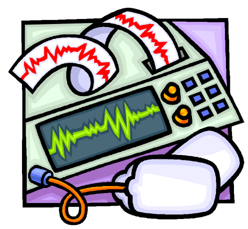
QuadTech

Application Note

Dielectric Strength Testing of External Cardiac Defibrillators: IEC60601-2-4

In America, approximately 350,000 people suffer sudden cardiac arrest each year. More than half of these victims do not survive. If a patient receives a defibrillation immediately after cardiac arrest, their chance of survival is 50%. For every minute that the patient does not receive care, their chance of survival drops almost 10%.

These staggering statistics have made it clear that the key to saving the lives of these victims is early treatment. In the early 1980's the concept of "chain of survival" was developed. This states that high survival rate of these victims requires:



- Early recognition and access to the patient
- Early CPR
- Early Defibrillation
- Early Advanced Cardiac Life Support

Prior to the 1970's, only hospitals had defibrillators. In the 1970's only highly trained paramedics were allowed to administer defibrillation. Automated External Defibrillators (AED's) were first introduced in the 1980's, making early care more possible by placing easy to use AED's in the hands of lesser-trained paramedics.

In 1991, the American Heart Association (AHA) published a statement that smart AED's should be placed in every ambulance and the vehicles used by "first responders" such as firemen or police. In 1993, the AHA started promoting "Public Access Defibrillators" (PAD's). These are very simple, low cost, and automated defibrillators intended for use by any bystander. These PAD's are intended for installation in homes, office buildings, factories, shopping malls, airports, and other public facilities. Although public implementation of these PAD's has begun, large-scale implementation is expected around 2005 to 2007.

Increased Risk of Electrical Hazard

Since AED's are now being placed in the hands of untrained bystanders, the risk of liability for medical device manufacturer's increases. It becomes tremendously important to perform extensive electrical safety testing not only in the design and production phase on all AED's, but also any time the defibrillator is being serviced or undergoes routine maintenance. These simple tests help ensure the AED's do not pose an electrical hazard risk to a patient, operator, or anyone within the PATIENT VICINITY.

In the IEC Particular Standard IEC 60601-2-4:2002, Second Edition (Particular requirements for the safety of cardiac defibrillators), Section Three (Protection Against Electrical Shock Hazards), clause 20 "Dielectric Strength", there are exceptions to the General Standard IEC 60601-1. The exceptions are in clauses 20.2 (Requirements for Equipment with an Applied Part), 20.3 (Values for test voltages), and 20.4 (Tests). Lets take a look at these exceptions.

Dielectric Strength Testing Particular Standard IEC60601-2-4 Exceptions

20.2: Requirements for EQUIPMENT with an APPLIED PART:

This section shows typical connections made to the defibrillator using an Electrical Safety Analyzer. By utilizing an Electrical Safety Analyzer with a High Voltage Output Scanning capability, the setup time and labor time can be greatly reduced as well as increasing operator safety. A scanner allows automatic switching of test point locations, eliminating the need for manually moving test leads from location to location.

When testing the defibrillator high-voltage circuit (Defibrillator Electrodes, Charging Circuit, and Switching Devices), the particular standard requires the following tests to be performed in addition to insulation category B-a, replacing insulation categories B-b, B-c, B-d, and B-e of the General Standard:

Test 1: With the switching devices of the DISCHARGE CIRCUIT activated, testing between each pair of DEFIBRILLATOR ELECTRODES connected together, to the following parts connected together:

a) Conductive ACCESSIBLE PARTS
b) PROTECTIVE EARTH TERMINAL (Class I Equipment) or Metal foil on which the EQUIPMENT rests (Class II Equipment or Internally Powered Equipment)
c) Metal foil in intimate contact with non-conductive parts liable to be handled in NORMAL USE
d) Any isolated DISCHARGE CONTROL CIRCUIT and any isolated SIGNAL INPUT or SIGNAL OUTPUT PART

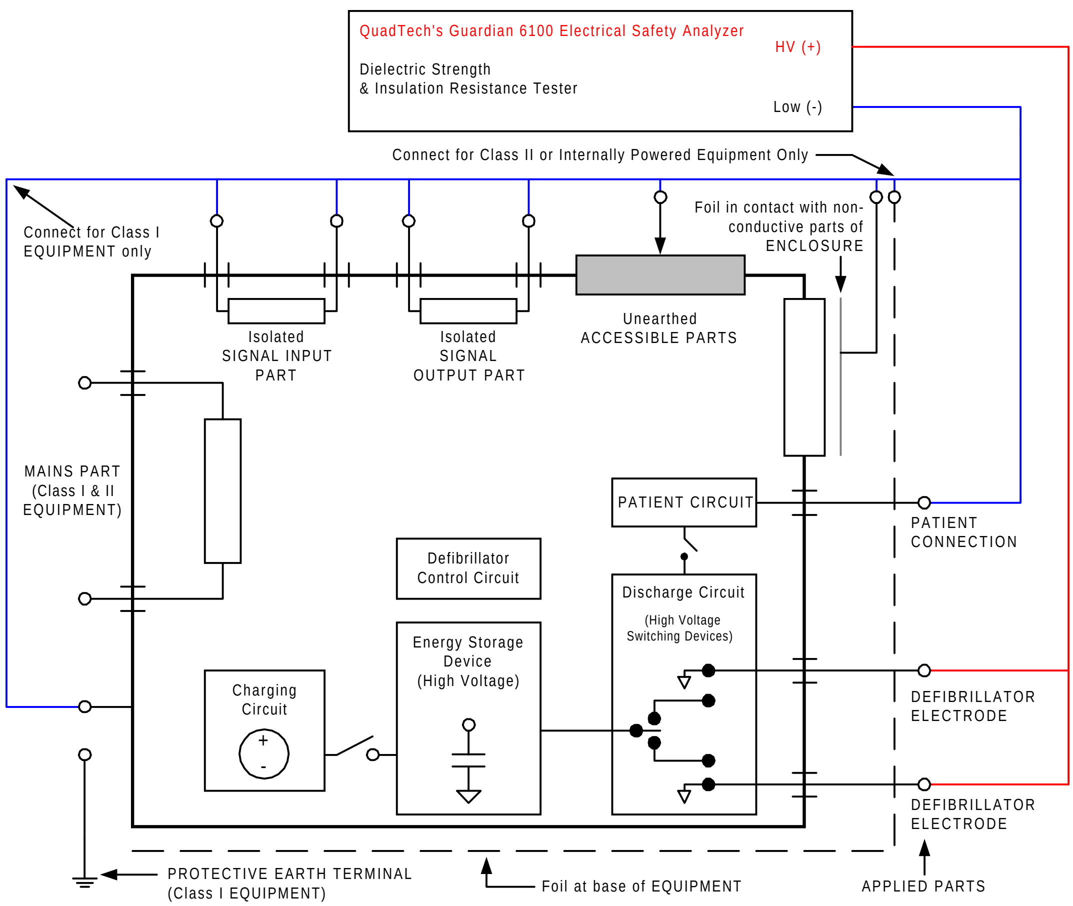


Figure 1: Test 1 Typical Connections

20.2: Requirements for EQUIPMENT with an APPLIED PART:

Test 2: Between DEFIBRILLATOR ELECTRODES of each pair – external and internal in turn – while:

a) ENERGY STORAGE DEVICE is disconnected
b) Switching devices of the DISCHARGE CIRCUIT are activated
c) Switching arrangements used to isolate the high-voltage circuit of the defibrillator from any PATIENT CIRCUITS are held in the open-circuit position
d) Any Components that would provide a conductive pathway between the DEFIBRILLATOR ELECTRODES during this test are disconnected.

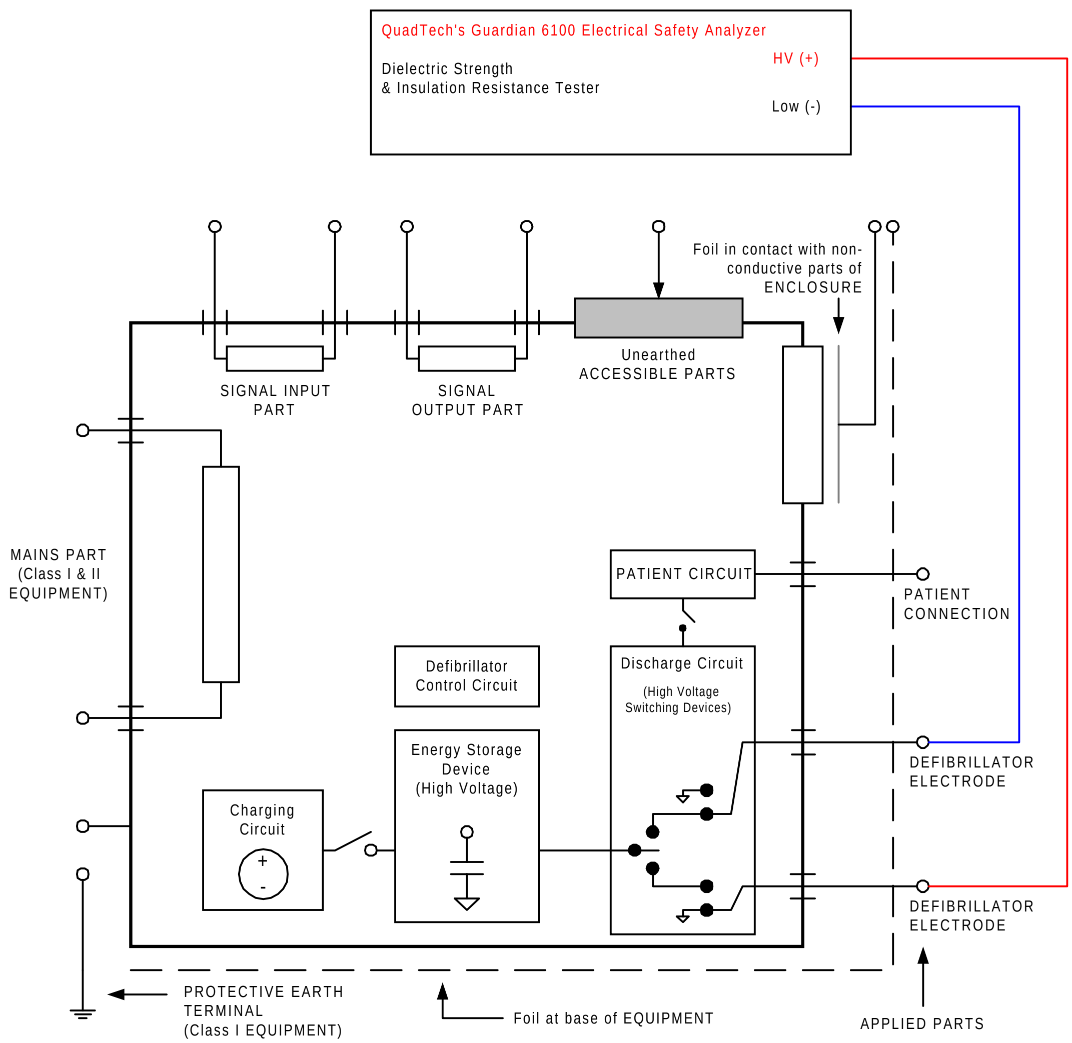


Figure 2: Test 2 Typical Connections

20.2: Requirements for EQUIPMENT with an APPLIED PART:

Test 3: Across each switching device in the DISCHARGE CIRCUIT and in the CHARGING CIRCUIT:

If the switching devices in the DISCHARGE CIRCUIT are intended to operate in series as a functional group, then the following tests also need to be performed:

a) Apply test voltage across each functional group in the polarity consistent with that of the ENERGY STORAGE DEVICE and verify the DC Withstand
b) Disconnect the ENERGY STORAGE DEVICE and substitute a test voltage

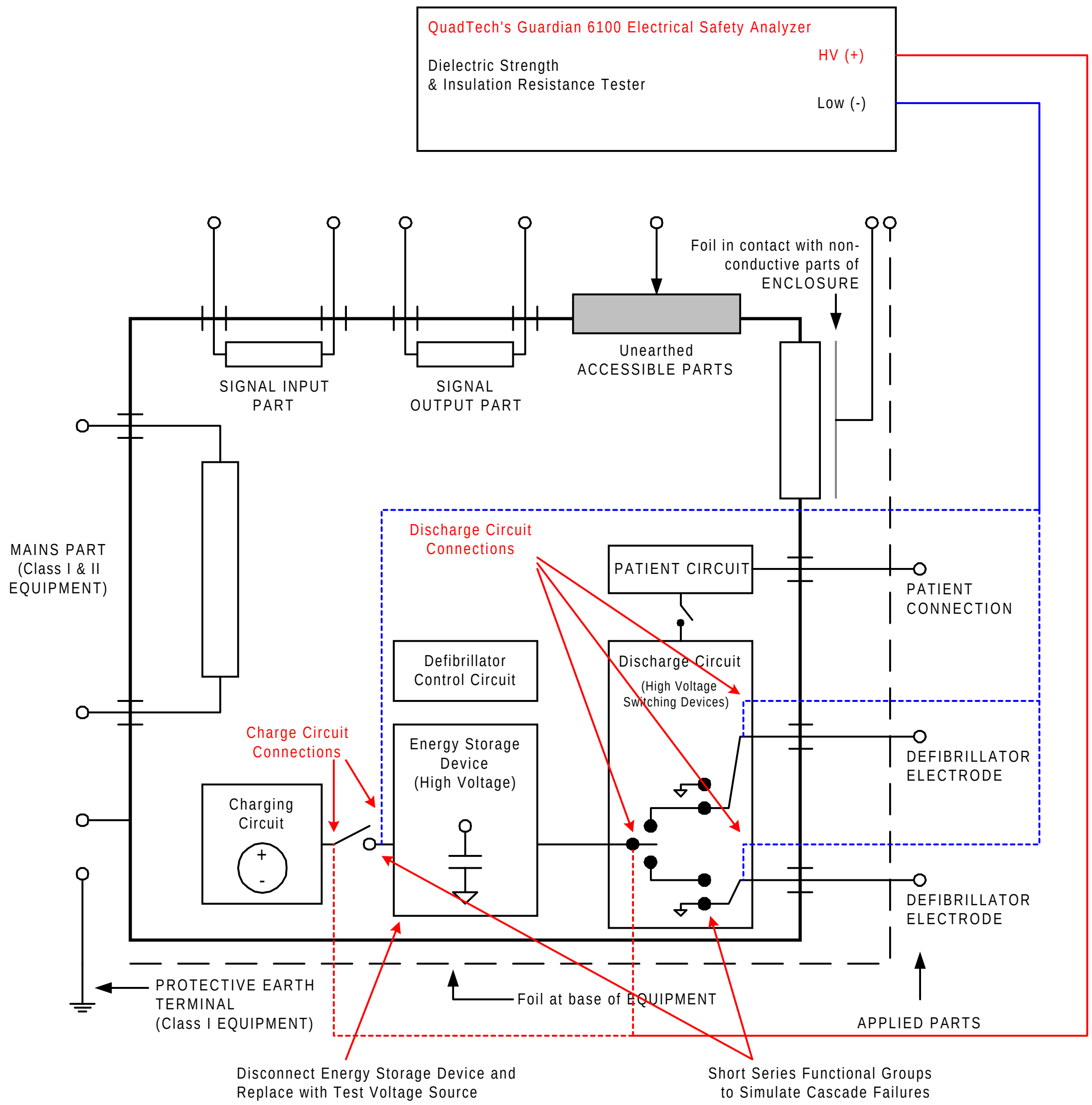


Figure 3: Test 3 Typical Connections

20.2: Requirements for EQUIPMENT with an APPLIED PART:

Test 4: Between the mains part and the DEFIBRILLATOR ELECTRODES connected together while the switching devices of the DISCHARGE CIRCUIT are activated.

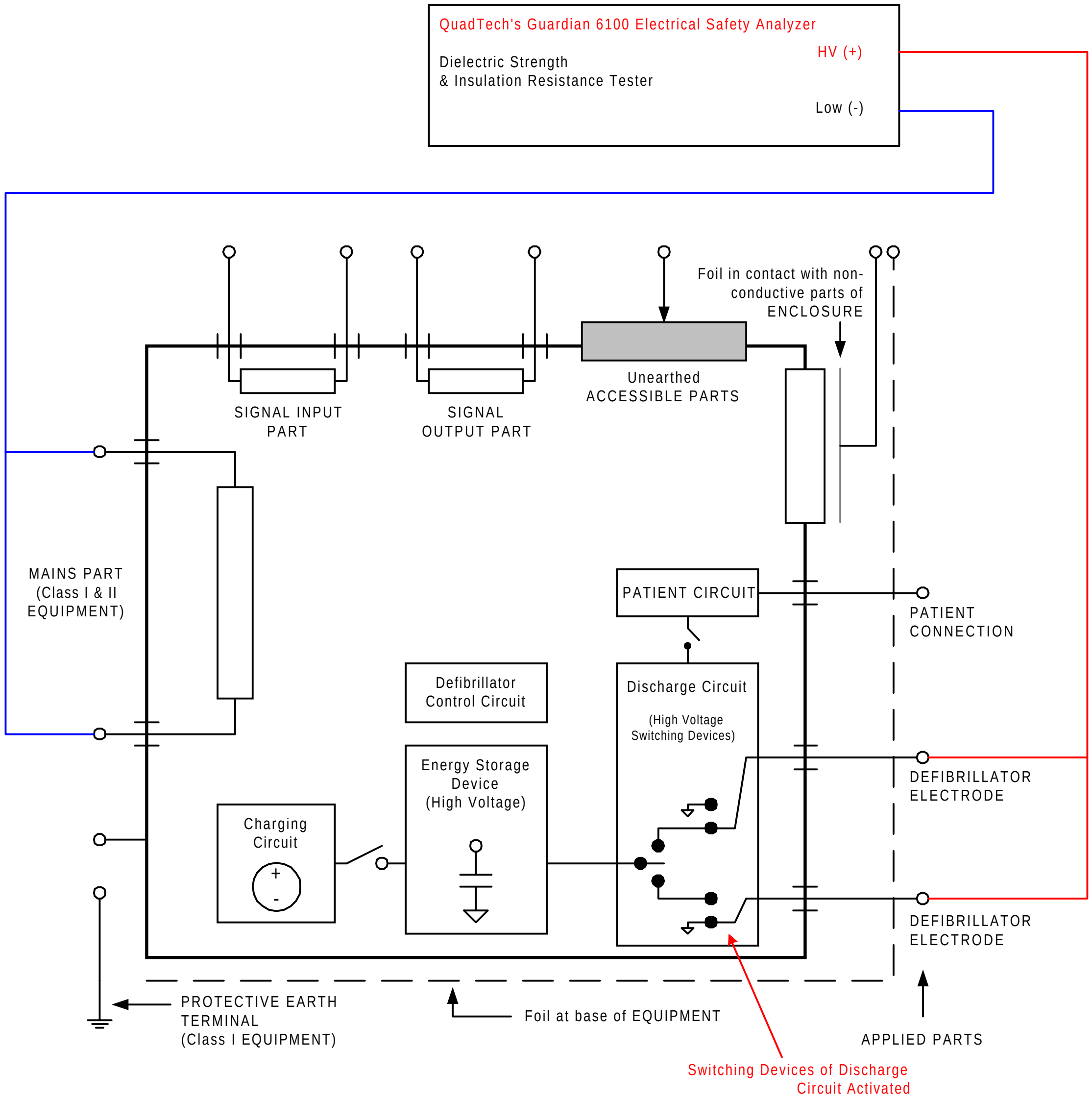


Figure 4: Test 4 Typical Connections

NOTE:

There are specific requirements and considerations for each test. One must review the appropriate IEC 60601-2-4 test to evaluate if these considerations apply to the defibrillator design being tested.

20.3: Values of Test Voltages

Now that the connections to the DUT have been made, the proper tests need to be run. This section outlines the deviations of the test types and values that are dependent on the circuit being tested. It will also show how to apply the test voltage.

There are two types of tests to run:

1. Dielectric Withstand Test (also called Hipot Test or Dielectric Breakdown Test). This test can be performed A.C. or D.C. For the case of this Particular Standard, the D.C. dielectric withstand test is performed, not the A.C. This test applies an external D.C. high voltage and measures the leakage current flowing through the insulation barrier.

2. Insulation Resistance Test. This test also applies an external D.C. high voltage across the insulation barrier, but measures the D.C. Resistance of the insulation material.

For the DEFIBRILLATOR high-voltage circuit (for example DEFIBRILLATOR ELECTRODES, CHARGING CIRCUIT, and switching devices) and tests 1, 2, 3, and 4, the insulation shall withstand a DC Dielectric Withstand Test of 1.5 times the highest peak voltage (U) occurring between the parts concerned during discharging in any mode of normal operation.

For all other circuits, the Dielectric Withstand Test values can be found in Table V of the General Standard. In addition, IEC 60601-2-4 also requires an Insulation Resistance Test for the DEFIBRILLATOR high-voltage circuit. The value of Insulation Resistance between the points being tested should not be less than 500MΩ.

NOTE:
There are specific requirements and considerations for each test. One must review the appropriate IEC 60601-2-4 test to evaluate if these considerations apply to the defibrillator design being tested.

When applying the test voltage, initially the test voltage shall not be more than half of the specified voltage, and then it shall be gradually raised over a period of 10 seconds to the full value. The full value shall be held for 1 minute, and then lowered over a period of 10 seconds back to half of the specified voltage before being turned off.

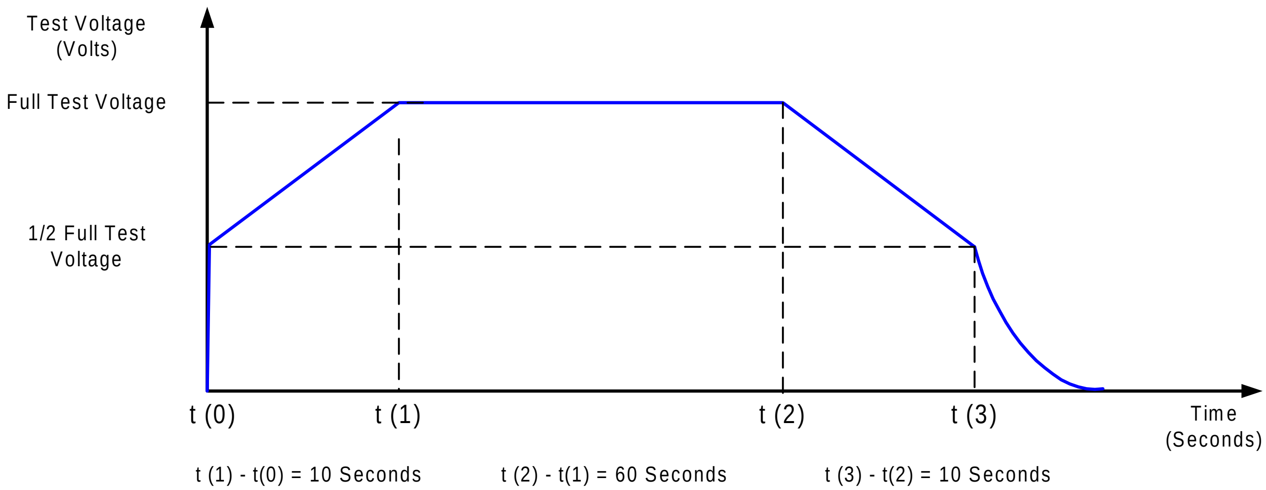


Figure 5: Timing Diagram of Applying Test Voltage from Table V of General Standard

However, for Test 4, this diagram does not apply. Figure 6 shows the correct timing and voltage application for Test 4.

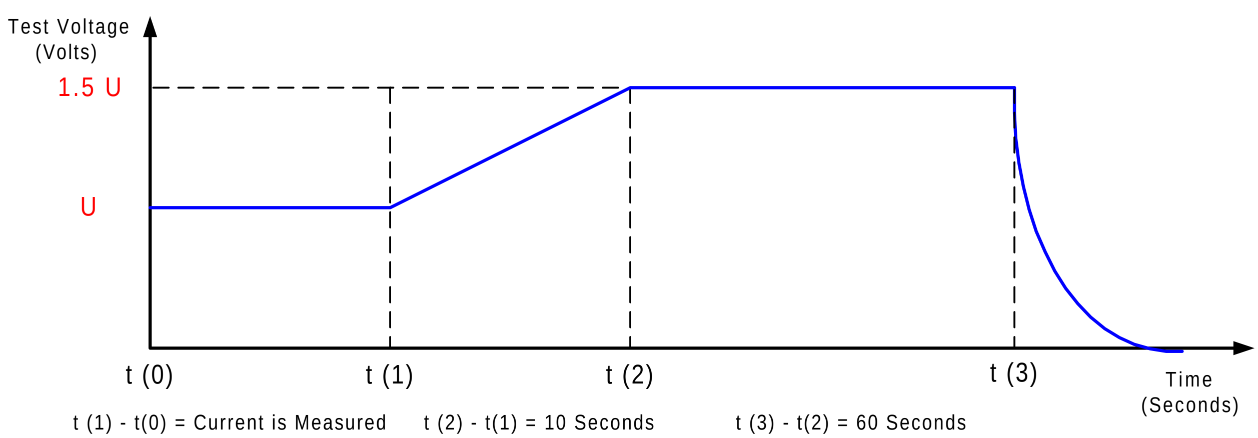


Figure 6: Timing Diagram for Applying Highest Peak Voltage (U) in Test 4

During these tests, there shall be no flashover or breakdown. Slight corona discharges are acceptable if they cease when the voltage is dropped to a lower value that is higher than the referenced value "*U*", and does not provoke a drop in test voltage.

The Guardian 6100 Electrical Safety Analyzer has a built in feature "IEC 601-1" in the Utilities section that enables the ramping feature as shown in Figure 5. The 6100 will not perform the ramping feature as shown in figure 6 for Test 4. However, it is acceptable to ramp from 0 to Full Test Voltage within 10 seconds, bypassing the need for an intermediary step.

A Deviation

The only deviation of 60601-2-4 in this clause from the General Standard is an amendment to 20.4.a) (first "dash"). The General Standard states:

"…immediately after warming up to operating temperature and de-energizing the EQUIPMENT with an incorporated mains switch closed, or"

The 60601-2-4 amendment changes this to:

"…immediately after attaining the steady-state temperature reached by the EQUIPMENT operating in STAND-BY"

So when selecting the test equipment for performing these tests, be sure to select a tester that can perform:

- Dielectric Tests and Insulation Resistance Tests
- Ramp and Test Times According to clause 20.4.a (Figure 5 of this note, not Figure 6)
- Scanner that can switch between Test Points Automatically without the operator having to manually move test leads to multiple locations
- RS232 or IEEE Communication for Process Automation and Data Collection
- Connection to a Printer for Hardcopy Test Data Results

QuadTech's Guardian 6100 Electrical Safety Analyzer can perform these functions as well as Line Leakage, Enclosure Leakage, Patient Leakage, and Patient Auxiliary Leakage Current per the requirements of IEC60601-1 and –2-4.

For complete product specifications on the Guardian 6100 or any of QuadTech's products, please visit http://www.quadtech.com/products. Call us at 1-800-253-1230 or email your questions to info@quadtech.com.

References:
IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-2-4:2002, Second Edition Particular requirements for the safety of cardiac defibrillators
UL 2601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety, U.S. Deviations

Telephone: 1- 800-253-1230, Website: http://www.quadtech.com
Printed in U.S.A. P/N 035126/A1 September 2003