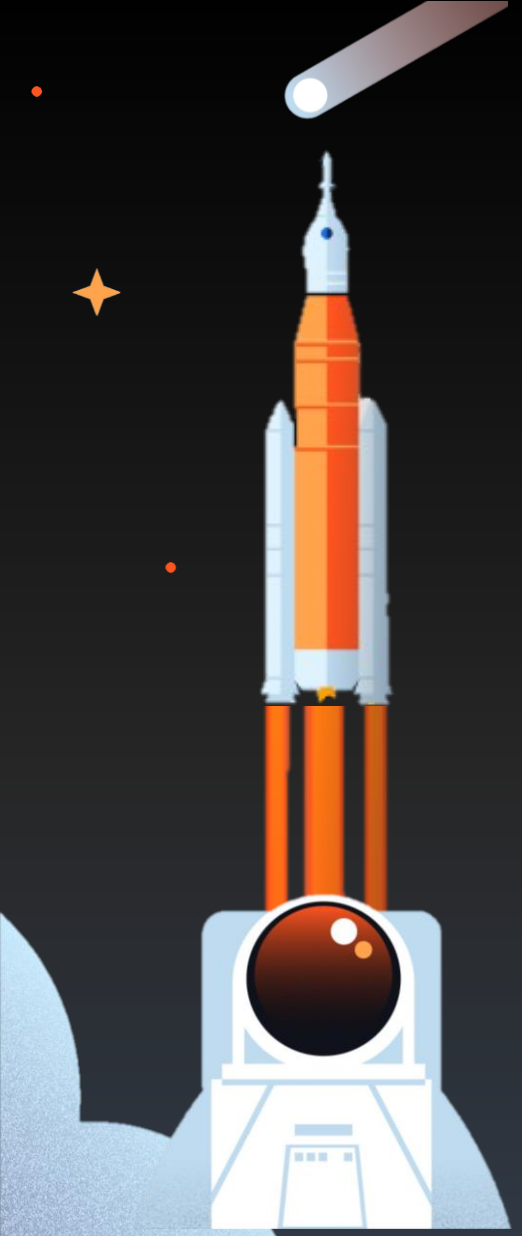

A Multi-faceted Approach to Demonstrating Multi-functional Integrated Medical Devices to Advance Earth-Independent Medical Operations

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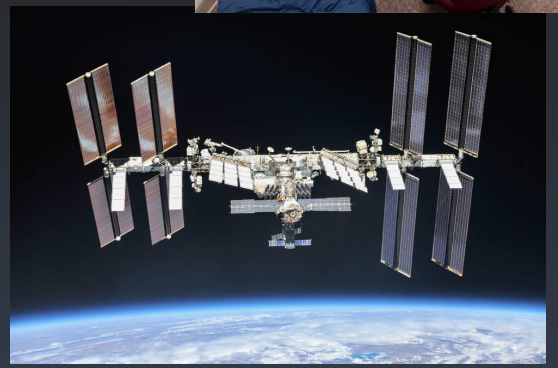
2024 Human Research Program Investigators' Workshop

Background – Components of the Multi-functional Integrated Medical (MIM) Device Evaluations

- Determine MIM device capabilities (Tempus Pro™ and LifeBot 10®) and compare to exploration medical system requirements
- Evaluate the ease of use of the MIM devices and the user experience
- Determine the clinical usability of MIM device measurements and images
- Evaluate MIM device survivability and usability in operational environments
- Determine MIM device compatibility with an Earth-independent Medical Operations (EIMO) system

Background – MIM Device Evaluation Platforms

- Demonstrations as part of the NASA Johnson Space Center (JSC) Exploration Atmospheres (EA) Studies
  - Tempus Pro™ demonstrated during EA-2 3-day and 11-day studies
  - LifeBot® demonstrated during EA-3 11-day study
- Ground-based evaluations in the ExMC Tech Demo Test Bed at the NASA Glenn Research Center (GRC)
  - MIM Device comparison study to begin in February 2024
- Demonstrations on the International Space Station (ISS)
  - European Space Agency (ESA) to flight certify the Tempus Pro™
  - NASA GRC/ZIN Technologies to flight certify the LifeBot®
  - Demonstrations will begin no earlier than FY25



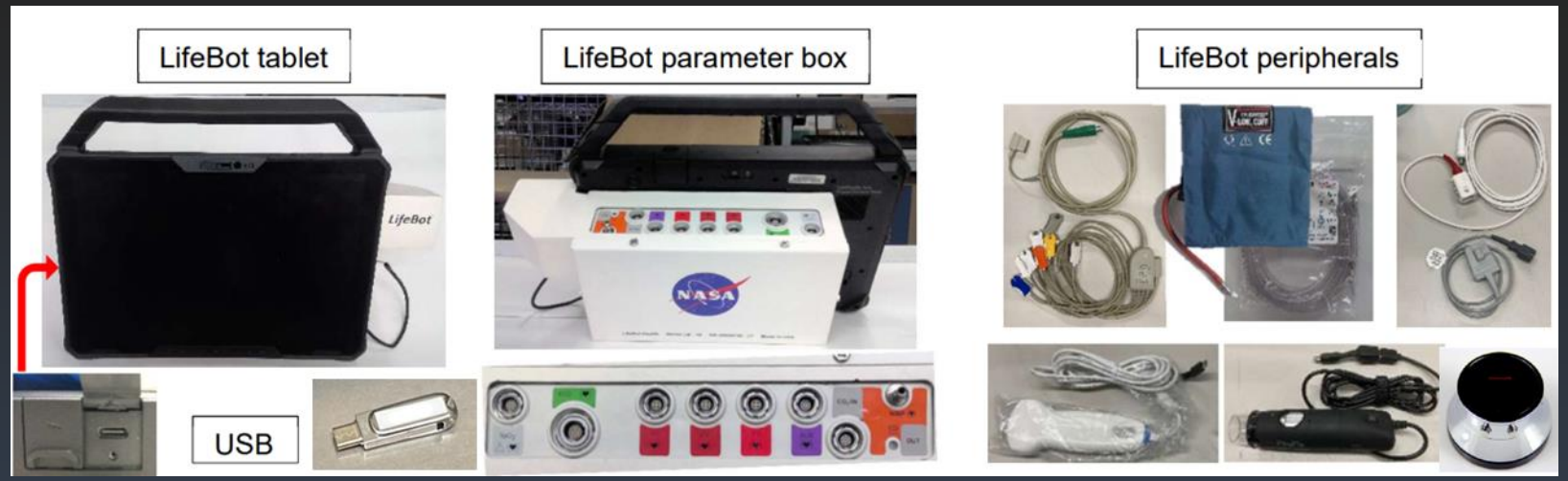
Background - Tempus Pro™* MIM Device

- Multi-parameter vital signs monitor (ECG, blood pressure, SpO2, temperature, etc.)
- Ultrasound imaging and video laryngoscopy
- Procedural guidance (iAssist)
- Data capture and transmission
- Communication capabilities

*Remote Diagnostic Technologies, Ltd., Philips Corp, Farnborough, UK

Background - LifeBot®* MIM Device

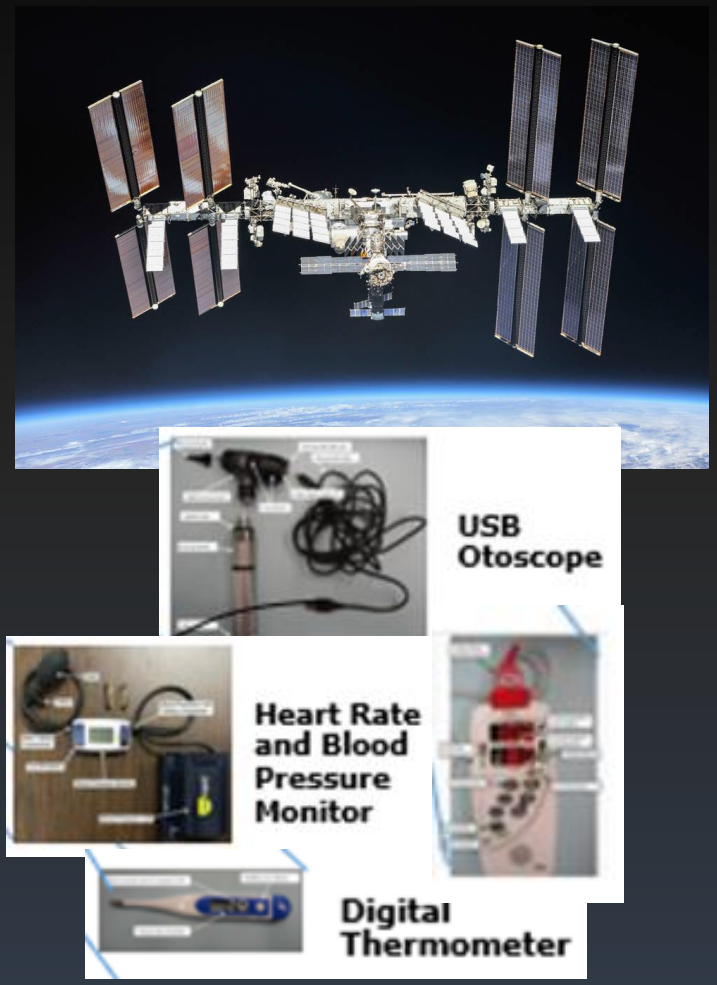
- Multi-parameter vital signs monitor (ECG, blood pressure, SpO2, etCO2)
- Ultrasound, digital stethoscope, otoscope, and dermotascope
- Data management of patient reports through electronic health records
- On-board audio, video and data communication capabilities



*LifeBot Health, Chicago, IL

MIM Device Capabilities Comparisons

- Multiple separate vital sign monitoring devices are currently used on the International Space Station (ISS)
- MIM devices integrate capabilities, potentially providing efficiencies over multiple separate devices
- MIM device capabilities also compared to:
  - The Long Duration Lunar Orbit and Lunar Surface (LDLOLS) medical system foundation capabilities
  - A Mars Medical System Capabilities Prioritization List created by NASA's Exploration Medical Integrated Product Team (XMIPT)



MIM Device Capabilities – Comparison to Lunar and Martian Medical System Requirements

LDLOLS & Mars Medical System Capabilities	LifeBot	Tempus Pro
390nm to 500nm Wavelength Lamp		
Alpha Stim CES device		
Anesthetic gas monitoring		X
Anoscope		
Audiometry		
Blood pressure	X	X
Camcorder	X	X
Camera	X	X
Cardiopulmonary telemetry	X	X
Clinical Decision Support Software	X	X
CO2 detector		
Computed Tomography (CT)		
CPAP		
CPR sensor		X
Defibrillation/Cardioversion/Pacing	X	X
Dermotoscope	X	
ECG	X	X
Electronic Health Records	X	X
E-mail	X	X
Endoscopy		
End-tidal CO2 capnometry	X	X
External pacing device cardiac monitor	X	X
Flexible Bronchoscope		

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Dermotoscope	X	
ECG	X	X
Electronic Health Records	X	X
E-mail	X	X
Endoscopy		
End-tidal CO2 capnometry	X	X
External pacing device cardiac monitor	X	X
Flexible Bronchoscope		

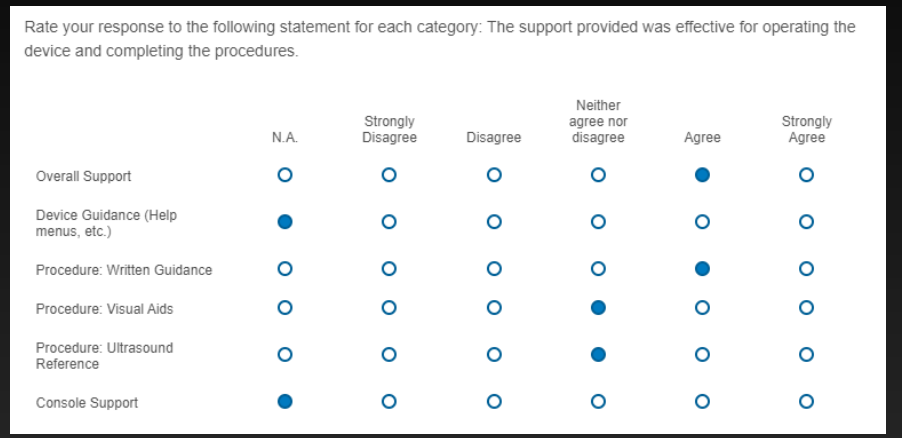
LDLOLS & Mars Medical System Capabilities	LifeBot	Tempus Pro
Point of Care Biochemisry Analysis Device		
Printer		X
Audio communication	X	X
Video communication	X	
Radiography		
Respiratory rate	X	X
Space Anticipation glasses		
SpCO blood oximetry		X
SpHb blood oximetry		X
SpMet blood oximetry		X
SpO2 blood oximetry	X	X
Stereoscopic biomicroscope		
Stethoscope	X	
Tablet computer	X	X
Thermometer	X	X
Timer		
Tympanometry		
Ultrasound	X	X
Ultraviolet light		
Video examination glasses	X	
Visual acuity assessment		
Visual fields assessment		

MIM Device Capabilities – Comparison to Lunar and Martian Medical System Requirements

Comparisons	Tempus Pro & Tempus LS	LifeBot 10 & Defib Module
Number of different capabilities	29	26
Number of LDLOLS capabilities met	17/39	17/39
Number of Mars Medical System capabilities met	20/36	16/36
Number of capabilities on neither requirement list	3	4
Number of capabilities unique to device	8	6

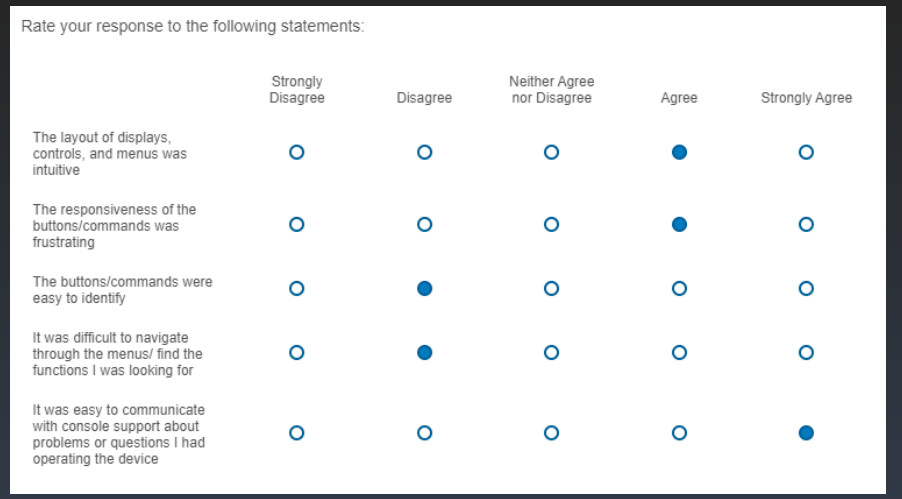
MIM Device Usability

- Usability information collected from caregivers and patients using user experience surveys administered during the EA Chamber studies
- The EA studies were performed to validate EVA prebreathe protocols and to study physiological responses to alternate atmospheric conditions (high oxygen concentration/low partial pressure)
- MIM devices were demonstrated during science days, where caregivers collected MIM device measurements and images on fellow crew members acting as patients or on themselves during self-exams
- Console support for device operations and clinical questions were provided during some demonstration sessions and other sessions were performed autonomously, without console support



Rate your response to the following statement for each category: The support provided was effective for operating the device and completing the procedures.

	N.A.	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
Overall Support	○	○	○	○	●	○
Device Guidance (Help menus, etc.)	●	○	○	○	○	○
Procedure: Written Guidance	○	○	○	○	●	○
Procedure: Visual Aids	○	○	○	●	○	○
Procedure: Ultrasound Reference	○	○	○	●	○	○
Console Support	●	○	○	○	○	○



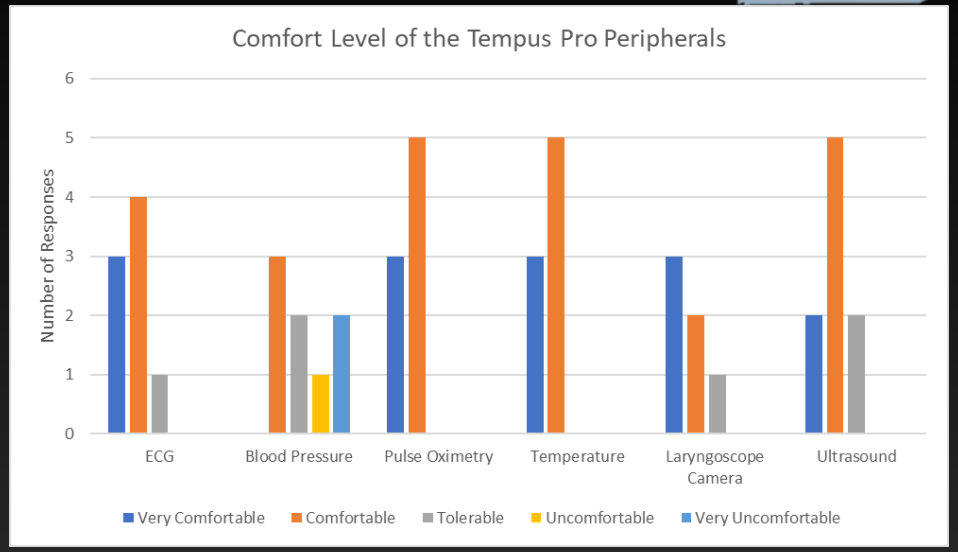
Rate your response to the following statements:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The layout of displays, controls, and menus was intuitive	○	○	○	●	○
The responsiveness of the buttons/commands was frustrating	○	○	○	●	○
The buttons/commands were easy to identify	○	●	○	○	○
It was difficult to navigate through the menus/ find the functions I was looking for	○	●	○	○	○
It was easy to communicate with console support about problems or questions I had operating the device	○	○	○	○	●

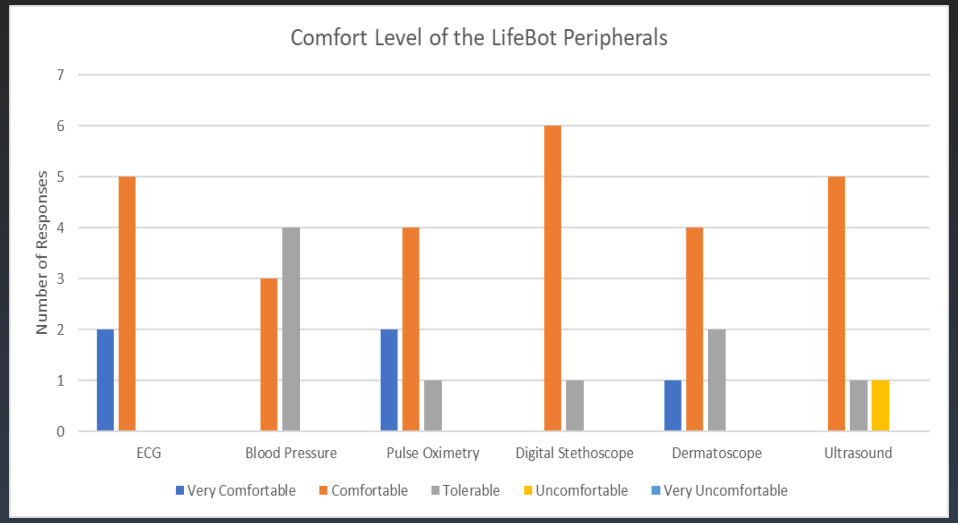
MIM Device Usability - Results

- Patients found the comfort level of the Tempus Pro™ and LifeBot® device peripherals acceptable, except for:
  - Excessive tightness of the blood pressure cuff during multiple measurement cycles
  - The coldness of the ultrasound gel and the pressure applied with the probe
- The caregivers found the devices and peripherals easy to use, although they felt uncertain about their ultrasound imaging performance
- The caregivers felt confident using the device and accomplished all test procedures, but felt additional familiarization with the devices, especially the LifeBot®, would have been beneficial

Tempus Pro™



LifeBot®



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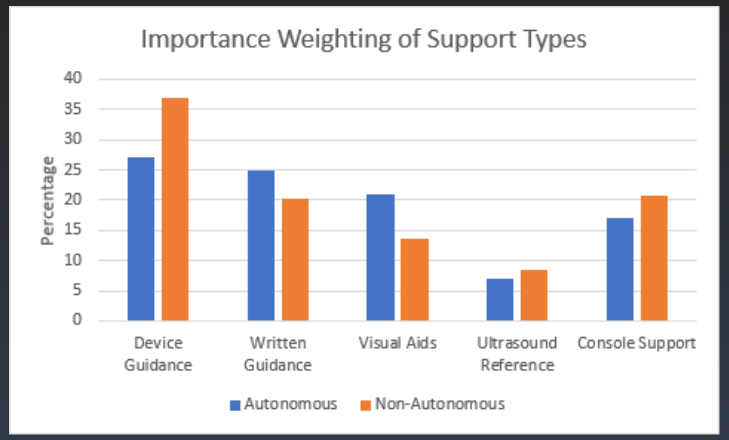
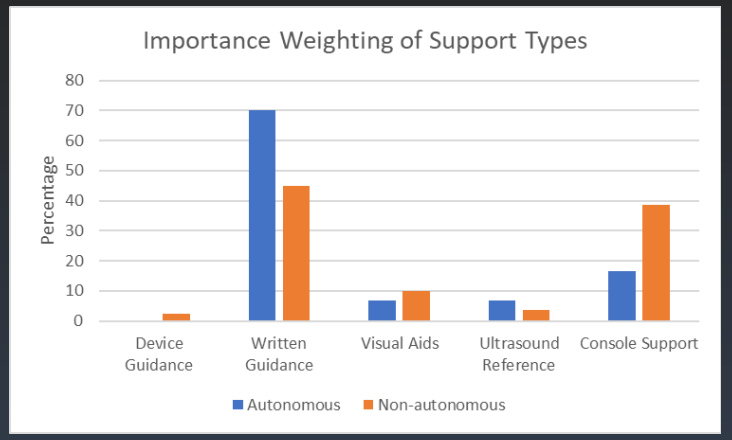
MIM Device Usability - Results

- Tempus Pro™ users relied heavily on device guidance; LifeBot® users relied on written guidance and did not use device guidance
- Autonomous Tempus Pro™ users who did not have pre-mission training did not rely heavily on device guidance
- Autonomous LifeBot® users relied most heavily on written guidance

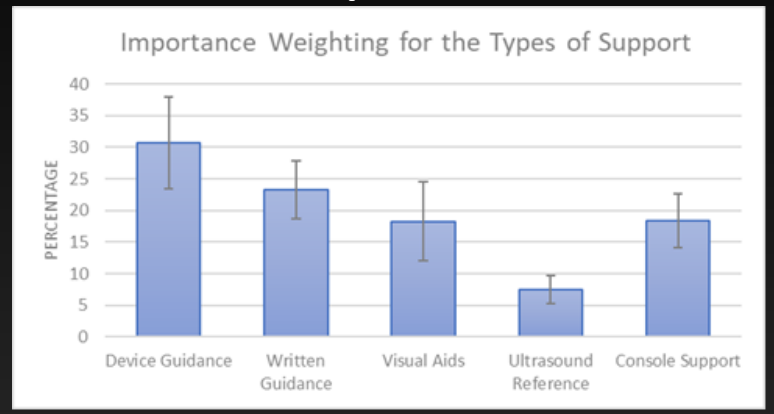
Tempus Pro™



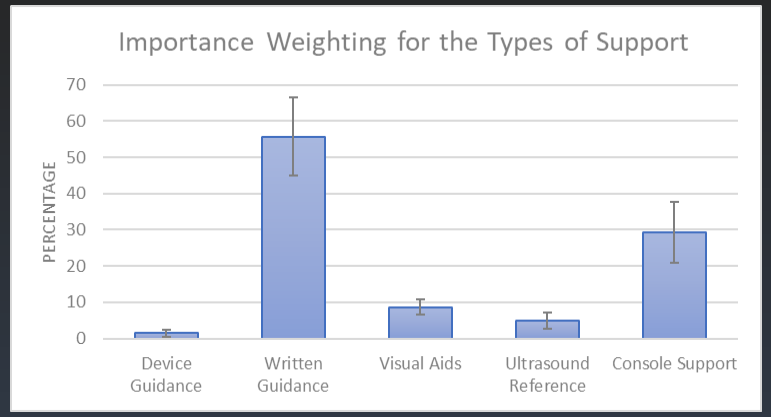
LifeBot®



Tempus Pro™



LifeBot®



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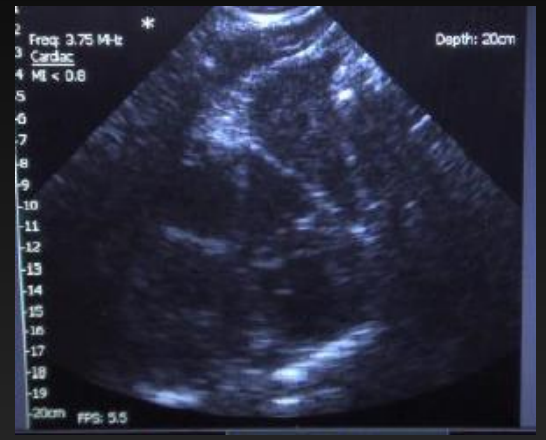
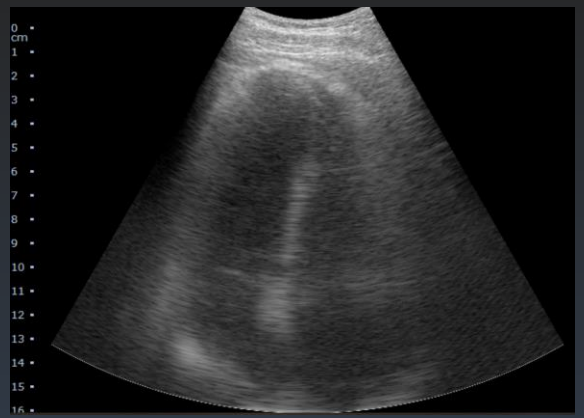
Clinical Effectiveness

- The participants within the EA chamber studies were not medically trained, except for one participant who was an Emergency Medical Technician. All participants had Basic Life Saving and First Aid certification.
- All participants were successful in performing the procedures and obtaining measurements with the MIM devices
- Participants were concerned about the quality of the ultrasound image that they captured and thought additional ultrasound training would have been beneficial
- Clinician “grading” of ultrasound images will be performed during ground studies
- Trained sonographers will also be asked to evaluate the ultrasound quality of the MIM devices

Tempus Pro™



LifeBot®



Survivability and Usability in Operational Environments

- Tempus Pro™ and LifeBot® performed nominally within the high oxygen/low pressure EA Chamber
- The MIM devices continued to provide accurate measurements after alternate atmosphere exposure, when tested against a BMET Pack Advanced Simulator (Pronk Technologies Inc., Sun Valley, CA) before and after chamber use
- The European Space Agency (ESA) is performing certification tests with the Tempus Pro™ in preparation for ISS demonstrations
- NASA Glenn Research Center and ZIN Technologies are performing certification tests with the LifeBot® in preparation for ISS demonstrations
- The ISS demonstrations will explore MIM device use within the microgravity environment

Conclusions - MIM Device Compatibility with Earth-Independent Medical Operations (EIMO) Systems

- Key features of an EIMO System include:
  - Technologies that support the prevention, diagnosis, treatment and rehabilitation of spaceflight medical events
  - System components that meet mass, volume, power and crew time/training constraints
  - Considers the medical skill level of the astronaut caregiver
  - Collects, stores and analyzes medical data within a central data architecture
  - Incorporates appropriate guidance and support tools to allow crew autonomy
- Evidence collected to date supporting the inclusion of MIM devices within EIMO Systems:
  - The MIM devices have a small footprint and contain a lot of capability
  - The MIM devices do include many of the capabilities that are required for Lunar and Martian medical systems, but also include some non-required capabilities
  - It may be beneficial to design a custom made MIM device for spaceflight medical systems only containing required capabilities

Conclusions - MIM Device Compatibility with Earth-Independent Medical Operations (EIMO) Systems

- Evidence collected to date supporting the inclusion of MIM devices within EIMO Systems (Continued):
  - Non-medically trained caregivers found the MIM devices easy to use and were able to successfully complete vital sign measurement and imaging procedures, however, more ultrasound guidance was desired
  - Built-in device guidance within the Tempus Pro™ (iAssist) was heavily leveraged during the demonstrations, the LifeBot® device guidance was not significantly leveraged
  - Tempus Pro™ and LifeBot® have different data integration capabilities with a central data architecture, such as a Crew Health and Performance Integrated Data Architecture (CHP-IDA)
  - LifeBot® may be better suited for data integration than Tempus Pro™
  - The MIM devices have desirable capabilities, but will need to be incorporated with additional procedural guidance, decision support and data analysis capabilities

Thank you!

Questions?

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