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Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

March 2020



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. It is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 C.F.R. 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19> and from the FDA webpage titled "Search for FDA Guidance Documents" available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 20014 and complete title of the guidance in the request.

Questions

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability and capability of non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID-19 during this pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act.

Given this public health emergency, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

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In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, appropriate clinical management and infection control in conjunction with implementation of community mitigation efforts are critical.

FDA believes the policy set forth in this guidance will help address these urgent public health concerns by helping to expand the availability and capability of remote patient monitoring devices. Modified use of these devices may increase access to important patient physiological data without the need for in-clinic visits and facilitate patient management by health care providers while reducing the need for in-office or in-hospital services during the COVID-19 public health emergency. Increased utilization of non-invasive remote patient monitoring devices may ease burdens on hospitals and other healthcare facilities and reduce the risk of exposure for patients and health care providers to SARS-CoV-2.

III. Scope

The enforcement policy described in this guidance applies to the following non-invasive remote monitoring devices³ that measure or detect common physiological parameters and that are used to support patient monitoring during the COVID-19 public health emergency:

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>).

² President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

³ Examples may include wearable, hand-held, stationary in-home monitoring and digital interfaces.

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Table 1

Device Type	Classification Regulation	Product Code ⁴
Clinical electronic thermometer	21 CFR 880.2910	FLL
Electrocardiograph (ECG)	21 CFR 870.2340	DPS
Cardiac monitor	21 CFR 870.2300	DRT, MWI, MSX, PLB
Electrocardiograph software for over-the-counter use	21 CFR 870.2345	QDA
Pulse Oximetry (SpO ₂)	21 CFR 870.2700	DQA
Non-invasive Blood Pressure (NIBP)	21 CFR 870.1130	DXN
Respiratory Rate/Breathing Frequency	21 CFR 868.2375	BZQ
Electronic Stethoscope	21 CFR 870.1875	DQD

These non-invasive monitoring devices have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's measurements directly to their health care provider or other monitoring entity.

Some of these devices also have the potential to apply algorithms to transform a patient's physiological parameters into a novel index or alarm that may aid a health care professional in the diagnosis of a particular condition or disease state/severity.

IV. Policy

In the context of the COVID-19 public health emergency, the leveraging of current non-invasive patient monitoring technology will help eliminate unnecessary patient contact and ease the burden on hospitals, other health care facilities, and health care professionals that are experiencing increased demand due to the COVID-19 pandemic as it relates to diagnosis and treatment of patients with COVID-19 and ensuring other patients who require monitoring for conditions unrelated to COVID-19 can be monitored outside of health care facilities. For that reason, FDA does not intend to object to limited modifications to the indications, claims, functionality, or hardware or software of FDA-cleared non-invasive remote monitoring devices that are used to support patient monitoring (hereinafter referred to as "subject devices") during the declared public health emergency, as described in more detail below, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81.⁵ Examples of such modifications include:

- The inclusion of monitoring statements related to patients with COVID-19 or co-existing conditions (such as hypertension or heart failure);
- For subject devices previously cleared only for use in hospitals or other health care facilities, a change to the indications or claims regarding use in the home setting; and

⁴ For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁵ For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.

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- Hardware or software changes to allow for increased remote monitoring capability.

A. Modifications to FDA-cleared Indications, Claims, or Functionality

In developing this policy, FDA's intent is to foster the continued availability of safe and effective medical devices while being flexible regarding modifications made to non-invasive monitoring devices in response to the COVID-19 public health emergency.

For the duration of the public health emergency, FDA does not intend to object to modifications to the FDA-cleared indications, claims, or functionality of the subject devices without prior submission of a premarket notification where the modification does not create an undue risk in light of the public health emergency. FDA currently believes a modification does not create such undue risk in the following scenario:

- 1) The device is intended for the purpose of displaying, printing or analyzing the physiological parameter(s) measured by the device; and
- 2) The device is intended for the purpose of supporting or providing adjunctive recommendations to the health care professional or patient about prevention, diagnosis or treatment of COVID-19 or co-existing conditions; and
- 3) The health care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations.

Examples of circumstances where FDA currently believes a modification would create such an undue risk are:

- 1) The device is intended to determine when patients need immediate clinical intervention to assure patient safety; or
- 2) The device is intended to be solely or primarily relied upon by the health care professional or patient to make a clinical diagnosis or treatment decision pertaining to COVID-19 or co-existing conditions; or
- 3) The modifications add 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.

In addition, FDA recommends that the labeling for devices described above include the following elements, where these elements are not already required by regulation. FDA is making these labeling recommendations because it believes they will help users better understand the device modifications.

- 1) 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:
 - a. Device performance;
 - b. Method of determining any diagnostic or treatment recommendations; and
 - c. Potential risks.

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- 2) A prominent notice to both the patient and health care 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.⁶
- 3) Information on use conditions, in particular whether the device is intended for spot-checking, trend monitoring, or continuous monitoring.
- 4) Clear distinction delineating FDA-cleared indications and claims from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.
- 5) For devices previously cleared for use only in a hospital or other health care facility and for which the environment of use has been expanded to include in-home use, adequate instructions for use in the home setting with appropriate lay terminology.

B. Modifications to FDA-cleared Hardware or Software Intended to Increase Remote Monitoring Availability or Capability

For the duration of the public health emergency, FDA does not intend to object to hardware or software architecture modifications to subject devices that allow for increased remote monitoring capability to support additional claims or indications without prior submission of a premarket notification, taking into account the considerations described above (in Section IV.A.) and where the modifications do not directly affect the physiological parameter measurement algorithms. One example is the addition of wireless and/or Bluetooth capability. FDA recommends any such changes be designed, evaluated and validated in accordance with FDA recognized standards, including (as applicable):

- IEC 60601-1: 2012 – *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014 – *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11: 2015 – *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
- AAMI TIR69: 2017 – *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017 – *American National Standard for Evaluation of Wireless Coexistence*
- IEC 62304: 2015 – *Medical Device Software – Software Life Cycle Processes*

In addition, for any such changes, manufacturers should develop and implement appropriate cybersecurity controls to assure device cybersecurity and maintain device functionality and safety.

⁶ For example, the following statement follows this recommendation: “This device is intended to provide recommendations that should be used in an adjunctive (supportive) manner and are not intended to be used as a primary means to make diagnosis, prevention, or treatment recommendations.”

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The following online resources may be helpful in developing and maintaining these cybersecurity controls:

- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0);⁷
- [Postmarket Management of Cybersecurity in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices).⁸

C. Clinical Decision Support Software for Monitoring related to COVID-19 and Co-existing Conditions

Software, including mobile apps, may be useful in connection with monitoring for patients with COVID-19 or co-existing conditions and providing clinical decision support.

Section 3060(a) of the Cures Act amended the FD&C Act to add section 520(o) of the FD&C Act, which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act. This includes certain clinical decision support (CDS) software functions which are excluded from the definition of a device by section 520(o)(1)(E) of the FD&C Act. Specifically, this section excludes, from the definition of device, software functions that meet all of the following four criteria:

- 1) 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 (section 520(o)(1)(E) of the FD&C Act);
- 2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);
- 3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition (section 520(o)(1)(E)(ii) of the FD&C Act); and
- 4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (section 520(o)(1)(E)(iii) of the FD&C Act).⁹

Following are examples of non-device functions under section 520(o):

⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices>.

⁹ The Cures Act provides that a software function described in section 520(o)(1)(E) of the FD&C Act will not be excluded from the device definition under section 201(h) if the software meets the criteria under section 513(a)(1)(C) of the FD&C Act or if the software is used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; section 520(o)(4)(B) and (C) of the FD&C Act. In addition, the Cures Act provides that software will not be excluded if the Secretary of Health and Human Services issues a final order, after notification and a period for comment, that the software function would be reasonably likely to have serious adverse health consequences; section 520(o)(3) of the FD&C Act.

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- 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 provides the source of the guidelines;
- Software that provides healthcare providers with recommendations on the use of a medical device to treat a patient with confirmed or suspected COVID-19 that are consistent with the FDA-required labeling or that are described in other sources, such that the healthcare provider does not rely primarily on the software’s recommendation;
- Software that compares patient signs, symptoms, or results with available practice guidelines (institutions-based or academic/clinical society-based) to recommend condition-specific diagnostic tests, investigations, or therapy or triaging patient care. The practice guidelines are described as the basis for the recommendation and provided for the health care professional to review, such that the healthcare 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, such as temperature and heart rate, to provide recommendations to the health care professional for opportunities for additional monitoring or care, and the basis for the recommendation, such as CDC guidelines, is provided so that the health care professional does not rely primarily on the recommendation.

The following online resources may be helpful regarding FDA’s digital health policies:

- [Clinical Decision Support Software \(Draft\)](#)¹⁰
- [Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act](#)¹¹
- [Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices](#)¹²
- [General Wellness: Policy for Low Risk Devices](#)¹³
- [Policy for Device Software Functions and Mobile Medical Applications](#)¹⁴

¹⁰ 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>). It is a draft for public comment only and not for implementation.

¹¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act>.

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices>.

¹³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>.

¹⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>.