Course Programme
Medical Device Usability

Instructor: Dr Nick Bradley, BERGO UK	

Day 1: Wednesday 4 December 2024

Time zone: London (GMT)

09.00 – 09.15	*Objectives, Overview and Introductions*
09.15 – 12.15	**1. Introduction to Usability Engineering** • What is Meant by Usability? • Legal Framework for Manufacturers • Overview of Usability Engineering Process in IEC 62366-1:2015 +AMD1:2020 *Discussion: Experiences and Challenges*
12.15 – 13.15	*Lunch*
13.15 – 16.30	**2. Usability Techniques** • Design Guidance in ANSI/AAMI HE75:2009/(R)2018 • User Research Techniques • User Interface Design Techniques *Workshop: Task Analysis*

Day 2: Thursday 5 December 2024

Time zone: London (GMT)

09.00 – 12.15	**3. Managing the Risk of Use Error** • Why do Use Errors occur? • Case Studies Involving Use Error • Techniques to Manage Use Error *Exercise: Error Types; Workshop: Use-Related Risk Analysis (URRA)*
12.15 – 13.15	*Lunch*
13.15 – 15.15	**4. Usability Evaluation** • Formative Evaluations • Summative Evaluations *Exercise: Cognitive Walkthrough*
15.15 – 16.20	**5. Usability Documentation and Integration** • The Usability Engineering File • The HFE/UE Report for the FDA • Developing a Usability Engineering Process *Discussion: Next steps and challenges*
16.20 – 16.30	***Course Summary and Conclusions***