

# Strategies for Bench Testing Medical Devices

For successful testing, choose the right tests and conduct them at the right time—in an appropriate facility.

*Robert Mosenkis*

Medical devices can be tested at various stages in their life cycle. During their initial design, it is important for the design team to check at least some aspects of performance or safety to be sure that they're on the right track. More-extensive prototype testing usually follows completion of the initial design phase, to demonstrate that the device meets its design specifications. Clinical trials may follow.

Testing for regulatory approval, to meet the stated or implicit requirements of one or more regulatory agencies, is performed next; this should be done on production units or on preproduction prototypes that reflect the manufactured product. Once a device has earned approval, production line start-up often requires additional testing to validate the production equipment (for instance, samples from each cavity of a mold) and inspection protocols.

Later in the life cycle, the marketing department might request product-testing data for use in brochures or on the company Web site. Comparative testing is sometimes appropriate; independent single-product testing may suffice. Also, if design or material changes are ever made to the device that could affect performance or safety, additional testing is warranted, even if a new regulatory submission is not required.

Finally, additional testing may follow a reported adverse incident, to determine what went wrong and why. Many of the special considerations associated with this particular round of testing are beyond the scope of this article; however, the information presented here may still prove helpful.

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### TESTING TO SUPPORT A 510(K)

The question of what to test is especially critical when the test report or results will be used to support a premarket notification, or 510(k), submission. In this case, it is important to keep in mind that the goal of the 510(k) is to demonstrate that the new device is substantially equivalent to one or more named predicate devices. This equivalence must be shown for all aspects of safety and effectiveness.

All clinical features of the device should be tested, as well as safety, materials biocompatibility, environmental withstand, electromagnetic compatibility, and other areas, as applicable. (See Figure 1 for examples.) FDA guidance documents, where they exist for a particular device, are available on the Internet and can be very helpful. However, it is important to look at the issue date of a guidance document and to consider any possible changes in FDA thinking since then.

In selecting the tests to support a 510(k), it is necessary to look first at all claims made for the device in the indications for use, as well as in any advertising, marketing, or instructional materials. For each claim or feature, testing should show that the device performs satisfactorily across all reasonable ranges of patient and environmental conditions. The FDA reviewer will be asking many “What if...” questions when considering a 510(k) submission; the more of them that can be anticipated and answered in the initial submission, the faster the review will proceed.

Years ago, the only way to demonstrate substantial equivalence was with side-by-side comparative testing of the new device and the predicate, showing that the new device was at least as good as the predicate. In 1998, FDA established the concept of recognized consensus standards. FDA publishes a list of U.S. and international standards that it recognizes as applicable to certain medical devices. The list is updated regularly. In brief,

recognition of a standard means that FDA will accept testing of a new device against all applicable parts of that standard as an alternative to comparative testing against the predicate device. Of course, the new device must pass all of the tests. Testing against recognized standards could, obviously, save considerable time and cost.

FDA recognition of a standard can be complete, but exceptions do exist. The place to start is at the section of the CDRH Web site dedicated to standards, [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html). That page provides links to more details of the application of recognized standards, as well as to the Recognized Consensus Standards Database, a search panel for specific standards. If a relevant standard is found, it is crucial to look at the page for that standard, which will list the date or edition of the standard, the devices to which the standard is applicable, and any exceptions or limitations to FDA’s recognition of the standard. Remember that the list of recognized standards is updated occasionally, with some being added and others withdrawn, as well as new editions of standards replacing old ones. It is also possible to formally request FDA recognition of a standard, but this process takes time.

When a recognized standard is not applicable, or when it doesn’t cover a particular aspect of a device, testing against the predicate is needed unless test data for the predicate can be found elsewhere (in promotional literature or prior 510(k)s, for example). It is often difficult or costly for the new product developer to obtain a competitive device—but there may be no

alternative. In comparative testing, standards—even those unrecognized by FDA—can provide relevant test methods. Alternatively, it may be appropriate to develop new tests for this purpose.

PERFORMANCE
<ol style="list-style-type: none"> <li>1. Performance and accuracy of every feature under normal and abnormal patient conditions, and under worst-case input power conditions.</li> <li>2. Alarm activation at intended levels.</li> </ol>
SAFETY
<ol style="list-style-type: none"> <li>1. Electrical (e.g., leakage current, dielectric withstand).</li> <li>2. Mechanical (e.g., tipover, sharp edges).</li> <li>3. Thermal.</li> <li>4. Connector protective incompatibility.</li> <li>5. Biocompatibility of patient- and operator-contact materials.</li> </ol>
ENVIRONMENTAL
<ol style="list-style-type: none"> <li>1. Extreme operating and storage temperatures/humidity.</li> <li>2. Vibration.</li> <li>3. Impact/drop.</li> <li>4. Cleaning/sterilizing.</li> <li>5. Durability.</li> </ol>
ELECTROMAGNETIC COMPATIBILITY

Figure 1. Examples of what to test for 510(k) clearance.

Each round of testing requires a different strategy. Failure to develop the optimal strategy for each could result in even more testing at a later time, or failure of the test results to meet the original goal. For example, using an existing standard to test a different device characteristic or technology may be inappropriate.

An example of this occurred when a company was asked to compare the resistance of several surgical masks to blood penetration. At the time, the only existing standards were for water-repellent fabrics under prolonged exposure or materials subjected to liquid under pressure—these were not suitable. To solve the problem, the company developed

a simple test methodology that involved squirting animal blood from a syringe for a short time.

All stakeholders must ask three basic questions when developing a testing strategy:

- What tests are needed?
- What devices should be tested, and when?
- Who should do the testing?

An effective strategy will emerge as these questions are discussed and answered.

### **What Tests Are Needed?**

The goal of the testing determines what tests are needed. If it is early in the design cycle, using crude test setups just to check that the device will perform its basic function will likely suffice. For an electrocardiographic (ECG) monitor, for instance, attaching electrodes to a volunteer (or the design engineer) and displaying the output on an oscilloscope can show whether the waveform looks like a typical ECG;

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comparing the rate display against palpated pulse will show whether the rate meter is functioning. Electromagnetic compatibility (EMC) testing, for example, is clearly not warranted at this stage. Later, the design can be tested against the full requirements of a relevant standard or against each of the product specifications.

The question of whether to test against recognized standards or to develop a different test methodology depends on who will review the results. Standards are written to yield consistent results, no matter who applies the standard, or when. This is why so many standards require complex, precise, and often costly test setups, as is the case with a recently developed standard for the blood-resistance testing of surgical masks mentioned earlier. While careful testing to standards is “overkill” in the initial design testing, it is often the best approach later on.

In some cases, the best strategy is to modify a standard. For example, an ISO standard includes tests for leaks in luer fittings under pressure or vacuum. The fitting is attached to a designated stainless-steel fitting, and pressure or vacuum is applied. But some safety syringes can be used only with their manufacturers' proprietary needles and do not include luer fittings. Because the concept of a leak-free connection would apply to these devices as well, it is appropriate to modify the standard by substituting the proprietary needle and its fitting for the standard steel fitting and applying the pressure and vacuum specified in the standard.

If your device uses a new technology or includes a novel

feature, you may have no choice but to develop a new test method, since standards simply don't apply. Another instance for which testing to a standard may not be the best approach is when products are being compared for marketing purposes. Because the results are intended for the customer, it may be better to simulate clinical use, rather than to use test equipment or fixtures that are typical of those mandated by standards.

Custom test methods may look crude when compared with the relatively complex methodology of standards. Although the former may lack repeatability, and the techniques of different test personnel can affect the results, such shortcomings are not a factor when all testing is done at one time and place, by the same people.

### **What Devices Should Be Tested, and When?**

The testing goal will often dictate which, and how many, devices to test, as well as when in the life cycle to do the testing. Prototypes are often constructed using materials and techniques quite different from those used in production; they are usually handcrafted and finely tuned. Some of the tests that are relevant to production units are not applicable at this stage; however, be aware of the trap hidden in their postponement.

Some tests that are required for a finished product involve aspects of the device that are not involved in normal use. EMC comes to mind, as do extreme storage and operating conditions and biocompatibility. While it is easy to delay these tests until the design is frozen, the cost of changes dictated by test failures at that point may be high. In some such cases, the solution might be an extra round of testing, with the idea that some of the successful test results might be valid later, especially if design changes are not needed.

Where the goal of testing is regulatory approval (see sidebar), the test samples must reflect production units for the results to be valid. The objective of this testing is to demonstrate that a quality device can be consistently produced. Therefore, these tests must be done only after the design process is complete; although, as mentioned earlier, it might not be necessary to repeat some previous tests.

The number of samples tested might well be dictated by the standard or guideline used. Relevance and/or statistical significance are prime considerations. Testing a single sample of a complex electronic device is usually sufficient for regulatory approval; testing 20 samples of a mass-produced device might be needed to demonstrate uniformity. When selecting samples, they should be as varied as necessary (for example, samples from each production line or each mold cavity), but consistent with the testing goal.

### **Who Should Do the Testing?**

In most cases, someone familiar with the device and its application should test the product; this usually points to doing so in-house. In larger firms, a separate group can conduct all testing; in smaller ones, it may fall to the design engineer, at least for initial testing. Some companies don't realize that self-testing may also be done when the report is included in a 510(k)—although this is not necessarily the case for other regulatory agencies. If testing is done in-

house, it's a good idea to have the test plan reviewed by someone who is not too close to the design, lest something be inadvertently overlooked.

It is part of some firms' quality procedures to have an outside laboratory perform final testing, to ensure objectivity. But when an outside lab is used, it should be one with experience in testing medical devices that understands the goal of the testing and the nature of the device being tested. A

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medical device firm once submitted the only prototype of its electronic system to a local test house for vibration and impact testing. Unfortunately, that lab's expertise was in testing for aerospace applications, and the impact test that it recommended demolished the sample.

The main reason for using an outside test house is that the test requires specialized equipment. Biocompatibility, tensile strength, environmental, and EMC testing are examples for which the equipment and facilities are too costly for the occasional needs of most medical device firms. But even simpler test equipment—and the skills to use it—might not be needed often enough to justify purchase.

Independent test houses can offer several other advantages, including the following:

- Familiarity with standards, including knowledge of common interpretations or upcoming changes.
- The objectivity to critique a company's test protocols.
- Experience with regulatory agency expectations of testing.
- Testing experience with similar devices, which can help in test setup and performance.
- Credibility with device users—especially when comparative testing is done for marketing purposes.

Some companies are concerned about the confidentiality of proprietary information that is shared with a test house, especially one that has worked for its competitors. While most test labs will be happy to sign nondisclosure agreements, remember that a lab relies on its reputation of integrity to survive and a single lapse will ruin this reputation. So it's likely the lab will be self-motivated to maintain its clients' confidentiality. Also, the very fact that a lab has tested a similar device for a competitor makes it better able to serve you.

### **Conclusion**

As is true of countless other endeavors, careful planning is one of the most important aspects of a medical device testing project. Choosing the appropriate tests and conducting them at the proper times, in an appropriate facility, can enhance the product development and marketing process. ■