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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 4.10 UPDATED ACCOMPANYING DOCUMENTATION

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	PU / RE (annexes restricted)
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Version	Final

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Document history

Version	Date	Comments	Authors
1.0	30/11/2016	Extended table of contents and probe related edits	Martina Giovannella (ICFO)
1.1	20/12/2016	Software, probe and TRS related edits	Victor Chamizo (HP) Udo Weigel (HP) AlessandroTorricelli (Polimi)

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Executive summary and introduction

This deliverable pertains to Work Package 4, Deliverable 4.10, " Updated accompanying documentation (Nature: R, Dissemination level, PU)".

A first version of the accompanying documentation was made available in deliverable 4.6. Here we present the updated version, improved with the feedback received during the usage in the clinical environment.

Three documents are presented in this deliverable:

- 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.

The main upgrades of the documentation, inspired by the usage of the device in the clinics, are:

- Improved wizard for the preparation of the measurement and check of data quality
- Usage of DuoDermE and a disposable cover for the probe
- Updated description of the TRS phantom and IRF/TRS measurements

User manual

The User manual in inserted in Annex A.

We report here the section regarding the last configuration of the probe and how to implement it before a measurement.

“The sensor should be covered by a layer of DuoDermE in order to protect the patient from any eventually hard and/or sharp edges. This layer has to be applied such that it covers well not only the surface of the sensor on the sapphire window side, which will be placed towards the skin, but also laterally. Sufficiently large openings for the probe sapphire windows have to be cut into the DuoDermE layer such that light transmission from and into the sensor is not compromised.
Being equipped with the DuoDermE, the sensor has be inserted in one of the covers normally used for ultrasound probes (not provided with the device). This cover should be gently stretched and fixed at the base of the sensor in order to avoid any folding on the patient’s skin.”

Furthermore, a section with detailed instructions for use of a new software feature to support user guidance has been included in the software manual.

Finally, a more precise definition of TRS phantom and IRF/TRS measurements were included: “For the IRF measurement the following procedure has to be followed. Place the probe, without the ultrasound cover, inside the probe holder. Then place the holder on the TRS-IRF holder unit. Due to the presence of DuoDerm pressure should be gently applied to properly fix the probe in the probe holder. During the IRF measurement it is important to avoid movement of the probe or of the probe holder with respect to the TRS-IRF holder unit. Therefore, it is better to fix the the probe to the probe holder with a black adhesive tape, and to keep the probe holder in position on the IRF holder unit by applying pressure with a finger or with a proper weight.

For the TRS phantom measurement the following procedure has to be followed.
Place the probe, without the ultrasound cover, inside the probe holder. Then place the holder on the TRS phantom holder unit. Due to the presence of DuoDerm pressure should be gently applied to properly fix the probe in the probe holder. The probe holder should be inserted in the TRS phantom holder unit till the probe is in contact with the phantom surface. It is better to keep the probe holder in position on the TRS phantom holder unit by applying pressure with a finger or with a proper weight."

Risk assessment and management documentation

The risk assessment and management documentation is inserted in Appendix B.

Measures of precaution for hazard 5 has been changed.

Below an extract of last version of "Table 3: hazard and risks" can be found.

Hazard	Triggering event	Consecutive Harm	Risk
H5	Using non disposable probe for different patients	Infections	R4

The following Measures of precaution are implemented:

- **MOP 4 - Biocompatible materials**
  All materials in direct contact with patient's skin are made of biocompatible materials as certified by the manufacturers. Materials compliant with the ISO 10993 standard can be considered inapt to be cytotoxic or to cause sensitization or irritation to the skin. The probe is inserted in a disposable cover, the one commonly used in the clinical routine for ultrasound probes (not provided with the device). The cover is the only material in direct contact with the skin.

- **MOP 5 - Disposable probe cover**
  Medical grade materials can be considered as inapt to irritate the skin or to cause infections. The sensor must not be placed on damaged skin. The sensor is resistant to disinfectants; the sensor is inserted in a disposable ultrasound probe cover, which has to be changed for every patient.

- **MOP 6 - Repositioning of the probe**
  When placing the probe care must be taken to avoid unnecessary tension on the bandage and positioning the probe under the infant to reduce the applied pressure. A layer of DuoDermE should be applied to the probe, in order to protect the skin from hard edges. Repositioning of the probe every 3 hours, see MOP 3.3, will also allow for inspection of the skin and prevent pressure related damages.

Investigator brochure

The IB has not been edited after the approval by the local authorities.

Appendix A – User manual

Appendix B – Risk assessment and management documentation

Appendix C – Investigator brochure