Buyers Guide

Diagnostic vs. Non-Diagnostic Enterprise Image-Viewers – **Know the Difference!**

Enterprise Image-Viewing Technology for Diagnosis, Review and Communication

Calgary Scientific

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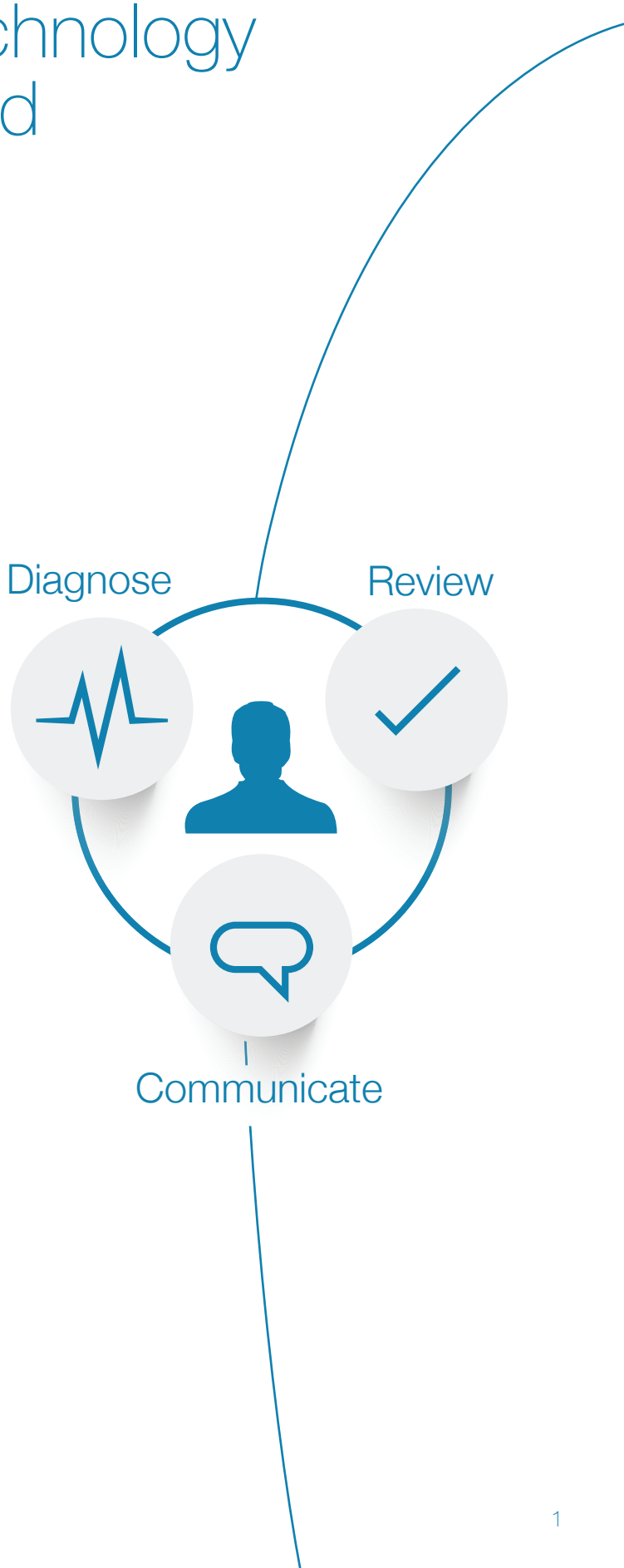
Healthcare and Technology in a Changing World

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.

Enterprise image-viewing technologies have enabled unprecedented levels of flexibility in the way diagnoses are made. Historically, medical professionals were limited in how they approached their work. In order to make an accurate diagnosis or review images, a doctor would need to be at a workstation. If they wanted a second or third opinion, they would need that person to have access to a workstation as well. Today, a diagnosis is now possible if the medical professional isn't at their workstation or even in the hospital at all. In fact, diagnostic images can now be securely reviewed and actioned on smartphones, tablets, and laptops from any location in the world.

The benefits of this flexibility are endless. Whether you are a radiologist, cardiologist, neurologist, specialist, general practitioner or any other healthcare provider, you can make quicker and better informed decisions to better serve patients. Additionally, there are opportunities for institutions to realize significant cost savings over older and more limited methodologies.



Navigating Image-Viewing Technology

Some of the hardest decisions medical institutions have to make are deciding what technologies to implement. These decisions impact all aspects of healthcare; from the level of service provided to patients, to provider and referring-base satisfaction, to the cost and risk incurred by the practitioner. Decisions about image-viewing technology are no different – there are many options and they are not all created equal.

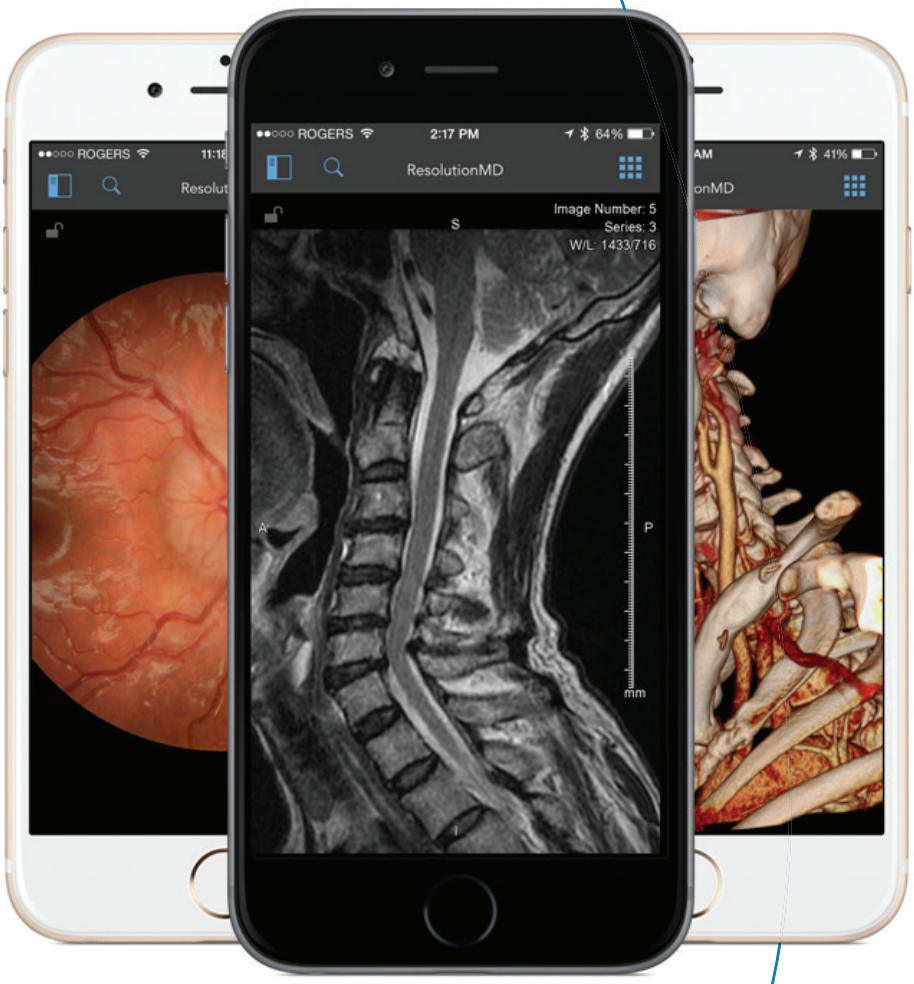
Major differences of enterprise image-viewing technologies lie in their overall functionality, data security and the terminology used to describe their intended use. This makes it difficult for the average medical practitioner or institution to distinguish between options -

in many cases it's nearly impossible to compare apples to apples.

Any company can claim their imaging technology is “good enough”, and while inexpensive or free imaging tools may appear to save funds in the short term, there are longer term considerations:

- What are the impacts on infrastructure, performance and data security?
- How do you know if it will perform the way you need it to?

Ultimately, whether you are diagnosing, reviewing or communicating results, you must have access to tools that offer the greatest functionality and carry the appropriate accreditations in the USA, your enterprise image-viewer must be FDA Class II cleared.



Purpose of the Guide

This guide was created to help you navigate the complex options available today and help you understand what criteria are important to consider when seeking the best option for your institution. In order to understand the differences between various image viewing technologies, we will explore the following:

1. **What is an acceptable enterprise image-viewer for diagnosis?**
2. **What is the risk of using an image viewer that hasn't been cleared for diagnostic use?**
3. **What factors should be considered when evaluating image viewers?**

To jump to any section throughout this guide, use the icons located in the upper right corner.


The Viewer


Diagnostic Quality


The Difference

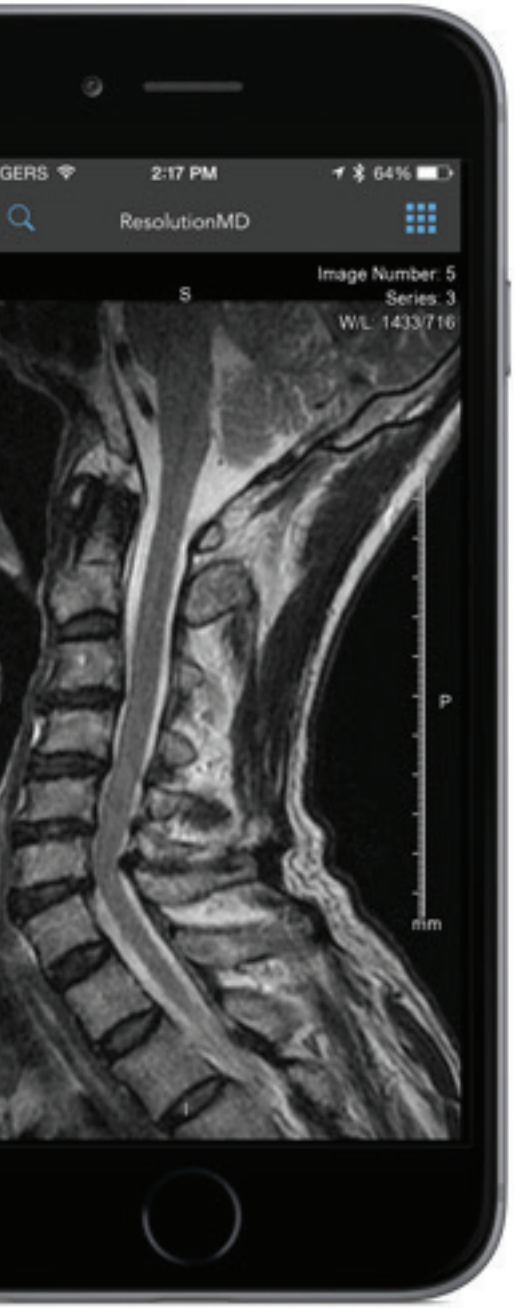

The Risks


Investing

What Constitutes a Diagnostic Image Viewer?

With all of the differences between image viewers, it can be nearly impossible for a medical institution to understand what information is most important. Anyone looking to make a decision on image-viewing technology should consider a few key criteria.

First off are accreditations. Medical image viewers should be accredited for diagnostic use by the FDA, CE and/or Health Canada. There are two FDA classes for accreditation, Class I and Class II. Class I only clears a solution for review, not diagnosis. 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

The extensive validation process 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 device and/or PACS workstation. 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 Clas II 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?

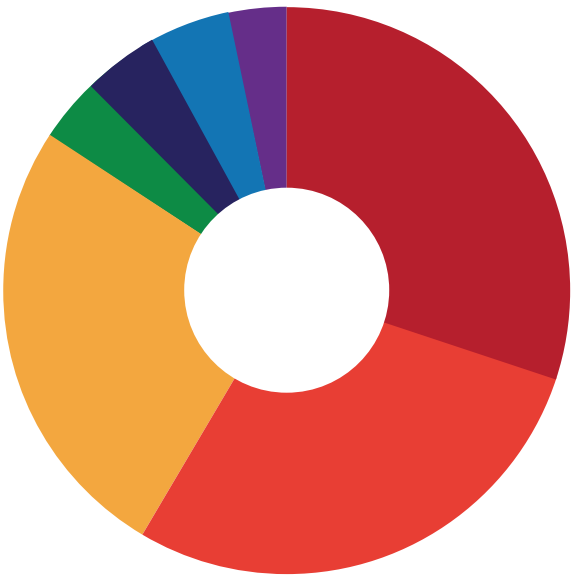
Risks of Using Non-Accredited Technology

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.[1]

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.



Percentage of Malpractice Claims[2]

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

[1] 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/

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

Access Logs

Medical practitioners who use an accredited diagnostic image viewer have the added benefit of access logs. The logs track three things:

1. If the image was viewed on a device that has been cleared for diagnostic use.

2. If the image was reviewed in an appropriate amount of time.

3. If a second opinion was obtained.

The logs also offer additional protection for medical practitioners. If a malpractice claim occurs, it is no longer one's word against another's, but rather a verified log of detail. This additional level of protection can ease the mind of medical practitioners who are responsible for making diagnoses.

For those medical practitioners that choose to use a non-diagnostic viewer, they need to understand that they're assuming liability if they're ever the subject of a lawsuit. In issuing a clearance, the FDA accepts risk associated with the software on behalf of American practitioners.

Investing in Image Viewing Technology

Decision makers are faced with countless options when it comes to image viewers. The sheer amount of information can make even the most dedicated medical professional cringe. There are several key criteria a medical practitioner or institution should look at before selecting which imaging technology they want to use for diagnosis, review and communication. They include accreditations, functionality, ease of use, data security and platform support.

1. Does the technology have the appropriate global clearances?
   Consider - if the technology hasn't been accredited, why not?

2. Does the technology have MPR and 3D viewing?
   Consider - some viewers don't offer 3D options or MPR, which means the medical practitioners using them aren't able to get a full view of what's happening with a patient. 3D also enables better communication between doctors and patients whether they are bedside or reading from their home office.

3. Does the solution work with key modalities, including CT, MR, CR, DX, ES, KO, MG, NM, OP, OT, PT, SC, US, XA?
   Consider - if it doesn’t, will your workflow be impacted?

4. Does the technology offer collaboration capability?
   Consider - in some situations, a second opinion is necessary. Will the solution allow you to quickly connect with specialists regardless of their location?

5. Does the technology offer quick access to side-by-side comparisons?
   Consider - when making a diagnosis, it can be helpful to quickly and easily display a side-by-side comparison of new and previous images to allow practitioners to see changes or progress made in the patients’ condition.

6. Does the viewer integrate into your EMR or other point of care system?
Consider - some viewers require you to leave your workflow and go to a separate portal just to access an image or report.

7. Can the solution integrate with multiple image archives?
Consider - if it can't you may have to log into multiple systems to get a full view of the patient, wasting precious time, which is significant especially in acute care situations.

8. Does the technology offer both web and mobile solutions?
Consider - by offering both, medical practitioners have the advantage of viewing diagnostic images from anywhere.

9. Is the technology FDA-cleared for both web and mobile use, or only one?
Consider - several diagnostic image viewers have only been cleared by the FDA for mobile or web use – not both. This means that using the diagnostic image viewer on a platform it's not cleared for still leaves the institution open to risk.

10. Is the technology FDA-cleared for use on leading device types?
Consider - diagnostic imaging software must be cleared for each device separately – an FDA clearance for iOS doesn't mean the software can immediately be used on Android.

11. Does the technology have a mobile solution that is fully functional, or is the functionality limited?
Consider - some image viewers may only offer a stripped down mobile solution.

12. How secure is the technology?
Consider - does it download data to the device, compromising both the medical institution and patient's confidentiality.

International Accreditations

In the US and Canada, ResolutionMD® has received FDA Class II certification and the Health Canada License, respectively. Across the Atlantic, the software has met the security, safety, health and environmental protection requirements of the European Union's CE Mark. In Asia, we are certified in China (CFDA), Japan (Pharmaceuticals and Medical Devices Agency, Class II), Hong Kong (Department of Health Medical Device Control Office), South Korea (Ministry of Food and Drug Safety) and Singapore (Health Sciences Authority). In Australia, ResolutionMD® is certified by the Australian Therapeutic Goods Administration. Our most recent certification is in Brazil, where ResolutionMD® is now registered with its health surveillance agency called Anvisa.

ResolutionMD® – the Leading Choice for Enterprise Imaging Solutions

ResolutionMD® meets all of the above criteria – and then some. The software is a true enterprise web and mobile tool on one platform, retrieves data from multiple PACS and archives, never downloads data to the device, increases speed of diagnosis by expanding the access to medical images beyond a standard PACS workstation and a second opinion is a click away with the collaboration capability. ResolutionMD® has most of the global diagnostic clearances available, including FDA Class II. This means that medical practitioners can feel confident using it.

ResolutionMD® offers features that other medical image-viewers simply can't match. That is why the world's top OEMs, partners and leading healthcare institutions choose it over the rest.

To see ResolutionMD® in action view the video, or access our self-serve demo.

About 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. ResolutionMD is globally accredited by the FDA, CFDA, TGA, PMDA, MDCO, MFDS, HSA, CE, ANVISA and Health Canada for mobile medical diagnosis. The 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 any 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 forty-five world class healthcare partners.

About Calgary Scientific Inc.

Calgary Scientific is the global leader in web and mobile diagnostic medical imaging solutions and application modernization technologies.

calgary scientific

www.calgaryscientific.com

Patient data in this document is anonymized