

Clinical thermometers —

Part 5: Performance of infra-red ear thermometers (with maximum device)

The European Standard EN 12470-5:2003 has the status of a
British Standard

ICS 17.200.20

6 Requirements

6.1 General

If the IR ear thermometer is designed for use with protective probe covers, the thermometer together with the probe cover (complete thermometer) shall meet the requirements specified in this standard.

6.2 Range of displayed temperature

The IR ear thermometer shall cover in all modes the range of displayed temperature from 35,5 °C to 42,0 °C.

NOTE The range of displayed temperature can differ from the measuring range by an instrumental offset.

Testing shall be performed in accordance with 7.3.

6.3 Maximum permissible error

6.3.1 Maximum permissible error within ambient operating range

The maximum permissible error within ambient operating range as in 6.4.1 and the range of the displayed temperature as in 6.2 shall be $\pm 0,2$ °C.

Testing shall be performed in accordance with 7.4.

6.3.2 Maximum permissible error under extended operating conditions

If the IR ear thermometer gives a temperature reading outside the conditions in 6.2 and 6.4.1, the maximum permissible error under those conditions shall be $\pm 0,3$ °C.

Testing shall be performed in accordance with 7.5.

6.3.3 Maximum permissible error under changing environmental conditions

The maximum permissible error shall comply with 6.3.1 under changing ambient conditions. If the thermometer is not capable of meeting the accuracy requirements, it shall not provide a temperature reading.

Testing shall be performed in accordance with 7.6.

6.3.4 Maximum permissible clinical repeatability

Clinical repeatability shall be determined separately for each device model, every patient age group (new-born, children, and adults) for which the IR ear thermometer is intended to be used including febrile subjects.

Clinical repeatability shall not exceed $\pm 0,3$ °C.

Testing shall be performed in accordance with 7.7.

6.4 Environmental requirements

6.4.1 Ambient operating conditions