

Course PM, HN2013/HN2025, autumn 2021

Final version 2021-09-09

with reference to Appendix A, B, C and D downloadable from the Canvas course web

“Ergonomics, Human Factors and Patient Safety”

HN2013, 6.0 credits - (for students in the Mastersprogram – Medical Engineering)

HN2025, 7.5 credits - (for students in the Mastersprogram – Technology, Work & Health)

Educational level: Second cycle

Subject area: Technology and Health **Grade scale:** A, B, C, D, E, FX, F

DISCLAIMER!

Due to the Corona Pandemia and Covid-19 disease spread in society alterations of the course may have to be done with short notice!!!

Any changes will be notified by mail via Canvas!!!

Course offered by

School of Engineering Sciences in Chemistry, Biotechnology and Health, Department of Ergonomics.

About the course

After the course students should be able to analyze how the health care system interacts with human physiology cognition and technology. The aim is that the students should be able to apply a "Human-Technology-Organization" perspective in the design, development and evaluation of medical devices.

Moreover, they should be able to explain the principles of system safety and analyze factors contributing to mishaps and injuries in health care. The students should also be able to analyze the impact of medical technology on the work environment and patient safety and give examples of how this can be applied by medical engineers in the work for a positive progress on safety. As well as being able to reflect on how the organization and the work environment affect patient safety.

Some major changes made of the course design autumn 2021 due to the Corona Pandemia and Covid-19 disease:

- The lectures will be given in a kind of “hybrid mode” both live in a lecture hall and by simultaneous use of Zoom. The hybrid lectures will NOT be recorded but prerecorded lectures from the last year will be possible to reach throughout the course.
- The number of seminars needed to physically be attended has been reduced from 4 to 3. However, if necessary, due to important reasons students can after discussion in beforehand with the examiner be allowed to attend by use of Zoom.

Learning outcomes

By the end of the course each student will be able to:

- describe, exemplify and reflect on methods for applying knowledge about humans in the design, development and evaluation of medical technology.
- describe and discuss different approaches in analyses of incidents in complex systems.
- describe, exemplify and reflect on the main principles of system safety and how factors on different levels in the system can contribute to patient safety and the safety of the healthcare personnel.
- describe, exemplify and explain how organizational issues and the work environment affects patient safety.
- describe, exemplify and reflect on how medical technology affects the work environment and patient safety.
- describe, exemplify and reflect on how medical technology engineers actively can contribute to improve the work environment and patient safety in healthcare.

Course main content

- Background, development and relationship between ergonomics, human factors and patient safety.
- Humans cognitive and physical capacities, as individuals and in work.
- The systems view and sociotechnical systems.
- Risks in healthcare.
- Methods and tools for analysis, design and evaluation of work, work environment and products.
- Human factors and ergonomics concepts and terminology.
- Methods for risk analysis from a systems perspective.
- Patient safety concepts and terminology.
- Measures for increased safety in healthcare systems.
- Read and discuss scientific papers within the area of patient safety and worker safety.

Eligibility

120 university credits (hp) in engineering or natural sciences and documented proficiency in English corresponding to English B.

Requirements for final grade

INL1 – Assignments – written report, 2.0 credits, grade scale: P, F

SEM1 – Seminars - active participation, 2.0 credits, grade scale: P, F

TEN1 – Written home exam, 2.0 credits, grade scale: A, B, C, D, E, FX, F (HN2013)

TEN1 – Written home exam, 3.5 credits, grade scale: A, B, C, D, E, FX, F (HN2025)

Literature

The course literature is mainly based on scientific papers freely provided to students in PDF-format available on the course pages on KTH:s learning management system (course web), “Canvas”.

- See literature list in Appendix A (downloadable from Canvas)
- Papers in conjunction with seminars.

Assignment (INL1)

The aim with the assignment (INL1) is for the students to start reading and reflect on some of the course literature and lectures. Each student should, individually or in pair of two, write a short report (no more than 15 pages) about patient safety and worker ergonomic conditions in the health care system. The report can be written in English or Swedish. The assignment report should be e-mailed to the examiner (merics@kth.se) no later than 11 pm on 2021-10-03.

HN2013

In the assignment you should focus on the design and use of medical devices using different kinds of “alarms”. The aim is for you to describe the pros and cons with device alarms and discuss the complexity in health care settings with regards to patient and worker safety using different kinds of clinical alarm strategies and systems. In order to pass you need to include at least the following aspects:

- Discuss the current scientific knowledge about the potential ergonomic and patient safety problems with the use of medical device alarms in clinical health care.
- Discuss different engineering and manufacturer strategies for the design and implementation of alarms in medical devices.

HN2025

In the assignment you should choose one of the common risks that affect patient and/or worker safety (e.g. alarms, infections, infusion pumps, hand overs etc). The aim is for you to describe the risk and discuss the complexity with regards to patient and worker safety. In order to pass you need to include the following aspects:

- a) Discuss how they may be affected by the system in which they appear.
- b) Discuss how these risks are and can be identified.
- c) Discuss what can be done to reduce risks.
- d) Discuss what can an engineer in medical technology working in the industry or at a hospital do to contribute to the safety.

HN2013/HN2025

To be able to fulfil the assignment you will have to read and use part of the course literature and seminar papers. You also have to find and read other relevant scientific literature or governmental statistics from the library or from internet search. You need to refer to a minimum of 5 of the papers that are on the course literature list in order to pass.

- a) Your assignment shall be written as an essay, not a report with the headlines as Abstract, Introduction etc.... Of course, you can make paragraph headings of different kinds to enhance the easiness of reading!
- b) Use a text font size of 12, single space, maximum 15 pages, not counting the reference list. You can use fewer pages but then of course risk to not be able to cover the topics completely.
- c) The system for the reference list can be freely chosen but must be some of the internationally accepted systems, e.g. Vancouver system. If possible, please also note in the essay what system you have chosen.
- d) Please also include your personal name in the file name of the assignment so that it is easier to handle in the review process.

Seminars (SEM1)

It is mandatory to participate in all three seminars (SEM1) apart from the last one (no: IV). Note that the seminars will cover the topics from the lectures, thus everyone is strongly recommended to attend the lectures in order to facilitate participation in the seminars. Before each seminar students are expected to read the listed papers (see below) and it is essential that all students do so in order to manage an active participation in the seminar exercises. The seminars (SEM1, 2 credits) craves a lot of reading and preparation before the group discussions and plenary discussions so plan your study efforts for that!

After the seminar everyone is asked to within 48 hours send the examiner a short summary AND personal reflection of what one has learned from the seminar literature and exercise (maximum 1 page). The seminars will be examined by an active participation at the seminars and the submission of a summary/reflection. A minimum of at least two out of the three mandatory seminars must be attended to pass. For the occasion that you might be missing one, a more extensive written reflection on the literature or processed cases must be written (2-3 pages) and submitted through mail (merics@kth.se) to the examiner. All submitted summaries and reflections must be given file names indicating your name and the seminar number!!! You have to put yourself in my position as a user of a computer handling lot of files → give your files an appropriate name! 😊

Seminar I – Technology and patient safety

The aim with seminar I is to do a group exercise with an accident analysis based on the Terac-25 case from the perspective of the different actors involved in the case. Hopefully, you will learn from the seminar that this kind of accidents with medical technology must be analysed and judged from different perspectives.

1. You will all be divided into small groups of (four to five persons each, done “randomly” by the teacher).
2. Each group spreads out in the building and work together to find good arguments to defend themselves and accuse/blame other parts in a “mockup trial”. You have to prepare for being representing each and every one of the stakeholders below;
 - a. The company that has built the Terac-25 equipment.
 - b. The hospital and its management and personell that has used the Terac-25 equipment.
 - c. The regulating agency (e.g. FDA) that has to supervise and control the use of medical technology.
 - d. The patient that has been subject to maltreatment from the use of the Terac-25 equipment.
3. After about two hours we start the mockup trials in the Jacobsson lecture hall (T2) by selecting pair of groups that are randomly appointed to represent either (a) the company, (b) the hospital, (c) the regulating body, and (d) the patient. Note that all groups have to prepare to represent each of the four different stakeholders! Hopefully all groups will get the chance to attend in the “court” at least one time. Each trial will last no more than 10 minutes. In the end of each trial, the other students in the audience make a popular vote on which part in each trial that can be considered to have won their case.
4. In the end of the seminar the teacher will lead a general discussion and make some concluding remarks.

*Literature to be read **before** seminar I:*

Leveson, N. (1995) Medical Devices: The Terac-25. *In Safeware: System Safety & Computers.* Addison-Wesley.

Skim through the paper by Leveson and do not have the ambition to learn all details (e.g. software engineering details). Try to grasp the big picture!

Some additional short texts and instructions to be read in beforehand might be delivered at least with 72 hours notice, watch out!

Seminar II – Different cases and system dynamics

At seminar II we will have a group exercise discussing different cases from different perspectives and in relation to Rasmussen's model of conflicting objectives. The teacher will divide You in to small working groups!

Everyone of You are supposed to before the seminar have thoroughly read (or watch) the four cases (see below). You are also supposed to have read the article by Rosness et al (see reference and reading instructions below). For the exercise at this seminar you will be randomly assigned to a group. The teacher will instruct which one of the following four following cases (A-D) to be analysed in your group. Each group then selects by themselves which theoretical model to apply to the given case.

For the exercise at this seminar, the teacher will instruct each group which one of the six perspectives and theories described in the paper of Rosness that should be used when analysing one of the four following cases (A-D). Each group can select by themselves which case (A-D) to be analysed with the perspective determined by the teacher.

A – Ben Kolb case.

B – Risks and potential consequences of hazards in health care (fatigue and working hours).

C – Human Error in the ICU.

D – Just a Routine Operation.

Papers about the cases can be downloaded from *Canvas/HN2013/File: Seminar II*. Case D can also be viewed on a video at the following link <https://vimeo.com/970665>.

Based on your chosen case you will be asked to discuss:

Q1. How can you apply any of the theoretical models of safety described in Rosness et al (2010) to your cases? Choose one theoretical model and give a motivation why you thought that one was the best to apply to your case. The level of details in the cases will differ, which means that you will have to use your imagination more or less. The important thing is that you speculate and reflect even if you may not have all the facts to know if it accurate or not.

Q2. Discuss if it would be possible to improve safety in the case you have chosen by any technical intervention (modification of existing technology or new technology). Argue why it is or isn't. Also highlight what the pros and cons would be.

At the end of the seminar each group will be asked to present what they have discussed and which answers they have reached. You should prepare a presentation where everyone in the group present at least one thing. Please also try to identify if you can illustrate parts of your discussion on the white board.

*Literature and cases to be read **before** the seminar:*

Rosness, R., et al (2010). Organisational Accident and Resilient Organisations: Six Perspectives . Revision 2. *SINTEF Rapport A17034. Trondheim, Norge.*

- Read, but just skim fastly through page 25-34 (the Snorre A blow out example).
- Read chapter 4, 5, 6, 7, 8, and 9 (page 35-109) except for the parts that are related to the train collision at Åsta.

Cook, R., Rasmussen, J. (2005). “Going Solid”: a model of system dynamics and consequences for patient safety. *Qual. Saf. Helath Care*, 14;130-4.

Debono, D., et al (2013). “Nurses’ workarounds in acute healthcare settings: a scoping review”. *BMC Health Service Research*, 13:175.

Case A, B, C and D (+ video).

Seminar III – Design of alarm systems in medical system and devices.

Seminar no: III will be a kind of follow up on lecture no: VII and the Assignment (INL1) and have focus on the design and use of different kinds of alarms in medical devices. Everyone of You are supposed to before the seminar have thoroughly read the two cases A & B (see below). You are also supposed to have read the six (6) papers concerning alarms listed below. For the exercise, at this seminar you will be randomly assigned to a group. The teacher will instruct which one of the two cases (A or B) to be analysed, investigated and worked with in your group.

Case A

Swedish Accident Investigation Authority (2013). Death at the cardiac clinic's heart intensive care unit N25 at Karolinska University Hospital in Solna, Stockholm, October 17, 2010. Dnr O-01/11 Final report RO 2013:02. (Partly translated from English to Swedish, 2019). *The original report is available in Swedish!*

Case B

Wachter, R. (2017). ”The overdose”, Chapter 12-17. Excerpts from the book ”The Digital Doctor – Hope, Hype and Harm at the Dawn of Medicine’s Computer Age”

Based on the case given, you as future engineers will be asked to discuss within the group if it would be possible to technically improve the alarm functions for increased safety and prevention of future similar accidents. Please, try to suggest different kinds of technical innovations or interventions (modification of existing technology or new technology) of the alarm functions. If you think it is needed also decide if there is any appropriate organisational or managerial changes that may improve safety regarding the need of getting the attention of the health care personell. Argue why it is or isn't. Also highlight what the pros and cons would be. If you think it would be useful, apply any of the theoretical models of safety described in Rosness et al (2010) to your case (see seminar II).

At the end of the seminar each group will be asked to present what they have discussed and which practical design suggestions they have reached. You should prepare a presentation where everyone in the group present at least one thing. Please also try to identify if you can illustrate parts of your discussion on the white board.

Literature and cases to also be read **before** the seminar as a knowledge background,
Papers Seminar III:

Borowski, M. et al (2011). Medical device alarms. *Biomed Tech*, 56:73-83.

Cvach (2012). Monitor alarm fatigue - an integrative review. *Biomedical Instruments & Technology*, July/August, 268-277.

ECRI-institute (2019). Culture of safety: an overview. (Web link:
<https://www.ecri.org/components/hrc/pages/RiskQual21.aspx?tab=2>).

Keller J.P. (2012). Clinical alarm hazards: a “top ten” health technology safety concern. *Journal of electrocardiology*. 45:588-591.

Raymer et al (2012). Anaesthesia monitor alarms: a theory-driven approach. *Ergonomics*, 55:1487- 1501.

Van Pul et al (2016). Pattern discovery in critical alarms originating from neonates under intensive care. *Physiological Measurement*.

Some additional papers, short texts and instructions to be read in beforehand might be delivered at least with 72 hours notice, watch out!

HN2013 - Lectures

The lectures will be given in a kind of “hybrid mode” both live in a lecture hall (see schedule, appendix B) and by simultaneous use of Zoom. The hybrid lectures will NOT be recorded but prerecorded lectures from the last year will be possible to reach throughout the course (see Appendix D for a link list).

If the number of students attending physically might exceed the number of students allowed in each different lecture hall, additional students are not allowed in to the lecture hall and therefore have to follow the “hybridlectures” through the videoconferencing tool Zoom (see link list in the schedule, Appendix B). In most of the lecture halls it is possible to withheld the required physical distancing of a minimum of 2 meters, but to reduce the burden and crowding on the regional traveling system (bus, subways and trains) you are most welcome to attend most of the course (except for seminar I-III) through Zoom!

HN2013 - Examination (TEN1)

The examination (TEN1) in the HN2013 course is made in the form of a home examination. Out of a list of ten (10) in depth questions (see Appendix C), each student will be individually and randomly be given four (4) questions that you should consider in a written essay / report of 20-25 pages (not counting the reference list). For further information see Appendix C with a list of the home exam questions together with instructions (Appendix C can be found on the Canvas course web). The specific questions that you should answer will be distributed to each of you by mail from the examiner no later than Friday 1st of October (2021-10-01). If you still have not received any questions after that date, please contact me promptly by mail!, (meric@kth.se).

I urge You to start read all of the literature already in the beginning of the course and eventually start to make preliminary answers to all of the ten questions below, even if You do not yet know what questions You will get!!!, “do not procrastinate”!, 😊

The completed paper (TEN1) that should be written individually (do not copy any other persons text!!!) must be submitted to the examiner for assessment no later than Sunday evening (11 pm) 24:th of October (2021-10-24). The papers received after this date and until three weeks later (2021-11-14) can only be considered for grades F, Fx, or E. Papers handed in after 2021-11-14 will not be graded at all. In order to obtain higher marks than E must timeout (2021-10-24) have been held.

Among the submitted home exam papers, some will be randomly selected where the student also must undergo an oral examination to reasonably ensure that it is the student who wrote the essay. The randomly selected students will be contacted by the examiner to set out a date for the additional oral examination. Every one of you has to be prepared for that!

The essays will be checked for plagiarism in accordance with KTH guidelines. A document about that, “*Guiding students away from plagiarism*” can be found on the HN2013 Canvas course web.

The grading will be made from the criteria listed below (page 9). In general a higher grade is associated with demonstrated ability to argue, reflect and critically analyse and summarise the issues based on the literature and your own reflections. For grades E-A, you must answer the questions from both a worker- and patient safety perspective in all questions. *Note that for grades D-A the exam must be submitted before 2021-10-24.*

HN2025 - Examination (TEN1)

The examination (TEN1) in the HN2025 course is made in the form of a home examination. You will be given *seven* (7) in depth questions that you should consider in a written essay / report of 35-40 pages (not counting the reference list). See the separate list (Appendix C) of the questions together with instructions (can be found on the Canvas course web). I urge You to start read all of the literature already in the beginning of the course and eventually start to make preliminary answers to all of the seven questions listed in Appendix C, “do not procrastinate”!, 😊

The completed paper (TEN1) that should be written individually (do not copy any other persons text!!!) must be submitted to the examiner for assessment no later than Sunday evening (11 pm) 24:th of October (2021-10-24). The papers received after this date and until three weeks later (2021-11-14) can only be considered for grades F, Fx, or E. Papers handed in after 2021-11-14 will not be graded at all. In order to obtain higher marks than E must timeout (2021-10-24) have been held.

Among the submitted home exam papers, some will be randomly selected where the student also must undergo an oral examination to reasonably ensure that it is the student who wrote the essay. The randomly selected students will be contacted by the examiner to set out a date for the additional oral examination. Every one of you has to be prepared for that!

The essays will be checked for plagiarism in accordance with KTH guidelines. A document about that, “*Guiding students away from plagiarism*” can be found on the HN2013 Canvas course web.

The grading will be made from the criteria listed below (page 9). In general a higher grade is associated with demonstrated ability to argue, reflect and critically analyse and summarise the issues based on the literature and your own reflections. For grades E-A, you must answer the questions from both a worker- and patient safety perspective in all questions. *Note that for grades D-A the exam must be submitted before 2021-10-24.*

Grading criteria HN2013/HN2025

Grade	Criteria	
F	<p>Very limited knowledge and understanding of the literature and key issues.</p> <p>A number of irrelevant and inaccurate claims.</p> <p>Brief or unfinished essay which prevents assessment.</p> <p>Deficiencies which may no longer be correct within a reasonable time frame</p>	
Fx	<p>Insufficient description of the issues related to the question.</p> <p>Not supporting statements with references to literature or sources.</p> <p>No clear structure of the essay and/or the text being hard to follow for the reader.</p> <p>Brief and unstructured text.</p> <p>Insufficient or inadequate resources.</p>	
E	<p>Covering the basic areas related to the issues that the question is related to.</p> <p>Uses literature and references to support description of the issues.</p> <p>Has a structure that makes it easy to follow and has a summary and conclusion.</p>	
D	<p>Has a structure that makes it easy to follow and has a summary and conclusion.</p> <p>A careful review of the used literature has been carried out.</p> <p>The home exam is well structured and well written.</p> <p>The student demonstrates a good understanding of the literature and important empirical and theoretical issues.</p>	
C	<p>Has a structure that makes it easy to follow and has a summary and conclusion.</p> <p>A solid understanding of the literature that has been used.</p> <p>An ability to apply this understanding in well-structured arguments and presentations.</p> <p>An ability to contextualize and compare the key parts of the literature that has been used.</p>	
B	<p>Has a structure that makes it easy to follow and has a summary and conclusion.</p> <p>A high degree of independence and originality in the discussion and analysis of the literature used.</p> <p>A high level of comparative ability and critical analysis.</p> <p>Well-written reflections and interpretations that are based on the literature that has been used.</p> <p>A high level of understanding of the relationship between theory and empirical material</p> <p>Being able to relate the issues to examples or discuss how issues related to the question can be applied.</p>	
A	<p>Has an excellent structure that makes it easy to follow and has a summary and conclusion.</p> <p>A high level of originality and critical synthesis.</p> <p>A high level of comparative ability.</p> <p>Well written and self-reflections and interpretations that are based on the literature that has been used.</p> <p>A deep understanding of the empirical evidence and theoretical issues.</p> <p>Gives examples and discuss application of relevant theories or empirical issues.</p> <p>Addresses major questions and counter-arguments that readers are likely to raise</p>	

Final grade

The final grade of the course (HN2013 and HN2025) will be determined by the grade on the home exam.

Course web and communication

Course material for the seminars will be distributed and available through the KTH-Canvas course web. Here will also other course related information and lecture power points be distributed.

Examiner

Mats Ericson, professor, merics@kth.se

Course administration

Mats Ericson, Head of course, E-mail: merics@kth.se, Mobile: +46-70-7494920

Schedule and Teachers

To be announced on KTH-Canvas at the start of the course.

Appendix, HN2013/HN2025:

- **Appendix A, HN2013/HN2025, Course literature, Autumn 2021**, *downloadable from the Canvas course web.*
- **Appendix B, HN2013/HN2025, Schedule, Autumn 2021**, *downloadable from the Canvas course web.*
- **Appendix C, HN2013/HN2025, Home exam questions (TEN1) – Instructions, Autumn 2021**, *downloadable from the Canvas course web.*
- **Appendix D, HN2013/HN2025, Link list to prerecorded videolectures, Autumn 2021**, *downloadable from the Canvas course web.*