Clinical Trial

ThermoFlash® LX-26 (MSFT V.4)
Contactless Medical Electronic Thermometer

Statistical Comparative Study - Axillary, Rectal, Tympanic
Paediatric Emergency Unit, Louis-Mourier Hospital

Period of Study (August 2007 - May 2008)

Contents

Authors

- **Dr. Stéphane ILLOUZE**

  Doctor, General Medical Intern at Necker Hospital - Faculty for Sick Children (Emergency Medicine)

  Coordinator / Writer of **Thermo*Flash*®** Clinical trial

  This study on Infrared Thermography was conducted for an upcoming thesis at the Faculty of Medicine (University of Paris Descartes / Paris V)

- **Dr. Arthur TENENHAUS**

  Doctor of Genetic Statistics (University of Pierre and Marie Curie / Paris VI)

  Research Engineer at C.E.A

- **Dr. Fanny AZIZA – TENENHAUS**

  Doctor of Biostatistics (Agro Paris Tech)

  Research Engineer at INRA / INAPG

  Silliker Prize Laureate 2008

Introduction

- When we have to measure the temperature of a subject, whether at home, in surgery or in a hospital, a multitude of choices are possible. Indeed, a wide range of devices are offered to measure fever, and while this multiplicity of modes and sites for taking temperature (skin, oral or rectal mucous membrane, tympanic membrane) may appear to provide flexibility and simplicity, the choice of site and type of thermometer to obtain a temperature as close as possible to the central temperature has never been more complex; more so when children and infants are concerned.

- A new device, the **Thermo*Flash*®**, based on the measurement of frontal infrared radiation, proposes a new approach to taking temperatures. The quality of this device can provide comfort in the measurement of temperature, particularly with infants.

- By conducting this study, we intend to test the reliability and to accumulate scientific information on the efficiency / sensitivity aspects of this device when it is used with children of under 15 years and, in particular, with children under six months at home, in urban medicine or in large-scale hospital set-ups.

Aim of Present Study

- Currently, 8,000 to 10,000 practitioners use this new technology proposed by **Thermo*Flash*®** to assess the temperature of their patients. More than 50% of pharmacies in France retail this product, praising the very interesting ergonomics of the device.

- More than 300,000 items have been sold to individuals in France, and the device is also sold abroad. This enthusiasm is undoubtedly linked to its ease of use. But I posed to myself a few questions about its reliability, asking if this mode of taking temperature was valid, and whether it was usable in another form for large-scale hospital set-ups.

- The purpose of this study is to accumulate scientific data on the efficiency / sensitivity aspects of this device when it is used with children of under 15 years, particularly with children of under six months.

Taking the Temperature – State Of The Art

- To establish an objective panel of the sites of temperature measurement, of available devices and of their reliability, I mention below excerpts of the work of Dr. Isabelle Sermet-Gaudelus, General Paediatric Unit for Sick Children at Necker Hospital.

  A - Axillary temperature
  B - Rectal temperature
  C - Oral temperature
  D - Tympanic / Auricular temperature

Synthesis

o Studies linked to the various sites for temperature taking show that the rectal measurement site is the most correlated to the site of the pulmonary artery, while extremely important discrepancies can be found at the axillary, oral or tympanic sites.

A. Axillary Temperature

- The validity of the axillary measurement is controversial. A mandatory condition for reliability is the need to leave the thermometer in place for at least 10 minutes, a duration which in practice is never observed. It is also the site of measurement that is most influenced by the outside temperature, for instance, in very thin subjects whose armpit occlusion is not possible, and vice versa for obese subjects because of their adipose tissues.

- This explains its bad correlation to the rectal site with differences that can approach 1°C and exposes it to the risk of false negative [8-11]. The values obtained are lower than in other measurement sites and in practice we add 0.5°C so it can be comparable to the rectal temperature. In his comparative meta-analysis of the rectal site, Craig shows an average difference of 0.92°C with the child but only 0.17°C with the newborn.

- This could be due to a more rigorous measurement in Neonatology services [11].

B. Rectal Temperature

- It is the measurement site where the body shows the highest temperature. As in the intragastric digestive tract, it is superior by 0.2°C to the temperature of the blood in the pulmonary artery of apyretic subjects [12]. This could be caused by local thermogenesis and by important variations of local blood flow that can lead to variations in rectal temperature of more than 0.5°C [13].

- The main drawback is its thermal inertia due to the fact that the rectum is a body filled with air and eventually with materials, resulting in a delay of balancing with differences of up to 2.4°C with the temperature of the pulmonary artery at the time of the variations of temperature [14]. During a state of shock, the collapse of the rectal blood flow is accompanied by a certain degree of exclusion and, in certain observations; the difference could reach close to 3°C (38°7 at the rectum and 41°6 in the pulmonary artery) [15].

- In addition, the rectum reflects central temperature changes with a delay of 30 to 45 minutes due to its distance from the thermo regulatory centre.

- For a precise measurement, certain conditions must be observed. The temperature is only stable when measured at more than 8 cm from the anal margin.

- With a position of the probe usually between 1 and 2.5 cm from the anal margin, the temperature can vary from 0.8°C depending on the position of the thermometer and, in this case, a temperature measurement is more anal than rectal [16]. The minimum duration of taking temperature must be 3 minutes.

- The few studies made on time measurement show that rectal temperature only stabilizes after 9 minutes in apyretic patients and 6 minutes among those who are febrile [17].

C. Oral Temperature

- The mouth is the most easily accessible site of measurement. However, oral temperature can only be performed in a compliant child because of the potential risk of inhaling the device.

- The values obtained are 0.1 to 0.4°C lower than the measures made in the oesophagus, aorta or rectum [12, 18]. In practice, we add 0.5°C to have a measurement comparative to the rectum. Its measurement calls for a rigorous methodology: a thermometer probe in sublingual and posterolateral position at the frenum, touching the lingual artery, lips closed to avoid exchanges with the exterior for 1 minute. Despite these precautions, this mode of measure is open to many possibilities of measurement error.

- The oral temperature is heterogeneous with thermal pockets situated between the deep lingual artery and the sublingual artery, which explains decreases of 1°C at 0.5 cm from the ideal point of measurement located at the contact with the sublingual artery [19].

- The oral temperature is modified by the ambient temperature through the air inhaled and modification of the internal carotid artery temperature [20].

- It also varies according to respiratory frequency and the ingestion of hot or cold beverages and the subsequent return to the original temperature several dozens of minutes later [21].

- The result is an underestimation of febrile states that covers up to 15% of all cases, meaning around 1 out of 6 subjects are diagnosed as non-febrile, whereas in reality his rectal temperature reaches more than 38°C [22].

D. Tympanic / Auricular Temperature

- Temperature measurement at the eardrum site is an excellent reflection of the central temperature because the eardrum shares the same vascularisation as the hypothalamus [7, 23].

- The variations are as fast as at the regulatory centre level. The measurement in one second allows its use with people who are sleeping, sedated, or just not cooperative. For an optimum measurement, the thermometer probe should be placed in a direct position in relation to the eardrum membrane, that is, ideally, the probe has a right angle "view" of the eardrum membrane through a wide auditory external duct [19]. But these conditions are subject to many anatomical variations, the angle of the auditory external duct relative to the eardrum averaging 60° (Figure 2) [24].

- In the newborn, this angle is extremely acute and a relatively open aspect is reached at around 7 - 9 months. These anatomical variations seem to explain why this measurement is only loosely correlated to the temperature measured in the pulmonary artery.

Choice of Thermometers

- Thermometers currently available are: the liquid crystal thermometer, the chemical thermometer, and especially the electronic thermometer and the infrared thermometer.

    1. The liquid crystal thermometer
    2. The phase change or dot matrix thermometer
    3. The electronic thermometer
    4. The infrared tympanic thermometer
    5. The gallium thermometer

- Analysis of related literature shows that temperature measurement remains the most faithful reflection of body temperature.

- The axillary site, due to constraints of the conditions of measurement, is exposed to false positives with differences that can approach 1°C as well as to the risk of false negatives.

Synthesis

- Analysis of related literature shows that temperature measurement remains the most faithful reflection of the body temperature.

- The axillary site, due to constraints of the conditions of measurement, is exposed to false positives with differences that can approach 1°C as well as to the risk of false negatives.

- The oral site imposes a rigorous method of taking temperature and is subject to many variables, leading to an underestimation of febrile states that can cover up to 15% of all cases.

- In the child, the ease of handling the tympanic thermometer and its short time measurement are incentives to use it for the detection of febrile conditions, but a lot of data in the literature show that the temperature measurement by infrared tympanic thermometer can be vague, especially when the child is less than 3 years old.

Context of the Present Study

- 10 months of clinical study on the **Thermo*Flash*®** equipped with the V.4 version of "**M**icro-**S**econd **F**lash **T**echnology" software made between August 2007 and May 2008.

- Studies, carried out at the reception of Paediatric Emergencies of the Louis-Mourier Hospital, a member of the **APHP** Group, supervised by the Head of the Paediatric Emergencies Unit, Professor M.P Jaby-Sergent.

- A team of 22 nurses and nurses' aides independently and systematically took the temperatures of all children under 6 months (temporal and/or auricular and/or axillary and/or rectal).

New Technology for Taking Temperature - Thermo*Flash*®

Principle

- Each object, whether solid, liquid or gaseous, has the property of emitting energy by radiation, at intensity depending on its temperature. The infrared thermometer **Thermo*Flash*®** can therefore measure the temperature of a person by measuring the energy emitted.

- This becomes possible, thanks to the external temperature probe of the device, which analyses and records the ambient temperature non-stop. So, the moment the operator with a thermometer approaches the body and triggers the radiation sensor, the measurement is performed instantaneously by detection of the infrared heat emitted by arterial blood flow.

- The result of this measurement of the body temperature is then obtained without interference from the surrounding temperature.

Benefits of Taking Temperature with Thermo*Flash*®

- This type of temperature measurement undeniably benefits the child. In a child of less than 6 months, all the traditional modes of taking temperature have their disadvantages either with regard to the accuracy and reproducibility of the measurement, or with regard to ergonomics.

- The axillary temperature is very controversial and difficult for a subject because the measurement protocol is delicate and must be followed rigorously. Oral temperature, in addition to the danger presented by the inhalation of the device, is deemed unreliable because of the many false-negatives.

- The auricular temperature of the newborn is impossible because the external ear duct presents an extremely acute angle that only acquires an appropriate configuration when the child is around 7-9 months.

- For an infant, we often come back to rectal temperature with an electronic thermometer but the follow-up of the fever is difficult.

- To repeat the measurement can be hurtful and can cause anusitis in the family; this can cause an obvious hygiene problem (especially in epidemics of gastroenteritis) when several members of the family use the thermometer.

- The hygiene problem can be solved by using adapted latex protection, but rigorously monitoring the development of a fever can give rise to a significant cost.

- Taking the temperature remotely with **Thermo*Flash*®** may therefore be given a privileged edge with a child under 6 months if it delivers sufficient qualities of accuracy, reproducibility and reliability.

- The use of **Thermo*Flash*®** allows rapid, non-invasive, remote and, if necessary, frequent measurements to ensure correct monitoring of the development of a temperature.

- The speed at which measurement is taken is particularly significant if the patient is a restless child.

- Taking the temperature remotely makes it also possible to measure the temperature of an infant without waking him up.

- The absence of contact eliminates all risks associated with taking temperature, be they risks of inhalation of the device on the oral site, perforation or anusitis on the rectal site or the transmission of germs among patients.

- The ergonomic aspect of the device can be useful for people with reduced mobility.

- Finally, **Thermo*Flash*®** can be integrated as an additional thermometer complementing another mode of temperature for sub-groups of patients.

  Example: In the case of a suspected ear infection in an emergency service that normally uses an auricular mode at reception

Study Conducted on Thermo*Flash*®

- This study was conducted in collaboration with the Louis-Mourier Hospital **A**ssistance **P**ublique des **H**ôpitaux de **P**aris (Paris Hospitals State Institution) on the one hand, and with a team of doctors in statistics to process the data collected, on the other.

- This study aims to evaluate the accuracy (effectiveness / specificity) and the reproducibility of the temperature taken with **Thermo*Flash*®**.

Temperature Collection Protocol at Louis-Mourier Hospital APHP

- This study was performed at the Louis-Mourier Hospital Assistance Publique des Hôpitaux de Paris at the Paediatric Emergency Unit of Dr. Jaby Sergent, Head of the Paediatric Emergency Unit, which has been overseeing the present study.

- A team of 22 nurses and nurses' aides took the temperatures of children aged less than 6 months between August 2007 and February 2008. These temperatures were taken at the rectal level, on the one hand, in order to constitute a valid reference, and with **Thermo*Flash*®** at the temporal artery level, right and left, on the other hand, in accordance with the precautions described.

- For children aged 0 to 15, the nurses were instructed to compare the **Thermo*Flash*®** temperatures to the axillary and auricular temperatures.

- This other set of data has been processed independently from the very first one, as the following statistical study will describe.

- The nurses in charge of taking the temperatures were also informed of the precautions to take in order to avoid overestimation or underestimation of temporal temperatures, in accordance with instructions given by the manufacturer, as will be mentioned later:

- Errors that may lead to an **overestimation** of the temporal temperature:

  - The intended skin surface may be exposed to an external heat source (incubator, phototherapy, etc…).

  - Taking the temperature without allowing the **Thermo*Flash*®** to remain at room temperature for 10 minutes (in fact, the principle of infrared temperature is a differential measure between room temperature and body heat).

- The device is subject to an ambient temperature lower than the room temperature where it will be used.

o Errors that may lead to an **underestimation** of the temporal temperature:

- The intended skin surface may be exposed to an external cold source (cold towel on the front, sweat).
- The device is subject to an ambient temperature higher than the room temperature where it will be used.
- The distance between skin and device is too large (> 10 cm).

Sampling Panel

o More than 800 patient data collected.

o Subjects aged between 0 months and 6 months.

o Subjects aged between 6 months and 15 years.

Results and Statistical Study

o Taking the temperature with **Thermo*Flash*®** is supposed to be done with scrupulous attention to the instructions in the notice and in this chapter, the "fever" condition is declared for a rectal temperature strictly over 37.8°C.

o The present statistical study comes in 4 parts:

1. Evaluation of variability of temporal temperature between two consecutive measurements taken on the same subject. For this study, we have 129 left/right temporal temperature observations taken consecutively on the same subject. The study will show that left and right temporal temperatures with **Thermo*Flash*®** are on the average equal and their difference does not exceed 0.9°C in absolute value.

   Left and right temporal temperatures with Thermo*Flash*® is on the average equal.

2. Assessment of similarity between rectal and temporal temperature. For this study, we had 103 observations of rectal and temporal temperatures taken consecutively on the same subject (infant between 0 and 6 months).

   The study will show that temporal temperature with **Thermo*Flash*®** underestimates the globally rectal temperature by approximately 0.2°C. Furthermore, the higher the rectal temperature, the more the temporal temperature measured with **Thermo*Flash*®** is undervalued.

   Thermo*Flash*® globally underestimates the rectal temperature by approximately 0.2°C.

3. Assessment of sensitivity and specificity of temporal temperature measured with **Thermo*Flash*®** in relation to rectal temperature. For this study, we have 103 observations of rectal and temporal temperatures taken consecutively on the same subject (infant between 0 and 6 months).

   The study will show that if **Thermo*Flash*®** indicates a temperature strictly higher than 37.6°C, then the user has a 92% chance of being right in diagnosing a fever condition. If the temperature indicated is lower than or equal to 37.6°C, then he has a 91% chance of correctly diagnosing a non-fever condition.

   Sensitivity = 92% and Specificity = 91%

4. Comparison between temporal temperature with **Thermo*Flash*®** and 2 types of temperatures modes frequently used in hospital: axillary temperature and auricular temperature. For this study, we have 134 observations of axillary and temporal temperatures taken consecutively on the same subject as well as 383 observations of auricular and temporal temperatures taken consecutively on the same subject.

   The study will show a similar efficiency in temporal and auricular temperature measurement and a lower efficiency in axillary temperature compared to temporal temperature.

   Thermo*Flash*® Efficiency > Axillary t°
   Thermo*Flash*® Efficiency > Auricular t°

Analysis Carried Out and Available Data

1. Variability between two consecutive t° readings on the same subject

   - **129** observations of **left and right temporal t°** taken at 60 sec. interval on the same subject aged between 0 and 6 months

2. Comparison between **rectal t° and temporal t°**

   - **103** observations of **rectal t° and temporal t°** taken consecutively on the same subject aged between 0 and 6 months

3. Sensitivity / specificity of **Thermo*Flash*®** compared to **rectal t°**

   - **103** observations of **rectal t° and temporal t°** taken consecutively on the same subject aged between 0 and 6 months

4. Comparison between **axillary t° and temporal t°**

   - **134** observations of **axillary t° and temporal t°** taken consecutively on the same subject aged between 0 and 6 months

5. Comparison between **auricular t° and temporal t°**

   - **383** observations of **auricular t° and temporal t°** taken consecutively on the same subject aged between 0 and 6 months

6. Sensitivity / specificity of **Thermo*Flash*®** in relation to **rectal t°**

    - **103** observations of **rectal t° and temporal t°** taken consecutively on the same subject aged between 0 and 6 months

Variability in Left and Right Temporal Temperature and Results (1)

o Test of normality of difference;
(Kolmogorov-Smirnov test) (p-value < 0.05)

- Between left and right temporal t° - Normality rejected

o Test of comparing the difference between t° to 0;
(Wilcoxon non- parametric test for paired samples)

- Acceptance of assumption of equality of the average difference to 0 to alpha risk = 5%

	N	Average	Minimum	Maximum	Statistics of signed ranks	p-value
Tg - td	129	0.007	-0.9	0.7	103.5	0.68

o **Intermediate result (1)**

Variability between left and right temporal t° is negligible.

o **Conclusion (1)**

Temperatures taken with **Thermo*Flash*®** are equal on the average and their difference does not exceed 0.9°C in absolute value.

Correspondence between Temporal and Rectal Temperature

o Study of the correspondence between

- Left temporal t° and rectal t°
- Right temporal t° and rectal t°

o Study of the correspondence

- Global comparison
- Comparison of temperature based on 5 classes:

  {36 ≤ t° < 37}
  {37 ≤ t° < 38}
  {38 ≤ t° < 39}
  {39 ≤ t° < 40}
  {40 ≤ t° < 41}

Global Comparison

o Test of normality of difference;
(Kolmogorov-Smirnov Test) (p-value < 0.05)

- Between left temporal t° and rectal t° - normality accepted
- Between right temporal t° and rectal t° - normality accepted

o Test of comparing the difference between t° to 0;
(Student Test for paired samples)

- Rejection of assumption of equality of differences tr – tf to 0, for f = d and g (p-value < 0.0001)

Left temporal t° - rectal t° = -0.20°C
Right temporal t° - rectal t° = -0.21°C

Comparison by Class

o Average difference between **left temporal t° and rectal t°** by class of temperature

- {36 ≤ t° < 37} **left temporal t° - rectal t° = -0.14°C**
- {37 ≤ t° < 38} **left temporal t° - rectal t° = -0.28°C**
- {38 ≤ t° < 39} **left temporal t° - rectal t° = -0.34°C**
- {39 ≤ t° < 40} **left temporal t° - rectal t° = -0.63°C**

o Average difference between **right temporal t° and rectal t°** by class of temperature

- {36 ≤ t° < 37} **right temporal t° - rectal t° = -0.07°C**
- {37 ≤ t° < 38} **right temporal t° - rectal t° = -0.25°C**
- {38 ≤ t° < 39} **right temporal t° - rectal t° = -0.42°C**
- {39 ≤ t° < 40} **right temporal t° - rectal t° = -0.56°C**

o For a class with a number too low, the Wilcoxon Test has been applied to classes {39 ≤ t° < 40} and {40 ≤ t° < 41} regrouped together.

Overall Comparison and Results (2)

o **Intermediate result (2)**

The average difference between left temporal t° (right temporal t°) and rectal t° is 0.20°C (0.21°C).

o **Conclusion (2)**

The temperature of **Thermo*Flash*®** globally underestimates the rectal temperature by 0.2°C.

Comparison by Class and Results (3)

- **Intermediate result (3)**

  The results show that for temperatures lower than or equal to 37°C on the average, there is no significant difference between rectal and temporal temperatures.

  However, for higher temperatures classes, the average of the difference between rectal and temporal temperatures is significantly different from 0 and increases as temperature increases.

- **Conclusion (3)**

  The higher the rectal temperature, the more the temporal temperature measured is undervalued.

Sensitivity and Specificity of Thermo*Flash*® for Fever Detection

- The objective of this analysis is to define the threshold **s** of the temperature situated between 36°C and 41°C, for which **Thermo*Flash*®** diagnoses a fever or non–fever condition.
- Let us recall that a fever is declared when the rectal temperature is strictly higher than 37.8°C.
- We must therefore define a threshold of temperature for which the best compromise between sensitivity and specificity is established.
- To determine the value of **Thermo*Flash*®** diagnostic, we use three indicators in this section:
  - Sensitivity
  - Specificity
  - ROC curve
- Let's set **tf** (temporal) and **tr** (rectal) as the temperature of an individual at a moment **t**.
  - If tr > 37.8°C, the subject is considered as febrile, and we can establish the indicative variable tr' defined by:
    - tr'(37.8°C) = 1 if tr > 37.8°C and tr'(37.8°C) = 0 if tr ≤ 37.8°C
- Also, if tf > s, the subject is considered febrile by **Thermo*Flash*®** and we can establish the indicative variable tf ' defined by:
  - tf'(s) = 1 if tf ≥ s and tf'(s) = 0 if ts < s
- Definition of Sensitivity **Se**
  - The sensitivity **Se(s)** of **Thermo*Flash*®** for the threshold **s** is the probability to diagnose a subject as febrile following the measurement of his temperature by **Thermo*Flash*®**, knowing that he is diagnosed as febrile following the measurement of his rectal temperature.

    Example
    Se(s) = P (tf > s / tr > 37.8) = P (tf'(s) = 1 / tr'(37.8) = 1)

- Definition of Specificity **Sp**

  - The specificity **Sp(s)** of **Thermo*Flash*®** for the threshold **s** is the probability to diagnose a subject as non-febrile following the measurement of his temperature by **Thermo*Flash*®**, knowing that he is diagnosed as non-febrile following the measurement of his rectal temperature.

    Example
    Sp(s) = P (tf < s / tr ≤ 37.8) = P (tf'(s) = 0 / tr'(37.8) = 0)

Comparison of Axillary, Auricular and Temporal Temperatures

Objective

- We intend here to compare the efficiency of temporal temperature with **Thermo*Flash*®**, to two other types of temperature measurement, commonly used in hospitals: auricular temperature and axillary temperature.

- Comparison of **axillary t° and temporal t°**

  - We have **134** temperature measurements taken consecutively on the same subject.

- Comparison of **auricular t° and temporal t°**

  - We have **383** temperature measurements taken consecutively on the same subject.

Sensitivity and Specificity of the Three Modes of Taking Temperature and Results (4)

- The Bayesian Approach

  The methodology used, published recently in the scientific literature is still being researched. It is based on the Bayesian Approach.

- The consecutive measurements of **axillary t° and temporal t°** and of **auricular t° and temporal t°** were made on a number of different subjects (**134** and **383** subjects respectively), but belonging to the same population, where the prevalent status of body fever, set at 37.8°C (unobserved directly) is assumed to equal to **P**, of unknown value.

- Given **Se**t (t = temporal), **Se**ax (ax = axillary), **Se**aur (aur = auricular), the sensitivities of the three types of temperature measurement and **Sp**t, **Sp**ax and **Sp**aur, their specificity.

- It is possible to establish inferences on these values by using the Bayesian Approach, as proposed in Joseph *et al* (reference).

- The basic idea of this approach is to create a statistical model linking the data to the parameters that must be estimated and for which *a priori* information is provided.

- This method, adapted to the case of three independent tests and a single prevalence allows the comparison of the efficiency of the three types of measure.

o The data are summarized in two contingency tables 2x2, dealing with the numbers of modalities (0 and 1) of variables **t**f' and **t**ax' (Table 5) and those of variables **t**f' and **t**aur' (Table 6).

Table 5

		tax'	
		0	1
tf'	0	88	7
	1	10	29

Table 6

		taur'	
		0	1
tf'	0	270	19
	1	15	79

Table 5: Results of **axillary t° and temporal t°** for 134 subjects
Table 6: Results of **auricular t° and temporal t°** for 383 subjects

o Estimate of sensitivity and specificity of the three types of temperature measurement

Parameters	Average	Confidence interval at 95%
P	25.9%	[20.9% 31.2%]
Set	89.8%	[78.6% 99.4%]
Spt	96.7%	[92.9% 99.8%]
Seax	80.6%	[64.0% 96.6%]
Spax	94.0%	[87.7% 99.3%]
Seaur	90.7%	[79.6% 99.5%]
Spaur	96.3%	[92.1% 99.8%]

o The results show a similar efficiency in temporal and auricular temperature measurements and a lower efficiency in axillary temperature as compared to temporal temperature.

o Let's suppose fever detection of **temporal t°** > 37.4°C

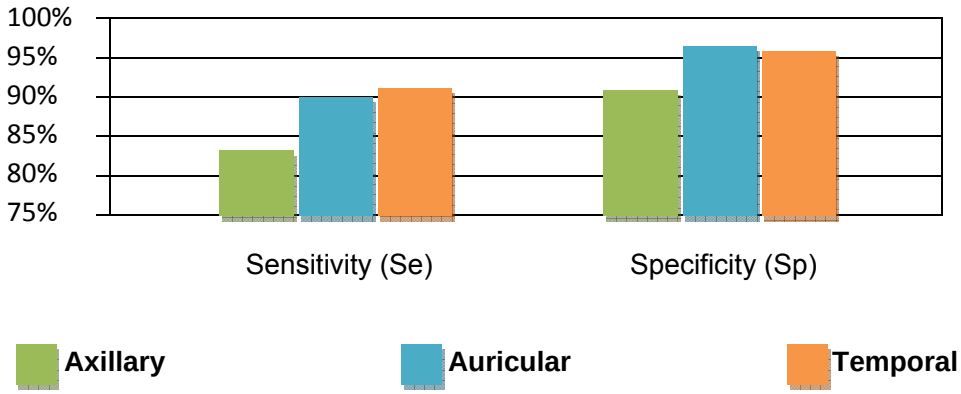
Sensitivity (Se) = 92%
Specificity (Sp) = 89%

o Sensitivity and specificity observed for **auricular t°** (bibliographic review)

57% < Sensitivity (Se) < 85%
31% < Specificity (Sp) < 94%

Sensitivity (Se) Thermo*Flash*® > Sensitivity (Se) auricular t°
Specificity (Sp) Thermo*Flash*® = Specificity (Sp) auricular t°

- Results of Sensitivity and Specificity data of the three modes of temperature



- **Intermediate result (4)**

  - **Auricular and Temporal temperatures**

    The results show that **ThermoFlash®** provides a higher sensitivity and a comparable specificity versus the auricular thermometer.

  - **Axillary and Temporal temperatures**

    The results show that **ThermoFlash®** provides a higher sensitivity and specificity versus the axillary thermometer.

- **Conclusion (4)**

  The confidence index can be granted as far as the use of **ThermoFlash®** is concerned, versus the auricular and axillary thermometer.

Conclusion by Dr. Stéphane ILLOUZE

- **Thermo*Flash*®** seemed to me an attractive device because of its ergonomics and the speed at which it can measure temperature, but no scientific study had so far put its validity to the test.

- This study provides some elements of answers which could be further refined if we multiply the cases. With the data at our disposal, we are in a position to reach the following conclusions:

    1. Left and right temporal temperatures with **Thermo*Flash*®** are equivalent on the average. Thus, the person who takes the temperature will not have to worry on which side the temperature has to be taken, which simplifies the act.

    2. The statistical study showed that temporal temperature with **Thermo*Flash*®** globally underestimates the rectal temperature by approximately 0.2°C. This can easily be corrected by suggesting to the manufacturer to recalibrate his device: the gap in the temperature on the device could be modified by systematically adding 0.2°C. However, a more refined analysis showed that the higher rectal temperature, the more the temporal temperature measured by **Thermo*Flash*®** is undervalued. Thus, calibration could also be more subtly adjusted, by using a mathematical function to calculate the value to be displayed.

    3. The clinical study showed, using the rectal temperature as the reference temperature, that **Thermo*Flash*®** had sensitivity equal to 92% and specificity equal to 91%.

    4. The **Thermo*Flash*®** device offers a higher sensitivity and an equivalent specificity than the auricular thermometer, and a better sensitivity and specificity than that of the axillary thermometer.

    5. Finally, and in a more general way, a satisfaction survey with the 22 nurses and nurses' aides of the Louis-Mourier Hospital who contributed to the study has shown that its use was fast and very satisfactory, even though **Thermo*Flash*®** displayed certain weaknesses in the case of intensive use, and the door of the batteries case show a certain fragility when the device is dropped.

- Points 2 and 5 have been taken into account by the manufacturer of **Thermo*Flash*®**, who will very soon propose a new product, more adapted to hospital needs;

Thermo*Flash*® << Pro LX-261 >>

- The **Thermo*Flash*® Pro LX-261** would present the same benefits as the **Thermo*Flash*® LX-26**, but with an increased sensitivity and specificity, and a better sturdiness in order to withstand more intensive use.

- This new device will be the subject of a future study from June 2008 to September 2008.