Practical Aspects of Cosmetic Testing
The idea of “practical guidebook” was born after a hands-on workshop where several participants asked about a recommendation for reading of practical aspects. The current handbooks offer a plethora of scientific overviews and cover the broad spectrum of noninvasive measurement devices for cosmetic skin testing. However, practical aspects of performing cosmetic aspects are not always covered. Also, the published guidelines do not always cover the day-to-day questions arising during the preparation, performance, and evaluation of clinical studies. The aim of the present book is to provide practical guidance for scientists, especially those new in the field or those who face practical problems with their studies. New lab members should have a useful first-to-read source at hand.

I would also like to honor some “corner stones” in the development of modern biophysical instrumentation such as Rony Marks, Harvey Blank, Pierre Agache, Gary Grove, Jorgen Serup, Howard Maibach, Peter Elsner, Enzo Berardesca, Albert Kligman, and the most innovative company in the field, Courage & Khazaka. Some of them have played an important role in the development of my personal career.

I would like to thank all authors of this book. Without their dedicated contributions this project would not have been possible. Special thanks should go to Ms. Blasig, from Springer. She supported this project during its entire process with enthusiasm and dedication.

Albert Kligman had a saying, which I would like to keep in mind when starting and advancing in the field of biophysical assessment of skin functions: “A fool with a tool is still a fool”. Thus, the brain of the scientist should be active when performing and analyzing measurements. Hopefully this book will fill the gap between the detailed scientific textbooks, original and review publications in international journals, and the practical hands-on training that needs to be integrated in the education of young scientists in cosmetic testing.

Berlin, October 2010
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In the era of evidence-based medicine we are witnessing a growing demand for standardization and objective assessment of different physiologic and pathologic conditions as well as for monitoring the efficacy of different therapeutic modalities. The same trend is seen for cosmetic studies. A great number of devices for efficacy testing of cosmetic products have been invented and developed in the past decades. However, a lot of questions remain open when proving efficacy and safety of cosmetic products:

- What parameters and devices are suited to test specific claims?
- How to perform the measurements in practice?
- What should be the test population and what study protocol is most appropriate?
- What environment-, subject-, and instrument-related conditions should be considered?
- What are the regulatory and ethical aspects of cosmetics testing?

This book is intended in the first line for answering the above-stated questions. It will be of practical interest especially to the “new-bees” in the field of cosmetic research, including cosmetic scientists, cosmetic chemists but also dermatological researchers of functional aspects (clinical assessment of disease activity and skin physiology), pharmacists, biologist, and biochemists. Furthermore, professionals working in clinical study centers and contract research organizations (including project managers, study nurses, and physicians) will benefit from the lecture of the present book. The targeted practical point of view together with the “step-by-step” approach when planning and performing cosmetic testing are the main advantages of this manual in comparison to former books in the field.

Skin physiology assessment is moving rapidly from a descriptive approach to a deeper understanding of biophysical and biochemical processes in the epidermis, namely epidermal barrier function, stratum corneum hydration, and the underlying regulated processes. The research with noninvasive biophysical measurements, formerly called bioengineering methods, offer now reliable and reproducible approaches for product testing in the cosmetic industry as well as in basic research. Herein, basic information on technical and legal aspects on cosmetic testing is presented. The authors give insight into very practical aspects of basic skin physiology and the assessment of skin functions in controlled studies. The last (and the broadest) part of the book is dedicated to specific typical examples of test
settings. Of course, a book dedicated to address basic aspects cannot cover the entire spectrum of possible test approaches. The most frequently used endpoints are described.

Research with non or minimal-invasive devices to study skin physiology and the effect of cosmetic products enters in its 5th decade. We are now using the “fourth generation” of instruments. It started in the early 1970s with the assessment of stratum corneum hydration, epidermal barrier function (by measuring transepidermal water loss), and skin mechanical properties. The instruments were often the size of a cupboard or table. Individual instruments were built in the labs and most of the time only prototypes were manufactured that never made their way to wide distribution and general acceptance.

These “first generation” individual instruments were often designed by cosmetic companies for testing their specific product claims. The “second generation” instruments were stand-alone devices, significantly smaller and cheaper. They were the first ones built on larger scales, thus accessible for broader public and academic institutions (Fig. 1).

The “third generation” of measurement devices consisted of instruments attached to a PC via a central-unit allowing direct storage of measurement values. Some manufacturers minimized the measurement technology in such a way that the device was actually in the handheld itself. A skin physiology lab could now fit into a small suitcase. The “fourth generation” is now available with easy to perform calibration check. State of the art instrumentation allows good validation studies and interlaboratory comparisons. The next step (maybe the “fifth generation”) should be to transform the measurement units, today in most cases arbitrary units (AU), to SI units.

The work on standardization led to the publication of several guidelines (see Chap. 2.4. by Pierard et al.) Unfortunately, the working group of European Group for Efficacy Measurements on Cosmetics and other Topical Products (EEMCO) is no longer in place and thus no update on these guidelines will be available in the near future. Maybe, widely accepted standard operation procedures (SOPs) will be implemented or guidelines will be published that are accepted by regulatory authorities. Systematic reviews on the evidence (EBM) for different methods or compounds might help to improve the standards in cosmetic testing. Another step would be to harmonize training courses and maybe to install training certificates based on standardized training sessions. There is still a lot of work to
do, but we have reliable instruments and knowledge available to perform good scientific studies. Rigorous scientific planning together with accurate data analysis will ensure and enhance the credibility of cosmetic testing, especially if some of the standards already in place for testing of topical drugs (e.g., comparing to placebo/control, sample size calculation, and submission to authorized ethic comities) are implemented in the cosmetic study protocols. Today, consumers are well informed not only via the internet, but also due to the easily accessible information especially by the big cosmetic companies. Thus, claims have to be substantiated with good science and controlled clinical studies. Noninvasive instrumentation is a cornerstone of standardized clinical testing.

The present book provides basic knowledge on how to plan, perform, and evaluate scientific studies. The authors are recognized experts in the field and describe in comprehensive chapters the practical aspects of noninvasive measurements. The first part of the book is dedicated to regulatory aspects of cosmetic testing including guidelines, ethical aspects, and claim support. The second part deals with the general aspects of cosmetic studies, namely requirements of the testing laboratory, testing staff, populations, study design, and the reporting of the study outcomes. The third part is dedicated to some typical examples of test settings including efficacy claim studies for moisturizers and emollients, antiaging and antiwrinkle products, antiperspirants and deodorants, and cosmetics for impure skin; and assessment of hair morphology, skin color, and others.

Getting acquainted with the good practice in cosmetic testing would be helpful to the reader not only for better practical performance of a study, but also to interpret and evaluate the strong and weak points of other investigators’ research.

The book should guide into good planning, careful performing, and critical interpretation of cosmetic studies. Of course, reading does not replace hands-on training and personal experience.