Battlefield Performance of the Infrascanner 2500 for Detection of Intracranial Hemorrhage and Penetrating Traumatic Brain Injury

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On behalf of the SAFETY Study Group:

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Disclaimer

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SAFETY 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.

The question is NOT:
Does it work?

The question is:
Does it help?

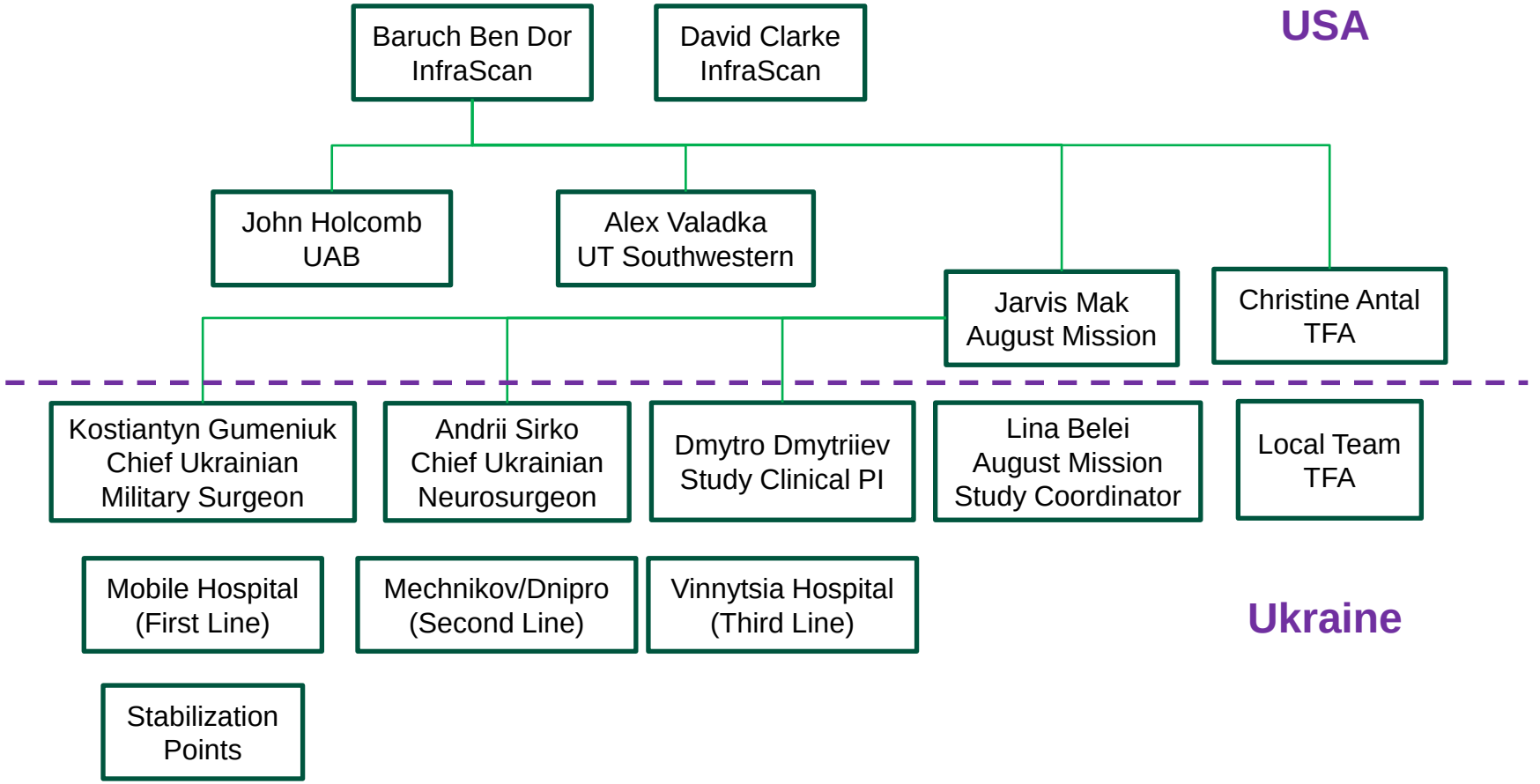
Infrascanner Model 2500

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.

SAFETY Study Organization



Training – Train the Trainer

Poland → Ukraine

Levels of Care Designations

SAFETY Study Location	Frontline first surgical care	Military Mobile Hospitals	Medical Center near the Battlefield	Overflow 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 (300 patients)	4 sites (50)	1 site (63)	1 site (119) Dnipro	1 site (68) Vinnytsia
Device Phase (300 patients)	5 sites (200)	-	1 site (50) Dnipro	1 site (50) Vinnytsia

Patient injury demographics

Age	38 years (21-96 years)
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	Stabilization Points (Role 2)	Dnipro (Role 4)	Vinnytsia (Role 4)
Intracranial hematomas	64.0%	79.0%	34.0%	34.0%
Skull fractures	47.0%	65.5%	14.0%	6.0%
Fragments in the head	18.7%	26.0%	2.0%	6.0%
Penetrating TBI	38.3%	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.)

Infrascanner Performance Results

Sensitivity	With Hematomas	Without Hematomas
Only Hematomas	87.4%	---
Fragments	88.7%	100%
Skull Fractures	88.4%	82.4%
Penetrating TBI	87.5%	81.8%
Structural Damage (either one of the above)	87.1%	---

- The sensitivity is comparable with 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.** Without bleeds those cases were considered false alarms.
  - Higher rate of external soft tissue injuries than civilian TBI driving lower specificity.

Stabilization Points Results – Time to CT (Role 2)

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 data
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.

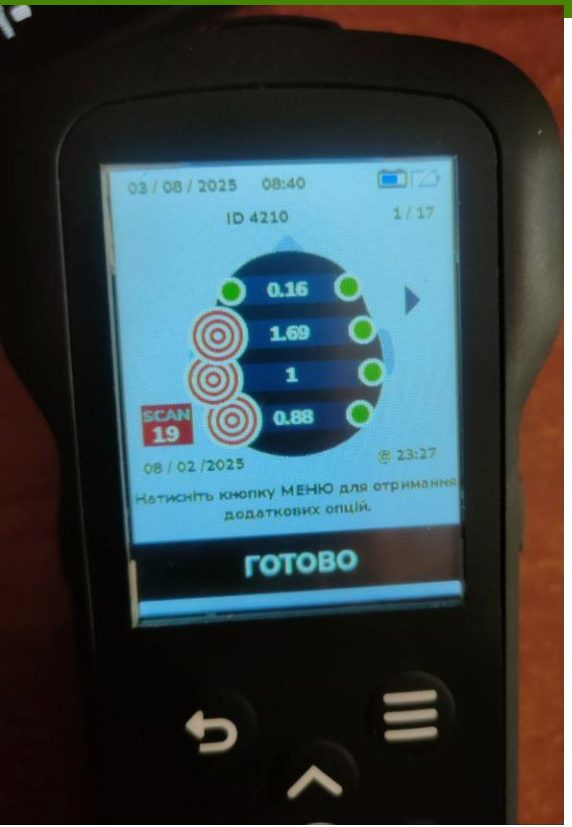
Medical providers' feedback

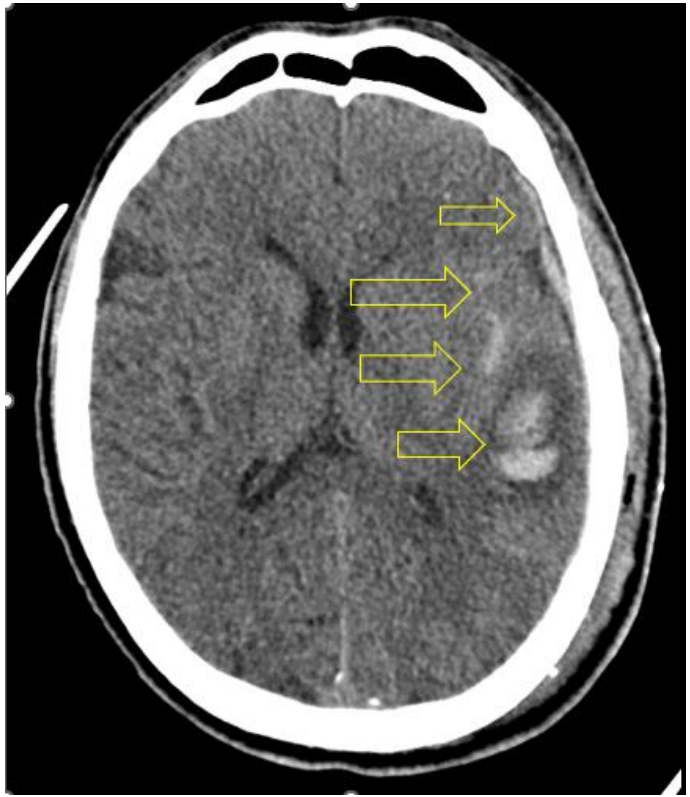
- "Did the results of this investigation change the patient's care (e.g. prioritization for transfer to another facility, surgery)?"
  - For 50% of patients at Vinnytsia
  - For 60% of patients at Dnipro
  - For 88.5% of patients at the stabilization points.
- The stabilization points' surgeons and administrators 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.

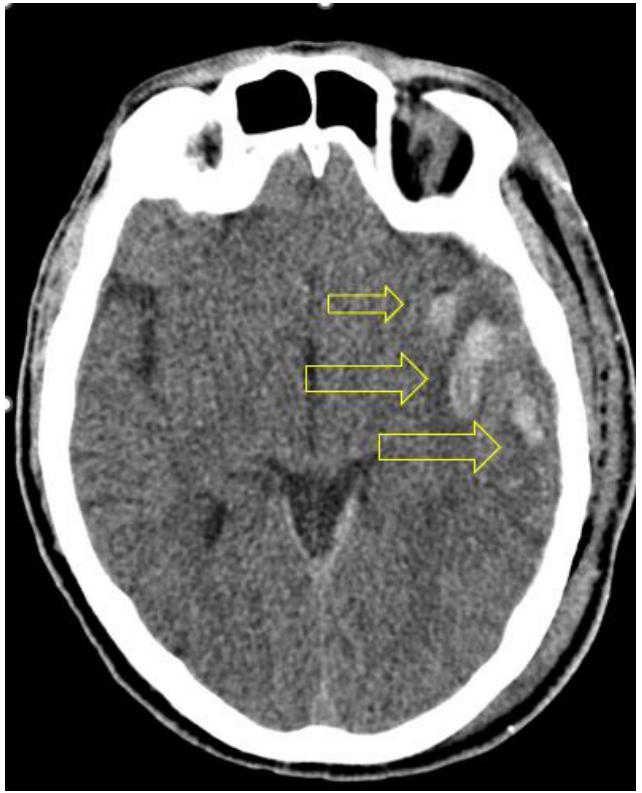
Study results in Dnipro (Role 4)

- The median time from admission until CT was 20min in baseline phase and 20.5min in device phase.
  - Efficient ER procedure sends patients quickly to CT, as is.
- **The median time from admission until surgery was 85min in baseline phase and 45min in device phase (47% shorter).**
  - Positive Infrascanner was used to alert and prep neurosurgical teams quicker.
- 100% sensitivity for patients who required neurosurgery.

Example of Infrascanner correlation to CT







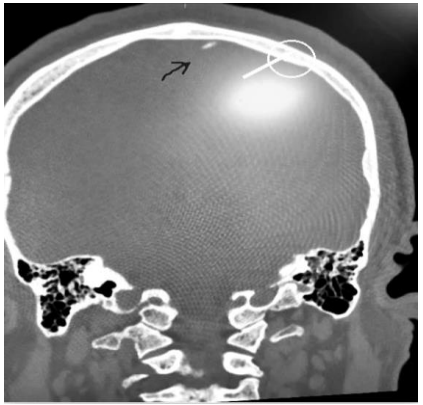
Study results in Vinnytsia (Role 4)

- Several polytrauma cases, where the intracranial abnormalities were missed or not detected on the initial CT scan. The positive Infrascanner findings prompted a repeat, targeted evaluation, which led to the identification of these abnormalities on the follow-up CT or during a focused re-review of the initial imaging.

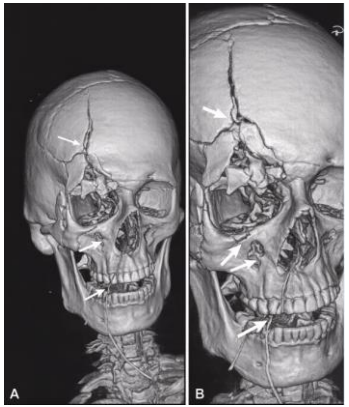
- The Infrascanner served as an important adjunctive screening tool by alerting clinicians to abnormalities that had been overlooked on the previous CT examination.

Cases of Positive Infrascanner Polytrauma Patients in Vinnytsia

#	Prior CT	Repeat CT	Comments
1	Negative	Intracranial hematoma	Delayed bleed appearing after prior CT was done
2	Negative	Displaced skull fragment	Fragment missed by radiologist on prior CT
3	Not done	Complex skull fracture	Head trauma missed on initial evaluation of the patient



Missed skull fragment



Missed skull fracture

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 ability to detect both ICH and pTBI at forward medical facilities may enhance triage accuracy and support timely evacuation decisions when CT imaging is unavailable.
- The Infrascanner cut time to surgery in a Role 4 hospital by 47%.
- These findings provide strong support for integrating the Infrascanner Model 2500 into future military medical systems, particularly in austere and combat environments.
- These findings may not be generalizable to standard civilian clinical settings.