

VII Gruppo Nazionale di Bioingegneria

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Tracks & Chairs

Theme 1 - Informatics and Electronics

1.1 - E-Health and clinical engineering

Mario Cesarelli, *Università di Napoli*

Giovanni D'Addio, *Istituti Clinici Scientifici Maugeri Spa*

1.2 - Biomedical signals, images, and Bioinformatics

Giuseppe Baselli, *Politecnico di Milano*

Maria Gabriella Signorini, *Politecnico di Milano*

Theme 2 - Clinical Biomechanics

2.1 - Biomechanics and mechanobiology

Francesco Migliavacca, *Politecnico di Milano*

Umberto Morbiducci, *Politecnico di Torino*

2.2 - Biomaterials, tissue engineering and regenerative medicine

Luca Cristofolini, *Università di Bologna*

Alberto Audenino, *Politecnico di Torino*

Theme 3 - Applied Bioengineering

3.1 - Artificial Organs, Medical and assistive robotics

Cecilia Laschi, *Scuola Superiore Sant'Anna di Pisa*

Leonardo Ricotti, *Scuola Superiore Sant'Anna di Pisa*

3.2 - Neural and rehabilitation engineering

Eugenio Guglielmelli, *Università Campus Bio-Medico di Roma*

Loredana Zollo, *Università Campus Bio-Medico di Roma*



Day 1: Informatics and electronics

Podium session:

[A Stochastic Language Model of Italian Applied to Functional MRI during Narrative Listening](#)

Andrea Gerardo Russo, Maria De Martino, Azzurra Mancuso, Francesco Di Salle, Alessandro Laudanna and Fabrizio Esposito

[Automated Detection and Counting of Acne Lesions for Evaluation of Acne Severity](#)

Antonella Melina, Pietro Salvagnini, Carlo Cosentino, Francesco Amato and Andrea Cherubini

[3D Printing open source non-critical spare parts of medical devices: the oxygen concentrator as a case study](#)

Licia Di Pietro, Carmelo De Maria, Giuseppe Gallone and Arti Devi Ahluwalia

[Towards classification of ovarian cancer via micro-arrays data analysis](#)

Diego Liberati

[Radiomics-based prediction of head and neck cancer recurrence: a multi-centric MRI study](#)

Marco Bologna, Valentina Corino, Giuseppina Calareso, Salvatore Alfieri, Rebecca Romanò, Laura Locati, Lisa Licitra and Luca Mainardi

[Does a medical device nomenclature suitable for all purposes exist? Twenty years of Italian experience with the CND and its adoption in EUDAMED at European level](#)

Michela Franzo', Federico D'Agostino, Catello Chierchia, Katuscia Cucchiara, Eugenio Carrani, Letizia Sampaolo, Elisabetta Stella, Marina Torre and Mauro Asaro

[Resting State Networks spatio-spectral fingerprints: the Default Mode Network case study](#)

Ilaria Mazzonetto, Ettore Ambrosini, Antonino Vallesi and Alessandra Bertoldo

[Comparison of different CNNs for breast tumor classification from ultrasound images](#)

Jorge Lazo, Elena De Momi and Sara Moccia

[Predicting the Onset of Chronic Obstructive Pulmonary Disease in the English Longitudinal Study of Ageing](#)

Martina Vettoretti, Andrea Facchinetti and Barbara Di Camillo

Poster session:

[Human exposure to electromagnetic fields generated in smart vehicle communications](#)

Gabriella Tognola, Silvia Gallucci, Marta Bonato, Serena Fiocchi, Emma Chiamarello, Laura Dossi, Marta Parazzini and Paolo Ravazzani

[CT-based FFR: paving the way to future hearts](#)

Clarissa Bargellini, Quan Long and Tarun Mittal

[A 3D CNN for preterm-infants' movement detection in NICUs from depth streams](#)

Lucia Migliorelli, Sara Moccia, Giuseppe Pio Cannata, Alessia Galli, Ilaria Ercoli, Luigi Mandolini, Virgilio Carnielli and Emanuele Frontoni

[Single-subject analysis of the variability of the latency of heart sounds over 25-day period](#)

Noemi Giordano and Marco Knaflitz

[A Machine Learning Approach for Muscle Activity Detection](#)

Marco Ghislieri, Elisa Pavanelli, Samanta Rosati, Gabriella Balestra, Marco Knaflitz and Valentina Agostini

[Detection of the N2/N2pc event-related potential \(ERP\) components buried in the EEG using phase angle distribution across sweeps](#)

Francesca Marturano, Sabrina Brigadoi, Mattia Doro, Roberto Dell'Acqua and Giovanni Sparacino

[Automatic estimation of nerve tortuosity in corneal images](#)

Alessia Colonna, Fabio Scarpa and Alfredo Ruggeri

[Detecting the neural processes of lie generation with low-cost EEG: a preliminary study](#)

Davide Garofalo, Francesco David Nota, Fabrizio Zoleo, Francesco Bardozzo, Mattia Delli Priscoli, Roberto Tagliaferri and Fabrizio Esposito

[Model-based assessment of incretin effect from OGTT data in healthy subjects](#)

Micaela Morettini, Elisea Creato, Jessica Di Monte, Ludovica Ilari and Laura Burattini

[Electrocardiographic Alternans in Hemodialysis: A Case Report](#)

Ilaria Marcantoni, Jessica Di Monte, Chiara Leoni, Zahara Mansour, Agnese Sbröllini, Micaela Morettini and Laura Burattini

[Novel recurrence features for prefall and fall detection in backward and forward fall types](#)

Amnah Nasim, David Chukwudi Nchekwube, Elnaz Khorasani, Nina E Van der Maaden, Micaela Morettini and Laura Burattini

[Boosting automated palynology via microfluidics and machine learning](#)

Michele D'orazio, Riccardo Reale, Adele De Ninno, Maria Antonia Brighetti, Arianna Mencattini, Luca Businaro, Eugenio Martinelli, Paolo Bisegna, Alessandro Travaglini and Federica Caselli

[Personalized Linear Data-Driven Algorithms for Real-Time Glucose Forecasting in Type 1 Diabetes](#)

Francesco Prendin, Simone Del Favero, Giovanni Sparacino and Andrea Facchinetti

[Sensitivity to carb-counting error in T1D management](#)

Chiara Roversi, Martina Vettoretti, Simone Del Favero, Andrea Facchinetti and Giovanni Sparacino

[Filtering techniques for whole body vibration artefact removal from low-SNR sEMG signals](#)

Simone Ranaldi, Carmen D'Anna, Fabio Botta, Andrea Scorza, Andrea Rossi, Calogero Foti, Stefano Faraci, Salvatore Andrea Sciuto, Maurizio Schmid and Silvia Conforto

[Mapping the sEMG distribution over the forearm for grip myotonia characterization: methodological aspects](#)

Enrica Tricomi, Alberto Botter, Peppino Tropea, Giacinto Luigi Cerone, Elda Judica, Barbara Fossati, Massimo Corbo and Marco Gazzoni

[Poincaré Image-Based Atrial Fibrillation Detection for Photoplethysmography Signals](#)

Guadalupe García Isla, Valetina Corino and Luca Mainardi

[Smoking effect on the circadian rhythm of blood pressure in hypertensive subjects](#)

Giulia Silveri, Lorenzo Pascazio, Aleksandar Miladinovic, Milos Ajcevic and Agostino Accardo

[Modelling the Meal Variability of Individuals with Type 1 Diabetes under Free-Living Conditions](#)

Nunzio Camerlingo, Martina Vettoretti, Simone Del Favero, Andrea Facchinetti, Giorgio Maria Di Nunzio and Giovanni Sparacino

[Performance of Dual-Augmented Lagrangian Method and Common Spatial Patterns applied in classification of Motor-Imagery BCI](#)

Aleksandar Miladinovic, Milos Ajcevic, Giulia Silveri and Agostino Accardo

[Human Activity Recognition through Wearable Sensors: a Deep Learning Approach](#)

Daniele Fortunato, Marco Ghislieri, Samanta Rosati, Gabriella Balestra, Marco Knafnitz and Valentina Agostini

[An Augmented-Reality App to communicate through the eye-gaze](#)

Mirko Rossi, Giuseppe D'Avenio, Febo Cincotti and Mauro Grigioni

[An application of DMAIC methodology for reducing voluntary departures from an Emergency Department](#)

Giovanni Improta, Maria Romano, Carlo Ricciardi, Carlo Cosentino and Francesco Amato

[Unobtrusive monitoring of stress indicators: a preliminary evaluation at rest](#)

Veronica Chiara Zuccalà, Riccardo Favilla and Giuseppe Coppini

[No-reference evaluation of the reconstructed images in single-shot K-Edge Subtraction X-ray Computed Tomography](#)

Giulia Saccomano, Vittorio Di Trapani, Pasquale Delogu and Francesco Brun

[Detecting low-to-moderate isometric muscle activity through a generalized CWT-based technique](#)

Tiwana Varrecchia, Carmen D'Anna, Daniele Bibbo, Maurizio Schmid and Silvia Conforto

[Preventive Healthcare through Air Pollution Exposure Modeling: the example of PULSE in Pavia](#)

Daniele Pala, Luigi Zurlo, Marica Franzini, Riccardo Bellazzi, Vittorio Casella, Domenico Vito and Cristiana Larizza

[Harmonisation of medical devices classification systems: development of a generalised approach starting from hip prostheses. A first example of an international and standardised nomenclature to be integrated within the European Medical Device Nomenclature](#)

Michela Franzo', Eugenio Carrani, Mauro Asaro, Edward Caton, John Keith Tucker, Richard Armstrong, Elaine Young, Letizia Sampaolo, Fabiano Bini, Franco Marinozzi and Marina Torre

[Deep learning for improving in room imaging in radiotherapy: CBCT to synthetic CT conversion](#)

Paolo Zaffino, Roberta Raso, Maria Chiara Angiocchi, Monica Merola, Sergio Canino, Matteo Nonnis, Antonella Bavasso, Caterina Mezzotero, Rosa Antonella Anoja, Elvira Mazzei and Maria Francesca Spadea

[Five years of Lean Six Sigma in the healthcare: an overview of main tools and results](#)

Giovanni Improta, Alfonso Maria Ponsiglione, Arianna Scala, Danilo Di Laura, Lucia Sara D'Angiolella and Giuseppe Cesarelli

[Play-Draw-Write: usability and acceptance of a tablet app for the early screening of handwriting difficulties in kindergartners](#)

Linda Greta Dui, Francesca Lunardini, Cristiano Termine, Matteo Matteucci and Simona Ferrante

[Geometric alterations of capillary network in hypertension: preliminary results](#)

Virginia Altamore, Francesco Giardini, Camilla Olianti, Irene Costantini, Leonardo Sacconi and Leonardo Bocchi

[Linear Regression Models to Improve the Estimation of Insulin Boluses in Type 1 Diabetes Therapy](#)

Giulia Noaro, Giacomo Cappon, Simone Del Favero, Giovanni Sparacino and Andrea Facchinetti

[A Heuristic-Sliding-Window-based RRT Path Planning for Endovascular Catheterization](#)

Zhen Li, Alice Segato, Alberto Favaro, Jenny Dankelman and Elena De Momi

[Correlation between hyper-acute EEG alterations and 7-Day NIHSS score in thrombolysis treated ischemic stroke patients](#)

Milos Ajcevic, Giovanni Furlanis, Aleksandar Miladinovic, Lara Stragapede, Giulia Silveri, Paola Caruso, Marcello Naccarato, Paolo Manganotti and Agostino Accardo

[Assessment of Indoor Exposure Scenario by an 8x8 Planar Array Antenna at 3.7 GHz](#)

Marta Bonato, Laura Dossi, Emma Chiaramello, Serena Fiocchi, Silvia Gallucci, Gabriella Tognola, Paolo Ravazzani and Marta Parazzini

[Blood glucose prediction from Flash Glucose Monitoring and Fitbit data: a deep learning approach](#)

Pietro Bosoni, Marco Meccariello, Valeria Calcaterra, Cristiana Larizza, Lucia Sacchi and Riccardo Bellazzi

[IoT ink pen for the ecological study of age-related changes in handwriting](#)

Davide Di Febbo, Francesca Lunardini, Milad Malavolti, Alessandra Pedrocchi, Alberto Borghese and Simona Ferrante

[Comparison of Parametric Linear Techniques for Glucose Prediction in Type-1 Diabetes](#)

Simone Faccioli, Andrea Facchinetti, Giovanni Sparacino and Simone Del Favero

[A markerless gait analysis protocol based on a single RGB-Depth camera: sensitivity to background changes](#)

Diletta Balta, Massimo Salvi, Filippo Molinari, Giulio Figari, Gabriele Paolini, Ugo Della Croce and Andrea Cereatti

[Quantification and reduction of crosstalk in surface electromyogram by inverse modelling](#)

Luca Mesin

[Combining autoencoder and artificial neural network for classifying colorectal cancer stages](#)

Antonio Brunetti, Maria Pia Caputo, Tommaso Maria Marvulli, Giacomo Donato Cascarano, Nicola Altini, Simona De Summa and Vitoantonio Bevilacqua

[Correlation analysis of PRSA-based parameters during labor: a simulation study](#)

Moira Barbieri, Tamara Stampalija, Massimo Walter Rivolta and Roberto Sassi

[Analysis of heart rate variability as evaluation method for the risk of sepsis in the low-weight preterm infant](#)

Fabio Tarricone, Viviana Bernocco, Domenico Buongiorno, Antonio Brunetti, Antonella D'Orazio, Antonio Del Vecchio, Vitoantonio Bevilacqua and Flavia Petrillo

[Connectivity in Parkinson's disease patients with cognitive impairment: a simultaneous PET/MRI study](#)

Erica Silvestri, Angelo Antonini, Marco Castellaro, Roberta Biundo, Diego Cecchin and Alessandra Bertoldo

[Improving the assessment of vascular complexity in peripheral artery occlusive disease](#)

Pierangela Bruno, Paolo Zaffino, Francesco Calimeri, Salvatore Scaramuzzino, Ciro Indolfi, Salvatore De Rosa and Maria Francesca Spadea



[Modeling Intraperitoneal Insulin Kinetics in Patients with Type 1 Diabetes](#)

Filippo Moret, Michele Schiavon, Claudio Cobelli and Chiara Dalla Man

[Human papillomavirus early promoter: Sensitivity analysis and biological behaviour](#)

Alberto Giaretta

[Experimental Validation of an E-Textile T-Shirt for ECG Monitoring](#)

Federica Amitrano, Armando Coccia, Leandro Donisi, Arcangelo Biancardi, Gaetano Pagano and Gianni D'Addio

[Benchmarking between a Sensorized E-textile Sock for Remote Monitoring and a Stereophotogrammetric System](#)

Leandro Donisi, Armando Coccia, Federica Amitrano, Carlo Ricciardi, Giuseppe Cesarelli and Gianni D'Addio

Day 2: Clinical Biomechanics

Podium session:

Cardiac fluid dynamics of patient-specific geometries in Pre and Post Mitral Valve Repair by Direct Numerical Simulation

Dario Collia and Gianni Pedrizzetti

Biomechanical implications of leg bending in popliteal stenting

Michele Conti, Alice Finotello, Anna Ferrarini, Giancarlo Salsano, Auricchio, Palombo, Spinella and Pane

Computational investigation of the male lower urinary tract in health and disease

Chiara Giulia Fontanella, Ilaria Toniolo, Alessandro Arduino, Joseph Vannel Fotso Fogang, Arturo Natali and Emanuele Luigi Carniel

Eulerian-based wall shear stress topological skeleton analysis and near-wall transport in aortic flow

Giuseppe De Nisco, Valentina Mazzi, Karol Calò, Raffaele Ponzini, Giovanna Rizzo, David A. Steinman, Diego Gallo and Umberto Morbiducci

3D nichoid substrates affect mesenchymal stem cell morphology and euchromatin organization

Emanuela Jacchetti, Emanuele Colombo, Tommaso Zandrini, Roberto Osellame, Giulio Cerullo, Davide Mazza and Manuela Raimondi

Advanced Firmware and Hardware for Multiscale and Multimaterial Bioprinting

Amedeo Franco Bonatti, Gabriele Maria Fortunato, Anna Lapomarda, Aurora De Acutis, Carmelo De Maria, Chiara Vitale Brovarone and Giovanni Vozzi

Are your cells alive?

Adele De Ninno, Riccardo Reale, Alessandro Giovinazzo, Francesca Romana Bertani, Luca Businaro, Paolo Bisegna, Claudia Matteucci and Federica Caselli

Ultrasound-triggered permeabilization of polyelectrolyte microcapsules

Marietta Pisano, Marta Clerici, Donatella Di Lisa, Roberto Raiteri and Laura Pastorino

Development of a compliance-matching biohybrid vascular graft through an integrated approach.

Elia Pederzani, Alessandro Caimi, Marco Pezzotta, Alice Caldiroli, Mattia Lupacchini, Matteo Tironi, Fabio Sangalli, Marina Figliuzzi, Nadia Azzollini, Sonia Fiori, Francesco G. Greco, Emiliano Votta, Gianfranco B. Fiore, Andrea Remuzzi, Stefania A. Riboldi, Monica Soncini and Alberto Redaelli

Poster session:

Abdominal visceral and subcutaneous adipose tissues in obese patients: mechanical behaviour

Chiara Giulia Fontanella, Mirto Foletto, Livio Corain and Emanuele Luigi Carniel

Computational tools for the evaluation of surgical parameters after LSG

Ilaria Toniolo, Chiara Giulia Fontanella, Mirto Foletto and Emanuele Luigi Carniel

[A novel step counting algorithm using a head-mounted sensor](#)

Alessia Cristiano, Alberto Sanna and Diana Trojaniello

[Hybrid membranes for blood-contacting surfaces: preliminary characterization](#)

Martina Todesco, Giorgia Merigliano, Valentina Candela, Laura Iop, Tiziana Palmosi, Gino Gerosa and Andrea Bagno

[Single cell fluid dynamics: a VOF model of a red blood cell vs a leukocyte](#)

Monica Piergiovanni, Elena Bianchi, Paola De Stefano and Gabriele Dubini

[Mechanical properties of oxidized polyvinyl alcohol hydrogel scaffolds for tissue engineering](#)

Silvia Todros, Silvia Barbon, Martina Favaron, Elena Stocco, Daniele Dalzoppo, Rafael Boscolo-Berto, Veronica Macchi, Claudio Grandi, Andrea Porzionato, Raffaele De Caro and Piero Pavan

[Biofabrication and characterization of a biphasic construct to study osteochondral tissue in vitro](#)

Irene Chiesa, Carmelo De Maria, Anna Lapomarda, Gabriele Maria Fortunato, Francesca Montemurro, Roberto Di Gesù, Rocky S Tuan, Giovanni Vozzi and Riccardo Gottardi

[Electrospun ultrathin scaffold for Bruch's membrane regeneration in retinal tissue engineering](#)

Beatrice Belgio, Gabriele Dubini, Federica Boschetti and Sara Mantero

[Surface coated chitosan microbeads for the sustained release of drugs](#)

Pietro Arnaldi, Orietta Monticelli and Laura Pastorino

[Balance control after tripping: Margin of Stability and Limb Support Quotient](#)

Alberto Finazzi, Adele Panarese Macrì, Paolo Gallina, Silvestro Micera and Vito Monaco

[Impact of the shear stress on cultured human gut microbiota](#)

Francesco Biagini, Marco Calvigioni, Ermes Botte, Alessandra Vecchione, Carmelo De Maria, Francesca Montemurro, Chiara Magliaro, Francesco Celandroni, Emilia Ghelardi and Giovanni Vozzi

[Pectin-based biomaterial ink for Green Tissue Engineering applications](#)

Anna Lapomarda, Aurora De Acutis, Irene Chiesa, Gabriele Maria Fortunato, Francesca Montemurro, Carmelo De Maria, Monica Mattioli Belmonte, Riccardo Gottardi and Giovanni Vozzi

[Polymeric microchambers arrays for cargo protection](#)

Stefania Boi, Valeriya Kudryavtseva, Jiaxin Zhang, Andrey Udalov, Evgeniy Shesterikov, Sergei Tverdokhlebov, Laura Pastorino and Gleb Sukhorukov

[A hydrogel channel-based system to model the blood flow dynamic stimuli](#)

Chiara Vitale, Arianna Fedi, Gabriele Varani, Alessandra Marrella, Marco Fato and Silvia Scaglione

[Rapid and affordable prototyping of bioinspired microfluidic networks for Tissue Engineering](#)

Guglielmo Pacetta, Aurora De Acutis, Francesca Montemurro, Carmelo De Maria and Giovanni Vozzi

[Tensile properties of porcine retina](#)

Beatrice Belgio, Sara Ragazzini, Paolo Arpa, Vito De Molfetta, Sara Mantero and Federica Boschetti

[SensRing, a wearable ring-shaped device for measuring kinematics in reach-to-grasp tasks](#)

Guenda Galperti, Erika Rovini, Laura Fiorini, Gianmaria Mancioffi, Radia Zeghari, Auriane Gros, Valeria Manera and Filippo Cavallo

[Driving neuronal network connectivity with a modular alginate mask](#)

Martina Brofiga, Elena Dellacasa, Enrica Vitali, Donatella Di Lisa, Paolo Massobrio and Laura Pastorino

[Bioactive silica-based glass nanoparticles containing boron and copper](#)

Elisa Piatti, Marta Miola and Enrica Vernè

[Strategies to speed up the standardized bone plates mechanical testing for regulatory purposes](#)

Mara Terzini, Gianpaolo Serino, Andrea Tancredi Lugas, Giancarlo Dichio, Piero Costa and Alberto L. Audenino

[DXA-based Finite Element models to improve hip fracture risk prediction: a comparison with CT-based models](#)

Alessandra Aldieri, Mara Terzini, Cristina Bignardi and Alberto Audenino

[A Multibody Model for Ligament Balancing Assessment in Total Knee Arthroplasty](#)

Giovanni Putame, Mara Terzini, Simone Borrelli, Cristina Bignardi and Alberto Audenino

[Influence of cartilage thickness on Human Femur Neck: a 3D Stress-Strain Analysis](#)

Andrada Pica, Fabiano Bini, Andrea Marinozzi and Franco Marinozzi

[Image processing for rheological characterization of blood under flow](#)

Giuseppe D'Avenio, Patrizia Caprari, Carla Daniele and Mauro Grigioni

[Fontan Computational Hemodynamics: Impact of Inlet Velocity Profile Features with Implications on Clinically Relevant Parameters](#)

Maurizio Lodi Rizzini, Paola Tasso, Diego Gallo, Giuseppe D'Avenio, Antonio Amodeo, Umberto Morbiducci and Mauro Grigioni

[From Mocap data to inertial data through a biomechanical model to classify countermeasure exercises performed on ISS](#)

Martina Ravizza, Alessandra Pedrocchi, John DeWitt and Giancarlo Ferrigno

[Thermosensitive hydrogels for the encapsulation of primary and human derived neuronal cells](#)

Donatella Di Lisa, Elena Dellacasa, Lorenzo Muzzi, Alberto Lagazzo, Monica Frega, Sergio Martinoia and Laura Pastorino

[Transcatheter Aortic Valve with Embolic Filter: Experiments and Simulations](#)

Dario Carbonaro, Claudio Chiastra, Umberto Morbiducci and Alberto Audenino

[Use of an optimized automatic procedure for measuring the hydraulic permeability of articular cartilage](#)

Naomi Giuliani, Arianna B Lovati, Marco Ferroni, Laura Ferrari, Laura Mangiavini, Giuseppe M Peretti and Federica Boschetti

[Design and validation of a novel low cost-bicompartmental platform for cell and tissue cultures](#)

Lorenzo Coppadoro, Chiara Foglieni, Gianfranco Fiore and Monica Soncini

[The eccentric phase of countermovement jump: comparing motion capture and inertial sensors](#)

Luigi Truppa, Michelangelo Guitolini, Carlo Castagna and Andrea Mannini

[Development of a novel bioreactor for the generation of controlled hydrodynamic stimuli on vascular planar tissue samples](#)

Elia Pederzani, Lorenzo Pietro Coppadoro, Aldo Josè Suria Roldan, Chiara Foglieni, Monica Soncini and Gianfranco Beniamino Fiore



[Versatile perfusion and electrical stimulation bioreactor for bone tissue engineering](#)

Diana Massai, Stefano Gabetti, Giovanni Putame, Ileana Armando, Elisa Fiume, Alessandro Sanginario, Dario Carbonaro, Francesco Baino, Alberto Audenino, Enrica Vernè and Cristina Bignardi

[Application of deer hearts for ex-vivo modelling of mitral valve pathology – preliminary results](#)

Michal Jaworek, Edoardo Maroncelli, Federico Lucherini, Guido Gelpi, Claudia Romagnoni, Rubina Rosa, Cristina Manenti, Carlo Antona, Gianfranco Beniamino Fiore and Riccardo Vismara

[Thrombogenicity of cardiovascular devices: mutual and relative effect of biomaterial and shear stress](#)

Silvia Bozzi, Federica Vercellino, Filippo Consolo, Yana Roka Moia, Tatiana Mencarini, Marvin Slepian and Alberto Redaelli

[Gellan gum-based hydrogels as injectable materials for cartilage tissue engineering](#)

Laura Riacci, Lorenzo Vannozzi, Lorena Garcia Hevia and Leonardo Ricotti

[The influence of turbulence modelling on thrombosis in cardiovascular devices](#)

Giuseppe Passoni, Silvia Bozzi, Alberto Redaelli and Davide Dominissini

[Internal fixation of femour fractures: a new wireless electromechanical dynamization system](#)

Giancarlo Dichio, Giovanni Putame, Mara Terzini, Sergio Cannata, Piero Costa, Eros Gian Alessandro Pasero and Alberto Audenino



Day 3: Applied Bioengineering

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Does a medical device nomenclature suitable for all purposes exist? Twenty years of Italian experience with the CND and its adoption in EUDAMED at European level

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Abstract— There are many purposes for using a nomenclature of medical devices.

The Italian CND is a free public available nomenclature, arises from a comparison with existing nomenclatures and is structured to allow a connection with other systems.

Since 2007 the CND is used, in the Italian database, for regulatory affairs in order to register and classify homogeneously medical devices from a technical and economics point of view; in 2019 the CND has been adopted from European Commission as official nomenclature.

It is not possible to think that a nomenclature can meet all needs. However, it is possible to guarantee the interoperability of different classification systems by adopting a single hierarchical nomenclature as a common basis from which to develop different "subclassifications" for different purposes.

Aim of this paper is to present the Italian experience in the development of the national medical device nomenclature and its extension to the European level.

Keywords— Medical Device legislation, European Union, classification, nomenclature

I. INTRODUCTION

ADVANCES in medical device (MD) technology have been dramatic in recent years resulting in both an increased number of medical devices (estimated to be approximately 500,000 different devices in Europe) and an increase in the invasiveness and critical function which devices perform [1].

According to the World Health organization, at present, there is no common standard name for each type of medical device, an inconsistency that causes confusion between the various types of devices, affects traceability and has an adverse impact on health care delivery [2]. Globalization of the medical device market and trading across economic borders requires prioritization of regulatory convergence which should be accompanied by a common and consistent language with which to communicate device information [3]. To describe and identify these medical devices in an unambiguous manner, there is a need for a common method [4]. A standardized classification and nomenclature of medical devices will serve as a common language for recording and reporting medical

devices across the whole health system at all levels of health care for a whole range of uses. Standardization of nomenclature is also essential for defining and naming innovative technologies, classifying the devices for regulatory approval (registration) and for streamlining procurement of these products (2 OMS).

The advent of the European directives, initiated a new era, where national and indeed international bodies were given the opportunity to cooperate and harmonize their efforts in achieving the one thing that they all needed, namely, a standardized method of identifying the products placed in the global market. Many nomenclature systems (CNMD, EDMA, ISO 9999, JFMDA, NKKK, UMDNS), all built upon different structures, and used locally or nationally for diverse purposes and with unusual approaches, were chosen to develop the Global Medical Device Nomenclature (GMDN) [4].

On 19th April 2010, the EU Commission adopted the decision of establishing the European Databank on Medical Devices (Eudamed). The aim of the European databank for medical devices was to strengthen market surveillance by providing competent authorities with fast access to information on manufacturers and authorised representatives, devices and certificates and to vigilance data, to share information on clinical investigation data, as well as to contribute to a uniform application of those Directives, in particular in relation to registration requirements [5]. With the New Regulation on Medical Devices, Eudamed was formally established and the Commission was recommended to ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature [6].

On 4th March 2019, the EU Commission adopted the Italian National Nomenclature of Medical Devices (Classificazione Nazionale dei Dispositivi medici, CND) as a base for the development of the European Medical Device Nomenclature (EMDN) to support the activity of the future European database of medical devices EUDAMED [7].

The aim of this paper is to present the Italian experience in the development of the Italian national medical device nomenclature and its further extension to the European level.

II. METHOD

Since 90's, Italy started to define a nomenclature that allow to classified biomedical technologies in a standard way (CIVAB): even through, this nomenclature did not include all the world of medical devices.

In the 00's, in according to the UE directives, the competent office decided to create a wider nomenclature including most of the medical devices placed on the market. Following which, was made a benchmarking with the other existing nomenclatures in the medical field [8] (Table I):

- **UNITED NATIONS COMMON CODING SYSTEM (UNCCS):** designed for the identification of both goods and services and used in supplies and tenders; 6 characters hierarchical coding system.
- **CIVAB:** was made from a project related to biomedical technologies with aim of developing a standard coding to support the purchase, management and maintenance of biomedical equipment; the coding is associated with an alphanumeric speaking code (3 class characters, 3 manufacturer characters, 2 model characters).
- **UNIVERSAL STANDARD PRODUCTS AND SERVICES CLASSIFICATION (UNSPSC):** multi-sector standard, evolution of the UNCCS, for classification of products and services, for achieving company-wide visibility of spend analysis, as well as, enabling procurement to deliver on cost-effectiveness demands and allowing full exploitation of electronic commerce capabilities; 8 characters hierarchical coding.
- **UNIVERSAL MEDICAL DEVICE NOMENCLATURE SYSTEM (UMDNS):** used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases; facilitates identifying, transferring, and communicating data about medical devices; not hierarchical 5 numeric codes nomenclature.
- **EUROPEAN DIAGNOSTIC MANUFACTURERS ASSOCIATION'S IN-VITRO DIAGNOSTIC PRODUCT CLASSIFICATION (EDMA):** used to code in vitro diagnostic medical devise, grouping reagents and instrumentation (accessories); represents the interests of IVD'S european manufacturers for the purpose to support the collection and analysis of market statistics; now is called as GIVD classification; 4 characters hierarchical classification.
- **GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN):** it provides a nomenclature used for the exchange of information of medical devices; the list of terms is updated through member modification requests; not hierarchical 5-digit list of numeric codes.

TABLE I

OTHER EXISTING NOMENCLATURES IN THE MEDICAL FIELD IN THE 00'S

Nomenclature	CIVAB, UMDNS GMDN
Classification	UNCCS, UNSPSC, EDMA

The Italian Financial Law 2003, among other things, established that medical devices should be classified in uniform classes and sub classes with an indication of the reference price. It has been giving the responsibility for this classification to the National Commission for Medical Devices (CUD), technical advisory body of the Ministry of Health.

The first version of the Classificazione Nazionale dei Dispositivi Medici (CND) was defined by the CUD in July 2005 and approved with the Ministerial Decree of 22 September 2005 [9].

Subsequently, the Italian Financial law of 2006 involved the State - Regions Conference, [10] for the approval of the national nomenclature.

The new CND version, was established by Italian Ministry of Health Decree of 20 February 2007. Since that date the CND became the official nomenclature of products identified as medical devices in accordance with European Legislation and national transposition standards [11] and valid at National level.

TABLE II

SEQUENCE OF MINISTERIAL DECREES THAT INTRODUCED THE NEW VERSIONS OF THE CND

CND Version	Ministerial Decree
1	22 September 2005
2	20 February 2007
3	13 March 2008
4	12 February 2010
5	7 October 2011
6	29 July 2013
7	8 June 2016
8	13 March 2018

The construction, the maintenance and the updates of the CND have been based on the following three fundamental principles [12]:

- Participative approach:** The medical device sector is very complex and heterogeneous, that's the reason why, it requires highly differentiated and qualified expertise in the field of MD. Besides, it has become necessary, for a reliable nomenclature for medical devices, the contribution of a broad participation of all stakeholders (economic operators and healthcare professional).
- Qualified validation of proposals:** Nomenclature proposals are technically validated to establish the actual need considering:
 - other existing nomenclature systems available also at international level
 - consumption and expense information
 - assessment with sector experts from the different disciplines
- Formal adoption and free public availability**

The nomenclature has an alpha-numeric structure which is developed in a multi-level hierarchical tree and it clusters medical devices in three main levels:

- **Category:** the first hierarchical level. There are 22 categories identified by a letter and each one includes devices for anatomical district (8), functional use (9) and other criteria (5).
- **Group:** the second hierarchical level. There are 146 anatomical/function groups, identified by a two-digit numbers from 01 to 99 for each category.
- **Type:** the third hierarchical level. There are, if necessary, until 5 levels of detail which one identified by a two-digit numbers.

Each medical device is classified by an alphanumeric code made of a letter referring to the “Category”, a couple of numbers referring to the “Group” and a series of other couples of numbers referring to the “Type” to a maximum of 7 levels (Figure 1).

Each level is identified by:

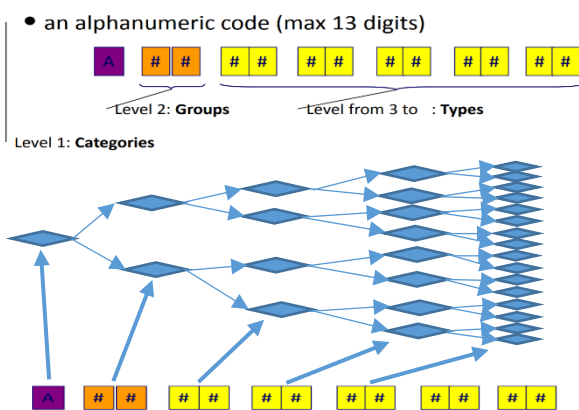


Figure 1: Representation of the CND structure

The nomenclature covers the whole panorama of medical devices, not only biomedical equipment (Z category) and in vitro diagnostic devices (W category).

The CND nomenclature is one of the tools used for the governance of the medical device sector characterized by extremely high complexity and fragmentation. It aims to support the improvement of patient safety and the quality of health systems by enabling information to be communicated in a standardized manner.

It allows more effectively monitoring the consumption and use of devices, a better evaluation of accidents and to obtain a reference prices for homogeneous classes of medical devices making the purchasing processes more transparent by the national health system.

The CND is used in:

- marketing activities
- vigilance and market surveillance
- analysis and definition of economic planning policies

The CND system, which represents the basis of the Italian information system for the registration of medical devices, constitutes an official, freely and available reference to all stakeholders: being a hierarchical nomenclature and therefore

not very flexible to changes, specific items have been inserted to code the equipment accessories (hardware "80", software "82", consumables "85") and devices that cannot be included in a specific type (other "99").

Although the shallow depth of the nomenclature levels, the periodic updates allow the creation of new branches with the possibility of including devices that were previously in the item "99".

A device with multiple functionalities could create ambiguity in the coding and make the choice fall on more terminal item: in this case, multiple choice is not possible and it is necessary to refer to the main intended use.

III. DISCUSSION

There are basically two different approaches for medical devices “categorisation”: nomenclatures (NOM) and a classifications (CLA). NOM give more detailed and specific information on the single element. The granularity of the information of each term of a NOM is not predefined. On the other hand, the granularity of a CLA is intrinsically related to its hierarchical structure. In choosing between the two approaches, a tradeoff must be considered: NOMs tend to describe DMs in more detail but do not allow easy management of large amounts of information, on the other hand, CLAs are more rigid and less flexible in describing DMs but allow for easier management of the information, due to a hierarchical structure that brings together and organizes the articles provided.

The choice in the construction of the CND was oriented on the second approach in consideration of the huge number of devices on the market (millions of different MDs) and related information that was intended to manage. It was decided to lose in descriptive precision to privilege the ability to organize and manage information in a simple and easily understandable way at all levels of the health system. For devices that are not complex in terms of technical and functional characteristics, classifying in a single terminal branch is quite easy; for devices with more complex technical characteristics and / or more functionalities, making a univocal classification and in a terminal branch could be more complicated.

IV. CONCLUSION

For its features, the CND has been adopted by the European Commission as official nomenclature for the future databank EUDAMED and will be reviewed, updated and renamed as European Medical Devices Nomenclature (EMDN).

The revision of the current CND with other existent nomenclatures will ensure that the new EMDN will be articulated in a way comparable with the other systems.

The experience of the Italian database of medical devices shows that the CND allows the classification of DMs for regulatory purposes and for monitoring expenditure, however it cannot be said that it is in itself usable for any purpose (for example, in the experience of the Italian Arthroprosthesis Registry, the CND is supported by further elements that allow to technically characterize the DMs of interest). The CND (and EMDN at European level) constitute a "classification root" from which specific systems can be developed for particular purposes and ensure interoperability between them.

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