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Business Plan

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Executive Summary

In the course of demographic change, so-called Comprehensive Geriatric Assessments (CGA) are becoming more and more common, developing them into a personalized care plan adequate to the elderly and his relatives' profile. This is quite time consuming for nurses and doctors, especially in times where it is hard to find appropriate personnel.

Our approach is to save about 75% of the working hours during a standard CGA by using an interactive mobile service robot in combination with a portable device developed for elderly people. We offer this as a full service solution in a subscription model to hospitals. In addition to a set-up fee, we charge € 15 per CGA that is completed and documented by the robot. With this model the barrier in testing the robot is quite low since there are almost no commercial risks for the clinic. The payback period is about a month. On top there are process improvements and the possibility to charge more CGAs compared to now. For us the subscription model generates continuous turnover on the long run and enables us to offer additional services with similar assessments with software updates later on.

Even today the market is already big. We identified clinics with geriatric patients in Germany and Spain as our primary target markets with a potential of about 500 robots. In Western Europe with high labour costs we estimate the potential with about 1,500 robots. The raising share of elderly people in combination with the skills shortage will lead to a continuously increasing demand.

The proof of concept is already done and three prototypes were developed in a running funded R&D project in a consortium with researchers of the University of Malaga, the Universidad Carlos III de Madrid, Andalusian Health Service, Troyes University of Technology and of the service robot company MetraLabs. MetraLabs is going to set-up a spin-off for the development and commercialization of healthcare robots. We need a team of 20 people to address the remaining technical challenges and to certify it as a medical device which is necessary to commercialize it, but also protects us from the fast market entry of competitors.

The required capital is € 5m. We plan to collect the capital in two steps: Raising a Seed-round of € 2.5m for 30-35% of the shares in 2019, which is supposed to finance market entry of the robot and then, once the first robots are in the field, raising a Series A round with an amount of another € 2.5m for further 15% of the shares.

1 The Problem

The ageing population across the EU is placing relentless pressure on increasingly scarce health and social care resources. More people live with multiple co-morbidities, and there are fewer people to care for them.

The Comprehensive Geriatric Assessment (CGA) serves to record the problems, but also to determine the functions of the elderly patient. It is widely used and during the last 20 years, it has become a standard clinical tool for healthcare professionals of around the world to identify medical, psychosocial, and functional limitations of frail elderly people; it is used to develop a coordinated plan to maximize their overall health. The CGA process is performed by a number of specialist of many disciplines in older people's health; it involves an holistic, multidimensional (not only medical diagnoses, but also functional impairments and the environmental and social issues which affect patient wellbeing), interdisciplinary (with inputs from doctors, nurses and other allied health professionals) assessment which has been demonstrated to be associated with improved outcomes in a variety of settings. CGA typically results in the formulation of a list of needs and issues to tackle, and develop an individualised goal-driven care and support plan, tailored to the patient's needs, deficits and priorities that it ultimately provides and coordinates an integrated plan for treatment, rehabilitation, support and long-term care.

Typically, the CGA is divided into three phases:

PHASE I **Clinical interview**	**PHASE II** **Multidimensional Assessment**	**PHASE III** **Individualised Care Plan**
Initial phase of the process where patients and relatives meet the healthcare professionals and discuss the main problems and worries concerning the elder while overviewing his personal health issues (allergies, diseases, surgeries and medications)	Multidimensional assessment tests are performed to assess the functional, mental and social status of the elderly person	Healthcare professionals evaluate patient's information gathered during the previous phases and devise a personalized care plan adequate to patient and relatives' profile. The individualized care plan includes for instance: additional diagnostic tests, therapeutic recommendations (medications, rehabilitation treatment, cognitive stimulation, etc.) and the more suitable setting for the patient to execute the care plan (ambulatory care unit, day care hospital, or hospitalization units).

Figure1.1 Phases of Comprehensive Geriatric Assessments.

The problem is that the CGA process takes in general a lot of time of Health professionals, and moreover Health professionals waste their time with tasks which can be automated today: On average, between 2 and 3 hours per patient are needed to complete the assessment. The Multidimensional Assessments (Phase 2) takes over 50% of the total time of the process while the individualised care (Phase 3) plan phase only lasts 11 % of the time. When CGA is performed in Ambulatory Care units the process lasts only 60 minutes. In this settings time is a handicap and the health professional needs to hurry in Phase 1 and Phase 2 in order to complete the process; but many times the CGA process is not completed in one session and has to be continued in further sessions also in other hospital setting (usually Day Care Hospital Unit). All in all, in ambulatory care units the health professional has a lack of time to perform the process; especially for the final and most important phase, where the personalised care plan is organised.

On the other hand, the elderly patients are evaluated in the hospital, ambulatory care units, or in residences at least once a year. For this purpose, functional, motor and cognitive tests such as Barthel, Mini Mental and Get up and Go are used. Usually, these evaluations are done manually on paper. Due to it, healthcare professionals after evaluation have to register the result of the tests on the electronic health record. However, the EHR is not prepared to record this information in a structured format. In this sense, they have to write the results in free text without following a template or structure format. This causes difficulties for the comparison and exploitation of data, especially for the evaluation process of the patients' evolution. In this context, having a system that allows the objective patient assessment would be a great achievement. Clinicians will be able to see patients' performances in order to compare them to previous years, also with the help of visualization videos from the same system. This will also save time and will optimize the evaluation process.

2. The Product

What is needed to solve this problem is a device that reduces the workload for doctors and nurses by automating repetitive assessments.

2.1 Our solution

Our solution is an autonomous service robot that autonomously executes repetitive tests and assists the Health Professionals during phase 2 of the CGA (e.g. Barthel, GetUp & Go, Minimental), discharging and freeing up time for them to focus on more important activities of phase 1 or phase 3.

2.2 Customer Benefit

We expect to save about 75% of Health Professional's time because the robot can be

+ **autonomous**. It is able not only to collect patient's responses autonomously. It is also able to receive the patient, explain the test and the way to perform it, monitor the patient while she/him is executing the test, provide a result based on given responses and show collected data in a friendly way using the CGAMed. None of these actions require human presence nor even teleoperation to be executed.
+ **pro-active**. The use of a mobile robot allows assuming an active role in the interaction with the patient. It is able to look for the patient and, once located, accompany her/him to the consultation room, introduce itself, explain the test in the context of a social interaction and drive it using natural interaction channels.
+ **embodied**: People are more motivated to interact with physically embedded agents than with screens.
+ **moveable**: The robot can move to change the viewpoint during a test, switch between different interaction channels on demand, run the test in a different room if requested, etc.

- provide a **natural interface** with the patient. Multiple interfaces are used to interact with the robot, taking into account accessibility criteria. The patient interface the robot using voice, or pushing a tactile screen or a button in a remote control. The robot speaks and shows text on its screen.
- **ease of use** for the clinician: The clinician can easily program CGA sessions, check the patient's performance and evaluate test results, using the CGAMed interface, that can be accessed via web. Additionally, no special requirements are imposed to the environment where the robot will work: it can operate in daily life scenarios and require no special systems, marks or devices to be installed around the place, apart from the charging base in the storing room.

Besides saving time it should decrease health professionals' tiredness or fatigue perception as consequence of doing tests. So, it saves costs for the hospital caused by failures of the clinician.

2.3 Hardware

The solution consists of the following parts

- Robot CLARC
- Charging Station of the robot
- Tablet

The current prototype of the robot has a footprint of 50 x 50 cm, a height of 140 cm and the weight is about 70 kgs. It has a simple, but robust drive system. It has several sensors for its orientation, obstacle and people detection. The robot can operate about 12 hrs per charge and needs about 5 hrs for recharging on its docking station.

Figure 2.1 3D-Drawing and current realization of the CLARC robot prototype.

The first evaluation of the solution in Troyes in January 2017 showed us that the combination of touch screen and voice were not always easy to use by the elderlies. On the contrary, they had no problems to use the tablet device, which was employed for performing the Minimental Test. In the subsequent focus groups, users proposed us to build a specific device for interacting with the robot. This device was initially built as an augmented tablet, adding large buttons for answering the questions on the Barthel test. The device also includes buttons for controlling the audio volume, for calling the doctor, or for providing yes/no answers. The device is connected to the wifi area created by the robot.

Figure 2.2 First version of the tablet device.

The weight and size of this device has been reduced for dealing with the Barthel test (where the tablet device is not necessary). The new device is built around a Rapsberry Pi Zero. An internal powerbank provides more than eight hours of autonomy.

Figure 2.3 Final version of the tablet device.

2.4 Software

For the embedded PC Shuttle we use an OS Linux Ubuntu 14.04 and for the embedded PC Intel NUC we use Windows 8.1.

For the functionality of the robot, the following software modules are needed:

+ MIRA: Framework for high performant data exchange (MetraLabs)
+ CogniDrive: Autonomous indoor navigation (MetraLabs)
+ CORTEX architecture (UMA): Built using the RoboComp framework, this architecture is the core of the software design. It is based on the existence of an internal, graph-based representation of the outer world, where the robot and the people are managed. This inner model includes geometric and symbolic information, and is shared by several task-based agents. Specifically, within CLARC, CORTEX provides agents for
    - Detection and tracking of people in the scene

  - Human motion capture and analysis
  - Speech management
  - Video recorder
  - Touch-screen management
  - External device (keyboard) management
  - Automatic Speech recognition
  - Capture from the RGB-D camera

  These last two agents run the Microsoft libraries for ASR and the Microsoft Kinect SDK respectively. Thus, they process the continuous flow of incoming data from the shotgun microphone and the RGB-D camera. CORTEX provides bridges to MIRA (and CogniDrive) and also to the Automatic planning and monitoring (PELEA-based) framework (UC3M).

+ Automatic planning and monitoring framework (UC3M)

2.5 Operation Requirements

Environmental requirements for the robot are:

+ Level surface
+ Minimum passage: 70 cm
+ Walls or similar immobile obstacles for orientation
+ Area of about 1x1,5 metres for the the charging station including a standard socket
+ WiFi access for the data exchange
+ Remote wifi access via ssh

To be ready to operate a set up has to be done by a technician. Parts of this set up are:

+ Mapping of the environment including marking of forbidden areas, target points
+ Fixing of the charging station
+ Network settings
+ Training of the employees
+ Tests

The whole set up process initially takes about a day, later it should be reduced to 4 hours.

2.6 Usability

The system's usability has been a vital point of relevance in the development of our robotic solution. In fact, it is currently possible to interact with the robot in three different languages: English, French and Spanish. It has been established through several usability tests both in France and Spain in hospitals and residential care centers. Impressions and reactions of patients, doctors, physiotherapists and other health professionals related to evaluation and geriatric care have been collected to improve the system. Using the information gathered, an easy-to-use and robust interface has been created so that patients can move autonomously (whenever possible) while conducting the tests.

Therefore, the interface design is focused on the user/patient. In addition, since CLARC users are people who may have different kinds of limitations and/ or disabilities, accessibility aspects have been taken into account in the development of the systems so that all patients can interact with the robot and complete the tests (regardless of their access characteristics). Finally, a fundamental requirement has been to make the system multimodal; various forms of interaction with the user have been allowed: voice, captioning, touch displays, physical buttons, etc.

Related to the inclusion criterias patients must have some characteristics to interact with the CLARC platform. It must be stand out that the cognitive stade must have a minimal punctuation in Minimental test corresponding to 23 points and besides, they must possess correct reader skills and auditory processing abilities to answer the tests provided to the robot by themself. With regard to locomotion capacities, it is necessary that they are patients who are able to move without the need for technical assistance other than the cane, given that more cumbersome devices or the help of a companion interfere with the results in the capture of the patient's image in the Get up and Go test.

Nevertheless, no special requirements are imposed to the health professionals. Thus, the only requisite is to be able to handle with technological devices concretely, with CLARC robot.

In addition to the accessibility and the interface, part of the work has also been focused on shaping other aspects such as the appearance of the robot and its voice. To this end, and through the opinions of experts and end users, an attempt has been made to humanise both the exterior and its voice but without attempting to imitate or replace the medical human figure.

2.7 Certification Requirements

The solution is a medical device class 1 since it records data for diagnostics. It needs to be certified according to the medical device directive. A manufacturer of medical devices must also be certified and approved according to specific guidelines. This process presents itself as a great challenge for small and medium-sized companies that have not been approved as medical device manufacturers yet. Since with the approval as a medical device manufacturer, higher demands are placed on the quality management system and the technical documentation (e.g. certification according to ISO 13485).[1]

Although in each community it varies with respect to another, more or less the procedure is similar, describing next the one that is carried out in Andalusia:

+ Once the product has completed its research phase and has been CE marked (European Conformity), it is considered to be a medical product, and it must submit a request for evaluation of the technology corresponding to the "Provincial Commissions for the Evaluation of New Products and Technologies and New indications". To do this, the applicant (must be someone from the Andalusian health service and have the approval of the Director of their clinical management unit), completes the GANT (Guide for the Acquisition of New Technologies) and remits it to the Commission. In the Commission, the GANT is reviewed and evidence (bibliographic, economic, etc.) is sought to validate whether or not the incorporation of this new technology into a specific service is appropriate[2].
+ If the technology is considered necessary and passes the evaluation, it could be incorporated and goes on to the circuit that follows any other platform (incorporation into the catalogue, assigning it an Andalusian health service code, assigning it a Generic Center code, associating it with the consumer branches of the clinical management units, etc.)[3].

2.8 IT Security

Another important requirement for the product is data security. On the one hand, the data recorded by the robot must be assigned to the right person, on the other hand, it must be ensured that this storage of the data also complies with the EU General Data Protection Regulation. Furthermore, there will be special requirements in the clinics of the respective countries for the compatibility of the data with the respective hospital information system (HIS).

[1] https://www.bvmed.de/de/recht/rechtsrahmen/eu-medizinprodukte-verordnung/eu-mdr-einfuehrung - [access 12.11.18].

[2] Creación de la comisión provincial de evaluación de nuevos productos y tecnologías y nuevas indicaciones de los mismos. Servicio Andaluz de Salud

https://juntadeandalucia.es/export/drupaljda/otras_disposiciones/16/05/SAS_0016_15.pdfhttps://juntadeandalucia.es/export/drupaljda/otras_disposiciones/16/05/SAS_0016_15.pdf [access 25/11/2018]

[3] http://www.sas.junta-andalucia.es/principal/documentosacc.asp?pagina=pv_bancopro_faq#faqp_1

[access 25/11/2018]

A HIS represents the entirety of all information-processing systems for the collection, processing and transmission of relevant medical data in a hospital. The data stored by the robot must therefore be able to be stored in encrypted form and sent.

Ideal, because time-saving, would be the direct storage of the data from the tests of the CGA directly to the respective HIS. However, due to the highly sensitive data in such a system, no hospital will allow access by the robot to its HIS. Therefore, the most practical interface for data exchange must be created, which on the one hand meets the requirements of data protection and on the other hand enables fast and secure data exchange.

2.9 Sourcing

The procurement of components for the construction of the robot must comply with the guidelines and standards of the EU-wide Medical Devices Act, which has come into force since May 2017. From May 2020, new medical devices may only be marketed under this new regulation.

For example, basic safety requirements for medical electrical equipment and electromagnetic compatibility guidelines, to name but a few, need to be considered.

In addition, the product we manufacture must also meet the hygienic requirements of a clinic, which means that the housing and touchscreen must be disinfectable.

Furthermore, the hardware components used must be electromagnetically compatible and should as far as possible pose no risk to, for example, a patient with a pacemaker.

Consequently, in the event of a planned market entry, the pilot lot must take into account all of these guidelines and standards when procuring the planned components

3. Market Analysis

3.1 General Forecast for Medical Service Robots

In general, digitalization and robotics are global trends. Professional service robots have already entered our daily lives. According to the IFR, their total sales volume increased by 39% to US$ 6.6 bn worldwide in 2017, in 2018 a growth of 33% to US$ 8.7 bn is expected.[4] Here, medical robots - as CLARC will be - are considered as “most

[4] https://ifr.org/downloads/press2018/WR_Presentation_Industry_and_Service_Robots_18_Oct_2018.pdf, page 19, [access November 2018].

valuable service robots”[5], with a sales volume increase of 75% in 2017 and high expectations for the coming years:[6]

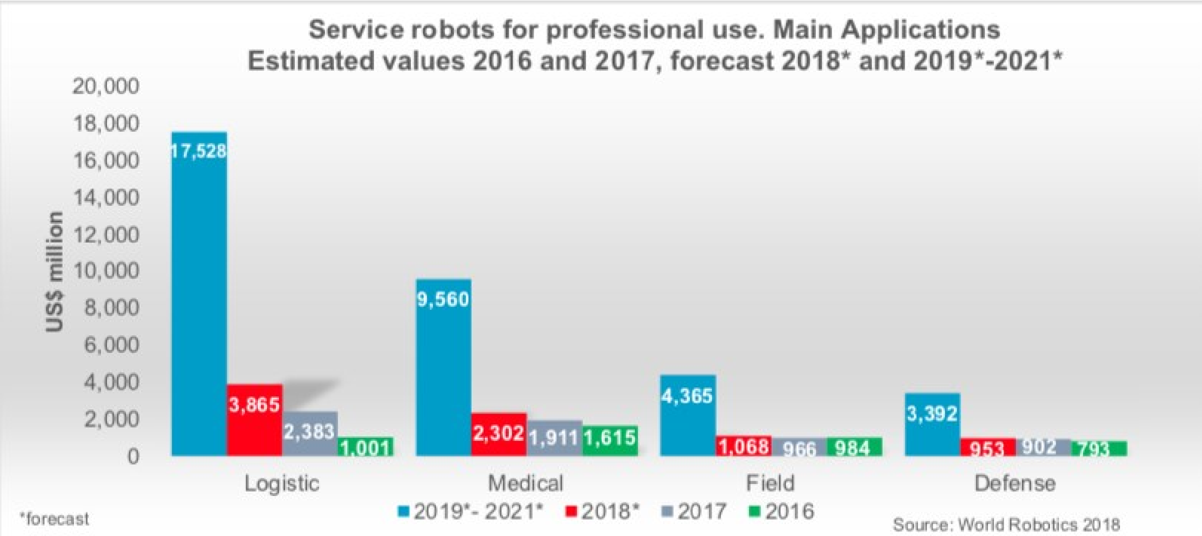


Figure 3.1 Growth of Medical Applications for Professional Service Robots.

In the following sections we describe the concrete local market sections in Germany and Spain to determine the amount of customers that need the services of CLARC.

3.2 Customer Segments

We see opportunities for use in clinics, in larger rehabilitation institutes and possibly even in large outpatient care institutes. In the following table we have summarized all possible applications. The possible uses are added to the reimbursement options in each sector and general conditions of use described. For example, when used in a neurological environment, the possible danger of falling in patients should be taken into account. This may involve limitations in the use of certain assessments, but other assessments could be integrated and used, and with them the time savings for the staff.

5 https://ifr.org/downloads/press2018/WR_Presentation_Industry_and_Service_Robots_18_Oct_2018.pdf, page 22, [access November 2018].

6 https://ifr.org/downloads/press2018/WR_Presentation_Industry_and_Service_Robots_18_Oct_2018.pdf, page 20, [access November 2018].

Definition of the Target Market Segment for Mobile Robots for Geriatric Basic Assessment			
	acute care hospitals departments	**outpatient or inpatient rehabilitation clinics**	**outpatient institution/ Centers in clinics**
applications	first acute phase after surgery or disease also specialist departments / centers at university hospitals (pre-hospital treatment)	after discharge from hospital or deterioration in quality of life -> geriatric (early) rehabilitation	for specific care in the sense of the family doctor system
reimbursement	DRG	Daily rates that the rehabilitation clinics individually agree with the statutory health insurance	Uniform rating scale (EBM) -> The benefits are assigned specific fees
Neurology			
specially:	depending on the degree of damage -> Use of the robot is not always possible without medical personnel (e.g. hemiplegia: Walking is restricted and with aids -> Danger of falling, Intellectual requirements of use could not be met due to the injury)		
generally:	Deployment to relieve the nursing / station staff must be specifically checked, can also be applied and used in parts (eg Get Up and Go only with therapists, the surveys while sitting in the presence of relatives WITHOUT staff possible)		
Orthopedics, Surgery, Internal Medicine			
generally:	Deployment to relieve the nursing / station staff must be specifically checked, can also be applied and used in parts (e.g. Get Up and Go only with therapists, the surveys while sitting in the presence of relatives WITHOUT staff possible)		

Table 3.1 Definition of market segments for CLARC.

Our primary customer segment are hospitals with geriatric departments. The robot will be a medicine device that requires certifications in each local target market. We will start with the European Union as a large internal market. Based on the locations and insights of the entrepreneurs of CLARC we decided to address the German and Spanish market at first. Due to the CLARC research project there are very good leads to sell the first robots in Spain, on the other hand we will focus on Germany as the biggest health care market in Europe.

3.2.1 Spain

In Spain, the population over 65 increased from 11.2% in 1981 to 17.3% in 2001 and reached 18.7% in 2015 (200,000 more elderly people from 1981 to 2015)[7]. It has been shown that the elderly population consumes more hospital resources because their morbidity and mortality rate is higher than other age groups[8].

[7] Las personas mayores en España. Datos estadísticos estatales y por comunidades autónomas. Imserso. 2017. http://www.imserso.es/InterPresent1/groups/imserso/documents/binario/112017001_informe-2016-persona.pdf [acces 24/11/2018]

[8] Geriatría XXI. Análisis de las necesidades y recursos en la atención a las personas mayores en España. Madrid: Sociedad Española de Geriatría y Gerontología. Editores Médicos, 2000.

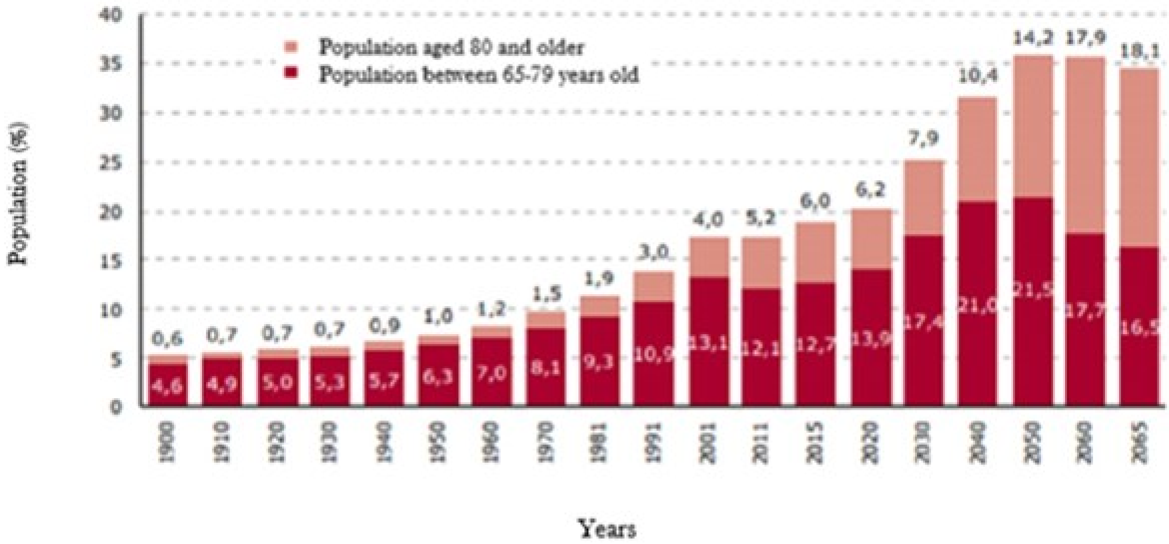


Figure 3.2 Evolution of the elderly population in Spain, 1900-2065 (%). Sources: 1900-2015: INE: INEbase: «Cifras de población. Resultados nacionales de población según sexo y edad desde 1900 hasta 2015». 2016-2065: INE: INEbase: «Proyección de la población 2016-2065. Resultados nacionales».

This increase in the elderly population requires the adaptation of the health system to the progressive ageing of society through preventive measures and the adaptation of hospital resources to the needs of elderly patients[9].

In Spain, practically every older people patients when they have an acute health problem are covered by the National Health System (approximately 98% of older people use public health when they need medical care)[10]. Even so, a certain group of the elderly population (15-20% of those over 65 years of age) needs more specific and continuous attention in order to solve the several problems they face, which tend to cause a high degree of incapacity and/or dependency. Therefore, the development of new evaluation models that allow a more effective and continuous follow-up will be of vital important for this age group.

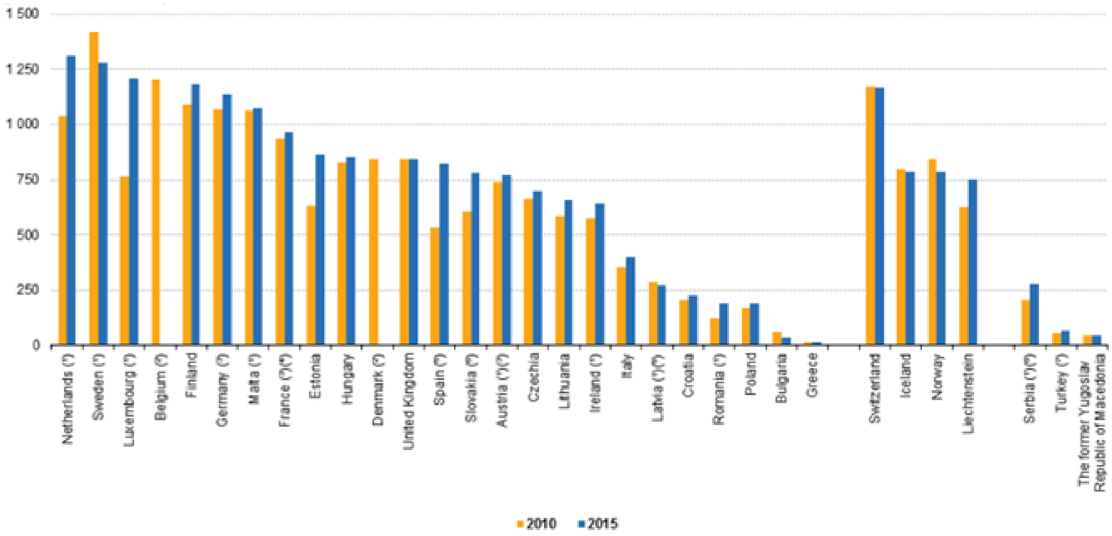
The most efficient and effective organizational model in elderly health care is the Geriatric Service, which may or may not be integrated into a general hospital. Despite the fact in 2003 the Spanish Society of Geriatrics and Gerontology published that only a

[9] O'Neill D, Wiliams B, Hastie I, en representación de la Sociedad de Medicina Geriátrica de la Unión Europea y División de Medicina Geriátrica de la Unión Europea de Médicos Especialistas. Retos, oportunidades y función de la asistencia sanitaria especializada en personas mayores. Rev Esp Geriatr Gerontol 2002;37:289-356.

[10] Análisis y evaluación de la red de servicios sanitarios dedicados a la dependencia: Programas de prevención, atención domiciliaria y hospitalización. Informe de la Sociedad Española de Geriatría y Gerontología. http://ibdigital.uib.es/greenstone/collect/portal_social/index/assoc/segg0021.dir/segg0021.pdf

[access 21/11/2018].

32% of Spanish hospitals provided specialized geriatric care[11], in 2018 it was published that Spain was the third European country with the greatest increase in the availability in long- term care beds in nursing and residential care facilities per 100.000 inhabitants (between 2010 and 2015)[12]. This notable increase in Spain is surpassed only by Luxembourg and the Netherlands.



Note: Cyprus, Portugal and Slovenia, not available.
(*) Break in the series.
(*) 2015: not available.
(*) 2011 instead of 2010.
(*) 2013 instead of 2015.
(*) Excludes beds for palliative care.
(*) 2014 instead of 2015.
(*) 2011 (estimate) instead of 2010.

Figure 3.3 Long-term care beds in nursing and residential care facilities per 100.000 inhabitants (2010-2015), Source: Eurostat, Statistics Explained.

The following table describes in greater detail the increase in the number of long-term care beds in nursing and residential care that took place in Spain between 2013 and 2015.

[11] I. Ruipérez, J. Midón, J. Gómez-Pavón, N. Maturana, P. Gil, M. Sancho, J.F. Macias. Adequacy of geriatric resources in Spanish general hospitals. Rev Esp Geriatr Gerontol 2003;38:281-287.

[12] https://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_resource_statistics_-_beds#Long-term_care_beds_in_nursing_and_residential_care_facilities

[acess 01/12/2018].

UNIT: Number **FACILITY:** Available beds in nursing and residential care facilities (HP.2)

TIME	2013	2014	2015	2016	2017
GEO					
Spain	371,064.00 (d)	377,920.00 (d)	381,333.00 (d)	383,995.00 (d)	:
Galicia	19,489.00	21,243.00	22,306.00	:	:
Principado de Asturias	14,775.00	14,881.00	14,564.00	:	:
Cantabria	5,543.00	5,597.00	5,639.00	:	:
País Vasco	17,964.00	20,466.00	20,054.00	:	:
Comunidad Foral de Navarra	5,821.00	6,580.00	6,621.00	:	:
La Rioja	3,039.00	3,072.00	3,218.00	:	:
Aragón	16,624.00	17,254.00	15,319.00	:	:
Comunidad de Madrid	50,889.00	52,087.00	52,245.00	:	:
Castilla y León	44,648.00	45,425.00	28,166.00	:	:
Castilla-la Mancha	25,821.00	27,579.00	45,783.00	:	:
Extremadura	13,072.00	8,843.00	12,878.00	:	:
Cataluña	63,089.00	64,000.00	64,334.00	:	:
Comunidad Valenciana	27,131.00	27,256.00	27,162.00	:	:
Illes Balears	5,328.00	5,452.00	5,516.00	:	:
Andalucía	42,913.00	43,560.00	44,219.00	:	:
Región de Murcia	4,949.00	4,632.00	3,194.00	:	:
Ciudad Autónoma de Ceuta (ES)	160.00	178.00	142.00	:	:
Ciudad Autónoma de Melilla (ES)	311.00	317.00	311.00	:	:
Canarias (ES)	9,498.00	9,498.00	9,662.00	:	:

Available flags:
b break in time series, **c** confidential, **d** definition differs, see metadata
e estimated, **f** forecast, **i** see metadata (phased out)
n not significant, **p** provisional, **r** revised
s Eurostat estimate (phased out), **u** low reliability, **z** not applicable

Special value:
: not available

Table 3.2 Long-term care beds in nursing and residential care facilities in Spanish regions. Source: Eurostat, Statistics Explained.

It should be noted that since February 2018 the Spanish Society of Geriatrics and Gerontology is committed to a significant improvement in this specialty. For example, all hospitals in Madrid will incorporate the specialty of Geriatrics in which it is not present yet. Specifically, they will be included through interconsultation and orthogeriatric care (fractures in the elderly) so that the portfolio of services is expanded.

About the number of geriatrics Hospitals, the National Catalogue of Hospitals reflects the number of specialised Hospitals by region. In the year 2017[13], it is determined that there are 118 geriatric and/or long-stay hospitals in Spain (including in this number both belonging to the public health system and to private companies or institutions). The next table shows that 83 of them was publics geriatric and long-stay hospitals and 35 of them correspond to private institutions.

[13] Catálogo Nacional de Hospitales 2017. https://www.mscbs.gob.es/ciudadanos/prestaciones/centrosServiciosSNS/hospitales/docs/CNH2017.pdf [acess 21/11/2018]

Functional dependence	Geriatric and/or long-stay Hospitals
National Health System	12
Autonomous Community	4
Deputation or Cabildo	6
Municipality	1
Other publics	12
Private Charity (Church)	7
Other private charity	23
Private non-beneficial	53
Total	**118**

Table 3.3 Number of geriatric and long-stay hospitals in Spain. Source: Catálogo Nacional de Hospitales 2017.

However, in addition to geriatric hospitals, it is in residential centers (collective accommodation for the elderly under different models) that the follow-up, assessment and treatment of this kind of patient is also developed. In July 2017, the CSIC (centro Superior de Investigaciones Científicas) published that 5378 residential centers coexisted in Spain[14].

As we have mentioned before, Spain is a country that in recent years has been allocating great efforts and resources, both in terms of infrastructure and human resources, to the development of the geriatrics area. In addition, according to what was published in The Annual Sustainability Report of the Spanish Federation of Healthcare Technology (Fenin) in 2017[15], the turnover of the healthcare technology sector in Spain invoiced 7,500 million euros, showing a growth of 3% over the previous year. This turnover has grown by 30% in the last five years.

[14] Informes Envejecimiento en red. Feb 2018. CSIC. http://envejecimiento.csic.es/documentos/documentos/enred-estadisticasresidencias2017.pdf

[access 25/11/2018].

[15] Memoria Anual de Sostenibilidad 2017 de la Federación Española de Tecnología Sanitaria. https://publicaciones-online.es/memoria-anual-2017/ [access 04/12/2018].

All these factors indicate that this is the appropriate period for investment in healthcare technology in geriatrics in Spain, as both the ageing of the population and investment in technological healthcare resources are experiencing exponential growth.

Finally, it should be noted that given the number of geriatric hospitals and residential centers, both public and private, and the evolution of the Spanish healthcare market we estimate that our sales may be around 150 robots.

3.2.2 Germany

According to the Federal Statistics Office, there are 360 geriatric departments in German hospitals in 2017[16]. The statistical analysis here refers to specifically in the field of geriatrics approved departments. An increase in the number of specialist departments / facilities is probable due to the current demographic development in Germany. In addition, departments in the field of neurology and psychiatry may also interface with geriatrics and may have additional potential for further sales.

The increasing number of geriatric departments is confronted with the acute shortage of skilled workers, so that in Germany, for some time, by means of tenders for research projects in the fields of care[17] and medical technology[18], innovative approaches to improving patient care have been sought.

A geriatric assessment is usually performed on at least one resumption and repeated annually. At the University Hospital Jena, for example, around 600 new patients are admitted every year to the Geriatric Department. At around 250 working days per year, this results in approximately 2.4 CGAs per working day alone for new admissions. If now the outstanding CGAs from the previous existing recordings are cumulated, it should surely result in 5-6 CGAs per day.

There is a complex reimbursement system in the German health care system for financing various treatment and examination methods. The aim is to be recognized by the statutory health insurance companies as the provider of an examination or treatment method. Thus, the service provided by a recognized examination or treatment method is financed or reimbursed by the statutory health insurance funds.

Prerequisite is the approval as a medical device within the EU regulatory area. In Germany, the type of reimbursement differs due to the division in outpatient and inpatient sector. In the inpatient sector, reimbursement is mainly via diagnosis related groups DRGs, which are discussed in more detail in the following paragraph, or admission as

[16] https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/Krankenhaeuser/Grunddaten-Krankenhaeuser2120611177004.pdf?__blob=publicationFile, page 26 [access 12.11.18].

[17] https://www.bmbf.de/de/technik-zum-menschen-bringen-149.html [access 12.11.18].

[18] https://www.bmbf.de/foerderungen/bekanntmachung-2010.html [access 12.11.18].

a "New Examination and Treatment Method (NUB)". In the outpatient sector, reimbursement is made via "Uniform Assessment Standards (EBM)".

The reimbursement in the inpatient sector takes place via so-called DRGs (Diagnosis Related Groups). Different cases are grouped by diagnosis and patients with similar costs are grouped together. For a reimbursement in the clientele of geriatric multi-morbid patients, the individual costs arising in the respective DRG must be considered more closely. Hospitals and rehabilitation clinics can also agree so-called additional charges with the respective payers, provided that they fulfill certain conditions.

A reimbursement of healthcare costs in Germany is not readily possible with a new examination and treatment method. A submission to the InEK (NUB template) must be made. [19]

Hospitals, which due to their content focus increasingly on receiving and treating geriatric patients, also generate higher costs due to the multimorbidity of patients (material resources, personnel costs, infrastructure). As this does not lead to a long-term structural imbalance, these clinics can negotiate these additional fees.

These additional fees are only paid to hospitals if they meet certain conditions. Hospitals specializing in the treatment of geriatric patients fulfill these requirements. However, these additional charges only cover the need for care due to the multimorbidity of the patients. The CGA assessment, in turn, is depicted in many primary diagnoses (DRGs). In order to calculate the savings from the use of the robot, the costs incurred by the personnel (CGA without robots) must first be charged. Due to the many key diagnoses (DRGs), this calculation is difficult and time consuming. An institute was tasked to determine these costs. Their results are shown as estimates and still pending. The institute relies on data that is reported to the InEK (Institute for the Remuneration System in Hospitals) for the quality assurance of the DRG system by specially selected hospitals in the whole of Germany.

Based on this database, the institute commissioned by us evaluated all DRGs reported to InEK for the position "Multidimensional Geriatric Screening and Minimal Assessment". Altogether, 224 hospitals in 395 departments reported a total of 12,651 times to have used this assessment. However, this information is based on clinics selected by the InEK, so it can be assumed that in the inpatient area in Germany as a whole, much more of this assessment will be used. Figure 3.4 shows the distribution of inpatient facilities that identified coding 1-770 as performance in 2016. This code refers to Multidimensional Geriatric Screening and Minimal Assessment.

[19] https://www.g-drg.de/Neue_Untersuchungs-_und_Behandlungsmethoden_NUB [access 19.11.18].

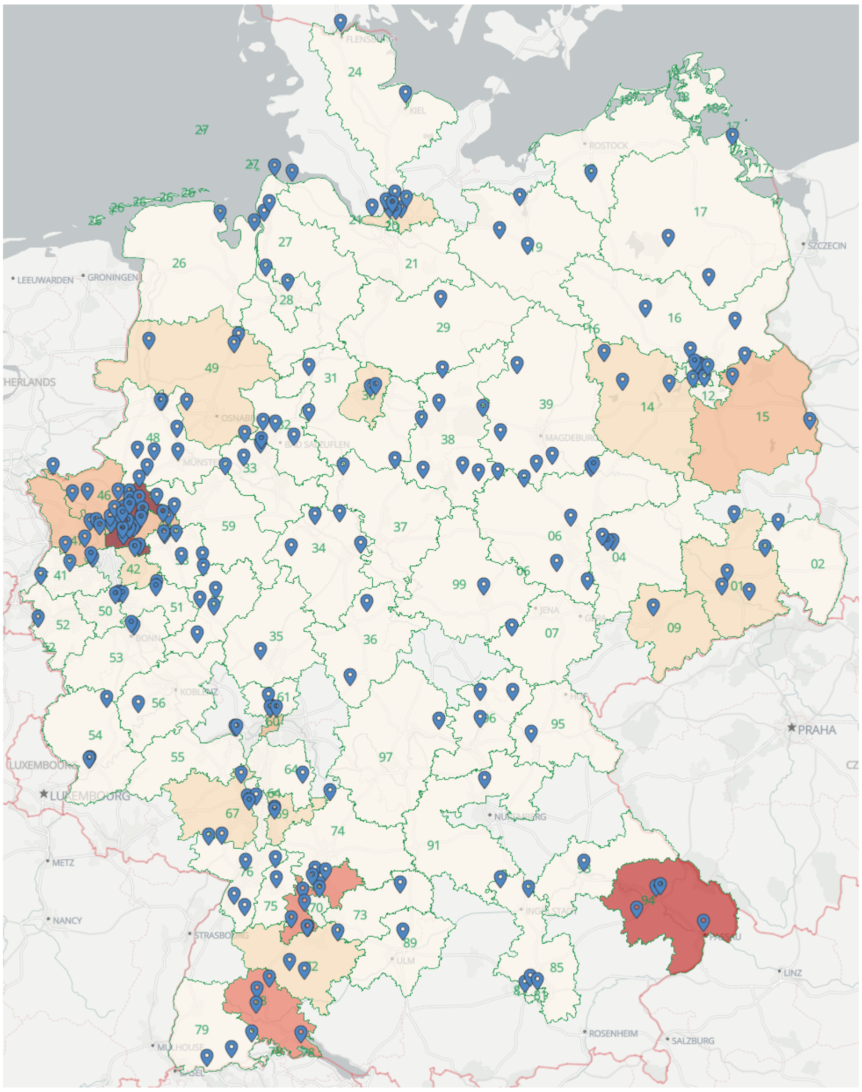


Figure 3.4 Distribution of DRG coding 1-770 in Germany. Source: Reimbursement Institute.

Hospitals in Germany can be run by both private and public providers. The term “private clinic” is used rather unevenly. In most cases, this refers to a clinic that is privately owned, not publicly owned. Private clinics, which finance themselves exclusively via the inpatient care of so-called self-payers or private patients, are also bound by the hospital fee law, if they are in close proximity to a public hospital and are associated with it organisationally. [20]For this reason, privately-owned clinics also participate in the care of patients with statutory health insurance.

The statutory health insured patients (GKV) make up the majority of the population and are therefore important for securing the income of the clinics. The following figure shows the proportion of the population in Germany in the statutory health insurance (GKV) in comparison to the privately insured patients (PKV). The GKV insured are divided into GKV members (about 50%) and non-contributory GKV insured (about

[20] https://www.pkv.de/themen/versorgung/krankenhaus/ratgeber-privatkliniken/ [access 10.12.18].

16%). Accordingly, the privately insured patients in Germany amounted to 8.75 million in 2018, in contrast to 72. 8 million statutory health insurance.[21]

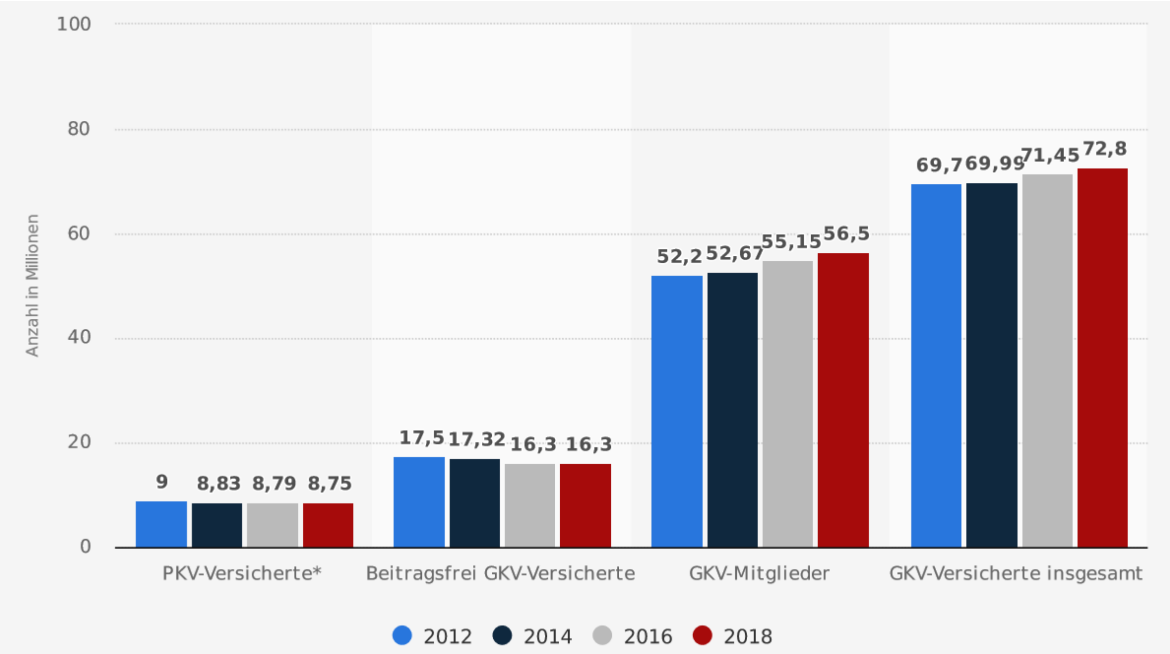


Figure 3.5 Proportion of the population in Germany in the statutory health insurance (GKV) in comparison to the privately insured patients (PKV).

The care of the geriatric clientele is independent of whether a clinic is privately or publicly owned. In addition, most patients are covered by the statutory health insurance system (GKV), through which most of the clinics secure their revenues. There is also a shortage of skilled workers in this area and we see great potential and demand here.

We assume that depending on the size of the clinics and the number of specialist departments within the clinics, we will sell 1-2 robots per system. According to our institute (395 specialist departments), we see in Germany alone a potential of about 400 robots sold in the inpatient area.

3.3 Competitors

First of all, there is no any other commercial solution that addresses the full framework for automatising the CGA. There is an increasing research towards the development of Socially Assistive Robots in Europe and other countries. The shown prototypes have demonstrated their great potential in multiple scenarios, however, most presented solutions do not include a proper evaluation of the interaction between the human and the robot, even though one of the biggest challenges of these approaches is precisely the design of this interaction. The following table shows the most relevant projects related to CLARC robot:

21 https://de.statista.com/statistik/daten/studie/155823/umfrage/gkv-pkv-mitglieder-und-versicherten-zahl-im-vergleich/ [access 10.12.18].

<table>
<tr><th>Projects</th><th>Goals / content</th><th>user group</th><th>Operating environment</th><th>Support of / time savings for:</th></tr>
<tr><td>ACCOMPANY</td><td>physical, cognitive and social support for everyday tasks</td><td>elderly people</td><td rowspan="6">domestic environment</td><td rowspan="6">Caring relatives, nursing staff

other medical personnel when using (video) calls in control centers by robots</td></tr>
<tr><td>HOBBIT</td><td>physical, cognitive and social support for everyday tasks</td><td>elderly people</td></tr>
<tr><td>SERROGA</td><td>Development of a "health robot" with communication assistance, reminder function and motivation to move</td><td>elderly people</td></tr>
<tr><td>Sympartner</td><td>Combining a mobile social robot with a smart home assistance system</td><td>elderly people</td></tr>
<tr><td>SIRMAVED</td><td>Using an intelligent and active environmental monitoring system and a social autonomous robot that provides interactive home stimulation</td><td>people with acquired brain injury or dependent people</td></tr>
<tr><td>DOMEO/ MARIO</td><td>Communication robot with the aim of physical activity and observation of users (emergency release)</td><td>Patients with cognitive deficits</td></tr>
<tr><td>ROREAS</td><td>Robot as a companion in gait and orientation training</td><td>people with acquired brain injury</td><td>Rehabilitation</td><td>Therapists</td></tr>
<tr><td>ROGER</td><td>Robot as a companion in gait training as well corrected and documented self-training</td><td>Patients after hip replacement TEP</td><td>Acute care clinic, hospital</td><td>Therapists</td></tr>
<tr><td>CLARC</td><td>Robot as a companion and supporter in conducting a geriatric assessment</td><td>geriatric patients</td><td>Clinics, rehabilitation and outpatient institutions performing the CGA</td><td>Therapists, nursing staff, physicians</td></tr>
</table>

Table 3.4 Overview of the most relevant projects related to CLARC robot.

All projects use a robot platform that supports and accompanies the target group, either in their home environment or in their respective environment, and interacts with the user in various ways. In all projects, the technical challenges are to recognize the environment and to cope with the task at hand (doors, obstacles, objects, fallen people, make an emergency call, etc.). While the project ROREAS and its follow-up project ROGER is more likely to support the therapeutic staff in the implementation and documentation of therapeutic exercises, CLARK is the only project so far that aims at supporting the medical staff in carrying out medical assessments.

The next table shows photos of the robot platforms for some of the presented projects.

DOMEO	**ROREAS / ROGER**
	
http://www.aal-europe.eu/projects/domeo/	http://www.roger-projekt.de/
SERROGA	**ACCOMPANY**
	
https://www.tu-ilmenau.de/fileadmin/media/neurob/publications/conferences_nat/2016/Gross-AAL-2016.pdf	https://www.aal.fraunhofer.de/de/projekte/accompany.html
SIRMAVED	
 MYRABot Evolution: Model I, II, III, IV	
https://gsyc.urjc.es/jmplaza/papers/caepia2015.pdf	

Table 3.5 Some photos of robot platforms of the presented projects.

- Besides, there are some mHealth applications mobile and/or tablet device developed to reduce the number of professionals in geriatric care, as:

- Geriatric Helper, has been developed to support access to up-to-date information because it is a pocket guide for conducting CGA. The goal of Geriatric Helper is reducing the workload for doctors and nurses but this application not interact with patients but only with physicians. The purpose is been tested in Portuguese health centers.
- iGeriatrics, designed to healthcare physicians and adding several of topics relating to older adults, from medication safety to cross-cultural assistance, but does not include information on how to perform CGA.
- PlusMED, pocket guide of medicaments where criterias can be consulted one by one or a search can be performed for a certain medication, medication class or disease, containing references for them.

The majority of this mobile applications are interesting to facilitate at health professionals the access to the medical guides and good uses of medicaments. However, they don't interact with seniors while the Socially Assistive Robots provide that added value, among other benefits.

An analysis of these proposals, and other Socially Assistive Robots projects, reveals that some existing Socially Assistive Robots solutions try to design not practical tools, but useful social companions. This ambitious objective is limiting the utility of proposed systems, as they require expensive platforms, complex safety considerations and too general design. The success of these solutions is also limited, as they usually fail in achieving long term acceptance and usability. On the other hand, Socially Assistive Robots that focus on very specific applications, such as the one presented in ROREAS, achieve much better results. The solution presented in the CLARC project align with these last approaches, as the proposed system is intended to be no more (and no less) than an useful tool to ease automation of CGA procedures.

In that sense, it should be pointed out that a recent study[22] to know the user's preferences between mobile devices and robots shows participants had more positive interactions with the robot compared to the computer tablet, including increased speech and positive emotion (smiling), and participation in the exercise proposed for the technological device. The results of the study suggested that elderly participants formed relationships with the robot had a better quality alliance than with the computer tablet. The authors attributed this findings to the physical appearance of the robot, which appears to have an integral role in determining a user's perceptions and adherence. Similar results have been reported in many research publications, in which the value of

[22] Cui, Y., Gong, D., Yang, B., Chen, H., Tu, M. H., Zhang, C., ... & Chang, P. (2018). Making the CARE Comprehensive Geriatric Assessment as the Core of a Total Mobile Long Term Care Support System in China. *Studies in health technology and informatics*, *247*, 770-774.

embodied robots over virtual agents are highlighted in many different aspects, as social influence and learning enhance, overall in special populations[23].

The communication robot KOMPAI was developed from the DOMEO project and further developed in the MARIO project. The company KOMPAI Robotics was founded as an independent company and sells the second generation of the robot since 2016[24].

SoftBank Robotics' Pepper robot has had an entertainment platform since 2015, which is used mainly in public buildings and facilities in Japan and, since 2016, in French stations for interacting with customers and providing information[25]. This robot is also used in a Japanese nursing home, for example, for the stimulation of simple gymnastic exercises[26]. It is likely that the potential of such a versatile robot platform continues to be researched, tested and developed. Consequently, the current research advantage should be used promptly for the development of a marketable product.

4. Business Case

4.1 Cost of the robot

The customer has either to pay a purchase price and an annual fee for support and maintenance or service fee per CGA. We decided to start with a subscription model to be able to grow faster since the customer has an extremely short payback period and the sales cycles for investment decision could otherwise be very long. In case the robot is able to perform a get-up, barthel and minimental test we suggest a fee per CGA of € 15. A further explanation to the price definition is given in the Appendix A.2.

The following table shows the potential costs of a hospital for the implementation and use of the CLARC robot depending on the number of CGAs performed with the assumption of € 15 per CGA.

23 Matarić, M. J., & Scassellati, B. (2016). Socially assistive robotics. In *Springer Handbook of Robotics* (pp. 1973-1994). Springer, Cham.

24 https://kompai.com/#about, [access 10.12.18].

25 Stiftung Münch (2018): Robotik in der Gesundheitswirtschaft, Einsatzfelder und Potenziale, S. 74

26 http://www.fr.de/fr-serien/mensch-roboter/roboter-serie-gymnastik-mit-pepper-a-1293851, [access 10.12.18].

The costs of implementing and using the Clark robot in the clinic								
Month 1 depends on number of performed CGA / day					**Month 2** depends on number of performed CGA / day			
initial costs for a hospital: **setup fee** (unique)	- 3.500,00 €							
Working days / month for medical staff:	22							
performed number of CGA/day:	**3**	**4**	**5**	**6**	**3**	**4**	**5**	**6**
costs for one CGA	15,00 €	15,00 €	15,00 €	15,00 €	15,00 €	15,00 €	15,00 €	15,00 €
total costs for number of CGA/day	**45,00 €**	**60,00 €**	**75,00 €**	**90,00 €**	**45,00 €**	**60,00 €**	**75,00 €**	**90,00 €**
total costs for number of CGA/month (22 working days)	- 990,00 €	- 1.320,00 €	- 1.650,00 €	- 1.980,00 €	**- 990,00 €**	**- 1.320,00 €**	**- 1.650,00 €**	**- 1.980,00 €**
Costs for Hospital including setup fee depending on the number of CGA	**- 4.490,00 €**	**- 4.820,00 €**	**- 5.150,00 €**	**- 5.480,00 €**				

Table 4.1 Costs for clinics through the implementation and use of the CLARC robot.

We expect about 6 CGA per day. According to a senior physician at the University Hospital Jena, about 2-3 new patients per day are admitted to the Geriatric Clinic. We have assumed that existing patients will be accumulated at regular intervals for these new admissions. Furthermore, the number of geriatric clients is increasing in the coming years. Thus, we currently expect a confident number of 6 CGA per day.

Furthermore, we assume that due to time constraints (absence of staff, difficulties in re-occupying due to a shortage of skilled workers) CGAs may not even performed in some clinics. Should the robot be able to prove in the other current functional tests that it can reliably support the personnel during execution, the adoption of 6 CGAs should not be unrealistic on the long run.

Assuming that a typical hospital has 1.500 CGA per year to be performed by the robot, the costs for the customer are then about € 22.000 € p.a. In addition we charge a setup fee of € 3.500. According to the amount and the extent of CGA per customer and year contracts and prices will be adapted.

Additional costs for the robot is for electrical energy consumption which is about 60 - 100 € per year.

4.2 Savings of the robot

To get an impression about the importance of the CGA and potential time savings we interviewed a doctor at the Universitätsklinikum Jena which also uses CGA. He said that it takes no more than an hour to complete this assessment. The physiotherapists perform the Timed Up & Go test and the Tinneti test, which takes about 15 minutes on average. The Barthel Index is collected by the nursing staff and also takes no more than 5 minutes. The time requirements depend on the level of training and experience of the participants. If one assumes that the robot reliably collects the necessary tests in the various areas and collects the results, then time savings would be:

+ For nurses: 5-10 min, Barthel Index is collected and documented by the robot. The advantage arises in storing of the data, the nurses do not have to deposit or record the value additionally, so no relevant information is lost.

+ Therapists: effective use of the therapists by performing the Get Up and Go test at a time that is independent of the presence of the therapist (requires a low fall hazard). The performance of the test is very objective through the documentation as a video. The collected measurements (walking speed, duration, number and size of steps) are objective and independent of the tester. The current tendency of skilled employees lack will also have a noticeable impact on therapists, so that the evaluation of the tests, irrespective of the presence of a therapist at the time of the survey, may in the long run be an advantage for the employer and result in job satisfaction for existing staff.
+ Physicians: time saving would have been around 60 min, if the questionnaire would be done.
+ However, during the CLARC project, it was decided to neglect and not implement this part of the CGA. Since there is this part of the CGA, especially in the medical field much time saving, it is recommended to complete the product and carry out functional tests in this area.

tests:	Get up and Go (Therapists)		Barthel-Index (Nurses)		Minimental (Physicians)	
Time spent on the tests and number of Pat./hour	In minutes	Number of patients / hour	In minutes	Number of patients / hour	in Minutes	Number of patients / hour
Performing the test **without** a robot	15	4	5	12	60	1
Performing the test **with** robot	5	12	1	60	15	4
Time savings per test through use of the robot (in min):	**10**		**4**		**45**	
Benefits	3-times the number of Pat. may be charged		5-times the number of Pat. may be charged		4-times the number of Pat. may be charged	
Time savings per hour for medical staff (in minutes)	40		48		45	
Time savings at, for example, 6 CGA / day	6*10Min=	**60 Min**	6*4Min=	**24 Min**	6*45Min=	**270 Min**

Table 4.2 Time savings for medical staff on the example of the University Hospital Jena and performing 6 CGA/day.

The following table shows the estimated savings in personnel costs, assuming that the facility performs 6 CGA per day.

occupational groups	**Salary per occupational group and year (Estimate!)**		**hourly rate (€ / h) Estimated at 220 working days per year and full time**	**Time Savings / day** by performing 6 CGA/day		**Saving hourly rate** by performing 6 CGA/day
physiotherapists	40.000,00 €	€/a	22,73 €	**60**	minutes /day	22,73 €
nurses	40.000,00 €	€/a	22,73 €	**24**	minutes /day	9,09 €
physicians	90.000,00 €	€/a	51,14 €	**270**	minutes /day	230,11 €
Total Savings by performing 6 CGA/day				**354**	minutes /day	**261,93 €**

Table 4.3 Savings in personnel costs by performing 6 CGA per day.

Based on the time savings by performing six CGA's a day, this will result in savings in personnel costs of € 261.93 per day. This means a monthly saving of € 5,762.46 (22 working days per month) and a saving of € 65,482.95 per year (250 working days).

Besides these obvious monetary savings, the use of the robot has also clear operational advantages. The robot picks up the patients in the treatment room at the agreed time regardless of the presence of the medical staff. This increases the satisfaction of the patient, because he does not have to wait and simplifies the spatial planning in the outpatient areas. The evaluation of the tests by the respective medical staff can take place at a later time in a relaxed atmosphere. This also avoids errors in the evaluation. The data are encrypted assigned to the respective patient and can also document the long-term course of treatment.

4.3 Additional Turnover

It is not easy to filter out the actual costs and revenues from the DRGs. In order to be able to assign a monetary value to patient cases or individual indications and procedures - ie the amount of the reimbursement - it is necessary to look at the true assignment to the diagnosis related groups (G-DRGs), the underlying costs and the resulting revenues.

For a valid and accurate presentation of the cost and revenue situation, it is important to set the right parameters. With regard to the use of the robot CLARC it was determined in advance which procedure encryption (OPS - operations and procedures encryption) the robot's use can be coded. According to the OPS classification, two OPS codes were eligible for the geriatric assessment:

+ 1-770 - Multidimensional Geriatric Screening and Minimal Assessment
+ 1-771 - Standardized Geriatric Basic Assessment (GBA)

The coding information of both codings define minimum features that must be fulfilled in order to be able to use the coding in everyday clinical practice:

+ 1-770 - The application of this code requires the investigation of at least three areas (such as mobility, self-help and cognition), which are examined using standardized measurement techniques.
+ 1-771 - The application of this code requires the investigation of at least five areas (eg mobility, self-help, mood, nutrition, continence, cognition and social situation), which are examined by standardized measurement methods.

The illustrated functions of the robot CLARC imply a total of three areas that can be covered by the mission. According to the coding information, therefore, the minimum characteristics for coding 1-770 are satisfied and used in our business case (Source: Reimbursement Institute).

In many large institutions that carry out CGA, one can assume that both sectors (outpatient and inpatient) are operated and also billed in both sectors. As a result, for larger facilities over a mixed-cost estimate, the cost of acquiring and implementing a robot could be worthwhile in any case.

For smaller facilities, the purchase of a robot should be relevant, especially because of the time savings for the staff. The documented results for the basic assessment (coding 1-770) provide time for an extended assessment (coding 1-771), provided that the robot records the basic assessment safely and reliably.

Then it will be possible for the staff to carry out an extended assessment and, on the one hand, to charge higher according to the service provided and, on the other hand, to provide this service with an increased documented quality with actually few resources.

4.4 Payback time

If you take the costs for the robot into account (15 € per CGA), the remaining savings for the clinic per day are 171,93 € - from day 1. If the clinic initially has to pay 3.500 € setup fee, the payback time for this is **about a month.**

5. Go-To-Market

To bring the solution into the market, we classified the challenges into those that are related to the product development, to the certification and to marketing & sales.

- **Development**

- Hardware engineering of the product based on the current prototype
    - Phase 1: Adapt the robot with medical proven components, e.g. touch display (2019)
    - Phase 2: Set up of two revised robots for tests (Q1/2020)
    - Phase 3: Test the new prototypes (Q2/2020)
    - Phase 4: Adapt the prototypes with findings of Q2/2020 and set up of 4 new prototypes (Q3/2020)
    - Phase 5: Pre-series production: 10 units in 2021 and preparation of small series production starting in 2022
- Development of algorithms for the person and motion detection to replace the Kinect sensor as the current main sensor for this (not available anymore, 2019-2020)
- Development and implementation of the minimental test (2019-2021)
- Implementation of data security standards to handle personal data conform to GDPR
- Improve the Graphical User Interface of the external tablet for robot-patient communication (2020, 12 person months) with
    - a more intuitive GUI enabling accessibility issues like sub-titles and audio-description and a more fashioned style.

    - wew videos explaining the different tests should be also recorded

Certification

- Official Request by BfArM Germany to identify the correct medicine class (2019)
- Implementation of a quality management system to fulfill the requirements for the production of medical devices (2019-2020)
- Certification of the quality management system (2020)
- Effectiveness analysis in preparation of the certification as a medicinal product (2020)
- Certification of the robot as a medical device (2021)

Marketing & Sales

- Increase the degree of awareness: Present the solution on important fairs and conferences (2020)
    - MEDICA 2019 and 2020, the the leading international trade fair for the medical sector (Düsseldorf/Germany in November): Application for the participation at the Start-up Park (€ 6k per event incl. travelling)
    - MEDICA 2021, 2022, 2023: Representative Booth with demonstration area (€ 50k incl. travelling)
    - Trade show in Spain (2020, 2021, 2022, 2023): 10k per event
- Creating website, social media activities, leaflets (2019, 10k, in the following years 5k)
- Public relation agency to increase awareness in relevant media (20k in 2019, 50k in 2020)
- Set up of contracts for the target markets (2020)
- Product presentations by field service employee in Germany and Spain, travelling costs in 2020 € 10k, 2021 € 10k, 2022 € 50k, 2023 € 100k)

After 2023 we plan to the internationalization and are going to start with other Western European countries since the product is certified for the European market in general and countries like France, United Kingdom, Denmark, the Netherlands have similar labor costs and expected savings. But, our analysis of the German and Spain market have shown us that each country has its own specifics in the reimbursement of the healthcare system, so we need to look in detail at each relevant country about the commercial barriers and real potential savings to the clinics.

6. Organization

6.1 Main contributors for the product development

The solution was developed within the subproject CLARC of the European project Echord Plus Plus. A Public end-user Driven Technological Innovation (PDTI) scheme offered R&D consortia the possibility to develop robotics technology according to the needs of public bodies. Two application areas have been identified: Healthcare and Urban Robotics. Various public bodies have submitted different challenges (technology needs) and out of this pool a panel of experts has selected one challenge for each scenario: Robotics for Comprehensive Geriatric Assessment (CGA) in the Healthcare scenario. The CLARC consortium won the challenge and developed the robot solution. The development consortium consists of the following partners:

UMA

The Integrated Systems Engineering Group (UMA-ISIS) of the University of Malaga[27] has developed the software architecture that manages the robot, including the working memory and the perceptive modules. The architecture is developed using RoboComp, but provides bridges to connect with MIRA, the middleware of the robot by MLAB and PELEA (UC3M). Moreover, the UMA team has built the keyboard adapted to elderly patients. UMA-ISIS was established in 1990 and its research topics include image processing, artificial and embedded vision, social robotics, sensor fusion and soft computing techniques (artificial neural networks, evolutive algorithms and fuzzy logic). It has a wide experience in previous European, national and regional projects related to autonomous robots, artificial vision and human-robot interaction. It also carries out an intense activity transferring knowledge to the industrial sector through different contracts and cooperative projects. In recent years, UMA-ISIS has been involved in projects and contracts related to develop Socially Assistive Robots, such as Adapta, Therapist or Lifebots. The group has focused on the design and development of the cognitive architecture of these robots, their perception systems and their interfaces with people.

UC3M

The software for the evaluation of the patients were designed and developed by the Planning and Learning research Group (PLG) of the Universidad Carlos III de Madrid. They also evaluated the human robot interaction. PLG research topics focus on Artificial Intelligence, specifically automated planning, machine learning, problem solving and their application in robotics. The group has a strong background in the use of Artificial Intelligence to develop the cognitive architecture of Social Assistive Robots and has participated in different projects with that role, as Adapta, Therapist, Lifebots or NaoTherapist, where kids are supported and monitorized to perform upper-limb evaluation and rehabilitation.

MLAB

MetraLabs is a German SME specializing in the development and in-house manufacturing of professional mobile robot platforms and complete service robot applications.

[27] The University of Málaga (www.uma.es) is a public university founded in 1972. In 2016 there were more than 36,000 students registered, in different courses from Bachelor's degrees to Doctorate studies. UMA has more than 250 research groups registered.

In total 250 service robots were produced. The core know how is the fully autonomous navigation in indoor environments - in commercial applications like stores, shopping malls, museums, industrial plants the robots have driven more than 80.000 kilometres. The company was founded in 2001, located in Ilmenau and has 15 employees. For CLARC MetraLabs has provided and adapted three mobile robots as a hardware and their autonomous navigation.

An important part of the development is the evaluation which was done by the Andalusian Health Service (SAS) and Troyes University of Technology (UTT-LL2A).

SAS

The Health and Biomedical Informatics R&D group of SAS has relevant experience in health informatics standards, clinical information modelling, interoperability, telemedicine, decision support, and natural language processing in Electronic Health Records, among others. The research group is currently involved in several EU-funded initiatives and projects. This group is located in the Biomedical Research Institute of Seville (IBIS) and VRUH, where other 35 basic and translational research groups also develop their projects within one of the largest Biomedical Research Institutes in Spain. For CLARC, this team provided the clinical information for the definition of requirements and use cases of the robotic platform. They performed the design of the communication between CLARC system and Information systems of the hospitals based on standards to ensure a secured data exchange. Furthermore, they are leading the pilot of the solution. The CLARC system are been validated in different scenarios such as specialized hospital, primary care center, residence, ambulatory, urban and rural health center, pensioner’s home center. The Andalusian Health Service (SAS) is in general an autonomous entity linked to the Ministry of Health of the Government of Andalusia. Its mission is to provide a quality public healthcare to citizens, while watching over its efficiency and optimal resource management. SAS fosters a network of integrated care services organized in order to ensure the accessibility of the population. There are 1.491 primary care centers, 29 hospitals and 84.706 employees. Virgen del Rocío University Hospital (VRUH) of Seville will be the hospital from this organization involved in the project.

UTT-LL2A

The ActivAgeing Living Lab (UTT-LL2A) of the Troyes University of Technology was created in 2013, specializing in the application domain which is the health and autonomy of elderly people, using a Living Lab and participatory design approach to design prevention, assistive and social interaction technologies. It is an interdisciplinary team currently composed of 7 PhDs (Social Sciences, Computer Science, and Biomechanics) and 3 research engineers (Ergonomics and Human Factors, Electronics). Since its creation, UTT-LL2A has been involved in several socially assistive robotics projects, whether in EU projects Accompany, Teresa, or more local partnerships: Kepa, Aloïs - in examining the social acceptability, usability, and interaction design. Besides the evaluation in a hospital in France, UTT-LL2A mainly designed the appearance of the robot centered on the users.

6.2 Exploitation strategy: Spin-off

MLAB wants to push the exploitation forward from now on and plans to set-up a spin-off in Germany focusing on robotics for the healthcare market. The company can start with a head count of 7 at the beginning:

- project manager,
- 2 software developers
- mechanical engineer
- engineer for documentation
- quality manager
- IT manager

and grow to 20 people in 2023

- project manager
- 4 software developer
- 2 mechanical engineers,
- engineer for documentation
- quality manager
- 4 mechanics
- operations assistant
- HR manager
- purchase manager
- 3 IT manager
- sales manager

7. Financials

For financial planning, we have made the following assumptions:

+ Due diligence of finance, recruiting of the team will take 6 months, we officially start with the product development in July 2019.
+ Development and certification will take 18 - 24 months, real sales will not start before 2021.
+ We will need 8 further prototypes for the development and certification of the product, bill of materials are calculated for the first 4 prototypes with € 15k, later with € 10k.
+ In 2022 we produce a small series of 10 units for the first pioneer customers for tests and promotion, bill of materials € 10k per robot.
+ We stay owner of the robots, the rented robots will be assets in our balance sheet, the consumables for the rented robots we depreciate the robots with a machine life of 5 years,

+ In 2023 we sell 25 robots per month, by end of 2023 we have 140 robots in operation.
+ Headcount starts with 7 at the beginning, raises up to 20 in 2023.

P&L planning

	2019	2020	2021	2022	2023
Sales Robots	0	0	10	50	100
Employees	7	12	15	19	20
Turnover	- €	- €	172.500 €	682.500 €	2.605.000 €
Consumables	30.000 €	70.000 €	- €	- €	- €
Gross Profit	- 30.000 €	- 70.000 €	172.500 €	682.500 €	2.605.000 €
Other operating income	- €	- €	- €	- €	- €
Costs					
Staff costs	258.750 €	938.625 €	1.107.750 €	1.252.125 €	1.293.375 €
Occupancy costs	50.000 €	100.000 €	100.000 €	100.000 €	100.000 €
Insurances	5.000 €	10.000 €	30.000 €	30.000 €	30.000 €
Certification & quality managment	100.000 €	200.000 €	110.000 €	20.000 €	20.000 €
Marketing & Travelling	40.000 €	120.000 €	120.000 €	140.000 €	200.000 €
Shipping costs	- €	- €	5.175 €	20.475 €	78.150 €
Depreciations	20.000 €	40.000 €	52.500 €	92.500 €	245.000 €
Other costs	30.000 €	60.000 €	60.000 €	60.000 €	60.000 €
Total costs	503.750 €	1.468.625 €	1.585.425 €	1.715.100 €	2.026.525 €
EBIT	**- 533.750 €**	**- 1.538.625 €**	**- 1.412.925 €**	**- 1.032.600 €**	**578.475 €**
+ Consumables for the rented robots	- €	- €	100.000 €	300.000 €	1.000.000 €
- Depreciations	20.000 €	40.000 €	52.500 €	92.500 €	245.000 €
Total Required cash	**- 513.750 €**	**- 2.012.375 €**	**- 3.472.800 €**	**- 4.712.900 €**	**- 4.889.425 €**

Table 7.1 P&L estimation for the next five years.

Main findings:

+ Required capital to develop and produce the robots is € 5m in the first 4 years
+ Break even is in Q2/2023.

We plan to collect the capital in two steps: Raising a Seed-round of € 2.5m beginning of Q3/2019, which is supposed to finance market entry of the robot and then, once the first robots are in the field, raising a Series A round with an amount of another € 2.5m. In January 2019, we already had some informal talks with a VC investor on the case who indicated that in the seed round, investors would typically demand 30-35% of the shares in the company, while once the product would have been approved and introduced into the market, investors would claim a further 15-20% of the company. So after the series A round, the investors would held about 50% of the shares of the company.

We discussed the valuation procedure with the VC and the statement was that only rule-of-thumb approaches are used here based on a tradeoff between keeping the founders motivated versus receiving a significant stake in the business that allows them a return of 5-10x their investment. Given our turnover estimation of € 17m in 2026, we are in this range and consider the projections of the VC to be realistic.

8. Intellectual Property Rights

A Freedom to Operate (FTO) analysis has yielded that no relevant intellectual property rights that the Consortium’s solution would infringe upon.

The prevalent corpus of intellectual property with respect to robotic devices in health care and/or medical applications falls within the groups of **tele-operated or remote controlled mobile devices** (such as US8849679, WO2004065073 or US20080255703) or **robotic arms** (such as US20110190790, WO2012131658 or US20160030116).

The few existing patents claiming non-tele-operated (i.e. autonomous) mobile robots in medical applications can be clearly differentiated from the our solution. In summary, existing patents cover different spectrums of robotic devices in medical applications, though there is none that can be applied to our solution.

It is planned to protect parts of the developed solution with a European patent. An investigation about that starts in January 2019.

9. Risk Overview

9.1.1 Technical Risks

Risk description	Severity 1..5	Impact	Avoidance / Mitigation
Robot not accepted by the elderly	5	No turnover	Already proven in short-term user trials
Microsoft Kinect 2 sensor with a complex software framework that was used so far is not delivered anymore and need to be replaced	4	Person and movement tracking is not possible, robot not useable	Check for alternative sensors and frameworks until the start of the product development
Minimental test cannot be done by the robot	3	Savings of the customer are much less	Reduced subscription fee and margin

Robot not robust and not autonomous enough	2	Too many manual interventions, unsatisfied customers	Use proven state of the art components, MetraLabs autonomous navigation solution already proven in 80.000 km commercial applications
Some components of the current robot prototype, e.g. the display, are not usable for a medical device and need to be replaced	1	Certified components are more expensive	Search for compatible components

Table 9.1 Main technical risks.

9.1.2 Commercial Risks

Risk description	Severity	Impact	Avoidance / Mitigation
Subscription model not accepted by the customer	5	Loss of profit	Change to a purchase model, offer purchase as an alternative
Effort in the certification of the product and the development and production processes exceeds the budget	4	No sales, break even will be later, increased time to market	Work on certification, technical documentation from start of the product development
Subscription price too high	3	Loss of profit	Offer several subscription fees based on potential savings
Long sales circles in case of investment decisions	2	No turnover	Should be already be reduced by the subscription model
Competitors enter the market	1	Less sales	Certification as a medicine product is a general high market barrier for new players

Table 9.2 Main commercial risks.

9.1.3 Conclusion

In general, the investment starts does not start after a concept phase, but in a quite advanced stage of the product development. The technical feasibility, the autonomy of robot and its acceptance was already shown in short time real users test during the research project CLARC. So, it is mainly to bring a proof-of-concept into a reliable, certified product. However, the devil is in the details to bring to a level of long-term reliability and long-term acceptance. We identified the need of the replacement of an important sensor as one of most technical risks, but we already have a list of potential substitutes and be sure that strong 3D sensors will be available in the century of robotics and autonomous driving. In terms of commercial risks, we think that the acceptance of the subscription model and the effort in certification are the most important. A subscription model is probably not the most established way in selling medicine devices, but it generates the most profit on the long run and it should convince skeptics to try an interactive autonomous service robot.

10. Appendix

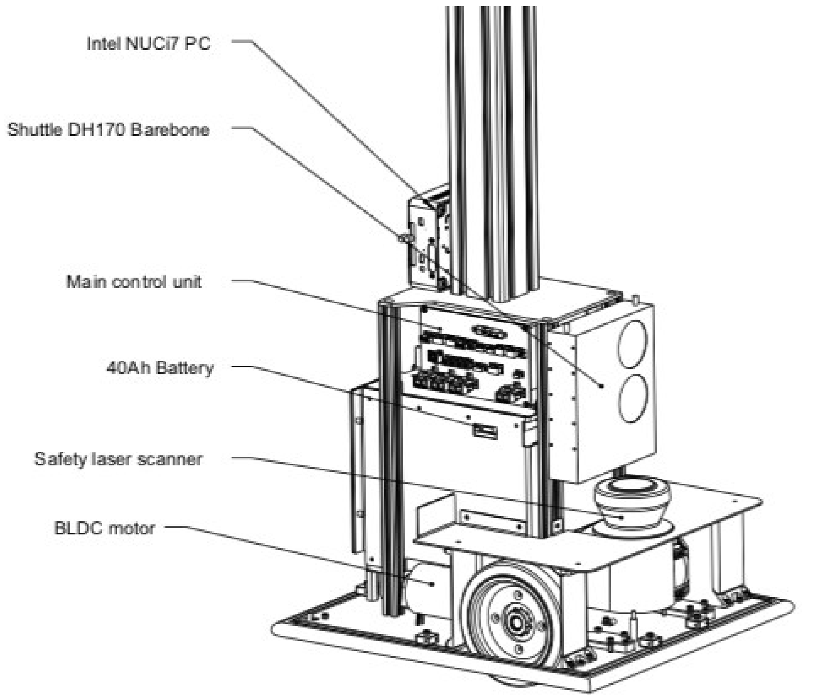
10.1.1 Technical Details

10.1.1.1 Robot

The robot is based on a differential driven platform by MetraLabs. Main components are:

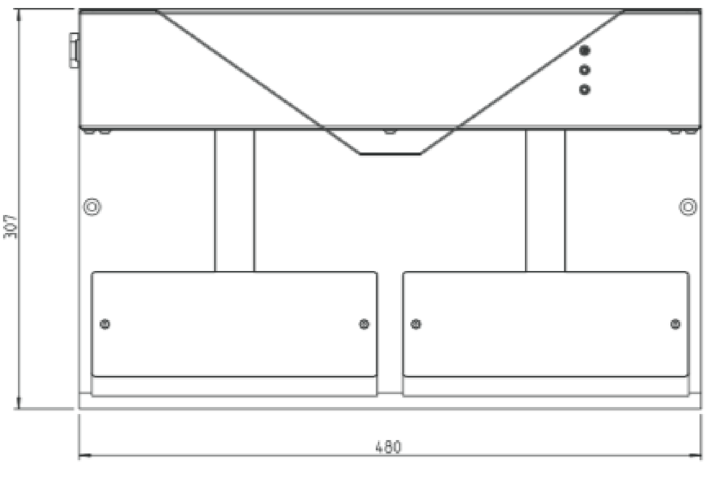
+ The motors & gearboxes
+ MetraLabs HG4 main control unit: safety motor controller and power supply, battery charging
+ Battery 40 Ahrs
+ Bumper: Stops the robot in case of collision
+ Safey LIDAR: measures distances to walls for orientation, measures distances to obstacles to avoid collisions, reduces the velocity of the robot if it is close to a person
+ Embedded PC Shuttle DH170: Linux based PC for navigation of the robot
+ Embedded PC Intel NUC: Windows based PC for the software application, person detection, speech recognition
+ Microsoft Kinect2: Sensor for motion detection
+ Network camera Edimax IC-3115W WiFi
+ Webcam Logitech C310 HD Logitech
+ Soundkarte USB 2.0 ROCCAT: Converts USB to Microphone
+ Display 13,3" with PCAP-Touchpanel
+ Microphone
+ Speakers

The structure of the mobile platform with the main components is shown in the following figure:



10.1.1.2 **Charging Station**

The robot has a charging station to be able to charge autonomously. The charging station is powered by standard main supply. In case of charging the power output is 400 W.



10.1.2 Price definition

We have derived the € 15 on calculations of the Reimbursement Institute for the relevant case-based lump sums (DRG). We asked the Reimbursement Institute to list the personnel costs for all relevant case-based lump sums and got a list of 153 DRGs. An extract from this is shown in Table 4.1. As an example in number 1) F62C: Personnel costs in total of € 89.30 have been incurred by the interviewed hospitals in the cost center "Other Diagnostic/Therapeutic Areas" for this special DRG. In this cost center, the cost of collecting a CGA can be mapped, as well as costs for an ECG or EEG. In another DRG, for example in the G67C (order number 8), costs in this area in the amount of € 30.35 were incurred.

These costs have formed the basis for the negotiations of the clinics with the statutory health insurance companies to the proceeds in 2018. The agreed revenues for 2018 are shown in the revenue matrix. Our listing of all 153 DRGs contains only 3 DRGs with total revenue for personnel costs below the estimated € 15 per CGA charge, so we are confident that this fee will be well-funded through a mixed cost estimate for the clinics.

DRG					Cost matrix 2016					Revenue Matrix 2018				
total Nominations:			2749	100%	11. Other diagnostic / therapeutic areas					11. Other diagnostic / therapeutic areas				
current number	DRG	description	Nominations	%	1. Personnel costs medical service	2. Personnel costs Nursing service	3. Personnel costs function Service/Therapists	DRG total cost	Total personnel costs within the DRG	1. Personnel costs medical service	2. Personnel costs Nursing service	3. Personnel costs function Service /Therapists	DRG total revenue	Revenue Personell costs 2018 witin DRG
1	**F62C**	Heart failure and shock without extre	257	9,35	49,49 €	0,32 €	39,49 €	2.522,49 €	**89,30 €**	58,51 €	0,38 €	46,68 €	2.943,74 €	**105,57 €**
2	**F71B**	Non-severe cardiac arrhythmia and c	102	3,71	51,15 €	0,33 €	44,16 €	1.346,33 €	**95,64 €**	60,47 €	0,39 €	52,20 €	1.581,09 €	**113,06 €**
3	**I68D**	Not surgically treated illnesses and in	85	3,09	13,21 €	0,20 €	11,63 €	1.714,90 €	**25,04 €**	15,62 €	0,24 €	13,75 €	2.011,03 €	**29,61 €**
4	**F67D**	Hypertension without complicated dia	75	2,73	44,10 €	0,18 €	33,91 €	1.419,68 €	**78,19 €**	52,13 €	0,21 €	40,09 €	1.667,77 €	**92,43 €**
5	**I08F**	Other interventions on the hip joint a	74	2,69	6,48 €	0,13 €	6,34 €	5.622,13 €	**12,95 €**	7,66 €	0,15 €	7,50 €	6.521,99 €	**15,31 €**
6	**F49G**	Invasive cardiological diagnosis excep	68	2,47	46,56 €	0,46 €	34,65 €	2.106,15 €	**81,67 €**	55,04 €	0,54 €	40,96 €	2.451,38 €	**96,54 €**
7	**K62B**	Various metabolic diseases in para- /	68	2,47	28,81 €	0,30 €	20,49 €	1.901,81 €	**49,60 €**	34,06 €	0,35 €	24,22 €	2.215,60 €	**58,63 €**
8	**G67C**	Esophagitis, gastroenteritis, gastroint	66	2,4	18,36 €	0,16 €	11,83 €	1.405,01 €	**30,35 €**	21,71 €	0,19 €	13,98 €	1.646,97 €	**35,88 €**
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
153	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Table A.1 Excerpt from the list of costs within the G-DRGs. Source: Reimbursement Institute.

The following table shows the potential costs of a hospital for the implementation and use of the CLARC robot depending on the number of CGAs performed with the assumption of € 15 per CGA.

10.1.3 Further Commercialization for the outpatient sector

While the above figures from the inpatient sector suggest a positive payback time, a different model needs to be chosen for the outpatient sector.

+ The settlement of the services to be provided there is based on so-called uniform valuation standards (EBM). According to the Reimbursement Institute, the currently valid EBM catalog includes the encryption of the "GP-Basic Assessment" service with the key number 03360. The obligatory service content includes:
    + personal doctor-patient contact,
    + Collection and / or monitoring of organ-related and overarching motor, emotional and cognitive functional limitations,
    + assessment of self-care abilities using standardized, scientifically validated test methods (eg Barthel Index, PGBA, Lawton / Brody IADL, geriatric screening according to LACHS),

+ Assessment of mobility and danger of falling through standardized test procedures (eg timed "up & go", tandem stand, Esslinger fall risk assessment).

The outpatient facility just receives € 13.00 for this service. However, investments in this area can be contrasted with these services. As a result, in the outpatient sector, the number of services provided per CGA could be compared to the acquisition costs for a robot. At a cost of 15,000 € per robot and about 600 CGA / year, the purchase would be amortized after 2 years.

In summary, calculating the time savings of implementing a CGA using a robot is already optimistic. All the expenses of a stationary facility through the purchase of a robot were compared to the time saved by the medical staff in the form of staff costs. It turns out that the payback period can be reached quite quickly.