Linzer Sabrina, BSc

Smart medication dispenser

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Univ.-Prof. Dipl.-Ing. Dr. Christian Baumgartner

Institute of Health Care Engineering with European

Testing Center of Medical Devices

Univ.-Prof. Dr.phil.-nat. Sven Stegemann

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Abstract

The demographic development of increasing numbers of elderly patients with chronic diseases requiring continuous polypharmacy represents a challenge for both the medical care system and the patients.

Patients with chronic diseases often have to deal with complex medication schedules. To improve patient compliance, medication dispensers are often proposed. In the easiest case these dispensers are devices with compartments, in which the pills are sorted due to the medication therapy plan. For patient with impaired eyesight, physical constraints (e.g. reduction of fine-motor skills) or forgetfulness those devices are prone to error. Patient adherence to medication is clinically crucial in reducing mortality of chronic disease and total health care costs.

The purpose of this work is to design a concept for a smart medication dispenser with an intelligent withdrawal system to avoid non-compliance errors and provide remote manageability. In order to improve the patient compliance the user requirements have to be collected and evaluated. Furthermore a very important component is the IT-structure as the medication dispenser is also working with sensible patient data. Therefore the medication dispenser has to be designed in a manner to be able to interoperate with existing healthcare platforms.

- User requirements
- Functional and non-functional requirements
- Regulatory Requirements (patient safety, Protection of Personal Data….)
- IT-structure of common healthcare platforms (Interoperability)

Keywords: medication dispenser, Adherence, compliance, ambient assisted living,

Zusammenfassung

Die demographische Entwicklung und das mit dem Alter steigende Risiko an einer chronischen Krankheit zu erkranken, sowie der damit verbundene Umgang mit Polypharmazie, stellt für das Gesundheitssystem und die Patienten eine große Herausforderung dar.

Bei komplexen Therapien müssen PatientInnen ihre unterschiedlichen Medikamente zu verschiedenen Tageszeiten und Wochentagen oral einnehmen. Hierbei werden sie von Hilfsmitteln, wie Dispensern, unterstützt. Im einfachsten Fall handelt es sich dabei um eine Vorrichtung mit mehreren Fächern, in denen die Tabletten oder Kapseln einsortiert werden. Gerade für Menschen mit verminderter Sehfähigkeit, körperlichen Einschränkungen (z.B. nachlassende Feinmotorik bei älteren Menschen) oder Vergesslichkeit, ist das bisherige System fehleranfällig. Die Adhärenz des Patienten spielt eine entscheidende Rolle in der Verringerung der Mortalität bei chronischen krankheiten als auch in der Senkung der Kosten im Gesundheitswesen.

Der Zweck dieser Arbeit besteht darin, ein Konzept für einen schlauen Medikamentenspender mit intelligentem Entnahmemanagement zu erarbeiten, um Fehler durch mangelnde Adhärenz des/der PatientIn zu vermeiden und eine Steuerung aus der Distanz zu ermöglichen. Um die Adhärenz der Patienten zu verbessern, müssen die Nutzeranforderungen erhoben und evaluiert werden. Ein weiterer wichtiger Aspekt ist die IT-Architektur des Systems, da hier mit sensiblen PatientInnendaten gearbeitet wird. In diesem Konzept soll auch die Interoperabilität mit existierenden Healthcare Plattformen berücksichtigt werden.

- Nutzeranforderungen
- Funktionelle und nicht-funktionelle Anforderungen
- Regulatorische Anforderungen (Patientensicherheit, Datenschutz, Datensicherheit etc.)
- IT-Struktur (Interoperabilität)

Keywords: medication dispenser, Adherence, compliance, ambient assisted living,

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1 Introduction

1.1 Medication adherence and the elderly

The demographic development of increasing numbers of elderly patients with chronic diseases requiring continuous polypharmacy represents a challenge for medical care. At present, 30–40% of all German patients > 65 years are prescribed four or more different medications, and this number is expected to increase [1].

Chronic diseases and conditions (cardiovascular pathologies, diabetes, obesity, COPD-chronic obstructive pulmonary disease, chronic pain, traumatic brain injuries, etc.) more common in elderly persons, typically are requiring long-term monitoring and treatment protocols both in traditional settings and in out-patient frameworks. Significant increases in managing this category of patients are due to clinical improvements, better screenings, and reliable diagnoses of medical and psychological pathologies that enable those with chronic conditions to live longer [2]. Poor compliance with rationally prescribed drug regimens attenuates benefits of treatment, making compliance a key link between process and outcome in ambulatory care.

Compliance is defined as 'the extent to which a person´s behaviour (in terms of taking medication, following diet or executing lifestyle changes) corresponds between the patient's actual dosing history and the prescribed regimen' [3, 4].

Compliance used to be the common term in the literature, but it is increasingly being replaced by the term ‘adherence’, which is less judgemental and more respectful of the role that patients can play in their own treatment [4].

Poor adherence to long-term therapies severely compromises the effectiveness of treatment making this a critical issue in population health both from the perspective of quality of life and of health economics [5]. Achieving optimal medication adherence requires patients being prescribed the right medication, filling it and taking it correctly over time. This requires appropriate prescribing, effective patient-provider communication, coordination among care-providers and active engagement and participation by patients [6].

Non-adherence is a multifactorial issue and it is likely that no single strategy will be effective in all patient groups. In general two types of non-adherent behaviours are commonly observed:

(i) Unintentional non-adherence by reason of forgetfulness, inability to follow the instructions due to poor understanding, regimen complexity and/or physical problems;

(ii) Intentional non-adherence when the patients wilfully decides not to take the treatment as instructed [7].

Many workshops and studies were conducted to identify potential risk factors and challenges for older people and carers to prevent unintentional non-adherence.

In one of those workshops, the public engagement workshop: How to improve medicines for older people [8], the challenges related to medicine use were mainly classified as:

- Physical difficulties
    - visual problems – not able to read small print on bottles or in information leaflets;
    - dexterity problems – not able to open packets, deal with gadgets, drop tablets;
    - tiredness/sleepiness – may lead to missing doses.
- Cognitive difficulties
    - confusion;
    - memory problems – forgetting to take tablets at all, forgetting when just taken;
    - comprehension – understanding of what medicines are for;
    - stress due to disease symptoms – lack of effect of slow release.
- Living difficulties
    - living alone – no one to assist;
    - carers requiring training in medicines use.
- Medicine related difficulties
    - usually polypharmacy –mixing tablets up when taking them and interactions of all meds;
    - co-morbidities;
    - medication reviews – lack of awareness of what they are prescribed to from a pharmacist and/or general practitioner (GP);
    - lack of advice from the pharmacist;
    - admissions to hospital – given all medications at once.
- Other shared difficulties

- disposal of medicines;
- relationship with and role of the pharmacist;
- relationship with and role of the GP.

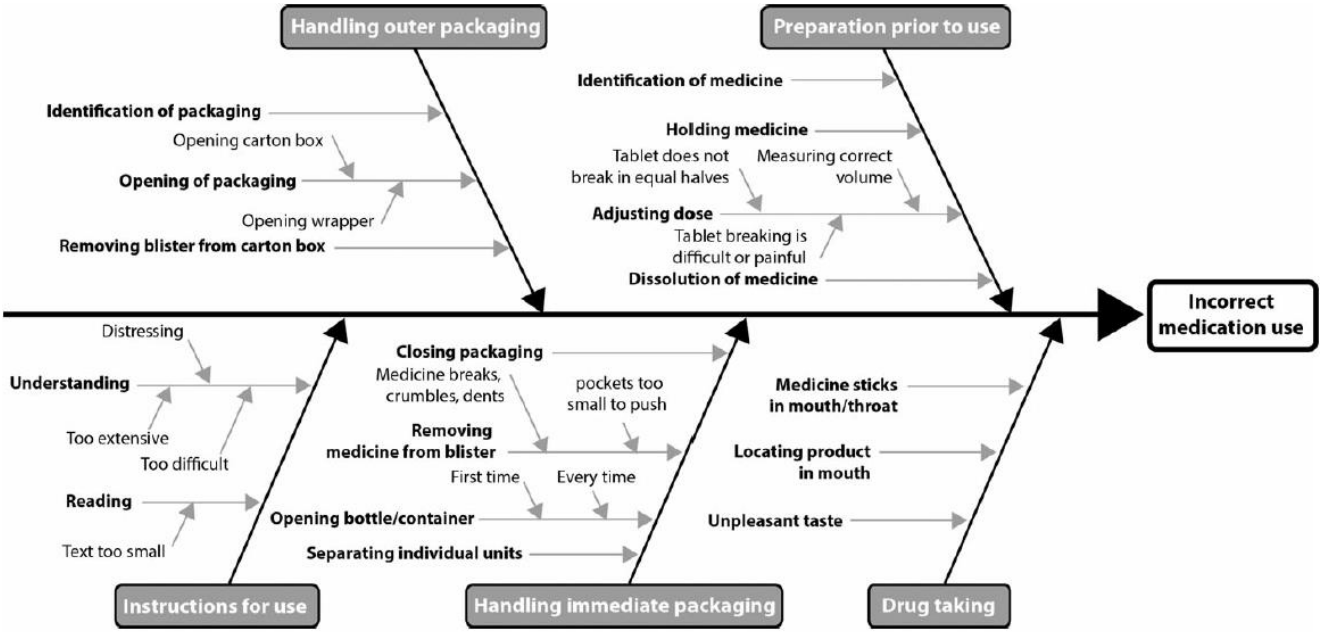


Figure 1: Ishikawa diagram outlining practical causes of incorrect medication use according to sequential step of the medication use process [9]

To support the non-intended non-adherence patients to stay compliant, it is very important to understand the extent and major reasons of the adherence problem. Therefore effective and trustworthy adherence measurement systems (AMS) have to be capable to understand the outlined causes. Adherence is mainly generated by a solid patient- healthcare professional connection, like the pharmacist or physician by providing necessary information on the prescribed medication and drug therapy. The developed AMS provides the physicians with information to allow a conclusion on the patients' drug therapy behaviour. That allows the physician to identify drug therapy related issues, like drug adverse drug reaction or to contribute suggestions of improvements and consultation to enhance the patients' adherence performance [10].

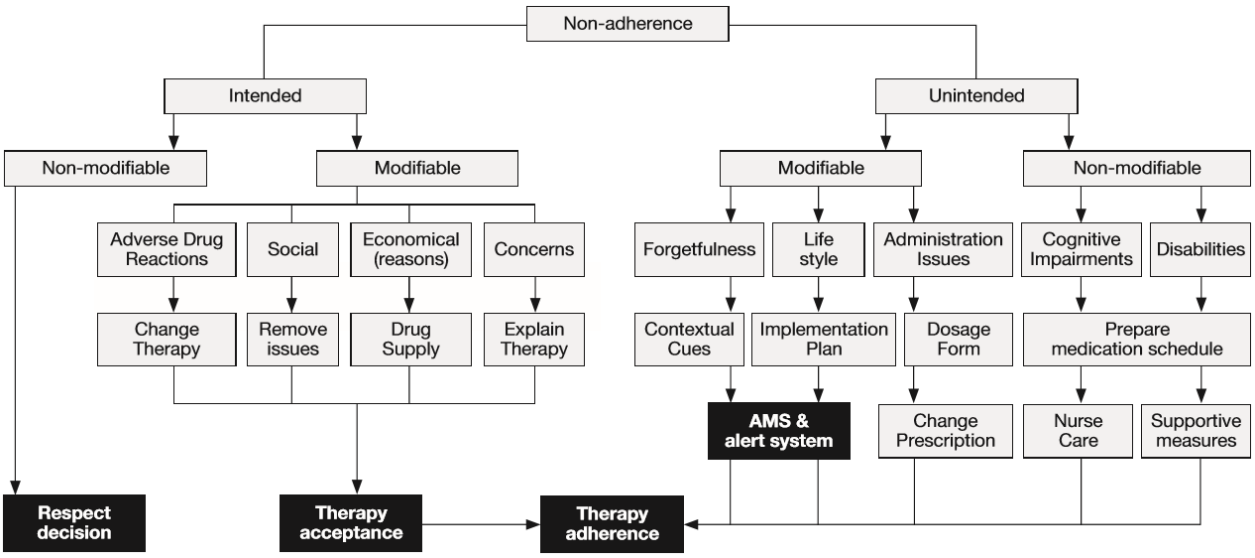


Figure 2.: Adherence measurement systems and alert systems within the framework of adherence [10]

Successful interventions to enhance adherence in the elderly used a combination of educational and behavioural strategies, but the effects of the individual components were not evaluated. Adherence to medications declines over time in the absence of periodic follow-up and reinforcement. Innovative ideas for enhancing medication adherence in the elderly and reliable measures of adherence are needed [7].

In order to underline the importance of medication adherence and the related research interest the numbers of publications to this very particular topic is shown in Diagram 1. As you can see, the number of publications in 2015 is three times higher than in 2010 and ten times higher than in 2005.

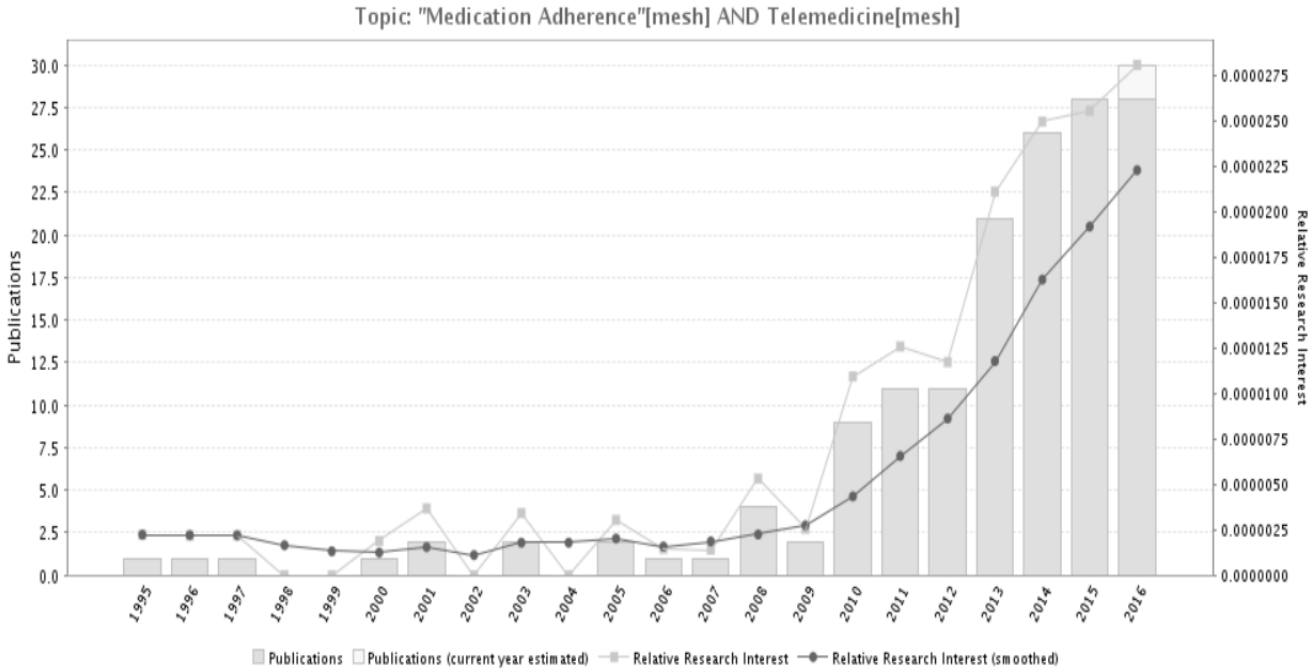


Diagram 1: Number of publications over time including Medication Adherence and Telemedicine (ehealth) in their Title or Abstract [11]

1.1.1 Polypharmacy

The current healthcare systems are facing an increasingly serious problem, the use of multiple medications, often termed as polypharmacy. The US General

Accounting Office reports significant morbidity and mortality associated with inappropriate polypharmacy [12].

“Polypharmacy is the concurrent use of multiple medications. It can be associated with the prescription and use of too many or unnecessary medicines at dosages or frequencies higher than therapeutically essential. However, multiple medications are often necessary and can constitute best care for patients” [13].

Number of medication	Total	Under 65 years	65-74 years	75-84 years	Over 85 years
4 or more	14.1	10.1	33.2	40.7	38.2
6 or more	4.6.	2.6	13.1	17	16.2

Table 1.: Proportion of higher users of medications (as a percentage of those taking at least one medication; excludes complementary medicines like vitamins, herbal preparations, etc.)[13]

Another analysis by the Danish Medicines Agency from 2003 showed that 90% of all people over the age of 64 purchases at least one prescription from the pharmacy per year [14].

Age groups	Number of users 2001	Number of users/ 1.000 inhabitants	Average number of prescriptions (Median, 1. quartile - 3. quartile)	Mean number of different drugs (Median, 1. quartile - 3. quartile)
65-69 years	185.629	843.9	2.4 (1.5 ; 0.4 – 3.3)	5.5 (4 ; 2 - 7)
70-74 years	169.284	876.8	2.7 (1.9 ; 0.7 – 3.8)	6.1 (5 ; 3 - 8)
75-79 years	150.847	913.0	3.0 (2.2 ; 0.9 – 4.2)	6.8 (6 ; 3 - 9)
80-84 years	108.507	942.3	3.2 (2.5 ; 1.1 – 4.5)	7.4 (6 ; 4 - 10)
85-89 years	63.656	955.2	3.4 (2.7 ; 1.2 – 4.8)	7.8 (7 ; 4 - 11)
90-94 years	25.299	974.1	3,3 (2.7 ; 1.2 – 4.7)	8.0 (7 ; 4 - 11)
95+ years	5.846	1000.0	3.0 (2.5 ; 1,1 - 4,3)	7.7 (7 ; 4 - 10)
Total	709.068	895.5		

Table 2: Medicine use among elderly patients. Data from the Danish Medicines Agency [14].

The proportion of medicine users using more than three different medications within one month (poly pharmacy patients) was 65% in 2001 (people older than 64 years). Between 2% and 4% of medicine users older than 65 years of age are using at least three different medications per months. Therefore, it can be expected that elderly medicine users will benefit from dose-dispensed medicine to increase compliance and implementation of drug therapy [14]

1.2 E-health

The use of information and communications technology (ICT) in health care has grown exponentially over the last 15 years and its potential to improve effectiveness has been recognized by governments worldwide [15]. The focus of health care information technology (IT) has been changing, from an emphasis on hardware, systems architectures and databases, to innovative uses of technology for facilitating communication and decision making, coupled with a growing recognition of the importance of human and organizational factors.

At the same time, Internet technologies have become increasingly pervasive. In parallel, the language of health care IT has been changing, and references to the concept of e-health have proliferated in international health policy, management and research areas. The two global definitions were suggested by Eng and Eysenbach early in the emergence of the field [16]:

„e-health is the use of emerging information and communications technology, especially the Internet, to improve or enable health and healthcare.“*[16]*

„e-health is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.“ [17]

1.2.1 What is telehealth?

Telehealth consists of clinical and non-clinical health services that are provided from a distance and do not require the physical presence of the medical professional, student, or the citizen.

The umbrella term for health and medical knowledge sharing, encompassing telemedicine, telecare, e-health, m-health, health systems management, surveillance, health promotion, provides access to health and medical literature and public health functions and most other related concepts related to health and medicine practiced over a distance.

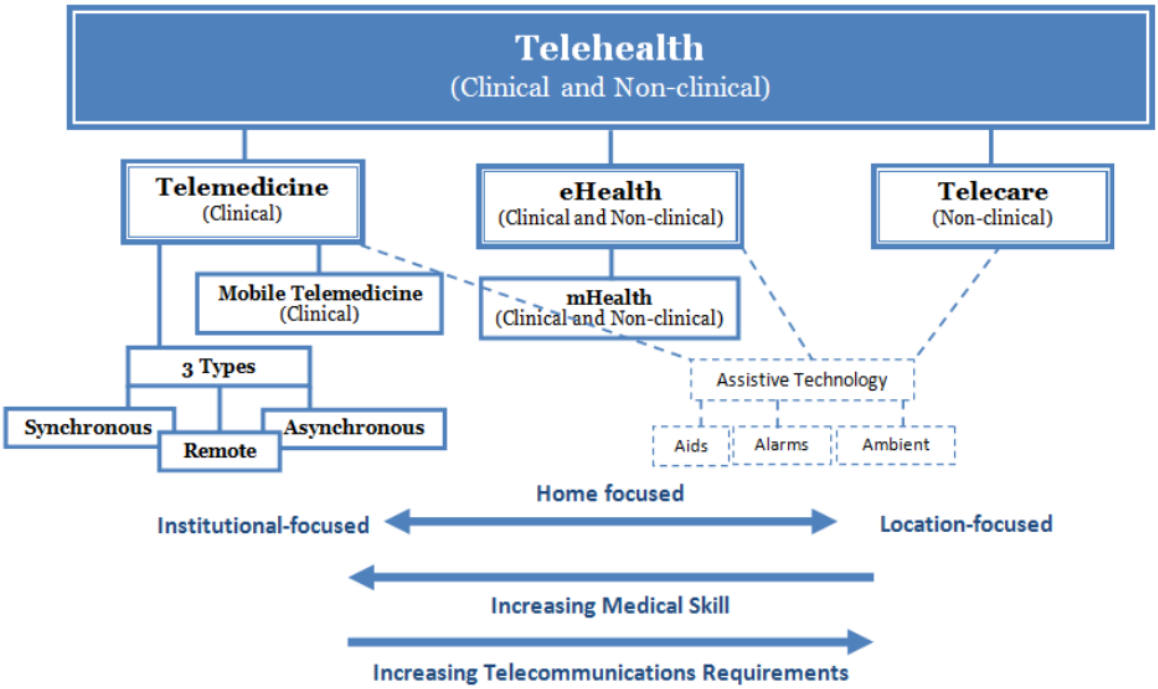


Figure 3: "tele"-terminology and their interrelation [18]

Telemedicine, a term coined in the 1970s, which literally means "healing at a distance", signifies the use of information and communication technologies to improve patient outcomes [19].

> *"The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities" (WHO)*

Telemedicine is a sub-set of e-health electronic process in health used for:

- *Teleconsultation*, a procedure whereby medical professionals can consult a patient remotely and interpret the necessary data remotely.

- *Medical Second Opinion Service or Teleexpertise*, whereby a medical professional can remotely seek an opinion of other medical professionals with relevant training or skills. It allows people to obtain a valuable medical second opinion concerning the diagnosis and treatment of illness.

- *Telemonitoring*, possibility to monitor and supervise patients remotely. The medical data can be obtained automatically on a pre-defined periodic basis (remote follow-up) or on a daily basis (remote monitoring) by the device which dispatches them from the patient's home to the medical doctor [20].

- *Remote handling or teleassistance*, "a procedure which enables a medical professional to assist remotely another healthcare professional during the realization of a medical act. This would correspond to two typical situations. First case: it may concern *robotic telesurgery* in which the expert surgeon performs the surgery form a distance through a robotic device. Second case: *remote ultrasound examination* in which the expert physician remotely directs the local ultrasonographer as to how to position the probe, and sometimes the expert may control the movements of a medical probe using ultrasonographic visualizations to perform useful assessments." [20].

The objectives of telemedicine and its applications are to enhance the availability of many medical services and healthcare regardless to geographical and economic barriers, save costs (direct or indirect) and to enhance consultation and co-operation among various units of healthcare in both special cases and primary care by bridging the geographical distance between practitioners and specialists [21] .

1.2.2 What is mHealth?

The traditional model of episodic care in clinic and hospital –based settings for treating chronic diseases like diabetes, asthma and obesity, is suboptimal for the outcome improvement. Mobile communication devices, like smartphones, in combination with Internet and social media platforms, are providing opportunities to enhance disease prevention and management by extending health interventions beyond the reach of traditional care settings – an approach referred to as mHealth [22]. The term mHealth

is used as a short form of mobile health, meaning the use of mobile technology in a wide array of health care settings, for example in-hospital, in-home and on-the-go [23]. Health could save 99 billion EUR in healthcare costs in the European Union (EU) and add 93 billion EUR to the EU GDP in 2017 if its adoption is encouraged.

Socio–economic impact of mHealth in 2017	100% adoption (full potential)	10% adoption (if no action taken)
Total healthcare cost saved (bn EUR)	99	6.6
Public care cost saved (bn EUR)	76	5.1
Private care cost saved (bn EUR)	23	1.5
GDP added (bn EUR)	93	6.5

Figure 4: Socio-economic impact of mHeatlh in 2017 [24]

The numbers, shown in Figure 4, outline the very high potential of healthcare costs by the use of mHealth technology. Cost savings are not the only reason to advocate the use of mHealth. “Mobile health can help in reducing the readmission rates of the patient. It can help in taking the care away from the healthcare facility to home. It could also help in establishing an early warning system.” [24]

1.2.3 Architecture of common ehealth platforms

The rapidly growing technology sector not only offers many technological possibilities but goes hand in hand with the difficulties of implementing tailored infrastructures for healthcare. Many standards are necessary for interoperability, but there is still a need for international consensus around which standards should be adopted and the exact implementing process. The development, approval, and adoption of standards for health ICT are proving a difficult and drawn out process (OECD 2010: 62f) [25].

Interoperability is generally thought to have at least 3 distinct levels, i.e.:

- Syntactic interoperability (e.g. Bluetooth, USB, ...)
- Semantic interoperability (IEEE X73, HL7 CDA, ...)
- Pragmatic interoperability.

2 Scope

Ageing comes with an increased prevalence of gradually declining human organ and body functions resulting in a wide variety of impairments and subsequently an increased risk of practical medication problems. The range of practical problems with the use of their medicines extends very wide. The aim of this work is to design a concept for a smart medication dispenser system to support the elderly to cope their everyday life successfully.

The smart medication dispenser system is designed to avoid non-compliance errors and provide remote manageability. To ensure a user- friendly handling and subsequently improve the patient's compliance, the user requirements have to be collected and evaluated. Furthermore a very important component is the IT-structure as the medication dispenser is also working with sensible patient data. Therefore the medication dispenser has to be designed in a manner to be able to interoperate with existing healthcare platforms.

- User requirements
- Functional and non-functional requirements
- Regulatory Requirements (patient safety, Protection of Personal Data….)
- IT-structure of common healthcare platforms (Interoperability)

3 Methods

3.1 Literature research

I started with doing some background reading to get a grasp of the context and the key terminology associated with the topic of polypharmacy and medication dispensers. For the literature research I used search engines like Web of Science, Science Direct, PubMed and the electronic Journals Library of the TU Graz. The keywords I used in the first search had to be modified and refined by reading the title, abstract and the used keywords in relevant articles.

After finishing the background reading I organized the identified keywords in groups of certain topics (max. 10-15 words/group). Boolean operators (AND, OR and NOT) were used to form relationships between words or phrases to further refine the output of search requests. To limit the number of search results and thereby the costs involved I defined exclusion criteria (e.g. impact factor, certain time period, source of information). I also used MeSH-terms (Medical Subject Headings), which is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing articles for PubMed. It consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity. With this set of terms I did not only search for literature but also for existing patents and competitor products in an effort to better understand what commercially available products, services and pricing models are existing for medication dispenser for solid medicine.

Exclusion criteria:

- Medication dispenser working with fluid drugs
- Medication dispenser was not programmable (changing drug regimen)
- No opportunity to measure adherence (time pills were/weren´t taken)
- Publication date before 2000

Following keywords were used to conduct the literature research:

Th.1:

Medication dispenser, pillbox device, electronic blister

TH.2:

Adherence, compliance, regimen, e-health, m-health, telemedicine, monitoring system, healthcare, ambient assisted living, embedded systems, smart home

TH.3:

Wireless communication, sensor, RFID (radio-frequency identification), NFC (*Near Field Communication)*, bluetooth, wearable tools, microcontroller, interoperability, user interface

Figure 5: Combined keywords with Boolean operators

3.2 Valuation and analysis of competitor products

The findings of the conducted search for commercially available competitor products, medication dispenser for solid medicine, were filtered by predefined exclusion criteria. In this thesis 14 medication dispensers, which are currently available on the market, are going to be presented shortly and analysed by an evaluation matrix.

To evaluate the products as detailed and fully as possible, the evaluation matrix is divided in two groups:

- Functional requirements
- Non-functional requirements

Those two groups are then divided into subcategories to describe the requirements as detailed as possible. Functional requirements are functions that must be provided by the dispenser or rather dispenser system. By contrast, the non-functional requirements describe the characteristics of a system. Table 3: Catalogue of requirements in order to gain an overall view.

			ID
functional requirements	facilitation	storage	F-F1
		reminder	F-F2
	compliance	compliance	F-C1
		selectivity	F-C2
non-functional requirements	storage	hygiene	NF-S1
		robustness	NF-S2
	facilitation	ergonomics	NF-F1
		data transmission	NF-F2
	compliance	functionality	NF-C1
	others	data protection	NF-O1
		transparency	NF-O2

Table 3: Catalogue of requirements

3.2.1 Functional requirements

As described above, functional requirements were used to evaluate the functions of the medication dispenser. Table 4 shows a detailed description of the demanded functions.

Functional requirements	**Description**
Storage (F-F1)	In this case the phrase storage is used to describe the methods and also the amount of medicine, with whom the dispenser is filled.

	The provided requirement is fulfilled the better, if the dispenser allows efficient dosing and dispensing. A better match of drug-intake services and simplified retrieval is the goal.
Reminder (F-F2)	This function describes the degree of scalability in the meaning of alarm management. Many dispensers have an alarm system to remind the patient to take the medicine at the right time. There are many ways to remind the patient, e.g. visual alarms, audio alarms, buzzers and so on. The requirement is fulfilled, if the dispenser has a highly efficient and scalable alarm handling.
Compliance (F-C1)	This requirement is a function of compliance itself, in the meaning of the extent of individually measuring compliance. Therefore different quality criteria have to be fulfilled, like an appropriate method of measuring compliance and the frequency of reviews.
Selectivity (F-C2)	An unambiguous patient dispenser allocation and related verification must be achieved to fulfil this requirement.

Table 4: Functional requirements for the evaluation matrix

3.2.2 Non-Functional requirements

Non-Functional requirements	**Description**
Hygiene(NF-S1)	In this requirement the dispensers are rated for how far the medicine is stored in a hygienic way. The more hygienic the drug is stored, the better the requirement is fulfilled.

Robustness(NF-S2)	In this context robustness is the ability to be unimpaired by changes from the environment. The more the dispensers are unaffected by variation of temperature, moisture and force disturbing, the better the requirement is fulfilled.
Ergonomics (NF-F1)	The target of ergonomics is an optimised interaction of all workplace components. Therefore user, target, technology and user interface are taken into consideration. The main focus in this requirement is the user-friendliness of the dispenser.
Data transmission (NF-F2)	Important factors for this requirement are on the one hand the possibility to transmit data and on the other hand the degree of interaction. To fulfil this requirement the data transmission has to be save and performed without any interaction of the patient.
Functionality (NF-C1)	In this function the controllability of the dispensed medicine or more specifically the intake-time of the medicine is under review. This requirement is addressed to the compliance-monitoring.
Data protection (NF-O1)	“ ‘personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person” [26]. This requirement verifies if the dispenser system is processing ‘personal data’. The process chain has

	to be adequate to the current legal situation (DSGVO: Art 44-49).
Transparency (NF-O2)	In this context transparency is used to describe how fast the user is able to identify which and how many drugs are stored in the dispenser. A clear design helps the user to prevent errors and simplifies the usage planning.

Table 5: Non-functional requirements for the evaluation matrix

3.3 Requirements capture phase

The first step of the requirements capture phase was to define the problems and objectives of the medication dispenser. The information used to define the problem came from many different sources.

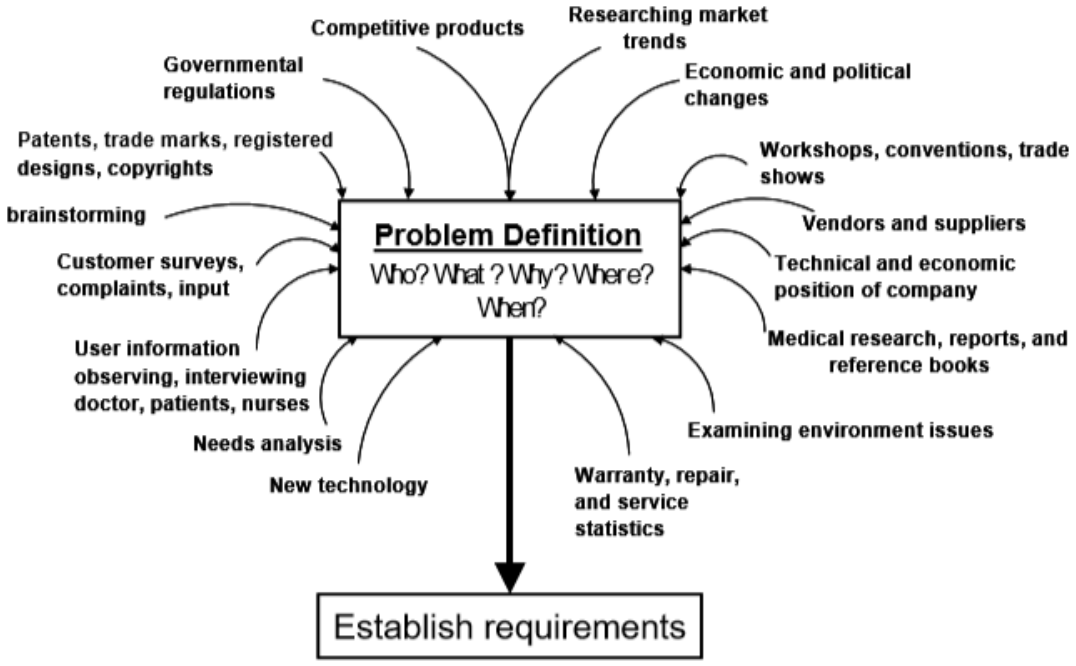


Figure 6: Example for problem definition and it´s information sources [27]

During the second phase functional analysis tools (that is, stating the problem in terms of functions) were used and were intended to identify functional and performance requirements. Therefore the functional analysis system technique (FAST -Diagram) was used to express the problems without specifying a particular solution. Figure 7 shows the FAST diagram for the mobile device.

A detailed description of all functional and non-functional requirements is listed in section 4.6 Specific requirements.

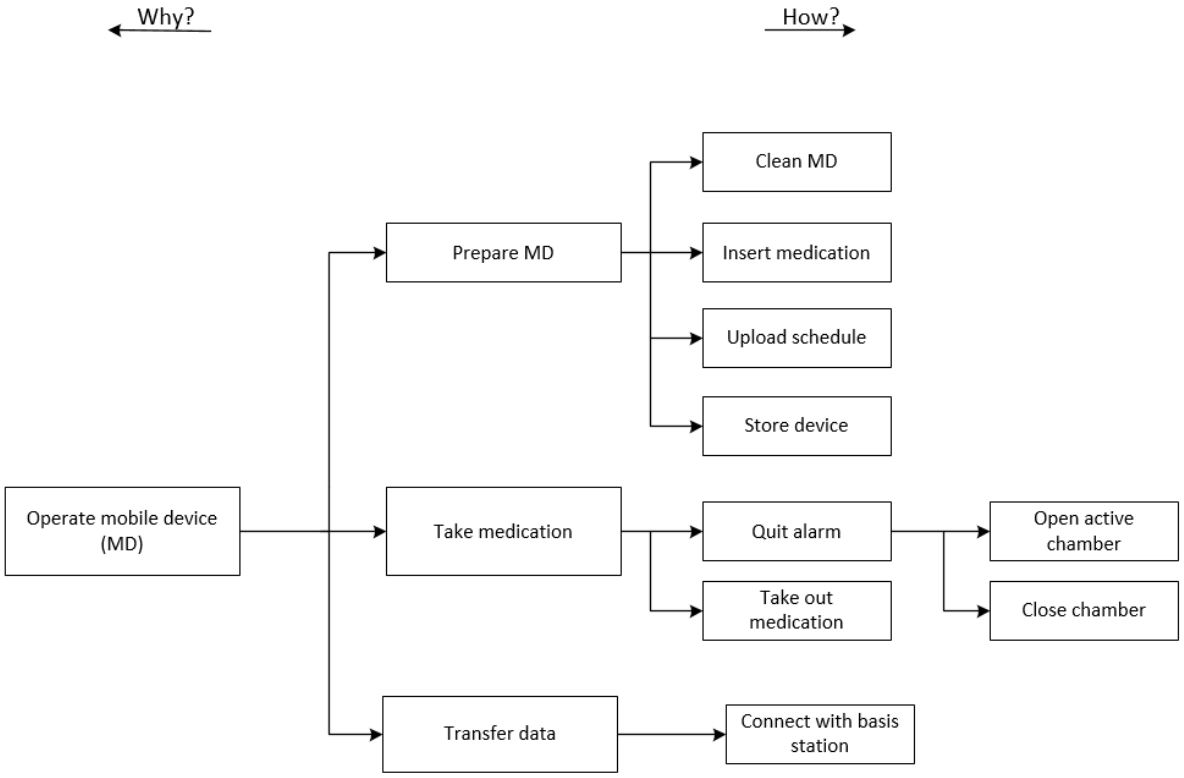


Figure 7: FAST diagram of the mobile device

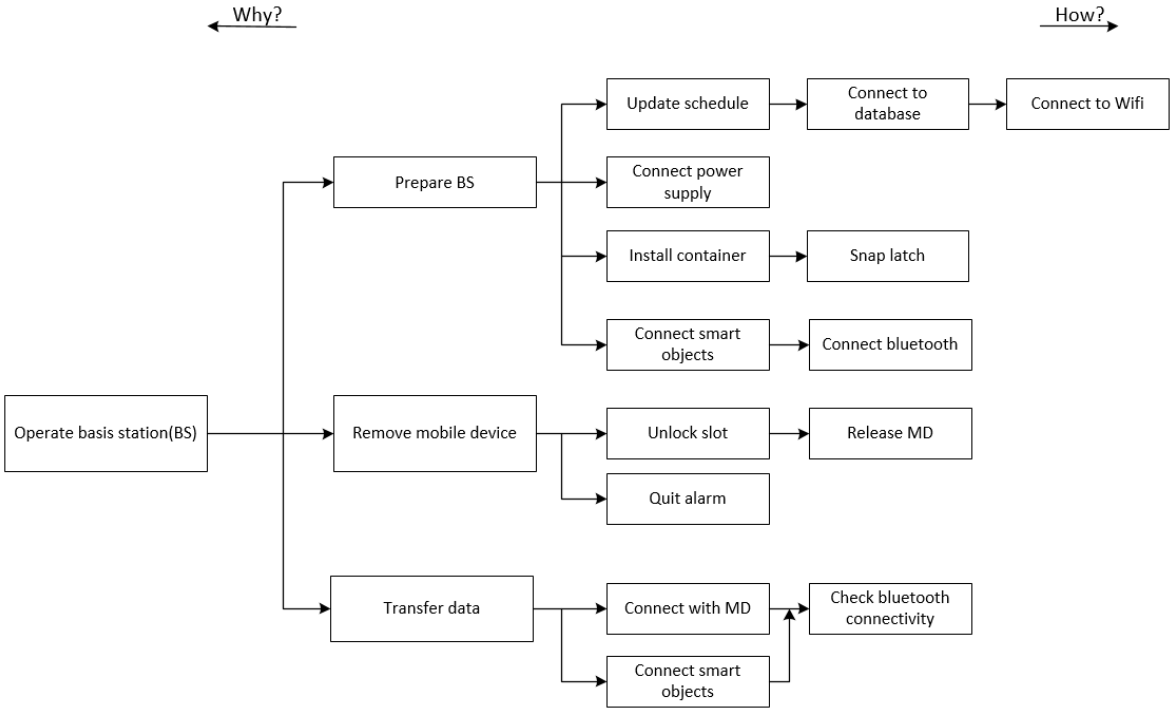


Figure 8: FAST diagram of the basis station

4 Results

4.1 Evaluation of competitor products

In the following section the findings of the market research will be described shortly and the results of the evaluation matrix will be presented. In order to get a good overview and understanding how existing systems are working, the products are described in Table 7 and Table 8 by their main characteristics, like storage capacity, method of alerting and mode of data transfer. Finally, this is followed by the examination of the previously defined functional and non-functional requirements. The findings of this examination are outlined in an evaluation matrix. The name of the examined product is indicated in the first column of the table. The columns 2-11 are indicating whether and to what extend the defined requirements are fulfilled. The functional and non-functional requirements are presented in the columns with their identifiers, which are outlined in Table 3: Catalogue of requirements. For the evaluation a scale with symbols, exemplified in Table 6, is used.

scale	**symbol**
exceeds requirement	++
meets requirement	+
partially meets requirement	-
does not meet requirement	--
not specified	0

Table 6: Short description of the applied scale

	capacity		Alarm	Network Connection			Data upload	
	chambers	day		wired	wireless	phone line	manual	automated
uBox-uPhone[1]	14	14	flash light, audio alarm	X			X	
Med-eMonitor[2]	5	not fixed, need setup further	flash light, musical chimes	X				X
MedFolio Pillbox[3]	28	7	flash light, audio alarm,text message, email		X			X
Dispense-HealthOneMed Dispense A-Pill (DAP)[4]	8	up to 90	audio, visual			X		X
MedReady P1650[5]	28	not fixed	visual, audio			X		X
Med-Time XL[6]	28	up to 28	visual, audio	X			X	

[1] http://newsoffice.mit.edu/2008/itw-india-tt0206
[2] http://www.medgadget.com/2006/08/the_medemonitor.html
[3] https://www.medfoliopillbox.com/
[4] http://www.medgadget.com/2011/03/healthonemed_introduces_dispenseapill_personal_medication_manager.html
[5] http://alertsforseniors.com/buymedready.htm
[6] http://www.epill.com/

Table 7: commercially available medication dispenser for solid medicine (1/2)

	capacity		Alarm	Network Connection			Data upload	
	chambers	day		wired	wireless	phone line	manual	automated
MedSmart (MD2)[7]	28	up to 28	audio,visual	X			X	
MedSmart PLUS (MD2 PLUS)	28	up to 28	audio, visual, text message, email, call			X		X
e-pill medimi	30 or 14	not fixed	visual, audio, vibrate		X		X	
TabSafe Medical Dispenser[8]	16 or 32	not fixed	visual, audio	X				X
Jon-locked Pill Dispenser(MedMinder)[9]	28	7	visual, audio		X			X
Smart Pill Box[10]	3...10	not fixed	visual, audio		X			X
Philips Medication Dispenser Service[11]	60	1..40	audio			X		X
MedSignals®[12]	4	not fixed	audio, flash light, email, call, text		X			X

[7] http://www.epill.com/
[8] http://www.tabsafe.com
[9] http://www.medminder.com/
[10] http://www.panhealth.com/?page_id=344
[11] http://www.managemypills.com/content/product-details
[12] http://www.medsignals.com/medsignals-pill-case

Table 8: commercially available medication dispenser for solid medicine (continued 2/2)

	F-F1	F-F2	F-C1	F-C2	NF-S1	NF-S2	NF-F1	NF-F2	NF-C1	NF-O1	NF-O2
uBox-uPhone	-	++	+	0	+	++	+	-	+	--	--
Med-eMonitor	+	++	++	0	-	++	+	-	+	-	-
MedFolio Pillbox	++	++	-	++	-	+	+	++	-	0	++
Dispense-HealthOneMed Dispense A-Pill (DAP)	++	+	-	+	+	++	--	-	--	0	--
MedReady P1650	++	+	+	-	+	++	+	-	+	0	-
Med-Time XL	++	+	--	--	+	++	+	--	+	--	--
MedSmart (MD2)	++	++	--	--	+	++	-	--	+	--	-
MedSmart PLUS (MD2 PLUS)	++	++	++	+	+	++	-	+	+	0	-
e-pill medimi	++	++	--	--	+	++	--	-	--	-	-
TabSafe Medical Dispenser	++	++	+	++	+	++	-	++	+	++	-
Jon-locked Pill Dispenser(MedMinder)	++	++	++	-	+	+	-	+	+	0	++
Smart Pill Box	++	-	-	-	+	-	+	++	+	+	-
Philips Medication Dispenser Service	++	-	-	-	++	++	-	+	+	0	+
MedSignals®	-	++	-	-	-	+	+	++	+	0	++
Own concept	++	++	++	+	+	+	+	++	+	++	++

Table 9: Evaluation matrix of competitor products including the introduced concept

4.2 Overall description

4.2.1 Product perspective

The smart medication dispenser - system provides timely alerts to help the user to stay compliant to his medication schedule. The system will function differently for the “medicine in takers” and the family member/caretaker or the physician. The user (patient) can grant other actors, who are involved in the caretaking process, access to the reports that are stored in a database. The physician can remotely adjust the medication schedule to the patient needs. The medication schedule will be updated automatically. The user has the opportunity to display, print or save the reports on a local PC.

4.2.2 Product functions and components

There are 3 main parts of the smart medication dispenser:

- The basis station, which acts not only as the gateway to the database but also charges the mobile devices via an inductive coupling.
- The mobile device, which is loaded with the medication for one day, reminds the user to take his/her pills at the right moment
- The web interface/database contains the medication schedule, compliance data, alert report and also the data from smart objects which are transferred via the basis station.

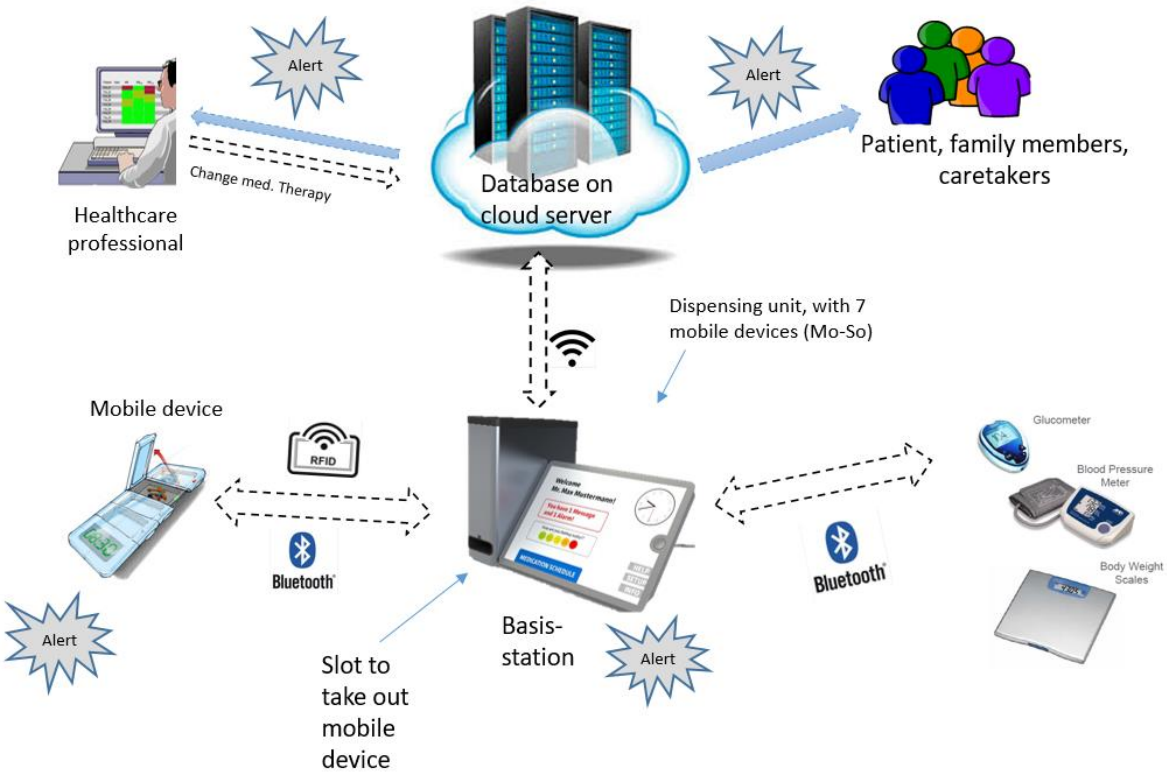


Figure 9: Overview of the system architecture

4.2.3 User characteristics

- The user (patient): The person who is suffering from chronic diseases and needs assistance for intake of medicines. The user is allowed to grant other persons, who are involved in the caretaking process, access to the database.
- Physician: The person who prescribes the medicine to the user (patient) and creates the medication schedule. The physician is also allowed to view the compliance report.
- Pharmacist: The person who refills the mobile devices with medicine. Therefore he/she is allowed to view the medication schedule and add comments to the prescribed medication.
- Caretaker: Assistive person who refills the mobile devices with the solid medicine. Therefore he/she is allowed to view the medication schedule and read the comments/ recommendation for the intake of the medication.
- Family member: Person, who is involved in the caretaking process. How much information they are allowed to see depends on the user.

User requirements

- The mobile device should be pocket sized, so that the patient can easily carry it around.
- The navigation through the website (database) has to be designed in a way that it seems intuitive and requires only minimal training and documentation.
- The alarm (to take the medicine) has to vary from other system alarms (e.g. new medication schedule, not connected to internet…).
- The medication alarm has to be clearly recognisable (at least 80dB).
- Overdosing has to be prohibited via the lock-mechanism of the mobile device.
- Removal verification with a sensor.
- Display settings: Font, colour and size of text should be easy to read

4.2.4 Use cases

To describe the actors of the system and their rights UML diagrams were created. Figure 10 and Figure 11 show the relationship between the actors. The functions that they are allowed to use or operate are concerning the online database. Family members are also identified as actors of the system, but the functions they would be allowed to use are all optional and are depending on the patient's decision. Therefore no UML-diagram was created for family members, because all intended functions for them are completely optional. All actors and their options of use are listed in Table 10 ("x" marks an actors right; "*" marks an optional right).

	log in/out	View medication schedule	change/create medication schedule	view compliance report	view data from sensor/smart object	add comments to medication	read comments	View alarm report
patient	x	x		x	x		x	x
physician	x	x	x	x	x	x	x	
pharmacist	x	x				x	x	
caretaker	x	x		x			x	
family member	*	*		*	*		*	*

Table 10: Actors and their rights

Figure 10: UML-Diagram: caretaker vs. patient

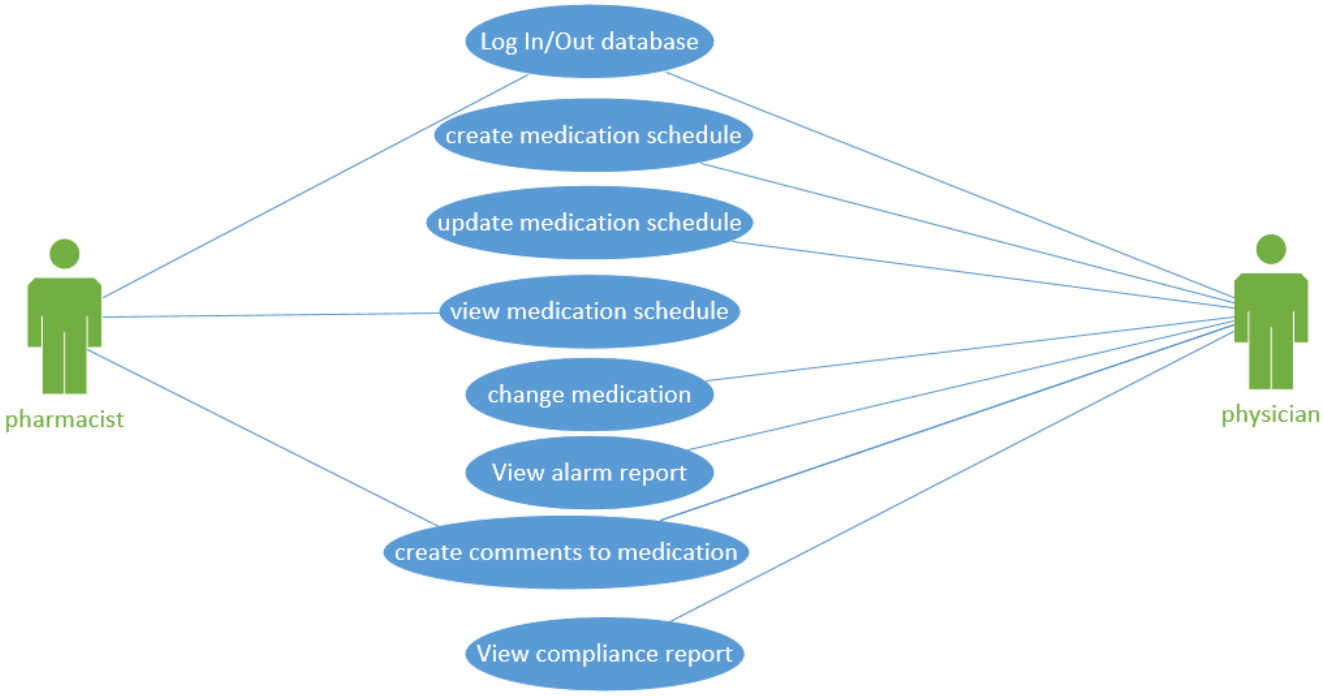


Figure 11: UML-Diagram: pharmacist vs. physician

Many factors influenced the decision of who prepares and fills the mobile devices - pharmacist or caretaker. Not only economic factors had impact on the decision.

	pharmacist fills MD	caretaker fills MD
advantages	• No home visit necessary • self-installation of the container • cost saving • proper storage of medicine • additional review of possible medication interactions with other drugs. • secure admission to medication • trained staff prepares mobile devices • the amount of stored medication in the patient home is reduced	• No possible contamination and damages in transit • personal contact with the patient
disadvantages	• no personal conversation and educational talks with the patient. • possible contamination and damages in transit • possible delay in delivery	• untrained personnel may lead to medication errors • not ideal storage conditions • unknown hygiene status at patients home

Table 11: Advantages and disadvantages of the MD preparation by pharmacist or caretaker

In consideration of all these advantages and disadvantages, it is strongly recommended that the pharmacist fills the mobile devices (MD), but still both opportunities are outlined in the following two diagrams.

All processes start with a successful login of the actors. Figure 12 shows a draft of the homepage including the login page.

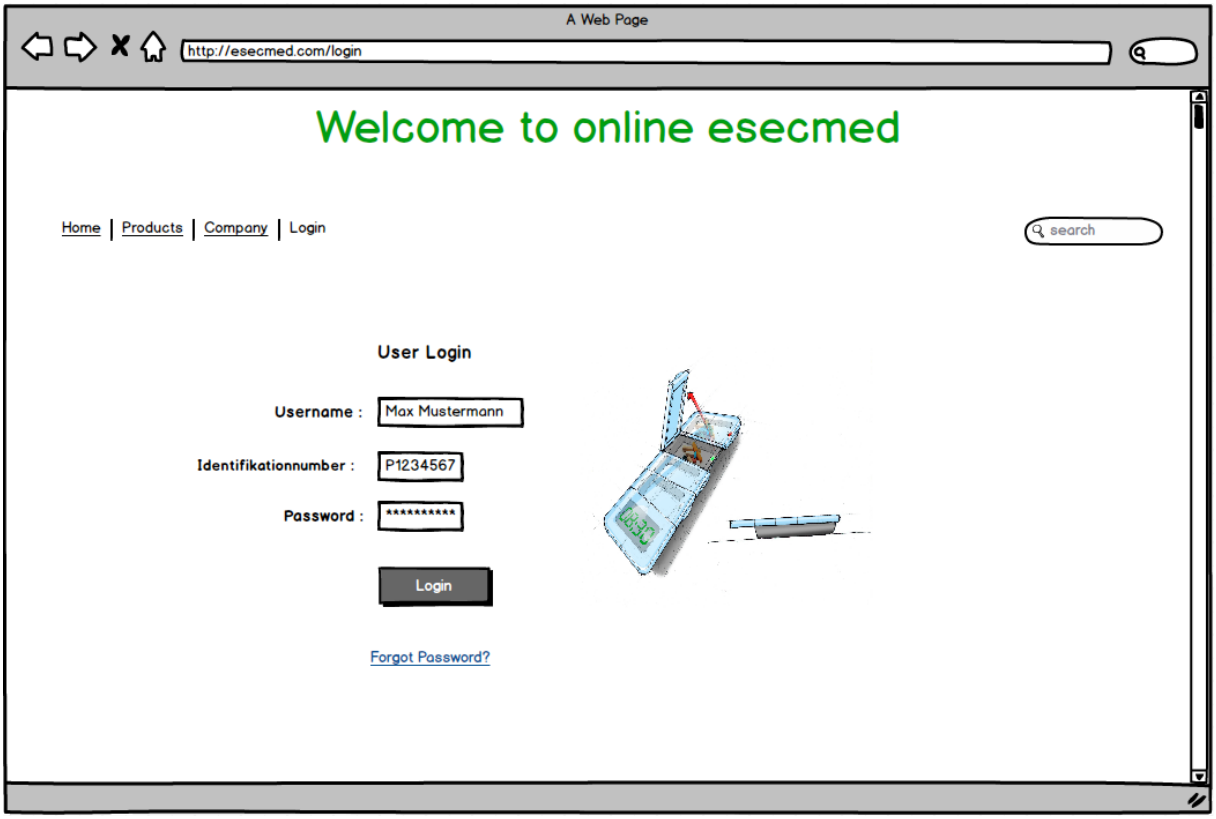


Figure 12: Sketched login page of the smart medication dispenser system

The process of filling the MD is shown in Diagram 2.

The process starts with the pharmacist login into the database. Therefore he has enter the correct user ID and password. Before the pharmacist is allowed to view the medication schedule and prescribed medication for the patient, he has to scan the MD. On the bottom of each MD there is an RFID tag to ensure that the right medication is filled in the right MD and therefore exclude medication errors in the first place. After checking, if the RFID tag fits the Patient ID, the pharmacist is allowed to view the medication schedule. The next step is to check, if the pharmacist has all the necessary medication in stock and checks the medication on possible interaction with other drugs. If that is not the case, the pharmacist is requested to order that medication. If the pharmacist has all the needed medication in stock, the process of sorting in the right medication in the right chambers starts. The pharmacist is also allowed to enter recommendations of use (e.g. take medication during meal). Finally the 7 MDs have to be packed into the provided container and the process of transporting the container to the patient has to be initiated.

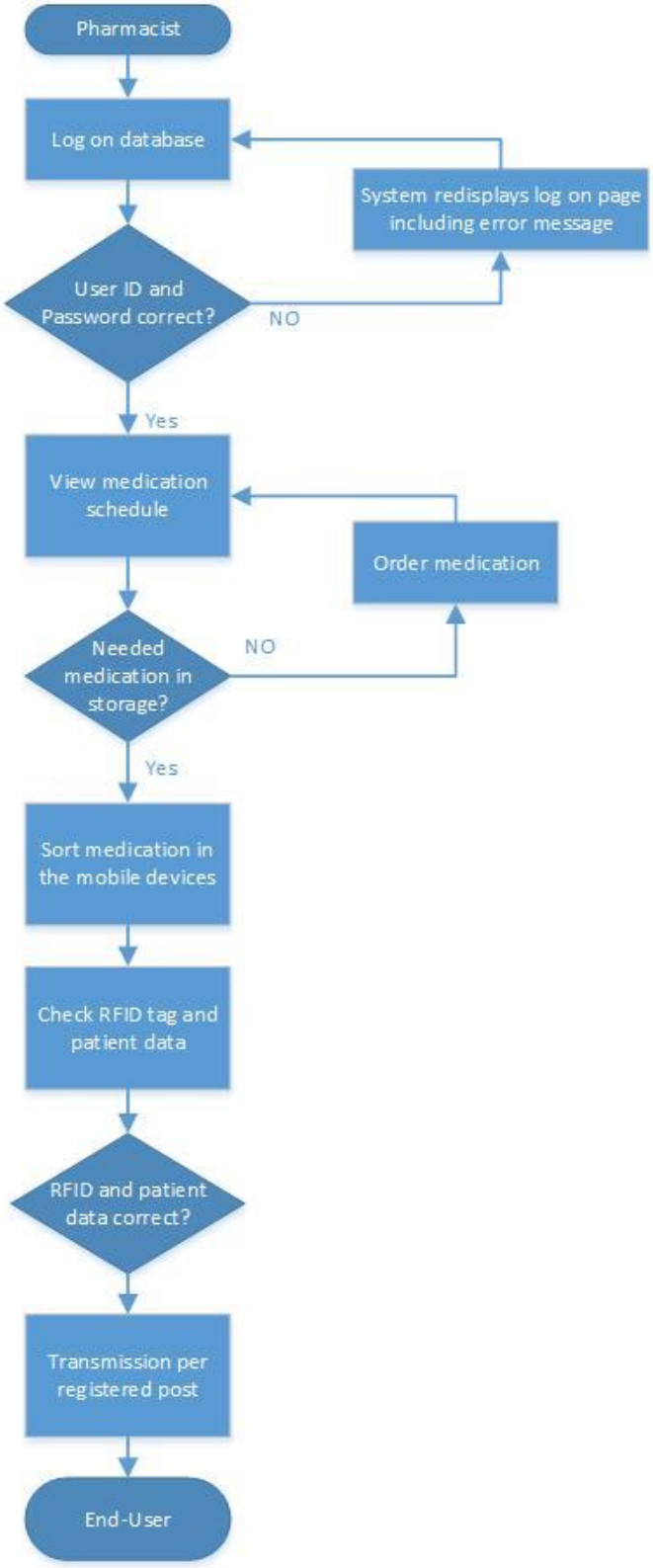


Diagram 2: Pharmacist fills mobile device

The filling process of the MD conducted by the caretaker is shown inDiagram 2.

The process starts with the caretaker login into the database. Therefore he has enter the correct user ID and password. After entering the correct user ID and password pharmacist is allowed to view the medication schedule. The next step is to check, if the

caretaker has all the necessary medication at the patients home. The process of sorting in the right medication in the right chambers starts. Finally the 7 MDs have to be packed into the provided container and installed in the docking station of the basis station.

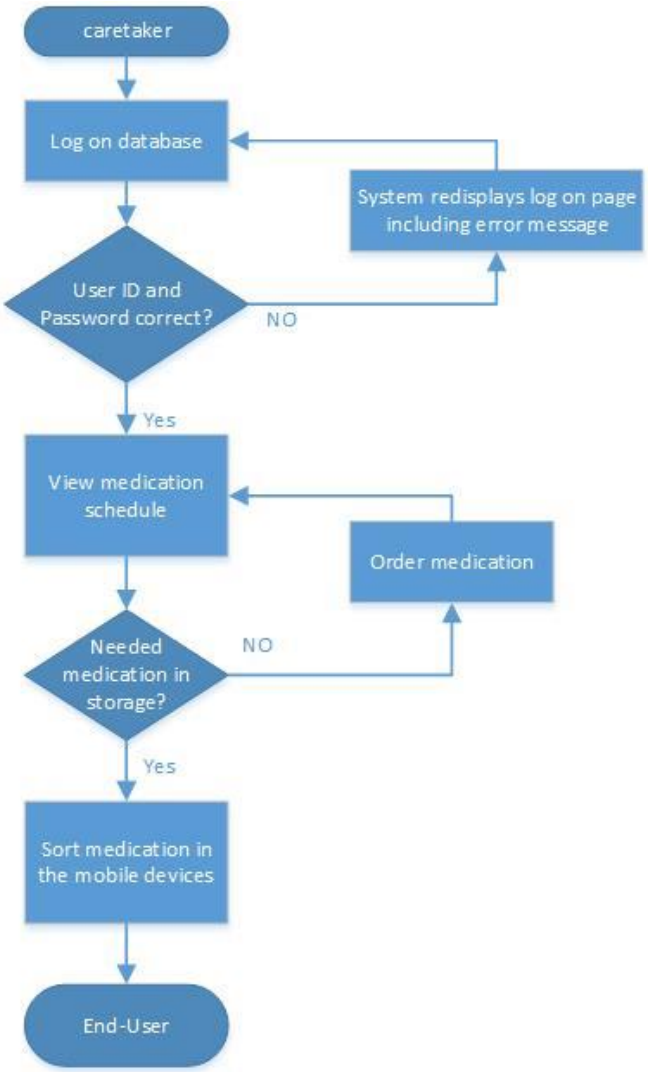


Diagram 3: caretaker fills mobile device

The physician is granted many rights like creating a medication schedule, view the compliance data and data from smart objects. After the attending physician managed a successful login, he is allowed to perform several tasks. The following Diagram 4 shows the process of viewing, creating or changing a medication schedule.

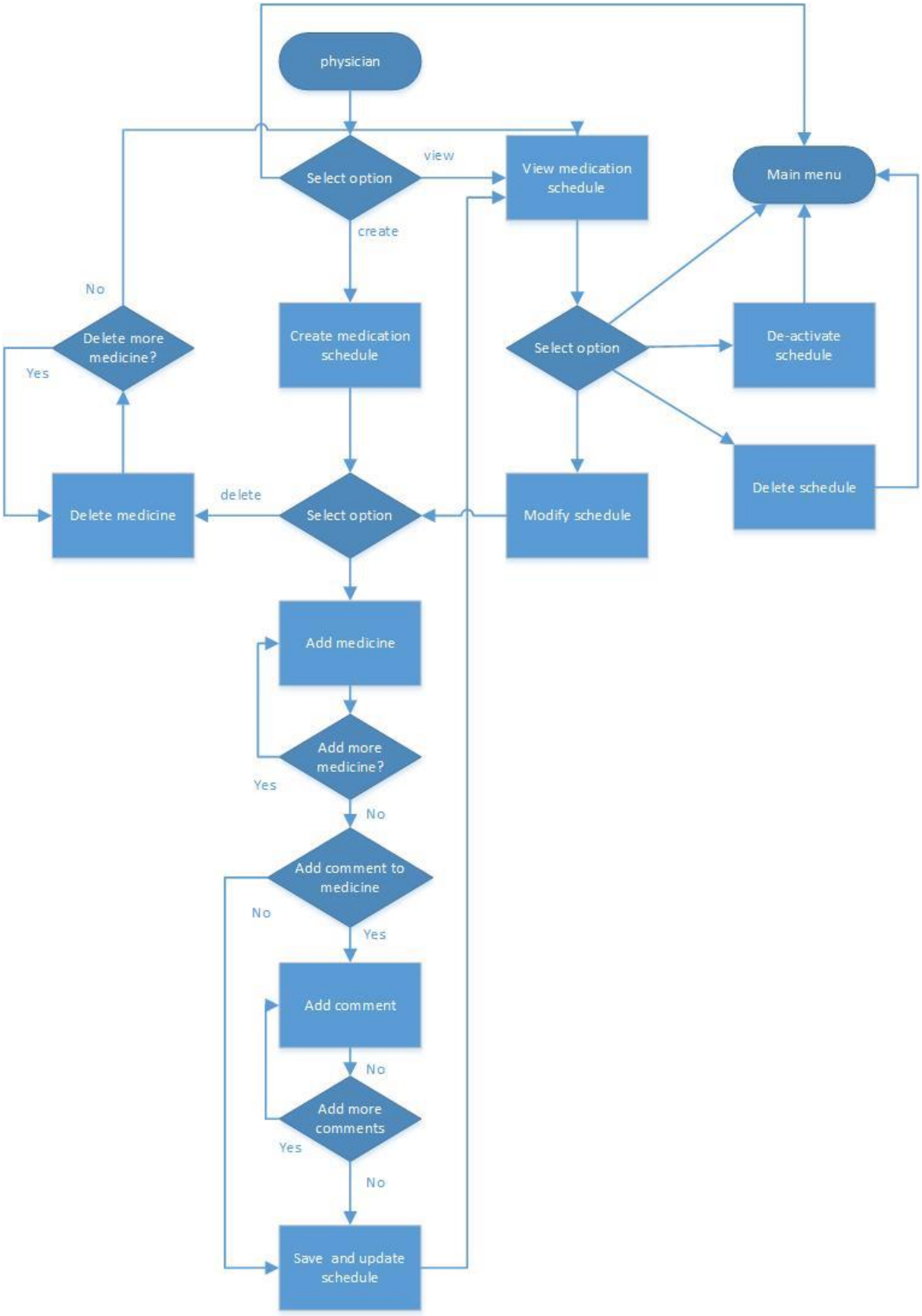
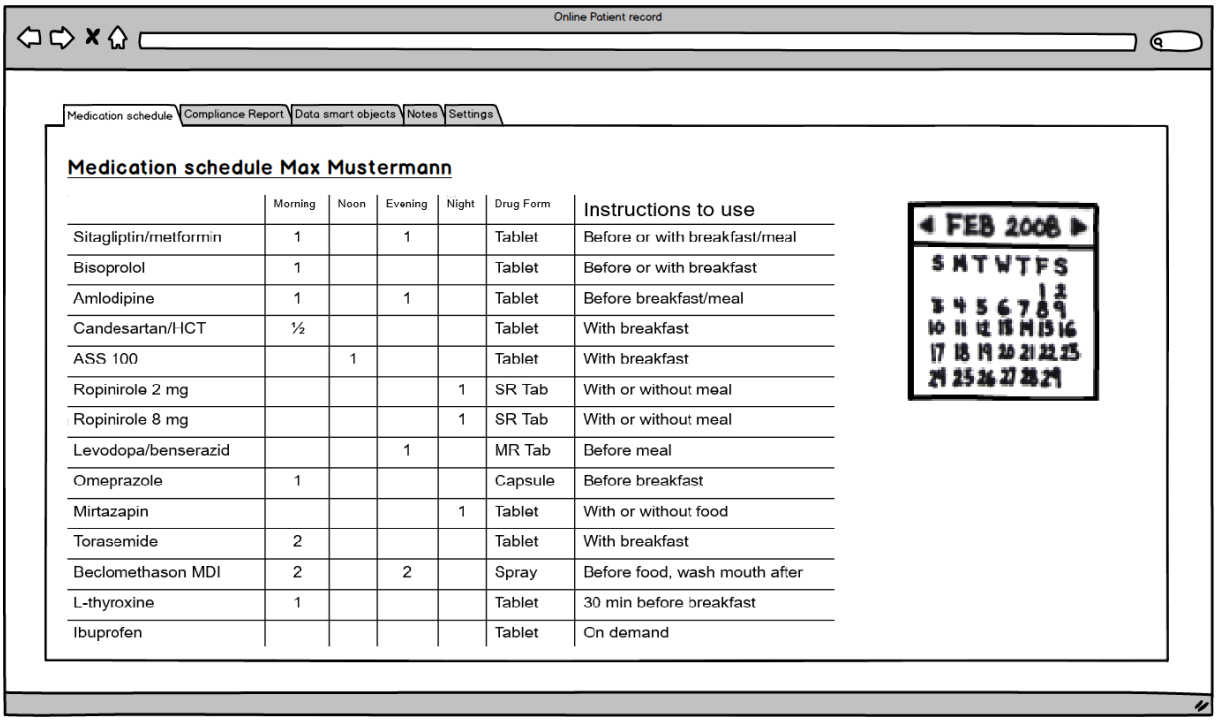


Diagram 4: Physician creates medication schedule

The process starts with selecting if the physician wants to view or create a medication schedule. If he wants to create a medication schedule, the physician is allowed whether to add or delete medicine. When a medicine is added to the medication schedule the physician has the option to add necessary comments. After completing this process the changes are saved and the physician views the updated medication schedule. By viewing the medication schedule the physician has more options, like modifying, deactivating or deleting an existing schedule. Furthermore he can go back to the main menu and select if we wants to view the compliance report, data from smart objects, read and/or change his notes or change his settings. Figure 13 shows a draft of this main menu.



	Morning	Noon	Evening	Night	Drug Form	Instructions to use
Sitagliptin/metformin	1		1		Tablet	Before or with breakfast/meal
Bisoprolol	1				Tablet	Before or with breakfast
Amlodipine	1		1		Tablet	Before breakfast/meal
Candesartan/HCT	½				Tablet	With breakfast
ASS 100		1			Tablet	With breakfast
Ropinirole 2 mg				1	SR Tab	With or without meal
Ropinirole 8 mg				1	SR Tab	With or without meal
Levodopa/benserazid			1		MR Tab	Before meal
Omeprazole	1				Capsule	Before breakfast
Mirtazapin				1	Tablet	With or without food
Torasemide	2				Tablet	With breakfast
Beclomethason MDI	2		2		Spray	Before food, wash mouth after
L-thyroxine	1				Tablet	30 min before breakfast
Ibuprofen					Tablet	On demand

Figure 13: Sketched main menu of the smart medication dispenser system

4.2.5 User documentation

A user manual will be delivered where all functions are described properly, including a first-installation guide to lead the user through the start-up. The navigation through the website (database) will be designed in a way that it seems intuitive and requires only minimal training and documentation. The user manual will also contain a general overview of the website and its options to work with the collected/saved data.

4.2.6 Assumption and dependencies

It is assumed that the caretaker or pharmacist is loading the mobile devices with the right medication. It is strongly recommended that only a qualified person, like the pharmacist, loads the mobile devices to avoid medication failures in the first place.
To fulfil all required functions of the basis station, the user needs a proper internet connection and power supply.

4.3 External interface requirements

4.3.1 User interfaces

- Physical interaction: inserting the container with the mobile devices and taking out a single mobile device, will be as easy as possible for every conceivable user.
- Set up power supply and internet connection for the basis station.

4.4 Hardware and physical interfaces

The smart medication dispenser- system mainly consists of three parts:

- The basis station
- The mobile devices (1 mobile device contains the medication for 1 day)
- Online database

4.4.1 Basis station

The basis station must have the ability to communicate with the mobile devices and smart objects via Bluetooth and RFID. Furthermore the basis station must have a Wi-Fi module to be able to connect to the online database and exchange data. The connection with the database has to be secure due to sensible patient data that is transmitted.
The basis station provides a touchscreen in order to inform and alert the patient. Furthermore this display provides the opportunity for short queries, e.g. how is the general well-being.
Figure 14 outlines the mentioned functions and also shows the data flow of the basis station. The description of all components and their functions is listed in Table 12.

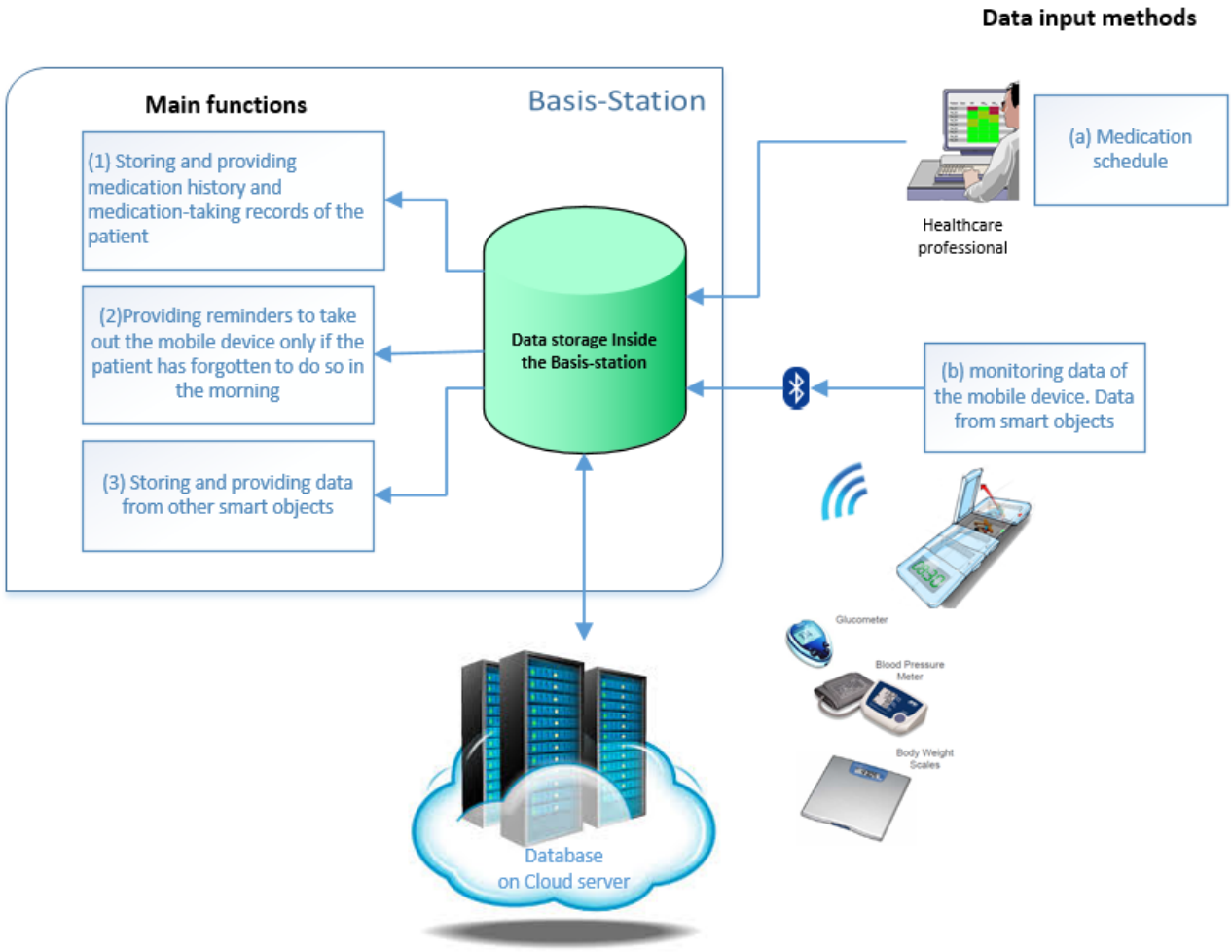


Figure 14: Main functions and data flow of the basis station

Figure 15: Conceptual design of the basis station

Components	***Function***
Touchscreen	Display information (time, instructing patients) Deliver message Interact with patient (overall wellbeing)
Container	Secure mobile devices (7 MDs)
LED	Visual alarm Provide guidance
Speaker	Provide alarm
Docking Station	Charging mobile devices in the container
Slot	Deliver mobile device (1 per day)
Body	Protect electronics Improve appearance Ensure steadiness

Table 12: Components and functions of the basis station

4.4.2 Mobile device

The mobile devices are stored in a container, which is connected via a docking station to the basis station. One container stores 7 mobile devices, which equates the needed medication for one week. The battery powered mobile devices are charged via inductive coupling. The transmitter coil is integrated in the docking station of the basis station and the receiver coil is installed in the mobile device.

The mobile device stores the time of taking or not taking the medication and controls the emptying of each chamber with a sensor. Furthermore the mobile devices have an integrated temperature sensor to measure the ambient temperature to check if the conditions for storage of the medication are complied. The measured data is transmitted via Bluetooth to the basis station to be stored in the database.

The user is allowed to take out the mobile device 20 min before the first “intake-time”. Only one mobile device is released from the container per day. A sensor controls if the user really took out the mobile device of the container´s slot. A locking mechanism avoids that the patient takes out more than one mobile device per day.

The mobile device consists of 4 separate chambers. The integrated microcontroller will only grant access to one specific chamber at a specific times. Those specific times are stored in the medication schedule.

The design of the mobile device is inspired by the medication packaging that we all know from hospitals. On the one hand, this is based on the fact the target group is already familiar with such designs and on the other hand operating the mobile device is practically self-explanatory.

It is not necessary that the user (patient) programs the alarms or has to start the data transfer, because all processes that are involved in the data exchange with the individual components run in the background and do not require any prior knowledge or interference of the user.

To get a better impression of the mobile device a conceptual design is shown in Figure 16: Conceptual design of the mobile deviceFigure 16. The different components and their functions are listed in Table 13.

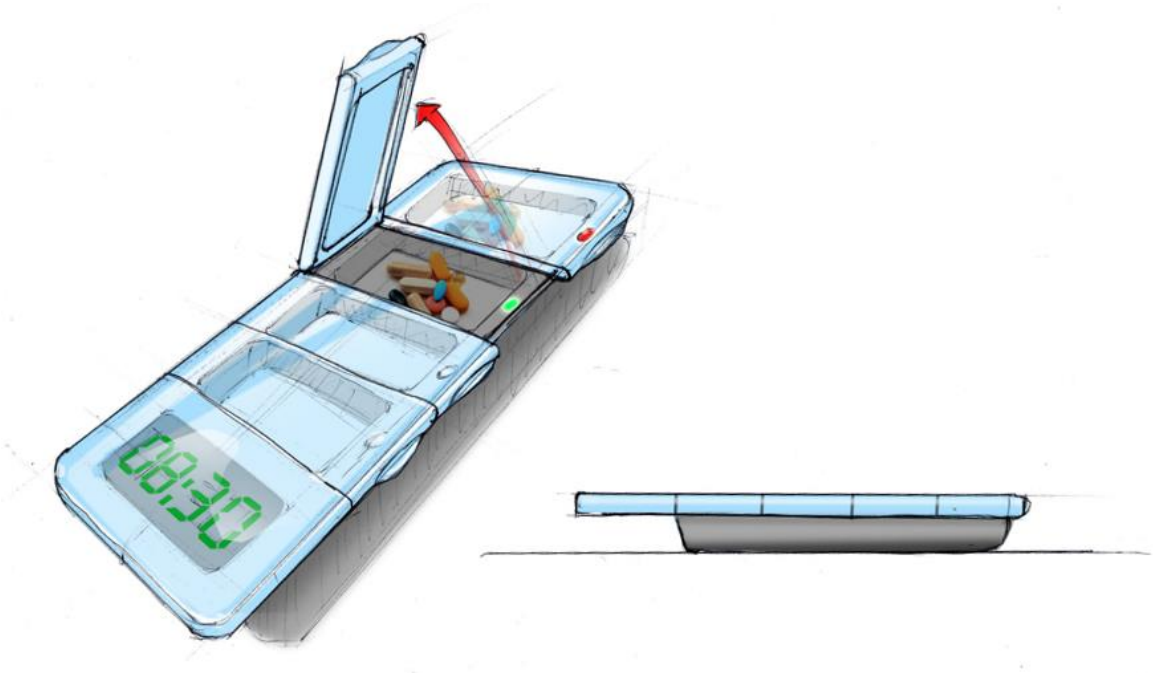


Figure 16: Conceptual design of the mobile device

Components	***Function***
Display	Display information (time) Deliver message
Chambers (4)	Secure drugs Deliver drugs
LEDs (4)	Visual alarm Provide guidance
Speaker	Provide alarm
Body	Protect electronics Accommodate grip Improve appearance

Table 13: Components and functions of the mobile device

4.5 Communications interfaces

4.5.1 Identifying the mobile device

To ensure that the mobile devices are filled with the right medication a double-checking regime is established in this concept. The pharmacist, who loads the mobile devices with medicine, has to scan the RFID tag on the bottom of the mobile device to get access to the patient's medication schedule. In addition the basis station with the installed container of mobile devices, scans and checks every mobile device to avoid any possibility of confusion. The RFID tag on the mobile device is a passive transponder, which stores a unique identification code. The identification is performed in close range (near field) and therefore the passive coupling mechanism is inductive. Figure 17 shows a brief overview of the European Computer Manufacturers Association (ECMA) NFC Standards.

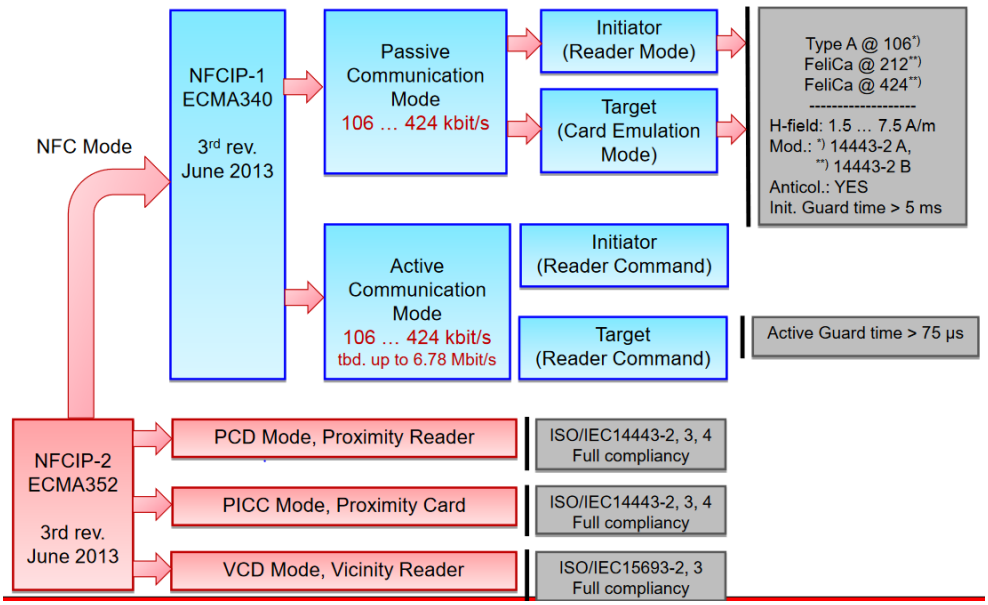


Figure 17: ECMA NFC standards brief overview [28].

The recommended standard for the communication between the in the basis station integrated reader and the tag on the mobile device is ISO/IEC 14443- Proximity coupling Smartcards.

4.5.2 Data transfer between mobile device and basis station

The communication and data exchange between the mobile device and the basis station is performed via Bluetooth. The basis station also uses the Bluetooth technology to communicate with smart objects. In this concept the Bluetooth Low Energy (BLE) is recommended as communication technology between the mentioned components.

Bluetooth	Frequency	Range	Technology Standard	Data rate
(PAN)	2,4GHZ - 2,48 GHz	Class 1: 100mW, ~100m	IEEE802.15	0,7 -3 Mbit/s
		Class 2: 2,5mW, ~20m		0,7 -3 Mbit/s
		Class 3: 1mW, ~10m		0,7 -3 Mbit/s
		4.1/ BLE: 10mW, ~100/10m		1 - 54 Mbit/s

Table 14: Brief overview Blutooth technology [29]

4.5.3 Communication between basis station and online database

The connection between the basis station and the online database is accomplished through a secure wireless network connection.

WLAN	Frequency	Range	Technology Standard	Netto-Data rate
	2,4-2,48 GHz	100m	802.11	1-2 Mbit/s
	2,4-2,48 GHz	50m	802.11b	5-6 Mbit/s
	2,4-2,48 GHZ	50m	802.11g	20-34 Mbit/s
	5,0 GHz	20m	802.11a	20-22 Mbit/s

Table 15: Brief overview WLAN framework [30]

4.6 Specific requirements

4.6.1 Functional requirements

Requirement ID	Requirement statement	Must/ Want	Comment
FR01	**Access website/database**		
FR01.1	Only authorized users shall access the system	Must	Physician, patient, caretaker, family member, pharmacist, admin
FR01.2	System administrator shall create, edit, and remove user accounts and access rights.	Must	
FR01.3	The user (patient) can grant other people, who are involved in the patient´s care, access to the medication schedule, data from smart objects and the compliance report	Must	
FR01.4	If the user is logged in and is inactive for more than 15 min., he must be logged out automatically	must	

Requirement ID	Requirement statement	Must/ Want	Comment
FR02	**Medication administration**		
FR02.1	The physician can create, modify, delete a medication schedule	Must	
FR02.2	The physician is allowed to add or remove single medications from the medication schedule	Must	
FR02.3	The physician and pharmacist are allowed to add comments to the medication schedule	Must	
FR02.4	Check for harmful interactions among the medications on a patient's medication list	Shall	
FR02.5	Recording of administration	Must	If the physician changes the medication schedule the time, date and changed medication (name, dosage, time) have to be recorded

Requirement ID	Requirement statement	Must/ Want	Comment
FR03	**Medication schedule management**		
FR03.1	The user (patient) can view the list of medication that he/she must take regularly	Must	including the prescription of the medication

FR03.2	The user can display the dosing instructions and comments (see FR02.3) of every single medication on his/her medication schedule	Must	
FR03.3	The medication schedule can be exported and saved in a pdf.-file or printed directly	Must	
FR03.4	The user can grant other people, who are involved in the patient´s care process (e.g. family members or caretaker) access to display the medication schedule	Must	

Requirement ID	Requirement statement	Must/ Want	Comment
FR04	**Medication dispensing**		
FR04.1	Recording of time and date when medicine is taken out of the mobile device	Must	Important for compliance report
FR04.2	Control if medicine was taken out of the dispenser	Must	Sensor
FR04.3	Prohibit overdosing	Must	Patient has 1 hour to take out the mobile device. After that time the specific chamber is locked again and he/she has missed one dose.

Requirement ID	Requirement statement	Must/ Want	Comment
FR05	**Compliance report**		
FR05.1	The user can choose if he/she wants the compliance data/ dispense record displayed in a graph or a list	Want	The compliance data contains the date when he/she should have taken the pill and the date he actually took the pill. This data is recorded from the mobile device.
FR05.2	The user can choose a specific time period to be displayed.	Must	Day, week, month.
FR05.3	The compliance report can be saved in an electronic format and it is also possible to print it	Want	.pdf

Requirement ID	Requirement statement	Must/ Want	Comment
FR06	**Data from smart objects**		
FR06.1	The user can choose if he/she wants the data displayed in a graph or a list		

FR06.2	The user can choose a specific time period to be displayed.		
FR06.3	The data can be saved in an electronic format and it is also possible to print it.		.pdf

Requirement ID	Requirement statement	Must/ Want	Comment
FR07	**Measuring the ambient temperature**		
FR07.1	The mobile device shall measure the ambient temperature to check if the conditions for storage are complied.	Must	
FR07.2	The basis station has to check the database, which contains the medical schedule and all information concerning the used drugs, to identify the max. temperature allowed.	Want	In general the max. temperature is 35°C
FR07.3	If the max. temperature is reached the mobile device should release an audible alarm.	Must	

Requirement ID	Requirement statement	Must/ Want	Comment
FR08	**Contactless charging of the mobile device**		
FR08.1	The basis station should charge the mobile device via an inductive coupling	Must	
FR08.2	Control the state of charge of the mobile device	Want	
FR08.3	If there is no need for charging the charging station goes into a standby-modus	Want	

Requirement ID	Requirement statement	Must/ Want	Comment
FR09	**Data transfer via wireless LAN**		
FR09.1	Basis station must check the internet connection.	Must	
FR09.2	It must send the measured data (e.g. alarm report, compliance data, temperature) via a secure internet connection to the database.	Must	

Requirement ID	Requirement statement	Must/ Want	Comment
FR10	**Update medication schedule**		
FR10.1	If the physician updates or changes the medication schedule, the basis station has to inform the patient about the change by displaying "Updated medication schedule".	Must	
FR10.2	The basis station has to transfer the new medication schedule to the mobile device	Must	via bluetooth

4.6.1.1 Alarm handling requirements

ID	Description	Type			Comments
		Visual	Audio	Email or sms to	
A001	Mobile device not taken out of the container	x	x	family,caretaker	When it is time to take out the MD the visual and audio alarm starts right away. Family members/caretaker gets notified if the patient doesn´t take out the MD within 1 h.
A002	Wrong MD in container (check RFID-Tag)	x	x	pharmacist, caretaker, family member	The container has to be changed
A003	Temperature too high	x		family, caretaker	temperature > 35°C
A004	No correct connection to the Internet	x		family, caretaker	No connection to the DB. It is not possible to upload the compliance and alarm report. Not possible to check if the treatment plan has changed
A005	Data upload failed	x		family, caretaker	Data: Alarm+time when they occurred, "time-pill-taken", temperature(sensor), maybe data of connected smart objects
A006	Power failure	x		family, caretaker	Basis Station has no power supply.
A007	Pill was not taken	x	x	family, caretaker	If the patient does not take the pill out of the MD within 1h the family + caretaker gets notified
A008	None or bad connection of container and basis station	x	x		If the container is not installed properly, the loading of the mobile device via an inductive coupling is not possible. The connection examined with an electrical switching contact.

4.6.2 Regulatory requirements

4.6.2.1 Classification of the smart medication dispenser

As a general rule, products making medical claims will be regulated either by the medical devices regulations or by medicinal legislation. Due to the fact that the smart medication dispenser stores medicinal substances to support and remind the patient to take their medications on time, it was not clear if it is regulated by the Directive

2004/27/EC for medicinal products, Regulation (EU) 2017/745 for medical devices or if it can be declared as an medical device in the first place.
In order to decide whether the product is considered as a medical device, medicinal product or as an electrical device, the relevant current legislation and guidance documents for classification of borderline products, like the MEDDEV 2. 4/1 Rev. 9 [31], were thoroughly examined in the decision making process.

Regulation (EU) 2017/745, Article 2 (1) defines a medical device as follows:

> *" 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
>
> - *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
> - *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
> - *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
> - *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*
>
> *and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means." [32]*

The intended use of the mobile device is to store the solid medicinal products, provide timely alerts and a locking mechanism to avoid medication errors or overdosing, to help the user to stay compliant to his/her medication schedule. In this context the medication dispenser itself has no effect in or on the body of the user.

The medication dispenser can also not be classified as an active medical device intended for diagnosis and monitoring, because it does not allow a direct diagnosis or monitoring of vital physiological. The mobile device records the time when the patient did or did not take his/her medicine and the only assertions that can be made from this data is related to the compliance of the patient.

In Article 1(8) of the Regulation (EU) 2017/745 outlines:

> *"Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the device, shall be assessed and authorised in accordance with this Regulation" [32].*

Even though the mobile device incorporates a medicinal substance, it is not used *as an integral part*, within the meaning of Article 1 (8) (EU) 2017/745 and does not come within the scope of this Regulation. The device and the substance are not physically or chemically combined at the time of administration (*i.e.* use, implantation, application etc) to the patient.

Typically, the medical device function is achieved by physical means (including mechanical action, physical barrier, replacement of or support to organs or body functions). In this case the intended use of the mobile device does not meet the definition of a medical device and has to be declared as electrical equipment designed for the use within certain voltage limits.

Furthermore the mobile device is an electrical or electronic product, which intentionally emits and receives radio waves for the purpose of communication with the basis station and the clear identification of the mobile devices.
The protection of natural persons in relation to the processing of personal data is a fundamental right. Article 8(1) of the Charter of Fundamental Rights of the European

Union (the ‘Charter’) provides that everyone has the right to the protection of personal data concerning him or her [26].

As the smart medication dispenser-system is working with sensible patient data, it has to be compliant to following laws (Table 16) and harmonized standards (Table 17and Table 18):

	Applicable law
Austrian law	○ Gesundheitstelematikgesetz 2012 (Health Telematics Act 2012 –GTelG 2012) ○ Datenschutzgesetz 2000 (Protection of Personal Data 2000), repealed by the Datenschutz-Grundverordnung (DSGVO) with effect from 25 May 2018 ○ Elektrotechnikgesetz 1992 (ETG 1992)
EU Directive	○ Low Voltage Directive (LVD) 2014/35/EU ○ Radio Equipment Directive (RED) 2014/53/EU ○ Electromagnetic Compatibility (EMC) Directive 2014/30/EU ○ Regulation (EU) 2016/679 ○ ePrivacy Directive 2002/58/EC

Table 16: Applicable law fort the European Economic Area and the Austrian legal situation

To provide a solution for compliance with the above mentioned legal provisions, requested standards must meet the essential requirements or other provisions of relevant European Union harmonized legislation. The following two tables are showing the recommended harmonized standards for the proposed medication dispenser system.

ESO [1]	Reference and title of the standard (and reference document)	First publication OJ	Standard aims to cover Article(s) of Directive 2014/53/EU
Cenelec	EN 50566:2017 Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body	17.11.2017	Article 3(1)(a)
Cenelec	EN 55035:2017 Electromagnetic compatibility of multi-media equipment — Immunity requirements CISPR 35:2016 (Modified)	17.11.2017	Article 3(1)(b)
ETSI	EN 300 328 V2.1.1 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of Article 3.2 of Directive 2014/53/EU	13.1.2017	Article 3(2)

[1] (1)ESO: European standardisation organisation:
CEN: Avenue Marnix 17, B-1000, Brussels, Tel. +32 2 5500811; fax + 32 2 5500819 (http://www.cen.eu)
Cenelec: Avenue Marnix 17, B-1000, Brussels, Tel. +32 2 5196871; fax + 32 2 5196919 (http://www.cenelec.eu)
ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel. +33 492 944200; fax +33 493 654716, (http://www.etsi.eu)

ETSI	EN 300 330 V2.1.1 Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	10.3.2017	Article 3(2)

Table 17:proposed harmonized standards under Directive 2014/53/EU [33]

ESO (1)	**Reference and title of the standard (and reference document)**	**First publicati on OJ**	**Reference of superseded standard**	**Date of cessation of presumption of conformity of superseded standard Note 1**
Cenelec	EN 60065:2014 Audio, video and similar electronic apparatus — Safety requirements IEC 60065:2014 (Modified)	8.7.2016	EN60065:2002 + A11:2008 + A12:2011 + A1:2006 + A2:2010 Note 2.1	17.11.2017
Cenelec	EN 50364:2010 Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0Hz to 300GHz, used in Electronic Article Surveillance (EAS), Radio Frequency	8.7.2016	EN 50364:2001 Note 2.1	

	Identification (RFID) and similar applications.			
Cenelec	EN 60950-1:2006 Information technology equipment — Safety — Part 1: General requirements IEC 60950-1:2005 (Modified)	8.7.2016	EN 60950-1:2001 + A11:2004 Note 2.1	

Table 18: proposed harmonized standards under Directive 2014/53/EU [34]

The complete summary list of titles and references of harmonised standards under those 3 Directives (LVD 2014/35/EU, RED 2014/53/EU, EMC Directive 2014/30/EU) can be found here : http://ec.europa.eu/growth/sectors/electrical-engineering_en .

4.7 Non-functional requirements

4.7.1 Safety requirements

By the reason the mobile devices are charged wirelessly via an inductive coupling one safety requirement is that the system should pose no risk to either the user, the device being charged, or any other devices in the environment. Risks include electric shock, damage to the device being charged, or damage to other electronic devices in the environment.

Frequency range	Magnetic flux density (mT)	Current density (mA/m^2) (rms)	Whole body average SAR (W/kg)	Localised SAR (head and trunk) (W/kg)	Localised SAR (limbs) (W/kg)	Power density, S (W/m^2)
0 Hz	40	—	—	—	—	—
>0-1 Hz	—	8	—	—	—	—
1-4 Hz	—	8/f	—	—	—	—
4-1 000 Hz	—	2	—	—	—	—
1 000 Hz-100 kHz	—	f/500	—	—	—	—
100 kHz-10 MHz	—	f/500	0,08	2	4	—
10 MHz-10 GHz	—	—	0,08	2	4	—
10-300 GHz	—	—	—	—	—	10

Table 19: Basic restrictions for electric, magnetic and electromagnetic fields (0 Hz to 300 GHz)[35]

4.7.2 Security requirements

The protection of the fundamental rights to privacy and data protection within the European Union is in the first place guaranteed by a legislative framework, which is needed since we deal with rights that are recognised in Article 8 of the European Convention of Human Rights and Fundamental Freedoms and in Article 7 and Article 8 of the Charter of Fundamental Rights of the Union. The relevant legislative framework for data protection basically consists of the Data Protection Directive 95/46/EC, which is repealed by the regulation (EU) 2016/679 of the European parliament with effect from 25 May 2018, and the ePrivacy Directive 2002/58/EC.

The definition of sensitive data and health data in conformity to the Data Protection

> *" 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person" [26].*

> *"Health Data means personal data pursuant to sect. 4 no. 1 DPA 2000 on the physical or psychological state of a person, including data collected in connection with the investigation of the reasons for this state, as well as with preventive medicine or healthcare provision, diagnosis, treatment or care methods, provision of care, prescribed or taken medicines ("medication data"), medical aids or aids, the charging of healthcare services, or data collected for the insurance of health risks." [36].*

As the smart medication dispenser-system is working and processing patient data, the security in electronic transfer of health data has to correspond to the law.

5 Discussion

The basis of this work is, that in this world of rapidly changing technology, a segment of population (mostly elderly) is not willing or not capable to keep up with the time.
Although the general trend is towards elderly people being healthier than they used to be in former generations, the growing age of the population is also linked to the increase in chronic diseases. The proposed concept was developed precisely for this population group, to help them to keep their autonomy and optimise their compliance behaviour.
The design of the smart medication dispenser system is strongly influenced by the challenges of an ageing population, like reduction of fine-motor skills or forgetfulness.

In the process of this work competitor products were analysed with an evaluation matrix. The dispensers were assessed with regard to effectiveness in fulfilling the stated requirements, which was exclusively performed by the author of this work.
Despite the efforts of objectivity, this can not guaranteed. Furthermore, the investigation need to be carried out by a larger number of people in order to achieve a more objective result based on the opinion of different researchers.
Also, the observation of real patients and their actual user behaviour could provide deeper insight into to the assessment of the requirements. The requirements have

been generalized to be applicable to all dispensers. This brings with it a blurring of the exact requirement and its fulfilment.
Many dispensers that have been evaluated failed the security and data protection requirement. The dispensers are processing personal data and most of them do not take the tightening of the data protection law in the processing of such data in consideration. Appropriate technical and organizational measures and procedures (such as pseudonymisation) must be taken to ensure that the processing complies with the requirements of the current Regulation (EU) 2016/679 and protects the rights of data subjects (privacy by design).
The modular architecture of the proposed concept and the implemented technical measures ensure a level of appropriate security of processing the personal data. The basis station transfers the patient's data via the WLAN connection only in encoded form to ensure privacy and comply with the requirements of the current Regulation (EU) 2016/679. In comparison with the evaluated competitor products, where only two products exceeded the data protection requirement and seven products with unspecified data transfer, the proposed concept convinces with verifiable and accurate data processing in line with the state of art.

The concept for the measurement of compliance was more difficult than expected. The mobile device checks to see if the medication has been taken, but that is no guarantee that the patient has actually swallowed it. The mobile device not only has a locking mechanism, when the patient fails to take the medication within the appointed time period, but also monitors with a sensors if the patient empties the active chamber. When the patient empties the active chamber, it is assumed that he/she also takes the medication promptly. Therefore, the assumption is that the patient accepts his/her drug therapy and wants to stay compliant to his/her medication regimen. Patients who refuse medical treatment are excluded from this concept.
It is possible to measure the typical emptying movement by using a special type of sensors, but it cannot draw a hundred percent conclusion on the actual use of the medication. The use of such sensors in the mobile device was discarded to keep the production costs lower.
The results of the evaluation matrix, regarding the measurement of compliance, outline a high potential for improvement. Unlike the smart medication dispenser system most of the evaluated products are equipped with a locking mechanism to prohibit

overdosing, but none of them check if all medications (tablets) were taken out of the chamber or compartment. Furthermore none of the evaluated products take the aspect of proper drug storage into consideration. The storage of medication is not trivial and should be taken in account due to the fact that many drugs can quickly lose their effect in different conditions of temperature. The smart medication dispenser system uses a temperature sensor to recognise errors in medication storage.

The capacity of the mobile device was deliberately chosen, as in most drug therapies four intakes per day are quite adequate. The reason for this decision is to reduce the amount of tablets that the patient is sent home with, and thus reduce the amount of wasted medicine if for example the therapy plan is changed or the patient is admitted to the hospital or deceases. In this concept on demand medications are not considered.

The system offers the great advantage that the user and authorized persons have the opportunity to manage his/her personal health data, which means the users compliance data and data from smart objects that the user wants to connect with the smart medication dispenser system. The data transfer starts automatically without the need of any intervention from the user.

6 Conclusion

The main purpose of this work is the compliance, its increase, cost saving potential and positive health effects on patients. The concept developed offers the opportunity to improve compliance but also to network with other smart objects without having to intervene much. This is particularly important because the concept was developed for the population group that is not familiar with or would not like to deal with new technologies such as smartphones and tablets. There are many solutions with smartphones to increase compliance and manage a healthy living in general. But these solutions are quite inappropriate for this population group. The concept offers a simple and efficient way of enabling such patients to live longer on a self-determined basis and offers the opportunity to increase their compliance to medication therapy.

The verification of compliance in this concept is not optimal but absolutely sufficient for its purposes, since there is an assumption that the patient wants to remain compliant and does not deliberately throw away his/her medication.

7 Literature

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8 Appendices

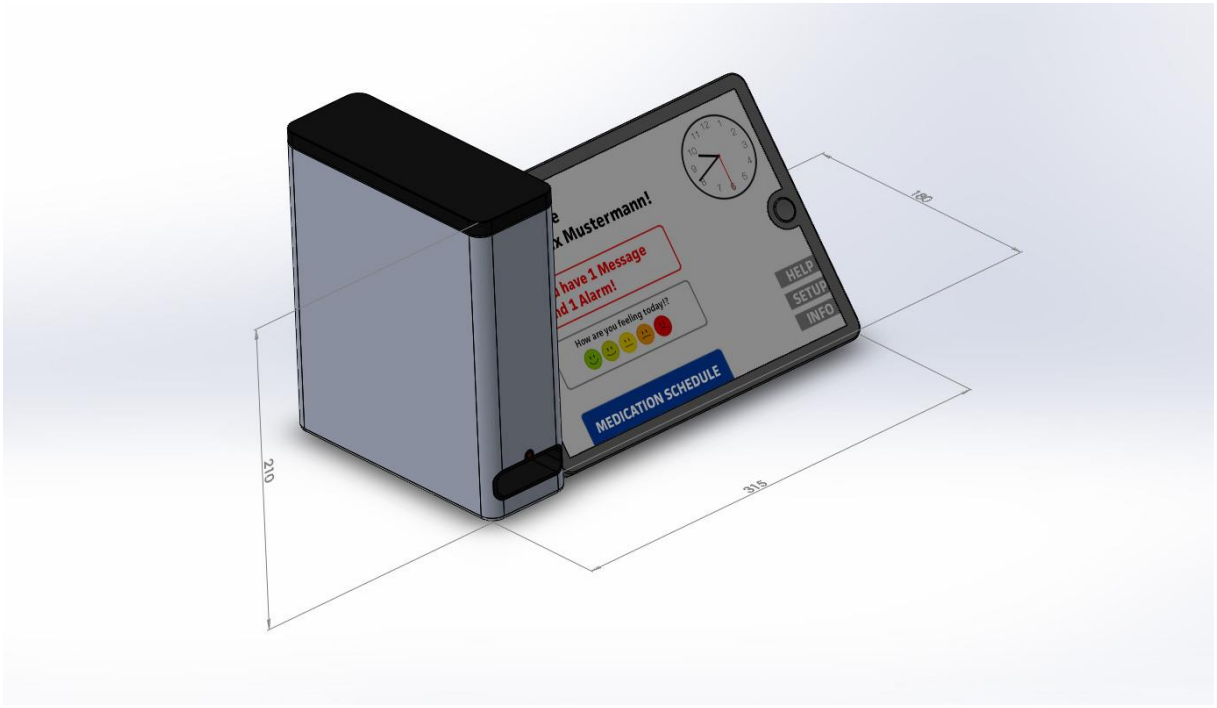


Figure 18: Physical dimensions of the basis station

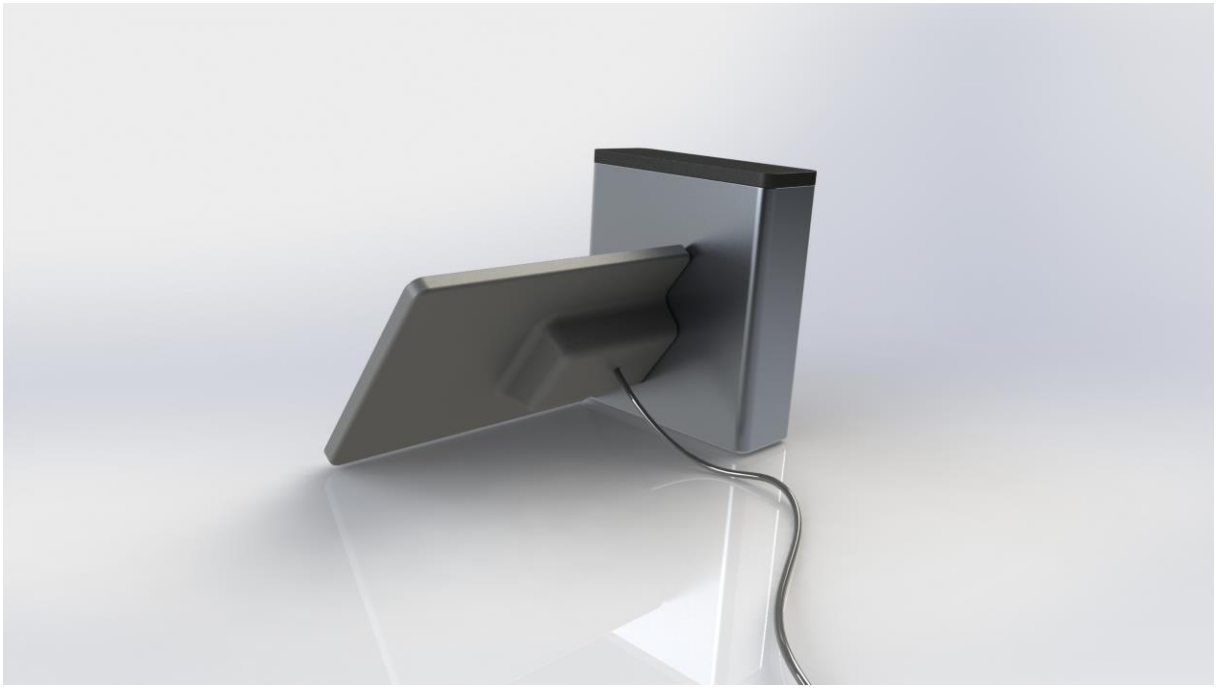


Figure 19: Rear view of the basis station

Name	capacity		Alarm	Network Connection	Data upload	Methodology	Design	Specifications	Costs
	chamber	day							
uBox-uPhone	14	14	flash light, audio alarm	x	manual	The first part of the two-component system is a kind of "smart" pillbox, called the uBox. It has 14 chambers that can each be loaded with several pills, which it dispenses from one chamber per day. To alert the patient the box flashes its lights and sounds a buzzer. After two weeks, a health care worker reloads the box and digitally records and transmits the information stored in it. U-Phone: By using special software, health care workers can record a patient's temperature, weight, and answers to a list of questions related to symptoms.			
Med-eMonitor	5	not fixed, need setup further	flash light musical chimes	wired	automated	The System comprises a portable patient interface device and automated data upload and download capability using a cradle connected to the patient's phone line. programmed remotely via the Internet. The system reminds, educates, monitors and reports on up to 25 medications per patient. The five most critical medications are physically held in the device storage compartments. Twenty additional medications, outside of the device, can be managed via a "Virtual Compartment" feature. This feature also allows for prompting, education and monitoring for non-oral forms of medication.			$59.95 + $44.95 per month
MedFolio Pillbox	28	7	flash light, audio alarm,text message, email	wireless	automated	Medication organizer, identifier, and reminder system, storing seven days of solid medication separated into four daily dosing intervals. The MedFolio Wireless Pillbox connects to any computer using a provided USB cable and a downloadable software program allows the user/caregiver to easily connect the pillbox to their home wireless router. Once a successful connection is achieved, the user/caregiver is directed to a web application in order to customize the pillbox to their specific medication regimens and dosing times.		Size: 14.4" long, 7" wide, 2.3" high Weight: 3 pounds Compatible with the following operating systems: Windows 7, Windows XP, Windows Vista Professional, Windows 8, Mac-OS 10.7 or later. Installation requires use of computer with a USB 2.0 port, DVD/CD drive, and internet connectivity	$199 + monthly fee for e-mail/ text message
Dispense-HealthOneMed Dispense A-Pill (DAP)	8	up to 90	audio, visual	phone line	automated	Dispenses drugs at preset times and in preset quantities. Pills are poured directly into the DAP and the device automatically sorts and dispenses the medications as directed. It skips the error-prone step of manually setting out the medication thus increasing safety. Manages up to 16 medications and manages alerts for non-pill medication like inhalers and insulin injections			
MedReady P1650	28	not fixed	visual, audio	phone line		"Early dosage" feature. Only the most recent medication dose is available. Pill tray rotates to the next dose when the next audible alarm sounds. If a patient misses a dose, the pill dispenser denies access to the missed dose. Calls up to 3 phone numbers, leaving messages, and sends e-mail, if dose is not taken. A record of the medication compliance and /or non-compliance is available on their website.			$255
MedSmart (MD2)	28	up to 28	audio,visual	x	x	Dispense meds up to 6 times per day. Fill every 14 days at 2 x Day, fill weekly at 4 x Day.Large digital display and programming buttons. Two 29 compartment med trays, lid, lock and 2 keys.The e- pill MedSmart will beep, flash and rotate when it's time to take your pills. Simply turn the unit over to dispense the correct pills.		Size: Diameter 8 1/2 inch (round) x 2 1/2 inch | Weight: 28 oz.	$595
MedSmart PLUS (MD2 PLUS)	28	up to 28	audio, visual, text message, email, call	phone line	x	Remote Event Monitoring. Alerts caregiver if meds have been missed. MedSmart PLUS calls your cell or regular phone, sends a sms or mail notification if meds have not been taken within 60 minutes of the scheduled alarm time. Dispense up to SIX (6) Times per day		Size: Diameter 8 1/2 inch (round) x 2 1/2 inch | Weight: 28 oz	$895

Figure 20: commercially available medication dispenser for solid medicine (1/2):

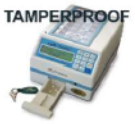
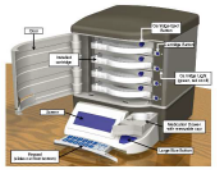
Name	capacity		Alarm	Network Connection	Data upload	Methodology	Design	Specifications	Costs
	chamber	day							
e-pill medimi	30 or 14	not fixed	visual, audio, vibrate	x	x	Dispense one or two medications up to 15 times per day. Alarms by sound, vibration and light. Also available as a Bluetooth Medication Dispenser (e-pill medimi Bluetooth)			$395
CompuMed (MD3)	28	395	audio, visual, text message	x	x	Tamper Proof (for patients who are trying to get to the medications before it is time). Lock with 2 keys. Secure and Refillable medication cassette for easy loading. Alarm and Text message reminders displayed on LCD		size: 7" wide, 6" high and 11" deep Weight: 7 lbs. Capacity: 25 aspirin sized tablets per dose. Maximum four (4) Doses per Day	$995
TabSafe Medical Dispenser	16 or 32	not fixed	visual, audio	wired	automated	Informative Screen ,Locked system for storing medication, Additional security with optional PIN for features; Advance option to release medications ahead of time. Secure login access to cartridge/message scheduling, configuration options and adherence reports. Alert Calls to up to three different phone numbers when medication is not released. Each TabSafe unit holds 4 cartridges; Cartridges come in both 16 and 32-section size. Capacity for up to 14 different messages. Up to 4 medication times can be scheduled for each cartridge.		Power Source 120 VAC 50/60 Hz Battery Life 12 Hours Display LCD Size 11 7/8 in W x 14 in D x 14 in H Weight 16.2 lbs (without cartridges) Operating Ranges For Indoor Use Altitude up to 2,000 m; (6,561 ft) Temperature 5 °C to 40 °C; (41°F -104°F)	$100 per month
Jon-locked Pill Dispenser(MedMinder)	28	7	visual, audio	wireless	automated	locking feature that allows users access to only the correct compartment at the correct dosage time. The medication dispenser is electronic and can be controlled remotely using the MedMinder website. Caregivers can also receive immediate email or text message notifications and weekly reports. MedMinder devices are equipped with bluetooth connectivity.			$64,99/ month
Smart Pill Box	3..10	not fixed		wireless or wired	automated	Prescription bottles can be kept in the medication bays for daily use. According to your medication setup, this device will give alarm at prescribed time and when a patient picks a bottle from the pill bay it sends message through following media: GSM, GPRS, WIFI and HTTP directly to server; transfer this data to iphones and android phones using Bluetooth; directly to computers via cable; It can be connected to various healthcare devices like blood pressure meter, blood glucose meter and weighing scale.			
Philips Medication Dispenser Service	60	1..40	audio	phone line	automated	Philips unit calls the caregiver when medication needs to be refilled, when the patient misses a dose, or when the power goes out in the patient's home (the dispenser continues running on a back-up battery)		Dispenses up to 60 cups Accommodates 1 to 40 days of medicine Holds up to 6 doses per day	$49/month
MedSignals	4	not fixed	audio, flash light, email, call, text	wireless		Data are captured in a cloud-resident SmartCharts™ system that processes timely alerts and reports to designated care team when and how they want them --via email, text, fax, customized to electronic records connections, or automated phone calls. Embedded cellular chip (SIM card) connects to multiple wireless networks, including GSM/GPRS and 3G communications.			

Figure 21:commercially available medication dispenser for solid medicine (2/2)

```
=> s Medication dispenser or  pillbox device or electronic blister

         37079 MEDICATION
          6623 DISPENSER
             4 MEDICATION DISPENSER
                 (MEDICATION(W)DISPENSER)
           121 PILLBOX
       1172759 DEVICE
             1 PILLBOX DEVICE
                 (PILLBOX(W)DEVICE)
        784176 ELECTRONIC
          8879 BLISTER
             0 ELECTRONIC BLISTER
                 (ELECTRONIC(W)BLISTER)
L1           5 MEDICATION DISPENSER OR  PILLBOX DEVICE OR ELECTRONIC BLISTER


=> s l1 and (Adherence or  compliance or  regimen or  ehealth or  mhealth or
telemedicine or  monitoring System or  healthcare or  ambient assisted living
or  embedded Systems or  Smart home)
         40206 ADHERENCE
         38703 COMPLIANCE
         58072 REGIMEN
             3 EHEALTH
             3 MHEALTH
           108 TELEMEDICINE
        391099 MONITORING
       3452526 SYSTEM
         11969 MONITORING SYSTEM
                 (MONITORING(W)SYSTEM)
          7785 HEALTHCARE
        191065 AMBIENT
        182088 ASSISTED
        131939 LIVING
             3 AMBIENT ASSISTED LIVING
                 (AMBIENT(W)ASSISTED(W)LIVING)
        146286 EMBEDDED
       1969836 SYSTEMS
            77 EMBEDDED SYSTEMS
                 (EMBEDDED(W)SYSTEMS)
         19332 SMART
         36021 HOME
             9 SMART HOME
                 (SMART(W)HOME)
L2           1 L1 AND (ADHERENCE OR  COMPLIANCE OR  REGIMEN OR  EHEALTH OR
               MHEALTH OR  TELEMEDICINE OR  MONITORING SYSTEM OR  HEALTHCARE
               OR  AMBIENT ASSISTED LIVING OR  EMBEDDED SYSTEMS OR  SMART
HOME)


=> s l1 and (Wireless communication or  Sensor or  RFID  or  NFC  or  Bluetooth
or    embedded    systems    or    wearable    tools    or    microcontroller    or
interoperability or  user interface)
          9048 WIRELESS
        105122 COMMUNICATION
          1834 WIRELESS COMMUNICATION
                 (WIRELESS(W)COMMUNICATION)
        271879 SENSOR
```

```
          2024 RFID
           913 NFC
           292 BLUETOOTH
        146286 EMBEDDED
       1969836 SYSTEMS
            77 EMBEDDED SYSTEMS
                 (EMBEDDED(W)SYSTEMS)
          1771 WEARABLE
        178743 TOOLS
             0 WEARABLE TOOLS
                 (WEARABLE(W)TOOLS)
          1411 MICROCONTROLLER
           246 INTEROPERABILITY
         42651 USER
        486279 INTERFACE
          3597 USER INTERFACE
                 (USER(W)INTERFACE)
L3            1 L1 AND (WIRELESS COMMUNICATION OR  SENSOR OR  RFID  OR  NFC
OR
                BLUETOOTH  OR   EMBEDDED  SYSTEMS  OR   WEARABLE  TOOLS  OR
MICROCONT
               ROLLER OR  INTEROPERABILITY OR  USER INTERFACE)


=> s Adherence or  compliance or  regimen or  ehealth or  mhealth or
telemedicine or  monitoring System or  healthcare or  ambient assisted living
or  embedded Systems or  Smart home

         40206 ADHERENCE
         38703 COMPLIANCE
         58072 REGIMEN
             3 EHEALTH
             3 MHEALTH
           108 TELEMEDICINE
        391099 MONITORING
       3452526 SYSTEM
         11969 MONITORING SYSTEM
                 (MONITORING(W)SYSTEM)
          7785 HEALTHCARE
        191065 AMBIENT
        182088 ASSISTED
        131939 LIVING
             3 AMBIENT ASSISTED LIVING
                 (AMBIENT(W)ASSISTED(W)LIVING)
        146286 EMBEDDED
       1969836 SYSTEMS
            77 EMBEDDED SYSTEMS
                 (EMBEDDED(W)SYSTEMS)
         19332 SMART
         36021 HOME
             9 SMART HOME
                 (SMART(W)HOME)
L4       153470 ADHERENCE OR  COMPLIANCE OR  REGIMEN OR  EHEALTH OR  MHEALTH
OR
                TELEMEDICINE OR  MONITORING SYSTEM OR  HEALTHCARE OR  AMBIENT
               ASSISTED LIVING OR  EMBEDDED SYSTEMS OR  SMART HOME


=> s Wireless communication or  Sensor or  RFID  or  NFC  or  Bluetooth or
embedded systems or  wearable tools or  microcontroller or  interoperability
or  user interface
          9048 WIRELESS
```

```
        105122 COMMUNICATION
          1834 WIRELESS COMMUNICATION
                 (WIRELESS(W)COMMUNICATION)
        271879 SENSOR
          2024 RFID
           913 NFC
           292 BLUETOOTH
        146286 EMBEDDED
       1969836 SYSTEMS
            77 EMBEDDED SYSTEMS
                 (EMBEDDED(W)SYSTEMS)
          1771 WEARABLE
        178743 TOOLS
             0 WEARABLE TOOLS
                 (WEARABLE(W)TOOLS)
          1411 MICROCONTROLLER
           246 INTEROPERABILITY
         42651 USER
        486279 INTERFACE
          3597 USER INTERFACE
                 (USER(W)INTERFACE)
L5       280681 WIRELESS COMMUNICATION OR  SENSOR OR  RFID  OR  NFC  OR
BLUETOO
               TH OR  EMBEDDED SYSTEMS OR  WEARABLE TOOLS OR  MICROCONTROLLER
               OR  INTEROPERABILITY OR  USER INTERFACE


=> s dispenser
L6         6623 DISPENSER


=> d hist

     (FILE 'HOME' ENTERED AT 10:15:57 ON 21 JUL 2015)
CHARGED TO COST=STEGEMANN

     FILE 'CA' ENTERED AT 10:16:06 ON 21 JUL 2015
CHARGED TO COST=STEGEMANN
L1               5 S MEDICATION DISPENSER OR  PILLBOX DEVICE OR ELECTRONIC
BLISTER
L2             1 S L1 AND (ADHERENCE OR  COMPLIANCE OR  REGIMEN OR  EHEALTH
OR
L3           1 S L1 AND (WIRELESS COMMUNICATION OR  SENSOR OR  RFID  OR  NFC
L4       153470 S ADHERENCE OR  COMPLIANCE OR  REGIMEN OR  EHEALTH OR  MHEALTH
L5       280681 S WIRELESS COMMUNICATION OR  SENSOR OR  RFID  OR  NFC  OR
BLUE
L6         6623 S DISPENSER


=> s l6 and l4
L7           48 L6 AND L4


=> s l6 and l5
L8          245 L6 AND L5


=> s l6/ti and l5
           1906 DISPENSER/TI
L9           65 (DISPENSER/TI) AND L5
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