Body Area Networks

Safety, Security, and Sustainability

Body area networks (BANs) are networks of wireless sensors and medical devices embedded in clothing, worn on or implanted in the body, and have the potential to revolutionize healthcare by enabling pervasive healthcare. However, due to their critical applications affecting human health, challenges arise when designing them to ensure they are safe for the user, sustainable without requiring frequent battery replacements, and secure from interference and malicious attacks. This book lays the foundations of how BANs can be redesigned from a cyber-physical systems perspective (CPS) to overcome these issues. Introducing cutting-edge theoretical and practical techniques, and taking into account the unique environment-coupled characteristics of BANs, the book examines how we can re-imagine the design of safe, secure, and sustainable BANs. It features real-world case studies, with suggestions for further investigation and project ideas, making it invaluable for anyone involved in pervasive and mobile healthcare, telemedicine, medical apps, and other cyber-physical systems.

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CAMBRIDGE
UNIVERSITY PRESS

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Shaftesbury Road, Cambridge CB2 8EA, United Kingdom

One Liberty Plaza, 20th Floor, New York, NY 10006, USA

477 Williamstown Road, Port Melbourne, VIC 3207, Australia

314–321, 3rd Floor, Plot 3, Splendor Forum, Jasola District Centre, New Delhi – 110025, India

103 Penang Road, #05–06/07, Visioncrest Commercial, Singapore 238467

Cambridge University Press is part of Cambridge University Press & Assessment, a department of the University of Cambridge.

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www.cambridge.org
Information on this title: www.cambridge.org/9781107021020

First published 2013

A catalogue record for this publication is available from the British Library

Library of Congress Cataloging-in-Publication data
Gupta, Sandeep K. S., 1966–
Body area networks : safety, security, and sustainability / SANDEEP K. S. GUPTA, TRIDIB MUKHERJEE, KRISHNA KUMAR VENKATASUBRAMANIAN.
pages cm
Includes index.
ISBN 978-1-107-02102-0
1. Body area networks (Electronics) I. Mukherjee, Tridib. II. Venkatasubramanian, Krishna Kumar. III. Title.
TK5103.35.G86 2013
610.285´468–dc23
2012042718

ISBN 978-1-107-02102-0 Hardback

To my mother and in loving memory of my father
Sandeep
To Trijoy
Tridib
To my parents
Krishna

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Foreword

Over the last decade, the looming collision of the healthcare domain with a number of factors has led to a stark realization that change is urgently required. One may see this change in political platforms and government reforms, but it is technology that has been – and will continue to be – a driving force for the improvement of healthcare.

Factors contributing to this collision in the healthcare domain include the often-documented fact that global aging (contributed largely by the "baby boomer" generation, those born between 1946 and 1964) has hastened the need for increased efficiencies and improved patient outcomes. People aged sixty years and older will comprise at least 21.8% of the population in 2050. Given chronic care expenditures (78% of healthcare costs) and global shortages in hospital beds, assisted living housing, and healthcare professionals, it has been widely acknowledged that the response needs to be swift and thorough. With the US gross domestic product predicted to be at least 25% healthcare-related by 2025, current healthcare costs simply cannot be maintained without causing significant negative impacts on economic and social indicators.

Concurrently, demands for electronic medical records (EMRs) and vast health-information exchanges – analogous to the overhaul of the banking industry that brought us ATMs and electronic banking – are increasing as the need for connectivity and mobility permeates society. Little tolerance remains for paper entries and the nearly 100,000 medical errors seen yearly in the USA alone. While many facilities have successfully embraced EMRs, the global adoption rate continues to be low. Efficiency tools such as Lean and Six Sigma have been used within healthcare facilities to reduce costs, with promising results, but with inconsistent application.

In its infancy telemedicine was not embraced by clinicians due to lack of reimbursement from government or private insurance, lack of strong evidence-based data tied to medical outcome, technology challenges, and lack of usability. Forty years later, telemedicine is being identified as a key to solving the impending onslaught of elders. Improvements of technology connectivity, infrastructure, and device interoperability have encouraged managed-care and government agencies to invest in studies of remote healthcare monitoring in a variety of clinical settings, with promising results. By connecting vital-sign body area sensors (e.g., blood-pressure monitors, glucose-level monitors, pulse oximeters, weight scales, peak-flow meters) to aggregate form-factor "managers" or "hubs" (e.g., computers, USB devices, smart phones, and purpose-built devices) patients can be remotely monitored to reduce office visits and unnecessary hospitalization, increase clinician efficiency, and provide healthier functioning of the chronically ill. Recently, telemedicine has had a profound impact on returning physically and/or mentally disabled war veterans, since leaving the safety and ease of their home compounds their anxiety about returning to civilian life.

As technology improves and Moore's law (transistor density doubles every 12–18 months) continues to prove true, simple point solutions within the healthcare domain are necessary but not sufficient to address healthcare costs and associated economic and social conundrums. The increase in computer processing speeds, hyperthreading, and multi-cores with ever-decreasing footprints have placed a large amount of computing power in the hands of the product developers as well as consumers. Features such as advanced vector floating-point operations, integrated graphics, and high-speed input/output (I/O) (combined with the decreasing cost of memory and mass storage) are hastening the implementation of real-time and predictive clinical and operational analytics, gesture recognition in neural rehabilitation, discrete sensor capture, and four-dimensional (4D) imaging. Network bandwidth improvement, servers capable of managing "big data," and the implementation of hardware virtualization are all contributing to this phenomenon. These hardware improvements – coupled with emerging software efficiencies – in innovative and networked devices and systems can positively impact patient outcomes and lower healthcare costs. Networked devices that are in, on, or around the body (i.e., body area networks or BANs) provide an exciting opportunity for the consumer or patient to take more responsibility for his/her own healthcare, bringing self-sufficiency and the possibility of revolutionary approaches to tackling global healthcare challenges.

With the advent of placing more and more sensors in the ecosystem, safety and security are paramount to user experience, clinical interpretation, and positive patient outcomes. Global regulatory and certification bodies oversee most aspects of safety; however, it is the modeling, design, experimental, and analytic testing acumen (discussed in Chapter 4) prior to formal clearance and approval that meet and exceed the requirements. These approaches are critical to ensuring that subsequent changes in hardware, software, and usage are unequivocally safe. Thorough verification and validation (even for a non-regulated medical product) are necessary to ensure we are testing the "right things right." That is inclusive of security as well – over 88,000 security breaches are occurring daily, with recent reports of medical-device malware and hospital-record breaches. Unique approaches (such as the physiological-signal-based key agreement detailed in Chapter 5), coupled with improvements to hardware and software security technology throughout the entire network, are critical for broad BAN acceptance and trust of sensor data.

Lastly, no product should be developed today without careful consideration of sustainability. Power harvesting from unique sources will allow BANs to be deployed with energy efficiency for reliable and user-friendly experiences (discussed in Chapter 6). Even frequent implanted battery changes (at intervals of 3–5 years) require more "patient-on-table" time, obvious risks notwithstanding. Thus, reducing energy needs through careful modeling and design methods can provide increased reliability and opportunities to analyze and design sustainable solutions.

In this book the reader shall discover a plethora of innovative guidance and solutions to BANs. BANs are a critical and technological response to increasing global healthcare challenges that embrace the very nature of the need: bring a systematic solution to the product developer and consumer for better patient accountability and outcomes. Gupta, Mukherjee, and Venkatasubramanian provide a critical and thorough assay of BANs, covering their architecture, models, and requirements, and enable the reader to invoke improved safety, security, and sustainability of BANs. With the congruence of aging populaces, rising healthcare costs, remote monitoring, EMRs, and advancing technology, it is now up to the reader to understand and implement BANs to positively change the future of global healthcare.

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CELESTE R. FRALICK is currently a Staff Architect and Principal Engineer at Intel Corporation. Her technical oversight includes the embedded intelligent systems in the medical sector. Her unique expertise spans 32 years, including positions with Medtronic, Texas Instruments, and Fairchild Semiconductor. She was a key developer of Intel's initial biotechnology strategies, culminating in Intel's first regulated medical device. She has served on the Advisory Board for the Biodesign Institute, the Bioengineering Advisory Committee, and the College of Nursing's Healthcare Innovation and Clinical Trials Advisory Board at Arizona State University. She has also served on the Scientific Advisory Board for the World Nanotechnology Conference, as chair of the 2005 International Global Digital Healthcare conference, and as a board member for Arizona State University's WinTECH, MacroTechnology Works' Healthcare Innovation Program, She continues to be an Associate Editor with the *Journal of Biomedical Microdevices*, remains on the Board of Directors for the AZ Health-e Connection and the International Essential Tremor Foundation, and on iNEMI's TIG for Medical Device Components, and recently became a research faculty member for Health and Medicine in the International Institute of Analytics.

Preface

Over the last decade, developments in miniaturization and low-powered electronics have led to the development of wireless sensor networks (WSNs), which are computational systems with the ability not only to sense their environments, but also to process and communicate the data obtained using a wireless channel. This book focuses on a specific class of WSNs, called body area networks (BANs) (also known in the literature as body sensor networks), which are networks of wireless sensors worn on or implanted within the human body and have the potential to revolutionize healthcare by enabling anytime and anywhere health monitoring and actuation. Already a plethora of applications for BANs is being developed for a variety of settings in order to provide managed care both for chronic and for acute conditions. For example, BANs have been developed for monitoring soldiers on the battlefield, managing patients in forward locations in a disaster-hit region, emergency management, elder care, and rehabilitation purposes. However, in order for these applications to be viable in the long run, it is necessary to design BANs to be safe in terms of not causing harm to the users, sustainable without requiring frequent battery replacements, and secure from clandestine eavesdropping or interference. These are particularly challenging problems given the complexity of BANs and the limited computational and communication resources available at the devices/sensors in the BANs.

An important feature of BANs is that their constituent devices/sensors directly interact with their environment (i.e., the human body) in order to operate. This environment-coupled nature of BANs puts them within a new class of systems called cyber-physical systems (CPSes), which are systems featuring a tight combination of, and coordination between, the system's computational (e.g., sensors) and physical elements (e.g., the human body). This book explores how BANs can be designed from this CPS perspective. One needs to employ a model-based approach for designing BANs taking into account their environment-coupled nature. Specifically, the book focuses on three aspects of BANs:

- safety – ensuring that side-effects of operation on the environment (human body) are within desired limits
- sustainability – ensuring uninterrupted operation of the BAN
- security – ensuring authorized actions on the BAN

This book is organized into seven chapters. Chapter 1 focuses on providing the context for this work in terms of sensors, which form the basis of BANs. It provides an overview of using sensors for health-monitoring purposes, thus providing an overview of the origin and need for BANs. Chapter 2 delves deeper and provides a comprehensive overview of BANs and their principal components and properties. Chapter 3 then moves on to providing an overview of the principal approach we take to designing BANs – a model-based environment-coupled approach – together with associated issues such as regulatory issues.

After the introduction provided by the first three chapters, we move on to the core of the book that pertains to designing safe, secure, and sustainable BANs. Each of the next three chapters tackles one of these issues using a model-based environment-coupled approach, and provides a case-study demonstrating the working of the approach. Chapter 4 presents a model-based engineering approach to improve the safety of BANs. The chapter also provides a case-study featuring the safety-design and analysis tool called BAND-AiDe to study the thermal effects of sensor operation on the human body. Chapter 5 presents an environment-coupled approach to improve the security of BANs. A case-study utilizing physiological signals to enable key agreement between sensors is presented. Chapter 6 then moves to sustainability issues in BANs. Here, models of various BAN architectures and energy sources are used in conjunction to design sustainable BANs. We present a case-study that demonstrates the effectiveness of various energy-scavenging mechanisms in sustaining a health-monitoring BAN. Each of these three chapters also features open research questions.

Finally, Chapter 7 concludes the book with a summary of how to actually go about implementing a safe, secure, and sustainable BAN designed in the earlier chapters, including a discussion on a systematic methodology for choosing a platform that is most suited for a given application.

This book has been written with advanced courses and graduate-level seminars in mind. It will allow students to gain a conceptual appreciation of BANs in general and, more specifically, using the model-based environment-coupled design methodology for designing them. At the end of each chapter bar one, the book provides questions that are designed to induce a student to think about the contents of the chapter and find solutions. Additional material, including programming assignments and lecture slides, is available online at `http://impact.asu.edu/BANBook.html`. This book will also be of interest to people who are interested in the up and coming field of cyber-physical systems and want an overview of how to go about designing them. Additionally, practitioners in the applications area will find the book useful as a book on the new domain.

Acknowledgments

Throughout the writing of this book, many people have helped us; without them, this book would not have been possible. First and foremost we thank Ayan Banerjee for helping immensely with various aspects of the book, including contributions to formal analysis and synthesis of BANs as well as implementation of body sensor networks, organizing and proof-reading the book, and help with the figures and indexing. We are grateful to Celeste Fralick, of Intel Corp., for her insightful foreword and her comments on various aspects of the book from the perspective of her vast experience in technologies for healthcare. Many thanks are due to Paul Jones, of the US Food and Drug Administration, for his comments on regulatory aspects covered in the book. The quality of this book has been much improved by their comments and contributions. The authors are solely responsible for any remaining errors or omissions in the book.

Various past and current researchers of the IMPACT Lab at Arizona State University have collaborated with us on topics related to this book. We greatly appreciate their visionary work and dedication.

Our heartfelt thanks go to Dr. Phil Meyler, Publishing Director, Engineering, Mathematical and Physical Sciences at Cambridge University Press for encouraging us to write this book and to Mia Balashova, Publishing Assistant, Engineering who provided the needed level of support and encouragement to see this book through from conception to completion. Her periodic emails enquiring about the status of the book draft served as an important beacon to see this book safely ashore. We also thank all the people at Cambridge University Press who oversaw the copyediting process, and the entire crew of Cambridge University Press.

We thank our respective present and past employers, Arizona State University, Xerox Corp., the University of Pennsylvania, and Worcester Polytechnic Institute, for providing the working environment that made this book possible. We are grateful to the National Science Foundation (NSF) for support through programs such as Information Technology Research (ITR), CyberTrust (CT), and Smart Health and Wellbeing (SHB), and to the National Institutes of Health (NIH), Food and Drug Administration (FDA), Google Corp., and Intel Corp. for supporting our research in the areas related to this book. We also thank Byron Gillespie, of Intel Corp., for helping us garner financial support to develop pedagogical material for this book.

Last but not least, we thank our family members and friends who accepted the time away from them spent writing this book. Without their understanding and support, this book could never have been finished.