US 20170251922A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2017/0251922 A1**

Roesicke et al. (43) **Pub. Date: Sep. 7, 2017**

(54) **SYSTEM FOR IN-VIVO MEASUREMENT OF AN ANALYTE CONCENTRATION**

(71) Applicant: **Roche Diagnostics Operations, Inc.**, Indianapolis, IN (US)

(72) Inventors: **Bernd Roesicke**, Mannheim (DE); **Karin Obermaier**, Bruehl (DE); **Stefan Lindegger**, Lotzwil (CH); **Andreas Menke**, Mannheim (DE); **Joerg Scherer**, Zuchwil (CH); **Karin Schwind**, Schifferstadt (DE); **Otto Gaa**, Worms (DE); **Gregor Bainczyk**, Mannheim (DE); **Michael Marquant**, Mannheim (DE); **Sandro Niederhauser**, Rutschelen (CH); **Michael Schoemaker**, Mannheim (DE); **Martin Mueri**, Basel (CH)

(73) Assignee: **Roche Diagnostics Operations, Inc.**, Indianapolis, IN (US)

(21) Appl. No.: **15/486,948**

(22) Filed: **Apr. 13, 2017**

Related U.S. Application Data

(63) Continuation of application No. 14/076,428, filed on Nov. 11, 2013, now Pat. No. 9,636,049, which is a continuation of application No. 12/052,382, filed on Mar. 20, 2008, now Pat. No. 8,721,544.

(30) **Foreign Application Priority Data**

Mar. 20, 2007 (EP) 07 005 638.7
Dec. 13, 2007 (EP) 07 024 174.0

Publication Classification

(51) **Int. Cl.**

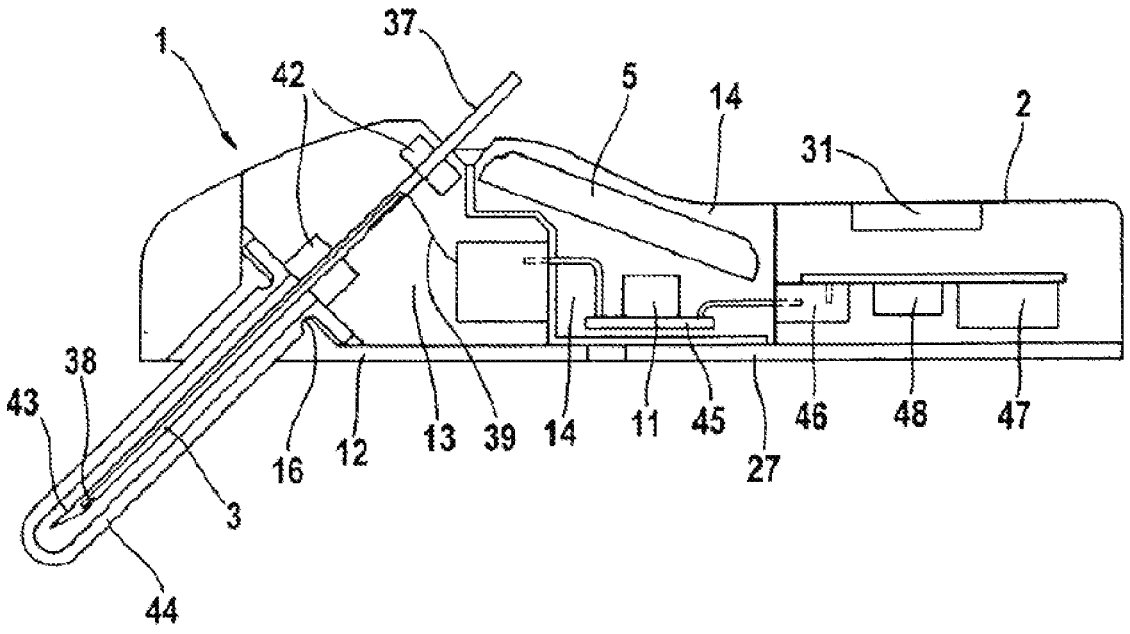
A61B 5/00	(2006.01)
A61B 90/98	(2006.01)
A61B 5/1459	(2006.01)
A61B 5/145	(2006.01)
A61B 5/1495	(2006.01)
A61B 5/1486	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/0031*** (2013.01); ***A61B 5/1495*** (2013.01); ***A61B 5/14865*** (2013.01); ***A61B 5/1459*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61B 5/6849*** (2013.01); ***A61B 5/7232*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 90/98*** (2016.02); *A61B 2560/0481* (2013.01); *A61B 2560/0219* (2013.01); *A61B 2560/0209* (2013.01)

(57) **ABSTRACT**

The analyte concentration, such as glucose, in a human or animal body is measured with an implantable sensor that generates measurement signals. The measurement signals are compressed through statistical techniques to produced compressed measurement data that can is easier to process and communicate. A base station carries the implantable sensor along with a signal processor, memory, and a transmitter. A display device is also disclosed that can receive the compressed measurement data from the base station for further processing and display.



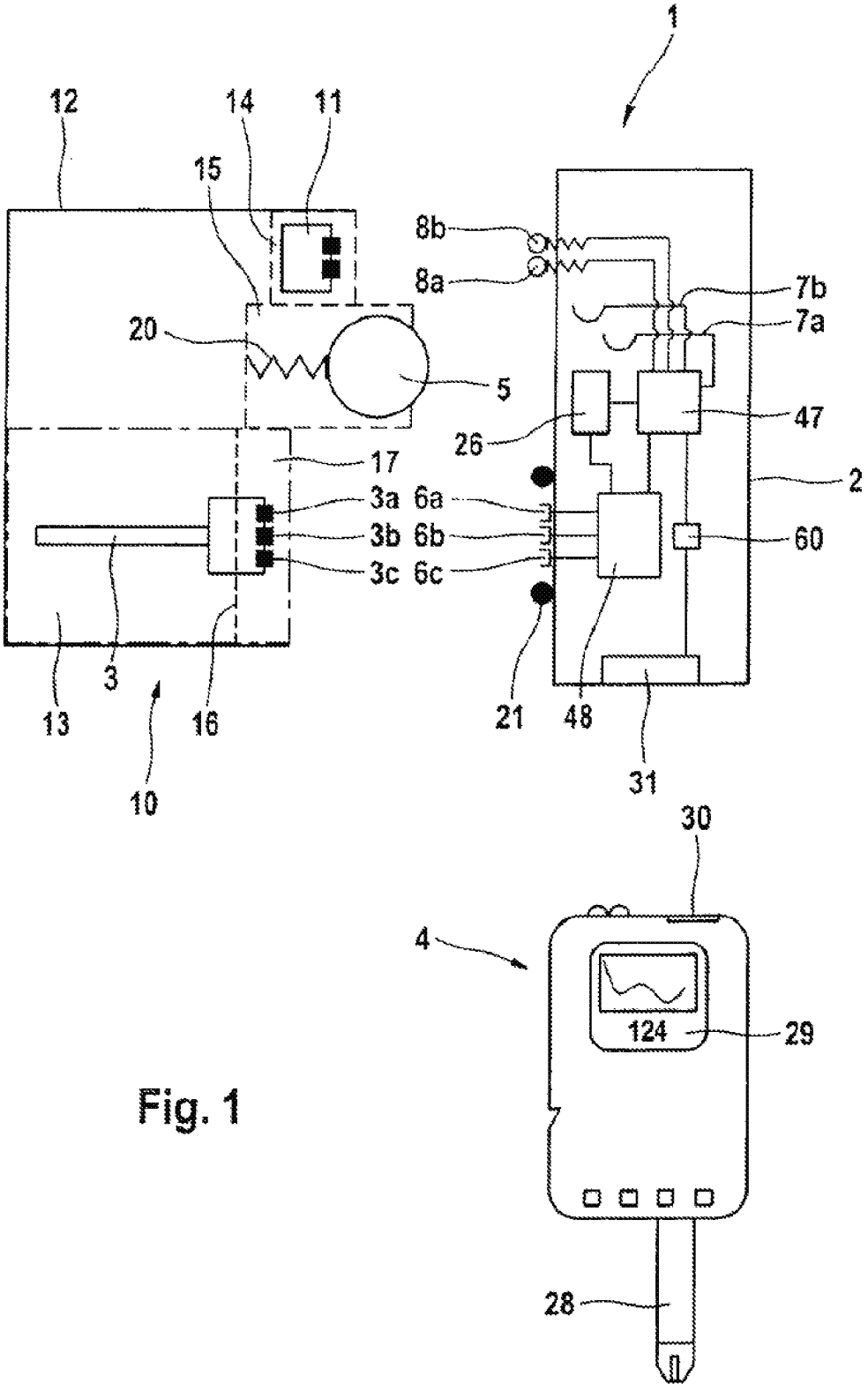

1
12
14
11
15
8b
8a
7b
7a
20
5
47
26
17
2
3a
6a
3b
6b
60
3c
6c
3
13
16
10
21
48
31
30
4
124
29
28

Fig. 1

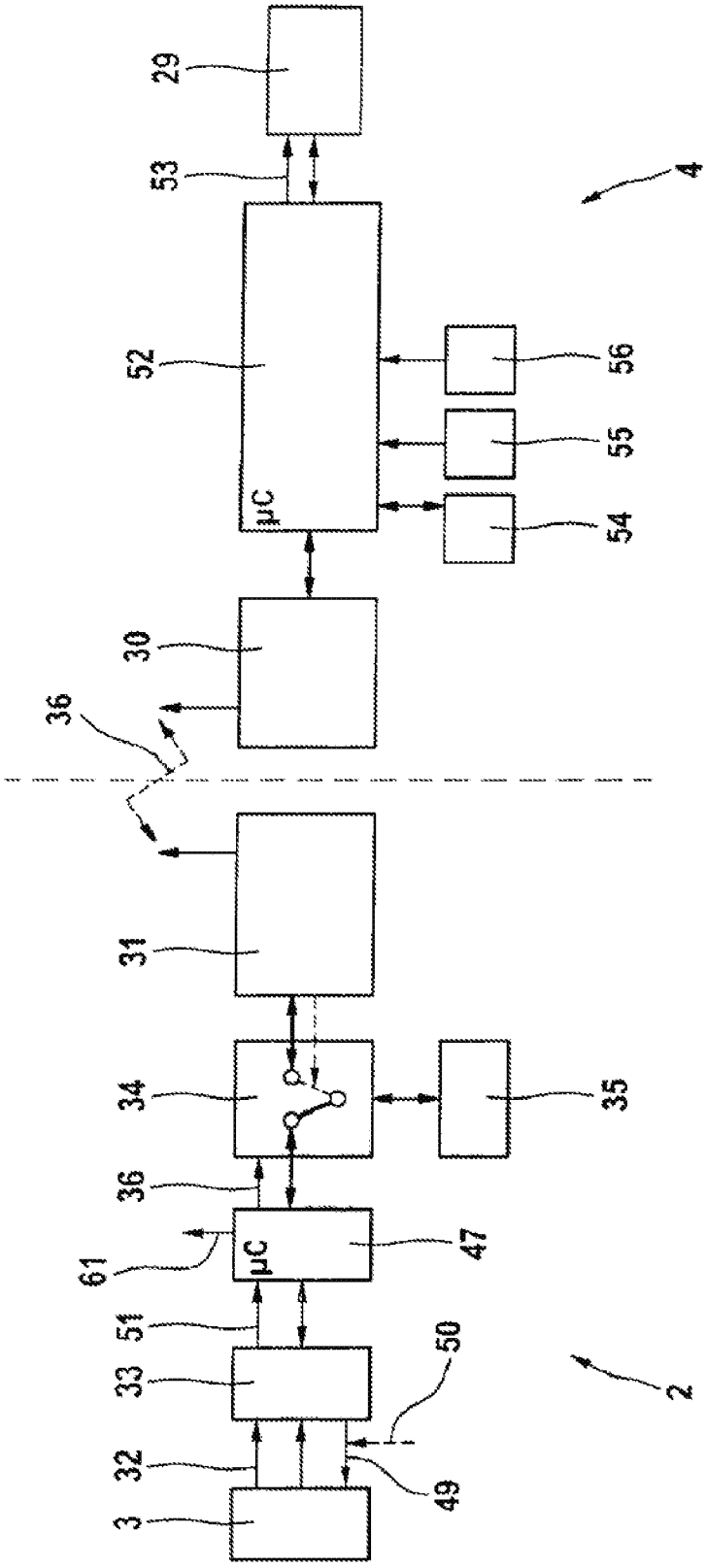


Fig. 2

Fig. 3

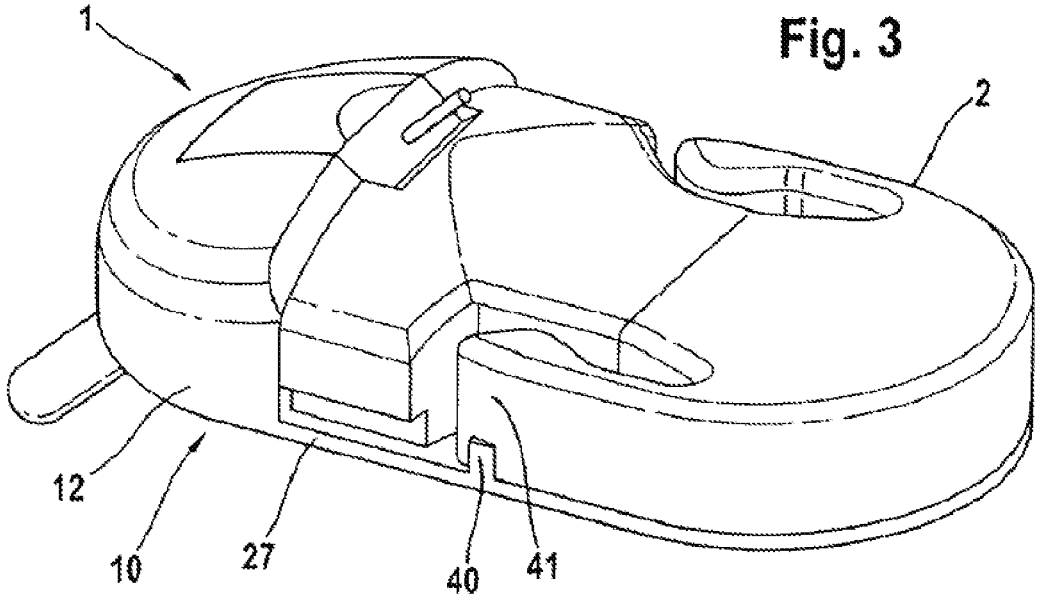


Fig. 4

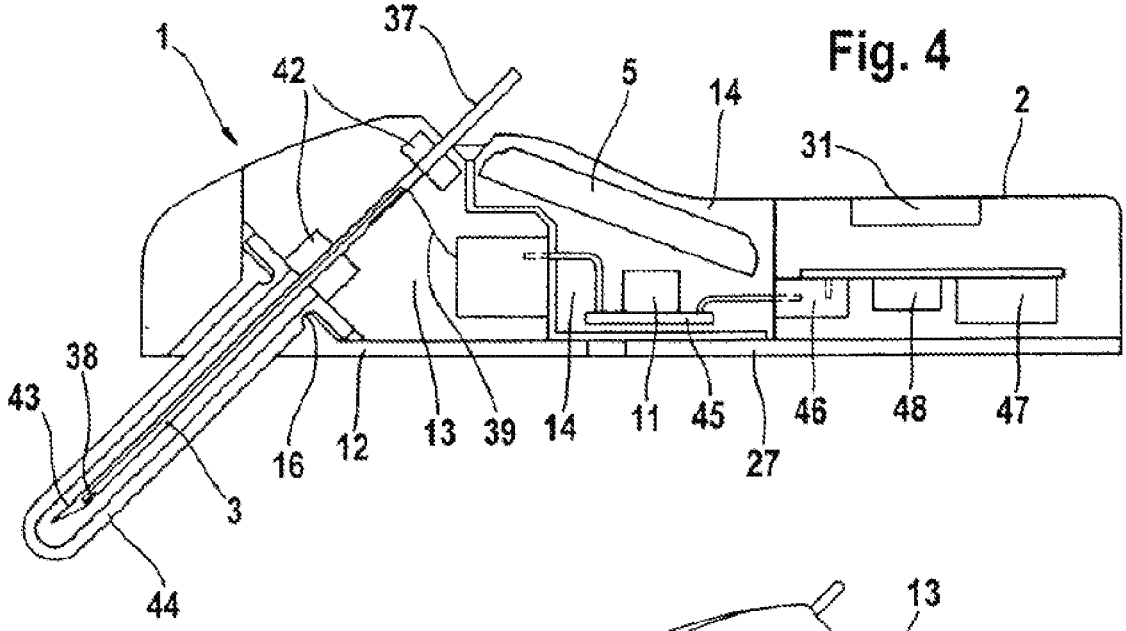
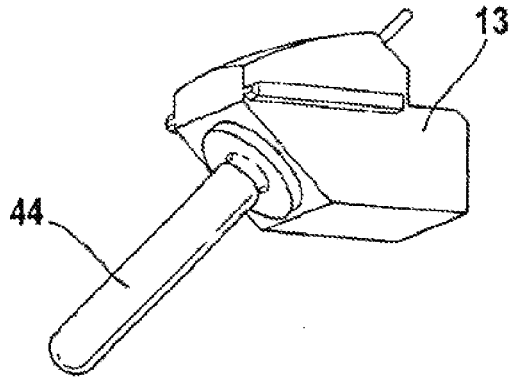


Fig. 5



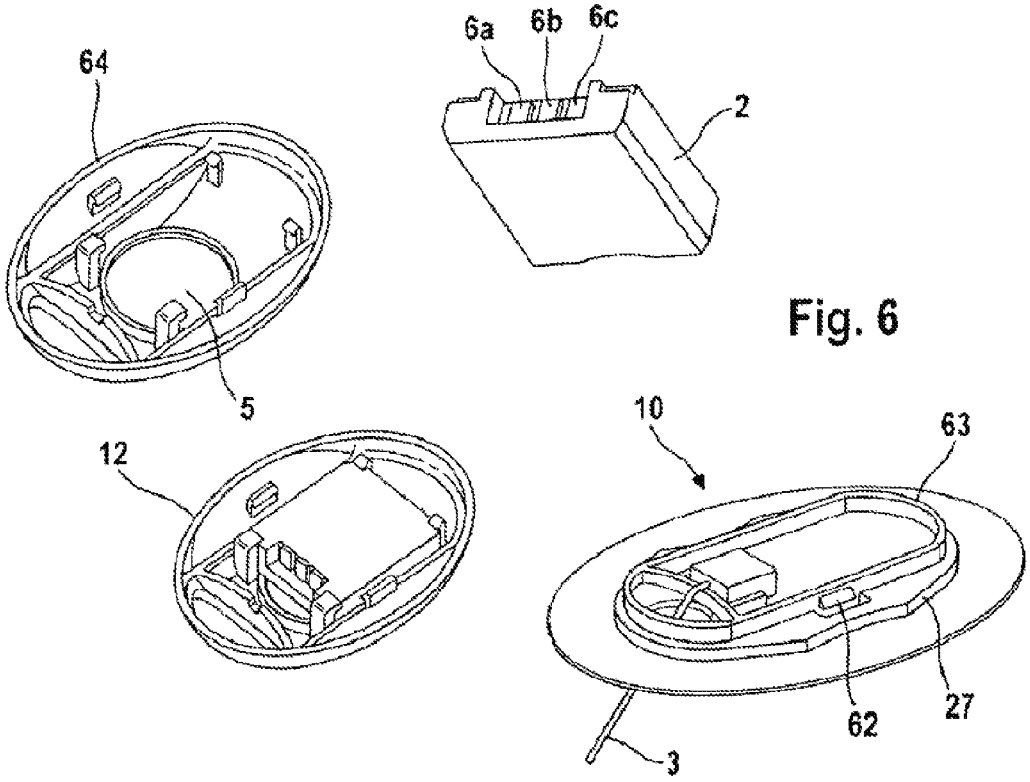


Fig. 6

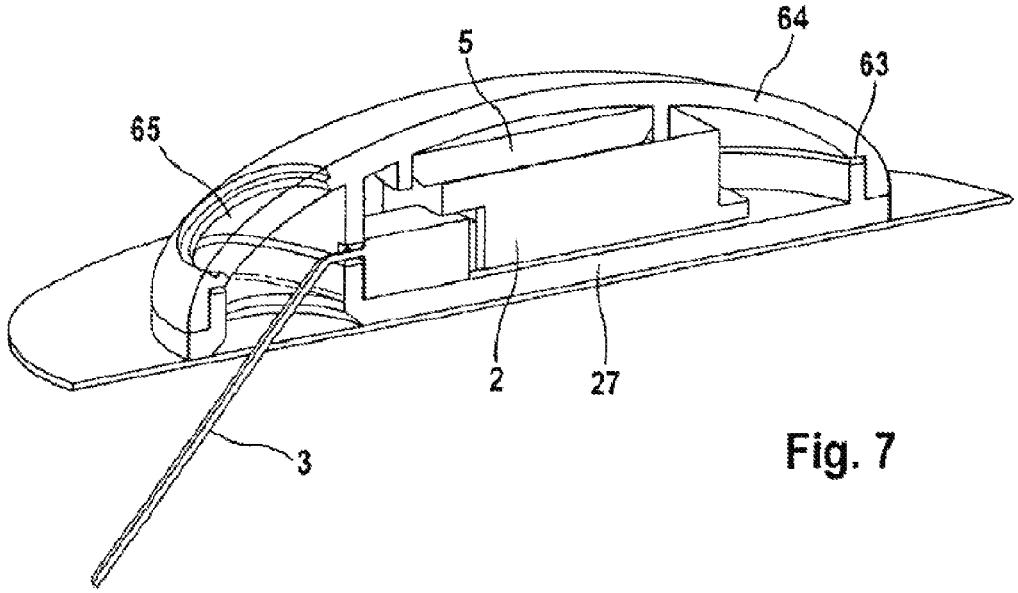


Fig. 7

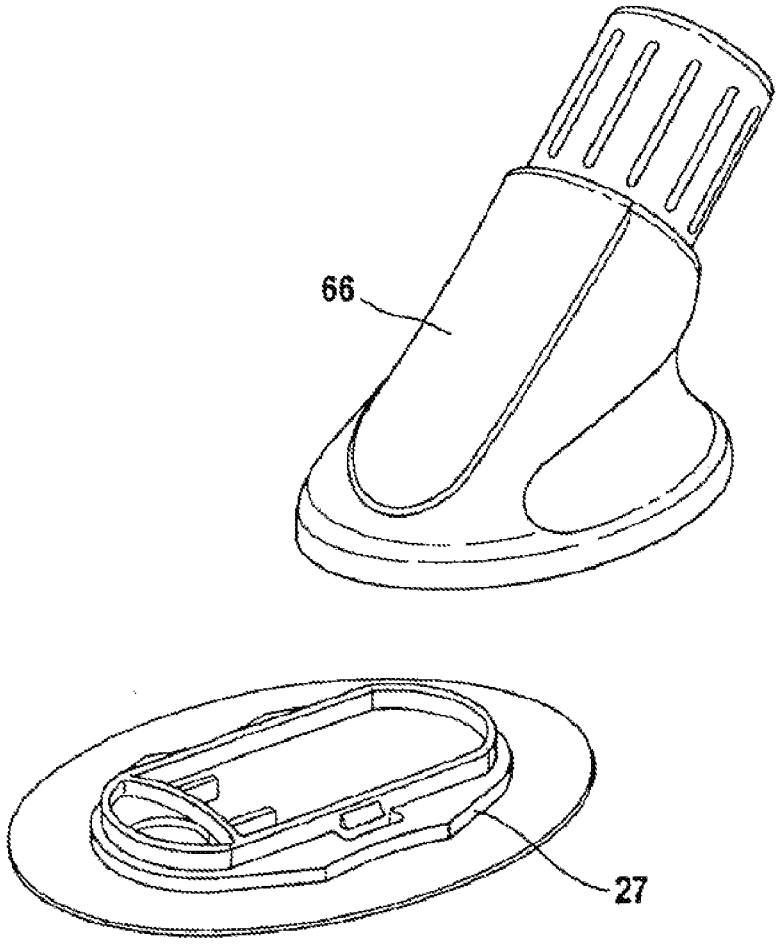


Fig. 8

Fig. 9

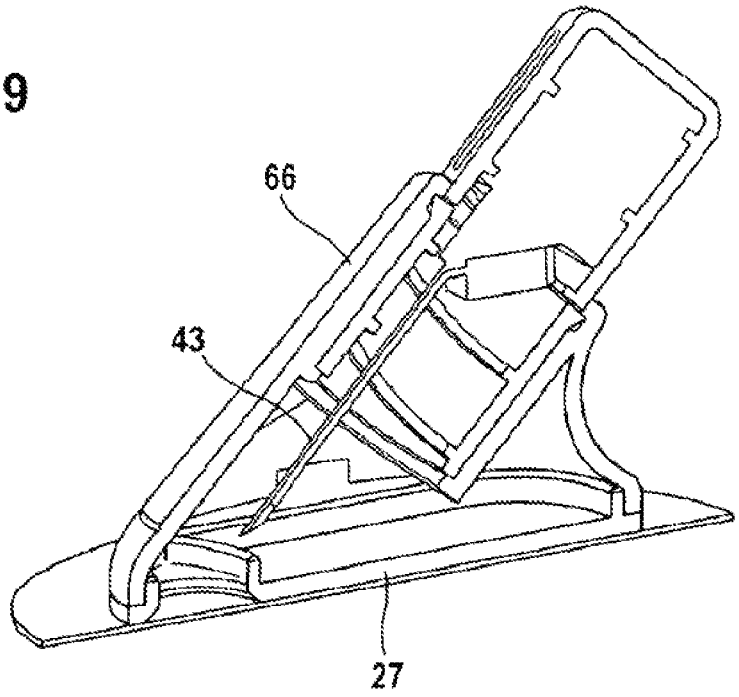
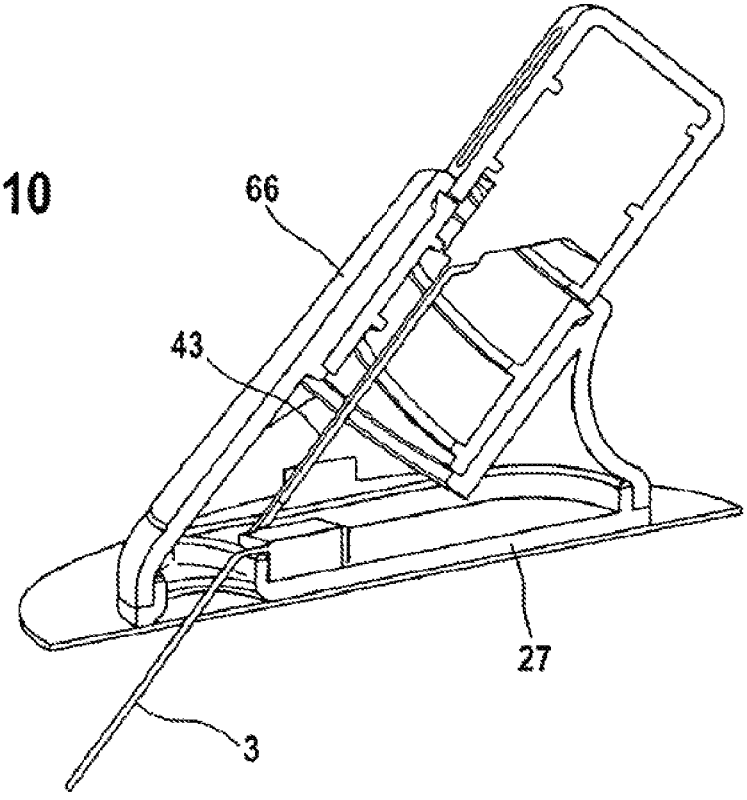


Fig. 10



SYSTEM FOR IN-VIVO MEASUREMENT OF AN ANALYTE CONCENTRATION

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to and is a continuation of U.S. patent application Ser. No. 14/076,428, filed on Nov. 11, 2013, which is a continuation of U.S. patent application Ser. No. 12/052,382, filed Mar. 20, 2008, which claims priority to European Patent Application No. EP 07 005 638.7 filed Mar. 20, 2007 and European Patent Application No. EP 07 024 174.0 filed Dec. 13, 2007, the disclosures of which are hereby expressly incorporated by reference herein in their entirety.

BACKGROUND

[0002] 1. Field of the Disclosure.

[0003] This disclosure relates to a system for in-vitro measurement of an analyte concentration in a human or animal body.

[0004] 2. Description of the Related Art.

[0005] Systems of this type for in-vivo measurement of analyte concentrations usually comprise replaceable sensors as replaceable or consumable components and a long-lived base station to which the replaceable sensors are connected. An example of such system is disclosed in US 2004/0133164 A1.

[0006] In-vitro measurement system can be monitor analyte concentration over many hours or days generate large amounts of data that can be difficult to store and transmit.

SUMMARY

[0007] The measure according to embodiments the invention to have the analytical unit of the base station, in operation, subject to statistical analysis the measuring signals that are supplied as raw data by a sensor connected to it and generate from the raw data condensed measuring data for transmission by the transmitter to the display device, and to have the display device contain an electronic analytical unit, which, in operation, determines an analyte concentration value by analyzing the condensed measuring data, allows the volume of data to be transmitted and therefore the energy consumption to be kept advantageously low while the advantage of a high measuring rate can still be utilized.

[0008] In order to keep the weight of the system components that are carried on the body as low as possible, it is advantageous for the energy consumption of the base station to be as low as possible, since a smaller and lighter-weight battery is then sufficient for supplying this system component with energy for a sufficiently long period of time.

[0009] Preferably, measuring or sensor signals that are supplied by a sensor are recorded for first time intervals, for example of duration from 0.5 seconds to 5 seconds, as raw data. The raw data are then used to generate condensed measuring data for second time intervals, for example of 10 to 1,000 seconds, whereby the second time intervals are at least 10-fold, preferably at least 50-fold, longer than the first time intervals. Preferably, both the first time intervals and the second time intervals each are invariable.

[0010] Accordingly, exactly one measuring signal value that is correlated to the analyte concentration to be determined is stored in the base station for a first time interval. In order to reduce the energy consumption associated with the transmission of data, it is preferred to generate from each at least 10, in particular at least 50, signal values that are stored as raw data a condensed measuring data value for a correspondingly larger time interval.

[0011] Measuring signals can be generated in very short time intervals of, for example, one second through the use of implantable sensors such that very large volumes of raw data may be obtained upon sustained measuring. Another aspect of embodiment of the invention, which may be of significance independently, relates to a method for condensing raw data that were determined using an implanted sensor, in which method pairs of measuring signal values arc formed from the raw data generated for a time interval, then a slope of a line connecting the two values of a pair of values is determined for each pair of measuring signal values, then a median value of the slopes thus determined is calculated, and then a condensed data value is calculated for said time interval from the median value of the slope and the condensed data value of the preceding time interval.

[0012] Since, initially, no condensed data value is available for the first time interval, the median or, for example, the arithmetic mean of the raw data values determined for the first time interval may be used as condensed data value of the first time interval. Raw data values that are non-plausible, for example due to uncommonly strong deviation from the remaining raw data values of a time interval, can be disregarded in the determination of the condensed data value, for example in that they are not used for forming pairs of values.

[0013] Preferably, the measuring signals supplied by a sensor are condensed as raw data in the base station into measuring data in a first step of analysis, the condensed measuring data are transmitted to the display device, and analyte concentration values are calculated from the measuring data by means of the analytical unit of the display device in a further step of analysis. Having a two-step analysis of this type including a first step of analysis in the base station and a further step of analysis in the display device allows the advantages of continuous or quasi-continuous measurement with regard to currentness and accuracy to be utilized and still keep the data volumes to be transmitted by the base station small. In particular, relatively simple and therefore cost-efficient microprocessors in the base station are sufficient for condensing the raw data, for example by forming the mean or by application of the repeated median procedure. For final analysis of the condensed measuring data, a powerful and more expensive microprocessor can be used in the display device, and can be used therein for other tasks as well, for example for a graphic presentation of the analyte concentration values thus determined and linking to other data that have been generated and stored by the display device or originate from other sources. Therefore, another aspect of the invention that may also be of significance independently relates to a system for in-vivo measurement of an analyte concentration in a human or animal body having at least one implantable sensor for generating measuring signals that are correlated to the analyte concentration to be measured, a base station that can be connected to the sensor and contains an electronic analytical unit for analysis of measuring signals of a sensor connected to it, and a transmitter for wireless transmission of analytical results, and a display device that comprises a receiver for receiving the analytical signals transmitted by the base station and a display facility for displaying analyte

concentration values, whereby the analytical unit of the base station, in operation, subjects the raw data supplied by a sensor connected to it to statistical analysis and generates from the raw data condensed measuring data that are then transmitted by the transmitter to the display device, and the display device contains an electronic analytical unit that, in operation, determines an analyte concentration value by analysis of the measuring data.

[0014] Therefore, a further aspect of embodiments of the invention that may be of significance independently relates to a system for in-vivo measurement of an analyte concentration in a human or animal body having at least one implantable sensor for generating measuring signals that are correlated to the analyte concentration to be measured, a base station that can be coupled to the sensor and contains a potentiostat for supplying voltage to a sensor of this type, as well as a receiver and a transmitter for wireless transmission of data, whereby the base station is adapted such that the transmission of data is initiated by receiving a control signal that is transmitted by wireless means. In order to prevent miscommunication with devices that are not part of the system, the control signal can include a characteristic identifier that is used by the sampling device to identify itself with respect to the base station. Likewise, the base station can transmit a characteristic identifier signal when it communicates in order to identify itself.

[0015] The data can, in particular, be condensed measuring data that have been determined by an analytical unit that is contained in the base station from raw data that was obtained as measuring signals of a connected sensor. A control signal initiating transmission of the measuring data can, for example, be transmitted by a display device.

[0016] In systems for in-vivo measurement of analyte concentrations, for example glucose, sensors usually need to be replaced every few days. Replacing a sensor and correctly connecting a new sensor to the base station prove to be cumbersome for many users, in particular for patients whose manual dexterity is restricted due to age or disease. By having the sensor be part of a replaceable sensor carrier unit that comprises a sealed housing in which the sensor is disposed, and having the housing of the sensor carrier unit lock to the base station in order to couple the sensor to the base station, the handling of the system, in particular the replacing of sensors, can be simplified significantly such that a system according to the invention can, in particular, he used by medical laymen also.

[0017] The scaled housing of the sensor carrier unit protects the sensitive sensor from adverse environmental influences. For this reason, the sensor carrier unit can be handled by laymen also without a risk of damaging or contaminating the sensor. Coupling the sensor carrier unit to the base station is made easy by locking. The sensor can be exposed for insertion after coupling, for example by means of a predetermined breaking point for the sensor that is provided on the housing of the sensor carrier unit.

[0018] The sensor can be coupled electrically to the base station by means of a data line, for example in the case of electrochemical sensors being used. If optical sensors arc used, such as those known from U.S. Pat. No. 6,584,335, the sensor can just as well be coupled to the base station by means of an optical data line.

[0019] However, it is also feasible for the sensor carrier unit to communicate with the base station in a wireless fashion, for example inductive or by means of RF1D. Having wireless communication between sensor carrier unit and base station is advantageous in that sealing problems of the sensor carrier unit and base station, which are carried on the body by the patient, arc largely prevented. In particular, the risk of leakage current interfering with measuring results can also be reduced. A wireless communication between the sensor carrier unit and the base station locked to it, i.e. over a very short distance, can be implemented in a cost-efficient fashion, for example by means of inductive coupling. A relatively cost-intensive transmitter with a larger range of, for example, one meter for communication with the display device is only needed in the base station.

[0020] The sensor carrier unit preferably contains a data carrier bearing calibration data of the sensor. This measure is advantageous in that it ensures reliably that data determined by a sensor arc always analyzed using matching calibration data. In particular in the case of a sensor carrier unit that communicates with the base station in a wireless fashion, it can be advantageous to dispose in the housing of the sensor carrier unit a data carrier onto which calibration data can be written through the sealed housing of the sensor carrier unit, for example an electronic memory that can also be read and/or written to by means of RFID. By this means it is feasible to sterilize the entire sensor carrier unit by exposure to radiation, determine the needed calibration data after the sterilization process using random samples of a production hatch, and then write the calibration data onto the data carriers of the sensor carrier units. It is also feasible, though, to dispose the sensor in a first chamber and the data carrier in a second chamber of the sensor carrier unit. By this means, the sensor can be sterilized inside a sealed chamber and a data carrier bearing calibration data can be inserted in the second chamber subsequently.

[0021] The sensor carrier unit preferably contains a battery. This battery can, in particular, also be used for supplying power to the base station such that consumable components of the system according to the invention can advantageously be combined in the sensor carrier unit. It is particularly preferred for the battery to be surrounded by the housing of the sensor carrier unit. This measure is advantageous in that the battery is well-protected and manipulations by users are made more difficult.

[0022] In a system according to the invention, the base station preferably comprises a housing that is adjusted to match the sensor carrier unit and comprises an interface that matches the interface of the sensor carrier unit such that the sensor becomes electrically connected to the base station by placing the housing of the base station against the housing of the sensor carrier unit. A reversible, i.e. subsequently releasable, coupling of the sensor carrier unit to the base station can be implemented, for example, by means of a form-fitting or a non-positive connection. In this context, it is particularly advantageous and therefore preferred for the sensor carrier unit to lock to the base station since this can be perceived by a user such that it is thus signaled to him that the sensor carrier unit is correctly connected to the base station.

[0023] The sensor can, for example, be an amperometric sensor that is supplied with power by a potentiostat that is contained in the base station. However, electrochemical sensors needing no potentiostat can be used for the system just as well, for example coulomb-metric sensors or, for example, optical sensors.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Further details of embodiments of the invention are illustrated by means of exemplary embodiments and reference being made to the appended drawings.

[0025] FIG. **1** shows a schematic view of an exemplary embodiment of a system according to the invention for in-vivo measurement of an analyte concentration in a human or animal body;

[0026] FIG. **2** shows a schematic view of the interaction of the system components of the exemplary embodiment shown in FIG. **1**;

[0027] FIG. **3** shows an exemplary embodiment of a base station and a sensor carrier unit of a system according to FIG. I connected to it;

[0028] FIG. **4** shows a cross-sectional view related to FIG. **3**;

[0029] FIG. **5** shows a sensor housing of the exemplary embodiment shown in FIGS. **3** and **4**;

[0030] FIG. **6** shows components of a further exemplary embodiment;

[0031] FIG. **7** shows a longitudinal sectional view of the components shown in FIG. **6** in the assembled state;

[0032] FIG. **8** shows a base plate of the exemplary embodiment shown in FIG. **7** having an insertion aid for application of the sensor in the body of a patient;

[0033] FIG. **9** shows a longitudinal sectional view through the base plate shown in FIG. **8** having the insertion aid placed on it, before application of the sensor; and,

[0034] FIG. **10** shows a longitudinal sectional view through the base plate shown in FIG. **8** having the insertion aid placed on it, after application of the sensor.

DETAILED DESCRIPTION

[0035] FIG. **1** shows a schematic view of a system **1** for in-vivo measurement of an analyte concentration in a human or animal body. The system I includes, as consumable or replaceable component, a sensor carrier unit **10** having at least one implantable sensor **3** for generating measuring signals that are correlated to the analyte concentration to be measured. The sensor carrier unit **10** has a housing **12** that is shown in FIG. **3** to have a bottom **27** that extends along the body surface when the sensor carrier unit **10** is attached to the body of a patient according to its purpose. The sensor carrier unit **10** contains a battery **5** and a data carrier **11** bearing calibration data of the sensor **3**. The battery **5** and the data carrier **11** are disposed within the housing **12** of the sensor carrier unit **10** such as to be inaccessible to a user in order to exclude, to the extent possible, erroneous results or damage from inappropriate handling.

[0036] The sensor carrier unit **10** can be connected to a base station **2** by means of a catch mechanism. The base station **2** is a multiply usable component of the system **1**. A spent sensor carrier unit **1 0** can be uncoupled from the base station **2** and replaced by a new sensor carrier unit **10**. The base station **2** contains a potentiostat **48** for supplying voltage to a sensor **3** of a sensor carrier unit **10** connected thereto, an electronic analytical unit **47** for analysis of measuring signals of a sensor **3** connected thereto, and a communication unit **31** having a transmitter for wireless transmission of analytical results. The base station **2** further contains an electronic intermediary memory **60** for storing measuring values or data obtained therefrom. In the exemplary embodiment shown, the base station **2** contains a memory for intermediate storage of raw data, for example a RAM memory, and a memory for storing condensed measuring data, for example an EEPROM or flash memory, until such data is transmitted and/or for the storage of data that were passed on to the base station **2** by the display device **4**.

[0037] The sensor carrier unit **10** has a housing **12** having an interface for electric connection of the sensor **3** to the base station **2**. In corresponding fashion, the base station **2** has a housing that is adapted to match the sensor carrier unit **10** and comprises an interface that matches the interface of the sensor carrier unit **10** such that the sensor **3** can be connected electrically to the potentiostat **48** by placing the housing of the base station **2** against the housing **12** of the sensor carrier unit **10** such that sensor contacts **3***a*, **3***b*, and **3***c* are connected to connections **6***a*, **6***b*, and **6***c* of the base station. In the process, the battery **5** and the data carrier **11** are also connected to contacts **7***a*, **7***b* and **8***a*, **8***b*, respectively, of the interface of the base station **2**. The mutually matching interfaces of the sensor carrier unit **10** and base station **2** can form a plug-in connection whereby the male part of the plug-in connection can be disposed on the base station **2** and the female part on the sensor carrier unit **10** or vice versa.

[0038] A start-up is caused by connecting the sensor carrier unit. **10** to the base station **2**, in particular the measuring process of sensor **3** is initiated in this way. Accordingly, the sensor **3** is activated by coupling to the base station **2** such that it commences to supply measuring signals. A reset and initialization command for this purpose can be effected in a processor forming the analytical unit **47** upon connecting the sensor carrier unit **10** to the base station **2**. This measure is advantageous in that no switch is required to switch-on the system and the start-up of the system is effected by a defined action of the user, namely by connecting a sensor carrier unit **10** to the base station **2**. As soon as a voltage is applied by connecting the battery to the potentiostat **48**, charge carriers are automatically transported away from the working electrode such that the risk of charge accumulation is minimized.

[0039] A further long-lived component belonging to the system is a display unit **4** that comprises a receiver **30** for receiving the data transmitted by the base station **2**, and a display facility **29**, for example a liquid crystal display, for displaying analyte concentration values. The receiver **30** of the display device **4** preferably also contains a transmitter and the transmitter **31** of the base station also contains a receiver such that a bidirectional communication between base station **2** and display device **4** is feasible. Transmissions of the base station **2** and of the display device **4** can be characterized by means of an identifier, for example a bit sequence. In order to exclude miscommunication with devices of other patients, signals that do not bear the expected identifier may be ignored by the base station **2** and the display device **4**.

[0040] The distribution of functions and components to the system components, sensor carrier unit **10**, base station **2**, and display device **4**, as described, allows an optimal result to be attained with regard to the weight of the system components that are to be carried on the body, the costs, and the user convenience. Consumable components of the system, for example sensor **3** and battery **5**, are part of the sensor carrier unit **10** that needs to be replaced periodically, for example every 5 days, such that all consumable components can be replaced as easily as possible. In order to

generate measuring data using a sensor **3** of the sensor carrier unit **10**, aside from the consumable components, long-livcd system components, such as for example the potentiostat **48** and an analytical unit, are also required. The distribution of these long-lived system components to the base station **2**, which is also carried on the body, and the display device **4** was effected to provide the best-possible user convenience in order to be able to implement the base station **2** to be as small and lightweight as possible. For this reason, the base station **2** contains a potentiostat **48** for supplying a sensor **3** connected to it, a transmitter for transmitting data to the display device **4**, and an analytical unit **48** for preliminary analysis of the measuring data supplied by a sensor connected to it. The base station **2** needs to have no own display facility since this function is assumed by the display device **4**. Having a preliminary analysis in the base station **2** in combination with a final analysis in the display device **4** allows the volume of data to be transmitted to be kept low. Accordingly, the base station **2** needs just a small memory, a simple analytical unit, and little energy such that a patient is required to carry as little mass as possible on the body.

[0041] The display device **4** can be equipped with a large memory and complex analytical electronics, in particular a powerful microprocessor, and therefore can perform even extensive mathematical analyses of data over long periods of time. In particular, the display device **4** can test for a newly implanted sensor whether or not the new sensor works properly by means of a comparison with measuring data of earlier sensors or defined level and/or gradient values and form factors or samples. Moreover, the display device **4** allows its user the convenient entry of patient data, for example individual threshold values, whereby the display unit **4** can generate a warning signal when these are exceeded or not reached. In addition to an analytical, display, and warning function, the display device **4** can also assume the function of a data and communication center with regard to further components of the system, for example an injection device.

[0042] According to its purpose, the base station **2** and the sensor carrier unit **10** are carried on the body by a patient during the in-vivo measurements. In the process, the electrochemical sensor **3** projects into the body of the patient and is supplied by the potentiostat **48** that is contained in the base unit. While measuring, a current flows between the working electrode and the counter-electrode of the sensor **3** with its amplitude being correlated to the analyte concentration to be measured, such as being proportional to it in an ideal case. In the process, the potentiostat **48** varies the electrical potential applied to the counter-electrode such that the potential of the reference electrode of the sensor **3** remains constant.

[0043] The system **1** shown can be used to monitor an analyte concentration in the body of a patient in a continuous or quasi-continuous fashion. This means that the sensor **3** can be used to perform measurements in short time intervals of less than 5 minutes, in particular of less than 1 minute or even less than 10 seconds. A measurement can be effected in this context by means of digitizing a raw signal, for example an electrical current, in order to generate a measuring signal. Further data can be collected simultaneous with these measurements, for example temperature and/or electrode voltages that can be used for plausibility checking and/or error compensation.

[0044] Measurements are taken in the system **1** described here at time intervals of approx. one second, for example between 0.5 and 2 seconds, such that very large volumes of raw data accrue. The measuring signals supplied by the sensor **3** in time intervals of this type can be values of a continuous signal that has already been amplified and/or filtered, for example using a low-pass filter, in order to filter out electrical interference such as can be generated by the frequency of the public electrical power network (50 Hz or 60 Hz), noise or radio communication. The cut-off frequency of a low-pass filter of this type is preferably between 3 Hz and 50 Hz, in particular between 5 Hz and 20 Hz. In this context and in accordance with general usage, cut-off frequency is understood to mean the frequency at which the low-pass filter effects 3 dB of attenuation.

[0045] Low-frequency interference in the measuring signals that may arise, for example, from disturbances of the electrochemistry at interfaces between the sensor and surrounding body tissue, can be removed by means of filter algorithms, for example, by the repeated median procedure described in the application.

[0046] The measuring signals supplied by a sensor **3** being in operation are subjected to a preliminary analysis by the analytical unit **47** that is contained in the base station **2**. In the process, the measuring signals are subjected to statistical analysis as raw data and condcnscd measuring data are thus produced from the raw data. The condensed measuring data are generated by the base station **2** for constant consecutive time intervals of, for example, one minute such that an unambiguous assignment of the time of the measuring data exists that results from the sequence and size of the time intervals. Subsequently, the condensed measuring data are transmitted in a wireless fashion to the display device **4** and further analyzed therein by means of an analytical unit, for example a microprocessor, in order to determine analyte concentration values.

[0047] In the exemplary embodiment shown, the base station **2** contains a memory in which the condensed measuring data can be stored such that they need not be transmitted right after being generated. The data sets stored can be provided with a check code that allows the condensed measuring data to be checked for data corruption and erroneous measuring data to be recognized in subsequent steps of analysis. Status information of the base station **2**, for example the charge status of the battery, results of internal functional tests and similar information can also be stored in the memory jointly with the measuring data. This status information can be stored as status code, for example as byte, and taken into account in the analysis.

[0048] Particularly efficient storage of the condensed measuring data can be attained by storing only the deviation from a preceding measuring data value as the measuring data value. By this means, it is sufficient to fully store the first measuring data value in the memory. All subsequent values can then be characterized unambiguously by their difference from the preceding measuring data value such it is sufficient to store this difference.

[0049] The measuring signals to be condensed are stored only temporarily as raw data in the base station until the condensed measuring data are generated. The base station **2** therefore comprises a raw data memory whose content is overwritten as soon as a condensed measuring data value was determined for the measuring signals of a time interval and there is no longer a need for the measuring signals. It

may be advantageous for some applications to provide for the option of later access to the raw data. This can be attained, for example, by transmitting raw data prior to over-writing them. This transmission can proceed unidirectional, i.e. without the reception of such data being confirmed by means of a receiving signal by a receiving device that stores the raw data. The base station **2** can comprise an additional transmitter for unidirectional transmissions.

[0050] FIG. **2** shows a schematic view of the interaction of the various system components. To the left of the dashed line are shown the sensor **3** and components of a base station **2** connected thereto, whereas components of the display device **4** are shown to the right of the dashed line.

[0051] The base station **2**, in operation, supplies the sensor **3** with voltage **49** of an amplitude that can depend on calibration data **50** that arc stored on the data carrier **11** shown in FIG. **1**. The sensor **3** supplies measuring signals **32** that are being digitized by an analog-digital converter **33** and subsequently subjected to statistical analysis as digital raw data **51** by the analytical unit **47**, preferably a microprocessor. In the process, condensed measuring data **36** are generated from the raw data **51**. The condensed measuring data **36** are placed in a memory **35** that can be accessed both by the analytical unit **47** and the communication unit **31** that contains a transmitter and a receiver. In order to prevent access conflicts, the analytical unit **47** and the communication unit **31** are connected to the memory **35** by means of a changeover switch **34** which provides access to the memory **35** either to the analytical unit **47** or to the communication unit **31** depending on its switch status.

[0052] The communication unit **31** of the base station **2** reads-out the condensed measuring data **36** from the memory **35** and transmits them to a communication unit **30** of the display device **4**. In the exemplary embodiment shown, the communication unit **30** contains a transmitter and a receiver such that a bidirectional data exchange is feasible. However, it is also feasible for the condensed measuring data **36** to be transmitted unidirectionally by the communication unit **31** of the base station **2**. It is feasible, in particular, to equip the analytical unit **47** with a transmitter **61** for unidirectional transmission of raw data.

[0053] The condensed measuring data **36** are analyzed in the analytical device **4** by the analytical unit **52**, for example a microprocessor, contained therein in order to determine analyte concentration values **53** that can be displayed by the display facility **29** and stored in a memory **54**, like the condensed measuring data **36**. During the analysis of the condensed measuring data **36**, the analytical unit **52** of the display device **4** also performs a calibration taking into account measuring results of a measuring device **56** that is integrated into the display device **4** and determines the analyte concentration of a body fluid sample that was obtained, for example, from a small puncturing wound.

[0054] During the analysis of the condensed measuring data **36**, the analytical unit **52** of the display device **4** can add a time of day and a date to the condensed measuring data **36** and the analyte concentration values determined therefrom by using a real-time clock **55**, since the condensed measuring data apply to time intervals of constant duration.

[0055] The statistical analysis of the measuring signals in the base station **2** can, in the simplest of cases, be the formation of a mean. However, the statistical analysis can just as well include filter and/or correction algorithms to exclude or correct error-containing values from the further analysis by filtering. Kalman filter procedures, for example, are suitable for this purpose.

[0056] A repeated median procedure can be used as method for filtering and condensing of the raw data. In a procedure of this type, the median value of the slopes between pairs of measuring signal values of a time interval is formed. Extreme, and therefore implausible, raw data values can be disregarded in this formation of the median, for example values that deviate by more than a given threshold value from the mean of all remaining raw data values of said time interval. However, it is also feasible in the formation of the median to actually take into account in the formation of the median of the slope all pairs of values that can possibly be formed from the raw data values of said time interval.

[0057] A measuring data value is then calculated for the current time interval from the median value of the slope and the condensed measuring data value for the preceding time interval. For this purpose, the product of the median value of the slope times the duration of the time interval can be added to the measuring data value of the preceding time interval. For the very first time interval, the median, for example, of the raw data values contained in said time interval can be used as condensed measuring data value.

[0058] In the repeated median procedure described above, it is favorable to select the time intervals for which a condensed measuring data value each is calculated from the median of the slope and the preceding measuring data value such that they overlap. It is also feasible, in particular, to apply the repeated median procedure multiply, i.e. to generate, for example, condensed or compressed measuring data values from raw data values in a first step and to further compress the compressed measuring data values by repeated application of the repeated median procedure in a further step.

[0059] To have a two-stage analysis, in which a first stage of analysis is performed in the base station **2** and a second stage of analysis is performed in the display device **4**, allows even very large volumes of raw data to be processed and thus to fully reap the advantages of continuous or quasi-continuous measurement with regard to relatedness to real-time and accuracy. Despite this fact, only small data volumes need to be transmitted from the base station **2** to the display device **4**. Consequently, the energy consumption of the base part **2**, which is being carried on the body, is low such that a small, light-weight, and cost-efficient battery **5** is sufficient to satisfy the energy need of the base part **2** and sensor carrier unit **10**. The two-stage analytical procedure therefore contributes to reducing, to the extent possible, the weight the patient needs to carry on the body and thereby increasing the user convenience.

[0060] In order to minimize the data traffic between the base station **2** and the display device **4**, a complete analysis of the raw data could be effected in the base station **2** such that only analyte concentration values needed to be transmitted to the display device **4**. In the two-stage analysis described above, though, only little processor power is required in the base station **2** such that a particularly cost-efficient microprocessor can be used as analytical unit **47**. It is another advantage of the two-stage analytical procedure described above that a calibration of the measuring data can be performed in the display device **4** within the scope of the second analytical step by means of a control

measurement. For this purpose, the display device **4** contains a measuring facility for determining an analyte concentration of a body fluid sample. This measuring facility can, for example, be structured in accordance with commercial blood sugar measuring devices and determine the glucose concentration of a body fluid sample that is applied to a test strip **28** by photometric or electrochemical means. Since the analytical unit of the display device **4** is connected to the measuring facility, the analyte concentration values that have been determined on body fluid samples can be used for calibration during the analysis of measuring data that have been transmitted to the base station **2**.

[0061] Aside from a measuring facility for determining an analyte concentration of a body fluid sample, the display device **4** can also comprise an input option for the input of patient data. Patient data can be, for example, information regarding meals that have been taken up or individual threshold values for the measuring data, with a warning signal being generated when these are exceeded or not reached. Moreover, the display device **4** can be adapted for communication with additional system components, for example an injection device or a higher-level HOST system, for example the PC of a physician, care provider or clinic.

[0062] The display device **4** is equipped with a transmitter **30** for transmitting control signals and the base station **2** is equipped with a receiver **31** for receiving control signals as well as with an electronic memory for storing the condensed measuring data. The transmission of the condensed measuring data is triggered by a control signal that is transmitted by the display device **4**. The display device **4** confirms receipt of the measuring data by transmitting a confirmation signal.

[0063] The display device **4** contains a clock for determining the actual time. When the display device **4** receives condensed measuring data from the base station **2**, the current measuring data value can be marked with a current time mark, in which the current time of day and date are coded, and stored. The time marks of forward-progressive measuring data values can be calculated based on said time mark. If, for example, a condensed measuring data value is generated for consecutive time intervals of one minute each, the time of day for which measuring data values were determined can be calculated for all measuring data values by incrementally decreasing the time by one minute each.

[0064] The display device **4** contains a memory that is sufficiently large to store measuring data that were determined over multiple sensor carrying periods, i.e. over multiple days using different sensor carrier units **10**. In the process, measuring data from different sensors **3** can each be provided with a sensor identifier such that information, such as the measuring time, can be calculated for the individual measuring data values from the sensor identifier and the time of day the measuring data of a sensor were received.

[0065] Upon repeated access of the display device **4** to the base station **2** in the exemplary embodiment shown, only measuring data that have been newly generated in the meantime are transmitted in order to minimize the transmission time and transmission energy. The time of the most recent access can be stored in the display device **4** in a data header, in which other general data, for example identifiers of the sensor carrier unit and time format, e.g. Universal Time Convention, can be stored as well.

[0066] The memory of the base station **2**, in which the condensed measuring data are stored, can be provided with a lock that permits over-writing of measuring data when a new sensor carrier unit **10** is connected only after the measuring data have been sent to the display device **4** and receipt of the data has been confirmed. For example, the start-up of the base station **2** that is effected by connecting a new sensor carrier unit **10** may initially effect the transmission of existing measuring data before new measuring data are recorded However, it is also feasible to select the memory of the base station **2** to be sufficiently large such that more measuring data than those generated with one sensor carrier unit **10** in, for example, 5 days can be stored in the memory of the base station **2** before it needs to be replaced. Automatic transmission of measuring data prior to replacement of a sensor carrier unit **10** can ensure that a time mark can be determined by the display device **4** for all measuring data that are stored in the base station **2**. Unless measuring data are generated continuously, there is a risk of data loss with regard to the allocation to an unambiguous time mark.

[0067] During replacement of a sensor it is common that no measuring data are generated for an indefinite period of time. In order to ensure that each measuring value can be allocated unambiguously to an absolute time, a sensor start data and time of day is stored for each sensor in the memory of the base station **2**. If transmission of any old data, generated using the preceding sensor, to the display device **4** is required prior to the connection of a new sensor, the sensor start date and time of day can be made available without any difficulty by the display device **4**. The sensor start date can be stored in the base station **2** and can be stored in a data header that is transmitted jointly with condensed measuring data. However, it is also feasible to store the sensor start-up date and time of day in the display device and utilize it to determine the times of the individual measuring data values. If measuring values for constant consecutive time intervals are determined, this allows to determine for each measuring value at which time it was measured even upon a change of sensors.

[0068] FIG. **1** shows connection contacts **6***a*, **6***b*, **6***c* of the base station **2** for connecting the sensor **3**, and connection contacts **7***a*, **7***b* of the base station **2** for connecting the battery **5**. Moreover, the base station **2** further has at least one data input **8***a*, **8***b* for connection and read-out of a data carrier **11** bearing calibration data. These calibration data identify the sensitivity of the sensor **3**, which is an electrochemical sensor that contains, for example, an enzyme that generates, by catalytic conversion of the analyte, charge carriers that can be measured in the form of an electric current flowing between the electrodes of the sensor. If the analyte is glucose, for example, the enzyme can he a glucose oxidase.

[0069] Usually, sensors for measuring analyte concentrations of body fluids, for example blood or interstitial fluid, cannot be manufactured to have exactly predetermined measuring sensitivities. Typically, there is substantial variation of the sensor sensitivity between production batches that can be taken into account in the analysis of measuring signals of a sensor by means of calibration data. The calibration data usually are determined by the manufacturer either using the respective sensor itself or by means of random samples of other sensors of the respective production batch. Calibration data of this type generally describe the difference between an ideal sensor sensitivity and a determined sensor sensitivity.

[0070] The data input **8***a*, **8***b* is coupled to spring elements **9** that render connecting a data carrier easier by means of

spring force. Preferably, the data carrier **11** is a memory chip such that the data input is formed by electrical connection contacts. The data carrier **11** can, for example, just as well be an RFID or a magnetic data carrier, and, accordingly, the data input **8***a*, **8***b* can comprise a reading head. In the exemplary embodiment described, the calibration data that are read by the data carrier **11** are transmitted from the base station **2** to the display device **4** and used therein for analysis of the measuring data. It is also feasible to already process the calibration data in the base station **2** and generate condensed measuring data, in which the calibration data are taken into account. This allows a risky mix-up of data carriers **11** bearing calibration data for different sensors **3** by a user to be prevented.

[0071] The base station **2** contains a test circuit **26** that is connected to the potentiostat **48** and supplies one response signal or more response signals to the analytical unit **47** of the base station **2** during a system test, which response signal(s) is/are analyzed by the analytical unit **47**, whereby the analytical unit **47** compares a value of the at least one response signal to an expected value and generates an error signal if the value of the at least one response signal deviates from the expected value by more than a predetermined tolerance value. This error signal can be transmitted, for example, via the transmitter **31** to the display device **4** which, in turn, indicates the error to a user. The test circuit simulates a sensor **3** being connected to the potentiostat **48** such that the analytical unit **47** can use the test circuit **26** to check the proper function of the potentiostat **48** and the charging status of the battery **5**. In the simplest case, the test circuit **26** can be provided in the form of a switchable fixed-value resistor.

[0072] The housing **12** of the sensor carrier unit **10** has at least two separate chambers **13**, **14**, **15**, whereby the sensor **3** is disposed in the first chamber **13** under sterile conditions, and the data carrier **11** bearing calibration data of the sensor **3** and a battery, if applicable, are disposed in a second chamber **14**. In the exemplary embodiment shown, the battery **5** is disposed in a third chamber **15**.

[0073] The housing **12** is adapted to an interface of the base station **2** such that the sensor **3** contained in the housing **12** and the corresponding data carrier **11** can be connected to the base station **2** by placing the housing **12** against the interface. Connecting the sensor carrier unit **10** to the base station **2** initializes the measuring system **1** automatically and starts-up the measuring process.

[0074] The housing **12** contains a spring element **20** that supports the process of connecting the battery **5** when the housing **12** is placed against the interface of the base station **2**. In corresponding fashion, spring elements can be disposed also in the first chamber **13** and in the second chamber **14** in order to support the process of connecting the sensor **3** and/or the data carrier **11** to the base station.

[0075] In the exemplary embodiment shown, the housing **12** and the interface of the base station **2** are adapted to each other such that, firstly, the battery **5** and the data carrier **11** are connected to the base station **2** when the housing **12** is placed against the interface, and only thereafter the sensor **3** gets connected to the base station **2** by means of the contacts **6***a*, **6***h*, **6***c* that are provided for this purpose. In the exemplary embodiment shown, the sensor **3** is flat in structure and is connected to the base station **2** by means of a zero insertion force connector **3***a*. The sensor **3** can just as well be of sandwich structure or made up to be wire-shaped or rotationally symmetrical and the contacts **6***a*, **6***b*, **6***c* may be provided to match.

[0076] In this context, a seal **21** of the base station **2**, which is provided in the form of a gasket in the exemplary embodiment shown, provides for water-tight coupling of the sensor **3** to the base station **2**, such that no moisture can penetrate into the internal space of the base station **2**. Accordingly, the base station **2** can be carried, for example, on the stomach of a patient without getting damaged by body fluids. The seal **21** effects high-resistance sealing of the base station **2** and the connected sensor **3**. By this means, the sensor **3**, being provided in the form of an electrochemical sensor, can be supplied with voltage by means of the potentiostat **48** that is disposed in the base station **2** without any interference by leakage currents.

[0077] FIG. **3** shows an oblique view of an exemplary embodiment of the base station **2** with sensor carrier unit **10** being connected to it. FIG. **4** shows a cross-sectional view related to FIG. **3**, in which the sterile housing chamber **13** and sensor **3** disposed therein as well as the second housing chamber **14** and battery **5** and data carrier **11** of the sensor carrier unit **10** being disposed therein are shown. Also shown is that the base station **2** contains a potentiostat **48** for supplying current and voltage to the sensor **3**, and an analytical unit **47** that is provided in the form of a microprocessor, and a transmitter and a receiver **31** for wireless communication with the display device **4**, whereby the antenna or antennae for wireless communication with the display device **4** are surrounded by the housing of the base station **2**.

[0078] Like the housing of the base station **2**, the housing **12** of the sensor carrier unit **10** is made of rigid plastic material. The interfaces of base station **2** and sensor carrier unit **10** are provided for a form-fitting connection in the exemplary embodiment shown. The housing **12** comprises catch pegs **40** that engage recesses of the base station **2** that match them. These recesses are disposed on the outsides of two spring legs **41** such that the catch pegs are pressed into the recesses by spring force. The spring legs **41** can be compressed such that the catch pegs **40** of the sensor carrier unit **10** detach from the recesses matching them and the sensor carrier unit **10** can be taken off the base station **2**. With the spring legs **41** being compressed, the sensor carrier unit **10** can be placed against the base station **2** in corresponding fashion.

[0079] Alternatively or in addition to a form-fitting connection, the sensor carrier unit **10** can just as well be provided such that it can be connected to the base station **2** in a friction-locked fashion.

[0080] The cross-sectional view shown in FIG. **4** shows that the sensor carrier unit **10** comprises two separate chambers **13**, **14**, whereby the sensor **3** is disposed in a first chamber **13** under sterile conditions and a data carrier **11** bearing calibration data of the sensor **3** and a battery **5** for supplying electrical power to the base station **2** are disposed in the second chamber **14**. Connection lines of the sensor **3** lead out from the first chamber **13** into the second chamber **14** to a printed board **45** that is contacted to the data carrier **11** that is provided in the form of a memory chip. The printed board **45** is connected to the base station **2** by means of a plug-in connection **46**, a multi-pole plug-in connection in the exemplary embodiment shown.

[0081] The sterile chamber **13**, in which the sensor **3** is stored, is closed off by means of two Septa **42**, whereby an insertion needle **43** for insertion of the sensor **3** into a human or animal body is guided through the Septa **42**. The front end of the insertion needle **43** protruding from the housing chamber **13** is surrounded by a sterile protective cap **44** that is taken off only when the sensor **3** is to he inserted into a human or animal body by means of the insertion needle **43**. The sterile protective cap **44** envelopes the insertion needle without touching it and is connected to the remaining housing **12** by a predetermined breakage site **16**.

[0082] For carrying convenience, it is advantageous for the sensor carrier unit **10** to have a sensor opening through which the sensor **3** or its connection line **39** is guided and which is situated as far as possible from the edge of the bottom **27** of the sensor carrier unit **10** in order to minimize tilting moments. In the exemplary embodiment shown, the sensor opening is disposed to be situated more than **1** cm distant from the edge of the bottom **27**. It is feasible just as well, in particular, to dispose the sensor opening in the center of base plate **27**, or in a position that deviates from the center by less than **20**% of the length of the base plate, in particular deviates from the center by less than **10**% of the length of the base plate.

[0083] For insertion of the sensor **3**, the sensor carrier unit **10** is disposed, fur example, on the stomach of a patient and the insertion needle **43** is punctured into the body of the patient. Subsequently, the insertion needle **43**, which can, for example, be provided in the form of a groove carrying the sensor **3**, can be retracted from the body of the patient, whereby the sensor **3** remains inside the body of the patient. In order to attain particularly good sealing against pathogens, a front region, in the direction of puncturing, of the insertion needle **43** can be provided in the form of an open groove adjacent to which there is a region that is provided in the form of a tube. Said tube-shaped region can be guided through a septum closing off the housing such as to be sealed against pathogens.

[0084] As a matter of principle, the insertion can proceed under any angle between the direction of puncturing and the surface of the skin. Angles between 30° and 60° are particularly advantageous for an insertion into subcutaneous fatty tissue. The sensor **3** has a sensor head **38** that is designed to be implanted and an electric connection line **39** that is connected to the sensor head **38**, whereby the connection line is guided in an arc in the housing **12** of the sensor carrier unit **10**, preferably being arced by 30° to 150°. The sensor carrier unit **10** shown is provided such that a user can actually see the puncturing site during the insertion of the sensor **3**.

[0085] The sensor carrier unit **10** has a base plate **27** which, according to its purpose, is glued to the body of the patient. The base station **2** is placed on the sensor carrier unit **10**, on the base plate **27** to be more exact. The housing of the base station **2** then touches laterally against the housing **12** of the sensor carrier unit **10**. The base plate **27** has an adhesive surface that is protected by a film that can be peeled off, and which is multi-part and whose parts each cover different areas of the adhesive surface and are separated from each other when the film is peeled off. Said adhesive surface can, for example, be provided in the form of a double-sided adhesive film or a pad that is adhesive on both sides such that one adhesive surface can be glued to the bottom side of the sensor carrier unit **10** and the other adhesive surfaces, according to its purpose, can be glued to the skin of a patient. The films for protecting the adhesive surfaces can be provided like in commercial plasters. The films can be removed more easily from the adhesive surfaces if the adhesive surfaces arc protected by multi-part films. By this means it is possible, for example, to proceed with adhesively attaching the sensor carrier unit **10** only after insertion of the sensor, since the individual parts of the films protecting the adhesive surfaces can be pulled from under the sensor carrier unit **10** from different directions.

[0086] Preferably, the carrier of the adhesive surface, for example a film or a pad, is stretchable such that the carrier can be removed from the body of the patient at a later time by pulling with the force vector of pull extending parallel to the plane of the adhesive surface. Adhesive pads with corresponding elastic properties arc commercially available, for example for attaching posters, under the brand name of tesa powerstrips.

[0087] A carrier of the adhesive surface that is suitable for attaching the sensor carrier unit **10** can be made, for example, from a foam, in particular a polyurethane foam. A carrier made of foam has the additional advantage that it reduces relative motions of the body with respect to the sensor carrier unit **10**.

[0088] During the manufacture of the sensor carrier unit **10**, the sensor **3** is initially disposed in the first housing chamber **13** and the chamber is then sealed. In order to manufacture the exemplary embodiment shown in FIG. **4**, a sterile protective cap **44** is also disposed in this assembly step around the end of the sensor **3** that protrudes from the first housing chamber **13** and around the insertion needle **43** that carries the sensor **3**, and the sterile protective cap **44** is connected to the housing chamber **13**. Subsequently, the housing chamber **13** is exposed to intense radiation, for example electron radiation, such that the sensor **3** and the insertion needle **43** are sterilized. FIG. **4** shows a detailed view of the first housing chamber **13** with the sterile protective cap **44** being attached to it and these being sterilized jointly by radiation exposure after insertion of the sensor **3**.

[0089] In a further assembly step, the first housing chamber **13** is joined with the second housing chamber **14** in order to create the sensor carrier unit **10**. In this process, an insertion aid **37** can be attached to the sensor carrier unit **10** that renders the puncturing of the sensor **3** and/or of an insertion cannula carrying the sensor into the body of a patient easier. The insertion aid can comprise a spring that can already be pre-tensioned on delivery of the sensor carrier unit or can be tensioned by the user by means of a pre-tensioning lever (not shown). A user can trigger the tensioned insertion spring by actuating a trigger button and thus effect a puncturing of the sensor or of an insertion cannula **43** carrying it.

[0090] In the exemplary embodiment described previously, the sensor carrier unit **10** communicates with the base station **2** via electrical lines. The sensor carrier unit **10** therefore has an interface having electrical contacts **3***a*, **3***b*, **3***c* that contact electrical contacts **6***a*, **6**h, **6***c* of an interface of the base station **2** in order to couple the sensor carrier unit **10** to the base station **2**. However, the exemplary embodiment described previously can just as well be modified such that the sensor carrier unit **10** communicates with the base station **2** in a wireless fashion. A data exchange can proceed, for example, by inductive coupling or RF-ID. This means makes the sealing of the base station **2** and also of the sensor

carrier unit **10** easier. As another advantage of this measure, the risk of falsification of measuring signals by leakage currents can be reduced markedly.

[0091] A sensor carrier unit **10** that is equipped for wireless communication with a base station **2** contains a potentiostat **48**, like the one disposed in the base station **2** in the exemplary embodiment described previously. The sensor carrier unit **10** preferably contains, in addition, a preamplifier for amplification of sensor signals.

[0092] The advantages of supplying power to the base station **2** by means of a battery **5** that is disposed in the sensor carrier unit **10** can be utilized also in the case of a wireless communication between the sensor carrier unit **10** and the base station **2**. For example, energy can be transferred from the sensor carrier unit **10** to base station **2** via inductive coupling. In order to generate the alternating voltage required for inductive coupling, a chopper can be disposed in the sensor carrier unit **10** in addition to the battery **5**.

[0093] FIG. **6** shows components of a further exemplary embodiment that differs from the exemplary embodiment described previously only in its mechanical structure. The base station **2** is structured in the form of an electronics unit that has contacts **6***a*, **6***b*, **6***c* for connection to a sensor **3** and, like the base station **2** of the exemplary embodiments described previously, contains an analytical unit, a potentiostat, a test circuit as well as transmitter and receiver for communication with a display device. Unlike the exemplary embodiments described previously, the base station **2**, in use, is protected by a removable housing that is formed by a base plate **27** and a housing lid **64** that can be placed thereupon.

[0094] In order to protect its electronic components while it is being handled by the user, the base station **2** has a separate housing which preferably is not removable. This housing can also effect electrical screening and insulation. It can, for example, be made of an epoxy casting compound or of injection molding parts.

[0095] The base plate **27** that is carried on the body forms the sensor carrier unit **10** in the exemplary embodiment shown in FIG. **6**. The base plate **27** has a hole through which the sensor **3** can be inserted into body tissue of a patient during the insertion process. According to purpose, the housing lid **64** is placed on the base plate **27**. The base plate **27** has catch or locking elements in order to hold the housing lid **64** in place. In addition, the base plate **27** carries a seal **63**, for example an 0-ring or a sealing lip, for sealing an internal space that is then enveloped by the base plate **27** and the housing lid **64**. Seal **63** and catch means can, alternatively or in addition, be provided just as well on the housing lid **64**.

[0096] FIG. **7** shows a longitudinal sectional view through the system components, in the assembled state, shown in FIG. **6**, in which a patient carries the unit on the body. In the process, the seal **63** effects sealing at the sensor shaft in front of the contacts **6***a*, **6***b*, **6***c* of the base station **2** such that these are protected in a hermetically sealed internal space.

[0097] The housing lid **64** has a transparent viewing window **65** through which the sensor puncturing site and thus the hole provided in the base plate **27** for the sensor **3** can be viewed. Having this viewing window **65** thus allows the sensor puncturing site to be checked visually such that problems, for example inflammations, can be detected at an early time.

[0098] FIG. **6** shows that a battery **5** is disposed in the housing lid **64**. However, the battery **5** can be disposed in the base plate **27** just as well. It is preferred for the battery **5** to be easy to remove by the user after removal of the housing lid **64** such that the battery can be disposed of separately.

[0099] Base plate **27**, housing lid **64**, battery **5**, and sensor **3** arc consumables designed for single use only, whereas the base station **2** can be used multiply. The consumable parts are packaged jointly with an injection aid **66** shown in FIGS. **8** to **10** during the manufacturing process and sterilized by exposure to radiation. Sterilization of the battery **5** is not absolutely necessary.

[0100] FIGS. **8** to **10** illustrate the individual steps involved in the application of a sensor **3** in the body of a patient. In a first step, the base plate **27** is glued to the body of a patient. Then an insertion aid **66** is placed on the base plate **27**, the insertion aid **66** preferably catches onto the base plate **27**. FIG. **9** shows a longitudinal sectional view of the insertion aid **66** with a matching base plate **27**. The insertion aid **66** contains an injection needle **43** that can be punctured through the opening of the base plate **27** into the body of a patient. In the process, a sensor **3** that has been disposed in the injection needle **43** by its manufacturer, is inserted into the body of a patient.

[0101] The sensor **3** is advanced jointly with the insertion needle **43** by the user in a guided linear motion at an angle that is predetermined by the insertion aid **66**. This linear motion can just as well be effected by rotation or a shear motion though this should best not generate a transverse motion with respect to the puncturing site. The insertion motion can also be effected with an automatic mechanism. For example, the puncturing of the insertion needle **43** can be supported by a spring.

[0102] After the puncture, the insertion needle **43** is retracted, whereby the sensor **3** remains inside the body of the patient. Subsequently, the insertion aid **66** can be removed from the base plate **27**. In a final step, the housing lid **64** having a base station **2** contacting the battery **5** disposed therein is placed on the base plate **27**. The base station **2** thus contacts the sensor **3**. The system then commences to work automatically. Accordingly, as soon as the housing lid **64** having a base station **2** is placed on the base plate **27**, measuring signals are generated and subjected to statistical analysis and condensed by the analytical unit contained in the base station **2**. The condensed raw data generated by this means arc transmitted by a transmitter of the base station **2** to a display device **4**, as is shown in Fig. I.

[0103] Preferably, a data carrier **11** (not shown) bearing calibration data of the sensor **3** is situated on the housing lid **64** or on the base plate **27**, as is described with reference being made to FIG. **1**, which data carrier II contacts the base station **2** and is read-out by it in the operational state shown in FIG. **7**.

[0104] Thus, embodiments of the system for in-vitro measurement of an analyte concentration are disclosed. One skilled in the art will appreciate that the teachings can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the invention is only limited by the claims that follow.

1. (canceled)

2. A system for in-vivo measurement of an analyte concentration in a human or animal body, comprising:

at least one implantable sensor configured to generate measuring signals correlated to the analyte concentration to be measured;

a base station operably coupled to the at least one implantable sensor and including a potentiostat configured to supply voltage to the at least one implantable sensor, the base station comprising:

a signal processor configured to execute instructions for processing the measuring signals to produce measurement data; and

a transmitter configured for wireless transmission, wherein the base station is adapted such that the transmission of data is initiated by receiving a control signal wirelessly transmitted from the transmitter; and

a receiver operably coupled to the base station and configured to receive data from the base station.

3. The system of claim **2**, wherein the control signal includes a characteristic identifier used by the receiver to identify the control signal with respect to the base station.

4. The system of claim **2**, wherein the base station is configured to transmit a characteristic identifier signal indicative of the base station.

5. The system of claim **2**, wherein the control signal initiating transmission of the measuring data is transmitted by a display device as part of the receiver.

6. The system of claim **2**, wherein the at least one implantable sensor is part of a replaceable sensor carrier unit that comprises a sealed housing in which the at least one implantable sensor is disposed, and the sealed housing of the sensor carrier unit is configured to couple with the base station such that the at least one implantable sensor is coupled to the base station.

7. The system of claim **6**, wherein the sensor carrier unit is configured to wirelessly communicate with the base station.

8. The system of claim **7**, wherein the wireless communication between the sensor carrier unit and the base station occurs inductively.

9. The system of claim **7**, wherein the wireless communication between the sensor carrier unit and the base station occurs by way of RFID.

10. The system of claim **6**, wherein the sensor carrier unit contains a data carrier having calibration data of the sensor.

11. The system of claim **10**, wherein the sealed housing of the sensor carrier unit includes the data carrier, and the data carrier is configured such that the calibration data is written through the sealed housing of the sensor carrier unit by way of at least one of an electronic memory configured to be read and RFID.

12. The system of claim **2**, wherein the at least one implantable sensor is activated by coupling with the base station such that the at least one implantable sensor commences to supply measuring signals, and wherein a command is generated by the processor upon connecting the sensor carrier unit to the base station.

13. The system of claim **2**, wherein the base station contains a memory in which the measurement data is stored, and wherein the stored measurement data stored includes a check code configured to allow the measurement data to be checked for data corruption and erroneous measurement data is configured to be recognized.

14. The system of claim **13**, wherein the base station includes status information comprised of at least one of a charge status of a battery and a result of an internal functional test, and the status information is configured to be stored in the memory with the measurement data, and wherein the status information is stored as a status code.

15. The system of claim **2**, wherein the base station further comprises a memory, an analytical unit, and a communication unit, and the communication unit includes the transmitter and the receiver, and the signal processor is configured to condense the measurement data, and the condensed measuring data is stored in the memory, and both the analytical unit and the communication unit are configured to access the memory, and wherein the analytical unit and the communication unit are connected to the memory by a changeover switch, and the changeover switch is configured to connect together the memory and one of the analytical unit the communication unit in response to a status of the switch.

16. The system of claim **2**, further comprising a display device including a measuring unit for determining values of the analyte concentration of a body fluid sample and an analytical unit, wherein the analytical unit is connected to the measuring unit, and the analyte concentration values are used for calibration during the analysis of the measurement data transmitted to the base station.

17. The system of claim **16**, wherein the base station comprises a test circuit that is connected to the potentiostat and supplies at least one response signal to the analytical unit of the base station during a system test, and wherein the at least one response signal is analyzed by the analytical unit, and wherein the analytical unit is configured to compare a value of the at least one response signal to an expected value and generate an error signal if the value of the at least one response signal deviates from the expected value by more than a predetermined tolerance value, and wherein the error signal is transmitted to a display device, and the display device is configured to provide the error signal to a user.

18. The system of claim **17**, wherein the test circuit is configured to simulate a sensor connected to the potentiostat such that the analytical unit is configured to use the test circuit to determine a function of the potentiostat and a charging status of a battery.

* * * * *