

FORA[®] FocusTemp Forehead Thermometer

System Performance Summary

Based on ISO 80601-2-56, ASTM E1965-98, and EN 12470-5 standards



Table of Contents

FORA® FocusTemp Forehead Thermometer	1
Introduction	1
Objective	1
Main Features	2
Product Specifications	3
Laboratory Accuracy Evaluation – ForaCare Laboratory	4
Clinical Accuracy Evaluation – ForaCare Laboratory	6
Clinical Bias	7
Clinical Repeatability	8
Summary	10
References	11

FORA® FocusTemp Forehead Thermometer

Introduction

FORA® FocusTemp is the name of a new non-contact infrared thermometer that was **Designed for Professional & Home Use**. The thermometer counts with various features that make it unique, such as a color-coded screen for quick fever alerts and three measuring modes, including Adult, Child, and Surface.

This innovative medical device uses advanced infrared (IR) technology to measure body temperatures instantly and accurately from the forehead, or any surface area. It delivers a body temperature reading from the thermal radiation emitted from the forehead without any body contact (**3 to 7 cm distance**) within **1 second**. Contactless measurements are especially useful in reducing the risk of cross-infection.

Objective

This document was created to evaluate the system accuracy and reliability of FORA® FocusTemp according to clinical and laboratory standards. The goal is to demonstrate the excellent performance of this infrared forehead thermometer when referring to ISO 80601-2-56^[1], ASTM E1965-98^[2], and EN 12470-5^[3] standards.

Main Features

The FORA® FocusTemp comes with a series of features that have been designed to facilitate and improve user experience.



Non-Contact Design

Non-invasive thermometers reduce cross-infection risks.



Accurate results in 1 sec

The thermometer only takes 1 second to take a measurement.



One-Touch Measurement

Easy to use. It can take temperature measurements with a single click.



Fever Alert

Quickly alerts fever with color-coded screen and acoustic beeps.



Surface Temperature

Useful when measuring temperatures of surface and ambient.



Automatic Switch-Off

Meter will automatically switch off after 30 seconds from the last measurement.



30 Memory Capacity

Useful for users to track temperature fluctuations over time.



At least 3000 tests

Patients and healthcare professionals will not need to often replace batteries.

Product Specifications

Table 1 – FORA® FocusTemp Specifications

FORA® FocusTemp Specifications	
Model No.	FORA IR42
Resolution	0.1°C
Temperature Mode	Adult / Child / Surface
Forehead Measurement Range	32°C to 43°C
Surface/Ambient Measurement Range	0°C to 100°C
Temperature Unit	°C
Measurement distance	Adult and Child mode: 3 to 7 cm Surface mode: 5 cm
Memory Capacity	30 measurements
Acoustic	Normal temp range: two short beep Fever: one long and three short beep
Backlight	Normal temp range: Green Fever range: Red
Dimension	155.46(L) x 40.14(W) x 39.45(H) mm
Weight	61.8 (without battery)



Laboratory Accuracy Evaluation – ForaCare Laboratory

The study was conducted by ForaCare Laboratory with Project No. FC03-0005904^[4] to assess the accuracy evaluation of FORA® FocusTemp.

Objective

To assess the laboratory accuracy of FORA® FocusTemp Forehead thermometer under the reference conditions specified in ASTM E 1965-98 and EN-12470-5 standards.

Method

Three blackbody temperatures (Table I) were measured by thermometers equilibrated at eight different ambient temperatures and humidity conditions (Table II). Each black body was measured 6 times, for each ambient condition, for a total sample size of 144 measurements.

Table 2 – Blackbody temperature sets

Types of thermometers	Blackbody temperature sets
Forehead thermometer	35.0°C (95.0°F)
	37.0°C (98.6°F)
	42.0°C (107.6°F)

Table 3 - Test Ambient Temperatures and Humidity Conditions

Condition	Operating temperature	Relative humidity (%)
A	16 - 18 °C, (60 - 65°F)	Less than 50
B	16 - 18 °C, (60 - 65°F)	80 - 85
C	16 - 18 °C, (60 - 65°F)	90 - 95
D	24 - 26 °C, (75 - 80°F)	40 - 60
E	33 - 35 °C, (100 - 104°F)	Less than 25
F	38 - 42 °C, (100 - 107°F)	Less than 25
G	33 - 35 °C, (100 - 104°F)	80 - 85
H	38 - 42 °C, (100 - 107°F)	75 - 85

Acceptance Criteria

Table 4 – Acceptance Criteria for Forehead Thermometer

Blackbody temperature sets	Acceptance criteria
35°C (95.0°F)	0.3°C (0.5°F)
37°C (98.6°F)	0.2°C (0.4°F)
42°C (107.6°F)	0.2°C (0.4°F)

Results

Table 5 – FORA® FocusTemp Maximum Laboratory Bias at Three Blackbodies

Black body temperature sets	The pooled maximum calculated bias
35°C (95.0°F)	0.2°C (0.4°F)
37°C (98.6°F)	0.2°C (0.4°F)
42°C (107.6°F)	0.2°C (0.4°F)

Conclusion

In the blackbody tests, bias analysis was calculated and demonstrated that the laboratory accuracy of FORA® FocusTemp is in accordance with the referenced international standard requirements.

The pooled maximum calculated bias between the measured results of FORA® FocusTemp and the blackbodies shows that its results were all within the acceptance criteria range.

Clinical Accuracy Evaluation – ForaCare Laboratory

The study was conducted by ForaCare Laboratory with Project No. FC03-0005904 to assess the clinical accuracy (clinical bias and clinical repeatability) of FORA® FocusTemp.

Objective

To determine the clinical accuracy (clinical bias and clinical repeatability) of temperatures measured by FORA® FocusTemp forehead thermometer under the reference conditions specified in ISO 80601-2-56, ASTM E1965-98, and EN 12470-5 standards.

- Clinical Bias: evaluated by comparing with actual reference temperature from a selected number of febrile and afebrile subjects in different age groups.
- Clinical Repeatability: evaluate how consistent the measurements are when taking several readings from the same patient, under the same conditions.

Sample Selection

Thirty subjects were randomly selected from four different age groups. Each group contained ten febrile subjects and twenty afebrile subjects, for a total sample size of 120 subjects.

Table 6 – Subject age groups and numbers represented in febrile and afebrile conditions

Subject Groups	Age Groups	Febrile Subjects	Afebrile Subjects	Total
Infants	1 to 5 years	10	20	30
Children	5 to 12 years	10	20	30
Adolescents and adults	12 to 64 years	10	20	30
The elderly	64 to 75 years	10	20	30

Clinical Bias

Method

Oral temperature measurements were taken by the reference digital thermometer Model 678 of Welch Allyn Sure Temp Thermometer and compared to FORA® FocusTemp forehead measurements. The mean difference and standard deviation between each group's measurements determined the clinical bias.

Results

Figure 1 – Bland & Altman plots of accuracy biases of FORA® IR42

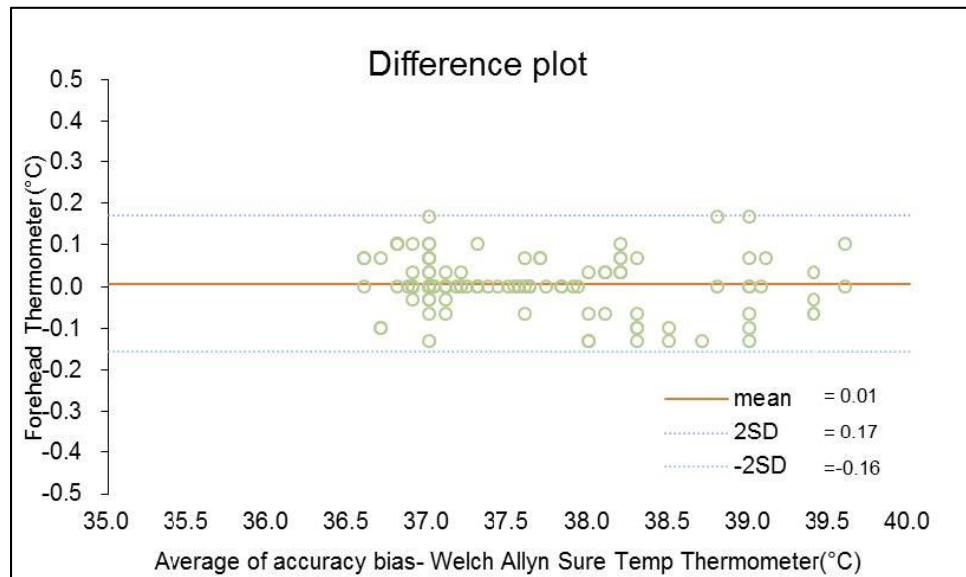


Table 7 – The pooled clinical bias and its standard deviation of FORA® IR42

Device	Sample Size	The pooled clinical bias	Bias + 1.96 SD	Bias – 1.96 SD	SD of the clinical bias
FORA IR42	120	0.01	0.17	-0.16	0.08

Conclusion

The variances obtained from FORA® FocusTemp were relatively small. The pooled clinical bias (0.01) and its standard deviation (0.08) of FORA® FocusTemp were also significantly small to represent accurate temperature readings when compared to the reference.

Clinical Repeatability

Method

Clinical repeatability was calculated by taking three sequential temperature measurements of the same subject under the same conditions. The pooled standard deviation determined the clinical repeatability.

Results

Table 8 – Statistics Analysis of forehead thermometers of febrile and afebrile subjects

	Febrile subjects	Afebrile subjects	Total
FORA® FocusTemp	(°C)	(°C)	(°C)
Number (withdraw subject)	40 (0)	80 (0)	120 (0)
Mean ± SD	38.58 ± 0.56	37.12 ± 0.32	37.61 ± 0.80
Minimum ~ Maximum	37.6 ~ 39.6	36.6 ~ 37.9	36.6 ~ 39.6
Median	38.4	37.0	37.3
Reference results			
Number (withdrawal subject)	40 (0)	80 (0)	120 (0)
Mean ± SD	38.58 ± 0.56	37.12 ± 0.33	37.60 ± 0.81
Minimum ~ Maximum	37.7 ~ 39.7	36.6 ~ 37.8	36.6 ~ 39.7
Median	38.4	37.0	37.3

Figure 2 – Box-and-Whisker of repeatability analysis of FORA® IR42

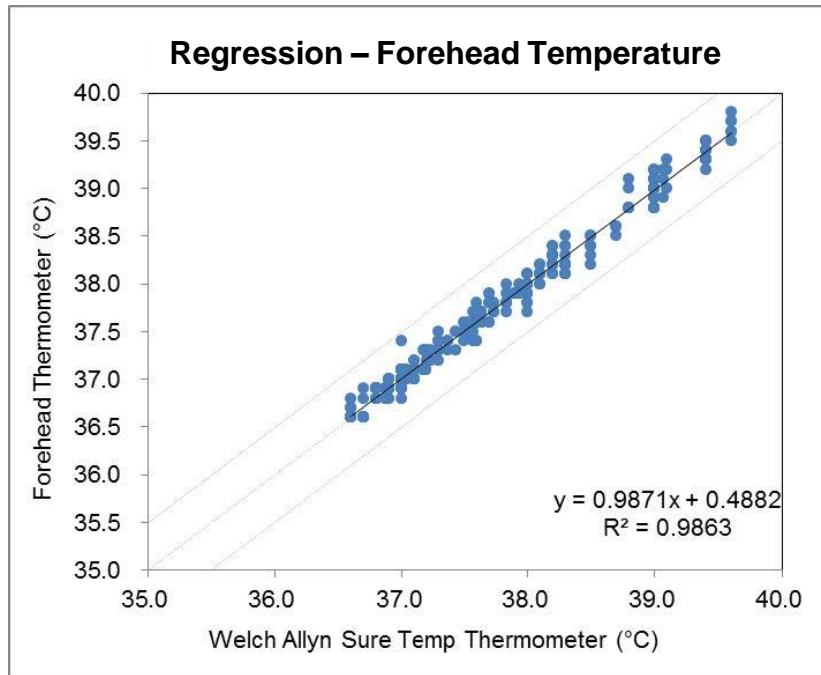


Table 9 – The pooled clinical repeatability of FORA® IR42

Device	n	Slope (95% CI)	Intercept (95% CI)	R ²
FORA IR42	120	0.9871 (0.9750 to 0.9992)	0.4882 (0.0334 to 0.9430)	0.9863

Conclusion

The data were analyzed and plotted using the Box-and-Whisker plots. The results show that measurements variability taken from FORA® FocusTemp were rationally small, and the pooled clinical repeatability is also considered to be logically small, having R² = 0.9863.

Summary

The results displayed throughout this report show that the system provides excellent measuring results for both laboratory accuracy evaluation and clinical accuracy evaluation. Based on its monitoring ability, FORA® FocusTemp is suitable for human body temperature assessment for professional care and home use.

In conclusion, the FORA® FocusTemp forehead thermometer (IR42) is not only an easy-to-use and feature-packed non-contact infrared thermometer, but also offers reliable measuring accuracy when referring to ISO 80601-2-56, ASTM E1965-98, and EN 12470-5 standards.

References

1. 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.
2. ASTM E 1965-98 Standard specification for infrared thermometers for intermittent determination of patient temperature. ASTM International, 2009.
3. EN 12470-5: 2003, Clinical Thermometers-Part 5: Performance of infra-red ear thermometers (with maximum device).
4. ForaCare Laboratory (2018). *Clinical Study Report for the Forehead Thermometer*. Document No. FC03-0005904.

ForaCare Suisse AG

Neugasse 55, 9000 St. Gallen, Switzerland

TEL: +41-71-220-1001 | FAX: +41-71-220-1075

URL: www.foracare.ch

E-mail: fcsmarketing@foracare.ch

