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**Enforcement Policy for
Telethermographic Systems
During the Coronavirus Disease
2019 (COVID-19) Public Health
Emergency**

**Guidance for Industry and
Food and Drug Administration Staff**

April 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) 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.

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 "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> and 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 an additional copy of the guidance. Please include the document number 20031 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-Thermography@fda.hhs.gov.

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Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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

FDA plays a critical role in protecting the United States from threats such as 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 of telethermographic systems used for body temperature measurements for triage use for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service (PHS) Act (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the

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Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) 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.

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 "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

Fever is a common symptom of COVID-19, typically appearing 2-14 days after exposure.³ Telethermographic systems are able to determine surface skin temperature, which is then used to estimate the temperature at a reference body site (e.g., oral, tympanic membrane). The advantage of using telethermographic systems for initial temperature assessment for triage use is the potential use in high throughput areas (e.g., airports, businesses, warehouses, factories) and in settings where other temperature assessment products may be in short supply. The available scientific literature supports the use of telethermographic systems in the context of initial human temperature measurement during such a triage process.⁴ Additionally, international standards and scientific literature have described guidelines for using telethermographic systems for initial temperature assessment for triage use and best practices for standardized performance testing of such products.^{5, 6, 7}

FDA believes the policy set forth in this guidance may help address urgent public health concerns raised by shortages of temperature measurement products by helping to clarify the regulatory landscape and expand the availability of telethermographic systems used for initial body temperature

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

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

³ <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

⁴ Ring, Francis J., and E. Y. K. Ng. "Infrared thermal imaging standards for human fever detection." *Medical Infrared Imaging: Principles and Practices*. CRC press, 2007.

⁵ ISO/TR 13154:2017: *Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*.

⁶ Ghassemi, Pejman, et al. "Best practices for standardized performance testing of infrared thermographs intended for fever screening." *PLoS One* 13.9 (2018).

⁷ IEC 80601-2-59:2017: *Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*.

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measurements for triage use during this public health emergency.

III. Scope

There are many products marketed in the United States as telethermographic systems that detect infrared radiation and convert such measurements into a temperature measurement. Telethermographic systems that meet the definition of a device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)) are regulated by FDA.

Generally, telethermographic systems fall within the definition of a device when they are intended for a medical purpose, including for use by health care professionals or others for body temperature assessment.⁸ Telethermographic systems that are not intended for a medical purpose are not medical devices as described in further detail below.

The enforcement policy in this guidance applies to telethermographic systems that are intended for adjunctive diagnostic screening during the COVID-19 pandemic. These products may be devices that are regulated under 21 CFR 884.2980(a), product code LHQ,⁹ and have been modified as explained below, or products that normally are not considered devices under the FD&C Act, but that may be used for a medical purpose during the COVID-19 pandemic to address availability concerns of such products.

IV. Policy for Telethermographic Systems

A. Overview

FDA is taking steps to help expand the availability of telethermographic systems and believes the policy set forth in this guidance may help address the urgent public health concerns raised by shortages of temperature measurement products such as thermometers and telethermographic systems by taking a risk-based approach and clarifying the policies that FDA intends to apply to telethermographic systems during the COVID-19 pandemic.

B. Telethermographic Systems Not Intended for a Medical Purpose

Telethermographic systems are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). Under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

⁸ As used in this guidance “intended for a medical purpose” means that the device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meets the definition of “device” set forth in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

⁹ Currently regulated telethermographic systems are identified under product code LHQ, and are class I devices subject to premarket notification requirements under section 510(k) of the FD&C Act (21 U.S.C. 360(k)).

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Telethermographic systems may be marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, when marketed for these non-medical applications, FDA device marketing authorization is **not** required, and all the other medical device requirements of the FD&C Act do **not** apply to manufacturers, importers, and distributors of these products.

Telethermographic systems are devices when they are intended for a medical purpose, such as measurement of the self-emanating infrared radiation that reveals the relative temperature variations of the surface of the body. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:

- 1) They are labeled or otherwise intended for use by a health care professional;
- 2) They are labeled or otherwise for use in a health care facility or environment; and
- 3) They are labeled for an intended use that meets the definition of a device, e.g., body temperature measurement for diagnostic purposes, including such use in non-medical environments (e.g., airports).

The enforcement policy outlined below is intended to apply to all telethermographic systems that are intended for medical purposes for the duration of the public health emergency related to COVID-19. As such, FDA recommends that manufacturers of telethermographic systems that were not previously intended for medical purposes, but that are now intended for medical purposes, review the enforcement policy in Section IV.C.

C. Telethermographic Systems Intended for Adjunctive Diagnostic Screening

In general, manufacturers of telethermographic systems intended for adjunctive diagnostic screening are required to submit a premarket notification pursuant to section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR 807.81 to FDA and receive FDA clearance prior to marketing these devices in the United States, as well as comply with postmarketing requirements.

To help ensure the availability of products that might offer benefit to health care providers and the general public during the public health emergency, FDA does not intend to object to the distribution and use of telethermographic systems intended for initial body temperature assessment for triage use as described in the Scope (Section III) without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: submission of a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR 807.81, Reports of Corrections and Removals requirements in 21 CFR Part 806, Registration and Listing requirements in 21 CFR Part 807, the Quality System Regulation in 21 CFR Part 820, and Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20.

An example of such a modification includes a change to the indications for use from the “measurement of the self-emanating infrared radiation that reveals the relative temperature variations of the surface of the body” to providing an “initial body temperature measurement for triage use.”

FDA believes devices included in this enforcement policy will not create such an undue risk where:

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- The performance and labeling elements in Section IV.D are met, and
- An elevated body temperature measurement is confirmed in the context of use with secondary evaluation methods (e.g., non-contact infrared thermometer (NCIT) or clinical grade contact thermometer).

D. Performance and Labeling

FDA believes such telethermographic devices will not create such an undue risk when the following circumstances related to the performance of the device and the transparency and clarity of information in the product labeling are present.

FDA recommends that the device:

- 1) Is tested and labeled consistent with the following standard: IEC 80601-2-59:2017: *Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*; OR
- 2) Is tested using alternative performance specifications that provide similar results to IEC 80601-2-59:2017. This could include:
 - a) The laboratory temperature accuracy of a screening telethermographic system, including the measurement uncertainty, is less than or equal to $\pm 0.5^{\circ}\text{C}$ ($\pm 0.9^{\circ}\text{F}$) over the temperature range of at least $34\text{-}39^{\circ}\text{C}$ ($93.2\text{-}102.2^{\circ}\text{F}$);
 - b) The system includes an accurate blackbody temperature reference source;¹⁰
 - c) Both stability and drift are less than 0.2°C (0.36°F) within a timeframe specified by the manufacturer; and
 - d) The device risk assessment addresses all potential safety issues, including:
 - i) Electrical safety;
 - ii) Electromagnetic compatibility;
 - iii) Mechanical safety;
 - iv) Excessive temperatures and other hazards;
 - v) Accuracy of controls, instruments, and information display;
 - vi) Considerations for software associated with Programmable Electrical Medical Systems including network connections;¹¹ and
 - vii) Usability.

In addition, FDA recommends that the devices described above use labeling that helps users better understand the device, such as:

- 1) The labeling includes a prominent notice that the measurement should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease;
- 2) The labeling includes a clear statement that:
 - a) Elevated body temperature in the context of use should be confirmed with secondary evaluation methods (e.g., an NCIT or clinical grade contact thermometer);¹²

¹⁰ This is usually a blackbody (idealized physical body that absorbs all incident electromagnetic radiation) with known temperature and emissivity that can be used for thermal drift compensation.

¹¹ For more information on this recommendation, see Clause 201.14 of IEC 80601-2-59: 2017.

¹² This labeling recommendation is consistent with IEC 80601-2-59: 2017.

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- b) Public health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement;
 - c) The technology should be used to measure only one subject's temperature at a time; and
 - d) Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.
- 3) The labeling includes a clear description of:
- a) Device performance specifications and the methodology and frequency of any calibration needed to maintain the labeled specifications;¹²
 - b) How to use the thermal image to make a temperature measurement to within the stated device accuracy;
 - c) A description and purpose of the blackbody reference source (used for thermal drift compensation) and its importance in obtaining an accurate temperature assessment;
 - d) The reference body site used for temperature estimation, including any calibration or correction needed to estimate the temperature at that location, and the accuracy of the measurement at the reference site (e.g., oral, tympanic membrane);
 - e) How different environmental and system setup factors can affect the measurement, including the body site chosen for measurement, the condition of the screening site (e.g., screening background, ambient temperature and humidity, airflow);¹³
 - f) Different factors to consider in the design of the facility protocol (e.g., installation, viewing angle, blackbody temperature reference source);¹⁴
 - g) The installation procedures and qualification testing that should be performed during installation or when imaging equipment is being relocated;¹⁵ and
 - h) The appropriate imaging distance based on the spatial resolution and performance of the camera.¹⁶
- 4) The labeling references and is consistent with the guidelines in ISO/TR 13154: 2017: *Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*; and
- 5) The labeling highlights the differences in design, indications, or functions, as applicable, compared to the unmodified, FDA-cleared version of the product or includes a clear identification that the device is not FDA-cleared or approved.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).¹⁷ For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)."¹⁸

¹³ This labeling recommendation is consistent with ISO/TR 13154: 2017.

¹⁴ *ibid*

¹⁵ *ibid*

¹⁶ This labeling recommendation is consistent with IEC 80601-2-59: 2017

¹⁷ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

¹⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

E. Additional Helpful Resources

The following online resources may also be helpful in evaluating the performance of the device:

- [Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff](#)¹⁹
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)²⁰
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#)²¹

¹⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>.

²⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>.

²¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.