

Regular Check-ups on Electrical Safety Analysers (ESA)

Over the years, Electrical Safety Analysers have become a “must have” Analyser for most professionals in the production, service and maintenance fields for Electrical Medical Equipment.

Most Manufacturers have Preventive Maintenance procedures that includes Electrical Safety Testing following International standards such as IEC 60601 or IEC62353.

On a daily basis, field Engineers and Technicians from Manufacturers, Service Companies and Biomedical Departments in Hospitals are performing Electrical Safety Tests in accordance with recommendations of the Manufacturers or based on their own test protocols and experience.

With so much usage of Electrical Safety Analyzers, there is a very important question :

How can you be sure that your ESA is working well ?

Most ESA users are sending their analyzers for calibration on an annual basis. Receiving the unit back with a calibration certificate is taken as a “guarantee” that the unit is doing the measurements in the limits specified by the manufacturer, and as a result, can be used for another 12 months or until the calibration is due again.

This is the typical business practice, but is not exactly the way the process should be understood.

We can consider the following on the calibration process:

The annual calibration of an Electrical Safety Analyser is to check that at a given date (the calibration date), the unit can complete the measurements in the limits specified by the manufacturer. If successful, then a calibration certificate is issued saying that, at this date, the ESA conforms with Manufacturer’s technical specifications and can be used.

From this point, Manufacturers, Service Companies, Biomedical Departments in hospitals can validate all the tests **previously done** by the ESA, but there is no way to have insurance that future tests will be valid until the next calibration is performed on the ESA.

Imagine this potential situation:

The ESA internal circuit for current leakage measurements is broken.

The measurements of leakage current is “0 μ Amp”.

This is interpreted by the ESA as a “Pass Result” because “0 μ Amp” is lower than the IEC limits.

What we have here is a “Pass” result with a faulty ESA!!!

During the next calibration, the unit will certainly fail and needs to be repaired.

This could have some severe consequences:

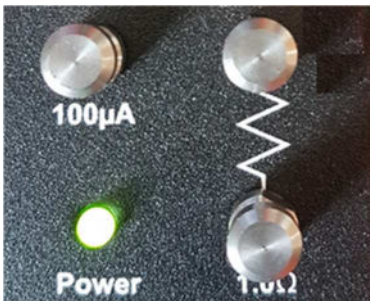
1. *All tests done before the next calibration is now in question. When did the unit fail? For How long?*
2. *The equipment tested using the broken ESA, will they put patient safety at risk?*

How can we avoid the risk of performing non valid or faulty tests with an ESA for long periods of time ?

A possible answer to this question is to run a verification of the ESA on regular basis.

The Datrend Electrical Safety Analyser, **vPad-Rugged 2 / vPad-ES 2** have the unique feature in the market of ESA's to allow the user to verify himself if the Analyser is performing the measurements in accordance with manufacturer specifications.

Knowing that an ESA test includes measurements of Protective Earth Impedance (in mΩ) and Leakage Current (in μAmp), the Datrend **vPad-Rugged 2 / ES 2** have the following test points build on the device:



- 100 μAmp Leakage current Reference
- 1Ω Impedance Reference

It is very easy and takes very little time to connect the measurement circuits of **vPad-Rugged 2** to the 2 test points and verify the results as you can see below :



In a quality process, Datrend **vPad-Rugged 2** users can easily add a verification of the ESA each day, each week, each month, or each quarter at your convenience.

These verification results can be used, in a case of an Audit, to prove that the ESA is regularly verified and annually calibrated to ensure tests done between these verifications are valid and accurate.

The **vPad Rugged 2** has this verification built in, it is useful as a reassurance that your safety testers are accurately measuring protective earth bonding and leakage correctly. Detecting a system which is out of specification could save time and resources for your business.

Until next time, be efficient and stay safe.

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