



Medical Device Usability Course

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| Instructor: Dr Nick Bradley, BERGO UK | |
| Day 1: Wednesday 2 December 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 HE75:2025 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 3 December 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 |