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Are there any published or unpublished studies that we may have overlooked?			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 intracranical 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*