



New European Regulations, MDR and IVDR

Ing. Stefano Bergamasco
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BioingTS

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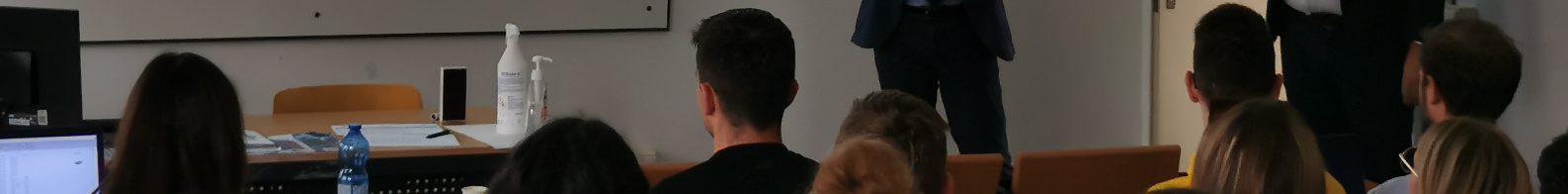
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INGEGNERI CLINICI

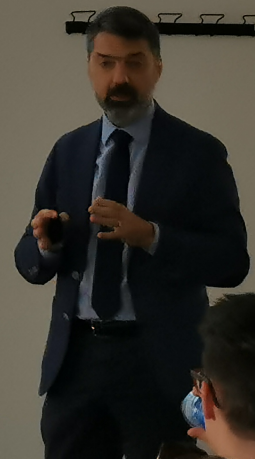
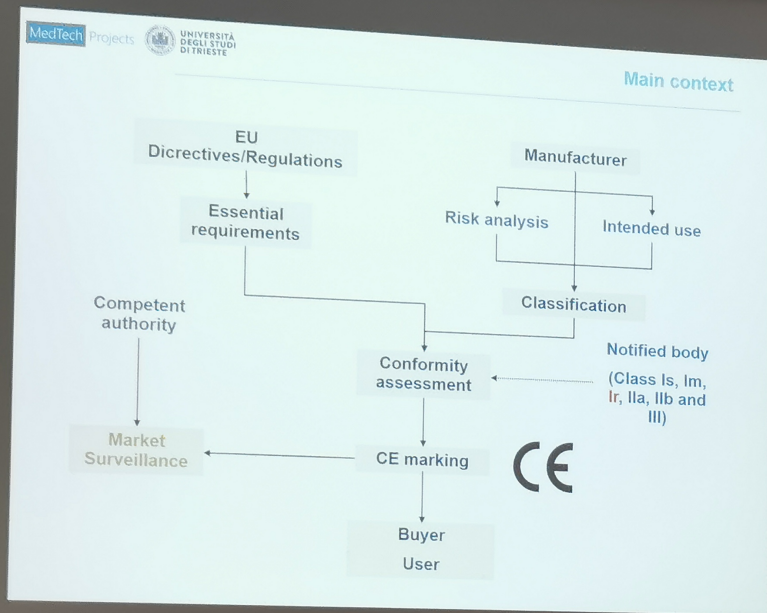
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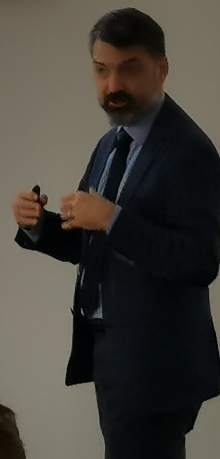
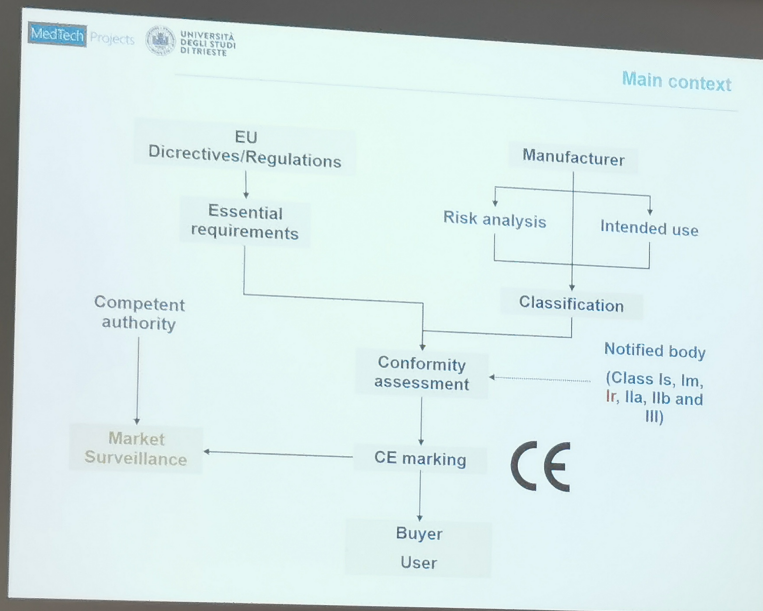
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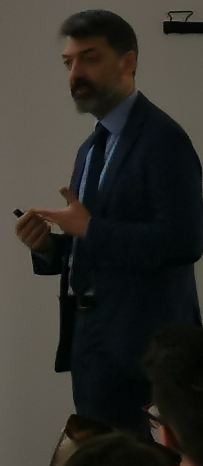

















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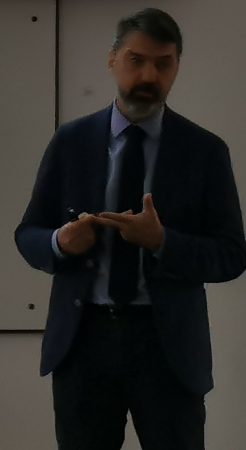
What has changed? Main points ...


-  Risk classification of devices and scope of the Regulations
-  Clinical investigations (MDR Articles 62 to 82) and performance studies (IVDR Articles 57 to 77)
-  Obligations and regulatory requirements of economic operators⁶
-  CE marking of conformity (MDR Article 20 and IVDR Article 18)
-  Traceability
-  Identification
-  EUDAMED database
-  Labelling and instructions for use
-  Carcinogenic, mutagenic or reprotoxic (CMR) substances and endocrine disruptors
-  In-house devices
-  Custom-made devices
-  Nanomaterials
-  Reprocessing of single-use medical devices
















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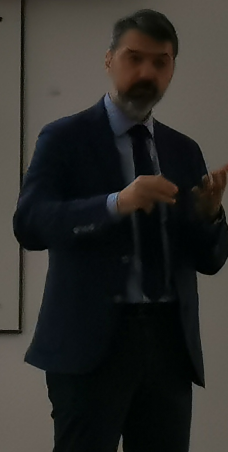
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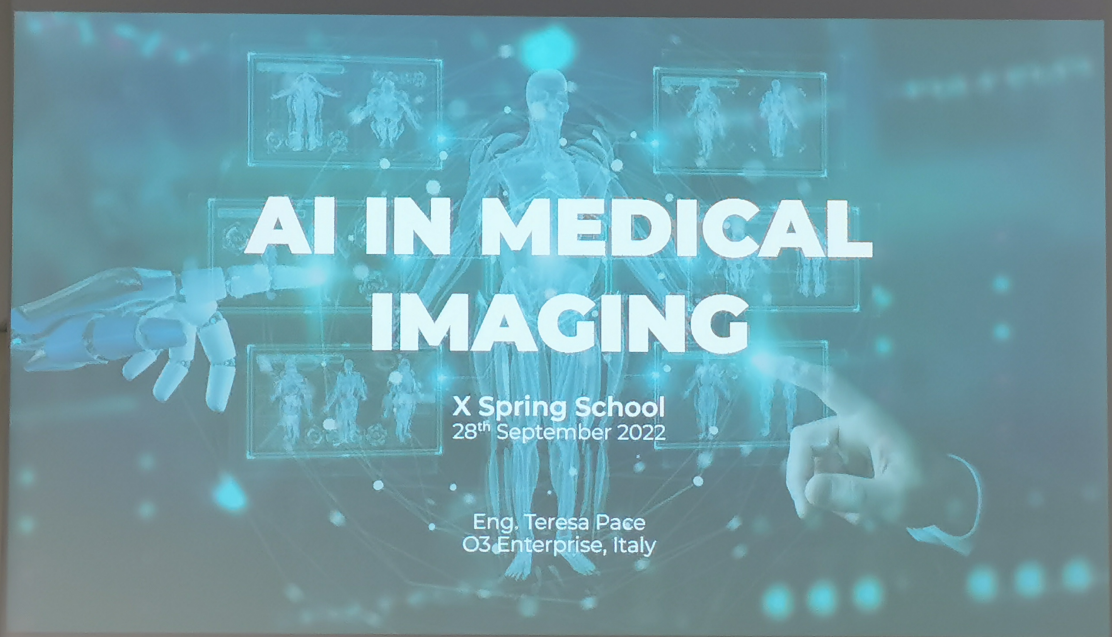
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AI IN MEDICAL IMAGING

X Spring School
28th September 2022

Eng. Teresa Pace
O3 Enterprise, Italy







MKS Ltd., Ljubljana profile

- R&D micro SME (1990) – service integrators & enablers
- Active nationally and internationally
- EU projects
 - NITICS (AAL), ACESO (AAL), Telescope – EAHC (Partner)
 - United4Health – ICT PSP (Subcontractor)
 - REHA2030 (SI-AT Interreg)
 - EASY-IMP (Personal engagement)
 - 18 unsuccessful applications
- National project: Telerehabilitation, Telecare, Obstetrics
- Set-up&run: telemedicine centre CEZAR (2014 GH SG), telecare centre (1991 Ljubljana, 1997 Celje)
- Contribution to the national strategies and legislation (active ageing, long-term care, telehealth, telecare)
- Collaboration with national academic institutions

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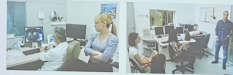
Public sector



- Institute for oncology and radiology of Serbia, <https://www.onc.rs/>
- Practical part for the course Clinical engineering: MRI (Magnetic Resonance Imaging) class.
- Photography: Medical radiology specialist Drasko Vidovic and dipl. engineering: Miroslav Petrovic, clinical engineer (left photo), and EIT students with M.Sc. E.E. Tihomir Zivc, clinical engineer (right photo). Photos were taken on June 6, 2018 @Institute of oncology and radiology.

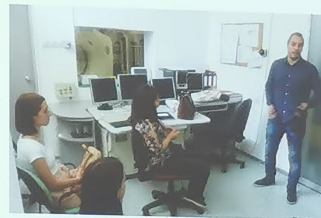


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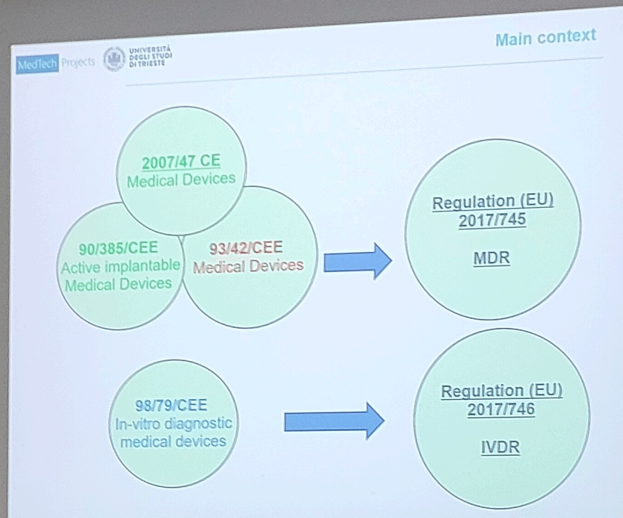


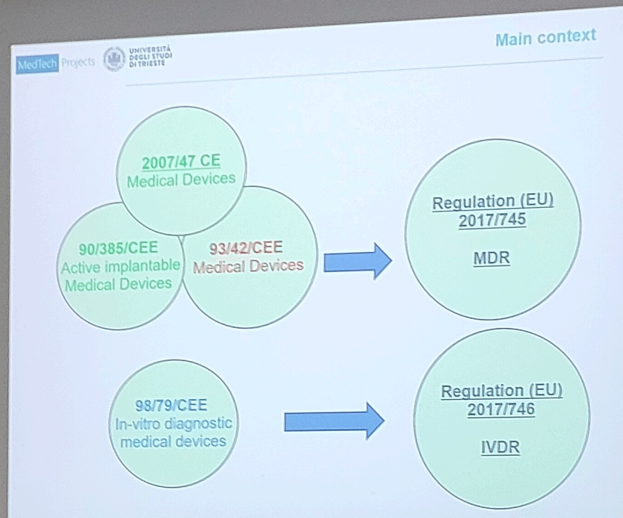












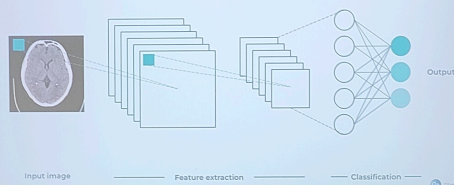




Convolutional Neural Networks



Convolutional Neural Networks

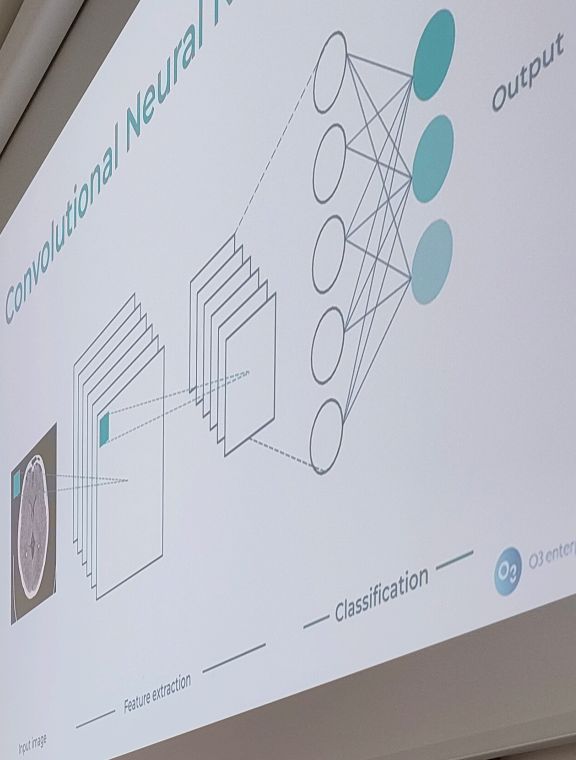








Convolutional Neural Network

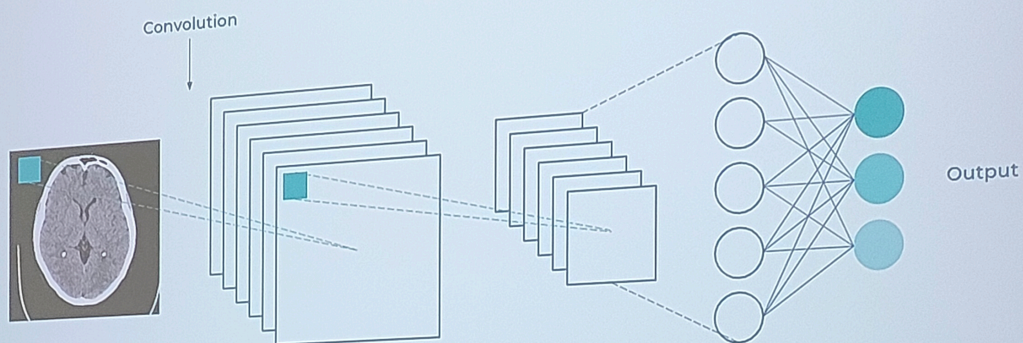




Convolutional Neural Net



Convolutional Neural Networks

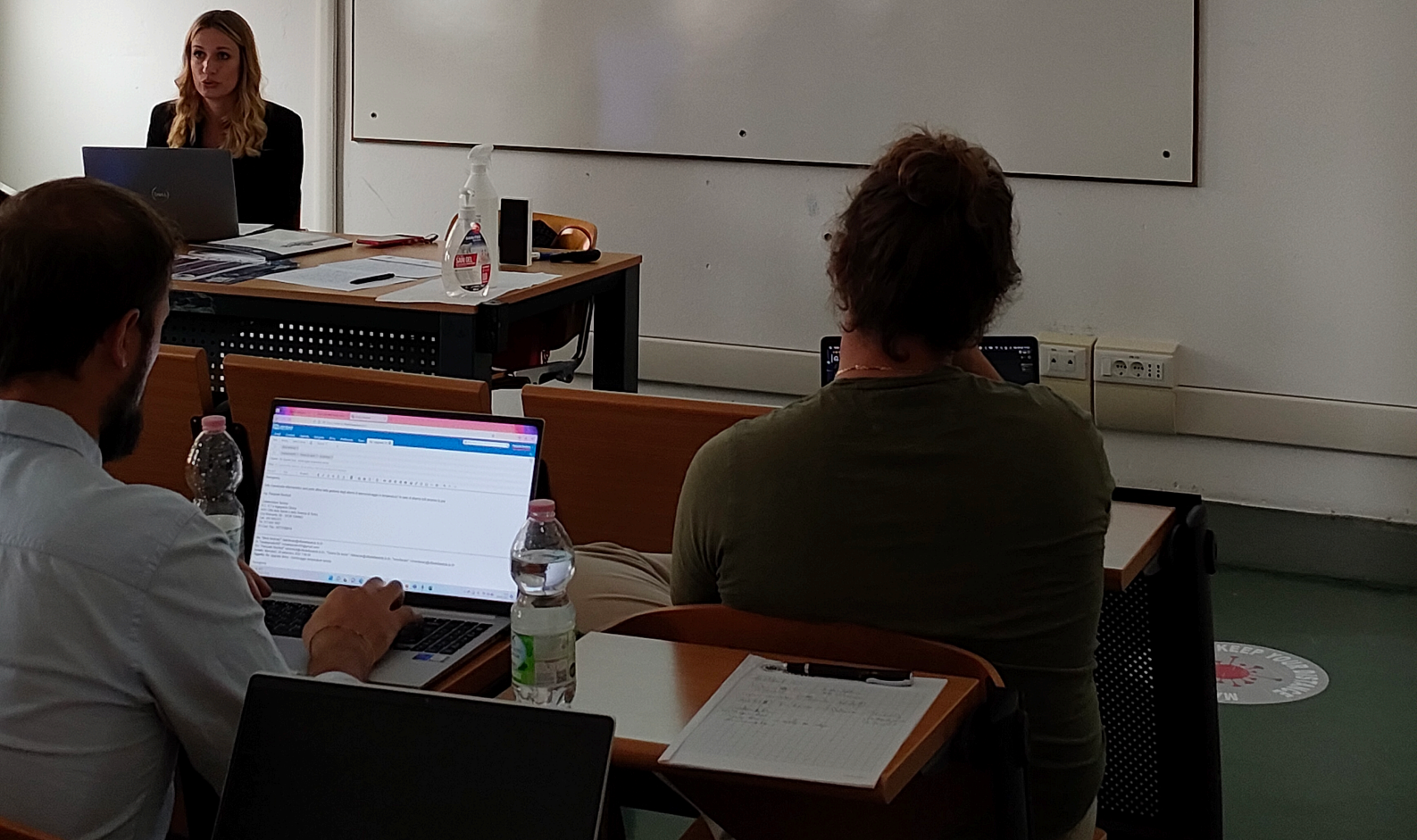


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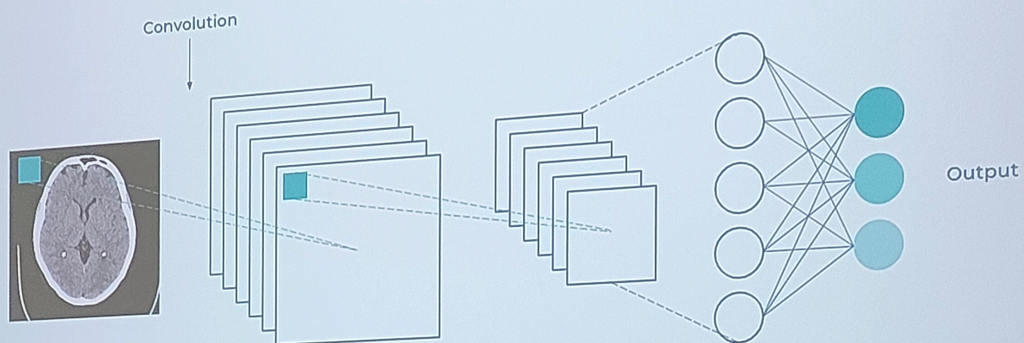
Feature extraction

Classification

O2 O3 enterprise



Convolutional Neural Networks

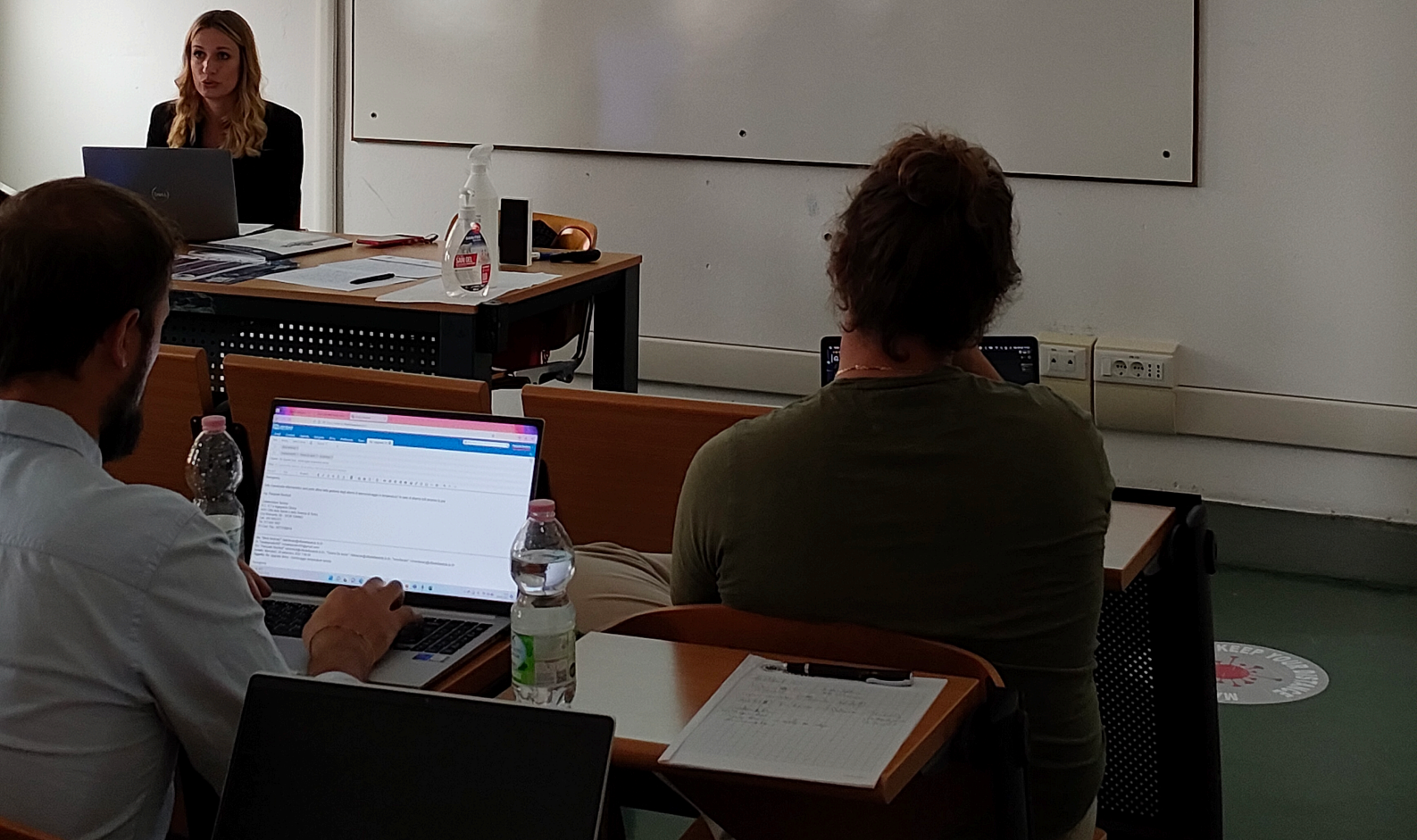


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Telerehabilitation at home -
arm exercising

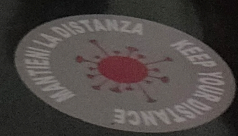
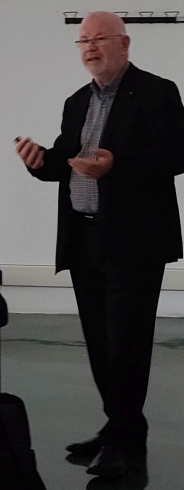
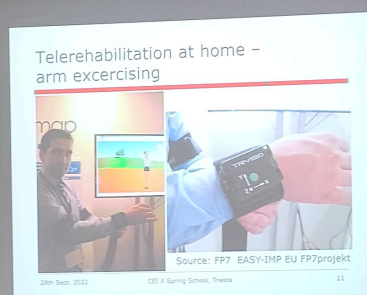


Source: FP7 EASY-DMP EU FP7project

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Chronic diseases – A challenge for today not tomorrow!

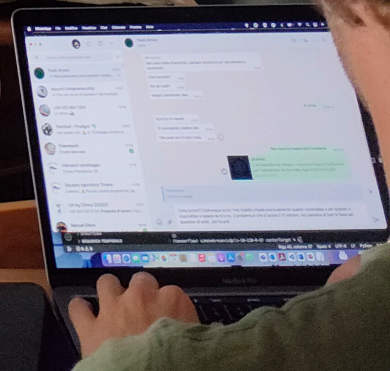
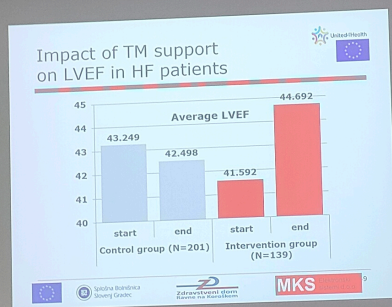


Source: British Medical Journal, 26 October 2002

Chronic diseases – A challenge for today not tomorrow!



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More study programs/courses in Serbia

- R&D center BiolRC and the R&D at the Faculty of Mechanical Engineering, University of Kragujevac (<http://www.biolrc.ac.rs/>)
 - Recently, they accredited a PhD in Bioengineering
- Faculty of sport and physical education, University of Belgrade (<http://www.dif.bg.ac.rs/en/>)
- Private Universities also have experts with the knowledge from biomedical engineering.
- There was only one course on Clinical engineering in Serbia. And I tech it! This year is 13th anniversary since this course was introduced.
 - Recently, one course on Clinical engineering was introduced at the Faculty of Mechanical Engineering, University of Belgrade (<https://www.mex.bg.ac.rs/studije/predmeti/0820>)





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