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RCS Versailles 808 040 075

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# TUCKY THERMOMETER CLINICAL DATA



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# 1 INTRODUCTION

## 1.1 References

The following references are mentioned in the document:

Reference	Description
[PRT2000_MAN]	BRAUN PRT2000 AGE PRECISION USER MANUAL Rev July 2014
[MT403S_MAN]	TORM flexible 10s thermometer V00 – june 2011
[KD-164_MAN]	Giphar 60s thermometer ed 04/2013
[MT1621_MAN]	Magnien MT1621 manual
[TUCKY_MAN]	22300xx-108_-y_INSTRUCTION-FOR-USE (latest version)
[ISO80601-2-56]	NF EN ISO 80601-2-56 - MEDICAL ELECTRICAL EQUIPMENT - PART 2-56: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF CLINICAL THERMOMETERS FOR BODY TEMPERATURE MEASUREMENT
[CADI_STUDY]	Evaluation of the Cadi Thermosensor Wireless skin-contact thermometer against ear and axillary temperatures in children <a href="https://www.pediatricnursing.org/article/S0882-5963(08)00497-1/fulltext">https://www.pediatricnursing.org/article/S0882-5963(08)00497-1/fulltext</a>
[ASTM_1965]	ASTM Standard about tests related to IR thermometers.

## 1.2 Context

This report describes validation data regarding Tucky temperature measurements on real persons, compared with other classical thermometers.

Test protocols have been elaborated following two standards: [ISO80601-2-56] and [ASTM\_E1965].

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## 2 FIRST STUDY

A first study was conducted on feb 2018 with Tucky calibrated in ovens. That study has been realized on babies, children, adolescents and adults from different gender and ages:

- 4 babies of 29 days (lower patient age limit),
- 2 children: 2 of 6 and 10 years old,
- 2 adolescents of 15 and 17 years old,
- 4 adults of 30, 46, 59 and 67 years old.

Comparison was done with 4 commercial thermometers which have the same technology as Tucky: they use a thermistor as a sensing element.

The following picture illustrates them:



Braun PRT2000E      Torm MT403      Giphar KD-164      Magnien MT1621



### 2.1 Test protocol

The test consisted of wearing Tucky during few hours while doing normal activity.

At 3 different times, patients took their temperatures with the 4 reference thermometers, and recorded Tucky real time values.

During 20 minutes before each measurement, patients were dressed, inside a room, with an environmental temperature between 19 and 23°C and did not smoke or eat.

The 4 reference thermometers were also placed in the same room during this period.

Comparisons were made between:

- Tucky vs Torm MT403S
- Tucky vs Braun PRT2000EU
- Tucky vs Giphar KD-164
- Tucky vs Magnien MT1621

and also:

- Torm MT403S vs Braun PRT2000EU

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Results were analysed through the statistical methods described in [ISO80601-2-56], which are also used in other clinical studies like [CADI\_STUDY].

## 2.2 Results

That study allowed to highlight some key points:

- The clinical bias differs with each reference thermometers, and varies from -0.21°C to 0,47°C.
- Limits of agreements range between 0,4 and 0,78.

Tucky vs	Torm	Braun	Giphar	Magnien
	MT403S	PRT2000EU	KD-164	MT1621
Clinical bias (°C)	0,64	-0,21	0,47	0,24
Limits of agreements (°C)	0,40	0,72	0,78	0,60

Those number are in the same range as those between 2 reference thermometers.

Torm MT403S vs	Braun
	PRT2000EU
Clinical bias	-0,86
Limits of agreements	0,68

- Temperatures measured by Tucky for each patient population are equivalent to thermometers already commercialized and using the same technology (a thermistor as a sensing element).

They thus appear to be reasonable and provide good confidence for further studies.

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### 3 SECOND STUDY

This second study has been conducted during in January 2021. Each Tucky used in this study have been calibrated thanks to a Heat Bath with an accuracy of  $\pm 0.1^{\circ}\text{C}$ . That protocol is based on test method described in standard [ASTM\_E1965].

#### 3.1 Subjects

The test subjects consisted of infant, children and adult population from different genders and ages, from which consent has been obtained. The three categories used and the number of persons for each one has been defined following the TABLE X2.1 of [ASTM\_E1965].

This test has been realized with the following 36 persons:

- 12 infants (from 29 days to less than 2 years old)
- 12 children (from 2 years to less than 12 years old)
- 12 adolescents and adults (more than 12 years old)

After 12 years old, apocrine glands appear, and sudation is more important. That is why adolescents and adults are in the same group. For each group, the genders were equally distributed.

A total of 36 patients participate to this test:

Infants	Children	Adolescents / Adults
Boys of 5, 8, 12, 16, 18 and 22 months	Boys of 3, 5, 6, 9, 10 and 11 years old	Men of 18, 23, 26, 33, 39 and 65 years old
Girls of 4, 5, 8, 12, 15, 18 and 22 months	Girls of 5, 7, 8, 10, 11 and 11 years old	Women of 22, 26, 33, 37, 45 and 62 years old

#### 3.2 Thermometers used

##### 3.2.1 Tucky used for the tests.

Several Tucky have been used for this test.

Old Tucky with CB PCB model, and recent Tucky with DA PCB model have been used, to guarantee the efficiency of both old and recent models.

Serial Number	PCB model
K00402250108	DA
1602A99999	CB
K00202250108	DA
K00102250108	DA
1940Y00322	CB
K00702250146	DA

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### 3.2.1.1 REFERENCE THERMOMETERS CHARACTERISTICS

During this test, the comparison was done with 4 contact thermometers already commercialized which have the same technology as Tucky: they use a thermistor as a sensing element.

Here are their characteristics:

Distributeur	Fabriquiant	Country	Model	Tps	Output range	Accuracy
LBS Medical	KellyUnion	CN	KD-601	60	[32.0-43.9°C]	$\pm 0.1^{\circ}\text{C}$ : 35.0 - 41°C $\pm 0.2^{\circ}\text{C}$ : outside the above range
TORM	Hangzhou Sejoy el.	CN	MT403S	10	[35,5-42°C]	$\pm 0,1^{\circ}\text{C}$
GENIAL	Genial Technology	CN	T15	30	[32.0-42.9°C]	$\pm 0.1^{\circ}\text{C}$ : 35.5 – 42.0°C $\pm 0.2^{\circ}\text{C}$ : outside the above range
MAGNIEN	Microlife corp	TW	MT1621	90	[34-42°C]	$\pm 0,1^{\circ}\text{C}$
e-TakesCare	e-TakesCare	FR	TUCKY-21	cont.	[24-42°C]	$\pm 0,1^{\circ}\text{C}$ : [37-39°C], $\pm 0,2^{\circ}\text{C}$ : [32 °C - 37 °C] and [39 – 42 °C], $\pm 0.3^{\circ}\text{C}$ : under 32 °C and above 42 °C

These thermometers are shown on the picture below:

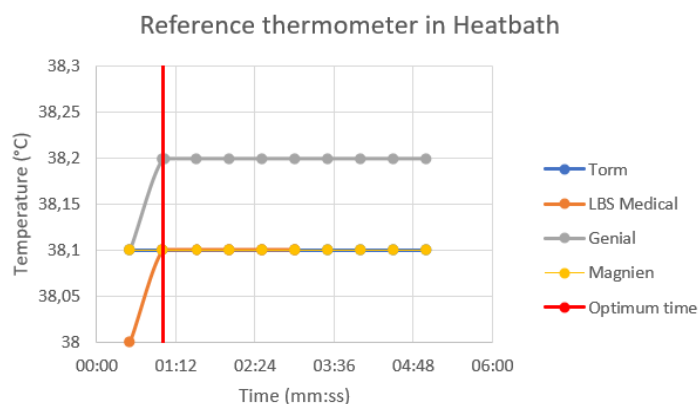


LBS Medical KD-601      Genial T15      Magnien MT1621      Torm MT403

### 3.2.2 Tests on reference thermometers before study

Each reference thermometer has been tested on both Heatbath and human body before the study. These tests aim to characterize the behaviour of each thermometer, and get the average time required to have the most accurate temperature possible.

The results of these tests are the following:

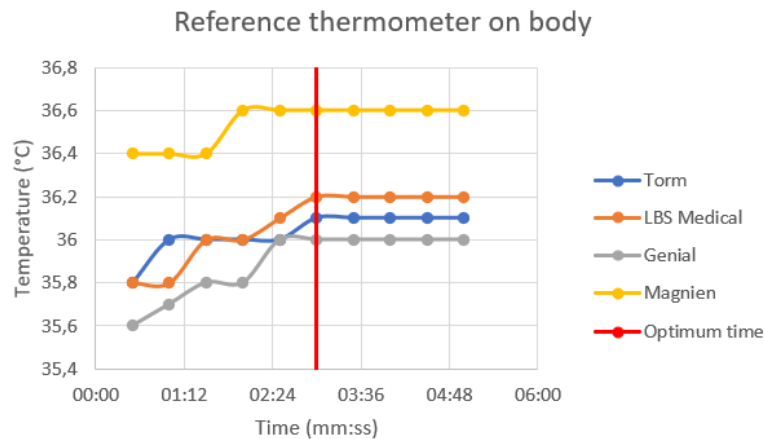


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As shown on the graph above, all reference thermometers reached their equilibrium temperature at **1 minute**.

The, the test has been performed on human body. The result is the following:



As shown on the graph above, all reference thermometers reached their equilibrium temperature at **3 minutes**. That allowed to determine the minimum heating time to obtain relevant temperatures. Therefore, in the following protocol the reference thermometers are kept 3 minutes under the armpit at each statement.

### 3.2.3 Test Protocol

To retrieve data from Tucky and reference thermometers, and compare them, the following protocol has been applied on the subjects listed at the beginning of this section:

#### Prerequisites:

The **armpits shall be shaved** to improve contact between the skin and the thermometer.

It is advised to **add a medical tape** over the Tucky to maintain its position.

The tester shall have **a profile** on its account name as follows: "FIRSTNAME\_tucky".

The tester shall **know the serial number** of the Tucky.

Reference thermometers and environment thermometer shall be placed **in the same room as the tester, in ambient conditions (Ambient temperature: + 15°C to + 40°C (59°F to 104 °F); Relative humidity: 15% to 95 %)**. Those conditions respect the operating conditions of all thermometers and conditions described in sections 5.6.1 and 5.6.2 of [ASTM\_E1965].

The tester shall **wear a garment** while doing the test and not be shirtless.

The tester shall **keep his/her arms closed** as much as possible.

The tester shall **have a stopwatch**.

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### Steps of the test:

- 1) Place the Tucky under the right armpit, **as high as possible** (it should not be possible to place a finger between Tucky and the top of the armpit).
- 2) Temperature must be taken 5 times in the day: at 8am, 12am, 4pm, 8pm and 12pm. Each time the temperature is taken, the tester shall take Tucky temperature, and then measure successively the temperature under the left armpit with all the reference thermometers in the following order: Torm, LBS Medical KD-601, Genial T15, and Magnien MT1621.  
For each of the reference thermometers, turn it on and wait until "Lo" appears on the display before placing it under the arm. Start a 3-minute timer and take the temperature at the end. Ignore the ringing of the thermometer.
- 3) At the end of the test, disinfect the thermometers with a suitable solution (such as 90° alcohol for example).

### Result analysis:

A total of around 900 measurements were recorded, allowing to compare thermometers with each other.

Comparisons were made between:

- Tucky vs Torm MT403S
- Tucky vs LBS Medical KD-601
- Tucky vs Genial T15
- Tucky vs Magnien MT1621

Results were analysed through the statistical methods described in [ISO80601-2-56] and [ASTM\_E1965].

- Clinical Bias

Clinical bias is computed with the following equation:

$$\Delta_{cb} = \frac{\sum_{i=1}^n (t_{TUT,i} - t_{RCT,i})}{n}$$

Where:

- **TUT** is the Thermometer Under Test,
- **RCT** is the Reference Thermometer,
- **n** is the total number of patients,
- **i** is the index number for an individual patient.

It is also represented graphically by plotting on a graph pairs of temperatures for each comparison.

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- Limits of agreement

Limits of agreement is computed with clinical bias standard deviation:

$$L_A = 2 \times \sigma_{\Delta_{cb}}$$

Standard deviation of the clinical bias is computed by the following equation:

$$\sigma_{\Delta_{cb}} = \sqrt{\frac{\sum_{i=1}^n [(t_{TUT,i} - t_{RCT,i}) - \Delta_{cb}]^2}{n-1}}$$

It is also graphically represented through Bland-Altman type plots, which show temperature differences against the average values of all measurements.

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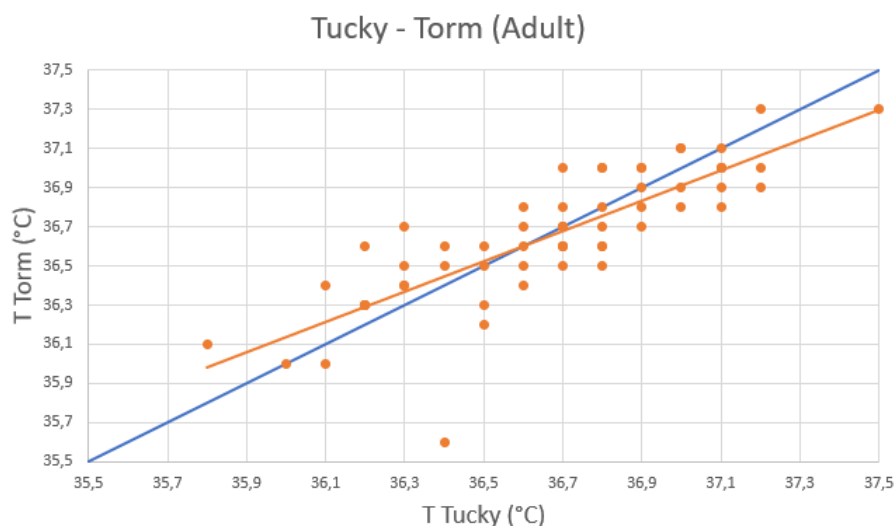
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### 3.3 Results

#### 3.3.1 Tucky vs Torm MT403

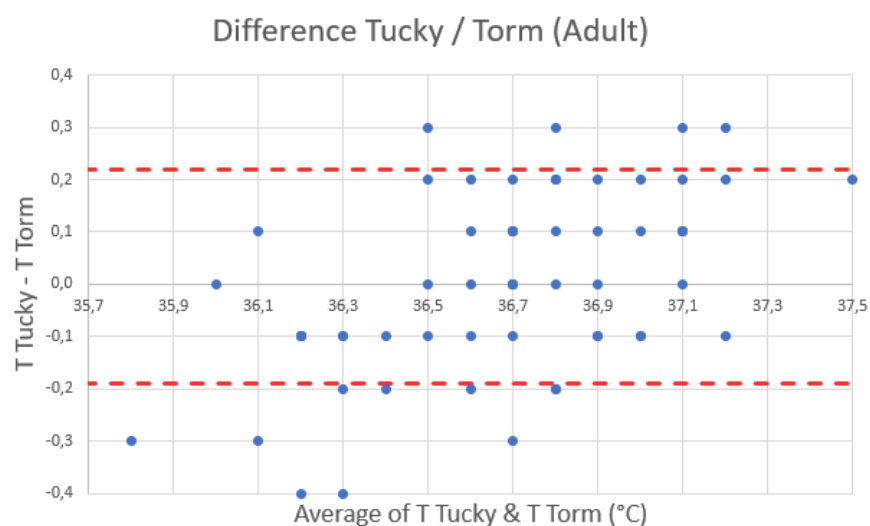
The following graphs represents pairs of temperature recorded at the same time with Tucky and Torm MT403 for the three subject groups:

- Adults and adolescents



The clinical bias for this set of measurements is :  $D = 0,01500^{\circ}\text{C}$ .

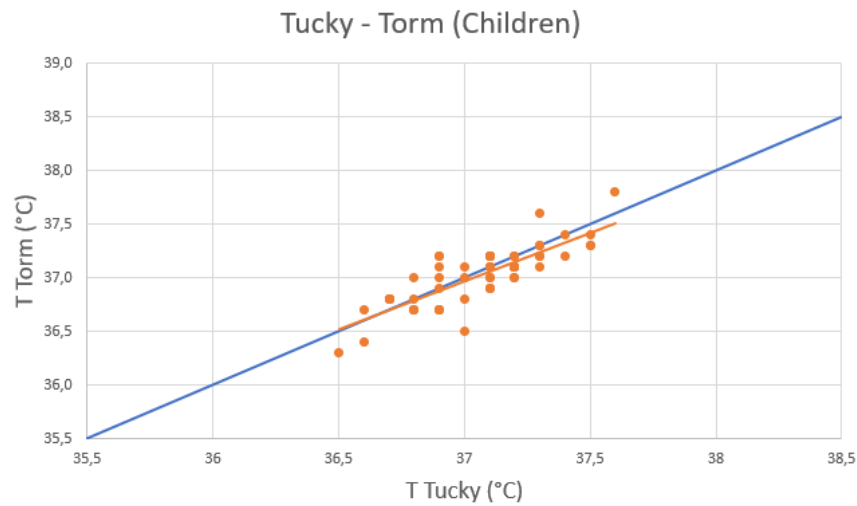
The standard deviation is  $0,20322^{\circ}\text{C}$ , so limits of agreement are  $0,40643^{\circ}\text{C}$ .



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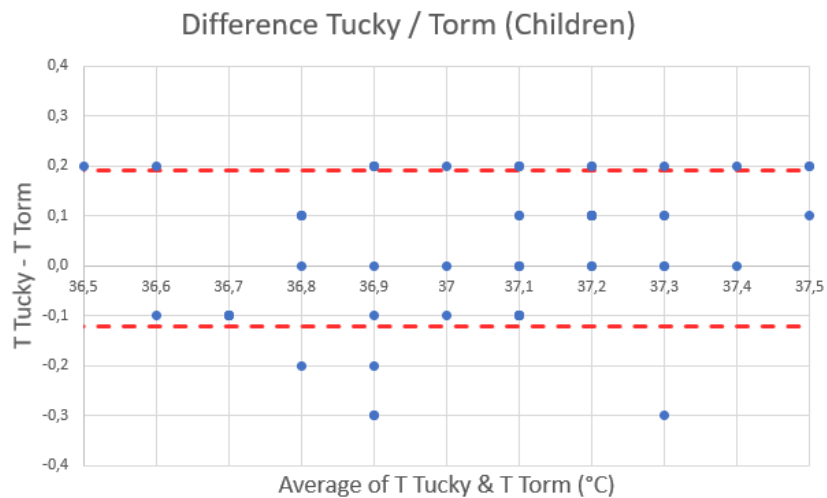
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- Children

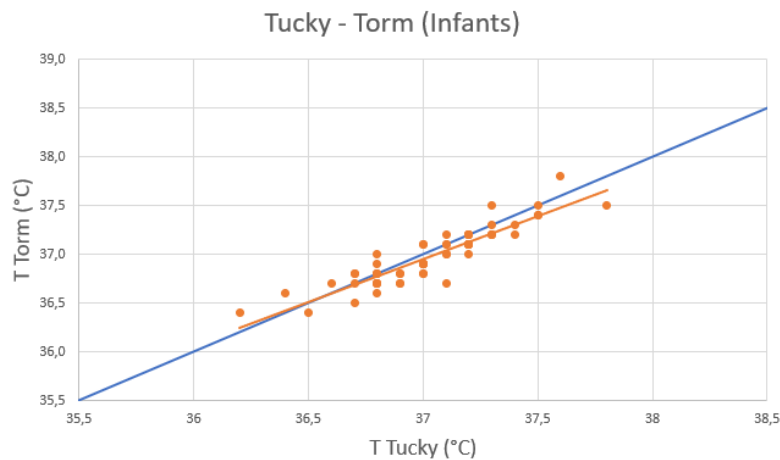



The clinical bias for this set of measurements is :  $D = 0,03500^{\circ}\text{C}$ .

The standard deviation is  $0,15604^{\circ}\text{C}$ , so limits of agreement are  $0,31207^{\circ}\text{C}$ .



- Infants

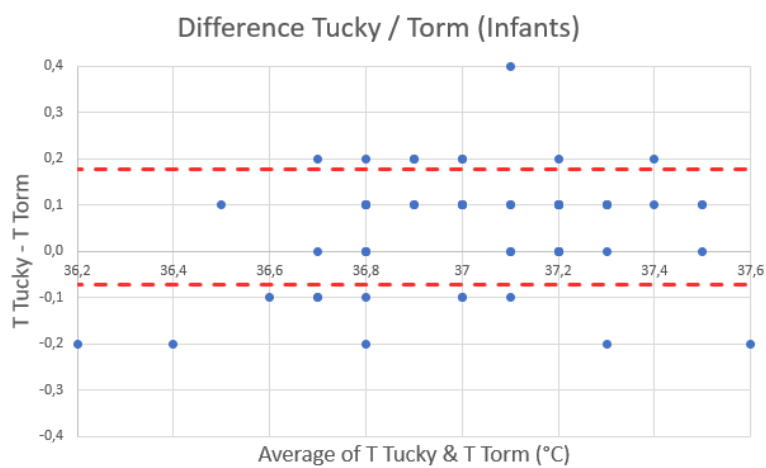



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The clinical bias for this set of measurements is :  $D = 0,05333^{\circ}\text{C}$ .

The standard deviation is  $0,12550^{\circ}\text{C}$ , so limits of agreement are  $0,25101^{\circ}\text{C}$ .



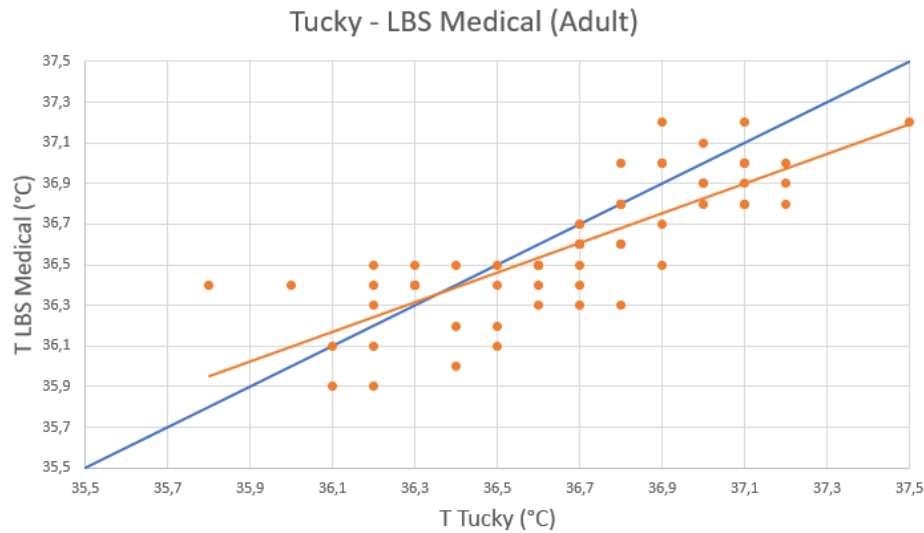
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### 3.3.2 Tucky vs LBS Medical KD-601

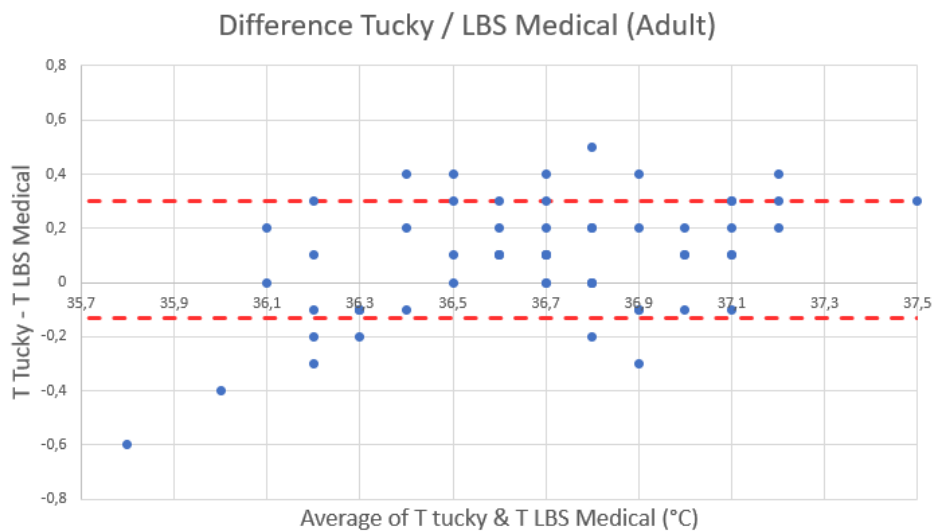
The following graph represents pairs of temperature recorded at the same time with Tucky and LBS Medical KD-601 for the three subject groups:

- Adults and adolescents



The clinical bias for this set of measurements is :  $D = 0,08500^{\circ}\text{C}$ .

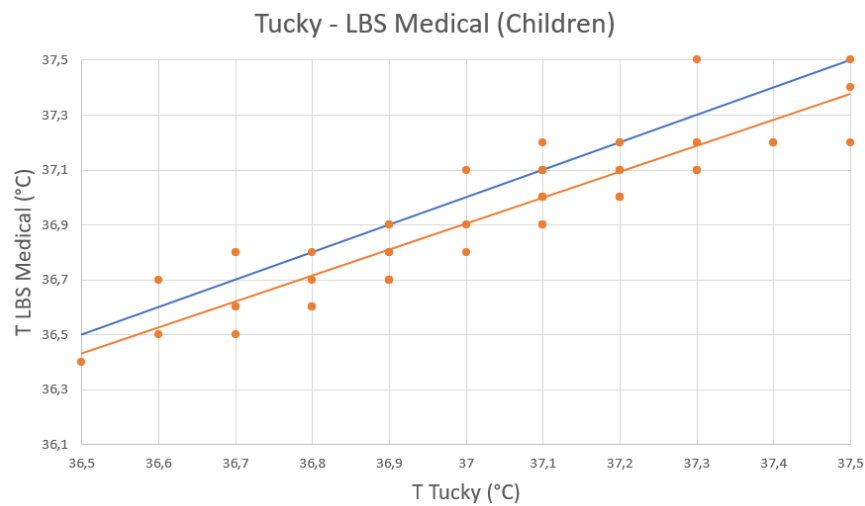
The standard deviation is  $0,21693^{\circ}\text{C}$ , so limits of agreement are  $0,43386^{\circ}\text{C}$ .



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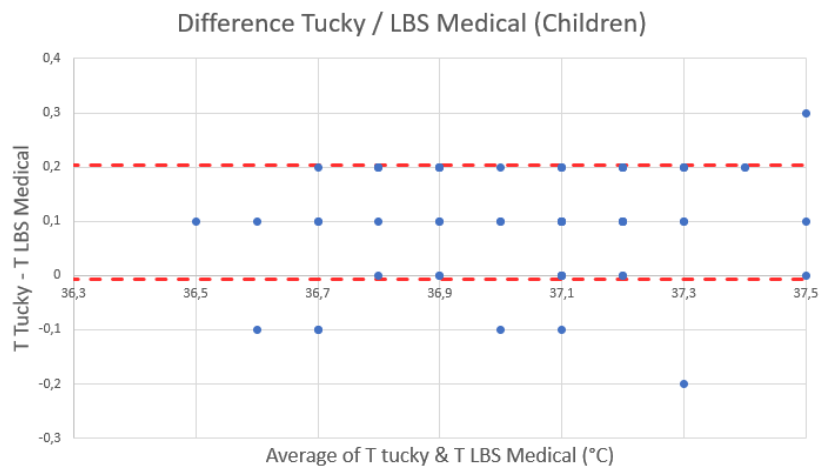
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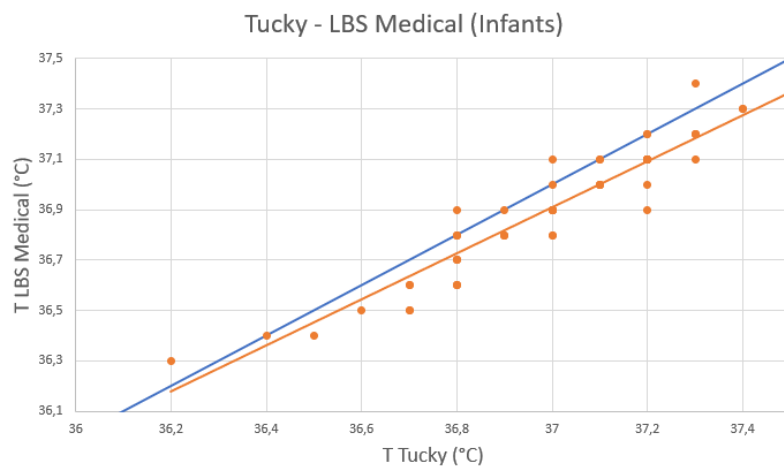



The clinical bias for this set of measurements is :  $D = 0,09833^{\circ}\text{C}$ .

The standard deviation is  $0,10495^{\circ}\text{C}$ , so limits of agreement are  $0,20990^{\circ}\text{C}$ .



- Infants

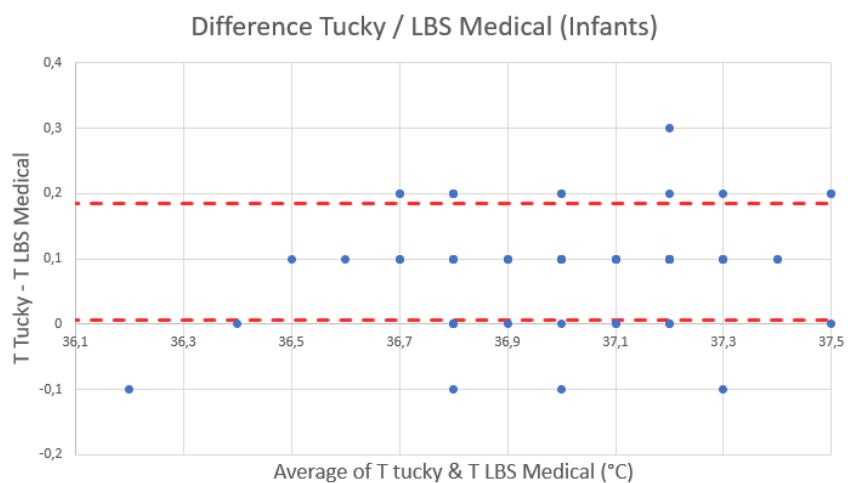



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The clinical bias for this set of measurements is :  $D = 0,09500^{\circ}\text{C}$ .

The standard deviation is  $0,08911^{\circ}\text{C}$ , so limits of agreement are  $0,17822^{\circ}\text{C}$ .



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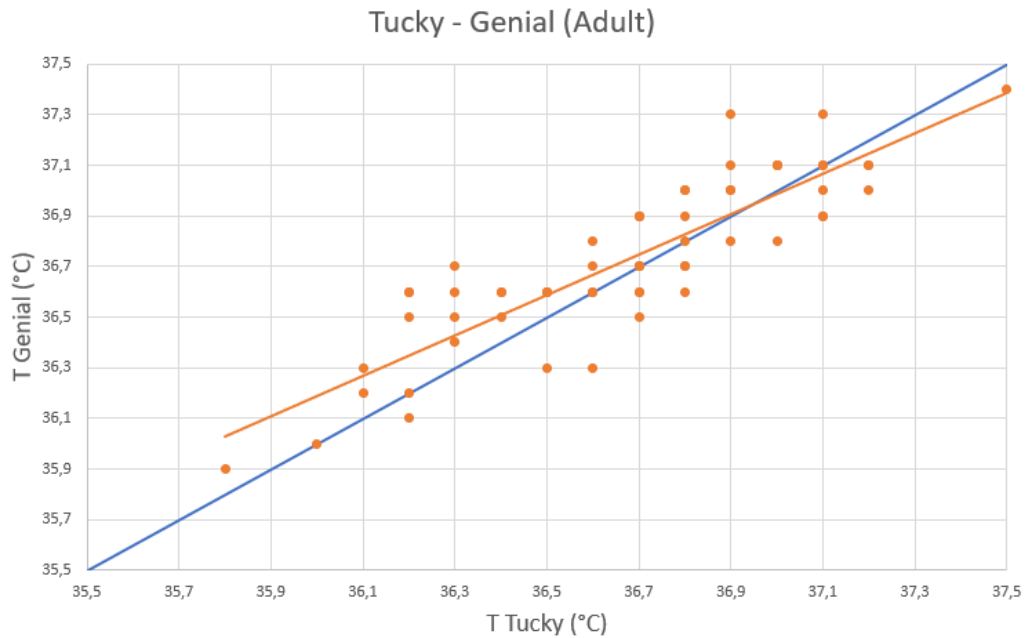
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### 3.3.3 Tucky vs Genial T15

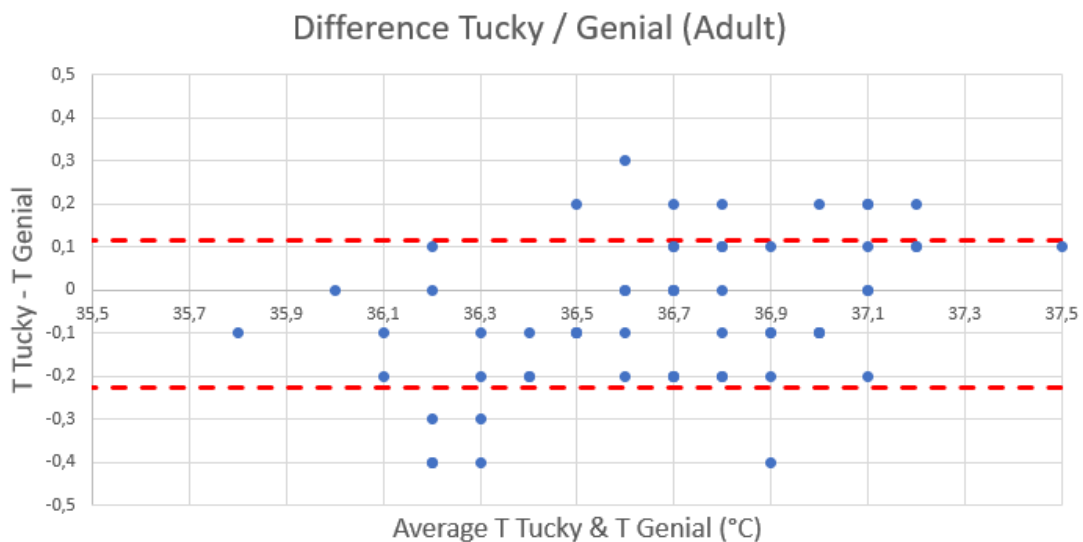
The following graph represents pairs of temperature recorded at the same time with Tucky and Genial T15 for the three subject groups:


- Adults and adolescents



The clinical bias for this set of measurements is :  $D = -0.05500^{\circ}\text{C}$ .

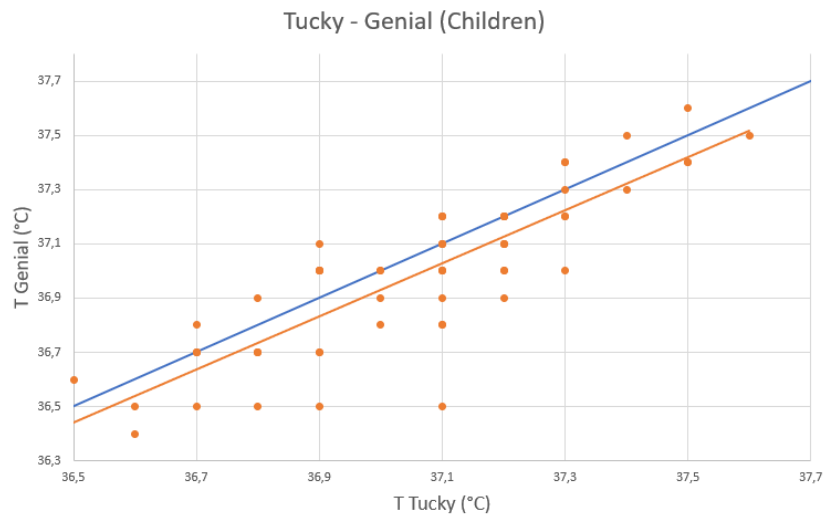
The standard deviation is  $0,17116^{\circ}\text{C}$ , so limits of agreement are  $0,34233^{\circ}\text{C}$ .



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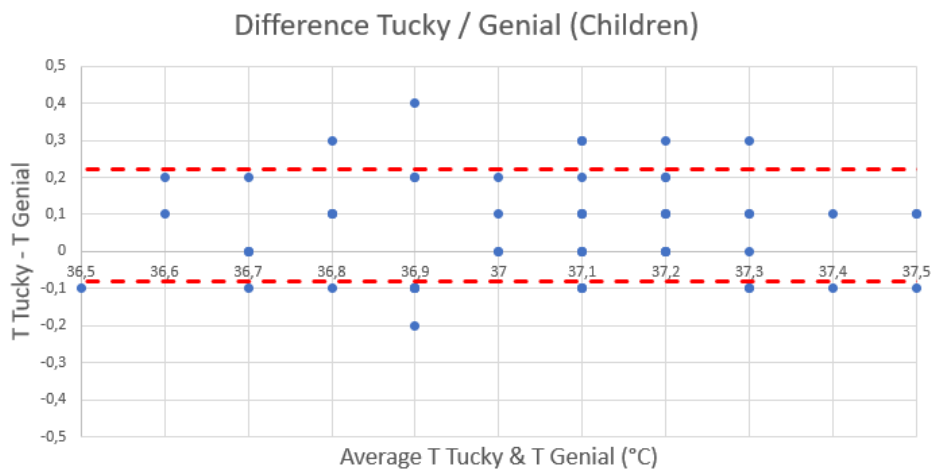
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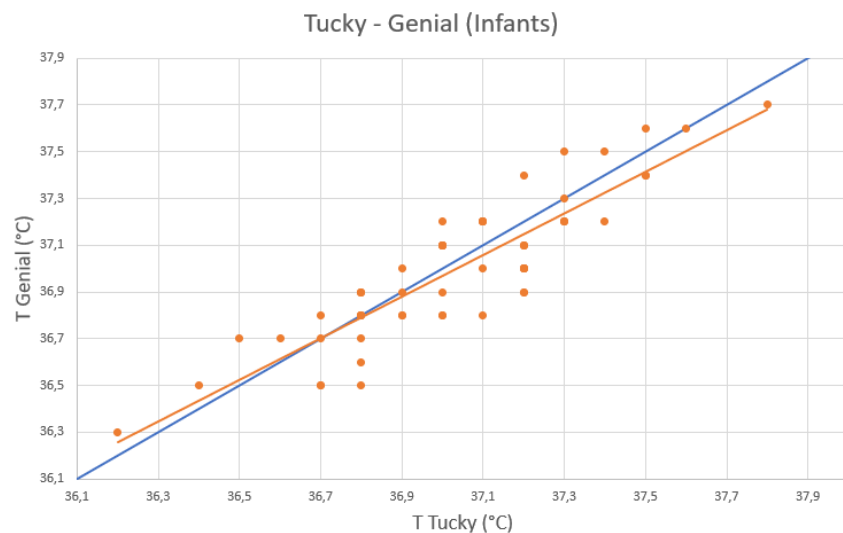


The clinical bias for this set of measurements is :  $D = 0.07000^{\circ}\text{C}$ .

The standard deviation is  $0,15104^{\circ}\text{C}$ , so limits of agreement are  $0,30208^{\circ}\text{C}$ .



- Infants

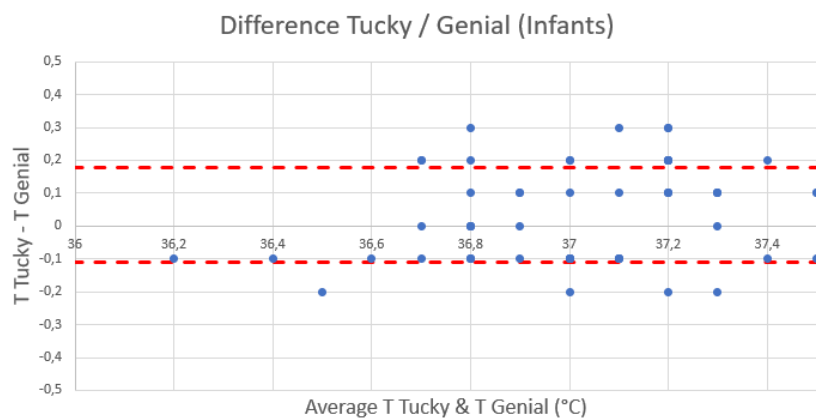



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The clinical bias for this set of measurements is :  $D = 0.03500^{\circ}\text{C}$ .

The standard deviation is  $0,14359^{\circ}\text{C}$ , so limits of agreement are  $0,28718^{\circ}\text{C}$ .



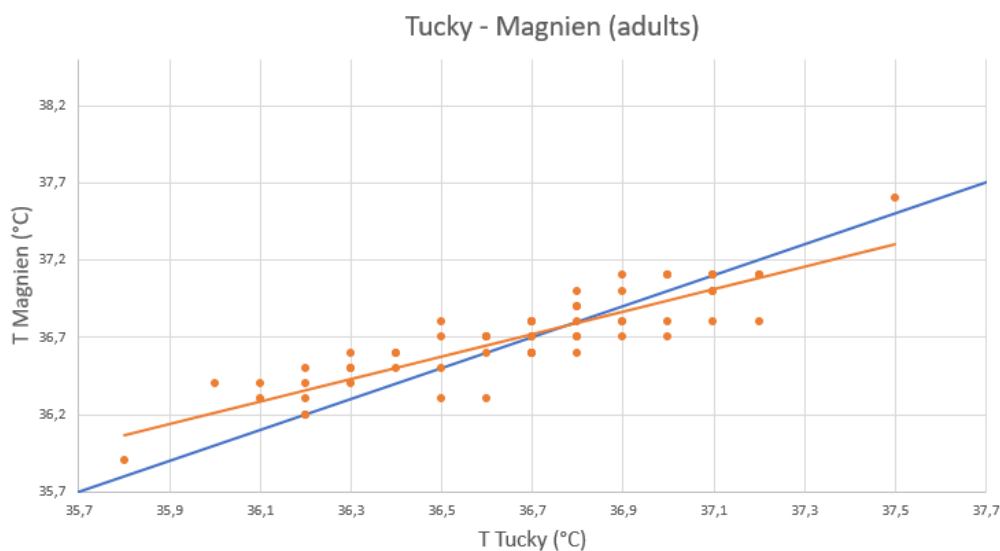
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### 3.3.4 Tucky vs Magnien MT1621

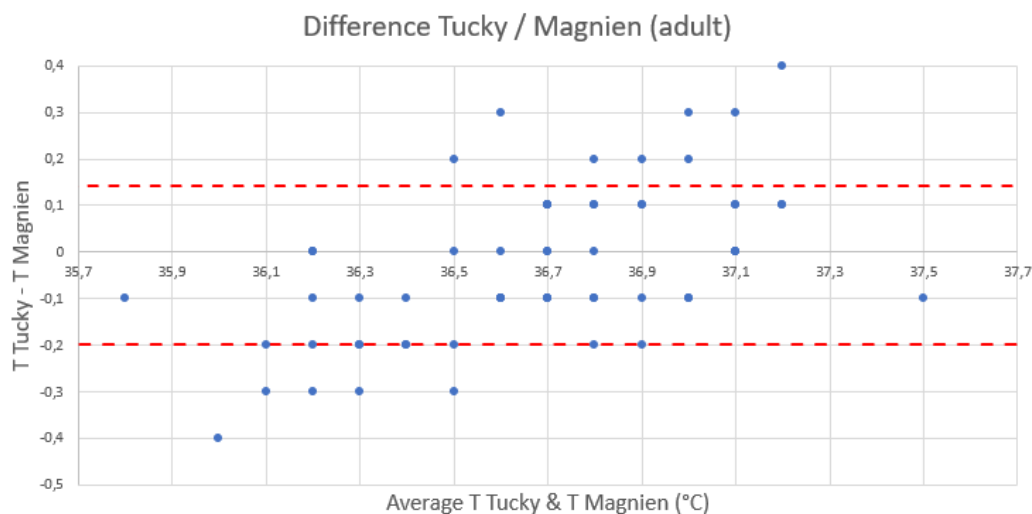
The following graph represents pairs of temperature recorded at the same time with Tucky and Magnien MT1621 for the three subject groups:

- Adults and adolescents



The clinical bias for this set of measurements is :  $D = 0.03500^{\circ}\text{C}$ .

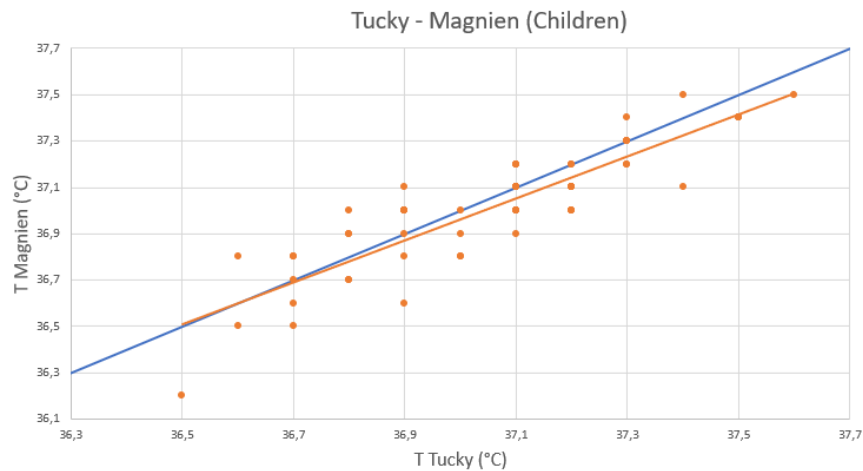
The standard deviation is  $0,14359^{\circ}\text{C}$ , so limits of agreement are  $0,28718^{\circ}\text{C}$ .



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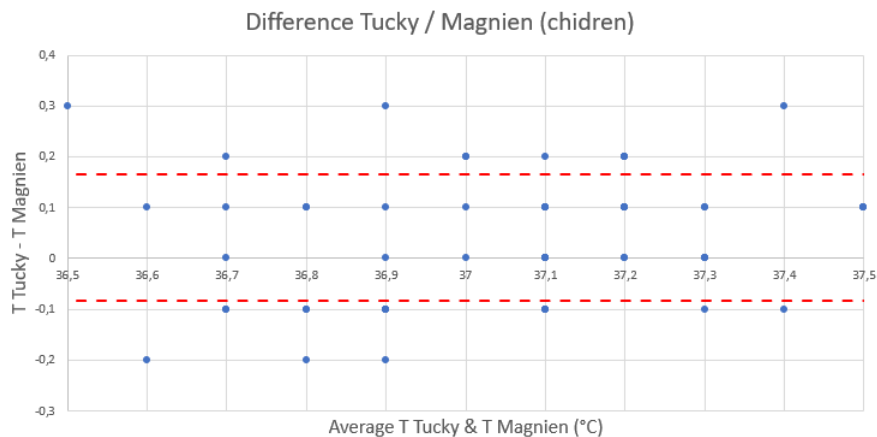
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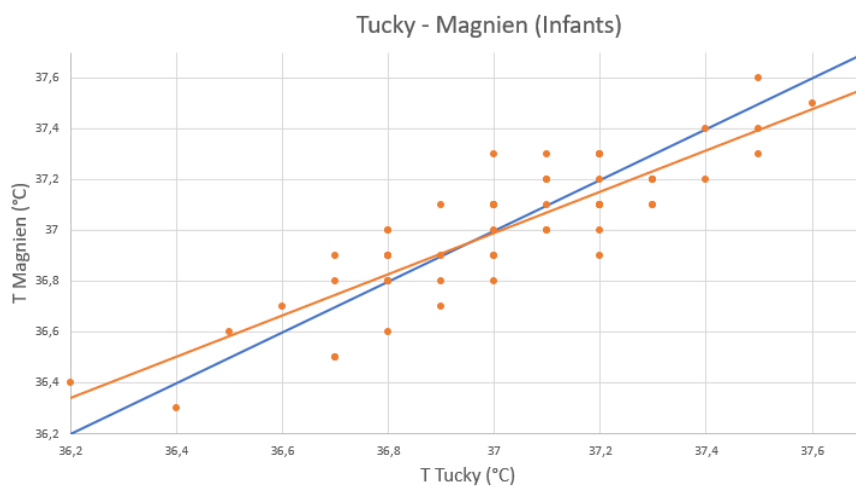


The clinical bias for this set of measurements is :  $D = 0.04167^{\circ}\text{C}$ .

The standard deviation is  $0,12391^{\circ}\text{C}$ , so limits of agreement are  $0,24782^{\circ}\text{C}$ .



- Infants

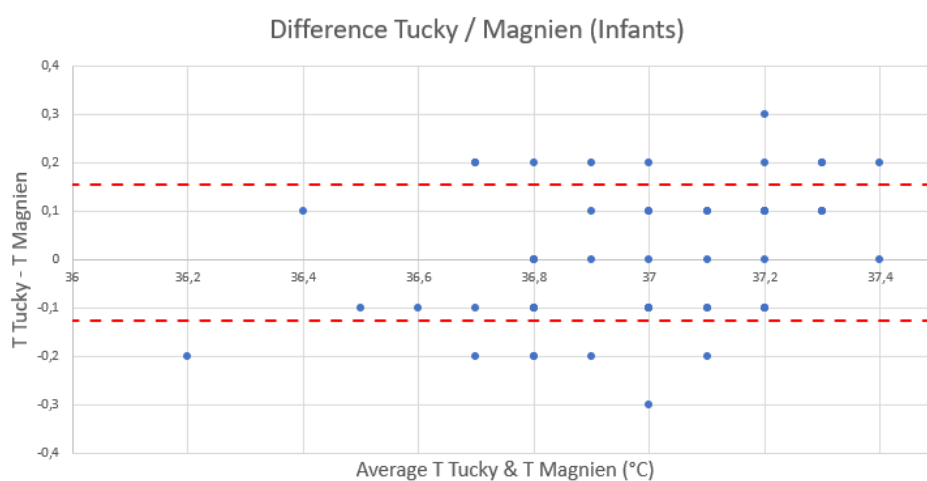


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The clinical bias for this set of measurements is :  $D = 0.01500^{\circ}\text{C}$ .

The standard deviation is  $0,14121^{\circ}\text{C}$ , so limits of agreement are  $0,28242^{\circ}\text{C}$ .



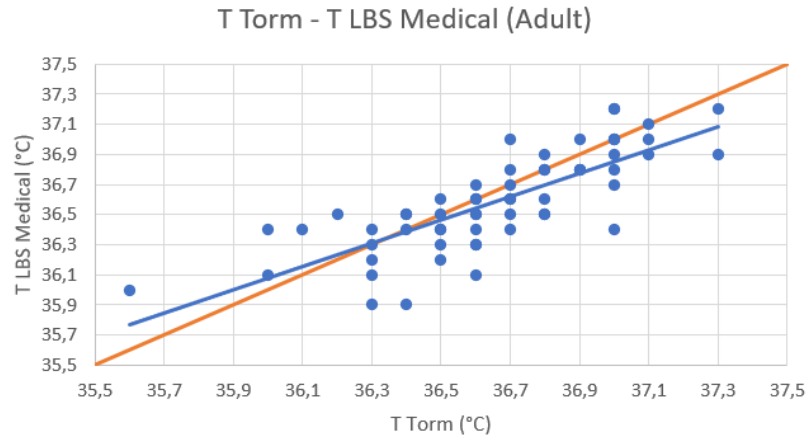
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### 3.3.5 Torm 403 vs LBS Medical KD-601

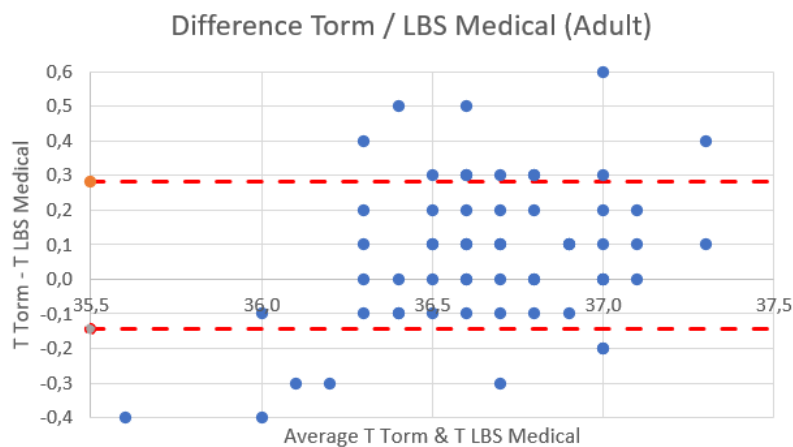
The following graph represents pairs of temperature recorded at the same time with Torm and LBS Medical KD-601 for the three subject groups:

- Adults and adolescents

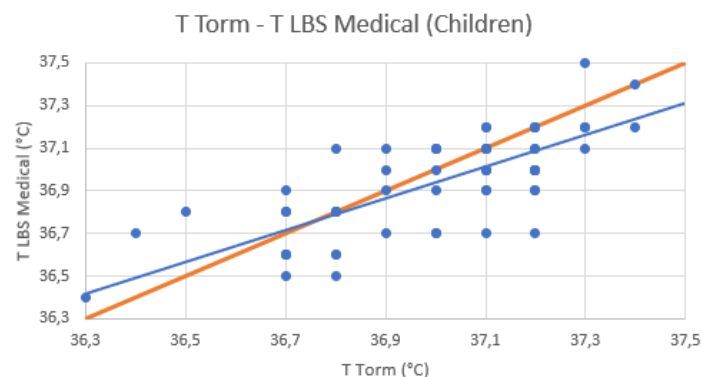


The clinical bias for this set of measurements is :  $D = 0,07000^{\circ}\text{C}$ .

The standard deviation is  $0,21337^{\circ}\text{C}$ , so limits of agreement are  $0,42673^{\circ}\text{C}$ .



- Children

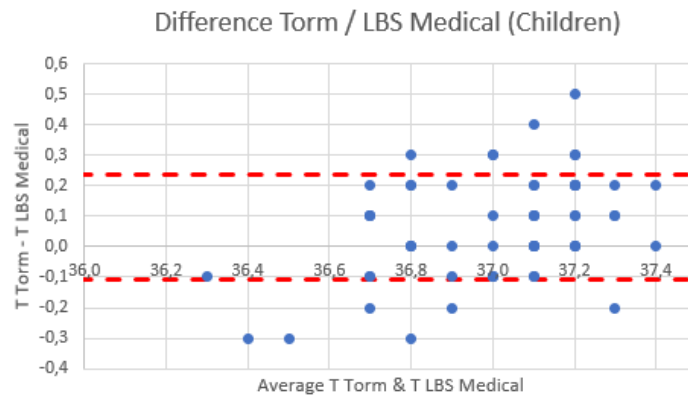


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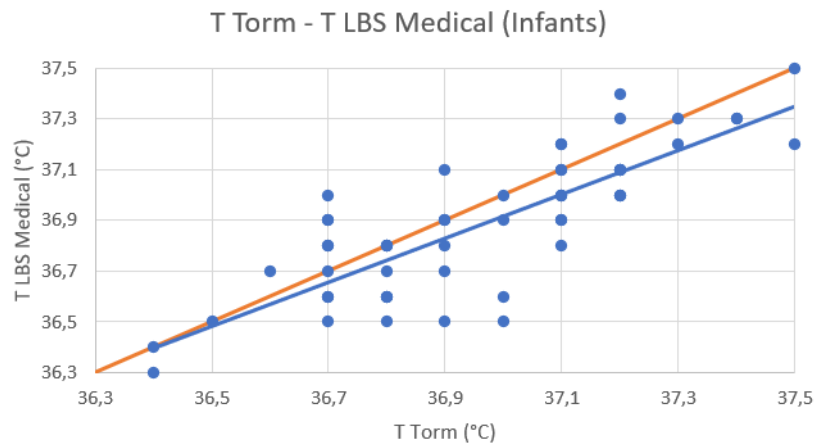
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The clinical bias for this set of measurements is :  $D = 0,06333^{\circ}\text{C}$ .

The standard deviation is  $0,17170^{\circ}\text{C}$ , so limits of agreement are  $0,34340^{\circ}\text{C}$ .

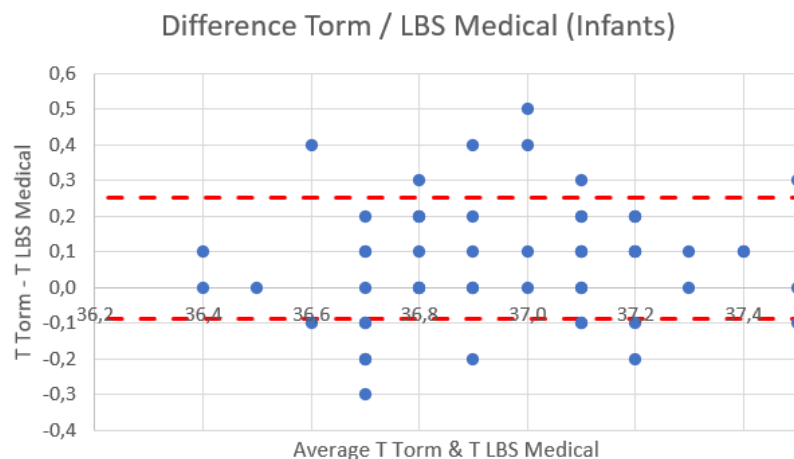


- Infants



The clinical bias for this set of measurements is :  $D = 0,08167^{\circ}\text{C}$ .

The standard deviation is  $0,17123^{\circ}\text{C}$ , so limits of agreement are  $0,34246^{\circ}\text{C}$ .



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### 3.4 Conclusion

Those tests allowed to highlight some key points:

1) The clinical bias differs with each reference thermometers, and varies from:

- -0,05500°C to 0,08500°C for adults and adolescents
- 0,03500°C to 0,09833°C for children,
- 0,01500°C to 0,09500°C for infants.

2) Limits of agreements range varies between:

- 0,33967 and 0,43386 for adults and adolescents,
- 0,20990 and 0,24782 for children,
- 0,17822 and 0,28718 infants.

Tucky vs	Torm			LBS Medical			Genial			Magnien		
	MT403S			KD-601			T15			MT1621		
Group	Adults & adolescents	Children	Infants	Adults & adolescents	Children	Infants	Adults & adolescents	Children	Infants	Adults & adolescents	Children	Infants
Clinical bias (°C)	-0,01500	0,03500	0,05333	0,08500	0,09833	0,09500	-0,05500	0,07000	0,03500	-0,02833	0,04167	0,01500
Limits of agreements (°C)	0,40643	0,31207	0,25101	0,43386	0,20990	0,17822	0,34233	0,30208	0,28718	0,33967	0,24782	0,28242

Those number are in the same range as those between 2 reference thermometers.

Torm MT403S vs	LBS Medical		
	KD-601		
Group	Adults & adolescents	Children	Infants
Clinical bias	0,0700	0,06333	0,04167
Limits of agreements	0,42673	0,34340	0,29295

Temperatures measured by Tucky for each patient population are equivalent to thermometers already commercialized and using the same technology (a thermistor as a sensing element).

In conclusion, this study proved that **Tucky is efficient and accurate** when used on both the three types of population tested: **adults and adolescents, children, and infants**.

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## 4 CONCLUSION

The results of the second study complete the results of the first study prove the efficiency and accuracy of Tucky when it is used on adults, adolescents, children, and infants.

Tucky vs	Torm	Braun	Giphar	Magnien
	MT403S	PRT2000EU	KD-164	MT1621
Clinical bias (°C)	0,64	-0,21	0,47	0,24
Limits of agreements (°C)	0,40	0,72	0,78	0,60

**Tab 1 - First study results**

Tucky vs	Torm			LBS Medical			Genial			Magnien		
	MT403S			KD-601			T15			MT1621		
Group	Adults & adolescents	Children	Infants	Adults & adolescents	Children	Infants	Adults & adolescents	Children	Infants	Adults & adolescents	Children	Infants
Clinical bias (°C)	-0,01500	0,03500	0,05333	0,08500	0,09833	0,09500	-0,05500	0,07000	0,03500	-0,02833	0,04167	0,01500
Limits of agreements (°C)	0,40643	0,31207	0,25101	0,43386	0,20990	0,17822	0,34233	0,30208	0,28718	0,33967	0,24782	0,28242

**Tab 2 - Second study results**

Comparing the results in the tabs below:

- 1) A calibration with Heat Bath induces a less important clinical bias, which means temperature measurements are more accurate.
- 2) The limit of agreement are also more restraints due to a lower standard deviation, which means temperature measurements are closer and more accurate.

In conclusion, Tucky is **more accurate** when calibrated with the Heat Bath method. Tucky is also **efficient and accurate** enough on all patient populations: infants, children, adults, and adolescents.

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