Display Devices for Diagnostic Radiology

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance is being distributed for comment purposes only.

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You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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When final, this guidance will supersede Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions issued May 30, 2008

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Food and Drug Administration
Center for Devices and Radiological Health
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Preface

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Display Devices for Diagnostic Radiology

Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or "we") is issuing this draft guidance to assist industry in preparing premarket notification submissions for display devices intended for use in diagnostic radiology.

This draft guidance is intended to apply to current technologies; however, FDA may request new or alternative test methods to fully evaluate the safety and effectiveness of future display technologies. In such instances, we recommend that you contact FDA to determine the appropriate regulatory pathway and testing for your device prior to submitting a premarket notification. See Section III - Scope for more details on types of devices covered by this draft guidance document.

FDA's guidance documents, including this draft 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 guidances means that something is suggested or recommended, but not required.

II. Background

This guidance, when finalized, will apply to display devices intended for diagnostic radiology as identified in Section III – Scope, and currently classified under 21 CFR 892.2050 as class II devices.

This guidance document provides recommendations for the types of information you should provide in your 510(k) submission for display devices intended for diagnostic radiology. This information supplements the requirements for a 510(k) submission found in 21 CFR 807 Subpart E, as well as recommendations provided in other FDA documents concerning the specific content of a 510(k) submission, including FDA's guidance entitled, "Format for Traditional and Abbreviated 510(k)s" (http://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm) and FDA's guidance entitled, "Refuse to Accept Policy for 510(k)s" (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf).

This guidance, when finalized, will supersede a previously issued final guidance entitled "Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions" issued on May 30, 2008.

III. Scope

This document recommends what to include in a 510(k) submission for display devices in diagnostic radiology as identified by their classification regulation (21 CFR 892.2050) and product code (PGY). These devices are classified as class II devices that are intended to be used in controlled viewing conditions to display and view digital images for primary image interpretation. Display devices for diagnostic radiology may also be referred to as soft-copy displays or medical grade monitors. The classification regulation for these devices reads as follows:

21 CFR 892.2050 Picture archiving and communications system

> (a) ***Identification***. A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.
>
> (b) ***Classification***. Class II (special controls; voluntary standards--Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

Typically, the 510(k) submission for display devices is separate from the 510(k) submissions of other image acquisition or management devices (e.g., hardware/software for image acquisition, long term storage, data transfer between computer systems, or image analysis). However, this guidance may apply when displays intended for diagnostic interpretation classified under

892.2050 (product code, PGY) are included as part of a 510(k) submission along with other software and/or hardware.

This guidance does not apply to real-time displays that are part of the image acquisition device classified under other regulations (e.g., the display on a fluoroscopy system classified under 21 CFR 892.1650 (product code OWB) or the display on an ultrasonic pulsed doppler imaging system classified under 21 CFR 892.1550 (product code IYN)).

This guidance does not apply to medical image hardcopy devices under 21 CFR 892.2040, for information on these types of devices see FDA's guidance entitled "Enforcement Policy for Premarket Notification Requirements for Certain *In Vitro* Diagnostic and Radiology Devices" (http://www.fda.gov/RegulatoryInformation/Guidances/ucm283904.htm).

This guidance does not apply to imaging software and software applications, for information on these types of devices see FDA's guidance entitled "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073721.pdf) and FDA's guidance entitled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf).

This guidance does not apply to ophthalmic image management systems (product code NFJ) classified under 21 CFR 892.2050; medical cathode-ray tube (product code DXJ) classified under 21 CFR 870.2450; displays intended for whole-slide imaging and digital surgical or anatomical pathology, or displays for other non-radiological applications. The guidance also does not apply to displays in handheld or mobile devices; for information on these types of devices see FDA's guidance entitled "Mobile Medical Applications" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf). Sponsors may wish to submit a pre-submission to the appropriate review divisions to receive guidance for displays not covered by this guidance. For information on FDA's pre-submission process, see FDA's guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf).

If you are submitting a 510(k) for modification(s) to a cleared display or the same modification(s) apply to a number of display models, please refer to Appendix B and C for further information.

IV. Describing Your Device in a 510(k) Premarket Notification

When submitting a 510(k), you should identify your device by regulation and product code as described in Section III Scope and include the information discussed below. You must provide information to FDA showing how your device is substantially equivalent (SE) to a predicate device (sections 513(f)(1) and 513(i) of the Federal Food, Drug, and Cosmetic Act (FD&C act)); 21 CFR 807.87(f)). We recommend your 510(k) include the information described below, if applicable.

A. Indications for Use

The Indications for Use statement (IFU) should provide a general description of the disease(s) or condition(s) that your device will be used to help diagnose and the patient population for which the device is intended. The IFU should state whether your device is or is not intended for mammography.

We recommend the IFU address how your device will be used, for example, if the device is intended for mammography:

> The _____ is indicated for use in displaying radiological images (including mammography) for review, analysis, and diagnosis by trained medical practitioners.

An example IFU if the device is not intended for mammography:

> The _____ is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

You should compare your device's IFU to the IFU of the predicate device, including any specific intended uses. Display devices that have been cleared for mammography can also be used clinically for digital breast tomosynthesis.

B. Device Description

We recommend that you provide a complete description of your device by including the information discussed below in your 510(k) submission. The items below should be presented in a tabular side-by-side comparison with the predicate device. The 510(k) submission should include a discussion of any differences in the technological characteristics between your device and the predicate device with additional information necessary to determine whether the differences raise new questions regarding the safety or effectiveness of the new device. Additional discussion in paragraph form is recommended for novel features. Your device description should include information such as the following:

- **Display Technology**: A description of the technological characteristics of the display device (e.g., in-plane switching LCD panel with TFT active-matrix array with CCFL backlight).

- **Screen size**: A description of the physical size of the viewable area in diagonal and aspect ratio.
- **Backlight type (transmissive displays only)**: A description of the backlight type and, if substantially different from the predicate device, main properties including temporal, spatial, and spectral characteristics.
- **Frame rate and refresh rate**: A description of the frame rate and refresh rate.
- **Pixel array, pitch, subpixel pattern, pixel aperture ratio**: A description of the pixel array including pixel size, pixel pitch, and subpixel pattern (e.g., chevron, RGBW);
- **Subpixel driving (spatial and temporal dithering)**: A description that indicates if the subpixels are used to improve gray-scale or temporal resolution.
- **Display Interface**: A description of the display interface (e.g., DVI, display port, HDMI).
- **Video bandwidth**: A description of the capabilities of the information transfer pipeline between the image source and the digital driving levels in all associated components including the CPU/GPU, graphics card, and display interface.
- **User controls**: A description of either the on-screen display (OSD) or software available for end users that relate to the display image quality (e.g., brightness and contrast controls, gamma, white point, power saving options, etc.).
- **Ambient light sensing**: A description of the ambient light sensing method, instrumentation, and software tool description.
- **Touch-screen technology**: A description of the method, functionality, and any calibration or periodical re-tuning requirements.
- **Luminance calibration tools**: A description of the sensor hardware and associated software for performing luminance calibration, and if applicable, details about the user-level procedures, service-action tolerances, and centralized automatic calibration tools.
- **Quality-control procedures**: A description of the frequency and nature of quality-control tests to be performed by the user and/or the physicist with associated action limits. A detailed quality control manual should be included for regulatory review.
- **Software/Firmware**: A list with descriptions of any additional firmware or software features for image manipulation or analysis not covered by any of the above items.

V. Electrical Safety

You should evaluate the electrical safety of your device according to one or more of the most recent FDA recognized version of the following standards[1], or any equivalent method being used as an alternative to evaluate electrical safety:

- International Electrotechnical Commission (IEC) 60601-1-1 *General requirements for safety - Collateral standard: Safety requirements for medical electrical systems*; and
- Underwriters Laboratories Inc. (UL) 60601-1 *Medical Electrical Equipment: Part 1: General Requirements for Safety.*

[1] Please refer to FDA's Recognized Consensus Standards Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm) for the currently recognized versions.

For 510(k) submissions for display devices intended for diagnostic radiology, in lieu of providing the actual electric safety test reports, you may simply submit a Declaration of Conformity to an FDA-recognized consensus standard to indicate that your device has been tested for compliance with the appropriate standards.[2] FDA may request to review the actual test reports if the IFU, device description, and/or labeling for your device raises concerns regarding the electrical safety. The features and design of your device will determine whether other standards are appropriate in addition to, or in place of the standards provided above. For more information on the use of standards, please refer to section 514(c)(1)(B) of the FD&C Act and FDA's guidance entitled "Use of Standards in Substantial Equivalence Determinations" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073756.pdf).

VI. Firmware and Software Documentation

Display devices intended for diagnostic radiology may include firmware and software for the following functionalities:

- Display controls;
- Ambient light sensing;
- Luminance calibration tools; and/or
- Quality-control software.

Your 510(k) submission should include documentation for the software and firmware that you have developed for use with your device. The kind of information we recommend you submit in your 510(k) is determined by the "level of concern", which is based on the risks associated with a potential software failure by your device. If the software/firmware is limited to the four functionalities listed above, the level of concern may be considered minor. If your device contains advanced software features, you may consider asking FDA for advice on whether the software would be a minor, moderate, or major level of concern. In most instances, the software documentation may be submitted at a minor level of concern. When preparing the software documentation for your 510(k) submission and for guidance on what information you should include based on the level of concern, please see the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (http://www.fda.gov/downloads/MedicalDevices/.../ucm089593.pdf);
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf); and
- Guidance for Off-the-Shelf Software Use in Medical Devices (http://www.fda.gov/downloads/MedicalDevices/.../ucm073779.pdf).

[2] For more information on the use of consensus standards, please visit FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm.

VII. Physical Laboratory Testing

We recommend that you provide the following performance testing data with a side-by-side comparison of technical performance testing data to the predicate device in your 510(k) submission. Table 3 below identifies what tests we recommend you perform in demonstrating substantial equivalence to a predicate device based on the IFU of your display device (Table 3 includes recommendations for both non-mammography and mammography intended uses). Please refer to Appendix A for additional guidance on each test and references for methods and procedures for display characterization.

Table 2. Recommended Physical Laboratory Tests

Measurements	Recommended for Non-mammography Display Submissions	Recommended for Mammography Display Submissions
a. Spatial resolution	Yes	Yes
b. Pixel defects (count and map)	Yes	Yes
c. Artifacts	Yes	Yes
d. Temporal Response	Yes (Limited)	Yes
e. Luminance (maximum, minimum, achievable, and recommended)	Yes	Yes
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	Yes	Yes
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and edge spots	No	Yes
h. Luminance uniformity or Mura test	No	Yes
i. Stability of luminance response with temperature and lifetime	No	Yes
j. Spatial noise	No	Yes
k. Bidirectional reflection distribution function	No	Yes
l. Veiling glare or small-spot contrast	No	Yes
m. Gray tracking	No	Yes

We recommend that you include a brief description of the test method(s) you have used to address each performance aspect identified in Table 3. If you follow a suggested test method, you may cite the method rather than describing it in your 510(k) submission. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. We recommend that you provide a description of all proprietary measurement systems used for performing quantitative tests, including the trade name, characteristics, and accuracy of the measurement tools.

For cases where the new device performs significantly lower than the predicate device on one or more of the physical laboratory tests in Table 3, an additional study that further characterizes underperforming features of the display may be necessary to demonstrate substantial equivalence to a predicate device.

VIII. Labeling

The following Section is intended to assist you in preparing labeling that satisfies FDA's labeling requirements under 21 CFR Part 801.[3]

A prescription device, under 21 CFR 801.109, is exempt from section 502(f)(1) of the FD&C Act that requires adequate directions for use by a lay person. As a prescription device, your device must meet the labeling requirements for prescription devices under 21 CFR 801.109, including a prescription use statement.

Your 510(k) submission must include proposed labels, labeling, and advertisements in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). We recommend you submit clear and concise instructions for use that delineate the technological features of your device and how your device is to be used. Instructions should encourage local/institutional training programs designed to familiarize users with the features of your device and instruct users on how to use your device in a safe and effective manner.

FDA recommends that the labeling for review workstation displays intended for mammography include the following statement:

> Mammographic images with lossy compression must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

In addition to meeting any requirements under 21 CFR Part 801, your device's user manual should include the following information, as appropriate:

- The Indications for Use as stated in your premarket submission;
- Warnings and precautions (and any mitigation measures);
- Overview of the device;
- Principles of operation;
- Directions for use (e.g., display controls and GUI);
- Technical specifications;
- Performance specifications (summary of physical laboratory testing);

[3] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of 21 CFR Part 801.

- Cleaning information;
- Hardware/software compatibility requirements;
- Conformity to any voluntary standards; and
- Manufacturer's contact information.

In addition, instructions for maintenance of the system performance (quality assurance processes) should include:

- A description of personnel authorized to service the system;
- Recommended maintenance schedule;
- Calibration procedures; and
- A full description of recommended quality assurance testing (with action limits), including detailed procedures for performing these tests, if applicable, and the frequency of testing. You may use the latest recognized version of NEMA Standards XR 22 and XR 23, for designing quality assurance tests.

Appendix A – Performance Tests

The following provides additional details on the individual tests recommended in Section VIII Physical Laboratory Testing along with an explanation of what information should be included for each test.

a. ***Spatial resolution:*** Measurements of the transfer of information from the image data to the luminance fields at different spatial frequencies of interest typically done by reporting the modulation transfer function. Non-isotropic resolution properties should be characterized properly by providing two-dimensional measurements or measurements along at least two representative axes.
b. ***Pixel defects:*** Measurements (counts) and location (map) of pixel defects. This is typically provided as a tolerance limit. Pixel defects can interfere with the visibility of small details in medical images.
c. ***Artifacts:*** Evaluate for image artifacts such as ghosting and/or image sticking from displaying a fixed test pattern for a period of time.
d. ***Temporal Response:*** Measurements of the temporal behavior of the display in responding to changes in image values from frame to frame. Since these transitions are typically not symmetric, rise and fall time constants are needed to characterize the system. Slow displays can alter details and contrast of the image when large image stacks are browsed or in video mode.
    - *For non-mammography displays*, you should measure the rise and fall time constants for 5–95% and 40–60% luminance transitions.
    - *For mammography monitors*, you should measure the rise and fall time constants at 15 grayscale intervals between 0 and 255 (resulting in an 18 x 18 grid of measured values).
e. ***Maximum and minimum luminance (achievable and recommended):*** Measurements of the maximum and minimum luminance that the device outputs as used in the application under recommended conditions and the achievable values if the device is set to expand the range to the limit.

f. ***Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF):*** Measurements of the mapping between image values and the luminance output following a target model response for 256 or more levels.
g. ***Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and edge spots:*** Measurements of the luminance response at off-normal viewing related to the target model for the luminance response (see *VESA Standard: Display Specifications and Test Procedures* for "center and edge" definitions).
h. ***Luminance uniformity or Mura test:*** Measurements of the uniformity of the luminance across the display screen.
i. ***Stability of luminance response with temperature and lifetime:*** Measurements of the change in luminance response with temperature and use time.
j. ***Spatial noise:*** Measurements of the spatial noise level as represented by the noise power spectrum using an appropriate ratio of camera and display pixels. Spatial noise and resolution affect the way images are presented to the viewer and can alter features that are relevant to the interpretation process of the physician or radiologist.
k. ***Bidirectional reflection distribution function:*** Measurements of the reflection coefficients of the display device. Specular and diffuse reflection coefficients can be used as surrogates for the full bidirectional reflection distribution function.
l. ***Veiling glare or small-spot contrast:*** Measurements of the contrast obtained for small targets.
m. ***Gray Tracking:*** Chromaticity at different luminance levels as indicated by the color coordinates in an appropriate units system (e.g., CIE *u'v'*) (see *IEC 62563-1-E1A1*).

For methods and procedures for display characterization, please refer to the following:

- American Association of Physicists in Medicine, Task Group 18 (TG18). *Assessment of Display Performance for Medical Imaging Systems.* January 2006. (http://deckard.mc.duke.edu/~samei/tg18);
- Video Electronics Standards Association, Flat Panel Display Measurements Task Group. *Flat Panel Display Measurements Standard, version 2.0.* June 2001;
- Video Electronics Standards Association, Measurement Standards Work Group. *VESA Standard: Display Specifications and Test Procedures, version 1.0.* October 1994;
- International Electrotechnical Commission (IEC) 62563-1-E1A1. *Medical electrical equipment - Medical image display systems – Part 1: Evaluation methods. Amendment 1*, March 2016; and
- International Committee for Display Metrology (ICDM). *Information Display Measurements Standard (IDMS), version 1.03.* June 2012. (http://www.icdm-sid.org/).

Appendix B – Device Modifications

We recommend that you refer to FDA's guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm) for subsequent models of the same device family that have previously received 510(k) clearance. The sponsor should perform regression testing and physical laboratory testing in conformance with relevant test standards to verify that the changes did not adversely impact image quality and ensure that the device conforms to specifications as required under the Quality System Regulation (21 CFR 820.70). For example, changes in the graphics driver, power supply, or upgrade in the calibration software most likely would not require a new 510(k) submission, but sponsors should review the appropriate regulations and standards to determine when a new 510(k) submission is necessary. Sponsors should contact FDA with any questions about modifications made to their devices.

Please note that in order for FDA to make a complete evaluation, your 510(k) submission should include a description of all changes made to your device since the most recent 510(k) clearance, including all changes that were made without submitting a 510(k).

Appendix C – Device Bundling

Often, firms may make the same modification(s) to all of their display models. Instead of submitting a separate 510(k) submission for each display model, FDA recommends submitting a bundled submission for all impacted display models. Bundling is appropriate for devices that present scientific and regulatory issues that can most efficiently be addressed during one 510(k) submission review. For more information, please refer to FDA's guidance entitled "Bundling Multiple Devices or Multiple Indications in a Single Submission" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089731.htm).