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(54) **Electrodes for a bio-impedance measuring device, and devices used during dialysis**

Elektroden für eine Bioimpedanzmessvorrichtung, und während der Dialyse verwendete Vorrichtungen

Électrodes pour dispositif de mesure de bio-impédance et dispositifs utilisés pendant une dialyse

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• **CREPALDI C ED - RONCO C ET AL: "Application**  
**of Body Composition Monitoring to Peritoneal**  
**Dialysis Patients", 1 January 2009 (2009-01-01),**  
**PERITONEAL DIALYSIS - FROM BASIC**  
**CONCEPTS TO CLINICAL EXCELL, KARGER,**  
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## Description

**[0001]** The present invention relates to a peritoneal dialysis apparatus according to claim 1.

**[0002]** In certain treatment procedures such as dialysis (hereinafter, this term and the term dialysis treatment each encompass peritoneal dialysis, ultrafiltration, hemodialysis, hemofiltration, hemo-ultrafiltration, hemodiafiltration and the like) excess body fluid is removed from the patient's body. An accurate knowledge of the patient's hydration state before starting a treatment session is desirable for determining the most appropriate dialysis treatment, for controlling of the dialysis apparatus, and for determining and achieving the patient's post treatment target weight.

**[0003]** For example, peritoneal dialysis is often conducted by the patient alone at home and without being constantly monitored or supervised by medically trained staff. In fact, home peritoneal dialysis patients are seen by the dialysis staff in charge only every 4-12 weeks. Therefore, hydration state measurements made in a professional setting are made only every now and then. For that reason, it is particularly important for peritoneal dialysis to be provided with accurate methods and devices in order to easily determine by oneself the present hydration state between examinations that are carried out by the medical staff every 4-12 weeks.

**[0004]** There are some methods available to estimate the hydration state of a patient including assessment of weight changes, edema, jugular venous pressure, blood pressure, the measurement of hematocrit, of natriuretic peptides (ANP, Pro-BNP, and BNP), cyclic guanine monophosphate (cGMP) and/or inferior vena cava diameter. These methods are not all clinically useful because of limited accuracy or practicability or both.

**[0005]** The estimation of the patient's hydration (also referred to as the patient's hydration state) before a dialysis treatment session using bio-impedance analysis can be a useful step toward revealing the patient's hydration status. Bio-impedance techniques measuring body fluid content are advantageous in that they are non-invasive, relatively cheap, generally easily to perform and reliable if carried out correctly. Further they can in theory be carried out by the patient himself and even without professional supervision. However, these clinical methods are still too cumbersome for some patients. Also, when carried out, the results depend strongly on how accurately the electrodes used for the bio-impedance measurement are placed by the patient. In practice, it has turned out that a number of patients are not capable of using the electrodes which have to be placed on both arms, one arm and one foot, both feet, or the like in the intended manner. In consequence, the results stemming from bio-impedance measurements - if carried out at all - and their interpretation can suffer remarkably.

**[0006]** From US 4,370 983 A a computer-control medical care system is known.

**[0007]** From US 2012/035432 A1 a medical device and

methods of monitoring a patient with renal dysfunction are known.

**[0008]** From DE 10 2010 031 530 A1 a treatment apparatus comprising a body composition monitor is known.

**[0009]** From US 2005/070778 A1 a method for hydration monitoring is known.

**[0010]** From WO 2009/036321 A1 an adherent device for cardiac rhythm management is known.

**[0011]** From US 2009/182204 A1 a body composition, circulation and vital signs monitor and methods are known.

**[0012]** From US 2011/196617 A1 a handheld unit for detecting body parameters is known.

**[0013]** From US 2003/120170 A1 a device and a method for monitoring and controlling physiologic parameters of a dialysis patient using segmental bioimpedance are known.

**[0014]** From US 2011/208097 A1 a device for dialysis and stimulation of a patient and a method are known.

**[0015]** From US 1009/118594 A1 a smart parenteral administration system is known.

**[0016]** CREPALDI C ED - RONCO C ET AL: "Application of Body Composition Monitoring to Peritoneal Dialysis Patients, 1 January 2009 (2009-01-01), PERITONEAL DIALYSIS - FROM BASIC CONCEPTS TO CLINICAL EXCELL, KARGER, PAGE(S) 1-6, XP009173151, ISBN: 978-3-8055-9202-4, discusses the assessment of body fluids in peritoneal dialysis.

**[0017]** From WO 2010/104952 A2 display systems for body-worn health monitoring devices are known.

**[0018]** From US 2008/249380 A1 a protection mechanism for spectroscopic analysis of biological tissue is known.

**[0019]** From WO 2009/036348 A1 methods and devices for monitoring and/or treating patients are known.

**[0020]** From US 2011/112405 A1 a hand wand for ultrasonic cosmetic treatment and imaging is known.

**[0021]** From US 2003/016033 A1 a body fat measuring device is known.

**[0022]** From EP 1 095 614 A1 a dividable type apparatus for measuring living body impedance is known.

**[0023]** It is therefore an object of the present invention to provide a peritoneal dialysis apparatus.

**[0024]** This object is solved by the feature combinations of the independent claim.

**[0025]** The apparatus according to the present invention comprises two, or more electrodes, or one, two, or more pairs of electrodes, for a bio-impedance measuring device or for a body composition monitor. The electrodes are integral with or attached to or into a portion or a surface of an organizer used during peritoneal dialysis.

**[0026]** A 'dialysis apparatus' or a 'dialysis machine' or 'dialysis device' within the meaning of the present invention is a peritoneal dialysis machine.

**[0027]** The method for determining parameters for estimating the hydration or the nutritional status of a dialysis patient as disclosed herein encompasses touching at least two electrodes according to the present invention

with at least two body portions while the electrodes are connected to a bioelectrical impedance analyzer or a body composition monitor or both. The method further comprises collecting and processing the information gained by the electrodes in a processing element in at least one bioelectrical impedance analyzer and/or body composition monitor.

**[0028]** Developments of the present invention are each also the subject of the dependent claims.

**[0029]** The use of the expression 'may be' or 'may have' and so on, is to be understood herein synonymously with preferably is' or preferably has', respectively, and so on, and is intended to illustrate exemplary embodiments according to the present invention.

**[0030]** Embodiments according to the present invention may comprise one, some or all of the following features in arbitrary combinations.

**[0031]** In some embodiments, the electrodes are detachably attached to the organizer.

**[0032]** In certain embodiments, the electrodes are non-detachably attached to the organizer.

**[0033]** In some embodiments according to the present invention, at least one electrode is a non-disposable and/or reusable electrode or intended to be used several times without being removed from a surface it has been attached to in the time between two measurements (taking place on different days).

**[0034]** In certain embodiments according to the present invention, a first electrode and a second electrode are integrated or arranged having a distance between them which is particularly in the range of 2.5 to 15 cm, and more particularly in a range of 4 to 7.5 cm.

**[0035]** In some embodiments, the electrodes according to the present invention have at least one connection element intended and/or configured to connect at least one electrode to at least one bioelectrical impedance analyzer or to at least one body composition monitor or both.

**[0036]** In certain embodiments according to the present invention, a first electrode and a second electrode are arranged on different surfaces of the organizer.

**[0037]** In some embodiments according to the present invention, these surfaces are the front side and rear side, in others these surfaces are the left and the right side, the upper and the bottom side or any combination of two arbitrary sides mentioned herein.

**[0038]** The organizer comprises a bioelectrical impedance analyzer or body composition monitor or both or is - in a wireless or a non-wireless manner - connected thereto.

**[0039]** In certain embodiments according to the present invention, the organizer is configured or arranged, e.g., by means of a corresponding device, to start measuring the bioelectrical impedance and/or the body composition measurements automatically upon touching one, at least one, two, three, four or more of the electrodes by the patient. To this end, in particular embodiments according to the present invention sensors are provided which detect the presence of the fingers or other

body sections of the patient on the device. The presence may be detected by resistance, skin resistance, skin temperature, pressure or the like. The presence may also be detected by contact buttons which close an electrical circuit once they are touched or pressed by the patient.

**[0040]** In some embodiments according to the present invention, the organizer comprises a button or switch or element that has to be pushed, switched, inserted, attached or otherwise activated or operated before a bioelectrical impedance and/or body composition measurement may be started at all. The activation or operation of the button, switch or element may be a precondition necessary to bring the device into a mode in which the measurement can be started (whereas the measurement cannot be started before this mode has been selected). Of course, it may be provided that for starting the measurement it may not be sufficient that the system has entered into above mentioned modus; additionally, some action from the patient may be required such as touching some sensors as described above, or the like.

**[0041]** In certain embodiments according to the present invention, for starting the bioelectrical impedance and/or body composition measurement a disc with a dial or another element such as a connector, for example a so-called stay safe connector (which may be a part of a disc of a so-called stay safe (organizer) which is commercially distributed by Fresenius Medical Care, Germany), has to be inserted into or connected with the device according to the present invention. The connector, disc or element may have the function of a key such that a measurement cannot be started before the 'key' is connected with the device. The connector, disc or element may be required to start a treatment in which the device according to the present invention is used.

**[0042]** In some embodiments according to the present invention, it may be provided that it is not sufficient to have the connector, the disc or another element inserted into or connected with the device. In these embodiments according to the present invention, it might be requested that the connector, the disc or the element has to be brought into a particular position on the device before measuring the bioelectrical impedance and/or body composition is enabled. For example, the disc might have to be rotated into a pre-set position or the element, if embodied as a switch, might have to be switched in a pre-determined manner. In certain embodiments according to the present invention, a device for checking whether the connector, the disc or the element is in the pre-set position or not is provided. For example, the disc may have to be connected with the device and be turned into a pre-determined position before the patient is allowed to measure his bioelectrical impedance and/or body composition.

**[0043]** In certain embodiments according to the present invention, an element of the device such as a switch for selecting between two or more operating states or modes of the device may be provided. Based on the operating state that is presently selected by means of

the switch a measurement may be allowed or blocked. In some embodiments according to the present invention, a sensor is provided for detecting in which operating state or modus the device is.

**[0044]** Since the results achieved by a bioelectrical impedance and/or body composition measurement may depend on circumstances such as a stage of a simultaneously conducted dialysis treatment, and since measurements conducted during some stages of the treatment might result in different findings compared to the measurements conducted during other stages of the same treatment session, in some embodiments of the present invention the patient is given an acoustical, optical or any other hint indicating that a bioelectrical impedance and/or body composition should or should not be carried out right now, or the like. For example, the patient might be informed by a tone or any other signal that he should start his measurement now. Such a signal might be given, e. g., right before his peritoneum is going to be filled or emptied or while the peritoneum is emptied. The signal might be sent based on the operating state of the device or the treatment device as detected by a suitable sensor.

**[0045]** In some embodiments according to the present invention, the organizer comprises another device for sending a measurement result to a dialysis machine, to a medical monitoring centre, the doctor in charge, to a clinic, to a hospital, to a dialysis centre, and/or the like.

**[0046]** In certain embodiments according to the present invention, the measurement results are sent or signalled in a wireless manner.

**[0047]** In some embodiments according to the present invention, the organizer comprises another device for sending a warning signal (a text message, for example, or any other signal) to a medical monitoring centre, the doctor in charge, to a clinic, to a hospital, to a dialysis centre, and/or the like, once the measurement results have exceeded an upper or lower threshold. This allows an easy determination for the remote working recipient to assess if or when the patient should be seen by a doctor or by medical staff in general.

**[0048]** In certain embodiments according to the present invention, the peritoneal dialysis apparatus comprises a control unit, the control unit being configured to control - with or without feedback control - the dialysis treatment based on the signal representing the results of the measurement carried out by means of the electrodes.

**[0049]** In some embodiments of the method not according to the present invention, the at least two body portions for touching the at least two electrodes according to the present invention are two fingers of one hand, or at least two fingers of different hands, or two fingers of each hand, or any part of a hand and any part of a foot, or any part of both feet, or another two separate parts of the body.

**[0050]** In certain embodiments, the method not according to the present invention encompasses manually inputting information into the bioelectrical impedance an-

alyzer and/or to the body composition monitor about the patient's parameters as for example height, weight, age, sex and/or with what part of the patient's body the electrodes have been touched.

**[0051]** In some embodiments, the method not according to the present invention additionally comprises adjusting the treatment parameters of a dialysis treatment to the results of the bioelectrical impedance analysis.

**[0052]** In certain embodiments, the method not according to the present invention comprises starting the bioelectrical impedance measurement solely by touching at least one electrode, two electrodes or two pairs of electrodes.

**[0053]** In some embodiments, the method not according to the present invention comprises adjusting or controlling the dialysis treatment in an automatic manner based on a measurement result achieved by the method according to the present invention.

**[0054]** In certain embodiments, the method not according to the present invention comprises filtering of the measurement results and in particular of the measured body resistance or any other mathematical scatter or noise reduction. This may enhance the accuracy of the input data used for a subsequent determination of the overhydration (herein also referred to as the overhydration state) or used for a body composition calculation, and for giving the patient a more precise feedback on his status.

**[0055]** The filtering or mathematical scatter or noise reduction may encompass the use of a Kalman filter, a mean, an average, or the like and combination thereof.

**[0056]** In certain embodiments, the method not according to the present invention comprises obtaining first bioimpedance measurement data of a patient from a first type of bioimpedance measurement, deriving bioimpedance calibration data from the first bioimpedance measurement data for calibrating second bioimpedance measurement data from a second type of bioimpedance measurement, obtaining the second bioimpedance measurement data from a second bioimpedance measurement of the patient, and calibrating the second bioimpedance measurement data using the calibration data to determine the overhydration parameter or the body composition parameter of the patient.

**[0057]** In some examples the step of obtaining first bioimpedance measurement data comprises performing a first bioimpedance measurement.

**[0058]** In certain embodiments, the method not according to the present invention the step of performing a first bioimpedance measurement comprises measuring a bioimpedance spectrum of the patient at one frequency or at multiple frequencies.

**[0059]** In some embodiments, the method not according to the present invention comprises receiving bioimpedance calibration data derived from first bioimpedance measurement data obtained by a first type of bioimpedance measurement, the bioimpedance calibration data being suitable for calibrating second bioimpedance

measurement data from a second type of bioimpedance measurement, obtaining the second bioimpedance measurement data from a second bioimpedance measurement of the patient and calibrating the second bioimpedance measurement data using the calibration data to determine the overhydration parameter or the body composition parameter of the patient.

**[0060]** In certain embodiments, the method not according to the present invention the step of obtaining the second bioimpedance measurement data comprises performing a second bioimpedance measurement.

**[0061]** In certain embodiments, the method not according to the present invention the step of performing a second bioimpedance measurement comprises measuring a bioimpedance of the patient at a single frequency.

**[0062]** In certain embodiments, the method not according to the present invention comprises obtaining a plurality of bioimpedance measurements of the second type at different times to generate a time series of bioimpedance measurements, performing time analysis of the time series to determine whether a current bioimpedance measurement of the time series deviates significantly from previous bioimpedance measurements of the time series, and generating an indication that a new measurement of the first type of bioimpedance measurements should be performed or a warning message.

**[0063]** In certain embodiments, the method not according to the present invention the step of deriving the calibration data comprises using bioimpedance reference data correlating bioimpedance measurement results of the first type and bioimpedance measurement results of the second type.

**[0064]** In certain embodiments, the method not according to the present invention comprises a step of deriving the reference data, wherein the first type of bioimpedance measurements comprises a first type of electrode configuration, wherein the second type of bioimpedance measurements comprises a second type of electrode configuration, and wherein the step of deriving the reference data comprises applying a conversion factor between a first format considering a measurement using the first type of electrode configuration and a second format considering a measurement using the second type of electrode configuration.

**[0065]** In some embodiments, the method not according to the present invention comprises obtaining the first bioimpedance measurement data, deriving the bioimpedance calibration data from the first bioimpedance measurement data, providing the bioimpedance calibration data to a device for determining the overhydration parameter or the body composition parameter.

**[0066]** In some embodiments, the method not according to the present invention comprises performing a plurality of bioimpedance reference measurements, each comprising a first reference measurement of the first type of bioimpedance measurement and a second reference measurement of the second type of bioimpedance reference measurement and correlating data from the first

and the second reference measurements to obtain the bioimpedance reference data.

**[0067]** The organizer and the apparatus according to the present invention, comprise in particular embodiments of the present invention devices, monitors and the like which are adapted and/or configured for carrying out at least one or all of the steps described in here.

**[0068]** For example, the organizer, or the peritoneal dialysis apparatus according to the present invention, comprises in some embodiments a data provisioning unit for obtaining first bioimpedance measurement data of a patient from a first type of bioimpedance measurement, a processing unit for deriving bioimpedance calibration data from the first bioimpedance measurement data for calibrating second bioimpedance measurement data from a second type of bioimpedance measurement, a data obtaining unit for obtaining the second bioimpedance measurement data from a second bioimpedance measurement of the patient, and a calibration unit for calibrating the second bioimpedance measurement data using the calibration data to determine the overhydration parameter or the body composition parameter of the patient.

**[0069]** In certain embodiments of the present invention, the organizer, or the peritoneal dialysis apparatus according to the present invention, or both, comprise a measurement unit for performing a bioimpedance measurement for obtaining the first bioimpedance measurement data.

**[0070]** In certain embodiments of the present invention, the measurement unit is adapted to measure the bioimpedance spectrum of the patient at multiple frequencies.

**[0071]** The organizer, or the peritoneal dialysis apparatus according to the present invention, comprises in some embodiments a receiving unit for receiving bioimpedance calibration data derived from first bioimpedance measurement data obtained by a first type of bioimpedance measurement, the bioimpedance calibration data being suitable for calibrating second bioimpedance measurement data from a second type of bioimpedance measurement, a data obtaining unit for obtaining the second bioimpedance measurement data from a second bioimpedance measurement, of the patient, and a calibration unit for calibrating the second bioimpedance measurement data using the calibration data to determine the overhydration parameter or the body composition parameter of the patient.

**[0072]** In certain embodiments of the present invention, the organizer, or the peritoneal dialysis apparatus according to the present invention, comprises a measurement unit for performing a bioimpedance measurement for obtaining the second bioimpedance measurement data.

**[0073]** In some embodiments of the present invention, the measurement unit is adapted to measure the bioimpedance of the patient at a single frequency.

**[0074]** In certain embodiments according to the

present invention the expressions 'bio-impedance analyzer', 'bioelectrical impedance analyzer', 'bio-impedance measuring device' and 'bio-impedance analysis', or 'bioelectrical impedance analysis' relate to bio-impedance measuring devices or bioelectrical impedance analysis methods that are known in the art. In some embodiments according to the present invention, such devices use the 50 kHz current frequency vector and/or the multifrequency bio-impedance measurement or spectroscopy.

**[0075]** In some embodiments according to the present invention, the bio-impedance measuring device is a monitor as described in WO 2006/002685 A1. The respective disclosure of WO 2006/002685 A1 is hereby incorporated in the present application by way of reference. Of course, the present invention must not be understood to be limited to monitors obtaining data by bio-impedance measurements as is described in WO 2006/002685 A1. Other bio-impedance measurement methods known in the art and also any other devices known in the art are also contemplated and encompassed by the present invention.

**[0076]** In certain embodiments according to the present invention, the bio-impedance measuring device is configured to measure the extracellular fluid volume over total body water (ECV/TBW) ratio, extracellular fluid volume over body mass (ECV/BM), and/or extracellular over intracellular volume (ECV/ICV).

**[0077]** In some embodiments according to the present invention, the organizer and/or the dialysis apparatus according to the present invention comprise a device for signalling or sending the measurement results achieved by means of the method according to the present invention to an electronic medical card of the patient comprising personal and/or treatment data of the patient for saving or storing the measurement results for a later use thereof.

**[0078]** Any embodiment according to the present invention may have one or more of the above or in the following mentioned advantages in any combination.

**[0079]** Since the electrodes intended for measuring the body's resistance at one or more frequencies or for measuring the bio-impedance of a patient's body by a bio-impedance measuring device are suggested herein to be integral with or permanently attached to the organizer, the patient does not need help in placing the electrodes on his limbs. Rather, it is quite easy to handle and use the electrodes, and the organizer. Therefore, the patient is capable of measuring his body fluid content whenever and as frequently as he wishes to. This is believed to increase the patient's compliance regarding using the device for measuring on a frequent basis. This may obviously result in higher quality treatment.

**[0080]** Also, since the patient does not have to place the electrodes anywhere on his limbs but has only to put his fingers or other parts of the body onto electrodes that are both attached to a device and determined to be used in a particular way, the patient cannot fail to use the elec-

trodes in the only correct manner. This obviously results in higher quality measurements. Besides, the measurements carried out are performed in a reproducible way. The results achieved can be compared to results gained earlier in a more reliable manner.

**[0081]** Further, since the electrodes are intended to be used more often than only once - in contrast to disposable electrodes known from the prior art - and since they may be reusable, waste material does not have to be disposed of after every single measurement. This implies the advantages well-known to the skilled person.

**[0082]** The electrodes may have a shape that only allows their use by pre-defined parts of the body, e. g. the fingers. Hence, the accuracy of the measurements carried out by means of those electrodes may be enhanced as their shape does not allow for contact with other body parts, e.g., the foot if this was not intended by the manufacturer.

**[0083]** Also, if at least some electrodes according to the present invention are arranged on different surfaces of the organizer, for example both on the front side and on the rear side, an incorrect use of the electrodes is further ruled out. Again this may lead to better measurement results.

**[0084]** In certain embodiments of the present invention, the devices comprise a device for signalling or sending the measurement results to a medical monitoring centre, to the doctor in charge, to a clinic, to a hospital, to a dialysis centre, and/or the like. Any of those recipients - such as the medical monitoring centre - can check for plausibility of the results, developments of the body fluid content and the like and contact and inform the patient if necessary to prevent harm.

**[0085]** If, as is also contemplated by embodiments of the present invention, the devices comprise a device for signalling or sending the measurement results to a dialysis apparatus, the device or the dialysis apparatus can check for plausibility of the results, developments of the body fluid content and the like and adapt or amend automatically the treatment or certain parameters thereof or suggest to do so to the patient or the doctor if necessary to prevent harm or to improve the treatment outcome or both by controlling the dialysis apparatus effectively.

**[0086]** Many characteristics of the patient such as for example age, sex, weight, height and some other conditions such as changing sodium and water intake, position of the body, position of the electrodes during measurement and the like can have some effect on the measurement results. Hence, the accuracy of the bio-impedance measurement can be further improved if the bioelectrical impedance analyzer or body composition monitor comprises an input element for manually inputting at least some (or all) of the above mentioned conditions to the bio-impedance device or the body composition monitor, be it by the patient himself or by the medical staff.

**[0087]** If certain signals as related to herein are transmitted in a wireless manner, all advantages known to the skilled person can be achieved.

**[0088]** If the bio-impedance measuring device starts automatically measuring once the patient has placed, for example, his fingers on the electrodes, operating a switch for starting the measurement is no longer required. This can render the operation of the devices involved in the measurements less cumbersome. The patient may receive a signal, an alarm or the like once the measurement is finished, or not.

**[0089]** The electrodes can be advantageously used to upgrade conventional organizers, in particular by means of sticking or gluing them to said devices. For example, this can happen by using a pad comprising the electrodes. This way it is easy and also economical to achieve the advantages discussed above while maintaining existing devices that are already in operation.

**[0090]** If for starting the bioelectrical impedance and/or body composition measurement a disc with a dial or another element has to be inserted into or connected with the organizer, the patient would notice that he has forgotten to insert or connect the disc or the element since he would not be able to carry out measurements. This way, the risk of overlooking to insert or connect elements that have to be inserted or connected for a proper function of, e. g., the blood treatment apparatus or the extracorporeal blood circuit is reduced.

**[0091]** In the following, the present invention will be exemplarily specified with reference to the appended drawing. In the drawing, identical reference numerals designate same or identical elements, wherein:

- Fig. 1 shows a top view of an organizer of the peritoneal dialysis apparatus according to the present invention having two electrodes on its upper side;
- Fig. 2 shows a perspective view of an ADP-cycler not according to the present invention having four electrodes;
- Fig. 3 shows a top view of a hand-held electrodes holder not according to the present invention;
- Fig. 4 shows a bottom view of the hand-held electrodes holder of Fig. 3; and
- Fig. 5 shows schematically a perspective view of an organizer of the peritoneal dialysis apparatus according to the present invention on a stand.

**[0092]** Fig. 1 schematically shows a top view of an organizer 20 in accordance with a first embodiment of the present invention having four electrodes 10. Below the organizer 20, Fig. 1 schematically shows a conventional bio-impedance measuring device 30.

**[0093]** Two of said electrodes 10 are placed on the top side 21 of the organizer 20, lateral to the disk having a dial 22 (the dial 22 also being called a stay safe connector herein). Two other electrodes 10 are placed on the bot-

tom side 23 of the organizer 20 and shown by dotted lines in Fig. 1. This way, the organizer 20 comprises a first pair of electrodes 10 (left from the dial 22) and a second pair of electrodes 10 (right from the dial 22).

**[0094]** In order to check his body composition or bio-electrical impedance, the patient has to place his thumbs on the two electrodes 10 of the top side 21 and his forefingers on the two electrodes 10 of the bottom side 23 of the organizer 20 for a bio-impedance measurement. The electrodes 10 are placed in such a manner that the patient can hold the organizer 20 with two hands and can reach every electrode 10 with the corresponding finger without effort. The position of the particular finger on the electrode is pre-determined by the form, configuration, position and/or shape of the electrode 10. This pre-determination makes the measurement reliable and reproducible.

**[0095]** In the embodiment according to the present invention shown in Fig. 1, the organizer 20 is connected to the bio-impedance measuring device 30 and/or a body composition monitor by means of a connecting element 24 connected to or plugged into a terminal or notch 25 of the organizer 20. In alternative embodiments according to the present invention, a wireless connection is provided instead of the connecting element 24 shown in Fig. 1. By means of wireless connection, the patient is less hampered by electric wires.

**[0096]** In some embodiments according to the present invention like the one shown in Fig. 1, the bio-impedance measuring device 30 is turned on or starts measuring automatically by touching the four electrodes 10 with the fingers.

**[0097]** The result of the measurement can be displayed on the display 31 of the bio-impedance measuring device 30. The bio-impedance measuring device 30 can include an alarm modus to alert the patient if the results of measurements are below or above pre-determined target values or if the results do not make sense. The alarm signal or alert can reach only the patient, with a sound or a message on the display of the bio-impedance measuring device 30, or it can reach a medical monitoring centre. The same applies to the measurement results. They can also be transferred to the medical monitoring centre. In addition or as an alternative, the measurement results can be sent to the dialysis device. In particular embodiments, the measurement results sent to the dialysis device can be used to automatically control the treatment.

**[0098]** The bio-impedance measuring device 30 below the organizer 20 can be replaced for a body composition monitor.

**[0099]** Fig. 2 shows a perspective view of a conventional ADP-cycler 40 (automated peritoneal dialysis-cycler) not according to the present invention having four electrodes 10 on its surfaces, the electrodes 10 being integral or attached to the ADP-cycler 40.

**[0100]** Two of the electrodes 10 are placed on the upper surface or upper part 41 of the ADP-cycler and another two on both lateral surfaces or lateral parts 42 (one of them being indicated by dotted lines), so that a patient

can effortlessly reach the electrodes 10 of the upper part 41 of the device with his thumbs and the electrodes 10 of the lateral parts 42 with his forefingers or with his middle fingers.

**[0101]** Upon touching of the electrodes 10 or upon activating a switch or the like the measurement automatically takes place. The results of the measurement can be displayed on a display 43.

**[0102]** In Fig. 2 the bio-impedance measuring device 30 is integrated into the ADP-cycler 40.

**[0103]** In other embodiments, the bio-impedance measuring device 30 is different from or non-integral with the ADP-cycler 40. It may be connected to the ADP-cycler 40 by a connecting element 44.

**[0104]** A conventional ADP-cycler 40 can be upgraded or interlinked by means of wires or wireless with a separate bio-impedance measuring device 30 by attaching four electrodes 10 to the casing, housing or the like of the ADP-cycler 40.

**[0105]** Fig. 3 shows a top view of a hand-held electrodes holder 50. The representation of Fig. 3 shows two electrodes 10 for the thumbs of the patient. The embodiment of the hand-held electrodes holder 50 shown in Fig. 3 is quite simple. Simply spoken, it may be a casing 51 comprising the electrodes 10 on its surfaces.

**[0106]** The hand-held electrodes holder 50 may have terminals or sockets 52 for connecting the hand-held electrodes holder 50 to another apparatus, e.g., for connecting the electrodes 10 to a bio-impedance measuring device 30 by means of connecting elements not shown. In further embodiments, the connection is wireless. More sophisticated embodiments include an input element 53 for inputting patient-related information that can be helpful to achieve a more accurate measurement result such as, for example, height, sex, age, etc.

**[0107]** The hand-held electrodes holder 50 includes in certain embodiments not according to the present invention a bio-impedance measuring device 30, too. In this case the patient may not need any device except for the hand-held electrodes holder 50 to perform a complete bio-impedance analysis.

**[0108]** The hand-held electrodes holder 50 may comprise a display 54.

**[0109]** Fig. 4 shows a bottom view of the hand-held electrodes holder 50 of Fig. 3. In Fig. 4, the two electrodes 10 for the forefingers or the middle fingers of the patient are shown.

**[0110]** Fig. 5 shows an example of an organizer 20, which is held on a moveable stand 60. The organizer 20 has four electrodes 10 positioned like in Fig. 2. The electrodes 10 are placed on the surface of the organizer 20 and are connected to a bio-impedance measuring device 30, which constitutes a separate unit from the organizer 20 and has been placed below it. The connection can be wireless.

**[0111]** The bio-impedance measuring device 30 can be embodied as in every other embodiment or configuration as shown by the figures or as described above.

## Reference numerals list

### [0112]

5	10	electrodes
	20	organizer
	21	top side of the organizer
	22	disk with dial
	23	bottom side of the organizer
10	24	connecting element
	25	terminal or notch
	30	bio-impedance measuring device
	31	display of the bio-impedance measuring device
	32	alarm modus button
15	40	ADP-cycler
	41	upper part of the ADP-cycler
	42	lateral parts of the ADP-cycler
	43	display of the ADP-cycler
	44	connecting element of the ADP-cycler
20	50	hand-held electrodes holder
	51	casing
	52	connecting element of the hand-held electrodes holder
	53	input element
25	54	display of the hand-held electrodes holder
	60	stand

## Claims

1. Peritoneal dialysis apparatus for a continuous ambulatory peritoneal dialysis, the peritoneal dialysis apparatus comprising at least one organizer (20) for use during a peritoneal dialysis treatment, and a bio-electrical impedance analyzer (30), a body composition monitor or both,  
the organizer (20) comprising or being connected to the bioelectrical impedance analyzer (30), the body composition monitor or both,  
the organizer (20) comprising electrodes (10) of the bioelectrical impedance analyzer (30) or the body composition monitor,  
the electrodes (10) being integral with or attached to a surface of the organizer (20), wherein the organizer (20) is configured to allow measuring the bioelectrical impedance or the body composition measurements, or both, only upon or by inserting a dial, that is required to start the peritoneal dialysis treatment, into the organizer (20).
2. Peritoneal dialysis apparatus according to claim 1, wherein the electrodes (10) are detachably attached to the organizer (20).
3. Peritoneal dialysis apparatus according to claim 1, wherein the electrodes (10) are non-detachably attached to the organizer (20).



4. Peritoneal dialysis apparatus according to any one of the claims 1 to 3, wherein at least one electrode (10) is a non-disposable and/or reusable electrode.
5. Peritoneal dialysis apparatus according to any one of the preceding claims, wherein a first electrode (10) and a second electrode (10) of the electrodes (10) are integrated or arranged having a distance between them, which is particularly in the range of 2.5 to 15cm, and more particularly in a range of 4 to 7.5cm.
6. Peritoneal dialysis apparatus according to any one of the preceding claims, wherein the electrodes (10) have at least one connection element (24) to connect at least one electrode (10) to at least one of the bioelectrical impedance analyzer (30) and the body composition monitor.
7. Peritoneal dialysis apparatus according to any one of the preceding claims, wherein a first electrode (10) and a second electrode (10) of the electrodes (10) are arranged on different surfaces of the organizer (20).
8. Peritoneal dialysis apparatus according to any one of the preceding claims, wherein the organizer (20) is configured to start measuring the bioelectrical impedance or the body composition measurements or both upon touching at least one of the electrodes (10).
9. Peritoneal dialysis apparatus according to any one of the preceding claims, the peritoneal dialysis apparatus comprising a control unit, the control unit being configured to control the dialysis treatment based on the signal representing the results of measurement carried out by means of the electrodes (10).

#### Patentansprüche

1. Peritonealdialyse-Vorrichtung für eine kontinuierliche ambulante Peritonealdialyse, wobei die Peritonealdialyse-Vorrichtung mindestens einen Organizer (20) zur Verwendung während einer Peritonealdialyse-Behandlung, und einen bioelektrischen Impedanz-Analysator (30), einen Körperzusammensetzungsmonitor oder beides aufweist, wobei der Organizer (20) den bioelektrischen Impedanz-Analysator (30), den Körperzusammensetzungsmonitor oder beide aufweist oder damit verbunden ist, wobei der Organizer (20) Elektroden (10) des bioelektrischen Impedanz-Analysators (30) oder des Körperzusammensetzungsmonitors aufweist, wobei die Elektroden (10), die in eine Oberfläche des Organizers (20) integriert oder daran angebracht sind,

wobei der Organizer (20) so konfiguriert ist, dass er Messungen der bioelektrischen Impedanz oder der Körperzusammensetzung oder beides nur ermöglicht, beim oder durch Einsetzen einer Wählscheibe, die zum Starten der Peritonealdialyse-Behandlung notwendig ist, in dem Organizer (20).

2. Peritonealdialyse-Vorrichtung nach Anspruch 1, wobei die Elektroden (10) lösbar am Organizer (20) angebracht sind.
3. Peritonealdialyse-Vorrichtung nach Anspruch 1, wobei die Elektroden (10) unlösbar am Organizer (20) angebracht sind.
4. Peritonealdialyse-Vorrichtung nach einem der Ansprüche 1 bis 3, wobei mindestens eine Elektrode (10) keine Wegwerfelektrode und/oder eine wiederverwendbare Elektrode ist.
5. Peritonealdialyse-Vorrichtung nach einem der vorangegangenen Ansprüche, wobei eine erste Elektrode (10) und eine zweite Elektrode (10) der Elektroden (10) in einem Abstand voneinander integriert oder angeordnet sind, der insbesondere in einem Bereich von 2,5 bis 15 cm und ganz insbesondere in einem Bereich von 4 bis 7,5 cm liegt.
6. Peritonealdialyse-Vorrichtung nach einem der vorangegangenen Ansprüche, wobei die Elektroden (10) mindestens ein Verbindungselement (24) aufweist zum Verbinden von mindestens einer Elektrode (10) mit dem bioelektrischen Impedanz-Analysator (30) und/oder dem Körperzusammensetzungsmonitor.
7. Peritonealdialyse-Vorrichtung nach einem der vorangegangenen Ansprüche, wobei eine erste Elektrode (10) und eine zweite Elektrode (10) der Elektroden (10) auf verschiedenen Oberflächen des Organizers (20) angeordnet sind.
8. Peritonealdialyse-Vorrichtung nach einem der vorangegangenen Ansprüche, wobei der Organizer (20) konfiguriert ist, um anzufangen, die bioelektrische Impedanz und/oder die Körperzusammensetzung durch oder bei Berühren von mindestens einer der Elektroden (10) zu messen.
9. Peritonealdialyse-Vorrichtung nach einem der vorangegangenen Ansprüche, wobei die Peritonealdialyse-Vorrichtung eine Steuereinheit aufweist, welche konfiguriert ist, um die Dialysebehandlung basierend auf dem Signal zu steuern, das die mittels der Elektroden (10) durchgeführten Messergebnisse wiedergibt.

## Revendications

1. Un appareil de dialyse péritonéale pour une dialyse péritonéale continue ambulatoire, où l'appareil de dialyse péritonéale comprend au moins un organisateur (20) pour utilisation lors d'un traitement de dialyse péritonéale ainsi qu'un analyseur d'impédance bioélectrique (30), un moniteur de composition corporelle, ou les deux, l'organisateur (20) comprenant ou étant connecté à l'analyseur d'impédance bioélectrique (30), au moniteur de composition corporelle, ou aux deux, l'organisateur (20) comprenant des électrodes (10) de l'analyseur d'impédance bioélectrique (30) ou du moniteur de composition corporelle, les électrodes (10) étant solidaires ou fixées à une surface de l'organisateur (20), où l'organisateur (20) est configuré de façon à permettre des mesures de l'impédance bioélectrique ou de la composition corporelle, ou des deux, uniquement à ou par l'insertion d'un cadran qui est nécessaire au démarrage du traitement de dialyse péritonéale dans l'organisateur (20). 5 10 15 20
2. L'appareil de dialyse péritonéale selon la première revendication, où les électrodes (10) sont fixées à l'organisateur (20) de manière amovible. 25
3. L'appareil de dialyse péritonéale selon la première revendication, où les électrodes (10) sont fixées à l'organisateur (20) de manière non-amovible. 30
4. L'appareil de dialyse péritonéale selon l'une quelconque des revendications 1 à 3, où au moins une électrode (10) est une électrode non-jetable et/ou réutilisable. 35
5. L'appareil de dialyse péritonéale selon l'une quelconque des revendications précédentes, où une première électrode (10) et une seconde électrode (10) des électrodes (10) sont intégrées ou agencées à une distance l'une de l'autre comprise notamment dans une plage de 2,5 à 15 cm, et plus particulièrement dans une plage de 4 à 7,5 cm. 40 45
6. L'appareil de dialyse péritonéale selon l'une quelconque des revendications précédentes, où les électrodes (10) comprennent au moins un élément de connexion (24) pour connecter au moins une électrode (10) à au moins l'analyseur d'impédance bioélectrique (30) ou au moniteur de composition corporelle. 50
7. L'appareil de dialyse péritonéale selon l'une quelconque des revendications précédentes, où une première électrode (10) et une seconde électrode (10) des électrodes (10) sont agencées sur différentes surfaces de l'organiseur (20). 55
8. L'appareil de dialyse péritonéale selon l'une quelconque des revendications précédentes, où l'organisateur (20) est configuré pour commencer les mesures de l'impédance bioélectrique ou de la composition corporelle, ou des deux, en touchant au moins l'une des électrodes (10).
9. L'appareil de dialyse péritonéale selon l'une quelconque des revendications précédentes, l'appareil de dialyse péritonéale comprenant une unité de commande, l'unité de commande étant configurée de façon à commander le traitement de dialyse sur la base du signal représentant les résultats de mesure effectués au moyen des électrodes (10).

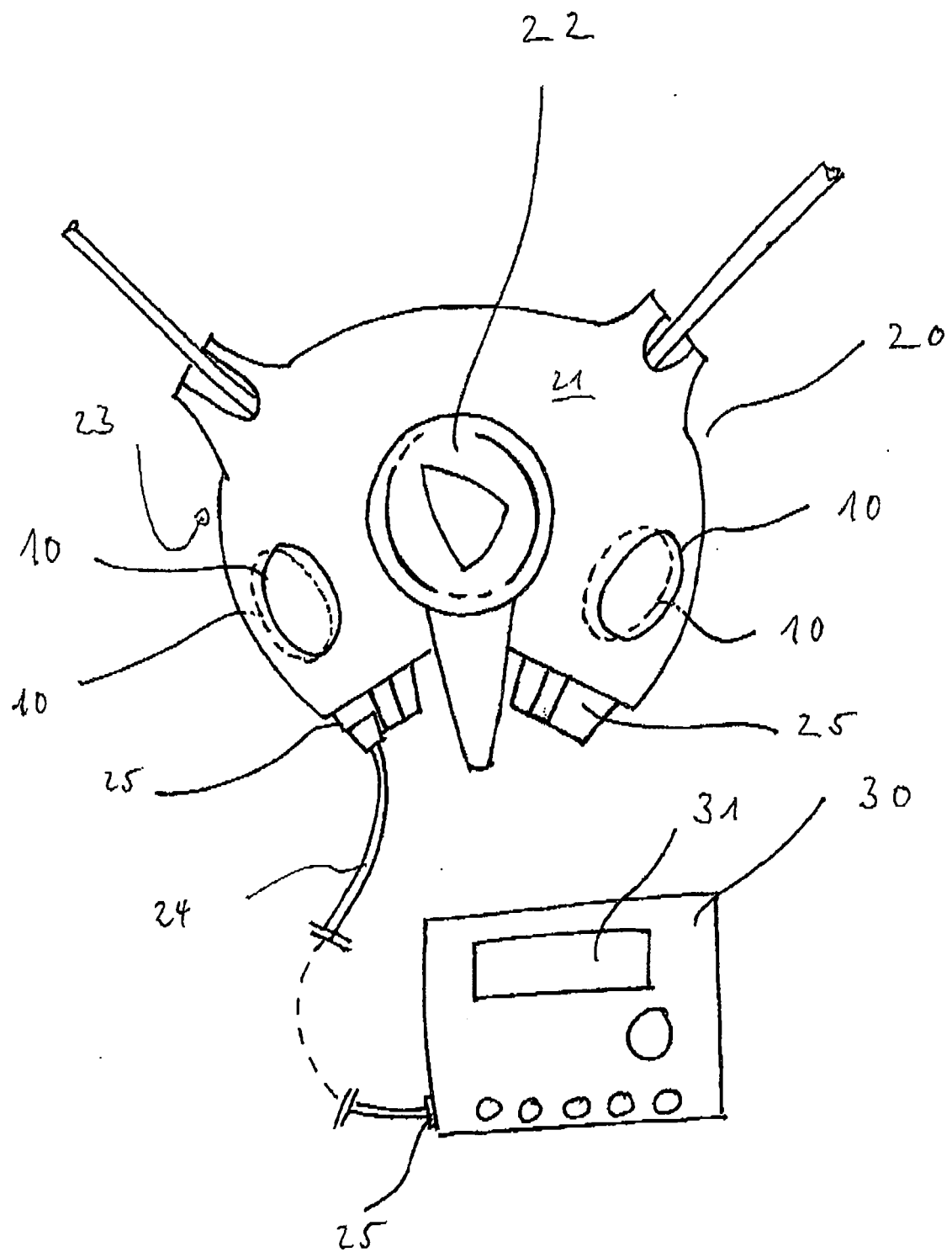


Fig. 1

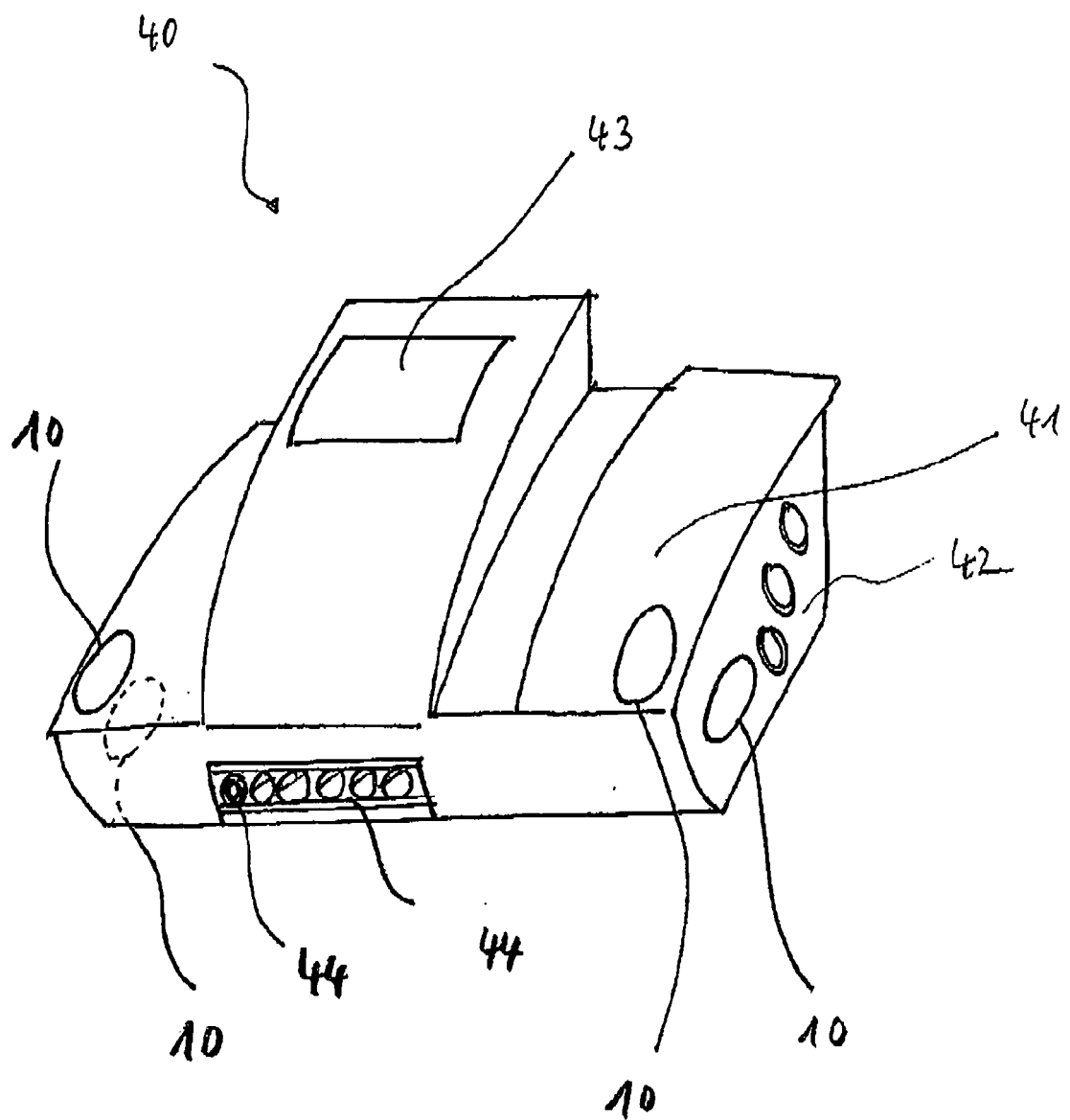
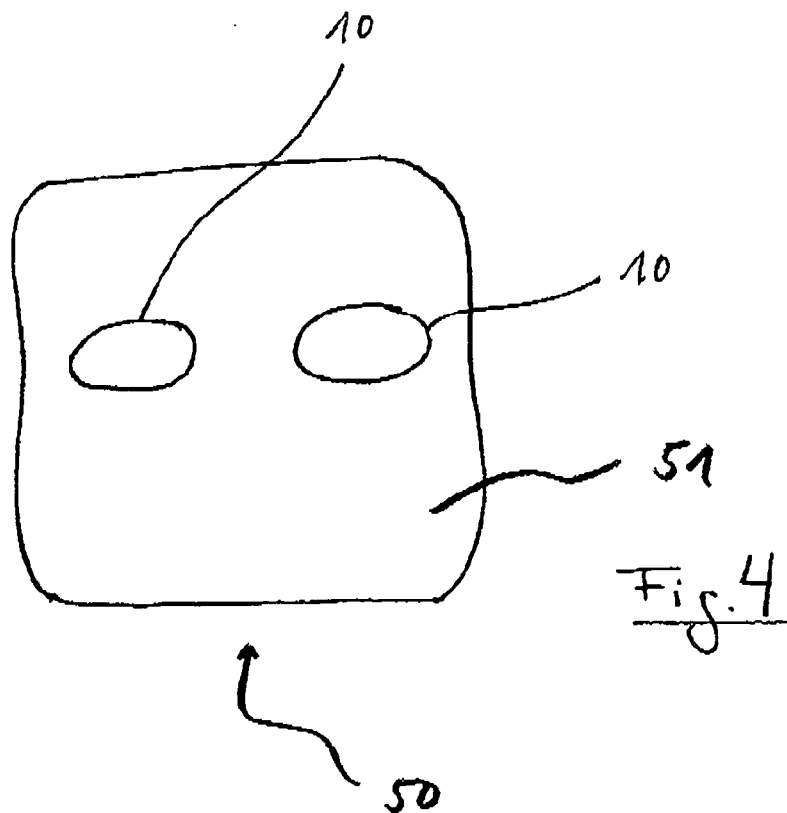
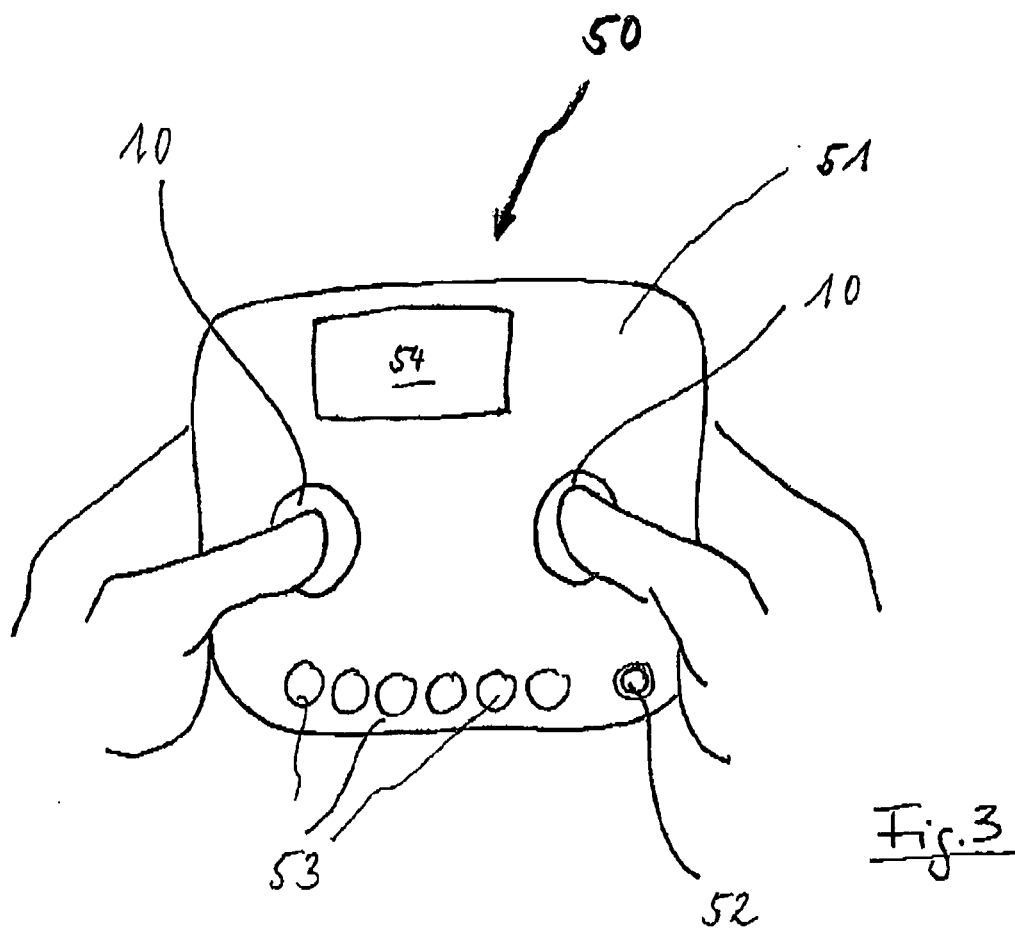


Fig. 2



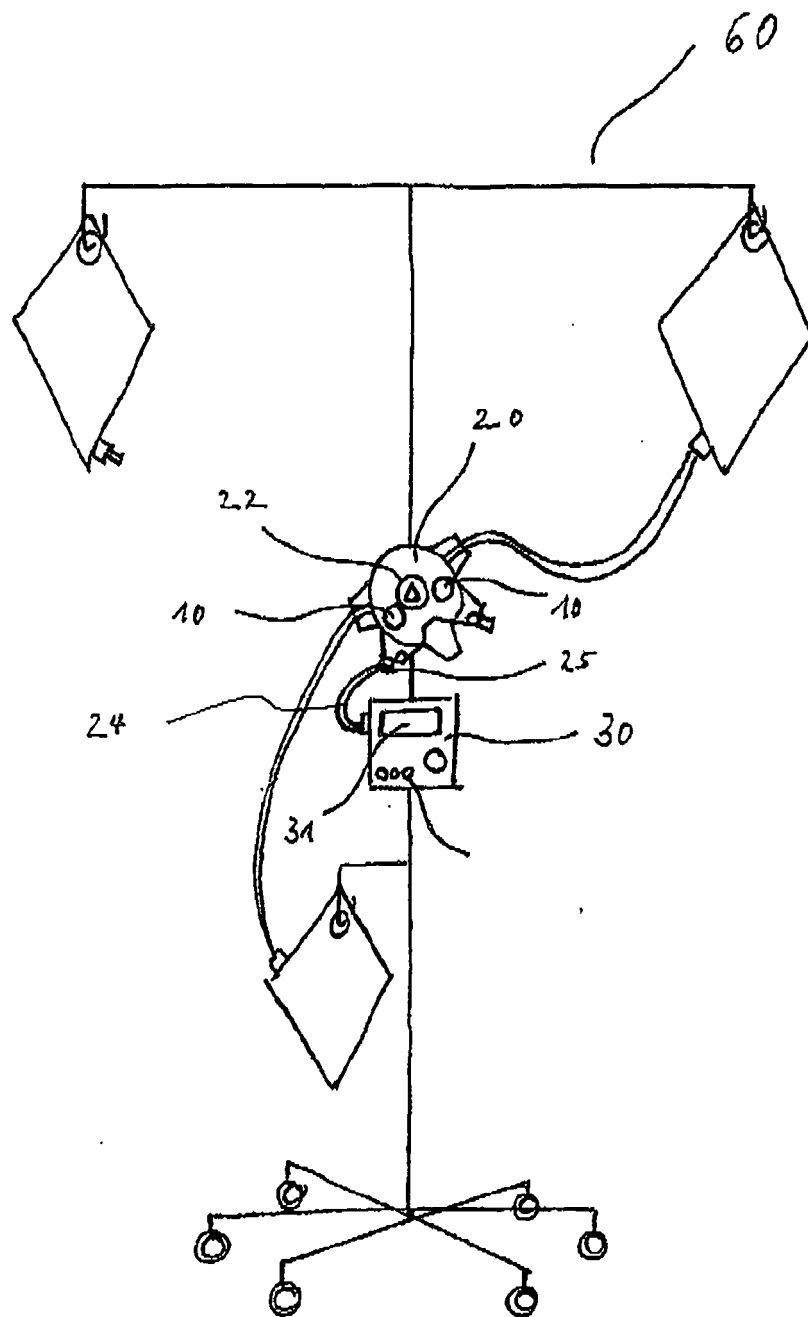


Fig. 5

## REFERENCES CITED IN THE DESCRIPTION

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