



EVALUATION OF THE BUTTERFLY iQ ULTRASOUND IMAGER FOR USE IN HUMAN SPACE FLIGHT PROGRAMS

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DISCLOSURE

**No actual or potential conflict
of interest in relation to this
investigation / presentation**

(All Investigators)



MOTIVATION

- **Known challenges and risks of human space flight**
- **Complexity and limitations of the current ISS imaging paradigm**
- **New challenges of highly constrained missions – a *strategic inflection point****
 - ✓ **Opportunities from point-of-care imaging on Earth**
 - ✓ **Opportunities from emerging imaging and data technologies**
 - ✓ **Prior experience of the team**

* *Only the Paranoid Survive* by Andrew Grove, Intel Corp.



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ORIGINAL GOAL

- **Ground-based evaluation of novel ultrasound transducer technology with integrated deep learning-based (AI) solutions**

SUPPLEMENTAL GOAL:

- **Demonstrate functionality and usability in conditions of space flight using the ISS as a testbed**

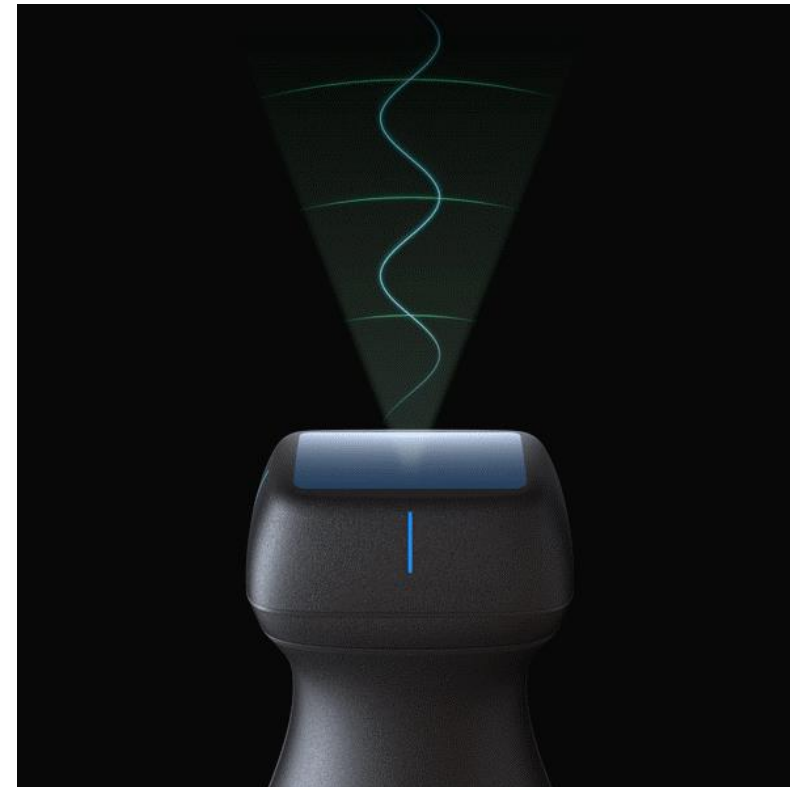
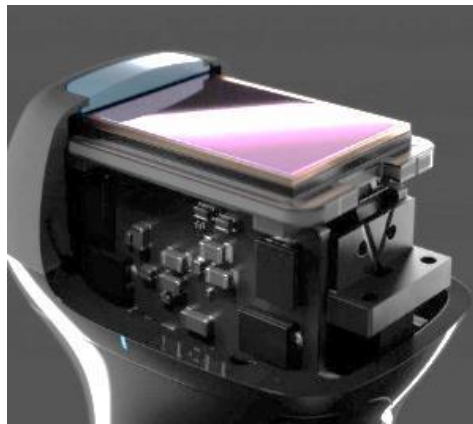
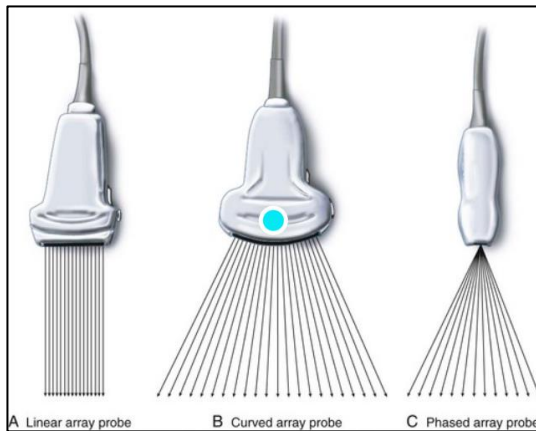
THE DEVICE

- M: 0.313 kg | V: 0.5 L | P <15W (charging)
- iPhone, iPad, Android mobile platform-based
- Preset modes for all “point-of-care” imaging applications
- Simple connectivity, streamlined data transfers

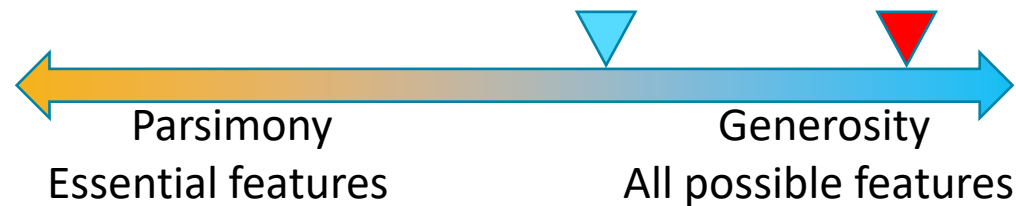


Clinical universality with a single probe
Rapid deployment and startup
Intuitive UI with minimal operator input
Wireless connectivity and DICOM compliance
Integrated AI modules
Upgradeability

TECHNOLOGY: TRADITIONAL VS. ULTRASOUND-ON-A-CHIP



- Single probe
- Works with mobile platforms
- Upgraded through append firmware pushes
- Highly integrated design
- Limited only by computing power



GROUND ENGINEERING EVALUATION - I

A Imaging assessment on QA phantoms

Multipurpose, multi-tissue ultrasound phantoms

Measures used for ACR accreditation, general QA

Parallel comparison with ISS Ultrasound II

2 qualified operators

B. Imaging performance in human subjects at various

depths: *Shallow* (0-1cm), *Intermediate* (1-5 cm), *Deep* (5-25 cm) tissue surveys

Parallel comparison with ISS Ultrasound II

10 human subjects

PHANTOM-BASED ASSESSMENTS

- Image uniformity
- Near field (dead zone)
- Depth of penetration
- Vertical calibration
- Horizontal calibration
- Axial and lateral resolution in 3cm and 10.5cm target groups
- Low contrast detectability
- Grayscale contrast sensitivity
- Anechoic cylinders

SAMPLE: PHANTOM TESTING

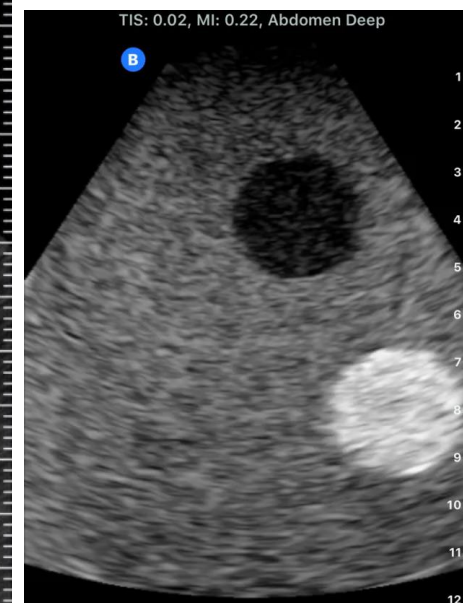
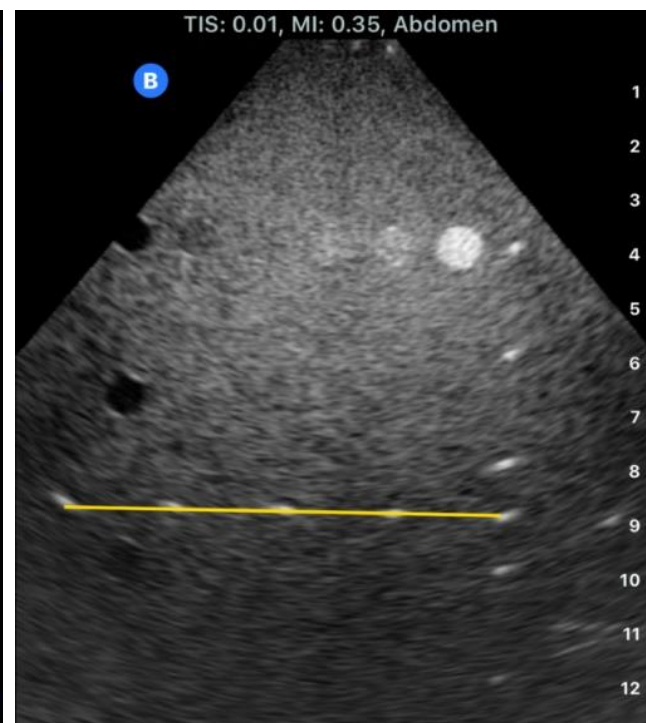
Horizontal Calibration



GE Vivid q – 8.23cm

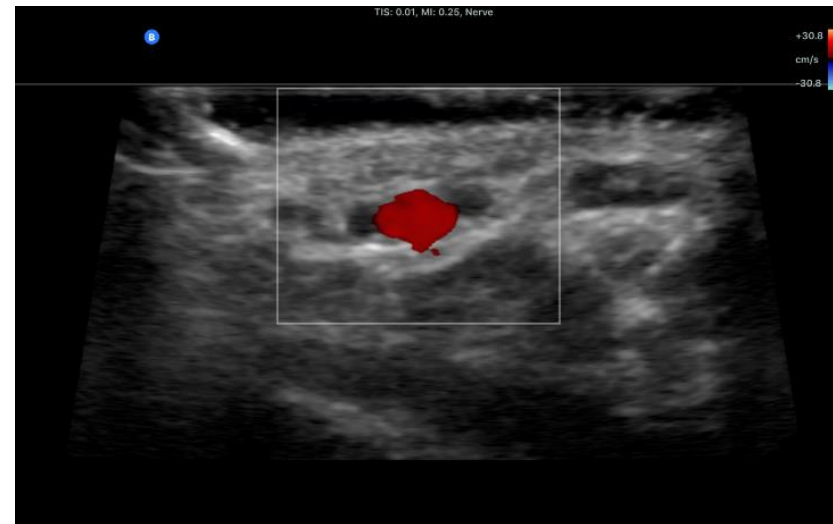
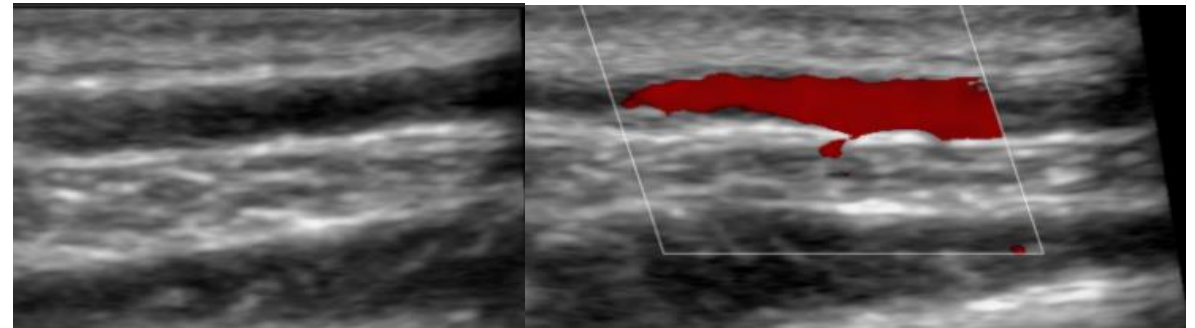
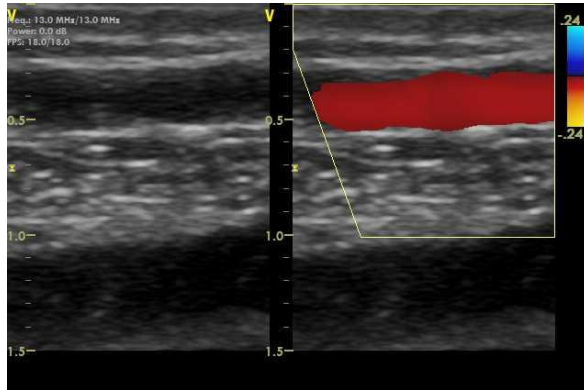


Butterfly iQ – 4/5, 8.04cm



SAMPLE: SUPERFICIAL TARGETS (RADIAL ARTERY)

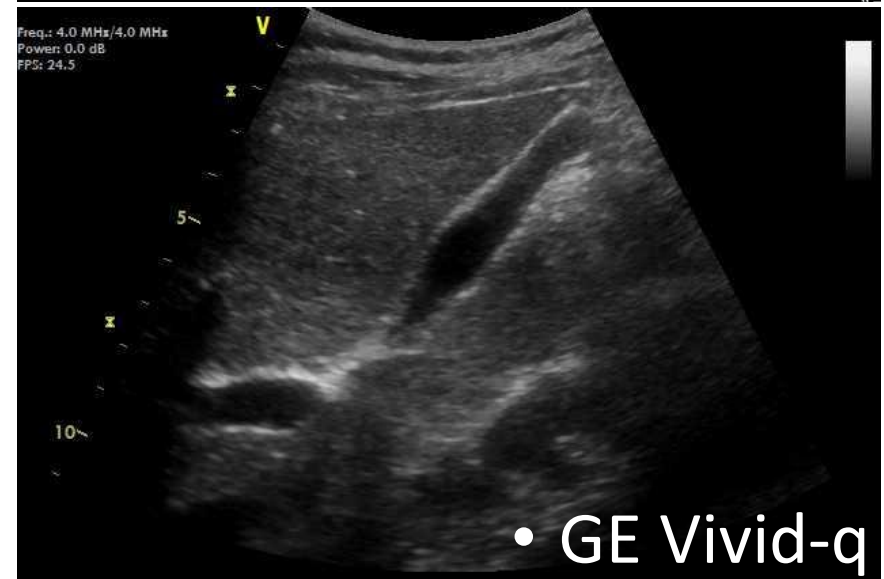
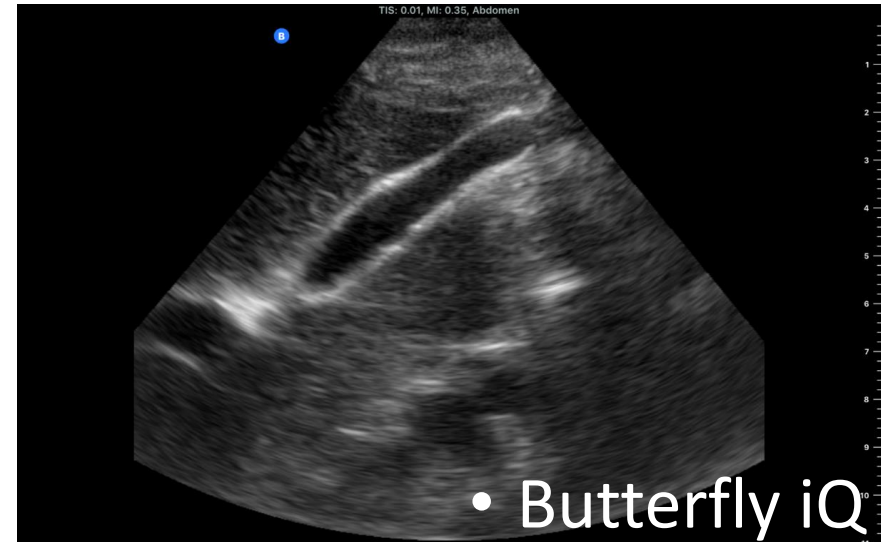
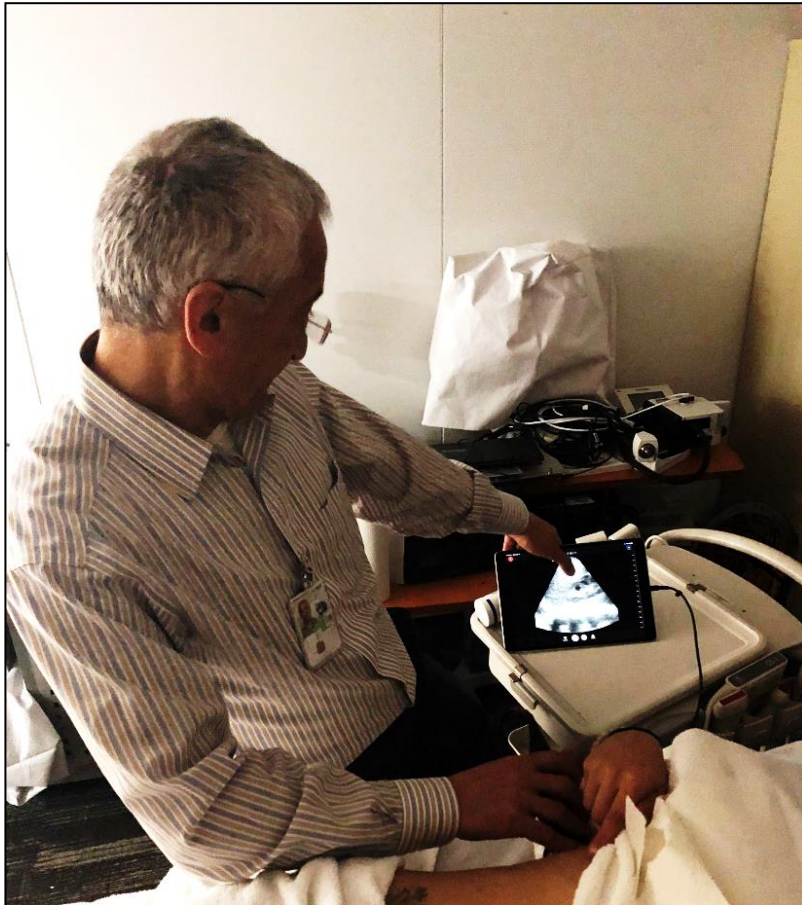
GE Vivid-q



Butterfly iQ

SAMPLE: DEEP TARGETS

Gallbladder and Portal Vein



GROUND ENGINEERING EVALUATION -II

C Performance in acute care protocols

FAST exam, Lung imaging for pneumothorax and pulmonary edema, image-guided vascular access

5 human subjects and vascular access phantom

- GE Vivid-q

D Remote guidance by experts

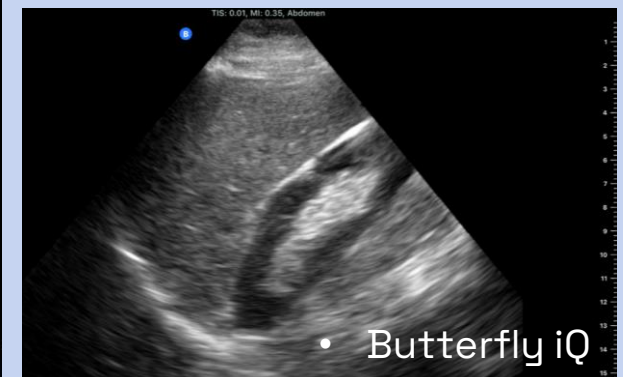
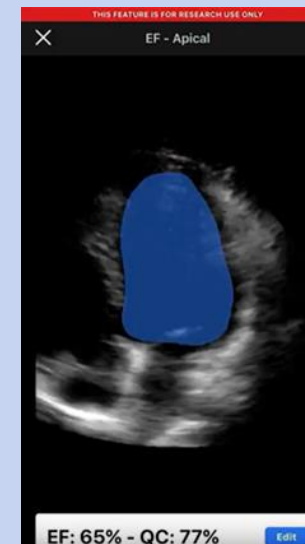
Like-ISS remote guidance, screen casting from iOS device

2 experienced guiders, 5 novice operators

E Remote autonomy scenario

Auto-EF module use, operator guidance by the device app, automated identification, quality assessment, and measurements

10 human subjects, 10 novice operators



GROUND ENGINEERING EVALUATION –III

- GENERAL HARDWARE FEATURES (mass, volume, power consumption, charging time, running time on a single charge (mode-dependent), materials, etc.)
- GENERAL OPERATIONAL CHARACTERISTICS (deployment time, effects of ambient lighting, setup
- SUBJECT AND OPERATOR SAFETY (Electrical, acoustical, chemical, mechanical, thermal)
- LIMITATIONS AND ERROR NOTES
- INTERFACES, CONNECTIVITY
- DATA SECURITY ASSESSMENT
- HUMAN FACTORS, ERGONOMICS, USER INTERFACE
- LIMITATIONS FOR SPECIFIC SCENARIOS (REQUIRED SURVEILLANCE AND LONGITUDINAL MONITORING, ACUTE CARE, PROCEDURAL SUPPORT, ETC)

DATA

- Static ultrasound images from Device and Reference Device (phantoms and human subjects)
- Ultrasound video clips
- Formal questionnaires (operators, subjects)
- Measurement and data tables
- Operator notes and expert assessments
- Recorded observations
- Other

LIMITATIONS AND CONTINUING DEVELOPMENT

- No Pulsed Doppler (added in 2020 for vascular presets)
- No ophthalmic mode (added in 2020)
- Single AI tool – Auto-EF (Auto-Bladder added in 2020)
- Lower frame rates than in reference device (improved in the new model)
- No ECG gating in Cardiac mode
- Limited adjustability of settings (intentional, preset-based operation)

STUDY LIMITATIONS

A large proportion of subjective expert assessments and questionnaires

Lack of blinding in image comparisons between devices

A limited number of operators

A limited number of test subjects

No testing in pathology (e.g., renal stones, vascular conditions)

INTERIM SUMMARY

- The prototype represents significant innovation
- Image quality is comparable to full-fledged systems
- Apparent promise for space health systems:
 - Ultra-compact, portable design and small footprint (mass, power, volume)
 - Near-instantaneous availability of imaging and streamlined data handling;
 - Deep learning-based tools with real-time image analysis
 - Upgradeability of firmware and software
 - Preset-based intuitive user interface supporting non-expert operators
 - Resource savings

Features of this prototype align with the concept of autonomous care capability of a constrained exploration flight with asynchronous communications

SUPPLEMENT (PHASE 2, 2021)

Demonstration of the Butterfly iQ using the ISS testbed:

- Autonomous performance of up to 5 imaging procedures relevant to recognized health risks
- Includes a deep learning-based module (Bladder Volume)
- Just-in-time guidance tools leverage the team's sizeable experience in ISS-based imaging

STEP 1: Prepare Device and App

1.1



PI's TIP: Adjust depth by swiping up-down. Adjust gain by swiping right-left.

1.2





TRANSLATIONAL
RESEARCH INSTITUTE FOR
SPACE HEALTH

This work is supported by the Translational
Research Institute for Space Health through
NASA Cooperative Agreement NNX16A069A,
Grant #FIP0007

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WORKING WITH T.R.I.S.H. means:

Working in dedicated community with a shared goal of furthering space health

Enjoying a collaborative environment with learning and sharing among multiple investigator teams

