



## ECG - Input Impedance and Noise

In ECG standards, clauses such as 201.5.3 cc) of IEC 60601-2-25 require that test signals are accurate to  $\pm 1\%$ . Although not explicitly stated in the standard, it's obvious that this includes noise. If for example a test requires the ECG under test to reproduce a test signal accurately within  $\pm 5\%$ , it would make no sense to perform the test if the test signal also had say  $\pm 20\%$  noise.

Some engineers however might consider environmental (common mode) noise as a separate issue. ECGs are required to work in noisy environments so they should have the ability to reject common mode noise. Hence testing in a normal "noisy" environment is representative of the real world. This is wrong for two related reasons: first the ECG is anyhow tested for the ability to reject noise including common mode noise; second is that in order to test objectively, we need to start with a low noise environment and then add test signals including noise in a known and accurate way.

As such, while there are no instructions, notes, requirements or methods in the standard to minimize noise, such actions are implicit in the requirement to apply test signals with an accuracy of  $\pm 1\%$ . In particular, most test signals are in the order of 1mV, which means noise of just 10 $\mu$ V is significant. Normal methods to minimize noise include using a ground plane under the ECG, cables and test equipment, and connecting the ECG equipment earth (PE or FE) and the test circuit ground to the ground plate.

The input impedance test is by far the most sensitive to noise, and sometimes the normal procedures are not enough. The reason for the high sensitivity to noise is the large imbalance impedance. To understand why this is so, it is useful to review the article on CMRR testing, which explains how CMRR is really a function of leakage currents flowing through the imbalance impedance. It follows that the size of the imbalance impedance directly impacts the size of the CMRR noise on the ECG.

For CMRR testing, the imbalance is 51k $\Omega$ , while for the input impedance test the imbalance is 620k $\Omega$ , some 12 times larger. This means that the input impedance test is 12 times more sensitive to noise than the CMRR test.

We can do some ball park calculations to illustrate the point. If say in an CMRR test the ECG records a 3mm indication; in voltage terms this is 0.3mVpp from a 10Vrms common mode voltage.



In the input impedance test, the typical test voltage is 3.2mVpp (80% of 40mm channel width @ 10mm/mV), so a 1% error is roughly 0.03mVpp, which is 1/10 of the above CMRR result. Since the set up is 12 times more sensitive to noise, it means the common mode voltage in the input impedance test needs to be less than:

$$V_{cm} = 10 V_{rms} / 10 / 12 = 0.083 V_{rms} = 83 mV_{rms}$$

A floating circuit with cables can easily pick up 2~10Vrms of common mode voltage from the environment, and people near a test site tend to make this worse. So, to get this down to 83mVrms may need some special shielding.

Additional measures may include adding a shield above the test set up (in particular for ECG cables), having the operator touch the ground plate during the test, and/or keeping ac power cables away from the test area as far as possible. The thickness of the shielding materials also helps: being very thin aluminum foil is sometimes not much help, but a 1mm thick aluminum plate usually works well.

Although not specified in IEC 60601-2-25 and IEC 60601-2-27, it is also possible to turn on the AC filter to remove 50 or 60Hz noise. The AC filter will reduce the common mode noise, should have no effect at 0.67Hz and may slightly reduce the signal at 30Hz. For example, you may need 3.5mVpp to get 32mm on the ECG due to the AC filter. Since the input impedance test is ratiometric, as long as the filter is on during the whole test the test result will still be valid.

Finally it is worth to note that some environments are naturally quiet while others are incredibly noisy. The input impedance test condition with the 620kΩ in circuit is a good worst case condition to check out the noise levels at different test sites. It can be useful to select a quiet site for all performance tests.

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