

## Noninvasive Glucose Monitoring: A Novel Approach

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### Abstract

#### Background:

The main concern in noninvasive (NI) glucose measurement is achieving high accuracy readings, although no blood (or other fluid) is involved in the process. Using methods based on different physical properties of a measured object can ensure the independence of each of the readings and therefore improve the validity of the end result. By using a combination of (three) independent technologies—ultrasonic, electromagnetic, and thermal—GlucoTrack™ presents a unique approach for a real-time, truly NI blood glucose spot measurement.

#### Methods:

Clinical trials were performed in two stages. Stage 1 was an initial method validation and performance verification of the device. In this stage, 50 type 1 and 2 diabetic patients, as well as healthy subjects, were evaluated with GlucoTrack against Ascensia Elite® (Bayer). In the second stage, 85 additional diabetic subjects were evaluated in half and full daytime sessions using a GlucoTrack comparison with HemoCue® (Glucose 201+).

#### Results:

A total of 135 subjects were tested during the trial period, producing 793 data pairs. Using Clarke error grid analysis, 92% of the readings fell in the clinically acceptable zones A and B, with 50% in the A zone. Mean and median relative absolute differences were 29.9 and 19.9%, respectively.

#### Conclusions:

Integrating several modalities for NI assessment of glucose level enables more accurate readings, while a possible aberration in one modality is bypassed by the others. The present generation of GlucoTrack gives promising results; however, further improvement of the accuracy of the device is needed.

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**Abbreviations:** (ARD) absolute relative difference, (BG) blood glucose, (CEG) Clarke error grid, (HT) heat transfer, (ISF) interstitial fluid, (MU) main unit, (NI) noninvasive, (PEC) personal ear clip, (SMBG) self-monitoring of blood glucose, (TW) tolerance window

**Keywords:** combination methodology, ear clip, GlucoTrack™, noninvasive glucose monitoring, self-monitoring of blood glucose

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