



FDA's Policy on Non-Invasive Remote Monitoring Devices During the COVID-19 Public Health Emergency

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In response to the COVID-19 pandemic, the Food and Drug Administration issued a guidance document on non-invasive remote monitoring devices to assist in facilitating patient monitoring during the COVID-19 public health emergency.¹ The guidance compliments the shift to telemedicine platforms during the pandemic to reduce patient and healthcare provider contact and exposure. According to FDA, modified use of non-invasive remote monitoring devices may increase access to important patient physiological data (e.g., heart rate) without in-person provider visits and help providers monitor and manage patients without in-person contact. Increased utilization of such devices may also decrease the burden on hospitals and other facilities and reduce the risk of exposure for patients and healthcare providers.

The guidance was implemented immediately upon its publication on March 20, 2020, and prior to public comment due to the public health emergency. It will remain only in effect during the duration of the public health emergency that the Department of Health and Human Services announced on January 31, 2020.

Scope

The guidance applies to the following medical devices that measure or detect common physiological parameters used to support patient monitoring:

Device Type	Classification Regulation	Product Code
Clinical electronic thermometer	21 C.F.R. § 880.2910	FLL
Electrocardiograph (ECG)	21 C.F.R. § 870.2340	DPS
Cardiac monitor	21 C.F.R. § 870.2300	DRT, MWI, MSX, PLB
Electrocardiograph software for over-the-counter use	21 C.F.R. § 870.2345	QDA
Pulse Oximetry (SpO2)	21 C.F.R. § 870.2700	DQA
Non-invasive Blood Pressure (NIBP)	21 C.F.R. § 870.1130	DXN
Respiratory Rate/Breathing Frequency	21 C.F.R. § 868.2375	BZQ
Electronic Stethoscope	21 C.F.R. § 870.1875	DQD

These devices may be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's measurements to a healthcare provider or other monitoring entity. Some of these devices also have the potential to assisted in diagnosis by applying algorithms to transform a patient's physiological parameters into an index or alarm.

¹ The guidance document is available at the following link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>.

Modifications to FDA-Cleared Indications, Claims, or Functionality

FDA does not intend to object to limited modifications without prior submission of a premarket notification (i.e., a 510(k)) to the indications, claims, functionality, or hardware or software of FDA-cleared non-invasive remote monitoring devices that are used to support patient monitoring. The guidance provides the following examples of such modifications:

- inclusion of monitoring statements related to patients with COVID-19 or co-existing conditions (such as hypertension or heart failure);
- if a device has been previously cleared only for use in hospitals or other healthcare facilities, a change to the indications or claims regarding use in the home setting; and
- hardware or software changes to allow for increased remote monitoring capability.

In addition, FDA does not intend to object to a modification to the FDA-cleared indication, claim, or functionality of a device without prior submission of a premarket notification where the modification does not create an undue risk in light of the public health emergency. The following is an example of a scenario that the agency believes does not create an undue risk:

- the device is intended for the purpose of displaying, printing or analyzing the physiological parameters that are measured by the device; and
- the device is intended to support or provide adjunctive recommendations to the healthcare professional or patient about prevention, diagnosis or treatment of COVID-19 or co-existing conditions; and
- the healthcare provider and/or patient can independently review the basis for the diagnosis or treatment recommendations.

In contrast, the following are examples of circumstances under which FDA believes a modification would create an undue risk:

- the device is intended to determine when patients need immediate clinical intervention to ensure safety; or
- the device is intended to be solely or primarily relied upon by the healthcare professional or patient to make a clinical diagnosis or treatment decision pertaining to COVID-19 or co-existing conditions; or
- the modification adds the functionality to acquire, process, or analyze a pattern or signal from a signal acquisition system that was not present in the FDA-cleared device.

Labeling Recommendations

To help users better understand the device modification, FDA recommends that the device labeling include the following elements (if not already required by regulation):

- a clear description of the available data on the device's new indications, claims, or functions related to COVID-19 or co-existing conditions, including: device performance, method of determining any diagnostic or treatment recommendations, and potential risks;
- a prominent notice to the patient and healthcare provider that recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to prevent, diagnose, or treat COVID-19 or co-existing conditions;
- information on use conditions, particularly whether the device is intended for spot-checking, trend monitoring, or continuous monitoring;
- a clear distinction delineating FDA-cleared indications and claims from those that are not FDA-cleared and a general statement about changes that have not been FDA-cleared;
- if a device was previously cleared for a facility settings (e.g., hospital) and the environment of use has been expanded to include in-home use, the labeling should include adequate instructions for use in the home setting with appropriate lay terminology.

Modifications to FDA-Cleared Hardware or Software

FDA does not intend to object to hardware or software architecture modifications to devices that allow for increased remote monitoring capability to support additional claims or indications without prior submission of a premarket notification, provided the considerations described above are taken into consideration and the modifications does not directly affect the physiological parameter measurement algorithms (e.g., the addition of wireless and/or Bluetooth capability).

FDA recommends these types of changes be designed, evaluated and validated in accordance with a long list of standards (e.g., IEC 60601-1: 2012 – *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*) included in the guidance document. In addition, for such changes, manufacturers should develop and implement appropriate cybersecurity controls that ensure device cybersecurity and maintain device functionality and safety. The guidance document also provides some links to online resources that may be helpful in developing and maintaining cybersecurity controls.

Clinical Decision Support Software²

The Federal Food, Drug, and Cosmetic Act excludes from the definition of device software functions that meet all of the following four criteria:

- not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
- intended for the purpose of displaying, analyzing, or printing medical information about a patient or other types of medical information (e.g., peer-reviewed clinical studies and clinical practice guidelines);
- intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and
- intended for the purpose of enabling healthcare professional to independently review the basis for treatment recommendations that such software presents so that it is not the intent that the healthcare professional rely primarily on any of the recommendations to make a clinical diagnosis or treatment decision.

Software functions that meet these criteria are not regulated by FDA. FDA provided the following examples of non-device functions that meet the criteria as described above:

- software that uses a patient's diagnosis to provide a healthcare provider with current practice treatment guidelines for COVID-19 or co-existing conditions, and that provides the source of the guidelines;
- software that provides recommendations on the use of a medical device to treat COVID-19 that are consistent with the FDA-required labeling or described in other sources, so the healthcare provider does not rely primarily on the software's recommendation;
- software that compares patient signs, symptoms, or results with available practice guidelines to recommend condition-specific diagnostic tests, investigations, or therapy or triaging patient care, if guidelines are described as the basis for the recommendation and provided for the provider's review, so the provider does not rely primarily on the software's recommendation; and
- a software function that is intended to analyze medical information about a patient diagnosed with COVID-19 (e.g., temperature or heart rate), to provide recommendations to the healthcare professional for opportunities for additional monitoring or care, and the basis for the recommendation is provided so that the healthcare professional does not rely primarily on the recommendation.

The guidance document provides a number of links to online resources that may be helpful regarding FDA's digital health policies.

² We note that FDA has issued a draft guidance on Clinical Decision Support software (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software>).

AGG Observations

- The guidance document represents FDA's attempts to take a nimble approach to medical device regulation during the public health emergency to increase access to non-invasive remote patient monitoring.
- Medical device companies should keep in mind that the enforcement policy will only be in place during the duration of the public health emergency.
- Even if a remote patient monitoring device minimizes in-person interactions between patients and healthcare providers, if it will present an undue risk to the patient, FDA may still take action.

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