

SEE QI project 5: Metrology for medical devices

Regional Consultancy Fund for Quality Infrastructure (QI) in South East Europe (SEE)

Main result: The capacities of National Metrology Institutes (NMIs) for calibration / verification / control of the most relevant types of medical devices with measuring function in WB6 countries are strengthened.

Duration: April 2020 – September 2021



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Background

The health of patients relies on the accuracy of medical instruments. Those medical instruments with measuring functions need to be approved, calibrated and controlled. Metrology plays an important role in this quality chain to ensure their accuracy. There are similar challenges in all WB6 countries so that it is more efficient and effective to address them conjointly. Most Medical devices with measuring functions in use are not being regulated, therefore not metrologically controlled. Capabilities for the control of various instruments are lacking. The project intended to support an alignment of WB6 countries to the EU Medical Device Regulation (EU) 2017/745 related to the control of medical instruments with measuring function.

The project was intended to be implemented according to the following steps:

- WB6 survey on medical devices with measuring function and procedures on their control
- Workshop for NMI management staff in a WB6 countries
- Implementation of the strategic plan for establishment/ improvement of the metrological capability including study tour for technical staff
- Implementation of the strategic plan as basis for legislation for control / verification of medical devices with measuring function
- Closing round table in WB6 country for common resolutions and awareness raising

As a first step, a questionnaire for the survey on the control of medical devices with measuring function in each of the 5 participating WB6 countries (Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia) was drafted in June 2020 and circulated to the national contact persons. Due to the upcoming pandemic, the feedback – in particularly from the side of the regulators – was impossible to receive. Due to everybody's focus on the COVID-19 pandemic, the project lost momentum at that stage.

Modification of project scope due to the COVID-19 pandemic

In late 2020, a new SEE QI project on the WB6 QI-response to the COVID-19 pandemic was prepared. In this context, stakeholders from the already ongoing SEE QI projects discussed how to contribute from the side of QI-institutions to the fight against the pandemic. One symptom of COVID-19 is an elevated body temperature. Body temperature measurement is therefore a crucial element in combating the pandemic. In many countries devices for temperature measurement are being used on a large scale — not only at airports, but also in shopping malls, etc. In public spaces, non-contact infrared forehead thermometers and thermographic cameras are widely in use. Due to the increased use of infrared thermometers (IRTs), the demand for their calibration at metrology institutes has also risen.

Governments expect metrology institutes to ensure that instruments measure accurately and that their measurements are traceable to the SI Units.

A questionnaire on the application on infrared body temperature measurements in the context of the fight against the pandemic was circulated to the participating National Metrology Institutes (NMIs) in November 2020. It became obvious, that non-contact infrared thermometers were widely used for this purpose. However, in none of those countries appropriate facilities for the control / calibration / verification of those instruments were available. Consequently, four WB6 countries addressed an official request to the PTB project management in late 2020 for the procurement of an infrared thermometry calibrator for the control / calibration of the instruments used in body temperature measurements in order to control the spread of the pandemic.

Considering the deadlock as regards the implementation of the original project design and the new priorities in the light of the COVID-19 pandemic, it was decided in March 2021 to stop the implementation of the original project design. Instead, it was agreed to exclusively focus on the procurement of the infrared thermometry calibrators and subsequent capacity development for their application.

Delivery of infrared thermometry calibrators

In late 2020 a tender process for the procurement of 4 infrared calibrators incl. transportation case was launched



FLUKE-TEMP-4180 infrared calibrator

As outcome of the tender process, a FLUKE-TEMP-4180 infrared calibrator was selected and purchased by PTB. In May 2021 the instruments were received in PTB and subsequently sent to the NMIs of Albania, Bosnia and Herzegovina, Montenegro and North Macedonia, where they were received in June 2021.

Related to the use and application of the new equipment, in a first step, freely available information material explaining non-contact thermometry in general and the use of the infrared calibrators in particular, was assembled and allocated to the NMI's staff of the respective thermometry laboratories of the 4 NMIs.

As a next and final step, it was intended to provide further virtual consultancy by PTB thermometry experts, who would reply to open questions remaining after the self-studies. But since no specific questions were raised by the receiving NMIs and the instruments were not perceived to be complicated to use, this last step of the planned project implementation was not pursued.

Project outputs

Information sources on the calibration of infrared thermometers

General information and links to guidelines and other websites, calibration guidelines:

<https://www.covid19.ptb.de/calibration-of-infrared-thermometers>

Use of FLUKE Temp-4180

Overview documents are available here:

1)Infrared Thermometer Calibration -- A Complete Guide

<https://eu.flukecal.com/de/literature/articles-and-education/temperature-calibration/application-notes/infrared-thermometer-cal>

2) Infrared Temperature Calibration 101

<https://eu.flukecal.com/de/literature/articles-and-education/temperature-calibration/application-notes/infrared-temperature-cal>

3) Emissivity compensation for Fluke Calibration 4180

<https://eu.flukecal.com/de/literature/articles-and-education/temperature-calibration/application-notes/emissivity-compensation->

The webinars further below however are more detailed and explain all uncertainty components in ASTM E2847)

1) <https://eu.flukecal.com/de/literature/on-demand-webinars/how-create-infrared-thermometer-uncertainty-budget>

2) <https://eu.flukecal.com/de/literature/on-demand-webinars/infrared-temperature-calibration-101>

3) <https://eu.flukecal.com/de/literature/on-demand-webinars/how-calibrate-infrared-thermometer>

4) <https://eu.flukecal.com/de/literature/on-demand-webinars/how-calibrate-infrared-thermometer-2020>