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OneTouch® Blood Glucose Monitoring System Accuracy Proven in New Long-Term Study

Research demonstrates clinical accuracy of OneTouch Select Plus® platform, and demonstrates the value of a continuous and systematic testing program to verify product performance for as long as it has been available to patients

CHESTERBROOK, Pennsylvania, February 8, 2019—New research published in a leading diabetes technology journal shows the long-term clinical accuracy of the OneTouch Select Plus® blood glucose test strip platform and highlights the products' consistently accurate performance. This is the latest study in a series of recent studies that confirm the OneTouch® brand blood glucose monitoring system accuracy.

[A study published this week in the *Journal of Diabetes Science and Technology \(JDST\)*](#) details the OneTouch Select Plus® blood glucose monitoring platform's three years of proven accuracy across multiple clinical studies in patients with diabetes. The study results were derived from more than 21,000 data points from over 200 different test strip batches released since the launch of the OneTouch Select Plus® test strip in 2015. Results show that the system consistently met the minimum requirements of the International Organization for Standardization (ISO) standard 15197:2013 and the European harmonized version EN ISO 15197:2015, with an average of 97.6% of results within specification, demonstrating both product accuracy and consistency.¹

"This study is an example of the clinical rigor and importance that LifeScan applies to its post-market program, which I consider to be a recommendable practice for diabetes device companies," said Dr. Guido Freckmann, Medical Director of the Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm and a leading blood glucose monitoring accuracy expert. "In this study, results are based on more than 21,000 blood glucose meter readings gathered in a clinical setting and paired against corresponding reference instrument readings – all using OneTouch Select Plus® test strips – over a period of years. This sort of continuous, systematic testing methodology enhances the picture of performance given by other accuracy studies, including those I have authored."

This study is the latest in a series of studies highlighting OneTouch® blood glucose monitoring system accuracy. In [a March 2018 JDST study](#), leading experts in self-monitoring of blood glucose (BG) tested the OneTouch Verio Flex® blood glucose monitoring system and found that the "new system showed a high level of measurement accuracy." All three lots that were tested met and exceeded the minimum requirements of the International Organization for Standardization (ISO) 15197:2013 standard for system accuracy.²

This study follows the publication of a [third study](#) in the April 2017 issue of the same journal that detailed the OneTouch Verio® platform's seven years of proven accuracy across more than 70,000 clinical data points.³

¹ Setford, et al. *Evidence from a Long-term, Systematic Post-Market Surveillance Program; Clinical Performance of a Haematocrit Insensitive Blood Glucose Test-Strip*. *Journal of Diabetes Science and Technology* (2019) 1-9

² Annette Baumstark, PhD, Nina Jendrike, MD, Stefan Pleus, MSc, Christina Liebing, PhD, Cornelia Haug, MD, and Guido Freckmann, MD *Accuracy evaluation of a new system for self-monitoring of blood glucose with three test strip lots based on ISO 15197:2013* (*Journal of Diabetes Science and Technology* (2017) 1-2

³ Setford, et al. *Seven-year surveillance of the clinical performance of a blood glucose test strip product*. *Journal of Diabetes Science and Technology* (2017) 1-8

“Self-monitoring of blood glucose is still the most accurate, effective and accessible way people with diabetes can track their blood sugars,” said Dr. David Shearer, Senior Director Worldwide Medical Affairs and Senior Safety Officer, LifeScan, Inc. “With the OneTouch Select Plus® and the OneTouch Verio® range of blood glucose monitoring systems, we are proud to offer people with diabetes and their care teams very accurate products that they know they can trust.”

The OneTouch Select Plus® blood glucose monitoring system and OneTouch Select Plus® test strips and the OneTouch Verio Flex® blood glucose monitoring system and OneTouch Verio® test strips are offerings from the iconic OneTouch® brand by LifeScan. Product availability varies by country. The three *Journal of Diabetes Science and Technology* studies mentioned were funded all or in part by LifeScan.

About LifeScan, Inc.

With a vision to create a world without limits for people with diabetes, LifeScan, Inc. is a world leader in blood glucose monitoring – globally more than 20 million people depend on OneTouch® brand products to help them manage their diabetes. For over 35 years, LifeScan has had an unwavering commitment to improving the quality of life for people with diabetes by developing products defined by simplicity, accuracy, and trust. For more information, visit www.LifeScan.com and www.OneTouch.com.