PeriCoach® Clinical Study and Real-World Data Insights

PERICOACH

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Objective

Technology available today has led to the development of vital eHealth tools that enhance treatments and outcomes. PeriCoach is one such pelvic floor muscle therapy (PFMT) eHealth system, designed to provide consistent, accurate biofeedback and additional motivation to the user, as well as reliable data collection for ongoing progress analysis.

Two investigations using the PeriCoach were conducted to determine and compare outcome measures: a randomized controlled trial (RCT) and an all-comer, real-world data study (RWD).

Methods

Study 1: RCT comparing clinician supported PFMT with PeriCoach V2 to clinician support PFMT over 20 weeks.

Study 2: Real-World Data retrospective study of PeriCoach V3 users using de-identified data.

Analysis of key efficacy endpoints for both studies, including quality of life scores, sexual function scores, PFM strength as well as number and volume of urine leakage episodes.

In both studies, women used PeriCoach, an eHealth perineometry system consisting of a vaginal probe, Smartphone app, web portal and database, as well as support from pelvic health clinicians for some users.

- The PeriCoach app provides a bladder diary and survey function for users to record key symptom data.
- Pelvic floor muscle (PFM) strength is measured via force sensors in the probe.

Rigorous statistical analyses were performed on both studies separately, and then compared to reassess the outcome of the RCT had V3 been used instead.

PeriCoach V3, released in mid-2017, introduced enhanced sensor readings through inclusion of a gyroscope/accelerometer which allowed for real-time technique guidance for the user, using movement and force data. Additionally a structured 8-week program along with enhanced user interface was integrated to further drive user engagement and motivation.
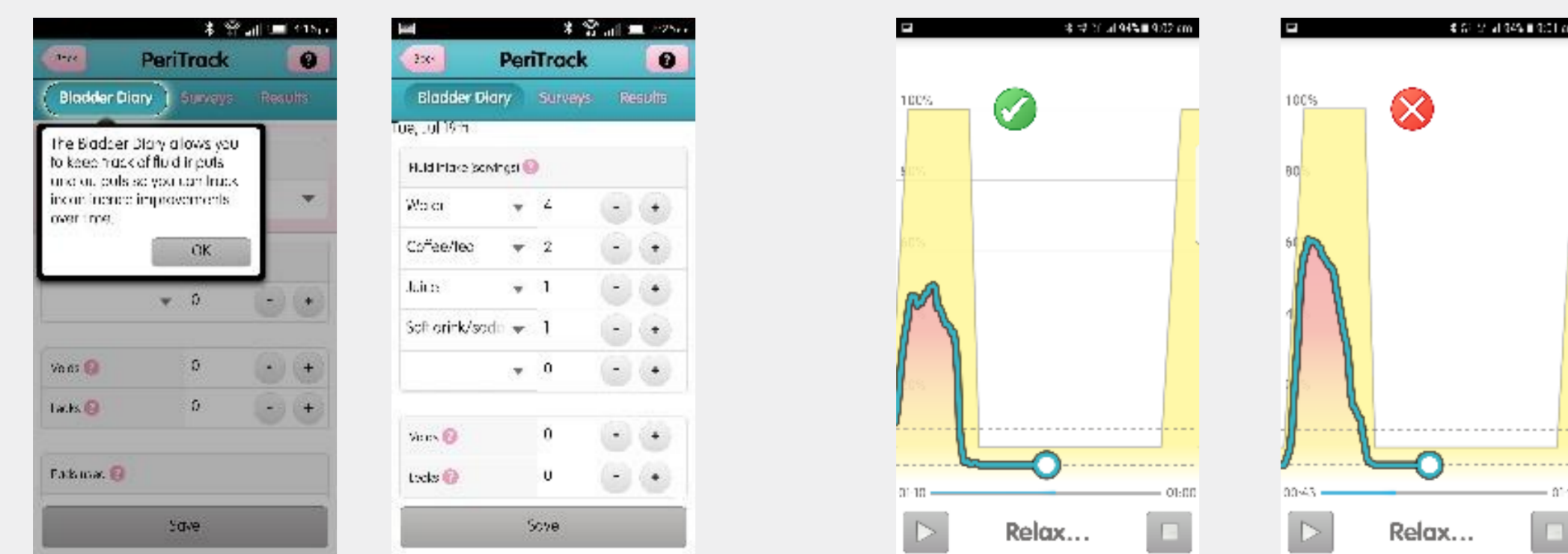
Figures 1. The PeriCoach app Bladder Diary   Figures 2. Technique feedback during exercise

Results

For both studies, outcomes for which statistical significance could be performed, considerable improvement were demonstrated.

- The RCT Q-IQOL and PSIQUIR scores revealed significance over control group (p=.0154, p=0.0061), pad weight did not meet significance yet trend in favor of interventional system.

- The RCT Q-IQOL scores revealed a significant improvement in PFMT+PeriCoach over PFMT group (mean change at week 4 to week 20: 11.50 to 18.67 vs. 5.73 to 10.85, p=0.0154, Table XX).

- Change in sexual satisfaction was measured only at baseline and at week 20, demonstrating improvement in PFMT+PeriCoach v2, and deterioration in PFMT group (Mean Change: 1.71 vs. -2.46, p=0.0061, Table YY).

- Both RCT and RWD studies demonstrated improvement in strength with PeriCoach use (**RCT** p=0.0985, **RWD** p=<0.0001).

- For the RWD study, at 3 weeks and beyond there was a reduction of leakage volume (p=0.0410) and episodes (p=0.0671).

When comparing the strength results across both studies, RCT participants who performed PFMT with the V2 device would have shown statistically significant improvement under the *modest assumption* of 10% impact improvement had the V3 been used in the study (mean change from baseline at Week 4 to 20: 3.7 to 4.3 in PFMT+PeriCoachV2 vs. 3.0 to 3.6 in PFMT group; p=0.0014), where V3 demonstrated between 20% to 30% improvement over V2 for different endpoints.

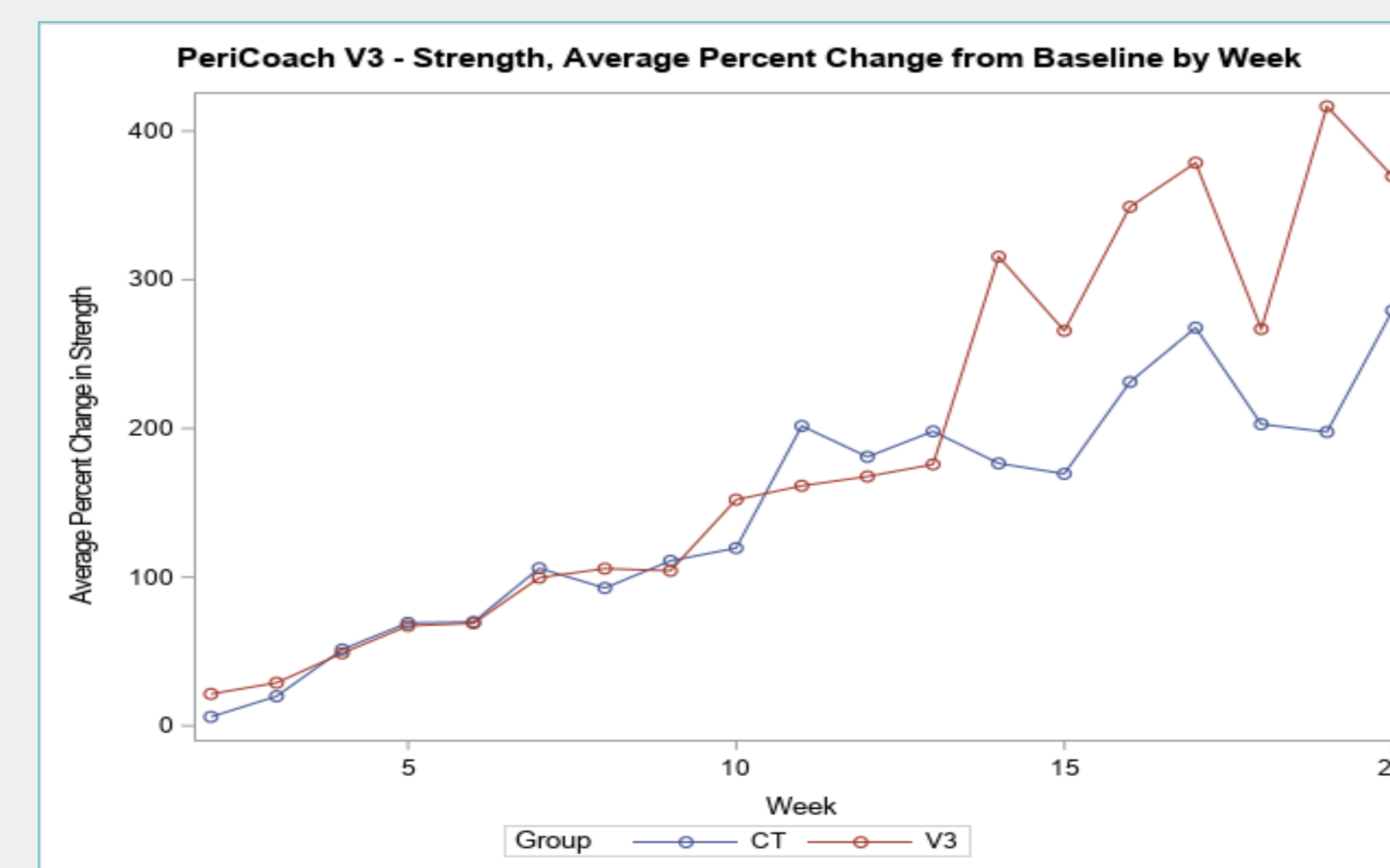**PeriCoach V3 - Strength, Average Percent Change from Baseline by Week**

Figure 3. Strength percent change from baseline for both groups

Conclusion

- The RCT results demonstrated that use of the PeriCoach eHealth biofeedback system for guided PFMT supports compliance, improved strength and positive outcome measures.

- The PeriCoach V3 – with the inclusion of real-time technique feedback and structured, comprehensive 8-week program - would see predictably more significant improvements in outcome measures for the same RCT based on analysis of de-identified RWD.

- eHealth systems enable the automated collection of data without interventional bias, whilst using platforms that are easily accessible and familiar to the patient.
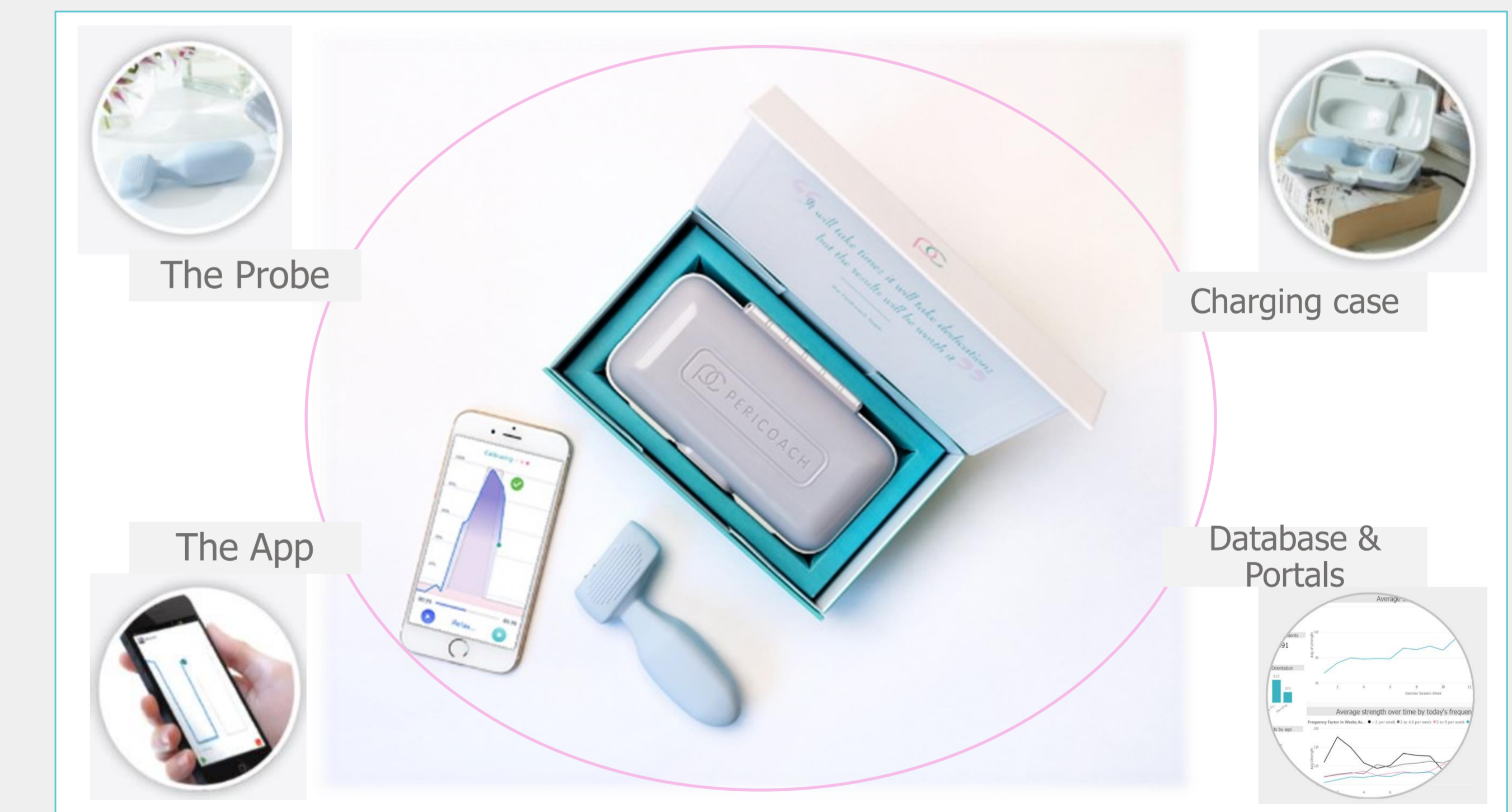
The Probe   Charging case

The App   Database & Portals

Figure 4. Elements of the PeriCoach System

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