

Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is warning consumers, patients, caregivers, and health care providers of risks related to using smartwatches or smart rings that claim to measure blood glucose levels (blood sugar) without piercing the skin. These devices are different than smartwatch applications that display data from FDA-authorized blood glucose measuring devices that pierce the skin, like continuous glucose monitoring devices (CGMs). The FDA has not authorized, cleared, or approved any smartwatch or smart ring that is intended to measure or estimate blood glucose values on its own.

For people with diabetes, inaccurate blood glucose measurements can lead to errors in diabetes management, including taking the wrong dose of insulin, sulfonylureas, or other medications that can rapidly lower blood glucose. Taking too much of these medications can quickly lead to dangerously low glucose, leading to mental confusion, coma, or death within hours of the error.

Recommendations for Consumers, Patients, and Caregivers

- Do not buy or use smartwatches or smart rings that claim to measure blood glucose levels. These devices may be sold through online marketplaces or directly from the seller.
- Be aware that the safety and effectiveness of these devices have not been reviewed by FDA, and the use of these devices could result in inaccurate measurements of blood glucose levels.
- If your medical care depends on accurate blood glucose measurements, talk to your health care provider about an appropriate FDA-authorized device for your needs.

Recommendations for Health Care Providers

- Read and follow the recommendations for consumers, patients, and caregivers.
- Talk to your patients about the risk of using unauthorized blood glucose measuring devices.
- Help your patients select an appropriate, FDA-authorized, blood glucose measuring device, if needed.

Device Description

Sellers of these smartwatches and smart rings claim their devices measure blood glucose levels without requiring people to prick their finger or pierce the skin. They claim to use non-invasive techniques. These smartwatches and smart rings do not directly test blood glucose levels.

These smartwatches and smart rings are manufactured by dozens of companies and sold under multiple brand names. This safety communication applies to any smartwatch or smart ring that claims to measure blood glucose without piercing the skin, regardless of manufacturer or brand.

FDA Actions

The FDA routinely monitors the medical device market and became aware of unauthorized products being marketed to consumers. The agency is working to ensure that manufacturers, distributors, and sellers do not illegally market unauthorized smartwatches or smart rings that claim to measure blood glucose levels. Additionally, the FDA is alerting consumers about this issue and making the public aware that smartwatches and smart rings should not be used to measure blood glucose levels.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with Your Device

If you think you had a problem with inaccurate blood glucose measurement or experience any adverse events from using an unauthorized smartwatch or smart ring, the FDA encourages you to [report the problem through the MedWatch Voluntary Reporting Form](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Prompt reporting can help the FDA improve patient safety by identifying and better understanding the risks associated with the medical devices.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>) or call 800-638-2041 or 301-796-7100.

Affected Devices

Any smartwatch or smart ring, regardless of brand, that claims to measure blood glucose levels.

Was this helpful?

Yes

No