Austere, Pre-Transport, Qualitative Clinical Testing

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14. ABSTRACT

It is not clear how well present or near-term medical technologies may align with critical physiological supportive measures that would increase early caregiver prognostic confidence at point-of-care.

In this study, we sought to address the following clinical question: What light-weight, compact, easily usable prehospital testing can be used to assist medical personnel and combat medics in determining triage, the need for rapid evacuation, the need for blood product administration, and other medical interventions?

The purpose of this project was to 1) conduct a thorough scoping review and a scientific market survey of present and near-term diagnostic technologies for adaptation to rigorous care environments and 2) evaluate the clinical priorities of candidate measures for various trauma and injury scenarios.

Methods: We gathered information about present and near term technologies in several ways. Team members who attended professional meetings visited vendors to observe technology demonstrations. Further, a computer-aided search of MEDLINE, the Cochrane Database of Systematic Reviews, and EMBASE was conducted through the OVID SP Web site. We queried PubMed using the same strategy. In addition, a search of Google scholar was conducted. We selected two technologies on which to conduct a thorough review of available evidence: point-of-care ultrasound (POCUS), and noninvasive hemoglobin (NIHB) monitoring.

Conclusions:
The body of evidence related to the use of POCUS by military medics is limited, but does provide proof of concept. More research with larger sample sizes and evaluation of patient outcomes is needed. The value of POCUS in austere environments has been demonstrated and could significantly impact care in the prehospital combat setting.
Most of the evidence related to the clinical accuracy of NIHb monitoring does not support its utility in combat casualty care. Studies recommend caution when using results for clinical decision-making.
However, there is limited evidence to support spot-check NIHb monitoring may be more accurate in some patients. More research is warranted to evaluate the use of spot check technology in combat casualty care.

15. SUBJECT TERMS- diagnostic technology, prehospital assessment, prehospital triage

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TABLE OF CONTENTS

1.0 EXECUTIVE SUMMARY

Point-of-care ultrasound (POCUS): POCUS offers multiple capabilities to military clinicians in multiple environments, in a relatively small, lightweight device. Its application in diagnostics, procedural guidance, and patient monitoring has not been fully explored by the Military Health System (MHS). The purpose of this narrative review of literature was to examine the current use and training provided for the use of POCUS in military settings.

Studies related to the use of POCUS by military clinicians, with reported sensitivity/specificity, accuracy of exam, and/or clinical decision impact met inclusion criteria. After initial topical review and removal of duplicates, two authors selected 17 papers for inclusion consideration. Those 17 articles were reviewed by four of the authors, and 14 were selected for inclusion in this review. Authors excluded reports that did not report sensitivity/specificity, accuracy of exam, and/or clinical decision impact, as well as literature reviews.

We identified seven prospective studies, three of which randomized subjects to groups. Five reports described use of POCUS in patients; two used healthy volunteers; two were in simulation training environments; three used animal models to simulate specific conditions; and one used a cadaver model. The number of clinician subjects in the studies ranged from one to 34. Conventional medics were subjects in five studies and four studies included special operations medics. One study included non-medical food service inspectors. The use of ultrasound in theater by deployed consultant radiologists is described in three reports.

Military clinicians demonstrated the ability to perform focused exams, including the Focused Assessment with Sonography for Trauma (FAST) exams and fracture detection with acceptable sensitivity and specificity. POCUS in the hands of trained military clinicians has the potential to improve diagnostic accuracy and ultimately care of the war fighter.

Noninvasive hemoglobin (NIHb) monitors: Traditional invasive measurement of Hemoglobin (Hb) is time-consuming, costly, and painful for the patient, and can pose a biohazard risk. The critically ill trauma patient may require frequent laboratory draws for Hb as a part of the ongoing assessment to determine the need for blood products or operative intervention. There are risks associated with both under- and over- transfusion of blood products, and an accurate continuous measurement of Hb may help avoid these extremes.[1] **NIHb monitors** provide both continuous and intermittent readings. For NIHb to be clinically relevant, it needs to be highly accurate at measuring blood Hb concentrations between 6 and 10 g/dL. NIHb monitoring tends to overestimate the true Hb concentration when Hb is low.[1,2] The purpose of this review was to summarize findings of studies comparing NIHb monitor readings to standard invasive methods of measuring Hb.

We reviewed 218 studies published since 2014, and included 19 studies comparing NIHb to laboratory Hb (LabHb), or co-oximetry Hb (CoOxHb). The summary results from three literature reviews[3,4,7] were also included in the report. One study of 70 adult trauma patients with major hemorrhage (Hb < 8g/dL) reported overall accuracy of the continuous NIHb monitor.[13] Results of nine studies evaluating continuous NIHb monitors did not demonstrate adequate accuracy for clinical decision making.[8,9,11,16,19,20,21,23,25] Continuous NIHb monitoring may have promise as trend monitor and use as indicator to check LabHb[8,13,14] Spot check devices may have more potential for clinical utility; however, they tend to overestimate Hb when values are < 11g/dL.[10,17,22,24] Continuous NIHb accuracy was decreased in patients with anemia[24] and spot-check NIHb was not accurate in patients with impaired peripheral perfusion.[18]

Most of the evidence related to the clinical accuracy of NIHb monitoring does not support its utility in combat casualty care. Studies recommend caution when using results for clinical decision-making. However, there is limited evidence to support that spot-check NIHb monitoring may be more accurate in some patients. More research is warranted to evaluate the use of spot-check technology in combat casualty care.

2.0 INTRODUCTION

Point-of-care ultrasound (POCUS): Ultrasound technology has the potential to improve diagnostic accuracy and enhance patient care in the emergency medicine and prehospital austere settings.[6,7,11,12] Diagnostic capabilities in the combat setting may be limited without access to X-ray or computed tomography (CT). Portable ultrasound can be used from point of injury forward to provide support for clinical decision making by military clinicians. The Defense Advanced Research Project Administration (DARPA) awarded a grant for the development of a portable ultrasound for battlefield use in 1996. SonoSite (formerly SonoSight) collaborated with the University of Washington to develop one of the first handheld ultrasound devices. Subsequently, several other companies began making portable ultrasound devices for civilian use.[13]

Rozanski et al.[14] describe the early use of the SonoSite 180 Plus by the US Army's 21st Combat Support Hospital (CSH) North facility in northern Iraq over a six month period. Multiple physician specialties performed 401 exams effectively and efficiently. The most common exam types were renal (n=174), FAST (n=69), nontrauma abdominal (n=44), and obstetric (n=40). They found the device to be versatile and reliable with clear and interpretable imaging. The use of portable ultrasound increased local diagnostic capabilities, decreased unnecessary evacuation and was considered greatly beneficial to the far forward-deployed CSH.[14] In 2011, the Joint Special Operations Medical Training Center (JSOMTC) began to incorporate a 24-hour ultrasound curriculum (Special Operator Level Clinical Ultrasound [SOLCUS] training) with didactic and hands-on training for special operations medics.[16] The Special Operations Medical Community values ultrasound as a diagnostic tool, and emphasizes the potential role of POCUS in prolonged field care.[16]

POCUS offers multiple capabilities in a relatively small, lightweight device to military clinicians of all types, and levels in multiple environments. Its application in diagnostics, procedural guidance, and patient monitoring has not been fully explored by the MHS.

Noninvasive hemoglobin (NIHb) monitors: One of the most common laboratory tests ordered in the injured patient is hemoglobin (Hb). Traditional invasive measurement of Hb is time-consuming, costly, and painful for the patient, and can pose a biohazard risk. The critically ill trauma patient may require frequent laboratory draws for Hb as a part of the ongoing assessment to determine the need for blood products or operative intervention. There are risks associated with both under- and over- transfusion of blood products, and an accurate continuous measurement of Hb may help avoid these extremes.[1] In the combat setting, blood product availability may be limited and require triage for allocation.

Non-invasive Hb (NIHb) monitors rely on spectrophotometry (light reflection) or photoplethsmography (volume changes) to calculate Hb and hematocrit. Some monitors provide continuous readings and others are used intermittently.[1] The accuracy of NIHb monitoring is impacted by Hb concentration and peripheral perfusion. For NIHb to be clinically relevant, it needs to be highly accurate at blood Hb concentrations between 6 and 10 g/dL. NIHb monitoring tends to overestimate the true Hb concentration when Hb is low. Inadequate accuracy of NIHb can also occur in patients receiving vasopressors or with other causes of decreased peripheral perfusion.[1,2] At the time of these published reviews[2-4] there was limited evidence related to the trending ability of NIHb monitoring.[2]

Masimo Technologies (Irvine, CA) is the primary source for NIHb monitors. Most studies included in current scientific reviews and in this report use one or more of Masimo Technologies brand devices. These devices provide the option for continuous and intermittent readings, and an upgrade including nine total parameters is available. See appendix for product brochures.[5]

Most of the evidence related to the clinical accuracy of NIHb monitoring does not support its utility in combat casualty care. Studies recommend caution when using results for clinical decision-making. However, there is limited evidence to support spot check NIHb monitoring may be more accurate in some patients. More research is warranted to evaluate the use of spot check technology in combat casualty care.

3.0 METHODS, ASSUMPTIONS AND PROCEDURES

We searched PubMed, Cochrane, Scopus, Web of Science, and the Defense Technical Information Center (DTIC) databases using the following key terms: "military" + "ultrasound" and "noninvasive" + "hemoglobin." Team members reviewed studies to determine inclusion. Results are summarized in text and presented in table format. The results related to POCUS have been presented in a technical report format (submitted to DTIC) and manuscript for publication in the Journal of Special Operations Medicine. The results related to NIHb will be submitted to DTIC in technical report format. There are no plans to submit a manuscript for these findings.

4.0 MAJOR EVENTS/MILESTONES/SUCCESS

In preparation for the execution of this project,

- IRB/IACUC Approval – 2/18
- All experimental procedures completed – 1/19
- Data Analysis – 08/19
- Poster presentation – SURF June 2020
- Manuscript submitted to – JSOM in press
- Dissemination of Results – 03/21

5.0 RISK ASSESSMENT

5.1 Risk Analysis:

This project involved compiling and analyzing previously published data with no link to human subjects and received a non-human research determination from the IRB.

5.2 Technical Challenges

The project required an extensive literature search and market search to identify the most pertinent technologies to the research question. There was a significant amount of results/data to manage and filter through; accordingly our greatest technical challenge was narrowing the search and selecting the technologies for inclusion.

6.0 TRANSITION PLAN

6.1 Military Relevance

Identification of usable prehospital testing that can assist medical personnel and combat medics in determining triage, the need for rapid evacuation, the need for blood product administration, and the need for other medical interventions and therapies can contribute to improved patient outcomes.

6.2 Transition Strategy

The results have been disseminated to the following:

1. The research community through national civilian and military academic conferences, and meetings;
2. Completed manuscripts submitted to peer-reviewed journals for publication;
3. The Defense Technical Information Center (DTIC) for publishing on their website;
4. 4. Appropriate military leadership and training agencies.

7.0 RESULTS

Point of Care Ultrasound (POCUS)	Non-invasive Hemoglobin (NIHB) Monitoring - SpHb
Studies related to use of POCUS by military clinicians, with reported sensitivity, specificity, accuracy of exam, and/or clinical decision impact met inclusion criteria. After initial topical review, and removal of duplicates, two authors reviewed 40 full-text publications and selected 17 papers for inclusion consideration. Four of the authors reviewed the 17 papers and determined the final inclusion of 14 studies. Authors excluded reports that did not report sensitivity/specificity, accuracy of exam, and/or clinical decision impact, as well as literature reviews.	**Reviews** Kim et al. 2014:[3] Review of studies assessing the accuracy of NIHb monitoring against central laboratory measurements. Thirty-two studies (4425 subjects, sample size ranged from 10 to 569 patients per study; median sample size of 44) were included in this meta-analysis. Conclusion: "Although the mean difference between noninvasive Hb and central laboratory measurements was small, the wide limits of agreement (LOA) mean clinicians should be cautious when making clinical decisions based on these devices." Hiscock et al. 2015:[4] Review of method comparison studies assessing agreement in Hb between either Masimo Radical-7 (continuous) or Pronto-7 (intermittent) readings, or HemoCue (capillary) and laboratory determination. Twenty-four articles (2011-2014) comparing Masimo NIHb monitors to laboratory determinations were included. The overall pooled mean difference (device versus laboratory) was -0.03 g/dL (95% prediction interval -0.30 to 0.23), SD 1.42 g/dL and associated 95% LOA -3.0 to 2.9 g/dL. For Masimo devices, both within subgroup and overall, 95% LOA are wide, approximately ±3 g/dl. Conclusion: "Clinicians should carefully consider these LOA before basing transfusion or other clinical decisions on these POC measurements alone."4 Shabaninejad et al. 2019[7]: Meta-analysis to compare the invasive and noninvasive measurements of Hb during surgery. Twenty-eight studies were included in the meta-analysis. The overall mean difference between NIHb and the laboratory Hb measurements was -0.27 g/dL (95% LOA -0.44, -0.10); $p < 0.05$), indicating a slight negative bias for NIHb measurements included in the Kim et al.[3] review and 11 (39%) were included in the Hiscock et al.[4] review. Conclusion: "Our meta-analysis showed that with a conservative point of view, regarding an acceptable agreement between invasive and noninvasive

	Hb measurements, based on clinical significance 1 g/dL, the clinician after first completing Hb assessment by both methods can follow the trend of variations in Hb using the noninvasive method.”
Training For five of the studies included,[21,22,24,25,32] training ranged from three to 25 minutes and included a brief lecture or slide show, followed by hands-on practice. Five studies[19,20,24,28,29] reported training ranging from 90 minutes to four hours that also included didactic instruction followed by hands-on practice. One study reported results after completion of the SOLCUS course by special operations medics. Participants attended various components (8 to 52 hours, mean of 16.7 hours) of the SOLCUS training prior to deployment.[27] With the exception of the three reports[30-32] on radiologists, all participants had little to no prior ultrasound experience. These studies demonstrate the ability of ultrasound naïve clinicians to successfully perform specific ultrasound exams with minimal training and practice.	**Recent Studies (2014-2020)** • Most studies tested the Rad7 Masimo continuous NIHb monitor.[8,9,11,13,14,15,18-20,23,25] • Five studies tested the Pronto-7 or Rad-57 Masimo hand-held spot check NIHb monitors.[10,12,17,22,24] • One study evaluated the NBM-200 monitor.[6]
Utilization by Military Medics and Other Non-physicians Conventional Army Medics were the subjects of four prospective studies[19-21,23] The medics in these studies had no prior experience or training with ultrasound. After completion of a 4-hour Extended FAST (EFAST) training, when compared to emergency medicine residents, medics took longer to complete the EFAST exam (532 vs. 227 seconds); but had similar diagnostic accuracy when comparing sensitivity (Medics 88-95%, Residents 92-95%).[19] Twenty-eight medics completed a 2-hour training and identified foreign bodies in a soft tissue model with sensitivities of 73% and 78% (size dependent), and specificity of 78%.[20] A cadaver model was used to evaluate the ability of medics to detect endotracheal tube placement after a 15-minute lecture and hands-on practice. Cadavers were randomly assigned to esophageal or tracheal tube placement for 32 participants. In an average time of 47.3 seconds, medics correctly identified tracheal placement at a rate of 72% and esophageal placement at 71%.[21] Twenty-two medics and physician assistants (number of each not specified) achieved a sensitivity of 99.2%, specificity of 95.5%, with an accuracy of 97.7% when evaluating abscesses in a tissue model.[23] Backlund et al.[22] conducted a pilot study to assess the ability of 12 Army National Guard medics to determine cardiac activity in healthy volunteers, after a 5-minute lecture and brief hands-on training. In this pilot study, 92% of the exams accurately documented the	• One study of 70 adult trauma patients with major hemorrhage (Hb < 8g/dL) reported overall accuracy of continuous NIHb monitor.[15] • Three[12,17,18] of the 19 studies reported data from pediatric patients; eight studies[15,16,19-21,22,25] included adult trauma patients, of which one[19] reported data on combat casualties; six studies included patients undergoing major surgery with anticipated blood loss.[8-11, 13,14] • Failure to detect rates (reported by 9 studies[10,12,15-18,22,24,25]) ranged from 0.01 to 29%, with 5 studies[12,15,16,22,25] reporting failure rates > 10%. • Four of the studies[15,16,22,25] reporting the highest detection failure rates were of adult ED/trauma/ICU patients with active or suspected hemorrhage.

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<td>presence of cardiac activity with a mean time to completion of 5.5 seconds.[22]

Two early publications report the ability of special operations medics to detect fracture in a simulated model,[26] and in four report the ability to detect fracture in human cases.[27] Twenty Army SOF medics with minimal to no previous US experience completed a 3-minute training, and correctly identified presence or absence of long bone fracture in a simulated model (Sensitivity 100%, Specificity 90%).[26] US Army Special Forces medics deployed to Afghanistan evaluated 109 patients using POCUS, after completion of an average of 16.7 hours training in the SOLCUS curriculum. Medics applied their SOLCUS training in four cases, and in all cases they correctly diagnosed fractures (femur, distal fibular, phalanx, tibial) which were later confirmed by X-ray.[27] In a prospective study,[25] 23 special operations medic trainees underwent training to measure the optic nerve sheath diameter (ONSD) in healthy volunteers and compared their measurements to those of emergency medicine physicians. After undergoing a 5-minute lecture and demonstration, medic trainees reported similar measurements in comparison to emergency medicine physicians (mean physician = 0.465mm vs. mean trainees = 0.459 mm, $p = 0.76$).[25]

Twenty-two physician assistants, special operations and conventional medics, veterinary technicians, and food service inspectors (numbers of each group not specified) were able to accurately detect pneumothorax in a porcine model after a 10-minute slide show and brief orientation to US equipment. These US naïve participants correctly identified 21 of 22 pneumothoraces achieving a sensitivity of 95.5% and a specificity of 100%.[24]</td>
<td>The results vary among studies (See table for specific values).

• Results of 9 studies evaluating continuous NIHb monitors did not demonstrate adequate accuracy for clinical decision making.[8,9,11,16,19-21,23,25]
• Continuous NIHb monitoring may have promise as trend monitor and use as indicator to check Lab-Hb.[8,13,14]
• Spot check devices may have more potential for clinical utility; however, they tend to overestimate Hb when values are < 11g/dL.[10,17,22,24]
• Continuous NIHb accuracy was decreased in patients with anemia[24] and spot-check NIHb was not accurate in patients with impaired peripheral perfusion.[18]

Overall, reports of correlations between Lab Hb and NIHb ranged from moderate to very strong ($r = 0.69$ to 0.94), [11,13-18,22] indicating NIHb measurements were similar to laboratory methods. Differences between NIHb and Lab-Hb measurements do raise concern, with LOAs ranging from approximately ±1 to ±4 g/dL across studies.[12,14,19,23,25] Such wide ranges indicate there is relatively small to large discrepancies between methods. These results necessitate using caution when making clinical decisions based on NIHb monitoring.</td>
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<td>Utilization by Military Physicians
Five studies[28-32] reported physician use of POCUS: one simulation study,[29] one in-garrison,[28] and three reports of the use of ultrasound in the combat setting[30-32]. Fifteen trainee physicians completed a 2-hour ultrasound course and were provided US devices to use at will, in a simulated combat setting. The participants performed EFAST/POCUS on 44 of 168 (26%) simulated patients and in 51% of US cases there was a significant impact on therapeutic and evacuation priorities. Therapeutic decisions changed in 67%</td>
<td>Note: The most accepted analysis to compare two quantitative measures is the Bland-Altman, which quantifies agreement or difference between two measures by studying the mean difference and constructing limits of agreement. It analyzes data sets; ideally, measures taken from the patient simultaneously. In studies comparing SpHb results to LabHb, the reported limits of agreements tell you how different the SpHb is from the LabHb. From a statistics viewpoint - 95% of the data points should lie within ± 2s (SDs) of the mean difference. From a clinical perspective for hemoglobin,</td>
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</table>

of cases and evacuation priorities in 72% of cases.[29] Two military medicine residents performed POCUS on 48 patients in a French Army teaching hospital. POCUS improved diagnostic accuracy in 73% of cases.[28] Two studies[31,32] reported the use of POCUS by radiologists, for 585 exams at a Role 3 MTF in Afghanistan. The reported FAST sensitivity was 56 and 75%; however, specificity reached 98 and 99%, with overall accuracy of 89 and 94.4%.[31,32] A prospective six-month survey of a consultant radiologist in a Role 2 MTF, where CT capability was not available, found POCUS increased diagnostic confidence in 68% of cases and led to change in patient management in 29% of cases.[30]	most sources reference the value of 1 g/dL as the significant threshold between methods. As we review studies we would like to see the limits of agreement between -1 and 1. In other words, noninvasive Hb should not under- or over -estimate the LabHb by more than 1g/dL in 95% of data pairs.

8.0 CONCLUSION/DISCUSSION

POCUS	NIHb - SpHb
With minimal training, conventional medics can achieve acceptable sensitivity and specificity in FAST exams and in fracture detection. However, we found no published reports related to retention of knowledge and ability. Conventional medics demonstrated less accuracy in the detection of foreign bodies, and confirmation of airway placement. Army Special Forces medics receive extensive training in POCUS, however only one study reported sensitivity (100%) and specificity (90%) in a simulated fracture model. Only two of five studies with physician subjects reported specificity and sensitivity. Military physicians report increased accuracy, and confidence in diagnoses, as well as impact on patient management. In-theater radiologists demonstrated an overall accuracy in FAST exams of 89 to 99% (specificity 98 to 99%); however, sensitivity was only 56 to 75%.[30,31] The findings of our review specific to military clinicians are similar to previous civilian literature reviews. Overall higher specificity verses sensitivity add support to the finding that POCUS has more utility in ruling in than ruling out specific conditions. The use of POCUS in the deployed setting has not been fully explored; however, the growing evidence in support of its utility warrants ongoing study. Research needs to address which applications have the most potential to improve outcomes in combat casualty care. Training guidelines and standards should be established to determine optimal course content, length, delivery method, and the minimum number of scans for each type to achieve competence. Evidence supports the idea that image acquisition and interpretation can be taught to medical novices; however, clinical background is important for appropriate patient management.[6] Future research should consider strategies to prevent skill decay and promote knowledge retention. Research to consider the role telemedicine can play to support prehospital POCUS, the logistics of image transmission and communication with higher-level providers is warranted. More research to determine sensitivity and specificity of various POCUS applications in the	**Conclusions** • Most of the evidence related to the clinical accuracy of NIHb monitoring does not support its utility in combat casualty care. Studies recommend caution when using results for clinical decision-making. • However, there is limited evidence to support the claim that spot-check NIHb monitoring may be more accurate in some patients. More research is warranted to evaluate the use of spot-check technology in combat casualty care. • Masimo Technologies (Irvine, CA) offers the most tested and somewhat empirically tested devices. • NIHb has poor accuracy in patients with decreased peripheral perfusion secondary to hemorrhagic shock and should not be used in such cases. This caveat significantly limits the efficacy of NIHb in combat environments. • Given that the MHS is facing the potential of prolonged field care scenarios in resource limited, austere combat environments, further research and consideration of the newest model Rad-67TM Pulse Co-Oximeter (Masimo SET® Combined with Next Generation SpHb Spot-check Monitoring Technology) is reasonable. See appendix for product information.

hands of military clinicians will inform best practices related to POCUS. Further investigation into which ultrasound machine is best suited for the combat environment is required. Portable ultrasound is lightweight, easy to carry, and has minimal power requirements when compared to portable x-ray, therefore increasing its utility in austere environments.[26] However, it is important to plan for anticipated conditions in the austere and resource constrained combat theater. Considerations for device selection include: performance at high altitudes, function in extreme temperatures, protection from moisture; ultrasound gel supply, storage, and response to extreme temperatures; battery life, condition, and supply; and overall ruggedness, and ability to withstand extreme conditions. SonoSite developed the first handheld device used by the military and the SonoSite M-Turbo was the most common device reported in the studies we reviewed. There are other devices (See Table 2) with potential utility in combat care. The end-users should be consulted to determine desired device characteristics. Forty combat medics compared a novel US finger transducer to a conventional transducer in a simulation study.[35] Diagnostic accuracy was similar between transducers, however the mean completion times were better with the conventional transducer (304 vs. 358 s; P = 0.03). In addition, the medics scored the conventional transducer higher for ease of use.[35] Additional research comparing available technology needs to be conducted. **Conclusion** Military clinicians demonstrated the ability to perform focused exams, including FAST exams and fracture detection with acceptable sensitivity and specificity. In the hands of trained military clinicians, POCUS has the potential to improve diagnostic accuracy and ultimately care for the war fighter.	

9.0 DELIVERABLES

9.1 Publications:

Savell SC, Baldwin DS, Blessing A, Medellin KL, Maddry JK. Military Use of Point of Care Ultrasound (POCUS). JSOM in press.

Technical Report - Savell SC, Baldwin DS, Blessing A, Maddry JK. Summary Report of Data Related to the Use of Noninvasive Hemoglobin Monitors

9.2 Presentations:

Poster - San Antonio Universities and Military Research Forum (SURF), June 2020.
Poster - 2020 Special Operations Medical Association Scientific Assembly.
Poster – 2020 Tri-Service Nursing Research Program Dissemination Course
Sept. 24 2020 - Joint Trauma System Weekly Case Presentation

10.0 COST

This work was funded by a JPC award. Total funding awarded for this Project Code Number J917EC0 in the amount of $350,000.00 were expended by 30 Sep 2020.

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POCUS

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NIHb

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FIGURES AND TABLES:

POCUS

Table 1: Reports of Military Use of Ultrasound

Reference	**Study Type & Aim**	**Subjects**	**Device**	**Training/ Intervention**	**Results**	**Conclusions**	**LOE** Level of Evidence
Monti et al.[19] 2020	Prospective, randomized, cohort study in the Medical Simulation Training Center at Joint Base Lewis McChord. The primary objective was to assess the impact of a 4-hour introductory training intervention on ultrasound-naïve military medic participants' knowledge/performance of the eFAST application.	34 Army medics naïve to US	Fukuda Denshi USA device with phased array (2-5 MHz) & linear array (5-12 MHz) transducer	Participants were randomized to receive either conventional, expert-led classroom didactic training or didactic training via an online, asynchronously available platform. Medic Cohorts: 1) 90-minute classroom didactic & 150 minutes hands-on scanning instruction (n=19)	50 question knowledge assessment pre/post Medic overall knowledge increased from 27 to 83%. EM residents score 92%. There was no statically significant difference in knowledge, technical performance, or diagnostic accuracy between groups. The medics took more than double the time to complete the exams compared to EM residents (532 vs. 227 seconds). Hemoperitoneum Present Sensitivity: Medics 95%; EM residents 93%. Hemoperitoneum Absent specificity:	A 4-hour introductory eFAST training intervention can effectively train conventional military medics to perform the eFAST exam.	2

				2) 90-minute video from SonoSim & 150 minutes hands-on scanning instruction (n=15)	Medics 90%; EM resident 95%. Hemopericardium Present Sensitivity: Medics 88%; EM Residents 92%. Hemopericardium Absent Specificity: Medics 60%; EM residents 100%.		
Driskell et al. [20]2018	Prospective, single blinded, observational simulation to determine army medics' accuracy performing bedside US to detect radiolucent foreign bodies (FBs) in a soft-tissue hand model.	28 Army medics naïve to US	SonoSite M-Turbo with 13-6 MHz linear transducer	1 hour didactic & 1 hour hands-on training, used chicken model, each medic was presented with 20 randomized models.	< 2 mm FB: Sensitivity 73%, Specificity 78% ≥ 2 mm FB: Sensitivity 78%, Specificity 78%	Army medics can detect FBs in tissue models with similar sensitivities and specificities as radiologists and emergency medicine physicians in similar studies.	2
Hanlin et al. [21] 2018	Prospective randomized trial to determine ability to detect endotracheal tube placement in a fresh human cadaver model.	32 Army Medics, recently completed EMT- B certification, enrolled in flight paramedic training	SonoSite M-Turbo with a 10-5 linear transducer	15-minute lecture on transtracheal US techniques, followed by hands-on practice	Sensitivity 66.7%, Specificity 76.4% Average time 47.3 seconds Correctly identified 13/18 tracheal placements & 10/14 esophageal placements	Trainees were moderately accurate when using transtracheal US to identify ETT placement after a short educational session.	2
Backlund et al. [22] 2010	Pilot study to assess ability of combat medics to perform a limited bedside	12 Army National Guard combat medics	Not specified	Received 5 -min. lecture and brief	44 of 48 (92%) exams accurately documented presence of cardiac	With minimal training, the majority of the	3

	echocardiography (BE) to determine cardiac activity in healthy volunteers.	trained to level of EMT-B		hands-on training.	activity. Median time to completion – 5.5 seconds	medics were able to rapidly perform a focused BE on live models that was adequate to assess for the presence of cardiac activity.	
LaDuke et al.[23] 2017	Single-blinded, randomized, prospective observational study to determine if non-physician military providers could use US to detect superficial abscesses in chicken tissue models.	22 US Army medics & PAs with minimal to no prior US training	SonoSite X-Porte or SonoSite M-Turbo	Attended 30-min. didactic session, followed by hands-on training	Performed 220 clinical exams & 220 US scans. US - Sensitivity 99.2%, Specificity 95.5%, Accuracy 97.7% Clinical exam - Sensitivity 73.5%, Specificity 77.2%, Accuracy 75%	With brief US training, non-physician military medical providers can accurately detect superficial abscesses in tissue models.	2
Monti et al. [24] 2009	Descriptive study to examine the potential for non-physician providers to determine the absence or presence of a pneumothorax in a porcine model, with the use of a portable ultrasound machine, after receiving minimal training.	22 participants (PAs, SOF & conventional force medics, veterinary technicians & food service inspectors) with no prior ultrasound training	SonoSite Vet (SonoSite 180 equivalen t) with 10-5MHz linear transduce r	Received 10-minute slide show training & orientation to ultrasound machine.	Sensitivity was 95.4% Specificity was 100% 21 of 22 pneumothoraces were correctly identified.	Non-physician healthcare providers can accurately detect a pneumothorax with portable ultrasound after receiving minimal focused training.	3
Betcher et al.[25] 2018	Proof of concept descriptive study to evaluate military trainees' ability to measure the optic nerve sheath	23 SOCM trainees during emergency medicine	Mindray® M7	5-minute lecture, followed by demonstration	Compared trainee measurements to those of EM physicians:	This study demonstrates that optic nerve sheath diameter	3

	diameter (ONSD) in healthy volunteers.	rotation with minimal prior training in US.		& 20-minute practice	$M_{physician}$ = 0.465mm vs. $M_{trainees}$ = 0.459 mm, P =0.76.	measurement can be accurately performed by novice ultrasonographers after a brief training session.	
Heiner et al. [26] 2010	Descriptive study - simulation to evaluate the ability of 18Ds to detect the presence of long bone fracture.	20 Army Special Forces (18Ds), had no or minimal prior use of ultrasound	SonoSite M-Turbo with 10-5 MHz transducer head	Received 3-min. orientation and training.	Sensitivity 100% Specificity 90% 5 fracture models (turkey legs) - 1 no fracture, 4 different fracture types	Using a portable ultrasound device, 18Ds were able to correctly detect the presence or absence of a simulated long bone fracture with a high degree of sensitivity and specificity.	3
Vasios et al. [27] 2010	Case Study to describe the use of portable US by 18Ds for fracture detection.	29 US Army Special Forces (18Ds) – 1st Battalion, 3rd Special Forces Group (Airborne) SFG(A) deployed to Afghanistan. 109 pts evaluated with ultrasound, 39 were musculoskeletal	Not specified	Received an average of 16.7 hours training using SOLCUS outline. Included FAST exam, pneumothorax detection & musculoskeletal exam.	4 cases presented – in all cases the medic correctly diagnosed fractures with ultrasound that were later confirmed by x-ray.	Hi-lights the potential role of the SOLCUS and the use of US by Special Operations Medics.	4

Perrier et al.[28] 2019	Prospective study to evaluate the usefulness of point-of-care ultrasound (POCUS) performed by young military medicine residents after short practical training in the diagnosis of medical emergencies.	2 military medicine residents in a French Army teaching hospital March 2015 – March 2016.	SonoSite M-Turbo	Received a 90 minute theoretical and practical (10 US in healthy students, 50 US in patients with symptoms, observed by trainer) US training focused on the gall bladder, kidney & upper urinary tract & the deep venous network of the lower extremities.	Did not report sensitivity & specificity. 48 patients had ultrasounds, 18 gall- bladder, 16 renal, 14 lower extremity. POCUS improved diagnostic accuracy in 73% of cases, was misleading in 2% and did not contribute to 25%.	POCUS performed after clinical examination increases the diagnostic accuracy of young military medicine residents.	4
Renard et al.[29] 2019	Prospective observational pilot study to evaluate whether the implementation of E-FAST was possible in conditions close to combat and if it changed the therapeutic and evacuation strategies.	15 trainee doctors during French pre-deployment simulation training	Vscan (GE)	MEDICHOS (medical courses in hostile environments) internship November 2017, March and June 2018; 2 hour training on the	eFAST or POCUS exams performed on 44 of 168 (26%) simulated patients. 51% of US cases had a significant impact of therapeutic and evacuation priorities, it changed therapeutic decisions in 67% of time and	US on the simulated battlefield was possible and useful.	4

				use of the Vscan & US devices were provided, trainees to use their discretion.	evacuation priorities in 72% of time		
Sellon et al.[30] 2019	Prospective questionnaire-based (6 month) study aimed to assess the usefulness of departmental diagnostic US in the remotely deployed role 2 hospital setting.	Consultant radiologist at a Role 2 MTF - Op TRENTON 3	SonoSite M-Turbo with a 2.5 MHz convex probe and 10 MHz linear probe	41 departmental scans 28 July – 28 December 2017 by radiologist	In 28 of 41 (68%) cases US increased diagnostic confidence & 29% (12/41) led to a change in patient management. 1 (3%) had no clinical impact. Musculoskeletal exams had the greatest impact.	This study highlights the utility of this capability at role 2, when CT scan is not available.	4
Carter et al.[31] 2018	Retrospective record review to determine accuracy of FAST in the deployed environment.	3 consultant radiologists, deployed to the Role 3 MTF, Camp Bastion Jan. - May 2014.	SonoSite 4-6 MHz with curviline ar probe	Radiologists were embedded in the trauma bay.	187 FAST exams performed. 169 of 187 had subsequent laparotomy or CT full body trauma scan and were included in analysis. Sensitivity 75%, Specificity 99.3% Overall accuracy 94.7% ID of intraperitoneal free fluid - PPV 96.2% & NPV 94.4%	FAST provided by the integrated radiologist as part of damage control radiology, gives the team leader rapid diagnostic information to improve decision-making & potentially patient outcomes in the combat MTF.	3
Smith et al.[32] 2015	Retrospective review of registry data to determine use	Attending radiologist at	Not specified	Attending radiologists	468 casualties, 85% underwent FAST &	FAST & CT were useful in	

	and accuracy of FAST and CT	Role 3 MTF, Camp Bastion July – Nov 2012			86.1% had CT, 34% had abdominal injury Detection of intra-abdominal injury; FAST: sensitivity 56%, specificity 98%, PPV 87%, NPV 90%, accuracy 89% CT: sensitivity 99%, specificity 99%, PPV 96%, NPV 100%, accuracy 99%	resuscitation care at Role 3, to enhance diagnostic sensitivity and specificity in battlefield injuries. The use of radiologists for FAST can free emergency MD to focus on other aspects of care.	

Table 2: Portable Hand-Held Devices

Model	Features	Size	Weight	Transducers
GE Healthcare Vscan Extend	Handheld device with dual-headed probe, store images through Wi-Fi or USB, 60-minute continuous scanning on full charge, online apps available to augment studies, educational videos available, requires gel https://www.gehealthcare.com/products/ultrasound/vscan-family	Device: 170 · 78 · 21 mm (6.6 · 3.0 · 0.8 in); Dual Probe: 12.9 · 3.9 · 2.8 cm (5.1 · 1.5 · 1.1 in)	Device: 365g (0.7 lbs); Dual probe: 120 g (0.3 lbs) Sector probe 85g Main unit with Dual probe 400g	Two transducers in one probe: linear and sector
SonoSite iViz	Durable aluminum tablet with multiple transducers, cloud storage, and 64 GB flash drive, three swappable batteries each with 1 hour continuous scan time, embedded educational tools, requires gel **Uses aircraft aluminum, can be dropped up to 3 feet** **IPX-7 rated – fully submergible in water** https://www.sonosite.com/	Tablet: 18.3 · 11.7 · 2.7 cm (7.2 · 4.6 · 1.1 in)	Tablet: 570 g (1.1 lbs)	Curved C60v, Linear L25v, Linear L38v, Phased P21v
Philips Lumify	Transducers attach to android devices, app-based, uses tablet as a power source, no long-term commitment, battery life depends on attached device, requires gel App based, transducers plug into devices, how-to videos Lumify System Bundle includes device https://www.usa.philips.com/healthcare/sites/lumify	Curved transducer: 4.5 · 11.4 cm (1.8 · 4.5 in)	Curved transducer: 136 g (0.3 lbs)	Linear L12–4, Curved C5–2, Phased S4–1

Butterfly iQ	Transducer attaches to Apple mobile devices, built-in battery, wireless charging, unlimited cloud storage, uses silicon chip, does not use Piezo crystal technology, 2 hours of continuous scanning on full charge, **no gel required** **Anodized aluminum body, thermally efficient,** educational videos available https://www.butterflynetwork.com/	Transducer: 185 – 56 – 35 mm (7.2 · 2.2 · 1.4 in)	Transducer:313g (0.7 lbs)	Single transducer emulates any kind of transducer
Clarius C3 Convex	App based, wireless, does not require internet access to operate Handheld device with 3 probes in 1, works on iOS and android. educational videos available **Has magnesium shell, waterproof & withstands drops up to 1 meter**, 60 min battery power, 3 swappable batteries 2 – 6 MHz, max depth 32cm https://clarius.com/	Device: 167 – 99 - 42 mm (6.6 – 3.9 – 1.6 in)	Device: 540g (1.2 lbs)	Three clip-on tips to scan entire body

Note. Adapted from Canepa and Harris (2019).[2]

NIHb

Recent studies assessing the accuracy of noninvasive Hb monitoring

Study	Device	Subjects	Results	Notes/Conclusions
Applegate et al. 2020[8]	Rad-7, Revision K Note: Compared SpHb, CoOxHb, and HemoCue Hb (using arterial blood not capillary) to lab-Hb. SpHb vs Lab-Hb reported here.	135 adult pts. Undergoing non-cardiac surgery	• 551 data sets: SpHb vs Lab Hb • Bias (LOA g/dl) 0.10 (-1.14 to 1.35 • 95% LOA 0.24 (-2.05 to 2.53) g/dl	Continuous SpHb monitoring may provide useful ongoing Hb trend information. Continuous SpHb decreases exceeding − 0.5 g/dl may prompt a decision to obtain a confirmatory Lab-Hb measurement if low Hb is clinically suspected, but not replace blood Hb measurement in guiding transfusion decision making.
De Rosa et al. 2020[9]	Rad7 (Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™)	48 adult patients undergoing abdominal aortic open surgery – intraoperative monitoring	• 192 data pairs: SpHb vs Lab-Hb • SpHb overestimated Hb concentration by 1.63 g/dL (±0.05) on average when compared to Lab-Hb. • In 95% of subjects SpHb was between 0.85 and 2.4 g/dL above Lab-Hb.	The Rad7 method lacks the precision required for measuring the instantaneous values of Hb concentration during vascular surgery.
Rascoe et al. 2020[10]	Masimo Pronto Pulse CO-Oximeter model with Rainbow SET Technology for spot Hb measurement	105 adult patients, undergoing orthopedic surgery post-op Hb Detection failure in 5 (4.8%)	• 100 data pairs: SpHb vs Lab-Hb • Mean post-op SpHb and Lab-Hb were 11.2 + 2.1 g/dl and 10.2 + 1.9 g/dL. • SpHb overestimated Lab-Hb in 76% of cases, when Hb was > 11 there was no significant statistical difference.	The device may have merit In a subgroup of patients undergoing procedures with minimal expected blood loss. Larger studies are required to determine the clinical relevance between the 2 methods. Did not report details of Bland-Altman analysis.

Study	Device	Subjects	Results	Notes/Conclusions
Chang et al. 2019[11]	Rad7 (Masimo Radical 7 Pulse CO-Oximetry™)	49 adult patients undergoing spine surgery, anticipated > 500 ml blood loss and/or transfusion	• 272 data pairs: SpHb vs CoOxHb. • Split into 2 groups based on PI: PI >1.0 vs PI < 1.0. • Correlations between SpHb and CoOxHb were high in the ≥ 1.0 group (r = 0.69, p < 0.001), and the < 1.0 group (r = 0.69, p < .001).	Estimated blood loss was 766.33 ± 564.71 mL (ranging from 100 to 2600 mL) Demonstrates acceptable accuracy of the Rad7 even with a low PI. However, the trending ability was limited.
Osborn et al. 2019[12]	Pronto-7 spot check Hb monitor Note: Also compared HemoCue 201+ capillary Hb to lab-Hb – not reported here	350 pediatric & adult ED pts scheduled to receive blood draw for venous Hb, excluded clinically unstable, suspected hemorrhage, receiving transfusion 14% (50) had incomplete Pronto-7 readings	• 297 data sets: SpHb vs lab-Hb • Mean (SD) -0.52 (1.41 g/dL • Bias -0.52 (-68 to -036) • 95% LOA (-3.9, 2.25) • R=0.773 For anemia: Sensitivity (95%CI) 81.6 (72.5-88.7), Specificity (95% CI) 75.4% (68.8-81.1)	LOA were too wide to recommend the device as a full replacement for a blood test. A potential difference of 2–3 g/dL in either direction is significant. However, the demonstrated sensitivity and specificity of the device, combined with ease of use, may mean the Pronto-7 can potentially be utilized to screen for anemia in patients in the ED setting.
Tang et al. 2019[13]	Radical-7® Pulse CO-Oximeter (software version V7740)	69 adult patients undergoing complex spine surgery, at risk for significant blood loss. RCT – patients randomized to no SpHb (standard) vs SpHb, SpHB decrease by 1g/dL triggered CoOxHb	• SpHb vs CoOxHb • Absolute bias ± precision was -0.29 ± 1.03 g/dL, LOA = -2.30, 1.72 g/dL. • In 28 data pairs, SpHb and CoOxHb were highly correlated, r = 0.69, 95% CI [0.53, 0.82], p < 0.001. • PPV of decrease in CoOxHb > 1 g/dL was 93.3%.	The trend in SpHb could detect a decrease in Hb in dynamic situations and indicate the appropriate timing for Lab-Hb measurements.

Study	Device	Subjects	• Results	Notes/Conclusions
Adel et al. 2018[14]	Rad7 (Masimo Radical 7 Pulse CO-Oximetry™)	70 adult patients undergoing major orthopedic surgery with anticipated major blood loss. 71% received blood transfusion.	• 210 data pairs: SpHb vs Lab-Hb • Correlation between SpHb and Lab-Hb was high, $r = 0.94$, 95% CI [0.92, 0.95]. • Mean bias (LOA) g/dl o overall sample: 0.01 (-1.33, 1.34) o fluid non-responsive: -0.08 (-1.27, 1.11) o fluid-responsive: 0.09 (-1.36, 1.54) o high-PI: 0.01 (-1.34, 1.31) o low-PI: 0.04 (-1.31, 1.39)	SpHb showed excellent correlation with Lab-Hb in fluid responders, fluid non-responders, low PI, and high PI states. Despite a favorable mean bias of 0.01 g/dL for SpHb, the relatively wide levels of agreement (-1.3 to 1.3 g/dL) might limit its accuracy. SpHb showed good performance as a trend monitor.
Gamal et al. 2018[15]	Rad7 (Masimo Radical 7 Pulse CO-Oximetry™)	70 adult trauma patients admitted to ED with major hemorrhage requiring surgery, with Hb < 8g/dL Poor device signal 10% of monitoring time.	• 184 data pairs: Baseline SpHb and SpHb after each unit of blood compared to Lab-Hb. • Mean SpHb = 6.58 + 0.6; mean Lab-Hb = 6.70 + 0.7 g/dL, with mean bias of 0.12, 95% CI [0.56, 0.79]. • SpHb and Lab-Hb were highly correlated, $r = 0.87$. • Mean bias between change in Lab-Hb and change in SpHb was -0.05, 95% CI [-0.62, 0.51].	Sp-Hb showed accurate precision in both absolute values and trend values compared with Lab-Hb measurement in trauma patients with low hemoglobin levels.
Baulig et al. 2017[16]	Rad7 (Masimo Radical 7 Pulse CO-Oximetry™)	35 adult emergency department patients requiring surgery 8 of 46 (17.4%) had detection failure, 2 had less than 30% data points detected.	• 141 data pairs: SpHb vs CoOxHb • strong correlation, $r = 0.81$ ($p < 0.001$) • Detection failure rate of SpHb was 24.5%. • SpHb agreed only moderately with CoOxHb • Values and predicted decreases of CoOxHb only if changes of SpHb 1.0 g/dL were excluded.	Additional refinements of the current technology are necessary to further improve performance of non-invasive hemoglobin measurement in the clinical setting.

Study	Device	Subjects	Results	Notes/Conclusions
Paksu et al. 2016[17]	Handheld Massimo Rad-57	217 of 232 pediatric patients who had CBC for any reason. SpHb obtained prior to lab draw. 15 (6.5%) detection failure	• SpHb vs Lab-Hb • SpHb and Lab-Hb were highly correlated, r = 0.67, 95%CI [0.58, 0.75].	Good correlation between transcutaneous and venous blood measurements of Hb.
Bhat et.al 2016[18]	Rad7 (Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™)	150 patients 80 neonates 70 children 2 (0.01%) patients with refractory shock – detection failure	• 148 data points: SpHb vs Lab-Hb • SpHb and Lab-Hb highly were correlated, r = 0.94, $p < 0.001$. • Mean bias (mean ± SD) between SpHb and Lab-Hb was −1.52±1.91 g/dL. • Bias was higher in sick subjects with shock as compared to healthy ones in both neonatal and pediatric population (-2.31±2.21 g/dL versus -0.77±1.2 g/dL, respectively).	SpHb showed good accuracy and correlated well with lab-Hb levels in healthy children. In children with impaired peripheral perfusion, its diagnostic accuracy was inadequate.
Bridges & Hatzfeld 2016[19]	Masimo Rainbow SET (Probe Rev E/Radical-7 Pulse CO-Oximeter v 7.6.2.1)	23 adult combat casualties undergoing resuscitation	• 49 data pairs: SpHb vs Lab-Hb • Hb ranged from 4.4 g/dL to 15.1 g/dL. • Mean lab-Hb overall: 11.0 + 2.0 g/dL; with Coulter (n = 32): 11.3 + 1.8 g/dL; with iStat (n = 17): 10.3 + 2.2 g/dL. • Mean SpHb = 11.5±1.7 g/dL. • Mean bias between SpHb and Lab-Hb was 0.51.8 g/dL, 95% CI [0.03, 1.0], p = 0.04, LOA (3.97, -2.97), indicating that on average the SpHb tended to overestimate the lab-Hb.	Using a threshold of 1 g/dL previously specified in the literature, continuous SpHb is not precise enough to serve as sole transfusion trigger in trauma patients. Further research is needed to determine if it is useful for trending Hb changes or as an early indicator of deterioration in combat casualties.

Study	Device	Subjects	• Results	Notes/Conclusions
Yang et al. 2016[20]	Rad-87	677 adult pts. with abnormal prehospital SI (≥0.62) directly admitted to Shock Trauma Center	• 677 data sets: SpHb vs lab-Hb • Mean bias -1.0 g/dL • 95% LOA 3.0 to -4.3 g/dL (bias ± 1.96 SD of differences) • $R^2 = 0.645$	LOAs are too wide for clinical use during trauma pt. resuscitation. SpHb added no benefit over conventional oximetry to predict urgent PRBC transfusion for trauma patients.
Singh et al. 2015[6]	NBM-200	485 prospective blood donors	• SpHb vs two invasive POCTs vs Lab-Hb • SpHb was the least sensitive method (sensitivity 71.7%) and the slowest.	The NBM-200 is not effective in excluding ineligible donors, which may pose a threat to donors' health.
Galvagno et al. 2015[21]	Rad7 (Masimo Radical 7 Pulse CO-Oximetry™)	711 adults directly admitted to the trauma center with shock index > 0.62	• Examined SpHb ability to predict need for transfusion • The addition of SpHb to any of the models did not significantly improve prediction of blood use within the first 3 hours of admission in comparison to analysis of conventional oximetry features.	In this population of trauma patients, noninvasive SpHb monitoring, including both trends and absolute values, did not enhance the ability to predict the need for blood transfusion.

Joseph et al. 2015[22]	Spot check Pronto-7 ® Masimo	525 trauma patients
		
		Unable to read in 14% of pts.
			• SpHb vs Lab-Hb
			• Mean Lab-Hb 11.5 ± 4.36 g/dL (range 6 to 16 g/dL), mean SpHb 11.1 ± 3.60 g/dL (range 6.4 to 16.3 g/dL), with mean difference of 0.3 ± 1.3 g/dL ($p = 0.23$)
			• SpHb values had strong correlation with Lab-Hb ($R^2 = 0.77$, $R = 0.86$, $p = 0.04$)
			• Grouped Hb ≤ 8 & >8
			  ○ Accuracy: 76%
			  ○ Sensitivity: 95.4%
				Application of Spot check has more clinical utility as compared to previous continuous SpHb monitoring.

Study	Device	Subjects	• Results	Notes/Conclusions
Marques et al. 2015[23]	Rad7 (Masimo Radical 7 Pulse CO-OximetryTM)	Healthy adult volunteers – under anesthesia, underwent a volume-controlled hemorrhage	• 106 data pairs: SpHb vs CoOxHb • Mean value of all tHb blood samples was 11.4 ± 1.7 g/dL; mean SpHb was 12.5 + 1.9 g/dL. • tHb ranged from 7.8 to 15.4 g/dL and SpHb from 8.3 to 16.9 g/dL • The calculated bias was 1.08 + 0.82 g/dL, 95% LOA (-0.5, 2.6). • 75% of the absolute differences between paired measurements of tHb and SpHb were 1.5 g/dL or less. Differences greater than 2 g/dL were found in 11% of the measurements.	The accuracy and spot measurement ability of the Masimo Radical-7 to assess a specific transfusion trigger are only modest, and a small delay in tracking hemoglobin changes was observed. Further evaluations are needed to assess how SpHb trending performs in patients.
DeBarros et al. 2015[24]	Pronto-7 spot-check Hb monitor	97 adult patients in ICU or on surgical ward, or adult soldiers undergoing elective surgery as a part of field training exercises for a US Army Combat Support Hospital Patients were stratified by location (ward, ICU, and FTX), then by presence of anemia. Failure to detect in 2 (0.2%) cases	• 291 data pairs: lab-Hb vs SpHb • Overall mean invasive Hb was 11.98 + 2.87 g/dL (range: 9.7 to 15.3 g/dL). Mean SpHb was 12.05 + 2.62 g/dL (range: 10.3 to 15.2 g/dL). No significant difference in precision (.07, *p* = .48). • Ward: invasive Hb = 10.7 + 2.04 g/dL; SpHb = 10.7 + 2.0 g/dL. No significant difference in precision (.06, *p* = .79). • ICU: mean invasive Hb = 9.7 + 1.71 g/dL; SpHb = 10.3 + 1.60 g/dL. Significant difference in precision (.58; *p* = .01). • FTX: mean invasive Hb = 15.1 + 1.22 g/dL; SpHb = 14.8 + 1.32 g/dL. No significant difference in precision (.29, *p* = .33). • Anemia: overall mean invasive Hb = 8.57 + 1.3 g/dL; SpHb = 9.36 + 1.6	The Pronto-7 device has strong correlation when compared with invasive methods such as those used in a hospital laboratory. In patients that have anemia, there is a weak correlation between Pronto-7 and invasive Hb measurements. This appears to be limitation of the device and should be used with caution in this patient population.

			g/dL. Significant difference in precision (.78, $p < .05$) • Overall Intraclass coefficient (ICC) = .83, $p < .05$; ward ICC = .67, $p < .05$ and ICU ICC = .78, $p < .05$ • Weak correlation between noninvasive and invasive methods at FTX locations (ICC = .08; $p = .2$).	
Study	**Device**	**Subjects**	• **Results**	**Notes/Conclusions**
Tsuei et al. 2014[25]	Rad7 (Masimo Radical 7 Pulse CO-OximetryTM)	88 adult patients with potential for hemorrhage admitted to surgical ICU Reported a detection failure rate of 15%	• 572 data sets: SpHb vs Lab-Hb vs iSTAT Hb • SpHb 15% detection failure rate • SpHb measurement averages 1.49 g/dL higher than lab-Hb and could be as much as 2.0 g/dL lower or 5.0 g/dL higher than the lab. iSTAT compared with lab-Hb resulted in an estimated bias of -0.63 g/dL, 95% LOA (-3.4, 2.2); SpHb compared with iSTAT resulted in a bias of 2.1 g/dL, 95% LOA (-1.7, 5.9).	Rad7 SpHb differs by more than T1.0 g/dL from criterion standard lab- Hb, with a wide confidence interval in patients at risk for hemorrhage. Concordance with lab-Hb changes only occurred in 60% of the cases, and SpHb measurements could not be obtained 15% of the time. These findings limit the utility of the Rad7 SpHb monitor in detecting ongoing hemorrhage.

Note. SpHb = Non-invasive; CoOxHb = Hb assessed with blood gas analyzer; tHb = Total hemoglobin; PI = perfusion index; r = Pearson's correlation coefficient; LOA = levels of agreement; PPV = positive predictive value; NPV = negative predictive value.

12.0 LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

DTIC – Defense Technical Information

POCUS – Point of care ultrasound

NIHB – Noninvasive hemoglobin

MHS – Military Health System

Hb – Hemoglobin

LabHb – Laboratory Hb

CoOxHb – Co-oximetry Hb

CT – Computed tomography

CSH – Combat Support Hospital

JSOMTC – Joint Special Operations Medical Training Center

SOLCUS – Special Operator Level Clinical Ultrasound

DARPA – Defense Advanced Research Project Administration

IRB – Institutional Review Board

IACUC – Institutional Animal Care and Use Committee

LOE – Level of Evidence

MHSRM – Military Health Science Research Symposium

EFAST – Extended Focused Assessment with Sonography for Trauma

SURF – San Antonio Universities and Military Research Forum