The present invention concerns a system according to the introductory part of claim 1.

In recent times, test carriers, for example in the form of test strips or in the form of flat, substantially quadratic platelets, are used increasingly for the analysis of body fluids, especially of urine and blood. Analytical determinations, especially for medical purposes, can be carried out especially simply with these test carriers. First, the test carriers are brought into contact with the sample which, in the case of the investigation of urine, generally takes place by dipping in of a strip-shaped test carrier, whereas for the investigation of blood, a blood droplet is usually applied to the test field of the test carrier and, after the full absorption of the test field, is wiped off or washed off. In every case, the test field, which represents the part of the test carrier decisive for the analytical determination, contains reagents which react with the component materials of the applied body fluid.

For the evaluation of the reaction, the test carrier is placed in an appropriate evaluation device. There, usually at a definite point of time after application of the sample, a physical measurement value is measured which serves as measure for the concentration of a particular component of the body fluid. In the case of the analysis of body fluids, a reaction is preponderantly used which leads to a colour change characteristic for the analysis to be carried out. In this case, the diffuse reflectance of the test field at a definite wavelength is determined as physical measurement value. The invention is directed especially to such test carriers to be evaluated photometrically. In the case of another known type of test carrier, an electrochemical reaction is used. In this case, a

voltage or a current strength is determined as physical measurement value characteristic for the analysis.

The test carriers are usually specifically suitable for a particular analysis, i.e. for the ascertainment of the concentration of a particular component of a body fluid, of a so called parameter, a particular test carrier type is offered by the manufacturer. For the evaluation of the test carrier, there are used not only apparatus which are specially directed to such as test carrier type (single parameter apparatus), but also those which can measure several different test carriers (multiple parameter apparatus).

Very high requirements of exactitude are placed on the test carriers and the associated evaluation apparatus, which together form a system. Usually, a large number of test carriers are produced together under conditions which remain the same. For example, in the case of photometrically evaluatable tests, for a production batch is used a particular carrier matrix for the test fields and a single batch of reagents. Therefore, the test carriers of such a production batch agree almost completely in their properties. On the other hand, the test carriers of different production batches differ in their evaluation curve, i.e. in the relationship between the physical measurement value determined by the apparatus, especially the diffuse reflectance of the test field, and the concentration to be determined of the parameter sought. These variations are so great that the high requirements for quantitative determinations demanded in medicine cannot be fulfilled when the differences between the different production batches are neglected.

In principle, the desired exactitude could be achieved by calibration with standard solutions before the use of a test carrier. However, this makes

difficult the handling of the analytical system.

Therefore, in the past it has already been suggested to transfer to the evaluation apparatus in a suitable way the information regarding the batch-specific evaluation curve of the particular test carrier batch. Thus, in the European Patent Application with the publication number 73,056 is described that the individual test carriers can be provided with a bar code which contains information regarding the batch-specific evaluation curve. The associated evaluation apparatus contains a bar code reader for the pick-up of the information. The European Patent Application with the publication number 132,790 describes strip-shaped test carriers which have a magnetic layer which is also suitable for the storage of information. This is introduced into the magnetic layer by the manufacturer of the test carrier and read off in the evaluation apparatus by means of an appropriate magnetic reading head.

These two known processes permit an especially convenient handling because the apparatus in each case automatically receives the necessary information without the user having to undertake any handling steps. However, this advantage is countered by a considerable expense. In the case of the production of the test carrier, the information must be conveyed to each individual test carrier and special test carriers adapted to the particular type of apparatus must be produced. In the apparatus, in each case an appropriate reading device must be present, which considerably increases the costs of the apparatus.

Therefore, for simpler apparatus, especially for the determination of blood glucose values for diabetics, it is widely usual to neglect the batch-specific variations of the test carriers. However, this leads

to medically non-tolerable inexactitudes. In the case of another known blood glucose determination apparatus, the batch-specific evaluation curve is applied to the test strip packages in each case on a film separate from the test carriers. The expenses in the case of the production of the test carriers are thereby admittedly reduced but in this case, too, the apparatus must have a code reader and is thereby made considerably more expensive.

It is the task of the present invention to improve a system of the initially described type in that the batch-specific evaluation curve is taken into account so that an exactitude fully satisfying the medical requirements is achieved and, at the same time, the production costs are as favourable as possible not only of the test carrier but also of the evaluation apparatus.

This task is solved by the invention defined in the patent claims.

On the basis of the invention, the apparatus can be adjusted very simply to the evaluation of the particular test strip batch. On the package of the associated test carriers is printed, for example, a sequence of numbers or marks, whereby preferably the totality of the calculation bearings is divided up into several preferably equal-sized part amounts, which are called sets, and the number of the marks corresponds to the number of the sets of the calculation bearings. This is adjusted on the apparatus by means of a suitable adjustment device. There come into question, for example, decimal actuators with a number of positions corresponding to the number of sets of calculation bearings which can, in each case, be adjusted, for example, to 10 different values. Another possibility consists in providing appropriate keys which can be used for the code introduction as is described further

below in more detail. In every case, the user of the apparatus must merely examine the code of the batch once in the case of opening of a new package with test carriers and possibly correspondingly change the adjustment device on the apparatus. On the basis of these few adjustment values, the apparatus can, on the basis of the novel process, according to which microprocessors calculate the concentration from the physical measurement values, determine this concentration with an exactitude which was hitherto not possible in the case of such simple apparatus.

The fact that the evaluation apparatus according to the invention does not require any code reader saves not only costs but also permits an especially small mode of construction. This is medically also of importance because precisely diabetics are to measure their blood sugar level if possible under normal living conditions and, therefore, also to use the measurement apparatus away from home. Therefore, the acceptance of a system for the blood sugar determination is the better, the smaller and easier transportable is the apparatus.

Generally said, the invention permits a considerable reduction of the amount of information which must be processed for the exact batch-specific evaluation of test carriers. Not only is the transfer of the evaluation curve to the apparatus thereby simplified but also the processing of the information on the apparatus itself. Consequently, there can frequently be used a simple 4 bit microprocessor instead of a considerably more expensive 8 bit microprocessor. A considerable saving of costs and constructional size is hereby also given.

Especially good results are achieved when a standard evaluation curve is stored in the apparatus

which has a similar course to the evaluation curves of the test carriers to be evaluated by the apparatus, whereby in the neighbourhood of the cusps of the curves, as well as of the curve ends, standard bearings are defined on the standard curve and the sets of the calculation bearings are provided in the neighbourhood of the standard bearings. Thereby especially the relationship of the distance of the calculation bearings to the next-lying measurement value, on the one hand, and the distance of the next-lying standard bearings, on the other hand, are thereby included in the calculation.

The invention is explained in more detail in the following on the basis of an embodimental example illustrated in the Figures. They show:

Figure 1 a circuit diagram of an evaluation apparatus according to the invention for test carriers

Figure 2 a graphic illustration of two batch-specific evaluation curves and of a standard evaluation curve

Figure 3 a section of a batch-specific evaluation curve and of a standard evaluation curve with, in comparison with Figure 2, changed position of the calculation bearing pairs of values

Figures 4 and 5 examples for the application of visible signs on the test carrier or its package or package enclosure.

The test field is illuminated by the light of a light emitter (16). The light diffusely reflected from the surface of the test field (14) is received by a measurement device (18). The measurement device usually comprises a light-sensitive receiver, for example a photodiode, an amplifier and an analogue-digital converter. Suitable measurement devices are known.

The central element of the apparatus is a processor (20) with associated, not separately illustrated memory. It serves the purpose of controlling the various functions of the apparatus and of converting the physical measurement values provided by the measurement device (18) into the sought concentration values. The so calculated values are shown on an indicator (24) by means of an indicator control (22). A digital display is usually employed as indicator.

In order to be able to calculate the corresponding concentration values from the physical measurement values, the processor (20) requires information regarding the batch-specific evaluation curve. In the illustrated embodimental example of the invention, this is supplied to it via three keys (26, 28, 30). The values selected with the help of the keys are shown on the display (24). When the indication of the display correctly reproduces, for example, the code given on the test carrier package, the processor (20) is given the order to take over and to store the code shown on the display.

The display can, for example, be constructed as a usual 7-segment display with which can be shown, besides the ten figures of the decimal system, also a series of signs. In a practically preferred embodimental form, each position of the display can show 16 different signs so that, with the help of the keys 26 to 28, for each position of the code, 16 different discrete values can be shown and transferred to the processor (20). The number 16 is especially preferred because up to 16 different values can easily be coded and processed, with the help of a 4-bit word, within the processor. However, according to the requirements, another number of discrete adjustment values can also be used.

Furthermore, in Figure 1 one also sees a timer (32) for the control of the microprocessor and a power pack (34) for the energy supply of the system. Other elements, such as for example elements for the control of the working voltage and the like, are, as mentioned, not illustrated for the sake of clarity.

The calculation of the concentration from the physical measurement values in the processor (20) takes place with the help of the code introduced, for example, via the keys 26, 28, 30 and the display (24) consisting of only few positions with, in each case, a small number of discrete values. This process is explained in more detail in the following on the basis of Figures 2 and 3. In Figure 2 are shown three curves S, I and J. The broken-line curve I shows the course of an exemplary evaluation curve for an optical test for the determination of glucose in the blood. On the ordinate is plotted the diffuse reflectance R in the case of a measurement wavelength determined by the optical system of the apparatus. On the abscissa axis is plotted the corresponding concentration of the parameter to be determined, thus here of the glucose. In the case of curve I, one can see that, on the basis of the characteristic properties of the test field of the analytical test carrier, the diffuse reflectance R is high in the case of low concentration values. In middle concentration range, it decreases with a convex curvature seen right from above. The course of the curve, after passing through a cusp, then passes over into a concave curvature. In this region, the diffuse reflectance R decreases less strongly with increasing concentration C and finally, in the case of high concentrations, only changes a little.

The general course of evaluation curves of test carriers is dependent upon the chosen reagents and

other properties of the test carrier and, therefore, is different from test to test. However, a course of the here-illustrated type if typical for many cases. It has the advantage that, in the middle region, there is given a high dependency of the remission on the concentration. This is favourable for a high measurement exactitude.

As mentioned, the evaluation curves for different test carriers of one production batch are not equal. For example, in Figure 2 a further evaluation curve is shown dot-dashed, which is designated with J. One can see that this curve is considerably different from the evaluation curve I. However, in some fundamental properties, it agrees with this. In particular, it also first has a concave and then, after a cusp, a convex course. For the sake of clarity, further evaluation curves are not illustrated. However, it is to be stressed that each batch has a different evaluation curve so that there is an infinitely large plurality of possible evaluation curves which, in the scope of the invention, can, with good approximation, be taken into account.

Now it is important for the present invention that a standard evaluation curve is fixed and is stored in the memory of the evaluation apparatus, the course of which is similar to the evaluation curves in the sense defined in the following. Such a standard curve is shown unbroken in Figure 2 and is designated with S.

The standard evaluation curve is first to run in the value range of the evaluation curves. It is therewith meant that the standard evaluation curve lies at least in the desired concentration range within the extreme values of the physical measurement value of the evaluation curves of the test carrier occurring in practice. As is shown in Figure 2, these extreme values

are not marked perhaps continuously from the same evaluation curves. In the illustrated embodimental form, the curve I has, for example, in the region of lower and higher concentrations, especially high R values and the curve J especially low R values. In the region of middle concentrations, it is precisely the other way round. The standard evaluation curve S is to lie somewhere in the region of the evaluation curves. In many cases, it is especially favourable when it runs about in the middle value region of the evaluation curves, thus about in the centre of the evaluation curves of different test carrier batches determined by a plurality of preliminary experiments.

Furthermore, the standard evaluation curve is to have a convex or concave curvature substantially in the same sections of values of the diffuse reflectance as the evaluation curves. Quantitatively it can be said that the cusp between a concave and a convex curved region of the standard curve should lie at such a value of the diffuse reflectance that the values of the diffuse reflectance corresponding to the cusps of the possible evaluation curves of the test carrier batches differ from these by at most 20%, preferably at most 10%.

As is to be seen from Figure 2, the concentration ranges in which the curves I and J show the same curvature do not agree well. In particular, the cusp does not lie at the same concentration value. Therefore, it is not possible and also not necessary that the standard evaluation curve shows, in precisely the same sections of concentration values, the same curvature as the evaluation curves. It suffices when these agree substantially so that, in the iteration process described in detail further below, sufficiently exact values of the measurement result are achieved.

The standard curve can e.g. be expressed in the form of a polynome, the coefficients of which are stored. Preferably, it is represented as polygon, i.e. points are stored which lie on the course of the curve and one interpolates linearly between the points. Of course, the standard curve can also be stored in a transformed form (e.g. linearly transformed). In this case, the transformation must be taken into account in the following calculations.

Furthermore, it is important for the invention that on the standard curve in the region of each cusp, between a concave and a convex curved section, a point is defined and stored in the memory which is called a standard bearing. In Figure 2, it is designated with R_{sb}, C_{sb}. The term "in the region" is here to be understood as analogous to the term "substantially" in the preceding section, i.e. the concentration value of the standard bearing must not differ so much from the concentration value of the cusp that the process for the calculation of the concentration from the measurement values leads to unsatisfactory results. How large this deviation can be in the individual case can easily be determined in the individual case on the basis of the teaching according to the invention. Quantitatively it can be said that the concentration value of the standard bearing is to deviate by not more than 20%, preferably not more than 10% from the concentration value of the cusp.

Further standard bearings are present in the region of the ends of the concentration range to be determined. Decisive is here the value range of concentration values actually employed in practical use, not the value range possibly going beyond this, admittedly technically possible but not used in practice in the case of the particular analytical system. The expression "in the region" is to be understood analogously as in the preceding section.

Furthermore, it is an important characteristic of the invention that the batch-specific evaluation curves are not transmitted to the apparatus in the form of, for example, a binary coded mathematical function which associates every value of the diffuse reflectance to a concentration value but rather that only a limited number of discrete pairs of values R_{ia}, C_{ia}; R_{ib}, C_{ib}; R_{ic}, C_{ic}; ... is transferred from a finite supply of fixedly programmed calculation bearings. Thus, the calculation bearings are, from the beginning, fixed independently of the evaluation curve and stored in the memory of the evaluation apparatus. In each case, a set of calculation bearings is present in the region of the standard bearings. Normally, in the region of each standard bearing, an equal number of calculation bearings is defined, i.e. each set has the same number of points. In the case of a curve course of the type illustrated in Figure 2 with a standard bearing in the region of the single cusp and two further standard bearings in the region of the ends of the concentration range to be determined, thus in all three standard bearings, three equal-sized sets of calculation bearings are thus defined. Each of these sets can advantageously contain 16 different calculation bearings (i.e. the pairs of values R_{ia}, C_{ia}; R_{ib}, C_{ib}; R_{ic}, C_{ic}; with in each case $i = 1 \ldots 16$). These pairs of values programmed in the apparatus are then selected in the manner described in connection with Figure 1, for example with the help of the keys 26, 28, 30 in adaptation to the particular test strip batch. Each of the 16 signs selectable with the keys 26, 28, 30 corresponds to a pair of values. Thus, for example, the first number serves the selection of one of the 16 calculation bearings R_{ia}, C_{ia}, the second number the selection of one of the 16 selection bearings R_{ib}, C_{ib}

and the third figure the selection of one of the 16 calculation bearings R_{ic}, C_{ic}. For each test carrier batch, the user of the evaluation apparatus receives an instruction, for example in the form of an imprint on the package, which sign sequence he is to select for the selection of the calculation bearings. By the keying in of this sign sequence, for each set of calculation bearings is, in each case, selected a pair of values.

The invention is especially advantageous when the number of the informations to be adjusted and to be transmitted for the selection of the pairs of values is kept small. Consequently, the number of sets of calculation bearings, which are associated with the standard bearings on the standard curve, is limited to at most ten, preferably at most five. Thus, for each test carrier batch, only a few pairs of values are transmitted from the calculation bearings to the processor. The number of calculation bearings per set preferably amounts to at most 256.

As mentioned, the sets of calculation bearings lie in the region of the standard bearings. The most precise position is given from the iteration process described further below and can easily be ascertained by the expert on the basis of the teaching according to the invention.

Preferably, the calculation bearings each lie on a line cutting the standard curve at an obtuse angle. In Figure 2 are indicated three such lines a, b and c. They are associated with the standard bearings R_{sa}, C_{sa}; R_{sb}, C_{sb} and R_{sc}, C_{sc}. In the illustrated preferred embodimental form, they cut the standard curve at these points. As shown, they are preferably made substantially straight.

Figure 3 shows only a part of a standard curve S and of an evaluation curve I, namely, the part lying between two standard bearings R_{sa}, C_{sa}; R_{sb}, C_{sb} and, respectively, two calculation bearings R_{ia}, C_{ia}; R_{ib}, C_{ib}. In the case of the here-illustrated especially simple embodimental form of the invention, the calculation bearings each lie on lines which run parallel to a coordinate of the coordinate system. In the drawing are, in each case, indicated ten calculation bearings associated with the standard bearings R_{sa}, C_{sa} and R_{sb}, C_{sb}. The calculation bearings R_{1a}, C_{1a}; ... ; R_{10a}, C_{10a} associated with the standard bearing R_{sa}, C_{sa} lie on the line a which runs parallel to the ordinate of the coordinate system. Consequently, all these calculation bearings have the same concentration value as the corresponding standard bearing ($C_{1a} = C_{2a} = \ldots = C_{10a} = C_{sa}$). This simplifies the storage in the apparatus because, for each calculation bearing and the standard bearing, in each case only the R value has to be stored separately, whereas the C value, which is the same for all calculation bearings and the standard bearing, is only stored once. The corresponding applies for calculation bearings R_{1b}, C_{1b}; ...; R_{10b}, C_{10b} lying on the line b parallel to the abscissa. The R value for all calculation bearings is here the same and agrees with the R value of the associated standard bearing R_{sb}.

The process for the calculation of a concentration value C_{ix} from the measured value of the diffuse reflection R_{ix} is also explained in the following on the basis of Figure 3.

There is measured, for example, a diffuse reflectance of the value R_{ix}. The true evaluation curve of the test carrier used is illustrated in Figure 3 as a broken line and designated with I. The

horizontal defined by the measurement value R_{ix} cuts the curve I at point P, thus the concentration value associated with this point P is the true concentration value which is to be determined. To determine it exactly is, however, only possible when the curve I for each batch is completely stored in the evaluation apparatus. Since the evaluation curves of analytical test carriers cannot be shown exactly even with very complicated functions of high order, this is, in principle, not possible. Therefore, one works with approximation processes with the help of which the evaluation curves are shown approximately, i.e. a concentration value C_{ix} is associated with each measurement value R_{ix} which corresponds to the true evaluation curve with the best possible approximation. This is, in principle, possible in that one shows the particular evaluation curve of the test carrier batch in the way already discussed above in the form of a function of higher order and transmits the parameters of this function to the evaluation apparatus. However, this requires a very great expense, especially with regard to the evaluation apparatus, as was also explained in detail further above.

Therefore, as a rule, for simpler evaluation apparatus, a single average evaluation curve is employed for all test carrier batches. If one assumes in Figure 3 that the there-indicated standard curve S is such an average evaluation curve, then one sees that the horizontal corresponding to the measurement value R_{ix} cuts this curve at the point Q. One immediately sees that the concentration value corresponding to this point Q differs very much from the true concentration value. Therefore, such a rough approximation is completely unsatisfactory.

Now the present invention achieves, with an extraordinarily small expense, a much better approximation to the true evaluation curve in that from the measurement curve R_{ix} is first calculated a standard measurement value R_{sx} on the standard curve S and then from the concentration value C_{sx} corresponding to the standard measurement value R_{sx} the sought concentration value C_{ix}. For the first calculation step is, on the one hand, used the distance of the two R values of the calculation bearings (e.g. $R_{ia} - R_{ib}$) lying next to the measurement value R_{ix} and, on the other hand, the distance of the two R values of the standard bearings (e.g. $R_{sa} - R_{sb}$) with which these calculation bearings are associated. The invention is thereby based substantially on the knowledge that, in the case of corresponding choice of the calculation bearings and of the standard bearings, as well as a curve course of the standard curve similar in the discussed sense to the evaluation curves, the relative change of a remission value with regard to the neighbouring calculation bearing values runs similarly with surprisingly good approximation, like the corresponding change on the standard curve in comparison with the standard bearings.

This is explained in more detail on the basis of Figure 3, whereby the especially preferred but not solely possible linear approximation is described. The operational sign convention of the given calculation example is thereby so chosen that, in the illustrated curve section, positive remission values and concentration values result. For curve sections of another type, the operational signs can be correspondingly changed.

For the calculation of the standard measurement value R_{sx} on the standard curve, there is first formed

the ratio α from the distance of the measurement value R_{ix} from the neighbouring calculation bearing R_{ia} to the distance of the calculation bearings R_{ia} and R_{ib}. This ratio is multiplied by the distance of the standard bearings R_{sa} and R_{sb} and the so obtained relative remission decrease with regard to the standard bearing R_{sa} is subtracted from this. The result is the standard measurement value R_{sx}, which represents the value on the standard curve corresponding to the measured diffuse reflectance R_{ix} in the sense of the present invention.

$$R_{sx} = R_{sa} - \alpha(R_{sa} - R_{sb}); \quad \alpha = \frac{R_{ia} - R_{ix}}{R_{ia} - R_{ib}}$$

This value R_{sx} corresponds to a concentration value C_{sx} on the standard curve S. This value is now converted in a corresponding approximation process having regard, on the one hand, to the distance of the concentration values C_{ia}, C_{ib} to the neighbouring calculation bearings and, on the other hand, to the concentration values of the neighbouring standard bearings C_{sa}, C_{sb}. In linear approximation is formed the relationship between the distance of the value C_{sx} from the neighbouring standard concentration value C_{sa} to the distance between the standard concentration values C_{sa} and C_{sb}. This ratio β is multiplied by the distance of the two concentration values of the calculation bearings C_{ib} and C_{ia} and added to the concentration value C_{ia} of the neighbouring calculation bearing.

$$C_{ix} = \beta\,(C_{ib} - C_{ia}) + C_{ia}; \quad \beta = \frac{C_{sx} - C_{sa}}{C_{sb} - C_{sa}}$$

The concentration value C_{ix} is obtained in this way. This corresponds not exactly but with very good approximation to the concentration value to be measured.

This is made clear in Figure 3 in that the points C_{ix}, R_{ix} differ only slightly from the point P lying on the true evaluation curve.

As mentioned, instead of the linear approximation described in detail, another approximation process can also be chosen in which is taken into account the relationship of the mentioned distances between the calculation bearings, on the one hand, and the standard bearings, on the other hand. In special cases, a logarithmic or quadratic approximation can, for example, be recommended. However, the described linear approximation is especially simple and leads to very satisfactory practical results.

The quality of the approximation according to the process according to the invention is very substantially dependent upon the choice of the standard curve, of the standard bearings and of the calculation bearings within the limits described in detail and claimed. For the optimisation, there is recommended an iteration process which takes place somewhat as follows:

First, a plurality of test carrier batches is produced and the associated evaluation curves measured exactly. Thereafter, a first standard curve is so placed that it runs approximately in the middle of the evaluation curves. The standard bearings are first laid exactly on the cusps of the standard curve and on the ends of the measurement region. By means of the standard bearings, curves are laid running straight or only slightly curved in an obtuse angle to the course of the standard curve in the particular standard bearing. Preferably, for the sake of simplicity, one should first seek lines which run parallel to the axes of the coordinate system. On these are defined calculation bearings which have the same distances

from one another. The distances and the distribution of the calculation bearings on both sides of the standard bearing are thereby so chosen that the outermost calculation bearings still lie outside of the outermost evaluation curves of the investigated test carrier batches.

For each test carrier batch are now first chosen those calculation bearings from each set of calculation bearings which lie as close as possible in the course of the curve. With the help of these calculation bearings and of the process according to the invention, there is calculated the approximate course of the evaluation curve, graphically illustrated and compared with the particular actual evaluation curve. If all previously measured evaluation curves correctly illustrate with the desired quality of approximation, then the process is finished. Usually, however, at least some evaluation curves, at least in part regions, are not reproduced with the necessary quality. In such cases, the course of the standard curve and/or the choice of the standard bearings and of the calculation bearings are changed and a new sample run carried out in order to test whether the necessary exactitude is now achieved. This process appears laborious but, with modern data processing apparatus, can be routinely carried out comparatively quickly. It is decisive that, on the basis of the fundamental teaching of the present invention defined in the claims, very complicatedly formed evaluation curves can also be calculated with an extremely small expense on the part of the evaluation apparatus and with very good exactitude, i.e. that it is at least possible to take into account batch-specific variations of the test carriers between one another in a comparatively simply constructed and cost-favourable apparatus, whereby, at

the same time, the system of apparatus and test carrier is especially simple to handle.

The invention can advantageously also be used for evaluation apparatus in which several different types of test carriers can be measured, i.e. with which the determination of several different parameters is possible. In this case, for each test carrier type, the standard curve, the standard bearings and the calculation bearings are stored separately. However, depending upon the course of the curve, it is also possible that the same calculation bearings or standard bearings and, under certain circumstances, also parts of the course of the standard curves can be used commonly for several types of test carriers. Memory capacity is thereby saved. Of course, for each test carrier batch of a particular test carrier type, the particular associated combination of the calculation bearings must be chosen separately. If, for example, for each test carrier type, three sets of calculation bearing are available, the selection can expediently take place by a sequence of four signs. The first sign then characterises the test carrier type. The further three signs characterise the choice of the calculation bearings from the finite supply of the calculation bearings stored for the particular test carrier type.

Fig. 4 shows, by way of example, how the visible signs, on the basis of which the calculation bearings are chosen, are applied to a test carrier 10. In this case, they are the alphanumerical signs "9F4", on the basis of which three calculation bearings are selected from a set of, in each case, 16 calculation bearings. They are applied to the base 12 of the test carrier 10. All test carriers of a production batch have the same visible signs.

Fig. 5 shows an example in which the visible signs are applied to a test carrier package 40 and/or to a corresponding package enclosure 42. In the case of this process, the production is simplified because not every test carrier has to be printed with the visible signs.

Patent Claims

1. System for the determination of the concentration (C) of components of body fluids comprising

(1) a test carrier (10) with a test field (14) which contains a reagent which, after application of the sample liquid, reacts with the component, whereby a measurable physical value, especially the diffuse reflectance of the test field (14), changes depending upon the concentration (C) of the component of the body fluid and

(2) an apparatus with a measurement device (18) for the measurement of the physical value and a memory and a processor (20) including evaluation electronics for the measurement of the test value (R) of the physical value and calculation of the concentration (C) from the test value (R) on the basis of information transmitted to the apparatus via the evaluation curve, i.e. the relation between the test value (R) of the physical value and the concentration (C) which is different depending upon the production batch of the test carrier, characterised in that

a) in the apparatus is stored a finite number of discrete calculation bearings, whereby each calculation bearing corresponds to a pair of values of, in each case, an R value and, in each case, a C value (R_{ia}, C_{ia}; R_{ib}, C_{ib}; .....)

b) on the test carriers, their packing or a packing enclosure is applied a plurality of visible marks which are associated with the particular production batch of the test carrier,

c) the apparatus has equipment (26,28,30) for the manual application of the visible marks,

d) in the apparatus, on the basis of the application, certain calculation bearings are selected from the

* C L M S *

finite number which are representative for the actual relation between the test value (R) and the concentration in the case of the particular production batch and

e) the processor (20) calculates the concentration corresponding to the particular test value (R) in an approximation process with the help of the selected calculation bearings.

2. System according to claim 1, characterised in that

a) in the memory is stored a standard evaluation curve the course of which is similar to the evaluation curves (I, J) of the test carrier to be evaluated by the apparatus in the sense

aa) that it runs in the value range of the evaluation curves (I, J) and

ab) that it displays a convex or concave bend essentially in the same section of concentration values as the evaluation curve;

b) on the standard curve in the region of the cusp between a concave and a convex bent section and in the region of the ends of the concentration range to be determined, a standard bearing is defined from, in each case, an R value and, in each case, a C value (R_{sa}, C_{sa}; R_{sb}, C_{sb}; .....);

c) with each standard bearing (e.g. R_{sa}, C_{sa}) is associated a set of calculation bearings (e.g. R_{ia}, C_{ia} with i = 1 .... 10) which lie in the region of the standard bearing;

d) the approximation process takes place in two steps, whereby

da) first, the particular measured test value (R_{ix}) is converted into a standard test value (R_{sx}) on the standard curve (S) having regard to the relative size of the distance of the two R values (R_{ia}, R_{ib})

* C L M S *

of the adjacent selected calculation bearings on the one hand and to the distance of the two R-values (R_{sa}, R_{sb}) of the standard bearings which are associated with these calculation bearings on the other hand, and

db) thereafter, the concentration value (C_{sx}) corresponding to the standard test value (R_{sx}) is converted into the desired concentration value (C_{ix}) having regard to the relative size of the distance of the two C values (C_{ia}, C_{ib}) of the adjacent calculation bearings on the one hand and of the distance of the two C values (C_{sa}, C_{sb}) of the adjacent standard bearings with which these calculation bearings are associated on the other hand.

3. System according to claim 2, characterised in that the standard test value R_{sx} (feature c of claim 1) is calculated in linear approximation

$$R_{sx} = R_{sa} - \alpha (R_{sa} - R_{sb}); \quad \alpha = \frac{R_{ia} - R_{ix}}{R_{ia} - R_{ib}}$$

and that the concentration sought is also calculated in linear approximation

$$C_{ix} = \beta (C_{ib} - C_{ia}) + C_{ia}; \quad \beta = \frac{C_{sx} - C_{sa}}{C_{sb} - C_{sa}}$$

4. System according to one of claims 2 or 3, characterised in that the calculation bearings belonging to one set (e.g. R_{ia}, C_{ia} with i = 1 .... 10) lies in the region of a standard bearing (R_{sa}, C_{sa}) on an approximately straight line (a,b,c) cutting the standard curve in an obtuse angle.

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5. System according to one of claims 2 or 3, characterised in that the calculation bearings (e.g. R_{ia}, C_{ia} with i = 1 .... 10) belonging to a set each lie on a line which runs parallel to a coordinate of the coordinate system R - C.

6. System according to one of claims 1 to 5, characterised in that at least two and at most five sets of calculation bearings are provided.

7. System according to claim 2, characterised in that the calculation bearings selected on the basis of the visible marks within a set of calculation bearings are those which lie next to or second next to the actual course of the evaluation curve of the particular production batch.

8. System according to claim 1, characterised in that the visible marks are alphanumeric marks.

9. System according to claim 1, characterised in that at most five alphanumeric marks are provided.

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