

Image Quality Characteristics of Handheld Medical Image Viewing Devices

Mobile Viewing Devices

Aldo Badano

Division of Imaging, Diagnostics and Software Reliability
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
U.S. Food and Drug Administration

SESSION: MOBILE VIEWING DEVICES

P Luetmer¹, A Badano², A Walz-Flannigan³

1 Mayo Clinic, Rochester, MN, 2 Food & Drug Administration, Silver Spring, MD, 3 Mayo Clinic, Rochester, MN

Presentations

- ▶ A Radiologist Perspective on Mobile View Devices - P Luetmer
- ▶ Image Quality Characteristics of Handheld Medical Image Viewing Devices - A Badano
- ▶ Setup, QC, and Usage Considerations for Mobile Image Viewing Platforms - A Walz-Flannigan
- ▶ Panel Discussion - A Walz-Flannigan

DISCLOSURES

- ▶ Equipment loans: EIZO, BARCO.
- ▶ Collaborative R&D agreement with FIMI/BARCO.
- ▶ Collaborative R&D agreement with VARIAN (ended 2014).
- ▶ Confidential research agreement with SHIMADZU.
- ▶ Mention of commercial products herein is not to be construed as either an actual or implied endorsement of such products by DHHS.

OUTLINE

Background on medical displays

Effect of ambient illumination

Spatial resolution

Luminance response

Regulatory perspective

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1995

2015

Technologies

Standards and recommendations

Regulatory

1995

2015

- 1996 5MP CRT



- 1999 5MP LCD



- 2000 Dynamic LCD



- 2001 9MP LCD



- 2003 Tiled



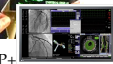
- 2005 Projection



- 2006 Portables



- 2006 Flexibles



- 2007 8MP+



- 2010 Retina



- 2011 Stereo



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Technologies

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- 2007 TG18



- 2009 IEC Intl Std



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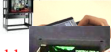
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- 2007 TG18



- 2009 IEC Intl Std



- 2000 FFDM approved

- 2001 Soft-copy FFDM cleared

- 2003 Mammo LCD cleared

- 2010 FFDM down-classified

- 2011 First app cleared

- 2011 DBT approved

- 2012 DBT display cleared

OUTLINE

Background on medical displays

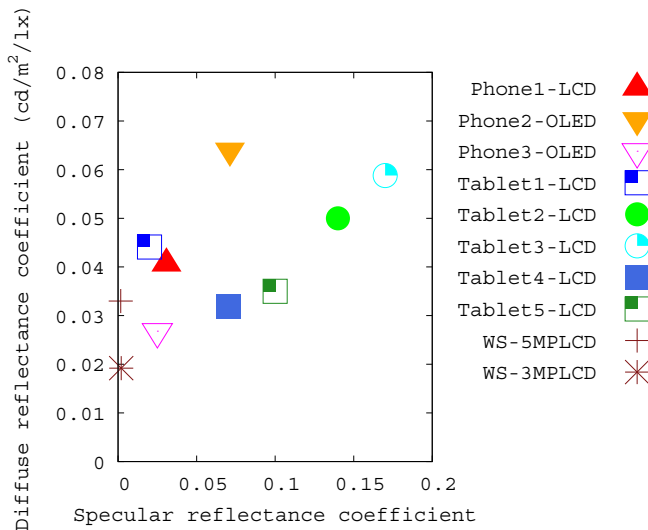
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REFLECTIONS





VISUAL TESTS FOR REAL-TIME QC

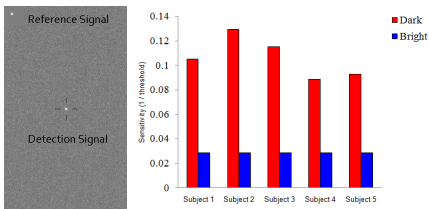
Are visual tests useful surrogates for (il)luminance measurements for determining appropriate viewing conditions for reading medical images in hand-held devices?¹

¹F. Zafar *et al.*, *J of Soc Information Displ* **20**, 124–132 (2012).

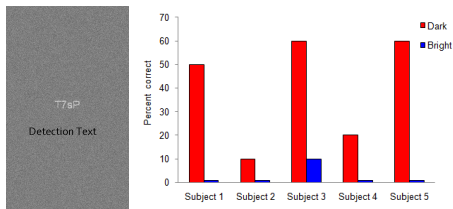


VISUAL TESTS FOR REAL-TIME QC

Are visual tests useful surrogates for (il)luminance measurements for determining appropriate viewing conditions for reading medical images in hand-held devices?¹



Staircase, ~ 120 s



DENOTE, ~ 5 s

Comparison of Staircase and DENOTE (DEtection of NOisy TExt) demonstrates consistent influence of ambient light.

¹F. Zafar et al., *J of Soc Information Displ* **20**, 124–132 (2012).

Correlating bench test results with real-world performance.²

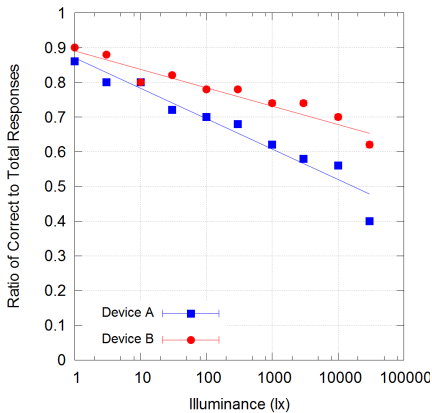


Nexus

Galaxy



Subject



Preliminary results

$$p \propto \ln(I)?$$

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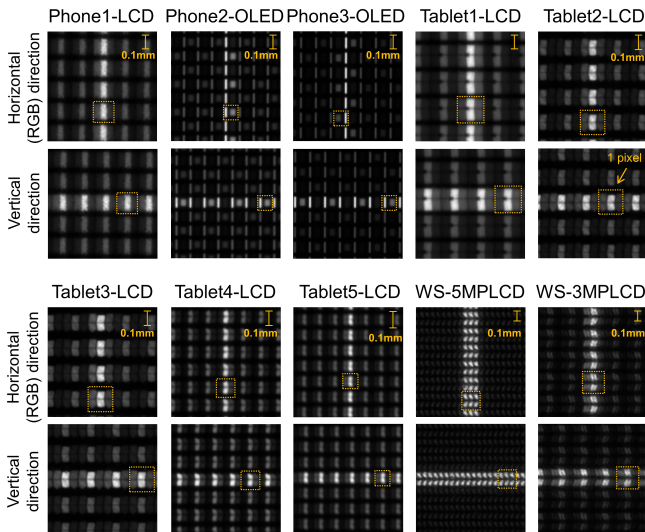
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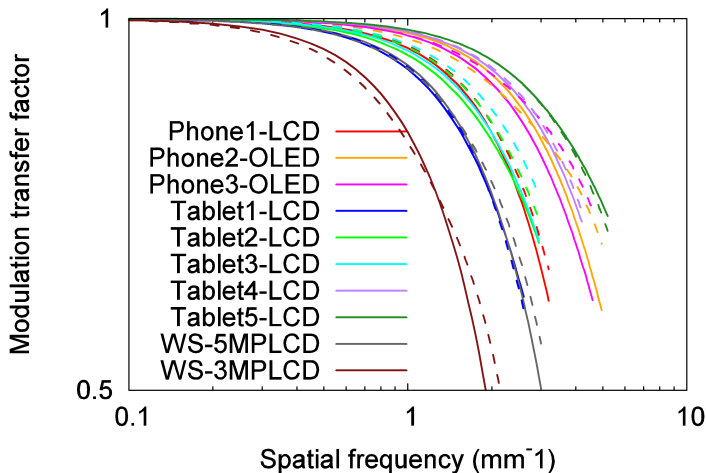
SPATIAL RESOLUTION³



³A. Yamasaki *et al.*, *Opt. Exp.* (2013).



SPATIAL RESOLUTION⁴



⁴A. Yamasaki *et al.*, PLOS One (2013).



SPATIAL RESOLUTION

Handheld resolution considerations:

- ▶ Effective MTF affected by viewing distance
- ▶ MTF affected by relative motion
- ▶ MTF affected by pixel value
- ▶ MTF affected by viewing angle



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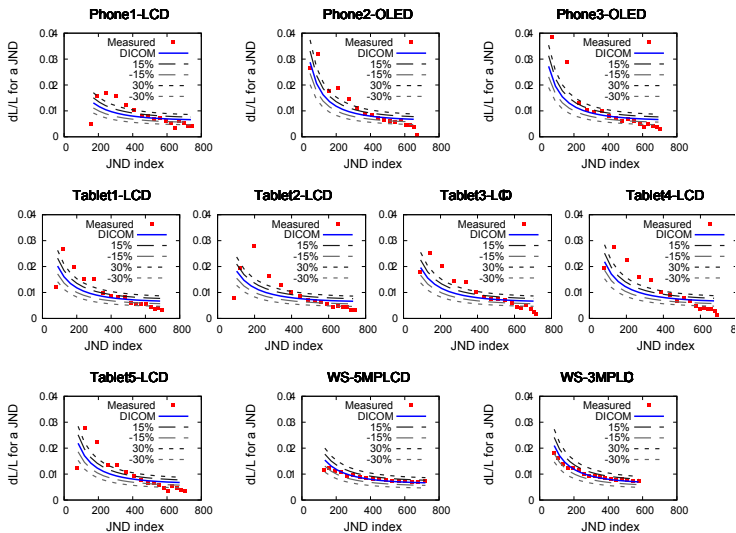
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CONTRAST PERFORMANCE



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REGULATORY CHALLENGES

Regulatory science questions still to be addressed:

- ▶ Under what circumstances are Sponsors relieved from providing bench test data for a new app on “known” devices?



MIM VISTA app

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- ▶ What other factor of device performance are critical for demanding modalities (see IFU)?



MIM VISTA app

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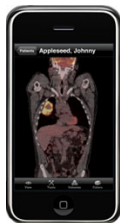
Research questions

- ▶ Compare image quality across a variety of technologies

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- ▶ Under what circumstances are Sponsors relieved from providing bench test data for a new app on “known” devices?
- ▶ What other device performance factors are critical for demanding modalities (see IFU)?



MIM VISTA app

Research questions

- ▶ Compare image quality across a variety of technologies
- ▶ Measure image quality in use conditions (with a focus on noise and resolution)

510(k)#	SPONSOR	INDICATION
K103785	MIM/MOBILE	IPHONE/IPAD, MULTI-MODALITY, DIAGNOSTIC, NOT INTENDED TO REPLACE FULL WORKSTATIONS, USE ONLY WHEN THERE IS NO ACCESS TO A WORKSTATION. LABELING: NOT TO BE USED IN AMBIENT LIGHT CONDITIONS HIGHER THAN 300 LUX
K110919	CARESTREAM	IPAD (NON-DIAGNOSTIC USE, IFU STATES FOR REFERRAL PURPOSES AFTER PRIMARY REVIEW HAS BEEN COMPLETE ON A DEDICATED WORKSTATIONS).
K111346	CALGARY/RESOLUTIONMD	IPHONE/IPAD; CT AND MR; CONDITIONAL DIAGNOSTIC USE.
K111694	CANDELIS/ASTRA	IPHONE, IPAD.
K112930	MIM/MOBILE	EXPANDS K103785 TO X-RAY, ULTRASOUND, RADIATION THERAPY TREATMENT PLANS (CONTOURS, DVH, AND ISODOSE CURVES).
K120115	ORTHOSIZE	SOFTWARE FOR PRE-OPERATIVE PLANNING IN ORTHOPEDIC SURGERY; IPAD USED ONLY TO REVIEW PLANS. NOT FOR DIAGNOSTIC USE.
K121916	TERARECON/INTUITION	MULTIFUNCTIONAL PACS.
K113599	MATERIALIZ	TO DISPLAY SURGICAL MODELS FOR PHYSICIAN REVIEW ON IPAD.
K122136	VITREA VIEW	MOBILE ACCESS, NON-DIAGNOSTIC.
K122260	AYCAN MOBILE	IPAD; DIAGNOSIS; CT AND MR.
K122657	CLARON/NILREAD	MULTIPLE PLATFORMS; MULTI-MODALITY; NON-DIAGNOSTIC.
K123082	NEPHOSITY/MOBILECT	IPAD; DIAGNOSTIC; CT, MRI, X-RAY.
K123186	CALGARY/RESOLUTIONMD	EXPANSION OF K111346 TO ANDROID.
K130624	GLOBALMEDIA/CONI	NON-DIAGNOSTIC.
K130724	STRAUMANN	DENTAL IMPLANT PLANNING, IPAD FOR PRESENTATION ONLY.
K131977	GE/CENTRICITY VIEWER	IPAD, NOT FOR DIAGNOSTIC USE.
K132824	CARESTREAM	DIAGNOSTIC USE, VARIOUS MOBILE PLATFORMS.
K132853	NOVARAD	NON-DIAGNOSTIC.
K133135	AGFA/IMPAX	MULTIPLE PURPOSE PACS (NON-DIAGNOSTIC MOBILE USE).
K133508	CALGARY/RESOLUTIONMD	EXPAND TO INCLUDE ALL DICOM MODALITIES (CR, DR, PET, SPECT, CT, MR, US) EXCLUDING MAMMOGRAPHY.
K140271	CARESTREAM	DIAGNOSTIC USE, VARIOUS MODALITIES, TG18 PATTERN FOR AMBIENT LIGHT LEVEL.

Data courtesy of Robert Ochs, Acting Director, DRH/OIR/CDRH, Robert.Ochs@fda.hhs.gov.

CITED WORK



F. Zafar, M. Choi, J. Wang, P. Liu, A. Badano, *J of Soc Information Displ* **20**, 124–132 (2012).



P. Liu, A. Badano, *J. Digital Imag.* (2013).



A. Yamasaki, P. Liu, W.-C. Cheng, A. Badano, *Opt. Exp.* (2013).



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