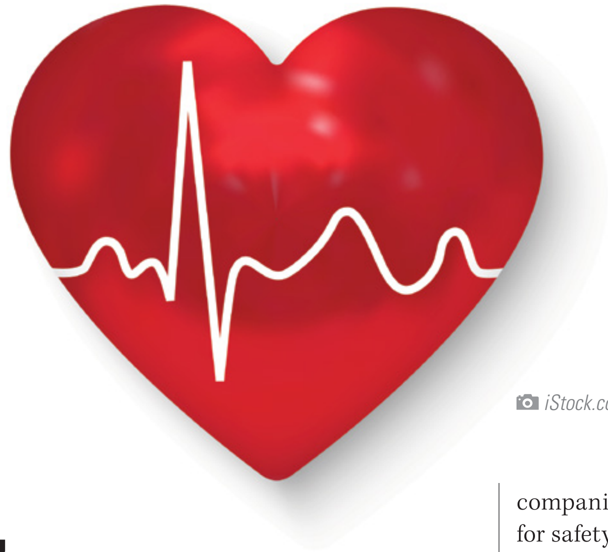

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SPECIAL REPORT

TELEMETRY, DIGITALIZATION DRIVING CHANGE IN MEDICAL TEST

By **Mike Hockett**, Editor-in-Chief

Of all the applications for electronic test & measurement, none have anything close to the direct impact on the health and well-being of consumers as in medical test. The stakes couldn't be higher when it comes to the protocols that go into testing electronic medical devices, as the consumer-applications for this field couldn't be more literal.

Unfortunately for the medical device market, the biggest news that comes from it is often bad: devices causing injury, malfunctions resulting in wrongful death lawsuits, or simply devices not functioning as intended. What's often lost through the reporting of all the bad that can result from oversights in medical testing is that millions of lives have been saved or made better thanks to medical devices. Nonetheless, it seems device manufacturers are constantly challenged to make sure they stay out of negative headlines. They do so, in large part, thanks to the products and solutions from test & measurement vendors.

Trending

Technological advances in electronic medical test continues to enable engineers to innovate new medical equipment and devices from those used in an emergency room, to wearable devices that allow patients and everyday consumers to monitor specific health factors by checking an app on their smartphone.

We at *Evaluation Engineering* gathered commentary from several leading test & measurement vendors about what they're seeing as key recent trends in the area of electronic medical test, or trends they're expecting to rise in the near future.

Montreal, Quebec-based ***Averna Technologies***, a provider of automated test and quality solutions, elaborated on procedures that go into testing of specific electronic medical devices. Company chief operations officer François Rainville and sales manager Javier Olea combined to pick the incorporation of telemetry into medical devices such as the top trend they're paying attention to.

"Medical devices that incorporate telemetry features—such as pacemakers, deep brain stimulation systems, insulin pumps, or ventricular assist devices—used to leverage custom protocols to exchange data with medical equipment, devices, or professionals," Rainville and Olea said. "The reason why medtech companies used custom protocols was for safety reasons, power consumption, and compliance. But now, as commercial technologies become more available, stable, and consume less power, med device companies are relying more and more on technologies like Bluetooth Low Energy (BLE) for their telemetry features. With off-the-shelf connectivity technologies, the development cycle is faster, and from a reliability and compliance point of view, BLE is no longer a concern."

The Averna duo went on to say that with commercial technologies comes the challenge of safety—specifically in that companies must ensure that unauthorized intrusion is not possible, doing so through incorporating safety features into these standard communication protocols.

"As medical devices integrate more RF and telemetry connectivity features, new test and compliance strategies are required," Rainville and Olea added. "Consequently, many medtech companies partner with RF test experts to create and implement the appropriate test and compliance strategies at both the R&D and manufacturing stages."

As another trend, Rainville and Olea said that for pharmaceutical companies, the actual medicine is no longer the only differentiator.

"Now companies are developing smart injectors that can give real-time insight to medical professionals or administer automatically precise doses," they explained. "Another technological breakthrough in this industry is the microelectronics pills or capsules that collect and share information and data."

Thierry Marchal, global industry director for healthcare at *ANSYS* and secretary general of the Avicenna Alliance, stressed to *EE* that the biggest trend he's seen in medical device test is the rapid increase in digitalization.

"Computer models are becoming increasingly popular in the medical device industry," Marchal said. "As they become very accurate and reliable in their prediction of the behavior of any medical device interacting with the human body, they have been used by all leading medical device companies for more than a decade to design and optimize new prototypes. Recently, the FDA, followed by the House of Congress and the US Senate, have paid more attention to this in silico approach (e.g. using computer models to complement the in vitro and in vivo approach)."

Marchal explained that the U.S. Food and Drug Administration (FDA) has been investigating the in silico approach since 2011 and is now strongly encouraging the adoption of this technology by medical device companies.

"After a very successful meeting between Sen. T. Cochran, the FDA, and leaders of the Avicenna Alliance including ANSYS, Medtronic, Johnson and Johnson, etc. in May 2017, the U.S. Senate and House of Congress published bills in July 2017 stating the value of the in silico approach to reduce the risk for the patient but also to reduce the cost of healthcare while accelerating the pace of medical device innovation. As a result, the U.S. Government will be providing funding to the FDA as part of its 2019 budget to support FDA's in silico and digital twin initiatives.

Marchal added that the European Parliament has similarly agreed to support the development of silico medicine in an event this past September. And this past Nov. 8, the American Society of Mechanical Engineers published a new standard—V&V 40—explaining how to properly verify & validate computer models targeting medical devices so that they could be used for regulatory approval.

"This is opening the door to 'in silico clinical trial', e.g. complementing and partially replacing clinical trial by virtual patients and computer models," Marchal said. "This progressive digitalization of the medical testing is probably one of the most important medical evolution of the last few decades."

Into use

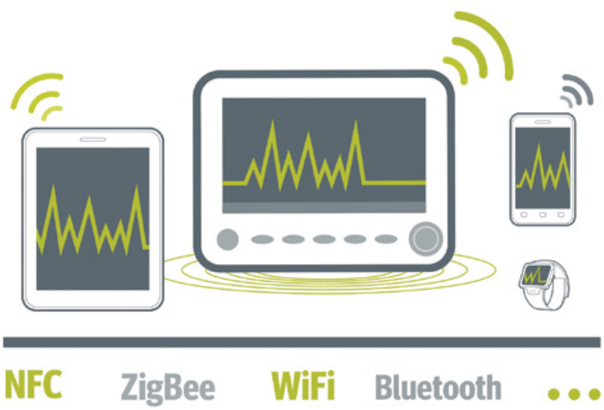
We asked our report respondents to describe a recently completed project that addressed a medical application, the shortcomings it addressed, and the key challenges involved. Here's what they had to say.

Rainville and Olea, Averna: "Great advances have been made recently in both the functionality and size of hearing aids and related accessories. As the devices get ever smaller, they also become ever more powerful with additional functionality and user options. But the trend of miniaturization brings with it multiple new challenges for product designers. That's why our client contacted Averna—to develop a flexible test solution for RF performance at the physical channel level, ensuring their Bluetooth LE-enabled devices conformed to design specifications. As well, they tasked Averna to architect the test system so it could easily be adapted for other purposes. In other words, they wanted to maximize their return on investment with a future-proof test solution for their evolving product line."

"Our highly-flexible and powerful test solution has significantly improved our client's production yields and sped up its product validation process. As well, the extensibility of the fixtures allows our client to easily adapt the station to handle a wide range of future products. Based on the client's technical and business requirements, Averna designed and engineered an advanced test system that comprises:

- A universal tester containing all required hardware, including National Instruments' PXI, PC, and power supply—neatly stored in a standard rack
- An expandable fixture on which two PCBAs can be placed at the same time
- A mechanical adapter that allows the operator to smoothly change the fixture to hold different types of products
- A suite of productivity tools for test sequencing, test data management, system calibration, user management, and other tasks

Marchal, ANSYS: "During a recent event in Brussels, Belgium, Michael Hill, vice president of science, technology, and clinical affairs at Medtronic, illustrated the concrete impact of modelling and simulation on providing regulatory evidence by mentioning one of their products—a pacemaker, recently released two years earlier



A recent client project involved Averna Technologies developing a flexible test solution for RF performance at the physical channel level, ensuring the client's Bluetooth LE-enabled devices confirmed to design specifications and archetyping the test system so that it could be adapted for other purposes.

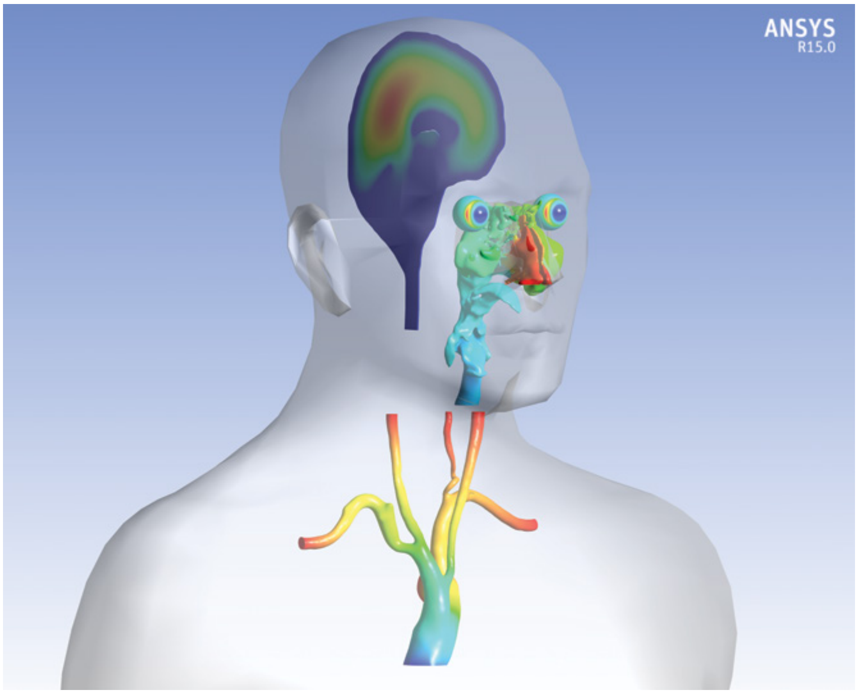
than expected, reducing the clinical trials by 256 patients and the estimated cost by $10 million while allowing to treat 10,000 patients during these two years. Medtronic is using ANSYS tools among others to test the electromagnetic interaction of implants and human body to avoid local necrosis of soft tissue.

"On one end, there is a strong public opinion and requests from governments all around the planet to minimize the risk for the patients by maximizing the number of tests on larger samples of the target population before approving the release of any new medical product. On the other end, considering that the cost of clinical trial could be up to $40,000 per patient participating in the trial, if regulatory authorities require that medical device companies must increase their clinical trials by thousands of additional patients to better validate the full safety of a device despite the population variability, this request would dramatically increase the cost of the regulatory approval process.

"The use of virtual patients and computer models in a first step, and patient digital twin in a second step, provide medical device companies the opportunity to complement, anticipate, and partially replace traditional clinical trials with 'in silico clinical trial'—bridging the gap between patient safety on one end, and affordable and profitable healthcare on the other.

"For the last 20 years ANSYS has been working to share best practices from industries that have successfully pioneered the adoption of engineering simulation to deploy them in the healthcare industry. By working closely with regulators and market leaders, ANSYS is ensuring that simulation is used pervasively by all healthcare actors.

"These computer models remain models, a representation of the reality. Therefore, it is crucial to make sure that medical device designers could rely on them before making any medical decision. Technically speaking, it is important for companies to develop reliable models able to accurately predict what is likely to happen in the very complex human body. This never-ending challenge requires more research and investment to improve the models in their accuracy, long-term predictability, and ensure we fully understand the limitations of the current model.



▲ ANSYS client Medtronic is using ANSYS tools to test the electromagnetic interaction of implants and the human body to avoid local necrosis of soft tissue.

"Validating the models is the second challenge. During the last few years—under the guidance of the FDA and ASME—ANSYS has collaborated closely with the leading medical device companies to develop the new standards for verification and validation of medical devices (ASME V&V 40). Finally, making sure that these models are accepted by regulatory authorities and clinicians is the third challenge requesting a lot of communication and education."

When things go wrong

This past December, the International Consortium of Investigative Journalists (ICIJ) released the results of a yearlong investigation into the harm caused by poorly-tested medical implants.[1] The findings were led by FDA data showing that more than 80,000 deaths and 1.7 million injuries were possibly linked to medical devices in the 10-year span between 2008 and 2017. It should be noted that the data covered implants of all types—from hip implants to breast implants—and didn't show results specially for electronic implants.

ICIJ's research found that in the U.S., the average time for a new device to be approved through the FDA's premarket approval process has dropped by more than 200 days since 1996. While that major time-to-market improvement is great news for device manufacturers, speeding up the approval process can also result in devices that are more prone to faults. Manufacturers certainly don't like overregulation, but minimal testing for the sake of faster marketing often spells disaster, no matter the industry. ICIJ pointed to a 2016 study by medical journal BMJ that found devices first approved in the European Union—known for light-touch regulations—were associated with a higher rate of safety alerts and recalls than those approved in the U.S.

In 2017, Market Research Engine forecasted that market for electronic medical device implants—also known as active implantable medical devices—was expected to exceed $256.75 billion by 2022.[2] EE

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1. International Consortium of Investigative Journalists, "Everything You Need to Know About the Implant Files," December 3, 2018.
2. Market Research Engine, "Active Implantable Medical Devices Market by Product Segment Analysis," May 2017.

By Daniel Bogdanoff

"Questioning anything and everything, to me, is punk rock."

—Henry Rollins, punk rock pioneer

If Henry Rollins were an engineer instead of a media icon, he'd still say it's time to question everything. Today's automated test environments (ATEs) need oscilloscopes. It's undeniable.

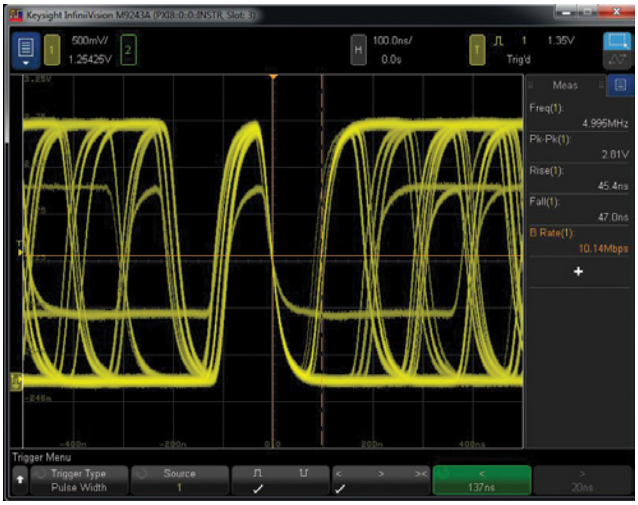
But what kind of oscilloscope do they need? A traditional, box-with-buttons-and-a-screen oscilloscope isn't necessarily the best option. ATEs have different requirements compared to design labs. Here's a quick rundown of common ATE oscilloscope requirements. They must:

- Be low profile and rack mountable to save floor space
- Have remote control and display capabilities to give engineers a consolidated view of their ATE
- Streamline data analysis and acquisition sizes to reduce test time
- Perform mask testing to test pass/fail

All these requirements are unusual for oscilloscopes. They're on the fringe of the test-and-measurement scene. That's why scope manufacturers have spent the last decade questioning what their oscilloscopes should look like. Can you imagine using an analog oscilloscope on a manufacturing line?

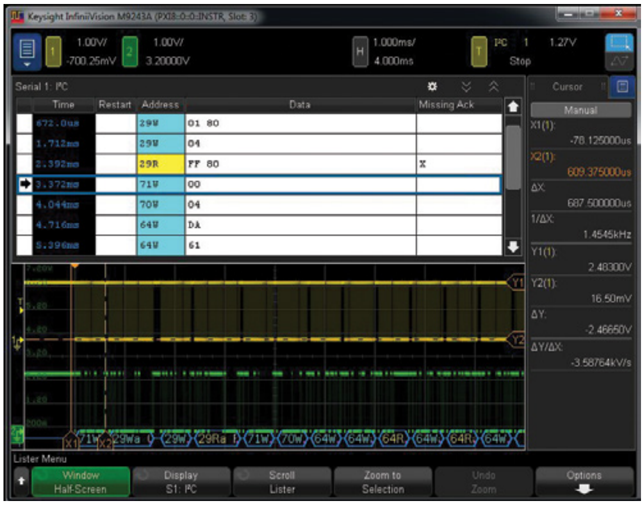
Much like punk rockers defined a new music genre in the 1970s, new oscilloscopes are building their own subculture in the engineering back alleys of the ATE world.

Here's what's converting classic oscilloscope fans over to the new genre.



▲ Figure 1: When a runt pulse occurs just a few times per second on a high-frequency signal, it takes a high waveform update rate to capture and display the signal. Advanced triggers can be utilized to further isolate the signal.

▲ Figure 2: Isolating a signal with a non-monotonic edge is as simple as drawing a box on the signal of interest and selecting "must intersect." With normal triggering circuitry, this would be much more complicated.



◀ **Figure 3:** Serial communications are decoded and events analyzed with advanced protocol analysis tools. Here we see a count of CRC errors on an automotive CAN communication link.

Low profile, rack-mountable design

Automated test environments almost always have racks of test gear. There's no "bench." Some companies made their way in the test and measurement world by doubling down on this design choice. ATEs don't want big, clunky instruments. They don't need every oscilloscope to have a screen. They don't need front panels. They want it all automated and they want it small.

Traditionally, ATE engineers had to make a choice. They had to decide between a small oscilloscope with compromised performance and a larger, full-featured scope. Not an easy choice.

Today, that choice is much less of an issue. Major oscilloscope manufacturers are actively designing oscilloscopes specifically for ATEs. They're leveraging existing technologies and chipsets to bring full benchtop scope capabilities into tiny form factors.

Sometimes these are standalone units, but often they are modular, chassis-based oscilloscopes that can be combined with other types of test gear to create a custom ATE solution.

Waveform visualization

All oscilloscopes acquire data, process it, and plot it on a screen for troubleshooting and signal analysis. But ATE engineers need to see their data from a physically separate location. They can't stand next to their oscilloscopes all day checking multiple screens.

So, ATEs traditionally tried to use digitizers in place of oscilloscopes. Digitizers just don't cut the mustard in some areas, though. ATEs are extremely sensitive to how long each test takes. Since digitizers don't do automatic interpolation and plotting, the end-user must do it. This becomes a testing bottleneck.

Oscilloscopes are designed to interpolate and plot data quickly. That's why manufacturers specify things like "waveform update rate." They do this so fast the human brain can't process it all at once. That's why scope "waveform intensity" control is critical.

Update rate and intensity control are commonplace on oscilloscopes for the design bench, but they are just recently making their way into the ATE world. For example, look at **Figure 1**. This scope display shows multiple waveforms overlaid onto the screen at the same time, thanks to its fast update rate. And waveform intensity controls allow the user to quickly identify errors in their signal. If you tried to see this much data at once with a digitizer, you'd be disappointed.

Additionally, modern benchtop oscilloscopes are known for their advanced trigger capabilities. Today's leading ATE oscilloscopes leverage the trigger circuitry and logic from their benchtop counterparts. For example, **Figure 2** shows a modern, ATE-focused oscilloscope that has imported zone trigger capability.

It's also worth noting that some sort of remote connectivity is a must-have. Notice that **Figures 1 and 2** are screenshots from a PC and not a screenshot from the scope itself. Ethernet or USB are preferred, but some legacy systems use GPIB and VGA for control and display.

Streamlined data acquisition

ATE test scenarios typically don't require every bit of acquired data. Extra data means unnecessary time spent on data analysis or transfer. Much of this can be avoided using advanced oscilloscope triggers—engineers capture only the data they want to see. It can be streamlined further using oscilloscope digitization using coded commands, which allows for capturing and collecting a smaller data size.

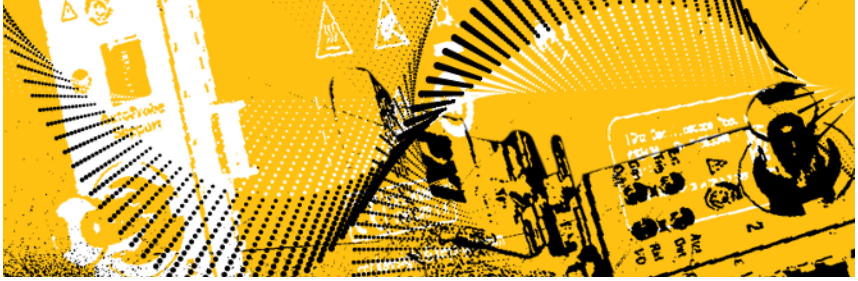
Sometimes engineers can even get away with zero waveform data. Simply identifying and counting trigger events is all that is needed.

Integrated tools

Integrated tools are all the rage for benchtop oscilloscopes. And since scope makers are starting to leverage those chipsets, why not use them for ATEs as well? Modern small form factor oscilloscopes are finally getting things like integrated arbitrary waveform generators arbs and counters. For basic tests, this can eliminate the need for extra equipment.

Advanced functionalities are also trickling down from benchtop oscilloscopes—capabilities that are unheard of in traditional ATEs. Take Figure 3, for example. This modular scope can decode and trigger on specific protocol packets and even trigger on errors.

These additional capabilities give ATE engineers unprecedented flexibility when designing and refining their test procedures.



Waveform mask testing

This one's clear, so I'll be brief, like a song off a Ramones album.

Pass/fail testing is a must-have. In the past, ATE systems often required custom FPGA work to provide real-time pass/fail data. Some of today's ATE-focused oscilloscopes, like the scope we've been looking at today, can run hundreds of thousands of tests per second using internal hardware. They also provide some quick troubleshooting capabilities like the ability to easily create a mask based on a previously-captured "ideal" signal and report test results as six sigma performance benchmarks.

Appropriate probing

There are two main considerations for ATE probing.

The first is signal integrity. In the past, most ATEs were only concerned with dozens or hundreds of MHz. As signal speeds increase in speed and decrease in amplitude, probing becomes more important. An off-the-shelf passive probe or cabled-in connection may not be enough for today's test requirements. The ability to leverage higher-end probes into ATEs is crucial.

The second consideration is probe diversity. ATE oscilloscopes should work with multiple types of probes. In addition to standard passive probes, many ATEs require high-temperature probes, high-sensitivity current probes, high-current/voltage probes, power-rail probes, or extra-long cabled probes. This simply isn't a possibility with many scopes.

Oscilloscopes for ATEs: "question everything"

Automated test environments often place a heavy burden on the software program (and the programmer). They must perform correct analysis while characteristics are still under development or while profiling a system's operational performance. Software processes are beyond the scope of this article, but it's fair to say that it rides on the back of the hardware.

In the past, ATE implementers had to rely on benchtop oscilloscopes to get the job done. Times have changed. ATE scopes have come to the masses. So, throw on your black leather antistatic jacket and rock on. EE

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