Clinical Accuracy of TRITEMP™ (non-contact infrared forehead thermometer)

EN ISO 80601-2-56:2017 and ASTM E1965-98:2016 are both FDA-recognised voluntary consensus standards used by device manufacturers to evaluate the performance of non-contact infrared thermometers by (i) testing the accuracy of the device against a standard blackbody source and (ii) performing a clinical study to evaluate the accuracy and the effectiveness of the device in clinical settings (*Sullivan et al., 2021*).

The CLINICAL ACCURACY of TRITEMP™ with REFERENCE CLINICAL THERMOMETERS widely used in hospitals was performed in accordance with the requirements of both EN ISO 80601-2-56 and ASTM E1965-98:2016.

TEST RESULTS

The results of CLINICAL ACCURACY VALIDATION are summarised in table below including the CLINICAL BIAS (Δcb), with its LIMITS OF AGREEMENT (LA) and the CLINICAL REPEATABILITY(σ_r).

	ISO 80601-2-56	ASTM E1965-98	
	All (n=771)	Paediatrics (n=253)	Adults (n=518)
CLINICAL BIAS (Δcb)	0.08˚C	0.03˚C	0.10˚C
LIMITS OF AGREEMENT (LA)	0.71˚C	0.55˚C	0.78˚C
CLINICAL REPEATABILITY(σ_r)	0.07˚C	0.09˚C	0.06˚C

Note: The reference body site was axilla and oral for paediatrics and adults, respectively.

CLINICAL BIAS (Δcb) – Mean difference between output temperatures of a clinical thermometer and a reference clinical thermometer for the intended reference body site with specified limits of agreement when measured from selected group of subjects.

LIMITS OF AGREEMENT (LA) – The magnitude of a potential disagreement between outputs of two clinical thermometers equal to double the standard deviation of output temperature differences when used on the same human subject.

CLINICAL REPEATABILITY (σ_r) – Pooled standard deviation (over a selected group of subjects) of changes in multiple output temperatures taken from the same subject at the same measuring site with the same clinical thermometer by the same operator within a relatively short time.

CONCLUSION

From the above results, it can be concluded that this product, a non-contact infrared forehead thermometer TRITEMP™, can be used for measuring body temperatures accurately within a clinical setting.

Clinical accuracy was validated in accordance with ISO 80601-2-56 on 771 subjects, adults and paediatrics, against a reference clinical thermometer for oral (adults) and axilla (paediatric) reference sites. Results found a clinical bias of 0.08˚C with limits of agreement of 0.71˚C and a clinical repeatability of 0.07˚C.

Clinical accuracy was validated in accordance with ASTM E1965-98 on 771 subjects, adults and paediatrics, against a reference clinical thermometer for oral (adults) and axilla (paediatric) reference sites. Results found a clinical bias of 0.10˚C with limits of agreement of 0.78˚C and a clinical repeatability of 0.06˚C for 518 oral (adult) measurements and a clinical bias of 0.03˚C with limits of agreement of 0.55˚C and a clinical repeatability of 0.09˚C for 253 axilla (paediatric) measurements.