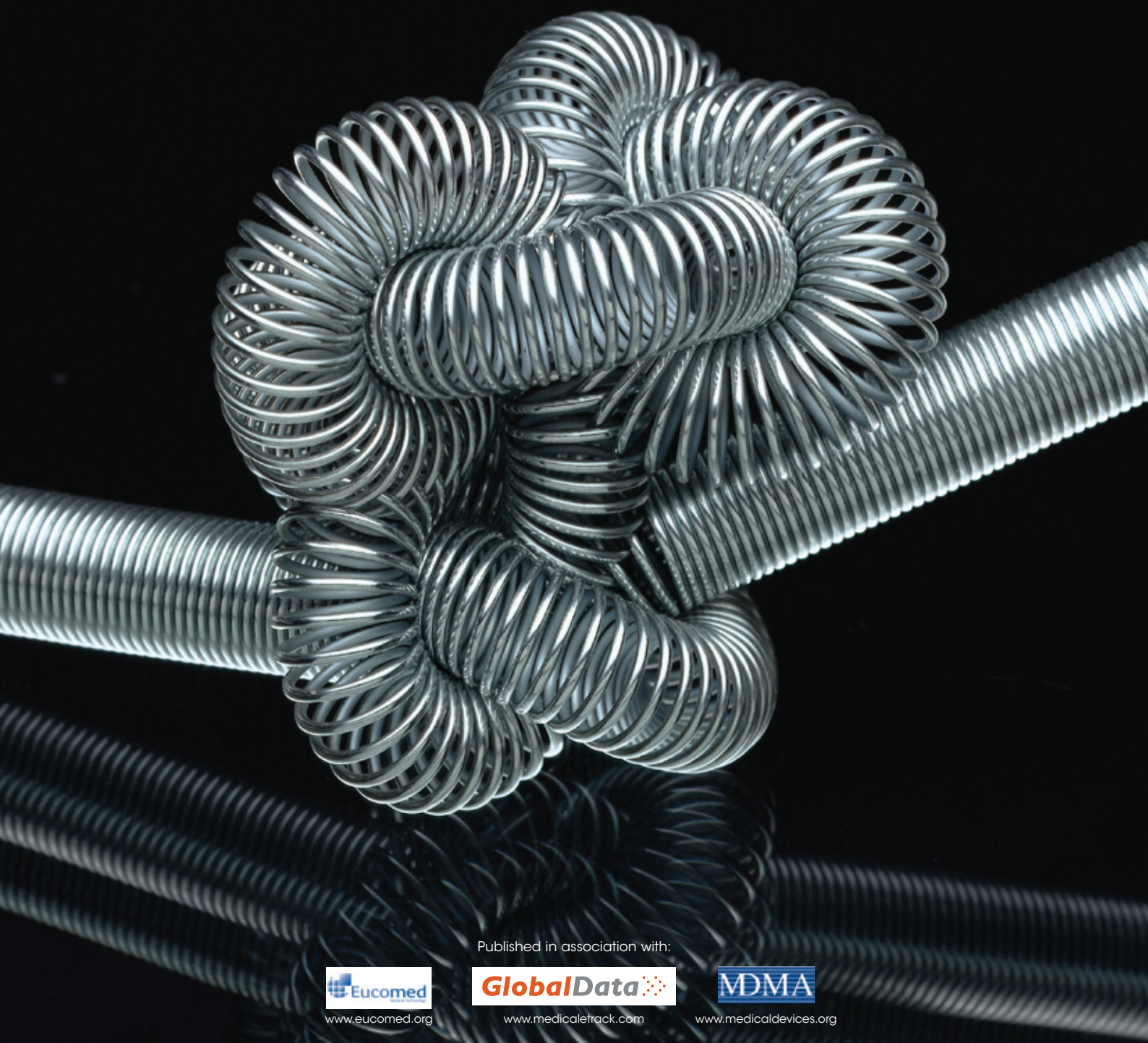


Tied in knots

How the sector can untangle the product pipeline



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Safer software

Many electronic devices require software to run, but how can its safety be proven? Bill McCaffrey looks at regulation to support manufacturers, users and patients and how technology can help.

Modern medicine is increasingly reliant on electronic devices to improve quality of life and medical care. Critical devices such as patient monitors, infusion pumps, pacemakers and defibrillators all now contain significant amounts of embedded software.

A key challenge for medical device manufacturers developing devices containing embedded software is the need to meet the US Food & Drug Administration's (FDA) stringent 'General Principles of Software Validation; Final Guidance for Industry and FDA Staff' document. This ensures that devices behave properly and consistently, and that patient safety is never compromised. Vector Software's Bill McCaffrey explores the FDA's regulations and how test automation can help companies meet the requirements.

Medical Device Developments: What does the FDA suggest for the testing of embedded software applications?

Bill McCaffrey: The FDA recommends organisations perform high-level (system) testing and low-level (unit) testing of embedded software. This involves stimulating the application code with a variety of input test vectors and verifying the test output matches the expected result. Additionally, the suite of test cases must be shown to completely execute all of the source code of the application.

The FDA also defines three 'levels of concern' for software – 'major', 'moderate' or 'minor' – based on how a failure or latent defect might affect a patient or the operator of the device. For example, cardiac rhythm devices such as defibrillators and pacemakers; infusion pumps, ventilators and automated patient monitoring systems are just a few of the applications that contain significant amounts of software and are classified by the FDA as 'major level of concern' devices.

Testing these applications requires accurate and consistent automated testing of software, along with an ability to automate regression testing, which is a necessity, not an option for satisfying FDA requirements.

MDD: How does VectorCAST support medical device manufacturers in the testing of embedded software?

BM: Vector Software's VectorCAST technology assists device manufacturers through the software validation process by providing automation of all unit, integration and system testing activities, including structural coverage analysis and completely automatic regression testing. Testing performed with VectorCAST can be done on the production hardware, on evaluation boards, or with target simulators if necessary.

The key to ensuring flawless, predictable software operation is proving that each part of the code has been tested. During system testing, VectorCAST/Cover enables engineers to automatically

monitor and record which parts of the application have been stimulated by each system test.

One challenge with system testing is that the code coverage that results is often below 100%, with a value of between 60% and 70% being relatively common. The solution is to use VectorCAST/C++, which allows manufacturers to perform unit testing of individual functions or groups of functions to fill in any holes in the system testing coverage.

Similarly, the VectorCAST/Requirements Gateway permits the traceability of requirement data between a requirements management tool and the VectorCAST testing tools. This information allows device manufacturers to easily create reports showing that all requirements have associated test cases.

MDD: Can you give some recent examples of projects using VectorCAST?

BM: VectorCAST was recently used by Impact Instrumentation in gaining FDA compliance for its Uni-Vent Model 731EMV portable intensive care ventilator. This is used in hospitals and during ambulance transportation for resuscitation and the management of acute or chronic respiratory failure. The use of VectorCAST was a critical component in the manufacturer's development process and in the subsequent device certification.

VectorCAST was also recently used by Hoana Medical to test and certify the software embedded in its Lifebed Patient Vigilance System. This device transforms any patient stretcher into an untethered 'alert network' for both cardiac and respiratory functions.

MDD: Why do your customers choose VectorCAST?

BM: The testing of embedded software applications requires the execution of hundreds to thousands of unit and integration test cases, and the need to effectively manage and archive the test results. The benefits of using VectorCAST are twofold. First, the initial development of the test cases is much more efficient. Second, once test cases are developed, VectorCAST allows these tests to be used as a completely automated regression test against new versions of the application.

Company profile

Vector Software is a leading independent provider of automated test tools for software developers. Established in 1989 as a consulting and service organisation, Vector's product focus is to empower software professionals to deliver the highest quality software in the least amount of time. Vector's VectorCAST line of products reduces the burden placed on individual developers by automating and standardising application component level testing. This innovative technology developed by Vector represents the next generation of intelligent test tools.

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