

Regulatory Considerations: AI-Guided Image Acquisition and Optimization

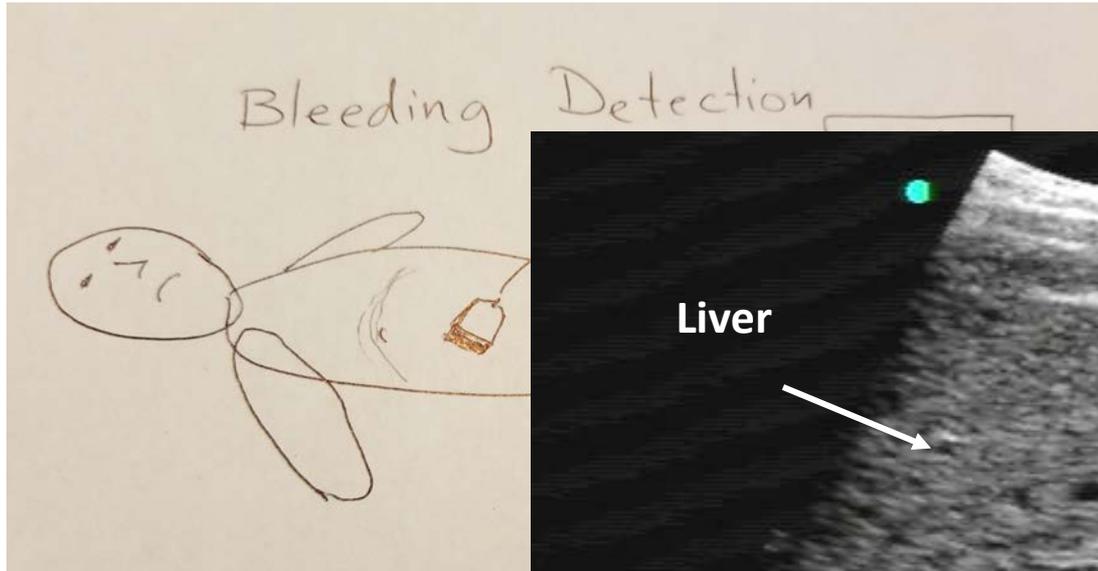
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Outline

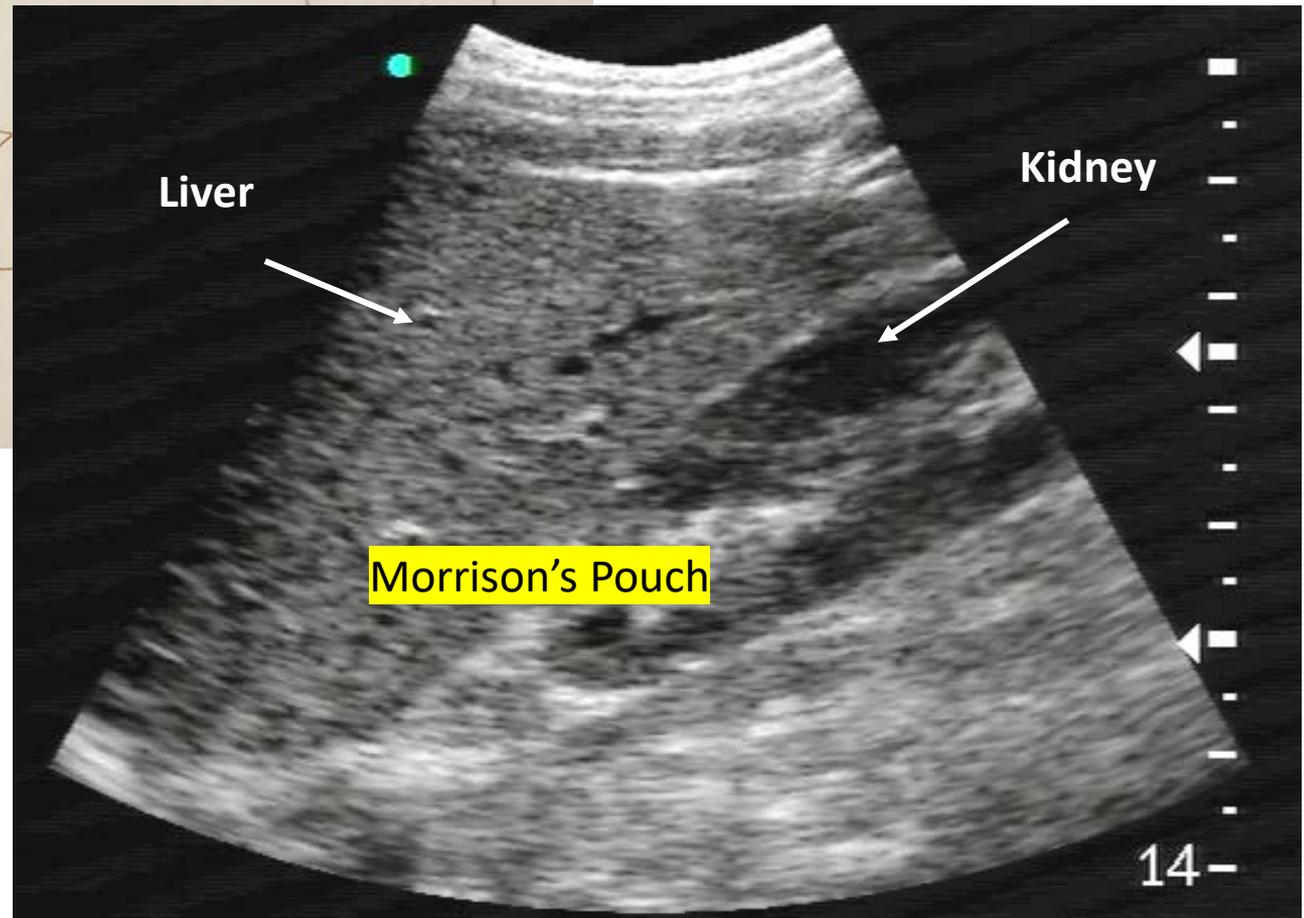


- AI-guided image acquisition and optimization:
 - Current regulatory status
 - Benefit/risk analysis
 - General and special controls
 - Device modifications
- Future Directions
- Key elements of regulatory success

AI-Guided Image Acquisition/Optimization



An Example:
Detection of internal
bleeding using
ultrasound imaging



AI-Guided Acquisition/Optimization



- FDA authorized the first AI-guided image acquisition system “Caption Guidance”, on February 7, 2020, via granting a De Novo request for classification as “Radiological acquisition and/or optimization guidance system.”
 - Special controls were developed for risk-mitigation to enable Class II – 510(k) regulatory pathway the device type.

Regulation

21 CFR 892.2100: Radiological acquisition and/or optimization guidance system

- A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.
 - Class II, Non-Exempt, 510(k) required
 - Prescription use, not over-the-counter
 - Images/signals interpreted/read by a qualified healthcare professional

Benefit/Risk Assessment



- Summary of the benefits
 - Improved access to clinical care: location and time
 - Improved performance
 - Patient convenience: location and time
- Summary of the risks
 - Low image/signal quality
 - Delayed clinical care
- Other factors
 - Clinical care gaps
- Patient perspective
 - How does the device impact the balance of risks and benefits, and what level of uncertainty could be expected.

Risk Assessment

The risks of the device and the associated mitigation methods should be considered.

Identified Risks to Health	Mitigation Measures
<p>Device Error – Failure to provide guidance on acquiring diagnostic-quality images or signals, leading to delay, prolonged examination, or additional unnecessary procedures, due to:</p> <ul style="list-style-type: none"> • Algorithm failure • Hardware or software failure 	<ul style="list-style-type: none"> • Design verification and validation • Labeling
<p>User Error – Operator failure to follow the guidance provided by the device to acquire diagnostic-quality images or signals, leading to delay, prolonged examination, or additional unnecessary procedures, due to human error</p>	<ul style="list-style-type: none"> • Design verification and validation • Labeling

General and Special Controls



- The general controls apply to all medical devices, unless exempted by regulation.
 - Examples: electrical safety, biocompatibility, labeling
- The special controls apply to specific types of devices
 - for which general controls are not sufficient to provide a reasonable assurance of safety and effectiveness
 - sufficient information is available to establish special controls for risk mitigation.
 - Examples: Performance testing relevant to the devices in the regulation, labeling

Special Controls - 1



1. Design verification and validation
 - Detailed device description
 - Detailed report on non-clinical performance testing
 - Detailed report on clinical performance testing
 - A thorough description of the testing protocol(s).
 - A thorough, quantitative evaluation of the diagnostic utility and quality of images/data acquired, or optimized, using the device.
 - A thorough, quantitative evaluation of the performance in a representative user population and patient population, under anticipated conditions and environments of use.
 - A thorough discussion on the generalizability of the clinical performance testing results.
 - A thorough discussion on use-related risk analysis/human factors.
 - Documentation of an effective training program
 - Detailed protocol for possible changes in the future

Special Controls - 2



2. Labeling

- A detailed description of the device, including information on all required and/or compatible parts.
- A detailed description of the patient population for which the device is indicated for use.
- A detailed description of the intended user population, and the recommended user training.
- Detailed instructions for use, including the information provided in the training program used to meet the requirements of paragraph (1)(e).
- A warning that the images and data acquired using the device are to be interpreted only by qualified medical professionals.
- A detailed summary of the reports required under paragraphs 1(b) and 1(c).
- A statement on upholding the As Low As Reasonably Achievable (ALARA) principle with a discussion on the associated device controls/options.

Possible Device Modifications



- A detailed protocol that describes, in the event of a future change, the level of change in the device technical specifications or indications for use at which the change or changes could significantly affect the safety or effectiveness of the device and the risks posed by these changes. The assessment metrics, acceptance criteria, and analytical methods used for the performance testing of changes that are within the scope of the protocol must be included.
- This was primarily based on the FDA White Paper: **Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback** <https://www.fda.gov/media/122535/download>
 - Applicable to devices with both locked and unlocked software

Future Considerations

- AI-guided image/signal acquisition and/or optimization
 - Most likely applicable to only ultrasound technology
 - Could include other indications for use / clinical application
 - Could include other users – Patients, home use
 - Could include other technological features – Measurements and analyses
- Performance testing must be specific to the device characteristics in terms of technology, clinical application/indications for use, and the user population.

Keys to a Successful Regulatory Pathway



- Early interaction with the FDA: Q-Submission program
 - Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program
<https://www.fda.gov/media/114034/download>
- Well-defined device characteristics
- Well-defined intended use
- Well-defined performance testing plans

THANK YOU FOR YOUR PARTICIPATION!

