FDA Warns People with Diabetes and Health Care Providers Against the Use of Devices for Diabetes Management Not Authorized for Sale in the United States: FDA Safety Communication

Date Issued:

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Audience:

- People with diabetes who use continuous glucose monitoring systems (CGMs), insulin pumps, or automated insulin dosing (AID) systems to manage their diabetes
- Health care providers treating or managing patients with diabetes who use continuous glucose monitoring systems, insulin pumps, or automated insulin dosing systems to manage their diabetes

Medical Specialties:

General Practice, Internal Medicine, Nursing, Endocrinology, Hematology, Cardiology, Diabetes Care Management

Devices:

People with diabetes may need medication, such as insulin, to control blood glucose and may use the glucose level obtained from certain continuous glucose monitoring systems to calculate insulin dosage.

A **continuous glucose monitoring system** combines a glucose sensor inserted under the skin that continuously tracks glucose levels throughout the day and night with software that translates the signal from the sensor into glucose levels that are displayed to the user.

An **insulin pump** is a small computerized device that delivers insulin through a catheter (a small, flexible tube) placed under a person's skin throughout the day. People with type 1 or type 2 diabetes may need an insulin pump when they require insulin to maintain acceptable blood glucose levels.

An **automated insulin dosing system is a system** that is intended to automatically deliver insulin doses based on glucose measurements from a continuous glucose monitoring system.

Purpose:

The U.S. Food and Drug Administration (FDA) is warning health care providers and people with diabetes of risks associated with use of devices for diabetes management unauthorized for sale in the U.S., whether used alone or along with other devices. These unauthorized diabetes management devices have not been reviewed by the FDA to ensure they provide a reasonable assurance of safety and effectiveness for their intended use. Use of unauthorized devices could result in inaccurate glucose level readings or unsafe insulin dosing, which can lead to injury requiring medical intervention or death.

Summary of Problem and Scope:

The FDA is concerned about people with diabetes using unauthorized devices for diabetes management used alone or along with authorized devices.

The FDA received a report of a serious adverse event in which a patient used an unauthorized device that receives the electronic signal from an FDA authorized glucose sensor and converts it to a glucose value using an unauthorized algorithm. Glucose values from this unauthorized continuous glucose monitoring system were sent to an unauthorized automated insulin dosing device to drive insulin dosing. The automated insulin dosing system gave too much insulin in response to repeated incorrect high glucose values sent from the continuous glucose monitoring system. This unauthorized system resulted in an insulin overdose requiring medical intervention. These devices were not designed to be used together and were combined in a way that had not been thoroughly tested for compatibility. Based on the available information, it is unclear whether the insulin overdose resulted from inaccurate glucose values reported from the unauthorized sensor, or a software malfunction in the unauthorized automated insulin dosing system that misinterpreted the electronic signal from the unauthorized continuous glucose monitoring system.

Some diabetes management devices are authorized for sale in the U.S. by the FDA only in a specific configuration, while others are authorized for use with other compatible devices, which may include automated insulin dosing systems, insulin pumps, blood glucose meters or other devices used for diabetes management.

For example, an authorized automated insulin dosing system will include a specific continuous glucose monitoring system, a specific insulin pump, and a specific algorithm. These devices are all tested and authorized together as a system.

Also, the FDA has authorized diabetes devices that have been designed to work safely with other devices, such as integrated continuous glucose monitoring systems (/news-events/press-announcements/fda-authorizes-first-fully-interoperable-continuous-glucose-monitoring-system-streamlines-review) and "automated controller enabled" insulin pumps (/news-events/press-announcements/fda-authorizes-first-interoperable-insulin-pump-intended-allow-patients-customize-treatment-through), that comprise diabetes therapy systems. This approach allows patients to safely tailor their diabetes management. Devices are labeled to indicate which compatible devices patients can safely use together as a system.

When patients combine devices that are not intended for use with other devices, or when patients use any unauthorized devices, new risks are introduced that the FDA has not evaluated for safety or effectiveness. Patient use of unauthorized diabetes management devices, alone or along with other devices, could result in inaccurate glucose level readings or unsafe insulin dosing. These inaccuracies may lead to injuries requiring medical intervention, such as severe low blood sugar, coma, diabetic ketoacidosis (buildup of acids in blood), and death.

In addition, the FDA is aware of manufacturers marketing unauthorized diabetes management devices that use an algorithm to convert raw data from an FDA authorized glucose sensor to a glucose level displayed to the patient. The FDA has not evaluated the algorithm that these unauthorized devices use. The algorithm may return inaccurate glucose values.

Recommendations for People with Diabetes Who Use Diabetes Management Devices:

- Talk to your health care provider about diabetes management devices and how to use them correctly.
- Use diabetes management devices that the FDA authorized for sale in the U.S. and use them according to manufacturer instructions. You may ask the

manufacturer or you may contact the FDA, at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100, if you have questions about the FDA regulatory status of any particular product.

- Be aware that the FDA has not evaluated the safety and effectiveness of unauthorized diabetes management devices or of systems that combine devices in unintended ways.
- Be aware that the use of unauthorized devices and systems may give you incorrect results and have unknown risks.
- If you experience an adverse event associated with the use of any diabetes management device, whether it is authorized or unauthorized, please report adverse events (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda) through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

Recommendations for Health Care Providers:

- Be aware that the FDA has not evaluated the safety and effectiveness of unauthorized diabetes management devices or the safety and effectiveness of systems that combine devices in unintended ways. Be aware that the use of these types of devices and systems may introduce unknown risks.
- Be aware that your patients should only use diabetes management devices the FDA has authorized for sale in the U.S. and should use them according to manufacturer instructions. You may ask the manufacturer or you may contact the FDA, at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100, if you have questions about the FDA regulatory status of any particular product.
- If any patients experience adverse events associated with the use of any diabetes management device, whether it is authorized or unauthorized, please report adverse events (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda) through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

FDA Actions:

The FDA understands that people with chronic conditions, such as diabetes, may prefer to have multiple treatment and management options they can tailor to fit their specific needs. The agency recently authorized the first interoperable insulin

pump (/news-events/press-announcements/fda-authorizes-first-interoperable-insulin-pump-intended-allow-patients-customize-treatment-through) and is committed to continuing to streamline regulatory pathways to promote innovation and patient access to these products.

As part of the FDA's Medical Device Safety Action Plan (/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health), the FDA is committed to alerting the public when safety issues are identified, such as our recent communication regarding purchasing pre-owned or unauthorized test strips (/medical-devices/safety-communications/fda-warns-against-use-previously-owned-test-strips-or-test-strips-not-authorized-sale-united-states).

The FDA will continue to closely monitor adverse event reports associated with diabetes management devices and will take additional steps as necessary. The FDA will update this communication if significant new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of continuous glucose monitoring systems, automated insulin dosing systems, and insulin pumps.

If you experience adverse events associated with the use of any device for treatment and management of diabetes, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Other Resources:

- FDA Safety Communication – The FDA Warns Against Use of Previously Owned Test Strips or Test Strips Not Authorized for Sale in the United States (/medical-devices/safety-communications/fda-warns-against-use-previously-owned-test-strips-or-test-strips-not-authorized-sale-united-states) (April 8, 2019)

- Blood Glucose Monitoring Devices (/medical-devices/vitro-diagnostics/blood-glucose-monitoring-devices)
- FDA Press Release: FDA Warns Against the Use of Unauthorized Devices for Diabetes Management (/news-events/press-announcements/fda-warns-against-use-unauthorized-devices-diabetes-management)

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.