

Accuracy Study for the Welch Allyn®
Model 692/690 SureTemp® Plus
Paediatric Axillary Thermometer



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Summary:

Clinical accuracy studies were performed using the SureTemp® Plus in the pediatric axillary mode (17 years and younger). One hundred ten temperature measurements were obtained from over 6 clinical sites. Sixteen percent of the data represent newborns ranging in age from just hours to 3 days old. Thirty percent of the data (excluding the newborns) represent fevers. Temperatures ranged from 35.88° C to 39.66° C. Subjects ranged in age from newborn to 16 years. Excluding newborns, an equal number of axillary data sets were collected from three age groups: one month to 4 years, 5 years to 10 years, and 11 years to 17 years. The average error was -0.044° C with a Standard Deviation of 0.185° C (Table1).

Definitions :

Monitor Mode Temperature: Monitor mode is a function of an electronic thermometer used to monitor a temperature reading until it reaches the thermal steady state. The thermal steady state for oral and rectal temperatures is reached in approximately three minutes. The thermal steady state for axillary temperatures is reached in approximately five minutes.

Predicted Temperatures: Predicted temperatures are from any thermometer that renders a temperature reading before the steady state is achieved. Predictive thermometers reduce the time required for measurement by predicting what the temperature would be if the probe were left in the site until steady state is reached..

Fever: For the purposes of this study, fever is defined as any temperature equal to or greater than 37.77° C.

Data Set: A data set is defined as a predicted temperature followed by a three-minute (oral and rectal) or a five-minute (axillary) monitor mode reference temperature.

Overview:

Normal body temperature in a healthy child is a range that fluctuates throughout the day. Body temperature can vary as much as 0.5° C to 1.0° C over a twenty-four hour period. Body temperature is lowest in the morning (2-4 am) while resting, and warmest in the afternoon (4-6 pm) while active. Body temperature is regulated by the hypothalamus, which continually adjusts temperature to stay within a set range of normal in the absence of illness (Table 2). Fever is defined as a temperature above an individual's range of normal.

Fever has always been recognized as an indication of illness. Today, in every clinical setting, the primary purpose for taking a patient's temperature is to screen for fever and to follow its course. Timely, accurate temperature measurement has always been an essential part of patient assessment.

Thermometer technology has changed over recent years. Temperature taking is FAST and clinicians must rely on a thermometer's accuracy to make important and informed decisions for patient care.

The purpose of this clinical paper is to summarize the studies performed to demonstrate the accuracy of the Welch Allyn® SureTemp Plus thermometer in Pediatric Axillary Mode.

Materials and Methods:

Six critical care nurses, trained on the use of the SureTempPlus, collected the data. All thermometers and probes were tested for accuracy before and after the study in a stirred water bath at three different temperatures as per ASTM testing standards.

One hundred ten data sets were collected. Sixteen percent of the data represent newborns. Thirty percent of the data (excluding the newborns) represent fevers. For each subject, an initial axillary temperature was taken in the predict mode. Once the temperature was recorded, the probe was left in place and the thermometer was switched to the monitor mode for five minutes to establish a reference temperature. A direct comparison was then made between each predicted temperature and the corresponding reference temperature.

Data Analysis:

Data were analyzed by comparing each subject's predicted temperature to the corresponding five-minute monitor mode reference temperature.

Results:

Newborn Data

Axillary temperatures ranged from 35.88° C to 37.38° C. The total number of data sets were twenty. Subjects ranged from 1 hour to 3 days old. The average error was 0.044° C with a Standard Deviation of 0.199° C.

**Paediatric Axillary Data
(17 years and younger, excluding newborns)**

Axillary temperatures ranged from 36.16° C to 39.66° C. The total number of data sets were 90, with 27 of those being febrile. Subjects ranged in age from 1 month to 16 years. An equal number of axillary data sets were collected from three age groups: one month to 4 years, 5 years to 10 years, and 11 years to 17 years. The average error was -- 0.055° C with a Standard Deviation of 0.175° C.

Conclusion:

These data show excellent correlation and no clinically significant differences between the five-minute monitor mode reference temperatures and the predicted axillary temperatures. Axillary temperatures in children are often preferred over other sites because of safety, hygiene, and simplicity. With the proven accuracy and speed of the SureTemp Plus in the paediatric axillary mode, clinicians can utilize the axillary site on all ages of paediatric patients with confidence.

**SureTemp® Plus Monitor Mode
Temperature vs. Predicted Temperature
Paediatric Axillary Mode**

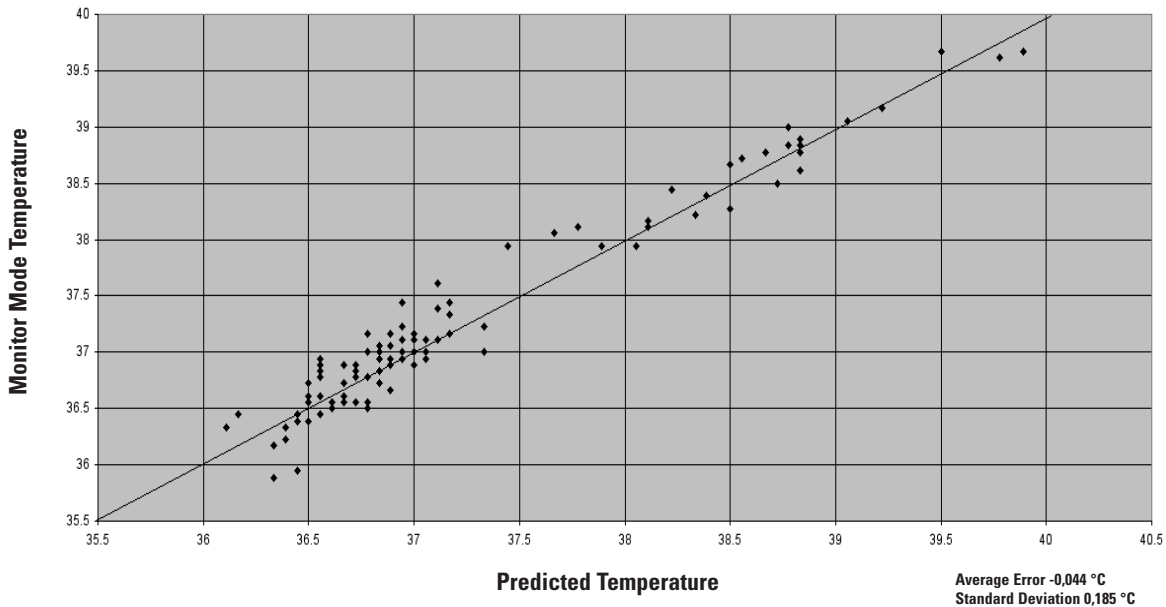


Table 1

Normal Body Temperature Ranges

°C	0 - 2 years	3 - 10 years	11 - 65 years	> 65 years
Oral	—	35,5 — 37,5	36,4 — 37,5	35,8 — 37,0
Rectal	36,6 — 38,0	36,6 — 38,0	37,0 — 38,1	36,1 — 37,3
Axillary	34,7 — 37,3	35,9 — 36,7	35,2 — 36,9	35,5 — 36,3
Ear	36,4 — 38,0	36,1 — 37,8	35,9 — 37,6	35,8 — 37,5
Core	36,4 — 37,8	36,4 — 37,8	36,8 — 37,9	35,9 — 37,1

Table 2

Normal body temperature is a range. This table shows that normal temperatures vary by site. Therefore, readings from different sites, even if taken at the same time, should not be directly compared.

References

- Chamberlain, J. & Terndrup, T., et. al.; "Determination of Normal Ear Temperature Using an Infrared Emission Detection Thermometer"; *Annals of Emergency Medicine*; January, 1995.
- Braun, S., Preston, P., and Smith, R.; "Getting a Better Read on Thermometry"; *RN Magazine*; March, 1998.
- "Temperature Measurement in Paediatrics"; *Paediatric Child Health* Vol 5 No 5; July / August, 2000.
- Brunner, L. and Suddarth, D., et. al.; *The Lippincott Manual of Nursing Practice*; 1982; p.1145.
- Erickson, R., *Temperature Taking Sourcebook*, IVAC Corporation, San Diego, CA, 1993.
- Houdas, Y., et. al.; *Human Body Temperature, Its Measurement and Regulation*; 1982; p.81-87.
- American Medical Association's International Classification of Diseases 9th Revision Clinical Modification*; Physician ICD-9-CM, 2003 Volumes 1 and 2; Ingenix, Inc., July, 2002; p.6.