Medical Device Usability Course

Instructor: Dr Nick Bradley, BERGO UK	
Day 1: Thursday 13 November 2025	
Time zone: London (GMT)	
09.00 – 09.15	*Objectives, Overview and Introductions*
09.15 – 12.15	**1. Introduction to Usability Engineering** a) What is meant by usability? b) Legal framework for manufacturers c) Overview of usability engineering process in IEC 62366-1:2015 +AMD1:2020 *Discussion: Experiences and Challenges*
12.15 – 13.15	*Lunch*
13.15 – 15:00	**2. User Research** a) Design guidance in ANSI/AAMI HE75:2009/(R)2018 b) User research techniques c) Preparing a use specification *Exercise: Use Specification*
15.10 – 16.30	**3. Task Analysis** a) Introduction to task analysis b) Task analysis techniques c) Hierarchical Task Analysis (HTA) *Workshop: Task Analysis*
Day 2: Friday 14 November 2025	
Time zone: London (GMT)	
09.00 – 12.15	**4. Managing the Risk of Use Error** a) Introduction to use error b) Why do use errors occur? *Exercise: Classifying Use Error Causes* c) Techniques to manage use error *Workshop: Use-Related Risk Analysis (URRA)*
12.15 – 13.15	*Lunch*
13.15 – 15.10	**5. Usability Evaluation** a) Formative evaluations b) Summative evaluation *Exercise: Cognitive Walkthrough*
15.20 – 16.20	**6. Usability Documentation and Integration** a) The usability engineering file b) The summary HFE/UE report for the FDA c) Developing a usability engineering procedure *Discussion: Next Steps and Challenges*
16.20 – 16.30	***Course Summary and Conclusions***