

Description

ELECTRONIC ADD-ON MODULE COMPRISING A MICROSWITCH

The present disclosure is generally directed to an electronic system, e.g. an electronic add-on module, which is configured to be releasably attached to a drug delivery device.

Electronic add-on modules for releasable attachment to drug delivery devices are generally known and often used to measure relevant data with respect to dose setting and/or dose dispensing.

An exemplary data collection device for attachment to an injection device is shown in WO 2016/198516 A1. Further injection monitoring modules are known from WO 2020/217094 A1, WO 2021/140352 A1, WO 2021/214275 A1, US 2021/330891 A1, WO 2023/078861 A1, US 2020/114087 A1 and US 2022/265937 A1. The modules typically comprise two portions, wherein one portion is attached and rotationally constrained to a dose dial grip of an injection device to measure for example rotational relative movement between components of the modules and/or the injection devices.

WO 2016/198516 A1, for example, discloses the use of a sensing arrangement inside the data collection device comprising optical, magnetic, capacitive or mechanical sensors configured to detect rotational movement between a first portion and a second portion of the data collection device. The first portion is configured for attaching to a dosage knob of the injection device and the second portion is coupled to the first portion and axially movable relative thereto. During dose dispensing of a medicament, for example, the first portion rotates with the dosage knob of the injection device, wherein the angle of rotation measured by the sensing arrangement allows to determine the amount of medicament expelled.

An electronic module with an electrical power source, a sensor arrangement and a processor is disclosed in WO 2021/214275 A1. In order to limit power consumption, the module further may comprise a switch configured to be operated by means of a deflectable switch arm. The switch may activate or deactivate power consuming components, i.e., the switch may be configured to activate a processor of the module from a no-power sleeping mode.

Similarly, WO 2021/140 352 A1 discloses an injection monitoring module with an injection detection switch configured to be activated by a translational movement between a proximal

activation button and a hollow main body. When activated, the switch may signal to an integrated data processing and control unit of the injection monitoring module the start of the injection.

However, the known electronic add-on modules have the disadvantage that a simple movement is sufficient to activate the switches, so that even, for example, the slightest axial movement may sometimes lead to operation of the switch and to unwanted powering of the electronic components.

It is therefore an object of the present disclosure to provide an electronic add-on module with an improved operation of a switch configured to power electronic components of the electronic add-on module.

This object is solved by an electronic add-on module according to claim 1.

The electronic add-on module for releasable attachment to a drug delivery device comprises a first portion, a second portion, an electrical power source, a circuit board assembly with a microswitch and a push element configured to operate the microswitch.

The drug delivery used for attachment of the electronic add-on module may comprise at least a dose button, a dose dial grip, a drive sleeve and a plunger. Although not required in the context of the present disclosure, the drug delivery device may optionally comprise further components such as a number sleeve, a clutch, a cap, a needle, a spring, a lead screw or the like, interacting with the dose button, the dose dial grip, the drive sleeve, the plunger and/or the housing, for example as disclosed in WO 2004/078239 A1. However, the present disclosure is not limited to the drug delivery device of WO 2004/078239 A1. Other suitable drug delivery devices to be used are described e.g. in EP 1 570 876 B1, EP 2 814 547 B1, EP 2 890 434 B1, WO 2005/018721 A1, WO 2009/132777 A1, WO 2014/033195 A1, US 5,693,027 A, US 6,663,602 B2, US 7,241,278 B2 or US 9,937,294 B2.

If the drug delivery device has a similar working principle as in the example of WO 2004/078239 A1, during dose setting components of the drug delivery device may perform the following movements. A housing may be stationary and may be used as a reference system for the further movements of other components. A plunger may be stationary and may be guided in a housing thread. A drive sleeve may perform a helical movement, i.e. a combined axial and rotational movement, and may be in threaded engagement with the plunger. A dial

grip may perform a helical movement. A dose button may be free to rotate but axially constrained to the drive sleeve. For example, the dose button may be axially retained to the drive sleeve by a clutch. An optional clutch may perform a helical movement and may couple a number sleeve to the drive sleeve. An optional clutch spring may perform an axial movement and may be guided in housing splines and may click over clutch teeth. An optional number sleeve may be permanently fixed on the dial grip and may perform a helical movement and may be guided in a housing thread. An optional last dose nut may perform a helical movement on a drive sleeve track of the drive sleeve and may be rotationally constrained to the housing. Hence, the last dose nut may perform axial movement relative to the housing and a helical movement with respect to the drive sleeve.

During dose dispensing components of the drug delivery device may perform the following movements. The housing may remain stationary as a reference system for the further movements of other components. The plunger may perform a helical movement and may be guided in the housing thread. The drive sleeve may perform a pure axial movement and may be in threaded engagement with the plunger. The dose dial grip may perform a helical movement and may be permanently fixed on the number sleeve. The dose button may perform an axial movement if coupled to the drive sleeve and/or the clutch. The optional clutch may perform pure axial movement and may de-couple the number sleeve from the drive sleeve. The optional clutch spring may perform pure axial movement and may be rotationally constrained to the clutch due to a pressure applied to the dose button. The optional number sleeve may perform a helical movement and may be guided in the housing thread. The optional last dose nut may maintain its axial position on the drive sleeve track and may be rotationally constrained to the housing.

The first portion of the electronic add-on module defines an auxiliary dose dial grip. Further, the first portion is configured to be releasably attached to the dose dial grip of the drug delivery device, such that the first portion follows axial and rotational movements, for example helical movements, of the dose dial grip when attached to the drug delivery device. Hence, when the auxiliary dose dial grip is attached to the dose dial grip of a drug delivery device and is for example rotated during dose setting, the dose dial grip of the drug delivery device is also rotated.

Furthermore, the first portion has a first longitudinal axis. Along the longitudinal axis, the electronic add-on module or first portion extends from a proximal region to a distal region. When the electronic add-on module is attached to a drug delivery device, the proximal region is generally closer to the second portion and the distal region is closer to the drug delivery device.

The drug delivery device may also comprise a second longitudinal axis. The drug delivery device may extend from a distal region, provided for example with a needle, to a proximal region, provided for example with the dose button. If the electronic add-on module is releasably attached to the drug delivery device, the first and second longitudinal axes are in line.

The second portion of the electronic add-on module is coupled to the first portion allowing relative axial movement parallel to the first longitudinal axis with respect to the first portion. The second portion is therefore configured to be axially moved from a dose setting position, in which the second portion is in a maximum proximal position relative to the first portion, into a dose dispensing position, in which the second portion is in a further distal position (compared with the dose setting position) relative to the first portion. The second portion may be retained in the first portion, for example by clips that engage in a groove. In addition, the second portion defines an auxiliary dose button configured to abut a dose button of the drug delivery device when attached to the drug delivery device. In other words, the auxiliary dose button may not be in abutment with the dose button of the drug delivery device initially but may be moved into abutment when the user applies pressure onto the auxiliary button. Hence, when a user applies pressure onto the auxiliary dose button, the auxiliary dose button may move relative to the dose button of the drug delivery device, e.g. causing and/or allowing activation of the electronic add-on module, and after this small relative movement the pressure is transferred onto the dose button of the drug delivery device. Consequently, the second portion is configured to apply pressure in axial direction onto the dose button of the drug delivery device, when attached.

In one aspect, the second portion of the electronic add-on module may be coupled to the first portion allowing relative rotational movement relative to the first portion. However, the coupling may also only allow relative axial movement between the second portion and the first portion. In this regard, the electronic add-on module may further comprise a third portion coupled to the second portion, wherein the third portion is free to rotate relative to the first portion and the second portion about the first longitudinal axis.

Further, the electronic add-on module comprises the electrical power source, such as a battery, arranged inside the electronic add-on module. In one example, the electrical power source is arranged inside the second portion of the electronic add-on module. The electrical power source is electrically connected to the circuit board assembly and therefore configured to power the circuit board assembly and respective electronic components of the electronic add-on module.

The circuit board assembly arranged inside the second portion comprises a microswitch. The power supply of the circuit board assembly may be dependent on the microswitch being operated. The circuit board assembly may comprise a printed circuit board assembly. The circuit board assembly may comprise a substrate equipped with electronic components. Electronic components may be chips, processors, conductors, wireless modules, sensor arrangements or the like. The electronic components may be electrically connected to the circuit board assembly and may therefore also be supplied by power of the electrical power source. The circuit board assembly may be at least partially arranged perpendicular to the direction of relative axial movement of the first portion and the second portion. In one example the entire circuit board assembly may be arranged perpendicular to the direction of relative axial movement. The direction of relative axial movement may be along the first longitudinal axis.

Further, the electronic add-on module additionally comprises the push element configured to be moved and/or deformed relative to the circuit board assembly in a second direction opposite to a first direction at least substantially parallel to the first longitudinal axis. The term "substantially" is used because, for example, a minimal lateral tilt of the push element may not be excluded. Likewise, for example, with a deformed push element, the preload is not necessarily only axially directed. However, when the force components are split up in a portion parallel to the first longitudinal axis and in a portion perpendicular to the first longitudinal axis, the portion of the biasing force parallel to the first longitudinal axis may be greater than the portion perpendicular to the first longitudinal axis. Further, the push element may be elastically biased in the first direction at least upon movement and/or deformation of the push element in the second direction. In other words, the push element may be biased in the first direction before being moved and/or deformed, or the push element may be unbiased before being moved and/or deformed. Regardless of whether the push element is elastically biased, e.g. in a fully returned position, or not biased, i.e. biased or not biased before being moved in the second direction, the push element is at least elastically biased when it is deformed and/or moved in the second direction. Still, during movement and/or deformation, the push element may be prevented from reaching a position in which the push element is parallel to the first longitudinal axis. Here, "substantially" is used because the push element may not reach the position in which the push element is parallel to the first longitudinal axis. The push element may be biased by a spring or due to deformation of elastic material. In this regard, the material may be flexible and elastic. The first direction may be a distal direction, i.e. a direction pointing away from the second portion in the direction of the first portion. The push element is further configured to be moved, for example pivotably moved, and/or deformed relative to the circuit board assembly in a second direction which is opposite to the first direction in order to operate the microswitch. The circuit board assembly which may be arranged perpendicular to the direction of axial movement

between the first portion and the second portion, may comprise a fixed position, for example inside a housing of the second portion. The second direction may be a proximal direction, i.e. a direction pointing to the second portion and away from the first portion.

"Operation of the microswitch" may mean activation or deactivation of the microswitch, i.e. the start or termination of the power supply to electronic components and/or triggering a signal for waking up the whole system from a sleep mode and/or activating one or more specific functions or operation modes of the system.

According to an independent aspect of the present disclosure, the sequence of activation of the electronic add-on module may be as follows: First, the user presses on the second portion, i.e. on the auxiliary dose button, which results in an axial movement of the second portion in the distal direction relative to the first portion and relative to the, in this moment axially stationary, dose button of the drug delivery device. This relative movement may cause the push element to act e.g. on a lever which in turn activates or operates the microswitch, thereby powering the electronic system of the electronic add-on module. If the user then continues pressing on the second portion, the dose button of the drug delivery device starts, after this activation of the electronic add-on module, moving axially from an initial position to an actuated position in which the dose dispensing starts.

In addition, the push element may not necessarily have to be operated directly. For example, a lever arm or the like could be arranged between the push element and the microswitch so that the push element deflects the lever arm and thereby operates the microswitch.

Furthermore, the biasing force may not be completely neutralized or eliminated by the movement of the push element in the second direction opposite to the first direction. Moreover, the movement of the push element in the second direction may be performed upon an external force, such as a pressure applied to the second portion, and may cause an increase of the biasing force in the first direction. Therefore, this increased biasing force may be used to return the push element to an initial state when the external force is not applied any more.

According to one aspect, the push element may be maximally biased in the first direction when the electronic add-on module is in the dose setting position. This does not mean that the biasing force is necessarily at a maximum with respect to a maximum achievable biasing force. However, the biasing force may cause the push element to a maximum position in the first direction with respect to the second portion. In other words, the push element may not be moved further in the first direction with respect to the second portion when the electronic add-

on module is in the dose setting position. Thus, although the second portion may move together with the push element in the first direction, for example during dose setting, the push element is not further moved in the first direction relative to the second portion or the circuit board assembly. A maximally biased push element in the first direction during dose setting may in addition allow greater movement and/or deformation of the push element in the second direction, i.e. opposite to the first biasing direction.

As already described before, in one example, the push element may be moved and/or deformed by the relative axial movement between first portion and the second portion.

In a further example the electronic add-on module may comprise a clutch arranged between the first portion and the second portion. The clutch may prevent relative rotational movement between the first portion and the second portion when engaged. The clutch may be engaged when the electronic add-on module is in the dose setting position. The clutch may be provided by interaction of the first clutch element arranged at the first portion and second clutch element arranged at the second portion. The clutch elements may be provided by teeth or protrusions configured for engagement. The teeth may be provided on an outer circumferential surface of the second portion and on an inner surface of the first portion. Provision of a clutch thus prevents relative rotational movement between the first portion and the second portion during dose setting. A relative rotational movement may therefore not be detected, for example by a sensor arrangement. Consequently, a relative rotational movement between the components only occurs when a dose is actually dispensed, because the setting of a dose may not necessarily mean its dispensing. Therefore, the clutch may help for sensor data to be more reliable.

In one example, when the push element may be moved and/or deformed from the dose setting position in the second direction, the microswitch may be operated prior to a disengagement of the clutch. Thus, an axial movement may be allowed between the first portion and the second portion without disengagement of the clutch. This additionally may ensure that electronic components such as sensor arrangements are supplied with power prior to the start of a rotational movement between the first portion and the second portion.

In one aspect, the push element may be configured for abutting against the dose button of the drug delivery device in the dose setting position in order to engage the clutch between the first portion and the second portion. In other words, the push element may directly abut and contact the dose button of the drug delivery device when the module is attached to the drug delivery device. As an alternative, further component parts may be interposed between the push element and the dose button of the drug delivery device. The push element may therefore be

configured to hold the clutch in engagement during dose setting. In this regard, the biasing force elastically biasing the push element in the first direction may cause the push element to abut or act against the dose button and thus may push the second portion in the second direction. This may have the advantage that the disengagement of the clutch may only occur dependent on an axial movement of the push element.

Further, the push element may be configured to operate the clutch and the microswitch. Consequently, only one element, namely the push element, may be required in order to operate both a clutch preventing relative rotational movement between the first portion and the second portion of the electronic add-on module as well as the operation of the microswitch. This also allows the clutch to be disengaged only after the microswitch has been actuated.

In one example, the push element may comprise a stop element. The stop element may prevent disengagement between the push element and the second portion. The stop element may exemplarily be provided by a stopper element or by push element clips. The stop element may comprise any form or shape. The stop element may comprise a block shape through which a push element extends. The stop element may, however, also be a clip, a protrusion or the like providing an integral feature of the push element or a separate feature attached to the push element which prevents disengagement of the push element from the second portion. The stop element may interact with a second portion housing, i.e., a portion of the housing of the second portion. The stop element may interact with an outer surface of the housing portion or may interact with an inner surface of the housing portion. The stop element may be releasable attached or permanently fixed to the push element and/or the housing portion.

According to a further aspect, the second portion may comprise a third alignment structure configured to rotationally constrain the second portion to the dose button. The third alignment structure may engage with a fourth alignment structure of the dose button. The alignment structures may act as clutches when engaged. The third alignment structure may comprise ribs and/or grooves that are configured to engage with a respective counterpart of the dose button. The third alignment structure may permanently rotationally constrain the second portion to the dose button or may only temporarily constrain the second portion to the dose button, when the electronic add-on module is attached to a drug delivery device. Rotationally constraining the second portion to the dose button may allow that the movements of the dose button are replicated by the auxiliary dose button.

In one example, the third alignment structure may comprise a protrusion, for example provided with ribs, configured to be engaged with a recess arranged at a proximal end surface of the

dose button of the drug delivery device. The protrusion may be cylindrical. At least one of the alignment structures may be rotationally symmetrically. Providing a protrusion as one alignment structure and a recess as the other alignment structure may allow that the structures may be engaged/disengaged upon relative axial movement.

In one example, the push element may at least be partially arranged inside the second portion. The push element may be guided by the second portion during the relative axial movement between the first portion and the second portion. Guiding the push element may prevent buckling, tilting or kinking of the push element with respect to the second portion. In addition, the push element may act on a microswitch located within the second portion.

In one example, the second portion may be at least partially arranged around the first portion. For example, the second portion may at least partially be arranged inside the first portion. However, the second portion may also be arranged completely in the first portion, for example, when the second portion is moved in its most distal position.

In one aspect, the push element may be already biased in the first direction before a movement and/or deformation of the push element in the second direction is performed. Consequently, when the push element is moved in the second direction the biasing force may increase or decrease. In one aspect, the biasing force may increase in order to facilitate return of the push element to the initial state in which no external force is applied to the second portion.

In one aspect, the push element may be configured to provide a sealing. At least upon movement and/or deformation in the second direction, the push element may extend inside the second portion housing of the second portion, for example in order to operate a lever arm and/or a microswitch. In this regard, the push element may comprise a push portion and a sealing portion, wherein the sealing portion may be in permanent abutment with the second portion housing, for example with a distally facing surface of the second portion housing. The sealing portion may extend from the rod portion substantially laterally, i.e. perpendicular to the longitudinal axis, and may surround the rod portion. The sealing portion may surround the rod portion like a parasol. The push element may thus be configured to seal an opening in the distally facing surface of the second portion housing. In this regard, the sealing portion of the push element may be configured to abut against the second portion housing independent of a relative axial position of the push element, i.e. at all times when being moved in the second direction. In other words, if pressure is applied to the push element which may, for example, move the rod portion of the push element proximally in order to operate for example a microswitch, the sealing portion may continuously or permanently abut against the second portion housing

and may thereby seal an opening in the second portion housing. In this respect, the sealing portion may provide a sealing lip. Consequently, the push element may improve ingress protection, for example protection against ingress of fluid such as of a medicament solution leaking through the opening and may impair electronic functionalities of the electronic add-on module.

In one aspect, the push element may be provided by an actuation rod. The push element may thus comprise a greater longitudinal extension than a lateral extension. The push element may be partially cylindrical shaped. The rod may also have a shaft section, which comprises further elements on at least one end side of the shaft section. For example, one end side may comprise an element forming an abutment surface, which may be configured to abut against the dose button.

In one alternative example, the third alignment structure may be provided by the push element. Consequently, the third alignment may be configured to engage a fourth alignment structure of the dose button to prevent relative rotational movement between the dose button and the second portion. Integration of the third alignment structure in the push element may limit the number of components of the electronic add-on module.

In one example, the push element may provide a distally facing surface of the second portion. When the second portion is in the dose setting position, the distally facing surface may provide the only axial abutment between the dose button and the second portion. The reduction of possible contact points between the second portion and the dose button may simplify an assembly of the electronic add-on module and the drug delivery device and may improve the mutual influence of the individual components. In addition, upon axial movement of the second portion relative to the first portion, the force may first be applied to the dose button via the push element, so that the push element may first be moved and/or deformed and the microswitch may be operated before other components of the electronic add-on module perform relative movements or are in axial abutment.

In one aspect, the push element may be provided by a flexible diaphragm. The flexible diaphragm may be made of rubber or other flexible materials which allow deformation relative to the circuit board assembly. The flexible diaphragm may be hinged or clipped to the second portion. The flexible diaphragm may provide part of the second portion housing so that the components inside the housing may be protected from external influences such as dust, moisture, etc. The flexible diaphragm may be stable in shape so that after deformation the flexible diaphragm substantially comprises the same shape as before deformation. The use of a flexible diaphragm has the advantage that no friction occurs between the push element and the

second portion when the flexible diaphragm is deformed and/or moved in the second direction. Consequently, related wear may be prevented.

In one aspect, the push element may be an elastically biased lever arm. The lever arm may be biased by a spring element. The lever arm may for example be biased by a leg spring. The lever arm may be configured to be pivotably moved. For example, the lever arm may be pivotably moved about a pivot axis which may be substantially perpendicular to the first longitudinal axis. The spring element may bias the lever arm so that a distance along the first longitudinal axis between a proximal region of the push element and a push element abutment surface is at a maximum. This distance would be at a maximum, when the lever arm is perfectly parallel to the longitudinal axis. Hence, although the spring element may bias the lever arm to reach this position, further elements or components may prevent the push element from reaching this position. Therefore, the push element may only be substantially parallel to the first longitudinal axis.

In one aspect, in the dose setting position, the push element may be abutting on a projection of the first portion. The projection may protrude from an inner surface of the first portion. The lever arm may thus abut on the projection with the push element abutment surface. The push element may further be arranged off-centered with respect to the first longitudinal axis. Thus, regardless of the pivoting position of the push element, neither the proximal region of the lever arm, nor the push element abutment surface may be arranged on the first longitudinal axis. The biasing force provided by the spring element together with the abutment of the push element on the projection protruding from the inner surface of the first portion may therefore push the second portion in the proximal direction with respect to the first portion. In other words, abutment of the push element on the projection may return the push element to an initial state when the external force is not applied any more.

The electronic add-on module may be an electronic dose recording system for determining, storing and/or transmitting data indicative of at least a condition of the drug delivery device or its use. For example, the system may detect if the drug delivery device is switched between a dose setting mode and a dose dispensing mode and vice versa. In addition or as an alternative, the system may detect if a dose is set and/or if a dose is dispensed. Still further, the system may detect the amount of dose selected and/or the amount of dose dispensed. Preferably, the electronic add-on module is configured such that it may be switched from a first state having lower energy consumption into a second state having higher energy consumption. This may be achieved by operation of the electronic add-on module, especially by actuating the micro-switch. The first state may be a sleeping mode and the second mode may be a detection and/or

communication mode. As an alternative, an electronic control unit may issue a command, e.g. a signal, to another unit of the electronic dose recording system such that this unit is switched on or rendered operational.

The electronic add-on module may further comprise a communication unit for communicating with another device, e.g. a wireless communications interface for communicating with another device via a wireless network such as Wi-Fi or Bluetooth, or even an interface for a wired communications link, such as a socket for receiving a Universal Serial Bus (USB), mini-USB or micro-USB connector. Preferably, the electronic add-on module comprises an RF, Wi-Fi and/or Bluetooth unit as the communication unit. The communication unit may be provided as a communication interface between the electronic add-on module and the exterior, such as other electronic devices, e.g. mobile phones, personal computers, laptops and so on. For example, dose data may be transmitted by the communication unit to the external device. The dose data may be used for a dose log or dose history established in the external device.

The terms “drug” or “medicament” are used synonymously herein and describe a pharmaceutical formulation containing one or more active pharmaceutical ingredients or pharmaceutically acceptable salts or solvates thereof, and optionally a pharmaceutically acceptable carrier. An active pharmaceutical ingredient (“API”), in the broadest terms, is a chemical structure that has a biological effect on humans or animals. In pharmacology, a drug or medicament is used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being. A drug or medicament may be used for a limited duration, or on a regular basis for chronic disorders.

As described below, a drug or medicament can include at least one API, or combinations thereof, in various types of formulations, for the treatment of one or more diseases. Examples of API may include small molecules having a molecular weight of 500 Da or less; polypeptides, peptides and proteins (e.g., hormones, growth factors, antibodies, antibody fragments, and enzymes); carbohydrates and polysaccharides; and nucleic acids, double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (siRNA), ribozymes, genes, and oligonucleotides. Nucleic acids may be incorporated into molecular delivery systems such as vectors, plasmids, or liposomes. Mixtures of one or more drugs are also contemplated.

The drug or medicament may be contained in a primary package or “drug container” adapted for use with a drug delivery device. The drug container may be, e.g., a cartridge, syringe, reservoir, or other solid or flexible vessel configured to provide a suitable chamber for storage

(e.g., short- or long-term storage) of one or more drugs. For example, in some instances, the chamber may be designed to store a drug for at least one day (e.g., 1 to at least 30 days). In some instances, the chamber may be designed to store a drug for about 1 month to about 2 years. Storage may occur at room temperature (e.g., about 20°C), or refrigerated temperatures (e.g., from about - 4°C to about 4°C). In some instances, the drug container may be or may include a dual-chamber cartridge configured to store two or more components of the pharmaceutical formulation to-be-administered (e.g., an API and a diluent, or two different drugs) separately, one in each chamber. In such instances, the two chambers of the dual-chamber cartridge may be configured to allow mixing between the two or more components prior to and/or during dispensing into the human or animal body. For example, the two chambers may be configured such that they are in fluid communication with each other (e.g., by way of a conduit between the two chambers) and allow mixing of the two components when desired by a user prior to dispensing. Alternatively or in addition, the two chambers may be configured to allow mixing as the components are being dispensed into the human or animal body.

The drugs or medicaments contained in the drug delivery devices as described herein can be used for the treatment and/or prophylaxis of many different types of medical disorders. Examples of disorders include, e.g., diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism. Further examples of disorders are acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis. Examples of APIs and drugs are those as described in handbooks such as Rote Liste 2014, for example, without limitation, main groups 12 (anti-diabetic drugs) or 86 (oncology drugs), and Merck Index, 15th edition.

Examples of APIs for the treatment and/or prophylaxis of type 1 or type 2 diabetes mellitus or complications associated with type 1 or type 2 diabetes mellitus include an insulin, e.g., human insulin, or a human insulin analogue or derivative, a glucagon-like peptide (GLP-1), GLP-1 analogues or GLP-1 receptor agonists, or an analogue or derivative thereof, a dipeptidyl peptidase-4 (DPP4) inhibitor, or a pharmaceutically acceptable salt or solvate thereof, or any mixture thereof. As used herein, the terms "analogue" and "derivative" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, by deleting and/or exchanging at least one amino acid residue occurring in the naturally occurring peptide and/or by adding at least one amino acid residue. The added and/or exchanged amino acid residue can either be codable amino acid residues or other naturally occurring residues or purely synthetic amino acid residues. Insulin analogues are also referred to as "insulin receptor ligands". In particular,

the term „derivative” refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, in which one or more organic substituent (e.g. a fatty acid) is bound to one or more of the amino acids. Optionally, one or more amino acids occurring in the naturally occurring peptide may have been deleted and/or replaced by other amino acids, including non-codeable amino acids, or amino acids, including non-codeable, have been added to the naturally occurring peptide.

Examples of insulin analogues are Gly(A21), Arg(B31), Arg(B32) human insulin (insulin glargine); Lys(B3), Glu(B29) human insulin (insulin glulisine); Lys(B28), Pro(B29) human insulin (insulin lispro); Asp(B28) human insulin (insulin aspart); human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

Examples of insulin derivatives are, for example, B29-N-myristoyl-des(B30) human insulin, Lys(B29) (N- tetradecanoyl)-des(B30) human insulin (insulin detemir, Levemir®); B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl- ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-gamma-glutamyl)-des(B30) human insulin, B29-N-omega-carboxypentadecanoyl-gamma-L-glutamyl-des(B30) human insulin (insulin degludec, Tresiba®); B29-N-(N-lithocholyl-gamma-glutamyl)-des(B30) human insulin; B29-N-(ω-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

Examples of GLP-1, GLP-1 analogues and GLP-1 receptor agonists are, for example, Lixisenatide (Lyxumia®), Exenatide (Exendin-4, Byetta®, Bydureon®, a 39 amino acid peptide which is produced by the salivary glands of the Gila monster), Liraglutide (Victoza®), Semaglutide, Taspoglutide, Albiglutide (Syncria®), Dulaglutide (Trulicity®), rExendin-4, CJC-1134-PC, PB-1023, TTP-054, Langlenatide / HM-11260C (Efpeglenatide), HM-15211, CM-3, GLP-1 Eligen, ORMD-0901, NN-9423, NN-9709, NN-9924, NN-9926, NN-9927, Nodexen, Viador-GLP-1, CVX-096, ZYOG-1, ZYD-1, GSK-2374697, DA-3091, MAR-701, MAR709, ZP-2929, ZP-3022, ZP-DI-70, TT-401 (Pegapamodtide), BHM-034, MOD-6030, CAM-2036, DA-15864, ARI-2651, ARI-2255, Tirzepatide (LY3298176), Bamadutide (SAR425899), Exenatide-XTEN and Glucagon-Xten.

An example of an oligonucleotide is, for example: mipomersen sodium (Kynamro®), a cholesterol-reducing antisense therapeutic for the treatment of familial hypercholesterolemia or RG012 for the treatment of Alport syndrom.

Examples of DPP4 inhibitors are Linagliptin, Vildagliptin, Sitagliptin, Denagliptin, Saxagliptin, Berberine.

Examples of hormones include hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin, Lutropin, Chorion-gonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuporelin, Buserelin, Nafarelin, and Goserelin.

Examples of polysaccharides include a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra-low molecular weight heparin or a derivative thereof, or a sulphated polysaccharide, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium. An example of a hyaluronic acid derivative is Hylan G-F 20 (Synvisc®), a sodium hyaluronate.

The term “antibody”, as used herein, refers to an immunoglobulin molecule or an antigen-binding portion thereof. Examples of antigen-binding portions of immunoglobulin molecules include F(ab) and F(ab')₂ fragments, which retain the ability to bind antigen. The antibody can be polyclonal, monoclonal, recombinant, chimeric, de-immunized or humanized, fully human, non-human, (e.g., murine), or single chain antibody. In some embodiments, the antibody has effector function and can fix complement. In some embodiments, the antibody has reduced or no ability to bind an Fc receptor. For example, the antibody can be an isotype or subtype, an antibody fragment or mutant, which does not support binding to an Fc receptor, e.g., it has a mutagenized or deleted Fc receptor binding region. The term antibody also includes an antigen-binding molecule based on tetravalent bispecific tandem immunoglobulins (TBTI) and/or a dual variable region antibody-like binding protein having cross-over binding region orientation (CODV).

The terms “fragment” or “antibody fragment” refer to a polypeptide derived from an antibody polypeptide molecule (e.g., an antibody heavy and/or light chain polypeptide) that does not comprise a full-length antibody polypeptide, but that still comprises at least a portion of a full-length antibody polypeptide that is capable of binding to an antigen. Antibody fragments can comprise a cleaved portion of a full length antibody polypeptide, although the term is not limited

to such cleaved fragments. Antibody fragments that are useful in the present invention include, for example, Fab fragments, F(ab')₂ fragments, scFv (single-chain Fv) fragments, linear antibodies, monospecific or multispecific antibody fragments such as bispecific, trispecific, tetraspecific and multispecific antibodies (e.g., diabodies, triabodies, tetrabodies), monovalent or multivalent antibody fragments such as bivalent, trivalent, tetravalent and multivalent antibodies, minibodies, chelating recombinant antibodies, tribodies or bibodies, intrabodies, small modular immunopharmaceuticals (SMIP), binding-domain immunoglobulin fusion proteins, camelized antibodies, and immunoglobulin single variable domains. Additional examples of antigen-binding antibody fragments are known in the art.

The term “immunoglobulin single variable domain” (ISV), interchangeably used with “single variable domain”, defines immunoglobulin molecules wherein the antigen binding site is present on, and formed by, a single immunoglobulin domain. As such, immunoglobulin single variable domains are capable of specifically binding to an epitope of the antigen without pairing with an additional immunoglobulin variable domain. The binding site of an immunoglobulin single variable domain is formed by a single heavy chain variable domain (VH domain or VHH domain) or a single light chain variable domain (VL domain). Hence, the antigen binding site of an immunoglobulin single variable domain is formed by no more than three CDRs.

An immunoglobulin single variable domain (ISV) can be a heavy chain ISV, such as a VH (derived from a conventional four-chain antibody), or VHH (derived from a heavy-chain antibody), including a camelized VH or humanized VHH. For example, the immunoglobulin single variable domain may be a (single) domain antibody, a “dAb” or dAb or a Nanobody® ISV (such as a VHH, including a humanized VHH or camelized VH) or a suitable fragment thereof. [Note: Nanobody® is a registered trademark of Ablynx N.V.]; other single variable domains, or any suitable fragment of any one thereof.

“VHH domains”, also known as VHHs, VHH antibody fragments, and VHH antibodies, have originally been described as the antigen binding immunoglobulin variable domain of “heavy chain antibodies” (i.e., of “antibodies devoid of light chains”; Hamers-Casterman et al. 1993 (Nature 363: 446-448). The term “VHH domain” has been chosen in order to distinguish these variable domains from the heavy chain variable domains that are present in conventional 4-chain antibodies (which are referred to herein as “VH domains”) and from the light chain variable domains that are present in conventional 4-chain antibodies (which are referred to herein as “VL domains”). For a further description of VHH's, reference is made to the review article by Muyldermans 2001 (Reviews in Molecular Biotechnology 74: 277-302).

For the term “dAb’s” and “domain antibody”, reference is for example made to Ward et al. 1989 (Nature 341: 544), to Holt et al. 2003 (Trends Biotechnol. 21: 484); as well as to WO 2004/068820, WO 2006/030220, WO 2006/003388. It should also be noted that, although less preferred in the context of the present invention because they are not of mammalian origin, single variable domains can be derived from certain species of shark (for example, the so-called “IgNAR domains”, see for example WO 2005/18629).

The terms “Complementarity-determining region” or “CDR” refer to short polypeptide sequences within the variable region of both heavy and light chain polypeptides that are primarily responsible for mediating specific antigen recognition. The term “framework region” refers to amino acid sequences within the variable region of both heavy and light chain polypeptides that are not CDR sequences and are primarily responsible for maintaining correct positioning of the CDR sequences to permit antigen binding. Although the framework regions themselves typically do not directly participate in antigen binding, as is known in the art, certain residues within the framework regions of certain antibodies can directly participate in antigen binding or can affect the ability of one or more amino acids in CDRs to interact with antigen.

Examples of antibodies are anti PCSK-9 mAb (e.g., Alirocumab), anti IL-6 mAb (e.g., Sarilumab), and anti IL-4 mAb (e.g., Dupilumab).

Pharmaceutically acceptable salts of any API described herein are also contemplated for use in a drug or medicament in a drug delivery device. Pharmaceutically acceptable salts are for example acid addition salts and basic salts.

Those of skill in the art will understand that modifications (additions and/or removals) of various components of the APIs, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope of the present invention, which encompass such modifications.

An example drug delivery device may involve a needle-based injection system as described in Table 1 of section 5.2 of ISO 11608-1:2014(E). As described in ISO 11608-1:2014(E), needle-based injection systems may be broadly distinguished into multi-dose container systems and single-dose (with partial or full evacuation) container systems. The container may be a replaceable container or an integrated non-replaceable container.

As further described in ISO 11608-1:2014(E), a multi-dose container system may involve a needle-based injection device with a replaceable container. In such a system, each container

holds multiple doses, the size of which may be fixed or variable (pre-set by the user). Another multi-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user).

As further described in ISO 11608-1:2014(E), a single-dose container system may involve a needle-based injection device with a replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation). As also described in ISO 11608-1:2014(E), a single-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation).

The terms "axial", "radial", or "circumferential" as used herein may be used with respect to a first longitudinal axis of the electronic add-on module, the first portion, the second portion, the drug delivery device, the cartridge, the housing, the cartridge holder or the assembly of the drug delivery device and the electronic add-on module, e.g. the axis which extends through the proximal and distal ends of the cartridge.

"Distal" is used herein to specify directions, ends or surfaces which are arranged or are to be arranged to face or point towards dispensing end of the electronic add-on module or the drug delivery device or components thereof and/or point away from, are to be arranged to face away from or face away from the proximal end. On the other hand, "proximal" is used to specify directions, ends or surfaces which are arranged or are to be arranged to face away from or point away from the dispensing end and/or from the distal end of the electronic add-on module or the drug delivery device or components thereof. The distal end may be the end closest to the dispensing and/or furthest away from the proximal end and the proximal end may be the end furthest away from the dispensing end. A proximal surface may face away from the distal end and/or towards the proximal end. A distal surface may face towards the distal end and/or away from the proximal end. The dispensing end may be the needle end where a needle unit is or is to be mounted to the device, for example. Similarly, a distal element compared to a proximal element is located closer to the dispensing end than to the proximal end. Furthermore, when the electronic add-on module is considered alone, the term "distal" may be used with regard to the more distal end of the electronic add-on module, which is located closer to the

dispensing end of the drug delivery device when attached to the drug delivery device, and the term "proximal" may be used with regard to the proximal end of the electronic add-on module, which is located further away from the dispensing end of the drug delivery device when attached to the drug delivery device.

In the following, non-limiting, examples of the electronic add-on module, the drug delivery device and the assembly of the drug delivery device and the electronic add-on module are described in more detail by making reference to the drawings, in which:

- Figure 1 shows a drug delivery device;
- Figure 2 shows a dose button and a dose dial grip;
- Figure 3 shows a further dose button and a dose dial grip;
- Figure 4 shows a top view of the dose button shown in Figure 3;
- Figure 5 shows a perspective view of an electronic add-on module;
- Figure 6 shows a perspective bottom view of the electronic add-on module according to Figure 5;
- Figure 7 shows an alternative bottom view of the electronic add-on module according to Figure 5;
- Figure 8 shows an exploded view of an electronic add-on module;
- Figure 9 shows an electronic add-on module, a dose dial grip and a dose button prior to assembly;
- Figure 10 shows a cross-sectional view through a third and fourth alignment structure of an assembled electronic add-on module and a drug delivery device as for example shown in Figure 9;
- Figure 11 shows an exploded view of a drive sleeve and a dose button of a drug delivery device;

- Figure 12 shows a cross-sectional view through a slot-spline engagement of the drive sleeve and the dose button shown in Figure 11;
- Figure 13A shows a cross-sectional view of an assembly comprising an electronic add-on module and a proximal part of a drug delivery device in a dose setting state;
- Figure 13B shows an exemplary coupling portion of an electronic add-on module;
- Figure 13C shows an exemplary sleeve portion of an electronic add-on module;
- Figure 13D shows a perspective bottom view of an engagement between the coupling portion of Figure 13B and the sleeve portion of Figure 13C;
- Figure 14 shows a cross-sectional view of the assembly according to Figure 13A in an interim state of the module;
- Figure 15 shows a cross-sectional view of the assembly according to Figure 13A and 14 in a dose dispensing state;
- Figure 16 shows a cross-sectional view of an assembly with an alternative a push element in a dose setting state;
- Figure 17 shows a cross-sectional view of the assembly according to Figure 16 in a dose dispensing state;
- Figure 18 shows a state during assembly of an electronic add-on module and a drug delivery in which the electronic add-on module is not yet completely pushed onto the drug delivery device;
- Figure 19A shows a cross-sectional view of a further example of an electronic add-on module in a first orientation;
- Figure 19B shows a cross-sectional view of the electronic add-on module of Figure 19A in a second orientation;
- Figure 19C shows the push element of Figures 19A and 19B;

- Figure 19D shows a detailed view of the arrangement of the push element in Figures 19A and 19B as seen from below;
- Figure 19E shows a detailed view of the arrangement of the push element in Figures 19A and 19B as seen from above;
- Figure 20A shows a cross-sectional view of a further example of an electronic add-on module in a first orientation;
- Figure 20B shows a cross-sectional view of the electronic add-on module of Figure 20B in a second orientation;
- Figure 21 shows a cross-sectional view of a further assembly comprising an electronic add-on module and a proximal part of a drug delivery device;
- Figure 22 shows the assembly of Figure 21 in an interim state of the module;
- Figure 23 shows the assembly of Figure 21 or 22 in a dose dispensing state;
- Figure 24 shows a further first portion of an electronic add-on module configured to be used with an optical sensor arrangement;
- Figure 25 shows an electronic add-on module comprising a light-pipe as part of a sensor arrangement;
- Figure 26 shows a light-pipe configured to be used in the example according to Figure 25;
- Figure 27 shows a further a light-pipe configured to be used in the example according to Figure 25;
- Figure 28A shows a perspective view of a further light-pipe configured to be used in an electronic add-on module;
- Figure 28B shows a cross-sectional view of the light-pipe of Figure 28A;

- Figure 29 shows a cross-sectional view of an electronic add-on module comprising an optical sensor arrangement configured to emit radiation perpendicular to a longitudinal axis of a first portion;
- Figure 30 shows a cross-sectional view of an electronic add-on module comprising an optical sensor arrangement arranged on a separate sensor circuit board;
- Figure 31 shows an exemplary circuit board assembly as used for the electronic add-on module in Figure 30;
- Figure 32 shows a perspective view of a coupling portion as part of a first portion comprising axially facing encoder flag segments;
- Figure 33 shows a cross-sectional view of an electronic add-on module comprising axially facing encoder flag segments and a respective optical sensor arrangement in a dose setting position;
- Figure 34 shows a cross-sectional view of the electronic add-on module according to Figure 30 in a dose dispensing position;
- Figure 35 shows a diagram of the relation between the distance between an encoder flag segment and an optical sensor arrangement as well as a corresponding sensor output;
- Figure 36 shows an exploded view of a further electronic add-on module comprising a separate encoder ring;
- Figure 37 shows a separate encoder ring arranged inside a first portion of an electronic add-on module;
- Figure 38 shows a separate encoder ring arranged on a second portion of an electronic add-on module; and
- Figure 39 shows a cross-sectional view of a further electronic add-on module comprising a separate encoder ring.

In the Figures, identical elements and components as well as identical elements and components in different examples or embodiments, i.e. elements and components acting identical or provided for the same purposes but belong to different examples, are provided with the same reference signs.

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Figure 1 shows an exploded view of an exemplary medicament or drug delivery device 1. The drug delivery device 1 is a pen-type injector comprising a housing 10 in which a drive mechanism for dose setting and dose dispensing is arranged. The drug delivery device 1 extends from a distal point to a proximal direction P or from a proximal point to a distal direction D along a second longitudinal axis Y of the drug delivery device 1. In order to set a dose for delivery a user may rotate or dial a dose dial grip 12 with respect to the housing 10, wherein the dose dial grip 12 is arranged at a distal end of the housing 10. During dose setting the dose dial grip 12 may perform a helical movement, i.e. a combined axial and rotational movement, or may perform pure rotational movement.

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The drive mechanism of the drug delivery device 1 may comprise a plunger, a drive sleeve 13, a clutch, a clutch spring, a number sleeve, a last dose nut and so on, which may move during dose setting and/or dose dispensing. Although not all of these components are shown in detail, for example, the drive mechanisms disclosed in EP 1 570 876, EP 2 814 547, US 9,937,294 B2 or WO 2004/078239 A1 represent suitable drive mechanisms for the present disclosure.

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Once the dose is set by means of the dose dial grip 12, the user may press a dose button 11 arranged at the proximal end of the drug delivery device 1 in the distal direction D in order to dispense the dose. When pressing the dose button 11, the user applies a force directed towards the proximal end of the drug delivery device 1, wherein the force moves the dose button 11 in the distal direction of the pen and parallel to the second longitudinal axis Y. This axial movement of the dose button 11 releases the drive mechanism for example by de-coupling a number sleeve from the drive sleeve, wherein irrespective of which component of the drug delivery device 1 performs a rotational movement during dose delivery, the dose dial grip 12 is coupled to a respective component in order to perform a rotational movement during dose delivery.

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This rotational movement of the dose dial grip 12 during dose delivery may be used to determine, for example, the actual dose delivered by means of an electronic add-on module 100 as shown in various examples in the Figures and described here below.

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The exemplary drug delivery device 1 shown in Figure 1 comprises in addition to the dose dial grip 12 and the dose button 11 an optional dosage window 14, a container 15, and a needle 16. The set dose may be displayed via the dosage window 14. The container 15 may be filled directly with a drug, for example, insulin or may be configured to receive a cartridge and thus act as a cartridge holder. The needle 16 may be affixed to the container or the receptacle. During dose dispensing the drug is dispensed through the needle 16. The needle 16 may be protected by an inner needle cap 17. In addition, the needle 16 may be protected by either an outer needle cap 18 or another cap 19.

In order for an electronic add-on module 100 to be functionally attached to a drug delivery device 1, i.e. attached and usable, either the drug delivery device 1 can be adapted to the electronic add-on module 100 or, conversely, the electronic add-on module 100 can be adapted to the drug delivery device 1. Regardless of this, the drug delivery device 1 as well as the electronic add-on module 100 may have different examples, wherein the further description with respect to the drug delivery device 1 essentially deals with the dose button 11, the dose dial grip 12 and the drive sleeve 13.

A corresponding first example of a dose button 11 and a dose dial grip 12 is shown in Figure 2. The dose dial grip 12 comprises at least one second mechanical coupling element 20 in form of a protruding nub which may have chamfered or angled second contact surfaces 21 in the proximal direction and in the distal direction, i.e. in the direction of the dose button 11 and in the opposite direction. The second contact surfaces 21 of the second mechanical coupling element 20 are angled with respect to a direction perpendicular to the second longitudinal axis Y. The second mechanical coupling element 20 is configured for engagement with respective mechanical coupling elements of an electronic add-on module 100 as will be described later on. Although not shown, the dose dial grip 12 may comprise multiple second mechanical coupling elements 20, for example, another coupling element on the opposite site of coupling element 20.

Furthermore, ribs 22 are arranged alternately around the circumferential surface of the dose dial grip 12 and a groove 23 is arranged between each two adjacent ribs 22. As soon as an electronic add-on module 100 is attached to the drug delivery device 1, the second mechanical coupling element 20, in cooperation with corresponding first mechanical coupling elements (not shown here), is able to limit relative axial as well as rotational movement between a first portion of the electronic add-on module 100 and the dose dial grip 12 of the drug delivery device 1. In addition, the ribs 22 and grooves 23 may transfer rotational movement between the drug delivery device 12 and the electronic add-on module 100. Depending on the

embodiment of the second contact surfaces 21, in particular the angle of the chamfered surfaces, a force needed to attach or remove an electronic add-on module 100 on or from a drug delivery device 1 may be determined. In addition, the structure of the grooves 23 and ribs 22 can be used to determine the force transmission between the dose dial grip 12 and the electronic add-on module 100. The grooves 23 shown here have a larger width in the proximal area, i.e. closer to the dose button 11, and a smaller width closer to the distal end. This configuration may facilitate attachment and alignment of corresponding counterparts of the electronic add-on module 100 to the drug delivery device 1. Therefore, the ribs 22 and grooves 23 may be seen as a second alignment structure arranged on an outer circumferential surface of the dose dial grip 12.

On the proximal end of the grooves 24, first abutment edges 24A are provided. The first abutment edges 24A are configured to abut end stops 114 of the electronic add-on module 100 which will be described below. On the distal end of the grooves 23, the grooves 23 are provided with a second abutment edge 24B configured to be in abutment with a respective counterpart of the electronic add-on module 100, when engaged with the drug delivery device 1. The second abutment edges 24B may limit the axial movement of the electronic add-on module 100 in the distal direction D, when the electronic add-on module 100 is engaged with the drug delivery device 1.

Although the second mechanical coupling element 20 is shown here as a protruding nub, the second mechanical coupling element 20 may also be formed as a recess which may engage with a corresponding counterpart of the electronic add-on module 100. The second mechanical coupling element 20 in form of a recess may then also comprise chamfered second contact surfaces, wherein the electronic add-on module 100 may comprise a counterpart in the form of a protrusion with chamfered contact surfaces configured to be engaged with the second mechanical coupling element 20. The second mechanical coupling element 20 is consequently only shown as one example.

The exact configuration of the first mechanical coupling element, which is preferably arranged on a first portion 101 of an electronic add-on module 100, and the configuration of the second mechanical coupling element 20, which is preferably arranged on the dose dial grip 12 of the drug delivery device 1 and forms the counterpart to the first mechanical coupling element, should be carried out in symbiosis. The specific structure of the mechanical coupling elements may be used to define the forces required for engagement or disengagement of the mechanical coupling elements. In addition, the mechanical coupling elements may be used to determine

which movements are coupled between the electronic add-on module 100 and the drug delivery device 1 during an engagement.

5 A further example of a dose button 11 and a dose dial grip 12 is shown in Figure 3. Here, the dose button 11 comprises a recess 25 on a proximal end surface 26 defining a fourth alignment structure configured to be engaged with a respective alignment structure of the electronic add-on module 100, i.e. a third alignment structure of a second portion 102 of the electronic add-on module 100 described in more detail below. Once the third alignment structure and the fourth alignment structure are engaged, the second portion 102 is rotationally constrained to the dose button 11 of the drug delivery device 1 such that the second portion 102 does not rotate if the dose button 11 remains stationary. The recess 25 is arranged centered with respect to the proximal end surface 26 of the dose button 11. As alternatives to the depicted interface between dose button 11 and the second portion 102, a toothed interface, a friction coupling, a ratchet, a clicker or other known rotational couplings may be used to rotationally constrain the dose button 11 to the second portion 102 at least in one direction, preferably in both directions.

Further, the fourth alignment structure comprises ribs and grooves configured to engage respective counterparts of the second portion 102 of the electronic add-on module 100. The second alignment structure arranged on the dose dial grip 12 may be configured to be engaged with a corresponding first alignment structure of the electronic add-on module 100 in a first number of different engagement positions. The fourth alignment structure arranged on the dose button 11 may be configured to be engaged with a third alignment structure of the electronic add-on module 100 in a second number of different engagement positions. The first number may be less than or equal to the second number. In Figure 3, the fourth alignment structure comprises ten ribs with ten grooves arranged in between a pair of ribs.

The ribs and grooves providing the fourth alignment structure of the dose button 11 is also shown in a top view in Figure 4, wherein the fourth alignment structure is arranged centered with respect to the proximal end surface 26 of the dose button 11. In addition, an abutment surface 27 is shown at the distal end of the recess 25, which may be configured for abutment of a push element 111, for example shown in Figures 6 to 9. An electronic add-on module 100 comprising a third alignment structure may be attached to a drug delivery device 1 comprising the dose button 11 shown in Figure 4.

A respective example of an electronic add-on module 100 comprising a first portion 101 and a second portion 102 is shown in Figure 5. The second portion 102 is retained in the first portion

101 allowing relative rotational movement about the first longitudinal axis X. In addition, relative axial movement between the first portion 101 and the second portion 102 parallel to the first longitudinal axis X is allowed. When attached to the drug delivery device 1, the first portion 101 of the electronic add-on module 100 defines an auxiliary dose dial grip and the second portion 102 defines an auxiliary dose button.

When the electronic add-on module 100 is attached to a drug delivery device 1, a user may rotate the first portion 101 in order to set a dose for delivery. The first portion 101 provides an auxiliary grip 103 allowing for a controlled rotational movement of the first portion 101. Further, pressure may be applied to a proximal end surface 104 of the second portion 102, for example by a thumb of a user, in order to axially move the second portion 102 with respect to the first portion 101 along the first longitudinal axis X.

Figure 6 depicts a bottom view of the electronic add-on module 100 shown in Figure 5. The first portion 101 comprises a hollow sleeve-like body with an inner surface provided with ribs 105 and grooves 106 as a first alignment structure configured to be engaged with the second alignment structure of the dose dial grip 12, in the present example ribs 22. When the first alignment structure is engaged with the second alignment structure, i.e. when the module is attached to the drug delivery device, the first portion 101 of the module is rotationally constrained to the dose dial grip 12, such that rotation of the first portion 101 of the module may entrain the dose dial grip 12 of the drug delivery device and vice versa. The second portion 102 is retained in the first portion 101 by means of clips 107. In addition, first mechanical coupling elements 108 are provided on the inner surface of the first portion 101 and more specifically the first mechanical coupling elements 108 extend parallel to the first longitudinal axis X closer to a distal end of the first portion 101 than the first alignment structure. The first mechanical coupling elements 108 are provided as recesses with angled or chamfered first contact surfaces 109. When the electronic add-on module 100 is releasably attached to the drug delivery device 1, the first longitudinal axis X and the second Y are in line with one another.

An assembly of the drug delivery device 1 and the electronic add-on module 100, therefore, allows rotational movement of the dose dial grip 12 and the first portion 101 about the first and second longitudinal axis X and Y during dose setting. In addition, the assembly allows axial movement of the second portion 102 and the dose button 11 parallel to the first and second longitudinal axis X and Y during dose dispensing.

Furthermore, one example of a third alignment structure is shown in Figure 6. The alignment structure is provided by a protrusion in form of a cylindrical portion provided with ribs 110 on its outer circumferential surface. The ribs 110 are configured to be aligned with the respective grooves of recess 25 depicted in Figures 3 and 4. Once the third alignment structure and the fourth alignment structure are engaged, the second portion 102 and the dose button 11 are rotationally constrained.

In addition, one example of a push element 111 is shown in Figure 6, wherein the push element 111 is elastically biased in the distal direction D by a spring 112. The push element 111 is provided by an actuation rod moveable in an axial direction relative to the second portion 102. In the shown state, the push element is maximally biased in the distal direction D, wherein the spring 112 is arranged around a portion of the rod, and wherein the spring 112 is in abutment with a distal surface of the third alignment structure and a surface of the push element 111 facing proximally. The push element 111 is provided with a push element abutment surface 113 at its distal end. When attached to the drug delivery device 1, the push element abutment surface 113 may be in abutment with abutment surface 27 in order to push the second portion 102 of the electronic add-on module in the proximal direction P.

Furthermore, and in addition to the first mechanical coupling element 108 of the first portion 101, the electronic add-on module 100 shown in Figure 6 comprises an end stop 114. The end stop 114 is provided as a flange portion protruding from the first portion 101 into the hollow-sleeve-like body and therefore perpendicular to the first longitudinal axis X. The end stop 114 is arranged at the proximal end of ribs 105 and grooves 106. Thus, even though the first mechanical coupling element 108 may prevent that the electronic add-on module 100 is pushed too far onto the drug delivery device 1 in the distal direction D, wherein pushing the electronic add-on module 100 too far onto the drug delivery device 1 may damage electronic components arranged inside the electronic add-on module 100, the additional end stop 114 ensures that the electronic add-on module 100 is not pushed too far. In this regard, the end stop 114 is configured to abut against a respective proximal facing surface of the drug delivery device, i.e. against the first abutment edges 24A.

Although the end stop 114 in Figure 6 is represented by a circumferentially continuous ring-flange, the end stop 114 may also comprise of one or more segments projecting in the direction perpendicular to the first longitudinal axis X as long as the end stop 114 is configured to limit the axial movement of the electronic add-on module 100 when attached to the drug delivery device 1.

Figure 7 shows the electronic add-on module 100 of Figure 6 in a different view, wherein the third alignment structure may be better observed. The cylindrical portion provided with ribs 110 on the outer circumferential surface provides an exemplary third alignment structure. The alignment structure comprises eight ribs 110 in total.

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In Figure 8, a further example of an electronic add-on module 100 is shown. Also here, the electronic add-on module 100 comprises a push element 111 provided with spring 112 biasing the push element 111 in the distal direction D. In addition, the first portion 101 is provided with a first clutch element 115 provided by teeth and the second portion 102 is provided with a second clutch element 116 provided by teeth. When the first and second portions 101 and 102 are assembled, preferably, both clutch elements 115 and 116 are in engagement, when the electronic add-on module 100 is in the dose setting position, i.e. when the second portion 102 is in the proximal position and the clutch elements 115 and 116 are in engagement. The clutch therefore rotationally constrains the second portion 102 to the first portion 101, wherein, when the user rotates the first portion 101 in order to set a dose, also the second portion 102 is rotated.

The push element abutment surface 113 may push the second portion 102 in a proximal direction P by abutting against the abutment surface 27 of the drug delivery device 1 with the help of the spring force of a spring 112, so that the clutch is engaged. Therefore, when pressure is applied on the proximal end surface 104 of the second portion 102, the pressure force directed in distal direction D may have to overcome the force of the spring 112 pushing the second portion 102 proximally by abutment against the abutment surface 27 in order to disengage the clutch.

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Correspondingly, when the electronic add-on module 100 is attached to the drug delivery device, the second portion 102 may be pushed in the dose setting position in which the clutch is in engagement. Hence, when the first portion 101 is rotationally moved also the second portion 102 is rotationally moved. If, in addition, the electronic add-on module 100 is attached to the dose dial grip 12 by means of mechanical coupling elements 20 and 108 and/or first and second alignment structures, rotational movement is transferred from the first portion 101 directly onto the second portion 102. Consequently, rotational movement of the first portion 101 during dose setting may rotate the dose dial grip 12 as well as the second portion 102.

However, when the second portion 102 of the electronic add-on module 100 is additionally provided with the third alignment structure, this structure may engage the fourth alignment structure of the dose button 11, when the second portion 102 is axially moved. Thus, axial

movement of the second portion 102 in the distal direction D may engage the third and fourth alignment structure, wherein disengagement of the clutch between the first portion 101 and the second portion 102 occurs after engagement of the third and fourth alignment structure. In other words, the distal travel of the second portion 102 needed to disengage the clutch may be greater than the distal travel needed to engage the third and fourth alignment structures. Therefore, during dose dispensing and when the user applies pressure onto the proximal end surface 104 of the second portion 102, the clutch is disengaged allowing relative rotational movement between the second portion 102 and the first portion 101. However, at the time of disengagement of the clutch, the second portion 102, moreover the third alignment structure is in engagement with the fourth alignment structure so that the second portion 102 is rotationally constrained to the dose button 11. The first portion 101, i.e. the auxiliary dose dial grip, attached to the dose dial grip 12 may thus rotate during dose dispensing relative to the dose button 11 rotationally constrained to the second portion 102.

An exemplary arrangement of an electronic add-on module 100 and a drug delivery device 1 or its dose dial grip 12 and its dose button 11 prior to assembly is shown in Figure 9. The previously mentioned alignment of the first and second longitudinal axis X and Y when the electronic add-on module 100 is attached to the drug delivery device 1 may be imagined. Here, only a number sleeve 28, the dose dial grip 12 and the dose button 11 of a respective drug delivery device 1 are shown. The number sleeve 28 may comprise an outer thread 29 which may be guided in a housing thread allowing for a helical movement of the number sleeve 28 with respect to the housing of the drug delivery device 1 during dose setting, i.e. upon rotation of the dose dial grip 12 or the auxiliary dose dial grip 101 when attached to the drug delivery device 1. The dose dial grip 12 may be permanently fixed to the number sleeve 28, so that the dose dial grip 12 and the electronic add-on module 100 or the first portion 101 when attached to the drug delivery device 1 may perform a helical movement with respect to the housing of the drug delivery device 1 during dose setting and dose dispensing.

Figure 10 illustrates a cross-sectional view through the engagement of the third and fourth alignment structure of an assembled electronic add-on module 100 and a drug delivery device 1. The ribs 22 are therefore in engagement with respective grooves 106 of the third alignment structure and the ribs 110 are in engagement with respective grooves of recess 25 forming the fourth alignment structure.

Further, Figure 11 depicts an exploded view of an example of a dose button 11 and drive sleeve 13, wherein the drive sleeve 13 comprises a slot 29 configured to receive a spline 30 as part of the dose button 11. An engagement between the slot 29 and the spline 30 therefore

rotationally constrains the dose button 11 to the drive sleeve 13 such that, if the drive sleeve is rotationally constrained to the housing 10 of the drug delivery device 1 during dose dispensing to perform a purely axial movement, the dose button 11 is also rotationally constrained to the housing. Still, the shown configuration of the slot 29 and spline 30 allows a relative axial
5 movement between the dose button 11 and the drive sleeve 13 along the longitudinal axis. As alternatives to the depicted interface between dose button 11 and drive sleeve 13, a toothed interface, a friction coupling, a ratchet, a clicker or other known rotational couplings may be used to rotationally constrain the dose button 11 to the drive sleeve 13 at least in one direction, preferably in both directions.

Therefore, when the drive sleeve 13, for example, performs a helical movement upon rotation of the dose dial grip 12 during dose setting, the dose button 11 also rotates. Consequently, there is no relative rotational movement between the dose button 11 and the dose dial grip 12 during dose setting. Further, when the drive sleeve 13 performs a pure axial movement during
15 dose dispensing, due to the slot-spline-engagement between the dose button 11 and the drive sleeve 13, also the dose button 11 does not perform rotational movement during dose dispensing. In consideration of attachment of an electronic add-on module 100 to the drug delivery device 1, rotation of the first portion 101 attached to the dial grip 12 rotates the dial grip 12 during dose setting. When the second portion 102 is clutched to the first portion 101 as described before, the spline 29 and slot 30 engagement between the drive sleeve 13 and the
20 dose button 11 may prevent that there is any relative rotational movement between dose button 11, dose dial grip 12, first portion 101 and second portion 102 during dose setting. This rotational coupling, irrespective of the type of the interface providing this coupling function, may be especially relevant if a sensor arrangement forms part of the electronic add-on module 100 configured to measure relative rotational movement between the first portion 101 and the second portion 102 as no relative movement occurs between the respective components during
25 dose setting. Further, and in order to initiate dose dispensing axial movement of the dose button 11 may disengage a clutch inside the drug delivery device 1, so that dispensing of a drug may be initiated.

Likewise, when the second portion 102 comprises a third alignment structure configured to engage a fourth alignment structure of the dose button 11 during dose dispensing as described before, i.e. when pressure is applied to the proximal end surface 104 of the second portion, the second portion 102 is rotationally constrained to the dose button 11. Due to the rotationally
35 constrained engagement therefore also the second portion 102 does not perform a rotational movement during dose dispensing even when the clutch is disengaged. However, as the first portion 101 and the dose dial grip 12 are rotated during dose dispensing, relative rotational

movement between the first portion 101 and the second portion 102 may be measured in order to determine the dispensed dose.

5 Figure 12 shows a respective cross-sectional view through the exemplary slot-spline engagement between the dose button 11 and the drive sleeve 13 as shown in Figure 11.

10 Figure 13A shows a cross-sectional view of an assembly of a further example of an electronic add-on module 100 and a proximal part of a drug delivery device 1 in a dose setting state. In the dose setting state, also called "at rest state", the first portion 101 is not rotated and no pressure is applied to the second portion 102. The proximal part of the drug delivery device 1 in Figure 13A comprises a dose button 11 with a proximal end surface 26, a dose dial grip 12, a drive sleeve 13 encompassed within a number sleeve 28. A clutch 31 is arranged between the number sleeve 28 and the drive sleeve 13. The drive mechanism of the drug delivery device 1 may be configured to perform the aforementioned relative rotational, axial and helical movements.

Further, the exemplary electronic add-on module 100 is attached to the dose dial grip 12, wherein respective first and second mechanical coupling elements 20 and 108 are engaged. The first portion 101 shown in Figure 13A is divided into a sleeve portion 117 and a coupling portion 118. The sleeve portion 117 comprises the auxiliary grip 103, wherein the coupling portion 118 comprises the first mechanical coupling element 108. The coupling portion 118 is partially arranged inside the sleeve portion 117 and the first mechanical coupling element 108 is arranged on inner surface 119 of the coupling portion 118. The coupling portion 118 is partially spaced from the sleeve portion 117 so that the coupling portion 118 is partially configured to be moved relative to the sleeve portion 117 in a direction perpendicular to the longitudinal axes X and Y.

30 An exemplary coupling portion 118 is shown in Figure 13B and an exemplary sleeve portion 117 is shown in Figure 13C. The sleeve portion 117 shown in Figure 13C comprises a sleeve portion clip 117A which may engage with a coupling portion clip 118A in order to couple the coupling portion 118 to the sleeve portion 117. A corresponding engagement between the coupling portion 118 shown in Figure 13B and the sleeve portion 117 shown in Figure 13C is depicted in Figure 13D. It may be noted from the perspective bottom view of Figure 13D, which also depicts the mechanical coupling elements 108 of the coupling portion 118, that the sleeve portion 117 as well as the coupling portion 118 in Figures 13B to 13D are different from the respective portions shown in Figure 13A. Further, it may be noted that the coupling portion 118 is partially spaced apart from the sleeve portion 117, especially in the region of the first contact

surfaces 109 of the coupling elements 108. This may allow outwards deflection of the coupling portion 118 with respect to the sleeve portion 117. In addition, it can be seen from Figure 13D that the coupling portion 118, as already described above in respect with first portion 101, comprises a structure with ribs 105 and grooves 106, which allows engagement with respective features of a dose button.

In Figure 13A, the first mechanical coupling element 108 extends from the inner surface 119 into a direction perpendicular to the longitudinal axes X and Y and away from the components of the drug delivery device 1, thereby forming a recess. The first contact surfaces 109 of the first mechanical coupling element 108 are angled with respect to the direction of extension. The more proximal contact surfaces comprise a smaller angle than the more contact distal surface. This may allow for an easy attachment of the electronic add-on module 100, wherein, however, more force is required to detach the electronic add-on module 100 from the drug delivery device 1. In addition, the end stop 114 limits the movement of the electronic add-on module 100 in the distal direction D during attachment.

Therefore, it can be seen that the mechanical coupling elements 20 and 108 on the dose dial grip 12 and the first portion 101 respectively comprise surfaces 21 and 109 angled relative to the axial direction in order to provide a cam action cause the necessary deflection to both assemble and disassemble the electronic add-on module 100 and the drug delivery device 1.

The second portion 102 comprising a proximal end surface 104 is retained in the first portion 101. The second clutch element 116 of the second portion 102 is fully engaged with the first clutch element 115 of the first portion 101 therefore preventing relative rotational movement between the first and second portion 101 and 102. A second portion housing 120 encompasses a battery 121 as an electrical power source, a circuit board assembly 122 electrically connected to the battery 121 and comprising a microswitch 123 operable by a lever arm 124. The battery 121, the circuit board assembly 122, the microswitch 123 and the lever arm 124 are provided inside the second portion housing 120, wherein the housing 120 comprises a distally facing surface 125. The distally facing surface 125 may be configured to be in abutment with the dose button 11 during dose dispensing.

To initiate dose dispensing the second portion 102 is axially moved in the distal direction D so that the push element 111, which is in abutment with the dose button 11 via the push element abutment surface 113, is further moved into the second portion 102. The push element 111 is therefore configured to act on the lever arm 124. The microswitch 123 may be, for example, directly coupled to the lever arm 124 so that a movement of the lever arm 124 operates the

microswitch 123. Alternatively, the microswitch 123 may, for example, be arranged on the circuit board assembly 122 and may therefore be operated, when the lever arm 124 flips in the proximal direction and contacts the microswitch 123. Importantly, the dose button 11 does not move axially during this first axial movement of the second portion 102 and the actuation of the lever arm 124 and the microswitch 123. Rather, movement of the dose button 11 only starts after the activation/operation of the microswitch 123. This ensures that the electronic components of the electronic add-on module 100, e.g. including the circuit board assembly 122, are powered and awake, i.e. ready for detecting the amount of dose dispensed from the drug delivery device.

In other words, the sequence of activation of the electronic add-on module 100 is as follows: First, the user presses, e.g. with his or her thumb, on the proximal end surface 104 of the second portion 102 which results in an axial movement of the second portion 102 in the distal direction relative to the first portion 101 and relative to the, in this moment stationary, button 11. This relative movement causes the push element 111 to act on the lever 124 which in turn activates or operates the microswitch 123, thereby powering the electronic system of the electronic add-on module 100. If the user then continues pressing on the proximal end surface 104 of the second portion 102, the button 11 starts after this activation of the electronic add-on module 100 moving axially from an initial position to an actuated position in which the dose dispensing starts.

However, for example, during dose setting, i.e. when no pressure is applied to the proximal end surface 104 of the second portion 102, the spring 112 acts to bias the push element 111 in the distal direction D preventing operation of the lever arm 124 and the microswitch 123. In the state shown here, the spring 112 maximally biases the push element 111 in the distal direction. At the same time the second portion 102 is in the most proximal position with respect to the first portion 101.

Operation of the microswitch 123 may activate or deactivate the electrical power source 121 and the circuit board assembly 122. Accordingly, other electronically controlled components such as sensors can also be activated by the microswitch.

To prevent the push element 111 from sliding out of the second portion housing 120 in the distal direction D, the push element 111 has a stopper element 126 which retains the push element 111 in the second portion 102 and prevents that the action of the spring 112 causes the push element 111 from disassembling from the second portion 102. In the example shown here, the third alignment structure is in the process of entering the recess 25 of the dose button

11 and engaging with the corresponding fourth alignment structure. Additionally, the dose button 11 may be rotationally constrained to the drive sleeve 13 as shown in Figures 11 and 12.

5 Figure 14 shows the assembly according to Figure 13A in an interim state of the module in which the second portion 102 has been moved in the distal direction D so that the push element 111 is pushed further into the second portion housing 120 in the proximal direction P. Due to the relative axial movement between the second portion 102 and the push element 111, the lever arm 124 is deflected and the microswitch 123 is operated. Therefore, the interim state of the module defines a state in which the microswitch is operated, i.e. a switch point, although
10 there may still be further relative axial movement possible, as can be seen in Figure 15.

In Figure 14, the clutch formed by first and second clutch element 115 and 116 between the first portion 101 and the second portion 102 is still in engagement. In addition, the third and fourth alignment structure of the second portion 102 and the dose button 11 are in engagement
15 although the dose button 11 is moved distally to its full extent with respect to the further components of the drive mechanism. Further, distal movement of the dose button 11 may have disengaged a clutch of the drive mechanism which would, without the electronic add-on module 100 being attached to the drug delivery device 1, start or allow dose dispensing. However, due to the rotational constraint between the first and second portion 101 and 102 via clutch elements 115 and 116, the rotational constraint between the second portion 102 and the dose
20 button 11 via the third and fourth alignment structures which are engaged, the rotational constraint between the dose button 11 and the drive sleeve 13, wherein the drive sleeve 13 is not rotatable during dose dispensing, and the rotational constraint between the first portion 101 and the dose dial grip 12, no dose dispensing is yet possible.

25 Hence, further distal movement of the second portion 102 relative to the first portion 101 as well as the drug delivery device 1 may still be required in order to transfer the assembly into a dose dispensing state as shown in Figure 15. In this state the second portion 102 has reached its most distal position. In addition, the push element 111 has deflected the lever arm 124 beyond the interim state of the module in which the microswitch was operated, for example
30 turned into an "on"-state. Due to the axial movement, the spring 112 has been compressed. The distally facing surface 125 abuts the proximal end surface 26 of the dose button 11. Further, the clutch between the first portion 101 and the second portion 102 is disengaged, therefore allowing relative rotational movement. The disengagement of the clutch elements 115 and
35 116, which allows relative rotational movement between the first portion 101 and the second portion 102, thus now permits dose dispensing. The axial movement of the second portion 102, which moves the dose button 11 axially in the distal direction D, provides for an axial movement

of the drive sleeve 13 and at the same time for a helical movement of the number sleeve 28. A dose dial grip 12 permanently fixed to the number sleeve 28 thus rotates with the number sleeve 28 and relative to the dose button 11. Considering an electronic add-on module 100 releasably attached to the dose dial grip 12, the dose dial grip 12 also rotates the dial grip 12 together with the first portion 101 and relative to the second portion 102. Dose dispensing is therefore permitted, wherein at the same time the amount delivered may be determined by a sensor arrangement.

Figures 16 and 17 show an alternative example of a push element 111 of an electronic add-on module 100 releasably attached to a proximal part of a drug delivery device 1. The main difference compared to the examples shown in Figures 13 to 15 is that the push element 111 is provided by portion of the second portion housing 120. The push element 111 is clipped by push element clips 127 to further second portion housing 120 components. The push element 111, however may also be an integral part of the second portion housing 120. The distally facing surface 125 of the second portion housing 120 may be deformed upon axial movement of the second portion 102 from a dose setting state shown in Figure 16 into a dose dispensing state shown in Figure 17, thereby acting on a microswitch 123. Consequently, the example of Figures 16 and 17 does not require an actuation rod, a spring 112 or a stopper element 126. Instead, the second portion housing 120 includes at least partially a flexible portion, which may for example be a flexible diaphragm as shown in Figures 16 and 17 or in Figures 20A and 20B.

The push element 111 shown in Figures 16 and 17 may be used together with the clutch between the first portion 101 and second portion 102 and/or the third and fourth alignment structures as described in respect to Figures 13 to 15. However, the push element 111 used for the example of Figures 16 and 17 may also be used without the clutch mechanism or the alignment structures.

In the dose setting state shown in Figure 16, the distally facing surface 125 of the second housing portion 120 comprising flexibility is at least partially separated from the dose button 11 and its proximal end surface 26. Upon distal axial movement of the second portion 102, however, the push element abutment surface 113 is pressed against a surface of the recess 25. The section of the push element 111 which is arranged inside the recess 25 may thus not be moved further distally in relation to the dose button 11. However, the outer areas of the distally facing surface 125, i.e. the areas closer to the first portion 101, may deform due to the continuous axial pressure and due to the flexibility of this housing portion. The distally facing surface 125 therefore partially moves axially in the distal direction D and comes into abutment with the proximal end surface 26 of the dose button 11. As a result, the section of the push

element 111 arranged in the recess 25 is moved closer to the proximal end surface 104 of the second portion 102 as shown in a dose dispensing state shown in Figure 17. Due to the axial movement and/or deformation of the push element 111, a microswitch 123 arranged on the circuit board assembly 122 may be operated.

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Figure 18 shows a state during assembly of an electronic add-on module 100 and a proximal part of a drug delivery 1 in which the electronic add-on module 100 is not yet completely pushed and fixed onto the drug delivery device 1. Consequently, although first and second alignment structures are already partially engaged, first and second mechanical coupling elements 20 and 108 are not yet coupled. The third and fourth alignment structures are therefore also not yet engaged. When the electronic add-on module 100 is moved further in the distal direction D relative to the part of the drug delivery device 1, the coupling portion 118 of the first portion 101 is therefore deflected outwards and pushed over the second mechanical coupling element 20. The end stop 114, in addition to the distal first contact surface 109 being engaged with the proximal second contact surface 21, prevents the electronic add-on module 100 from being moved too far in the distal direction D relative to the dose dial grip 12.

In Figures 19A and 19B a further example of an electronic add-on module 100 comprising a further example of a push element 111 is shown in two different orientations, i.e. in different rotational positions with respect to axis X. The push element 111 of Figure 119A is shown in more detail in Figure 19B. The push element 111 comprises a flange 111A. Instead of or in addition to the use of a spring 112, the push element 111 comprises legs 111B as part of the push element 111. Figure 19C shows the push element 111. The push element 111 as shown in Figure 19C may be made of plastic. A lever arm 124 may be received in a receiving section 111C of the push element 111. As soon as a force may be applied to the push element abutment surface 113, the receiving section 111C travels in the proximal direction P, thereby moving relative to the legs 111B of the push element 111. In this regard, legs 111B may abut against the circuit board assembly 122. The lever arm 124 may switch microswitch 123 and the battery 121, which is fixed to the assembly by a battery clip 121A, may power for example a sensor arrangement. Further, a light element 120A, which may be a light ring, may indicate different conditions of the electronic add-on module 100. For example, the light element 120A may indicate when enough pressure is applied so that the microswitch 123 is activated or conditions of the battery 121, for example that the battery 1221 has only little energy left. Accordingly, the lighting element 120A may change its color depending on the information to be displayed.

The legs 111B may be deformed upon proximal movement of the receiving section 111C with respect to the legs 111B and the push element 111 may thus be biased. When a load applied to the proximal end surface 104 ends, for example because the user no longer presses on the proximal end surface 104, the biasing force of the deformed legs 111B may return the push element 111 to its initial position, thereby moving the receiving section 111C distally relative to the legs 111B, and the lever arm 124 may no longer actuate the microswitch 123. In this regard, the push element 111 may be returned until flange 111A abuts against the second portion housing 120 as shown in Figure 19A. The biasing force provided upon movement of the push element 111 may thus ensure that the microswitch 123 is switched off, when the proximal end surface 104 is released. Thus, although the lever arm 124 itself may comprise a small spring which may in general be configured to return the lever arm 124 to its initial position in which the microswitch 123 is switched off, this spring may not be configured to move the second portion 102 in the proximal direction P with respect to the first portion 101.

In Figure 19D the push element abutment surface 113 of the push element 111 is shown in more detail. Figure 19D shows a state of the push element 111 in which no pressure is applied to the proximal end surface 104 and the flange 111A abuts against the second portion housing 120. It may thus be noted that in this state a leak path 111D between the distally facing surface 125 of the second portion housing 120 and the push element 111 is present. Consequently, this push element 111 of Figures 19A to 19E may be less suitable if a high level of ingress protection is required. In other words, for example ingress of fluid such as of a medicament solution leaking through the leak path 111D may impair the electronic functionalities or other functionalities of the electronic add-on module 100. An example of a push element 111 which allows for improved ingress protection is presented with respect to Figures 20A and 20B.

In Figure 19E, the push element 111 is shown from an opposite direction to Figure 19D. It may be noted that the push element 111 is arranged in such a way that lateral movement is prevented, i.e., the push element 111 and legs 111B are guided by a housing portion.

Figures 20A and 20B show a further example of an electronic add-on module 100 in two different orientations, i.e. different rotational positions with respect to axis X. As aforementioned, the electronic add-on module 100 shown in Figures 20A and 20B discloses a further example of a push element 111 which especially allows for improved ingress protection. In this regard, the push element 111 is formed by a push portion 111E, which may actuate the lever arm 124 when moved in the proximal direction P, and a sealing portion 111F. As can be better seen in the orientation depicted in Figure 19B, the push element 111 further comprises a spring 112, which may be a metal spring and which deforms, when the push element abutment surface

113 is proximally moved. Consequently, the spring 112 allows the push element 111 to return to its initial position shown in Figures 19A and 19B when for example no more pressure is applied to the proximal end surface 104. In this position, the microswitch 123 is switched off.

5 Further, due to the abutment of the spring 112 against the second portion housing 120, the spring 112 also couples the push element 111 to the second portion 102. In this regard, the spring 112 may partially embrace the rod portion 111E of the push element 111 in order to couple the push element 111 to the second portion 102. The sealing portion 111F extends from the rod portion 111E substantially laterally, i.e. perpendicular to the axis X, and surrounds the
10 rod portion 111E.

The second portion housing 120 further comprises an opening in the distally facing surface 125 through which the spring 112 partially protrudes in order to embrace to the push portion 111E of the push element 111 when the push element 111 is in the position in which the microswitch 123 is switched off. The opening in the second portion housing 120 through which the lever arm 124 may protrude when the microswitch 123 is switched off may be sealed by the sealing portion 111F of the push element 111. In this regard, the sealing portion 111F of the push element 111 is configured to abut against the distally facing surface 125 of the second portion housing 120 independent of a relative axial position of the push element abutment surface 113 of the push element 111 with respect to the distally facing surface 125. In other words, if pressure is applied to the push element abutment surface 113 which may move the rod portion 111E of the push element 111 proximally with respect to the distally facing surface 125, the sealing portion 111F continuously abuts against the distally facing surface 125 and thereby seals the opening. Thus, the sealing portion 111F may provide a sealing lip.
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The push element 111 may be made of an elastomeric material. Deformation of the push element 111, especially deformations of the sealing portion 111F of the push element 111, may provide a biasing force directed in the distal direction D. The push element 111 may thus be a diaphragm which is coupled and additionally biased when deformed by the spring 112.

30 In Figure 21 a further example of an electronic add-on module 100 comprising a further example of a push element 111 is shown. The electronic add-on module 100 shown in Figure 21 comprises three portions. A third portion is here attached onto a spigot 149 of the second portion 102 and may be free to rotate relative thereto.

35 The push element 111 in Figure 21 comprises an elastically biased lever arm which is abutting on a projection 150 of the first portion 101. The push element 111 is abutting on the projection 150 with the push element abutment surface 113. The push element 111 may be biased by a

spring element (not shown) which biases the push element 111 into the state shown in Figure 21. The spring element biases the push element 111 towards a position in which the axial distance, i.e. the distance along the first longitudinal axis X between a proximal region 151 of the push element 111 and the push element abutment surface 113, which is in contact with the projection 150, is at a maximum. The biasing force provided by the spring element together with the abutment of the push element 111 on the projection 150 protruding from the inner surface of the first portion 101 therefore pushes the second portion 102 in the proximal direction P with respect to the first portion 101.

In the state shown in Figure 21, the second portion 102 is maximally pushed in the proximal direction P relative to the first portion 101 by the elastically biased lever arm abutting against the projection 150. Therefore, the second portion 102 is not abutting against the dose button 11 of the drug delivery device 1. Hence, there is an axial gap between the second portion and the distally facing surface 125 of the second portion 102 and the dose button 11.

However, when the second portion 102 is axially moved relative to the first portion as shown in Figures 22 and 23, the push element 111 is pivotably moved. To be more precise, the push element 111 is pivoted about a pivot axis which is substantially perpendicular to the first longitudinal axis X.

Figure 22 shows an interim state of the module in which the second portion 102 comes into contact with the dose button 11 due to the axial movement of the second portion 102 relative to the first portion 101. In this state, a microswitch (not shown) may be actuated by the elastically biased lever arm. Figure 23 shows a dose dispensing state in which the axial movement of the second portion 102 has moved the dose button 11 in the distal direction D, which may have caused the dose delivery. In other words, the second portion 102 has applied sufficient pressure on the proximal end surface 26 of the dose button 11 in order to move the dose button 11 in the distal direction D to cause dose dispensing.

As can be seen from Figures 21 to 23, the distal movement of the second portion 102 relative to the first portion 101 may be limited by the push element 111 as the push element 111 may not move beyond a position perpendicular to the first longitudinal axis X.

A further example of a first portion 101 of an electronic add-on module 100 configured to be used with an optical sensor arrangement is shown in Figure 24. In contrast to the first portions 101 described before, the first portion 101 shown in Figure 24 particularly includes an encoder ring 128 formed by radially facing first flag segments 129 and radially facing second encoder flag segments 130. The radially facing first encoder flag segments 129 may be reflective and

the radially facing second encoder flag segments 130 may be non-reflective. The radially facing encoder flag segments 129 and 130 are provided on an inner surface of the first portion 101. The circular encoder ring 128 comprises a center that correlates to a center of the first portion 101, wherein a radius varies from the center of the encoder ring 128 to the various radially facing encoder flag segments 129 and 130. Accordingly, the radially facing first encoder flag segments 129, which may be reflective, are arranged on a radius viewed from the center of the encoder ring 128 that is less than a radius to the radially facing second encoder flags 130, which may be non-reflective. Therefore, the radially facing first encoder flag segments 129 may be configured to be closer to an optical sensor arrangement that emits and/or guides radiation perpendicular to the first longitudinal axis X of the first portion 101. Consequently, the radially facing first encoder flag segments 129 may reflect more radiation, for example electromagnetic radiation such as light.

The radially facing second encoder flag segments 130 of the encoder ring 128 may be made from black material and the radially facing first encoder flag segments 129 may be made from white material. Additionally, or alternatively, the radially facing encoder flag segments 129 and 130 may comprise different surface finishes to increase or decrease reflectivity. The non-reflective encoder flag segments may for example be twin-shot molded.

The fact that the radially facing encoder flag segments 129 and 130 are radially facing is advantageous when an optical sensor arrangement emitting and/or guiding radiation towards the encoder flag segments 129 and 130 is moved in an axial direction. If, for example, the optical sensor arrangement is arranged on the second portion 102 in order to detect relative rotational movement between the first portion 101 and the second portion 102, axial movement of the second portion 102 relative to the first portion 101 does not affect the amount of radiation which is reflected and detected.

Figure 25 shows a respective optical sensor arrangement 131 comprising a light-pipe 132 configured to guide radiation in a direction perpendicular to the first longitudinal axis X to and from the encoder flag segments 129 and 130. The optical sensor arrangement 131 comprises a fixation surface 133 comprising a normal direction which is parallel to the longitudinal axis X. The radiation exits the light-pipe 132 through the exit surface 135. The optical sensor arrangement 131 may be configured to be activated upon operation of the microswitch 123. However, and as described above, the sensor arrangement could also be provided by a magnetic, a mechanical or a capacitive sensor arrangement.

Further, the first portion 101 or more precisely the coupling portion 118 comprises first mechanical coupling elements 108 in form of protrusions extending in a direction perpendicular to the first longitudinal axis X instead of recesses as for example shown in Figure 6.

5 The circuit board assembly 122 to which the optical sensor arrangement 131 is electrically connected may comprise further modules in order to transmit, monitor, display, store etc. the data detected by the optical sensor arrangement 131. The optical sensor arrangement 131 is configured to detect relative rotational movement between the first portion 101 and the second portion 102, especially in order to calculate based on the relative rotation a dispensed dose.

10 Figures 26, 27, 28A and 28B show three examples of a respective light-pipe 132 configured to be used with an optical sensor arrangement 131. The light-pipes 132 comprise entry surfaces 134 and exit surfaces 135. Radiation, for example, light emitted from the sensor arrangement 131 may enter the light-pipe 132 at the entry surface 134. The light-pipe 132 may be a hollow tube. The light-pipe 132 may be made of glass, plastic, for example polycarbonate or acrylic, metal, or a combination of the aforementioned materials such as metal coated plastic. The light-pipe 132 may be an integral part of the second portion 102 or may be a separate component. Instead of a light-pipe 132 a prism, mirrors or the like could be used.

20 The entry surface 134 and the exit surface 135 of the light-pipe 132 may have the same shape as shown in Figure 26 or may have different shapes as shown in Figures 27, 28A or 28B. Also, the size of the surfaces 134 and 135 may be the same or different. The light-pipes 132 shown in Figures 26, 27, 28A and 28B comprise a continuous curvature, wherein however the light-pipes 132 may comprises straight sections instead.

25 Further, the light-pipe 132 may comprise at least one aperture portion 132A as shown in Figure 28B. An aperture portion 132A may define a section or an area within the light-pipe 132 comprising a reduced cross-section with respect to surrounding sections or areas of the light-pipe 132, i.e. with respect to a light-pipe portion 132B. The surrounding sections or areas may thus be arranged before and/or after the aperture portion 132A with respect to the light path. In other words, the light-pipe 132 may comprise a section or area with reduced diameter, width and/or height. The aperture portion 132A may thus be a thin section. Having a section within the light-pipe 132 with a reduced cross-section may improve light transmission. In other words, the aperture portion 132A may be regarded as an aperture within the light-pipe 132A, i.e. an opening with a reduced cross-section through which light passes and which may collimate light.

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Figures 29 and 30 show further examples of optical sensor arrangements 131 which may be operated without light-pipes 132. In Figure 29 the fixation surface 133 of the optical sensor arrangement 131 comprises a normal direction parallel to the first longitudinal axis X. The optical sensor arrangement 131, however, is configured to emit light in a direction perpendicular to the first longitudinal axis X and may be a so-called side-firing optical sensor arrangement 132.

Figure 30 shows an alternative example, wherein the optical sensor arrangement 131 is provided on a separate sensor circuit board 136. "Separate" means in this regard that the sensor circuit board 136 may be detached or removed from the circuit board assembly 122 without affecting or impairing the functionality of the circuit board assembly 122, except that the circuit board assembly 122 no longer comprises a corresponding optical sensor assembly 131 and a corresponding sensor circuit board 136.

The sensor circuit board 136 as shown in Figure 30 comprises a normal direction perpendicular to the first longitudinal axis X. Consequently, the fixation surface 133 of the optical sensor arrangement 131 also comprises a direction normal to the sensor arrangement 131 which is perpendicular to the first longitudinal axis X.

The radiation emitted by the sensor arrangements 131 in Figures 29 and 30 is exemplary depicted by dotted lines.

Figure 31 shows a circuit board assembly 122 and a separate sensor circuit board 136 arranged perpendicular to the circuit board assembly 122. The sensor circuit board 136 shown in Figure 31 is electrically connected to the circuit board assembly 122 by leads 137. The circuit board assembly 122 comprises a substrate 138 equipped with electronic components 139 such as a chip, a processor, a conductor or the like.

In Figure 32 shows an alternative example of a coupling portion 118 of a first portion 101 of an electronic add-on module 100. The coupling portion 118 comprises axially facing encoder flag segments 140 and 141 with different distances from a distal end of the coupling portion 118. The axially facing first encoder flag segments 140 comprising a smaller distance from the distal end of the coupling portion 118 give peak reflection intensity. The axially facing second encoder flag segments 141 comprising a greater distance from the distal end of the coupling portion 118 are configured to substantially block the radiation so that substantially no radiation returns from these segments to a detector portion of the sensor arrangement 131.

Using axially facing encoder flag segments 140 and 141 allows for measurement of the change in distance of, for example, the second portion 102 and the first portion 101 of an electronic add-on module 100, when the second portion 102 is axially moved with respect to the first portion 101. Figures 33 and 34 for example show the change in distance between the axially facing encoder flag segments 140 and 141 and a respective sensor arrangement 131. The radiation emitted is again exemplary depicted by dotted-lines. Figure 33 shows an electronic add-on module 100 e.g. in a dose setting position. Figure 34 shows an electronic add-on module 100 e.g. in a dose dispensing position in which the second portion 102 is moved distally with respect to the first portion 101, thus reducing the distance between the axially facing encoder flag segments 140 and 141 and the sensor arrangement 131. The microswitch 123 is also operated due to the axial movement of the second portion 102 with respect to the first portion 101.

Figure 35 illustrates the relation between a sensor output and a reflector distance. The "reflector distance" defines the distance between an optical sensor arrangement and an encoder flag segment. The "sensor output" defines a signal strength, for example a current, provided by a detector portion of the sensor arrangement as a result of the detected radiation. Increasing the distance between the encoder flag segments and the sensor arrangement thus increases the sensor output until a peak output 142. However, when the distance is further increased after reaching the peak output 142, the sensor output is decreased. The peak output 142 is typically provided as the focal length of the sensor arrangement. Having this knowledge, a change in distance between encoder flag segments and an optical sensor arrangement may be used to determine, for example, a change in state of an electronic add-on module.

For example, reference sign 143 may refer to a range with a minimum distance between sensor arrangement 131 and axially facing first encoder flag segment 140 on the left side of the distance range 143 and a maximum distance between sensor arrangement 131 and axially facing first encoder flag segment 140 on the right side of the distance range 143. For example, the minimum distance may refer to the distance according to Figure 34 and the maximum distance may refer to the distance according to Figure 33. Reference sign 144 thus indicates a minimum sensor output for the axially facing first encoder flag segment 140.

Accordingly, for example, the reference sign 145 may belong to the distance between an axially facing second encoder flag segment 141 and the sensor arrangement 131, wherein likewise the left side end of the distance range 145 belongs to a minimum distance and the right side of the distance range 145 belongs to a maximum distance. Therefore, reference sign 146 indicates a maximum sensor output for the axially facing second encoder flag segment 141.

Although the relationship between axial facing encoder flag segments and sensor output is shown in Figure 35, the relation also applies to the distance from an optical sensor arrangement to radially facing encoder flag segments.

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Figure 36 shows an exploded view of a further example of an electronic add-on module 100 comprising a first portion 101 and a second portion 102 with respective clutch elements 115 and 116. Further, Figure 36 shows a separate encoder ring 147 as a separate component. The separate encoder ring 147 is rotationally constrained to the first portion 101 and axially constrained to the second portion 102. The separate encoder ring 147 is not an integral part of the electronic add-on module 100 and may be arranged inside the first portion 101 as shown in Figure 37 or located at a distal end of the second portion 102 as shown in Figure 38. This means that the separate encoder ring 147, for example, is not molded as one component together with the second portion 102.

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Regardless of the exact position of the separate encoder ring 147 with respect to the first and second portion 101 and 102, the separate encoder ring 147 distinguishes from the aforementioned encoder ring in further features. In this regard, the separate encoder ring 147 comprises radially facing encoder flag segments and axially facing encoder flag segments. Empty spaces 148 are arranged between the respective encoder flag segments. The encoder flag segments 129, 130 and 140, 141 may therefore be reflective, with the empty spaces 148 forming non-reflective or less reflective regions. However, it is equally possible, and regardless of the reference signs used in Figure 36, that the empty spaces 148 of the separate encoder ring 147 expose reflective areas, for example reflective areas of an inner surface of the first portion 101 and the encoder flag segments 129, 130 and 140, 141 cover these reflective areas and substantially absorb radiation.

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As shown in Figure 38, the various surfaces of the separate encoder ring 147 may be used to form axial or radial facing encoder flag segments. An optical sensor arrangement may therefore use the various surfaces of the separate encoder ring 147 and the respective sensor output to determine or, for example, correlate specific motion sequences in order to obtain more accurate measurement results. As can be seen from Figure 38, the separate encoder ring 147 is in abutment with the second portion 102 and may as such be axially constrained to the second portion 102.

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Figure 39 shows a cross-sectional view of an electronic add-on module 100 attached to a dose dial grip 12, wherein the electronic add-on module 100 comprises a separate encoder ring 147.

This separate encoder ring 147 is only irradiated by an optical sensor arrangement 131, which emits radiation parallel to the first and second longitudinal axes X and Y. The exemplary radiation emitted by the sensor arrangement 131 is again shown as a dotted line. The illustrated radiation hits an axially facing encoder flag segment 140, 141. The radially facing encoder flag segments 129, 130 are not irradiated. The separate encoder ring 147 is rotationally constrained to the first portion 101 and axially constrained to the second portion 102.

It is noted that in Figures 29, 30, 33, 34 and 39 the optical sensor arrangement 131 is arranged inside the second portion housing 120. Accordingly, the housing 120 must be transparent to radiation, at least in certain areas. For example, the second portion of the housing 120 may be made of a translucent material or may have a window that allows the radiation to pass through. The arrangement of the optical sensor arrangement 131 inside the housing 120 provides for several advantages. For example, the sensor arrangement 131 may be better protected from environmental influences such as dust, moisture, etc.

Reference Numerals

1	drug delivery device
10	housing
11	dose button
12	dose dial grip
13	drive sleeve
14	display window
15	container
16	needle
17	inner needle cap
18	outer needle cap
19	cap
20	second mechanical coupling element
21	second contact surface
22	ribs
23	groove
24A	first abutment edge
24B	second abutment edge
25	recess
26	proximal end surface (of the dose button)
27	abutment surface
28	number sleeve
29	slot
30	spline
31	clutch
100	electronic add-on module
101	first portion
102	second portion
103	auxiliary grip
104	proximal end surface (of the second portion)
105	ribs
106	grooves
107	clips
108	first mechanical coupling element

109	first contact surfaces	
110	ribs	
111	push element	
111A	flange	
111B	leg	
111C	receiving section	
111D	leak path	
111E	rod portion	
111F	sealing portion	
112	spring	
113	push element abutment surface	
114	end stop	
115	first clutch element	
116	second clutch element	
117	sleeve portion	
117A	sleeve portion clip	
118	coupling portion	
118A	coupling portion clip	
119	inner surface120	second portion housing
120A	light element	
121	battery	
121A	battery clip	
122	circuit board assembly	
123	microswitch	
124	lever arm	
125	distally facing surface	
126	stopper element	
127	push element clips	
128	encoder ring	
129	radially facing first encoder flag segments	
130	radially facing second encoder flag segments	
131	optical sensor arrangement	
132	light-pipe	
132A	aperture portion	
132B	light-pipe portion	
133	fixation surface	
134	entry surface	

135	exit surface
136	sensor circuit board
137	leads
138	substrate
139	electronic components
140	axially facing first encoder flag segments
141	axially facing second flag segments
142	peak output
143	distance range for axially facing first encoder flag segment
144	minimum sensor output for axially facing first encoder flag segment
145	distance range for axially facing second encoder flag segment
146	minimum sensor output for axially facing second encoder flag segment
147	separate encoder ring
148	empty space
149	spigot
150	projection
151	proximal region (push element)
D	distal direction
P	proximal direction
X	first Longitudinal axis (of the first portion)
Y	second longitudinal axis (of the drug delivery device)

Claims

1. An electronic add-on module (100) for releasable attachment to a drug delivery device
5 (1) comprising:
- a first portion (101) defining an auxiliary dose dial grip and configured to be releasably attached to a dose dial grip (12) of the drug delivery device, such that the first portion follows axial and rotational movements of the dose dial grip when attached to the drug delivery device, wherein the first portion has a first longitudinal axis (X),
 - 10 • a second portion (102) coupled to the first portion allowing relative axial movement parallel to the first longitudinal axis with respect to the first portion from a dose setting position, in which the second portion is in a maximum proximal position relative to the first portion, into a dose dispensing position, and wherein the second portion defines an auxiliary dose button configured to abut a dose button (11) when attached to the
15 drug delivery device and configured to apply pressure in axial direction onto the dose button of the drug delivery device,
 - an electrical power source (121) arranged inside the electronic add-on module and electrically connected to a circuit board assembly (122),
 - the circuit board assembly being arranged inside the second portion of the electronic
20 add-on module and comprising a microswitch (123),
- characterized in that, the electronic add-on module additionally comprises a push element (111) configured to be moved and/or deformed relative to the circuit board assembly in a second direction opposite to a first direction at least substantially parallel to the first longitudinal axis in order to operate the microswitch, and wherein the push element is elastically biased in
25 the first direction at least upon movement and/or deformation of the push element in the second direction.
2. The electronic add-on module (100) according to claim 1, wherein the push element (111) is maximally biased in the first direction when the electronic add-on module is in the dose
30 setting position.
3. The electronic add-on module (100) according to claim 1 or 2, wherein the push element (111) is moved and/or deformed by the relative axial movement between first portion (101) and the second portion (102).
- 35 4. The electronic add-on module (100) according to any one of the preceding claims, wherein the electronic add-on module comprises a clutch (115, 116) arranged between the

first portion (101) and the second portion (102), wherein the clutch prevents relative rotational movement between the first portion and the second portion when engaged, and wherein the clutch is engaged when the electronic add-on module is in the dose setting position.

- 5 5. The electronic add-on module (100) according to claim 4, wherein, when the push element (111) is moved and/or deformed from the dose setting position in the second direction, the microswitch (123) is operated prior to a disengagement of the clutch (115, 116).
- 10 6. The electronic add-on module (100) according to claim 4 or 5, wherein the push element (111) is configured for abutting against the dose button (11) of the drug delivery device (1) in the dose setting position in order to engage the clutch (115, 116) between the first portion (101) and the second portion (102).
- 15 7. The electronic add-on module (100) according to any one of claims 4 to 6, wherein the push element (111) is configured to operate the clutch (115, 116) and the microswitch (123).
- 20 8. The electronic add-on module (100) according to any one of the preceding claims, wherein the push element (111) comprises a stop element (126; 127), and wherein the stop element prevents disengagement between the push element and the second portion (102), and/or wherein the second portion (102) comprises a third alignment structure configured to rotationally constrain the second portion to the dose button (11).
- 25 9. The electronic add-on module (100) according to claim 8, wherein the third alignment structure comprises a protrusion, for example provided with ribs (110), configured to be engaged with a recess (25) arranged at a proximal end surface (26) of the dose button (11) of the drug delivery device (1).
- 30 10. The electronic add-on module (100) according to any one of the preceding claims,
 - wherein the push element (111) is at least partially arranged inside the second portion (102), and wherein the push element is guided by the second portion during the relative axial movement between the first portion (101) and the second portion, and/or
 - wherein the second portion is at least partially arranged around the first portion, and/or
 - wherein the push element (111) is already biased in the first direction before a movement and/or deformation of the push element in the second direction is performed,
 - 35 and/or
 - wherein the push element (111) is configured to provide a sealing.

11. The electronic add-on module (100) according to claim 10, wherein the push element (111) is provided by an actuation rod.
12. The electronic add-on module (100) according to any one of claims 8 or 9, wherein the
5 third alignment structure is provided by the push element (111).
13. The electronic add-on module (100) according to claim 12, wherein the push element (111) provides a distally facing surface (125) of the second portion (102), and wherein, when the second portion is in the dose setting position, the distally facing surface provides the only
10 axial abutment between the dose button (11) and the second portion.
14. The electronic add-on module (100) according to any one of the preceding claims, wherein the push element (111) is provided by a flexible diaphragm, or wherein the push element (111) is an elastically biased lever arm, and wherein the lever arm is configured to be
15 pivotably moved.
15. The electronic add-on module (100) according to claim 14, wherein, in the dose setting position, the push element (111) is abutting on a projection (150) of the first portion (101), wherein the projection protrudes from an inner surface of the first portion, and wherein the
20 push element (111) is arranged off-centered with respect to the first longitudinal axis (X).