APPENDIX C: EVIDENCE TABLES

DATA ABSTRACTION OF INCLUDED PRIMARY STUDIES: PATIENT CHARACTERISTICS

Author Year N	NIRS Device	Mean Age (range) % male	Race Skin Pigment	Hair Characteristics	Injury Characteristics
Akyol 2016[1] N= 151	Infrascanner 1000*	49.9 (18-94) 51% male	NR	5.3% no hair 37.7% dark hair	Falling on the same level=45% Fall from high=6% Traffic accident=17.2% Non-vehicle traffic accident=4% Motorcycle accident= 4.6% Assault=8% Other=15.2%
Coskun 2010[2] N= 92	Infrascanner 1000*	NR†	NR	NR	NR
Francis 2005[3] N= 71	Developed by authors	Normal volunteers: 35 (17-53) Patients referred for CT: NR	NR	NR	NR
Ghalenoui 2008[4] N= 148	CrainScan‡	36.8 (11-78) 36.5% male	NR	NR	Falling=16.9% Accident=70.9% Fight=10.1% Exercise=2%
Hennes 1997[5] N= 212	Runman§	NR	NR	NR	NR
Hennes 1999[6] N= 19	Runman§	NR	NR	NR	NR
Kahraman 2006[7] N= 60	Smartscan	59.73 (4-103) 80% male	NR	NR	Falls= 23.3% Non-traumatic injury=40% Head stroke=16.7% Motor vehicle collision=20%
Kessel 2007[8] N= 110	CrainScan‡	56.2 58.1% male	NR	NR	
Leon-	Infrascanner 1000*	47.6	100% white	48.6% light	Fall=51.4%

Carrion 2010[9] N= 35		(17-76) 82.9% male	82.9% light 17.1% dark	42.9% brown 8.6% black 54.3% thin 31.4% normal 14.3% thick	Traffic accident=34.3% Assault=5.7% Other=8.6%
Peters 2017[10] N= 22	Infrascanner 2000*	54 (7-79) 60% male	NR	NR	Falls from heights=24% Traffic accidents=36% Blunt trauma to the head=4% Other causes=36%
Robertson 2010[11] N= 365	Infrascanner 1000*	36.7 (1-88) 74.8% male	23.3% white 26.3% black 32.1% Asian 0.2% Hawaiian 18.1% Hispanic 26.8% light 34.2% dark 38.9% black	0.8% bald‖ 16.1% light 38.6% dark 44.1% black 0.3% unknown 19.7% thin 60.5% normal 18.1% thick 0.3% unknown	Falls=43.8% Accident= 41.9% Assault=11.2% Gunshot wound=2.2% Other=0.8%
Xu 2017[12] N= 85	Infrascanner 2000*	48.3 (8-89) 65% male	100% Han Chinese 67% light 33% dark	16% light 22% brown 61% black 25% thin 55% normal 20% thick	NR

*Infrascanner 1000, and Infrascanner 2000 were developed by Infrascan Inc. (Philadelphia, USA)

†161 pediatric patients included in study population were excluded from this review

‡Crainscan was developed by BYTech (Germany)

§Runman was developed by NIM Inc. (Philadelphia, USA) and later acquired by Infrascan Inc. (Philadelphia, USA)

‖Three patients were described as bald (0.8%) under the 'hair color' category and 5 (1.3%) were described as bald under the 'hair thickness' category

DATA ABSTRACTION OF INCLUDED PRIMARY STUDIES: PERFORMANCE CHARACTERISTICS

Author Year N	NIRS Device Hematoma Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Prevalence (95% CI)
Hennes 1997[26] N= 212	Runman Type: Type: Intracranial hemorrhage including SDH	.96 (.91-.99)	.29 (.20-.39)	.65 (.61-.68)	.84 (.68-.93)	.58 (.51-.64)
Hennes 1999[27]‡ N= 19	Runman Type: SDH	.84 (.60-.97)	NA*	NA*	NA*	1.00 (.82-1.00)
Francis 2005[17]‡ N= 71	Developed by authors Type: Any	.82 (.48-.98)	.88 (.77-.95)	.56 (.38-.73)	.96 (.88-.99)	.15 (.08-.26)
Kahraman 2006[28] N= 60	Smartscan Type: EDH, SDH	.87 (.69-.96)	1.00 (.88-1.00)	1.00 (1.00-1.00)	.88 (.75-.95)	.50 (.37-.63)
Kessel 2007[29]§ N= 110	CrainScan Type: Any	.68 (.48-.84)	.95 (.88-.99)	.83 (.64-.93)	.90 (.83-.94)	.25 (.18-.35)
Ghalenoui 2008[25] N= 148	CrainScan Type: Any	.89 (.77-.96)	.78 (.68-.86)	.70 (.61-.77)	.92 (.85-.96)	.36 (.29-.45)
Coskun 2010[24] N= 92	Infrascanner 1000† Type: NR	.88 (.47-1.00)	.38 (.28-.49)	.12 (.09-.16)	.97 (.83-1.00)	.09 (.04-.16)
Leon-Carrion 2010[19] N= 35	Infrascanner 1000 Type: Any	.89 (.67-.99)	.81 (.54-.96)	.85 (.67-.94)	.87 (.63-.96)	.54 (.37-.71)
Robertson 2010[13] N= 365	Infrascanner 1000 Type: Any	.69 (.58-.78)	.91 (.87-.94)	.73 (.64-.80)	.89 (.86-.92)	.26 (.22-.31)
Akyol 2016[23] N= 151	Infrascanner 1000 Type: SAH, EDH, SDH	.86 (.42-1.00)	.67 (.58-.74)	.11 (.08-.15)	.99 (.94-.94)	.05 (.02-.09)
Peters 2017[30]§ N= 22	Infrascanner 2000 Type: Any	.85 (.55-0.98)	.78 (.40-.97)	.85 (.61-.95)	.78 (.48-.93)	.59 (.36-.79)
Xu	Infrascanner 2000	.96	.93	.93	.95	.53

Author Year N	NIRS Device Hematoma Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Prevalence (95% CI)
2017[6] N= 85	Type: Any >3.5ml and <2.5cm from brain surface	(.85-.99)	(.80-.98)	(.83-.98)	(.83-.99)	(.41-.64)

Abbreviation: NA= not applicable; cm= centimeter; ml= milliliter; SDH= subdural hematoma; EDH= epidural hematoma; SAH= subarachnoid hematoma

*This study only tested a population of patients with hematoma

†Model not reported, but is assumed to be the Infrascanner 1000 because it was the only model available at the time of the study

‡ESP calculated values from study data

§ESP calculated numbers differed from reported values (ESP calculated values are shown)

QUALITY ASSESSMENT OF INCLUDED SYSTEMATIC REVIEWS

Brogan 2017[13]

Domain	Concern (Low/High/Unclear)	Rationale for Concern
1. Study eligibility criteria	Low	Review adhered to clearly stated pre-defined objectives and eligibility criteria, which were appropriate for the review question No inappropriate restrictions in eligibility criteria
2. Identification and selection of studies	Low	Appropriate range of databases searched Appropriate restrictions regarding dates, language Appropriate methods for identifying additional studies (reviewing article references) and minimizing error (multiple reviewers)
3. Data collection and study appraisal	Unclear	Dual independent data abstraction Unclear methods for risk of bias assessment
4. Synthesis and findings	Unclear	Potential sources of bias in some individual studies were included in the discussion and in table comments, but not addressed formally for every study Lacking information on meta-analysis methods or assessment of heterogeneity
5. Overall Risk of Bias		
Did the interpretation of findings address all the concerns identified in Domains 1 to 4? (Y/ N/ NI)	N	
Was the relevance of identified studies to the review's research question appropriately considered? (Y/ N/ NI)	Y	
Did the reviewers avoid emphasizing results based on their statistical significance? (Y/ N/ NI)	Y	
Risk of bias in the review (Low/ High/ Unclear)		Unclear
Rationale for risk		Clear methods for eligibility criteria, searching, study selection, data abstraction. Methods for individual study assessment or meta-analysis are not described, and there is no discussion of heterogeneity.

QUALITY ASSESSMENT OF INCLUDED PRIMARY STUDIES

Author Year	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Could the patient flow have introduced bias?	Overall Risk of Bias
Akyol 2016[1]	Unclear Several exclusion criteria, including patients with severe pain. Only 37.3% of patients with minor head trauma who received CT were included	No Infrascanner done prior to CT	No Diagnosing physicians did not have knowledge of NIRS results	No Timing between scans unclear. All patients received CT and were included in analysis	Unclear
Coskun 2010[2]	No Stated all patients admitted to ED with CT included	No NIRS done prior to CT	No Radiologist did not have knowledge of NIRS results	No Timing between scans unclear. All patients received CT and were included in analysis	Low
Francis 2005[3]	Unclear Unclear how study cohort was formed	Unclear Unclear order of testing or if result from CT were known; stated as "patients referred for brain CT scan were simultaneously subjected to NIRS"	Unclear Unclear order of testing or if result from NIRS were known; stated as "patients referred for brain CT scan were simultaneously subjected to NIRS"	No Timing between scans unclear. All patients received CT and were included in analysis	Unclear
Ghalenoui 2008[4]	No Patients admitted to hospital with head injuries requiring CTs	No CT scan prior to NIRS, but NIRS physician blinded from CT scan results	No CT scan prior to NIRS	No Timing between scans unclear. All patients received CT and were included in analysis	Low

Author Year	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Could the patient flow have introduced bias?	Overall Risk of Bias
Hennes 1997[5]	No	No	Unclear	No	Unclear
	Patients admitted to hospital with neurologic symptoms possibly associated with head trauma or stroke	NIRS done prior to CT	Not stated if CT was interpreted with knowledge of NIRS results	Timing between scans unclear. All patients received CT and were included in analysis	
Hennes 1999[6]	No	Unclear	No	No	Unclear
	Patients with CT diagnosis of subdural hematoma	CT scan prior to NIRS, unclear if knowledge of CT scan results	CT scan prior to NIRS	CT scan "immediately" prior to NIRS. All but 1 patient received CT and included in analysis	
Kahraman 2006[7]	Yes	Unclear	No	No	Unclear
	Case-control design was used.	The investigator performing the NIRS measurement was likely aware of CT results, but there was no mention of blinding to reference standard. However, due to the objective nature of the NIRS test it is unlikely that knowledge of CT results biased assessment.	CT was conducted before index test.	All patients received CT.	
Kessel 2007[8]	No	No	Unclear	No	Unclear
	All patients with possible head injury mandating CT included during shifts when investigators worked	NIRS conducted before reference standard	No mention of blinding to index test findings.	All patients received CT.	Funded by Thomas & Thomas Medical Marketing, representing Odicain GmbH in Israel.

Author Year	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Could the patient flow have introduced bias?	Overall Risk of Bias
Leon-Carrion 2010[9]	No	No CT scan prior to NIRS in some cases, but blinded	No Radiologist was blinded to index test results	No All patients received CT.	Low Leon-Carrion resides on Infrascan Inc.'s Scientific Advisory Board.
Peters 2017[10]	Unclear Not all consecutive TBI patients were scanned, most severe patients immediately triaged to trauma center per need	Yes Due to patient transport methods (cervical spine immobilization), scans were incomplete (back/dorsal side of head was inaccessible) in 10/25 patients. However, these were still analyzed as if they were completed scans.	Unclear No mention of blinding to index test findings.	No All patients received CT.	Unclear
Robertson 2010[11]	No All patients undergoing CT scan for head injury	No NIRS conducted before reference standard	No Radiologist was blinded to index test results	No NIRS done within 40 min of CT. All patients received CT.	Low Funded by Infrascan Inc. Robertson is credited with the co-invention of the device and resides on company's Scientific Advisory Board.
Xu 2017[12]	Yes Partial convivence sample of healthy volunteers without hematomas were enrolled.	No NIRS conducted before reference standard	No Radiologist was blinded to index test results	Unclear Not all patients received the same reference standard. Subjects suspected of TBI underwent CCT. Healthy volunteers underwent MRI.	Unclear

STRENGTH OF EVIDENCE FOR INCLUDED STUDIES

Strength of Evidence for Infrascanner 2000

SOE Grade	Study Design: No. Studies (N)	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Sensitivity: Low	Cohort: 2 (N=107)[10,12]	Medium	Direct	Consistent	Imprecise	Undetected	None	Sensitivity = .93 (95% CI .83 to .98)
Specificity: Low	Cohort: 2 (N=107)[10,12]	Medium	Direct	Inconsistent	Imprecise	Undetected	None	Specificity = 0.90 (95% CI 0.78 to 0.97)

Strength of Evidence for Crainscan

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Sensitivity: Low	Cohort: 2 (N=258)[4,8]	Medium	Direct	Inconsistent	Imprecise	Undetected	None	Sensitivity = 0.82 (95% CI 0.72 to 0.89)
Specificity: Low	Cohort: 2 (N=258)[4,8]	Medium	Direct	Inconsistent	Imprecise	Undetected	None	Specificity = 0.86 (95% CI 0.80 to 0.91)