutic purposes.

10       **Background of the Invention**

          Today blood collection facilities routinely separate whole blood into its various therapeutic components, such as red blood cells, platelets, and plasma.

15           One separation technique that is in widespread use today uses a multiple blood bag system. The bag system includes a primary blood bag and one or more transfer bags, which are integrally connected to the primary bag by tubing. The  
20       technique collects from a donor a single unit (about 450 ml) of whole blood in the primary blood bag. The donor is then free to leave.

          The donor's whole blood later undergoes centrifugal separation within the primary bag into  
25       red blood cells and plasma rich in platelets. The plasma rich in platelets is expressed out of the primary bag into a transfer bag, leaving the red blood cells behind. The plasma rich in platelets then undergoes further centrifugal separation within  
30       the transfer bag into a concentration of platelets

- 2 -

and plasma poor in platelets. The plasma poor in platelets is expressed from the transfer bag into another transfer bag, leaving the concentration of platelets behind.

5           Using multiple blood bag systems, all three major components of whole blood can be collected for therapeutic use. However, the yield for each component collected is limited to the volume of the components that are contained in a single unit of  
10 whole blood. Furthermore, because red blood cells are retained, United States governmental regulations prohibit collecting another unit of whole blood from the donor until six weeks later.

          Certain therapies transfuse large volumes  
15 of a single blood component. For example, some patients undergoing chemotherapy require the transfusion of large numbers of platelets on a routine basis. Multiple blood bag systems simply are not an efficient way to collect these large  
20 numbers of platelets from individual donors.

          On line blood separation systems are today used to collect large numbers of platelets to meet this demand. On line systems perform the separation steps necessary to separate concentration of  
25 platelets from whole blood in a sequential process with the donor present. On line systems establish a flow of whole blood from the donor, separate out the desired platelets from the flow, and return the remaining red blood cells and plasma to the donor,  
30 all in a sequential flow loop.

          Large volumes of whole blood (for example, 2.0 liters) can be processed using an on line system. Due to the large processing volumes, large yields of concentrated platelets (for example,  $4 \times 10^{11}$  platelets suspended in 200 ml of fluid) can be  
35

- 3 -

collected. Moreover, since the donor's red blood cells are returned, the donor can donate whole blood for on line processing much more frequently than donors for processing in multiple blood bag systems.

5           Regardless of the separation technique used, when collecting blood components for transfusion, it is desirable to minimize the presence of impurities or other materials that may cause undesired side effects in the recipient. For  
10           example, because of possible febrile reactions, it is generally considered desirable to transfuse red blood cells and platelets that are substantially free of leukocytes, particularly for recipients who undergo frequent transfusions.

15           Several United States Patents are directed to the removal of leukocytes from red blood cells and platelet components in multiple blood bag systems. For example, see United States Patent  
20           Number 4,767,541; 5,089,146; 5,100,564; and 5,128,048.

          United States Patent Number 5,427,695 is directed to the removal of leukocytes from platelet-rich plasma during on line blood processing.

25           The platelet-rich suspension product obtained using prior on line blood collection systems and methods may still lack the desired physiologic characteristics imposed by the end user (typically a blood bank or hospital) for long term storage and transfusion. For example, the platelet-  
30           rich suspension may include residual leukocytes that, while very small in relation to the leukocyte population in whole blood, are still greater than the leukocyte population standards desired by the end user.

35           Therefore, despite significant advances in

- 4 -

blood processing technology, a need still exists for further improved systems and methods for removing undesired matter like leukocytes from blood components in a way that lends itself to use in high volume, on line blood collection environments.

Summary of the Invention

The invention provides on line blood processing systems and methods for obtaining a finished platelet suspension having a desired physiologic characteristic. In a preferred embodiment, the desired physiologic characteristic comprises a desired reduced residual population of leukocytes.

The systems and methods that embody features of the invention establish on line communication between a container and a source of blood containing leukocytes and platelets, such as a human donor. The systems and methods create a centrifugal field between the source of blood and the container. The centrifugal field separates from the blood an unfinished suspension of platelets having a first physiologic characteristic different than the desired physiologic characteristic. In a preferred embodiment, the unfinished platelet suspension contains an initial leukocyte population greater than the desired residual leukocyte population.

According to the invention, the systems and methods pump the unfinished platelet suspension outside the centrifugal field through a finishing device. The finishing device changes the first physiologic characteristic to the desired physiological characteristic, thereby creating the finished platelet suspension. In a preferred embodiment, the finishing device reduces the

- 5 -

leukocyte population by filtration. The systems and methods convey the finished platelet suspension from the finishing device directly into the container for storage or transfusion.

5           The systems and methods that embody the features of the invention function without interrupting the on line communication between the container and the source of blood.

10           Other features and advantages of the invention can be found in the drawings, accompanying description, and claims of this Specification.

#### Brief Description of the Drawings

15           Fig. 1 is a diagrammatic view of a blood processing system, which includes a finishing device that embodies the features of the invention; and

            Fig. 2 is a diagrammatic view of a centrifugal blood processing system that can be use in association with the finishing device shown in Fig. 1.

20           The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All em-  
25           bodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

#### Description of the Preferred Embodiments

30           Fig. 1 shows in diagrammatic form an on line blood processing system 10 that embodies features of the invention. According to the invention, the on line system 10 provides a finished, high quality platelet-rich blood product (PLT<sub>FIN</sub>), with a significantly reduced residual  
35           population of leukocytes and/or other enhanced

- 6 -

physiological properties, suited for long term storage and transfusion.

As used in this Specification, the term "on line blood separation process" refers to a blood separation system or method that (i) establishes communication between a blood source (typically, a human blood donor) and an extracorporeal flow path; (ii) draws a blood volume from the donor into the flow path; and (iii) maintains communication with the circulatory system of the donor for at least a portion of the time that the blood volume undergoes separation within the extracorporeal flow path.

As used in this Specification, an "on line blood separation process" can separate the blood volume either in a continuous manner or in an interrupted manner. However, an "on line blood separation process" maintains communication between the flow path and the donor for at least a portion of the time the separation process occurs within the flow path, regardless of specific timing or sequencing of the separation process itself.

As used in this Specification, an "on line blood separation process" can include external or internal valves or clamps to interrupt flow within the path to or from the donor. However, in the context of this Specification, such valves or clamps do not break the communication between the blood donor and the flow path. Instead, the valves or clamps control fluid flow within the path while maintaining communication between it and the blood donor.

The on line system 10 draws whole blood (WB) from a donor through a phlebotomized tubing flow path 12. WB contains, as its principal components, red blood cells, platelets, leukocytes,



- 7 -

and plasma. The system 10 adds anticoagulant to the drawn WB and conveys anticoagulated WB into a centrifugal field 14 for processing.

5 In the centrifugal field 14, the system 10 ultimately separates anticoagulated WB into two components. The first component is a red blood cell concentration. It is desirable that the red blood cell concentration also carry with it a majority of the leukocyte population (LK) present in the WB. For  
10 this reason, the first component is referred to as  $RBC_{LK}$ .

$RBC_{LK}$  is returned to the donor during processing. This avoids depletion of the donor's red blood cell and leukocyte populations while high  
15 volume yields of platelets are obtained.

The second component comprises an unfinished platelet-rich plasma suspension  $PLT_{UM}$ .  $PLT_{UM}$  is considered "unfinished" because the platelet-rich plasma suspension still lacks the  
20 desired physiologic characteristics imposed by the end user (typically a blood bank or hospital) for long term storage and transfusion. Centrifugal processing within the field 14 often cannot provide these desired characteristics.

25 The specific physical makeup of the platelet-rich suspension comprising  $PLT_{UM}$  can vary. The makeup will largely depend upon the efficiency of the centrifugal separation process in terms of the how many platelets are separated (i.e., the platelet yields) and how much platelet-poor plasma  
30 product is withdrawn and not returned to the donor.

As used in this Specification,  $PLT_{UM}$  is intended to encompass any suspension in which platelets are present in concentrations greater than  
35 in whole blood.  $PLT_{UM}$  can comprise what is commonly

- 8 -

referred to as platelet-rich plasma (PRP) or platelet concentrate (PC), or suspensions of platelets and plasma lying in between.

5 PLT<sub>UW</sub> can include, in addition to platelets, other components or ingredients, depending upon the choice of the end user. For example, PLT<sub>UW</sub> can include essentially only plasma as the platelet suspension media. Alternatively or in addition to plasma, PLT<sub>UW</sub> can include a specially formulated  
10 platelet storage media to suspend the platelets.

The structural details of the centrifugation field 14 can vary and are not essential to the invention. For example, the field 14 can comprise a centrifuge and multiple stage  
15 centrifugal processing chambers of the type shown in Brown U.S. 5,427,695 or Brown U.S. 5,370,802, both of which are incorporated herein by reference.

As Fig. 2 shows in diagrammatic form, the multiple stage processing chambers that Brown '695 and '802 embody separate WB into RBC and PRP in a  
20 first stage separation chamber 16. The special fluid flow dynamics that occur in the first stage chamber 16 shown in Brown '802 or '695 keep a large majority of leukocytes out of PRP and with the RBC  
25 in the first stage chamber 16 for return to the donor as RBC<sub>UK</sub>. The special fluid flow dynamics occurring in the first stage chamber 16 in Brown '802 or Brown '695 also provide a high yield of platelets in the PRP.

30 In Brown '802 or '695, PRP is transported from the first stage chamber 16. A portion is recirculated back to the WB entering the first stage chamber 16, and the rest is conveyed into a second stage chamber 18. The PRP is separated in the  
35 second stage chamber 18 into PC and platelet-poor

- 9 -

plasma (PPP).

PC retained in the second stage chamber 18 is later resuspended in a volume of PPP or (optionally) a suitable platelet storage medium for transfer from the second stage chamber as  $PLT_{UN}$ . A portion of the PPP is returned to the donor, while another portion of PPP is retained for use as a recirculation or keep-open or rinse-back or resuspension media, or for storage for fractionation or transfusion.

One reason why  $PLT_{UN}$  can be considered "unfinished" in the context of the above described system is the presence of residual leukocytes in the platelet suspension. This residual population of leukocytes with the platelets, while small, still can be greater than the leukocyte population standards demanded by the end user.

Often, centrifugal processing alone often is not effective at isolating enough leukocytes from PRP to meet these demands. Unintended perturbations and secondary flows along the interface between RBC and plasma, where leukocytes reside, can sweep lighter leukocyte species away from RBC into the plasma. Other desirable flow patterns that sweep heavier leukocytes species in the interface back into the RBC mass can also fail to develop to their fullest potential. The dynamic processes under which leukocytes are separated from platelets during centrifugation are complex and subject to variation from donor to donor.

Additional steps can be provided to augment the primary centrifugal separation process to thereby reduce the number of residual leukocytes present in  $PLT_{UN}$ . For example, as disclosed in Brown '695, a leukocyte filter 20 can be provided after

- 10 -

the first stage chamber 16 to filter leukocytes from PRP before entering the second stage chamber 18 for separation into PC and PPP. The filter 20 is preferably located outside the centrifugal field 14, being connected by a rotating umbilicus arrangement 22 of conventional construction. Alternatively, though, the filter 20 can be located within the centrifugal field 14.

Alternatively, or in combination with such other ancillary leukocyte-reduction devices,  $PLT_{UN}$  can be subject to particle bed separation effects within the centrifugal field 14 to separate leukocytes from the platelets. Still, the degree of leukocyte reduction demanded by the user can exceed the capabilities of even these ancillary steps during the centrifugal separation process.

For this reason (see Fig. 1), the system includes an in line finishing device 24 located outside the centrifugal field 14. A pump 26 conveys  $PLT_{UN}$  under pressure from the centrifugal field 14 through the finishing device 24. In Fig. 1, the pump 26 is shown downstream of the centrifugal field 14. Alternatively, the pump 26 could be located upstream of the centrifugal field 14, thereby supplying the requisite machine pressure to convey  $PLT_{UN}$  from the centrifugal field 14.

The finishing device 24 serves to affect a desired alteration in the makeup or physiological of  $PLT_{UN}$  that could not be effectively achieved in the centrifugal field 14, such as, for example, a further incremental reduction in the leukocyte population. The in line finishing device 24 performs its function on line, while the donor remains connected in communication with the system 10.

The output of the finishing device 24 is a

- 11 -

finished platelet-rich suspension ( $PLT_{FIN}$ ).  $PLT_{FIN}$  is considered "finished" because the platelet-rich plasma suspension possesses the desired physiologic characteristics imposed by the end user for long term storage and transfusion. In the context of the illustrated embodiment, the platelet-rich suspension comprising  $PLT_{FIN}$  possesses a more-reduced leukocyte population and/or additional physiological attributes not present in  $PLT_{INI}$ .

As used in this Specification, the term "reduced" or "more-reduced" does not denote that all the residual leukocytes have been removed. The term is intended to more broadly indicate only that the number of residual leukocytes have been incrementally reduced by the finishing device 24, compared with the number before processing by the finishing device.

The finishing device 24 can accomplish its function by centrifugation, absorption, columns, chemical, electrical, and electromagnetic means. In the illustrated and preferred embodiment, the finishing device 24 comprises a filter that employs a non-woven, fibrous filter media 28.

The composition of the filter media 28 can vary. The media 28 comprises fibers that contain nonionic hydrophillic groups and nitrogen-containing basic functional groups. Fibers of this type are disclosed in Nishimura et al U.S. Patent 4,936,998, which is incorporated herein by reference. Filter media containing these fibers are commercially sold by Asahi Medical Company. Filter media containing these fibers have demonstrated the capacity to remove leukocytes while holding down the loss of platelets. Alternatively, the filter media 28 can comprise fibers that have been surface treated as

- 12 -

disclosed in Gsell et al U.S. 5,258,127 to increase their ability to pass platelets while removing leukocytes. Gsell et al. U.S. 5,258, 127 is also incorporated herein by reference.

5           Furthermore, because the pump 26 is used to convey  $PLT_{INI}$  through the finishing device 24, the external machine pressure it creates can be used to overcome passive resistance of the finishing media 28. Therefore, the finishing media 28 can be  
10 densely packed within the finishing device 24 to achieve maximum efficiencies.

The system 10 conveys  $PLT_{FIN}$  to one or more containers 30 suitable for transfusion or long term storage. The container(s) 30 intended to store  $PLT_{FIN}$   
15 can be made of polyolefin material (as disclosed in Gajewski et al U.S. Patent 4,140,162) or a polyvinyl chloride material plasticized with tri-2-ethylhexyl trimellitate (TEHTM). These materials, when compared to DEHP-plasticized polyvinyl chloride materials,  
20 have greater gas permeability that is beneficial for platelet storage.

The system 10 shown in Fig. 1 can be readily incorporated into a continuous single or double needle on line blood processing systems.

25           As used in this Specification, the "on line blood separation process" differs from a multiple blood bag process. In a multiple blood bag process, the donor's circulatory system does not remain in communication with the flow path where separation of  
30 the collected blood volume occurs. In a multiple blood bag system, after a given blood volume is collected in the primary bag, the donor's circulatory system is disconnected from the primary bag before separation occurs within the bag. Also,  
35 in a multiple blood bag system, the separation

- 13 -

processes do not occur continuously. The first stage separation of red blood cells and plasma rich in platelets and the second stage separation of platelets from plasma occur at different points in time as separate, discontinuous steps.

5

Various features of the inventions are set forth in the following claims.

- 14 -

I claim:

1. An on line blood processing system for obtaining a finished platelet suspension having a desired physiologic characteristic comprising  
a tubing system that establishes on line  
5 communication between a container and a source of blood containing leukocytes and platelets,  
a device communicating with the tubing system that, without interrupting the on line communication between the container and the source  
10 of blood, creates a centrifugal field that separates from the blood an unfinished suspension of platelets having a first physiologic characteristic different than the desired physiologic characteristic,  
a finishing device communicating with the  
15 tubing system outside the centrifugal field that, upon contact with the unfinished platelet suspension, changes the first physiologic characteristic to the desired physiological characteristic, thereby creating the finished  
20 platelet suspension,  
a pump communicating with the tubing system that, without interrupting the on line communication between the container and the source of blood, pumps the unfinished platelet suspension outside the  
25 centrifugal field through the finishing device, and tubing communicating with the tubing system that, without interrupting the on line communication between the container and the source of blood, conveys the finished platelet suspension from the  
30 finishing device directly into the container.
2. An on line blood processing system for obtaining a finished platelet suspension having a reduced residual leukocyte population comprising  
a tubing system that establishes on line



- 15 -

5 communication between a container and a source of  
blood containing leukocytes and platelets,

a device communicating with the tubing  
system that, without interrupting the on line  
communication between the container and the source  
10 of blood, creates a centrifugal field that separates  
from the blood an unfinished suspension of platelets  
an initial population of leukocytes greater than the  
reduced residual population of leukocytes,

a finishing device communicating with the  
15 tubing system outside the centrifugal field that,  
upon contact with the unfinished platelet  
suspension, reduces the initial leukocyte population  
in the unfinished platelet suspension to the reduced  
residual leukocyte population, thereby creating the  
20 finished platelet suspension,

a pump communicating with the tubing system  
that, without interrupting the on line communication  
between the container and the source of blood, pumps  
the unfinished platelet suspension outside the  
25 centrifugal field through the finishing device, and

tubing communicating with the tubing system  
that, without interrupting the on line communication  
between the container and the source of blood,  
conveys the finished platelet suspension from the  
30 finishing device directly into the container.

3. A system according to claim 1 or 2  
wherein the finishing element comprises a  
filter media.

4. An on line blood processing system for  
obtaining a finished platelet suspension having a  
reduced residual leukocyte population comprising  
a flow path establishing on line  
5 communication between a container and a source of  
blood containing leukocytes and platelets,

- 16 -

10 a separation device communicating in line  
with the flow path between the source and the  
container to receive blood from the source, the  
separation device including a centrifugal separation  
15 element that, without interrupting the on line  
communication between the container and the source  
of blood, creates a centrifugal field that separates  
from the blood an unfinished suspension of platelets  
having an initial population of leukocytes greater  
than the reduced residual population of leukocytes,

15 a finishing device communicating in line  
with the flow path outside the centrifugal field,  
the finishing device including an inlet  
20 communicating with the separation device and an  
outlet communicating with the container and not the  
separation device, the finishing device including a  
finishing element that, during passage of the  
unfinished suspension of platelets between the inlet  
25 and outlet, reduces the initial leukocyte population  
in the unfinished platelet suspension to the reduced  
residual leukocyte population, and

30 a pump in line with the flow path that,  
without interrupting the on line communication  
between the flow path and the blood source, pumps  
the unfinished platelet suspension outside the  
centrifugal field through the finishing device inlet  
for passage through the finishing element, to  
thereby change the unfinished platelet suspension  
35 into the finished platelet suspension, and pumps the  
finished platelet suspension from the finishing  
device outlet into the container.

5. An on line blood processing system for  
obtaining a finished platelet suspension having a  
reduced residual leukocyte population comprising

a flow path establishing on line

- 17 -

5 communication between a container and a whole blood donor,

a separation device communicating in line with the flow path between the donor and the container to receive whole blood from the donor, the  
10 separation device including a centrifugal separation element that, without interrupting the on line communication between the container and the donor, creates a centrifugal field that separates from whole blood a first component comprises red blood  
15 cells and leukocytes and a second component comprising an unfinished suspension of platelets having an initial population of leukocytes greater than the reduced residual population of leukocytes,

a return branch communicating in line with  
20 the flow path that returns the first component to the donor at least in part while the separation element separates whole blood,

a finishing device communicating in line with the flow path outside the centrifugal field,  
25 the finishing device including an inlet communicating with the separation device and an outlet communicating with the container and not the separation device, the finishing device including a finishing element that, during passage of the  
30 unfinished suspension of platelets between the inlet and outlet, reduces the initial leukocyte population in the unfinished platelet suspension to the reduced residual leukocyte population, and

a pump in line with the flow path that,  
35 without interrupting the on line communication between the flow path and the blood source, pumps the unfinished platelet suspension outside the centrifugal field through the finishing device inlet for passage through the finishing element, to

- 18 -

40 thereby change the unfinished platelet suspension into the finished platelet suspension, and pumps the finished platelet suspension from the finishing device outlet into the container.

6. An on line blood processing system for obtaining a finished platelet suspension having a desired physiologic characteristic comprising

5 a flow path establishing on line communication between a container and a source of blood containing platelets,

a separation device communicating in line with the flow path between the source and the container to receive blood from the source, the  
10 separation device including a centrifugal separation element that, without interrupting the on line communication between the container and the source of blood, creates a centrifugal field that separates from the blood an unfinished suspension of platelets  
15 having a first physiologic characteristic different than the desired physiologic characteristic,

a finishing device communicating in line with the flow path outside the centrifugal field, the finishing device including an inlet  
20 communicating with the separation device and an outlet communicating with the container and not the separation device, the finishing device including a finishing element that, during passage of the unfinished suspension of platelets between the inlet  
25 and outlet, changes the first physiologic characteristic to the desired physiological characteristic, and

a pump in line with the flow path that, without interrupting the on line communication  
30 between the flow path and the blood source, pumps the unfinished platelet suspension outside the

- 19 -

centrifugal field through the finishing device inlet for passage through the finishing element, to thereby change the unfinished platelet suspension into the finished platelet suspension, and pumps the finished platelet suspension from the finishing device outlet into the container.

7. A system according to claim 4 or 5 or 6

wherein the finishing element comprises a filter media.

8. An on line blood processing method for obtaining a finished platelet suspension having a reduced residual leukocyte population comprising the steps of

(1) establishing on line communication between a container and a source of blood containing leukocytes and platelets,

(2) creating a centrifugal field between the source of blood and the container that separates from the blood an unfinished suspension of platelets having an initial population of leukocytes greater than the reduced residual population of leukocytes,

(3) pumping the unfinished platelet suspension through a finishing device outside the centrifugal field that reduces the initial leukocyte population in the unfinished platelet suspension to the reduced residual leukocyte population, thereby creating the finished platelet suspension, and

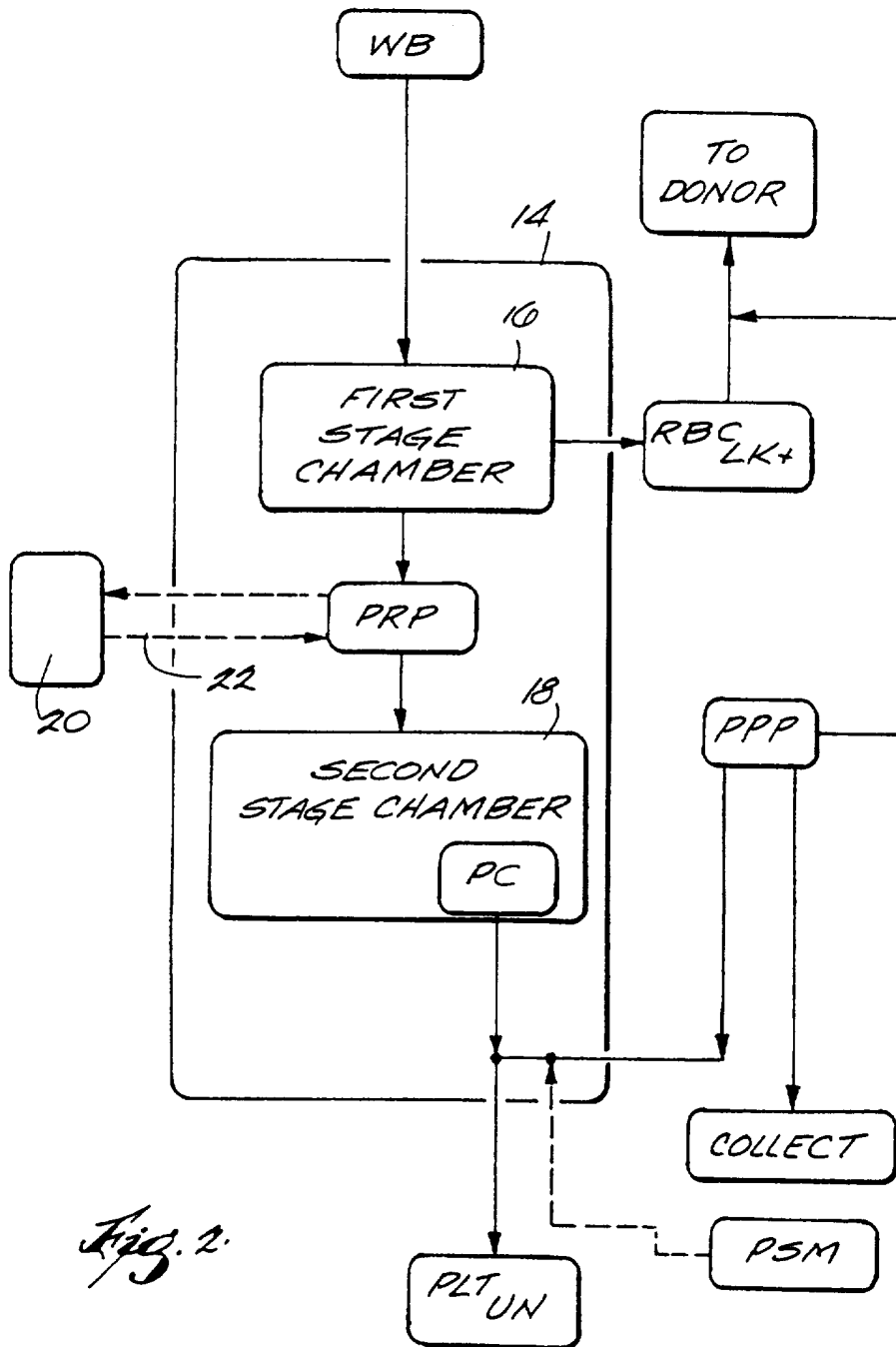
(4) conveying the finished platelet suspension from the finishing device directly into the container,

(5) the preceding steps (2) to (4) being conducted without interrupting the on line communication between the container and the source of blood.

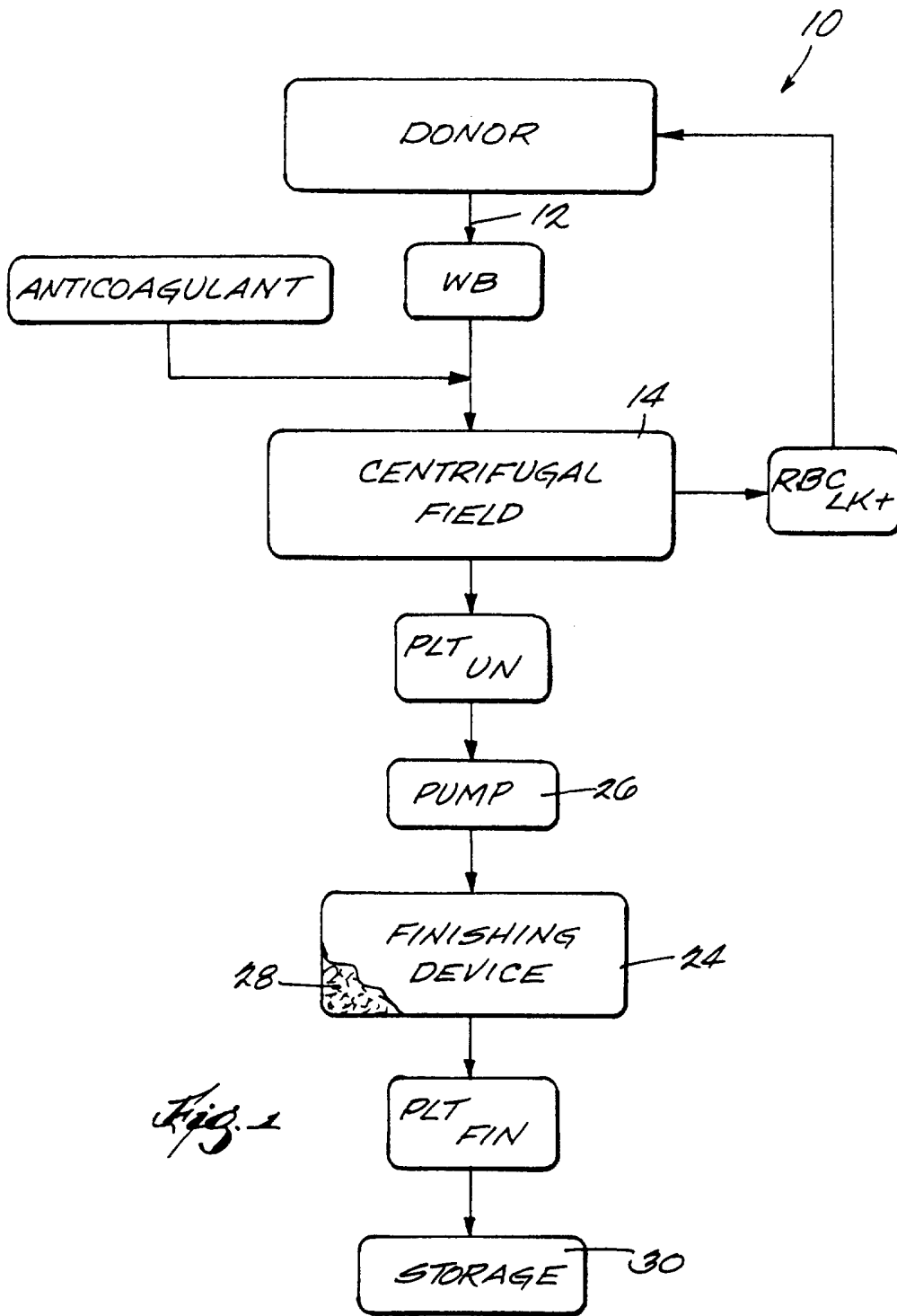
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9. An on line blood processing method for obtaining a finished platelet suspension having a desired physiologic characteristic comprising the steps of

- 5 (1) establishing on line communication between a container and a source of blood containing leukocytes and platelets,
- (2) creating a centrifugal field between the source of blood and the container that separates  
10 from the blood an unfinished suspension of platelets having a first physiologic characteristic different than the desired physiologic characteristic,
- (3) pumping the unfinished platelet suspension through a finishing device outside the  
15 centrifugal field that changes the first physiologic characteristic to the desired physiological characteristic, thereby creating the finished platelet suspension, and
- (4) conveying the finished platelet  
20 suspension from the finishing device directly into the container,
- (5) the preceding steps (2) to (4) being conducted without interrupting the on line communication between the container and the source  
25 of blood.



*Fig. 2.*

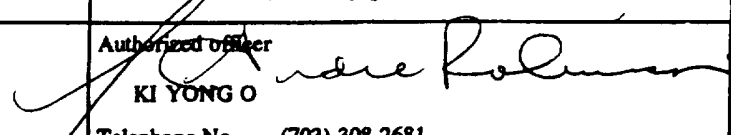


*Fig. 1*



INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/01950

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) : A61M 35/00 US CL : 604/5 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/5 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 practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 5,494,592 A (LATHAM, JR. et al) 27 February 1996.	1-9
A, P	US 5,545,339 A (BORMANN et al) 13 August 1996.	1-9
A, P	US 5,549,834 A (BROWN) 27 August 1996.	1-9
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