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Medical device risk management of electromagnetic disturbances

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EMC-ESD Praktijkdag 9 November 2016, Elektrum, Arnhem

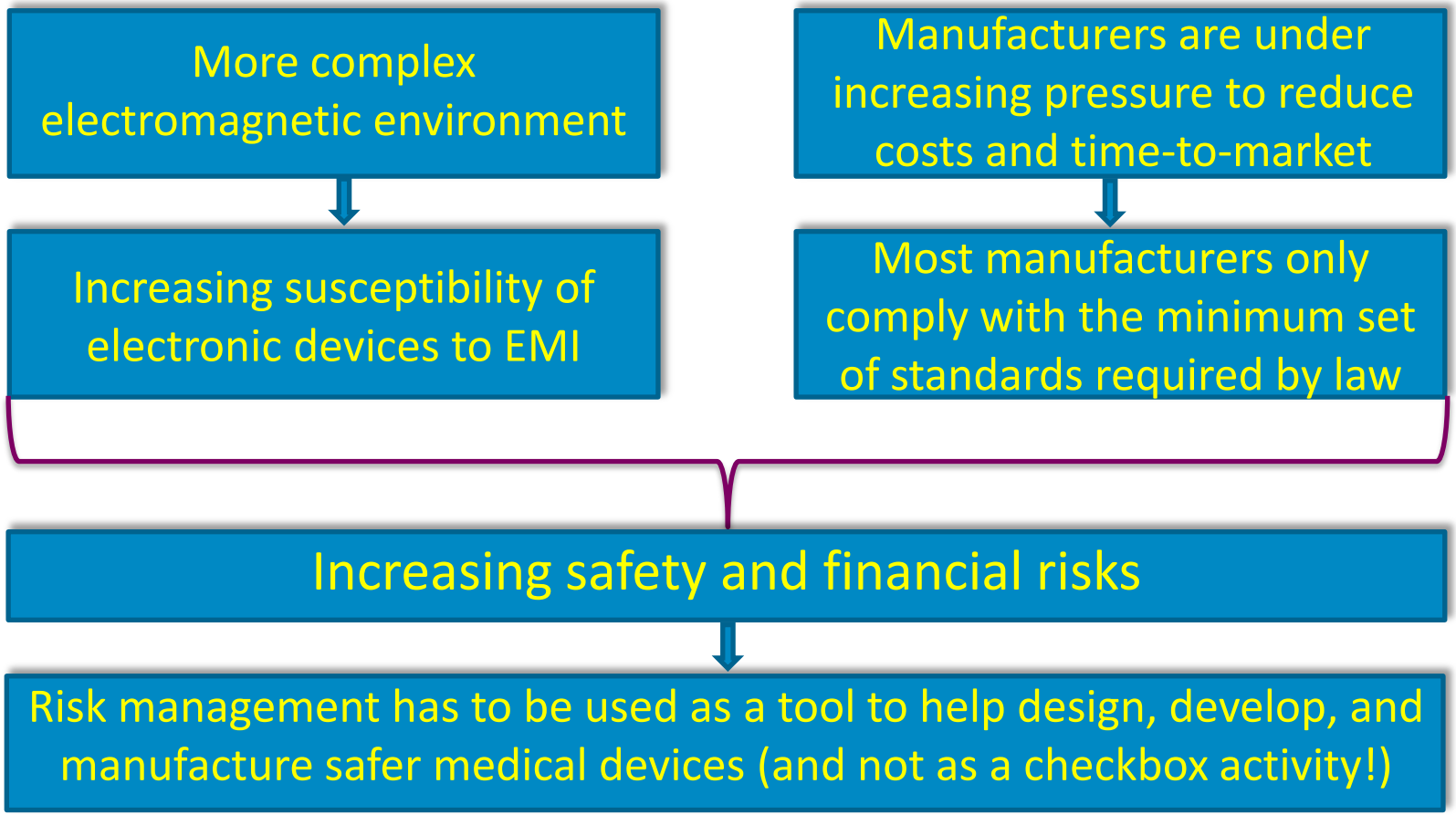
Outline

Risk management process for Electro-Magnetic (EM) disturbances

1. Introduction
2. Essential performance
3. EM risk analysis
4. EM risk evaluation
5. EM risk control
6. EM risk acceptability
7. EM risk management report
8. Summary

Introduction

Increasing risks due to Electro-Magnetic Interference



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Introduction

The safety standard for medical devices

- **IEC 60601-1-2:2014** General requirements for basic safety and essential performance of medical electrical equipment – *requirements and tests for electromagnetic disturbances*

Becomes mandatory in the US (FDA) and Europe 31 December 2018!

- ***Compliance is checked by inspection of the test report and the risk management file.***

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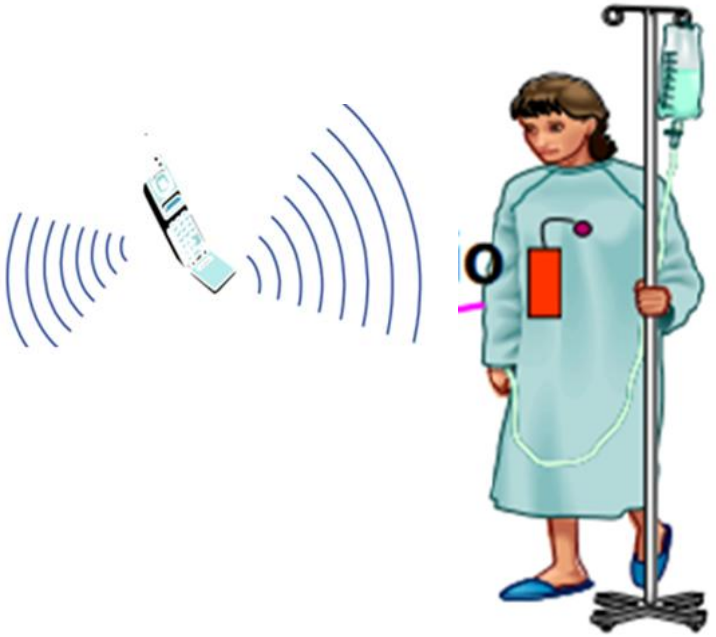
Introduction

Application of risk management: ISO 14971:2007

- **Risk management** is carried out to **identify** the hazards associated with medical devices, to **estimate** and **evaluate** the associated risks, to **control** these risks, and to **monitor** the effectiveness of controls throughout the **life-cycle** of a medical device.



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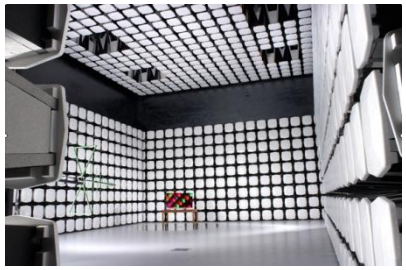
Introduction

EMC testing is insufficient



1. Conventional testing uses too few angles of incidence, plus only horizontal and vertical antenna polarization.
2. EMC testing ignores ageing (e.g. corrosion).
3. EMC testing ignores assembly, maintenance and repair.
4. Simultaneous EM disturbances are not taken into account.
5. Future changes in EM environment are not taken into account: EMC standard lags 5 years behind.
6. In-band immunity testing of RF wireless devices is excluded.

☞ ***Safety engineering methods are required for risk managment of electromagnetic disturbances: immunity testing, EM design, verification and validation.***

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Essential performance

Definition

- Performance of a clinical function, other than that related to basic safety where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk.
- A product may have no essential performance.

- ***Unacceptable risk occurs when a product's failure will cause harm to a patient, operator, or the environment.***

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Essential performance

Example (un)acceptable risk thermometer

Acceptable risk:

– Thermometer fails to display patient's temperature (no physical hurt).

Unacceptable risk:

– Thermometer displays patient's temperature incorrectly (could cause harm to the patient, because doctor would not give proper treatment).

Essential performance:
display correct temperature
Temperature accuracy: $\pm 0.6\ ^{0}C$

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EM risk analysis (1)

Intended-use environments medical equipment

Professional healthcare environment

Hospitals, clinics, …

EM environments

Home healthcare environment

Homes, shops, restaurants, vehicles, hotels, …

Special environment

Military areas, medical treatment areas with high power equipment, …

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EM risk analysis (2)

Electromagnetic phenomena

EM phenomenon	Consider in a risk analysis
Conducted 	• Harmonics, interharmonics, frequency variations • AC/DC voltage fluctuations/dips/interruptions • Directly coupled or induced voltages or currents • Single or repetitive transients
Radiated 	• Electric fields • Magnetic fields • Electromagnetic fields: continuous waves, single/repetitive transients
Electrostatic discharge (ESD)	• Human • Machine 
Intentional EMI	To be considered in case of special conditions

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EM risk analysis (3)

Immunity test levels Editions 3 and 4 compared

Immunity test	Edition 3 IEC 60601-1-2:2007	Edition 4 IEC 60601-1-2:2014
Electrostatic discharge	6 kV contact 8 kV air	**8 kV contact** **15 kV air**
RF Radiated fields	3 V/m, 10 V/m for life-support 80 – 2500 MHz	**10 V/m home healthcare** 80 – **2700 MHz AM**
RF Proximity fields (30 cm)	--------	**28 V/m** **385 – 5785 MHz PM**
50 / 60 Hz magnetic fields	3 A/m	**30 A/m**

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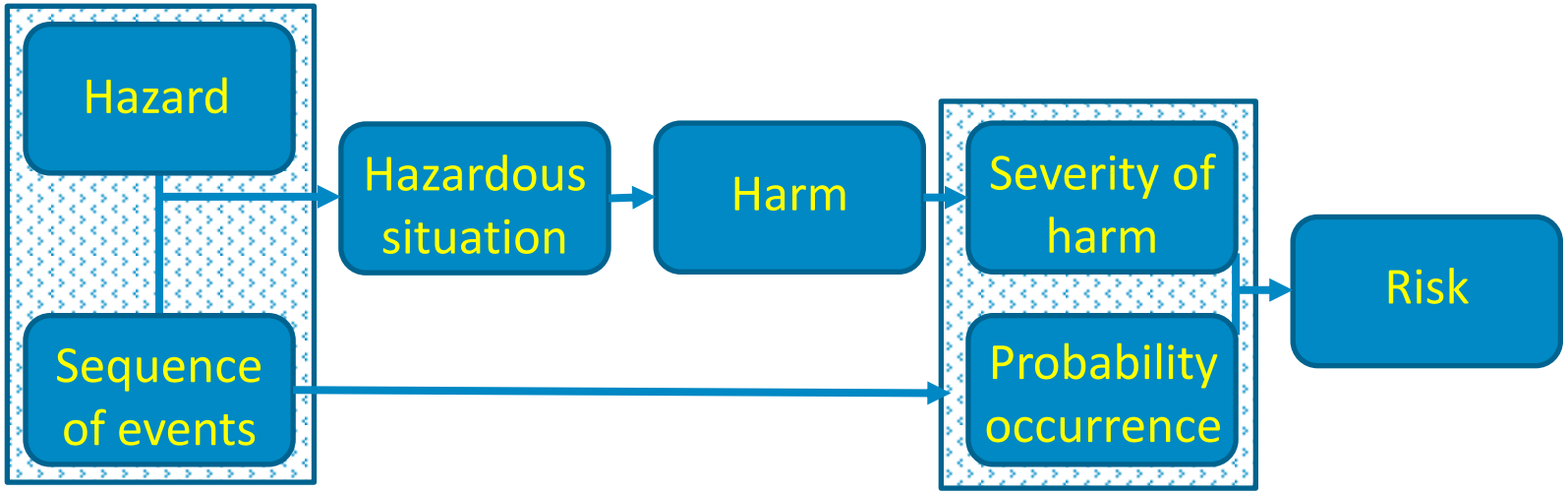
EM risk analysis (4)

Identification of hazards

Hazards, set off by a sequence of events, create harm.
Severity & probability combine to measure risk.



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EM risk analysis (5)

Estimation of risks

Example:

Hazard	Chain of events	Hazardous situation	Potential harms	Severity	Probability
R1 ESD	1: charged patient touches infusion pump 2: pump fails 3: insulin not delivered to patient	Failure to deliver insulin to patient	Minor organ damage, decreased consciousnes, coma, death	significant	medium
R2 H-field					
R3 Lightning					
R4 RF field					

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EM risk evaluation

Qualitative probability levels	Qualitative severity levels: Negligible	Moderate	Significant
High	R4		
Medium	R3		R1
Low		R2	

Unacceptable risk | Acceptable risk

R1 ... R4 = hazardous situations

Severity levels:

Neglible: temporary discomfort
Moderate: long term damage, burn
Significant: permanent damage, life-threatening

Probability levels (frequency):

Low: e.g. 1 in 300, yearly
Medium: e.g. 1 in 30, monthly
High: e.g. 1 in 1, daily

For the hazardous situations that cause an unacceptable risk appropriate risk control measures have to be implemented.

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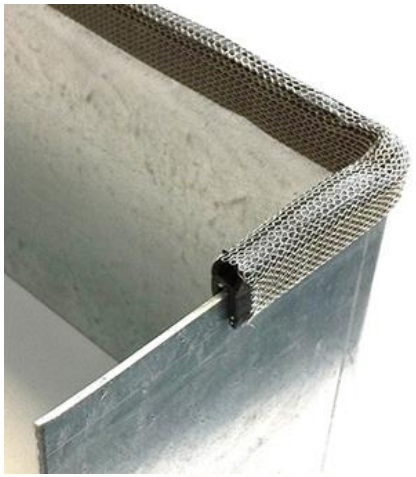
EM risk control (1)

Measures

- EMI mitigation design techniques
  - Shielding (screening)
  - filtering
  - grounding (RF reference)
  - galvanic isolation
  - transient suppression (ESD, EFT, surge)
- Software: error detection & correction
- 3D EM simulations
- Physical mitigation techniques
  - Conductive paint, cable ties, minimum humidity
- Highly accelerated life testing (HALT)
- Installation measures and techniques
- Operation, maintenance, repair instructions
- Control of suppliers



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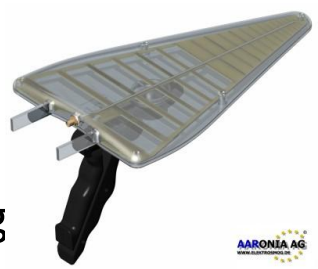
EM risk control (2)

Verification and validation

- Design checklists/reviews
- Audits & inspections
  - EM specification, design, assembly, installation
- Non-standardized checks/tests
  - Relative EM tests with close field probes, current probes, noise generators (filter/shield performance)
- EMC testing
  - Extend standard EMC testing
  - Real-life EM environments (reverberation chamber, all angles and polarizations)
  - Use two (or more) simultaneous frequencies
  - Repeat EMC tests after accelerating ageing
  - In-band immunity and wireless coexistence testing



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EM risk acceptability

The risks from all identified hazards (R1 ... R4) have been evaluated and decided to be acceptable.

Hazards	Number of risk control measures	Evaluation	
		Acceptable	Unacceptable
R1: ESD	6	👍 ⟸	
R2: Magn. field	-	👍	
R3: Lightning	-	👍	
R4: RF field	3	👍 ⟸	

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EM risk management report

The risk management report ensures that:

- The risk management plan has been appropriately implemented;
- The overall residual risk is acceptable (summary of results);
- Appropriate methods are in place to obtain relevant production and post-production information;
- The ongoing safety and performance of the device is acceptable.

The risk management report should be available before a medical device is released for commercial distribution.

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Summary

The standard method for **medical device risk management** is **ISO 14971**.
It starts with a risk management plan.
The implementation flows through a series of steps:

1. Risk analysis
2. Risk evaluation
3. Risk control
4. Residual risk evaluation
5. Risk management report
6. Production & post-production information

The information is maintained in the risk management file. That's a living document over the operational lifetime of the medical device.

Risk management of **electromagnetic disturbances** is required by the safety standard for medical electrical equipment **IEC 60601-1-2:2014**.

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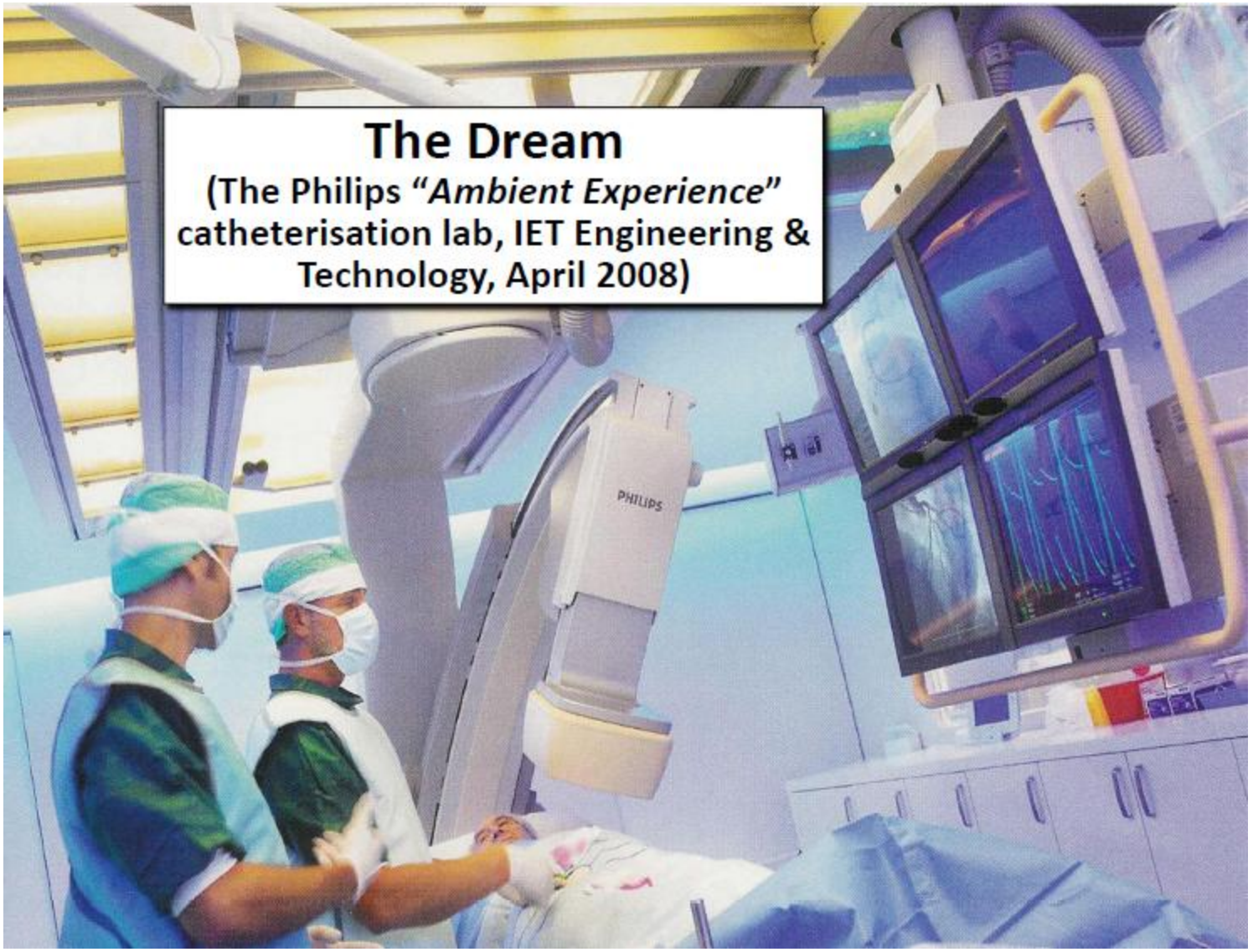
The Dream
(The Philips "*Ambient Experience*" catheterisation lab, IET Engineering & Technology, April 2008)
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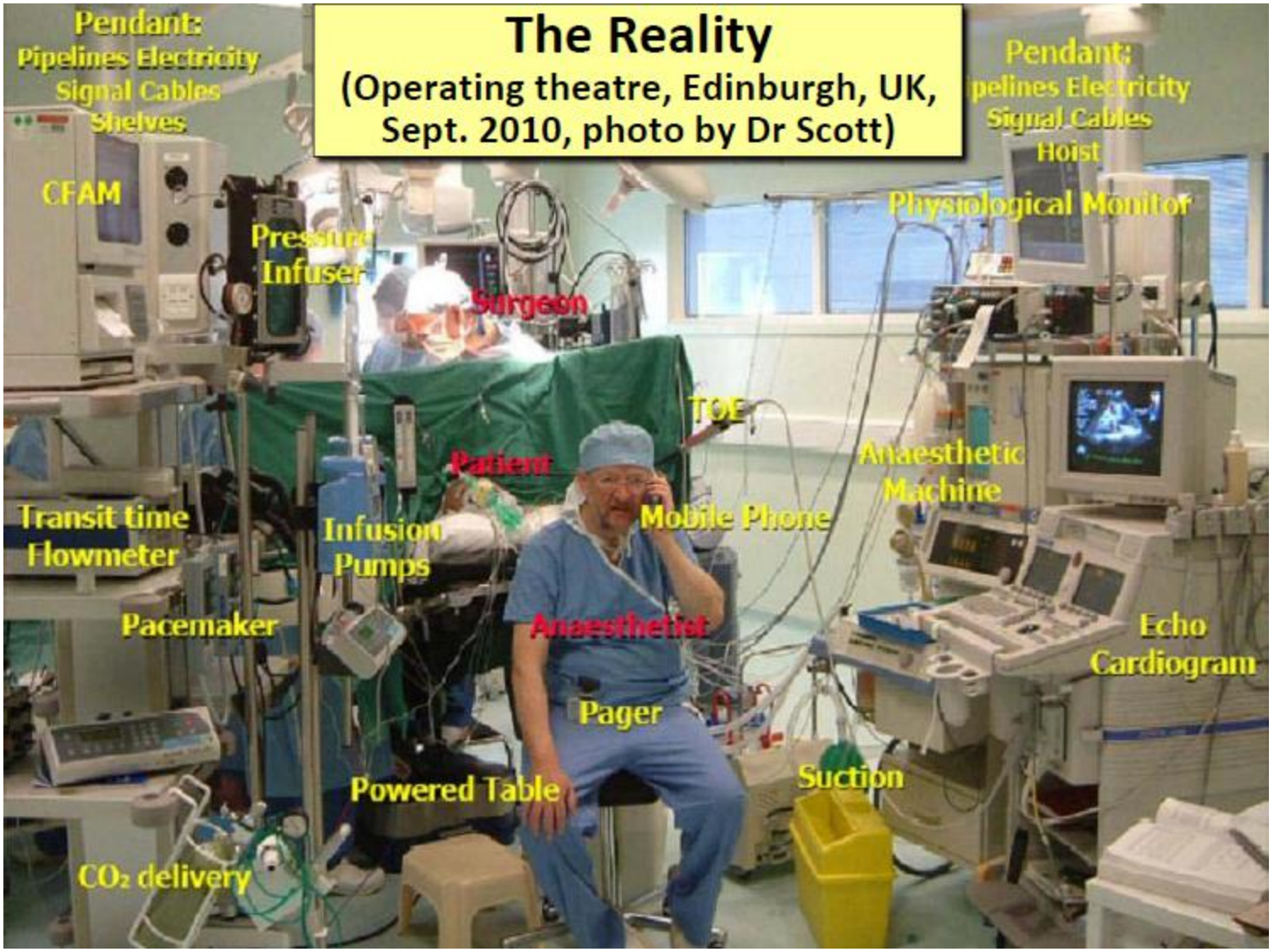
The Reality
(Operating theatre, Edinburgh, UK, Sept. 2010, photo by Dr Scott)
Pendant:
Pipelines Electricity
Signal Cables
Shelves
CFAM
Pressure Infuser
Surgeon
Pendant:
pelines Electricity
Signal Cables
Hoist
Physiological Monitor
TOE
Patient
Anaesthetic Machine
Transit time Flowmeter
Infusion Pumps
Mobile Phone
Pacemaker
Anaesthetist
Echo Cardiogram
Pager
Powered Table
Suction
CO_2 delivery

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