Modern health care increasingly relies on electronic devices to improve quality of life and medical care. Medical devices provide life-saving capabilities: patient monitors, infusion pumps, pacemakers, and defibrillators. The common element is, all contain significant amounts of embedded software. These devices need to behave properly and consistently, otherwise the well-being of patients is compromised. Vector provides medical device manufacturers and suppliers with a professional and open development platform of tools, solutions and services for creating embedded systems. Vector products and services give medical engineers a key advantage in making this challenging and highly complex subject area as simple and understandable as possible.

Vector Testing Solution for Embedded Systems
Embedded system testing tools from Vector support you in the implementation of simulation and test environments in an efficient way. Regardless of your task in the development process the Vector testing tools provide a scalable and re-usable solution from pure SIL simulations to HIL testing with functional acceptance tests. No matter whether your microcontroller is part of an MRI scanner or an infusion pump. Due to the parallel access to Networks (CAN/CANopen, Ethernet, Wifi, …) as well as by acquiring and stimulating of I/Os (analog, digital, SPI, I2C, PSII, SENT, …) via DAQ and external hardware you can easily realize development accompanying tests. Therefore, you ensure a process conformant development of the embedded medical system functionality and network communication.

Software testing is a critical part of ensuring the performance of medical devices to pass FDA audits and support the guidelines defined in IEC 62304. VectorCAST by Vector is the solution for FDA-compliant and IEC 62304-compliant medical embedded application testing. Qualification documents consisting of Tool Operational Requirements (TOR) and Tool Qualification Data (TQD) are available for tool validation. VectorCAST supports testing activities such as:

- Unit testing and integration testing
- Code coverage analysis
- Continuous integration with Change-Based-Testing
- Embedded target support

Supported Testing Activities
- Black box testing
- White box testing on host and target
- Full support in the development process, from software unit test to system validation
- Uniform test management, test automation (continuous integration), result analysis and traceability
- Measuring of code coverage of system tests
- Efficient test design by reuse of test sequences and test data (e.g. for variant handling)
Fact Sheet Solutions for Medical Engineering

Test Tools for All Test Phases

**VectorCAST/C++**
- Automate C and C++ unit testing
- Pass/fail analysis as well as code coverage analysis

**CANoe**
- Develop, test and analyse individual microcontrollers and networks of connected microcontrollers
- Supports engineers throughout the entire development process, from planning to system-level test

**VectorCAST/QA**
- Automate system tests and code coverage
- Coverage levels for statement, branch and modified condition/decision coverage (MC/DC)
- FDA Class III or IEC 62304 Class C code coverage standard for many leading medical device companies

**vTESTstudio**
- Design automated test sequences
- Programming-based, table-based and graphical test notations and test development methods

**VT System**
- Modular test hardware for I/O interfaces
- Simplified setup of test benches and HIL test systems

**Squore**
- Software analytics and decision-making dashboard
- Manage quality, process and standard compliance

Model-Based Systems Engineering
The development of medical embedded systems is strongly regulated, processes must comply with regulatory requirements from standards as IEC 62304 and ISO 14971. A profound documentation of the requirements and the respective system/software architecture as well as their relations are important preconditions for successful regulatory audits. To keep this complexity manageable, model-based processes in systems engineering are on the rise.

**PREEvision**
- Engineering environment for model-based development
- Supports abstraction, decomposition and reuse
- Can serve as engineering backbone

**Vector Consulting Services**
For companies within the health care sector, Vector Consulting Services provides professional support in developing and optimizing business processes and performing necessary change management.

**Consulting Solutions for Medical**
- Software development process according to IEC 62304
- Quality management according to ISO 13485
- Support in risk management according to ISO 14971
- Usability engineering according to IEC 62366
- Efficiency improvement and cycle time reduction
- Organizational change management
- Requirements engineering and product management
- Process improvements with reference to CMMI and Medical SPICE

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**Vector Testing Solution: Proven test tools for all test phases in medical engineering.**