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(54) DETERMINATION OF SAMPLE VOLUME ADEQUACY IN BIOSENSOR DEVICES

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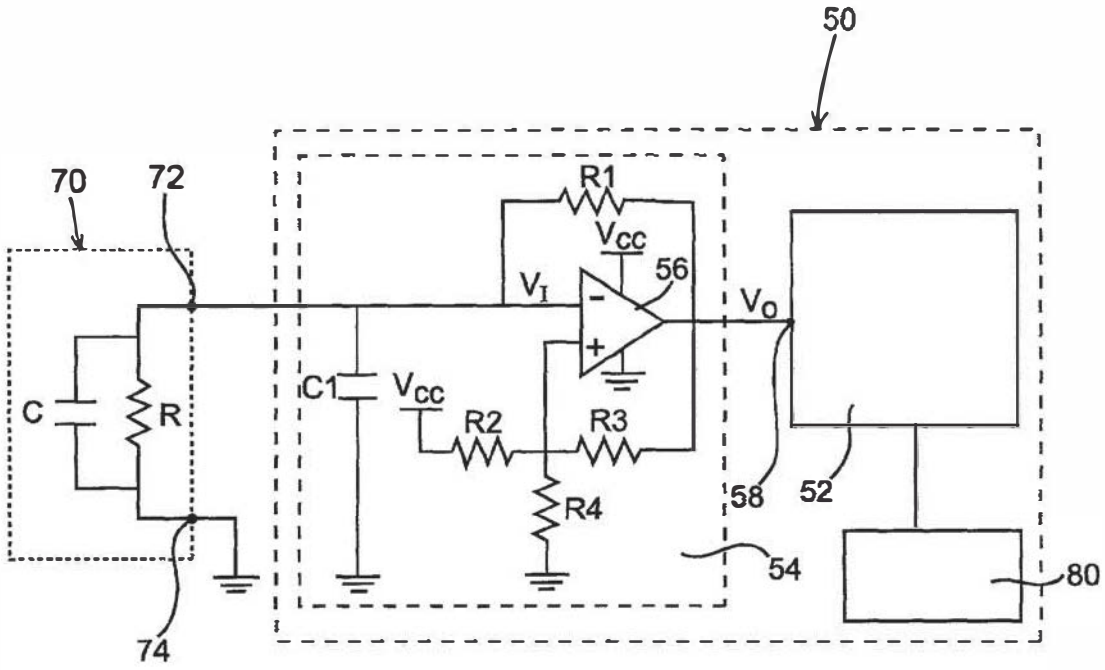
(57) ABSTRACT

Systems and methods are provided for determining whether a volume of biological sample is adequate to produce an accurate analyte concentration measurement. Certain such systems and methods provide the additional function of compensating for a sample volume determined to be less than adequate in order to proceed with an accurate analyte concentration measurement. The present invention is employed with a biosensor, such as an electrochemical test strip to which the sample volume of biological solution is deposited, and a meter configured to receive such test strip and to measure the concentration of selected analytes within the biological sample.



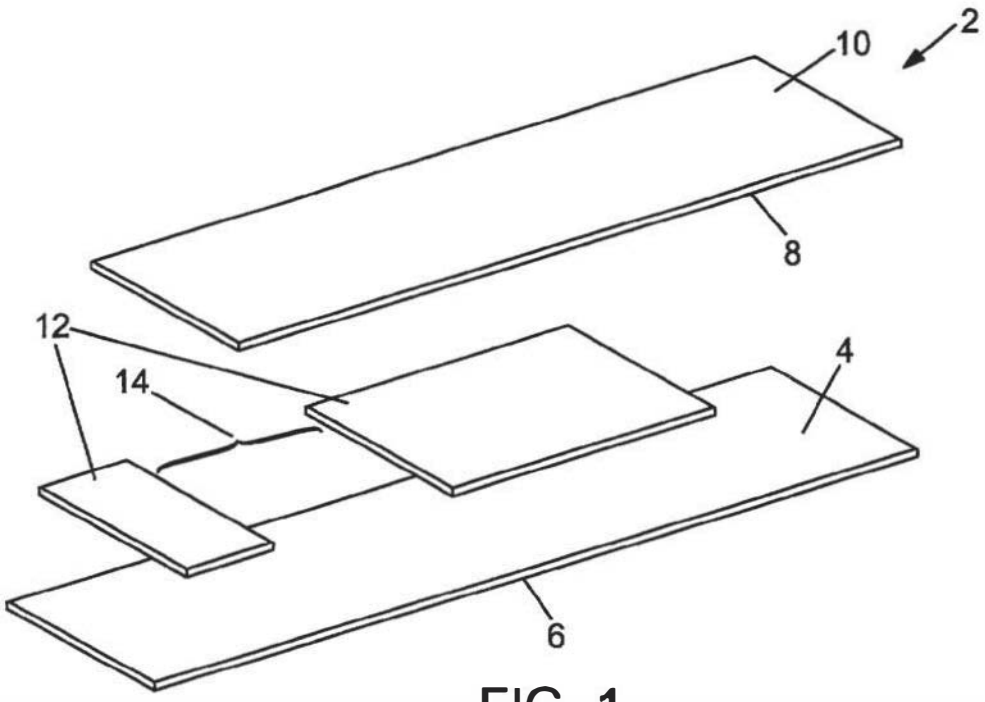


FIG. 1

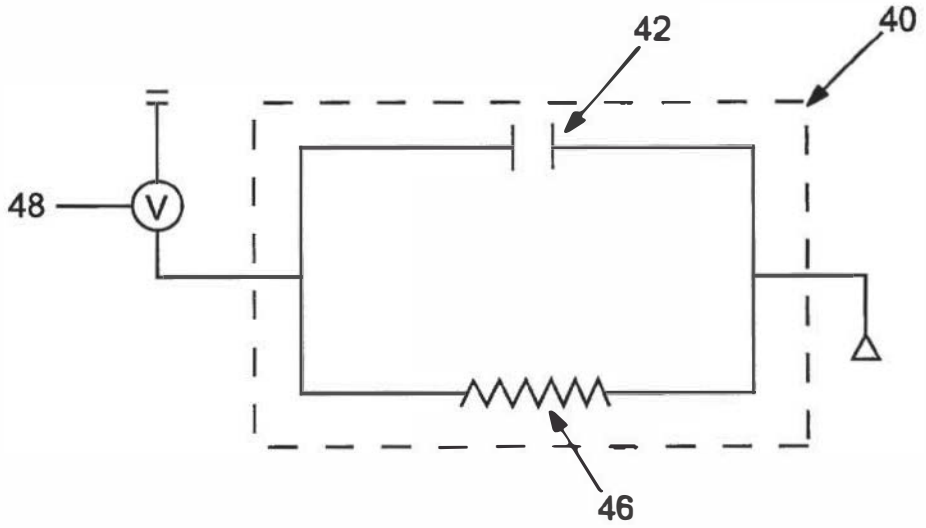


FIG. 2

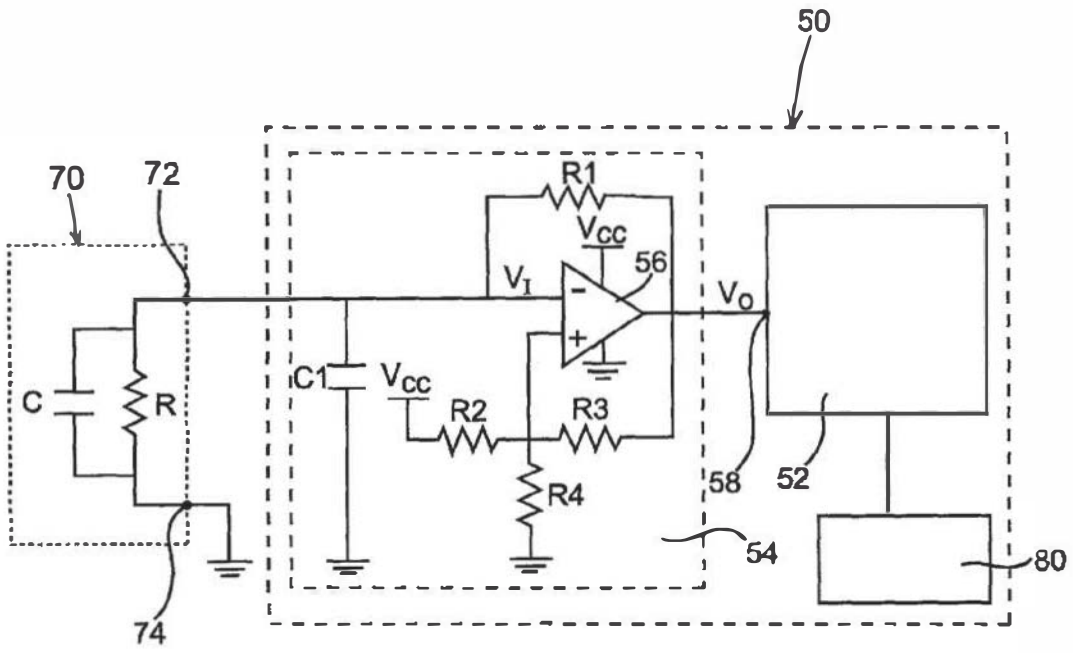


FIG. 3

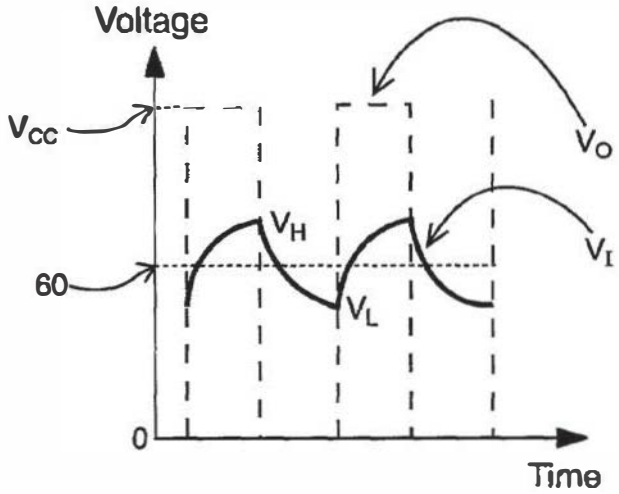


FIG. 4

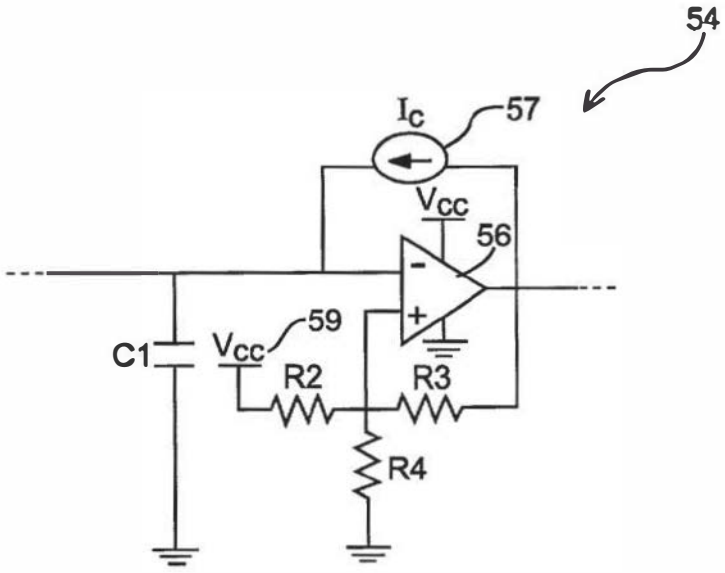


FIG. 5

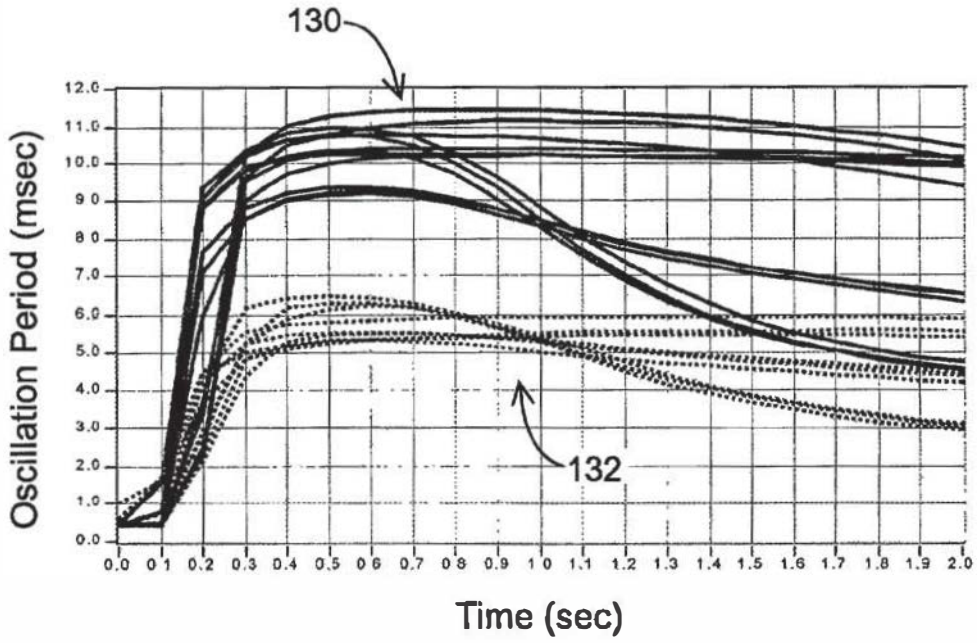


FIG. 6

DETERMINATION OF SAMPLE VOLUME ADEQUACY IN BIOSENSOR DEVICES

FIELD OF THE INVENTION

[0001] The field of this invention is the electrochemical determination of analyte in biological fluids, particularly the electrochemical determination of the adequacy of the volume of the biological fluid sample to be tested for analyte concentration.

BACKGROUND OF THE INVENTION

[0002] Analyte concentration determination in biological fluids, e.g., blood or blood-derived products such as plasma, is of ever increasing importance to today's society. Such assays find use in a variety of applications and settings, including clinical laboratory testing, home testing, etc., where the results of such testing play a prominent role in the diagnosis and management of a variety of disease conditions. Common analytes of interest include glucose for diabetes management, cholesterol for monitoring cardiovascular conditions, and the like. In response to this growing importance of analyte concentration detection, a variety of analyte detection protocols and devices for both clinical and home use have been developed.

[0003] One type of method that is employed for analyte detection is an electrochemical-based method. In such methods, an aqueous liquid sample is placed into a reaction zone in an electrochemical cell made up of at least two electrodes, i.e., a counter/reference electrode and a working electrode, where the electrodes have an impedance which renders them suitable for amperometric measurement. The component to be analyzed, e.g., an analyte, is allowed to react directly with an electrode, or directly or indirectly with a redox reagent to form an oxidisable (or reducible) substance in an amount corresponding to the concentration of the component to be analyzed, i.e., analyte. The quantity of the oxidisable (or reducible) substance present is then estimated electrochemically and related to the amount of analyte present in the initial sample.

[0004] Commonly, the electrochemical cell is in the form of a disposable test strip on which the biological sample is deposited and which is receivable within a meter by which the electrochemical analyte concentration is made. Examples of assay systems that employ these types of test strips, often referred to as biosensors, and meters may be found in U.S. Pat. Nos. 5,942,102, 6,174,420 B1 and 6,179,979 B1, the disclosures of which are herein incorporated by reference. With these systems, determination of the concentration of an analyte in a biological sample first involves obtaining a biological sample and bringing that sample into contact with a reaction area of the test strip so that the biological sample, and more particularly the analyte of interest or derivative thereof, may react with the chemistry, e.g., the testing reagent(s), associated with the reaction area. In order to obtain an accurate measurement of the particular analyte(s) of interest, a minimum sample volume must be applied to the reaction area. It is not uncommon for an inadequate amount of sample volume to be provided, often due to user error or patient inexperience or misjudgment. Inaccurate measurements can result in a misdiagnosis or improper treatment, such as administering an inappropriate dosage of a drug, patient non-compliance, etc. Such can result in serious and even life-threatening consequences for those whose lives depend on frequent monitoring of an analyte in their body, for example, diabetics.

[0005] One approach to ensuring an adequate biological sample volume is to over-saturate or use a greater volume of sampled fluid than is necessary to fill the reaction area of the test strip. A disadvantage of using an unnecessarily large volume of sampled fluid, a blood sample in particular, is the need to draw a greater volume of blood sample from the patient. This requires use of a blood sample volume which is rather large, thus necessitating use of a larger diameter needle and/or deeper penetration into the skin. These factors can increase the discomfort and pain felt by the patient, and may be difficult to achieve for those individuals whose capillary blood does not readily express. As this sampling process may be repeated frequently within a single day, for many diabetics, for example, an increase in pain quickly becomes less tolerable or intolerable all together.

[0006] Some analyte detection biosensors have been developed to provide visual confirmation of the adequacy of sample volume, however, this feature does not exclude potential error by the patient in judging the adequacy of the sample's volume, e.g., diabetics may experience deteriorated vision. Certain other analyte determination biosensors do provide user-independent means for determining the adequacy of the sample volume. Examples of such biosensors are disclosed in U.S. Pat. Nos. 5,628,890 and 5,650,062 and PCT Patent Application Publication No. WO 99/32881 (PCT Patent Application No. PCT/US98/27203). In particular, the '881 publication describes an electrochemical glucose monitoring system which attempts to determine the adequacy of a volume of sample applied to a biosensor by applying a low-level AC voltage signal (without a DC voltage offset) at a known frequency to the biosensor and then measuring both the real component and the imaginary component of the resulting impedance. These impedance values are then compared to a look-up table in the microprocessor's program memory. The accuracy of this method may be additionally questionable considering that this system is dependent on blood hematocrit levels and environmental temperature variations.

[0007] Another disadvantage of the technique disclosed in the '881 publication is that the analyte measurement test must be aborted if the sample volume is determined to be inadequate, i.e., a "go-no-go" situation. This results in the need to take yet another sample from the patient which, as mentioned above, is inconvenient and may be very painful to the patient, likely resulting in patient non-compliance in his or her medication regime. Additionally, the test must be repeated resulting in the waste of test strips and increasing the cost of the procedure.

[0008] As such, there is continued interest in the identification of new techniques for accurately and precisely measuring the adequacy of the volume of the sample used for electrochemical analyte concentration determination. Of particular interest would be the development of devices and methods that can very accurately and expeditiously determine the adequacy of the volume of sample. It would be additionally beneficial to develop such a sample volume adequacy determination device and technique in which a determination that a sample volume is inadequate does not require abortion of the analyte concentration measurement

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