Human Centered Design

Raimund Erdmann

EMH Scripts

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international enterprises.

Research and development results from this
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DESIGN?

Synopsis
An informal recap of a roundtable discussion at Erdmann Design between Hanspeter Kersten, Patrick Roth and Raimund Erdmann.

A broad query: What do we really mean when we speak of design?
On what do we base our current perceptions of design? Which ideas supplied the matrix for the roots of contemporary design? In order to be able to answer these questions, we have to look back. Design, it is said, has its origin in the mother of all arts: architecture.

After its heyday in Greek and Roman antiquity, architecture slid into obscurity for a long time. It was not rediscovered until the Renaissance with the writings of Vitruvius. These writings were what inspired Leonardo da Vinci to create the portrayal of the Vitruvian Man. Here da Vinci shows us human proportions in harmony with geometry and mathematics. Anyone who has ever ascended a staircase by Michelangelo knows what proportional design feels like.

The Vitruvian world of ideas was taken up again by American architect Christopher Alexander in the 1960s. Alexander developed what is known as pattern design, which includes humans in architectural decisions. He distinguished between creational pattern, structural pattern and behavioral pattern.

Behavioral patterns, for example, determine the social setting—people move differently in a department store than in an apartment building. This fact not only influences the structure of architecture with respect to proportions, it also supports the implementation of proportions through engineering and materials.

Patterns supply the undergirding of pattern design. A pattern is based on real-world design and offers a proven concept that solves one or more complex problems. It surpasses the conspicuously obvious, including the user in the design process. With respect to architecture, it means the inclusion of occupants and user groups in the design process for the structures to be built.

Pattern design did not enjoy especially great appeal in architecture; however, it was rediscovered in the 1980s as an apt principle for software development. Which brings us up to the subject of usability. The instigators of this were (and are) the design and engineering labs of Stanford University in California. We recognize the concepts of design thinking and human centered design from there.

We also find a significant pioneer in human centered design in the field of sociology. Swiss sociologist and design theorist Lucius Burckhardt was a pioneer of the social sustainability setting in architecture and urban design. Burckhardt focused on personal experience—inspecting, experiencing and walking through architecture. His message: "Design is invisible."

Swiss-born Max Bill counts as one of the best-known luminaries in industrial design matters. Along with Otl Aicher, Bill played a vital role in the founding and establishment of the Ulm School of Design. From Bill we know classics like the Ulm Stool. Its design incorporates functionality, proportion and simple fabrication. The object is stackable and space-saving. It embodies the simplest form of a stool.

Radically reduced design was the hallmark of electrical appliance manufacturer Braun. There Dieter Rams, head of the design department from 1961 to 1995, exacted truth to materials and simple operability as basic principles of design .

The designer Hartmut Esslinger, who made a name for himself with his industrial design for electronics manufacturer Wega, designed the Apple IIc for Apple and its CEO Steve Jobs in 1984, for which he was honored with Time Magazine's "Design of the Year" award.

"Form follows function" and "Less is more"—these two formulas attributed to architects Louis Sullivan and Mies van der Rohe—shaped the thoughts and actions of architects, industrial designers and media designers for generations. With the dawn of the Internet age, a new constellation appeared in the designer firmament: Apple. Its stars: the user, usability and gamification. In 1980 the computer mouse by Apple was celebrated as a milestone of interaction design. The design studio IDEO from Palo Alto, California, set new standards with this work. Cofounders of the company were David Kelley, Stanford University professor

and head of the d.school, and Bill Moggridge, a pioneer of interaction design (see page 27ff.).

IDEO defined communication, engineering, software design, branding, business administration, anthropology and psychology as necessary components of the inventive process. The interdisciplinary integration of many individuals and the need to demonstrate relationships of in-depth human perception and interaction mechanisms were something novel in this form, yet based on the pattern-design idea. This time it was not about "occupants" but "users."

Another American cognitive scientist who contemplated the usability of everyday objects at an early date was Don Norman. Early on in his lectures and publications he emphasized the necessity of user-friendly design and the combination of emotion and function.

Increasingly, not only aesthetics, function, ergonomics and good form stood on the agenda of the professionals. Little by little, concepts like user experience, design thinking or human centered design defined the discussions of the experts. Apple was repeatedly cited as a good and successful example.

When dispassionate aesthetic design and function principles meet the emotional and give rise to completely new products, the need for entrepreneurial trailblazers for them also emerges. Companies that believe in the exploitation of the new products. That was Apple. The Californians under the leadership of Steve Jobs introduced a congenial cube to the

market that greeted users with a friendly "Welcome!" They did not present a cryptic algorithm processing machine to the world, but a partner, assistant and friend.

Anyone who witnessed the digital awakening in the early 1980s, may possibly recall this. It was not until then that the principle of human—computer interaction turned a functional computer console into an empathy-driven desktop. This is what initially prepared the way for a directly emotional (because true-to-life) bond between user and product.

Perhaps this may sound simple to the digital native generation. Without the emotional connection between product and user and the resulting identification and customer loyalty, the new stars and global market players—Apple, Samsung or Google, for example—would be nothing more than an interchangeable, arbitrary computer manufacturer. Today, this phenomenon is very simply called brand.

New thinking requires new methods and approaches for the development of solutions. Today, as an emotionally involved component of the user process, the user gives priority to those products whose function help him and assist him in a friendly manner. This means that design is a broadly defined enterprise value derived not only based on aesthetic and functional criteria, but from the direct user experience. Product design gives birth to experience design, then human centered design.

How is this approach implemented in the development of products? Human centered design needs broadly conceived, agile structures that are determined not solely

through the process or through a predefined user requirements specification. The new design process is heuristic. Diverse professions and perspectives come to the fore. Communication, engineering, marketing, psychology and the lessons learned from direct experience of the application are included from the start.

Working hierarchically, chronologically from "top left to bottom right," is not flexible enough. Classical project management structures offer too little latitude. Human centered design permits these processes to be structured more openly and agilely.

Hierarchical structures contain the risk that, due to less flexibility, goals cannot be reached because they change during development. With fatal consequences depending the circumstances. Especially in a globally structured market in which goals, perceptions and, not least, also budgets can be fluently and quickly changed. The risk exists that products will reach the market for which it is unknown whether they are still usable in this form and/or one will be displaced by an astute competitor with better ideas.

Today products and services are expected to be uncomplicated, and because what is new is compared against what exists, the demands for a positive user experience increase from generation to generation. For companies and their product development people this means: you should get to know your user groups and their needs as precisely as possible.

Here is where human centered design and design thinking start. It helps people in leading roles, designers, engineers and marketing specialists gain a good understanding of exactly who the users of devices or services are.

All who work on such development processes and possess sufficient empathy fortunately have a common experience: just like their customers, they are all users.

Make Space at Erdmann Design in Brugg, Switzerland

Motivation

Products must be introduced ever more swiftly to the market, as it can no longer be controlled through unique technical features. They are quickly copied or implemented by other manufacturers by circumventing patents. It is consequently becoming ever more important to develop products whose utilization offers an extraordinary experience in terms of usability and convenience. For success to endure on this basis, it makes sense to ally product and user experience in a brand.

The first chapter (p. 17) starts with a consideration of the market situation of medical engineering and pharmaceutical products. With human centered design, Chapter 2 (p. 27) introduces a strategy that can meet this situation with different approaches.

Chapter 3 (p. 43) presents the strategic design approach of the Braun brand.

Chapter 4 (p. 47) introduces the usability engineering development phases. In Chapter 5 (p. 51) the approach of HCD, which is successfully practiced by Erdmann Design, is illustrated by reference to a case study.

Chapter 6 (p. 56) presents trends in product development. Chapter 7 (p. 58) deals with testing.

Chapter 8 (p. 62) describes a case from real life.

Raimund Erdmann, HFG, IDSA, SWB
Founder and owner of Erdmann Design AG

The author

Raimund Erdmann studied industrial design at the Zurich University of the Arts from 1974 to 1978. From 1981 to 1983, he studied architecture and cultural history and interned in Buddhist temple architecture in Kyoto. In 1977, he founded Erdmann Design, Industrial Design and Corporate Branding. In parallel he established the Industrial Design Institute with the design collection at the Museum of Design in Zurich. The first medical projects were repatriation devices for Swiss Air-Rescue and first aid kits for the International Red Cross.

As CEO and owner of the internationally operating design agency with over fifty design awards, Raimund Erdmann imparts innovation development in the teaching methodology master's program at the University of Bern and medical design methodology through innovation workshops at Bern University of Applied Sciences. In the years between 1984 and 1995, he taught human centered design methods at Zurich University of the Arts, the University of Washington, Seattle (USA), Stanford University (USA), Syracuse University (USA) and Virginia University, Blacksburg (USA). The development cooperation with CTI (Commission for Technology and Innovation) involves numerous research projects with Swiss universities.

1 Market expectations and requirements

The dramatic changes of the last two decades include most notably the new ways to communicate, acquire information and make everyday purchases. The establishment of the Internet and increased use of smartphones have fundamentally changed our consumer behavior. Today it is estimated that by the end of 2018 around 53% of the world's population (about 78% of the people in industrialized nations and about 32% in developing countries) will be connected to the Internet and 68% of mobile phone subscribers worldwide will own a smartphone with 42% on the go in social media. The widespread use of these technologies forms the basis of increasingly flourishing product–service interactions.

This has greatly influenced our expectations with respect to services and the use of devices which accompany and support us in various stages of life. Our society's expectations toward medical technology products and pharmaceuticals is interesting in this context. PricewaterhouseCoopers has observed: "Patients are becoming more well-informed decision makers. They take an active role in decisions about their health." These changes require enterprises that will be exposing their products in a market to devote increased attention and consideration during product development and marketing authorization.

At the same time, cost awareness is growing as a result of increasing raw materials prices, the change to generic products, exploding healthcare costs and the

resulting curtailment of spending on treatment. Cost savings are also being increasingly realized by shifting medical functions from professional care to lay care. This gives rise to a heterogeneous user group (physicians, caregivers, family members) who must be viewed from a differentiated perspective with their specific knowledge and skills. Moreover, the treatment itself takes place at various locations (clinic, doctor's office, private home). For market success under these circumstances, the medical technology and pharmaceuticals industry must reconsider its present approach to the development and provisioning of products and services that focuses mainly on the optimal safety and efficacy of processes without considering user requirements.

Regulatory measures

The regulatory environment in regard to user-friendliness has changed in recent years. Standards of supervisory authorities expect manufacturers to have a better understanding of patient and user behavior. The U.S. Food and Drug Administration (FDA) and other certification agencies now greatly emphasize a thorough implementation of usability standards such as IEC 62366-1. Based on the change in the proof of efficacy of a product, the FDA is verifying the fulfillment of user requirements ever more intensively on the basis of audits. It is therefore a necessity for medical and pharmaceutical companies to continually review and update the human centered design documentation of the

product portfolio with robust test procedures over the entire product life cycle.

USA (FDA)

The definition of use-related risks adopted by the U.S. Food and Drug Administration in 2014 stipulates that, when using the device, the user should be able to recognize and understand as well as interpret, eliminate or avoid special situations—such as errors or failures.

As additional use-related risks, the FDA considers the following scenarios:
• The physical and/or cognitive abilities required to use the device exceed the abilities of the user.
• The use environment affects the operation of the appliance, and the user does not recognize or is unaware of this.
• The particular use environment impairs the user's physical and/or cognitive capabilities when using the device.
• Device use is inconsistent with the user's expectations and/or intuition about device operation.
• Devices are used in ways that were unanticipated or inappropriate.

The FDA guidelines divide usability testing into formative and summative tests with different objectives. Formative tests are part of the iterative development process with

the goal of recognizing and eliminating usability weaknesses during development as well as verifying individual usability requirements. The development team thus receives feedback on individual usability characteristics of the product under development and, when there are discernible weaknesses, can immediately make changes in the specification and in the design. The preparation, performance and evaluation of a formative test is unregulated by the FDA and is less formal than for that of a summative test.

The timing and duration of formative and summative tests are scheduled by the development team in the project plan during project planning. It should be kept in mind as well that, just like technical changes, formative usability tests can also become unexpectedly necessary. In the case of formative tests, five to eight participants are recommended per user group. Usability requirements should be oriented towards the functions of the product under consideration and be tied to the product requirements. Results—such as persona, scenario and function analysis—that are generated with analytic tools are also to be taken into consideration in the process. The test can include an array of objective and subjective usability requirements that are to be validated—for example, the time for completion of the task, error rate and user satisfaction.

A summative test serves to verify and validate the product and not to analyze and correct specific design problems as in the case of formative evaluation. It cannot be conducted until development is largely complete and

a prototype that is close to production is available. For this, the FDA prescribes the participation of representative users, clearly defined test functions and the specification of acceptance criteria with regard to effectiveness, efficiency and satisfaction. The procedure is similar to that in a controlled experiment. The product is used in a controlled environment. It must be kept in mind that common usability is required during testing, and participants are to be interviewed with regard to the given task in order to obtain a clear understanding of the problem.

For the result of the summative tests to be statistically significant, the FDA recommends a minimum participation number of fifteen persons (formative test: five to eight participants) per user group.

European Union (DIN EN 62366-1)

With DIN EN 62366-1 ("Application of usability engineering to medical devices"), the European Medicines Agency (EMA) compels medical device manufacturers to demonstrate the usability of their products. It describes the development process for realizing usability with the safe use of medical devices as its aim and the avoidance of unnecessary risks under all possible influences. The minimization of risk through safety information in the operating instructions is inadequate.

The essential requirements found in the annex to the Directive Concerning Medical Devices were revised: today, manufacturers must document all identified risks with respect to the use of the devices in a risk–benefit analysis ("clinical evaluation"). Moreover, the standard requires that usability and risk management be dovetailed with regard to the intended use and deviations therefrom. The early involvement of usability specialists and the ongoing correlation of results are important in the evaluation of usability. The analysis must pay attention to the correct selection of users, user groups and their environment. The evaluation and elimination of risks based on insufficient usability must be documented in the usability engineering file (UEF). With the aid of the usability engineering file, the certification bodies review whether a product was developed in conformity with standards and meets the claims to usability and safety. The requirements imposed must be verifiable. The end product must conform to the requirements.

Applying the standard, the manufacturer is obligated to conduct an iterative process in regard to the following aspects:

- Analysis
- Design
- Verification
- Validation

Demographic development

Products with long product cycles (five to twenty years) are frequently designed according to user studies that were conducted at the time of development and not for the target population at market launch. Design teams are often unaware that they are devising for people who will not belong to the target group until later. This is of great importance, as drastic changes in user attitudes and behavior occur from one generation to the next—consider digital immigrants vs. digital natives. To approximate the development trends of the future, we must be familiar with the demographic developments of the society as well as the sociocultural influences that define our lives both today and tomorrow. Individual insights are not significant enough for this. A system is needed to interlink the various trends and transpose them into a comprehensive everyday context.

Digitalization versus rediscovery of analog

Digitalization is advancing unstoppably with an ever grow-ing influence on the development of our professional and private lives. Artificial intelligence is changing the work-place in the form of software or robots and will also lead to increasing automation in healthcare. Digital tools enable us to organize life more autonomously: with their help we can "monitor" our health at any time.

The results of digitalization are greater efficiency and transparency. But this also gives rise to new challenges in dealing with the exponentially growing mounds of data. The overextension that is urged on by the pace and in-creasing abstraction of virtual parallel worlds is resulting in an increased desire for real experiences, a decoupling of technology and deceleration in everyday life. This gives rise to a wish for analog solutions in products wherever they are possible without sacrificing performance.

Individualization versus community

Our social structures form the basis for operating efficiency and the flow of materials in the market. Individuals occupy the center of western affluent society. The personalization of products and services characterizes the transition from the era of the masses to individualization.

The focus on the individual opens new design possibil-ities and promotes economic growth. This is apparent in different areas (food, medicines, tools, medical technol-ogy). Even children can be conceived and raised today

apart from a traditional relationship. But with the increasing focus on the individual, personal isolation is waxing and social cohesion waning. The Internet is simultaneously giving birth to new communities, but they promote no genuine communication between people. The reinforcement of community by new solidarities of common usage is thus becoming the central challenge of the future.

2 Human centered design (HCD) as a new approach

In the following, the previous approach to product development and the human centered design approach are introduced and compared.

Previous approach

Medical technology products and those of the pharmaceuticals industry are usually developed with the primary goal of optimizing the safety and efficacy of processes without consideration of additional user requirements.

In the development of a product, the timetable of the clinical study determines the project schedule. Upon completion of the clinical studies, the developed product is then released for clinical use and commercialization. Tests on the user-friendliness of the dispensing system are thus performed exclusively in a summative manner, with the developed product as a component of the certification. More extensive modifications are usually difficult, as the development budget in this phase is often depleted and the market launch date is imminent.

As a result, the market perceives a product from the pharmaceuticals industry as drug delivery and not as a medicine system with training and simulation services.

Human Centered Design

Human centered design is the umbrella term and the procedure for user-oriented development processes. With process models and heuristic design methods, these generate proximity to the user and produce a use-oriented alignment of the product. The centerpiece of HCD is the knowledge that defines user requirements and is determined, for example, through question and observation. The goal is to determine which explicit and implicit needs exist and how new fields of opportunity and innovation result therefrom. With this knowledge, ideas are developed which are then considered from economic and organizational perspectives.

The hallmark of an HCD process is that, from the start, developers experience, study and document usability in real situations together with the users. That starts already when the problem is posed. A deep understanding of user concerns is vital for human centered design. Because of the company's overly insider-weighted perspective, development tasks without this approach often already include the preconceived and thus undeliberated solution.

In the HCD process, the developers interview and observe the users in order to understand the task from their perspective first. To deepen personal knowledge, developers research in the users' environment. In the process, they learn through observation alone much more than in the conventional work process. HCD professionals call this a "deep dive"; the developer plunges deep into the world of the user

and acquires impressions which might otherwise remain hidden and which can inspire him to a new user experience.

Inclusion of user expectations
A user-oriented process goes beyond safety and efficacy and takes into consideration how the device is received by the intended user, how it fits into the lifestyle and work routine and how users handle and treat the devices. HCD ensures that the developed solutions can be put into operation as easy-to-use tools for the corresponding work environment. A creative investigation into human needs, knowledge and experiences that aims to support the learned capabilities and thereby improve the quality of life is the basis of a successful product development process and of a product that elicits a positive user experience.

Innovative potential
Tim Brown, Don Norman, Gerhard Beckau and David Kelley present and explain HCD in inspiring TED Talks [Tim Brown, 2009; Don Norman, 2009; Gerhard Beckau, 2010; David Kelley, 2012] and illustrate its potential for profound changes in product development and the resulting products.

Through the user's intensive consideration, it is highly likely that unknown, implicit requirements will be apprehended and implemented in the product. This can lead to market success and thus to innovation. "A company's capacity to innovate is the driver of growth and market success." [McKinsey, 2014, Experience Studio, New York]

Influence on branding and corporate image

High customer satisfaction creates positive brand recognition and produces loyalty. The improvement of customer satisfaction is of great importance. Herrling says: "If their [the patients'] expectations are met, they are more inclined to follow an instruction for treatment and remain committed customers much longer." [Nurse Herrling, 2013, Johns Hopkins Hospital, Baltimore, USA]

In connection with waning acceptance and discontinuation of medical treatments which are inconsistent with the patient's notions, information on the patient's opinion during treatment is crucial for product improvement and thus for the business strategy of the medical technology and pharmaceuticals industry.

HCD studies are a prerequisite to analyzing user experience and satisfaction and developing user-oriented solutions—thus generating considerable added value for the company. Based on satisfied return customers and their positive communication, success spreads.

**Comparison of conventional approach
with human centered design**

Conventional product development approaches provide for only a single usability test, the summative, at the end of development instead of several formative tests during development. Problems in regard to usability are consequently recognized too late—in the worst case not until after the completion of development. This results either in

suboptimal solutions or, in the case of troubleshooting, in cost increases and late project completion.

Human centered design is distinguished from conventional approaches through the intense, systematic focus on the user and in the continuous iteration, from the start, of prototype creation, evaluation and correction. This allows usability deficiencies to be recognized early in the development process and not only to be corrected in a timely matter, but also less expensively than if they were detected at a later time.

Revisions of introduced products are usually handled through market surveys and a user-centered design approach. The density of interfaces connected with the user makes it possible to tap a huge potential in the services business segment, above all in the medical technology and pharmaceuticals industry. However, because the interest groups in this business segment (patients, physicians, caregivers, investors, company representatives) have very diverse concepts of value, this potential can only be exploited with user-oriented approaches.

The potential of the HCD approach for a development project, as compared with the conventional approach, can easily be estimated with the following questions:

- Why should HCD be used for development?
- What values can result from development according to an HCD approach?
- Is HCD more efficient than conventional approaches in regard to the avoidance of risks in the user environment?

Training and support

Because of its potential, HCD is discussed and imparted by Erdmann Design with the assistance of experts and users in the context of lectures and workshops.

Erdmann Design instructs and assists companies in the execution of HCD. In collaboration with anatomy labs, Erdmann Design offers courses in creativity-fostering techniques and development methods. Successful practical examples and hands-on participation in projects illustrate this. Thus complex medical treatments and pharmaceutical delivery systems using design thinking could be developed in a user-oriented way, continually improved or excluded as alternative solutions for medical technology and pharmaceutical companies. Many successful products distinguish themselves because of deliberations on usability and can therefore immediately be put to use.

Design thinking as a method of HCD

Unlike analytic thinking, design thinking is a creative process based on the "structure" of an idea. Design thinking is an approach for solving problems and developing new ideas with the aim to conceive solutions that are satisfying from a user's perspective.

The following three equivalent key principles apply to design thinking:

• Team
• Space
• Process

In practice this means that an interdisciplinary team develops a problem together in a creativity-fostering environment—the so-called "Make Space." In this, the requirements and motivation of people are considered and concepts are developed, reviewed and improved iteratively on this basis. This approach is oriented toward the methods of designers for understanding, observing, generating ideas, refining, executing and learning in regard to a definition of task.

To foster creativity, there should initially be no judgments made in the design-thinking process. In order to develop realistic solutions, the ideas are rapidly implemented and discussed prototypically with simple resources (paper, paper clips, ice-cream sticks, pipe cleaners, etc.).

According to the experiences of Kelley [Kelley, 2007], design thinking supports the capacity to see and exploit new opportunities; it is a proven way to foster both incremental and disruptive innovation. Innovation boosters are cross-functional teams and so-called "T-shaped persons"—individuals who possess broad knowledge distributed over various disciplines (horizontal T stroke) and in-depth knowledge in at least one discipline (vertical T stroke).

According to Moggridge [2007], design thinking is a defined, systematic and problem-oriented process for generating innovation in products and services. This process is based on methods from technology and design. It combines ideas from art, tools from the social sciences and insights from the business world. The most important pillars of this iterative process are early prototyping and usability tests.

Design thinking and human centered design were developed by Kelley, the American design company IDEO and the Hasso Plattner Institute for Design (HPI) at Stanford University in California, the world-famous d.school. Now HCD is also being used and taught by a large number of international universities (HPI Potsdam, Germany; Aalto University, Finland; Tokyo Institute of Technology, Japan; University of St. Gallen, Switzerland). Beyond the university environment, this methodology is also being successfully applied in many start-up enterprises and established development companies like Apple, SAP, Swisscom, Pfizer, Stryker, Erdmann Design, etc.

The Stanford d.school describes design thinking in the following way: "Design thinking strives to optimize feasibility (what is functionally possible in a given time). Creating profitability (what is likely part of a sustainable business model), appeal (what makes sense for people and society) and innovative solutions is its message." [Stanford d.school, 2014]

Many participative design techniques, such as usability tests, are borrowed from science; others include mock-ups, prototypes and even role-playing games.

Design–thinking process according to Norman

With respect to the establishment of user-oriented development in design, the contribution of design theoretician Donald Norman is probably the most important. Norman [1989] defined participative design and coined "user-centered design." His model is based on the three phases outlined briefly below:

Inspiration phase:

It comprises all possibilities affected by the perception of a problem and the motivation behind the search for solutions.

Ideation phase:

It describes the process of the formation, development and trial of alternative solutions. User tests as part of the trial concentrate principally on the users with their interests and requirements and less on user-friendliness.

Implementation phase:

It describes the path to the marketing of solutions.

Design-thinking process according to Kelley

Kelley [2007] describes design thinking in the following five steps:

Step 1:
Understanding of market, customers and technology of the task with perceived limitations. The limitations can be discussed later in the project. According to Kelley, it is important to understand the current perception.

Step 2:
Observe people in real situations and figure out what confuses them, what they like, what they reject, what interests them.

Step 3:
Visualization of how the new concepts are used by the customers. Creation of a number of prototypes to this end in the form of visualizations, computerized presentations and simulation models.

Step 4:
Evaluation of the visualizations by customers and experts and refinement for the target market. The primary goal of these measures is to find out which ideas work and which don't, which ideas confuse and which have good usability characteristics.

Step 5:
Implementation of the new concept for commercialization. This step is described as the longest and technically most challenging.

Design-thinking process according to IDEO
1. Inspiration
2. Ideation
3. Implementation

Design-thinking process according to Stanford d.school
Stanford University divides the development process in the Stanford/IDEO approach [Stanford d.school, 2014] into the following five phases:

Empathy phase:
Most important phase together with the Define phase. Identification of the users and their requirements, which are often unknown to them. Discovery and recognition of emotions and behavior.

Define phase:
Analysis and structuring of the results of the Empathy phase with the following goals:
Facilitating a deep understanding of the user. Understanding the environment and its underlying conditions.

Define the requirements and problems. Based on this, the task and the insights are then described and presented in a meaningful scope.

Ideate phase:
Generation of ideas. Identification of solutions to problems for the user scenarios identified. In order to be able to exploit the collective perspective of the variety of options, in this phase the team should have a diverse and multidisciplinary composition.

Prototype phase:
Trial of the prototype in the real environment. The implementation of the prototype is not regulated and can vary greatly, as the following examples indicate: wall with Post-its, role-play, model room, object analogy, interface maquette, storyboard. The insights from the trial are intended to be in harmony with the project progress. The handling of early tests must be fast and rudimentary so that learning occurs quickly on many different examples. Subsequent prototypes can then deliver more and more sophisticated messages.

Test phase:
Last phase before planning of the market launch. Opportunity to further refine and improve detailed solutions. The test mode is conducted with refined models and proposed solutions and makes it possible, through empathic obser-

vation, to recognize and learn even more about the user and his involvement.

Iteration:
The last three phases (Ideate phase, Prototype phase, Test phase) are iterative—that is to say, they are to be passed through in the stated order as often as necessary and meaningful.

Erdmann Design workshop in the Braun Collection
on the development of a design strategy

3 Branding through design using the example of Braun

For generations, products bearing the Braun trademark have signified functional and innovative design. The designer leitmotiv "Strength in simplicity" describes solidarity with company tradition and, at the same time, future orientation. The clarity of the corporate design, practicality and utmost production precision right down to the last detail characterize the identity of this trademark and ensure a uniform image for the entire portfolio. This is realized through design principles that are construed in a way that applies them to all products. In the Braunsammlung in Kronberg im Taunus, Braun company values are conveyed to interested parties by means of a design collection.

After World War II, Braun was able to set a clear example for technical developments with these strategic design values. The successful guidelines for innovative products at Braun, which define rules for form, details, material, color and graphics as well as user-related services that are based thereon, also inspired other companies, such as Apple, to its international marketing success.

The rapid corporate development of Apple under the leadership of Steve Jobs is legendary and paradigmatic in its complexity. Through the HDC method, Apple was able to corner the global market with strikingly exemplary icons in product development.

The design principles of Braun are outlined briefly below:

Reduction:
Visual elements are reduced to a minimum. The operation and functionality of the product become the focus.

Geometry and form:
With their flowing geometry, Braun products conform to the human sense of beauty. They are symmetrical and distinguished by geometric, controlled lines. Separation lines define the functional areas of the product, conferring a visual structure and thereby specifying a direction that clarifies the use.

Stylistic idiom:
The visual appearance is determined by architectonic or ergonomic forms and invests the products with a distinct, unmistakable silhouette.

Order and balance:
Design elements are arranged within a geometric pattern with an easily perceived hierarchy of functions. This gives rise to visual clarity and a harmonious appearance.

Interface elements:
All controls are always shaped as a circle or slot. These can vary in proportion, color and material in accordance with their function.

Iconic details:
Special details make the product unmistakable on the market and simultaneously into a distinct Braun product.

Color and materials:
Black, white, gray and metallized surfaces constitute the dominant product colors. Color accents are found in the details in order to bring out the function or operation.

Clear product graphics:
The product graphics are functional, restrained and uniform through the entire product portfolio.

Problems are worked on in the medical context
with anatomic specimens.

4 Usability engineering development phases

The expectations for a development project increase constantly. Dealing with complex engineering, cost and deadline pressure, compliance with standards, increasing functional range, quality assurance, ergonomics and good functionality are only part of a list that keeps growing longer. Today the development of a successful product all the more requires the interaction of specialists from all disciplines (users, ergonomists, marketing specialists, standards specialists, designers, developers, production specialists).

Project planning, acquisition of specialists

The developer is greatly challenged with the development of the technical solution. He needs design and usability specialists for support. The collaboration between developers and usability specialists should start as early as possible, and the results should be continually reconciled.

User-oriented development involves pragmatism and good common sense!

Ascertaining the requirements of the effective user

The customer is not necessarily the user! Of importance, therefore, is the defining of user groups and gaining familiarity with their requirements and their surroundings through observation and questioning.

Analysis of use in real surroundings
The sales department will often be consulted in the course of a new development. However, it has only limited knowledge of the intricacies of the user requirements. The developer focuses primarily on the technical solution as well as price, compliance with standards and producibility. The usability specialist concentrates on the user and his behavior.

**Evaluation of the results, determination
of the requirements**
The results are evaluated and incorporated into the usability engineering file, the functional specification and the risk analysis.

Preparation of the validation protocol for use
It was recently declared in EN 62366-1 that the methods to be used to test the result must be specified before the start of the effective development. A validation plan must be prepared for this and the result recorded in the usability engineering file.

**Review of alternative solutions during
product development**
Alternative solutions are already created and reviewed as prototypes during the product development process—e.g. through depiction and simulation in the CAD system.

Individual work steps can be reviewed with functional models in the effective environment.

Verification and validation of the end product

Usability in the environment of the user is reviewed and documented with functioning prototypes. If not all usability requirements can be met, it is verified with the risk analysis whether further steps are necessary. The iteration process is not completed until there is no longer an increased risk.

The project goals are worked on through systematic questioning in workshops.

5 Holistic approach for MedTech and pharmaceutical products by Erdmann Design

Erdmann Design has developed products for the medical technology and pharmaceuticals industry for decades and has accumulated profound experience based on the multitude of projects and developed a best practice approach from this. In Chapter 8, we describe the most important aspects of product development with human centered design based on a case study from the pharmaceuticals industry.

User-oriented product development at Erdmann Design

The process is divided into four phases: planning, observing, understanding and making. Various methods associated with each phase can be drawn on for processing the phase; they are briefly outlined in part in the following paragraphs. The selection of methods is project-dependent and is not firmly prescribed.

Stakeholder Mapping

Only with a holistic overview of the interests and nexuses of the persons and groups involved can the problem be realistically formulated. The question about interests and nexuses with various influence groups involved in the product is answered with stakeholder mapping. With stakeholder mapping, an overview of the involved groups and individuals is generated and their individual interests and relationships with each other are depicted.

Contextual Inquiry

One of the prerequisites to the successful HCD process is to bring together designers and users before the design phase. In order to understand the problem realistically, it is of fundamental importance to experience the actual situation in which the product under development will be used. Contextual inquiry serves the purpose of answering the questions according to the users, the use environment and the situation for the use of the product under development and to clarify ambiguities, preferences and dislikes directly with the users. Contextual inquiry occurs with the users at the place of use, ideally in real situations.

Heuristic Review

Heuristic review answers the question about the places in a process or product where details emerge which require user-oriented consideration.

During the heuristic review, a real situation is juxtaposed against the perceptions of this situation and the underlying principles—such as "Cognition is superior to memory"—and the insights gained are documented on Post-its.

Hands-on Experience

The hands-on experience method addresses the question posed after the situation is experienced by the users. The development team steps into the shoes of the users of the product under development and experiences the situation firsthand. This supports the empathic approach.

Persona Profile

The persona profile shows the development team who they are developing for. That users have a face and a history is one of the most important insights.

The persona profile method addresses the question of how one or more target groups can be taken into consideration in the development project. In a persona profile, the representative of a target group for which the product is being developed is characterized and personalized. Upon completion this is equivalent to a profile. The representative is, for example, also given a name so that it is always possible in the development process to ask how this person will deal with certain product details. The persona profile supports empathy with respect to different user groups—such as doctor and nurse.

Experience Mapping

"Experience mapping" answers the question concerning what the users are doing during a process being considered and what experience they have in the process. The experience mapping diagram consists of a time line (horizontal), which represents the observation period. In addition, the vertical axis documents all observations in various categories—such as activity, comments of the stakeholders, emotions, interpretations of responses. Important details such as "moments of truth"—in other words, items that may represent a hurdle a simplification in the process—can then be read with the aid of this log. In addition, this can

yield important insights into the qualities and features that the product under development should have.

Early Models

The early models method deals with the question whether the design of an alternative solution appears interesting and should be pursued. In order to separate good alternative solutions from bad ones early on, alternative solutions are implemented as prototypes as early as possible in a simple and quick manner. Model-making materials—such as paper, cardboard, strips of wood, semifinished products, wire, rapid prototyping, etc.—lend themselves for this purpose.

Early models produce quick insights.

6 Trends in product development

Ecosystem

In order to exhaust the full innovative potential of HCD during development, a decision on the strategic objective, the system design, must be made. This new paradigm facilitates a holistic view of the product range as well as its environment and makes it possible to profit from the already sustainably developed results.

Continuous development

A holistic way of thinking in development projects requires a reduction of intense specialization in development organizations and the introduction of broad, multidisciplinary teams. Based on platform development, for the purpose of ongoing development, a team should no longer be assembled ad hoc but with synchronized teams represented by specialists from all functional areas and user groups.

Make Space

Consciously or unconsciously, we internalize what the space of the development environment tells us and how creatively we act there [Steelcase, 2010]. Most workspaces were developed according to lessons learned from industrial work models. Whether or not intended, the form, functionality and surfaces in a room reflect the culture, the behavior patterns and the mentality within the group. It is

therefore of vital importance to create special rooms which promote mobility during teamwork and creation.

Outsourcing versus self-reliance
In recent decades, globalization has contributed to ever greater fragmentation of the value chain and to increasing specialization of work. Activities which are not part of the core competencies of a business are outsourced today. The result is more efficient production. It offers more products and services, and these with lower costs and higher quality—of foods available in enormous variety regardless of the season, of a variety of products with deluxe versions, and of medicinal products with the same active ingredients in varying price classes. However, with specialization, the understanding of the big picture gets lost. The global production chain is increasingly converging; credibility is declining due to poor transparency. In response to alienation, the need for more self-reliance in development is growing. "Make spaces" and "do it yourself" are the new catchphrases of California's urban society. Autarchy is becoming the emblem of self-reliance (start-up companies) and sustainability (differentiation) in the global world.

7 Testing

For ethical reasons, the testing of prototypes or products of the medical technology industry cannot be easily realized. Here diverse anatomic institutions offer themselves as centers of excellence for medical training and medical simulation. The institutes offer professional support and advanced training courses for physicians and medical personnel with a focus in musculoskeletal surgery. The key concern is to train on and understand the realistic depiction of complex medical processes through practical exercises on the anatomic specimens.

Practical training is absolutely essential when a deepening of anatomical knowledge and the development of surgical skills are involved. Thanks to qualitatively optimal equipment and perfect preparation of the specimens, specialist content can be shared in the best manner.

The infrastructures of some institutions make it possible to work in small groups that are independent from each other. In this way, the instructors can optimally meet the needs of the individual course participants.

The medical technology industry must understand the latest technical developments in practical surgery, the economic framework of the hospitals and insurance companies as well as the resulting influences on the treatment situation. Besides theoretical dealings with usability standards, developers must therefore also gain insight into the practice.

In this connection, Erdmann Design facilitates the holding of interdisciplinary workshops in which medical procedures and situations in the treatment room can be followed and experienced directly or via live broadcast. This opportunity for interaction is crucial for the development of innovative medical technology products.

Sustainability considerations
The sustainability of a development is absolutely necessary in competition. Lubin and Esty [2010] identify sustainability as the new megatrend in business. This also applies increasingly to the healthcare sector. Sustainability is no longer only a philanthropic endeavor, but destined to reduce energy demands or the amount of waste. The goal is, for example, to bring down the need for water or the volume of waste and the associated costs and in this way generate a direct financial return from the new investments.
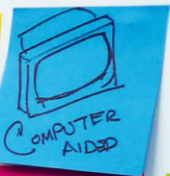
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8 Practical challenges in a Johnson & Johnson innovation project with a pharmaceutical device

Human Centered Design is the way to get and leverage customer input for new medical devices.

Wrong: Ask customers what features they want in your products or services.

Right: Ask customers what outcomes they want from using your product or service.

Most of the time, when we ask customers about solutions, we are setting ourselves up for failure. It is not the responsibility of customers to figure out what features will provide the experience they desire or achieve the result they want. What customers can meaningfully talk about is what experience and outcomes they want. Once we know that, we can delve into the question why those outcomes are important. Then we translate that understanding into a product requirement and validate its accuracy and importance in a design study.

For example, we might hear a chronical medication patient tell us in focus groups that they want the device to be a certain shape. That's a solution. If we took that solution at face value and passed it on to the engineers and designers as a recommendation, we would likely be misleading them because we don't yet know the desired outcome. We learn that the outcome is about maximizing patient com-

fort. We can then propose and validate a measurable requirement designed to achieve that outcome, such as "maximize comfort for older patients". Now the engineers and designers take over to bring the requirement to function. Bottom line: Asking the right questions provides customer input that leads to better products that solve meaningful customer problems.

Findings from resuscitator user research: Assembling a resuscitator kit under the stress of an actual emergency requires the rescuer's full attention on the patient. For easier assembly of resuscitators there is still no color-coded help at the joints. Many lives could be saved in the time figuring out which part goes where.

Gaining Clinical Insight: Physician Interviews

The first, and most important, order of business is to know what information you are trying to extract. Our assumption here is that you need detailed, qualitative clinical insight on a topic of interest, which suggests that in-person interviews would be most suitable. Who can provide the insight you seek? What clinical specialties should be represented? Where should they be working—academic institutions, community hospitals or private practice? In other words, what kinds of physicians are most likely to contribute the insight you seek? And how do you identify these doctors and entice them to participate? In our experience the incentives that matter most are, first, interest in the topic of discussion, and second, cash. However, you must first

identify some candidates with experience in the matters at hand. Academics are the easiest to identify because they publish, while physicians in private practice and those employed by hospitals are more challenging. Professional associations can sometimes help. Once identified, the candidates can be invited to participate by e-mail and phone. The discussion, whether it takes place by telephone or in person, should be just that—a discussion between peers, not a survey. Of course, to qualify as a peer you must know a good deal about the topic of interest before the discussion takes place. While a written discussion guide is essential to start, it's best if the discussion is wide-ranging and both parties can contribute equally. Treat the respondent as a professional person, not a medical authority from whom you are attempting to pry data; establish some personal rapport; no deception and no selling. Throughout the Q&A process try to understand the respondent's frame of reference and concerns. On each issue, is the nurse motivated by purely clinical preferences, concern for the patient, procedural efficiency, economics, or what?

Now for the creative part: converting fact and opinion into insight. It's really a matter of collating the data, stepping back to see the big picture, then drilling down into a few key issues. There's no recipe for this interpretive process, and it's important to keep in mind potential respondent biases along the way. You can expect a few lies and half-truths, some hidden (or not so hidden) agendas,

and some important personal economic drivers. Neverthe-less, in most situations a doctor's concern for the patient will trump other motivations. Just be sure you weigh each respondent's answer against that physician's depth of ex-perience and credibility.

- Your Objectives
- The Recruiting
- The Interview
- Your Interpretation

Our strategic consulting provides Human Centered Design through custom research, develops grounded strategies and creates design solutions to help companies in the health business bring products from idea to market.

www.erdmann.ch

The human centered design method cards are developed and used as a tool with our customers following the definition of task. You can obtain a list of the method cards upon request at info@erdmann.ch.

Appendix

The list of publications on the subject of design thinking and human centered design is long. Below is a small selection for getting started with the subject.

A Pattern Language: Towns, Buildings, Construction / Alexander, Christopher; Ishikawa, Sara; Silverstein, Murray; Oxford University Press; 1977; ISBN 0-19-501919-9

Mit Mustern arbeiten – Eine Einführung / Leitner, Helmut; http://band2.dieweltdercommons.de/essays/ mit_mustern_arbeiten.html

Design ist unsichtbar: Entwurf, Gesellschaft & Pädagogik / Lucius Burckhardt. Published by Silvan Blumenthal and Martin Schmitz; Berlin: Schmitz; 2012; EAN: 9783927795617

TED Talk 2002, Kelley, David; Human Centered Design; https://www.ted.com/talks/david_kelley_on_human_ centered_design