

PROTOCOL TITLE: SAFETY: Stabilization points to third hospital line Assessment of the impact of the use of Infrascanner Model 2500 to provide decision support for diagnosis/screening of Traumatic Brain Injury in Ukraine

SECTION A: RESEARCH TEAM AND LOCATIONS

A1. RESEARCH TEAM

<u>Study Role</u>	<u>Institution/Company and Contact Information</u>
Sponsor	<i>Organization/Institution/Company:</i> USARMY USAMRMC <i>Address:</i> 810 Scheider Street, Fort Detrick, MD 21702 <i>Point of Contact:</i> <i>Name and Degree:</i> Dr. James B. Phillips <i>Title:</i> Head of Neurotrauma, Combat Casualty Care <i>Phone Number:</i> (240) 529-7264 <i>Email:</i> james.b.phillips10.civ@health.mil
Principal Investigator	<i>Name, Rank, and Degree:</i> Dr. Baruch Ben-Dor <i>Title:</i> CEO <i>Institution:</i> InfraScan, Inc. <i>Address:</i> 3508 Market St, Philadelphia, PA 19104 <i>Phone Number:</i> (610) 608-3112 <i>Email:</i> bbendor@infrascanner.com
Clinical Principal Investigator	<i>Name, Rank, and Degree:</i> Dr. Dmytro Dmytriiev, Professor, MD, PhD, MBA <i>Title:</i> Anesthesiologist, Chief of Pain Medicine department <i>Institution:</i> Vinnytsia City Clinical Hospital named after M.I.Pirogov of Vinnitsya Regional Council <i>Address:</i> Vinnytsia, Ukraine <i>Phone Number:</i> +380674309449 <i>Email:</i> mddmytriiev@gmail.com
Clinical Associate Investigator(s)	<i>Name, Rank, and Degree:</i> Dr. Andrii Sirko, Professor, MD, PhD. <i>Title:</i> Head of the Center of Cerebral Neurosurgery <i>Institution/Company:</i> Dnipropetrovsk Regional Clinical Hospital named after I.I. Mechnikov of Dnipropetrovsk Regional Council <i>Address:</i> Sq. Soborna 14, Dnipro, Ukraine <i>Phone Number:</i> + 3800505583055 <i>Email:</i> neurosirko75@gmail.com
Clinical Associate Investigator(s)	<i>Name, Rank, and Degree:</i> Dr. Kostiantyn Humeniuk, COL <i>Title:</i> Chief Surgeon of the Armed Forces of Ukraine <i>Institution/Company:</i> Ukrainian Military <i>Address:</i> Kyiv, Ukraine <i>Email:</i> gkv73@ukr.net
Consultant	<i>Name, Rank, and Degree:</i> Dr. John Holcomb, COL (ret) <i>Title:</i> Trauma Surgeon <i>Institution/Company:</i> UAB (University of Alabama in Birmingham) <i>Phone Number:</i> (281) 865-8732 <i>Email:</i> JBHolcomb@uabmc.edu
Consultant	<i>Name, Rank, and Degree:</i> Dr. Alex Valadka <i>Title:</i> Director of Neurotrauma <i>Institution/Company:</i> UTSW (University of Texas Southwestern) <i>Phone Number:</i> (713) 899-6177 <i>Email:</i> Alex.Valadka@UTSouthwestern.edu

A2. ROLES AND RESPONSIBILITIES

A2.1 MTEC Grantee, Principal Investigator

Name: Baruch Ben-Dor, PhD., President/CEO, Infrascan, Inc.

Study Responsibilities: Responsible for the development and commercialization of the Infrascanner device. As the prime grantee, InfraScan, Inc. is responsible for the grant administration of the overall project driver and authority on decisions related to the use of the product's results to aid in decision support in the care of humans in combat and civilian settings in Ukraine. InfraScan, Inc. is responsible for all financial and administrative functions of the grant and will manage the IRB and FDA approval processes in the U.S. InfraScan will work with the Ukrainian team from August Mission (AM), Dr. Dmytriiev (Clinical PI), Dr. Sirko and Dr. Humeniuk (Clinical Associate-PIs) to receive approvals from the relevant Ukraine regulators. InfraScan will provide the product itself, the training (in Poland), and ongoing coaching of the Site PIs and team for this observational, implementation science study utilizing the Infrascanner to detect brain bleeds and hematomas in civilian and military settings.

A2.2 Clinical, Principal Investigator

Name: Dr. Dymtro Dmytriiev

Study Responsibilities: Responsible for conducting the study according to the protocol and maintaining a list of appropriately qualified persons to whom significant study-related responsibilities have been delegated. Perform and review data analysis and participate in result dissemination.

A2.3 Clinical, Associate Investigator(s)

Name(s): Dr. Andrii Sirko

Study Responsibilities: Responsible for the conduct of the study and data collection in accordance with the protocol. Perform and review data analysis and participate in result dissemination.

Name(s): Dr. Kostiantyn Humeniuk, COL

Study Responsibilities: Responsible for the conduct of the study and data collection in accordance with the protocol. Perform and review data analysis and participate in result dissemination.

A2.4 Consultants

Name(s): Dr. John Holcomb (American), Dr. Alex Valadka (American)

Study Responsibilities: Drs. Holcomb and Valadka will provide support to the design and the conduct of the study and serve as advisors to InfraScan.

A2.5 Logistic Subcontractor

Name(s): Jarvis Mak, Lina Belei, and Colleen Copple, August Mission

Study Responsibilities: August Mission (AM) has the Ukrainian staff on the ground with the know-how, relationships with the Ministries of Health and Defense, and Chief Surgeon of the Armed Forces of Ukraine, as well as numerous healthcare facilities, universities, and experienced principal investigators. AM will arrange Infrascanner training in Poland, facilitate monthly virtual project team meetings, conduct weekly onsite project oversight, grant compliance, and support grant reporting.

A3. RESEARCH LOCATIONS

Three Ukrainian trauma centers (first-, second-, and third-line hospitals/Roles 3 and 4) connected to about five stabilization points (Role 2) will be the site for the clinical data collection. Data will be collected at the bedside in Ukraine using Case Report Forms (CRF). All text from the radiologist reports will be entered on the CRF, and the forms and CT scans will be uploaded via a secure file exchange service. The data will be sent to

The University of Alabama at Birmingham (UAB) for analysis. All received data will be entered into a REDCap database managed by UAB.

Before initiating the Device phase, a dedicated group of Ukrainian nurses will be trained as "superusers" in Rzeszow, Poland. These "superusers" will be able to not only use the device, but also be able to orient others with the device and conduct training. The trained superusers will perform onsite training and conduct user proficiency evaluations.

A4. MULTISITE RESEARCH

The selected hospitals are high-quality, high-volume facilities that manage to deal with high numbers of combat casualties. The clinical principal investigators and both NATO Role 4 hospitals have led or participated in high volumes of clinical trials and have published peer-reviewed journal articles.

Lead Site: Vinnytsia M.I. Pyrohov Regional Clinical Hospital (Vinnytsia)

Lead Site Investigator: Dr. Dymtro Dmytriiev

IRB that will review for the lead site: The Hospital has a local Helsinki ethics committee

Function/Role of Lead Site: The hospital provides Role 4 North Atlantic Treaty Organization (NATO) medical support and serves as the main clinical base for Vinnytsia National Pirogov Memorial Medical University, and it receives a high number of combat and civilian-related injuries. To date, over 100 clinical trials have been conducted at this high-volume site that partners with a local university to support postgraduate clinical education. Doctoral students are onsite and able to participate in research projects and data collection. Dr. Dmytriiev's team is able to support the efforts needed to monitor the use of the Infrascanner in a forward theater setting.

Performance Site: Mechnikov Dnipropetrovsk Regional Clinical Hospital (Dnipro)

Performance Site Investigator: Dr. Andrii Sirko

IRB that will review for the Performance Site: The Hospital has a local Helsinki ethics committee

Function/Role of Performance Site: This hospital currently serves to treat combat and civilian-related injuries. Dr. Sirko's team has the experience and capacity to collect research-related data. This site's structure is similar to that of a NATO Role 4 site.

Performance Site: Mobile Military Hospital (to be determined)

Performance Site Investigator: Dr. Kostiantyn Humeniuk

IRB that will review for the Performance Site: Medical Ethics Commission of the Ukrainian Military Medical Academy

Function/Role of Performance Site: Mobile hospitals provide NATO Role 3 medical care and are used in combat areas to triage and treat patients. Dr. Humeniuk will ensure that the data is collected at the bedside.

Performance Site: Military Stabilization Points (to be determined)

Performance Site Investigator: Dr. Kostiantyn Humeniuk

IRB that will review for the Performance Site: Medical Ethics Commission of the Ukrainian Military Medical Academy

Function/Role of Performance Site: Field stabilization points are dynamic sites for triage and initial treatment, providing NATO Role 2 medical support. Dr. Humeniuk will ensure that the Infrascanner device is used when possible and per protocol.

SECTION B: RESEARCH METHODOLOGY

B1. ABSTRACT

The Infrascanner model 2500 is a handheld, noninvasive device that is FDA-cleared to detect traumatic intracranial hematomas. FDA clearance K200203 was issued in 2020, K211617 added pediatric age group to the IFU in 2022, and K241389 approved higher laser power use to address dark skinned patients in 2024. This non randomized observational study aims to **evaluate the utility of this device** by evaluating its ability to provide decision support information to optimize care for patients with suspected traumatic intracranial hematomas. It is important to note that the intended use of the device is in accordance with its FDA approved indication. The intent is to generate actionable knowledge that along with standard clinical signs, facilitates the **early detection of intracranial hemorrhage (ICH)** in patients with suspected traumatic brain injury (TBI) in a combat setting. The ultimate goal is to modify and optimize international protocols for inexpensive, bedside, portable, and noninvasive detection of traumatic ICH in conflict zones across the globe.

This multicenter, prospective, observational, implementation science study will evaluate the field utility of the Infrascanner Model 2500 in an active combat setting using a pragmatic, sequential research design consisting of two phases—baseline phase and device phase. Using the current Ukrainian medical care system, patients with suspected TBIs will be monitored, and their outcomes will be tracked using standard-of-care practices (baseline phase). After the baseline data collection period is complete, an amendment to the protocol will be submitted to initiate the device phase. After training and upon approval, the Infrascanner device will be deployed to the facilities described above to provide health care providers with additional decision support, and the impact of its use will be compared to the baseline data. The outcome of interest is the time from admission at each enrollment study location to a definitive CT scan diagnosis of ICH. We **hypothesize that the use of the device will provide decision support to health care providers, decrease the time to traumatic ICH detection, thus enabling more expedient care.**

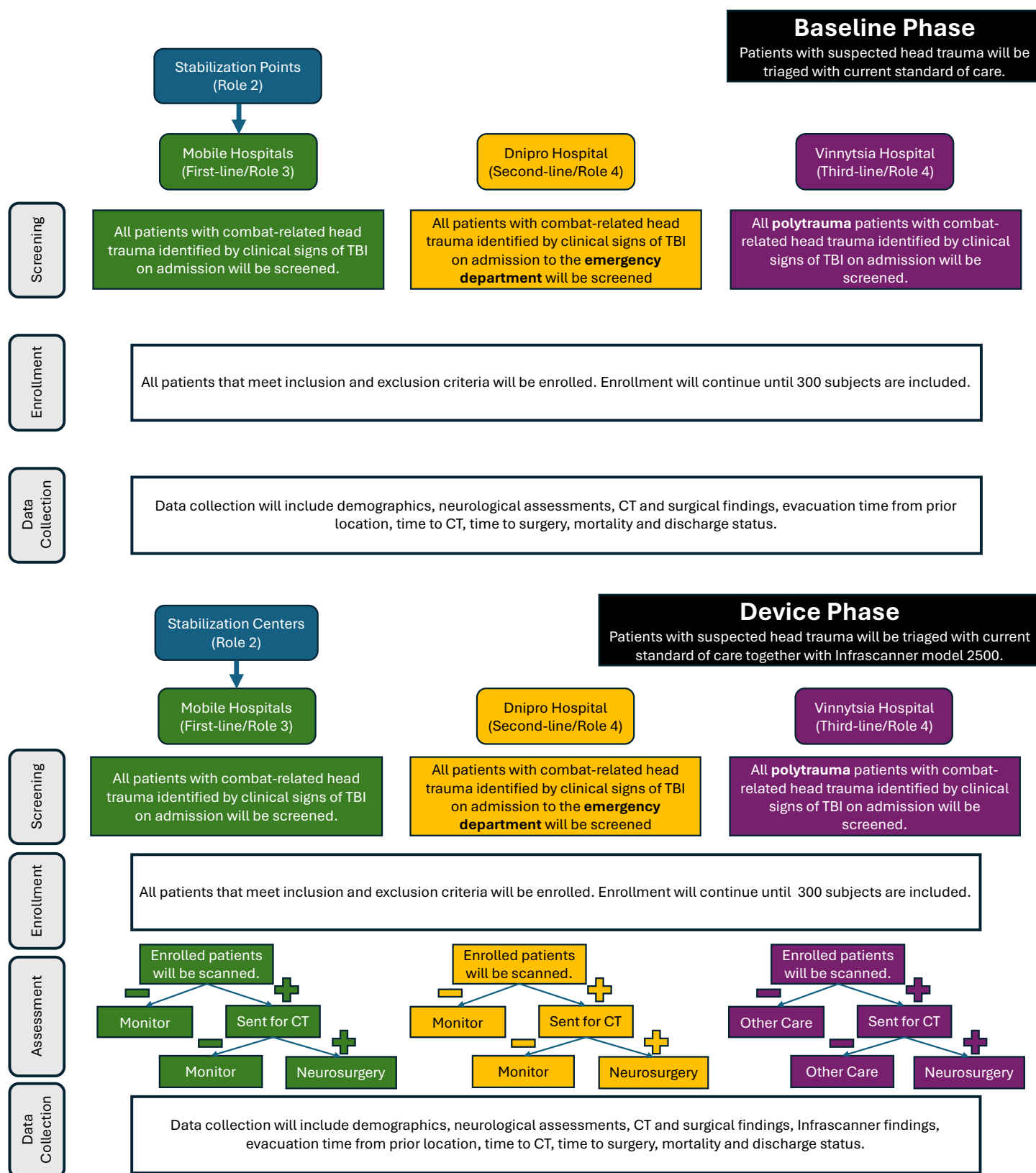
This prospective study will **include** all patients with suspected combat-related head trauma identified by clinical signs of TBI, such as decreased GCS score, abnormal pupil exam, and/or asymmetrical motor exam, on admission to the clinical enrollment site (mobile hospital or regional clinical hospital) regardless of the presence of pharmacologic sedation. At the Vinnytsia hospital (Role 4), combat polytrauma preoperative patients will also be screened. **Exclusion** criteria include evidence of extensive scalp injury, including lacerations, avulsions, or abrasions that prevent proper placement of the Infrascanner device on a subject's head or prevent placement of the device in the specified locations.

During the baseline phase (**Figure 1**), a total of up to 300 subjects will be enrolled from the stabilization points, the mobile/first-line hospital, the second-line hospital and the third-line hospital. Baseline data on the time from admission at each enrollment study location to a definitive CT scan diagnosis of ICH and treatment and early outcomes will be collected.

Once the baseline phase is complete and the amendment for the device phase is approved, it will be initiated. During this device phase, the Infrascanner will be deployed to stabilization points and the three levels of care (mobile hospitals and regional clinical hospitals). Data collection will continue until a total of up to 300 subjects are enrolled in the device phase for the three levels of care. All data collection at the baseline and device phases will occur at the same locations, and the data elements will be identical, except for Infrascanner data collected during the device phase.

By comparing data from the baseline and device phase, we will assess the utility of the device to provide decision support information to providers and potentially reduce time to definitive diagnosis by CT scan and thus treatment, as well as the association between Infrascanner use and early patient outcomes.

Figure 1. Overall Research Design



B3. MILITARY RELEVANCE

The Infrascanner is a TBI clinical decision assist device for detection of traumatic intracranial hematomas (Robertson 2010; Gramer 2023). The Infrascanner is FDA-cleared and has a very specific application in detecting traumatic intracranial hematomas where timely triage is critical [Shackelford 2018]. Early intracranial hematoma detection is life-saving and also supports prioritized evacuation of injured military personnel. The Infrascanner has the potential to lead to earlier ICH detection, resulting in less brain injury, as well as faster and more complete recovery. The Infrascanner model 2500 has finished the transition to manufacturing under contract W81XWH-21-C-0070 with USAMMDA.

Intracranial hematomas are an important and often treatable cause of secondary brain injury in patients with head trauma. Data from Iraq show that 30% of all wounded in action had head injuries, of which 40% had brain hematomas (Owens 2008). Rapid triage, diagnosis, and treatment are critical in minimizing the adverse consequences of more serious brain injuries. Since many TBIs are associated with extensive polytrauma, pre-hospital and battlefield care is often challenging. For patients with moderate-to-severe TBI in particular, diagnosis within the first hour (the "golden" hour) of the traumatic event is critical as intracranial hematomas can result in death or significant neurological impairment (Corrigan 2010; Folkerson 2015; Newgard 2015). Current standard operating procedures (SOP) involve an immediate clinical evaluation and neurological examination. Compounding management is the potential for delayed development of intracranial hematomas, which are often not diagnosed until significant neurological impairment occurs. A rapid clinical exam that reveals the standard clinical signs, followed by immediate evacuation to a treatment facility with a computed tomography scan (CT) for definitive diagnosis and neurosurgical intervention capability, is paramount to maximizing survivability and minimizing irreversible neurological impairment [Shackelford 2024]. CT of the head currently provides the definitive diagnostic modality for identifying intracranial hematomas. By adding the the Infrascanner to the clinical exam, as a decision assist tool, the health care team could potentially decrease the time to CT scan and neurosurgical intervention. The Marines' used the Infrascanner exactly this way. Their rationale for using the Infrascanner is summarized by COL Dr. Luis Becerra, who evaluated the system in Iraq: "The Infrascanner located in Fallujah provided immediate information that was not available by any other means, and offered life-saving triage prioritization of patients who required immediate surgical intervention." In Ukraine, there is an urgent need to triage a large number of trauma injury victims and to help prioritize the urgency and destination of evacuation. The sheer number of injured arriving daily at hospitals puts pressure on the few medical imaging resources that they have. Many patients with suspected TBI either don't get CT imaging or get it after considerable delays.

The Combat Casualty Care Research Program (CCCRP) area prioritizes technologies that are easily transportable (i.e., small, lightweight, and durable in extreme environments and handling), easy to use, and require low maintenance. The Infrascanner exactly meets this priority. The Infrascanner Model 2500 is a lightweight and handheld brain scanner that provides a simple positive or negative graphic report for the detection of traumatic supratentorial hematomas of greater than 3.5 mL in volume that are less than 2.5 cm from the brain surface. While the Infrascanner addresses the pre-hospital and in-hospital mass triage problems of the Ukrainian military and health systems, the proposed research will provide very valuable input for US military medical planning for future large scale multi-domain conflicts, where the US will not have air superiority and speedy and efficient triage will be challenging. Thus, the results of this study have the potential to inform relevant US Joint Trauma System CPGs (Clinical Practice Guidelines).

This multicenter, prospective, observational, implementation science study will provide value to both civilian and military settings in Ukraine and provide training for the civilian and military healthcare systems operating in Ukraine. The collection of these data presents minimal risk to patients.

In addition to the military value that the Infrascanner brings to Ukraine, it has significant relevance in civilian settings as well including hospital and emergency room monitoring. Infrascanner provides mobile brain scanning and bedside monitoring for patients undergoing observation for small or delayed hematomas. Since approximately 20% of trauma-related hematomas do not appear for more than 12 hours following injury (McKee 2015), Infrascanner could be used effectively as a pre-hospital or bedside monitoring tool for patients undergoing observation after trauma. This application is currently being studied in the US under contract

W81XWH-21-9-0006 in the frame of the MOBI trial (Noninvasive Monitoring of Traumatic Brain Injury Progression Using the Infrascanner).

B4. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS

The **primary objective** of the study is to **evaluate the time** from admission at each enrollment study location to a definitive CT scan diagnosis of intracranial hemorrhage (ICH). The **secondary objective** is to evaluate the impact of Infrascanner data on early **patient outcomes**.

B5. RESEARCH PLAN

B5.1 Research Design

This multicenter, prospective, observational, implementation science study will evaluate the use of the FDA cleared Infrascanner Model 2500 in the Ukrainian medical care system. This pragmatic, sequential study will enroll patients at multiple levels of care (Role 3/First-line/Mobile hospitals, Role 4/Second and Third-line/Regional hospitals). We will first enroll baseline patients using the standard of care neurological checks (Baseline Phase) and then transition to the device use (Device Phase) upon approval of a protocol amendment. The baseline and device cohorts will be compared (time from injury to CT in patients with ICH) to understand device utility and impact at the different levels of medical care in combat arenas. Of note, the device will be deployed at stabilization points (Role 2) during the device phase. The analysis will identify if device use is compatible with patient care activities and if it can provide decision support to health care providers, decrease the time to traumatic ICH detection, and enable more expedient care.

B5.2 Research Subjects/Population(s)

B5.2.1 Subject Population(s)

Patients with suspected combat-related head trauma who are admitted to the participating hospitals that provide Role 3 or 4 medical support will be eligible for enrollment in this trial.

B5.2.2 Number of Subjects, Records, and/or Specimens

This study will enroll a total of up to **600 patients**. During the baseline phase, 300 eligible patients will be enrolled: at the mobile hospital, at the second-line hospital, and at a third-line hospital (total of up to 300 **baseline subjects**). These patients will receive the current standard of care. After 300 eligible subjects have been enrolled and the protocol amendment for initiation of the device phase has been approved, the Infrascanner device will be deployed to the sites, and enrollment in the device phase will begin. Patients will be enrolled at the mobile hospital, at the second-line hospital, and at a third-line hospital (a total of up to 300 **device subjects**).

B5.2.3 Inclusion Criteria

This prospective study will include all patients with suspected combat-related head trauma identified by clinical signs of TBI, such as decreased GCS score, abnormal pupil exam, and/or asymmetrical motor exam, on admission to the clinical enrollment site (mobile hospital or regional clinical hospital) regardless of the presence of pharmacologic sedation.

B5.2.4 Exclusion Criteria

Evidence of extensive scalp injury, including lacerations, avulsions, or abrasions that prevent proper placement of the Infrascanner device on a subject's head or prevent placement of the device in the specified locations.

B5.3 Research Procedures

In Ukraine, there are stabilization points (equivalent to NATO Role 2) where doctors can assess and stabilize patients and send them for care (Table 1). Mobile hospitals (equivalent to NATO Role 3) serve as the first line of hospital care for injured soldiers and individuals. The Mechnikov (second-line) and Vinnytsia (third-line) hospitals are able to provide higher levels of care and interventions (both equivalent to Role 4).

Table 1. Levels of Care Designations

SAFETY Study Location	Centers of care near the frontlines	Mobile Hospitals	Regional Hospital	University-affiliated major medical center
Ukrainian Term	Stabilization Points	First Line Hospital	Second Line Hospital	Third-line Hospital
NATO Term	Role 2	Role 3	Role 4	Role 4

By placing the devices at the stabilization centers (Role 2), we will obtain data on how the device can aid in triaging injured patients in warfare environments where resources are limited. Information on the scans from Role 2 centers may be difficult to attain or be incomplete, so the exploration of its use is limited. It is anticipated that most patients who arrive at a stabilization point will be transferred to the mobile hospital/Role 3. Those who arrive at a mobile or regional hospital (Role 3 or 4) that is an enrolling site will be included if they meet the eligibility criteria. Any information from the stabilization point (Role 2), including results from the use of an Infrascanner device in the field, will be captured. Analysis possibilities on any Role 2 data will be determined once enrollment is completed.

B5.3.1 Baseline Phase

Mobile Hospital (First-Line/Role 3 Setting)

Screening & Enrollment

At selected and trained mobile hospitals, all patients who arrive with suspected head trauma will be screened for eligibility. Those who meet the eligibility criteria will be enrolled.

Procedures

Enrolled patients will be monitored using standard clinical neurological checks, which are the standard of care practice and include GCS, pupil exam, and motor exam. Per the physician's assessment of the physical exam findings, patients will be sent for a CT scan and if indicated a neurosurgical intervention.

Data Collection

Basic patient demographic information will be entered into the CRF (See Appendix 1). The hospital record will also provide the time of arrival, the time of evacuation from the stabilization point, and the time of the CT scan, along with the results of the CT scan. All surgical information will be recorded and attained. Outcome and discharge information will also be recorded.

The data collection will cease once 100 patients have been enrolled.

Mechnikov Hospital (Second-Line/Role 4 Setting)

Screening & Enrollment

At the Mechnikov Hospital, all patients admitted to the emergency department will be screened. Those with suspected head trauma will be evaluated for eligibility. Those that meet the eligibility criteria will be enrolled.

Procedures

Enrolled patients will be monitored using standard clinical neurological checks, which are the standard of

care practice and include GCS, pupil exam, and motor exam. Per the physician's assessment of the physical exam findings, patients will be sent for a CT scan and if indicated a neurosurgical intervention.

Data Collection

Basic patient demographic information will be entered into the CRF. The hospital record will also provide the time of arrival, neurological check data, and time of the CT scan (if completed), along with the results of the CT scan (if completed). All surgical information (if completed) will be recorded and attained. Outcome and discharge information will also be recorded.

Data collection will cease once 100 patients have been enrolled.

Vinnytsia Hospital (Third-Line/Role 4 Setting)

Screening & Enrollment

At the Vinnytsia Hospital, all polytrauma patients will be evaluated for eligibility. Those who meet the eligibility criteria will be enrolled.

Procedures

Enrolled patients will be monitored using standard clinical neurological checks, which are the standard of care practice and include GCS, pupil exam, and motor exam. Per the physician's assessment of the physical exam findings, patients will be sent for a CT scan and if indicated a neurosurgical intervention.

Data Collection

Basic patient demographic information will be entered into the CRF. The hospital record will also provide the time of arrival, neurological check data, and time of the CT scan (if completed), along with the results of the CT scan (if completed). All surgical information (if completed) will be recorded and attained. All brain-related complications will be recorded (See Appendix 1). Outcome and discharge information will also be recorded.

Data collection will cease once 100 patients have been enrolled.

B5.3.2 Device Phase

Stabilization Points/Role 2 Procedure

At selected (by COL Humeniuk) and trained stabilization points, all patients with suspected head trauma will be evaluated with standard of care neurological checks plus the Infrascanner 2500. Triage assignments by the clinical team will be made and the patients evacuated to the next level of care.

If the patient has abnormal clinical exam and a **positive scan**, their evacuation to a mobile hospital will be prioritized for evacuation.

If the patient has abnormal clinical exam and a **negative scan**, the casualty will be evacuated in a triage category as determined by the clinical team.

Standard neurological checks will be completed per standard of care for both groups of patients. Providers may always prioritize a patient with a negative scan.

Each casualty has a standard clinical care card filled out. If an Infrascanner device is used, the results of the scan will be recorded on the card.

Mobile Hospital (First-Line/Role 3 Setting)

Screening & Enrollment

At selected and trained mobile hospitals, patients' medical cards will be reviewed. Any patient who has already been scanned at the stabilization point will be enrolled as long as all eligibility criteria are met. In addition, any patient who arrives with suspected head trauma will be evaluated for eligibility. Those who meet the eligibility criteria will be enrolled.

Procedures

All enrolled patients will be evaluated with standard neurologic clinical exam and the Infrascanner device upon admission.

Patients with a **positive scan** at the stabilization point or upon admission to the mobile hospital will be prioritized for CT evaluation. Standard serial neurological checks will also be completed until the CT scan is completed.

Patients with a second **negative scan** (stabilization point and/or mobile hospital) will receive the usual care, and the Infrascanner will be used to repeat the scan if there is a change in GCS to identify delayed bleeds. Providers may always prioritize a patient with a negative scan.

Further intervention, such as surgery, is done at the mobile hospital, per the physician's opinion.

Data Collection

Basic patient demographic information will be entered into the CRF. The hospital record will also provide the time of arrival, the time of evacuation from the stabilization point, and the time of the CT scan (if completed), along with the results of the CT scan (if completed). All surgical information (if completed) will be recorded and attained. The neurological checks are recorded via standard-of-care practices, which include GCS. Outcome and discharge information will also be recorded. The time and outcome of all Infrascanner results will be recorded.

Patients will be enrolled until data from 100 subjects at mobile hospitals are collected.

Mechnikov Hospital (Second-Line/Role 4 Setting)

Screening & Enrollment

At the Mechnikov Hospital, all patients with suspected head trauma who are admitted to the **emergency department** will be screened. Those that meet the eligibility criteria will be enrolled.

Procedures

All enrolled patients will be evaluated with the Infrascanner device upon admission.

Patients with a **positive Infrascanner scan** will be prioritized for CT evaluation. Standard neurological checks will also be completed until the CT scan is completed. If the CT scan is positive, surgery will be performed.

Patients with a **negative Infrascanner scan** will undergo continued standard neurological check monitoring, and the Infrascanner will be used to repeat the scan if there is a change in GCS to identify delayed bleeds. Providers may always prioritize a patient with a negative scan.

Data Collection

Basic patient demographic information will be entered into the CRF. The hospital record will also provide the time of arrival, neurological check data, and time of the CT scan (if completed), along with the results of the CT scan (if completed). All surgical information (if completed) will be recorded and attained. Outcome and discharge information will also be recorded. The time and outcome of all Infrascanner results will be recorded.

Patients will be enrolled until data from 100 subjects from this site are collected.

Vinnytsia Hospital (Third-Line/Role 4 Setting)

Screening & Enrollment

At the Vinnytsia Hospital, all **combat polytrauma patients** and **preoperative non-neuro patients** will be evaluated for eligibility. Those that meet the eligibility criteria will be enrolled.

Procedures

Combat polytrauma patients will be scanned with the Infrascanner 2500. Scans can occur during the preoperative and perioperative periods on all patients who undergo non-neuro surgery.

Patients with a **positive scan** prior to or upon admission to the hospital will be prioritized for CT evaluation. Standard neurological checks will also be completed until the CT scan is completed. If a CT scan has already been completed, neurosurgery will be prioritized for those with a positive scan. If the CT is negative, monitoring will continue with standard neurochecks and scans by the Infrascanner 2500.

Patients with a **negative scan** prior to or upon admission will undergo continued monitoring with standard neurochecks and scans by the Infrascanner 2500 to identify delayed bleeds. Providers may always prioritize a patient with a negative scan.

Data Collection

Basic patient demographic information will be entered into the CRF. The hospital record will also provide the time of arrival, neurological check data, and time of CT scan (if completed), along with the results of CT scan (if completed). All surgical information (if completed) will be recorded and attained. All brain-related complications will be recorded. Outcome and discharge information will also be recorded. The time and outcome of all Infrascanner results will be recorded.

Patients will be enrolled until data from 100 subjects from this site are collected.

B5.3.3 Data Curation

Due to the study design, there is a potential for enrollment at more than one site. The same patient can be evaluated at different sites. At each site, the subject will be evaluated separately for the utility of the Infrascanner (decreasing the time from admission to a definitive CT scan diagnosis of ICH) at that specific level of care.

At the end of the enrollment, the Ukrainian Site PIs will correlate their master patient records to see if the same patient passed via different hospitals and will report a correlation (for example, Patient 23 at Mobile Hospital is Patient 34 in Dnipro and Patient 16 at Vinnytsia).

We expect this number to be low; however, it will be documented and accounted for in the analysis.

B5.4 Data Collection

The following elements will be collected at the bedside and recorded on paper CRFs that will be entered into a secure electronic database (Appendix 1).

- Age (years)
- Sex (Male/Female)
- Warfighter status (Yes/No)
- Date/Time of Head Injury
- Time of Evaluation (From Prior Triage Point)
- Mechanism(s) of Injury (motor vehicle collision, gunshot, assault, direct impact/blow to the head, direct impact/head against object, crush, blast, fragment (eg, shrapnel), ground-level fall, fall from height >1 meter, other)
- Documentation of any lacerations or scalp hematomas
- Glasgow Coma Score
- Pupil reactivity and size
- Date/Time of Discharge (if applicable)
- Date/Cause of Death (if applicable)
- Final Glasgow Coma Scale at discharge or transfer (if applicable)
- Documentation of any unanticipated adverse device effects

Additional Data will be collected on subjects admitted to the Emergency Department

- Date/Time of Admission
- Admission Evaluation (presence/absence of any of the following: isolated head trauma, non-head trauma, hypotension, hypoxia, intubation, seizures)
- Medications

Data collected from all patients with CT Scan

- Corresponding NIRS Exam Number (if in device phase)
- Repeat CT Status
- Date/Time of CT Exam
- Location of CT/Hospital Name
- Penetrating Brain Injury Status
- Radiologist Report
- Documentation of Brain-related complications
- Rotterdam Score

Data collected from all patients with Surgery

- Date/Time of Surgery
- Location of Surgery/Hospital Name
- Surgery Type
- Surgical Report

B5.4.1 Additional Data Collection

Data collected from all patients in the **Device Phase**

- NIRS Exam Number
- Prior NIRS examination data
- Examiner information

- Date/Time of NIRS Exam
- NIRS measurement Data
- Locations of NIRS readings

Data collected from all clinical providers at stabilization points in the **Device Phase**

- Survey answers (as presented in Appendix 4).

B5.5 Managing Data and/or Human Biological Specimens for this Research

August Mission provides a study management team on the ground in Ukraine with strong working relationships with all the key stakeholders and regulatory entities. They will facilitate the training of personnel in Poland and ensure the security of data collection and entry. Study data will be collected on paper CRF and securely entered into an electronic database that will be securely transmitted to the US. All CRF data and scans will be uploaded to a REDCap server at UAB. UAB will conduct basic statistical analysis, and InfraScan Inc. will conduct the rest of the analysis.

B5.7 Devices, Drugs, Dietary Supplements, Nutritional Supplements, And Biologics

B5.7.1 Devices

5.7.1.1 FDA-approved device being used in this research according to the approved labeling

InfraScan, Inc. is a medical device company that invented and distributes handheld diagnostic devices for head injury and stroke assessment based on Near-Infrared (NIR) technology. The Infrascanner enables clinicians to effectively, conveniently, and accurately detect intracranial bleeding in patients with head trauma. Dr. Britton Chance (University of Pennsylvania) and Dr. Claudia Robertson (Baylor College of Medicine) invented a NIR system for detecting brain hematomas and tested it successfully on 305 patients in Baylor (Robertson 1997). The Office of Naval Research SBIR phases 1 and 2 funded the development of Infrascanner model 1000. A multicenter clinical study to support an FDA submission started in July 2006 (study results Robertson 2010), and in February 2008, an application was submitted to the FDA. After four years of review, the FDA cleared Infrascanner Model 1000 as a DeNovo medical technology. The Marine Corps funded the development of the ruggedized Infrascanner model 2000 and fielded 200 scanners in battalion aid stations in 2015. In 2023 a Duke University team published a 500 patients Infrascanner model 2000 study (Gramer 2023). In 2017, USAMMDA funded the development of the miniaturized Infrascanner Model 2500, and the FDA cleared the system in 2020 (K200203). In 2022, the FDA cleared the pediatric application of the scanner (K211617) and in 2024 cleared higher laser power use for dark skinned patients (K241389). The system started serial production in 2024.

B8 Statistical Analysis

B5.8.1 Sample Size Estimation

As this is a multicenter, prospective, observational, implementation science study, a convenience sample of 300 was chosen for each cohort. We anticipate that the military and warfare environments will complicate data collection; thus, we chose a target that could compensate for the loss of or incomplete data collection. Based on current admission rates, we also believe that the total 600 is a feasible target to reach within one year.

B5.8.2 Data analysis

For any subject that had a scan at the stabilization center prior to enrollment at a role 3 or 4 site:

The time from the stabilization center scan to the arrival at the enrollment site will be calculated. These times will be compared to the average time from stabilization centers to enrollment sites for subjects from the baseline phase.

The time from injury to time to CT or surgery will also be attained and compared between the baseline and device cohorts. The percentage of subjects that go directly to a hospital with neurosurgical capability will also be compared between cohorts.

For any subject that enrolled at the mobile hospital:

The time between arrival and CT scan and/or surgery will be compared between the baseline and device cohorts. The percentage of subjects that go for CT scans and the rate of positive CT scans will also be compared between cohorts.

For any subject that enrolled at the Mechnikov Hospital:

The time between arrival, CT scan, and/or surgery will be compared between the baseline and device cohorts. Data will be stratified by injury severity.

For any subject that enrolled at the Vinnytsia Hospital:

The number of brain-related complications that occur in polytrauma patients and preoperative non-neuro patients will be compared between the baseline and device cohorts. The rate of false-negative infrascanner results will be calculated.

SECTION C: HUMAN RESEARCH PROTECTIONS

C1. RECRUITMENT AND CONSENT

C1.1 Identification and Selection of Subjects

At mobile and regional hospitals, patients who have suspected combat-related head trauma are identified by symptoms upon admission, regardless of the presence of pharmacologic sedation. At the Vinnytsia hospital (Role 4), the screening population is widened, as this level of care often encounters surgical procedures and has reported concerns with brain-related complications. Thus, combat polytrauma and non-neuro preoperative patients will also be screened for enrollment at the Vinnytsia Hospital (Role 4).

C1.2 Recruitment Process

Specific recruitment are not necessary as this observational, non randomized study of an FDA cleared device is based on patient injuries.

C1.3 Eligibility

Upon arrival at a clinical site, patients are evaluated for head injuries. Patients who demonstrate head injury clinical symptoms (e.g., decreased GCS score, abnormal pupil exam, and/or asymmetrical motor exam) are considered eligible. The only exclusion would be if the scalp injuries interfere with an Infrascanners ability to be placed correctly on the head. The screening population is widened for the Vinnytsia hospital population, as noted in C1.1.

C1.4 Consent Process

C1.4.1 Research involving subjects with cognitive impairment or who lack the capacity to provide informed consent

Baseline Phase

Due to the nature of head injuries and conflict zones, informed consent is not a feasible option for this research study. The eligible subjects for this study are in a life-threatening situation requiring urgent intervention (Newgard 2015). Since an altered GCS and evidence of head trauma is a critical part of the eligibility requirements for enrollment, patients who would be included in this study are not likely able to provide informed consent. Even in the event that a subject could be determined to be able to provide consent, it is impractical to assess their ability to consent—a process that would delay their treatment decisions. In addition, due to the battlefield environment, there is no reasonable way to contact the subject's legally authorized representative before medical decisions and interventions for care need to happen. Further, the baseline phase is observational, so there is no more than minimal risk to the subjects. Data collected from patients will be captured and stored in a coded fashion to ensure the security of the medical information. A waiver of informed consent is the ideal mechanism for this prospective study, as participation in this study will not adversely affect the rights and welfare of the subjects enrolled.

Research confirms that current standards of practice still result in a high mortality rate (Corrigan 2010; Folkerson 2015; Owens 2008, McKee 2015, Shackelford 2018). This study enables the collection of data necessary to determine the baseline statistics related to the current standard of care for suspected TBI and ICH in an active conflict zone in the modern era. Modern, evidence-based data and outcomes on these conditions and related care will directly benefit patients with TBI and ICH, as it will inform care and related decisions and guidelines for care. Indeed, this research could not be carried out without the waiver of consent. However, the subject or their legally authorized representative will be provided with an information sheet containing pertinent information, whenever possible.

Device Phase

As the Infrascanner device is a non-significant risk device being used in accordance with its FDA cleared indications for use (IFU) and the device provides supplemental information to the standard of care, minimal risk is added with the intervention of its use on the battlefield. Just like the baseline phase, eligible subjects for this study are in a life-threatening situation that necessitates urgent CT diagnosis and intervention (Newgard 2015). The eligibility requirements for enrollment remain the same; thus, patients who would be included in this study are not able to provide informed consent, and there is no reasonable way to contact the subject's legally authorized representative before medical decisions and interventions for care need to happen. Any data collected will be captured and stored in a coded fashion to ensure the security of medical information. Of particular note, there is an intent to benefit all subjects in the device phase by using the Infrascanner.

A waiver of informed consent is the ideal mechanism for this portion of the prospective study. Data collection during the device phase will provide valid scientific evidence needed to determine efficacy of using the Infrascanner in the modern military era, and it can only be collected in a fashion and time the makes traditional informed consent impossible. Further, the research outlined in the device phase is necessary to advance the development of medical products for the military services. The data collected will directly benefit the individuals who receive the scans by providing the clinical team with more information. However, the medical decision making remains that of the physicians providing care; therefore, participation in this study will not adversely affect the rights or welfare of the subjects. The Device phase simply provides more information to the clinical care team. Once again, this research could not be carried out without the waiver of consent. The subject or their legally authorized representative will be provided with any pertinent study information after participation.

C1.4.2 Research involving non-English speaking subjects

This study is conducted in Ukraine. Thus, all protocols and forms will be translated into Ukrainian.

C2. COMPENSATION FOR PARTICIPATION

No compensation will be provided for participation.

C3. WITHDRAWAL FROM RESEARCH PARTICIPATION

This study will operate with a waiver of informed consent format. If, at some time after enrollment in this study, a patient requests to have their data withdrawn from the study, all their data will be withdrawn.

C4. PRIVACY FOR SUBJECTS

This study will not require divulging any additional patient information. All data collected from the patient will be held in confidence (see section C5). All information sent to the US will be coded. US investigators will have no access to the study identifiers.

C5. CONFIDENTIALITY PROCEDURES FOR RESEARCH RECORDS, DATA, HUMAN BIOLOGICAL SPECIMENS

All information that is recorded for this study, including the demographic information, the CT scan coded data, the Infrascanner exam data, and the surgical history and outcome, will be identified only by a patient number (study ID), not by the name of the patient. Each Ukrainian clinical site PI will have the master record for that site, connecting the patient number to the patient ID. The coded information from all of the centers will be password-protected under REDCap and accessible only by the investigators and their co-workers. Study PI access to the study database will be only to coded data and with "read-only" authority. Representatives of the US DoD may require access to research records as part of the sponsor's human subject protection oversight.

C6. RISKS OF HARM, MEASURES TO REDUCE THE RISKS OF HARM, AND BENEFITS OF PARTICIPATION

C6.1 Risks of Harm

There is the risk of accidental disclosure of medical information. All possible, standard and reasonable safeguards will be in place to ensure the privacy of their medical information; thus, the risk is minimal. The use of the Infrascanner device during the second phase will be in accordance with its FDA cleared IFU, and only provides additional clinical decision support to the standard clinical exam, and all patient care decisions remains in the hands of the clinical team.

C6.2 Potential Benefits

This study will provide pivotal data on the incidence of TBI and ICH in the modern battlefield, and it will detail the relevant times related to care and evacuation as well as the resulting outcomes. With the approval of the device phase, we will learn how the Infrascanner device can work in combat arenas, and ideally, it will improve the time to definitive ICH diagnosis through augmented decision making by providers and result in better outcomes for the participants. More efficient use of resources in military environments directly benefits users. Findings from this study will have direct implications for hospital and emergency room monitoring of patients with TBI and ICH.

SECTION D: REFERENCES

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SECTION E: **ABBREVIATIONS AND ACRONYMS**

AM	August Mission
CCCRP	Combat Casualty Care Research Program
CPGs	Clinical Practice Guidelines
CRF	Case report forms
CT	Computed tomography
FDA	United States Food and Drug Administration
GCS	Glasgow Coma Score
ICH	Intracranial hemorrhage
IFU	Indications for use
NATO	North Atlantic Treaty Organization
NIR	Near-infrared
PI	Principal Investigator
SOP	Standard operating procedures
TBI	Traumatic brain injury
UAB	University of Alabama at Birmingham
US	United States

Appendix 1: Baseline Phase Case Report Form

HOSPITAL/SITE ГОСПІТАЛЬ ЛІКАРНЯ / ЛОКАЦІЯ

DEMOGRAPHICS / СТАТИСТИЧНІ ДАНІ

ARRIVAL DETAILS AND INCLUSION/EXCLUSION CRITERIA VERIFICATION / ІНФОРМАЦІЯ ПРО ПОСТУПЛЕННЯ ТА ПЕРЕВІРКА КРИТЕРІЇВ ВКЛЮЧЕННЯ/ВИКЛЮЧЕННЯ

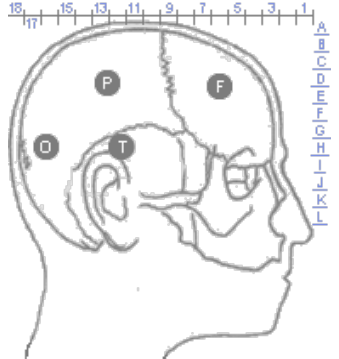
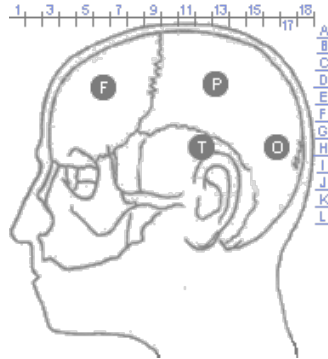
PRIMARY OUTCOME / ПЕРВИННИЙ РЕЗУЛЬТАТ	
1	2
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71	72
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75	76
77	78
79	80
81	82
83	84
85	86
87	88
89	90
91	92
93	94
95	96
97	98
99	100

Infrascan performed?/ Діагностика на «Інфрасканері» проводилась?	☐ Yes/ Так	☐ No/ Ні	CT head/brain performed? КТ голови / головного мозку проводилась?	☐ Yes/Так	☐ No/Ні
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IN-PATIENT RESULTS/РЕЗУЛЬТАТИ УНПРАКАНЕРА	CT RESULTS/РЕЗУЛЬТАТИ КТ
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Скільки ліній Injury lines	Якщо на лівій стороні є поранення, тоді на правій поранення між вушми, середньою лінійю черепа If there are injuries on the left side, then on the right side between the ears, the middle line of the skull	1) Green/Зелений 2) Red/Червоний	1) Green/Зелений 2) Red/Червоний	Intracranial hematoma present/ Наявна ВЧГ Hematoma location/ розташування ВЧГ Hematoma type/ тип ВЧГ	☐ Yes/Так ☐ Left/Зліва ☐ SAH/САК ☐ SDH/СДГ	☐ No/Hi ☐ Right/Справа ☐ EDH/ЕДГ ☐ ICH/ВМГ
Осередок/Пошкодження Lesion/Damage	Вказати тип удару, поранення, падіння та/або поранення, розчавлення. Поводу артерій, вен, спинного мозку, поранення між вушми, пошкодження виступом Specify the type of impact, injury, fall and/or injury, crushing. Damage to arteries, veins, spinal cord, injury between the ears, damage to the protrusion	1) Green/Зелений 2) Red/Червоний	1) Green/Зелений 2) Red/Червоний	Radiologist report/Радіологічний звіт:		
					Did the results of this investigation change the patient's care (e.g. prioritization for transfer to another facility, surgery)? Чи змінили результати цього дослідження хід лікування пацієнта (наприклад, пріоритетність переведення в інший заклад, хірургічне втручання)?	☐ Yes/Так ☐ No/Hi

INJURY DETAILS/ ДЕТАЛЬНІШЕ ПРО ТРАВМУ							
Date of injury / дата травми		☐ estimated/приблизно		Date of Evacuation / дата евакуації		☐ estimated/приблизно	
Time of Injury / час(24h)		☐ estimated/приблизно		Time of Evacuation / час евакуації (24h)		☐ estimated/приблизно	
☐ Motor vehicle collision / ДТП ☐ Crush / розчавлення ☐ Gunshot wound / вогнепальне поранення ☐ Burns / опіки		☐ Impact: blow to head / удар: удар по голові ☐ Blast / вибух ☐ Ground level fall / падіння на землю ☐ Penetrating brain injury / проникна травма головного мозку		☐ Impact/удар: head against object/ удар головою об предмет ☐ Fragment (e.g., shrapnel) / осколки (наприклад, шрапнель) ☐ Other/ інше:			

CLINICAL EXAM/ КЛІНІЧНЕ ОБСТЕЖЕННЯ			
Intubated?/ Інтубація? ☐ Yes/Так ☐ No/Hi		Hypotension (SBP<90mmHg at any time)/ Гіпотензія (АТ<90 мм рт.ст в будь-який час) ☐ Yes/Так ☐ No/Hi	
Seizures/ Судоми ☐ Yes/Так ☐ No/Hi		Hypoxia (SpO ₂ <90% at any time)/ Гіпоксія (SpO ₂ <90% в будь-який час) ☐ Yes/Так ☐ No/Hi	
GLASGOW COMA SCALE/ ПОКАЗНИКИ ЗА ШКАЛОЮ КОМИ ГЛАЗГО			
Eye Opening / розплющування очей	Verbal Response/ мовна реакція	Motor Response / рухова реакція	LACERATIONS & HEMATOMAS/ РВАНІ РАНИ ТА ГЕМАТОМИ ШКИРИ ГОЛОВИ
☐ Spontaneous/ спонтанне ☐ To voice/ на звернену мову ☐ To pain/ на больовий подразник ☐ No eye opening / відсутнє ☐ Cannot assess/ неможливо оцінити	☐ Orientated/ повна орієнтованість ☐ Confused/ сплутана орієнтованість. ☐ Inappropriate words/ незрозумілі слова ☐ Inappropriate sounds/ нечленороздільні звуки ☐ No verbal response/ мовна реакція відсутня ☐ Cannot assess/ неможливо оцінити	☐ Obeys commands/ виконує команди ☐ Localizing to pain/ цілеспрямована реакція на больовий подразник ☐ Withdrawal from pain/ нецілеспрямована реакція на больовий подразник ☐ Abnormal flexion to pain / Патологічне згинання на больовий подразник ☐ Abnormal extension to pain / Патологічне розгинання на больовий подразник ☐ No motor response / рухова реакція відсутня	Right / Справа  Left / Зліва 
PUPIL EXAM / ОБСТЕЖЕННЯ ЗІНИЦЬ			
Reactivity/ реакція	Right / Права	Left / Ліва	
Size / розмір			

TREATMENT ADMINISTERED ON ARRIVAL AT THIS FACILITY/ ЛІКУВАННЯ, ПРИЗНАЧЕНЕ ПІСЛЯ ПРИБУТТЯ ДО ЦЬОГО ЗАКЛАДУ													
☐ Tranexamic acid / транексамова кислота			☐ Antiepileptics / протиепілептичні препарати			☐ Mannitol / манітол			☐ Red Blood Cell transfusion / переливання еритроцитів				
☐ Vasopressors / судинозвужувальні препарати			☐ Hypertonic saline / гіпертонічний розчин			☐ Antibiotics / антибіотики			☐ Coagulopathy reversal agents / засоби для зниження коагулопатії				
NEUROSURGICAL PROCEDURES PERFORMED AT THIS FACILITY / НЕЙРОХІРУРГІЧНІ ПРОЦЕДУРИ, ПРОВЕДЕНІ В ЦЬОМУ ЗАКЛАДІ													
Procedure date / дата проведення процедури		DD / ДЕНЬ	/	MM / МІСЯЦЬ	/	YYYY/РІК	Procedure time / час проведення процедури		HR/ Год	:	MIN/ Хв	Procedure name / назва процедури	
Details/notes / деталі/примітки													
Procedure date / дата проведення процедури		DD/ ДЕНЬ	/	MM/ МІСЯЦЬ	/	YYYY/РІК	Procedure time / час проведення процедури		HR/ Год	:	MIN/ Хв	Procedure name / назва процедури	
Details/notes / деталі/примітки													

Appendix 2: Device Phase Case Report Form

HOSPITAL/SITE ГОСПІТАЛЬ ЛІКАРНЯ / ЛОКАЦІЯ

Subject Number / Пациєнт №	XXXX	1 XXX Mobile Hospital 1 / Мобільний госпіталь 1	2 XXX Mobile Hospital 2 / Мобільний госпіталь 2	3 XXX Mobile Hospital 3 / Мобільний госпіталь 3
		4 XXX Mechnikov Hospital, Dnipro / Дніпровська ОКЛ ім. І. Мечникова	5 XXX Vinnytsia hospital / Вінницька ОКЛ ім. М. Пирогова	6 XXX Stabilization Point 1 / Стабілізаційний пункт 1
		7 XXX Stabilization Point 2 / Стабілізаційний пункт 2	8 XXX Stabilization Point 3 / Стабілізаційний пункт 3	9 XXX Stabilization Point 4 / Стабілізаційний пункт 4

Age / Вік		Years / Повних років		Sex / Стать	☐ male/чол.	☐ female/жін.
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Date of admission / дата поступлення	/	/	DD/DE	MM/MISCЯЧЬ	YYYY/РІК	Confirm that the following are <i>present</i> : Підтвердіть <i>нааявність</i> наступного: ☐ Trauma patient / Травматологічний пацієнт And one or more of / а також щонайменше одне з:	☐ War-related trauma / Травма, отримана внаслідок бойових дій ☐ Impaired consciousness / Порушена свідомість ☐ Symptoms of concussion / Симптоми струсу головного мозку	Massive lacerations to the patients scalp which would prevent conducting Infrascanner measurements/ Масивні рани на шкірі голови пацієнта, які перешкоджали б проведенню вимірювань інфрасканером ☐ Yes/ Так ☐ No / Ні
Time of Admission / час поступлення (24h)	:		HR/ГОД	MIN/ХВ				
Investigator Name/ПІБ дослідника								
Entered in local register? /В місцевий реєстр занесено?	☐ Yes/Так							

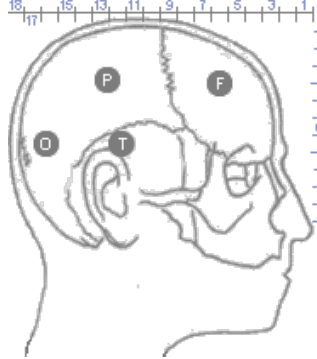
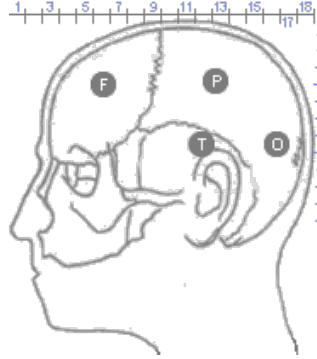
Did the patient have an Intracranial Hematoma (ICH)? Чи була у пацієнта внутрішньочерепна гематома (ВЧГ) ☐ No / Ні ☐ Yes / Так - Complete sections below / Заповніть розділи нижче

Infrascan performed?/ Діагностика на «Інфрасканері» проводилась? ☐ Yes/ Так ☐ No/Hi				CT head/brain performed? КТ голови / головного мозку проводилось? ☐ Yes/Так ☐ No/Hi					
If yes/ Якщо так:	Date/Дата	DD/DE / MM/MIC / YYYY/PIK	Time/Час(24h)	HH/ГОД : MIN/ХВ	If yes/Якщо так:	Date/Дата	DD/ДЕНЬ / MM/МІСЯЦЬ / YYYY/PIK	Time/Час (24h)	HH/ГОД : MIN/ХВ
Scan #/№ дослідження:		Scanner #/Сканер №:		Operator/Оператор:	Hospital/Госпіталь / Лікарня:				

CT RESULTS/РЕЗУЛЬТАТИ КТ

Position/ Розміщення	Probe placement/landmarks Розміщення датчика/орієнтири	Right/Справа	ΔOD value/ значення	Left/Зліва
Frontal/ Лобове	On forehead, above frontal sinus/На лобі, над лобовою пазухою	☐ Green/Зелений ☐ Red/Червоний		☐ Green/Зелений ☐ Red/Червоний
Temporal/ Скроневе	In temporal fossa, on top of ear/У скроневій ямці, над вухом	☐ Green/Зелений ☐ Red/Червоний		☐ Green/Зелений ☐ Red/Червоний
Parietal/ Тім'яне	Above ear, midway between ear and midline of skull/ Над вухом, посередині між вухом і середньою лінією черепа	☐ Green/Зелений ☐ Red/Червоний		☐ Green/Зелений ☐ Red/Червоний
Occipital/ Потиличне	Behind top of ear, midway between ear and occipital protuberance/ Позаду верхньої частини вуха, посередині між вухом і потиличним виступом	☐ Green/Зелений ☐ Red/Червоний		☐ Green/Зелений ☐ Red/Червоний

Rotterdam Score: шкала		
Basal cisterns/Базальні цистерни	☐ normal/нормальні ☐ compressed/ стиснуті	☐ absent/відсутні
Midline shift/Зміщення середньої лінії	☐ ≤5mm/мм	☐ >5mm/мм
Epidural mass lesion/Ушкодження епідурального простору	☐ present/присутні	☐ absent/відсутні
IVH or/або SAH	☐ present/присутні	☐ absent/відсутні
Radiologist report/Радіологічний звіт:		
Intracranial hematoma present/ Наявна ВЧГ Hematoma location/ розташування ВЧГ Hematoma type/ тип ВЧГ	☐ Yes/Так ☐ Left/Зліва ☐ SAH/САК ☐ SDH/СДГ	☐ No/Hi ☐ Right/Справа ☐ EDH/ЕДГ ☐ ICH/ВМГ
Radiologist report/Радіологічний звіт:		

		Did the results of this investigation change the patient's care (e.g. prioritization for transfer to another facility, surgery)? Чи змінили результати цього дослідження хід лікування пацієнта (наприклад, пріоритетність переведення в інший заклад, хірургічне втручання)?		☐ Yes/Так ☐ No/Hi
INJURY DETAILS/ ДЕТАЛЬНІШЕ ПРО ТРАВМУ				
Date of injury / дата травми DD/DE / MM/MIC / YYYY/PIK Time of Injury / час(24h) HR/ГОД : MIN/ХВ		Date of Evacuation / дата евакуації DD/DE / MM/MIC / YYYY/PIK Time of Evacuation / час евакуації (24h) HR/ГОД : MIN/ХВ		
☐ Motor vehicle collision / ДТП ☐ Crush / розчавлення ☐ Gunshot wound / вогнепальне поранення ☐ Burns / опіки		☐ Impact: blow to head / удар: удар по голові ☐ Blast / вибух ☐ Ground level fall / падіння на землю ☐ Penetrating brain injury / проникна травма головного мозку		
☐ Impact/удар: head against object/ удар головою об предмет ☐ Fragment (e.g., shrapnel) / осколки (наприклад, шрапнель) ☐ Other/ інше:				
CLINICAL EXAM/ КЛІНІЧНЕ ОБСТЕЖЕННЯ				
Intubated?/ Інтубація? ☐ Yes/Так ☐ No/Hi		Hypotension (SBP<90mmHg at any time)/ Гіпотензія (АТ<90 мм рт.ст в будь-який час) ☐ Yes/Так ☐ No/Hi		
Seizures/ Судоми ☐ Yes/Так ☐ No/Hi		Hypoxia (SpO2<90% at any time)/ Гіпоксія (SpO2<90% в будь-який час) ☐ Yes/Так ☐ No/Hi		
GLASGOW COMA SCALE/ ПОКАЗНИКИ ЗА ШКАЛОЮ КОМІ ГЛАЗГО			LACERATIONS & HEMATOMAS/ РВАНІ РАНИ ТА ГЕМАТОМИ ШКІРИ ГОЛОВИ	
Eye Opening / розплющування очей ☐ Spontaneous/ спонтанне ☐ To voice/ на звернену мову ☐ To pain/ на больовий подразник ☐ No eye opening / відсутнє ☐ Cannot assess/ неможливо оцінити	Verbal Response/ мовна реакція ☐ Orientated/ повна орієнтованість ☐ Confused/ сплутана орієнтованість. ☐ Inappropriate words/ незрозумілі слова ☐ Inappropriate sounds/ нечленороздільні звуки ☐ No verbal response/ мовна реакція відсутня ☐ Cannot assess/ неможливо оцінити	Motor Response / рухова реакція ☐ Obeys commands/ виконує команди ☐ Localizing to pain/ цілеспрямована реакція на больовий подразник ☐ Withdrawal from pain/ нецілеспрямована реакція на больовий подразник ☐ Abnormal flexion to pain / Патологічне згинання на больовий подразник ☐ Abnormal extension to pain / Патологічне розгинання на больовий подразник ☐ No motor response / рухова реакція відсутня	Right / Справа 	Left / Зліва 
PUPIL EXAM / ОБСТЕЖЕННЯ ЗІНИЦЬ		Right / Права Left / Ліва		
Reactivity/ реакція	☐ Brisk / жвава ☐ Sluggish / млява ☐ Nonreactive / відсутня	☐ Brisk / жвава ☐ Sluggish / млява ☐ Nonreactive / відсутня		
Size / розмір	☐ Pinpoint / звужена ☐ Midsized / нормальна ☐ Dilated / розширена ☐ Cannot assess / неможливо оцінити	☐ Pinpoint / звужена ☐ Midsized / нормальна ☐ Dilated / розширена ☐ Cannot assess / неможливо оцінити		
TREATMENT ADMINISTERED ON ARRIVAL AT THIS FACILITY/ ЛІКУВАННЯ, ПРИЗНАЧЕНЕ ПІСЛЯ ПРИБУТТЯ ДО ЦЬОГО ЗАКЛАДУ				
☐ Tranexamic acid / транексамова кислота ☐ Vasopressors / судинозвужувальні препарати		☐ Antiepileptics / протиепілептичні препарати ☐ Hypertonic saline / гіпертонічний розчин		☐ Mannitol / манітол ☐ Antibiotics / антибіотики
☐ Red Blood Cell transfusion / переливання еритроцитів ☐ Coagulopathy reversal agents / засоби для зниження коагулопатії				
NEUROSURGICAL PROCEDURES PERFORMED AT THIS FACILITY / НЕЙРОХІРУРГІЧНІ ПРОЦЕДУРИ, ПРОВЕДЕНІ В ЦЬОМУ ЗАКЛАДІ				
Procedure date / дата проведення процедури DD / ДЕНЬ / MM / МІСЯЦЬ / YYYY/PIK		Procedure time / час проведення процедури HR/ Год : MIN/ Хв		
Procedure name / назва процедури				

Details/notes / деталі/примітки													
Procedure date / дата проведення процедури		DD/ ДЕНЬ	/	MM/ МІСЯЦЬ	/	YYYY/РІК	Procedure time / час проведення процедури		HR/ Год	:	MIN/ Хв	Procedure name / назва процедури	
Details/notes / деталі/примітки													

Appendix 3: Patient Summary Report Form (same for both study phases)

Data Collection Worksheets for SAFETY study\
Робочі таблиці для збору даних для дослідження
під назвою «БЕЗПЕЧНІСТЬ»

Hospital Number _____
Номер госпіталю_лікарні:
Subject Number\Номер пацієнта

PATIENT SUMMARY / FINAL STATUS \ РЕЗЮМЕ ПАЦІЄНТА / ОСТАТОЧНИЙ СТАН

Is patient record complete & evaluable? \ Медична картка пацієнта заповнена і оцінена

☐ Yes \Так ☐ No \Ні

If no, reason(s)\Якщо ні, чому

☐ First Infrascanner exam was not performed within 48 hours of head injury \
Перше обстеження «Інфрасканером» не було проведено протягом 48
годин після травми голови

☐ A device malfunction prevented completing an Infrascanner exam\
Несправність апарату не дозволила провести обстеження на
«Інфрасканері»

Explain\Поясніть:

All device failures should be immediately reported to sponsor\
Про всі несправності апарату слід негайно повідомляти спонсору

☐ Missing required CT or NIRS data\ Відсутні необхідні дані КТ або NIRS
Explain\ Поясніть:

Did patient experience any UNANTICIPATED ADVERSE DEVICE EFFECTS (UADEs)? \
Чи виникали у пацієнта будь-які НЕПЕРЕДБАЧЕНІ ПОБІЧНІ РЕАКЦІЇ НА ПРИСТРІЙ (НПРНП)?

☐ Yes \Так ☐ No \Ні

If yes....list the UADE(s) in the following table\ Якщо так....перелічіть НПРНП в наступній таблиці:

Date of UADE (DD/MM/YYYY)\ Дата НПРНП (ДЕНЬ/МІСЯЦЬ/РІК)	Time of UADE\ Час НПРНП	Event Description\ Опис події	Relationship to Device\ Пов'язано з пристроєм
	☐ Unknown\ Невідомо		☐ Not Related \ Не пов'язано ☐ Possibly Related \ Можливо пов'язано ☐ Definitely Related\ точно пов'язано

All Device-related (possibly or definitely) UADEs must be immediately reported to Sponsor and Helsinki committee!\ Про всі пов'язані з пристроєм (можливо або точно) НПРНП необхідно негайно повідомляти спонсора та Гельсінкський комітет!

Hospital Discharge Destination (choose one)\ Місце після виписки з лікарні (оберіть одне):

☐ Another Acute Care Hospital\ Інша лікарня невідкладної допомоги ☐ Long-term Care Hospital or Nursing Home\ Лікарня довготривалого лікування або будинок по догляду ☐ Rehabilitation \ Реабілітація ☐
☐ Home\ Дома ☐ Died in hospital \ Помер(ла) в лікарні ☐ Other\ Інше: _____

If Died, reason\ Якщо помер(ла), причина:

☐ Death from brain injury ☐ Death from other injuries/complications ☐ Active Treatment stopped
Смерть від травми головного мозку Смерть від інших травм/ускладнень Активне лікування припинено

Date of Discharge\ Дата виписки:

(or Transfer or Death\ або переведення чи смерті) DD\ДЕНЬ MON\МІСЯЦЬ YYYY\РІК

Time of Discharge\ Час виписки:

(or Transfer or Death\ або переведення чи смерті)

HOUR\ГОД MINUTE\ХВ

Glasgow Coma Scale Score AT HOSPITAL DISCHARGE (OR TRANSFER) \

Бал за шкалою коми Глазго ПРИ ВИПИСЦІ З ГОСПІТАЛЮ\ЛІКАРНІ (АБО ПЕРЕВЕДЕННІ)

☐ Patient Sedated /Intubated\ Пацієнт штучна комалінтубація

☐ Patient Died\Пацієнт(ка) помер(ла)

Appendix 4: SAFETY Study Survey

Purpose: To better understand responses to the following question: “Did the results of this assessment influence the patient’s treatment (for example, by affecting evacuation priority or surgical decisions)?”.

If you answered “Yes” for some or all of your patients, please indicate how you modified treatment (check all that apply):

#	Yes	No	Question
1	☐	☐	Did you organize faster evacuation?
2	☐	☐	Did you evacuate patients with a positive Infrascanner result first?
3	☐	☐	Did you use the Infrascanner results as a factor when determining the urgency or priority of evacuation?
4	☐	☐	Did the results affect the choice of destination for evacuation?
5	☐	☐	Did this change your own surgical intervention?
6	☐	☐	Did you contact a neurosurgeon because of a positive Infrascanner result?
7	☐	☐	Did the Infrascanner assist you in examining the patient?
8	☐	☐	In your opinion, is the Infrascanner needed at the stabilization point?
9	☐	☐	In your opinion, is the Infrascanner needed at the forward surgical team?
10	☐	☐	In your opinion, is the Infrascanner needed at a mobile military hospital?

Additional Comments (device limitations, specific features): _____
