

This guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. For further information, refer to 88 FR 15417, March 13, 2023, available at <https://www.federalregister.gov/d/2023-05094>.

Contains Nonbinding Recommendations

Enforcement Policy for Imaging 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 the 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) 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 20026 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or Office of Health Technology 7: Office of In Vitro Diagnostics and Radiological Health (OIR)/Division of Radiological Health (DRH) at RadHealth@fda.hhs.gov.

Table of Contents

I.	Introduction.....	4
II.	Background	5
III.	Scope.....	6
IV.	Policy	7
A.	Modifications to Indications, Technical Specifications, Functionality, Hardware, Software, and Materials of Imaging Systems	8
B.	Modifications to Indications and Functionality of Ultrasound Imaging Systems.....	9
C.	Modifications to the Indications and Functionality of Image Analysis Software.....	10
D.	Validation of Changes Made to Hardware, Software, Materials, or Duration of Use	11
E.	Labeling of Modified Products	13
F.	Clinical Decision Support Software for Imaging related to COVID-19 and Co-existing Conditions	15
V.	Policy to Help Increase Availability and Minimize Supply Chain Disruptions	16
VI.	Additional Helpful Resources.....	18

Enforcement Policy for Imaging Systems Used 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

The Food and Drug Administration (FDA or the Agency) 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 and capability of medical x-ray, ultrasound, and magnetic resonance imaging systems, and image analysis software that are used to diagnose and monitor medical conditions while mitigating circumstances that could lead to patient, healthcare provider, and healthcare technology management (HTM) exposure to COVID-19 for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and renewed for 90 days on April 21, 2020, effective April 26, 2020.

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

Contains Nonbinding Recommendations

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 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.

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, effective January 27, 2020, and mobilized the Operating Divisions of HHS. The declaration was renewed for another 90 days on April 21, 2020, effective April 26, 2020.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

FDA believes the policy set forth in this guidance will address these urgent public health concerns by helping to increase availability and capability of imaging products needed for diagnosis and treatment monitoring of lung disease in patients with COVID-19. Imaging devices can help visualize pulmonary abnormalities and are used routinely to diagnose and evaluate the causes of reduced lung function. Accordingly, there is increased demand for imaging devices that may assist in the diagnosis and treatment monitoring of lung disease. This policy will also help to ensure the availability and capability of imaging products to image patients due to increased demand during this public health emergency. The need to expand the capability to conduct imaging was emphasized by the American College of Radiology (ACR) statement regarding chest radiography: "Facilities may consider deploying portable radiography units in ambulatory care facilities for use when CXRs [chest radiographs] are considered medically necessary. The surfaces of these machines can be easily cleaned, avoiding the need to bring patients into radiography rooms."³

FDA is issuing this guidance to provide a policy to help expand the availability, functional capability, and portability of imaging systems to help address these urgent public health concerns.

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists (Jan. 31, 2020 (effective Jan. 27, 2020, and April 21, 2020, effective April 26, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.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 ACR Recommendations for the use of Chest Radiography and Computed Tomography (CT) for Suspected COVID-19 Infection (Mar. 22, 2020), available at <https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Recommendations-for-Chest-Radiography-and-CT-for-Suspected-COVID19-Infection>.

Contains Nonbinding Recommendations

Increasing the availability of mobile and portable systems may increase options to image patients inside and outside of healthcare facilities, which could help to reduce the spread of COVID-19. Additionally, modified use of ultrasound imaging systems may expand the number of healthcare practitioners capable of performing this imaging technique. This policy, which applies to the repurchase, repair, or replacement and reporting requirements for electronic products⁴ under the Electronic Product Radiation Control provisions under sections 531-542 of the FD&C Act and 21 CFR Chapter I – Subchapter J, among other things, may help hospitals and other healthcare facilities more quickly address the COVID-19 public health emergency and reduce the risk of exposure for healthcare providers and HTM personnel to SARS-CoV-2.

III. Scope

The enforcement policy described in Section IV.A of this guidance applies to the imaging products in Table 1 used during the COVID-19 public health emergency.

Table 1

Classification Regulation	Product Type	Product Code(s)⁵	Class
892.1000	Magnetic resonance (MR) diagnostic device	LNH, MOS	II
892.1200	Emission computed tomography system	KPS	II
892.1600	Angiographic x-ray system	IZI, QHA	II
892.1650	Image-intensified fluoroscopic x-ray system	JAA, OXO, OWB, RCC, QHY	II
892.1680	Stationary x-ray system	KPR, MQB	II
892.1710	Mammographic x-ray system	IZH	II
892.1715 ⁶	Full-field digital mammography system	MUE	II
No corresponding CFR section	Digital breast tomosynthesis	OTE	III
No corresponding CFR section	Automated breast ultrasound	PAA	III
892.1720	Mobile x-ray system	IZL	II
892.1740	Tomographic x-ray system	IZF	II
892.1750	Computed tomography (CT) x-ray system	JAK	II

The enforcement policy described in Sections IV.A and IV.B below of this guidance applies to the

⁴ An electronic product is defined in 21 CFR 1000.3(j) as (1) any manufactured or assembled product which, when in operation: (i) Contains or acts as part of an electronic circuit and (ii) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

⁵ For more information, see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁶ This classification regulation is subject to special controls. See 21 CFR 892.1715(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

Contains Nonbinding Recommendations

ultrasound imaging systems in Table 2 used during the COVID-19 public health emergency.

Table 2

Classification Regulation	Product Type	Product Code(s)	Class
892.1550	Ultrasonic pulsed doppler imaging system	NCS, IYN	II
892.1560	Ultrasonic pulsed echo imaging system	IYO	II
892.1570	Diagnostic ultrasonic transducer	ITX	II
892.2100 ⁷	Radiological acquisition and/or optimization guidance system	QJU	II

The enforcement policy described in Section IV.C of this guidance applies to the image analysis software in Table 3 or embedded as part of the imaging systems identified in Tables 1 and 2 used during the COVID-19 public health emergency.

Table 3

Classification Regulation	Product Type	Product Code(s)	Class
892.2050 ⁸	Picture archiving and communications system	LLZ, OMJ, OEB, QIH	II
892.2060 ⁹	Radiological computer-aided diagnostic software for lesions suspicious for cancer	POK	II
892.2070 ¹⁰	Medical image analyzer	MYN	II
892.2080 ¹¹	Radiological computer-aided triage and notification software	QAS, QFM	II
892.2090 ¹²	Radiological computer assisted detection/diagnosis software for fracture	QBS, QDQ	II

IV. Policy

FDA believes that it is important to help facilitate availability of the devices listed above and to help leverage the use of current mobile and portable radiological products, which may help ease the

⁷ This classification regulation is subject to special controls. See 21 CFR 892.2100(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

⁸ This classification regulation is subject to special controls. See 21 CFR 892.2050(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

⁹ This classification regulation is subject to special controls. See 21 CFR 892.2060(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

¹⁰ This classification regulation is subject to special controls. See 21 CFR 892.2070(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

¹¹ This classification regulation is subject to special controls. See 21 CFR 892.2080(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

¹² This classification regulation is subject to special controls. See 21 CFR 892.2090(b). The special controls associated with this classification regulation remain in effect during the declared public health emergency.

Contains Nonbinding Recommendations

burden on hospitals, other healthcare facilities, and healthcare professionals that are experiencing increased demand due to the COVID-19 pandemic. Additionally, some of the imaging systems identified in Tables 1 or 2 have the potential to be modified into mobile or portable systems so that patients who may warrant imaging can undergo such procedures without entering a large healthcare facility. Also, some of these products that are software-based have the potential to provide radiological findings that could aid a healthcare professional in diagnosis of a particular condition or monitoring of disease state/severity.

Wherever possible, health care facilities should use FDA-cleared or FDA-approved imaging systems. However, to help ensure the greatest possible number of products for medical imaging are available to address healthcare needs during the public health emergency, FDA does not intend to object to limited modifications to the indications, technical specifications, functionality, hardware, software, or materials of the identified FDA-cleared or FDA-approved imaging systems that are used to diagnose and/or monitor medical conditions (hereinafter referred to as “subject products”), or to limited modifications to the indications or functionality of image analysis software to address urgent COVID-19 image analysis needs during the declared public health emergency where such modification does not create an undue risk, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81(a)(3)¹³ or submission of a premarket approval application (PMA) Supplement under section 515 of the FD&C Act and 21 CFR 814.39,¹⁴ as described in more detail below.

A. Modifications to Indications, Technical Specifications, Functionality, Hardware, Software, and Materials of Imaging Systems

In developing this policy, FDA’s intent is to foster the continued availability of safe and effective medical products while being flexible regarding modifications made to imaging systems that are used to diagnose and/or monitor medical conditions during 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 or approved indications, functionality, hardware, software, and materials of the subject products without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81(a)(3) or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39 where the modification does not create an undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a modification would not create such undue risk include:

¹³ 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,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.

¹⁴ For further guidance on modifications that trigger the requirement that a manufacturer submit a PMA supplement to FDA, refer to “Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process>.

Contains Nonbinding Recommendations

- 1) Expansion of indications for use beyond the cleared/approved indications (e.g., extremity-only use expanded to other body parts) to acquire images in situations where no alternatives exist at a facility;
- 2) Modifications that expand mobility, portability, or relocation of medical imaging systems (e.g., motors, batteries, electrical components, or other hardware and/or software modifications that enable conversion of fixed to mobile imaging systems; provide or increase the capability for wireless use or remote use; design changes intended to reduce electromagnetic emissions in confined spaces to prevent electromagnetic interference with surrounding systems);¹⁵
- 3) Modifications to protect the operator or patient (e.g., addition of a barrier to protect the operator or patient from scatter radiation or provide additional protection against disease transmission);
- 4) Design modifications to improve the ability to clean, disinfect, and/or sterilize the product; and,
- 5) Material changes to components (e.g., use of portable solid-state detectors) where the change does not significantly degrade image quality, and potential hazards associated with the modifications (e.g., scatter radiation or pinch-points) are identified and mitigated by design and/or labeling.

Examples of circumstances where FDA currently believes the modification would create such an undue risk include:

- 1) Modifications to reduce the amount of radiation shielding for either the patient or operator without providing an equivalent alternative;
- 2) Modifications that increase the amount of radiation administered to the patient or result in insufficient image quality for the clinical purpose;
- 3) Modifications that reduce the ability to clean, disinfect, and/or sterilize portions of the device that come into direct contact with the patient; and
- 4) Modifications that introduce new types of reconstruction algorithms.

B. Modifications to Indications and Functionality of Ultrasound Imaging Systems

Because ultrasound imaging systems do not emit ionizing radiation, there are modifications, in addition to those identified in Section IV.A, where FDA currently believes additional flexibility regarding modifications would not create undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a modification would not create such

¹⁵ For any changes that provide or increase the capability for wireless or remote use, manufacturers should develop and implement appropriate cybersecurity controls to ensure device cybersecurity and maintain device functionality and safety. FDA recommends firms refer to the following FDA guidance documents for consideration when pursuing these design changes: “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>; “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>; “Radio Frequency Wireless Technology in Medical Devices” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>; and “Design Considerations and Pre-market Submission Recommendations for Interoperable Devices,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices>.

Contains Nonbinding Recommendations

undue risk include:

- 1) Modifications to enable the use of ultrasound outside of its cleared environment of use (e.g., in a temporary imaging situation with different or more variable environmental conditions, such as a general practitioner's office or a field hospital).
- 2) Modifications to enable the collection of images by healthcare practitioners who are not trained in sonography, under the guidance or supervision of a trained or licensed healthcare practitioner (e.g., functionality to enable remote guidance). For such a modification, the ultrasound imaging system should also include labeling (see Section IV.E below) that sufficiently reduces the risk of use by including information that the supervising healthcare practitioner can use to provide the necessary training, guidance, and supervision.
- 3) Addition of a lung scanning clinical application (and/or lung scanning pre-sets). For such a modification, the ultrasound imaging system should include labeling (see Section IV.E below) that sufficiently reduces the risk of use by referencing practice guidelines or literature that provides essential information on clinical protocols used for lung scanning.¹⁶ FDA recommends using the official statements of the American Institute of Ultrasound in Medicine (AIUM) to determine the technological characteristics that sufficiently reduce the risk of use for lung scanning by:
 - a) Having probes and machine settings appropriate for lung scanning that are based on referenced clinical guidance or literature. Examples include a probe with transducer frequency of 3 MHz and above, linear, curvilinear, and phase array transducer technologies, and probe selection and machine settings that are adequate for lung scanning; and
 - b) The use of a Mechanical Index (MI) < 1.4, as an overall indicator for potential biological effects on tissues containing gas bodies.

Examples of circumstances where FDA currently believes the modification would create an undue risk include:

- 1) Modifications that result in an increase of the derated global maximum acoustic output parameters (see parameters identified in the FDA guidance entitled [Marketing Clearance of Diagnostic Ultrasound Systems and Transducers](#));¹⁷
- 2) Modifications that result in a mechanical index that exceeds known safety limits for the type of clinical exam (e.g., use of a Mechanical Index ≥ 1.4 for lung imaging); and
- 3) Modifications to enable lay users to acquire images without in-person guidance or supervision of a trained or licensed healthcare practitioner.

C. Modifications to the Indications and Functionality of Image Analysis Software

For the duration of the public health emergency, FDA does not intend to object to modifications to the indications or functionality of image analysis software in Table 3 or embedded as part of the imaging systems identified in Tables 1 and 2 to address urgent COVID-19 image analysis needs

¹⁶ For example, see Volpicelli et al, "International evidence-based recommendations for point-of-care lung ultrasound," *Intensive Care Med* (2012) 38:577–591.

¹⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers>.

Contains Nonbinding Recommendations

using the subject products without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39, 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 scenarios:

- 1) Modifications to add additional capability for lung segmentation and measurements;
- 2) Modification of image analysis tools to aid in the identification and evaluation of non-specific findings associated with COVID-19 (e.g., identification of ground-glass opacities on CT, identification of Kerley B-lines on radiographs or ultrasound); and
- 3) Modification of image analysis tools to aid the evaluation and monitoring of patients with COVID-19 and their response to therapy based on quantitative metrics derived from patient images.

Examples of circumstances where FDA currently believes the modification would create such an undue risk include:

- 1) Modifications to indicate the device can be solely or primarily relied upon to diagnose COVID-19;
- 2) Modifications to indicate the device can be solely or primarily relied upon to triage patients suspected of COVID-19;
- 3) Modifications to indicate the device can predict outcome and/or response to treatment in patients with COVID-19; and
- 4) Modifications to distinguish COVID-19 from other lung diseases.

Manufacturers and other stakeholders interested in seeking these or other similar indications are encouraged to contact FDA via email at RadHealth@fda.hhs.gov to discuss an appropriate regulatory pathway, such as Emergency Use Authorization, Breakthrough Designation Request, or one of the Expanded Access Programs.

D. Validation of Changes Made to Hardware, Software, Materials, or Duration of Use

Under design controls, manufacturers are required to conduct verification and validation (21 CFR 820.30(f) and (g)). Verification and validation include procedures to ensure that design outputs meet design inputs and that devices conform to defined user needs and intended uses. In designing, evaluating, and validating changes made to hardware, software, materials or duration of use, FDA recommends considering the following FDA-recognized standards for the specific device type including (as applicable):

Electrical Standards

- IEC 60601-1: 2012: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

Contains Nonbinding Recommendations

- 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

Software Standards

- IEC 62304: 2015: Medical Device Software – Software Life Cycle Processes
- EC 80001-2-2: 2012: Application of risk management for IT Networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls
- IEC TS 62443-1-1: 2009: Industrial communication networks -Network and system security - Part 1-1: Terminology, concepts and models
- IEC 62443-2-1: 2010: Industrial communication networks -Network and system security - Part 2-1: Establishing an industrial automation and control system security program
- IEC 62443-3-1: 2009: Industrial communication networks -Network and system security - Part 3-1: Security technologies for industrial automation and control systems

Wireless Connectivity Standards

- 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
- AAMI TIR69: 2017: Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems12-105 NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

Imaging System Standards

- IEC 61391-2: Edition 1.0 2010-01 Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range
- IEC 62127-1: Edition 1.1 2013-02 Ultrasonics -- Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz
- IEC 62127-2: Edition 1.1 2013-02 Ultrasonics -- Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz
- IEC 62127-03: Edition 1.1 2013-05 Ultrasonics -- Hydrophones-- Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz
- IEC 60601-2-37: Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 61391-1: Edition 1.1 2017-07 CONSOLIDATED VERSION: Ultrasonics – Pulse-echo scanners – Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response

Contains Nonbinding Recommendations

- IEC 62359: Edition 2.1 2017-09 CONSOLIDATED VERSION: Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- IEC, 60601-2-43: Edition 2.2 2019-10 CONSOLIDATED VERSION: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
- IEC, 60601-2-54: Edition 1.1 2015-04 CONSOLIDATED VERSION: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- 12-302 IEC 60601-2-44: Edition 3.2: 2016 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
- IEC, 60601-2-45: Edition 3.1 2015: Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
- IEC 61223-3-5: Edition 2.0 2019-09 Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
- IEC 60601-2-33: Ed. 3.2b: 2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- NEMA MS 10-2010: Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS 12-2016: Quantification and Mapping of Geometric Distortion for Special Applications
- NEMA MS 8-2016: Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- NEMA MS 5-2018: Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).¹⁸ 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](#).”¹⁹

E. Labeling of Modified Products

In addition, FDA recommends that the products described above include labeling that helps users

¹⁸ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

¹⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

Contains Nonbinding Recommendations

better understand the product modifications, such as:²⁰

- 1) A clear description of the product's modified indications, technical specifications or functions, and information on the product's performance and potential risks.
- 2) Adequate instructions for use for the intended user and indicated environment(s) of use. FDA recommends that the labeling highlight the differences in design compared to the unmodified, FDA-cleared or FDA-approved version of the product, along with instructions for mitigating any known risks associated with these differences.²¹
- 3) The minimum installation and qualification testing to be performed during installation or when an imaging system is being relocated, which as is currently only required for manufacturers of diagnostic x-ray systems who must provide revised instructions for assembly, installation, adjustment, and testing information required in accordance with 21 CFR 1020.30(g) as necessary based on the modifications.
- 4) The minimum post-installation inspection, calibration, testing, and maintenance to be performed to sustain safe and effective operation of the product, that result from the product modifications.
- 5) A clear distinction delineating FDA-cleared or FDA-approved indications and technical specifications from those that are not FDA-cleared or FDA-approved. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared or approved by FDA.
- 6) A prominent notice to both the patient and healthcare provider that recommendations provided by the product are adjunctive (supporting) and should not be solely or primarily relied upon to diagnose or treat COVID-19.
- 7) A statement that the device is not indicated for the diagnosis of COVID-19 and that *in vitro* diagnostic testing is currently the only definitive method to diagnose COVID-19.
- 8) A prominent notice that all images should be interpreted only by a licensed healthcare practitioner with the appropriate training.
- 9) Labeling that is consistent with the most recent guidelines on the appropriate use of imaging issued during the COVID-19 pandemic by the Centers for Disease Control (CDC), World Health Organization (WHO), or professional medical societies (e.g., the Fleischner Society,²² the American College of Radiology,²³ AIUM,^{24,25,26} or the Radiological Society of North America.²⁷

²⁰ For modifications to cleared devices that are subject to special controls relating to labeling, FDA believes that manufacturers meeting those special controls would also be consistent with the recommended labeling elements in Section IV.E.

²¹ Different manufacturers often implement different solutions for mitigation measures, which includes labeling among other measures.

²² See The Role of Chest Imaging in Patient Management during the COVID-19 Pandemic: A Multinational Consensus Statement from the Fleischner Society <https://pubs.rsna.org/doi/10.1148/radiol.2020201365>.

²³ See <https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Recommendations-for-Chest-Radiography-and-CT-for-Suspected-COVID19-Infection>.

²⁴ See AIUM Official Statement: Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as well as Safe Handling and Use of Ultrasound Coupling Gel. <https://www.aium.org/officialStatements/57>.

²⁵ See Quick Guide on COVID-19 Protections — Patient and Ultrasound Provider Protection. https://aium.s3.amazonaws.com/covid19/Covid19_Quick_Guide_UTEG.pdf.

²⁶ See Quick Guide on COVID-19 Protections — Ultrasound Transducers, Equipment, and Gel. https://aium.s3.amazonaws.com/covid19/Covid19_Quick_Guide_UTEG.pdf.

²⁷ Radiological Society of North America Expert Consensus Statement on Reporting Chest CT Findings Related to COVID-19. Endorsed by the Society of Thoracic Radiology, the American College of Radiology, and RSNA',

Contains Nonbinding Recommendations

- 10) A prominent notice to users that they should be cognizant of state and local requirements regarding use of imaging systems.
- 11) For all image analysis software:
 - a) Alerts (e.g., prominent on-screen notification) that specify that the image analysis should only be used as an aid and that final interpretation should be performed by a licensed healthcare practitioner with the appropriate training.
 - b) A prominent notice that the results from the image analysis software (e.g., draft report) should not be used for screening, specific disease detection/classifications, disease diagnosis, or patient management decisions.²⁸
 - c) A summary of the dataset characteristics used in the development of the device and limitations that may impact the generalizability (e.g., development using a dataset from only a few hospitals in a foreign country that limits generalizability to performance when used in a U.S. population).

F. Clinical Decision Support Software for Imaging related to COVID-19 and Co-existing Conditions

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

Section 3060(a) of the 21st Century Cures Act (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).²⁹

Radiology: Cardiothoracic Imaging (Vol. 2, No. 2 published online: March 25, 2020)

<https://pubs.rsna.org/doi/10.1148/ryct.2020200152>.

²⁸ This recommendation does not apply to devices with marketing authorization for such indications.

²⁹ 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

Contains Nonbinding Recommendations

The following are examples of non-device functions under section 520(o) consistent with the draft guidance on Clinical Decision Support Software:³⁰

- Software that uses a patient's diagnosis (or presumptive diagnosis) to provide a healthcare provider with current practice treatment guidelines based on any imaging findings of COVID-19 or co-existing conditions, and provides the source of the guidelines;
- Software that provides healthcare providers with recommendations on the appropriate use of imaging and recommended protocols for a patient with confirmed or suspected COVID-19 that are consistent with the FDA-required labeling or that are described in other sources from professional medical imaging societies. The practice guidelines are described as the basis for the recommendation and provided for the healthcare professional to review, such that the healthcare provider does not rely primarily on the software's recommendation; and
- Software that compares imaging findings with available practice guidelines (institutions-based or academic/clinical society-based) to recommend condition-specific diagnostic tests, investigations, monitoring, or therapy or triaging patient care. The practice guidelines are described as the basis for the recommendation and provided for the healthcare professional to review, such that the healthcare provider does not rely primarily on the software's recommendation.

V. Policy to Help Increase Availability and Minimize Supply Chain Disruptions

In developing this policy, FDA's intent is to help expand the availability of imaging products, including mobile and portable diagnostic imaging systems, in the United States for the duration of the public health emergency while being flexible regarding the maintenance of devices and the reporting required under 21 CFR Chapter I – Subchapter J to help ensure the continued availability of safe and effective medical imaging systems. Wherever possible, health care facilities should use FDA-cleared or approved medical imaging systems and maintain this system following the manufacturer's or other recommended maintenance schedule.

FDA encourages facilities to ensure essential imaging systems continue to be operational, safe, and effective. However, FDA recommends prioritization of those tasks most essential to maintaining continuity of patient care and to protecting the public health and safety from electronic product radiation.

Under existing policies, FDA generally has not enforced FD&C Act requirements with respect to

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.

³⁰ FDA has issued a draft guidance on Clinical Decision Support Software (<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.

Contains Nonbinding Recommendations

servicing activities,³¹ including the use of alternative available components that are compatible with and do not significantly change the performance or safety specifications, or intended use, of the product.³² However, activities that significantly change the performance or safety specifications, or intended use of the device are remanufacturing and are not servicing. These existing policies might be relevant in the context of identifying alternative components or suppliers to address anticipated shortages or to meeting increased demand for mobile and portable imaging systems.³³

In addition to the available considerations above, for the duration of the public health emergency, FDA does not intend to object to the following:

- Delay of actions required pursuant to 21 CFR 1004 to repurchase, repair, or replace defects or failures in electronic products that are non-life threatening or non-serious if the manufacturer cannot access the system, is partially shutdown, or is having difficulty obtaining parts from suppliers. FDA intends to place the completion timeline specified in any Corrective Action Approval letter on hold for the duration of the public health emergency. In such cases, the manufacturer should take actions that sufficiently reduce the risk by:
 - Notifying affected persons, including the requirement under 21 CFR 1003.21 to provide instructions with respect to the use of the product pending the correction of the defect.
 - Internally documenting any circumstance due to the public health emergency that the manufacturer cannot control and that leads to such delays.
- Delay in reporting of Accidental Radiation Occurrence Reports required by 21 CFR 1002.20 for events that are not required to be reported to FDA under 21 CFR 803 where:
 - Manufacturers are unable to identify the root cause to determine whether an event is a defect or failure to comply with a performance standard due to limited access to a facility or difficulty in communication with that facility.
 - Manufacturers internally document the cause of the delay in their ability to sufficiently identify and reduce the risk.
- Discontinuation of submission of FDA Form 2579 *Report of Assembly of a Diagnostic X-Ray System* to FDA by assemblers of diagnostic x-ray systems as required by 21 CFR 1020.30(d)(1). However, FDA expects reports to be submitted to the purchaser and, where applicable, to the State agency³⁴ responsible for radiation protection within 15 days following completion of the assembly pursuant to 21 CFR 1020.30(d)(1).
- Discontinuation of report submission by manufacturers of diagnostic x-ray products required by 21 CFR 1002 and identified in Table 1 of 21 CFR 1002.1.

Additionally, for the duration of the public health emergency, FDA does not intend to determine

³¹ Servicing activities include actions to refurbish, recondition, rebuild, repair, and remarket medical devices.

³² See FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices (May 2018) at 4, 5, 24, available at <https://www.fda.gov/media/113431/download> (explaining FDA's approach to servicing activities and distinguishing those activities from remanufacturing, which "significantly changes the finished device's performance or safety specifications, or intended use"), quoting 21 CFR 820.3(w).

³³ For example, see "Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-food-and-drug-administration-staff-assemblers-guide-diagnostic-x-ray-equipment>.

³⁴ This statement applies unless such State agency provided additional guidance on delayed reporting.

Contains Nonbinding Recommendations

whether there is an accession number during the importation of shipments of diagnostic x-ray systems. To expedite receipt for other types of products, FDA intends to issue accession numbers to firms by email for Electronic Product Radiation Control reports that FDA receives by postal mail that include a contact email address.³⁵

VI. Additional Helpful Resources

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

- [Marketing Clearance of Diagnostic Ultrasound Systems and Transducers](#)³⁶
- [Medical X-Ray Imaging Devices Conformance with IEC Standards](#)³⁷
- [Policy Clarification for Certain Fluoroscopic Equipment Requirements](#)³⁸
- [Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices](#)³⁹
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)⁴⁰
- [Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories \(SPECT and PET\) and Nuclear Tomography Systems](#)⁴¹
- [Full Field Digital Mammography System - Class II Special Controls Guidance](#)⁴²
- [Guidance for the Submission of 510\(k\)s for Solid State X-ray Imaging Devices](#)⁴³
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#)⁴⁴
- [Radio Frequency Wireless Technology in Medical Devices](#)⁴⁵

³⁵ FDA already issues Accession Numbers by email for reports prepared with eSubmitter and received through the Electronic Submissions Gateway. For more information on that submission process, see the FDA website at <https://www.fda.gov/industry/fda-esubmitter> and <https://www.fda.gov/industry/electronic-submissions-gateway>.

³⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers>.

³⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards>.

³⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements>.

³⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices>.

⁴⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>.

⁴¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-submission-premarket-notifications-emission-computed-tomography-devices-and-accessories>.

⁴² <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/full-field-digital-mammography-system-class-ii-special-controls-guidance-industry-and-fda-staff>.

⁴³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-submission-510ks-solid-state-x-ray-imaging-devices>.

⁴⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

⁴⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>.

Contains Nonbinding Recommendations

- [Design Considerations and Pre-market Submission Recommendations for Interoperable Devices](#)⁴⁶
- [Clinical Decision Support Software \(Draft\)](#)⁴⁷
- [Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act](#)⁴⁸
- [Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices](#)⁴⁹
- [General Wellness: Policy for Low Risk Devices](#)⁵⁰
- [Policy for Device Software Functions and Mobile Medical Applications](#)⁵¹

⁴⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices>.

⁴⁷ FDA has issued a draft guidance on Clinical Decision Support Software (<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.

⁴⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act>.

⁴⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices>.

⁵⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>.

⁵¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>.