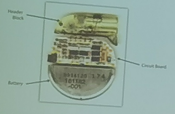




Implantable Pacemaker Circuit

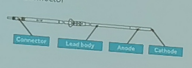
Implantable pulse generator (IPG)

- Battery (lithium-iodine)
- Electrical circuitry
- Microprocessor and memory
- Connector(s)

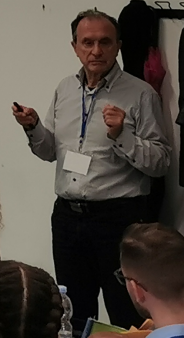


Leads (wires)

- Cathode (negative electrode)
- Anode (positive electrode)
- Lead body
- Connector




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Implantable Pacemaker Circuit


Implantable pulse generator (IPG)

- Battery (lithium-iodine)
- Electrical circuitry
- Microprocessor and memory
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Leads (wires)

- Cathode (negative electrode)
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- Connector



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Pacemaker systems
Basic classification

Single chamber

- Implanted one lead only
- Usually in the right ventricle

Dual chamber

- One lead implanted in right atrium and one in the right ventricle

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Pacemaker systems
Basic classification

Single chamber

- Implanted one lead only
- Usually in the right ventricle

Dual chamber

- One lead implanted in right atrium and one in the right ventricle


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Pacemaker systems
Biventricular


Single chamber

- Implanted one lead only
- Usually in the right ventricle



Dual chamber

- One lead implanted in right atrium and one in the right ventricle



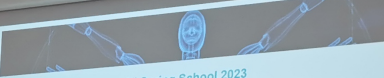
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XI Spring School 2023
**IoT, economic and management challenges
for e-health integration in the enlarged Europe**
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CEI COOPERATION ACTIVITY
WITHIN THE HIGHER EDUCATION IN CLINICAL ENGINEERING (SSIC-HECE) MASTER'S PROGRAMME
TRIESTE 5TH-6TH JUNE 2023
Piazzale Europa, Trieste, Italy
eProcurement in Health
Dr. Jozef Grčar, Professor Emeritus, University of Maribor, Slovenia
Program Coordinator, Inter-Municipality Initiative: Cross-border eCollaboration in the eRegion
So-Coordinator, Global Network of Associations & Networks: Retirees Developing Silver Economy
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eProcurement in Health

Dr. Jozse Grigar, Professor Emeritus, University of Maribor, Slovenia
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The issues in eProcurement in Health Sector

- Implementation complexity
- Data integration and interoperability
- Supplier onboarding and integration
- User adoption and training
- Security and data privacy
- Supplier diversity and competition
- Maintenance and upgrades
- Legal and regulatory compliance



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Advances in Digital Health

Convergence of Digital Health
and MedTech

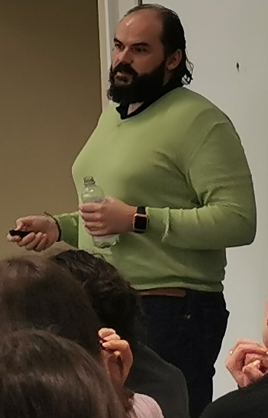


Mate Bestek, PhD
Head of MedTech and Digital Healthcare

VERSION 1
6 June 2022
University of Twente

MedTech Digital Transformation

- Connectivity
- Data Management
- Digital Twins
- Software as Medical Device (SaMD)







Clinical expertise
and investments

FY21
data

\$2.5B
in R&D
investments


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Cardioverter-Defibrillators
"High-voltage" devices


External Defibrillator

- Delivers 360J
- Not in CRM portfolio
- PhysioControl (former MDT)

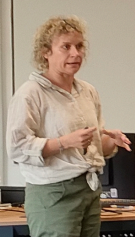


Implantable Cardioverter-Defibrillator

- Delivers 25-40J directly to the heart
- For this capacitors need to be charged to ~800V



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Sudden Cardiac Arrest vs. Heart Attack

SUDDEN CARDIAC ARREST (SCA)

An electrical problem



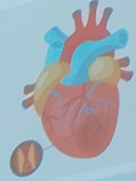
CAUSE: Electrical malfunction of the heart that causes the heart to stop beating.

RISK FACTORS: Previous heart attack, heart failure, abnormal heart rhythm, low ejection fraction (EF), 35% family history of SCA, coronary artery disease.

SYMPTOMS: Generally no symptoms, may experience racing heartbeats, lightheadedness, dizziness, fainting.

HEART ATTACK

A circulation or plumbing problem



CAUSE: Blockage in a vessel that supplied blood to the heart muscle, which may permanently damage part of the heart.

RISK FACTORS: High cholesterol, high blood pressure, obesity, smoking, family history of heart attack, diabetes, coronary artery disease.

SYMPTOMS: May be accompanied by pressure in the chest, pain radiation to the arm, shortness of breath, sweating, nausea. Women may have different symptoms such as pain or discomfort in the back, neck, jaw, or stomach.

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What are the
challenges?

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MedTech QMS key components

- Design Control - regulatory requirements and customer needs
- Risk Management - identify and mitigate risks
- Document Control - SOPs
- Supplier Management - evaluate, select and monitor
- Corrective and Preventive Actions - identify, investigate and resolve quality issues
- Complaint Handling - identify, document, investigate and resolve customer complaints



24 MedTech QMS key components

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25 MedTech QMS key components

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Thank you for your attention!

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