Animas Response to the Black Hat Conference Presentation and Insulin On Board Feature

At Animas, patient safety is our top concern. We take every product complaint concerning our insulin pumps seriously and investigate each in accordance with FDA's regulations and reporting requirements for all complaints.

An Animas patient and data researcher is scheduled to give a presentation at the Black Hat USA Security Conference in Las Vegas on July 31 that is expected to be highly critical of how the OneTouch® Ping® insulin pump On Board (IOB) feature functions after a battery change.

Insulin pumps are sophisticated medical devices that require comprehensive training and patient engagement in monitoring, calculating and administrating insulin doses. Animas insulin pumps are designed and certified to comply with U.S. Federal regulations, Part 15 of the Federal Communications Commission (FCC) Rules regarding devices with RF (wireless) capability, and the company has stringent proprietary security measures in place to protect our patients.

It's important to clarify that it is inaccurate to call this a software flaw or cybersecurity issue, as it is a deliberate pump design decision. We investigated the situation and the product is operating as intended, as described in our Instructions for Use Manual, and as explained to patients during training.

The "Insulin On Board" battery reset feature helps to prevent inaccurate dosing calculations that could result from the pump's inability to take into account any self-administered insulin injections given during the time the pump is without a battery. The feature also helps to avoid inaccurate dosing calculations due to the steady decline in the calculated amount of insulin remaining in the patient's system over time from a bolus of insulin administered, depending on how long the pump is detached from the body.

Animas has been in communication with this patient to address his concern and will consider it, as we do feedback from our other customers, as we continue to develop new products and enhancements to existing products. This patient's experience reinforces our goal of thoughtful product design, comprehensive patient training and the need to continually improve how patients interact with our devices to ensure they are as simple, clear and intuitive as possible.