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

D4.11 Report on Medical Device Compliance testing

Work Package	WP 4
Lead Partner	HemoPhotonics
Contributing Partner(s)	1 Polimi 3 ICFO, 4 IPT, 5 HP, 7 Loop
Security Classification	PU (Public)
Date	20/01/17
Version	1.0

The BabyLux project (620996) is co-funded by the European Union under the CIP competitiveness and innovation framework program 2007-2013.

Document history

Version	Date	Comments	Authors
0.9	20.01.2017	First document draft	Udo Weigel (HP)
1.0	28.01.2017	Final edits	Udo Weigel (HP)
1.1	31.01.2017	Editing	A.Torricelli (PoliMi)

Statement of originality:

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

The work leading to these results has received funding from the European Community's CIP competitiveness and innovation framework program under grant agreement nº. 620996.

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1. Introduction

This deliverable D4.11 belongs to **Work Package 4** and reports the outcome of the task 4.4. medical device compliance testing. Medical device compliance according to the Medical Device Directive 93/42/EEC is mainly based on two principles; First, providing patients, users and third parties with a high level of protection and second, attaining the performance levels attributed to them by the manufacturer.

The first aspect of a high level of protection is subject of the work performed in task 4.4 described here and is strongly related to the one performed on the component level (task 2.5 Medical device compliance of components) as reported in the related deliverable D2.6 Conformity documentation of components; A report on the procedures, the results and the related documentation of the compliance tests of system components.

The second aspect of the performance of the BabyLux device is subject and objective of the BabyLux project itself namely the clinical evaluations herein. By making the two identical BabyLux demonstrators available to the hospital partners in Copenhagen and Milan, we evaluate the performance level of the present devices and the technology as being reported in work package 5, service demonstration in real-life settings.

To ensure safety, our general approach on the component level was to select where ever available commercial components which have already a high level of safety according to the specific certification provided by the manufacturers. For components developed or modified within the project by project partners, we distinguished on one hand those having a certain probability of impacting medical device compliance, e.g. electronic components operating with pulsed signals and/or 240V and on the other hand components without expected substantial probability of impacting medical device compliance.

For the first group, specific tests were performed to evaluate their level of safety and assure compliance as a single component. Nevertheless, some safety aspects, e.g. EMC cannot be contemplated solely on the component level since the final device EMC characteristics will be determined by the device as a whole. Components being both source of and susceptible to electromagnetic disturbances can only be evaluated in combination with the BabyLux device case providing some shielding or maybe even altering the properties in an potentially unfavorable way. In this sense, final evaluation results of the device as a whole confirm compliance not only for the first group of components but also for components of the second group where no impact on medical device compliance is expected (and which were not considered to require individual tests before). Other aspects like e.g. the mechanical stability of the BabyLux rack can only be evaluated realistically when tests are performed on the final device as a whole. Taking this into consideration, we opted for an iterative approach in which the safest solution within the given conditions was implemented. Then, we tested the overall device and based on this outcome, the given solution was accepted or specific new solutions were designed to achieve full compliance as described in this deliverable D4.11.

2. Executive summary

The safety considerations from a hygienic point of view were guided by the medical practitioners of the hospital partners. Further, the evaluation of the sensor/cover design and the final measures to comply with the hygienic and usability standards were implemented based on feedback of the medical partners. These aspects are presented in paragraph 3.

Paragraph 4 presents the mechanical tests performed on the BabyLux demonstrator II and the design revision implemented on both demonstrators taking into account the conclusions from the test session.

Finally, in paragraph 5, the electrical and electromagnetic compatibility tests are presented. The initial electrical evaluation of each BabyLux demonstrator was performed at ICFO with certified equipment followed by tests by a certified external test laboratory. Additionally, as prerequisite for admission of the devices to the hospitals each demonstrator underwent an electrical safety test by the hospital's responsible technical department. Electromagnetic compatibility was tested for each demonstrator separately at a certified external test laboratory.

3. Hygienic aspects

The first design concept for the BabyLux probe with a fibre sensor and a partially enclosing silicone cover allowed to clean the sensor by wiping with a preferably lint free tissue, moistened with standard hospital cleaning liquids before and after each application to the subject. The silicone cover making the primary contact was suited to undergo the same cleaning procedure or - if considered necessary - to be replaced for a new one.

The practical evaluation of the fibre sensors revealed possible hygienic issues for small cavities which might have posed a health risk by residual contamination even after correct cleaning procedure. Cleaning procedures based on higher temperatures and liquids with a stronger disinfectant effect have been discarded without further testing for practical reasons and the risk of damage on the fibre sensor.

As second option to comply with hygienic requirements was based on a fully enclosing cover separating the internal fibre sensor from the skin/subject. Special medical grade covers used for ultrasound transducers allowed to cover the sensor entirely and up to >10cm of the attached fibre strand.

Since a single use procedure (replacement after each application) of the ultrasound cover fully complies with the hygienic requirements, this solution was tested for its feasibility in terms of optical data quality. Test of the possible deterioration of the optical data quality due to an additional thin layer of the ultrasound cover in the light path have been performed for DCS and TRS. The result of the optical evaluation confirmed that this solution will not significantly alter the optical data quality and it has been adopted for the measurements with the BabyLux demonstrator at both hospitals.

4. Mechanical safety

The BabyLux demonstrator has been tested for several relevant instability hazards according to EN 60601-1, chapter 9.4 at a certified test laboratory. Figure 1 (below) shows few examples of stability tests performed with the demonstrator II:

a) movement over a threshold (left)

b) instability from unwanted lateral movement on a hard flat and inclined surface (middle)

c) instability form unwanted lateral movement applying a defined lateral force (right)

a) **b)** **c)**

Figure 1: Mechanical safety testing according to EN 60601-1, examples.

Two of the test have revealed failures which were addressed by an improved based design (see deliverable D2.6, rack) and additional locking devices (additional brakes). After these measures have been implemented, the BabyLux demonstrators are considered compliant with respect to the relevant parts of the mechanical test procedures of EN 60601-1, chapter 9.4.

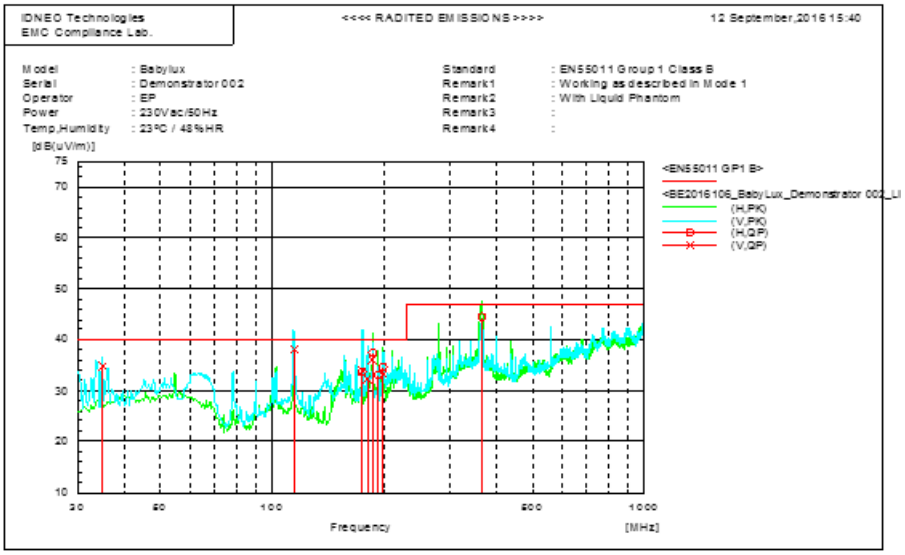
5. Electrical and electromagnetic safety

5.1 Electrical safety testing

Tests for electrical and electromagnetic safety have been done for each BabyLux demonstrator independently right after the final assembly of the devices. The first electrical test according to EN 60601-1, (earth leakage, enclosure leakage and patient leakage) has been performed with a hand-held electrical safety analyzer type Rigel Medical 288 and successfully passed. At each hospital in Copenhagen and Mila, as a prerequisite for admission of the equipment, it underwent another electrical safety test performed by the hospital's technical department in charge.

5.2 Electromagnetic safety testing

The certified test EMC test lab, IDNEO Technologies S.L. Compliance Department, 8232 Viladecavalls (Barcelona), Spain, tested each BabyLux demonstrator independently for electromagnetic compliance.



Final Result

No.	Frequency [MHz]	(P)	Reading QP [dB(uV)]	c.f [dB(1/m)]	Result QP [dB(uV/m)]	Limit [dB(uV/m)]	Margin QP [dB]	Height [cm]	Angle [deg]
1	34.959	V	15.8	19.0	34.8	40.0	5.2	100.0	359.8
2	114.338	V	17.4	20.7	38.1	40.0	1.9	100.0	65.8
3	174.334	H	16.1	17.6	33.7	40.0	6.3	125.0	242.1
4	176.262	V	17.4	16.5	33.9	40.0	6.1	175.0	244.9
5	180.000	V	15.6	16.6	32.2	40.0	7.8	270.0	164.0
6	185.703	H	19.0	18.3	37.3	40.0	2.7	100.0	255.9
7	185.703	V	18.7	17.3	36.0	40.0	4.0	175.0	85.6
8	192.002	H	14.1	19.0	33.1	40.0	6.9	100.0	271.4
9	198.292	H	15.5	19.2	34.7	40.0	5.3	100.0	89.4
10	198.292	V	13.9	19.3	33.2	40.0	6.8	100.0	55.2
11	365.424	H	18.4	26.2	44.6	47.0	2.4	100.0	128.4

Figure 2: BabyLux demonstrator II, Radiated emissions 30MHz-1GHz.

BabyLux demonstrator I has been tested in several sessions with intermediate modifications in order to assure compliance in the final session. BabyLux demonstrator II has been tested fully in a single session.

5.2.1 Radiated Emissions in semianechoic chamber (30MHz – 1GHz)

Figure 2 shows radiated emissions of the demonstrator II in normal operation conditions, electromagnetic field strength at 3m according to EN 55011:2009+A1:2010 in horizontal and vertical emission conditions between 30MHz and 1GHz. Specifically high quasi peak measurements (red peaks) are listed in the table below with the column “Margin QP [dB]” indicating the margin with respect to the limits established by the standard.

5.2.2 Conducted Emissions (150kHz – 30MHz)

Figure 3 shows the disturbance voltage on mains caused by the BabyLux demonstrator including the corresponding safety limits established by the standard are indicated by the horizontal red line (QP) and purple lins (av).

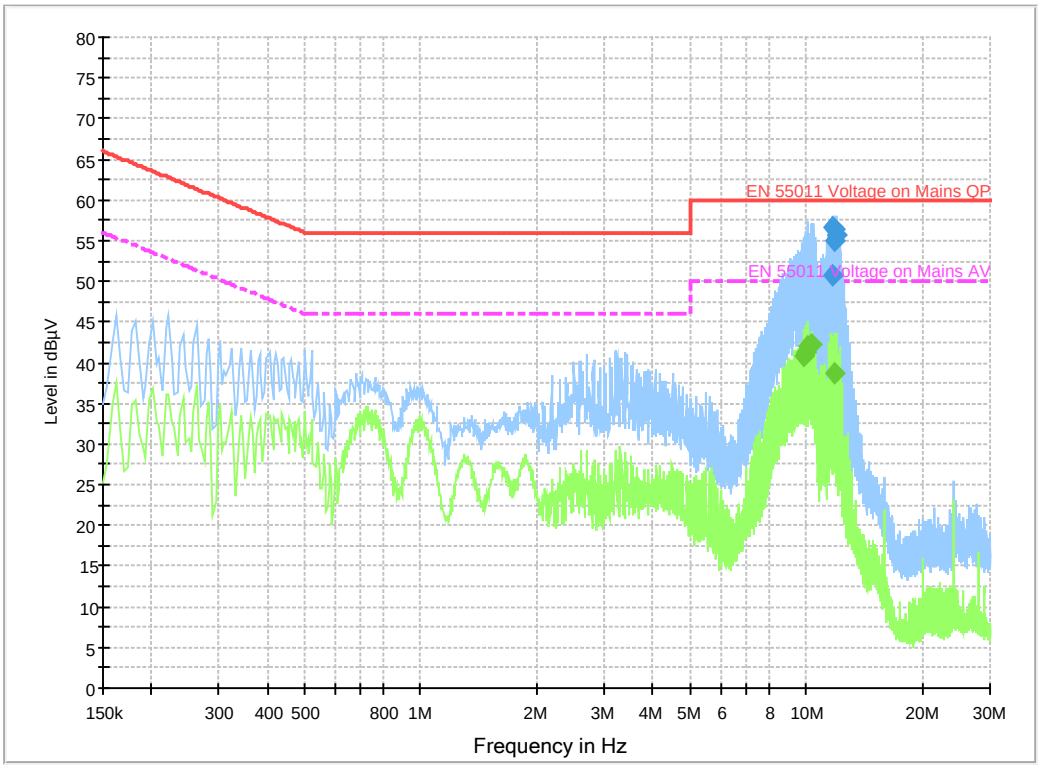


Figure 3: BabyLux demonstrator II, Conducted emissions 150kHz-30MHz.

5.2.3 Susceptibility to Radiated, radio-frequency electromagnetic field (80MHz-1GHz)

Figure 4 shows an example scan of the radiated, radio-frequency electromagnetic field between 80MHz-1GHz in horizontal polarity according to EN 61000-4-3:2006+A1:2008+A2:2010. The indicated field strength of 3V/m was applied to demonstrator II and correct operation without failure observed. The same susceptibility has been tested successfully for vertical polarity .

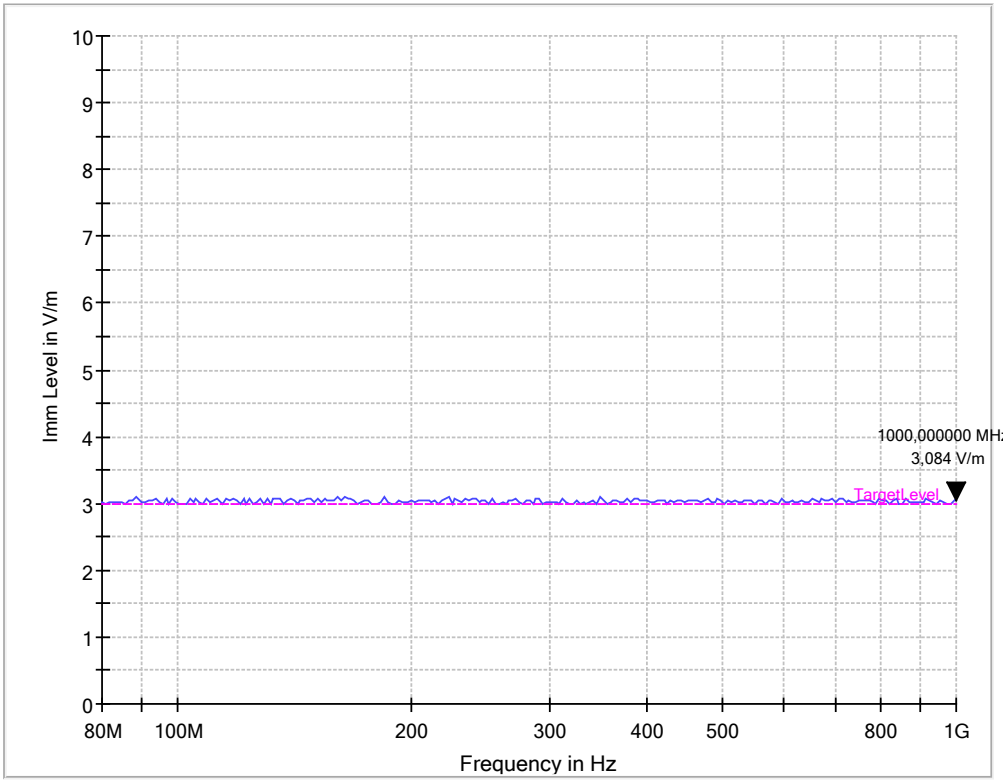


Figure 4: BabyLux demonstrator II, Susceptibility to radiated, rf-fields (80MHz-1GHz).

5.2.4 Susceptibility to Radiated, radio-frequency electromagnetic field (1GHz-2,5GHz)

Figure 5 shows an example scan of the radiated, radio-frequency electromagnetic field between 1GHz-2,5GHz in horizontal polarity according to EN 61000-4-3:2006+A1:2008 +A2:2010 which was passed successfully.

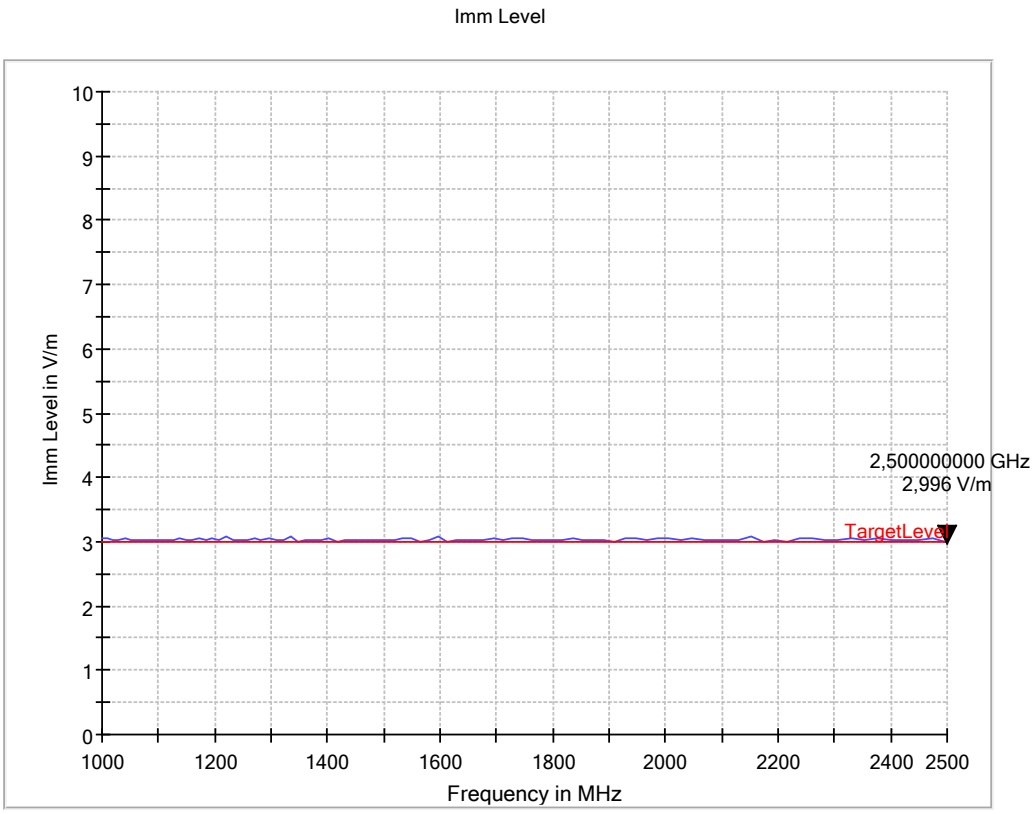


Figure 5: BabyLux demonstrator II, Susceptibility to radiated, rf-fields (1GHz-2,5GHz).

5.2.5 Immunity to conducted disturbances, induced by rf-fields (150kHz-80MHz)

Figure 6 shows a scan of the conducted, radio-frequency electromagnetic field applied to the AC port of demonstrator II between 150kHz-80MHz according to EN 61000-4-6:2009. The immunity test was passed successfully.

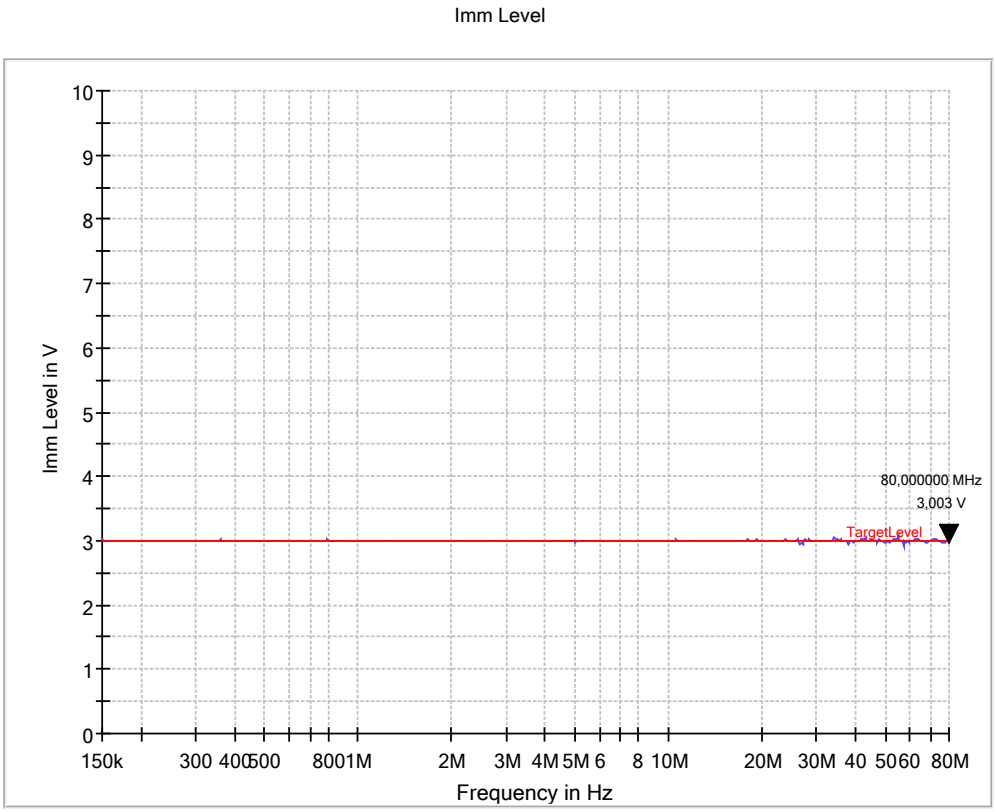


Figure 6: BabyLux demonstrator II, Susceptibility to conducted, rf-fields (150kHz-80MHz)

3. Conclusion & and future work

All the work invested and reported here served to make the BabyLux demonstrator devices as good as possible compliant with the the multiple requirements for medical devices.

During the compliance tests new insights were obtained and exploited to improve as much as possible the safety of the overall device and stay within the time frame imposed by the BabyLux project plan.

By best knowledge it can be summarized that the demonstrators developed within the BabyLux project are well prepared to market the system after the completion of the project to medical users. The legally required test measurements of the complete system will be done after the end of the project and the implementation of the feedback from clinical users.