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Acronym	BabyLux
Project n.	620996

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Deliverable 1.5 – Final report

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Contributing Partner(s)	ALL PARTNERS
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This deliverable contains original unpublished work except where clearly indicated otherwise.

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1. Introduction

This document is the final report of the project activities conducted from month 1 to month 40 of the BabyLux project: from January 2014 to April 2017.

2. Summary description of the project objectives

The BabyLux project (http://www.babylux-project.eu/, Figure 1) closely aligns with the general objectives of Theme 3 “ICT for Health, ageing well and inclusion” of the Work Programme and specifically with Objective 3.5 “Biophotonics solutions for diagnosis, monitoring and treatment of diseases”.
The BabyLux project aims to provide a precise, accurate and robust integrated system to monitoring cerebral oxygen metabolism and blood flow in critically ill newborn babies.
Over the last two decades, the percentage of preterm births in the Western hemisphere rose by 20%. During early stages of brain development, the injury from lack of blood flow and oxygen delivery may induce cognitive and physical handicaps. In fact, preterm births now account for a significant portion of children with cerebral palsy and cognitive, visual, and hearing impairments. A non-invasive, continuous, cot-side monitor of cerebral oxygen metabolism and blood flow is an unfilled niche in clinical care.

Figure 1: Screenshot of BabyLux home page - web site http://www.babylux-project.eu/.

The project takes up complete R&D works and extends already tested prototypes to the level of demonstrator, bridging the gap between research products and commercialization. The system uses photonic technologies: diffuse correlation spectroscopy (DCS), and time resolved near-infrared spectroscopy (TRS) for non-invasively and safely measurements of cerebral oxygen metabolism and blood flow. This innovative combination provides the state-of-the-art in accuracy and robustness in TRS, and introduces, for the first time, DCS in a combined instrument.
The instrument has been demonstrated in laboratory settings at first and then in real-life settings, conducted in parallel in two public hospitals of two different countries. The advantages of the proposed system are being evaluated by professional end-users during validation tests carried out in conditions fitting in the clinical workflow, protocols and procedures.
Dissemination and exploitation activities are promoting the accelerated acceptance and the wider deployment of the proposed biophotonic solution. The BabyLux consortium gathers service content providers (physicists and engineers for biophotonic applications), professional end-users (neonatologists), and SMEs (photonic components producer, medical device manufacturer).

3. Description of the work performed since the beginning of the project

3.1. The BabyLux demonstrator

The existing DCS and TRS systems have been utilized to demonstrate the work-flow and functioning principles to the clinical partners' teams. On the bases of feedbacks received, requirements for hardware, software and procedures were defined for the design and development of BabyLux demonstrator.

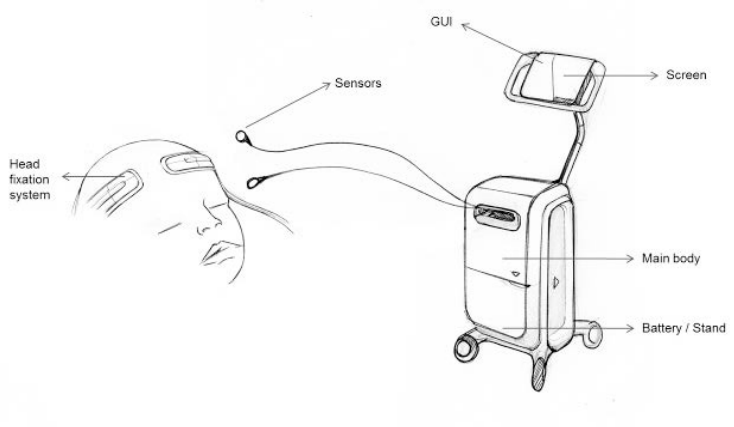

Figure 2: Preliminary design concept for BabyLux demonstrator.

The design strategy for style and iconography aspects was defined (see Figure 2) and the product technology and costs defined. The preliminary external case was developed and the BabyLux mock-up (Figure 3) was shown in various dissemination events (Light4Health, EAPS2014, Researcher's' Night 2015, ICT2015) in order to receive feedbacks and raise awareness and interest in the project solution. The external case was released for medical trials with the necessary changes in order to cope with new volume constrains of internal final HW, to improve usability and security and accomplish electromagnetic standards (Figure 4). Improvements identified during the testing in real-life conditions led to the final design (Figure 5).

Figure 3: BabyLux Mock-up at Light4Health conference (Barcelona, October 2104).

Figure 4: BabyLux demonstrator at Rigshospitalet (Copenhagen).

Figure 5: Final design of the BabyLux external chassis.

For different integration levels of hardware solutions, challenges versus benefits were analysed. Prioritizing performance and robustness, independent TRS and DCS modules solution was selected providing the highest reliability in accuracy and operation. The hardware specifications and the design for DCS and TRS modules and for the integrated compact optical fibre probe were completed and the preliminary modules implemented. The overall internal layout was designed and the corresponding base plate manufactured. Optimized version of TRS, DCS and probe were released and whole demonstrator developed.
The performances evaluation of the preliminary and optimised separate components of the TRS and DCS modules (i.e., laser, detectors and acquisition electronics) was completed. Evaluation parameters for the TRS and DCS modules were selected, the laboratory settings for the evaluation of modules were prepared, the evaluation of draft and optimised TRS and DCS modules and the overall demonstrator were performed. The integration and the evaluation of components, modules and the second prototype started.
Based on the existing DCS software, the first and final software and firmware implementation for the data acquisition, analysis and control were released. The final version includes the new hardware (HW) control and data representation of TRS components, the drivers of the HW correlator and TRS HW. BabyLux graphical user interface (GUI) and operation concepts according to the clinical partners' requirements were integrated into the software.

3.2. Service demonstration in real-life setting

The protocol for the verification of BabyLux demonstrator in the clinical care of newborn infants was defined. The purposes have been to assess the re-positioning variability, verify that the instrument measures the expected changes in brain oxygenation and blood flow after birth, and that the signal loss due to movement and other disturbances during clinical care is of acceptable magnitude. Further, clinical staff have reported on user-friendliness, usefulness and trustworthiness of the data.
The necessary documentation was submitted for ethical approval in Milan (Comitato Etico Area B Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico) and Copenhagen (de Videnskabsetiske komiteer for Region Hovedstaden) and preliminary approvals to conduct the verification of BabyLux demonstrator in neonatal units of Policlinico and Rigshospitalet were obtained. Relevant documents to complete the clinical investigation plan as required by the Italian Ministry of Health and the Danish Board of Health, Device Agency, and fulfil the other obligations were prepared and submitted. All the approvals were obtained for Rigshospitalet and for Policlinico. The demonstrators were delivered in Copenhagen and Milano, training sessions were fulfilled (see Figure 6). Newborn infants were enrolled for the studies of changes in cerebral oxygenation and hemodynamic after birth (30), repeatability of measurements (29) and cerebral vaso-reactivity to arterial carbon dioxide (4).

Figure 6: Training for end-users in Copenhagen (June 2016)..

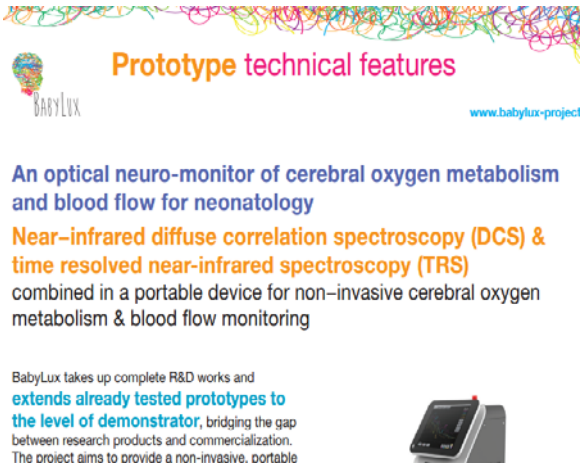

Figure 7: BabyLux prototype leaflet – page heading.

3.3. Dissemination and Exploitation

Basic activities have been the creation of the project identity and the project image, the identification of target groups, the dissemination of the projects results and the refinement of annual dissemination plans. The project logo was created to build a strong project identity and fast recognition with coordinated headed paper, poster, power point and leaflet templates.
The project image consists with all the information to present content and the objectives of the BabyLux project to an external audience. A multimedia concept for the project image was created in order to reach the various target groups according to the best media and in various dissemination opportunities. BabyLux Web site, YouTube, Google Plus pages, and videos have been created with the contribution of all partners. The first press release was translated into 5 languages and press kit (Project information sheet, Project coordinator profile, Partners profile, additional multimedia material, Leaflet) was published on the Web to provide to journalists what BabyLux is and what it intends to do (Figure 7). Seven newsletters were written to inform target groups about project activities.
Dissemination took place targeting both stakeholders and generic public. Email distribution list for stakeholder groups was created and continuously updated. Press releases obtained 65 publications on specialized magazines. In order to meet stakeholders BabyLux participated to more than 29 events including international conferences, exhibitions and workshops. Scientific publications (3) were accepted. General public was additionally involved through traditional media channels, i.e., an interview of the project coordinator was broadcasted by Rai3 (national TV channel) and interviews of partners was broadcasted by EuroNews, Articles (3) have been published in national newspapers. Networking occasions with other projects have also been created and synergies have been built with other scientific and research initiatives in the field.
The BabyLux reference market has been analysed considering industry competitors, substitutive products, suppliers, buyers and potential newcomers. BabyLux strengths, weaknesses, opportunities and treats in the mid and long term have been identified. On the basis of this investigation, the strategic plan was designed and the business and cost model developed with Lean Canvas for research medical market and the medical market. The methodology tackling the relationship between business and cost model was recommended and the first exercise to position the product was done also on the basis of the interview with potential users. The first steps for IP development strategy have been taken and rules and regulations for EU market investigated. Contributions based on BabyLux solution have been submitted to target standard bodies.

4. Main results

BabyLux has developed an innovative optical monitor demonstrator to measure cerebral oxygen metabolism and blood flow in preterm neonates. The demonstrator consists mainly of TRS module, DCS module, probe, the control SW module and external layout. The development has followed a step-by-step approach considering at first single components, integrating them into modules, up to the final integration of two complete optical monitors (Figure 4).

At first advantages of the proposed solution has been demonstrated at first in laboratory. Performances have been measured by means of specific protocols for all components (lasers, photodetectors, fibre optics, micro-electronics), at module level (TRS, DCS modules and probe) and for the complete demonstrator. In additional to internal labs, the demonstrator passed successfully emission electromagnetic compliance (EMC) and mechanical tests done at an accredited external laboratory.

The Consortium fulfilled all the necessary tasks to fit the proposed solution into clinical protocols and procedures and obtained the authorizations of Ethical Committees and of national health care authorities to demonstrate BabyLux optical monitor with neonates. Clinic partners have demonstrated the advantages of the optical monitor with preterms and neonates according specific protocols at Policlinico (Milano) and Rigshospitalet (Copenhagen).

Stakeholders and final users have been involved to raise awareness about BabyLux solution in the most suitable occasions. General public has been informed using most impacting media with clear messages. Market strategies for BabyLux business and cost model have defined and strategies to enter the market analysed. Contributions based on BabyLux TRS solutions have been submitted to relevant standardization bodies.

5. The final results and their potential impact and use

The socio-economic impact and the wider societal implications of the project have the different goals:
To accelerate the acceptance and wider deployment of innovative Biophotonics based solutions leading to more effective health care with the involvement of professional end-users (doctors and clinicians) from definition of the specifications and to the demonstration in the laboratory and clinical settings. Additionally, an effective dissemination activity is running with the involvement of external professional end-user communities, public authorities and other relevant stakeholders.
To increase competitiveness of the European medical equipment industry: the key of access will be the unique know-how on TRS, DCS and on their combination that the BabyLux solution is proposing.
To improve cerebral monitoring of critically ill preterm newborn so as to reduce brain damage and neurodevelopmental deficit: the added value for the user is the possibility to obtain reliable information on cerebral perfusion at the microvascular level, to link this information to the delivery of oxygen and nutrient to relevant tissues and eventually to devise improved therapeutic procedures. The same solution properly adapted could be used to support the diagnosis and therapy of age-related diseases including Alzheimer's disease, cardiac infarction, and stroke.
To raise the awareness of the potential of Biophotonics based solutions in the health care sector: BabyLux aims at creating successful case studies about the usage of optical techniques, extensively validated in the laboratory against the clinically-driven requirements, and finally validated in the intensive care units of Neonatology with ad-hoc clinical protocols.

6. Project references

6.1. Project

GA Number: 620996 Programme: CIP Competitive and Innovation Framework – 2007-2013 Contact: Prof. Alessandro Torricelli Tel: +39 02 2399 6087 Fax: +39 02 2399 6126 alessandro.torricelli@polimi.it Affiliation and Address: Politecnico di Milano - Dipartimento di Fisica piazza Leonardo da Vinci, 32 I-20133 Milan Italy Web site: http://www.babylux-project.eu Timeline: Start Date**:** 01/01/2014 End Date: 30/04/2017	Budget: Total Cost: 4'006'000 EUR Funding: 2'003'000 EUR Project Partners: P1. Politecnico di Milano (PoliMi) P2. Fondazione Politecnico di Milano (FPM) P3. Fundacio Institut de Ciencies Fotoniques (ICFO) P4. Fraunhofer-Gesellschaft zur Foerderung der Angewandten Forschung E.V (IPT) P5. Hemophotonics S.L. (HP) P6. PicoQuant GmbH (PQ) P7. Competitive Network S.L. (Loop) P8. Region Hovedstaden (RH-Neo) P9. Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico (IRCCS Ca' Granda)

6.1. Contact information for project partners

No.	Participant organisation name	Participant acronym	Country	Contact person	email
1	POLITECNICO DI MILANO	PoliMi	Italy	Alessandro Torricelli	alessandro.torricelli@polimi.it
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5	HEMOPHOTONICS SL	HP	Spain	Udo Weigel	udo.weigel@hemophotonics.com
6	PicoQuant GmbH	PQ	Germany	Rainer Erdmann	erdmann@picoquant.com
7	COMPETITIVE NETWORK S.L.	Loop	Spain	Ignacio Rocchetti	i.rocchetti@loop-cn.com
8	REGION HOVEDSTADEN	RH-Neo	Denmark	Gorm Greisen	gorm.greisen@regionh.dk
9	FONDAZIONE IRCCS CA' GRANDA - OSPEDALE MAGGIORE POLICLINICO	IRCCS Ca' Granda	Italy	Monica Fumagalli	monica.fumagalli@mangiagalli.it

7. Dissemination activities

The BabyLux project has been promoter of several dissemination activities.

7.1. Web site

Released on March 24, 2014
Available at the URL address: www.BabyLux-project.eu

7.2. Social media

Social media have played an important role in promoting the project to a general audience. A coordinated action has been developed and actively performed by all partners. Fondazione Politecnico has acted as pivot in developing the social media planning and timeline.

These are the social media accounts that partners have made available and their potential reach (data refer to May 30, 2017):

	TWITTER		FACEBOOK		LINKEDIN	
ICFO @ICFOnians	https://twitter.com/ICFOnians	3326	https://www.facebook.com/ICFOnians	2020	https://www.linkedin.com/company/icfo?trk=top_nav_home	2018
FRAUNHOFER IPT @FraunhoferIPT	https://twitter.com/fraunhofeript	1010	https://de-de.facebook.com/FraunhoferIPT?sk=wall	1155	https://www.linkedin.com/company/fraunhofer-ipt	1117
LOOP @loop_cn	https://twitter.com/loop_cn	729	https://www.facebook.com/LoopCN	247	https://www.linkedin.com/company-beta/321698/	969
REGION H @RegionH	https://twitter.com/RegionH	8096	https://www.facebook.com/RegionHovedstaden	14853		7700
MANGIAGALLI			https://it-it.facebook.com/pages/Fondazione-IRCCS-Ca-Granda-Ospedale-Maggiore-Policlinico/351484081567839	902		
FPM	https://twitter.com/FondaPoliMi	1730	https://www.facebook.com/Fondazione.Politecnico.di.Milano?fref=ts	1724		
HEMOPHOTONICS						
PICOQUANT						
		14891		20901		11804

As per results on partners' accounts, the social media campaigned reached about **20,000 people** (potential reach) and got more than **2,000** interactions (reactions to the news whith likes or retweets or comments).

7.3. Newsletters

BabyLux newsletters contains a series of highlights of the most important and interesting stories about our project. Seven newsletters have been prepapred and distributed to about 800 contacts, variously addressing the project's target groups (e.g. parents associations-organisations, healthcare, scientific associations, authorities, medical associations).
The list of newsletters is the following:

- Newsletter n.1 | March-June 2014 - "Welcome to BabyLux"
- Newsletter n.2 | June-December 2014 - "People and goals"
- Newsletter n.3 | December 2014-June 2015 - "The Babylux mock-up presented in Barcelona"
- Newsletter n.4 | June-December 2015 - "The sensor"
- Newsletter n.5 | December 2015 - June 2016 - "Babylux prototype: a step away from the starting blocks"
- Newsletter n.6 | June 2016 - December 2016 - "The time has come for BabyLux to start the clinical demonstration"
- Newsletter n.7 | January 2017 - June 2017 - "BabyLux, the next step is the market!"

All newsletters can be downloaded here :
http://www.babylux-project.eu/press/newsletter

7.4. Interviews and videos

Having its own You Tube channel, BabyLux has used video clips to interview and therefore to involve stakeholders in the project.
BabyLux YouTube channel is now composed of two playlists:

- BabyLux Talks, which is a collection of all the nine episodes released during the project lifetime (interviews with partners and stakeholders as mentioned above) ;
- BabyLux Final Event, which is a collection of all the speeches given during the project final event that took place in Milan on April 2017.

The analytics of the YouTube Channel during its whole lifetime reported >2000 visualizations. (https://www.youtube.com/user/BabyLuxProject).

During the first year BabyLux has been commented, endorsed and criticized by:

- PUBLIC ADMINISTRATION (Mario Melazzini, Lombardy Region);
- CLINICIANS (Daniel Licht, Children's Hospital Philadelphia).

During the second year, more stakeholders have joined BabyLux inteview series:

- BUSSINESS – Frank Depiereux, Fionec ;
- EU COMMUNITY – Tanya Nikolova, Photinics Unit ;
- SCIENTIFIC COMMUNITY – Roberta Ramponi, Photonics 21 and CNR ;
- GENERAL PUBLIC – comments by the public opinion.

In the third year, other target groups have been taken into account, such as :

- PARENTS – JANNI RISE LARSEN & KRISTIAN MALVANG FRELLSEN, parents of a preterm baby born at Rigshospitalet; DEANNA FEI, Author of "Girl in Glass: How My 'Distressed Baby' Defied the Odds, Shamed a CEO, and Taught Me the Essence of Love, Heartbreak, and Miracles";
- BUSINESS | MEDICAL DEVICES– Paul Borm, Nano4Imaging.

All interviews can be downloaded here :
http://www.babylux-project.eu/multimedia/video-gallery

7.5. Press releases and press review

Press releases have been written with the contribution of all partners. It has initially been distributed to the Italian media on occasion of the final event (April 28). Translations and adjustments have then follwed in Danish, German and Spanish in ordet to be distributed to local media. All things considered, BabyLux has obtained an excellent visibility on traditional media with a total amount of 35 hits, in 2016 and 2017 only.
All press releases can be downloaded here:
http://www.babylux-project.eu/press/press-releases

7.6. Events

BabyLux partners took part to several international events.

25 June 2017, European Conferences on Biomedical Optics (ECBO), Munich, Germany
Sponsored by OSA and SPIE, the European Conferences on Biomedical Optics (ECBO) bring together scientists, engineers, and clinicians who work with optics and photonics to solve problems in medicine and biomedicine. The paper "Baseline haemodynamic and optical properties of the newborn brain and the reproducibility of the measurements: a preliminary report from the BabyLux project" will be presented during the Neurophotonics Session on June

25 at 4:00 pm.

3-4 May 2017, HELTHIO, Barcellona, Spain
In May 2017, Fira de Barcelona became the hub of healthcare innovation. Nurses and other healthcare professionals got first-hand knowledge of the latest medical developments, new products, technologies and ideas for improving patient health. BabyLux took part to the event.

28 April 2017, BabyLux final conference: "Light-to-Cure": Steps from Photonics to Improved Care of Neonates Born Preterm, Milan, Italy
The final event delivered and discussed BabyLux results during a public meeting at Politecnico di Milano. International speakers took part in the conference, such as Adelina Pellicer, Hospital Universitario La Paz, Madrid (ES); Heidrun Wabnitz, PTB (Physikalisch-Technische Bundesanstalt Braunschweig), Berlin and Martin Wolf, University Hospital Zurich (CH). The event also hosted a round table - "BabyLux project and then? Priorities in technical development, standardization and clinical studies" - as well as a section dedicated to the exploitation strategy - "The point of view of the market: ready for BabyLux?" with the participation of Margherita Milite from Siemens Healthineers.

1-4 April 2017, 28th Symposium on Cerebral Blood Flow, Metabolism and Function. 13th Conference on Quantification of Brain Function with PET, Berlin, Germany
The abstract"Baseline haemodynamic and optical properties of the newborn brain and the reproducibility of the measurements: a preliminary report from the BabyLux project" was presented in the "Cerebral ischemia: clinical" session on April 3rd.

15 October 2016, PolimiOpenLabs - La Fisica e la Matematica scendono in piazza, Milan, Italy
For those interested in the world of physics, mathematics and its applications, Politecnico di Milano organized guided tours of its research laboratories, entertaining and stimulating activities, experiments to introduce visitors of all ages to world of science. BabyLux was there.

13 October 2016, fNIRS 2016, Paris, France
The Society for functional near-infrared spectroscopy (SfNIRS) is a professional organization of basic and clinical scientists who seek to understand the functional properties of biological tissues, especially the brain, using optical methods. The aim of the Society is to promote the exchange of ideas, interdisciplinary collaboration, and education. Gorm Greisen (Capital Region of Denmark) gave an invited talk on October 16, "Testing the benefit and harms of cerebral oxygenation monitoring in preterm infants", during the 2016 fNIRS conference.

30-31 May 2016, Biomedica 2016 – Make the health care field of tomorrow today, Aachen, Germany
Biomedica, The Euregional LifeSciences summit, started in 2007, as the first Euregional conference on Lifesciences and Medical Technology. This was the tenth year that companies and organizations from the Life Sciences fields presented their innovations to a thousand mainly European trade visitors, ranging from health care center representatives and investors to politicians and government officials. Fraunhofer IPT attended the event.

25/28 April 2016, OSA Biomed, Fort Lauderdale, USA
This OSA (The Optical Society) Congress focused on technological solutions to medical challenges and medical applications, complementing the OSA Congress on Optics in Life Sciences. It has covered a diversity of cutting-edge research and innovative new tools and techniques, and brought together an international group of leading engineers, optical and

medical scientists, and physicians, as well as junior researchers and graduate students, who are engaged in optical methods to advance discovery and application of medical science to clinical practice. Politecnico di Milano, Picoquant and Hemophotinics took part to the event with a few specific talks and posters on BabyLux.

14/16 April 2016, EURONEURO, Barcelona, Spain
EuroNeuro is a biennial multidisciplinary meeting aimed at neurologists, neurosurgeons, (neuro-) intensivists, (neuro-) anaesthesiologists and basic neuroscientists, as well as neurocritical care nurses, anaesthesia nurses and other healthcare practitioners who care for patients with neurological diseases and brain injuries. EuroNeuro brings together specialists and scientists with diverse backgrounds. ICFO and Hemophotonic took part to the event.

28 January 2016, La ricerca e l'innovazione: motori del miglioramento, Piacenza, Italy
Fondazione Politecnico di Milano presented and introduced its role in fostering research and innovation, with a specific focus on the medical field. BabyLux was mentioned as a case study

2 December 2015, Loop Breakfast Club: "Innovation and new business models in the health sector", Barcelona, Spain
Professionals and businesses related to the health sector in Spain, together with journalists, Ceos and General managers from 17 different companies from the health sector attended the meeting. Loop talked about its experience in the health care domain through some of the projects the company is working on. BabyLux, of course, was one of them.

2 November 2015, 13th European short course on "Principles and Applications of Time-resolved Fluorescence Spectroscopy", Berlin, Germany
During a lecture on "Instrumentation for Time-Resolved Fluorescence Measurements", Rainer Erdmann from PicoQuant addressed BabyLux project. The course was intended for individuals wishing an in-depth introduction to the principles of fluorescence spectroscopy and its applications to the Life Sciences. Attendees were typically professionals using or intended to use fluorescence in their research. The course was held in cooperation with Prof. J.R. Lakowicz from the Center for Fluorescence Spectroscopy and the Department of Biochemistry and Molecular Biology, University of Maryland School of Medicine, Baltimore, Maryland, USA.

20-22 October 2015, ICT 2015 - Innovate, Connect, Transform, Lisbon, Portugal
From 20 to 22 October 2015, BabyLux exhibited at the ICT 2015 at the Centro de Congressos de Lisboa. You could find us in the Connect Area, where Hemophotonics took care of the booth and was able to show people a working mock-up. The exhibition showcased the best-in-class results of the existing European ICT Research & Innovation (from FP7, CIP and H2020 programmes), presenting very advanced research, future visions and being a showcase for activities with a high potential impact on the European industry, competitiveness and the future life and well-being of European citizens. What's more, Alessandro Torricelli, BabyLux Coordinator, gave a speech during the Session 3T "A strong ICT industry for a strong economy", Auditorium 8, 20/10/2015 (16:00-17:30)

2-4 October 2015, Vermont Oxford Network Annual Quality Congress, Chicago, USA
BabyLux as the topic of a lecture on cerebral oxygenation given by Gorm Griesen at "Vermont Oxford Network Annual Quality Congress and Newborn Intensive Collaboration for Quality Symposium". Nearly 1200 members of the worldwide community of neonatology converged in Chicago for the meeting. Vermont Oxford Network, founded in 1988, is a nonprofit voluntary collaboration of health care professionals working together as an interdisciplinary community

to change the landscape of neonatal care.

24 September / 3 October 2015, GoPhoton!, Milan, Italy
The European Commission has financed several initiatives for the promotion of Photonics in 2015, which has been declared by UNESCO as the “International Year of Light”. Among these initiatives, one of the most relevant projects is GoPhoton, involving 8 major European Universities and Research Institutions including Politecnico di Milano, with the aim of setting up outreach activities in Photonics for the general public. These activities have been organised in a full week of events (“Photonics Week”) for school kids, students from high school to university, entrepreneurs and general public BabyLux prototype has been shown to the public during the tour and the presentation of the Department of Physics' labs on Saturday, October 3.

25-26 September 2015, Meet me Tonight, Milan, Italy
BabyLux was back again at "Meet Me Tonight", the Milanese edition of the European Researchers' Night, where scientists translate complex concepts into everyday language. On Saturday, September 26, at the Giardini Idro Montanelli, booth C06, from 11.00 to 22.00, people learned about the project and saw, for the first time in Italy, the prototype that would be operational in a few months at Mangiagalli Clinic Hospital Milan General Hospital and Rigshospitalet in Copenhagen.

16-20 September 2015, 1st Congress of Joint European Neonatal Societies (jENS), Budapest, Hungary
The 1st Congress of joint European Neonatal Societies (jENS 2015) has been a unique event in the field of neonatology. Attendees from all levels of neonatal care attended the meeting, whose panel was composed by more than 120 leading international experts who have personally contributed to the state of the art and who will review cutting-edge developments in the areas of neonatal care and research. Among them, Gorm Griesern, a key person in the BabyLux project, and keynote speaker in the cardiovascular track at jENS 2015.

25-29 August 2015, 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC 2015), MiCo - Milano Congressi (Conference Center), Milan, Italy
Alessandro Torricelli, Project Coordinator of BabyLux project and Professor at Politecnico di Milano, was the Co-Chair of the symposium 'Functional Near Infrared Spectroscopy: Engineering Challenges and Translation to the Clinic'. The symposium took place on Saturday, 29 August 2015, from 12:45 to 14:15, in the framework of the international conference EMBC 2015.
The theme of EMBC 2015, “Biomedical Engineering: a bridge to improve the Quality of Health Care and the Quality of Life”, remarked the central role of BME in the improvement and innovation of health care (with a direct impact on the quality of life) but also focused on how to reach and maintain a “wellness” through proper and advanced technologies, devices and protocols.

22-25 June 2015, Laser Photonics, Messe München, Munich, Germany
LASER World of PHOTONICS is well known as the international trade fair for the laser and photonics industry. Together with the World of Photonics Congress, the fair unites research and industry and promotes the use and ongoing development of optical technologies. A big event, held since 1973, that gathers participants from 70 countries in a 42,000 square meter exhibition space. Those who were interested in BabyLux and wanted to find out more joined Picoquant at Booth 226, Hall B2

3-4 June 2015, Photonic Event, NH Conference Centre Koningshof, Veldhoven, Netherlands
BabyLux has been the topic of an invited talk given by the project coordinator, Alessandro Torricelli. An important occasion to address designers, developers and users of photonics-based applications, instruments, machines, equipment and services. The Photonics Event was organized at the same time as Vision, Robotics & Mechatronics. Special attention was paid to the added value of the crossovers between the two events, both by exhibitors as in the lecture program.

18-20 May 2015, ICOB 2015, International Conference on Biophotonics, Florence, Italy
Antonio Pifferi, Professor at Politecnico di Milano, was one of the speakers at the 4th International Congress on Biophotonics (ICOB 2015). BabyLux has been the topic of an invited talk on translational activities from bench to clinics. From medical and biological end users to decision makers from industry, ICOB 2015 addressed different groups in biophotonics with custom-tailored sessions. ICOB 2015 took place within the "Florence Biophotonics Week" together with IEEE BioPhotonics 2015, 20 - 22 May 2015 (biophotonics2015.ifac.cnr.it).

13 February 2015, ICFO Open Day, ICFO – The Institute of Photonic Sciences, Mediterranean Technology Park - Av. Carl Friedrich Gauss 3, Castelldefels (Barcelona), Spain
On Friday, February 13th ICFO opened its doors to offer a day full of activities designed to highlight many of light's applications as well as its most fascinating properties. The Open Day event took place within the framework of the celebration of the International Year of Light. Members of the ICFO community offered activities and lab tours for schools and the general public to show the research that is being carried out at the institute and demonstrate the many ways that light affects our daily lives. BabyLux was one of them!

3 February 2015, ICFO CLP Day: Wearable Technologies, ICFO – The Institute of Photonic Sciences, Mediterranean Technology Park - Av. Carl Friedrich Gauss 3, Castelldefels (Barcelona), Spain
The Corporate Liaison Program (CLP) Day is an annual meeting where ICFOnians, representatives of international platforms, multinational corporations, local business representatives and researchers of other institutions have the opportunity to interact with experts from around the world in a particular sector to review the latest advances in photonic technologies while focusing on the generation of joint research projects. The theme of each edition of the CLP Day changes in order to highlight topics of interest and relevance to ICFO's corporate partners and collaborators. In 2015 the CLP Day focused on Wearable Technologies. Though not part of the event, the BabyLux mock-up has been shown to the participants during the lab tour presentation.

15-17 December 2014, A networking occasion for BabyLux at OILTEBIA LABORATORY TRAINING PLATFORM, Politecnico di Milano - P.zza L. Da Vinci 32, Milan, Italy
Within the framework of the OILTEBIA Thematic Network a Laboratory Training Platform has been jointly organized in Milan by Politecnico di Milano - Dipartimento di Fisica - and Micro Photon Devices. The Laboratory Platform was an opportunity to train young researchers (e.g. PhD students, post-doc, ...) on time domain diffuse optics and single photon counting detectors and electronics in the field of biomedical applications. Aiming at establishing networking activities with other EU funded projects, people from the BabyLux consortium attended the Platform.

17 - 21 October 2014, BabyLux at EAPS 2014, CCIB - Centre Convencions Internacional de

Barcelona - Plaça de Willy Brandt 11-14, Barcelona (Spain)
BabyLux was present at EAPS 2014, the 5th Congress of the European Academy of Paediatric Societies, an international meeting that brought together paediatric professionals from around the world. The event took place in Barcelona, from October 17 to October 21. The BabyLux stand was the No.32 in the exhibition area of the international congress.
EAPS aimed to engage the best professionals in an exchange of experiences and expertise in research and clinical care, where the participants gained access to the best scientific research programmes in the field. The Congress has been organised by the three societies European Academy of Paediatrics (EAP), European Society for Paediatric Research (ESPR) and European Society of Paediatric and Neonatal Intensive Care (ESPNIC) including the Nurses Section of ESPNIC.

16 October 2014, BabyLux at “Light for Health 2014”, ICFO – The Institute of Photonic Sciences, Mediterranean Technology Park - Av. Carl Friedrich Gauss 3, Castelldefels (Barcelona), Spain
Barcelona, the home town of ICFO – The Institute of Photonic Sciences, hosted the fifth edition of the Light for Health event. The focus was set on "LIGHT & PEDIATRICS - PHOTONICS FOR NON-INVASIVE PEDIATRIC MONITORING". L4H2014 was dedicated to understanding, discussing and sharing the possibilities and potential that light-based technologies offer to the pediatrics community, bringing together experts in pediatrics and biophotonics. The forum comprised lectures by renowned leaders in these fields, as well as clinical and technological round-table discussions.

10 - 12 October 2014, BabyLux at fNIRS2014 Conference, Université de Montréal, École Polytechnique - 2900 boul. Édouard-Montpetit, Montreal (Canada)
Politecnico di Milano attended the 3rd fNIRS2014 biennial conference in Canada next October. Again, another worldwide event where BabyLux was presented to a selected audience. The conference discussed the recent advances in technology and application.

26th September 2014, BabyLux @ European Researchers' Night, Meet Me Tonight - Giardini Idro Montanelli, Bastioni di Porta Venezia, Milan, Italy
A mega event that simultaneously takes place every year in several hundred cities all over Europe and beyond. Whether with family, friends or school, common people found themselves exploring science in engaging ways. MEETmeTONIGHT is Researchers' Night in Lombardy, the annual event that aims to spread scientific culture and research among citizens of all ages through events and initiatives that are both amusing and challenging. 48 stands have been set up to entertain and involve the participants in experiments and demonstrations. BabyLux was one of them!

26 - 30 April 2014, BabyLux at OSA Biomedical Optics | BIOMED Conference, Miami Hilton Downtown - Miami, Florida (USA)
The international Biomedical Optics meeting has brought together leading scientists, engineers, biologists, and physicians engaged in biological and medical research using optical methods. It offered an exceptional opportunity to learn the latest results in the field of biomedical optics and has provided the opportunity to discuss biomedical science and applications with the world leaders in this area.
HemoPhotonics took part in the conference as an exhibitor and gave voice to the BabyLux project. An important occasion to learn about the project oversea and worldwide. As a matter of fact, this meeting has been rewarded and appreciated over the years because of the high quality of research topics and presentations.

21 - 22 January 2014, BabyLux project | Kick-off meeting, Fondazione Politecnico di Milano - P.zza L. da Vinci 32, Milano

All events are reported in here:
http://www.babylux-project.eu/press/2014-02-07-11-42-07

7.7. Networking

In order to expand its network, BabyLux has established contacts with other projects, consortia, internarional activities and associations that are close in terms of content and potenitialities. Some of them are listed below:

- Safe BoosC
https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/safeboosc/Sider/default.aspx
- Laserlab Europe
http://www.laserlab-europe.net/
- Oiltebia
http://portal.uc3m.es/portal/page/portal/grupos_investigacion/optoelectronics/european_projects/oiltebia
- Graphene Flagship
http://graphene-flagship.eu/
- fNIRS society (SfNIRS)
http://fnirs.org/
- LIGHT2015
http://www.light2015.org/Home.html
- LUCA - Laser and Ultrasound Co-analyzer for Thyroid Nodules
http://www.luca-project.eu/
- OPENMIND
http://www.openmind-project.eu/
- BITMAP
http://cordis.europa.eu/project/rcn/198508_en.html
- SOLUS
http://www.solus-project.eu/

7.8. Articles

Six papers were published in international journals:

- A.Torricelli et al., Neurophotonic non-invasive optical techniques for monitoring brain functions, Functional Neurology (2014), doi: 10.11138/FNeur/2014.29.4.223
- A.Pifferi et al., Mechanically switchable solid inhomogeneous phantom for performance tests in diffuse imaging and spectroscopy, Journal of Biomedical Optics 2015; 20(12):121304. doi: 10.1117/1.JBO.20.12.121304
- M.Rehberger et al., Fiber-based hybrid probe for non-invasive cerebral monitoring in neonatology, Proc. SPIE. 9538, Diffuse Optical Imaging V, 95381J. (July 16, 2015) doi: 10.1117/12.2197927
- F.Martelli et al. “There’s plenty of light at the bottom: statistics of photon penetration depth in random media” Sci. Rep. 6, 27057; doi: 10.1038/srep27057 (2016).
- A.Pifferi et al., New frontiers in time-domain diffuse optics, a review, J. Biomed. Opt. 21(9), 091310 (2016), doi: 10.1117/1.JBO.21.9.091310.

- A.Torricelli, "BabyLux: shining light on premature babies", SPIE Newsroom, http://newsroom.spie.org

Other papers are in preparation for international peer-reviewed journals:
Technical papers
1) system description: a paper on a technical / physical / engineering journal with description of the system, basic characterization of phantom and on adult volunteer (e.g. cuff occlusion).
2) Sensitivity of TRS and DCS: a paper describing the sensitivity to errors in the estimate of the optical properties.
Clinical papers
3) c-section: results of measurements after birth.
4) reproducibility: results of multiple re-positioning experiment.
5) ventilation: results of the ventilation experiment

7.9. Leaflet

A project leaflet, giving a general description of the project's activities and goals, and an accompanying "technical" leaflet have been prepared and updated during the whole project lifetime. The final version are attached to this document and can be downloaded at:
http://www.babylux-project.eu/images/pdf/BabyLux_Leaflet_2014_EN.pdf
http://www.babylux-project.eu/images/pdf/2017_final_event/Brochure_Babylux.pdf

8. Photo gallery

Some pictures from different events.

Figure 8 – Final workshop in Milan 28th April 2017

Figure 9 – BabyLux demonstrator at the final workshop in Milan 28th April 2017

Figure 10 – Training of end users

Figure 11 – The demonstrator in Copenhagen

Figure 12 – Mockup of the demonstrator at the ICT2015 conference in Lisbon

Figure 13 – Screenshot of the device

A selected photo gallery is also available on the website at:
http://www.babylux-project.eu/multimedia/photo-gallery

9. Conclusions

The BabyLux project has been active from January 2014 to April 2017. Several activities will continue also in the next future. Updates will be reported in the project web site (http://www.babylux-project.eu).

10. Annex

General Leaflet
Technical Leaflet

BabyLux

This project is partially funded under the ICT Policy Support Programme (ICT PSP) as part of the Competitiveness and Innovation Framework Programme by the European Community
Grant agreement n. 620996

Reducing the risk of brain lesions

BabyLux - An Optical Neuro-Monitor of Cerebral Oxygen Metabolism and Blood Flow for Neonatology - is a project that aims to provide an **innovative** and **reliable** tool to monitor and assess brain blood flow and oxygenation in extremely preterm neonates.

Provide a **precise**, **non-invasive** and **robust** integrated system is the key to enable neonatologists to prevent neurological damages due to lack of oxygenation in the brain, frequently accompanying premature births.

The main goal is to diminish the risk of brain lesions **in extremely preterm babies** from 25% to 20%, eventually reducing the number of children with disabilities by more than 1,000 per year in Europe alone.

An innovative technique

BabyLux takes up complete R&D works and **extends already tested prototypes to the level of demonstrator**, bridging the gap between research products and commercialization. The project aims to provide a non-invasive, portable and highly reliable tool, easy to operate by busy clinical staff. The device can be brought to the bedside, measurements can be done in a few minutes and repeatedly, if the condition is critical.

The system uses **photonic technologies**, such as diffuse correlation spectroscopy, DCS, and time resolved near-infrared spectroscopy (TRS). This innovative combination provides an accurate state-of-the-art and robustness in TRS, and introduces, for the first time, DCS in a combined instrument.

After an initial laboratory demonstration, a **trial period** in real-life settings will follow, at both Mangiagalli Clinic, Ospedale Policlinico in Milan (Italy) and at Rigshospitalet in Copenhagen (Denmark). Functioning and benefits will be evaluated by professional end-users during validation tests, carried out in conditions fitting in the clinical workflow, protocols and procedures.

According to the Global Action Report published by The World Health Organization in 2012, preterm births are 15 million every year and rising. About 1.1 million babies die from preterm birth complications. 5-18% is the range of preterm birth rates across 184 countries of the world. More than 80% of preterm births occur between 32-37 weeks of gestation and most of these babies can survive with essential newborn care. More than 75% of deaths of preterm births can be prevented without intensive care. The extremely preterm infants (born at less than 28 weeks of gestation) represent 0.5% of all births which when translated into numbers is equivalent to more than 25,000 cases per year in Europe. These children have a higher risk of death, approximately 20%.

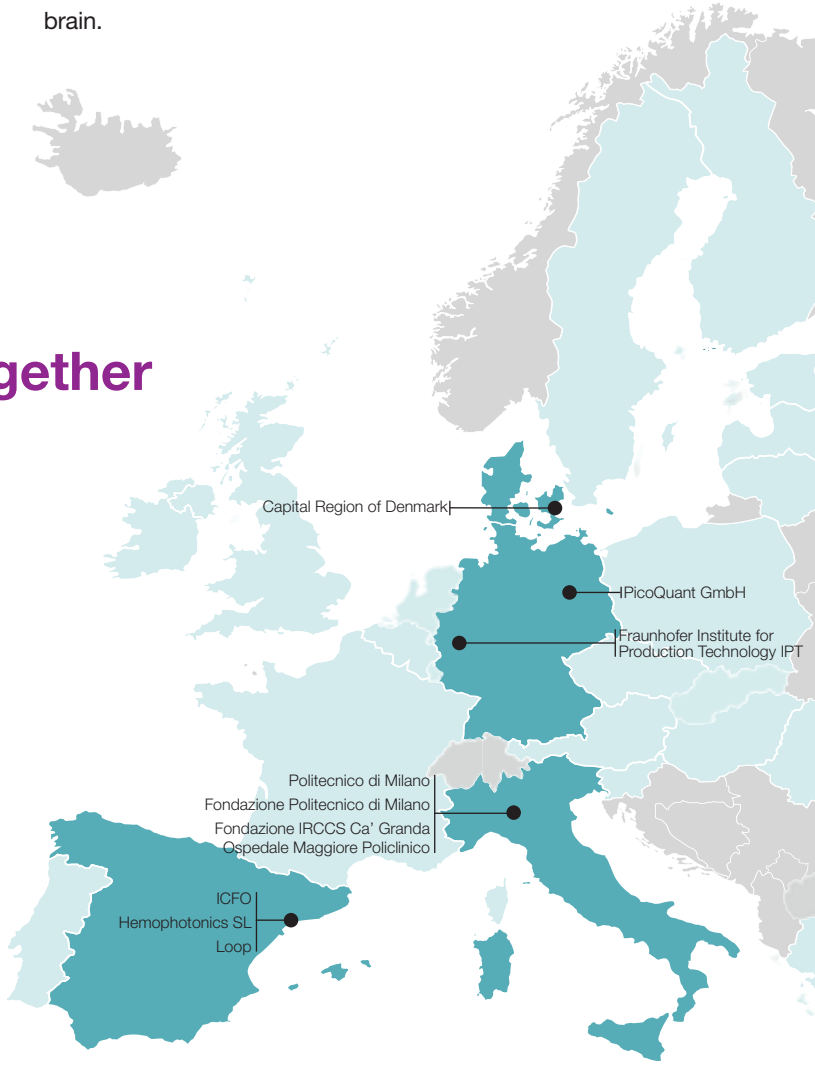
They usually remain in intensive care for several weeks and then in the hospital for 2-3 months before going home. Furthermore, one in four grows up with cognitive and physical handicaps, mainly due to injury from lack of blood flow and oxygen delivery in the brain.

A challenge we can face together

Partially funded by the European Commission under the ICT Policy Support Programme (ICT PSP), as part of the Competitiveness and Innovation Framework Program, BabyLux is a quite demanding challenge, an important initiative lead at an international level in **4 different countries**: Italy, Spain, Germany and Denmark.

9 scientific and technical partners are involved: Politecnico di Milano, Fondazione Politecnico di Milano, ICFO-Institute of Photonic Sciences, Fraunhofer Institute for Production Technology IPT, Hemophotonics SL, PicoQuant GmbH, Loop, Capital Region of Denmark and Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico.

The project will last **3 years**, from January 2014 to December 2016.



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on our website **www.babylux-project.eu**

Contacts
info@babylux-project.eu

Partners

About the BabyLux Project

Funded by the European Union under the Competitiveness and Innovation Framework Programme 2007-2013, BabyLux has been a challenging project led by

- **9 scientific and technical partners**: Politecnico di Milano, Fondazione Politecnico di Milano, ICFO-Institute of Photonic Sciences, Fraunhofer Institute for Production Technology IPT,
- Hemophotonics SL, PicoQuant GmbH, Loop, Capital Region of Denmark and Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

- in **4 different countries**: Italy, Spain, Germany and Denmark

- for **more than 3 years**, from January 2014 to April 2017

BabyLux has taken up complete R&D works and has extended already tested prototypes to the level of demonstrator, bridging the gap between research and development, and the market.

To know more, visit the website **http://www.babylux-project.eu**

This project is partially funded under the ICT Policy Support Programme (ICT PSP) as part of the Competitiveness and Innovation Framework Programme by the European Community Grant agreement n. 620996

BabyLux

An optical neuro-monitor of cerebral oxygen metabolism and blood flow for neonatal research

The goal is to reduce the risk of brain lesions in extremely preterm babies and eventually decrease the number of children with disabilities.

The Babylux device can be brought to the bedside, measurements can be done in a few minutes (<2 min) and continuously, both under critical and non-critical conditions.

The system is based on near-infrared diffuse correlation spectroscopy (DCS) and time-resolved reflectance spectroscopy (TRS). Both technologies work in a wavelength range called the "physiological window" (600nm-900nm) which allows to reach deeper tissue layers, sampling at the depth of the cerebral cortex. DCS provides tissue hemodynamic information, the local micro-vascular cerebral blood flow (CBF), and TRS measures locally the optical tissue properties allowing to deduce information on oxygen saturation and total hemoglobin concentration. By this innovative combination of an accurate state-of-the-art TRS and DCS for the first time in a single instrument, a set of information for monitoring the local cerebral oxygen metabolism becomes accessible.

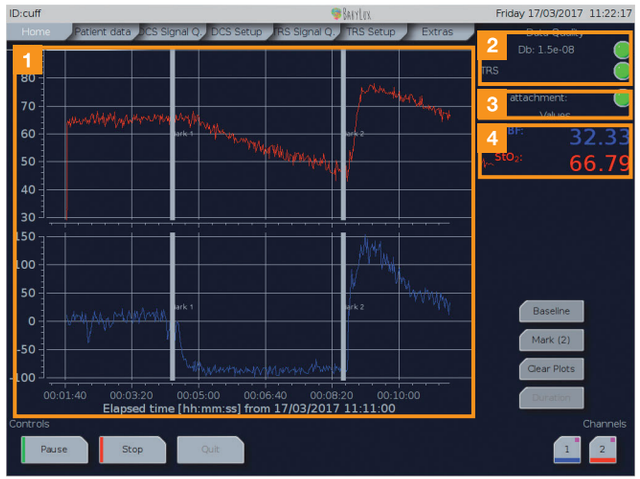
Preclinical testing - the clinical protocol has been authorized by the Danish Medical Agency and by the Italian Ministry of Health: two demonstrators have been tested at the Rigshospitalet in Copenhagen (Denmark) and the Mangiagalli Hospital in Milan (Italy) for at least 6 months.

Essential features

With its bottom trolley, the device is **easily movable** by means of the rear handle. For final placement, the two wheel lock system assures stable positioning in the ICU room.

- **Three wavelengths for TRS, one for DCS**
- **Time resolution up to 1 s**

1. **Time chart updated online**
2. **Online evaluation of data quality**
3. **Safety measures employed**
4. **Online results shown**



The graphical user interface and data representation is designed for two principal application scenarios. First, as an **easy control monitor** with large number representation of main parameters and second, as continuous monitor providing **graphical representation of the parameter evolution over time**. Furthermore, additional information is offered on demand by changing between the main window and secondary windows.

Technical data

Medical Applications

Monitoring of brain hemodynamics in neonates: cerebral blood flow (CBF) and cerebral tissue oxygenation (StO_2)

Estimation of cerebrovascular reactivity in response to different treatments

Measurement Specifications

Optical data	Absorption μ_a & scattering μ_s' coefficients (cm^{-1}), photon intensities (s^{-1}), For expert users: full DCS autocorrelation curve, TRS photon time of flight distribution
Hemodynamics	Concentration of de-, oxygenated and total hemoglobin (µM), StO_2 (%), CBF (cm^2/s), relative cerebral metabolic rate of oxygen ($CMRO_2$)
Max. acquisition rate	1 s
Data collection rate	1-3 s
Data storage	>50 days of uninterrupted measurement
Tissue penetration depth	~ 1 cm

Technical Specifications

Dimensions & Weight (screen folded)	672 x 1372 x 673 mm; 100 kg
Lasers	1 x DCS CW laser 3 x TRS pulsed lasers
Detector	DCS: 2 x single APDs TRS: PMA hybrid photomultiplier detector
Acquisition electronics	DCS: custom-made hardware correlator, 2-channels TRS: Time-correlated SPC board
Sensor	34 x 20 x 5 mm 1 light emitting window and 2 light collecting windows 2 source/detector separations (0.5 and 1.5 cm) 7 fibers and connectors integrated in a 3 m shielded cable (Ø 175 mm) fiber connectors: 1 x SMA, 3x FC/APC (TRS), 3 x FC/PC (DCS)
PC	Touch screen monitor 15”, 250 GB HDD
OS	Linux
Power requirements	UPS: 110-240 V, 200 W; operation time while battery supplied >30