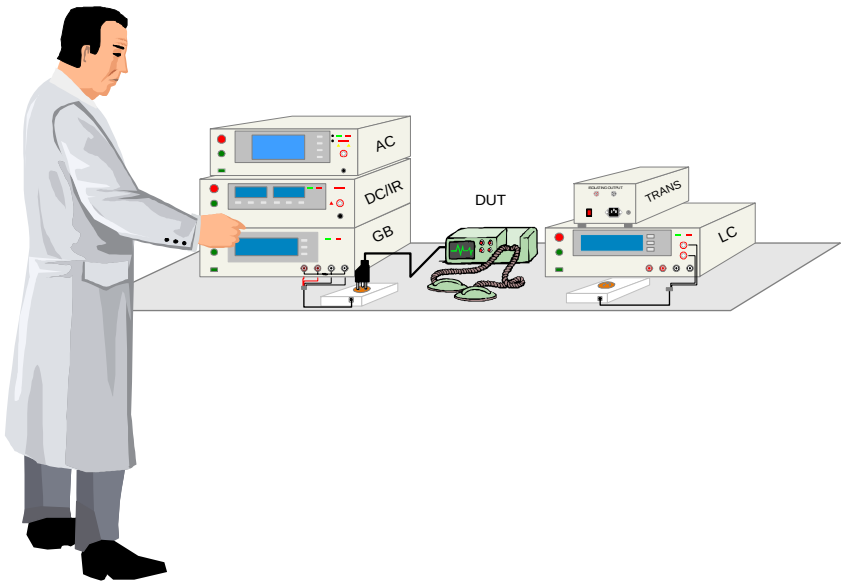
Embedded Software in Medical Devices Increases Manufacturing Process Efficiency

One of the most economically draining expenditures in the manufacturing process of electro-medical devices is the functional and safety testing processes. Manufacturers commonly incur high labor costs due to the number of tests performed throughout the manufacturing processes. Efforts to reduce labor costs many times result in outsourced overseas manufacturing, where labor rates are less. While labor rates are reduced, the manufacturer loses control of the testing process, and thus the final quality of the medical device.

Today's medical devices are beginning to address this issue by means of embedded software. Medical devices are incorporating information technology not just for purposes of allowing the medical device to be more collaborative with the hospital information systems, but the embedded software and information technology allow a porthole for automated test equipment control software to be able to communicate interactively with the medical device.

Take a look at the old process:

The operator connects the medical device to fixturing cables and connections which allow the test instrument(s) to apply test signals and receive data. The operator then has to turn on the medical device, and typically has to perform some factory configuration of the medical device software and/or hardware. After the configuration is complete, the operator can start activating functions of the medical device, and at the correct moments, the operator then initiates the signal from the test instruments, and manually triggers the instruments to measure data. Sometimes it is up to the operator to visually judge pass and fail functionality of the medical device.



The operator is continually repeating this process for other functions of the medical device, and then repeating the process for each medical device. In many cases, this very time consuming process is unavoidable, simply because there is no means of an interface between the medical device and the automated test equipment other than a real live person.

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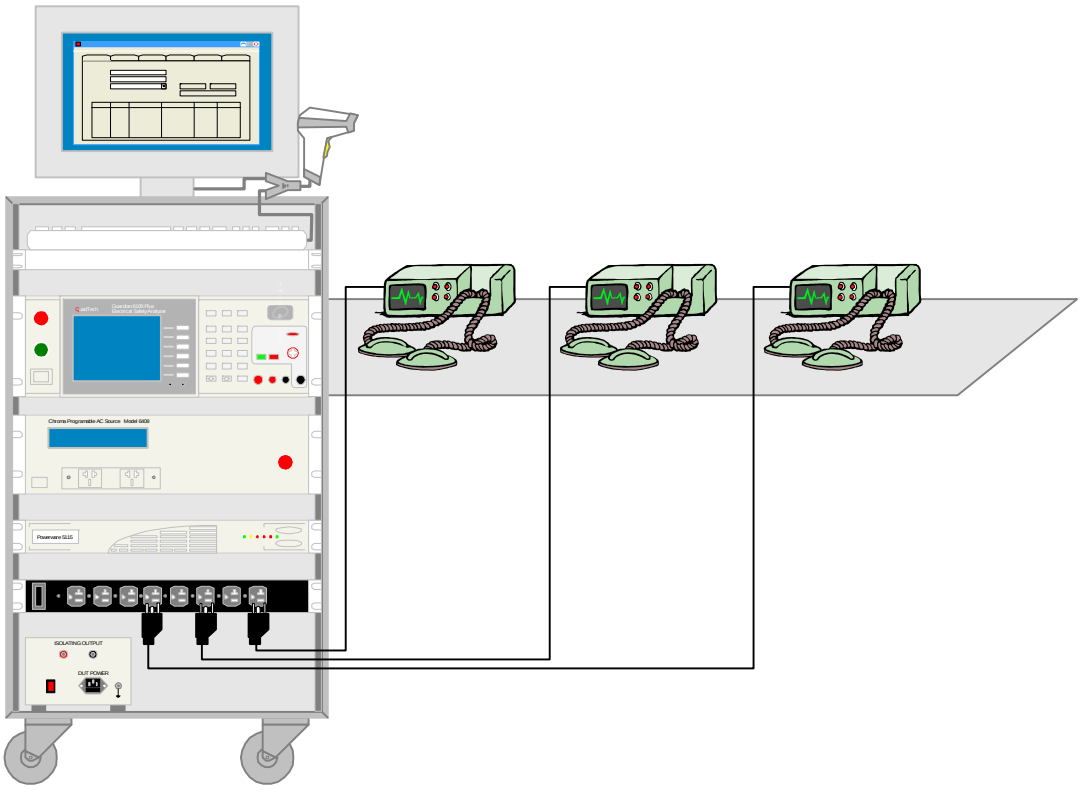
Introducing the new process:

Let's imagine a process in which the operator pulls the medical device over to the test station, set's it down on the bench, plugs it's communication port into the communication cable of the test equipment, makes all the other cable connections, turns on the device, and clicks "Start Test" on the test station software interface screen, then walks away to hook up the next device, and the next one…Let's say the operator has connected 10 medical devices all at the same time, all the while the test station takes control of the testing process! Now the operator can go off and perform some other tasks while the automated testing processes are performing the work of 10 operators.



The identification and planning for production should start back in the beginning of the product development process. Many corporations do a fantastic job at brainstorming new and exciting products, features, and technologies. They even take time to perform Risk Assessment exercises to find areas that guide the mitigation of risk in the designing process. Yet just now are corporations asking themselves the question "How can we most efficiently test this product when it moves into production?"

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Under the hood:

When developing the medical device, it will be necessary to provide a communication port (USB, Ethernet, Serial, etc…) which provides connection to the test station control software. The test control software is going to tell the medical device to enter some type of diagnostic or test mode. The diagnostic mode allows the test station control software to take control of the functions of the medical device, as well as transmit and receive data.

For example, the control software may tell an electro-surgical generator to output a bi-phasic waveform at 390kHz, at 25Watts. The control software also engages a 100Ohm load across the generator output as well as voltage and current meters across the load to verify generator output. Data is then collected, stored, and transmitted via electronic network to the electronic device history record via 21 CFR Part 11 compliant methods.

Communication and Planning:

It all comes down to planning and communication between the product managers, design engineers, software engineers, regulatory affairs, quality assurance, test development group, manufacturing group and everyone else responsible for launching, manufacturing, and supporting the product. Understanding the impacts and requirements of the product to meet market needs, regulatory requirements, and operational requirements at the beginning of the product development process will allow you corporation to increase its process efficiency, while improving the quality of your product.

For complete product specifications on CaptivATE Automation Software for the Guardian 6100 Medical Safety Analyzer or any of QuadTech's products, visit us at http://www.quadtech.com/products. Call us at 1-800-253-1230 or email your questions to info@quadtech.com. The information presented in this application note is subject to change and is intended for general information only.

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