SureCRIC Standardized Patient Study - NCT03488849.

September 15, 2017

Human Factors Validation of the SureCRIC Device

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I. BACKGROUND AND PURPOSE OF THE STUDY

1 Background

The SureCRIC usability study is a two-part, validation study of a device intended to assist users with identification of surface anatomical landmarks relevant to creation of a surgical airway. The study design is based on FDA guidance to-date. The first part of the study is a human study that will focus on evaluating SureCRIC's intended use of helping to identify anatomical landmarks for establishing an airway. The human study will include representative novice, pre-hospital end users and human patient volunteers. The second part of the study is a manikin study will focus on evaluating SureCRIC use as part of the cricothyrotomy procedure and will include representative end users.

Per FDA feedback, human testing will be performed to evaluate the successful identification of the cricothyroid membrane (CTM) using the SureCRIC device. FDA agreed that the study results could be extrapolated to the following users and use cases: (a) intended user population including those who are more highly-trained and experienced at performing cricothyrotomy; and (b) the tracheotomy procedure where the same anatomic landmarks are identified and the procedure is performed in less chaotic, in-hospital environments. Twenty-four (24) medics (participants) will identify the CTM's of six (6) total healthy human volunteer subjects (subjects) representing a range of anatomical variation (including 5^{th}, 50^{th}, and 95^{th} percentiles of height for men and women). Half of the participants will perform SureCRIC-aided CTM identification. The other half will use a standard, freehand approach for CTM identification. CTM location will be verified by an expert clinician.

Per FDA feedback, manikin testing will be performed to evaluate for potential interference of the SureCRIC with representative cricothyrotomy kits and tools, and to assess SureCRIC usability with these kits and tools. FDA agreed that the study results could be extrapolated to the following users and use cases: (a) intended user population including those who are more highly trained and experienced at performing cricothyrotomy; and (b) the tracheotomy procedure where the same anatomic landmarks are identified and the procedure is performed in less chaotic, in-hospital environments. Fifteen representative pre-hospital (novice) users and two representative experienced users will complete the cricothyrotomy procedure using three different representative cricothyrotomy kits for a total of 51 manikin testing scenarios. The cricothyrotomy kits will allow the participant to perform the cricothyrotomy procedure on the manikin via (a) the direct percutaneous access approach, (b) the Seldinger approach, and (c) the direct scalpel incision approach.

Participants in the study will complete study sessions that will consist of: 1) signing of necessary documents and pre-evaluation interview; 2) SureCRIC training (SureCRIC group only); 3) decay period (SureCRIC group only); 4) testing; 5) semi-structured interviews and critical error debriefing; 6) completion of knowledge tasks and labeling validation (SureCRIC group only); and 7) compensation arrangement.

2 Purpose of the Study

Overall validation study objectives are:

- To measure SureCRIC effectiveness with regard to the intended use of helping to identify anatomical landmarks
- To demonstrate that SureCRIC can be used by representative users under simulated conditions with minimal critical errors
- To evaluate the effectiveness of user training and instructional materials

The human validation study is one of two parts of the final evaluation method intended to demonstrate the safety and effectiveness of the device, labeling and related materials (e.g., materials, packaging, labeling). From the human factors perspective, the validation study serves to ensure that risks associated with the use of a medical device have been identified and adequately addressed, and that the impacts of residual risks are minimized. InnoVital Systems, Inc. (InnoVital) has engaged the National Center for Human Factors in Healthcare (Human Factors Center) to conduct the validation (also referred to as summative) study for the SureCRIC. Validation conducted by the Human Factors Center will focus on evaluating the use of the device by its intended users in simulated use environments. Specifically, the objectives of the human evaluation are:

- Primary endpoint: pass/fail assessment for CTM identification. The use of ultrasound to predefine / pre-mark CTM boundaries on the skin was discussed in the pre-submission supplement meetings. However, internal testing suggests that skin movements with SureCRIC use, and small head and neck movements by subjects may cause the pre-marked skin to shift and result in inaccurate assessments. This finding is in line with the limitations reported in a recent study evaluating CTM identification success in conscious human volunteers [Lamb 2015]. For the purposes of the current study, and as discussed with FDA, an expert in neck / airway anatomy (e.g., otolaryngologist or trauma surgeon) will palpate the area to verify accurate CTM localization.
- Secondary endpoints: time to CTM identification will be measured for descriptive statistics only per FDA request. Additionally, medics will be asked to report their confidence in accurate CTM identification (e.g., on a visual analog scale). Pre-participation, post-training, and post-participation human factors data will also be collected, as well as data from labeling validation.

The manikin validation study is one of two parts of the final evaluation method intended to demonstrate the safety and effectiveness of the device, labeling and related materials (e.g., materials, packaging, labeling). From the human factors perspective, the validation study serves to ensure that risks associated with the use of a medical device have been identified and adequately addressed, and that the impacts of residual risks are minimized. InnoVital Systems, Inc. (InnoVital) has engaged the National Center for Human Factors in Healthcare (Human Factors Center) to conduct the validation (also referred to as summative) study for the SureCRIC. Validation conducted by the Human Factors Center will focus on evaluating the use of the device by its intended users in simulated use environments. Specifically, the objectives of the manikin evaluation are:

- Primary endpoint: user-reported interference of the SureCRIC with the tools used for cricothyrotomy. Interference will be defined as problems with or errors caused by the SureCRIC with the use of these cricothyrotomy tools. Assessment for interference will

be limited to the tools used up to and including the step where the SureCRIC is removed because after this step interference is no longer a concern.

- Secondary endpoints: NCHFH staff will assess the usability of the SureCRIC with the representative kits and tools and document possible procedure interference due to the SureCRIC. NCHFH staff will ask participants about these issues after completion of study participation.

The methods outlined in the protocol were determined based on feedback from the FDA obtained by InnoVital.

II. CHARACTERISTICS OF THE RESEARCH POPULATION

1 Study Sites and Number of Subjects.

Both parts of the SureCRIC validation study will take place in the Human Factors Center's usability lab in downtown Washington, DC. The human portion of the study will consist of 24 novice (pre-hospital) participants and 6 volunteer patients as subjects. One back-up subject for each size will also be recruited to serve "on call" in case of a no-show in one of the primary subject roles. The manikin portion of the study will consist of 18 novice (pre-hospital) participants and 3 expert participants, for a total of 21 participants.

Pre-hospital (novice) study participants will be paramedics and/or combat medics (together referred to here as "medics"). Medics are non-expert users who are seldom called upon to perform cricothyrotomy. As such, medics represent the most challenging users. Medic recruitment will exclude participants with atypical knowledge of, training in, or experience with cricothyrotomy. For example, instructors of cricothyrotomy and airway management will be excluded. FDA agreed that novice users represent the most challenging users and that results obtained with novice users can be extrapolated to the rest of the intended user population which includes more highly trained and experienced users. All attempts will be made to ensure that 10% or more of the subjects recruited are left-handed, corresponding to the prevalence of left-handedness in the general population. For the human study, participants will be randomly pre-drawn into either an Experimental Group (using the SureCRIC) or a Control Group (not using the SureCRIC).

No participants in the study will have taken part in any formative activities or have previous familiarization with the SureCRIC. Participants will be recruited from the Washington, DC, or Baltimore area, and demographic information will be collected. User requirements will be screened by over-the-phone interviews and then validated during the informed consent process prior to the study.

2 Gender, Age, Racial or Ethnic origin of Subjects.

No specific characteristics (e.g. gender, age, racial or ethnicity origin) are required or will be taken into consideration for recruitment of the participants. The study population will be limited to the characteristics of the available participants.

3 Inclusion Criteria.

Pre-hospital study participants will be registered and licensed paramedics (https://www.nremt.org/rwd/public/document/paramedic) and/or current or former combat medics (e.g., http://www.cs.amedd.army.mil/ems.aspx). In the pre-submission meeting, FDA agreed that civilian paramedics and military medics may be considered part of a single user group because many of them have similar training and often switch between the two clinical fields. As novice users, they represent the most challenging population.

The patient volunteers (subjects) in the human study will be healthy male and female volunteers who meet the height percentiles discussed with FDA. Six subjects representing the 5th, 50th, and 95th percentile heights for males and females will be included:

- Subject 1: 4'9" female, up to 138 lb (5th percentile female)
- Subject 2: 5'3" female, up to 169 lb (50th percentile female)
- Subject 3: 5'9" female, up to 202 lb (95th percentile female)
- Subject 4: 5'2.5" male, up to 166 lb (5th percentile male)
- Subject 5: 5'8.5" male, up to 199 lb (50th percentile male)
- Subject 6: 6'2.5" male, up to 236 lb (95th percentile male)

Per FDA request, three experienced users will be included in the manikin study to provide additional insight that may otherwise be overlooked by the novice users, as discussed in the pre-submission supplement meeting. These users will be medics, physician assistants, physicians, or surgeons who are / have:

- An instructor of cricothyrotomy, airway management, or neck anatomy OR
- Experience performing cricothyrotomy on a patient in the last 6 months OR
- A trauma surgeon, interventional pulmonologist, or otolaryngologist

An expert clinician (site verifier) will be recruited to assess whether the sites identified on subjects by users is the CTM. The expert will fit any one of the following inclusion criteria:

- Otolaryngologist
- Trauma surgeon
- Interventional pulmonologist
- Emergency physician who is / has been an instructor of cricothyrotomy

4 **Exclusion Criteria**.

No minors (under the age of 18) will be enrolled in this study as participants or subjects. For subjects, obese and underweight humans will be excluded. Note that at the pre-submission supplement meeting, FDA agreed with a precaution statement for obese patients.

Exclusion criteria for the pre-hospital (novice) participants are as follows:

- Current or former instructor of cricothyrotomy, airway management, or anatomy
- Experience performing cricothyrotomy on a patient in the last 6 months
- Training on cricothyrotomy in the last 3 months
- Previous or current participation in a study related to cricothyrotomy
- Any condition or physical impairment that limits dexterity and/or tactile feedback
- Performed two or more cricothyrotomies on live humans
- Previous exposure to the SureCRIC

Exclusion criteria for the subjects are as follows:

- Previous exposure to the SureCRIC
- Age under 18 or over 60
- Any skin condition including, but not limited to, eczema and hives
- Skin that is thin, fragile, sensitive and/or prone to redness or irritation including skin that maintains a red, irritated appearance after the light application of pressure
- Easy bruising or use of any blood thinning medication (including aspirin)
- Beard on the neck
- Use of a steroid medication by mouth or in a topical formulation like a cream or ointment
- Any of the following chronic conditions: chronic kidney disease, chronic liver disease, coagulation disorders such as hemophilia or von Willebrand disease, low or dysfunctional platelets (e.g., thrombocytopenia), leukemia, Cushing's syndrome, Ehlers Danlos syndrome, celiac disease, any condition that causes easy bruising or sensitive or fragile skin.
- Previous neck surgery, previous neck trauma, thyroid mass or enlargement, or other neck abnormalities
- Any condition that would make lying supine or without a pillow painful or impossible

Exclusion criteria for the experienced users are as follows:

- Previous exposure to the SureCRIC

5 **Vulnerable Subjects**.

Though not specifically planned or expected, it is possible that hospital / health system employees will be included as participants. No hospital or health system employees will be included as subjects. Participants and subjects will be protected in two ways. First, no identifying information will be recorded during the study, except for faces of the participants, subjects, and study investigators. Third-party recruiters and administrative staff will coordinate logistics of participants and subjects; therefore, researchers do not need or have access to participants' and subjects' phone numbers or emails. Once participants and subjects have signed their respective consent forms, there will be no connecting information between the person and their participant number or subject number. The data that is collected and analyzed will not contain any identifiers regarding subject name, date of birth or any other identifiers. Secondly, the recruitment material and information letter will make it explicitly clear that participants and subjects are free to end participation at any point in the study.

III. METHODS AND PROCEDURES

1 Methods and Data Analysis (Human Study)

The study will be a two-arm, open-label study. The Control Group will perform CTM identification with the standard, freehand approach. The Experimental Group will perform CTM identification with the help of the SureCRIC. The Experimental Group will be trained on

SureCRIC operation prior to testing. The expert verifier will not be blinded in order to reduce any error that may be introduced by SureCRIC removal and subsequent skin movement. Participants in the human study will complete study sessions that will consist of the following:

1. Signing of Documents and Pre-Evaluation Interview (~5 minutes). Prior to study participation, relevant information on clinical experience will be collected from all participants. Sample data points include handedness, years of and nature of clinical experience, cricothyrotomy training, and previous cricothyrotomy performance. Upon arrival, participants and subjects will be asked to sign an informed consent form that describes their role in the evaluation, explains risks involved, and consents to the use of audio and video recordings for analysis purposes. Participants and subjects will also be asked not to disclose any information about the product or materials they see during the training and evaluation.

2. Device Training (approximately 30 minutes – Experimental Group only). Participants assigned to the Experimental Group will undergo SureCRIC training by Dr. Amit Shah. SureCRIC training will consist of a review of the Instructions for Use (IFU) and supervised practice on a manikin and the trainer following a brief introduction to the device and operation. A copy of the IFU is attached. Participants assigned to the Control Group will not undergo SureCRIC training. Audio and video recording will be utilized for reference and use in data reduction and analysis (if applicable). Cameras will be positioned on tripods so as not to interfere with the training.

   After completion of the training, the Human Factors Center will individually interview each participant using open-ended questions to garner subjective feedback on the training and instructional materials, as well as preparedness to perform SureCRIC-aided procedures.

3. Decay Period (minimum 60 minutes – Experimental Group only). After training, Experimental group participants will be removed from the facility for a minimum of 60 minutes. Participants will then report to the testing facility at an agreed-upon time.

4. Testing (approximately 30 minutes). Prior to the participants returning to the test facility, the expert confirmer may, at his/her discretion, palpate the neck surface anatomical landmarks of the subjects to familiarize himself/herself with the anatomy. An ultrasound machine will be available to help the expert confirm anatomical landmarks if desired. Subjects may also have neck measurements taken (e.g., neck circumference and length). The verifier may also place a popsicle stick on the neck to indicate the position of the cricothyroid membrane. Pictures of the neck may be taken.
   After returning to the testing facility, Experimental Group participants will utilize the SureCRIC to perform various scenarios. Control Group participants will utilize a freehand approach to perform various scenarios. Subjects will be positioned supine with their necks in the neutral position consistent with standard practice for trauma patients. Testing is the only portion of the study where subjects will be involved.

   During each scenario, participants will identify the CTM on one of the six subjects. Control Group participants will perform CTM identification freehand and Experimental Group participants will use the SureCRIC as an aid in CTM identification. Participants will be made aware that they will be timed prior to testing.

Once the participant has identified the CTM, he/she will gently place a popsicle stick with smooth, round edge on the CTM. The expert verifier will then take control of the stick. The SureCRIC, if used, will then be carefully disassembled with the stick in place. Pictures of the stick on the skin may be taken with the popsicle stick on the neck. The expert verifier will palpate the structures of the anterior neck to confirm accurate CTM localization. In the Experimental Group, the SureCRIC device may be gently and intentionally shifted in position by the verifier as he/she palpates the neck. The expert verifier will indicate to the NCHFH staff (but not the participant) whether the popsicle stick is at the level of the CTM and at the midline of the neck.

After each CTM identification, the participant will report their confidence in accurately identifying the CTM. A slight modification to the procedure described by Lamb [2015] may be used, employing a 10-cm horizontal visual analogue scale (VAS) ranging from "very confident" (0) to "not at all confident" (10).

Only one subject will be available for CTM identification at a time though ultimately each participant will palpate each subject's neck, serially. The medic will not be informed of the success or failure of their identification attempt until the end of their involvement in the study. CTM identification attempts may be recorded for off-line analysis as needed.

Scenarios will include the following:

- Scenario #1: CTM identification of Subject 1 (with or without SureCRIC)
- Scenario #2: CTM identification of Subject 2 (with or without SureCRIC)
- Scenario #3: CTM identification of Subject 3 (with or without SureCRIC)
- Scenario #4: CTM identification of Subject 4 (with or without SureCRIC)
- Scenario #5: CTM identification of Subject 5 (with or without SureCRIC)
- Scenario #6: CTM identification of Subject 6 (with or without SureCRIC)

Each session will be observed by at least one Human Factors Center moderator, who will only be present to observe and give instructions and will not help participants with task completion in any way. Audio and video recording will be utilized for post-hoc data analysis. NCHFH staff will observe each CTM identification procedure focusing on procedural performance and usability in both user groups. NCHFH staff will additionally observe performance of critical tasks and essential tasks.

5. Semi-structured Interviews and Critical Error Debriefing (~15 minutes). Human Factors Center moderators will follow up with participants on any critical errors, close calls, or confusion/difficulty observed during task completion to determine the participant's perspective on the root cause of the error(s). Feedback will also be collected regarding perceived difficulty and usability of the device and IFU for the Experimental Group. Also for the Experimental Group, time is allotted for the moderator to ask the participants open-ended questions regarding their overall impressions of the SureCRIC, whether any tasks were particularly difficult to perform, whether training was adequate and how it might be improved, use of instructions during testing, and thoughts about SureCRIC use in the field.

6. Labeling Validation (~15 minutes – Experimental Group only). After completing use scenarios, the session moderator will complete a labeling validation study by having Experimental Group participants to review the IFU and/or device labeling and asking

content-related knowledge questions. Per FDA's request, results of the labeling validation portion of the study will be compared to existing data from the formative SureCRIC evaluation.

Human Study Data Analysis. Through direct observation as well as video/audio data reduction and analysis, usability test measures will be taken to evaluate the safe and correct performance of critical tasks and other essential tasks. Both performance data and participant feedback will be collected. Given the limited sample size and non-numerical nature of much of the data (e.g., subjective feedback), raw data presentation will be made. In compliance with FDA request, the study will present descriptive data only, as it is not designed for statistical analysis. Also, as discussed in the pre-submission meeting, no comparisons will be performed. A description and analysis of all usability issues will be presented along with root causes and implications for additional risk elimination or reduction.

Descriptive data only will be presented for each subject – *A*, *B C, D, E, and F*. The study is not designed for statistical comparisons between the Control (i.e., freehand) and Experimental (i.e., SureCRIC) groups. The following is an example of a summary data table that will be presented. Note that the data points presented in this table are placeholders used for demonstration purposely only and are not real data. As in previous studies [Bair 2015; Elliott 2010; Kristensen 2015; Lamb 2015], the "time to CTM identification" for each attempt will start when the participant first touches the subject's neck and end when the participant indicates that he/she has identified the CTM.

Example of Summary Data Table for Subject *A* (sample, not real, data)

Participant	**Group**	**Success**	**VAS Visual Analog Scale**	**Time to CTM ID (sec)**
1	Control	Y	3	20
2	Control	Y	9	17
3	Control	N	2	23
4	Control	N	8	19
5	Control	Y	7	30
6	Control	N	5	35
7	Control	Y	6	17
8	Control	Y	4	18
9	Control	N	3	28
10	Control	N	8	23
Control Total / Average		*5/10 (50%) success*	*5.5*	*23*
Participant	**Group**	**Success**	**VAS**	**Time to CTM ID (sec)**
11	Experimental	Y	2	25
12	Experimental	Y	3	19
13	Experimental	Y	0	38
14	Experimental	N	4	22
15	Experimental	N	5	40
16	Experimental	Y	7	15

17	Experimental	Y	3	28
18	Experimental	Y	6	33
19	Experimental	Y	3	26
20	Experimental	Y	6	30
Experimental Total / Average		*8/10 (80%) success*	*4*	*27.6*

Human factors data will be presented in both tabular and paragraph form. These will include data on critical and non-critical tasks, subjective feedback, and labeling comprehension information. A description and analysis of all use errors and difficulties that could cause harm will be provided along with root causes of the problems and implications for additional risk elimination or reduction.

2 Methods and Data Analysis (Manikin Study)

The study will be a single-arm, open label study. Each of the participants will perform three cricothyrotomy procedures on a manikin. Each procedure will be performed with the SureCRIC and one of three representative cricothyrotomy kits. Participants in the manikin study will complete study sessions that will consist of the following:

1. Signing of Documents and Pre-Evaluation Interview (~5 minutes). Prior to study participation, relevant information on clinical experience will be collected from all participants. Sample data points include handedness, years of and nature of clinical experience, cricothyrotomy training with various approaches and kits, and previous cricothyrotomy performance. Upon arrival, participants will be asked to sign an informed consent form that describes participant's role in the evaluation, explains risks involved and consents to the use of audio and video recordings for analysis purposes. Participants will also be asked not to disclose any information about the product or materials they see during the training and evaluation.

2. Device Training (approximately 60 minutes). Participants will be introduced to each of the three cricothyrotomy kits as well as the SureCRIC and allowed to practice use on a manikin. SureCRIC training will consist of a review of the Instructions for Use (IFU) and supervised practice following a brief introduction to the device and procedure. A copy of the IFU is attached. Training with the three cricothyrotomy kits will include a review of the kit components and the IFU, and an opportunity to practice kit use, including with the SureCRIC, on a manikin model. Training will be conducted by Dr. Amit Shah. Audio and video recording will be utilized for reference and use in data reduction and analysis (if applicable). Cameras will be positioned on tripods so as not to interfere with the training.

   After completion of the training, the Human Factors Center will individually interview each participant using open-ended questions to garner subjective feedback on the training and instructional materials, as well as preparedness to perform SureCRIC-aided procedures.

3. Decay Period (minimum 60 minutes). After training, participants will be removed from the facility for a minimum of 60 minutes. Participants will then report to the testing facility at an agreed-upon time.

4. Usability Testing (approximately 30 minutes). After returning to the testing facility, participants will utilize the SureCRIC to perform various scenarios. A *Nasco Life/Form Cricothyrotomy Simulator* will be placed at the head of a table, fitted with a laryngeal insert, and covered with elastomeric "skin." The tool kit and packaged SureCRIC will be placed by the simulator. A new laryngeal insert and skin will be used for each scenario.

   Manikin scenarios will include the following:
   - Scenario #1: Direct percutaneous approach with Rusch QuickTrach Cricothyrotomy Kit
   - Scenario #2: Seldinger approach with Melker Emergency Cricothyrotomy Catheter Set
   - Scenario #3: Direct scalpel incision with North American Rescue Tactical Crickit

   Each session will be observed by at least one Human Factors Center moderator, who will only be present to observe and give instructions and will not help participants with task completion in any way. Audio and video recording will be utilized for post-hoc data analysis. NCHFH staff will observe each manikin procedure focusing on usability and potential interference of the SureCRIC with the cricothyrotomy tools. NCHFH staff will additionally observe performance of critical tasks and essential tasks, focusing on the steps up to and including the step where the SureCRIC is removed from the manikin.

5. Semi-structured Interviews and Critical Error Debriefing (~15 minutes). Human Factors Center moderators will follow up with participants on any critical errors, close calls, or confusion/difficulty observed during task completion to determine the participant's perspective on the root cause of the error(s). Feedback will also be collected regarding perceived difficulty and usability of the device and IFU. Time is allotted for the moderator to ask the participants open-ended questions regarding their overall impressions of the SureCRIC, whether any tasks were particularly difficult to perform, whether training was adequate and how it might be improved, use of instructions during testing, and thoughts about SureCRIC use in the field. Participants will report on interference of the SureCRIC with his/her intended use of the cricothyrotomy tools.

6. Labeling Validation (~15 minutes). After completing use scenarios, the session moderator will complete a labeling validation study by having participants to review the IFU and/or device labeling and asking content-related knowledge questions. Per FDA's request, results of the labeling validation portion of the study will be compared to existing data from the formative SureCRIC evaluation.

Manikin Study Data Analysis. Through direct observation as well as video/audio data reduction and analysis, usability test measures will be taken to evaluate the safe and correct performance of critical tasks and other essential tasks. Both performance data and participant feedback will be collected. Given the limited sample size and non-numerical nature of much of the data (e.g., subjective feedback), raw data presentation will be made. In compliance with FDA request, the study will present descriptive data only, as it is not designed for statistical analysis. A description and analysis of all interference and usability issues will be presented along with root causes and implications for additional risk elimination or reduction.

3 **Data Storage and Confidentiality**.

Upon completion of the validation sessions, video/audio data will be transferred to both InnoVital's and the Human Factors Center's secure, password-protected data servers in preparation for data reduction efforts. Recordings will be identified by assigned participant number and will not utilize any identifying participant information, such that each observational session will remain anonymous. No provider identifying information will be collected as part of the research dataset. Access to all study data will be limited to study investigators. Recordings will be kept for three years following the completion of the study so they can be revisited to verify collected data, if necessary, at any point during the FDA pre-market approval process. After three years, the recordings will be destroyed.

IV. RISK/BENEFIT ASSESSMENT

1 **Risk Category**. Minimal risk (for subject and participants)

2 **Potential Risk**.

This study does not involve any interventions or procedures to participants. In the human study, participants are simply identifying a surface anatomical landmark on healthy human volunteer subjects – either with or without a non-invasive device. In the manikin study, participants are only performing cricothyrotomies on manikins. Therefore, risk to participants is minimal, with the greatest risk being a breach of participation confidentiality. Participants can opt out of the study at any time.

Subjects in the human study will lay on tables for 5- to 10-minute durations, expected to occur 5 to 6 times during each day of evaluation. Subjects will have free time in which they are not required to perform any tasks, and frequent opportunities to get up and stretch in the interim. While laying supine, they will have their neck anatomy palpated with light pressure either freehand or with the non-invasive SureCRIC device. The purpose of the palpation is to identify the surface anatomical cricothyroid membrane landmark. A popsicle stick with a round, smooth edge may also be used to note the position of the cricothyroid membrane. Subjects will be asked to report greater than minimal discomfort. Reported greater than minimal discomfort will trigger study termination for that subject. Cooling packs will be made available for subjects should they want to use them for any mild skin irritation or redness. Therefore, risk to subjects is minimal. Subjects can opt out of the study at any time.

3 **Protection Against Risks**.

To protect against the risks described above, identifying information that can be linked to the participants and subjects is limited to audio and video recordings and heavily protected, not to be shared with any outside parties. For details, please reference Section III-3 Data Storage and Confidentiality.

Participants will be given a consent form explaining the study. Though hospital / health system employees are not specifically being recruited, any participating employee will be made aware that the study is not linked to their employment or employee evaluations, and results will not be shared with hospital administration or leadership. Because adverse event reporting systems are already in place, there is limited risk of an observed adverse event going unreported.

Subjects will be given a consent form explaining the study. Subjects will have frequent opportunities to get up and stretch. Subjects will have break time between sessions and will only actively participate for approximately 5 to 10 minutes during testing sessions (expected

5 to 6 sessions per day). Subjects will be asked to report greater than minimal discomfort. Subjects can opt out of the study at any time. Because adverse event reporting systems are already in place, there is limited risk of an observed adverse event going unreported

4 **Potential Benefits to the Subjects**
Individual participants and subjects benefit from compensation. This study also provides an opportunity for a net benefit, by potentially introducing a useful tool into the medical environment.

V. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

1 **Method of Subject Identification and Recruitment.**
Recruitment of participants and subjects will be conducted through (a) third-party recruiting companies (e.g., Observation Baltimore), (b) training centers and schools (e.g., Uniformed Services University), and (c) NCHFH and/or InnoVital clinician networks.

2 **Process of Consent**.
After participants and subjects have arrived at the study site, they will be given an informed consent letter. After an opportunity to read the information and ask any questions, they will sign the form. Video recording will begin only after participants have signed the consent form. For participants that are hospital employees, they will be instructed that participation, or lack of participation will have no ill effects on their employment.

3 **Payment for Participation**.
Control Group participants in the human study will be compensated $125 for participation of approximately 1 hour. Experimental Group participants in the human study will be compensated $175 for participation of approximately 2.5 hours. Subjects in the human study will be compensated approximately $30/hour, and will be present on 4 consecutive, 9-hour days, and therefore be compensated $1,080 each. One back-up subject will be recruited for each size and compensated $75 per day of being "on call." In the manikin study, novice participants will be compensated $225 for participation, and expert participants will be compensated $750. The expert, verifier clinician will be compensated at a rate of $250/hr. For 4 consecutive, 9-hour days, the expert verifier will be compensated a total of $9,000.

VI. REFERENCES

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