

# **Diagnostics: A Focus on Imaging, Portability, and Regulations**

Kasey Panetta, Managing Editor, ECN

Diagnostic technology covers a broad range of equipment, tests, and medical fields, and recent advancements in technique and materials means that innovations are widespread and growing rapidly.

## **Imaging**

Though current economic conditions are preventing huge advancements in diagnostic imaging—if hospitals and imaging centers can't afford the new technology, there is no point in designing it—the medical imaging community is focusing on refinement, rather than redesign, according to Stephen Holloway, senior analyst, InMedica, part of IHS Inc. Instead of massive overhauls, the focus will be on automation of technology with tools like auto-positioning x-ray machines and the addition of wireless controls. At the same time, the machines will be shrinking—particularly ultrasounds—down to tablet or smartphone size, which will allow for more access in remote areas. Some technology (i.e., x-rays) are limited in this capacity because despite advances allowing for a smaller design, issues like radiation mean they're usually restricted to specific types of rooms.

On the reading side, image quality will improve with more channels processing power and improved resolution. “High-field 3T MRI is becoming increasingly common for diagnostic use in hospitals, as is 128 or 256 slice CT; such systems boast far greater capability in terms of image resolution and processing power. In ultrasound, major steps have been made in base image quality, particularly in 3D and 4D imaging, navigation, and automated measurement,” says Holloway. “In x-ray, the majority of users are shifting to digital technology, facilitated by application and evolution of flat panel detector technology.”

Past the actual design changes, the medical community will see further integration of imaging with healthcare IT systems with the advancement of digitized medical records (PAC, EMR) to allow for a future of widespread tele-radiology and remote imaging, says Holloway.

## **Oncology Diagnostics**

For companies that specialize in oncology, genome sequencing and handheld real-time diagnostics are making the largest impact on future designs.

When dealing with cancer, precision and speed can greatly affect success rates. Hand-held sensors that use electromagnetic pulses to detect single cells remaining after surgery offer the surgeon the ability to make a real-time diagnosis, instead of assessing if the cancer remains after the surgery, says Robert Stephan, Ph.D., medical director for The Arcas Group.

“There is a lot of work in blood cancers on using quantitative PCR to measure minimal remaining disease and being able to quantify the presence of one in a million or one in 10 million, which can mean we need to treat it more or we don’t need to treat it more,” says Dr. Stephan. “We’ve gone from palpation to an x-ray to now PET CT scans and each allows us to better see what the next step needs to be.”

The availability of genome sequencing for tumors and humans is reducing some of the guessing game that can be involved in cancer diagnoses. The more knowledge a doctor has about a patient’s specific DNA makeup, and the makeup of various tumors, the more accurate the diagnosis and the more efficient the treatment. Additionally, some pharmaceutical companies are releasing diagnostic kits with their treatment options, so doctors can identify which patient will benefit the most from that particular treatment, says Jan Heybroek, MSc, MBA, MBI, president of The Arcas Group. “The availability, but also the affordability of these types of options—the sequencing of your DNA, the tumors, and medication—will be a trend moving forward,” says Heybroek. “Plus, because of the super-specialization and affordability of the techniques, it’s becoming more available in the smaller cancer markets like melanoma. We’re seeing more tests for more specific diseases and more specific stages.”

### **Smaller Devices**

As noted previously with imaging, diagnostic designs will continue to move toward a future of smaller, lighter, more mobile designs. Some will be restricted in screen size and location, but, in general, the trend will be toward convenience and flexibility of design.

“You’re taking existing technology and stripping it down to the core components of imaging and diagnostic technique to make them portable and you don’t necessarily need an expert to be physically there to read it because you can send the image to them,” says Venkat Rajan, Medical Devices analyst at Frost & Sullivan. “In emerging markets, you may not have a cardiologist that specializes in pediatrics on staff, so you can go out, do the diagnostic scans, and upload it in real time to an expert in a different country.”

One barrier to this is network infrastructure that might be unable to handle the size of the data being transferred. At this point, the basic diagnostic equipment (i.e., blood pressure, electronic stethoscope, pulse) can be tracked using a briefcase-sized piece of technology, but there are still problems in terms of what to do with the data and how to transfer and store it.

### **Regulation**

With an increasing amount of improvements comes increasing amounts of regulations and limitations. Outside of the financial limitations of having your genomes sequenced—Steve Jobs, former Apple co-founder paid \$100,000—there are issues with having all of these new handheld technologies approved by the FDA and questions about how effective they will actually be.

Some of these diagnostic technologies—particularly any home-based options—are going to be more early indicators that something is wrong and you should see a

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doctor, rather than actual home-based diagnosis, says Jonathan Collins, Principal Analyst, mHealth & M2M.

“It’s not just regulation,” says Collins. “There’s an aspect to diagnosis that is an art and not a science, which may well need the experience and knowledge of a doctor, but also to supply the responsibility for the diagnosis.”

### **Conclusion**

With more remote diagnosis on the horizon, the issues of responsibility, data size, and regulation are also looming, but so is the promise of faster, more efficient diagnostic equipment. Striking a balance between the two might be the key to an improved, healthier future.

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