Usability Evaluation Protocol

Mapping of Standard Requirements to Document Sections

IEC 62366-1:2015 Section	Title	Document Section
4.2	Usability Engineering File	(all)
4.3	Tailoring of the Usability Engineering effort	(all)

1. User Group and Environment

Describe the user group here, e.g., physicians with experience in a certain field.

Also, describe the environment in which the user test is being conducted. Obviously, both the user group and environment should match whatever you described in your Intended Use. So, if your app is intended to be used by emergency physicians in a brightly-lit hospital environment, you should also have these people do the usability test in a similar environment.

2. Preparation

Describe whether you prepare users in any way. Again, this should be based on the use context in which your users will be using your device in real life. So, if people typically carefully read the user manual before (not sure in which parallel universe that happens), you can give them the manual and some time to study it. More realistically, you'll probably test how users handle your device when they haven't read the manual.

If there are official training which are required before users can use your device, you should do this training first, of course.

3. List of Tasks

This table lists the tasks you want your users to perform. It's kind of the master table which will be copy-pasted for each user below - you'll be filling out the observations and hazards encountered by each user.

As always, using a spreadsheet (e.g., Google Sheets) instead of a document is a very good idea here.

ID	Description	App State / Environment	Instructions	Acceptance Criteria	Observations	Hazards encountered

4. Protocols

Copy-paste the table above for each user and fill it out during the test. Note down the names and ages (or any other important characteristics) per user.

User 1 (Name, Age)

ID	Description	App State / Environment	Instructions	Acceptance Criteria	Observations	Hazards encountered

User 2 (Name, Age)

ID	Description	App State / Environment	Instructions	Acceptance Criteria	Observations	Hazards encountered