MOTORE++

A new Rehabilitation Robot for the upper limb: refinement and experimental trials

Final Report

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Section 1: Executive summary

Keep things short and simple here. The text should precisely and concisely answer to the following questions (see examples)

- What was the goal of the project?
- Why the solution to the problem was important?
- What was proposed as a solution?
- What was proposed as an impact of your solution?
- What is the final impact at the end of the project and what are the deviations in achieving the impact?

Stroke is one of the leading causes of adult disability in the world, and is the second cause of death for individuals over 60 years of age. Most of the patients who survive such an accident are left with a severe partial paralysis and need professional help for rehabilitation. Data available from the World Health Organization indicate a constant increase in cerebrovascular disease (CVD) accidents, and a great increase in the number of CVD survivors discharged from hospitals, meaning that emergency treatment of CVD is improving (http://data.euro.who.int/hfadb/). In the European area alone, over the decade from 2000 to 2010 the number of patients discharged from hospitals has increased by 18%, from 381 to 450 per 100000. This suggests that the need for rehabilitation of patients with neurological impairments is rising as well, and will continue to rise for the foreseeable future. And unfortunately this will lead to a steady growth in expenses for medical care and rehabilitation.

In the recent past, several studies have shown that quantity, duration, content, and intensity of training sessions are important variables in relearning motor skills and in changing the underlying neural architecture after stroke. Due to repeatability, flexibility and precision of robots, robotic rehabilitation is a growing practice in hospitals, and it is also useful to personalize therapies with goal directed tasks. These devices increase the amount of rehabilitation delivered per patient, they can assess the recovery status of the patient, they can deliver customized, programmable therapies and they definitely improve the quality of recovery [1-4]. Among these devices, InMotion ARM [5,6] has been the first to be massively experimented in hospitals for robotic based rehabilitation. Unfortunately, to date, robotic devices are expensive, bulky and have large power consumption due to heavy motors and long links; essentially they need a solid grounding base to transfer the interaction or haptic forces to the ground.

Additionally, studies have shown that for patients with neurological impairments a first stage of rehabilitation therapy delivered on a plane is preferable compared to rehabilitation exercises in which the patient is requested to perform actions in three dimensions. Working on a horizontal plane reduces muscular fatigue and concentrates the rehabilitation specifically on motion and coordination tasks

The goal of this experiment is to continue the development of a planar rehabilitation robot named MOTORE (MObile roboT for upper limb neurOrtho Rehabilitation) [7-9] aimed to

restore upper limb functionality and to assess performance in patients with neurological diseases. MOTORE is a prototype developed during the last years: a small omnidirectional robot moving on *transwheels* on a desk, able to interact with a patient providing assistance and force feedback when needed during rehabilitation sessions**. MOTORE is a new haptic portable rehabilitation device moving on wheels, an autonomous (without any links or wire) robot; and since it is the first robot small enough to be easily carried, it is the first robot really suitable for home based rehabilitation**. A proprietary software has been developed with several exercises/games (e.g. path following, car racing, fetching objects, dish washing simulation, etc.), a wide range of exercise parameters (number of movements, range of motion, desired speed) and parameters related to robot behavior in the human-robot interaction (e.g., weight compensation or stiffness when the robots moves away from the desired trajectory, etc.). The possibility to set several parameters and scenarios, together with a patient database, allows a precise customization of the therapy. The kinematical/dynamical data recorded during exercises allows the medical staff to assess and refine the delivered therapy.

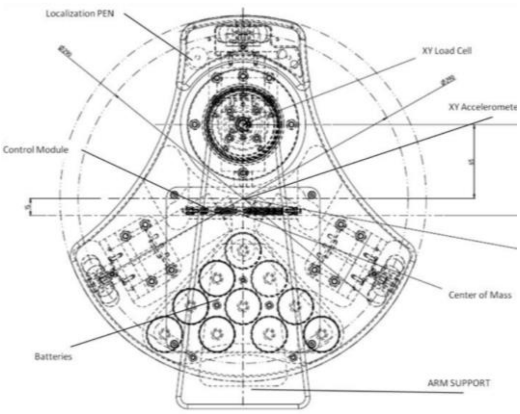
The possibility of increasing the efficacy of rehabilitation by exploiting the potentialities of robot-mediated therapies is becoming more and more popular around the world. In this case, the physiotherapist, instead of performing the rehabilitation manually, has to configure and supervise a mechatronic device able to replicate (and when possible improve) the traditional therapeutic strategies making also possible a quantitative, intensive, and repeatable “dosage” of the therapy and a quantitative evaluation of the results for each patient. In the recent past several robotic systems have been developed to achieve this important goal. In particular, two different types of devices can be defined

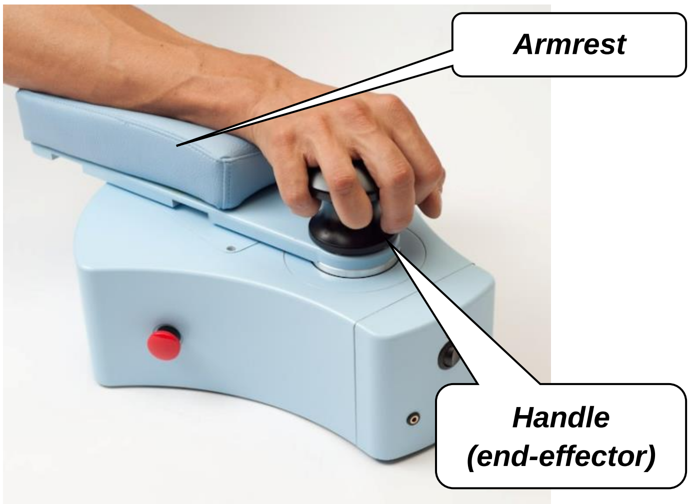
- Exoskeleton-like machines [10-12]: these are wearable biomechatronic systems that support the limb movement of the subject for each limb segment. The motor exercise can be directly defined in the joint space and for this reason these machines are very complex very useful for severely disabled persons whose natural synergies have been altered and need a separate control of the different joints in order to restore the natural motor control strategies;
- Operational machines [13-19]: the contact between the patient and the machine is only at the end effector, through a purposive mechanical interface (e.g., a handle). The movements are programmed in the robot operational space and the patient is expected to exploit his own synergies at joint level to follow the handle. These machines are usually used with patients with moderate disabilities (with a sufficient level of natural motor synergies)

Operational machines are simpler and smaller, but nonetheless bulky because conceived as industrial robots, with huge links and motors, and then they have been transferred to the medical field to be used as rehabilitation robots (e.g. InMotion ARM is in fact a SCARA robot with a new control strategy).

A natural step to overcome this problem is to build a portable device, removing rigid connections to the environment and powering the motors with on-board batteries. Thus, we conceived MOTORE as an autonomous robot, in fact a mobile omnidirectional platform able to interact with the patient providing force-feedback and adequate rehabilitation assistance. When exercising, the patient is requested to perform movements on the desk in order to move objects on the screen. The robot (according to the force interaction and the current position on the desk) can help the patient to start the movements or to avoid going in the wrong direction, just like a human therapist would do.

The overall design of the device is summarized in the following figures:





The basic kinematics is provided with three *transwheels* by Kornylak Corp coupled on the shafts of 3 DC motors by Faulhaber arranged in a 120 degrees configuration (Killough type kinematics [20]). The user's handle is not in the geometric center of the device but close to the robot front, in order to provide a comfortable support to the user arm and to achieve a better weight distribution. The patient's forearm lies on an armrest, which is constrained to rotate using cylindrical bearings around the vertical handle axis allowing a frictionless rotation of the forearm. A bi-axial load cell has been placed in the handle (decoupled from the forearm support) in order to measure the interaction forces between the hand and the handle.MOTORE is powered by on-board batteries. It communicates with a PC over a Bluetooth connection. The connection is used to send commands to the robot and allows to transmit status data such as position, speed, acceleration and force exerted. MOTORE is able to react to the force exerted by the patient and to provide force feedback so that the therapy can reach the maximum effectiveness. Its electronic board handles all the hardware functions of the device, such as powering the motors, handling the wireless connections, executing the control algorithms, acquiring and processing sensor data, and calculating statistical information regarding the exercise. A software suite with several exercises allows the therapist to quickly set up an optimized rehabilitation program for the patient [21].

A further peculiarity of this system is that in order to operate the robot, the patient is supposed to be actively involved therefore he/she has to exert a minimum amount of force and stay concentrated on the exercise, which is fundamental in neuro-motor rehabilitation, because the attention of the patient is part of the process. Nevertheless, a passive mode is also implemented for patients with no residual functionality, in which the robot carries the patient arm during the exercise. This is useful for early rehabilitation of sub-acute patients. The audio-visual feedback together with the force feedback are used to make the exercises more appealing, as in a videogame. **The software also records and assesses all the exercises performed by the patient**.

Compared to other devices conceived for the same purpose and compared to the traditional physiotherapist practices, MOTORE has the following features:

Motivation: enhances the patient motivation with enthusing and challenging exercises.

Assistance and Force Feedback: MOTORE relieves the patients from having to bear the weight of their affected arm during the exercises. It acts as a "force multiplier" so that the patients are able to move their affected arm with very little force (the robot starts to move with forces as low as 0.3N). It assists the patients in performing the exercise movements when the patients cannot complete them by themselves. It prevents the patients from doing the wrong movements by gently pushing them.

Therapy Quality and cost effectiveness: It allows precise measurement (in terms of positioning and force exerted) useful for functional assessment. It provides tools for a continuous optimization and customization of the therapy (thanks to the functional assessment results). It is suitable for home based therapy. It increases the therapy duration while reducing its cost. It can be used for patients with mild or severe injuries. It allows a single therapist to supervise more than one patient exercising with MOTORE.

Even though a mobile platform represents a step forward towards achieving an effective and small rehabilitation robot, a mobile device introduces several issues to be solved. The best known limitation is in the accuracy of localization: wheeled devices have severe slip issues [22,23], and odometry errors propagate on localization through integrals of simple differential motions. In addition, the small positional errors (even few millimeters) generated during haptic feedback, typically cause high force disturbances in typical working conditions. Usually, in order to attenuate these errors, Kalman Filters (KF), Extended Kalman Filters (EKF) or Unscented Kalman Filtering (UKF) are adopted [24,25]. These algorithms allow to obtain a better estimation of the robot location which improves trajectory control of these units. However, to be effective Kalman filters require one or more “complementary sensors”, i.e. additional sources of information that are not affected by the same type of error.

At the beginning of the Echord++ experiment, the MOTORE robot was endowed with encoders on each motor shaft and a digital pen by Anoto [26], which was used a complementary position sensor. This *pen* embedded a small infrared CCD camera to recognize a special dot pattern that is printed on the working surface where the robot moves. The dot pattern is non-repeating, so the pen is able to determine the absolute position of the robot on the working surface. The resolution of this sensor is of 0.3mm at 50Hz. This sensor supports data transfer via Bluetooth to a PC to which it sends the coordinates. The coordinates then have to be sent by the PC to the robot. In the MOTORE prototype, the *pen* was disassembled and its core board and the camera installed in the robot. Unfortunately, since this *pen* transmits its data only over Bluetooth, the data transmission generated a delay estimated in the order of hundreds of ms, which in turn led to unstable states in the robot control loop. Moreover, since wheel slippage could cause rotation of the robot and the *pen* was not able to report this rotation; it was not easy to identify and quickly react to slippage or undesired rotation, especially given the consistent transmission delays.

Other problems of the prototype to be faced before release the robot as an effective rehabilitation tool, as well as a real product were: the lack of possibility to swap the battery pack, some maintenance issues (e.g. the change of the wheels in an easy and safe manner or the easy update of the firmware), the computation power embedded in the robot, the storage of data in the robot in order to reduce the traffic data on the wireless connection, the reliability of the wireless connection, the amout of force delivered to the patient (related to the friction between the robot and the working surface).

To overcome these problems, during the experiment ECHORD++ a new robot called MOTORE++ has been built and evidence of the efficacy of the new robot as a rehabilitation device has been provided by means of clinical trials.

The technical solution implemented will be described in the following sections.

The ergonomic and hardware improvements have been strongly suggested by our stakeholders. The achievement of the above mentioned improvements makes the difference among a prototype and a marketable product.

We estimated the **impact** of the technological improvement in 5 units sales between month 10 and month 18.

Another expected impact was the 40% reduction of cost therapy for the hospital: we estimated to sell the robot at 35k€ (and 10% per year for the maintenance fees) and the robot lifetime is 5 years. Let us assume an example scenario in which a hospital buys 3 robots (the physiotherapist is expected to be able to supervise simultaneously 3 patients using MOTORE). Standing the previous assumptions, the traditional therapy in 5 year will cost 40K€ x 5years x 3 physiotherapists= 600k€ ; the robot mediated therapy will cost (3 x 35k€) +[(3 x 35k€ x 10%) +1 x 40k€] x5 = 357.5k€. The cost reduction in 5 years is 242.5k€ (or 48.5k€ per year). Hence, in this example scenario the cost will be reduced by 40%.

Section 1.1: Milestone overview

(Add a row and copy the contents for extending the table. Give a one point explanation for “deviated” and “not achieved” items)

#	Description	status
M1	MOTORE INTEGRATED PLATFORM	Deviated
M2	TEST RESULTS	Deviated

- The first milestone has been delayed by 2 months because of some supply problems, hence the second milestone has been delayed accordingly.

Section 1.2: Deliverable overview

#	Description	status
TR1	Monthly report	submitted
TR2	Monthly report	submitted
D1.1	New device Design	submitted
D2.1	New software and firmware implementation	submitted
D2.2	New device prototype release	Deviated
RIF	Report on RIF	Deviated
D3.1	Test report	Deviated

- The D2.2 has been delayed by 2 months because of some supply problems, hence the RIF and the D3.1 have been delayed accordingly. Moreover in June the consortium has requested an extension in order to collect a larger amount of clinical data.

Section 1.3: Technical KPIs

#	Description	status
1	**Hardware improvement**: ***Start:*** -NiMh Battery 10Ah not swappable (efficiency drops at 50% after 6 months) -The robot exerts 15N (for higher interaction forces the wheels slip) -Optical position sensor (Anoto DP201 Bluetooth with communication issues) -CPU Texas Instruments f28335 150Mhz -No IMU -No on-board storage ***End:*** -Li-Ion battery 10Ah swappable (Month 02) -The robot will exert at least 30N (new wheels and working surface)(Month 04) -Anoto DP 103 with wired connection and with rotation information (Month 04) -Cortex M4 180MHz 9150 (Month 06) -IMU invensense 9150 (Month 06) -SD card slot on board (Month 08) -Device firmware can now be upgraded via USB cable (less effort for maintainance)	Achieved
2	**Ergonomic and usability studies:**	Achieved
3	**Clinical Trials**	Achieved
4	**New rehabilitation games** ***Start:*** 4 games implemented in the prototype (motor coordination, motor apraxia, neglect disorders) ***End:*** 2 new games for further 2 disorders according to the advisors' suggestions and 1 evaluation scenario (Month 06)	Achieved
5	**Home based rehabilitation test:** ***Start:*** No remote rehabilitation implemented ***End:*** Implementation and simulation of home based rehabilitation at RIF premises (month 16)	Achieved

For details about the technical achievement please see D2.1, D2.1 and D.2 and section 2 of this document.

Section 1.4: Impact KPIs

#	Description	status
1	decrease of time spent by the therapist with the patient during a rehabilitation session. This means a cost reduction by 2/3	Achieved
2	TRL from 6 to 8	Achieved
3	production costs of 12k€. The targeted sales prices is 35k€,	Achieved
4	CE marking within the last three months of the experiment	Achieved
4	5 devices sold in the last 3 months of the project	Achieved

Section 1.5: Dissemination KPIs

#	Description	status
1	Press release	Achieved
2	3 Scientific Papers	Achieved
3	2 events attended	Achieved

Section 1.6: Additional (unplanned) achievements

- Collaboration with Fondazione Don Gnocchi and Istituto Maugeri.

Section 2: Detailed description

Section 2.1: Scientific and technological progress

➔ The project duration was 18 months and was structured into four main Tasks:

Task T1 - Device Development (integrated hardware redesign): The first task T1 dealt with identification of the requirements together with the stakeholder and the new hardware development for an enhanced device.

Task T2 - Platform development (software, firmware and control strategies redesign): the new software and firmware for the implementation of new games, new exercises and new control strategies has been developed

Task T3 - Experiment trials: the new system has been deployed and tested then validated in real scenarios Peccioli RIF (i.e. Auxilium Vitae Lab) with patients: in order to assess the effectiveness of the device and to better understand how the therapy is delivered by the robot wearable sensors have been used together with the robotic platform (muscle activation measured by means of EMG, limb segment displacement measured by means of wearable inertial sensors, etc.)

Task T4 – Dissemination: a press release has been distributed, 3 Scientific papers have been submitted and 2 events have been attended (see section 2.4) .

Section 2.2: Scientific and technological achievements

➔ The technical achievements have been achieved as described in the D1.1, D2.1 and D2.2 (which are related to the technical KPIs 1 and 4). Thanks to the technical achievement the new device is more reliable (new wireless connection, new position sensor, new control strategies), more effective (increased friction and thus more force exerted on the patient) and more appealing (new software and new games). With these improvements it has been possible to visit the RIF and deal with a real working environment, including therapists and patients. The therapists and the medical staff of the RIF were also involved in the drafting of the technical and functional requirements. The clinical trials and the scientific data collected have been the key to penetrate the clinical market and the device has been sold to private hospitals which are planning to reduce the therapy cost according to our starting hypothesis.

Section 2.3: Socio-economic achievements

- The Echord++ experiment at the RIF showed how the integrated information collected from a mobile haptic rehabilitation robot and a wearable system provides insight in the evaluation of motor disabilities. We focused on the aspect of muscular and force measures with the aim of differentiating patients from healthy subjects through computed measures. A set of seven weakness and force indicators were automatically extracted by the system during the operation. A clear distinction was highlighted by the scored indexes not only between healthy and the affected subjects but also within each specific subject when any sort of spasmodic event occurs. The preliminary results shows high confidence to use this metric for extensive patient validation.

  Preliminary results also show how an increase of the FM values after the robot-assisted upper limb treatment was observed in subacute subjects (T0: 44.9±11.9; T1: 54.2±6.1, ns). A statistically significant improvement was found in chronic subjects (T0: 23.8±15.0; T1: 36.8±16.9, $p<0.05$). MAS-S and MAS-E values in subacute subjects did not change after the upper limb rehabilitation treatment. A decrease, even though not statistically significant, was observed in chronic subjects both in MAS-S (T0: 1.40±1.14; T1: 1.20±0.45) and MAS-E (T0: 2.60±1.34; T1: 2.00±1.22). A significant increase of the B&B test was observed only in subacute subjects (T0: 44.9±11.9; T1: 54.2±6.1, $p<0.05$).

  During the project, the device has been shown in two major events and demoed in several private hospitals, leading to the sale of five units during the last months of the project.

Section 2.4: Dissemination activities

- a press release has been distributed

  https://www.dropbox.com/s/qrthnnqr1n9uaub/MotorePP_Press_Release_Feb2015.zip?dl=0,

  a second press release will be distributed with the once the clinical data analisys will be consolidated (some months after the end of the project)

- 3 Scientific papers have been submitted
  - Lucia Saracino, Carlo Alberto Avizzano, Emanuele Ruffaldi, Giovanni Cappiello, Zoran Curto, Andrea Scoglio. "MOTORE++ A Portable Haptic Device for Domestic Rehabilitation". The 42nd Annual Conference of IEEE Industrial Electronics Society, October 24-27, 2016
  - Saracino L.A., Ruffaldi E., Graziano A. & Avizzano C.A. (2016). Fusion of wearable sensors and mobile haptic robot for the assessment in upper limb rehabilitation. In IEEE International Conference on Multisensor Fusion and Integration for Intelligent Systems (MFI).
  - Stefano Mazzoleni, Elena Battini, Rossella Crecchi, and Federico Posteraro, Upper limb rehabilitation after stroke using a portable haptic robotic device: preliminary results

  More papers will be submitted in order to disseminate the RIF resuls

- 2 events have been attended demoing the robot:

- IROS 2015 (https://iros2015.informatik.uni-hamburg.de/)
- Automatica 2016 (http://exhibitors.automatica-munich.com/en/)

Section 3: Resource usage summary

➔ Put a table on your resource usage

	HMW	F136	RT	Total
Personnel	98’611		57.059 €	
Man Months	25		14	
Components for prototypes	27’124		1.613 €	
Equipment			853 €	
Travel	2’000		0 €	
Dissemination			0 €	
Indirect cost	76’641		35.715 €	
TOTAL	204’307		95.240 €	

Section 4: Deviations and mitigation

➔ The activities at the RIF have been delayed because of the late deployment of the new device. Nevertheless, the Data have been collected and analyzed. Preliminary results are promising but the number of patients is still not sufficient. In order to obtain more significant scientific results the data collection (and the comparison with healthy subject) will continue after the end of ECHORD++ and published.

Section 5: Future work

➔ For the future :
- The data collection of therapy with the device will continue
- The data collection of the device with wearable sensor will continue (data analysis expected by the end of the year)
- The latest version of the device will be certified (the version being sold at the moment is the intermediate version)
- The marketing of the device will be carried on (3 more device sales expected by the end of the year 2016)

Section 6: Lessons learned (optional)

➔ the experience gained in the project will be beneficial to the whole consortium. All partners have learnt more information on the market of biomedical devices, rehabilitation of patients with neurological impairments and robotic devices.
The only critical issue during the project has been time management with respect to supplying materials. The timeframe between the design phase and production phase was too short and didn't account for the delays we experienced.

The project extension that we requested was intended to analyze and evaluate more patients, aiming to confirm the promising results shown by the analysis of the first patients.