Medical innovation is going at a fast pace due to new minimal invasive procedures enabled by the integration of equipment originally used independent by different imaging or treatment modalities. Open surgery rooms are converted to advanced hybrid interventional suites where a broad range of medical procedures can be performed from diagnosis to full surgery. Equipment originally not designed with the intent to interact is all of a sudden interacting with other medical equipment. Due to the long life time of medical equipment, this interaction spans products developed over the past 5-20 years, which were designed and released to different or predecessors of modern medical EMC standards. The system manufacturer and system integrator have a key role in EM risk management. EM risk management is the key new focus of the latest Medical EMC standard amongst a further increase in immunity test levels.
Imagine yourself being at a nice family gathering. Everyone has fun and is joking....
...al of a sudden you see your father at the other end of the table. One side of his face is drooping. He reaches up his arms but one arm seems to fall down almost instantly. You call out Father what’s wrong ???
He replies slurred and you can hardly hear him.

You recognize this as a serious event STROKE!!! and you should immediately call for help...
...within 15 minutes the ambulance arrives. The medics place your father on a stretcher, put him in the ambulance and they drive off. You are clear of mind enough to ask them what hospital they will bring him to.
You leave the party, take your care and hurry to the hospital. Luckily you didn’t drink alcohol yet at the party.
In the mean time, your father has arrived at the hospital and is directly brought to one of the available catheterization labs.
When you finally arrive at the hospital there is a warm welcome sign above the entrance, but you feel a cold shiver going all through your body.
...after finding your way through the hospital, you finally arrive at the catheterization lab where the staff is busy tearing your father. You are not allowed to enter the lab, but a kind nurse takes you to the control room where you are allowed to watch the ongoing medical procedure.
After all the stress of the past hour you feel more at rest now. You are near your father. He seems to be in good hands and the staff seems to be confident in what they are doing. For them this is routine.....

The staff tells you that your father was lucky to reach the hospital within the ‘golden’ hour after the event, which significantly increased the probability of recovery without long-term brain damage.
At that moment you decide to call your brother informing him that everything is fine, your father is being treated and will probably recover. At the moment you hear the first ring of your phone, the situation completely changes.
The two main work spot monitors go blank, the monitors in the examination room goes blank as well......what is happening???
...you notice the worried faces of the clinicians that are pressing buttons trying to het the system back to life....
...then the image you saw above the entrance door to the cauterization lab pops-up in your mind.....Did my phone just bring the system down ????
Medical innovation is going at a fast pace due to new minimal invasive procedures enabled by the integration of equipment originally used independent by different imaging or treatment modalities. Open surgery rooms are converted to advanced hybrid interventional suites where a broad range of medical procedures can be performed from diagnosis to full surgery. Equipment originally not designed with the intent to interact is all of a sudden interacting with other medical equipment. Due to the long life time of medical equipment, this interaction spans products developed over the past 5-20 years, which were designed and released to different or predecessors of modern medical EMC standards. The system manufacturer and system integrator have a key role in EM risk management. EM risk management is the key new focus of the latest Medical EMC standard amongst a further increase in immunity test levels.
Philips Image Guided Therapy – Systems has developed the Design for EMC approach to gain broad insight and remain in control of both EMC compliance but also functional safety, product reliability as well as business concerns like project cost and lead-time.
Within the DfEMC process we try to answer three main questions:

- What is the intended use and the intended use environment for the product we are designing?
- What are the legal requirements for the product we are designing?
- What are our business and project goals?
The DfEMC process execution is done in two lanes:

- The EMC Compliance lane, coupled to system release
- The EMC Risk Control Lane, continuous for the full product portfolio (including PQ&M)
The EMC requirements for medical equipment and systems are different for different countries, but presumption of compliance is generally achieved by complying with the medical EMC consensus standard IEC60601-1-2, which is a collateral standard of the basic safety standard for medical electrical equipment and systems.
The title of this standard changed from 3rd to 4th edition (which was hardly noticed in the EMC community). This emphasizes the notion that disturbances are a fact of life and need to be considered via EMC risk management.

Collateral has been harmonized with the IEC 60601-1 edition 3.1 and the definitions of “Basic Safety” (BS) and “Essential Performance” (EP)

• Compliance criteria are based on risk management (BS and EP considering the intended environment)
• Compliance criteria are no longer fixed
EMC risk management follows medical risk management standard 14971 for one particular risk: “Electromagnetic disturbances”

EMC tests in the lab are ‘only’ the final validation step in the EM Risk management process.
**FDA concern**

- Rapidly changing technology and environment
- Wireless on Medical is both a source and victim for Electromagnetic Interference (EMI), including QoS, data integrity, coexistence, security, EMC.

New technology introduces risks but surely also an opportunities.
The IEC60601-1-2 recognizes limited the classification to three possible environments:
• Professional Healthcare Environment
• Home Healthcare Environment
• Special Environment

Note that the special environment can be a sub-set of the other two like e.g. a surgical room in a professional healthcare environment. Due to the use of surgical equipment with known disturbance levels exceeding the normal, additional risk control measures are required.
Models applicable to EMC activities
EM disturbance source, coupling path and victim

**Disturbance sources:**
- Quantification via:

  ![Measurement results](image)

**Coupling paths:**
- Quantification/qualification via:

  ![Design review](image)

**Disturbance victims:**
- Quantification/qualification via:

  ![EMC risk control](image)
In order to make the analysis manageable, large complex systems have to be partitioned and decomposed to address specific concerns at EMC cluster, unit or sometimes even on component level.
EMC starts with System level EMC risk management. 4\textsuperscript{th} edition EMC risk management has been applied already for our next system release.

4\textsuperscript{th} edition compliance requires inclusion of EMC risk management in system Risk Management File.
There are two main changes between edition 3 and 4 of the standard:
- Introduction of EMC risk management as basis for compliance
- Increase of ‘default’ immunity test levels and intended use environments
EMC risk management may not be outsourced and is a sole responsibility of the manufacturer.
Testing against the risk management defined immunity test levels is a responsibility of an accredited test lab (NRTL). This requires investments in new equipment (RF antenna, RF amplifiers and education of personnel).
Cluster #1 contains 2 sub-systems #1a (L-Arc) and #1b (Clea-C) because they are highly different in geometry and we need to test multiple detector variants to cover EMC compliance evidence for our full portfolio.
Cluster #2 is Ploy-G and cluster #3 is patient table + pedestal + all ER UI's
Cluster #4 consists of 2 Monitor Ceiling suspensions with all monitor variants
Cluster #5 and cluster #6 are basic and extended control room equipment (tested together)
Cluster #7 (Technical room control cabinets) and cluster #8 (X-ray generator cabinets) are tested together.
We keep EMC under control using DfEMC which is and was already based on EMC risk management activities.

The well known compliance tests, ‘just’ provide objective evidence of compliance and can be interpreted as a validation of the preceding DfEMC activities during the design and engineering of medical electrical equipment and systems.

EMC analysis and training is one of the control measures required by the EMC risk management process. It is a continuous effort gradually gaining more insight and control over electromagnetic phenomena in the medical environment.
Summary: Safety in the medical domain is about risk management, risk management and ... risk management.

That is what keeps our beloved ones free from unacceptable risks in the case that they are in need of medical support.
Thank you!