REHYB

D2.1
Use case scenarios and stakeholder identification

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Disclaimer

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Executive Summary

Stroke-survivors show very frequently reduced ability and motivation to use their affected upper limb. The performance of typical activities of daily living (ADL) is highly conditioned by the capacity of using the upper limb. Thus, a loss of upper limb functionality entails a serious obstacle for the performance of ADL's. For this reason, the goal of this project is to develop a patient-specific, assist-as-needed device which maximises the training efficiency during clinical and home-based rehabilitation by means of serious gaming, and offers a pleasant user experience by supporting patients during ADL. The new ReHyb rehabilitation system will be adaptable to the individual needs of stroke patients by combining an exoskeleton with functional electrical stimulation and virtual / augmented reality.

The first framework of requirements for the ReHyb system is outlined in this deliverable by defining **use case scenarios** and identifying relevant **stakeholders**.

This deliverable informs the Research and Development (R&D) activities by providing relevant data and analyses necessary to conceive an acceptable, useful, customizable assistive device.

In this deliverable, **first clinical hypotheses** involving upper limb multi-joint movements based on literature review are presented. A **users' wish list** and **user requirements** were compiled by performing questionnaires surveys and semi-structured interviews with patients and healthcare operators, and by reviewing important literature. To provide detailed information about the needs and expectations of the core user – a patient who survived a stroke – three **personas** were created, each representing a different impairment level, ranging from mild to moderate to severe. In addition to the personas, more **general characteristics of the targeted patient group** for the use of the system in a *rehabilitation hospital* as well as *at home* are described. For this, large patient data generated from the clinical information system and from former funded projects addressing the treatment of the upper limb with robotic devices were analysed. The insights into personas and also the more general characteristics of the targeted patient group were then transferred into **system requirements**. For setting up the use case scenarios several **gamified tasks** and **ADL tasks** are presented which can be implemented in the specific ReHyb modules. The ADL tasks are described as motion primitives. And finally, **stakeholders** relevant for the ReHyb system were identified and described regarding their roles, interests, knowledge, expectations, influence, tangible incentives, intangible incentives, and risks.

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1 Introduction

People suffering from an acute cerebral event like stroke see very frequently reduced their ability to use the upper and lower limbs on one side of their body. Such disability is caused by the loss of strength and sensitivity of the shoulder, arm, forearm and/or hand muscles.

In general, the ability to perform typical activities of daily living (ADL) and to define behaviours and relationships with human beings is highly conditioned by the capacity of using the upper limbs in a single or combined and correct way. In fact, movements performed by the upper limb during ADL are characterized by a remarkable complexity and a strong possibility of adaptation to different situations and interactions with objects and other human beings. For these reasons, the loss of the ability to use even one of the upper limbs entails a serious obstacle for the person to perform ADL. Furthermore, in post-stroke subjects this inability (disability) usually persists over time.

For all these reasons, a rehabilitation pathway aimed at promoting the recovery of a person affected by a stroke and therefore, oriented at improving his ability to perform ADL, will inevitably tend at improving both efficiency and quality of movement of the affected upper limb.

Although current knowledge in the biomechanical and medical fields have made it possible to know some neurophysiological foundations of upper limb movement, the definitive understanding of the mechanism by which the loss of functionality of the upper limb is produced in the subject affected by a stroke has not been clarified yet.

The complexity and considerable variety of movement generated by the upper limb in its entirety is determined by several factors, such as:

1. The upper limb is a functional unit composed of several interconnected joints, namely shoulder, elbow, wrist and fingers, which are in a close anatomical and functional relationship with the spine and the trunk through a skeletal and musculotendinous interface (the scapula and the costal wall).
2. The movement generated by the upper limb is characterized by a remarkable coordination in the activation timing between different muscle groups which act according to a pattern that seems to have its own intrinsic organization at the level of the central nervous system and which defines the concept of muscle synergy.

Therefore, in the person suffering from a lesion of the central nervous system, there is a loss of the possibility to:

- activate with sufficient force one or more different muscle groups with different levels of weakness
- completely move one or more joints of the upper limb
- take full advantage of the sensory inputs that derive from the skin and myotendinous structures of the upper limb
- activate in a coordinated and harmonious way, the different joint structures of the upper limb according to the individual's intentions: what derives from it is the execution of a movement that loses its fluidity and overall efficiency, resulting in a perception by the

individual of heaviness, effort and inability to perform a complete movement. This often means making a movement in an alternative way, taking advantage of the so-called compensations, namely alteration of the activation pattern or modification of the movement itself, which primary cause is not yet fully understood.

From all these elements it may be deduced that the guiding principle of the recovery pathway for the upper limb function and the ability to perform ADL must include the possibility of:

- increasing or compensating the force expressed by the patient in one or more muscle groups;
- encouraging and guiding an organized and harmonious activation of the different muscle groups and joints of the upper limb according to the individual's intentions so as to minimize the appearance of compensation movements and to better retrace the development of synergistic patterns of sequential muscle activation;
- providing the person with the best possible perception of the type of movement that is performed, so as to correlate it to his primitive intentions, whether they are inserted in a context of "training" or execution of actual activities of daily living;
- significantly modifying the type of movement and task performed by the person during the functional recovery period, starting from the subacute phase immediately after the acute event up to the chronic phase in general considered after six months from the acute event. In this way, it is possible to allow a personalization of the treatment pathway and its adaptation to the different contexts of life in which the person finds herself over time.

Literature supports the idea that there is an intrinsic organization of the central nervous system capable of creating intentional movement patterns with the upper limb and that this is dysregulated or otherwise altered in case of injury. The rehabilitation treatment aimed at the qualitative improvement of the execution of an upper limb movement through the use of technological equipment for instance, favours the reactivation of the neuronal pathways that connect the areas of the central nervous system predisposed to the programming and creation of a movement and the nervous and muscular structures responsible for carrying it out. The quality of this interaction, through the correct choice of the characteristics and methods of stimulation and execution of the movement, can therefore facilitate a more correct reorganization of the central nervous system in the post stroke recovery phase.

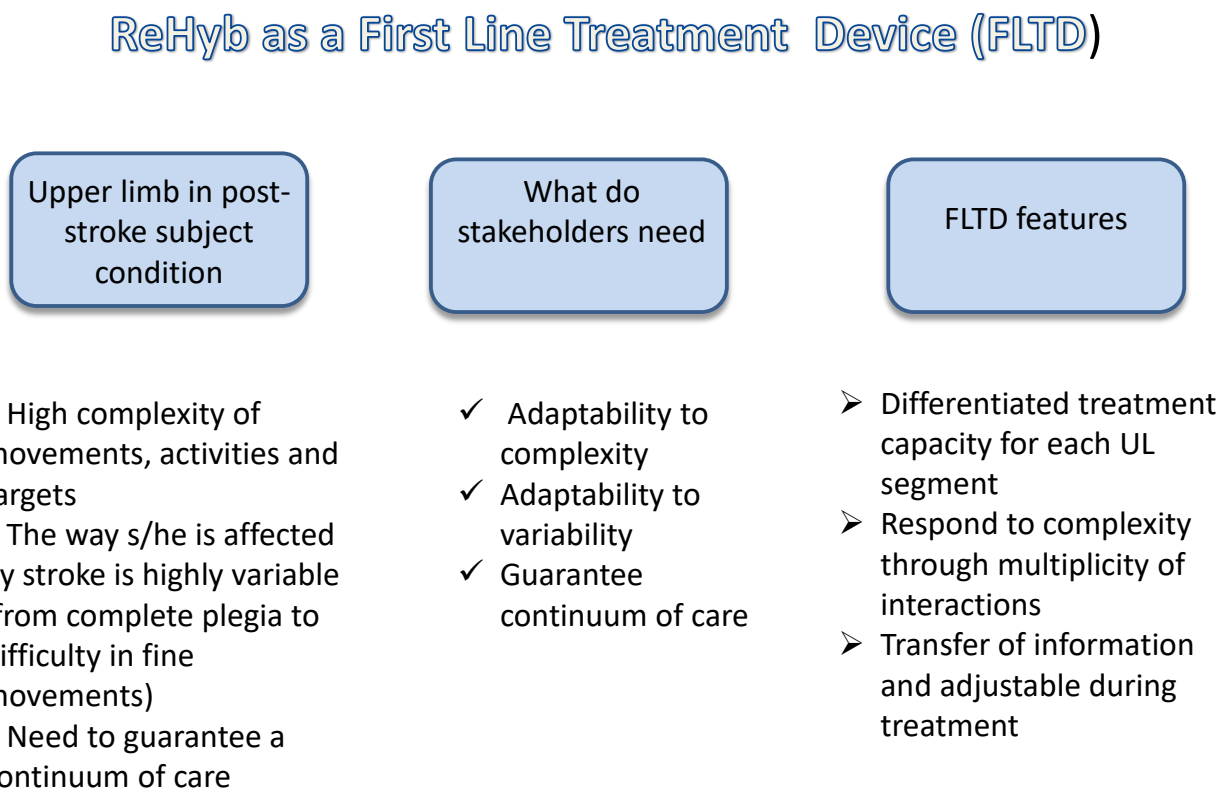
In this context, the use of robotic equipment able to support the rehabilitative treatment of post-stroke patient becomes a factor of considerable help because it may allow:

- movement support through the creation of forces expressed by motorized systems or elastic resistances;
- interaction with patient’s intention of movement;
- interaction with the environment;
- a remarkable adaptability to individual dimensional differences through the creation of adjustable systems;
- the performance of coordinated movements of the upper limb through the intervention of computerized systems able to process the information received from the equipment

in terms of its movement characteristics (speed, range of displacement) and the person's intentionality of movement, ability and muscle activation level;

- the differential action in the different segments of the upper limb (proximal region of shoulder and arm aimed at guiding the upper limb in the space, elbow aimed at approaching or removal of the hand from the body, wrist and hand for direct interaction with the surrounding space) by means of a mechanism of modularity, which enables specific configurations according to person's needs;
- the performance of different movements carried out in a variety of ways and contexts, through the adaptability to the simplicity or complexity of the movement requested and of the environment and circumstance in which it is performed, i.e. in the healthcare environment during rehabilitation treatment, in patient's home environment during the continuation of the rehabilitation pathway or in real life ADL. In this way, the technological support for the recovery of the functionality of the upper limb becomes a factor always available during the different phases of recovery.

The combination of all these features suggests the possibility to make available for the clinicians a first line treatment device. Even if some of these characteristics may be found in different devices currently available in the market ,up to date it is not possible to find a solution that combines them in a flexible, modular and usable way. Consequently, a first line treatment device for post-stroke upper limb rehabilitation may be reflected in the following general hypothesis:



1.1 Overview

The REHYB project envisions a new rehabilitation system with novel communication capability through multi-modal sensing and actuation technologies based on digital user twin, interfaced with an exoskeleton and functional electrical stimulation. Predictive information generated by the digital user can then be mapped onto the real environment to intuitively navigate the user with the most appropriate set of movements. Our goal is to develop a patient-specific, assist-as-needed device which maximises the training efficiency during home-based rehabilitation by means of serious gaming, and offers a pleasant user experience by supporting patients during activities of daily living (ADL). The core system developments will be performed at modular level. For simplicity and a strong societal impact, the ReHyb project adapts its use case to the healthcare of stroke patients in the participatory design which will allow a full exploration of the concepts and techniques as a user-centric device.

In general, any training and rehabilitation devices must address the unique requirements of a particular individual. The development of an adaptive, personalised robotic system imposes significant challenges as it requires extensive knowledge about the user. In order to develop a rehabilitation system that is considered profitable by users and therefore accepted by those, the definition of the usability requirements is a crucial part within the development process. Apart from satisfying the user, developing medical devices to the needs of the user and implementing a good usability, contributes to the safety of the device.

This deliverable D2.1 is part of Milestone (MS) 2 which outlines the first framework of requirements for the ReHyb project by defining use case scenarios and identifying relevant stakeholders. The objective was to systematically identify the users suitable for our use case and their requirements using a participatory design. We specified typical characteristics of a reference population of stroke survivors that can interact safely with the ReHyb system for which the inclusion criteria were set out and agreed on by medical experts. User-centric system requirements were identified in order to describe realistic scenarios of physical human-robotic interface (pHRI) and robot-motion primitives. The user requirements were mapped onto the system levels to specific functional requirements by modules composing of the hybrid exoskeleton.

End-users of the ReHyb system at the clinical partners sites Schön Klinik (SK) and Congregazione Suore Infermiere dell'Addolorata (VALDUCE) contributed to the specification of the system requirements. System requirements consider both, patients' and therapists' needs. User requirements and task definitions were constructed from surveys, focus group outputs and literature review of the medical, psychological, and therapeutic literature. Surveys and focus group outputs were conducted at the clinical sites to collect expert knowledge regarding the ergonomic and practical aspects of therapeutic interaction with potential users, in a wide range of scenarios informed by the literature review and specialist knowledge.

1.2 Structure of the deliverable

According to the objectives of D2.1, chapter 2 focusses on the definition of the use case scenarios and chapter 3 on stakeholder identification. To achieve this task different hypothesis

were explored, which are addressed by this deliverable. First of all, user requirements (chapter 2.1) were defined by literature review and a survey (Appendix I) to generate a wish list that presents patient's and healthcare operators' opinions and needs. As a first step, during the months of January to March 2020 ReHyb clinical partners SK and VALDUCE have gathered information of potential users (post-stroke patients and healthcare operators) on their opinion about and experience with currently used devices related to the three main components of the ReHyb system, i.e., robotics, Functional Electrical Stimulation (FES) and Augmented/Virtual Reality (AR/VR).

As second aspect of the Use Case Scenarios, patients' characteristics (chapter 2.2) were described including the definition of 1) personas, 2) patients' clinical characteristics, 3) patients' characteristics at home and 4) inclusion an exclusion criteria. To provide technical partners with an individual description of possible users on a wide theoretical continuum, three personas were created representing a mild, moderate and severe impairment condition in post-stroke patients. Personas are described in chapter 2.2.1. Chapter 2.2.2 focusses on a more detailed description of the identified users and general patient characteristics. Data relevant to describe patients after a stroke was assessed from patients who were receiving robotic treatment in the rehabilitation hospital with different therapeutic devices, i.e., with a fully powered exoskeleton and with a spring-based device. This data is valuable for the description of potential ReHyb system users. Characteristics of patients using AR/VR in the home setting are described in chapter 2.2.3. Furthermore, inclusion and exclusion criteria are proposed in chapter 2.2.4 in order to specify a reference population of stroke survivors that can interact safely with the ReHyb system.

User-centric system requirements (chapter 2.3) are the content of the third subchapter under the topic Use Case Scenarios. Here, the previously defined user requirements are mapped onto the system levels to specific functional requirements by modules composing on the hybrid exoskeleton. This chapter focusses on two aspects: 1) on the definition of the system requirements adapted from the pre-defined impairments of the created personas, and 2) on outcome related system requirements discussed during a clinical workshops with respect to outcome parameters that the system should provide as feedback to the users.

Part four of the definition of the use case scenarios (chapter 2.4) contains information on the robot-patient interactions by defining tasks that could be performed by the patient using the ReHyb system. Serious games provided by the technical partners are described, as well as ADL tasks considered by therapists and patients to be important for a more independent life in patients.

Chapter 3 describes the stakeholder identification. Clinical partners defined relevant stakeholders for the development of the ReHyb system and characteristics of stakeholder groups were listed.

In chapter 4 conclusions drawn are described and further steps are discussed.

1.3 Hypothesis of the deliverable

In detail, five relevant clinical hypothesis (hypothesis 1 – 5 (H1-H5)) were explored.

H1. Relevance of trunk stability

"Give me a place to stand and I will move the earth." (Archimedes): Upper limb movements require a stable place to stand. Such stability is given by the trunk.

In fact, in order to perform complex movements like those involved in upper limb (UL), it is necessary to count on a stable support. Such a support is provided by the trunk. Literature defines trunk control as "…the ability of the trunk muscles to allow the body to remain upright, adjust weight shifts and perform selective movements of the trunk that maintains the base of support during static and dynamic postural adjustments." [1]

Absence of fixation elicits a difficulty of generating UL movements in a fluid and coordinate way.[2] Although hemiplegia affects unilateral limb activity, it has a potential to deteriorate the function of trunk muscles on both sides of the body affecting the proximal control.[1] In fact, when attempting to move upright against gravity, this lack of trunk control may derive in a distal compensatory muscle activation pattern, that affects the quality of UL movement.

Given the aforementioned functional as well as anatomical interactions of the trunk and the upper limbs, it is essential that a robotic tool aiming at improving the segmental and global functionality of UL should provide a transparent interaction between the ReHyb System and the trunk. This means it should:

- Avoid to adversely affect the maintenance of trunk control due to global weighting both perceived and objective,
- Avoid the realization of forces that require the construction of unfavourable torques and forces on the trunk which may require some compensatory activations either by the abdominal muscles and/or spinal erectors;
- Eventually, have a constant and effective awareness of the position of the trunk through the use of sensors preferably if positioned on the device itself.

Consequently, first clinical hypothesis involving UL multi-joint movements is defined as:

H1: A transparent interaction between the ReHyb System and the trunk will allow a stable and dynamic control of the trunk in hemiplegic subjects allowing the performance of complex and multi-joint UL movements.

H2. Relevance of shoulder joint control

Shoulder joint is by itself a very complex structure that may be considered from different perspective. In fact, literature suggests that the "… shoulder complex must be considered a part of a larger kinetic chain made up of several joints."[3]

In this sense, literature highlights the importance of the interaction between scapula, scapulothoracic muscles and the influence of the shoulder position on pathways to distal muscles.[3, 4] Nevertheless, few studies are reported on the role of the scapula in shoulder instability or glenohumeral joint stiffness.[5]

Since there is no bony articulation between the scapula and thorax, the variety of movements allowed by this joint goes from retraction to protraction, as well as elevation, depression, anterior/posterior tilt, and internal/external and upward/downward rotation.[3] However, this characteristics also predisposes this region to pathologic movement. In fact, Paine and Voight [3] have reported that "Weakness of the scapulothoracic muscles potentially leads to abnormal positioning of the scapula, disturbances in scapulohumeral rhythm, and generalized shoulder complex dysfunction."[6] These muscle groups have the function to anchor the scapula and guide the UL movement.[7]

Among the main stabilizers of scapula are the trapezii which functional role is mainly related to upward rotation and elevation, retraction and upward rotation and depression. Additionally, they may also contribute to posterior tilt and external rotation of the scapula during arm elevation.[3] Studies report that increased upper trapezius activation may be viewed as a common compensatory strategy used by people with shoulder pain and pathology to elevate their arm.[8]

At the glenohumeral joint, the deltoid is the prime mover of the arm into humeral elevation. Main functions of deltoids are stabilizing the arm while the lateral head assists in raising the arm from 15 to 100 degrees, prevent inferior displacement of the glenohumeral joint and provide compensatory force during abduction of the arm.[9]

In this sense, the main clinical point is to reduce as much as possible the need of triggering compensatory movements by the cervico-dorsal / cervico-brachial / thoraco-brachial muscles. Therefore, the device should allow the highest possible supportive interaction between the structure of the exoskeleton, the upper limb and the scapula/trunk. In this way it will be possible to avoid the creation of unfavourable forces or torques that may play against the possibility of performing fluid and controlled movements by the patient and which may require compensatory muscle activations.

Consequently, second clinical hypothesis involving UL multi-joint movements is defined as:

H2: The dynamic stabilization of shoulder joint given by the ReHyb System will allow a correct interaction between scapula, trapezii and deltoids in hemiplegic subjects facilitating the performance of complex UL movements.

H3. Relevance of arm gravity support

In general, literature supports the idea that gravity compensation increases active range of motion during multi-joint UL movements.[10] Additionally, it has been observed the application of gravity compensation involves a simultaneous decrease in the level of muscle activity. "More fundamental research of Beer and colleagues (Beer et al, 2004) identified an involuntary coupling between shoulder abduction and elbow flexion in stroke patients, which is less strong when the arm is supported, resulting in a larger elbow extension during maximal planar reach tasks with arm support. This abnormal coupling probably results from an increased use of alternative neural pathways to compensate for the damaged corticospinal tracts after stroke, which limit the selectivity of muscle activation."[11] "…preliminary results of Amirabdollahian et al. indicated that training while deweighting the arm against gravity can improve motor function of the arm".[12]

Following consequences have been reported for post-stroke patients when applying gravity support thanks to the reduction of the level of muscle activity:

- active arm movement may be facilitated
- patients may use their residual capacity to perform a functional movement
- patient may start motor training at a very early stage and perform longer and/or more frequent training sessions

Additionally, there is evidence that hand grip is the function that appears to be more affected by the weakness of the other UL muscle groups. This suggests that arm gravity support may have a positive effect on distal functional movement.[13]

H3: The support of the weight of the arm given by the ReHyb System will facilitate active multi-joint UL movement using patient's residual capacity and avoiding compensatory strategies.

H4. Relevance of bimanual movements and interhemispheric motor pathways

Inability to use the arm in daily actions significantly lowers quality of life after stroke. Most actions of daily life engage the two arms in a highly coordinated manner. In contrast, most rehabilitation approaches predominantly focus on restitution of the impairments and unilateral practice of the weaker hand alone.[14]
Clinical efforts in improving arm function after stroke have had limited success, with only 5% of stroke survivors regaining full arm function in daily life despite extensive therapy.[15]

Interlimb coordination is essential to perform goal-directed daily tasks. The neuroanatomical basis of bimanual coordination in humans is quite complex: the execution of coordinated bimanual tasks during goal-directed activities requires spatiotemporal regulation of the upper limb movement pattern. Neuroanatomical and neurophysiological linkages at the spinal and brain level are responsible for the coordination. The linkage is termed ‘‘neural coupling". There is an interhemispheric synchronization and disinhibition to control the coupled bimanual upper and lower limb movement.[16] This regulation occurs despite neural constraints between two hemispheres. Furthermore, information received through visual feedback enhances the control for bimanual functional tasks.[17]

Different theories try to explain the neurological structure underlying bimanual activities and the neurological pathways in the central nervous system. anyway, the inter-limb coupling effects during bilateral reaching are retained even after chronic stroke and can be used to produce an immediate improvement in paretic arm reaching performance.[18]

Corpus callosum, a unique feature of the mammalian brain is the most commonly known neuroanatomical structure for interhemispheric communication. However, the corpus callosum is not the only structure that is responsible for bilateral coordination. The ipsilateral brain via lateral and ventral tracts plays an indirect role in bimanual movements. The role of the corpus callosum is vital in tasks that require intensive bimanual coordination. The callosum regulates the spatial aspect of a coordinated movement.

The supplementary motor area (SMA), a primary motor cortical region, is substantially responsible for the organization and control of inter-limb coordination. The routine bimanual tasks cause network extension in the bilateral primary sensorimotor cortex (SM1), cingulate motor area, dorsal premotor cortex, and posterior parietal cortex.

Moreover, it is known that practice can change Central Nervous System (CNS) functional connections: the interhemispheric inhibition changes to disinhibition with practice of the bimanual task; for instance professional musicians like drummers or pianists. Repetitive bimanual coordinated movements may enhance motor function and encourage activity-dependent neural plasticity.

Bimanual coordination is a skilled inter-limb coordination of two arms in any bimanual task. It also requires intra- and inter-limb coordination (integration and sequencing of action within and between the limb/s, respectively) for a successful task performance.

The skillful movements place less demand on the cortical and subcortical systems. Haslinger, et al. [19] compared functional magnetic resonance imaging (fMRI) findings for bimanual movements in professional pianists with controls. The control subjects demonstrated stronger activation in anterior cingulated cortex, dorsal premotor cortex, both cerebellums, and right basal ganglia compared with the pianists. The finding strongly supports the development of rehabilitation protocols that emphasize the practice of bimanual tasks.

H4. The ReHyb system may enhance inter-limb coordination during bimanual activities and training, allowing improvement in "real life" ADL performances.

H5. Relevance of neuro-plasticity

Clinical recovery from stroke has been often associated to plastic reorganization of the CNS, usually defined as cortical plasticity and/or neuroplasticity[20]. Such reorganization is usually referred to the recruitment of areas previously not engaged in a specific task in order to substitute some lesioned area.[21] This means that besides the areas located in the lesioned hemisphere homologous areas of the contra-lesional hemisphere may be activated in order to take over some activities after a stroke event.

In general, the motor system consists of cortical and extra-cortical areas, and a close interaction with sensory systems is considered a pre-requisite both for motor learning and correct movement execution.[22]

Literature suggest that ipsilateral motor pathways may play an important role in the recovery of motor function after stroke through the phenomenon of neuroplasticity, which has been defined as the capacity of the CNS to modulate its physiology and anatomy at a cellular level in response to different internal or external events.[23]

Although the triggering of such plasticity may be due to different causes, it has been recognized that one of the most powerful modulators of cortical structure and function is behavioural experience. In fact, the changing properties of different cortical areas are constantly shaped by different behavioural demands.[20] Since both hemispheres contribute to the recovery of a particular function, frequency and repetition of specific exercises may become crucial for functional recovery in post-stroke patients.

It has been reported that another important factor to be considered for functional recovery in post-stroke patients, is the time window for recovery. In fact, it has been recently demonstrated that, in spite of the traditional view that considered the first period after the acute event as the most favourable for function recovery, such time window may be extended to 18 months after acute event.[24] Consequently, Ballester, et al. [24] suggest that there is a long-lasting critical period of enhanced neuroplasticity post-stroke that enables improvement in body function and structure even at late chronic stages.

However, studies also show that there may be a wide range of differences between post-stroke subjects, mainly depending on the individual lesion pattern and other patient's characteristics.[25] In fact, it has been demonstrated that even with intense task-specific training, around 15% and 30% of post-stroke patients are permanently disabled.[26] Furthermore, despite the fact that the dynamic process of changing brain activation patterns has been studied, the relationship of this process to the recovery of specific functions is still not completely understood.[25]

H5. Since neuro-plasticity has a crucial role in post-stroke short and medium term recovery, the ReHyb system will promote such process through the possibility to perform tailor-made, complex and repetitive tasks.

2 Use Case Scenarios

According to the objectives of D2.1, the first part of this deliverable focusses on the definition of the use case scenarios. Here we describe the steps which were taken to develop the relevant Use Case scenarios for the ReHyb system. Resulting findings to define user requirements are based on literature review and structured questionnaires. Patients' characteristics were identified by clinical data analyses and workshops. Personas were created representing the addressed patient population, leading to a detailed description of the patients' personal and clinical characteristics. System requirements were described based of an in-depth analysis of the user's requirements, i.e., patients and healthcare operators. Besides the system requirements, relevant therapeutic and ADL task were described.

2.1 User requirements

Adopting a patient-centred approach in neurorehabilitation is repeatedly stated to be important.[27] Identifying and considering patient's opinions, values, goals and capacity is essential for the success of neurorehabilitation. The probability of an intervention to succeed increases when the patient values the target outcome, engages in the therapy, or expects the intervention to be effective.[27] A patient-centred approach can further include the identification of movements the patient wants to practice, games the patient likes to play and the progress of treatment adjusted to patient's individualities.[28]

Therefore, the first step of the use case definition was the development of a users' wish list. The wish list includes opinions and wishes of patients as well as healthcare operators. The wish list was created based on: 1) findings from literature and 2) patient's and healthcare operator's responses.

Current literature on patients' wishes and needs assessed by interviews shows the wish for a home-based **robotic** system that is portable and targets the whole arm. Further, patients aim to practice functional movements during upper-limb robotic rehabilitation. According to patient opinions the device should give feedback on their performance while they want to enjoy the treatment.[28] The need for a home-based treatment is also given regarding **functional electrical stimulation.**[29] Regarding the use of **VR/AR** systems in the upper limb rehabilitation, patients after stroke describe the therapy as enjoyable (93%), helpful (80%) and something they would like to integrate in their therapy (88% of 40 patients with a mean age of 63 years). Furthermore, this patient group reported that the games were fun and especially liked competitive elements of games. Further, games that involved cognition, such as memory, were appreciated. On the other hand, some patients experienced gaming as monotonous due to a lack in variety and repetitive exercises. Especially, elderly people did not feel to benefit from gaming *("I don't understand how it would help. It would probably help for a younger person but not for me. I'm over 80. It's hard to understand for elderly people"*). Additionally, the result that games were too easy for a proportion of patients while others experienced them as too difficult, highlights the need to adapt VR/AR systems and task difficulty to individual characteristics and capabilities.[30] Another VR-based intervention included tasks that involved memory, attention, visuo-spatial abilities and executive function. In comparison to conventional therapy, this VR-based intervention was followed by greater improvements in cognitive functioning, attention and executive functions. Furthermore, the system led to high satisfaction in the patient group (System Usability Scale (median) = 80/100).[31] Currently, VR-based treatments show a lack in interventions that focus on spatial neglect. In addition to that, interventions that address proprioception (e.g., the robot used force pulses to guide arms toward target elbow angles) and sensory deficits (e.g., treatments that use electrical cutaneous stimulation and discrimination task training) are missing.[32]

Patients who tested a **robotic device in combination with AR** report that they liked the treatment in the beginning, but got bored over time (n=20). Thus, more variation between the games but also within games should be considered. Changes within one game can be made by different levels of difficulty, implemented by a change in task or design of the game.[33]

Lehmann, et al. [34] interviewed five patients who used a **robotic device in combination with gaming**. Patients reported positive experiences, they described the system as very interesting and easy to use. They liked system's features, such as the competitive character of games, visual feedback and a summary of the progress after each training. In addition, patients already show improvements in functions (grasping, reaching, and lifting which has an influence on ADL) and expect further progress. Furthermore, having the therapist beside gives some patients a feeling of safety and control. One aspect of the system that patients perceived as negative is missing social interaction, as they enjoy talking to the therapist during training and laughing together. Some patients report that games could be more challenging regarding cognition, but other experience fatigue which has a negative impact on their performance.[34] Once again, this highlights the individual user capacity and the need for an assist as needed treatment.

Literature about therapists' opinion show that **robotic devices** should be usable in a seated position. Additionally, therapists wish for a repetitive and bilateral (both arms simultaneously) training option, feedback to the user and the facilitation of many arm movements. Furthermore,

the training with a robotic device is recommended to be task-orientated, to have virtual activities specific for ADL and to include strengthening exercises as well as context-specific cognitive learning. The training should be adapted to patients' individual capacities. Again, the need for a device to use at home is expressed.[35]

A focus group discussion of nine therapists regarding the **use of a robotic device in combination with serious games** showed that therapists are sceptical. They doubt that a computer alone can lead to the needed motivation and that every patient can train without the assistance of a therapist. Therapists mention the importance of giving good instructions. Additionally, a functioning system is essential, since malfunctioning leads to patients' frustration. The possibility of getting feedback and including ADL in gaming is perceived as positive aspect and VR-based training is expected to have motivating effects. Lastly, therapists wish for a cheaper, less fragile and more robust device that additionally includes haptic feedback. Haptic feedback is important to perceive a weight or the material of an object, the surface and the temperature.[36]

Beside findings from literature, information about opinions, experience and values of patients and healthcare operators were gathered from clinical partners (SK and VALDUCE). To adopt a patient-centred approach in the development of the ReHyb system and thus increase the probability of success, patients' and healthcare operators' opinions, values and goals were identified to create a wish list.

This wish list is based on the results of a survey, conducted in the most relevant user groups concerning usability and functionality of the ReHyb system: 1) patients and 2) healthcare operators (physical therapists (n=30), physicians (n=13), occupational therapists (n=5), sport therapists (n=3), neuropsychologists (n=2), sport / movement therapists (n=1) and a nurse (n=1)). The scientific literature as described above was included in the wish list for additional information.

For each of the three technological domains of the ReHyb system (robotic, FES, AR/VR) separate questionnaires were provided with questions adapted to specifically address each domain separately. The questionnaires are provided in the appendix (Appendix I). All three questionnaires were proposed to both user groups. Each participant answered all questionnaire(s) on the respective component(s) they were experienced with.

In total, we received 28 (16 SK + 12 VALDUCE) questionnaires answered by 18 patients (12 SK + 6 VALDUCE). As some of the participants had experience in more than one technological domain, the number of completed questionnaires is higher than the number of participants. They had a mean age of 47 ± 16.9 years (VALDUCE) and 58.1 ± 12.9 years (SK). 13 patients were male and 5 female of whom 16 had prior experience with robotic therapy, 12 with FES, and 6 with AR/VR. Four different nationalities were present in the patient group, namely Germany (n=10), Italy (n=6), Bosnia (n=1) and Turkey (n=1). Regarding the level of education, 1 patient had an university degree, 5 patients graduated at high school and 11 patients had a degree lower than high school (1 missing data).

The second user group included 55 healthcare operators (14 SK + 41 VALDUCE) who returned overall a number of 110 (23 SK + 87 VALDUCE) questionnaires. Healthcare operators had a

mean age of 46 ± 10.9 years (VALDUCE) and 43 ± 9.9 years (SK). 25 healthcare operators were male and 30 female. The majority of healthcare operators had an university degree (n=50), 5 graduated from high school (2 with baccalaureate). On average the participating clinical staff from SK had an experience of 7.8 ± 6.4 years in using robotic, FES or AR/VR. On average, the participating clinical staff from VALDUCE had an experience of 8.4 ± 4.9 years in using robotic, 8.6 ± 6 years in using FES and 8.3 ± 4.9 years in using AR/VR.

38 healthcare operators had prior experience with robotic devices, 36 with FES and 38 with AR. It's worth to note that at VALDUCE the numbers for responding healthcare operators were lowest regarding FES. This is because healthcare operators at VALDUCE have stated that FES is not used / less frequently used for upper limb rehabilitation due to the fact that there are no specific / just a few FES devices for upper limb treatment. Consequently most of the answers obtained in VALDUCE on this domain correspond to the experience of healthcare operators using FES for lower limb rehabilitation. In contrast, numbers for responding healthcare operators from SK are just as high for FES as for robotic and VR/AR.

Patients' responses to question 4 as well as responses of healthcare operators to question 6 and 7 (Table 1) have been evaluated for the three technological domains separately to generate a more specific wish list separable into several ReHyb system modules. These two questions aim to identify 1) which features users would like to find in the system that are not present in the currently used therapeutic devices and 2) which features users would like to change in current available devices. Answers are separated for the source of information: medical staff, patients and literature. Results from SK are also presented separately from results from VALDUCE (Table 2). Since the expert group at SK was smaller due to different clinical structures, the proportion of mentioned aspects from SK is small in relation to the high number of answers from VALDUCE. This means that very frequently stated responses from SK staff and patients ranked low in the overall table, due to the fact that less people were asked. Nevertheless, those answers were highly rated in the SK population. To cover potential sites differences, SK results were resented separately.

To sum up answers provided by patients and healthcare operators from SK and VALDUCE, the following main clusters were obtained related to the desired features of the ReHyb system:

- the system should target the whole arm including:
    - provide antigravity support
    - allow multi-segment training
    - facilitate/emulate ADL and bimanual activities
    - integrate with FES/electromyography (EMG)-triggered actuation
- it should be easy to use in an autonomous way both by patients and health care operators, including following characteristics:
    - lightness
    - portability
    - wearability
    - easy instructions for its use
- it should be reliable, which is mainly referred to:
    - safety (refers to both, technical and perceived safety)
    - robustness

- it should be adaptable to patient condition, from both motor and cognitive perspective. This includes:
    - variability of tasks
    - usable both, in standing and seated position
    - different levels of difficulty of exercises
    - combining motor and cognitive tasks as much as possible
- enhance patient motivation and engagement, including
    - different types of feedback
    - integration with virtual environment
    - facilitate embodiment

Answers to the questionnaire have been codified into 12 categories. The main contents of each category are:

- *Adaptability* refers to the capacity of the device to be adapted for each patient condition which include tailor made, personalization, etc.
- *Clinical features* refers to the inclusion or exclusion criteria necessary to be selected for using the system. Answers refer mainly to cognitive aspects and residual functionality of the subjects.
- *Feedback* refers to the need of the patient and the healthcare operator to receive information through visual, auditive, olfactory or haptic stimuli about the performance.
- *Functionality* refers to the capacity of the system to train the patients in specific activities. Includes answers like movement variability, multi-joint and multitasking activities, combination of motor and cognitive tasks, kind of support, modularity, range of motion (ROM), etc.
- *Hardware & Software* features refers to characteristic like encumbrance, lightness, dimensions, software interface, etc.
- *Portability* refers to the possibility to move the device either to the hospital room where the patient is or to patient's home setting.
- *Usability* refers to the easiness of use of the device from the operators' point of view.

The highest amount of replies was registered for the category *Functionality*, followed by *Usability* and *Reliability* (Figure 1).

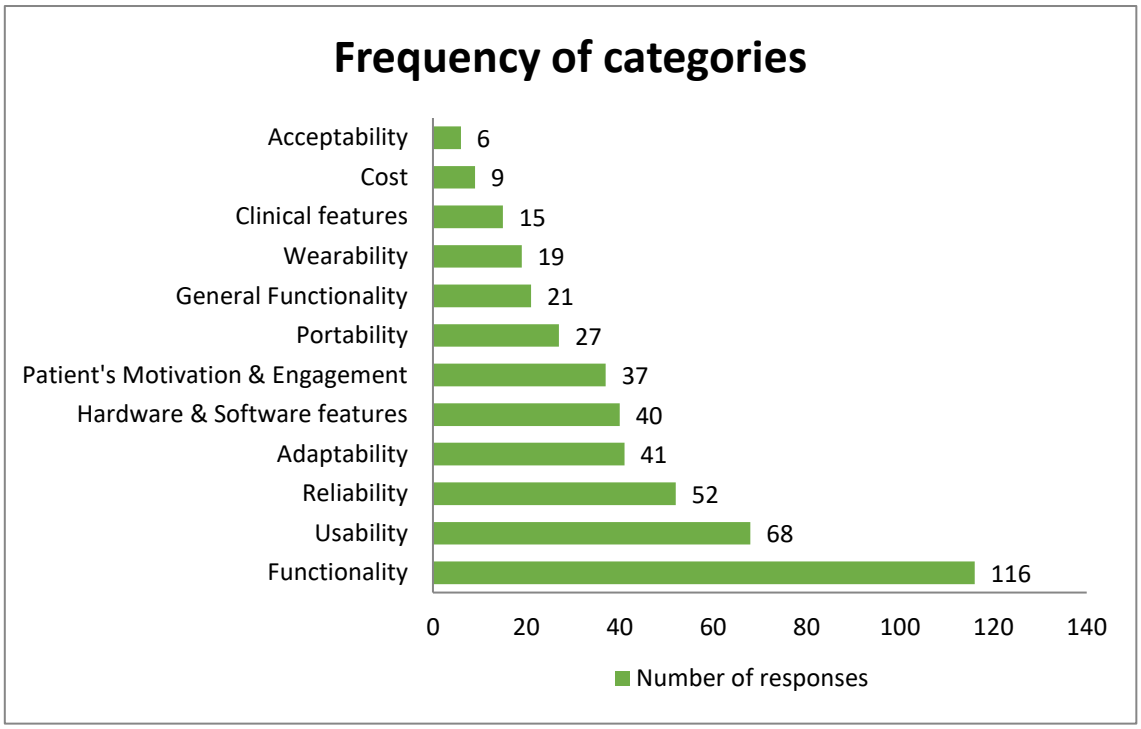


Figure 1. Number of responses (wishes) within each category.

Table 1. Opinions of medical staff, patient and literature upon needed features of robotic, FES and AR/VR.

Category	Aspect	Robotic				FES				AR/VR				Sum
		Med	Pat	Lit	Tot	Med	Pat	Lit	Tot	Med	Pat	Lit	Tot	
	Number of questionnaires	39	14		53	25	8		33	44	6		49	136
Usability	Easy handling and clear instructions for self-administration of the device	26	3		29	21			21	13	1	4	18	68
Reliability	Increase safety, robust and functioning system	23			23	10			10	15		4	19	52
Adaptability	Variation in tasks/ games to adapt to individual capacities (e.g. ROM, wheel-chair, cognition, difficulty of games)	22	1	2	23	1			1	11		6	17	41
Hardware & Software features	Portable / light device	18		2	20	8			8	11		0	12	40
Patient's Motivation & Engagement	Motivational aspects: such as goals, VR, feedback (also haptic), trigger emotions	16		4	20	3			3	7	1	4	11	35
Portability	Home-use of the device	4	8	4	16	1	4	2	7	4			4	27
Functionality	Include ADL: transfer tasks to daily life, using real objects and bimanual tasks	13	1	4	17					5	1	4	9	28
General Functionality	Antigravity support, Attention, Hygiene, EMG integration, dual task, pain control, no-operator support	12			12	2			2	7			7	21
Functionality	Target the whole arm	11		4	14	3			3	2			2	20
Wearability		15			15	4			4					19
Functionality	Recognize if patient performs compensational movements	9			9					8			8	17
Clinical Features		9			9	6			6					15
Functionality	Combination of FES and robotic	6			6	3			3	1			1	10
Functionality	Activation of small muscles should be possible	6			6	2			2	2			2	10
Functionality	Usable in a seated position	2		2	4					6			6	10
Functionality	Involve cognitive (coordination tasks, memory training, spatial neglect) and sensory deficits (proprioception)									2		8	10	10
Cost	Cheap device	3			3	1			1	3		2	5	9
Functionality	Repetitive training	4		2	6					1			1	7
Acceptability		2			2	3			3	1			1	6
Functionality	Combination of VR and robotic	3			3					1			1	4
Patient's Motivation & Engagement	Include social interaction											2	2	2

Abbreviations: ADL: Activities of Daily Living; AR: Augmented Reality; FES: functional electrical stimulation; Lit: literature; Med: medical staff; Pat: patients; ROM: range of motion; Tot: total; VR: Virtual Reality

Table 2. Opinions of medical staff, patient and literature upon needed features of robotic, FES and AR/VR from SK.

Category	Aspect	Robotic				FES				AR/VR				Sum
		Med	Pat	Lit	Tot	Med	Pat	Lit	Tot	Med	Pat	Lit	Tot	
	Number of questionnaires	6	10		16	7	5		12	8			8	36
Usability	Easy handling and clear instructions for self-administration of the device	2	2		4	9			9	5		4	9	22
Portability	Home-use of the device		8	4	12		4	2	6				0	18
Functionality	Include ADL: transfer tasks to daily life by using real objects and bimanual tasks	5	1	4	10					3	1	4	8	18
Adaptability	Variation in tasks and games to adapt to patients' individual capacities	3	1	2	6					5		2	7	13
Patient's Motivation & Engagement	Motivational aspects such as goals, VR, feedback, trigger emotions	1		4	5	1			1	1	1	4	6	12
Reliability	Increase safety, robust and functioning system					1			1	2		4	6	7
Hardware & Software features	Portable / light device	2		2	4					1			1	5
Functionality	Target the whole arm			4	4									4
Functionality	Combination of FES and robotic					3			3					3
Functionality	Repetitive training	1		2	3									3
Functionality	Activation of small muscles should be possible					2			2					2
Functionality	Usable in a seated position			2	2									2
Cost	Cheap device											2	2	2
Patient's Motivation & Engagement	Include social interaction											2	2	2
Functionality	Combination of VR and robotic	2			2									2
Functionality	Recognize if patient performs compensational movements									1				1
Functionality	Coordination tasks									1				1

ADL: Activities of Daily Living; AR: Augmented Reality; FES: functional electrical stimulation; Lit: literature; Med: medical staff; Pat: patients; VR: Virtual Reality

Beside the generation of a wish list, responses from the survey were used to provide information about patient's and healthcare operator's experience with robotic, FES or AR/VR.

The intensity of the use of technological devices for upper limb rehabilitation varies with respect to the technology used. Healthcare operators at SK and VALDUCE use robotic devices most frequently for neurorehabilitation, followed by AR/VR. The application of FES is rather low (Table 3).

Table 3. Frequency of use.

	Robotic	FES	AR/VR	Sum
Number of questionnaires	43	30	44	117
High	22	7	15	44
Medium	13	8	20	41
Low	6	12	8	26
No Answer	2	3	1	6

At both rehabilitation hospitals the rehab structure differs slightly. While at VALDUCE a majority of the healthcare operators have experience with applying robotic therapies, in SK only a few therapists are responsible for the so called "arm studio", a room where all the robotic training for the upper limb is performed. Thus, those therapists have daily experience with robotic devices. In contrast, the therapy schedule of other therapists shows more variation. Therefore, functional multichannel stimulation is applied less frequently compared to the robotic training applied by therapists of the arm studio. Similar to FES, therapists of SK include AR/VR treatments occasionally as part of the regular one-on-one treatment schedule.

During the discussion on the different healthcare providers to be included for the survey, it turned out that in Valduce the physicians have a higher responsibility in decision making for therapy content, while in SK this decision is more in the therapists hands.

An interesting information from the questionnaires addresses the patients' functions which the therapists aim to improve, and the functions that have improved as rated by the patient's subjective evaluation. Responses show that therapists primarily aim at two aspects, the improvement of motor and cognitive functions, with a main focus in motor function when using robotic and FES, and a main focus in cognitive function when using AR/VR technology (Table 4).

Table 4. Function to be improved by the therapeutic intervention.

	Robotic			FES			AR/VR			Sum
	Med	Pat	Tot	Med	Pat	Tot	Med	Pat	Tot	
Number of statements	94	9	103	38	4	42	80	5	85	230
Cognitive functions: attention, reaction, concentration, perception, organization	13		13	3		3	15	2	17	33
Arm movement: ROM, motor functions, precision	20	6	26	12	2	14	4	2	6	46
ADL		3	3		2	2	2	1	3	8
Patient Motivation and engagement	3		3				5		5	8
Coordination	3		3	1		1				4

Strength	2		2	1		1				3
Stability and posture							2		2	2
Muscle activation				2		2				2
Endurance				2		2				2

Healthcare operators were also asked to specify the reason for choosing the respective technology (Table 5). For robotic, FES as well as AR/VR the main reason to choose the therapy is that patient's first improvements in motor and cognitive functions can be achieved, and that these improvements are displayable also to the patient. Secondly, the use of robotic devices or AR/VR is used to increase the patient's motivation and the degree of involvement. Another reason is to improve the sensory input and body perception of the patient.

Table 5. Reasons for choosing the technology for therapy.

	Robotic	**FES**	**AR/VR**	Sum
Number of questionnaires	81	43	83	207
First improvements in (motor and cognitive) functioning; displayable to patient	23	21	33	77
Motivation, high degree of involvement	10		16	26
Perception Issue: improve body perception of patient / improved sensory input	5	5	6	16
Repetitive, functional training	4	2		6
Combination with other therapies: mirror therapy, Botox	1	2	2	5
Specific activation of muscles that show deficits		3		3
Automatic learning through realistic visualization			2	2
Important for ADL			2	2
Improved self-efficacy, Empowerment	1			1
Complex movement of the arm over complete ROM	1			1
No motion-sickness with AR devices			1	1
Evidence-based		1		1

Another user requirement that was identified by the questionnaire survey is the desire to use therapeutic devices at home (Table 6). Half of the patients wished for a device that can be used at home in order to practice more frequently (n=12) and improve functions even after the stay at the rehabilitation clinic (n=7). Furthermore, with a home based therapy, daily transport to the clinic is not necessary anymore (n=4). Lastly, three patients think that the technology is easy to used and thus can be applied at home. When the ReHyb system will be used at home, this will require to specifically train patients in the use of the system on their own. For those patients with cognitive impairments who will not be able to train alone at home, their caregivers would be the person to be trained to use the system.

Table 6. Home use of technological devices.

	Robotic	**FES**	**AR/VR**	Sum
Number of questionnaires	26	13	13	52
Yes (no specific reason)	13	7	6	26
Practice more frequently	7	2	3	12
For further functional improvements	3	3	1	7
No need for a daily transport to clinic	1	1	2	4
Easy to use	2		1	3

Healthcare operators were asked about advantages (Table 7) and disadvantages (Table 8) they experienced with technological devices in the upper limb rehabilitation after stroke. The main advantage therapists see in using robotics, FES and AR/VR, is the fast functional improvement, which is present even in severely impaired patients. Secondly, healthcare operators like the aspect of motivation through games, giving feedback and providing high variability in therapy to patients. Thirdly, the quality and the easy handling of robotics and AR/VR are seen as an advantage, what makes home-use of the device possible. Regarding FES, healthcare operators are happy about the possibility to include ADLs and multi-channel stimulation.

Table 7. Experienced advantages with previously used devices of healthcare operators.

	Robotic	**FES**	**AR/VR**	Sum
Number of questionnaires	120	73	105	298
Fast functional improvements, even in severely impaired patients	58	39	54	151
Motivation, high degree of involvement, Games, Feedback, Variability	43	17	32	92
Good quality, easy handling, small, home-use possible	6		16	22
Complex and individual movement of the arm over complete ROM; active, passive or supportive movements	7			7
Repetitive, functional training	4	1		5
Includes ADL		4		4
Multi-channel stimulation		4		4
Low requirements for patients		4		4
Muscle activation		3		3
Individuality			2	2
Improves attention		1	1	2
Additional therapy	1			1
Improved self-efficacy, Empowerment	1			1

On the other hand, healthcare operators mention disadvantages of currently existing devices. The most frequently mentioned disadvantage is related to technical aspects, like for example technical failure, the application of the device including the positioning of the patient. Furthermore, the patient has to fulfil some requirements (e.g., ability to maintain (supported or unsupported) sitting posture for the duration of the therapy session, sufficient attention, ease of use, no peripheral impairments) what limits the applicability of the device for certain patient groups.

Table 8. Experienced disadvantages with previously used devices of healthcare operators.

	Robotic	**FES**	**AR/VR**	Sum
Number of questionnaires	81	42	67	190
Technical aspects: failure, application, precise positioning, low sensitivity, compensatory movements are not detected, time-consuming, uncomfortable head-mounting, small displays	51	24	43	118
Patient has to fulfil some requirements: sitting posture, attention, ease of use in older generation, cognitively “fit”, no peripheral impairments	13	8	12	33
Only little variation in games, often childish	5	3	6	14

Missing relevance of daily activities: real environment, unilateral training only, tactile feedback	5	2	3	10
Costs	3	3	3	9
Stationary use only	3			3
No complex arm movements		2		2
No proprioceptive testing possible	1			1

Nevertheless, patients as well as health care providers seem to like the therapy with robotic devices, FES or AR/VR. The great majority of healthcare providers states that they would recommend this form of treatment to colleagues. We observed additionally that our current patients would recommend the rehabilitation to fellow patients (Table 9).

Table 9. Recommendation of therapy to other patients or colleagues.

	Robotic			FES			AR/VR			Sum
	Med	Pat	Tot	Med	Pat	Tot	Med	Pat	Tot	
Number of statements	42	15	57	29	7	36	47	5	52	145
Yes	37	14	51	24	7	31	41	5	46	128
No	1	1	2	1	0	1	0	0	0	3
Undecided/No answer	4	0	4	4	0	4	6	0	6	14

Lastly, we received comments from patients and medical staff at the last page of the questionnaire. Patients mentioned that they perceive the robotic treatment as comfortable. They also appreciated the additional therapeutic supervision during robotic training. One patient criticized the application of magnets, which is necessary for training with the AMADEO® robot for the hand. He wished for a more sustainable application, as the adhesive tape is thrown away after each therapy. Regarding FES therapy one patient commented that he was scared of the electric impulses in the beginning, but after the first session not anymore. Comments to AR/VR therapy described the exercises as being fun and emphasize the motivating aspect of providing feedback of patients performance.

Regarding the therapy with AR/VR medical staff reported about experienced difficulties with neurological patients who are sitting in a wheel-chair or have cognitive impairments, specifically attention deficits. They highlighted that for an effective AR/VR training this would require 1) a quiet room without distractors, 2) sufficient work space to perform the training, 3) good possibility to position patients and/or patients' arm in order to achieve ideal recordings, and 4) a camera that captures hand movements from a position that allows a gamified training with both arms placed on the table (e.g. from underneath). The last point would enable patients to also practice fine motor functions, where arms could be placed on the table.

In addition to the above named survey, we here report results from a survey that was performed within a previous project at SK (RobExReha project; funded by the German Federal Ministry of Education and Research) to gather patients' opinions on the tasks they would like to train.

Findings from this survey (n=20) show that patients would like to practice the following (ADL) tasks:

- grasp objects from a shelf: show movement limits
- story telling: serious games should provide different scenarios like walk through house, children come for a visit, cleaning up
- emotional engagement: possibility to have serious games that trigger emotions, e.g. by caring for a dog
- driving
- tool use: screwdriver, hammer
- ADLs: open a bottle, traffic
- bimanual tasks
- adapt ROM to pain limits

2.2 Patients' characteristics

2.2.1 Personas

Personas provide detailed information about the needs and expectations of the core user, the patients who survived a stroke. The functionality of the system will be designed primarily to meet the users requirements. Personas transfer information from the clinical to the technical developers by visualizing the user profile into a generally understandable format.[37]

Typically, post-stroke patients present a wide variety of motor and cognitive deficits, as well as different rhythms of recovery. To give a more precise idea about some of the characteristics of post-stroke patients who may be targeted within the ReHyb project, both clinical partners analysed data of the stroke cohort admitted to the rehabilitation hospitals. This approach was used to create representative personas based on clinical data.

In order to know the condition of post-stroke patients in terms of their ability to perform ADL, Barthel Index (BI)[38] values have been reviewed.

Scoring of the BI is done through assignment of different values to different activities. Individuals are scored on 10 activities which are summed to give a score of 0 (totally dependent) to 100 (fully independent). The scores are designed to reflect the amount of time and assistance a patient requires.

Areas evaluated are.

- feeding
- personal toileting
- bathing
- dressing and undressing
- getting on and off a toilet
- controlling bladder
- controlling bowel
- moving from wheelchair to bed and returning
- walking on level surface (or propelling a wheelchair if unable to walk) and
- ascending and descending stairs.

Patients hospitalized in VALDUCE Rehab Centre between February 2019 and February 2020 (n=331) were reviewed, showing following general features:

They were mainly males (54.38%), with a mean age of 62.9 (SD 15.4) for male population and 64.9 (SD 15.8) for female patients. Hemisyndrome was mainly present on left side (58.91%) and according to time-lapse from acute event, most of them were in a subacute situation (time-lapse lower than six months) (54.68%).

In VALDUCE, the following categories are used for patient's level of dependence:

Category	Total points from scale	Level of dependence
1	0-24	Total dependence
2	25-49	Severe dependence
3	50-74	Moderate dependence
4	75-90	Mild dependence
5	91-99	Minimum dependence
6	100	Completely independent

The results obtained for the referred population are as follows:

Table 10. General Level of dependence (BI).

Level of dependence	Percentage
Total dependence	25.68 %
Severe dependence	27.79 %
Moderate dependence	28.40 %
Mild dependence	8.16 %
Minimum dependence	3.02 %
Completely independent	4.23 %

Table 11. Level of dependence according to affected side.

Level of dependence	Bilateral	Right	Left
Total dependence	1.18 %	35.29 %	63.53 %
Severe dependence	2.17 %	35.87 %	61.96 %
Moderate dependence	1.06 %	43.62 %	55.32 %
Mild dependence	0.00 %	55.56 %	44.44 %
Minimum dependence	0.00 %	50.00 %	50.00 %
Completely independent	0.00 %	42.86 %	57.14 %

Table 12. Level of dependence according to time-lapse from acute event.

Level of dependence	Chronic	Sub-acute
Total dependence	29.41 %	70.59 %
Severe dependence	41.30 %	58.60 %
Moderate dependence	48.94 %	51.06 %
Mild dependence	77.78 %	22.22 %
Minimum dependence	70.00 %	30.00 %
Completely independent	71.43 %	28.57 %

In order to better describe patients' capacities to independently perform ADLs, the BI was also analysed for a cohort of stroke patients in SK (n=375). Patients admission and discharge BI data were analysed as well as some basic personal characteristics and information on the rehabilitation stay.

In this cohort at SK, 53.8 % of patients were male with a mean age of 67 ± 11 years, and 46.2 % were female with a mean age of 66 ± 17 years. A paresis was apparent at the right body side in 49.9 % while on the left body side in 50.1 %. Regarding the time from stroke to admission to the rehabilitation program, 50 % of patients came to the hospital about 2 weeks after their stroke, while this happened at 4 weeks after the stroke in 75 % of the patients. The clear majority (98.4 %) was in a subacute phase (< 6 months) after their stroke. The mean duration of the hospital stay was about 9 ± 42 weeks, while 75 % of patients received rehabilitation treatment for 12 weeks.

For the analysis of BI data from SK, gross categories for the patient's level of dependence were used to pool the BI data. These categories are based on the so called "Phase Model" (German: Phasenmodell) provided by the German Federal Rehabilitation Association (Bundesarbeitsgemeinschaft Rehabilitation/BAR) used in the German health care system. According to this model, the amount/intensity of therapies are provided to the patients, i.e., patients who are highly dependent on assistance to perform ADLs (phase B) receive more therapies and more support than patients who are more independent (phase D) in their activities. Table 13 provides the three most relevant phases in the SK hospital with their respective BI scores.

Table 13. Levels of dependence in activities of daily living based on the Barthel Index.

Category	Total BI score	Level of dependence/ impairment
Phase B	0-30	High/ severe impairment
Phase C	35-65	Moderate/ moderate impairment
Phase D	70-100	Low/ mild impairment

Patients post-stroke who were consecutively admitted to SK neurorehabilitation during a 1-year period were selected (n=369) to analyse their admission and discharge data. The number of patients in each of the three BI-based phases is shown in Table 14 for admission to and discharge from the rehabilitation hospital.

Table 14. Admission and discharge data for BI-based categories.

	Admission status	Discharge status
Phase B	62.5 %	27.1 %
Phase C	20.6 %	22.8 %
Phase D	16.9 %	50.1 %

Values are number of patients within this phase.

Besides the analysis of the BI, also motor function capabilities and therewith the needs of patients after a stroke in a rehabilitation hospital were analyzed in order to better define representative personas. To describe the motor function capacities, the Motor Function

Assessment Scale (MFAS)[39] was analysed for another cohort of stroke patients. All patients admitted to SK between beginning of January 2019 until end of April 2020 who have had an ischemic or haemorrhagic stroke were included in the analysis (n=550).

The severity of motor and functional impairments is routinely assessed on admission and at discharge by physiotherapists at SK by means of the MFAS. The MFAS examines 4 groups of 44 motor functions in total: sitting, standing up and standing, walking, and functioning of the upper extremities. Each function is rated by *0=fulfilled* or *1=not fulfilled*, i.e., a patient who cannot fulfil any of the tasks scores 44 points.

Emphasis of the MFAS analysis was on the items covering the functioning of the upper extremities.

These items test several functions, like putting the hand on the mouth, reaching the left ear with the right hand across head or the right ear with the left hand, bouncing a ball 8 times with the hand (in standing or sitting position), holding a paper between thumb and forefinger, or drawing a line without touching the margins. These five items are tested for both sides separately. In addition two items cover the ability to knock alternatively with both hands on support with propped arms, or to make 5 knots in 20 seconds.

Table 15: Admission and discharge data for MFAS

	Admission status			Discharge status		
	No impairment	Unilateral impairment	Bilateral impairment	No impairment	Unilateral impairment	Bilateral impairment
hand to mouth	43	33	24	58	37	5
reaching ear with hand across head	25	33	42	35	42	23
bouncing ball	10	8	82	13	14	73
Holding paper between thumb and forefinger	41	30	29	59	34	7
drawing line	15	17	68	23	23	54
Knocking with both hands	26	-	74	40	-	60
5 knots in 20 sec	13	-	87	20	-	80

Values indicate the amount [%] of patients who were not able to perform the specific task just with one side (unilateral impairment) or with both body sides/with bimanual task (bilateral impairment).

These results in Table 15 show that at discharge, 37% of the discharged patients have still problems with putting their paretic hand to their mouth, 42 % are not able to reach to their ear with their paretic hand across the head, and 34% have still problems holding a paper between their thumb and index finger.

The characteristics of the personas described below are real-data-based. In fact, each persona corresponds to the selection of a subject that was considered the most representative case of the above mentioned categories.

- **Persona 1** was selected among subjects included in *mild or minimum* dependence according to BI. This is the largest stroke group at discharge in SK.
- **Persona 2** was selected among subjects included with a *moderate* dependence according to BI as this group represents about 30 % of the patients in the hospital, and
- **Persona 3** was selected among subjects included in *severe or total* dependence according to BI, which is the largest group presented in VALDUCE and SK.

Persona 1 and Persona 2 are belonging to the patient group who will potentially use the ReHyb device at home. Whether also patients who are represented by Persona 3 will be able to use the ReHyb device, is not clear yet, since safety of the patients has to be considered as well as the effectiveness of the treatment.

Persona 1: **Alfred (Mild impairment condition)**

Alfred is a 69 year old man. Alfred is widowed and lives at home independently. His son and daughter help him with grocery shopping and come to visit with his grandkids at least every other week. He arrived at the hospital 8 days after a left hemispheric ischemic stroke.

Alfred shows following clinical condition:

a. *motor condition*: Mild hemiparesis on right upper limb, good control of proximal arm, able to perform antigravity movement and good control of the elbow flex-extension; no major pain or spasticity. Main impairment located on wrist control and fine hand movements.
b. *cognitive condition*: patient oriented in space and time, collaborative, able to respond and follow instructions, no major cognitive impairment but mild language and attention deficit.
c. *functional condition*: patient is dependent for activities that involve movements of grasp and release and pinch.
d. *general expected results*: improve the use of the hand in ADL. Improve social participation.

Persona 2: **Luca (Moderate impairment condition)**

Luca is a 75 year old man. Luca is married and lives independently at home with his wife. He arrived at the hospital 7 days after a left hemispheric ischemic stroke.

He shows the following clinical condition:

a. *motor condition*: moderate hemiparesis on right upper limb, moderate global control of upper limb , weakness on antigravity movement, good control of the elbow flex-extension; no major pain or spasticity. Main impairment located on pro-supination and fine hand movements.
b. *cognitive condition*: patient moderately oriented in space and time, collaborative, able to respond and follow instructions, mild language deficit, mild attention and problem solving deficit.
c. *functional condition*: patient is dependent for activities that involve global upper limb movement.
d. *general expected results*: improve global functionality of the upper limb in space exploration and for object managing. Increase social participation, improve language.

Persona 3: **Amalia (Severe impairment condition)**

Amalia is a 56 year old woman. Amalia is single and lives in a nursing home. She has no kids but one very good friend. She arrived at the hospital 11 months after a right hemispheric ischemic stroke.

She shows the following clinical condition:

a. *motor condition*: severe hemiparesis on left upper limb, general upper limb weakness, unable to perform antigravity movement and to perform flexion-extension of the elbow, no major pain or spasticity. Difficulties on movement coordination and mild trunk control deficit.
b. *cognitive condition*: patient disoriented in space and time, good collaboration, able to respond and follow simple instructions, severe memory and attention deficit, mild visual perceptive deficit.
c. *functional condition*: patient is highly dependent for all upper limb functional activities.
d. *general expected results*: improve coordination, increase global functionality of upper limb to improve autonomy in ADL. Improve cognitive global functions.

2.2.2 Patients' clinical characteristics

To provide the technical partners with more information about the patients who are usually assigned to device-based upper limb therapy, clinical data of patients was analysed. Data about residual functions of patients who have received treatment with the ARMEO Power (Hocoma, Switzerland, Figure 2), gives valuable information about the potential end-user (patient) of a fully powered robotic system. On the other hand, characteristics of the patient group for which the ARMEO Spring device (Hocoma, Switzerland) is applied, are interesting regarding the development of an assistive system operating without motorized actuators.

Figure 2. ARMEO Power treatment of the upper limb.

The ARMEO Power is a fully motorized upper limb exoskeleton that enables mobilization of several arm joints. Patients after stroke performing ARMEO Power therapy were analysed in SK. The following patient characteristics are informative for the fully actuated exoskeleton that will be developed by the ReHyb consortium:

Overall, 16 patients after a stroke who were scheduled for the ARMEO Power therapy (73% male; mean age 57 ± 14 years) were characterized. Results show that 63% of the patients were oriented to person, time, space and situation. Half of the patients were able to communicate verbally, what may be important regarding handling AR / VR via an optional voice control. 19% suffer from apraxia, indicating difficulties in planning movements and following a movement sequence, and further showing problems in pantomiming real tool use. Neglect was present in 38% of patients. A patient with neglect typically shows difficulties in orientation and attention with respect to the contra-lesional personal and extrapersonal space.

The following table (Table 16) shows additional patient characteristics that are valuable for the development of a fully powered exoskeleton.

Table 16. Characteristics of patients at the begin of ARMEO Power therapy.

Characteristic	**Amount of patients affected [%]**
Upper limb pain	50
Affected side unilateral	75
Affected side bilateral	13
Support for keeping sitting position	75
No active grasping	100
Hypertonus	19

As Table 16 indicates, half of patients suffer from upper limb pain, which has to be considered in the development of an exoskeleton. Further, both upper limbs were affected in 13 % of patients, and three quarters of patients were not able to sit without support. Thus, the positioning of the patient should be considered. The result, that no patient is able to grasp actively emphasizes the need to support grasping movements by implementing a hand / wrist module to the exoskeleton. Lastly, the muscle tone of 19 % of patients was increased what either leads to inclusion of potential use cases or can be included by the system.

In Table 17, the residual muscle strength of patients after stroke is presented. Muscle strength was evaluated using the Medical Research Council scale (MRC)[40], ranging from 0 (no muscle contraction at all) to 5 (normal strength). Several categories of the MRC scale are given in Table 18. Muscle strength of patients using the ARMEO Power was assessed by differentiating between the different muscles of the upper extremity. A trend towards higher impairment in the distal part (hand) than in the proximal (shoulder) was observed.

Table 17. Residual muscle strength (MRC scale) of patients at the beginning of ARMEO Power therapy.

	Shoulder	**Elbow**	**Wrist flexion**	**Wrist extension**	**Finger & thumb flexion**	**Finger & thumb extension**
Mean	1.6	1.6	1.4	1.3	1.5	1.3
SD	1.5	1.6	1.6	1.6	1.6	1.6
Min	0	0	0	0	0	0
Max	4	4	4	4	4	4
Median	1.5	1	0.5	0.5	1	1

Regarding the muscle strength in the shoulder, the median value of 1.5 indicates that 50 % of patients after a stroke using the ARMEO Power have either no muscle contraction at all, or have a visible muscle contraction which, however, does not lead to a visible limb movement. The most impaired part of the upper limb is the hand with a median of 0.5 in hand flexion and extension.

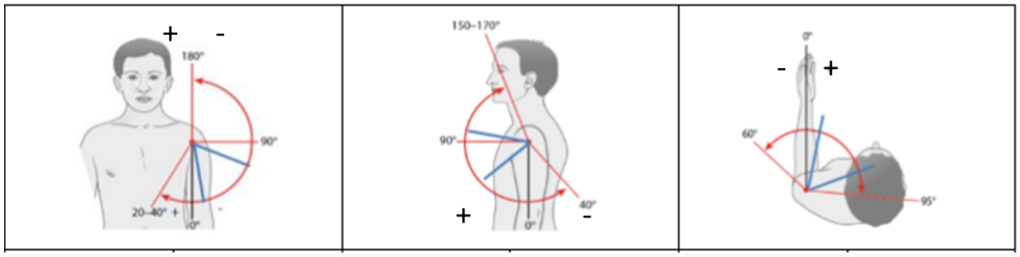
Table 18. Categories of the Medical Research Council scale

Grade	**Description**
0	no muscle contraction at all
1	visible muscle contraction, but no movement
2	movement without influence of gravity
3	movement against gravity
4	movement against resistance
5	normal strength

Furthermore, the passive range of motion (pROM) was assessed in these patients. Data is reported separately for the different joints of the upper limb, i.e., the shoulder, the elbow.

For the shoulder, abduction / adduction, flexion / extension, and internal rotation / external rotation were examined (Figure 3**Fehler! Verweisquelle konnte nicht gefunden werden.**). Norm data is represented by red lines, while blue lines indicate the mean pROM for the

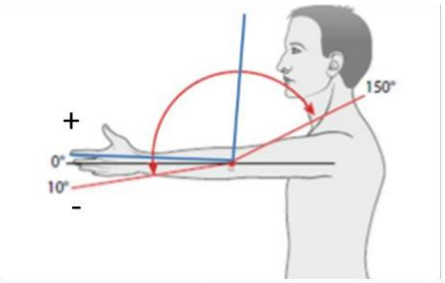
examined patient group. Patients after stroke achieve on average -62.8° in the passive abduction and -7.4° in the passive adduction movement. Passive shoulder flexion and extension is on average in a range of 47.7° (extension) and 108.2° (flexion). Furthermore, patients after stroke with ARMEO Power treatment have on average an external rotation in the shoulder of 18.6° and an internal rotation of 84.0°.

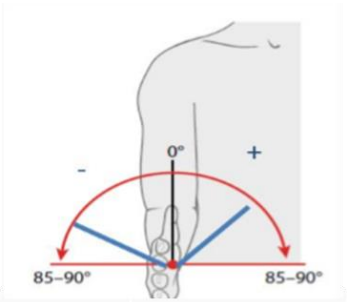


	Abduction / Adduction min [°]	Abduction / **Adduction** max [°]	Flexion / **Extension** min [°]	**Flexion** / Extension max [°]	Internal rotation / **external** rotation min [°]	**Internal** rotation / external rotation max [°]
Mean	-62.8	-7.4	47.7	108.2	18.6	84.0
SD	13.3	4.5	4.2	7.5	10.8	3.7
Min	-78.1	-13.4	42.2	96.0	2.4	74.3
Max	-43.3	4.5	56.9	117.4	42.2	86.2

Figure 3. Passive ROM in the shoulder joint in patients after stroke at the begin of the ARMEO Power therapy.

Beside the shoulder, pROM was assessed in the elbow and forearm (Figure 4**Fehler! Verweisquelle konnte nicht gefunden werden.**). Again, red lines represent norm data and blue lines show the average pROM of patients after stroke using the ARMEO Power at SK. On average, the patient group range between 4.4° (extension) and 99.4° (flexion) in elbow flexion / extension. Regarding forearm supination and pronation, patients' pROM is on average in the range of -61.2° (supination) and 48.9° (pronation).





	Flexion / **Extenison** min [°]	**Flexion** / Extenison max [°]	Pronation / **Supination** min [°]	**Pronation** / Supination max [°]
Mean	4.4	99.4	-61.2	48.9
SD	5.3	1.3	6.7	18.3
Min	1.8	95.8	-64.3	16.5
Max	21.2	100.0	-38.3	64.2

Figure 4. Passive ROM in the elbow (left) and forearm (right) in patients after stroke at the begin of the ARMEO Power therapy.

Lastly, the muscle tone of patients after stroke was assessed before therapy with the ARMEO Power (pre) and after the therapy (post) for the shoulder as well as the proximal and distal part of the upper limb (Figure 5). Muscle tone describes the state of tension of a muscle or a muscle group. This passive tension of the muscle (group) can be either low (hypoton), normal (normoton) or high (hyperton).

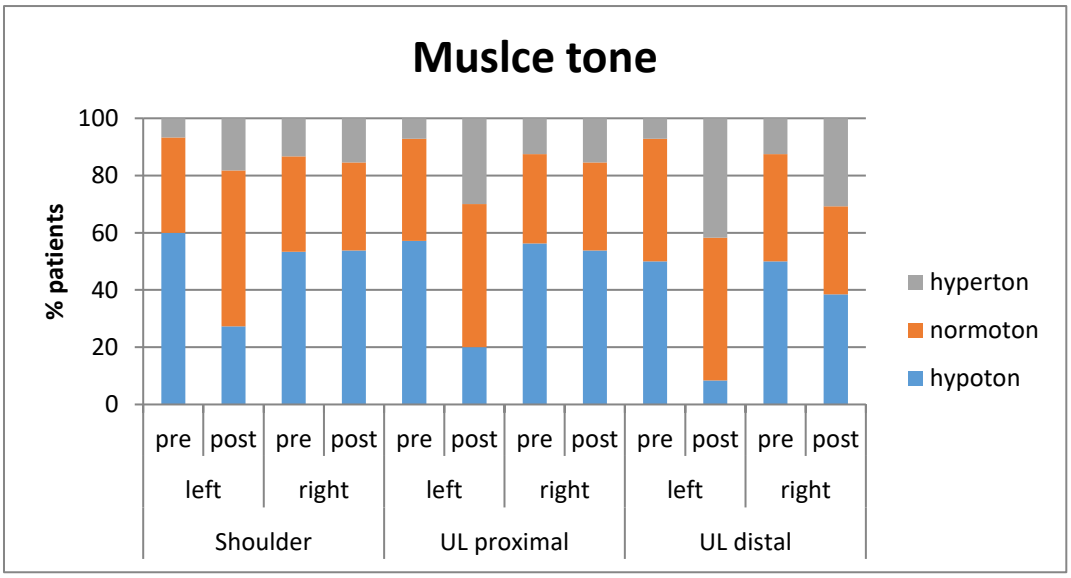


Figure 5. Muscle tone of patients' shoulder and proximal and distal part of the upper limb before (pre) and after (post) therapy with the ARMEO Power.

As Figure 5 visualizes, around 50% of the patients had hypotonic upper limb muscles at the beginning of the ARMEO Power therapy. Further, the proportion of patients demonstrating hypoton muscles decreases with the progress of therapy. In contrast, the proportion of patients

with hypertonic muscles increases with the progress of therapy, especially in the distal part (forearm/hand) of the upper limb. This finding should be considered during the development and the construction of the ReHyb system.

Figure 6. ARMEO Spring treatment of the upper limb.

In addition, nine patients who were scheduled for the ARMEO Spring therapy (Figure 6) were characterised (age: 57.7± 16.9 years; 2 female, 7 male). The ARMEO Spring is a spring based upper limb exoskeleton that enables spring based anti-gravity support during active movements. The following patient characteristics are informative for a system operating without motorized actuators:

Four patients were unilaterally impaired, with three having their affected side on the left, and one on the right. Five patients had bilateral impairments. All patients were able to communicate verbally and had no signs of apraxia. One patient had a left-sided neglect. Eight out of the nine patients had residual active grasping function, and only one patient had no active grasp function at all. Five patients could walk independently without aids, one was able to walk with aids, and three patients were not able to walk at all. All patients were able to sit, however, five out of nine patients required support or supervision for sitting.

Table 19. Muscle strength of the patients training with the ARMEO Spring assessed with the MRC score.

	Shoulder		**Elbow**		**Wrist**		**Finger & thumb**	
	Flexion	**Extension**	**Flexion**	**Extension**	**Flexion**	**Extension**	**Flexion**	**Extension**
Mean	2.22	2.44	3.22	3.11	2.88	3.13	3.22	2.89
SD	0.97	1.13	0.83	0.93	0.83	0.64	0.97	0.78
Min	1	1	2	2	2	2	2	2
Max	4	4	5	5	4	4	5	4
Median	2	2	3	3	3	3	3	3

In Table 19 the residual muscle strength of the patients with stroke that trained on the ARMEO Spring device is presented. All patients were able to voluntarily contract their upper limb (MRC>=1) muscles. Some were even able to execute movements against resistance. However, the median of the MRC scores of this cohort lies between 2 and 3, reflecting the ability to move

without resistance and the influence of gravity. Thus, these patients are very likely to profit from the ReHyb system module providing anti-gravity support. With this support, they are most likely to independently train and execute activities of daily living which require movements against gravity, e.g. placing a glass in a shelf.

Table 20: Passive range of motion of shoulder and elbow joints of patients at beginning of ARMEO Spring training

	Shoulder ROM						Elbow ROM			
	horizontal Abduction	horizontal Adduction	Extension	Flexion	external rotation	Internal rotation	Extension	Flexion	Supination	Pronation
Mean (± SD)	-69.5 (± 11.7)	5.6 (± 16.6)	56.2 (± 9.0)	111.2 (± 8.2)	25.4 (± 20.3)	103.6 (± 13.3)	18.5 (± 8.7)	102.5 (± 4.5)	-24.2 (± 26.7)	49.7 (± 12.4)
min	-83.5	-22.1	45.9	99.1	0.0	79.5	5.0	90.4	-64.2	20.9
max	-41.4	35.9	71.5	126.8	63.6	124.3	38.7	105.0	33.2	64.0
median	-68.0	8.7	55.6	108.7	24.5	107.9	17.4	105.0	-20.6	51.7

Table 20 shows the characteristics of the subjects after a stroke who trained with the ARMEO Spring device regarding their pROM. Similar to the ARMEO Power patient group (compare Figure 3 and Figure 4), these patients showed a reduced pROM in the shoulder and elbow as compared to norm data. In fact, concerning the elbow extension and supination, the patients who trained with the ARMEO Spring seemed to have even greater limitations in pROM compared to the ARMEO Power patients.

Concluding the results from the evaluation of the patients training with the ARMEO Spring and ARMEO Power, the following can be stated: Patients training with the spring-based system showed more mobility and less dependency regarding gait and trunk stability, as well as higher levels of muscle strength in their affected upper limb. The pROM, however, did not seem to differ from the patient sample training with the ARMEO Power. Further, the patients performing training with the ARMEO Power device had also additional symptoms such as neglect or dysarthria that need to be considered when planning therapy settings.

2.2.3 Patients' characteristics at home

One of the main aspects of ReHyb project is to ensure continuity of care, understood as the possibility to continue rehabilitation training after hospital discharge, or even using some of the ReHyb modules as assistive devices for performing ADL. Nevertheless, tele-rehabilitation itself puts some specific challenges which must be explicitly considered during the phases of definition of system characteristics.

In order to maximize available information, following observations and discussion come from the experience of Villa Beretta Rehab Centre (VALDUCE) during the performance of the project HEAD: **Human Empowerment, Aging and Disability: technologies and network for a rehabilitation tele-service**. This was a project performed during the years 2014-2017 under the sponsorship of Fondazione Cariplo. Data coming from this project is still being

analyzed. Some results have been presented in public events[1][2][3][4][5][6][7][8] and two articles are being submitted for publication.

The main goal of the project was to develop a sustainable rehabilitation model applicable both at hospital site and at patient's home.

Main aspects of the protocol were:

- Population under study: adult patients with chronic disabilities treated at the clinic (n=99) or at home (n=30) of which 45 were stroke patients at the clinic and 12 were stroke patients at home.
- Exercises were specifically designed and developed on an AR base.

Main project results

Technical results:

- Development of 26 exercises for motor-cognitive rehabilitation, with three levels of complexity each. Exercises were specifically designed for the project. Some of them were video-based, other followed the serious game scheme. The concept of each exercise was defined by the clinical staff involved along with the technical developers, based on five criteria: a) a combination of motor-cognitive content should be present; b) adequate to different motor-cognitive rehabilitation targets; c) able to be performed by the patient in an autonomous way; d) easy to start, manage and stop the whole system

[1] Convention Handimatica: Digital technologies for an inclusive society, Bologna, Nov. 28th 2014 – Conference F. Molteni "HEAD (Human Empowerment Aging and Disability): technologies for a tele-neuro-rehabilitation service, description of the project ".

[2] Convention "Stroke: to cure and to care" Costa Masnaga, September 27th, 2016 – Conference M. Rossini "Telerehabilitation: The experience of Villa Beretta".

[3] Molteni, F.;Gramigna, C.;Canobbio, S.;Peverelli, M.; Aggujaro, S.;Proserpio, D.;Liberali, D.; Rossini, M.; HEAD Project (Human Empowerment Aging and Disability): An Information Communication Technology Platform For Cognitive And Motor Rehabilitation – poster - 11° International Society of Physical and Rehabilitation Medicine (ISPRM) World Congress, Buenos Aires, April 30th to May 4th, 2017.

[4] Convention "New Challenges in Neuro-rehabilitation: Innovation through Experience: Human Empowerment Aging and Disability (HEAD) - technologies and network for a rehabilitation tele-service. Milan, June 16th, 2017.

[5] Convention "New Challenges in Neuro-rehabilitation: Innovation through Experience: Human Empowerment Aging and Disability (HEAD) - technologies and network for a rehabilitation tele-service. Turin, October 20th, 2017.

[6] 45th SIMFER (Italian Society of Physical and Rehabilitation Medicine) National Congress 2017, Genoa, October 22th to 25th 2017. Gramigna Cristina, Canobbio Samuela, Peverelli Milena, Agujaro Silvia, Isernia Sara, Pagliari Chiara, Castiglioni Carlotta, Gindri Patrizia, Rossini Mauro, Molteni Franco: Presentation: Monitoring of patient's engagement using wearable EEG technologies.

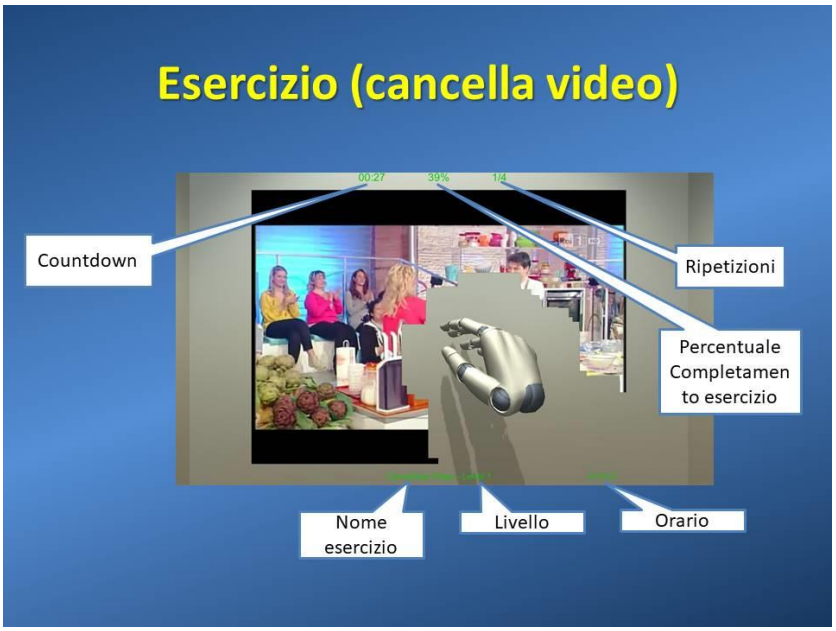
[7] Convention Handimatica: Digital technologies for an inclusive society, 2017 - Bologna November 30th to December 2nd 2017 - "HEAD (Human Empowerment Aging and Disability): technologies for a tele-neuro-rehabilitation service, Development of technical and organizational aspects.

[8] Convention Technology Hub – Milan, June 7th- 9th 2019 -Conference F. Molteni "HEAD (Human Empowerment Aging and Disability): technologies for a tele-neuro-rehabilitation service, Main Results Obtained".

and e) able to be performed in a safe way. Data security was guaranteed by the platform for what concerns rehab treatment application.

- Development of a database containing 1100 images for all categories of videos. The images selected, coming from free royalty database and from the archives of Italian National Broadcasting (RAI – RadioTelevisione Italiana), were related to ADL objects. The goal was to create different types of motor-cognitive exercises based on sport, music, fashion, cooking and TV entertainment events that were engaging for the different patients.

Example of image used in the exercise "Delete Image of video"



- According to the System Usability Scale (SUS) in general more than 70 % of participants assessed positively the usability of the system, as may be observed in following table:

	Parkinson Disease	Multiple Sclerosis	Stroke	All
System Usability Scale	70.3 ± 17.2	70.0 ± 25.8	75.8 ± 10.6	72.8 ± 17.3

For what concerns ReHyb, the main message in this point is that user's perceptions are important and must be included when evaluating the project results. In this particular case, technology acceptance and user's perception on usability of technologies (administered only in post-treatment evaluation), were performed using the two main instruments referred by literature, namely Technology Acceptance Model - TAM3 and System Usability Scale. Up to date, other models and instruments have been developed which may be carefully considered when defining the set of measures that will be used for ReHyb evaluation of results.

Clinical results:
For what concerns some motor-functional aspects of post-stroke patients, following results were observed:

- A decrease in the risk of falling (Berg Balance Scale)
- Increased walking speed (Timed 10-meter Walk Test)
- Increased endurance during walking (2-minute walk test)
- Gross manual dexterity improved on both the dominant and non-dominant sides (Box&Blocks Test)
- Improved finger dexterity (9-Hole Peg Test)

In terms of neuro-cognitive aspects following results were observed in post-stroke patients:

- The aspects of positive sensations related to the proposed program were always higher than the negative ones, both at hospital and at home (Positive and Negative Affect Scale - short version in Italian Language- PANAS);
- The General Memory Index improved in the short and long term (Rivermead Behavioral Memory Test - Third Edition);

Aspects to be considered in a home-based scenario

Some difficulties occurred when working at home, which should be taken into consideration for future home-based rehabilitation programs.

The first difficulty was that patients were not always able to use the technology by themselves for different reasons, some of them related to the pathology itself. Main reasons were referred to the subject's pathological condition itself, which in some cases, did not allow him/her to manage all the needed instruments by him/herself (it must be considered that the whole set for home-use included the use of a computer, a leap-motion and a Kinect. But there were other reasons such as the fact that not all subjects were familiarized with the use of technology, and others had to arrange their home setting in order to be able to install the HEAD instruments in a comfortable way, while others believed they could not work by themselves alone at home.This was the main reason why caregivers were trained along with patient before hospital discharge. It was observed that the involvement of a caregiver able to deal with technology was crucial to ensure compliance.

The second difficulty was related to the fact that not all people were technological skilled, so it was necessary to simplify the process of installation and switch the system on and off and to let patients know that if they need help for overcoming any technical problem or doubt they'll get such help. That was the reason why a patients' Service Center was put into function and specific written instructions were provided to patients and caregivers. Nevertheless, what happened in practice was that most often they searched for help calling to the hospital they referred to. Where present the bioengineer team would take in charge this aspect otherwise the request was forwarded to the patients' Service Center.

The third difficulty was to ensure that home setting had the characteristics able to guarantee patient's safety and an appropriate installation of the kit to be used. In this sense, and in order to expose patients to the less possible risk, all exercises chosen for being performed at home

were to be performed in a sitting position and appropriate instruction and/or suggestion was given to prepare an adequate environment to perform the exercises.

In order to minimize potential difficulties at home, patients and caregivers were trained during their period of hospitalization. Once at home, the kit to be used was accompanied by detailed instructions of use with installing graphics included. Additionally, a list of phone numbers and e-mails to be contacted in case of problems was provided, in order to be able to contact either clinical or technological staff depending on the problem. Furthermore, the computer used at home had a remote controller software (TeamViewer) that allowed checking any software trouble.

Altogether, main criteria for implementing a home-based rehabilitation scenario for post-stroke patients should include:

a. Clinical evaluation of patient's ability to work in a standing position. If this may not be ensured, then the selection of treatment must concentrate on exercises able to be performed in a sitting position.
b. Setting: Patient's home must have enough space available for the patient being able to perform the exercises in a comfortable way, mainly without obstacles or dangerous objects around.
c. Asking for help: in case the patient needs any kind of help, two main possibilities may be considered: the presence of a caregiver and/or the availability of a user's service centre to be contacted in case of some trouble or doubt.

Communication with patients and caregivers

Two types of communication were considered, namely:

a) Communication related to technological functioning aspects. This type of communication was performed during the installation process at home setting and whenever patient or caregiver required assistance during the whole period of rehabilitation program execution through the patient's Service Center

b) Communication related to rehab program performance: once a week one of the members of the clinical team performed the review of the patient's execution of exercises and the results obtained and decided if changing or not the set of exercises. As it usually occurs in a rehab hospital setting, every 15 days a tele-consultancy with the patient was made to share the results of the exercises and to check if everything was ok. The tele-consultancy connection was important to discuss and share with the patients the results obtained and define further targets.

If some irregularity in the execution of the rehab program was observed, like not performing exercises or being performed but with very bad results, a phone communication was established in order to check the reason behind such events. As for the 15-day check, a web-based video-communication software was used, this software was pre-installed on the device provided for the exercises.

Compliance

In general, each exercise included a pre-programed frequency of execution and the approximate time needed for each exercise to be completed. Even if no specific daily time schedule was assigned, patients were supposed to work during one hour, 5 days a week during 12 weeks. However, if there weren't specific clinical issues, the patient was free to organize the time to spend for the exercises during the day in order to complete the assigned tasks. They were free to choose in which moment of the day they would perform the session and they could even divide each session in more than one part. In this case, the number of sessions/exercises per day was considered for the compliance evaluation.

Using information coming from the platform, clinical staff were able to check aspects like:

- Effective execution of exercises (register of exercises performed)
- How long it took to perform assigned exercises in each session (in minutes)
- How the exercise was performed (report on results obtained in each exercise based on a pre-programmed scale)

since they had been automatically registered each time the system was switched on. The weekly check-up and possible modification of exercises as well as the 15-day conference call were crucial to ensure the best possible compliance and actual patient's follow-up. In this sense, patients knew they were actually followed up, and this may be considered one of the reasons for obtaining a rather high compliance.

The specific level of compliance for each patient working at home was evaluated based on the number of sessions performed and the duration of sessions. In order to increase the probability of compliance at home setting, patients were trained while still in hospital. In fact, they were supposed to perform a total of 12 sessions in hospital setting before discharge and then 60 sessions at home in a period of three months. Caregivers were supposed to be trained during at least three sessions. For the compliance in hospital setting, results showed a mean of 10.94 sessions for stroke patients. Among patients who performed the treatment at home, a mean of 57 sessions executed at home with a median of 60 sessions.

The presence/absence of a caregiver should not be used as an inclusion/exclusion criteria. In fact, some patient are able to deal with technology by him/herself, in such cases it is not necessary to train a caregiver. It would be better to say that a caregiver must be trained when: 1) the patient needs a caregiver to be able to perform the treatment, or 2) the patient's preference is that also the caregiver must be trained even if s/he may autonomously deal with the technology, and the safety of the patient requires to also train the caregiver

2.2.4 Inclusion and exclusion criteria

To further specify and discuss the patients' clinical characteristics beyond the analysis of current therapy data, a discussion on inclusion and exclusion criteria was part of the use case scenario workshop which was performed at SK and VALDUCE together with technical partners of the ReHyb consortium on May 20th. Due to the Corona crisis with its travel and gathering restrictions, the workshop was partly performed as an online meeting via Zoom and partly as an in-person meeting with the therapist at the hospital sites. At note, this neither the complete

nor the final list of inclusion and exclusion criteria used for the ReHyb system or the evaluation procedures. Following inclusion criteria, which are based on clinical experience, were proposed in advance and were the basis for the discussion:

- Person in rehabilitation after a stroke event
- Stroke may be both ischemic or hemorrhagic
- Adults male or female subjects (18 or more years old)
- No restrictions about the time lapse from the acute event (both sub-acute and chronic patients)
- Functional impairment of upper limb on any side of the body
- Not completely paralyzed
- No history of previous major psychiatric disorders
- Cognitive conditions that enable patients to follow at least basic instructions
- Low level or no spasticity (MAS <=2)
- Low level or no pain (NRS < 4)

At VALDUCE, the workshop focussed on the shoulder / elbow module of the ReHyb system.

Two therapists and one medical doctor and two researchers from VALDUCE discussed together with technical partners about the clinical characteristics of the potential users of the ReHyb system.

About inclusion/exclusion criteria the main points discussed were about that in this moment the inclusion criteria are very wide. This would facilitate the trial of ReHyb system as a first line treatment, since a high variety of cases may be potentially involved, but could put a limit to the analysis of results. In this sense, it was suggested to maintain them as they are and after data collection, try to make sub-groups for analysis purposes.

At SK, the workshop focused on the wrist / hand module of the ReHyb system. Six therapists and two researchers from SK discussed together with technical partners about the clinical characteristics of the potential users of the ReHyb system. This therapist group consisted of highly experienced healthcare operators in the areas robotic, FES and AR/VR: a physical therapist with a master degree in health and rehabilitation technology, an occupational therapist specialised in FES application, a movement therapist specialised in robotic application, an occupational therapist and head of the robotic “arm studio”, an occupational therapist and deputy head of occupational therapy department, and a sport therapist specialised in VR (Kinect) application. Based on their experience with patients in robotic, FES or AR/VR therapy, inclusion and exclusion criteria were discussed and defined (Figure 7).

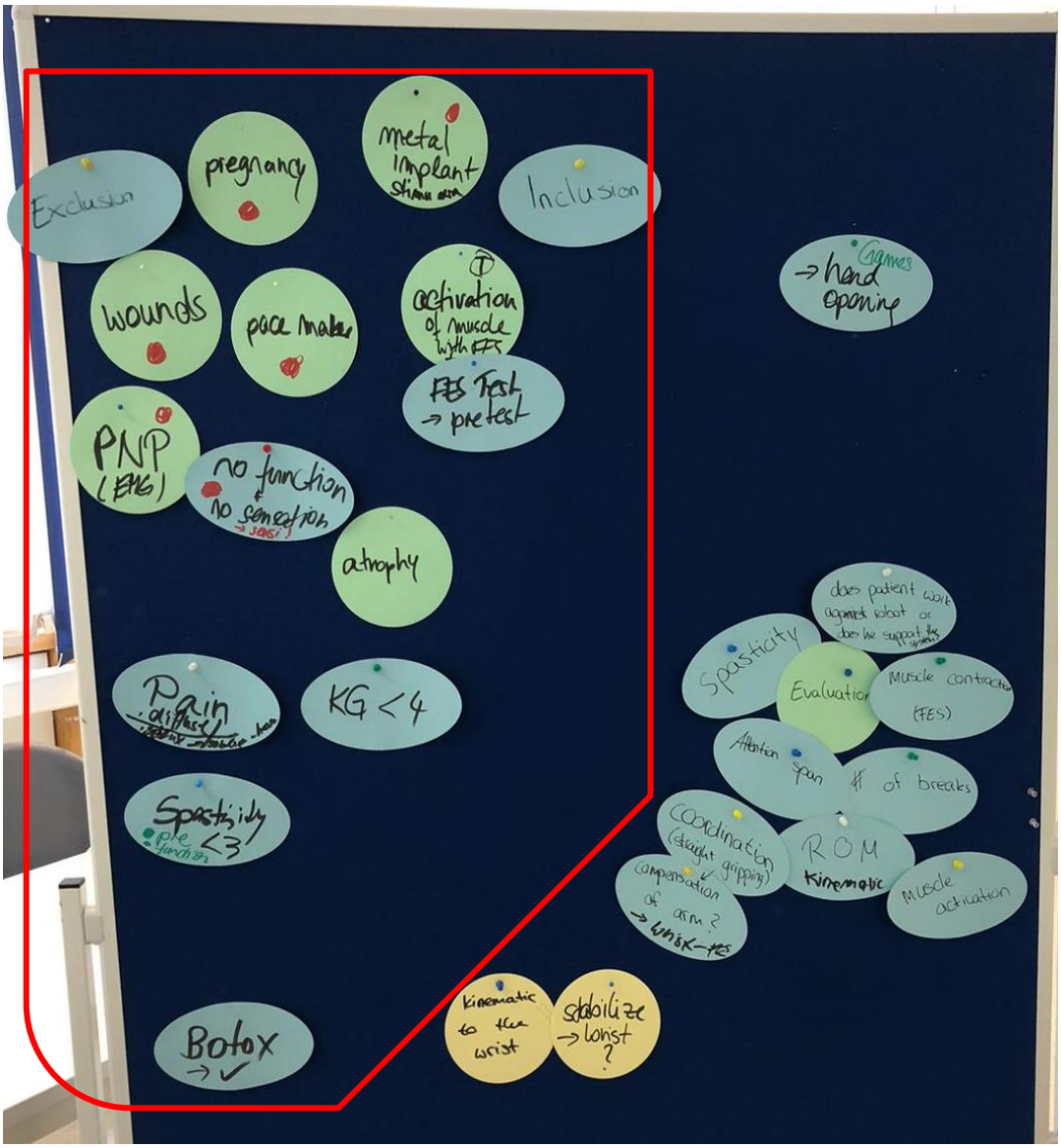


Figure 7. Defined in- and exclusion criteria (red bordered) from the workshop, module: hand / wrist.

Within the workshop, general exclusion criteria for the ReHyb system were defined on the one hand and complemented by specific exclusion criteria for the components (robotic, FES) on the other hand. These specific criteria are mentioned separately in order to comply with the modularity of the system. Criteria for the use of AR/VR were not discussed in the workshop as they are strongly related to the device used. Since the device is not developed yet, in- and exclusion criteria for AR/VR cannot be set by now. Furthermore, there is already good knowledge about this topic on behalf of the technical partner IBEC.

Hereafter, results of the workshop are presented. They do not represent final in- and exclusion criteria, but rather opinions of medical professionals. These should be taken into account together with the specifications of the devices when finally setting in- and exclusion criteria.

General exclusion criteria for the use of the ReHyb system were defined:

- Residual muscle strength in the hand / wrist is sufficient to move against resistance or shows normal strength (MRC > 3, see Table 18). These patients will not be in need of the ReHyb system.
- Patient has no function AND no deep sensitivity in the hand / wrist

Exclusion criteria for the use of FES were defined:

- Pregnancy
- Wounds in the application area
- Active implantable devices (e.g. pace maker)
- Metal implants within the stimulated area as a local exclusion criteria
- No muscle activation with FES possible (e.g. atrophy)
- Patients who suffer from peripheral nerve damage (e.g., Polyneuropathy). The threshold of muscle excitability needs to be defined (e.g. by EMG). If the test of whether or not the muscle can be stimulated is negative, the patient will be excluded from using the FES module. Otherwise the patient is included.

Following exclusion criteria for the use of robotic devices were defined:

- Unspecific pain in shoulder or wrist while using the device that cannot be eliminated by changing settings
- Specific pain in shoulder (e.g. subluxation) or wrist (e.g. misalignment of joints)

Therapists agreed that Botox therapy does not lead to exclusion.

Furthermore, inclusion criteria for the use of the ReHyb system were defined. Patients with a spasticity grade of 3 or less at the Modified Ashworth scale (Table 21) can be included. If the patient's spasticity grade is 3 at the Modified Ashworth scale (MAS), it was mentioned that a special spastic release FES program should be included prior to functional training as a „warm up".

Patients can be included in the fully powered robotic system, if the hand / wrist shows no muscle contraction at all or a visible muscle contraction, but no movement (MRC 0 or 1, see Table 18). Using the spring based device is intended for patients with a MRC of 2 or 3 (see Table 18), meaning that movement without the influence of gravity or movement against gravity is possible.

Table 21. Modified Ashworth scale for grading spasticity (from Scheinberg, et al. [41])

Grade	Description
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part/s is/are moved in flexion or extension
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part(s) rigid in flexion or extension
Abbreviation: ROM, range of motion.	

2.3 System requirements

According to post-stroke patients' needs, the ReHyb system will develop following modules for neuro-motor (Table 22) and neuro-cognitive activities (Table 23).

Table 22. ReHyb Modules for neuro-motor activities.

Device Module Code	Anatomical Correspondence	Indication of use
A	Shoulder	Antigravity support, passive trunk control support
B	Elbow	Flex/extension movement
C	Forearm	Pro-supination movement
D	Wrist	Wrist Control/Support
E	Fingers/Thumb	Grasp and Release movement,

Table 23. ReHyb Modules for neuro-cognitive activities.

Device Module Code	Cognitive area to be treated	Indication of use
G	Attention deficit	Alert, selective, divided (multi-tasking) and sustained attention
H	Language deficit	Language production, comprehension, reading, writing and general deficit
I	Executive function deficit	Problem solving
J	Visual perceptive deficit	Neglect
K	Memory deficit	Long/short term memory Working memory
I	Space-time orientation deficit	Space-time orientation

Taking the created Personas with their specific clinical impairments into account, the ReHyb device modules were further assigned to the patients' conditions.

According to Alfred's clinical condition, rehabilitation treatment will be defined based on following considerations:

Table 24. Alfred's motor aspects.

Condition	Yes	No	ReHyb module to be used	Exercise to be performed	Specific expected results
Does he need antigravity arm movement?		X			
Does he need help to perform elbow flex-extension movement?		X			
Does he need trunk control support?		X			

Condition	Yes	No	ReHyb module to be used	Exercise to be performed	Specific expected results
Does he need help to perform pro-supination movement?		X			
Does he need help to control wrist position?	X		Wrist module	Flex-extension or stabilization of the wrist	Control of wrist position
Does he need help to perform grasp-release movements?	X		Finger/Thumb module	Open and close finger, grasping exercises	Increase grasp control/force
Does he need FES application in upper limb?	X		FES module	Increase muscle activity	Increase force or coordination
Is he able to use ipsi-lesional limb as movement-intention trigger?	X		Complete robotics module	Bimanual exercises	Increase movement control and coordination

Table 25. Alfred's cognitive aspects.

Condition	Yes	No	ReHyb AR/VR module to be used	Exercise to be performed	Specific expected results
Is he able to interact with an augmented or virtual environment?	X		AR/VR modules	Application of VR exercises	
Does he present attention deficit?	X		VR/VR module	Selective attention exercises	Improve attention
Does he present language deficit?	X		VR/AR module	Speech exercises	Improve language
Does he present executive function deficit?		X			
Does he present visual perceptive deficit?		X			
Does he present memory deficit?		X			
Does he present space-time orientation deficit?		X			

Table 26. Alfred's upper limb rehab program aspects.

Aspects	Description
Training Program	• Coordination of upper limb in the space. • Bimanual coordination. • Improve grasp and pinch ability. • Improve fine fingers movement. • Dual task exercise. • Muscular strengthening
Delivery of treatment	• Computerized task-oriented training exercise (ReJoyce) • Physiotherapy • Occupational Therapy • FES • Sensorized glove for wrist and hand training (Raphael) • AR/VR exercise for motor coordination and attention training (Riablo)
Movements involved	• Flex-extension of the wrist • Open and close fingers • Grasp and pinch • Intra-extra-rotation of elbow

Aspects	Description
Cognitive aspects	• Selective attention • Speech

According to Luca's clinical condition, rehabilitation treatment will be defined based on following considerations:

Table 27. Luca's motor aspects.

Condition	Yes	No	ReHyb module to be used	Exercise to be performed	Specific expected results
Does he need antigravity arm movement?	X		Shoulder module	Arm up and down, reaching movement, hand to body/mouth movement	Increase space exploration, increase body perception
Does he need help to perform elbow flexion-extension movement?		X			
Does he need trunk control support?		X			
Does he need help to perform pro-supination movement?	X		Forearm module	Pro-supination exercises	Improve motor schema for grasping function
Does he need help to control wrist position?		X			
Does he need help to perform grasp-release movements?	X		Finger/thumb module	Grasp and release objects	Improve grasping function, manage objects
Does he need FES application in upper limb?	X		FES module	Increase muscle activity	Increase force or coordination
Is he able to use ipsi-lesional limb as movement-intention trigger?	X		Complete robotics module	Bimanual exercises	Increase movement control and coordination

Table 28. Luca's cognitive aspects.

Condition	Yes	No	ReHyb AR/VR module to be used	Exercise to be performed	Specific expected results
Is he able to interact with an augmented or virtual environment?	X		AR and/or VR module	Serious games	Increase Social participation
Does he present attention deficit?	X		AR and/or VR module	Selective attention exercises	Improve selective attention
Does he present language deficit?	X		AR and/or VR module	Language comprehension and speech exercises	Improve language
Does he present executive function deficit?	X		AR and/or VR module	Problem solving exercises	Improve executive function
Does he present visual perceptive deficit?		X			
Does he present memory deficit?		X			

Condition	Yes	No	ReHyb AR/VR module to be used	Exercise to be performed	Specific expected results
Does he present space-time orientation deficit?	X		AR and/or VR module	Space-time orientation exercises	Reinforce space-time orientation

Table 29. Luca's upper limb rehab program aspects.

Aspects	Description
Training Program	• Increase space exploration • Increase body perception • Improve grasp ability. • Increase force • Increase movement control and coordination • Coordination of upper limb in the space. • Bimanual coordination.
Delivery of treatment	• Computerized task-oriented training exercise (ReJoyce) • FES • Physiotherapy • Occupational Therapy • Antigravity space exploration training (Diego) • Body perception Training (Vibramov) • AR/VR exercise for motor coordination and attention training (Riablo, Myro)
Movements involved	• Flexion-extension, ab-adduction and intra-extra-rotation of shoulder • Flex-extension and intra-extra-rotation of the elbow • Pro-supination of forearm • Flex-extension of the wrist • Open and close fingers • Grasp and pinch
Cognitive aspects	• Attention • Executive function • Space-time orientation • Speech

According to Amalia's clinical condition, rehabilitation treatment will be defined based on following considerations:

Table 30. Amalia's motor aspects.

Condition	Yes	No	ReHyb module to be used	Exercise to be performed	Specific expected results
Does she need antigravity arm movement?	X		Shoulder module	Arm up and down, reaching movement, hand to body/mouth movement	Increase space exploration, increase body perception
Does she need help to perform elbow flexion-extension movement?	X		Elbow module	Reaching and Hand to body movement	Increase space exploration, increase Reaching movement
Does she need trunk control support?	X		Trunk support module	Allowing trunk control	Avoiding compensatory movements

Condition	Yes	No	ReHyb module to be used	Exercise to be performed	Specific expected results
Does she need help to perform pro-supination movement?	X		Forearm module	Pro-supination exercises	Improve motor schema for grasping function
Does she need help to control wrist position?	X		Wrist module	Flex extension of the wrist	Control of wrist position
Does she need help to perform grasp-release movements?	X		Finger/thumb module	Grasp and release objects	Improve grasping function, manage objects
Does she need FES application in upper limb?	X		FES module	Increase muscle activity	Increase force or coordination
Is she able to use ipsi-lesional limb as movement-intention trigger?	X		Complete robotics module	Bimanual exercise	Increase movement control and coordination

Table 31. Amalia's cognitive aspects.

Condition	Yes	No	ReHyb AR/VR module to be used	Exercise to be performed	Specific expected results
Is she able to interact with an augmented or virtual environment?	X		AR/VR module	Serious games	Increase Social participation
Does she present attention deficit?	X		AR/VR module	Sustained and selective attention exercises	Improve attention
Does she present language deficit?	X		AR/VR module	Language comprehension and speech exercises	Improve language comprehension and production
Does she present executive function deficit?	X		AR/VR module	Problem solving exercises	Improve possibility to perform executive tasks
Does she present visual perceptive deficit?	X		AR/VR module	Visual perceptive exercises	Improve visual perceptive skills
Does she present memory deficit?	X		AR/VR module	Memory exercises	Improve memory capabilities
Does she present space-time orientation deficit?	X		AR/VR module	Space-time orientation exercises	Reinforce space-time orientation

Table 32. Amalia's upper limb rehab program aspects.

Aspects	Description
Training Program	• Increase space exploration • Increase body perception • Improve grasp ability. • Increase force • Increase movement control and coordination • Coordination of upper limb in the space. • Bimanual coordination. • Avoid compensatory strategies

Aspects	Description
Delivery of treatment	• FES • Physiotherapy • Antigravity space exploration training (ARMEO Spring) • Body perception Training (Vibramov) • AR/VR exercise for motor coordination and attention training (Myro)
Movements involved	• Flex-extension, ab-adduction and intra-extra-rotation of shoulder • Flex-extension and intra-extra-rotation of the elbow • Pro-supination of forearm • Flex-extension of the wrist • Open and close fingers • Grasp and pinch
Cognitive aspects	• Attention • Memory • Visual perceptive skills • Executive function • Space-time orientation • Speech and language comprehension

To further specify system requirements especially regarding the AR/VR component, SK initiated a study in cooperation with the DTU evaluating an AR device. The purpose of this investigation is to investigate whether persons with impairments in stereovision in the real environment do have depth perception of virtual holograms projected by the Microsoft HoloLens®.

Depth perception in the real environment is assessed using standard clinical tests for stereoscopic vision (Titmus Test (Stereo Optical Co., Chicago, IL), Lang II Stereotest (LANG-STEREOTEST AG, Küsnacht, Switzerland)). Assessments of depth perception in the AR setting include four different tasks programmed by DTU. To adapt the testing environment to a near-real therapy session, ADL objects are presented in the near field of the user. The only cues for depth in these tests are binocular, thus pure stereoscopic vision has been tested under elimination of monocular cues. The first test in the AR setting is the *perceptual matching task* (Figure 8 A) that requests the subject to actively adjust the position of a target object to the perceived distance of a fixed object in this space. The second test is an *Alternative forced choice task*, where the participant decides which out of four objects is perceived as closest to the observer (Figure 8 B). In the *Position task*, a holographic object is randomly presented in front of, in the middle of or behind a translucent cube (Figure 8 C). The user is asked to name the position of the holographic object in relation to the cube. Lastly, the *3D detection task* (Figure 8 D) was designed to test the ability to perceive objects in three dimensions (3D). Therefore, four geometric objects were presented to the user. Three of them were presented at the same depth plane and in two dimensions, while one was a projecting as outstanding and in 3D. The user is asked to detect the outstanding ring.

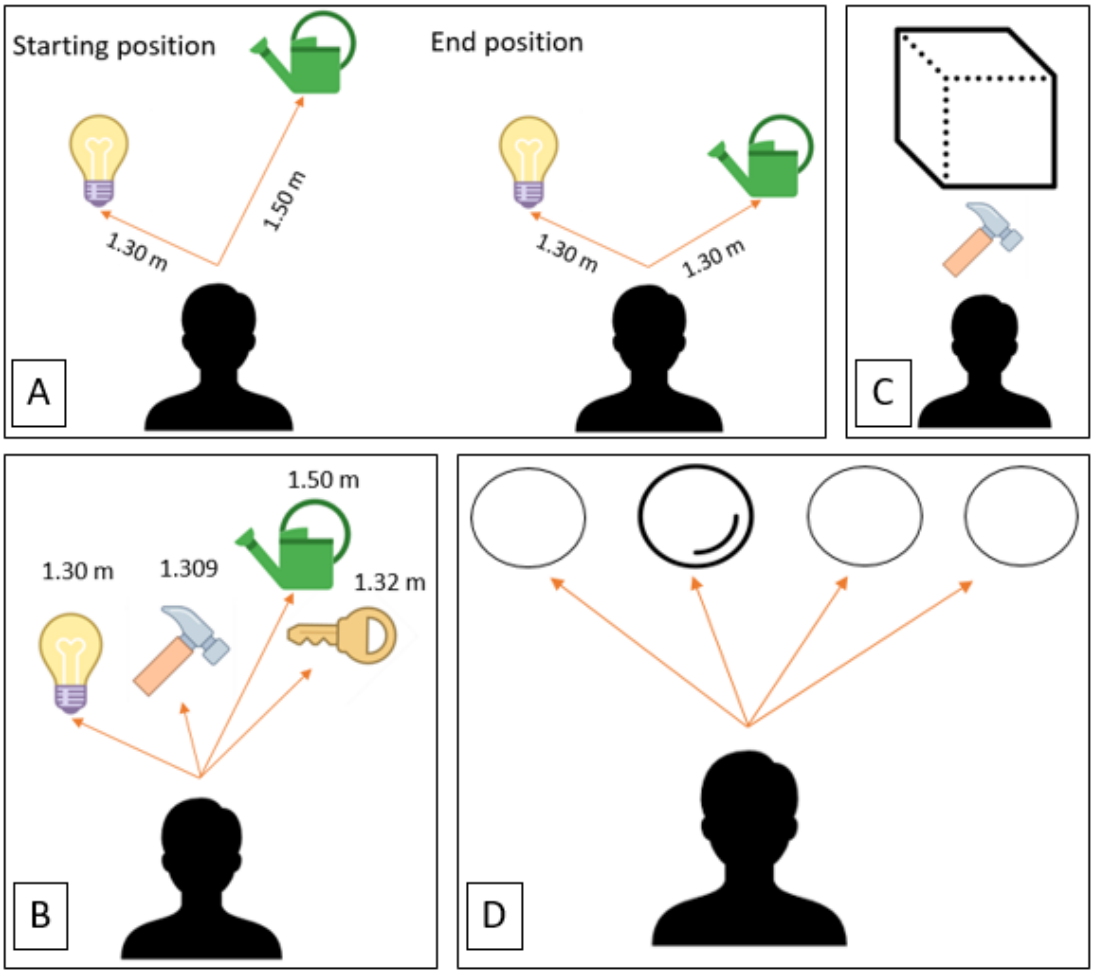


Figure 8. Assessments in the AR setting: A - Perceptual matching task, B - Alternative forced choice task, C - Position task, D- 3D detection task.

So far, visual-spatial perception of holographic objects was performed in healthy subjects with normal vision (n=10) as well as with impairments in stereovision (n=10). Experimental setting will now be evaluated in stroke patients. Results will be reported in D2.3. Findings of this study should be considered in designing AR games, especially when these games require the patient to judge and react to distances (e.g. catch water drop with a cup).

The next step is to modify this study and add different monocular cues in order to figure out which cues are valuable for patients with impairments in stereoscopic vision. Results of this study will inform technical partners who are responsible for setting up the gaming environment.

System requirements were also discussed in the workshop in May under the use case scenarios.

The following aspects were discussed during the shoulder/elbow workshop:

Exoskeleton design

a. It would be useful to include some anthropometric measures for being able to adapt it to different sizes. In this sense, it has been suggested to provide some mean measure for small, medium and large size and some idea about minimum

and maximum variation on different potential sizes. If it is considered useful/possible, add a differentiation between men and women sizes.

b. For what concerns the use of sensors, when considering the design it would be important to distinguish between active and passive exoskeleton, since there are different possible solutions to be applied.
c. It would be important to define if in severe impairment cases it would be better to use shoulder-elbow support or also wrist support for rehab training.
d. Another important decision involves the way to track the position and/or movement of elbow and arm. In this sense, it would be important to know how patient positions elbow and arm and if it can be actually tracked. In fact, it may be tracked either by the exoskeleton itself or using a Kinect. In this sense it was observed that, in any case, Kinect registers the position of the wrist.
e. Angle of elbow and shoulder must be known. It must be taken into account that, up until now, the passive exoskeleton has no sensors. In this case we could use Kinect along with markers.
f. It must be decided which are the movements to be considered for the design: wider hypothesis includes pronation-supination, intra-extra rotation, flex-extension at both levels, shoulder and elbow.

Main aspects from a clinical perspective

a. For each patient it must be defined if it would be better to use AR instead of VR, or if it would be better to develop both and deploy each for their most relevant patient groups and use cases
b. From a clinical perspective, it is important not only how easy is the practical connection between exoskeleton and videogames, but it will also be very useful to measure accurately the patient's movement during the performance of serious games exercises.
c. It would be important to register kinematics of the movements, namely, active range of motion, strategy of movement, velocity of performance of the movement and compensation strategy and smoothness, in order to orient treatment decisions. It would also be important to register EMG data in order to have information about the intention of movement and the muscle activation strategy during the execution of the task. Additionally, it would also be decided how those indicators will be measured. Maybe, it would be necessary to get a trade off in order to work with a rather light device in order to facilitate its use from a patient perspective.

At SK site, the workshop focused on the topic wrist / hand module of the ReHyb system. We hereby defined to distinguish between "decision parameters" and "evaluation criteria". Decision parameters indicate therapists when to change game settings in order to adapt to the patient's progress. Evaluation criteria are commonly assessed pre- and post-therapy to document the overall treatment effect.

Currently, therapists at SK rely on their experience when deciding to change therapy settings, Based on their experience with patients in robotic, therapists defined decision parameters they would like to get from the system (Figure 9):

- Spasticity
- Cognitive aspects: attention span + number of breaks

- ROM kinematic
- Muscle response: Muscle activation + muscle contraction (FES)
- Does the patient work against the robot or does the patient support the system?
- Electrical stimulation parameters
- Coordination (e.g. does the patient have a straight grip?) in order to detect compensatory movements by the arm or wrist
- Kinematic of the wrist (e.g. joint angle measured by goniometer sensors, information about wrist stabilization)
- Game levels, game based parameters that indicate the progression

Furthermore, therapists agreed that games should include hand opening.

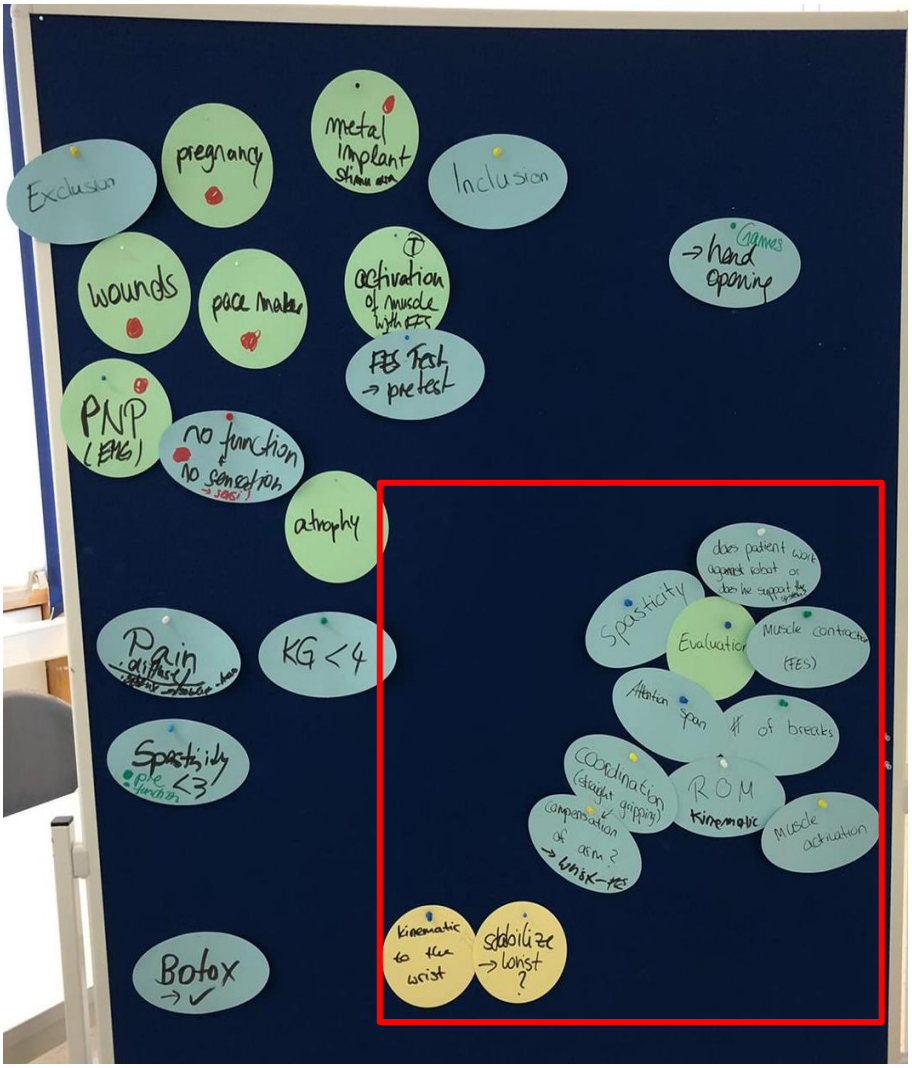


Figure 9. Defined decision parameters (red bordered) from the workshop, module: hand / wrist.

During a workshop of another project which has targeted also on upper limb robotic therapy (RobExReha project; funded by the German Federal Ministry of Education and Research) performed at SK with occupational therapists, system requirements of robotic devices were discussed likewise. In addition to the desired decision parameters that were defined during the

ReHyb use case definition workshop, occupational therapists of this previous workshop stated to be interested on the following parameters on patients' performance:

- Movement velocity
- Fluidity of motion
- Accuracy of movements

Furthermore, sensory system requirements were discussed in this previous workshop:

- Analysis of user's intention of voluntary movement by biomedical sensors (e.g. EMG, eye control)
- Provision of realistic kinesthetic or tactile feedback (in addition to visual information)
- Information about patient's psychophysiological state during therapy (e.g. heart rate, electro dermal activity)

System requirements that specifically arise when the ReHyb system will be used at home, refer to safety aspects (see also section 2.2.3) and also data protection and privacy requirements with respect to patient-therapist interactions when consultation is necessary.

As for what concerns home rehabilitation programs, patient's safety must be considered as the first requirement to be fulfilled. When applied to post-stroke patients, safety may be defined using three main aspects:

1. Clinical evaluation of patient's ability to work in a standing position. If this may not be ensured, then the selection of treatment must concentrate on exercises able to be performed in a sitting position.
2. Environment: Patient's home must have enough space available for the patient being able to perform the exercises in a comfortable way, mainly without obstacles or dangerous objects around.
3. Asking for help: in case the patient needs any kind of help, two main possibilities may be considered: the presence of a caregiver and/or the availability of a User's Service Centre to be contacted in case of some trouble or doubt.

A user's Service Centre also has to meet specific requirements on data protection and privacy. Especially when an "alert sending option" should be implemented notifying the treating therapist or physician about, for example, the non-execution of therapy sessions or irregularities in the execution of the rehab program. These issues in the design of the ReHyb system will, from the very beginning, incorporate the principles of Privacy by Design, which means that privacy will be taken into account, especially for the potential system use at home. Special attention in the treatment of patient has to be payed also to the fact that a subgroup of stroke patients is considered more vulnerable when they have a Legal Authorized Representative (LAR). Data protection and privacy requirements will be addressed in the activities under WP10.

2.4 Task definition

The goal of the ReHyb project is to develop a patient-specific, assist-as-needed device which maximises the training efficiency during hospital and home-based rehabilitation by means of serious gaming, and offers a pleasant user experience by supporting patients during ADLs.

The core system developments will be performed at modular level. Different modules composed of different technical solutions, like robotic, FES and VR/AR components or different sensors essential for creating the digital user twin, will be developed within the frame work of this project. Besides these **technical modules**, the modularity of the ReHyb system can also be described from a more patient-centred goal oriented, less technical perspective. These **application modules** cover on the one hand the two main application environments (rehabilitation hospital and home care) and on the other hand the two main therapeutic application goals (orthotic effect or therapeutic effect). Figure 10 illustrates the resulting four application modules which can be defined by combining both aspects, i.e., 1) Module therapy at home, 2) Module orthosis at home, 3) Module therapy at hospital, and 4) Module orthosis at hospital.

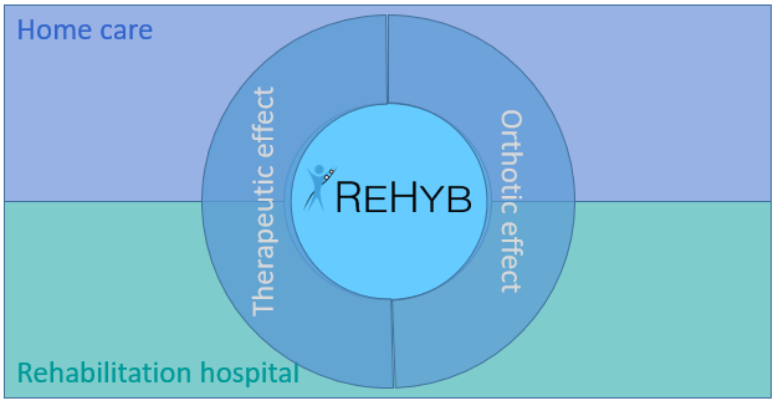


Figure 10: Application modules with their respective application environment and application goals.

Within the ReHyb project the 4 application modules have a different prioritisation. The project clearly focuses on the development of a system that is used to enhance patient's motor and cognitive functionality. When the system is applied in its therapy modules, the system is used for a specific period of time to improve a specific function. It is important to highlight that the patient shows an improved function without the device on, after one or several training sessions. This *therapeutic effect* is the main goal in rehabilitation after a stroke. However, the ReHyb system has also the capacity to cover *orthotic effects* which describes functional improvements only during the usage of the system but not without the device on. This is the main goal of the assistive module for patients where no further improvements are expected.

In this chapter some already existing and investigated serious gaming tasks developed by the technical partners are described as well as ADLs where the ReHyb system could be a beneficial support solution. The ADL tasks can be provided as simulated ADLs used for therapy targeting training and functional improvements of patients. The training can target the full movement or

parts of it. Simulated ADLs can be performed in engaging VR/AR games and a near-real environment. In distinction, applied ADLs are a naturally occurring set of behaviours which include real object/tool use.

From the serious gaming options developed by the technical partner IBEC, the following tasks were picked from IBEC's Rehabilitation Gaming System (RGS) for motor and cognitive training. The RGS is a science-based information and communications technology (ICT) solution for the personalized rehabilitation of people suffering from motor and cognitive deficits after stroke.[42-44] RGS is based on the integration of a wide range of highly innovative ICT technologies, such as Virtual Reality, artificial intelligence (AI), learning and adaptive systems, image and scene analysis, wireless technologies, multimodal interfaces, simulation tools, sensors, telehealth and information systems and, wearable physiological data sensors.

RGS advances and further validates concepts of (1) conjunctive motor and cognitive training [45], (2) treatment frequency, intensity, and duration, (3) multisensory stimulation in enriched training environments, (4) training adaptation to individual performance, and (5) counteracting learned non-use.

Via RGS, we map these principles into methods for diagnosis and treatment of cognitive and affective deficits in conjunction with embodied motor-based training.[42-45]

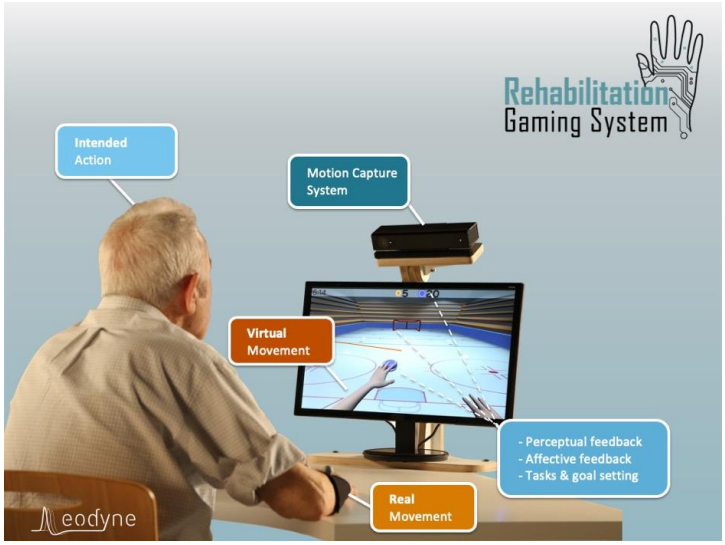


Figure 11. RGS integrates a paradigm of action execution with motor imagery and action observation, including reinforcement mechanisms, online adaptation, and multimodal feedback.

The goal for the use of RGS is to improve the recovery of function in post-stroke patients in particular recovery of the upper limb range of movements and correct posture and conjunctively improve cognitive performance for attention and memory.[44] RGS promotes the spontaneous use of the paretic limb and facilitates massed practice inducing use-dependent recovery. RGS establishes a closed loop of recovery in which limb use and functional recovery reinforce each other or a virtuous cycle of recovery.[45-47]

Table 33 summarizes the type of motor interventions, the ReHyb modules, and the RGS protocols proposed for the project, table 34 cognitive interventions.

Table 33. Motor interventions including the RGS protocols.

Module Code	Upper limbs	Indication of use	VR Protocols	Sensors for VR
Passive exoskeleton	Shoulder	Antigravity support, passive trunk control support	Clean the table Pinball	Kinect
Active/passive exoskeleton	Elbow	Flex/extension movement	Pinball Grab & Place	Kinect
Active/Passive exoskeleton	Forearm	Pronation/supination movement	Bubbles Demolition	Leap motion
Active/Passive exoskeleton	Wrist	Wrist control/support	Bubbles Demolition	Leap motion
Passive/Passive exoskeleton	Fingers	Grasp and Release	Grasp & Place	Kinect, Leap motion
Passive/Passive exoskeleton	Thumb	Pinch movement	Bubbles Demolition	Kinect, Leap motion

Table 34. Cognitive interventions including the RGS protocols.

Device Module Code	Cognitive deficit	Indication of use	Protocols
Active/Passive exoskeleton	Attention deficit	Multi-tasking and sustained attention	All
Active/Passive exoskeleton	Executive function	Problem-solving	All
Active/Passive exoskeleton	Visual perceptive	Neglect	Pinball Grasp & Place
Active/Passive exoskeleton	Memory deficit	Long/short term memory Working memory	PinBall Grasp & Place
Active/Passive exoskeleton	Space-time orientation	Space-time orientation	All

In the following, the RGS protocols suggested to be implemented in the ReHyb system as motor (Table 33) and cognitive (Table 34) interventions are description.

Clean the table

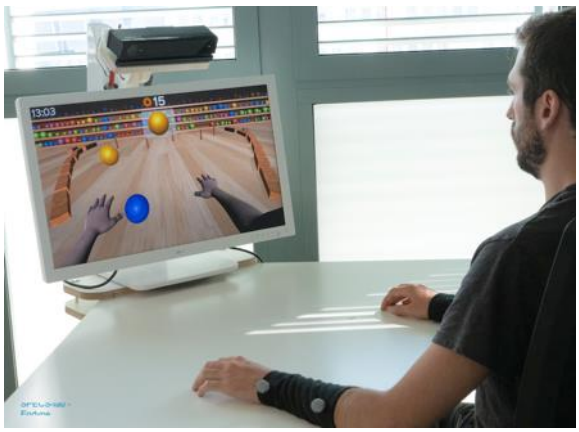
A table is covered with white cubes that the patient must move outside the virtual table´s edges. The session ends when all the cubes are cleared or when the time runs up. The activity is presented at least three times to let the patient fine-tune the movements. This protocol allows the evaluation of movement range and speed for both arms.

Motor function	*Cognitive function*
Maximum flexion/extension of the elbow	Space orientation
Flexion/adduction of the shoulder to cover as much surface as possible with the arms.	Sustained attention
	Problem solving

Pin Ball

Spheres with different patterns and colours roll down the obstacle ramp. At the top centre of the screen, a sphere is shown with the target colour. Only spheres whose colour is equal to the target must be intercepted, and spheres of different colours should be avoided.

The RGS algorithm adapts the size, frequency, speed, dispersion of the spheres, and the number of obstacles rolling down the ramp, all according to the performance of the user.



Motor function	*Cognitive function*
Flexion & adduction of the shoulder with lateral movements of the arms while resting them on a table.	Hemineglect
Flexion & extension of the elbow. Occasionally crossing the midline with the arms is required.	Working memory
	Attention and divided
	Inhibition of movement (go/no-go)

Grab and Place

In this protocol, spheres of different colours and size will come forward in pairs (left and right) at variable speed. Once the spheres have been intercepted they can be grasped and released in the basked with a corresponding colour.

The RGS AI-based adaptive system will control the density speed and colour of the spheres according to the user´s performance which is measured as the ability to grasp and release the sphere. https://youtu.be/yA7d1vU0zvk

Motor function	*Cognitive function*
Movement range and speed for both arms/hands.	This protocol is useful for:
Flexion & adduction of the shoulder	Action planning
Movements against gravity	Dual-task training (mov. coordination & goal)
Precision in reaching	Attention and divided attention
Flexion & extension of the elbow	Hemineglect
Flexion & extension of the fingers	Inhibition of movement (go/no go)
Wrist flexion/extension	

Bubbles

Bubbles of different sizes emerge from a lake. These bubbles must be intercepted with open hands to be able to grasp them and then close the hands by flexing the fingers as much as possible to burst the bubbles.

The smaller the bubbles, the more the fingers need to be flexed to close the hands and explode the bubbles.

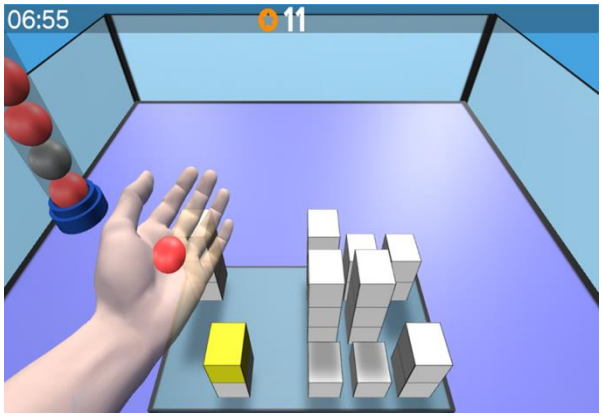
The bubbles' size can be configured according to the hand control of the patient. When the bubbles are red they can be passed from one hand to another.

Motor function	*Cognitive function*
Training hand and fingers movements, precision and strength for both hands.	This protocol is useful for
Hand Pronation and Supination	Sustained attention
Grasp, hold and release	Divided attention
Pinch	Action planning
Finger extension	Memory
Strength & Bimanual coordination	

Demolition

Different blocks randomly appear and pile up on a platform at the center of the screen. The goal is to prevent these blocks from piling up. To do so, "bombs" must be grasped by making a supination movement of the hand and then make a pronation movement to release the bomb and make it fall on the blocks.

The amplitude of the supination and pronation movements required to collect objects (the bombs) can be adjusted according to the patient's condition.



Motor function	*Cognitive function*
Training for hands, fingers' movements, precision, and strength one hand at the time.	This protocol is useful for:

Hand Pronation and Supination	Sustained attention
Hold and release	Divided attention
Pinch	Action planning
Finger extension	Memory
Strength	

The RGS system includes:

1. a screen with an integrated CPU
2. a support for placing the Motion Sensor above the screen
3. a table that provides support to the arms.

During a training session, the patient sits in a chair facing the screen while resting the arms on the table. The motion sensor tracks the patient's arms (elbow and shoulder joints), and the RGS tracking system maps them into the VR-limbs. The screen displays a first person view of gamified rehabilitation scenarios in a virtual environment.

In addition to the gamified treatment options for the upper extremity, this chapter also includes the description of relevant ADL tasks. First, ADLs were defined to be used in the project, depending on the patients' most important ADL domains:

1. Eating & Drinking
2. Hygiene
3. Dressing

Within these domains, tasks representing also different movement control aspects, i.e., unimanual tasks and bimanual tasks with symmetric or asymmetric arm movement pattern, or representing different hand functions like spherical or cylindrical grasp, and pinch or palmar grip.

Within the domain of eating & drinking, the following tasks were selected:

- *grasp and place a glass* (unimanual, cylindrical grasp),
- *carry and place a tray with handles* (bimanual symmetric, palmar grip),
- *cut food* (bimanual asymmetric, spherical grasp or palmar grip) and
- *open vessel* (bimanual asymmetric, spherical grasp)

The proposed tasks within the hygiene domain are:

- *open toothpaste*, *squeeze out toothpaste* (and
- *clip nails* (unimanual, pinch grip)

Tasks picked within the dressing domain are:

- *button up* and *close a zipper* (both bimanual asymmetric, pinch grip).

These tasks were presented at the consortium meeting and different task variations were discussed with technical partners at the meeting and again afterwards to prioritise a selection. The inclusion of real objects places various challenges onto a system like the ReHyb system. When objects with unstable surfaces (e.g. plastic bottle/paper cup) the deformability of the objects need to be tracked to appropriately control the grip force. Tasks including objects with an unstable surface were reset from the project's task list, as this would include a technical solution to control grip force which is not intended within ReHyb. Consequently, manipulating toothpaste or a nail clipper was reset. It has also been agreed that the unimanual cylindrical grasp will be performed only with objects of stable surfaces like a glass but not with plastic or paper alternatives with an unstable surface.

Movements with hand-mouth interaction (e.g. drinking) were excluded as well, as they might raise safety issues from technical point of view (possible self-injury) or medical point of view (e.g. patients with swallowing disorders).

For the selected relevant ADL tasks, basic motion primitives were then further described. This basic description of the motion primitives will be then further described and analysed in more detail (MS 7, Motion primitives for interaction scenarios) and reported in D2.4, D6.2, and D6.3.

In order to generate basic motion primitives, in a first step the tasks were split up in sub-tasks as exemplarily illustrated for the ASL task example *opening a jar* (Figure 12). These steps were then subsequently described in tabular form from a motion based perspective for each of the above given tasks (compare Table 35

Table 40). The required actions on joint level for each of the joints, i.e., shoulder, elbow, wrist and hand + fingers, was determined. With this approach, a better understanding for the technical requirements in each of the steps within a certain task can be achieved.

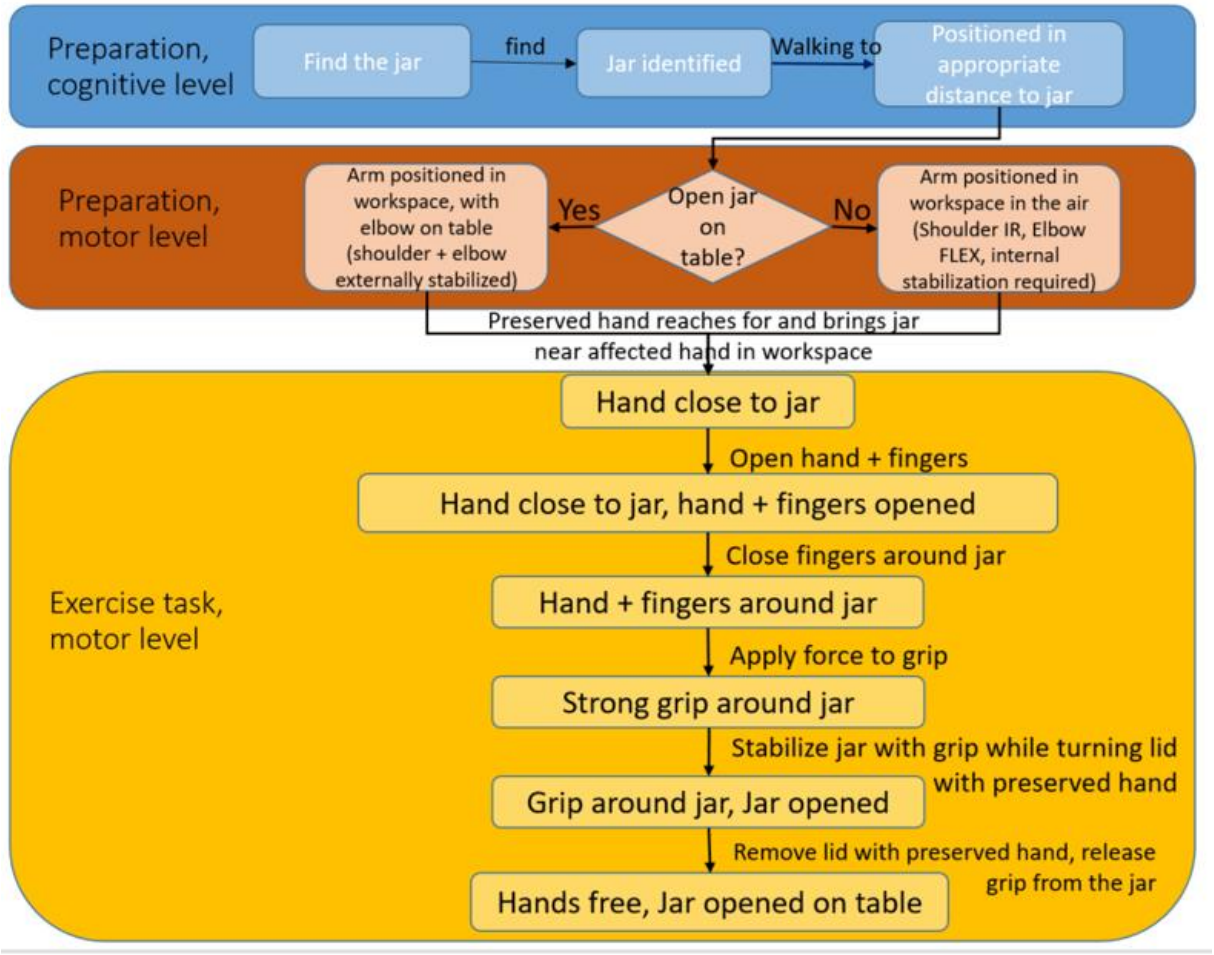


Figure 12: Flowchart of the ADL task *open a jar*

Table 35. Motion primitives for the task *open a jar*.

Option A) on table; Option B) without table			**Required movement of affected limb**			
primitives	**arm primitive**		shoulder	elbow	wrist	hand + fingers
	affected	preserved				
1) finding a jar	x	x	x	n.a.	x	x
2) walking to a reachable distance	x	x	x	n.a.	x	x
3) position affected arm in workspace	x		A)stabilized by placing elbow on table, in FLEX/IRO position B) stabilization throughout entire task necessary, IRO	A)placed on table for stability B) stabilizing in flexed position required for entire task		
4) reaching to the jar	x	reach, grasp and bring jar to workspace	x	x	x	x
5) open the hand	open the hand	x	stabilize position	stabilize position, sup/pro to neutral position; (depending on patients capabilities, opening may be performed in neutral or in supinated position)	x	open (extend)
6) positioning fingers around jar	place fingers around jar	x	stabilize position	depending on hand opening position, either: stabilize neutral position or pronation to neutral position for grasping	not defined, should be adaptable to patients capabilities (e.g. spasticity/ hypertonus)	modelling fingers around jar
7) apply force to grip	apply force to grip	apply force to grip	stabilize position			grasp and apply force (flexion)
8) turn the lid	stabilize and counteract movement of other hand	turn the lid	stabilize position & counteract movement of other hand			keep grip
9) remove the lid	stabilize jar	remove the lid and place it on the table	stabilize position	stabilize position	stabilize position	x
10) release the grip from the jar	release the grip from the jar	remove jar from affected hand	stabilize position	stabilize position	stabilize position	open (extend)

Table 36. Motion primitives for the task *grasp and place a glass*.

start position: NN, arm hanging at side		Required movement of affected limb					
primitives		**arm primitive**		shoulder	elbow	wrist	hand + fingers
		affected	preserved				
1)	finding a glass	x	x	x	x	x	x
2)	walking to reachable distance	x	x	x	x	x	x
3)	reaching to the glass	see column to the left	x (unilateral task)	FLEX +(depending on position of glass) ABD/ADD + ERO/IRO	depending on position (table? position glass?) FLEX then EXT	x	x
4)	opening hand to grasp glass			stabilize position reached above	stabilize EXT/FLEX, PRO/SUPI: depending on hand opening position, either: stabilize neutral position or pronation to neutral position for grasping	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	open (extend)
5)	positioning hand + fingers around glass			stabilize position	depending on hand opening position, either: stabilize neutral position or pronation to neutral position for grasping	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	modelling fingers around glass
6)	apply force to grip			stabilize position			grasp and apply force (flexion)
7)	elevate glass			elevate slightly (FLEX or ABD), stabilize the other directions	stabilize	stabilize	hold grip
8)	move glass to intended place			depends on target position, though always elevating activity required for control	depends on target place	stabilize	hold grip
9)	put glass on intended place			control movement, eccentric activation of flexors/Abductor muscles resulting in EXT	stabilize	stabilize	hold grip
10)	release grip			stabilize position	stabilize position	stabilize position	release grip (open/extend fingers)
11)	move back to NN position			EXT(eccentric activation of FLEX/ABD/ADD) + ERO/IRO depending on position	Extension (eccentric activation of flexors)	x	x

Table 37. Motion primitives for the task *hold and move a food tray with handles*.

* tray should be aligned orthogonal in front of patient.

start position: NN, arms hanging at sides			**Required movement of affected limb**			
primitives	**arm primitive**		shoulder	elbow	wrist	hand + fingers
	affected	preserved				
1) finding a tray	x		x	x	x	x
2) walking to reachable distance	x		x	x	x	x
3) reaching to the handles of the tray	lift hands symmetrically to reach handles		Flexion, depending on distance to tray, Rotation/ABD depending on size of tray	initially: flexion, depending on distance eventually subsequently extension, stabilize neutral position of SUPI/PRO	x	x
4) open hands to grasp handles	open both hands to prepare for grasping handles		stabilize position	stabilize position	ulnar abduction, FLEX/EXT positions may be compensated through abduction in the shoulders	open (extend)
5) positioning fingers around handles	grasp handles		stabilize position	stabilize position	stabilize position	align fingers around handles (flexion)
6) apply force to grip	apply force to prepare for lifting tray		stabilize position	stabilize position	stabilize position	grasp and apply force (flexion)
7) elevate tablet	lift tray with both hands symmetrically		minimally FLEX	symmetrical flexion	stabilize position	keep grip
8) position tablet close to body in "carry position"	move tray with both hands close to belly to achieve comfortable carry-position		depending on position, maybe controlled extension (eccentric flexor activity)	symmetrical flexion	stabilize position	keep grip
9) carry tray	walk while stabilizing the tray in the position (optional, only if patient is able to walk)		stabilize position	stabilize position	stabilize position	keep grip
10) put tray on intended place	put tray on intended place with both hands symmetrically		depending on target position: FLEX	depending on target position: FLEX/EXT	stabilize position	keep grip
11) release grip	open both hands to release grasp around handles		stabilize position	stabilize position	stabilize position	release grip (open/extend fingers)

Table 38. Motion primitives for the task *grab sensitized object from above*.

start position: NN, arms hanging at sides			**Required movement of affected limb**			
primitives (both sides, affected+ preserved)	arm primitive		shoulder	elbow	wrist	hand + fingers
	affected	preserved				
1) finding object	x	x unilateral task	x	x	x	x
2) walking to reachable distance	x		x	x	x	x
3) reaching to object	See left column		FLEX +ABD/ADD + ERO/IRO (depending on position of object)	depending on position of object FLEX and EXT; Pronation	x	x
4) open hand to grasp object			stabilize position reached above	stabilize position	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	open (extend)
5) position finger around object			stabilize position, slightly EXT to reach object (eccentric flexor activation)	stabilize position	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	modelling fingers around object
6) apply force to grip			stabilize position			grasp and apply force (flexion)
7) elevate object			elevate slightly (FLEX or ABD), stabilize the other directions	stabilize	stabilize position	keep grip
8) move object to intended position			depending on target position, though always elevating activity required for control	depends on target place	stabilize position	keep grip
9) put object on intended place			control movement, eccentric activation of flexors/Abductor muscles resulting in EXT	stabilize position	stabilize position	keep grip
10) release grip			stabilize position	stabilize position	stabilize position	release grip (open/extend fingers)
11) move back to NN position			Extension(eccentric activation of FLEX/ABD/ADD)+ ERO/IRO depending on position	Extension (eccentric activation of flexors)	x	x

Table 39. Motion primitives for the task *cut food*.

start position: NN, arms hanging at sides			Required movement of affected limb			
primitives	arm primitive		shoulder	elbow	wrist	hand + fingers
	affected	preserved				
1) finding object	x	x	x	x	x	x
2) walking to reachable distance	x	x	x	x	x	x
3) reaching to fork	elevate arm to approach fork	x	FLEX +ABD/ADD + ERO/IRO (depending on position of object)	depending on position of object FLEX and EXT; Pronation	x	x
4) open hand to grasp object	open hand to prepare to grasp fork	elevate and stabilize fork to simplify grasping of fork	stabilize position reached above, depending on grip used, ABD or rotational component need to be adjusted	stabilize position	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	open (extend)
5) position finger around object A)palmar grasp B)lateral pinch C)pinch	close fingers/hand around fork	elevate and stabilize fork to simplify grasping of fork	stabilize position reached above, depending on grip used, ABD or rotational component need to be adjusted	stabilize position	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus) and the fork and grip used	modelling fingers around object
6) apply force to grip	grasp and apply force	elevate and stabilize fork to simplify grasping of fork	stabilize position	stabilize position	stabilize position	grasp and apply force (flexion)
7) elevate object	elevate fork to prepare for fixating object to be cut	move object to be cut under fork and fix object there with hand until it is fixated by fork	elevate slightly (Flex and/or ABD), stabilize the other directions	stabilize position	stabilize position	keep grip
8) fixate object with fork	pin object on cutting board with fork	hold object in place	Extension(eccentric activation of FLEX/ABD/ADD)+ ERO/IRO depending on position	stabilize position	stabilize position	keep grip
9) fixate object while cutting	stabilize position	cut object	stabilize position	stabilize position	stabilize position	keep grip
10) release fork from object	elevate fork to release from cut object	fixate object to enable separation from fork	elevate slightly (Flex and/or ABD), stabilize the other directions	stabilize position	stabilize position	keep grip
11) place fork on table	lower arm to place fork on table	x	Extension(eccentric activation of FLEX/ABD/ADD)+ ERO/IRO depending on position	stabilize position	stabilize position	keep grip
12) release grip	open hand to release grip around fork	if required, help to remove fork from grip	stabilize position	stabilize position	stabilize position	release grip (open/extend fingers)
13) move back to NN position			Extension(eccentric activation of FLEX/ABD/ADD)+ ERO/IRO depending on position	Extension (eccentric activation of flexors) (depending on table, eventually first flexion, then extension)	x	x

Table 40. Motion primitives for the task *close zipper*.

Option 1: close seperatable zipper (e.g. jacket). A)Counterpart B) zipper handle ;
Option 2:close non-seperatable zipper (e.g. to close pocket) --> without point 7; A) cloth at end of zipper B) zipper handle
start position: NN, arms hanging at sides

primitives	arm primitive		Required movement of affected limb			
	affected	preserved	shoulder	elbow	wrist	hand + fingers
1) finding object 2) walking to reachable distance	x x	x x	x x	x x	x x	x x
3) reaching to object	elevate arm to approach zipper	elevate arm to approach zipper	FLEX +ADD + IRO (though depending on position of zipper)	FLEX	x	x
4) open hand to grasp object	open hand position fingers in pinch or lateral pinch around A)	grab object to stabilize it for grabbing with affected hand	stabilize position reached above	stabilize position	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	open (extend)
5) position finger around object	counterpart of zipper or B) zipper handle	stabilize cloth, to facilitate grabbing of other hand	stabilize position	stabilize position	not defined, should be adaptable to patients capabilities (e.g. spasticity/hypertonus)	modelling fingers around object
6) apply force to grip	grasp and apply force to grip	grab A) zipper handle or B)counterpart of zipper	stabilize position	stabilize position	stabilize position	grasp and apply force (flexion)
7) thread up zipper	A)thread up zipper by inserting counterpart in zipper, extension B) stabilize zipper by pulling down	A) stabilize zipper by pulling down B) thread up zipper by inserting counterpart in zipper, extension	stabilize position	A) flexion and Extension to thread up counterpart to Zipper B) extension to stabilize zipper	stabilize position	keep grip
8) thighten zipper	A)stabilize zipper by pulling down counterpart B) zip up zipper handle, elevation	A)zip up zipper handle, elevation B) stabilize zipper by pulling down counterpart	A) stabilize position by isometric extension B) FLEX	A)isometric extension to create stabilization B) depending on positioning of zipper FLEX (e.g. when wearing the jacket to close) or EXT to zip up (e.g. when zipper lays on table)	stabilize position	keep grip release grip (open/extend fingers)
9) release grip	open hand	open hand	stabilize position	stabilize position	stabilize position	
10) move back to NN position			Extension(eccentric activation of FLEX/ABD/ADD)+ ERO/IRO depending on position	Extension (eccentric activation of flexors)	x	x

The following Table 41 shows lists the feedback modalities that would be appreciated from medical perspective for the respective joint levels.

Table 41. Sensing for feedback while performing the tasks.

shoulder	elbow	wrist	hand + fingers
force, joint angle	EMG, joint angle	joint angle, EMG	force

Herein, after some objects requirements for the tasks described above are provided (Table 42). As mentioned above, all surfaces should be stable and in case of jars/glasses, the tasks shall always be executed without liquids inside.

Table 42. Object specifications corresponding to the proposed task primitives.

Task	**Object requirements**
Open a jar	Round jars: - small: Ø 5.5 cm - medium: Ø 7 cm - large: Ø 9.5 cm Rectangular jars/bottles: - small: 5.5 x 5.5 cm - large: 7 x 7 cm
Grasp and place a glass	Shape: round Sizes: - small: Ø 6 cm - medium: Ø 7 cm - large: Ø 8 cm
Hold an move a food tray with handles	Handles: Ø 3 cm
Grab sensitized object	Object with included force sensors
Cut food	Different kinds of forks: - with thickened handles - with curved handle - normal fork additional material required: - cutting board - knife + object to cut (may be realised differently in AR/VR environment)
Close zipper	Option 1: separable zipper Option 2: inseparable zipper Sizes of zipper handle: - normal zipper approximately 20 x 6mm - enlarged zipper (e.g. with 3d printed extension: https://www.thingiverse.com/thing:1103082) In order to train both sides, one zipper should have the zipper handle on the left, and one on the right side (when wearing a zippable cloth, it will be closed the other way round then when „training“ on a zipper in front of the subject

3 Stakeholder Identification

According to the objectives of D2.1, chapter 3 focusses on the stakeholder identification.

The purpose of stakeholder definition and analysis is to indicate whose interests should be taken into account when making a decision and to indicate why those interests should be considered.[48] For the development of the ReHyb system, stakeholders (SH) were identified by SK and VALDUCE, resulting in ten identified different stakeholder groups (Figure 13).

Those different stakeholder groups were collected and organized in a stakeholder list.[49, 50] Stakeholder lists are simple tables naming stakeholders and their characteristics as shown in Figure 14. Furthermore, stakeholder lists are often used as a first step to understand the roles, interests, concerns and influences of stakeholders. A stakeholder list was elaborated, in order to understand who the ReHyb related stakeholders are and to record relevant, basic information of each stakeholder – not least to support the basic understanding among project members and to interact with stakeholders. Moreover, project members maintain a whole picture of stakeholders over time. From this perspective, it is clear that making the list of stakeholders and their roles, interests etc. is not the ultimate purpose, but utilizing it is crucial. The list is used to better communicate between project members and stakeholders over the ReHyb system development period by reminding one another that stakeholders who are not in the discussion shall not be neglected. Moreover, different sites who are superficially similar may turn out to have either different configurations of stakeholders or different characteristics (interests, power of influence, incentives).

The stakeholder list identifies details of the directly involved stakeholders as well as the most important key ones with the following 8 aspects: roles, interests, knowledge, expectations, influence, tangible incentives, intangible incentives, and risks. These aspects are meant to capture not only the relatively obvious characteristics but also the more implicit ones. SK and VALDUCE collected and organized ReHyb relevant stakeholders from a clinical point of view in a stakeholder list (Figure 14).

Stakeholder identification is a useful initial step, but a more detailed analysis is required that allows for a context specific weighting. Based on the stakeholder list that is reported in this deliverable (D 2.1), an in-depth stakeholder analysis will be conducted by the clinical and technical partners and results will be reported in D 2.3.

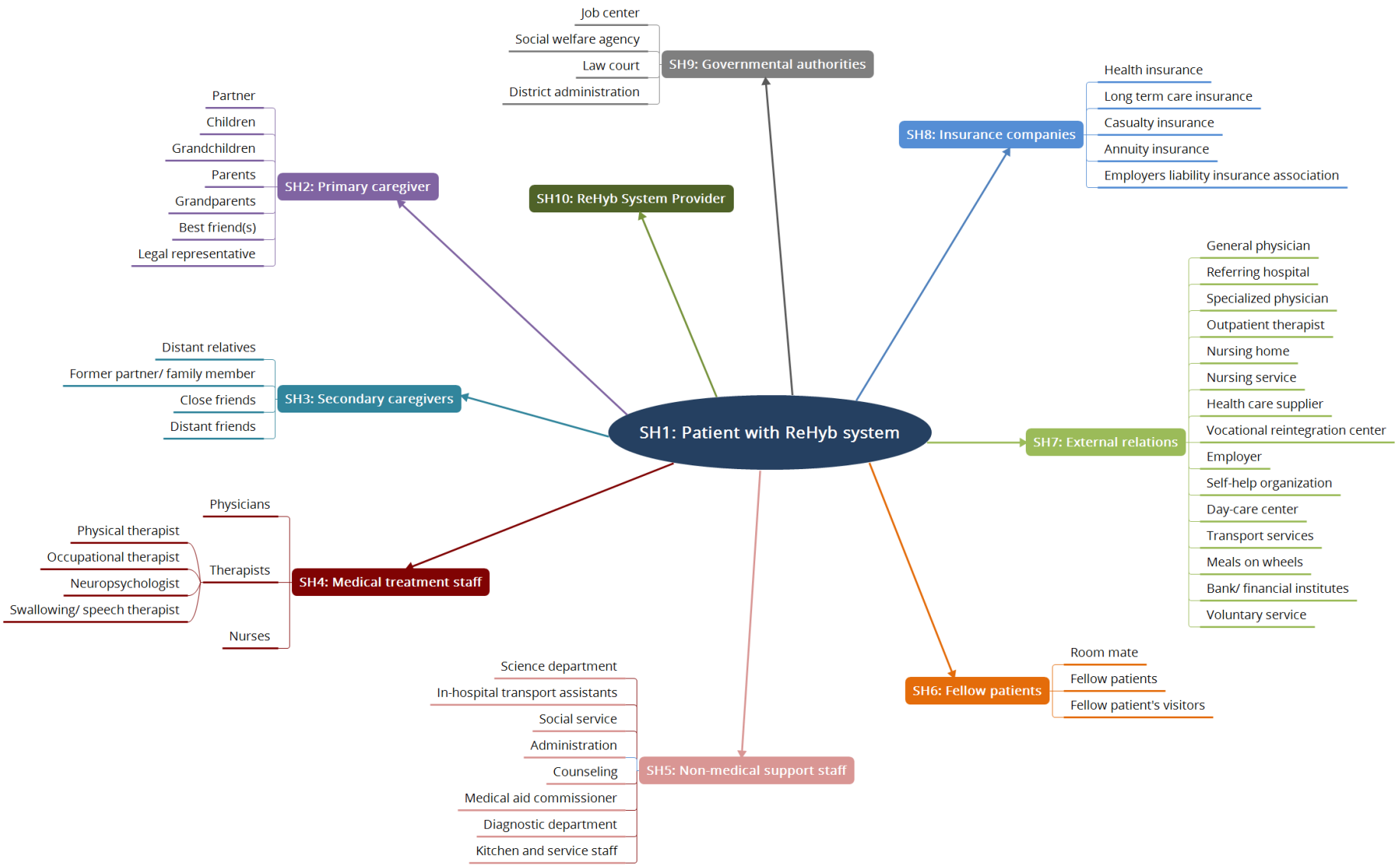


Figure 13. Different stakeholder groups created based on the stakeholder list from a clinicl point of view.

	Characteristics	Role	Interests	Knowledge needs	Expectations	Influence uptake	Tangible incentives	Intangible incentives	Risks
Regarding to the ReHyb system:	*What kind of stakeholder are they? The target stakeholders could be different from location to location.*	*The role toward end-user. What kind of role they have towards end-user?*	*What kind of intersts do they have ?*	*What kind of knowledge need do they have? Or What kind of knowledge do they already have to support the use?*	*What is the initial motivations to the use?*	*How much influence do they have to uptake the use? Fill out in a scale of 1(No influence) to 10 (Strong influence)*	*What are the obvious/short-term incentives? (This answer clarifies how to approach them to device use)*	*What are the long term incentives, often subconscious level?*	*What could be a risk for them to use the devive?*
SH1: Patient (in rehabilitation hospital or at home)	Patients after stroke, hospitalized or undergoing rehabilitation in day-care hospital or at home	End User	More independence in ADL; improvement of QoL; development of positive emotions; mobilization; pain-free living; smooth transition from rehabilitation clinic to home; more security	Recommendation for the suitable system configuration; system training and support for use of technology	Individual support in daily life (rehabilitation clinic and after discharge); enhancement of independence level	10	More independence; more self-efficacy; less anxiety (regarding transition and future life)	Improve physical condition; increased motivation; feeling comfortable and safe; keep privacy and control;	Private data disclosure; reservations and concerns about new technology; financial burden; over-dependent on ReHyb system; under/over-challenge due to modules which do not match the patient's current situation
SH2:Primary caregivers	Partner, children, grandchildren, parents, close relatives, best friends, legal representatives	Supporter/consultants for the use in daily life, contact persons in case of problems or in need of system alterations	reduced burden (e.g., transportation); support close caregiver; information about the patient's condition	System training and technical support	Reduced care time; better outcome (physically and mentally); informed about the person being cared for	9 - 10	More time for themselfs; more time for socializing with the patient; better feeling about the transition to home	Reduce worries, guilts and regrets. Feeling comfortable and safe	Private data disclosure; feeling stressed from technical demands (e.g. when patient cannot cope with technical requirements of Rehyb system); financial burden (purchase and support of Rehyb system)
SH3:Secondary caregivers	Distant relatives, former partner/ family member, close and distant friends	Supporter (in case of non-availability of primary caregivers)	discussion topic; information on patient's progress	System training & occasional technical support.	slightly increased feeling of safety and information about the person being cared for	2-3	Better feeling about the transition to home	higher motivation to support the patient after discharge	stress with new technology; less contact caused by the impression that patient is well supported

Figure 14. Stakeholder list.

	Characteristics	Role	Interests	Knowledge needs	Expectations	Influence uptake	Tangible incentives	Intangible incentives	Risks
SH4: Rehab. clinic: medical treatment staff	Physicians, therapists, nurses	Data user, trainer, supporter, monitoring of system functionality	Better understanding of patient needs based on therapy data; early indications for changes in functional state; conduct best individualized treatment programm and schedule; smooth transition from rehabilitation hospital to home; easier monitoring of development; improved therapy outcome; longer more frequent treatment; less therapist effort; independently perform ADL	System training; options for data output and analysis	Better understanding of patient needs; better outcome due to more activity during treatment sessions (and after rehabilitation); objective data to corroborate medical/therapeutic interventions	8-9	Best rehabilitation treatment and more self-determination (independence) for the patients; more time for quality contacts with patients (increase self-esteem)	Rehabilitation hospital is more attractive for patients when offering Rehyb system; feeling that patient has a sense of better support	Reduced interpersonal contacts with the patients
SH5:Rehab. clinic: non-medical support staff	Medical aid commissioner, administration, counseling, social service, science department, in-hospital transport assistants, diagnostic department, kitchen and service staff	Data user, supporter/consultants, monitoring of system functionality	Better understanding of patient needs; indications for changes in functional state; smooth transition from rehabilitation hospital to home (higher patient's independence); easier monitoring of development	System knowledge; system training; options for data output and analysis	Better understanding of patient needs	5 - 6	Optimized operational processes; more information about patient's progress; better planning of patient's discharge	Patient is more independent in ADL; needs less personal support	Reduced interpersonal contacts with the patients
SH6.Rehab. clinic: fellow patients	Room mate, fellow patients, fellow patients' visitors	Members of target user group	contact to people in the same situation; more possibilities to interact with fellow patients and support and motivate each other	Information about Rehyb system	easier and more information exchange between the patients; (partner-activities during Rehyb application; dependent on gamification)	2 - 3	More social contacts and support from fellows in rehabilitation process	Knowledge about a system which provides support after discharge and may help to live more independent	Increased need to purchase the Rehyb system without having the necessary financial resources; increased feeling of inequality when not having the device
SH7: External relations	General physician, referring hospital, specialized physician, outpatient therapist, nursing home, nursing service, health care supplier, vocational reintegration center, employer, day-care center, transport services, meals on wheels, bank/financial institutes, self-help organizations, voluntary services	Data user; technical support	Individualized support; monitoring of progress and/or health status; economic use of resources	System training; options for data output and analysis; occational technical support	More information about the patient after discharge	3	Better coordination/communication between different supporter after discharge	Better understanding what kind of support the patient will need after discharge	Reduction of support portfolio for patients after discharge

Figure 14. Stakeholder list (continued).

	Characteristics	Role	Interests	Knowledge needs	Expectations	Influence uptake	Tangible incentives	Intangible incentives	Risks
SH8: Insurance companies	Health insurances, long-term care insurances, casualty insurances, annuity insurances, employers liability insurances	Data user, financing	Economic use of resources; lower costs due to prevention of comorbities (mental and physical activity); reduced amount of rehab hospital programms; prevention of care dependency	Information about Rehyb system	Cost reduction and economic use regarding insurance expenses; more information about policyholder	6	Sound and attractive insurance program	Shows competence through successful company policy	reduction of insurance payout to individual; misinterpretation of ReHyb sytem usage data; false conclusion drawn from data
S9: Governmental authorities	Job center, social welfare agencies, law courts, district administrations	Data user, financing	Economic use of resources; data about needs and capabilities of stroke population; prevention of care dependency	Information about Rehyb system; data from Rehyb provider	Cost reduction and economic use regarding expenses in the health care system; more information about stroke patients	4	Less costs/expenditure in healthcare sector	Shows competence through successful political strategy	misinterpretation of ReHyb sytem usage data; false conclusion drawn from data
SH10: ReHyb system provider	Provider	System configuration, technical support, consulting	Realization of profits; market leadership; cooperation with other companies (synergetic effects)	Knowledge about Rehyb system; Patients' and other stakeholders' needs; user feedback; user's potential functional improvements	Profit; high customer satisfaction; support of stroke patients	4-5	Solid company; good contact/relationship between provider and user	Feeling good about supporting patients, medical staff and caregivers	Providing/developing a system that does not meet the market requirements

Figure 14. Stakeholder list (continued).

Following the identification of stakeholders, information about their different personal characteristics should be considered when performing the stakeholder analysis. Developing the system with respect to the stakeholder description ensures continuous resonance and sensitizes patients to get more acceptance for the proposed system.

It is reported in previous research that the general enthusiasm about technical devices negatively correlates with age. Similarity, self-efficacy and competence in handling of technical devices decreases with age.[51] Since the majority of the target stroke group consists of older adults, the development of technological devices should consider patients' attitude towards technical devices.

SK and VALDUCE therefore started to describe the most important user groups (SH 1: patient with ReHyb system; and SH 4: medical treatment staff) regarding their technical affinity. Until now, technical affinity was assessed in stakeholders at SK by means of the Technical affinity questionnaire (TA-EG), a valid and reliable questionnaire available in German. [52]

The TA-EG (Table 43) was answered by patients at SK (n=12) and clinical staff members at SK (n=15), who are highly experienced in the usage and application of technical therapeutic devices. Following statements were rated with a 5 point Likert Scale ranging from 1 = low affinity to 5 = high affinity.

Table 43. Technical affinity questionnaire TA-EG.

	Clinical staff rating	Patient rating
Statement	Mean (SD)	Mean (SD)
I love to own new electronic devices.	3.4 (1.2)	3.8 (1.5)
I inform myself about electronic devices even if I have no intention of buying.	2.9 (1.3)	3.6 (1.8)
I am excited about new electronic devices coming on to the market.	2.4 (1.0)	2.5 (1.7)
I enjoy going to the specialized trade for electronic devices.	2.5 (1.1)	3.5 (1.9)
Trying out a new electronic device is fun.	3.9 (1.1)	3.7 (1.6)
I know most of the features of my electronic devices.	3.5 (1.1	4.2 (1.3)
I (would) have problems in understanding electronic or computer related magazines.	3.3 (0.9	3.1 (1.8)
Learning how to operate an electronic device is easy.	3.7 (0.7)	3.4 (1.7)
I know a lot about electronic devices.	2.9 (0.7)	3.1 (1.5)
Electronic devices help to get information.	4.4 (0.5)	4.3 (1.4)

Electronic devices enable to a higher standard of living.	3.5 (0.5)	4.0 (1.1)
Electronic devices increase safety.	3.5 (0.6)	4,1 (1.1)
Electronic devices increase independence.	3.2 (0.9)	3,8 (1.5)
Electronic devices make my everyday life easier.	4.0 (0.8)	4.1 (1.3)
Electronic devices reduce personal contact between people.	2.9 (0.7)	2.8 (1.4)
Electronic devices cause stress.	3.9 (1.0)	2.5 (1.5)
Electronic devices lead to illness	3.8 (0.8)	4.1 (1.0)
Things are more complicated due to electronic devices	4.3 (0.6)	3.6 (1.3)
Electronic devices lead to mental impoverishment.	3.6 (0.9)	3.6 (1.3)

In total, the TA-EG consist of 19 statements, which can be grouped into four categories: *Enthusiasm*, *Competence*, *Positive attitude* and *Negative attitude towards technology*. Regarding the responses of therapists, the average rating of each category is presented in Figure 15. Overall, healthcare operators showed a tendency to high affinity with an average value of 3.5. High affinity scores with values of 3.7 are observed in the categories *Positive attitude towards technology* and *Negative attitude towards technology*, while the *Enthusiasm* about technical devices has the lowest affinity score with a value of 3.0. Lastly, healthcare operators show an affinity value of 3.4 in the category *Competence*.

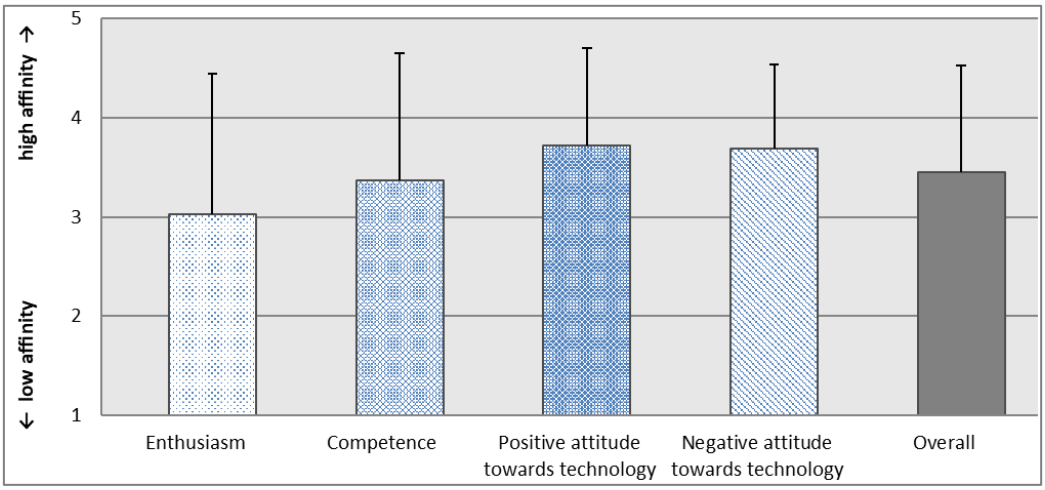


Figure 15. Average affinity score for different categories in healthcare operators.

Patients' responses with their average rating of each category is presented in Figure 16. Similar to healthcare operators, patients have an overall affinity score of 3.5. While patients' affinity is higher regarding the category *Enthusiasm* (3.4) than in healthcare operators (3.0), the category *Negative attitude towards technology* achieved a lower affinity score in the patient group (3.3). This indicates that patients have a more negative impression of technical devices

regarding the influence of technology on stress, illness, personnel contact and mental impoverishment. Furthermore, *Negative attitude towards technology* includes the aspect that technical devices make things more complicated. The reason for this low affinity value could be specific for the user group after stroke or due to the age range of the patients, what should be further investigated. On the other hand patients showed a high affinity value (4.0) in the category *Positive attitude towards technology*. Lastly, patients rate their *Competence* with an average affinity score of 3.4.

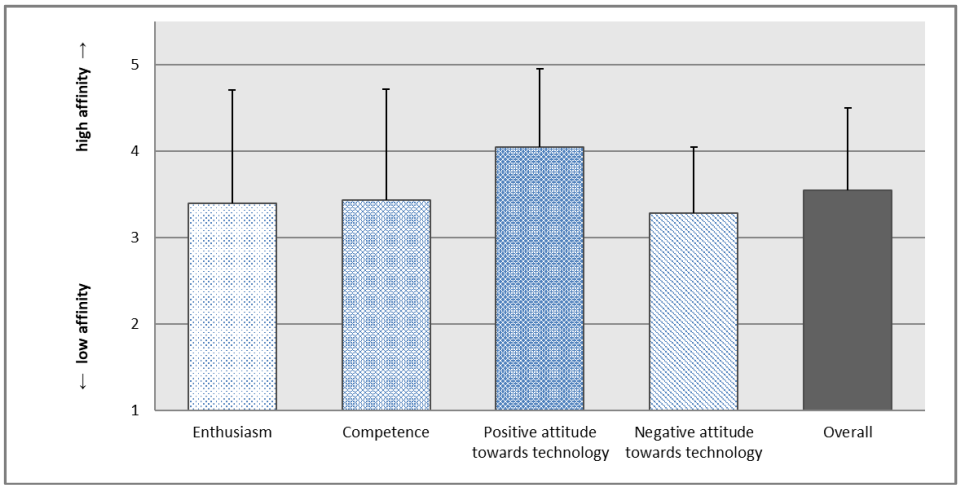


Figure 16. Average affinity score for different categories in patients.

For the assessment of stakeholder's technical affinity within the ReHyb project, SK and VALDUCE worked on an Italian translation of this questionnaire as the TA-EG or an equivalent scale was not available in Italian language. The translation has been performed following Beaton's six stages for a standardized translation and cross cultural adaptation of the source questionnaire.[53] Currently, the Italian translation of the technical affinity questionnaire is being evaluated at VALDUCE for the assessment of SH 1 and SH 4. In addition, we will continue to gather data for technical affinity of other stakeholder groups relevant for the ReHyb system.

As a next step for the in-depth stakeholder analysis (D2.4) which is based on the stakeholder identification (D2.1), the stakeholder list is used to prioritize stakeholders in the relative scale with the central end-user - the patient - using an Onion Diagram (Figure 17).[54, 55] Within this step , the stakeholder analysis will be separated for the two different environments in which the ReHyb system can be applied, i.e., the rehabilitation clinic and the patient's home. This onion diagram will be used to prioritize importance key stakeholders in relation scale from the centre. Putting our target end-user - the patient after stroke - in the middle of the diagram, the business system, organization and environment layers are arranged as onion shape.

The diagram is created in a two steps process:

1. Stakeholders in relative relations to the central person, patient after stroke, are allocated.
2. Information/money flows are described between allocated stakeholders.

As explained before, this template is useful for understanding relative relations among stakeholders in visual format. By visualizing relative relations, the template indicates who could be the key players in relation to our target user, the patient after stroke.

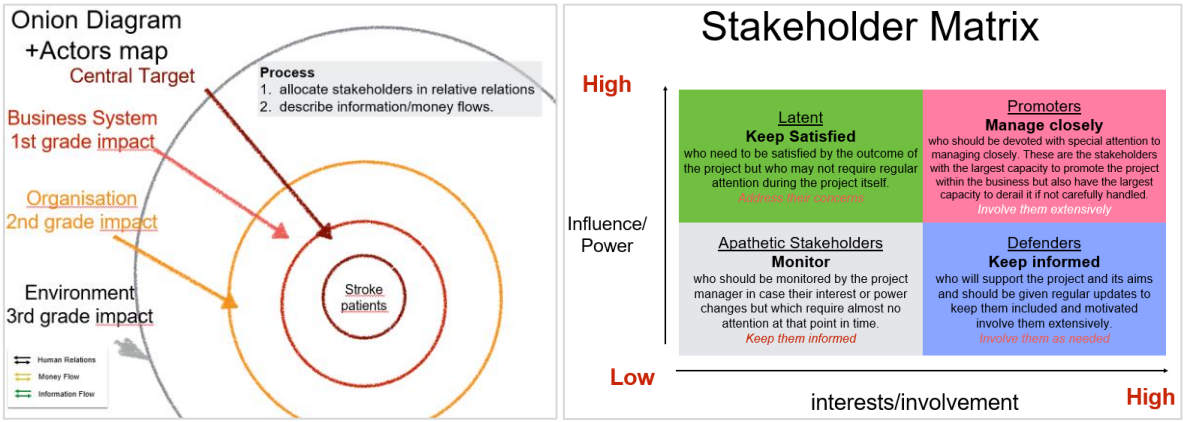


Figure 17. Templates for the Onion Diagram in the second step (left) and Stakeholder Matrix in the third step(right).

In the third and last step of the stakeholder analysis, each stakeholder and its influence for further strategy planning will be represented in a Stakeholder Matrix (Figure 17).[56, 57] Probably, we will work on two different Stakeholder Matrices, one for the rehabilitation use and one for home use, as the setting in which the ReHyb system is used may influence the significance of different stakeholders. A stakeholder matrix represents stakeholders' relative power on and interest in the use of the technology. In this 2-by-2 matrix, the x-axis indicates interests or involvements while the y-axis indicates influence or power. For example, the second quadrant is the "promoters" space, so that stakeholders allocated to this quadrant should be managed closely in decision making and their ideas should be noted.

The matrix will be created also in a two steps process:

1. Stakeholders are allocated to their appropriate quadrant.
2. Each stakeholder in the quadrants is compared and defined in relative distance to other stakeholders.

4 Conclusion

In this deliverable we presented the activities undertaken to define the use case scenarios and to identify stakeholders as part of WP2. Activities involved healthcare providers as well as end-users to define the use cases and guide the Research and Development (R&D) activities performed under WP3 - WP9.

As a first step, patients and clinical experts in the field of robotics, FES and VR/AR application were asked for their user opinion on devices they have experience with and literature was reviewed. To sum up the responses provided by patients and healthcare operators from SK and VALDUCE, the following main clusters were obtained related to the desired features of the ReHyb system: 1) the system should target the whole arm (including: provide antigravity support, allow multi-segment training, facilitate/emulate ADL and bimanual activities, integrate FES/electromyography (EMG); 2) it should be easy to use in an autonomous way by both, patients and healthcare operators (including following characteristics: lightness, portability, wearability, easy instructions for its use); 3) it should be reliable, which is mainly referred to safety and robustness; 4) it should be adaptable to patient condition, from both motor and cognitive perspective (includes: variability of tasks, usable in standing and seated position, different levels of difficulty of exercises, combining motor and cognitive tasks as much as possible); and 5) enhance patient motivation and engagement (including: different types of feedback, integration with virtual environment, facilitate embodiment). The ReHyb system aims to cover as many aspects of the wish list as possible.

The detailed description of the user requirements informs and improves the next steps of the R&D activities of the ReHyb system. One aspect has to be mentioned here as it does not directly belong to the developmental project activities: During the discussion on the different health care providers to be included for the survey, it turned out that at VALDUCE the physicians have a higher responsibility in decision making for therapy content, while at SK this decision is more in the therapists hands. This should be taken into account for the evaluation and dissemination activities when the consortium has to decide on information and data flow.

From the above given requirements the following are highlighted here as they specifically belong to the settings which envisions individualised, patient-adaptive and safe physical interaction and therewith, lead to a higher **personalisation** of training programs. Patients greatly differ from each other and also change their functions over time which the ReHyb system ideally should consider: 1) the ability to *keep a sitting or standing posture* during a therapy session, i.e., the ReHyb system should be able to allow for therapy sessions in sitting and standing, and should be able to support patients in their capacity to stay in upright sitting. 2) Patients *muscle tonus,* e.g., spasticity, can change within a single therapy session, i.e., the system should be able to detect spasticity/hypertonus and its changes. 3) The *range of motion* can vary depending on muscle strength, pain, muscle tone, or the joint structure etc.. As the ROM defines one's working space, this should be considered especially in the VR/AR gamification module of the system. 4) Increased *muscle strength* can not only increase the ROM, it can also change the need for support to perform a movement within a given ROM. A change in muscle strength needs to be detected to individually adapt and modulate the support of the system coming from several modules. 5) Last but not least, the information about the

patient's psychophysiological state during and in course of the therapy is a relevant factor to appropriately address the gamified tasks. The patient's attentional and motivational level has to be taken into account to keep her or him engaged and interested in the rehabilitation activities.

In creating personas - a methodology used to provide the technical partners with detailed information about the needs and expectations of the core user – clinical data of the targeted patient population were analysed at both hospital sites. Based on these data, three diverse personas were created, each representing a patient of a group with different impairment levels. Characteristics of patients in the hospital scheduled of robotic therapy or of patients at home further help to understand patients special needs. Concluding the results from the evaluation of the patients training with the ARMEO Spring and ARMEO Power, the following can be stated: Patients training with the spring-based system showed more mobility and less dependency regarding gait and trunk stability, as well as higher levels of muscle strength in their affected upper limb. The pROM, however, did not seem to differ from the patient sample training with the ARMEO Power. Further, the patients performing training with the ARMEO Power device had also additional symptoms such as neglect or dysarthria that need to be considered when planning therapy settings.

Identified challenges in the home use of the device have been identified: 1) the patient's safety has to be the mainline principle, 2) the patients and/or caregivers have to be properly trained, 3) patients and caregivers must not be left alone which could be ensured by implementation of a User's Service Centre which can be used for consultations (a 24/hour service is not necessary, since it is not an emergency service, but schedule of service availability must be clear for users), and 4) treatment monitoring is crucial both from a technical and a clinical perspective.

The consortium supports the idea that women and men should benefit equally from advances in science and technology. For the ReHyb project we ensure that within the evaluation, consultation and implementation processes research must address women's needs as much as men's needs, and that research must be carried out to contribute to an enhanced understanding of gender issues. In this context, for all scientific results and the technologies, the consortium will promote an gender-balance in all research and innovation activities. Implementing gender-balanced research not only means that **men's and women's needs will be equally considered**, but also that the **proportion of genders in the population under investigation** is reflected in the evaluation procedure. At both hospital sites, SK and VALDUCE, men and women were almost evenly distributed in the cohort of stroke patients admitted to the hospital during a one year period with 53.8 % and 54.4 % of men, respectively. Consequently, for the evaluation of the system the consortium should strive for an equal distribution of men and women.

Results of a workshops held with medical experts at both clinical sites and the ReHyb consortium members shows that for different ReHyb modules different inclusion and exclusion criteria have been discussed. This leads to the conclusion that the inclusion/exclusion criteria should – according to the ReHyb system – ideally be also organized on a modular level instead of setting up general criteria for the entire ReHyb system.

This deliverable provides tasks which can potentially be applied with the modular ReHyb system. The proposed tasks include some already existing and investigated serious gaming tasks developed by the technical partners as well as important ADL tasks. For the selected relevant ADL tasks, basic motion primitives were then further described. This basic description of the motion primitives will be further described and analysed in more detail as part of MS 5 (Motion primitives for interaction scenarios) and reported in D2.3, and D6.3.

The stakeholder identification process revealed relevant stakeholders of the ReHyb system who were grouped in 10 stakeholder groups, i.e., patient with ReHyb system, primary caregiver, secondary caregivers, medical treatment staff, non-medical treatment staff, fellow patients, external relations, insurance companies, governmental authorities and ReHyb system provider. Consecutively, details of the directly involved stakeholders as well as the most important key ones were identified and the following 8 aspects were excerpted: roles, interests, knowledge, expectations, influence, tangible incentives, intangible incentives, and risks. Based on the stakeholder identification, as a next step the in-depth stakeholder analysis will be reported in D2.4. The stakeholder list will then be used to prioritize stakeholders using an Onion Diagram. Stakeholder and their influence on the ReHyb system will be organized in a Stakeholder Matrix for further strategy planning.

To assess stakeholders' technical affinity being one indicator for a successful use of technical systems, the German version of the Technical Affinity Questionnaire was translated into Italian following a standardized translation procedure. As a next step this questionnaire will be evaluated in Italian stakeholders. Overall, the healthcare operators showed a moderate affinity with an average value of 3.5 (on a scale from 0 to 5). Similar to healthcare operators, patients have an overall affinity score of 3.5. While patients' affinity is higher regarding the category *Enthusiasm* (3.4) than in healthcare operators (3.0), the category *Negative attitude towards technology* achieved a lower affinity score in the patient group (3.3). The reason for this low affinity value could be specific for the user group after stroke or due to the age range of the patients, which should be further investigated. On the other hand patients showed a high affinity value (4.0) in the category *Positive attitude towards technology.* These values have been found in healthcare operators and patients who are used to work with therapy devices. For later distribution of the ReHyb system also the attitude of unexperienced users and other stakeholders should be investigated and needs to be considered.

To finally conclude, we want to highlight that the ReHyb system should be seen as a first line treatment option with the need to be maximally flexible to be able to address as many patients as possible within the divers cohort of patients after a stroke. The user and system requirements defining the use case scenarios are manifold, listed in detail in the chapters above. However, for the different modules specific requirements need specific attention. These requirements are delineated in Table 44.

Table 44: Table highlights *specific* requirements for the use case scenarios with respect to the ReHyb modules

Application modules		Therapeutic use / Orthotic			
	Overall	**Hospital**			**Home-care**
Patient condition:			*severe*	*moderate to mild*	
User requirements (inclusion/exclusion criteria)	- ability to understand games - at least some residual somatosensory function - no unspecific pain - willing to use technology-based therapeutic device	Robotic	- ability to sit (supported or unsupported)pre-therapy spasticity reduction	- MRC ≥ 3 (incl. FES)	- training of patients and caregivers in system use - support structure (e.g. user's Service Centre)
		FES	- stimulation of muscle(s) possible - pre-therapy spasticity reduction		
		VR/ AR	- attention minimum 5 min - impairments in stereovision		
System requirements	- real object use - partially or full movement performance of activity - personalization criteria - detection of movement intention - bilateral tasks/movements - information for creating digital user	Robotic	- sitting support actuation with movement initiation critical	-	- safety - data protection and privacy (e.g. Service Centre) - "Alert sending option" (e.g. notification of non-execution or irregularities of therapy)
		FES	- hand opening important - small muscles		
		VR/ AR	- difficulty level/ increase motivation - performance feedback - generation of depth		

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Definitions, Acronyms and Abbreviations

Acronyms abbreviations	Description
3D	3 dimensions
ABD	Abduction
ADD	Adduction
ADL	activity of daily living
AI	Artificial intelligence
AR/VR	Augmented Reality/Virtual Reality
BI	Barthel Index
CNS	Central Nervous System
D	Deliverable
EMG	Electromyography
ERO	External rotation
EXT	Extension
FES	Functional Electrical Stimulation
FLEX	Flexion
FLTD	First line treatment device
fMRI	functional magnetic resonance imaging
H	Hypothesis
IRO	Internal rotation
Lit	Literature
MAS	Modified Ashworth scale
Med	Medical staff
MFAS	Motor Function Assessment Scale
MRC	Medical Research Council scale
MS	Milestone
NN	Normal null
Pat	Patient
pHRI	physical Human-Robotic Interface
PM	Person month
PRO	Pronation
pROM	Passive range of motion
R&D	Research and Development
REHYB	Rehabilitation based on Hybrid neuroprosthesis
RGS	Rehabilitation Gaming System
ROM	Range of motion
SD	Standard deviation
SH	Stakeholder
SM1	Primary sensorimotor cortex
SMA	Supplementary Motor Area
SUPI	Supination
TA-EG	Technical affinity questionnaire
Tot	Total
UL	Upper limb
WP	Work package

Appendix I. Questions to patients and healthcare operators

Patients		
Robotic	FES	AR/VR
1. Did you feel comfortable while using it?	1. Did you feel comfortable while using it?	1. Did you feel comfortable while using it?
2. Did you get tired during the session?	2. Did you get tired during the session?	2. Did you get tired during the session?
3. Do you think robotic treatment was useful for functional recovery? If yes, in which way?	3. Do you think FES treatment was useful for functional recovery? If yes, in which way?	3. Do you think AR treatment was useful for functional recovery? If yes, in which way?
4. Which characteristics would you like to find in an upper limb robotic device that are not present up to date?	4. Which characteristics would you like to find in a FES treatment that are not present up to date?	4. Which characteristics would you like to find in AR treatment that are not present up to date?
5. Do you think that the upper limb robotic treatment has been useful for your Activities of Daily Living?	5. Do you think that FES treatment has been useful for your Activities of Daily Living?	5. Do you think that AR treatment has been useful for your Activities of Daily Living?
6. Would you like to have such robotic treatment also at home? If yes, why? If no, why?	6. Would you like to have such FES treatment also at home? If yes, why? If no, why?	6. Would you like to have such AR treatment also at home? If yes, why? If no, why?
7. Would you recommend a robotic device to your family and friends if they were affected?	7. Would you recommend a FES treatment to your family and friends if they were affected?	7. Would you recommend AR treatment to your family and friends if they were affected?

Healthcare operators		
Robotic	FES	AR/VR
1. Whenever you include robotic training in the rehab program, what are the main reason?	1. Whenever you include FES training in the rehab program, what are the main reason?	1. Whenever you include AR/VR training in the rehab program, what are the main reason?
2. Whenever you include robotic training in the rehab program, what kind of patient's functions are you trying to improve?	2. Whenever you include FES training in the rehab program, what kind of patient's functions are you trying to improve?	2. Whenever you include AR/VR training in the rehab program, what kind of patient's functions are you trying to improve?

3. How often do you use robotic devices for upper limb rehab programs?	3. How often do you use FES for upper limb rehab programs?	3. How often do you use AR for upper limb rehab programs?
4. What kind of **advantages** do you think robotic training gives to the rehab program?	4. What kind of **advantages** do you think FES gives to the rehab program?	4. What kind of advantages do you think AR gives to the rehab program?
5. What kind of **disadvantages** do you think robotic training gives to the rehab program?	5. What kind of **disadvantages** do you think FES gives to the rehab program?	5. What kind of disadvantages do you think AR gives to the rehab program?
6. Which characteristics would you like to find in an upper limb robotic device that are not present up to date (please rank according to personal relevance if there are more than one)?	6. Which characteristics would you like to find in FES training that are not present up to date (please rank according to personal relevance if there are more than one)?	6. Which characteristics would you like to find in AR training that are not present up to date (please rank according to personal relevance if there are more than one)?
7. What would you change in upper limb robotics devices currently available (please rank according to personal relevance if there are more than one)?	7. Which aspects of current FES training would you change (please rank according to personal relevance if there are more than one)?	7. Which aspects of current AR training would you change (please rank according to personal relevance if there are more than one)?
8. Would you recommend the use of robotic devices for rehabilitation to your colleagues?	8. Would you recommend the use of FES for rehabilitation to your colleagues?	8. Would you recommend the use of AR for rehabilitation to your colleagues?
9. If you were a patient, would you use a robotic device in upper limb rehab?	9. If you were a patient, would you use FES training in upper limb rehab?	9. If you were a patient, would you use AR training in upper limb rehab?