

A HAT-TRICK THAT CLICKS!

STROKE DETECTION TECHNOLOGY CLINICAL TRIAL

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**DETROIT
Fire Department**

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DISCLOSURES



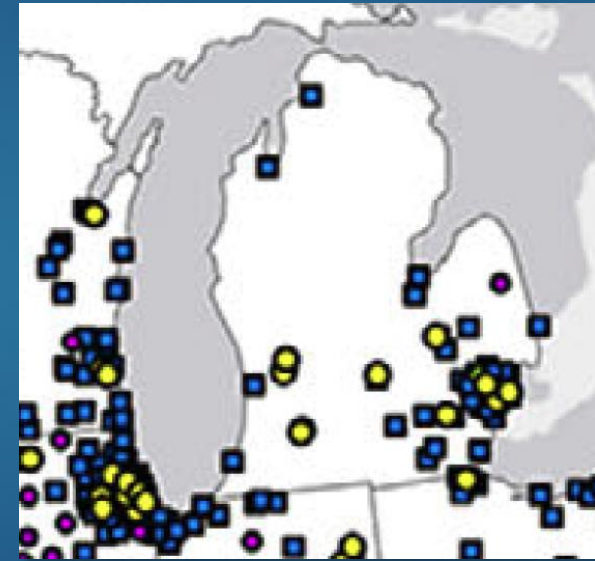
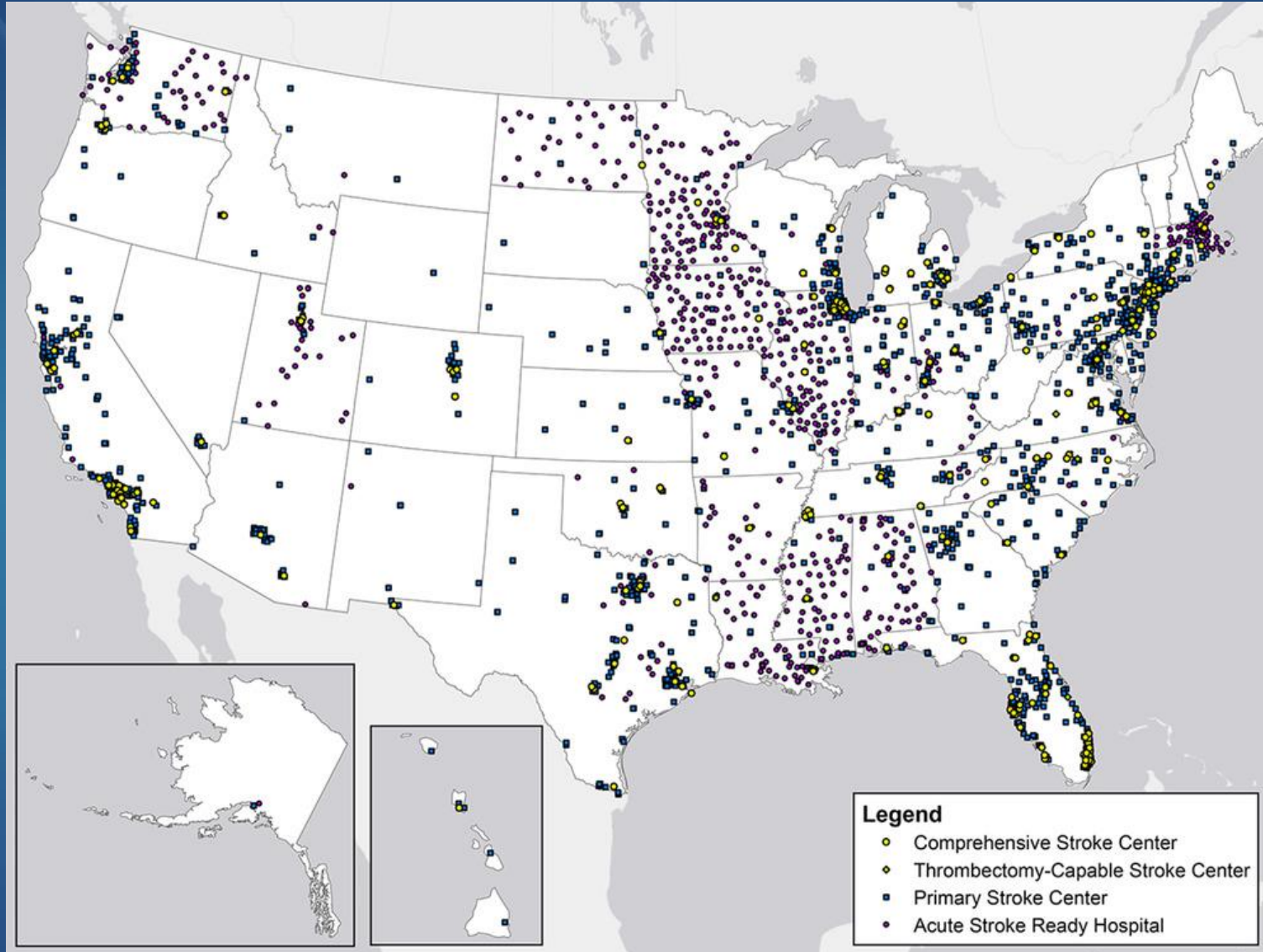
- Research funding from MindRhythm, Inc (Cupertino, CA)
- Paxton JH, Keenan KJ, Wilburn JM, Wise SL, Klausner HA, Ball MT, Dunne RB, Kreitel KD, Morgan LF, Fales WD, Madhok D, Barazangi N, McLean ST, Cross K, Distenfield L, Sykes J, Lovoi P, Johnson B, Smith WS; EPISODE-PS-COVID Collaborators. Headpulse measurement can reliably identify large-vessel occlusion stroke in prehospital suspected stroke patients: Results from the EPISODE-PS-COVID study. Acad Emerg Med. 2024



BACKGROUND / OBJECTIVES

- Large vessel occlusion (LVO) ischemic stroke represents only one-third of acute ischemic stroke (AIS) in the United States, but accounts for two-thirds of post-stroke dependence and > 90% of post-stroke mortality.
- Prehospital LVO detection is essential to providing efficient EMS transport to a thrombectomy-capable center.
- Clinical stroke scales lack adequate sensitivity and specificity to reliably diagnose LVO.
- Our objective was to determine whether a portable cranial accelerometry (CA) headband device with ECG monitoring could reliably predict LVO stroke in the prehospital setting.





LVO TREATMENT

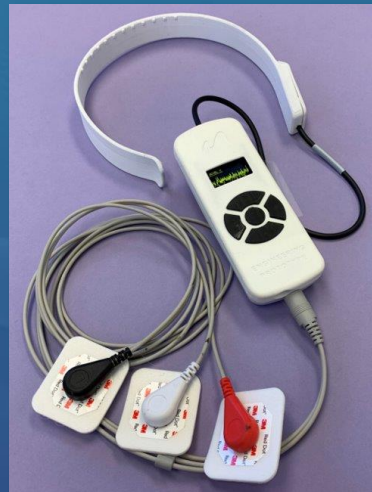
- Thrombolytics alone achieve recanalization in 10-20% of LVO cases
 - ▶ Time-dependent relationship (i.e., earlier = better)
- Endovascular (mechanical) thrombectomy (EVT) is the preferred treatment for LVO, especially effective for anterior LVO.
- Estimated 80,000 LVO cases annually in US, but < 40% are eligible for EVT within 6-24 hours of symptom onset.
- Most major LVO stroke trials focus upon anterior LVO, as these lesions are generally more amenable to EVT.



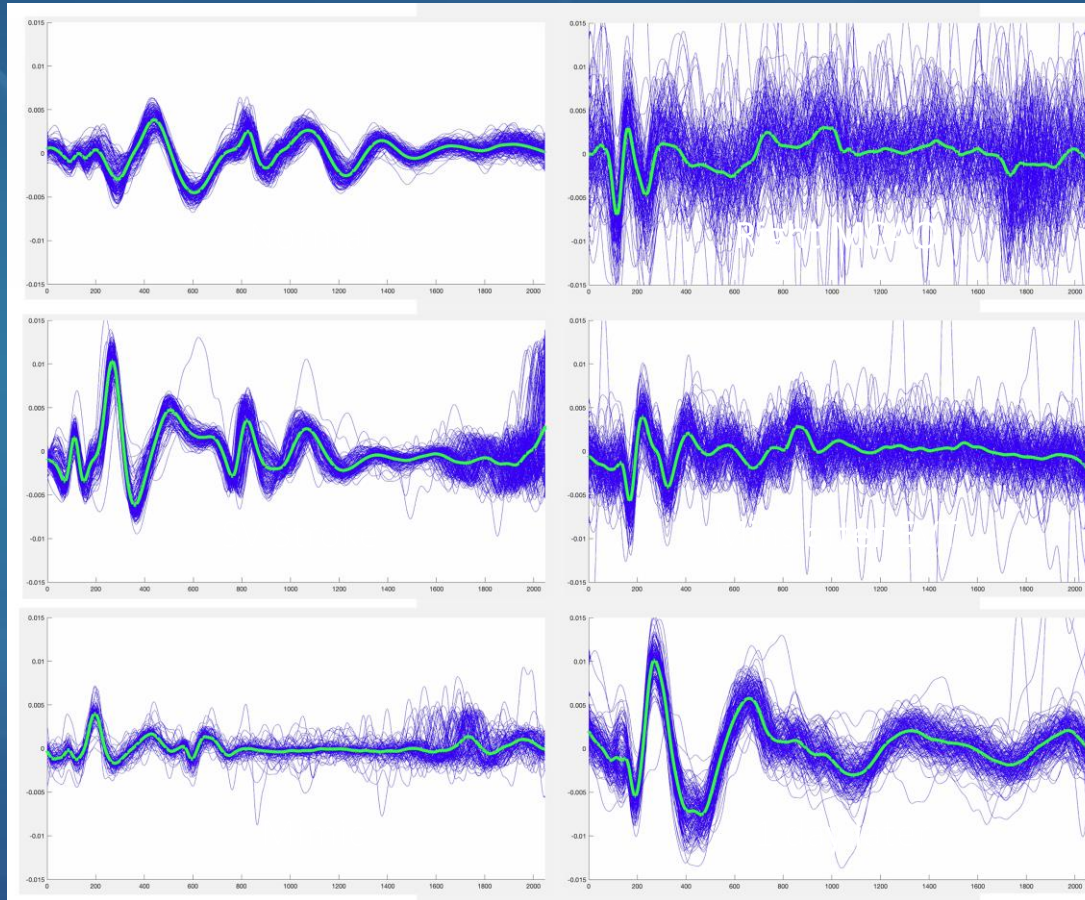
CRANIAL ACCELEROMETRY



- ▶ Measures tiny vibrations within the skull due to blood flow
- ▶ Harmony™ 4000 (MindRhythm, Inc.) device was used with initial roll-out
- ▶ Device upgraded to Harmony™ 5000 device on 16 May 2022
- ▶ Three-axis accelerometer affixed to headset, with ECG digitized at 1.6 kHz to match heartbeat to intracranial “pulse”



CRANIAL ACCELEROMETRY: THE HEADPULSE



METHODS

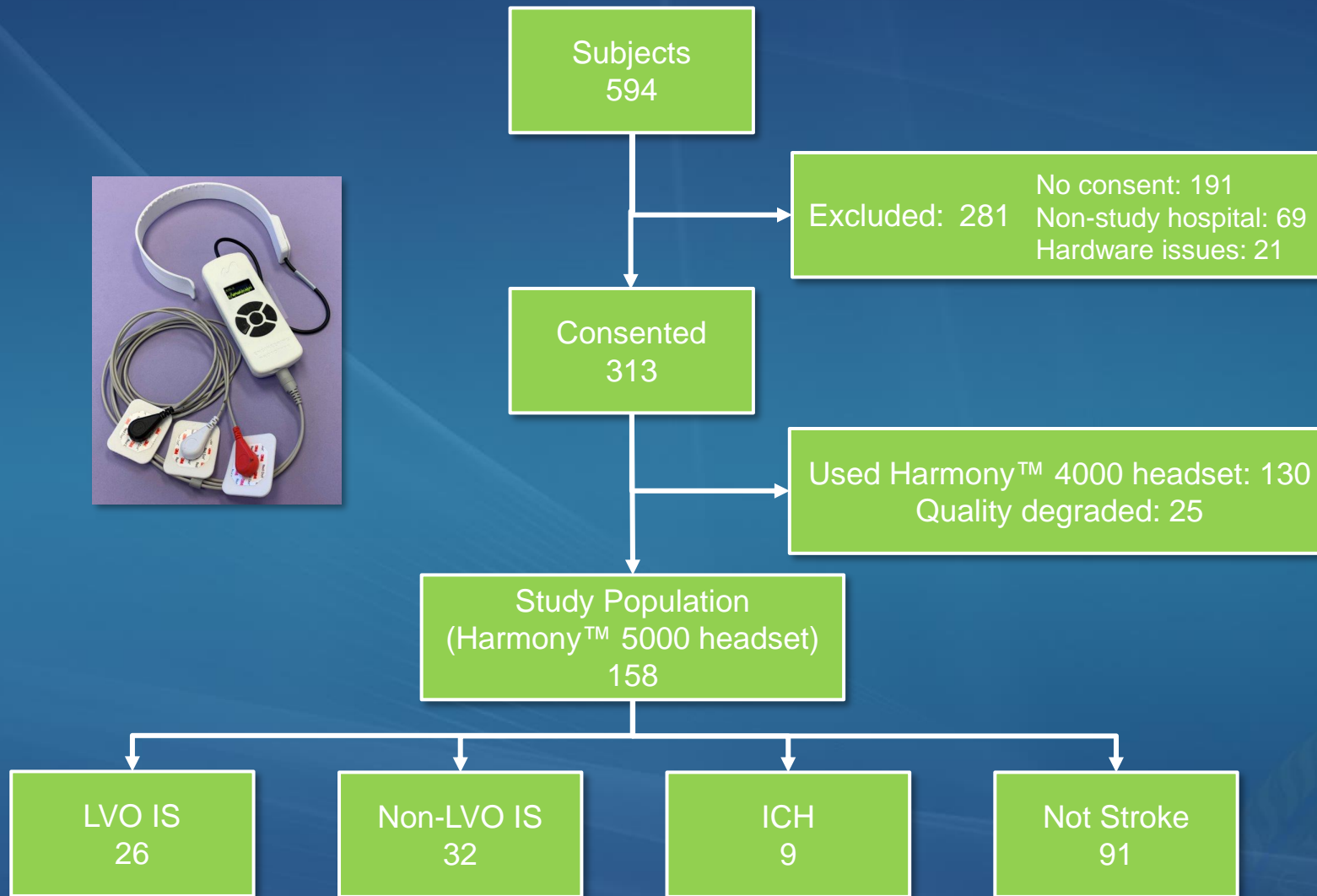
- Enrolled consecutive adult (≥ 18 years old) patients suspected of acute ischemic stroke (AIS) from 11 study hospitals in four different geographical regions (i.e., Detroit, Kalamazoo, Saginaw, San Francisco) over a 21-month period.
- Enrolled patients received Harmony™ 5000 device placement by prehospital EMS personnel, with headset data only matched with clinical data following informed consent.



METHODS

- Exclusions included evidence of head trauma, declined consent, or < 90 seconds of useable headset data obtained.
- Device performance was compared to contemporaneously derived Los Angeles Motor Scale (LAMS) scores.
- COVID-19 status was recorded, with testing and positivity rates compared between groups.





RESULTS

- Most (26/27) LVO strokes identified on imaging were in the anterior circulation (2 intracranial internal carotid artery, 14 M1 segment, 10 M2 segment)
 - ▶ One posterior (basilar) LVO was deemed non-LVO for statistical purposes.
 - ▶ One “vessel-open” presumed LVO was categorized as non-LVO.
- COVID-19 testing and positivity rates were not significantly different between groups.
- Treatment of LVO included t-PA in seven (25%) cases, and EVT in 17 (60.7%) cases.



Demographics	N (%)
Study Patients	158
Female	84 (53%)
Median Age (yrs., IQR)	69 (20)
Hispanic or Latino	4 (3%)
Black / African American	89 (56%)
White	46 (29%)
Asian	8 (5%)
American Indian / Alaskan Native	1 (<1%)
Other	8 (5%)
Unknown Race	6 (4%)
Atrial Fibrillation	33 (21%)
History of prior ischemic stroke	39 (25%)
History of prior hemorrhagic stroke	5 (3%)



RESULTS

- We found a sensitivity of 40.7% and specificity of 90.0% for the LAMS score in detecting LVO stroke, versus sensitivity of 85.0% and specificity of 89.0% for the study device.
- The Harmony™ 5000 device was found to have an area under the receiver-operator curve (AUC) of 0.91, compared to AUC of 0.83 for the contemporaneous LAMS examination in the detection of LVO stroke.

Category	Sensitivity	Specificity
Harmony	85.0%	89.0%
LAMS Score	40.7%	90.0



RESULTS

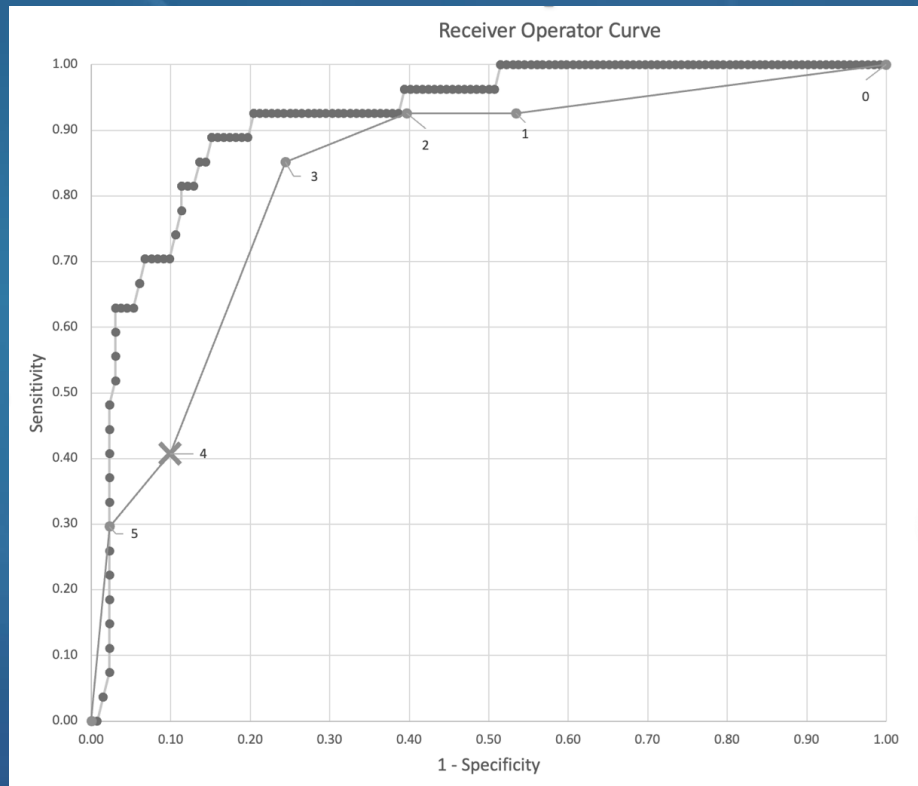
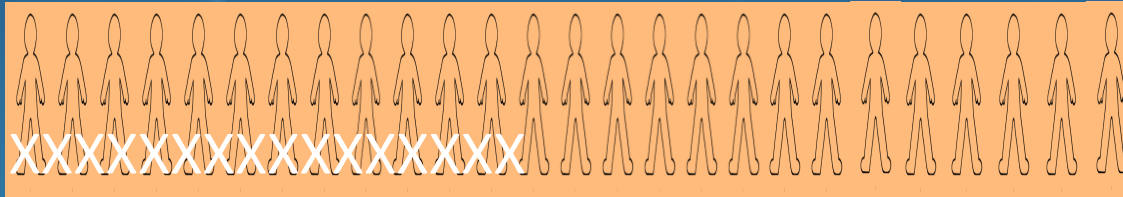


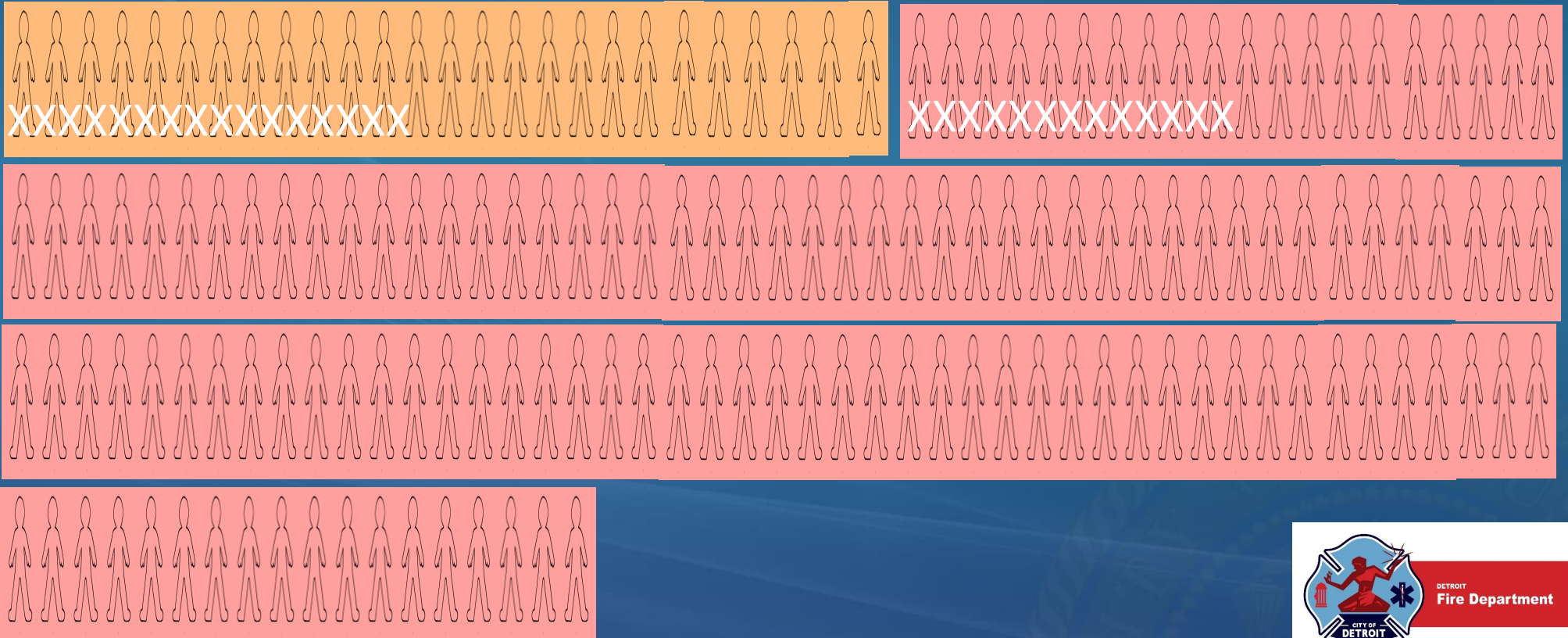
Figure 1. Receiver-operator curve for Harmony™ 5000 device (thick line) and LAMS score (thin line). Standard threshold of ≥ 4 for LAMS cut-off (marked with X) is shown, along with other potential LAMS score thresholds.

LAMS Performance

Missed 16/26 LVO

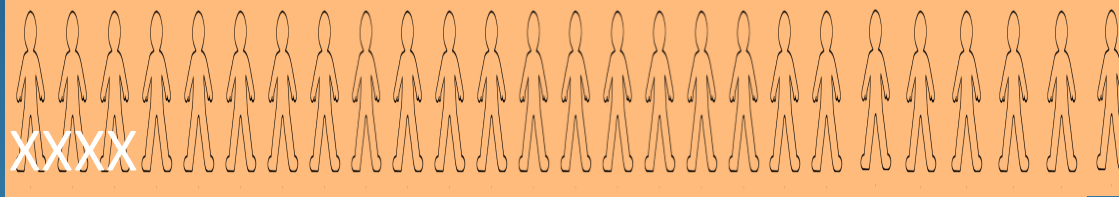


Identified 13 False Positives

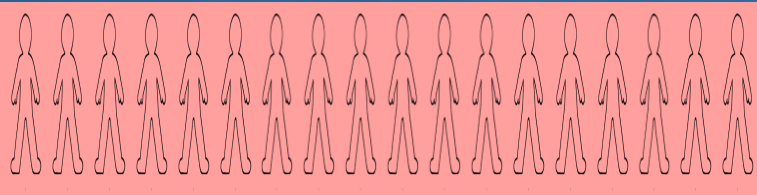
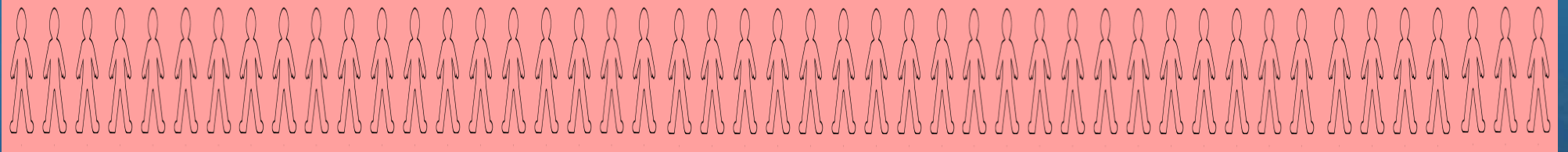
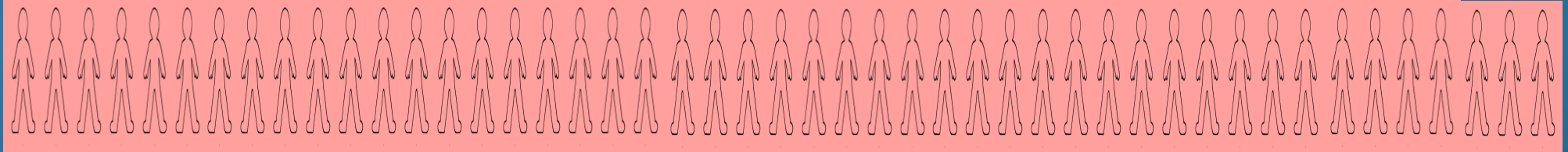
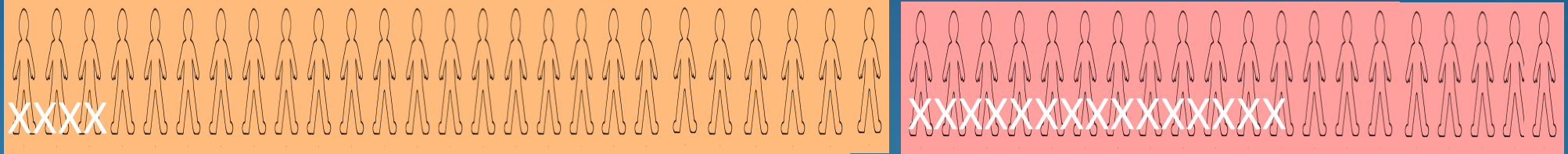


HARMONY™ 5000 Performance

Missed 4/26 LVO



Identified 15 False Positives



Harmony™ 5000 device 2.1 times more sensitive than LAMS ($p = 0.002$)

Similar specificity ($p=0.01$ for non-inferiority)

	LAMS	Device
False Positive	13	15
True Positive	10	22
False Negative	16	4
True Negative	119	117



CONCLUSIONS

- Our results suggest that cranial accelerometry can be used to detect LVO ischemic stroke with performance characteristics comparable, if not superior, to clinical stroke detection methods such as the LAMS score.
- The use of cranial accelerometry technology may help to improve triage and stroke transport to appropriate EVT-capable hospitals when LVO stroke is suspected.
- Further study is needed to determine whether earlier and more reliable LVO detection can lead to improved clinical patient outcomes.
- FDA review is ongoing

