WSC high-level workshop on

International Standards for Medical Technologies

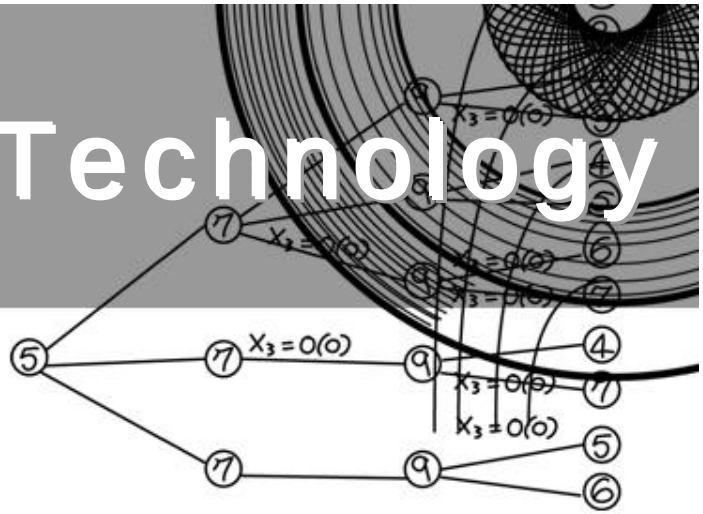
Standards and New Technology

or

Choosing what you want to be when you grow up.

Charles Sidebottom
February 2004

Standards and New Technology



- **When should standards lead technology?**
  - Case study – Cardiac pacemakers and mobile telephones
  - Case Study – Cardiac valve prostheses
- **What is necessary for success?**

Standards and New Technology

Medtronic

Medtronic is the world leader in medical technology providing lifelong solutions for people with chronic disease.

Medtronic's first office building and manufacturing facility in Minneapolis, Minnesota

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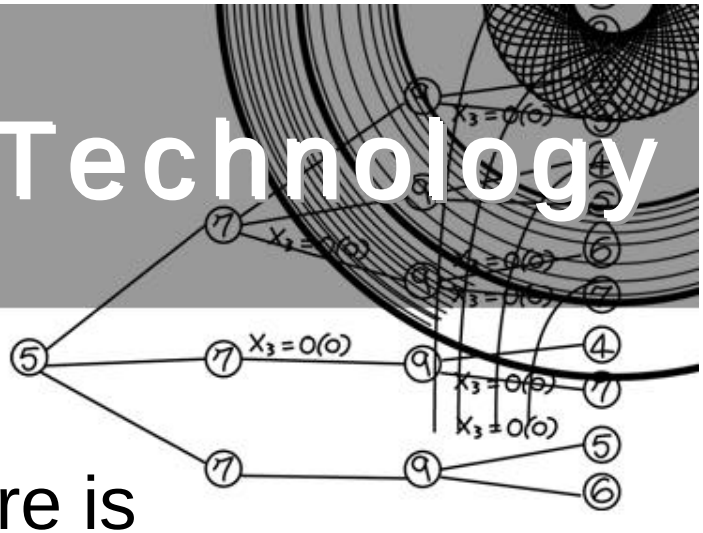

Guiding principles

- Write a standard only when there is a clear patient safety need validated by risk assessment.
- Focus on requirements that address basic safety and essential performance.
- Ensure that the stakeholders are involved from the beginning.

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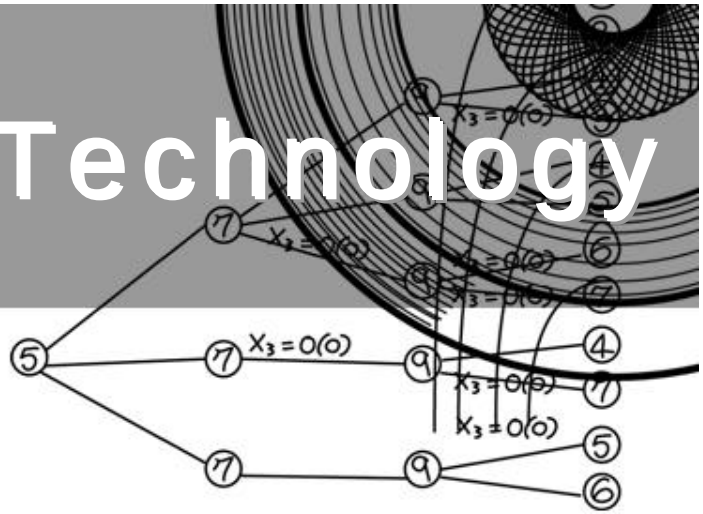

Case Studies:

- **Cardiac Pacemakers and Mobile Telephones**
- **Cardiac valve prostheses**

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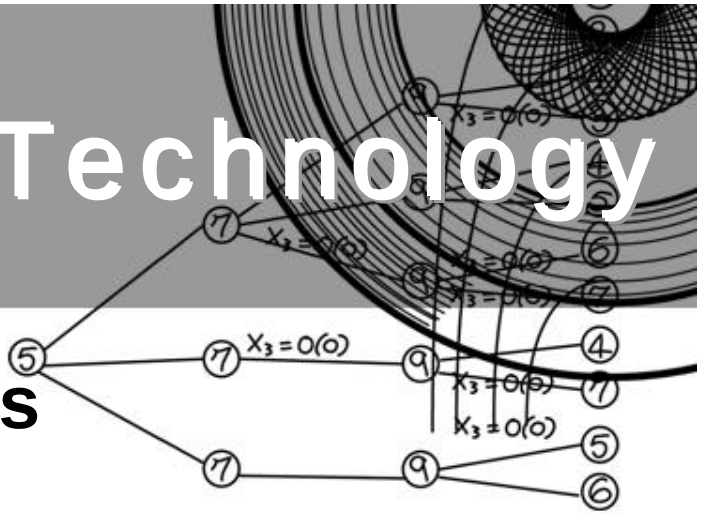

Case Study: Cardiac Pacemakers and Mobile Telephones

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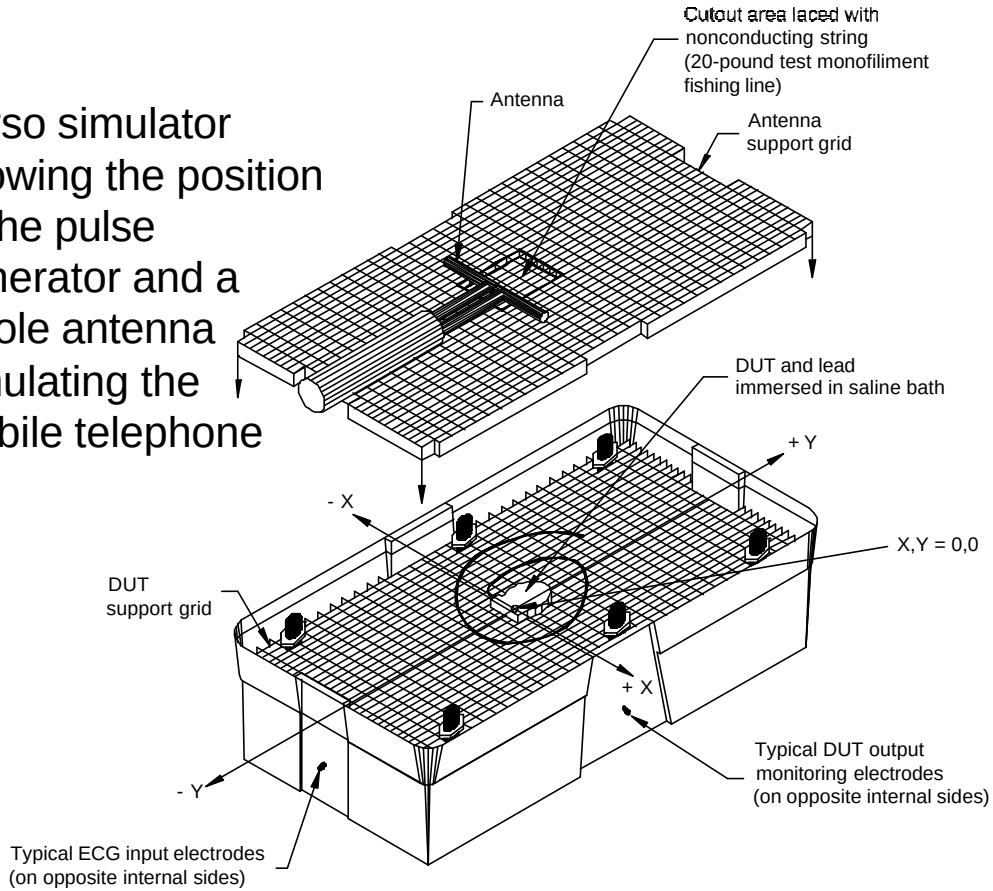
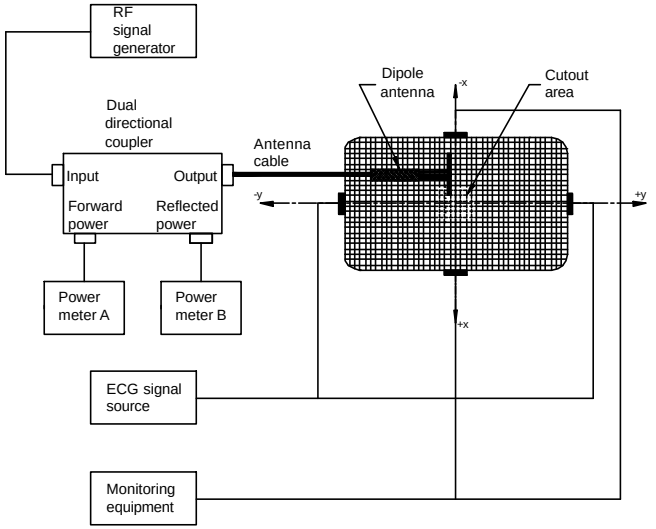
Case Study: Cardiac Pacemakers and Mobile Telephones

Torso simulator showing the position of the pulse generator and a dipole antenna simulating the mobile telephone



The test system uses a dipole antenna and worst-case modulation at mobile phone operating frequencies to test for interactions.



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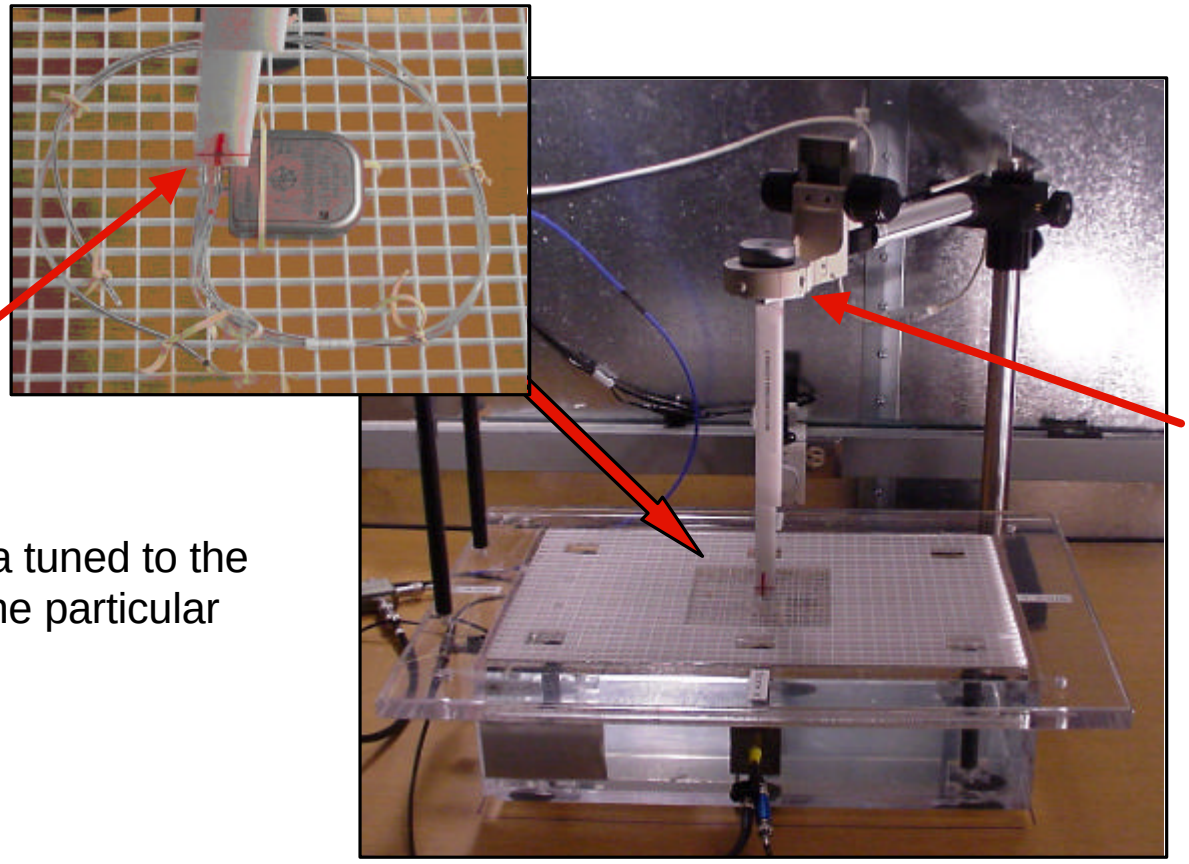
Case Study: Cardiac Pacemakers and Mobile Telephones



Dipole antenna tuned to the frequency of the particular test.

Computer controlled robot arm that precisely positions and orients the dipole antenna relative to the pulse generator

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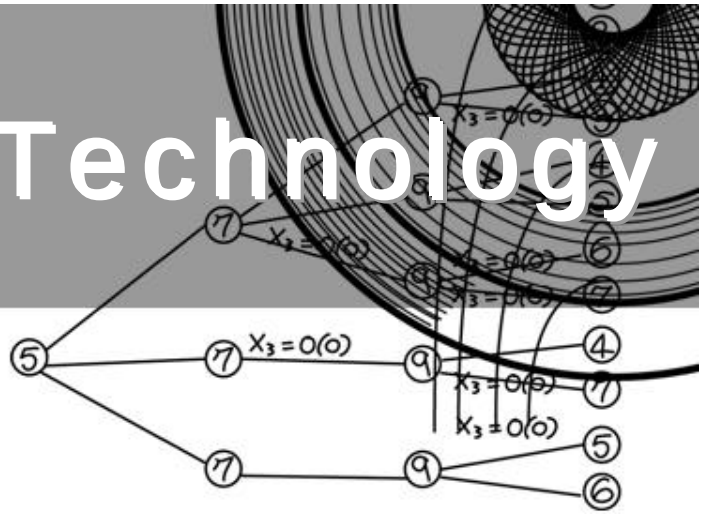

Case Studies:

- Cardiac Pacemakers and Mobile Telephones
- **Cardiac valve prostheses**

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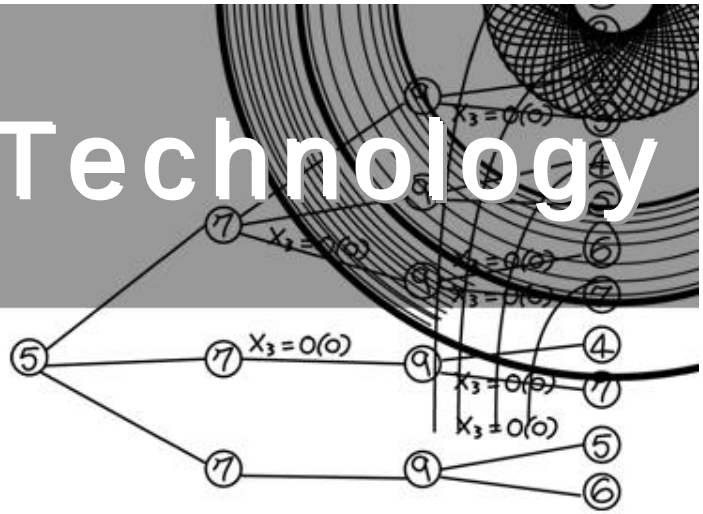
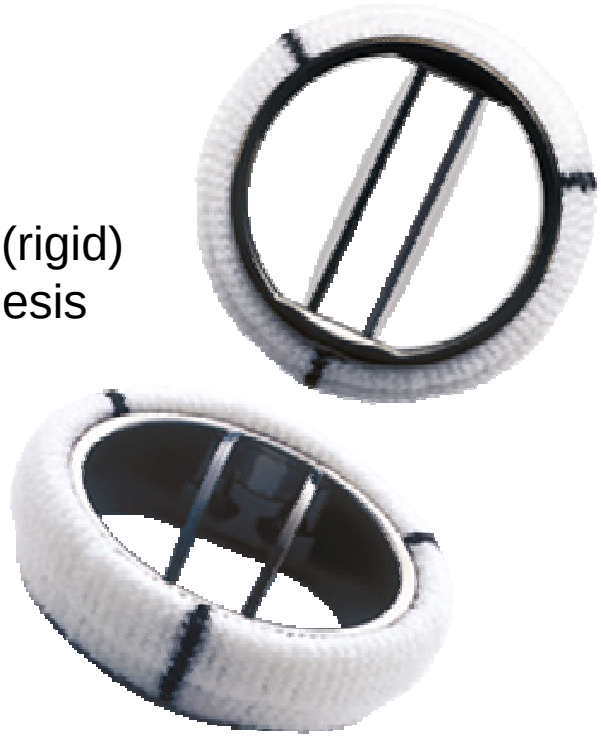


Case Study: Cardiac valve prostheses

Mechanical (rigid) valve prosthesis



Tissue (flexible) valve prosthesis

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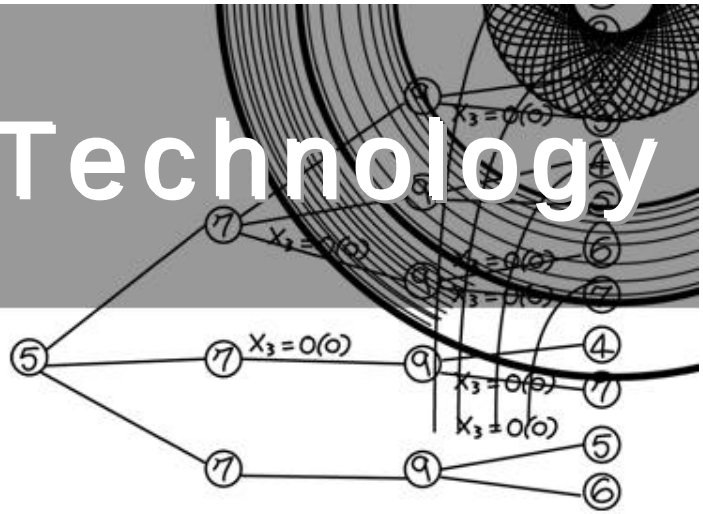
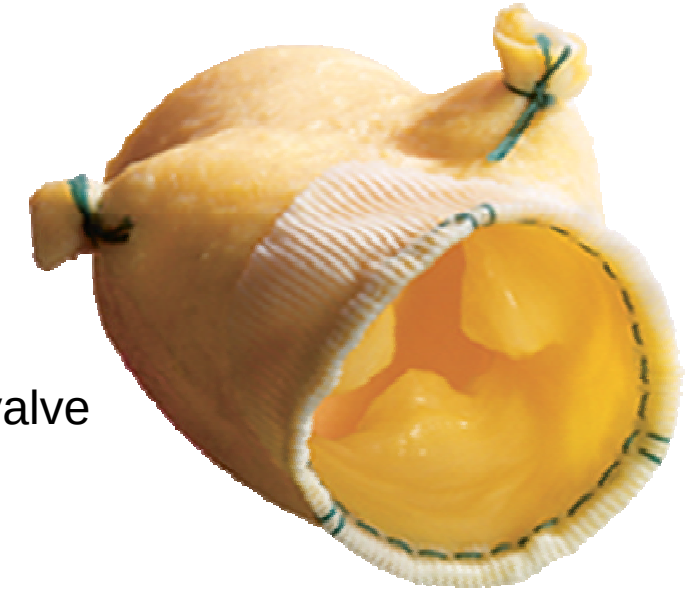


Case Study: Cardiac valve prostheses

Stented valve prosthesis

Unstented valve prosthesis



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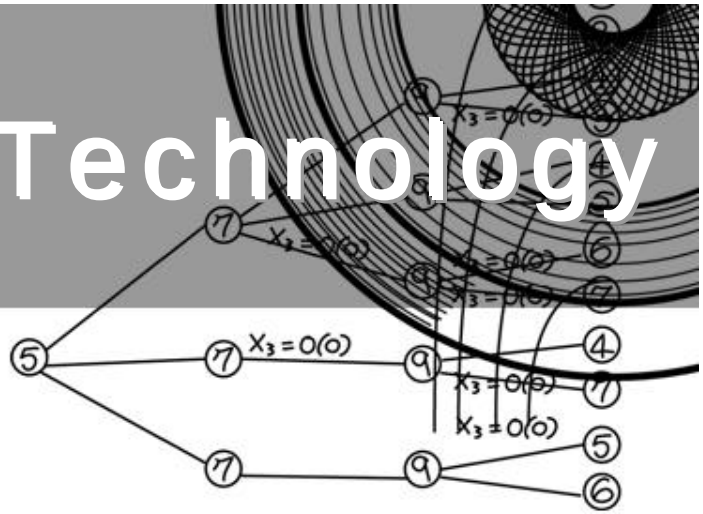

Case Study: Cardiac valve prostheses

- **ISO 5840**
  - First edition published in 1984
  - Revised three times (1989, 1996 and 2004)
  - The first three editions were written using a “traditional” requirements-based model
  - In recent years, this model has proved unsatisfactory because of the speed of technological innovation

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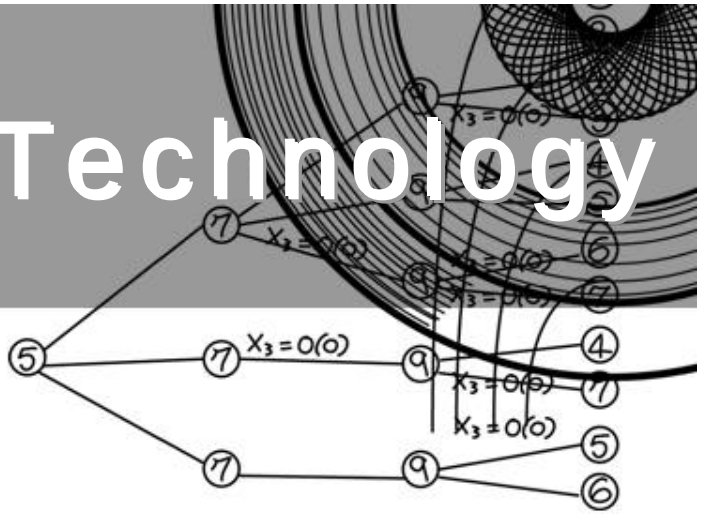

Case Study: Cardiac valve prostheses

- **ISO 5840** (4th edition)
  - Risk-based model
  - Includes best practice methods for verification testing
  - Provides guidance on a risk classification system

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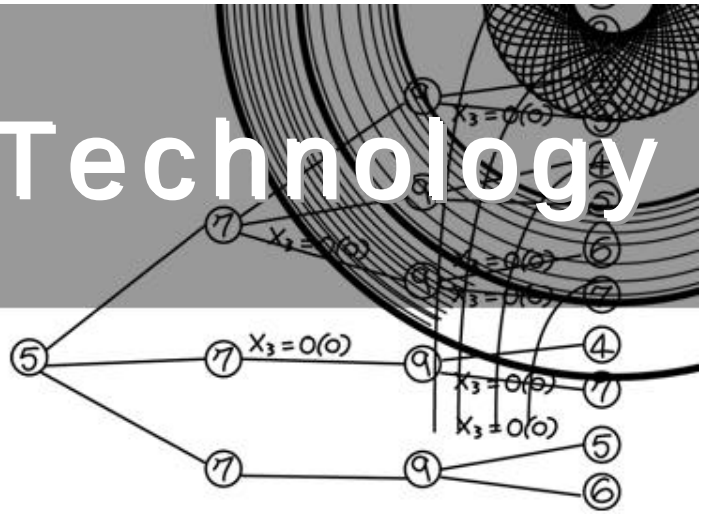

- **When should standards attempt to lead technology?**
  - When there is a clear patient safety need that can be validated
- **What is necessary for success?**
  - A focus on requirements that address basic safety and essential performance
  - Ensuring that all the key stakeholders are involved from the beginning