Real-World Post-Market Evaluation of the EasyTouch Plus Glucose System: Random Cohort of Users

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Abstract

Background: Post-market, real-world evidence (RWE) complements pre-market evaluations by quantifying performance under routine conditions.

Objective: To assess absolute agreement (mg/dL) between EasyTouch Plus readings and a reference value using a random selection of cohort of users

Methods: Retrospective analysis of de-identified user-generated records. Comparisons were paired to meal-time anchors as per product use; the **Calibration generation and calibration logic are proprietary (IP)**. The publication cohort comprised users with **random selction of their usage and calibration data** (no time or quality filters). Primary outcomes were the proportions of comparisons within **±15** and **±20 mg/dL** of the anchor reference; secondary outcomes were mean absolute difference (MAD), median absolute difference (MdAD), bias, SD, and Bland–Altman limits of agreement (LoA). Bland–Altman and Deming (λ=1) analyses were performed on the cohort pairs.

Results: In the ≥85% cohort (**N pairs = 337**), **98.52%** (332/337; 95% CI **96.57–99.36**) of comparisons were within **±20 mg/dL**, and **84.87%** (286/337; 95% CI **80.65–88.30**) were within **±15 mg/dL**. MAD was **7.99 mg/dL**, MdAD **5.00 mg/dL**; bias (comparison − anchor) **−2.16 mg/dL** with SD **11.53 mg/dL**, yielding LoA **−24.75 to 20.43 mg/dL**.

Conclusions: Among users under routine use, EasyTouch Plus demonstrated high absolute agreement in mg/dL with tight LoA. These findings support effective real-world performance in an engaged user cohort.

Design: Post-market, retrospective, real-world evidence study using de-identified user data.

1. Introduction

Glucose self-monitoring technologies require evaluation both under controlled conditions and during real-world use. Real-world evidence (RWE) can reveal operational drivers of agreement (e.g., timing

relative to calibration anchors, user behaviors) that are not fully captured pre-market. This study reports post-market performance of the EasyTouch Plus system in a **random selction cohort**—users whose prior all-cases had both calibration data from prick based glucometer and Touch Based Easytouch Plus.

Methods

Study design and data source

Retrospective analysis of de-identified, app-captured user records collected during routine product use. Data were collected in **India** from **April 2025 through July 2025**. No demographic variables were accessed. Analyses used reproducible code; **internal calibration and anchoring logic remain proprietary (IP)**.

Device and reference

EasyTouch Plus device readings ("comparison" values) were evaluated against a **reference value at anchor points**. Anchors follow product use; **their generation and any transformation are proprietary (IP)**. All reporting is in **mg/dL**.

Cohort definition (primary analysis set)

We included users whose **per-user calibration and touch based Sugar data** under an **all-cases** pairing (no time or quality filters) was **available**.

For these selected users, we then analyzed **all of their comparison–anchor pairs** (N pairs shown below), without applying additional filters, to reflect the data-generating process of the cohort definition.

Outcomes

- **Primary:** Proportions within **±15 mg/dL** and **±20 mg/dL** of the anchor.
- **Secondary: MAD**, **MdAD**, **bias**, **SD**, and **95% LoA** (Bland–Altman).

Statistical analysis

For each pair we computed the absolute difference (mg/dL), within-band indicators (±15, ±20 mg/dL), and Bland–Altman metrics (difference vs. mean of methods). Deming regression ($\lambda=1$) summarized linear relation with identity line. Proportions are shown with **95% Wilson confidence intervals**. All computations were performed on de-identified data; any algorithmic details beyond these calculations are **(IP)**.

Cohort flow

Flow of records from all user-generated data to the randomly selected cohort. Initial dataset: **Users 1,280; Anchors 4,703; Comparisons 34,481**. Selected cohort: **114 users**, yielding **337 pairs**.

Results

Cohort characteristics and primary outcomes

- **Pairs (N):** 337
- **Within ±20 mg/dL: 98.52%** (332/337; 95% CI **96.57–99.36**)
- **Within ±15 mg/dL: 84.87%** (286/337; 95% CI **80.65–88.30**)

Secondary outcomes

- **MAD (mean absolute difference): 7.99 mg/dL**
- **MdAD (median absolute difference): 5.00 mg/dL**
- **Bias (comparison − anchor): −2.16 mg/dL**
- **SD of difference: 11.53 mg/dL**
- **Bland–Altman LoA: −24.75 to 20.43 mg/dL**
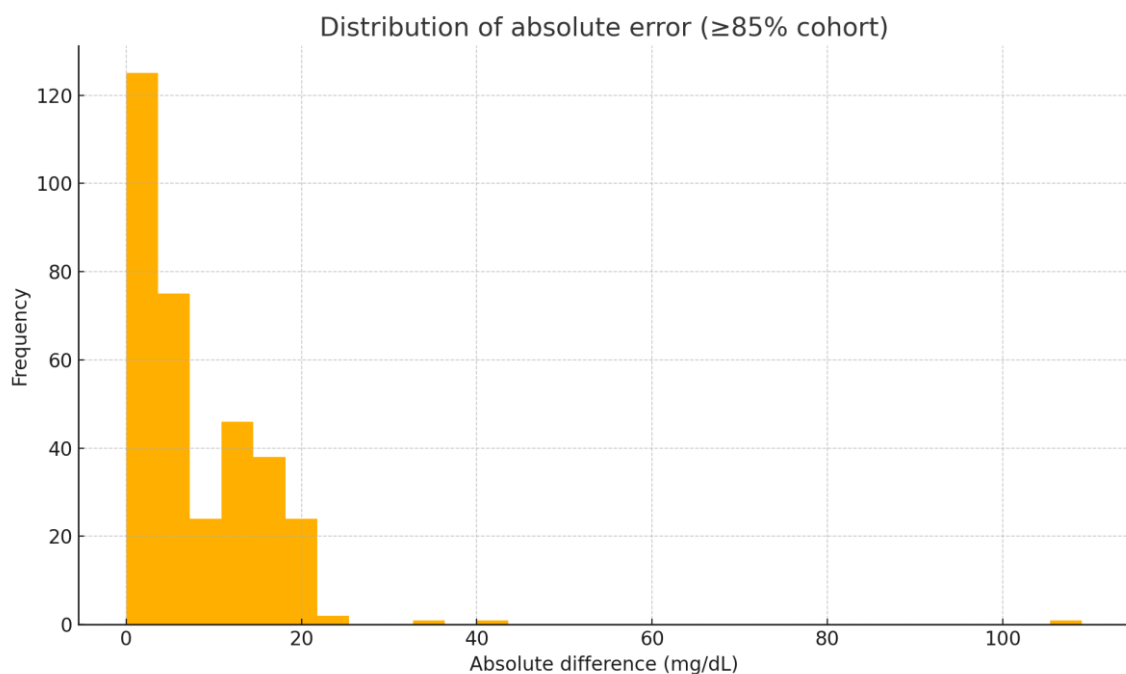
Agreement visualizations
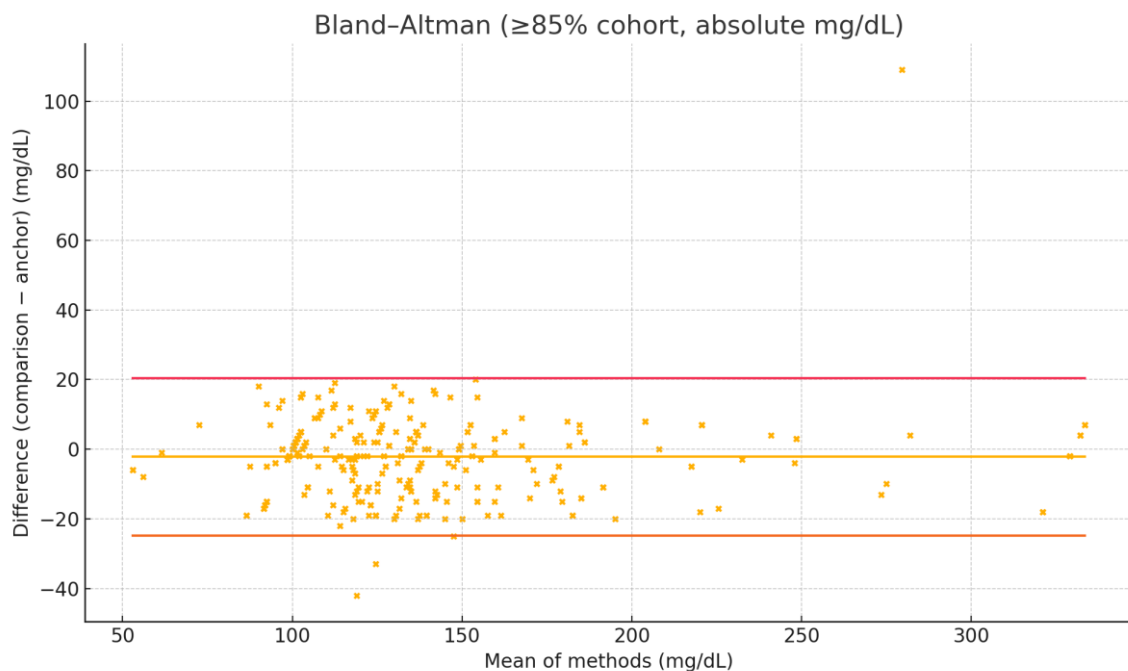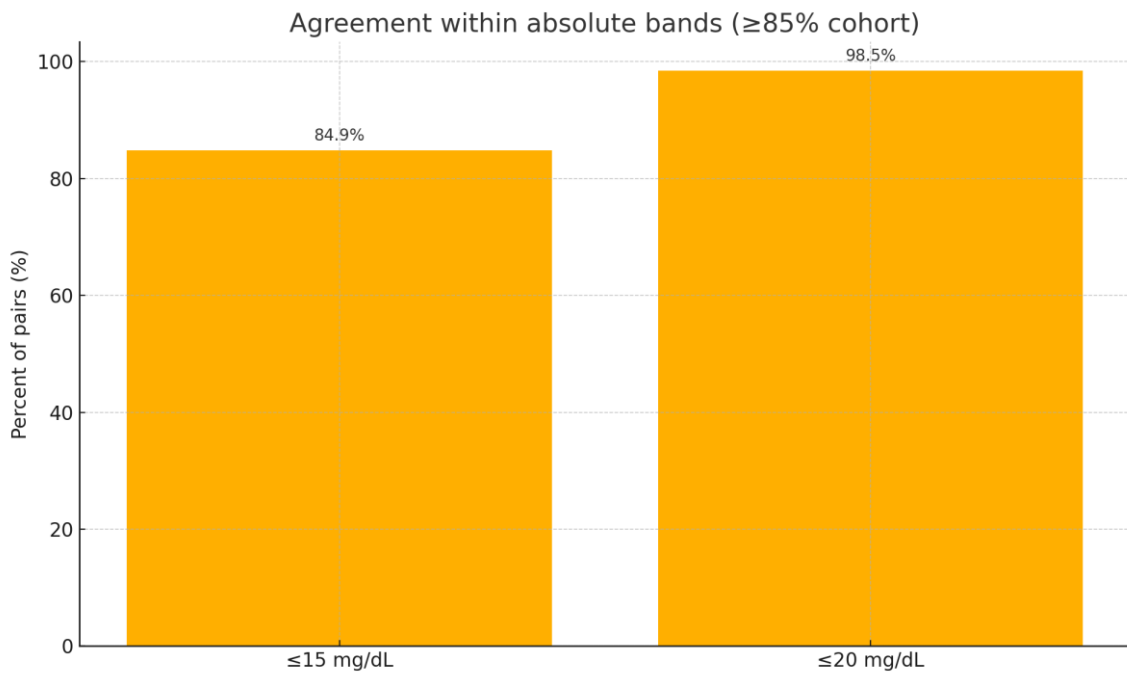

Figure 1 caption. Bland–Altman plot (difference vs. mean) for all pairs in the ≥85% cohort. Solid horizontal lines show bias and 95% LoA.
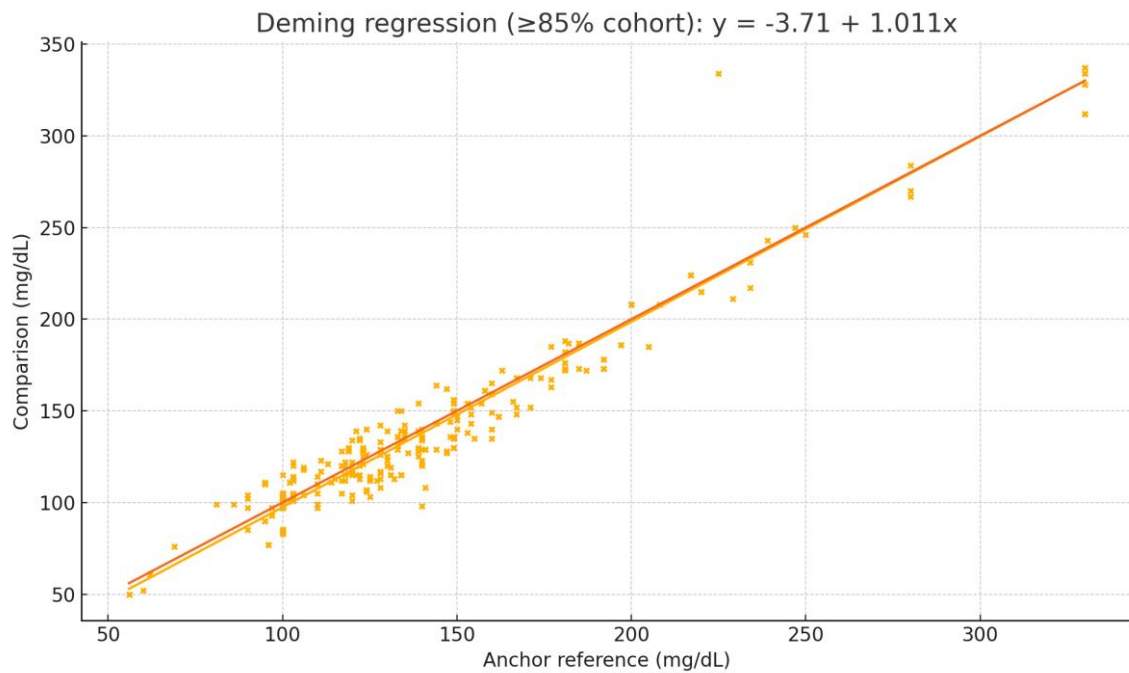
Figure 2 caption. Deming regression ($\lambda=1$) with identity line for cohort pairs.

Figure 3 caption. Histogram of absolute difference (mg/dL) across all pairs in the ≥85% cohort.

Figure 4 caption. Percent of pairs within ≤15 mg/dL and ≤20 mg/dL bands (labels show exact percentages).

Figure 5 caption. Scatter of per-user mean absolute difference (mg/dL) vs. per-user number of comparisons (N) for the cohort.

Data Availability: De-identified aggregate tables and figure files underlying this article are provided as Supplementary Material (Tables S1–S3). Event-level raw data and proprietary processing logic are intellectual property (IP) of the sponsor and are available from the corresponding author upon reasonable request under a data use agreement.

Discussion

In this pre-specified high-accuracy cohort, EasyTouch Plus demonstrates **very high absolute agreement in mg/dL**, with **98.5%** of comparisons within **±20 mg/dL** and a modest negative bias (−2 mg/dL). Limits of agreement (≈ −25 to 20 mg/dL) indicate tight dispersion around the anchor across routine use in an engaged user subset. These results contextualize device performance under real-world conditions among users with consistently high prior accuracy.

Clinical relevance. Absolute error bands (±15/±20 mg/dL) and LoA provide interpretable bounds for day-to-day self-management. The Deming and BA views suggest no gross systematic deviation in this cohort.

Positioning. This cohort intentionally reflects "best-case" routine use—users who already demonstrate high agreement under an all-cases rule. Broader population metrics (not the focus here) may be lower due to timing behaviors, labeling, or anchor quality; those analyses are outside this cohort and are not emphasized to avoid conflating objectives.

Limitations

- Cohort is **selected** by random; not representative of the full user base.
- Retrospective RWE without laboratory comparators; anchors are the reference and their generation is **(IP)**.
- Lack of demographic/clinical covariates; potential residual confounding.

Conclusions

Among users cohort, randomly selected, EasyTouch Plus shows **high agreement** in absolute mg/dL with tight limits of agreement. These results support effective performance in real-world settings for an engaged cohort.

Ethics and compliance

- **IRB/ethics:** Retrospective analysis of fully de-identified, user-generated records collected in India (April–July 2025). **No IRB approval is available.** The sponsor will seek a formal non–human subjects determination/exemption if required by the target journal or jurisdiction. No interventions were performed and no identifiable data were analyzed.
- **Consent/ToS:** Use of de-identified data for secondary analytics is governed by the product's **English-language Terms of Service**; no individual-level re-identification was attempted. [Provide exact clause reference if required by journal.]

- **Data availability:** De-identified aggregate tables and figure files associated with this article are available **upon reasonable request** from the corresponding author, subject to a **data use agreement**. Event-level raw data and proprietary processing logic are **intellectual property (IP)** of the sponsor and are not publicly shareable.

Author contributions, funding, and disclosures

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