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(54) **DEVICE FOR PROCESSING AND TRANSMITTING MEASURED SIGNALS FOR MONITORING AND/OR CONTROLLING MEDICAL IMPLANTS**

VORRICHTUNG ZUR VERARBEITUNG UND SENDUNG VON GEMESSENEN SIGNALEN ZUR ÜBERWACHUNG UND/ODER KONTROLLE VON MEDIZINISCHEN IMPLANTATEN

DISPOSITIF DE TRAITEMENT ET D'ÉMISSION DE SIGNAUX MESURÉS POUR SURVEILLER ET / OU COMMANDER DES IMPLANTS MÉDICAUX

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EP 2 440 112 B1

Description

FIELD OF THE INVENTION

[0001] The invention relates to a device for processing measured signals which correspond to implant parameters or biological parameters for monitoring and/or controlling medical implants, diagnostic devices or biological processes.

[0002] Monitoring and controlling of medical implant behaviour has become more and more important. The measurement of implant parameters as strain, displacement, transferred force gives valuable information about the process of bone healing and/or implant distraction. Current wireless techniques allow only short measurements providing restricted information or need to transfer huge amounts of data from the implanted measurement device to an external receiver.

DESCRIPTION OF THE PRIOR ART

[0003] A device for providing in vivo diagnostics of loads, wear, and infection in orthopaedic implants is known from US 7,097,662 EVANS. This known device includes a signal processing device which is operable to receive an output signal from at least one sensor and to transmit a signal corresponding with this output signal.

[0004] From Graichen F., Rohlmann A., Bergmann G.: "Implantable 9-channel telemetry system for in vivo load measurements with orthopaedic implants", IEEE TRANSACTIONS ON BIOMEDICAL ENGENEERING, Vol. 54, No. 2 February 2007 another device for in vivo measuring loads to which orthopaedic implants are subjected is known. This known device includes an inductively powered integrated circuit inside the implant which measures six load components as well as the temperature and supplied voltage and a wireless telemetric data transfer system. This known telemetric system requires a power consumption of 5mW.

[0005] The important factors for an implantable data transfer unit are energy consumption and required space. A disadvantage of this known device would be that relatively large lithium button cell (diameter 24mm x 5mm, 3V) which has a capacity of 540mAh would have to be implanted. At 5mW this would mean a theoretical lifetime of this known system of approximatively 13.5 days. Therefore an external power supply via induction is used. Only real-time data can be transmitted since no memory is on board. During the measurements, the patient has to carry a bulky induction coil around his leg plus the RF receiver, since 5mW only allow a maximum of 0.5m transmission range.

[0006] A system for storing and processing physiological data in a medical recording device that allows continuous data collection and storage of such data is known from US-A 2005/113647 LEE ET AL.

[0007] US-A 2005/085864 SCHULMAN ET AL. discloses an implantable device for processing neurological signals.

[0008] From WO 2008/052082 LEYDE a telemetry receive unit for use in an implantable medical device is known.

[0009] US2006/052782 is the closest prior art and discloses features A) to D) and G) to J) of claim 1.

SUMMARY OF THE INVENTION

[0010] It is an object of the invention to provide an electronic device for monitoring of implants which allows to obtain long term measurements of relevant parameters at an implant under minimal energy consumption and minimal required space of the implanted electronic device.

[0011] The invention solves the posed problem with a device for processing measured signals which correspond to implant parameters or biological parameters for monitoring medical implants or biological processes that incorporates the features of claim 1.

[0012] The advantages achieved by the invention are essentially to be seen in the fact that, thanks to the device according to the invention:

- long term measurements which are most relevant for gaining information about bone healing can be performed by summing up the amplitudes of a cyclic sensor response during physiological loading/unloading and transferring only the sum, the number of cycles and the current sensor value to a wireless receiver outside of the patient;
- a complete assembly including the inventive device and a sensor can be implanted in the patient's body; and
- the data volume can be significantly reduced by providing long term information of the medical implant behaviour at the same time.

[0013] The important factors for an implantable data transfer unit are energy consumption and required space. Both are somehow related, the more energy is needed, the bigger the energy carrier has to be. The wireless data transfer is the process requiring the major portion of the energy when using active radio frequency transmission.

[0014] energy carrier has to be. The wireless data transfer is the process requiring the major portion of the energy when using active radio frequency transmission.

[0015] By minimizing the amount of data to be transferred, the proposed system guarantees autonomous function for theoretically 9 month, which can also cover healing periods of complicated fractures like mal-unions or critical size defects at an overall size: diameter 30 mm x height 10 mm. Furthermore, the data is believed to be more meaningful since the complete time period is reflected in the values. Particularly relevant statistical data are the sum of the measured signals, the number of measured signals, average value, minimal value and maximal value.

[0016] In a special embodiment said signal processing device comprises a programmable electronic data processing unit. The programmable electronic data processing unit can be a programmable microprocessor which allows further data processing and if necessary provides the processed data for a closed control loop e.g. in case of an application of the device as a controller (Measurement of blood sugar and controlling of a device for the deliverance of the medication).

[0017] In another embodiment said data transmission device is configured as transreceiver allowing to transmit data and to receive data from an external transmitting source. This configuration allows a transfer of data in both directions, particularly between the device and an external computer.

[0018] Said device comprises an electronic data processing unit with an integrator.

[0019] In still another embodiment said device further comprises a power supply arranged in said covering. Preferably the power supply is a battery, e.g. a lithium button cell.

[0020] Said electronic data processing unit comprises a counter unit allowing to supply the amount of processed signal samples to the data memory. Further, the device can be provided with a timer, an analog/digital converter and signal conditioner.

[0021] In yet another embodiment said electronic data processing unit comprises a minimum/ maximum unit allowing to identify extreme values in the curve of measured signals. The minmax unit supplies the actual count of cycles in the signal received from the sensor above a predefined threshold to the data memory. This value represents the amount of physiological load cycles or other cyclic processes during a period of time and is a measure for the activity of the patient.

Said data transmission device includes a radio frequency based transmission means. A radio frequency identification device (RFID) is used. The device sends the information by means of Radio Frequency Identification (RFID) through the skin. The use of RFID is a further reason for minimizing the data. Here, no internal energy is needed, since the process is fed by induction from outside. Typical data volumes to be transmitted by RFID range between Bytes and 1kB. RFID is a preferred solution, since required space for the transponder is minimal and the transmission process is fast and simple.

In still another embodiment said device further includes a multi-channel multiplexer. The multiplexer allows to electronically connect a plurality of sensors to the device and to intermittently process the signals received from said sensors.

[0022] According to the invention, the device comprises a sensor in form of a strain gauge. Examples of sensors types not necessarily falling under the scope of the claims are the following:

- Displacement, inductivity or other known principles; and/or
- Strain, Strain gauges, particularly wire resistance strain gauges; and/or
- Force, Load cells, strain gage or Piezo based Pressure sensors; and/or
- Acceleration sensors or Temperature sensors; and/or
- Sensors for arterial blood gas parameters (e.g. CO_2; O_2); and/or
- Sensors for blood sugar; and/or
- Sensors for lactate concentration.

A BRIEF DESCRIPTION OF THE DRAWINGS

[0023] The preferred embodiment of the invention will be described in the following by way of example and with reference to the accompanying drawing in which:

Fig. 1 illustrates a schematic block diagram of an embodiment of the device according to the invention.

[0024] The embodiment of the device 1 for processing measured signals illustrated in Fig. 1 comprises a biocompatible sterilizable covering 9 in which an electronic signal processing device 2 allowing to process measured signals received from a sensor 5, a data memory 16 allowing to store data received from said signal processing device 2 and a data transmission device 4 for transmitting data received from said data memory 16 to a remote data receiving device 6 are arranged and electrically connected to each other. Said signal processing device 2 is programmed to calculate statistically relevant data obtained from the said measured signals to reduce the stored data. Particularly, relevant statistical data are the sum of the measured signals, the number of measured signals, average value, minimal value and maximal value. The electronic data processing unit 7 can include an integrator 13, a counter unit 14 allowing to supply the amount of processed signal samples to the data memory 16, a timer 12, an analog/digital signal converter 11 and a signal conditioner 10. Further, the electronic data processing unit 7 is provided with a minmax unit 15 allowing to identify extreme values in the curve of measured signals. The data transmission device 4 is configured as a RFID transponder (Radio Frequency Identification transponder). A power supply 3 is additionally arranged in said covering 9 to operate the device 1 and the sensor 5 (dotted line in fig. 1) but excluding the data transmission device 4 since the RFID transponder is fed by induction from an external source.

Implantation:

[0025] The device 1 comprising the signal processing device 2 and the data transmission device 4 and a power supply 3 in the form of a battery is placed in a biocompatible and sterilizable covering 9 or housing or may be covered by an elastic and biocompatible skin like Latex or Silicon. The sensor 5 is connected via a cable to the device 1. A unit of sensor 5 and the device 1 shall be sterilized prior implantation. In case the sensor 5 can not be mounted to the implant interoperatively (e.g. strain gages) the complete unit of the implant, the device 1 and the sensor 5 have to be preassembled and sterilized together. Another possible solution would be a plug connection between the sensor 5 and the device 1. The complete assembly will then be placed subcutaneously into a pocket of two skin layers.

Internal data processing:

[0026] The analog signal of the sensor 5 is conditioned by a signal conditioner 10, i.e. a measuring-amplifier and converted to digital data by an 16bit A/D converter 11 at about 64Hz sample frequency. All values received from the sensor 5 and further processed by the signal conditioner 10 and the analog/digital converter 11 are digitally summed by an integrator 13 and the sum is stored in the internal data memory 16. Moreover a counter unit 14 is supplying the amount of processed samples (running time) to the data memory 16. A minmax unit 15 identifies extreme values in the curve of measured values and supplies the actual count of cycles in the sensor signal above a predefined threshold to the internal data memory 16. This value represents the amount of physiological load cycles during a time period and is a measure for the activity of the patient. As 4th parameter the actual sensor signal is provided to the data memory 16.

Data transmission:

[0027] The data transmission between the device 1 and an external data processing device 8, e.g. a computer is performed by means of the known technology of Radio Frequency Identification. Four current integer values representing the above described parameters will be provided from the internal data memory 16 to the data transmission device 4, e.g. a RFID transponder and can be transferred to the data receiving device 6, e.g. an RFID receiver at time points to be chosen by the operator. Reasonable data acquisition intervals may range between 1 day and 1 week but depend on the application of the device 1.

[0028] The device 1 including the electronic for data acquisition and internal data processing is provided with electrical energy, preferable from a battery like a lithium button cell or comparable. The data transmission device 4 itself is fed by induction based on the RFID principle. With an overall size of the device 1 of: diameter 30mm x height 10mm, an autonomous function for theoretically 9 month is possible. The data acquisition frequency is 64Hz to account for the sampling theorem assuming fast walking or running of the patient. The electronic device 1 is supposed to be implanted subcutaneously and separated to the implant.

Operation of the device 1:

[0029] The assembly including the device 1 and the sensor 5 is in continuous function from the point in time when the power supply 3, i.e. the battery is inserted. This should be when assembling the covering or housing prior sterilization and surgery. The operation of the device 1 ends with removal of the power supply 3, i.e. the battery or loss of electric power, resulting in loss of data in the data memory 16. The current content in the data memory 16 can be read out at any time by means of the data transfer system including the data transmission device 4 and the data receiving device 6.

External data processing:

[0030] The parameters may be either downloaded and stored on an external data processing device 8, e.g. a computer or directly processed in the data receiving device 6, i.e. the RFID receiver. The sum of sensor response is calibrated to actual units using a linear approach. Subtracting the values of the previous time point from the actual values deliver information about the current period. The sample count divided by the sample frequency provides the running time. The sum of sensor response divided by number of samples gives the mean sensor response of the current period. The sum of sensor response divided by the number of physiological load cycles represents a measure for the sensor response per load cycle.

Meaning of the results and presentation:

[0031] The mentioned evaluations may be visualized by plotting the measured and processed values over time. For instance, the healing process may be visualized with decreasing average sensor response over time. A threshold can be set for determining the optimal time point for implant removal. For research purposes different dynamization protocols can be evaluated, mal-unions may be identified at an early stage. The progression of the number of physiological load cycles gives information about the patients activity over time and therefore about the stimulation of the bone. For monitoring distraction implants, the current sensor value provides valuable information about the progression of the distraction process.

Application Examples:

[0032]

1. Monitoring of bone healing in osteosynthesis following the principle of secondary healing. The strain in a standard bone plate or intramedullary nail measured by strain gages, could be acquired and processed with the proposed device 1. Reduction of strain could be interpreted as enhanced load sharing of the bone and as progress in the bone consolidation. Knowledge about the healing progression is valuable information to detect mal-unions at an early

stage or to determine an optimal time-point for implant removal.

Mechanical stimulation of bone is known to foster bone formation. A tool to monitor dynamization of newly proposed dynamic implants and its progression over time is also an interesting application field for the device 1. It offers the opportunity to acquire long term data rather than repeated short term measurements as done by known techniques.

2. Monitoring of a distraction implant. The method of distracting bone is used for generation of new bone tissue for critical size defects or bone lengthening. The exact telescoping of the implant, like an intramedullary distraction nail is essential to know for optimized bone generation. The inventive device 1 can be used for transmitting the current distraction of the implant as well as the progression of the distraction over time.

The following examples are not part of the claimed invention:

3. Measurement of blood sugar and counteraction by controlled release of Insulin. Blood sugar values are monitored and processed over a certain time period and used for controlling deliverance of medication. This can be realized as autonomous control loop inside the body. The values have to be transferred to an external receiver to control the process.

[0033] Other application examples are:

- Arterial blood gas monitoring (O_2, CO_2, blood pressure)
- Lactate concentrations

[0034] While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. The scope of the present invention is accordingly defined as set forth in the appended claims.

Claims

1. A monitoring and/or controlling device (1) for processing and transmitting measured signals which correspond to implant parameters for monitoring and/or controlling of bone healing in osteosynthesis comprising:

A) a biocompatible sterilizable covering (9);
B) an electronic signal processing device (2) arranged in said covering (9) and electrically connectable to at least one sensor (5) allowing to process measured signals received from said at least one sensor (5);
C) a data memory (16) arranged in said covering (9) and electrically connected to said signal processing device (2) allowing to store data received from said signal processing device (2); and
D) a data transmission device (4) arranged in said covering (9) and electrically connected to said data memory (16) for transmitting data received from said data memory (16) to a remote data receiving device (6) which is connectable to an external data processing device (8), and
E) the monitoring and/or controlling device (1) comprising an electronic data processing unit (7) comprising a counter unit (14) allowing to supply the amount of processed signal samples to the data memory (16), wherein
F) the electronic data processing unit (7) comprises an integrator (13); wherein
G) said signal processing device (2) is programmed to calculate statistically relevant data obtained from the said measured signals to reduce the stored data; wherein
H) the monitoring and/or controlling device (1) further comprises at least one sensor (5), wherein
I) the monitoring and/or controlling device (1) further comprises a bone plate or an intramedullary nail; and
J) the at least one sensor (5) is a strain gauge suitable to measure the strain in the bone plate or intramedullary nail.

2. The device (1) according to claim 1, wherein said signal processing device (2) comprises a programmable electronic data processing unit (7).

3. The device (1) according to claim 1 or 2, wherein said data transmission device (4) is configure as transreceiver allowing to transmit data and to receive data from an external transmitting source.

4. The device (1) according to one of the claims 1 to 3, wherein said device (1) further comprises a power supply (3) arranged in said covering.

5. The device (1) according to one of the claims 1 to 4, wherein said electronic data processing unit (7) comprises a minimum/maximum unit (15) allowing to identify extreme values in the curve of measured signals.

6. The device (1) according to one of the claims 1 to 5, wherein said data transmission device (4) includes a radio frequency based transmission means.

7. The device (1) according to one of the claims 1 to 6, wherein said device (1) further includes a multi-channel multiplexer.

8. Use of the device (1) according to one of the claims 1 to 7 for providing the processed data in a closed control loop.

Patentansprüche

1. Überwachungs- und/oder Kontrollvorrichtung (1) zum Verarbeiten und Senden von gemessenen Signalen, die Implantatparametern entsprechen, zum Überwachen und/oder Kontrollieren der Knochenheilung bei der Osteosynthese, umfassend:

   A) eine biokompatible sterilisierbare Abdeckung (9);
   B) eine elektronische Signalverarbeitungsvorrichtung (2), die in der Abdeckung (9) angeordnet und mit mindestens einem Sensor (5) elektrisch verbindbar ist, um zu ermöglichen, von dem mindestens einen Sensor (5) empfangene gemessene Signale zu verarbeiten;
   C) einen Datenspeicher (16), der in der Abdeckung (9) angeordnet und mit der Signalverarbeitungsvorrichtung (2) elektrisch verbunden ist, um zu ermöglichen, von der Signalverarbeitungsvorrichtung (2) empfangene Daten zu speichern; und
   D) eine Datensendevorrichtung (4), die in der Abdeckung (9) angeordnet und mit dem Datenspeicher (16) elektrisch verbunden ist, um von dem Datenspeicher (16) empfangene Daten zu einer entfernten Datenempfangsvorrichtung (6) zu senden, die mit einer externen Datenverarbeitungsvorrichtung (8) verbindbar ist, und
   E) wobei die Überwachungs- und/oder Kontrollvorrichtung (1) eine elektronische Datenverarbeitungseinheit (7) umfasst, die eine Zählereinheit (14) umfasst, um zu ermöglichen, dass die Menge an verarbeiteten Signalproben dem Datenspeicher (16) zugeführt wird, wobei
   F) die elektronische Datenverarbeitungseinheit (7) einen Integrator (13) umfasst; wobei
   G) die Signalverarbeitungsvorrichtung (2) dazu programmiert ist, statistisch relevante Daten zu berechnen, die aus den gemessenen Signalen erhalten werden, um die gespeicherten Daten zu reduzieren; wobei
   H) die Überwachungs- und/oder Steuervorrichtung (1) ferner mindestens einen Sensor (5) umfasst,
   wobei
   I) die Überwachungs- und/oder Kontrollvorrichtung (1) ferner eine Knochenplatte oder einen Marknagel umfasst; und
   J) der mindestens eine Sensor (5) ein Dehnungsmesser ist, der geeignet ist, die Dehnung in der Knochenplatte oder in dem Marknagel zu messen.

2. Vorrichtung (1) nach Anspruch 1, wobei die Signalverarbeitungsvorrichtung (2) eine programmierbare elektronische Datenverarbeitungseinheit (7) umfasst.

3. Vorrichtung (1) nach Anspruch 1 oder 2, wobei die Datensendevorrichtung (4) als Transceiver ausgebildet ist, um zu ermöglichen, Daten zu senden und Daten von einer externen Sendequelle zu empfangen.

4. Vorrichtung (1) nach einem der Ansprüche 1 bis 3, wobei die Vorrichtung (1) ferner eine Stromversorgung (3) umfasst, die in der Abdeckung angeordnet ist.

5. Vorrichtung (1) nach einem der Ansprüche 1 bis 4, wobei die elektronische Datenverarbeitungseinheit (7) eine Minimum/Maximum-Einheit (15) umfasst, um zu ermöglichen, Extremwerte in der Kurve von gemessenen Signalen zu identifizieren.

6. Vorrichtung (1) nach einem der Ansprüche 1 bis 5, wobei die Datensendevorrichtung (4) eine hochfrequenzbasierte Sendeeinrichtung enthält.

7. Vorrichtung (1) nach einem der Ansprüche 1 bis 6, wobei die Vorrichtung (1) ferner einen Mehrkanal-Multiplexer enthält.

8. Verwendung der Vorrichtung (1) nach einem der Ansprüche 1 bis 7 zum Bereitstellen der verarbeiteten Daten in einem geschlossenen Regelkreis.

Revendications

1. Dispositif de surveillance et/ou de régulation (1) pour traiter et transmettre des signaux mesurés qui correspondent à des paramètres d'implant pour surveiller et/ou réguler la consolidation osseuse dans une ostéosynthèse, comprenant :

   A) une enveloppe biocompatible stérilisable (9) ;
   B) un dispositif de traitement de signaux électroniques (2) disposé dans ladite enveloppe (9) et pouvant être connecté électriquement à au moins un capteur (5) permettant de traiter des signaux mesurés reçus en provenance dudit au moins un capteur (5) ;
   C) une mémoire de données (16) disposée dans ladite enveloppe (9) et électriquement connectée audit dispositif de traitement de signaux (2) permettant de stocker des données reçues en provenance dudit dispositif de traitement de signaux (2) ; et
   D) un dispositif de transmission de données (4) disposé dans ladite enveloppe (9) et électriquement connecté à ladite mémoire de données

(16) pour transmettre des données reçues en provenance de ladite mémoire de données (16) à un dispositif de réception de données distant (6) qui peut être connecté à un dispositif de traitement de données externe (8), et
E) le dispositif de surveillance et/ou de régulation (1) comprenant une unité de traitement de données électroniques (7) comprenant une unité de compteur (14) permettant d'appliquer la quantité d'échantillons de signaux traités à la mémoire de données (16), dans lequel
F) l'unité de traitement de données électroniques (7) comprend un intégrateur (13) ; dans lequel
G) ledit dispositif de traitement de signaux (2) est programmé pour calculer des données statistiquement pertinentes obtenues à partir desdits signaux mesurés pour réduire les données stockées ; dans lequel
H) le dispositif de surveillance et/ou de régulation (1) comprend en outre au moins un capteur (5), dans lequel
I) le dispositif de surveillance et/ou de régulation (1) comprend en outre une plaque d'ostéosynthèse ou un clou intramédullaire ; et
J) l'au moins un capteur (5) est une jauge de déformation adaptée pour mesurer la déformation dans la plaque d'ostéosynthèse ou le clou intramédullaire.

2. Dispositif (1) selon la revendication 1, dans lequel ledit dispositif de traitement de signaux (2) comprend une unité de traitement de données électroniques programmable (7).

3. Dispositif (1) selon la revendication 1 ou 2, dans lequel ledit dispositif de transmission de données (4) est configuré en tant qu'émetteur-récepteur permettant d'émettre des données et de recevoir des données d'une source de transmission externe.

4. Dispositif (1) selon l'une des revendications 1 à 3, dans lequel ledit dispositif (1) comprend en outre une alimentation électrique (3) disposée dans ladite enveloppe.

5. Dispositif (1) selon l'une des revendications 1 à 4, dans lequel ladite unité de traitement de données électroniques (7) comprend une unité de minimum/maximum (15) permettant d'identifier des valeurs extrêmes sur la courbe de signaux mesurés.

6. Dispositif (1) selon l'une des revendications 1 à 5, dans lequel ledit dispositif de transmission de données (4) comprend un moyen de transmission basé sur les radiofréquences.

7. Dispositif (1) selon l'une des revendications 1 à 6, dans lequel ledit dispositif (1) comprend en outre un multiplexeur multi-canal.

8. Utilisation du dispositif (1) selon l'une des revendications 1 à 7 pour appliquer les données traitées dans une boucle d'asservissement fermée.

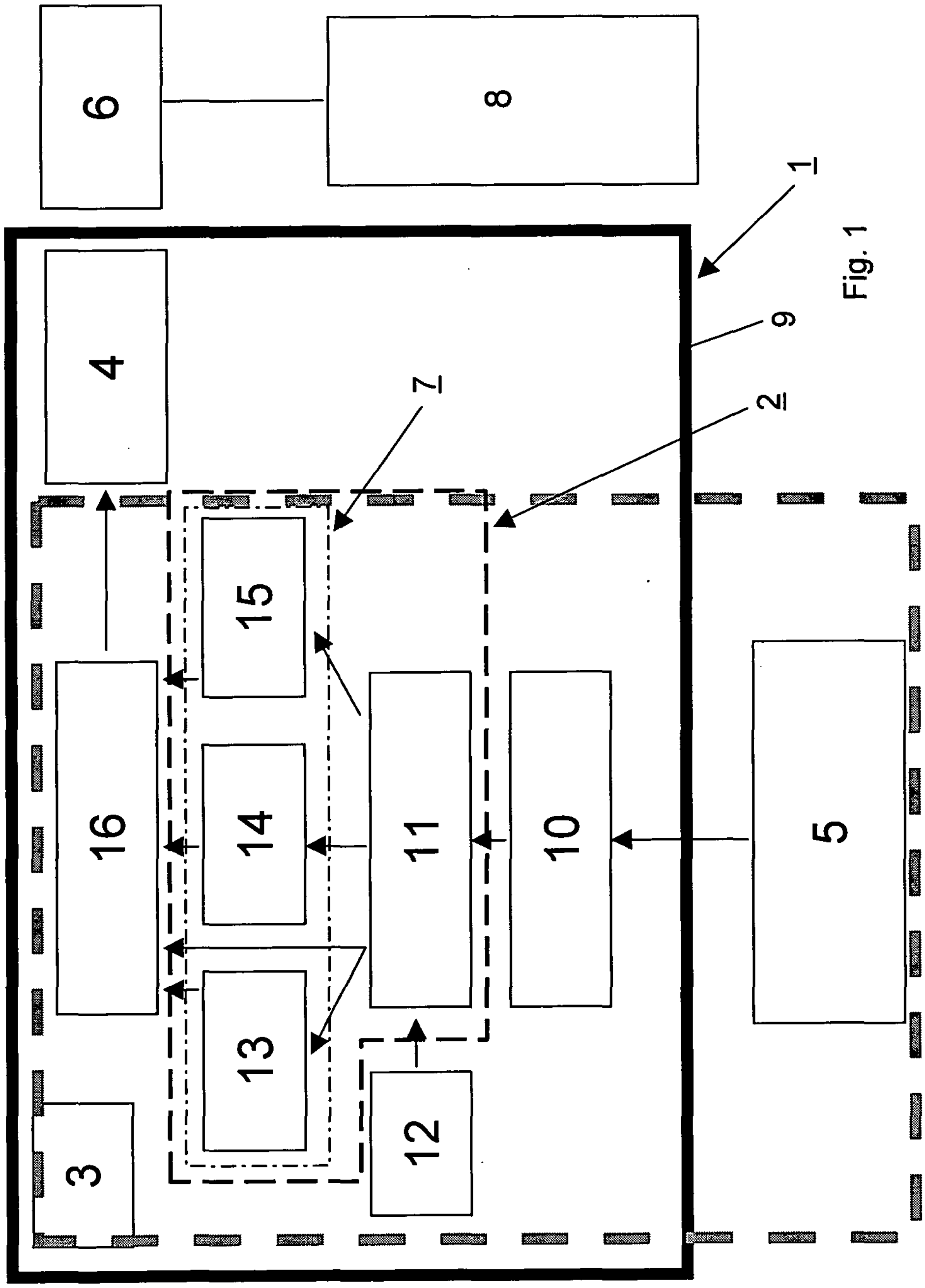

Fig. 1

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于处理和传输测量信号的装置，用于监测和/或控制医疗植入物，诊断装置或生物过程		
公开(公告)号	EP2440112A1	公开(公告)日	2012-04-18
申请号	EP2009775726	申请日	2009-06-11
申请(专利权)人(译)	AO科技集团		
当前申请(专利权)人(译)	AO科技集团		
[标]发明人	WINDOLF MARKUS		
发明人	WINDOLF, MARKUS		
IPC分类号	A61B5/00 G06F19/00 A61B5/103		
代理机构(译)	lusuardi，沃瑟		
其他公开文献	EP2440112B1 EP2440112B9		
外部链接	Espacenet		

摘要(译)

公开了一种用于处理和传输与用于监视和/或控制医疗植入物，诊断装置或生物过程的植入物参数或生物学参数相对应的测量信号的装置（1），该装置（1）包括：A）生物相容的可消毒覆盖物（9）；B）一种电子信号处理装置（2），其布置在所述覆盖物（9）中并且可电连接至至少一个传感器（5），从而允许处理从所述至少一个传感器（5）接收的测量信号；C）布置在所述覆盖物（9）中并电连接到所述信号处理装置（2）的数据存储器（16），允许存储从所述信号处理装置（2）接收的数据；D）布置在所述覆盖物（9）中并电连接到所述数据存储器（16）的数据传输设备（4），用于将从所述数据存储器（16）接收的数据传输到可连接的远程数据接收设备（6）到外部数据处理设备（8），其中E）所述信号处理设备（2）被编程为计算从所述测量信号获得的统计上相关的数据以减少所存储的数据。此外公开了监测或控制骨愈合或骨牵引植入物的方法。