Research, development, manufacture and product launch of whole blood glucose and coagulation sensors

Ronald C. Chatelier[*]

Consultant in Electrochemical Biosensors,
Melbourne, Victoria, Australia
ron.chatelier@gmail.com)

This talk will summarise the work done between ca. 1994-2014 which led to the launch of the OneTouch® Verio® whole blood glucose sensor (marketed by LifeScan) and the Xprecia Stride™ PT/INR blood coagulation sensor (initially marketed by Siemens).

The platform technology used co-facing electrodes which allowed the diffusion coefficient of the limiting electrochemical mediator to be measured[1]. This allowed correction for variations in viscosity (*e.g.*, with changing hematocrit).

The electrodes[2], enzymes and electrochemical mediators were stabilized[3], a novel method was used to correct for antioxidant interferents using only two electrodes[4], and blood was automatically distinguished from control solution[5].

High speed, high volume manufacturing was made possible using rolls of electrodes and double-sided adhesive tape in bespoke rotary conversion machines at Universal Biosensors (Rowville, VIC, Australia).

These processes rapidly generated a large number of sensors which could be used in optimization, stability, clinical trials and product launch.

A total of more than 10 billion sensors based on this platform technology have been sold so far.

References

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[3] Teodorczyk, M., Chatelier, R. C., Hodges, A. M., Ohara, T., Dato, R., "Mediator stabilized reagent compositions and methods for their use in electrochemical analyte detection assays", US patent 7,291,256
[4] Chatelier, R. C., Hodges, A. M., Verity, B., "Methods and apparatus for analyzing a sample in the presence of interferents", US patent 8,163,162
[5] Chatelier, R. C., Hodges, A. M., Teodorczyk, M., Dato, R., "Systems and methods for discriminating control solution from a physiological sample", US patent 8,449,740