Ludwig Boltzmann Cluster
kardiovaskuläre Forschung

Zentrum für Medizinische Physik und Biomedizinische Technik

MEDIZINISCHE UNIVERSITÄT WIEN

Praktische Auswirkungen erhöhter regulatorischer Anforderungen auf die Entwicklung innovativer Medizinprodukte

a.o.Univ.Prof. DI Dr. Heinrich Schima

European Alliance for EAMBES Medical and Biological Engineering & Science

© H.Schima LISA-Meeting June 16

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Inhalt:

- kein Vortrag, sondern ein kurzer Lagebericht
aus BMT-Forschungs-Sicht!

- Hintergrund der eigenen Arbeitsgruppe

- Medizintechnik als Treiber für klinische Fächer

- Die neue Medical Device Regulation:
  Standpunkte aus F&E-Sicht

- Diskussion über weitere Schritte

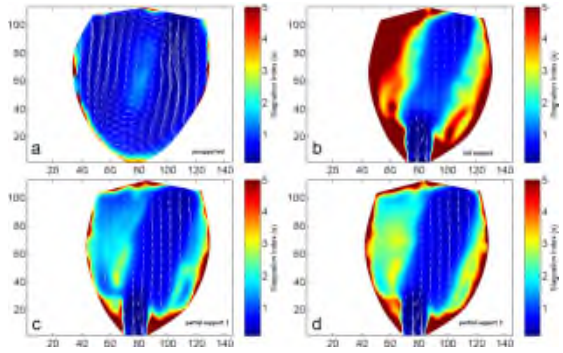
Cardiovascular Dynamics and Internal Artif. Organs

40 Years of Research and
Clincial Application of
Artif. Heart & Assist Devices,
Cardiovascular Implants,
Cardiovascular Diagnostics

- Pump development & Evaluation
- Component development
- Algorithm development and clin. test
- Usability Studies
- Clinical care for currently 80 ongoing pts
- Studies on Grafts, Ultrasound Diag.

* Worldwide first physiological Control
* Ww. first discharge of a patient with rot.Pump
* Unique noninvasive diagnostics

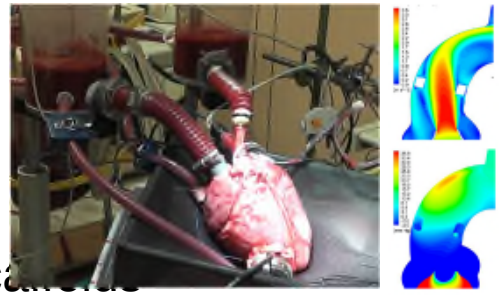
1 year and 21 years
after Vie Artif Heart

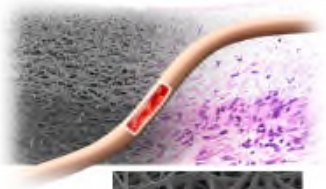


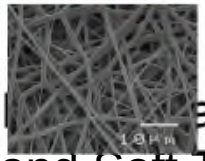
Examples:
- Flow visualization
- Ww. patented Cannula
- 7/24 Data Recorder

Cardiovascular Dynamics: Expertise and Offers

- Haemodynamic Testing
  and Simulation, Bioreactors
  Prof. Schima

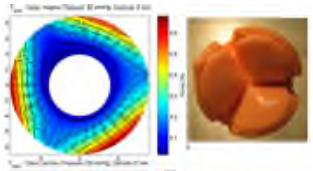


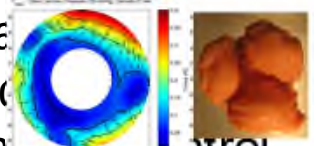


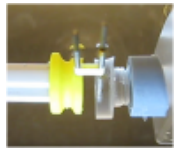


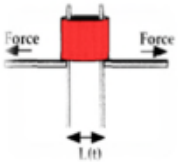
- Nano-Electrospinning
  DI Grasl

- Prostheses
  and Soft Tissues DI Stoiber

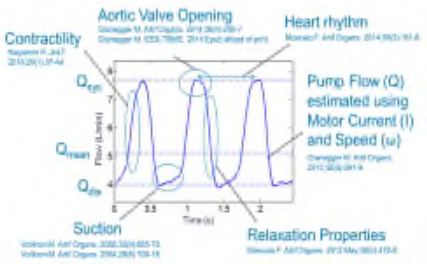


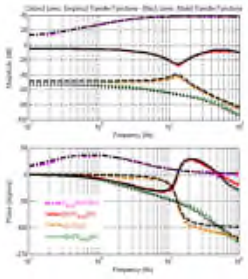


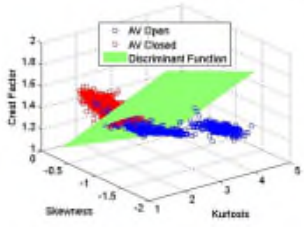




- Mathematica
  Biosignal Pr
  Identification
  cato



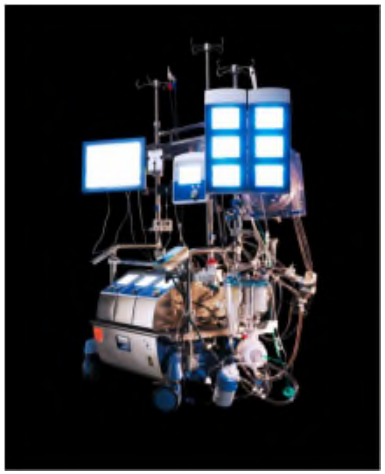




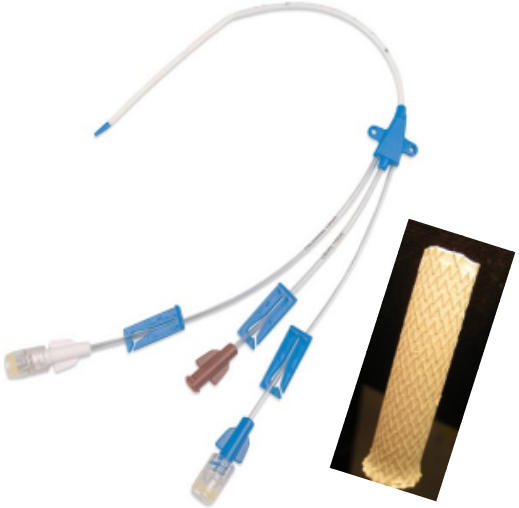
Biomedical Engineering is a key driver for medical specialities:

Example: From the Homepage of the Austrian Society for Cardiology:

" The reason for cardiology to become an early speciality of internal medicine was the rapid development of Biomedical Engineering particularly for cardiovascular applications, which could not be even imagined before",



such as - Echocardiography,
- Cardiac Catheter
- Angiography
- Heart-Lung-Machine
- Pacemaker
- Artificial valves
- Stents



www.atcardio.at © Riedler, www.photography.at

Die neue Medical-Device Regulation

- Regulation, nicht Directive!

- Ursprünglich schon für 2013 geplant, verschiedene Verzögerungen

- Spannungsfelder zwischen Ärzten, Patientenvertretern, Behörden, Prüfstellen, Großunternehmen, KMUs und Forschungsinstitutionen

- Ein Kompromiss-Beschluß erfolgte am 25. Mai, dieser scheint jedoch von der Kommission noch nicht akzeptiert worden zu sein. Weitere Beschlüsse sind für Frühsommer und Ende/Anfang nächsten Jahres zu erwarten.

- Die derzeitige Fassung ist nicht öffentlich bekannt!

EAMBES Position Paper about the MDR

- Status as of August 2015

- Describes aspects mainly from the academic and development perspective

- The MDR will not affect only patient care and medical industry, but also the biomedical engineering research community.

- "There is no doubt, that after 20 years the current MDDs require an overhaul"

- Many of the proposed changes are welcomed, such as the introduction of investigational devices..."

Eambes Position paper (II)

- For many devices, an upward classification to class III would lead to a dramatic increase of clinical studies. This would e.g. affect all devices with closed loop controllers (such as Anaesthesia machines..., many in the market for decades with excellent safety records)

- Exclusion of the option to provide clinical data of equivalent devices

- Medical device studies are different to pharmacological studies
  - Many devices considered as tools, not as therapy,
  - Different behavior in side effects
  - Different study size,
  - Different number in applications, market size
  - Many niche products, personalized applications

Eambes Position paper (III)

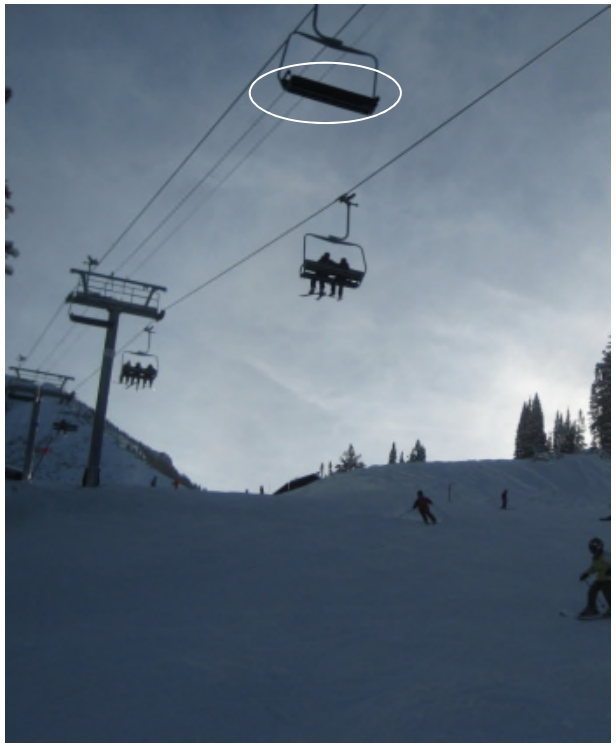
- An overregulation would massively impede small and medium enterprises, which currently provide technologies for many niche applications.
- Less BME research would be translated into new, better, safer and less costly diagnostics and treatments for patients.
- Less BME research outside the mainsream wil lbe sponsored by the large industry players.
- Large players may experience the least relative impact, but may continue to focus on large lucrative segments in the medical device wolrd on a global scale.

Eambes Position paper (IV)

"Increase in Regulatory burden beyond certain levels
does not improve patient safety!"

- "The longer and more expensive processes of the FDA have not led to improved patient safety. "

Usability and Liability: The US Viewpoint



We have intentionally no bar at the seat, so we cannot be sued for malfunctions!

(Park City, Utah 2007)

"...we do not provide an automatic switch-over of wall supply to compressor, that may fail. It is the responsibility of the nurse! (Leading Engineer, xx-company 2000)

Eambes Position paper (V): Recommendations

- Reconsider the need for clinical investigations for med. devices, especially long standing safe technologies;

- Allow conclusive demonstration of safety by compliance with standards; allow alternatives such as registries

- Be careful with classification in class III (e.g. closed loop controllers);

- Non-therapeutic devices and tools should be exempt from the need for clinical studies.

- A centralized complaints database with public access (like FDA MAUDE) should be established (EUDAMED..).

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Founding a BMT-European Parliament Interest Group

May 31st, 2016

© H.Schima LISA-Meeting June 16

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Next steps scheduled:

- Better involvement of European Biomed. Engineers

- Acknowledgement of Biomedical Engineers as a registered Profession

- Details of the MDR-Implementations ("Durchführungsakte") still to be negotiated !

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Thank you!