

Medical Device Testing with National Instruments Software and Modular Instruments

Introduction

Medical device testing is becoming increasingly important as it determines the safety and efficacy of devices. As the regulatory climate becomes increasingly stringent, and the demand for these products grows, the ability to test devices becomes a key element to a medical device company's success. This whitepaper defines the field of medical devices, and outlines the issues and trends driving the market. It also describes several example applications showing how medical device testing is performed with emphasis on software validation as a key component of the process.

What is a Medical Device?

Medical devices are instruments used to treat people for disease or injury without the use of pharmaceutical means. Medical devices are tested to prove safety (does not harm people) and efficacy (it does what the manufacturer claims it does.) Regulatory agencies require extensive documentation and test procedures to prove safety and efficacy.

What are Examples of Medical Devices?

A wide range of medical devices are available on the market today. They cover all aspects of the physical condition. Here is an example set of devices:

- Audiology – hearing aids
- Cardiovascular – defibrillators, pacemakers, stents
- Tissue Engineering – artificial muscle tissues
- Dental – caps, crowns, etc
- Urologic -- catheters
- Orthopedic – artificial hip joints
- Drug Delivery --syringes
- Ophthalmology – contact lenses
- Others -- electronic thermometers, glucose monitoring devices

What are the Trends in Medical Devices?

The Life Science industry is growing at a steady rate. This growth is driven by several factors including:

- Aging of the population
- Advent of managed care and cost containment
- Miniaturization of devices and equipment

The aging population demands greater resource investment into the Life Science area. The goal of cost containment is to encourage patients to minimize time in the hospital which in your turn drives the need for devices that can support healthcare in the home. Finally, miniaturization of devices requires manufacturers to perform precision machining and testing on components and parts used to build the device which in turn drives the demand for automation. Each device area has its own growth drivers. For

example, in the Cardio Rhythm Management market, growth is due to an increase in sales in Asia such as to India and China, the aging of the population in the Western world, and an increasing demand for lower end devices.

What are the Elements of a Medical Device to be Tested?

In testing a medical device, there are five major elements to cover. The first is the display of the unit. The graphical display must be tested to ensure all pixels are working, and the output on the display is correct for the functioning of the device. NI offers vision tools to perform this type of testing. The second area is battery testing. Most devices require battery power even if only for data backup purposes. NI provides modular instrumentation including Digital Multimeters and Switching to perform battery tests. Also, switching tools are available for manufacturers who want to test multiple units at the same time or minimize the number of instruments needed for a test cell. The third area is power. The unit must be tested to ensure the user does not receive a shock from the power supply. NI tools can perform these tests. The fourth area is Electromagnetic Emissions/Immunity testing. These tests ensure that the medical device does not radiate EMI or malfunctions from susceptibility to EMI. NI provides RF tools to perform precompliance testing. Finally, many medical devices use electronics that must be tested for functionality. NI provides a set of modular instruments that can test the electronics in your medical device.

The digital thermometer is an example of a medical device requiring testing. The tests include the following:

1. Displays – LCD displays must be verified for pixel on/off, brightness, and contrast.
2. Battery – current/voltage draws must be tested as well as the life cycle of the battery under maximum usage conditions.
3. Temperature accuracy – the accuracy of the temperature readout must be calibrated and measured.
4. EMC – electromagnetic emissions must be tested to ensure the unit is not radiating EMC signals beyond the allocated spectrum.
5. Internal Self Tests – must be performed to verify proper functioning.
6. Computer interfaces – for those devices designed to connect to a computer, the interfacing (serial, parallel, etc) must be tested.

Other outputs – if the digital thermometer generates analog voltage, analog current, frequency, or alarm signals, these must be tested for accuracy.

In addition to testing the basic functionality of the device, other tests may be performed. These include safety, environmental testing such as shock, vibration, thermal, humidity testing, etc, biocompatibility and sterility testing, and life-cycle testing.

What is Software Validation?

Validation requirements demand that manufacturers test and document software to prove the software performs as the manufacturer describes. Through a series of module and system level testing, the manufacturer proves the functioning of the software.

Documentation is generated to describe the testing process and verify the test results. Software validation mimics the clinical process which demands predictive results. The testing should prescribe the results. For example, if testing ten units produces two failures then were those failures predicted by the experimental setup or did they just happen for no apparent reason?

How is Software Validation Performed?

Software validation is achieved through a combination of process, testing, and code-review techniques. A process must be in place for designing, reviewing, testing, and validating the code. Test setups must be employed to test the software on both the modular and system level using a variety of inputs. Code review techniques are critical in the verification of the software.

Software test validation can be divided into four categories:

1. Performance – does the input of good data generate good data out?
2. Failure modes – if the setup is wrong, does the test results reflect it?
3. Repeatability – if one tests with the same input vectors, does one get the same output results time after time?
4. Special Case – completely test dependent for specific requirements.

An example test setup for software validation typically includes a test engine that manages the instruments, test services, and software applications to be validated. Also, the test results need to be stored, and the configuration parameters from the Manufacturing Control System are used. Here's an example configuration of a test setup:

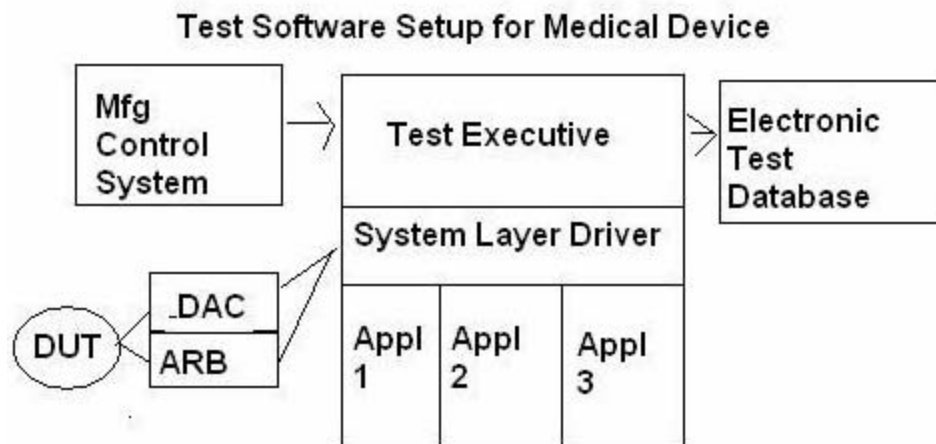


Figure 1: Setup for software validation of test programs.

What are some example applications of medical device testing?

We will look at two example applications and describe the test setup in each. The first is the Pacemaker and Implantable Cardioverter Defibrillator (ICD). The second is glucose monitoring devices.

Testing Pacemakers and Defibrillators

A defibrillator is a device implanted into the body and under cardiac arrest conditions provides a shock to the heart to reestablish a beat. It also provides a pulse generation to pace the heart. A pacemaker provides primarily the later function.

Pacemakers and defibrillators consist of complex digital circuitry that must interface to its exterior environment through analog connections. A telemetry channel provides interfacing for device diagnostic purposes after implantation. Defibrillators must provide a kilovolt level shock to the heart without damaging the internal circuitry of the device. Because the device is implanted it must have a substantial battery life.

The test challenge relates to making precision measurements on complex digital circuitry that has been stimulating and interfaced through analog signals. While this is not a traditional mixed-signal test, signal analysis is a key element of testing the device. The second challenge is the wide range of signals to measure. The shock voltage reaches kilovolts and amperes, but must run on nanoamps and sense microvolts.

For pacemakers, the primary function is generating a pace pulse to ensure continuous heart beats. This pace pulse consists of a waveform signal, whose rise time, droop, and recharge pulse amplitude yields information about the condition of the digital circuitry. Figure 2 shows a graphical representation of the pulse signal to be measured.

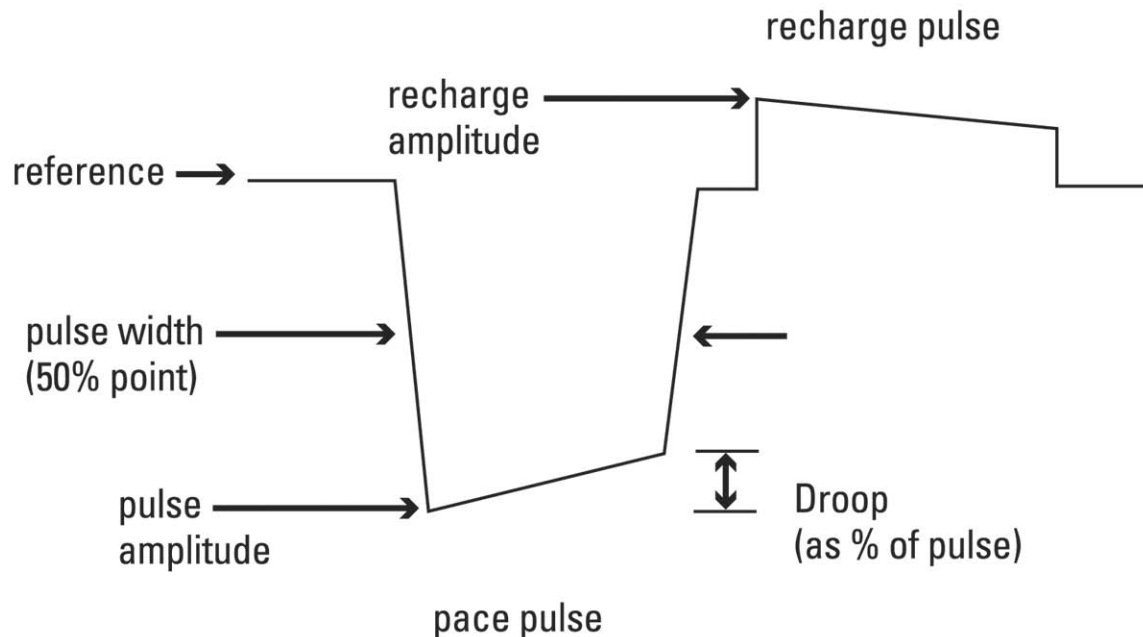


Figure 2: Pace pulse from a pacemaker.

Test instrumentation for the pace pulse test consists of a signal source and a digitizer. The signal source provides the stimulus representing the heartbeat. A digitizer reads the response from the device representing the pacing pulse from the device to the heart.

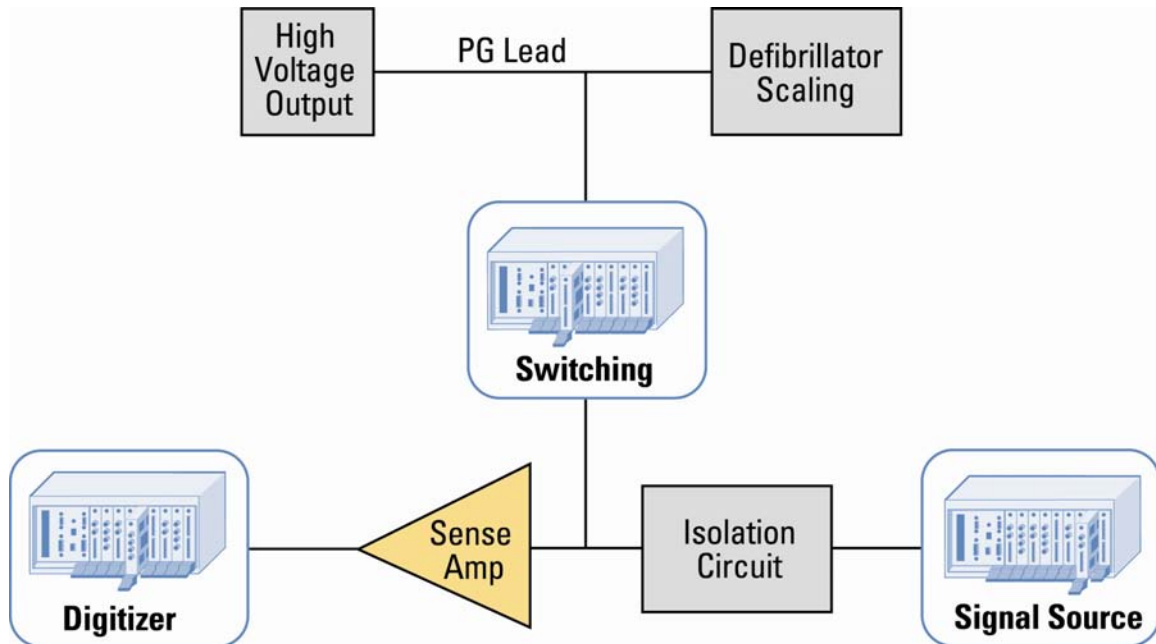


Figure 3: Instrument Setup for Pacemaker Test

The sensing test uses the signal source to generate Haversine waveforms that simulate the electrical activity of a heartbeat. External shock tests the sensing circuitry after an external shock has been applied. This simulates the condition in which an external defibrillator has generated a shock to a patient with a pacemaker implanted. To perform this test, relays are used to switch high voltage capacitors onto the leads. With an external voltage applied, the device is tested to confirm its ability to detect heart rhythms.

Additional tests include the following:

- 1-Battery Voltage
- 2-Lead impedance
- 3-Safety core
- 4-Gross Fail Shock
- 5-Timm – Leads
- 6-Sense Amp Differential Gain
- 7-Sense Amp Common Mode
- 8-Temperature Measurement
- 9-Battery usage
- 10-Sensitivity Refractory Testing

LabVIEW provides an environment for developing individual tests for pacemakers and defibrillators. Here is an example application screenshot.

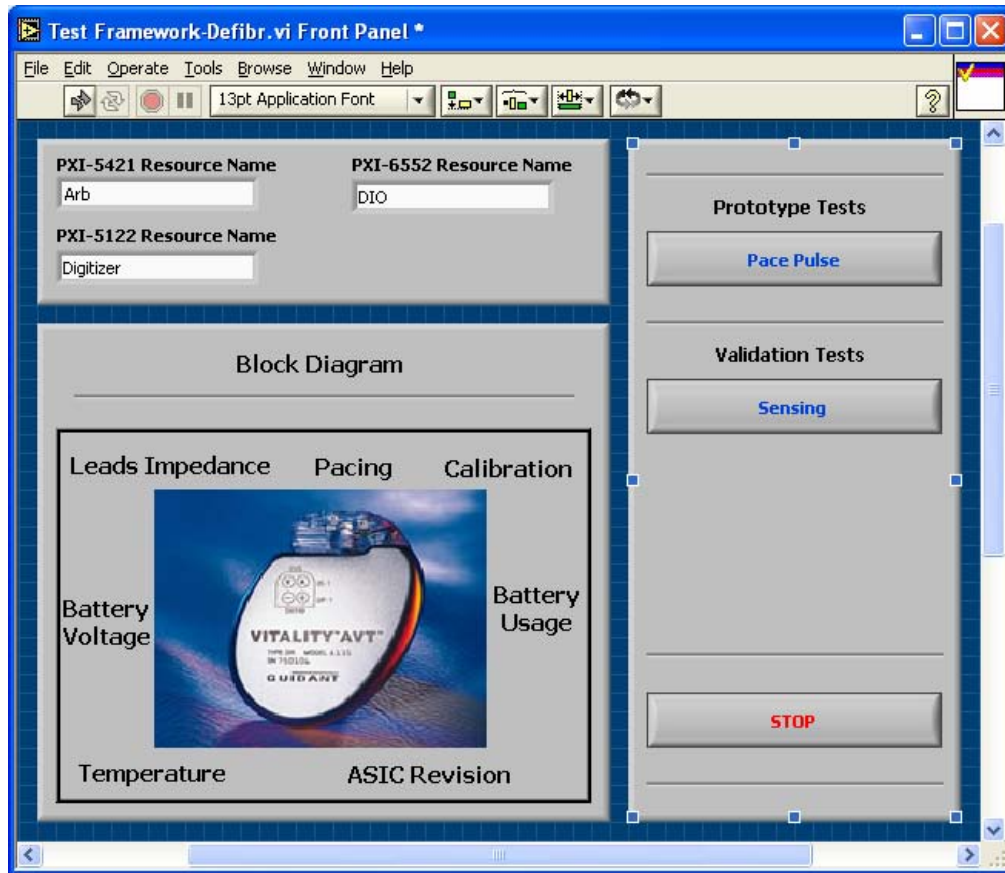


Figure 4: Example implementation of a Pacemaker test in a LabVIEW program.

A series of tests could be run in a sequence.

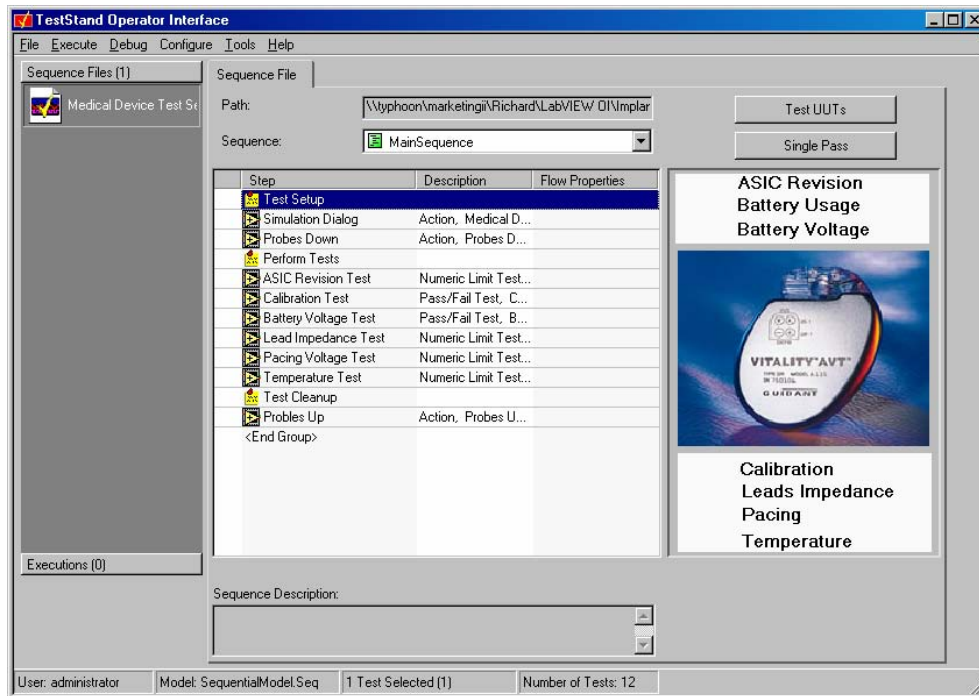


Figure 5: Teststand Sequence for Defibrillator testing

Glucose Monitoring Tester

Glucose monitoring is moving from the hospital bedside to at-home patient care. Handheld testers are coming onto the market to fulfill this demand. Testing a glucose monitor device is another example of NI tools performing medical device testing.

The elements of a glucose monitor device include:

- Built-in microprocessor provides data collection, processing, user interface
- Patient interface for applying a fiber optic tip probe to a patient's finger.
- Fiber probe tips are in standard fiber optic connector
- LCD Display and electronics enclosure
- Serial port for internal program updates

The National Instruments Mixed-Signal Platform tools test the internal electronics used for data collection and processing. NI data acquisition tools test the fiber optic interface to calibrate it for the measurement. For high-volume manufacturing, NI Vision tools can test the LCD display to ensure the proper functioning of the display and automate the testing of the correlation of the displayed information with the state of the instrument. NI motion tools can test the mechanical action of the fiber optic tip to ensure the precise positioning of the tip. Finally, NI LabVIEW can read the serial interface to compare external test results with internal test results for validation and verification purposes as the device must meet FDA requirements.

Innoventor Embedded Controls (IEC) worked with a start-up company that was developing a new glucose measurement technique. The technique is based on measuring the reduction in a fluorescence signal returned from a fiber sensor. The fiber sensor is etched to a sharp point and coated with a proprietary chemical mixture that produces the fluorescing signal when stimulated with the proper wavelength.

IEC developed a meter to be used in the clinical trials of the new technique. The meter saves raw data internally to support more in-depth evaluations of probe responses. A simple LabVIEW application was created to simplify reading the data files, presenting the data of multiple probe samples and doing additional analysis.

Operating the glucose meter during development and production of clinical trial units required separating the performance of the meter from the variations of the fiber probe. Since the probe chemistry was still being modified and adjusted and the production of these probes was not consistent, a predictable and repeatable method of test was required. This was achieved by using an output of a PXI-MIO16E series board to create a programmable optical source.

The output of a National Instruments data acquisition board is used to drive a simple voltage-to-current drive circuit fashioned with an op amp to modulate the current of an LED. The LED is selected for the actual probe fluorescence wavelength peak. Light from the LED is coupled to a fiber with a simple lens thus completing the probe simulator.

A LabVIEW program is created that generates a waveform of any desired probe model. This allows a flexibility to follow any probe changes be a simple adjustment of a model in the program.

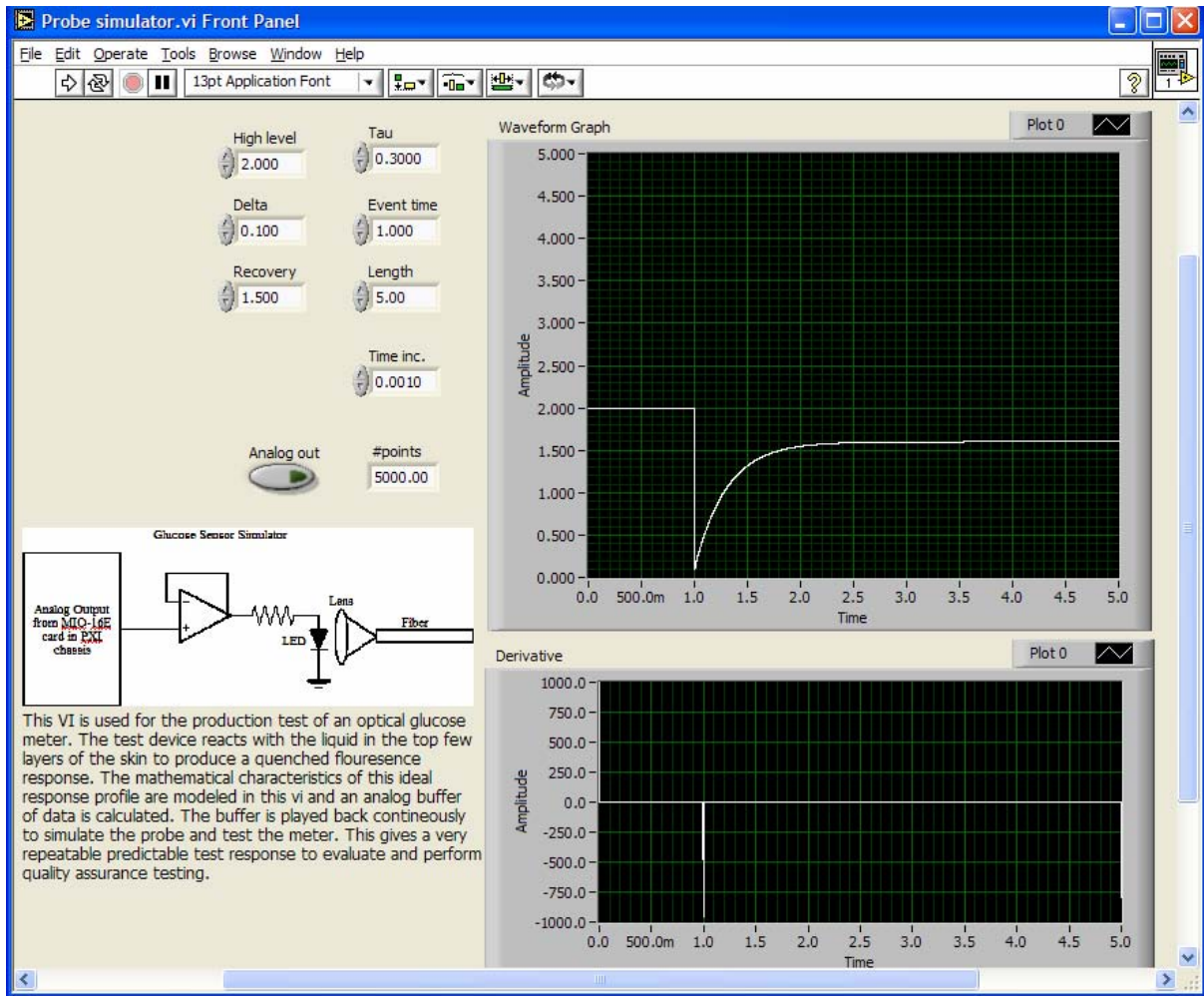


Figure 5: LabVIEW example program for Glucose Monitor testing

What are the Benefits of National Instruments tools for Medical Device testing?

National Instruments LabVIEW and instrumentation tools are well suited for the test of medical device testing for the following reasons.

- Sophisticated analysis required – complex digital circuitry requires custom signal analysis specific to the device under test. Advanced analysis capabilities in LabVIEW provide this capability.
- Complex waveform generation and capture – unique waveforms must be generated to simulate the subject input. A combination of LabVIEW and NI modular instruments provide this waveform generation and capture.
- Tight timing and synchronization requirements – the generated input and measured output may need to be synchronized. A common timing bus between the instrumentation modules and high-level software control provide this timing capability.

- Variety of signals used – a wide variety of signals which can encompass analog, digital, visual images, and motion control may be used for automating the final test in production. The wide variety of instrumentation modules encompassed in the LabVIEW environment provides a complete test environment for medical device testing.

Conclusion

Medical devices are becoming increasingly sophisticated requiring more complex testing. Regulatory compliance requirements also impact test requirements. In this paper we describe several examples of medical devices and how they are tested including pacemakers, defibrillators, glucose monitors, and digital thermometers. Software validation is also described.

Sources:

“Testing Implantable Medical Devices”, J. Max Cortner, Guidant, Evaluation Engineering, June 2004, page 38.