

# **An Introduction to AI-Guided Image Acquisition**

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# Outline

- Advantages of Ultrasound imaging
- Challenges associated with Ultrasound image acquisition
- How AI can assist with image acquisition
- Portable point-of-care Ultrasound systems
- Future Direction

# Advantages of Ultrasound Imaging

No ionizing radiation

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Low cost and widely accessible

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Portability

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Real-time imaging/ Real-time feedback

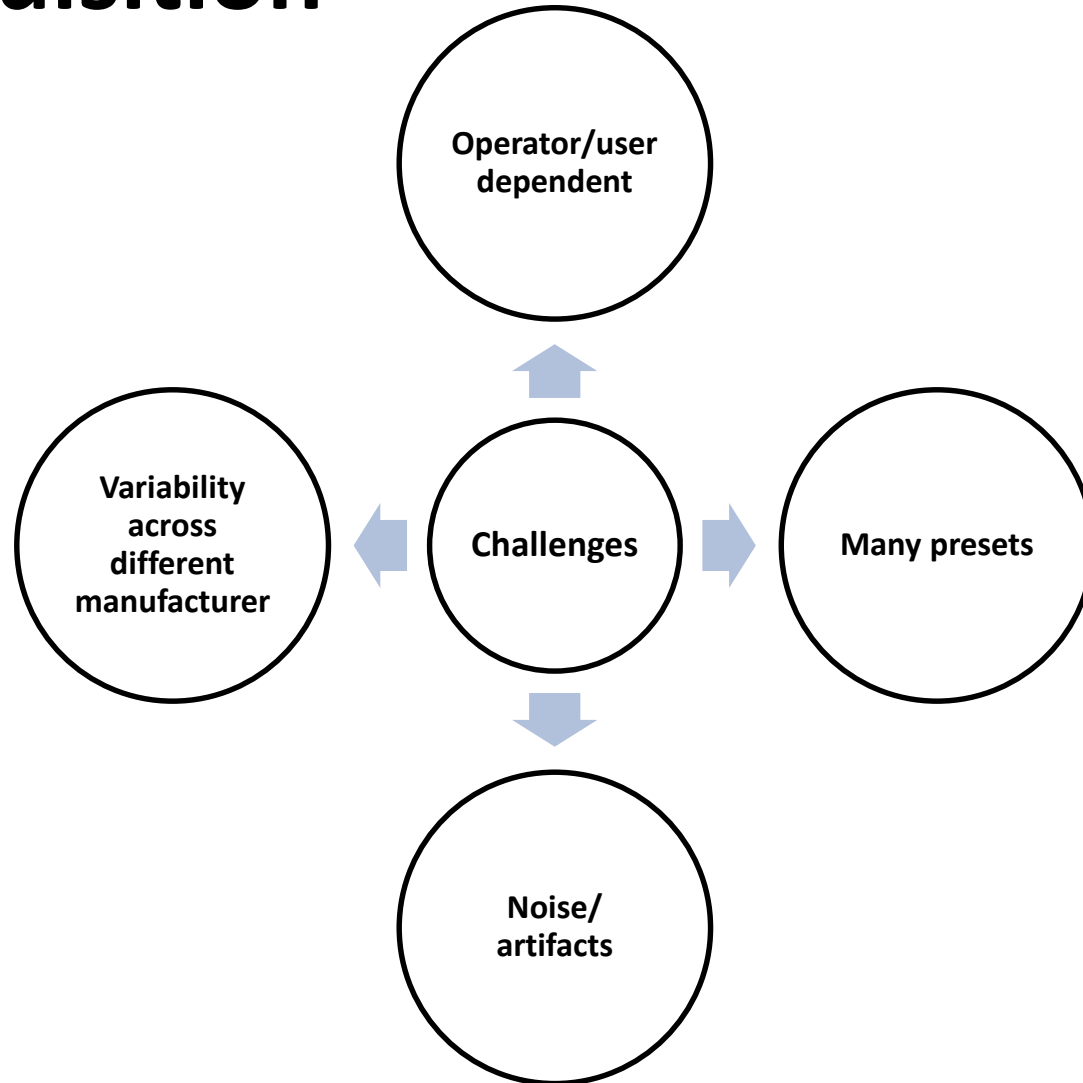
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Variety of clinical applications

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Ultrasound could be an attractive modality for AI/ML space both for image acquisition and post processing.

# Challenges linked with ultrasound image acquisition



# AI-guided Image Acquisition



What could be the benefits:

Reproducibility

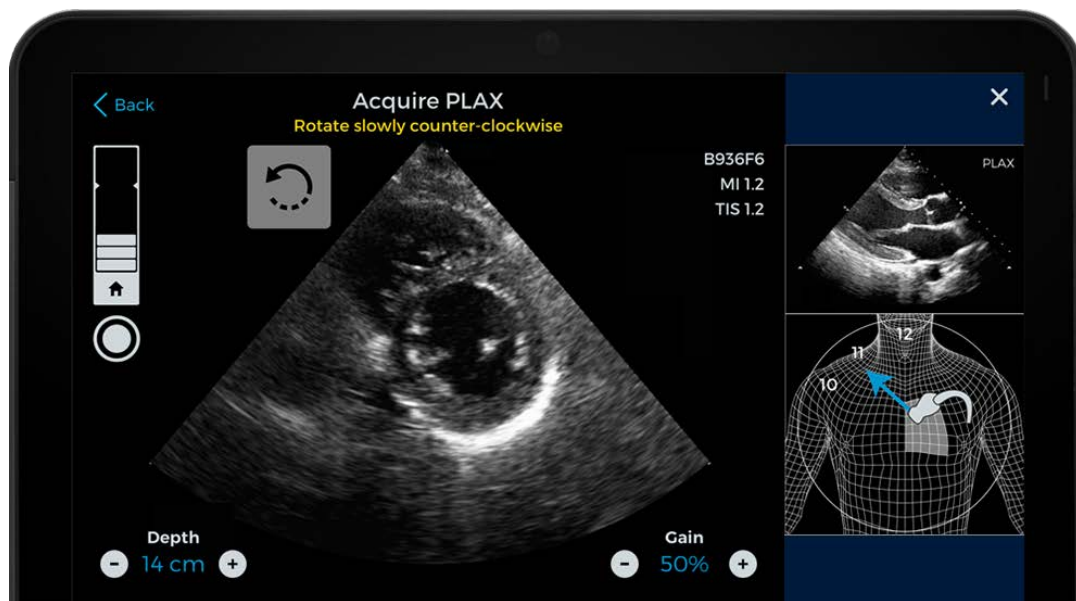
Standardized procedures

Improve efficiency and reliability

Clinical AI applications may assist the acquisition of standardized images independent of the operator, guiding both sonographers and non-experts in sonography, potentially including lay users, to acquire images with equivalent diagnostic quality.

# AI-guided Image Acquisition

Recently the FDA authorized marketing of software to assist medical professionals in the acquisition of cardiac ultrasound, or echocardiography, images.



<https://captionhealth.com/>

Other AI-guided/ less automated examples which assist with image acquisition and optimization

- auto focus, auto depth, auto EF, etc.


# Challenges with AI-guided image acquisition

**Device error** - Failure to provide guidance on acquiring diagnostic-quality images or signals

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**User error** - Operator failure to follow the guidance provided by the device to acquire diagnostic-quality images or signals

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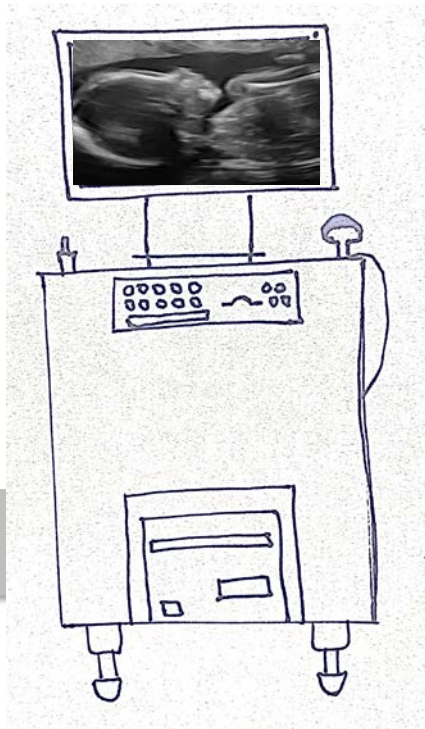
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Errors could lead to delay, prolonged examination, or additional unnecessary procedures, due to algorithm failure.



# Point-of-care Ultrasound

Evolution of mobile computing technology along with advancement of US systems into more portable devices



1980s

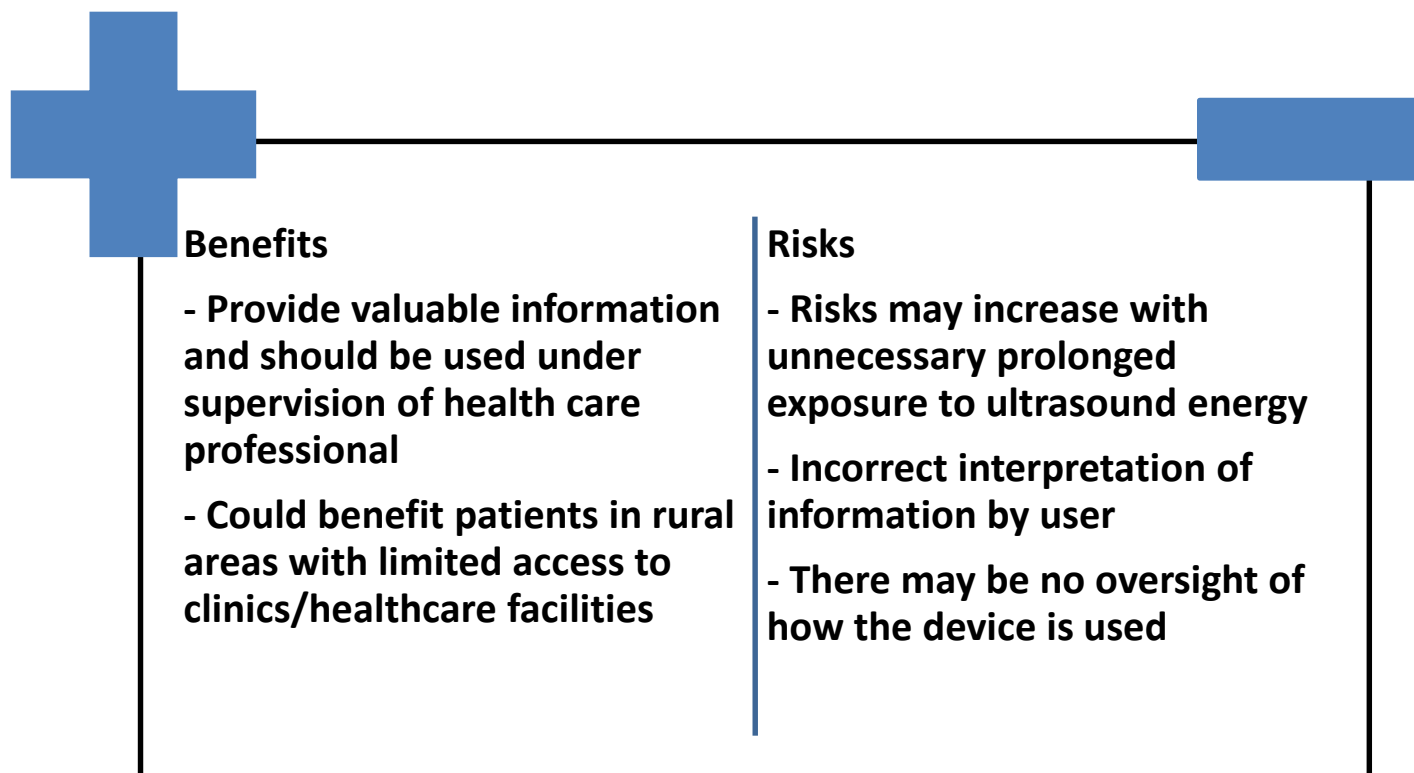


Present

# Future Direction

Advantages of ultrasound imaging makes it an attractive modality for **in-home** monitoring tool with real-time feedback

- Safety and effectiveness should match the professional use environment





# Pre-Submissions to FDA

- Requesting feedback regarding potential or planned medical device applications
- Example questions could include:
  - Appropriate regulatory pathway for a specific intended use
  - Feedback on whether a proposed set of performance testing would be sufficient to support the intended use
  - Feedback on whether a proposed set of performance testing and labeling addresses any applicable special controls
- FDA Guidance Document: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff, dated May 7, 2019 <https://www.fda.gov/media/114034/download>

# Summary

- Through this workshop, FDA is seeking to engage with stakeholders to explore benefits and risks of evolving applications of AI in radiology.
- As the benefit-risk profile changes, it is critical to adapt the methods used to evaluate and characterize their performance.
- In this workshop, FDA is also seeking innovative and consistent ways to leverage existing methods and to develop new methods for validation of these AI-based algorithms and explore opportunities for stakeholder collaboration in these efforts.

