

## Clinical Evaluation of a Transcutaneous Interrogated Fluorescence Lifetime-Based Microsensor for Continuous Glucose Reading

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### Abstract

#### Background:

Continuous glucose monitoring is presently used worldwide. Accuracy, precision, durability, invasiveness, and lack of drift of sensors and lag time are key parameters essential to these systems. This article describes a new online minimally invasive biodegradable microsensor for optical, transcutaneous interrogation, which has at least 14 days of functionality.

#### Method:

Studies were performed *in vitro* and *in vivo* on pigs, as well as on type 1 diabetic humans. Functionality has been ensured in laboratory settings, and precision and durability have been tested *in vivo*. During *in vivo* studies, venous blood samples were used as reference.

Results were based on one single point calibration per experiment.

#### Results:

Excellent stability was found in 14-day *in vitro* trials as well as *in vivo* in up to 70-hour trials. The overall median relative absolute difference of type 1 diabetic patients was 11.4%. Error grid analysis showed 97.7% of all values in the A+B zone. Comparable results were found in animal studies. No sensor drift was observed in any trial.

#### Conclusion:

Results point toward the possibility of developing a stable and precise minimally invasive glucose reader for at least 2 weeks of continuous use.

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**Abbreviations:** (AF594) Alexa Fluor™ 594, (AF594-MBL) conjugated human mannan-binding lectin, (CG-EGA) continuous glucose (Clarke) error grid analysis, (CGM) continuous glucose monitoring, (FDA) Food and Drug Administration, (HMCV1-Dex) hexamethoxy crystal violet-conjugated dextran, (ISF) interstitial fluid, (LED) light-emitting diode, (RAD) relative absolute difference

**Keywords:** accuracy, continuous glucose monitoring, fluorescence, lifetime, variability

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