

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA allows expanded use of devices to monitor patients' vital signs remotely

For Immediate Release:

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Today, as part of the U.S. Food and Drug Administration's ongoing efforts to address the coronavirus outbreak (COVID-19), the agency issued a new policy ([/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during](#)) that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate and blood pressure.

“Allowing these devices to be used remotely can help health care providers access information about a patient’s vital signs while the patient is at home, reducing the need for hospital visits and minimizing the risk of exposure to coronavirus,” said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. “This policy reflects the FDA’s commitment to ease burdens on health care providers and facilities as they face this public health emergency. Such devices include technologies capable of enabling remote interactions to provide crucial information to be used as an adjunctive when health care providers diagnose or treat COVID-19 or co-existing conditions. During this public health emergency, it is imperative that the FDA provide regulatory relief and adapt as the situation warrants to act upon measures to save lives.”

This policy applies to certain modifications to the indications, claims, functionality, or hardware or software of FDA-cleared non-invasive remote monitoring devices used to support patient monitoring. This policy is limited to the duration of the emergency.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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