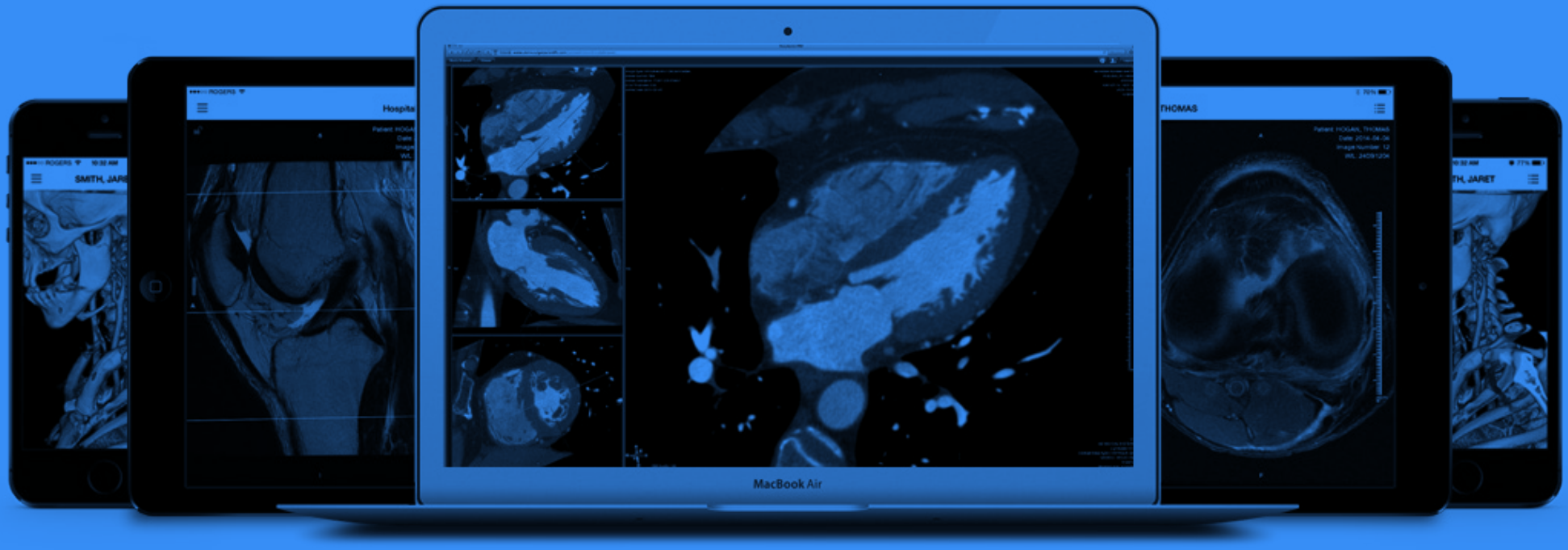


# The Importance of Using an Accredited Enterprise Image-Viewing Solution

ResolutionMD®

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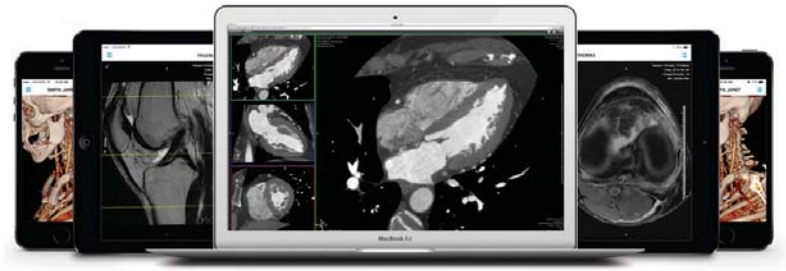
# THE IMPORTANCE OF USING AN ACCREDITED ENTERPRISE IMAGE-VIEWING SOLUTION



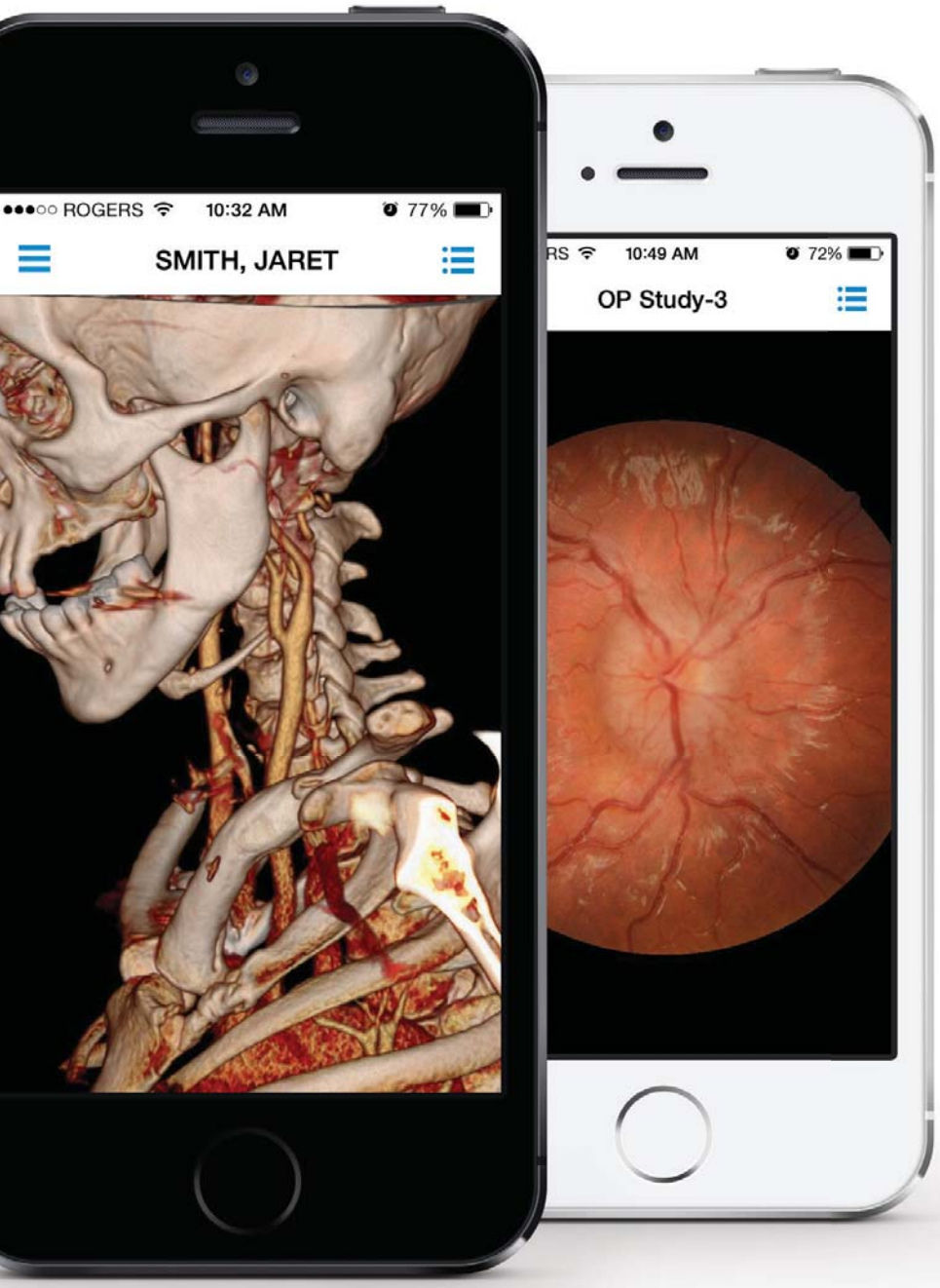
The healthcare industry is more dynamic than ever before. Innovative technologies have significantly enhanced the way medical practitioners diagnose patients, review images, seek second opinions, communicate results and generally approach the care they give. According to the Government Accountability Office, 75% of all imaging procedures are performed outside of the hospital setting. Because images are now being accessed remotely, it has become crucial to understand if the technology has been accredited. If it has not, diagnosis or treatment decisions using that technology should never be made.

This guide describes how to decipher between an accredited and non-accredited enterprise image-viewing solution and the risks of not understanding the differences.

# What Constitutes a Diagnostic Image Viewer?

Medical image-viewers should be accredited for diagnostic use by the various governing agencies. They should be FDA cleared in the U.S., CFDA certified in China, CE marked in Europe and/or Health Canada licensed.

In the U.S. there are two FDA classes for accreditation, Class I and Class II. Class I viewers are to be used to review patient images only, not to perform diagnosis. They are not reviewed for safety and effectiveness by the FDA. The process to obtain Class II clearance by the FDA is both lengthy and rigorous. If the image viewer does not have Class II accreditation, then it's not suitable to perform diagnosis. You can trust Class II accredited imaging technology as it has achieved the highest quality standards available and is classified in the same category as PACS.




# The Process

It is a lengthy and rigorous process to become accredited by governing agencies. The extensive validation includes steps such as independent laboratory testing to validate the performance characteristics of the device's display against the technical criteria from the American Association of Physicists, as well as clinical validation by board certified radiologists accredited by the American College of Radiology. The solution that is applying for FDA clearance will be tested against a previously validated mobile and/or PACS application. A panel of expert radiologists is used to establish the diagnostic safety and effectiveness of the combined hardware and software system. Each expert has to confirm that their criteria have been satisfied in the manufacturer's submission.

# “Diagnostic Quality” vs. Being Cleared for Diagnosis

Don’t be fooled with this tricky terminology. No governing body or individual regulates the term “diagnostic quality” – a term which means nothing if it’s not backed by FDA clearance.  There is no middle ground. Before investing in image-viewing technology that hasn’t been cleared by the FDA, medical practitioners should ask: what evidence does the creator of the technology have to back up their claims that the technology is effective? If they haven’t submitted their viewer to the FDA, why not?

# Risks of Using Non-Accredited Technology

Any treatment decision or treatment adjustment a medical practitioner makes upon viewing an image, could be considered a diagnosis.

Diagnostic errors are the most common type of medical mistake and it's estimated that they cost the healthcare system $38.8 billion in malpractice claims.

Non-accredited viewers with malfunctions or safety issues are not obligated to inform their customer base. Developers of FDA-cleared software are required to file reports with the FDA, notify customers and recall the product if necessary.

Every medical practitioner has the opportunity to minimize their risk by using technology that is accredited.


Sifferlin, Alexandra."Diagnostic Errors Are the Most Common Type of Medical Mistake." Time Health and Family, 24 April 2013. Web. 12 June 2013. http://healthland.time.com/2013/04/24/diagnostic-errors-are-more-common-and-harmful-for-patients/

Lowes, Robert."Diagnostic Errors Dominate Malpractice Payouts." Medscape News Today, 23 April 2013. Web. 12 June 2013. http://www.medscape.com/viewarticle/803026


**Medical Mistake Types**

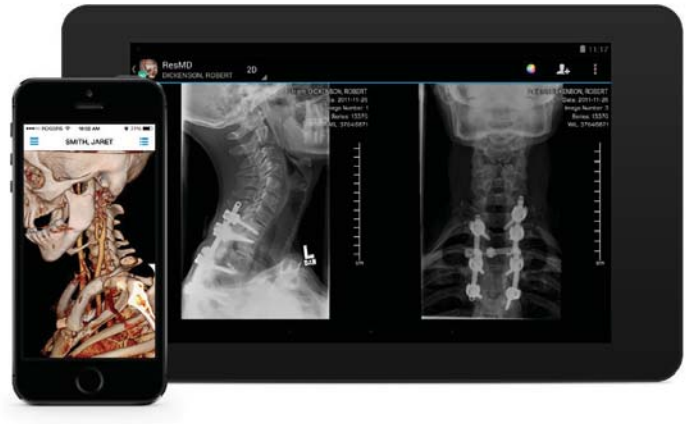
28.6% Diagnostic Errors
27.2% Injury Related Treatment
24.2% Surgery
6.5% Obstetrics
5.3% Medication
5.2% Other
3% Anesthesia and the like

Children's
of Alabama®

"We chose to implement ResolutionMD because it gives us the ability to quickly disseminate the images from our Pediatric Imaging Departments so that clinicians can provide the fastest and best care and treatment to our patients. Their fully accredited, diagnostic image quality and secure solution gives us the flexibility to make clinical decisions from any device type, portable or desktop throughout our healthcare system and off-site."

**Stuart Royal** ***M.S., M.D.,***
***Radiologist-in-Chief at***
***Children's Hospital of Alabama***

# ResolutionMD®



ResolutionMD® enables doctors to securely view patient images and reports from a wide variety of computers and mobile devices, collaborate with other practitioners and diagnose from any location. Whether you are a single facility or a large healthcare system with tens of thousands of users, ResolutionMD® is the best choice for seamless image access across multiple departments. The FDA cleared, CFDA registered, Health Canada licensed and CE marked mobile medical diagnosis software can be integrated into any EMR and easily plugs into existing distributed storage systems. ResolutionMD's federated approach is an important differentiator from other solutions as highly sensitive data is never moved to a device and no additional data storage locations are created. ResolutionMD® is currently installed in leading healthcare institutions around the world via a network of more than 45 world class healthcare partners. To see ResolutionMD® in action, access the self-serve demo.