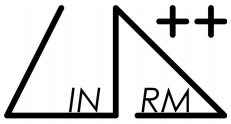

LINarm++

Affordable and Advanced LINear device for ARM rehabilitation

Deliverable D1.1

Requirements and specifications

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Authors	Carlo Seneci (IDRO) Michele Cotti Cottini (IDRO) Ignazio Mario (IDRO) Elisabetta Cropelli (IDRO) Matteo Malosio (CNR) Marco Caimmi (CNR) Matjaž Mihelj (UL) Janez Podobnik (UL) Andrea Crema (EPFL)

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Executive summary

This deliverable deals with the definition of requirements and specifications of LINarm++, a multisensory and multimodal device for neuromuscular rehabilitation of the upper limb. The presence of different subsystems, some of them to be partially improved or redesigned and some of them to be designed and realized from scratch, required to analyse the different modules with the common aim of being integrated in a functional and effective way from the application point of view. This report is therefore organized in different sections, each of them facing aspects of different nature, ranging from usability and exploitability to technical ones. For each of them, development guidelines and requirements are given, together with warnings about aspects which could affect longed-for positive outcomes. Moreover, since market-oriented aspects are crucial to succeed in developing an actually marketable solution, two appendices complete the report in order to orient strategic choices of development. They face both intellectual property and market-competition possible issues, analysing both existing patents, which could influence or restrict future market exploitation, and products of competitors.

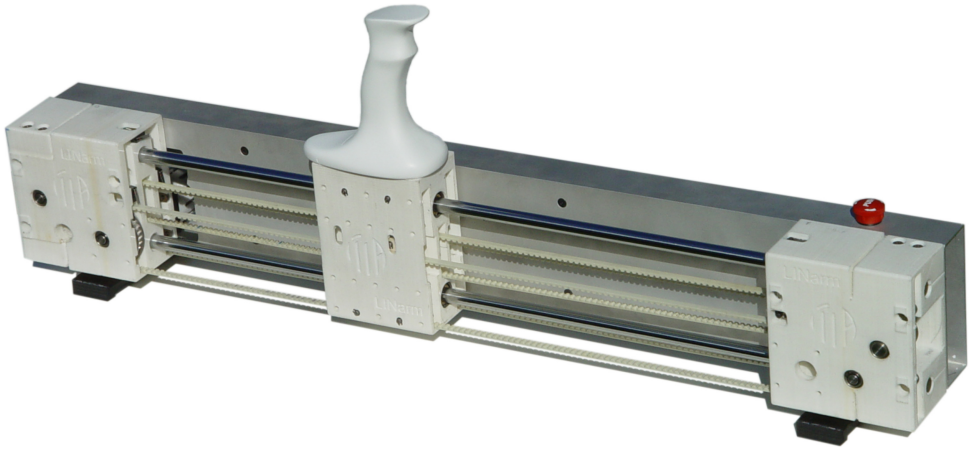
Introduction

Scenario

Stroke rehabilitation can take advantage by the exploitation of robotic devices specifically designed to assist the patient and the medical personnel during the recovery. Patients can typically benefit of a period of hospitalization in the first weeks after stroke, during the acute and part of the subacute phase, in which neuroplasticity plays an important role in the recovery process. However experimental studies show that plasticity phenomena can be stimulated by robotic intervention even in the chronic phase thus underlying the importance of rehabilitation after discharge [1], [2], [3]. Clinics can afford the purchase of expensive, complex and cumbersome devices, but these same aspects make such devices not suitable to be installed and used at patients' home. The development of widely affordable devices can therefore represent a breakthrough solution to increase the overall quality of recovery for a large amount of stroke patients. Different upper-limb home rehabilitation devices are currently available, but they are typically passive or passively gravity-balanced [4].

LINarm

In this scenario, LINarm, an assistive device for the rehabilitation of the upper limb, specifically designed to minimize the overall realization costs to enable rehabilitation exercises at home, was developed [5]. It features a variable stiffness mechanism, making it possible to adjust the level of assistance by modifying the manipulandum mechanical stiffness on the basis of the actual requirements of the therapy. Both the mechanics and electronics have been specifically studied to fulfill the low-cost stringent requirement.



On the other hand, no additional systems and other sensors are currently integrated in the LINarm prototype, limiting the possibility of increasing the engagement of the patient during the training and enhancing the rehabilitation outcome.

LINarm++

In order to enhance the currently available functionalities of LINarm, the LINarm++ experiment aims at realizing a multisensory and multimodal device for neuromuscular rehabilitation of the upper limb by integrating, augmenting and greatly expanding the functionality of the LINarm device, including:

- An easily wearable FES (Functional Electrical Stimulation) system, allowing effective stimulations of shoulder and elbow muscles.
- An engaging on-line adaptable rehabilitation scenario and virtual environment, augmented with additional feedback signals (audio, haptic, tactile,...).
- A low-cost unobtrusive sensory system for measuring patient's physical activity and physiological state, realized by embedding most of the sensors directly into the handle of the device. These sensors, together with sensors embedded in the device, will provide information about kinematic and kinetic quantities as well as physiological quantities.
- A patient model for adapting training task parameters in relation to user's performance and physical/physiological state. The aim is to influence the user's engagement and performance.
- A central control system able to constantly update rehabilitation parameters with the aim of fulfilling the needs of the patient. Exploiting sensor-fusion techniques to merge all available data, it will be able to estimate how the user is behaving during a single training session and to evaluate changes during the entire training period.

The application scenario and functionalities to be developed have been analyzed, leading to draw development guidelines, grouped by topics and presented hereafter.

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2. S. Mazzoleni et al., "Upper limb robot-assisted therapy in chronic and subacute stroke patients: a kinematic analysis," *Am J Phys Med Rehabil*, vol. 92, pp. 26–37, Oct 2013.
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1. From linear movement to function-oriented movement

The main goal of neurorehabilitation is relearning of Activities of Daily Living (ADLs), the most common of which refer to the upper limb: reaching (with the arm and forearm), grasping and picking (with the hand).

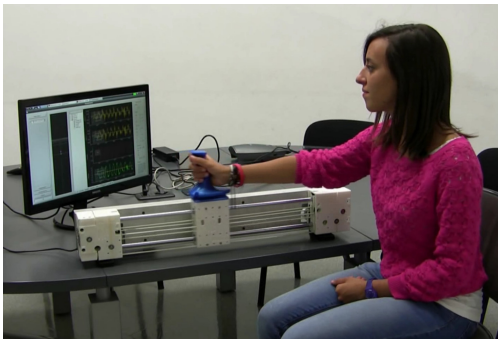
The linear motion of LINarm is a good starting point to train and keep patients used to the reaching motion. It is worth to underline that the reaching movement is, in general terms, not necessarily performed in an horizontal direction.

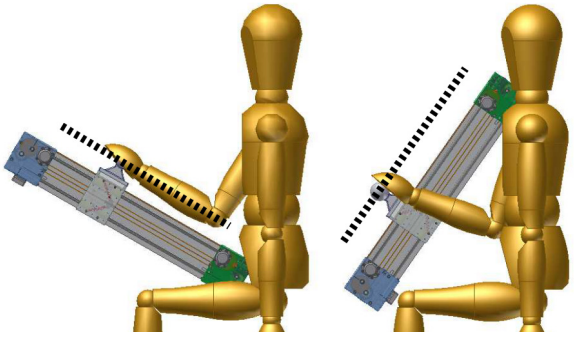
Guidelines and requirements

- A spherical (or cardan or similar) joint placed at one extremity of the LINarm, would allow the possibility to change the orientation of the device in space, increasing a lot the possible therapeutic uses of the device.
- Angling the device as a ramp, would increase the difficulty of the linear movement, offering more challenging exercises to patients.
- Also, several ADLs are made with the arm bringing objects to mouth (Hand to Mouth Movement - HtMM) and this joint would permit a configuration of the device very close to the physiologic HtMM. This is also a concept used in Tailwind device (patent US20030207739), which demonstrated to be effective in neurorehab.
- LINarm is not currently securely fixed to the table for use. Designers should consider to make a proper joint to firmly fix it to a table. The solutions used in Tailwind are simple and effective.

Warnings

- The joint will bear the weight of both the device (which is quite long and might generate a significant torque to the joint) and patient's arm, and should be properly dimensioned.
- The position of the joint should not change during the execution of therapy, even more importantly, the LINarm should never fall down during usage: this is to be considered carefully.
- The regulation of the joint should be easy and quick, but only possible when the patient is not using the device.





2. Portability, design and lightness

Portability and lightness are very appreciated attributes in any medical device. Devices for rehabilitation are connected to limbs of the patients' body and any improvement in these terms means more easiness of use, less costs and encumbrances, increased possibility to enlarge possible applications and therapies.
Portability and lightness are needed requirements for home-use devices.
Compared with competitor devices, which are almost exclusively designed for hospital use, LINarm++ might have remarkable advantages in market positioning.

Guidelines and requirements

- LINarm has a concept similar to the one used with Tailwind, which has demonstrated to be effective in neurorehab and is one of the few home-use devices for upper limb. LINarm++ will have more and improved features but, even in its more advanced version, it should not lose the small dimensions and light weight
- The LINarm prototype can be considerably reduced to LINarm++ in its external dimensions
  - ❑ re-designing the internal parts,
  - ❑ reducing distances among them,
  - ❑ cancelling unnecessary parts (or parts which brings low added value),
  - ❑ placing the hidden parts (not to be used daily) in the internal empty spaces.
- LINarm is a prototype: LINarm++ should not have sharp corners on external parts, but smooth edges. The general shape of the device should be designed taking care of the look. A medical robot should be seen as technological but also ergonomic, friendly and modern at same time.
- Designers should consider using plastic parts / light alloys (aluminium in first place) whenever this is possible.
- Designers should consider to use plastic clips for assembling parts, whenever it is possible, avoiding metal screws and bolts as possible. This will save times in manufacturing and repairs.
- Designer should consider to make few big, plastic parts as external covers: this would reduce the cost of molds (there will be few molds, even if more expensive) and make the assembly process quicker.
- (optional) The LINarm++ should be designed to be easily disassembled and assembled again in few minutes. Designer should think about how to separate easily mechanical parts from electric ones in order to make ordinary assembly (for daily use) and extraordinary assembly (for repairs) fast and secure.
- (optional) On the contrary, if the LINarm++ will be designed as a one device (with no need to be assembled for ordinary use), it would be necessary to place a proper, comfortable handle at the top of it, which would guide the user to move the device safely.

Warnings

- (optional) In case of medical system used in home healthcare environments consider that there is an additional standard to accomplish: see the IEC 60601-1-11:2010.
- LINarm is a quite long device (this is necessary to allow the complete extension of the arm) and requires a computer to stay in front of the patient during use. Consider a proper layout of the components (LINarm++, PC) in order to let the use be comfortable and safe on a common table. Suggest the correct layout on the manuals.
- It won't be possible to keep all features of LINarm++ (hospital version) in home version, which must be simplier and easier to use. After the realization and assessment of the Linarm++ prototype at the end of the project, consider which features/parts could/should be neglected in the home version.

3. Possible integration with GLOREHA

The integration of LINarm with Gloreha is not an essential point of the experiment, but it is also something that could increase the attractiveness of the LINarm++ device. The software integration between the two systems is out of the scope of this experiment's purposes and targets, and will represent the final step of integration in a modular system targeting the rehabilitation of the whole upper limb (i.e. both the hand and the arm).

Anyway, the first aspects to be considered at this stage, aiming at the complete integration of the two systems in the next future, are purely mechanical: how could Gloreha effectively be coupled to LINarm?

Guidelines and requirements

- LINarm is connected to the patient's hand by a handle that the patient must hold firmly. In order to allow the use of Gloreha or fingers flexion and extension movements, a proper mechanical joint placed nearby the wrist of the patient and connecting Gloreha to LINarm should be considered. Designers can think about joining LINarm with the Gloreha brace or with the cable of mechanical wires.
- Some exercises should be already developed considering the closure of the fingers as a trigger for "grasping is done" after the reaching movement assisted by LINarm. This is strongly in line with the most common and effective ADLs to be used during rehab.
- Joining LINarm to Gloreha should be an operation taking few seconds, using quick joints any time it is possible.
- (optional) When closing fingers with Gloreha a prono-supination movement should better be allowed, as it represents an important movement during the reaching+grasping movement. A joint which let the prono-supination possible would have a positive impact on usability and effectiveness of the LINarm++.

Warnings

- Movements of wrist and fingers made by Gloreha should not make the hand touch the device or any moving parts.

4. Other mechanical improvements

Guidelines and requirements

- LINarm has a quite high noise level. This might be a problem, as the motors are placed near to patient. New actuators and motors / reduction bareers should be investigated to reduce the noise general level.
- Finding the correct position of the patient (sitting on a chair or wheelchair) when using LINarm at the moment is not very clear / intuitive. The shape of the device itself should have to suggest the correct position of the patient, when using the device. This would avoid many risks of misuse of the device.
- The mechanical parts which stay close to the chest of the patient are now big and cumbersone, and have sharp corners. Designers should consider to realize round shapes and to move the majority of mechanical parts far from the human body.

5. Integration with FES systems

The integration of the FES system with LINarm can increase attractiveness of the whole system by introducing the possibility of actively training selected muscle groups, or by providing cortical afferent stimuli through supraliminar sensory cues about the muscles activation timing. Within this project, the FES system will be integrated to be used in ADL based tasks like reaching and grasping and the hand-to-mouth (see suggestions in chapter 1). The first aspects to consider in the current phase are functional.

Guidelines and requirements

- LINarm is connected to the patient's hand by a handle. The patient, if able, must hold such handle firmly, otherwise a support structure should conveniently be used to constrain the hand of the subject.
- Donning and doffing of the FES garment should be performed by an operator in a few minutes. The shoulder-arm-elbow garment, used to host the electrodes should be easy to adapt to the patients' needs.
- Wearing the FES garment shall always be possible in conjunction with LINarm and GloReha.
- The FES system should be an easily wearable set of standard electrodes incorporated in a garment, with reference anatomical landmarks in order to simplify positioning and the donning/doffing process. Each garment should be preconfigured for use by a skilled operator that ensures repeatable donning on selected motor points.
- The choice of materials for the garment should be compatible with washing.

Warnings

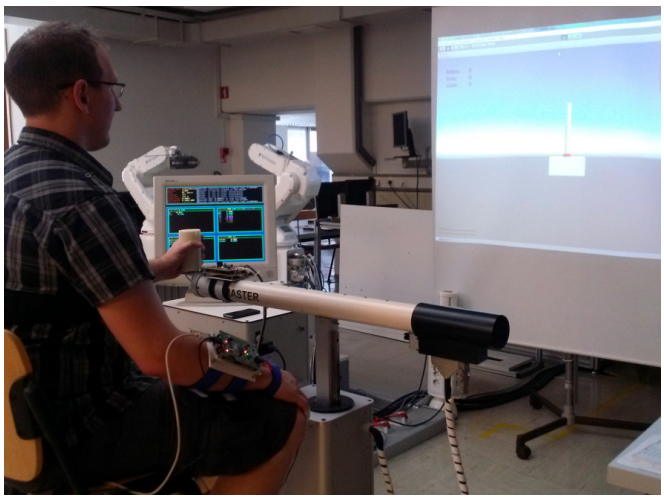
- Movements of the shoulder, elbow, wrist and fingers made by the FES system should not touch the device.
- Electrodes for stimulation should be properly placed for avoiding bad skin contact, and covered by protective layers able to prevent unwanted electrode removal
- The garment placement should be performed and verified by a trained operator able to detect potential mispositioning.
- The isolation of the FES electrodes should be verified before the execution of each exercise.
- The cables for stimulation should always be loose throughout the range of motion of each exercise, and not interfere with the chosen tasks or with other modules of the LINarm, or the used chair/wheelchair.

6. Integration with biological sensors

Control of a robotic device relies on high quality measurements. At the same time quality of rehabilitation depends on good assessment of patient's performance and adaptation of the training protocol to the patient's needs (biocooperative control, assist-as-needed control). Results of objective assessment are important also for physicians to properly plan the rehabilitation process. However, assessment might not only be related to patient's performance, it could also be related to his/her engagement during the training. This would provide an insight into the motivation for training and also allow adaptation of the training task according to patient's requirements.

Guidelines and requirements

- The sensor setup needs to be low-cost.
- The sensor setup needs to be unobtrusive. Therefore, most of the sensors should be embedded directly into the mechanism and the handle of the device or simply attached to the patient (e.g. bracelets).
- Sensors embedded in the robot itself should provide information about the arm (hand) position, velocity and interaction force (including grasping force) between the robot and the patient. The acquired information can provide an insight into the physical interaction between the robot and the patient (supporting forces, exchange of power).
- The measurement system of the robot should be augmented with simple wearable sensors to complement information from the embedded sensors in the robot itself. The wearable sensory system should consist of magneto-inertial, small, lightweight, wireless and battery powered devices that allow natural human movements.
    - The system should consist of devices for measuring upper arm and forearm movement.
    - The output of the system should be a complete kinematic model of the upper limb that includes shoulder and elbow angles. These are required to properly activate electrical stimulation.
    - The measurement system should be compliant with the system for electrical stimulation.
    - The system can potentially enable assessment of patient's compensatory movements.
    - The system should be easily attachable (e.g. Velcro straps).
- A sensory system should be implemented that will enable measurement of patient's physiological parameters. The output of these sensors will be used as the input into the patient's model (together with kinetic and kinematic measurements).
- The most relevant physiological parameters to be measured are (at least some of the following measurements should be implemented):
    - heartrate,
    - galvanic skin response (skin conductance),
    - skin temperature (at the finger or similar location),
    - electromyography of arm muscles to provide more



insight into the subject's voluntary physical activity,
    - breathing frequency (not easily measured without obtrusive sensors – chest belt or thermistor under the nose).
- The most suitable integration for the physiological sensors is to embed them into the robot handle. In this way the patient would not be disturbed by the measurement procedure. The drawbacks of such implementation might be
    - the artefacts resulting from the movement of the hand and the robot can affect quality of measurements,
    - such measurement approach is not compliant with the use of Gloreha glove in combination with the LINarm++ robot,
    - ergonomic issues - different hand sizes might require different sizes of handles.
- As an alternative to putting physiological sensors into the robot handle the following solutions should be considered
    - bracelet with embedded sensors (battery powered and wireless – certain modern wrist watches use this concept),
    - measurements conducted on the resting arm (sensors embedded into a form of handle or another approach can be considered),
    - bimanual measurement of physiological signals (heartrate can be measured as in the fitness devices.
- All sensors should be interfaced to the control computer. Sensors signals should be processed on a low cost hardware meaning that complexity of processing algorithms needs to be limited.

Warnings

- Sensory system and its output might be influenced by artefacts resulting from arm movement.
- Sterilization of robot handle and embedded sensors should be considered. The problem is less critical for home use and more critical for clinical use.

Literature on physiological sensors and sensor signal processing

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5. P.S. Pandian, K. Mohanavelu, K.P. Safeer, T.M. Kotresh, D.T. Shakunthala, Parvati Gopal, V.C. Padaki, "Smart Vest: Wearable multi-parameter remote physiological monitoring system," *Medical Engineering & Physics*, vol. 30, pp. 466–477, 2008.

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8. D. Novak, B. Beyeler, X. Omlin and R. Riener, "Workload estimation in physical human- robot interaction using physiological measurements," *Interacting with Computers*, pp. 1-14, 2014.
9. D. Novak, A. Nagle and R. Riener, "Linking recognition accuracy and user experience in an affective feedback loop," *IEEE Transactions on Affective Computing*, 2014, vol. 5, no. 2, pp. 168-172, 2014.
10. J. Ogorevc, G. Geršak, D. Novak and J. Drnovšek, "Metrological evaluation of skin conductance measurements," *Measurement*, vol. 46, pp. 2993-3001, 2013.
11. D. Novak, M. Mihelj and M. Munih, "A survey of methods for data fusion and system adaptation using autonomic nervous system responses in physiological computing," *Interacting with Computers*, vol. 24, pp. 154-172, 2012.
12. D. Novak, M. Mihelj and M. Munih, "Dual-task performance in multimodal human-computer interaction: a psychophysiological perspective," *Multimedia Tools and Applications*, vol. 56, pp. 553-567, 2012.
13. M. Mihelj, D. Novak, M. Milavec, J. Ziherl, A. Olenšek and M. Munih, "Virtual rehabilitation environment using principles of intrinsic motivation and game design," *Presence: Teleoperators and Virtual Environments*, vol. 21, pp. 1-15, 2012.
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7. Patient model for adapting training task parameters

Patient model will make use of the collected sensory information to estimate the user's physical and physiological state and activity and to optimize parameters of the training task. Patient model will output: i) an estimated user's physical and physiological state and ii) decision how to change the training scenario.

Guidelines and requirements

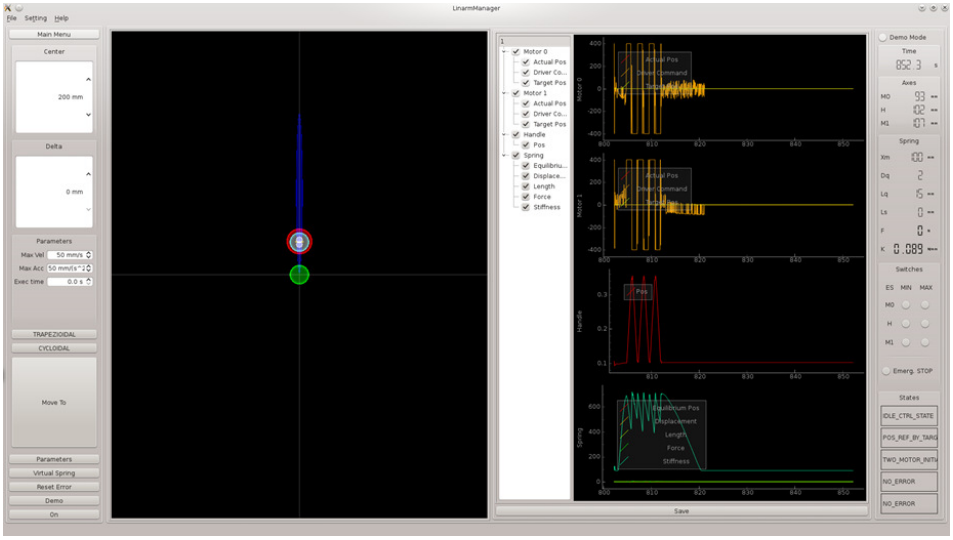
- Since the collected data from sensors will be raw sensor signals and the outputs need to be parameters of the training scenarios the algorithms should be organised in several steps:
    - Signal pre-processing (filtering, noise removal, bias removal, normalization, etc.). The output signals will be fed into patient model.
    - Patient model will be divided into three sub-models:
        - Kinetic model will consist of arm kinematics and arm dynamics model. Sensory fusion algorithms with kinematic and dynamic model of the arm will be used to estimate the trajectory of joint angles and joint torques in real-time.
        - Physiological model will fuse data from sensors (embedded into the handle and bracelet), which will measure physiological signals. Outputs are parameters summarizing the information about the physiological state of the user (heart rate, skin conductance). The main focus will be on observation of trends of physiological parameters in order to optimize training activity.
        - Patient performance model will estimate various parameters related to physical activity and task performance such as level of physical work, kinematic parameters, interaction and grasp force, as well as game scores.
    - Output of patient model should not be analysed only in terms of absolute parameter values, but more importantly it should be analysed in terms of trends of signals. Based on that training settings should be optimized in order to keep the parameter values within the adequate boundaries.
- We should define the initial set of rehabilitation parameters suitable for all patients, while the optimal set of rehabilitation parameters for the particular patient should be adapted from the initial set during the rehabilitation from the analysed trends of patient model outputs.
- For the best rehabilitation outcomes, we should be able to control the level of required physical engagement from the patient. We should also consider how can we assess psychological engagement from physical engagement.

Warnings

- Since low cost micro-controller devices will be used, special algorithms for signal processing will have to be developed, which will be less computationally intensive, but will still provide reliable estimates of the parameters and trajectories.
- It may be impractical for users to use all features of the patient model, so we should consider how to simplify the patient model for various modes of use, but still preserve majority of functionality of the automated patient model.

8. User interface - General aspects

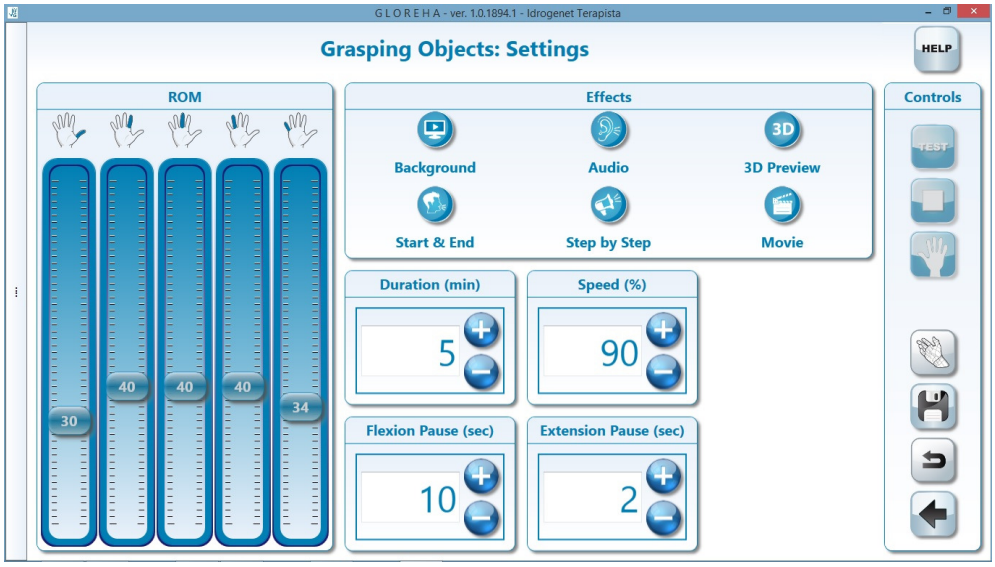
The software of LINarm is already at a good stage. It allows a precise definition of the therapies, and it already has several functionalities and features.



Nevertheless, in order to make it a professional product, it should become less "for engineers" and more "user friendly".

Guidelines and requirements

- Patients and care-givers (hereinafter called "users") need simple screenshots to interact with: a new architecture of the software should be made, starting from beginning, and keeping simplicity as first target.
- Few, big, self-explanatory icons should be used. LINarm sfw is now made with small menus and too many words. Words should be replaced by self explanatory icons all times it is possible.
  A good example of user-friendly software is shown by the screenshots below (from Gloreha software):



- Integrations: LINarm++ will join LINarm to other additional devices (FES, physiological parameters sensors, position sensors). The new software should include control modules of all of them with same graphics and architectures.
- Hospital use device will have more features than home device: implement first the software for hospitals, and then reduce it properly for home.

Warnings

- (optional) It would be important to properly design the software graphics ready for future use on touch-screens / devices.

9. User interface - Clinical protocols

LINarm's software now can work in three different modalities: "passive" (the device guides the arm which is passively moved (with a degree of compliance allowed by the variable-stiffness architecture), "triggered" (the patient exert a pushing/pulling force beyond a threshold value and the device assists the movement when the threshold is overcome, "force-controlled" (the device follows the movement of the patient, on the basis of the forces applied by the patient). All of them are useful in upper-limb neurorehabilitation, but significant improvements could be achieved with proper changes in LINarm++ software.

Guidelines and requirements

- Implement further control modalities, according to the "assist-as-needed" paradigm [1].
- For each modality, software developers should consider to fix a proper protocol, setting parameters (speed, forces level, triggers) according to the condition of the patients. In this way the users will only choose between some pre-set scenarios and then adapt them with minor changes. This procedures make the initial part of preparation shorter and easier.
- When starting an exercise, the software should effectively communicate to patient what he is going to do, and how he is asked to do it, with video/sounds/icons/speeches coming from the computer; the required actions to be done by patient should be clear and easy to understand. This will reduce the misuse and the possible frustration of patient.
- Software developers should consider to offer to the patient (while using LINarm++) continuous audio and video feedbacks: data and parameters should be changed into icons, targets, motivational pictures; patients should recognise in real-time if he is doing the proper action or not, and be encouraged to do it in the right way; patient using LINarm++ should be highly motivated with multi-sensorial interactive feedback or stimuli (music, rhythm and sounds, changing video effects).
- Software developers should consider to log and track the parameters of the active actions of the patient (speeds, accuracy of movements, ROM, forces, triggers level, responses times, smoothness, repeatability...) which are so important for diagnosis and for measurement of the recovery process. Data should be exported and investigated from clinicians; developers should consult clinicians in order to determinate which of those parameters are most important for these targets.
- Using these informations, the software should be able to print reports for each patient, describing the history of his recovery.
- In the setting screens, software developers should consider to put easy regulations, with few number/text fields, and more icons and level bars, better with suggested levels.

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Appendix A - Patents survey

Introduction

LINarm is (and LINarm++ will be) a device using many already-known devices and mechanisms. Most of those mechanisms are simple, public and known since very long time and it is not possible to protect them with patents.
The most important used mechanisms are the inclined plane, the linear rail and several, different kinds of joints and sensors.
The mechanical core of the LINarm is the variable stiffness mechanism placed in the cursor which is connected to the hand of the patient and allows a peculiar sliding behaviour.
It also allows to adjust the level of assistance by modifying the manipulandum mechanical stiffness on the basis of the actual requirements of the therapy.
This is something peculiar and innovative, which has not been used in rehab devices yet, and **the partners of the experiment could decide to patent**.
Experiment's partners should discuss this topic in time before publishing any concerning document.

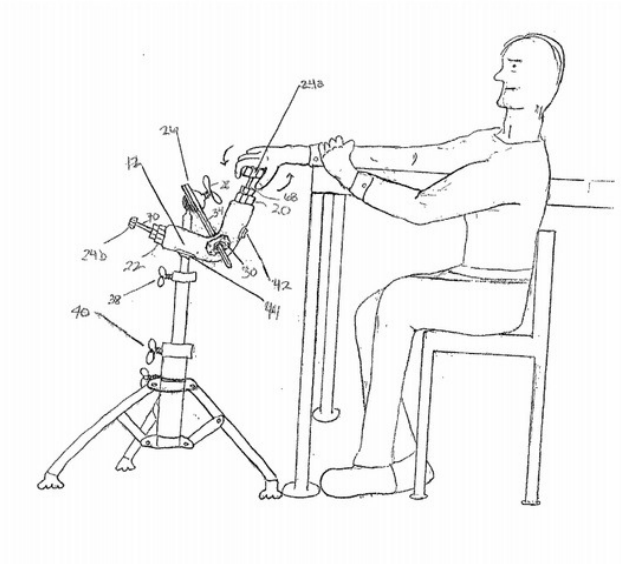
The most relevant patents of similar arm rehabilitation devices have been searched and collected, some of which are not commercial products, in order to look for possible conflicts with the concepts of the LINarm design.

It seems that also those devices use already-known mechanisms in most places, but in original way.
We found out no problematic conflict with these patents, if we consider the peculiar variable stiffness mechanism placed in the cursor, which isn't applied in any of those.

Some concerns come from patents of Tailwind (US 2003/0207739 A1 - US 7.121.981 - US 7.850.579), whome concept is very similar to LINarm, and from patent US 7.037.244 B2, but **the only use inclined planes and linear rails should not be sufficient, according to the LINarm++ team's experience, to raise a legal dispute from that side**.

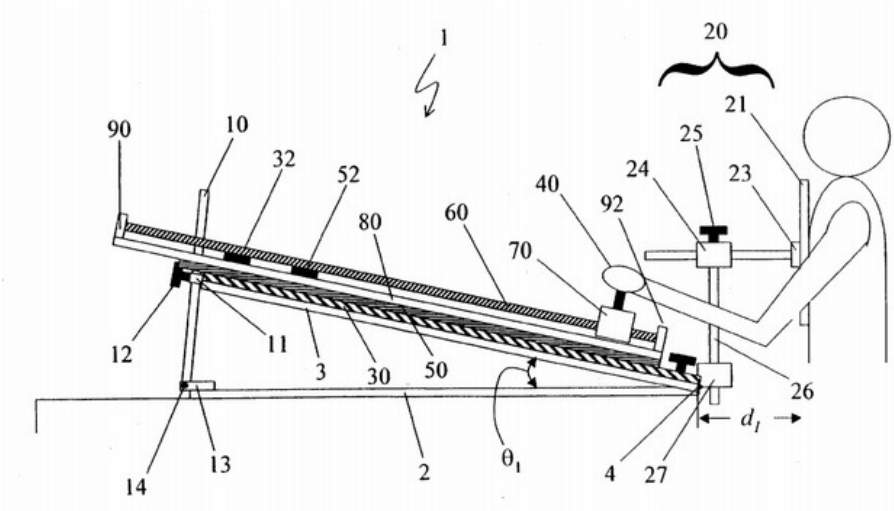
Specific patents evaluations

US 2002/0094913 A1 (18/07/20028)



It is a wrist and upper extremity motion system with motors and sensors, focused on hand grabbing movements and prone-supination. It does not provide or allow the linear motion of the upper limb.
It does not use the variable stiffness mechanism.
The part shown in fig. 3A of the patent could be similar to the future joint connecting LINarm to the wrist of the patient, allowing prono-supination.

US 2003/0207739 A1 (06/11/2003) - US 7.121.981 - US 7.850.579



This device (and method for bilateral arm training) is known with the commercial names of Batrac and more recently **Tailwind**.
It has linear shafts where two cursors can slide. The shafts can be moved in different positions / angles so the exercises for the patient will change accordingly.
There is a chest rest where patient can lean on.
The concept is quite similar to LINarm's but it does not use the variable stiffness mechanism and does not feature any motorized actuator.

US 2004/0243027 A1 (02/12/2004)

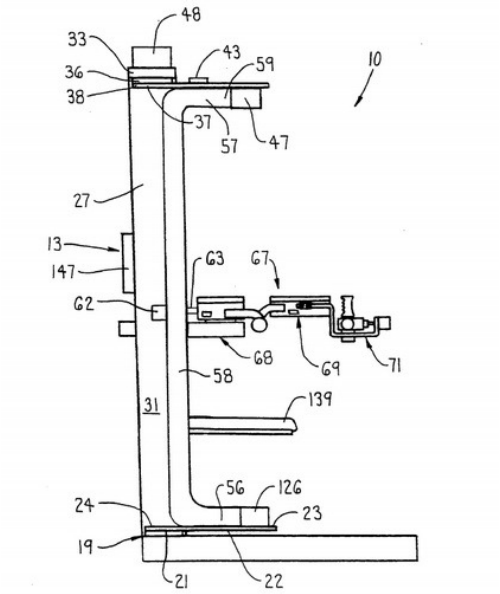


FIG. 3

It is a complex hexoskeleton with a seat for the patient. It is similar to Armeo in concept. It is much more complex than LINarm++ and should not conflict with it.
It does not use the variable stiffness mechanism.

US 2006/0106326 A1 (18/05/2006)

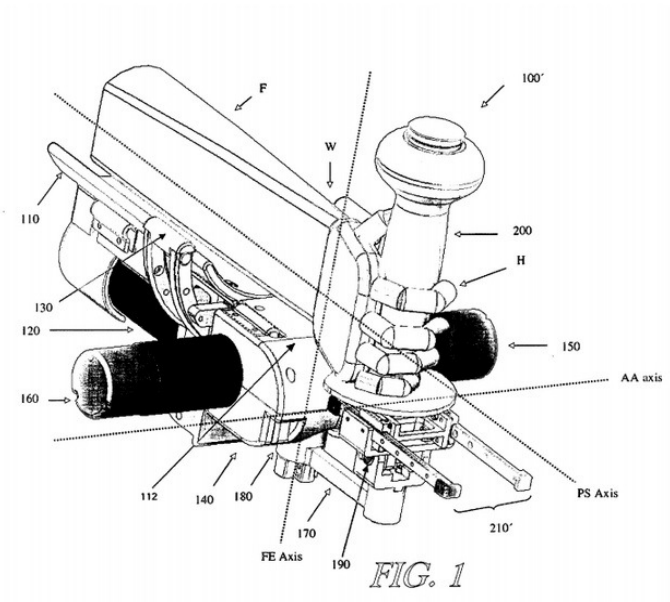


FIG. 1

It is a handle-shaped device, used to train/mobilize wrist with low impedance. It seems to be a part of the commercial **Inmotion** device. The handle may have lots of degrees of freedom. It is a complex device, which does not use linear arm movement itself and it does not use the variable stiffness mechanism.

US 2011/0300994 A1 (08/12/2011)

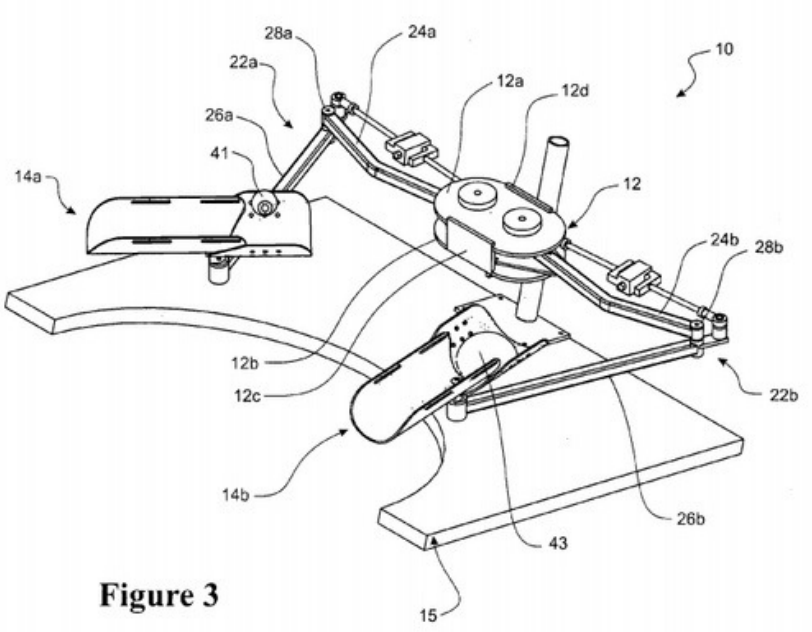
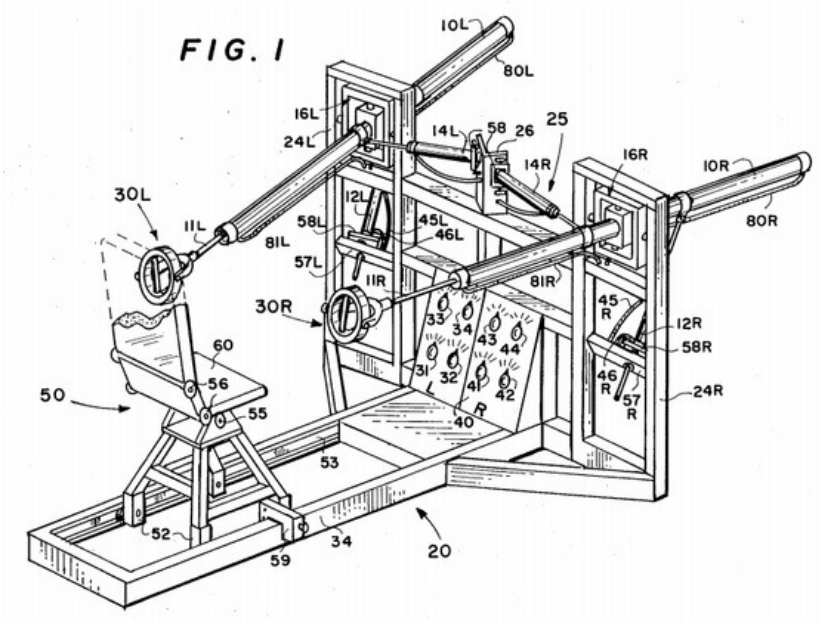


Figure 3

It is a complex end-effector device with a seat for the patient. It is similar to Mit-Manus / Inmotion in concept. It is much more complex than LINarm++ and should not conflict with it.
It does not use the variable stiffness mechanism.

US 4.629.185 (16/12/1986) - expired -



This device has two linear (for bilateral training) hydraulic cylinders onto which the handles are attached. The patient can perform linear movements with valiable stiffness. The position of cylinders can be regulated so the exercises for the patient will change accordingly.
The concept is quite similar to LINarm's but it does not use the same variable stiffness mechanism.

US 4.773.398 (27/09/1988) - expired -

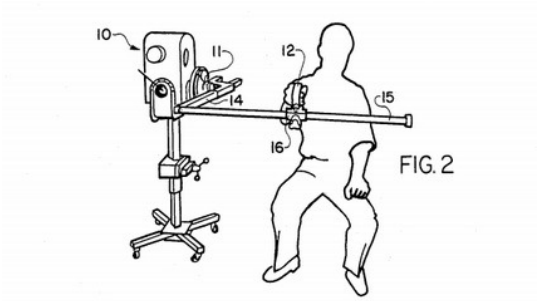


FIG. 2

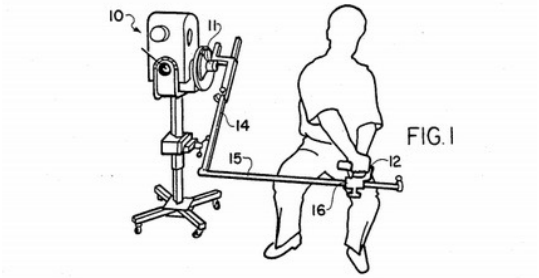


FIG. 1

This device has a linear shaft where a cursor can slide. The shaft can be moved in different positions so the exercises for the patient will change accordingly.
The concept is quite similar to LINarm's but it does not use the variable stiffness mechanism.

US 5.254.066 (19/10/1993) - expired -

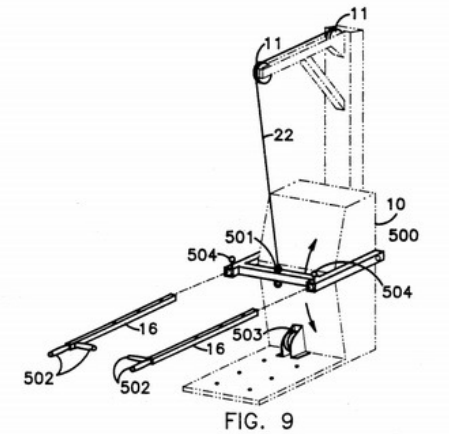


FIG. 9

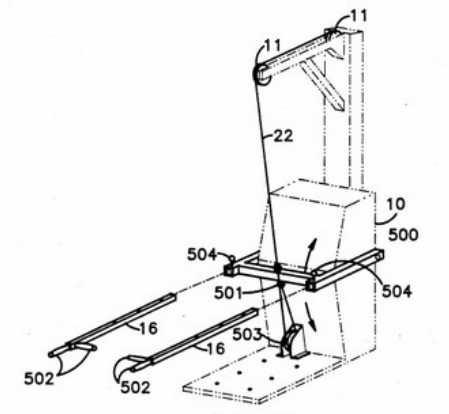


FIG. 10

The rehab device is linear like LINarm is, but the device is much more cumbersome and does not use the variable stiffness mechanism.

US 5.755.645 (26/05/1998)

It is a passive exercise apparatus for upper limb, similar to haptic devices in concept. It is much more complex than LINarm++ and should not conflict with it.
It does not use the variable stiffness mechanism.
The part shown in Fig. 3 of the patent could be similar to the future joint connecting LINarm to the wrist of the patient, allowing prono-supination.

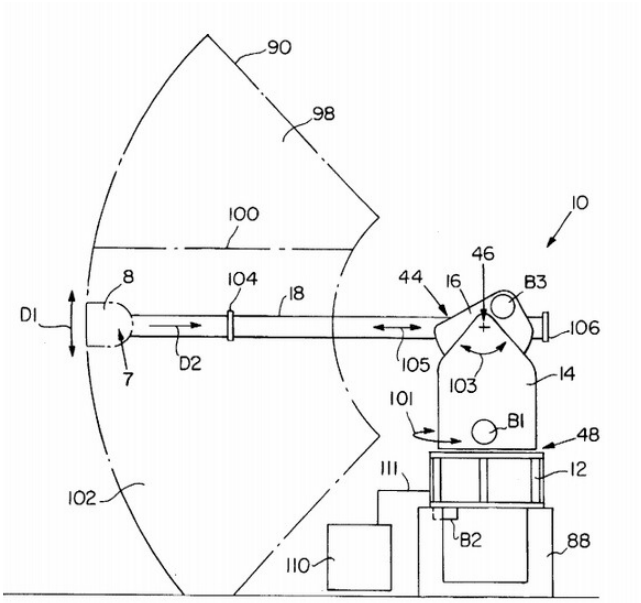


FIG. 1

US 7.037.244 B2 (02/05/2006)

This device is an arm exercise device
It has linear shaft where a cursors can slide. The shaft can be moved in different angles (from horizontal to vertical) and the resistance (weight of the cursor) can be changed so the exercises for the patient will change accordingly.

- The concept is quite similar to Tailwind's but this is mono-lateral and the mechanisms for adjusting angles are different.
- The concept is quite similar to LINarm's but it does not use the variable stiffness mechanism.

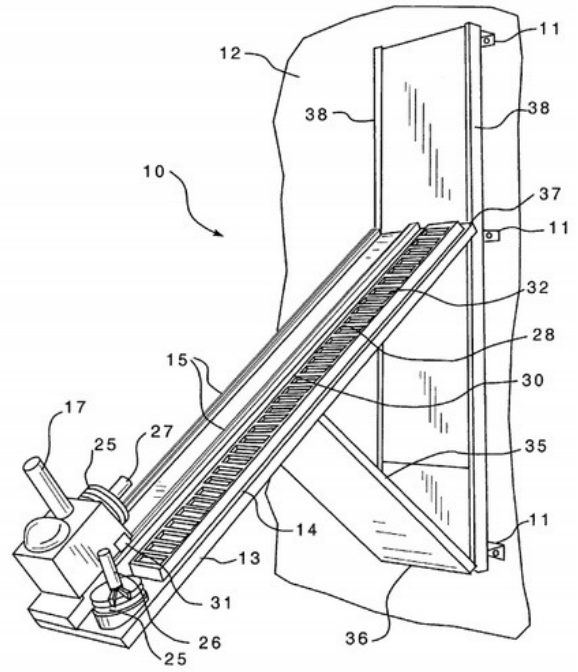
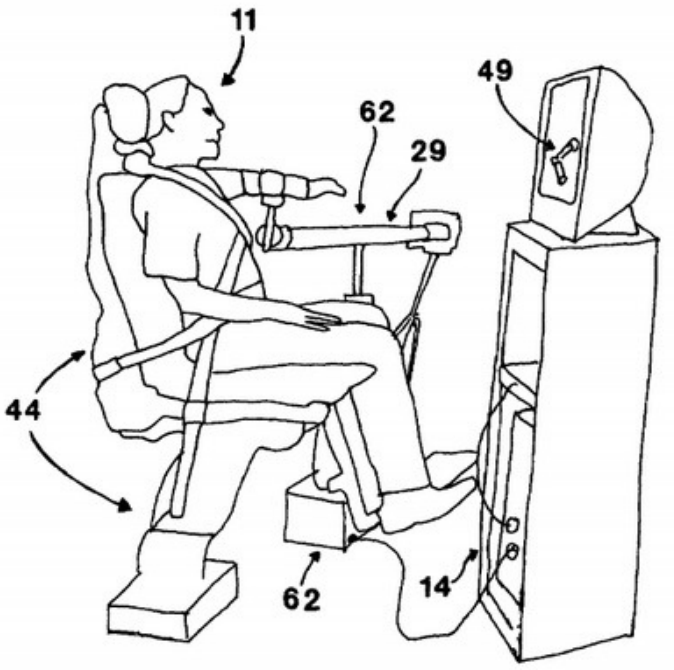


FIG. 2

US 7.252.644 B2 (07/08/2007)

This is a haptic system used to provide an assistive robotic device in combination with a 3D virtual reality workspace, to overcome gravity-induced dysfunction in upper limb.
It is much more complex than LINarm++ and should not conflict with it. It does not use the variable stiffness mechanism.



US 8.317.730 B2 (27/11/2012)

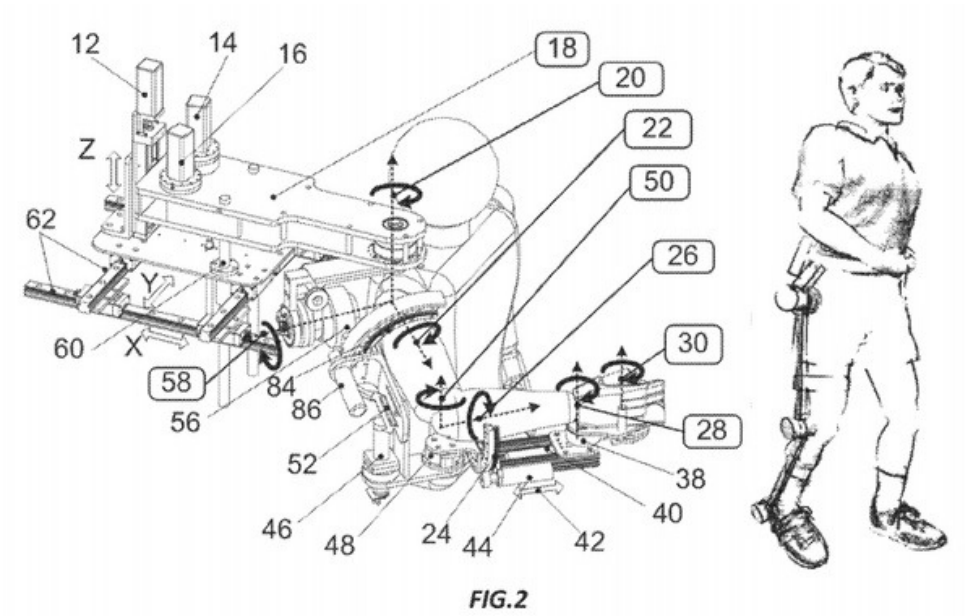


FIG.2

It is a complex hexoskeleton (8 DOF) similar to Armeo in concept. It is much more complex than LINarm++ and should not conflict with it.
It does not use the variable stiffness mechanism.
The part number 24 (circular guide) could be similar to the future joint connecting LINarm to the wrist of the patient, allowing prone-supination movement.

US 8.795.207 B2 (05/08/2014)

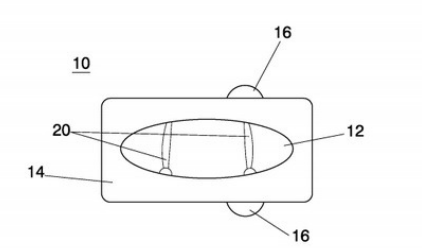


FIG. 1

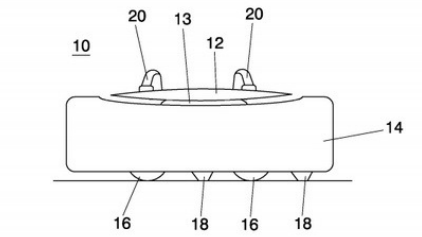
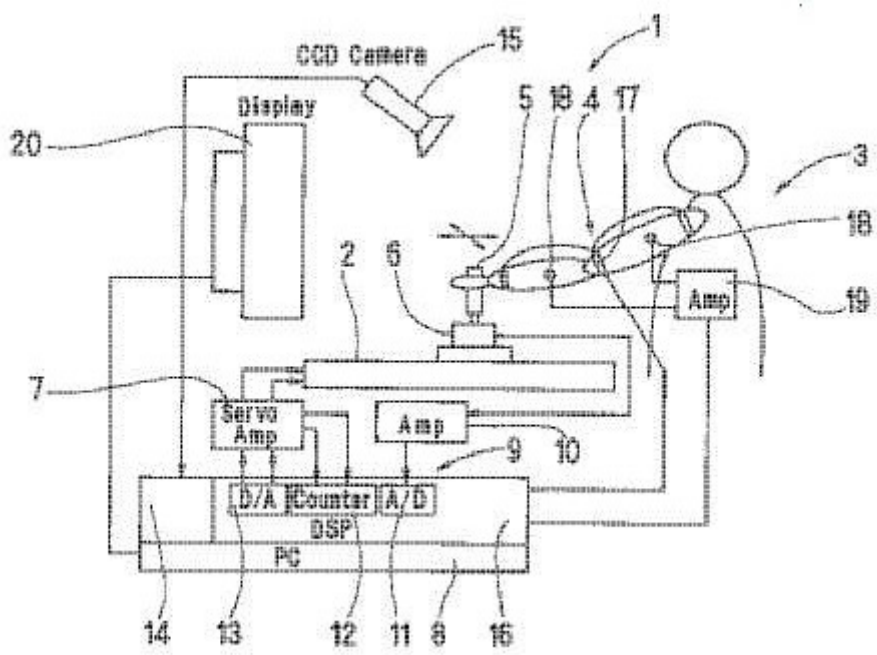


FIG. 2

This device is a kind of complex armrest. Portable, easy to use, it is something with same rehabilitation targets with LINarm.
On the other hand the mechanical architecture is completely different (it is more similar to Bi-manu track) and the motion is not linear. It does not use the variable stiffness mechanism.

JP2002272795 (A) (24/09/2002)



This Japanese patent was not found in other countries of the world and the available information is few. Its concept seems similar to LINarm's and Tailwind's. It does not use the variable stiffness mechanism.

Other patents were analyzed and classified as not confilcting / concerning with LINarm:

- US20070021692
- US4936299
- US7311643
- US5466213
- US20050273022
- US6155993
- US6613000

Appendix B - Competitors analysis

Introduction

Neurorehabilitation robotic devices are conceived and realized with the aim of increasing the intensity and the duration of rehabilitation after stroke or others brain injury. Life expectancy continues to increase while the duration of hospital recover is getting shorter and shorter. This means that the number of patients that need support in the rehabilitation is increasing. All types of robotic devices are developed to face this problem in different ways.
All the movement disorders reduce the capability to perform activities of daily living (ADL) and consequently reduce the patient's quality of life.
The main goals of robotic devices are:

- maximize the number of movement/exercise repetition,
- maximize the patient attention and engagement during therapy,
- provide motivating training context,
- involve the patient in the therapy through game and virtual reality,
- record the therapies performed by the patients,
- supply an assessment tool.

Several types of robotic devices have been developed for different parts of the body and different pathologies. We will focus on devices designed for upper limb rehabilitation, already on the market and developed for neurological diseases. Stroke is the most common cause among neurological diseases leading to upper limb movement disorders. Other causes include traumatic brain injury, spinal cord injury and other neurological diseases like cerebral palsy, Gullian-Barre syndrome and Parkinson.

There are two main application field of robotic device: support to perform ADL and providing neuromuscular training. In this paper we will focus mainly on the second one.
Devices for upper limb rehabilitation may provide different type of assistance supplying different types of therapy for the patient:

- **Active Device for Passive Therapy**: this type of device are able to produce movement and provide continuous passive motion exercises of the upper limb, independently from the force applied by the patient. In this case the patient's effort is not required and the patient can remain inactive while the device actively moves the joints of the arm.
- **Passive Device for Active Therapy**: this type of device doesn't have actuators but helps the patients during the therapy. The support can be physical (if the device give to the patient only a guide of the movement as Tailwind) or virtual (if the patient is involved in the therapy thanks to virtual reality). Devices

with virtual support are sensorized and provide different feedbacks for the patient. These devices are able to track the movement and provide feedback related to the performance of the subject. In this case an active movement performed by the patient is required.

- **Actively-Assisted Device and Therapy**: this type of devices, endowed of actuators and sensors, provide exercises in which the subject actively moves the limb and the device may provide some assistance. The patient can interact with virtual realities and games and the device can help him by actuators if it is required.

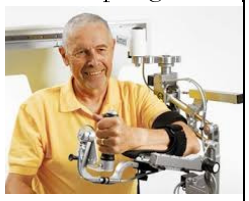
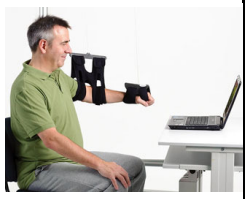
Given the importance of gravity in influencing the quality of upper-limb movements performed by neurological patients, passive devices are, in some cases, conveniently weight-compensated, i.e. these devices can passively support the weight of the patient's arm through suspension mechanisms or by springs. In this case the device doesn't generate movement of the arm but, by compensating the weight of the arm, makes movements easier.
Referring to mechanical design, two main categories of robotic devices can be identified: end-effector-based and exoskeleton-based. The difference is how the movement is transferred from the device to the patient's upper extremity and how the device can support the position of the arm:

- **End-effector based device**: this type of device physically interacts with the patient's upper extremity at its distal segment. Movements of the end effector change the position of the upper limb to which it is attached. The structure of these devices is simple but it could be difficult to isolate specific movements of a particular joint because the system produces movements that involve the upper limb but that could involve movement of other parts of the body, without constraining both the elbow and shoulder articulations.
- **Exoskeleton-based device**: this type of device have a mechanical structure that reproduce the skeletal structure of the limb, each segment of the limb is coupled to the corresponding segment of the device. They allow a precise control of the joints but have a more complex and heavy structure.

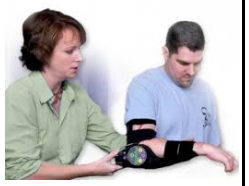
The main products on the market for upper limb rehabilitation are listed in the following table. A comparison is performed on the basis of:

- type of therapy provided by the device (Active = the patient actively moves his arm; Passive = the device moves the arm of the patient; Actively-Assisted = the patient starts the movement and the device support it only if it is necessary)
- presence of sensors (YES or NO)
- destination of use (Hospital/Home)
- price
- DOF (Degree Of Freedom)
- Mechanical design (End-effector based; Exoskeleton; weight compensation)
- Strengths and Weakness

The information of this introduction comes from one of the last and more complete reviews of robotic devices: Maciejasz, P., Eschweiler, J., Gerlach-Hahn, K., Jansen-Troy, A., & Leonhardt, S. (2014). A survey on robotic devices for upper limb rehabilitation. *Journal of NeuroEngineering and Rehabilitation*, 11, 3. doi:10.1186/1743-0003-11-3

Product	Producer	Type of therapy	Sensors	Destination of use	Price (euro)	DOF	Mechanical design	Strengths	Weakness
Armeo Power 	Hocoma	- Passive - Active - Actively-assisted	YES	Hospital	150.000,00	6	exoskeleton	- involving virtual reality - it can be used also by patient without capability to move the arm - it is an assessment tool	- very expensive - complex to use - heavy structure
Armeo Spring 	Hocoma	- Active	YES	Hospital	70.000,00 euro	7	exoskeleton +weight compensation	- involving virtual reality - compensation of the arm's weight adjustable - it is an assessment tool	- expensive - it can only be used by patients able to move the arm
Armeo Boom 	Hocoma	- Active	YES	Home	18.500$	-	weight compensation	- involving virtual reality - compensation of the arm - it is an assessment tool - no heavy structure on patient arm - quick to set up	- it can only be used by patients able to move the arm

Arm Tutor 	Meditouch	- Active	YES	Hospital and Home	5.000,00	1	exoskeleton	- presence of virtual reality - cheap - no heavy structure on patient arm - quick to set up - it is an assessment tool	- it can only be used by patients able to move the arm - it doesn't support the control of limb position
BiManutrack 	Reha Stim	- Active - Actively-Assisted	YES	Hospital	20.000,00	1	end-effector	- it can be used also by patient without capability to move the arm - it is an assessment tool - quick to set up - it allows bi-manual therapy	- it allows only one movement of the arm
Bimeo 	Kinestica	Active	YES	Hospital and Home	6.000,00	-	-	- presence of virtual reality - cheap - the healthy arm can support the movement of affected arm - it is an assessment tool - no heavy structure on patient arm	- it can only be used by patient able to move the arm - it doesn't support the control of limb position

								- quick to set up	
Diego 	Tyromotion	Active - Actively-Assisted	YES	Hospital	50.000,00	-	weight compensation	- involving virtual reality - it is an assessment tool - no heavy structure on patient arm - quick to set up - it allows bi-manual therapy	- it can only be used by patient able to move the arm
InMotion ARM 	InteractivM	- Active - Actively-Assisted	YES	Hospital	120.000,00	2	end-effector	- presence of virtual reality - it can be used also by patients without capability to move the arm - it is an assessment tool - no heavy structure on patient arm	- expensive - it doesn't support the control of limb position
Myomo 	Myomo	- Actively-Assisted	YES	Hospital and Home	-	up to 4	exoskeleton	- can helps the patient in ADL	- it can only be used by patienst able to move the arm - it doesn't support the control of limb position

Reha-Slide 	Reha Stim	- Active	NO	Hospital and Home	-	-	-	- easy to use - cheap - no heavy structure on patient arm	- it can only be used by patient able to move the arm - it doesn't support the control of limb position
Re Joice 	Saebo	- Active	YES	Hospital		-	end-effector	- involving virtual reality - it is an assessment tool - no heavy structure on patient arm	- it can only be used by patient able to move the arm - it doesn't support the control of limb position
Reo Go 	Motorika	- Passive - Active - Actively-assisted	YES	Hospital	40.000,00	2	end-effector	- involving virtual reality - it can be used also by patient without capability to move the arm - it is an assessment tool - no heavy structure on patient arm	- it doesn't support the control of limb position
Tailwind	Encore Path	- Active	NO	Hospital and Home	3.000,00	1	end-effector	- cheap - easy to use - lighter	- it can only be used by patients able to move the arm

									- no software interface - uninvolving - it isn't an assesment tools

Armeo Power (http://www.hocoma.com/): it has been designed for arm therapy in an early stage of rehabilitation. The device enables even patients with movement impairments to perform exercises with a high number of repetitions. The robotic exoskeleton with six actuated degrees of freedom allows training in a 3D workspace. The device recognizes when the patient is not able to carry out a movement and assists the patient's arm if necessary to perform the exercise. It adapts the arm support to the individual needs and changing abilities of each patient (from full movement guidance for patients with very little activity to no support at all for more advanced patients).

Armeo Spring (http://www.hocoma.com/): it is an exoskeleton with integrated springs. It embraces the whole arm, from shoulder to hand, and counterbalances the weight of the patient's arm, enhancing any residual function and neuromuscular control, and assisting active movement across a large 3D workspace. The exoskeleton structure allows to control the position and the movement of the arm. It doesn't mobilize the arm of the patient.

Armeo Boom (http://www.hocoma.com/): it has an overhead sling suspension system with low inertia to provide an adjustable amount of arm weight support and allows patients to perform self-directed, free movement exercises of the impaired arm in a 3D workspace. The system is lightweight and compact, quick and simple to set up. It doesn't mobilize the arm of the patient.

Arm Tutor (http://www.meditouch.co.il/): the system consists of a wereable and sensorised arm brace and a therapy software. It allows the patients to perform exercises and games. It doesn't provide any type of support for the upper limb and it doesn't mobilize the arm of the patient.

Bi-Manu-Track (http://www.reha-stim.de/): the device allows one movement of the arm that can be performed passively or actively with an individually adjustable difficulty. It can be use to record the improvement of the patient.

Bimeo (www.kinestica.com): the patients use their less affected arm to assist the activity of their more affected arm. The software encourages the patient to use both arms during exercises: the affected arm supported by the healthy one. It allow bi-manual therapy, uni-manual therapy, in a support surface or in a free space. It can be use to record the improvement of the patient. It doesn't provide any type of support for the upper limb and it doesn't mobilize the arm of the patient.

Diego (http://tyromotion.com/): throught a system of weight compensation the device supports the arm and allows various exercises in involving 3D virtual reality. It can be used also for bimanual therapy. It doesn't mobilize the arm of the patient.

InMotion ARM (http://interactive-motion.com/): it is an end-effector robotic device, the patient places his hand and his arm on a support. The support is linked to the actuators and allows active, passive and actively-assisted therapy. The device has 2 degrees of freedom and allows various exercises and games supported by software.

Myomo (http://www.myomo.com/): the device consists in a sensor that sits on the skin's surface and it is used to detect a person's muscle signal as he or she attempts movement. When muscles start the movement, the signal is processed by a controller to make the robot assist the person in achieving movements by the affected arm.

Reha-Slide (http://www.reha-stim.de/): the device consists of two handles that can be moved along tracks. It is designed to stimulate shoulder, elbow and wrist. The user moves the handles along the tracks. It is possible to change the work plane bending.

Re Joice (http://www.saebo.com/products/saeborejoyce/): it is an end-effector device for active rehabilitation of the upper limb. The patient places the hand on a support and through sensors it will be able to move his arm by following some games on the screen.

ReoGo (http://www.motorika.com/): the patient pleaces the arm and the hand on a support. The device allows passive, active and actively-assisted therapy with the supports of the software that propose games and exercises. The device has two degrees of freedom.

Tailwind (http://www.tailwindtherapy.com/): The device consists of two handles that move along independent, friction-free tracks. The user moves the handles along each track at a certain starting mark, in response to auditory cues. It is possible to change the tracks bending.