

ISO 80601-2-56 Clinical Validation
Exergen TemporalScanner

Clause	Requirement + Test	Result - Remark	
201.102.2	Human subject population requirements		
	Total number of febrile subjects not less than 30 % and not greater than 50 % of all subjects in the selected age group	See Exhibit A.	
	CLINICAL ACCURACY VALIDATION carried out on all age groups indicated in the instructions for use.. :	See Exhibit A. Peer-reviewed published studies are included which validate accuracy in all areas of clinical care and all age groups from preterm to geriatrics.	
	Number of subjects in each age group is sufficiently large to minimize the effect of random components of measurement error (minimum of all groups is 105; minimum in age group is 35; minimum 15 subjects in A1 or A2 if subgroup A is not excluded):	See Exhibit A.	
	– age group A1 (0-3 months)..... :	20 patients 30% fevers	
	– age group A2 (3-12 months)..... :	69 patients 33% fevers	
	– age group B (>1 and <5 years)..... :	56 patients 50% fevers	
	– age group C (>5 years)..... :	152 patients 34% fevers	
201.102.3	Calculated CLINICAL BIAS for the OPERATING MODE being evaluated (Δ_{cb})	A1: VS. RECTAL: CLINICAL BIAS=0.02 A2: VS. RECTAL: CLINICAL BIAS=0.02 B: VS. RECTAL: CLINICAL BIAS=0.07 C: VS. ORAL: CLINICAL BIAS=0.52	
201.102.4	Calculated LIMITS OF AGREEMENT (L_A)..... :	A1: VS. RECTAL: LIMITS OF AGREEMENT=0.87 A2: VS. RECTAL: LIMITS OF AGREEMENT=1.15 B: VS. RECTAL: LIMITS OF AGREEMENT=1.07 C: VS. ORAL: LIMITS OF AGREEMENT=1.24	
201.102.5	Calculated CLINICAL REPEATABILITY for particular OPERATING MODE (σ_r)	CLINICAL REPEATABILITY: 0.13	
Exergen Comment	Clinical Bias and Limits of Agreement for any thermometer can only be interpreted as approximations due to reference site artifacts. For the most reliable assessment of clinical accuracy, peer-reviewed published studies should be consulted.		

Exhibit A

ISO 80601-2-56 Clinical Studies Tabulation for Clinical Bias, Limits of Agreement, and Clinical Repeatability (deg C)

Age group	Age range	Study Identification	Date	Patient type	Reference site	no. of patients	Fever %	Clinical Bias	Limits of Agreement
A1: 0-3mo	0-3mo	Children's pilot study	1999	Emergency Dept	Rectal	20	30%	0.02	0.87
A2: 3mo-1yr	3mo - 1 yr	Children's pilot study	1999	Emergency Dept	Rectal	69	33%	0.02	1.15
B: 1yr-5yr	1yr - 5yr	Children's pilot study	1999	Emergency Dept	Rectal	56	50%	0.07	1.07
C: >5yr	> 5yrs	Children's pilot study	1999	Emergency Dept	Oral	152	34%	0.52	1.24
Clinical Repeatability									
Clinical Repeatability	0 to >5yo	Children's pilot study	1999	Emergency Dept	Clinical Repeatability	603	49%		0.13

Peer-Reviewed Published Clinical Studies With Reported Clinical Bias, Limits of Agreement (deg C)

	Age range	Study Identification	Date	Patient type	Reference site	no. of patients	Fever %	Clinical Bias	Limits of Agreement
	Preterm	Lee	2011	Neonatal ICU	Rectal	34	None*	0.30	0.88
	0 - 3mo	Children's pilot study	1999	Emergency Dept	Rectal	74	18%	0.25	1.02
	0-24mos	Carr	2010	Inpatients	Rectal	450	30%	0.03	1.00
	<24mos	Schuh	2003/2004	Emergency Dept	Rectal	327	34%	0.19	1.13
	2yr-12yr	Batra	2013	Emergency Dept	Rectal	100	50%	0.02	0.58
	18yr to 86yr	Barringer	2011	Perianesthesia Care Unit	Oral	86	None*	0.15	1.18
	32yr to 81yr	Calonder	2010	Surgery	Esophageal	23	None*	0.07	0.39
	57yr ±14 yr	Langham	2009	Perianesthesia Care Unit	Bladder	50	None*	-0.23	0.98
	57yr ±15yr sd	Lawson	2007	Adult ICU	Pulmonary Artery	60	13%	0.02	0.90
	64yr ±26yr sd	Carleton	2012	Ambulance	Oral	69	3%	0.11	1.05
	60yr ±14.9yr sd	Myny	2005	ICU	Pulmonary Artery	57	21%	-0.14	1.00
	Mean 66yr	Carrol	2004	ICU	Pulmonary Artery	86	20%	-0.09	1.22

*No fevers, thermometers required for thermal management only in this patient population.

Measuring site is temporal artery. Device has only one operating mode.

Peer-Reviewed Published Papers, Abstracts, Letters on Exergen Temporal Artery Thermometry as of February 2014

Supporting Clinical Accuracy

1	Al-Mukhaizeem F, Allen U, Komar L, et al (University of Toronto/Hospital for Sick Children). Validation of the temporal artery thermometry by its comparison with the esophageal method in children. Pediatric Academic Societies Annual Meeting, May 3-6, 2003, Seattle, WA
2	Al-Mukhaizeem F, Allen U, Komar L, et al (University of Toronto/Hospital for Sick Children). Comparison of temporal artery, rectal and esophageal core temperatures in children: Results of a pilot study. Journal of Pediatric and Child Health, Vol 9, No 7, pp 461-465, 2004
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15	Carroll D, Finn C, Gill S, et al (Massachusetts General Hospital). A comparison of measurements from a temporal artery thermometer and a pulmonary artery catheter thermometer. Am J Crit Care. 2004;13:258.
16	Chiu SH, Anderson GC, Burkhammer MD (University of Akron/Case Western Reserve University). Newborn temperature during skin-to-skin breastfeeding in couples having breastfeeding difficulties. Birth. 2005 Jun;32(2):115-21.
17	Crossley B. Blanket warmers revisited and temporal thermometers. Biomedical Instrumentation and Technology, March/April 2012 p147.
18	Dybwik K, Nielsen EW. Infrared temporal temperature measurement. Journal of the Norwegian Medical Association 2003; 123: 3025-6.

19	Espenhein A (County Hospital in Herlev, Denmark). Temporal temperature measurement. <i>Sygeplejersken</i> 2006;(17):50-2.
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