Infrascanner Adult Clinical Data Summary Table

Study	Type	Patients (N)	Age (Range, AVG)	Method of Selection	NIRS	CT	ICH	Results
Robertson et al. (2010) (USA and India)	Multicenter study (4 centers in USA and 1 in India)	365	1-88, 36.7 years	Admitted to emergency room with TBI and were sent for a head CT	Model 1000 Evaluated within 40 minutes of CT	All patients received CT	50	• Sensitivity = 88% • Specificity = 90.7% • PPV = 63.6% • NPV = 97.7%
Leon-Carrion et al. (2010) (Spain)	Single center study	35	17-76, 47.6 years	Admitted to emergency room with TBI and were sent for a head CT	Model 1000 Evaluated within 0.5-14.5 hours of CT (5.7 hours avg)	All patients received CT	19	• Sensitivity = 89.5% • Specificity = 81.2% • PPV = 85% • NPV = 86.7%
Willy et al. (2014) (Germany)	Single center study in Kunduz, Afghanistan	11		Admitted to field emergency service with TBI	Model 1000 Evaluated	None of the patients received CT	0	• Specificity = 100% • NPV = 100%
Xu et al. (2017) (China)	Single center study in Beijing, China	85	8-89, 48.3 years	Admitted to Neuro ICU with TBI and were sent for a head CT	Model 2000 Evaluated within 40 minutes of CT	All patients received CT or MRI	45	• Sensitivity = 95.6% • Specificity = 92.5% • PPV = 93.5% • NPV = 94.9%
Tan et al. (2017) (Nederlands)	Helicopter pre-hospital study in Nederlands	25	7-79, 54 years	Picked up by helicopter with TBI and were sent for a head CT in a hospital	Model 2000 evaluated before or during flight in the helicopter	All patients received CT in a hospital	14	• Sensitivity = 93.3% • Specificity = 78.6%
Liang et al. (2018) (China)	Single center study in Beijing, China	102	9-86, 41 years	Admitted to emergency room with TBI and were sent for a head CT	Model 2000 Evaluated within 40 minutes of CT	All patients received CT or MRI	24	• Sensitivity = 100% • Specificity = 93.6% • PPV = 82.8% • NPV = 100%
Total		**N = 623**					**N = 152**	**Sensitivity = 92.8%** **Specificity = 90.9%**

Infrascanner Pediatric Clinical Data Summary Table

Study	Type	Pediatric (N)	Age (Range, AVG)	Method of Selection	NIRS	CT	ICH	Results
Robertson et al. (2010) (USA and India)	Multicenter study (4 centers in USA and 1 in India)	36	0-17, 8.0 years	Admitted to emergency room with TBI and were sent for a head CT	Model 1000 Evaluated within 40 minutes of CT	All 36 patients received CT	5	• Sensitivity = 100% • Specificity = 93.5% • PPV = 71.4% • NPV = 100%
Coskun et al. (2010) (Turkey)	Single center study	161	1-15 years	Admitted to emergency service with TBI	Model 1000 Evaluated prior to CT. No repeats for positive results.	All 161 patients received CT. Radiologist was blind regarding Infrascanner result.	14	• Sensitivity = 85.7% • Specificity = 65.3% • PPV = 18.5% • NPV = 97.9%
Salonia et al. (2012) (USA)	Single center, prospective, case-control study	28	0-14, 2.6 years	Patient underwent CT as part of clinical care, not necessarily triggered by trauma	Model 1000 Evaluated within 24 hours of CT	All 28 patients received CT	12 patients	• Sensitivity = 100% • Specificity = 80% • PPV = 80% • NPV = 100%
Bressen et al. (2013) (Italy)	Dual center, prospective observational study	103	0-15 years 50% were less than 2 years old	Minor Head Injury Children presenting with intermediate or high risk for intracranial injury according to PECARN	Model 1000	18 The rest were followed on the phone 7-90 days later to exclude initially missed hematoma.	1	• Sensitivity = 100% • Specificity = 93.1% • PPV = 12.5% • NPV = 100%

Study	Type	Pediatric (N)	Age (Range, AVG)	Method of Selection	NIRS	CT	ICH	Results
Medical University of Lodz (2017) (Poland)	Singe center study	155	2-18 years	Presenting with mild head injury (i.e., no focal or meningeal signs, and GCS score of 14-15)	Model 1000 Evaluated up to 72 hours post-injury	28 The rest were followed for 2 months' post-enrollment	3	• Sensitivity = 66.7% • Specificity = 98.7% • PPV = 50% • NPV = 99.3%
Semenova et al. (2016) (Russia)	Singe center study	95 • 42 medium-high risk *(GCS score 13-14)*; • 53 low risk *(GCS score 15)*	0-17, 9.1 years	Presented with mild TBI (GCS 13-15)	Model 1000	42 medium-high risk patients + 1 low risk patient (Not included in results analysis because CT scan occurred 24 hours post-Infrascanner.)	8	Medium-High Risk Pop. • Sensitivity = 100% • Specificity = 91.2% • PPV = 72.7% • NPV = 100% Low Risk Pop. • Specificity = 91.7% • NPV = 100%
Total		**N = 578**				**N = 313**	**43**	**Sensitivity = 93%** **Specificity = 86.5%**