



BABYLUX

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D 4.6 ACCOMPANYING DOCUMENTATION

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1. Executive summary and introduction

This deliverable pertains to Work Package 4, Deliverable 4.6, "Accompanying documentation: the documentation required for obtaining the authorization from national authorities (i.e. user manual, risk assessment, investigator brochure) is made available (Nature: R, Dissemination level, RE)".

As indicated in the deliverable title, there are three sections in this deliverable which are explained in the paragraph below and which correspond to three documents necessary for obtaining the approval from national authorities:

- User manual: this document will help both the healthcare professional and technical personnel to operate the demonstrator
- Risk assessment and management documentation; according to International Standard ISO 14971:2012.
- Investigator brochure explaining usage, safety and protocol information.

We note that according to the project plan, description-of-work (DoW) the demonstrators will not be ready until the last quarter of 2015. Accordingly, here we provide the general outline of user manual and the first, not finalized, version of the risk assessment and management documentation and investigator brochure.

The documentation will be completed prior to the submission of the approval of the local authority and prior to the beginning of the studies according to the DoW.

Furthermore, given that the documentation is not yet in a final state, we have decided to change the dissemination of this deliverable to "restricted" until the complete documentation is available. At that point, the specific documents will be submitted as a public deliverable, as described in the DoW.

2. User manual

In this section the table of contents of the manual and a schematic of the procedure to perform a measurement are presented.

The first draft of the user manual is inserted in Appendix A.

The user manual will be completed after the building of the first demonstrator in the last quarter of 2015.

User manual table of contents

1. Introduction
 - 1.1. Intended purpose
 - 1.2. Overview of the technology
2. Principal units of the device
 - 2.1. Detailed description of the components
 - 2.1.1. Supply of the device
 - 2.1.2. Time Resolved Spectroscopy (TRS) module



- 2.1.2.1. Sources unit
- 2.1.2.2. Detection unit
- 2.1.2.3. Time Correlated Single Photon Counting Board
- 2.1.3. Diffuse Correlation Spectroscopy (DCS) module
 - 2.1.3.1. Source unit
 - 2.1.3.2. Detection unit
 - 2.1.3.3. Correlator
- 2.1.4. Micro-controller based control input/output board
- 2.1.5. Fiber-optics sensor
- 3. Installation and safety measure
- 4. Instruction of the usage
 - 4.1. How to start the device
 - 4.2. How to place the probe on the patient's head
 - 4.3. How to prepare a measurement (Software manual)
 - 4.3.1. Normal User
 - 4.3.1.1. Log in screen
 - 4.3.1.2. New user account
 - 4.3.1.3. Account options
 - 4.3.1.4. New ID
 - 4.3.1.4.1. Calibration
 - 4.3.1.4.2. Load settings.
 - 4.3.1.4.3. Define sensors
 - 4.3.1.4.4. Phantom/tissue test
 - 4.3.1.5. Scan
 - 4.3.1.5.1. Scan duration
 - 4.3.1.5.2. Baseline
 - 4.3.1.5.3. Marks
 - 4.3.1.5.3.1. Mark description
 - 4.3.1.5.4. Axis setup
 - 4.3.1.5.5. Plot visualization
 - 4.3.1.6. Export stored data
 - 4.3.2. Advanced user
 - 4.3.2.1. Advanced user creation
 - 4.3.2.2. DCS setup tab
 - 4.3.2.2.1. Optimization parameters
 - 4.3.2.2.2. Define sensors
 - 4.3.2.2.3. Load stored probe
 - 4.3.2.2.4. Define new probe
 - 4.3.2.2.5. Internal check
 - 4.3.2.2.6. Directory path
 - 4.3.2.3. TRS setup tab
 - 4.3.2.3.1. Optimization parameters



- 4.3.2.3.2. Define sensors
- 4.3.2.3.3. Load stored probe
- 4.3.2.3.4. Define new probe
- 4.3.2.3.5. Internal check
- 4.3.2.3.6. Directory path
- 4.3.2.4. Load configuration
- 4.3.2.5. Save configuration
- 4.3.2.6. Define home tab plot
- 4.3.3. System administrator user
 - 4.3.3.1. System administrator user creation
 - 4.3.3.2. Reset user password
 - 4.3.3.3. Manage system log
- 4.4. How to perform a measurement
- 4.5. How to switch off the device
- 4.6. How to calibrate the device and when
- 5. Maintenance and cleaning
- 6. Dimensions
- 7. Technical specifications

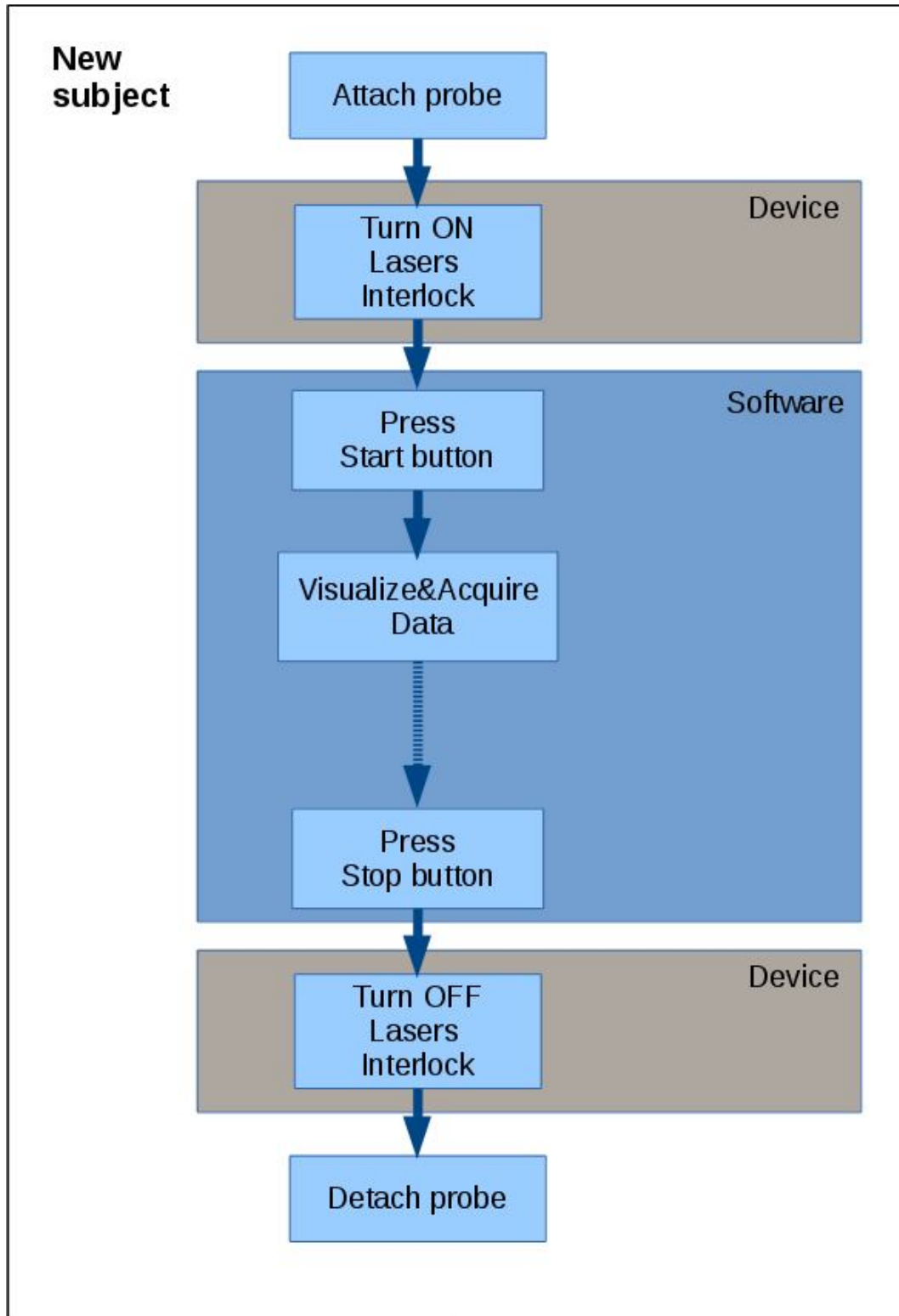


Figure 1. Schematic of the procedure to follow to use the device.



3. Risk assessment and management documentation

The risk assessment and management documentation that is presented in this deliverable in Appendix B is not complete, in particular regarding the full compliance to the standard ISO 14971:2012.

It is the most complete document that could have been written at this stage of the project.

It will be updated with the compliance to the standard, after the building of the first demonstrator.

4. Investigator brochure

The first version of the investigator brochure is inserted in Appendix C.

It will be updated after the building of the first demonstrator.

Appendix A – User manual

Appendix B – Risk assessment and management documentation

Appendix C – Investigator brochure
