Topics for the Final State Examination (FSE)
for the bachelor's degree programme
B0914A360003 Biomedical Technology

(applicable for students have been starting their studies in the academic year 2020/2021 or later)

Pursuant to Article 7 (3) of the Directive of the Dean concerning the implementation of bachelor's and follow-up master's degree programmes at the Czech Technical University in Prague - Faculty of Biomedical Engineering, the Dean determines the below-listed topics based on a proposal by the Head of the Department of Biomedical Technology for the given academic year.

The topics are in accordance with the content of the application approved by the National Accreditation Bureau for Higher Education (NAÚ) by the Decision on granting accreditation to the academic bachelor study programme Biomedical Technology of 20 February 2020 under ref. N.:NAU-368/2019-9 with a validity period of 10 years until 13 March 2030, with a set length of study of 3 years in the full–time form, which is listed within the meaning of § 44a of the Higher Education Act in the field of education of Healthcare Professions, with the approval of the Ministry of Health of the Czech Republic dated 13 June 2018 under ref. No.: MZDR 19163/2018-4/ONP and also with the qualification standard of preparation for the performance of the healthcare profession Biomedical Technician with respect to Decree No. 39/2005 Sb. as amended.

The said study programme Biomedical Technology fulfils the requirements for electrical engineering education according to § 2, a), (4) of the Government Decree N. 194/2022 Sb. on requirements for professional competence to work with electrical equipment and for professional competence in electrical engineering with respect to the Act No. 250/2021 Sb.

The topics are designed as the necessary minimum of knowledge and skills (theoretical and practical) that are necessary for the successful employment of the graduate of the field of study Biomedical technology in practice. For better orientation of students, at the end of each topic, the titles of compulsory courses which contained the below-listed topics are given. In accordance with (3) of Article 7, the student applies for the Final state examination, in which **only 3 topics are compulsory**. During the FSE, the student is assigned a minimum of 2 questions from each topic. Questions that are directly related to the subject area or to the topic of the BT and are part of the curriculum of theoretical and preparatory subjects (typically biology, physics, chemistry, statistics, computer science, electrical engineering subjects and medical subjects) are not excluded. Questions may be asked by all members of the committee or by a committee member designated by the chair or vice-chair of the committee. A member of the committee, who is simultaneously the supervisor of the student's bachelor thesis cannot ask any questions on any topic due to the conflict of interests. Answers to the questions may follow immediately after their assignment and answers are always given without written preparation.

Topic 1 (compulsory): **Biological Signals, Modeling and Hospital Information Systems** (*BSMNIS):*

Classification of signals, deterministic and stochastic signals. Sampling and quantization, sampling theorem. Aliasing. Signal to computer conversion chain. A/D and D/A converter principle. Time domain signal processing. FIR and IIR digital filters. Linear and nonlinear

phase. Frequency domain signal processing. Fourier analysis, discrete Fourier transform, FFT, amplitude and phase spectrum, coherence, spectral power density, estimation of the spectrum using the periodogram. Systems and their description. Continuous systems. Outer and inner state description. Linear and nonlinear systems. Outer description of the continuous linear system. Feedback. Systems stability evaluation. Responses systems to the determined signals and their utilization for system identification. Systems with discrete time. Outer description of the discrete linear system - difference equation, transfer functions, frequency response, distribution of zeros and poles, temporal characteristics. Systems connections. Basic types of the linear dynamic continuous systems. Systems behavior, regulation accuracy. (*F7ABBUSS*)

Modeling and simulation (objectives and process of modeling, model description tools, modeling vs. simulation). Compartmental models. Analogies within the selected physical domains. Population models - single population, dual population, continuous models, discrete models. Models with age structure. Epidemiological models - SIR model, cross models of venereal diseases. Modeling of biological systems. Pharmacokinetic models. Empirical models. Model analysis, phase diagram, cobwebbing. Parameters model identification based on the gradient method with Jacobian. *(F7ABBMS)*

Cell membrane structure. Genesis and properties of basic electrophysiological signals (EEG, ECG, EOG, EP, EMG and others). Physiological and electrophysiological processes associated with individual biosignals (formation and propagation of action potential, charge transfer, role of ions). Artefacts. Diagnostic use. Statistical characteristics. Frequency range and bands. EEG and ECG leads systems. Biosignals spectral analysis, parametric and non-parametric models of spectrum estimation. Periodogram, AR spectrum model. Mutual spectrum, coherence and phase. Spectral analysis and signal synthesis using FFT. Filtering, noise removal. Windowing. CSA-compressed spectral array. Inter-hemispheric and local coherence. Mapping of frequency bands. Topographical mapping of electrophysiological activity in amplitude and frequency domain. Long-term EEG signals analysis, adaptive segmentation, features extraction, cluster analysis videomonitoring. ECG data processing methods. *(F7ABBBLS, F7ABBELF)*

Information systems - IS (classification, system development, IS development life cycle, IS analysis, types of SW maintenance). Server (types, purpose), client-server communication/ thin, thick client). Hospital information systems (HIS) definition, HIS components, PACS, DICOM. The connection of the medical devices into the HIS. Data formats for communication of the health-care facilities and government administration, national health registers. Systems of the diagnoses and procedures classification, nomenclature (SNOMED). Data standards - definition, use (HL7, DICOM, PACS, ePACS). Healthcare documentation - legislation, management issues within the HIS (user roles, security). Electronic health records (EHR, EMR, EPR). eHealth concept - definition, healthcare digitization. Quantitative decision model (evaluation - ROC curve and efficiency - sensitivity, specificity). Databases, the system of database control, data models, integrity limitation, data normalization and transactional processing. Recovering from IS errors. IT safety requirements. Mechanisms of cryptography. Digital signature, certificate, certificate authority, hash function, digital signature application. Identification and authentication: passwords, passwords attack, requirements, biometrics, cryptography application, another possibility - chip card. Antivir SW principle. *(F7ABBISZ)*

Relevant courses: *Electrophysiology (F7ABBELF), Introduction to Signals and Systems (F7ABBUSS), Modelling and Simulation (F7ABBMS), Biological Signals (F7ABBBLS), Communication Technology (F7ABBKT), Probability and Mathematical Statistics (F7ABBPMS), Information Systems in Health Care (F7ABBISZ)*

Topic 2 (compulsory): **Medical Devices** (LPT*):*

Principles of scaling for volume and tension. Overview of forces acting on the body. Computational and experimental determination of the position of the centre of gravity. Stability. Biomechanics of muscle as a force generator. Biomechanics of the upper limb brachial plexus. Biomechanics of the elbow joint, forearm and hand. Biomechanics of the hip joint. Biomechanics of the knee joint. Biomechanics of the spine. Principles of kinematic analysis of movement. Coordinate systems in biomechanics. Dynamics of human movement. Biomechanics of walking and running. Conservation laws in biomechanics. Solution of the problem of muscle redundancy. Bone mechanics: structure-function relationship, mechanical stresses. Mechanics of ligaments and tendons. Mechanics of cartilage. Biomaterials and biocompatibility. Principles of implant design. *(F7ABBBB)*

Physical principles, materials, electronic circuits, signal evaluation, construction, applications, static and dynamic parameters of electronic elements and sensors: diodes, transistors, switch elements, electronic elements for galvanic isolation, temperature sensors (metal, semiconductor, resistive, PN junction, MOS structure, integrated, cryogenic, special, contactless), sensors of mechanical quantities including accelerometers and gyroscopes (pressure, force, position, flow, level), piezoelectric sensors, capacitive, sensors with inductance (induction, inductance, magnetoelastic, magnetostrictive), sensors of magnetic quantities (Hall and magnetoresistance effect, megnetodiode, magnetotransistor), sensors of chemical and biochemical quantities (gases, pH, ISFET). Nanosensors and nanomaterials. Sensor networks BAN and Internet of Things (IoT). Smart sensors. For the above mentioned areas, related knowledge, skills and aspects of physics, chemistry, physical chemistry, theory of electrical engineering, electrical measurements, electronic circuits and medical device design and construction are assumed. *(F7ABBSM)*

Medical devices categories in accordance with international documents and recommendations. Biopotential amplifiers (dynamic range, frequency response, differential operational amplifier (OA), common mode rejection ratio - CMRR, CMR). Issues of excitable tissues (muscles and nervous system) in terms of the origin, measurement and use of changes in electrical parameters (action, resting potential, nerve, synapse). Possibilities of measurement of electrical parameters at the level - cell, tissue and whole organ. Examples of the use of electrical parameters of cells, tissues and organs. Electrocardiographs, lead systems, vectorcardiography. Methods and equipment for blood pressure measurement (invasive and non-invasive methods). Dilution methods for blood flow and cardiac output (C.O.) measurement. Plethysmography and blood oxygen saturation (regional and pulse oximetry). Electroencephalography. Medical devices and methods for audiometry. Electromyography. Evoked potentials. Capnometry/capnography. Vital signs monitors and Holter monitoring. Related knowledge, skills and aspects of anatomy, physiology, electrophysiology, medical device design and construction, pathology, hygiene and epidemiology, ethics and first aid are assumed for the above categories of active diagnostic medical devices. *(F7ABBELF, F7ABBTEL, F7ABBEO, F7ABBLPZI)*

Electrical stimulation (basic principle, use). Medical electrical equipment in therapy (ultrasound equipment, electrotherapy, phototherapy, magnetotherapy – LF and HF, equipment for dialysis). Defibrillators. Electrosurgery units (ESU) (ESU). Pacemakers. Infusion devices (syringe pump, elastomeric pump, a peristaltic pump). Related knowledge, skills and aspects of anatomy, physiology, electrophysiology, medical device design and construction, pathology, hygiene and epidemiology, ethics and first aid are assumed for the above categories of active diagnostic medical devices. *(F7ABBELF, F7ABBLPZ2)*

Blood gases, their measurement and results interpretation. Modelling of the fluidic systems, parameters and properties of the fluidic models. Principles and adverse effects of artificial lung ventilation (ALV). Conventional lung ventilation and related modes of operations, basic elements of the lung ventilator. Extracorporeal membrane oxygenation (ECMO). Humidification of ventilatory gases. Anaesthesia equipment, basic elements and principles of construction, patient circuits. Anaesthetic vaporisers and thermodynamic principles in the anaesthesia equipment. Equipment for monitoring and support of blood circulation. Related knowledge, skills and aspects of anatomy, physiology, physical chemistry, medical device design and construction, pathology, hygiene and epidemiology and ethics are assummed for the above categories of active diagnostic medical devices. *(F7ABBSPT)*

Patient and device simulators and testers – differences, application examples. Fundamental principles of patients simulators, analogies among physical domains. Cardiovascular subsystem model description. Selected examples descriptions of the patient simulators and medical device testers (ECG, SpO2, NIBP). Control and scenario development environment for patient simulator, methodology and posibility of the scenario usage and development. Applied pharmacology and anaesthesiology fundamentals for the wholebody patient simulators. Other simulators, testers and analyzers including phantoms and possible application within the clinical practice. Related knowledge, skills and aspects of anatomy, physiology, electrophysiology, biochemistry, medical device design and construction, pathology, hygiene and epidemiology, ethics and first aid are assummed for the above categories of active diagnostic medical devices. *(F7ABBPPS)*

Classification of imaging systems (according to the imaging manner, relation to the electromagnetic spectrum, need for an external energy source, method of interaction of radiation or mechanical waves with the object, morphological and functional evaluation, relation of field of view and detector size). Transfer properties of imaging systems (PSF, OTF, MTF, PTF). Microscopy (fluorescence, confocal, super-resolution, electron). TV imaging systems. Sensing, digitization and basic methods of image processing (look-up-table - LUT, histogram, arithmetic and logical operations, convolution, the relationship among image brightness operations, contrast, LUT and histogram). Infrared imaging systems including thermovision systems. Conventional X-ray imaging systems. RTG-TV imaging systems. Endoscopic imaging systems including videoendoscopic imaging systems. Angiography including DSA. Computed radiography (CR). Digital radiography (DR, direct and in-direct conversion). Conventional imaging systems in nuclear medicine. Related knowledge, skills and aspects of anatomy, physiology, medical device design and construction, pathology, hygiene and epidemiology and ethics are assummed for the above categories of active diagnostic medical devices. *(F7ABBKZS, F7ABBOIZ, F7ABBFY2)*

Ultrasound imaging systems including Doppler modules. Computed tomography imaging systems - CT, MR, PET, SPECT. Hybrid imaging systems (SPECT/CT, PET/CT, PET/MR). Phantoms for calibration and spatial resolution verification. There is required knowledge of the physical principle, image formation based on the primary parameter, properties, parameters and important applications for all above mentioned medical imaging systems. Related knowledge, skills and aspects of anatomy, physiology, chemie, biochemistry, medical device design and construction, pathology, hygiene and epidemiology and ethics are assummed for the above categories of active diagnostic medical devices. *(F7ABBTZS, F7ABBOIZ, F7ABBFY2)*

Optical methods (atomic spectrometry and molecular spectrophotometry in UV-VIS domain, other optical methods). Chromatography (thin-layer, gas, liquid). Electrophoresis (zone and

capillary). Centrifugation. Mass spectrometry. Electrochemical methods (potentiometry, methods using electrolysis, conductimetry, electrodes). Biosensors. POCT. Membrane processes. Osmometry. Basic methods of molecular genetics (PCR, restriction analysis). Principles of immunochemical methods. Automated analyzers (complete and modular systems, computers blood particles, flow cytometry). Related knowledge, skills and aspects of chemistry, physical chemistry, biochemistry, pathology, hygiene and epidemiology are assumed for the above categories of devices. *(F7ABBLT, F7ABBFCH)*

Relevant courses: *Biomechanics and Biomaterials (F7ABBBB), Electronic Elements and Sensors in Medicine (F7ABBSM), Theory of Electrical Engineering (F7ABBTEL), Electronic Circuits (F7ABBEO), Electrophysiology (F7ABBELF), Medical Devices and Equipment I (Diagnostic Devices) (F7ABBLPZ1), Medical Devices and Equipment II (Therapeutical Devices) (F7ABBLPZ2), Equipments for Anaesthesiology and Resuscitation (F7ABBSPT), Conventional Imaging Systems (F7ABBKZS), Tomographical Imaging Systems (F7ABBTZS), Clinical Laboratory Instrumentation (F7ABBLT), Protection Against Ionizing Radiation (F7ABBOIZ)*

Topic 3 (compulsory): **Administration, Maintenance, Service, Acquisition, Purchasing and Legislation of Medical Devices** *(ESPLZT):*

Basic tasks and competencies of the technical staff within the hospital - within the health care facilities in general. Department of Medical Technology and/or Department of Biomedical Engineering. Examples of daily and long-term operational activities within the department. Requirements for education and competences of a biomedical technician. Terminology in the health care sector. Medical device risk classes, rules for its designation under applicable law. Procurement of equipment and their acceptance, entry into service and documentation. Vigilance system of the medical device. Maintenance and repair via internal staff or via contractors. Technical data of medical devices collecting and storing. Metrology and medical devices. The calibration and verification assurance, measurement uncertainty and their importance in applications. Selection of suitable measuring instruments. Checking of the medical devices electrical safety and technical safety inspection (preventive maitenance). Relation to the technical standards of the EN 60601 and EN 62353 series in the current edition. Preparation of documents for tenders. Specific requirements for equipment at intensive care units (ICU) and departments of anaesthesia and critical care medicine (ACCM). Related guidelines for design and standards. Quality Management System for the department of medical technology. The purchase contract and service agreement. Cleaning and sterilization and type of sterilization. Ionizing radiation. Protection against its adverse effects. Dosimetry. Standards for the use of ionizing radiation sources. Pressure containers in health care. Medical gases and water vapor. Maintenance of pressure containers. The introduction of new software and technology in health care facilities. Project management and design (design documentation) when installing new technology. Related knowledge, skills and aspects of professional terminology, hygiene and epidemiology, project design and management, and healthcare management and administration are expected for the above areas. *(F7ABBESP, F7ABBOIZ, F7ABBNMP)*

Types of distribution networks (grids, earthing systems - TN, TT, IT). Transformers, autotransformers, single-phase, three-phase, construction, cores, parameters, characteristics, basic wiring, clock angle. Specifics of transformers for medical devices. Types of power. Hospital power system. Essential specifics. Grounding. Isolated power system. Category of spaces/rooms in the hospital based on classification of external factors. Color coded sockets, cables, technical standards applied in the hospital or in general within the infrastructure in

health care, backup power system in the hospital (uninterruptible power supply - UPS, diesel generator). Connection of single-phase and three-phase loads to individual types of distribution networks. Wiring of single-phase and three-phase sockets. Medical electrical equipment - safety and leakage currents. Drivers used in the devices in health care (types of engines - application), torque characteristics, speed control. Electrical devices - protective devices and guards (circuit breakers and protectors), short-circuits, overcurrents, conductors selection process. Technical standards relevant to the hospital power system. Protection against electric shock (EN 61140) - protection ensured under normal conditions and protection ensured under single fault condition, principles and means including combined ones (SELV, PELV, FELV). Principles of operation of inspection instruments (safety testers), their use for MD (measured parameters) and performance of safety and functional check (EN 62353 in the current edition). For the above areas, related knowledge, skills and aspects of theory of electrical engineering, electrical measurements, electronic circuits and medical device design and construction are assumed. *(F7ABBTEL, F7ABBEO, F7ABBSEL)*

Public health. Patient safety and mobility. System adoption of the EU documents in EU countries. EU regulations. Assignment to a class of medical devices. Requirements for education and competences of a biomedical technician. Lifelong learning for healthcare professionals. Professional competence in electrical engineering (qualifications). Products technical requirements legislation. Technical normalization in the world and in Europe. The structure of institutions in a health care technical standards area and technical standards including series EN 60601 and EN IEC/ISO 80601. Harmonized technical standard. Metrology in healthcare. Determination of gauges as provided and not provided one. Medical devices introducing in the market, medical devices conformity assessment procedures, EC and EU conformity declaration, medical devices notification, product certificate. Good clinical practice. Clinical trials. The practice of clinical trials. Ethics committee and informed consent. The quality system in hospitals. The quality of medical devices. Standards, certification, ISO 9000. The nuclear law and its application in health care. The nuclear law and personal safety. Dosimetry. *(F7ABBZLN, F7ABBOIZ)*

Relevant courses: *Management of Health Care Technology (F7ABBESP), Theory of Electrical Engineering (F7ABBTEL), Electronic Circuits (F7ABBEO), Power Engineering (F7ABBSEL), Legislation in Health Care and Technical Standards (F7ABBZLN), Protection Against Ionizing Radiation (F7ABBOIZ)*

Approved at the Biomedical Technology study programme board meeting on 3. 11. 2023.

Kladno, 18th December 2023

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