Preface

OVERVIEW OF THE SUBJECT

Neonatal monitoring refers to the monitoring of vital physiological parameters of premature infants and full term infants that are critically ill. Babies that are born before 37 weeks of gestation are typically considered premature. In particular, these neonates can weigh as little as 500g, be the size of a palm and are highly vulnerable to external disturbances. Infants who suffer from diseases that are mainly caused by immaturity of their organs are normally admitted to a Neonatal Intensive Care Unit (NICU).

Continuous health monitoring of the neonates provides crucial parameters for early detection of adverse events (such as cessation of breathing, heart rhythm disturbances and drop in blood oxygen saturation), and possible complications (such as seizures). Immediate action based on this detection increases survival rates and positively supports further development of the neonates. Advances in medical treatments over the last decades resulted in a significant increase of survival. As a result, neonates born after 25 weeks of pregnancy can survive with adequate medical care and appropriate medical care in the NICU. Because of this success NICUs are populated by a large proportion of infants born at very low gestational age. Survival and long-term health prospects strongly depend on medical care and the reliability and comfort of health-status monitoring systems.

In the last decades several important treatment modalities emerged that had a substantial impact on the mortality of prematurely born infants. However there is a concomitant increase of neuro-behavioural problems on long-term follow-up. Follow-up studies indicate that preterm infants show more developmental delay compared to their full-term peers. More than 50% of them show deficits in their further development, such as visual-motor integration problems, motor impairments, speech and language delay, behavioral, attention, and learning problems. Medical conditions including chronic lung disease, apnea and episodes of bradycardia, transient thyroid dysfunction, jaundice and nutritional deficiencies, are potential contributing factors. In addition infants in a busy NICU are often exposed to stressful environmental conditions. Examples are the attachment to multiple monitoring devices and intravenous lines, high noise levels and bright light. Preterm infants, in particular the ones with an immature central nervous system, are highly sensitive for external stimuli such as noise, bright light, and pain. These negative stimuli can interfere with the normal growth and development of the neonates and hamper the parent-child interaction.

Therefore, it is essential to develop comfortable care solutions for NICUs and follow-up. Clearly, such solutions must minimize stress, but also improve vital parameter monitoring quality and robustness.

This book discusses enabling monitoring techniques, medical signal processing and interpretation, and integrated care solutions design for neonatal monitoring. An integration of knowledge from multidisciplinary fields is presented consisting of engineering, industrial design and medical science. While the book focuses primarily on support for premature infants, the envisioned monitoring solutions may well extend to healthy
newborns for home care needs. The design, technologies and systems presented in this book have great potential to be applied to healthcare facilitation for people of any age at home, in hospital and at work.

MISSION AND OBJECTIVES

The mission of this book is to provide an overview on the topic of neonatal monitoring, including the current practice and future trends. The key objectives are as follows:

- To discuss the challenges of non-invasive neonatal monitoring
- To discuss cutting edge monitoring techniques
- To present the new developments on medical signal processing and interpretation
- To demonstrate novel design for non-invasive neonatal monitoring
- To present design process for user centered design solutions
- To discuss the technological, clinical and social impact of non-invasive neonatal monitoring
- To encourage multi-disciplinary corporation
- To serve as material for higher educational courses
- To inspire other applications for healthcare and wellbeing

The book presents a unique integration of knowledge from multidisciplinary fields of engineering, industrial design and medical science for the healthcare of a specific user group. The process, design and technologies will have impacts clinically and technologically as well as on families and society. The process, design and technologies can be transferred to other applications in a broader scope or market.

PROSPECTIVE AUDIENCE

The book is intended to support audience ranging from clinical and medical professionals, academic researchers and students, technical professionals and managers, policy makers of different sectors, to family members of patients, for example:

- Neonatologists and medical staff could benefit from this book the new developments on neonatal monitoring, automated clinical decision support, and novel designs for improve the comfort of the patients and parent-child interaction.
- Industrial designers can learn the design process, the way to conduct user research and clinical validation, and the approach to integrate technology. Furthermore, they will be inspired to design for health care applications and other user centered applications.
- Engineers will be refreshed by the cutting edge technologies and system implementation. The technologies presented in the book encompass non-invasive sensing, wearable sensors, feedback actuators, sensor fusion, clinical signal correlation, motion artifacts reduction algorithms, etc.
- Healthcare professionals and managers will be informed the new developments on patient monitoring and clinical data interpretation and novel design for patient comfort and social bonding.
- Manufacturers will be inspired by the opportunities to produce new materials, devices, and systems for healthcare applications.
ORGANIZATION OF THE BOOK

This book contains 20 chapters, written by 57 authors from 26 institutions in 12 countries. Among the authors, many are international renowned medical doctors, professors, and researchers in the area of neonatal monitoring and enabling technologies. We also welcome a set of younger authors contributing to this work who demonstrate a promising potential for future research and development. Worldwide contributions are received from many countries in Europe, USA and Asia. The 20 chapters in the book represent a comprehensive knowledge of the state-of-the-art developments on neonatal monitoring technologies and integrated design solutions that addresses several aspects of this evolutionary field.

The book starts with an introductory chapter: Chapter 1 “Neonatal Monitoring - Current Practice and Future Trends.” In this chapter, we describe how neonatal monitoring has become a multidisciplinary area which involves a unique integration of knowledge from medical science, design, technology and social study. Firstly, neonatology, neonatal monitoring are introduced including explaining the vital signs and the special requirements for neonatal monitoring. Secondly, current neonatal monitoring techniques and the sensing principles are described. Finally, a historic perspective of neonatal monitoring is discussed followed by recent developments including the scientific and research work contained in this book on non-invasive sensing and signal processing technologies, improving NICU environments, enhancing parent child bonding and new methods for clinical signal interpretation.

After the introductory chapter, three thematic parts are presented:

1. Emerging Technique Opportunities for Neonatal Monitoring
2. Clinical Signal Processing and Interpretation
3. Design Challenges and Applications

Section 1: Emerging Technological Opportunities for Neonatal Monitoring

The advance of technological development is enabling new approaches for neonatal monitoring. The six chapters in this part present new sensing, communication technologies and the proposal of standards for medical devices, including wearable sensors and devices, smart textiles, near-infrared spectroscopy, infrared thermography, body area communication technique, and the ISO/IEEE11073 family of standards.

Chapter 2 “Wearable Technologies for Neonatal Monitoring” reviews state-of-the art wearable technologies and medical systems. Five key aspects for the design of wearable devices are discussed, including Miniaturisation, Intelligence, Networking, Digitalisation, and Standardisation. The chapter starts by reviewing wearable sensors for measuring physiological parameters, such as heart rate (HR), breathing rate (BR), blood oxygen saturation (SaO2), temperature, pulse transit time (PTT) and blood pressure (BP), followed by discussing the analogue integrated circuit design for the front-end amplification, filtering and signal processing. Then the authors address the physiological model development and sensor design for context aware systems and motion artifact reduction. With respect to networking and digitalization, the chapter presents body area networks (BAN) for information integration, relevant communication techniques, and signal compressing theory for digitalization of physiological data. Regarding the standardization, the needs and development on standardization of wearable medical devices are addressed with examples, such as ISO/IEEE 11073 (X73) and IEEE P1708. The X73 family of standards will be discussed further in detail in Chapter 7. Some existing prototypes of wearable medical systems for both adult and neonates are presented to demonstrate the integration of sensing, communication and system level design.
One of the important applications of wearable technologies is unobtrusive monitoring, which requires new sensing principles, more reliable sensor design and user friendly integration. In the next three chapters, smart textile technology, near-infrared spectroscopy (NIRS) and infrared (IR) thermography are introduced. These technologies are emerging research areas with enormous potential for greatly improving the comfort and interface of the monitoring systems.

Chapter 3 “Smart Textiles in Neonatal Monitoring - Enabling Unobtrusive Monitoring at the NICU” presents the research work on ECG and EEG monitoring by replacing the adhesive electrodes with smart textiles. The designs of a neonatal jacket containing textile electrodes for ECG monitoring and textile electrodes to be integrated in a cap for brain functioning monitoring are demonstrated. The initial results presented show good prospect for further development. The challenges for the medical application of smart textiles are pointed out, including accuracy and reliability, washing property and durability, hospital acceptance and mass production. In addition to the technical efforts, in the specific case of introducing unobtrusive wearable systems to the NICU, usability and trust issues must be well considered throughout the design process.

Chapter 4 “Use of Near-Infrared Spectroscopy in the Neonatal Intensive Care Unit” describes the non-invasive technique (NIRS) for cerebral oxygenation measurements. In this chapter the physiology and pathophysiology in relation to the measurement of cerebral oxygenation are explained and the direct possible clinical use enlightened, with special focus on measurement of ischemic cerebral hypoxia. Furthermore, the future prospects of using NIRS in the clinical setting are illustrated, including the potential use to measure cerebral autoregulation and neurovascular coupling in combination with other parameters like blood pressure and EEG, and the measurements of other organs like the liver, the gastro-intestinal system, the muscle, the kidney and the overall peripheral venous oxygenation in a non-invasive way.

Chapter 5 “Neonatal Infrared Thermography Monitoring” presents a contact-free monitoring technique. The chapter starts with overviews on neonatal incubators and thermal conditions, heat transfer mechanisms in premature infants, and medical infrared thermography. Then the authors present principles of infrared thermography, imaging parameters in infrared thermography and some neonatal temperature monitoring technique. Experimental setup for neonatal infrared imaging are described followed by application examples for Kangaroo mother care, thermal effects of neonatal phototherapy, and breathing monitoring. The infrared thermography technique allows quantitative evaluation of the heat transfer processes over the nostrils region, which may have significant impact on non-contact respiratory monitoring. The investigation into thermoregulation physiology during kangaroo mother care illustrates the potential of infrared thermography for standardized neonatal intensive care unit (NICU) procedures. The infrared thermography monitoring is one of the enabling non-invasive monitoring technologies with detailed information about the thermoregulation status of newborn infants, which contributes to the development for the smart integrated neonatal monitoring solutions.

Body area networks (BAN) play significant roles for future medical and healthcare services based on wearable technologies. Advanced wireless communication techniques are critically important for the reliability of the healthcare data acquisition and the comfort level of the monitoring environment.

Chapter 6 “On-body UWB Communications for Health Monitoring” presents on-body communication aspects using ultra-wide band (UWB) technique for neonates and infants monitoring service. Two major aspects addressed in the chapter are channel modeling and communication performance. The transmission characteristics around the infant body are first investigated with a numerical analysis tool. An on-body UWB path loss model is derived and the communication performance for the impulse radio (IR) scheme system is evaluated. Human body safety and bio-electromagnetic compatibility (Bio-EMC) issues are raised up for the design and standardization of BAN communication systems due to the possible body tissue energy absorption and inter-device interference.
Chapter 7 “Overview of the ISO/IEEE11073 Family of Standards and their Applications to Health Monitoring” is the last chapter in Part 1 Emerging Technological Opportunities for Neonatal Monitoring. It introduces the evolution of the standards, the technical features and the new transport technology profiles for developing highly efficient portable and wearable medical devices (MDs) and personal health devices (PHDs). With this evolution, X73PoC on the Point-of-Care of the patient maintains its relevance in ICU and hospital environments and X73PHD evolves to personal, mobile and ubiquitous healthcare solutions. The chapter envisions the application of X73 family of standards to health monitoring and NICUs. The most interesting X73PHD specializations for NICUs are recommended for e-Health solution designers. Moreover, the authors discuss challenges of applying the X73 family of standard at NICUs and foresee the advantages brought by this emerging user case, such as the need for standards on miniaturization, wireless communication and patient safety.

Section 2: Clinical Signal Processing and Interpretation

It is critical to process and interpret the clinical signal appropriately for early detection of diseases, possible complications and pain in neonates. The eight chapters in this part introduce the recent development of clinical signal processing and interpretation tools for neonatal care and research. This part of the book consists of topics on heart rate characteristics monitoring, autonomic cardiovascular regulation, neonatal brain monitoring, neonatal pain and discomfort assessment and advanced clinical decision support systems.

Chapter 8 “Heart Rate Characteristics Monitoring in the NICU: A New Tool for Clinical Care and Research” describes an approach to quantify heart rate characteristics (HRC) associated with sepsis and continuously calculates an HRC index from the conventional electrocardiogram waveform tracing. The monitor provides clinical decision support for clinicians and corresponding medical interventions. The results from a multicenter randomized clinical trial of 3003 very low birth weight infants completed in 2010 showed a significant impact of continuous HRC monitoring on outcomes of preterm infants.

Chapter 9 “Autonomic Cardiovascular Regulation in the Newborn” reviews the baroreflex mediated heart rate response in human infants with a focus on data acquisition, signal processing and autonomic cardiovascular modeling. Continuous ECG and blood pressure waveforms are recorded for calculation of spontaneous baroreflex sensitivity. The clinical relevance of the baroreflex function is discussed in the chapter.

Since neuro cognitive deficits in preterm infants still often happen, it is important to monitor the brain function of neonates, for example identifying seizures and assessing the response to treatment. Chapters 10 through 13 address the research and clinical relevance of neonatal brain monitoring. Chapter 10 presents “Introduction to CFM and the Clinical Applications.” Chapter 11 “Automated Neonatal Brain Monitoring” focuses on automated detection of neonatal seizures and its possible impact in clinical practice by reviewing model-based, heuristic and classifier-based detection approaches and discussing the vision on automated EEG analysis systems. Chapter 12 “Monitoring Brain Development in Preterm Infants: the Value of Automated Analysis of the Electroencephalogram (EEG)” addresses the research of investigation of preterm brain development. Different aspects of EEG maturation suitable for automated analysis including changes in continuity and changes in frequency are discussed in the chapter as well as the challenges for automated EEG analysis.

Pain is a critical factor related to the experience of neonates at NICU and their quality of life. However, it is especially challenging to assess pain on babies, since they cannot express their feelings and conditions well. Presently, no established gold standard for pain assessment exists.
Chapter 13 “Pain Assessment in Neonates” discuss the limits and advantages of different approaches for pain assessment, including physiological, behavioural and biochemical tools. The requirements for neonatal pain assessment consist of: be independent of the infant’s level of maturity and level of illness; give accurate pain measurement; be in real time, etc.

Regarding behavioural approaches, Chapter 14 “Neonatal Monitoring Based on Facial Expression Analysis” presents an automated video monitoring system for the detection of discomfort in newborns. Several algorithmic blocks are developed in the system consisting of the face detection, region of interests (ROI) determination, facial feature extraction, and behavior stage classification.

The last chapter in Part 2 Clinical Signal Processing and Interpretation is Chapter 15 “Clinical Decision Support Systems for ‘Making it Easy to do it Right’.” Clinical decision support systems (CDSS) have been developed with computer based information systems to support implementation of clinical protocols and guidelines. The chapter discusses challenges and requirements for successful use of CDSS in clinical practice and illustrates the development of one example CDSS, Gaston, at the Catharina hospital in the Netherlands.

Section 3: Design Challenges and Applications

The experience of newborns at neonatal intensive care units (NICU) will have both short term impact on their recovery and long term impact on their future development. Thus it is essential to design comfortable care solutions for NICU and follow-up. This part discusses design challenges and example applications. The four chapters present the research and development on the topics of human centered design in NICU, smart jacket design with embedded wearable sensors for improving comfort of neonatal monitoring, design for parent-child bonding and the proposal of a context sensitive clinical monitoring alarm system.

Chapter 16 “Experiencing the Unexpected: Human-Centred Design in Neonatal Intensive Care” describes human-centered and participatory design process which addresses the social, emotional and intimate aspects in the design of neonatal monitoring technologies. The NICU environments pose special challenges on design for multi-stakeholders. The features envisioned for the future NICU design consist of instrumental qualities, aesthetic qualities, innovation, ethical qualities and human values. The chapter also illustrates the development of a new incubator system composed of different technologies, such as a sensory mattress, the Bio-belt for vital sign monitoring, and the NICU browser enabling the end user to construct assemblies of devices and services.

Chapter 17 “Smart Jacket Design for Improving Comfort of Neonatal Monitoring” presents the ongoing design work of a smart jacket for improving comfort of neonatal monitoring. The smart jacket is designed to monitor vital signs of neonates unobtrusively with multiple sensors embedded into the jacket, such as textile sensors, a reflectance pulse oximeter and a wearable temperature sensor. Locations of sensors, materials and appearance of the jacket are designed to optimize the functionality, patient comfort and the possibilities for aesthetic features. From the system level, the chapter also reports a power supply and wireless communication system developed for the smart jacket. Design prototypes and test results on premature babies at the NICU of Máxima Medical Centre (MMC) in Veldhoven, the Netherlands are discussed in the chapter.

Comfort and bonding are two key factors for the development of neonates at NICU and their quality of life. Chapter 18 “Designing Remote Connectedness between Parents and Their Premature Newly Born – a Design Proposal” focuses on the bonding aspect of neonatal care. The chapter reports the design achievements from a master graduation project. A remote consoling system is proposed to support the parent-child bonding and interaction when the parents are not at NICU with their babies. With close collaboration with
medical staff at MMC, the design concept and development went through a multi-iterative design process. Parent evaluation of the prototype and future developments are discussed in the chapter for further design.

Alarms at NICU play both positive and negative roles. On one hand the alarm systems support medical staff to detect abnormalities and emergency conditions of the patients. On the other hand, many false alarms lead to negative stimuli by raising high level of noise at NICU. Chapter 19 “Silent Alarms for the Neonatal Intensive Care Unit (NICU)” proposes a design concept of a context sensitive clinical monitoring alarm system to make the future Neonatal Intensive Care Unit (NICU) quieter. The chapter analyses alarms, their causes and explores how to present them. A work domain analysis and experimental results show that the proposed multi-modality alarm system has potential to reduce more than half of the alarm events in the NICU by reacting on a context aware basis.

The book is concluded in Chapter 20 “Conclusion and Outlook.” This chapter summarizes the book and shows where the field is going and how it fits into a larger societal context. The chapter considers six main trends which are important in health care and in neonatal care in particular. They are electronic medical record and personal health record, cost containment, patient centric care and tele-health, patient safety, comfort, and bonding. The contents of the other chapters in the book are highlighted hand in hand with the trends.

**EXPECTATIONS**

This book offers a comprehensive coverage on neonatal monitoring technologies and integrated design development, providing medical professionals, scholars, designers, industrial companies, and family members of neonates with some of the most advanced research and clinical solutions, developments and innovations.

We sincerely expect that this work will stimulate further research and multi-disciplinary cooperation on the area of designing for neonatal monitoring solutions. We foresee that the research and design efforts will significantly impact the development of neonates during their stay at neonatal intensive care units, by non-invasive monitoring and clinical care, reducing pain and stress, creating a positive NICU experience and promoting parent-child bonding. Consequently, these children are expected to grow up with less complication, so that the quality of life for the neonates and their families at a later stage will be further improved.

Moreover, the technologies and design presented in this book will make a remarkable contribution to the research and application areas of wearable sensors, body area networks and standardization, clinical signal processing and interpretation (brain, cardiovascular and pain monitoring), medical imaging, clinical decision support, and user-centered design for comfort and bonding.

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