

PERFORMANCE MEASUREMENT OF COMON MEDICAL DEVICES

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INTRODUCTION



Nowadays there is a high availability of medical devices with measuring function to populations. This availability has very positive aspects such as enhancing the capacity of measures of physiological parameters by population actively monitoring their health.

In addition, there are inexpensive medical devices, sold not only in pharmacies but also everywhere. They are generally manufactured in Far Eastern countries, mostly supplying the buyer with few technical specifications.

These medical devices are often used by the population, who decides whether or not to take medication, whether or not to consult a doctor, whether or not to go to the hospital. The metrological quality of these instruments must therefore be assessed [1].

In this work we have studied several common Medical Devices with measuring function and compared the measurements performed in a group of volunteers of various ages and genera, all healthy. The medical devices studied were clinical thermometers, sphymomanometers, weighing instruments and oximeters.

METHODOLOGY



Measurement

The applied methodology was based on the accomplishment of the measurements using several instruments for the measurement of physiological signals in the same volunteer, sequentially, almost immediately and maintaining the same environmental and emotional conditions of the volunteers.

Outliers

The selection of outliers is based in the rule that a data point is an outlier if it is more than 1.5· IQR above the third quartile or below the first quartile.

$IQR = Q3 - Q1$

$Lsup = Q3 + 1,5 \times IQR$

$Linf = Q1 - 1,5 \times IQR$

F-Test

The test was applied to assess whether the precision between measurements are statistically identical to a p = 0.05.

$F = \frac{s_1^2}{s_2^2}$

t-Test


To evaluate whether the two sets of data were statistically identical, the t-test paired at p = 0.05 was applied.

$$t = \frac{\bar{x}1 - \bar{x}2}{Sp} \sqrt{\frac{N1N2}{N1 + N2}}$$

$$Sp = \sqrt{\frac{\sum(xi1 - \bar{x}1)^2 + \sum(xi2 - \bar{x}2)^2}{N1 + N2 - 2}}$$

EXPERIMENTAL RESULTS

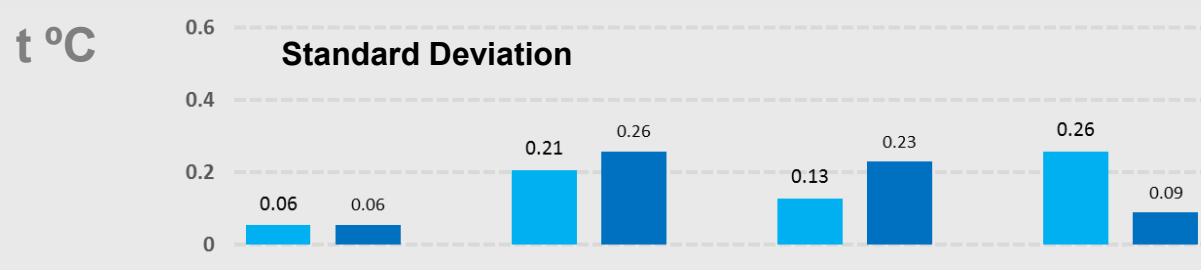




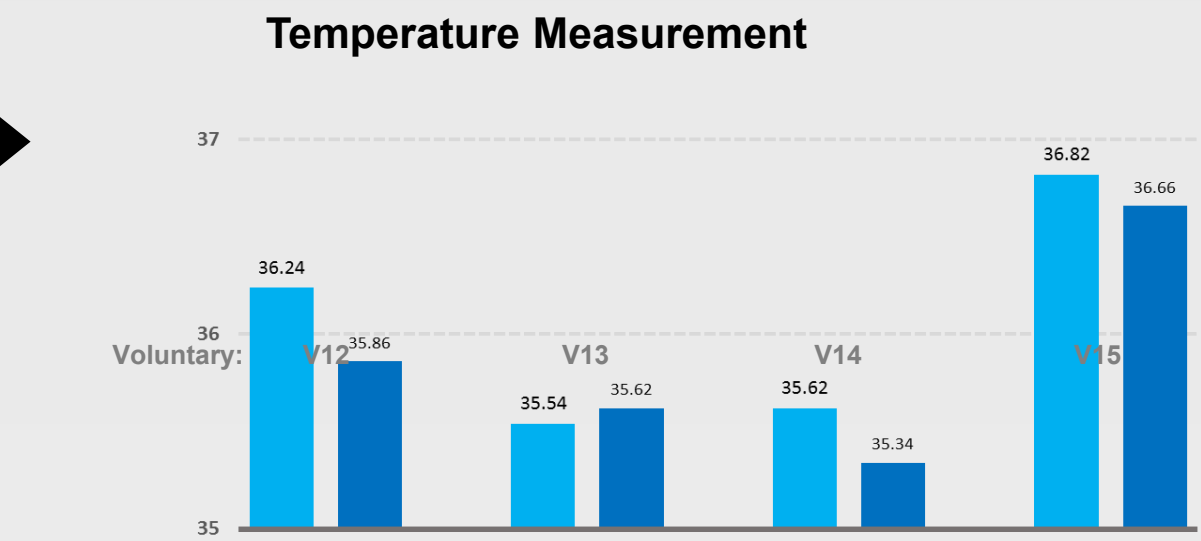
Body temperature measured with axial thermometers

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t-test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Standard Deviation




Temperature Measurement



The results showed that the medical devices evaluated were highly accurate, with the exception of sphymomanometers whose measurements generally show some dispersion.

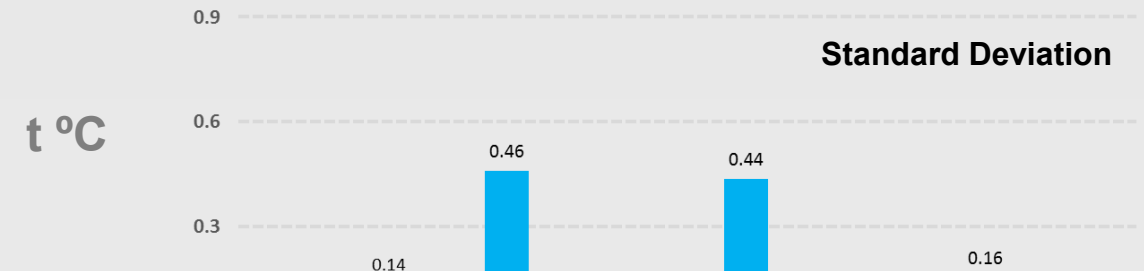
Precision values, repeated and sequential measures, have low standard deviations. This leads to increase users' confidence in the instruments and their measures. However, when these Medical Devices are compared to each other, there is a low agreement rate of values at a 95 % confidence level.



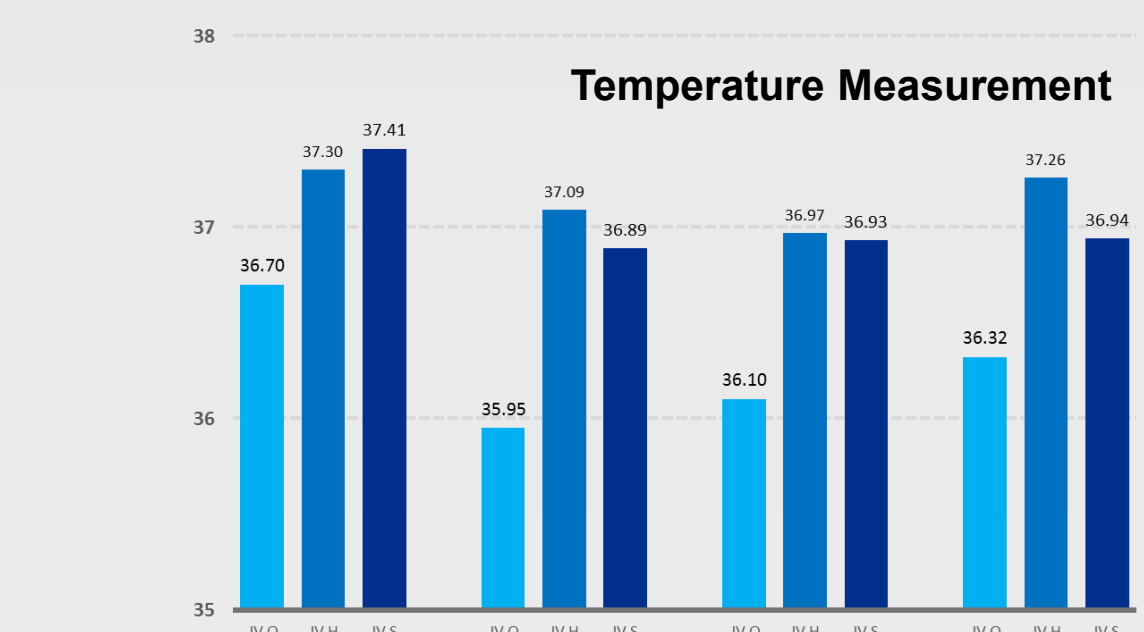
Body temperature measured with infrared thermometers


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Standard Deviation



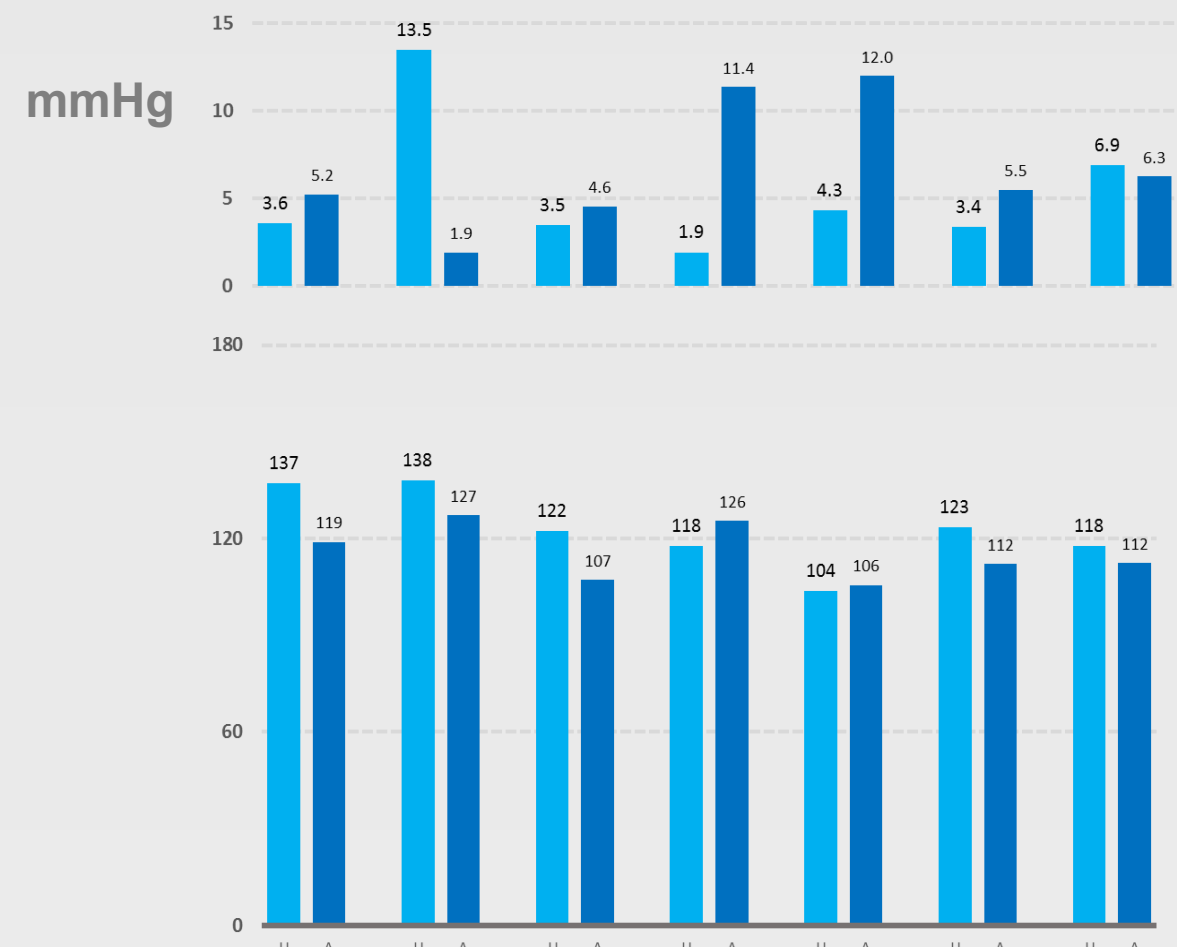
Temperature Measurement





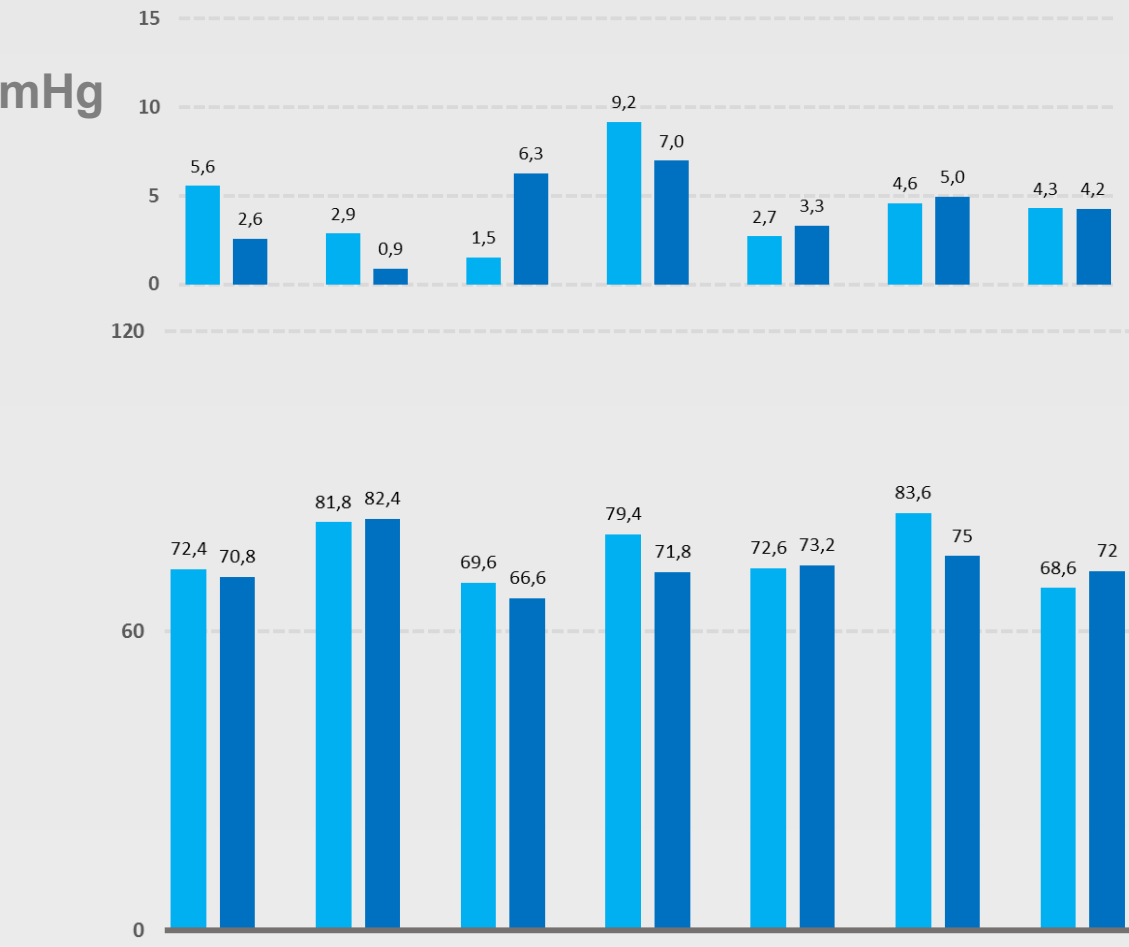
Systolic blood pressure measurements

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t-test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



Diastolic blood pressure measurements

F-test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
t-test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



For the clinical thermometers tested for body temperature measurements, 55 % of the measurements with axial thermometers showed the same accuracy. In the case of infrared thermometers this value drops to 38 % of cases of identical accuracy. For sphymomanometers, it was found that only 25 % of the results were statistically identical to the precision of both systolic pressure and diastolic pressure.

FINAL COMMENTS



These values show that measurements taken with these medical devices should be faced with some caution in the light of the dispersion of their results. Thus, there is a need for procedure and good practices harmonization, not only to improve accuracy and comparability of measurements but also to assess the benefits of clinical decisions.

Considering the regulatory surveillance system for medical devices in Portugal is still far away of its major audience (users and health professionals), any strategy for future development in this field has to pass by Legislative orders in order to increase the metrological requirements for these equipment's and consequently to protect users.

REFERENCES



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