

## **Title: Metrology for medical electrical equipment**

### **Abstract**

Risks arise when medical electrical equipment is not regularly calibrated during manufacturing and operation. However, harmonised measurement methods and traceability are lacking for most common medical electrical equipment, such as defibrillators, electrosurgical units, electrocardiographs and electroencephalographs. A key challenge is that medical electrical signals are typically non-steady, with parameters influenced by bioimpedance. Proposals addressing this topic should aim to establish a metrological framework for widely used medical electrical equipment by developing reference measurement systems and calibration procedures and exploiting artificial intelligence to extract key parameters to enhance safety and performance of medical equipment.

### **Keywords**

Traceability architecture, medical electrical equipment, defibrillator, electrosurgical unit, electroencephalograph, electrocardiograph, bioimpedance

### **Background to the Metrological Challenges**

The EU Medical Device Regulation (MDR 2017/745) mandates that medical devices meet stringent requirements for performance, patient safety, diagnostic reliability and maintenance, including calibration. The IEC 60601 standards series is widely accepted for basic safety and essential performance of medical electrical equipment. This includes tight controls on leakage currents, voltages applied, and energy limits that can be applied to the patient. To comply with the regulations and standards, manufacturers rely on harmonised measurement and calibration methods. However, due to the non-steady nature of medical electrical signals and bioimpedance due to patient variability, a traceability architecture for defibrillators, electrosurgical units, electrocardiographs (ECGs), electroencephalographs (EEGs) and bioimpedance analysers is needed, supported by procedures and good practice guidance to promote a harmonised measurement infrastructure that will support future updates of European Regulations. The performance of these essential medical devices can be verified using commercial instrumentation or the specific multi-parameter calibrators/analysers such as defibrillators analysers, electrosurgical unit (ESU) analysers, EEG and ECG simulators, and patient simulators. However, a complete traceability calibration infrastructure is needed that includes reference standards, the determination of key device parameters including electrical measurement functions in test result documentation for these important analyser devices.

Safety and performance requirements for defibrillators and electrosurgical units are specified in IEC 60601-2-4 and IEC 60601-2-2, respectively and commercial analysers are available that can measure energy with an accuracy of  $1\% + 0.1\text{ J}$ , or power with an accuracy of  $6.25\% + 1\text{ W}$ . However, the test methods for verifying a test device's accuracy are poorly described in the standards, and the uncertainty analysis is missing. Because these devices deliver energy and power directly to patients, ensuring measurement accuracy is crucial for patient safety, as incorrect power delivery could lead to ineffective treatment or serious harm. The IEC 60601-1 standard provides a simplified human body impedance model (a  $1\text{ k}\Omega$  resistor in parallel with a  $0.015\text{ }\mu\text{F}$  capacitor), but this model has limitations as human body impedance varies significantly due to biological or environmental factors and electrode-skin contact effects may be substantial. Differently from other medical electrical instrumentation, covered by the IEC 60601-2 standards series, instrumentation for bioelectrical impedance analysis (BIA) and spectroscopy (BIS) is not subject to standardised calibration and performance verification. Presently, BIA/BIS instruments' design may substantially differ from laboratory-oriented impedance analysers because of clinical application requirements. Non-clinical impedance analysers

have specified basic accuracy of the order of 0.05 %, whereas BIA/BIS instrument specifications typically have an accuracy of approximately 1 % and a resolution of typically 0.1  $\Omega$ .

In Europe, some institutions have constructed impulse energy and surgical power measurement devices, but no institute is able to provide impulse energy or high-frequency surgical power traceability in the BIPM KCDB. To develop a European traceability architecture for bioimpedance signals up to MHz frequencies or impulse waveforms with amplitudes of hundreds to thousands of volts are required. Even more challenging is the fact that modulated waveforms are employed in many surgical procedures, necessitating additional research into traceability systems and calibration techniques.

Electrocardiographs that analyse and display global time intervals can be calibrated using waveforms from reference databases or the EMPIR project 18HLT07 MedalCare novel synthetic reference ECG measurement database. However, for ECG devices without these capabilities, OIML recommends verification using simplified harmonic waveform testing (sine, square, triangle), though more recent standards increasingly favour physiologically relevant test signals. Electroencephalographs could be tested using harmonic waveforms, but these may not fully represent the complexity of real EEG signals (i.e., periodic waveforms with many spectral components), potentially limiting the accuracy of device verification. Traceability for key EEG signal parameters (frequency bands, amplitude levels, and waveform morphology) is required to ensure accuracy, repeatability, and comparability across different EEG devices. Commercially available EEG and ECG simulators that generate harmonic as well as complex waveforms can be used for determining EEG and ECG measuring functions but traceability for the waveforms generated is lacking so undermining diagnostic reliability.

European research is required for the establishment of defibrillator analysers, ESU analysers, EEG and ECG simulators, and bioimpedance analysers calibration capabilities. This research is to include the investigation of measurement parameters and uncertainties, with validation using novel measurement methods and data analytic techniques for sampled measurements of the complex waveforms, Monte Carlo uncertainty analysis, and parameter extraction based on artificial intelligence algorithms. These developments should extend the EMPIR project 15RPT04 TracePQM's open modular sampling system and uncertainty analysis of sampled data from EMRP project SIB59 Q-WAVE.

## Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The proposal shall focus on the development of a metrology infrastructure for the traceability of the most commonly used medical electrical equipment to improve diagnostic accuracy and to enable healthcare systems in the European Union to be more reliable, competitive and resilient.

The specific objectives are:

1. To develop high-voltage and high-current impulse measurement equipment and analysis algorithms for pulse waveform parameter determination to establish a defibrillator analyser calibration system up to 360 J with 0.3 % impulse energy measurement uncertainty. In addition, to develop high-precision broadband generation and measurement equipment and analysis algorithms for modulated waveform parameter determination to establish a calibration system for electrosurgical unit analysers up to 1 MHz and 300 W with 2 % high-frequency power measurement uncertainty.
2. To develop a metrological traceability route with procedures and uncertainty analysis for Electrocardiographs and Electroencephalographs by investigating techniques for time-domain characteristics of ECGs and EEGs low-level voltage waveforms (10  $\mu$ V to 5 mV, 0.05 Hz to 150 Hz). Then to develop and validate a reference measurement system using sampling techniques for the traceable calibration of EEG and ECG simulators, aiming for an uncertainty of 1 % in the voltage amplitude and 1 ms in time intervals measurements.
3. To establish measurement traceability of bioimpedance analysers in an extended frequency and magnitude range (up to hundreds of kHz, 10  $\Omega$  to 100 k $\Omega$ ). In addition, to investigate the limitations of using indirect primary bioimpedance standards (phantoms, empirical models) by characterising the frequency-dependence of the human body impedance network and then to develop suitable reference systems and verification techniques with an uncertainty of 0.3 %.

4. To develop calibration techniques and to ensure robust traceability for defibrillators, electrical surgery units, ECGs, EEGs and bioimpedance measurements in order to provide a basis for future updates of European regulations and to disseminate these to health communities, particularly medical equipment calibrator manufacturers and calibration service providers as best practice guidance.
5. To facilitate the take up of the technology and measurement infrastructure developed in the project by the measurement supply chain (analyser manufacturers), standards developing organisations (ISO), and end users (e.g. clinical stakeholders, manufacturers of medical and healthcare products).

These objectives will require large-scale approaches that are beyond the capabilities of single National Metrology Institutes and Designated Institutes, and it is expected that multidisciplinary teams will be required. To enhance the impact of the research, the involvement of the appropriate user community such as medical practitioners, medical (academic) hospitals and industry is strongly recommended, both prior to and during methodology development. Where relevant, proposals are encouraged to build on, or seek collaboration with, existing projects and develop synergies with other relevant European, national or regional initiatives and funding programmes. In particular, links are encouraged with (i) the projects funded under earlier relevant topics of the Horizon Europe programme; or (ii) other relevant European Partnerships.

Proposers should establish the current state of the art and explain how their proposed project goes beyond this. In particular, proposers should outline the achievements of the EMRP project SIB59 Q-WAVE, EMPIR projects 15RPT04 TracePQM and 18HLT07 MedalCare and how their proposal will build on those.

Proposers should note that the programme funds the activity of researchers to develop the capability, not the required infrastructure and capital equipment, which must be provided from other sources.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 2.1 M€ and has defined an upper limit of 2.6 M€ for this proposal.

EURAMET also expects the EU Contribution to the external funded beneficiaries to not exceed 35 % of the total EU Contribution across all selected projects in this TP.

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated partners.

## Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the 'end user' community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the "end user" community (e.g. letters of support) is also encouraged.

You should detail how your proposal's results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Facilitate improved industrial capability, or improved quality of life for European citizens in terms of personal health, protection of the environment and the climate, or energy security,
- Transfer knowledge to the medical sector.

You should detail other impacts of your proposed JRP as specified in the document "Guide 4: Writing Joint Research Projects (JRPs)"

You should also detail how your approach to realising the objectives will further the aim of the Metrology Partnership to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically, the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work.

## Timescale

The project should be of up to 3 years duration.