Safety First: How we test Medical Embedded Systems

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Quadigi by Draeger

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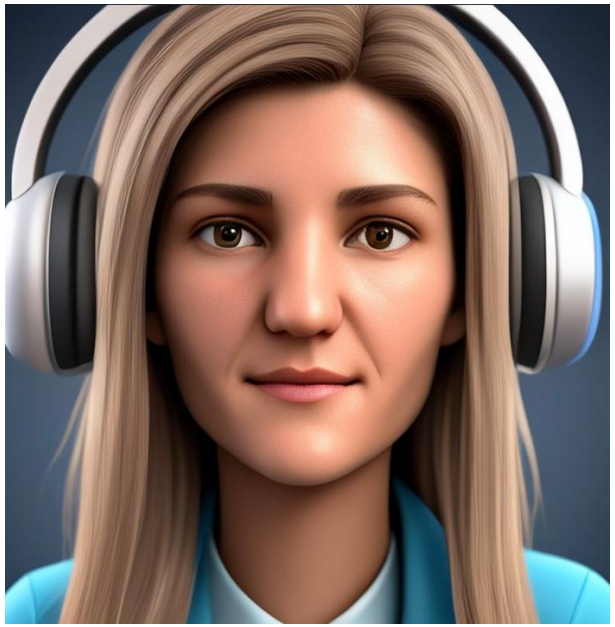
About me



https://www.linkedin.com/in/laura-audinyte/

Draeger products overview

Firefighter equipment
Personal protection equipment
Respiratory protective equipment
Gas detectors
Alcotests
Drug testing kits
Anesthesia devices
Lung ventilators
Neonatal incubators
Patient monitoring systems
and many more..

Question for the audience

How is beer related to Draeger company?

Patient Monitoring Systems

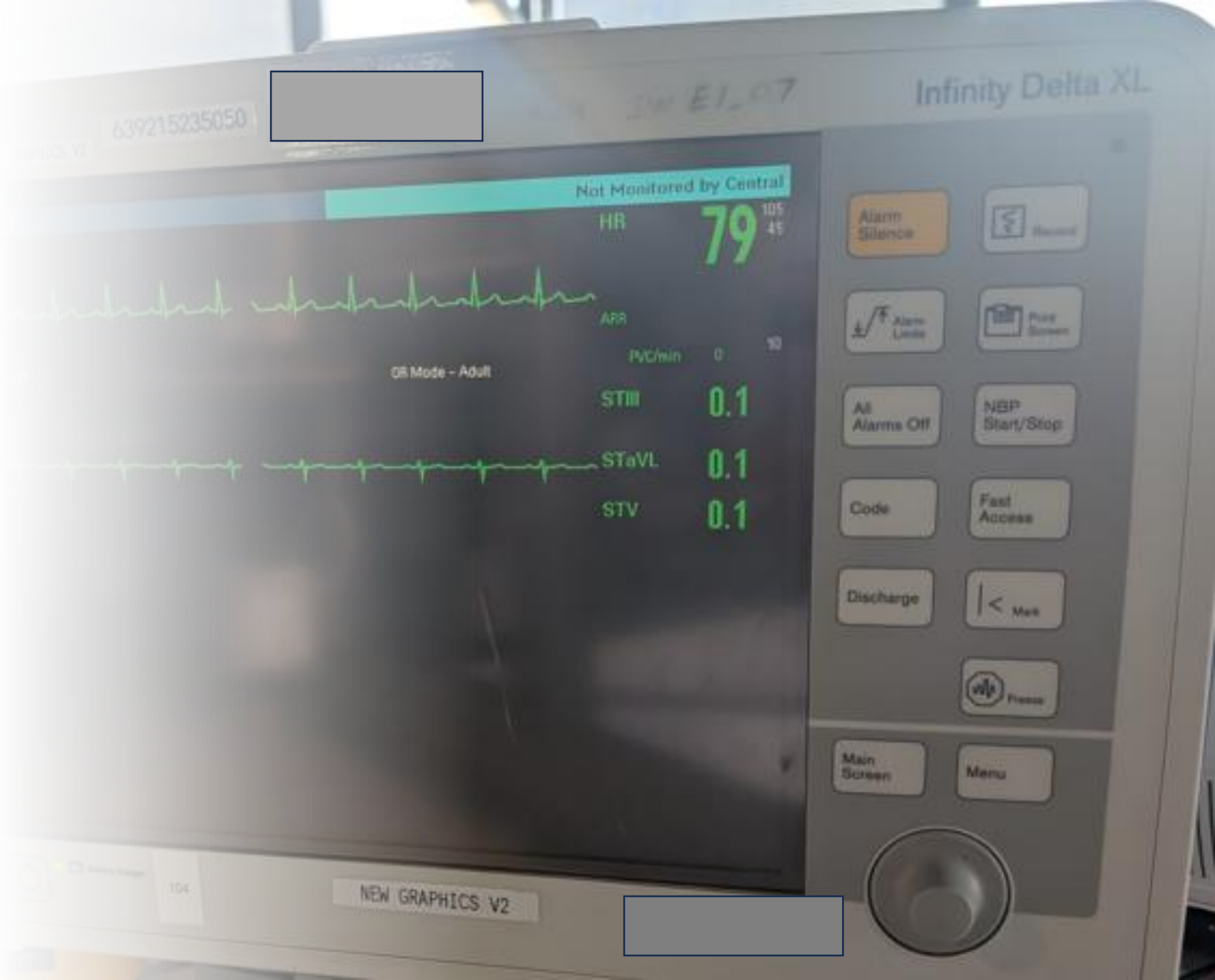
Infinity Acute Care System (IACS)

Infinity M540 (M540SA)

Infinity M300

Infinity Central Station (ICS)

Infinity Delta Series



What does “Safety” mean in Medical Devices?

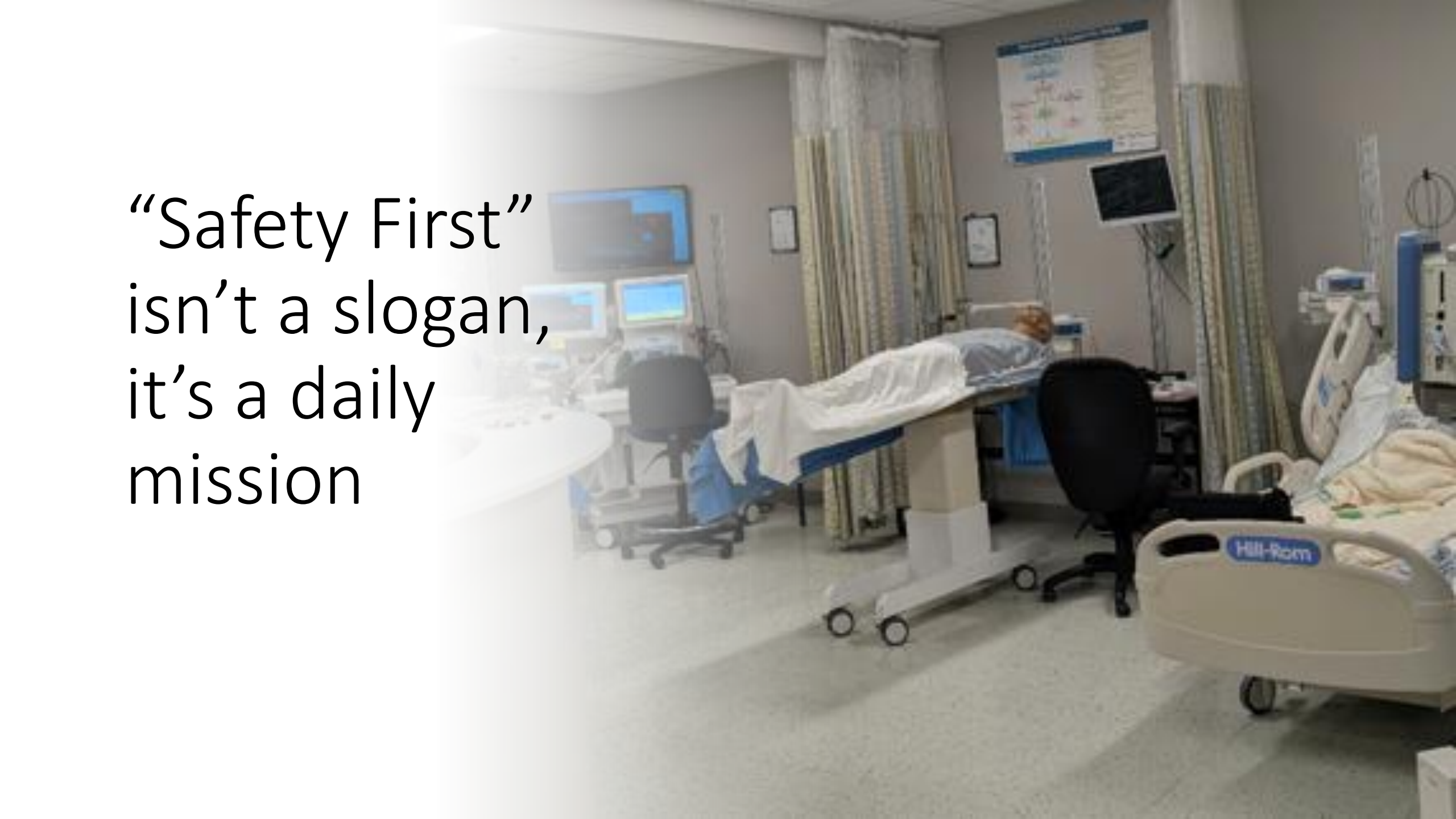
In medical technology, **safety** means ensuring a device will not harm the patient, clinician, or environment—even under failure or misuse.

Medical embedded systems (monitors, ventilators, infusion pumps) are **directly responsible for patient lives**. A single malfunction can have catastrophic consequences.

Core Dimensions of Safety

- Patient protection
- Risk management
- Performance under all conditions
- Biocompatibility and Material Safety
- Electrical and Cybersecurity Safety
- Usability and Human Factors
- Regulatory Context

“Safety First” isn’t a slogan, it’s a daily mission



TUV and FDA requirements shape our testing approach

Technical Inspection Association

Food and Drug Administration

Why are medical embedded systems challenging to test?

- Half-day setup reality
- Patient simulator configuration and calibration
- Network topology and system integration setup
- Environment validation before testing begins
- Strict regulatory requirement: FDA, TUV
- Version compatibility matrix across devices

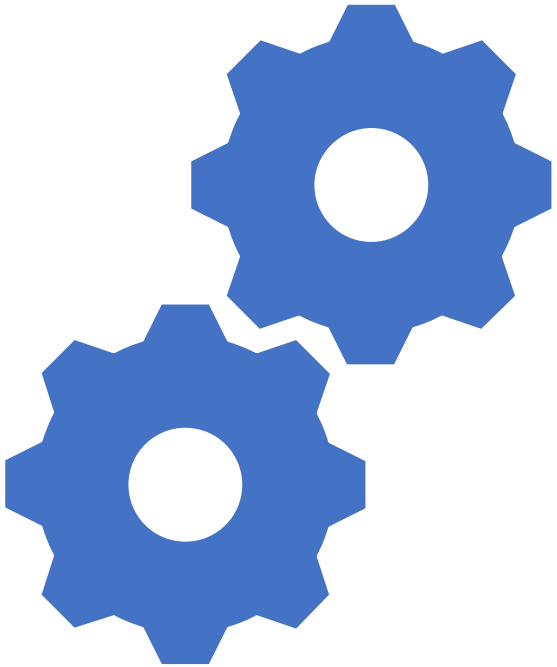
Setup for testing

Time zone

From hundreds to thousands tests before release

Equipment table

Traveling to US



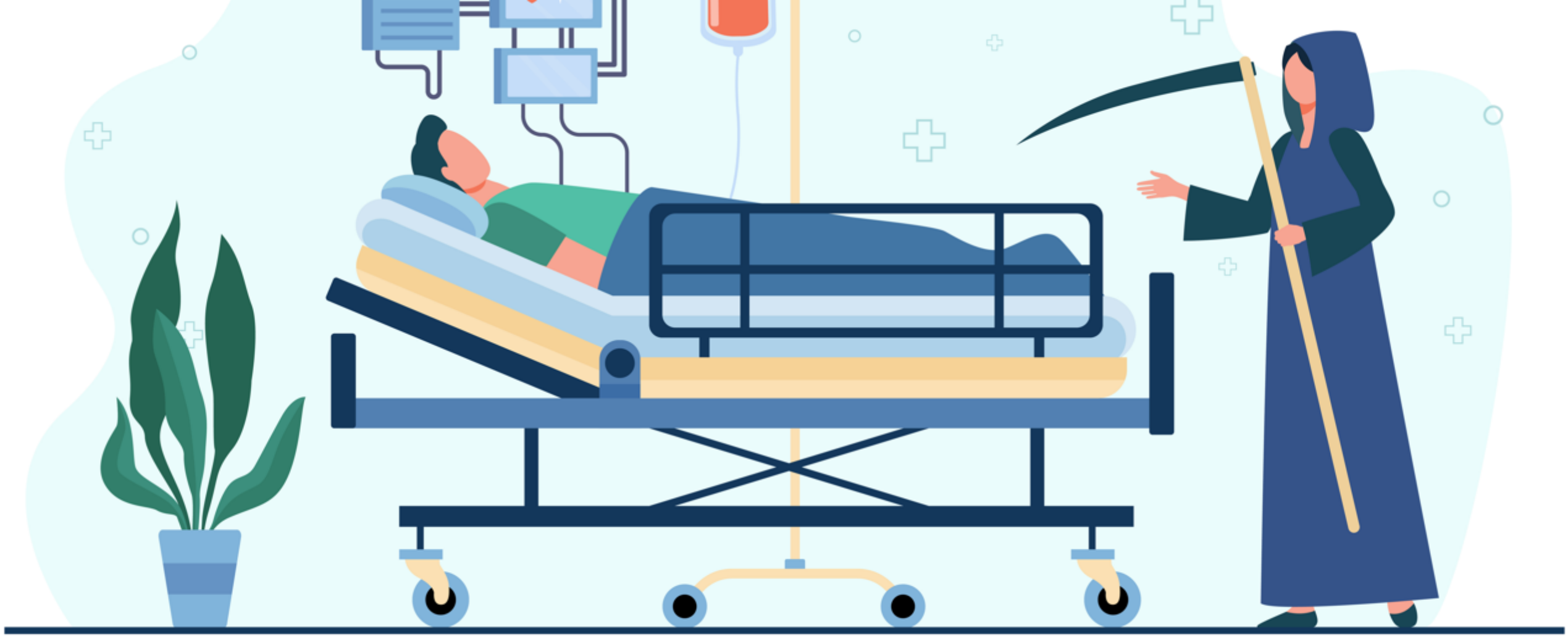
Lots of different simulators, accessories

Some other challenges

Accessories

Simulating Vital Signals—Making "Patients"

Parameter Type	Examples
ECG	Multiple leads
Heart Rate	HR
Respiration	RR
Pulse Oximetry	SpO_2
Blood Pressure	NIBP, IBP, ART, CVP, PAP, ICP
Temperature	T1, T2
Gas Monitoring	$etCO_2$, FiO_2
Cardiac	CO, SvO_2
Arrhythmia/Event	Asystole, VFib, PVC, etc.

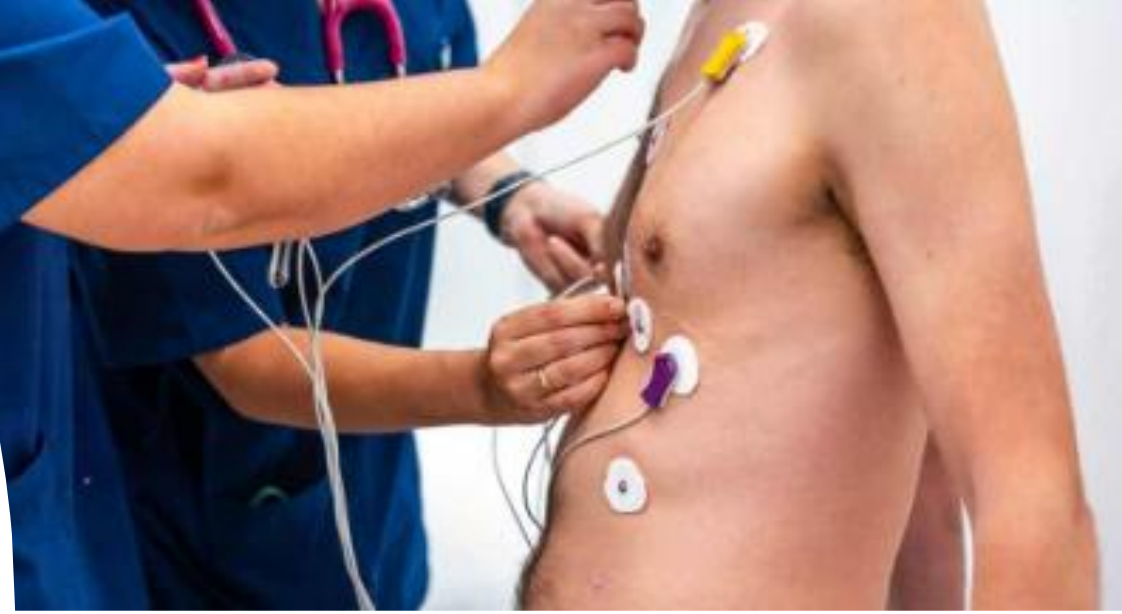


Why we constantly “kill” the patiens?

Several patients on ICS


Dräger
11:00
13-Oct-2025
Asystole
Cannot analyze ST
T252_02: ASY
ARR
ASY
ASY
PVC/min
0
10 %
ST I
ST V
ST aVL
***
***
***
QTc
QT
SpO2
PLS
Alarms...
Mark event
Code
Views...
Freeze waveforms
Trends/ Data...
Procedures...
Sensor parameters...
NIBP start/stop
System setup...

Real world scenario #1



ECG Lead-Off

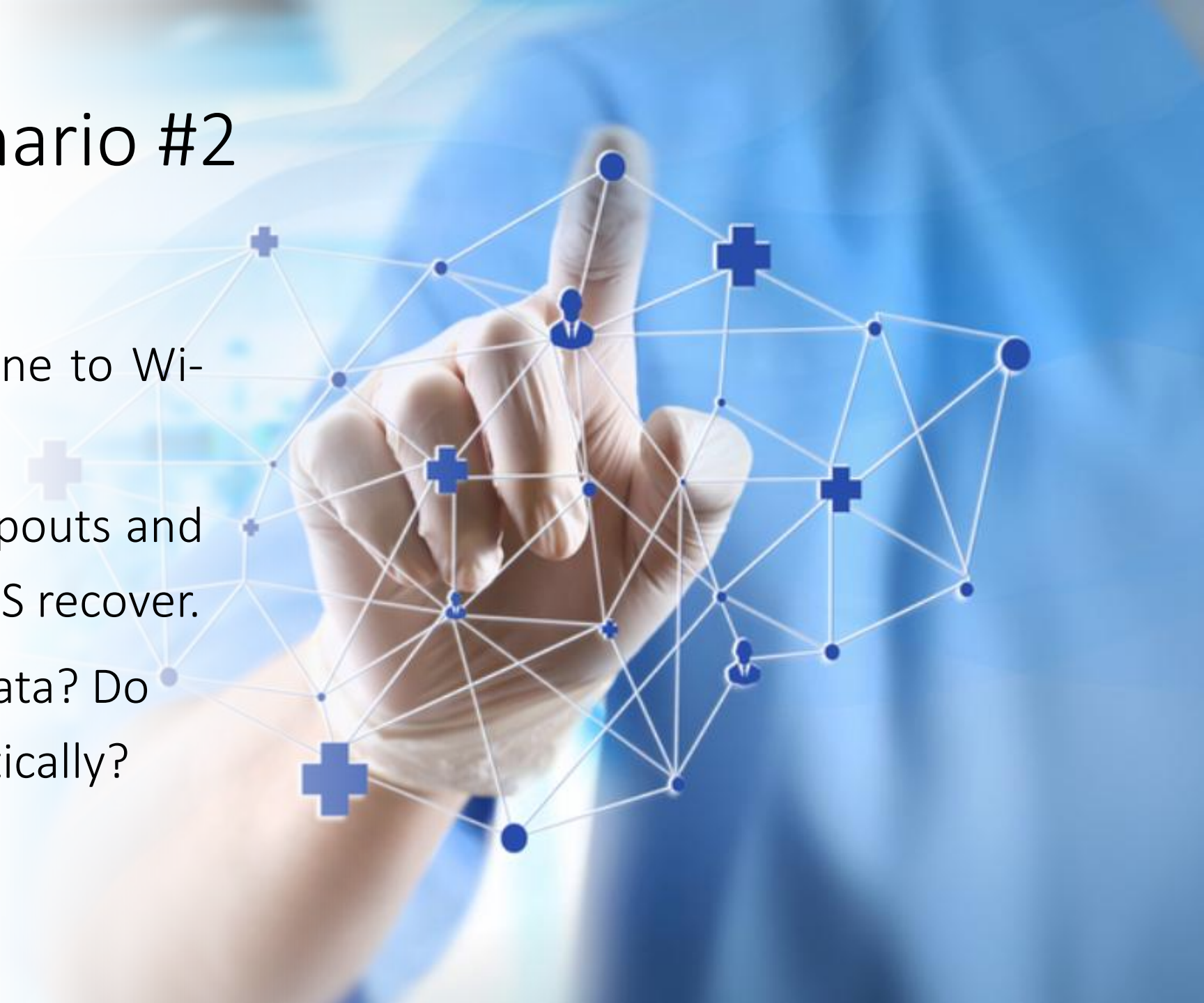
Nurses sometimes forget to reattach ECG leads.

We disconnect them in the middle of tests.

The M540 and M300 must detect this within 3 seconds and trigger a clear, unmistakable alarm.

We count the seconds. Every time.

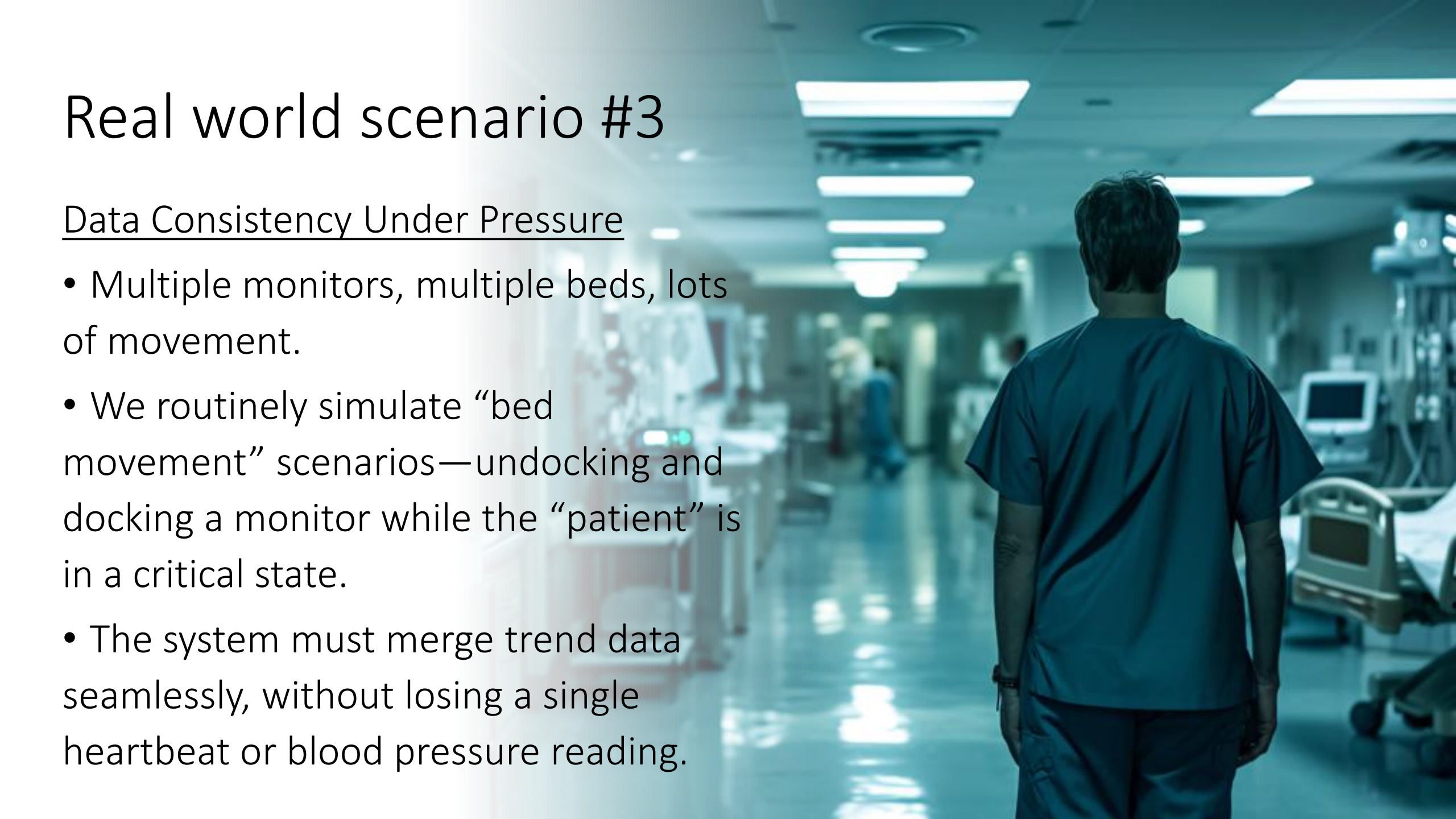
Real world scenario #2



Network Outage

- Hospitals aren’t immune to Wi-Fi glitches.
- We force network dropouts and see how the ICS and IACS recover.
- Do they lose patient data? Do they reconnect automatically?

Real world scenario #3



Data Consistency Under Pressure

- Multiple monitors, multiple beds, lots of movement.
- We routinely simulate “bed movement” scenarios—undocking and docking a monitor while the “patient” is in a critical state.
- The system must merge trend data seamlessly, without losing a single heartbeat or blood pressure reading.

So, how much testing is being done?

- HW testing
- SW testing
- Documentation testing
- Labeling testing
- Battery life testing
- Stress, stability, longevity, robustness, interoperability testing
- Drop testing
- Testing in controlled environmental chamber

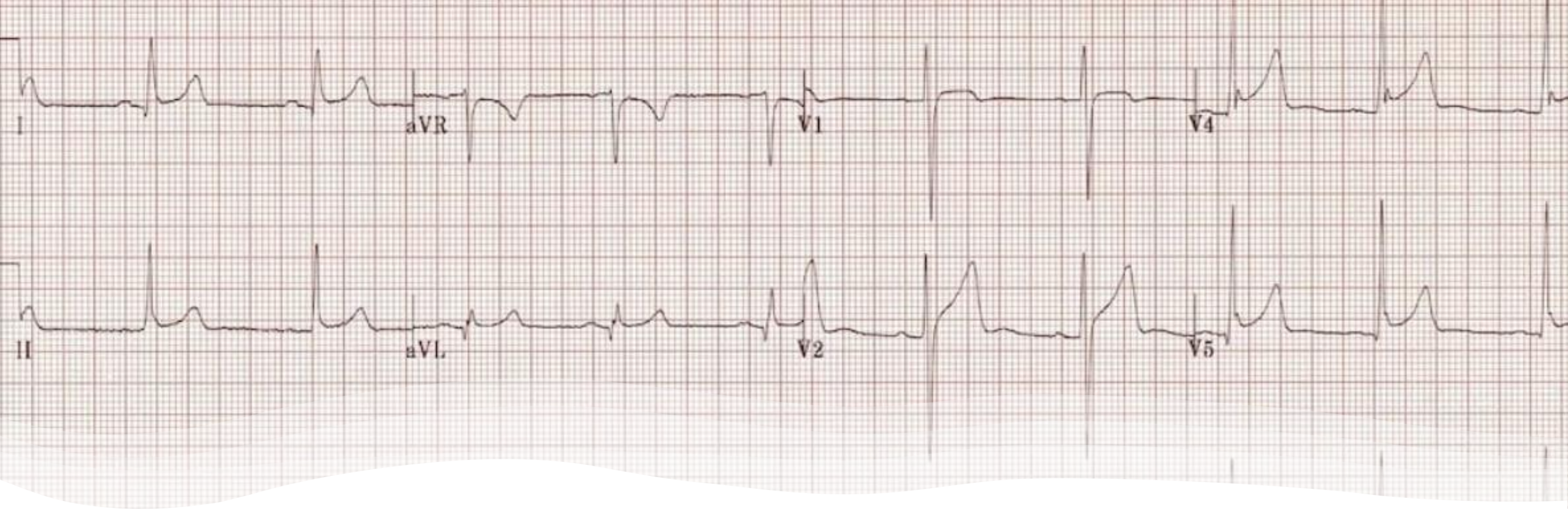
What is also important?

Testing isn’t just about technical excellence—it’s about traceability and documentation:

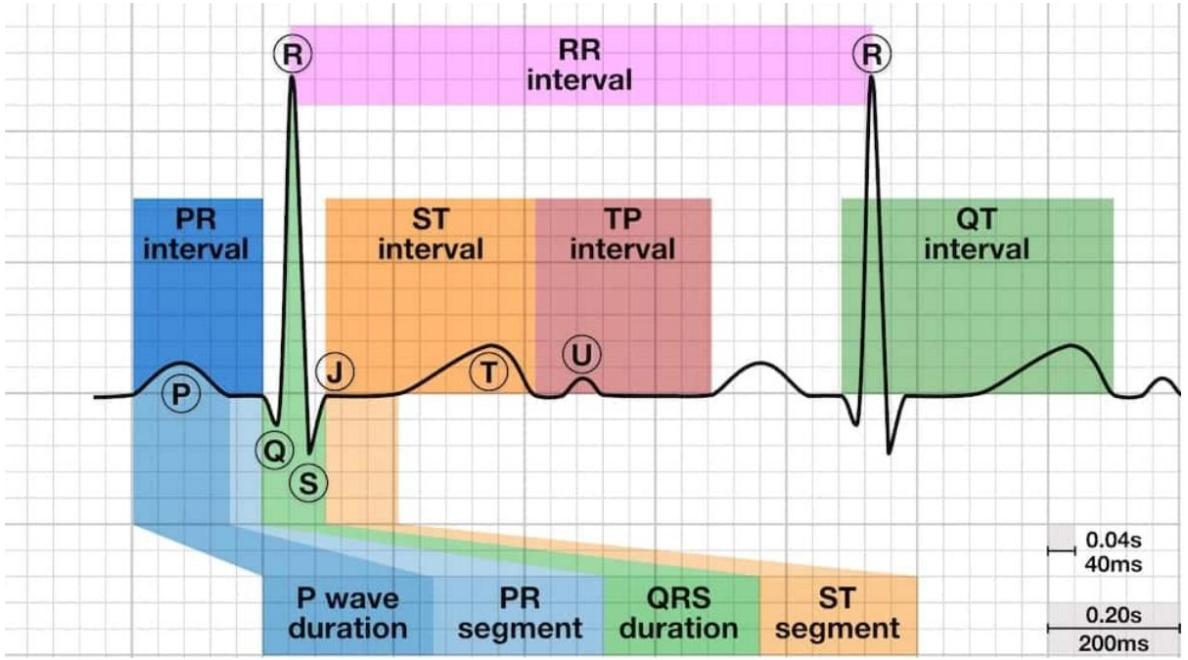
-Every test is documented, with evidence.

-Failed tests are root-caused and retested.

-TUV and FDA don’t just want proof that the device works—they want proof it fails safely, predictably, and with proper alarms.



Standard tests



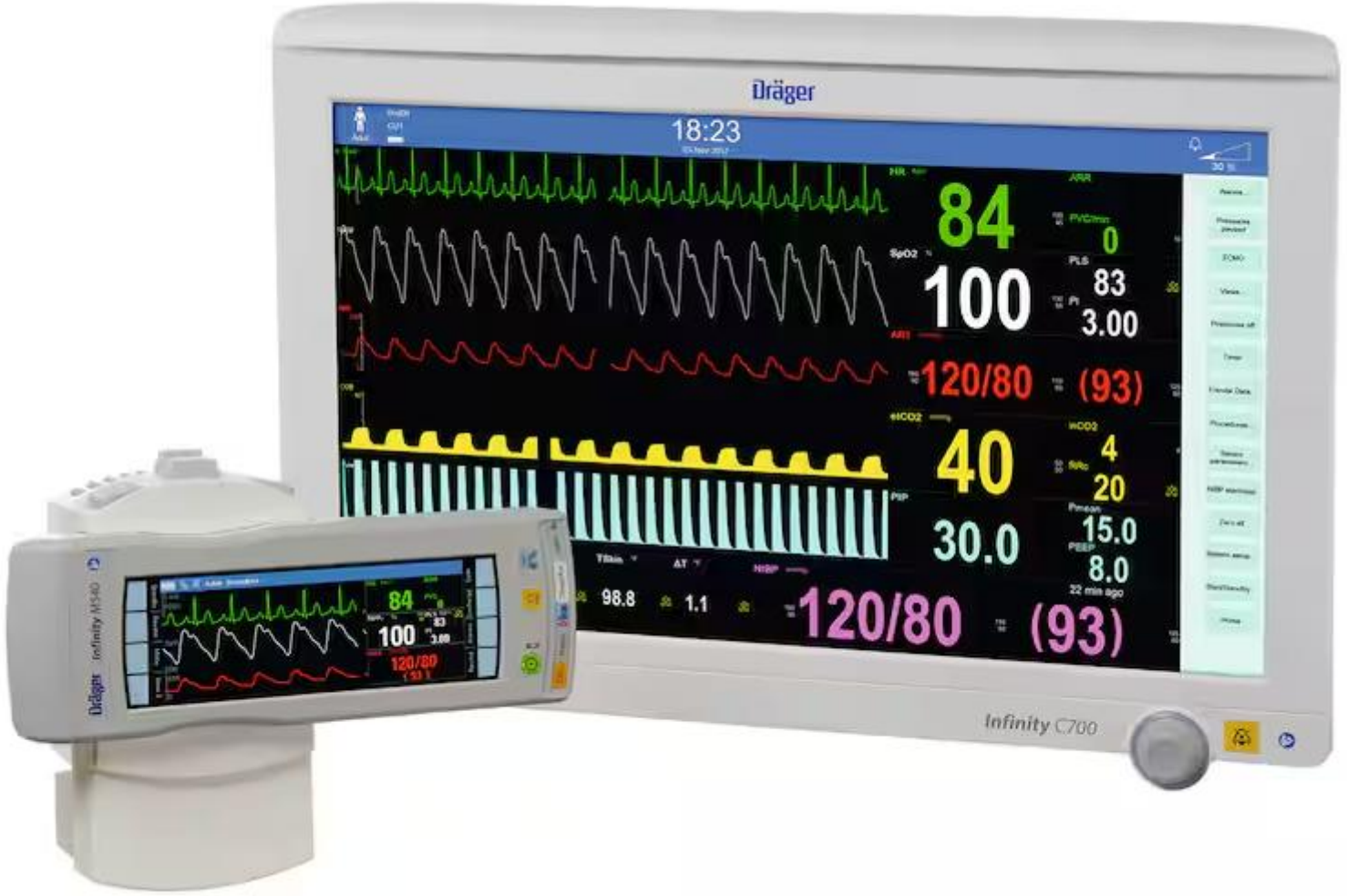
Standard tests

What about Automation?

AI?

When Infinity M300 patient-worn monitor was first installed at the hospital?

How many different physiological parameters Infinity Acute Care System monitors simultaneously?



So, how I feel testing medical embedded systems?

Thank you!

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