

## Dose Accuracy of the ClikSTAR, NovoPen 4, and Luxura Insulin Pens: Results of Laboratory and Field Studies

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### Abstract

#### **Background:**

A high dosing accuracy is needed to maintain normal glycemia in patients with diabetes. This study investigated the dose accuracy of the commonly used reusable insulin pens ClikSTAR<sup>®</sup>, NovoPen<sup>®</sup> 4, and Luxura<sup>®</sup>.

#### **Methods:**

Pens were tested in a laboratory setting by one trained technician who delivered four doses of 30 U from each of 15 pens per pen model (a total of 60 doses from each pen model). Pens were also tested in a simulated clinical setting by 48 people with diabetes. Each participant delivered 27 doses: three doses of 30 U from each of three pens per pen model. Overall, the technician delivered 180 doses and the participants 1296 doses.

#### **Results:**

All pens met the tolerance limits defined by the German edition of the International Standardization Organization (ISO) 11608-1:2000 standard [ $30 \pm 1.5$  U (28.5–31.5 U)]. All doses were delivered within the limits proposed by the ISO, except for two doses with Luxura in the clinical setting. In laboratory testing, the mean dose delivered by ClikSTAR (29.69 U) or Luxura (29.89 U) was less than the expected 30 U and significantly less than the mean dose delivered by NovoPen 4 (30.04 U;  $p < .001$  for both comparisons). Similar results were observed in the simulated clinical setting. NovoPen 4 had the greatest variance in laboratory testing but the least in the simulated clinical setting.

#### **Conclusions:**

This study demonstrates comparable dose accuracy and variability of the ClikSTAR, Luxura, and NovoPen 4 insulin pens. The slight differences in mean doses between pens are unlikely to be clinically significant.

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**Abbreviations:** (CI) confidence interval, (ISO) International Standardization Organization, (SD) standard deviation

**Keywords:** Berlipen, ClikSTAR, dose accuracy, insulin pens, Luxura, NovoPen 4

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