

MegaPulse Defib-5: FAQ

Overview: The Defib-5 was designed and built to perform the “Defib-safe” tests in many Medical Standards, which proves that a device will function correctly if connected to a patient when a defibrillation pulse is delivered. The Defib-5 is designed to output the waveform as shown in IEC 60601-1, Issue 3 Figures 9, 10 and 11 as well as many tests in other Standards, please see first question below. It is built for high reliability and accurate output in conformance with the circuit shown in the Standard. The output of the Defib-5 is in agreement with pspice simulations of the circuit given in the Standard. The standard Defib-5 is suitable for laboratory use. Its output is within 2% and it can output a pulse every minute. Use of the FCD option is suitable for production line use and allows 12 second pulse times, as well as providing an autotrigger circuit which provides very repeatable results. The TMMD option allows computer control of sequenced tests.

FAQ:

What Standards can the Defib-5 test to?

It can test to IEC 60601-1 Issue 2, Figure 50; and IEC 60601-1 Issue 3, Figures 9, 10 and 11. Its 100 ohm port on the rear panel allows energy measurements to be taken. Compliance West USA has developed a program to allow the energy measurement to be determined automatically; information is available at <http://www.compwest.com/dgsb.html>.

Tests to the following Standards:

IEC 60601-1 Issue 3 Figures 9 and 10; Figure 11 including energy measurement

AAMI EC-13 Fig. 9B (Para. 5.2.2.2.3)

AAMI EC-53 Fig. 7

IEC 60601-2-49 Fig. 101

IEC 60601-2-27 Fig. 101, 104 and 105

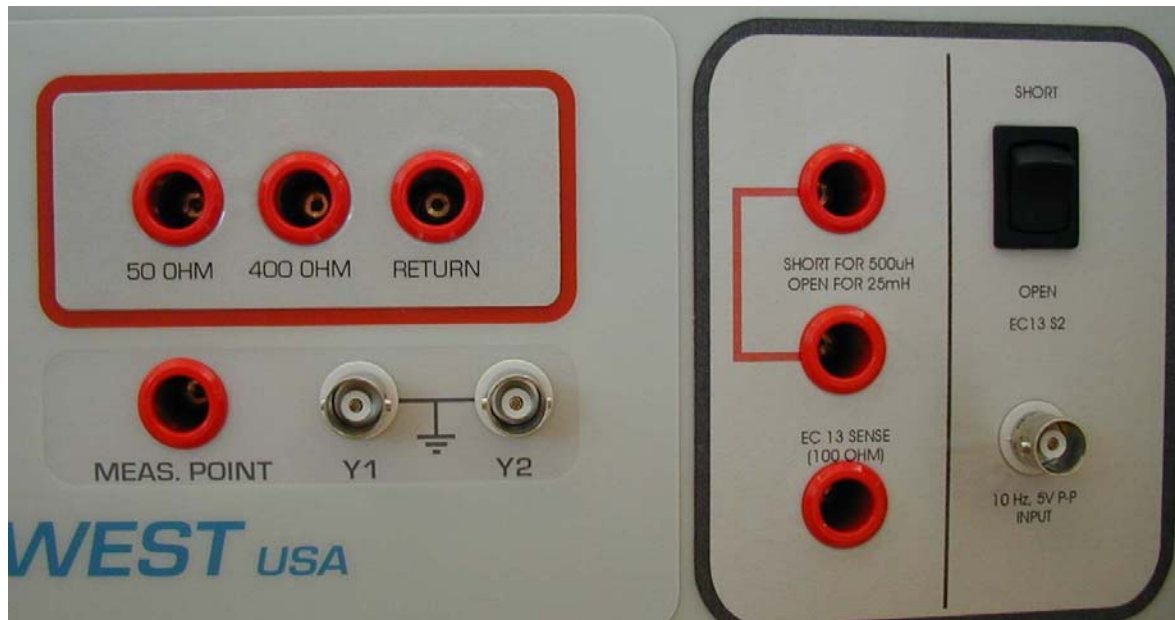
AAMI EC-13 Fig. 9A and AAMI EC-11.

What is the 'PASSFAIL Defib-5 Pass-Fail Reference' meant for?

The Pass./Fail Reference is meant to be a check of the operation of the Defib-5, and of the entire test setup. The Pass/Fail reference is substituted for the DUT in IEC 60601-1 Figure 50, and outputs a barely passing (1V) signal to the oscilloscope connected to the Y1-Y2 BNC connectors on the front of the defib-5. If the Defib-5 and test setup are working correctly, the output to the oscilloscope will be a long duration waveform with a 1V peak. There is a picture of the expected waveform and explanatory information on our website at http://www.compwest.com/our_products/mega-imp/Defib-5passfail.htm.

AAMI EC-13 and the other tests conducted with the Defib-5 require different inductor and resistance values than the standard Defib-5 tester. How does the operator change the inductance and resistance values in the Defib-5?

There is a jumper to set the capacitance and a separate output for the different resistance value, as seen in this picture of the front panel of a Defib-5 with both the 00-13 and 00-27 options. For standard Defib-5 testing to IEC 60601-1 Issue 3 Figure 10, the jumper would be put in place and the output would be taken from the 50 ohm output and the return. For testing to EC-13 etc., the jumper would be removed and the output would be taken from the 400 ohm output and the return.



Is the high repeatability related to the FCD only? What accuracy and lifecycle can be expected w/o the FCD option?

Yes, the high repeatability is related to the FCD option. This option includes a circuit which triggers the pulse when exactly 5000V is available on the capacitor. The standard Defib-5 is manually triggered, and the accuracy of the meter is 2% full scale, so if the operator triggers the pulse exactly when 5000V appears on the display, the output pulse will be +/- 100V. While we think the 2% accuracy of the output pulse is pretty good on the standard Defib-5, we have worked with some customers who have demanded the extreme accuracy offered by the autotrigger circuit.

The capacitor bank life is assigned by the capacitor manufacturer at 20,000 cycles, and we have verified that number. After 20,000 cycles of continuous use, we have seen failures of single capacitors in the bank which lower the capacitance of the bank and therefore decrease the power available in the pulse. As part of the calibration of the Defib-5, the power output of the pulse is checked. If the power is appreciably lower than when new (by comparison to as-new power calculations), the capacitor bank can be replaced for approximately \$500 and the output is again in accordance with the simulations of the output pulse. (No waveforms are given by the Standard, but we have simulated the output with pspice so we understand the circuit which is described in the Standard).

We think 20,000 cycles is sufficient for laboratory use for many years of service. As an aside, we have noted in our tests that sporadic use of the tester as would be seen in a laboratory environment, increases the life of the capacitor bank substantially.

Can you provide certified calibration data (A2LA or NAVLAB or ...)?

We solely recommend the services of World Cal for the Defib-5 ISO 17025 calibration. Their cost for calibration of the Defib-5 by World Cal is slightly more than \$1000, and we recommend contacting them for exact pricing. We have sent products directly to them for calibration enroute to our customer. If you would like us to do that for you, or if you would like to use a different lab, please let us know. If a laboratory will be used for referee calibration to judge the acceptability of the output of the Defib-5, we will require use of World Cal's services.