

The invention relates to a method and a device of permitting an indication as to the health condition of a living creature on the basis of a comparison of a selected physiological characteristic of the living creature to a corresponding reference characteristic of the healthy condition.

The invention relates in particular to a method and a device of which enable an indication as to the overall health condition of a human or animal.

All instruments employed in medical diagnosis acquire a specific characteristic or specific parameter of a patient, e.g. pulse frequency, blood pressure, chemical composition of the blood etc. Since the normal ranges are known from the corresponding measured values of a healthy population, a criterion for the nature and severity of an illness can be established from the deviation of the actual values from the standard. The diagnosis is made from a plurality of different characteristics, medical experience being the determining factor in selecting the characteristics in each case. However, until now it has not been achieved to establish explicit and objective criteria for the "overall health" condition of a patient even by means of "alternative" methods.

Accordingly it is an object of the present invention to provide a method and device of the aforementioned kind which permit a reliable indication as to the overall health condition of a test person. In addition, the invention is intended to permit establishing to what degree the condition of the test person deviates overall from an ideal condition. The device is further intended to permit economic examination of a large number of test persons by enabling the examination to be made in a quick and cost effective manner.

The method according to the invention is characterized by the features of the characterizing part of claim 1. Accordingly the selected physiological characteristic is detected at a statistically significant plurality of measuring points distributed over a pretermind surface portion of the living creature and the evaluation performed by means of statistical methods by a comparison of the frequency distribution of the measured values with a reference statistical distribution in the form of the logarithmic normal distribution. While it is known from the DE-A-27 19 341, for determining the surface roughness of the human skin, to use the frequency distribution of this parameter, results of measurements of a large circle of test persons are taken obtained at different times and locations. With the invention the evaluation is performed on the basis of the measurement values of a test person obtained essentially at a time across a selected predetermined body portion of the person, i.e. the logarithmic normal reference distribution is also derived from the detected measurement values of the specific test person. Due to it being easily available the skin of the test person is preferably used as the body region in question, the electrical

conductivity of the skin or its radiation intensity being taken as the physiological characteristic. However, the invention is restricted neither to such special physiological characteristic nor to the body region "skin". Instead, the method according to the invention is generally applicable also to other characteristics and other suitable internal or external body regions.

The invention makes use of the fact that according to the rules of statistics, parameters irrespective of which kind always follow a specific statistical distribution (viz. L. Sachs: Statistische Auswertungsmethoden, 2nd Edition, Springer Verlag Berlin 1969, pages 105-106), "statistical distribution" being understood to mean the probability function $p(x)$ indicating the probability of encountering a specific measured value x in an arbitrary test object, whereby x can encompass the total scale of values available.

The physiological characteristics of living creatures such as, for instance, body height, blood pressure, drug tolerance etc. are also always distributed according to a logarithmic normal distribution, the reason for this being assumed a multiplicative configurational principle (viz. e.g. also: H. Gebelein and H.J. Heite, Klin. Wschr. 28 (1959), page 41). Within the framework of tests according to the invention it was further established that the logarithmic normal distribution exists not only for a specific characteristic in measurements made on a plurality of individuals, but also for a single healthy individual when the characteristic concerned is measured on a sufficiently large number of measured values of the individual. "Sufficiently" in this context means no further significant change occurring in the resulting statistical

distribution when the number of measured values is further increased.

The ideal log-normal distribution of such measured values obtainable from a single test person exists only when the ideal "multiplicative configuration principle" - i.e. the combined effect of all sub-units in space and time in the sense of an ideal organization - is satisfied. Therefore, by comparing the statistical distribution, as measured or as determined by suitably transforming the measured values, to the logarithmic normal distribution an explicit classification of the "overall" condition with reference to the condition of an ideal biological organisation can be obtained. Further indications in this respect can be obtained in addition to the comparison when according to further embodiments of the invention the deviations of the same order, e.g. the relative differences of the moments of the first to nth order are determined and/or the change in the statistical distribution with time is established and subjected to a correlation analysis. The temporal development of the statistical distribution describes the dynamic behaviour of the network of internal dependencies forming the basis of the measurement. The correlation analysis (e.g. factor analysis) enables the internal relationships between the skin areas to be described dynamically for a known assignment of the measured values, these relationships including all interrelationships with the organs.

From this it follows that in the sense of the invention a test person is able to be classified "overall" as being "healthy" when his distribution function $p(x)$ does not significantly deviate from $p_n(x)$, where $p(x)$ represents the measured distribution function and $p_n(x)$ the ideal distribution function for a healthy

individual. This distribution function $p_n(x)$ is a logarithmic normal distribution and can be established according to the invention from the measured values of the test person, i.e. it not being necessary to obtain the normal distribution as an empirical function of the the measured values of a plurality of healthy test persons.

Inversely the "illness condition" in this "overall" sense can be defined by the systematic (and fully) listed deviations between the functions $p(x)$ and $p_n(x)$. One important advantage of the method according to the invention is, among other things, that there is no need to recourse to establishing the measured values of a plurality of test persons, but to calculate the ideal distribution function applicable to the individual test person directly from the measured values and to compare it to the actual statistical distribution.

Concerning the device of implementing the method according to the invention reference is made to claim 8. The device permits a quick detection of the measurement values and their evaluation on the spot. Because of its uncomplicated structure the device for its operation requires no specific experience and it can be realized with little costs.

The invention will now be explained in more detail with reference to an example and the drawing in which.

Fig. 1a, 1b show the statistical distribution of the conductivity values of the skin of a patient before treatment (Fig. 1a) and after treatment (Fig. 1b) as compared to the logarithmic normal

distribution employing the same mean values and variances in each case.

Fig. 2a, 2b show the ratio of the moments of the r th order ($r = 1...6$) for a logarithmic normal distribution and a measured distribution before treatment (Fig. 2a) and after treatment (Fig. 2b).

Fig. 3 is a block diagram of a device for detecting the conductivity of the skin and for processing the obtained measured values according to one embodiment of the invention

Fig. 4 is a section view showing the sensor member of a sensor arrangement of the device according to Fig. 3 and

Fig. 5 is a view of the sensor arrangement according to Fig. 3 as seen from below.

With reference first to Figs 3 - 5 one embodiment of a device or an apparatus for implementing the method according to the invention will now be described on the basis of measuring the electrical conductivity of the skin of a patient. The device includes according to Fig. 3 a sensor arrangement 1, a signal processing means 2 and a processor 3.

The sensor arrangement 1 can be a multichannel electrode comprising a sensor member 4 and a scanner member 5. The sensor member 4 is shown in more detail in Figs. 4 and 5 and includes a

plurality of needle-shaped electrodes or sensor elements 13 located longitudinally shiftable in a base member. Each sensor element 13 is assigned a spring to preload the sensor element in its initial position as shown in Fig. 4 in which the free ends of the sensor elements 13 protruding from the base member are located in a plane which may be flat or curved in accordance with the curvature of a bodily region, e.g. of the hand to be tested of a test person. The preloading of the sensor elements 13 causes them to exert a defined pressure on the skin surface when brought into contact therewith. An "adequate" number of sensor elements 13 is provided, it having been established that a number between 50 and 150, e.g. 60 sensor elements 13 is adequate in the aforementioned sense.

The sensor elements 13 are further distributed over a defined e.g. circular measurement area 14 of the sensor member 4. The scanner member 5 of the sensor arrangement 1 which can be of a type as generally known to the person skilled in the art, serves to successively scan the individual sensor elements 13 and to furnish the signals characterizing the conductivity values obtained at the individual sensor elements 13 to the processing means 2. The measurement values obtained may be e.g. "pointer drops" of "electroacupuncture" methods as usual nowadays which result as soon as the measurement electrode is applied to the measurement point with constant contact pressure on the basis of a maximum value.

The signal processing means 2 includes an amplifier 6 for amplifying the individual signals output by the sensor arrangement 1. The output of the amplifier 6 is connected to a

bypass filter 7 which has the effect of filtering out any noise signals from the measurement signals. The filtered measurement signals are then applied to an AD converter 8. The digital output signals of the AD converter 8 are passed via an interface 9 of the signal processing means 2 to a processor 3. In this way the processor 3 receives digital signals which are amplified and free of noise, these signals corresponding to the measurement signals established by the sensor arrangement 1.

In addition, the signal processing means 2 includes a means of applying a defined reference AC voltage to a suitable body location of the test person. If the measured values are obtained on one side of the hand of the test person, a suitable measurement point for applying the reference voltage is the other side of the hand. The means for applying the reference voltage includes a voltage generator 10, the output of which is furnished to a suitable hand electrode 12 via a variable amplifier 11.

The processor 3 establishes from the signals output by the processor 2 the logarithmic normal distribution $p_n(x)$ corresponding to the measurement values obtained from and initially applicable to the test person, i.e. the ideal distribution function of the latter and, furthermore, the real distribution function $p(x)$. The logarithmic normal distribution is that which has the same mean value $\bar{x}$ and the same dispersion σ as the measured distribution $p(x)$. From the deviations between $p(x)$ and $p_n(x)$ an indication is possible as to the nature and scope of the health problems involved.

The processor 3 also establishes other parameters characteristic of the health condition of the test person such as e.g. the ratio of the moments of the rth order of the logarithmic normal distribution to the measured statistical distribution. The result of the computations can be displayed on a computer monitor and/or printed out in the form of graphs or tabulated data. The processor 3 also handles localization and computation of the maximum conductivity value within the measured matrix.

Computation of the measured distribution function $p(x)$ and the logarithmic normal distribution $p_n(x)$ is explained in the following on the basis of an example computation in which the numerical values are those as tabulated in Table 1.

Example computation

1. Dividing the frequency values into n classes, whereby in this case $n = 14$. The class ^{mean values} marks are given over the full measurement range (as stated in Tab. 1) as 4, 12, 20, 28, ..., 108 in steps of 8 (as the x axis of Fig. 1a, b shows). In the following these values are identified $k_m(i)$ where $i = 1, \dots, 14$. For example $k_m(2) = 12$, $k_m(3) = 20$.

2. Computation of the measured distribution $p(x)$

a) Computation of the sum of the frequency values ($p(x)$) given in Table 1. As an example the values before treatment are given.

The sum stated N in the following is

$$N = \sum_{i=1}^{k=14} P(x_i)$$

Thus $N = 0+14+22+34+18+32+2+0 = 122$

The frequency values $P(x)$ are then divided by the sum N

$$\begin{aligned} \frac{0}{122} &= 0, \frac{14}{122} = 0.115, \frac{22}{122} = 0.18, \frac{34}{122} = 0.279, \frac{18}{122} = 0.148, \\ \frac{32}{122} &= 0.262, \frac{2}{122} = 0.016, \frac{0}{122} = 0. \end{aligned}$$

Expressed as an equation:

$$p(x_i) = \frac{1}{N}P(x_i) = P_i$$

This measured distribution is depicted as a bar graph.

3. Computation of log. normal distribution

- Computing central value $\bar{x}$ and dispersion σ :

$$\begin{aligned} \bar{x} &= \frac{1}{N} \sum_{i=1}^k P(x_i) * Km(i) \\ \sigma &= \sqrt{\frac{1}{N-1} \sum_{i=1}^k (Km(i) - \bar{x})^2 P(x_i)} \end{aligned}$$

Example:

$$\bar{x} = \frac{1}{122}(14 * 52 + 22 * 60 + 34 * 68 + 18 * 76 + 32 * 84 + 2 * 92) = 70.49.$$

$$\begin{aligned} h\sigma &= (52 - 70.49)^2 * 14 + (60 - 70.49)^2 * 22 + (68 - 70.49)^2 * 34 \\ &\quad + (76 - 70.49)^2 * 18 + (84 - 70.49)^2 * 32 + (92 - 70.49)^2 * 2 \end{aligned}$$

$$\sigma = \sqrt{\frac{1}{121} * h\sigma}$$

expedients:

$$\kappa = \sqrt{\ln\left(\frac{\sigma^2}{\bar{x}^2} + 1\right)} = 0.156.$$

$$\mu = \ln \bar{x} - \frac{\ln \sigma^2}{2} = 4.243$$

log. normal distribution

$$p_n(x_i) = \frac{1}{\sqrt{2\pi \ln \sigma Km(x)}} \exp \left(-\frac{1}{2} \left(\frac{\ln Km(x_i) - \mu}{\kappa} \right)^2 \right)$$

Example for class ^{value} mark 68:

$$p_n(68) = \frac{1}{\sqrt{2 * \pi * 0.156 * 68}} \exp \left(-\frac{1}{2} \left(\frac{4.219 - 4.243}{0.156} \right)^2 \right) = 0.121$$

All values of $p_n(x_i)$ are then summed over all i 's and divided by the total sum. This total sum $\sum_{i=1}^{k=14} p_n(x_i) = 0.412$ so that e.g. at the mark 68 is not 0.121 but according to this standarization

$$p_n(68) = \frac{0.121}{0.412} = 0.294$$

Example

On a patient seriously afflicted with bronchial asthma the electrical conductivity values were established at 112 measurement points on the skin and the relative frequency of the values entered on a scale from 0 to 100.

The frequencies at which the values in the various scale ranges were measured are listed in Table 1 for $n = 8$ measurement intervals. The left-hand column relates to the values prior to treatment, those in the right to the values following relatively successful treatment (patient suffered less).

The data itself indicates neither an objective criterion for the health condition of the patient prior to treatment nor the degree of improvement following treatment, whereas when testing the frequencies $p(n)$ in obtaining specific values of conductivity n as to their agreements with the logarithmic normal distribution (represented in Figs. 1a and 1b by the solid line curve) we then find:

1) Before treatment there are significant deviations from the normal distribution (Fig. 1a) as well as in the deviations of the moments of third and higher order (Fig. 2a) defined as

$$(m^r = \sum_{i=1}^N p(n_i) \cdot (n_i - \bar{n})^r)$$

This indicates that the patient is not healthy, the nature and seriousness of the affliction being recognizable in this

projection as the nature and degree of deviation from the logarithmic normal distribution.

2) Following treatment both a significantly better agreement with the logarithmic normal distribution (Fig.2b) and also a lesser deviation of the higher order moments from the ideal moments of the normal distribution are recognizable, the curves being transformed so that the moments of the first and second order (averages and variances) of the ideal and measured distribution agree.

Table 1: Measured frequencies of conductivity values obtained at 112 points on the skin in an assigned measurement range of 0 to 100 on a test person suffering from bronchial asthma

	<u>before</u>	treatment	<u>after</u>
Measurement range	frequencies		frequencies
0 - 48	0		0
48 - 56	14		15
56 - 64	22		34
64 - 72	34		34
72 - 80	18		30
80 - 88	32		8
88 - 96	2		1
96 - 112	0		0

Up until now the invention has been described on the basis of measuring the electrical conductivity of the skin as the physiological characteristic. When other characteristics are made use of the means of the invention must be modified accordingly. For example, the intensity with which the skin radiates in the

infrared or optical range can be utilized as the characteristic. In this case proximity sensor elements are used preferably in an arrangement and number corresponding to that of the needle-shaped sensor elements of the embodiment already described. Other means for sensing the physiological characteristics can take the form of grid, roller or brush-type electrodes. Although, in addition, the above describes in particular the preferred assessment of the overall health condition of a test person on the basis of comparing the real distribution function to the ideal, i.e. logarithmic normal distribution of the measured values obtained from the test person, the invention is understood to also cover a comparison on the basis of a reference statistical distribution of the data established for the physiological characteristic in question from measurements made on a number of healthy individuals.



Claims

1. A method of permitting an indication as to the health condition of a living creature on the basis of a comparison of a selected physiological characteristic of the living creature to a corresponding reference characteristic of the healthy condition characterized by said selected physiological characteristic being detected by means of a multi-channel sensor unit having a plurality of sensor elements distributed over a predetermined surface area, at a plurality of measurement points corresponding to said plurality of sensor elements, determining by means of statistical methods the statistical distribution and the logarithmic normal distribution of the signal levels of the signals output by said sensor unit and corresponding to the measurement values of said selected physiological characteristic, performing an establishing of the departures of the statistical distribution from the logarithmic normal distribution of said signal levels, whereby said logarithmic normal distribution being taken as a reference characteristic.
2. A method according to claim 1, wherein a region of the skin of the living creature is employed as the body region.
3. A method according to claim 1, wherein the physiological characteristic to be detected is the conductivity of the skin to which a specific electric potential is applied.
4. A method according to claim 3, wherein the change with time in the conductivity is established according to methods of electroacupuncture.
5. A method according to claim 1, wherein the physiological characteristic to be detected is the radiation intensity of the skin, particularly in the optical or infrared range.
6. A method according to any of the preceding claims, wherein the deviations of the same order are determined from the comparison.



7. A method according to any of the preceding claims, wherein furthermore the change in the statistical distribution is established as a function of time and subjected to a correlation analysis.

8. A device for permitting an indication as to the health condition of a living creature according to claim 1, characterized by a multi-channel sensor unit (1) for detecting a selected physiological characteristic of the living creature at a plurality of measurement points distributed over a defined ~~body~~ region and for outputting corresponding signals, a means (2,3) for processing the signals output by said multi-channel sensor unit, and a means for calculating from the signals output by said signal processing means the actual statistical distribution and the logarithmic normal distribution of the signal-related measured values of the physiological characteristic obtained.

9. A device according to claim 8, wherein said multi-channel sensor unit (1) includes a plurality of sensor elements (13) distributed over a defined surface area and means (15) of successively scanning said sensor elements.

10. A device according to claim 9, wherein said sensor elements include needle-shaped elements (15) similar to acupuncture needles.

11. A device according to claim 8 or 9, wherein said multi-channel sensor unit (1) comprises sensor elements for obtaining the measured values by proximity.

12. A device according to claim 8 or 9, wherein said multi-channel sensor unit (1) includes grid, roller or brush-type electrodes to obtain the physiological characteristic.