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(54) **Title**: FLUID PROCESSING DEVICE

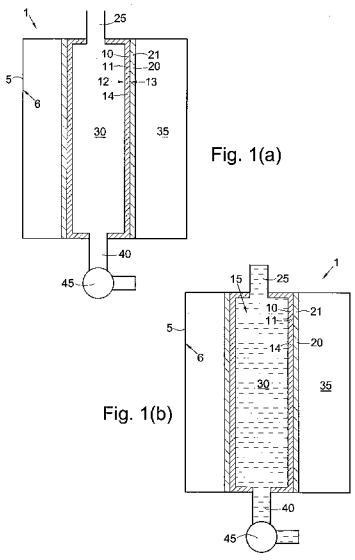

Fig. 1(a)

Fig. 1(b)

(57) **Abstract**: The present invention relates to a system, apparatus, and method for separating components of a fluid, e.g. blood, which eliminates the need for expensive hardware and produces a stabilised waste product. The system comprises an apparatus or device (V) for separating components of a fluid (15') comprising a container (5') having at least one separation or filtration member (10') capable of selectively separating or filtering at least one component from the fluid, and a superabsorbent material (20') capable of absorbing the at least one component separated from the fluid, and thereby providing a processed fluid free or substantially free of said at least one component; and agitation means.

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FLUID PROCESSING DEVICE

FIELD OF INVENTION

The present invention relates to a device for processing a fluid, and in particular, though not exclusively, to a passive cell separation device for use in processing blood, for example, in a surgical environment.

BACKGROUND TO INVENTION

Blood recovery in the surgical environment or during trauma can be performed by a variety of processes. Blood lost from a surgical site is commonly required to be processed into a cell concentrate prior to readministration. With blood being generally in short supply and increasingly becoming a rechargeable commodity, there is an increasing interest in recovering blood that would have traditionally been lost to surgical drainage.

The recovery of blood commonly requires a suction system and a centrifuge device to concentrate the blood, which necessitates the purchase and maintenance of expensive and cumbersome equipment.

Additionally, the current concern in both the medical and public sectors regarding hospital or blood-borne infections has triggered a greater interest in auto-transfusion during surgical procedures.

Typically, in the case of post-cardiac surgery, there is a need to concentrate the blood of a haemodeficient patient from a concentration of approximately 22% packed cell volume to about 70 to 80% packed cell volume.

It is an object of at least one embodiment of at least one aspect of the present invention to seek to obviate or at least mitigate one or more disadvantages in the prior art.

It is an object of at least one embodiment of at least one aspect of the present invention to provide a convenient single use disposible device for processing blood, suitable for flat-pack storage, and which eliminates the need for expensive hardware.

It is an object of at least one embodiment of at least one aspect of the present invention to provide a blood-processing device which produces a stabilised waste product.

It is an object of at least one embodiment of at least one aspect of the present invention to provide a device for processing blood into a concentrate comprising cellular components. This may be particularly useful in third world or military field environments where access to expensive centrifugal processing technologies is restricted, but there remains a significant need for processed donor blood products.

It is an object of at least one embodiment of at least one aspect of the present invention to provide a system comprising a blood-processing device; and agitation means, e.g. an orbital shaker, for improving the efficiency of the blood-processing device.

It is an object of at least one embodiment of at least one aspect of the present invention to provide a method of concentrating blood or removing specific blood components comprising separating or filtering at least one component from the fluid through at least one separation or filtration member, wherein the at least one component separated or filtered from the fluid may be permanently removed or retained by a superabsorbent material.

It is an object of at least one embodiment of at least one aspect of the present invention to provide a use of a superabsorbent material for separating or removing at least one component from a fluid such as blood.

SUMMARY OF INVENTION

According to a first aspect of the present invention there is provided an apparatus or device for separating components of a fluid comprising a container having at least one separation or filtration member capable of selectively separating or filtering at least one component from the fluid, and a superabsorbent material capable of absorbing the at least one component separated from the fluid, and thereby providing a processed fluid free or substantially free of the said at least one component. It is to be understood that the filtration member and the superabsorbent material may be unitary in nature or formed from two or more components.

Conveniently, the separation device may be capable of reducing the volume of the fluid-to-be-processed by at least 20%, preferably at least 30%, more preferably at least 40%, and typically approximately 50-80%.

Typically, the filtration member and the superabsorbent material may form two separate components.

The container may comprise an inlet, first opening or first aperture, typically near a top portion thereof for introducing the fluid into the container.

The inlet, first opening or first aperture may be in communication with a receiving portion, compartment or cavity located inside the device and into which the fluid to be processed is initially received, prior to the separation/filtration step.

In use, a fluid may be provided into the receiving portion of the device through the inlet, first opening or first aperture.

The inlet, first opening or first aperture may be further equipped with means for feeding a fluid into the device, e.g. tubing.

The inlet, first opening or first aperture may be equipped with a flow control system, e.g. a valve or a seal, to prevent fluid from escaping from the receiving portion, compartment or cavity.

The volume and shape of the receiving portion, compartment or cavity may be at least partially defined by said at least one separation or filtration member.

Said at least one separation or filtration member may be a rigid and/or self-supported member.

Alternatively, said member may be flexible and/or supported by a non-reactive supporting material, e.g. a perforated plastic material.

The member may comprise a first side facing toward the receiving portion, compartment or cavity and a second side facing in the opposite direction.

In use, a fluid fed into the receiving portion, compartment or cavity of the device comes into contact with a first side of said at least one separation or filtration member.

Typically, the superabsorbent material may be in contact with or adjacent the second side face of said member.

Conveniently, the second side face of the member may be in contact with a support material impregnated with the superabsorbent material.

The superabsorbent material may be located between the second side face of the member and an inside wall of the container. In such an arrangement, in use, the at least one component selectively separated or filtered from the fluid may migrate outwardly, with respect to the wall of the container, from the receiving portion, compartment or cavity towards the superabsorbent material.

The device may comprise a substantially hollow portion between the superabsorbent material and the inside wall of the container. By such provision the impregnated material may be allowed to expand upon absorption of the at least one filtered component.

Alternatively, the receiving portion, compartment or cavity may be provided between an inside wall of the container and a first side face of the at least one separation or filtration member. In such an arrangement, in use, the at least one component selectively separated or filtered from the fluid may migrate inwardly, with respect to the wall of the container, from the receiving portion, compartment or cavity towards the superabsorbent material.

Preferably, the superabsorbent material may be provided or enclosed within a volume defined by the second side face of the at least one separation or filtration member. By such provision the at least one separation or filtration member and the superabsorbent material may define a pad-like assembly provided inside the container.

In such an arrangement, the device may further comprise a substantially hollow portion inside the volume defined by the second side face of the at least one separation or filtration member. By such provision the impregnated material may be allowed to expand or swell upon absorption of the at least one filtered component.

Advantageously, the separation or filtration member may be attached to e.g., an inside wall of the container.

In use, absorption by the superabsorbent material "draws" a portion of fluid comprising the at least one component through the separation or filtration member whilst other components are retained in the receiving portion, compartment or cavity. By such provision the apparatus does not require application of any external force to

separate the at least one component from the initial fluid. It will be appreciated that the at least one component of the fluid may simply be a portion of the fluid lacking or substantially lacking any solid or particulate material. In this manner, removal of a portion of the fluid will serve to concentrate solid or particulate material, such as proteins, cells, and the like, in the case of blood, in the processed fluid. However, the at least one component will generally comprise a portion of any solid or particulate material formed in the fluid.

The receiving portion, compartment or cavity may be in communication with an outlet, second opening or second aperture, typically near a bottom portion of the container, for removal of said processed fluid.

The outlet, second opening or second aperture may be further equipped with means for retrieving or recovering a processed fluid from the device, e.g. tubing.

The outlet, second opening or second aperture may be equipped with a flow control system, e.g. a valve or a seal.

In use, a processed fluid may be retrieved or recovered from the receiving portion, compartment or cavity of the device through the outlet, second opening or second aperture.

Alternatively, a processed fluid may be retrieved or recovered from the receiving portion, compartment or cavity of the device through the inlet, first opening or first aperture, e.g. by inverting the device.

Conveniently, the container may be in the form of a flexible bag or pouch. By such provision the device may be suitable for flat pack storage.

The bag may be made from a polymeric material, e.g. medical grade polyvinyl chloride (PVC) or a polyolefin material.

Alternatively, the container may be rigid, e.g. in the form of a rigid cylinder. In such instance the container may be made from e.g. medical grade polycarbonate.

Typically, the container may be substantially cylindrical.

Conveniently, the container may comprise a substantially transparent portion, e.g. a transparent vertical strip. By such provision the inside of the receiving portion, compartment or cavity of the device may be visible by a user.

The substantially transparent portion of the container may be provided with measuring means to indicate the level or volume of fluid present inside the receiving portion, compartment or cavity of the device. By such provision, after filling the device with a desired quantity of fluid, a user may be able to determine when a sufficient amount of the component-to-be-removed has been absorbed by the superabsorbent material.

The at least one separation or filtration member may be a membrane, e.g. a semi-permeable membrane.

Preferably, the membrane may be a porous filtration membrane.

The membrane may be made from a polyolefin material, e.g. polypropylene, or another polymeric material such as nylon or polyethersulfone.

The permeability of the membrane may be chosen according to the type of fluid to be processed and/or the specific components to be separated or removed from the fluid.

Typically, permeability may be determined by selecting a specific pore size for the membrane.

In use, when processing blood, an effective membrane pore size of 0.2 μm, for example, may allow water, small salts and proteins to pass through the membrane and be removed from the blood. Alternatively, an effective membrane pore size of 5 to 8

μm, for example, may also allow platelets and larger proteins to pass through the membrane. Thus, it is possible to concentrate the cellular components of blood.

The superabsorbent material may be made from a superabsorbent polymer, e.g. a polyacrylate or a polyacrylamide.

Preferably, the superabsorbent material may be made from sodium polyacrylate.

Conveniently, the superabsorbent material may be in powder form.

In use, the superabsorbent material may form a stable gel upon absorption of a fluid, e.g. water.

The at least one component separated from a fluid may be permanently removed from the fluid and/or retained by the superabsorbent.

The support material impregnated with the superabsorbent material may comprise a cellulosic material or a polyester material, e.g. a cellulose tissue material or a polyester fibre material.

The superabsorbent material and/or the support material may further comprise additives.

Conveniently, the superabsorbent material and/or the support material may be impregnated with stabilising agents, e.g. anti-microbial agents, to further stabilise the waste product for safe disposal.

Typically, the device may be a bodily fluid separation device, e.g. a blood separation device. By such provision specific blood components may be removed or separated, and the processed blood may be further processed, e.g. readministered into a patient.

The device may be further equipped with further processing means, e.g. a leukocyte depleting filter which may be connected to the outlet, second opening or second aperture of the device.

In use, the device may be used in a surgical environment.

In use, the device may be attachable to a static piece of surgical equipment, e.g. a stand or a bed.

In use, the device may be attached to agitation means, e.g. vibrating means or shaking means such as an orbital shaker, in order to improve the efficiency of the separation device.

According to a second aspect of the present invention there is provided a system comprising an apparatus or device for separating components of a fluid; and agitation means. By such provision the efficiency of the fluid-processing device may be enhanced.

Preferably, the apparatus or device may be a separation device according to the present invention as described herein above.

Typically, the agitation means may comprise e.g. vibrating means or shaking means.

Preferably, the agitation means may comprise an orbital shaker.

Conveniently, the agitation means may be adapted for agitating the separation device.

Typically, the agitation means may be provided with a receiving portion for receiving the separation device.

Typically, the receiving portion may comprise a receiving surface for receiving the separation device.

In use, the receiving surface may be substantially horizontal.

Typically also, the receiving portion may be provided with a raised portion, e.g. a substantially vertically-extending portion, around its periphery for maintaining the separation device on the receiving surface.

Conveniently, the agitation means may be provided with attaching means for securing the separation device to the receiving portion.

Advantageously, the agitation means may be further provided with a closably openable and substantially rigid covering portion, e.g. a lid, for protecting the separation device. By such provision, in use, the separation device may be protected from accidental damage and/or contamination.

Conveniently, the agitation means may be operated by mains power supply, battery pack, or manually.

Typically, the separation device or apparatus may be a bodily fluid separation device, e.g. a blood separation device.

According to a third aspect of the present invention there is provided a method for processing a fluid comprising separating or filtering at least one component from the fluid using at least one separation or filtration member, and retaining or removing said at least one separated or filtered component by a superabsorbent material.

The method may comprise a preliminary step consisting of providing a fluid into a separation device.

The method may comprise a final step consisting of retrieving or recovering a processed fluid from the separation device.

The method may be driven by the combined action of gravity and absorption of the at least one component by the superabsorbent material after passing through the

separation or filtration member. Absorption by the superabsorbent material "draws" the at least one component through the separation or filtration member.

By such provision the method does not require the application of an external force to separate the at least one component from the fluid.

The fluid may be provided into a receiving portion, compartment or cavity of the device via an inlet, first opening or first aperture near a top portion thereof.

The fluid may be provided into the receiving portion via feeding means, e.g. tubing, which may be connected to the inlet, first opening or first aperture.

The fluid may be fed at a rate controlled by a flow control system, e.g. a valve or a seal, thereby preventing fluid from escaping from the top of the receiving portion.

The processed fluid may be retrieved or recovered from the receiving portion, compartment or cavity of the device via an outlet, second opening or second aperture near a bottom portion of the device.

The processed fluid may be retrieved or recovered at a rate controlled by a flow control system, e.g. a valve or a seal, connected with the outlet, second opening or second aperture.

Alternatively, the processed fluid may be retrieved or recovered from the receiving portion of the device through the inlet, first opening or first aperture, e.g. by inverting the device.

The method may comprise continuously providing a fluid inside the device via an inlet, first opening or first aperture, and continuously retrieving the processed fluid via an outlet, second opening or second aperture. By such provision the level of fluid inside the device may be maintained at a substantially constant level.

Conveniently, the method may comprise providing a fluid into the separation device according the present invention as described herein above.

The method may comprise the superabsorbent permanently removing and/or retaining the at least one component separated from the fluid.

The method may comprise agitating the device during processing of the fluid. By such provision the rate at which the fluid is processed may be increased.

The method may comprise further processing the processed fluid, e.g. removing at least one further component from the processed fluid, e.g. removing leukocytes from processed blood by further processing it through using e.g. a leukocyte-depleting filter.

The method may further comprise disposing of the separation device upon retrieval or recovery of the processed fluid.

Typically, the method comprises processing a bodily fluid, e.g. blood. By such provision specific blood components may be removed or separated, and the processed blood may be further processed, e.g. readministered into a patient.

In use, a subject's bodily fluid may be provided into the receiving portion of the separation device while the device is provided on or attached to a static piece of surgical equipment such as a stand or a bed. When a desired amount of bodily fluid is provided in the separation device, the inlet may be closed to prevent leakage, and the device transferred to agitation means to improve separation efficiency.

Alternatively, the separation device may be provided on or in said agitation means prior to its receiving portion being filled with a subject's bodily fluid. By such provision agitation may be applied either simultaneous or subsequent to a subject's bodily fluid being provided into the receiving portion of the device.

According to a fourth aspect of the present invention there is provided a use of a superabsorbent material for separating or removing at least one component from a bodily fluid, e.g. blood.

The superabsorbent material may be made from a superabsorbent polymer, e.g. a polyacrylate.

Conveniently, the superabsorbent material may be in powder form.

In use, the superabsorbent material may form a stable gel upon absorption of a fluid, e.g. water.

The at least one component separated from a fluid may be permanently removed from the fluid and/or retained by the superabsorbent.

The superabsorbent material may be impregnated into a support material.

The support material impregnated with the superabsorbent material may comprise a cellulosic material or a polyester material, e.g. a cellulose tissue material or a polyester fibre material.

The superabsorbent material and/or the support material may further comprise additives.

Conveniently, the superabsorbent material and/or the support material may be impregnated with stabilising agents, e.g. anti-microbial agents, to further stabilise the waste product for safe disposal.

BRIEF DESCRIPTION OF DRAWINGS

Embodiments of the invention will now be given by way of example only, and with reference to the accompanying drawings, which are:

Figure 1(a) a cross-sectional view of a separation device according to a first embodiment of the present invention;

Figure 1(b) a cross-sectional view of the separation device of Figure 1(a), the receiving portion of which is filled with a fluid to be processed;

Figure 1(c) a cross-sectional view of the separation device of Figure 1(a) at or near the final stage of the separation process;

Figure 2(a) a cross-sectional front view of a separation device according to a second embodiment of the present invention;

Figure 2(b) a cross-sectional side view of the separation device of Figure 2(a), the receiving portion of which is filled with a fluid to be processed;

Figure 2(c) a cross-sectional side view of the separation device of Figure 2(a); at or near the final stage of the separation process; and

Figure 3 a graph representing the effect of agitation (using an orbital shaker) on the efficiency of the separation device of Figure 2(a), when the processed fluid is blood.

DETAILED DESCRIPTION OF DRAWINGS

Referring to Figures 1(a), 1(b) and 1(c) there is shown an apparatus or device for separating components of a fluid, generally designated 1, according to a first embodiment of the present invention. The separation device 1 comprises a container 5 which contains at least one separation or filtration member 10 capable of separating

or filtering at least one component from the fluid 15, and a superabsorbent material 20 capable of removing the at least one component filtered through or separated by the member 10 disposed therein.

Conveniently, the separation device is capable of reducing the volume of the fluid-to-be-processed by at least 20%, preferably at least 30%, more preferably at least 40%, and typically approximately 50-80%.

In this embodiment, the filtration member 10 and the superabsorbent material 20 form two separate components.

The container 5 comprises an inlet, first opening or first aperture 25, typically near a top portion thereof for introducing the fluid 15 into the container 5.

The inlet, first opening or first aperture 25 is in communication with a receiving portion, compartment or cavity 30 located inside the device 1 and into which the fluid 15 to be processed is initially received, prior to the separation/filtration step.

In use, the fluid 15 is provided into the receiving portion, compartment or cavity 30 of the device 1 through the inlet, first opening or first aperture 25.

The volume and shape of the receiving portion, compartment or cavity 30 is at least partially defined by a first separation or filtration member 11.

In this embodiment, the first member 11 is a rigid and/or self-supported member.

The member 11 comprises a first side 12 facing toward the receiving portion, compartment or cavity 30 and a second side 13 facing in the opposite direction.

In use, a fluid 15 fed into the receiving portion, compartment or cavity 30 of the device 1 comes into contact with a first side 12 of the member 11.

The superabsorbent material 20 is in contact with a second side 13 of the member 11.

In this embodiment, the second side 13 of the member 11 is in contact with a support material 21 impregnated with the superabsorbent material 20.

In this embodiment, the superabsorbent material 20 is located between the second side 13 of the member 11 and an inside wall 6 of the container 5. By such provision, in use, the at least one component selectively separated or filtered from the fluid 15 migrates outwardly, with respect to the wall of the container 5, from the receiving portion, compartment or cavity 30 towards the superabsorbent material 20.

In this embodiment, the device 1 comprises a substantially hollow portion 35 between the superabsorbent material 20 and the inside wall 6 of the container 5. By such provision the impregnated material 21 is allowed to expand or swell upon absorption of fluid comprising the at least one filtered component.

In use, absorption by the superabsorbent material 20 "draws" a portion of fluid 15 comprising the at least one component through the separation or filtration member 10 whilst other components are retained in the receiving portion, compartment or cavity 30. By such provision the apparatus 1 does not require application of any external force to separate the at least one component from the fluid 15.

The receiving portion, compartment or cavity 30 is in communication with an outlet, second opening or second aperture 40, typically near a bottom portion of the container 5, for removal of the processed fluid.

The outlet, bottom opening or bottom aperture 40 is further equipped with a flow control system 45, e.g. a valve or a seal.

In use, a processed fluid 16 may be retrieved or recovered from the receiving portion, compartment or cavity 30 of the device through the outlet, second opening or second aperture 40.

Alternatively, the processed fluid 16 may be retrieved or recovered from the receiving portion, compartment or cavity 30 of the device 1 through the inlet, first opening or first aperture 25, e.g. by inverting the device.

In this embodiment, the container 5 is in the form of a rigid cylinder.

The container 5 is made from a polymeric material, e.g. medical grade polyvinyl chloride (PVC).

The container 5 comprises a substantially transparent portion (not shown), e.g. a transparent vertical strip. By such provision the inside of the receiving portion, compartment or cavity 30 of the device 1 is visible by a user during use.

The substantially transparent portion of the container 5 is provided with measuring means to indicate the level or volume of fluid present inside the receiving portion, compartment or cavity 30. By such provision, after filling the device 1 with a desired quantity of fluid 15, a user may be able to determine when a sufficient amount of the component-to-be-removed has been absorbed by the superabsorbent material 20.

The at least one separation or filtration member 10 is a membrane 14, e.g. a semi-permeable porous filtration membrane.

The membrane 14 is made from a polyolefin material, e.g. "Celgard 2500" microporous polypropylene flat sheet membrane (0.2 μm pore size) from Celgard LLC, 13800 South Lakes Dr, Charlotte, NC 28273, U.S., or another polymeric material such as nylon or a MicroPES® polyethersulfone hydrophilic flat membrane

(Type "4F toa", "5F M", or "6F") from Membrana GmbH, Oehder Straβe 28, D-42289 Wuppertal, Germany.

The permeability of the membrane 14 is chosen according to the type of fluid 15 to be processed and/or the specific components to be separated or removed from the fluid 15.

For example, when using a Celgard 2500 membrane, an effective membrane pore size of 0.2 μm will allow water, small salts and proteins to pass through the membrane.

The superabsorbent material 20 is made from a superabsorbent polymer, e.g. "Super Absorber" (99%+ Cellulose Sodium Polyacrylate superabsorber) from Brightwake Ltd, Lowmoor Business Park, Kirkby-in-Ashfield, Nottinghamshire NG17 7JZ, UK.

In this embodiment, the superabsorbent material 20 is in powder form.

In use, the superabsorbent material 20 forms a stable gel upon absorption of a fluid, e.g. water.

The at least one component separated from a fluid 15 is permanently removed from the fluid 15 and/or retained by the superabsorbent 20.

The support material 21 impregnated with the superabsorbent material 20 comprises a cellulosic material or a polyester material, e.g. a cellulose tissue material or a polyester fibre material.

In this embodiment, the polyacrylate superabsorbent material impregnated in a cellulosic fibrous material is in the form of a Brightwake wound dressing.

The superabsorbent material 20 and/or the support material 21 may further comprise additives.

Conveniently, the superabsorbent material 20 and/or the support material 21 are impregnated with stabilising agents, e.g. anti-microbial agents, to further stabilise the waste product for safe disposal.

In this embodiment, the device 1 is a bodily fluid separation device, e.g. a blood separation device.

Referring now to Figures 2(a), 2(b) and 2(c) there is shown an apparatus or device for separating components of a fluid, generally designated 1', according to a second embodiment of the present invention. In this embodiment the container 5' is in the form of a flexible bag or pouch.

The separation device 1' comprises a container 5' which contains at least one separation or filtration member 10' capable of separating or filtering at least one component from a fluid 15', and a superabsorbent material 20' capable of removing the at least one component filtered through or separated by the member 10' disposed therein.

Conveniently, the separation device is capable of reducing the volume of the fluid-to-be-processed by at least 20%, preferably at least 30%, more preferably at least 40%, and typically approximately 50-80%.

In this embodiment, the filtration member 10' and the superabsorbent material 20' form two separate components.

The container 5' comprises an inlet, first opening or first aperture 25', typically near a top portion thereof for introducing the fluid 15' into the container 5'.

The inlet, first opening or first aperture 25' is in communication with a receiving portion, compartment or cavity 30' located inside the device 1' and into which the fluid 15' to be processed is initially received, prior to the separation/filtration step.

In use, the fluid 15' is provided into the receiving portion, compartment or cavity 30' of the device 1' through the inlet, first opening or first aperture 25'.

The volume and shape of the receiving portion, compartment or cavity 30' is at least partially defined by a first separation or filtration member 11'.

In this embodiment, the first member 11' is a self-supported member.

The member 11' comprises a first side 12' facing toward the receiving portion, compartment or cavity 30' and a second side 13' facing in the opposite direction.

In use, a fluid 15' fed into the receiving portion, compartment or cavity 30' of the device 1' comes into contact with a first side 12' of the member 11'.

The superabsorbent material 20' is in contact with or adjacent the second side 13' of the member 11'.

In this embodiment, the second side 13' of the member 11' is in contact with a support material 21' impregnated with the superabsorbent material 20'.

In this embodiment, the receiving portion, compartment or cavity 30' is provided between an inside wall 6' of the container 5' and a first side face of the at least one separation or filtration member 11'. In such an arrangement, in use, the at least one component selectively separated or filtered from the fluid 15' migrates inwardly, with respect to the wall of the container 5', from the receiving portion, compartment or cavity 30' towards the superabsorbent material 20'.

The superabsorbent material 20'is provided or enclosed within a volume defined by the second side face 13' of the at least one separation or filtration member 11'. By such provision the at least one separation or filtration member 11' and the superabsorbent material 20' define a pad-like assembly provided inside the container 5'.

In this embodiment, the member 11' comprises a substantially hollow portion 36' inside the volume defined by the second side face 13' of the member 11'. By such provision the impregnated material 21' is allowed to expand or swell upon absorption of the at least one filtered component.

Advantageously, the separation or filtration member 11' is attached to e.g., an inside wall 6' of the container.

In use, absorption by the superabsorbent material 20' "draws" a portion of fluid 15' comprising the at least one component through the separation or filtration member 10' whilst other components are retained in the receiving portion, compartment or cavity 30'. By such provision the apparatus 1' does not require application of any external force to separate the at least one component from the fluid 15'.

The receiving portion, compartment or cavity 30' is in communication with an outlet, second opening or second aperture 40', typically near a bottom portion of the container 5', for removal of the processed fluid.

The outlet, bottom opening or bottom aperture 40' is further equipped with a flow control system 45', e.g. a valve or a seal.

In use, a processed fluid 16' may be retrieved or recovered from the receiving portion, compartment or cavity 30' of the device through the outlet, second opening or second aperture 40'.

Alternatively, the processed fluid 16' may be retrieved or recovered from the receiving portion, compartment or cavity 30' of the device 1' through the inlet, first opening or first aperture 25', e.g. by inverting the device.

In this embodiment, the container 5' is in the form of a flexible bag or pouch. By such provision the device is suitable for flat pack storage.

The container 5' is made from a polymeric material, e.g. medical grade polyvinyl chloride (PVC).

The container 5' comprises a substantially transparent portion (not shown), e.g. a transparent vertical strip. By such provision the inside of the receiving portion, compartment or cavity 30' of the device 1' is visible by a user during use.

The substantially transparent portion of the container 5' is provided with measuring means to indicate the level or volume of fluid present inside the receiving portion, compartment or cavity 30'. By such provision, after filling the device 1' with a desired quantity of fluid 15', a user may be able to determine when a sufficient amount of the component-to-be-removed has been absorbed by the superabsorbent material 20'.

The at least one separation or filtration member 10' is a membrane 14', e.g. a semi-permeable porous filtration membrane.

The membrane 14' is made from a polyolefin material, e.g. "Celgard 2500" microporous polypropylene flat sheet membrane (0.2 μm pore size) from Celgard LLC, 13800 South Lakes Dr, Charlotte, NC 28273, U.S., or another polymeric material such as nylon or a MicroPES® polyethersulfone hydrophilic flat membrane (Type "4F toa", "5F M", or "6F") from Membrana GmbH, Oehder Straβe 28, D-42289 Wuppertal, Germany.

The permeability of the membrane 14' is chosen according to the type of fluid 15' to be processed and/or the specific components to be separated or removed from the fluid 15'.

For example, when using a Celgard 2500 membrane, an effective membrane pore size of 0.2 μm will allow water, small salts and proteins to pass through the membrane.

The superabsorbent material 20 is made from a superabsorbent polymer, e.g. "Super Absorber" (99%+ Cellulose Sodium Polyacrylate superabsorber) from Brightwake Ltd, Lowmoor Business Park, Kirkby-in-Ashfield, Nottinghamshire NG17 7JZ, UK.

In this embodiment, the superabsorbent material 20' is in powder form.

In use, the superabsorbent material 20' forms a stable gel upon absorption of a fluid, e.g. water.

The at least one component separated from a fluid 15' is permanently removed from the fluid 15' and/or retained by the superabsorbent 20'.

The support material 21' impregnated with the superabsorbent material 20' comprises a cellulosic material or a polyester material, e.g. a cellulose tissue material or a polyester fibre material.

In this embodiment, the polyacrylate superabsorbent material impregnated in a cellulosic fibrous material is in the form of a Brightwake wound dressing.

The superabsorbent material 20' and/or the support material 21' may further comprise additives.

Conveniently, the superabsorbent material 20' and/or the support material 21' are impregnated with stabilising agents, e.g. anti-microbial agents, to further stabilise the waste product for safe disposal.

The device 1' is provided with attaching means or holes 50' for attaching the device 1' to a static piece of surgical equipment, e.g. a stand or a bed, or to agitation means.

In this embodiment, the device 1' is a bodily fluid separation device, e.g. a blood separation device.

In use, a subject's bodily fluid may provided into the receiving portion 30' of the separation device 1', while the device 1' is provided on or attached to a static piece of surgical equipment such as a stand or a bed. When a desired amount of bodily fluid 15' is provided in the separation device 1', the inlet 25' is closed or sealed to prevent leakage, and the device 1' is transferred to agitation means to improve separation efficiency.

Alternatively, the separation device 1' may be provided on or in said agitation means prior to its receiving portion 30' being filled with a subject's bodily fluid 15'. By such provision agitation may be applied either simultaneous or subsequent to a subject's bodily fluid 15' being provided into the receiving portion 30' of the device 1'.

Figure 3 shows the effect of agitation on the efficiency of a separation device according to the second embodiment of the present invention, when the processed fluid is blood. Figure 3 illustrates the significant enhancement of the efficiency of the separation device when an orbital shaker is used in combination with the separation device. For example, Figure 3 shows approximately a 2-fold increase in packed cell volume concentration after 30 minutes when an orbital shaker is used. It is believed that agitation prevents the larger blood particles from covering or aggregating on the surface of the filtration member, e.g. a semi-permeable membrane. Such effect can occur as the filtered component is drawn from the fluid and absorbed by or into the superabsorbent material through the filtration member. Agitation ensures, in use, homogeneous mixing of the fluid to-be-processed, e.g. blood, thus maintaining the efficiency of the filtering member by preventing covering of its surface by larger particles.

It will be appreciated that the embodiments of the invention hereinbefore described are given by way of example only and are not meant to limit the scope thereof in any way.

It will particularly be appreciated that while the fluid processed by the separation device of the disclosed embodiments consists of blood, the invention may be applied to process other fluids, e.g. other types of bodily fluids.

CLAIMS

1. A system comprising:

an apparatus or device for separating components of a fluid comprising a container having at least one separation or filtration member capable of selectively separating or filtering at least one component from the fluid, and a superabsorbent material capable of absorbing the at least one component separated from the fluid, and thereby providing a processed fluid free or substantially free of said at least one component; and

agitation means.

2. The system of claim 1, wherein the agitation means comprises a receiving portion for receiving the separation apparatus.

3 The system of claim 1 or claim 2, wherein the agitation means comprises a closably openable covering portion for protecting the separation device.

4. The system according to any of claims 1 to 3, wherein the agitation means comprises an orbital shaker.

5. An apparatus or device for separating components of a fluid comprising a container having at least one separation or filtration member capable of selectively separating or filtering at least one component from the fluid, and a superabsorbent material capable of absorbing the at least one component separated from the fluid, and thereby providing a processed fluid free or substantially free of said at least one component.

6. The apparatus of claim 5, the apparatus being capable of reducing the volume of the fluid-to-be-processed by at least 20%, preferably at least 30%, more preferably at least 40%, and typically approximately 50-80%.

7. The apparatus of claim 5 or claim 6, wherein the filtration member and the superabsorbent material are formed from two separate components.

8. The apparatus accordingly to any of claim 5 to 7, wherein the container comprises a receiving portion, compartment or cavity located inside the device, the receiving portion, compartment or cavity being in communication with an inlet, first opening or first aperture for introducing the fluid into the container, and with an outlet, second opening or second aperture for removal of the processed fluid.

9. The apparatus of claim 8, wherein the volume and shape of the receiving portion, compartment or cavity is at least partially defined by the at least one separation or filtration member.

10. The apparatus accordingly to any of claims 5 to 9, wherein the at least one separation or filtration member is a self-supported member.

11. The apparatus accordingly to any of claims 5 to 10, wherein the at least one separation or filtration member comprises a first side face facing toward the receiving portion, compartment or cavity and a second side face facing in the opposite direction.

12. The apparatus of claim 11, wherein the superabsorbent material is in contact with or adjacent the second side face of the at least one separation or filtration member, and located between the second side face of the member and an inside wall of the container, the apparatus comprising a substantially hollow portion between the superabsorbent material and the inside wall of the container.

13. The apparatus of claim 12, wherein the receiving portion, compartment or cavity is provided between an inside wall of the container and a first side face of the at least one separation or filtration member.

14. The apparatus of claim 13, wherein the superabsorbent material is provided or enclosed within a volume defined by the second side face of the at least one separation or filtration member, said volume further comprising a substantially hollow portion.

15. The apparatus accordingly to any of claims 5 to 14, wherein the superabsorbent material is impregnated in a support material.

16. The apparatus accordingly to any of claims 5 to 15, wherein the container is in the form of a flexible bag or pouch.

17. The apparatus of claim 16, wherein the bag or pouch is made from a polymeric material, such as medical grade polyvinyl chloride (PVC) or a polyolefin material.

18. The apparatus accordingly to any of claims 5 to 17, wherein the at least one separation or filtration member is a membrane, such as a semi-permeable porous filtration membrane.

19. The apparatus accordingly to claim 18, wherein the membrane is made from a polyolefin material such as polypropylene, or another polymeric material such as nylon or polyethersulfone.

20. The apparatus of claim 18 or claim 19, wherein the effective membrane pore size is in the range of approximately 0.1 μm - 10 μm, especially approximately 0.2 μm - 8 μm.

21. The apparatus accordingly to any of claims 5 to 20, wherein the superabsorbent material is in powder form, and form a stable gel upon absorption of a fluid, e.g. water.

22. The apparatus of claim 21, wherein the superabsorbent material is made from a superabsorbent polymer such as a polyacrylate or a polyacrylamide, especially sodium polyacrylate.

23. The apparatus according to any of claims 15 to 22, wherein the support material impregnated with the superabsorbent material comprises a cellulosic material or a polyester material, such as a cellulose tissue material or a polyester fibre material.

24. The apparatus according to any of claims 5 to 23, wherein the apparatus is a bodily fluid separation device, such as a blood separation device.

25. The apparatus according to any of claims 5 to 24, further comprising attaching means for attaching the apparatus to a static piece of surgical equipment, e.g. a stand or a bed, or to agitation means, e.g. to vibrating or shaking means.

26. A system comprising an apparatus or device for separating components of a fluid according to any of claims 6 to 25; and agitation means.

27. The system of claim 26, wherein the agitation means comprises a receiving portion for receiving the separation apparatus.

28 The system of claim 26 or claim 27, wherein the agitation means comprises a closably openable covering portion for protecting the separation device.

29. The system according to any of claims 26 to 28, wherein the agitation means comprises an orbital shaker.

30. A method for processing a fluid comprising separating or filtering at least one component from the fluid using at least one separation or filtration member,

and retaining or removing said at least one separated or filtered component by a superabsorbent material.

31. The method of claim 30, further comprising a preliminary step consisting of providing a fluid into a separation apparatus, and a subsequent step consisting of retrieving or recovering a processed fluid from the separation apparatus.

32. The method of claim 31, comprising continuously providing a fluid inside the apparatus via an inlet, first opening or first aperture, and continuously retrieving the processed fluid via an outlet, second opening or second aperture.

33. The method according to any of claims 30 to 32, comprising agitating the device during processing of the fluid.

34. The method according to any of claims 30 to 33, further comprising disposing of the separation device upon retrieval or recovery of the processed fluid.

35. The method according to any of claim 30 to 34, comprising processing a bodily fluid, e.g. blood.

36. The method according to any of claims 30 to 35, comprising using the apparatus according to any of claims 5 to 25, or the system according to any of claims 1 to 4 or 26 to 29.

37. Use of a superabsorbent material for separating or removing at least one component from a bodily fluid.

38. The use according to claim 37, wherein the bodily fluid is blood.

39. The use according to claim 37 or claim 38, wherein the superabsorbent material is made from a superabsorbent polymer such as a polyacrylate or a polyacrylamide, especially sodium polyacrylate.

40. The use according to claim 39, wherein the superabsorbent material is in powder form, and forms a stable gel upon absorption of a fluid, e.g. water.

41. The use according to any of claims 37 to 40, wherein the superabsorbent material is impregnated into a support material made from a material such as a cellulose tissue material or a polyester fibre material.

42. An apparatus for separating components of a fluid as described herein with reference to the accompanying drawings.

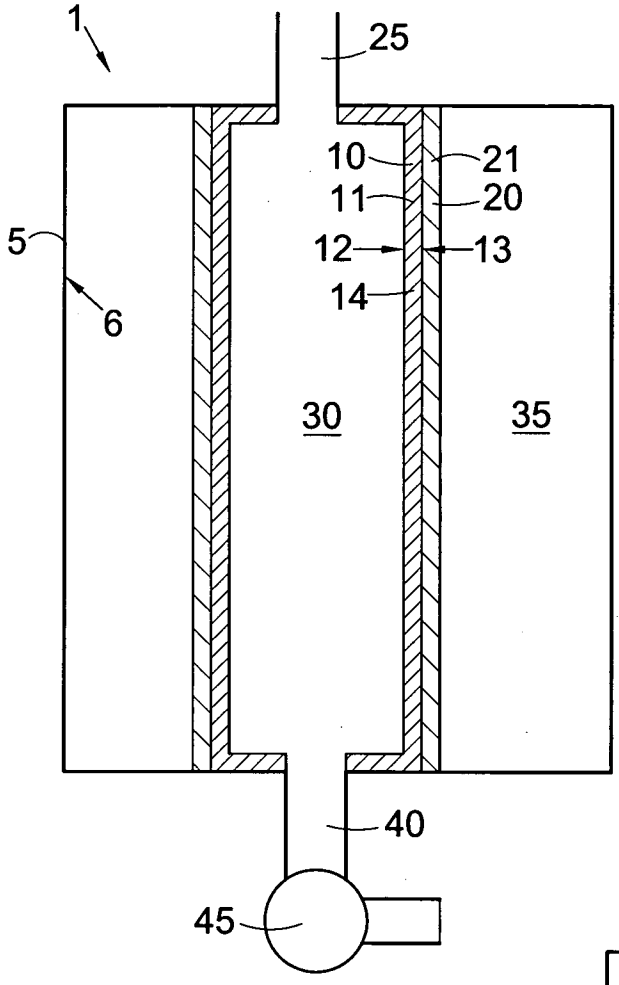
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Fig. 1(a)

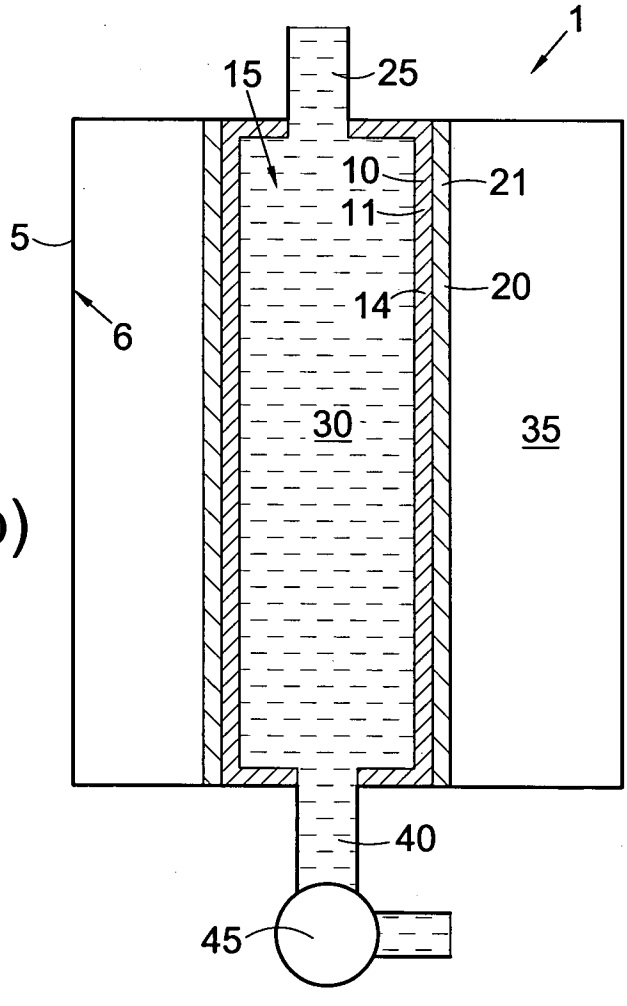
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Fig. 1(b)

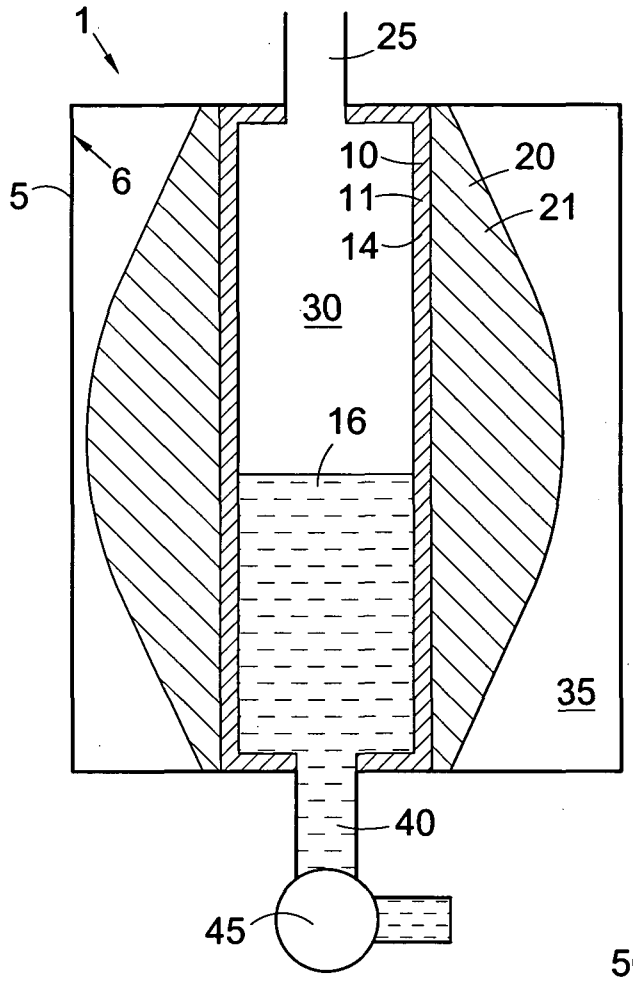


Fig. 1(c)

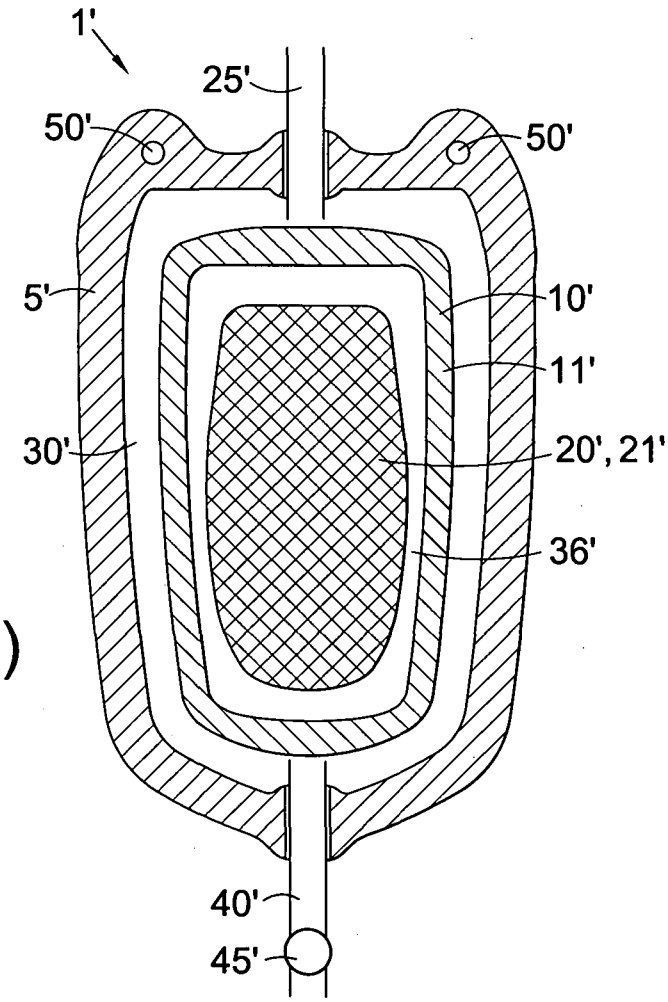
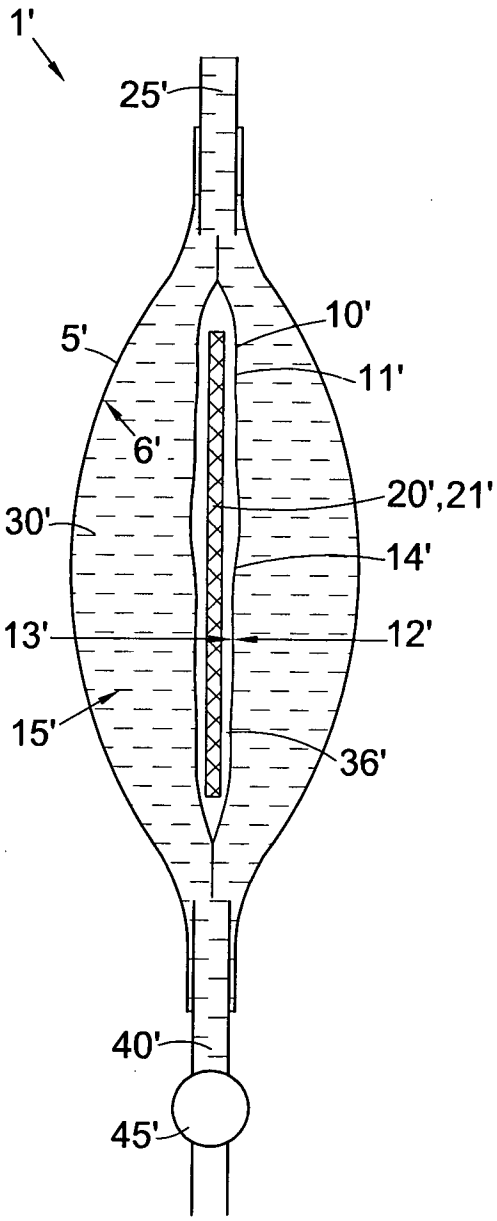


Fig. 2(a)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14'
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12'
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45'

Fig. 2(b)

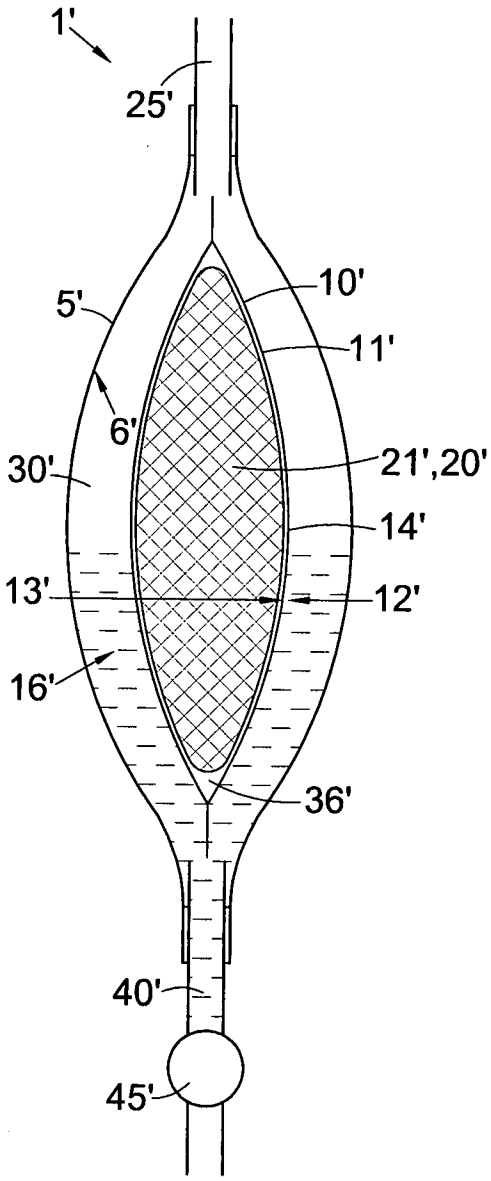
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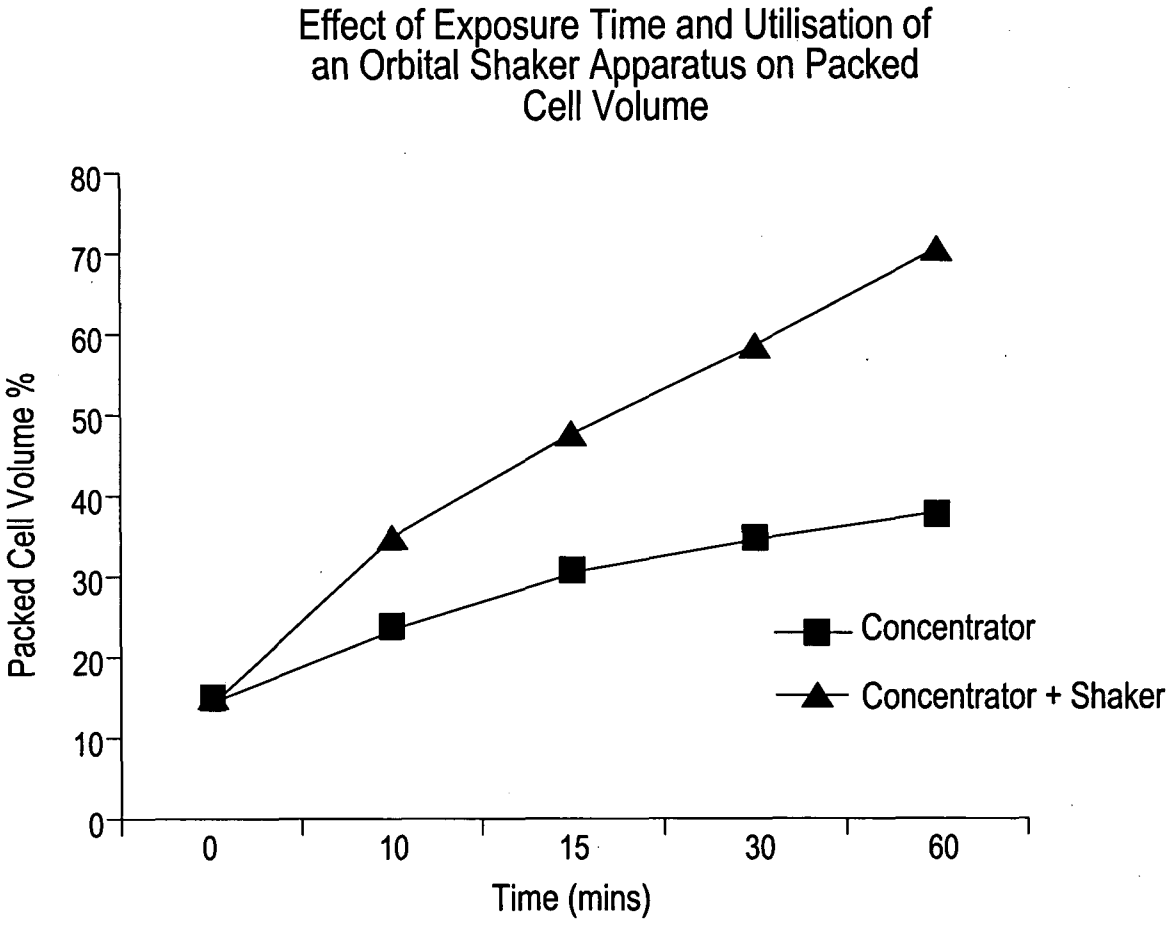
Fig. 2(c)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60
50
40
30
20
10
0
0
10
15
30
60
Time (mins)
Concentrator
Concentrator + Shaker

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001233

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/34 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/175242 A1 (DORIAN RANDEL [US]; LEACH MICHAEL D [US]) 10 August 2006 (2006-08-10) paragraph [0126] - paragraph [0139]; figures 18-28 paragraph [0083] paragraph [0116]	1-11,15, 25-31, 33-41
X	US 3 485 751 A (HERRMANN WALTER L; SPADONI LEON R) 23 December 1969 (1969-12-23) claims 1-3; figures	1-3,5-9, 11-14, 16-28, 30-31, 33-37, 39-41

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 October 2009	20/10/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Villeneuve, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001233

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 3 742 946 A (GROSSMAN C) 3 July 1973 (1973-07-03) column 3, line 6 - line 46; figures	5-12, 18-25 1-4, 15-17, 19-41
Y	US 5 211 850 A (SHETTIGAR UDIPI [US]; MCREA JAMES C [US]) 18 May 1993 (1993-05-18) abstract	1-4, 15-17, 19-41
A	US 4 206 050 A (LAMMERS LUDWIG [DE]; MICHEL WOLFGANG [DE]; WALCH AXEL [DE]) 3 June 1980 (1980-06-03)	1,5

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB2009 /001233

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 42

Art 6 PCT

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2009/001233

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 42
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2009/001233

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006175242 A1	10-08-2006	EP 1848474 A2	31-10-2007
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		EP 0643614 A1	22-03-1995
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		JP 53142092 A	11-12-1978
		NL 7805215 A	20-11-1978
		SE 7805484 A	17-11-1978