

Validity of Calibration as a Function of Intervals between Re-Calibrations in Non-Invasive Self-Monitoring of Blood Glucose

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Background:

In general, Non-Invasive (NI) glucose monitors require calibration process, performed by using an invasive reference, prior to glucose measurements.

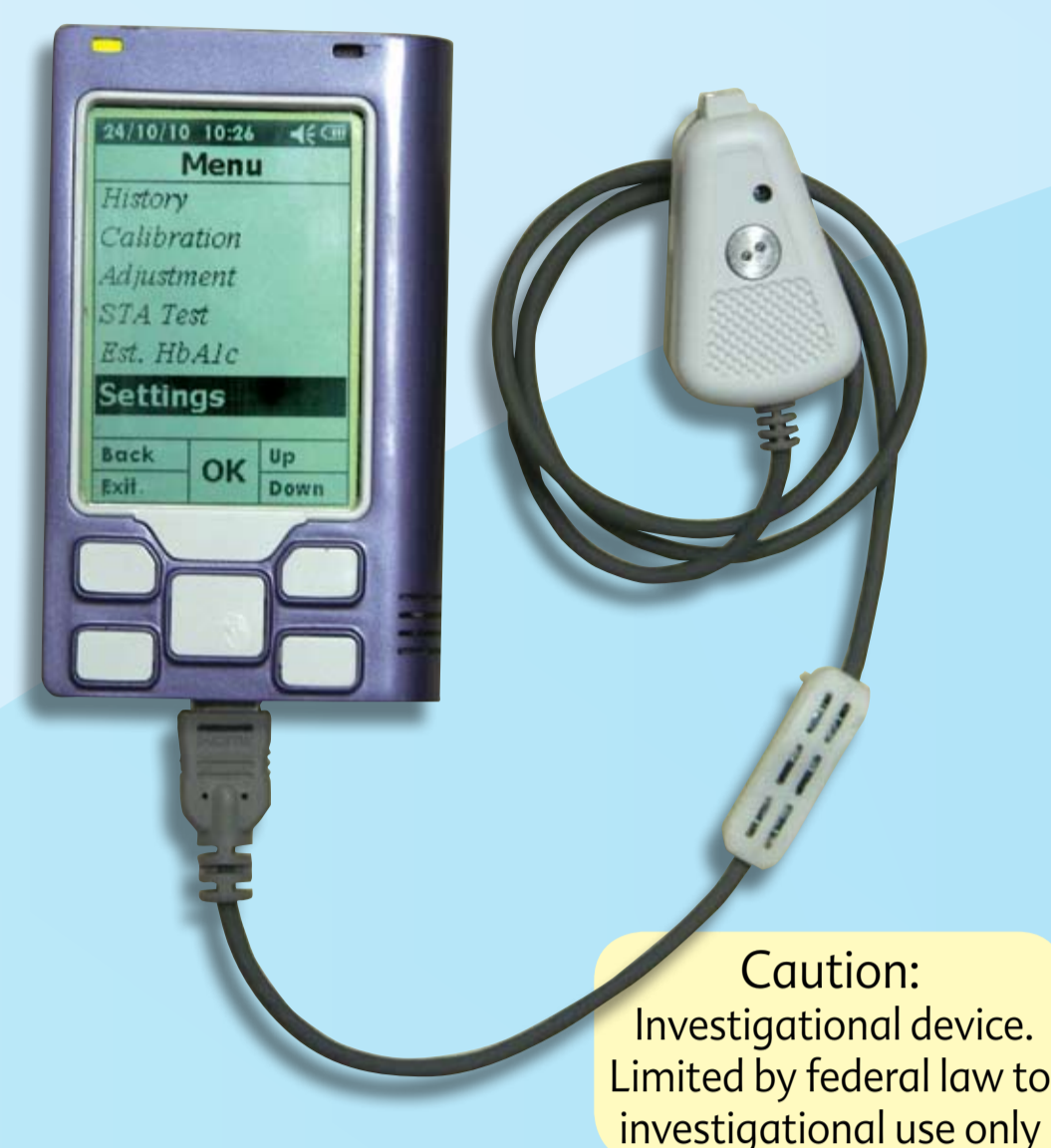
In home use application, the duration of calibration procedure, number of prickings and the interval between re-calibrations play a major role in the device efficacy and utilization.

As opposed to invasive devices, **Glucotrack**[®] (Figure 1) glucose monitor promotes frequent testing, since no pain is involved and no disposables are required. Furthermore, the higher the measurement incidence, the more worthwhile and cost effective the device is. The aim of such NI device is to improve monitoring adherence and to suggest diabetics a frequent and painless way to monitor and track their blood glucose, which lead to tighter glucose control.

Method:

Glucotrack uses a combination of three technologies: Ultrasonic, Electromagnetic and Thermal. The measured tissue parameters are integrated into a glucose value by individual calibration (Figure 2), which minimizes the effects of individual quasi-stable factors, such as tissue thickness and structure, and allows adjusting the glucose behavior model for each user.

Figure 1: **Glucotrack Glucose Monitor**



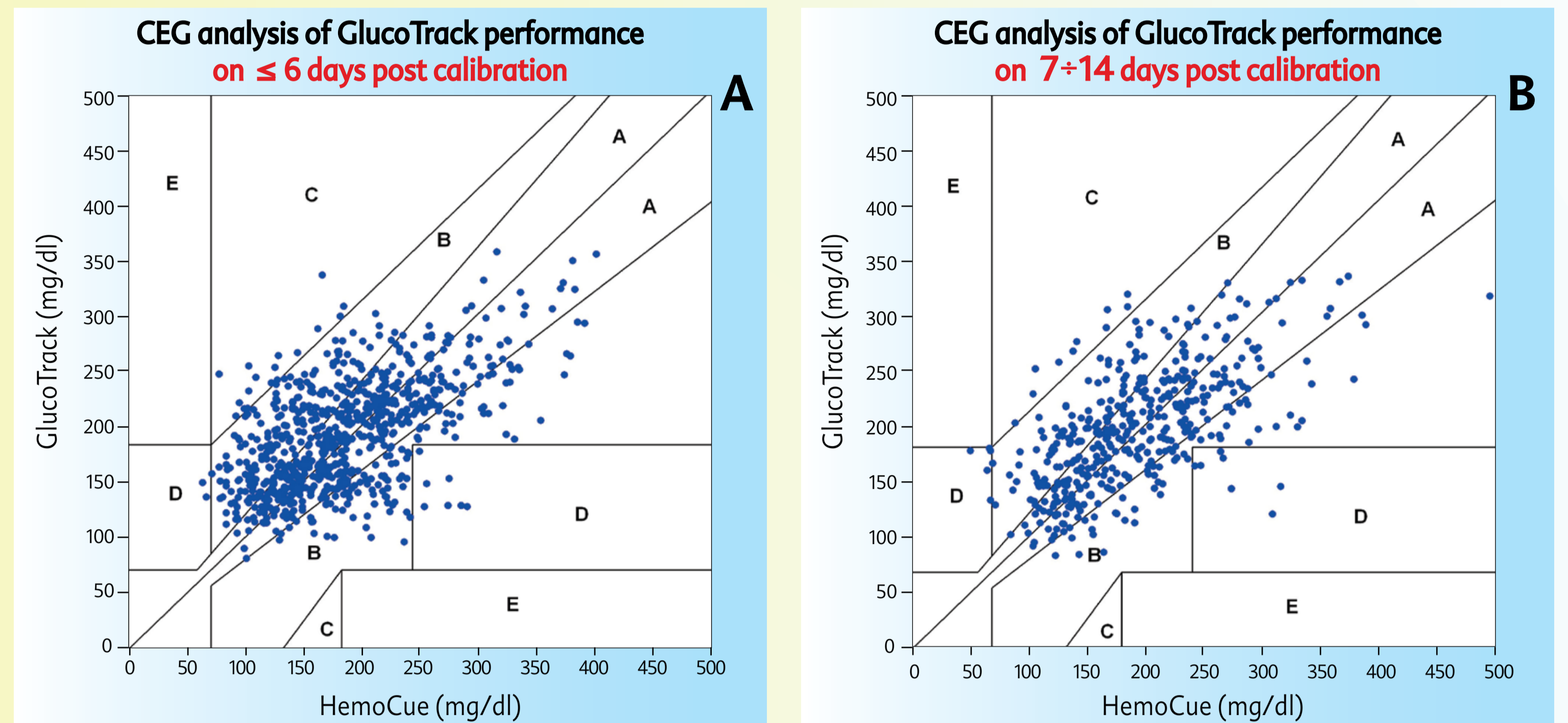
Caution: Investigational device. Limited by federal law to investigational use only.

with a median of 6 days. Thereafter, all the post calibration readings were divided into three time intervals (1 week each): ≤ 6 days, 7-14 days and 15-22 days post calibration.

Results:

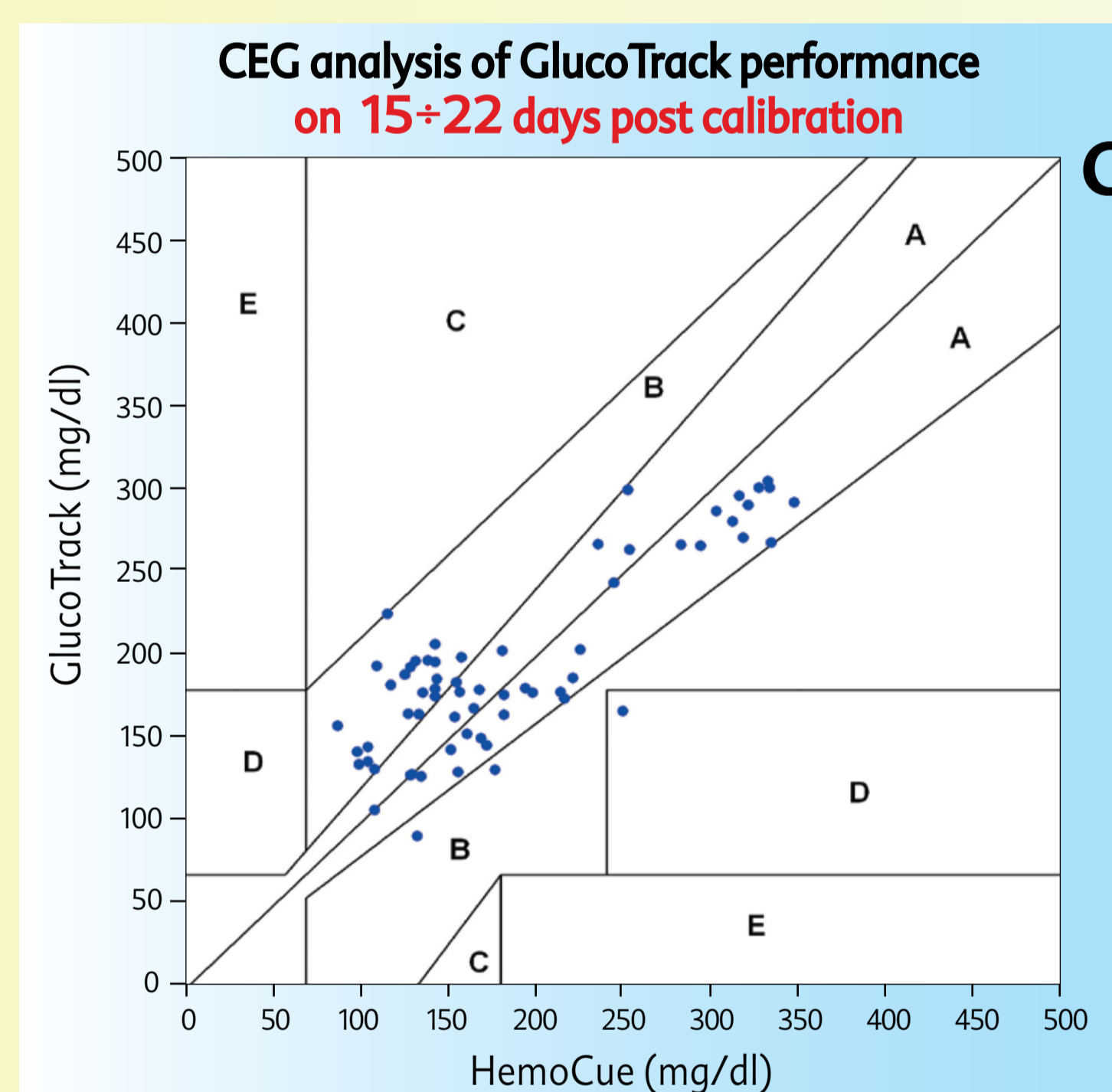
Clarke Error Grid (CEG) analysis of **Glucotrack** performances, across the three time intervals from both Day 1 and 2, are shown in Figure 4 A-C.

Figure 4: CEG of **Glucotrack** Readings Performed on ≤ 6 (A), 7-14 (B) and 15-22 (C) Days Post Calibration.



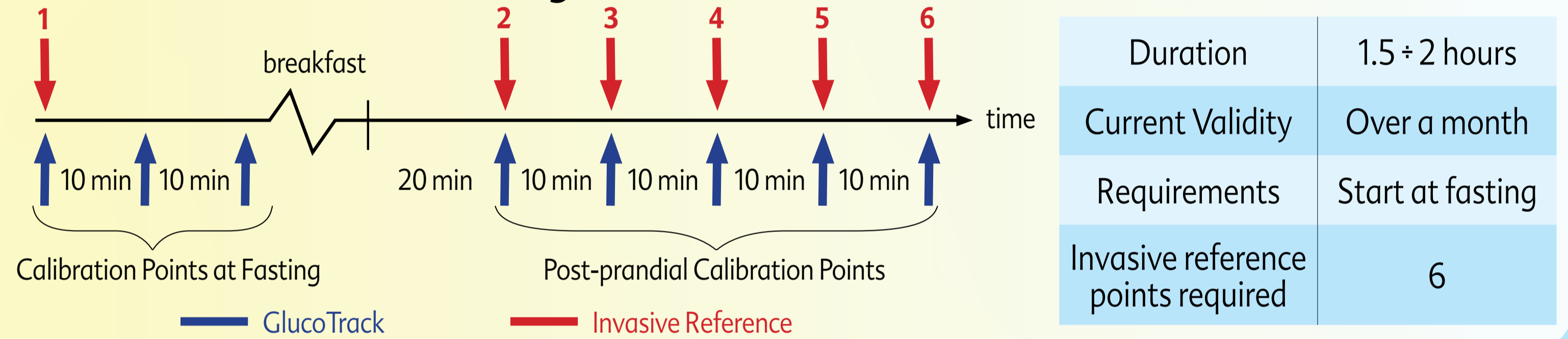
Zone	Number	Percent	A+B Zones
A	768	60%	97%
B	461	36%	
C	20	2%	
D	24	2%	
E	0	0%	
Total	1273	100%	

Zone	Number	Percent	A+B Zones
A	265	59%	95%
B	159	36%	
C	10	2%	
D	12	3%	
E	0	0%	
Total	446	100%	



Zone	Number	Percent	A+B Zones
A	39	61%	98%
B	24	37%	
C	0	0%	
D	1	2%	
E	0	0%	
Total	64	100%	

Figure 2: Calibration Process



Initial tests show that calibration is valid for a few months, as shown (for example) in Figure 3. Temporarily, until sufficient data will be collected from a wide range of subjects, a monthly calibration is advised.

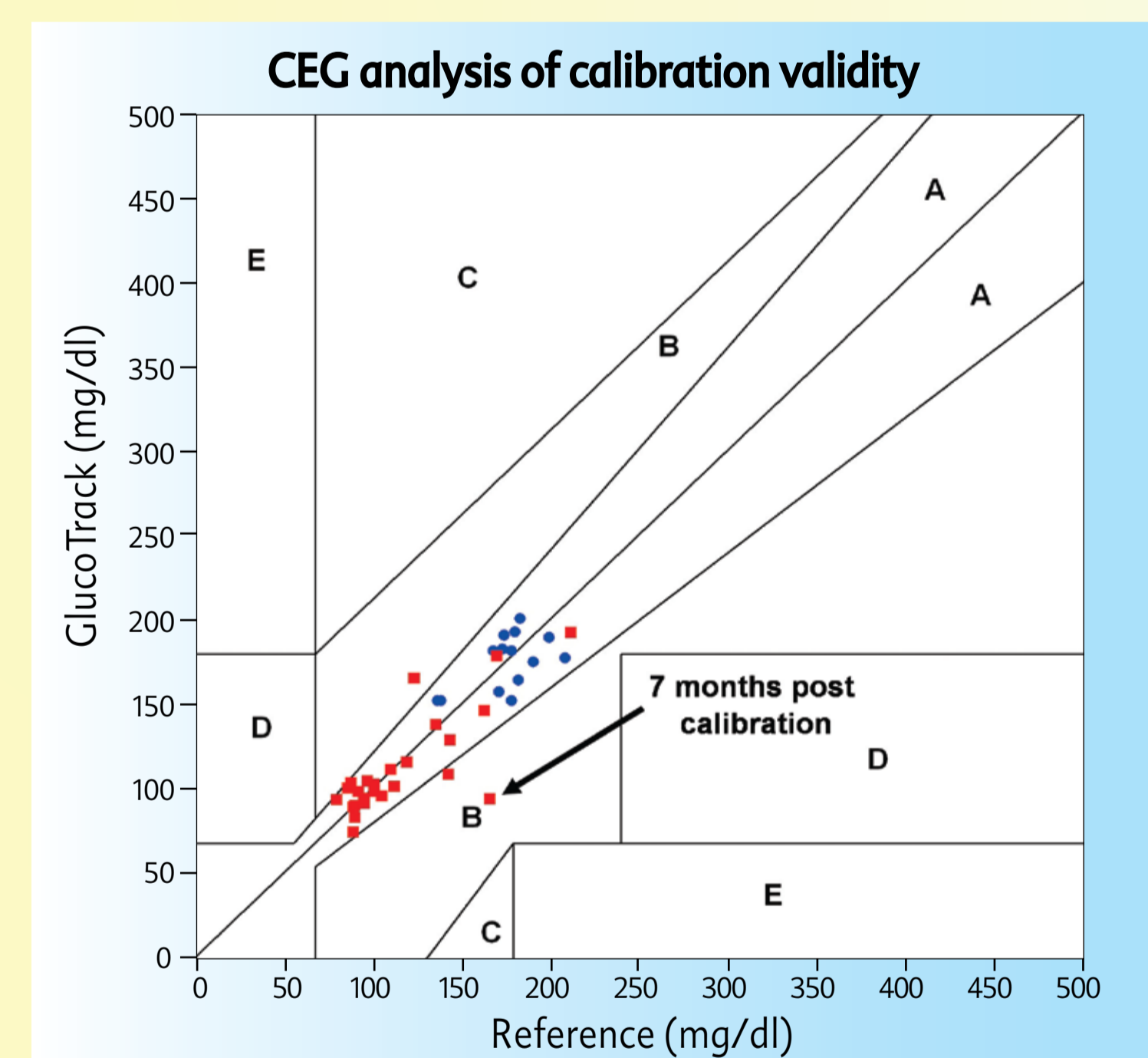


Figure 3: Example of long term calibration validity:
 (■) 30 year-old healthy male,
 (●) 49 year-old type 2 diabetic male;
 readings were taken through 7 and 3 months, correspondingly, using a single calibration process per each individual.

To evaluate **Glucotrack** performances and calibration validity length, 91 subjects were tested (Table 1).

Table 1: Subjects' Demography

Diabetes Type	12 Type 1, 79 Type 2
Gender	50 M, 41 F
BMI (Kg/m ²)	30.0 ± 10.0
Age (Years)	51 ± 30

Each individual trial was performed in two different days:

- During **Day 1**, calibration was individually performed using **HemoCue**[®] as invasive reference, followed by 6 measurement pairs.
- On **Day 2**, a full-day measurements' session was conducted (including two meals and a snack), with identical reference device.

The intervals between Day 1 and Day 2 were 1-22 days, according to subjects' availability,

No increment in the degree of error was observed as a function of days post calibration (Table 2).

Table 2: Relationship between the Degree of Error and Time Post Calibration

	≤ 6 days post calibration	7-14 days post calibration	15-22 days post calibration
# of Subjects	59	28	14
# of Points	1273	446	64
CEG A Zone (%)	60	59	61
CEG A+B Zones (%)	97	95	98
Mean ARD (%)	22.2	23.1	21.7
Median ARD (%)	15.8	16.5	15.5

Conclusions:

- Calibration of **Glucotrack** remains valid for a long term.
- No degradation in performances was observed during time elapsed after calibration. This indicates that the intervals between re-calibrations indeed may be increased.
- The long duration between re-calibrations supports the use of **Glucotrack** as a useful solution for SMBG by diabetics.
- Further home trials are expected to begin in 1Q/2011, where a calibration validity for over a month will be tested.
- Further activity to increase the calibration validity period for up to six months is currently in process.