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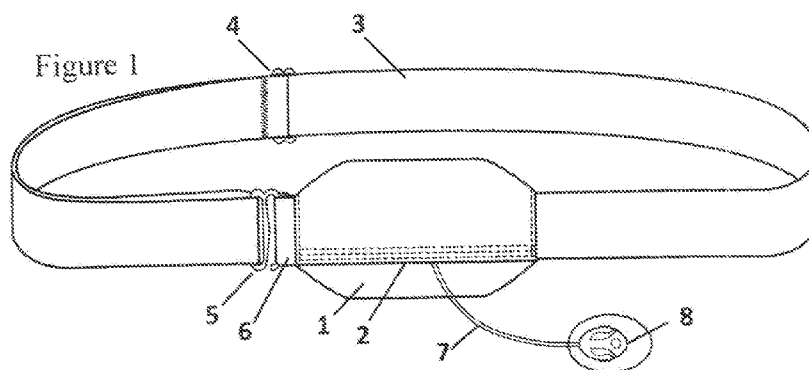
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(54) Title: GARMENT FOR RETAINING MEDICAL DEVICES



(57) Abstract: Garments for retaining medical devices, particularly insulin pumps and continuous glucose monitors, are disclosed. They contain an elastic pouch (1) which is designed to be very unobtrusive, and which does not have poppers, zips or the like but is exclusively of elastic fabric. The pouch is incorporated into an item of underwear such as a belt (3) or briefs.



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GARMENT FOR RETAINING MEDICAL DEVICES

This invention relates to garments for retaining medical devices, in particular insulin pumps.

5

Many people suffering from a variety of medical conditions need to carry with them some form of medical device. In order to do so, a variety of pockets, pouches, clips or the like are known which can be worn by the person in question. Because the devices are generally at least a few centimetres long 10 and a few centimetres wide, and sometimes more than a centimetre thick, wearing the device in some form of pouch, pocket or clip is often very obvious to others, i.e. the fact that someone is wearing such a medical device can be seen by others with whom the wearer comes into contact. Insulin pumps are on average about 9 cm x 5.5 cm x 2 cm.

15

The standard issue cases and clips given to patients with their devices add bulk, and volume to the device and suspend it away from the body on a belt or clothing. These make the pump more cumbersome and prominent and keep insulin tubing exposed outside the clothing to get caught and snagged. 20 This can be a danger, a discomfort and an inconvenience.

For some people, this may not be of concern, but for many people with medical conditions requiring the continuous carrying of a medical device, the inability to conceal the fact or to do so easily and simply disinclines the 25 sufferer to wear the device as much as is medically desirable.

The visibility of the device deters many, particularly women, from taking up pump therapy at all, opting instead potentially to risk their long term health by staying with the less effective injection pen system.

30

This is of particular concern in the case of insulin pumps which are desirably worn for substantial periods of time or, indeed, continuously by sufferers from

type 1 diabetes. Many of those are women and while some of them are happy to use existing pouches, these tend to be obtrusive, particularly if the wearer wishes to wear summer clothing. Analogous considerations apply to continuous glucose monitors. These connect to a cannula style head to enable the glucose level in interstitial tissue to be monitored and displayed on a handset. Such devices are of particular value for diabetics who are unable to feel the rise or fall of their blood sugar levels, and should be worn by such diabetics at all times. Continuous glucose monitors are generally about 9 cm x 4.5 cm x 1 cm in size.

10

Though appearance is often of greater concern to women, the problems of convenience, comfort and concealment apply to many men who need to carry such medical devices.

15 Currently available pouch units do not address the problems of being tethered to a device while sleeping. Sleeping with a pump can be uncomfortable and interrupt sleep, with the possibility of the tubing getting tangled around the wearer or caught beneath a partner. Anything that adds uncomfortable bulk and edges to the medical device, such as a case or clip, is impractical and uncomfortable to lay on and can also require nightwear garments to be worn to attach to, which does not suit everyone. It would be desirable to keep the device stable, secure and in a place of comfort, so that the wearer can move freely without physical disturbance.

25 According to the present invention, there is provided an elasticated garment for wear about the body which includes within it a pouch exclusively made of elastic fabric material and which is configured to receive as a snug fit a medical device, the opening of the pouch enabling a connection to be made between the device itself and means in contact with or penetrating the skin of the wearer.

30

The device is preferably in the form of a belt or of an elasticated undergarment.

Because the pouch is exclusively formed of the elastic fabric, it has no fastening devices which project from its surface. The fabric is preferably a high performance stretch fabric such as a highly elasticated micro or shape-wear/performance fabric.

A particularly preferred construction for the pouch is that of an envelope having a pair of overlapping sides so that the medical device may be inserted by pulling the overlapping sides apart to enable the device to be inserted into the interior of the envelope and, when the sides are released, because of the elastic nature of the fabric of the pouch, the two overlapping sides return to an overlapping position. A connection between the medical device and the wearer, for example a cannula through which insulin is provided by means of an insulin pump in the pouch simply lies between the two overlapping folds of material.

In an alternative construction, a pair of ladies' elastic briefs, knickers or panties or men's boxers, trunks or briefs may have an elasticated pouch formed in it and suitably sized so that, when inserted into the pouch, the medical device is a snug fit. The pouch may be located on the inside of the garment. Its elasticity prevents the device being able to escape, no matter how active the wearer and the part of the pouch between the device and the skin of the wearer provides a comfortable, hygienic and breathable barrier between the device and the skin. If the opening of the pouch through which the medical device is inserted is adjacent the waistband of the garment, the connection to the wearer's body may pass through it and then routed as appropriate. The pouch is preferably made of a high performance stretch fabric, for example cotton jersey blended with an elastic synthetic fibre such as elastane, and possibly containing other synthetic fibre components.

The elastic nature of the pouch assists in easy insertion of the medical device into the pouch or its removal from the pouch, so enabling the user to insert or remove the device without needing to disconnect it from the connection to the person's body.

5

The elastic pouch structure of the present invention may be incorporated into undergarments using standard underwear manufacturing techniques, and the garment itself can be appropriately configured and designed to appear both attractive and not to look or feel different from conventional underwear.

10 If the device is in the form of a belt, this may be provided with a customary mechanism for adjustment in order to enable the belt to fit snugly around the hips, waist or torso of the wearer. In the case of a belt, it can be worn with the pouch receiving the medical device at any appropriate position around the body, for example on the front, side or back of the wearer. By appropriate
15 design, the garments of the present invention may be presented so that, as well as being ergonomically sound, they are aesthetically pleasing and look and feel like regular underwear. Once the medical device is removed, they can be treated, for example for washing, in the usual way.

20 The garments of the present invention may be used with a wide variety of different types, makes and generations of insulin pumps, both older generation pumps which need regular manual contact with the pump, and the more recently available "hands-free" pumps operated by a Bluetooth handset.

25

The present invention is illustrated by way of example with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic perspective view of a garment according to the
30 present invention in the form of a body band designed to receive an insulin pump.

Figures 2, 3 and 4 show details of the body band shown in Figure 1.

Figure 5 shows diagrammatically an insulin pump, its connector and its connection to the person concerned.

5

Figures 6 and 7 are diagrammatic illustrations of a pair of knickers including a pouch and in accordance with the present invention; and

Figures 8 and 9 are diagrammatic illustrations of a pair of men's briefs
10 according to the present invention.

Referring to Figures 1 to 5, these show a microfibre pouch 1 with envelope back flaps 2 that hold an insulin pump shown diagrammatically in Figure 5.

15 As shown in Figure 3, the pouch has inner and outer flaps of elastic material which close around the pump to hold it securely; the edges of the flaps are denoted 2 and 10.

The pouch 1 is connected at one end to a soft elastic adjustable belt 3. Belt 3
20 has a "figure 8" adjusting slide 4 that can be moved to the left or right as seen in the drawing in order to adjust the size and fit of the belt, and is looped into a swan hook fastener 5, the neck of which may be inserted into an elastic loop 6 on the other end of pouch 1.

25 The infusion pump has an infusion tube 12 of clear plastics material through which insulin may be pumped from the pump itself to the infusion site denoted 8.

As shown in Figure 1, the insulin pump is concealed in the pouch 1, fitting
30 snugly into the space 9 within the pouch. The pump is not visible from the outside when the pouch 1 is closed around the pump, as shown in Figure 4,

where 11 denotes the inner flap of the envelope back and 12 the small opening to the inner flap of the pouch.

Figure 5 shows an insulin delivery head 13 on the end of tube 7 which may engage with a socket on an adhesive pad 16 which secures a cannula or catheter, which penetrates the skin, in position on the wearer's body by sticking to the skin. The insulin supply can be connected and disconnected to a socket 14 located on the adhesive pad 16. When connected, insulin is pumped via tube 7 into the body via the cannula or catheter.

10

The insulin supply may be disconnected from the cannula or catheter at the infusion site by pinching together finger grips 15 on the side of the delivery head 13. Figure 5 also includes a side view of the adhesive pad 16 showing the catheter needle or cannula which is inserted into the wearer via the skin 15 in order to deliver the insulin.

The garment shown in Figures 1 to 4, including the elastic microfibre pouch 1 with a horizontal envelope back opening 2 sewn on to a soft elastic adjustable belt 3, enables an insulin pump to fit in the space 9 in the pouch 20 under the first flap and second overlapping second flap so it is secured without the need for zips or fasteners. The modulus of the pouch and elastic enable the size and fit of the belt to be adjusted using the figure 8 sliding adjuster 4 for example from a smallest untensioned circumference of e.g. 44 centimetres up to a fully-extended tensioned circumference of around 184 centimetres. The swan hook 5 enables the belt to be fitted easily around the body by connecting with the elastic loop 6 on the edge of the pouch 1.

Referring now to Figures 6 and 7, these show diagrammatically a pair of knickers or panties 20 having an elasticated waist 21 enabling the garment to be held in place about the body of the wearer. Sewn on three sides to the material of the panties 20, which is itself elastic, is a generally trapezoidal piece of elastic material 22. The upper edge of material 22 as shown in

Figure 6 is seamed but not attached to the material of the garment 20 so that it forms an elasticated pocket in which an insulin pump may be snugly located. The outline of the insulin pump is denoted 23 and insulin is delivered via a tube 7 as described above with reference to Figure 5. Figure 7 shows the front view 24 and rear view 25 of the garment 20, which has the appearance of a standard item of underwear.

Figures 8 and 9 show the invention applied to a pair of men's briefs; this includes two elasticated pockets, one each side, so that the user may insert the medical device 23 into whichever is more comfortable and convenient.

Figure 9 shows the front and rear views of the briefs, denoted 27 and 28 respectively.

The garments of the present invention may be designed to provide, in contrast to the many items already on the market and disclosed in prior art literature, a combination of several desirable features. In particular, and with specific reference to the garment shown in Figure 1:

Adjustability

The garments can be configured to ensure that they can fit any size shape and area of the body.

Multiway/ Versatility

The stretch and adjustability with a slider as shown in Figure 1 enables the garment to be worn in many different positions and for many occupations and occasions. Unlike a closed circle band it can be worn in multiple positions. It can be moved and repositioned, so constituting for the user a single accessory suitable for many occasions. It allows the pump to be worn outside or inside the clothing depending on the level of access that is required, and can be worn either way up and with the pouch opening facing out or in for an even smoother look.

Comfort

The garment is preferably made from high performance micro fibre used for sports and support garments, and super soft elastics. All components should be adapted to be worn next the skin under pressure and friction. The garments are super soft and absorbent as well hard wearing.

Slender Profile

The slender width of the swan hooks, slider and pouch itself enable the belt shown in Figure 1 to have a flat profile of less than 5mm. Rather than adding to the width, bulk and protrusion of the pump as in the case of a standard issue cradle and clip, the garments according to the invention means that the bump is only as wide as the widest part of the pump.

Pillow Closure - Easy pump access

The envelope construction, rather like a standard pillowcase closure, allows the cable to thread out at any angle and from both sides of the pouch without having to thread and fiddle with it. It is a simple but effective way of securing the device whilst allowing access, which constitutes a major improvement when compared with known devices which have pouches with zips, poppers and burr fastener closure systems, and sometimes tiny buttonholes to thread the cannula through some form of overlapping fabric structure.

Easy "On & Off"

The Swan Hook and loop system is a tried and tested method for enabling a garment to be put on or removed. Many of the soft bands that are already commercially available for insulin pump wearers, in a variety of patterns and prints but generally to one basic design, are simply loops of fabric with no option to fasten and release. Such garments, when they are to be worn, need to be rolled up the legs or over the head, which is not convenient or ideal for the less mobile. They also tend to lose elasticity through the day, but

in such a case nothing can be done to improve their fit, i.e. they cannot be tightened.

Unisex

5Garments according to the present invention may be designed and manufactured for both men and women, with appropriate design and materials to suit the desired market. The garments may be presented as ladies' or men's underwear, or simply as a unisex item wearable by users of either sex.

CLAIMS

- 5 1. An elasticated garment for wear about the body which includes within it a pouch exclusively made of elastic fabric material and which is configured to receive as a snug fit a medical device, the opening of the pouch enabling a connection to be made between the device itself and means in contact with or penetrating the skin of the wearer.
- 10 2. A garment according to Claim 1 in the form of a belt.
3. A garment according to Claim 1 in the form of an elasticated undergarment.
- 15 4. A garment according to any one of Claims 1 to 3 wherein the pouch is constructed as an envelope having a pair of overlapping sides enabling a medical device to be inserted by pulling the overlapping sides apart into the interior of the envelope and wherein once the sides are released, the two overlapping sides return to an overlapping position.
- 20 5. A garment according to any one of Claims 1 to 3 constructed as a pair of elastic briefs, knickers, panties, boxers or trunks including an elasticated pouch suitably sized so that, when inserted into the pouch, the medical device is a snug fit.
- 25 6. A garment according to Claim 5 wherein the opening of the pouch through which the medical device is inserted is adjacent the waistband of the garment, enabling the connection between the device and the wearer's body to pass through it and then routed as appropriate.

Figure 1

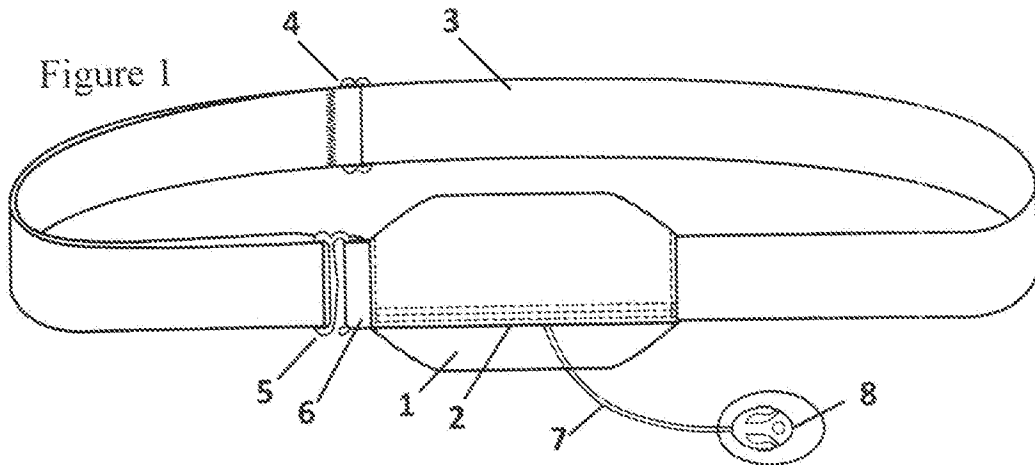


Figure 2

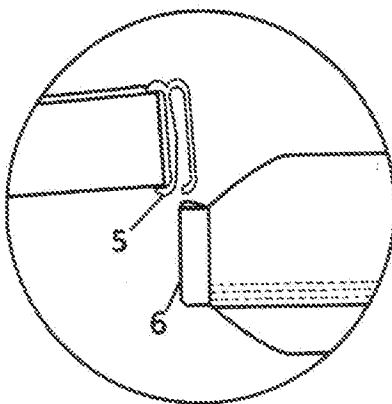


Figure 3

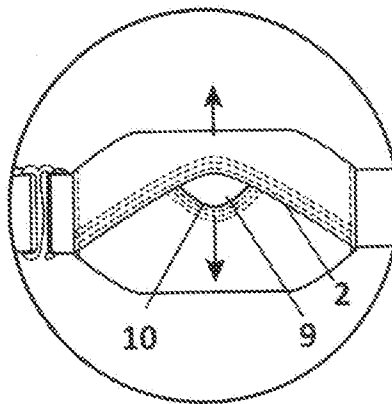


Figure 4

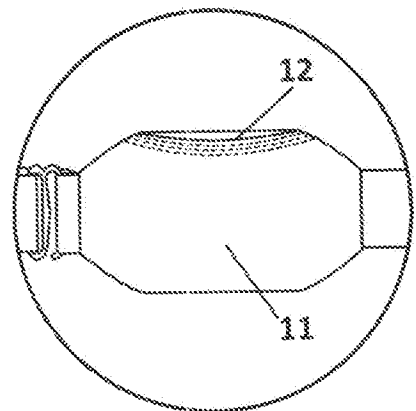


Figure 5

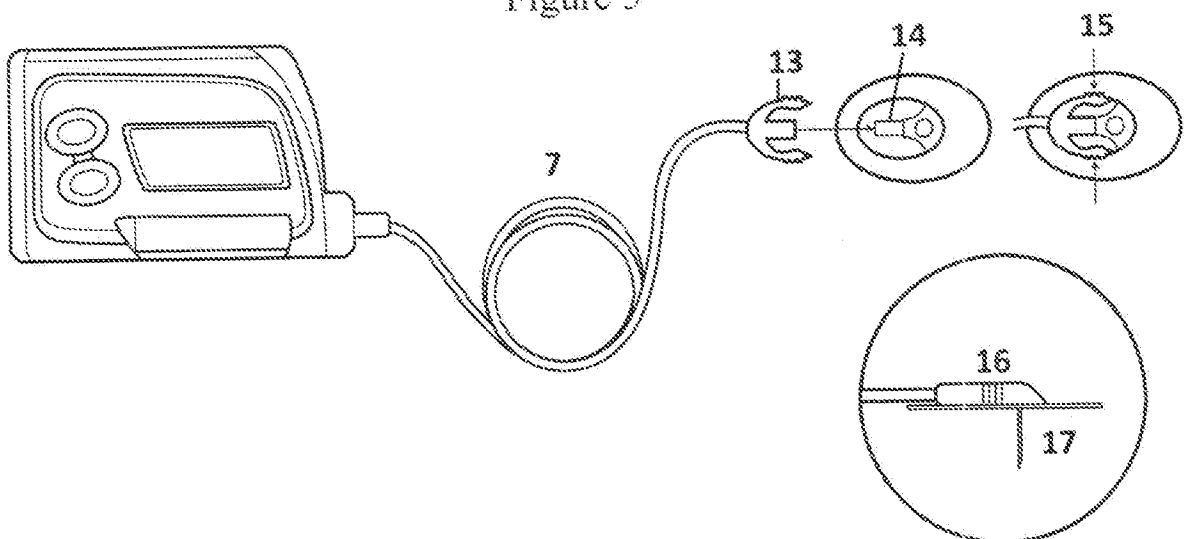


Figure 6

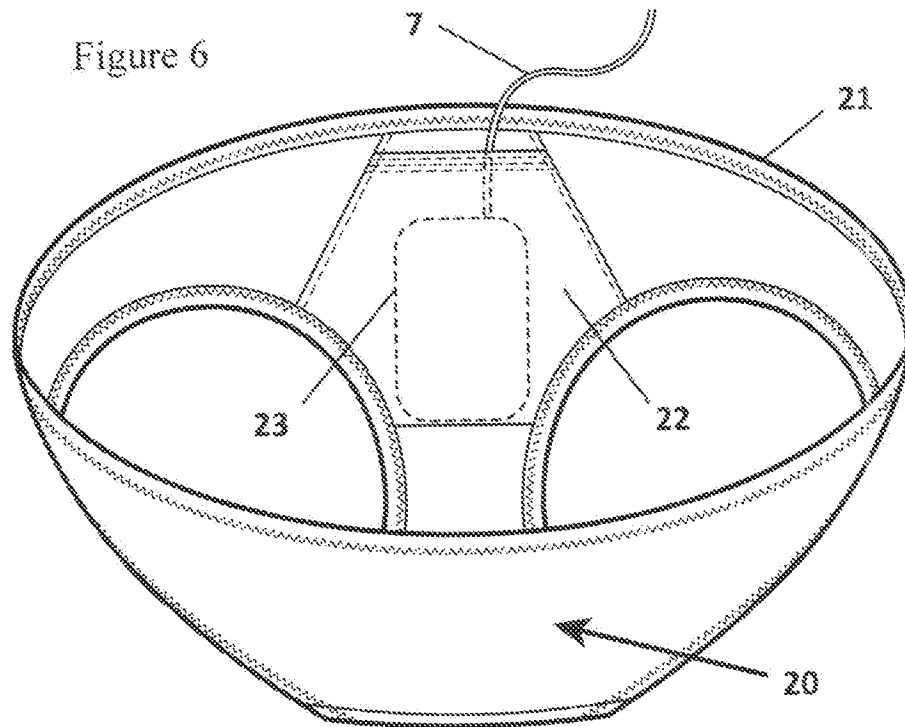


Figure 7

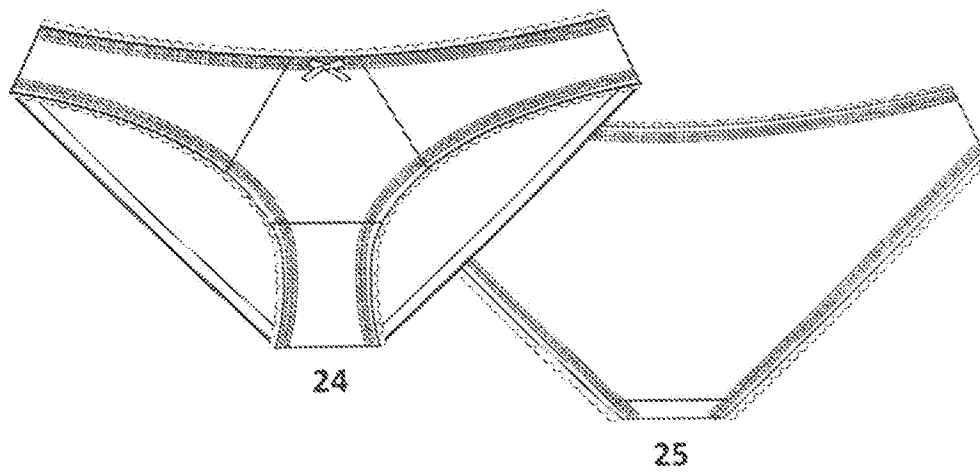


Figure 8

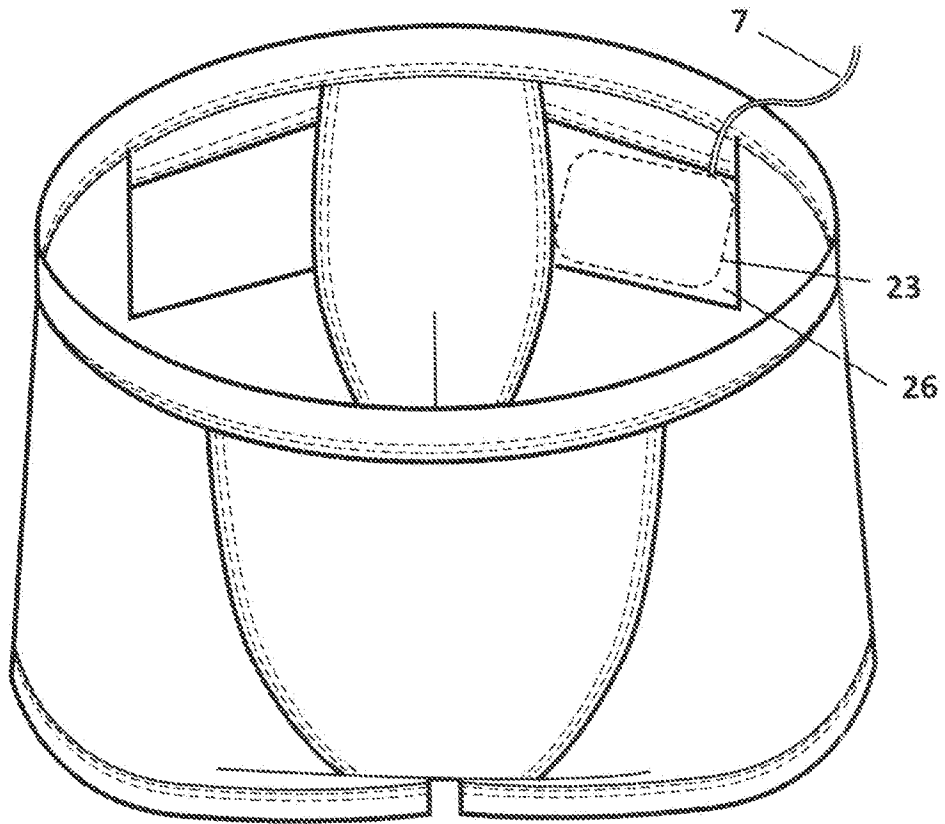
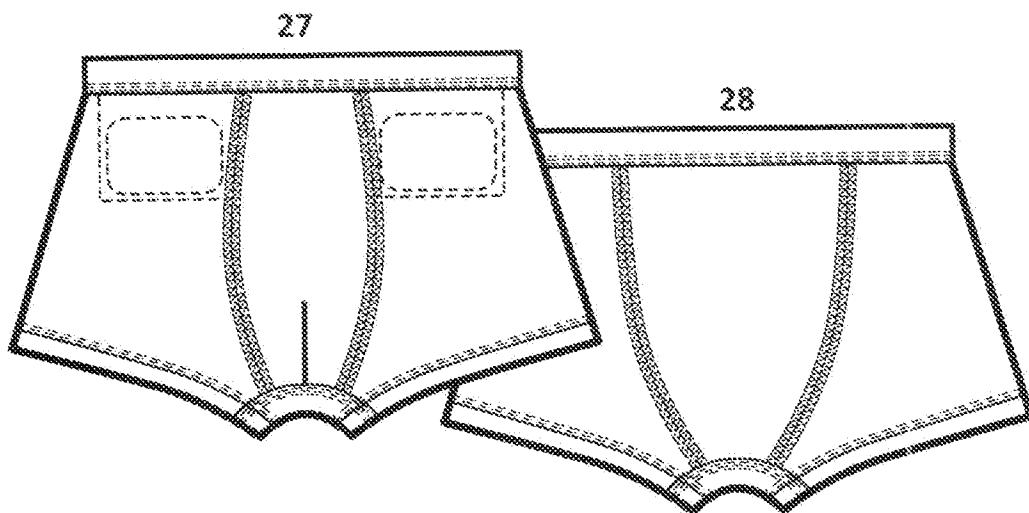


Figure 9



INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2015/051859

A. CLASSIFICATION OF SUBJECT MATTER

INV. A41B9/12 A41D13/12
 ADD. A41F9/00 A41D27/20

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)

A41B A41F A41D A41C 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 practicable, 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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X	US 2007/298684 A1 (SPAGNA LAURA [US]) 27 December 2007 (2007-12-27) paragraphs [0016] - [0020]; figures 2,3	1,3
X	US 2012/311758 A1 (NICHOLSON JOSEPH J [US] ET AL) 13 December 2012 (2012-12-13) paragraphs [0022] - [0030]; figures 1,3	1,3-6
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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

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07/10/2015

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INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2015/051859

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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