

FDA Wises Up to Smartphones (see page 35)



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NEWS



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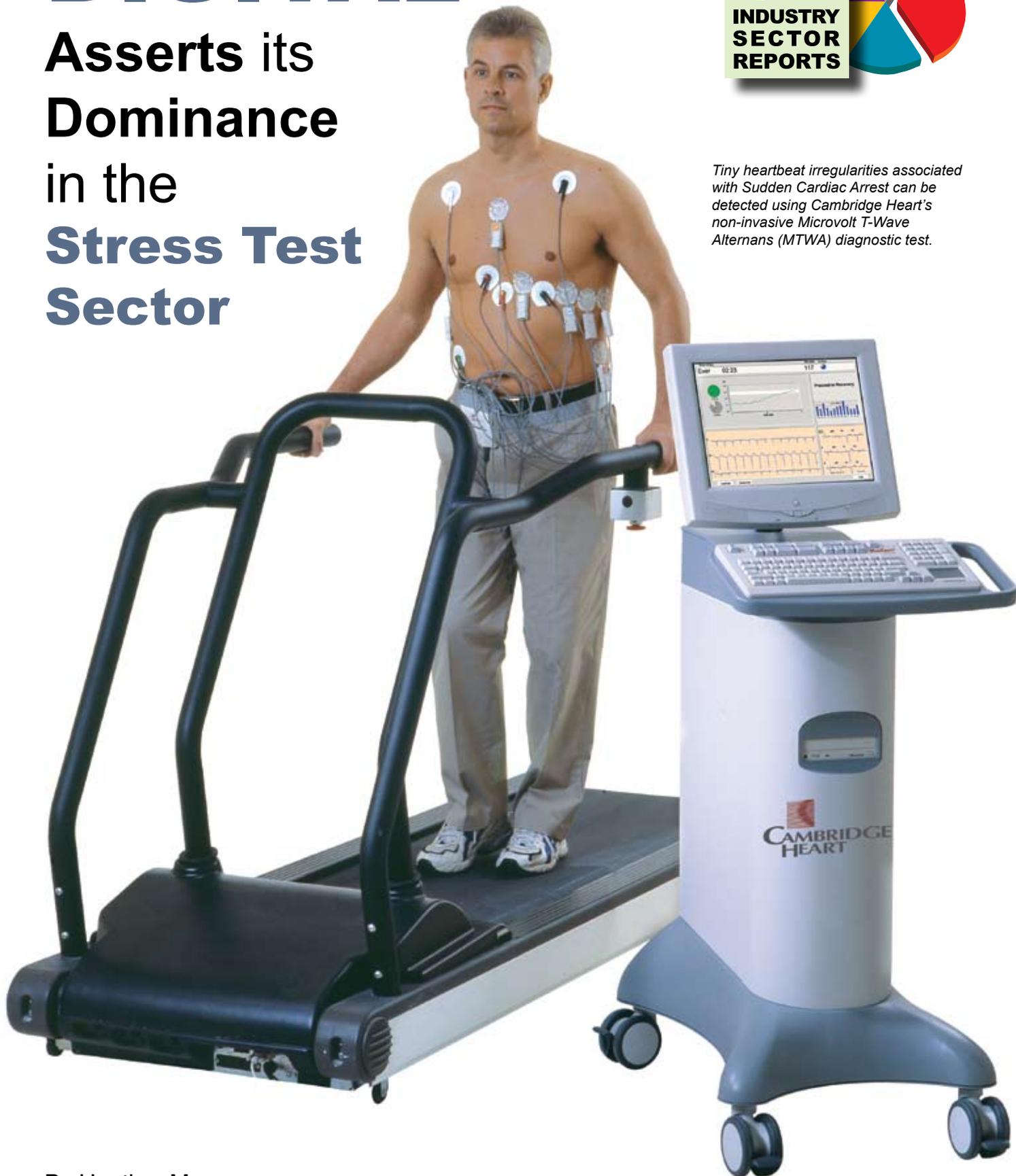
- **Robotic Surgery: Robots in the O/R, Monopoly in the Market**
- **Reimbursements No Longer Stress Tests**

DIGITAL

Asserts its Dominance in the Stress Test Sector



Tiny heartbeat irregularities associated with Sudden Cardiac Arrest can be detected using Cambridge Heart's non-invasive Microvolt T-Wave Alternans (MTWA) diagnostic test.



By Heather Mayer

The move toward digital technology is infiltrating the cardiac stress testing market — and fast. While 75 percent of the market still uses a traditional stress test, professionals in the industry expect a complete transition to digital within three to five years.

But the push toward digital systems — PC-based modalities — isn't being done to improve the accuracy or efficacy of the actual tests. In fact, the majority of tests being done today are very similar to those performed for the last few decades and there seems to be little reason to change them. Instead, using a PC-based system allows physicians to have access to their patients' records and test results all in a neat, easily accessible electronic medical record (EMR).

"It's not just stress tests [that are moving toward digital]," says Gordon Huckestein, general manager of EdanUSA. "It's every diagnostic test out there. Everything is migrating toward the PC because of the fact that doctors are required to have a medical record system. That is really driving the growth."

Michael Moore, the director of sales for Nasiff Associates, Inc., points out that while about 80 percent of doctors today do not use PC-based systems, he expects that in just five years, half of those systems will be replaced by a PC-based stress test.

"That is the future that has to be," Moore says.

With the growing number of health care providers beginning to use electronic medical records, a PC-based system would allow for a "smooth" transition from test system to a patient's electronic record, says Moore.

Huckestein also acknowledges that benefit. Having a PC-based system allows physicians to seamlessly go through a test and have that information reported right into their patients' records.

"Doctors realize, 'If I am going to have to convert my results into a digital format, I might as well already be on the PC when performing the diagnostic procedure,'" he says. "This eliminates the extra step of uploading."

Stress test manufacturers recognize the trend, but it was Nasiff Associates, Inc. that came out with the first

PC-based PC ECG/PC EKG system 20 years ago.

"As you can imagine, when Nasiff designed the PC system in 1989, it was not as accepted as it is today because computers were not as common in a physician's office," Moore says.

But now, older stress testing machines are on the outs.

"Most of our old stress machines will be obsolete in about 10 years," says Bulent Buyukoglu, manager of US-medevise, LLC.

Not only does the PC-based system make stress testing simpler for physicians, it also makes communication between doctors easier, say Buyukoglu and Huckestein.

"The digital aspect allows communication between specialists to be more efficient because you'll have a physician who wants a second opinion, and he'll e-mail the ECG over to the hospital or a cardiologist," says Huckestein. "It creates improvement in communication within the medical field."

All-in-one stress testing

Not only is Nasiff Associates, Inc. a leader in PC-based stress testing technology, the company has just introduced a complete turnkey system: CardioStress Complete.

"It's easy as plugging it in," Moore says, with regard to the system, which comes fully equipped with a treadmill and computer software. "A turnkey system needs to be complete. It gives the customer peace of mind that we're not leaving anything out."

Nasiff Associates, Inc.'s system,

says Moore, is \$6,000 less than the competing system. The CardioStress Complete goes for about \$12,800.

"Given our current economic climate, it comes down to a price alternative," he says.

Same service for less

Nasiff Associates, Inc. isn't the only company capitalizing on users' need for low-cost alternatives to the brand names like GE Healthcare. While the refurbished marketplace is seeing a rise in sales, smaller, lesser-known OEMs — largely Chinese manufacturers — are also making waves.

"The refurbished marketplace is stronger these days, but people also look to alternative solutions, like other brands, which are less-known than big brands like Philips or Nellcor," says Buyukoglu. "Our position is exactly on these alternative brands with more affordable pricing. But when you sell other brands, you have to explain that they are at least as effective as big brands."

As a cardiologist, Buyukoglu says part of his job is to give confidence with this "primordial point in business."

"I know how it works because I use them myself," he says.

Huckestein, with EdanUSA, says that physicians are looking for those "less expensive, secondary brands." His company introduced a PC-based stress system last month, selling for less than \$10,000.

"Our focus is on selling those kinds of products that match the budget of someone who doesn't want to spend \$15,000 to \$20,000 on a premium-branded product," Huckestein says.



Nasiff CardioStress™
Turnkey System

Currently, cardiologists use machines in their private practices, but Huckestein speculates that practices might revert back to the old trend: directing patients to a hospital for stress testing.

“Reimbursement is now less than \$100 — the national average,” he says. “We are seeing a new trend now where the primary care market is referring stress test exams to their local hospitals or cardiology groups. When the market was favorable, we saw the opposite. Outsourcing is now the trend versus performing these exams in-house. The costs just don’t justify the means.”

“Our response to that is, ‘Hey, let’s give doctors what they want, and that’s something less expensive,’” says Huckestein.

But Joe Avina of American International Medical, a refurbishing company, says the trend toward mostly foreign secondary companies will be short-lived.

“We’re already getting people on the rebound,” he says. “They tried it and want American.”

Avina says the refurbishing market is booming right now, as more and more providers turn to less expensive equipment; he says the average price for a refurbished PC-based system is \$12,000 to \$15,000, and \$5,000 to \$9,000 for a traditional test.

American International Medical boasts a 40 percent increase in sales from last year, and it’s expected that number will grow.

“A major trend is huge growth in requests for refurbished systems,” he says. “I think it’s the economy.”

But the passage of health care reform is also expected to drive sales in the refurbished market, he explains. This could be attributed to the millions of Americans who will receive health coverage under the new law.

“[The health care law] seems to be increasing activity tremendously,” he says. “I see it because we’re in this market. We’re going to benefit from the health care reform.”

Correction boosts reimbursement

The Centers for Medicare and Medicaid (CMS) announced last month it would boost reimbursement for SPECT nucle-

ar imaging by 16 percent. The increase is a correction to the 2010 reimbursement, which cut nuclear stress testing to 36 percent, according to a CMS report.

“This is a very significant occurrence, perhaps among the most important, especially since Obama has become president, as far as cardiologists are concerned,” says Avi Soffer, CEO and vice president of University Nuclear & Diagnostics.

The cut decreased from 36 percent to 20 percent, which will allow cardiologists some breathing room, Soffer says.

“[The 36 percent cut] was an unsustainable blow,” he says. “It’s a deal breaker for the business.”

Soffer points out that stress testing is the most effective tool for diagnosing cardiovascular disease (CVD) — the number-one killer in the country.

“This modality is the only way to look into the heart effectively, without cracking someone open,” Soffer says.

A heavier population means more business

According to the World Health Organization, more than 16 million people die of CVD. Stress testing is considered the top diagnosis tool for CVD and respiratory conditions, which is “expected to drive revenue growth and investor interests in the global [cardiopulmonary stress testing systems] market,” states GlobalData, a market research company, in its Global Cardiopulmonary Stress Testing Systems Market Analysis and Forecasts to 2015 report.

In fact, the United States remains the largest revenue generator within the global CPST systems market; it’s expected to grow at a compound annual growth rate of 9.5 percent between 2008 and 2015, according to the report. That’s higher than the global average of 8.7 percent.

Manufacturers and refurbishing companies aren’t surprised by this information. Both Avina and Buyukoglu recognize that heart disease related to obesity will cause an increase in the need for stress testing.

“One [trend] is linked to the rich countries’ obesity and diabetes, [which is] still growing,” says Buyukoglu. “They represent all of the potential coronary diseases in the near future and

will need stress testing.”

Over the last five years, the number of indications for the prescription of a CPST test has almost tripled, according to the GlobalData report. The test is being used as a diagnostic tool for more than 10 clinical symptoms, whereas before, used mainly for assessment of cardiac or pulmonary function prior to surgery.

Stress testing makes headlines

In March, Delaware resident Michael Fields was denied a cardiac stress test three times. He ultimately underwent life-saving quadruple bypass surgery to clear an arterial blockage that would have been found in a stress test and could have been treated in a less invasive way.

Stress testing has been the subject of insurance denials in Delaware by four top companies, including Aetna, Blue Cross Blue Shield of Delaware, Coventry Health Care and Cigna. The companies, which contracted MedSolutions to review preauthorization claims, are being investigated by Delaware insurance Commissioner, Karen Weldin Stewart.

The nuclear stress test, which uses thallium to show how well blood flows to the heart, is much more accurate than the exercise stress test, says Barbara Andrewin, an EKG clinical technician at St. John’s Health Center in Santa Monica, Calif.

“The nuclear stress test is more definitive,” she says.

It’s 90 percent effective in diagnosing cardiac problems, says Andrewin.

Andrewin points out that physicians “really don’t like doing [exercise stress tests] because [they’re] wasting a lot of time,” when a physician knows the patient’s history and knows the problem is heart-related.

But that doesn’t mean the exercise stress test will become obsolete, as it is still a key tool in ruling out heart problems in healthy patients, says Andrewin.

“I don’t think it will be phased out,” she says. “Doctors believe in them. We still have healthy people that [think they have cardiac pain], but they’re having GI problems... With that in mind, we’re still going to do regular stress tests.”

Something new in the sector

Today, companies are adding new testing features to the exercise stress test, allowing them to perform multiple tests at once.

One test in particular studies the microvolt T-wave alternans (MTWA) phenomenon, which is an indicator of a person's risk for sudden cardiac arrest — a leading killer in the United States.

“What’s new for stress testing is that the addition of microvolt T-wave alternans testing may be the first significant change,” says Ali Haghghi-Mood, CEO of Cambridge Heart. “[The addition of MTWA testing] has the potential to introduce a new standard for stress tests.”

Cambridge Heart, based in Tewksbury, Mass., recently received FDA ap-

proval to sell its OEM module that uses the analytic spectral method of measuring MTWA. This particular method was originally developed by the Massachusetts Institute of Technology.

Lahn Fendelander, Cambridge Heart’s vice president of clinical affairs, explains that the analytic spectral method is patented by Cambridge Heart and the only MTWA testing method that is Medicare-reimbursable.

“The traditional stress test, in layman’s terms, is looking for a plumbing problem — coronary heart disease,” says Fendelander. “The MTWA test looks for an electrical problem...By adding [the MTWA feature], if you do a stress test, you have assessment of the plumbing, and now you have assess-

ment of the electrical.”

Cambridge Heart has teamed up with Cardiac Science, a leader in stress testing equipment, to sell its MTWA module with Cardiac Science’s equipment.

As far as trends go, other OEMs such as GE and Burdick, also have an MTWA test, and the trend seems to be growing.

“Having [the test] as an OEM module on other manufacturer’s stress system is one of our biggest goals,” says Fendelander. “So far, we’re moving pretty well with Cardiac Science, and to have it on an existing stress system is an important step.”

● **Online:** dotmed.com/dm12649

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Phil Lonbeck	DB Medical Electronics	Diamond Bar	CA		
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Joe Avina	American International Medical	Sylmar	CA	●	●
Gordon Huckestein	Cardiac Direct	Ventura	CA		
Ryan Davis	Davis Medical Electronics, Inc.	Vista	CA	●	●
Moshe Alkalay	Hi Tech Int’l Group	Boca Raton	FL	●	
Avi Soffer	University Nuclear Diagnostics	Davie	FL		
Clinton Courson	Quest Medical Supply, Inc.	Longwood	FL		●
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Alda Clemmey	Saffire Medical	Taunton	MA		
Lahn Fendelander	Cambridge Heart, Inc.	Tewksbury	MA		
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Zeina Karaky	Cedars Medical Equipment Co.	Dearborn	MI		
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Jason Eden	Bio Basics Global	Park Hills	MO	●	●
Steve Arey	BEST of Rowan, LLC	Salisbury	NC	●	
Roger Nasiff	Nasiff Associates, Inc.	Central Square	NY		
Mordy Eisenberg	Absolute Medical	Wesley Hills	NY		●
Ben Holloway	Southwest Medical Corporation	Broken Arrow	OK	●	●
Rafael Contador	MD Depot, Inc.	San Juan	Puerto Rico		
Bulent Buyukoglu	USmedevice, LLC	Cumberland	RI	●	
Charles Tucker	MedSurg Equipment, LLC	Beaumont	TX	●	
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