

Module: Medical Technology II – Safety Concepts

Level	Master	Short Name	MT II
Responsible Lecturers	Müller, Stefan, Prof. Dr.-Ing		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	ECTS Credit Points	5
Semester of Studies	2	Semester Hours per Week	4
Length (semesters)	1	Workload (hours)	150
Frequency	SuSe	Presence Hours	
Teaching Language	English	Self-Study Hours	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	Exam Language	English
Exam Length (minutes)		Exam Grading System	One-third Grades
Learning Outcomes	• Students are familiar with the key safety concepts employed in medical technology and can explain the underlying principles. • Students are able to functionally analyze major generic medical devices (specifically infusion pumps and ECGs), identify hazards, assess risks, and design safety measures (using a risk-based approach). • Students are familiar with the essential principles and methods of biological safety and can plan and evaluate a biological safety assessment. • Students are familiar with the safety principles for electromedical devices and can apply these principles to generic product groups. • Students are familiar with the methodology for weighing the risks—including residual risks—of a medical device against its benefits • Students understand safety issues of software in medical devices on a prominent medical device example (Therac-25) • Students understand how software for medical devices must be developed, tested, and maintained to ensure patient safety according to IEC 62304 standard		
Participation Prerequisites			

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✓ Use of gender-neutral language (THL standard) ✓ Target group specific adjustment of didactic methods ✓ Making subject diversity visible (female researchers, cultures etc.)
Applicability	

Remarks	
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Module Course: Medical Technology II – Safety Concepts

(of Module: Medical Technology II – Safety Concepts)

Course Type	Online Course	Form of Learning	Online supported
Mandatory Attendance	no	ECTS Credit Points	5
Participation Limit		Semester Hours per Week	4
Group Size		Workload (hours)	150
Teaching Language	English	Presence Hours	0
Study Achievements ("Studienleistung", SL)		Self-Study Hours	150
SL Length (minutes)		SL Grading System	

The following section is filled only if there is a course-specific exam.

Exam Type		Exam Language	
Exam Length (minutes)		Exam Grading System	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Introduction (Fundamentals, Definitions, Safety, Balancing Safety and Effectiveness/Benefit) • Risk-Based Approach – Concepts for Risk Management • Regulatory Framework and Standards (Technical Standards) for Safety: Process Standards, General Product Standards, and Standards for Specific Products • Physical and Mechanical Safety • Electrical Safety • Biological Safety • Functional Safety • Application Safety – Usability • Software development and Lifecycle process management to ensure safe software
Literature	1. Wintermantel E, Ha S-W: Medical Technology – Life Science Engineering. 5th Edition, Springer Heidelberg, Berlin (2009); ISBN: 978-3-540-93935-1 (e-ISBN: 978-3-540-93936-8) 2. Rüdiger Kramme (Ed.): Medical Technology. 3rd Edition; Springer Medizin Verlag Heidelberg (2007); ISBN-13: 978-3-540-34102-4 3. Alexander K, et al.: Good Design Practice for Medical Devices and Equipment – A Framework. University of Cambridge Engineering Design Centre (2001); ISBN: 1-902546-08-3 4. Havel, P.: How to Design Safe Medical Products. Machine Design (2014): 62–69; ISSN: 0024-9114, www.machinedesign.com/medical/how-design-safe-medical-products

	5. IEC 62304
Remarks	