# Automated insulin dosage titration system demonstrates positive clinical study results

Newly published results from a clinical study of the Diabetes Insulin Guidance System (DIGS™), under development by Hygieia, Inc., demonstrate DIGS' potential to improve blood glucose control for insulin-using patients with type 2 or type 1 diabetes. DIGS automatically adjusted insulin dosage based on each individual's reported blood glucose results. Over the 12-week intervention period of the study, investigators observed:

- Out of a total of 1,734 individual dosage adjustments, the study team over-rode the DIGS-instructed dosage only twice.
- Mean HbA1c levels decreased from a baseline of 8.4%(±0.8) to 7.9%(±0.9); ($p<0.05$);
- Average patient blood glucose levels improved progressively from a baseline of 174.2 mg/dL(±36.7) to 163.3mg/dL(±35.1); ($p<0.03$); and
- Glucose levels falling below the hypoglycemic threshold (glucose < 65 mg/dL) during the 12-week active phase were significantly milder than the ones reported during the 4-week run-in period ($P = 0.02$).

The Phase 1 study, published online this week in Diabetes Technology and Therapeutics, took place at the International Diabetes Center at Park Nicollet, Minneapolis, MN under the direction of principal investigator, Richard M. Bergenstal, MD. The study was funded by the National Institutes of Health, NIDDK Program (award number R41DK085974).

Ultimately, most patients with type 2 diabetes and all patients with type 1 diabetes require insulin therapy. However, despite the availability of a variety of insulin formulations and treatment regimens, most insulin users do not achieve an optimal glycemic target (e.g. HbA1c<7%) and are thus at increased risk of developing complications of diabetes. Over the years, multiple clinical studies have shown that frequent insulin dosage titration is a key element for achieving and maintaining good glycemic control, with physicians or other diabetes experts contacting patients every few days or weeks to make dosage adjustments. Unfortunately, implementation of such frequent insulin titration in day-to-day clinical practice has been hindered by a lack of sufficient medical expertise as well as limited time for frequent health care provider contact.

"The proprietary DIGS technology developed by Hygieia, Inc. measures blood glucose, analyzes patterns in those measurements, and automates insulin dosage titration," said Dr. Bergenstal. "In this study, our team found that DIGS worked amazingly well. After a four-week run-in to establish baseline glucose levels for each patient, 1734 individual insulin dosage adjustments were made by the DIGS software over the 12 week intervention period. Our team gave those newly determined insulin dosage instructions to the study participants each week without

changing the suggested intervention in all but two instances. This demonstrates the possibility that DIGS could automate weekly dosage adjustment safely and effectively – something that none of our current tools is capable of achieving."

Mary Johnson, Director of Research at the International Diabetes Center, stated regarding results achieved by one of the study participants, "We accomplished in 12 weeks using DIGS what our usual standard of care might have taken three years to do."

Asked what DIGS in a handheld device might afford those on insulin therapy, Martha Funnell, MS, RN, CDE, Research Scientist, Michigan Diabetes Research and Training Center, University of Michigan remarked, "This technology might just enable us to provide many more patients with the ability to achieve our best standards of care. The benefits could go beyond better glycemic control and help people with diabetes feel more confident about managing their insulin between health care appointments."

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