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Considerations for the Use of Handheld Image Viewers

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Considerations for the Use of Handheld Image Viewers: A report of AAPM Task Group 260

Aldo Badano*

DIDSR/OSEL/CDRH/USFDA

Nicholas Bevins (nickb@rad.hfh.edu),† Michael J Flynn (mikef@rad.hfh.edu),† Ogan Gurel (oganguerel@gmail.com),‡ Mikio Hasegawa (hasegawa.mikio@jvckenwood.com),† Juergen Heckel (juergen.heckel@eizo.com),† Koichi Kakuda (koichi.kakuda@eizo.com),† Jessica Lamb (jessica.lamb@fda.hhs.gov),‡ Steve Langer (langer.steve@mayo.edu),‡ Andy Masia (amasia@xrite.com),† J. Ross Mitchell(mitchell.ross@mayo.edu),‡ Balazs Nagy (nagybal@usp.br),† John Penczek (john.penczek@nist.gov),‡ Kyle Peterson (kyle.peterson@calgaryscientific.com),† George Redmond (gr34m@nih.gov),† Girish Srinivasan (srinivasan.girish@gmail.com),‡ Peter Steven (peter.m.steven@gmail.com),‡ Rachel Toomey (rachel.toomey@ucd.ie),‡ Gert Van Hoey (gert.vanhoey@barco.com),‡ and Alisa Walz-Flannigan (walzflannigan.alisa@mayo.edu)‡

* Task Group 260 Chair; Contributing author; Corresponding author, aldo.badano@fda.hhs.gov.

† Task Group 260 member.

‡ Task Group 260 member and contributing author.

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Abstract

Mobile devices, such as phones and tablet computers, have become ubiquitous. The availability of access to patient images on mobile thin clients can facilitate the utilization of these devices in a variety of medical environments. When considering the uses of mobile devices in healthcare imaging, users will benefit from understanding how devices can be used and the necessary considerations associated with these uses to ensure medical practitioners make optimal decisions for patient care. Clear articulation of how a practice might utilize mobile technology can also assist in properly selecting equipment, software, and quality control procedures that deliver the desired quality and safety. In this work, we provide examples of potential use cases for the display of medical images on handheld devices that have been considered or studied. Current mobile viewing technologies with limited workspaces are unlikely to replace dedicated radiology workstations better suited for conventional radiology workflow and standard primary reporting. However, mobile devices are enabling timely patient management and collaboration in care. In this context, capabilities and limitations of the displays of mobile devices must be understood by users. In addition, clear procedures to promote best practices in the use of handhelds are required.

The use of handheld devices in imaging introduces a number of special considerations related to information technology infrastructure, requirements for adequate performance in terms of uptime, support, and access via cellular, internet, or intranet systems, loss or theft and adequate security policies and procedures, and the adequacy of representing image details. This report focuses on providing overarching considerations for the use of handheld devices in medical imaging. Operational differences for handheld image viewers include variable ambient illumination, variable viewing angle and viewing distance, motion, touch, calibration issues, and connectivity and image compression. The ambient lighting environment for handheld displays can be substantially different from the standard viewing conditions for medical monitors. The unlimited mobility available to the handhelds means that they may be used in a wide range of illumination conditions, from the dark of night to full daylight.

The addition of the touch screen typically tends to increase the amount of reflected light since many technologies require high refractive index films. The manufacturers partially

mitigate this effect with anti-reflection coatings. But users often add protective cases for their handheld devices which defeat the manufacturer's efforts in reducing screen reflections. Most commercial handheld displays are calibrated at the factory to render images in the sRGB color space. Therefore, they will not render a grayscale image the same as a medical monitor with a standard grayscale calibration. Likewise, as the medical industry works toward standardizing the color space for medical imagery, most off-the-shelf handheld devices will need to be re-calibrated in order to match that color space. The calibration process is complex for the handheld devices due to the limited access provided by the operating system software. Current operating system restrictions prevent a general and open means for the calibration information to be shared between different image viewing software. Therefore, present calibration solutions are typically closed systems. However, limiting what software can be used to view calibrated images significantly hampers the flexibility and value of the calibration. There is a great need for the major operating system developers to allow greater access to the color management attribute. A calibration through look-up table correction might reduce the number of gray levels being displayed. An indication of such a calibration to the user should be good practice. In addition, a visual check with a full gray ramp might visualize possible banding issues. In most cases, there will be unavoidable reflections from diffuse ambient lighting that reduce image contrast.

Handheld image viewers are practical and widespread. Understanding the limitations of their use and knowing when and how to use them is paramount to high-quality patient care delivery. The considerations described in this report are useful in expanding and ensuring safe use of these devices in the clinical environment.

1 Viewing medical images on handhelds: use cases and applications

Mobile devices, such as smartphones and tablet computers, have become ubiquitous. The increasing availability of quick and easy access to patient images on mobile thin clients can facilitate the utilization of these devices in a variety of medical environments. When considering the uses of mobile devices in healthcare imaging, users will benefit from understanding how devices can be used and the necessary considerations associated with these uses to ensure medical practitioners make optimal decisions for patient care. Clear articulation of how a practice might utilize mobile technology can also assist in properly selecting equipment, software, and quality control procedures that deliver the desired quality and safety.[1, 2]

Over the last decade, a considerable volume of literature has been published investigating or describing the uses and proposed uses of handheld devices in radiology. These have included a wide variety of tasks including education,[3, 4] patient briefing,[5, 6] and to view and interpret radiological images.[7, 8] In addition, there exist a variety of other uses not yet discussed in the literature.

In the following, we provide examples of potential use cases for the display of medical images on handheld devices that have been considered or studied.[9–30] First, radiologists may wish to view images on handheld devices for reasons such as viewing an examination that is in progress, to advise a technologist on acquisition considerations, consult with a trainee radiologist regarding a finding, or offer an opinion to emergency care providers prior to intervention. Secondly, practitioners might use handhelds to deliver preliminary or final interpretations of examinations, with or without full access to prior examinations, reports, or other clinical data. Thirdly, handhelds might enable real-time, in-person or remote consultation with other care providers with simultaneous image viewing with real-time, visual, written and/or audible communication about findings. An example of this application is surgical planning. Other medical professionals could use handhelds for surgical and interventional imaging prior to or during procedures, for navigation during interventions, for accessing previous examinations, before or during portable or theatre-based examinations to inform decisions regarding patient or equipment positioning and exposure technique, or

to view images immediately after acquisition for determining quality and need for further imaging.[31] Moreover, care providers can utilize handhelds for viewing finalised examinations and reports to aid in planning the course of care, to communicate imaging findings to patients, for interdisciplinary conferences and tumor boards, and for resident training.

Current mobile viewing technologies with limited workspaces will most likely not replace dedicated radiology PACS workstations better suited for conventional radiology workflow and standard primary reporting. However, mobile devices are enabling timely patient management and collaboration in care. In this context, capabilities and limitations of the displays of mobile devices must be understood by users. In addition, clear procedures to promote best practices in the use of handhelds are required.

The use of handheld devices in imaging introduces a number of special considerations. Some of these concern the information technology infrastructure available including the system architecture, accessibility, and integration points to facilitate required workflows. An associated concern is the requirements for adequate performance in terms of uptime, support, and access via cellular/internet/intranet systems. With handheld devices, particularly those that are popular consumer products, the possibility of loss or theft must be considered, and adequate security policies and procedures should be put in place. A recent study has shown that handheld devices that use touch screens carry a variety of pathogens making appropriate infection control techniques to be considered.[32]

Finally, the most obvious concern with viewing medical images on handheld devices is the issue of whether the display itself can adequately represent the necessary image details and how environmental factors may affect image quality. This report focuses on providing overarching considerations for the use of handheld devices in medical imaging.

2 Brief overview of handheld technology

Image display technology transitioned from analog film to digital format around 1995 with the evolution of cathode-ray tubes (CRT) capable of providing sufficient spatial resolution.[33] Today, the majority of displays used in radiology are liquid-crystal displays (LCDs) backlit with cold-cathode fluorescent lamps (CCFLs). Newer display options include light-emitting diode (LED)-backlit displays.[34]

With the extensive variety in mobile display solutions, the rapid pace of innovation in mobile platforms, and the potential benefits and risks to public health represented by these solutions, the Food and Drug Administration (FDA) has issued a guidance document to clarify when a mobile application is considered a medical device.[35] In recent years, handheld devices including mobile phones and tablet computers have become widespread and have been proposed as components in medical imaging solutions, especially in emergency medicine where immediate consultation is required.

LCD technology continues to advance with improved power usage and contrast visibility under bright ambient light environments. However, a major innovation in display technology is the availability of organic light-emitting diode (OLED) screens with smaller footprint and fast response times for reduced temporal blur. OLED medical-grade monitors were first introduced in 2012.[36–39] An OLED display works without a backlight which allows for deep black levels and a thinner and lighter device. In low ambient light conditions, an OLED screen can achieve a higher contrast ratio than an LCD. The technology typically offers a wider viewing angle compared to LCDs. The viewing angle of a device refers to its ability to maintain a given contrast performance at off-normal viewing directions. OLED pixels can achieve higher color fidelity even at large viewing angles. In addition, OLEDs can be manufactured into thin, transparent, flexible, foldable, and rolled devices enabling possibilities for their use in a variety of wearable display configurations.

Recently, non-demanding needs such as medical and patient text records are finding electronic paper as a solution that mimics the appearance of ordinary ink on paper.[40] Unlike conventional backlit, flat-panel displays that emit light, electronic paper displays reflect ambient light.

Reflective-type handheld color displays[41] with optimized optical design and scattering layers allow for low power consumption when still images are displayed using a memory-in-pixel structure with low-temperature, poly-Silicon technology. Full-color moving images are also becoming available supporting the development of new applications including smart watches and e-readers.

Quantum-dots (QD) LCD technology provides high performance, with highly saturated primary colors similar to those produced by OLEDs.[42] In addition, QD-LCD have improved brightness and power efficiency and can be manufactured using printable and flexible large-area displays with improved lifetimes compared to OLED.

Most handheld devices contain at least one ambient light sensor (ALS), also called illumination, light, or optical sensor. ALS enables automatic control of backlight brightness over a wide range of illumination conditions from dark to direct sunlight.[43] With ALS, a microcontroller processor increases or decreases display brightness depending on the ambient illumination in the environment. This control dramatically improves visibility while reducing power consumption but, if not properly accounted for, might affect the consistency of the display presentation.

Another aspect of importance in handhelds is the touch screen.[44] A separate layer works to provide feedback imitating physical buttons and textures dynamically on the screen surface. This process happens dynamically with the device rendering virtual buttons or surface textures transiently on the screen. Subtle structural variations may be perceived through touch as opposed to only visually. Visual feedback can be provided in laparoscopic surgery[45] with imaging from a video camera positioned inside the patient's body during the procedure. One limitation to these minimally invasive approaches is the impairment or complete lack of tactile sensation normally used to assist in surgical dissection and decision-making. Tactile screens might minimize this limitation.

The increase in pixel density seen in recent years for handheld devices is dependent on smaller transistors. Transistors exist in all display panels and supply each individual pixel with required voltage levels. The trend towards high-resolution displays is evident in all segments of the display industry. 4K delivers 4,000 pixels per line across the screen.[46] A 4K-display screen has 4 times the resolution of a 1080p HDTV. Similar trends are present in the handheld market.

Recently, there has been interest in the use of handhelds in virtual reality (VR) applications. VR technology can present virtual objects or complete scenes similar to natural experiences.[47] VR has been proposed as a tool for medical imaging including in the simulation of three-dimensional reconstruction of organs from radiological cross-sectional imaging, in the preoperative planning in radiation therapy, craniofacial surgery, and neurosurgery, and in the compilation of computerized three-dimensional atlases of human anatomy, physiology, and pathology for teaching purposes. In addition, several VR systems have been developed and tested for the physical or mental patient rehabilitation and for supporting mental health therapy. Lastly, VR technology will continue to increase its role in telemedicine from remote diagnosis to complex tele-interventions.

TABLE I. Major considerations for the use of handheld image viewers.

Characteristic	**Relevance**
Variable ambient illumination	Might affect consistency and accuracy of the visualization
Variable viewing angle and viewing distance	Might affect perceived detail and image presentation
Image size and resolution	Smaller display size challenges workflow
Motion	Affects visibility of spatial detail
Touch	Can be inaccurate and requires frequent screen cleaning
Calibration	Challenging in most current devices
Connectivity	Variable and sudden changes to functionality
Image compression	Lower quality in lower-bandwidth networks

Finally, the use of 3D imaging in the medical field has proven to benefit diagnosing patients with 3D models of the human body and has assisted medical manufacturers in developing better medical devices and treatments. For different medical domains (radiology, minimally invasive surgery, and teaching/training) a stereoscopic display could be advantageous in terms of a better spatial understanding of anatomical structures, better perception of ambiguous anatomical structures, better performance of tasks that require high level of dexterity, increased learning performance and improved communication with patients or between doctors.[48]

3 What is different in handhelds?

Operational differences for handheld devices include variable ambient illumination, variable viewing angle and viewing distance, motion, touch, calibration issues, and connectivity and image compression. Handheld hardware has restricted computing, rendering and memory resources due to size, weight, and power constraints.

The ambient lighting environment for handheld displays can be substantially different than the standard viewing conditions for medical monitors. The unlimited mobility available to the handhelds means that they may be used in a wide range of illumination conditions, from the dark of night to full daylight. This huge variability not only challenges a display technology's ability to maintain its performance characteristics, but also influences how the human visual system (HVS) perceives the rendered images. When viewing information under moderate background illumination environments, most handheld displays are able to

generate images that are bright enough to overcome most of the confounding reflections originating from background lighting. In this modest background lighting environment, the performance of the HVS is largely dictated by the brightness and color content of the rendered image, and adapts as the content changes. However, handheld device manufacturers also recognize that the HVS is sensitive to the ambient light level, and often include sensors that regulate display brightness for a more comfortable viewing experience. This may work well for dim and moderate background light levels but can eventually saturate at higher levels.

In addition, as background light levels increase, the lighting environment plays a more prominent role in the luminance and chromatic adaptation mechanisms of the HVS. Vision models[49] have been developed to understand these perceptual dependencies but are often too complex to be applied as background compensation methods in consumer products. It becomes necessary for the user to understand their sensitivity to ambient background illumination effect and strive to position themselves in relation to the device in a constant modest lighting environment for consistent image evaluation.

Liu *et al.* [50] reported on the effect of ambient illumination on handheld display image quality and measured image quality characteristics of handheld devices for medical imaging applications. The authors described experiments conducted to analyze how certain mobile devices perform under various ambient illumination conditions and found that due to the high reflectivity characteristics of handheld devices, performance deteriorates as the user

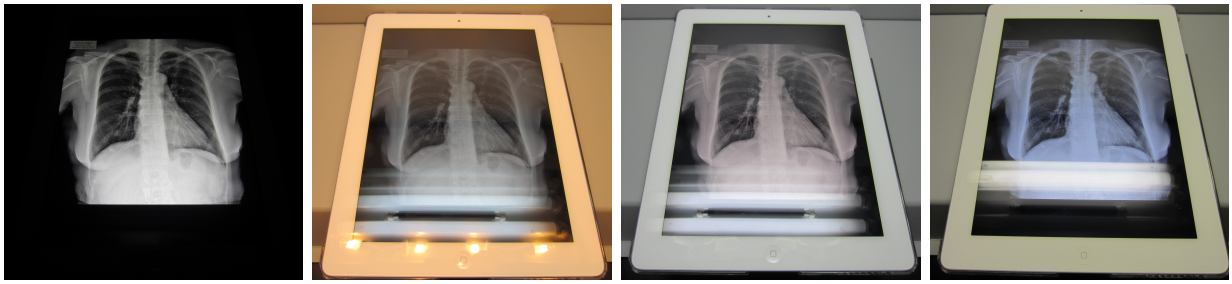

FIG. 1. Demonstration of the effect of different ambient illuminations on image quality. A handheld device was placed on the floor of a light cabinet (PDV-2e, GTI Graphic Technology, Inc., Newburgh, NY) that simulates four lighting conditions: (from left to right) no light, D65 (artificial daylight industry standard), CWF (typical store environment), and incandescent lighting (home lights). An illuminance meter (T-10) was placed directly on the face of the device with the sensor above the heart position and the following illuminance values were measured at 2 lx, 1305 lx, 1556 lx, and 1300 lx, respectively. Reprinted with permission from Ref. [50].

moves from dark areas into environments with greater ambient illumination (see Fig. 3).

Ambient light for handheld reading is uncontrolled, can vary during reading, and often includes significant specular (mirror-like) reflections. Evaluation of the environment is crucial, if not for allowing ideal visualization, at least for documenting the reading environment, which should be part of every reading session. The impact of ambient light on reading is difficult, if not impossible, to assess, as one cannot notice what one does not see. For many image readings, ambient light will have little or insignificant impact. However, for subtle cases, secondary observations can be missed if ambient reading conditions distort image perception. For this reason, it is hard to argue that handheld devices are appropriate for anything other than "wet reads" for cases where more careful examination is indicated.

LCDs are the dominant display technology being used for handheld devices. However, organic light emitting diode (OLED) displays are growing in popularity. Both of these technologies render the desired image by creating their own light. The perceived luminance and color are largely dictated by the native characteristics of the display design. Emissive displays work well for low to moderate ambient lighting environments. However, rendered images can get washed out under high ambient light levels.

The introduction of reflective displays has provided users with a viable option for comfortable reading at the higher lighting levels. The recent addition of front-lights to the reflective displays has extended their viewing range to dim environments. However, current reflective display products have limited and insufficient resolution and color capabilities.

Transflective displays represent a blending of the emissive and reflective concepts into one design. The transflective display compromises the high performance of the emissive and reflective technologies in exchange for a modest viewing performance over a wide range of ambient lighting environments. Once popular in mobile phone displays, their higher cost has relegated their use to special purpose applications including GPS displays and fish finders.

3.1 Variable viewing angle and distance

Viewing angle should primarily be perpendicular. Even though the handheld display is not rigidly positioned, it is likely to be naturally held perpendicularly and may be more often correctly positioned than reading room monitors given the ease of adjustment. Viewing distance is typically close reading which for most viewers is around 30 cm. This corresponds

to half the ACR recommended diagnostic viewing distance and could cause increased eye strain.[51] However, eye strain seems unlikely as it would be rare to use a handheld device for an extended reading period. A large, handheld, 10-inch diagonal 3MP display, held at 30 cm gives an equivalent visual experience as a 20-inch medical monitor at twice the distance.

3.2 Image size and resolution

Handheld devices are smaller than radiology monitors but can give a similar visual experience to a 3-million-pixel radiology display, as mentioned above. Even the iPad mini offers 3MP resolution in a 7.9-inch display, where a 24 cm viewing distance would emulate a 20-inch medical display. The iPad Pro offers a 5.5MP 13-inch display, about the size of a standard mammography film offering arguably a better chest film image than a standard 3MP display. This assumes that the image quality on the handheld devices is the same as in medical monitors. Non-Apple brand tablets offer similar displays and resolutions, though they tend to be centered around 16x9 aspect ratios. Phone displays seem too small for practical use. However, 5-inch, 1-2 million pixels, 500 cd/m^2 displays could be comparable to half a radiology display and thus capable of CT or MR stack-mode viewing.

An important point to note is that the conventional notion of display resolution as the number of addressable pixel elements is quickly being challenged with new display designs. PenTile©[52] and white-red-green-blue[53] (WRGB) pixel structures are currently used in handheld displays in an effort to increase visible resolution with reduced power consumption. Each sub-pixel color in these pixel designs can differ in size and shape meaning pixel layout no longer rectilinear as in traditional stripe patterns. These new structures require more sophisticated image processing to drive them. Determining the resolution of a handheld device from an internet browser can often result in a lower resolution compared to the native resolution performed to improve readability. This in turn can generate scaling artifacts when resolution-dependent test patterns are displayed. It is worth noting that with these advanced pixel structures, perceived resolution may depend on the color being rendered on the handheld screen.

3.3 Motion

Movement of the display could be a serious impediment to accurate and complete image evaluation. Gestalt viewing becomes nearly impossible with a moving display. However, the movement of the display can be minimized as long as the person holding the display is not moving. Normal hand-eye feedback stabilizes the display. The ability to easily move the display is an important feature of handheld devices. The display can easily be tilted to avoid glare reflections or some bright background lighting. However, in general, there are usually some background reflections present. In some cases, it may be necessary to view medical video on handheld displays. Fast refresh rates are not a problem for desktop monitors and advanced graphics processors. However, space and power limitations generally require the computer processor to also handle graphics operations. Although more powerful processors are being implemented, the refresh rates on the top handheld displays are acceptable for relatively slow video motions, but may introduce motion artifacts for smaller features and faster movements.

3.4 Touch

Touch-screen displays offer unique user interface opportunities. A collection of commonly used gestures would allow for intuitive image manipulation and enhancement. However, all handheld displays have smooth glass surfaces which easily show fingerprints and streaks. Clever user interface (UI) design can isolate the image presentation controls to a corner or side of the display to help keep the image area clean. Keeping the display clear enough for unimpeded reading will require frequent routine cleaning. Even with a carefully designed UI, the display will get streaked because other apps won't share the same UI restrictions.

The addition of the touch screen typically tends to increase the amount of reflected light since many technologies require high refractive index films. The manufacturers partially mitigate this effect with anti-reflection coatings. But users often add protective cases for their handheld devices which defeat the manufacturer's efforts in reducing screen reflections.

3.5 Calibration

Most commercial handheld displays are calibrated at the factory to render images in the sRGB color space. Therefore, they will not render a grayscale image the same as a medical monitor with a grayscale standard display function (GSDF) calibration. Likewise, as the medical industry works toward standardizing the color space for medical imagery, most off-the-shelf handheld devices will need to be re-calibrated in order to match that color space. The calibration process is complex for the handheld devices due to the limited access provided by the operating system software. Current operating system restrictions prevent a general and open means for the calibration information to be shared between different image viewing software. Therefore, present calibration solutions are typically closed systems. However, limiting what software can be used to view calibrated images significantly hampers the flexibility and value of the calibration. There is a great need for the major operating system developers to allow greater access to the color management attribute.

Currently software applications do their own calibration, sometimes using special test patterns, sometimes photometers, and sometimes interactive contrast adjustments. Calibration is a two step process: Characterization and correction. Both steps are challenging on handheld devices. Ideal characterization is time-consuming because it reads every driving level of the LCD to account for the discontinuities in the voltage-luminance function. Fortunately, this process needs to be done only once. The LCD will not change significantly during its lifetime. Changes in the underlying LCD behavior are less likely than errors due to poor measurements, inappropriate measurement equipment, or sampling and extrapolating approximations. The device needs to be characterized completely and carefully, with the characterization data stored in the device or in a database where it can be uniquely associated with the device. This methodology offers the best chance of accurate display correction. Once the characteristic function is known, adjusting the output to a target function is easily done, if the target is clear. Unfortunately, the GSDF target function is dependent on the ambient light and the specific ambient reflectivity of the display. Most handheld displays have smooth reflective surfaces and extremely low diffuse ambient reflections to ensure very black blacks. It may be convenient to assume the display is in a low ambient light environment for the purposes of GSDF calibration and later address specular reflections. Reflections from diffuse backgrounds are generally not negligible, especially in high ambient

lighting environments.

A DICOM GSDF calibration through look-up table correction might reduce the number of gray levels being displayed. An indication of such a calibration to the user should be good practice. In addition, a visual check with a full gray ramp might visualize possible banding issues. Furthermore, some recent handheld products now include a rendering (electronic) filtering of blue regions of the emission spectrum because of alleged eye strain and effect on the user's circadian rhythm. This product feature might have a significant effect on color output of the display and have to be considered within calibration and use procedures.

3.6 Hardware

Handheld devices may not have enough resources to hold all the slices in a large medical imaging study in memory. This, combined with reduced computational and graphical processing unit (GPU) capability means that handhelds may not provide advanced interactive rendering of 3D image volumes (e.g., high definition ray-casting, oblique and curvilinear multi-planar reformatting). Fortunately, these issues may be largely alleviated through IT architecture considerations, discussed in section VII.

4 Test patterns

Digital test images are useful tools for qualitative visual assessment and as a means for measuring reproducible quantitative performance metrics of display quality. Many of the same test images used for desktop display assessment and readily available can be employed by handheld devices. However, the smaller screens in handhelds limit the amount of detail that can be viewed. In addition to the standard QC patterns[54, 55], horizontal and vertical ramps for 8- and 10-bit can be used to visually check grayscale calibration. Fixed resolution targets, such as a 512x512 box within a 1024x1024 can be used to illustrate the physical resolution. TG-18LN or equivalent test patterns with a larger test area (75% instead of the current 10%) might be useful to study conformance to a luminance target model.

On the other hand, dynamic test patterns provide an opportunity for display evaluation along with the viewing environment. Among them, visual search of randomly generated low-

contrast targets, or low-contrast random text strings or words can provide interactive tests but might suffer from UI issues interfering with image viewing, either from new fingerprints from touching the screen targets or displaying a keyboard for entering a text string changing the average luminance of the display. Nevertheless, these interactive test patterns are capable of providing real-time feedback to the radiologist or practitioner about the dynamic viewing environment. The score on target-searching or text entry could be reported in terms relative to the radiologist's previous performance. A poor score could alert the radiologist of an inferior viewing environment and potentially disable image readings. However, dynamic patterns might suffer from reproducibility.

5 QC APPROACHES

Assessing display image quality is an important part of ensuring that settings and viewing conditions are appropriate. If the performance level is not acceptable, the user will need to adjust the viewing environment. The evaluation of image quality will be discussed in the context of three use cases: (i) a visual assessment by a user in the actual lighting environment, (ii) a visual assessment by a professional in a standard lighting environment, and (iii) a rigorous quantitative evaluation in a laboratory under a standard lighting environment. The complexity and time involved for each these is dictated by the situational necessity.

User visual assessment will typically involve time constraints and arbitrary lighting environments. Therefore, the evaluation needs to be simple, general, and quick. These evaluations typically involve a visual assessment of simple grayscale ramps or resolution targets which can serve as confirmation that the current viewing environment is adequate. Otherwise, the lighting environment or device settings need to be adjusted.

The TG-270QC[54] static patterns have already been mentioned as possible test patterns. It would also be desirable for the viewing software to be interactive so that a knowledgeable user could make small adjustments to the display settings in an effort to improve image quality. A simplified method similar to that described in ISO 9241-306[56], Annex D, could serve as example. Often, a visual assessment by a trained professional can quickly determine if a handheld image viewer has image quality problems. The professional visual assessment would entail a more detailed version of grayscale ramps and resolution targets similar to

TG-18QC. Separate test patterns may also be needed to evaluate blemishes, uniformity, and color gamut. These assessments should be done in a controlled lighting environment to ensure applicability and reproducibility. Most ambient lighting conditions involve simultaneous multiple light sources. These can be simulated by directed sources to represent the sun and a hemispherical diffuse source that represents the skylight or background room light. At a minimum, a single directed source (at a 45 degree inclination angle) and a hemispherical diffuse source should be used to simulate a realistic lighting environment. Several international standards have been developed using this lighting geometry for both indoor and outdoor illumination levels.

The visual assessment would be most efficient if the evaluation process is interactive. A software application could run on the handheld device presenting a series of test patterns to the viewer. Each test pattern could consist of two regions, one with a uniform driving level, and one with a spatial mix of two different driving levels. By having the user interactively manipulate the driving level of the uniform region until it visually matches the lightness of the spatially mixed region, the luminance behavior of the handheld device can be estimated.

Quantitative characterization of image quality provides the most detailed and reproducible evaluation of the handheld image viewer. The characterization can also calibrate the device if its performance was found to be inadequate. The optical characterization of the display is generally divided into darkroom measurements and ambient measurements. The darkroom measurements determine the display's intrinsic emissive properties. For non-transparent displays, these characteristics define the ultimate capabilities of the display performance. The display darkroom attributes that impact the image quality include the luminance, color gamut, luminance and color uniformity, contrast ratio, and deviations from the DICOM GSDF. Since some display technologies (OLEDs) exhibit luminance loading effects, it is recommended that less than 10% average-pixel-level (APL) test patterns be used to measure the device performance. This would require the grayscale to be measured one gray level at a time. Motion artifacts are also generally measured under darkroom conditions while display resolution for static and moving images are measured using a 1-D sinusoidal black-white pattern similar to that used in IEC61988-2-4.[57] An example of a quantitative and comprehensive characterization study is described in Refs. 58 and 33.

Since the perceived image on a mobile display can be significantly affected by the ambient lighting environment, the influence of the lighting environment on the image also needs to

be evaluated. For non-transparent displays, the main impact of the lighting environment on the perceived image is by how the light is reflected to the viewer. This is commonly characterized by photometric or spectral reflection coefficients. In general, these coefficients are different for directed sources (like the sun) or for hemispherical diffuse illumination (from skylight and background room light). In most cases, the viewing conditions have both types of illumination. The contribution from all the illumination sources should be taken into account.

Our ability to efficiently characterize and calibrate handheld devices is determined by how much access is permitted to external software. Characterizing the behavior of a handheld device using a light meter is often not practical since many types of devices do not offer the possibility to interface with an external light meter. One solution is to connect a light meter to a different device (PC, laptop), and use two communicating software components to obtain measurements of the handheld device. In this approach, one component is running on the PC or laptop which acquires measurements from the light meter, and the other component runs on the handheld device for displaying the appropriate patterns to be measured.

6 IT architecture considerations

The available information technology architecture is paramount in enabling use cases for handheld devices as medical image viewers. Consider one scenario where a radiologist wishes to view a trauma CT while it is in progress, and later a clinician wishes to consult with that radiologist while viewing the patient's Electronic Medical Record (EMR). In the former case, the radiologist needs to be able to log into the mobile viewer (MV) directly and query for the patient (via MRN) or on the in-progress exam (via accession number). In the latter case, the clinician searches the EMR for the patient's CT report. When finished reading, they click on the "View Images" button and assume that: the MV will launch and auto-log them in, open the correct patient, and the correct image study. One can image additional scenarios by considering moving from the fast, secure hospital networks to the slow and insecure world of cellular communications.

The above use cases point to certain requirements on both the server and client sides of the MV. First, the MV needs to be able to access the images that are in the site's DICOM

image archive. However, live viewing requires images sent directly from the scanner to the MV server (or at the same time as to the PACS). Ideally, the images should be full fidelity and brought over only in a just-in-time basis and later purged to avoid duplication. Once on the MV server, images can be served to the mobile client via one of many available methods: some vendors convert DICOM to compressed JPG stills and then send them over HTTP to the client. More recently, vendors are using DICOMweb services.[59, 60]

Since it is in the data center, the architecture of the MV server can be flexible. All that is required is for the interfaces to be standard. In contrast the MV client, practically speaking, has to be Apple (iOS) or Android compatible. Client-server communication has to be over a common internet protocol within or outside the medical facility firewall. For these reasons, most MV clients communicate over HTTP (or the encrypted version HTTPS). Open standards for sending DICOM images that are HIPAA-compliant via the World Wide Web are defined by the Integrating the Health Care Enterprise (IHE) consortium.[61] The older version is called Cross-enterprise Document Sharing.[62, 63]

The MV, as any other healthcare IT system, must be HIPAA-compliant.[64] This drives several more requirements. Communications to/from the server to the client have to be logged, auditable, and encrypted. In addition, the client software should leave no persistent data on the mobile device after either a normal or abnormal program termination.

One solution is to offload the computational and rendering capabilities to a backend server located behind the hospital firewall. This approach splits the application functions into model, view, and controller (MVC) components. The server performs the model and controller functions, and the handheld device provides the view (display) functionality. This may be accomplished via a native or web application. The latter can take advantage of widely available web technologies, like HTML5, Javascript, and WebGL to eliminate the need to distribute, install, and update iOS and Android applications. With this approach, the server creates an image in response to input provided by the user on the handheld (e.g., a touch or drag event). The created image (a 2D image or a 3D volume rendering) is then streamed from the server to the handheld device interactively.[12]

The system should handle varying bandwidth between the handheld device and the server with sophisticated and flexible data compression and transmission algorithms. In practice, this design also requires frequent synchronization of application state between the handheld and the server. In turn, this requires an abstraction of the application into a state-machine

form, and intelligent algorithms to synchronize application states between server and handheld. Once these design considerations are applied, several advantages are realized: (a) all data except the displayed frame remain on the central server behind a firewall improving security, (b) large imaging exams can be manipulated (rendered) at high speed, (c) imaging studies can be loaded very rapidly since the server can have a high-speed dedicated connection to the PACS, (d) time-to-first-image is short, and, (e) advanced rendering of 3D image volumes can be visualized interactively on the handheld. The application-state-machine design also allows for the visualization to be synchronized among multiple handheld and/or desktop devices for multi-user collaborative sessions.[7, 65]

7 Regulatory landscape

The first iPhone was released in 2007. Since then, developers have been eagerly designing mobile apps for a wide variety of purposes, including medical image viewing. In the United States such apps are considered medical devices, and therefore regulated by the Food and Drug Administration (FDA) under the authority granted in the 1976 Medical Device Amendments. Apps intended to allow radiologists to read medical images from their mobile devices reached the US market in 2011. To date, no app has been cleared by the FDA for interpreting surgical digital pathology images produced from whole-slide scanning systems.

Medical device regulation focuses on the intended use of the device. A mobile app intended to display pictures for the user, without clear intent about what type of pictures, is not a medical device. An app that is intended to display medical images is a medical device. If the mobile app is actively labeled "Not for diagnostic use" it might be considered a class I medical device classified under 21 CFR 892.2020 as a Medical Image Communications Device. These devices might display images for educational or reference purposes. In addition, an app intended to display medical images for a radiologist to diagnose is a class II medical device that requires premarket notification. These apps are discussed in the remainder of this section. They are classified as Picture Archiving and Communications Systems under 21 CFR 892.2050. This is the same regulation that covers diagnostic displays for desktop systems and software for advanced medical image analysis.

Premarket notification is used for most class II medical devices. It is a comparative review that serves several purposes; the most significant is that it allows regulators to decide whether the device is substantially equivalent in terms of safety and effectiveness to a similar device (a predicate) that is already on the market. This review includes evaluating the intended use, technology, and whether appropriate decisions regarding device design, labeling, risk mitigation, and testing were made during development. Now that there are several radiological mobile apps on the market, manufacturers compare their device to another similar app when submitting information to the FDA. Originally, however, they were compared to the desktop hardware and software also covered by the same regulation.

Diagnostic desktop displays are usually reviewed separately from the software used with them to access and load medical images. This is because on these systems, hardware is modular; it is easy to connect a display that is labeled as medical grade and cleared by the FDA to any computer system with image visualization software installed. Standard methods and calibration tools exist to further aid in evaluating the performance of displays, including conformance to the DICOM GSDF. In contrast, when these distinct devices are integrated in mobile applications, the display hardware, operating system, and the radiological mobile apps are intrinsically connected with each other within a mobile platform in order to deliver the same intended use. Therefore, the FDA evaluates the risks and performance of a mobile radiology app together with its associated mobile platform(s), operating system(s), and software in a premarket submission. This is to address the risk of the use of radiological mobile apps on incompatible mobile platforms (e.g., low grade display) on which the risks cannot be controlled.

To this end the FDA requests evidence, in the form of test records and that a radiological mobile app has been validated on the hardware it is to be used on. This usually takes the form of bench testing and a limited study asking radiologists to evaluate the image quality on the mobile device with a small set of images. It is intended to confirm the app, and any adjustment it makes to the display, projects an image that is suitable for the intended imaging modalities and hardware platforms. This means that an app that has been validated on a Galaxy Tab II is not considered valid for all Android devices.

While mobility of mobile devices creates convenience and opportunities, the environment to perform radiology image reading should be properly considered. While the FDA does not formally assess the reading environment, it does examine labeling and other risk mit-

igation measures that come with devices. For desktop environments, established practices or institutional standards ensure the environment in the reading room. Practices for mobile medical image viewing for diagnostic use were not established when the devices first came on the market. FDA recommends labeling to instruct users to use a reading environment than would be comparable to conventional desktop reading. This labeling tends to be similar between devices, with the exception of the maximum recommended light level, which can vary as manufacturers have varied in their selection and testing of the mobile applications in different reading environments.

Another means to address the likely variation in reading environments with mobile devices is within-app light assessment tools. A formal lighting assessment is impractical in most circumstances for mobile device use. However, early devices developed on-board tools to help the user assess the environment and partly mitigate risks associated with bright lighting. To date these tools all rely on the user inspecting low-contrast objects in the reading environment. For these tools, the FDA usually asks for information on what type of test images are used, how many there are, and the way they are presented to the user. These apps are intended to provide the user with an additional tool that, along with the device labeling and professional expertise, help identify appropriate lighting environments for reading images.

8 Prospects

Surprisingly, size, resolution, viewing distance, and even brightness appear to not be significant problems for handheld image viewing. Touch screen interfaces can be designed to leave an image area clear of fingerprints and streaks, but even in this best case, radiologist should still be expected to clean the display before each viewing session as it will likely be dirty from use of other apps or simply from being carried around. Specular reflections may be the most significant issue facing handheld device use. Every effort must be made to encourage user awareness of this issue in general, as well as the specific issues of each new viewing environment. The display can be tilted, even during reading, to avoid glare, but the user needs to be aware of the possibility of disruptive reflections.

In most cases, there will be unavoidable reflections from diffuse ambient lighting that re-

duce image contrast. The recent popularity of curved displays introduces further complexity in the assessment of mobile devices. Displays with a convex shape will sample more of the ambient environment and can be more prone to create unreadable regions on the display due to glare. The recent offering of concave mobile displays helps to restrict the reflected field of view to mainly the viewer's face. This tends to be beneficial, since the illuminance from the face can be less than the surrounding background. Although this approach is promising, it has yet to be widely adopted. But curved displays also create new measurements challenges for reproducible testing.

In summary, handheld image viewers are practical and widespread. Understanding the limitations of their use and knowing when and how to use them is paramount to high-quality patient care delivery. The considerations described in this report are useful in expanding and ensuring safe use of these devices in the clinical environment.

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