In-Vitro Performance of the Enlite Sensor in Various Glucose Concentrations during Hypobaric and Hyperbaric Conditions

Peter Adolfsson, M.D.,¹ Hans Örnhagen, M.D., Ph.D.,² Bengt M. Eriksson, M.D.,³ Raghavendhar Gautham, M.E.,⁴ and Johan Jendle, M.D., Ph.D.^{5,6}

Abstract

Background:

There is a need for reliable methods of glucose measurement in different environmental conditions. The objective of this *in vitro* study was to evaluate the performance of the Enlite[®] Sensor when connected to either the *i*ProTM Continuous Glucose Monitor recording device or the Guardian[®] REAL-Time transmitting device, in hypobaric and hyperbaric conditions.

Methods:

Sixteen sensors connected to eight iPro devices and eight Guardian REAL-Time devices were immersed in three beakers containing separate glucose concentrations: 52, 88, and 207 mg/dl (2.9, 4.9, and 11.3 mmol/liter). Two different pressure tests were conducted: a hypobaric test, corresponding to maximum 18000 ft/5500 m height, and a hyperbaric test, corresponding to maximum 100 ft/30 m depth. The linearity of the sensor signals in the different conditions was evaluated.

Results:

The sensors worked continuously, and the sensor signals were collected without interruption at all pressures tested. When comparing the input signals for glucose (ISIGs) and the different glucose concentrations during altered pressure, linearity (R^2) of 0.98 was found. During the hypobaric test, significant differences (p < .005) were seen when comparing the ISIGs during varying pressure at two of the glucose concentrations (52 and 207 mg/dl), whereas no difference was seen at the 88 mg/dl glucose concentration. During the hyperbaric test, no differences were found.

Conclusions:

The Enlite Sensors connected to either the *i*Pro or the Guardian REAL-Time device provided values continuously. In hyperbaric conditions, no significant differences were seen during changes in ambient pressure; however, during hypobaric conditions, the ISIG was significantly different in the low and high glucose concentrations.

J Diabetes Sci Technol 2012;6(6):1375-1382

Author Affiliations: ¹Göteborg Pediatric Growth Research Center, Department of Pediatrics, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg, The Queen Silvia Children's Hospital, Göteborg, Sweden; ²Swedish Sports Diving Federation, Idrottshuset, Farsta, Sweden; ³Hyperbaric Medicine, Department of Anesthesiology, Karolinska Universitetssjukhuset, Stockholm, Sweden; ⁴Medtronic Diabetes, Northridge, California; ⁵Endocrine and Diabetes Center, Karlstad Hospital, Karlstad, Sweden; and ⁶Faculty of Medicine and Health, Örebro University Hospital, Örebro, Sweden

Abbreviations: (CGM) continuous glucose monitoring, (CI) confidence interval, (ISIG) input signal for glucose, (PO₂) partial pressure of oxygen

Keywords: barometric pressure, continuous glucose monitoring, diabetes mellitus, glucose, sensor

Corresponding Author: Peter Adolfsson, M.D., Göteborg Pediatric Growth Research Center, Department of Pediatrics, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg, The Queen Silvia Children's Hospital, S-41685 Göteborg, Sweden; email address <u>peter.adolfsson@ogregion.se</u>