

Title: Support for a European Metrology Network on medical device regulation

Abstract

The introduction of the Medical Device Directive (MDD) 93/42/EEC in 1994 deregulated some European medical devices. The MDD allowed the traceability requirements for medical devices with a measuring function (MDMF) to be left the discretion of national legislators which has resulted in a largely inhomogeneous situation across Europe. In May 2020, the new Medical Device Regulation (EU) 2017/745 (MDR) will supersede the current directive, however, little may change for MDMFs, because the metrology needed to support improved post-market surveillance is not currently, uniformly available across Europe. This frustrating situation is detrimental for patients, clinicians, NMIs, test houses, and manufacturers. Therefore, a European network for medical device metrology is needed to develop a harmonised approach for ensuring the accuracy of MDMF.

Keywords

Medical devices, Medical Device Directive (MDD), Medical Device Regulation (EU) 2017/745 (MDR), European Metrology Network, medical devices with a measuring function (MDMF)

Background

In many European countries, current national authorities responsible for establishing, overseeing and enforcing the legal regulations for medical devices, are suffering from a lack of metrological support. As a result, the accuracy of MDMFs is uncertain, their deterioration over time cannot be properly detected or prevented and the diagnostic value of their measurements becomes questionable. This situation is compounded by the fact that current, metrological verification of MDMFs is commonly restricted to isolated accuracy checks of simple physical sensors. Such isolated checks ignore the complexity of the physiological measurement process and that the sensor is only one link in the measurement chain; the physical quantity being the first step towards a medically relevant measurand.

Currently, a coordinated European approach for medical device metrology does not exist. Medical device metrology is arguably one of the most inhomogeneously developed fields and lacks any comparable dissemination of traceability. The traceability requirements of MDMFs also differs vastly from country to country, as more often than not it is determined by the respective financial resources and NMI capabilities rather than by national policy or societal needs. Thus, to prevent the metrological gap between countries from widening further, a unified approach to medical device metrology across European is needed.

In terms of identify and prioritise the most urgently required metrological data for medical devices, input from end-users and stakeholders is vital. Although, sphygmomanometers, thermometers, and tonometers are the most common MDMF for which metrological checks are mandatory in the EU, the list of MDMF in use in Europe does not stop there.

How and where NMIs should focus limited resources to obtain maximum impact for society urgently requires a strategic plan and significant coordination both at European and global levels. No single NMI has the expertise or resource to tackle all or even a significant fraction of the most critical priorities without collaboration. Without coordination, there is a strong likelihood of unnecessary duplication, with NMIs (nationally and/or regionally) potentially independently choosing to focus efforts on the same challenge with consequential neglect of others. EURAMET is considering establishing a European Metrology Network to coordinate the European NMI response, to establish close links to the stakeholder community, to develop and implement a strategic agenda and establish a knowledge, technology transfer and promotion plan, to ensure an effective response is put in place. This SNT is intended to elaborate how a network could support EURAMET and to support that network in its initial tasks.

Objectives

Proposers should address the objectives stated below, which are mainly based on the PNT 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 / legal / regulatory / market constraints, but the reasons for this should be clearly stated in the protocol.

The JNP shall focus on developing a long term ongoing dialogue between the metrology community and relevant stakeholders. This dialogue should support the take-up of research outputs from the metrology community and the collection of needs from stakeholders to inform future research.

The specific objectives are:

1. To establish regular, constructive dialogue between the project and stakeholders of medical device metrology including manufacturers, regulatory authorities, and standards development organisations related to the Medical Device Regulation (EU) 2017/745. Then using this feedback to develop a web-based platform for stakeholders. The platform should include easy access to European metrology capabilities and a service desk to answer stakeholder questions. The platform should also be developed in a manner that allows it to be maintained by a future EMN.
2. Using the feedback from key stakeholders in Objective 1, to develop a Strategic Research Agenda (SRA) and roadmaps for medical device metrology. This should include a priority list of medical devices with a measuring function (MDMF) and their ability to meet the requirements of the MDR. The list should be sustainable, and procedures should be defined for its maintenance and future revision (using stakeholder input).
3. Using the feedback from stakeholders in Objective 1, to set up and promote a knowledge-sharing programme for medical device metrology. This should include a range of regularly hosted stakeholder activities, such as the exchange of researchers between organisations, metrology workshops, stakeholder events and training courses.
4. Using the feedback from stakeholders in Objective 1, to develop a plan for a harmonised metrological response to the requirements of the MDR, in particular MDMF. This should include the development of best-practice guides for establishing and maintaining traceability for medical devices. The guides should be applicable to a wide range of stakeholders and promoted via the web-based platform in objective 1 and the knowledge-sharing programme in objective 3.

To develop a plan for a joint and sustainable European infrastructure for Medical Device Metrology via a European Metrology Network capable to provide metrological services and guidance to all interested parties. The plan should be completed within 12 months of the start of the project and should (i) develop coordination and smart specialisation of capabilities (ii) align with other running initiatives and projects, (iii) promote the development of emerging member states, and (iv) consider how to extend collaboration to third countries.

The proposed activities shall be justified by clear reference to the measurement needs within strategic documents published by the relevant stakeholders. Proposers should establish the current state of the coordination in this area, and explain how their proposed project goes beyond this.

The proposed activities should not include those essential for the establishment and operation of the EMN. EMNs will be established and operated by the EURAMET members using their own national resources regardless of whether specific EMPIR proposals are funded. EMPIR funding is for specific tasks aimed at ensuring a proposed EMN will progress quickly towards its establishment and implementation and contribution to the objectives of the programme.

EURAMET expects the average EU Contribution for the selected JNPs in this TP to be 0.4 M€, and has defined an upper limit of 0.5 M€ for this project.

Potential Impact

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

You should detail how your JNP results are going to:

- Address the SNT objectives and deliver solutions to the documented needs,
- Provide a lasting improvement to coordination in the European metrological community and communication with their stakeholders beyond the lifetime of the project,

You should detail other impacts of your proposed JNP.

You should also detail how your approach to realising the objectives will further the aim of EMPIR 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

Time-scale

The project should be of up to 4 years duration.