Comissão Setorial para a CS/09 Saúde

Metrology in Health

Good Practices Guide - Part II
Chapter II

Clinical Thermometers

Instituto Português da Qualidade

Metrology in Health – Good Practices Guide
Part II
Chapter II
Clinical thermometers

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CHAPTER II
Clinical Thermometers

TABLE INDEX

1. Clinical Thermometers

In clinical practice, several decisions related to diagnosis and treatment results from the analysis of body temperature. These values are usually measured using a clinical thermometer. The correct measure of body temperature is very important in daily healthcare as this vital sign is often assessed in the patient's diagnosis and monitoring of the patient's health.

1.1 Characterization

A thermometer is a device that measures temperature and is composed of a temperature sensor and a mechanism that transforms the signal detected into a temperature numeric value. It is used to measure the temperature of a body or object.
In clinical practice thermometers are instruments that measure body temperature and are used in the diagnosis and monitoring of several health problems.
Since the 16th century, body temperature has been an important indicator of the health of human beings (Hutton *et al.*, 2009). It was measured for the first time in 1592 when Galileo Galilei invented the first thermoscope without scale, which allowed for the comparison of the temperature of two bodies or objects (Shimek *et al.*, 2011).
Body temperature can be measured using several types of measuring devices in different sites of the body, such as blood vessels, oral cavities, armpits, rectum, tympanic membrane or temporal artery. Despite the variation in temperature in these sites of the body (Rubia et al, 2010; Zhen et al., 2014) it is estimated that they approximate the real value, which is the temperature of the blood that passes through the pulmonary artery and aorta (temperature used by the hypothalamus to regulate the temperature of the body). Variations of body temperature can be a warning sign for pathologies or health problems (infection, adverse reaction to medicines, critical losses of body temperature, etc.), which enhances the need to correctly measure the temperature and the importance of knowing the error associated with each measurement.

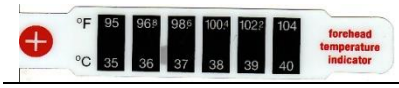
1.1.1 Typologies of Clinical Thermometers

Currently there are several types of clinical thermometers that are designated according to their measurement methodology, such as liquid-in-glass thermometers (mercury[1], gallium and alcohol), digital thermometers (armpit, rectal and oral), infrared thermometers (tympanic and temple), phase change disposable thermometers and thermocouple thermometers with liquid crystals (Table 1).

Table 1 – Typologies of clinical thermometers
(Source: Hutton *et al.*, 2009)

Liquid-in-glass thermometers[2] 	Device that has a container connected to a glass capillary tube that contains the thermometric liquid - which completely fills the container and partially fills the capillary tube - and a graduated scale that allows for reading the level of the liquid in the tube. With temperature variations, the liquid will expand or contract, rising or falling through the capillary. Due to a constriction in the container, the liquid only returns to the initial temperature after the thermometer is shaken.
Digital thermometers (armpit, rectal and oral) 	Electronic device containing thermistors. These components have temperature-sensitive electrical resistance. Whenever temperature changes, the thermistor varies its conductivity.
Infrared thermometers 	Device that measures the thermal radiation of the tympanic membrane or the surface of the skin on the forehead to measure temple temperature. They contain a lens that concentrates infrared radiation in a detector which converts it into an electrical signal.

[1] According to Portuguese law (Decree-Law no. 76/2008 of 28 April) and European law (Directive 2007/51/CE) the sale of devices containing mercury is forbidden.
[2] A liquid-in-glass expansion thermometer is a measuring device whose indications are dependent on the relationship between the coefficient of the liquid thermal expansion and the coefficient of its glass container. These devices are characterized by their stability and reproducibility.

Phase change disposable thermometers[3] 	A device that has a matrix of dots of inert chemical elements that change colour with an increase of temperature. Each line of the matrix corresponds to a temperature and the last point that changes colour corresponds to the body temperature.
Thermochromic thermometers 	A device with liquid crystals that indicates different temperatures by changing its colour. These thermometers are generally used as disposable devices.

Despite the different types of clinical thermometers and their measurement methods, they all have advantages and disadvantages regarding the accuracy of the instrument and the reliability and feasibility of the method used in different healthcare units.

The measurement errors are then directly related to the type of thermometer and the measurement site of the body. In addition, the temperature values are easily influenced by external factors, such as the warming of the device during the measurement.

Traditionally the mercury liquid-in-glass thermometer was used in clinical practice to measure body temperature due to its low price and user-friendly features. However, in this particular case, and in addition to the slow response time (between 2 to 5 minutes), this thermometer is a potential risk for public health[4] and thus its sale is forbidden.

Healthcare units have increasingly been using tympanic infrared thermometers in accordance with European standard EN 12470-5. These are non-invasive devices that measure the thermal radiation of the ear canal and are user-friendly, of low risk, with high sterilization conditions and have more accurate results (the accuracy of the temperature readings results from the proximity between the tympanic membrane and the hypothalamus that share the same source of blood, which comes from the internal and external carotid arteries).

[3] Device with a qualitative result.
[4] Due to the cumulative and toxic potential of mercury.

As clinical thermometers have different features and applications, the choice of measurement device must take into account several factors that influence and determine the measurement accuracy, as well as the application field of each thermometer.

1.2 Technical and Metrological Requirements

The definition of technical and metrological requirements is essential for the characterization of the instrument and the measurement process.

Healthcare units should develop processes and procedures that allow for monitoring the measurement instrument in accordance with the metrological requirements.

According to the recommendations of the International Organization of Legal Metrology (OIML R 16-1, 2002), (OIML R 16-2, 2002) and the International Electrotechnical Commission (IEC 80601-2-30: 2013), measurement instruments must have general, metrological, technical and safety requirements.

Conformity Assessment

According to Portuguese law (Decree-Law no. 145/2009, of 17th June and Ordinance no. 136/96, of 3rd May) instruments available in the market must follow the established requirements, must have previously undergone a conformity assessment and must respect reciprocal compatibility between manufacturers. The clinical thermometers that comply with the essential requirements presented in Table 2 of this Guide must have the CE mark applied by the manufacturer.

The manufacturer must follow the standards established in EN 1041 standards for manufacturer information and the EN 980 standard applied to the symbols and labelling.

From another perspective, and in order to support the essential requirements of the European Directives, the EN 12470 standard was developed with five parts and this applies to the clinical thermometers that are used to measure human body temperature.

The EN 12470-3 and EN 12470- 5 standards allow for understanding the requirements of digital and infrared thermometers respectively, such as maximum permissible errors, measurement range, accuracy, environmental conditions and user skills (Table 2).

Table 2 – Main technical and metrological requirements of clinical thermometers

	Parameters	**Digital Thermometers** EN 12470-3:2000	**Infrared Tympanic Thermometers** NP EN 12470-5:2009
General Requirements	**Measurement unit**	Derived from the temperature unit of the International System (T): degree Celsius, symbol °C.	
	Identification of the measurement device	Clear and legible identification of the manufacturer and the equipment (brand, model, serial number, ID number)	
	Manufacturer guidelines	Indication of the method of use and specifications of the device.	
	Environmental operating conditions	Temperature: 18 °C to 28 °C	Temperature: 16 °C to 35 °C Relative Humidity: < 85 %
Metrological Requirements	**Maximum permissible error**[5]	± -0,1 °C	± 0,2 °C
	Range	35,5 °C to 42,0 °C	35,5 °C to 42,0 °C
	Accuracy	The accuracy of the display must be less or equal to 0,1 °C	
Safety requirements	**Electrical Safety**	The electrical compatibility of the measurement equipment must be in accordance with the IEC 60601-1:2015.	
	Mechanical Safety	Avoid the use of the device on irregular or sharp surfaces that may cause damage.	

[5] Whenever calibrations are performed in wider environmental conditions, the maximum permissible error must increase 0,1 °C, i.e. it must increase 0,2 °C for digital thermometers and 0 °C for infrared tympanic thermometers.

Detailed information about phase change disposable thermometers and infrared temple thermometers is available in the American Society for Testing and Materials guidelines (ASTM).

1.3 Traceability and Metrological Conformity

The measurement of body temperature is widely used by the general population and this must be properly done, so the metrological conditions of the thermometer are important.

Among other reasons, the error and uncertainty associated with body temperature measurement depend on the condition of thermometer.

Taking into account the several thermometers found in healthcare facilities, priorities are often defined according to their critical use.

In order to guarantee an effective metrological traceability, the healthcare units must have a calibration plan for the thermometers (Table 3), which may define the periodicity of calibrations considering the history of the equipment, the application field, the manufacturer's guidelines and the critical use of each thermometer.

The fulfilment of the tasks set out in the plan leads to the accomplishment of the defined metrological operations. Additionally, the application of this procedure allows for monitoring the compliance of the clinical thermometers. The calibration periodicity defined initially can be changed according to the performance of thermometer and the maximum permissible error defined.

It is recommended to see additional information in the Good Practices Guide – I Part (IPQ, 2015).

Table 3 – Example of a calibration plan.

Device	Brand	Serial Number	ID Number	Calibration periodicity	Date of last calibration	Date of next calibration

1.3.1 Validation of Calibration Certificate/Report

The maximum permissible errors associated to the assessment of the thermometers must be defined previously and these are directly related to the error and uncertainty described in subchapter 2.2.3 of the Good Practices Guide – I Part (IPQ, 2015) as well as other applicable documents.

In order to approve the use of thermometers, the maximum permissible error (MPE) is defined, using the following equation:

$$|E| + |U| \leq MPE \qquad \text{(Equation 1)}$$

where E is the error indicated and U the expanded measurement uncertainty. Therefore, after a calibration (performed by a recognized entity) the instrument is accepted and considered approved for its use if the sum of the absolute error and uncertainty is less or equal to the MPE, which is usually the acceptance criterion defined by the user/owner of the equipment. This parameter can also be established according to reference documents (e.g. manufacturer's guidelines). However, the MPE value must always be justified by the user/owner of the device.

For clinical thermometers, is recommended that criteria established in Table 2 be used.

The identification of the metrological condition of the clinical thermometer should be foreseen, implemented and easily accessible, e.g. by labelling the equipment. It is also recommended to use integrated information systems to share data regarding the metrological condition of the measurement devices being used.

1.4 Maintenance

The main aim of the maintenance is the reduction and elimination of failures and thus this consists in all preventive and corrective activities necessary to the proper functioning of the devices and all their accessories (NP EN 13306).

The aim of preventive maintenance is to prevent failures, increasing mean time between failures (MTBF) and hence the reliability and operational availability of the

devices. For this reason, inspection and hygiene of the devices are crucial and mandatory for good practice. Visual inspection and hygiene should be carried out on a daily basis. However, the maintenance periodicity appropriated to each thermometer must be defined according to the use, location and critical results of the device. It is important to notice that preventive maintenance should always follow the manufacturer's instructions (NP EN ISO 13460).

It is also suggested that all information about maintenance interventions and incidents be recorded and the condition of device identified and visible to all users.

Although preventive maintenance should always follow the manufacturer's instructions, in Tables 4 and 5 actions are described that might help in the absence of a maintenance user manual.

Table 4 – Parameters to consider in the preventive maintenance of digital and infrared thermometers

Inspection	- Check the general appearance of the device - Check the digital display - Check the sensor and in case of infrared tympanic thermometers also check the cone-shaped surface
Hygiene/Disinfection	Check general hygiene of the device (according to good practices). For infrared tympanic thermometers, the lens must often be gently cleaned. Additionally, compressed air should also be used as a cleaning tool. Reading the manufacturer's instructions is recommended.

1.5 Good Practices in the use of clinical thermometers

The measurement of body temperature is influenced by several factors, such as the condition of the device and its limitations, its handling, the measurement procedure, the patient's behaviour, etc.

The correct measurement of body temperature does not depend solely on the measurement site and/or the error related to the device. Correct measurement also comes from the good practices in the use of clinical thermometers.

Table 5 – Good practices in the use of clinical thermometers

Clinical Thermometers (Digital and Infrared)	**Condition of the Device**	Check the preventive maintenance of the thermometer, as well as the activities that ensure the metrological traceability. The hygiene and disinfection of the instrument should be done regularly with the application of a washing solution of soap and water. As an option instructions of manufacturer can be followed. For infrared tympanic thermometers, the lens of the sensor must be cleaned regularly.
	Patient	The patient must keep calm and quiet while his/her temperature is being measured. In case of infrared tympanic thermometers, it must be ensured that there is no cerumen or any other type of alterations in the ear canal.
	Measurement technique	Thermometers should be handled carefully in order to prevent warming of the sensor before the measurement begins. For infrared tympanic thermometers, repeated measurements in the same ear must respect a pre-defined waiting time between each measurement.

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Annex 1

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