AI-GUIDE™
AI-Guided Ultrasound Intervention Device

Automation, Artificial Intelligence Applied to Medical Technologies for Use in Austere Environments

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THOR RDCR Symposium 2022

26 June 2022

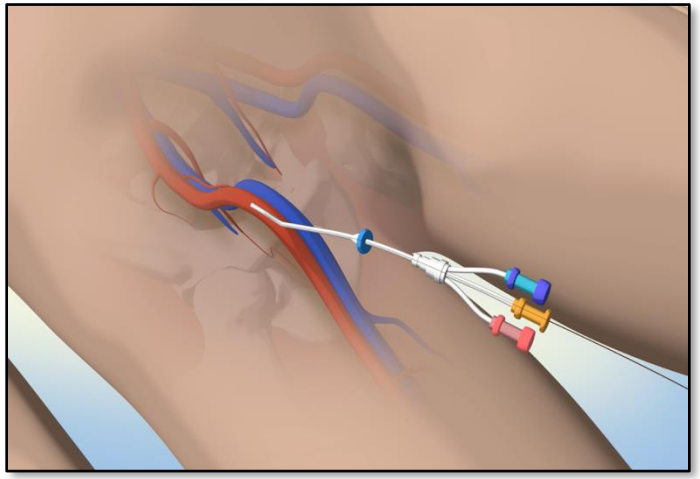
1951–2021
70 YEARS
LINCOLN LABORATORY
MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Sponsored by US Army Combat Casualty Care Research Program and Joint Program Committee 6. DISTRIBUTION STATEMENT A. Approved for public release. Distribution is unlimited. This material is based upon work supported by the Department of the Army under Air Force Contract No. FA8702-15-D-0001. Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Department of the Army.

Capability for Combat Casualty Care

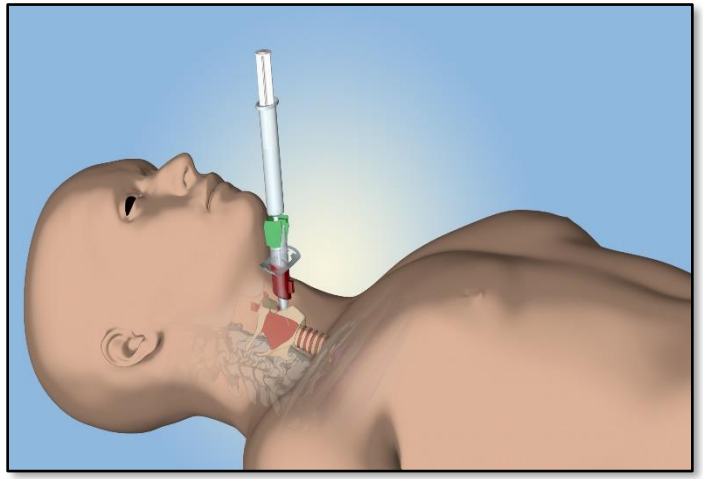
Top Three Causes of Preventable Battlefield Death

Non-compressible torso hemorrhage



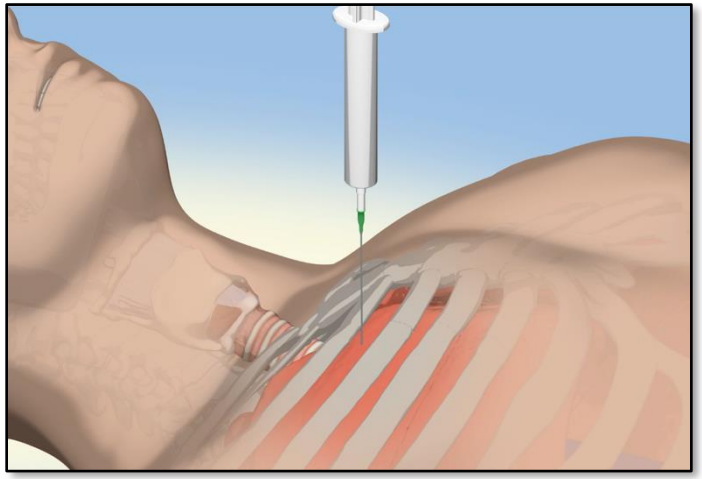
Vascular access

Loss of airway



Cricothyrotomy

Collapsed lung



Needle decompression

Develop AI technology to assist emergency interventions on the battlefield

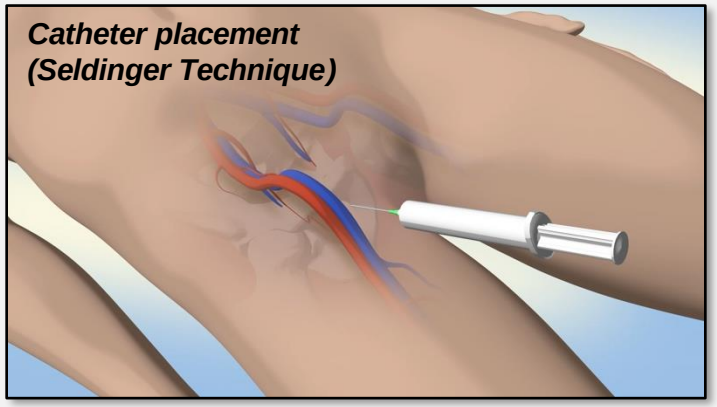
Sponsor: U.S. Army Combat Casualty Care Research Program and Joint Program Committee-6

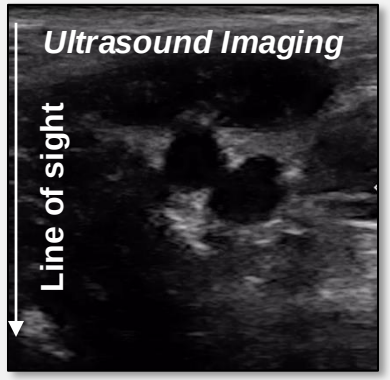
AI-Guided Ultrasound Intervention DEvice

Prototype an intelligent medical platform that enables multiple life-saving interventions in the field

Central Vascular Access Procedure

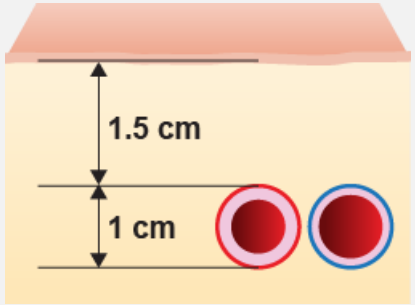
Procedure Performed by Surgeons and ER Physicians



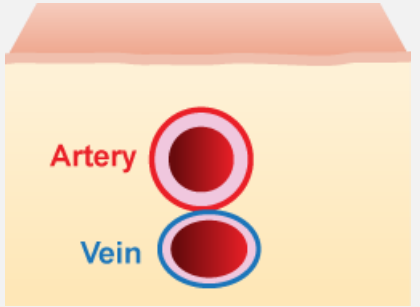


Anatomical Challenges for Accessing Femoral Vessels

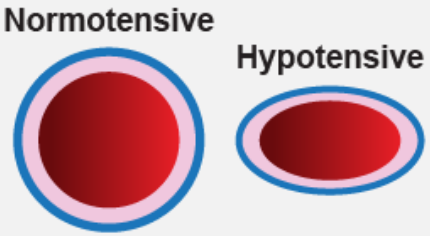
Artery and Vein Lie Deep Below Skin



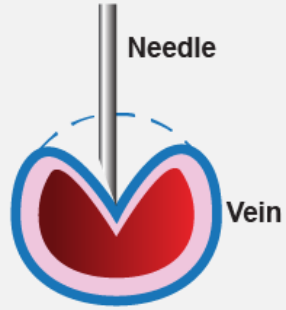
Artery May Occlude Vein



Blood Loss Reduces Vessel Diameter



Needle May Deform Vein (Tenting)



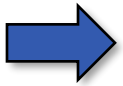
Significant medical expertise currently needed for successful central vascular access

Requirements for Prehospital Vascular Access

Military Use Case

- **Treat casualties in austere combat environments**
- **Enable users of varying medical experience**
- **Deliver intervention rapidly to ease mass casualty demands**
- **Function without reachback for communications denied environments**
- **Fit within combat medic bag and battalion aid station materiel**

Outline



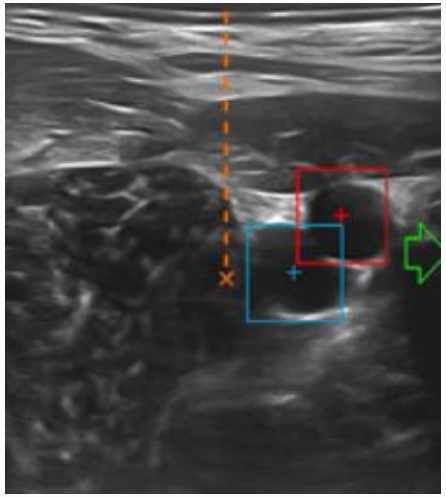
- Motivation
- System Prototyping
- On-device AI
- Integrated System Testing
- Next Steps and Summary

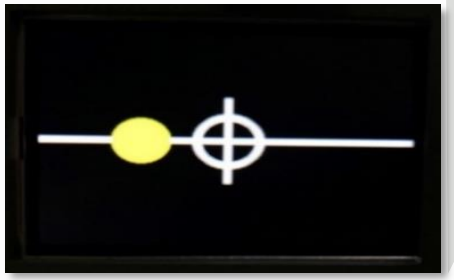
AI-GUIDE Platform

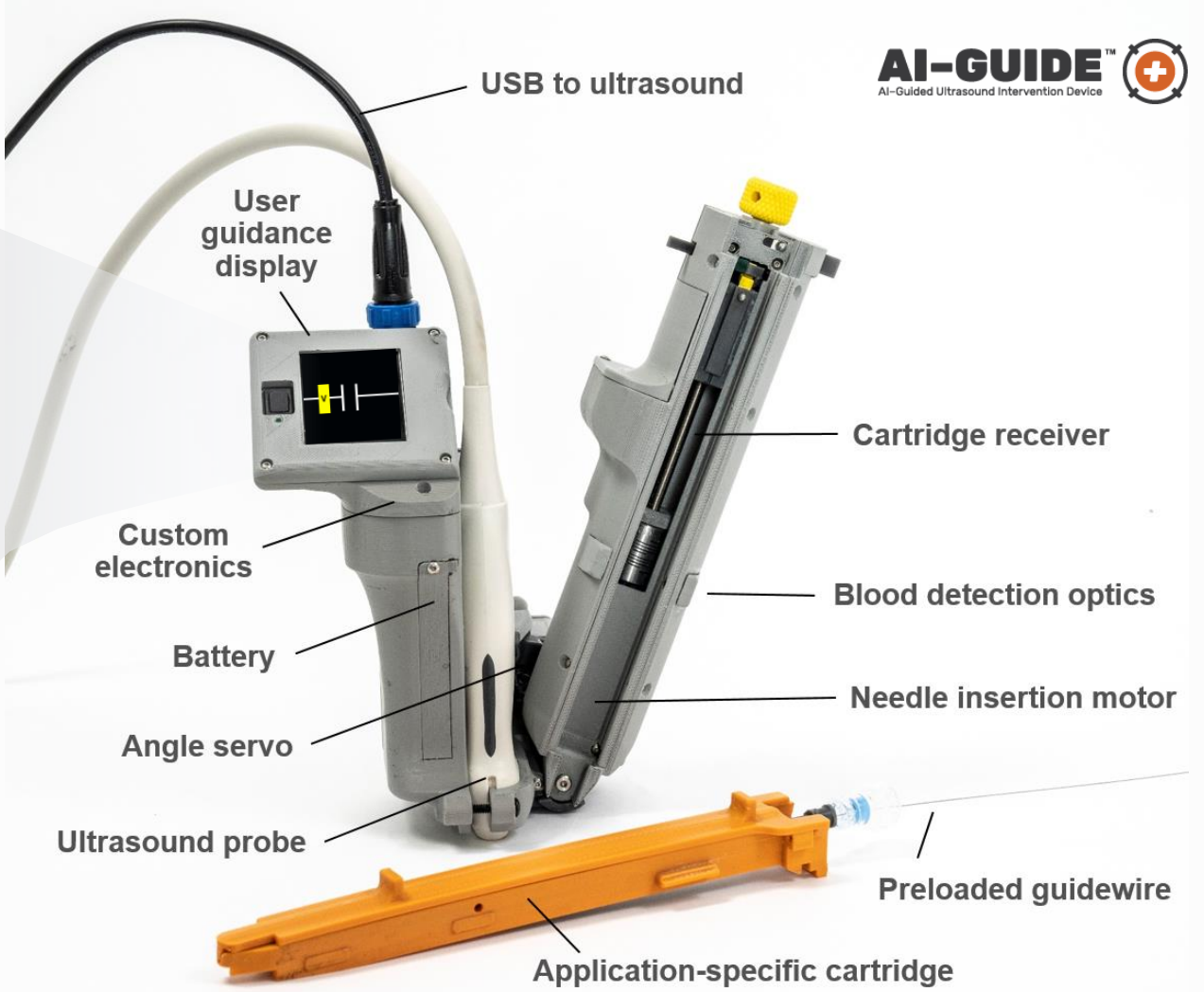
Needle and guidewire insertion workflow

- Scan
- Detect
- Guide
- Insert
- Confirm

Tunable user guidance

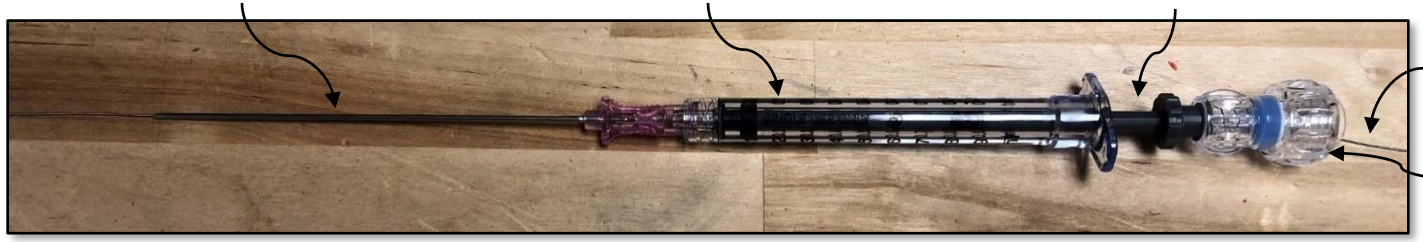






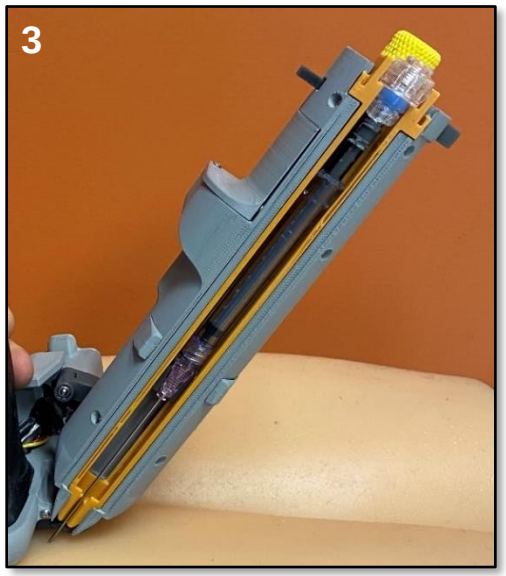
Operator | AI Subsystem | Robotic Subsystem

Needle Placement Verification: Automatic Blood Flashback

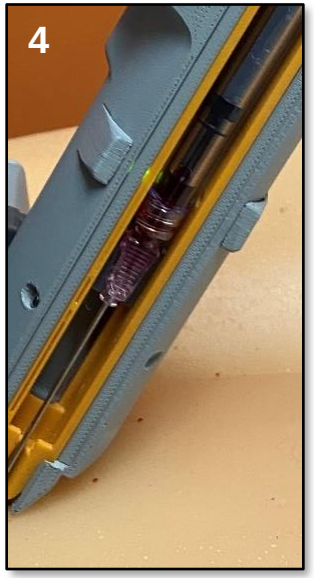


Needle advances toward vessel and creates suction

Blood-sensing circuit activated



Injection length dithers



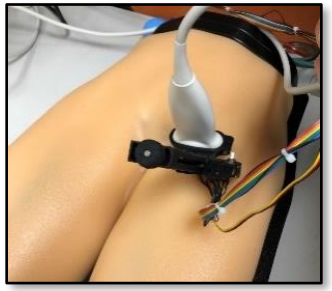
Blood drawn into syringe, blocking light and tripping blood-sensing circuit

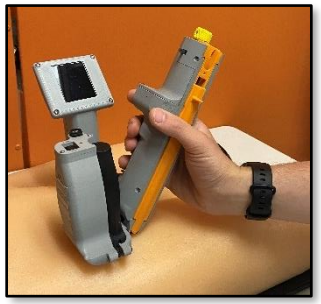
Blood flashback confirmed
- Drive motor stops
- Operator notified

Iterative System Prototype, Test, and Evaluation

Components integrated:

- COTS ultrasound probe and tablet
- Real-time AI algorithm
- Mechanical control
- Electronics
- Firmware
- Optics





Nov 2019

Jan 2020

Feb 2020

June 2020

Oct 2020

Feb 2021

Mar 2021

June 2021

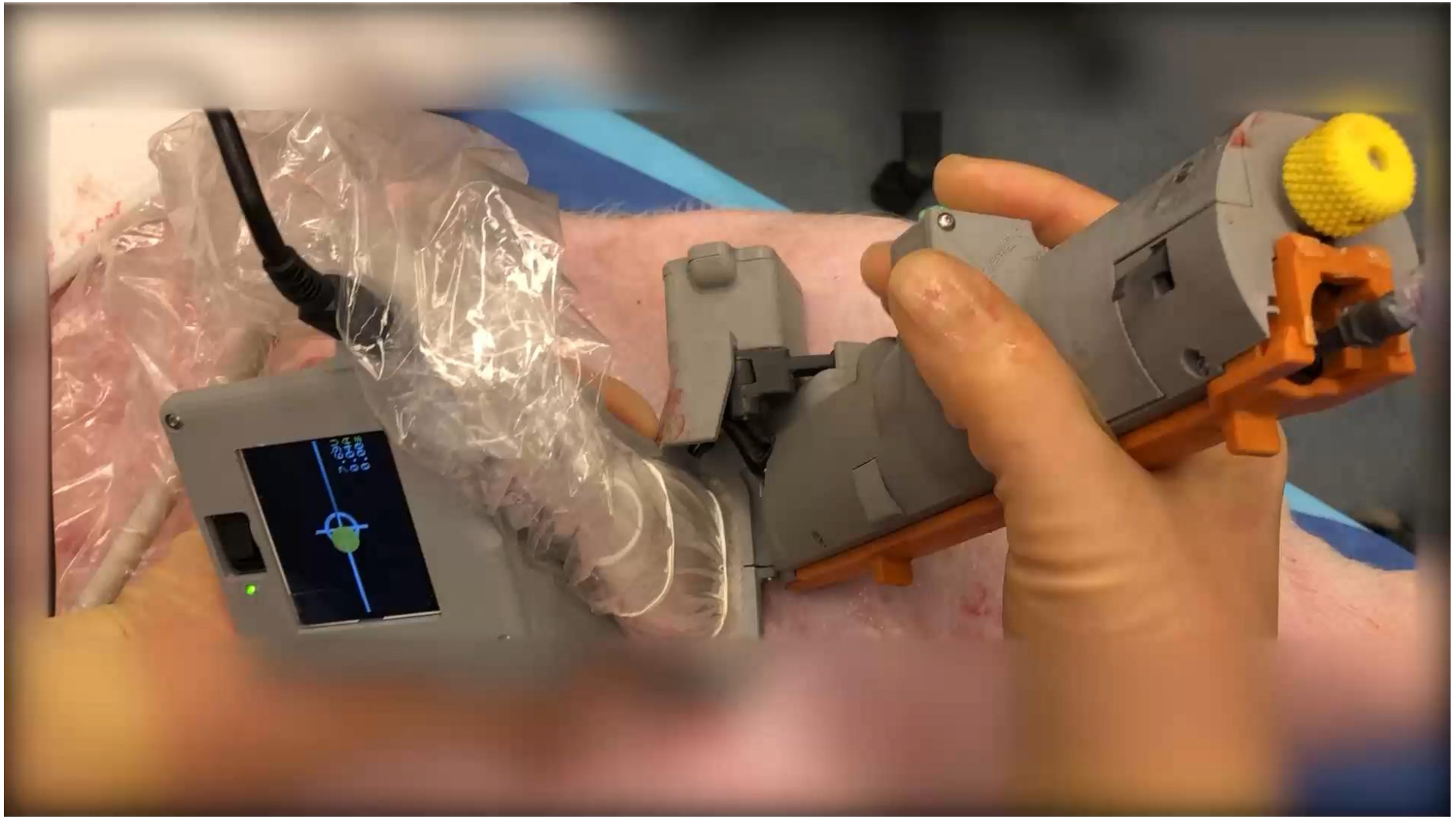
Preclinical study

AI-GUIDE™
AI-Guided Ultrasound Intervention Device

Multiple build-test iterations with increasing accuracy, automation, and integration

AI-GUIDE System Demonstration

Preclinical Testing Result



Studies approved by the IACUC Institutional Animal Care and Use Committee at Massachusetts General Hospital

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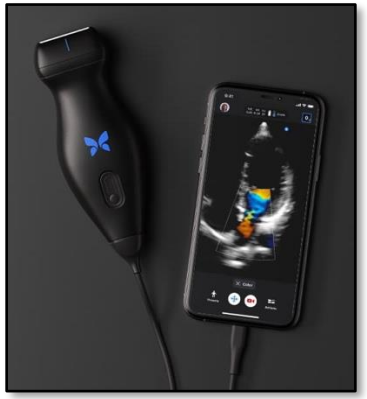
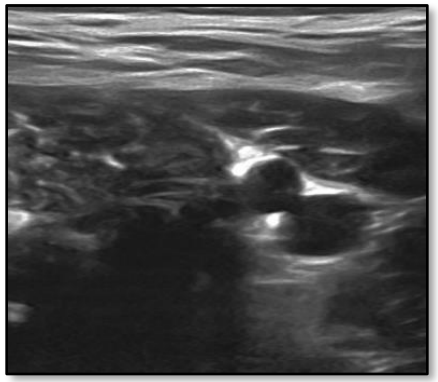
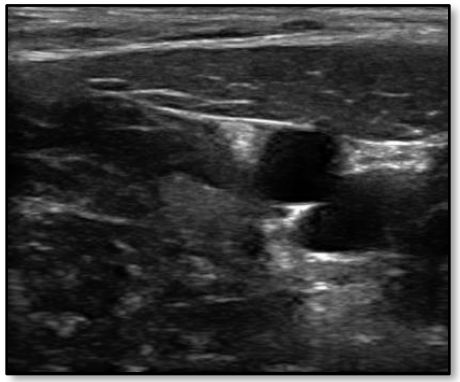
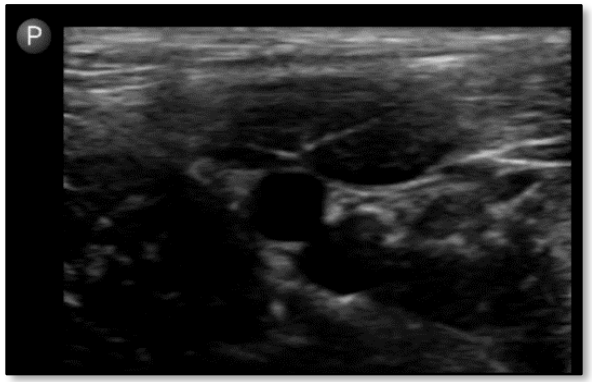
Multi-vendor Femoral Vessel Database

Terason	*Clarius*	*Philips Lumify*	*Butterfly Network*	*GE Vscan Extend*
				

Informed AI to Capture Clinical Workflow

Ultrasound image

Check image quality

Check safety of probe position

Detect vessels individually and as a group

Segment vessel boundary and calculate centroid

Guide probe to optimal insertion position

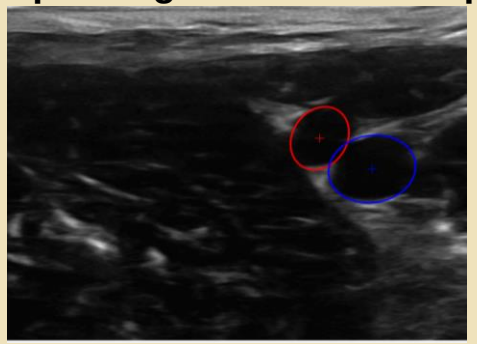
Check for sufficient vessel separation

GUI display

Signal for needle insertion

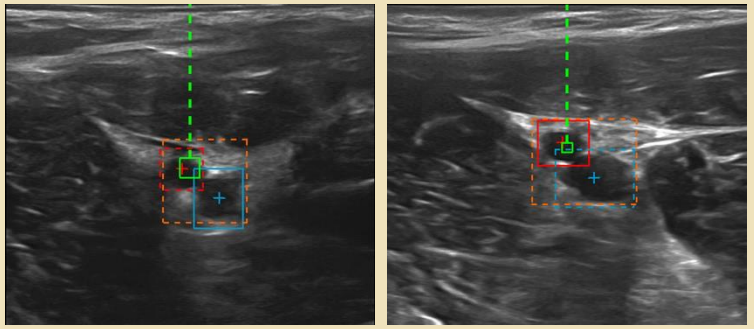
Needle detection/confirmation

Ellipse Segmentation Example



Improved vessel centroid localization accuracy with ellipse segmentation algorithm[1]

Fixed Insertion Box (2mm) | **Dynamic Insertion Box (20%)**



Dynamic scaling of insertion

Change detection

Legend

Input/output

Algorithm module

Signal to hardware

[1] D.C. Wang, *et al.* (2009), *IEEE Trans. Biomed. Eng.*

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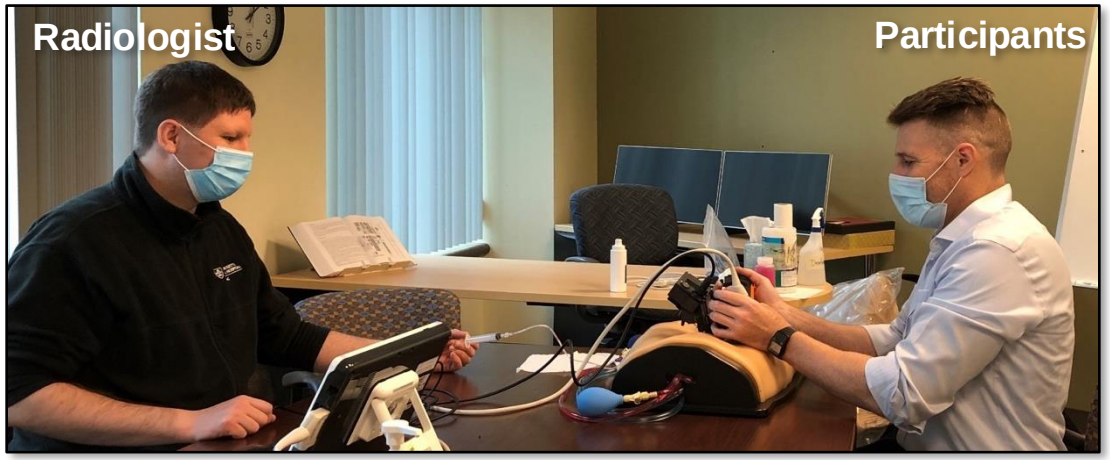
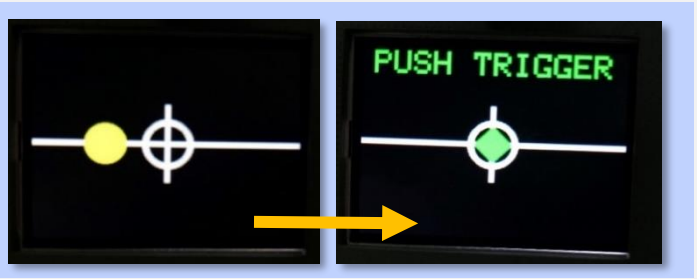
System Prototype Results
Phantom Testing

Set-up

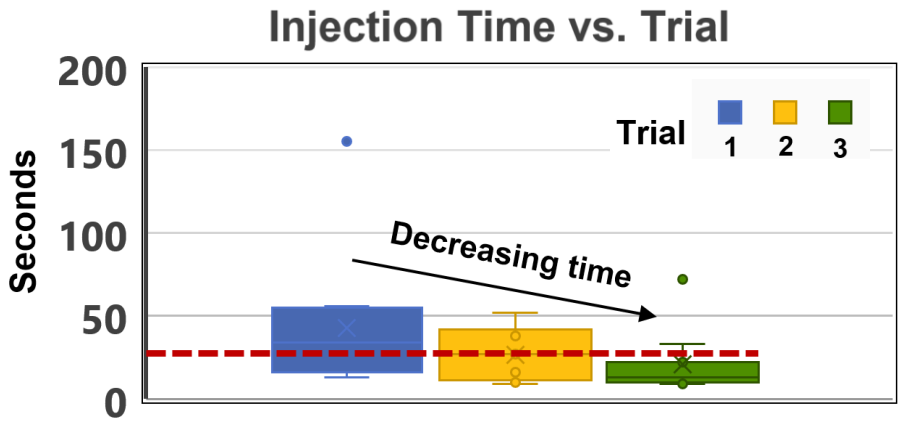


Each user given 2-minute verbal tutorial on device operation (no demonstration)



User guided by simplified interface

Results



- **11 users with 0 – 15+ years experience**
- **3 needle insertion trials per person**
- **32 / 34 trials in less than 1 minute**
- **<u>100% insertion accuracy</u>**

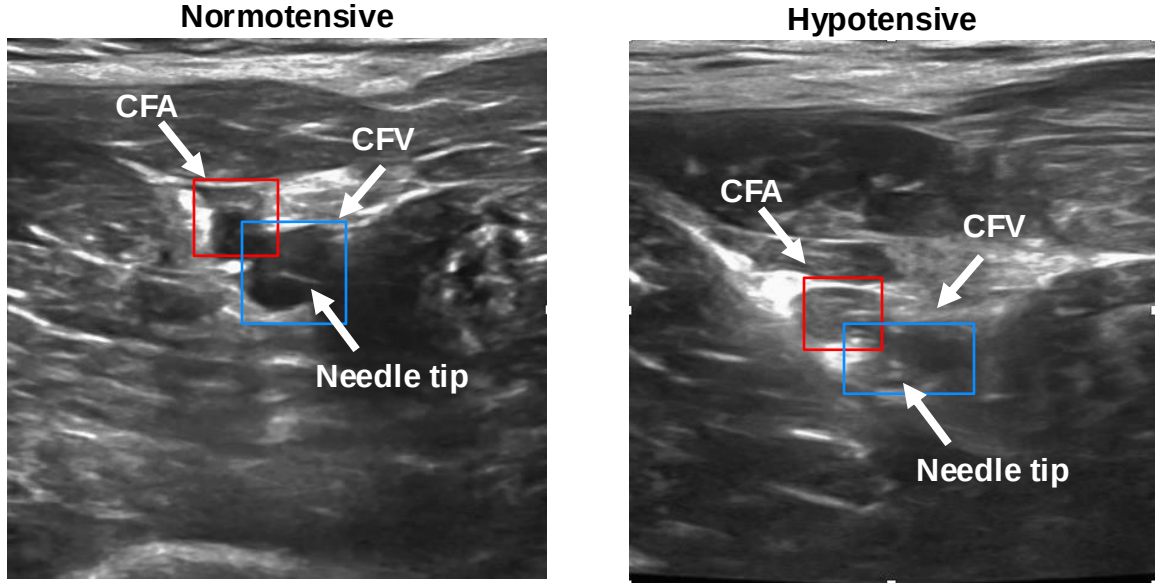
Efficient system guidance for lightly trained users to achieve target insertion point

System Prototype Results
Porcine Testing

Needle Insertion to Femoral Vein

- Up to 3 attempts
- Normotensive: 31/32 success rate
  - 1 trial needed 2 attempts
  - 1 trial needed 3 attempts
  - 1 trial failed after 3 attempts
- Hypotensive: 31/32 success rate
  - 6 trials needed 2 attempts
  - 1 trial failed after 3 attempts

Examples of successful needle insertion to femoral vein



Initial data indicates needle placement accuracy requirement is met on high-fidelity preclinical model

Studies approved by the IACUC from Massachusetts General Hospital
IACUC: Institutional Animal Care and Use Committee

CFA: Common Femoral Artery
CFV: Common Femoral Vein

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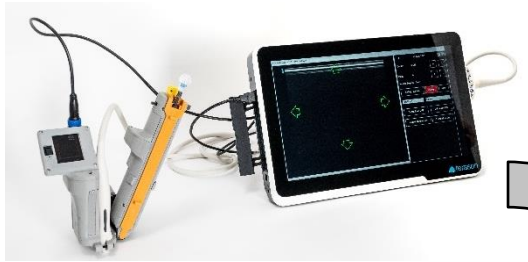
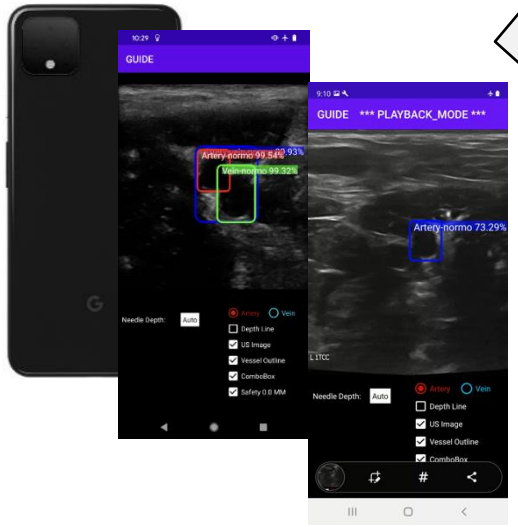
Expanding Use Cases for AI-GUIDE Platform

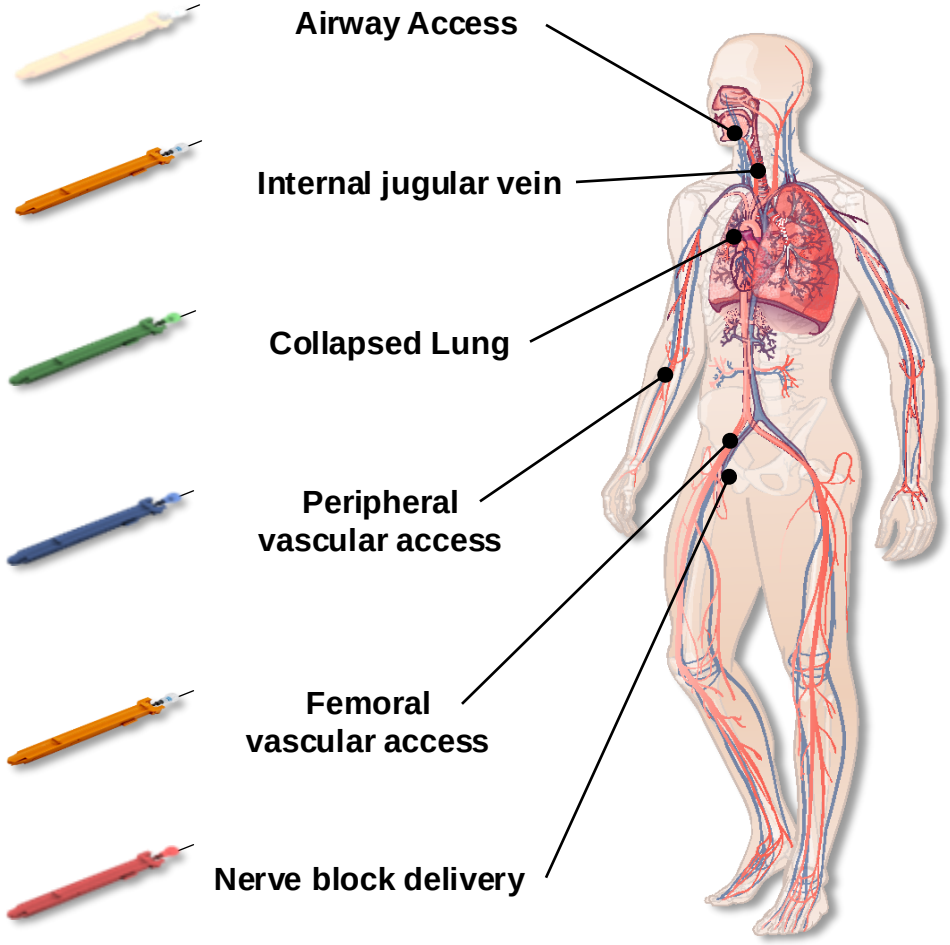
Improved Portability



On-phone processing



Additional Applications



Technology Development Roadmap

- Iterative prototyping and testing
- Quantify ability to meet goals:
  - Accurate, fast, usable by non-experts
  - Low-SWaP

2021 R&D 100 WINNER

- Increasing automation
- Generalizing to additional blood vessels
- Extending to interventions for loss of airway and collapsed lung

Continued Research and Technology Prototyping

R&D Funding:
- *Lincoln Internal*
- *CCCRP*

AI-GUIDE™ AI-Guided Ultrasound Intervention Device

Licensing of platform technology patent, AI models, and one-of-a-kind ultrasound database*

Translation / Tech Transition

- Productization
- Human trials
- Regulatory approval
- Commercialization
- Civilian spin-off

Identifying Acquisition Funding:
- *U.S. Government*
- *Commercial investment*

*International patent (US20210045711); follow-on provision filed; copyright filing on software and AI models in progress
CCCRP: Combat Casualty Care Research Program

Summary

- Vascular access is a key step for life-saving interventions
- MIT LL has demonstrated a handheld, AI-enabled ultrasound prototype to assist an operator to cannulate a deep vessel
  - Phantom and porcine studies indicate quick and accurate operation
- Continue to mature prototype to decrease SWaP and ruggedize for fielding
- Working toward translating technology to first-in-human testing
  - Identifying an application for routine civilian use
- Expanding to additional applications such as nerve block

Thank you

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