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UNIVERSITAT POLITÈCNICA DE VALÈNCIA

METHOD FOR CONTINUOUS MONITORING OF GLUCOSE LEVELS IN HUMANS

DESCRIPTION OF THE INVENTION

In recent years, the continuous monitoring of glucose in subcutaneous tissue has become consolidated as an additional tool for improving glycemic control. Thus type of monitoring is based on measuring the concentration of glucose in the interstitial fluid, that is to say, in a different compartment to the traditionally used plasma.

The direct or indirect measurement of the concentration of glucose in compartments other than plasma implies the need to for algorithms in order to estimate glycaemia. These algorithms are known as calibration algorithms and they contribute to improving the preciseness of the estimation of the glucose concentration in plasma.

In this field, researchers at the Institute for Automatics and Informatics at the Universitat Politècnica de València and researchers from the Universitat de Girona have developed a method based on a calibration algorithm that allows them to improve the preciseness of devices designed for the continuous monitoring of glucose and enables its integration into the development of an artificial pancreas for the automation of glycemic control in type 1 diabetic patients.

The method developed consists of an algorithm based on a set of local models (obtained from data on a representative population of patients to be monitored) which, when adequately weighted according to the current state of the patient, provide an estimation of levels of glucose in plasma. The models reflect the glycaemia-sensor output dynamic relation, which is representative of the dynamic transportation of glucose from the plasma to the remote measurement compartment.

APPLICABLE BUSINESS SECTORS

The technology is mainly aimed at manufacturers of devices for monitoring glucose that are both minimally invasive and non-invasive. It could also be adapted for other analytes that require monitoring.

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

Current procedures for continuous monitoring have a large degree of error, as the measurement is carried out at a compartment that is different to the reference point. This method allows us to obtain a more precise signal than existing methods on the market.

Considering the dynamics of glucose between compartments via the use of local models is a novel introduction in comparison with currently used methods and permits greater preciseness in continuously monitoring glucose. During the stage of identifying the local models, the methodology allows for the detection of different dynamics corresponding to different subpopulations or different metabolic states.

This in turn leads to the application of truer models to the physiological processes based on the state and type of patient. The methodology also allow for adaptation to changes in the sensitivity of the sensor during its lifetime.

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DEVELOPMENT STAGE OF THE TECHNOLOGY

The method has been validated in two conceptual studies:

• A clamp study monitoring 8 healthy people with the microdialysis monitor Glucoday (Menarini, Firenze)

•A study on 12 type 1 diabetics monitored with the retrospective electrochemical monitor CGMS Gold (Medtronic, Northridge). This study was complemented by a simulation study to evaluate the adaptation mechanism to sensitivity changes in the sensor during its lifetime. (7 days)

It is necessary to carry out broader studies with a sufficient number of patients to represent the population of type 1 diabetes patients and an extensive validation of the method.

INDUSTRIAL PROPERTY RIGHTS

The technology has been patented by the UPV, with a registered Spanish patent pending number P201130811 with a priority listing dated 19/05/2011.
The Spanish patent has been extended via PCT (ES2012/070358).

COLLABORATION REQUIRED

The UPV is looking for firms that make medical devices and hospitals interested in carrying out trials on a larger number of patients along with any clinical tests deemed necessary.

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