A modification in the configuration of the blood microtubular filter/dializer used in many kinds of renal replacement therapy systems can provide highly effective mechanism for removing air from the blood circuit of such systems. In embodiments, for example, the invention takes advantage of the slow flow rate that usually occurs where blood exits the microtubules into a header area of the filter to provide a settling area and, preferably, a air relief mechanism.
BLOOD TREATMENT DIALYZER/FILTER DESIGN TO TRAP ENTRAINED AIR IN A FLUID CIRCUIT

BACKGROUND

[0001] One of the problems with fluid circuits in blood treatment systems is entrained air (bubbles) in treatment fluids, infusate, or blood. Treatment systems normally have air detectors to prevent air from being injected into a patient, either because a venous line carrying blood back to the patient contains air or because an infusate line, such as the replacement fluid line of a hemofiltration system, contains air. It is desirable for the air detectors to be made sufficiently sensitive to prevent the rare instances of long trains of air bubbles being injected into a patient. But sensitivity high enough to prevent long trains of bubbles may be high enough to alarm very small amounts of air which pose no risk. In other words, sensitive air detectors alarm on a lot of false positives if they protect against all possible risks.

[0002] To eliminate false positives, a prior art approach has been to remove as much air from a protected fluid circuit as possible. Putting air traps in fluid circuits, particularly blood lines, has drawbacks. Air-settling chambers necessarily involve stagnant flow, which creates a risk of forming clots (e.g., for blood) or sedimentation or other concentration of entrained material (e.g., medication).

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] FIG. 1 is a cross-section view of a filter usable in a variety of different types of blood treatment systems oriented to trap air in one or two header portions of the filter.

[0004] FIG. 2 illustrates a holder of a blood treatment machine to orient the filter of FIG. 1.

[0005] FIG. 3 illustrates a filter similar to that of FIG. 1 but with a header port for removing air and/or disrupting or cleaning clots.

[0006] FIG. 4 illustrates an assembly for use with the port of FIG. 3 for removing air and/or disrupting or cleaning clots.

[0007] FIG. 5 illustrates a header cap with a hydrophobic membrane for automatically venting air.

DETAILED DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a cross-section view of a filter usable in a variety of different types of blood treatment systems oriented to trap air in one or two header portions of the filter. A filter 100, which may be a dialyzer, hemofilter, hemodialfiltr, or any other compatible blood treatment has a bundle of tubular media 132 connecting an arterial 160 and venous 155 head space which is isolated from a filtrate space 130. Blood flows through ports 122 and 124 in header caps 110 and 136 as indicated by arrows 112 and 116 into and out of the arterial 160 and venous 155 head spaces, respectively. A cylindrical filter body 128 encloses the filtrate space 130 and contains filtrate (e.g., dialyzer) ports 126 and 120. Arterial and venous headers 142 and 134 isolate the filtrate space 130 from the respective arterial 160 and venous 155 head spaces.

[0009] The orientation of the filter 100 with respect to the pull of gravity is shown with the understanding that gravity is assumed to pull down with respect to the profile orientation of the drawing page. If any air is entrained in the blood, it may settle in pockets 151 and 153 in the arterial 160 and venous 155 head spaces as indicated by air/liquid interfaces 152 and 150. The flow of blood through the arterial 160 and venous 155 head spaces is extremely slow due to the very small cross-sectional areas of the filter fibers in the bundle 132. As a result, the arterial 160 and venous 155 head spaces are an ideal place for air to settle out. With the indicated orientation, with blood outlet 124 pointing down and away from the pocket 151. Since the blood moves at a very slow rate in the arterial 160 and venous 155 head spaces, there is little risk of reentrainment and air settles out very effectively.

[0010] Air trapped in pocket 153 may travel through filter fibers in bundle 132 up to venous head space 155 and accumulate in pocket 151. Since the pocket 153 is located near the top of the arterial head space 160, air will tend to travel up a few of the fibers closest to the top and collect in the pocket 151 without mixing in with blood. This keeps the vast majority of fibers filled with blood.

[0011] FIG. 2 illustrates a holder 175 of a blood treatment machine to orient the filter of FIG. 1. The holder 175 may be attached at a base thereof (not shown separately) to a blood treatment machine 172 which may contain actuators, sensors, and control elements as well as a fluid circuit, here illustrated as a cartridge 180 enclosed between two parts 171 and 172 of the blood treatment machine 172. A filter 100 that is preconnected to the fluid circuit can easily be mounted in such an apparatus. The holder 175 may be articulating to allow for some movement or change of orientation of the filter 100 and is preferably a spring tensioned clamp that allows for one-handed insertion of a filter 100. In an alternative embodiment, the holder 175 may be attached to the 180 cartridge such that its orientation is obtained when the cartridge 180 is positioned with respect to the blood treatment machine 170.

[0012] FIG. 3 illustrates a filter similar to that of FIG. 1 but with a header cap 210 having an integrated header port 200 for removing air and/or disrupting or cleaning clots. Tubing 265 may be connected to the port and provided with a clamp 260. The clamp 260 may be released, at intervals, by an operator, to vent air from the air pocket 251 and re-engaged to prevent blood loss. The clamp 260 may be a normally-closed type clamp with a strong spring so that it reclamps tubing 265 when released. The tubing 265 may be copped with a microporous filter end cap 253 to prevent any contamination re-entering the blood in the venous head space 155. The entire assembly that includes the filter 100, tubing 265, and microporous filter end cap 253 may be fused, sealed, and sterilized as a unit. In addition the same may be fused, sealed and sterilized as a unit with an entire treatment circuit, combining it with the circuit described in U.S. patent application Ser. No. 10/650,935 published as US 2004-0069709, which is hereby incorporated by reference as if full set forth in its entirety herein. With this combination, the entire circuit may be isolated from contamination.

[0013] FIG. 4 illustrates an assembly 350 for use with the port of FIG. 3 for removing air and/or disrupting or cleaning clots. The port 200 has a tube 310 connecting the venous head space 155 with a stopcock 312. The stopcock 312 is further connected to a syringe 320 and tubing 375 connecting a supply of blood normal saline 375 and 360. The stopcock allows the syringe to be connected, in a first position, to draw saline from the source of saline 375 and, in a second position, air from the venous head space 155. In the second position, saline may be pushed into the head space 155 to clear clots or for prophylaxis by injecting heparin. In an illustrative usen method, the stopcock 312 is set in the second position and air is drawn from the head space 155. Then it is set in the first position and saline is drawn into the syringe 320. Then the
stopcock 312 is set in the second position again and saline (or saline and heparin) is injected into the venous head space 155. The apparatus including the stopcock 312, syringe 320, tubing 310, 375, 360 and clamp 260 may be pre-attached to the filter 100 and presterilized as a unit.

[0014] FIG. 5 illustrates a header cap 210 with cover 280 sealed to and covering the header port 200. The cover includes a hydrophobic membrane 285 that allows air in the head space 155 to vent automatically while preventing any contamination from entering.

1. A blood treatment apparatus, comprising:
   a blood processing element including filter media through which blood passes;
   said processing element having a header chamber at a position
   where blood exits a portion of said blood processing element, said header chamber having at least one outlet;
   a holder configured to support said processing element in a
   position and orientation such that air can accumulate in
   said header chamber in a position remote from said
   outlet whereby said header chamber is enabled to
   remove air from blood.

2. Apparatus as in claim 1, wherein said processing element
   is attached to a fluid circuit and forms a part of a
   disposable set.

3. Apparatus as in claim 1, wherein said holder is fixedly
   attachable to a blood treatment machine.

4. Apparatus as in claim 1, wherein said holder is configured
   to support said filter at an angle with respect to the
   vertical, as defined with respect to the force of gravity.

5. Apparatus as in claim 1, wherein said processing element
   includes tubular membrane media that are vertically
   oriented in ordinary use.

6. A blood treatment apparatus, comprising:
   a blood dialyzer or hemofilter processing element includ-
   ing filter media through which blood passes;
   said processing element having a header chamber at a position
   where blood exits a portion of said blood processing element, said header chamber having at least one blood outlet and at least one auxiliary outlet;
   said holder configured to support said dialyzer or hemofilter in
   a position and orientation such that air can accumulate in
   said header chamber in a position in said header space
   that is adjacent and in communication with said auxiliary
   outlet.

7. Apparatus as in claim 6, wherein said auxiliary outlet is
   remote from said blood outlet.

8. Apparatus as in claim 6, wherein said auxiliary outlet is
   opposite said blood outlet.

9. Apparatus as in claim 6, further comprising a valve
   connected to said auxiliary port and pre-connected and ster-
   ilized together with said blood processing element.

10. Apparatus as in claim 6, further comprising a stopcock
    connected to said auxiliary port and pre-connected and ster-
    ilized together with said blood processing element.

11. Apparatus as in claim 6, further comprising a syringe
    connected to said auxiliary port and pre-connected and ster-
    ilized together with said blood processing element.

12. Apparatus as in claim 6, further comprising a holder
    configured to orient said blood processing element such that
    said at least one blood outlet is lower, with respect to a
    direction of gravity, than said auxiliary outlet.

13. Apparatus as in claim 6, further comprising an gas
    release component connected to said auxiliary port and pre-
    connected and sterilized together with said blood processing
    element, said air release component being configured to per-
    mit gas to egress from said header space without permitting
    blood to egress from said header space.

14. Apparatus as in claim 13, wherein said air release component
    includes a hydrophobic membrane.

15. A blood treatment apparatus, comprising:
    a blood dialyzer or hemofilter processing element includ-
    ing filter media through which blood passes;
    said processing element having a chamber at an exit of a
    treatment portion thereof where blood flow velocity drops to
    a low rate, said chamber having at least one outlet;
    a holder attachable to a blood treatment machine and con-
    figurable to support said processing element in a posi-
    tion and orientation such that air can accumulate in said
    header chamber in a position remote from said outlet
    whereby said header chamber is enabled to remove air
    from blood.

16. Apparatus as in claim 15, wherein said processing element
    is attached to a fluid circuit and forms a part of a
    disposable set.

17. Apparatus as in claim 16, wherein said holder is configured
    to support said filter at an angle with respect to the
    vertical, as defined with respect to the force of gravity.

18. Apparatus as in claim 15, wherein said holder is configured
    to support said filter at an angle with respect to the
    vertical, as defined with respect to the force of gravity.

19. Apparatus as in claim 15, wherein said processing element
    includes tubular membrane media that are vertically
    oriented in ordinary use.

20. A blood treatment apparatus, comprising:
    a blood processing element including filter media through
    which blood passes;
    said processing element having a header chamber at a position
    where blood exits a portion of said blood processing element, said header chamber having at least one blood outlet and one auxiliary outlet;
    said auxiliary outlet being configured to permit the removal
    of air accumulated in said header chamber and/or addi-
    tion and removal of biocompatible non-blood fluid.

21. Apparatus as in claim 20, further comprising a valve
    connected to said auxiliary port and pre-connected and ster-
    ilized together with said blood processing element.

22. Apparatus as in claim 20, further comprising a stopcock
    connected to said auxiliary port and pre-connected and ster-
    ilized together with said blood processing element.

23. Apparatus as in claim 20, further comprising a syringe
    connected to said auxiliary port and pre-connected and ster-
    ilized together with said blood processing element.

24. Apparatus as in claim 20, further comprising a holder
    configured to orient said blood processing element such that
    said at least one blood outlet is lower, with respect to a
    direction of gravity, than said auxiliary outlet.

25. Apparatus as in claim 20, further comprising a gas
    release component connected to said auxiliary port and pre-
    connected and sterilized together with said blood processing
    element, said air release component being configured to per-
    mit gas to egress from said header space without permitting
    blood to egress from said header space.

26. Apparatus as in claim 25, wherein said air release component
    includes a hydrophobic membrane.

* * * * *