Method and device for mobile or in-patient detecting corporeal functional and metabolic data of a living organism

The invention relates to a method for mobile or in-patient detecting corporeal functional and metabolic data of a living organism, and a device for carrying out said method.

Many facilities are known whose measuring techniques are based on taking blood sample from patients and indirect evaluating these samples. Use and evaluating are painful and complicated, and a special precision in this procedure is necessary. This is a problem in active life and for elder people. Therefore, tests often are carried out in too limited frequencies or wrongly so that often only incomplete results are available for the physician in charge. Portable measuring instruments are known, too, in particular for example measuring instruments according to the patent specifications DE 196 39 224 and 196 39 228. In these patent specifications, the concentration of at least one substance is determined by means of measuring optics and a circuitry for evaluation. Moreover, according to the patent specification DE 32 28 551, a method for detecting the blood sugar level is known. In this method, blood sugar is determined in the presence of interfering substances by means of a measuring electrode with a before connected membrane. In this case, both components form an electrocatalytic blood sugar sensor. The measuring electrode is connected with a potentiostat, and a reaction potential and a measuring potential are detected. The electric current flowing during a measuring period is evaluated as a measuring signal. In the invention, a third potential, that is more negative than the measuring potential, is impressed to the measuring electrode after the reaction potential and before the measuring potential for a short time.

Moreover, a transcutaneous non-invasive method for determination of concentration of substances in blood according to the patent specification DE 195 18511 is known. In this invention, substances in the blood of a patient such as lactate, glucose, cholesterin, blood sugar, alcohol, drugs, and other substances are determined in the following way:

a) A signal corresponding to the amount of a substance and to the amount of water in a given body region is produced by spectroscopic methods and is measured.

b) The concentration in water is detected by the ratio of the signal value and the

amount of a substance and of water.

c) From this ratio, the value of concentration of a substance in blood is calculated.

Moreover, a method and a device for polarometric determination of substances in the human body according to the patent specification DE 195 19 051 are known. In this invention, scattered light which escapes from a body region supplied with blood which is irradiated with linear-polarized light is analyzed. From the correlation between the detected rotational angle of polarization and the concentration of blood sugar, the particular blood sugar level is determined.

Generally, the majority of all known solutions suffers from disadvantages that it is necessary to take a blood sample from the patient and to evaluate this blood indirectly. In addition, the use of the customary invasive measuring methods requires a precise handling during an exactly defined period of time, and this is not satisfiable for certain disabled people. An additional serious disadvantage of all known and used devices consists in the insufficient data collection and (manual) filing by the patients. Apart from the fact that the data often is input insufficiently and the results are "massaged", the "paper" is unsuited for physicians as documentation for the detailed statistical interpretation because of the necessary time involved and missing software.

Object of the invention is to develop a method and a device which it makes possible for patients to carry out a self-checking of their corporeal values. This method on the living organism is painless, easy to use and practicable as often as required. Simultaneously, an individual data collection is possible.

The object is achieved by a method and a device for mobileor in-patient detecting corporeal functional and metabolic data of a living organism in a non-invasive way. For this, a substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is in the organism of a test person. According to this invention, it can be a lactate, an alcohol, cholesterin, stearin, protein, drugs, blodd lipids, blood sugar, or glucose.

Electrodes are installed on the skin or nearly of the skin or nearly of the skin or are implanted in the body surface area of the test person. These electrodes are used alternately as sensor and as actuator, register caused and reflected signals and save these signals. The saved signals are input in a following computer system. Then sum values are calculated from the detected values on the basis of

the course of time. These sum values are assigned to reference values and displayed regularly together with these reference values for comparison purposes. The data can be displayed on a screen but also on a recorder. Both devices can be connected with a printer for data output of the detected values. The detected and balanced values can also be input in a data storage system for comparison, for further disposal and for recalling them if required.

The signal for assessment of the test person can be obtained continuously or discontinuously.

The available natural and artificial electric, electrochemical, and electromagnetic values are physical parameters. A relevant physical parameter can be the field strength. It is also possible to register the density of field lines, a potential difference, an amperage, a voltage, or at least two quantities in combination. For storage and documentation purposes, the body temperature, the skin resistance, and the gas exchange through the skin per unit of time are relevant.

Referring to specific relevant body regions of the test person, it is possible to influence relevant skin areas as a whole or partially and concentratedly. The data collection is possible point-like, in the form of a line, or in the form of an area. It is also possible to adapt the arrangement to the relevant skin areas, for example in the form of a matrix. It is also possible to implant at least one electrode in the body of the test person. An arrangement of the electrodes outside of the test person is disregarded here.

A device according to this invention, first, comprises electrodes which can be used as sensors or as actuators. These electrodes are arranged with reference to the skin surface of the test person and are electrically/electronically connected with an analog changeover facility which is arranged before an operational amplifier stage. The operational amplifier stage consists of an impedance converter preamplifier with filter. An analog-digital converter with a digital signal processor is arranged behind the operational amplifier stage which is for conditioning. This processor is connected to a computer stage which processes and stores the normalized and digitized measuring values. Therefore, the computer stage can preferably have an integrated storage module.

When the individual components of the device according to this invention are arranged separately, the device can be designed so that the data is transmitted wireless. But it is also possible to equip the individual components with an optical

communication interface for transmitting the data.

The operational amplifier stage is adapted to the physical properties of the electrodes. A preferential version according to this invention intends to equip the analog-digital converter with the signal processor scalably according to the number of the used primary contacts. Preferably, the computer stage can be designed also scalably.

A further preferential version according to the invention intends that the computer stage controls the generator for adaptive stimulation and with this the changeover between sensor and actuator operation.

Preferably, a display is arranged behind the computer stage in order to can interpret the obtained diagrams. It is also possible to equip the computer stage with a deposit regulator, which is located behind the computer stage and controls this unit.

To eliminate detected interferences, the operational amplifier stage is equipped with an adaptive filter element

At least individual components can be implanted in the living organism. When the whole unit is sufficiently miniaturized it is also possible to arrange it in the living organism.

Starting point for the development of the method and for the use according to the invention was that there is a natural human field which can be established in the living organism. It was also established that the influence of substances in blood, which can be correlated, is measurable as abnormality in the natural human field. This makes it possible to use advantageously the method and the device according to the invention in a complete non-invasive way.

Therefore, it is possible considerably to simplify the continuous check of corporeal values of a living organism by means of a non-invasive method. It is also possible continuously and stably to adjust corporeal values during a medical treatment.

It is also possible to obtain body values for the assessment of metabolic phenomena such as change of blood substances, blood alcohol, glucose, muscle efficiency, skin resistance, cutaneous circulation, pain location, and other values of that kind from a seemingly healthy organism.

All data can be stored, analyzed and visualized separately for each person, can be displayed as individual daily profiles, weekly profiles and/or any other time profiles of physical data and their consequences such as concentration of substances and so on, and can be telecommunicated to other data systems.

It is a disadvantage of customary methods that they are complicated because of use of a lot of paper, when established data are collected, and mistakes, which are connected with that. This disadvantage is eliminated by the computer-aided data collection and the possibility, to transfer the established data to a specialist for further medical treatment or something like that.

In the following, the invention is described on the basis of an embodiment, in which the method as well as the device are explained in detail.

In the accompanying drawings show

Fig. 1 the basic principle of course of measurement in case of use of the method according to the invention,

Fig. 2 a presentation of preferred sensor positions on a human organism, and

Fig. 3 a principle circuitry of a device equipped according to the invention.

A number of 1 ... n electrodes 1 is fixed onto the body surface of a test person. All well-tolerated precious metals (gold, silver, platinum) or also conductive plastics or ceramics can be used as conductive material. All insulating substances such plastics or textiles can be used as carrier for the electrodes. In the embodiment, 6 electrodes are used which are miniaturized and embedded in conductive rubber. The rubber is enclosed for its fixture in a flexible polymer so that it adapts to the body of the test person.

The electronic system is also arranged on the carrier. The carrier is also intended to fix it on the body of the test person.

The electrodes 1 are designed so that they can act both as a sensor and as an actuator.

The component behind the electrodes is the signal conditioning (A). In this component, an arrangement exists consisting of the single channel analog switch 2, the impedance converter preamplifier 3, and the filter 4. The latter components form together the operational amplifier stage as unit.

If the electrodes 1 are used as sensor, the sensor signal is input in the impedance converter preamplifier 3. The downstream filter 4 achieves two objects. Firstly, it is supposed to suppress interferences caused by induced fields in the environment and, secondly, it is supposed to limit the signal that is to transfer for data converting. In the embodiment, the filter 4 is designed as an active multistage unit. The filter parameters are adapted and adjusted by means of the digital signal processor 5 and the processor 6. In this way, an analog signal is available that is suitable for processing.

If the electrodes are used as actuator, they are linked to the generator 7 by means of the single channel analog switch 2.

The data converting is carried out in the component C. In this component, a scalable interface is integrated in the data converting stage 8 which is linked to the signal processor 5 so that it is possible to operate several electrodes. Thus the electrodes 1 can be used as single elements or as matrix on the data converting stage 8. The selecting is achieved by the processor 6.

A high-resolution rapid analog-digital converter 8 is connected downstream of the scalable interface. This converter is provided with a signal processor interface. The analog-digital converter 8 is directly selected by the signal processor 5 and serves as data source for the signal processor 5. (Anm: neuer Absatz)

In the signal processor 5, the incoming data stream is preprocessed by detecting and eliminating the interferences. Moreover, the parameters for the adaptive filter are determined.

All raw data is transferred via a bus system, and the processor 6 controls the signal processor 5 via a control bus.

The generator 7 in this component is also controlled via this bus system (data bus and control bus). Several stored signal courses can be activated. Further parameters for the generator 7 are intensity and frequency. If new signal courses

are synthesized, these can be stored specifically for each user.

The component D is the so-called controller segment. It serves as central control instance in the system. It observes all system functions, generates cyclically self-tests and carries out the online calibration of the whole system. It can also observe comparison measurements using classical analytical methods.

The components communication module 9, storage unit 12, system display 10, and keyboard 11 are connected with the controller via the bus system. The communication module 9 is designed in modular technique, and therefore it can be adapted to different transmission channels. It is also possible to implement software or hardware protocols.

The storage unit 12 is intended for long-term storage of the obtained data and for temporary intermediate storage of the current data. These storage unit 12 is preferably subdivided into a store, which is implemented in the system as an integral part, and a extendable external storage.

A further external storage device can be equipped with interchangeable storage devices.

A specific evaluation program carries out the analysis of the measuring data for each person separately and program steps such as a correlation which, for example, reference data for these people, historical values and values like that, and deviations of time values and values like that. Moreover, the evaluation program carries out calculations such as calculations for determining the concentration of particular chemical substances.

Claims:

1. Method for mobile or in-patient detecting corporeal functional and metabolic data of a living organism characterized by the fact that there is a substance in a test person which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields in the organism of these test person, that the change of natural and artificial electric, electrochemical, and electromagnetic fields as physical parameters is detected by electrodes which alternately are used as sensor and as actuator and are related to the skin surface of a test person, that the detected signals are registered and stored, that the stored signals are input in data processing equipment, that sum values are formed from the determined signals on the basis of their course of time, and that these sum values are provided for the computer-aided determination and evaluation of a substance which supports the exertion of influence on the existing natural electric, electrochemical, and electromagnetic fields.

2. Method according to claim 1 characterized by the fact that the collection of change of the natural and artificial electric, electrochemical, and electromagnetic fields is carried out continuously.

3. Method according to claim 1 characterized by the fact that the collection of change of the natural and not natural electric, electrochemical, and electromagnetic fields is carried out discontinuously.

4. Method according to one of the claims 1 to 3 characterized by the fact that the effect of the electrodes, which can be used as sensor and as actuator, on relevant skin areas occurs partially.

5. Method according to one of the claims 1 to 3 characterized by the fact that the effect of the electrodes, which can be used as sensor and as actuator, on relevant skin areas occurs globally.

6. Method according to one of the claims 1 to 5 characterized by the fact that the detection of the change of natural and artificial electric, electrochemical, and electromagnetic fields occurs point-like.

7. Method according to one of the claims 1 to 5 characterized by the fact that the detection of the change of natural and artificial electric, electrochemical, and

electromagnetic fields occurs in the form of a line.

8. Method according to one of the claims 1 to 5 characterized by the fact that the detection of the change of natural and artificial electric, electrochemical, and electromagnetic fields occurs in the form of an area.

9. Method according to one of the claims 1 to 8 characterized by the fact that the considered physical parameter is the field strength.

10. Method according to one of the claims 1 to 9 characterized by the fact that the considered physical parameter is the density of field lines.

11. Method according to one of the claims 1 to 10 characterized by the fact that the considered physical parameter is a potential difference.

12. Method according to one of the claims 1 to 11 characterized by the fact that the considered physical parameter is the amperage.

13. Method according to one of the claims 1 to 12 characterized by the fact that the considered physical parameter is the electric voltage.

14. Method according to one of the claims 1 to 13 characterized by the fact that the detected signals are provided for diagrams.

15. Method according to one of the claims 1 to 14 characterized by the fact that parallel reflected signals are detected adequately to the body temperature.

16. Method according to one of the claims 1 to 15 characterized by the fact that parallel reflected signals are detected adequately to the skin resistance.

17. Method according to one of the claims 1 to 16 characterized by the fact that parallel reflected signals are detected adequately to gas exchange through the skin per time unit.

18. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is a lactate.

19. Method according to one of the claims 1 to 17 characterized by the fact that

the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is an alcohol.

20. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is cholesterin.

21. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is a stearin.

22. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is a protein.

23. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields are drugs.

24. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields are blood lipids.

25. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is glucose.

26. Method according to one of the claims 1 to 17 characterized by the fact that the substance which supports the exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields is blood sugar.

27. Device for realization of the method according to one of the claims 1 to 26 characterized by the fact that electrodes (1) are arranged which are related to the skin surface of a test person and can be used as sensor and as actuator and which are electrically/electronically connected with an analog changeover

facility (2) arranged before an operational amplifier stage (3, 4), which further are connected with the impedance preamplifier (3) for conditioning and an analog-digital converter (8) with a downstream digital signal processor (5), and that this processor is connected with a computer system stage for processing of the normalized and digitized measuring values.

28. Device according to claim 27, characterized by the fact that individual components are arranged separately.

29. Device according to claim 27 or claim 28 characterized by the fact are designed in such a way that the data is transmitted wireless.

30. Device according to one of the claims 27 to 29 characterized by the fact that the components are designed in such a way that they transmit the data via an optical communication interface.

31. Device according to one of the claims 27 to 30 characterized by the fact that the electrodes (1), which can be used as sensor and as actuator, are arranged in groups.

32. Device according to one of the claims 27 to 31 characterized by the fact that the electrodes (1), which can be used as sensor and as actuator, are arranged in groups in a matrix.

33. Device according to one of the claims 27 to 32 characterized by the fact that at least individual components of the system are implanted in the body of a test person.

34. Device according to one of the claims 27 to 33 characterized by the fact that the operational amplifier stage is adapted to the physical properties of the electrodes.

35. Device according to one of the claims 27 to 34 characterized by the fact that the analog-digital converter (8) with the digital signal processor (5) is designed scalably according to the number of the used primary contacts.

36. Device according to one of the claims 27 to 35 characterized by the fact that the computer system stage is designed scalably.

37. Device according to one of the claims 27 to 36 characterized by the fact that the computer system stage is designed in such a way that it controls the generator (7) for the adaptive stimulation and with this the changeover between sensor and actuator operation.

38. Device according to one of the claims 27 to 37 characterized by the fact that a display (10) is arranged downstream of the computer system stage.

39. Device according to one of the claims 27 to 38 characterized by the fact that the computer system stage has an integrated storage unit (12).

40. Device according to one of the claims 27 to 39 characterized by the fact that the operational amplifier stage (3; 4) has an adaptive filter element (4) for the elimination of recognized interferences.

41. Device according to claim 40 characterized by the fact that the adaptive filter element (4) is designed as a multistage type.

42. Device according to one of the claims 27 to 41 characterized by the fact that the computer system stage is connected with a depot regulator and controls the same.

43. Device according to claim 42 characterized by the fact that the depot regulator is arranged within the living organism.

44. Device according to claim 42 characterized by the fact that the depot regulator is arranged outside the living organism.

Summary

The invention relates to a method for detecting functional data of a living organism, and a device for carrying out said method. Aim of the invention is to carry out a pain-free control of the corporeal values of a living organism in a simple manner, said control being able to be carried out as often as required. The exertion of influence on the existing natural and artificial electric, electrochemical, and electromagnetic fields and the changes resulting therefrom are determined. Electrodes which are used alternately as sensors and as actuators detect values and transmit the same to a downstream data detection which is embodied in an expedient manner.

Reference signs

Electrodes	1
Single channel analog switch	2
Impedance converter preamplifier	3
Filter	4
Signal processor	5
Processor	6
Generator	7
Analog-digital converter	8
Communication module	9
System display	10
Keyboard	11
Storage unit	12