



Medical Device Usability Course

Instructor: Dr Nick Bradley, BERGO UK	
Day 1: Wednesday 25 March 2026	
<i>Time zone: London (GMT)</i>	
09.00 – 09.15	<i>Objectives, Overview and Introductions</i>
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 <i>Discussion: Experiences and Challenges</i>
12.15 – 13.15	<i>Lunch</i>
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 <i>Exercise: Use Specification</i>
15.10 – 16.30	3. Task Analysis a) Introduction to task analysis b) Task analysis techniques c) Hierarchical Task Analysis (HTA) <i>Workshop: Task Analysis</i>
Day 2: Thursday 26 March 2026	
<i>Time zone: London (GMT)</i>	
09.00 – 12.15	4. Managing the Risk of Use Error a) Introduction to use error b) Why do use errors occur? <i>Exercise: Classifying Use Error Causes</i> c) Techniques to manage use error <i>Workshop: Use-Related Risk Analysis (URRA)</i>
12.15 – 13.15	<i>Lunch</i>
13.15 – 15.10	5. Usability Evaluation a) Formative evaluations b) Summative evaluation <i>Exercise: Cognitive Walkthrough</i>
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 <i>Discussion: Next Steps and Challenges</i>
16.20 – 16.30	Course Summary and Conclusions