

Topics for the Final state examination (FSE) in the bachelor's study specialization "Biomedical Technician" within the bachelor's study program B3921 "Biomedical and Clinical Technology"

Pursuant to article 7 (3) of the Directive of the dean concerning the bachelor and master's study programs at Czech technical university in Prague – Faculty of Biomedical Engineering, the Dean stipulates on the basis of the proposal of the head of the department of biomedical technology the below mentioned topics.

At the beginning of the summer semester, i.e. before the FSE, there is required in accordance with a paragraph 3 of Art. 7 of the directive mentioned above to select 3 mandatory thematic areas.

The topics are in correspondence with the approved content of the application to the Ministry of Education, Youth and Sports on the prolongation of the accreditation of the 3 year bachelor's study program of the study branch "Biomedical technician", file N. 40866/2011-M3 of 20. 12. 2011 valid until 1. 3. 2020. The topics are in correspondence with the approved content of the application to the Ministry of Health, with specific criteria of the Accreditation Commission of the Czech Republic and with the content of the Guidelines Ministry of Health (Ministry of Health Bulletin No. 10/2010) as well. **There are included study plan changes approved by the scientific board of the CTU FBME with validity for the 1st year students from academic year 2017/2018, 2018/2019 and 2019/2020.**

The topics are set as the minimum necessary knowledge and skills essential for the graduate of the study branch "Biomedical technician" to be able to succeed in the labour market. For better orientation of students at the end of the thematic group titles of the mandatory courses are included. In compliance with the accreditation, all topics are obligatory for the student. The FSE is opened by the defence of the diploma thesis. The exams from 3 compulsory selected topics before follow. The examiner asks two questions at least belonging to the drawn topic. The questions are directly connected with the topic or the topic of the diploma thesis but which are part of another related topic are not forbidden. The complementary questions are posed by the members of the committee or by a member of the committee chosen by the chairman of the committee. The answers to the questions follow immediately after posting them and without written preparation.

Topic Hospital Information Systems (NIS):

Classification of signals, one dimensional and two dimensional signals, stochastic, stationary and ergodic signals, sampling and quantization, sampling theorem. Signal to computer conversion chain. A/D 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. 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, autonomous control in multidimensional systems. (17ABBUSS)

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 identification. (17ABBMS)

Cardiovascular system biosignals. Phonocardiography, apexcardiography. Heart rate variability (HRV). Biosignals of skeletal muscles and tendons, EMG. Evoked potentials. EOG. Audiometry. Sleep polygraphy. AR, MA, ARMA data models - properties. Selected biosignal processing specifics, basic EEG parameters, frequency bands, electrode montages. Biosignals spectral analysis, parametric and non-parametric models of spectrum estimation. Periodogram. Principle and advantages of parametric models of spectrum estimation. Resolution of the neighbouring frequencies. Displaying the results of spectral analysis. CSA-compressed spectral array. Topographical mapping of electrophysiological activity in amplitude and frequency domain. Long-term EEG signals analysis, adaptive segmentation, features extraction, cluster analysis videomonitoring. (17ABBLS)

Information systems - IS (classification, system development, IS development life cycle, IS analysis, types of SW maintenance). Computer networks classification. Layer model TCP/IP, addressing within TCP/IP (MAC and IP address, network mask), IPv4 and IPv6, DHCP, network address translation (DNS), network hardware (switch, router). Server (types, purpose). Hospital information systems (HIS), HIS components, PACS, DICOM. The connection of the medical devices into the HIS. Data formats for communication of the health-care facilities and Ministry of Health of the Czech Republic. Systems of the diagnoses and procedures classification. 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. (17ABBISZ)

Relevant courses: *Introduction to Signals and Systems (17ABBUSS), Modelling and Simulation (17ABBMS), Biological Signals (17ABBLS)*

Topic Medical Devices (LPT):

Anthropometry and description of the position and movement of the human body in space. Methods and systems of measurement, calculation and quantitative evaluation of the movement in biomechanics. Kinematics and dynamics of the human body movement. Measurement and calculation of forces and moments in biomechanics. Interpretation methods and quantitative evaluation of forces and moments in biomechanics. Methods of measurement and calculation of stresses and deformations in biomechanics and prosthetics. Gait biomechanics and gait assessment methods. Biomechanics of the upper and lower extremities. The stability of the body and postural stability evaluation methods. Calculation and application of work, energy and power in biomechanics. Mechanical structure and physical function of the musculoskeletal

system. Biomaterials and biocompatibility. Rheological models of biological materials. Modeling of ligaments, tendons and muscles. Types of stresses strains and material properties of bones. Types of stress, deformations and material properties of ligaments, tendons and muscles. Orthotic and prosthetic devices, types and applications. Exoprosthesis and endoprosthesis of upper and lower extremities. Calculations of stresses and deformations in orthotic and prosthetic device structures. Myoelectric prosthesis and methods of EMG signal measurement and processing. (17ABBBB)

Physical principles, static and dynamic parameters of electronic elements and sensors,— electronic circuit connections and applications, temperature sensors, sensors of mechanical quantities (pressure, force, position, flow, level accelerometers etc., piezoelectric sensors, magnetic, capacitive, sensors with inductance, sensors of magnetic quantities (Hall and magnetoresistance effect, magnetotransistor, SQUID), sensors of chemical and biochemical quantities (gases, pH, ISFET), sensors with optical fibers, diodes and transistors. (17ABBESL)

Medical devices categories in accordance with EU directives. Biopotential amplifiers (dynamic range, frequency response, differential operational amplifier (OA), common mode rejection ratio - CMRR, CMR). Electrocardiographs, lead systems. 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 and signals in the nervous system. Medical devices and methods for audiometry. Electromyography and electromyogram. Evoked potentials. Methods of lung ventilation and lung ventilators. Capnometry/capnography. Vital signs monitors and Holter monitoring. (17ABBLPZI)

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). (17ABBLPZ2)

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 and unconventional modes of lung ventilation and related ventilators. Equipment in Anaesthesia and Critical Care. Anaesthetic vaporisers, description and thermodynamic principles. Humidification of ventilatory gases. Equipment for monitoring and support of blood circulation. (17ABBSP)

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 possibility 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. (17ABBPPSA)

Electromagnetic spectrum and medical imaging systems. 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. Digital radiography. Conventional imaging systems in nuclear medicine. (17ABBKZS)

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. (17ABBTZS)

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. 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, POCT, immunoassay analyzers) (17ABBLT)

Relevant courses: *Biomechanics and Biomaterials (17ABBBB), Electronic Elements and Sensors in Medicine (17ABBESL), Medical Devices and Equipment I (Diagnostic Devices) (17ABBLPZ1), Medical Devices and Equipment II (Therapeutical Devices) (17ABBLPZ2), Equipments for Anaesthesiology and Resuscitation (17ABBSPT), Conventional Imaging Systems (17ABBKZS), Tomographical Imaging Systems (17ABBTZS), Clinical Laboratory Instrumentation (17ABBLT)*

Administration, Maintenance, Service and Legislation of Medical Devices (SUSLZT):

The mission of the technical staff within the hospital - within the health care facilities in general. Department of Medical Technology and/or Department of Biomedical Engineering. Portfolio of specialized procedures applied onto medical devices, responsibilities and competencies. Organization of daily and long-term operational activities within the department. 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. 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. (17ABBMZT)

Types of distribution networks (grids, earthing systems - TN, TT, IT). Hospital power system. Essential specifics. Grounding. Isolated power system. Transformers. Autotransformer.

Category of spaces/rooms in the hospital. 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 - protection ensured under normal conditions and protection ensured under single fault condition, principles and means. (17ABBSEL)

Public health. Patient safety and mobility. System adoption of the EU directives in EU countries. EU directives. Assignment to a class of medical devices – MEDDEV. Products technical requirements legislation. Technical normalization in the world and in Europe. The structure of institutions in a health care technical standards area. 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. Formal content. Flow chart – how to prepare clinical trial for new medical device. The quality system in hospitals. The quality of medical devices. Standards, certification, ISO 9000. Medical devices EU directives and regulations. The nuclear law and its application in the resort of health care. The nuclear law and personal safety. Dosimetry. (17ABBZLN)

Relevant courses: *Management of Health Care Technology (17ABBMZT), Power Engineering (17ABBSEL), Legislation in Health Care and Technical Standards (17ABBZLN)*

Topic Fundamentals of Medical Sciences and Health Care Service (ZLZ):

Cell. Control and regulation (thermoregulation, acid-base balance). Nerve and muscle. The autonomic nervous system. Blood. Respiration. Kidneys. Heart and blood circulation. Body temperature and its regulation. Nutrition and digestion. Endocrine system and hormones. Central nervous system and sensory organs. The above mentioned topics are understood as broader thematic topics from the field of human physiology. There will be emphasized understanding and interpretation of human physiology functions via schemes and context. There is required knowledge of basic anatomical terms and medical terminology as well. (17ABBAF1+17ABBAF2)

Excitable tissues (muscles and nervous system) from the origin point of view, measurement possibilities and electrical parameters changes utilization (action, resting potential, nerve, synapse). Possibilities of electrical parameters measurement on the level of – cell, tissue and the whole organ. Examples of utilization of electrical parameters of cells, tissues and organs. Electrical stimulation (basic principle, utilization). (17ABBELF)

Tumors. Inflammations. Physical examination of the patients, anamnesis, physiological basis of the electrocardiogram and blood pressure. Selected diseases and their diagnostics including instrumentation in cardiology, angiology, pneumatology, nephrology, gastroenterology, hematology, endocrinology, internal environment, i.e. water, electrolyte and acid-base balance, skeletal, joints and muscular system. Laboratory diagnostic methods (hematology,

transfusiology, biochemistry, immunology, microbiology, serology). (*17ABBZPD - part of the course related to pathology*)

Hygiene and waste disposal, possibilities of liquidation and potential health risks. Physical environmental factors and their effect on the human organism. Hygienist requirements for the medical devices, the operation of the medical department, construction and technical requirements/standards. Principles of the sanitary-epidemics regime (disinfection, sterilization, principles of medical devices care in connection with the valid legislation). Work environment hygiene. Epidemic process (characteristics, measures). Principles of non-infectious epidemiology. Acute respiratory and diarrheal diseases. Acute infective hepatitis, HIV/AIDS. Nosocomial infections (factors affecting their emergence and spread, prevention, resistance to antibiotics, the principles of immunization). (*17ABBZPD - part of the course related to the hygiene and epidemiology*)

Cardiopulmonary resuscitation. Defibrillation including AED. Controlled breathing. Resuscitation for children. Stop bleeding. Coma. Life-threatening injuries (head injuries, chest injuries, pneumothorax, abdominal injuries). Fractures. Evacuation and transport. First aid by seizures. First aid in selected serious clinical conditions and suspected: acute myocardial infarction, hypo-/ hyperglycemia, exacerbation of bronchial asthma, acute allergic reaction, and stroke. First aid for burns and electrical shock. First aid for damage of the eyes and mucosae. Hypothermia and hyperthermia first aid. (*17ABBPP*)

Basic difference between ethics and law. Ethical codes. Informed consent. Ethical relationship of the healthcare professional and the manufacturer (equipment, drugs), ethical issues associated with advertising in health-care, conflict of interest issues in medicine. Research in medicine and its regulation. Ethics committee. Ethical issues of organ transplantation and artificial organs, ethical problems of introducing new technologies - artificial organs. (*17ABBEBI*)

The structure of the healthcare sector. Architecture, structure and healthcare facilities types. Types and description of medical and technical staff in a hospital type of healthcare facilities. Positions of technical staff and healthcare workers and their interrelationship/communication (examples). Status and activities of a biomedical technician in medical facilities (educational requirements, typical activities at the department of medical equipment, specifics). The system of continuous education in health care. Quality management systems (QMS) and hospital accreditation. (*17ABBMAZ*)

Relevant courses: *Anatomy and Physiology (17ABBAF1+17ABBAF2), Electrophysiology (17ABBELEF), Fundamentals of Pathology, Hygiene and Epidemiology (17ABBZPD), First Aid (17ABBPP), Ethics in Biomedical Engineering (17ABBEBI), Management and Administration in Health Care (17ABBMAZ)*

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