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Jusiak et al.

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(45) **Date of Patent: May 31, 2005**

(54) **INSERTABLE FLUID WARMING CASSETTE UNIT**

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(73) Assignee: **Gaymar Industries, Inc.**, Orchard Park, NY (US)

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(21) Appl. No.: **10/793,547**

(22) Filed: **Mar. 4, 2004**

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Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61F 7/12**
(52) **U.S. Cl.** **392/470**; 604/113; 165/46
(58) **Field of Search** 392/470; 604/93.01, 604/113, 114; 165/46

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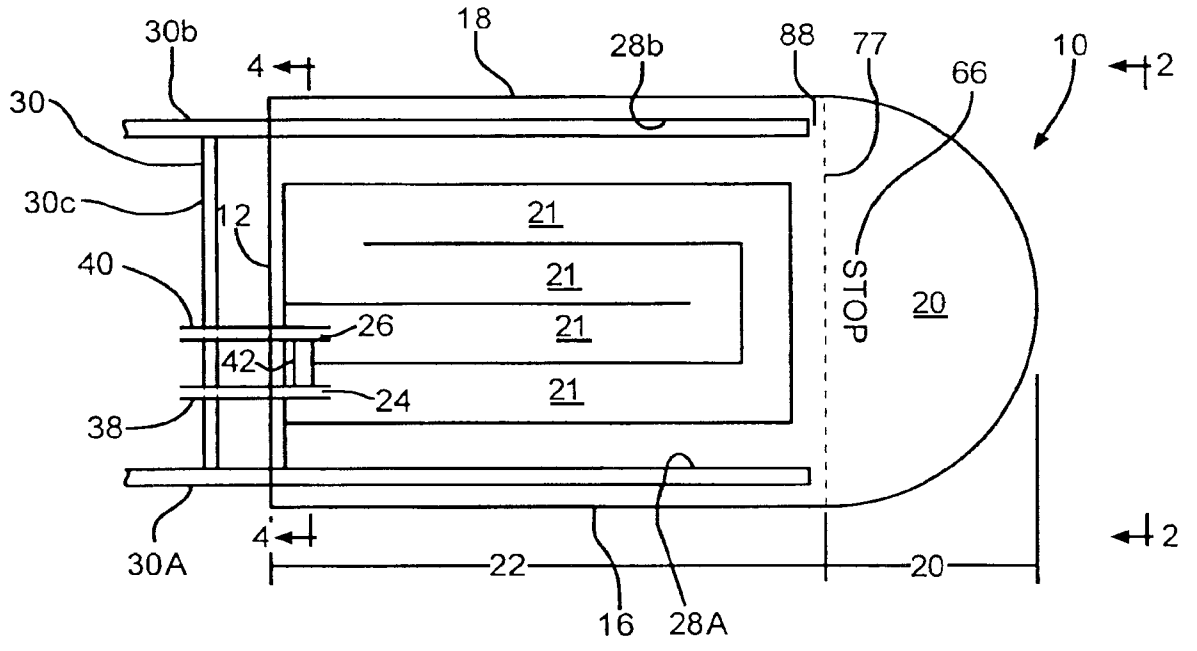
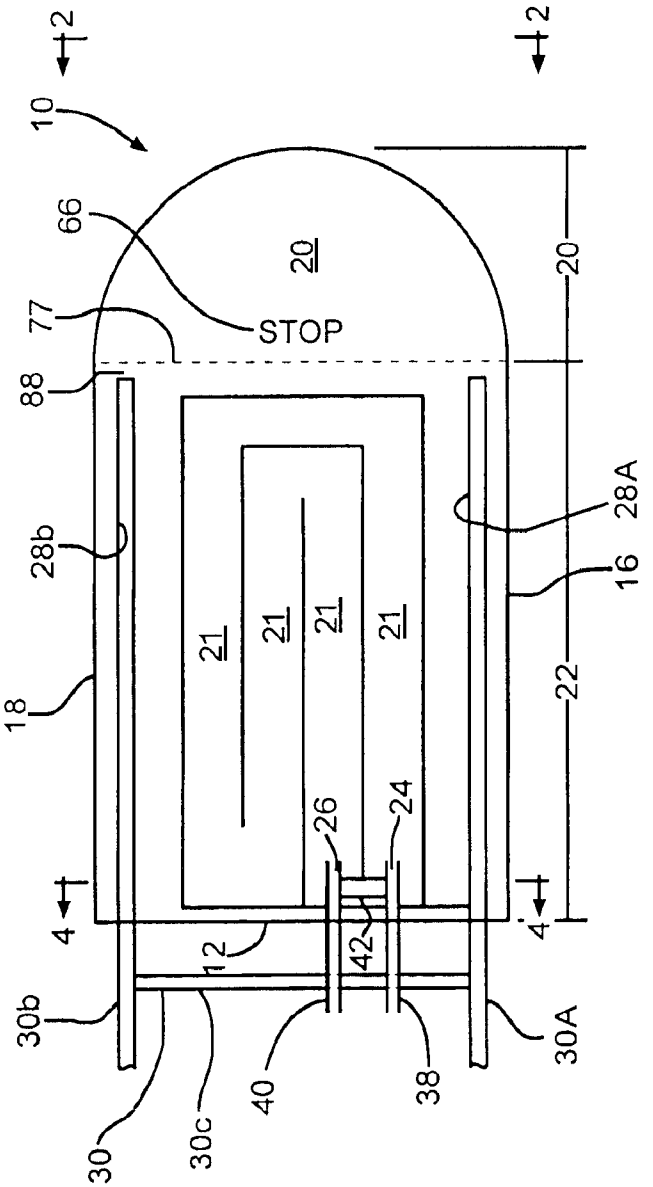
(57) **ABSTRACT**

The present invention is directed to a fluid warming cassette. The cassette has two polymeric films and at least two guide rails. A difference between this fluid warming cassette and those of the prior art is that this fluid warming cassette has a tongue section thereon. This tongue section assists the user insert the cassette into a warming unit's aperture. That aperture is relatively narrow because the heating elements of the warming unit must be sufficiently close to the cassette to alter the temperature of the fluid in the cassette to a desired temperature. In addition, the user can confirm if the cassette is properly inserted into the warming device's aperture by seeing that the tongue portion is sticking out of the other end of the warming device's aperture.

42 Claims, 5 Drawing Sheets

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10
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77
88
20
28b
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21
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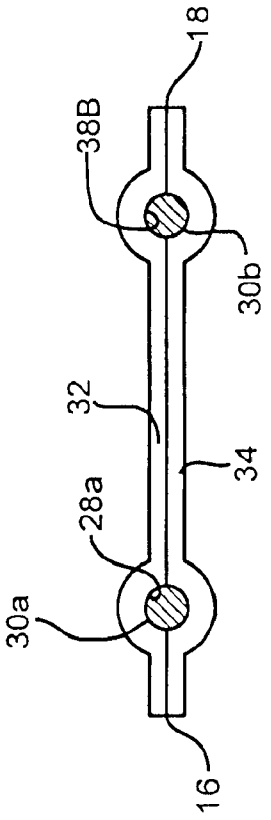
24
4
12
42
30b
30A
30
30c
40
38

FIG. 1


18
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32
34
28a
30a
16

FIG. 2

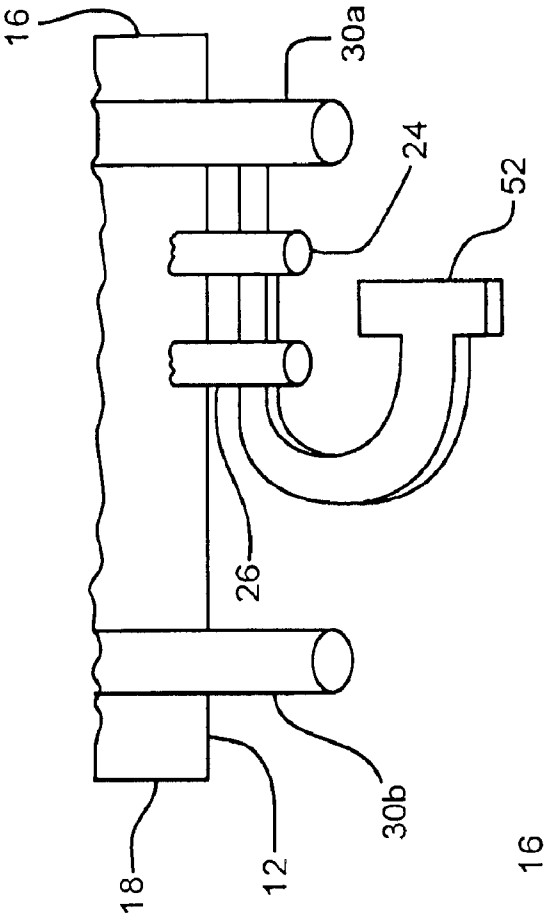


FIG. 4b

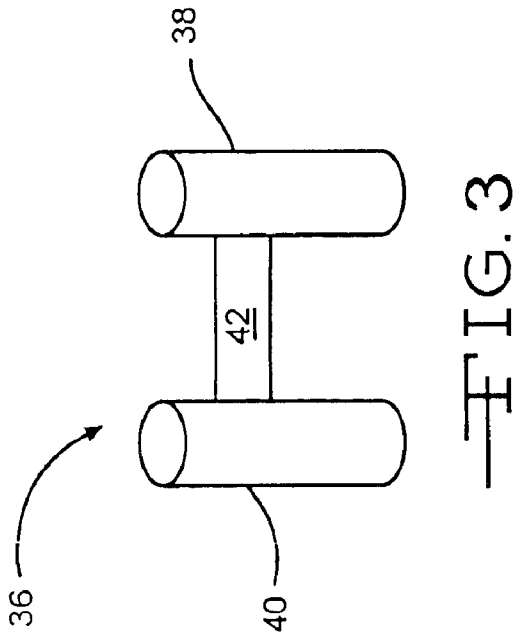


FIG. 3

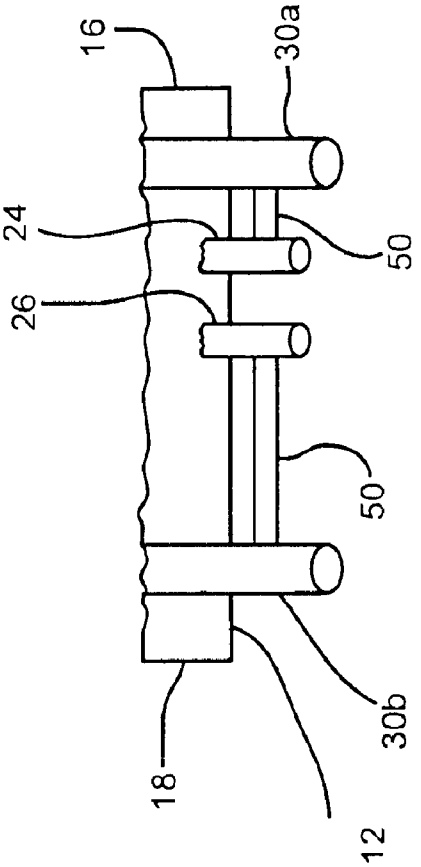


FIG. 4a

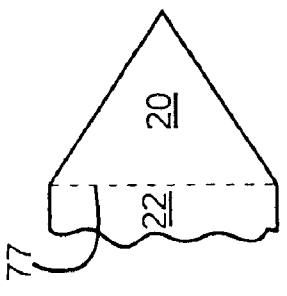


FIG. 5a

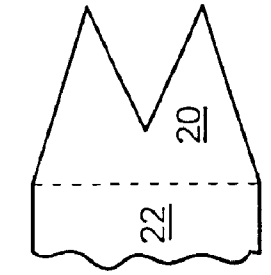


FIG. 5b

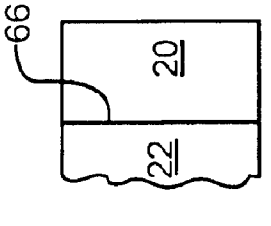


FIG. 5e

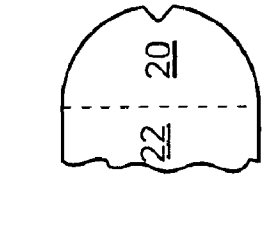


FIG. 5g

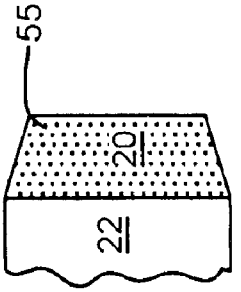


FIG. 5c

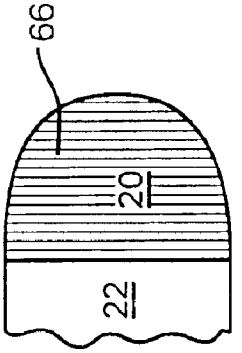


FIG. 5d

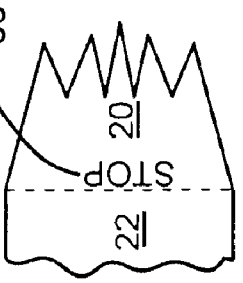


FIG. 5f

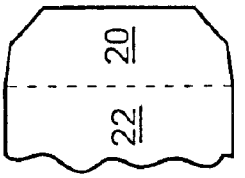


FIG. 5h

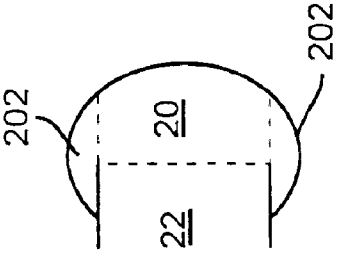


FIG. 5i

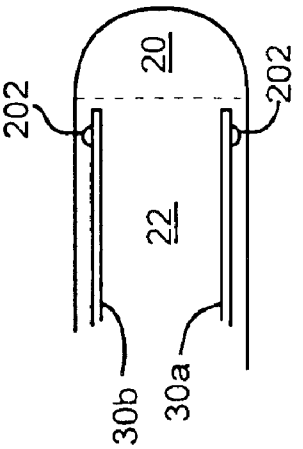


FIG. 5j

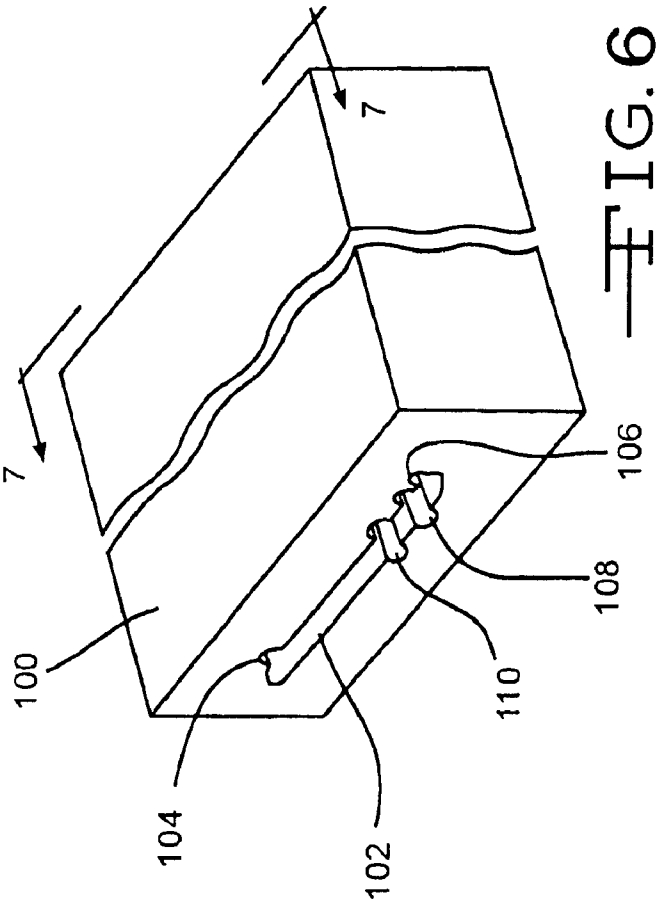


FIG. 6

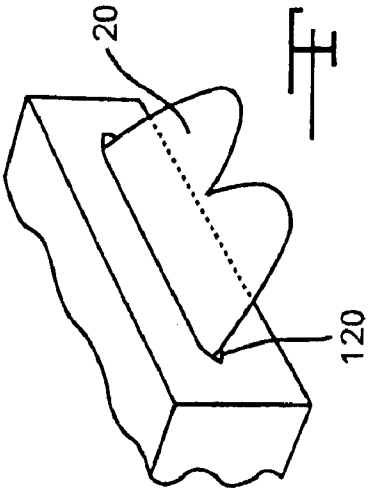


FIG. 7

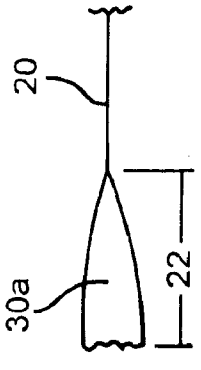


FIG. 8a

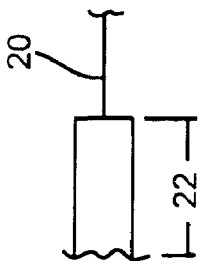


FIG. 8b

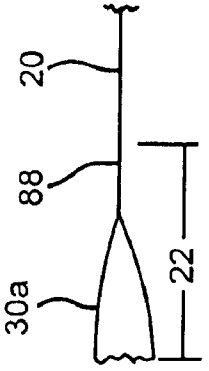


FIG. 8c

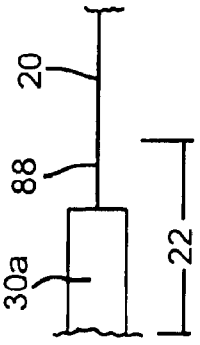
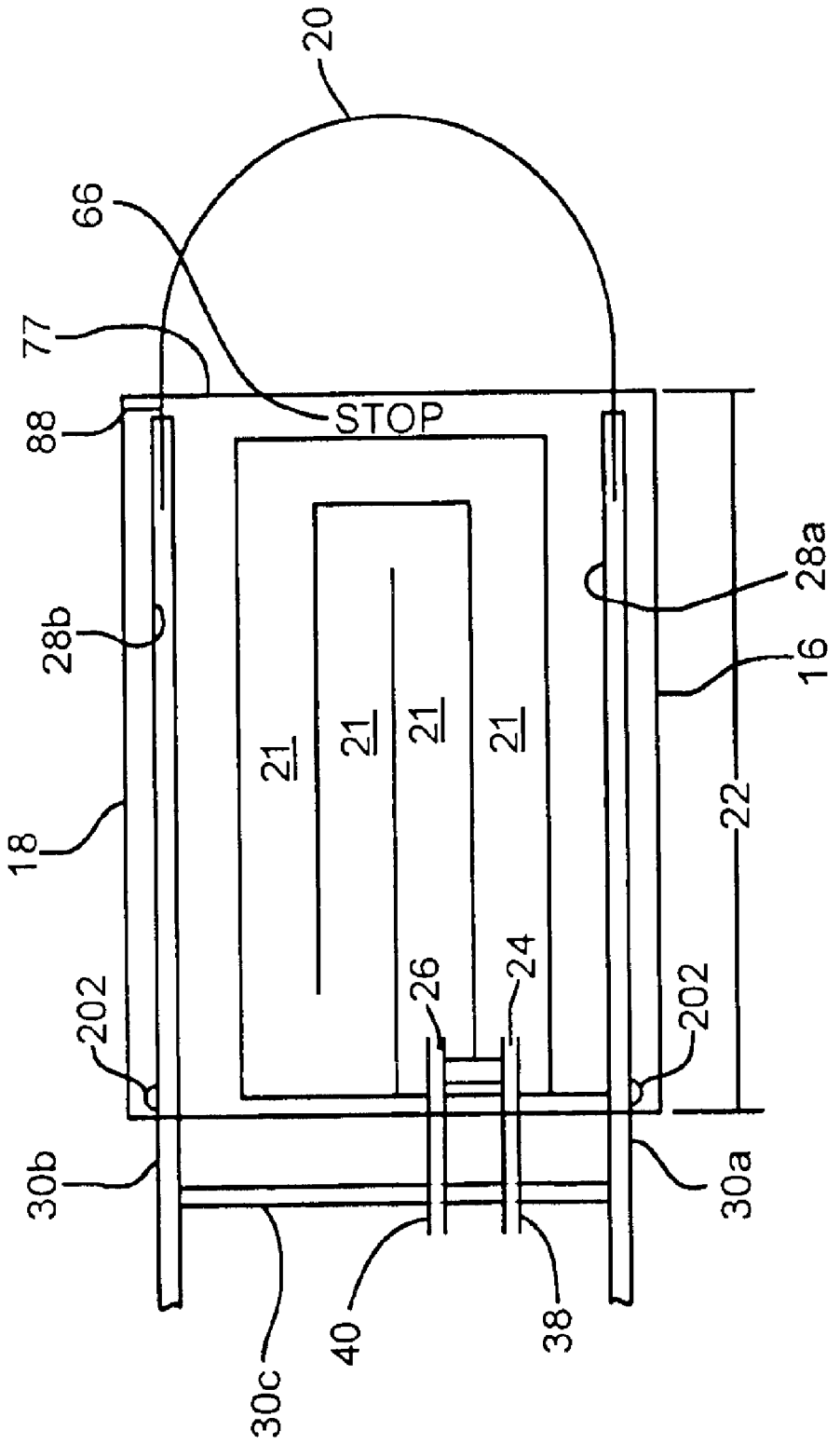


FIG. 8d


20
66
77
88
STOP
28a
28b
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21
21
21
21
18
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202
26
24
202
30b
30a
30c
40
38

FIG. 9

INSERTABLE FLUID WARMING CASSETTE UNIT

CLAIM OF PRIORITY

This application claims priority to U.S. provisional patent application Ser. No. 60/451,731 which was filed on Mar. 4, 2003.

FIELD OF THE INVENTION

The present invention is directed to fluid warming cassettes.

BACKGROUND OF THE INVENTION

There are numerous types of fluid warming cassettes. Some of them are disclosed in U.S. Pat. No. 6,464,666 to Augustine; U.S. Pat. No. 5,875,282 to Jordan et al.; U.S. Pat. No. 4,731,072 to Aid; U.S. Pat. No. 4,707,587 to Greenblatt; and U.S. Pat. No. 3,485,245 to Lahr et al.

Lahr et al. disclose a fluid warming cassette. That fluid cassette has an inlet to allow a fluid enter a counter-flow serpentine fluid path. The counter-flow serpentine fluid path is defined in the fluid warming cassette by joining portions of at least two layers of polymeric film together. The fluid exits the fluid warming cassette through at output. Inlet and outlet conduits transport the fluid to the inlet of and from the outlet of the fluid warming cassette. Neither conduit is integrally connected to the fluid warming cassette. The Lahr et al. design had no guide rails because the fluid warming cassette was inserted into a warming unit having an adjustable aperture to receive the fluid warming cassette. See FIGS. 1–4 of U.S. Pat. No. 3,485,245.

Greenblatt discloses an alternative design of a warming cassette and a warming unit. That warming unit had a non-adjustable aperture to receive a fluid warming cassette. Greenblatt's fluid warming cassette is substantially equivalent to Lahr et al.'s fluid warming cassette except Greenblatt has (1) a plurality of holes along the perimeter of the fluid warming cassette and (2) the inlet and outlet are integrally connected to the cassette but not connected to each other. Greenblatt's fluid warming cassette was then attached to a frame unit that was inserted into the non-adjustable aperture of the warming unit. See FIGS. 7, 8, and 10 of U.S. Pat. No. 4,707,587.

Aid discloses a tapered fluid warming cassette. The warming cassette has a top end, a bottom end, and two sides. The length of the top end is greater than the length of the bottom side, hence the cassette is tapered. At the top end, the cassette has an inlet and an outlet tube integrally connected to a quasi-serpentine fluid path. It is a quasi-serpentine path because the fluid path has "short-cuts" for the fluid to go through. Along each side is a sleeve. The sleeve is designed to receive a stiffener device. The stiffener device is shaped in the letter "U" wherein the extensions of the device go into each sleeve at the top end so the remaining portion of the device acts as a handle for the cassette. In addition, the stiffener device is a guide rail for inserting the cassette into a warming unit's narrower, in relation to the apertures of Lahr et al. and Greenblatt, and non-adjustable aperture. The stiffener device, however, is not an integral part of the cassette and can cause problems with removing and inserting the cassette into and out of the aperture of the warming device. One of those problems can be puncturing the cassette. See FIGS. 2, 7 and 10 of U.S. Pat. No. 4,731,072.

The patent which Jordan et al. are listed as the inventors is assigned to the assignee of this application. In particular,

Jordan et al. disclose a fluid warming cassette having a counter-flow serpentine fluid path and two independent inlet and outlet nozzles integrally attached to the cassette. The inlet and outlet nozzles act as a stop mechanism to prevent the cassette from being inserted too far into the aperture of the warming unit. Since Jordan et al.'s cassette is thin; the guide rails are integrally attached to the sides of the cassette. A problem with Jordan et al.'s design is that the cassette is too flimsy and difficult to insert into the warming unit's aperture. See FIG. 3 of U.S. Pat. No. 5,875,282.

Augustine attempts to solve Jordan et al.'s flimsiness issue. Augustine's attempt requires placing a quadrilateral frame structure onto the perimeter of a fluid cassette. That quadrilateral frame must have (1) a stop mechanism positioned at the top end that prevents further insertion of the cassette into the aperture of a warming unit, and (2) guide rails to help assist the cassette into the aperture. In any case, Augustine's frame unit creates further problems. First, it does not solve the insertion problem because the quadrilateral shape is sometimes difficult to align with warming unit's aperature. Second, it requires an expanded aperture of the warming unit to accommodate the quadrilateral frame. By expanding the aperture, the effectiveness of the warming unit is slightly diminished. See FIGS. 1B and 2A of U.S. Pat. No. 6,464,666.

After reviewing these references, we noticed that the bottom end of each fluid warming cassette has two squared or nearly squared corners. That means, the bottom end is essentially parallel to the top end and perpendicular to the other sides. It is our understanding that the bottom end has this shape so the cassette remains within the warming unit.

The present invention has a unique design which solves the flimsiness and insertion problems of Jordan et al. and the other cited references.

SUMMARY OF THE INVENTION

The present invention is directed to a fluid warming cassette. The cassette has two polymeric films and at least two guide rails. A difference between this fluid warming cassette and those of the prior art is that this fluid warming cassette has a tongue section thereon. This tongue section assists the user insert the cassette into a warming unit's aperture and also not alters the spacing of a warming unit's aperture. That aperture is relatively narrow because the heating elements of the warming unit must be sufficiently close to the cassette to effectively alter the temperature of the fluid in the cassette to a desired temperature. In addition, the user can confirm if the cassette is properly inserted into the warming device's aperture by seeing that the tongue portion is sticking out of the other end of the warming device's aperture.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a top view of the present invention.

FIG. **2** is a view of FIG. **1** taken along the lines **2**—**2**.

FIG. **3** is a view of the inlet and outlet tube system.

FIGS. **4***a* and *b* are alternative embodiments of FIG. **1** taken along the lines **4**—**4**.

FIGS. **5***a* to *j* are alternative embodiments of the tongue section **20**, and ear section.

FIG. **6** is a schematic drawing of a conventional warming unit.

FIG. **7** is a view of FIG. **6** taken along lines **7**—**7** with the present invention therein.

FIGS. **8***a–d* illustrate alternative embodiments directed to the guide rails and the tongue section of the present invention.

FIG. **9** illustrates an alternative embodiment of FIG. **1**.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a fluid warming cassette. Admittedly, this fluid warming cassette is a variation of the cassette disclosed by Jordan et al. because the present invention will be used in a warming unit **100** having an aperture **102**, preferably the same size as the one used in and disclosed by Jordan et al.—same assignee as this invention.

The present cassette **10** has a proximal end **12**, a distal end **14**, a first side **16**, a second side **18**, a tongue section **20** that is toward the distal end **14**, a fluid path **21** within a fluid path section **22** having an inlet **24** and an outlet **26** and positioned between the tongue section **20** and the proximal end **12**, and guide rail sections **28***a* and *b*. The guide rail section **28***a* is positioned between the first side **16** and the fluid path section **22** and the second guide rail section **28***b* is positioned between the second side **18** and the fluid path section **22**.

The present cassette **10** is constructed from at least a guide rail system **30** and two relatively thin polymeric films **32**, **34**. The two relatively thin polymeric films **32**, **34** are sealed together in predetermined positions to form at least the guide rail sections **28***a* and *b*, and a tortuous pattern for the fluid path section **22**. In particular, it is desired that the inlet **24** and outlet **28** of the tortuous pattern be positioned adjacent to each other.

When the inlet **24** and the outlet **26** are adjacent to each other, the applicants can utilize an interconnected inlet/outlet system **36**, as illustrated in FIG. **3**. The system **36** has an inlet tube **38** that is positioned at the inlet **24**, an outlet tube **40** that is positioned at the outlet **26**, and an interconnect bar **42** that connects the inlet tube **38** and the outlet tube **40** together. The interconnected inlet/outlet system **36** is attached to the cassette **10** in a superior manner than the individual tube method of Jordan et al. This superior attachment is possible because the system **36** has more planar space in which the films **32**, **34** can seal around. Thereby there is less chance that the tubes will be unintentionally released from the seal when the cassette **10** is removed from the warming unit.

The seal between the two films **32**, **34** can be accomplished by numerous methods. Many of these methods are conventional to those of ordinary skill in the art. In particular, some of these methods use, and are not limited, radio frequency, heat, ultraviolet, and/or ultrasound to form the desired seals between the films **32**, **34**.

Prior to the films **32**, **34** being sealed, the guide rail system **30**, and the inlet tube **38** and the outlet tube **40** (preferably, the system **36**), are positioned between the films **32**, **34**. The films are then sealed so the tubes **38**, **40** (and the interconnected inlet/outlet system **36**) and the guide rail system **30** are securely positioned to the cassette.

The guide rail system **30** can be a single unit, as illustrated in FIG. **1**, or two separate units, as illustrated in FIGS. **4***a* and *b*. In either embodiment, there needs to be at least two guide rails **30***a* and **30***b* that must be in the respective guide rail section **28***a* and *b*. These rails can be the same shape and size. Alternatively, the rails can be different sizes and shapes to ensure the cassette is properly inserted into the warming unit **100**. The warming device **100** has guide rail slots **108**, **110** that receive the respective rails **30***a* and *b*. Those slots **108**, **110** can be the same size or different sizes. In any case, the rails **30***a* and *b* can be any conventional material, for example, and not limited to, plastic or metal.

In one embodiment, the rails **30***a* and *b* are integrally connected together by a support bar **30***c*. In this embodiment, the support bar **30***c* acts as a grasping member for the cassette **10**. In addition, the support bar **30***c* can support tubes **38** and **40**. With such support, there is a decreased chance the tubes **38** and **40** will be displaced from the cassette **10**.

In another embodiment, each rail **30***a* and *b* has a support member **50** that supports a respective, preferably adjacent, tube **38** and **40**, as illustrated in FIG. **4***a*.

In another embodiment, at least one rail **30***a* and *b* has a support member **52** that supports at least one tube **38** and/or **40**, and preferably both tubes, as shown in FIG. **4***b*.

A version of the tongue section **20** is illustrated in FIG. **1**. The tongue section **20** is designed to assist the user of the cassette **10** insert the cassette **10** into the aperture **102**. It has been our experience, that the tongue **20** provides stability and ease of insertion of the cassette into the warming unit's aperture. A criterion of the tongue section is that it extends beyond the four corners of the fluid path section **22**. The fluid path section must remain within the warming device **100** when the cassette is in the aperture **102**. The shape of the tongue can be any shape. For example, the tongue section **20** can be rounded, shaped like a triangle or any other polygon shape, and/or a combination of rounded and polygonal, as illustrated in FIGS. **5***a–h*. In addition, the tongue section **20** can have various apertures (which can be trademarks and/or designs) within the tongue section, which do not alter the function of the tongue section to stiffen the cassette **10** and assist the user insert the cassette **10** into the aperture **102** of the warming unit **100**.

The tongue section **20** can be the same material as the films **32**, **34** or a different material. The different material can be other polymeric materials or metal wire. Metal wire has been shown to keep the cassette **10** taut. In one embodiment, the wire is interconnected to the guide rails **30***a* and *b*.

In a preferred embodiment, the tongue section **20** is made of a stiffer material than the films **32**, **34**. If the tongue section is made of a different polymeric material, the tongue section **20** may be sealed to the cassette in a similar manner as the rails **30***a* and *b* are to the films **32**, **34**.

Alternatively, if the tongue **20** material is the same material, the films **32** and **34** can be hardened in the tongue section to make the tongue **20** sturdier than the fluid path section **22**. This hardening process can occur by numerous methods. One of those methods is by dipping the tongue section into another polymeric solution that will essentially stiffen the tongue section **20**. Other methods include and are not limited to radiating and curing the tongue section **20**.

The warming unit **70** has two apertures. The first aperture **102** receives the cassette **10**. The other aperture **120** allows the tongue section **20** to stick out of the warming unit **100**, when the cassette **10** is positioned within the aperture **102**. When the tongue section **20** is fully exposed, the user will know that the cassette **10** is properly positioned within the warming unit **70**. In one embodiment, the tongue section **20** and the fluid path section **22** are separated by a perforation **77**, or any other equivalent method (for example, scissors, knife, tear, pull, or equivalent thereof) in which to separate the tongue from the fluid path section. Which ever method is used, but preferably the perforated way, allows the user to remove the tongue section once the cassette **10** is properly positioned in the warming unit.

Alternatively, the tongue section **20** has a length that is equal to or greater than the length of the fluid path section **22**. That way, when the tongue section **20** is inserted into aperture **102** and exits aperture **120**, the user can pull on

tongue section **20** to properly position the fluid section **22** in the warming unit **100**.

In addition, the tongue section **20**, or alternatively the fluid path section **22**, can have indicia **66** that indicates when the fluid path section **22** is fully inserted. This indicia can be writing, a line, or a visual indicator, like a change in color for example red, that indicates when the user should stop inserting or pulling the cassette **10** into the aperture **102**.

In another embodiment, the guide rails **30***a* and *b* at the distal end merge into the tongue section **20**, as shown in FIGS. **8***a* and *b*. That way, the tongue section **20** acts as a self-guiding apparatus for the rail guides **30***a* and *b*. Alternatively, there is a gap **88** between the tongue section **20** and the fluid path section **20**, as shown in FIGS. **8***c* and *d*.

In another embodiment, the tongue section **20** can have an abrasive **55** thereon. The abrasive **55** can be applied prior to the cassette **10** being inserted into aperture **102** or when the tongue section **20** is already sticking out of aperture **120**. In any case, the abrasive material is any conventional material that can clean the heater elements of the warming unit **100**. Known abrasive material includes and is not limited to felt, bristle material and pipe cleaner. When the abrasive material **55** is pulled or pushed through the heater elements, the heater elements become clean.

Alternatively, the cassette **10**, without a fluid path section **22**, can have an abrasive **55** thereon.

Like Jordan et al., the tubes **38** and **40** are the stopping mechanism to prevent over insertion of the cassette **10** into the warming unit, not the guide rail system.

The cassette can also have ear-like projections **202** extending from a portion of the rails **30***a,b* and/or the tongue section **20**. The ears **202** can be made of the same material as the rails **30***a,b* and/or the tongue section **20**. The ears **202** can be positioned on one rails, both rails, or extensions of the tongue section **20**. In a preferred embodiment the ears **202** extend from predetermined portions of both rails.

One the predetermined portions can be near the distal end of the rail (near the tongue section **20**) and protruding away from the fluid path section. That way, the ears **202** can prevent the cassette from being improperly inserted (for example, backwards) into the warming device. The ears also assist a user in aligning the rails into aperture **102** of the warming device. See FIGS. **5***h* and *i*.

And in another predetermined position near the distal end of the rails, the ears **202** can act as a hinderance to the continued over-insertion of the cassette into the aperture **102** of the fluid warming device. These ears **202** are not prototypical stop mechanisms, instead they act like a road bump to allow the user to have an indication that the insertion of the cassette is complete. See FIG. **9**.

In a preferred embodiment, the films **38**, **40** are four thousandth of an inch (0.004") thick polyethylene.

While the preferred embodiment of the invention has been illustrated and described, it will be clear that the invention is not so limited. Numerous modifications, changes, variations, substitutions and equivalents will occur to those skilled in the art without departing from the spirit and scope of the present invention as defined by the appended claims.

We claim:

1. A fluid warming cassette comprising:

a first polymeric film and a second polymeric film sealed together in predetermined locations to form a tortuous fluid path within a fluid path section of the cassette, the fluid path section is defined by a proximal end of the cassette, a tongue section which extends toward a distal end of the cassette, a first guide rail section and a second guide rail section of the cassette;

an inlet tube and an outlet tube for fluid to enter and exit the tortuous fluid path, the inlet and the outlet are positioned at the proximal end;

a first guide rail extending from the proximal end to a distal end of the cassette and positioned in the first guide rail section;

a second guide rail extending from the proximal end to the distal end and positioned in the second guide rail section;

the tongue section extends beyond the fluid path section toward the distal end, the tongue section assists a user insert the cassette into a warmer unit's aperture.

2. The cassette of claim **1** wherein the first and second polymeric films are the same material.

3. The cassette of claim **2** wherein the tongue section is a different material than the first and second polymeric films.

4. The cassette of claim **2** wherein the tongue section is the same material as the first and second polymeric films.

5. The cassette of claim **4** wherein the tongue section is stiffer than the first and second polymeric films.

6. The cassette of claim **1** wherein the first and second polymeric films are different materials.

7. The cassette of claim **6** wherein the tongue section is a different material than the first and second polymeric films.

8. The cassette of claim **6** wherein the tongue section is the same material as the first polymeric film.

9. The cassette of claim **1** wherein the inlet tube and the outlet tube are interconnected together.

10. The cassette of claim **1** wherein the first and second rail guides are interconnected together by a support bar.

11. The cassette of claim **10** wherein the support bar supports the inlet tube, the outlet tube or both the inlet tube and outlet tube.

12. The cassette of claim **1** wherein the first or the second rail guide has a support member that supports the inlet tube, the outlet tube or both the inlet tube and outlet tube.

13. The cassette of claim **1** wherein the first and second rail guides have different sizes and/or shapes.

14. The cassette of claim **1** wherein the tongue section and the fluid path section can be separated along a perforation.

15. The cassette of claim **1** wherein the tongue section has an abrasive material thereon.

16. The cassette of claim **1** wherein the tongue section is made of metal.

17. The cassette of claim **16** wherein the metal is metal wire.

18. The cassette of claim **1** wherein there is a gap between the distal portion of at least one guide rail and the tongue section.

19. The cassette of claim **1** wherein the fluid path section or the tongue section has an indicia that informs the user that the cassette is properly positioned within the warming unit.

20. The cassette of claim **1** wherein at least one guide rail merges into the tongue section.

21. A method of inserting a fluid warming cassette into an aperture of a warming unit comprising:

inserting a cassette having

a first polymeric film and a second polymeric film sealed together in predetermined locations to form a tortuous fluid path within a fluid path section of the cassette, the fluid path section is defined by a proximal end of the cassette, a tongue section which extends toward a distal end of the cassette, a first guide rail section and a second guide rail section of the cassette;

an inlet tube and an outlet tube for fluid to enter and exit the tortuous fluid path, the inlet and the outlet are positioned at the proximal end;

a first guide rail extending from the proximal end to a distal end of the cassette and positioned in the first guide rail section;

a second guide rail extending from the proximal end to the distal end and positioned in the second guide rail section;

the tongue section extends beyond the fluid path section toward the distal end, into a first side of a warmer unit's aperture; and

confirming the cassette is properly inserted in the warmer unit by confirming the tongue section extends through a second side of a warmer unit's aperture.

22. The method of claim **21** wherein the first and second polymeric films are the same material.

23. The method of claim **22** wherein the tongue section is a different material than the first and second polymeric films.

24. The method of claim **22** wherein the tongue section is the same material as the first and second polymeric films.

25. The method of claim **24** wherein the tongue section is stiffer than the first and second polymeric films.

26. The method of claim **21** wherein the first and second polymeric films are different materials.

27. The method of claim **26** wherein the tongue section is a different material than the first and second polymeric films.

28. The method of claim **26** wherein the tongue section is the same material as the first polymeric film.

29. The method of claim **21** wherein the inlet tube and the outlet tube are interconnected together.

30. The method of claim **21** wherein the first and second rail guides are interconnected together by a support bar.

31. The method of claim **30** wherein the support bar supports the inlet tube, the outlet tube or both the inlet tube and outlet tube.

32. The method of claim **21** wherein the first or the second rail guide has a support member that supports the inlet tube, the outlet tube or both the inlet tube and outlet tube.

33. The method of claim **21** wherein the first and second rail guides have different sizes and/or shapes.

34. The method of claim **21** wherein the tongue section and the fluid path section can be separated along a perforation.

35. The method of claim **21** wherein the tongue section has an abrasive material thereon.

36. The method of claim **21** wherein the tongue section is made of metal.

37. The method of claim **36** wherein the metal is metal wire.

38. The method of claim **21** wherein there is a gap between the distal portion of at least one guide rail and the tongue section.

39. The method of claim **21** wherein the fluid path section or the tongue section has an indicia that informs the user that the cassette is properly positioned within the warming unit.

40. The method of claim **21** wherein at least one guide rail merges into the tongue section.

41. The method of claim **21** wherein the cassette has at least one ear-like projection extending from at least one guide rail or the tongue section.

42. The cassette of claim **1** wherein the cassette has at least one ear-like projection extending from at least one guide rail or the tongue section.

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