International Journal of Design Sciences & Technology

Volume 25 Number 1

Editor-in-Chief:
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ISSN 1630 - 7267

europia

ISSN 1630 - 7267

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International Journal of
Design Sciences and Technology

Volume 25 Number 1

ISSN 1630 - 7267

International Journal of ***Design Sciences and Technology***

Full-stack User-Centered Approach for Wearable technology design

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Wearable systems are easing the transition towards a personalized medicine, bringing healthcare to anyone, anytime and anywhere by removing locational, time and other restraints, while increasing its coverage, customization and quality.

For wearable devices, the human factors are essential in all the phases, from conception to subsequent design development. Current solutions are cumbersome and, despite they are designed according to standardized guidelines, they are developed for skilled users (physicians or engineers), without taking into consideration the real actors who will use and wear them: the patients.

This paper aims to describe a new full-stack approach integrating design and technology requirements for the development of wearable systems and applying this for a new system dedicated to rehabilitation, based on a modular textile sensing platform fitting to different users and applications.

Keywords
Wearable technology, Pervasive Healthcare, Human-centered design, design methodology

1. Introduction

The current COVID-19 pandemic situation is leading to rethink the “shape” of the healthcare system intended as service types and channels; the increase of chronic diseases and age-related illness are forcing under pressure the entire system. These circumstances changed people habits, lifestyle, work, and health. Healthcare system has been forced to change, modifying protocols and medical environments, bringing prevention, diagnosis and treatment of diseases no longer in clinics, but in everyone’s houses.

Technology plays a fundamental role in this transition, bringing diagnosis and treatment systems directly to home, in order to improve both the quality of life of the patients and safety for all (patients and caregivers).

Nowadays, in a plethora of advanced technologies, wearable devices can offer not intrusive ecological solutions for monitoring people anywhere [1][2]. For this reasons, wearable devices can ease the transition from today medicine to a more personalized and distributed one, for a healthcare to anyone, anytime and anywhere by removing locational, time and other restraints, while increasing its coverage, customization and quality [3]. By providing a set of measurement about our health and working in synergy with dedicated Apps, wearable systems also represent engaging and motivational tools for health interventions. For this reason, their great importance is pushing the design and development of new and customized solutions. But this process is more technologically driven rather than user driven.

Being devices in close relation with our body, human factors are essential in the entire development process, from conception to subsequent design and finally to the test and production phase. Nevertheless, current solutions are cumbersome and, despite they are often designed according to standardized guidelines, they are developed for experienced users such as physicians or engineers; these two main experts focus their experience driving the design of the system towards two directions: clinical and technological. This does not take into consideration the real actors who will use and wear such systems: the patients themselves.

Moreover, the use of technology for measuring human bio-signals and movements requires addressing difficult-to-satisfy requirements, which means that the applications of these technologies are restrained by a series of accessibility barriers, especially regarding usability.

Starting from the design requirements analysis for personalized home rehabilitation wearable system, this paper aims to define a design approach applied for developing a modular sensing platform, to be used into different environments and suitable to fit a wide range of actors (including not only patients but also clinicians, caregivers and relatives).

Is it possible to implement a full stack method, which includes user needs, human factor, technology, and mechanics, for wearable system design? This research tries to reply to this research question developing a new full-stack approach and applying it to the design of a multimodal wearable system for motor rehabilitation.

2. User-Centered Design

User-Centered Design (UCD) is the commonly used approach to develop products and solutions by involving human perspective (the users) in all the steps of the process [4].

UCD does not simply lead designer to consider desires, wants, and needs of the users, but targets the studies for not suitable lay users satisfy needs at two different levels: functional and emotional.

In order to better understand these two levels of satisfaction, three general principles have to be investigated

- Collaboration: all the users are involved in all the design and development phases.
- Empathy: in order to create a product/service for the people, it is mandatory to deeply learn about desires and motivation that drive them.
- Experimentation: hypotheses need to be verified by means of iteration and experimentations.

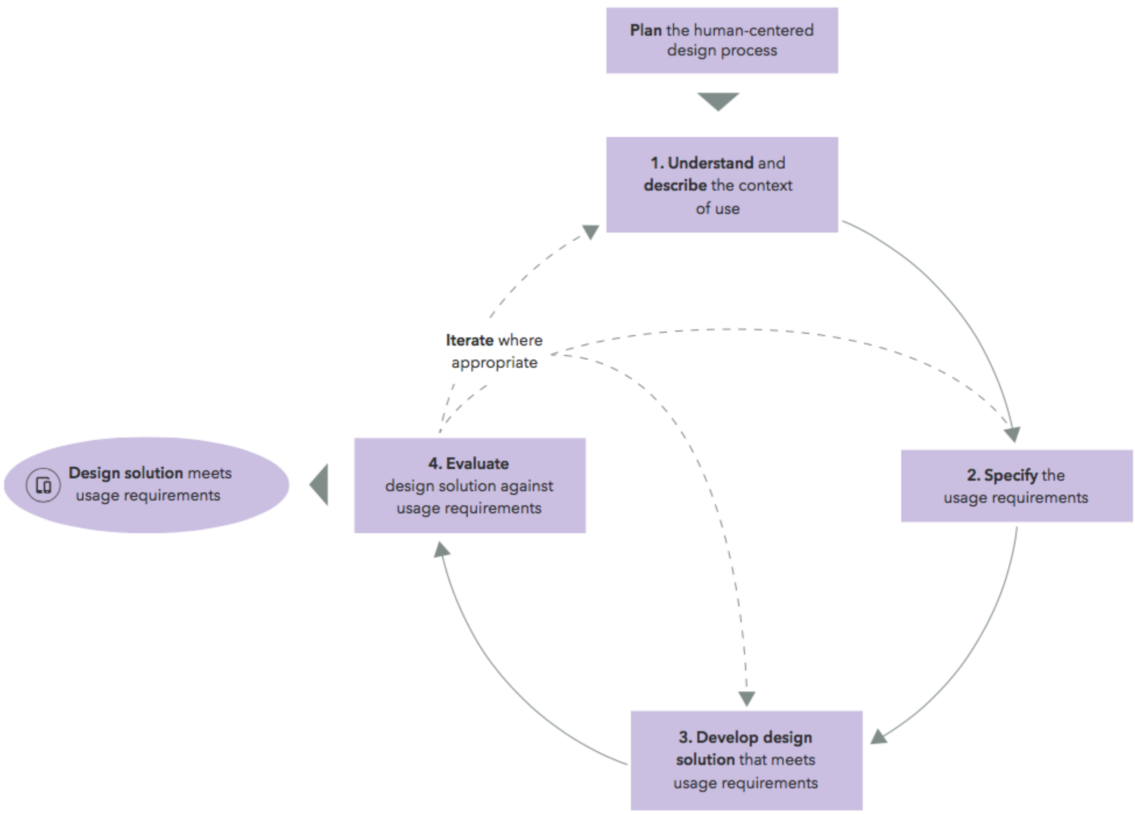

Figure 1: User-Centered design process study [5].

In general, these three principles are studied, as shown in Figure 1, through five different iterative stages: planning, context of use, usage requirements, design, evaluation.

Figure 1 shows a summary of part 210 of ISO 9241, otherwise known as “Human-Centered design for interactive system”, which explains how to manage an iterative design process.

The ISO define relationship and separation between usability and user experience (UX), which are two mandatory aspects to be taken into consideration when developing a wearable system.

The UCD approach described in Figure 1 is abstract and labile, despite being described in an ISO. Whether and how is it possible to implement this rule by designing a wearable system? The first step is to realize the iterative stages of the UCD process, and compare them with a main literature methodology, in order to highlight possible flaws in its application for designing a wearable system.

The preliminary stage “planning” consists in drawing up the protocol which describe the entire design process and will be used to guide both developers and users into all the iteration.

After the draft of the design process protocol, there are the main 4 stages, which can be repeated and iterated even indefinitely, or up to the design solution meets all requirements.

Understand and design the context of use consists in collecting and analyzing information about the intended users, their tasks, the behavior, the environment and all the possible constraints. The results are user characteristics, tasks and equipment, as well as the physical and social environment which the product/system “lives” or is used in. From the UX point of view, this stage identifies all the previous features and pathways for each targeted user group or actors, since each of them can have different needs and uses for the product/system.

Second stage is the specification of usage requirements; this information is derived from the stage one. From the UX point of view, the design process tries to extract the tasks which users perform during a contextual scenario, or rather which actions the user should be able to perform while interacting with the product/system. It is important, for the drafting of the approach, to take into consideration that this information is closely related with system requirements, which are more technical and directly describe how the system could work.

Stage three starts from usage and system requirements and tries to design a solution to meet all (or most) of them. Depending on the last stage, evaluation and testing, the result of design stage could be a simple or and high-fidelity prototype (almost final product). The characteristics of the prototype are also usually related to the number of iterations during the design process. Prototyping is considered one of the most important steps into design process; prototyping means “do not spend” too much time for creating something which can be used to test and validate options with real users [6].

The last stage consists in the evaluation and testing of the design solution from the user’s perspective. Usability and acceptability tests are performed at this point proposing to the users a scenario-based walkthrough, in which they attempt to use the system.

For each of these stages, literature underlines specific design methods and processes. Starting from Design for Wearability by Gemperle et al [7], which describes the relation between the physical shape of wearables and their active relationship with the human form, to get to the most recent work by Lee et al [8] which uses Design Thinking and Design sprint processes to generate innovative ideas for wearable devices.

While aspects related to user analysis are widely covered by multiple studies concerning quantitative and qualitative analysis tools (eg. surveys, focus groups, card sorting, wizard of oz prototyping…) and their application [9][10][11], the study of methodologies which fully cover research and development of a wearable device or system are mostly left to the decision of the designer. Nevertheless, the design methods usually described are strictly related to the system typology and purpose, and for this reason they do not cover all the aspects that wearable design needs.

The goal of the paper's related project is the design and implementation of a wearable system for motor rehabilitation. After injury, illness or aging, people are all exposed to losing motor skills at some stage; the project, funded by INAIL Centro Protesi (Italy), aims to carry out a system for re-education, training and rehabilitation that re-teach to users how to correctly move. In this sense, Motion Capture (MoCap) is one of the possible solutions for quantifying information regarding mobility, exercise and, in general, user health.

The study starts analyzing wearable design applied methodologies [12][13][14][15] in order to discover the best solution for designing a new concept of rehabilitation wearable system. Due of the intrinsic complexity of such a system, most of methodologies have a lack on different aspects (user analysis, technology assessment…). Octopus methodology presented by Marin et al [16], is the state of the art of wearable design approach; it suggests an in depth process for the experimentation of the UCD stages described above, specifically studied to design a MoCap-wearable system. Figure 2 shows a summary of the Octpopus methodology. This work starts from the analysis of the Octopus methodology compared with the UCD approach in order to identify strengths and shortcomings, with the aim to design and test the new full-stack complete approach.

2.1 The Octopus methodology

Octopus methodology [16] is the result of an ad-hoc study which involved different disciplinary actors, with the aim to create an optimal strategy for MoCap wearable product/service development. Figure 2 shows the representation of the MoCap wearable product/service and its ecosystem.
Octopus consists into three areas: context, device, and data processing. These three main areas of study recall partially the UCD approach described in the previous paragraph.
Using these three areas, Octopus methodology proposes to design the product/service with a sequential design approach, based on 8 steps (hence the name):

1. Design goal;
2. Context study;
3. Service Design;
4. User Interaction;
5. Technology;
6. Body attachment;
7. Physical properties;
8. Data Processing.

Octopus methodology shows a highly correspondence with the user-centered design iterative stages illustrated in the previous paragraph. Design goal step correspond to the Planning stage which consists in the initial product/service brief and target definition, which are then optimized by the design process evolution and the continuous iteration with the user.

This first step can assume different levels of abstraction based on the involvement of the end users and the methodologies applied for ideas generation. This step, depending on the number of ideas produced, the prototype feasibility and the technological level required, can influence the starting point of the development phase, the number of iterations on the prototype and the final success of the project.

The context study is really closed to the stage called “context of use” which is included in the user-centered design method. Once the brief and the target have been defined (but they can still change during iterations on the prototype and with users), the context study step analyzes the different user types in order to define and model all the actors which can come into contact with and/or use the product/service (use, users and environmental). After this analysis, designers can apply different methods [9] which can be used to extract user wants, needs and desires. The following two steps, Service Design and User Interaction, consist in the first tuning of the experience that user will have with the product. Service design, as the name suggest, is the process used for gathering information on to define how all the parts and actors should work together. Service design tools [17], [18] is an important starting point for service design and user interaction steps. Personas, scenario, and blueprint are the three main design tools used into this work. The outcomes of these steps will influence both UX and usability of product/system. After the first iteration of one to four steps, based on user and UX study and by means of design tools, it is possible to write a first version of usage and user requirements definitions. User and usage requirements allow for processing development and technical steps (Technology, Body attachment, Physical properties, Data Processing). These steps are mandatory in order to define the technological content (electronics, battery…), where and how to attach devices to the body, to define materials, aesthetics and how to process data.

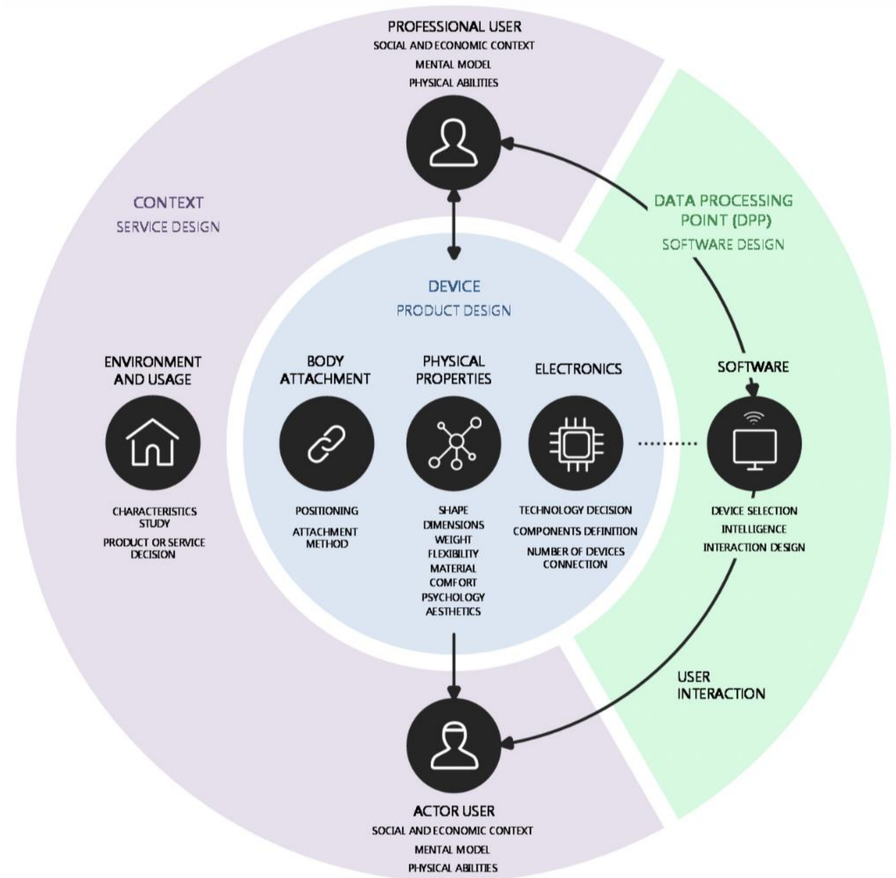

Figure 2: Octopus methodology for Wearable MoCap system design [16].

Finally, all these design choices are implemented into working prototypes. As described in the previous paragraph, prototypes are very important tools for user testing, but they have to be considered a preliminary version or a test sample that require minimum effort yet look like the final products (MVP - Minimum Viable Product). Human-centered design guide [9] suggests prototypes should be designed with minimal effort, yet look like as much as possible like the final product, with the aim to perform user tests gathering information regarding usability and acceptability. The base rules for prototyping is the so called Pareto Principle[19]; the 80-20 rules underline to focus on principal features and task to be tested, in order to get the 80% of the results with the minimum effort of 20%.

Octopus methodology has been tested with the aim to applying our project development phase. During the application of this methodology, we found out three important issues which this process doesn't take into consideration, but which are mandatory for the development of a good wearable device system. Octopus methodology is described as a sequential iterative process; all the steps need to be accomplished in a sequence, this can cause a different allocation of resources for the various steps, and consequently unbalanced developments. Octopus lacks two other components, which are indeed required: the optimization of the wearable device connectivity and the cloud. These two parts may seem particularly related to the technological components of the system, however these are the features which are the most valuable ones because they allow the servitization of products [20].

From this analysis, we developed our motion capture wearable system as a case study for a new iterative and all-encompassing method, therefore called full stack approach.

3. Full-stack approach

MEMs (microelectromechanical system) based Motion Capture system is a technology now widespread in different markets, from medicine to gaming. In the last years, MEMs tech, electronics miniaturization and the simultaneous increase in the ratio of computing capability vs power consumption, as well as new high capacity batteries, allow for developing a new type of Motion Capture systems: the wearables [21], [22].

As most new tech system they are mainly built upon innovation technology: they consist in the so-called technology-driver product rather than user-driver, or design-driven ones. They are indeed difficult to wear, configure and use, even more if all operations need to be accomplished by only a single subject. Other attempts have been done regarding the use of these system and technology for rehabilitation and telemedicine [23]–[25] but they consist in using wearable motion sensing unit in safe laboratory environment for experimentation, without taking into consideration all the issues related to real life applications.

The Multimodal Wearable (MW) project aims at designing a wearable system for monitoring and evaluating rehabilitation activity in post-stroke patients with the objective to reintegrate them into the work environment. The core strength of the project is the migration from the classic hospital rehabilitation, to a more personalized at home rehabilitation, with the purpose to improve both the well-being and effectiveness of the treatment. As described above, the project objective underlines the importance of studying user's experience and needs, for the correct development of the entire wearable.

Starting from the MW project's brief, we focus our research on UCD approach and Octopus methodology to identify the pain-points and implement a complete approach which help to design from the idea to the MVP.

Based on Octopus methodology we define the full-stack ten tails (FSTT) approach as a four stages ten steps process. The four stages, born from ISO 9421 on UCD, consists in:

- Brief analysis and user evaluation
- Co-design [26] with users
- Features Definition

- Developing and testing

All these stages are not standalone, but they continuously have inputs and output from/to each other stages, allowing a continuous optimization at all levels, even the brief when necessary [27].

The ten steps consist in:

- Brief analysis and users definition;
- User research;
- Service Design and UX;
- User Interaction and testing
- Human Factor;
- Technology definition;
- Data communication;
- Data Processing and visualization;
- Mechanical features;
- Cloud functions.

These steps bring the developer from the study and definition of a scenario, to the development of the MVP prototype; but for the four stages of full-stack approach, unlike what happens in the Octopus methodology, these ten points are not sequential, but continuously interacting with each other for a complete optimization (hence the half name “ten tails”).

The ten tails can be iterated multiple times in order to optimize all the steps. The iteration number and real users involvement depends on budget and timing, but can be accompanied by techniques that make use of qualitative analysis [4] or expert users [28], in order to minimize costs. Figure 3 shows an overview of our approach. As visible in the image, there are four circles that overlay all and consists into the four stages. The overlay of these four steps underlines the multidisciplinary and multifactoriality of the approach, and the interconnections of all the ten steps. The length of the ten steps represents the different concurrence of the development: some of these can start with the first stage while other need previous development before starting.

The full-stack ten tails approach is applied for the design and development of the wearable system described above.

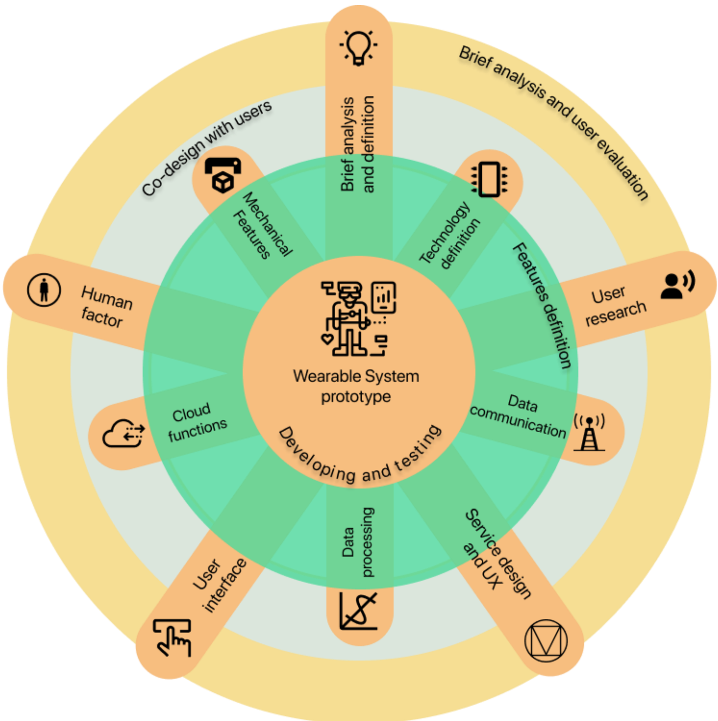

Figure 3: Overview of the Full-stack ten tails (FSTT) approach

4. Full stack ten tails application

The FSTT method just described was deployed in the Multimodal Wearable (MW) project for monitoring the rehabilitation processes. Here after the descriptions of all the stages and steps are reported.

4.1 Brief analysis and users' definition

The word "Wearable" defines by itself pieces of technologies which are in close contact with the user's body: clothes, garments, or several types of accessories (watch, bracelet, earrings, necklace, patches...). For this reason, it seems quite easy to define the context of study and scenario of system like these, but it is only reasonable for commercial devices such as fitness tracker, which is a non-medical but personal device used only by a single actor in a friendly and safe environment.
When wearables are contextualized within telemedicine or pervasive health (in terms of medicine for everyone, regardless of geolocation, timing, and personalization), the context of study and any servitization became more complex due to the presence of multiple actors which operates with the product/system.

For wearables-based motion capture systems, two types of users are defined: professional users and everyday users. Both of these types can contain different sub-categories which need to be analyzed and defined with proper methods. One of the methods suggested by the handbook of human-centered design are the Personas [4]. A persona is defined as a fictional character that represents a typical member of a target audience. Personas help researchers focus on images of final users, make calculated decisions regarding required functionality, and avoid making products with lots of great yet unnecessary features. Moreover, personas help researchers identifying the main users of the product/system.
Due to the presence of multiple actors, we defined five different personas (see Figure 4 for an example), supported by different scenarios.
In our case, scenarios are fictional stories written to define how a persona use a product/service. Scenarios are useful defining context in which the product is adopted and allow considering additional details; for example, users who were not initially taken into consideration or, as in our project, studying the best, the average, and the worst use cases.
Service and user experience design can be based both on the same tools described before. Service design allows for study thoroughly all the part of the system structure (from electronics features to cloud perspective), while UX design allows for creating user friendly and acceptable system.

Personas and scenarios are very useful in the first steps, both for extracting the system features but also to identify possible real users who can be involved during tests.

In fact, these steps are not consequential, but can be parallelized and iterated, getting inputs and advice from each other.

The drafting of personas and scenarios allow for a first technologies skimming and the identification of all the categories of users which can be involved during the system operation (patient, family members, caregivers, nurses, doctors, or specialists).
With these tools, Multimodal Wearable project defines the following users:

1. Expert or Professional users:
    a. *Physicians:* they do not directly use the system, but they “prescribe” it to the subject and give directives of use for an effective rehabilitation process.
    b. Health workers: they include nurses, orthopedic technicians, and social health workers. They are those who, in the first period, help the subject to wear and try the system to perform the first rehabilitation exercises in a supervised way.
    c. Technicians: Engineers and other technical persons who can come in contact with the system to help the subject setting and connecting the system.

2. Common or lay users:
    a. Who need rehabilitation: they are user with pathologies that require clinical intervention, in our case people who have suffered a stroke and need for motor rehabilitation.
    b. *Relatives:* they are familiar caregivers, depending on the social context and the severity of the stroke, i.e. family members or other people supporting and helping the subject in daily actions, like performing rehabilitation exercises at home.

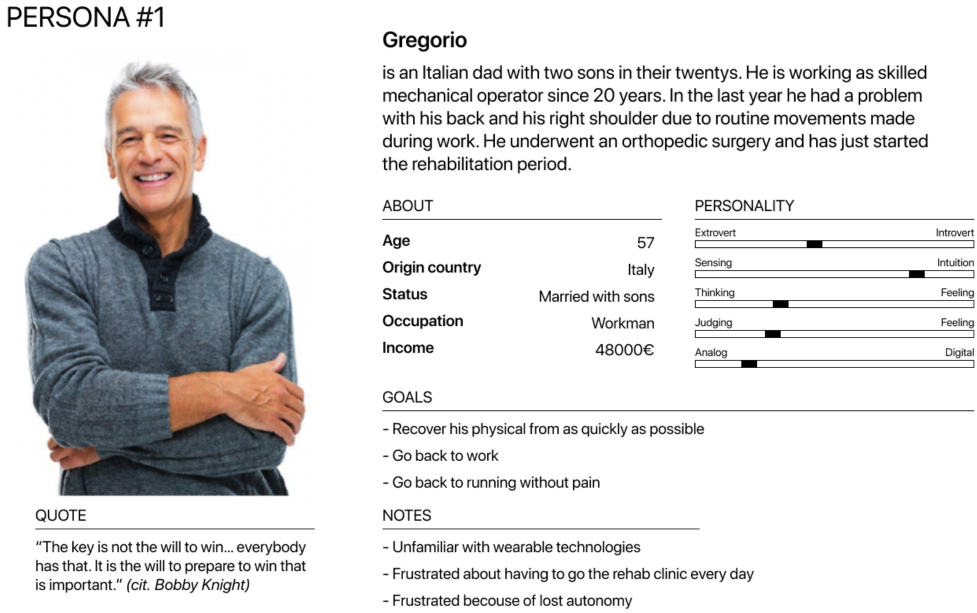

Figure 4: A Persona example developed for the Multimodal Wearable project

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In fact, these steps are not consequential, but can be parallelized and iterated, getting inputs and advice from each other.

4.2 Co-design with users

After defining users and actors types, one of the main goals of the approach is to define how the users interact with the system. One of the best methods for collecting this information is the involvement of the users in the phases of the project. The most common method for engaging users in the design phases are the focus groups. They consist of a group of between 5 and 10 users who work with a moderator who has the role to pose questions in order to lead the discussion between users in order to define the features that the product/system should have.

During MW project, three design interactions with users were carried out:

- two focus group, one at Centro di Riabilitazione Villa Beretta (CRVB), a renowned center for rehab medicine and one at INAIL Centro Protesi di Budrio, a renowned center for prosthesis and work rehabilitation, with all the actors found during the context study, followed by a questionnaire administered to the end-users;
- interviews with patients and therapist;
- a user questionnaire for acceptability and usability.

The first focus groups were carried out in clinic with a heterogeneous group of 13 representative users composed by:

- 2 clinicians and 1 technologist of CRVB
- 1 therapist of CRVB
- 3 technologist of Centro Protesi Inail Budrio
- 3 researchers of Design Department, Politecnico di Milano
- 3 patients of CRVB with different pathologies (post stokes, paraplegic)

The purpose of the first focus group was to investigate the wants and desires of the different actors involved in the rehabilitation process, the preferences in terms of use, comfort and wearability, the analysis of technologies, output data for clinicians and caregivers, and the different modalities of interaction between users and devices.

Data gathered in this focus group allows to start thinking about the possible technologies (technology definition step) to use, as well as to understand the dimensional impact (mechanical features step) which some of these tech components of the system could have. With this information, the second focus group was carried out with 5 therapists of INAL Centro Protesi, Budrio specialized in post stroke rehabilitation. The second focus group had the aim to investigate more precisely the needs of post-stroke users (one of the personas defined in the previously described steps).

Furthermore, after-focus group interviews allowed to comprehensively understand the parameters to be taken into consideration for the development of the system: from the analysis of human factors and biomechanical models related to the various body segments, to the monitoring of heart rate and respiratory activity.

The interviews were carried out at CRVB, with a heterogeneous group composed of 3 post-stokes patients and 2 therapists. The interviews were structured to evaluate various issues such as usability, aesthetic acceptability, privacy, technological aspects, methods of use and preferences in the use of the system. They were carried out through a direct dialogue with users with ad hoc prepared questions. The results of this qualitative analysis shown how patients require an extremely easy to wear system, with an aesthetic that does not differ from the solutions on the market for able-bodied and non-pathological users. That can guarantee high levels of comfort in terms of breathability and ease of washing and cleaning. The therapists stressed the need to have a system with an easy-to-use interface. This can provide a series of ad hoc physiological data for the monitoring of the rehabilitation activity carried out by patients at home.

After the two focus groups and Interviews, a wider analysis was conducted through a web-based questionnaire including multiple choice questions Likert scale evaluations in order to investigate users' preferences in term of wearable technologies, as well as for lifestyle description. This second aspect allow for a preventive evaluation of risks at home and at work, related to postures and to the possible presence of musculoskeletal disorders. The questionnaire also includes preferences to define the requirements in term of form factor development and daily motion activities. Questionnaires consist of 30 multiple-answer questions, divided into four categories. The categories are related to personal medical history, home activities, work activities, preferences on the future wearable system.

Figure 5A shows extract part of the questionnaire administered to 54 people. Figure 5B shows graphical example of data extracted from questionaries' results.

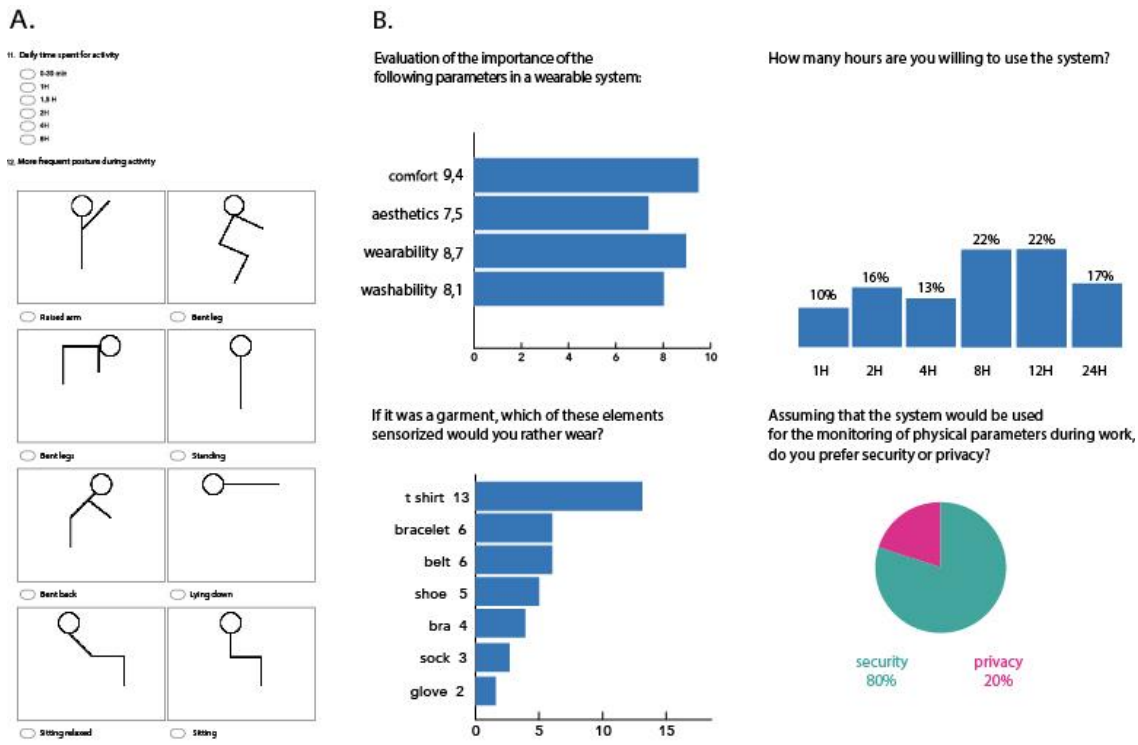

Figure 5: A. Example of questions extracted from the questionnaire;
B. Example of graphics extracted from the user research analysis

4.3 Features Definition

The Results carried out from the Co-design step is used for selecting the proper technologies and start the developing of the first prototype.
At the same time, during prototype development there is a continuous dialogue with the users in order to obtain a continuous refinement of the prototype requested features.
FSTT divides the technology definition step into two parts: wearable devices and smart garment.
Especially in the last decade, wearables are undergoing a transition towards the so-so called wearables 2.0, devices in which the sensitive part is no longer only in electronics, but it is invisible and part of the garment itself. Based on this, wearable devices are the electronics device which will collect inertial and vital data; the smart garment is the sensorized suit Figure 7, with all the hooks for connecting the wearable devices.

Wearable device block diagram is shown in Figure 8: it consists of nine main parts. The structure of the scheme was co-designed with all the actors during focus groups. Participants can build the desired wearable device by means of Lego blocks; each block represent a different component of the electronic device. Participants at the focus group can build the desired electronics by connecting the various Lego blocks together. This allows for minimizing the effort to include the features required by different users. The most important part is the microcontroller, which is the brain of the entire device and should have the computational power in order to measure all the necessary data, pre-process them and send them to an external device (smartphone or tablet). The features of the microcontroller are essential for its selection and are strongly correlated with the other block of the diagram. Thus, the microcontroller is indirectly selected by users. Wearable device includes two input blocks: IMU and Heartrate: the first one is the inertial sensor which is mandatory to collect information regarding movements; the second one is the part for measuring the heart signal and computing heartrate, and possibly the breath rate. Microcontroller manages the signals acquisition by means of connection with the smartphone/tablet and the user interface which consists in buttons and LEDs. Blocks diagram shows multiple connection between microcontroller and data processing and visualization: this is related to the modularity of the system; the user, depending on the rehabilitation exercise to be done, can decide how many sensors to wear.

Figure 6: Lego blocks for the co-design of electronic device. Each LEGO color corresponds to a set of features (technical, medical, design, general...). The users combine the various parts that they consider important in making the product.

The modularity of the system is strictly related to the communication technology; the choice of the communication protocol (WiFi, Bluetooth, LoRa…) changes the way the system is used, acting directly on the user journey (battery life, interconnection modality, compatibility with mobile devices). Data communication definition step is for this reason a main part of the approach. User involvement in this step is mandatory because connection and communication are the pain points of the entire system and need to be well defined in order to avoid acceptability problem.
Data processing and visualization step, in the MW project it was part of the needs expressed during the user analysis. Processing, visualization, and feedback are demanded to the mobile platform (smartphone or tablet): this allows also for saving battery consumption and create personalized interface for expert and common users.
During the service design step, users underline how could be helpful to have a double visualization for different users; common users will receive only simple and summarized data in order to avoid stress, related to low usability, while expert and professional users will receive complete data with the aim to comprehensively assess the correctness of the rehabilitation exercise.

Mechanical features step consists in the definition of all the aspects related to shape, dimensions, weight, flexibility, material, and comfort. The design of the sensorized suit is achieved within this step. The sensorized suit has been developed focusing on ease of wearing for post-stroke patient. For this reason, the suit is divided into two parts: the upper and the lower. Both of them have a zipper which allows to completely open the garment on the side, simplifying the wearing phase even for subjects with reduced motility. The two parts can connect up to six sensors (on the limbs) and a central unit (on the chest and on the pelvis). The user, depending on the exercise, chose to wear one of the two parts or both for a full body monitoring. In order to simplify the connection of 14 device to the sensorized suit, snap button that were used on the old version of the sensorized t-shirt [29] has been removed in favor of magnets and spring contacts, which allow to connect everything more quickly and effortlessly.

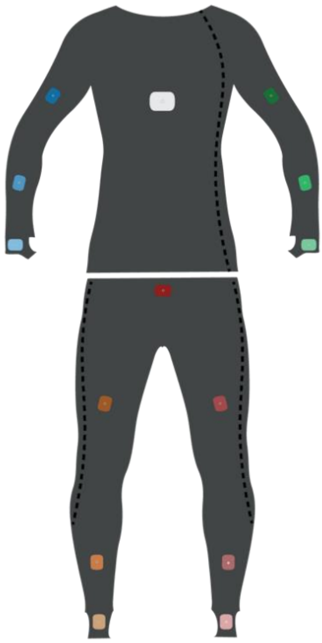

Figure 7: The sensorized suit; the dotted lines are the zipper for easy wearing; the colored square are the wearble devices.

A first draft of the system has been proposed during the second focus group, with a QI wireless charging for the wearable devices. However, this solution has been discarded and replaced with spring contacts, as users stressed a certain health concern related to the use of wireless charging technology, as well as difficulty in recharging so many devices simultaneously. We propose a special case which contains all the system's devices and, at the same time, recharge them by means of spring contacts and micro-usb port.

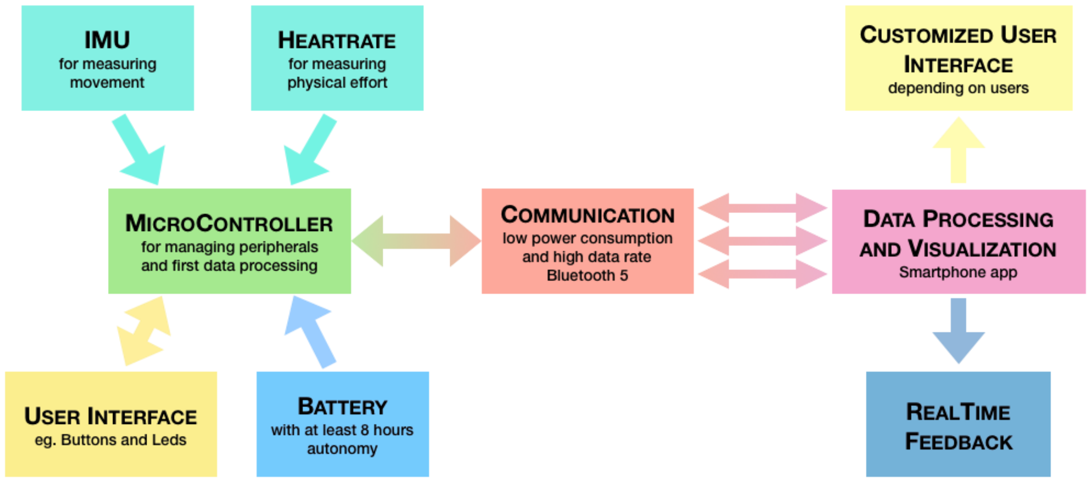

Figure 8: Block diagram of the wearable device. The division between wearable device and mobile application is evident: the wearable device mainly consists in sensors (e.g IMU and Heartrate); it communicates with different wireless protocol to an application which can process and show data and feedback.

The cloud functions step describes all the features related to online needs. Wearable system can include an online part which can be used for data processing and visualization, for sharing capability and communication with physicians. The main features of cloud are defined during brief analysis and user research; but an in-depth analysis of the requirements need to be accomplished in order to optimize, in addition to the choice of cloud typology (e.g. IaaS.- Infrastructure-as-a-Service, PaaS – Platform-as-a-Service or SaaS – Software-as-a-Service), all the parts related to privacy and data security (e.g. GDPR).

4.4 MVP Prototype

The preliminary prototype was designed according to the specifications emerged during user research and technological analysis. A suit made of two distinct parts was designed: a t-shirt for the upper body segment and trousers for the lower part.

The System, as introduced in the previous paragraph, has been structured in this way to allow the patient to use only the necessary garment to carry out the rehabilitation activity. On the t-shirt there are 7 inertial units and an ECG unit. The sensors are located on the arms in the center of the body mass segments such as arm, forearm, and hand. An additional inertial unit is placed in the center of the trunk together with the ECG unit. This module is located in the lower part of the sternum, where are placed the sensors for the detecting the ECG signals which are made in 3D silver-based fabric.

The ECG device was developed through the implementation of textile sensors embedded in the t-shirt with the aim of maximizing the user's comfort level, as underlined by patients during focus groups. The ECG device and the inertial sensors were created using rapid prototyping technologies: the devices were printed using SLA Form 2 - 3D printer, while the textile sensors were made by laser cutting and applied with thermal-adhesivation. The complete system has been firstly created as an empty non-functional box (Figure 9) in order to understand usability and acceptability issues. In the meanwhile, the development of the electronics proceeded following the guidelines indicated by the co-design steps.

The ECG module, housed in the appropriate case, detects the ECG signal through magnetic contacts that carry the signal from the textile sensors to the electronics. The trousers are developed in a similar way to the t-shirt: there are 6 inertial units placed on the legs, positioned in the center of body mass of the thigh, leg and foot, and an inertial sensor placed in the pelvic area. The complete system - t-shirt and trousers - has a total of 14 inertial units and an EGC unit, with the aim of evaluating the rehabilitation activity through the biomechanical model and the evaluation of physiological parameters such as ECG and heart rate. In fact the inertial units were positioned at specific points mentioned above, identified for the subsequently design of the virtual biomechanical model, in order to evaluate the movement of the various body segments and the opening angles during the rehabilitation activity.

After the first tests with the non-functional system, the t-shirt was tested by the design team to verify some preliminary aspects such as wearability, thermal and movement comfort, the correct functioning and positioning of the ECG and inertial sensors and the virtual biomechanical model obtained from them.

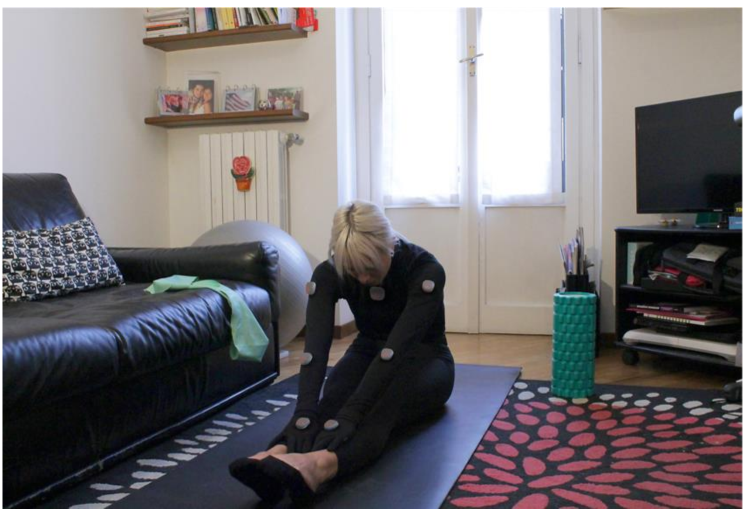

Figure 9: The sensorized suit prototype with Wizard of Oz devices.

5. Discussion

In the wearable systems each key component is inter-related with the others; as happens for complex network of components, a variation into one part produces effects and modifications on the other ones, and consequently it requires a constant process of supervision of whole the system.

In the project development according to the full-stack ten tails method, the interaction and co-design with the users, the main feature of the UCD approach, it further enhanced and related to technological aspects of the system. If the UCD methodology (e.g. the Octopus Methodology) focuses particularly on the Form Factors and usability linked to the product, the FSTT approach expands the user-product relationship to the user-product-service relationship, considering a series of aspects of cognitive ergonomics, which characterized the user experience in the complex relationship with the system. According to this logic, in the process it is mandatory to include UX and UI, without which it becomes impossible translate technological aspects into useful data and experiences for a heterogeneous range of users such as clinicians, caregivers and user with and without pathologies.

FSTT approach allows for incorporating in the system design all those aspects of product/service-related user experience, in which the technological aspects become easy and invisible for the end user, thanks to the integration of interactive components into the process. These components (e.g. connection, mobile application, cloud…) act as intermediaries between the different users and the technological components, easing their usage, interoperability and acceptance.

The experience of the application of the full-stack ten tails method in the design of wearable system evidenced that, in the new panorama of the product-service design, the proposed method is more respondent to the completeness of the technological component but also to the user requirements about usability and services. In relation to the “servitization” of products, to assess the capacity of the service and mainly of the cloud, a usability test was conducted.

The usability tests were carried out on a panel of 15 subjects (6 males and 9 females, aged between 25 and 60 years). Out of total of 15 subjects, 5 are healthy subjects, 5 are therapists from CRVB, 5 are subjects with pathologies under treatment at CRVB. As described by Nielsen [30][31] and Faulkner [32], 5 to 15 users would reveal up to 99.6% of all the usability problem and avoid the risk of being misled by the spurious behavior of using only few person who can perform certain actions by accident or in an unrepresentative manner. MW system has more than one set of users; as described in the previous paragraph, we can define different type of users. For this reason, the usability tests need to be done on more than 5 users in order to cover the majority of users’ sets. Wearability tests and biometric surveys were performed by healthy subjects and therapists, and subsequently was administered to them a standardized questionnaire (SUS - System Usability Scale)[33], and other questions based on the Likert scale to measure the degree of acceptability of the system. For the pathological subjects it was not possible to carry out the wearability tests for precautionary reasons due to the diffusion of Sars-Cov2. The results (Figure 10) emerged from the final overall evaluation show that there is an excellent adherence between the high initial expectations of the subjects involved and the post-test evaluation of the system. This means that the system has responded to the expected needs of the users. In general, the perceived quality of the system is high, a value that is substantially confirmed by the totality of the parameters analyzed in the usability assessment. It should be emphasized that the quality of the information received by the system, the overall acceptance and appropriateness of the operations carried out by MW reach an optimal score (>6/7) while the other evaluation parameters are at very good values, close to the optimal. The slightly lower scores relate to wearability (4.1/5) and aesthetic acceptability (5.40/7). These values underline the opportunity to improve the system, by intervening on specific points such as aesthetics and the methods of dressing and undressing. The usability test also measured the wearing times of the system, which is around 4 ' for dressing, and around 1'30' ' for undressing, which are acceptable values when compared with standard clothes dressing.

Finally, the application developed to detect data, and tested by users, was well accepted - overall score SUS 75.5/100 – and, in particular, by the category of users for which it was developed – therapists - where the score achieved is 87.5/100.

Preliminary Evaluation	A01	A02	A03	A04	A05	B06	B07	B08	B09	B10	C11	C12	C13	C14	C15	AVD	STD	MEDIAN
Evaluation of expected functionality (1-7)	7	6	6	6	7	6	6	6	6	6	6	6	5	6	5	6,00	0,53	6,00
Wearability(1-5)	4	3	4	5	4	4	4	4	5	4	3	4	3	2	2	3,67	0,90	4,00
Level of expected comfort (1-5)	4	4	4	4	4	4	3	5	5	4	4	4	4	4	4	4,07	0,46	4,00
Aesthetics(1-7)	7	4	4	7	4	6	6	7	6	6	6	6	6	6	6	5,80	1,01	6,00
Overall acceptance (1-7)	7	5	6	6	7	6	6	7	6	6	6	6	6	6	6	6,13	0,52	6,00
Quality of information(1-7)	7	6	6	7	6	6	7	7	6	5	6	6	6	6	5	6,13	0,64	6,00
Global importance of the MW system(1-7)	6	6	7	6	6	6	6	6	6	5	6	6	6	6	5	5,93	0,46	6,00
Final Assessment	A01	A02	A03	A04	A05	B06	B07	B08	B09	B10	C11	C12	C13	C14	C15	AVD	STD	MEDIAN
Evaluation of perceived functionality (1-7)	6	6	5	5	6	6	6	7	7	6						6,00	0,67	6,00
Wearability (1-5)	3	4	2	5	3	4	5	5	5	5						4,10	1,10	4,50
Comfort perceived (1-5)	5	4	4	4	4	5	4	5	5	5						4,50	0,53	4,50
Aesthetics (1-7)	7	4	6	6	4	6	6	7	6	6						5,80	1,03	6,00
Overall perceived acceptance (1-7)	7	4	6	5	6	6	6	6	7	7						6,00	0,94	6,00
Quality of the information received by the system (1-7)	7	4	7	6	7	6	7	7	7	6						6,40	0,97	7,00
Evaluation of the operations appropriateness with MW system (1-7)	7	4	6	4	6	6	7	7	7	6						6,00	1,15	6,00
Evaluation of the overall importance of the system (1-7)	7	6	7	5	7	6	6	7	7	4						6,20	1,03	6,50
Level of satisfaction (1-7)	6	4	6	4	6	6	7	6	7	6						5,80	1,03	6,00
level of global quality of the MW system (1-5)	5	5	4	4	5	4	4	5	5	5						4,60	0,52	5,00
Legend																		
A1/A2/A3/A4/A5 Healty subjects																		
B6/B7/B8/B9/B10 Therapist																		
C11/C12/C13/C14/C15 Patients																		

Figure 10: The chart shows the results of the Usability Test

The application of the approach to a real project and the results of usability test for the milestones, highlighted good results in terms of design outcome with respect to users' expectations and needs. Moreover, the qualitative analysis showed that all the actors involved in the rehabilitation process would gladly accept and use this system for home rehabilitation.

Once the prototype has been made and the usability tests have been carried out, the FSTT process is considered concluded. Based on the outputs that emerged in the evaluation of the prototype carried out through usability tests, refinement actions can be undertaken with the aim of optimizing the final prototype. It is possible to act indistinctly on one or more process tails. The FSTT method foresees that the optimization process can be repeated starting from any project action. If the results that have emerged are particularly negative, should be evaluated whether it is necessary to repeat the whole process from the beginning. If the results are acceptable, it is possible to act on one or more of the ten process tails. The prototype refinement process, which also includes the subsequent evaluation through usability and functional tests, can be repeated several times until the final prototype satisfies the design requirements.

6. Conclusion

Here we have presented a new combined approach for solving the problem related to the difficulty of considering multiple aspects during wearable system design (human factor, ergonomics, material, electronics, communication system…). Full-stack ten tails approach is based on the study of User Centered Design and Octopus Methodology to integrate and simplify the design process in ten connected steps.
The approach has been tested during the development of the Multimodal Wearable system for motor rehabilitation obtaining good results in terms of design outcome with respect to users' expectations and needs. The qualitative analysis showed that the system has excellent approval ratings from all the actors involved in the rehabilitation process: from users to caregivers and clinicians.
Thus, this integrated but design-driven approach to wearable technology development could be considered as the methodological basis for future works in the field. Technology is the tool that design is exploiting while Design is becoming the subject and not the tool.

6. Acknowledgements

This work has been supported by "Centro Protesi INAIL" – Vigorso di Budrio (BO), Italy, the main research center of the National Institute for Insurance against Accidents at Work. The authors would also like to thank all the focus group participant for their willingness and patience, and to eng. Angelo Davalli, eng Emanuele Gruppioni and eng. Rinaldo Sacchetti of INAIL Centro Protesi for supervising the research. Authors would also like to thank dr. Martina Scagnoli for her help to the research during her master thesis.

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