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A bag system comprising a means of associating sampling receptacles

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(56) Related Art
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EP 1136087
US 5871699
EP 0678279
US 6387086
EP 0510615

ABSTRACT

The invention concerns a bag system (1) for taking a biological fluid, in particular blood, the said system comprising a device for taking the fluid which is in fluid communication with at least one fluid collecting bag (2), and a device for sampling the fluid to be collected which comprises at least one sampling receptacle (15), the said sampling device comprising a means (10) of transferring the fluid from the bag system (1) into the sampling receptacle or receptacles (15), in which the transfer means (10) is provided with a means of associating the receptacle or receptacles (15), the said means being arranged to allow the supporting of the receptacle or receptacles (15) in a standby position, the guidance of the receptacle or receptacles (15) to a transfer position and, after transfer, the dissociation of the receptacle or receptacles (15) from the bag system (1).

Figure 1a.

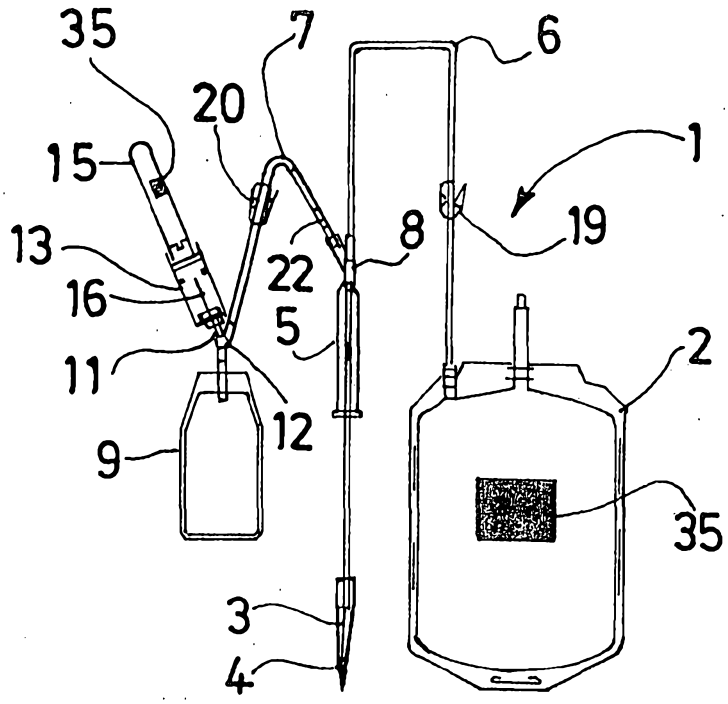
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FIG.1a

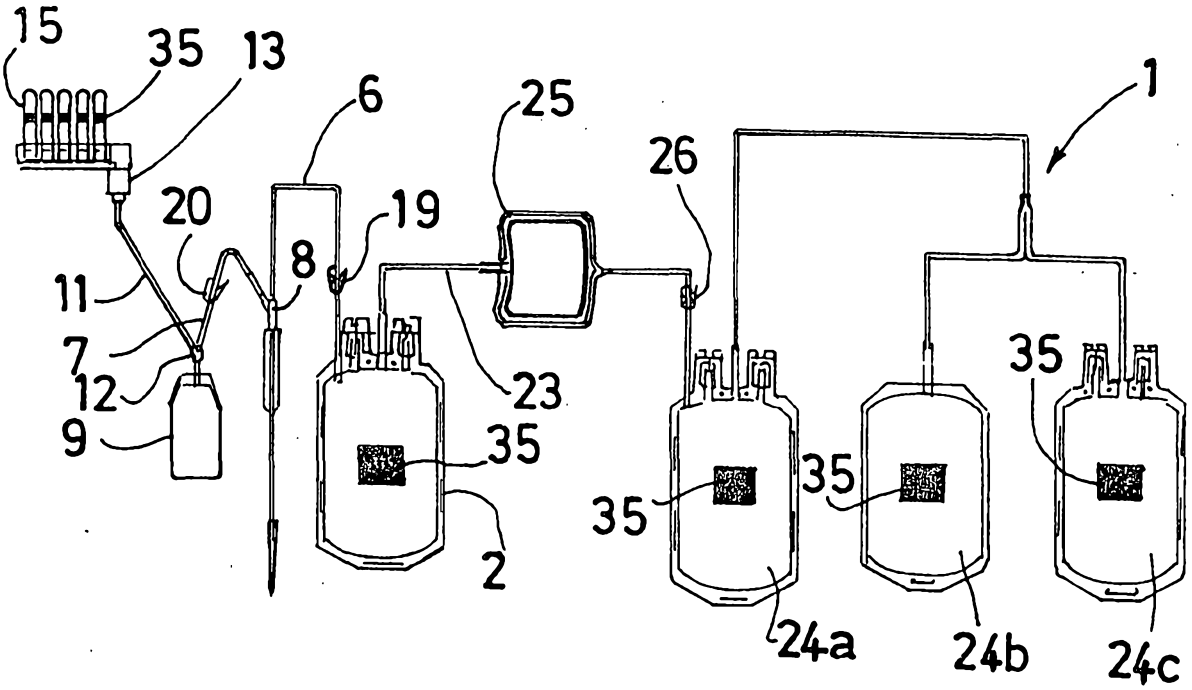
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FIG 1b

P/00/011
Regulation 3.2

AUSTRALIA

Patents Act 1990

ORIGINAL
COMPLETE SPECIFICATION
STANDARD PATENT

Invention title: A bag system comprising a means of associating sampling receptacles

The following statement is a full description of this invention, including the best method of performing it known to us:

A bag system comprising a means of associating sampling receptacles

Field of the invention

The invention concerns a bag system for taking a biological fluid.

Background of the invention

In this specification, where a document, act or item of knowledge is referred to or discussed, this reference or discussion is not an admission that the document, act or item of knowledge or any combination thereof was at the priority date:

(i) part of common general knowledge; or

(ii) known to be relevant to an attempt to solve any problem with which this specification is concerned.

It applies typically to the case where the biological fluid is whole blood which must be taken from a donor in a collecting bag. To do this, the bag system comprises, in closed circuit, a device for taking the blood which is in fluid communication with at least one blood collecting bag. In addition, the system comprises a device for sampling the blood which is intended to receive some of the blood taken, the said device comprising at least one sampling receptacle.

The use of such a sampling device makes it possible to obtain, in each receptacle, a sample of blood intended to be analysed, in particular for carrying out serology, virology and a blood count.

In particular, the bag system can be used by taking off the first millilitres of blood in the sampling device, which has a certain number of advantages. Firstly, this reduces the risk of contamination resulting from the presence of bacteria or other foreign substances on the skin of the donor, since the first millilitres of blood taken off affected by this contamination are sent into the sampling device rather than into the collecting bag. Secondly, this makes it possible to take samples before the bag is completely filled and consequently does not waste time. Finally, during the taking off, the loss of blood volume for the donor being compensated for the addition of plasma, the haematocrit reading of the blood to be analysed would be lower if the sampling device were filled after the collecting bag, and consequently the count would be falsified.

One problem which is posed is that of the difficulty in handling known bag systems.

This is because the user must position several receptacles in order to obtain the samples, which gives rise to a loss of time.

Summary of the invention

According to a first aspect of the present invention there is provided a bag system for taking a biological fluid, in particular blood, the said system comprising:

a device for taking the fluid, the device arranged in fluid communication with at least one fluid collection bag, and a sampling device for sampling the fluid to be collected which comprises at least one sampling receptacle, the sampling device comprising a means of transferring the fluid from the bag system into the or each sampling receptacle, wherein the transfer means is provided with an associating means arranged to allow the supporting of the or each receptacle in a standby position, the guidance of the or each receptacle to a transfer position and, after transfer, the dissociation of the or each receptacle from the bag system, the transfer means having a hollow guide which is open at the front part to allow the introduction of a sampling receptacle, the or each receptacle each comprising a closure element whose diameter is greater than that of the body of the receptacle, the association means arranged so as to allow the supporting of the or each receptacle at a distance from the guide in a standby position and their sequential guidance in the guide, wherein the associating means comprises a housing associated with the guide, the housing being provided with a skirt in which a closed end of the or each receptacle are introduced in order to allow for the longitudinal sliding of the or each receptacle in the housing towards the guide, the skirt having an internal wall provided with a projection intended, by interaction with the closure elements, to prevent the transverse withdrawal of the or each receptacle from the housing, and wherein the skirt comprises an open end disposed opposite a scallop formed in the guide, and an opposite closed end.

In one embodiment, the proposed invention may be advantageous by providing a bag system in which each sampling receptacle may be stored at the means of

transferring fluid from the bag system into it, the said receptacle then being able to be guided by the operator in the transfer means for taking a sample.

According to a second aspect of the present invention, there is provided a bag system for collecting a biological fluid comprising:

a collection device;

a fluid collection bag in fluid communication with the collection device; and

a sampling device in fluid communication with the collection device, the sampling device comprising:

a plurality of sampling receptacles each comprising:

a body having a first diameter; and a closure element having a second diameter greater than the first diameter; and

a transfer device comprising:

a single hollow guide configured to accommodate a single sampling receptacle at one time and open at a front part to allow introduction of the at least two sampling receptacles sequentially;

a hollow needle in fluid communication with the bag system,

wherein the hollow needle passes through a rear part of the guide so that a downstream part of the needle extends inside the guide and an upstream part of the needle extends outside the guide, and

wherein the hollow needle is adapted to perforate the closure element of each of the plurality of receptacles sequentially when the receptacle having the perforated closure element is in a transfer position, placing the downstream part of the needle inside the receptacle when it is in a transfer position; and

an associating device configured to support at least one of the plurality of receptacles in a standby position, guide the receptacles sequentially into to a transfer position in the hollow guide, and allow dissociation of each of the plurality of receptacles from the bag system; the association device comprising:

a housing associated with the hollow guide; and

a skirt provided on the housing into which the closed end of each of the plurality of receptacles is introduced in order to allow the lateral sliding of each of the plurality of receptacles in the housing towards the guide,

wherein an internal wall of the skirt is provided with a projection intended, by interaction with the closure element, to prevent transverse withdrawal of each of the plurality of receptacles from the housing.

According to a third aspect of the present invention, there is provided a method of collecting a biological fluid comprising:

placing a collection device in a donor;

collecting the fluid in a sampling device having a plurality of receptacles each having a closure element and a transfer device comprising:

a single hollow guide configured to accommodate a single sampling receptacle at one time and open at a front part to allow introduction of the at least two sampling receptacles sequentially;

a hollow needle in fluid communication with a bag system,

wherein the hollow needle passes through a rear part of the guide so that a downstream part of the needle extends inside the guide and an upstream part of the needle extends outside the guide; and an associating device comprising a housing associated with the hollow guide; and

a skirt provided on the housing into which the closed end of each of the plurality of receptacles is introduced in order to allow the lateral sliding of each of the plurality of receptacles in the housing towards the guide,

wherein an internal wall of the skirt is provided with a projection intended, by interaction with the closure element, to prevent transverse withdrawal of each of the plurality of receptacles from the housing;

placing a first receptacle of the plurality of receptacles in a standby position in the transfer device;

moving the first receptacle to a transfer position in the transfer device to allow flow of the biological fluid into the first receptacle, wherein in the transfer position the downstream part of the needle pierces the closure element and is inside the receptacle;

removing the first receptacle from the single hollow guide;

after removing the first receptacle from the single hollow guide, laterally sliding a second receptacle of the plurality of receptacles in the housing towards the single hollow guide to place the second receptacle in a standby position in the transfer device;

moving the second receptacle to the transfer position in the transfer device to allow flow of the biological fluid into the second receptacle; and removing the second receptacle from the single hollow guide.

Description of the Drawings

Other objects and advantages of the invention will emerge during the following description given with reference to the accompanying drawings, in which:

- Figure 1a depicts schematically a bag system for taking blood which comprises a sampling device according to a first embodiment;

- Figure 1b depicts schematically a bag system for taking the blood and separating the blood components which comprises a sampling device according to a second embodiment;

- Figure 2 depicts schematically the transfer means of the sampling device depicted in Figure 1a;

- Figures 3a and 3b depict schematically the transfer means of Figure 2 in which a sampling receptacle is disposed respectively in a position at a distance and in a transfer position; Figure 3c is a representation similar to Figure 3b showing a variant embodiment of the transfer means;

- Figure 4 depicts schematically a bag system for taking blood which comprises a sampling device provided with several transfer means according to Figure 2;

- Figures 5a to 5e depict schematically the transfer means of the sampling device of Figure 2, respectively front on, in perspective, in profile, in plan view and in transverse section, the sampling receptacles being in the standby position;

- Figures 6a and 6b depict schematically the transfer means of Figures 5 according to a variant embodiment, respectively front on and in profile, the receptacles being in the standby position; Figure 6c is a view similar to Figure 6b in which a receptacle is in the transfer position.

Figures 1a and 1b depict a bag system 1 comprising means of taking fluid from a donor and at least one collecting bag 2 intended to receive the fluid taken off, in particular blood.

The sampling means consist in particular of a needle 3 allowing access to the vein of the donor and a cap 4 protecting the needle 3. In addition, a needle protector 5 can be placed slidably on a first tube 6 putting the collecting bag 2 in communication with the means of taking off.

The bag system 1 also comprises a sampling device, which is in fluid communication with the collecting bag 2 by means of the first 6 and a second tube 7 connected at a first connector 8 in the form of a three-way junction.

In the embodiments depicted, the sampling device comprises a sampling bag 9 which is connected to the downstream end of the second tube 7. The terms

downstream and upstream are defined with respect to the direction of flow of the blood, from the taking off device to the bags and sampling device.

The sampling device also comprises a fluid transfer means 10 which is in fluid communication with the collecting bag 2 by means of the first 6 and second tube 7, and possibly a third tube 11 connected to the second tube 7 at a second connector 12 in the form of a three-way junction.

As depicted in Figure 2, the transfer means 10 comprises a hollow guide 13, open at the front part 14 to allow the insertion of a sampling receptacle 15, and a hollow needle 16 passing through the rear part 17 of the guide, so that a downstream part of the said needle extends inside the guide and an upstream part of the said needle 16 extends outside the guide. The downstream segment of the hollow needle 16 is enclosed in an elastic sheath 18. The upstream segment of the hollow needle 16 allows the connection of the transfer means with the bag system 1. A fluid communication means or tube is then connected to the said upstream segment.

First 19 and second 20 clamps can be situated respectively on the first tube 6, downstream of the connector 8, and on the second tube 7. The clamps 19, 20 make it possible to orient the flow of fluid taken off, either to the sampling bag 9, when the first clamp 19 is closed whilst the second clamp 20 is open, or to the collecting bag 2, when the second clamp 20 is closed whilst the first clamp 19 is open.

The sampling receptacle 15 is filled with the taken-off blood contained in the sampling bag 9, when the said receptacle 15 is placed in the transfer position, namely when the downstream end of the needle 16 is in fluid communication with the inside of the receptacle 15, by perforation of a closure element 21 of the receptacle 15.

Circuit openers can be provided within the bag system 1. In particular a circuit opener 22 can be situated on the second tube 7 close to the first connector 8.

As depicted in Figure 1b, in order to perform filtration and separation steps as well as the removal of the leukocytes from the various constituents of the blood,

the collecting bag 2 can be in fluid communication, by means of a fourth tube 23, with satellite bags 24a-c. A filter 25 for removing leukocytes is situated between the collecting bag 2 and a satellite bag 24a. The satellite bag 24a can be in fluid communication with one or more other satellite bags, for example the satellite bag 24a can be in fluid communication with two other satellite bags 24b, c. A clamp 26 can be provided on the fourth tube 23 between the collecting bag 2 and the filter 25 for removing leukocytes. According to one embodiment, the satellite bags 24a-c can be provided with an identification means 35.

According to a first embodiment, the transfer means 10 is provided with a means of associating the sampling receptacle 15, as depicted in Figure 2. The association means comprises first 27 and second 28 sets of projections distributed longitudinally on the internal surface of the guide 13, respectively close to the needle 16 of the guide and close to the front part 14 of the guide 13. The projections are arranged so as to be deformable by sliding of the receptacle 15 within the guide 13 so as to allow a reversible association of the receptacle 15 inside the guide 13, and a sliding of the receptacle 15 inside the guide 13 between a standby position (Figure 3a), at a distance from the needle 16, and the transfer position (Figure 3b).

As depicted in Figures 2, 3a and 3b, the projections are flexible, in particular elastic, and are reversibly deformable from a forward inclined position to a rearward inclined position by contact of the receptacle 15 when it slides inside the guide 13 in the front to rear direction. When the receptacle 15 is withdrawn from the guide 13, the projections incline from rear to front so that the receptacle is not dissociated from its closure element 21. In the embodiment depicted, the sampling receptacle 15 comprises a closure element 21 whose diameter is greater than that of the body of the receptacle 15, it is during the passage of the closure element 21 that the projections incline in one direction or the other.

According to a variant, depicted in Figure 3c, the projections of the first set 27 situated close to the needle 16 are breakable under the effect of the sliding of the receptacle 15 placed in the transfer position. The perforation of the closure

element 21 is thus visible, and the user can check that the perforation has not taken place prior to the taking of samples.

As depicted in Figure 4, several transfer means 10, in each of which a sampling receptacle 15 is associated in a dissociable fashion, can be connected to the bag system 1 by means of the second tube 7 or the third tube 11, connected to the second tube 7 by the second connector 12. Associating several receptacles 15 in a dissociable fashion with several transfer means 10 has advantages, firstly a saving in time for the person responsible for taking the fluid since he does not need to place the receptacle 15 in the transfer means 10, and secondly a reduction in the risk of error in traceability of the donations, since this makes it possible to fix traceability labels prior to the taking of samples, in particular at the time of manufacture.

According to a second embodiment, the association means is arranged to enable the supporting of several receptacles 15 at a distance from the guide 13 in a standby position and their sequential guidance in the guide 13, as depicted in Figures 1b and 5a to 5e.

The association means and the transfer means 10 are associated by clipping on or welding, or can be moulded in one and the same piece.

The association means comprises a housing 29 associated with the guide 13. The said housing 29 is provided with a skirt 30 in which the closure element 21 of the receptacles 15 is introduced to allow the longitudinal sliding of the receptacles 15 in the housing 29 towards the guide 13. The internal wall of the said skirt 30 is provided with a projection 31 intended, by interaction with the closure elements 21, to prevent the transverse withdrawal of the receptacles 15 from the housing 29.

The skirt 30 comprises an open end disposed opposite a scallop formed in the guide, and an opposite closed end. In the other axis, a first open end is disposed opposite the other end which is open so that the body of the receptacle or receptacles 15 extends beyond the housing 29.

At the time of manufacture, the sampling receptacles 15 are introduced into the guide 13 through its open front part 14 so that the closure element 21 is situated level with the groove 32 in the housing 29 so that it can be slid therein.

A cap 33 is then placed on the guide 13 making it possible to hold the receptacles 15 in the housing 29 until the samples are taken by the user of the system 1.

The housing can be of variable size so as to contain from two to ten receptacles 15. The number of receptacles 15 used varies according to the legislation, in France in particular five receptacles 15 are used for carrying out normal analyses.

When samples are taken, the person responsible for taking off removes the cap 33 from the guide 13, makes the receptacles 15 slide as far as the guide 13, and then introduces them so that, by perforation of a closure element 21 of the receptacle 15, the downstream end of the needle 16 is in fluid communication with the inside of the receptacle 15. After a receptacle 15 has been filled, the user withdraws it from the guide 13. In one example embodiment, the cap 33 can be provided with a tamper-evident element, such as a tongue which is broken on first opening, so as to be able to identify the first handling of the plug 33.

According to a variant, depicted in Figures 6a to 6c, the transfer means 10 can slide on the association means, so that it can be placed level with each receptacle 15. When the transfer means 10 is placed level with a receptacle 15, the user can then move the said transfer means 10 transversely so that the closure element 21 is perforated by the needle 16. So that the transfer means 10 can slide on the association means, two opposite scallops are then formed in the guide 13.

As depicted in Figure 1b, the transfer means 10 associating several sampling receptacles 15 can be connected to a bag system 1 by means of the second tube 7 and possibly the third tube 11.

With the known bag systems for taking off blood, the person responsible for taking off must identify, by means of a marking, the collecting bag 2 and the sample receptacle or receptacles 15 corresponding to one and the same donation.

According to the invention, the possibility of error in traceability of these donations is considerably reduced since the sampling receptacle or receptacles 15 and the collecting bag 2 are associated at the time of manufacture in a dissociable fashion. In addition, as from manufacture, the collecting bag 2 and the sampling receptacle or receptacles 15, as well as any satellite bags 24a-c, are each provided with an identification means 35, for example by means of a self-adhesive label with bar codes, which comprises information making it possible, after dissociation of the receptacle from the bag system 1, to unequivocally establish that the sampling receptacle 15 and the collecting bag 2, as well as any satellite bags 24a-c, come from the same bag system 1.

The word 'comprising' or forms of the word 'comprising' as used in this description and in the claims do not limit the invention claimed to exclude any variants or additions.

The claims defining the invention are as follows:

1. A bag system for taking a biological fluid, in particular blood, the said system comprising:

a device for taking the fluid, the device arranged in fluid communication with at least one fluid collection bag, and a sampling device for sampling the fluid to be collected which comprises at least one sampling receptacle, the sampling device comprising a means of transferring the fluid from the bag system into the or each sampling receptacle, wherein the transfer means is provided with an associating means arranged to allow the supporting of the or each receptacle in a standby position, the guidance of the or each receptacle to a transfer position and, after transfer, the dissociation of the or each receptacle from the bag system, the transfer means having a hollow guide which is open at the front part to allow the introduction of a sampling receptacle, the or each receptacle each comprising a closure element whose diameter is greater than that of the body of the receptacle, the associating means arranged so as to allow the supporting of the or each receptacle at a distance from the guide in a standby position and their sequential guidance in the guide, wherein the association means comprises a housing associated with the guide, the housing being provided with a skirt in which a closed end of the or each receptacle are introduced in order to allow for the longitudinal sliding of the receptacle in the housing towards the guide, the skirt having an internal wall provided with a projection intended, by interaction with the closure elements, to prevent the transverse withdrawal of the or each receptacle from the housing, and wherein the skirt comprises an open end disposed opposite a scallop formed in the guide, and an opposite closed end.

2. A system according to Claim 1, wherein the collecting bag is in fluid communication with a taking-off device by means of a first tube to which the sampling device is connected by means of a second tube.

3. A system according to Claim 2, wherein the sampling device comprises a sampling bag which is connected to the downstream end of the second tube.

4. A system according to any one of Claims 1 to 3, wherein the transfer means comprises a hollow needle passing through the rear part of the guide so that a downstream part of the said needle extends inside the guide and an upstream part of the said needle extends outside the guide, the said needle being in fluid communication with the bag system, in order, by translation, to allow the arrangement of the receptacle in the transfer position in which, by perforation of a closure element of the receptacle, the downstream end of the needle is in fluid communication with the inside of the receptacle.

5. A system according to Claim 4, wherein the associating means comprises a first and a second set of projections distributed longitudinally on the internal face of the guide, the said projections being arranged so as to be deformable by sliding of the receptacle inside the guide so as to permit a reversible association of the receptacle inside the guide and a sliding of the receptacle inside the guide between a standby position at a distance from the needle and the transfer position.

6. A system according to Claim 5, wherein at least some projections are flexible, in particular elastic, and are reversibly deformable from a position inclined towards the rear towards a position inclined towards the front by contact of the receptacle during its sliding inside the guide in the rear to front direction, or respectively front to rear.

7. A system according to Claim 5 or Claim 6, wherein the projections in the first set which is situated close to the needle are breakable under the effect of the deformation.

8. A system according to any one of Claims 1 to 7, wherein it comprises several transfer means in each of which a receptacle is associated in a dissociable fashion, the said means being connected to the system by means of the second tube or a third tube.

9. A system according to any one of Claims 1 to 8, wherein the guide is provided with a cap which is provided with a tamper-evident element.

10. A system according to any one of Claims 1 to 9, wherein the system further comprises a transfer means associating several receptacles, the said means being connected to the system by means of the second tube or a third tube.

11. A system according to any one of Claims 1 to 10, wherein the collecting bag and the sampling receptacle or receptacles are each provided with an identification means which comprises information making it possible, after dissociation of the receptacle from the bag system, to unequivocally establish that the sampling receptacle and the collecting bag come from the same bag system.

12. A system according to any one of the preceding claims, wherein the collecting bag is in fluid communication, by means of a fourth tube, with satellite bags, the said satellite bags being provided with an identification means.

13. A bag system for collecting a biological fluid comprising:

a collection device;

a fluid collection bag in fluid communication with the collection device; and

a sampling device in fluid communication with the collection device, the sampling device comprising:

a plurality of sampling receptacles each comprising:

a body having a first diameter; and a closure element having a second diameter greater than the first diameter; and

a transfer device comprising:

a single hollow guide configured to accommodate a single sampling receptacle at one time and open at a front part to allow introduction of the at least two sampling receptacles sequentially;

a hollow needle in fluid communication with the bag system,

wherein the hollow needle passes through a rear part of the guide so that a downstream part of the needle extends inside the guide and an upstream part of the needle extends outside the guide, and

wherein the hollow needle is adapted to perforate the closure element of each of the plurality of receptacles sequentially when the receptacle having the perforated closure element is in a transfer position, placing the downstream part of the needle inside the receptacle when it is in a transfer position; and

an associating device configured to support at least one of the plurality of receptacles in a standby position, guide the receptacles sequentially into to a transfer position in the hollow guide, and allow dissociation of each of the plurality of receptacles from the bag system; the association device comprising:

a housing associated with the hollow guide; and

a skirt provided on the housing into which the closed end of each of the plurality of receptacles is introduced in order to allow the lateral sliding of each of the plurality of receptacles in the housing towards the guide,

wherein an internal wall of the skirt is provided with a projection intended, by interaction with the closure element, to prevent transverse withdrawal of each of the plurality of receptacles from the housing.

14. A method of collecting a biological fluid comprising:

placing a collection device in a donor;

collecting the fluid in a sampling device having a plurality of receptacles each having a closure element and a transfer device comprising:

a single hollow guide configured to accommodate a single sampling receptacle at one time and open at a front part to allow introduction of the at least two sampling receptacles sequentially;

a hollow needle in fluid communication with a bag system,

wherein the hollow needle passes through a rear part of the guide so that a downstream part of the needle extends inside the guide and an upstream part of the needle extends outside the guide; and an associating device comprising a housing associated with the hollow guide; and

a skirt provided on the housing into which the closed end of each of the plurality of receptacles is introduced in order to allow the lateral sliding of each of the plurality of receptacles in the housing towards the guide,

wherein an internal wall of the skirt is provided with a projection intended, by interaction with the closure element, to prevent transverse withdrawal of each of the plurality of receptacles from the housing;

placing a first receptacle of the plurality of receptacles in a standby position in the transfer device;

moving the first receptacle to a transfer position in the transfer device to allow flow of the biological fluid into the first receptacle, wherein in the transfer position the downstream part of the needle pierces the closure element and is inside the receptacle;

removing the first receptacle from the single hollow guide;

after removing the first receptacle from the single hollow guide, laterally sliding a second receptacle of the plurality of receptacles in the housing towards the single hollow guide to place the second receptacle in a standby position in the transfer device;

moving the second receptacle to the transfer position in the transfer device to allow flow of the biological fluid into the second

receptacle; and removing the second receptacle from the single hollow guide.

15. The method of claim 14, wherein the moving and removing steps do not include transverse withdrawal of the receptacle from the housing.

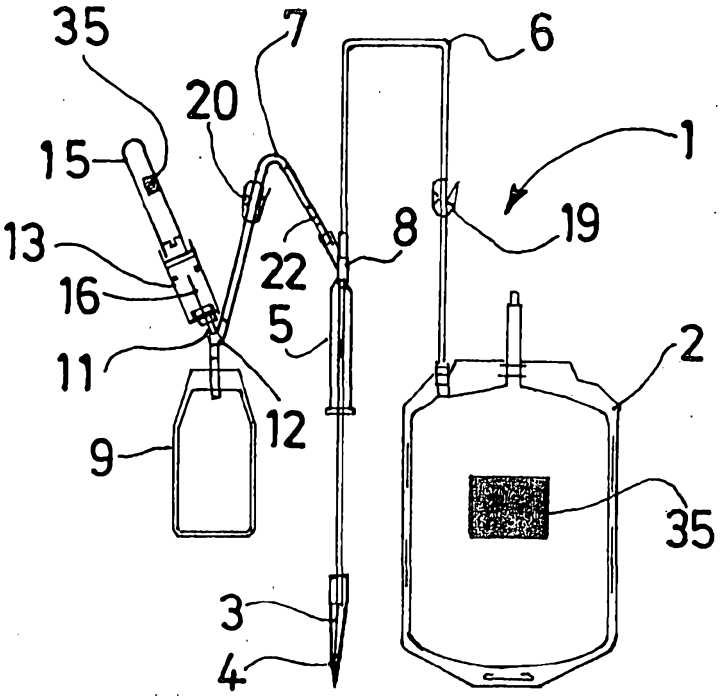
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FIG.1a

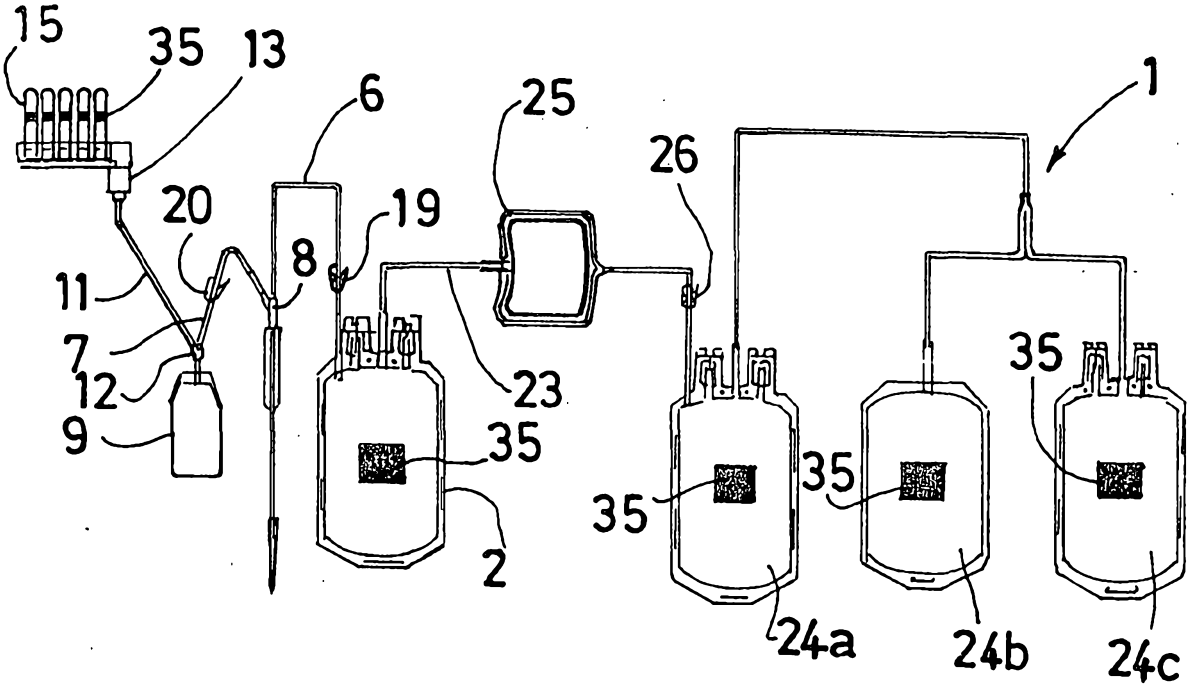
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FIG 1b

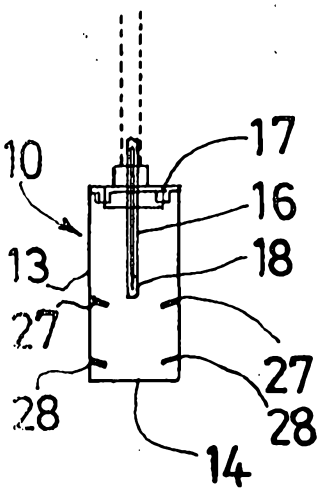

FIG.2

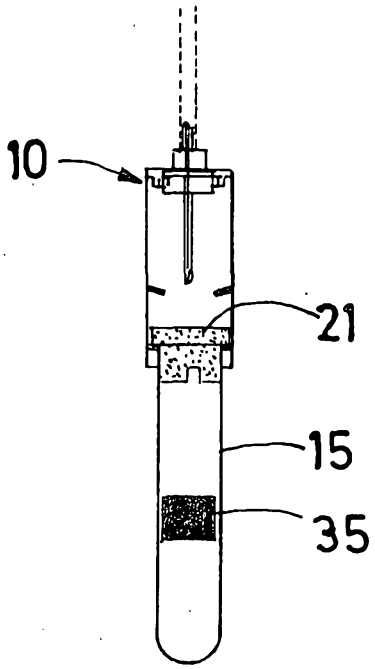

FIG.3a

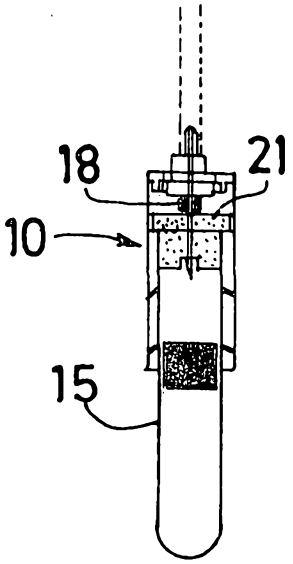

FIG.3b

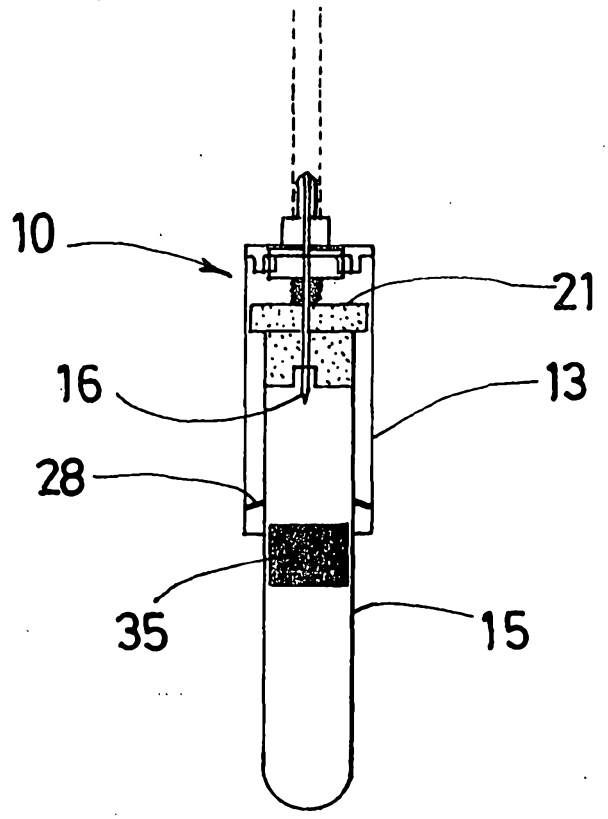

FIG.3c

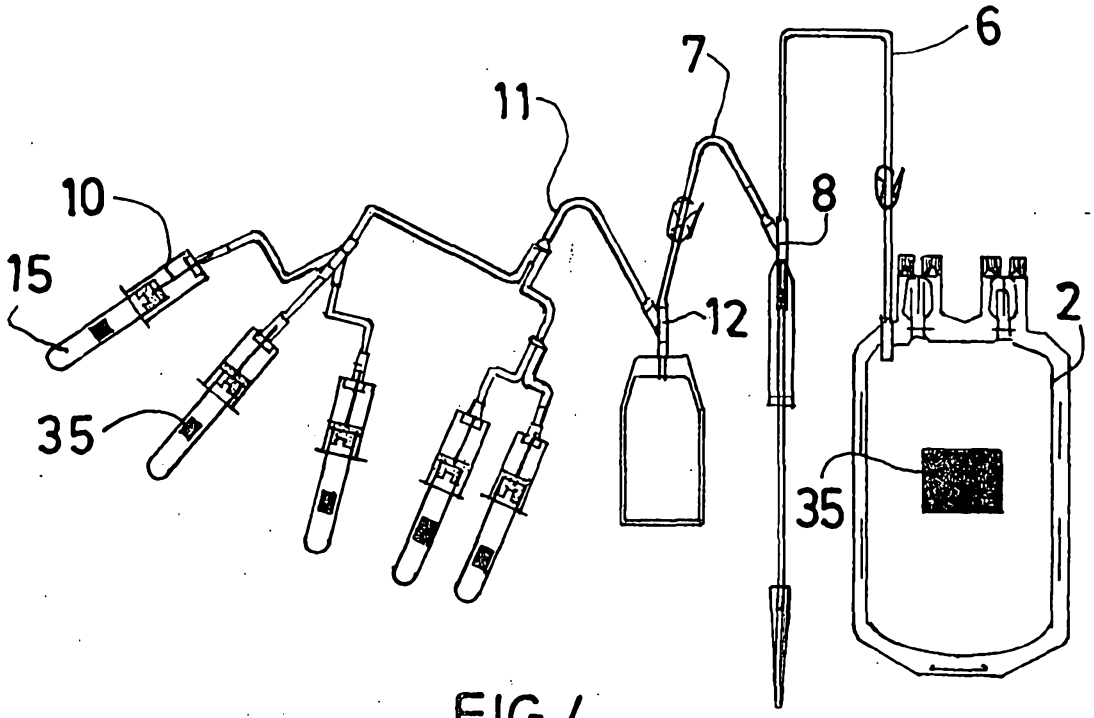

FIG.4

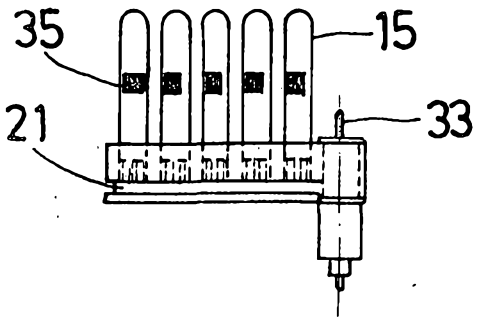

FIG. 5a

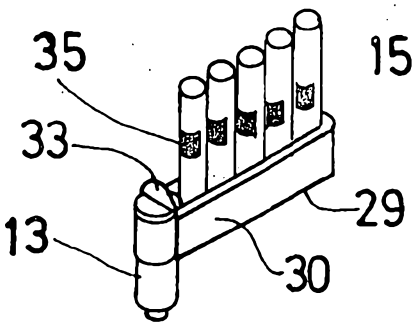

FIG.5b

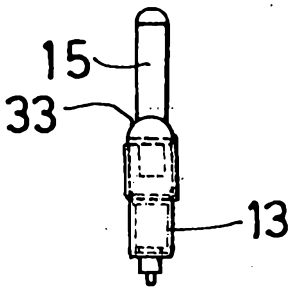

FIG.5c

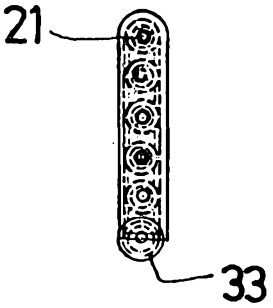

FIG.5d

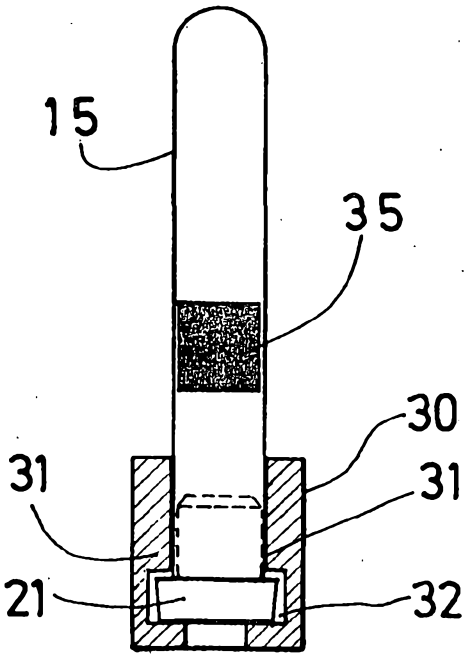

FIG.5e

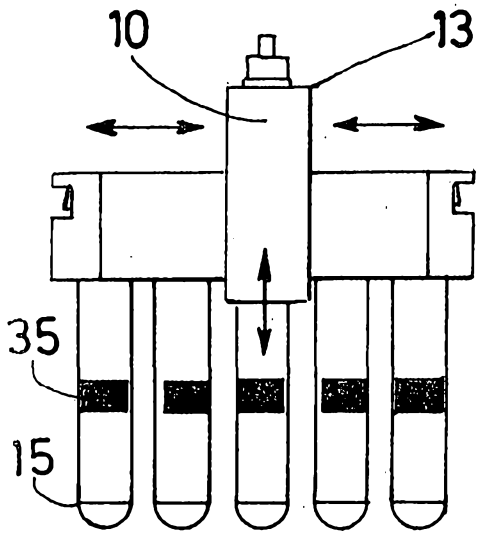

FIG.6a

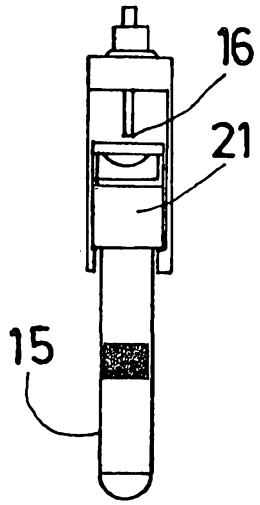

FIG.6b

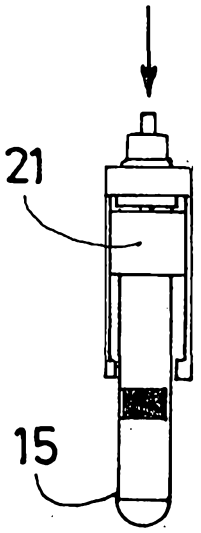

FIG.6c