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(54) Title: MEDICAL DEVICE WITH SAFETY VERIFICATION AND SAFETY VERIFICATION METHOD THEREOF

(57) Abstract: A medical device with safety verification, comprising: a remote device (100); a functional device (110), the functional device (110) can receive certain functional instructions from the remote device (100), the functional instructions include drug infusion instructions or non-infusion instructions; and a safety verification module (111) installed in the functional device (110). After the safety verification module (111) receives a verification instruction that matches the functional instruction, the functional device (110) can execute the functional instruction; and the verification instruction includes the user's body movement. Before the medical device performs various functions, safety verification is required in order to improve the safety of the medical device.

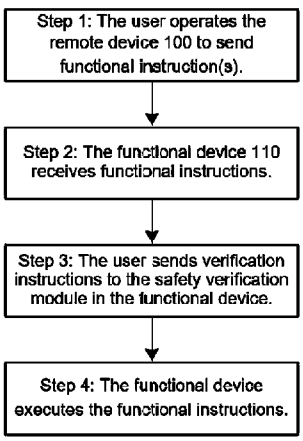


FIG.1

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MEDICAL DEVICE WITH SAFETY VERIFICATION AND SAFETY VERIFICATION METHOD THEREOF

TECHNICAL FIELD

The present invention mainly relates to the field of medical device, and in particular, to a medical device provided with safety verification and a safety verification method thereof.

BACKGROUND

Diabetes is mainly a metabolic disease caused by abnormal human pancreatic function. Diabetes is a lifelong disease. At present, medical technology cannot cure diabetes. It can only control the occurrence and development of diabetes and its complications by stabilizing blood glucose. The normal human pancreas automatically monitors changes in the body's blood glucose levels and automatically secretes the required insulin. At present, the medical device for stabilizing blood glucose works by dynamically monitoring the blood glucose changes of the human body by a glucose sensor implanted in the subcutaneous tissue of the human body; and continuously accurately infusing insulin into the subcutaneous tissue of the human body through a medical cannula implanted in the subcutaneous tissue of the human body.

With the development of the Internet and software technology, patients can now remotely control drug infusions through software. However, remote devices connected to the Internet are vulnerable to interference, attacks, tampering, etc., posing great security risks. Prior art devices require safety verification before drug infusion. The device will only perform the drug infusion function if the safety verification matches the infusion instruction. However, in addition to infusion functions, non-infusion functions are also important, but the prior art does not provide safety guarantees for these non-infusion functions.

Therefore, there is an urgent need in the prior art for a medical device that requires safety verification for both infusion and non-infusion functions.

BRIEF SUMMARY OF THE INVENTION

The embodiment of the invention discloses a medical device provided with safety verification and a safety verification method thereof. Before the medical device performs various functions, safety verification is required in order to improve the safety of the medical device.

The invention discloses a medical device with safety verification, comprising: a remote device and a functional device; the functional device can receive certain functional instruction(s) from the remote device; the functional instruction(s) include drug infusion instructions or non-infusion instructions; and a safety verification module installed in the functional device; after the safety verification module

receives a verification instruction that matches the functional instruction, the functional device can execute the functional instruction; and the verification instruction includes the user's body movement.

According to one aspect of the present invention, the safety verification module includes a linear acceleration sensor or a gyroscope sensor.

According to one aspect of the present invention, the linear acceleration sensor is a three-axis linear acceleration sensor.

According to one aspect of the present invention, the drug includes insulin, and the drug infusion instruction includes basal insulin infusion instruction or bolus insulin infusion instruction.

According to one aspect of the present invention, the non-infusion instruction(s) include one of start/stop instruction of the functional device, function switching instruction, function selection instruction, data recording/display instruction, failure detection instruction, reconnection/disconnection instruction or pairing instruction between the remote device and the functional device, or a combination of these said instructions.

According to one aspect of the present invention, the body movements include one of jumping, squatting, leg movements, arm movements, taps on the functional device, bending over, torso twist, special way of walking, or a combination of these said movements, and verification instructions that match different functional instructions are not exactly the same.

The invention also discloses a method for safety verification of a medical device, comprising: providing a remote device, a functional device and a safety verification module, the safety verification module is set in the functional device; user operates the remote device to wirelessly send certain functional instruction(s) to the functional device, functional instructions include drug infusion instructions or non-infusion instructions; the user sends a verification instruction that matches the functional instruction to the safety verification module, and the verification instruction includes the user's body movement; the safety verification module receives the verification instruction; and the functional device executes the functional instruction.

According to one aspect of the present invention, the safety verification module includes a linear acceleration sensor or a gyroscope sensor.

According to one aspect of the present invention, the linear acceleration sensor is a three-axis linear acceleration sensor.

According to one aspect of the present invention, the drug includes insulin, and the drug infusion instruction includes basal insulin infusion instruction or bolus insulin infusion instruction.

According to one aspect of the present invention, the non-infusion instruction(s) include one of start/stop instruction of the functional device, function switching instruction, function selection instruction, data recording/display instruction, failure detection instruction, reconnection/disconnection instruction or pairing instruction between the remote device and the functional device, or a combination of these said instructions.

According to one aspect of the present invention, the body movements include one of jumping,

squatting, leg movements, arm movements, taps on the functional device, bending over, torso twist, special way of walking, or a combination of these said movements, and verification instructions that match different functional instructions are not exactly the same.

Compared with the prior art, the technical solution of the present invention has the following advantages:

In the medical device provided with safety verification, the functional device can receive functional instruction(s) from a remote device. The functional instruction(s) include drug infusion instructions or non-infusion instructions, and after the safety verification module receives a verification instruction that matches the functional instruction(s), the functional device can execute the functional instruction(s). The functional device needs to pass safety verification before performing drug infusion or non-infusion functions. Adding an extra verification step can prevent the device from being hacked, attacked, tampered with or damaged, thus avoiding incorrect or undesired infusion, health data breaches, device parameter tampering, device function stop, etc. Therefore, this design will improve the safety of medical devices. Secondly, the verification instructions include user's body movement which is easy for users to perform. And moreover, the user does not need to carry other parts or devices to complete the verification step, which enhances the user experience.

Furthermore, the linear acceleration sensor is a three-axis linear acceleration sensor. The three-axis linear acceleration sensor can more easily perceive the user's body movements and enhance the device's sensitivity for motion detection.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG.1 is a schematic flowchart of a medical device executing a functional instruction according to an embodiment of the present invention;

FIG.2 is a schematic structural diagram of a medical device according to an embodiment of the present invention.

DETAILED DESCRIPTION

As mentioned previously, prior art medical devices don't have safety verification for non-infusion functional instructions.

It was found that the cause of the above problems is that the drug infusion functions are closely related to the physiological condition, and non-infusion functions are mostly supporting functions of the medical device. Such medical devices are exposed to safety risks in some aspects during use.

In order to solve this problem, the present invention provides a medical device with safety verification, and simultaneously performs safety verification on infusion functions and non-infusion functions, which eliminates the safety risk of data breach, parameter tampering and incorrect or undesired infusion caused by equipment being attacked or tampered with. Therefore, this method increases the

safety of medical devices.

Various exemplary embodiments of the present invention will now be described in detail with reference to the drawings. The relative arrangement of the components and the steps, numerical expressions and numerical values set forth in the embodiments are not to be construed as limiting the scope of the invention.

In addition, it should be understood that, for ease of description, the dimensions of the various components shown in the figures are not necessarily drawn in the actual scale relationship, for example, the thickness, width, length or distance of certain units may be exaggerated relative to other structures.

The following description of the exemplary embodiments is merely illustrative, and is not intended to be in any way limiting the invention and its application or use. The techniques, methods and devices that are known to those of ordinary skill in the art may not be discussed in detail, but such techniques, methods and devices should be considered as part of the specification.

It should be noted that similar reference numerals and letters indicate similar items in the following figures. Therefore, once an item is defined or illustrated in a drawing, it will not be discussed further in following description of the drawings.

FIG. 1 is a schematic diagram of a workflow of a medical device executing a functional instruction according to an embodiment of the present invention, and FIG. 2 is a schematic diagram of a structure of each part of the medical device according to an embodiment of the present invention.

Step 1: The user operates the remote device 100 to send functional instruction(s).

In the embodiment of the present invention, information is exchanged between the remote device 100 and the functional device 110 through wireless communication. The user can control the functional device 110 to perform various functions through the remote device 100. The functional device 110 also feeds back the execution information or acquired information to the remote device 100.

The remote device 100 includes, but is not limited to, a mobile phone, a tablet computer, a smart watch (band), and a Personal Diabetes Manager (PDM). Specifically, in the embodiment of the present invention, the remote device 100 is a mobile phone. In another embodiment of the present invention, the remote device 100 is a PDM. In still another embodiment of the present invention, the remote device 100 is a smart watch.

The functional device 110 is used to perform functions directly related to medical purposes. In the embodiment of the present invention, the functional device 110 is adhered to the skin surface of the user through the adhesive tape 120. The functional device 110 can be a drug infusion device, a physiological condition detection device, or an integrated device for both detection and infusion. Specifically, in the embodiment of the present invention, the functional device 110 is a drug infusion device, and the functional device 110 injects the drug into the user through the infusion needle 121. In another embodiment of the present invention, the functional device 110 is an integrated device that combines detection and infusion. At this time, the structure 121 is provided with functions of both infusion and detection.

The drugs in the functional device 110 include insulin, glucagon, antibiotics, nutrient solutions, analgesics, morphine, anticoagulants, gene therapy drugs, cardiovascular drugs or chemotherapy drugs, which are not specifically limited here. Specifically, in the embodiment of the present invention, the drug in the functional device 110 is insulin. In other embodiments of the present invention, the functional device 110 may store a plurality of drugs described above.

The functional device 110 is capable of performing various functions, such as the basic drug infusion function. The user may send a drug infusion instruction to the functional device 110 through the remote device 100. Specifically, in one embodiment of the present invention, the drug infusion instructions include basal insulin infusion instructions and bolus insulin infusion instructions. For example, in an open-loop system or a semi-closed-loop system, the user operates the remote device 100 to issue basal insulin infusion instructions according to the amount of basal insulin required by the body at different time periods. Depending on the situation of food intake, the user can operate the remote device 100 to send bolus insulin infusion instructions.

In addition, the remote device 100, according to the embodiment of the present invention, can also send non-infusion instructions, so that the functional device 110 can realize other functions which will be described in detail below.

In actual operation, the user sends various functional instructions to the functional device 110 through the remote device 100. For example, when the functional device 110 is installed, the remote device 100 may send an instruction to activate or start the functional device 110. At the same time, the remote device 100 needs to be paired with the functional device 110, so they can interact with each other. In an embodiment of the present invention, when the functional device 110 is being activated, the remote device 100 can also send an instruction including remote device model information, so that the remote device 100 can pair with the functional device 110.

During use, the remote device 100 may send instructions to the functional device 110 to enable the functional device 110 to switch among different functions. For example, in one embodiment of the present invention, the functional device 110, as an open-loop system or a semi-closed-loop system or a closed-loop artificial pancreas, is a medical device for both detection and infusion and is used in the field of diabetes care. Receiving functional instructions from the remote device 100, the functional device 110 can be controlled to switch among these three systems.

The functional device 110 can also receive instructions for smart selection from the remote device 100. As in an embodiment of the present invention, the user sends an instruction through the remote device 100 to instruct the functional device 110 to intelligently select detection or infusion functions, or to intelligently select drug infusion amount, etc.

The functional device 110 also has a function of feeding back information to the remote device 100 as required. For example, the functional device 110 can feed back the detected physiological condition information, drug infusion data, or device condition information. The remote device 100 can therefore display the above information to the user according to the user's needs by communicating with the functional device 110.

During the use of the medical device, malfunctions may occur, such as suspension of drug infusion,

loss of data, stop of detection, connection failure between the functional device 110 and other devices. The user may send a detection instruction for the above-mentioned faults to the functional device 110 through the remote device 100 to restore the medical device to normal operation.

In one embodiment of the present invention, the remote device 100 can be used as a supporting tool. When the medical device enters normal operation, the remote device 100 can send instructions to the functional device 110 to disconnect from the functional device 110. When necessary, the remote device 100 can send instructions to restore the connection with the functional device 110.

Step 2: The functional device 110 receives functional instructions.

At present, most of the remote devices 100 can be connected to the Internet, and the remote devices 100 and functional devices 110 are interconnected via Bluetooth. The remote device 100 and the functional device 110 are both exposed to risks of being hacked, tampered with, damaged, maliciously invaded, etc. There is also a risk that the remote device 100 is operated or misused by others, posing potential safety hazards, even life-threatening ones. For example, when the wireless communication is hacked, the drug infusion can be controlled by others, thereby endangering the user's health and life. Or when the remote device 100 is unintentionally touched by a child, the drug infusion amount may be increased or decreased, creating a safety hazard. As another example, when the communication between the remote device 100 and the functional device 110 is attacked, others can easily obtain the user's physiological condition information, resulting in data leakage. For another example, the device parameters and the communication between the devices may be easily tampered with or damaged, so that the device can no longer work normally, leading to potential safety risks and higher maintenance cost for the user. Therefore, in the embodiment of the present invention, after the functional device 110 receives the above-mentioned functional instruction, it needs to pass safety verification before the functional device 110 executes the corresponding function.

Step 3: The user sends verification instructions to the safety verification module in the functional device.

Specifically, in the embodiment of the present invention, the functional device 110 is provided with a safety verification module 111. After the safety verification module 111 receives verification instructions from the user, the functional device 110 starts to execute a corresponding function. Obviously, since there are many kinds of functional instructions, there also need to be many types of verification instructions to correspond to different functional instructions.

In the embodiment of the present invention, the safety verification module 111 includes a linear acceleration sensor or a gyroscope sensor. With a linear acceleration sensor or a gyroscope sensor as the safety verification module 111, the user only needs to perform simple body movements to complete the verification. In this way, the user does not need to carry other parts or devices, or may not even need to touch the functional device to complete the verification, which improves the convenience of the safety verification and enhances the user experience. Specifically, in the embodiment of the present invention, the linear acceleration sensor is a three-axis linear acceleration sensor. The three-axis linear acceleration sensor can detect acceleration changes in the three directions of X, Y, and Z axes. It has the advantage of enhanced sensitivity for motion detection and is

capable of rapid detection of body movements. In another embodiment of the present invention, the safety verification module 111 is a gyroscope sensor. The gyroscope sensor can accurately detect the user's rotational body movements such as, torso twist, special way of walking and circling. In another embodiment of the present invention, the safety verification module 111 adopts a combination of a linear acceleration sensor and a gyroscope sensor, allowing the functional device 110 to detect the user's body movements more quickly and accurately.

In the embodiment of the present invention, the user's body movements include, but are not limited to, jumping, squatting, leg movements, arm movements, tap on the functional device 110, bending over, torso twist and special way of walking. It needs to be explained here that tapping on the functional device 110 includes not only direct contact with the functional device 110 but also indirect contact and non-contact. For example, the user can tap the clothing around the functional device 110. Leg movements include, but are not limited to, raising the leg and shaking the leg. Arm movements include, but are not limited to, vibrating arms and swinging arms. Special walking methods include, but are not limited to, forward and backward walking, circle walking and zigzag.

In the embodiment of the present invention, the verification instructions include single movement or a combination of multiple movements among the above-mentioned body movements, and no limit is set on the frequency of a certain body movement. Preferably, in the embodiment of the present invention, a certain verification instruction is to tap the functional device 110 three times. Tapping three times is chosen instead of one, two, or more than three times, which avoids the interference caused by accidental movements, and is more convenient and more user-friendly than tapping more than three times. In another embodiment of the present invention, the verification instruction for the basal insulin infusion is that the user bends down first, and then twists the torso twice. In still another embodiment of the present invention, the verification instruction for activating the functional device 110 is zigzagging.

As mentioned before, there are many kinds of functional instructions, so there should be also many kinds of verification instructions that match the functional instructions, and the body movements of some different verification instructions can be different or the same, but all different body movements are not exactly the same. Preferably, in the embodiment of the present invention, the verification instructions for starting and stopping the functional device 110 are the same, or the verification instructions for disconnecting and reconnecting are the same. Using the same movement for certain verification instructions can reduce the types of movements, which will reduce the manufacturing cost and improve user experience.

It should be noted that, in other embodiments of the present invention, more verification instructions may be allowed to use the same body movement, which is not specifically limited herein.

Step 4: The functional device executes the functional instructions.

After the safety verification module 111 receives the corresponding verification instruction, the functional device 110 starts executing the functional instruction. Obviously, in the embodiment of the present invention, if the verification instruction and the functional instruction do not match, the functional device 110 will not execute the instruction which improves the safety of the device.

In one safety verification method of a medical device, only the drug infusion instructions need verification, while other functions do not need to be verified, therefore the safety level of the medical device is relatively low. Moreover, it is necessary to use extra parts to perform verification via contact or electromagnetic induction, which requires complicated actions and generates poor user experience.

The safety verification method of the medical device according to the embodiment of the present invention can not only verify the drug infusion function but also other non-infusion functions with simpler method, higher safety level and better user's experience.

In summary, the present invention discloses a method for safety verification of a medical device. After a remote device issues a functional instruction for drug infusion or non-infusion functions, it is necessary to pass safety verifications before the functional device performs the corresponding functions, thereby improving medical device safety and enhancing user's experience.

Please continue to refer to FIG.1 and FIG.2. Correspondingly, the present invention also provides a medical device for setting security verification, which includes a remote device 100 and a functional device 110. The functional device 110 is provided with a security verification module 111.

In the embodiment of the present invention, information is exchanged between the remote device 100 and the functional device 110 through wireless communication. The user can control the functional device 110 to perform various functions through the remote device 100. The functional device 110 also feeds back the execution information or acquired information to the remote device 100.

The remote device 100 includes, but is not limited to, a mobile phone, a tablet computer, a smart watch (band), and a Personal Diabetes Manager (PDM). Specifically, in the embodiment of the present invention, the remote device 100 is a mobile phone. In another embodiment of the present invention, the remote device 100 is a PDM. In still another embodiment of the present invention, the remote device 100 is a smart watch.

The functional device 110 is used to perform functions directly related to medical purposes. In the embodiment of the present invention, the functional device 110 is adhered to the skin surface of the user through the adhesive tape 120. The functional device 110 can be a drug infusion device, a physiological condition detection device, or an integrated device for both detection and infusion. Specifically, in the embodiment of the present invention, the functional device 110 is a drug infusion device, and the functional device 110 injects the drug into the user through the infusion needle 121. In another embodiment of the present invention, the functional device 110 is an integrated device that combines detection and infusion. At this time, the structure 121 is provided with functions of both infusion and detection.

The drugs in the functional device 110 include insulin, glucagon, antibiotics, nutrient solutions, analgesics, morphine, anticoagulants, gene therapy drugs, cardiovascular drugs or chemotherapy drugs, which are not specifically limited here. Specifically, in the embodiment of the present invention, the drug in the functional device 110 is insulin. In other embodiments of the present invention, the functional device 110 may store a plurality of drugs described above.

The functional device 110 is capable of performing various functions, such as the basic drug infusion function. The user may send a drug infusion instruction to the functional device 110 through the remote device 100. Specifically, in one embodiment of the present invention, the drug infusion instructions include basal insulin infusion instructions and bolus insulin infusion instructions. For example, in an open-loop system or a semi-closed-loop system, the user operates the remote device 100 to issue basal insulin infusion instructions according to the amount of basal insulin required by the body at different time periods. Depending on the situation of food intake, the user can operate the remote device 100 to send bolus insulin infusion instructions.

In addition, the remote device 100, according to the embodiment of the present invention, can also send non-infusion instructions, so that the functional device 110 can realize other functions which will be described in detail below.

In actual operation, the user sends various functional instructions to the functional device 110 through the remote device 100. For example, when the functional device 110 is installed, the remote device 100 may send an instruction to activate or start the functional device 110. At the same time, the remote device 100 needs to be paired with the functional device 110, so they can interact with each other. In an embodiment of the present invention, when the functional device 110 is being activated, the remote device 100 can also send an instruction including remote device model information, so that the remote device 100 can pair with the functional device 110.

During use, the remote device 100 may send instructions to the functional device 110 to enable the functional device 110 to switch among different functions. For example, in one embodiment of the present invention, the functional device 110, as an open-loop system or a semi-closed-loop system or a closed-loop artificial pancreas, is a medical device for both detection and infusion and is used in the field of diabetes care. Receiving functional instructions from the remote device 100, the functional device 110 can be controlled to switch among these three systems.

The functional device 110 can also receive instructions for smart selection from the remote device 100. As in an embodiment of the present invention, the user sends an instruction through the remote device 100 to instruct the functional device 110 to intelligently select detection or infusion functions, or to intelligently select drug infusion amount, etc.

The functional device 110 also has a function of feeding back information to the remote device 100 as required. For example, the functional device 110 can feed back the detected physiological condition information, drug infusion data, or device condition information. The remote device 100 can therefore display the above information to the user according to the user's needs by communicating with the functional device 110.

During the use of the medical device, malfunctions may occur, such as suspension of drug infusion, loss of data, stop of detection, connection failure between the functional device 110 and other devices. The user may send a detection instruction for the above-mentioned faults to the functional device 110 through the remote device 100 to restore the medical device to normal operation.

In one embodiment of the present invention, the remote device 100 can be used as a supporting tool. When the medical device enters normal operation, the remote device 100 can send instructions to the

functional device 110 to disconnect from the functional device 110. When necessary, the remote device 100 can send instructions to restore the connection with the functional device 110.

At present, most of the remote devices 100 can be connected to the Internet, and the remote devices 100 and functional devices 110 are interconnected via Bluetooth. The remote device 100 and the functional device 110 are both exposed to risks of being hacked, tampered with, damaged, maliciously invaded, etc. There is also a risk that the remote device 100 is operated or misused by others, posing potential safety hazards, even life-threatening ones. For example, when the wireless communication is hacked, the drug infusion can be controlled by others, thereby endangering the user's health and life. Or when the remote device 100 is unintentionally touched by a child, the drug infusion amount may be increased or decreased, creating a safety hazard. As another example, when the communication between the remote device 100 and the functional device 110 is attacked, others can easily obtain the user's physiological condition information, resulting in data leakage. For another example, the device parameters and the communication between the devices may be easily tampered with or damaged, so that the device can no longer work normally, leading to potential safety risks and higher maintenance cost for the user. Therefore, in the embodiment of the present invention, after the functional device 110 receives the above-mentioned functional instruction, it needs to pass safety verification before the functional device 110 executes the corresponding function.

Specifically, in the embodiment of the present invention, the functional device 110 is provided with a safety verification module 111. After the safety verification module 111 receives verification instructions from the user, the functional device 110 starts to execute a corresponding function. Obviously, since there are many kinds of functional instructions, there also need to be many types of verification instructions to correspond to different functional instructions.

In the embodiment of the present invention, the safety verification module 111 includes a linear acceleration sensor or a gyroscope sensor. With a linear acceleration sensor or a gyroscope sensor as the safety verification module 111, the user only needs to perform simple body movements to complete the verification. In this way, the user does not need to carry other parts or devices, or may not even need to touch the functional device to complete the verification, which improves the convenience of the safety verification and enhances the user experience. Specifically, in the embodiment of the present invention, the linear acceleration sensor is a three-axis linear acceleration sensor. The three-axis linear acceleration sensor can detect acceleration changes in the three directions of X, Y, and Z axes. It has the advantage of enhanced sensitivity for motion detection and is capable of rapid detection of body movements. In another embodiment of the present invention, the safety verification module 111 is a gyroscope sensor. The gyroscope sensor can accurately detect the user's rotational body movements such as, torso twist, special way of walking and circling. In another embodiment of the present invention, the safety verification module 111 adopts a combination of a linear acceleration sensor and a gyroscope sensor, allowing the functional device 110 to detect the user's body movements more quickly and accurately.

In the embodiment of the present invention, the user's body movements include, but are not limited to, jumping, squatting, leg movements, arm movements, tap on the functional device 110, bending over, torso twist and special way of walking. It needs to be explained here that tapping on the functional

device 110 includes not only direct contact with the functional device 110 but also indirect contact and non-contact. For example, the user can tap the clothing around the functional device 110. Leg movements include, but are not limited to, raising the leg and shaking the leg. Arm movements include, but are not limited to, vibrating arms and swinging arms. Special walking methods include, but are not limited to, forward and backward walking, circle walking and zigzag.

In the embodiment of the present invention, the verification instructions include single movement or a combination of multiple movements among the above-mentioned body movements, and no limit is set on the frequency of a certain body movement. Preferably, in the embodiment of the present invention, a certain verification instruction is to tap the functional device 110 three times. Tapping three times is chosen instead of one, two, or more than three times, which avoids the interference caused by accidental movements, and is more convenient and more user-friendly than tapping more than three times. In another embodiment of the present invention, the verification instruction for the basal insulin infusion is that the user bends down first, and then twists the torso twice. In still another embodiment of the present invention, the verification instruction for activating the functional device 110 is zigzagging.

As mentioned before, there are many kinds of functional instructions, so there should be also many kinds of verification instructions that match the functional instructions, and the body movements of some different verification instructions can be different or the same, but all different body movements are not exactly the same. Preferably, in the embodiment of the present invention, the verification instructions for starting and stopping the functional device 110 are the same, or the verification instructions for disconnecting and reconnecting are the same. Using the same movement for certain verification instructions can reduce the types of movements, which will reduce the manufacturing cost and improve user experience.

It should be noted that, in other embodiments of the present invention, more verification instructions may be allowed to use the same body movement, which is not specifically limited herein.

After the safety verification module 111 receives the corresponding verification instruction, the functional device 110 starts executing the functional instruction. Obviously, in the embodiment of the present invention, if the verification instruction and the functional instruction do not match, the functional device 110 will not execute the instruction which improves the safety of the device.

In a kind of medical device with safety verification, only the drug infusion instructions need verification, while other functions do not need to be verified, therefore the safety level of the medical device is relatively low. Moreover, it is necessary to use extra parts to perform verification via contact or electromagnetic induction, which requires complicated actions and generates poor user experience. The medical device with safety verification according to the embodiment of the present invention can not only verify the drug infusion function but also other non-infusion functions with simpler method, higher safety level and better user's experience.

In summary, the present invention discloses a medical device with safety verification. After a remote device issues a functional instruction for drug infusion or non-infusion functions, it is necessary to pass safety verifications before the functional device performs the corresponding functions, thereby

improving medical device safety and enhancing user's experience.

While the invention has been described in detail with reference to the specific embodiments of the present invention, it should be understood that it will be appreciated by those skilled in the art that the above embodiments may be modified without departing from the scope and spirit of the invention. The scope of the invention is defined by the appended claims.

CLAIMS

1. A medical device with safety verification, comprising:

   a remote device;

   a functional device, the functional device can receive certain functional instruction(s) from the remote device, the functional instruction(s) include drug infusion instructions or non-infusion instructions; and

   a safety verification module installed in the functional device, after the safety verification module receives a verification instruction that matches the functional instruction, the functional device can execute the functional instruction; the verification instruction includes the user's body movement.

2. A medical device with safety verification of claim 1, wherein:

   the safety verification module includes a linear acceleration sensor or a gyroscope sensor.

3. A medical device with safety verification of claim 2, wherein:

   the linear acceleration sensor is a three-axis linear acceleration sensor.

4. A medical device with safety verification of claim 1, wherein:

   the drug includes insulin, and the drug infusion instruction includes basal insulin infusion instruction or bolus insulin infusion instruction.

5. A medical device with safety verification of claim 4, wherein:

   the non-infusion instruction(s) include one of start/stop instruction of the functional device, function switching instruction, function selection instruction, data recording/display instruction, failure detection instruction, reconnection/disconnection instruction or pairing instruction between the remote device and the functional device, or a combination of these said instructions.

6. A medical device with safety verification of claim 5, wherein:

   the body movements include one of jumping, squatting, leg movements, arm movements, taps on the functional device, bending over, torso twist, special way of walking, or a combination of these said movements, and verification instructions that match different functional instructions are not exactly the same.

7. A method for safety verification of a medical device, comprising:

   providing a remote device, a functional device and a safety verification module, the safety verification module is set in the functional device;

   user operates the remote device to wirelessly send certain functional instruction(s) to the functional device, functional instructions include drug infusion instructions or non-infusion instructions;

the user sends a verification instruction that matches the functional instruction to the safety verification module, and the verification instruction includes the user's body movement;

the safety verification module receives the verification instruction; and

the functional device executes the functional instruction.

8. A method for safety verification of a medical device of claim 7, wherein:

the safety verification module includes a linear acceleration sensor or a gyroscope sensor.

9. A method for safety verification of a medical device of claim 8, wherein:

the linear acceleration sensor is a three-axis linear acceleration sensor.

10. A method for safety verification of a medical device of claim 7, wherein:

the drug includes insulin, and the drug infusion instruction includes basal insulin infusion instruction or bolus insulin infusion instruction.

11. A method for safety verification of a medical device of claim 10, wherein:

the non-infusion instruction(s) include one of start/stop instruction of the functional device, function switching instruction, function selection instruction, data recording/display instruction, failure detection instruction, reconnection/disconnection instruction or pairing instruction between the remote device and the functional device, or a combination of these said instructions.

12. A method for safety verification of a medical device of claim 11, wherein:

the body movements include one of jumping, squatting, leg movements, arm movements, taps on the functional device, bending over, torso twist, special way of walking, or a combination of these said movements, and verification instructions that match different functional instructions are not exactly the same.

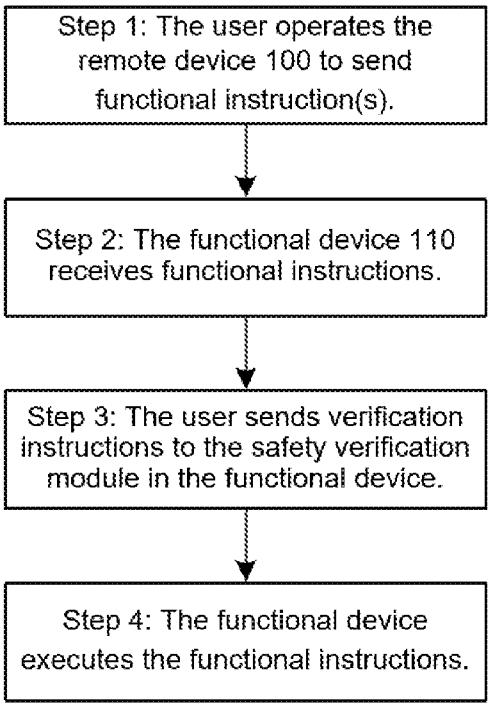

Step 1: The user operates the remote device 100 to send functional instruction(s).
Step 2: The functional device 110 receives functional instructions.
Step 3: The user sends verification instructions to the safety verification module in the functional device.
Step 4: The functional device executes the functional instructions.

FIG.1

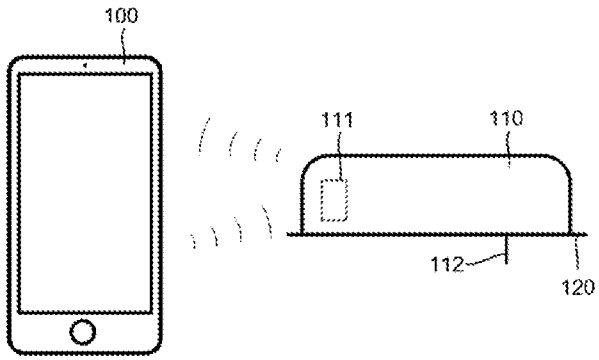

100
111
110
112
120

FIG.2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2020/073460

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/14(2006.01)i; H04L 9/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M5; H04L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

USTXT;VEN;CNABS;CNTXT:MEDTRUM,safety, security, verificat+, authenticat+, instruction?, command?, gyroscope, acceleration, accelerometer, movement?, motion?, walk+, jump+, squat+, twisting

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2018058287 A1 (MEDTRUM TECH INC) 05 April 2018 (2018-04-05) description, page 4, line 33 to page 8, line 24, and figures 1-8	1-5, 7-11
X	US 2017173261 A1 (ALLIS DANIEL et al.) 22 June 2017 (2017-06-22) description, paragraphs [0021]-[0053] and figures 1A-4	1-5, 7-11
A	WO 2015047693 A1 (ANIMAS CORP) 02 April 2015 (2015-04-02) the whole document	1-12
A	US 2019099551 A1 (TRIPLE JUMP ISRAEL LTD) 04 April 2019 (2019-04-04) the whole document	1-12
A	US 10341866 B1 (BIGFOOT BIOMEDICAL INC) 02 July 2019 (2019-07-02) the whole document	1-12
A	CN 108601890 A (BIGFOOT BIOMEDICAL INC) 28 September 2018 (2018-09-28) the whole document	1-12
A	WO 2014009876 A2 (DEBIOTECH SA) 16 January 2014 (2014-01-16) the whole document	1-12

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 April 2020	**02 June 2020**
Name and mailing address of the ISA/CN **National Intellectual Property Administration, PRC** **6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088** **China** Facsimile No. **(86-10)62019451**	Authorized officer **CUI,Wenhao** Telephone No. **(86-10)62085472**

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2020/073460

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				TW	201524543	A	01 July 2015
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				CN	105684319	A	15 June 2016
				BR	112016006893	A2	01 August 2017
				AU	2018226471	A1	27 September 2018
				CA	2926606	A1	02 April 2015
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