



US 20080033255A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2008/0033255 A1**  
**Essenpreis et al.** (43) **Pub. Date: Feb. 7, 2008**

(54) **AMBULATORY MEDICAL DEVICE AND METHOD FOR COMMUNICATION BETWEEN MEDICAL DEVICES**

**Related U.S. Application Data**

(63) Continuation of application No. PCT/EP06/00663, filed on Jan. 26, 2006.

(76) Inventors: **Matthias Essenpreis**, Burgdorf (CH);  
**Ulrich Haueter**, Grosshoechstetten (CH);  
**Nicole Bernini**, Ersigen (CH);  
**Sybille Fankhauser**, Zollikofen (CH);  
**Sebastian La Bastide**, Muri bie Bern (CH);  
**Gunnar Meyer Olden**, Burgdorf (CH);  
**Michael Schoemaker**, Mannheim (DE);  
**Kelly Heaton**, Ersigen (CH);  
**Joel Jackelmann**, Villars-sur-Glane (CH)

(30) **Foreign Application Priority Data**

Feb. 2, 2005 (EP) ..... EP 05 002 074.2

**Publication Classification**

(51) **Int. Cl.**  
**A61B 5/00** (2006.01)  
(52) **U.S. Cl.** ..... **600/300; 604/66**

(57) **ABSTRACT**

An ambulatory medical device and a method of communication between medical devices are disclosed. In one embodiment, the medical device includes a module for communication with at least a second medical device wherein the module for communication is adapted to be activated by a value of a physiological parameter of an animal. In one embodiment, the method of the present invention involves a first medical device and at least a second medical device wherein the communication between said medical devices is activated by a value of a physiological parameter of an animal.

Correspondence Address:  
**DORSEY & WHITNEY LLP**  
**INTELLECTUAL PROPERTY DEPARTMENT**  
**SUITE 1500**  
**50 SOUTH SIXTH STREET**  
**MINNEAPOLIS, MN 55402-1498 (US)**

(21) Appl. No.: **11/832,421**  
(22) Filed: **Aug. 1, 2007**

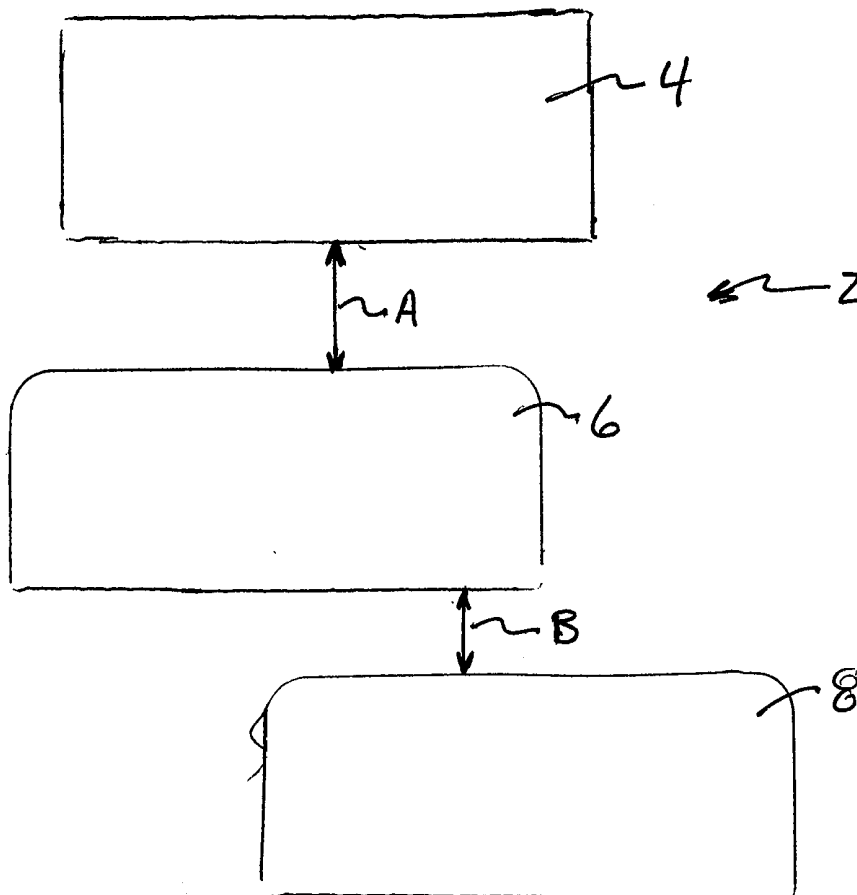


FIGURE 1

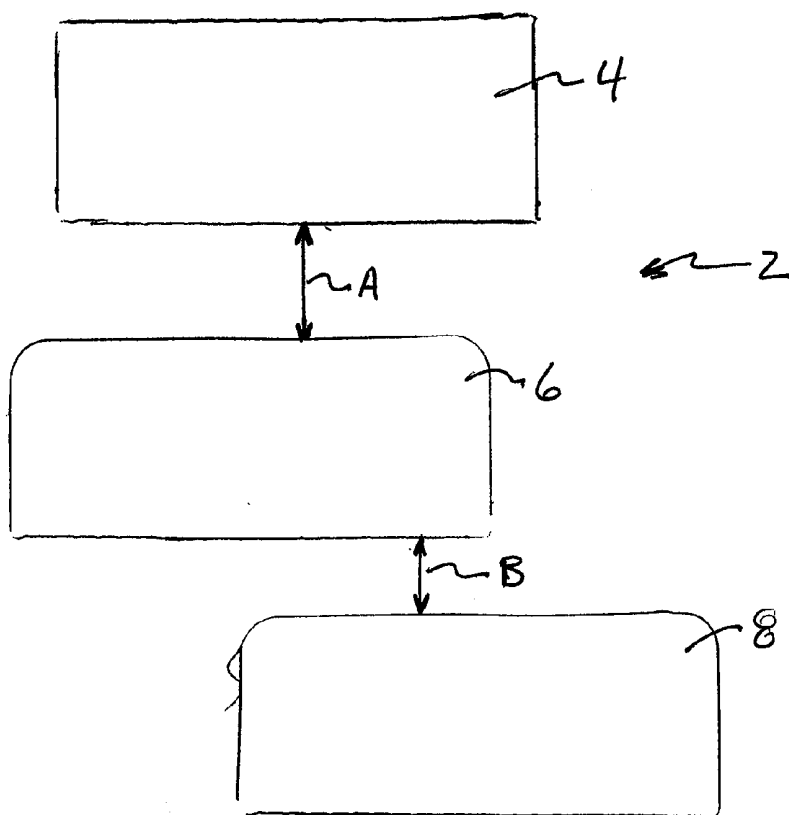


FIGURE 2

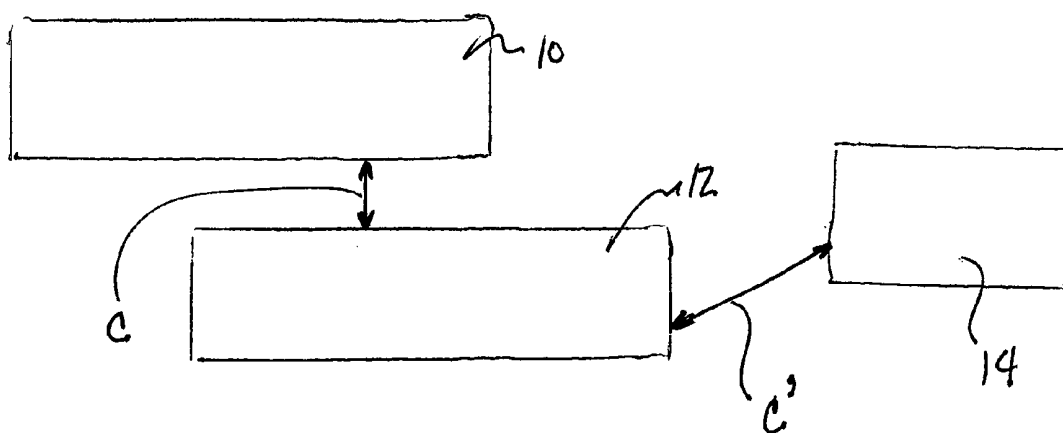


FIGURE 3

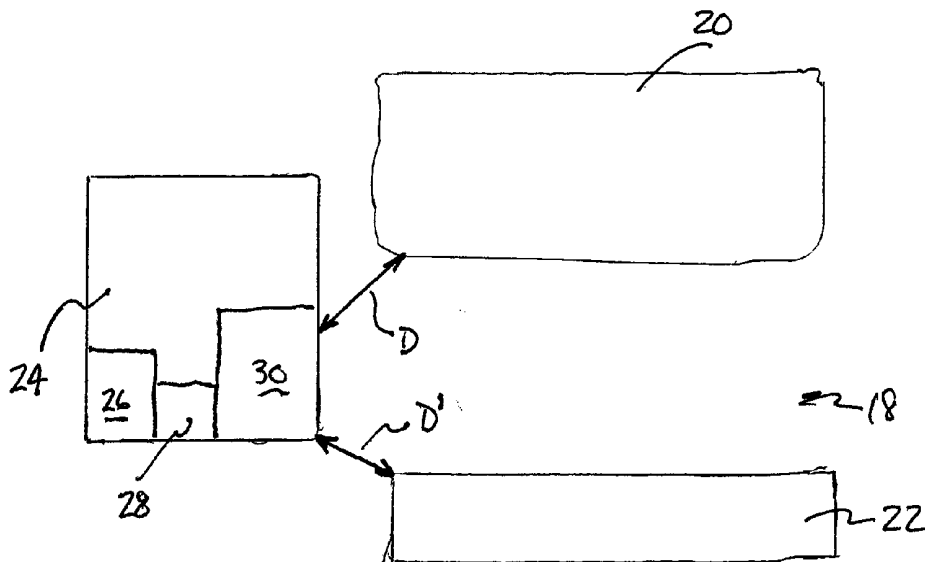
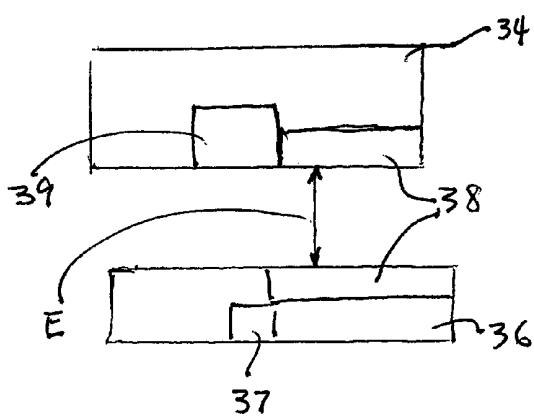
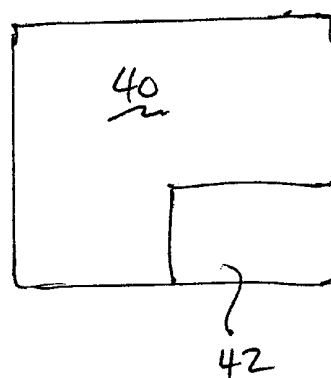


FIGURE 4



FIGURES 5



**AMBULATORY MEDICAL DEVICE AND METHOD  
FOR COMMUNICATION BETWEEN MEDICAL  
DEVICES**

CROSS-REFERENCE TO RELATED  
APPLICATION(S)

[0001] This application is a continuation of International Application No. PCT/EP2006/000663, filed on Jan. 26, 2006, which claims priority to European Patent Application No. 05 002 074.2, filed on Feb. 2, 2005, the contents of both of which are incorporated in their entirety herein by reference.

BACKGROUND

[0002] The present invention relates devices for injecting, infusing, delivering, dispensing or administering substances, and to methods of making and using such devices. More particularly, it relates to an ambulatory medical device and a method of communication for or communicating between or among medical devices.

[0003] Ambulatory medical devices include devices for the treatment of diabetes, e.g. extra corporal insulin pumps and blood glucose measuring devices such as hand held glucose meters. Insulin pumps allow a good control of blood glucose concentrations by continuously infusing a basic amount of insulin in a human body (basal insulin rate) and by allowing manually controlled delivery of additional "meal bolus" insulin quantities thereby reflecting the insulin secretion by the pancreas. Furthermore, the development of continuous glucose sensors will allow measuring in vivo glucose concentrations over the whole day. The measured glucose data can be used to adjust the diabetes therapy to individual needs.

[0004] To improve the treatment of medical conditions, including diabetes, it would be helpful to provide a way to transfer data and/or communicate information between and/or among medical devices in a way that assures optimal quality and accuracy of the function of the devices, the information being communicated, and the exchange of the information.

SUMMARY

[0005] It is an object of the present invention to provide a medical system and method providing a controlled data transfer between medical devices.

[0006] In one embodiment, the present invention comprises a medical device comprising a module for communication with at least a second medical device wherein the module for communication in the medical device is adapted to be activated by a value of a physiological parameter of an animal.

[0007] In one embodiment, the medical device and/or devices comprise a telemetry system or feature for wireless communication, e.g. in one preferred embodiment, a telemetry system for RF communication.

[0008] In some preferred embodiments, the medical device is selected from the group consisting of a remote control, a PDA, an analyte measuring device, e.g., a glucose measuring device such as a hand held glucose meter, a strip based or strip type glucose meter, or combinations thereof.

[0009] In some embodiments, the physiological parameter may be selected from the group consisting of an analyte concentration, a physiological characteristic like conductivity of an animal, a physiological vital sign such as heart or breath rate, temperature, movement, air- or structure-borne sound, ECG (electrocardiogram), etc. In one preferred embodiment of the present invention, the analyte concentration is a blood glucose concentration.

[0010] In some preferred embodiments, the medical device of the present invention comprises an electrochemical or photometric module for measuring blood glucose. Suitable medical devices are include strip based glucose meters such as the meter known as the AccuChek Compact.

[0011] In one embodiment, the present invention relates to and/or comprises a system of medical devices. The system comprises a first medical device of the present invention as described above and at least a second medical device capable of communicating with the first medical device.

[0012] In one preferred embodiment, the second medical device may be selected from the group consisting of an extra corporal infusion pump, an implantable infusion pump, a pacesetter, an analyte or vital sign sensor, a continuous analyte or vital sign sensor, and a continuous glucose sensor.

[0013] In another preferred embodiment, the first medical device and the at least second medical device comprise a telemetry system for wireless communication, in some preferred embodiments, a telemetry system for RF communication.

[0014] In another aspect, the present invention relates to or comprises a method of communication between a first medical device and at least a second medical device wherein the communication between said medical devices is enabled and/or activated by a value of a physiological parameter of an animal. In a preferred embodiment, the communication between the at least two medical devices is enabled and/or activated for a predetermined time. The time duration can be fixed, random, dependent on the physiological parameter enabling and/or activating the communication, or dependent on other physiological parameters of the animal body.

[0015] In some preferred embodiments, the physiological parameter may be selected from the group consisting of an analyte concentration, a physiological characteristic like conductivity of an animal, a physiological vital sign like heart or breath rate, temperature, movement, air- or structure-borne sound, ECG (electrocardiogram), etc. In some preferred embodiments, the analyte concentration is a blood glucose concentration.

[0016] In one preferred embodiment, the activation of communication between the medical devices is performed on the first medical device by a value of the physiological parameter.

[0017] In some preferred embodiments, the first medical device may be selected from the group consisting of a remote control, a PDA, an analyte measuring device, a glucose measuring device, and a strip based glucose meter. The second medical device may be selected from the group consisting of an extra corporal infusion pump, an implantable infusion pump, a pacesetter, an analyte sensor, a continuous analyte sensor, and a continuous glucose sensor.

[0018] In one preferred embodiment, the communication between the medical devices is a wireless communication, e.g., a RF communication. In other preferred embodiments, other suitable forms or methods of communicating information, sensed parameters, data, commands, etc. may be used.

[0019] In one preferred embodiment, the first medical device receives data or information from the second medical device, and in another preferred embodiment, the first medical device sends commands to the second medical device controlling at least partially the function or operation of the second medical device.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 depicts one exemplary embodiment of the present invention, including arrows depicting the communication and/or flow of information to and from components.

[0021] FIG. 2 depicts another exemplary embodiment of the present invention, including arrows depicting the flow of information to and from components.

[0022] FIG. 3 depicts another exemplary embodiment in accordance with the present invention, including arrows depicting the communication among components.

[0023] FIG. 4 depicts another exemplary embodiment of the present invention, including arrows depicting the flow of information to and from components.

[0024] FIG. 5 depicts an exemplary embodiment of a component in accordance with the present invention.

#### DETAILED DESCRIPTION

[0025] With regard to fastening, mounting, attaching or connecting components of the present invention, unless specifically described as otherwise, conventional mechanical fasteners and methods may be used. Other appropriate fastening or attachment methods include adhesives, welding and soldering, the latter particularly with regard to the electronics associated with the invention, if any. Suitable electrical components and circuitry, wires, wireless components, chips, boards, microprocessors, receivers, transmitters, inputs, outputs, displays, control components, etc. may be used. Generally, unless otherwise indicated, the materials used in the invention and/or its components may be selected from appropriate materials such as metal, metallic alloys, ceramics, plastics, etc.

[0026] In one aspect, the present invention relates to a method for controlling and/or enabling communication between medical devices, such as medical sensory devices such as continuous glucose sensors and/or therapeutic devices such as insulin pumps and/or diagnostic medical devices such as glucose meters.

[0027] For example, referring to FIG. 1, in one exemplary system 2 in accordance with the present invention, the communication between a continuous glucose sensor 4 applied to a human body and a blood glucose meter 6 can only be established when a blood glucose measurement has been made in the blood glucose meter 6. The generation of the blood glucose value in the blood glucose meter 6 enables and/or activates communication, represented at arrow A, between the two devices for a specified time limit. During the time window data can be transferred from the sensor 4 to the glucose meter 6 and/or commands from the glucose

meter 6 can be sent to the sensor 4. After expiration of a time limit, communication between the two devices is deactivated. To establish a further or subsequent communication, the communication link between the two devices has to be activated by generating a further blood glucose value in the glucose meter 6.

[0028] The term "generation of a value" as it is used herein encompasses any method or procedure for the determination of physiological parameters such as methods for the measurement of analyte values, e.g., blood glucose values. Suitable methods for the determination of blood glucose values include electrochemical methods, photometric methods and others which are known to a person skilled in the art.

[0029] The dependence of the communication link between medical devices on an actual analyte value ensures the quality of the data transmitted from the medical sensory device and/or medical therapeutic device to the medical diagnostic device.

[0030] The data transferred from the sensor 4 to the diagnostic device, e.g., the meter 6, can be stored on the diagnostic device and be transferred, as represented by arrow B to a third device 8 such as a PDA or a computer, for further processing and/or analysis. The data can be analyzed and/or processed by suitable software and used, for example, for bolus recommendation or adjustment of basal insulin rates for patients using an extra- or intra corporal insulin pump. The communication link between the diagnostic device 6 and a third device 8 does not necessarily need activation by generation of a blood glucose value in the diagnostic device 6.

[0031] Referring to FIG. 2, in one preferred embodiment, the present invention relates to a method of communication between a diagnostic medical device 10, e.g., a blood glucose meter, and an infusion pump 12, e.g., an extra corporal insulin pump. In this embodiment, the diagnostic medical device 10 is used as or functions as a remote control to control the function of the infusion pump 12. After a blood glucose value has been generated in the blood glucose meter 10 a communication link, represented by arrow C, between meter 10 and pump 12 is enabled and/or activated for a defined time and commands can be transferred from the remote control, i.e. the glucose meter, to the pump 12. It is also possible to transfer data stored on the pump 12 to the diagnostic device 10 during the communication time window.

[0032] With further reference to FIG. 2, in some embodiments comprising a remote controller 14 for the infusion pump 12, the remote controller 14 may not comprise a feature or device for measuring blood glucose concentration. In such embodiments, the communication, represented by arrow C', between pump 12 and remote control 14 is activated by entering a current blood glucose value measured in a blood glucose meter in the remote control 14. The value may be entered using inputs of the remote control 14 or can be transferred via a wireless or wired connection to the glucose meter 10. After the blood glucose value has been entered in the remote control 14, a communication link between remote control 14 and infusion pump 12 is established, preferably for a predetermined time span. After expiration of the time span, the communication is interrupted and no data exchange between the two devices is anymore possible. A further round of communication needs

a new activation of the communication by entering a new, current blood glucose value in the remote control 14. The term remote control or controller as used herein encompasses PDA's, smart phones, pump specific remote controllers, etc.

[0033] The data transfer between the medical devices can be performed using known and/or available technologies, and may comprise wired and/or wireless components, connections and/or communications. These technologies are known to a person skilled in the art. In one preferred embodiment, communication may be provided RF communication. In some embodiments, the data transfer between the devices can be encrypted to ensure that non-authorized third parties do not gain access to personal data of patients. Any suitable method of encrypting data, including those known to a person skilled in the art, may be used. In some preferred embodiments, the communication between the medical devices may be activated by a manipulation of or on the second medical device, e.g. insulin pump 12, such as pressing a button or lever, inserting a battery, using the touch screen, shaking, bumping or squeezing or the like.

[0034] Referring to FIG. 3, in one preferred embodiment, the present invention comprises a system 18 of medical devices comprising a continuous glucose sensor device 20 which is placed on a human body to measure glucose value in interstitial fluid and a glucose meter 22. The sensor device 20 comprises an electrochemical glucose sensor measuring the glucose concentration in the interstitial tissue in a predetermined manner. The sensor device 20 further comprises an extra-corporal part 24 including a suitable processor or computer 26 for controlling the sensor 20, a suitable memory 28 for storing measured glucose values and a telemetry system or module 30 for transmitting the data to the glucose meter 22, e.g., a strip-based glucose meter. The glucose values stored on the sensor device 20 may then be transferred to a glucose meter 22 via the telemetry system 30 (as represented by arrows D and D').

[0035] The communication between the devices, i.e. the wireless link, is established and/or activated by measuring the glucose concentration in a blood sample of a patient using the glucose meter 22. When a strip-based glucose meter is used, the patient inserts a strip in the glucose meter and puts a droplet of blood on the strip. The glucose meter 22 measures and indicates the blood glucose value, e.g., on an associated display. After measurement of the blood glucose value, the communication link can then be activated/established either by, for example, pressing an input on the glucose meter 22, e.g. an activation button, or by a direct electronic link to the processor 26 controlling the glucose telemetry system 30 such that the completion of the blood glucose measurement automatically activates the wireless link between the devices.

[0036] The communication link is then established and a data transfer between the medical devices is possible and/or occurs for a defined time span. After expiration of the defined time span the communication link is deactivated and no further data/commands can be transmitted between the medical devices. A new blood glucose measurement in the glucose meter 22 is then necessary to open a new wireless link between the medical devices.

[0037] In a further aspect, the present invention relates to a method of data processing or data use, wherein the data

processing or data use is only possible and/or only occurs after activation by a value of a physiological parameter. The method is may be used for the processing of medical data such as data measured by a sensor applied on a human body.

[0038] Referring to FIG. 4, in one preferred embodiment, the method in accordance with the present invention may be used for the processing of medical data sensed or measured by a sensor device 34 applied on a human being, e.g., a continuous glucose sensor. The data is then transferred, as shown by arrow E, to a diagnostic medical device 36, e.g., a blood glucose meter. The data may be transferred via a wireless link from the sensor device 34 to the diagnostic device 36. In this case, each of the at least two medical devices comprises a telemetry system 38 for wireless communication. The wireless communication can be bidirectional or unidirectional.

[0039] In some preferred embodiments, there is a permanent communication link between said two medical devices, but the data stored in a memory 39 of the medical sensor device 34 and transferred to the diagnostic device 36 can only be further processed on the diagnostic device 36 after the processing has been activated by a value of a physiological parameter. After activation by a value of a physiological parameter, preferably a blood glucose value, the data stored in the memory 39 of the diagnostic device 36 can be processed or used. For example, data are transferred from a continuous glucose sensor 34 to a glucose meter 36 and stored in the memory of the glucose meter. The further processing of these data is then only possible after activation of the processing by a value of a physiological parameter, e.g., a blood glucose value. In one preferred embodiment, the processing of the data is only possible for a limited time span after activation by a value of a physiological parameter. When the defined time span for data processing has lapsed, no further data processing is possible without a new activation by a value of a physiological parameter.

[0040] Referring to FIG. 5, in a further aspect the present invention may comprise a medical device 40 comprising a module, feature or component 42 for data processing which is adapted to be activated by a value of a physiological parameter. The module 42 comprises a suitable microprocessor or computer with a memory for storing data. In some preferred embodiments, the medical device 40 is a blood glucose meter. The processing of data stored in the memory of the blood glucose meter 40 may be activated either by pressing an input associated with the glucose meter 40 (e.g., an activation button or switch) or by a direct electronic link to the hardware, firmware and/or software of the data processing module 42 such that the completion of the blood glucose measurement automatically activates data processing. The terms "data processing" or "data use" as they are used herein refer to any manipulation of data and comprise analysis of data, presentation of data, communication of data, interpretation of data, indication of data, etc.

[0041] Embodiments of the present invention, including preferred embodiments, have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise forms and steps disclosed. The embodiments were chosen and described to provide the best illustration of the principles of the invention and the practical application thereof, and to enable one of ordinary skill in the art to utilize the invention

in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.

1. A medical device comprising a module for communicating with at least a second medical device wherein the module for communicating is adapted to be activated by a value of a physiological parameter of an animal.

2. The medical device of claim 1, wherein the module for communication comprises a telemetry system for wireless communication.

3. The medical device according to claim 2, wherein the telemetry system is for RF communication.

4. The medical device of claim 2, wherein the medical device is selected from the group consisting of a remote control, a PDA, and an analyte measuring device.

5. The medical device according to claim 4, wherein the analyte measuring device is a glucose measuring device.

6. The medical device according to claim 5, wherein the glucose measuring device is a strip type glucose measuring device.

7. The medical device of claim 2, wherein the physiological parameter is an analyte concentration of an animal.

8. The medical device of claim 7, wherein the analyte concentration is a blood glucose concentration.

6. The medical device of claim 4, further comprising an electrochemical module for measuring blood glucose.

7. The medical device of claim 4, further comprising a photometric module for measuring blood glucose.

8. A system of medical devices comprising a first medical device and a second medical device, the first and second medical devices adapted to provide communication between said devices, wherein communication is activated by a value of a physiological parameter of an animal.

9. The system of claim 8, wherein the second medical device is selected from the group consisting of an extra corporal infusion pump, an implantable infusion pump, a pacesetter, an analyte sensor, a continuous analyte sensor, and a continuous glucose sensor.

10. The system of claim 9, wherein the first and second medical devices comprise telemetry features for wireless communication.

11. A method of communicating between a first medical device and at least a second medical device wherein the

communicating is at least one of enabled and activated by a value of a physiological parameter of an animal.

12. The method of claim 11, wherein the communicating is at least one of enabled and activated for a predetermined time.

13. The method of claim 12, wherein the predetermined time is established according to at least one of a value of a physiological characteristic of an animal or a set of data obtained during previous times.

14. The method of claim 13, wherein the physiological parameter is selected from the group consisting of an analyte concentration of an animal, a heart rate and an electrophysiological value

15. The method according to claim 14, wherein the analyte concentration is a blood glucose concentration.

15. The method of claim 11, wherein the activation of the communicating is performed on the first medical device by generating a value of the physiological parameter in the first medical device.

16. The method of claim 15, wherein the first medical device is selected from the group consisting of a remote control, a PDA and an analyte measuring device.

17. The method according to claim 16, wherein the analyte measuring device is a glucose measuring device.

18. The method according to claim 17, wherein the glucose measuring device is a strip type glucose measuring device.

19. The method of claim 16, wherein the second medical device is selected from the group consisting of an extra corporal infusion pump, an implantable infusion pump, a pacesetter and an analyte sensor.

20. The method according to claim 19, wherein the second medical device is a continuous analyte sensor.

21. The method according to claim 20, wherein the continuous analyte sensor is a continuous glucose sensor.

22. The method of claim 11, wherein the communicating between said medical devices is wireless.

23. The method according to claim 22, wherein the communicating is RF based.

24. The method of claim 11, wherein the first medical device receives data from the second medical device.

25. The method of claim 11, wherein the first medical device sends commands to the second medical device to at least partially control said second device.

\* \* \* \* \*

专利名称(译)	医疗器械与医疗器械通信方法		
公开(公告)号	<a href="#">US20080033255A1</a>	公开(公告)日	2008-02-07
申请号	US11/832421	申请日	2007-08-01
[标]申请(专利权)人(译)	ESSENPREIS MATTHIAS HAUETER ULRICH BERNINI NICOLE FANKHAUSER西比尔 拉巴斯蒂特SEBASTIAAN MEYER古代GUNNAR 苏梅克尔MICHAEL HEATON KELLY JACKELMANN JOEL		
申请(专利权)人(译)	ESSENPREIS MATTHIAS HAUETER ULRICH BERNINI NICOLE FANKHAUSER西比尔 拉巴斯蒂特SEBASTIAAN MEYER古代GUNNAR 苏梅克尔MICHAEL HEATON KELLY JACKELMANN JOEL		
当前申请(专利权)人(译)	ESSENPREIS MATTHIAS HAUETER ULRICH BERNINI NICOLE FANKHAUSER西比尔 拉巴斯蒂特SEBASTIAAN MEYER古代GUNNAR 苏梅克尔MICHAEL HEATON KELLY JACKELMANN JOEL		
[标]发明人	ESSENPREIS MATTHIAS HAUETER ULRICH BERNINI NICOLE FANKHAUSER SYBILLE LA BASTIDE SEBASTIAAN MEYER OLDEN GUNNAR SCHOEMAKER MICHAEL HEATON KELLY JACKELMANN JOEL		
发明人	ESSENPREIS, MATTHIAS HAUETER, ULRICH BERNINI, NICOLE FANKHAUSER, SYBILLE LA BASTIDE, SEBASTIAAN MEYER OLDEN, GUNNAR SCHOEMAKER, MICHAEL HEATON, KELLY JACKELMANN, JOEL		

IPC分类号	A61B5/00
CPC分类号	A61B5/0002 A61B5/14532 A61M5/14244 A61M2230/201 A61M2205/3523 A61M2205/3569 A61M2205/3592 A61M5/14276
优先权	2005002074 2005-02-02 EP
外部链接	<a href="#">Espacenet</a> <a href="#">USPTO</a>

摘要(译)

公开了一种移动医疗设备和医疗设备之间的通信方法。在一个实施例中，医疗设备包括用于与至少第二医疗设备通信的模块，其中用于通信的模块适于由动物的生理参数的值激活。在一个实施例中，本发明的方法涉及第一医疗设备和至少第二医疗设备，其中所述医疗设备之间的通信由动物的生理参数的值激活。

