



Initial Results of the SAFETY Study: Use of the Infrascanner Model 2500 to manage TBI patients on frontlines of Ukraine

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

COL Kostiantyn Gumeniuk, MD.

Chief Surgeon of the Armed Forces of Ukraine

On behalf of the SAFETY Study Group:

COL Kostiantyn Gumeniuk, MD, John B. Holcomb, MD , Dmytro Dmytriiev, MD, PhD, Shannon W Stephens, EMTP, Jan O. Jansen, MBBS, PhD, Joshua S. Richman, MD, PhD, Baruch Ben Dor, PhD, David Clarke, MS, Alex Valadka, MD, Andrii Sirko, MD, PhD



Disclaimer

This effort was awarded through MTEC solicitation MTEC-24-01-MPAI and is funded by Combat Casualty Research Program (CCCRP) in accordance with Congressional direction to establish medical partnering with the Ukraine specified in Sec 736 NDAA 2023 and Sec 721 NDAA 2024.

The views and conclusions contained herein are those of the author(s) and should not be interpreted as representing the official policies or endorsements, either expressed or implied, of the U.S. Government.



SAFETY Study Team

Dr./Col Kostiantyn Gumeniuk



Chief Surgeon of
the Armed Forces
of Ukraine

Dr. Andrii Sirko



President of
the Ukrainian
Neurosurgical
Association

Dr. Dmytro Dmytriv



Chief of Pain
Medicine
Research,
Vinnytsia

Dr./Col John Holcomb



Military Trauma
Expert

Dr. Alex Valadka



Leading TBI Expert,
Past president of
AANS

Dr. Baruch Ben Dor



CEO of
InfraScan



Study Objectives

- The primary objective of this study is to assess the utility of the Infrascanner Model 2500 device to integrate with patient care activities in combat settings (hospitals and field).
- Specifically, this study will determine if the use of the Infrascanner device reduces the time to detect traumatic ICH as compared to the standard clinical practice
- Joint Trauma System Clinical Practice Guidelines #68 discusses both the Infrascanner and pupillometry as adjunctive technologies in the assessment of traumatic brain injury.



Infrascanner Model 2500

The question is NOT:
Does it work?

The question is:
Does it help?



Before and After Study Design

Main methodology to accomplish the research

600 patients in a sequential study design

- **First 300:** Baseline Phase to evaluate the current “Standard of Care”
- **Second 300:** Device Phase to evaluate the utility of the Infrascanner

Key parameter to evaluate is the time from admission until definitive diagnosis by a CT scan.

➤ **Expected outcomes**

Potentially modify the TBI Clinical Practice Guidelines (CPG) in military settings across the US and NATO forces.



Inclusion and Exclusion Criteria

Inclusion Criteria

- All combat-related head trauma identified by clinical signs of TBI on admission, regardless of the presence of pharmacologic sedation.

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



Levels of Care Designations

SAFETY STUDY Location	Frontline first surgical care	Military Mobile Hospitals	Medical Center near the Battlefield	Medical Center far from the Battlefield
Ukrainian Term	Stabilization Points	First Line Hospital	Second Line Hospital	Third- line Hospital
NATO Term	Role 2	Role 3	Role 4	Role 4

Baseline phase sites (300 patients):

- 4 stabilization points (50 patients)
- Mobile hospital (63)
- Mechnikov Hospital, Dnipro (119)
- Pirogov Hospital, Vinnytsia (68)

Device phase sites (300 patients):

- 5 stabilization points (200 patients)
- Mechnikov Hospital, Dnipro (50)
- Pirogov Hospital, Vinnytsia (50)



Patient injury demographics

Age	38 years (21-96)
Sex	Male: 97,6% Female: 2,4%
Blast	84,7%
Fragments(shrapnel) anywhere in the body	64,7%
Head impact against an object	12%
Ground – level fall	10,7%
Motor vehicle collision (MVC)	5,3%
Blow to the head	4,7%

(Mechanism-of-injury data were not collected at the stabilization points during the baseline phase; therefore, only device-phase data are presented.)



Patient head injury demographics

	All	Role 2	Role 4 Dnipro	Role 4 Vinnitsia
Intracranial hematomas	64,0%	79,0%	34%	34%
Skull fractures	47,0%	65,5%	14%	6,0%
Fragments in the head	18,7%	26,0%	2,0%	6,0%
Penetrating TBI	38,8%	50,5%	22,0%	6,0%

(Mechanism-of-injury data were not collected at the stabilization points during the baseline phase; therefore, only device-phase data are presented)



Stabilization Points – Time to CT

Time difference for Infrascanner positive and Infrascanner negative patients.
The time is from admission at stabilization point until CT scan at the evacuation hospital

Stabilization Point	Time difference in the first 60 days	Time difference after 60 days
1	108 min	No date
2	25 min	- 5 min
3	42 min	2 min
4	115 min	9 min

- Early on, Infrascanner positive patients were evacuated faster for neurosurgical treatment.
- From October 2025 the drone hazard led to evacuations when possible and not when needed. This led for similar times to CT for Infrascanner positive and negative patients.



Medical providers' feedback

“Did the results of this investigation change the patient's care (e.g. prioritization for transfer to another facility, surgery)?”

For 50% of patients at Vinnytsia

For 60% of patients at Dnipro

For 88.5% of patients at the stabilization points.

The stabilization points' surgeons and administrators filled a survey. The administrators are the ones taking care of organizing and deciding on the timing of patient evacuation.

2/3 of the surgeons used the Infrascanner in making evacuation and prioritization decisions, while all administrators used the Infrascanner diagnosis for this goal.

Almost none of the surgeons and administrators used the Infrascanner to guide the surgical procedures.

There was a unanimous agreement that the Infrascanner is needed at the stabilization points or a forward surgical team.



Infrascanner Performance Results

- The sensitivity (**87.4%**) was similar to prior **500**-patients study by Duke, which showed **85.6%** sensitivity in all bleeds and **94.2%** in bleeds over **3.5 mL**.
- Specificity – Lower specificity than prior studies.
 - The Infrascanner detected structural damage to the head, even without bleeds, which included penetrating TBI (pTBI), fragments and skull fractures. Without bleeds those cases were considered false alarms.
 - Sensitivity for structural Damage (either one of hematomas, pTBI, fragments or skull fractures) was **87.1%**.
 - Higher rate of external soft tissue injuries than civilian TBI driving lower specificity.

Unexpected result: Infrascanner detects pTBI, fragments and skull fractures (not seen in prior studies)

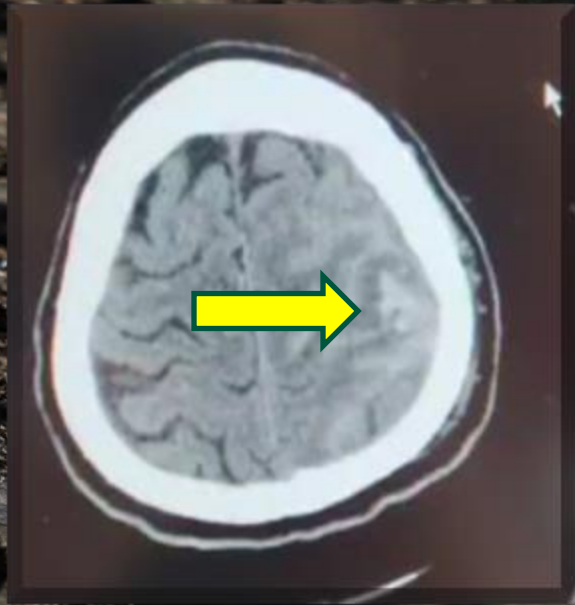
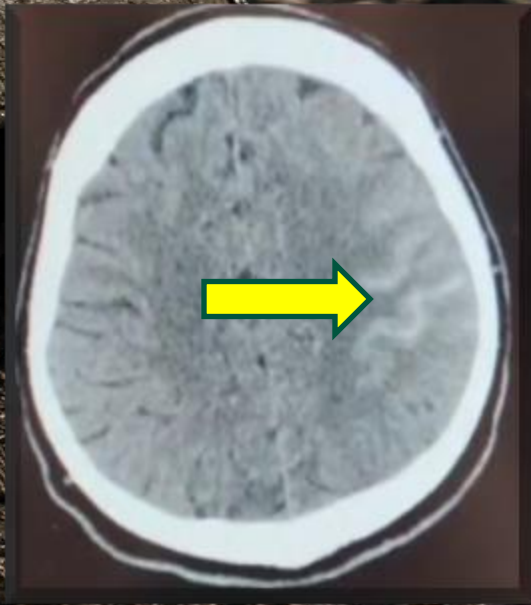


Examples of external soft tissue injuries





Example of Infrascanner correlation to CT





Hospitals' Results (Roles 4)

Dnipro:

- The median time from admission until CT was **20min** in baseline phase and **20.5min** in device phase.
- The median time from admission until surgery was 85min in baseline phase and **45min** in device phase.
- **100%** sensitivity for patients who required neurosurgery.

Vinnytsia Utility in catching delayed bleeds that were not on the initial CT scan in a prior hospital:

- A burn patient arrived with a prior negative head CTs. The patient had positive Infrascanner, and was sent for a repeat CT. Unfortunately, he got the repeat CT a full **3 hours** after the Infrascanner (which confirmed the positive hematoma diagnosis) and died before his life could be saved.



Study Results: Reliability

- In the **7 months** of the device phase, **20** Infrascanners had no failures in the field (including in five field stabilization points in Ukrainian winter).
- Two software issues were cleared on the same day in the field by restarting the scanner.



Conclusions

- The **Infrascanner Model 2500** demonstrated high diagnostic sensitivity and excellent user acceptance in large-scale combat operations.
- Its use has the potential to enhance TBI triage accuracy and optimize evacuation decisions in modern warfare.
- The Infrascanner cut time to surgery in a Role 4 hospital by **47%**.
- First large-scale combat validation of forward TBI triage technology.



Thank you for the help and support for Ukraine!

