

EMC testing and certification for large medical system families

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'The call you wished you'd never made'



'The call you wished you'd never made'



'The call you wished you'd never made'



Did my phone just bring the system down?

Open hart surgery v.s. minimally invasive



Source: Catharina hospital Eindhoven

<https://www.facebook.com/CatharinaZiekenhuis/videos/594387667656919/>

Open hart surgery v.s. minimally invasive



Source: Catharina hospital Eindhoven

<https://www.facebook.com/CatharinaZiekenhuis/videos/553146435146478/>



Healthy living

Prevention

Diagnosis

Treatment

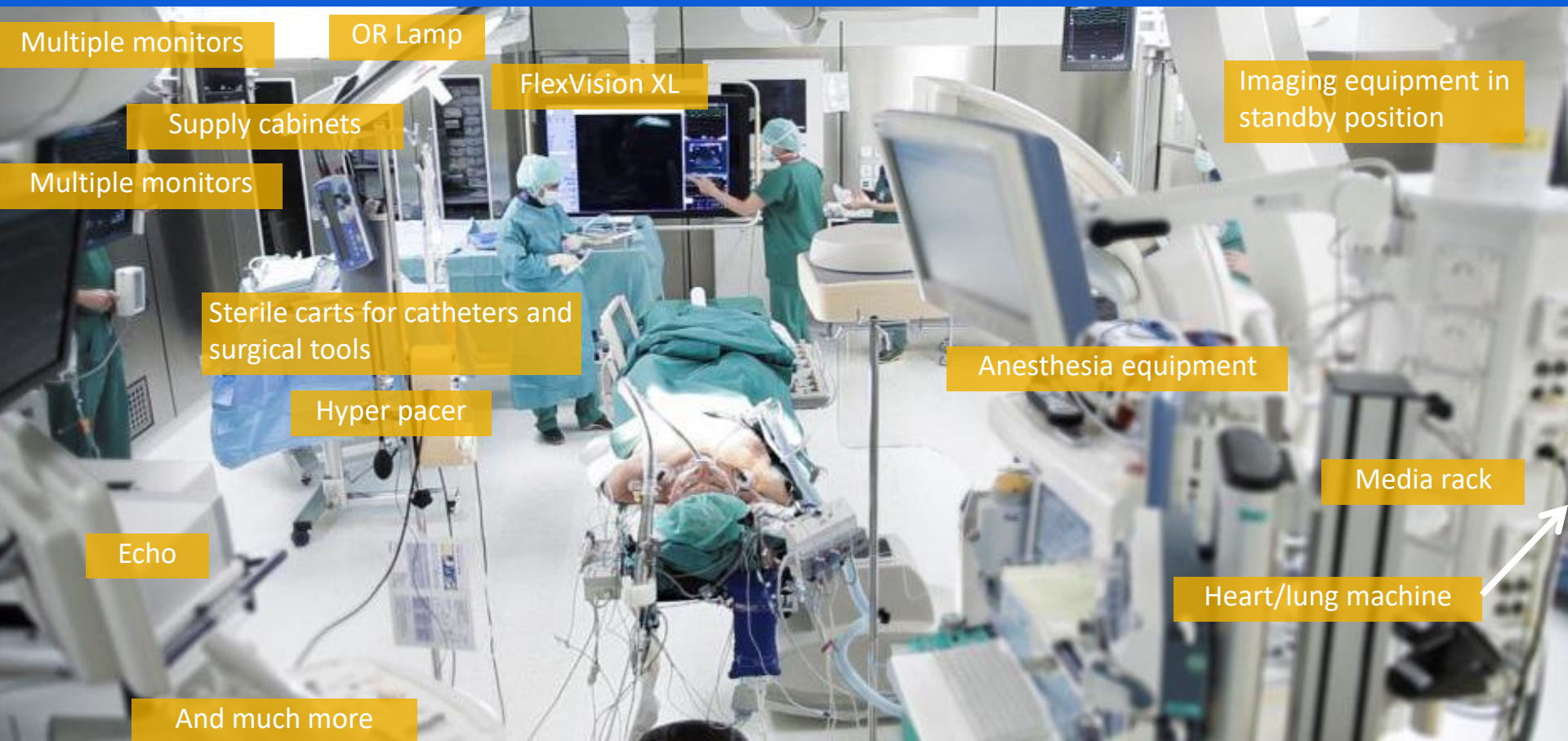
Home care

Clinical practice example ORT system



University of Colorado School of Medicine

Clinical practice example FlexMove lab



Multiple monitors

OR Lamp

FlexVision XL

Supply cabinets

Imaging equipment in
standby position

Multiple monitors

Sterile carts for catheters and
surgical tools

Anesthesia equipment

Hyper pacer

Media rack

Echo

Heart/lung machine

And much more

Clinical practice example FlexMove lab



Technician (not visible)

Perfusionist (not visible)

Surgeon

Interventional cardiologist

Scrub nurse

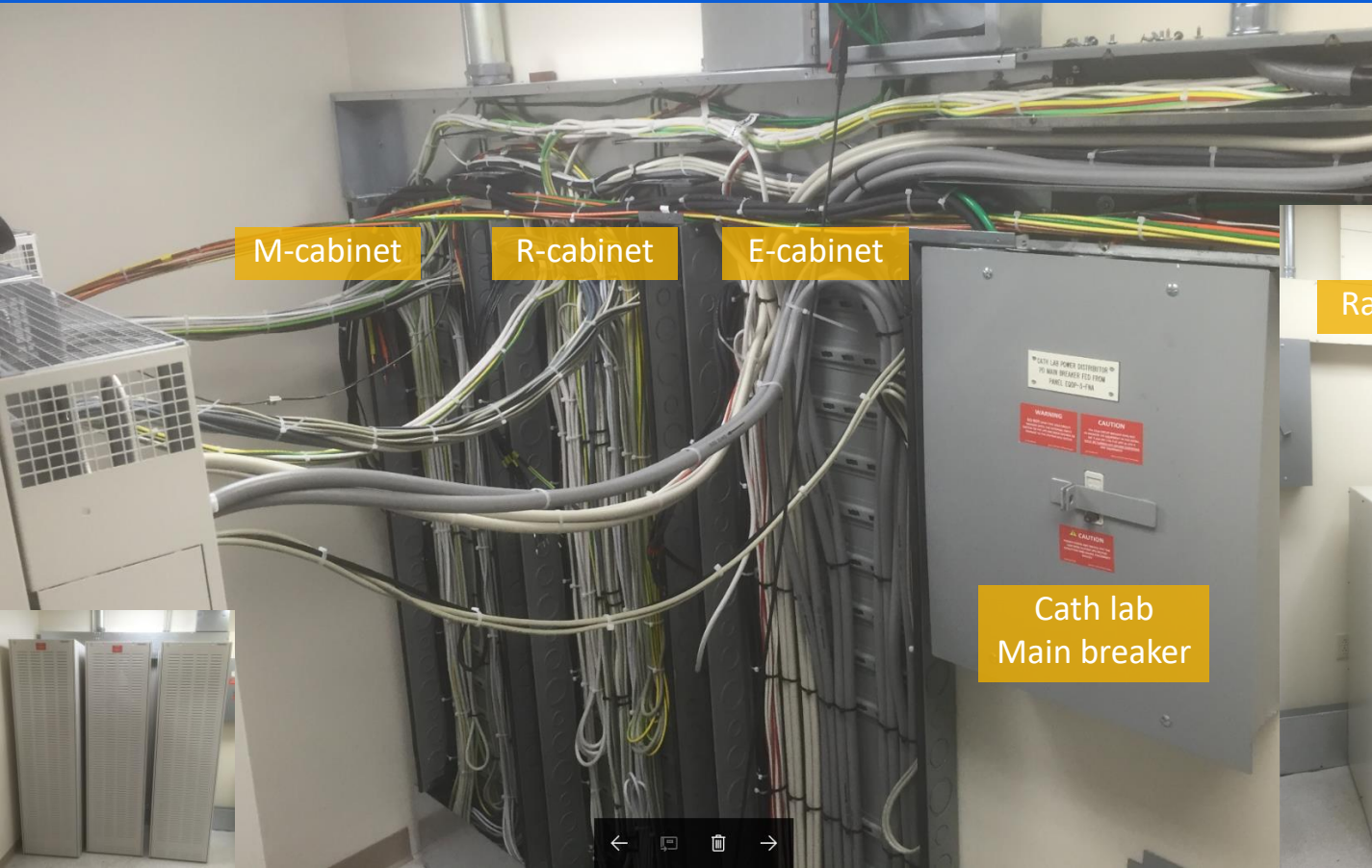
Fellow

Echographer

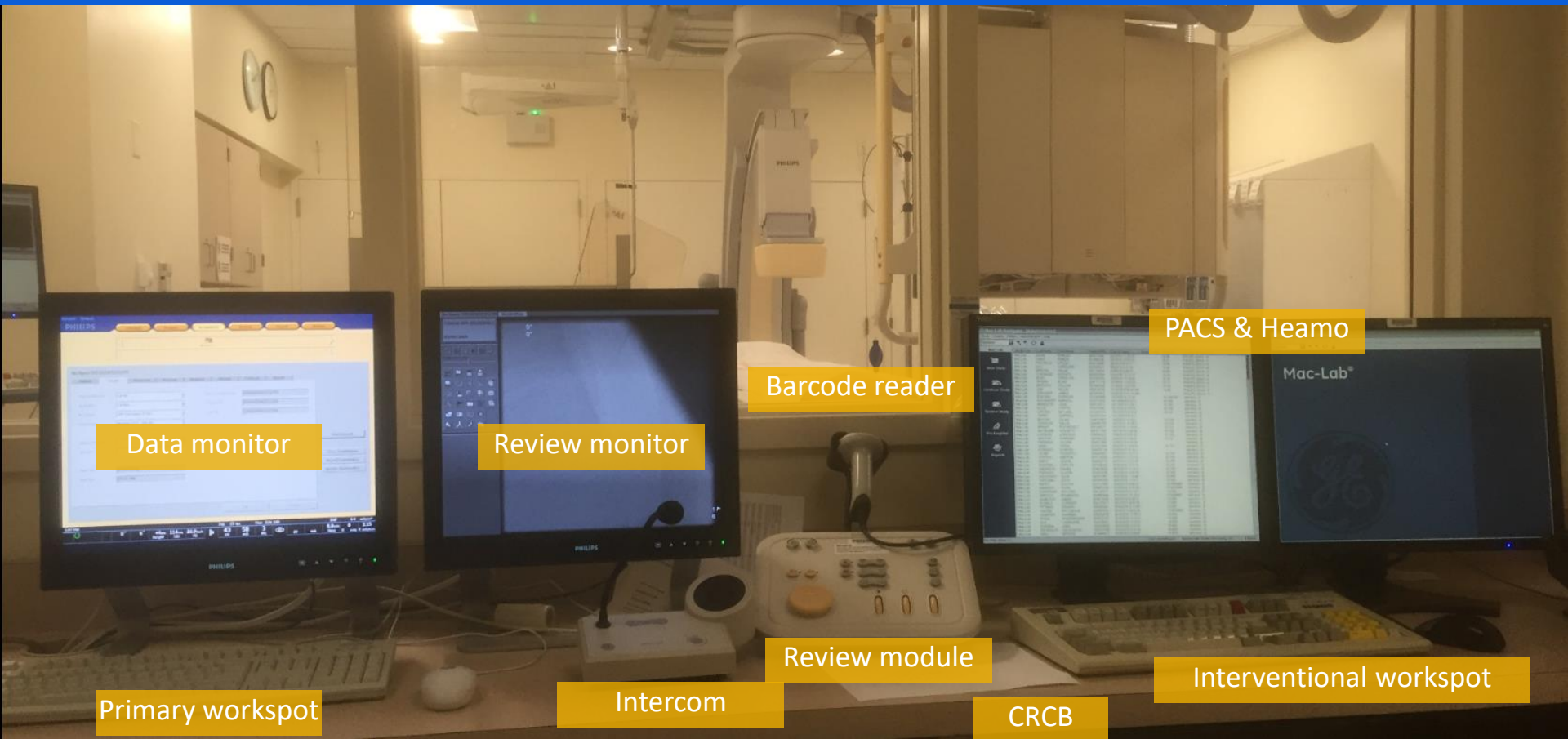
And many more

Anesthesiologist

Clinical practice technical room (mono-plane)



Clinical practice control room (mono-plane)



PACS & Heamo

Barcode reader

Data monitor

Review monitor

Review module

Interventional workspot

Primary workspot

Intercom

CRCB



Compliance

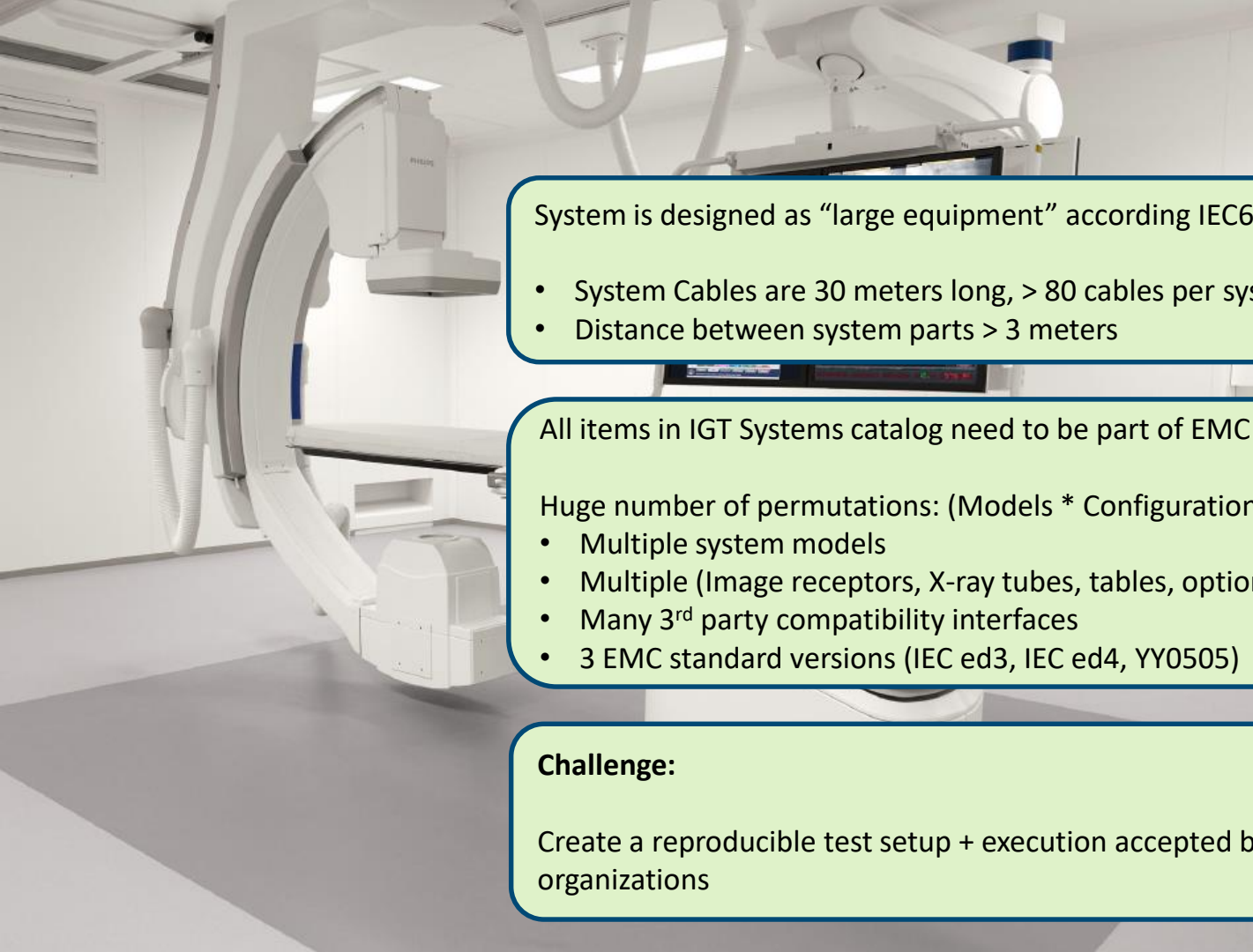
- Requirements analysis
- Risk analysis
- Evidence build-up
- Compliance tests
- Reporting & signoff



Risk Control

- Select & implement measures
- EMC Design Guides
- Deployment & training
- Design reviews

Annual DfEMC plan

A large, white, C-shaped medical imaging system (likely a linear accelerator) in a clinical setting. The machine has a large circular gantry with various components attached, including a patient table and a control console. The background is a clean, white clinical room.

System is designed as “large equipment” according IEC60601-1-2 / YY0505

- System Cables are 30 meters long, > 80 cables per system (routed in bundles)
- Distance between system parts > 3 meters

All items in IGT Systems catalog need to be part of EMC certification

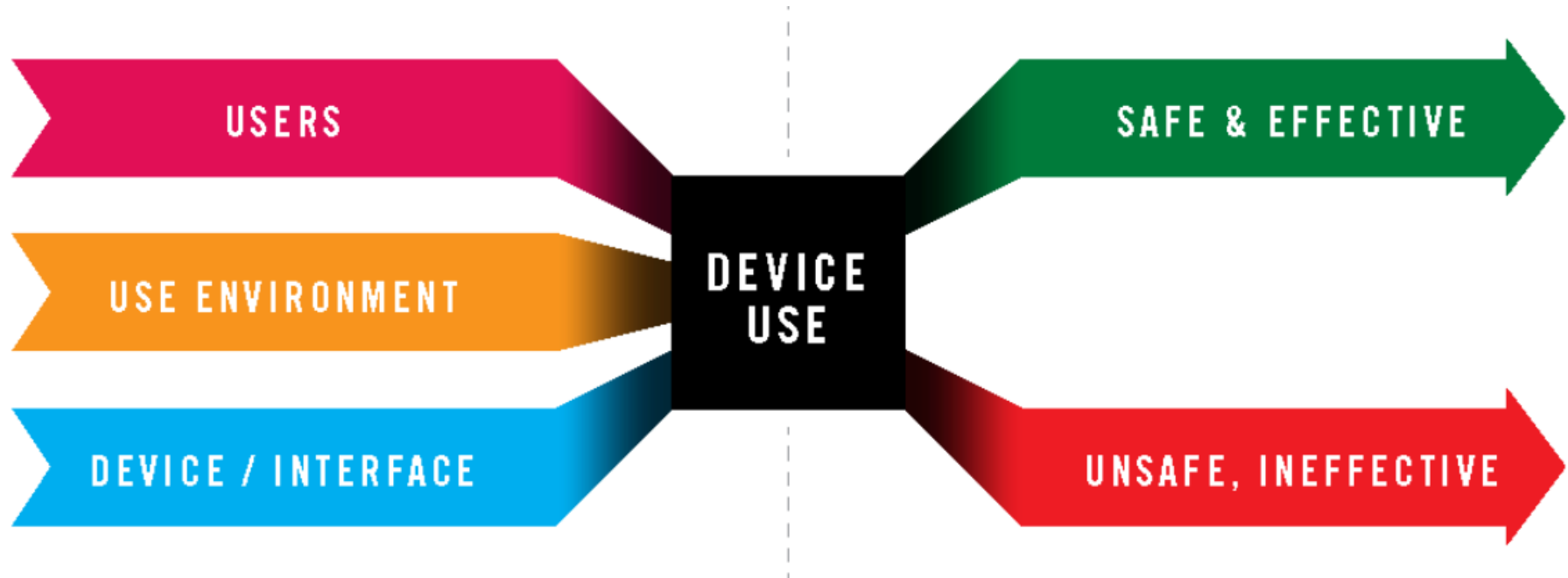
Huge number of permutations: (Models * Configurations * Options)

- Multiple system models
- Multiple (Image receptors, X-ray tubes, tables, option) configurations
- Many 3rd party compatibility interfaces
- 3 EMC standard versions (IEC ed3, IEC ed4, YY0505)

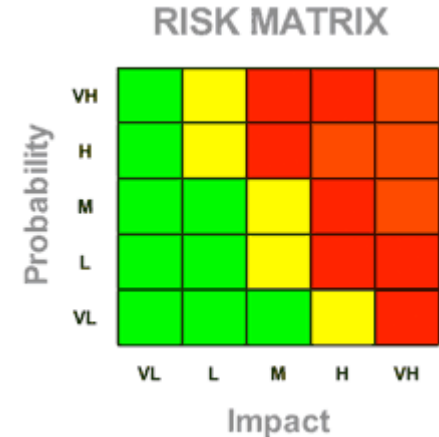
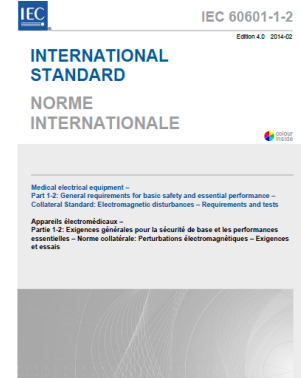
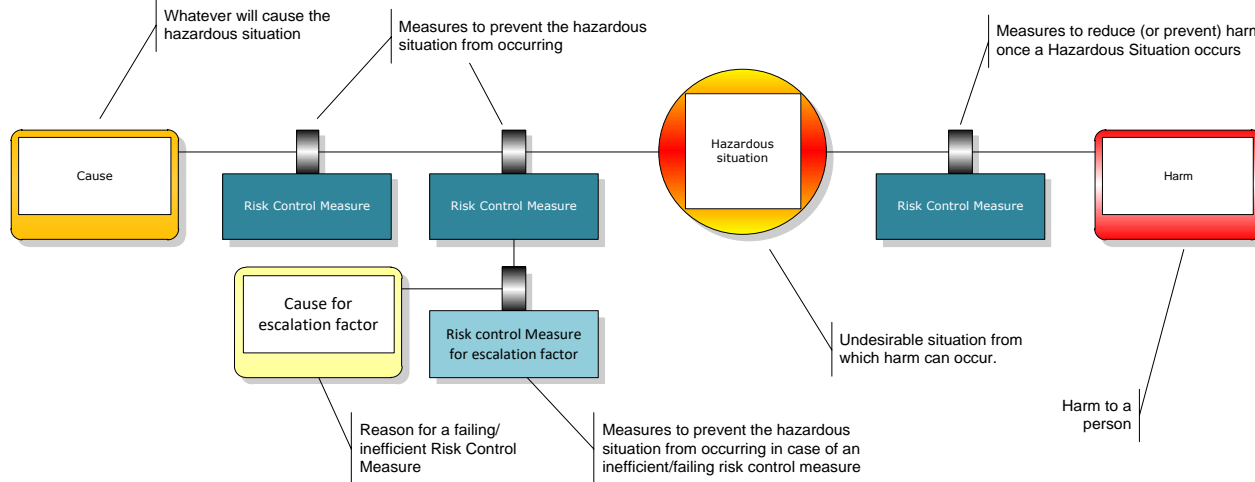
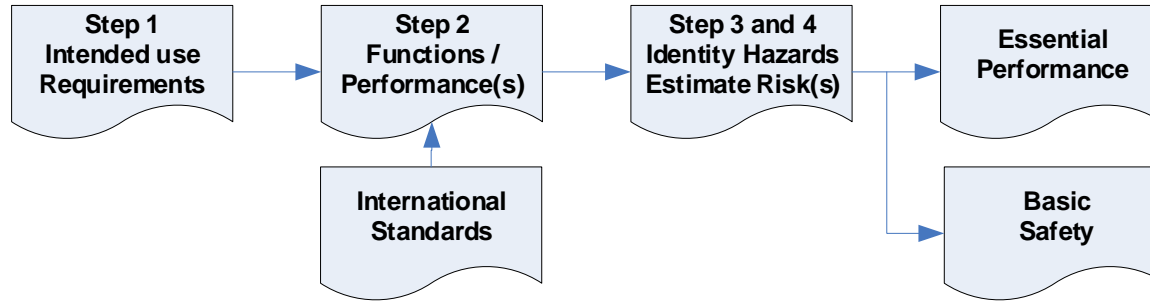
Challenge:

Create a reproducible test setup + execution accepted by national regulatory organizations

Intended Use (Environment)



Essential Performance & Basic Safety



IEC 60601-1-2

Electromagnetic environments

EMC test methods

EMC design techniques
(for hardware and software)

Mitigation Methods

- Bonding
- Filtering
- Shielding
- Galvanic isolation
- Overvoltage Protection
- etc.

ISO 14971

Risk Management

Shock risks

Fire risks

Mechanical risks

Risks caused by
electromagnetic
disturbances

Risks caused by
climatic conditions

Risks from misuse

Etc.

Risk Management File

IEC 60601-1-2

EM Risk analysis

EM Risk evaluation

EM Risk control

Using verification and
validation methods such as:

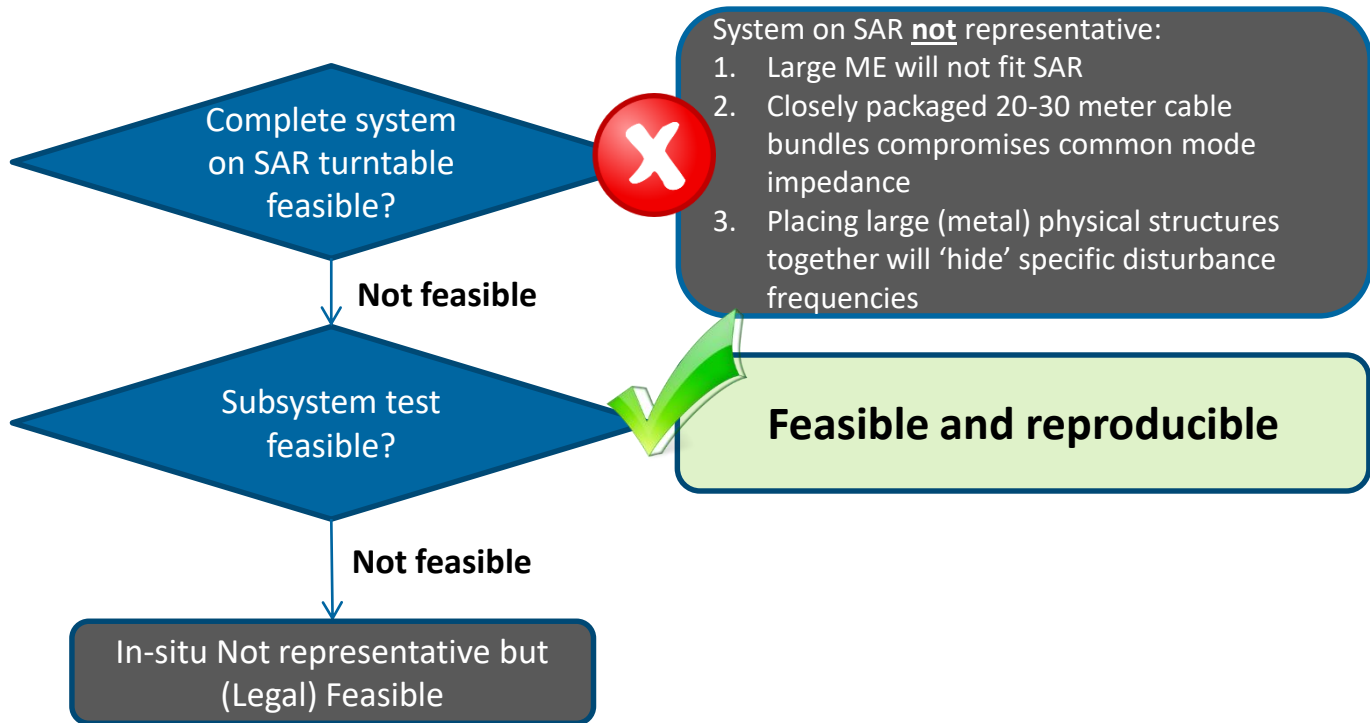
- Demonstrations
- Checklists
- Inspections
- Reviews & assessments
- Independent reviews and assessments
- Audits
- Non-standardized checks and tests
- Individual and/or integrated hardware tests
- Computer simulation
- EM testing

EM Risk acceptability

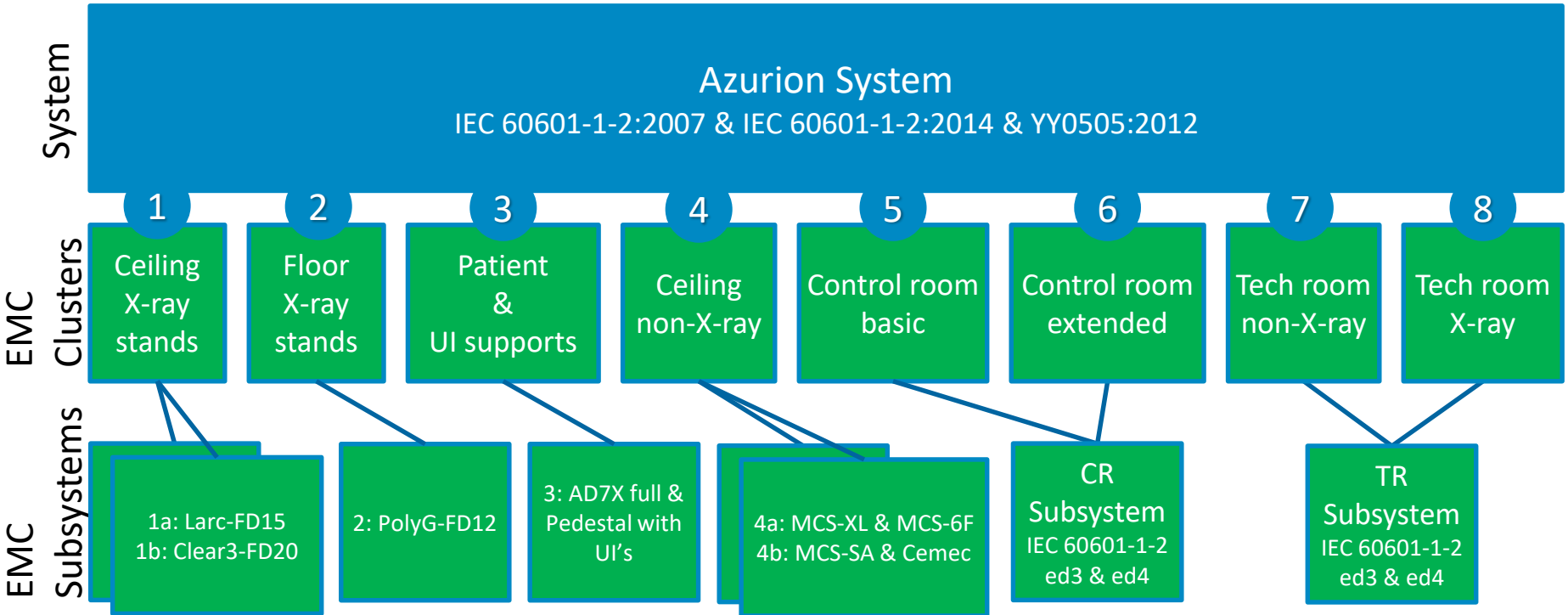
EM Risk management
report

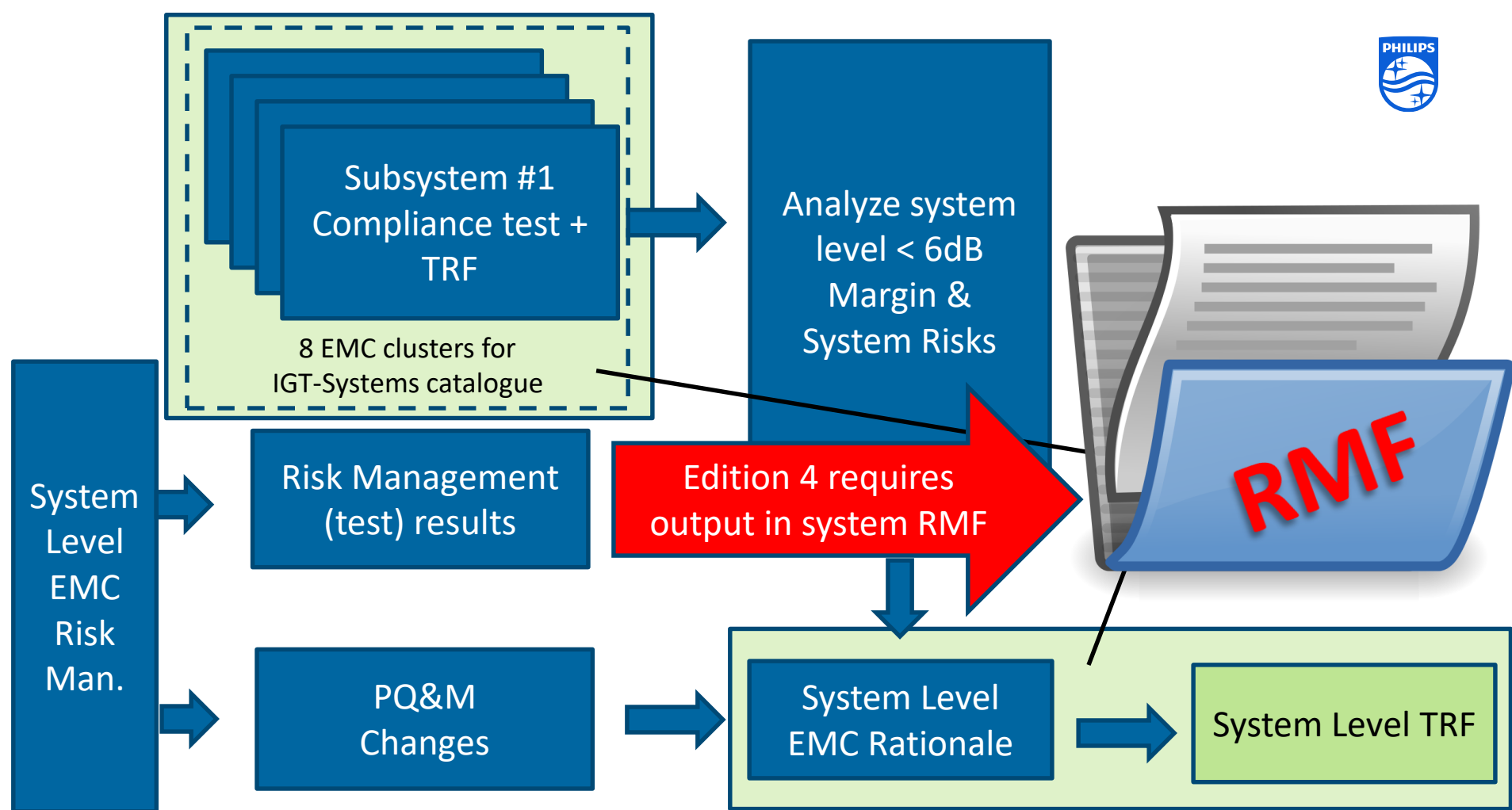
EM Production and post-
production information

The well-known "EMC tests"
are the verification of the
mitigation methods.



Certification overview



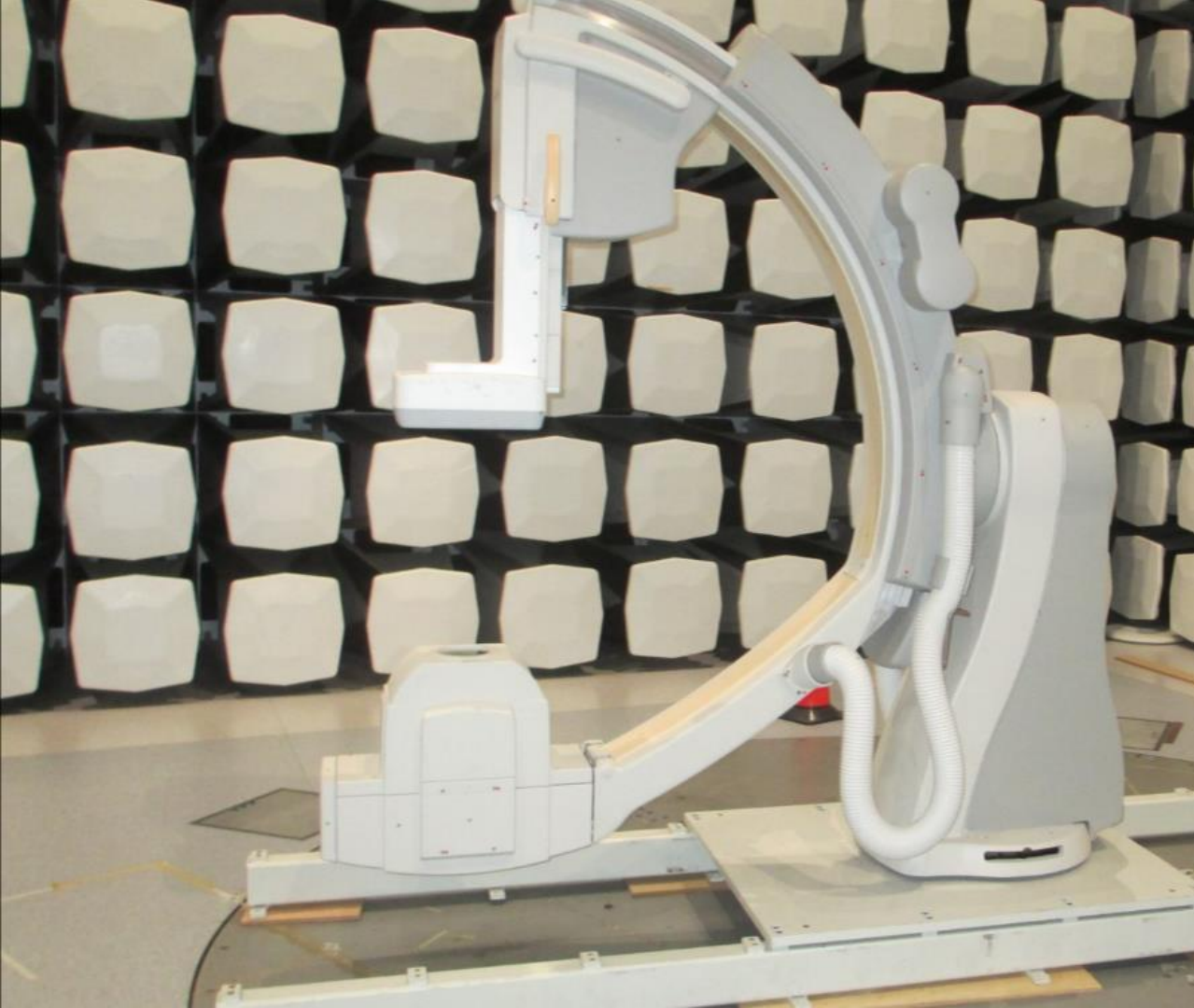




Subsystem 1a

X-ray stand lateral, suspended in a wooden support at 290cm ceiling height





Subsystem 2

X-ray stand frontal, standing on isolating supports.



Subsystem 3

Patient & UI supports with external interfaces.



Subsystem 4

Monitor Ceiling suspensions. Left a 6-fold MCS, right an XL+2, below 3-fold springarm.



Subsystem 4b

Monitor Ceiling suspensions on boom with Equipment rack and Exam light.



Subsystem 5/6

Basic + Extended control room
equipment observed with
camera's.



Subsystem 7/8

Technical room cabinets





Philips delivers
**innovation that
matters to you**

Thank you !!!