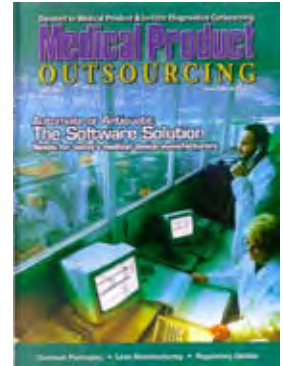


# Solid Strategy, Sound Management: *Keys to Testing Software*

by David A. Vogel  
Intertech Engineering Associates, Inc.

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*Testing is but one activity in a good software validation program. A good testing program encompasses a diverse collection of test protocols. However, when taken seriously testing (along with all validation activities) can produce solid software that can stand the test of time in the field.*

System-level testing, also known as “black-box testing,” tests software with no knowledge of the design and implementation details of the software. On the other hand, unit-level (white-box) testing individually tests each unit for function, subroutine, and other software standards and is based on intimate knowledge of design and implementation details. Integration-level testing lives somewhere in the middle and is mostly concerned with the interactions and interfaces between modules of code.

With all three types, well-written test procedures must detail every step the tester should take. Highly detailed procedures increase the probability that others will be able to re-create any defect observed and assure consistency in testing results from tester to tester. A high level of detail also makes it easier to bring relatively non-expert testers into the project. Not only does this add resources to a testing program, it also has another benefit: inexperienced testers often see obvious defects that the experienced testers have become blinded to and accept as normal.

*Ad hoc* tests go a step further in this direction. They are intentionally not detailed to introduce an element of randomness into the test process. *Ad hoc* tests generally ask the tester to accomplish a task without providing any details about how to do it. This sets up the tester to accomplish the task in ways that would differ from the detailed procedures. User error can exercise parts of the code that may not be normally exercised because the developer didn't anticipate the user errors.

## COMPANY PROFILE

### Intertech Engineering Associates, Inc.

**Address:** 100 Lowder Brook Avenue  
Suite 2500  
Westwood, MA 02090  
www.inea.com - (781) 801-1100

**Industry:** (Electro)Medical Devices

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## Surprising Considerations for Useful Testing

A good testing program encompasses a collection of test protocols of diverse types. Good test designs, test execution and documentation are all necessary for useful test outcomes. Several soft factors also strongly influence the success of a testing program.

**A tester's experience level.** The experience level of the tester and test designer is highly correlated with success in testing (finding defects). Experienced testers are well trained in the skills of observation and seldom intimidated from asking questions or writing up observations. They have a sixth sense about where they will find defects in the software. Much of this has to do with past experience in other testing programs or in their past lives as developers. Inexperienced testers, however, tend to make the unexpected mistakes that often uncover defects the experienced tester may never encounter. A diverse collection of testers with different experience levels yields best results.

**Software complexity.** The complexity of the software is also related to the likelihood of finding defects. However, test designers too often under-test complex functionality because they may not understand it well. Paradoxically, the most complex - and most likely to be defective - software is tested least. Managers need to be aware of this tendency and work diligently to focus efforts in the complex areas most likely to yield defects.

**Independent (objective) evaluation.** Independence is another soft attribute that affects test outcomes. A developer cannot be objective enough to produce reliable test results on his or her own code. However, other types of independence also can affect outcomes. It's desirable to have those who execute tests be independent from those who design them. This will help surface errors in the test procedures themselves. It is even desirable to have independent groups of testers rotate in and out of a testing program to reduce tester fatigue. Tester fatigue allows testers to become too familiar with the software and, thus, overlook anomalous behaviors they have come to accept as normal.

Even independence of organizational responsibility is important. Testers and test designers should not report to the management that is responsible for development of the software. A tester's success in finding a defect is likely to be viewed as a development failure (delaying release dates, etc.). This obvious conflict of interest will impact the quality of test outcomes if the tester is blamed for delaying the project.

**State of Mind.** This is also important to a successful testing or validation program. All team members, developers, designers and testers need to be coached that finding defects, reporting them and tracking them to resolution represents success. These are defects that will not make it to the field and potentially become life-threatening.

## Can You Over-test?

The flip side of under-testing complex software is over-testing simple functionality. Testers have a tendency to "camp out" in areas of functionality in which they are comfortable. Management should be aware of this tendency and look for signs of it in schedules, plans and in the test procedures themselves.

Test engineering management should constantly channel resources to where they will produce the most benefit and find the most defects; that usually is in the most safety critical code or the most complex code. Over-testing simple functionality or well-exercised functionality is not a good investment of scarce testing resources.

Sometimes, certain functionality exists in many places in software-driven systems. For example, a data-input field may appear identically in each of a number of operating modes for the device. It may not be necessary to do full testing of that input field in every instance (eg, normal/abnormal inputs, boundary values, etc.) if one can assume that the software implementing that field is common for each mode in which it is used. In cases like this, the test designer can identify an equivalence class of functionality that is tested once and assumed to be applicable to all occurrences in the system. This greatly reduces the testing.

Exercise care when using equivalence-class logic. The reduction in test effort is only valid if the assumption

behind the equivalence relationship is true. Every assumption should be documented and tested to assure that the equivalence-class logic is valid.

How do you know how much testing is enough testing, and when to stop? Ideal defect-testing finds defects at a steady rate until testing is complete, and no defects are found after that. More typically, however, the defect-testing function is asymptotic. One never knows for sure that all defects have been identified and repaired.

A test plan - written and agreed before the testing process begins - should contain some thought about what the strategy will be to end testing. Things to consider in devising the “stop test” policy are:

- Number of unresolved defects
- Number of reported defects that could not be reproduced
- Severity of defects reported on last test run
- Rate of defect identification

This policy will differ for all devices, depending on their criticality in the clinical setting, their size and their complexity.

Testing is but one activity in a good software validation program, and is not by itself sufficient to validate software, according to the FDA’s definition. Testing is a bona fide discipline of its own and is part art, part science, part common sense and part good organization. When taken seriously, testing - and all validation activities - can produce solid software that can stand the test of time in the field.

## ABOUT THE AUTHOR:



David Vogel is the founder and president of Intertech Engineering Associates, Inc.

Dr. Vogel was a participant in a joint AAMI/FDA workgroup to develop a standard for Critical Device Software Validation which was subsequently included in the IEC 62304 Software Lifecycle Standard. He was also a participant on the joint AAMI/FDA workgroup to develop a Technical Information Report (TIR) for Medical Device Software Risk Management. Currently, Dr. Vogel is a member of the AAMI/FDA workgroup developing a TIR on Quality System Software Validation.

A frequent lecturer for workshops and seminars on topics related to medical device development and validation, Dr. Vogel also is the author of numerous publications and holds several patents.

Dr. Vogel received a bachelor's degree in electrical engineering from Massachusetts Institute of Technology. He earned a master's degree in biomedical engineering, a master's degree in electrical and computer engineering, and a doctorate in biomedical engineering from the University of Michigan.

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**INTERTECH** Engineering Associates, Inc.

100 Lowder Brook Drive Suite 2500 Westwood, MA 02090 USA

www.inea.com - info@inea.com - Tel: (781) 801-1100 - Fax: (781) 801-1108