Department of Veterans Affairs
Health Services Research & Development Service

Evidence-based Synthesis Program

QUERI

Evidence Brief: Near Infrared Spectroscopy for Detecting Brain Hematoma

Supplemental Materials

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APPENDIX A: SEARCH STRATEGIES

1. Primary Databases **Date Searched: 6/30/17**	
Sources:	**Search Strategy/ Evidence:**
Medline	Database: Ovid MEDLINE(R) <1946 to June Week 4 2017>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <June 29, 2017> Search Strategy: -- 1 exp Hematoma/ (32815) 2 exp Craniocerebral Trauma/ (143473) 3 exp Intracranial Hemorrhages/ (64114) 4 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)).mp. (111165) 5 1 or 2 or 3 or 4 (251563) 6 exp Spectroscopy, Near-Infrared/ (10636) 7 exp Spectrophotometry, Infrared/ (59671) 8 exp Infrared Rays/ (11625) 9 (NIR or NIRS).mp. (15794) 10 (infrared and spectro*).mp. (102190) 11 (infrascan* or crainscan* or smartscan* or RunMan).mp. (13) 12 6 or 7 or 8 or 9 or 10 or 11 (117038) 13 5 and 12 (514) 14 remove duplicates from 13 (497) 15 limit 14 to english language (445) ***************************
CDSR	Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 29, 2017> Search Strategy: -- 1 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)).mp. (1496) 2 (NIR or NIRS).mp. (17) 3 (infrared and spectro*).mp. (24) 4 (infrascan* or crainscan* or smartscan* or RunMan).mp. (0) 5 2 or 3 or 4 (30) 6 1 and 5 (19) ***************************
CCRCT	Database: EBM Reviews - Cochrane Central Register of Controlled Trials <May 2017> Search Strategy: -- 1 exp Hematoma/ (471) 2 exp Craniocerebral Trauma/ (2009) 3 exp Intracranial Hemorrhages/ (1315) 4 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)).mp. (6922) 5 1 or 2 or 3 or 4 (9061) 6 exp Spectroscopy, Near-Infrared/ (242) 7 exp Spectrophotometry, Infrared/ (83) 8 exp Infrared Rays/ (193)

	9 (NIR or NIRS).mp. (365) 10 (infrared and spectro*).mp. (856) 11 (infrascan* or crainscan* or smartscan* or RunMan).mp. (0) 12 6 or 7 or 8 or 9 or 10 or 11 (1126) 13 5 and 12 (17) 14 remove duplicates from 13 (15) 15 limit 14 to english language (13) ***************************
PsycINFO	Database: PsycINFO <1806 to June Week 4 2017> Search Strategy: -- 1 exp hemorrhage/ (3510) 2 exp Brain Damage/ (32812) 3 exp head injuries/ (5641) 4 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or hemorrhage* or haemorrhage*)).mp. (5477) 5 1 or 2 or 3 or4.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (35950) 6 (NIR or NIRS).mp. (741) 7 (infrared and spectro*).mp. (1411) 8 (infrascan* or crainscan* or smartscan* or RunMan).mp. (2) 9 6 or 7 or 8 (1548) 10 5 and 9 (37) 11 limit 10 to english language (36) ***************************
HTA	Database: EBM Reviews - Health Technology Assessment <4th Quarter 2016> Search Strategy: -- 1 exp Hematoma/ (0) 2 exp Craniocerebral Trauma/ (45) 3 exp Intracranial Hemorrhages/ (18) 4 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)).mp. (49) 5 1 or 2 or 3 or 4 (92) 6 exp Spectroscopy, Near-Infrared/ (3) 7 exp Spectrophotometry, Infrared/ (2) 8 exp Infrared Rays/ (6) 9 (NIR or NIRS).mp. (2) 10 (infrared and spectro*).mp. (5) 11 (infrascan* or crainscan* or smartscan* or RunMan).mp. (0) 12 6 or 7 or 8 or 9 or 10 or 11 (11) 13 5 and 12 (0) 14 remove duplicates from 13 (0) 15 limit 14 to english language (0) ***************************
DARE	Database: EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2016> Search Strategy: -- 1 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or

	hemorrhage* or haemorrhage* or bleed*)).mp. (373) 2 (NIR or NIRS).mp. (4) 3 (infrared and spectro*).mp. (8) 4 (infrascan* or crainscan* or smartscan* or RunMan).mp. (1) 5 2 or 3 or 4 (10) 6 1 and 5 (0) ***************************
NHS EED	Database: EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016> Search Strategy: -- 1 exp Hematoma/ (4) 2 exp Craniocerebral Trauma/ (78) 3 exp Intracranial Hemorrhages/ (55) 4 ((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid) and (hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)).mp. (189) 5 1 or 2 or 3 or 4 (269) 6 exp Spectroscopy, Near-Infrared/ (1) 7 exp Spectrophotometry, Infrared/ (0) 8 exp Infrared Rays/ (2) 9 (NIR or NIRS).mp. (2) 10 (infrared and spectro*).mp. (1) 11 (infrascan* or crainscan* or smartscan* or RunMan).mp. (0) 12 6 or 7 or 8 or 9 or 10 or 11 (5) 13 5 and 12 (0) 14 remove duplicates from 13 (0) 15 limit 14 to english language (0) ***************************
CINAHL	Database: EBSCOhost - CINAHL Plus with Full Text Search Strategy: -- S1 (MH "Hematoma+") (4,158) S2 (MH "Intracranial Hemorrhage+") (10,947) S3 (MH "Head Injuries+") (31,332) S4 TX (((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid)) AND TX ((hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)) (42,314) S5 S1 OR S2 OR S3 OR S4 (73,222) S6 (MH "Spectroscopy, Near-Infrared") (1,291) S7 (MH "Spectrophotometry, Infrared") (686) S8 TX NIR OR NIRS (2,134) S9 TX infrared AND TX spectro$ (53) S10 TX (infrascan* OR crainscan* OR smartscan* OR RunMan) (20) S11 S6 OR S7 OR S8 OR S9 OR S10 (3,800) S12 S5 AND S11 (169) S13 S5 AND S11 [English] (169) ***************************
Military & Government Collection	Database: EBSCOhost - CINAHL Plus with Full Text Search Strategy: -- S1 (MH "Hematoma+") (14) S2 (MH "Intracranial Hemorrhage+") (0) S3 (MH "Head Injuries+") (94)

	S4 TX (((brain or head or subdural or epidural or intraparenchymal or intracranial or intercrainial or cranial or cerebral or subarachnoid)) AND TX ((hematoma* or haematoma* or hemorrhage* or haemorrhage* or bleed*)) (5,131) S5 S1 OR S2 OR S3 OR S4 (5,220) S6 (MH "Spectroscopy, Near-Infrared") (0) S7 (MH "Spectrophotometry, Infrared") (0) S8 TX NIR OR NIRS (2,150) S9 TX infrared AND TX spectro$ (41) S10 TX (infrascan* OR crainscan* OR smartscan* OR RunMan) (26) S11 S6 OR S7 OR S8 OR S9 OR S10 (2,212) S12 S5 AND S11 (18) S13 S5 AND S11 [English] (18) **************************
Scopus	Database: Scopus Search Strategy: -- 1 ((TITLE-ABS-KEY (infrared)) AND (TITLE-ABS-KEY (spectroscopy OR spectrophotometry))) (414,078) 2 ((TITLE-ABS-KEY (brain OR head OR subdural OR epidural OR intraparenchymal OR intracranial OR intercrainial OR cranial OR cerebral OR subarachnoid)) (2,722,741) 3 (TITLE-ABS-KEY (hematoma OR haematoma OR hemorrhage OR haemorrhage OR bleed))) (468,007) 4 1 AND 2 AND 3 (386)

2. Non-Database/ Grey Literature Sources Date Searched: 6/30/17	
Sources:	**Search Strategy/ Evidence:**
VA Products: VATAP, PBM, HSR&D publications, VA ART Database	A. http://www.hsrd.research.va.gov/research/default.cfm Search: infrared Relevant Results: None B. http://www.research.va.gov/research_topics/ Relevant Results: None C. http://art.puget-sound.med.va.gov/default.cfm Search: WHERE (1 = 1) AND (Abstract LIKE "%infrared%") OR (Project Title LIKE ("%infrared%")) Relevant Results: None
AHRQ	http://www.ahrq.gov/research/findings/evidence-based-reports/search.html Search: infrared Relevant Results: None
CADTH	https://www.cadth.ca Search: infrared Relevant Results: None
ECRI Institute	https://www.ecri.org/Pages/default.aspx Search: infrared

	Relevant Results: FDA approves handheld device to detect bleeding in skull. 12/16/2011
NICE	http://www.evidence.nhs.uk/default.aspx Search: infrared Relevant Results: None
NLM	http://www.ncbi.nlm.nih.gov/pubmedhealth/ Search: infrared Relevant Results: None
RePORT: Research Portfolio Online Reporting Tools	https://projectreporter.nih.gov/reporter.cfm Search: (infrared AND (spectroscopy OR spectrophotometry)) AND ((brain OR head OR subdural OR epidural OR intraparenchymal OR intracranial OR intercrainial OR cranial OR cerebral OR subarachnoid) AND (hematoma OR haematoma OR hemorrhage OR haemorrhage or bleed)) Relevant results: None
Trip: Turning Research Into Practice	https://www.tripdatabase.com/ Search: (infrared AND (spectroscopy OR spectrophotometry)) AND ((brain OR head OR subdural OR epidural OR intraparenchymal OR intracranial OR intercrainial OR cranial OR cerebral OR subarachnoid) AND (hematoma OR haematoma OR hemorrhage OR haemorrhage or bleed)) Relevant results: None
Epistemonikos	https://www.epistemonikos.org/ Search: infrared Relevant Results: None
Military Medicine	http://militarymedicine.amsus.org/ Search: infrared Relevant Results: None
BestBETs	http://bestbets.org/index.php Search: infrared Relevant Results: None
Google Scholar	http://scholar.google.com/ Search: near infrared spectroscopy and hematoma; near infrared spectroscopy and hemorrhage; infrascanner; crainscan Relevant Results: Kessel B, Jeroukhimov I, Ashkenazi I, Oren M, Halevy A, Alfici R. Early detection of life threatening intracranial haemorrhage using a portable near infrared spectroscopy device. Injury Extra. 2009;40(10):213. Coskun F, Sezer EA, Karamercan MA, Akinci E, Vural K. An assessment on the use of infrascanner for the diagnosis of the brain hemotoma by using support vector machine. Scientific Research and Essays. 2010;5(14):1911-1915. Robertson C, Gopinath S, Chance B. Identifying intracracranial hematomas with near-infrared spectroscopy. Transcranial Cerebral Oximetry, G. Litscher and G. Schwarz. Eds; 1997; Pabst Science, Berlin. Park, Jung Yul, et al. "Usefulness of portable optical measuring device using near-infrared in detection of intracranial hemorrhage." *World Congress on Medical Physics*

	and Biomedical Engineering 2006. Springer Berlin Heidelberg, 2007.
Google	www.google.com Search: near infrared spectroscopy and hematoma; near infrared spectroscopy and hemorrhage; infrascanner; crainscan Relevant Results: Schulz P, Kunz U. Experiences using a mobile near-infrered spectroscopy system for noninvasive detection of traumatic intracranial hematoma. Accepted abstracts from the International Brain Injury Association's Eighth World Congress on Brain Injury. March 10-14, 2010. Washington DC, USA.
Secondary sources:	**Search Strategy/ Evidence:**
BlueCross BlueShield Foundation	http://bluecrossfoundation.org/publications Search: infrared Relevant Results: None
Campbell Collaboration	https://www.campbellcollaboration.org/library.html?&searchword= Search: infrared Relevant Results: None
CMS Policies	http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-List.html Search: infrared Relevant Results: None
Hayes	http://www.hayesinc.com/hayes/ Search: infrared Relevant Results: None
Institute for Clinical Evaluative Sciences	http://www.ices.on.ca/Publications/Atlases-and-Reports Search: infrared Relevant Results: None
IOM	http://www.nationalacademies.org/hmd/Reports.aspx Search: infrared Relevant Results: None
McMaster Health Systems Evidence	http://www.healthsystemsevidence.org/open-search.aspx Search: infrared Relevant Results: None
Robert Wood Johnson	http://www.rwjf.org/en/research-publications.html Search: infrared Relevant Results: None
Systematic Reviews (Journal)	http://link.springer.com/journal/13643 Search: infrared Relevant Results: None
UBC Centre for Health Services and Policy Research	http://chspr.ubc.ca/pubs/pub-search Search: infrared Relevant Results: None

WHO Health Evidence Network	http://www.euro.who.int/en/what-we-do/data-and-evidence/health-evidence-network-hen/publications/by-keyword Search: infrared Relevant Results: None
Infrascanner.com	https://infrascanner.com/research/ Relevant Results: Tyzo B, Trojanowski T, D. S, Rola R. Algorithm of initial management of mild head injury using the portable near-infrared spectroscope. Neurologia Praktyczna. 2014:13-20.

3. Current Guidelines Date Searched: 8/4/17	
Sources:	**Search Strategy/ Evidence:**
VA/DoD Clinical Practice Guidelines	https://www.healthquality.va.gov/ Relevant Results: "VA/DoD clinical practice guideline for management of concussion/mild traumatic brain injury." (2016). The Department of Veterans Affairs (VA) published guidelines on the management of concussion or mild traumatic brain injury (mTBI) in 2016; these guidelines do not discuss a role for NIR brain hematoma detection using NIRS.
National Guideline Clearinghouse	http://www.guideline.gov/ Search: infrared; brain injury; head injury Relevant Results: None
American Academy of Neurology	https://www.aan.com/ Search: infrared; brain injury; head injury Relevant Results: None
World Federation of Neurology	https://www.wfneurology.org Search: infrared; brain injury; head injury Relevant Results: None
American Association of Neurological Surgeons	http://www.aans.org/ Search: infrared; brain injury; head injury Relevant Results: None
American Association of Neurological Nurses	http://aann.org/ Search: infrared; brain injury; head injury Relevant Results: None
American Neurological Association	https://myana.org/ Search: infrared; brain injury; head injury Relevant Results: None

4. Literature currently under development (forthcoming studies & protocols) Date Searched: 6/30/17	
Sources:	**Search Strategy/ Evidence:**

AHRQ topics in development (EPC Status Report)	https://www.epc-src.org/src/logon.cfm Emailed Robin.Paynter@va.gov and she reported no future, ongoing, or completed AHRQ Effective Health Care program reviews on this topic.
PROSPERO (SR registry)	http://www.crd.york.ac.uk/PROSPERO/ Search: infrared Relevant Results: None
DoPHER (SR Protocols)	http://eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=9 Search: infrared Relevant Results: None
Clinicaltrials.gov	Search: infrared Relevant Results: An Evaluation of Near-Infrared Spectroscopy for Intracranial Hematoma Detection of Head Trauma Patients in the Emergency Department. NCT02222597
UK Clinical Trials Gateway	Search: infrared Relevant Results: None
metaRegister of Controlled Trials (mRCT)	http://www.isrctn.com/page/mrct Search: infrared Relevant results: None
WHO International Clinical Trials Registry Platform	http://apps.who.int/trialsearch/default.aspx Search: infrared Relevant results: None

APPENDIX B: LIST OF EXCLUDED STUDIES

Exclude reasons: B=Relevant for background information only, 1=Ineligible population, 2=Ineligible intervention, 3=Ineligible comparator, 4=Ineligible outcome, 5=Ineligible timing, 6=Ineligible study design, 7=Ineligible publication type 8=Outdated or ineligible systematic review, 9=non-English language, 10=Full text not available

#	Citation	Exclude reason
1	Al-Rawi PG. Near infrared spectroscopy in brain injury: today's perspective. *Acta Neurochir Suppl.* 2005;95:453-457.	E7
2	Arshi B, Mack WJ, Emanuel B. Invasive and noninvasive multimodal bedside monitoring in subarachnoid hemorrhage: a review of techniques and available data. *Neurol Res Int.* 2013;2013:987934.	E4
3	Bein B, Dörges V, Tonner PH. Near-infrared spectroscopy. *J. Anasth. Intensivbehandl.* 2003;10(1):286-287.	E9
4	Braun T, Kunz U, Schulz C, Lieber A, Willy C. Near-infrared spectroscopy for the detection of traumatic intracranial hemorrhage: Feasibility study in a German army field hospital in Afghanistan. *Unfallchirurg.* 2015;118(8):693-700.	E9
5	Colier WN, Ringnalda BE, Evers JA, Oeseburg B. Evaluation of the algorithm used in near infrared spectrophotometry. *Adv Exp Med Biol.* 1992;317:305-311.	E1
6	Cruz J. Near-infrared spectroscopy. *J Neurosurg.* Jan 1994;80(1):181-182.	E7
7	Cruz J. Relevant limitations of near-infrared spectroscopy. *Crit Care Med.* Mar 1997;25(3):555-556.	E7
8	Davies DJ, Su Z, Clancy MT, et al. Near-Infrared Spectroscopy in the Monitoring of Adult Traumatic Brain Injury: A Review. *Journal of Neurotrauma.* Jul 01 2015;32(13):933-941.	B
9	Dieters EI, Hidding SH, Kalisvaart M, Mik EG. Near infrared spectroscopy: an asset to the diagnosis and treatment of traumatic brain injury. *Erasmus J Med.* 2011;1(2):23-26.	E8
10	Food Drug Administration HHS. Medical devices; neurological devices; classification of the Near Infrared Brain Hematoma Detector. Final rule. *Fed Regist.* Mar 23 2012;77(57):16925-16927.	B
11	Francis R, Khan B, Alexandrakis G, Florence J, MacFarlane D. NIR light propagation in a digital head model for traumatic brain injury (TBI). *Biomed Opt Express.* Sep 01 2015;6(9):3256-3267.	E1
12	Fuentes G. Hand-held brain scanners. *Navy Times.* 08/16/ 2010;59(47):3-3.	E10
13	Ganapathy P, Joshi SH, Yadegar J, Kamat N, Caluser C. An intelligent and portable ambulatory medical toolkit for automatic detection and assessment of traumatic brain injuries. Paper presented at: 1st Wireless Health Conference,	E10

	WH'102010; San Diego, CA.	
14	Goldberg S, Lott C, Ostermeyer M, Hennes HJ. Near-infrared spectroscopy as a diagnostic tool in patients with suspected stroke or traumatic brain injury. Paper presented at: Diagnostic Optical Spectroscopy in Biomedicine2001; Munich.	E10
15	Gopinath S.P., Chance B., C.S. R. Near-infrared spectroscopy in head injury. In: Narayan RK, Wilberger J, J. P, eds. *Neurotrauma.* Vol 1. New York, NY McGraw-Hill; 1994:169-184.	E4
16	Gopinath SP, Robertson CS, Contant CF, Narayan RK, Grossman RG, Chance B. Early detection of delayed traumatic intracranial hematomas using near-infrared spectroscopy. *J Neurosurg.* Sep 1995;83(3):438-444.	E4
17	Gopinath SP, Robertson CS, Grossman RG, Chance B. Near-infrared spectroscopic localization of intracranial hematomas. *J Neurosurg.* Jul 1993;79(1):43-47.	E4
18	Hänggi D. Monitoring and detection of vasospasm II: EEG and invasive monitoring. *Neurocrit Care.* 2011;15(2):318-323.	E4
19	Hanley DF, Chabot R, Mould WA, et al. Use of brain electrical activity for the identification of hematomas in mild traumatic brain injury. *Journal of Neurotrauma.* Dec 15 2013;30(24):2051-2056.	E2
20	Harkins G. A portable brain scanner. *Air Force Times.* 07/09/2012 2012;72(52):3-3.	B
21	Hongo K, Kobayashi S, Okudera H, Hokama M, Nakagawa F. Noninvasive cerebral optical spectroscopy: Depth-resolved measurements of cerebral haemodynamics using indocyanine green. *Neurol Res.* 1995;17(2):89-93.	E4
22	InfraScan receives CE mark for brain hematoma detector. *Diagnostics & Imaging Week.* 2008;11(43):1-8.	B
23	Irani F, Platek SM, Bunce S, Ruocco AC, Chute D. Functional near infrared spectroscopy (fNIRS): an emerging neuroimaging technology with important applications for the study of brain disorders. *Clin Neuropsychol.* Jan 2007;21(1):9-37.	B
24	Kakihana Y, Arimura T, Oda T, Yoshimura N. Non-invasive monitoring of cerebral oxygenation by NIR spectrophotometry (clinical trial). *JPN. J. ANESTHESIOL.* 1995;44(6):853-857.	E9
25	Kampfl A, Pfausler B, Denchev D, Jaring HP, Schmutzhard E. Near infrared spectroscopy (NIRS) in patients with severe brain injury and elevated intracranial pressure. A pilot study. *Acta Neurochir Suppl.* 1997;70:112-114.	E4
26	Kannan R, Przekwas A. A near-infrared spectroscopy computational model for cerebral hemodynamics. *Int j numer method biomed eng.* Nov 2012;28(11):1093-1106.	E1
27	Keller E, Froehlich J, Baumann D, et al. Detection of delayed cerebral ischemia (DCI) in subarachnoid haemorrhage applying near-infrared spectroscopy: elimination of the extracerebral signal by transcutaneous and intraparenchymatous	E4

	measurements in parallel. *Acta Neurochir Suppl.* 2015;120:243-247.	
28	Keller E, Froehlich J, Muroi C, Sikorski C, Muser M. Neuromonitoring in intensive care: a new brain tissue probe for combined monitoring of intracranial pressure (ICP) cerebral blood flow (CBF) and oxygenation. *Acta Neurochir Suppl.* 2011;110(Pt 2):217-220.	E4
29	Keller E, Ishihara H, Nadler A, et al. Evaluation of brain toxicity following near infrared light exposure after indocyanine green dye injection. *J Neurosci Methods.* May 30 2002;117(1):23-31.	E4
30	Keller E, Mudra R. Measurement of cerebral blood flow with near infrared spectroscopy and indocyanine green dye dilution. *Curr. Med. Imaging Rev.* 2007;3(2):139-150.	E4
31	Keller E, Nadler A, Imhof HG, Niederer P, Roth P, Yonekawa Y. New methods for monitoring cerebral oxygenation and hemodynamics in patients with subarachnoid hemorrhage. *Acta Neurochir Suppl.* 2002;82:87-92.	E4
32	Keller E, Wolf M, Martin M, Yonekawa Y. Estimation of cerebral oxygenation and hemodynamics in cerebral vasospasm using indocyaningreen dye dilution and near infrared spectroscopy: a case report. *J Neurosurg Anesthesiol.* Jan 2001;13(1):43-48.	E4
33	Kerr ME, Marion D, Orndoff PA, Weber BB, Sereika SM. Evaluation of near infrared spectroscopy in patients with traumatic brain injury. *Adv Exp Med Biol.* 1998;454:131-137.	E4
34	Kessel B, Jeroukhimov I, Ashkenazi I, Oren M, Halevy A, Alfici R. Early detection of life threatening intracranial haemorrhage using a portable near infrared spectroscopy device. *Injury Extra.* 2009;40(10):213.	E7
35	Kim AL. Portable traumatic brain injury detection with near-infrared technology: infrascanner model 2000. *Mil Med.* May 2015;180(5):597-598.	E7
36	Kirkman MA, Smith M. Supratentorial intracerebral hemorrhage: A Review of the underlying pathophysiology and its relevance for multimodality neuromonitoring in neurointensive care. *J Neurosurg Anesthesiol.* 2013;25(3):228-239.	B
37	Kirkpatrick PJ, Smielewski P, Czosnyka M, Menon DK, Pickard JD. Near-infrared spectroscopy use in patients with head injury. *J Neurosurg.* Dec 1995;83(6):963-970.	E4
38	Leonard Kim A. Portable Traumatic Brain Injury Detection With Near-Infrared Technology: Infrascanner Model 2000. Vol 180: AMSUS; 2015:597-598.	B
39	Mahdavi Z, Pierre-Louis N, Thuy-Tien H, Figueroa SA, Olson DM. Advances in Cerebral Monitoring for the Patient with Traumatic Brain Injury. *Critical Care Nursing Clinics of North America.* 2015;27(2):213-223.	E7
40	March K. Application of technology in the treatment of traumatic brain injury. *Critical Care Nursing Quarterly.* 2000;23(3):26-37.	E7
41	Martinez-Coll A, Morgan MK, Nguyen H, Hunyor SN. Near infrared spectroscopy (NIRS) measurements following subarachnoid hemorrhage (SAH): Potential for	E10

	the detection of vasospasm. Paper presented at: Proceedings of the 1999 IEEE Engineering in Medicine and Biology 21st Annual Conference and the 1999 Fall Meeting of the Biomedical Engineering Society (1st Joint BMES / EMBS)1999; Atlanta, GA, USA.	
42	Maslehaty H, Krause-Titz U, Petridis AK, Barth H, Mehdorn HM. Continuous measurement of cerebral oxygenation with near-infrared spectroscopy after spontaneous subarachnoid hemorrhage. *ISRN neurol.* 2012;2012:907187.	E2
43	Messerer M, Daniel RT, Oddo M. Neuromonitoring after major neurosurgical procedures. *Minerva Anestesiol.* Jul 2012;78(7):810-822.	E7
44	Michaelson SM. Are your workers exposed to non-ionizing radiant energy? *IMS Ind Med Surg.* Oct 1973;42(9):9-13.	E1
45	Misra M, Alp MS, Dujovny M, Ausman JI. Near-infrared spectroscopy. *J Neurosurg.* Aug 1996;85(2):363-364.	E7
46	Mobile device identifies head injuries. *Emergency Nurse.* 2016;23(9):7-7.	E7
47	Newbold D. New hand-held assessment device may save lives. *British Journal of Neuroscience Nursing.* 2007;3(5):217-217.	B
48	Novoseltseva A, Aristov A, Timchenko K. Experimental facility control system for optical studies in the frame of problem solving of brain hematoma diagnostics. Paper presented at: 21st International Conference for Students and Young Scientists: Modern Technique and Technologies, MTT 20152015.	B
49	Petrov A, Prough DS, Petrov Y, et al. Noninvasive, optoacoustic detection and characterization of intra- and extracranial hematomas and cerebral hypoxia. Paper presented at: Photons Plus Ultrasound: Imaging and Sensing 20152015.	E10
50	Polito MZ, Thompson JWG, DeFina PA. A review of the International Brain Research Foundation novel approach to mild traumatic brain injury presented at the International Conference on Behavioral Health and Traumatic Brain Injury. *Journal of the American Academy of Nurse Practitioners.* 2010;22(9):504-509.	B
51	Ricker JH, DeLuca J, Frey SH. On the changing roles of neuroimaging in rehabilitation science. *Brain imaging behav.* Sep 2014;8(3):333-334.	E7
52	Riley JD, Amyot F, Pohida T, et al. A hematoma detector-a practical application of instrumental motion as signal in near infra-red imaging. *Biomed Opt Express.* Jan 01 2012;3(1):192-205.	E1
53	Robertson C, Gopinath S, Chance B. Identifying intracracranial hematomas with near-infrared spectroscopy. Transcranial Cerebral Oximetry, G. Litscher and G. Schwarz. Eds; 1997; Pabst Science, Berlin.	E7
54	Robertson CS, Gopinath SP, Chance B. A new application for near-infrared spectroscopy: detection of delayed intracranial hematomas after head injury. *Journal of Neurotrauma.* Aug 1995;12(4):591-600.	B
55	Robertson CS, Gopinath SP, Chance B. Use of near infrared spectroscopy to identify traumatic intracranial hematomas. *J Biomed Opt.* 1997;2(1):31-41.	E7

56	Schober P, Bossers SM, Schwarte LA. Intracranial Hematoma Detection by Near Infrared Spectroscopy in a Helicopter Emergency Medical Service: Practical Experience. *BioMed Research International.* 2017:1-6.	E1
57	Sen AN, Gopinath SP, Robertson CS. Clinical application of near-infrared spectroscopy in patients with traumatic brain injury: a review of the progress of the field. *Neurophotonics.* Jul 2016;3(3):031409.	B
58	Sensintaffar EL, Sliney DH, Parr WH. An analysis of a reported occupational exposure to infrared radiation. *Am Ind Hyg Assoc J.* Jan 1978;39(1):63-69.	E2
59	Smith M, Elwell C. Near-infrared spectroscopy: shedding light on the injured brain. *Anesth Analg.* Apr 2009;108(4):1055-1057.	E7
60	Smith M. Shedding light on the adult brain: a review of the clinical applications of near-infrared spectroscopy. *Philos Transact Ser A Math Phys Eng Sci.* Nov 28 2011;369(1955):4452-4469.	B
61	Stocchetti N, Le Roux P, Vespa P, et al. Clinical review: neuromonitoring - an update. *Crit Care.* Jan 15 2013;17(1):201.	E7
62	Sultan E, Manseta K, Gandjbakhche A, Daryoush AS. Untethered helmet mounted functional near infrared (fNIR) biomedical imaging for hematoma detection! Paper presented at: 2013 IEEE MTT-S International Microwave and RF Conference, IMaRC 20132013; New Delhi.	E10
63	Tandon PN. Near infrared spectroscopy : An emerging non-invasive optical imaging technique. *Neurol. India.* 1999;47(2):83-84.	E7
64	Timchenko KA, Aristov AA, Musorov IS, Evtushenko TG. Development of optoelectronic system for subdural hematoma diagnostics. Paper presented at: 2014 IEEE 15th International Conference of Young Specialists on Micro/Nanotechnologies and Electron Devices, EDM 20142014; Altai.	E10
65	Tyzo B, Trojanowski T, D. S, Rola R. Algorithm of initial management of mild head injury using the portable near-infrared spectroscope. *Neurologia Praktyczna.* 2014:13-20.	E10
66	Vinciguerra L, Bösel J. Noninvasive Neuromonitoring: Current Utility in Subarachnoid Hemorrhage, Traumatic Brain Injury, and Stroke. *Neurocrit Care.* 2016:1-19.	E4
67	Zabel TA, Chute DL. Educational neuroimaging: a proposed neuropsychological application of near-infrared spectroscopy (nIRS). *J Head Trauma Rehabil.* Oct 2002;17(5):477-488.	B
68	Zhang Q, Ma H, Nioka S, Chance B. Study of near infrared technology for intracranial hematoma detection. *J Biomed Opt.* 2000;5(2):206-213.	E1
69	Zheng L, Lee HS, Wilson DA, Hanley DF, Lokos S, Kim J. Experimental studies on brain hematoma detection and oxygenation monitoring using PRM/NIR sensors. Paper presented at: Proceedings of Optical Tomography and Spectroscopy of Tissue: Theory, Instrumentation, Model and Human Studies II1997; San Jose, CA.	E1

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 Patients admitted to hospital with neurologic symptoms possibly associated with head trauma or stroke	No NIRS done prior to CT	Unclear Not stated if CT was interpreted with knowledge of NIRS results	No Timing between scans unclear. All patients received CT and were included in analysis	Unclear
Hennes 1999[6]	No Patients with CT diagnosis of subdural hematoma	Unclear CT scan prior to NIRS, unclear if knowledge of CT scan results	No CT scan prior to NIRS	No CT scan “immediately” prior to NIRS. All but 1 patient received CT and included in analysis	Unclear
Kahraman 2006[7]	Yes Case-control design was used.	Unclear 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.	No CT was conducted before index test.	No All patients received CT.	Unclear
Kessel 2007[8]	No All patients with possible head injury mandating CT included during shifts when investigators worked	No NIRS conducted before reference standard	Unclear No mention of blinding to index test findings.	No All patients received CT.	Unclear 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

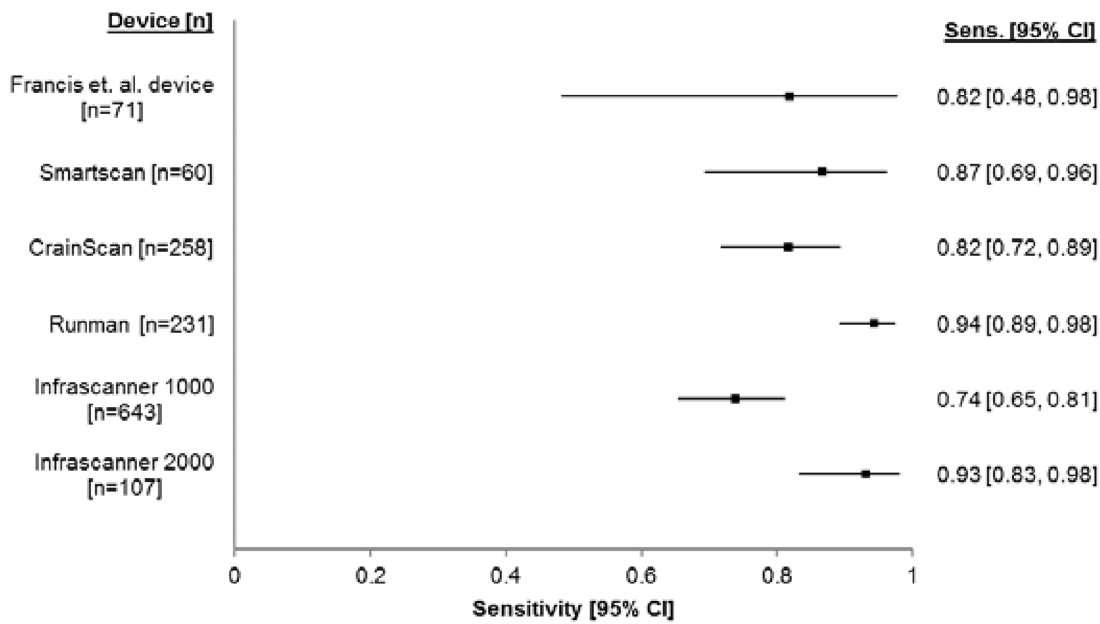
Strength of Evidence for Infrascanner 2000

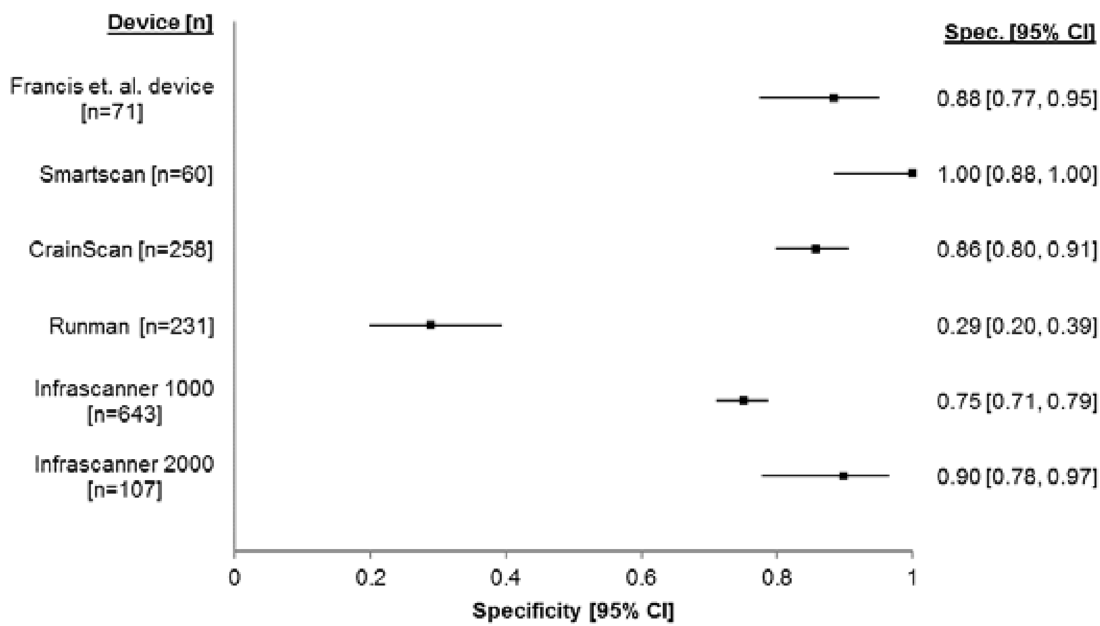
SOE Grade	Study Design: No. Studies (N)	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Sensitivity: Low	Cohort: 2 (N=107)[10,12]	Medium	Direct	Consistent	Imprecise	Undetected	None	Sensitivity = .93 (95% CI .83 to .98)
Specificity: Low	Cohort: 2 (N=107)[10,12]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

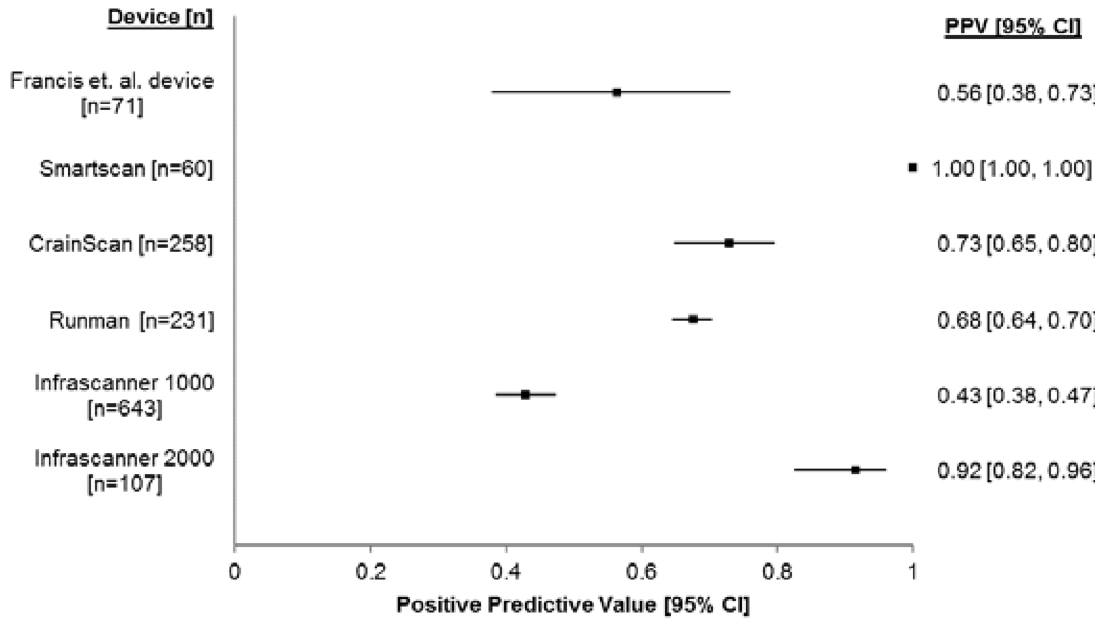
Strength of Evidence for Crainscan

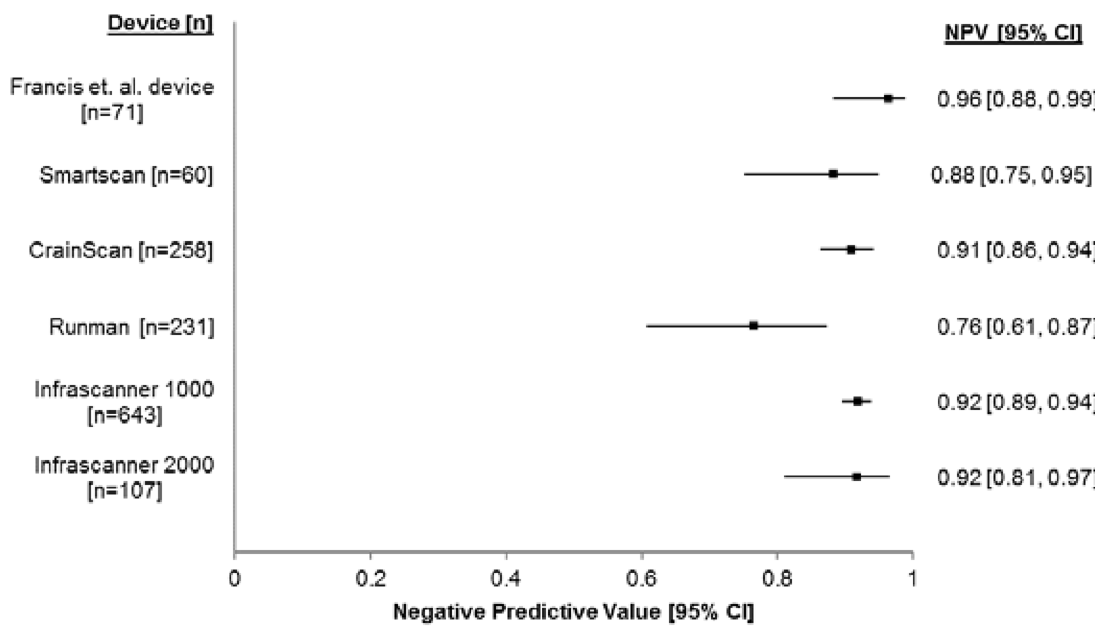
SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Sensitivity: Low	Cohort: 2 (N=258)[4,8]	Medium	Direct	Inconsistent	Imprecise	Undetected	None	Sensitivity = 0.82 (95% CI 0.72 to 0.89)
Specificity: Low	Cohort: 2 (N=258)[4,8]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

APPENDIX D: FOREST PLOTS






Device [n]
PPV [95% CI]
Francis et. al. device [n=71]
0.56 [0.38, 0.73]
Smartscan [n=60]
1.00 [1.00, 1.00]
CrainScan [n=258]
0.73 [0.65, 0.80]
Runman [n=231]
0.68 [0.64, 0.70]
Infrascanner 1000 [n=643]
0.43 [0.38, 0.47]
Infrascanner 2000 [n=107]
0.92 [0.82, 0.96]
0
0.2
0.4
0.6
0.8
1
Positive Predictive Value [95% CI]


Device [n]
NPV [95% CI]
Francis et. al. device [n=71]
0.96 [0.88, 0.99]
Smartscan [n=60]
0.88 [0.75, 0.95]
CrainScan [n=258]
0.91 [0.86, 0.94]
Runman [n=231]
0.76 [0.61, 0.87]
Infrascanner 1000 [n=643]
0.92 [0.89, 0.94]
Infrascanner 2000 [n=107]
0.92 [0.81, 0.97]
0
0.2
0.4
0.6
0.8
1
Negative Predictive Value [95% CI]

APPENDIX E: PERFORMANCE CHARACTERISTICS

Author Year N	Device	True Positive	False Positives	False Negatives	True Negatives
Hennes 1997[5] N= 212	Runman	117	64	5	26
Hennes 1999[6] N= 19	Runman	16	0	3	0
Francis 2005[3] N= 71	Developed by authors	9	7	2	53
Kahraman 2006[7] N= 60	Smartscan	26	0	4	30
Kessel 2007[8] N= 110	CrainScan	19	4	9	78
Ghalenoui 2008[4] N= 148	CrainScan	48	21	6	73
Coskun 2010[2] N= 92	Infrascanner 1000‡	7	52	1	32
Leon-Carrion 2010[9] N= 35	Infrascanner 1000	17	3	2	13
Robertson 2010[11] N= 365	Infrascanner 1000	66	25	30	244
Akyol 2016[1] N= 151	Infrascanner 1000	6	48	1	96
Peters 2017[10] N= 22	Infrascanner 2000	11	2	2	7
Xu 2017[12] N= 85	Infrascanner 2000	43	3	2	37

APPENDIX F: PEER REVIEW

Comment #	**Reviewer #**	**Comment**	***Author Response***
Are the objectives, scope, and methods for this review clearly described?			
1	1	Yes	*None*
2	2	Yes	*None*
3	3	Yes	*None*
4	4	Yes	*None*
5	5	Yes	
Is there any indication of bias in our synthesis of the evidence?			
6	1	No	*None*
7	2	No	*None*
8	3	No	*None*
9	4	No	*None*
10	5	No	*None*
Are there any published or unpublished studies that we may have overlooked?			
11	1	No	*None*
12	2	No	*None*
13	3	No	*None*
14	4	Yes - While for more mature technologies, the methodology described in the report is very reasonable, for newer technology such as the one described in this report, it means that most of the existing literature was excluded from the analysis: 1. The most comprehensive and informative study of NIR technology for brain hematoma detection, by Robertson et al (Robertson CS, Gopinath SP, Chance B. Use of near infrared spectroscopy to identify traumatic intracranial hematomas. J Biomed Opt. 1997;2(1):31-41.) was excluded. It includes a lot of basic clinical performance data, but not structured as sensitivity and specificity. This information can be derived by using the raw data of the study and the different detection thresholds published for mentioned devices (0.45 for Crainscan/Smartscan and 0.2 for Infrascanner models 1000 and 2000). However, without this analysis, the study was just excluded. 2. About half of the existing clinical studies published were in pediatric population and were excluded due to lower relevance for elderly population. 3. Substantial part of clinical research was done overseas, and while most of it was published in English, some good studies were excluded, such as Braun T, Kunz U, Schulz C, Lieber A, Willy C.	We have addressed our exclusion of the 1997 Robertson et al. study and similar earlier studies of NIRS in the "Summary and Clinical Implications" section of the report. Additionally, we agree that we excluded studies in pediatric populations that could be informative for a broader audience evaluating the use of NIRS in a range of clinical scenarios. We acknowledge that a limitation of our methods was exclusion of non-English studies in our search. However, we disagree that we excluded good studies because they were not published in English. Our search results included the German study by Braun et al., which is a feasibility study of NIRS among TBI patients in a military medical rescue center. The English abstract reported that the study assessed "practicability" and shows that NIRS is "easy to learn and can be repeatedly used", but did not report any performance characteristics, diagnostic or therapeutic impact, or patient outcomes. In addition to this study, we identified two other non-English studies. One (Kakihana 1995) was a study of NIRS in three patients examining cerebral oxygenation as the primary outcome

		Near-infrared spectroscopy for the detection of traumatic intracranial hemorrhage: Feasibility study in a German army field hospital in Afghanistan. Unfallchirurg. 2015;118(8):693-700.	and the other (Bein 2003) is described as an addendum and we suspect is a commentary. These are studies or articles that would not have contributed any relevant test performance or clinical outcome data even if published in English. We also hand searched reference lists and received a scientific information packet from Infrascan, Inc. which did not include studies that we had not otherwise identified.
15	5	No	*None*
Additional suggestions or comments can be provided below. If applicable, please indicate the page and line numbers from the draft report.			
16	1	There is no actionable information included since there is no published research on the device being used in the population of interest. It would be helpful to more thoroughly describe limitations in other imaging technology (such as high levels of radiation exposure from CT scans) and how this device may help address these limitations. I feel that this may be a helpful suggestion for the scientific community to guide future research.	We revised the text on page 7 to quantify the radiation dose associated with a head CT to include the line, "The radiation exposure associated with a head CT is equivalent to the radiation dose of 30 chest x-rays."
17	2	The findings are presented in a helpful and easy to understand way. I would suggest adding some information about the guidelines related to CT scanning - how often can you do it, how much radiation is used, how often nursing home residents are exposed to repeat CTs? This may help us better understand the problem that we are addressing.	Please see above regarding text revisions to quantify the radiation exposure associated with a head CT. We agree that understanding how often nursing home residents are exposed to repeat CTs would help evaluate the potential benefits of NIRS and have highlighted this issue is a gap in the current literature in the "Future Research" section with the line, "Another gap in the literature is better characterization of how many elderly patients with mild injuries after falls undergo CTs that are negative and therefore could have been avoided. Quantifying the rate of unnecessary CT use could strengthen the rationale for the use of NIRS as a tool to aid clinical decision-making for nursing home patients after falls."
18	3	Clearly stated objectives, sound methodology and clear results addressing the key questions. The repot overall is easy to follow. Addresses some of the main concerns	We have added cohort numbers to the forest plots.

		regarding false negatives and the potential impact of this. I agree with the conclusions regarding a large multi centre study to address the low incidence of intracranial haematomas. My only suggestion would be to add in cohort numbers to the forest plots. An interesting niche area of clinical practice where NIRS could be of potential benefit due to its portability and potential as a triage tool. As a triage tool NIRS has great potential but needs to be paired with clinical examination and used with caution due to the possible consequences of false negatives.	
19	4	The report didn't address the ability of NIR devices to scan patients periodically at or near the point of injury. The additional scans don't add cost or hazard to the patient and are key for detecting a delayed bleed or a development of initially harmless small bleed.	We agree with this point and highlighted this benefit of NIRS in the Background section on page 5 with the statement, "Handheld NIRS devices provide results within minutes, require minimal staff training, and do not expose patients to radiation. Because they are portable, handheld NIRS devices can be used in multiple settings, including nursing homes, and can be used repeatedly to monitor patients after falls without harms associated with the scan itself." As discussed above, serial NIRS exams have been evaluated as a monitoring tool in hospitalized TBI patients. It would be helpful to know how serial NIRS exams (rather than a single NIRS exam at the time of injury) perform as a monitoring tool in nursing home patients after falls. We added the following line to the "Future Research" section, "In addition to evaluating the use of a single NIRS scan as diagnostic tool at the time of injury, future studies should evaluate the performance of serial NIRS scans for monitoring nursing home patients after falls who are not transferred to the ED. NIRS can be performed repeatedly on the same patient without exposure to radiation or harms associated with the scan itself and results from a series of scans may prove to be

			more clinically useful than a single scan."
20	4	In studies results analysis and comparison, the report didn't address the size and the location of hematomas. For example, due to higher detection threshold the Crainscan studies included only subdural and epidural large hematomas. In contrast Robertson 2010 study included all hematoma depths and sizes. Hence, the comparison of sensitivity is like comparing apples and oranges: In Robertson 2010 study the sensitivity for all hematoma sizes was 69%, but was 88% for hematomas within the detection range of the device. Other studies included only analysis of hematomas within the detection range.	For studies that reported NIRS performance characteristics for a subset of hematoma types, we performed additional calculations for all hematoma types when possible. For example, although Kessel et al. reported sensitivity and specificity for epidural and subdural hematomas, we performed calculations for all types of intracranial hemorrhage and included this result in "Table 2: Performance Characteristics." We added information on hematoma type to the table so that these distinctions would be clear.
21	5	I found the Evidence Brief remarkably inclusive and detailed. As was pointed out in the Brief, most of the studies were completed on patients in the ED or hospital settings. Falls among the elderly are a frequent and major and hazard, prompting the Joint Commission to cite fall prevention as one of their National Patient Safety Goals. Use of the Infrascanner in the CLC and nursing home settings has many advantages, particularly when access to a CT scanner is limited. Its use can be expanded to assess those with unexplained mental status changes, also frequent among the elderly. Although, a cost savings analysis has not been formally performed, it could easily be imputed that the $9000 cost of the Infrascanner device would be easily recouped after a short period of use. The cost of ambulance transport is considerable as are repetitive CT scans. Patients can also be continually and closely monitored at pre-defined intervals when felt to be warranted, thus avoiding potentially unnecessary and excessive radiation exposure. I think a multicenter CLC pilot study with the Infrascanner would serve as an excellent scientific platform from which to determine the feasibility of its use across the VA enterprise.	*None*

REFERENCES

1. Akyol PY, Bayram B, Acerer A, et al. Comparison of near-infrared spectroscopy and head ct interpretations of the ed patients with minor head injury. *Am J Emerg Med.* Aug 2016;34(8):1364-1368.

2. Coskun F, Sezer EA, Karamercan MA, Akinci E, Vural K. An assessment on the use of infrascanner for the diagnosis of the brain hemotoma by using support vector machine. *Scientific Research and Essays.* 2010;5(14):1911-1915.

3. Francis SV, Ravindran G, Visvanathan K, Ganapathy K. Screening for unilateral intracranial abnormalities using near infrared spectroscopy: A preliminary report. *J Clin Neurosci.* Apr 2005;12(3):291-295.

4. Ghalenoui H, Saidi H, Azar M, Yahyavi ST, Borghei Razavi H, Khalatbari M. Near-infrared laser spectroscopy as a screening tool for detecting hematoma in patients with head trauma. *Prehospital Disaster Med.* Nov-Dec 2008;23(6):558-561.

5. Hennes HJ, Lott C, Windirsch M, et al. Non invasive detection of intracerebral hemorrhage using near infrared spectroscopy (nirs). *SPIE.* 1997;3194:42-54.

6. Hennes HJ, Richter B, Lott C, Dick W, Boor S, Hanley DF. Follow-up in patients with subdural haematomas using near infrared spectroscopy (nirs). *Proc SPIE Int Soc Opt Eng.* 1999;3566:182-192.

7. Kahraman S, Kayali H, Atabey C, Acar F, Gocmen S. The accuracy of near-infrared spectroscopy in detection of subdural and epidural hematomas. *J Trauma.* Dec 2006;61(6):1480-1483.

8. Kessel B, Jeroukhimov I, Ashkenazi I, et al. Early detection of life-threatening intracranial haemorrhage using a portable near-infrared spectroscopy device. *Injury.* Sep 2007;38(9):1065-1068.

9. Leon-Carrion J, Dominguez-Roldan JM, Leon-Dominguez U, Murillo-Cabezas F. The infrascanner, a handheld device for screening in situ for the presence of brain haematomas. *Brain Inj.* 2010;24(10):1193-1201.

10. Peters J, Van Wageningen B, Hoogerwerf N, Tan E. Near-infrared spectroscopy: A promising prehospital tool for management of traumatic brain injury. *Prehospital Disaster Med.* 2017:1-5.

11. Robertson CS, Zager EL, Narayan RK, et al. Clinical evaluation of a portable near-infrared device for detection of traumatic intracranial hematomas. *Journal of Neurotrauma.* Sep 2010;27(9):1597-1604.

12. Xu L, Tao X, Liu W, et al. Portable near-infrared rapid detection of intracranial hemorrhage in chinese population. *J Clin Neurosci.* 2017;26.

13. Brogan RJ, Kontojannis V, Garara B, Marcus HJ, Wilson MH. Near-infrared spectroscopy (nirs) to detect traumatic intracranial haematoma: A systematic review and meta-analysis. *Brain Inj.* 2017;31(5):581-588.