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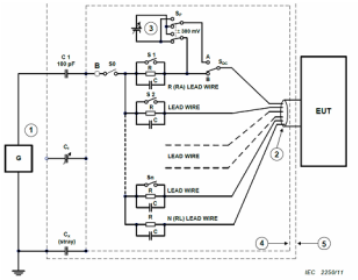
CMRR Testing – Application Note



Like EMC, CMRR testing is often considered somewhat of a black art in that the results are unpredictable and variable.

This article attempts to clear up some of the issues by first looking at exactly how CMRR works in ECG applications, where the "noise" indication comes from and how manufacturers deal with the problem.

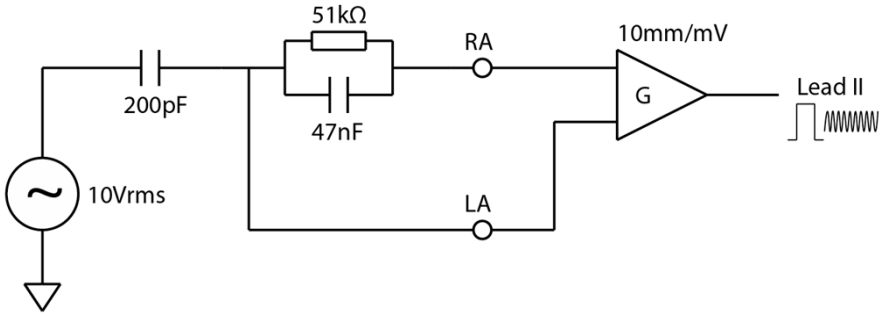
It also has a look at the importance of external noise, methods to eliminate and verify the set up is relatively free from external noise.

This application note is intended to support engineers that may already have some experience with CMRR testing but remained confused by variable results in individual set ups.

CMRR analysis from basics

CMRR is often considered a function of the op-amp performance, but for the CMRR test in the IEC / AAMI standard it turns out the indication on the ECG is mostly due to **leakage currents** passing through the 51k/47nF impedance.

First, let's consider the basic circuit test circuit:



For those wondering about the 10V/200pF, this is the "Thevenin equivalent" of the 20V 100pF:100pF divider in the circuit found in IEC/AAMI standards.

If this circuit were perfect, with the ECG inputs and gain element G are floating with infinite input impedance, the 51k/47nF should have no effect and Lead II indication should be zero.

In practice, there will always be some small stray or deliberate capacitance in the system in the order 5pF to 1000pF. This means the ECG inputs are not perfectly floating and small amounts of leakage will flow in the circuit.

The main cause of leakage is the capacitance between each input and shield or ground of the floating ECG circuit, and between that ECG shield/ground and the test system ground.

To understand how these influence the test it is best to re-arrange the circuit in a "long" fashion to appreciate the currents and current flow through the stray capacitance:

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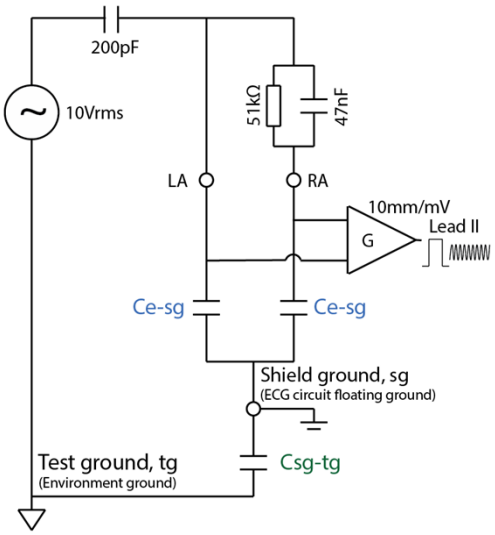


In this diagram, stray capacitance Ce-sg is added between the ECG electrode inputs and the ECG circuit ground (which is usually floating).

This capacitance is fairly high due to cable shielding and the internal electronics. Also each electrode has roughly the same stray capacitance. For example, a 12 lead diagnostic ECG measured around 600pF between RA and the shield, with a similar result for LA.

Capacitance Csg-tg between the ECG circuit ground (shield ground) and the test ground is also added. This value can vary greatly, from as little as 5pF for a battery operated device with the cable well removed from the ground plane, to around 200pF for a mains operated device.

Lets assume $C_{e\text{-}sg}$ are both 100pF, and Csg-tg is 10pF, and try to calculate the current that flows into the circuit. Although it looks complicated, it turns out the 51k/47nF is much smaller impedance compared to the stray capacitance, so at first step we can ignore it. The calculation of the total capacitance seen by the source is then "relatively" simple:

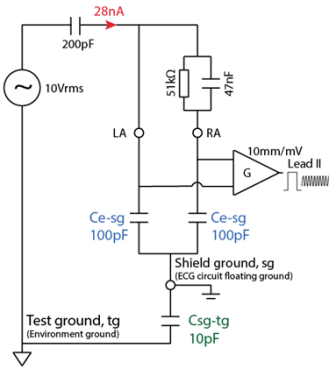
Ct = 1/(1/200+ 1/(100+100) + 1/10) = 9pF

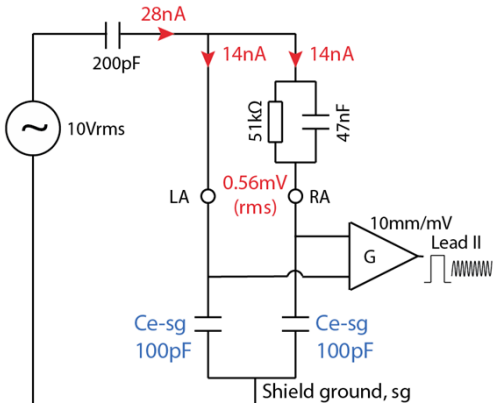
We can see here that the largest impedance $C_{sg\text{-}tg}$ (shield to test ground) influences this result the most.

We can then calculate the total current flowing into the ECG:

I = 10Vrms x 2π x 50Hz x 9pF = 28nArms

This seems very tiny, but keep in mind ECGs work of very small voltages.





The trick here is to realize that because Ce-sg is similar for RA and LA, this current will split roughly equally into both leads; around 14nA in our example.

RA has the imbalance impedance of 51kΩ/47nF which has an impedance of Z = 40kΩ at 50Hz. When the 14nA flows thought this it creates 0.56mVrms between RA and LA. This is measured normally and on a 10mm/mV results in around 8mm peak to peak on Lead II of the ECG display.

To summarize, the 10Vrms will cause a small but significant amount of leakage to flow into the ECG circuit. This leakage will split roughly the same into each electrode. If there is an impedance in one electrode, the leakage will cause a voltage drop in that electrode that shows up on the ECG.

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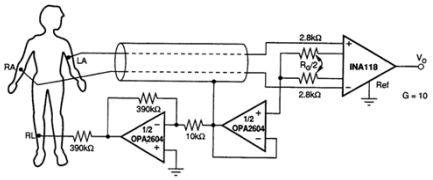
In the above example, we can see that the capacitance Csg-tg between the ECG shield and the test ground had the largest effect on the result. We assumed 10pF, but increasing this to just 13pF would be enough to change this to a fail result. Many devices have 100pF or more; and the value can be highly variable due to the position of the shielded cable with respect to ground.

With such a small amount of highly variable capacitance having such a big effect, how can ECGs ensure compliance in practice?

The right leg drive

Most ECGs use a "right leg drive", which is active noise cancellation and is similar to the methods used by noise cancellation headphones. Although noise "cancellation" implies a simple -1 feedback, it is often implemented a medium gain negative feedback loop, and sometimes with shield also driven at the +1 gain.



Regardless of the method, the basic effect is to absorb the leakage current through the RL electrode, which prevents it from creating a voltage across any impedance imbalance (51k/47nF).

In reality these circuits are not perfect, and in particular it is necessary to include a reasonable size resistor in the RL to prevent high dc currents going to the patient especially in fault condition. This resistor degrades the CMRR performance.

The residual indication on most ECGs (usually 3-7mm) is mostly a measure of the imperfection of the RL drive. This will be different for every manufacturer, but generally repeatable. Two test labs testing the same device should get similar results. Two samples of the same device type (e.g. production line testing) should give roughly the same results.

Since each RL drive system is different it can no longer be predicted how the system will react to changes in the position of the cable with respect to the ground plane. Test experience indicates that most ECGs with a RL drive, the indication reduces if the cable is closer to the test ground (Csg-tg capacitance is increased). Experiments (not required by standards) with a Fukuda Denshi 12 lead diagnostic ECG found that wrapping a portion of the cable tightly in foil and connecting that to test ground caused the signal to reduce by 50%.

For repeatable results, it is recommended that the cable is supported at 3cm or more off the ground plane. With this rule, small changes in the cable position should not have a big effect.

Systems without RL drive

In general, all mains operated ECG will employ a RL drive as the leakage will be otherwise too high.

In battery operated systems, some manufacturers may decide not use a RL drive.

Without a RL drive the analysis shows the test result will highly sensitive to the cable position with respect to the test ground. The result is predicted to *increase* if the ECG device and cables are closer to test ground. This experience has been confirmed in tests, with one device passing tests with WhaleTeq ECG breakout box positioned normally with the leads supported away from the test

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ground plane, and failed just by turning the box on the side causing the leads positioned closer to the ground plane.

With the advent of wireless medical monitoring, there may be battery operated equipment intended for monitoring or diagnostic applications, together with inexperienced manufacturers that may not know the importance of RL drive. The current standards (-2-25, -2-27) are not written well since they do not define what is done with the cable.

If a RL drive is not used, the above analysis indicates the intended use should be limited to being *always* worn on the patient and tested similar to IEC 60601-2-47. If the device has long cables and the recorder may be situated *away* from the patient, an RL drive should be used to avoid trouble.

For ambulatory equipment, the standard IEC 60601-2-47 specifies that the cable is wrapped in foil and connected to the *common mode voltage,* not the test ground, simulating the cable being close to the patient. The above analysis indicates this will *improve* the result, as the foil helps to divert the current from the flowing through the 51k/47nF. The test voltage for ambulatory is also much smaller. As such ambulatory equipment may pass without a RL drive.

External noise

In the actual CMRR test set up, the ECG electrodes are floating with around 10-15MΩ impedance to ground. This high impedance makes the circuit very susceptible to external noise, far more than normal ECG testing. The noise can interfere with the true CMRR result.

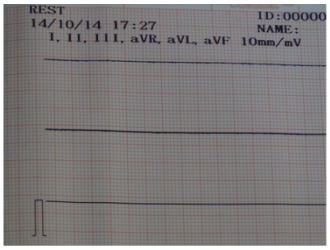
Therefore for repeatable results, the test engineer must first set up to eliminate external noise as far as possible, and the test (verify) that there is no significant noise remaining.

To eliminate the noise the following steps should be taken:

- Equipment on earthed metal bench or ground plane (recommended at least 1mm thick)
- All of the ECG cable over the bench or ground plane
- Connect CMRR test unit ground, ground plane, ECG/EUT ground (if provided), and check the are using ohm meter (<0.5Ω)
- During the test, any people standing near the set up should touch the ground plane

To check the set up has no significant noise:

- Set up the equipment as normal, including the initial test with 20Vrms
- Set RA lead *with* impedance (51k/47n)
- Turn the generator voltage off
- Verify the indication on Lead I or Lead II is essentially a flat line at 10mm/mV. A small amount of noise is acceptable (e.g. 1mm) as long as the final result has some margin to the limit.



With function generator off, indication should be <1mm even with an imbalance

If noise is still apparent, a ground plane over the cables may also help reduce the noise.

Prepared by Peter Selvey, MEDTEQ Japan, 15 December 2016