Electrical Safety Verification & Validation

For medical device manufactures changing equipment can be a grueling task. Obtaining new test equipment to combine processes and eliminate errors is exciting. However, the implementation of the new equipment quickly removes the excitement. The new tester must be verified and validated. In Verification and Validation Part 1, the steps involved for verifying an electrical safety tester were discussed. In this application note, Part 2, we discuss the validation process.

Part 2: Validation

The key portion of the validation process is the process itself. All too often manufactures try to validate the test equipment without a process in place. It is absolutely necessary to have the process nailed down before the validation can occur. Validation is a series of tests to ensure the tester does what it is intended to do. Without knowing what the tester is intended to do, it is impossible to verify it is doing it properly.

Documentation is extremely important in the validation process. The task, how the task is performed, the expected result, and the actual result must be documented. Validation of an electrical safety tester will involve testing the performance of the tester for expected results as well testing the repeatability of the tester.

The following are samples validations for each test mode for the electrical safety tests of a device using the QuadTech Guardian 6100 Plus, AC Source and load boxes. Validation of expected results can be done with loads that produce the desired result or with a known good product and known bad to induce each desired failure.

Ground Bond Validation

Objective

The objectives of this section are to verify and document the performance of the Ground Bond Test.

Procedure

Ground bond is performed between the connections of Drive-/Sense- and Drive+/Sense+
These connections are the power line ground and the rear ground stud on the DUT.
The Test is performed with the product power cord.
Program the Guardian with the following conditions per internal work instruction:
Test Current 25A
Maximum Limit 200mohm
A ground resistance greater than 200mOhm shall produce a failure.
A ground resistance less than 200mOhm shall produce a pass

Connect the ground connections To the Load Box Pass post.

The Displayed Output shall be 25A ±1%
The measured value shall be less than 200mohm
The result shall be a pass
Connect the ground connection to the Load Box Fail post.
Execute the same test through CaptivATE.
The Displayed Output shall be 25A ±1%
The measured value shall be greater than 200mohm
The result shall be a fail.

25A Ground Bond Acceptance Criteria:

- The output was 25A ±1% for each test
- The measured value was less than 200mOhm for the Pass condition
- The measured value was greater than 200mOhm for the Fail condition
- The System reported Pass or Fail correctly for each condition

Mains to Ground AC Hipot Validation

Objective

The objectives of this section are to verify and document the performance of the Mains to Ground AC Hipot Test using the Sentinel IIa and CaptivATE software.

Procedure

AC Hipot is performed through Line and Neutral of the power cord to the power cord ground.
Program the Guardian per internal work instructions for an AC Hipot test of 1500V, with high limit of 5mA.
Execute the test with the power cord connected to the Pass power inlet of the load box
The Displayed Output shall be 1500V ±1%
The measured value shall be less than 5mA
The result shall be a pass

Repeat the test with e power cord connected to the Fail power inlet of the load box
The Displayed Output shall be 1500V ±1%
The measured value shall be greater than 5mA
The result shall be a fail

Mains to Ground AC Hipot Acceptance Criteria:

- The Displayed Output was 1500V ±1% for each test
- The measured value was less than 5mA for the Pass condition
- The measured value was greater than 5mA for the Fail condition
- The System reported Pass or Fail correctly for each condition

Patient AC Hipot Validation

Objective

The objectives of this section are to verify and document the performance of Patient AC Hipot Test using the Sentinel IIa and CaptivATE software.

Procedure

AC Hipot is performed between the patient connection (Channel 3) and the power cord ground.
Program the Guardian per internal work instructions for an AC Hipot test with an output of 4000V and high limit of 0.5mA.

Connect the power cord to the Pass power inlet and the patient connection cable to the Pass binding post on the Patient Load Box.

The Displayed Output for AC Hipot shall be 4000V ±1%
The measured value for AC Hipot shall be less than 0.5mA
The result shall be a pass

Repeat the test with the power cord connected to the Fail power inlet and the patient connection to the Fail binding post of the Patient Load Box
The Displayed Output for AC Hipot shall be 4000V ±1%
The measured value for AC Hipot shall be greater than 0.5mA
The result shall be a fail

Patient AC Hipot Acceptance Criteria:

- The Displayed Output was 4000V ±1% for each test
- The measured value was less than 0.5mA for the Pass condition
- The measured value was greater than 0.5mA for the Fail condition
- The System reported Pass or Fail correctly for each condition

Earth Leakage Normal Condition Validation

Objective

The objectives of this section are to verify and document the performance of the Earth Leakage Test under Normal Switch Condition.

Procedure

Earth Leakage test is performed measuring leakage between Line and Ground of the product while the product is powered on. The AC Source is used to input the voltage to power on the device under test through the Guardian 6100 Plus. Program the Guardian for an earth leakage test per internal work instructions. Execute the Guardian and AC Source programmed to output 132Volts. The Test is performed with the product power cord

Connect the power cord to the Pass power inlet of the Load Box
The Displayed Output shall be 132V ± 1%
The measured value shall be less than 0.5mA
The result shall be a pass

Repeat the test with the power cord connected to the Fail power inlet of the Load Box
The Displayed Output for shall be 132V ±1%
The measured value shall be greater than 0.5mA
The result shall be a fail

Earth Leakage Normal Condition Acceptance Criteria:

- The Displayed Output was 132V ±1% for each test
- The measured value was less than 0.5mA for the Pass condition
- The measured value was greater than 0.5mA for the Fail condition
- The System reported Pass or Fail correctly for each condition

Earth Leakage Single Fault Condition Validation

Objective

The objectives of this section are to verify and document the performance of the Earth Leakage Test under Single Fault (Neutral Open) Condition using the Sentinel IIa and CaptivATE software.

Procedure

Earth Leakage test is performed measuring leakage between Line and Ground of the product while the product is powered on without connection to Neutral. Program the Guardian for an earth leakage test with single fault condition per internal work instructions. Execute the Guardian and AC Source programmed to output 132Volts.

The Test is performed with the product power cord

Connect the power cord to the Pass power inlet of the Load Box
The Displayed Output shall be 132V ± 1%
The measured value shall be less than 1.0mA
The result shall be a pass

Repeat the test with the power cord connected to the Fail power inlet of the Load Box
The Displayed Output for shall be 132V ±1%
The measured value shall be greater than 1.0mA
The result shall be a fail

Earth Leakage Single Fault Condition Acceptance Criteria:

- The Displayed Output was 132V ±1% for each test
- The measured value was less than 1.0mA for the Pass condition
- The measured value was greater than 1.0mA for the Fail condition
- The System reported Pass or Fail correctly for each condition

Patient Leakage Normal Condition Validation

Objective

The objectives of this section are to verify and document the performance of the Patient Leakage Test under Normal Switch Condition using the Sentinel IIa and CaptivATE software

Procedure

Patient Leakage is performed measuring leakage between Line and the patient connection of the product while the product is powered on. Program the Guardian for an patient leakage test per internal work instructions. Execute the Guardian and AC Source programmed to output 132Volts.

The Test is performed with the product power cord

Connect the power cord to the Pass power inlet and the patient connection to the Pass binding post of the Patient Load Box
The Displayed Output shall be 132V ± 1%
The measured value shall be less than 0.01mA
The result shall be a pass

Repeat the test with the power cord connected to the Fail power inlet and the enclosure connection to the Fail binding post of the Patient Load Box
The Displayed Output for shall be 132V ±1%

The measured value shall be greater than 0.01mA
The result shall be a fail

Patient Leakage Normal Condition Acceptance Criteria:

- The Displayed Output was 132V ±1% for each test
- The measured value was less than 0.01mA for the Pass condition
- The measured value was greater than 0.01mA for the Fail condition
- The System reported Pass or Fail correctly for each condition

Patient Leakage Single Fault Condition Validation

Objective

The objectives of this section are to verify and document the performance of the Patient Leakage Test under Single Fault (Neutral Open) Condition using the Sentinel IIa and CaptivATE software

Procedure

Patient Leakage Single Fault Condition Verification
Patient Leakage is performed measuring leakage between Line and Line and the patient connection of the product while the product is powered on without connection to Neutral. Program the Guardian for a patient leakage test with single fault conditions per internal work instructions. Execute the Guardian and AC Source programmed to output 132Volts.

The Test is performed with the product power cord
Connect the power cord to the Pass power inlet and the patient connection to the Pass binding post of the Patient Load Box

The Displayed Output shall be 132V ± 1%
The measured value shall be less than 0.05mA
The result shall be a pass
Repeat the test with the power cord connected to the Fail power inlet and the enclosure connection to the Fail binding post of the Patient Load Box
The Displayed Output for shall be 132V ±1%
The measured value shall be greater than 0.05mA
The result shall be a fail

Patient Leakage Single Fault Condition Acceptance Criteria:

- The Displayed Output was 132V ±1% for each test
- The measured value was less than 0.05mA for the Pass condition
- The measured value was greater than 0.05mA for the Fail condition
- The System reported Pass or Fail correctly for each condition

Table 1 shows a sample of tests performed during validation. Note there is no DC hipot or insulation resistance test listed. Tests performed during validation are the tests defined in the process. Manufactures will have different test requirements depending on the device being tested; this application note should be used only as a guide and not used to define the validation process.

Table 1: Sample Pass/ Fail Validation Tests

Verification	Displayed Output Value	Displayed Measured Value	Displayed Test Result	Verified By:	Date:
Ground Bond Pass					
Ground Bond Fail					
Mains to Ground AC Hipot Pass					
Mains to Ground AC Hipot Fail					
Mains to Patient AC Hipot Pass					
Mains to Patient AC Hipot Fail					
Earth Leakage Normal Condition Pass					
Earth Leakage Normal Condition Fail					
Earth Leakage Single Fault Condition Pass					
Earth Leakage Single Fault Condition Fail					
Patient Leakage Normal Condition Pass					
Patient Leakage Normal Condition Fail					
Patient Leakage Single Fault Condition Pass					
Patient Leakage Single Fault Condition Fail					

So forth this application has reviewed the validation of the tester passing a good product and failing a bad product. Offset is a function to remove any excess resistance or leakage due to fixturing and hardware. This function is often used when testing a medical device. For that reason the validation process must ensure the offset functions as intended.

Offset Validation

Ground Bond Offset

Objective

The purpose of this test is to verify and document that the Ground Bond Offset function is operating as intended.

Procedure

Ground Bond offset is performed by shorting the power line ground to the ground post socket connector.

Perform the ground bond test with no Device attached. Record the measured value as ***Offset***
Perform the ground bond test with the device attached. Record the measured value as ***Measured***

Next select offset on the Guardian, remove the device and short the test leads together. When offset is complete the display will instruct to attach the device. Attach the device and complete the test.

Record the measured values as ***Measured with Offset .***
The offset display on the Guardian 6100 Plus shall be backlight.
Verify the following ***Measured = Measured with Offset + Offse***t within 1%

Acceptance Criteria:

- The offset light on the Guardian 6100 Plus was backlight after Offset was performed
- The correct offset was correctly subtracted from the measured value

AC Hipot Offset Validation

Objective

The purpose of this test is to verify and document that the AC Hipot Offset function is operating as intended.

Procedure:

Hipot offset is performed with an open circuit; no connections shall be shorted together.

Perform the AC Hipot test with no Device attached. Record the measured value as ***Offset***
Perform the AC Hipot test with the device attached. Record the measured value as ***Measured***

Select offset on the Guardian, remove the device and perform offset with an open circuit. When offset is complete the display will instruct to attach the device. Attach the device and complete the test.

Record the measured values as ***Measured with Offset***.
The offset display on the Guardian 6100 Plus shall be backlight.

Verify the following ***Measured = Measured with Offset + Offset*** within 1%

Acceptance Criteria:

- The offset light on the Guardian 6100 Plus was backlight after Offset was performed
- The correct offset was correctly subtracted from the measured value

Leakage Current Offset Validation

Objective

The purpose of this test is to verify and document that the Leakage Current Offset function is operating as intended.

Leakage Current test mode is used for Earth Leakage and Patient Leakage. The intent of this test is validating the Offset function within the Leakage Current mode therefore each Fault does not need to be tested. Each Leakage test utilizes different test connections and has different allowed leakage limits, to ensure functionality of the Offset Function Offset will be performed on each leakage current type (Earth, and Patient)

Procedure

Leakage current Offset is performed with an open circuit, no connections shall be shorted together.

Perform the Leakage Current test with no Device attached. Record the measured value as ***Offset***
Perform the Leakage Current with the device attached. Record the measured value as ***Measured***

Select offset on the Guardian, remove the device and perform offset with an open circuit. When offset is complete the display will instruct to attach the device. Attach the device and complete the test.

Record the measured values as ***Measured with Offset***.
The offset display on the Guardian 6100 Plus shall be backlight.

Verify the following ***Measured = Measured with Offset + Offset*** within 1%

Repeat for patient leakage

Acceptance Criteria:

- The offset light on the Guardian 6100 Plus was backlight after Offset was performed
- The correct offset was correctly subtracted from the measured value

Table 2 outlines a breakdown of offset validation and the data which should be recorded during the validation. Offset validation should be performed for all test modes used.

Table 2 Offset Validation

Verification	Offset	Measured	Measured with Offset	Measured with Offset + Offset	Does Measured with Offset + Offset = Measured (±1%)	Verified By:	Date:
Ground Bond							
AC Hipot							
Earth Leakage Current							
Patient Leakage Current							

For Ground Bond and Leakage current measurements the standard specifies the high limit (maximum measurement), most testers such as the Guardian 6100 Plus allow for a low limit to be programmed. A low limit is useful to ensure the device under test is connected and being tested.

In order to set the low limit expected values must be know before determining reasonable limits. This leads us to the repeatability portion of validation.

Repeatability

Safety test validation includes repeatability; can anyone perform the test and get the same results? This proves the process is sound as well as the equipment. Repeatability is typically performed using three known good products and three users.

Following the defined process the each user shall test three known good products. The results are recorded and compared. For a safety test, each user should obtain results which vary no more than the specification of the test hardware for each product.

Repeatability will provide a spread of expected measurements; these measurements can be used to refine the process to add low limits to the settings. Once the process has been refined, validation of the low limits must be completed.

Connection Validation

Setting low limits will ensure if a connection is not in place with the device under test the test will not pass. In some cases such as patient leakage it may not be possible to set a low limit due to the low levels of leakage current. Other means should be used to confirm connection is present.

Ground Bond Connection Validation

It is not necessary to set a low limit for ground bond, if there is an open circuit, a ground bond test will not pass. Validation can be done to prove the test will fail on open circuit.

Procedure

Remove ground connection from device undertest

Acceptance Criteria:

- The Ground Bond test fails when connection is not in place
- The Guardian will sound an alarm

AC Hipot Connection Validation

Objective

The purpose of this section is to verify the Mains to Ground AC Hipot test will produce a fail result if the connection to the DUT is not attached or broken.

Procedure

A Low limit is required to detect the Mains and Ground connection for AC Hipot.
Execute the test with the power cord of the DUT not connected
The test shall fail.

Plug the power cord into the G30 Adapter, disconnect the Drive – Sense – connection
The test shall fail

Reconnect the Drive – Sense – connection, disconnect Lout and Nout connection
The test shall fail.

Mains to Ground AC Hipot Acceptance Criteria:

- The AC Hipot test fails when the DUT power cord is not connected
- The AC Hipot test fails when the Drive – Sense – connection is broken
- The AC Hipot Test fails when the Lout and Nout connection is broken

- The Guardian alarm was sounded on each failure

Patient AC Hipot Connection Validation

Objective

The purpose of this test is to verify the Patient to Ground AC Hipot test will produce a fail result if the connection to the DUT is not attached or broken.

Procedure

A Low limit is required to detect the Ground and Patient connection for AC Hipot.

Execute the test with the power entry adapter not connected to the DUT.
The test shall fail.

Disconnect the power entry cord from the Guardian 6100 Plus.
Execute the test.
The test shall fail.

Attach the power entry adapter and disconnect the patient cable.
Execute the test.
The test shall fail.

Disconnect Channel 3 from the Guardian 6100 Plus.
Execute the test.
The test shall fail.

Patient to Ground AC Hipot Acceptance Criteria:

- The AC Hipot test fails when the DUT power entry cord is not connected or broken
- The AC Hipot Test fails when the patient is not connected or broken
- The Guardian alarm was sounded on each failure

Earth Leakage connections used to perform this test are the same as Mains to ground AC Hipot. AC Hipot is performed before the Earth Leakage Current test therefore any cable disconnects will be detected during AC Hipot. Depending on the setup this may also be the case for patient leakage.

Conclusion

This application note reviews the basics of validating a safety test system. Depending on where the safety tester is installed other validation may be required. If safety interlocks are installed. The interlock must also be validated. If the interlock is open, does the test stop? All conditions shall be performed during validation. As with the examples throughout this note the procedure, the expected result and actual result needs to be documented.

