CogWatch – Cognitive Rehabilitation of Apraxia and Action Disorganisation Syndrome

D5.3.2 Exploitation Plan II

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EXECUTIVE SUMMARY

This document presents the final exploitation plan for the two CogWatch Prototypes. The final exploitation plan is an update of the initial plan and based on analysis of the market (e.g., stroke patients, cognitive rehabilitation practices, competitors) as well as the sales and marketing strategy. Even though there is a look at potential of the global market, more focused analysis is provided for Spain and the UK since commercial partners can offer a more valuable insight into Spanish and UK medical devices markets and stroke care.

The first section summarises the final CogWatch Prototype describing its architecture and components outlining the main advances and innovations achieved during the second development phase.

The second section describes the main users of CogWatch from a functional rather than market perspective, therefore providing the reason for developing CogWatch. This section remains the same with the initial exploitation plan.

The third section provides an analysis of CogWatch's potential market. This analysis includes information about the users, regulations for medical devices, current cognitive rehabilitation practices and competitors. The competitors section has been updated with the entry of two commercially available cognitive rehabilitation platforms. The platforms are briefly reviewed and compared against CogWatch. It is shown that while the potential market is significant there are no major commercial competitors.

In the fourth section, an update of the initial estimate about the costs of deploying CogWatch in a healthcare setting, including purchasing and service/support costs is presented. A multidimensional framework of development, financing and organizational activities that can be potentially used to set up and run a business plan, is outlined. It is argued that a successful marketing strategy should be based on evidence about clinical effectiveness, satisfaction of regulatory requirements and cost-effectiveness. An updated estimate of the competitiveness of CogWatch is provided based on the 'headroom' method and the estimated costs of the basic CogWatch system. A SWOT analysis is also updated followed by issues and actions related to IP.

In Section 5, partners report progress on their individual exploitation plans defined in D5.3.1. This includes individual activities within their operational sectors as well as collaborative activities.

The report reinforces the conclusion that, at least in the UK market, CogWatch can potentially be a very promising and cost-effective solution for personalised home-based cognitive rehabilitation.

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REVISION HISTORY

Revision no.	Date of Issue	Author(s)	Brief Description of Change
V4	20 May 15	C Giachritsis	Compile deliverable
V4a	21 May 15	M Pastorino	Update UPM exploitation plan
V5	22 May 15	A Wing, W Chua	Update partner plans, editing
V6	25 May 15	A Wing	Harmonisation of final prototype system description

LIST OF ABBREVIATIONS AND DEFINITIONS [REVIEW]

Abbreviation	Abbreviation
AADS	Apraxia and Action Disorganisation Syndrome
ADL	Activities of Daily Living
B2B	Business-To-Business
B2C	Business-To-Consumer
CCGs	Clinical Commissioning Groups
CLEAR	Clinical Leading Environment for the Assessment and validation of Rehabilitation protocols for home care
COACH	Cognitive Orthosis for Assisting with aCtivites in the Home
CONTRAST	Cognitive Enhancement Training for Successful Rehabilitation After Stroke
CSUs	Commissioning Support Units
DALYs	Disability-Adjusted Life Years
DEM@CARE	Dementia Ambient Care
DOH	Department of Health
HES	Hospital Episode Statistics
MDD	Medical Devices Directive
MDT	Medical Devices Technology
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Care Excellence.
OECD	Organisation for Economic Co-operation and Development
POMDP	partially observable Markov decision

	process
TRL	Technology Readiness Level
QUALYs	Quality-Adjusted Life-Years
WTP	Willing To Pay
ZET	Zero Effort Technologies

1. INTRODUCTION TO COGWATCH

The CogWatch project has generated two main outcomes: first, the advancement of scientific knowledge about *Apraxia* and *Action Disorganisation Syndrome* (AADS) and, second, the development of a personalised ICT system that offers cognitive rehabilitation to stroke patients suffering from AADS. Both scientific knowledge and technology has strong potential to be exploited by the beneficiaries in order to gain a competitive advantage within their operating sectors.

1.1 The CogWatch Concept

CogWatch is an ICT system with two main purposes: first, to provide personalised *cognitive rehabilitation* to stroke patients suffering from AADS and, second, to provide health professionals with the tools that will enable them to *monitor the progress* of individual patients and revise their rehabilitation course, whenever necessary, in order to improve the rehabilitation outcome.

The CogWatch system includes instrumented common objects and tools, wearable and ambient sensors that are part of patients' everyday environment and can be used to monitor his/her behaviour as well as providing cognitive cues to guide action and/or correct task related error in order to complete ADL tasks successfully. Figure 1 shows the CogWatch concept and Figure 2 shows how CogWatch action monitoring and intervention will work.

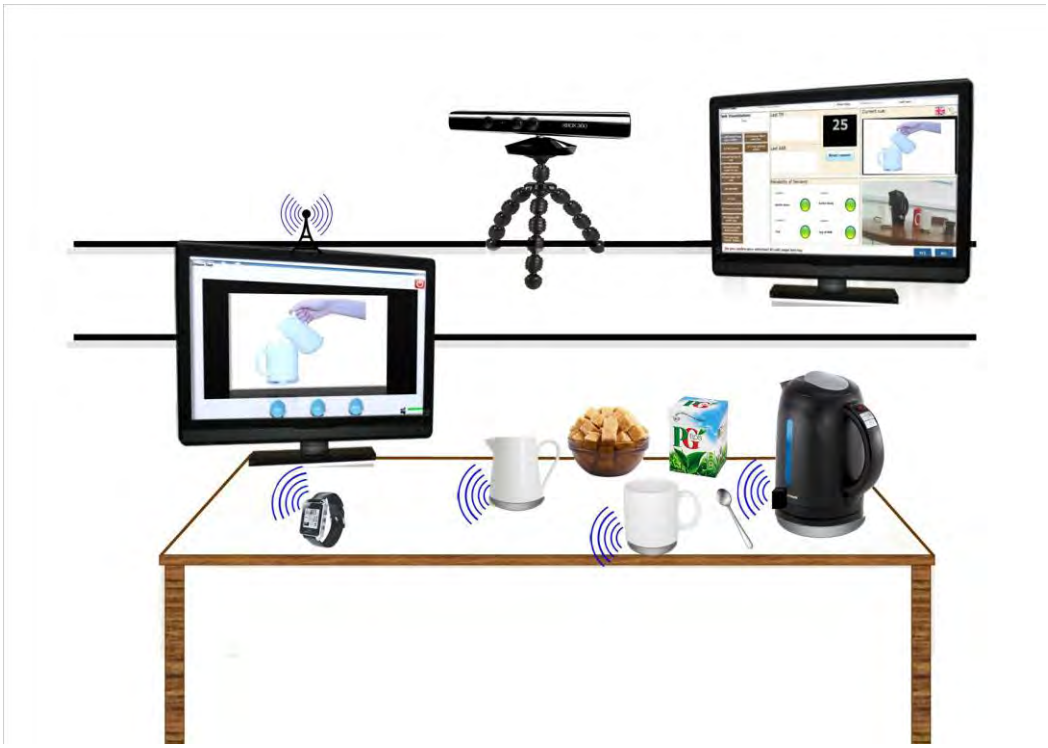

Figure 1: The CogWatch concept.

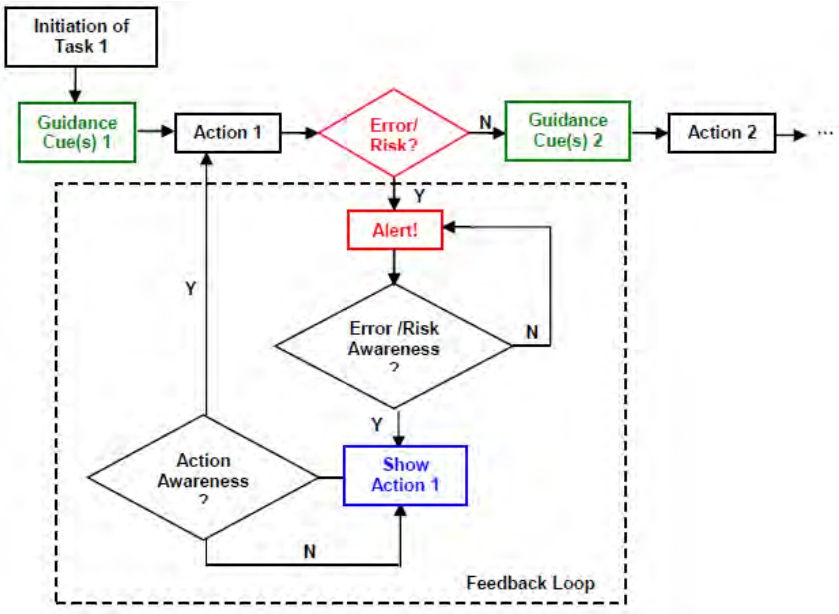

Figure 2: Schematic representation of the CogWatch action monitoring and intervention.

1.2 Final Prototype

1.2.1.1 Global Architecture

The final CogWatch architecture was designed during the development of Prototype 2 (tooth brushing) and was based on the central subsystems of Prototype I: the *CogWatch-Client* and the *CogWatch-Professional*. The *CogWatch-Client* subsystem is responsible for allowing the patient to select the ADL task for execution, monitoring patients' actions during ADL tasks and providing guidance and/or error-correction cues that will enable AADS patients to compete the ADL task successfully. The final architecture is *flexible* and *expandable* enabling the integration of additional heterogeneous sensors that can extend the range of ADL tasks for cognitive rehabilitation. In the final version (Prototype III) of CogWatch (see Figure 3), the *CogWatch Client* supports both Prototype I (tea making task) and Prototype II (tooth brushing). The *CogWatch-Clinician* subsystem is responsible for monitoring rehabilitation progress in the selected ADL task. The *Configuration module* is responsible for session management (eg through the cue designer). Data from the rehabilitation sessions are stored in the *Healthcare Server subsystem* for statistical analysis that will be used to advance knowledge of the AADS and rehabilitation practices as well as improve the CogWatch system (Figure 3).

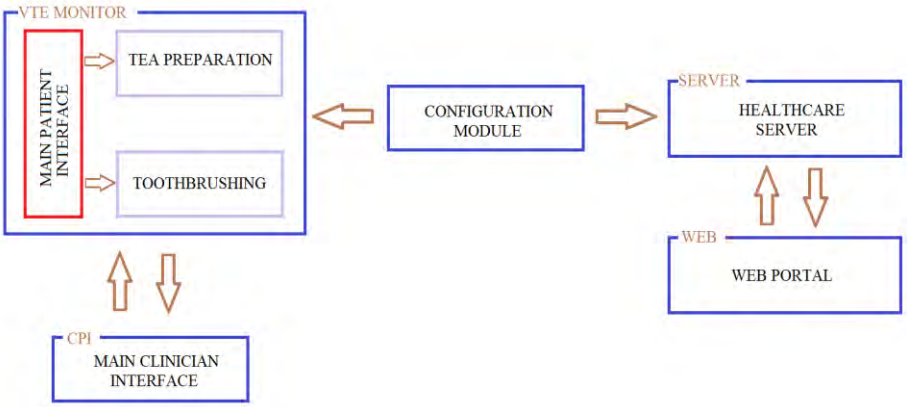

Figure 3: The final global architecture which was designed during the development of the second Prototype (tooth brushing). The architecture is flexible and expandable and can be used for the integration of heterogeneous sensors.

1.2.1.2 System components

The final prototype consists of two main sets of components: the *core* components and the *ADL-specific* components. The *core* components are installed both at *patient* and *clinician* sides and include: the client Gateway (all-in-one home PC), the Metawatch, and the clinician PC (upgrades may include RAM for servers and External HDs). The core components support the patient and clinician interfaces for executing and monitoring the progress of the task, respectively (Figure 4). The *ADL-specific* components depend on the task that the patient will need to retrain and are installed at the *patient-side*. If the patient needs to be retrained in tea-making then *patient-side* will also include the following components: sensorised mug, teabag container, sugar bowl, sensorised milk jug, sensorised kettle and Kinect (Figure 5). If the patient needs to retrain in tooth brushing then the *patient-side* will also include the following components: sensorised cup, a wrist-worn shimmer, a Kinect and a LEAP sensor (Figure 6). For more details see D2.2.1, D2.2.2, D3.2.1 and D2.3.2.

Figure 4: The *patient-side* interface displaying selection of task and cue for feedback (left) and the *clinician-side* interface for monitoring progress of task.

Figure 5: The patient-side components for retraining patients in tea-making: 1) sensorised mug; 2) waste tea bag bowl 3) tea bag bowl 4) sensorised milk jug; 5) sensorised kettle; 6) Kinect

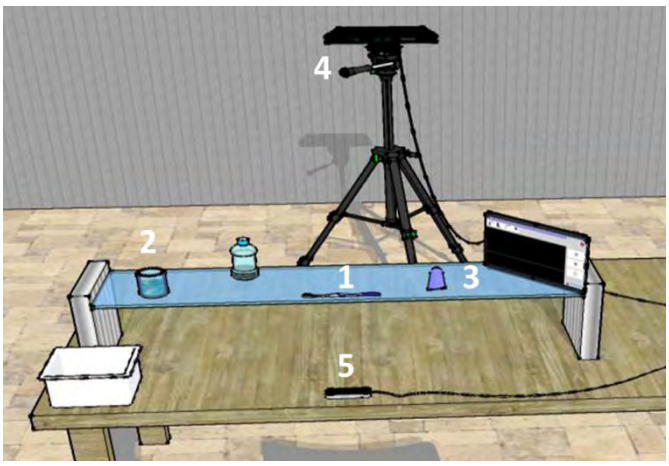

Figure 6: The *patient-side* components for retraining patients in tooth brushing. 1) sensorised brush; 2) sensorised cup; 3) toothpaste; 4) Kinect; 5) LEAP.

In addition, the CogWatch system includes provisions for monitoring the physiological status of the patient in terms of e.g. blood pressure with the intention of allowing the clinician to assess risk of future stroke episodes. Figure 7 shows the physiological modules that have been developed as part of the Prototype I.

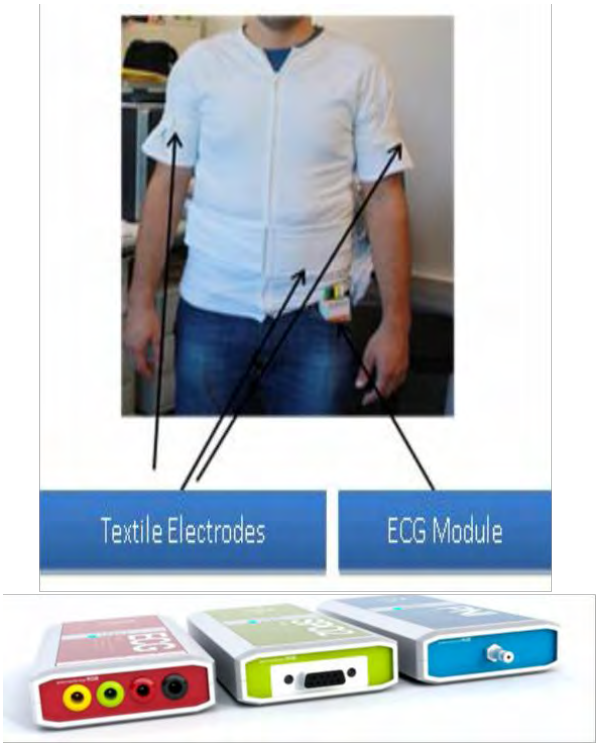

Figure 7: The new design of the physiological modules.

1.2.1.3 Cost

Since CogWatch is designed to meet the rehabilitation needs of individual patients, it will be highly customisable and personalised and therefore the total cost of purchasing and installing the whole system will vary. Moreover, the cost will also depend on the design of the components and the instrumented objects. For example, designing a series of objects that can accommodate one size sensors could significantly reduce the development and maintenance costs. This exercise was undertaken by BMT who produced an instrumented mug for dissemination and exploitation purposes (it was not an integrated working component of the CogWatch prototype). The design included the *one-size-fits-all* electronic module concept which was filed on 24 November 2014 (UK Patent Application No: 1420858.1). The electronic module is enclosed in a rubber case which can be easily removed with one hand so that the mug can be placed in a dishwasher (the rubber enclosure can also be made waterproof). In addition, the electronic module can be recharged using an induction recharger base (Figure 8).

Figure 8: The one-size-fits all electronic module concept (top). The electronic module can fit a series of objects that can be used for drinking and eating ADL tasks. The electronic module is enclosed in a rubber case which can easily be removed with one hand to allow the mug to be washed in a dishwasher and it is rechargeable through induction (bottom).

There are several advantages of this design. First, the *one-size-fits* all concept can help keep production and maintenance costs down since the manufacturer will need to produce a single electronic module to fit multiple objects. Moreover, the user can easily replace either part of the device (sensor or mug) independently reducing the costs of maintenance. For example, if the mug breaks then the user can order a mug replacement rather than the whole set. Similarly, if the electronic unit breaks it can order just the electronic unit or replace it from another object that he/she does not use very often. In this case, the recalibration of the coupling between the electronic module and the object would be achieved through the detection of the different weight of the object. Second, the one-hand removable electronic module means that hemi-paretic patients can also detach it from the mug. Third, the detachable electronic module increases the practicality of the mug since it can be placed in a dishwasher. Fourth, the unit is easily rechargeable through an induction base (similar to electric toothbrushes). A specially designed recharging base can be produced to recharge objects when not in use. Finally, the instrumented objects look and feel like ordinary objects, avoiding stigmatisation of the patients. Figure 9 shows the ceramic version of the one-size-fits-all concept mug which was exhibited during the UK Stroke Forum UKSF2014 in Harrogate, UK.

Figure 9: The final demonstrator of the one-size-fits-all concept coupled with a useable ceramic mug next to the sensorised toothbrush fitted with a shimmer sensor. From the exhibition at the UKSF2014 in Harrogate, UK.

Taking into account the development costs of the one-size-fits-all concept we can calculate an estimate of the total production costs for a basic CogWatch system which includes the core components and components to retrain the patient in the tea-making task. (see Table

1). The costs of the basic CogWatch unit will be used in Section 4 to provide the economic evidence necessary to show that a CogWatch system could potential be a viable business proposition as well as an affordable ICT cognitive rehabilitation system.

Table 1: Estimated breakdown of development costs for the CogWatch system

Core System	**Unit cost (€)**	**Quantity**	**Total (€)**
Client Gateway (all-in-one PC)	1,250	1	1,250
Metawatch	100	1	100
RAM server	315	2	630
External HD	150	2	300
Clinician Laptop	1,000	1	1,000
Vital Signs sensor	400.00	1	400
Labour (5 days)	500.00	5	2500
Tea Making			
Electronic module (design)	1,067		1,067
Electronic module (dev)	300	5	1500
Tableware design	14,028	1	14,028
Mug (development)	100	1	100
Teabag bowl (development)	100	1	100
Sugar bowl (development)	100	1	100
Milk Jug (development)	100	1	100
Kettle (des+dev)	14,528	1	14,528
Kinect	200.00	1	200
Labour (5 days)	500.00	5	2500
TOTAL	31,023	**24.00**	40,403

*Given that the know-how exists, it is predicted that two skilled workers can develop the basic system in ten days.

2. USERS

The primary aim of the CogWatch system is to improve the rehabilitation outcome of stroke patients suffering from AADS which can result from lesions in different brain regions. For example, imitation of gestures is affected by lesions in the left hemisphere (single gesture) and right hemisphere (sequence of gestures). Right hemisphere damage also affects multi-step actions while tool and object use is affected by large, left sided unilateral lesions (see D1.2).

In addition to physiological causes, such as vascular blockage (ischemic) or bleeding (haemorrhagic), damage to these brain regions can also result from neurodegenerative disease and traumatic brain injuries (TBI). Therefore, even though, in principle, the CogWatch project concerns mainly stroke patients, the resulting cognitive rehabilitation system may potentially benefit patients suffering from the above conditions. However, since only stroke patients are recruited in the CogWatch project in order to identify user requirements and evaluate the Prototypes, the present report will focus on stroke patients.

In addition to AADS patients, healthcare practitioners are also an important user-group who has been included in the design, development and evaluation of both prototypes. Below, we summarise how CogWatch will address the needs of these two groups.

2.1 Patients with Apraxia and Action Disorganisation Syndrome

Apraxia and action disorganisation syndrome (AADS) are two common cognitive disorders resulting from stroke. In principle, apraxia may be defined as a neurological disorder of learned purposive movement skill that is not explained by deficits of elementary motor or sensory systems [1] while ADS may be defined as a neurological disorder of cognitive errors which occur when performing familiar multiple step tasks and which are not a characteristic of motor incapacity [2].

Stroke patients diagnosed with AADS show impairment of cognitive abilities which enable them to carry out independently *activities of daily living* (ADL) such as dressing, preparing and eating meals and grooming (Goldenberg 1998; Sundet 1988; in [3]). There are two main types of apraxia: *ideomotor* and *ideational* apraxia. *Ideomotor apraxia* can affect the patient by hindering their ability to select, sequence and use objects (Heilman 1985; in [3]) and it is thought to affect people more in test situations than in normal ADL tasks. Furthermore, patients with *ideational apraxia* may be unable to perform a skilled activity because they have lost the conceptual ability to organise the actions required to achieve their goal such as trying to put clothes on the wrong part of their body (Jackson 1999; in [3]).

The CogWatch system aims to provide guidance and error correction multimodal cues allowing AADS patients to complete ADL tasks successfully. CogWatch can be personalised and highly customisable to suit the rehabilitation needs of individual patients. In addition, since it is based on sensorised everyday objects, it can be adapted and installed in different settings depending on the rehabilitation programme of each patient. For example, it can be installed at the hospital so that continuous and persistent rehabilitation can start as soon as possible after the stroke incident and the diagnosis in order to maximise recovery. At the hospital, patients can familiarise themselves with the CogWatch system while healthcare professionals identify a training programme suitable for home installation in order to continue the personalised rehabilitation plan.

2.2 Health practitioners and carers

In the UK, currently therapists work on a one-to-one basis with patients to train them in activities of daily living. Not only is this very resource-intensive but patients leaving hospital may be treated by different therapists offering different therapies in the community, so consistency and efficiency are sacrificed. However, the CogWatch system will allow the implementation of a therapy plan tailored to the needs of individual patients offering consistent and continuous rehabilitation independently of the location and/or the carer implementing the plan.

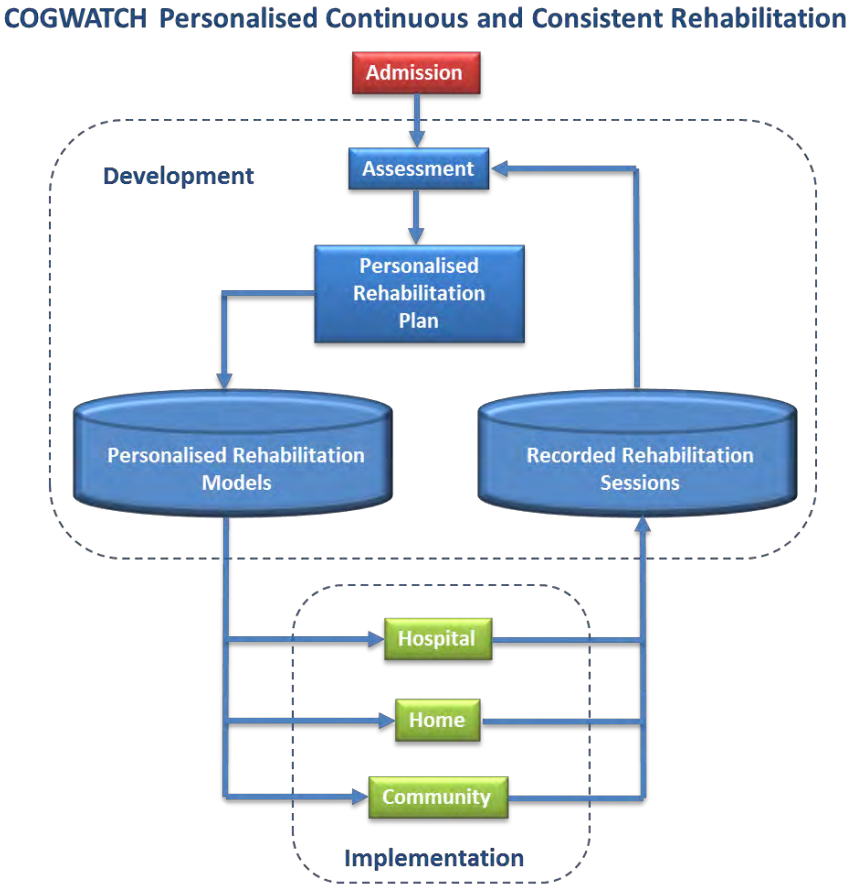

Figure 10: CogWatch allows healthcare practitioners and carers to develop and implement a personalised, continuous and consistent rehabilitation plan.

After admission to the hospital, the patient is assessed by health practitioners in order to identify his/her individual dysfunctions and set up a personalised rehabilitation plan that will have the best possible outcome. This plan is used to create a personalised rehabilitation model and can include, for example, tasks that the patient finds difficult to perform as well as type of cues they respond well to. Then this personalised rehabilitation model will be used to implement the personalised rehabilitation strategy through the everyday sensorised objects and feedback devices offering continuous and consistent rehabilitation. The rehabilitation sessions are recorded and can be assessed by health practitioners in order to confirm or adjust the current personalised rehabilitation plan to maximise its effectiveness (Figure 10).

3. MARKET ANALYSIS

The medical devices technology (MDT) market is a growing market that offers significant opportunities for growing. Globally, the home healthcare equipment market was valued at $32.6 billion in 2010 and is forecasted to grow to $47.9 billion by 2017 [4]. In 2005, USA was leading the world MDT market with an approximate €80bn nearly four times more than the second Germany. The MDT market in France, Italy and UK was up to €10bn while in the rest of Europe it was nearly €20bn [5] (Figure 11). Moreover, in Europe, the medical technology industry is growing at more than 5% per year and in 2009 sales were almost €95bn, more than 30% of the global sales [6]. In the UK, funding for services that support people when they return home from hospital, increased from £150m a year in 2011/12 to £300m a year in 2012/13 [7]. Moreover, the UK market is likely to grow between 30%-50% over the next decade as a conservative estimate [8]. This section reports important characteristics of the potential markets that CogWatch will target. These include patients and carers as well as national health systems. The regulations of medical devices are also considered.

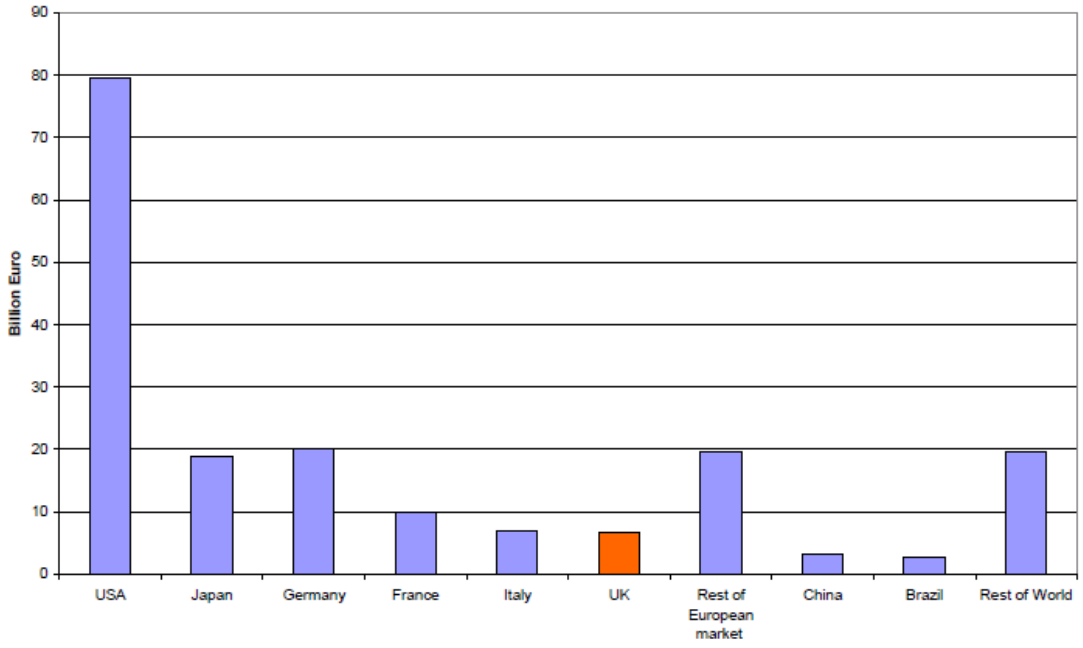

Figure 11: The global MDT market (source: [5]).

3.1 Target market characteristics

3.1.1 Patients

A third of the citizens in the EU27 will be over 65 by 2060 with a 50% increase of people aged 65-79 and a triple increase of those aged 80 and over. At the same time the working population will keep falling resulting in an increase in the ratio of dependents to people of working age. It is predicted that by 2060 the ratio of working-to-dependent citizens will be 2:1 compared to 4:1 in 2009 (Figure 12) [9]. An increase in ageing population will result in an increase in age-related disease such as cerebrovascular disease.

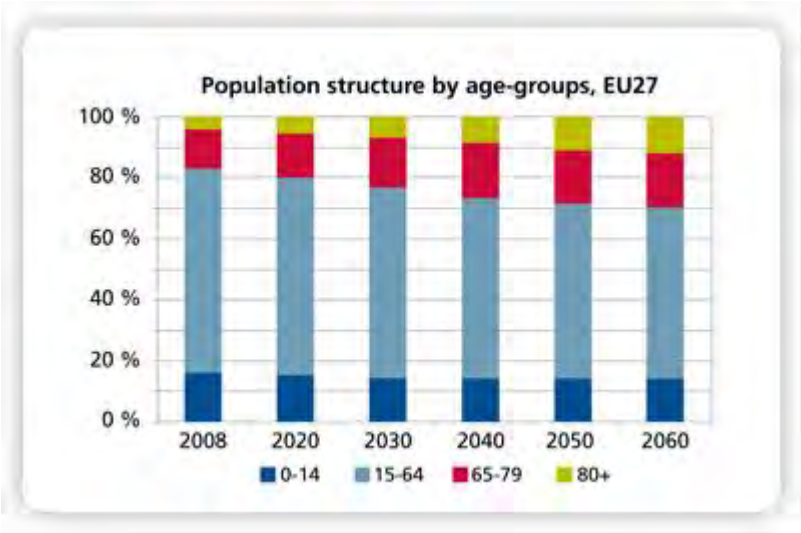

Figure 12: Predicted population structure in EU by 2060 (Source: 2009 Ageing Report, European Commission).

Even though in Europe deaths from heart diseases have been reduced since 2008 by 1%, stroke still results in approximately 1.5 million deaths per year [10]. In the EU, stroke is responsible for 463,924 deaths (41% men and 59% women) each year. This number is expected to rise following the predicted dramatic increase of older population in the EU. After coronary heart disease, stroke is the second leading cause of deaths worldwide killing 5.7 million people (8.6% of total deaths) every year (WHO, 2004). Moreover, half of stroke victims will be disabled with 40% experiencing moderate to severe impairments requiring special care while 10% will require long-term care in a nursing home or similar facility [11].

The most recent figures in 2012 indicate that in Central and Eastern Europe, stroke occurrences are many times higher than in Northern, Southern and Western Europe (Figure 13) [12].

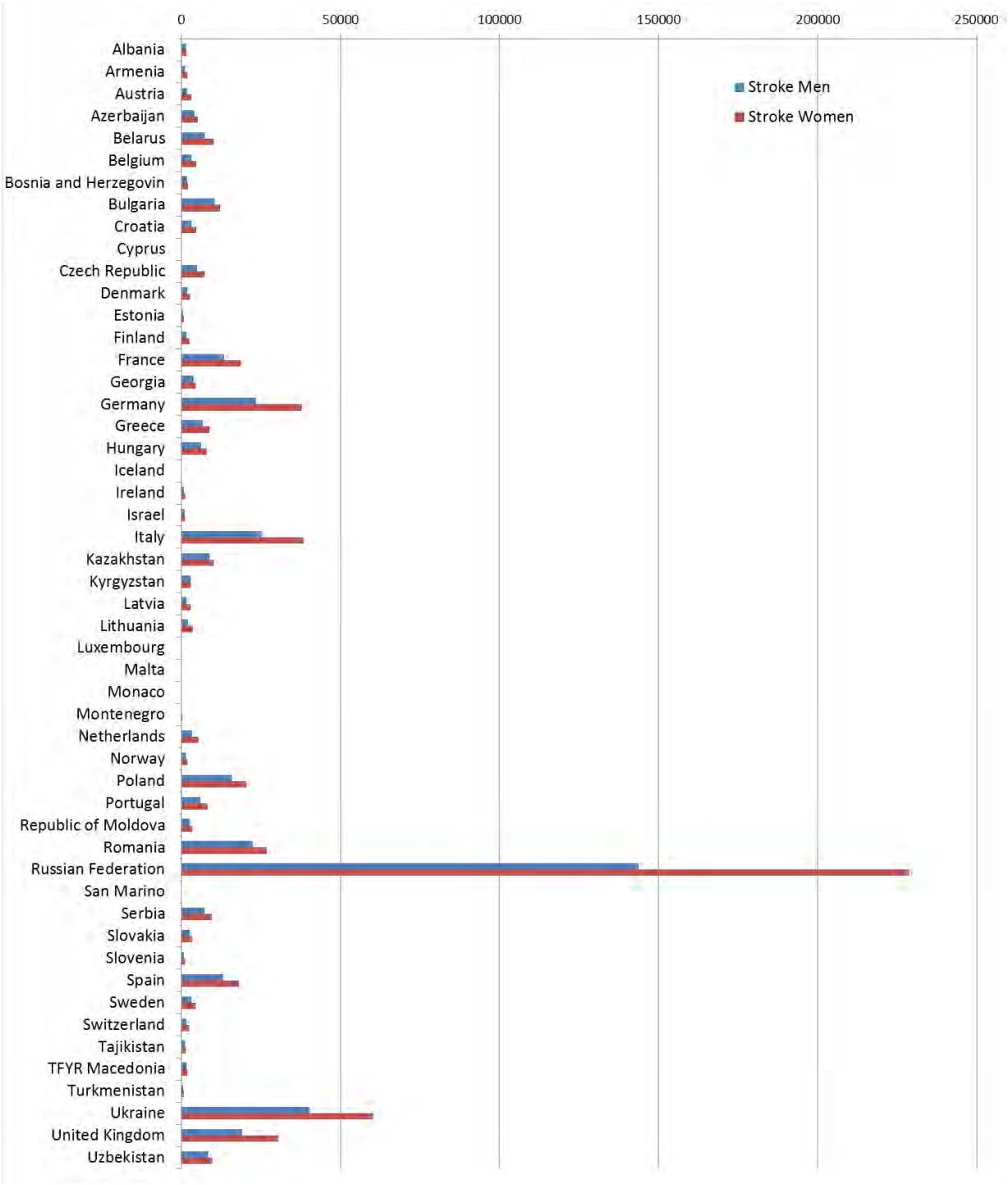

Figure 13: Stroke deaths in Europe. The year of data depends on the country. It is worth noticing the much greater number of stroke occurrences in Russian Federation.

Due to lack of standardised diagnostic tools, the exact proportion of stroke survivors that suffer from AADS is difficult to determine. Nonetheless, it has been reported that the proportion of stroke survivors that may suffer from executive dysfunction due to impairments

of working memory may be as high as 75% with spontaneous recovery limited to three months [13]. Moreover, there is evidence that approximately 30% of patients in the acute phase of stroke suffer from apraxia (50% with left hemisphere damage and <10% with right hemisphere damage) [14]. In the UK, recent research reported that 46% of stroke patients may show difficulties when tested on multiple praxis tasks and 52% of these had not recovered spontaneously when re-tested after nine months [15]. This data is now routinely collected in the UK. Hospital Episode Statistics (HES) revealed almost 100,000 admissions to hospital in England alone in 2011-2012 for stroke and related conditions. The table below illustrates a small but significant number of these episodes concerned young children, and a large proportion affected people under 60 years of age (www.hscic.goc.uk/hes).

Table 2: Stroke hospital admissions statistics in the UK for the period 2011-2012

HES data 2011-12	*Number of hospital admissions*	*Mean age (years)*	*Mean length of stay (days)*	*0-14 years old*	*15-59 years old*
Cerebral infarction	60,593	75	18.4	147	14,499
Subarachnoid haemorrhage	5,996	60	17.5	35	4,320
Intracerebral haemorrhage	12,072	72	19.6	129	3,811
Other stroke – unspecified	11,794	77	13.8	12	2,342
Other non-traumatic Intracerebral bleed	6,754	75	12.7	143	1,322
Subtotals	**97,209**	**71.8**	**16.4**	**466**	**26,294**

Data from the UK suggests that while incidence rates have decreased in recent years, prevalence increased as a result of better acute care by 12.5% from 1999 to 2008 [16]. Recently published figures indicate that there are 440 stroke discharges per 100,000 across Europe as a whole [17]. As there were 504 million people living in the EU in 2012 [18], this equates to 2,217,600 stroke discharges per year. In the UK, it is estimated that some 1600 people every day are newly diagnosed with a neurological condition, affecting one in six of the population, one million of whom are significantly disabled and require continuous care and treatment [19].

In this context, the notion of *disability-adjusted life years* (DALYs) is relevant [20], with one DALY representing one lost year of healthy life. Figures for 2002 (published in 2012) indicate that 3.675 million DALYs were lost as a result of stroke in the EU (accounting for

6% of all DALYs lost), while in Europe as a whole the figure was 10.793 million DALYs lost (7% of the total). Rates of DALYs lost per 100,000 due to stroke, standardised for age, vary considerably from consortium nations Spain (294), Germany (338) and the UK (359) to well over 1000 per 100,000 in many eastern European countries such as Latvia (1,102) and the Russian Federation (1,747). Moreover, 16-20% of stroke patients suffering from cognitive decline may show significant improvement in the first three months of recovery which may continue for at least the first year post stroke. Patients with cognitive impairments have decreased ADL and may require long-term, on-going rehabilitation [21].

CogWatch is a rehabilitation tool that currently enables people to carry out two ADLs (tea-making and toothbrushing). For AADS patients, it will contribute significantly to reducing time spent in a state of disability. This will also have a positive effect on the carers since it can enable patients to be more independent.

3.1.2 National Health Systems

Stroke costs EU €38 billion per year and accounts for 2-3% of the total healthcare EU budget [22]. In the UK, caring for stroke patients has a budget of around £7 billion yearly with direct costs to NHS of around £3 billion. This cost, which is more than the cost of treating coronary heart disease, includes both inpatient beds and nursing home places. In addition, the lost productivity due to stroke costs the economy around £1.8 billion while informal care (home nursing and care provided by families) costs around £2.4 billion [23].

In the UK, care and treatment for neurological disabilities formed the basis for the UK government's National Service Framework for Long Term Conditions (Department of Health, 2005) which included quality requirements (QRs) relating to early and appropriate treatment (QR2), providing rehabilitation at home (QR5), and provision of up to date and assistive technology to maximise independence (QR7), all underpinned by a personalised service (QR1).

In addition, National Health Systems face the challenge of delivering cost-effective improved interventions.. Therefore, it is expected that new interventions should not only improve rehabilitation outcome but they are also economical. In the UK, while the impact of a disability is measured in terms of DALYs, the effectiveness of an intervention is measured in terms of *quality-adjusted life-years* (QALYs)[1]. QALYs take into account both the patient's quantity of life (life expectancy) and quality of life after the stroke incident; that is, QALY = Life Expectancy * Quality of Life. Quality of life is based on the state of the health of the patient and can vary from 1 (perfect health state) to negative values (worst possible health state), with 0 being death (the quality of life is based on *health utilities* and expresses a subjective health state). Healthcare commissioners are using QALYs to evaluate the effectiveness of the technology.

As a personalised home-based assistive technology system aimed at increasing independence CogWatch is therefore well placed to satisfy key government objectives for the future of rehabilitation.

[1] The QALY has also been recommended for "reference case" analyses of cost-effectiveness in the US [24].

In Spain, in addition to public healthcare providers which include health regional services and public hospitals, private healthcare providers such as insurance companies, private hospitals and medical boards can also provide a significant market for the CogWatch system.

3.1.3 Community Care

According to the WHO (2008), *"home care aims at satisfying people's health and social needs while in their home by providing appropriate and high-quality home-based healthcare and social services, by formal and informal caregivers, with the use of technology when appropriate, within a balanced and affordable continuum of care."* It is recognised that there is a growing need for home care in Europe based on the following heterogeneous reasons

- demographic changes (i.e., ageing population, changing dependency ratios),
- social changes (i.e., small family units, cross-border mobility, participation of female population into the health market),
- epidemiology changes (i.e., increase of non-communicative diseases)
- scientific and technological advances (i.e., medical advance, medical and non-medical technology advances)
- changes in attitudes and expectations (i.e., focus of attention to individual care, listening to the needs of patients for greater freedom and choices of treatments)
- policy priorities and choices (i.e., emphasis on community-based care, reduction of public spending, deinstitutionalisation)

The specific way that a nation decides to fund home care may depend on public, private as wells as family resources. Nonetheless, many OECD (Organisation for Economic Co-operation and Development) countries spend on home care over 30% of the total resources for long-term care. Moreover, the proportion of GDP allocated to home care varies dramatically from 0.2% in Spain to 2.75% in Sweden (Figure 14).

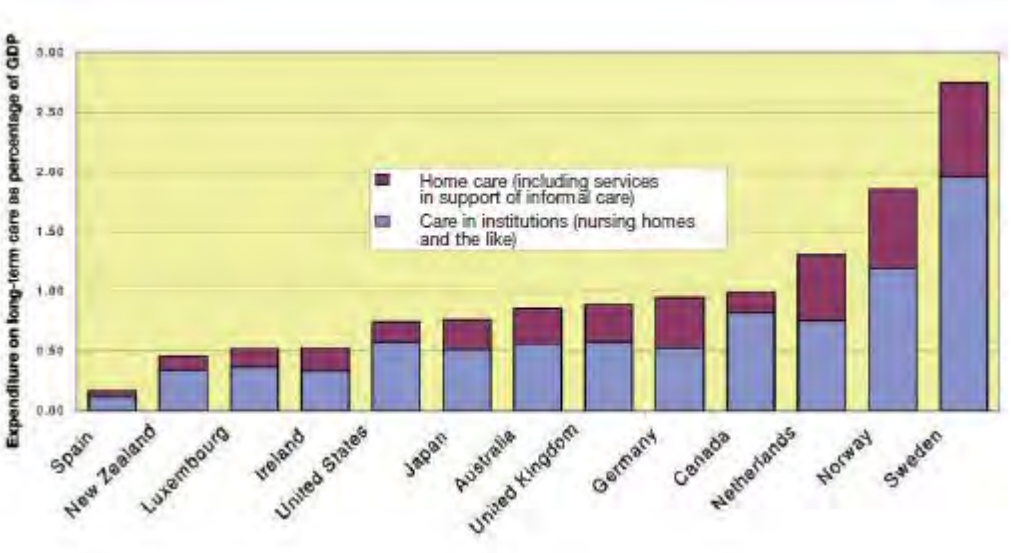

Figure 14: Proportion of gross domestic product (GDP) directed to covering the needs of home care in selected OECD countries, 2004 (Homecare in Europe, WHO, 2008).

In the EU, the organisation of home care is dependent on the way governments manage health budgets and the availability of health services structures that are in place. For example, in Spain and Germany, home care is delivered through social insurance while in the UK is delivered through central and regional governments [25].

In the UK, Local Authorities (LA) provided 84% of adults with community based care and only 6% with home care [26]. Moreover, within the community based care, the role of home care is the most prominent with over 600,000 patients being treated at home. Moreover, in 2011-12, the formal home care cost over £3.8bn (€4.51bn) and was covered as self-direct support or direct payments to the end-user. In addition, it was delivered mostly by independent health providers (around 67%) with 439,232 workers [27]. However, informal home care is also very important for providing quality health care at home. It is estimated that one in three adults will become a carer in the next 10 years, with over 20% caring for more than 50 hours a week, and most doing so without outside assistance [28]. In Europe, According to the second European Quality of Life Survey (EQLS), there 128 million people caring for an elderly or disabled person [29].

Home care becomes more effective if it happens as early as possible after hospitalisation. In the UK, there is provision for Early Supported Discharge for stroke patients which results in 6% fewer deaths or daily dependencies. However, only 36% of hospitals provide this specialised rehabilitation service [30].

It is evident that there is a strong need for delivering health care at home in order to reduce hospitalisation time and improve the cost effectiveness of the treatment. This is one of the main objectives of CogWatch: to provide intensive personalised cognitive rehabilitation in the community and home settings.

3.2 Medical Devices Regulations

In order to be able to launch any type of medical device or technology into the European market it is necessary to comply with the European Regulations for medical devices as outlined in the Council Directive 93/42/EEC [31].

The Article 1 defines as follows:

"a) 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, **monitoring**, treatment, **alleviation of or compensation for an injury handicap**,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;"

*In Annex 9 Directive 93-42, there is an additional definition for active medical device which states that "**Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity** and which acts by converting this energy… **Stand alone software** is considered to be an active medical device."*

The bolded text would be applicable to CogWatch system including all components and software. In addition, guidance document MEDDEV 2.1/1 indicates that aids for handicapped persons are considered medical devices when there is a direct link between the corrective function and the person concerned.

According to medical devices directive, any medical device placed on the market or put in service in the European Union must comply with the requirements of MDD. There are several routes to demonstrate this compliance, but the available ones depend on the classification of the medical device. This classification is established according to Article 9 and Annex IX of MDD and divides the medical devices into four classes based on the risk factor involved and the intended use of the device:

- Class I for low risk devices.
- Class IIa and Class IIb for medium risk devices
- Class III for high risk devices

Conformity assessment routes are more or less complex according to risk of the medical device (all routes requires intervention of a notified body except for devices of class I without measuring function). Classification of the device is also a complex issue and it requires defining exactly the type of device and its intended use. There is a document guidance about classification (MEDDEV 2.4/1 rev.9).

In order to comply with MDD, the medical device must meet the essential requirements set out in Annex I which apply to them, taking into account the intended purpose of the device (Article 3). Moreover, a quality system must be implemented to assure adequate quality during manufacturing. Conformity assessment procedures are defined in Article 11 of MDD. The simplest way to demonstrate compliance with the essential requirements is to meet the requirements of harmonized standards (see Article 5 of MDD) published by European Union (http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm). There would be quite different applicable standards, but the more important are:

- EN 60601-1:2006. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN ISO 14971:2012. Medical devices - Application of risk management to medical devices

MDD conformity assessment is binding for all the countries of European Union. Each country can have different processes to begin marketing of the product in his territory, but they usually are simpler and based on CE certification of the product according to MDD.

3.3 Current cognitive rehabilitation practices

According to Cicerone (2000) Cognitive rehabilitation is defined as a *"…systematic, functionally oriented service of therapeutic activities that is based on assessment and understanding of the patient's brain-behavioural deficits."* [32]. Moreover, the Cochrane Protocol (2010) suggests that in the case of cognitive impairments, rehabilitation may focus on the recovery of patient's ability to problem solve, use strategies or increase self-awareness. In addition, strategies or technologies providing task-execution feedback may improve patient's ability to compensate for impaired executive function. The improvement of executive function may result from increasing accessibility to information therefore compensating for attention and memory impairments [33].

In terms of best practices, Cicerone's *Recommendations for Clinical Practice* (2005) suggest that integrated and individualised cognitive therapies may achieve the best rehabilitation outcome. In addition, cognitive deficits may be treated using computer-based interventions while therapists monitor patient's progress in order to develop compensatory strategies and facilitate the transfer of gained skills to real-life situations.

As noted in Section 2.2, therapists currently work on a one-to-one basis with patients to train them in activities of daily living. Not only is this very resource-intensive but many clinicians are unfamiliar with the variety of presentations of AADS and therefore treatment is not always evidence-based. Furthermore, patients leaving hospital may be treated by different therapists and with different therapies in the community, so integration, consistency and efficiency of therapy are sacrificed. By using the CogWatch system all clinicians across different organisations and settings would be able to track and evaluate the progress of the patient during all stages of the illness and therefore would be able to prescribe more consistent and effective rehabilitation sessions which, in turn, would contribute to a more integrated treatment.

Systematic reviews of the available evidence suggest that early supported discharge (ESD) and stroke rehabilitation at home is cost-effective if delivered by a multidisciplinary team and is at least as effective as rehabilitation in the stroke unit [34, 35]. The CogWatch system is designed to be programmable for the specific needs and environments of individual patients, and the customised system will be as easily installed at home as in a large hospital.

A major limitation to the effectiveness of rehabilitation is lack of therapy resources. Figures in the UK put the skills shortage, according to discipline, at 15-30% [36]. CogWatch is not intended to replace therapists but the system will help to address this shortfall in four important respects:

- By providing up to date information on patient progress, empowering clinicians and aiding clinical decision making;
- Through regular self-initiated use CogWatch will increase input to patients for the same unit staff cost;
- By providing consistent and timely feedback, learning will be optimised and therapy duration and therefore cost will be minimised;

- By freeing up therapy time for other tasks CogWatch will increase efficiency and maximise output for the same unit cost.

In brief, it is evident that CogWatch addresses all the major limitations of the current practices for cognitive rehabilitation and therefore its appropriate implementation would make a difference to the delivery and effectiveness of the treatment.

3.4 Competitors analysis

The purpose of CogWatch is to provide personalised cognitive rehabilitation to stroke patients suffering from cognitive impairments associated with AADS. Therefore, CogWatch will have to compete with other ICT platforms and systems that aim to provide cognitive rehabilitation to neurological patients.

ICT systems known as Cognitive Orthosis, Cognitive Prosthesis, Assistive Technologies for Cognitive Disabilities can also address aspects of cognitive impairments which are commonly found in AADS patients such as working memory deficits and disruption of executive functions.

Below we review a few systems that are currently commercially available or are at research stage and identify their main differences with the CogWatch system.

3.4.1 Commercial Cognitive Rehabilitation ICT Systems

3.4.1.1 COACH – AI Home Systems (http://aihomesystems.com)

The COACH (Cognitive Orthosis for Assisting with aCtivites in the Home) is a system similar to CogWatch. It is an ambient intelligent system designed to assist people with cognitive impairments to carry out ADL tasks successfully. The COACH has successfully (10-45% individual changes) completed clinical trials based on the ADL of hand washing with patients having moderate-to-severe dementia. It comprises of three components: the tracking system, the planning system and the prompting system (Figure 15) (see http://www.ot.utoronto.ca/iatsl/).

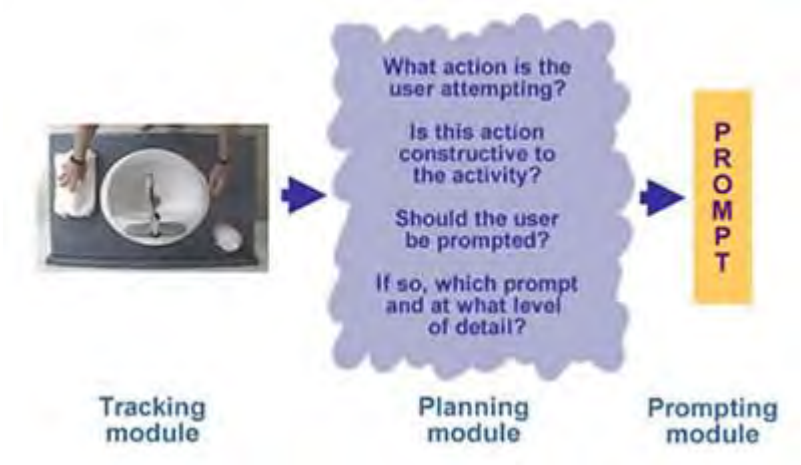

Figure 15: The COACH components.

The tracking system includes a video camera monitoring the position of the hands and their interactions with task related objects such as soap, tap, water, sink and towel. The planning

system determines the progress of the action and is based on partially observable Markov decision process (POMDP). Finally, the prompting system intervenes when necessary to provide the user with feedback (based on individual abilities) in order to complete the task successfully. The COACH setup is relatively simple with only a video camera and a monitor (Figure 16)

Figure 16: The COACH setup with the video camera and the monitor.

The COACH system can learn optimal prompts for each patient and adapt the prompting strategy to maximise outcome. In addition, the system can take into account short and long term changes in the patient's cognitive abilities and respond appropriately. The developers of COACH claim that the system can be used as an assistive tool for patients with Alzheimer's type dementia and as training tool for children with ASD (Autism spectrum disorder).

AIHS claim that COACH could be used for other ADL tasks including tea making. However, there is no evidence that COACH has been used successfully in tea making. Tea making is a more complex taks with more objects involved and sub-actions rquired by the patient. While video analysis may be sufficient for recognising specific objects in the very well defined space of a basin it may not be sufficient in the context of tea making where multiple objects may occlude each other. In this case instrumentation may be necessary to position the object and define the action with greater certainty, as in the case of CogWatch.

3.4.1.2 ISAAC – Cogent Systems Inc.

ISAAC™ has been developed by Congent Systems (http://www.cosys.us/index.htm) with the aim to provide individualised cognitive aid to people with cognitive disabilities including brain injury, stroke, and dementia. It consists of a small computer and monitor that can be attached on the patient's belt. ISAAC can deliver (audio, text, graphics) prompts and messages to assist patients with successful completion of tasks, directions, remembering schedules and other functions. The patient can use the touch screen to acknowledge a prompt (Figure 17).

Figure 17: The ISAAC touch screen.

The system records data from the interaction with the patient so that rehabilitation professionals can monitor the progress of the patient. The content of ISAAC can be updated based on the current patient requirements.

One of the main drawbacks of the ISAAC system is that the user has to manually confirm an action during the completion of a task. CogWatch will do this automatically by monitoring the state of an object (through sensors) in the context of given task model.

3.4.1.3 Guttmann, Neuro Personal Trainer

Guttmann, NeuroPersonalTrainer® (GNPT) (https://www.gnpt.es/en/) is a cognitive rehabilitation platform providing personalised training through computerised cognitive exercises. The personalised training sessions are automatically selected, configured and scheduled by the Intelligent Therapy Assistant (ITA) to suit the rehabilitation needs of the individual patient. Once retraining sessions have been completed, health care professionals can review them remotely and assess the progress of the patient. GNPT offers cognitive rehabilitation through interactive tasks with a computer monitor (Figure 18) [37, 38].

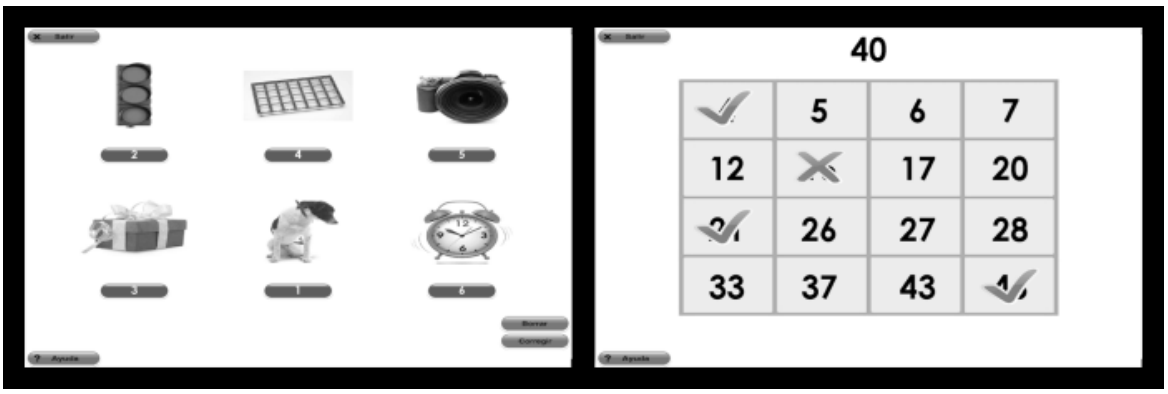

Figure 18: GNPT working memory task (left) and sustained attention task (right).

However, by operating as rehabilitation PC station, GNPT requires the patient to learn how to use and perform abstract tasks which may not be related to ADL tasks.

3.4.1.4 Neuroathome Rehabilitation Platform

A similar cognitive rehabilitation system is the NeuroAtHome rehabilitation platform (http://www.neuroathome.net/p/home.html). NeuroAtHome offers a range of exercises for physical and cognitive rehabilitation at home and stores data for assessment by occupational therapists.

Figure 19:The NeuroAtHome intractive interfaces are based on a touch-screen and body movement tracking.

The NeuroAtHome also requires the patient to learn how to operate the interactive interfaces before he/she can start retraining. It also uses abstract tasks that may not directly

relate to ADL tasks and, therefore, may have fewer chances to access cognitive schemata which may be intact and can help regain the ability to perform previously familiar tasks.

3.4.2 Research Projects

3.4.2.1 Guide – Technology for Independent Living

The GUIDE (http://www.guide-research.com/) is a research project that aims to develop software to assist patients with ADL tasks. It will be developed for Windows XP and will run on desktop, laptops and PDAs. The programme will verbally prompt users to complete ADL tasks. In addition, he users will be able to interact with the GUIDE though verbal communication. The current ADL tasks include making tea, smoothie, dressing and transfer from a wheelchair to a bed. Figure 20 shows the dressing (limb donning) protocol. The task protocol, or decision tree, is the core module of the GUIDE system. A second module includes the audio files with the instructions that assist the user to navigate through the task. A third module includes voice recognition software allowing the user to give voice commands to the system. The developers of the GUIDE system will evaluated in randomised controlled trials.

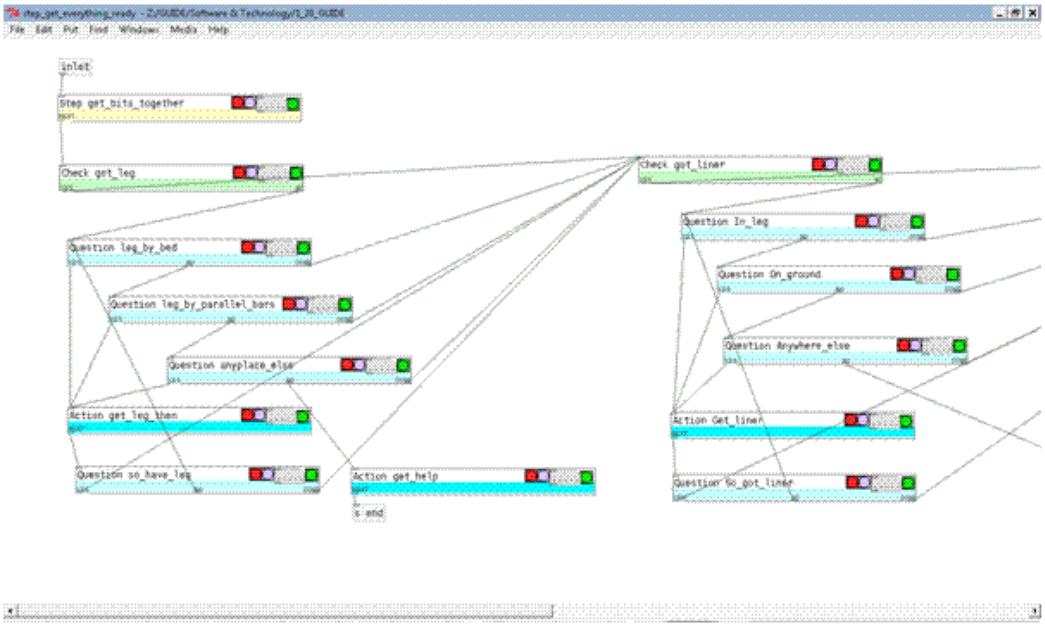

Figure 20: The limb donning protocol of the GUIDE system.

The GUIDE system is similar to the ISAAC system in that it provides guidance to complete ADL tasks and allows the user to interact with the software during the execution of a task. However, similarly it seems that it requires constant verbal input from the patient to verify that a certain step of the task has been completed. This setup that requires significant interaction with the system in order to complete a task may not be the optimal solution for patients with already impaired cognitive skills.

CogWatch uses instrumented objects and sophisticated action recognition and prediction algorithms to minimise interaction between the patient and the system (Zero Effort Technology – ZET; [39]) and maximise its effectiveness.

3.4.2.2 Contrast (Cognitive Enhancement Training for Successful Rehabilitation After Stroke)

The CONTRAST project (http://www.contrast-project.eu/) is an FP7 project aiming to provide an adaptive HCI that will improve impaired cognitive function through neurofeedback training. This technique is using EEG signals which are fed back to the patient who learns how to alter them in order to improve his cognitive functioning (Figure 21). The treatment will take place at home through regular remote-sessions with the therapist who is able to monitor and interact with the patient to decide on the course of necessary training. The main cognitive functions that CONTRAST addresses are attention and memory.

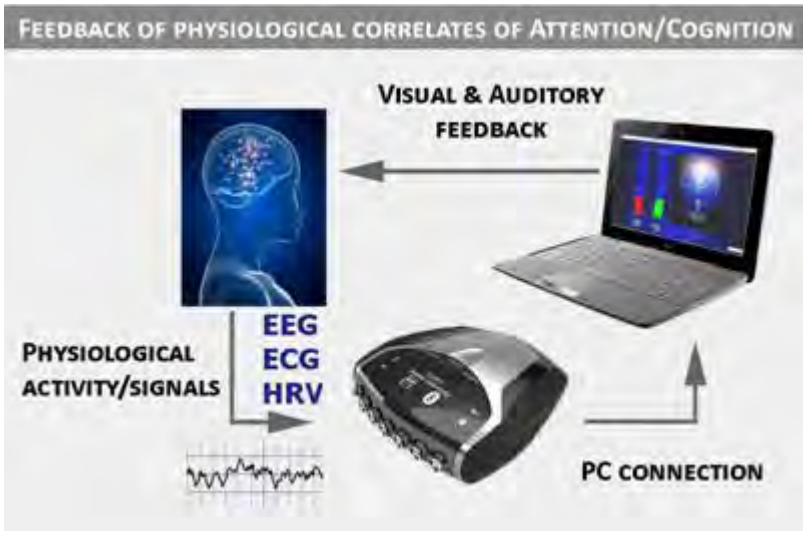

Figure 21: The CONTRAST setup for neurofeedback training.

In order to rehabilitate, patients have to interrupt their daily activities and attend training sessions which are remotely supervised. Therefore, CONTRAST does not offer continuous and consistent rehabilitation. In addition, even though it takes place at home, it still requires commitment of health care resources since rehabilitation sessions are supervised by a health professional. Moreover, it is not a ZET since it requires from the patient to train on how to use neurofeedback. On the contrary, through the use of everyday objects, CogWatch follows the ZET philosophy and will provide consistent and continues rehabilitation without telesupervision.

3.4.2.3 CLEAR (Clinical Leading Environment for the Assessment and validation of Rehabilitation protocols for home care)

CLEAR is a Policy Support Programme project conducted a large scale pilot study in Intaly, Spain, Netherlands and Poland to demonstrate the feasibility of the Habilis reahbilitation platform (http://www.habiliseurope.eu/). The Habilis platform allows patients to continue their cognitive rehabilitation in the community. Patients visit the health/community centre where the Habilis platform has been installed and carry out their rehabilitation sessions. The sessions are then evaluated by a health professional who decides on a course of action. Sessions include instructions to complete abstract cogntive tasks on the computer or using a specially developed battery of instruments (Figure 22).

Figure 22: The Habilis cognitive rehabilitation platform.

It seems that patients who have used Habilis have had positive experience. Nonetheless, even though Habilis may offer the posibility of providing cognitive rehabilitation in the community it faces some of the shortcomes of other ICT platforms. For example, it is not a ZET since it is an ICT rehabilitation system which the patient will have to learn and adapt to. Moreover, it cannot provide continues and persistent rehabilitation since patients can use it through visits to their local health/community centre. In contrast, CogWatch can provide continues and persistent rehabillitation at home requiring no or minimum learning effort from the patient since it involved commonly used everyday objects.

3.4.2.4 DEM@CARE (Dementia Ambient Care: Multi-Sensing Monitoring for Intelligent Remote Management and Decision Support)

Dem@care is an FP7 project aiming to develop an ICT system that provides diagnosis, assessment, maintenance and promotion of independence for dementia patients. A network of wearable and ambient sensors will monitor and assess the cognitive and behavioural status of the patient in order to build an accurate profile that would support proactive and reactive care.

Clinicians will be able to observe the progress of the patients remotely and adjust their treatment accordingly. The system coprises of two loops: a loop for people with dementia and their informal caregivers and a a loop for dementia clinicians (Figure 23).

Figure 23: The Dem@care concept.

The Dem@care concept sounds similar to the CogWatch concept. However, it is not clear how the wearable and ambient sensors can build an accurate profile of the patients neither how the feedback will be delivered to the patients. For example, do the sensors collect data about task related performance or data about generic behavioural trends of dementia patients (e.g., apathy). Moreover, is the feedback delivered when it is needed or through a clinician during a visit?

CogWatch aims to monitor cognitive performance during the execution of a task and deliver guidance and/or error correction fedback during the task in order to enable the patients to complete the task successfully.

3.4.2.5 TEBRA (TEeth Brushing Assistance)

TEBRA is cognitive assistive technology prototype which helps people with cognitive disabilities to complete the tooth brushing task successfully [40]. TEBRA uses 2D cameras, a water flow sensor and an instrumented tooth brush to monitor user actions and prompt them to follow instructions in order to execute the task successfully according to the system task model (Figure 24). TEBRA uses the state of the objects to infer user actions and task progress while it applies State Machine and dynamic timing models to cope with different task execution speeds. Results from trials with healthy adults have shown that TEBRA is more successful when the user collaborates with the system rather than when the user freely executes the tooth brushing task.

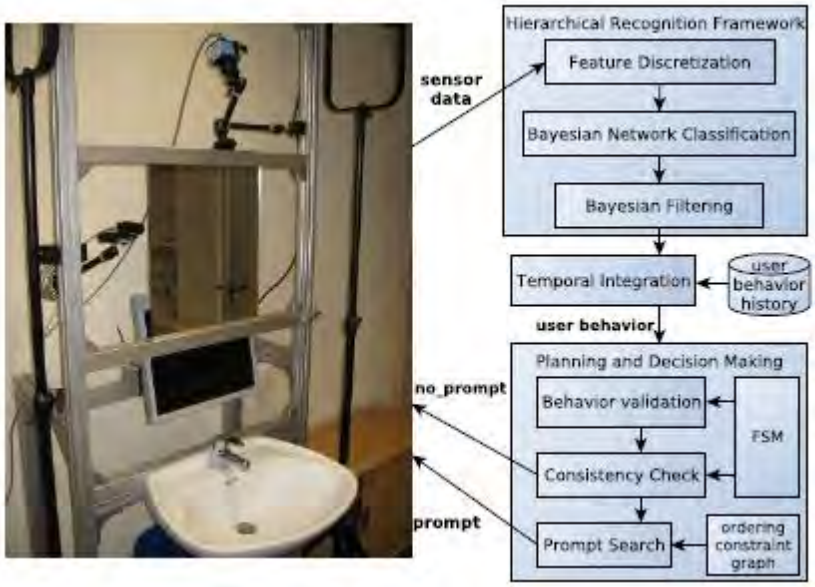

Figure 24: The TEBRA setup.

TEBRA concept is very similar to COGWATCH using both environmental and instrumented objects to monitor action and providing instructions to complete the task successfully. When the user follows instructions, it seems capable of providing semantically correct prompts for the user to complete the task successfully. TEBRA has also been tested with 7 users with cognitive disabilities [41].

Table 3: Summary of comparison of key features of CogWatch against other ICT systems for cognitive rehabilitation.

	Home	Personalised	Continuous	Persistent	Remote Assessment	ZET	Complex Tasks
CogWatch							
COACH							
ISAAC							
NeuroAtHome							
Guttmann							
Guide							
Contrast							
CLEAR							
DEM@CARE							
TEBRA							

4. SALES & MARKETING STRATEGY

In Section 3, we reported that the market for the CogWatch system is potentially significant since stroke affects millions of people in Europe every year with a reportedly high proportion suffering from cognitive impairments. In addition, the lack of major commercial competitors gives CogWatch an advantage for establishing early dominance in the market. Nonetheless, it is important to understand that the need for cognitive rehabilitation has to be accompanied by appropriate budgets that can be invested on ICT technologies to address this need. For example, if a health care system is not prepared to invest on an ICT system then the market potential is reduced significantly. Therefore, a successful commercial exploitation of the CogWatch system (given that clinical evidence about its effectiveness as rehabilitation tool for AADS patients have been obtained) should be based on realistic business models that take into account the dynamics of the specific health care market as defined at national level. .

Even though there are common issues regarding the commercialisation of medical devices in EU, such as regulations (outside EU-27 these regulations may be different), the business models and marketing strategies may vary depending on the provision of healthcare, the economic model as well as the current state of the economy in each country. Due to these issues, here we present business models that are suitable for UK and Spain since the CogWatch commercial partners (RGB, HW and BMT) operate in these countries. In the future, business models should be developed to suit other European markets.

4.1 Business model

The health market in UK and Spain include both public and private stakeholders including individual patients. Therefore, it is important that CogWatch can be purchased as a standalone device for an individual patient, and as a system that can be installed in an institution for multiple users.

There are no reliable figures for the number of private hospitals in the UK but there are approximately 360 NHS hospitals, and probably as many privately run centres. At a conservative estimate if CogWatch systems were purchased by 10% of the hospital market it would involve about 70 CogWatch systems. Based on a basic system similar to the Prototype I (see Section 1.2.1.3) this would cost approximately €750,000 during a 5 year rehabilitation plan. Additional smaller profits would be accrued in subsequent years for support services, but the device would also be developed with investment of profits and new versions brought to market.

In addition, there will be take-up by individuals at home or purchasing agencies on their behalf. As there are approximately 2.2 million stroke discharges per year in the EU, conservatively assuming a 50% survival rate, and an AADS incidence rate 50% rate of AADS after stroke, which becomes chronic in 50% of patients (based on Bickerton et al., 2912), this suggests a potential EU market of 275,000 individuals per annum (given that no competitors operate in the same market). If CogWatch systems were available to just 1% of this population then the revenue would be in the region of approx. €36.55M for development, setup (at €1000 per basic unit) and support (€500 per basic unit per year). Figure 25 shows the increase in revenue with basic units sold (see Appendix 1).

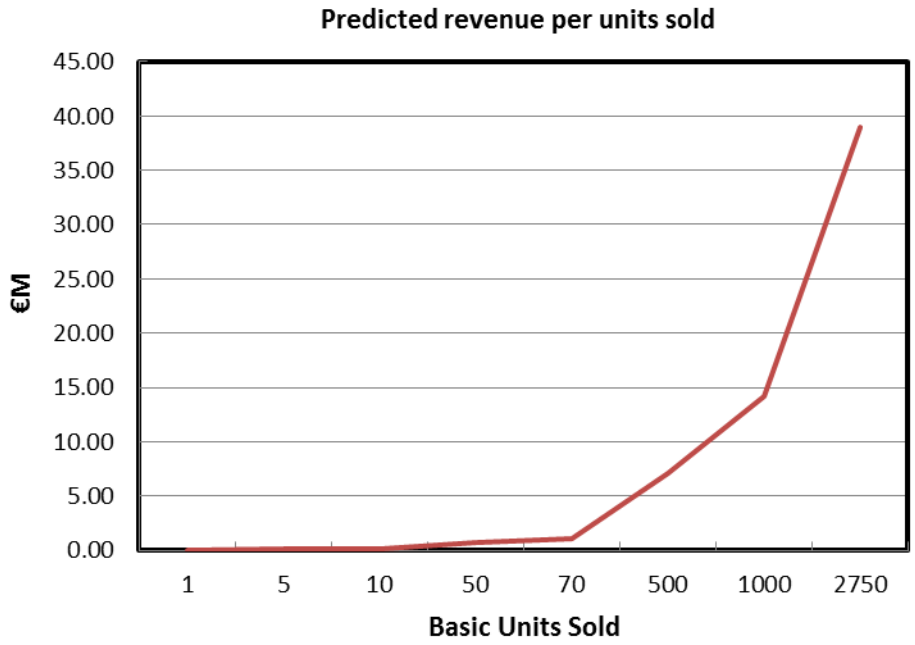

Figure 25: Revenue from deploying a basic CogWatch unit (TRL7 costs).

Bearing in mind the huge costs of delayed discharge, premature discharge and emergency readmission this would make it one of the most cost-effective medical devices/rehabilitation tools available, potentially attracting much wider global interest, where the WHO estimates that 15 million people annually suffer a stroke. However, it should be noted that due to high development costs (TRL7) the CogWatch would have to sell more than 10 units in order to be cost effective comparing to the current treatment (see section 4.2.1.2).

In principle, the CogWatch system (or its components) could be explored commercially using at least the following two routes: first, commercial partners (HW, BMT and RGB) incorporate CogWatch solutions into their individual business model for healthcare services and, second, creation of a new company (a start-up or a spin-off) to exploit CogWatch solutions. Incorporating CogWatch technologies and solution into an existing business model may be a quicker route to market. For example, HW and RGB could potentially include CogWatch in their existing rehabilitation practices while BMT could use to improve consultation services to NHS. RGB has already included the physiological monitoring device in their business model. The advantage of this approach is that funds may be more easily accessible if a successful business model is already in place.

Starting a new company in the medical devices sector is challenging but has the potential for significant growth as we show in Section 3. Generally, a successful medical technology business needs to adopt a multidimensional framework of action that aims to create continuous incremental value in the three core aspects of the business; that is, product development, financing and organisational structure [42]. Figure 26 shows the non-linear idealised growth trajectory of an MDT company which succeeds to create incremental value in each core aspect of its multidimensional framework of activities. One of the advantages of a spin-out is that it is more focused and can address all aspects of the CogWatch solutions including development, service provision and consultation.

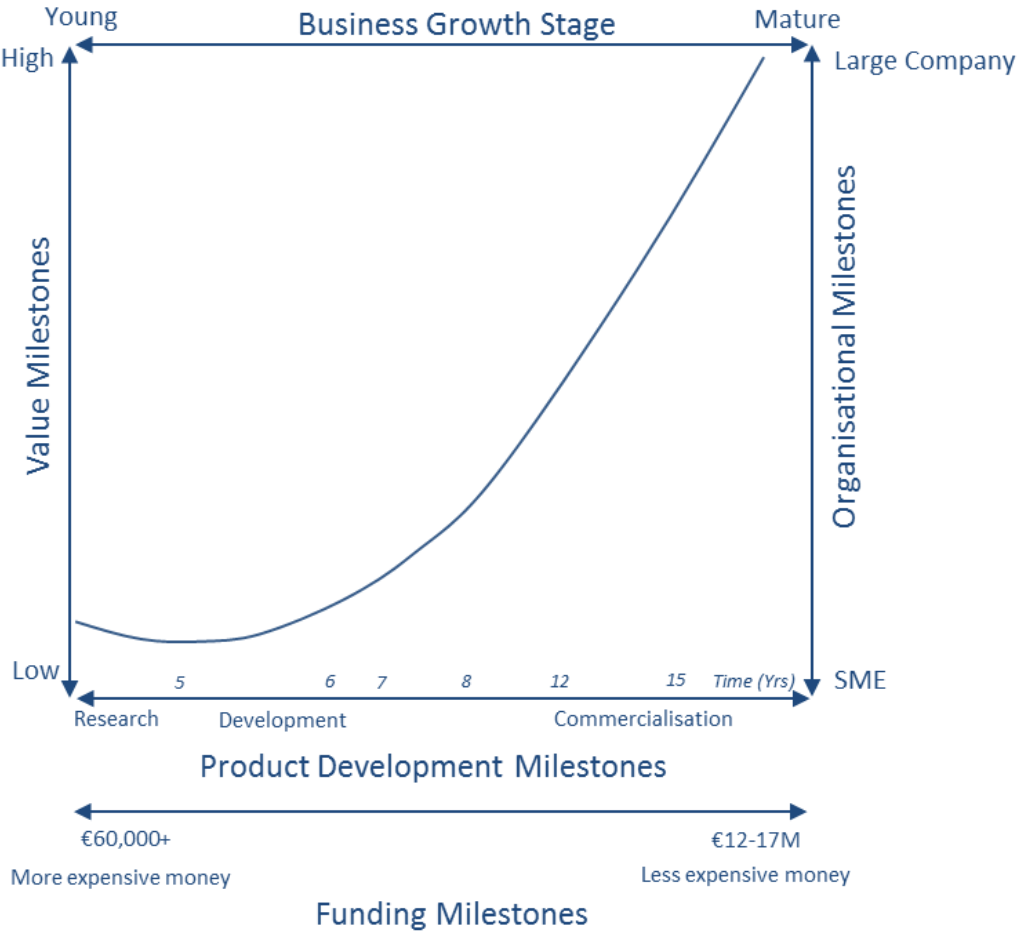

Figure 26: Idealised non-linear growth trajectory based on value creation for each aspect of the multidimensional framework of an MDT enterprise (adapted from [38]).

Irrespectively of the path that the consortium or individual partners may choose to commercially exploit CogWatch technologies, a sound business plan should include strong evidence of the added value based on the comparative effectiveness (relative to other practices and/or ICT systems – if any) of three crucial aspects of MDT: clinical effectiveness, safety and financial gains [43]. Therefore, in addition to a clinical evaluation and the satisfaction of safety regulatory requirements, a sound business plan will have to consider the impact of its implementation on the entire health system providing the stroke care. In the UK, there are models which can be used to assess the impact of a technology in stroke care provision. For example, Cox and colleagues [44] have described a model which includes different phases of stroke patient care. Three main phases are identified: *pre-hospital*, *hospital* and *post-acute care*. The pre-hospital phase concerns with what happens to the patient from the stroke onset to hospital admission. The hospital phase includes admission to A&E and recovery in the Stroke unit. The post-acute phase concerns with the release of the patient from the hospital and the after-hospital care including community based care, home based rehabilitation and care homes (Figure 27).

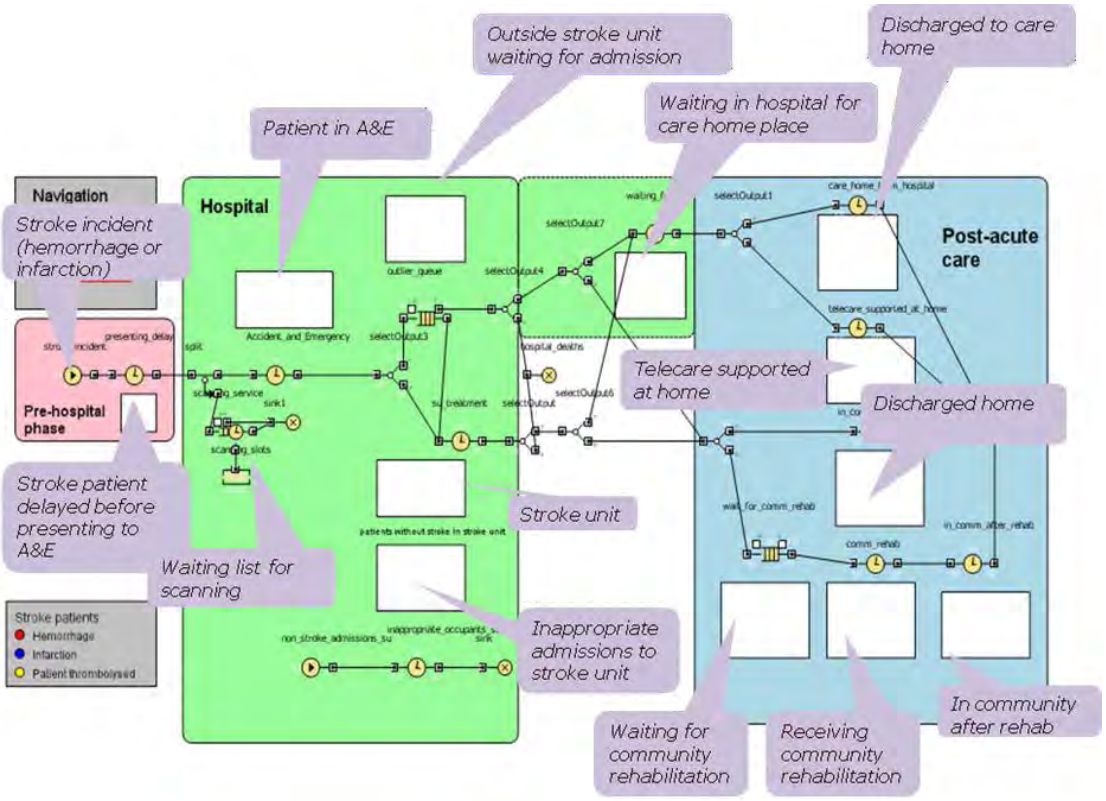

Figure 27: The Cox et al. model of stroke care provision in the UK [40].

More complex models have also been described where the re-introduction of stroke patients into the health care system, due to recurrence, and the event of death are considered [45]. A successful business model should take into account both the effectiveness of the technology on improving rehabilitation outcomes as well as the reduction of health care provider's operational costs (e.g., duration of hospitalisation, staff costs).

4.2 Market strategy

Successful marketing of CogWatch depends on the supply of effective technologies that are clinically effective, satisfy the regulatory requirements and are cost effective. In addition, knowledge of the buyer is fundamental in order to understand procurement procedures, criteria and priorities.

4.2.1 Obtaining the evidence

4.2.1.1 Regulations and clinical evaluation

Before starting marketing the CogWatch system (or its components) the CE mark needs to be obtained. The CE mark will allow the free marketing of CogWatch in the European Economic Area [46, 5] and show that it complies with relevant regulations and it is fit for its intended purpose [47]. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) appoints an independent certification body Notified Body to verify that the device can obtain the CE mark [48].

The Medical Devices Directive 93/42/EEC outlines the *essential requirements* that medical devices have to satisfy including general requirements (e.g., safety of users, performance, risk assessment, reduction of error due to ergonomic design, etc.) and requirements regarding the design and construction (e.g., risk of injury due to physical features, accurate measurements, electrical safety, etc.). There are also requirements for *conformity* including quality assurance, evaluation of design, monitoring of the device to ensure proper functioning and documentation.

The compliance with essential requirements related to performance and risk assessment, under normal conditions of use, has to be based on *clinical evaluation*. A clinical evaluation *"will demonstrate which clinical data are necessary, which clinical data can be adequately supplemented by other methods, such as literature search, prior clinical investigations, clinical experience or by using suitable clinical data from equivalent devices, and which clinical data remain to be delivered by clinical investigations"* [49]. Randomised controlled trials (RCTs) provide the most compelling evidence for the effectiveness of a treatment [50, 51].

4.2.1.2 Economic evidence

Providing clinical evidence and satisfying regulatory requirements is only part of successfully marketing the CogWatch. Another very important factor is to provide evidence about its cost effectiveness. Due to the global economic crisis the strategy of selling medical devices to the health care providers can no longer be based solely on evidence about clinical effectiveness. Therefore, it is necessary to conduct an economic evaluation of the CogWatch in order to determine value for money and the potential investment returns.

As noted in section 4.1, high development costs may have a negative effect on the cost effectiveness of CogWatch for treating less than 10 patients. For example, in the UK the minimum cost of five years post-stroke treatment per patient is estimated to be £15000 (≈ €18,292) [52]. Figure 28 shows how the costs of CogWatch treatment compare to the costs of the current treatment as the number of users increases. Based on this comparison, it can be seen that for very small number of patients (approx. < 10) the current rehabilitation practice appears to be cheaper than the CogWatch treatment method. However, CogWatch seems to become a much cheaper method of rehabilitation as the number of patients increases.

A simple measure of evaluating the potential value and financial gains of new MDTs has been suggested by McAteer and Lilford: the *headroom* [51]. The headroom method is based on the calculation of the *incremental cost effectiveness ratio* (ICER)

ICER = ΔCost/ ΔQALY,

where ΔCost is the cost difference between the current gold standard and the new treatment and ΔQALY is the difference between the effectiveness of the two treatments. We can use the headroom method to provide an initial assessment of the potential value and investment returns of CogWatch. The following estimates are based on the cost of treating 10 patients (which at this stage we have taken to be the baseline for CogWatch competitiveness).

Assuming that setup (€1,000), and support charges (€500 per year) do not change, we can estimate that the total cost of CogWatch over 5 years in order to rehabilitate 10 patients is

€162,462 or €16,246 per unit/patient[2]. Since the current treatment would cost €18,292 per patient, CogWatch deployment would save €2,046 per patient (i.e., ΔCost = -€2,046).

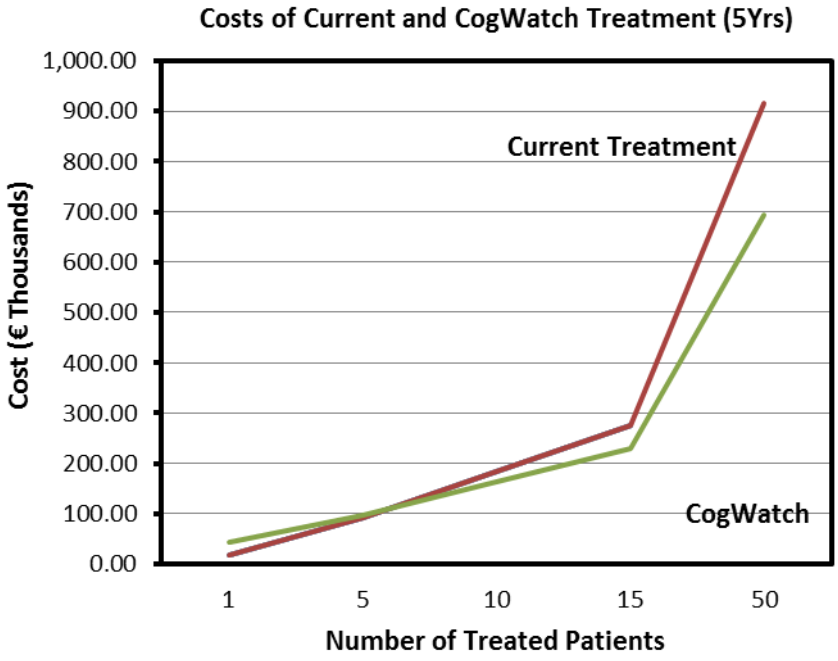

Figure 28: Costs of current and CogWatch treatments for different number of patients treated over a 5 year period.

Now, if we assume that the current cognitive rehabilitation treatment yields a minimum quality of life, or heath utility of 0.6 [54] and the implementation of CogWatch will result in maximum utility of 0.7 then the patient would gain an extra half year of perfect health within the 5 years treatment with CogWatch (ΔQALY = 0.5QALY). Based on these assumptions, the ICER would be -€4,093per QALY. That means that with CogWatch a gained QALY would be €4,093 cheaper than the current practice.

Furthermore, if we know what the NHS is *willing to pay* (WTP) to gain a QALY, we can calculate the maximum ΔCost, or headroom, as follows:

maxΔCost = WTP * maxΔQALY,

where maxΔQALY, the maximum incremental QALY is calculated on the basis of the maximum potential *effectiveness gap* which is the difference between the max utility perceived under the current treatment and the max utility perceived under CogWatch during the duration of the treatment which is taken to be 5 years. Assuming that CogWatch achieves perfect life (i.e., Utility=1 or unassisted preparation of tea) we have

maxΔQALY = (1-0.6) * 5 = 2QALY.

[2] The cost for the sensorised components is calculated as follows: *(D/N)+P*N*, where *D* is the design cost; *P* is the production cost and *N* is the number of units produced. For simplicity, *P* is kept constant. The costs are higher than the estimate in D5.3.2 because the addition of the sensorised tea cuddy and sugar bowl which, in principle, enable allow for accurate and quicker action recognition.

According to NICE (National Institute for Health and Care Excellence), the minimum NHS WTP is approximately €24,390 per gained QALY [55] over the lifespan of the treatment. This results in the following headroom for CogWatch

maxΔCost = €24,390 * 2 = €48,780.

Therefore, given the current assumptions (including that the perfect health outcome from rehabilitating with CogWatch), the CogWatch could cost up to €48,780 per patient treated and still be cost effective. This is also known as *value of extra health*.

Finally, in order to calculate the *commercial headroom* (or revenue) we need to take into account the buying and service costs of CogWatch. We have already seen that the total costs for treating a single patient with a basic CogWatch system over 5 years period is €16,246. Therefore, the commercial headroom is:

Commercial headroom = (headroom (Value of extra health) – CogWatch costs) * Volume,

giving (€48,780 - €16,246) * 10 = €325,337

Therefore, the return on €162,462 investment could potentially be €325,337 assuming that 10 patients are using CogWatch over a five year period.

Figure 29 shows the cost-effectiveness plane and the commercial headroom (per QALY gained) for the deployment of the basic CogWatch system. The green area is where CogWatch should be in order to be considered potentially by NHS procurement authorities. Medical technologies falling within the red area may not be considered by the NHS. Moreover, in order to be more competitive, CogWatch will have to be in quadrant (iv). In quadrant (iv) CogWatch is evaluated to be more effective and cheaper than the current cognitive rehabilitation practices. Moving into quadrant (i) means that, CogWatch is evaluated to be less effective and more expensive than the current treatment. This will inevitably result in an automatic rejection by NHS procurement authorities. In quadrant (ii), the system is considered to be more effective and more expensive and is likely to be considered if falls within the green area. In quadrant (iii), the system is evaluated to be less effective and cheaper than the current treatment. Again, it may be considered if it falls within the green area. This preliminary analysis has shown that a basic CogWatch system may be competitive as it could potentially be more effective and cheaper than the current practices. Keeping production and service costs down will allow CogWatch to remain competitive increasing the commercial headroom.

It is important to notice that the headroom method is designed to be used by the supplier in order to obtain an early indication of the potential commercialisation of the medical device. While high headroom may be a good indicator that a prototype may be worth of further investment it does not warrantee commercial success. For example, the end product may be less effective, more expensive or less competitive than newer alternative technologies. In the final exploitation plan where the final version of the prototype will be known, additional CogWatch costs, such as regulation compliance and marketing, will be included in the calculation of cost effectiveness in order to provide more accurate economic evidence and financial forecast.

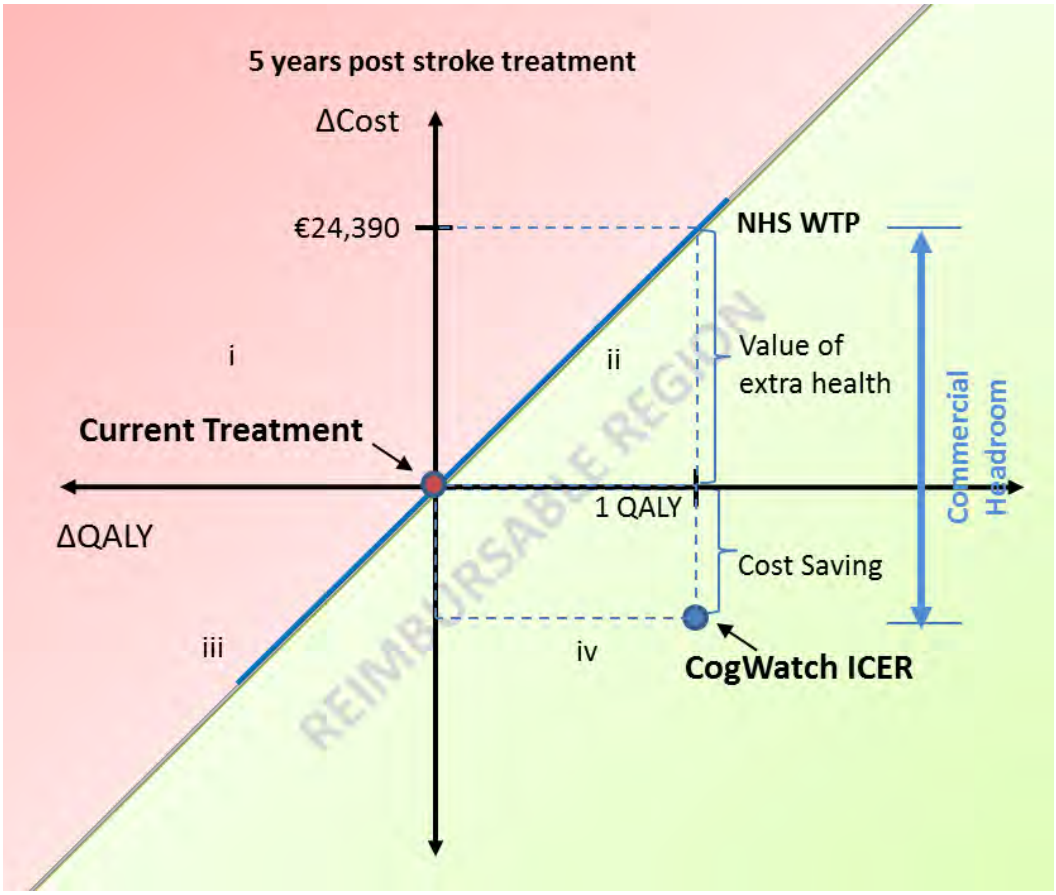

Figure 29: The commercial headroom for a basic CogWatch system in the UK healthcare market (not to scale).

4.2.2 The Buyer

Depending on the magnitude of the impact of the financial crisis on national GDPs, the decision making for the acquisition of MDT by healthcare providers may be based on different criteria and priorities. For example, in Netherlands, Switzerland and Belgium medical professionals may have more influence in decision process and therefore the clinical effectiveness of the MDT could be given priority. On the other hand, in the UK, France and some German private hospitals the aim is on reducing the total costs of the business. Following this rationale, committees consisting of both medical professionals and procurement managers select MDT on the basis of their value. In Scandinavia and Germany, healthcare systems make purchase decisions on a 'lowest bid' criterion basis [56]. Therefore, the route to market for CogWatch technologies should take into account the heterogeneity of the MDT market across different countries and within each country.

For example, in the UK, the NHS is involved in the evaluation and procurement of new MDT through a number of organisations. In April 2013, the entire procurement structure was re-organised [57]. There is a growing role of the local councils and clinicians in planning and delivering health care for the local population. The local clinicians, or general practitioners (GPs), will form the Clinical Commissioning Groups (CCGs) and will be supported by the

Commissioning Support Units (CSUs) on the deployment of healthcare solutions including healthcare procurement and contract negotiations and monitoring [58]. In addition, the Academic Health Science Networks (AHSN) is another organisation with the objective to identify and adopt innovative healthcare solutions in the NHS [59].

Moreover, the Department of Health (DOH) has introduced legilslation giving people access to a personal health budget so that they can have an increasing role in the management of their own heathcare and wellbeing. The healthc budget will be planned and aggreed between the user, or a representative, and the local NHS team [60]. Under this legislation, the end user may be considered as a co-buyer and therefore it is important to take his/her needs into acount when designing, developing and marketing the CogWatch system.

In order for the Cogwatch technologies to be adopted by healthcare providers it is important to clearly identify patients as well as business needs. BMT is in contact with the Associate Clinical Director of the Tees, Esk and Wear Valleys NHS Foundation Trust to discuss type of sensors that can be used to better monitor the activities of elderly patients so that the clinicians can provide better diagnosis and treatment as well as reducing their costs. The Trust has expressed an interest in CogWatch technologies particularly for the monitor daily activities of dementia patients. BMT will work with the Trust to address their challenges and use their clinical procedures and business plan to improve the headroom model and promote the CogWatch concept and technologies. Headwise are also considering how CogWatch technologies can improve their rehabilitation services.

BMT are also in contact with a number of organisations and professionals who play an important role in the development and deployment of health innovation in the UK. For example, BMT is an member Medilink West Midlands providing market information and networking opportunities. Through this membership and other activities, BMT have developed an important network of experts in commercialisation of MDT.

In Spain, marketing CogWatch technologies can be done on a business-to-consumer (B2C) or business-to-business (B2B) basis. In the first case, the devices are sold directly to the individual customer while in the second case they are sold to healthcare service providers.

4.3 SWOT analysis

4.3.1 Strengths

- CogWatch is innovative. It is using unobtrusive sensors to monitor complex ADL task progress in real time. Currently, there are no other Cognitive Rehabilitation and Monitoring tools available with the same features (see Section 3.4).
- Health practitioners recognise the need for a system with the features of CogWatch
- It is relatively cheap. The ‘headroom’ analysis has shown that CogWatch could be potentially cheaper and more effective than the current practices.
- CogWatch be installed at home or at the hospital.
- CogWatch can be adapted to suit the needs of individual patients
- The concept of embedded sensors in everyday objects means that the patients will not feel ‘stigmatised’ while retraining to complete ADL tasks

- Innovative one-size-fits-all design with one-hand removable electronic module means that CogWatch can be practical as well as affordable to produce and maintain.

4.3.2 Weaknesses

- No brand recognition of the CogWatch name.
- Some users might not be cognitively able to operate the system.
- The current economic climate (recession) may prevent national health systems and private companies from trying new – untested – technologies. In times of recession they may prefer safe ways to provide rehabilitation services.

4.3.3 Opportunities

- There is a large number of patients suffering from AADS throughout Europe that would benefit from the CogWatch system.
- There is pressure from National Health Systems to outsource rehabilitation services in order to cut costs and increase efficiency.
- The medical technology sector enjoys continuous growth even during the global financial crisis
- Demographic changes characterised by dramatic increase of older population means that more people may suffer from CVD and stroke.

4.3.4 Threats

- Competitors may emerge with systems offering the features of CogWatch for cognitive rehabilitation at home. However, CogWatch will retain competitive advantage by being the first of its kind.
- Users may be resistant to the use of technology in the home acceptance. Nonetheless, the concept of embedded sensors in everyday objects makes it more likely that CogWatch would meet user's acceptance.
- Stroke prevention is advancing and dramatic improvement of lifestyle is leading to substantial reduction of CVD and stroke. However, a cure for stroke is unlikely and the system is potentially usable with other diseases that threaten ADL skills such as closed head injury and dementia.

4.4 IP Protection and Licencing

Prototype technologies

BMT has filed a UK Patent Application on 24 November 2014 (No: 1420858.1) for the protection of the one-size-fits-all concept (see Figure 8).

UOB has investigated the potential to IP protect developments on acoustic recognition of tooth brushing. However, tooth brushing companies had already worked extensively in the area.

CogWatch Name and Logo

It was decided not to copyright the CogWatch name and Logo since CogWatch is not a recognised brand this is not expected to have any significant commercial value.

Action Recognition Software

UOB will release the Activity Recogniser (AR) as open source on a sharing website such as GitHub using a GPL licence. GitHub includes version control and allows other people to share derivatives of the code. The GPL licence means that anyone can use the software, but that any derivatives that they produce have to be made available under the same GPL licence. This means that enhancements made to the software by other parties would be available to all. If a particular user does not want to make their derivative software available to everyone (e.g., due to development of commercial applications) then they would have to negotiate a separate agreement/licence with the university.

Clinician Side and Hand Recognition software

UPM is strongly committed to apply for software registration in order to protect and remark results of the CogWatch project. This step will be supported by the "OTRI" (Oficina de Transferencia de Resultados de Investigación), which is a UPM office focused in this kind of activities.

Wearable sensors

For this purpose, RGB plans to make a search on license agreements, selecting those which are most relevant. A clear view has been achieved of the main characteristics to guarantee a larger technology deployment. It considers the need to comply with specific regulations in every country. RGB is undergoing an internal process to adapt the company to the FDA requirements. This step is mandatory to gain access to USA and Latin America countries. The draft documents take into account a number of aspects to consider, such as::

- Exclusivity
- Licensing rights
- Sub-license capabilities
- Territory
- Duration

We have obtained conclusions on the way how to conduct the negotiation process of current or future licenses. The analysis has been focused both on the license purpose (exclusivity, scope and rights, duration, sublicense, territory) as well as in the evaluation of economic conditions (royalties, fixed payment amounts and other measures) of the final agreement. The result of this study provides insight on basic terms on economic conditions traditionally settled on technology exploitation, especially indirectly via licensing.

However, it must be taken into account that current market situation and technology evolution expectations can directly affect very deeply along the negotiation.

5. INDIVIDUAL PARTNER EXPLOITATION PROGRESS

In this section progress on each partner's exploitation plans set out in D5.3.1 is summarised.

5.1 UOB

UOB's progress in exploitation of results divides into two fields, Psychology working in WPs 1, 4 and Electronic Electrical and Systems Engineering working in WPs 2, 3, and covers academic (postgraduate student theses, grant applications) and licensing of software.

(1) User behaviour (WPs 1&4).

Five postgraduate research projects were completed as part of their MSc requirements:

- Dyar Karim – visual guided of actions toward one's own face or an external face image. The project will use magnetic field motion tracking to record patients' movement and on-line feedback will provided on a monitor. Accuracy and movement trajectory will be analysed.
- Victoria Caines– effectiveness of cues to guide body- (e.g. brush teeth) and object centred (e.g. stir tea) gestures. Data will include motion tracking and video recording.
- Joanne Howe – A RCT of ADL training for stroke apraxia and action disorganisation syndrome.
- Qixiu Miao – "Quantity-error estimation for stroke rehabilitation using the CogWatch Instrumented Coaster"
- Wenbo Wei – "Real-time detection of quantity errors in tea-making using electronic scales"

Two PhDs entered their final year:

- Amy Arnold – actions sequence learning – from ADL to abstract sequences
- Melanie Wulff – Pair object affordance and its interaction with selective processes.

A number of follow-up grants on ADL skills retraining and rehabilitation based on CogWatch have been applied for including: General cognitive training contributes to specific skill rehabilitation UK Stroke Assoc £625k; ASTech - Efficacy of new technology for ADL skills training in acute stroke UK Stroke Assoc £264k; We can cook Nesta UK £69k; Baking with CogWatch UK SBRI £97k; Investigating Barriers to Assistive Technology UK ABIA £20k.

(2) System development (WPs 2&3).

Two PhDs entered their final year:

- Emilie Jean-Baptiste - Task modelling
- Roozbeh Nabiei - Action recognition

A follow-up grant on a multimodal version of CogWatch was submitted: CogDial - Multi-modal Daily Living Assistance for Language, Speech and Planning Impairments EU H2020 3.6M€;

The AR software will be released as open source on a sharing website such as GitHub using a GPL licence. GitHub includes version control and allows other people to share derivatives of the code. We believe there would be a significant number of users for the AR software. People can build HMMs using HTK but they cannot run a real-time recogniser and therefore cannot build an application. With the AR, developers could build anything from a simple speech recogniser to an action recogniser using input from any type of sensor. For example, someone could build a system to listen out for a range of different birds or wildlife in a particular location over a 24 hour period as part of an eco-census – one detector for each type of sound that you are listening for. In addition, an 'action recognition toolkit' which included the design of the coasters is planned.

In the future, the software could be extended to include a facility to train models in real time. So, for example, if someone had the CogWatch setup with coasters they could ask the software to learn a particular set of actions/movements/gestures and then subsequently recognise them.

5.2 UPM

UPM, as a non-profit research institution, will exploit the results of the project mainly by increasing and improving the knowledge in the research areas of current expertise related with its role in CogWatch (Human computer interaction, innovative interaction, networking techniques and tools, user experience assessment, monitoring devices, etc.), transferring technology to the industry, and deepening the experience in new possible research areas of interest. Taking this into account, UPM has engaged in the following exploitation activities.

Design of 3D models for everyday objects

The LST-UPM group have designed a collection of 3D models for everyday object to be used within the CogWatch project and printable using the 3D printing technology. All the designed objects are available at http://www.thingiverse.com/Cogwatch/designs. Object are protected by the Creative commons Licence, in particular the Attribution-ShareAlike Licence. The sizes of the objects can be customizable by the user and printable using 3D technology. Objects are compatible with UOB designed sensors and other commercial technologies like Shimmer® and Microduino®. The object catalogue will be improved in the future, considering the research line started at LST.

The activity is receiving favorable feedbacks has observed from the web statistics (see Figure 30 and Figure 31).

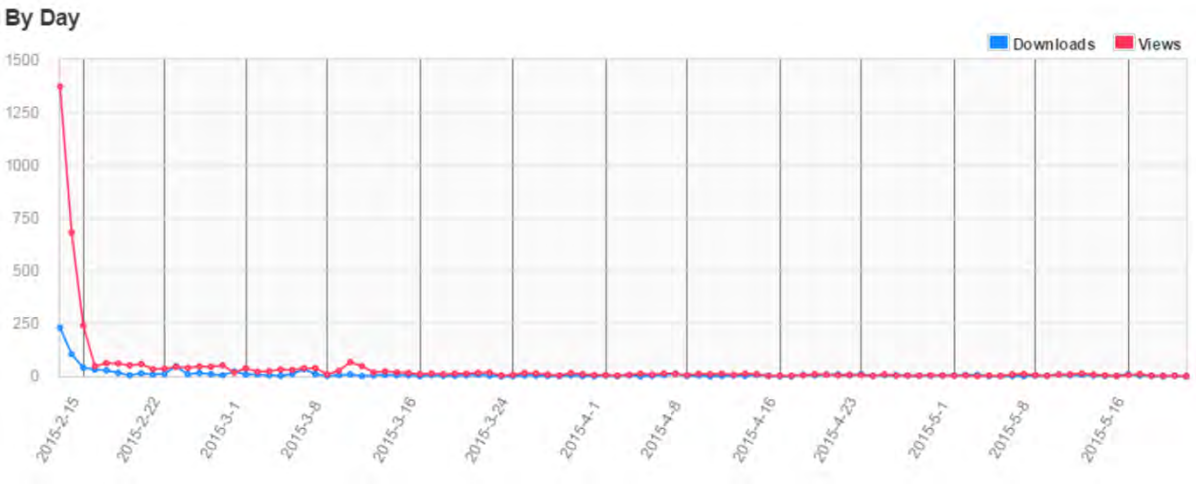

Figure 30: Statistics of Views and Downloads by day.

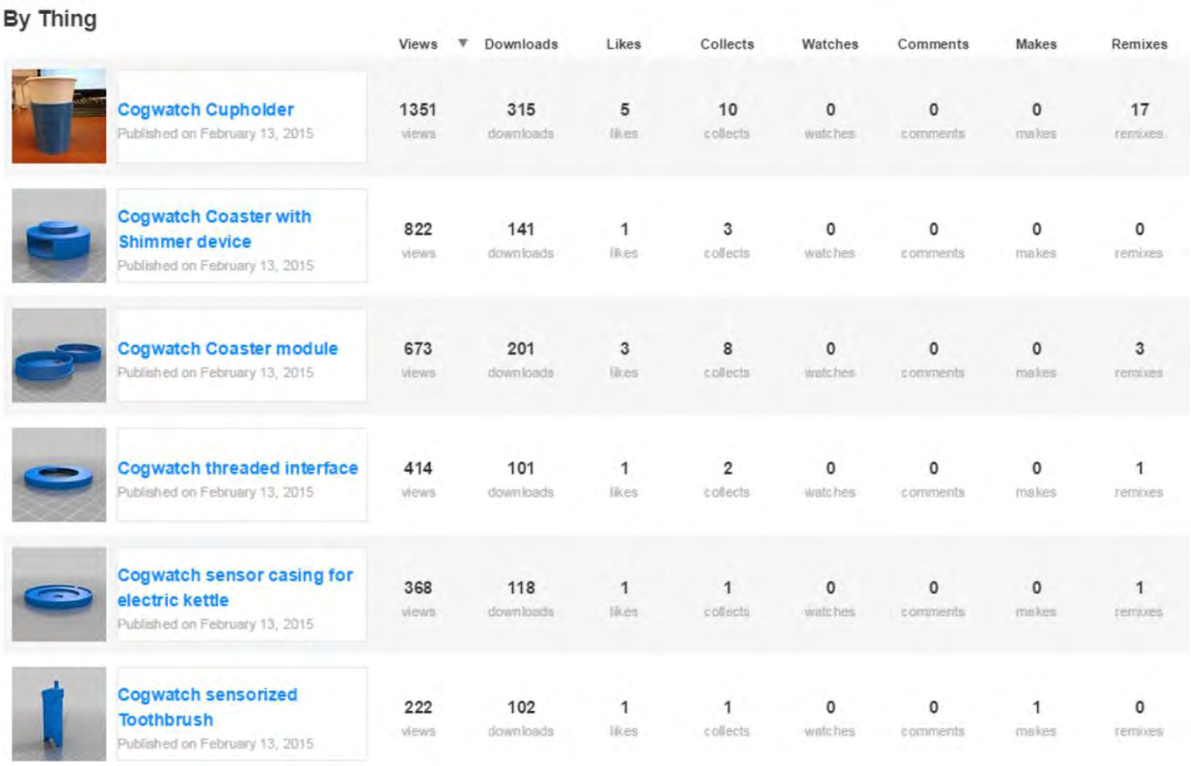

Figure 31: Statistics of Views and Downloads by object.

Industrial dissemination of the CogWatch project

UPM has also a technological park that aims to foster innovation. Thanks to the facilities provided by the Technological Park, UPM create commercial cards of projects suitable to be exploited. CogWatch has been included in the UPM technology offer in order to increase the

visibility and impact our project. In 2014, information about CogWatch was included in the UPM-Innovatech and "CAIT" (Centro de Apoyo a la Investigación Tecnológica, Centre for Support of Technology Research) catalogues.

The UPM Technological Park is in charge of promoting the projects outcomes and to find potential investors. Moreover, UPM is examining the possibility to create a new spin-off company based on the scientific results achieved in the project. All this resources are offered to CogWatch and will be used in order to achieve the most impact as possible for this project results.

Software licensing of CogWatch modules developed by UPM

UPM is strongly committed to apply for software registration in order to protect and remark results of the CogWatch project. This step will be supported by the "OTRI" (Oficina de Transferencia de Resultados de Investigación), which is a UPM office focused in this kind of activities. In particular, UPM will apply for the software registration of:

- **Cogwatch Professional Interface**: A pc based application for the validation of monitoring algorithms in real time. The CPI allows developers to remotely detect and validate the outcome of real time recognition algorithms, improving the accuracy of the developed tools.
- **CogWatch Web Portal**: A web application that allow clinical professionals and occupational therapist to follow the rehabilitation progress of the assigned patients.
- **Cue designer:** A PC based application for the dynamic and customizable design of cue plan based on a tabular description of possible errors given in that process.

Commercial plans

As technical research institution, UPM maintains several institutional contacts with big enterprises as well as with SME's (small and medium-sized enterprises). Those contacts are crucial in the activity of exploitation of the scientific knowledge produced within the University. Within the CogWatch project, one of the roles of UPM will be the dissemination of the CogWatch system among its contacts in order to find possible partnership for the cognitive rehabilitation, not only focused on AADS.

Considering that the system could be used for rehabilitation after any post-stroke disease, not only AADS, initially, there are two main possible clients:

- Neurorehabilitation centers.
- Nursing houses.

Especially, nursing houses offer to their elderly people different activities and games mainly focused on training their brains, moreover, considering that the most of them usually suffer from Alzheimer. So, CogWatch system could be quite interesting and useful for these centers since those rehabilitation techniques and "games" nowadays are carried out by the healthcare personnel. If the caregivers invest their time on caring people who need more help while the others are interacting with CogWatch, the effectiveness and security of the center will also increase.

5.3 TUM

Education

The CogWatch approach is lectured in the Master Program “Movement & Health. Diagnostics, Prevention & Intervention in the Life-Span” offered by the Department of Sport and Health Science at TUM. A special course in the second part of the Master concentrates on a project in Neurology. In the “CogWatch project”, students study the clinical conditions of apraxia, test patients and analyze their ADL performance as well as their responses to cues. AADS and the CogWatch approach are therefore used as a showcase to teach neurorehabilitation. It is planned to offer this course again in the next winter semester.

Master theses related to CogWatch evaluation are currently offered to the upcoming cohort of students ending their master program.

In collaboration with the Departments of Informatics and Electronics at TUM, master theses are planned to be conducted on topics related to future developments of the CogWatch system. Topics include pattern detection and action recognition in CogWatch typical scenarios like ADL in home environments.

Dissemination

In 2013 two open days of the CogWatch Lab at TUM had been conducted. One was for the academic personal of the Department of Sport and Health Science including colleagues from other departments and academic institutions and the other one was for health personal in particular occupational therapists of the partner hospital STKM as well as of other health institution. Both open days were very successful and will be repeated in 2014.

Funding Plans

Research funding applications based on developments of CogWatch have been prepared:

A description of a project titled “ACITVE HANDS – Evaluation, rehabilitation, and assistance of hand function in ageing and chronic CNS diseases” has been submitted to the German pre-call for the EIT KIC „Innovation for Healthy Living and Active Aging“. EIT (European Institute of Innovation and Technology) is a European funding initiative with various KICs. TUM will apply as a major partner of a large consortium for the InnoLIFE KIC in September 2014.

It is planned to apply for funding of research within the new European funding framework Horizon 2020. The applied project should include partners from the current CogWatch project and should also be oriented towards clinical application and business exploitation of the approach.

In addition, it is currently investigated whether the funding format of “Clinical Studies” offered by the German Research Foundation (DFG) provides an adequate framework to support clinical trials aiming to evaluate the effectiveness of the CogWatch approach.

The market will be scanned for companies that potentially have commercial interests in the CogWatch approach. TUM will in particular care for the German market. Firms and companies that are already active in the medical market concerned with rehabilitation using

information-communication technologies seem of particular interest. However, also firms with loser associations with the CogWatch approach will be considered. TUM has special programs to support in-house start-up companies and contact will be made to determine the potential of these offers for the exploitation of CogWatch.

5.4 BMT

BMT is exploiting CogWatch by merging the novel results from the project with our existing know-how (e.g., PRISM software) and results from previous related projects (e.g., eREMEDY, Doc@Hand) to offer improved consultancy services and technology to new customers and to those organizations we already have relationships with. BMT are in contact with a number of organisations and professionals who play an important role in the development and deployment of health innovation in the UK. For example, BMT is a member of Medilink West Midlands providing market information and networking opportunities. Through this membership and other activities, BMT have developed an important network of healthcare providers and experts in commercialisation of medical devices.

BMT will work towards the adoption of Cogwatch technologies by healthcare providers by working with them to clearly identify their patients as well as business needs. BMT is in contact with the Tees, Esk and Wear Valleys NHS Foundation Trust discussing type of sensors that can be used to better monitor the activities of elderly patients so that the clinicians can provide better diagnosis and treatment as well as reducing their costs. BMT, UOB, UPM and the Trust have collaborated in a Horizon202 proposal suggesting the use of CogWatch technologies for the early detection of functional risk in older people. BMT will also work with the Trust to address their challenges and use their clinical procedures and business plan to improve the headroom model and promote the CogWatch concept and technologies.

Moreover, if the patent application is successful, BMT will look into licencing the design to medical device companies. BMT are already in contact with Canard Design who designed the *one-size-fits-all* design for the potential of further developing the concept and licencing if there is demand from health care providers.

In addition to applications in the health sector, BMT is particularly interested in applying AR algorithms to the core business of transport security and risk management. AR algorithms could improve the identification and classification of a wide range of events (e.g., waterborne and airborne security threats from illicit activities) from data gathered from SAR, SOI, hydro-acoustic devices and UAVs.

BMT will also continue to disseminate CogWatch foreground in conferences and organised events. For example, Dr Christos Giachritsis has been invited to organise a session in “Innovative ICT Systems for the Monitoring and Treatment of Brain Related Impairments” during the international Conference on Innovation in Medicine and Healthcare, which will take place in San Sebastian, Spain.

5.5 HW

As a commercial healthcare provider Headwise is interested in both primary and secondary exploitation opportunities of CogWatch. The Headwise exploitation plan is to build on the organisation's profile as a leading company in the application and evaluation of assistive cognitive technology. This is a small but growing market in which Headwise has a track record of working with developers to provide bespoke solutions to improve individuals and organisations. Whereas most off-the-shelf commercial systems and devices for assisting daily living are limited in sensitivity and flexibility for individuals with complex neuropsychological disability, CogWatch will allow Headwise to demonstrate it's involvement at the leading edge of technological innovation. Through provision of the family of CogWatch tools to improve function in a range of daily living tasks Headwise will demonstrate its commitment to developing and robust practical technologies to improve living skills and quality of life.

Through social media, print media (both popular and professional) and on the company website Headwise intends to promote the company's involvement in this innovative research. In addition, Headwise intends to work towards the development of a prototype which has been robustly evaluated and which can be developed by the consortium and potential other parties into a commercially viable product. Initial cost evaluations (see D4.2.1) based on our business model have shown that adopting CogWatch technology can be profitable.

Secondary exploitation opportunities will arise through continuing collaboration with project partners on related projects, and in raising the organisation's profile through CogWatch which will attract other markets for the company's services.

5.6 TSA

The Stroke Association is a charity that funds and promotes stroke research. In addition, TSA is involved in policy making and raising awareness about the prevention, treatment and impact of stroke on patients their carers and the healthcare system. As such, it does not participate directly in commercial exploitation. However, it supports exploitation by other partners by disseminating research results and stressing the potential positive impact by the technology on the quality of life of users and on the costs of healthcare itself.

5.7 RGB

Selected product

Within Cogwatch, after much evolution, the most clearly expected visible product is the NIBP (Non Invasive Blood Pressure) module. The innovations perceived in this device are two folds: On one side, the measurement procedure itself, based on a variation of the Oscillometric method that allows:

- Quicker measurements (15 -30 seconds instead of 45+ seconds with the traditional way,

- New measurement procedure, that implies a lesser impact on the patient, thus reducing a typical side effect called the White collar syndrome. Precision of measurement achieved is thus higher.
- High ergonomic specifications, as a result of the very demanding requirements for APRAXIA patients.

We are still further improving the module, trying to reach a markeatable product at the end of the project.

Selling Strategies

RGB is already familiar with direct product selling, as it has been the traditional way since our foundation, 27+ years ago. In this type of product, however, our view is that the selling procedure should be done differently, via licensing. RGB would also like to know the future potential economical revenues of the CogWatch results, and thus, estimate the technology price. However this data is the result of a negotiation. Being a unique product as it is the case, and transactions being also complex, there is not a “market price” itself.

Our approach will be to analyse the main characteristics of similar licensing transactions. Our purpose is to follow the trend of ecosystem concepts in business strategy.

Exploitation Plans

At the moment, RGB exploitation plans (outside Cogwatch timeframe) are focused on the concept of licensing the NIBP module based on a personalised approach. Current technology for Medical service is quickly developing in parallel in many synergic fields, and it is expected to develop into a kind of “ecosystem” of solutions, that could be provided “off-the-shelf” to service providers. That is why, RGB Medical will strongly support emerging service oriented platforms that may eventually become the clients. For this purpose, a demo price will be offered, as well as protocols and technical support, with the intention to become an interesting alternative to product provider to for service providers. We acknowledge that the difficult part is to have clients “using” our technology, as –once they are in- it is difficult that they step out (under reasonable economical offer on our side) given the high integration cost that is required to pay in these kind of operations. We hope to be able to help those service providers as designer and manufacturer with certification capability, providing personalised solutions for each particular case (as is the case of CogWatch). In this case, exploitation could be done on a licensing bases in a way that RGB can have revenues on a regular basis and not just by selling the technology. We could therefore become a partner of the service provider. This way, both parties win. In conclusion RGB can offer:

- A transfer price for the technology
  - The use becomes the technology owner
  - By paying a maintenance fee, it can be guaranteed the availability of devices at all times with minimum time to repair.
- A kind of rented agreement based on “pay per use” case
  - In this case the product can be upgraded on a regular basis

- The service provider does not need to make upfront payment of the equipment.

Collaborative exploitation

CogWatch generates technology for service, which in our opinion is a step further to RGB product orientation as is our case. However, at component level, we acknowledge that the coaster and the Tooth-Brush devices would be in line with our Business Model. There are also potential synergies with service institutions within Cogwatch, to apply the formulas indicated in the section above.

Therefore, we expect to initiate conversations with partners in the direction of evaluating the potential for initiating (not within CogWatch timeframe) business with these very innovative products and services. The sectors to be addressed would not only be the Medical (specially the coaster), as the sensor can be used in other applications.

RGB has experience in these kind of operations. For example, after years of development, RGB has concluded an advanced monitor for Muscle relaxation during Operation in a Hospital O.R. (www.tofcuff.com). In this case, partial development, industrialization, certification as well as commercialization is carried out by RGB. We are already exporting, and in a natural transition, we are already talking on the creation of a spin-off company. There are two other companies in the consortium, and the general agreement is to share in equal parts the benefits, given in this case the contribution to success of each partner. Each partner has expertise in areas that are necessary, so that joining efforts, the final result has been achieved, while none of the partners could have done it on its own.

6. CONCLUSIONS

This report outlined the final exploitation plan for the CogWatch system. The analysis of the market (e.g., stroke patients, cognitive rehabilitation practices, competitors) as well as the sales and marketing strategy was focused on Spain and the UK since commercial partners can offer a more valuable insight into these to markets.

The report presented the final integrated prototype and the users that it intends to serve. The characteristics of the target market were also presented showing that the ground for commercialisation is substantial, particularly since CogWatch is designed to offer significant improvements over the current practices. In addition, this potential for commercialisation increases further since there are no significant commercial rivals.

The updated costs of purchasing, installing and servicing a basic CogWatch system were estimated taking into account the actual costs of designing and developing an actual near-commercial sensorised mug. It was argued that commercialisation should be driven by continuing achievement of milestones in multiple activities including product development, financing and organisational structure.

In addition, it was recognised that marketing should be based on solid evidence about clinical effectiveness, compliance with national and European regulations and standards as well as cost-effectiveness. An updated estimate of the competitiveness of CogWatch was provided based on the 'headroom' method and the estimated costs of the basic CogWatch system with the near-commercial prototype units.

IP licencing and individual partner exploitation plans were also updated with the filing of a UK Patent Application and related investigations into the potential protection of acoustic recognition technologies.

The final conclusion is that, at least in the UK market, the CogWatch system can potentially be a very promising and cost-effective solution for personalised hospital and home-based cognitive rehabilitation.

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Appendix 1: COGWATCH DEVELOPMENT Costs

The table below provides an estimate of development and deployment of costs as a function of units produced.

	Units (patients)						
Device	**1**	**5**	**10**	**50**	**100**	**1000**	**2750**
Client Geteway (all-in-one F	1,250.00	6,250.00	12,500.00	62,500.00	125,000.00	1,250,000.00	3,437,500.00
MetaWatch	100.00	500.00	1,000.00	5,000.00	10,000.00	100,000.00	275,000.00
RAM for Server	630.00	3,150.00	6,300.00	31,500.00	63,000.00	630,000.00	1,732,500.00
External HD	300.00	1,500.00	3,000.00	15,000.00	30,000.00	300,000.00	825,000.00
Clinician Laptop	1,000.00	5,000.00	10,000.00	50,000.00	100,000.00	1,000,000.00	2,750,000.00
Electronic Module	2,567.00	1,713.40	1,606.70	1,521.34	1,510.67	1,501.07	1,500.39
Sensorised Kettle	14,528.00	16,528.00	19,028.00	39,028.00	64,028.00	514,028.00	1,389,028.00
Sensorised Tableware	14,428.00	16,028.00	18,028.00	34,028.00	54,028.00	414,028.00	1,114,028.00
Kinect	200.00	1,000.00	2,000.00	10,000.00	20,000.00	200,000.00	550,000.00
Vital Sign Sensors (NIBP+gar	400.00	2,000.00	4,000.00	20,000.00	40,000.00	400,000.00	1,100,000.00
Labour (10 days)	5,000.00	25,000.00	50,000.00	250,000.00	500,000.00	5,000,000.00	13,750,000.00
TOTAL DEVEOPEMENT (TRL7	**40,403.00**	**78,669.40**	**127,462.70**	**518,577.34**	**1,007,566.67**	**9,809,557.07**	**26,924,556.39**
Cost of Current Treatment	18,292.68	91,463.41	182,926.83	914,634.15	1,829,268.29	18,292,682.93	50,304,878.05
Deployment Costs	**3,500.00**	**17,500.00**	**35,000.00**	**175,000.00**	**350,000.00**	**3,500,000.00**	**9,625,000.00**
Total Cost (Deveop+Deployr	**43,903.00**	**96,169.40**	**162,462.70**	**693,577.34**	**1,357,566.67**	**13,309,557.07**	**36,549,556.39**
Target Profit	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Selling price	**43,903.00**	**96,169.40**	**162,462.70**	**693,577.34**	**1,357,566.67**	**13,309,557.07**	**36,549,556.39**
Cost Per CogWatch Unit	**43,903.00**	**19,233.88**	**16,246.27**	**13,871.55**	**13,575.67**	**13,309.56**	**13,290.75**

The estimates are based on the actual costs occurred during the design and development of the rechargeable instrumented mug with the one-size-fits-all sensor module. For example, the design costs are equally distributed across all the units produced. Nonetheless, the following simplified assumptions have been applied:

- *Design costs*: The design costs for *whole range of the tableware* equals the design cost for the mug divided by the number of different pieces/units in the tableware range. Since, the design costs for the mug (Stage 1-4 which resulted in the one-size-fits-all design) were €14,028 and we have included four different pieces of tableware (i.e., mug, milk jug, tea caddy and sugar bowl), the design cost per unit is €3,607. We assume that the design *cost for the kettle* is the same as the design cost for the mug; i.e., €14,028.
- *Production costs*: The production costs depend on variables such materials used, machinery and tools deployed, write-off time, and existing manufacturing facilities, number of units produced, etc. Therefore, it was decided to keep the kettle and tableware production costs constant at €500 and €100, respectively. These include the rechargeable base.
- *Deployment costs*: These include €1000 for *installation* and €500 per year for *servicing*. These costs were introduced in D5.3.1
- *Labour costs*: This includes skilled labour at €500 per day. This cost was introduced in D5.3.1
- The costs for the client side and hospital hardware are similar with the ones provided in D5.3.1

Finally, since the costs are estimated based on a system at TRL7 the target profit is set to 0%.