

SUMMARY

For such devices, the provision of non-visual user indications to the user is critical due to the sealed housing. In particular, a vibration device in form of a vibrator motor is common for providing user indications in a well recognizable but discrete manner. The vibrator motors are of generally the same type as widely used for example in cell phones or pager devices. Normally the vibrator respectively vibrator motor is mounted on the inside of the housing in a substantially rigid way. For transmitting the vibration to the outside, the whole housing or at least a substantial part thereof needs to be excited to mechanically vibrate. Only a fraction of the acceleration that results from the vibration of the vibrator, however, is transferred to the housing structure. Consequently, the vibration that is sensed by the person carrying the device is low and in extreme cases nothing can be sensed at all. This is particularly critical for a number of persons, e.g. many diabetics, who suffer from reduced tactile sensitivity.

Further, if a vibration is transmitted from a vibrator to the housing as a whole, a skin-piercing element, such as an infusion cannula or a transcutaneous glucose sensing element, may also be caused to vibrate, resulting in discomfort and potentially severe pain. Further, in case of an infusion cannula, the vibration may adversely affect the infusion, since the cannula channel in the skin is likely to be widened, resulting in a potential drug flow of infused drug out of the body along the outer side of the cannula.

US6126595 discloses a housing that has a locally reduced thickness of a housing wall in an area surrounding a piezo vibrator that is mounted to the housing wall. Due to the reduced wall thickness, the ability of the housing wall to be mechanically excited and move forth and backwards is somewhat improved.

It is the overall objective of the present disclosure to improve the state of the art regarding the provision of tactile indications for an ambulatory medical device. Favorably, the drawbacks of the state of the art as mentioned before are at least partially avoided.

In a general way, the overall objective is achieved by the subject matter of the independent
5 claims. Exemplary and favorable examples are defined by the subject of the dependent claims as well as the descriptions and figures.

In an aspect, the overall objective is achieved by an ambulatory medical device that is designed for attachment to a person's body. The ambulatory medical device includes a housing, the housing having a wall element and a vibrator coupling element. A convex outer surface of the vibrator
10 coupling element projects from the wall element towards the outside of the housing. The vibrator coupling element is coupled to the wall element via a connection element, with the connection element being arranged along a circumference of the vibrator coupling element. The ambulatory medical device further includes a vibrator. The vibrator is configured to mechanically vibrate upon activation. The vibrator is at least partially arranged inside a volume defined by the
15 vibrator coupling element and mounted to the vibrator coupling element. In some examples, the vibrator is completely or substantially completely arranged inside the volume of the vibrator coupling element.

In another aspect, the overall objective is achieved by a skin attachment device. The skin attachment device includes a substantially planar body with a skin attachment side and an opposing
20 medical device mounting side. The skin attachment side includes a skin attachment structure configured to releasably attach the skin attachment device to a person's skin. The medical device mounting side includes a medical device mounting structure configured to releasably engage with an attachment device mounting structure of an ambulatory medical device. The ambulatory medical device includes a housing having a wall element and a vibrator coupling element.
25 A convex outer surface of the vibrator coupling element projects from the wall element towards

the outside of the housing, and the vibrator coupling element is coupled to the wall element via a connection element, with the connection element being arranged along a circumference of the vibrator coupling element. The housing further includes the attachment device mounting structure configured to releasably mount the ambulatory medical device to the skin attachment device. The ambulatory medical device further includes a vibrator configured to mechanically vibrate upon activation. The vibrator is at least partially arranged inside a volume defined by the vibrator coupling element and mounted to the vibrator coupling element. The substantially planar body includes a vibrator coupling opening which is configured such that in a configuration in which the ambulatory medical device is mounted to the skin attachment device, the vibrator coupling element projects through the vibrator coupling opening towards the skin attachment side, and the skin attachment device further includes a cannula coupling structure configured to couple with a cannula and/or a fluidic coupling structure.

The wall element, the vibrator coupling element and the connection element are typically structurally distinct. They may, however, be permanently or releasably connected.

The ambulatory medical device is skin-mountable by direct attachment to the skin, and/or via a skin attachment device as intermediate element as discussed in more detail further below.

The mounting of the vibrator to the vibrator coupling element is a rigid mounting, resulting in a stiff mechanical coupling. Consequently, a mechanical vibration of the vibrator is mainly and favorably substantially completely transferred to the vibrator coupling member. Typically, the vibrator is not mechanically coupled or attached to other parts of the medical device in a way that would limit or influence its freedom to move, respectively to vibrate. The mounting of the vibrator to the vibrator coupling element may be achieved, for example, by gluing, clamping, or screwing. The electrical connection of the vibrator with further circuitry of the ambulatory medical device is favorably flexible and compensates for the relative movement of the vibrator relative to the further components of the medical device. The electrical connection may, for example, be flexible cables or a flexible printed circuited board (flexprint).

The housing may be of any desired shape, for example box-or disc-shaped. Further, the housing may have planar and/or non-planar walls. The wall element as mentioned before is substantially planar and faces, in application, towards the person's skin. Both the housing and the vibrator coupling element are typically made from plastics. The vibrator coupling element may in some examples be arranged in a vibrator coupling opening in form of a cutout or aperture of the wall element, with an edge of the aperture circumferentially surrounding the vibrator coupling element. Typically, but not necessarily, a footprint of the aperture and of the vibrator coupling element (transverse to the wall element) is circular. The aperture and the vibrator coupling element may have corresponding footprints. In some examples, the footprint of the aperture is somewhat larger as compared to the vibrator coupling element to enable displacement of the vibrator coupling element relative to the wall element.

The convex outer surface of the vibrator coupling element may be smooth. In alternative examples, the convex outer surface of the vibrator coupling element may be provided with a single or a plurality of additional burls or protrusions, in particular in an area that contacts

the skin during application, thereby creating a non-smooth surface. Such a non-smooth surface favorably increases the tactile sensing of the vibrations by the user. Similarly, the outer surface of the vibrator coupling element may be roughened in particular in an area that contacts the skin during application.

5 Via the design described herein, the vibration transfer from the vibrator to the user's skin is improved, resulting in an improved vibration sensing. Further, disadvantageous vibration of a skin-piercing element such as an infusion cannula or transcutaneous glucose-sensor is reduced and favorably eliminated. These advantages are caused by the fact that a vibration is largely or even fully limited to the vibrator coupling element, rather than the housing as a whole.

10 In some examples, the vibrator is configured to vibrate in a plane parallel to the wall element. In such example, the vibration is accordingly tangential to the wall element. A vibration in a plane may be one dimensional (in a direction along one axis), or two-dimensional. In some alternative examples, the vibrator may be configured to vibrate in a direction transverse or perpendicular to the wall element and/or oblique to the wall element.

15 In some examples, the vibrator coupling element is calotte-shaped. In such example, the convex side of the calotte, respectively the vibrator coupling element projects from the wall element. Further, the vibrator is at least partly arranged inside the calotte, respectively the vibrator coupling element. This type of example is particularly favorable for transmitting the vibration to the user's skin. In application, an apex region of the calotte is favorably gently pressed into the skin
20 without causing skin irritation. Further, the arrangement of the vibrator inside the calotte is favorable regarding an efficient space usage and the desired stiff coupling. The calotte may have the shape of a sphere or ellipsoid section. In alternative examples, the vibrator coupling element may have a different shape, for example a generally

cylindrical shape with a tubular side wall and planar skin-contacting bottom wall, or a tubular section that projects from the wall element and a calotte-shaped skin-contacting section.

In some examples, the vibrator coupling element is displaceable relative to the wall element. The vibrator coupling element may especially be displaceable in a direction that corresponds to, respectively is parallel to a vibration direction of the vibrator. That is, in examples in which the vibrator is configured to vibrate in a plane parallel, respectively tangential to the wall element, the vibrator coupling element may also be displaceable relative to the wall element in a plane parallel, respectively tangential to the wall element. In examples in which the vibrator is configured to vibrate in a direction perpendicular to the wall element, the vibrator coupling element may also be displaceable relative to the wall element in a direction perpendicular to the wall element. The vibrator coupling element being displaceable in this way improves the vibration transfer from the vibrator to the skin. Favorably, the possible displacement of the vibrator coupling element is sufficiently large in order not to hinder the movement of the vibrator coupling element resulting from the vibration. A displacement of the vibrator coupling element is to be understood in the sense of a movement of the vibrator coupling element as a whole. A displaceable arrangement of the vibrator coupling element is particularly efficient in decoupling the vibrator coupling element from the wall element, thereby restring the vibration to the vibrator coupling element. In alternative examples, the vibrator coupling element is configured to vibrate via small internal deformation, without being displaced, respectively moved as a whole.

In some examples, the connection element is flexible. A flexible connector element is particularly favorable to enable a displacement of the vibrator coupling element relative to the wall element, respectively the housing as a whole as explained before.

The connection element may in some examples surround the vibrator coupling element, favorably over its full circumference. It may be attached to the vibrator coupling element along its outer circumference and to the wall element. In some examples, the footprint of the vibrator coupling element is normally somewhat smaller as compared to an aperture of the wall element in which the vibrator coupling element is arranged as explained before. In such examples, a transversal, respectively radial gap accordingly exists between the wall element and the vibrator coupling element. This gap is bridged by the connection element. Further in some examples, the vibrator coupling element is axially displaced with respect to the wall element, respectively a plane defined by the wall element, resulting in an axial gap that is also bridged by the connection element. In this context, axial refers to a direction transverse to the wall element, while radial refers to a direction parallel to the wall element.

In some examples, the connection element is designed as bellows. The connection element may be made of any suited material of sufficient flexibility, for example rubber or silicone. The connection element may be a separate component that is connected to the wall element and the vibrator coupling element via corresponding mating structures, or may be formed integrally with the housing respectively wall element and/or the vibrator coupling element, for example by two-component injection molding.

In some examples, the connection element comprises at least one swage. Swages are a particularly favorable way for realizing a flexible coupling between wall element and vibrator coupling element. A single or a number of swages may be present in functional sequential arrangement.

In some further examples, the connection element is an adhesive element via which the vibrator coupling element is adhesively attached to the wall element. In such examples, the connection element may be rigid or substantially rigid.

In some examples, the housing is substantially rigid. A generally rigid housing is favorable and may be necessary in order to withstand external forces that typically act on the ambulatory medical device in use and may, if not absorbed, damage the device and/or lead to critical malfunctions. A rigid housing, however, is disadvantageous for transmitting vibrations from inside the housing to the outside. In this context, the present disclosure at hand has the particular advantage of ensuring, by means of the vibrator coupling element, a good vibration transmission even though the housing in general is stiff and rigid.

In some examples, a mass of the vibrator coupling element is small as compared to a mass of the housing. A small mass of the vibrator coupling element results in a large vibration amplitude and therefore good tactile sensing by the person carrying the device. Favorably, the mass of the vibrator coupling element is also small against the wall element.

In some examples, the wall element is coupled to the vibrator coupling element in a hermetically sealing manner. This may be achieved by a circumferentially closed connection element without openings. Such example is particularly favorable in combination with a generally tight, respectively hermetically sealed housing. The expression “sealed” refers to a protection against the passing of one or more of liquids, gas, steam, and particles, such as dust.

In some examples, the vibrator is a coin vibration motor. Generally, vibration motors are based on the rotation of an eccentric mass coupled to the motor shaft causing vibration due to the unbalanced mass. A coin vibration motor (also referred to as flat vibration motor or pancake vibration motor) comprises of a particularly thin, coin-shaped motor. Such coin vibrator motor is favorably mounted with the motor axis being transverse to the plane of the wall element and may be favorably fully arranged within the e. g. calotte-shaped vibrator coupling element.

In some further examples, the vibrator is an eccentric rotating mass vibration motor (ERM). For this type of design, an eccentric mass is mounted to the axis of a miniaturized electric motor of typical cylindrical shape.

In some further examples, the vibrator is a linear resonant actuator (LRA). Such LRAs are generally designed similar to a dynamic loudspeaker as known in the art, but are provided with a vibration mass instead of a membrane. Their overall shape may be coin-like as for a coin vibration motor. For a coin vibration motor, however, the vibration direction is parallel, respectively tangential to the top and bottom surface of the coin-shaped housing. For an LRA, in contrast it is transverse, respectively perpendicular.

Generally, the term “vibrator” is to be understood as an electrically actuated device that generates a mechanical vibration upon actuation. Vibrators within this meaning are also commonly used, e. g., in cell phones or pager devices.

In some examples, the ambulatory medical device is an ambulatory infusion device, in particular an insulin pump. Such ambulatory infusion device as used, in particular in diabetes therapy via continuous subcutaneous insulin infusion (CSII) and is designed to administer a liquid drug, for example a liquid insulin formulation, in small quantities substantially continuously typically according to a time-varying infusion schedule, and further administer larger drug amounts on demand. A variety of general designs for ambulatory infusion devices is known in the art. In alternative examples, the ambulatory medical device is or includes additionally or alternatively other types of therapeutic devices, such as a stimulation device, and/or is a diagnostic device, such as a continuous glucose monitor, as also used in diabetes therapy in increasing numbers. Typically, the ambulatory medical device is an electronic device and includes control circuitry as generally known in the art, based on, e.g., one or more microcomputers or microcontrollers.

In some examples, the housing includes an attachment device mounting structure for releasable mounting the ambulatory medical device to a skin attachment device. The attachment device mounting structure is typically designed for releasable positive locking and may be designed by one or more catches hooks or notches that are designed for engagement with complementary counter elements as explained further below.

There is disclosed a skin attachment device. The skin attachment device includes a substantially planar body with a skin attachment side and an opposing medical device mounting side. The skin attachment side includes a skin attachment structure for releasably attaching the skin attachment device to a person's skin. The medical device mounting side includes a medical device mounting structure for releasably engaging with the attachment device mounting structure of an ambulatory medical device as discussed before and/or further below. The body includes a vibrator coupling opening. The vibrator coupling opening, typically in form of a cutout or aperture, is through-going and arranged to allow the projection of a vibrator coupling element as explained further below in more detail. A skin attachment device is frequently also referred to as "cradle".

The skin attachment structure is typically realized by way of an adhesive coating and/or layer that is initially covered by a removable liner. The medical device mounting structure may in particular be realized as one or more counter elements for the attachment device mounting structure of the ambulatory medical device. The attachment device mounting structure and the medical device mounting structure may, in combination, form a releasable snap fit connection. In other examples, the attachment device mounting structure and the medical device mounting structure may cooperate according to a different principle. For example, one of the attachment device mounting structure and the medical device mounting structure may

be or comprise a magnet and the other may be or comprise a corresponding ferromagnetic element, thereby realizing a magnetic coupling.

The skin attachment device further includes a cannula coupling structure for coupling with a cannula and/or a fluidic coupling structure as explained further below in the context of exemplary examples. Typically, the cannula attachment structure is distinct from the vibrator coupling opening.

There is disclosed an ambulatory medical system. The ambulatory medical system includes an ambulatory medical device and at least one skin attachment device. In a configuration in which the medical device is mounted to the skin attachment device, the vibrator coupling element projects through the vibrator coupling opening towards the skin attachment side.

Typically, the skin attachment device is designed for single use over a certain time-period of, e. g., a number of days or weeks and subsequent disposal, while the ambulatory medical device is designed for a longer usage time of, e. g. several months up to several years. Such ambulatory medical system allows to carry the ambulatory medical device in sequence with a number of skin attachment devices, with the skin-contacting skin attachment device being repeatedly replaced.

In such ambulatory medical system, the skin attachment device is, during application, arranged between the skin and the ambulatory medical device, with the wall element of the ambulatory medical device facing and contacting the medical device mounting side of the skin attachment device. Due to the vibrator coupling element projecting through the vibrator coupling opening, the distance between the wall element and the skin (as defined by the

thickness of the body of the skin attachment device) is bridged, such that the vibrator coupling element directly contacts the skin. The vibrator coupling device projects beyond the plane that is defined by the skin attachment side.

In alternative examples of the ambulatory medical device, however, the ambulatory medical
5 device is designed for direct skin attachment and may carry a skin attachment structure, e. g. an adhesive layer or coating, directly on the wall element that surrounds the vibrator coupling element.

There is disclosed a method for providing tactile indications to a person carrying an ambulatory medical device. The method includes actuating the vibrator motor thereby transmitting a vibra-
10 tion in a plane parallel to the wall element to the person's skin.

Tactile indications may be provided as particularly discrete user feedback and/or alerting the person in case of exceptional situations that may require immediate attention, such as an empty battery, an empty drug reservoir or a malfunction, in addition or alternatively to visual and/or audio indications.

15 **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 shows part of an ambulatory medical device in a schematic side view;

Fig. 2 shows an ambulatory medical system in a schematic side view;

Fig. 3 schematically shows a further embodiment with a different attachment of the vibrator coupling element to the wall element.

CLAIMS

1. An ambulatory medical device, the ambulatory medical device being designed for attachment to a person's body, the ambulatory medical device including:
 - a) a housing, the housing having a wall element and a vibrator coupling element,

5 wherein a convex outer surface of the vibrator coupling element projects from the wall element towards the outside of the housing, and the vibrator coupling element is coupled to the wall element via a connection element, with the connection element being arranged along a circumference of the vibrator coupling element;
 - b) a vibrator, the vibrator being configured to mechanically vibrate upon activation,
10 wherein the vibrator is at least partially arranged inside a volume defined by the vibrator coupling element and mounted to the vibrator coupling element.
2. The ambulatory medical device according to claim 1, wherein the vibrator is configured to vibrate in a plane parallel to the wall element.
3. The ambulatory medical device according to either of the preceding claims, wherein the
15 vibrator coupling element is calotte-shaped.
4. The ambulatory medical device according to either of the preceding claims, wherein the vibrator coupling element is displaceable relative to the wall element.
5. The ambulatory medical device according to either of the preceding claims, wherein the connection element is flexible.

6. The ambulatory medical device according to either of the preceding claims, wherein the connection element is designed as bellows.
7. The ambulatory medical device according to either of the preceding claims, wherein the housing is substantially rigid.
- 5 8. The ambulatory medical device according to either of the preceding claims, wherein a mass of the vibrator coupling element is small as compared to a mass of the housing.
9. The ambulatory medical device according to either of the preceding claims, wherein the wall element is coupled to the vibrator coupling element in a hermetically sealing manner.
- 10 10. The ambulatory medical device according to either of the preceding claims, wherein the vibrator is a coin vibration motor.
11. The ambulatory medical device according to either of the preceding claims, wherein the ambulatory medical device is an ambulatory infusion device, in particular an insulin pump.
12. The ambulatory medical device according to either of the preceding claims, wherein the housing includes an attachment device mounting structure for releasable mounting the ambulatory medical device to a skin attachment device.
- 15 13. A skin attachment device, the skin attachment device includes a substantially planar body with a skin attachment side and an opposing medical device mounting side;
 - wherein the skin attachment side includes a skin attachment structure configured to releasably attach the skin attachment device to a person's skin;

- wherein the medical device mounting side includes a medical device mounting structure configured to releasably engage with an attachment device mounting structure of an ambulatory medical device, wherein the ambulatory medical device includes:
 - a) a housing having a wall element and a vibrator coupling element,
5 wherein a convex outer surface of the vibrator coupling element projects from the wall element towards the outside of the housing, and the vibrator coupling element is coupled to the wall element via a connection element, with the connection element being arranged along a circumference of the vibrator coupling element, wherein the housing further includes the attachment device mounting structure configured to
10 releasably mount the ambulatory medical device to the skin attachment device; and
 - b) a vibrator configured to mechanically vibrate upon activation, wherein
15 the vibrator is at least partially arranged inside a volume defined by the vibrator coupling element and mounted to the vibrator coupling element;
- wherein the substantially planar body includes a vibrator coupling opening which is configured such that in a configuration in which the ambulatory medical device is mounted to the skin attachment device, the vibrator coupling element projects
20 through the vibrator coupling opening towards the skin attachment side, and
- wherein the skin attachment device further includes a cannula coupling structure configured to couple with a cannula and/or a fluidic coupling structure.

- 14.** An ambulatory medical system, the ambulatory medical system including the ambulatory medical device according to claim 13 and at least one skin attachment device according to claim 13,

wherein, in a configuration in which the ambulatory medical device is mounted to the skin attachment device, the vibrator coupling element projects through the vibrator coupling opening towards the skin attachment side.

- 15.** A method for providing tactile indications to a person carrying the ambulatory medical device according to either of claims 1 to 12 or the ambulatory medical system according to claim 14, the method including actuating the vibrator, thereby transmitting a vibration in a plane parallel to the wall element to the person's skin.