

# Ensuring Proper Electrical Safety Analyzer (ESA) Performance between Calibrations

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

Most manufacturers have Preventive Maintenance procedures that include Electrical Safety Testing following International standards such as IEC 60601, IEC62353, NFPA-99, and so on. On a daily basis, field Engineers and Technicians from Manufacturers, Service Companies, and Biomedical Engineering 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, we must ask a very important question:

## How can you ensure that your ESA is working properly?

Most ESA users are sending their analyzers for calibration on an annual basis. Receiving the unit back with a calibration certificate 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 a typical 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, where on this date, the ESA is in conformity with Manufacturer’s technical specifications.

From this point, Manufacturers, Service Companies, Biomedical Engineers in hospitals can confirm that **all tests previously done** by the ESA are valid, but there is no insurance that future tests will be valid until the next calibration is completed on the ESA.

**Imagine this potential situation:**

The ESA internal circuit for current leakage measurements is damaged. The measurements of leakage current reads “0  $\mu$ Amp”. This is interpreted by the ESA as a “Pass Result” because “0  $\mu$ Amp” is lower than the IEC limits.

What we have here is a “Pass” result with a defective 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 during this period, will they put patient safety at risk?

## How can we avoid the risk of performing non-valid or faulty tests with an ESA?

A possible solution to reduce this risk is to run a verification of the ESA on regular basis.

The Datrend Electrical Safety Analysers, **vPad-Rugged 2** and **vPad-ES 2**, both have a unique feature in the market of ESA’s to allow users to verify if the Analyser is performing the measurements in accordance with manufacturer specifications.

Knowing that an ESA test includes measurements of Protective Earth Impedance (in  $m\Omega$ ) for Class I Electrical Medical Equipment and Leakage Current (in  $\mu$ Amp), the Datrend **vPad-Rugged 2** and **vPad-ES 2** have the following test points build-on the device:

- 1  $\Omega$  Impedance Reference
- 100  $\mu$ Amp Leakage Current Reference



It is very easy and takes very little time to connect the measurement circuits of **vPad-Rugged 2** or **vPad-ES 2** to these test points and verify the results.

In a quality process, Datrend’s **vPad-Rugged 2 / ES 2** users can easily add a verification of the ESA each day, each week, each month, or at the organization’s determined intervals. These verification results can be used during an audit to prove that the ESA is regularly verified and annually calibrated to ensure tests done between these verifications are valid and accurate.

This is a safety precaution and certainly makes sense to consider with Electrical Safety Testing, and if issues were detected, it could save significant amount of time and resource for your business.

Until next time, be efficient and stay safe.