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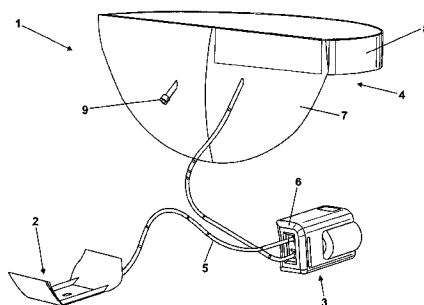
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(54) Title: INCONTINENCE AID



(57) Abstract: An incontinence aid (1) comprises an interface (2), a control unit (3), a storage unit (4), at least one unidirectional valve and an absorbent pad (10) having a number of layers, wherein the control unit includes a pump, which pumps urine and/or air from the interface (2) to the storage unit (4) and wherein at least one layer of the pad is raised away from an adjacent layer to form an air space between the layers.

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Incontinence Aid

Field of the Invention

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The invention relates to an incontinence aid, in particular an incontinence aid for women who experience urinary incontinence.

10 Background of the Invention

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Incontinence is a distressing and embarrassing condition which affects the lives of a large number of people. Incontinence is more common in women than men and is often associated with elderly people. However, there are a significant number of younger people who are also affected by the condition.

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The causes of incontinence vary. Pregnancy and vaginal delivery are risk factors in younger women for what is termed “stress incontinence”. This refers to leakage of urine in response to any physical activity that raises intra-abdominal pressure (e.g. coughing, laughing, sneezing, exercise etc).

25

The sphincter and detrusor pelvic floor muscles weaken with age and hence older women are more likely to suffer from both “stress incontinence” and also “urge incontinence”. In the case of the latter, the sufferer usually has a very strong desire to urinate and does not have enough time to make it to a toilet.

30

Some individuals suffer from chronic urine retention, which can be the result of nerve damage. With this condition, the bladder is always full, leading to constant or frequent dribbling of urine.

Some people suffer urinary loss without warning or sensory awareness. This is usually as a result of neurological disease or injury. In some cases, people with normal urinary control cannot get to a toilet before urinating because their movement is slowed by arthritis or other physical or mental disorders.

Other causes of incontinence in women include detrusor instability, anatomical abnormality, pelvic surgery, cervical cancer and radiotherapy.

5 There are a number of products available to people suffering from incontinence. Many of the products are designed for bed-ridden individuals and include bed pans and similar urine collection devices. Other products include systems incorporating internal catheters, through which urine flows out of the body and is collected in a bedside receptacle.

10 However, many suffers of incontinence are not bed-ridden.

These individuals need to go about their daily lives whilst dealing with the problem in the best way they can. Urine needs to be stored until they have an opportunity to empty the storage container.

15

Because incontinence is still regarded as an embarrassing condition to be concealed, it is important that the products for mobile individuals are discreet, effective and allow sufferers to live as normally as possible. Clearly, wearing uncomfortable bed-pan type devices or carrying large and conspicuous urine receptacles is undesirable. Ineffective
20 products lead to users frequently experiencing odour, leakage and/or skin irritation.

One solution to the problem of urine storage is the "leg bag". This is usually a flexible container that is strapped to a user's leg and urine is fed into the bag under gravity. Many users find the leg bag uncomfortable and suffer chaffing as it rubs against the skin while
25 walking.

The BellybagTM overcomes some of the problems associated with leg bags. This device is described in US4449971. Urine is stored in a bag around a user's abdomen. However, unlike the leg bag which collects urine under gravity, the BellybagTM system requires urine
30 to be transferred against gravity, up towards the abdomen. Therefore the BellybagTM system requires the user to wear an internal catheter (into the bladder), so that the urine is transferred to a bag at the abdomen by intra-peritoneal pressure.

There are many disadvantages in using internal catheters. They are a direct opening into the body and carry a risk of infection. They can also become blocked easily.

5 Absorbent pads designed to collect urine are probably the most widely used incontinence products. Some incontinence pads are similar to sanitary towels and are worn inside underwear. Others include “all in one” products such as special padded underwear. They vary greatly in size, style, cost, capacity and usability.

10 Absorbent pads are more comfortable to wear than rigid urine collection devices and are a very convenient way of managing a mild incontinence problem. However, for more severe problems, pads are prone to leaks and/or odours.

In EP1520566 and US6706027, absorbent pads are used in conjunction with systems to collect and store urine.

15 EP1520566 describes a urine disposal device with a pad, pump and storage tank. The pad has a urine sensor in the form of electrodes between a top sheet and a backflow prevention sheet in the pad.

20 US6706027 describes a bladder relief system comprising a pad, suction pump and storage bag. The pad has four layers - a facing layer (against the skin), a wicking layer (for drawing urine through), a urine collection layer (made for example, of foam), and a moisture-proof outer layer. It also has a urine cavity or cup to collect the urine and air holes to allow drying of the layers of the pad. The pad is sealed at the sides by the
25 moisture-proof layer, which wraps partially around the other layers. The pad may also have a urine sensor.

WO0057784 and US2004/0230181 describe systems for collecting urine that incorporate the use of an abdominal bag.

30 WO0057784 discloses a device for collecting urine in which an absorbent pad contains a urine sensor, which when activated, causes urine to be drawn into an abdominal storage bag (Figure 4). A vacuum is maintained in the storage bag and the system further

includes a valve to prevent back-flow of urine and which, when opened, allows urine to flow into the storage bag.

5 US2004/0230181 describes an abdominal urine collection bag connected to an external (condom type) collection vessel with a pump, through which urine is automatically pumped into the Bellybag™. The document states that other types of urine collection devices may be used for females.

10 The devices disclosed in the prior art are cumbersome and indiscreet. They make it very difficult for a user to lead a normal life while coping with the problem of incontinence. The urine collection interfaces are often uncomfortable and undesirable to wear. They are prone to saturation and/or leaking. The urine storage containers are uncomfortable to wear and the pumping systems are inefficient and require large pumps and power sources to be carried.

15

It would therefore be desirable to provide an improved incontinence aid.

Summary of the Invention

20

One aspect of the invention provides an incontinence aid as specified in to Claim 1.

In a preferred embodiment, the control unit includes a pump, which pumps urine and/or air from the interface to the storage unit.

25

Preferably, the incontinence aid includes at least one unidirectional valve, which prevents backflow of liquid.

30 Another aspect of the invention provides an interface of an incontinence aid comprising an absorbent pad having a number of layers.

Advantageously, the interface further includes a collection plate in which liquid is collected from the pad.

In a preferred embodiment the pad has at least one air space between the layers.

Advantageously, at least one layer of the pad is raised away from the adjacent layer to form an air space between the layers.

5

At least one layer of the pad may form folds so that the layer rises away from the adjacent layer.

The pad may include a skin layer, a transport layer, an acquisition layer and a backing layer. The transport layer may have a rough surface.

10

In a preferred embodiment the skin layer is not attached to the transport layer.

The skin layer may be partially attached to the backing layer. Advantageously, the skin layer forms folds at the edges of the pad.

15

The folds may cause the skin layer to be raised further away from the transport layer.

The interface of the incontinence aid may further include a sensor to detect that urination has occurred or is about to occur.

20

Another aspect of the invention provides a compact and discreet control unit including a power source and pump system.

Preferably the pump is activated by a sensor.

25

In a preferred embodiment the pump is a suction pump.

The pump may be a peristaltic pump, diaphragm pump or other type of suction pump.

30

The control unit may be small and lightweight enough to be clipped to a belt or carried in a pocket.

Another aspect of the invention provides a storage container for storing liquid.

The storage unit may include a bag worn in the abdominal region and may include an adjustable waist strap.

- 5 Advantageously, the storage unit includes a drainage port, which may be opened manually to drain liquid from the storage unit.

Preferably the capacity of the storage unit is sufficient to store all urine produced in one day.

10

A further aspect of the invention provides an absorbent pad which may have a flared front end arranged to curve around the front of a user's pelvic floor region.

- In a preferred embodiment the absorbent pad further includes an extended core arranged to extend forward of the urethral opening of a user.
- 15

Brief Description of the Drawings

- 20 Figure 1 shows a schematic representation of one embodiment of the incontinence aid. Figure 2a shows a schematic representation of the interface of the incontinence aid of Figure 1
- Figure 2b shows cross sectional view of the interface of the incontinence aid of Figure 1
- Figure 3a shows a schematic representation of an alternative embodiment of the interface of the incontinence aid of Figure 1
- 25 Figure 3b shows a plan view of an alternative embodiment of the interface of the incontinence aid of Figure 1

30 Detailed Description of the Preferred Embodiments

As shown in Figure 1 an incontinence aid 1 comprises an interface 2, a control unit 3 and a storage unit 4. In a preferred embodiment the interface 2 includes an absorbent pad 10. It may incorporate an alternative container or liquid absorbing material.

The interface 2 is connected to the control unit 3 by a flexible tube 5. The flexible tube 5 extends inside the housing 6 of the control unit 3 to a pump (not shown). The flexible tube 5 also connects the storage unit 4 to the control unit 3.

5

The control unit 3 includes a pump and power source (not shown). The control unit 3 and its contents are lightweight, discreet and small enough to be worn by the user in a pocket or clipped to a belt or to the waist strap 8 of the storage unit 4. The control unit 3 may further include lights and control keys.

10

The storage unit 4 includes a flexible bag 7 that is worn by a user in the abdominal area. An adjustable waist strap 8 enables a user to comfortably attach the flexible bag 7 to the desired position. The flexible bag 7 further includes a drainage port 9, which can be opened by a user to drain urine from the flexible bag. This gives the user the option of emptying the flexible bag 7 without the need to remove the storage unit 4 from around the waist. This allows a user to visit a toilet and release urine in a more normal way.

15

Referring to Figure 2a the interface 2 comprises an absorbent pad 10 attached to a capture plate 11. The pad 10 can be worn with conventional underwear and may include adhesive portions to help to secure the absorbent pad 10 in place inside underwear. Alternatively the same pad design could be used with special underwear or formed in an item of underwear.

20

Urine is drawn down through the pad 10 into the capture plate 11, from which it is transported to the storage unit 4 through the flexible tube 5. The absorbent pad 10 comprises a number of layers having different properties.

25

The skin layer 12 is the part of the pad that, when worn, is in contact with a user's skin. A transport layer 13 is next to the skin layer. The transport layer 13 has a rough surface, which helps to secure it in position on the acquisition layer 14. The acquisition layer 14 is attached to the capture plate 11 and a seal is formed at the point of connection. This seal encourages flow of urine through the layers of the pad.

30

A waterproof backing layer 15 prevents urine from leaking through the pad into a user's underwear. The waterproof backing layer partially overlaps the other layers.

5 The skin layer 12 is not attached to the transport layer 13, leaving an air space 16 in between the layers.

10 The central portion of the skin layer 12 is not attached to the waterproof backing layer 15, thus when the pad 10 is worn in the correct position by a user, the skin layer 12 is raised even further away from the transport layer 13. In the portion of the pad 10 where the skin layer 12 is not attached to the waterproof backing layer 15, the skin layer forms folds. The folds at the edges of the pad 10 encourages the skin layer 12 to raise away from the transport layer.

15 This aids drying of the layers and prevents the skin layer 12 from becoming attached to the transport layer 13 and saturating during periods of high urine flow. This helps to prevent skin irritation and is more comfortable for a user.

20 The air gap in the pad allows the layers to breathe and in cases where high instantaneous flow rates are possible, also gives the interface extra volumetric capacity to act as a buffer. In such circumstances, this buffer is required temporarily whilst liquid is pooled in the bottom layer and removed.

25 The air gap also ensures that liquid does not travel back through the pad towards the skin. Consequently the contact area between the user and the interface stays dry for the maximum period of time.

30 The incontinence device prevents the pad from exceeding its capacity point, thus preventing leakage or breaking of the skin-interface seal. Furthermore, the pumping of air through the pad aids drainage and drying processes.

Further air spaces may be incorporated between the other layers of the pad 10.

Additional layers of absorbent material such as foam may be added to the pad. Figure 2b shows a foam layer 17 on top of the skin layer 12. The foam layer 17 is not always required and may be omitted for some users of the incontinence aid 1.

5 The pad 10 also includes elasticated sides 18 and corner seals 19 to prevent leaks. The pad 10 or the underwear in which it is incorporated may be disposable. Replacement pads can easily be attached to the incontinence aid 1. The interface 2 includes a sensor (not shown) which may be in the form of an electrode, temperature, liquid, pH or other sensor.

10

Figures 3a and 3b show an alternative embodiment of the interface 2. Existing incontinence pads position the core of those pads centrally under a users pelvic floor. However the core 19 of an incontinence pad should be positioned further forward so that it catches liquid moving down the front of the pelvic floor as well as being under the urethral outlet and having further extension back so that it still captures urine at high rotational angles. The shape of the pad 10 and position of the core shown in the embodiments in Figures 3a and 3b enables urine to be collected more efficiently. The flared frontal part 20 of the pad is designed to be longer and designed so that it is able to curve upwards around the front of the pelvic floor region. The rest of the pad 10 is flatter and has a raised lip 21 to prevent leakage of urine out of the pad.

20

In use, the pad 10 is worn by a user either in conventional underwear, special underwear or as part of an item of incontinence underwear. When a sensor at the interface 2 detects the presence of urine or an impending urine event, a pump (not shown) located in the control unit 3 is activated. The pump may be a diaphragm pump, a peristaltic pump or an alternative pump/one way valve system. The pump is capable of pumping both urine and air (as air may also be drawn down through the pad 10).

25

The pump helps to draw urine through the pad 10, into the capture plate 11. Urine is pumped from the interface 2 along the flexible tube 5, through the pump in the control unit 3 and into the storage unit 4. A one way valve (not shown) prevents urine from flowing out of the storage unit 4 back down to the interface 2. Urine is held in the storage unit 4, which is a sealed waterproof container, through which odours and liquid are unable to escape.

30

When the user wishes to empty the storage unit 4, the drainage port 9 can be opened manually to allow urine to exit. A further sensor may be included at the storage unit 4 to alert the user when the storage container is becoming full. This may be a discreet alert at
5 the control unit such as a light or a vibration. In a preferred embodiment the capacity of the storage unit 4 is sufficient to enable the incontinence aid 1 to be worn for one day without the need to empty the storage unit.

The pump is activated automatically upon the sensor detecting a urine event. However,
10 the control unit may also include means for manual activation of the pump.

The incontinence aid 1 is a very lightweight system and easily transportable and comfortable to wear. It is also versatile in that it can also be used with bedridden patients because the capacity is such that the storage container 4 requires emptying only
15 once per day.

Claims

1. An incontinence aid comprising an interface, a control unit, a storage unit, at least one unidirectional valve and an absorbent pad having a number of layers, wherein the control unit includes a pump, which pumps urine and/or air from the interface to the storage unit and wherein at least one layer of the pad is raised away from an adjacent layer to form an air space between the layers.
2. An incontinence aid as claimed in Claim 1, wherein the interface further includes a collection plate in which liquid is collected from the pad.
3. An incontinence aid as claimed in Claims 1 or 2, wherein the interface further includes a sensor to detect that urination has occurred or is about to occur.
4. An incontinence aid as claimed in Claim 3, wherein the pump is activated by the sensor.
5. An incontinence aid as claimed in any preceding claim, wherein the pump is a suction pump.
6. An incontinence aid as claimed in any preceding claim, wherein the pad comprises a skin layer and a transport layer,
7. An incontinence aid as claimed in Claim 6, wherein the pad further comprises an acquisition layer and a waterproof backing layer.
8. An incontinence aid as claimed in Claim 6 or 7, wherein the skin layer is not attached to the transport layer.
9. An incontinence aid as claimed in Claim 7 or 8, wherein the central portion of the skin layer is not attached to the waterproof backing layer.

10. An incontinence aid as claimed in any of Claims 6 to 9, wherein in use the skin layer forms folds at the edges of the pad.
11. An incontinence aid as claimed in any of Claims 6 to 10, wherein the skin layer is raised away from the transport layer to form an air space between the layers.
12. An incontinence aid as claimed in any preceding claim wherein the pad has a flared end arranged to curve around the front of a user's pelvic floor region.
13. An incontinence aid substantially as shown in and described with reference to the drawings.

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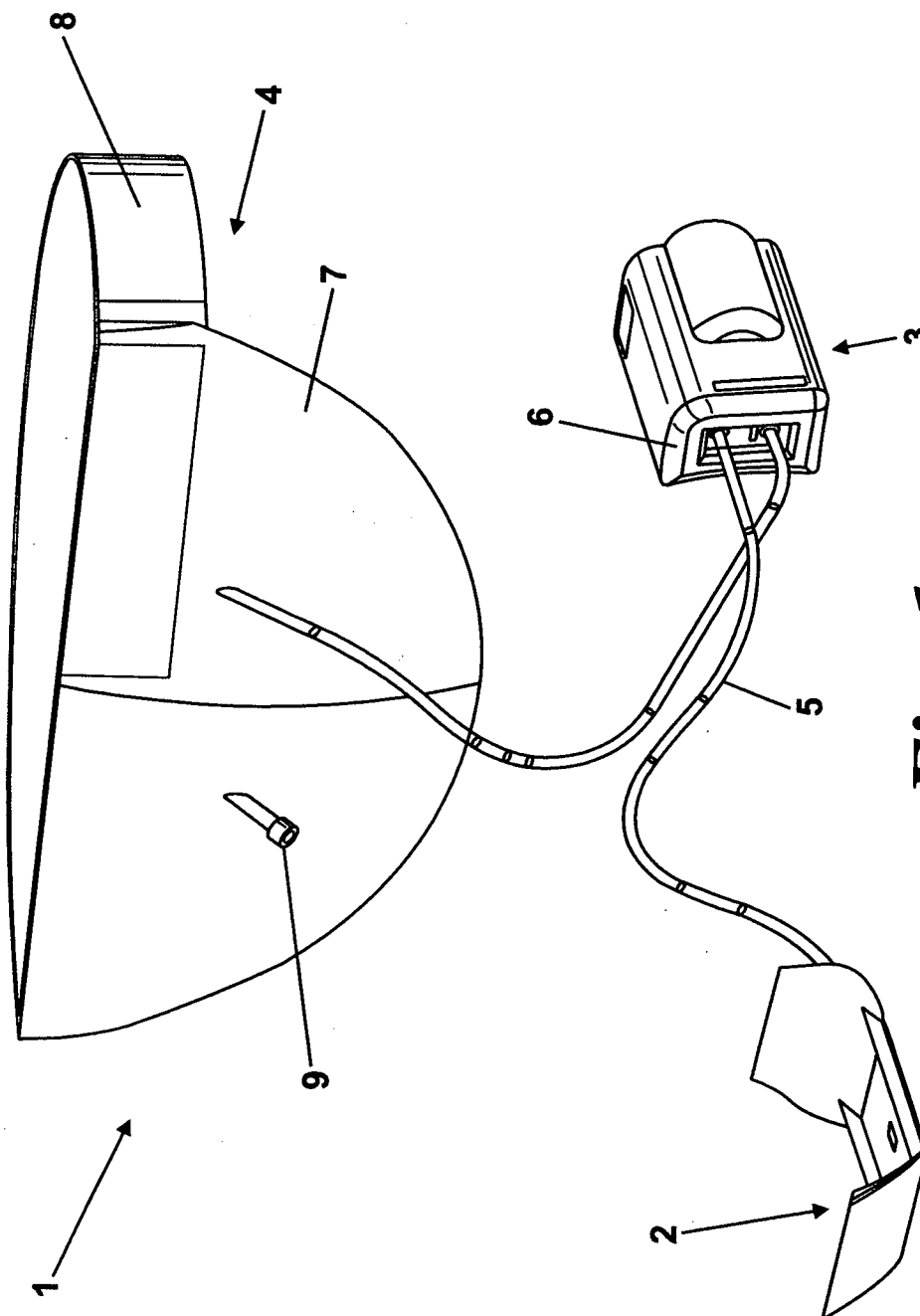


Fig. 1

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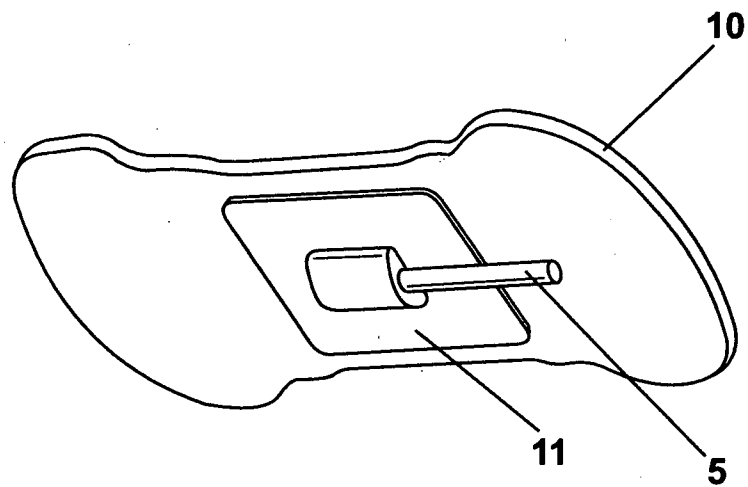


Fig. 2a

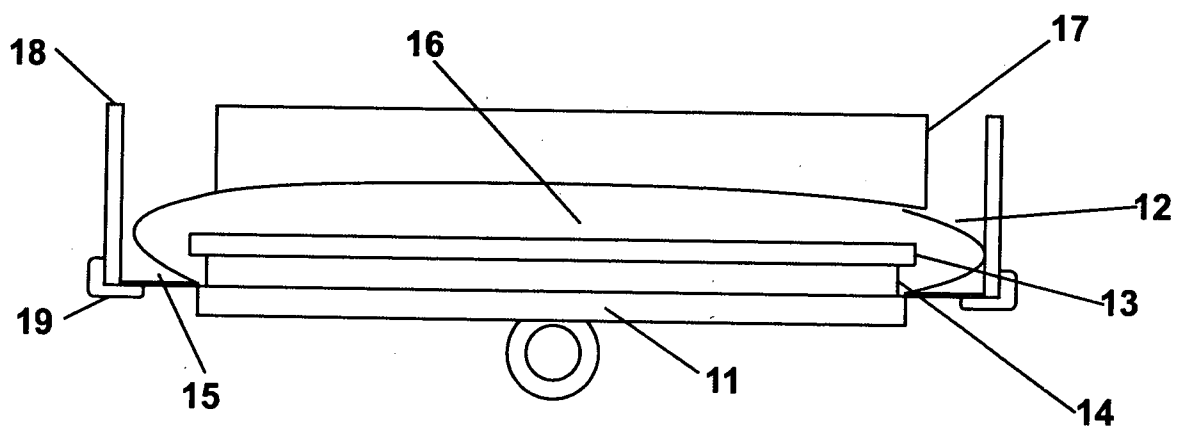


Fig. 2b

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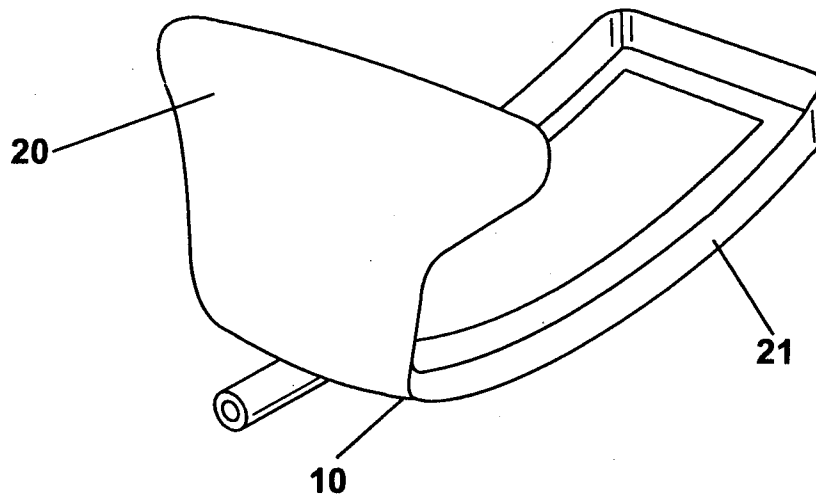


Fig. 3a

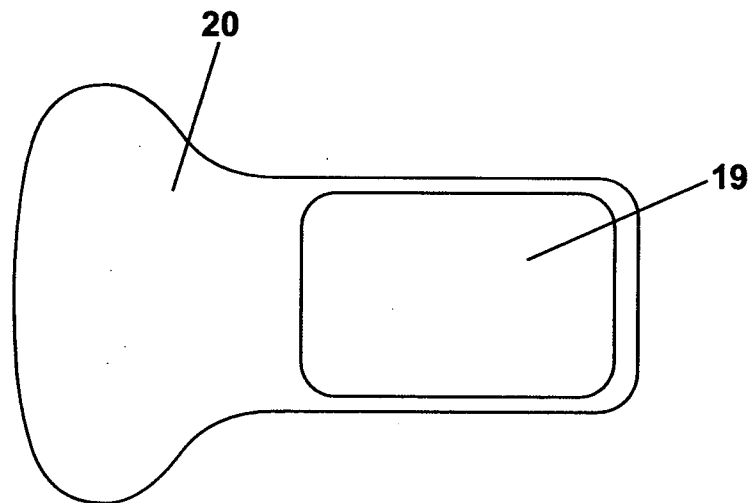


Fig. 3b

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/451 A61F13/15

ADD. A61F5/44

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)

A61F

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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

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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

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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

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