

Testing the suitability of cavity radiators used for the metrological verification of infrared thermometers

(Supplement to Part 1, Section B, Chapter 2.2 of the “Guidelines for metrological verifications of medical devices with a measuring function – LMKM”)

This recommendation describes the procedure of testing the suitability of infrared cavity radiators that are used for the metrological verification of infrared thermometers. It also specifies the limits of error to be complied with when using this procedure. The procedure is based on comparison measurements between the infrared cavity radiator to be tested, in the following referred to as the “calibration radiator”, and a reference cavity radiator under reference laboratory conditions.

1 Verification procedure and scope of the verification

The calibration radiator must be checked under laboratory conditions against a reference cavity radiator by means of the infrared thermometer for which it is intended by the manufacturer. The suitability of the calibration radiator refers only to that type of infrared thermometer for which the test had been carried out. If metrologically different infrared thermometers are to be tested with the calibration radiator, the procedure described in this supplement must be carried out anew. The calibration of the radiation temperature of the reference cavity radiator must be either certified by a national metrology institute or by a calibration laboratory that is competent for the calibration of infrared radiators and certified according to LMKM, Part 1, Section A, General legal requirements placed on medical devices, and it must be traceable to the International Temperature Scale (ITS-90).

2 Metrological requirements

2.1 Requirements placed on the laboratory

The test must be conducted under the following reference conditions:

- Ambient temperature: $23\text{ °C} \pm 5\text{ °C}$, however not lower or higher than the permissible ambient temperature for the calibration radiator (transfer standard) and for the infrared thermometer during operation.
- Relative air humidity: $50\% \pm 20\%$, however not lower or higher than the air permissible humidity for the calibration radiator (transfer standard) and for the infrared thermometer during operation.
- Power supply voltage: within the permissible range of the calibration radiator used.

2.2 Requirements placed on the reference cavity radiator

To conduct the test in the correct manner, the reference cavity radiator that is designed as a bath radiator (cavity operated in a controlled reference water bath with a reference thermometer, e.g. according to Figure 1) shall comply with the following requirements:

- Reference thermometer for the determination of the water bath temperature: measurement uncertainty $\leq 0.03 \text{ }^\circ\text{C}$ (coverage factor $k = 2$). The thermometer must be traceable to the International Temperature Scale (ITS-90).
- Controlled reference water bath with circulation and a minimum volume of 5 litres: temperature stability of $\pm 0.02 \text{ }^\circ\text{C}$, a local temperature deviation of $\pm 0.01 \text{ }^\circ\text{C}$ at a specified temperature within the working area.
- Reference cavity radiator (black-body radiator) immersed in the reference water bath: measurement uncertainty of its radiance temperature $\leq 0.05 \text{ }^\circ\text{C}$ (coverage factor $k = 2$) within the temperature measurement range. Figure 1 shows an example of a suitable reference cavity radiator.

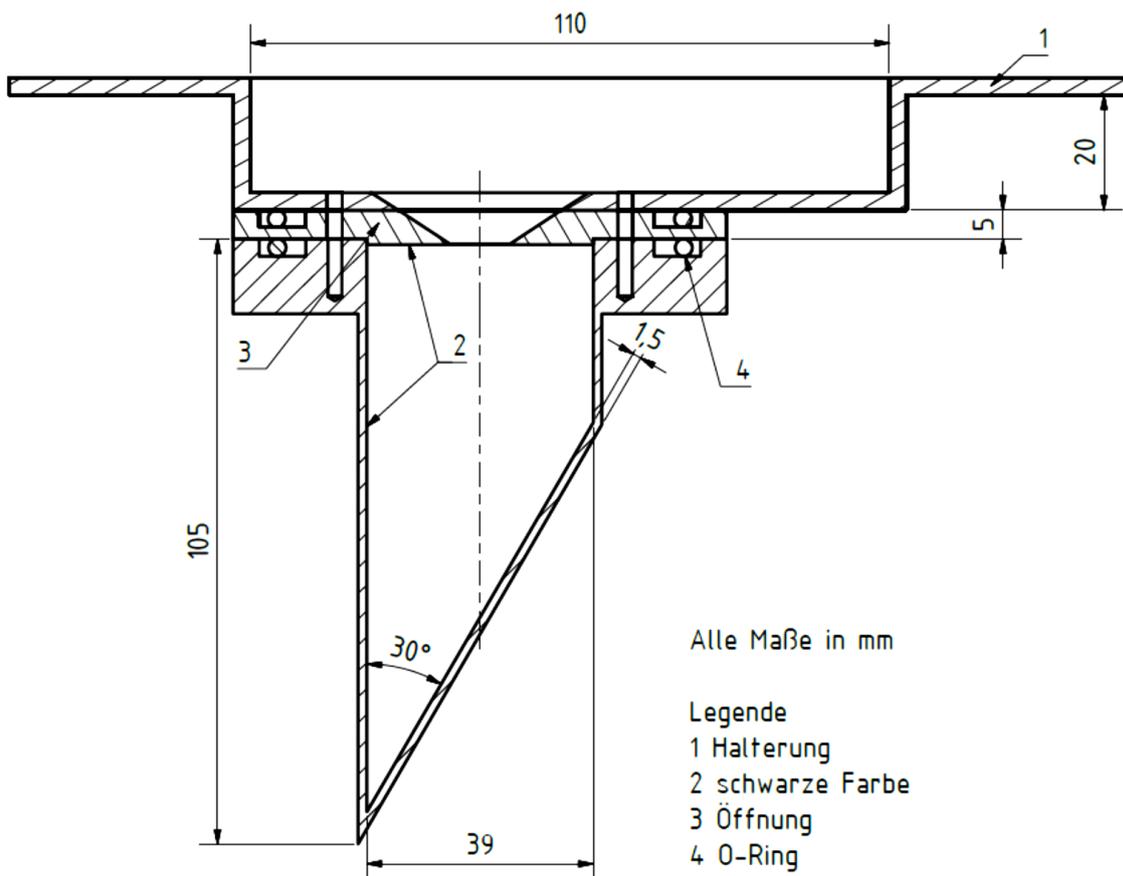


Figure 1: Example of a reference cavity radiator

3 Performance of the metrological verification

3.1 Condition check

The instructions for use for the calibration radiator and for the infrared thermometer must be available. The devices, in all their components, must correspond to the descriptions in the instructions for use. Scales, labels and descriptions must correspond to the manufacturer's specifications. The devices must be free of obvious defects.

3.2 Metrological verification

The measurements shall be carried out under laboratory conditions (see 2.1). The calibration radiator and the reference cavity radiator shall be set to the same radiation temperature. The probe of the infrared thermometer alternately measures the radiation temperature of the calibration radiator and of the reference cavity radiator under examination. For this purpose, the infrared thermometer must be introduced into the calibration radiator and into the reference cavity radiator in alternating intervals. This comparison measurement must be repeated at least 15 times. To keep the overall measurement uncertainty within the limits of 120 mK, the standard deviation of the comparison measurement must not exceed 40 mK. The infrared thermometer must be operated in its calibration mode. The radiation temperature of the calibration radiator that is indicated by the infrared thermometer must be compared with the radiation temperature of the reference cavity radiator. If the infrared thermometer has been calibrated in a mode other than the calibration mode, the measurement values obtained must be converted according to the correction procedure specified by the manufacturer before the difference between the temperatures is determined. The correction values or the respective calibration values of the reference cavity radiator must be considered. The uncorrected and, if applicable, the converted measurement values as well as the correction values and/or calibration values must be documented.

The comparison measurements must be conducted for three radiation temperatures that are distributed as evenly as possible over the temperature range of the calibration radiator.

4 Maximum permissible errors (MPEs)

The measured radiation temperatures of the calibration radiator must meet the requirements for maximum permissible errors according to DIN EN ISO 80601-2-56 [1]. Mathematically speaking, this means that none of the three measured radiation temperatures of the calibration radiator must have a deviation greater than 0.07 °C in relation to the reference cavity radiator and, consequently, to the standard ITS-90.

Due to the fact that in the case of the procedure described here, the influence of the measurement uncertainty of the reference cavity radiator cannot be avoided, the maximum permissible mean value of the deviation of the calibration radiator amounts to:

0.120 °C.

If this value is complied with, the tested calibration radiator can be presumed to be suitable.

5 References

[1] ISO 80601-2-56:2017 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement