

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance is being distributed for comment purposes only.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draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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*.

For questions regarding this document, contact Mary Pastel (OIR) at 301-796-6887 or by e-mail at mary.pastel@fda.hhs.gov.

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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Division of Radiological Health

Office of Science and Engineering Laboratories
Division of Imaging Diagnostics and Software Reliability

Preface

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30

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32

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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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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The Food and Drug Administration (FDA or “we”) is issuing this draft guidance to assist industry in preparing premarket notification submissions for display devices intended for use in diagnostic radiology.

This draft guidance is intended to apply to current technologies; however, FDA may request new or alternative test methods to fully evaluate the safety and effectiveness of future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.

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89
90 This guidance document provides recommendations for the types of information you should
91 provide in your 510(k) submission for display devices intended for diagnostic radiology. This
92 information supplements the requirements for a 510(k) submission found in 21 CFR 807 Subpart
93 E, as well as recommendations provided in other FDA documents concerning the specific
94 content of a 510(k) submission, including FDA’s guidance entitled, “Format for Traditional and
95 Abbreviated 510(k)s” (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm>)
96 and FDA’s guidance entitled, “Refuse to Accept Policy for 510(k)s”
97 ([http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocumen](http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf)
98 [ts/ucm315014.pdf](http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf)).
99

100 This guidance, when finalized, will supersede a previously issued final guidance entitled
101 “Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification
102 (510(k)) Submissions” issued on May 30, 2008.
103

104 **III. Scope**

105
106 This document recommends what to include in a 510(k) submission for display devices in
107 diagnostic radiology as identified by their classification regulation (21 CFR 892.2050) and
108 product code (PGY). These devices are classified as class II devices that are intended to be used
109 in controlled viewing conditions to display and view digital images for primary image
110 interpretation. Display devices for diagnostic radiology may also be referred to as soft-copy
111 displays or medical grade monitors. The classification regulation for these devices reads as
112 follows:

113 **21 CFR 892.2050 Picture archiving and communications system**

114
115 (a) **Identification.** A picture archiving and communications system is a device that
116 provides one or more capabilities relating to the acceptance, transfer, display, storage,
117 and digital processing of medical images. Its hardware components may include
118 workstations, digitizers, communications devices, computers, video monitors, magnetic,
119 optical disk, or other digital data storage devices, and hardcopy devices. The software
120 components may provide functions for performing operations related to image
121 manipulation, enhancement, compression or quantification.
122

123 (b) **Classification.** Class II (special controls; voluntary standards--Digital Imaging and
124 Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG)
125 Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).
126

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

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131 892.2050 (product code, PGY) are included as part of a 510(k) submission along with other
132 software and/or hardware.

133
134 This guidance does not apply to real-time displays that are part of the image acquisition device
135 classified under other regulations (e.g., the display on a fluoroscopy system classified under 21
136 CFR 892.1650 (product code OWB) or the display on an ultrasonic pulsed doppler imaging
137 system classified under 21 CFR 892.1550 (product code IYN)).

138
139 This guidance does not apply to medical image hardcopy devices under 21 CFR 892.2040, for
140 information on these types of devices see FDA’s guidance entitled “Enforcement Policy for
141 Premarket Notification Requirements for Certain *In Vitro* Diagnostic and Radiology Devices”
142 (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm283904.htm>).

143
144 This guidance does not apply to imaging software and software applications, for information on
145 these types of devices see FDA’s guidance entitled “Guidance for the Submission of Premarket
146 Notifications for Medical Image Management Devices”
147 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073721.pdf)
148 [ments/ucm073721.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf)) and FDA’s guidance entitled “Medical Device Data Systems, Medical
149 Image Storage Devices, and Medical Image Communications Devices
150 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf)
151 [ments/UCM401996.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf)).

152
153 This guidance does not apply to ophthalmic image management systems (product code NFJ)
154 classified under 21 CFR 892.2050; medical cathode-ray tube (product code DXJ) classified
155 under 21 CFR 870.2450; displays intended for whole-slide imaging and digital surgical or
156 anatomical pathology, or displays for other non-radiological applications. The guidance also
157 does not apply to displays in handheld or mobile devices; for information on these types of
158 devices see FDA’s guidance entitled “Mobile Medical Applications”
159 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)
160 [ments/UCM263366.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)). Sponsors may wish to submit a pre-submission to the appropriate
161 review divisions to receive guidance for displays not covered by this guidance. For information
162 on FDA’s pre-submission process, see FDA’s guidance entitled “Requests for Feedback on
163 Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug
164 Administration Staff”
165 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf)
166 [ments/UCM311176.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf)).

167
168 If you are submitting a 510(k) for modification(s) to a cleared display or the same
169 modification(s) apply to a number of display models, please refer to Appendix B and C for
170 further information.

171

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

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175 When submitting a 510(k), you should identify your device by regulation and product code as
176 described in Section III Scope and include the information discussed below. You must provide
177 information to FDA showing how your device is substantially equivalent (SE) to a predicate
178 device (sections 513(f)(1) and 513(i) of the Federal Food, Drug, and Cosmetic Act (FD&C act));
179 21 CFR 807.87(f)). We recommend your 510(k) include the information described below, if
180 applicable.

181 **A. Indications for Use**

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

186
187 We recommend the IFU address how your device will be used, for example, if the device is
188 intended for mammography:

189
190 The _____ is indicated for use in displaying radiological images (including
191 mammography) for review, analysis, and diagnosis by trained medical practitioners.

192
193 An example IFU if the device is not intended for mammography:

194
195 The _____ is indicated for use in displaying radiological images for review, analysis,
196 and diagnosis by trained medical practitioners. The display is not intended for
197 mammography.

198
199 You should compare your device's IFU to the IFU of the predicate device, including any specific
200 intended uses. Display devices that have been cleared for mammography can also be used
201 clinically for digital breast tomosynthesis.



202 203 **B. Device Description**

204
205 We recommend that you provide a complete description of your device by including the
206 information discussed below in your 510(k) submission. The items below should be presented in
207 a tabular side-by-side comparison with the predicate device. The 510(k) submission should
208 include a discussion of any differences in the technological characteristics between your device
209 and the predicate device with additional information necessary to determine whether the
210 differences raise new questions regarding the safety or effectiveness of the new device.
211 Additional discussion in paragraph form is recommended for novel features. Your device
212 description should include information such as the following:

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

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- 216 • **Screen size:** A description of the physical size of the viewable area in diagonal and
217 aspect ratio.
- 218 • **Backlight type (transmissive displays only):** A description of the backlight type and, if
219 substantially different from the predicate device, main properties including temporal,
220 spatial, and spectral characteristics.
- 221 • **Frame rate and refresh rate:** A description of the frame rate and refresh rate.
- 222 • **Pixel array, pitch, subpixel pattern, pixel aperture ratio:** A description of the pixel
223 array including pixel size, pixel pitch, and subpixel pattern (e.g., chevron, RGBW);
- 224 • **Subpixel driving (spatial and temporal dithering):** A description that indicates if the
225 subpixels are used to improve gray-scale or temporal resolution. 
- 226 • **Display Interface:** A description of the display interface (e.g., DVI, display port, HDMI).
- 227 • **Video bandwidth:** A description of the capabilities of the information transfer pipeline
228 between the image source and the digital driving levels in all associated components
229 including the CPU/GPU, graphics card, and display interface.
- 230 • **User controls:** A description of either the on-screen display (OSD) or software available
231 for end users that relate to the display image quality (e.g., brightness and contrast controls,
232 gamma, white point, power saving options, etc.).
- 233 • **Ambient light sensing:** A description of the ambient light sensing method, 
234 instrumentation, and software tool description.
- 235 • **Touch-screen technology:** A description of the method, functionality, and any
236 calibration or periodical re-tuning requirements.
- 237 • **Luminance calibration tools:** A description of the sensor hardware and associated
238 software for performing luminance calibration, and if applicable, details about the user-
239 level procedures, service-action tolerances, and centralized automatic calibration tools.
- 240 • **Quality-control procedures:** A description of the frequency and nature of quality-
241 control tests to be performed by the user and/or the physicist with associated action limits.
242 A detailed quality control manual should be included for regulatory review.
- 243 • **Software/Firmware:** A list with descriptions of any additional firmware or software
244 features for image manipulation or analysis not covered by any of the above items.
245

246 V. Electrical Safety

247 You should evaluate the electrical safety of your device according to one or more of the most
248 recent FDA recognized version of the following standards¹, or any equivalent method being used
249 as an alternative to evaluate electrical safety:

- 250 • International Electrotechnical Commission (IEC) 60601-1-1 *General requirements for*
251 *safety - Collateral standard: Safety requirements for medical electrical systems*; and
- 252 • Underwriters Laboratories Inc. (UL) 60601-1 *Medical Electrical Equipment: Part 1:*
253 *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.

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254 For 510(k) submissions for display devices intended for diagnostic radiology, in lieu of
255 providing the actual electric safety test reports, you may simply submit a Declaration of
256 Conformity to an FDA-recognized consensus standard to indicate that your device has been
257 tested for compliance with the appropriate standards.² FDA may request to review the actual test
258 reports if the IFU, device description, and/or labeling for your device raises concerns regarding
259 the electrical safety. The features and design of your device will determine whether other
260 standards are appropriate in addition to, or in place of the standards provided above. For more
261 information on the use of standards, please refer to section 514(c)(1)(B) of the FD&C Act and
262 FDA’s guidance entitled “Use of Standards in Substantial Equivalence Determinations”
263 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073756.pdf)
264 [ments/ucm073756.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073756.pdf)).
265

VI. Firmware and Software Documentation

266
267
268 Display devices intended for diagnostic radiology may include firmware and software for the
269 following functionalities:

- 270 • Display controls;
- 271 • Ambient light sensing;
- 272 • Luminance calibration tools; and/or
- 273 • Quality-control software.

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




- 284 • Guidance for the Content of Premarket Submissions for Software Contained in Medical
285 Devices (<http://www.fda.gov/downloads/MedicalDevices/.../ucm089593.pdf>);
- 286 • General Principles of Software Validation; Final Guidance for Industry and FDA Staff
287 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf)
288 [eDocuments/ucm085371.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf)); and
- 289 • Guidance for Off-the-Shelf Software Use in Medical Devices
290 (<http://www.fda.gov/downloads/MedicalDevices/.../ucm073779.pdf>).
291

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>.

292 **VII. Physical Laboratory Testing**

293
294 We recommend that you provide the following performance testing data with a side-by-side
295 comparison of technical performance testing data to the predicate device in your 510(k)
296 submission. Table 3 below identifies what tests we recommend you perform in demonstrating
297 substantial equivalence to a predicate device based on the IFU of your display device (Table 3
298 includes recommendations for both non-mammography and mammography intended uses).
299 Please refer to Appendix A for additional guidance on each test and references for methods and
300 procedures for display characterization.

301 **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

303
304 We recommend that you include a brief description of the test method(s) you have used to
305 address each performance aspect identified in Table 3. If you follow a suggested test method,
306 you may cite the method rather than describing it in your 510(k) submission. If you modify a
307 suggested test method, you may cite the method but should provide sufficient information to
308 explain the nature of and reason for the modification. We recommend that you provide a
309 description of all proprietary measurement systems used for performing quantitative tests,
310 including the trade name, characteristics, and accuracy of the measurement tools.

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

315 **VIII. Labeling**

316 The following Section is intended to assist you in preparing labeling that satisfies FDA’s labeling
317 requirements under 21 CFR Part 801.³

318
319 A prescription device, under 21 CFR 801.109, is exempt from section 502(f)(1) of the FD&C
320 Act that requires adequate directions for use by a lay person. As a prescription device, your
321 device must meet the labeling requirements for prescription devices under 21 CFR 801.109,
322 including a prescription use statement.

323
324 Your 510(k) submission must include proposed labels, labeling, and advertisements in sufficient
325 detail to satisfy the requirements of 21 CFR 807.87(e). We recommend you submit clear and
326 concise instructions for use that delineate the technological features of your device and how your
327 device is to be used. Instructions should encourage local/institutional training programs
328 designed to familiarize users with the features of your device and instruct users on how to use
329 your device in a safe and effective manner.

330
331 FDA recommends that the labeling for review workstation displays intended for mammography
332 include the following statement:

333
334 Mammographic images with lossy compression must not be reviewed for primary image
335 interpretations. Mammographic images may only be interpreted using an FDA cleared
336 display that meets technical specifications reviewed and accepted by FDA.

337
338 In addition to meeting any requirements under 21 CFR Part 801, your device’s user manual
339 should include the following information, as appropriate:

- 340 • The Indications for Use as stated in your premarket submission;
- 341 • Warnings and precautions (and any mitigation measures);
- 342 • Overview of the device;
- 343 • Principles of operation;
- 344 • Directions for use (e.g., display controls and GUI);
- 345 • Technical specifications;
- 346 • 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.

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- 347 • Cleaning information;
- 348 • Hardware/software compatibility requirements;
- 349 • Conformity to any voluntary standards; and
- 350 • Manufacturer’s contact information.

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

- 353 • A description of personnel authorized to service the system;
- 354 • Recommended maintenance schedule;
- 355 • Calibration procedures; and
- 356 • A full description of recommended quality assurance testing (with action limits),
357 including detailed procedures for performing these tests, if applicable, and the frequency
358 of testing. You may use the latest recognized version of NEMA Standards XR 22 and XR
359 23, for designing quality assurance tests.

360

361 **Appendix A – Performance Tests**

362

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

366 a. ***Spatial resolution:*** Measurements of the transfer of information from the image data to
367 the luminance fields at different spatial frequencies of interest typically done by reporting
368 the modulation transfer function. Non-isotropic resolution properties should be
369 characterized properly by providing two-dimensional measurements or measurements
370 along at least two representative axes.

371 b. ***Pixel defects:*** Measurements (counts) and location (map) of pixel defects. This is
372 typically provided as a tolerance limit. Pixel defects can interfere with the visibility of
373 small details in medical images.

374 c. ***Artifacts:*** Evaluate for image artifacts such as ghosting and/or image sticking from
375 displaying a fixed test pattern for a period of time.

376 d. ***Temporal Response:*** Measurements of the temporal behavior of the display in
377 responding to changes in image values from frame to frame. Since these transitions are
378 typically not symmetric, rise and fall time constants are needed to characterize the
379 system. Slow displays can alter details and contrast of the image when large image
380 stacks are browsed or in video mode.

381 ○ *For non-mammography displays*, you should measure the rise and fall time
382 constants for 5–95% and 40–60% luminance transitions.

383 ○ *For mammography monitors*, you should measure the rise and fall time constants
384 at 15 grayscale intervals between 0 and 255 (resulting in an 18 x 18 grid of
385 measured values).

386 e. ***Maximum and minimum luminance (achievable and recommended):*** Measurements of
387 the maximum and minimum luminance that the device outputs as used in the application
388 under recommended conditions and the achievable values if the device is set to expand
389 the range to the limit.



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- 390 f. **Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF):**
391 Measurements of the mapping between image values and the luminance output following
392 a target model response for 256 or more levels.
- 393 g. **Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and**
394 **edge spots:** Measurements of the luminance response at off-normal viewing related to the
395 target model for the luminance response (see *VESA Standard: Display Specifications and*
396 *Test Procedures* for “center and edge” definitions).
- 397 h. **Luminance uniformity or Mura test:** Measurements of the uniformity of the luminance
398 across the display screen.
- 399 i. **Stability of luminance response with temperature and lifetime:** Measurements of the
400 change in luminance response with temperature and use time.
- 401 j. **Spatial noise:** Measurements of the spatial noise level as represented by the noise power
402 spectrum using an appropriate ratio of camera and display pixels. Spatial noise and
403 resolution affect the way images are presented to the viewer and can alter features that
404 are relevant to the interpretation process of the physician or radiologist.
- 405 k. **Bidirectional reflection distribution function:** Measurements of the reflection
406 coefficients of the display device. Specular and diffuse reflection coefficients can be
407 used as surrogates for the full bidirectional reflection distribution function.
- 408 l. **Veiling glare or small-spot contrast:** Measurements of the contrast obtained for small
409 targets.
- 410 m. **Gray Tracking:** Chromaticity at different luminance levels as indicated by the color
411 coordinates in an appropriate units system (e.g., CIE $u'v'$) (see *IEC 62563-1-E1A1*).
412

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

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

426

427 Appendix B – Device Modifications

428 We recommend that you refer to FDA’s guidance entitled “Deciding When to Submit a 510(k)
429 for a Change to an Existing Device”

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430 (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0>
431 [80235.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0)) for subsequent models of the same device family that have previously received
432 510(k) clearance. The sponsor should perform regression testing and physical laboratory testing
433 in conformance with relevant test standards to verify that the changes did not adversely impact
434 image quality and ensure that the device conforms to specifications as required under the Quality
435 System Regulation (21 CFR 820.70). For example, changes in the graphics driver, power supply,
436 or upgrade in the calibration software most likely would not require a new 510(k) submission,
437 but sponsors should review the appropriate regulations and standards to determine when a new
438 510(k) submission is necessary. Sponsors should contact FDA with any questions about
439 modifications made to their devices.

440 Please note that in order for FDA to make a complete evaluation, your 510(k) submission should
441 include a description of all changes made to your device since the most recent 510(k) clearance,
442 including all changes that were made without submitting a 510(k).
443

444 **Appendix C – Device Bundling**

445
446 Often, firms may make the same modification(s) to all of their display models. Instead of
447 submitting a separate 510(k) submission for each display model, FDA recommends submitting a
448 bundled submission for all impacted display models. Bundling is appropriate for devices that
449 present scientific and regulatory issues that can most efficiently be addressed during one 510(k)
450 submission review. For more information, please refer to FDA’s guidance entitled “Bundling
451 Multiple Devices or Multiple Indications in a Single Submission”
452 (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0>
453 [89731.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0)).
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457