GlucoTrack™

An Innovative Approach to Non Invasive Glucose Monitoring

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Background and Aims

Attempts to develop an accurate non-invasive glucose monitoring device have been only partially successful. Depending on the particular method, the readings might vary with changes in glucose level, but might also be affected by changes in other components in the blood. In order to achieve an accurate reading, there is a need for a mechanism which will idle the impact of the non-glucose components and isolate the changes caused by the glucose per se.

Materials and Methods

An innovative approach to the problem is the simultaneous utilization of three different, independent technologies and comparison of the separate results by using a unique algorithm. For each glucose reading, achieved by one method, a Tolerance Window (TW) of ±N% is opened around the original value. The three Tolerance Windows are then correlated and compared, while overlapping is expected. If there is a full correlation, meaning three overlaps are achieved, then the final result will be a weighted average of the three measured values. If only two overlaps occur, then the Tolerance Windows are shrunken (N_S = 0.75 x N) and an overlapping between the two windows is then checked. Failure of overlapping causes a reading error and auto repeat of the measurement. Three trials are allowed. Failure in all three attempts brings an error message, requesting a new personal calibration. Fig. 1 demonstrates a case of complete (3 technologies) overlapping, while Fig. 2 shows a case where two separate overlaps exist. In both cases, the original TW is set to ±20%, therefore the shrunken window (in Fig. 2) equals ±15%. The weight for each reading in these examples is set equally to 1/3 (33.3%).

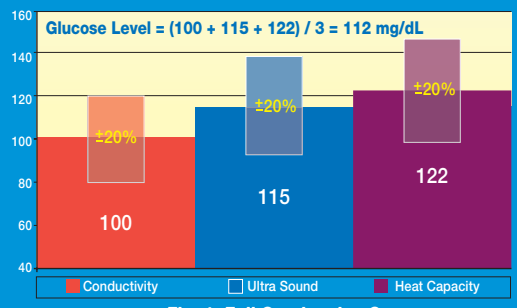


Fig. 1: Full Overlapping Case

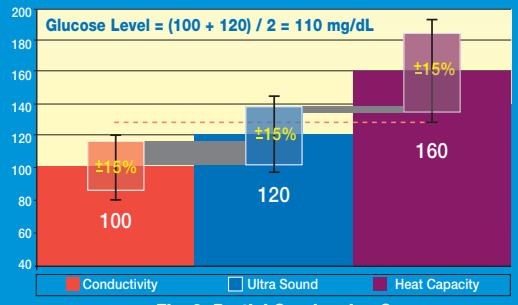


Fig. 2: Partial Overlapping Case

Results

GlucoTrack uses Ultra Sound, Conductivity and Heat Capacity technologies for measuring the glucose level. A basic tolerance window of N = ±20% was used in the measurements. As a reference, we used the Ascensia Elite® and FreeStyle® invasive glucose measurement devices. The results are shown in Figs. 3 & 4. Raw glucose readings of the three different technologies are shown on a single Clarke Error Grid (CEG) (Fig. 3), demonstrating a relatively sporadic distribution. Fig. 4 depicts the final results on a CEG, after activating the algorithm. The enhancement in precision level is clearly noticeable. The device has been used by 71 patients with variety of personal characteristics. The integration of three different modalities for the glucose determination permits accurate measurement in a range of clinical settings; a possible aberration in one modality being compensated for by the others. A total of 498 points were measured: 73% fell in Zone A of CEG and 27% in Zone B (relatively close to the "drain" of zone A). No reading falls in other zones.

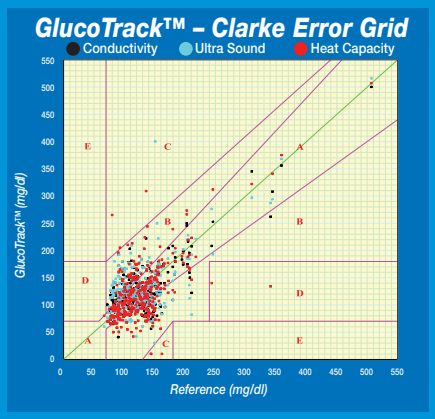


Fig. 3: Three Technologies Results

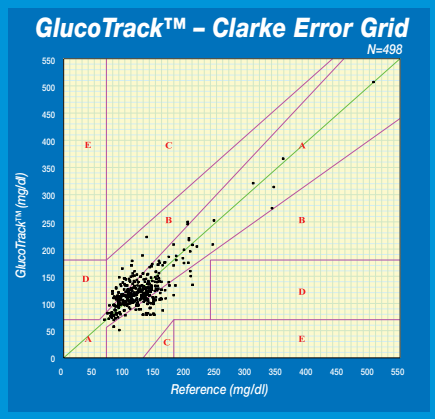


Fig. 4: DF-F Results After Algorithm Activation

Analysis

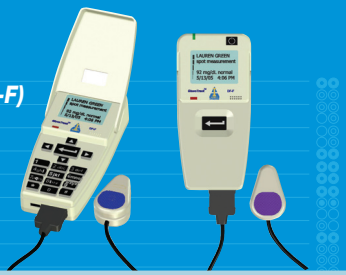
Intercept Point:	26.4 mg/dL
Slope:	0.765
Correlation Coefficient:	0.795
R^2:	0.632
Mean Average Error:	15.83%
RMS Error:	20.34
95% Confidence Limit:	40.68
Zone A:	73%
Zone B:	27%
Zone C:	0%
Zone D:	0%
Zone E:	0%

Conclusions

Using a combination of three different technologies and integrating the results by the suggested algorithm improves the overall accuracy level of the glucose measurement and brings it to a par with that of invasive monitoring devices. ***GlucoTrack*** is a novel non-invasive device for accurate measurement of blood glucose.

GlucoTrack™ (Model DF-F)
US Patent 6,954,662

Caution:
Investigational device.
Limited by federal law to investigational use only.
Not available for sale.



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