



GE HealthCare

# Fostering Innovation in Medtech: Cross-Functional Collaboration for Advanced Imaging Solutions

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# A leading global medtech, diagnostic and digital solutions innovator



**\$19.7B**

2024 Annual Revenue



**4M+**

Installed base



**1B+**

Patients served annually



**>\$1B**

Annual R&D & product investment spend



**18.3K**

Customer-facing colleagues



**100**

AI-enabled device authorizations in U.S., top of recent FDA list<sup>(1)</sup>

Notes: Figures as of 2025 unless otherwise noted

<sup>1</sup>U.S. Food and Drug Administration. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. May 31, 2025

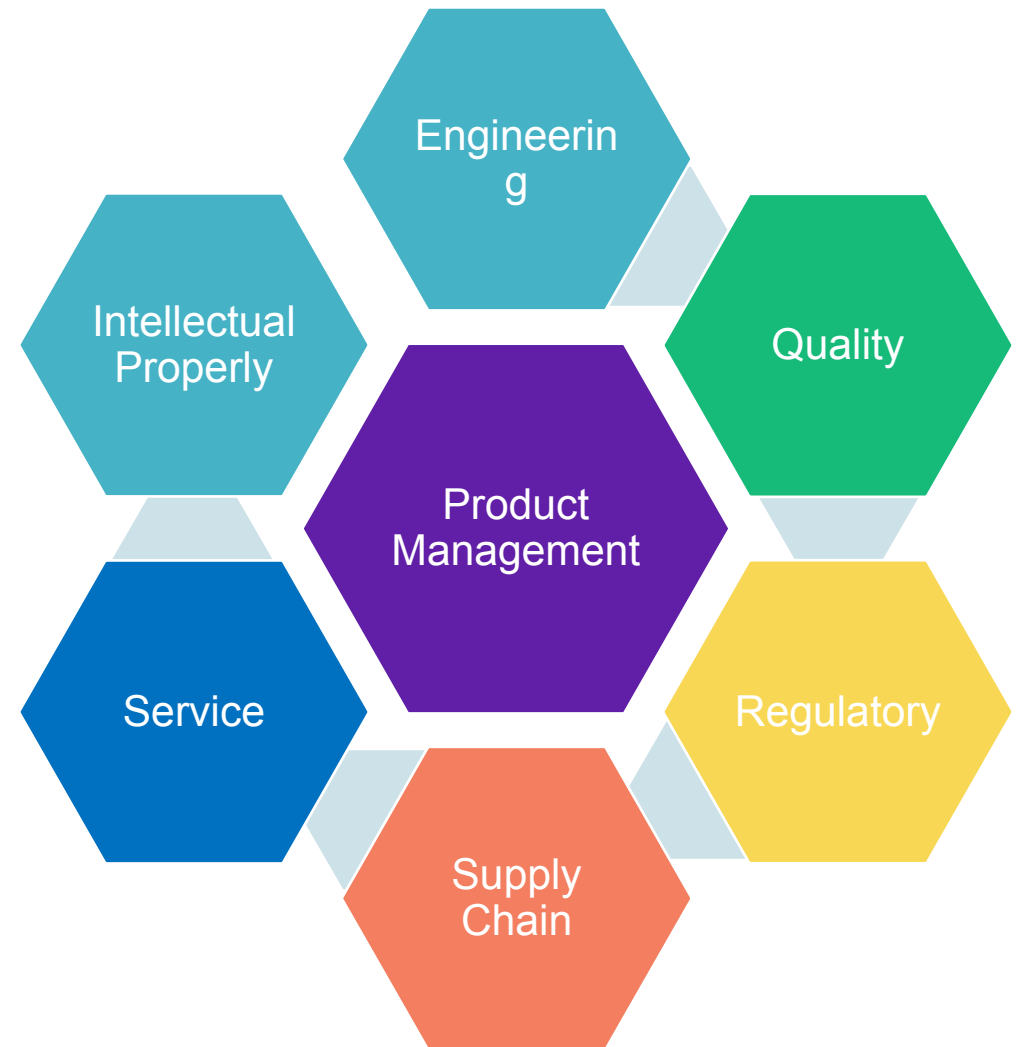
Available at: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

# The Power of Cross-Functional Teams

Enhanced Creativity and Innovation  
Improved Problem Solving  
Increased Flexibility  
Faster Decision-Making  
Better Communication  
Higher Employee Engagement



Deliver products and solutions on time that are safe, compliant and delightful to customers



“Innovation is not a solo act—it’s a team sport played across disciplines.”  
- Professor Linda A. Hill of the Harvard Business School

# Fueling Innovation via Cross-Functional Teams in Medical Devices

## Design and Development

- Clinical Experts
- Systems Engineers
- UX Designers
- Mechanical Engineers
- Data Scientists
- Software Engineers
- Project Managers
- System Designers
- Usability Engineers
- Reliability Engineers
- Risk Management Specialists
- Verification & Validation experts
- Cyber Security Experts
- ..

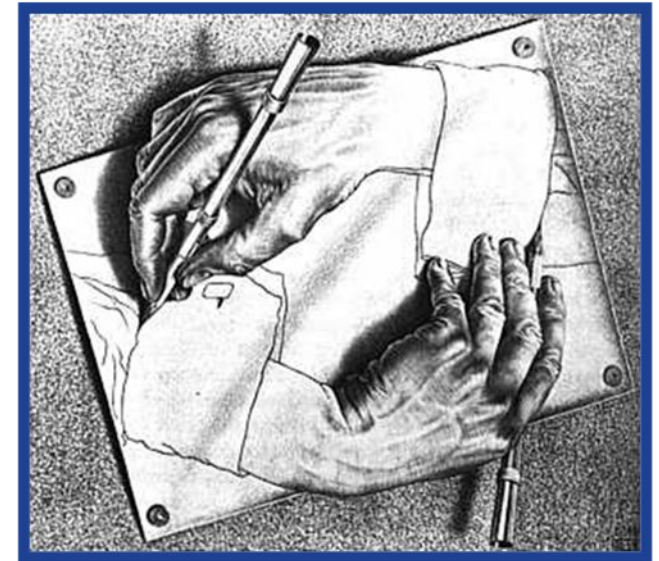
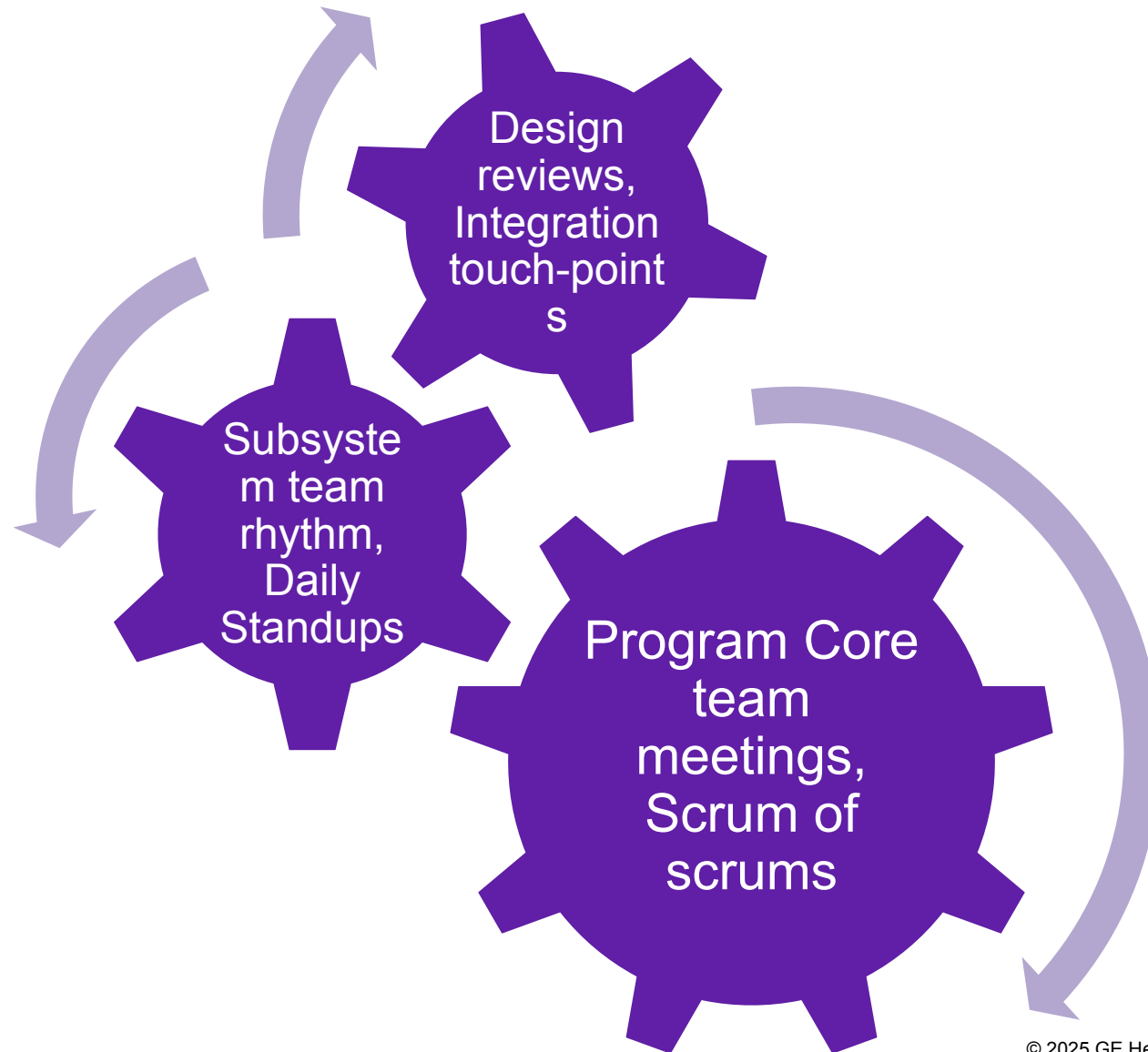
## Quality and Regulatory

- Quality Affairs Specialists
- Regulatory Affairs Specialists
- Documentation Specialists
- Cyber Security
- Intellectual Property Specialists
- Supplier Quality Engineer
- Design Quality Engineer
- Manufacturing Quality Engineer
- Labeling and Compliance Specialist
- Post-Market Surveillance Specialist
- ...

## Supply Chain, Sales & Service

- Manufacturing Engineers
- Manufacturing Test Specialists
- Sourcing Specialists
- Quality Control Engineers
- Packaging Engineers
- Service Designers
- Service Project Managers
- Online Engineers
- Field Engineers
- Installation engineers
- ...

# Driving Innovation via Smarter Operations



# Obstacles to Effective Cross-Functional Teamwork



# Key Strategies for Leading Collaborative Teams



Great products are built by great teams working together with clarity, empathy, and purpose.

# Innovation case studies



D3 framework:  
 Smart devices,  
 disease-state focus,  
 and digital solutions



Deliver  
 precision care



# Smart Devices

Make smart devices  
**smarter, improve guidance,  
and speed**

# How can we acquire better images for every patient?

## Cardiac MRI

Lying still for 30–90 minutes.

Requires holding breath

Challenging for patients due to  
**age, pathology, other conditions**



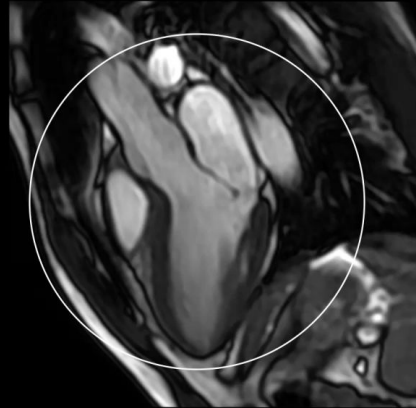


# Sonic DL™

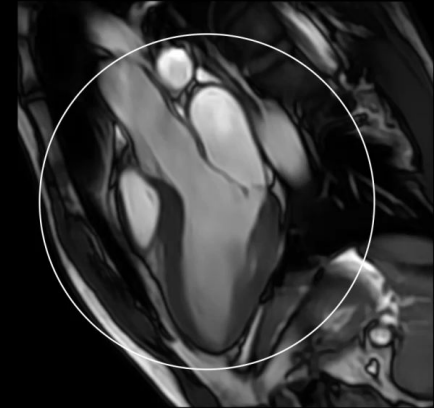
for cardiac MRI

**Scan times go  
from minutes to  
seconds**  
reducing motion blur and  
the need for rescans.

Conventional



Sonic DL™



# How do we prioritize the right exams?

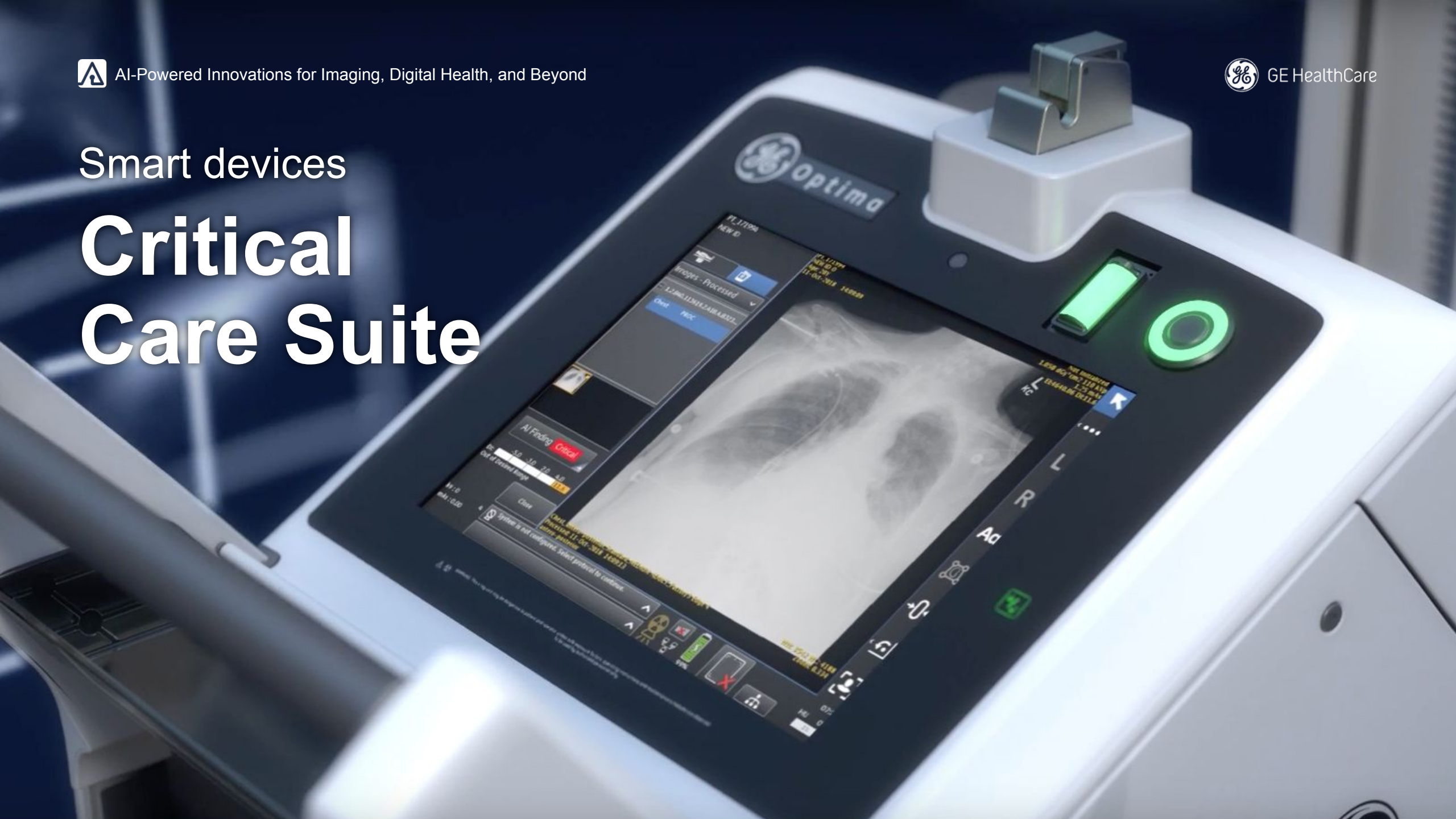
Review can take **eight hours**

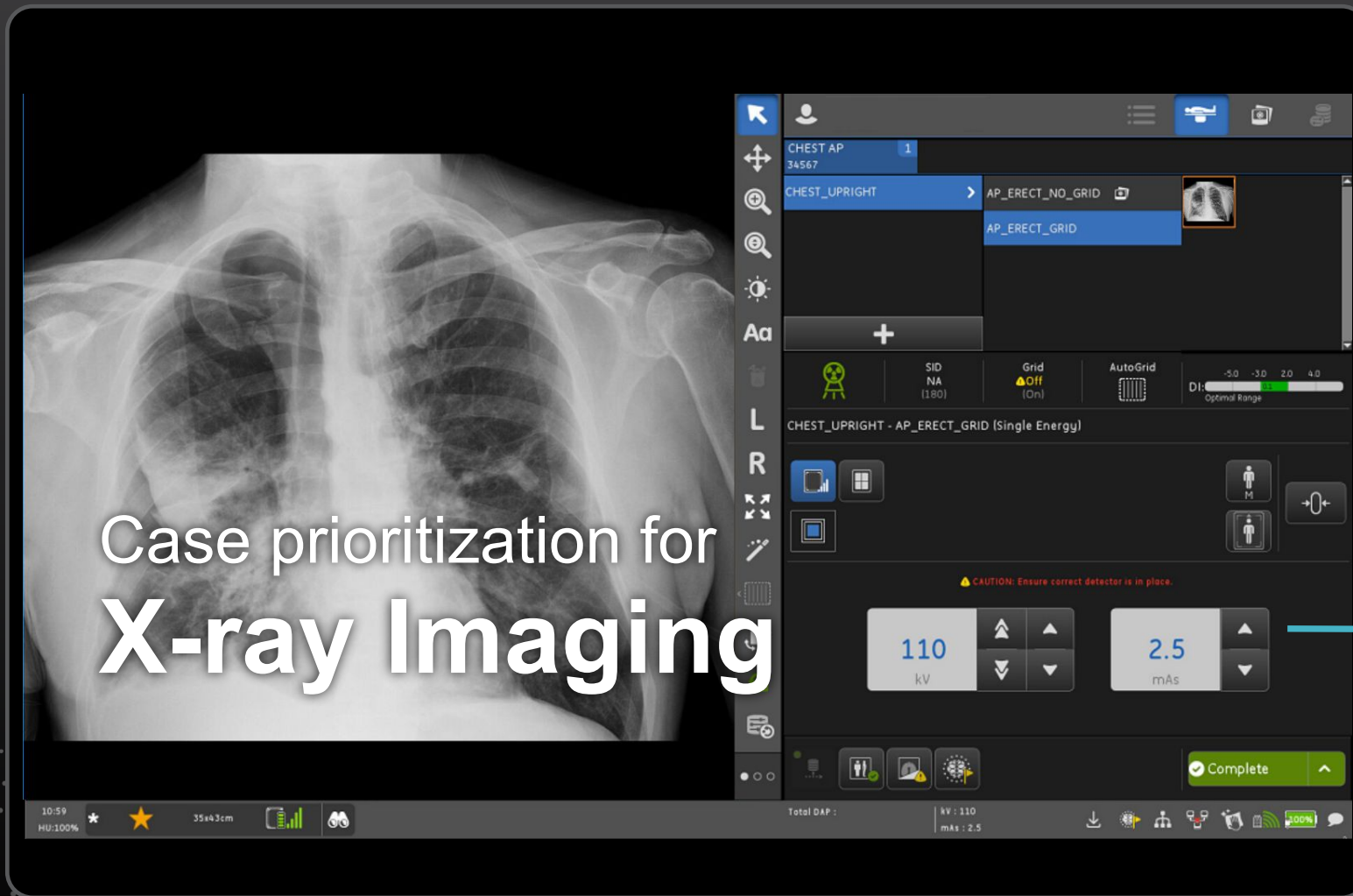
**Every minute matters** in life-threatening  
situations such as **Pneumothorax**



Smart devices

# Critical Care Suite





CHEST AP  
34567

CHEST\_UPRIGHT > AP\_ERECT\_NO\_GRID  
AP\_ERECT\_GRID

SID NA (180) Grid Off (On) AutoGrid DI: -5.0 -3.0 2.0 4.0 Optimal Range

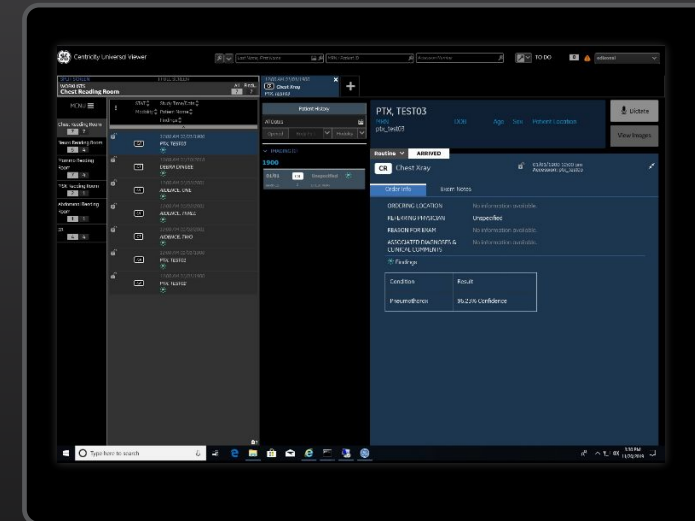
CHEST\_UPRIGHT - AP\_ERECT\_GRID (Single Energy)

110 kV 2.5 mAs

Complete

Total DAP: kV: 110 mAs: 2.5

# Case prioritization for X-ray Imaging



PTX, TEST03

APERTURE

CONDITION

Result: ABNORM

CONDITION

Condition	Result
Pneumothorax	32.2% Confidence

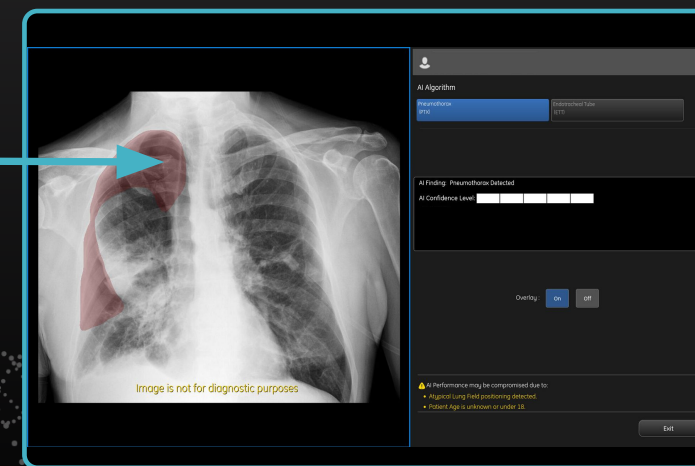


Image is not for diagnostic purposes

AI Algorithm

Pneumothorax

AI Finding: Pneumothorax Detected

AI Confidence Level

Overlay: on off

Performance may be compromised due to:  
- Algorithm used for screening purposes  
- Patient Age is unknown or under 18

How do we  
**expand access to care?**



## Dr. Keigo Yasukawa The Jet Ski Doctor



**8** Islands make up  
The Miyakojima chain

**20+** Miles via  
jet ski

**1** Island not  
reachable by car

**Expanding  
access to care**



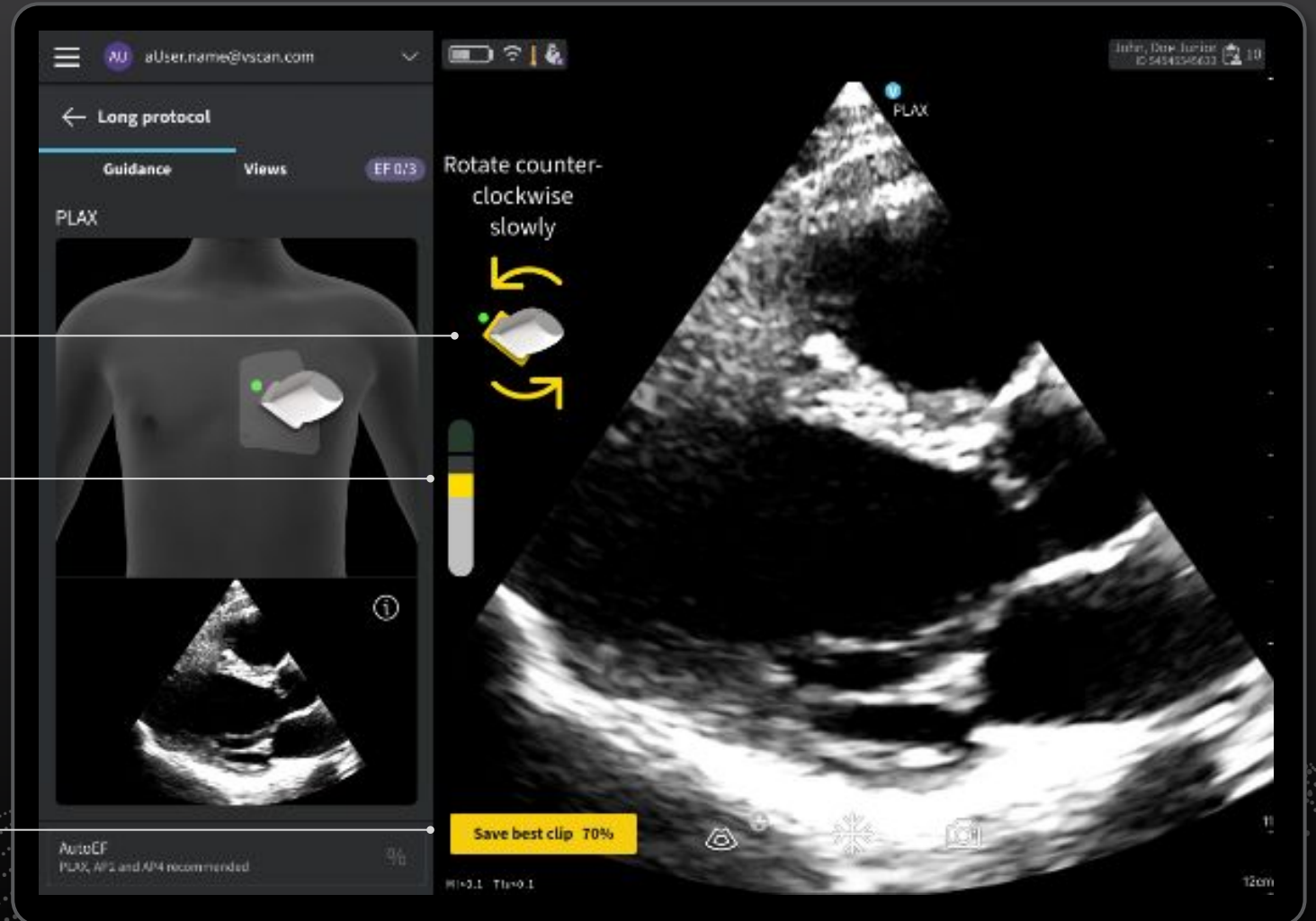
# Smart devices Vscan Air™ SL with Caption AI

TM

Real-time  
guidance

Quality meter

Save best  
clip



# Q&A

*(I will be around after the session for more Q & A)*



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# Enhancing product design for quality, reliability & rapid delivery

## Quality Design

- **User Needs & Requirements:** Align Clinical, Operational and regulatory needs.
- **Design Controls:** Follow FDA/ISO guidelines throughout development.
- **Human Factors Engineering:** Ensure usability and safety.
- **Material Selection:** Use durable, biocompatible materials

## Ensuring Reliability

- **Risk Management:** Apply ISO 14971 and FMEA for risk mitigation.
- **Redundancy & Fail-Safes:** Build in system redundancy and fail-safe mechanisms.
- **Robust Testing:** Verify and validate under diverse conditions and user loads
- **Component Reliability:** Use high-quality, trusted components.

## Rapid Delivery

- **Modular Design:** Enable flexibility and faster iterations.
- **Design for Manufacturability (DFM):** Simplify production to reduce time and costs.
- **Rapid Prototyping:** Use 3D printing for quick testing and iteration.
- **Agile Development:** Apply agile frameworks like SAFe

# Software strategies for advanced imaging technology

## Imaging Expertise & Algorithm Optimization & AI

- Master core imaging modalities (MRI, CT, Ultrasound).
- Use high performance compute techniques such as parallel compute programming
- Implement separation of concerns
- Use machine learning techniques for enhanced analysis.

## Hardware Integration & Data Management

- Real-time processing with embedded systems (RTOS, GPUs).
- Ensure secure data handling (DICOM, encryption).
- Utilize efficient data storage and compression techniques.

## Agile Development & Regulatory Compliance

- Use agile development for rapid iterations and cross-team collaboration.
- Trunk based development to build across the portfolio
- Ensure compliance with FDA, IEC 62304, and ISO 14971.

# Enhancing software design for quality, reliability & rapid delivery

## Ensuring Quality

- **Structured SDLC:** Follow a well-defined software development lifecycle (SDLC) for traceability.
- **Regulatory Compliance:** Adhere to IEC 62304 and FDA guidelines, with risk management per ISO 14971.
- **User Experience Design:** Invest in Design Research, Visual Design, Interaction Design, Human Factors engineering.

## Achieving Reliability

- **Robust Architecture:** Use modular or layered design with Real-Time Operating Systems (RTOS) for stability.
- **Risk Management & Safety:** Implement FMEA, fail-safes, and alarm management for error recovery.
- **Comprehensive Testing:** Perform unit, integration, system, and automated testing. Focus on cybersecurity (encryption, access control) to protect data.

## Support Rapid Delivery

- **Agile Development:** Use agile practices for fast iterations and frequent feedback.
- **Rapid Prototyping & Reusability:** Leverage prototypes and build modular, reusable code.
- **Automated Testing & CI/CD:** Employ continuous integration/delivery pipelines and automated testing for faster releases.

# Critical Care Suite 2.1

Critical Care Suite is a collection of on-device AI algorithms for automated measurements, case prioritization, and quality control



## **Pneumothorax (PTX) detection and triage<sup>1</sup>**

provides an immediate notification for the presence or absence of PTX, along with a graphical representation of the AI algorithm's confidence level in detection. Additionally, an overlay helps localize a detected PTX.



## **Endotracheal tube (ETT) positioning<sup>2</sup>**

automatically detects ETT in chest images, enabling an on-device AI viewer and immediate access to AI-derived measurements in PACS worklist. Displays AI-generated measurements with an image overlay in PACS.

1. GE HealthCare 510(k) K223491. Not commercially available in all markets. Check with your local GE HealthCare representative for availability in your country.

2. GE HealthCare 510(k) K211161.

