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| **Programme** | CIP – Competitiveness for innovation |
| **Type of Action** | Pilot B |
| **Project Title** | An optical neuro-monitor of cerebral oxygen metabolism and blood flow for neonatology |
| **Acronym** | BabyLux |
| **Project n.** | 620996 |

# D 4.6 ACCOMPANYING DOCUMENTATION

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|---|---|
| **Work Package** | WP4 |
| **Lead Partner** | HemoPhotonics (5 HP) |
| **Contributing Partner(s)** | 1 PoliMi, 3 ICFO, 7 Loop, 8 RH-Neo, 9 IRCCS Ca' Granda |
| **Security Classification** | RE |
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| **Version** | Final |


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## Document history

| Version | Date | Comments | Authors |
|---|---|---|---|
| 1.0 | 28/06/2015 | Extended table of contents, introduction, user manual table of contents | Martina Giovannella (ICFO) |
| 1.1 | 14/06/2015 | User Manual section completed | Victor Chamizo (HP) |
| 2.0 | 19/06/2015 | Documentation attached | Martina Giovannella (ICFO) |
| 2.1 | 25/06/2015 | Overall revision | Udo Weigel (HP) |
| 2.2 | 29/06/2015 | Overall revision | Alessandro Torricelli (PoliMi) |

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# Contents

# 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

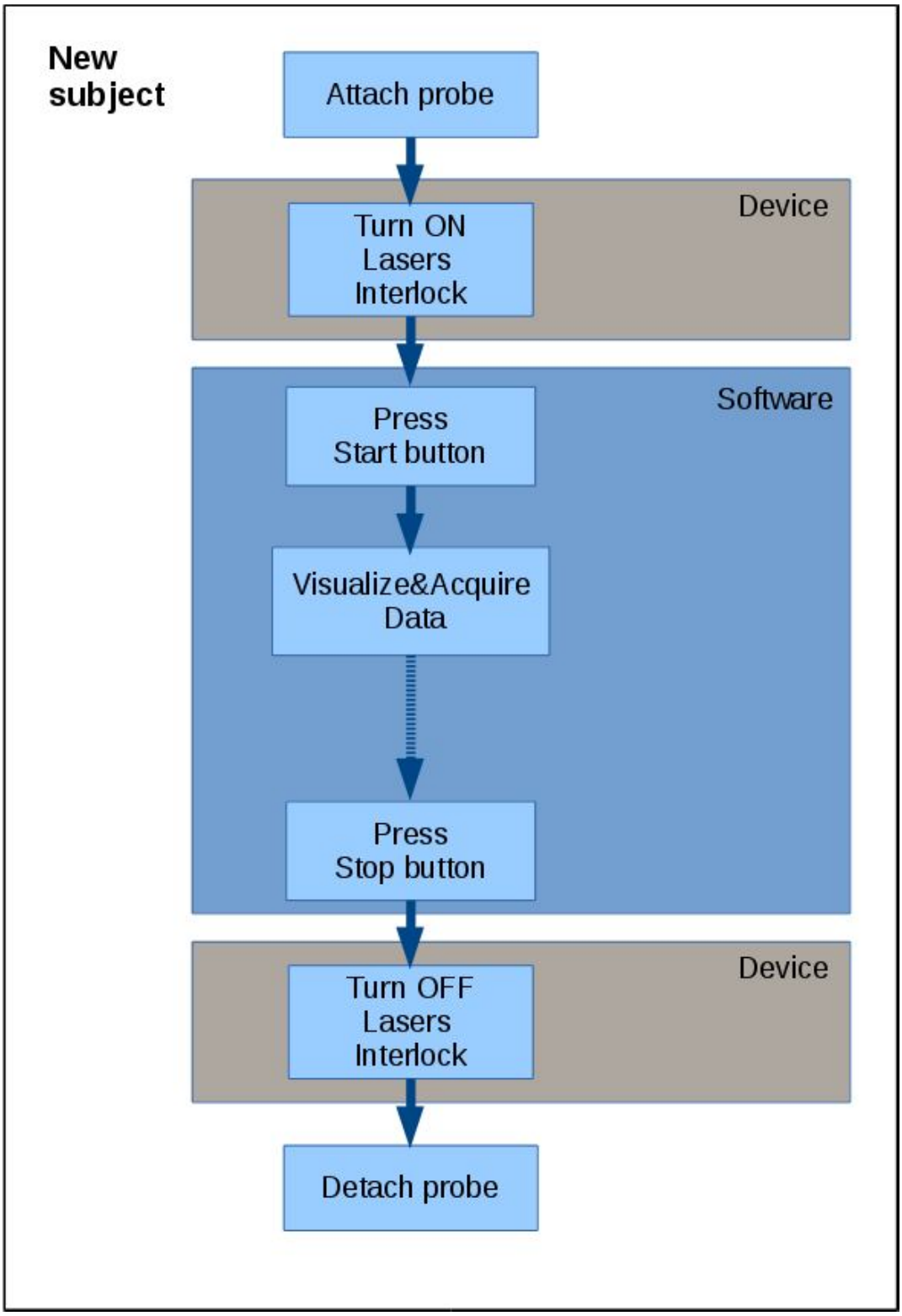


Figure 1. Schematic of the procedure to follow to use the device.

## 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