

# Applying usability engineering to medical device design

Medi'Nov

September 9, 2020

Presented by

**Veerle Migchelbrink**

Senior Human Factors Specialist – Emergo by UL



# Human factors for medical device design

Optimize the quality of interaction between people and products, and help make products that are:



Safe



Effective



Satisfying

# The regulatory imperative



# Intent

- Understand users
- Understand use environment
- Identify hazards and use-related risks
- Generate user interface requirements
- Design a safe, effective product
- Perform formative evaluations
- Validate (confirm) that users can interact safely and effectively with “production equivalent” product
- Produce complete design history file, providing evidence that human factors has been applied as required



Understanding users and  
use environments

# User groups

Identify device users





# User groups

## Identify device users

### Characteristics to consider:

- Physical abilities
- Sensory abilities
- Cognitive abilities
- Medical condition, comorbidities (patients)
- Knowledge, experience
- Education, training
- Emotional state



# EXERCISE 1 – Identify potential use errors (users)





# Use environments

## Identify use environments



# Use environments

## Identify use environments

### Characteristics to consider:

- Lighting level
- Ambient noise
- Movement, vibration
- Other equipment
- Surrounding activity



## EXERCISE 2 – Identify potential use errors (use environment)







# Usability testing

# Usability testing – Steps

- Define use scenarios
- Recruit representative test participants
- Create representative use environment
- Engage test participants in scenario
- Document user performance
- Analyze test results
- Draw conclusion





## EXERCISE 3 – Identify design recommendations





65+ human factors specialists  
focused on helping clients  
develop medical products



# Contact Information

## **Emergo by UL**

Human Factors Research & Design  
Arthur van Schendelstraat 600-G  
3511 MJ Utrecht  
[humanfactors.emergobyul.com](https://humanfactors.emergobyul.com)

## **HFR&D practice locations**

Concord, MA/USA | Chicago, IL/USA | Utrecht, NL | Cambridge, UK | Tokyo, JPN

## **Presenter**

Veerle Migchelbrink  
Senior Human Factors Specialist  
[Veerle.Migchelbrink@ul.com](mailto:Veerle.Migchelbrink@ul.com)



[EmergobyUL.com](https://EmergobyUL.com)