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(54) **TRANSPORT ELEMENT FOR TRANSPORTING A SUBSTANCE CONTAINED IN A RESERVOIR, INFUSION SET COMPRISING SUCH A TRANSPORT ELEMENT, SYSTEM FOR REGULATING THE CONCENTRATION OF GLUCOSE IN THE BLOOD OF A PERSON COMPRISING SUCH AN INFUSION SET, COMBINATION OF A RESERVOIR AND SUCH A TRANSPORT ELEMENT, INFUSION SET OR SYSTEM, AND METHOD OF AT LEAST FLUIDLY CONNECTING SUCH A TRANSPORT ELEMENT TO A RESERVOIR**

(57) The invention relates to a transport element for transporting a substance contained in a reservoir comprising a transport means, such as a conduit, tube, hose or the like, and a connector arranged at an inlet end of the transport means for connecting to said reservoir such that in a connected condition in which the connector is connected to said reservoir a medium through flow connection is provided between said reservoir and the inlet end of the transport means for receiving said substance from said reservoir, wherein the connector comprises aligning and holding means for aligning and holding the reservoir in a predetermined orientation with respect to and/or position along a longitudinal axis of the connector.

The invention also relates to an infusion set, system or combination comprising such transport element, and to a method of at least fluidly connecting such a transport element to a reservoir.

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Dit octrooi is verleend ongeacht het bijgevoegde resultaat van het onderzoek naar de stand van de techniek en schriftelijke opinie. Het octrooischrift komt overeen met de oorspronkelijk ingediende stukken.

TRANSPORT ELEMENT FOR TRANSPORTING A SUBSTANCE CONTAINED IN A RESERVOIR, INFUSION SET COMPRISING SUCH A TRANSPORT ELEMENT, SYSTEM FOR REGULATING THE CONCENTRATION OF GLUCOSE IN THE BLOOD OF A PERSON COMPRISING SUCH AN INFUSION SET, COMBINATION OF A RESERVOIR AND SUCH A TRANSPORT ELEMENT, INFUSION SET OR SYSTEM, AND METHOD OF AT LEAST FLUIDLY CONNECTING SUCH A TRANSPORT ELEMENT TO A RESERVOIR

The invention relates to a transport element for transporting a substance contained in a reservoir, said transport element being arranged to be part of an infusion set, said transport element comprising a transport means, such as a conduit, tube, hose or the like, and a connector arranged at an inlet end of the transport means for connecting to said reservoir such that in a connected condition in which the connector is connected to said reservoir a medium through flow connection is provided between said reservoir and the inlet end of the transport means for receiving said substance from said reservoir.

Such a transport element is known per se and may be used by diabetes patients as a part of a system for regulating the concentration of glucose in the blood of a person, e.g. with a substance such as or comprising insulin or glucagon. An example of such a system can be found in the international patent application WO 2007/049961, but the transport element may also be used in any other type of a system for regulating the concentration of glucose in the blood of a person.

With currently known transport elements, it requires specific attention to reliably connect the reservoir, which is typically embodied as an ampule, to the connector of the transport element. This is of particular importance, since the process of connecting is a task which is typically carried out by patients themselves, not by trained medical professionals. When the reservoir is connected in an incorrect manner, malfunctions such as leakages may occur.

It is an object of this invention to at least partially overcome these disadvantages and/or to improve said known transport element.

This object is met by a transport element according to the preamble, wherein said connector comprises aligning and holding means for aligning and holding the reservoir in a predetermined orientation with respect to and/or position along a longitudinal axis of the connector.

The provision of such aligning and holding means, i.e. means which are arranged for both aligning and holding the reservoir in a predetermined orientation with respect to and/or position along such a longitudinal axis, reduces the chance of misalignment and/or inadequate positioning of the reservoir with respect to the connector. Said longitudinal axis may correspond to the intended direction of insertion of said reservoir into the connector or may alternatively, where applicable, be substantially parallel with respect to and/or may coincide with the longitudinal axis of a penetrating means, as will be discussed below. Said predetermined orientation may be substantially parallel to said longitudinal axis, i.e. a longitudinal axis of said reservoir may be substantially parallel to the

longitudinal axis of said connector. Said position may in particular be a position along the longitudinal axis in which the reservoir has a substantially leak tight connection with the connector. An example of such a position will be discussed with respect to an exemplary embodiment discussed in the following.

In said predetermined orientation and/or position said reservoir may be connected to the connector in such a manner that it is rotatable with respect to the connector, preferably about the longitudinal axis of the connector, while being held by the aligning and holding means such that it can only be removed from the connector by overcoming the holding force by which the reservoir is held by the aligning and holding means.

The aligning and holding means can be made into a wide variety of embodiments, for example for connecting to different types of reservoirs, typically embodied as an ampule. In particular, the connector of the transport element according to the current invention may connect to a reservoir with a standard featureless end. A featureless end may be defined here as an end which does not comprise features intended or primarily intended for connecting the reservoir to the connector, such as notches on a head portion of the reservoir specifically designed to interact with corresponding parts in specific types of connectors. As a consequence, the versatility of the connector of the transport element is increased. As an example, the ampule may comprise a neck portion wherein the aligning and holding means are arranged to protrude into an area of and/or engage said neck portion.

The connector of the transport element according to the invention is typically made of a plastic.

The connector and the transport means may either be one integral part or may be separate elements that may be connectable to each other to form the transport element.

In a preferred embodiment of the transport element according to the invention, the connector of the transport element comprises additional aligning means, said additional aligning means extending before and/or after the aligning and holding means as seen in the direction of the longitudinal axis.

Before and after can be seen in said insertion direction of the reservoir into the connector, which insertion direction is parallel to the longitudinal direction. In other words, the additional aligning means may extend upstream and/or downstream of the aligning and holding means as seen in said insertion direction. In other words, the additional aligning means may extend beyond the aligning and holding means in one or both directions as seen in the longitudinal direction.

The additional aligning means may for example be continuously formed, such that these extend from before the aligning and holding means, along the aligning and holding means and after the aligning and holding means. Alternatively the additional aligning means may comprise one, two, or even more separate parts, wherein if one part is provided that one part may extend either before or after the aligning and holding means and if two parts are provided one part thereof may extend before and the other part may extend after the aligning and holding means.

Said additional aligning means extending before the aligning and holding means may in particular be arranged for pre-aligning the reservoir with respect to the longitudinal axis of the connector in a first part of a connection path of connecting the reservoir to the connector, wherein in a second, subsequent part of said connection path said reservoir is aligned by said aligning and holding means and optionally said additional aligning means, and is subsequently held by the aligning and holding means at the end of the connection path in the connected condition.

An advantage thereof is that the reservoir is already pre-aligned with respect to the longitudinal axis when it contacts the aligning and holding means, in order to bring the reservoir into an orientation which is at least relatively close and preferably identical to the predetermined orientation prior to being aligned and held by the aligning and holding means. It is noted in this respect that if the reservoir is pre-aligned in the predetermined orientation it can alternatively be said that the aligning and holding means are arranged to maintain the alignment of the reservoir in said predetermined orientation.

Said additional aligning means extending after the aligning and holding means may be arranged for maintaining the alignment of said reservoir in said predetermined orientation in the connected condition.

This may alternatively be formulated as said additional aligning means extending after the aligning and holding means being arranged for post-aligning the reservoir in the predetermined orientation.

In a preferred embodiment of the transport element according to the invention, the aligning and holding means are more flexible than the additional aligning means.

An advantage of such flexibility of the aligning and holding means is that the reservoir may be easily connected thereto. An advantage of the additional aligning means being less flexible is that this may enhance the alignment of the reservoir in the predetermined orientation.

In particular the additional aligning means may be embodied as rigid and/or stiff and/or non-flexible additional aligning means. This may be achieved by means of a suitable material choice and/or design choice, such as a suitable shape and/or thickness, of the additional aligning means.

In particular the aligning and holding means may be embodied as flexible and/or resilient aligning and holding means. This may be achieved by means of a suitable material choice and/or design choice, such as a suitable shape and/or thickness, of the aligning and holding means.

An advantage of achieving the difference in flexibility as a result of a different design of the aligning and holding means in comparison to the additional aligning means is that these may be made of the same material, which may preferably the same material from which the whole connector is made.

In a preferred embodiment of the transport element according to the invention, the additional aligning means comprise at least one elongated rib that protrudes inwardly from the inner side of a circumferential wall of said connector and extends substantially parallel to said longitudinal axis.

Such a rib, which is configured to touch a part of the reservoir with a protruding edge thereof in order to obtain pre-alignment and/or post-alignment of the reservoir, is relatively simple in construction, and is thereby easy to produce. It may for instance be made integrally with the circumferential wall of the connector, e.g. by injection moulding. This may especially be the case if the rib and the circumferential wall are made of the same material, typically a plastic. If the additional aligning means extend on both sides of the aligning and holding means as seen along the longitudinal axis, said rib is preferably continuously formed, which may mean that it is at least not interrupted by said aligning and holding means.

Said at least one rib may in particular protrude in a radial direction from the inner side of the circumferential wall of the connector.

In particular the at least one rib may extend substantially parallel to the longitudinal axis with a longitudinal axis thereof.

The circumferential wall of the connector may have a substantially cylindrical shape, at least the inner side thereof. Such a shape may conveniently accommodate a cylindrical neck and/or head portion of a reservoir.

In a preferred embodiment of the transport element according to the invention, the additional aligning means comprise a plurality of said ribs distributed along the circumference of the circumferential wall, preferably in a uniform distribution.

By providing a plurality of ribs that are distributed along the circumference of the circumferential wall, preferably in said uniform distribution, the reservoir can be centred within the connector. In such an embodiment the reservoir is arranged coaxially with the connector in the predetermined orientation, i.e. the longitudinal axis of the reservoir coincides with the longitudinal axis of the connector. The number of ribs may for instance be at least three, at least four, at least five, at least six, or even more. The number of ribs is typically determined by a person skilled in the art based on the requirements for the connector, for example dependent on the size thereof.

The angular distance between neighbouring ribs is preferably the same for the various ribs and may be calculated by dividing 360 degrees by the number of ribs.

In a preferred embodiment of the transport element according to the invention, the aligning and holding means comprise at least one resilient member, said resilient member having a first state for holding said reservoir and being moveable to a second state when said reservoir is pushed against said resilient member when said reservoir is connected to or disconnected from said connector, and which resilient member is elastically urged to its first state.

An advantage of such a resilient member that is elastically urged to its first state and that is temporarily moveable to its second state is during connecting the reservoir to and disconnecting the reservoir from the connector is that the reservoir may easily be connected thereto and disconnected therefrom by temporarily moving the resilient member to the second state, while said reservoir may be

accurately held in said predetermined orientation and/or position in the connected condition in which the resilient member is in its first state.

In a preferred embodiment of the transport element according to the invention, said at least one resilient member comprises at least one substantially crescent-shaped member, wherein the substantially crescent-shaped member is attached to the inner side of a or the circumferential wall of the connector with two opposing end zones thereof and wherein a convex side of said substantially crescent-shaped member that extends between the two opposing end zones protrudes inwardly from the inner side of said circumferential wall of the connector.

Such a substantially crescent-shaped resilient member is an advantageous embodiment of a resilient member, since it has been found that such a crescent-shaped member is a particular example of a resilient member which is well able to reliably hold the reservoir, in particular if multiple substantially crescent-shaped members are provided. An alternative or additional advantage of such a crescent-shaped member is that it may substantially maintain its shape in the first state, even after repeatedly connecting and disconnecting a reservoir to and from the connector.

A substantially crescent-shaped member may alternatively be defined as an arcuate member, or a member comprising a mid-zone between said end zones, which mid-zone is closer to the reservoir than said end zones, i.e. extend radially more inwards than said end zones, preferably both in a non-connected condition, as well as in the connected condition. Substantially crescent-shaped may in particular mean that such a mid-zone is at least partially, but preferably entirely, curved.

During connecting to or disconnecting the reservoir from the connector the convex side of the crescent-shaped member may be pressed by the reservoir into the direction of the circumferential wall, which is the before called second state of the resilient member, and may return to its crescent or arcuate shape when the reservoir is connected to or removed from the connector.

The shape of the substantially crescent-shaped member is in particular substantially crescent-shaped in a plane substantially orthogonal to the longitudinal axis of the connector.

The end zones of the substantially crescent-shaped member are preferably fixed to the circumferential wall at substantially the same position along the longitudinal axis of said connector, i.e. the substantially crescent-shaped member extends substantially orthogonal to the longitudinal axis. In other words, said substantially crescent-shaped member is bound by a plane substantially perpendicular to the longitudinal axis. Such a configuration increases the grip of said crescent-shaped member on a reservoir, in particular when the reservoir comprises a narrowed portion in the end of the reservoir, such as a neck portion, and when the connector is designed to hold the reservoir in the connected condition by said narrowed portion.

In a preferred embodiment of the transport element according to the invention, a hole or opening is provided in said circumferential wall in an area between said two opposing end zones of the at least one substantially crescent-shaped member.

This may increase the ease of production of such a connector, especially when the connector is produced using injection moulding.

If multiple substantially crescent-shaped members are provided a such hole or opening may be provided between the opposing end zones of any one or more of the substantially crescent-shaped members.

In a preferred embodiment of the transport element according to the invention, the transport element comprises a plurality of said resilient members and wherein the resilient members are distributed along the circumference of a or the circumferential wall, preferably in a uniform distribution and/or arranged at a substantially same position along the longitudinal axis.

Providing a plurality of said resilient members improves the alignment and holding of the reservoir. The resilient members may together define a ring of resilient members.

Preferably, the connector comprises a plurality of said substantially crescent-shaped members. The end zones of the substantially crescent-shaped member are preferably fixed to the circumferential wall at substantially the same position along the longitudinal axis of said connector.

When the additional aligning means comprise a plurality of ribs, the number of ribs may be equal to the number of resilient members of the connector.

The ribs and resilient members are preferably provided as separate, individual elements.

In a preferred embodiment of the transport element according to the invention, the ribs and resilient members are arranged alternatingly along the circumference of the circumferential wall, preferably in an uniform distribution and/or spaced apart from each other.

Providing the ribs and resilient members in an alternating manner and preferably in an even distribution along the circumference of the circumferential wall may aid the correct alignment of the reservoir.

In a preferred embodiment of the transport element according to the invention, said connector comprises a penetrating means, such as a needle, that extends substantially parallel to the longitudinal axis with a free end thereof in the direction of the aligning and holding means for penetrating a membrane or the like of said reservoir in at least the connected condition, wherein said aligning and holding means and optionally said additional aligning means are configured for aligning the reservoir in a predetermined orientation with respect to said penetrating means such that the penetrating means are oriented substantially perpendicular to the membrane of said reservoir during penetrating the membrane during connecting of the connector to said reservoir, and for holding said reservoir in said predetermined orientation and in such a position that the penetrating means substantially completely penetrates the membrane in the connected condition.

A typically used reservoir comprises a piercable membrane for closing said reservoir. In accordance with the invention said membrane is pierced in a substantially orthogonal manner by the penetrating means, thereby reducing or even preventing leakage of substance.

Orthogonal may be defined between the local plane or area of the membrane where it is penetrated and the longitudinal direction of the penetrating means.

Said needle is in particular a hollow needle for transporting said substance there through.

The position of the reservoir in which the reservoir is held with respect to the connector, in this respect also referred to as the depth of the reservoir, is chosen such that the penetrating means, in the connected condition, fully penetrate the membrane of the reservoir in order to reduce or prevent leakage of substance and to provide a correct fluid connection between the transport element and the reservoir. Such a position or depth of the reservoir with respect to the connector may be suitably chosen by arranging the aligning and holding means at such a position along the longitudinal axis with respect to the penetrating means that the penetrating means will completely penetrate the membrane in the connected condition. For example, the penetrating end or free end of the penetrating means may be located in the vicinity and for example slightly above the aligning and holding means as seen in the direction of insertion of the reservoir, such that in the connected condition in which a head portion of the reservoir extends above the aligning and holding means as seen in the direction of insertion the membrane that is comprised by the head portion is completely penetrated.

The aligning and holding means and, where applicable, the additional aligning means, are preferably configured for centring the reservoir with respect to the penetrating means during connecting the reservoir to the connector and/or in the connected condition.

In a preferred embodiment of the transport element according to the invention, the aligning and holding means are configured to protrude into an area of and/or grip a neck portion of said reservoir in the connected condition.

When the aligning and holding means are configured to protrude into an area of and/or grip such a neck portion, which is narrowed with respect to a broader end or head portion of the reservoir, the reservoir is held by the aligning and holding means in a reliable manner.

The invention further relates to an infusion set, comprising:

- a transport element as described above in any of the above described embodiments and/or comprising any feature as described above, alone or in any suitable combination, further comprising an additional connector arranged at an outlet end of the transport means, and

- an infusion element comprising an infusion means for infusing a substance into a body of a person, said infusion means for example being a cannula, catheter, needle, or nozzle, said infusion means comprising an inlet end for receiving said substance and an outlet end for infusing said substance into said body, wherein said infusion element comprises a connector for connecting to said additional connector of said transport element of the infusion set,

wherein said additional connector of said transport element is connectable to said connector of said infusion element such that in a connected condition in which the additional connector of the transport element is connected to the connector of the infusion element a medium through flow

connection is provided between the outlet end of the transport means and the inlet end of the infusion means for feeding the substance to the infusion means.

The transport element according to the present invention may thus be used as a part of an infusion set, allowing the substance contained in the reservoir to be infused into said body via said infusion set.

In order to distinguish between the different connectors of said infusion set, the connector of the infusion element may be referred to as the first connector, whereas the additional connector of the transport element that is connectable to said first connector may be referred to as the second connector. The connector connectable to the reservoir is than referred to as the third connector.

The invention further relates to a system for regulating the concentration of glucose in the blood of a person, comprising at least one infusion set as described above and a device for selectively supplying at least one substance contained in at least one reservoir, said device comprising:

- at least one receiving space, for accommodating a said reservoir;
- at least one port, for connecting to a said connector of a said transport element of the infusion set, and
- a controller for controlling said device such that a certain amount of a said substance is supplied and thereby infused into the body of the person.

The at least one port is arranged in vicinity of the at least one receiving space, for example at or near an insert opening of the receiving space via which the reservoir may be inserted.

In a connected condition in which the connector of the transport element is connected to the port of the device, said connector is also connected to the reservoir contained in the receiving space. The connection to the port provides a mechanical connection between the device and the infusion set, while the connection to the reservoir provides said fluid through flow connection between the reservoir and the infusion set.

The device is not restricted to just one receiving space and may thus comprise more than one receiving space. In the same way, the device may comprise more than one port, preferably one port per receiving space. Such a device may be used with one or more than one infusion set, preferably one infusion set for each receiving space. In particular, the number of receiving spaces and ports may be two, wherein a first receiving space may serve to accommodate a reservoir containing insulin, whereas a second receiving space may serve to accommodate a reservoir containing glucagon.

The connector of the transport element according to the invention typically also comprises means for connecting the connector to said port of the device. For example said connector bayonet may be of the bayonet type.

In a preferred embodiment of the system according to the invention, the system is configured for inserting the reservoir in said receiving space of the device after connecting the outlet end of the reservoir to the connector of the transport element, thereby aligning and holding said reservoir with the aligning and holding means of the connector prior to inserting the reservoir into the receiving space.

The invention further relates to a combination of a reservoir, preferably a reservoir pre-filled with a substance such as or comprising insulin or glucagon, and:

- a transport element as described above in any of the above described embodiments and/or comprising any feature as described above, alone or in any suitable combination;
- an infusion set as described above, or
- a system as described above.

The reservoir is preferably a reservoir which is pre-filled with a said substance. In order to regulate the concentration of glucose in the blood of a person, said substance preferably is or comprises insulin or glucagon.

The invention further relates to a method of at least fluidly connecting a transport element to a reservoir, comprising the steps of:

a) providing a transport element as described above in any of the above described embodiments and/or comprising any feature as described above, alone or in any suitable combination, an infusion set as described above or a system as described above;

b) providing a reservoir comprising an outlet end;

c) connecting the outlet end of the reservoir to the connector of the transport element, thereby aligning and holding said reservoir with the aligning and holding means of the connector in a connected condition.

Preferably, in step c) said reservoir is connected to the connector along a connection path, wherein in a first part of said path the reservoir is pre-aligned by said additional aligning means, wherein in a second, subsequent part of said path the reservoir is aligned by said aligning and holding means and optionally the additional aligning means, and wherein said reservoir is subsequently held by said aligning and holding means in said connected condition and optionally aligned by said additional aligning means.

In a preferred embodiment of the method according to the invention, in step a) a system as described above is provided, and the method further comprises step d) of inserting the reservoir in said receiving space of the device for selectively supplying at least one substance, wherein step d) is preferably executed after step c).

Executing step d) after step c) allows the reservoir to be aligned and held by the connector of the transport prior to being inserted into the receiving space.

The invention will be further explained with respect to Figures 1 to 6, wherein:

Figure 1 provides a schematic overview of a system according to a first embodiment of the invention.

Figure 2 shows a perspective view of a connector comprise by a transport element of the system according to Figure 1.

Figure 3 shows another perspective view of the connector according to Figure 2.

Figure 4 shows a bottom view of the connector according to Figure 2.

Figures 5A, 5B, 5C and 5D show the connector according to Figure 2 during the process of inserting the reservoir into said connector.

Figure 6 shows a method according to the invention.

In Figure 1, a system 1 for regulating the concentration of glucose in the blood of a person is shown. The system 1 comprises a device 2 with a first receiving space 3a for accommodating a first reservoir 100a and a second receiving space 3b for accommodating a, second reservoir 100b.The reservoirs 100a,100b may be embodied as a so-called ampule and may contain a respective substance, in particular a substance affecting the glucose concentration in the blood of a person. For example, the reservoir 100a may contain insulin and the reservoir 100b may contain glucagon. The device 2 comprises two ports 4a, 4b for connecting a respective transport element 10a,10b, in particular a respective connector 11a, 11b thereof, thereto. Said connectors 11a, 11b are arranged at an inlet end of a respective transport means 12a, 12b of a respective transport element 10a, 10b. In this example of the system 1 the transport means 12a, 12b are each embodied as a conduit. Said conduits 10a, 10b each comprise an additional connector 14a, 14b arranged at an outlet end of that conduit 10a, 10b for connecting to a respective infusion element 20a, 20b, in particular to a connector 21a, 21b thereof that fluidly connect to an inlet end of an infusion means 22a, 22b of the infusion element 20a, 20b, herein embodied as a needle, wherein an outlet end of the needle 22a, 22b is configured for being inserted into a body of a person for infusing said substance into said body. The combination of a transport element 10a, 10b and an infusion element 20a, 20b may also be referred to as an infusion set. In order to distinguish between said connectors, the connectors 21a, 21b, 14a, 14b and 11a, 11b may also be referred to as first, second and third connectors, respectively.

In a connected condition in which the connectors 11a, 11b are connected to their respective ports 4a, 4b and the connectors 14a, 14b to connectors 21a, 21b, respectively, a medium through flow connection is provided between the reservoir 100a, 100b and the respective infusion means 22a, 22b, allowing the substance to be fed from the reservoir 100a, 100b via the respective transport element 10a, 10b to the infusion means 22a, 22b and into the body of a person. The device 2 further comprises a controller 5 for controlling the device 2 such that a certain amount of a substance from any of the reservoirs 100a, 100b is infused into the body of the person as described above.

The connector 11, which may be any of the connectors 11a, 11b of figure 1, is shown in greater detail in Figures 2, 3 and 4. The connector 11 comprises a handle 30 and is provided with aligning and holding means for aligning and holding a reservoir 100, which may be any of the reservoirs 100a, 100b of figure 1, connected to the connector 11 in a predetermined orientation with respect to a longitudinal axis of the connector (see Figure 5D) as well as a predetermined position with respect to the connector 11 for obtaining a substantially fluid-tight connection between the connector 11 and the reservoir 100. Said aligning and holding means in this embodiment comprise a plurality of resilient substantially crescent-shaped members 31 that are attached to and uniformly distributed along the interior of a circumferential wall 32 of the connector 11 with two opposing end zones 33, 34

thereof. In this case, the number of such crescent-shaped members 31 is six, but this number may be different from that, such as larger or smaller than that. A convex side 35 of said substantially crescent-shaped members 31 that extends between the two opposing end zones 33, 34 protrudes inwardly from the inner side of said circumferential wall 32 of the connector 11. The two opposing end zones 33, 34 are arranged at substantially the same position with respect to the longitudinal axis of the connector 11. The resiliency of these substantially crescent-shaped members 31 allows these members 31 to move from a first state for holding the reservoir 100 to a second state when said reservoir 100 is pushed against said members 31 when said reservoir 100 is brought towards said connected condition and/or when said reservoir 100 is disconnected from said connector 11, upon which the resilient members 31 are configured to return to the first state because these are urged to the first state. In the present embodiment, the circumferential wall 32 of the connector 11 is provided with slot-shaped through-holes 36, extending between the opposing end zones 33, 34 of the substantially crescent-shaped members 31. The exterior of the circumferential wall 32 is provided with two connecting means 37 for connecting to the port 4 of the device 2.

In this embodiment, the connector 11 also comprises additional aligning means, embodied in this example as a plurality of elongated ribs 40 that are attached to and uniformly distributed along the inner side of the circumferential wall 31 of the connector 11. These ribs 40 extend substantially parallel to the longitudinal axis of the connector 11 and are configured for being in contact with the reservoir 100 upon insertion into the connector 11, thereby at least pre-aligning the reservoir 100 with respect to the longitudinal axis of the connector 11 in a first part of a connection path of connecting the reservoir 100 to the connector 11. These ribs 40 are arranged with respect to the crescent-shaped members 31 such that in a second, subsequent part of said connection path, said reservoir is aligned by the crescent-shaped members 31 and is subsequently held by the crescent-shaped members 31 at the end of the connection path in the connected condition. In the present embodiment, the ribs 40 extend on both sides of the aligning and holding means 31, such that in addition to said pre-alignment the ribs also provide post-alignment of the reservoir in the connected condition. In the present embodiment, the number of ribs 40 is equal to the number of substantially crescent-shaped members 31. In particular, the ribs 40 and the substantially crescent-shaped members 31 are alternatingly arranged around the circumference of the wall 32, spaced apart from each other.

In particular from figure 4 it is clear that as seen in a radially inward direction from the circumferential wall 32, the crescent-shaped members 31 extend further inwards, in particular a center of the convex side 35 thereof, than the ribs 40.This allows the crescent-shaped members 31 to protrude into an area of a neck portion of the reservoir 100 in a fully inserted position of the reservoir into the connector 11 for holding the reservoir.

The connector 11 is further provided with a needle 50, which is in a fluid connection with the inlet end of the transport means 12 and extends through handle 30. Said needle 50 is configured for penetrating a membrane or the like in the cap of the reservoir 100 in the connected condition, wherein

said crescent-shaped members 31 are configured for aligning the reservoir 100 in a predetermined orientation with respect to said needle 50 such that the needle 50 is oriented substantially perpendicular to the membrane of said reservoir 100 during penetrating the membrane during connecting the connector 11 to said reservoir, and for holding said reservoir 100 in said predetermined orientation and in such a position that the needle 50 substantially completely penetrates the membrane in the connected condition, in a position or depth with respect to the connector in which a substantially leak-tight fluid connection is obtained between the reservoir 100 and the connector 11. The needle 50 extends from a surface 51 of the connector 11, which surface 51 is opposite to an insertion opening of the connector 11 via which insertion opening the reservoir 100 can be inserted. The needle 50 extends substantially parallel to the longitudinal axis and with a free end thereof in the direction of the crescent-shaped members 31, i.e. in the direction of the insertion opening.

The process of connection of the reservoir 100 to the connector 11 is shown in more detail in Figures 5A to 5D. In Figure 5A, the reservoir 100 is shown separate from the connector 11. It is clear from this figure that reservoir 100 has an outlet end 101 with a neck portion 102, closed off by a head portion 103 comprising a membrane 104 and a side wall 105. In the next step, shown in Figure 5B, the reservoir 100 is inserted into the connector 11 via the insertion opening thereof, and the reservoir 100 is pre-aligned by a part of the ribs 40 extending before the aligning and holding means 31, as seen in a direction of insertion, as the side wall 105 of the head portion 103 slides along the ribs 40 and is in contact therewith. During this step, the needle 50 does not yet contact the membrane 104. In the next step, shown in Figure 5C, the insertion proceeds and the side wall 105 of the head portion 103 slides along the substantially crescent-shaped members 31 and is in contact therewith, which crescent-shaped members 31 are, as a consequence thereof, forced from the first state shown in Figure 5A and 5B, to a second state and wherein the reservoir 100 is aligned thereby. The second state is not clearly visible in figure 5C but the crescent-shaped members 31 are pressed towards the inner side of the circumferential wall 32. The position of the needle 50 with respect to the membrane 104 is such that the needle 50 still does not penetrate the membrane 104 but is about to. As is shown in figure 5C, the reservoir 100 is aligned with respect to the needle 50 such that the needle 50 extends substantially orthogonal to the membrane 104 at the location where it is about to pierce the membrane 104. When the reservoir 100 is inserted further into the connector 11, the needle 50 punctures the membrane 104. In a fully inserted position of the reservoir the needle 50 fully extends through the membrane such that a position or depth of the reservoir 100 is achieved where there is a substantially leak-tight fluid connection with the connector 11. Because of the pre-alignment by the ribs 40 and/or the alignment by the substantially crescent-shaped members 31, it is ensured that the membrane is correctly aligned with respect to the longitudinal axis L of the connector 11, i.e. with the surface of the membrane where the needle pierces the membrane 104 substantially perpendicular to this axis. The needle 50 extends substantially parallel to the longitudinal axis L. More in particular, the longitudinal axis of the needle 50 coincides with the longitudinal axis L of the connector 11. As a consequence of the further

insertion, the crescent-shaped members 31 return to their first state automatically when the head portion 103 has passed the crescent-shaped members 31 because these are elastically urged to the first state, and then protrude into the area of the neck portion 102 of the reservoir 100 for holding the reservoir 100.

The method of connecting the reservoir 100 to the connector 11, which is shown in Figure 6, may comprise the step 1001 of providing a transport element, either individually, or as a part of an infusion set according to the invention or a system according to the invention, the step 1002 of providing a reservoir comprising an outlet end, the step 1003 of connecting the outlet end of the reservoir to the connector of the transport element, thereby aligning and holding said reservoir with the aligning and holding means of the connector in a connected condition. The method comprises a step 1004 of inserting the reservoir in said receiving space of the device for selectively supplying at least one substance, which step is preferably carried out after step 1003.

It is noted that the invention is not limited to the shown embodiments but also extends to variants within the scope of the appended claims.

Conclusies

1. Transportelement voor het transporteren van een substantie die is bevat in een reservoir, welk transportelement is ingericht om deel uit te maken van een infusieset, welk transportelement transportmiddelen omvat, zoals een leiding, buis, slang, of dergelijk, en een verbindingselement dat is opgesteld aan een inlaateinde van de transportmiddelen voor verbinding met het reservoir, zodanig, dat in een verbonden conditie waarin het verbindingselement is verbonden met het reservoir een mediumdoorstroombare verbinding is verschaft tussen het reservoir en het inlaateinde van de transportmiddelen voor het ontvangen van de substantie uit het reservoir, **met het kenmerk, dat** het verbindingselement uitlijn- en vasthoudmiddelen omvat voor het uitlijnen en vasthouden van het reservoir in een vooraf bepaalde oriëntatie ten opzichte van en/of positie langs een langsas van het verbindingselement.

2. Transportelement volgens conclusie 2, waarbij het verbindingselement van het transportelement aanvullende uitlijnmiddelen omvat, welke aanvullende uitlijnmiddelen zich uitstrekken vóór en/of na de uitlijn- en vasthoudmiddelen zoals gezien in de richting van de langsas.

3. Transportelement volgens conclusie 2, waarbij de aanvullende uitlijnmiddelen die zich vóór de uitlijn- en vasthoudmiddelen uitstrekken zijn ingericht voor het vooruitlijnen van het reservoir ten opzichte van de langsas van het verbindingselement in een eerste deel van een verbindingspad van het verbinden van het reservoir met het verbindingselement, waarbij in een tweede, opvolgend deel van het verbindingspad het reservoir wordt uitgelijnd door de uitlijn- en vasthoudmiddelen en optioneel de aanvullende uitlijnmiddelen, en vervolgens aan het einde van het verbindingspad wordt vastgehouden door de uitlijn- en vasthoudmiddelen in de verbonden conditie.

4. Transportelement volgens conclusie 2 of 3, waarbij de aanvullende uitlijnmiddelen die zich uitstrekken na de uitlijn- en vasthoudmiddelen zijn ingericht voor het handhaven van de uitlijning van het reservoir in de vooraf bepaalde oriëntatie in de verbonden conditie.

5. Transportelement volgens een der conclusies 2 – 4, waarbij de uitlijn- en vasthoudmiddelen meer flexibel zijn dan de aanvullende uitlijnmiddelen.

6. Transportelement volgens een der conclusies 2- 5, waarbij de aanvullende uitlijnmiddelen ten minste één langwerpige rib omvatten die binnenwaarts uitsteekt vanaf de binnenzijde van een omtrekswand van het verbindingelement en zich in hoofdzaak parallel aan de langsas uitstrekt.

7. Transportelement volgens conclusie 6, waarbij de aanvullende uitlijnmiddelen een aantal van dergelijke ribben omvatten welke over de omtrek van de omtrekswand verspreid zijn op gesteld, bij voorkeur in een uniforme verdeling.

8. Transportelement volgens een der voorgaande conclusies, waarbij de uitlijn- en vasthoudmiddelen ten minste één veerkrachtig element omvatten, welk veerkrachtige element een eerste toestand voor het vasthouden van het reservoir bezit en verplaatsbaar is naar een tweede toestand wanneer het reservoir tegen het veerkrachtige element aan wordt gedrukt wanneer het reservoir wordt verbonden met of ontkoppeld wordt van het verbindingselement, en waarbij het veerkrachtige element elastisch naar zijn eerste toestand is geneigd.

9. Transportelement volgens conclusie 8, waarbij het ten minste ene veerkrachtige element ten minste één in hoofdzaak maanvormig element omvat, waarbij het in hoofdzaak maanvorige element is bevestigd aan de binnenzijde van een of de omtrekswand van het verbindingselement met twee tegenoverliggende eindzones daarvan en waarbij een convexe zijde van het in hoofdzaak maanvormige element dat zich tussen de twee tegenoverliggende eindzones uitstrekt naar binnen uitsteekt vanaf de binnenzijde van de omtrekswand van het verbindingselement.

10. Transportelement volgens conclusie 9, waarbij een gat of opening is verschaft in de omtrekswand in een gebied tussen de twee tegenovergelegend eindzones van het ten minste ene in hoofdzaak maanvormige element.

11. Transportelement volgens een der voorgaande conclusies 8 – 10, omvattende een aantal van de genoemde veerkrachtige elementen en waarbij de veerkrachtige elementen verspreid over de omtrek van een of de omtrekswand zijn opgesteld, bij voorkeur in een uniforme verdeling en/of bij voorkeur aangebracht op dezelfde positie langs de langsas.

12. Transportelement volgens conclusie 6 of 7, waarbij de ribben en veerkrachtige elementen afwisselend zijn opgesteld over de omtrek van de omtrekswand, bij voorkeur met een uniforme verdeling en/of op afstand van elkaar.

13. Transportelement volgens een der voorgaande conclusies, waarbij het verbindingselement penetreermiddelen omvat, zoals een naald, die zich in hoofdzaak parallel aan de langsas uitstrekken met een vrij einde daarvan in de richting van de uitlijn- en vasthoudmiddelen voor het penetreren van een membraan of dergelijk van het reservoir althans in de verbonden conditie, waarbij de uitlijn- en vasthoudmiddelen en optioneel de aanvullende uitlijnmiddelen zijn ingericht voor het zodanig uitlijnen van het reservoir in de vooraf bepaalde orientatie dat de pentereermiddelen in hoofdzaak

loodrecht ten opzichte van het membraan van het reservoir geörienteerd zijn gedurende penetratie van het membraan gedurende het verbinden van het verbindingselement met het reservoir, en voor het houden van het reservoir in de vooraf bepaalde oriëntatie en op een zodanige positie dat de penetreermiddelen het membraan volledig penetreren in de verbonden conditie.

14. Transportelement volgens een der voorgaande conclusies, waarbij de uitlijn- en vasthoudmiddelen zijn ingericht om uit te steken in een gebied van en/of om aan te grijpen op een nekdeel van het reservoir in de verbonden conditie.

15. Infusieset, omvattende:
- een transportelement volgens een der voorgaande conclusies, verder omvattende een aanvullend verbindingselement opgesteld aan een uitlaateinde van de transportmiddelen, en
- een infusie-element omvattende infusiemiddelen voor het toedienen van een substantie in een lichaam van een persoon, welke infusiemiddelen bijvoorbeeld een canule, katheter, naald, of spuitmond zijn, waarbij de infusiemiddelen een inlaateinde voor het ontvangen van de substantie en een uitlaateinde voor het toedienen van de substantie in het lichaam omvatten, waarbij het infusie-element een verbindingselement omvat voor verbinding met het aanvullende verbindingselement van het transportelement van de infusieset, en
- waarbij het aanvullende verbindingselement van het transportelement verbindbaar is met het verbindingselement van het infusie-element, zodanig, dat in de verbonden conditie waarin het aanvullende verbindingselement van het transportelement is verbonden met het verbindingselement van het infusie-element een mediumdoorstroombare verbinding is verschaft tussen het uitlaateinde van de transportmiddelen en het inlaateinde van de infusiemiddelen voor het toevoeren van de substantie aan de infusiemiddelen.

16. Systeem voor het reguleren van de concentratie van glucose in het bloed van een persoon, omvattende ten minste één infusieset volgens conclusie 15 en een inrichting voor het selectief toevoeren van ten minste één substantie bevat in ten minste één reservoir, welke inrichting omvat:
- ten minste één ontvangstruimte voor het accommoderen van het reservoir;
- ten minste één poort voor verbinding met een genoemd verbindingselement van een genoemd transportelement van de infusieset, en
- een controller voor het zodanig aansturen van de inrichting, dat een bepaalde hoeveelheid van de substantie wordt toegevoerd en daardoor in het lichaam van de persoon wordt toegediend.

17. Combinatie van een reservoir, bij voorkeur een reservoir dat voorgevuld is met een substantie zoals of omvattende insulin of glucagon, en::
- een transportelement volgens een der conclusies 1- 14;

- een infusieset volgens conclusie 15, or
- een systeem volgens conclusie 16.

18. Werkwijze voor het althans fluïdisch verbinden van een transportelement met een reservoir, omvattende de stappen:
a) het verschaffen van een transportelement volgens een der conclusies 1 – 14, een infusieset volgens conclusie 15, of een systeem volgens conclusie 16;
b) het verschaffen van een reservoir met een uitlaateinde;
c) het verbinden van het uitlaateinde van het reservoir met het verbindingselement van het transportelement, waardoor het reservoir in een verbonden conditie wordt uitgelijnd en vastgehouden door de uitlijn- en vasthoudmiddelen van het verbindingselement.

19. Werkwijze volgens conclusie 18, waarbij in stap c) het reservoir wordt verbonden met het verbindingselement over een verbindinspad, waarbij in een eerste deel van het pad het reservoir wordt vooruitgelijnd door de aanvullende uitlijnmiddelen, waarbij in een tweede, opvolgend deel van het pad het reservoir wordt uitgelijnd door de uitlijn- en vasthoudmiddelen en optioneel de aanvullende uitlijnmiddelen, en waarbij het reservoir vervolgens in de verbonden conditie wordt vastgehouden door de uitlijn- en vasthoudmiddelen en optioneel wordt uitgelijnd door de aanvullende uitlijnmiddelen.

20. Werkwijze volgens een der voorgaande conclusies 18 of 19, waarbij in stap a) een systeem volgens conclusie 16 is verschaft, en waarbij de werkwijze verder stap d) omvat van het invoeren van het reservoir in de ontvangstruimte van de inrichting, waarbij stap d) bij voorkeur na stap c) wordt uitgevoerd.

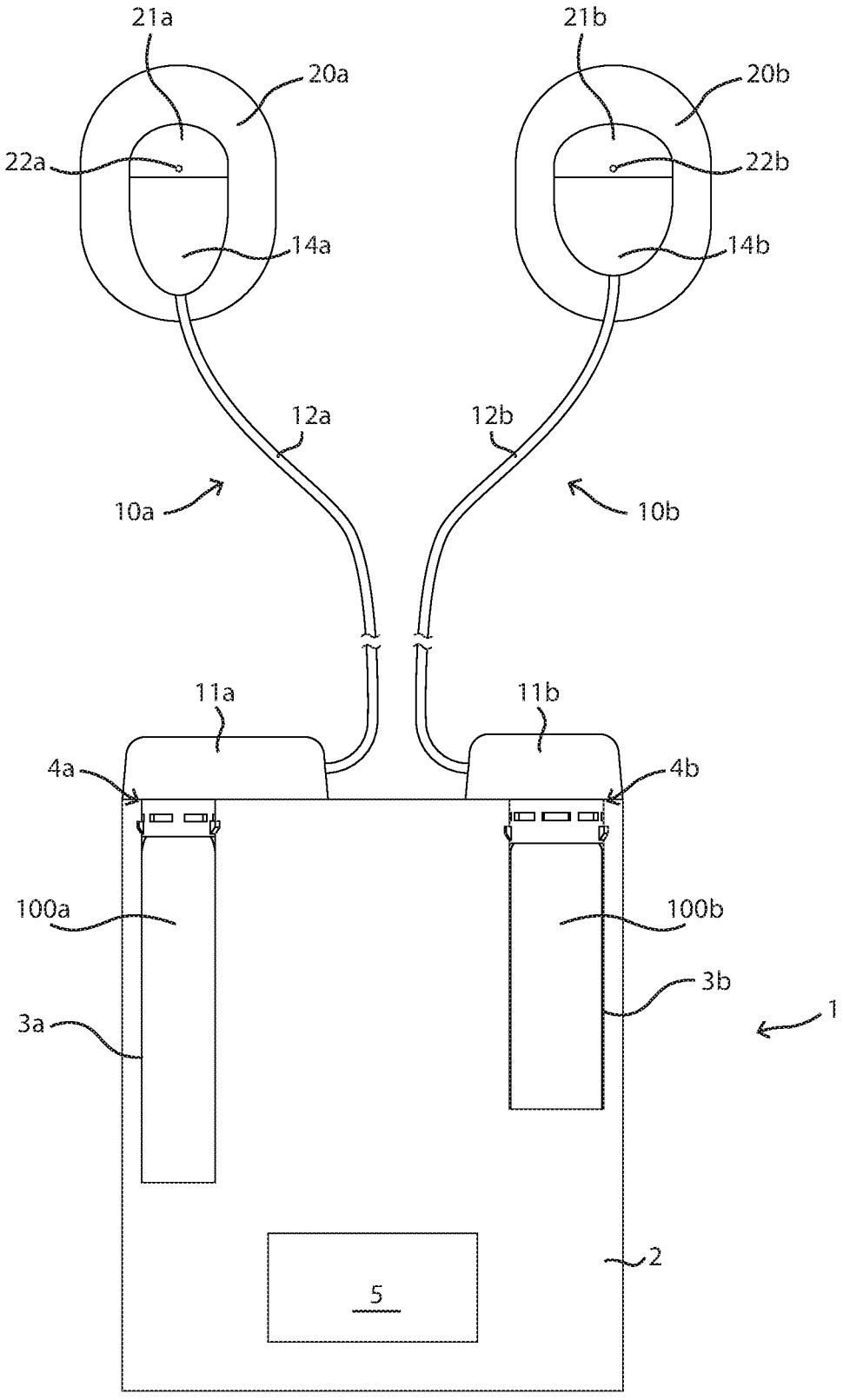
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Fig. 1

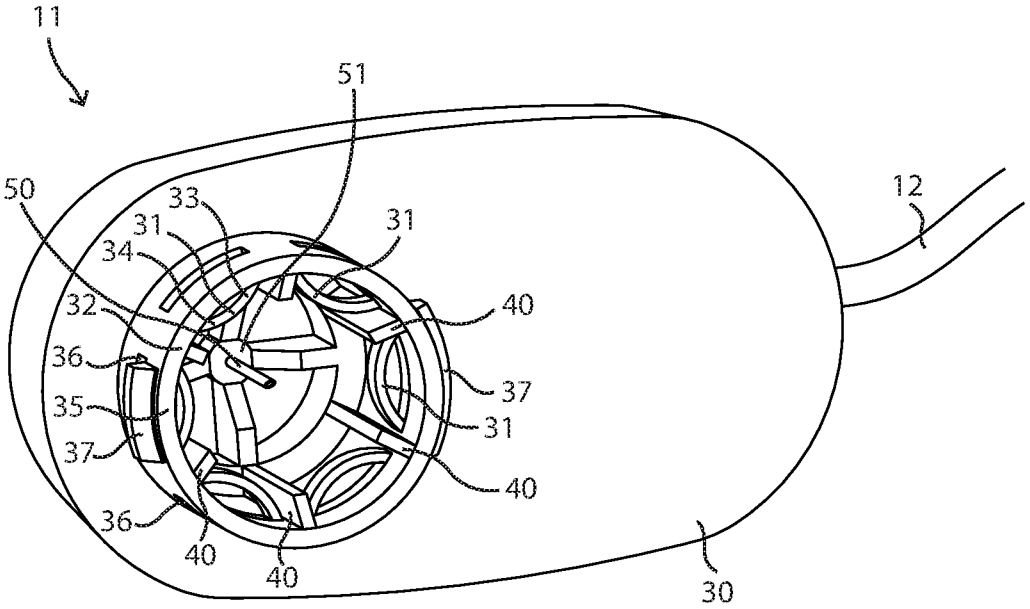
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Fig. 2

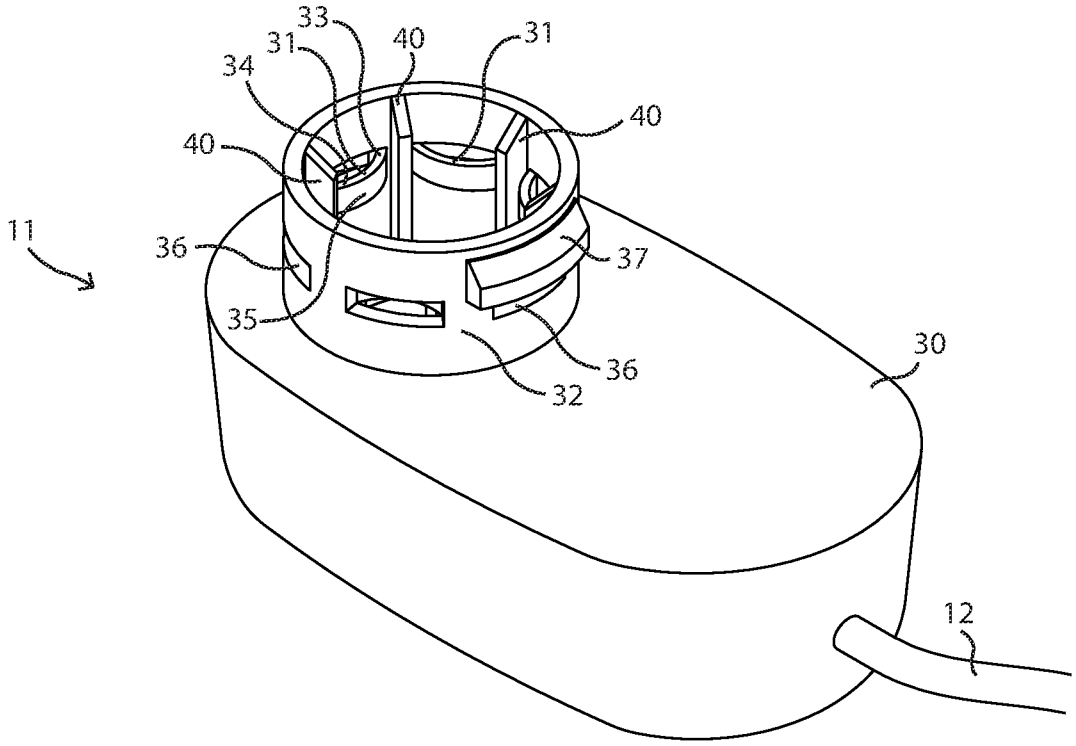
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Fig. 3

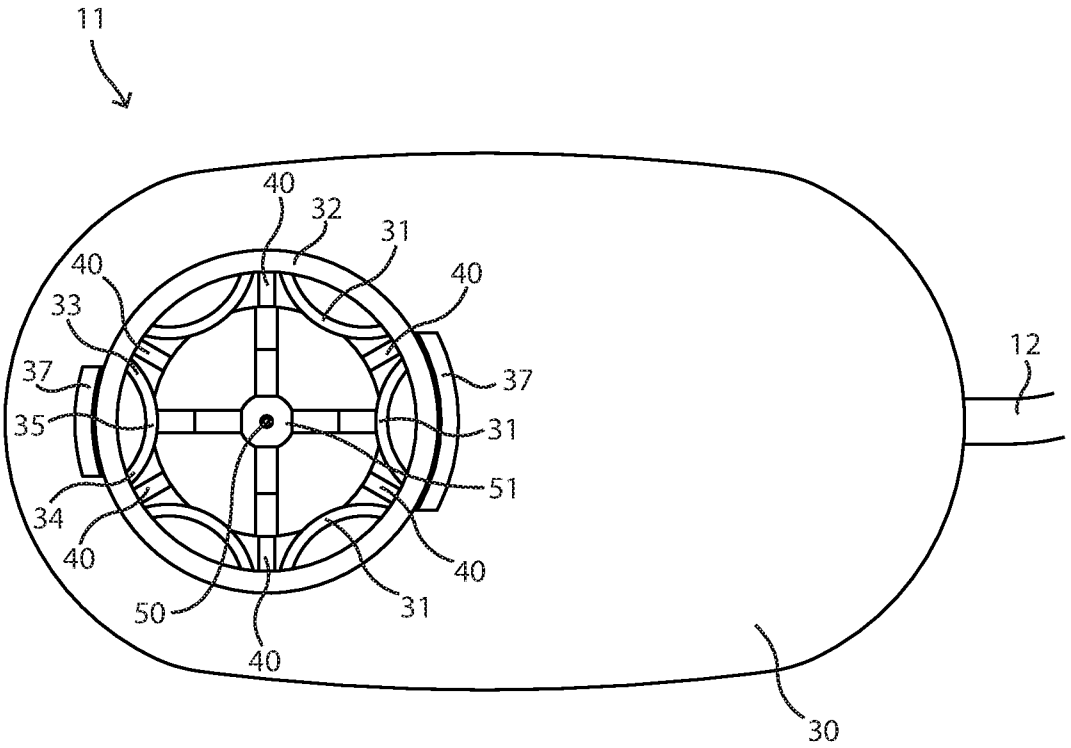

Fig. 4

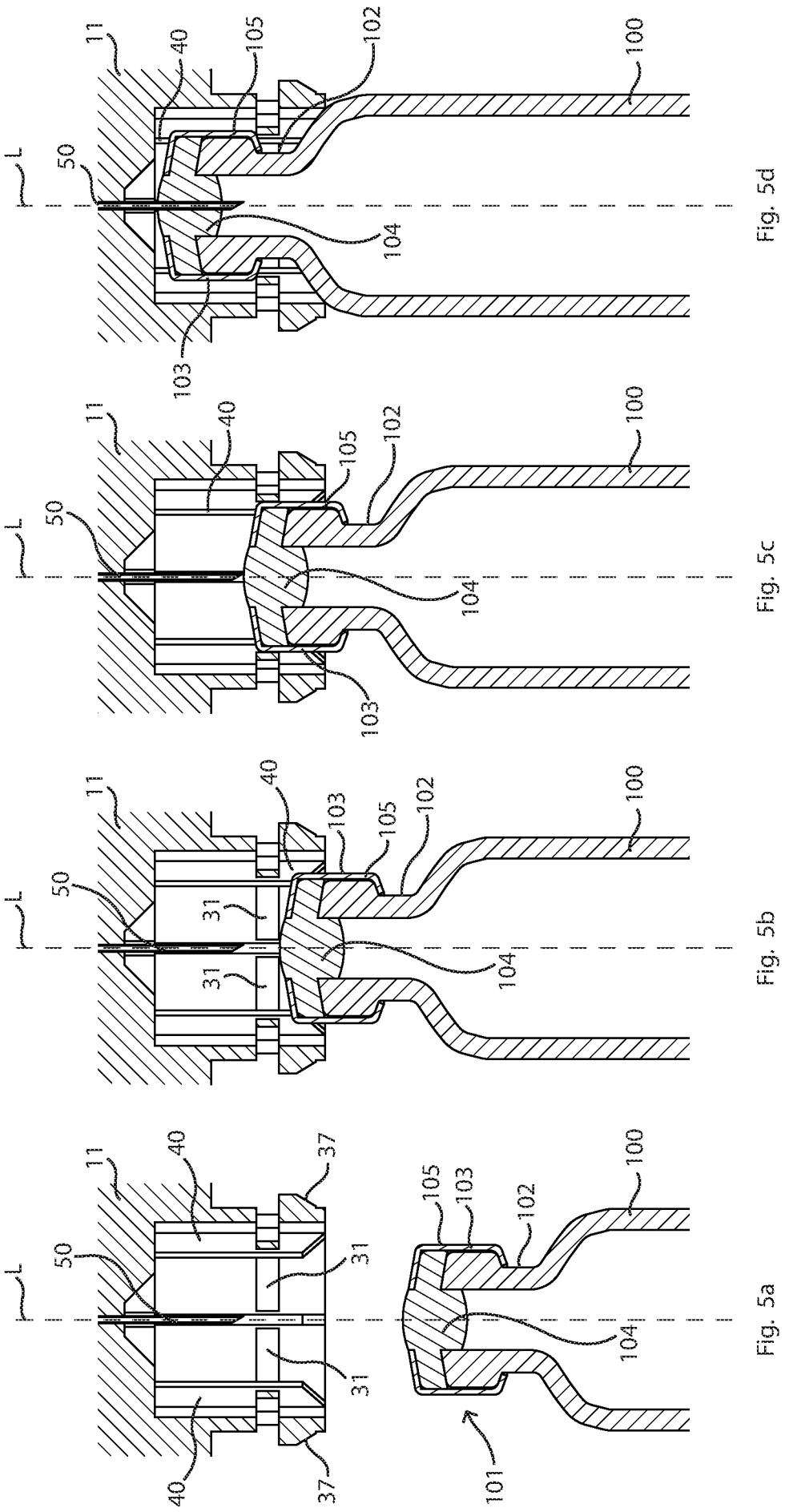

Fig. 5d

Fig. 5c

Fig. 5b

Fig. 5a

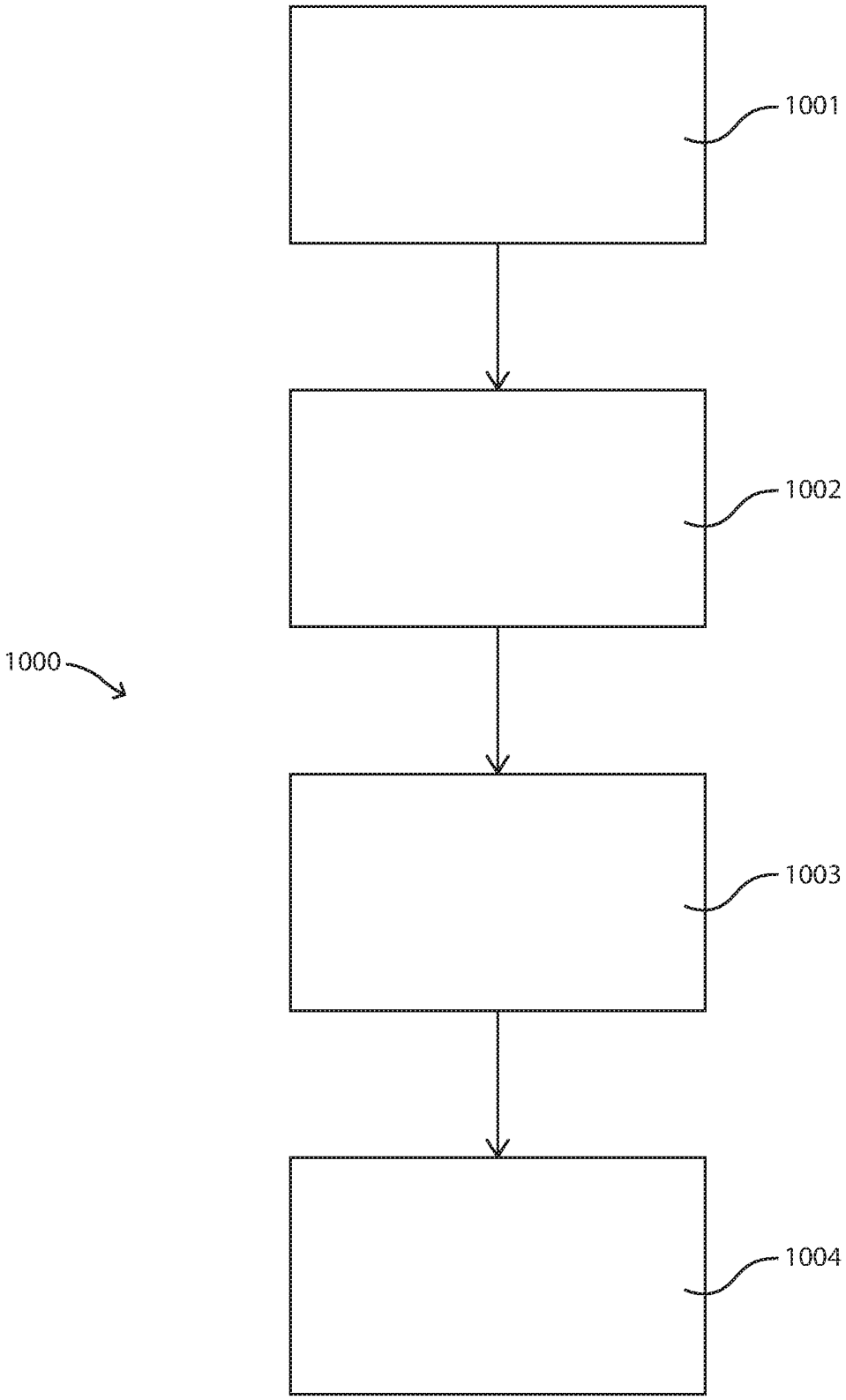

Fig. 6

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
Nederlands aanvraag nr. **2028804**	Indieningsdatum **22-07-2021**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **INREDA DIABETIC B.V.**	
Datum van het verzoek voor een onderzoek van internationaal type **09-10-2021**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN79785**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

Zie onderzoeksrapport

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**Zie onderzoeksrapport**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III.	☐	**GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV.	☐	**GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2028804

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61M5/162 A61M39/10 A61M39/14
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61M A61J

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	US 8 382 696 B2 (FRESENIUS MED CARE HLDG INC [US]; BEIRIGER MICHAEL JAMES [US] ET AL.) 26 februari 2013 (2013-02-26)	1,8,11, 13-20
A	* kolom 20, laatste alinea; figuren 1-6 *	9,10
X	WO 2019/026796 A1 (JMS CO LTD [JP]) 7 februari 2019 (2019-02-07) * alineas [0007], [0028], [0045], [0048], [0052], [0065]; figuren 1-7 *	1-8, 11-20
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X	US 2008/249498 A1 (FANGROW THOMAS F [US]) 9 oktober 2008 (2008-10-09) * figuren 4-5 *	1,8,11, 13-20

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[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
7 april 2022	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	**Diamantouros, S**

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Formulier PCT/ISA/201 (tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2028804

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	US 2010/108681 A1 (JEPSON STEVEN C [US] ET AL) 6 mei 2010 (2010-05-06) * alinea [0075]; figuren 1-8 * -----	1,13, 15-20
X	US 9 254 361 B2 (RAHIMY ISMAEL [DE]; BRANDENBURGER TORSTEN [DE] ET AL.) 9 februari 2016 (2016-02-09) * figuren 2-5 * -----	1,8,11, 13-20

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek

NL 2028804

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ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek

NL 2028804

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 2010108681 A1	06-05-2010	CA 2732838 A1	25-02-2010
		EP 2326385 A2	01-06-2011
		US 2010049160 A1	25-02-2010
		US 2010108681 A1	06-05-2010
		WO 2010022068 A2	25-02-2010
US 9254361 B2	09-02-2016	AT 485068 T	15-11-2010
		AU 2007321437 A1	22-05-2008
		BR PI0718689 A2	31-12-2013
		CA 2669161 A1	22-05-2008
		DE 102006053219 A1	21-05-2008
		EP 2086610 A1	12-08-2009
		ES 2353923 T3	08-03-2011
		HK 1132944 A1	12-03-2010
		JP 5290184 B2	18-09-2013
		JP 2010508922 A	25-03-2010
		KR 20090085617 A	07-08-2009
		NO 341522 B1	27-11-2017
		PL 2086610 T3	29-04-2011
		US 2010063456 A1	11-03-2010
		WO 2008058656 A1	22-05-2008
		ZA 200902752 B	28-04-2010

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN79785	22.07.2021		NL2028804

International Patent Classification (IPC)
INV. A61M5/162 A61M39/10 A61M39/14

Applicant
INREDA DIABETIC B.V.

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☒ Box No. VIII Certain observations on the application

	Examiner
	Diamantouros, S

Application number

WRITTEN OPINION

NL2028804

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	9, 10, 16-20
	No:	Claims	1-8, 11-15
Inventive step	Yes:	Claims	9, 10
	No:	Claims	1-8, 11-20
Industrial applicability	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VII Certain defects in the application

see separate sheet

Box No. VIII Certain observations on the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 US 8 382 696 B2 (FRESENIUS MED CARE HLDG INC [US]; BEIRIGER MICHAEL JAMES [US] ET AL.) 26 februari 2013 (2013-02-26)

D2 WO 2019/026796 A1 (JMS CO LTD [JP]) 7 februari 2019 (2019-02-07)

D3 US 2019/022344 A1 (LAU ANDREW CHI LUP [NZ] ET AL) 24 januari 2019 (2019-01-24)

D4 US 2008/249498 A1 (FANGROW THOMAS F [US]) 9 oktober 2008 (2008-10-09)

D5 US 2010/108681 A1 (JEPSON STEVEN C [US] ET AL) 6 mei 2010 (2010-05-06)

D6 US 9 254 361 B2 (RAHIMY ISMAEL [DE]; BRANDENBURGER TORSTEN [DE] ET AL.) 9 februari 2016 (2016-02-09)

2 The present application does not meet the criteria of patentability, because the subject-matter of claim1 is not new.

2.1 It appears that claim 1 is so broadly formulated that a large number of documents would be novelty destroying. In particular, the preamble of claim 1 is directed to any infusion tube connected to a reservoir, which encompasses the majority of infusion tubes that are used in any medical or research application. The characterising part does not pose any practical restrictions, as it claims an "aligning and holding means", which is an implicit function of most connectors. Any thread, snap connection or bayonet connection can be considered as aligning and holding means as they perform both of these functions. For example, a standard luer lock connector would be novelty destroying for claim 1.

2.2 Several documents (D1-D6) have been cited against novelty of claim 1. More specifically, D1 discloses (references to D1):

A transport element for transporting a substance contained in a reservoir (125, figure 3), said transport element being arranged to be part of an infusion set, said transport element comprising a transport means (122), such as a conduit, tube, hose or the like, and a connector (120) arranged at an inlet end of the transport means for connecting to said reservoir such that in a connected condition in which the connector is connected to said reservoir a medium through flow connection is provided between said reservoir and the inlet end of the transport means for receiving said substance from said reservoir (see summary of the invention), wherein said connector comprises aligning and holding means (flange 150, figure 4) for aligning and holding the reservoir in a predetermined orientation with respect to and/or position along a longitudinal axis of the connector (column 20, lines 57-61).

3 Documents D2-D6 also disclose the subject-matter of claim 1.

In document D2 see figures 5-7: A connector is being attached on a vial and comprises several aligning and holding means (59, 33). Furthermore, D2 also discloses one adapter (50, figure 1) being attached on a connector (10), which adapter also comprises aligning means (56, 57, figure 3B). This embodiment is also novelty destroying for claim 1.

Document D3 discloses a connector for a breathing circuit, disclosing several aligning elements (see figure 36, alignment features 210, 211, 212).

In document D4, see figures 4 and 5. The connector to the reservoir comprises alignment features 237.

Document D5 discloses a perforator with a cylindrical collar 166 (see figure 3 and paragraph 75).

Similarly, in document D6 see figures 2 and 5.

4 Dependent claims 2-8 and 11-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of novelty and/or inventive step. More specifically:

Claims 2-7: See D2, figure 6, additional aligning means 59, or figure 3B, additional aligning means 56. Also D3, figure 36, additional aligning means 211. For claim 5, see also the corresponding clarity objection.

Claims 8, 11: See D1, D2, D4 and D6 - references as in connection to claim 1.

Claim 12: See document D2, figures 3B, 6.

Claim 13: These features are disclosed in documents D1, D2 and D4-D6 - references in the search report.

Claim 14: See D1, D2, D4 and D6 - references in the search report.

Claim 15: See D1-D2, D4-D6: All these documents disclose an infusion element with a connector.

Claims 16-17: The skilled person looking for a treatment for regulating glucose would be able to implement any of the solutions of D1-D6 for the alignment and holding of a connector. The subject-matter of this claim does not appear inventive.

Claims 18-20: The subject-matter of these claims is also obvious to the skilled person. These claims merely describe a standard connection of a reservoir to a connector and a tube.

4.1 The subject-matter of claims 9-10 is not disclosed nor hinted in the cited prior art documents and could serve as the basis for a novel and inventive independent claim.

Re Item VII

Certain defects in the application

1 Independent claims should be in the two-part form.

2 The features of the claims are not provided with reference signs placed in parentheses.

Re Item VIII

Certain observations on the application

1 It seems that the subject matter of claim 14 is essential for the definition of the invention. Unless the aligning and holding means are not configured to protrude in order to grip a neck portion of the container, the element will not perform is function as *holding* means. Its subject-matter should therefore be included in claim 1.

2 In claim 5 it is not clear how the flexibility of the alignment means is defined. The claims are vague as to the form of the alignment means and therefore their flexibility can be measured in different ways and depend on several factors. As a result, the restrictions posed by the subject-matter of this claim are not clear to the skilled person.