Request for Project Proposals

Solicitation Number: MTEC-E24-02-AutoDocPrize

"DEMONSTRATION AND PRIZE COMPETITION for the Passive Data Collection using Autonomous Documentation (AutoDoc) Project"

Issued by:
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for the
Medical Technology Enterprise Consortium (MTEC)

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Table of Contents

1 Executive Summary 3
1.1. The Medical Technology Enterprise Consortium 3
1.2. Purpose 3
2 Administrative Overview 4
2.1. Solicitation Process 4
2.2. Offeror Eligibility 5
2.3. Funding Availability and Type of Funding Instrument Issued 5
2.4. Proposers Conference 5
2.5. Proprietary Information 5
2.6. Intellectual Property 5
2.7. Expected Prize Date 5
2.8. Anticipated Solutions Brief Selection Notification 6
3 Technical Requirements 6
3.1. Background 6
3.2. Technical Objective 10
3.3. Desired Solution Characteristics 11
3.4. Potential Future Work 14
4 Solution Brief Preparation and Process 14
4.1. Solution Brief Submission 14
4.2. Instructions for the Preparation of the Stage 1 Solution Brief 14
4.3. Instructions for the Preparation of the Stage 2 Solution Brief Pitch 15
4.4. Instructions for the Preparation of the Stage 3 Demonstration 17
4.5. Solution Brief, Pitch, and Demonstration Preparation and Other Costs 17
5 Selection 17
5.1. General Information 17
5.2. Solution Brief (Stage 1) - Selection and Evaluation Process 18
5.3. Solution Brief Pitch (Stage 2) - Selection and Evaluation Process 19
5.4. Demonstration (Stage 3) Evaluation 19
5.5. Definition of General Terms Used in Evaluations 20
6 Points-of-Contact 20
7 Acronyms/Abbreviations 20
8 Solution Brief Template 22

1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

(a) biomedical research and prototyping;
(b) exploration of private sector technology opportunities;
(c) technology transfer; and
(d) deployment of intellectual property (IP) and follow-on production.

MTEC is a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, "nontraditional" defense contractors (refer to the MTEC Proposal Preparation Guide (PPG), Section 3 for definition), academic research institutions, and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website (www.mtec-sc.org).

MTEC operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. In accordance with 10 USC 4022, the MTEC OTA enables the Government to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. As defined in the DoD OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), and with support from the Telemedicine and Advanced Technology Research Center (TATRC), represents a Request for Project Proposals (RPP) focused on identifying a system of sensor suites that can reliably and passively collect the core data needed to identify casualty status, key tasks performed by medics, and real-time resource use in casualty care scenarios under realistic battlefield conditions.

This demonstration and prize competition focuses on the use of mature sensor technologies to support passive data collection for autonomous tactical combat casualty care (TCCC). It will focus on the "art of the possible" in terms of novel combinations of commercially off the shelf (COTS) sensor solutions to collect data regarding:

- Medic performance of casualty care (e.g., medic registration, actions, tasks, decisions, etc.);
- Patient status (e.g., registration, physiologic, injury patterns, mental status, etc.); and
- Resource utilization (e.g., IVs, blood, tubing, bandages, dressings, medications, etc.).

Several prizes are expected to be awarded for the most innovative/novel approaches that leverage existing sensor technologies to collect data for the 3 use cases listed above. To the largest extent possible, the proposed sensor devices are suitable for future use in austere, tactical environments (e.g., extreme temperatures [heat/cold], variable lighting venues, noisy/loud [gunfire, explosives, rockets et al] environments, urban warfare conditions, disrupted, disconnected, intermittent and low-bandwidth [DDIL] communication venues, etc.)

2 Administrative Overview

2.1. Solicitation Process

This **MTEC Demonstration and Prize Competition** will be conducted using a multi-staged approach:

- **Stage 1 [Solution Brief]:** Current MTEC members are invited to submit Solution Briefs using the mandatory format contained in this RPP (see Section 8 of this RPP). The Government will evaluate Solution Briefs submitted and will select the Solution Briefs that best meet the criteria in Section 5 of this RPP. Offerors whose proposed work is selected for further consideration based on the Solution Brief evaluation will be invited to submit a Solution Brief "pitch" in Stage 2.

- **Stage 2 [Solution Brief Pitch]:** Offerors will participate in a virtual judging round [deep dive/pitch], from which several Offerors will be selected for Stage 3. The evaluation panel may be comprised of Government staff, military representatives, and independent subject matter experts (under confidentiality agreements) to help evaluate the technical and commercial merits of the applicant. It is expected that no more than ten (10) Offerors will be selected to participate in a demonstration to the Government in Stage 3.

- **Stage 3 [Demonstration]:** Offerors selected for Stage 3 of this effort will arrange for their proposed prototype solution to be transported and demonstrated at the TATRC headquarters (Fort Detrick, MD). It is preferred that those selected for demonstrations will travel to Fort Detrick, MD. Costs incurred by those selected for Stage 3 will be at the Offerors' own expense (costs will neither be reimbursed by MTEC nor the Government). After an initial live demonstration by the Offeror, the Government will complete a technical evaluation of the product over the course of four (4) weeks. During this time, the Government expects a technical representative for the offeror to be available for phone or video conferencing in order to answer questions from the Government. During this stage, the Government will evaluate the submitted technologies and assign winners of the prize competition. It is expected that at least two (2) prizes will be awarded by MTEC. Evaluations will be made available after all selection notifications have been provided.

Note that the terms "Solution Brief" and "Proposal" are used interchangeably throughout this RPP.

2.2. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit a proposal. Offerors submitting Solution Briefs as the prime performer must be MTEC members of good standing at least 3 days prior to submission of the Solution Brief. To join MTEC, please visit http://mtec-sc.org/how-to-join/. Membership dues are prorated throughout the year. For more information on membership dues, please visit https://mtec-sc.org/membership-dues/.

2.3. Funding Availability and Type of Funding Instrument Issued

MTEC currently has available a total of approximately $75,000 to issue in prizes of equal amounts for this effort. It is anticipated that at least two (2) and no more than three (3) Offerors will be issued prizes after government evaluations from Stage 3 of this effort. *[NOTE: MTEC will be the sole funder of the prizes resulting from this RPP. The Government will **not** provide funding in support of this RPP.]*

2.4. Proposers Conference

MTEC intends to host a Proposers Conference that will be conducted via webinar within two (2) weeks of the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this demonstration and prize competition and to present further insight into the technical requirements outlined in Section 3. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

2.5. Proprietary Information

The MTEC CM will oversee submission of Solution Briefs submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Solution Brief, Solution Brief Pitch, and the Demonstration of a proposed technology. In accordance with the MTEC Proposal Preparation Guide (PPG), please mark all Confidential or Proprietary Information as such. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

MTEC Officers and Directors who are granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.6. Intellectual Property

The Federal Government may not gain an interest in intellectual property developed by a participant in this demonstration and prize competition without the written consent of the participant.

2.7. Expected Prize Date

Prizes are expected to be announced and awarded in January 2024 (subject to change).

2.8. Anticipated Solutions Brief Selection Notification

As the basis of selections is completed, the Government will forward its selections to the MTEC CM to notify Offerors. All Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next stage of the process.

Offerors are hereby notified that once a Solution Brief has been submitted, neither the Government nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 Technical Requirements

3.1. Background

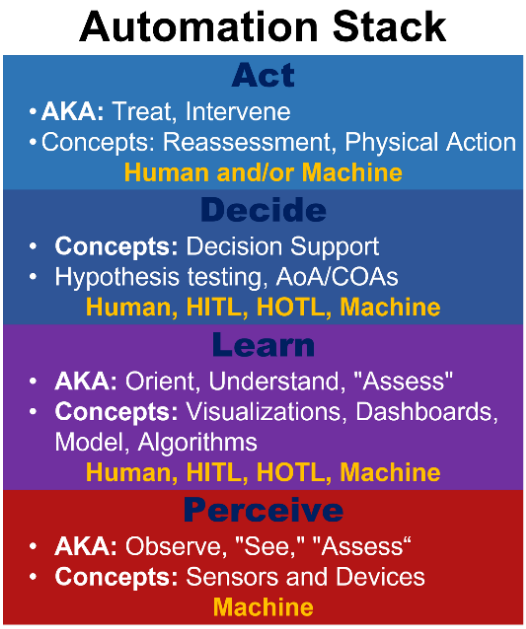
The Military Health System (MHS) lacks a robust, accurate, and reliable methodology to collect, store, and track TCCC data. Establishing a prehospital environment medical data set is an essential, foundational step to modernizing Military TCCC medical care. Without a means to collect and seamlessly transmit data reliably and passively from the point of need/care (e.g., point of injury [POI] through higher echelons of care), the MHS will continue to lack the essential data to develop a trustworthy artificial intelligence (AI) stack[1,2] to support future concepts that will sustain Military medical operations in the various environments of Multi-Domain Operations (MDO), including, but not limited to Large Scale Combat Operations (LSCO). By leveraging trustworthy AI in future conflicts, the MHS can reduce the caregiver cognitive load and mitigate impacts of a LSCO medical asset overburden, enabling greater efficiencies and capabilities.

Military prehospital care often occurs in austere, chaotic environments. Military medics and combat lifesavers in the battlespace are focused on prioritizing casualty severity and managing a large patient load with limited supplies and assistance. During times of intense activity, they must prioritize their patients over documenting delivering care to save the lives of their fellow warfighters. Medical documentation for these providers is challenging, if not impossible in many instances. Being able to capture the medical care being delivered in these venues may be secondary to saving lives in that moment; however, the need for timely, accurate medical documentation remains. In the near term, this data generates valuable information to higher echelons of care, medical resupply/logistics systems, and Command situational awareness (SA). The additional, long-term benefit is the ability to leverage machine learning (ML) and AI to enhance care delivery in the tactical environment in the future based on lessons learned from current care requirements (see **Figure 1**).

Figure 1. Automation Stack[1,2]

[1] Cindy Crump, Loretta M. Schlachta-Fairchild, "Achieving a trusted, reliable, AI-ready infrastructure for military medicine and civilian care," Proc. SPIE 11413, Artificial Intelligence and Machine Learning for Multi-Domain Operations Applications II, 114130C (21 April 2020); doi: 10.1117/12.2557514

[2] Carnegie Mellon University School of Computer Science, “AI Stack,” (2019).



*Note: Adapted from the Carnegie Mellon University School of Computer Science

To enhance TCCC and improve medical documentation in the MHS, a passive, (e.g., with minimal human effort) autonomous documentation solution of medical care in operational environments is an essential requirement to establishing these critical TCCC data sets. Furthermore, it is vital that the processes in collecting this data does not distract the medic/caregiver's capability and capacity to deliver care.

Current medical IT capabilities rely on combat medics diverting their attention away from care delivery to document their efforts. This either detracts from the medics' capability and capacity for performing essential care tasks or necessitates documentation in a delayed manner, often under significant time constraints, that reduce the quality and accuracy of the documentation. In future LSCO engagements, medical assets will be significantly stressed, increasing the likelihood of a complete absence, or incomplete, poor-quality documentation.

At present, the MHS has two programs of record (POR)/program instructions that focus on providing resources to document combat casualty care:

(1) The Joint Operational Medicine Information Systems (JOMIS) under the Program Executive Office, Defense Healthcare Management Systems (PEO DHMS) provides interoperable medical information technology (IT) capabilities across the full spectrum of military operations using tactical communication networks. The JOMIS portfolio includes capabilities for Medical Mission Command, MHS Genesis Theater electronic health record (EHR), Operational Medical Data cloud, and a virtual health capability. A recent additional to the JOMIS portfolio is a medical IT software solution to document combat causality care called Battlefield Assisted Trauma Distributed Observation Kit (BATDOK). BATDOK's software tools were developed by the Air Force Research Laboratory (AFRL) and are leveraged at the POI and lower echelons (e.g., Role 1-2 care).

(2) The Medical Communications for Combat Casualty Care (MC4) under the Program Executive Office, Enterprise Information Systems (PEO EIS), will transition to Operational Medical Information System – Army (OMIS-A) in fiscal year (FY) 24. The OMIS-A Role 1 and 2 centered portfolios include the MC4 semi-ruggedized system of systems containing fielded medical software systems, for initial EHR documentation, medical logistic ordering, and medic screening.

Thus, both the JOMIS and MC4 programs could benefit from the research, development and use of passive, autonomous documentation in tactical military medical care, largely independent of caregiver interactions. This will lead to opportunities to inform and potentially achieve the following modernizations (see **Figure 2**):

- Semi-autonomous casualty care delivery
- Autonomous resource triage/assessments
- Autonomous resupply
- Autonomous resupply / medical regulating
- Just in Time (JIT) decision making across echelons of care
- JIT situational awareness for military leaders / decision makers

Figure 2. Operational Viewpoint (OV-1):
High Level Operational Concept Graphic for the A2C Portfolio

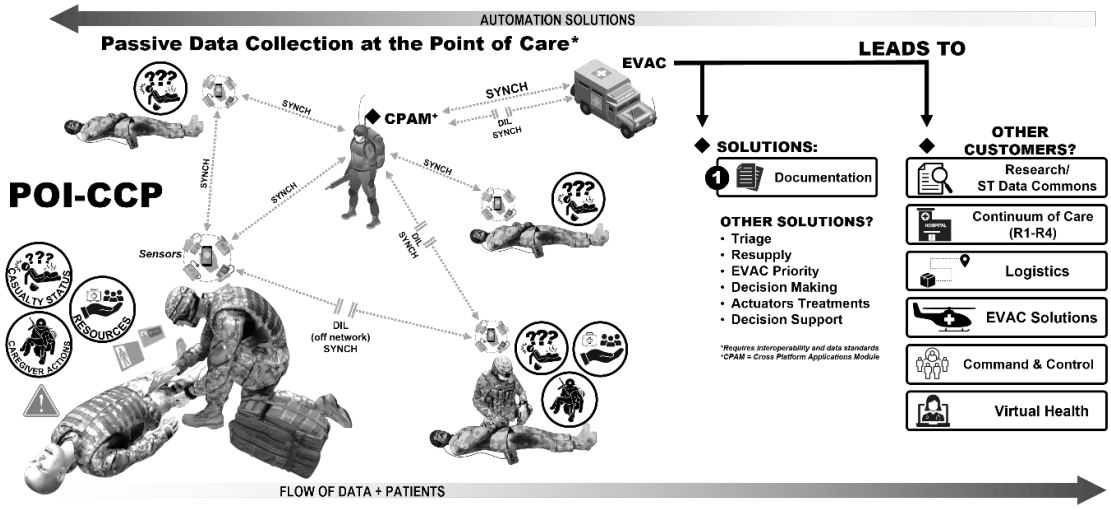


Table 1. Description of Sensor Types/Classifications

Sensor Categories	Sensor Technology Examples*	Patient Status	Caregiver Actions	Resource Consumption	Potential DD1380 Section/Form Fields
Audio Inputs	Wireless, wearable microphones	☑	☑	☑	Identification Injury Signs/Symptoms Treatments Notes
Video Inputs	Body Cameras Action Cameras Eye Tracking Systems	☑	☑	☑	Identification Injury Signs/Symptoms Treatments Notes
Physiological Monitors / Vital Sign Monitors (VSMs)	Wireless Vital Sign Monitors (WVSMs) - Pulse Oximeter (finger clip) - Blood Pressure (BP) Cuff - Electrocardiogram (ECG), etc.	☑	☑		Signs/Symptoms Notes
Wearables	Smart Devices (watches, glasses, bracelets, rings, finger clip applications) Skin Patches/dermal sensors Smart Clothing (shirts, pants, belts, socks, shoes etc.) Smart Helmets Ingestible Sensors Simultaneous Global Positioning System (S-GPS) body controls General Packet Radio Service (GPRS) body controls Bluetooth key trackers	☑	☑		Injury Signs/Symptoms Notes
Radio Frequency Identification (RFID) technologies	Bar Codes/Quick Response (QR) codes Smart Dog Tags	☑	☑	☑	Identification Treatments Notes

*Note: Table above is NOT an exhaustive list of sensor technologies or DD Form 1380 (TCCC card) documentation opportunities, it is intended for illustrative purposes only

3.2. Technical Objective

To augment and supplement the current processes of medical documentation for TCCC, it is necessary to develop passive data inputs into the medical IT systems of record to reduce and or eliminate the need for manual entry of care delivery into these systems. This will allow the medic/combat lifesaver to remain focused on their primary task, saving lives. The A2C Research Portfolio and the Passive Data Collection using AutoDoc project seeks to develop a minimum of two systems of sensor suites that passively collect accurate and reliable data about casualty status, caregiver (e.g., medic and/or combat lifesaver) actions, and real time resource usage. This passive data collection will be leveraged in a follow-on project phase (see Section 3.4 of this RPP) to create algorithms that will autonomously document a DD Form 1380 (TCCC card) (See **Addendum 1**).

The current aim of the AutoDoc project being solicited for in this RPP is to establish a system of sensor suites that can reliably collect the core data needed to identify casualty status, key tasks performed by medics, and real-time resource use in casualty care scenarios under realistic battlefield conditions. This system is expected to be a multi-modal suite of sensors (medic centric, casualty centric, environmental, robotic or drone based) that can provide a reliable source of passive data to algorithms that can describe casualty care activities including:

- Medic performance of casualty care (e.g., medic registration, actions, tasks, decisions, etc.);
- Patient status (e.g., registration, physiologic, injury patterns, mental status, etc.); and
- Resource utilization (e.g., IVs, blood, tubing, bandages, dressings, medications, etc.).

We are seeking Solution Briefs describing a passive technology solution set(s) that supports the above-mentioned aim of the Passive Data Collection using AutoDoc project. Offerors should describe the current sensor capabilities of their passive technology solution set(s) and explore the art of the possible, e.g., using mature sensor technologies in <u>novel</u> ways to support passive data collection for autonomous TCCC. Candidate passive technology solution sets described in Solution Briefs in response to this RPP will <u>NOT</u> be constrained to tactical communications in this initial phase, but those constraints should be considered for future phases (for example, follow-on RPPs). PLEASE NOTE: the demonstration and prize competition will NOT require the proposers to develop a physical data aggregation point for their sensors, but proposers will be requested to define/outline their approach for future development of a physical data aggregation point.

<u>For awareness only:</u> The government anticipates the release of a solicitation in the near future seeking to satisfy the following aims of the AutoDoc Project:

- Establish a suite of sensors with a data aggregation point that can reliably collect the core data needed to identify casualty status, key tasks performed by medics, and real-time resource use in casualty care scenarios under realistic battlefield conditions.
- Develop task identification algorithms that reliably document elements of a DD Form 1380 TCCC card (see **Addendum 1**).
- Prototype system that incorporates sensor suite, algorithms, Application Programming Interfaces (APIs) and interoperability standards to automate documentation of a DD Form 1380 (TCCC card)
- Build an infrastructure database of data passively collected from combat medics performing casualty care tasks in lab, training, and hyper-realistic battlefield settings

3.3. Desired Solution Characteristics

These solution sets will conform to the following desired solution characteristics to satisfy a Minimum Viable Product (MVP), characterized by Technology Requirements, Data Output Requirements, and Documentation Requirements outlined below. These desired solution characteristics are required at the time of Solution Brief submission. **Offerors who are selected to advance to Stage 3 of this RPP process are expected to provide the government with 4 complete, fully functional passive sensor solution set(s) that meet the desired solution characteristics outlined below:**

Technology Requirements:

The passive technology solution set(s) will be:

1) The passive technology solution set(s) will be inclusive of multiple sensors technologies (e.g., more than one). The resulting sensor technology combination will be inclusive of the passive observation of all the following:
    - Individual patient status(es)
    - Caregiver actions
    - Resource consumption (use of medical supplies/logistics)

2) Individual sensor technology components (e.g., hardware and software) can be inclusive of, but not limited to:
    - Audio inputs/devices
    - Video inputs/devices
    - Physiological monitors/VSMs (e.g., heart rate, blood pressure, respiratory rate, SpO2, other telemetry, et al)
    - Wearables
    - RFID technologies

3) Sensor components of the passive sensor technology solution set(s) can be leveraged by the patient AND caregiver, and data outputs generated from these sensor devices should be able to distinguish the user origin/user roles, when relevant/applicable.

4) Comprised of existing, proven sensor technologies (e.g., performers should NOT focus on notional/pilot sensor concepts, but rather the aggregation/combination of mature sensor technologies into a deliverable set)

5) Reliable and valid (e.g., generates consistent/repeatable, and accurate data outputs)

6) Effective and intuitive with respect to form factor and end user interfaces (e.g., does not interfere with care delivery, does not require extensive training to use, etc.

7) Effective regarding size, weight, and power (SWaP), and provide a minimum of 2 hours of run time

8) Relevant/applicable to data collection for combat casualty care at the point of injury/point of care; (e.g., care under fire, tactical field care, prolonged casualty care, etc.)

9) Effective and efficient with respect to data processing (e.g., time sensitive data is processed via edge computing, and cloud computing is leveraged for non-time triggered data)

10) Leverages multi-modal communication strategies (e.g., capable of functioning with real time [synchronous] communication venues as well as offering store and forward [asynchronous] options when communications are intermittent)

11) To the largest extent possible, suitable for future use in austere, tactical environments (e.g., extreme temperatures [heat/cold], variable lighting venues, noisy/loud [gunfire, explosives, rockets et al] environments, urban warfare conditions, disrupted, disconnected, intermittent and low-bandwidth [DDIL] communication venues, etc.)

Data Output Requirements:

1) The passive technology solution set(s) will generate standardized data outputs that are capable of being can be exported and aggregated into a centralized data repository/data collection system maintained by the government.

2) During the demonstration and prize completion, these standardized data outputs are NOT required to provide an automated export feature. Manual and/or local exports to a government maintained common data responsory/data collection system will be accepted for the purposes of government assessment of the proposed solutions.

For Information Only: Future solicitations for the AutoDoc Project may require the following data output MVPs:

- Standardized data outputs to be exported electronically using a government-maintained API or Software Development Kit (SDK) to a government sponsored common data repository/data collection system.
- Electronic based, standardized data outputs from the passive technology solution set must be synchronized with the government-maintained data repository/data collection system in a timely fashion
- Standardized data outputs must be transferred to the government-maintained data repository/data collection system using recognized industry standard formats, as applicable and appropriate.
- Standardized data outputs from the passive technology solution set(s) must be inclusive of descriptive information (e.g., meta tagging et al) for future phases of development and analytics (e.g., algorithm development and ML/AI)
- To the greatest extent possible, data outputs from the sensor suites must accommodate or be inclusive of date/time synchronization and/or annotations.
- To the greatest extent possible, raw sensor data should be provided in the standardized data outputs. This will allow the government to leverage the raw data outputs for algorithm development in future project phases

- Standardized data outputs from the passive technology solution sets must be accessible to multiple echelons of care (e.g., POI, Role 1, Role 2, Role 3 etc.) to account for patient movement/evacuation

Documentation Requirements: Documentation of the passive technology solution set(s) will include the following electronic files:

Stage 1 Solution Brief: Documentation should include:

1) Summary of the specific data elements on the DD Form 1380 (TCCC card) which can currently be captured and a proposed conceptual plan of how the prototype passive technology solution set could inform future algorithms.

Stage 2 Solution Brief Pitch: Documentation should include:

1) Summary of passive technology solution set data format(s) (e.g., data dictionary et al.) is required. When applicable, the specific data formats (JSON, XML, MP4 [resolution/frames per second/.mp4/.m4a/.m4b/.m4r/.m4v etc.], SSML, WAV, MOV, CSV [with column header descriptions]) and industry standards (e.g., Integrated Clinical Environment (ICE), Institute of Electrical and Electronics Engineers (IEEE) 11073, Health Level Seven (HL7), Audio/Video CODECs, Observation Medical Outcomes Partnership [OMOP] Common Data Model [CDM], Lab Streaming Layer [LSL] et al.) must be identified as part of this data output format documentation packet.

   When raw data outputs are not possible, if the passive technology solution set includes sensors that capture waveform data and feature internal algorithms to locally process data elements, general descriptions of algorithm function(s) and waveform data are required.

2) Description of the estimated output data size (per hour of use) and projected bandwidth requirements and formats for communications for the prototype equipment set.

3) Identify power requirements and/or battery life of the prototype equipment set.

4) Complete, comprehensible, and concise user manuals and training documentation of the passive technology solution set will be provided (to include, but not limited to a quick start guide).

5) Training curriculum/plan (includes both end user and system technical operations information)

For Information Only: Future solicitations for the AutoDoc Project may require the following documentation MVPs:

- Proposed project plan (e.g., conceptual how the initial prototype can be enhanced/expanded over time), to include options to integrate with external algorithms and enterprise systems (e.g., BATDOK, Operational Medical Information System-Army (OMIS-A) et al.) beyond the 24-month AutoDoc project period of performance.

3.4. Potential Future Work

In Sections 3.2. and 3.3. of this RPP, there is information related to future solictations. This potential work may be awarded through a separate, competitive RPP process with MTEC. Therefore, Offerors with capabilities or solutions to these described needs are encouraged to monitor the MTEC website (https://mtec-sc.org/solicitations/) and www.sam.gov for potential future solicitations.

4 Solution Brief Preparation and Process

4.1. Solution Brief Submission

Solution Briefs shall be submitted by the date and time specified on the cover page using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. Include the **MTEC-E24-02-AutoDocPrize Solicitation Number** on each Solution Brief submitted. See Attachment 7 of the PPG for further information regarding BIDS registration and submission.

An automated BIDS receipt confirmation will be provided by email. Offerors may submit in advance of the deadline**. Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein until the Proposal due date/time to clarify requirements (both administrative and technical in nature).

4.2. Instructions for the Preparation of the Stage 1 Solution Brief

Offerors submitting Solution Briefs in response to this RPP should prepare all documents in accordance with the following instructions:

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

Stage 1 Solution Brief Required Submission Documents (2): Submitted via BIDS

- **Solution Brief:** One Word or PDF document 5MB or lower (Required template is provided in **Section 8 of this RPP**)
- **Appendix 1 Documentation Requirements:** No format is provided**.** One Word or PDF document 5MB or lower that includes the following information:
    a. Summary of the specific data elements on the DD Form 1380 (TCCC card) which can currently be captured.

Solution Briefs must be prepared **according to the mandatory format provided in Section 8** of this

RPP. The Solution Brief is **limited to five pages (plus a cover page for a total of six pages)**. References may be included in the Solution Brief and must be included within the page limitation. Appendices are also **excluded** from the page limitation. Formatting requirements include 12-point font (or larger), single-spaced, single-sided, inches x 11 inches. Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. **Solution Briefs exceeding the page limit may not be accepted.**

Do not submit any classified information in the Solution Brief submission.

NOTE: When submitting Solution Briefs, you do not need to fill out the cost or period of performance fields. However, the BIDS system may require you to make an entry for these fields. If so, the following can be entered: $0.00 for Cost/Price Estimate and 1 month for the Period of Performance.

FOR INFORMATION ONLY: Additional attachments/appendices (henceforth referred to as supplemental information) to the Solution Brief Pitch submission may be requested after completion of the Stage 1 Solution Brief evaluation. The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the Stage 1 evaluation summary is provided.

4.3. Instructions for the Preparation of the Stage 2 Solution Brief Pitch

Upon review of the Solution Briefs, Offerors may be invited into Stage 2 of this effort. Offerors that are recommended for Stage 2 will receive notification letters which serve as formal requests for Stage 2 (Solution Brief Pitches) and may contain requested revisions or supplemental information. These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Stage 2 Solution Brief Pitch Required Submission Documents (2): Submitted via BIDS

1) **Solution Brief Pitch:** One PDF document 5MB or lower.
2) **Appendix 2 Documentation Requirements:** No format is provided. one Word or PDF document 5MB or lower including the following information:
    a. Summary of the passive technology solution set data format(s) (e.g., data dictionary et al.) is required.
    b. Description of the estimated output data size (per hour of use) and projected bandwidth requirements and formats for communications for the prototype equipment set.
    c. Identify power requirements and/or battery life of the prototype equipment set.
    d. Complete, comprehensible, and concise user manuals and training documentation of the passive technology solution set will be provided (to include, but not limited to a quick start guide).
    e. Training curriculum/plan (includes both end user and system technical operations information)

In Stage 2, the Offeror(s) will provide a virtual “pitch” of the proposed project during a meeting with the Government. The solution brief pitch should provide more details about the proposed technology

outlined in Stage 1 (Solution Brief). The information discussed during the solution brief pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the proposal and the Offeror's capabilities. The solution brief pitch should be restricted to **a maximum of 20 minutes for the presentation by the Offeror with a total time of 45 minutes** to include questions from the Government. Any materials that will be presented during the solution brief pitch or included as supplementary material must be provided in advance of the meeting date. Briefing slides or documents or a combination thereof can be used to support this effort.

The Solution Brief Pitch is expected to include the following:

- **Technology Description and Approach:** A more robust description of the technology, approach and emphasize why this approach is expected to result in a successful outcome. This discussion should include relevance to the military use cases.

- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory pathway, indication of use and designation, strategy for obtaining regulatory approvals or clearances. Offerors are also encouraged to include costs associated with their development strategy.

- **Interoperability**: The Offeror will convey details related to product interoperability with compatible systems and plans for future algorithm inclusion.

- **Relevant Experience:** The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the program objective and solution requirements described in Section 3 of this RPP and build confidence in the team's capabilities.

- **Effectiveness (Opportunity and Risk):** The Offeror will identify, assess, evaluate, and clearly convey items for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project measure, and the mitigation plan for each identified risk item.

- **Partnerships/Collaborations:** The Offeror will describe any current or potential partnerships or collaborations that may be of use when developing this product, especially in regards to algorithm development. Partnering with Government laboratories may be required downstream.

- **Competitive Advantage:** A clearly defined competitive advantage of the proposed technology over already existing solutions and other solutions in development by others in the field.

- **Market and Business Model:** Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

- **Military Transition:** Offeror will describe the pathway to developing this into a product that can be used by the military.

At the conclusion of the Stage 2 evaluation, Offerors who are favorably evaluated will be invited to submit for Stage 3 of this effort (Demonstration).

4.4. Instructions for the Preparation of the Stage 3 Demonstration

During this stage, offerors will be invited to demonstrate their technology for TATRC personnel at Fort Detrick, MD. During this stage:

- The Offerors selected for Stage 3 Demonstrations will provide the government with 4 complete, fully functional passive technology solution set(s) that meet the desired solution characteristics outlined in Section 3.3 for independent assessment.
- Offerors will participate in a dedicated planning meeting to introduce the capability to the government assessment team. During this planning meeting, the Offeror will provide a detailed briefing on all the features and capabilities of the passive technology solution set(s).
- Offerors will provide an in-person guided demonstration to the government (at Fort Detrick, Maryland) of the passive technology solution set(s) on day 1 of the scheduled government assessment event.
- Offerors will allow an independent, government assessment team to use their candidate passive technology solution set during a multi-day clinical scenario driven assessment (e.g., as a standalone solution without guidance/mentorship).
- Offeror will provide a technical POC to support the government in the preparation, execution, and post execution independent assessment process.

4.5. Solution Brief, Pitch, and Demonstration Preparation and Other Costs

The cost of preparing Solution Briefs, Pitches and Demonstrations (including travel) is solely the responsibility of the Offeror.

5 Selection

5.1. General Information

Evaluations at all stages of the Solution Brief acquisition process shall be based on an independent, comprehensive review and assessment of the work proposed against stated evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The Solution Brief and/or the Solution Brief Pitch process may involve the use of contractors as subject matter experts (SME) consultants or reviewers. Where appropriate, MTEC will employ NDAs to protect information contained in submissions. The evaluation panels may be comprised of SMEs appointed by the representatives from the U.S. military with relevant expertise.

5.2. Solution Brief (Stage 1) - Selection and Evaluation Process

The CM will distribute all Proposals that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 (Solution Brief Pitch) based on the following Stage 1 criteria. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Proposals against established criteria to determine technical merit. Regardless of whether or not the evaluation includes a peer review, all Solution Briefs will be evaluated based on the following factors. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 3. Feedback will be provided to the Offerors.

Stage 1 - Solution Brief Evaluation Factors (of equal importance):

1. **Programmatic and Technical Relevance**
2. **Personnel and Team**

Evaluation Factor 1 – Programmatic and Technical Relevance: The Offeror's proposal will be assessed for the extent at which the following are satisfied:

- **Programmatic Relevance:** The degree to which the Offeror demonstrates a strong solution to the defined unmet military medical need consistent with Section 3 of the RPP.
- **Technical Merit:** The degree to which the Offeror presents a medical technology with strong supporting preliminary data that meets the Desired Solution Characteristics outlined in Section 3.3.

Evaluation Factor 2 – Personnel and Team: This factor will evaluate the strength of the organization/team that has proposed a solution to the military requirement. The Offeror's resources, expertise, and experience of personnel may be considered as part of this factor.

TABLE 3- GENERAL MERIT RATING ASSESSMENTS

RATING	DESCRIPTION
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.

MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies.

5.3. Solution Brief Pitch (Stage 2) - Selection and Evaluation Process

Offerors invited to Stage 2 (Solution Brief Pitch) will then be evaluated by a judging panel. The judging panel will make recommendations for invitation to Stage 3 (Demonstration). The judging panel may involve some or all of the following:

- Several members of MTEC's professional staff, such as the MTEC Director of Research, Director of Commercialization, and Chief Operating Officer
- SME(s) to provide input on the feasibility of the proposed solution
- Representative(s) from the military to provide input on alignment with military needs

Stage 2 - Solution Brief Pitch Evaluation Factors (of equal descending importance):

1. **Technical Feasibility**
2. **Scalability and Sustainment**

Evaluation Factor 1 – Technical Feasibility: Feasibility of the proposed solution and its alignment with the RPP's topic area. This factor will also include evaluation of the Offeror's approach to the solution set and product development strategy.

Evaluation Factor 2 –Scalability and Sustainment: This factor will evaluate the Offeror's:

- Plan for interoperability
- Plan for future algorithms
- Partnership/collaboration potential

5.4. Demonstration (Stage 3) Evaluation

Technology submitted by invited Offerors will be evaluated by the Government. Evaluation will include three specific government lead, independent assessments:

- Assessment 1: Face Validity Assessment (e.g., Technical Specifications Documentation [TSD] and Heuristic Usability Evaluation (HUE)
- Assessment 2: Simulated Use Testing (e.g., assessment of usability of the technology solution sets under simulated conditions leveraging medic participants and TCCC scenarios)
- Assessment 3: Data Quality Assessments (DQA)

The Government and MTEC CM will request additional information or clarification as necessary.

5.5. Definition of General Terms Used in Evaluations

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous during the demonstration.

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous during the demonstration.

Weakness - A flaw in the proposal that increases the risk of unsuccessful demonstration.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful demonstration.

Deficiency - A material failure of a proposal to meet the requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful demonstration to an unacceptable level.

6 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, mtec-contracts@ati.org

- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@mtec-sc.org

- All other questions should be directed to Evan Kellinger, MTEC Program Manager mtec-sc@ati.org

7 Acronyms/Abbreviations

AI	Artificial Intelligence
AFRL	Air Force Research Laboratory
API	Application Programing Interface
ATI	Advanced Technology International
AutoDoc	Autonomous Documentation
BATDOK	Battlefield Assisted Trauma Distributed Observation Kit
BIDS	System for Submission of the Solution
BP	Blood Preasure
CM	Consortium Manager
DHA-PI	Defense Health Agency Procedural Instruction
DoD	Department of Defense
DQA	Data Quality Assessments
ECG	Electrocardiogram

FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
GPRS	General Packet Radio Services
HITL	Human-In-the-Loop
HOTL	Human-On-the-Loop
HUE	Heuristic Usability Evaluation
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IT	Information Technology
JIT	Just In Time
JOMIS	Joint Operational Medicine Information Systems
MDO	Multi-Domain Operations
MHS	Military Health System
ML	Machine Learning
MTEC	Medical Technology Enterprise Consortium
MVP	Minimum Viable Product
NDA	Non-disclosure Agreement
OCI	Organizational Conflict of Interest
OTA	Other Transaction Agreement
OV	Operational Viewpoint
POC	Point-of-Contact
PPG	Proposal Preparation Guide
QR	Quick Response
RFID	Radio Frequency Identification
RPP	Request for Project Proposals
SA	Situational Awareness
SDK	Software Development Kit
S-GPS	Simultaneous Global Positioning System
SME	Subject Matter Expert
SWaP	Size, Weight, and Power
TATRC	Telemedicine and Advanced Technology Research Center
TCCC	Tactical Combat Casualty Care
TSD	Technical Specifications Documentation
UEI	Unique Entity Identifier
USAMRDC	U.S. Army Medical Research and Development Command
Government	U.S. Government, specifically the DoD
VSM	Vital Sign Monitor

8 Solution Brief Template

Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

Unique Entity Identifier (UEI) #: [UEI #]
CAGE code: [CAGE code]

[Title of Solution Brief]

[A proprietary data disclosure statement if proprietary data is included. Sample: This Solution Brief includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Solution Brief and negotiate any subsequent prize. If, however, a prize agreement is a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Solution Brief]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Provide a description of how the proposed technology meets the overall objective specified in this RPP.

Scientific Rationale / Preliminary Data

- Demonstrate how your proposed solution meets all of the Desired Solution Characteristics described in Section 3.3.
- Include previous studies or preliminary data [non-clinical and/or clinical] that support the feasibility of the proposed passive technology solution set.
- Describe your demonstration of the manufacturing feasibility of the prototype.

Team

- Describe the qualifications and expertise of the key personnel and organizations associated with the proposed passive technology solution.

Resources

- Identify any key facilities, equipment and other resources relevant for the technical solution being proposed.
- Describe any current or potential partnerships or collaborations that may be of use when developing this product, especially in regards to algorithm development.
- Note: collaboration with government laboratories may be required in future AutoDoc efforts.

Market and Business Model

- Clearly articulate the value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

Product Development Strategy

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required) and civilian use (if applicable).
- Include any information or plans for product interoperability with established military health systems.
- Detail any plans for future algorithm development / inclusion.
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances (as applicable).
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military or civilian market.

- If commercialization is not relevant to the proposed project, then describe the plan to transition the technology to the military market for government use/implementation.

Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

APPENDICES excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: Documentation Requirements (no template provided)

- Summary of the specific data elements on the DD Form 1380 (TCCC card) which can currently be captured and a proposed conceptual plan of how the prototype passive technology solution set could inform future algorithms. Note that Offerors invited for Stage 2 (Solution Brief Pitch) may be asked questions regarding this information.

Addendum 1 – Front and Back of the DD Form 1380, TCCC Card

TACTICAL COMBAT CASUALTY CARE (TCCC) CARD

BATTLE ROSTER #: _____

EVAC: ☐ Urgent ☐ Priority ☐ Routine

NAME (Last, First): _____ LAST 4: _____

GENDER: ☐ M ☐ F DATE (DD-MMM-YY): _____ TIME: _____

SERVICE: _____ UNIT: _____ ALLERGIES: _____

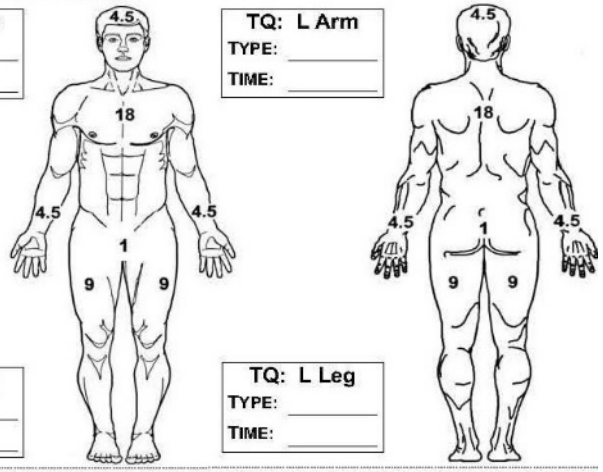
Mechanism of Injury: (X all that apply)

☐ Artillery ☐ Blunt ☐ Burn ☐ Fall ☐ Grenade ☐ GSW ☐ IED
☐ Landmine ☐ MVC ☐ RPG ☐ Other: _____

Injury: (Mark injuries with an X)

TQ: R Arm
TYPE: _____
TIME: _____

TQ: L Arm
TYPE: _____
TIME: _____



TQ: R Leg
TYPE: _____
TIME: _____

TQ: L Leg
TYPE: _____
TIME: _____

Signs & Symptoms: (Fill in the blank)

Time				
Pulse (Rate & Location)				
Blood Pressure	/	/	/	/
Respiratory Rate				
Pulse Ox % O2 Sat				
AVPU				
Pain Scale (0-10)				

DD Form 1380, JUN 2014 TCCC CARD

BATTLE ROSTER #: _____

EVAC: ☐ Urgent ☐ Priority ☐ Routine

Treatments: (X all that apply, and fill in the blank) *Type*

C: TQ- ☐ Extremity ☐ Junctional ☐ Truncal _____

Dressing- ☐ Hemostatic ☐ Pressure ☐ Other _____

A: ☐ Intact ☐ NPA ☐ CRIC ☐ ET-Tube ☐ SGA _____

B: ☐ O2 ☐ Needle-D ☐ Chest-Tube ☐ Chest-Seal _____

C:

	Name	*Volume*	*Route*	*Time*
Fluid				
Blood Product				

MEDS:

	Name	*Dose*	*Route*	*Time*
Analgesic (e.g., Ketamine, Fentanyl, Morphine)				
Antibiotic (e.g., Moxifloxacin, Ertapenem)				
Other (e.g., TXA)				

OTHER: ☐ Combat-Pill-Pack ☐ Eye-Shield (☐ R ☐ L) ☐ Splint
☐ Hypothermia-Prevention Type: _____

NOTES:

FIRST RESPONDER
NAME (Last, First): _____ LAST 4: _____

DD Form 1380, JUN 2014 (Back) TCCC CARD