**Background**

Achieving and maintaining controlled glycemic levels is challenging in people with insulin-treated DM, being poor treatment adherence and suboptimal insulin injections the main obstacles to treatment success. **Insulclock®** is an electronic device to be plugged into insulin pen devices and connected with a smartphone app to improve insulin management. **Insulclock®** tracks the date, time, dose, type of insulin, temperature, and duration of insulin injections. This information is stored and available for monitoring and analysis by patients and healthcare providers. This device also has a reminder system with visual and acoustic alerts to reduce insulin omissions and mistiming.

**Methods**

**Insulin type detection**: tested by performing 100 detections with 12 different Insulclock® devices to recognize 7 KwikpenTM insulin pens performed under different light settings. **Dose detection**: 9 trained volunteers (1TDM, 4 women, 21-56 years) carried out 566 injections with their right hand. Insulin doses delivered ranged from 1 to 25 units. **Injection duration**: 8 participants (1TDM, 4 women, 21-56 years) was monitored to detect if they complied with manufacturer’s recommendations. **Temperature storage and fluctuation**: **Insulclock®** incorporates a temperature sensor. Insulin pens were subjected to heating and cooling conditions and the temperatures achieved were measured either with **Insulclock®** or with an external thermometer. The temperatures under routine conditions of usage and storage of 49 users (1TDM, 28 women, 20-56 years) who used the Humalog KwikPen insulin pen were recorded (July-August 2017). **Statistical Analyses**: Study variables were described by frequency distribution, Pearson’s correlation and root-mean-square deviation (RMSD) for the accuracy of temperature and injection duration detections, and dose accuracy detection is presented with the associated relative error.

**Results**

**Insulin type detection**: 97% were correctly detected by Insulclock®.

**Dose detection**: As shown in Figure 1, most of the injections fell within the deviation = 0 group. The relative error of dose accuracy detection ranged from 2.9% to 6.8% across all the dose groups.

**Injection duration**: Figure 2 shows that the time detected by both **Insulclock®** and the chronometer was highly correlated ($R^2 = 0.99$). From 2 to 20 seconds, the root-mean-square deviation (RMSD) was 0.39 seconds.

**Temperature storage and fluctuation in daily practice**: As shown in Figure 3, the temperatures measured with **Insulclock®** and with an external thermometer were correlated ($R^2 = 0.90$). Temperatures under routine conditions of usage rapid insulin are described in figure 4.

**Conclusions**

**Insulclock®** is a novel optimization device capable to track in dosing, timing and missing insulin administration. The promising possibilities it offers for DM self-management will likely help healthcare providers, researchers and insulin users to detect and avoid frequent errors in insulin administration.