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Acronym: ALLADIN

D2.1: Diagnostic Device and Method for Force-Torque Measurement Based Therapy Assessment

List of Partners: Arteveldehogeschool (B)
Language and Computing NV (B)
Budapest University of Technology and Economics (HU)
Univerza v Ljubljani, Fakulteta za Elektrotehniko (SL)
Zenon SA, Robotics and Informatics (EL)
University of Wales Cardiff (UK)
Multitel ASBL (B)
The Provost Fellows and Scholars of the College of the Holy and Undivided Trinity of Queen Elizabeth near Dublin (IRL)
Országos Orvosi Rehabilitációs Intézet (HU)
Scuola Superiore di studi universitari e di perfezionamento Sant'Anna (I)

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Authors:	Stefano Mazzoleni, Eugenio Guglielmelli, Paolo Dario, Jo Van Vaerenbergh, contributions from all partners
Editing	Stefano Mazzoleni
External Review	Prof. Tommaso Leo, University of Ancona

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1. Executive summary

This document presents part of the results of Workpackage 2 (Diagnostic device) of the ALLADIN project. The content of this document was mainly built on the basis of previous achievements made in the first four months of the project, as reported in deliverable *'**D1.1** Methodology for multi centre trials'* and from the outcome of the effort carried out in the months 5-12 within Tasks 2.1, 2.2, 2.3, 2.4. Such tasks are related to the different steps of the design and development process of the ALLADIN Diagnostic Device (**ADD**). The document was produced by the SSSA ALLADIN Team, with contribution from all partners, in the period from September to December of Project Year 1 (2004). The following are the main achievements that are presented in this document:

- an in-depth review of recent biomedical literature regarding the neuroscientific basis of the ALLADIN methodology for assessment of stroke patients by means of isometric force/torque measurements has been carried out. This analysis confirmed the novelty of the proposed approach and gave additional inputs for the definition of the application scenarios (e.g. simulated tasks) and for detailed identification of the clinical protocols to be used for the experimental trials;
- starting from the ALLADIN platform specifications as defined in D1.1, the final functional and technical specifications have been defined following an iterative task-oriented approach: clinical partners have been deeply involved, also by means of two dedicated meetings between WP2 and WP3 working groups, to evaluate early prototypes and mock-ups of the ADD;
- all the mechanical structure of the ADD was designed and implemented by the WP2 partners, with the aim of realizing the best set-up for accurate measurements but taking into account safety, acceptability and anthropometric requirements for the whole range of patients and clinical operators who are supposed to interact with the ADD. A dedicated seat, three upper limb measurement modules, on adjustable foot measurement module, and related fixation solutions for the different body segments have been identified and realized;
- three sets of the F/T sensors, together with the driving & acquisition electronic equipment, have been identified, purchased and delivered to BUTE, the responsible partner for system integration. An additional back-up set of F/T sensors was also purchased for maintenance purposes;
- the general software architecture was defined and the single modules were implemented together with the main cover application and the user interface. An early prototype of ALLADIN software was circulated at month 9 to all ALLADIN partners in order to verify the appropriateness of the interaction modalities;
- one final ADD platform was integrated in BUTE on November 26-28 and verified in a dedicated project with all partners on November 29-30;
- by December 15, 2004, two additional ADD platforms were developed and tested, with minor refinements deriving from the feedback received by the clinicians;
- three final ADD platforms are now ready to be delivered to the three ALLADIN clinical centres by the end of 2004/beginning of 2005, in line with the workplan.

This document does not contain all the technical details, guideline for maintenance and the user manual of the ADD, that have been reported in the separate deliverable *'D2.2. Technical Documentation of the ADD'*.

2. The problem of quantitative assessment during the rehabilitation treatment of stroke patients

2.1 Recent findings in neuro-rehabilitation and brain sciences

2.1.1 The forward model in stroke

2.1.1.1 Definition of forward model

Motor control is fundamentally concerned with the relationship between sensory signals and motor commands. Much of this complexity arises as a simple coupling of these two transformations. Models that describe these transformations are known as 'internal models' because they model the causal relationship. One of these models is called the forward model. *This model contains information about the properties of the sensory-motor system and maps motor commands onto their sensory consequences*. Such a model is not static but change according new situations. However for a lot of functional task (drinking, opening a door, picking up a spoon, reaching to objects...), given all possibilities, it is amazing to see how highly stereotyped these categorized movement patterns are, both between repetitions of the task and between individuals on the same task.
Theories of motor imagery have been embedded within the same conceptual framework with regards to the transformation of perceived actions into motor images and motor performance. Moreover, the durations of mentally simulated movements are tightly correlated with the durations of actual movements. This is key in the ALLADIN project and bolstered by observation of activity in motor areas during imagery tasks. Studies of brain-injured, hemiplegic patients suggest that they may retain some ability to generate accurate motor images of even those actions that they cannot perform. This brings us to the formulation of three different situations that can be analyzed within the ALLADIN approach.

1. *A preserved forward model with a reduced motor output*

In that case the measured ADD parameters are very similar to normal activity during the observation of the tasks and during the imagination. Nonetheless the measured ADD parameters during movement initiation can be either a strong or weak copy of the former. In both case a motor correlate of the imagined movement exists.

2. *A preserved forward model with a disorganized motor output*

Another possibility is that although the imagined sequence exists the movement initiation yields a complete disorganized output. In that case doubt exists about the quality of the motor correlate.

3. *A modified forward model with an adapted motor output*

Paralysis involves changes in behavior that arise from altered interactions with the environment. This leads to a transformation of the expected sensory consequences related to a remaining motor output capacity. The ADD values will show new movement representations during watching and preparation connected to a reconfigured but repeatable motor output.

4. *A Failing forward model*

In specific types of stroke involving frontal, parietal and temporal areas the forward model can fail or be absent. In the first case movement simulation as well as motor output will show timing inconsistencies but a quite well kept directional vector is present. The absence of a forward model leads to misunderstanding of the task and in most cases a random output during imagination and initiation.

2.1.1.2 Anatomical structures

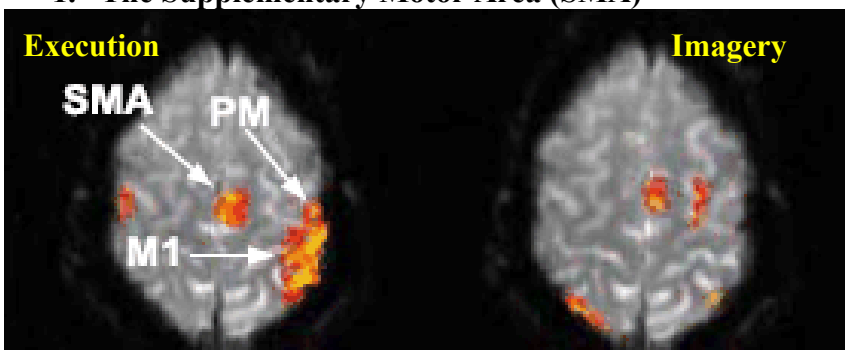
The forward model is built on the information coming from multiple motor and sensory areas and results from bi-directional excitatory links between sensory and motor representation that are formed largely from correlated experiences of observing and executing action.

Imagery of voluntary movement engages somatotopically organized sections of the primary motor cortex in a systematic manner and some body-part-specific region in the non primary motor areas. A strongly activation of the Anterior Intraparietal Cortex (IPC) is also present during motor imagination.

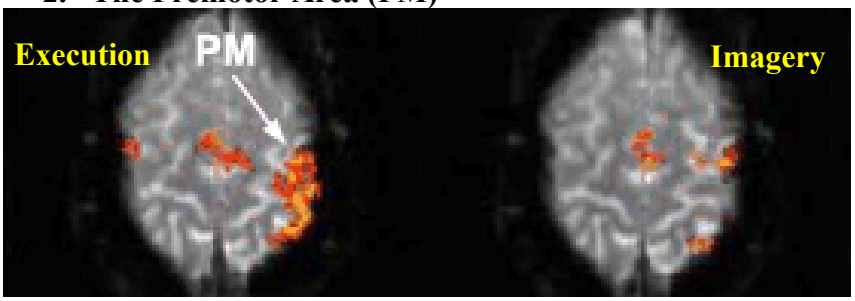
Observation and explicit motor imagery show consistent effects which facilitate corticospinal excitability and are both tested during the ADD measurements. The greatest facilitation is observed during actual imitation of the previously seen action. This is consistent with the test design, where a patient must imitate a task that was immediately shown before. Since the facilitation of corticospinal excitability is present during active (no instructions) and passive (with instructions) observation, in both conditions changes in the ADD parameters are expected.

Summary of typical activation areas:

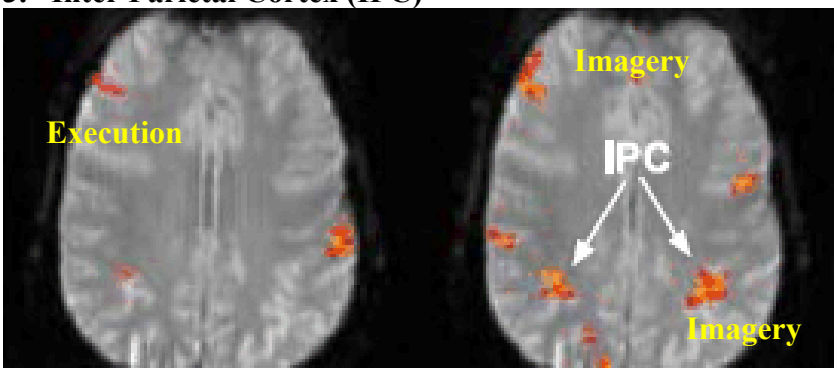
1. **The Supplementary Motor Area (SMA)**



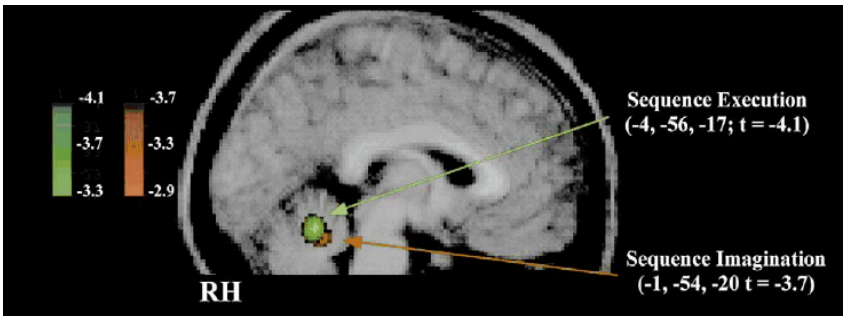
2. **The Premotor Area (PM)**



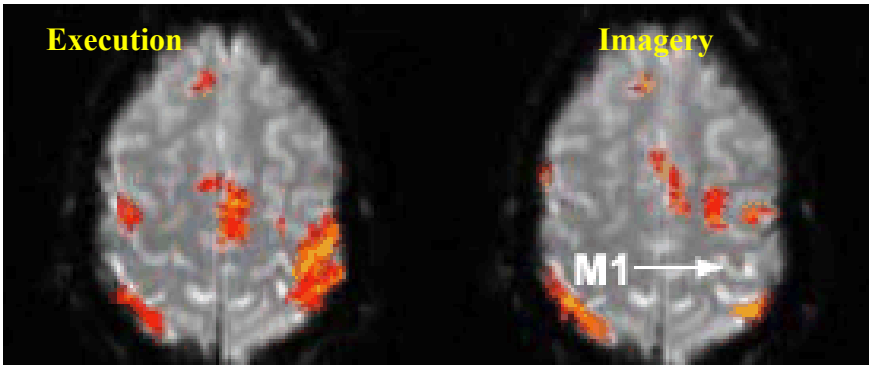
3. **Inter Parietal Cortex (IPC)**



4. **Cerebellum**



5. The Primary motor cortex



2.1.2 The ALLADIN approach of the analysis of the forward model

2.1.2.1 Introduction

The emphasis in the ALLADIN stroke evaluation lays on the evaluation and interpretation of brain processes responsible for of task specific performance. ALLADIN uses Activities of Daily Living (ADL) as prime movers for its measurements.

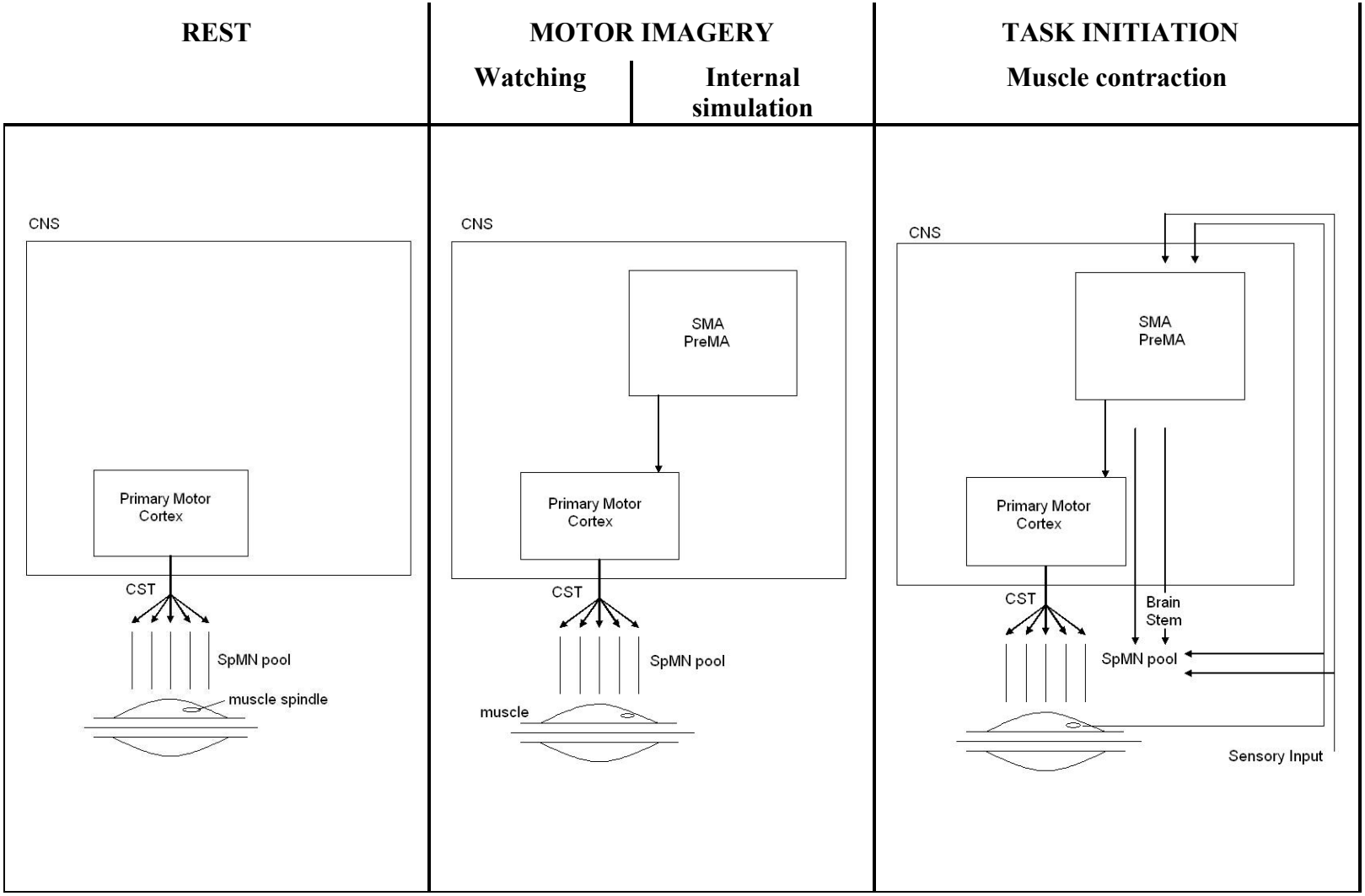
Six tasks were selected each demonstrating features of reachable functional milestone during recovering from stroke.

Drinking a glass of water
Taking a spoon
Turning a key
Lifting a bag
Reaching to a bottle
Lifting and carrying a bottle to the opposite side

Table 1. The list of the six tasks

These tasks are routine behaviors with strong associated forward models. For that reason, they are easier to measure than isolated movements. Also the motor pattern is expected to be highly predictable and easy repeatable.
The ADD sensors are located as such that each of them can deliver supplementary and complementary information on the forward model and its motor representation. The behavior of the patient is the combined output of all parameters registered by all sensors during all proposed tasks.

2.1.2.2 Protocol design explaining the anatomical involvement during the different ALLADIN measurement steps.



2.2 *The use of isometric force-torque measurements for functional assessment*

2.2.1 Introduction

In ALLADIN it was decided to follow an Unsupervised Learning approach; however some uncertainty existed about the parameters. Indeed force torque measurements consist of a huge pool of information that must be canalized to neurological coherence.
The combination of all investigated values represents the status of the system and will define its performance. In some cases different combinations with different values can lead to similar performance. These differences are the expression of natural variations and must be taking in to account when analyzing recovery.

What follows is a description of all parameters in an attempt to improve data selection and data preprocessing an essential shackle in the flowchart hereunder.

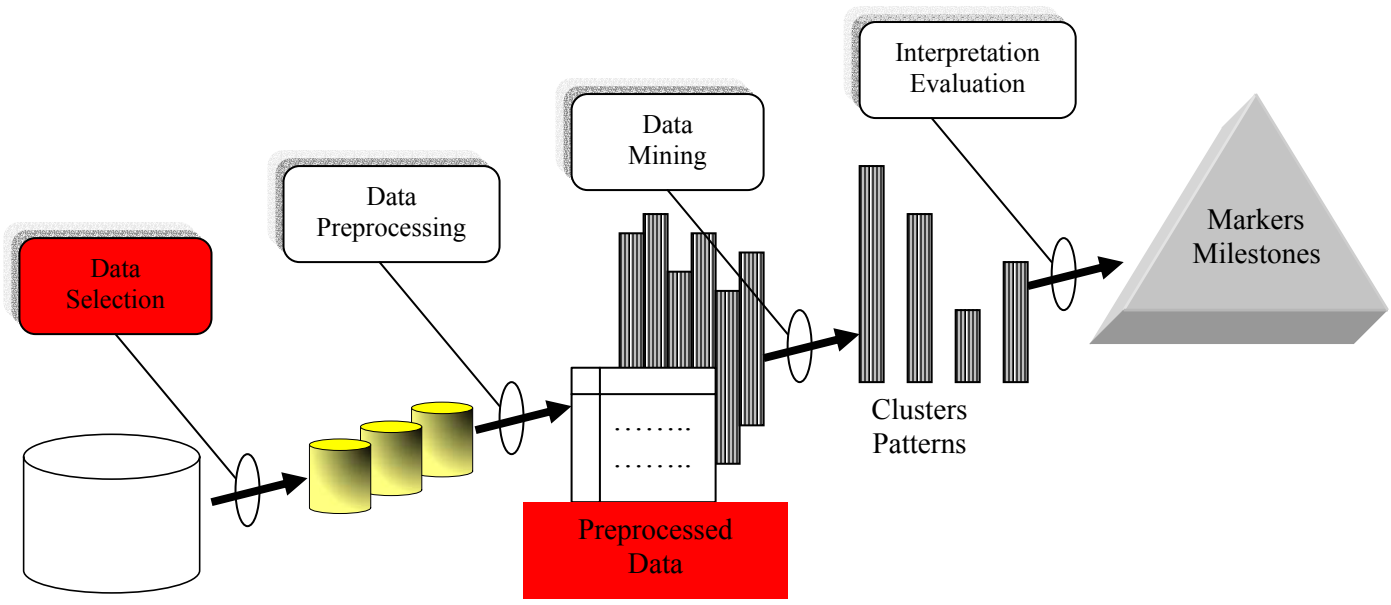
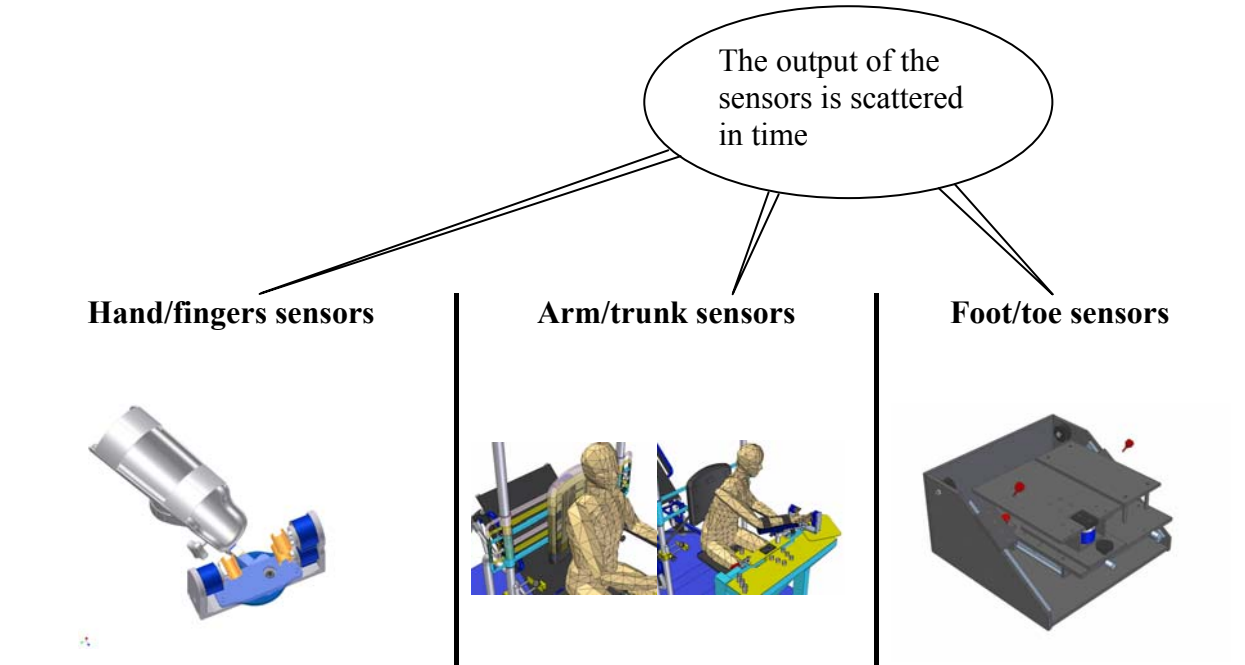


Figure 1. The process of data processing and interpretation in ALLADIN

The number of data increases rapidly because of

1. The number of available channels.
2. The specific time relation that exist between the channels, which is on itself a valuable parameter.

A calculation and estimation of the number of parameters will be described at the end of section 2.2.



Thumb	Index	Middle finger	Arm	Back	Seat	Foot	Big toe
Ch 1	Ch 1	Ch 1	Ch 1	Ch 1	Ch 1	Ch 1	Ch 1
Ch 2	Ch 2	Ch 2	Ch 2	Ch 2	Ch 2	Ch 2	Ch 2
Ch 3	Ch 3	Ch 3	Ch 3	Ch 3	Ch 3	Ch 3	Ch 3
Ch 4	Ch 4	Ch 4	Ch 4	Ch 4	Ch 4	Ch 4	Ch 4
Ch 5	Ch 5	Ch 5	Ch 5	Ch 5	Ch 5	Ch 5	Ch 5
Ch 6	Ch 6	Ch 6	Ch 6	Ch 6	Ch 6	Ch 6	Ch 6

For each channel the following variables are available: (forces) Fx, Fy, Fz, (torques) Mx, My, Mz.

Figure 2. Measurement channels for the different sensors of the ADD

2.2.2 Parameter

2.2.2.1 Introduction

The following described parameters are measured during the different phases of the functional tasks containing the imagination and initiation activity. The parameters are always obtained during the first second of each measurement. The raw signal, the fitted model and the signal timing are the coarse categories.

2.2.2.2 The raw signal

2.2.2.1.1 Force measurements

From the force measurement the mean **force**, **peak force** and **RMS** are captured.

2.2.2.1.2 Torque measurements

The **mechanomyogram** represents the mechanical vibration or the mechanical activity of the contracting muscle and is produced by lateral dimensional changes of a number of active muscle fibers. The recording of the mechanomyogram is important in ALLADIN because it gives a good estimation of the motor output of the system. The recording of this oscillation is indicative of the motor unit activation strategy involving both the number and type of recruited motor units (time domain) and their firing rate (frequency domain) and this on the basis of the MMG/force relationship during voluntary contraction (Figure 3).

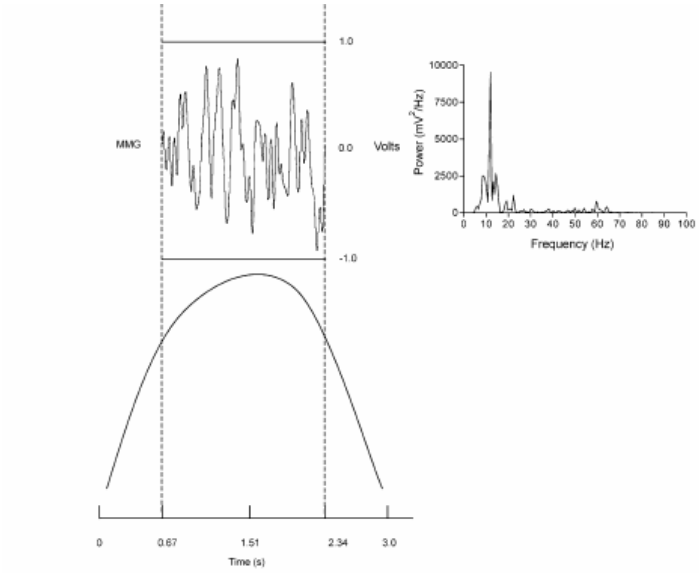


Figure 3. Example of mechanomyogram of an arm flexion (time and frequency domain)

In ALLADIN it is not the aim to measure the involvement of one muscle but a functional chain of muscles. This is a very new approach. An example can be seen in Figure 4.

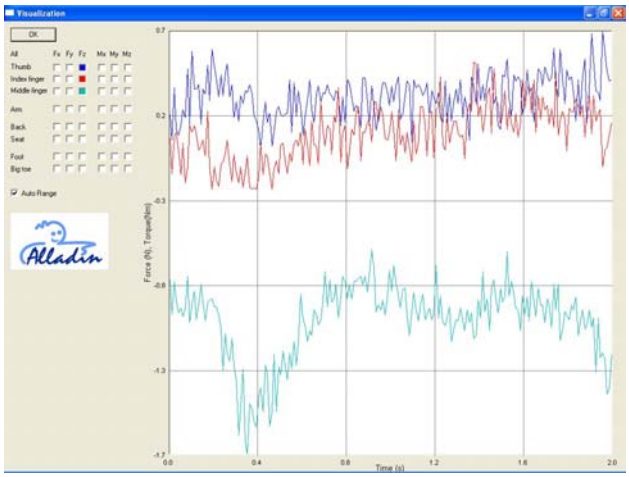


Figure 4: Force torque measurement of thumb, index and middle finger

The **peak amplitude**, **mean amplitude** and **RMS** in the signal approximate the number of motor unit involved and **the peak frequency** the firing rate of the units.

This knowledge is very important to describe:

- A correct, adapted or absent motor correlate of the forward model
- A correct, absent, reduced or disorganized motor output during movement preparation.

The **end point deviation** is another parameter during the torque measurements and will compare the virtual endpoint of segment derived from the torque measurement with the required endpoint. This explains in another way the existing of a task dependent forward model.

2.2.2.2 System identification

Human functional movements are highly stereotyped and posses a considerable degree of smoothness. The latter is an important marker for the movement quality. Abnormal interruptions stand for low level of control. An optimal model must exist for each measured channel and will be described as a mathematical linear or non linear function. During recovery the coefficients of these functions will move to those seen in normal controls.

2.2.2.3 Signal timing

Between the different body segments and consequently between data from the different sensors exists an optimal timing. Possible delays will reflect the neural organization within the functional movement and are critical for recovery. Decay of this marked synchronization underlines the disintegration of the forward model.

2.2.1 Analysis

The ADD is a new challenging instrument that requires a database containing reference values with models for healthy subjects with a same average age than the experimental group. Arteveldehogeschool undertakes this task during January and the first months of the clinical trial when the number of stroke patients is still low.

A very quick calculation shows a high number of ‘variables’ determining a particular state (behavior). If we take the forces parameters: **mean force**, **peak force, RMS,** the torque parameters: **peak amplitude**, **mean amplitude, RMS, peak frequency** and the **endpoint determination**, we arrive at 8 x 48 channels = 384. If we add a minimum of 3 determinants for the fitted model, 3 x 48 = 144 and 8! possibilities (in that case we reduce the possible values to the number of sensors) for describing the movement synchronization = 13440, we arrive at 13668 variables. This string of ‘numbers’ (value of a variable) will deliver the code of a particular state that can vary from normal to complete deficient. However this means not that there exists only 1 normal condition.

3. General presentation of the ALLADIN system

3.1 Introduction

The ALLADIN system, according to the methodolgy described in Deliverable D1.1, is composed by a platform, called ALLADIN Diagnostic Device (ADD), and a software, which aim is to provide the users, that are mainly the physiotherapists, all the functionalities that are needed to perform the measurements recorded during the proposed ADL tasks. In the following sections, all the components which form the ALLADIN system will be described in details. These components are:

- The user interface
- The ALLADIN Diagnostic Device (ADD)
- The Force/Torque data acquisition
- The Natural Language descriptions
- The Audio recording
- The ALLADIN database

3.2 The user interface

3.2.1 The ALLADIN PC interface

In order to accomplish the different operations of measurement on the patients during all proposed tasks a software is been developed. The design process of the software has been carried out by implementing the functionalities which have been presented in D1.1 and taking into account the comments and the suggestions from all partners.
A brief introduction to the functionalities offered by the ALLADIN PC interface follows. A detailed technical documentation is presented in Deliverable 2.2, Technical Documentation of the ALLADIN Diagnostic Device.

At start up, the ALLADIN software presents a first window, which allow the user to log in, by inserting username and password. (Figure 5)

Figure 5. The login window

From the main menu (Figure 6) it is possible to access to all the functionalities requested by the ALLADIN Force-Torque Measurement Method, described in D1.1. The main menu is sub-divided in 4 frames:

- Medical data
- Users
- Synchronization
- Administrative tools

From the 'Medical Data' frame, the following functionalities are available:

- Open a patient record
- Start a new session of measurements
- Create a new patient record

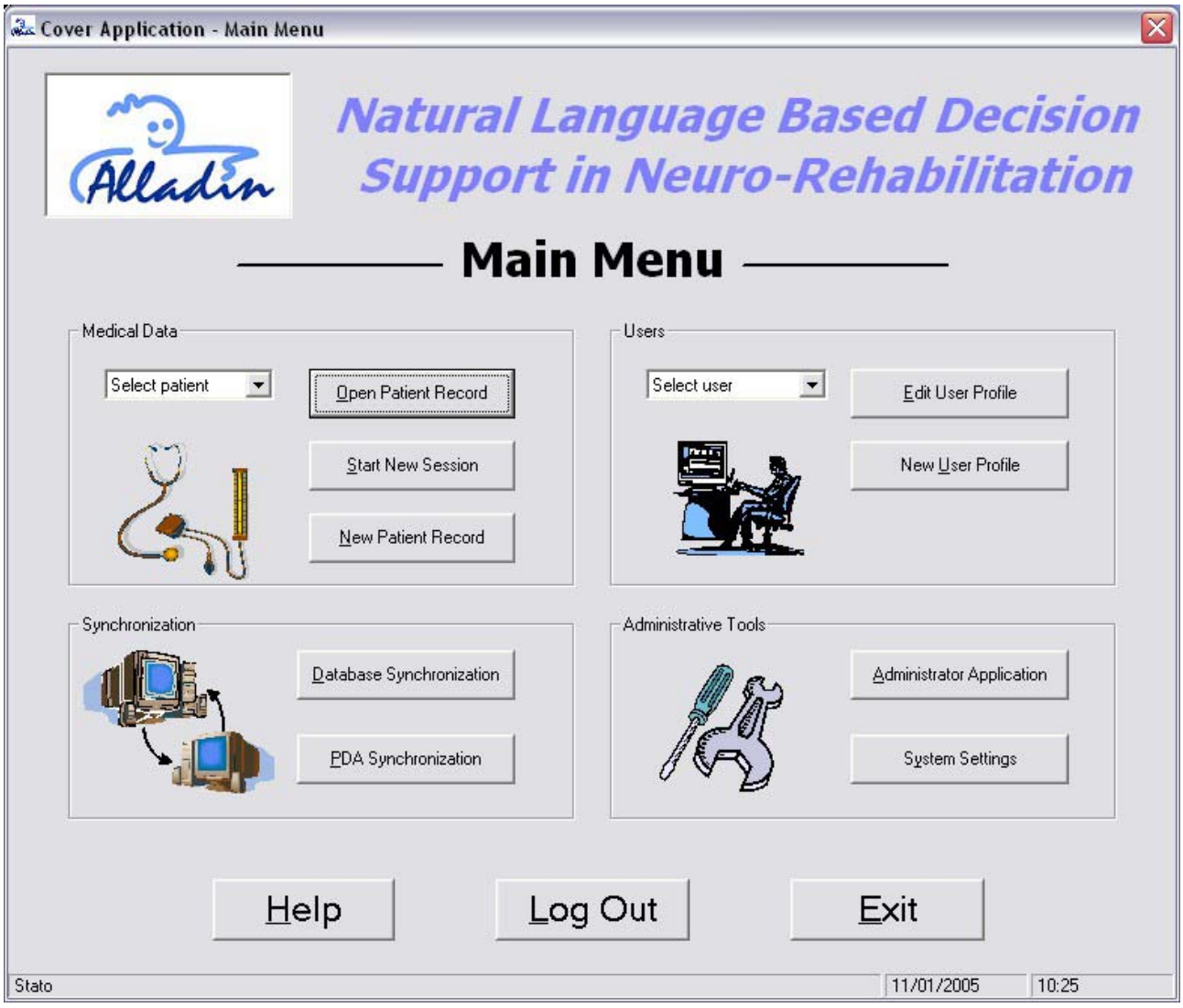


Figure 6. The main menu window of the ALLADIN PC interface

From the 'Users' frame, the following functionalities are available:

- Edit an user's profile
- Create a new user's profile

From the 'Synchronization' frame, the following functionalities are available:

- Synchronization with the global database
- Synchronization with the PDA

From the 'Administrative tools' frame, the following functionalities are available:

- Administrator Application
- System Settings

Besides, from the main menu window, an user can logout, allowing a different user to login, ask for an online help and definitively exit.

There different types of users:

- The ALLADIN Diagnostic Device physiotherapist (*ADD PT*)
- The Natural Language physiotherapist (*NL PT*)
- The *Principal Investigator*
- The *System Administrator*

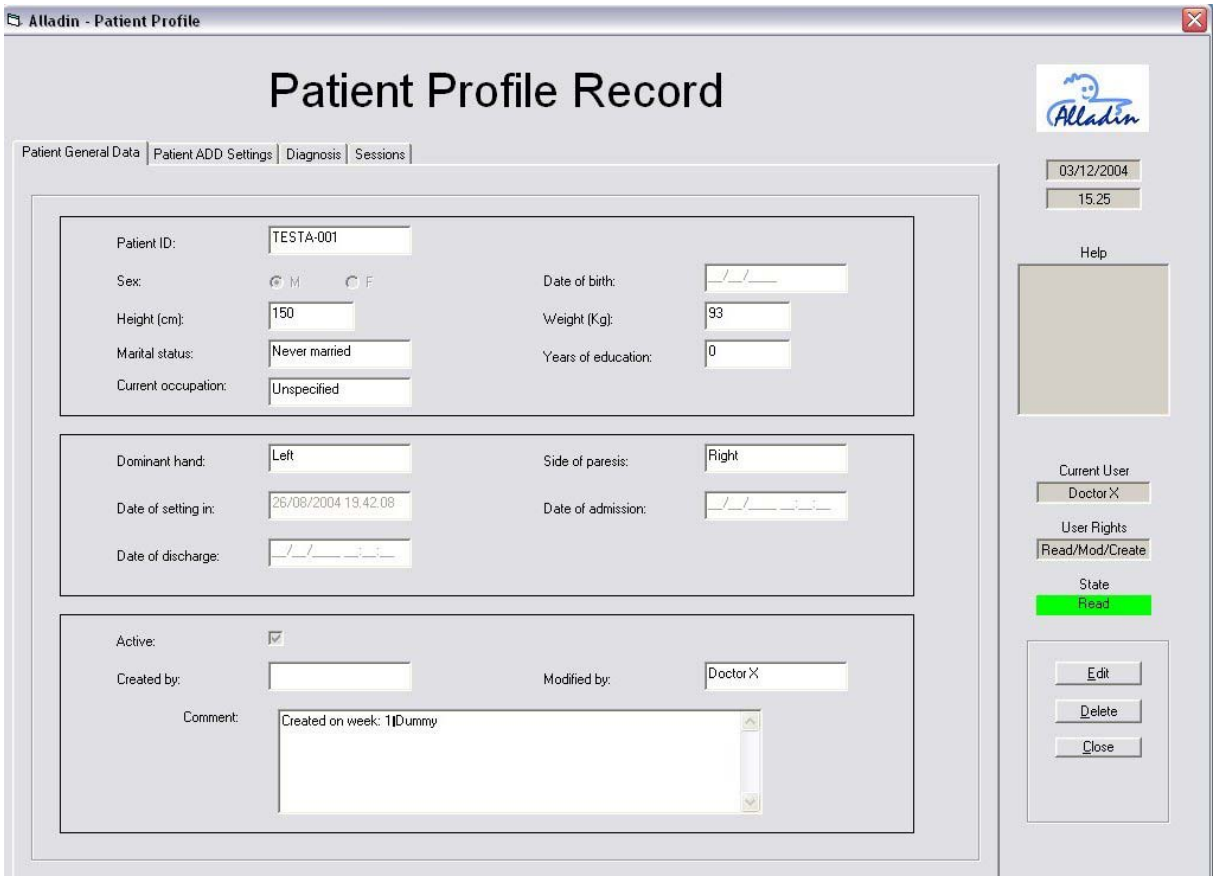


Figure 7. The patient profile record – General data

Each type of user has different access rights in the use of the functionalities of the software. Figure 7 shows the Patient Profile Record window which collect different type of data:

- General data
- ADD settings
- Diagnosis
- Sessions

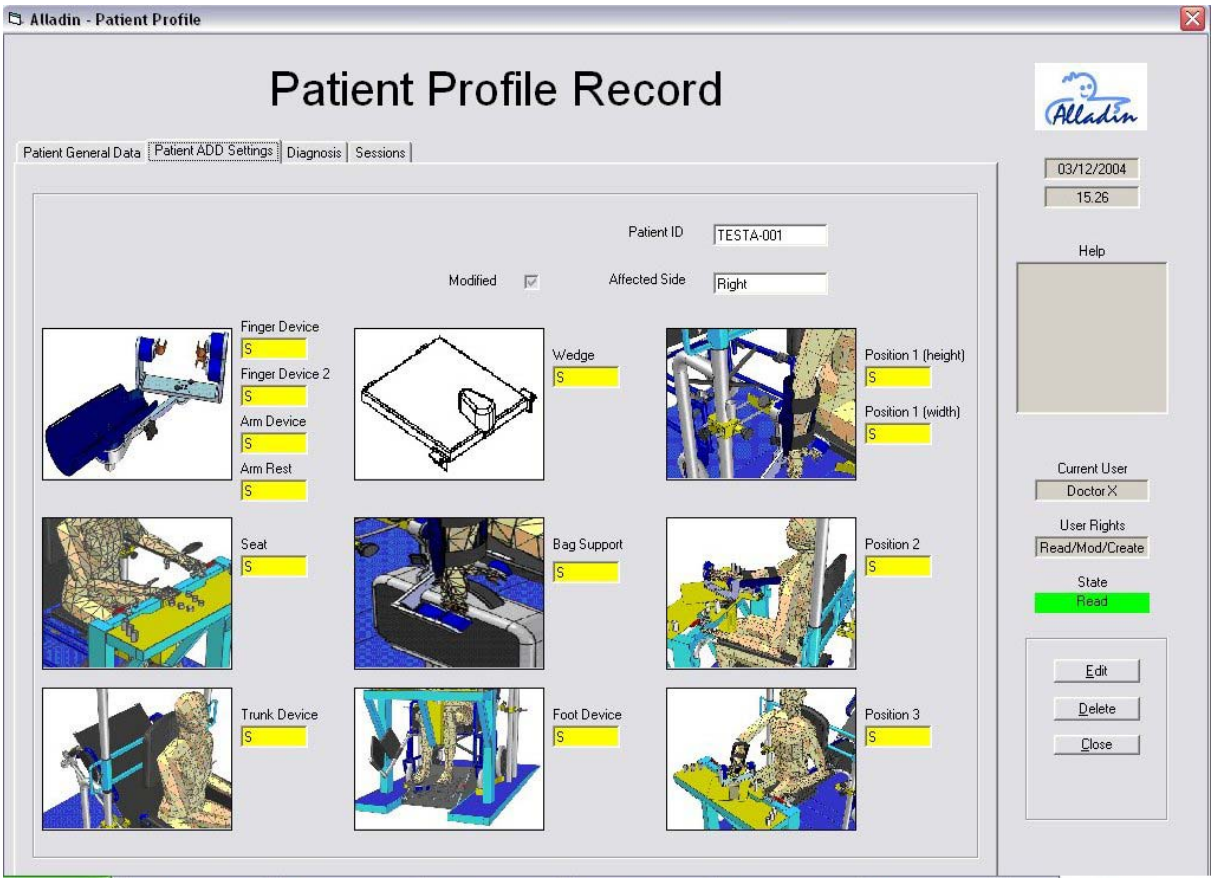


Figure 8. The patient profile record-ADD settings

The user can edit the size (S, M, L) of the different devices in the Patient Profile Record/Patient ADD settings. Each size is code with different colours, according the same coding that can be found on the ADD (Figure 8):

- Small size: yellow
- Medium size: green
- Large size: blue

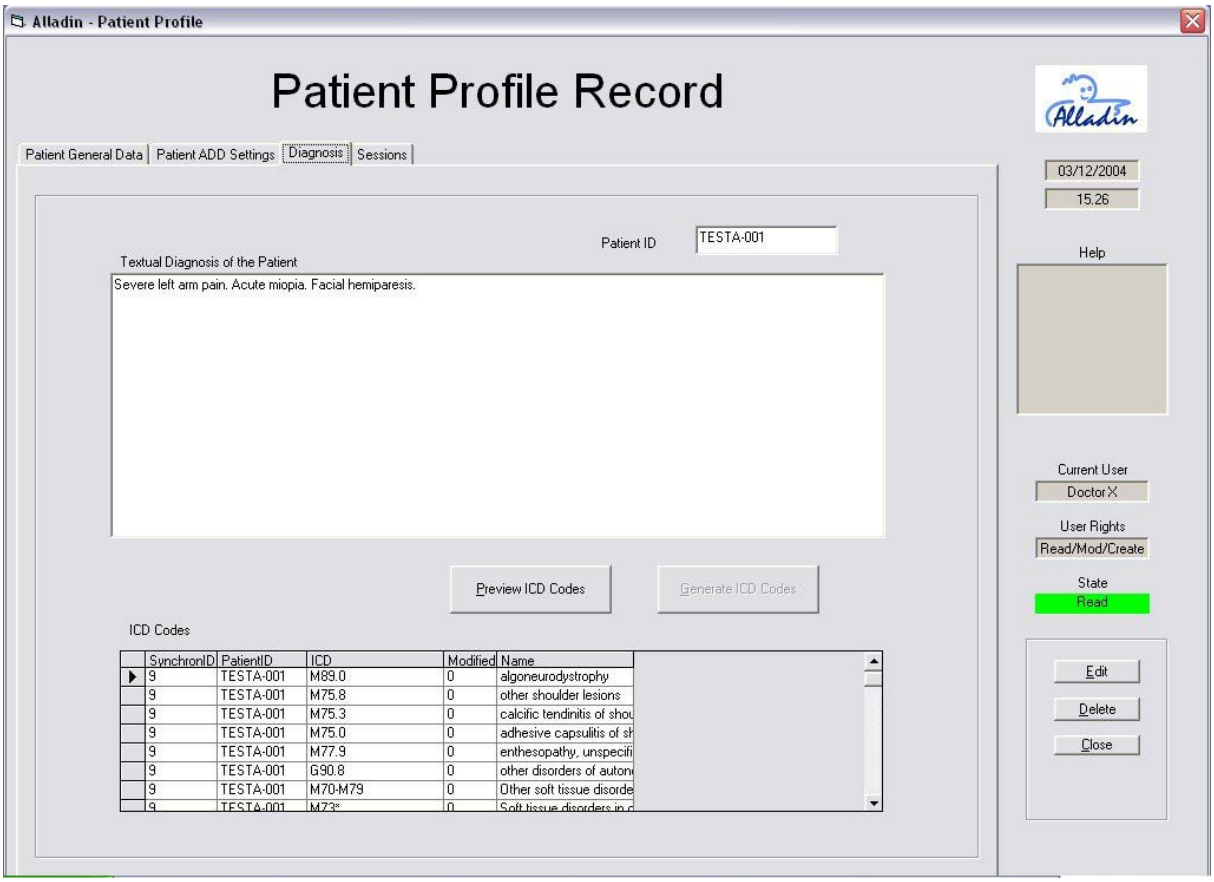


Figure 9. The patient profile record-Diagnosis

Figure 9 shows the Patient Profile Record part related to the Diagnosis: a textual description of the patient's diagnosis can be edited in the box and a calculation of the ICD codes related to the present diagnosis can be made.

The ICD codes can be stored in the Local Database. The user can also choose to generate the ICD codes related the single words which form the text.

Moreover, once the ICD codes are generated, the user can delete some of them from the list and they will be deleted from the Local Database.

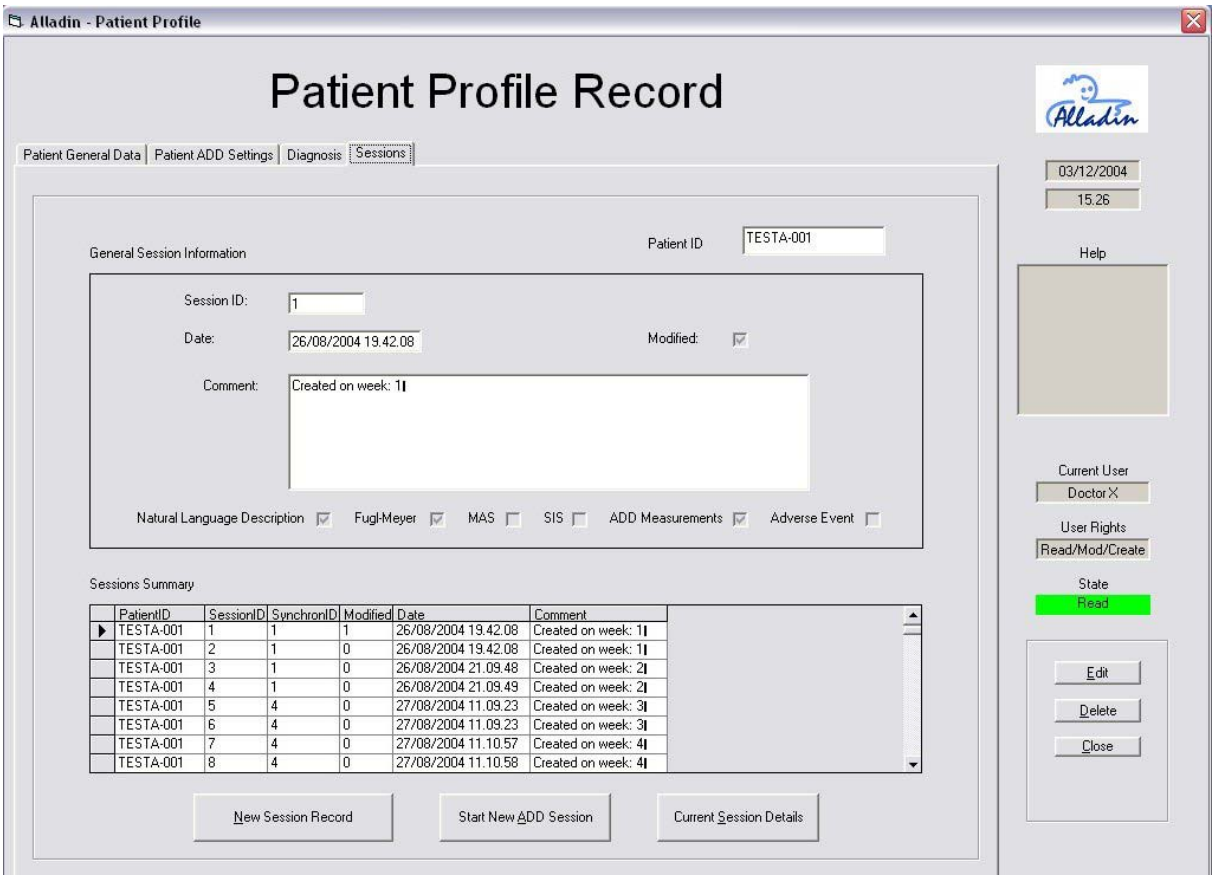


Figure 10. The patient profile record-Sessions

All the information related to the Sessions can be found in the Patient Profile Record/Sessions. From this panel (Figure 10) it is possible also to:

- add a new session record;
- start a new ADD session;
- visualize the current session details

From this window the user can visualize all the details related to the current session.

The details are composed by the following items:

- Natural language description
- Fugl-Meyer scale description
- Motor Assessment Scale description
- SIS score description
- ADD measurement description
- Adverse event

Figure 12. The User Profile Manager

The Administrator can insert the profiles of different users through the User Profile Manager (Figure 12). From this panel he can insert all the information related to each user:

- User ID: it identifies the user, through the abbreviation of the clinical centre and a progressive number;
- Name: the name the user must insert at login;
- Password: the password the user must insert at login;
- Group: Natural language PT, ADD PT, Principal Investigator, Administrator. Each user is assigned by the System Administrator to one group among the previous ones;
- Active: it allows to insert or to delete the user among the active profiles;
- Language model: can be chosen between British English (ENUK) and American English (ENUS);

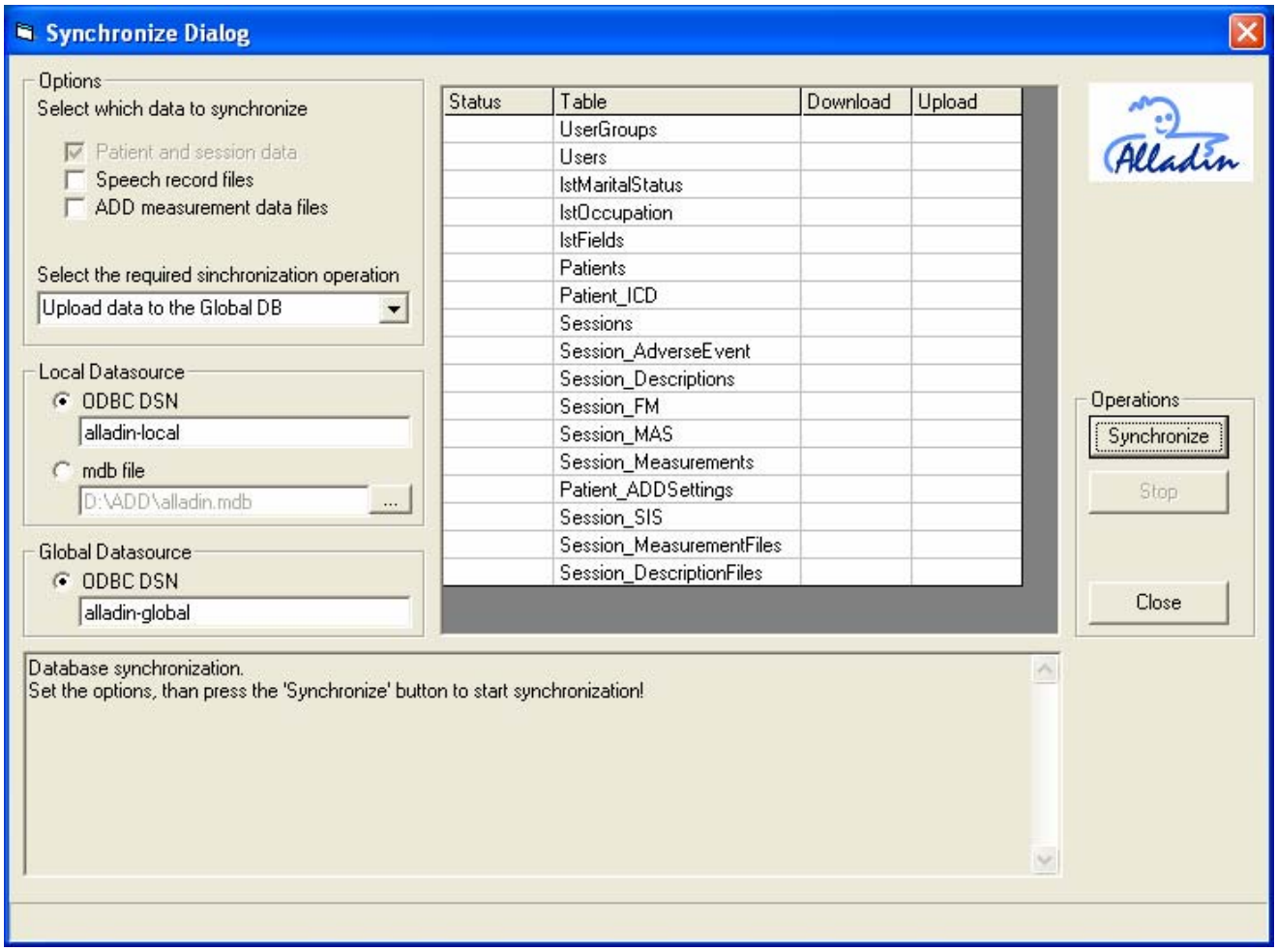


Figure 13. The Synchronize Dialog

The data collected in the three different clinical centre has to be weekly upload to the Global Database. The engineering Partners can download the data from the Global Database in order to perform the data analysis. Figure 13 shows the panel from which the user can select one the following synchronization operations:

- Download data from the Global Database
- Upload data to the Global Database
- Both download and upload

and choose the type of data (Patient and Session data, Speech record data, ADD measurement data) to download/upload.

As regards the PDA Synchronization, see paragraph 3.2.2 (The ALLADIN PDA interface).

The System Administrator can use some administrative tools in order to monitor and set the parameters related to the measurements:

- Administrator application
- System settings

The Administrator application allows to visualize the status of the sensors, through bars which show the present readings for each of the six components (F_x, F_y, F_z, M_x, M_y, M_z).

From the System settings panel it is possible to set the Natural language files and the ADD measurement paths, the ID of the clinical centre and some other information, such as synchronization details, week and database version.

The window related to the Start New Session functionality shows anthropometric information and the settings for the ADD (Figure 14).

Before patient entering in the ADD, the ADD PT has to calibrate the sensors. It can make to start this operation ("Calibrate sensors"). After the completion of this operation, the user has to follow ten instructions in order to set the ADD for the patient.

For each task, four measurements have to be recorded (Figure 15). At the end of each measurement, the user has the possibility to choose if the data are valid or not, clicking on the respective button. He can also visualise the data just recorded ("Plot"). At the end of the session, composed by six ADL tasks, if some measurement is not yet marked as "valid" or "invalid", a measurement validation summary window appears, in order to allow the user to mark each measurement.

During the measurement session, the patient watch a second monitor, where he can watch the video related to each task and listen to the audio instructions, in order to perform the exercises in the correct way and with the correct temporization (Figure 16).

The audio and written instructions are available in four different languages: Dutch, French, English and Hungarian.

If the measurement session, for some reasons, linked to the safety of the patient, is stopped by the user through the "Abort" button, the Adverse event realization must be filled, in order to record the reasons of stopping and the necessary measures which have been taken (Figure 17).

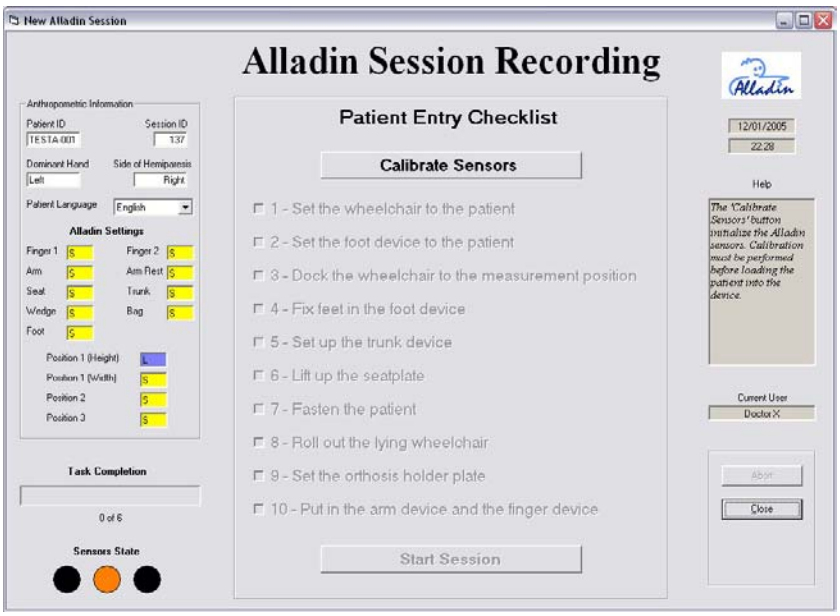


Figure 14. The ALLADIN Session recording panel-first window

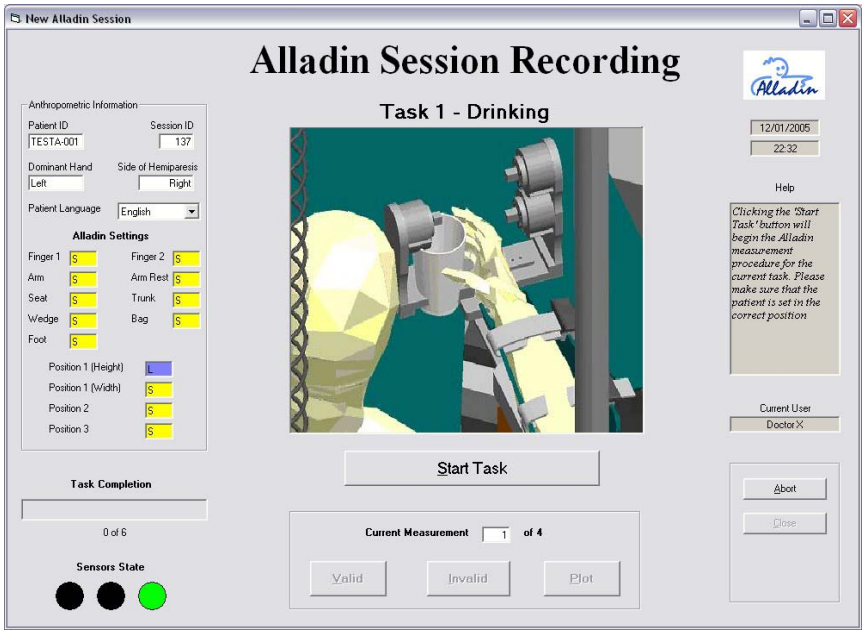


Figure 15. The ALLADIN Session recording panel-second window

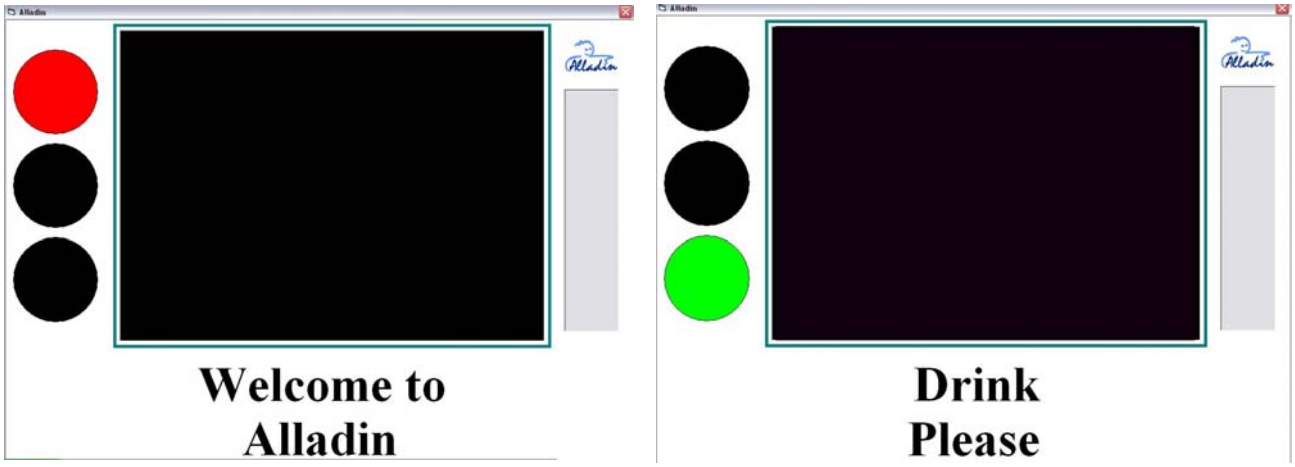


Figure 16. The windows on the patient's monitor

Figure 17. The Adverse event realization

3.2.2 The ALLADIN PDA interface

One of the goals of the ALLADIN project is to use natural language descriptions to do the assessment of the patients. These assessments are recorded on PDA so that the physiotherapist is not "bound" to his desk and can perform the assessment close to the patient.

To store these assessments into the ALLADIN Cover Application database (Figure 18), there is the need to convert the speech into text. This part is performed using speech recognition engine provided by the Multitel ASBL. It can be seen as a way to transcribe the physiotherapist natural language diagnostics faster than having to type it directly using a keyboard.

As can be seen in Figure 66. ALLADIN Software Architecture, the physiotherapist will use a PDA to record patients' functional recovery. The therapist will pronounce the sentences quasi naturally and use the ALLADIN PDA interface to convert speech into text.

The ALLADIN PDA interface or patient transcription manager is a module dedicated to automatically import those speech audio recordings and use a speech recognition engine to transcribe it into text. After manual validation, the results are stored in the ALLADIN Cover Application local database. This module is part of the Cover Application but it can also work as a stand alone application. This, to prevent the PC from being blocked when therapeutic sessions are hold.

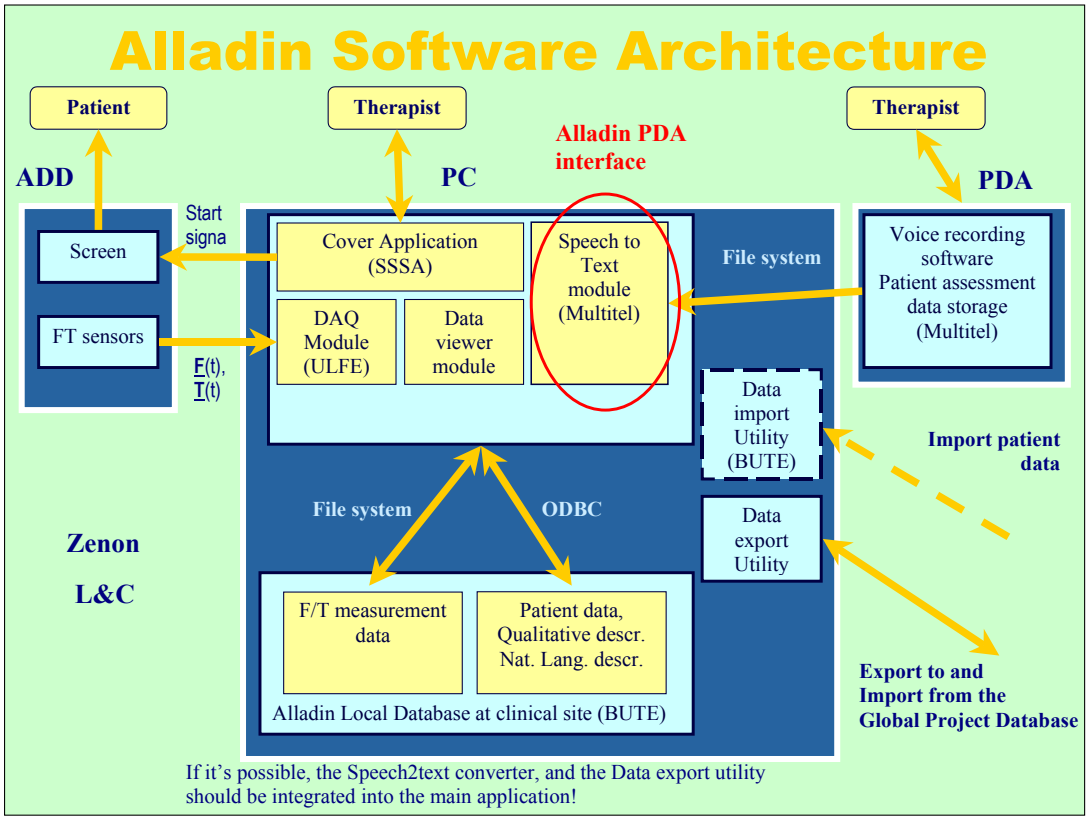


Figure 18. The ALLADIN Software Architecture

This module is easy to understand:

- On the one hand, you have audio recordings of speech, which were recorded per session / patient / physiotherapist. The audio quality of these recordings is immediately verified by the PDA software.
- On the other hand, you have the speech to text module embedded into the ALLADIN Cover Application which:
    - Automatically import the audio recordings,
    - Performs speech recognition analysis and translates speech into text,
    - Let user manually validate the results,
    - Stores the verified results into the ALLADIN Cover Application database.

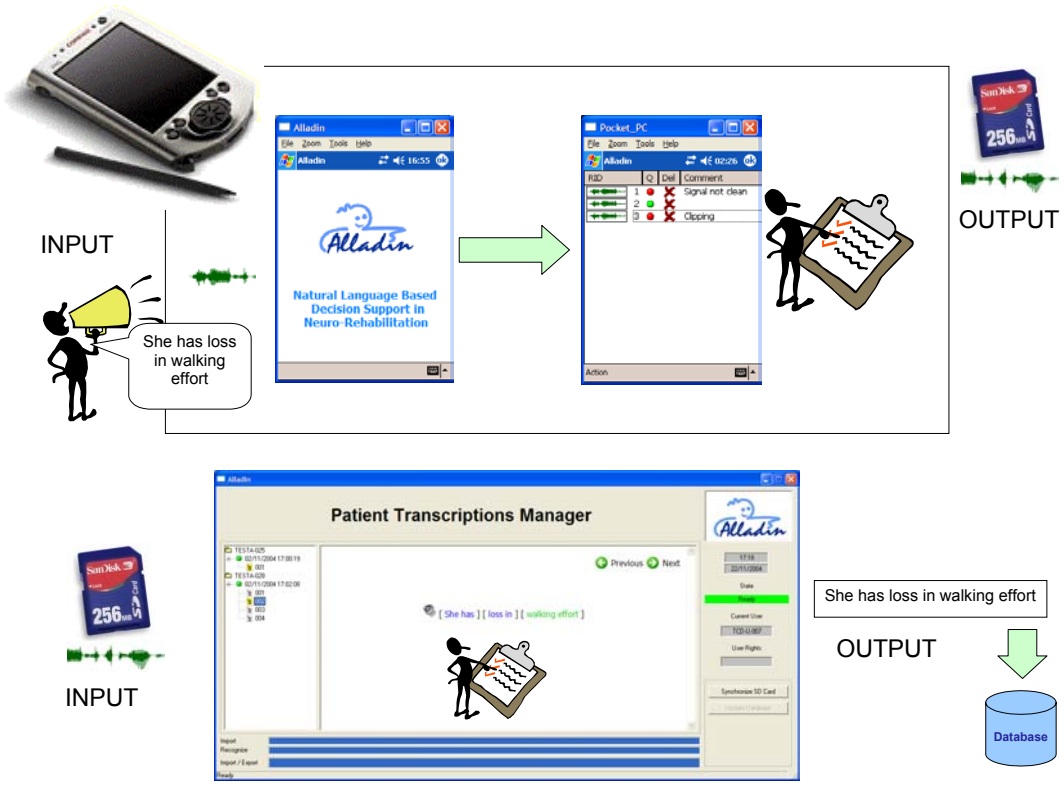


Figure 19. The ALLADIN PDA interface

The user interface helps to transcribe speech into text faster than having to type text on keyboard. When a physiotherapist is logged on the ALLADIN Cover Application, he can use the ALLADIN PDA interface to:

- **Synchronize** the SD Card sessions with the ALLADIN local database,
- **Check and validate** the audio recordings,
- **Update** the ALLADIN local database with the verified transcriptions.

The ALLADIN PDA user interface helps physiotherapist to easily check and validate each recordings created on the PDA using a multimodal user interface. The therapist has access to the recordings he has created with the PDA Software[1], he can listen to these recordings and compare them with the text output of the speech recognition engine. When there is a mistake, he is able to correct the sentence and store the output in the database.

Typical use of the patient transcription manager

When using the patient transcription manager:

- Launch the patient transcriptions manager (ALLADIN PDA interface),
- Put the SD Card in the SD Card Reader of the PC,
- Push the Synchronize SD Card button to **create the patient files** on the PDA from the ALLADIN local database,

[1] Please read section 4.6 Audio recordings for more information

- Remove the SD Card from the SD Card Reader of the PC and put it in the PDA slot above the device,
- Use the PDA Software to record diagnostics[2].

Once sessions are recorded:

- Launch the patient transcriptions manager.
- Put the SD Card in the SD Card Reader of the PC.
- Push the Synchronize SD Card button in order to:
  - **Update the database**,
  - **Create the patient files** on the PDA.

During the synchronization, the recognition engine will process all the recordings one by one in the background. The user can select the transcriptions in the left panel of the user interface and verify/validate them in parallel with the recognition process.

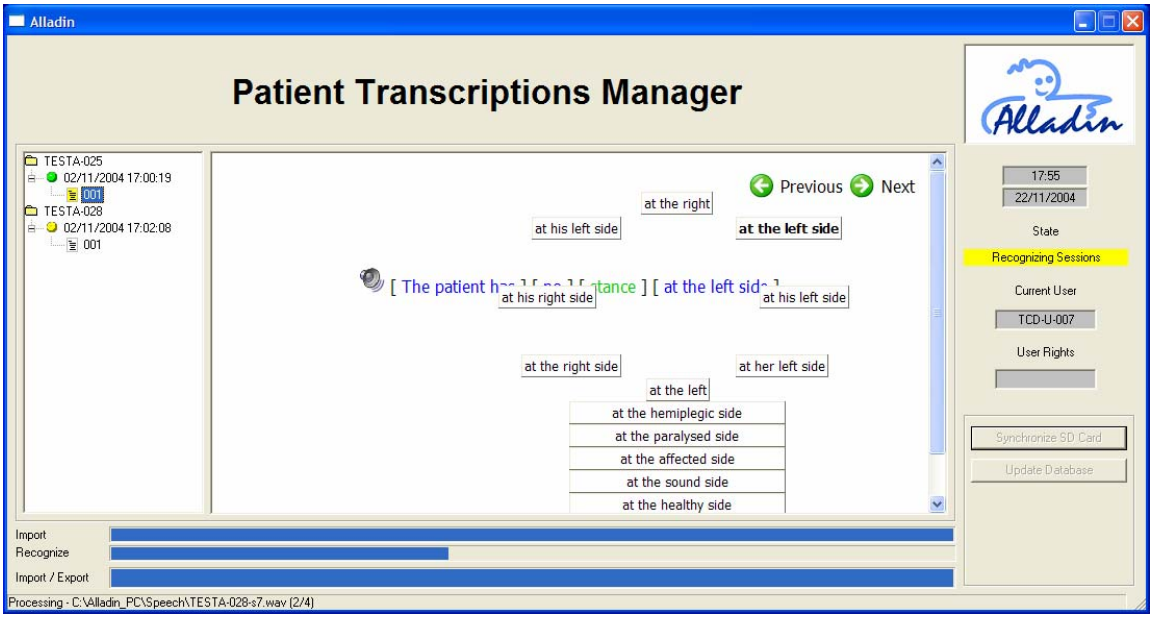


Figure 20. The Patient Transcriptions Manager interface

Figure 20 illustrates how a user can correct a sentence. Here, the user said "The patient has no stance at his left side". The interface enables him to set "at his left side" instead of "at the left side".

Although the meaning of the two sentences is the same, these audio recordings will be reused afterwards by the speaker adaptation module to improve gradually the recognition system during usage.

Several progress bars show the status of the global recognition/synchronization process:

- "Import" indicates the status of the synchronization of the current logged physiotherapist user.

[2] Please read section 3.6 *Audio recordings* for more information

This progress bar indicates the status when copying files from SD Card to a local temporary working directory of the PC.

- "Recognize" gives the recognition engine status.

  This progress bar indicates the overall status of the recognition engine processing all the data imported. When it is complete, no more files have to be processed.

- "Import/Export" gives information regarding the SD Card readiness.

  This progress bar indicates the import status of all users who recorded sessions with the same SD Card. It shows also the status of the patient file creation. When this last progress bar is complete, the physiotherapist user can safely remove the SD Card from the SD Card Reader and use it with the PDA Software to record new diagnostics.

When the physiotherapist has verified the session, the selected icon's colour changes to notify him. In order to update the database, the user will have to verify all sentences of the session. The following procedure can be followed to correct a sentence:

- Move the mouse pointer over the sound icon to listen to the diagnostic.
- If a word or group of word was not well recognized, move the mouse pointer over the faulty word or group of word (like described in the above figure) and select the right value.

When all progress bars are complete. The user can quit the application if he prefers to verify the sentences afterwards.

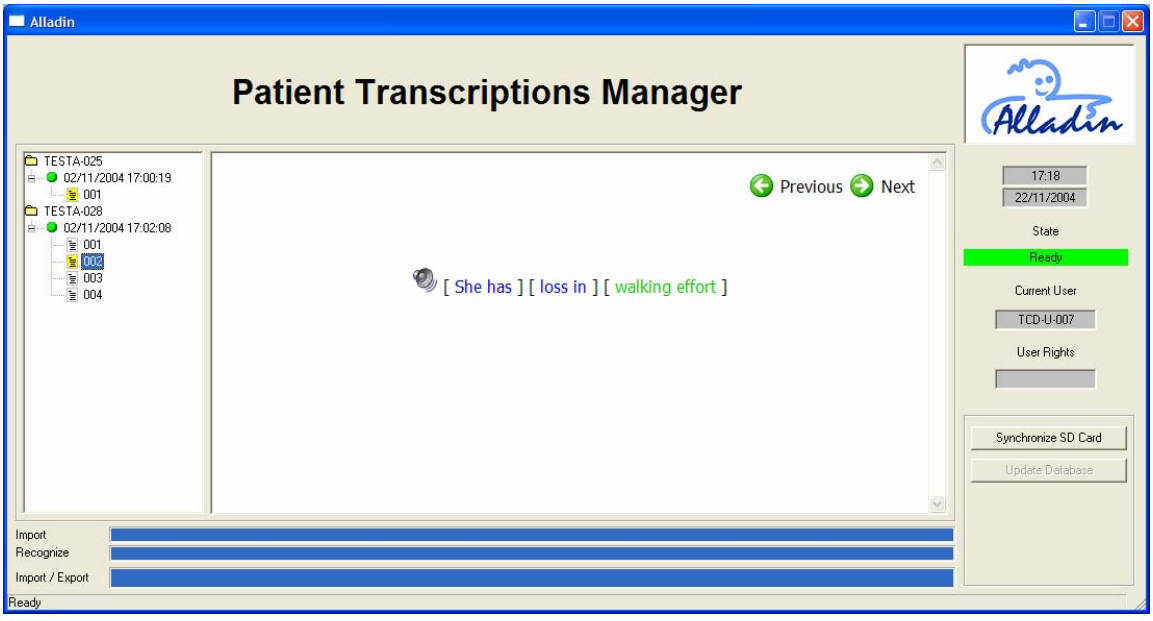


Figure 21. The Patient Transcriptions Manager interface

When he logs in the next time, all the sessions which were not verified remain listed in the sessions column.

The user can update the ALLADIN local database by selecting a session, by clicking on the "Update Database" button. A popup message asks for confirmation. When the user has clicked YES, the database is updated and the session is removed from the GUI panel.

3.3 The ALLADIN Diagnostic Device

3.3.1 General Description of the ADD

3.3.1.1 The Role of the Device

The main objective of the ALLADIN Diagnostic Device to perform valid and reliable isometric force-torque measurements at stroke patients during the execution of the 6 ADLs defined in Deliverable 1.1. Three identical ALLADIN Diagnostic Devices installed in the three clinical centres (Gent-Belgium, Dublin-Ireland, Budapest-Hungary) will collect force torque data during approximately 3000 sessions, each producing 24 samples of 48 synchronous force-torque trajectories. Not only the ADLs but for validity reasons also the anatomical starting postures should be the same for each patient. Standardisation of the measurements therefore is critical for the success of the ALLADIN hypothesis. The standardisation achieved both in terms of the mechanics of the device, the force-torque sensor unit, the measurement control software, and the unambiguous guidelines on the operation of the device will result in high reproducibility and comparability of the force torque measurements during the entire evaluation period.

Deliverable 1.1 described the conceptual design of the ALLADIN Diagnostic Device. Since April 2004 the engineering partners implemented a complete product design and development cycle which included the computer aided design and development of three ADD prototypes, and feedback from the testing made by the clinical partners of the project. Refinement, and detailing of the conceptual design was a natural result of this cyclic process. The conceptual design of the ALLADIN Diagnostic Device was amended at only three attributes:

1. ADL1 was placed to the fourth place in the order of the execution. During the tests with the prototype device we observed the physiotherapist put first the orthosis plate onto the tray holder plate in order to securely fix the patient's arm into the arm device and the finger device. It is reasonable to measure first all the exercises here, and only then move the patient's arm to lift the bag. The new order of the ADLs is the following:

Drinking a glass of water
Taking a spoon
Turning a key
Lifting a bag
Reaching to a bottle
Lifting and carrying a bottle

Table 2. New final order of the ADL tasks

2. In addition to the already decided 7 places for the force-torque measurements the sitting balance of the patient will be measured also by a 6 DOF force-torque sensor placed under the seat plate of the ADD. The final list of the parts of the body where isometric force-torque measurement will be made is listed in Table .

Thumb
Index finger
Middle finger
Lower arm
Trunk
Posterior
Foot
Toe

Table 3. Parts of the body where isometric force-torque measurements are made by the ALLADIN Diagnostic Device

3. Forward inclination of the trunk was increased in Position 3 of the ADL exercises. Clinical tests with the ADD prototype concluded that reach forward posture is unnatural. The new better bent forward postures for far reaching at ADL5 and ADL6 are shown in **Figure 23**. **Table** lists the old and the new anatomical angles at far reaching.

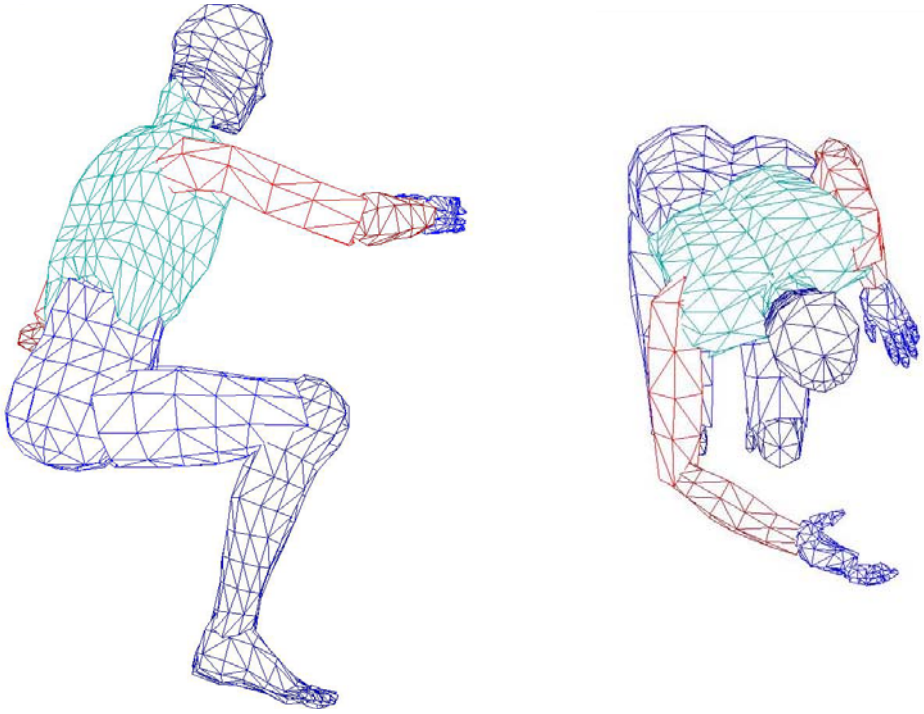


Figure 23. Far reaching posture is better bent forward. (Side and top views)

Articular movement	Anatomical angles in Deliverable 1.1	Amended anatomical angles
Shoulder flexion	70	*100*
Shoulder internal rotation	45	45
Elbow flexion	35	*20*
Thumb abduction	50	50
Finger metacarpophalangeal flexion	15	15
Finger proximal interphalangeal flexion	20	20
Finger distal interphalangeal flexion	20	20
Lumbar-thoracic flexion	15	*30*

Lumbar-thoracic rotation	20	20
Lumbar-thoracic lateral flexion	18	18
Hip flexion	90	90
Knee flexion	105	*110*
Ankle dorsiflexion	8	8
Toe metatarsophalangeal flexion	7	7

Table 4. The amended anatomical angles in Position 3

3.3.1.2 The Structure of the device

The ALLADIN Diagnostic Device includes the following main units (Figure 24):

1. Control and data acquisition workstation
2. Transit lying wheelchair
3. Monitor for the patient
4. Trunk device
5. Seat device
6. Arm device
7. Finger device
8. Foot device
9. Frame
10. Accessory storage board

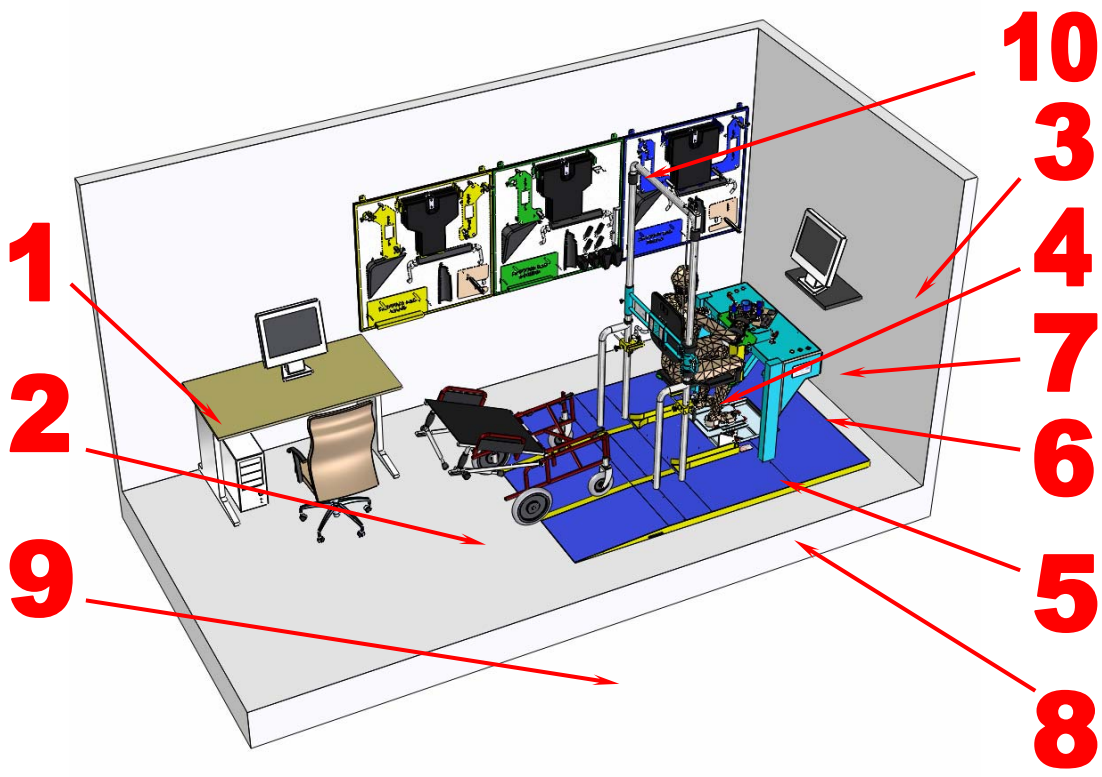


Figure 14. The ALLADIN Diagnostic Device

The seat sensor was defined in line with the requirements set in Deliverable 1.1. Table 5 updates the basic characteristics of the selected JR3 6-axis FT transducers.

6-axis FT transducers						
Qty.	**Model**	**Description**	**Lateral forces (Fx, Fy)**	**Axial force (Fz)**	**Torques (Tx, Ty, Tz)**	**Dimension**
3	50M31A-I25 150N8	Type-H(and)	150 N	300N	8 Nm	Ø 50 x 31 mm
1	67M25A-I40 150N10	Type-A(rm)	150 N	200 N	10 Nm	Ø 67 x 35 mm
1	90M40A-I50 250N20	Type-B(ack)	250 N	250 N	20 Nm	Ø 90 x 40 mm
1	45E15A-U760 1200N120.	Type-S(eat)	600 N	1200 N	120 Nm	Ø 114 x 40 mm
1	90M40A-I50 400N25	Type-F(oot)	400 N	800 N	25 Nm	Ø 90 x 40 mm
1	50M31A-I25 150N8	Type-T(oe)	150 N	300 N	8 Nm	Ø 50 x 31 mm

Table 5. Updated list and characteristics of the 6-axis FT transducers

Figure 25. shows the photograph of a JR3 force-torque transducer. The orthogonal reference frame for the force and torque vectors is located inside the transducer.

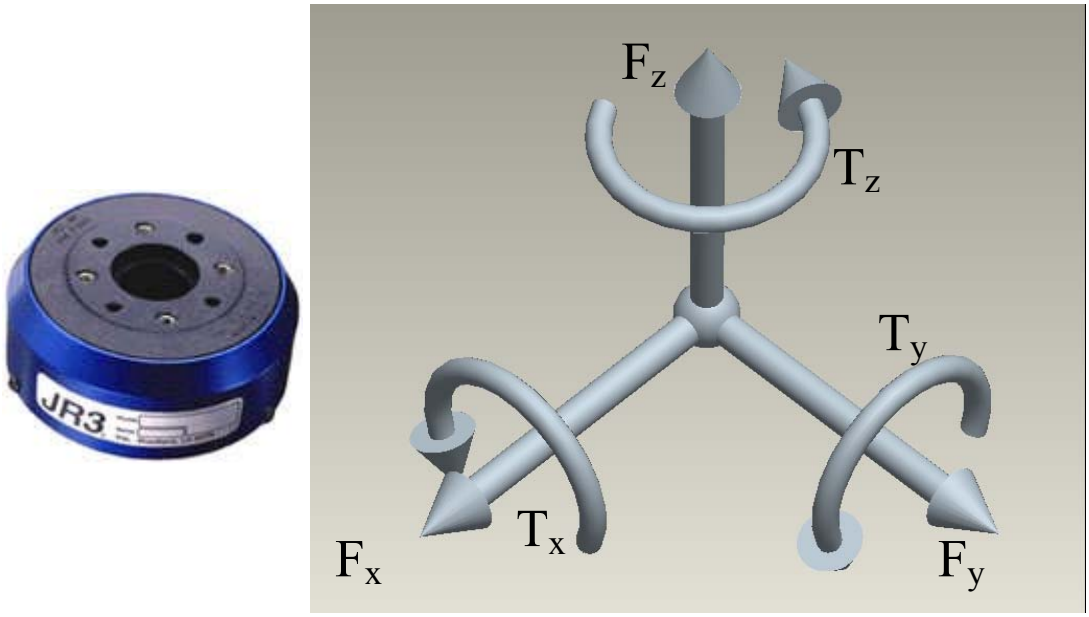


Figure 25. A JR3 Inc. 6-axis force torque sensor, and the definition of the orthogonal reference frame for the 3 force and 3 torque components

The precise location of the 8 force-torque sensors in the ALLADIN Diagnostic Device is shown on Figure 26.

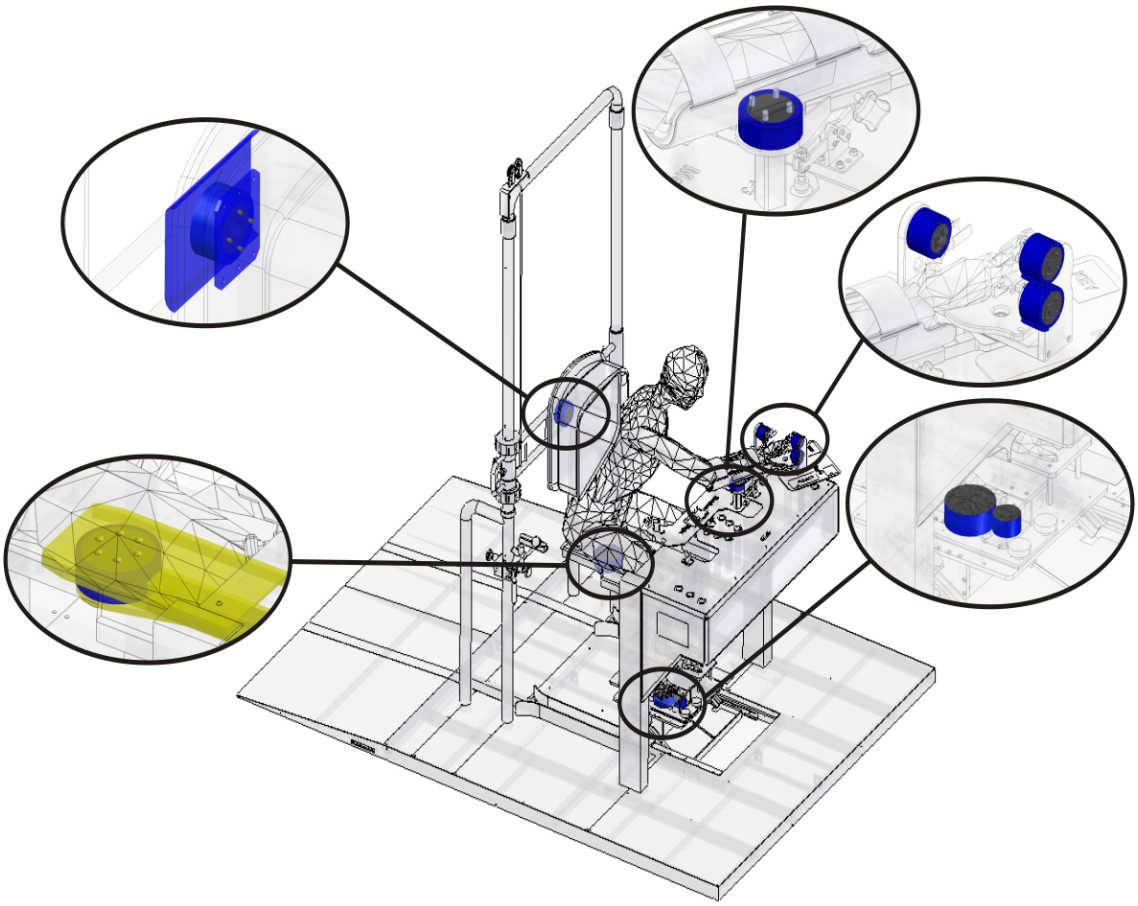


Figure 26. Force-torque sensors in the ALLADIN Diagnostic Device

The orientation of the sensor coordinate system depends on the mounting of the sensor. The coordinate systems are shown on the Figure F1 according to the installation manual for JR3 force-torque sensors. The sensor has two sides, ROBOT SIDE and TOOL SIDE. The sensor measures positive force and torque according to Figure F1/a when the TOOL SIDE is fixed and the ROBOT SIDE is loaded and moved. For example positive F_z is measured when the ROBOT SIDE of the sensor is pulled towards the positive "Z" direction. Positive T_z is measured when the ROBOT SIDE of the sensor is turned counter-clockwise around the positive "Z" direction (right hand rule). The directions will be opposite when the ROBOT SIDE is fixed and the TOOL SIDE is loaded and moved. (Figure F1/b), it's left hand rule.

Sensors fixed to the frame with the TOOL SIDE:

- Trunk sensor
- Arm sensor

Sensors fixed to the frame with the ROBOT SIDE:

- Thumb sensor
- Index finger sensor
- Middle finger sensors
- Seat sensor
- Foot sensor

- Toe sensor.

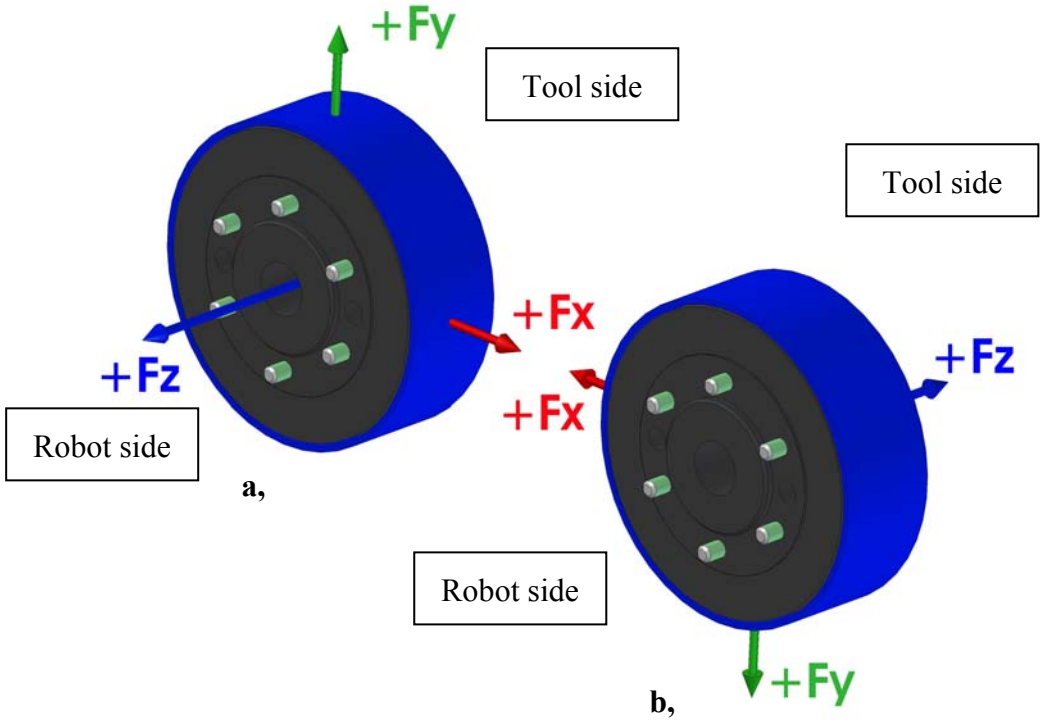


Figure F1 The coordinate systems according to the installation manual for JR3 force-torque sensors

The coordinate axes are colour coded (Figure F2). The X-coordinate axis is red, the Y-coordinate axis is green and the Z- coordinate axis is blue.

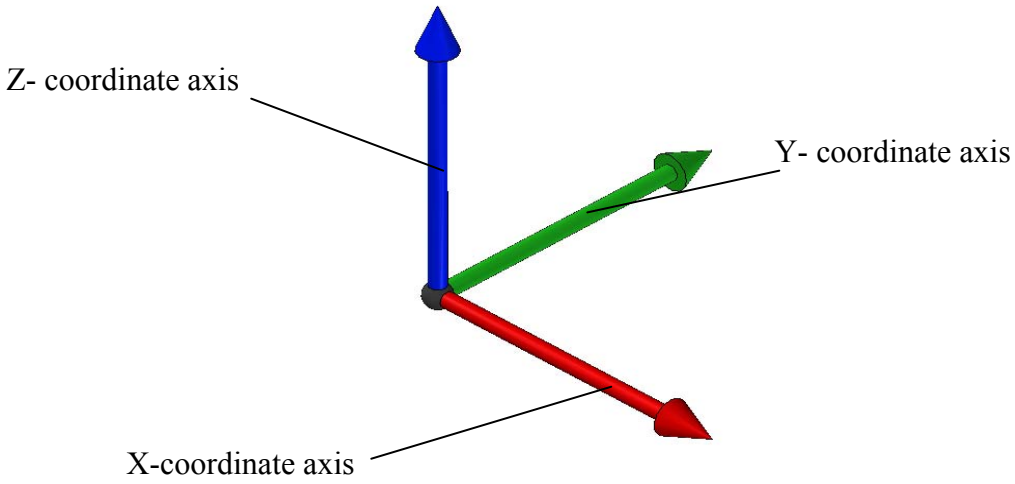


Figure F2

The location and orientation of the coordinate system attached to the different sensors is shown on the Figure F3-F7. The interpretation of force and torque measured by any of the sensors is now homogenous and standard for the ADD:

- Positive measured force indicates a pulling action by the patient towards the arrow of the corresponding coordinate axis.
- Positive measured torque indicates a counter clockwise turning action by the patient around the corresponding coordinate axis (right hand rule).

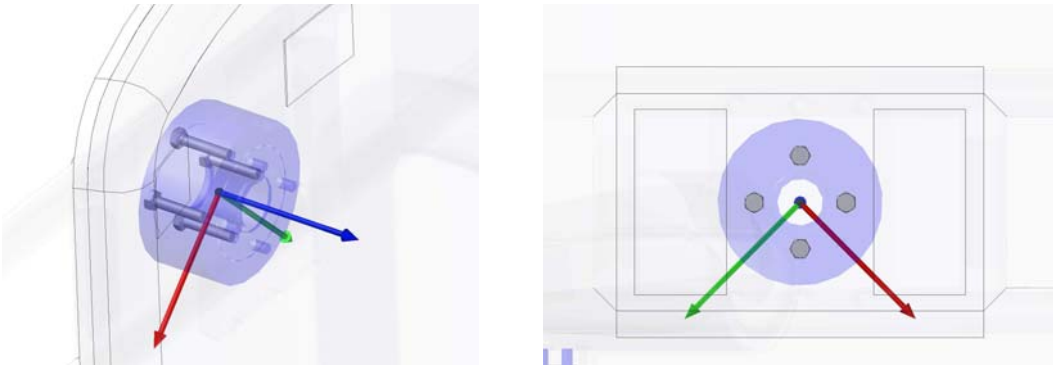


Figure F3

Coordinate system of the back sensor (rotation angle is 45 degree)

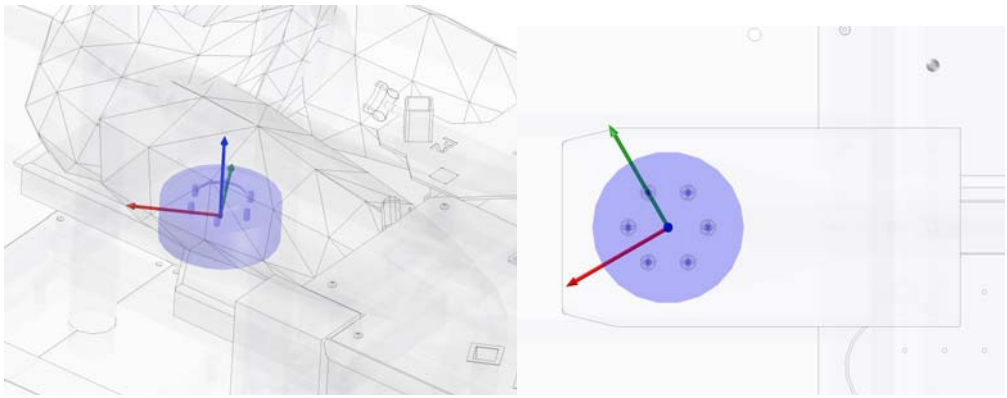


Figure F4
Coordinate system of the seat sensor (rotation angle is 30 degree)

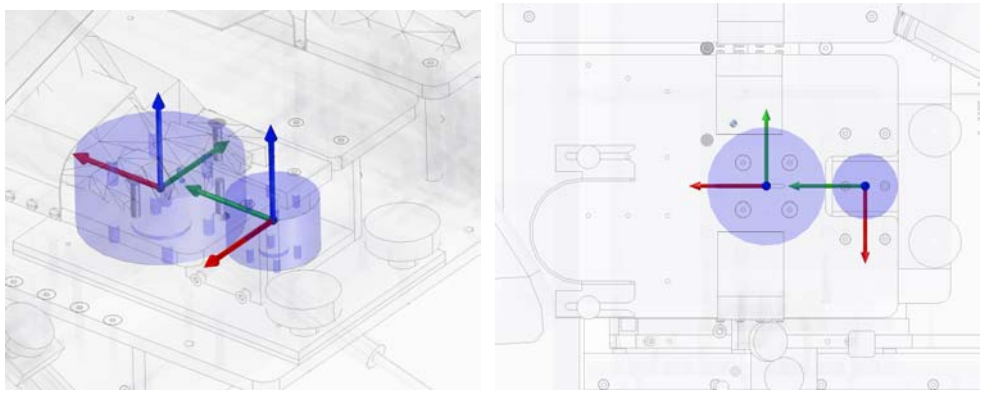


Figure F5
Coordinate systems of the foot sensor and toe sensor

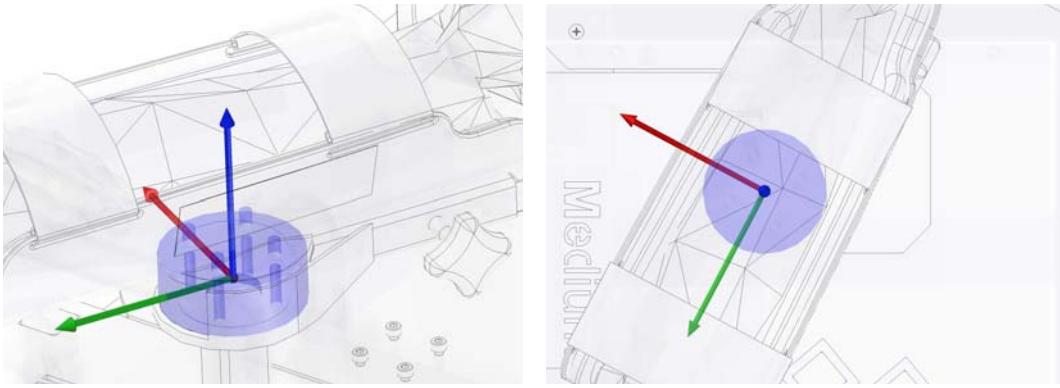


Figure F6
Coordinate system of the arm sensor (Interpretation of the left and right sides are different!)

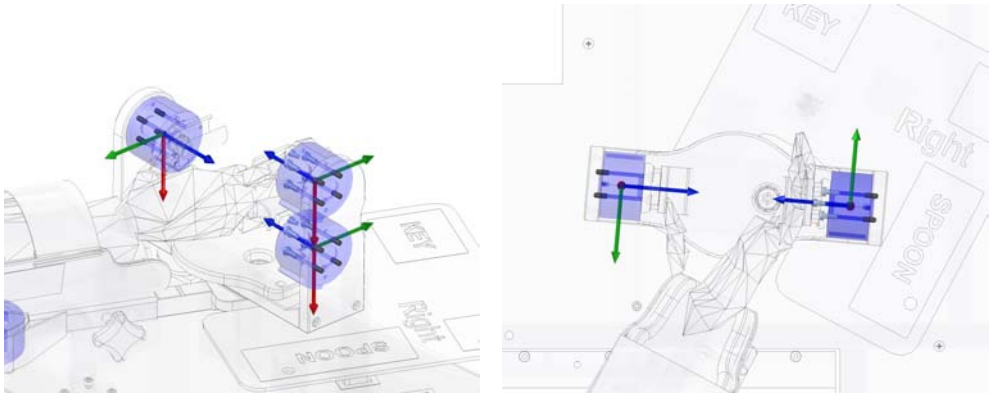


Figure F7
Coordinate systems of the hand sensors (Thumb, Index and Middle finger)
(Interpretation of the left and right sides are different!)

3.3.1.3 Main Dimensions

Individual adjustability is not cost effective in case of the ALLADIN Diagnostic Device, thus adjustability of the device to three discrete patient sizes was implemented. The ALLADIN Diagnostic Device was designed using an anthropometric design approach (See Deliverable 1.1.) To minimize the error in the anatomical angles set at each of the 6 ADLs, as well as to keep the handling complexity of the diagnostic device on a tolerable level for the operating physiotherapist the patients accepted for the isometric force-torque measurements are classified into three groups according to their height (Table). During the measurements the appropriate size accessories and device settings must be used. The size groups are denoted by the S, M, L labels, and beside this colour codes are used.

Label	Colour code	Height
S	Yellow	<1625 [*mm*]
M	Green	1625 .. 1751 [*mm*]
L	Blue	1751 [*mm*] <

Table 6. Definition of the ALLADIN patient size

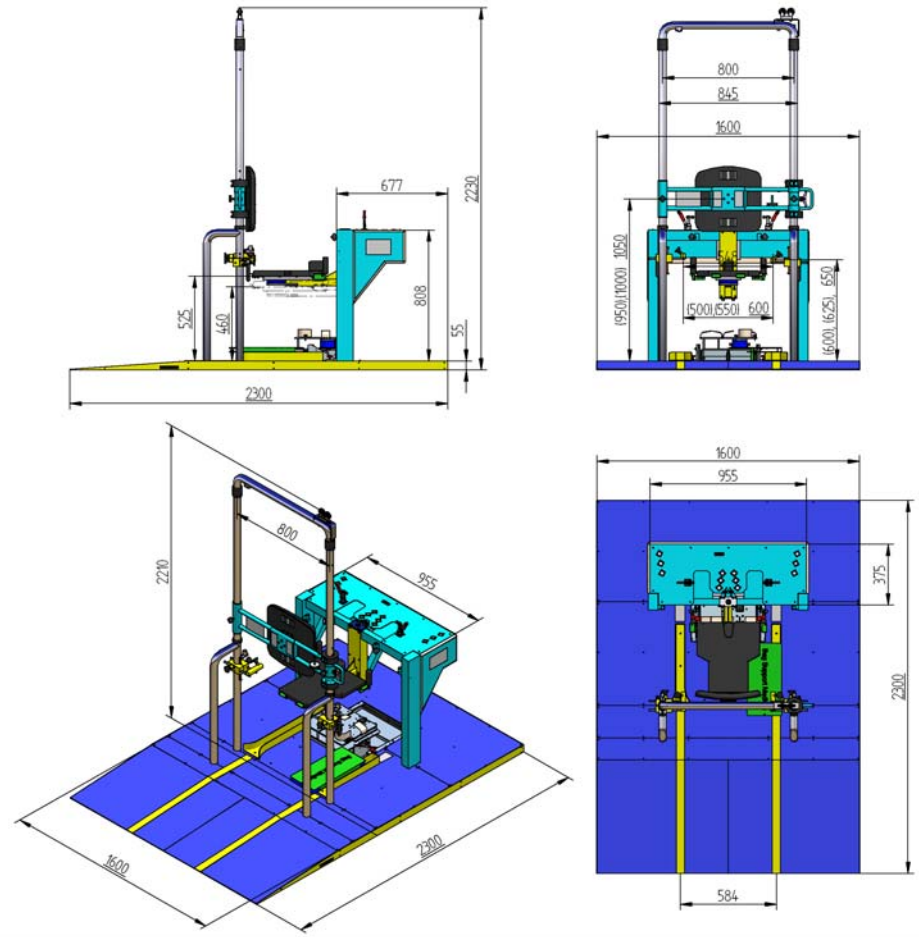


Figure 27. Overall dimensions of the ALLADIN Diagnostic Device

The ALLADIN Diagnostic Device was designed to fit a small hospital room. Figure 27 shows the dimensions of the system, and specifies the settings for the S, M, and L size patients.

3.3.1.4 Settings of the device

The ALLADIN Diagnostic device has to be set to 3 positions for the 6 selected ADL exercises. The following description shows a patient with paretic right side, so in the text the right corresponds to the paretic, and the left to the healthy side.

Position 1

Position 1 of the ADD covers three ADL tasks: No. 1 grasping a glass and drinking, No. 2 reaching for a key to turn it, and No. 3 reaching for a spoon to grasp it.

Figure 28 shows the ADD set to ADL2. The patient is sitting on the seat device, and leaning against the trunk device which is lowered to the measuring position on its frame. The arm and finger devices are in the fixture at the front frame, and holding the paretic arm, the thumb, the index and middle fingers of the patient. The object of the ADL No. 1 – the glass – is close to the patient's fingers. The patient has a good view of the real objects.

The right foot (the paretic side) and the right toe fit precisely the foot device. The patient is watching the monitor showing the video demonstration of ADL1. Figure 29 left shows the ADL2 object: a lock with a vertically oriented blade. Vertical orientation is

important to maintain the same starting posture for the hand as in ADL1. Figure 29 right shows the object of ADL3: the spoon. The spoon will always be positioned on the external side of the hand, i.e. in the case of a right hand exercise the spoon is located on the right side of the arm. It is important to place the spoon on a small box in order to induce a small upwards motion with rotation. Also in ADL3 the starting posture of the hand is the same as in ADL1, and ADL2. Stickers mark the positions of the real objects on the tray.

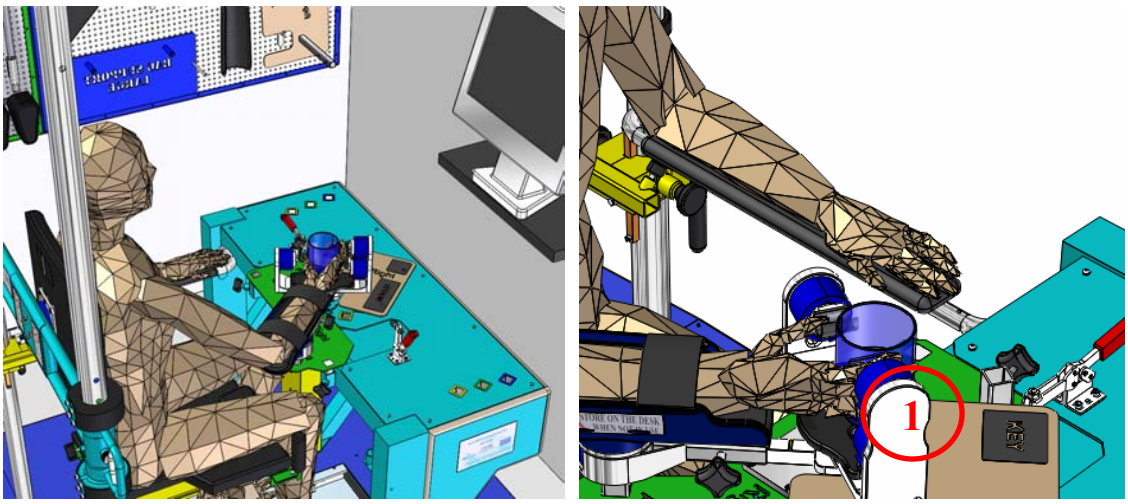


Figure 28. 50%-ile male in Pos1 ADL1: drinking

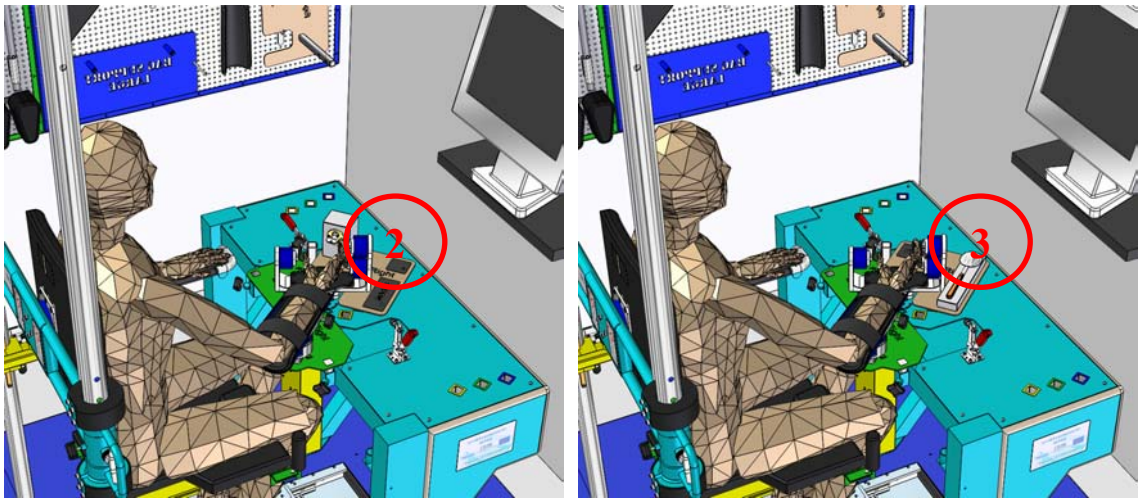


Figure 29. 50%-ile male in Pos1 ADL2: turning a key (left) and ADL3 taking a spoon (right)

Position 2

Figure 30 shows the patient in ADL4 in the Pos2 of the ALLADIN device. The patient is sitting on the seat device, and leaning against the trunk device, which is lowered to the measuring position on its frame. The patient is fixed to the trunk device by a 6-point jacket. The arm and finger devices are positioned on the right arm, and set to the Pos1 fixture. The patient can hold his arm right at the side of his body, since the width of the seat device is adjusted to his size. This results in a normal (low) shoulder abduction angle. The Pos2 fixtures are adjustable both horizontally and vertically, and can be fixed in 3-3 positions

according to the 25%, the 50%, and the 75% anthropometrical sizes. The bag support also has three different settings to allow the patient's fingers to be in permanent contact with the handle of the bag. The arm is fixed in the arm device, and the thumb, the index and middle fingers are fixed in the finger-fixations of the finger device.

The foot remains in the same natural sitting position as in Pos1. The right (paretic) foot and its toe are fixed into the foot device.

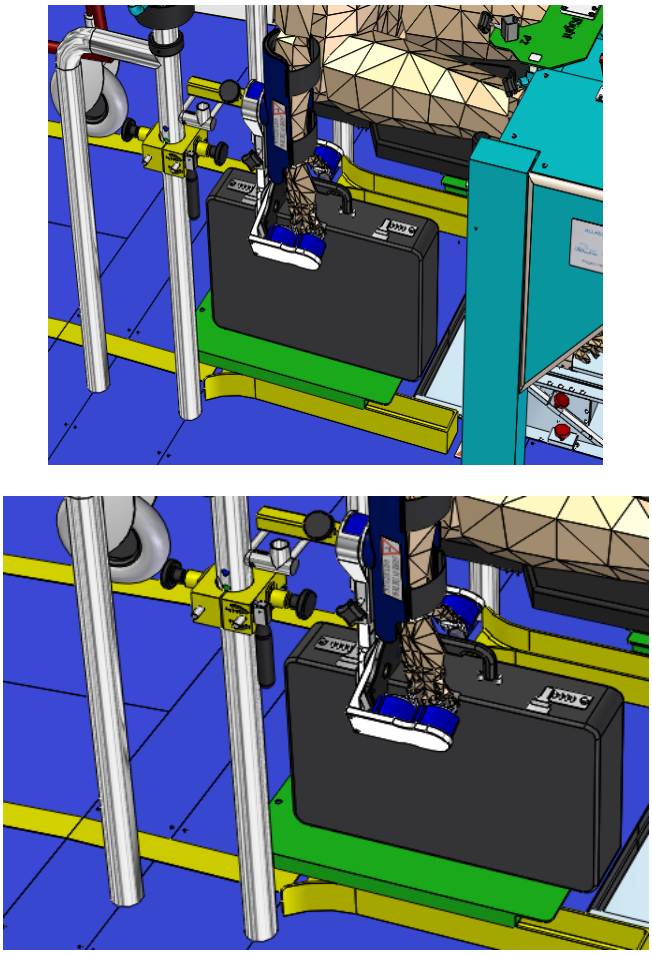


Figure 30. The 50%-ile male is measured in Pos1, ADL4: lifting a bag

Position 3

The patient's posture in Pos3 radically differs from Pos1 and Pos2. In position 3 the patient's posture is set to far reach: the trunk leans forward and is twisted towards the non-affected side. In order to allow the patient to reach as far forward as possible the foot will slide back under the seat device. This natural position is realized by adjusting the foot device. The S, M, L positions of the horizontal slide are set by knobs. The foot device holds only the patient's toe and feet, so the heel can elevate to a natural position. To visualise this movement please refer to Figure 31.

To move the patient from Pos2 to Pos3 the PT shall move the integrated arm and finger devices into the P3 socket of the orthosis plate. In the case of the trunk device, an upholstered right or left sided wedge should be inserted between the patient's back and the trunk device. Before doing so, the patient's jacket must be loosened and the patient must be leaned forward.

The wedge has Velcro fixtures so the PT can easily fit it in place. After wedge insertion, the patient's jacket belts must be tightened.

In ADL5 the patient will reach for a bottle (Figure 32). In ADL6 the bottle is placed close to the fingers and should be moved to a table on the other side – coloured grey in Figure . The hand posture is the same in ADL5 and ADL6 as in the previous cases, so the hand posture is fixed for all ADLs. A sticker marks the positions of the bottle on the tray.

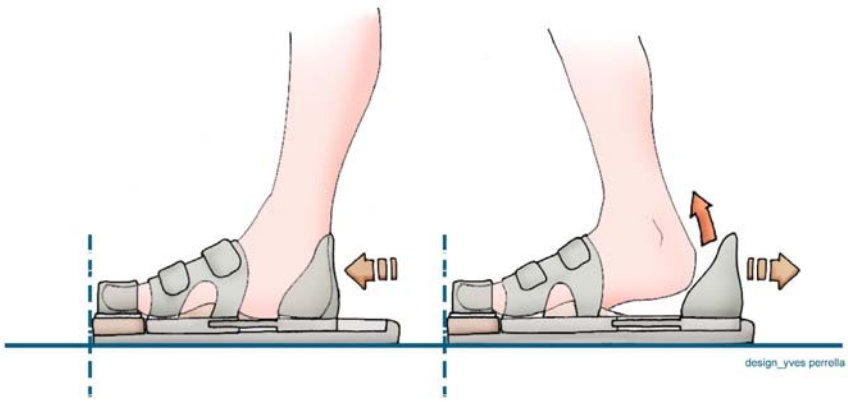


Figure 31. The heel is elevated in Pos 3

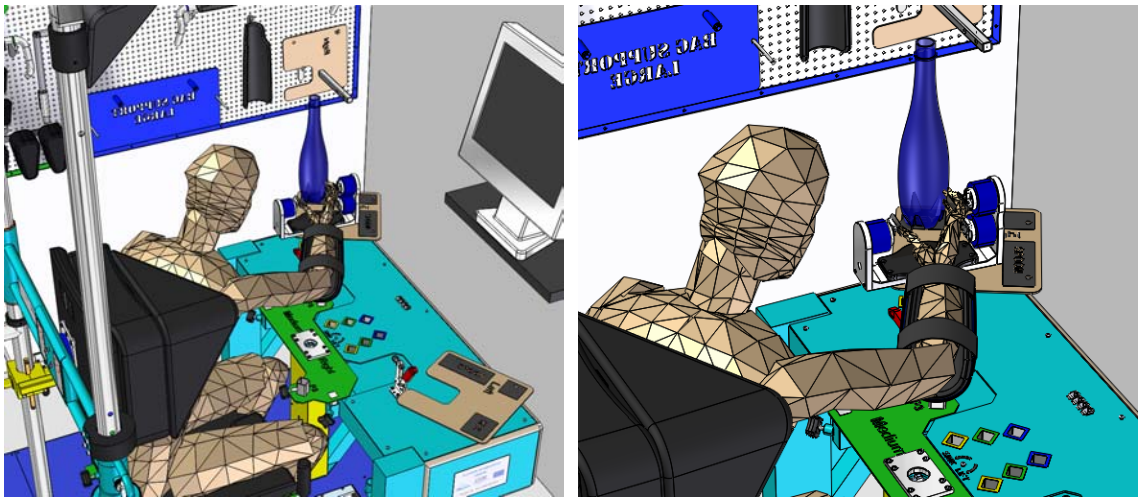


Figure 32. 50% male in Pos3 ADL5

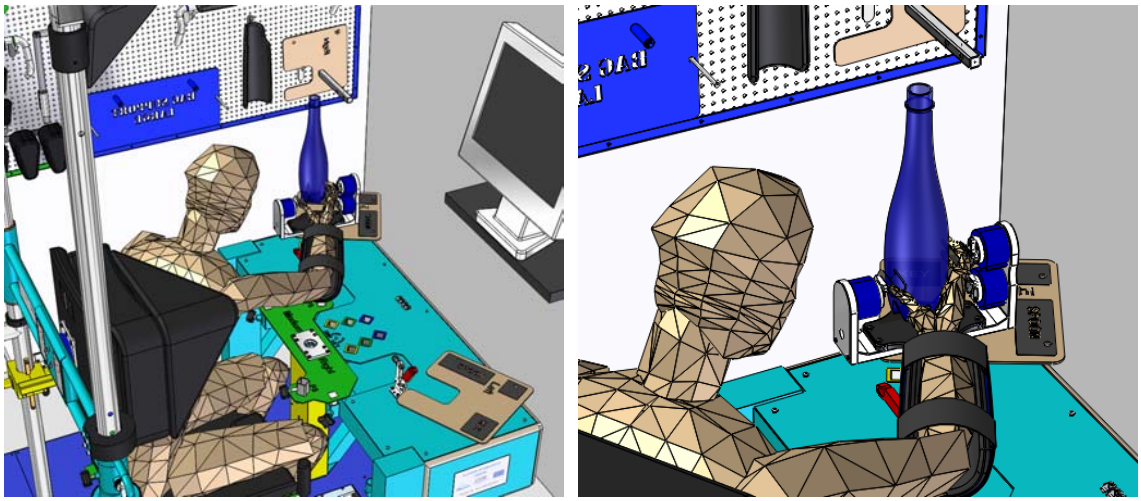


Figure 33. 50% male in Pos3 ADL6

3.3.2 The Trunk Device

The main role of the trunk device (Figure) of the ALLADIN Diagnostic Device is the measurement of the efforts of the patient's trunk during the ADL exercises. The frame has been designed to provide adequate stiffness for this. The frame itself is the guide of the trunk device in order to move it vertically and set to the measurement position. In addition to the trunk device, the frame supports the right and left side ADL position 2 holders of the arm device.

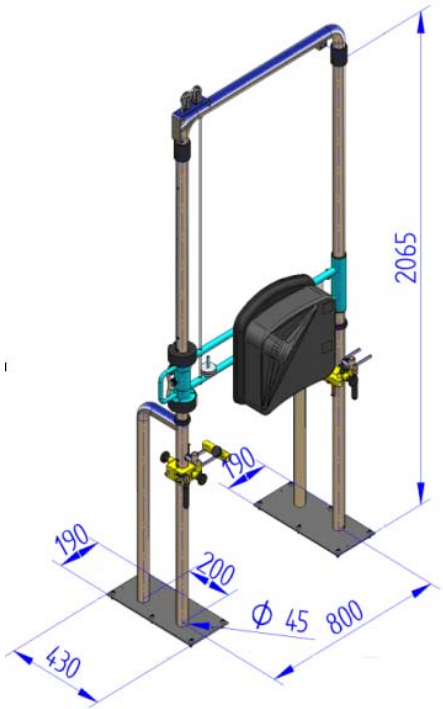


Figure 34. Main dimensions of the Trunk device

Figure shows the trunk frame with the trunk device of the ALLADIN Diagnostic Device set to measurement position, and the main dimensions. The distance between centre lines of the two vertical columns is 800 mm; the height of the centre line of the top horizontal bar is 2105 mm in order to allow secure entering with the wheelchair, when the sliding frame of the trunk device is set to its storage position. The dimensions of each component are presented later, when the component is discussed. The height of the trunk device, furthermore the height and the lateral position of the Position 2 holder of the arm device can be set to the S, M, and L patient size. These settings has three-three steps according to the patient size, which are marked with colour codes (yellow, green and blue).

The trunk device and its frame consist of several sub-components. The main structural elements are presented on Figure 5. These are:

1. Base
2. Frame
3. Sliding frame
4. Backrest
5. Position 2 orthosis fixture
6. Counterbalance mechanism
7. Trunk support
8. Trunk support wedge
9. Auxiliary counterbalance weights

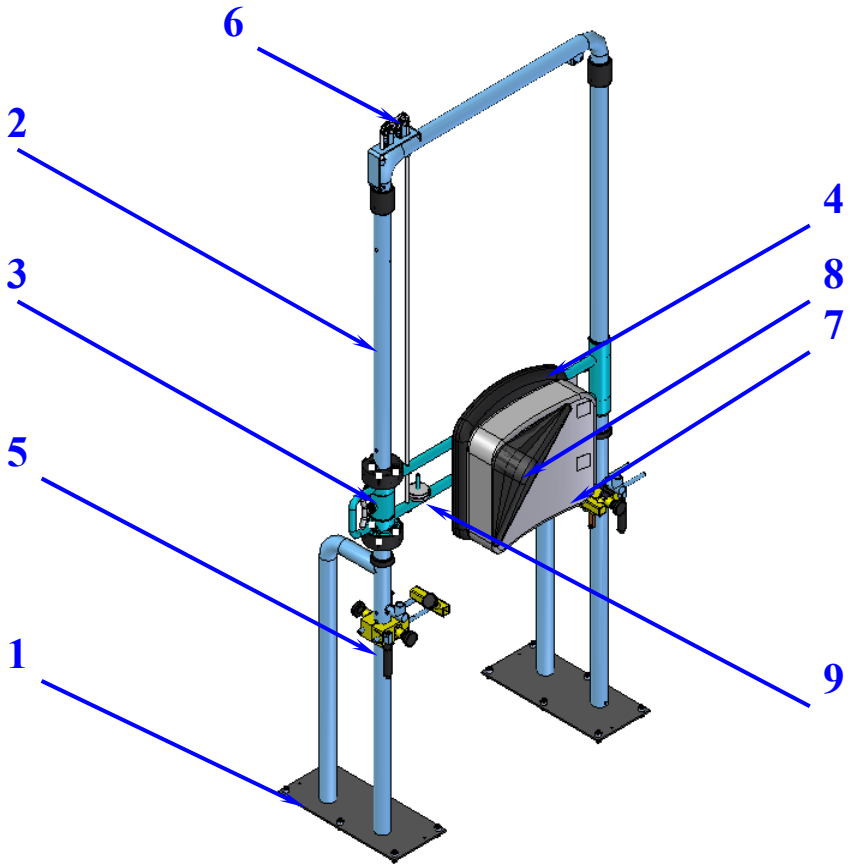


Figure 35. The components of the trunk device

The trunk device is fixed to the podium by the base with 12 screws. The accurate positioning of the base is established by guide pins. The backrest with the Trunk sensor is assembled to the sliding frame, which can be seen on Figure . This frame is a welded aluminium structure, which consist of several functional parts. These are:

1. Rolling guide sleeve
2. Sliding guide sleeve
3. Snap-in handle
4. Screw clamp
5. Handle
6. Pipe frame
7. Sensor support
8. Auxiliary counterbalance weight holder pin
9. Nameplate
10. Rope guiding sleeve

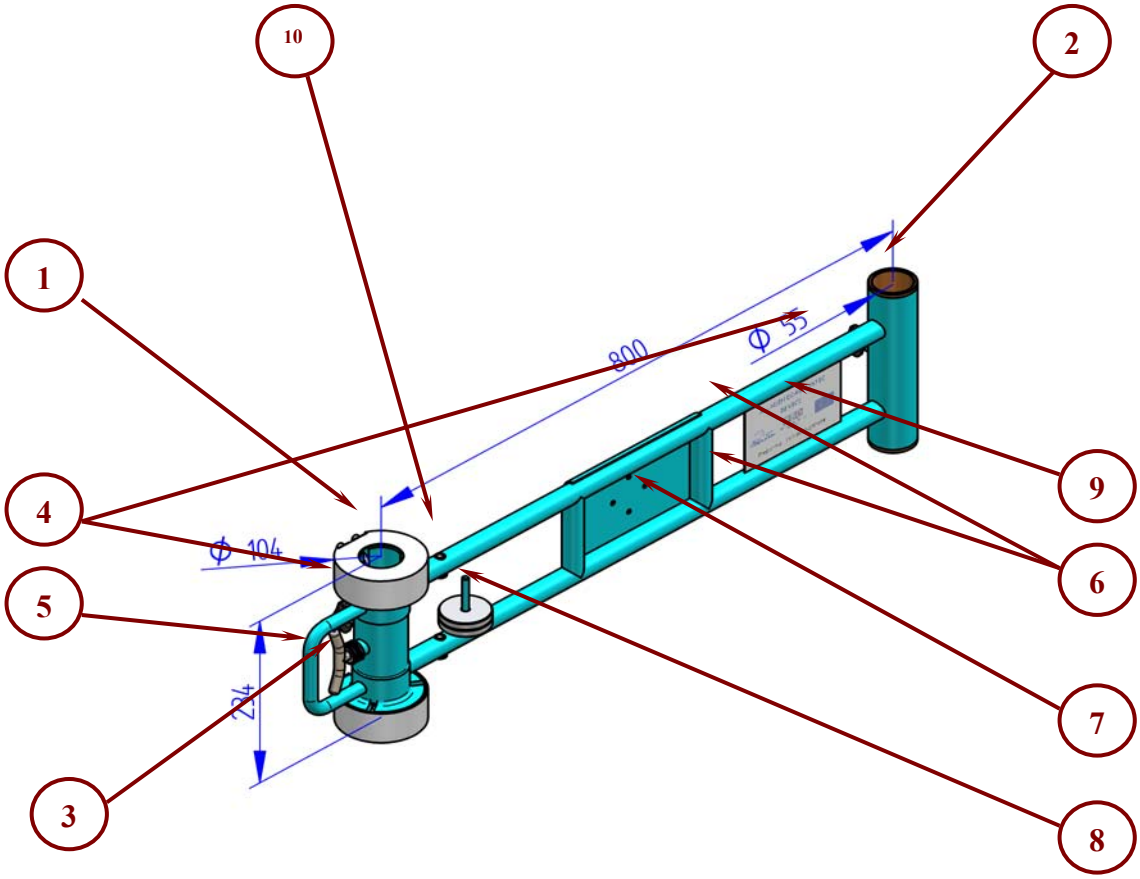


Figure 36. Components of the backrest slide

The trunk device is set to different vertical positions during the measurements, so the backrest with the trunk sensor is assembled onto a vertically sliding frame by 4 M6 screws. The sliding frame is guided by a roller guide on one side (Figure 37) and a sliding guide on the other, in order to prevent stick-slip motion and provide easy handling.

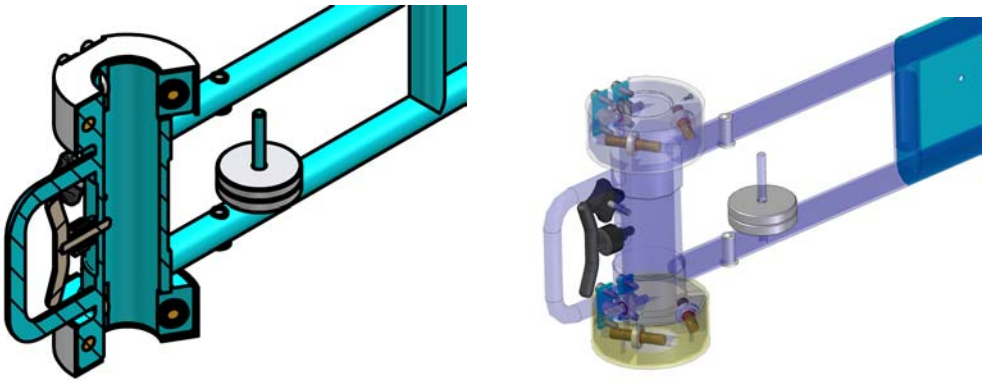


Figure 37. Components of the framework at the roller guided side

The welded structure of the backrest slide has been sintered after manufacturing. At the middle of the sliding frame there is a plane surface for mounting the trunk sensor. At the left side there is a pin for the Auxiliary counterbalance weights.

The storage position of the sliding frame is at the top of the frame, and it is fixed by the snap in handle, and the screw clamps. The sliding frame must be moved up until the handle snaps in into its hole at the upper position (Figure 38). The sliding frame must be securely tightened with two screw clamps, in order to avoid its accidental releasing (Figure **39**39). To prevent falling down of the sliding frame, there is a counterbalance mechanism on the right column. This counterbalance mechanism has not only a safety function but it also makes the movement of the sliding frame easy for the physiotherapist. The long steel rod counterweight is hidden inside the column (Figure 40.).

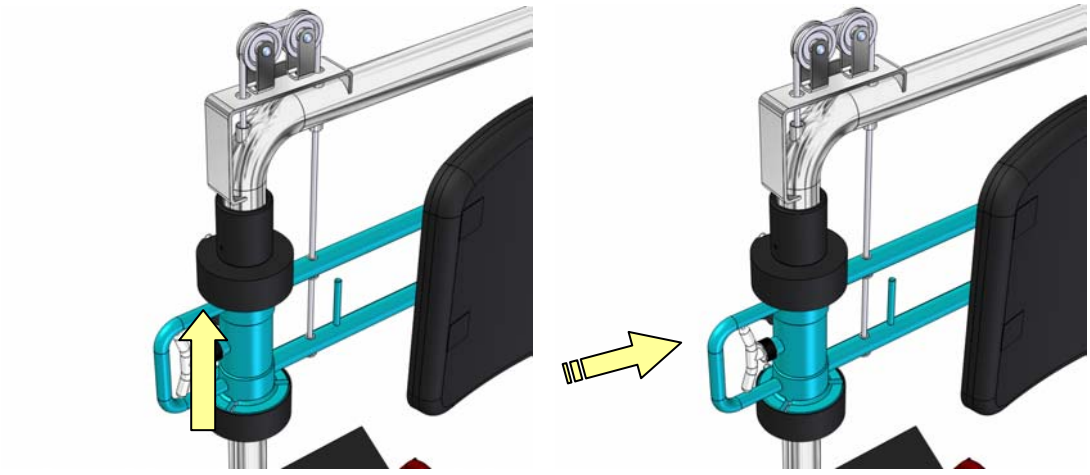


Figure 38. The snap in handle secures the position of the backrest framework

Figure 39. Two screw clamps fix the backrest framework

Figure 40. Counterbalancing rod slides inside the trunk frame

Before setting the trunk device to the measurement position, the screw clamps and the snap in handle must be released, and then the device can be pulled down vertically by its handle. At the bottom terminal position the snap in arm secures its position at the appropriate height, and the tightened screw clamps provides adequate stiffness for the measurements. The setting of the appropriate height is helped by colour code marks on the frame (Figure 42). The yellow mark is for the small, the green is for the medium and the blue is for the large size patient position.

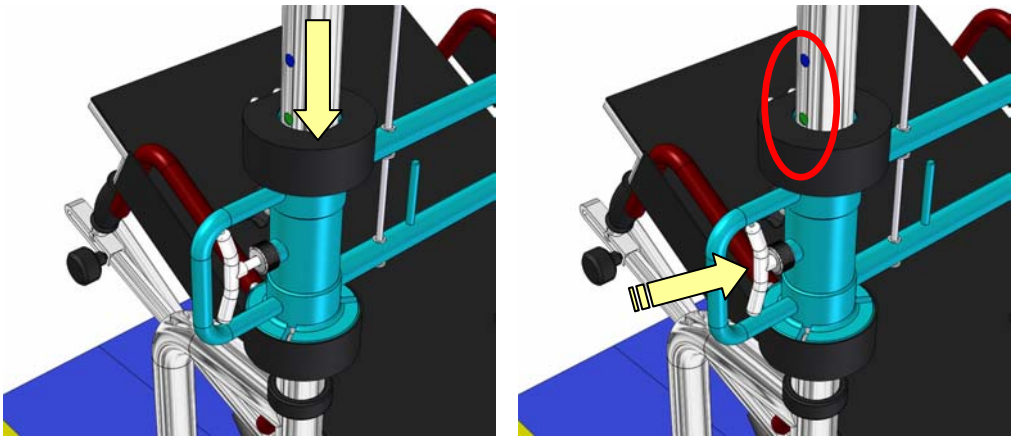


Figure 42. The appropriate measurement positions are marked by colours

During the force-torque measurement the patient's trunk is kept fixed to the backrest by a six point jacket (Figure 43). This will ensure that the trunk sensor measures not only the pressing but the pulling forces, as well as any torque in the orthogonal reference frame. The backrest – similarly to the seat plate – is a foamed and upholstered laminated plate. The covering linen holds TÜV certification for medical use. The laminated plate has been ergonomically bent for the convenience of the patient. Velcro straps have been sewed on the front side of the upholstery in order to fix the trunk support. There are two fastening hooks on the top back of the backrest, to which the two upper straps of the jacket is hooked. The sensor is assembled onto the sensor supporting plate.

Figure 43. The six point jacket of the ADD

In Pos3, for the ADL No 5 and 6 measurements trunk supports are to applied because the patient bends forward and the trunk would not touch the backrest. The trunk support is a upholstered foam block, on which the counter pairs of the Velcro patches have been placed (Figure 43). In this way the insertion and the removal of the trunk support can be very fast.

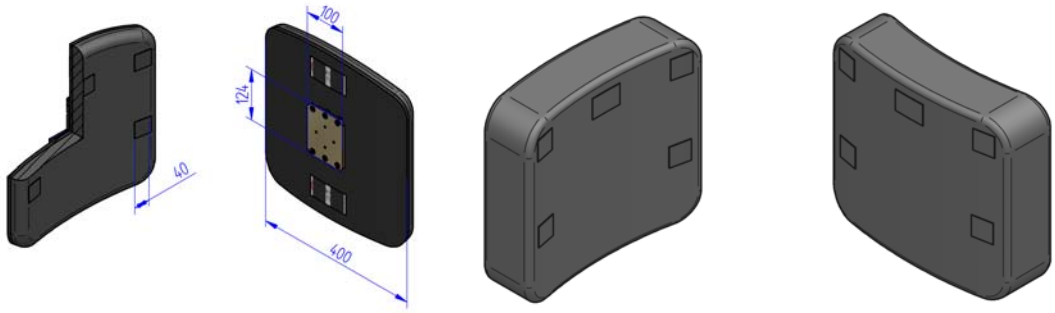


Figure 43. The backrest and the trunk support

Beside the trunk support, a trunk supporting wedge is required because the patient's trunk is not only bent forward but twisted to the non-affected side in the forward bent position 3. The material of the trunk supporting wedge is the same polyurethane foam used everywhere in the ALLADIN Diagnostic Device. These are fixed also by Velcro patches, and have different thickness according to the S, M L sizes (Figure 44).

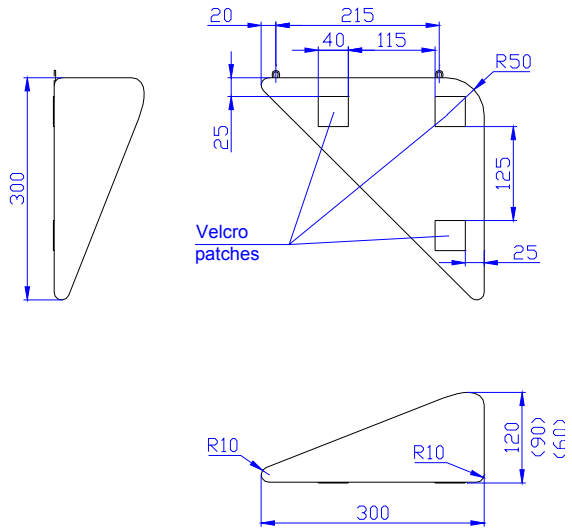


Figure 44. Dimensions of the trunk supporting wedges

The trunk sensor is connected to the PC by a six-pole cable, according to the specification of the manufacturer (JR3) of the sensors. The cable is led to the socket at the left column (Figure 45). It is twisted spirally around a rubber band, and at the top position it is contracted, so it does not hang and swing, and does not embarrass the work.

Figure 45. Leading the cable from the trunk sensor to the trunk frame

After the measurement the backrest slide can be lifted by loosening the screw clamps, and releasing the snap in arm. At the top position the snap in arm secures the trunk device, than both screw clamps must be tightened.

Maintenance

The minimal maintenance requirement was an important aspect of the design of the complete device, thus neither the trunk device require special maintenance. One essential task is the cleaning, which is regular in the medical devices, furthermore it is recommended to check monthly the rope and its rollers for the safe operation.

Keep clean of contaminations the gaps between the guide rail, the pipe and the house parts, because it would decrease the tightening efficiency.

3.3.3 The Arm Device

The arm device of the ALLADIN Diagnostic Device has two roles:

- to locate and keep fixed the patient's lower arm in the 3D positions and orientations determined using the anthropometric design approach to all the six ADLs,
- to include a 6 DOF force-torque measurements sensor for the measurement of patient's lower arm isometric effort

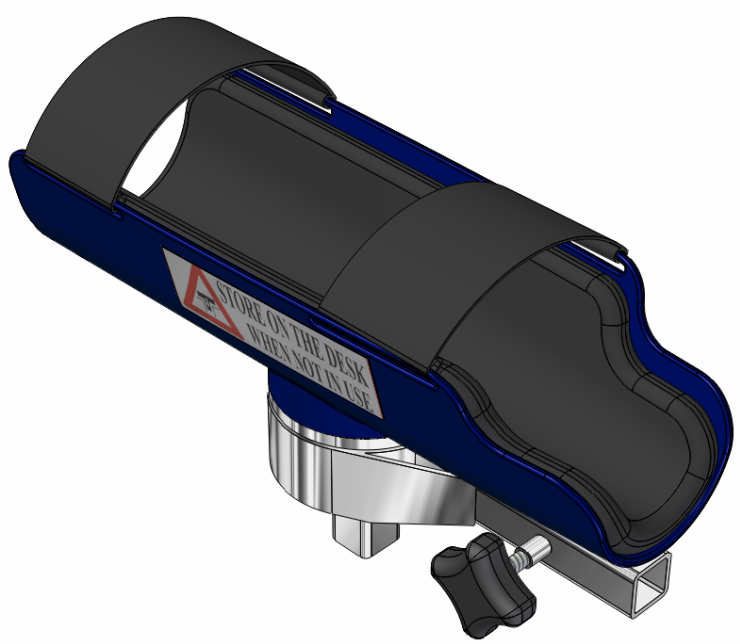


Figure 46. The Arm device of the ADD

The arm device holds the finger device which measures the forces exerted by the thumb, the index finger and the middle finger. For the force torque measuring the patient's lower are should be laid to the arm device, then the three fingers mentioned above should be slipped into the fixations of the finger device, finally the lower arm should be fixed by using the two Velcro straps.

The arm device is actually an instrumented orthosis which includes three main parts (Figure 47):

1. Orthosis
2. Force-torque measurement sensor
3. Socket

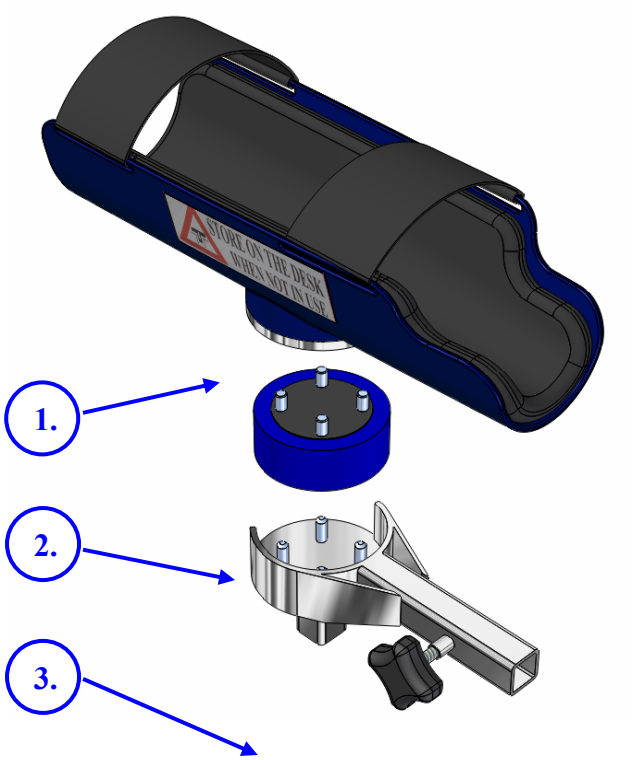


Figure 47. Main parts of the Arm device

The orthosis is a plastic shell and serves the stable holding of the lower arm. The geometrical shape of the shell is a section of a cone. Its dimensions were determined by the S:25%-ile, M:50%-ile, and the 75%-ile anthropometric data. The largest diameter of the cone is 234 mm, while the smallest diameter of the cone is 124 mm. The is a cut out in the orthosis at the wrist. Figure 48 shows the main dimensions of the orthosis. The shell has larger dimension than all the above referred percentile values because we use foam inserts compensate for the smaller dimensions required for the S, M, L size patients. The three different foam inserts are 5 mm (L), 12 mm (M), and 20 mm (S) thick. The foam inserts are fixed to the internal surface of the orthosis through Velcro straps.

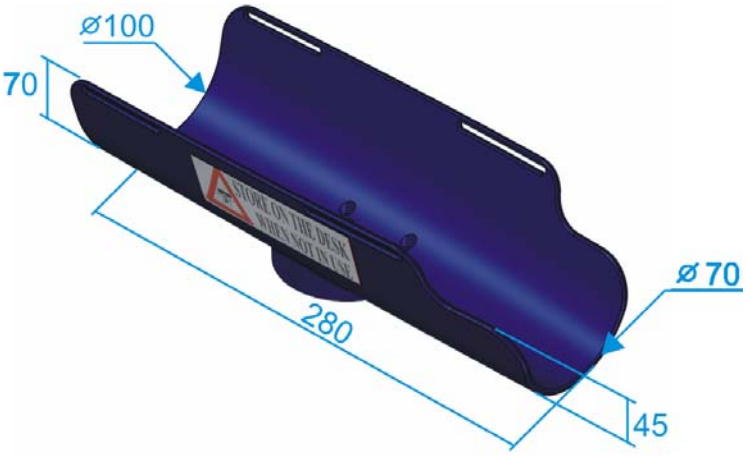


Figure 48. Main dimensions of the orthosis

At the bottom of the orthosis a cylindrical protrusion is formed (Figure 49.). This is the mechanical interface to the arm sensor. The arm sensor (3) is fixed to the cylindrical protrusion (1) through the sensor adapter plate (2) with 4 M4x8 screws (4). The thickness and

the surface quality of the adapter plate was designed in line with the guidelines of the sensor manufacturer. All the metal parts of the arm device are made from stainless steel.

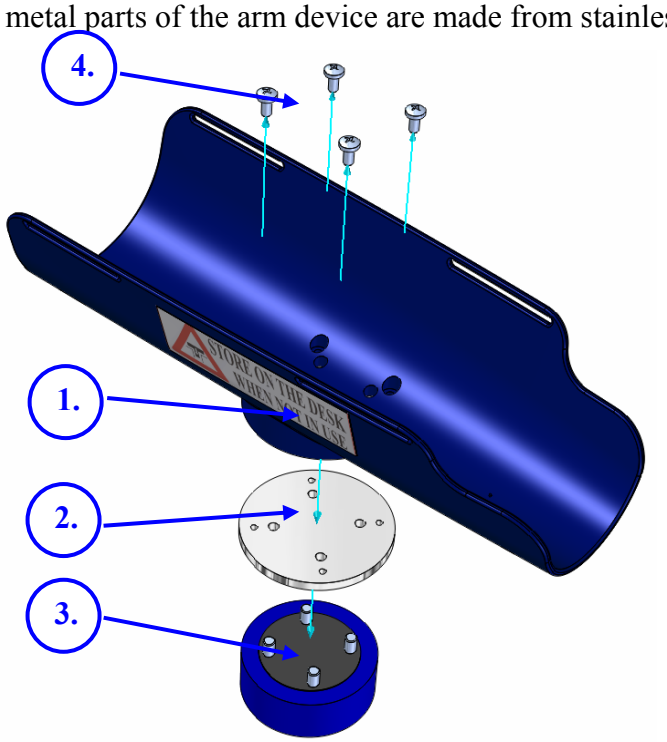


Figure 49. Fixation of the arm sensor

The socket shown in Figure 50. has three different roles:

- to fix the sensor. The sensor socket (1) is made of 5 mm thick plate just as the adapter plate. The sensor (2) is fixed to the sensor socket with 4 M6x20 screws (3).
- to fix the finger device to the arm device. The square stick of the finger device joins the arm device through a square socket. The square socket of the arm device is 100 mm long, in which the square stick of the finger device can be fixed in the S, M, and L sizes with the use of the screw clamp (4). On the bottom of the square stick there is long groove. The square socket has at the same place a threaded pin that allows to slide the square stick between the S and L settings. This is a very simple mechanism for the prevention of accidental separation of the finger device from the arm device
- to fix the arm device to the ground. The arm device cannot be fixed directly to the ground due the collision problems. The so called orthosis plates or at the ADL4 the so called Pos2 orthosis holder have to be set first onto the frames of the ADD, then the leg of the orthosis socket has to be fixed to these devices.

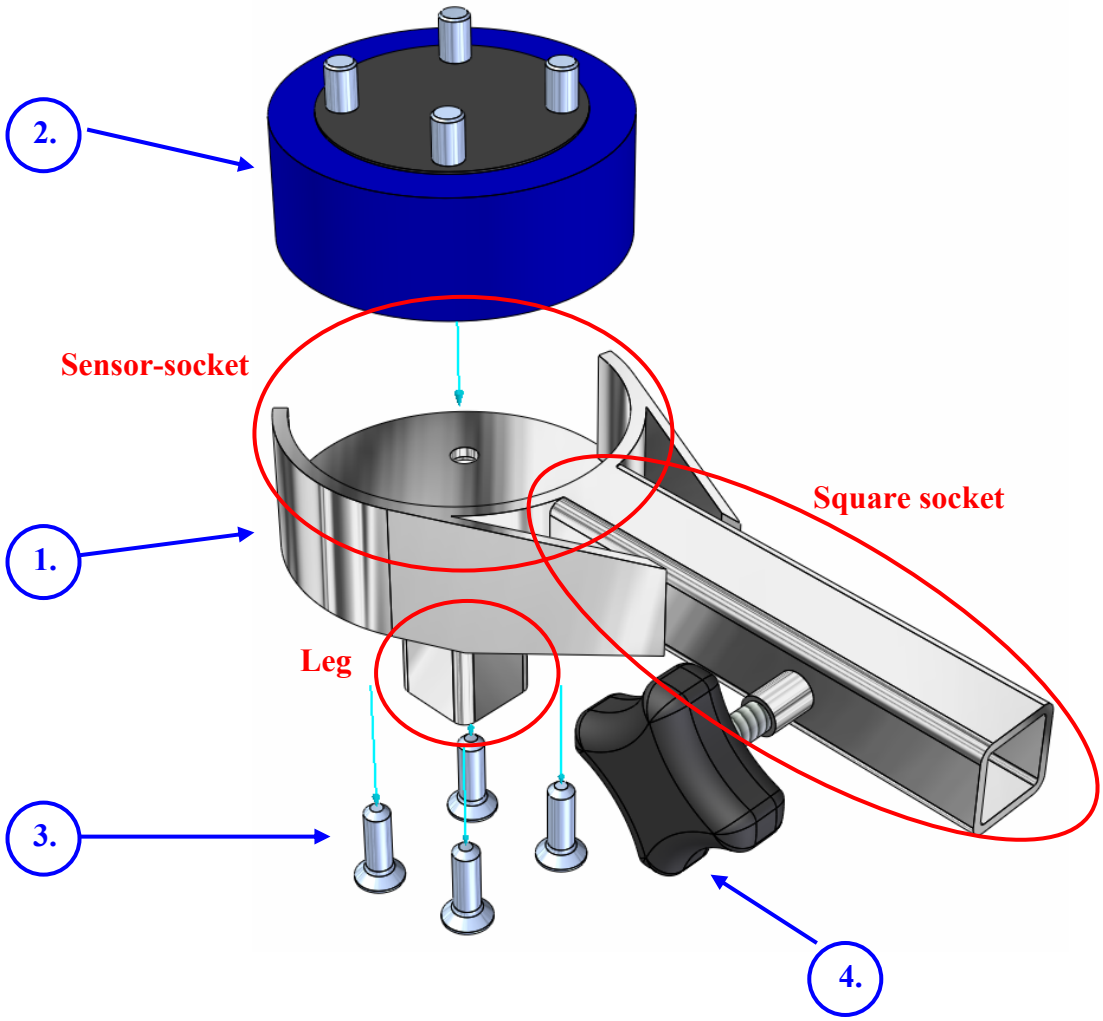


Figure 50. Main parts of the socket

The arm device does not require special maintenance tasks. The cable connections must be checked regularly. The device should be cleaned with the regular dry cleaning methods used in medical environment. The foam inserts are proposed to cover by disposable linen at each measurement. If they get stained they can be washed.

For the measurement of extremely spastic arms two small (50 mm x 30 mm) pillows can be inserted between the standard foam inserts and the patient arm.

The fixing procedure of the arm device is described in the following pages. The ALLADIN Diagnostic Device measures 6 different ADLs in 3 different body postures. Translating this requirement to the arm fixing, the Arm device must be fixed in Position 1 (ADL1, ADL2, and ADL3), in Position 2 (ADL4), and in Position3 (ADL5 and ADL6). For the three positions two type of orthosis holders are used:

- The orthosis holder plate for the Pos1 and Pos3 fixtures,
- The Pos2 orthosis fixture.

The orthosis holder plates are available in three different sizes (S, M, L), and in two sides according to the patient size and the affected side. Altogether 6 orthosis holder plates can be used for the measurements. The orthosis holder plates (Figure 51, Figure 52) were designed to position both in area and in height the square sockets that accommodate the legs of the arm device.

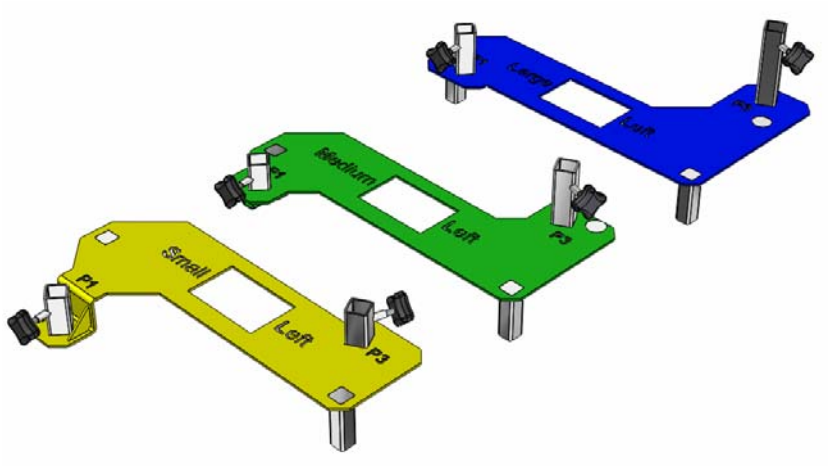


Figure 51. Left side orthosis holder plates

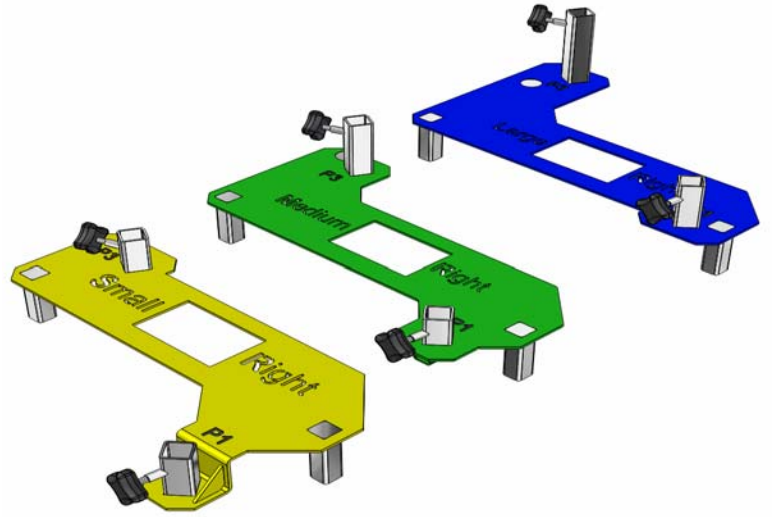


Figure 52. Right side orthosis holder plates

The left and the right side orthosis holder plates are mirror symmetrical to each other, so only the righ side orthosis plates are described in details. Figure 54, Figure 54., and Figure 55. show the structure of the S, M, and L size orthosis holder plate respectively:

1. Baseplate
    a. Aligning cutout
2. Pos1 socket
3. Pos2 socket
4. Screw clamp
5. Leg
6. Stiffening rib
7. Stiffening sticks

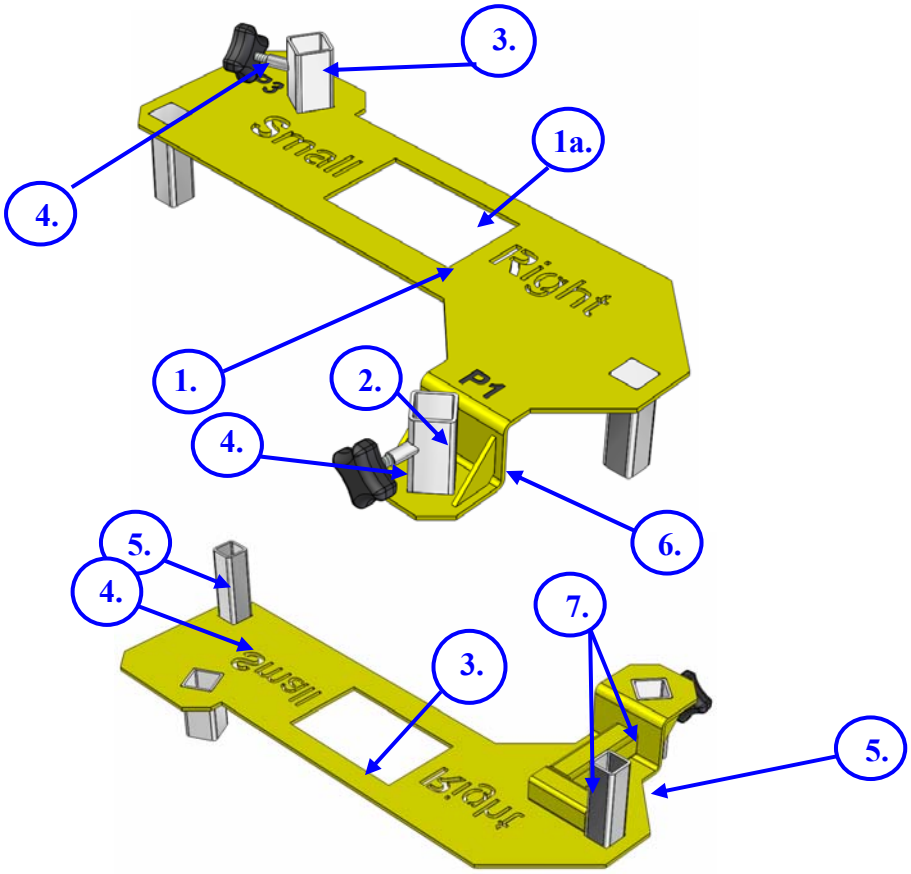


Figure 54. Structure of the S size orthosis holder plate. (Top and bottom views)

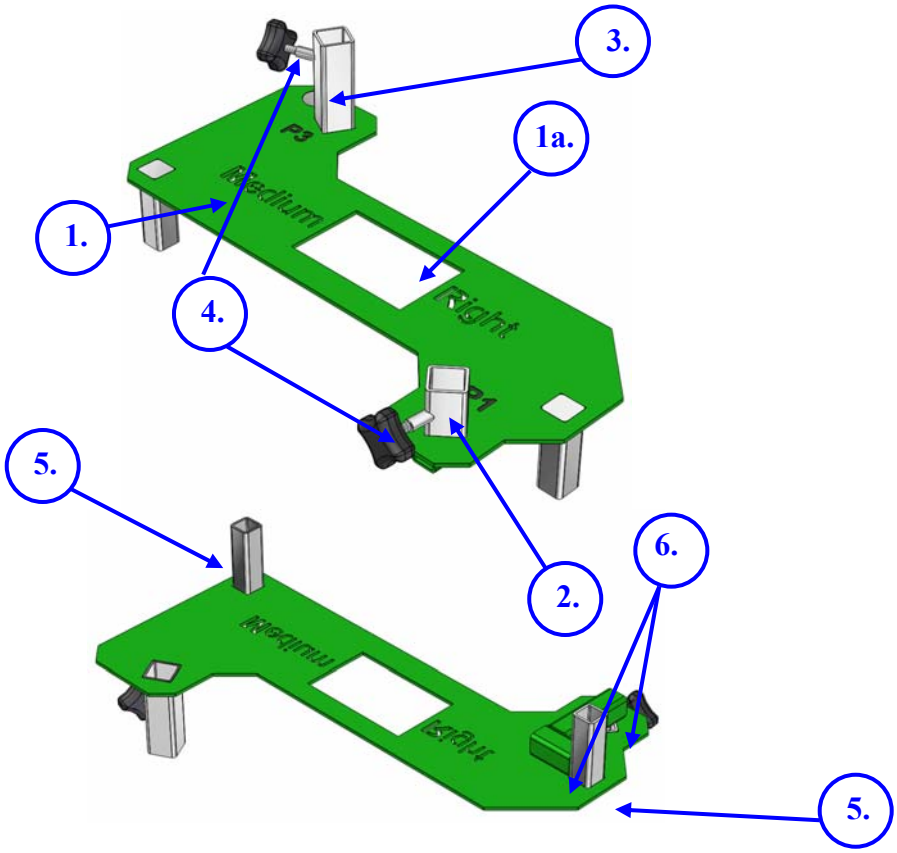


Figure 54. Structure of the S size orthosis holder plate. (Top and bottom views)

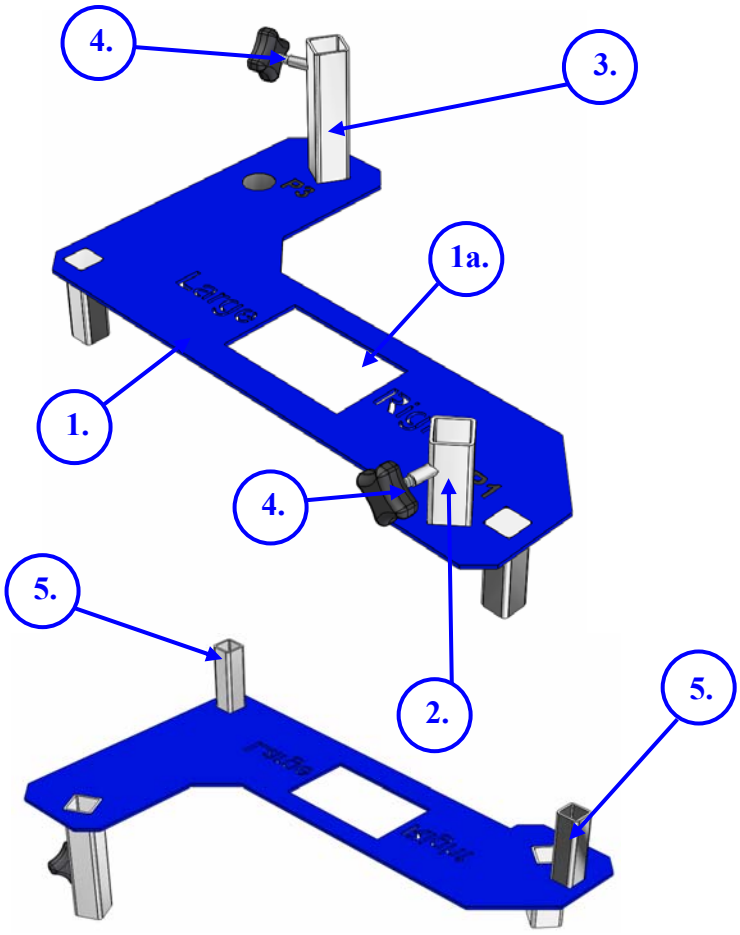


Figure 55. Structure of the L size orthosis holder plate. (Top and bottom views)

Selection of the right orthosis holder plate is easy because the colour coding defines the size, and the side and the size are marked by a cut out label on each plate. The orthosis holder plates must be fixed to the seat lift frame by inserting their legs (5) into the corresponding sockets and tightened by screw clamps. Similarly, the leg of the arm device must be fixed to the square sockets (2 or 3) and tightened by the screw clamps (4).

The Pos2 orthosis fixture differs from the orthosis holder plate. The role of the Pos2 orthosis fixture is to position the patient's arm for ADL4: lifting a bag. A left and a right side Pos2 orthosis fixtures assembled on the trunk frame are used in the ALLADIN Diagnostic Device

Figure 56. shows the structure of the right side Pos2 orthosis fixture. The house of the fixture is split into two symmetrical blocks. The blocks are fixed to each other by a screw at the inner side, and with a manually operated eccentric clamp at the outer side. Two sliding circular sticks stand out from the house towards the inner side of the ADD. The sticks hold the square sockets identical to those used on the orthosis holder plates. The leg of the arm device must be fixed to this square socket.

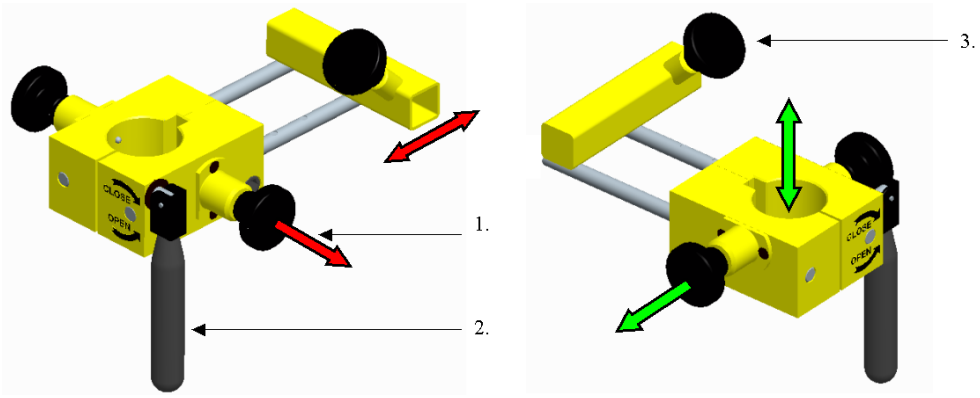


Figure 56. Structure of the Pos2 orthosis fixture. (Front and rear views)

The anthropometric design in Deliverable 1.1 concluded that the S, M, L size patient's fingertips reach three different lateral and vertical co-ordinates during ADL4: lifting a bag. The Pos2 orthosis fixture must render therefore the vertical and horizontal positioning of the square socket possible. The vertical and horizontal adjustment directions are shown by the red and the green arrows in Figure 56.. Before starting the setting of the device the eccentric clamp (2) must be released by turning up the handle. For the horizontal setting of the device the snap in pin (1) must be pulled out (green arrow), and released in the S, M, L widths. For the vertical setting of the device the screw clamp (opposite to 1) must be loosened (red arrow), and tightened in the selected S, M, L heights. There is guiding key at the inner side of the tube of the trunk frame to keep the exact vertical displacement as well as to prevent any undesired rotation of the Pos2 orthosis fixture during the isometric force measurement. The S, M, L positions of the Pos2 orthosis fixture are all preset and color coded. Finally, the arm device must be fixed to the square socket by the screw clamp (3).

Figure 577 shows the main dimensions of the Pos2 orthosis fixture. The Pos2 orthosis fixture was designed to maintenance free for the full lifetime of the ALLADIN Diagnostic Device. When the closure angle of the eccentric clamp changes the manufacturer should be notified. This check must be performed each month.

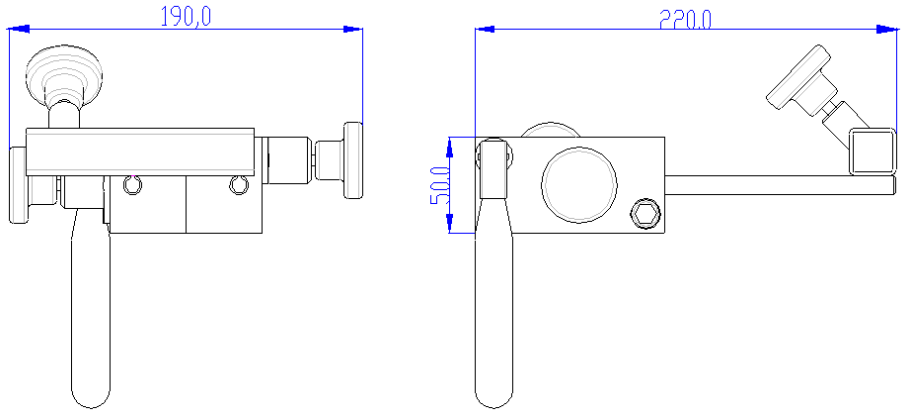


Figure 57. Main dimensions of the Pos2 orthosis fixture

The tray and the tray holder

The role of the tray is to provide place for the objects near the patient's hand when executing the ADL exercises at the Position 1 and 3. There are stickers for the following

objects: key, spoon, and bottle (The glass of ADL 1 is placed on the finger device between the fingers).

The ADD has two trays for the affected left- and right side of the patients (Figure 58).

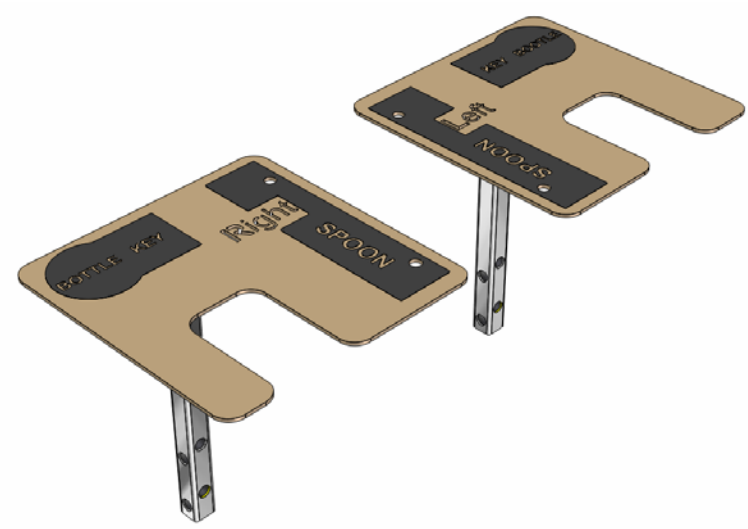


Figure 58. Right and left tray

The tray can be divided into the following two parts:

- a horizontal plate, which is really "the tray",
- and a long "leg".

The leg, which is made of stainless square tube, can be fitted into the appropriate tray socket of the tray holder plate, which is the top cover of the seat frame. The sockets for the tray in the Pos1 and Pos2 are available in this plate (Figure 59.).

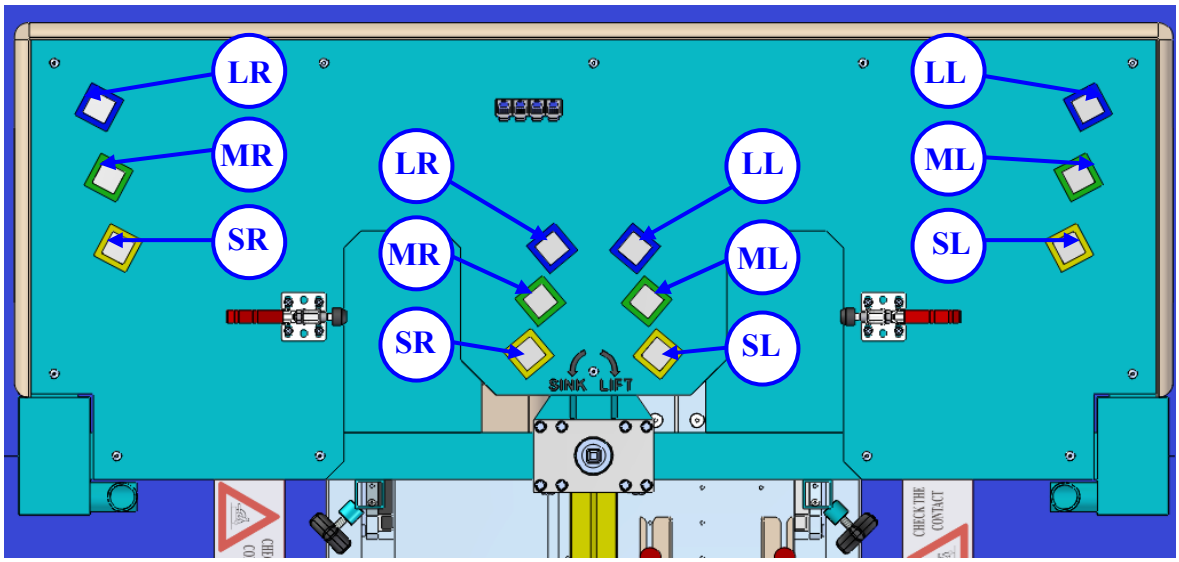


Figure 59. The tray holder plate

There are 12 sockets on the tray holder plate, as both the Pos1 and the Pos3 have three distinguished positions, that are six sockets per side.

The sockets are made of stainless square tube. The sockets are marked by colour stickers according to the size, to help finding the appropriate socket.

Socket codes:

LR	Large size, Right side	LL	Large size, Left side
MR	Medium size, Right side	ML	Medium size, Left side
SR	Small size, Right side	SL	Small size, Left side

The height of the arm device varies with the S, M, L sizes, and so does the height of the tray, too, because the tray must be placed just under the finger device. The same tray is used for the S, M, L sizes, and the length of the leg cannot be changed, so the deepness of the sockets is varying. The hollow tubes are covered at the bottom for this reason.

The tray should be placed into its socket before inserting the arm device. In the leg double spring pre-stressed bearing balls on two sides provide the tray fixation without backlash. The bearing balls and the springs are placed into a plastic sleeve within the hollow pipe. There are holes on the side of the tray leg. The size of these holes is designed to let the bearing balls to stand out from the hollow pipe by 1.5 – 2 mm. The pre-stress of the springs are adequately set to do away with backlash. The structure of the leg is displayed on Figure 60..

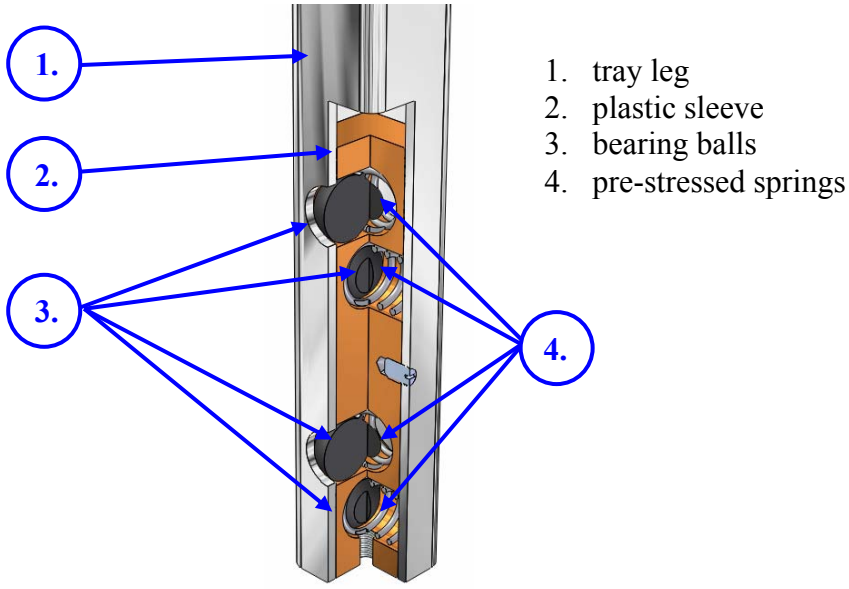


Figure 60. The structure of the tray-leg

3.3.4 The Finger Device

3.3.4.1 General description

The ALLADIN Finger Device (AFD) consists of three f/t sensors located on the outer side of the hand. The aluminum construction allows a firm support for the sensors during the measurement. The approximate measures of the device itself are 225x100x160 mm. The weight of the AFD is approximately 1.8 kg. The support plate with a rectangular stick is attached for the integration with the ALLADIN Arm Device. During the measurement the

hand is positioned between the sensor for the thumb and the two sensors for the index and middle finger, while the forearm is resting on the arm support. Finger fixations are used to fixate the fingers and thumb in the correct configuration and provide transfer of forces and torques to the sensors.

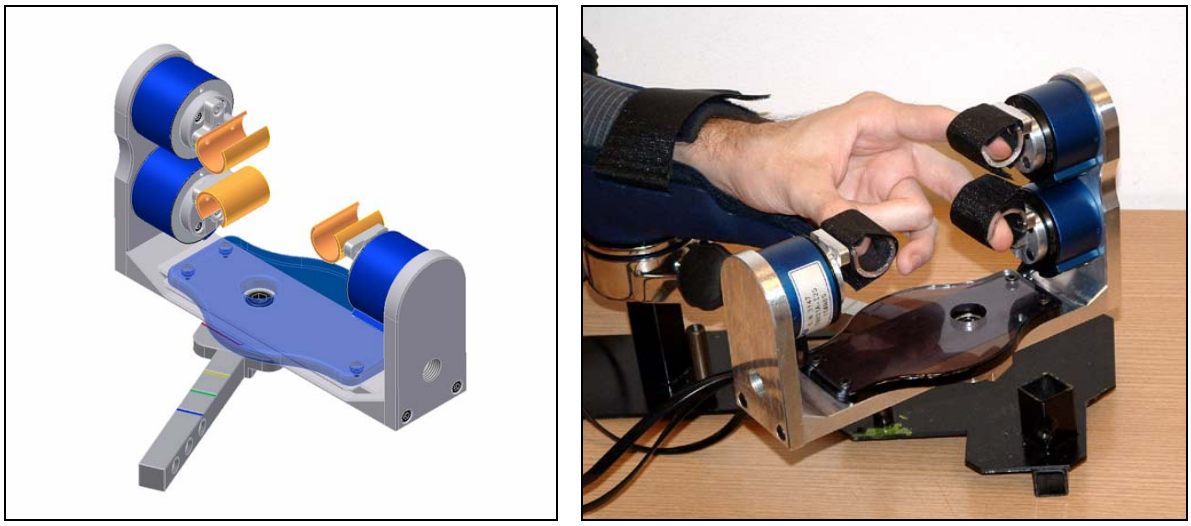


Figure 61. 3D model and the final version of the ALLADIN Finger Device (AFD)

The fingers are attached to the device through specially designed finger fixations. The finger fixations are made of plexiglass which provides compact support for the fingers and increases the rigidity of the connection between the finger and the sensor. The shape of the finger support is ergonomically designed without any sharp edges. The shape is slightly curved outwards to allow comfortable positioning of each finger. For the dimensions of the finger fixations, anthropometric data on finger thickness was considered[3]. The fingers are attached to the finger support using Velcro straps. Finger wraps could be used if the size of the finger is too small to fit tightly when strapped into the finger support. The finger fixations are fastened on the aluminum support which is fixed to the sensor through a circular interface plate. This allows easy replacement of the finger fixation in case of damage. The smooth and transparent plexiglass of the finger support allows easy cleaning and compliance with the hygiene requirements.

3.3.4.2 Functional specifications

The AFD was designed to accustom different patient sizes. To minimize the complexity of operating the device, the hand aperture was fixed to one size for all patients. The distance between the thumb and index finger is set at about 65 mm to allow insertion of objects (i.e. glass and small bottle) between the fingers while providing a comfortable position of the hand for patients of different sizes.

[3] Pheasant S., Bodyspace. Anthropometry, ergonomics and the design of work. 1999, Taylor & Francis, London, pp. 84-85.

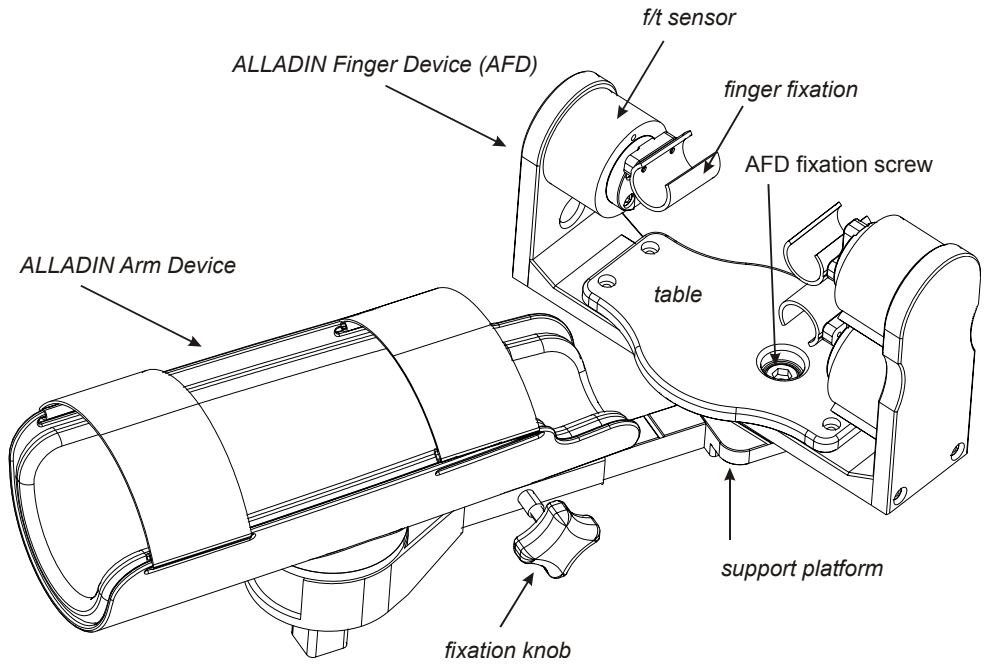


Figure 62. The ALLADIN Finger Device integrated with the ALLADIN Arm Device

The orientation of the AFD relatively to the Arm Device is set at the angle of 67 ° between the forearm and the wrist. The orientation angle and the position of the device were determined through extensive testing to find the optimal orientation which would comfortably fit people of different sizes. The device is fixed to the support platform with a fixation screw while the orientation is fixed through an insert-hole configuration. The bottom plate of the AFD has a rectangular insert which fits to a hole located on the support platform. The device can be fixed only in one orientation either for the left or the right hand measurement.

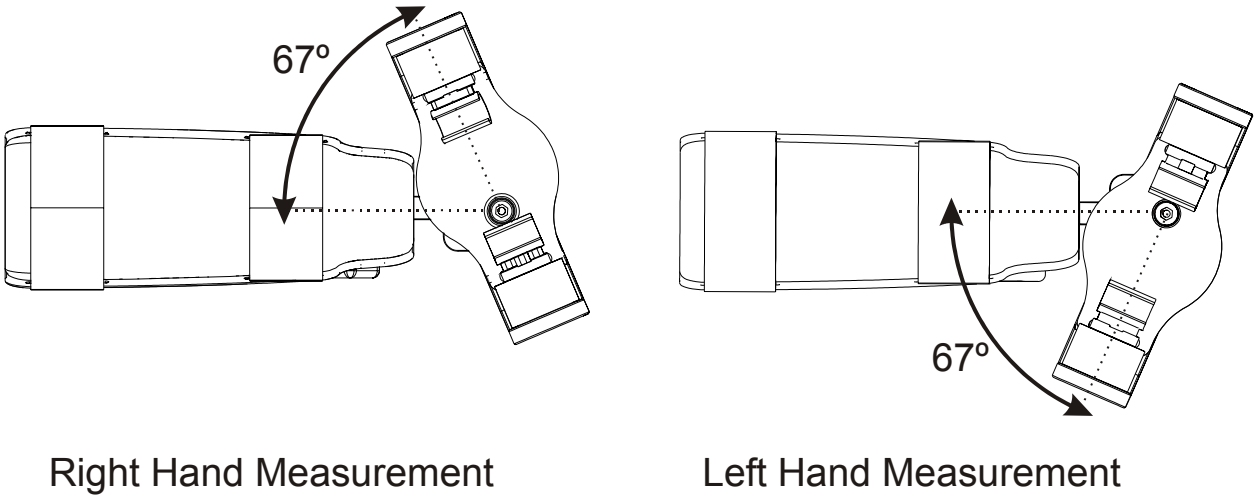


Figure 63. The orientation angles for the right and left hand measurements

The design of the AFD allows measurements of the left or right hand. The exchange between the two configurations is performed by unfastening the fixation screw located at the bottom plate of the AFD. When the fixation screw is unscrewed, the device can be lifted and the orientation can be changed by fitting the insert at the bottom plate into the hole of the support platform. The bottom plate of the AFD is covered with a small table made of plexiglass to provide support for placing the glass and small bottle during the grasping tasks. The table is semi-transparent to allow easier placement of the AFD when exchanging the orientation.

3.3.4.3 Interfaces

3.3.4.3.1 Electrical interface

Each of the three sensors has a flat six-wire cable leading from the housing of the sensors. On the AFD the cables of the two finger sensors are lead inside a groove of the bottom plate and joined with the third cable. All three cables are lead through the opening of the side plate. The cables are then joined with the arm device cable. The bundle of four cables is then lead to the ADD System socket located at the front of the main table.

3.3.4.3.2 Software interface

The three cables from the AFD exit from the general socket placed on the podium and reach one of the two PCI receiver/processor boards on the ALLADIN PC. From the PCI receiver/processor board a single record for each of the three sensors for each measurement is created and, using the Cover Application, stored in the local database.

3.3.4.3.3 Mechanical interface

The integration of the AFD with the Arm Device is achieved through a support platform which is located underneath the device. The support plate is inserted into a rectangular hollow stick of the Arm Device. The position of the AFD can be adjusted relatively to the arm support. Three different fixed positions are defined for S(mall), M(edium) and L(arge) patients. The pre-set positions are marked on the insertion stick with the colors corresponding to each of the sizes as defined for all the parts of the ALLADIN Diagnostic Device. The AFD is fixed to the arm device using a fixation knob located at the side under the arm support. There is a mechanical constraint to prevent the complete pulling of the AFD out of the Arm Device in order to prevent damage of the device due to falling.

3.3.5 The Foot Device

3.3.5.1 General description

The functional design of the ALLADIN Foot Device is illustrated in this section. During the first year of the project, many different concepts were realized, addressing also the problem of the fixation of the lower extremities of the patient during the measurements. Figure x shows the latest version of the Foot Device. Two sensors are placed on the Foot Device: one for measuring forces and torques of the foot and another for big toe ones.

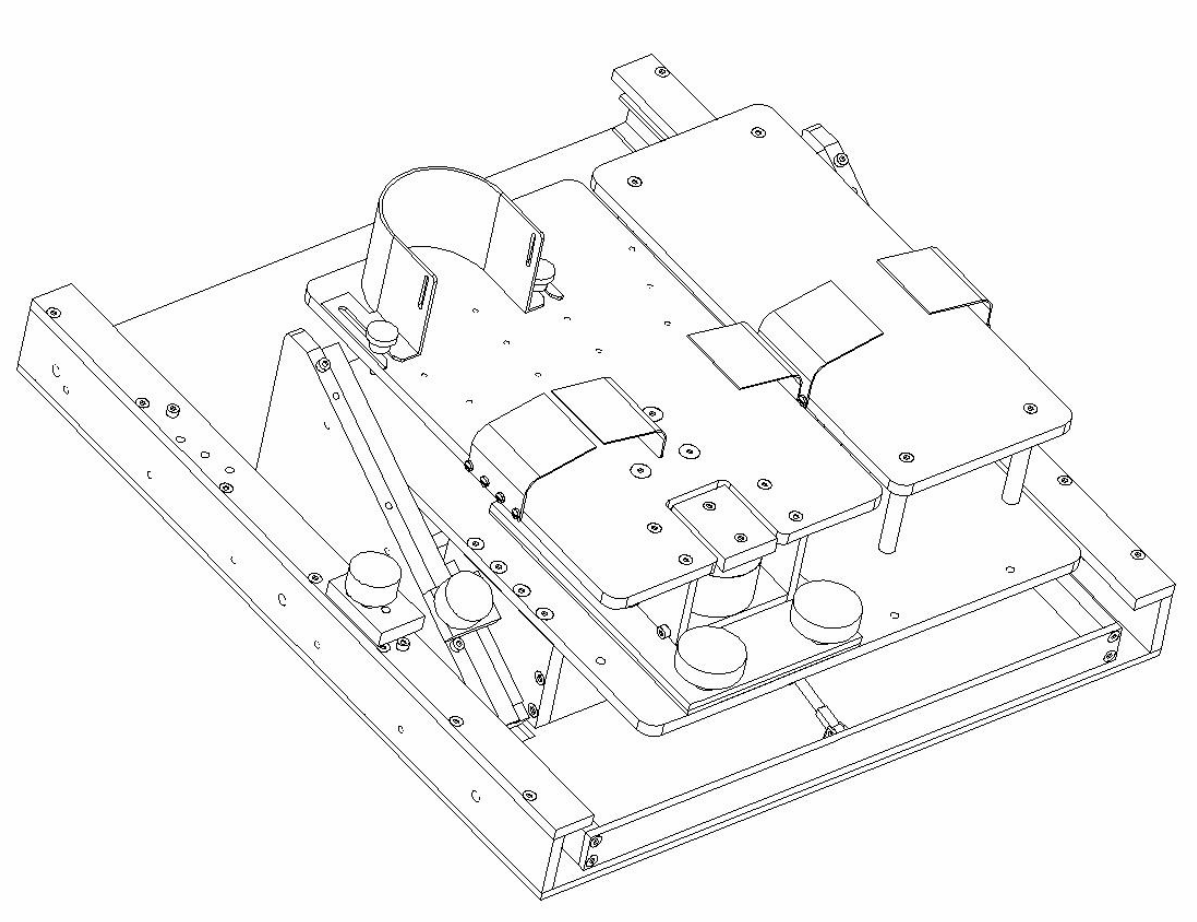


Figure 64. The ALLADIN Foot Device

The Foot Device is formed by two inclined walls on which a base platform can slide. On the base platform two platforms are placed: one is provided with the two sensors and it allows to perform the measurements of the affected foot, the other simply supports the not affected foot. The two inclined walls allows to move the base platform in order to adjust the height of the device according to the different patients sizes.

3.3.5.2 Functional specifications

The Foot Device allows to adjust the height of the platforms, according to the different height sizes of the patients. This is realized pushing the base platform, up or down along the inclined walls and fixing it through a simple movement of insertion of two fastener knobs, situated on the two sides of the base platform. In Figure 65 the position of the fastener knobs is shown.

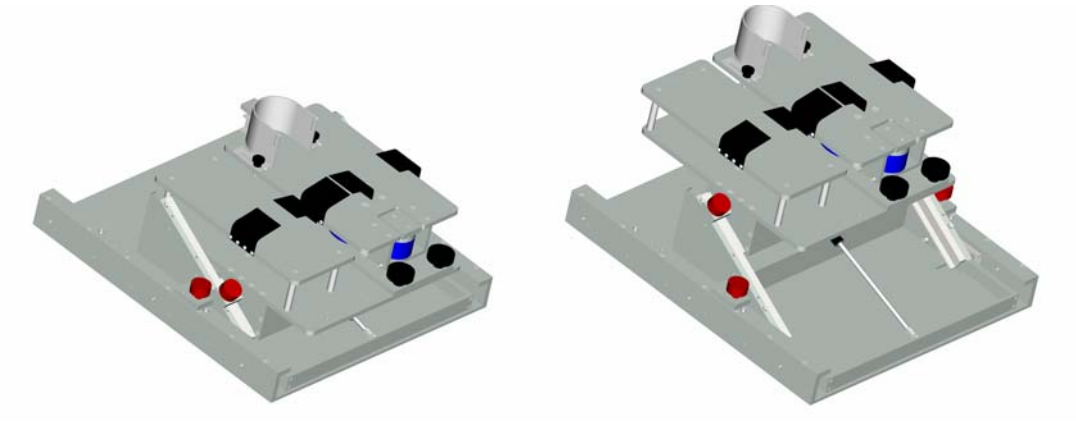


Figure 65. 3D model of the final the ALLADIN Foot Device

A gas spring assures a soft movement during the change of the S, M, L setting. The Foot device allows to perform measurements on both feet: a simple exchanging mechanism of the platforms is provided. The physiotherapist lifts the support platform and put it away, unscrew two fastener knobs from the base platform, pulls the platform provided with sensors to the opposite side (from left to right or from right to left), fix it on the base platform with the fastener knobs and put the support platform to the empty side. Figure 66 shows the illustrated mechanism.

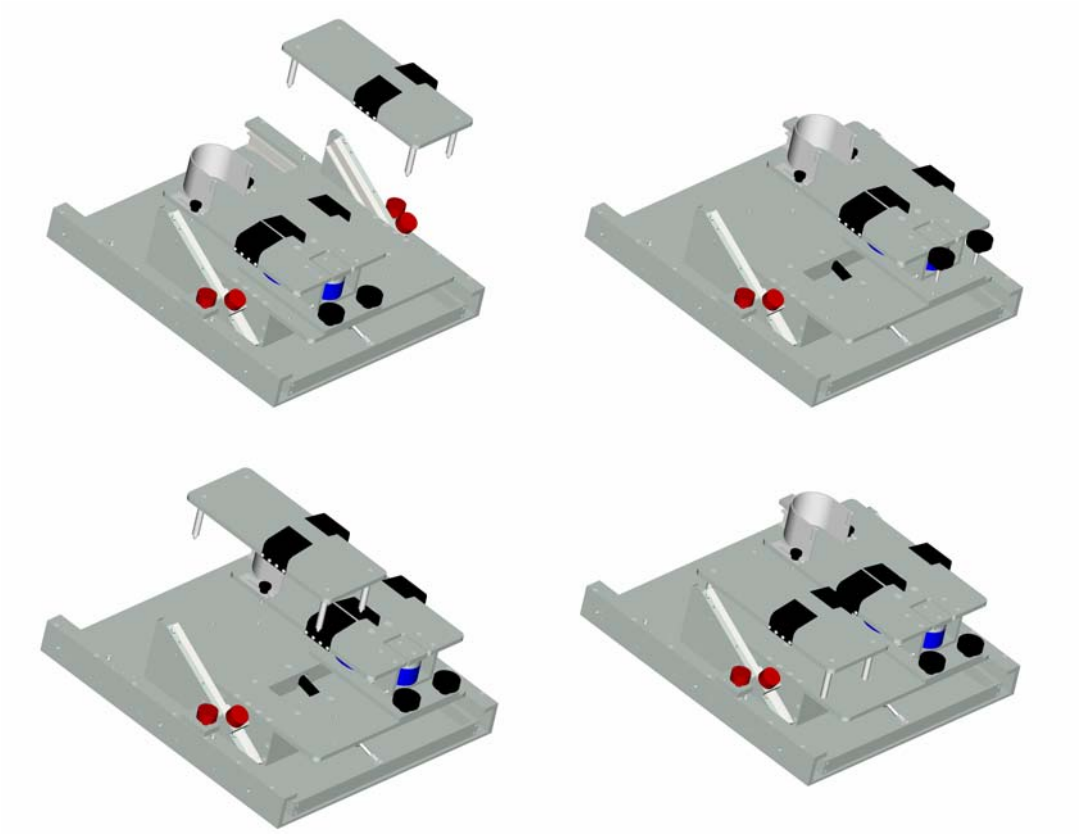


Figure 66. The exchanging mechanism of the platforms

When the ADD physiotherapist has to pass from the ADL exercises of position 1 and position 2 to the ADL5 and ADL6 exercises of position 3, the Foot Device must be pushed back on the horizontal guideways until the relevant S, M, or L position is reached and locked through a fastener knob (Figure 67).

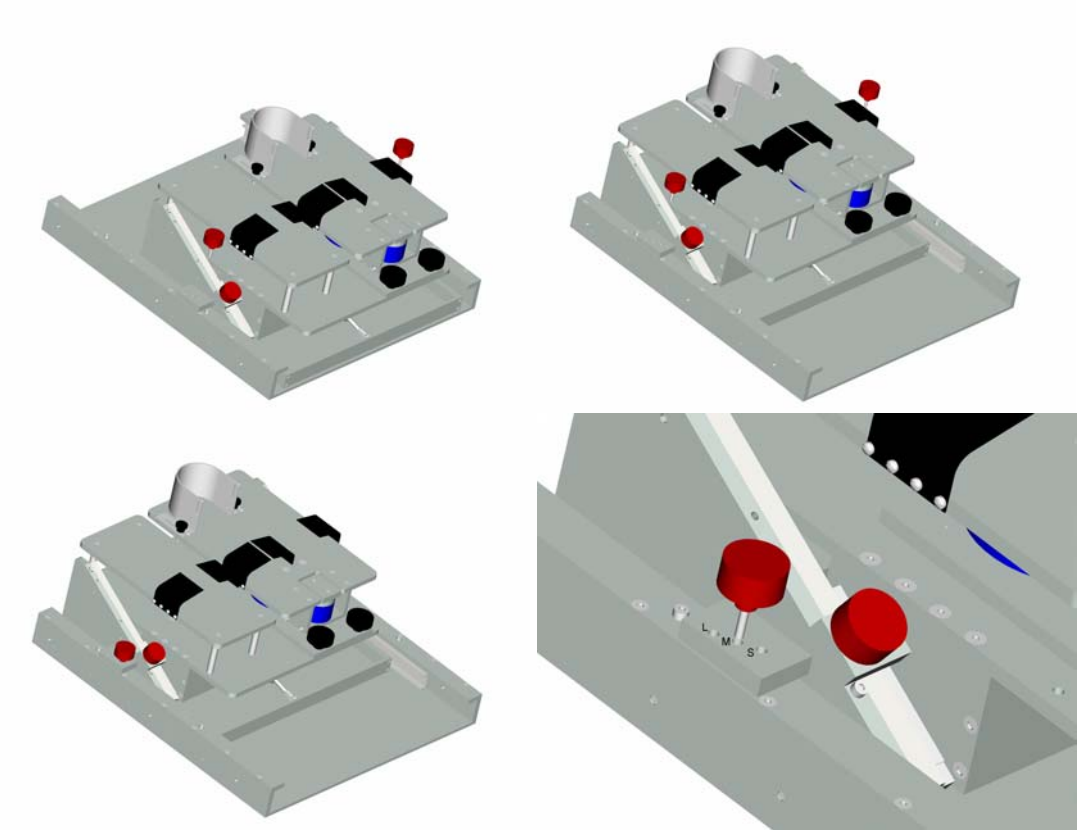


Figure 67. The mechanism between the different positions in the ALLADIN Foot Device

3.3.5.3 Interfaces

3.3.5.3.1 Electrical interface

Two cables exit from the rear side of Foot Device toward the podium. A 6 pin cable + 6 pin cable from the foot and big toe sensors reach the rear side of the slot and through a socket are connected to the general socket, placed on the left-rear side of the podium. Figure 68 illustrates the pathways of the cables from the two sensors of the ALLADIN Foot Device.

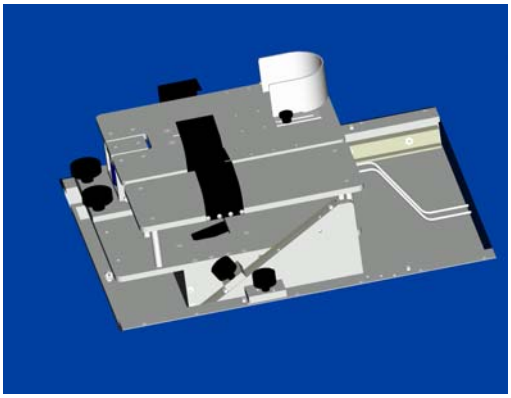


Figure 68. The cables of the sensors in the ALLADIN Foot Device

3.3.5.3.2 Software interface

The cables from the foot and big toe sensors exit from the general socket placed on the podium and reach one of the two PCI receiver/processor boards on the ALLADIN PC. From the PCI receiver/processor board a single record for each of the two sensors for each measurement is created and, using the Cover Application, stored in the local database.

3.3.5.3.3 Mechanical interface

The Foot Device is situated into a slot, placed in the podium of the ADD, as shown in Figure 69. It is fixed to the podium itself through 6 screws on the lateral side, 3 for each side.

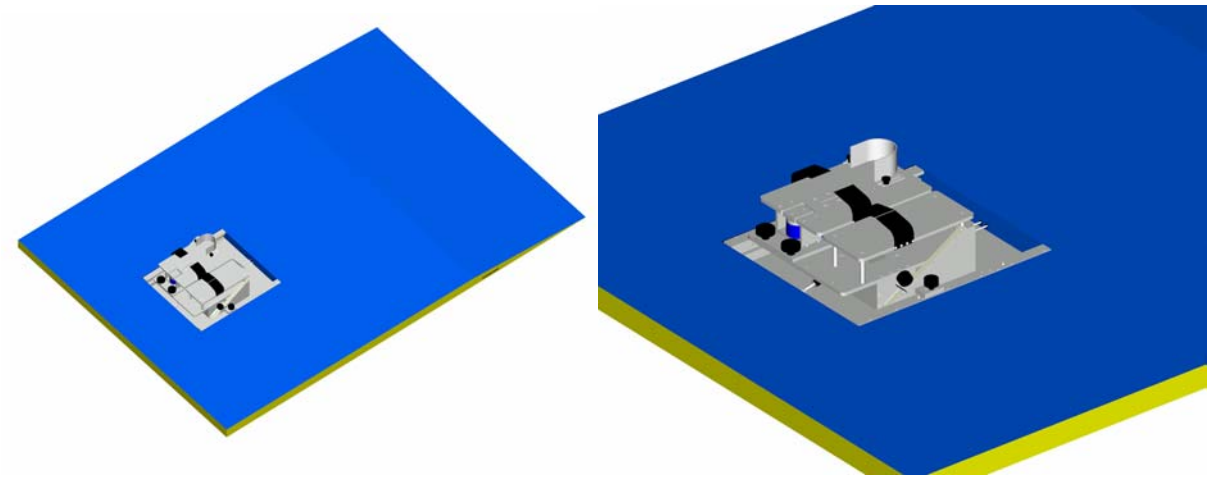


Figure 69. The cables of the sensors in the ALLADIN Foot Device

The edges of the platforms of the Foot Device have been chamfered in order to assure the safety for the physiotherapist and the patient.

3.3.6 The Seat Device

The main role of the seat device is the measurement of the patient's balance during the ADL exercises. The other roles of the seat device are the following:

- Lifting the patient to measurement position.
- Setting a fixed measurement position for ALL patients
- Connecting to the transit lying wheelchair
- Supporting the weight of the patient

The seat device is composed of the following components (Figure 70)

1. Front frame
2. Seat lift
3. Seat plate

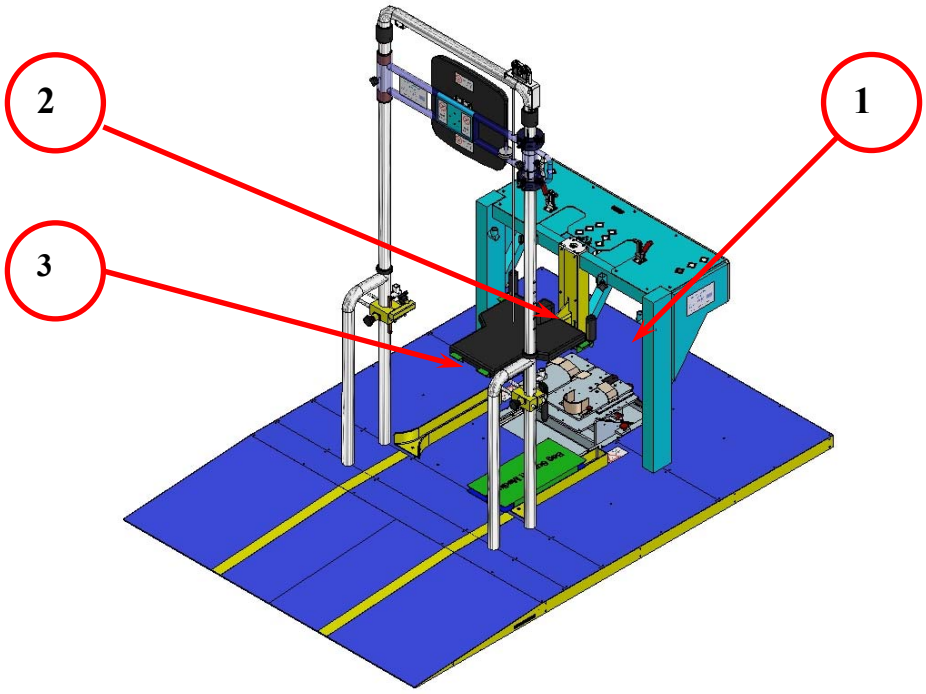


Figure 70. The components of the seat device

The *front frame* is a welded frame placed in front of the patient. The seat lift is fixed onto this component, which holds the complete weight of the patient. Therefore the main role of the front frame is to support the load of the patient and other components, which are fixed to it. For the adequate stiffness for the measurements, the frame is a welded truss structure. The frame is fixed to the base of the ALLADIN Diagnostic device by bolts.

The other role of the front frame is to hold the tray holder plate, into which the tray is inserted before the Pos1 and Pos3 measurements. Furthermore the sockets of the ADD arm support and the orthosis holder plate are welded also onto this frame.

After docking the transit lying wheelchair, its seat plate with the patient is lifted to the measurement position by the seat lift.

The pure mechanical device is operated manually. The vertical linear movement is guided by a spindle-nut-pair. After docking the wheelchair, the physiotherapist lifts the patient to measurement position by turning the winch (Figure 721). The spindle-nut connection is self-locking, furthermore the up and down terminal positions are secured by bumpers. The maximum lifting is 80 mm, and the corresponding top and bottom heights from the top of the podium are presented on Figure 75.

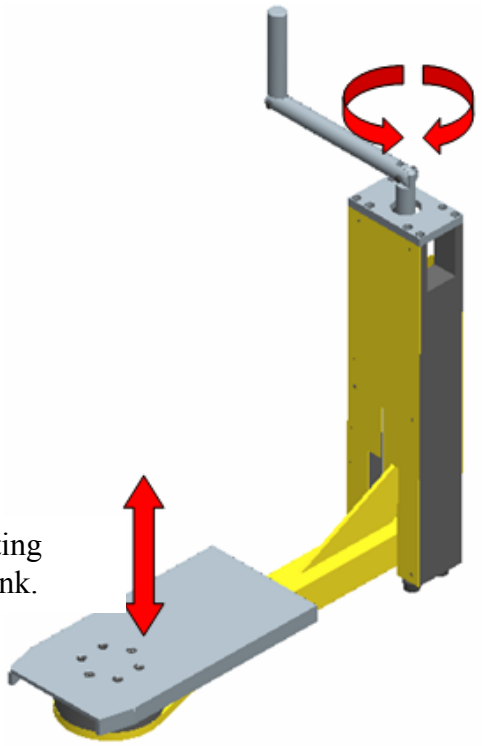


Figure 71. The assembled seat lift

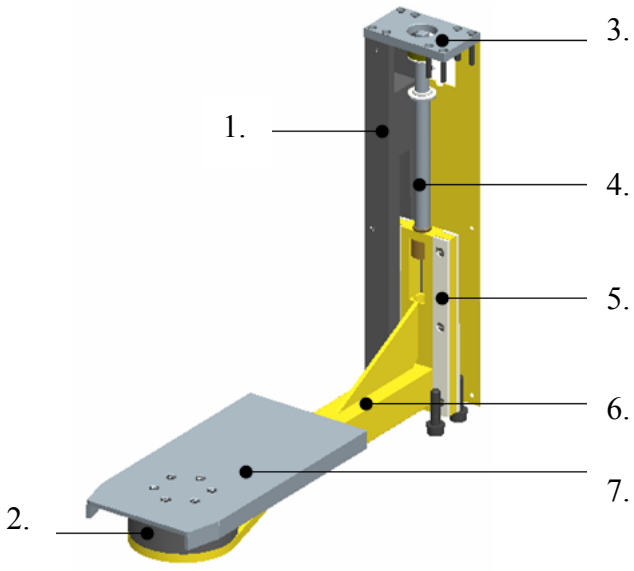


Figure 72. The seat lift without the cover plate and the right sliding guide

The structure of the seat lift is displayed on Figure 72. The frame of the device is the welded structure, denoted by 6. It ends in a oven pan like part, which holds the 6 DOF force torque sensor – the so called "seat sensor" (2). The orientation of the sensor coordinate system is as follows: the x-axis is parallel with the axle of the seat supporting arm, its positive direction points from the centre of the sensor to the spindle; the y-axis points to the left side of the patient, and the z-axis points upwards. The upper face of the sensor holds the seat lift plate (7), which has a wedge-like front, in order to help the orientation of the guide rails on the seat plate of the wheelchair, during docking.

The vertical guide rails (1) are made of 60x40 square profile, which are fixed and aligned by a connecting profile (3) at the top, and the supporting plate of the I frame. The friction between the moving parts is decreased by Teflon inserts (5). The sleeve-nut is in the housing at the top of the slide. The rotation is locked by its non rotational symmetric shape, while the vertical translation is locked by a ring. The Tr16x3 chrome steel spindle is sitting on a SKF thrust ball bearing, its radial guiding is provided by two Teflon bushes. Its upper free end is flat, onto which its negative counter-pair, the housing of the winch is connected. This latter is connected to the seat lift only during lifting. The lift is covered by plates at the front- and back sides, which decreases the possibility of accidents by the moving parts, and provides more ergonomic shape. The component is free of backlash, and its required stiffness is proven by the design for strength. The maximum allowed lifting load is 120 kg. The weak part of the structure is the spindle, in which the resultant stress is 16.3 MPa (safety factor >>8) for the 1000 N load.

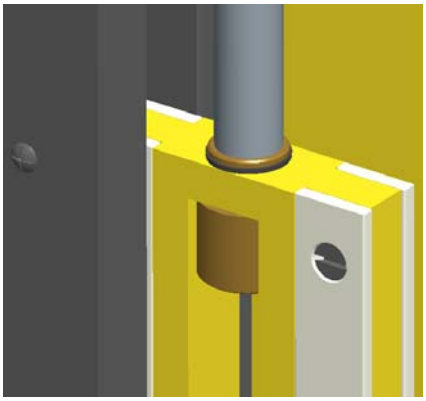


Figure 73. The spindle-nut connection

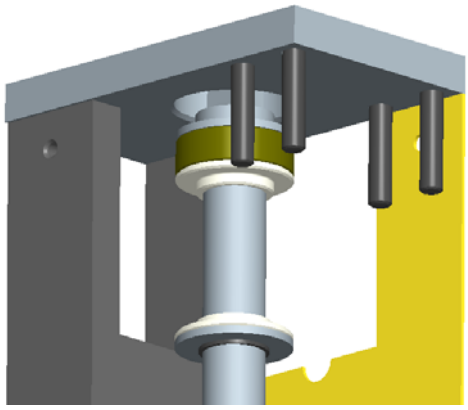


Figure 75. The alignment and guiding of the spindle at the upper end.

At the assembling the sliding surfaces must be greased in a thin layer. It is recommended to check the tightness of the bolt joints monthly. The device does not require further maintenance during its life time, the 3000 measurements. Figure 75 shows the main dimensions of the seat lift.

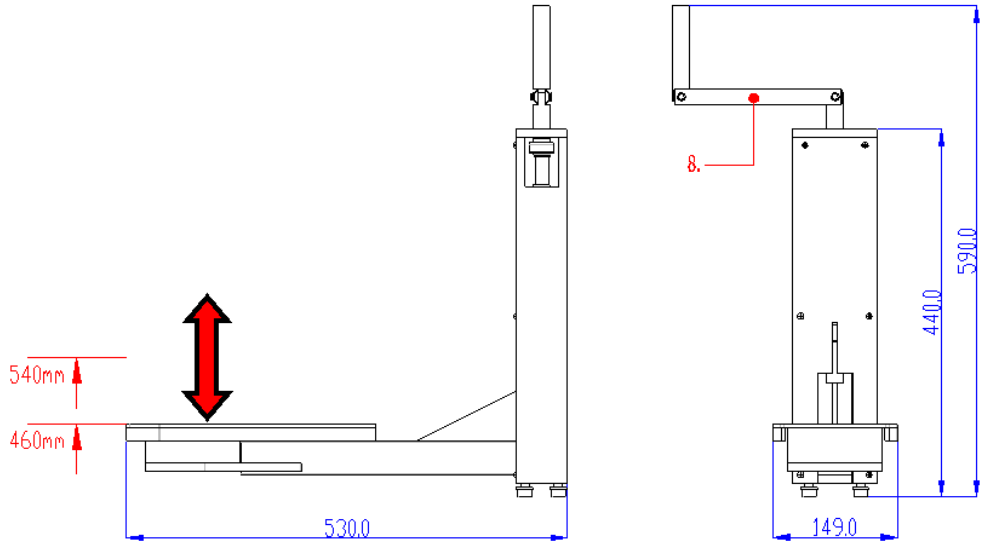


Figure 75. The dimensions and the stroke of the seat lift

The ALLADIN Diagnostic Device has a specially formed seat plate. The seat plates placed into the wheelchair render the movement of the patient to and from the ADD possible. In addition they are the appropriate connectors to both the wheelchair and the measuring device. The device has three seat plates for the S, M, L patient sizes (Figure 76). The particular seat plates differ in their width.

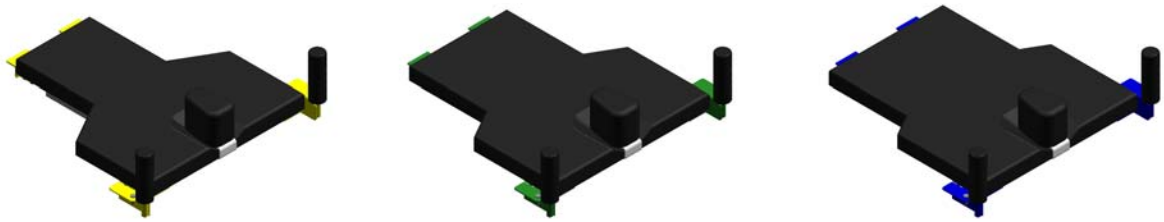


Figure 76. The three different sized seat plates

The shape of the seat plates differ in the width of the side cut-outs for the finger device. The surface of the seat plate is 430 mm in length, and the width at the cut-outs is 180 mm for the "S", 240 mm for the "M" and 280 mm for the "L" size. The width at the front side between the centre lines of the aligning pins is 445 mm for all seat plate. The height is 60 mm without the anchoring and straddling wedge, and 130 mm with it. Further details can be seen in Figure .

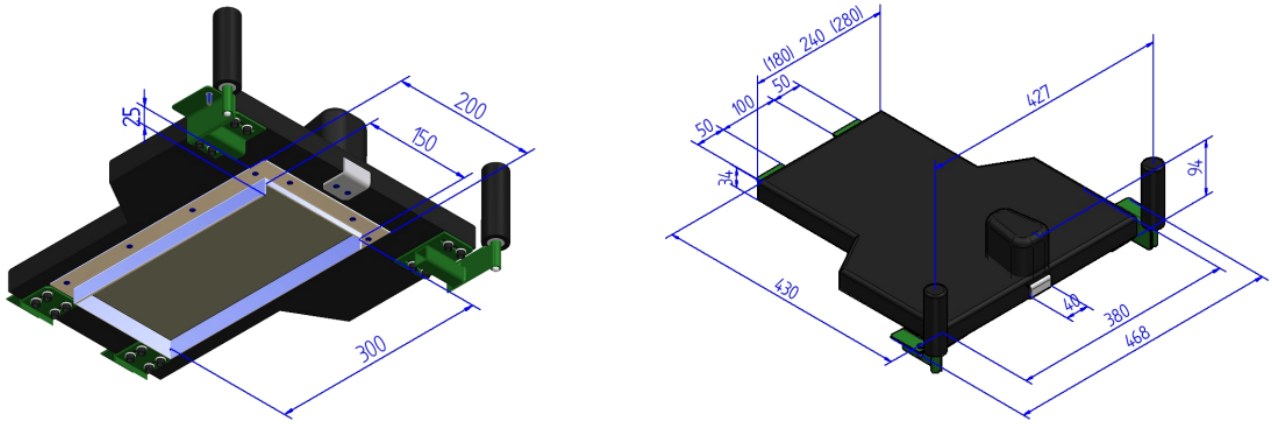


Figure 77. The seat plate

The functional components of the seat plate are:

1. layered plate
2. foam inserts (20 mm thick)
3. upholstery
4. side support tabs
5. back support tabs
6. guiding frame
7. holder plate of the anchoring and straddling wedge
8. anchoring and straddling wedge (can be taken out, and be replaced)
9. aligning pin

10. thigh supports
11. deerskin inserts

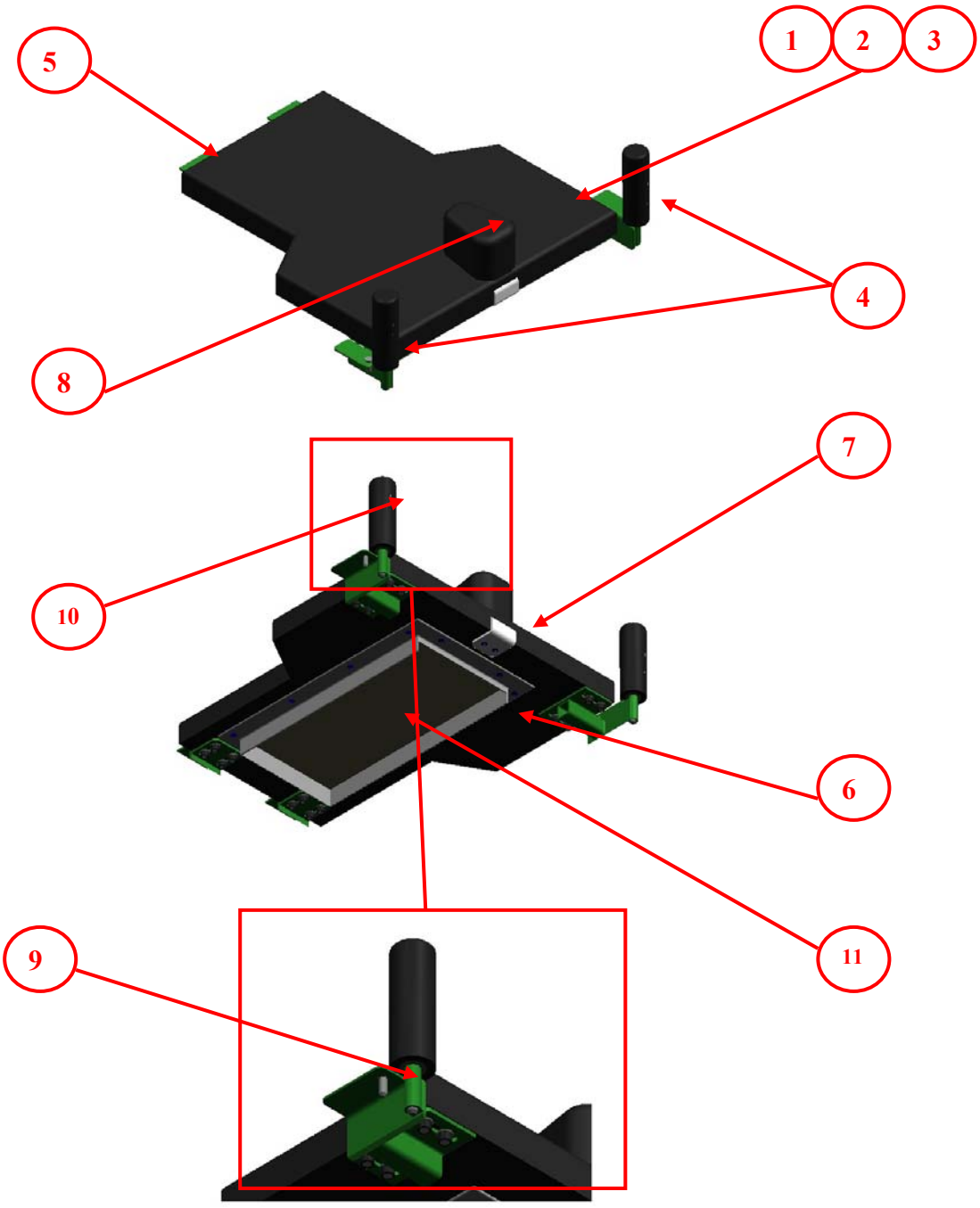


Figure 78. Components of the seat plate

The function of the 12 mm thick layered plate is to hold the load of the patient during moving and measuring. The seat plate has been designed for a 120 kg human. There are sleeve-nuts in the layered plate, to which the support ears are screwed. There is a 20 mm thick foam on the layered plate, which is fixed by the link pinned upholster cover. This upholster cover is made of a black canvas that conforms to the requirements for the medical devices.

The side support tabs are sintered, welded steel structural elements, which are jointed to the layered plate by 4 M6 internal locked screws, in adjustable way for the appropriate

connection. Before each patient session, it is required to check the aligning pins fitting into the holes at the wheelchair (**Figure 79**).

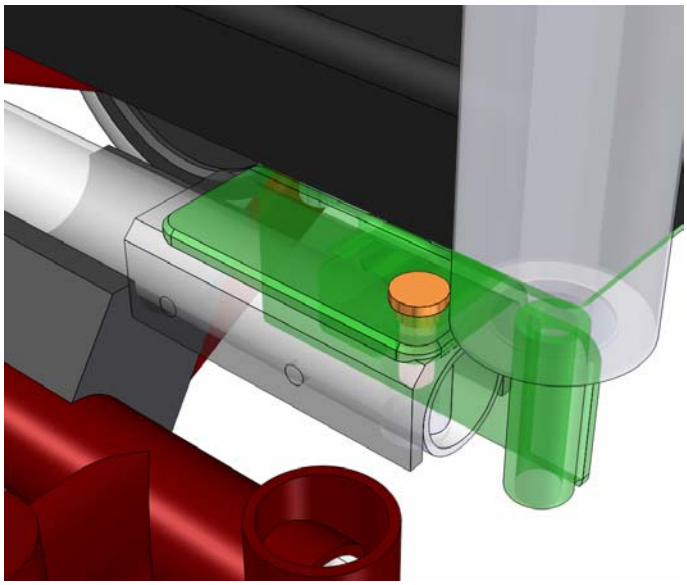


Figure 79. Appropriately fitting seat plate aligning pin in the holes

The back support tabs are also sintered welded steel structural elements, which are similarly jointed to the layered plate by 4 M6 internal locked screws, in adjustable way for the appropriate connection. Before each patient session, it is required to check the flat plates of the back supporting tabs sit well onto the back cantilever beam (Figure).

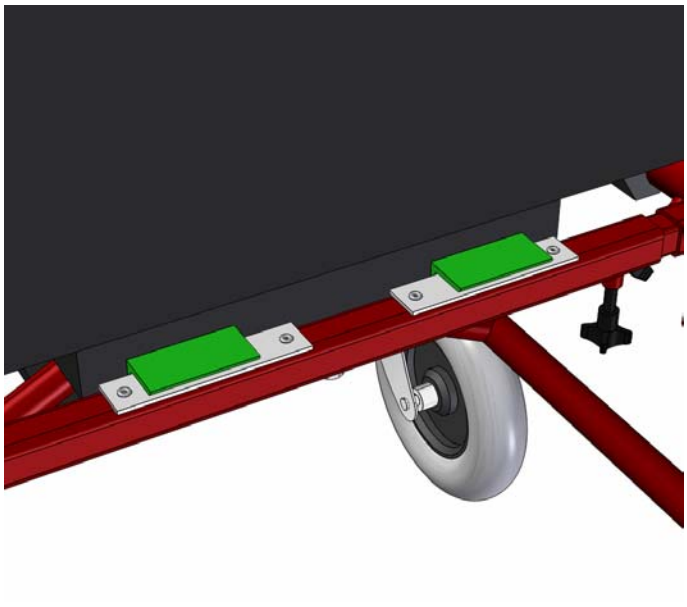


Figure 80. Appropriately sitting back supporting ears on the cantilever beam

On the bottom of the seat plate there is a special guiding frame. The main role of this guiding frame is to guide the seat plate (and thus the wheelchair) to the seat lift plate on patient entry. This structural element secures the identical measurement position of the patient during the repetitive measurements. Furthermore the 25 mm flange of the guiding frame protects the seat plate from tipping out, and hinders shifting when the patient is moving.

The internal dimension of the guiding frame is 150 mm by 300 mm, to which a 149 by 299 mm lifting plate is connected. The guiding frame secures both the axial and the lateral position.

The main role of the anchoring and straddling wedge is to hinder sliding down the patient, furthermore it also helps the positioning of the patient. The anchoring and straddling wedge is manufactured in two sizes, which differ in their length (Figure 81). The wedges are foam inserts with the same upholstery as the seat plate, thus easily cleaned, and are comfortable for the patient.

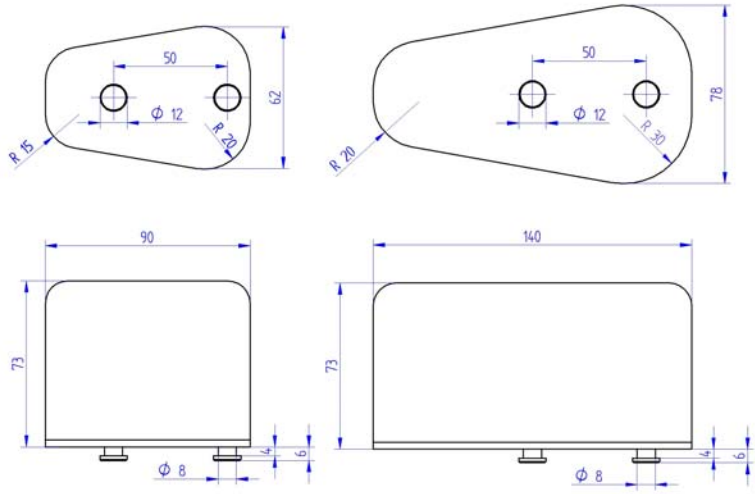


Figure 81. Anchoring and straddling wedges in two sizes

The components of the anchoring and straddling wedge:

1. upholstery
2. foam insert
3. cover plate
4. tightening screws
5. aligning pins

The anchoring and straddling wedges are connected to the seat plate by a holder plate. The role of this component is to provide fast and easy wedge replacement. The different sized wedges are connecting in the same way, by two riveted pins (Figure 82).

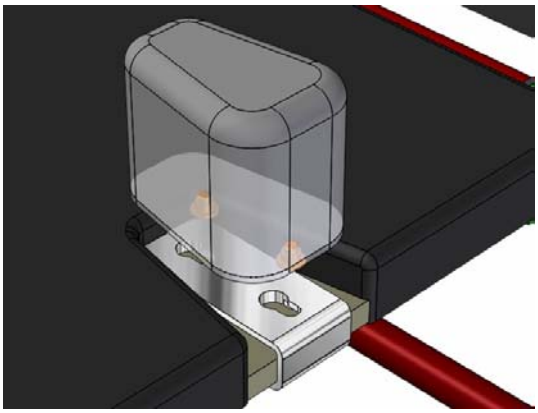


Figure 82. The anchoring and straddling wedge connection to the seat plate

Putting in the anchoring and straddling wedge (Figure 83.):

1. Fit the two guiding pin on the wedge into the bigger holes on seat plate holder plate.
2. Push down the wedge until it bumps.
3. Push forward the wedge, while keeping pressed it down.

Note: handle the anchoring and straddling wedge as close to its bottom as possible, to avoid unnecessary upholstery straining.

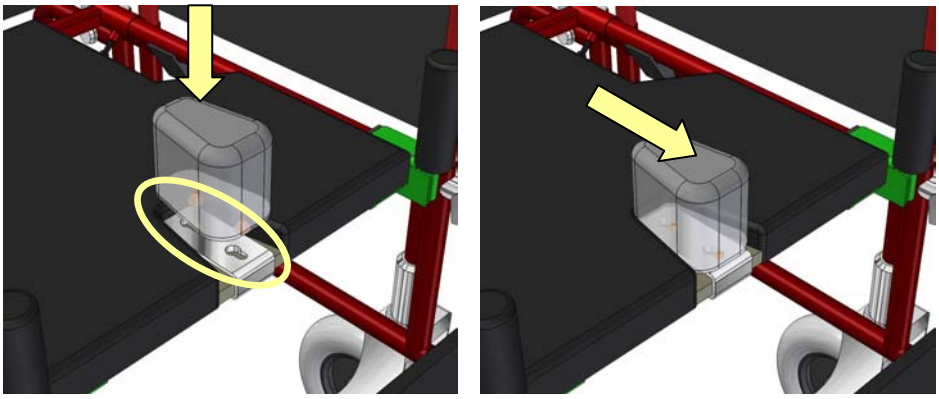


Figure 83. Putting in the anchoring and straddling wedge

Figure 84. The B-4205 transit lying wheelchair of REHAB Inc.

The seat plate height, footrest- and backrest angles are adjustable on the ALLADIN wheelchair. The backrest can be fully reclined, in order to lie the patient if the patient lose consciousness. The feet and calf supports can be turned out, or the complete foot support can be taken down from the wheelchair. Furthermore the armrest and seat plate can be taken out, too.

The seat plates are stored on the accessory storage board. One-one seat plate can be stored on the two wheelchairs. On the maintenance of the seat plates, the bolt joints must be tightened, and the seat plate must be checked for damages.

The patients are transferred to the ALLADIN Diagnostic Device in a reclining wheelchair, which has been manufactured by the Rehab Inc. The special seat plate of the wheelchair fits to the seat lift of the ADD, it is easily removable and replaceable after the measurement. The wheelchair does not corresponds tightly to the seat plate, but they get into direct connection, thus the wheelchair is an important component.

3.4 Force/torque data acquisition

3.4.1 Introduction

Force/torque data acquisition consist of multiple hardware/software layers as shown in Figure 54. The hardware layer is the lowest layer and consist of the JR3 force/torque sensors and the receiver boards. Above the hardware layer are placed three software layers. The device driver

communicates directly with the hardware and resides in the Windows kernel space. The driver is used by the interface between the user space and the kernel space. This interface is implemented as a dynamic link library (DLL). It simplifies use of the driver from perspective of the cover application.

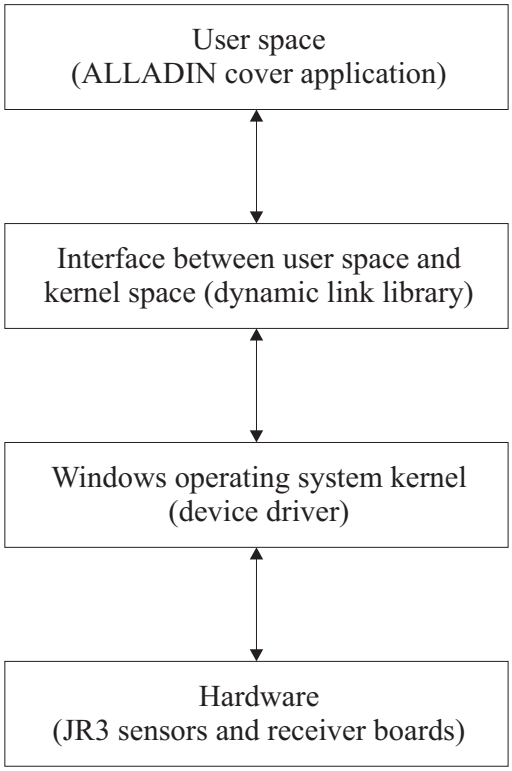


Figure 54. Conceptual structure of data acquisition

3.4.2 Hardware layer

3.4.2.1 Sensor

The JR3 sensor is a monolithic aluminum device containing analog and digital electronic systems. Signals from foil strain gage bridges are amplified, and converted to digital representations of the force and moment loading data by electronic systems contained within the sensor. Data is transmitted to the receiver electronics in a synchronous serial format. All low level analog signals and the A/D circuitry are within the sensor body, shielded from electromagnetic interference by the metal sensor body.

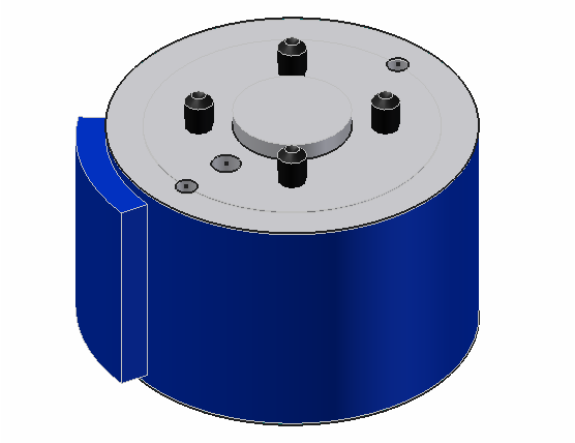


Figure 55. JR3 force/torque sensor

A/D converter samples analog signals with speed of 8 kHz per axis. With this speed are data also transferred to receiver board. The data stream also includes information about sensor characteristics and calibration, and feedback monitoring the sensor power voltage. The stored sensor calibration data allows sensors to be changed with no need for any adjustment of the receiver circuitry. Feedback of the sensor power voltage allows use of long lengths of small gage wire in the sensor cable. Power and data signals can be passed through slip rings if necessary.

3.4.2.2 Receiver board

The JR3 DSP-based force sensor receiver provides 6 degree-of-freedom (6DOF) force and torque data at very high bandwidths. Use of a digital signal processing chip (DSP) enables the JR3 system to provide decoupled and digitally filtered data at 8 kHz per channel.

The receiver board contains circuitry to receive the serial digital data transmission from the sensor, as well as circuitry to monitor and adjust the power supply voltage to the sensor. The automatic remote power supply adjustment means that the sensor cable requirements are very forgiving. Long, small gage wires can be used with success. This means JR3's sensors with onboard electronics no longer need stiff expensive cables.

The JR3 DSP is used to process the raw data transmitted from the sensor. The JR3 DSP performs several functions. These include:
- offset removal,
- data decoupling,
- saturation detection,
- digital low-pass filtering,
- force and moment vector magnitude calculation,
- peak detection,
- rate calculation,
- coordinate translation and rotation,
- and threshold monitoring.

The raw data from the sensor is first passed through a decoupling matrix and offsets are removed. This process removes sensor cross-coupling as well as tare loads.

The decoupled data is passed through cascaded low-pass filters. Each succeeding filter is calculated 1/4 as often, and has a cutoff frequency of 1/4 of the preceding filter. The cutoff frequency of a filter is 1/16 of the sample rate for that filter. For a typical sensor with a sample rate of 8 kHz, the cutoff frequency of the first filter would be 500 Hz. Table 7 shows important parameters for all filters.

Filter	Sampling frequency [samples / s]	Cutoff frequency [Hz]	Delay (approx.) [ms]
1	8000	500	2
2	2000	125	8
3	500	32.25	32
4	125	7.81	128
5	31.25	1.95	512
6	7.8125	0.49	2048

Table 7: Main filter parameters on JR3 receiver board

3.4.2.3 Driver for JR3 receiver board

JR3 company does not provide device drivers for their receiver boards. For operating system Windows it is suggested use of a driver from http://robotics.dem.uc.pt/norberto/jr3pci/, author J. Norberto Pires. However with this driver it is possible to simultaneously use only one receiver board. One receiver board can transmit data from 4 sensors only. Project ALLADIN requires use of 8 sensors and 2 receiver boards and because of that a new driver had to be developed.

The driver enables configuration of the receiver boards and reading of the force/torque data. It also provides buffering of the acquired data. This buffering is essential for the proper acquisition of forces/torques, since receiver board buffers only the very last sample for each sensor. Project ALLADIN requires sampling frequency of 100 Hz. Software running on Windows XP does not guarantee a stable, accurate and robust sampling at this relatively high frequency, especially when it executes other complex tasks.

The driver code resides in the kernel space, so it is closer to the hardware than the user space programs. This makes the driver very suitable place for implementation of buffering. Driver first creates a special thread, which is during the acquisition used for buffering. This thread uses all available time on one processor. Therefore use of a dual processor machine is required, so that the second processor can execute other programs. It is sufficient to use Pentium 4 processor with hyper threading technology (within one physical processor package are contained two logical processors).

Figure 56 shows a timing diagram for sampling frequency of 1 KHz (time between samples 1 ms). Although is the requested frequency 10-times higher than necessarily, is sampling still done with minimal error (+/- 1 microsecond). Other tested approaches did either perform unsatisfactory in sense of the timing accuracy or did actually work only on some computers, depending on operating system internal use of computer hardware (interrupts etc.).

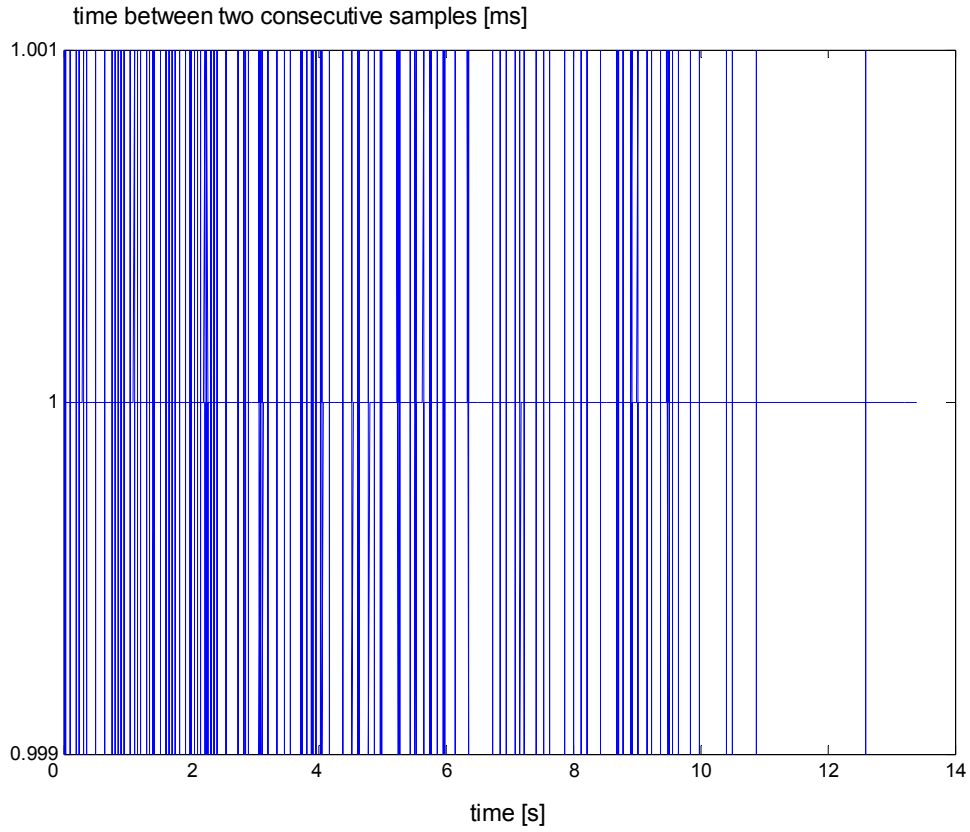


Figure 56. Timing diagram

3.4.2.4 Interface between driver and user application

The JR3 device driver runs in the kernel space and has unlimited access to computer resources. Operating system can't supervisor the driver as it does user mode programs. Because of that will even a small programming bug in the driver crash not only the driver (as a bug in the user mode program crashes the program), but also the whole operating system. That requires robustness as the most important property of any driver. Robustness can most easily and most surely be achieved if the driver is as simple as possible.

However the final user of the driver (the cover application in our example) needs a simple, high level abstraction of the driver functionality. This two conflicting goals are solved by the use of an additional layer between the driver and the cover application. This layer is implemented as a dynamic link library, which can be simply used from many different programming languages. Simple functionality of the driver is used to build more complex and

useful functions for working with hardware. The cover application then uses higher level functions, so that acquisition start/stop, self diagnosis etc. require only one function call.

3.4.3 Administrator application

The Administrator application is used for set-up and integrity check of the ALLADIN Diagnostic Device. It is used during initial setup of the system and in a case that data acquisition module reports an error (for example if a sensor is not plugged correctly in a receiver board). During the diagnostic device setup the administrator application is used also read serial number of force/torque sensors. Serial numbers can be found on labels attached to sensors. This serial numbers should be manually written into the initialization file for data acquisition. The procedure is done only once. Care must be taken to associate the correct serial number with the correct sensor. Acquired data will be useless if you fail to do so. After the serial numbers are written to initialization file, the administrator application should be restarted to check sensor connections.
Administrator application initializes on startup first two JR3 receiver boards present in the system. Force/torque sensors must be plugged in this two boards. A message box is displayed in case of an error. Sensors serial numbers are loaded from data acquisition initialization file. The file name can be specified as a command line parameter or it can be located with *Open* dialog box. *Cancel* can be used to skip reading of the initialization file. *Select sensor* box enables selection of the force/torque sensor. All displayed data then refer to the selected sensor.

3.4.3.1 Basic Force/Torque tab

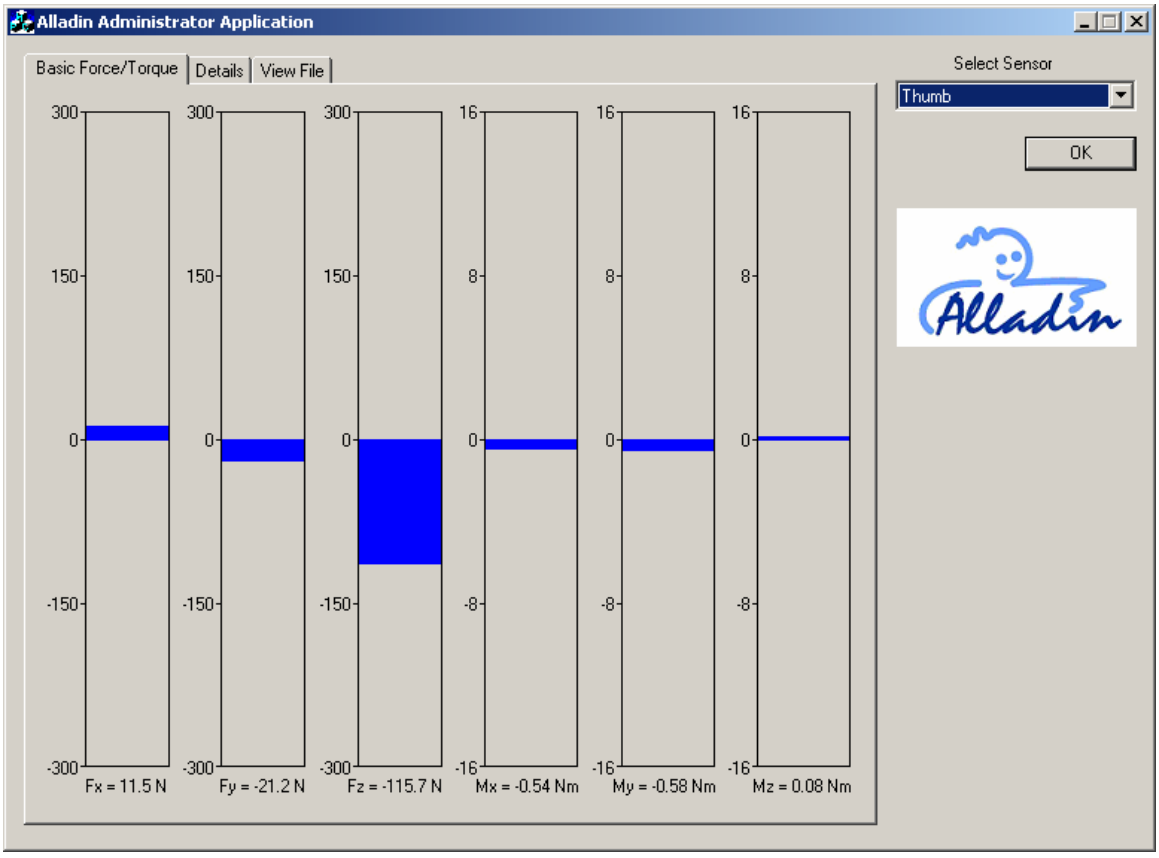


Figure 57. Administrator Application, Basic Force/Torque tab

In the first tab (*Basic Force/Torque*) are plotted in real time bar graphs for all 6 forces/torques of the selected sensor. If force/torque is larger than the default full scale (which is equal to nominal load for this axis), the bar color changes from blue to yellow to indicate overload. In a case of saturation color changes to red to indicate even more severe overload. In Figure 57 the default full scale for forces +/- 150 N and for torques +/- 8 Nm is shown.

3.4.3.2 Details tab

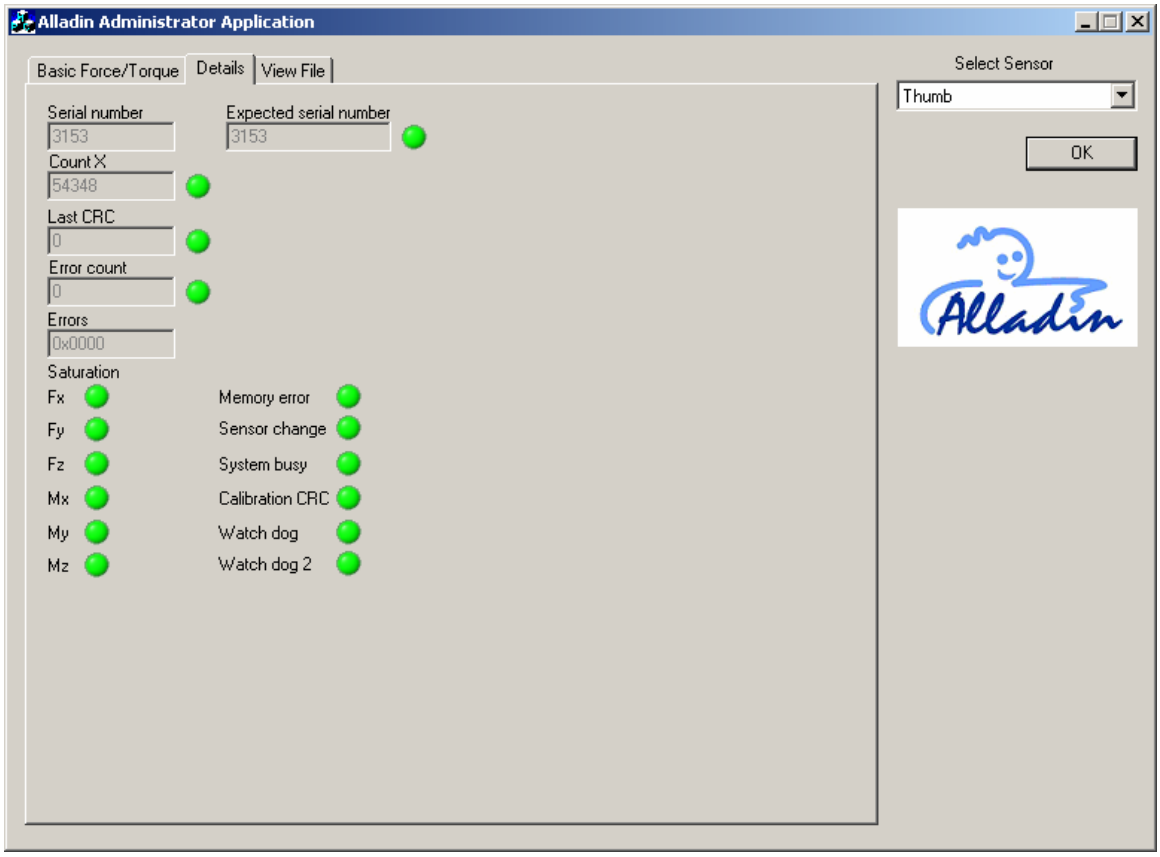


Figure 58. Administrator Application, Details tab

A second tab displays more details about the sensor (Figure 58):

- *Serial number* is the sensor actual serial number and *Expected serial number* is a value read from the initialization file. The numbers should be equal.
- *CountX* is incremented by the JR3 receiver board. It should be changing all the time.
- *Last CRC* is 0 if calibration data were successfully transmitted from the sensor to the receiver board.
- *Error count* contains number of samples, which were not successfully transmitted from the sensor to the receiver board. It should be constant (typically 0) and only in extremely noisy environment it can be slowly changing.
- *Errors* should be 0x0000. In case of an error, that error is marked with a red LED in the display below. During normal operation all LEDs should be green.
    - *Saturation Fx, Fy, Fz, Mx, My* and *Mz* report saturation of the sensor along particular axis.

- *Memory error* is set if an error in the on-board RAM was detected during receiver board power-up initialization.
- *Sensor change* is set to 1 by the receiver board if the sensor is replaced (you unplug one sensor from a slot and then plug a different sensor into that slot). Since it latches, it is constantly reset to 0 by the application. Thus you should be able to see it being set (red LED) only during short transients.
- *System busy* is set when the receiver board has some work to do (for example, immediately after plugging a sensor in the receiver board).
- *Calibration CRC* is 0 if calibration data were successfully transmitted from a sensor to a receiver board.
- *Watch dog* is set if sensor data lines are not working properly.

Watch dog 2 is set if sensor data and clock are not received correctly. If either watch dog is set, data are not received correctly.

3.4.3.3 View File tab

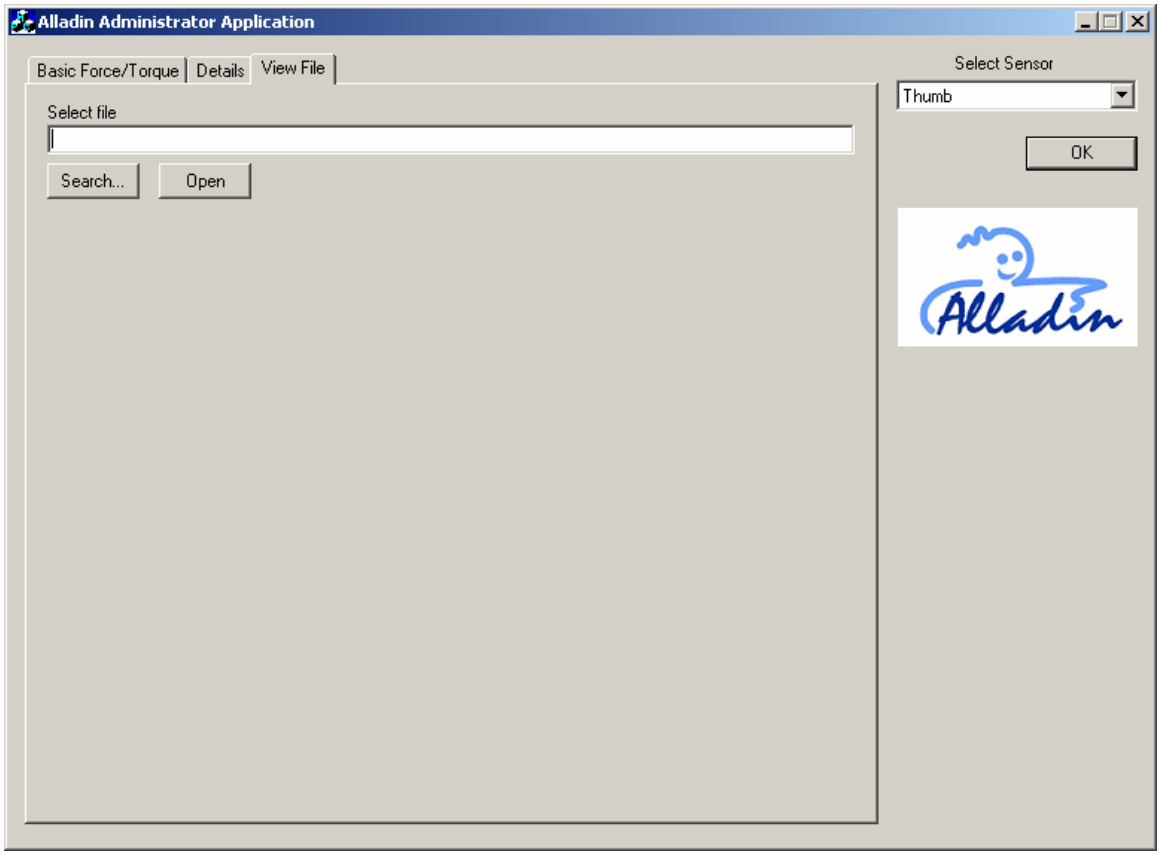


Figure 59. Administrator Application, View File tab

In the tab *View File* it is possible to view measurement created by the data acquisition module. Click *Search* to locate a file or manually enter path and file name and click *Open*. A Visualization window in which acquired data can be viewed is opened.

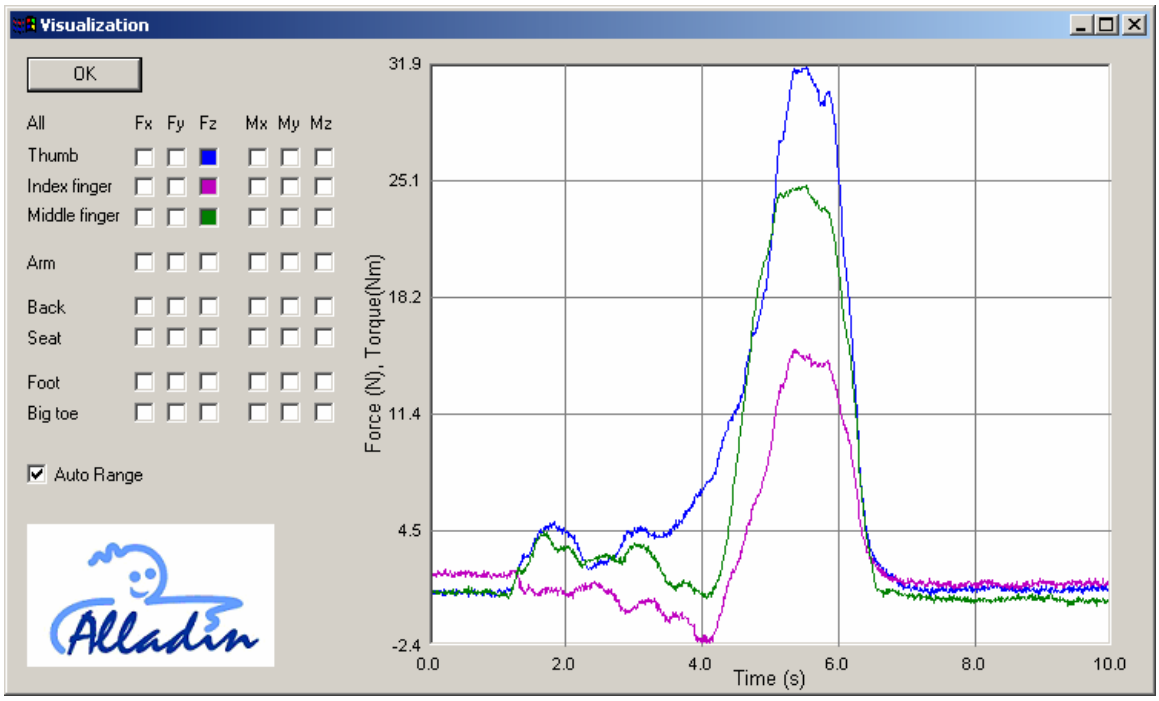


Figure 60. Administrator Application, Visualization dialog box

It allows visualization of individual axis of each and all sensors (as opposed to data visualization module, where only absolute forces can be seen). Visibility of a single axis can be toggled by clicking on checkboxes on the left side. Visibility of more than one axis can be toggled by clicking on labels *Fx*…, *Thumb*…, *All*. The checkbox *Auto Range* controls if graph range is changed after toggling visibility of an axis. Trajectory color matches the color in checkbox for the corresponding sensor and axis.

3.4.4 Data visualization

Data visualization tool is used to verify validity of force/torque data. The verification is done by a physiotherapist after each measurement completion by visual inspection. Guidelines for the typical correct and incorrect measurement cannot be given at the moment. This can be done only after normative data are collected and analyzed (most likely in February 2005).

Data visualization tool displays a dialog box with 4 graphs (hand, arm, trunk/seat, foot) as shown in Figure 61. In each graph are displayed absolute forces for the corresponding sensors. Left from the graphs are pictures of corresponding measurement device subsystems. Each sensor is marked with a colored rectangle. In the upper left corner are a checkbox *Data Invalid* and a button *Done*. The physiotherapist should check the *Data Invalid* checkbox if she/he considers measurement as invalid or leave it unchecked if the data are correct. After that the *Done* button is used to close the window.

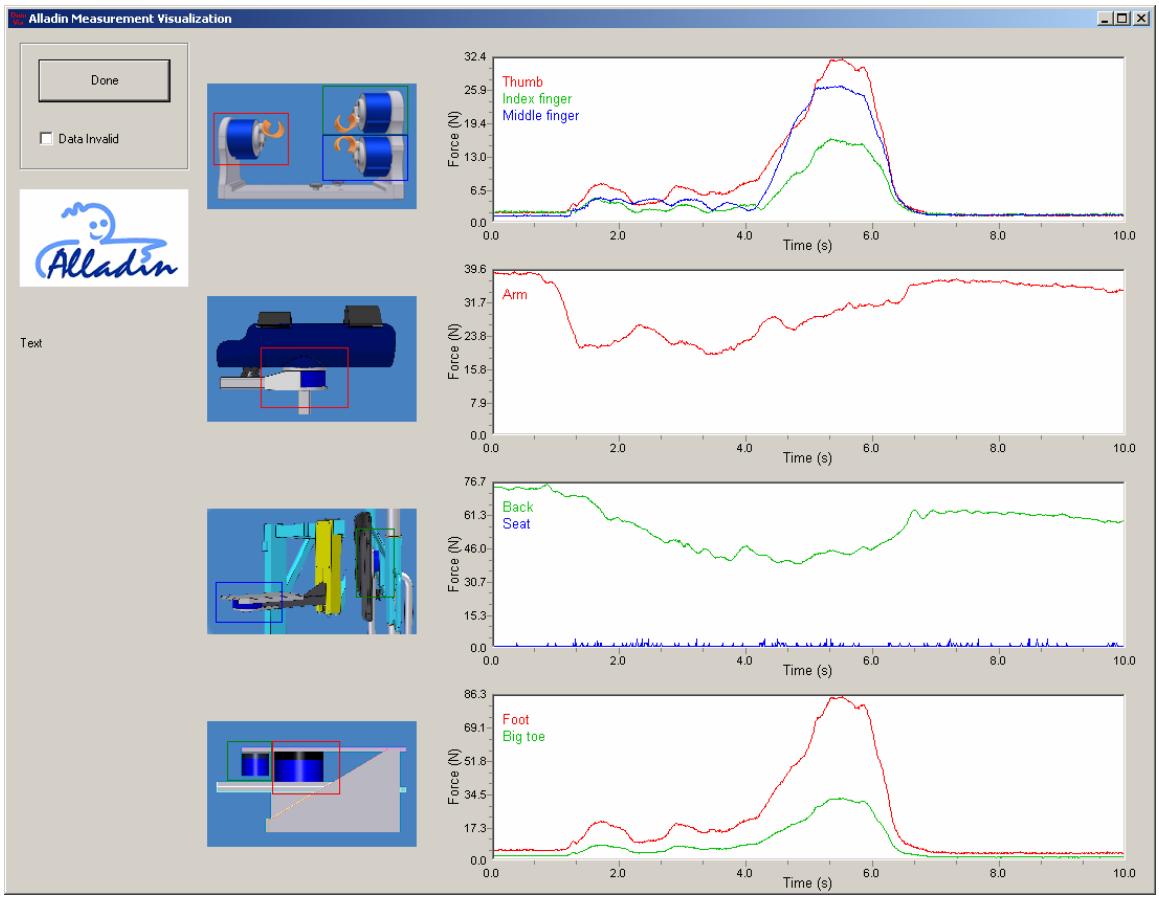


Figure 61. Visualization dialog box

In the visualization dialog box, the sensors are marked with colored rectangles; the force trajectories are plotted with the same color of the relative sensor. The force trajectories for each sensor can be displayed in a separate window by double clicking inside the colored rectangle on the picture of the measurement device subsystem.

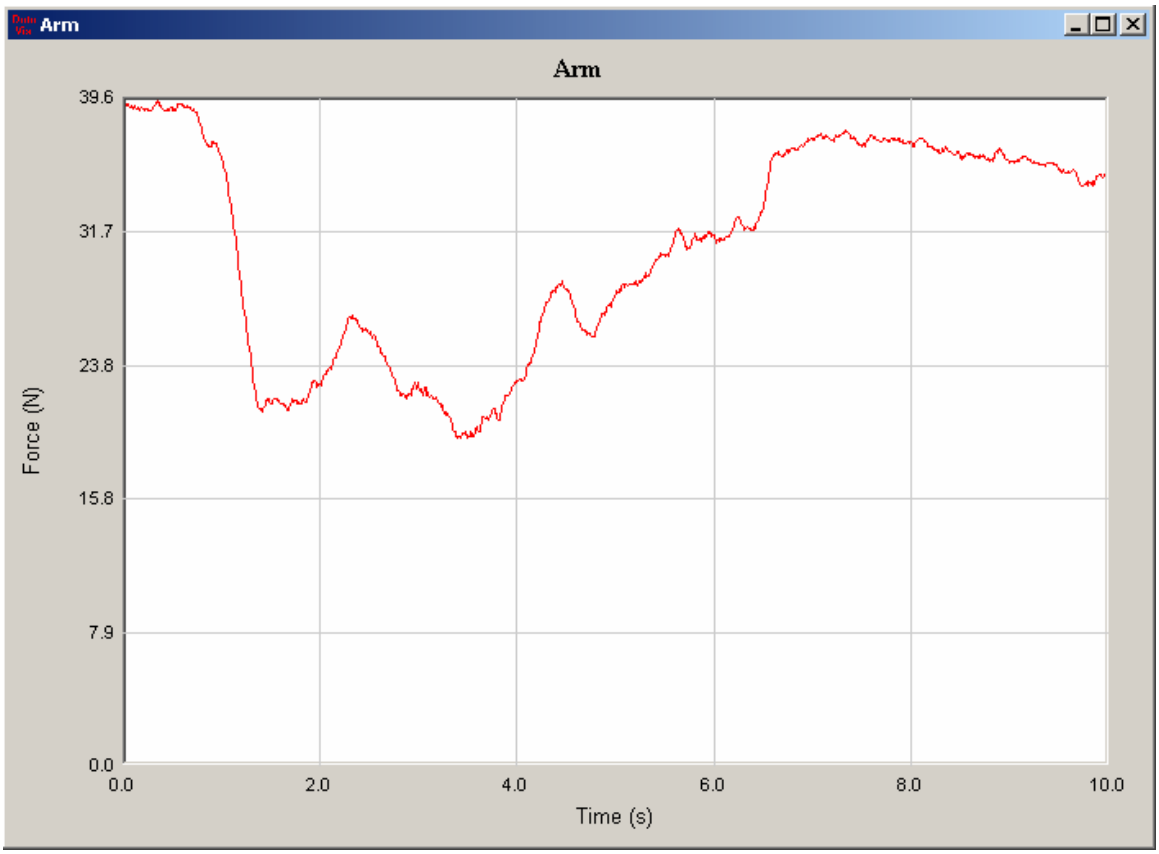


Figure 62. Visualization dialog box for a single sensor

After the physiotherapist analyses the data, she/he marks the data as valid by clearing a *Data Invalid* checkbox or as invalid by checking the *Data Invalid* checkbox. User then confirms her/his decision and closes the dialog with a *Done* button. Since user is expected to verify the data, she/he can leave the dialog box only with the button *Done* or *Enter* key. Figure 63 shows the *Data Invalid* checkbox and the *Done* button. If user tries to close the dialog box by pressing the *ESC* key or by clicking the *Close* button () in upper right corner of the dialog, an error message will be shown, as in Figure 64.

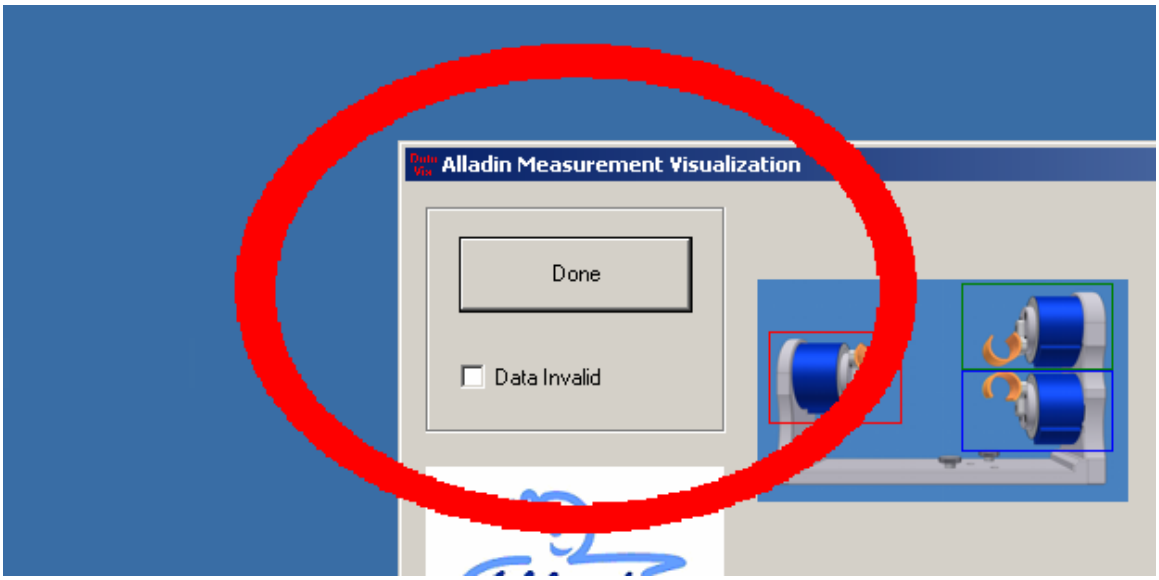


Figure 63. Location of Done button and Data Invalid checkbox

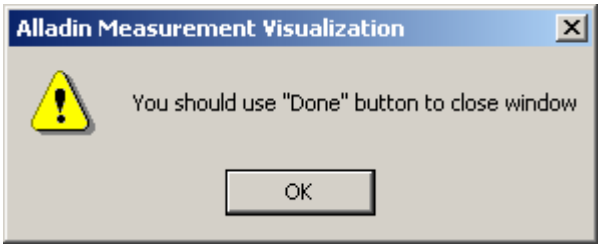


Figure 64. Error message

It is also possible that the data were already validated (in case the user is viewing the data from an older session). In that case is the *Data Invalid* checkbox disabled and only shows current status of the data validity. User may in this case finish the visualization session also with the *ESC* key of by pressing the *Close* button in the upper right corner of the dialog box. Both dialog boxes can also be resized by dragging a border or by clicking a *maximize/minimize* button in the upper right corner of the dialog box.

3.5 Natural language descriptions

The following tools will be used to build the ALLADIN Classification System or taxonomy, to fully model the ALLADIN concepts in the existing medical ontology LinKBase® and to structure and map the taxonomy to the ontology and finally to query the ALLADIN classification with patient data. The enriched ontology LinKBase® describes the ALLADIN concepts in full detail by its relations with other concepts of the ontology. Those descriptions allow computers to “understand” the ALLADIN concepts and to support intelligent data mining and querying.

- **LinkFactory**®: formal ontology management system (OMS):
  In ALLADIN, LinkFactory® is used to extend the ontology LinkBase® for the neurorehabilitation domain, to structure and map the ALLADIN classificatie to the ontology and to query the ALLADIN classification. A set of API functions of LinKFactory®, that are natural when dealing with ontologies, will be used by the data mining application.

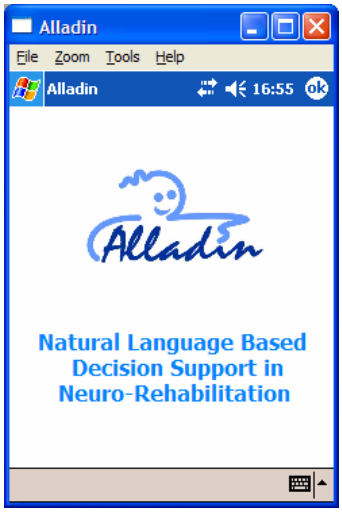
- **LinkBase®**: medico-linguistic formal ontology:
  Used in ALLADIN as a source of (para)medical concepts; it will be extended for the domain of neurorehabilitation, in order to be used with TeSSI® and within the ALLADIN Classification System.

- **Tessi®** : Terminology-Supported Semantic Indexing:
  In ALLADIN the system will be used to process documents and to place the ALLADIN concepts in the right context for supporting the knowledge engineers in modelling the ALLADIN concepts; it will also be adapted to the new domain of neurorehabilitation via the ontology LinkBase®.

- **FastCode®**: semi-automatic ontology-based classification/coding middleware. In ALLADIN it will be adapted to the needs of the ALLADIN project. It will be used by the physiotherapist to code the patient diagnosis with ICD10 concepts.

3.6 Audio recording

3.6.1 Introduction



As said in 4.2.2 ALLADIN PDA interface, audio recordings play an important role in ALLADIN in the sense that all natural language descriptions are recorded and stored in the ALLADIN database for data mining. The physiotherapist will use a PDA to record patients' functional recovery, since this allows to organize the audio recordings more practically and give immediate feedback to the user about the audio quality. This audio quality gives an indication if the minimal requirements for speech recognition are met.

In this section, you will find an overview of the ALLADIN PDA Software and also a brief explanation about the grammatical structures used by the recognition engine. As can be seen in Figure 66. ALLADIN Software Architecture the recordings created with the PDA are synchronized with the Cover Application using a File System. Practically, a SD Card will be used to store all the data and it is as easy to use as a floppy disk.

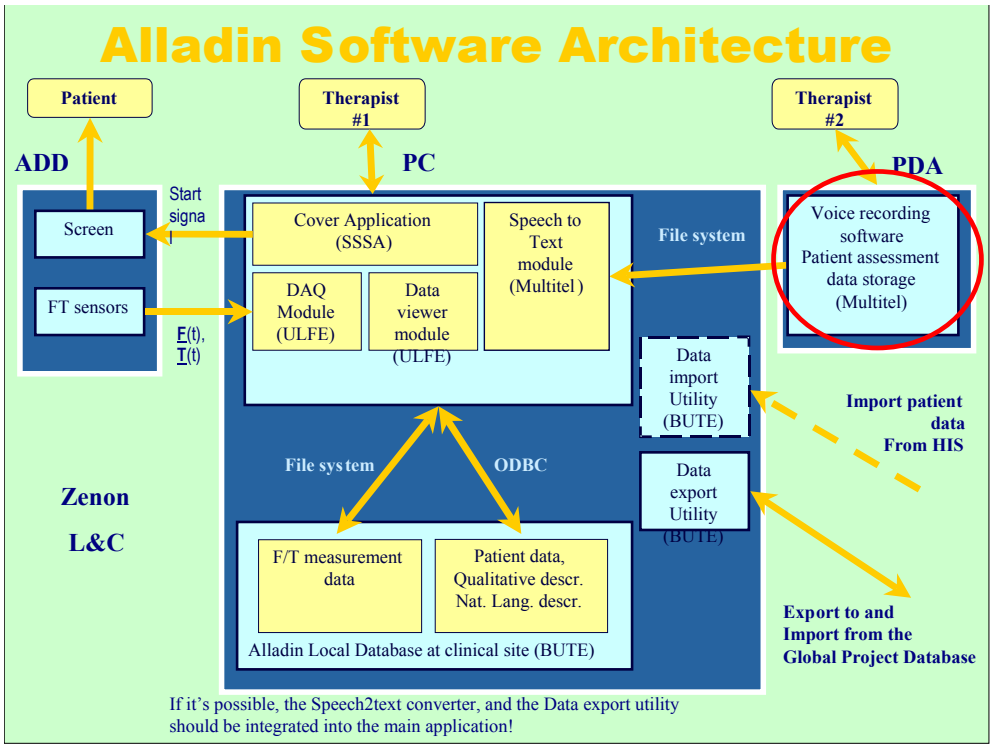


Figure 66. ALLADIN Software Architecture

3.6.2 The ALLADIN PDA Software

When the physiotherapist has launched the software, he is invited to click on his profile and to enter his password. If the physiotherapist did not put the SD Card in the PDA, a message informs him/her to use the **ALLADIN PC interface (Cover Application)** in order to create a valid database and to insert the SD Card in the device.

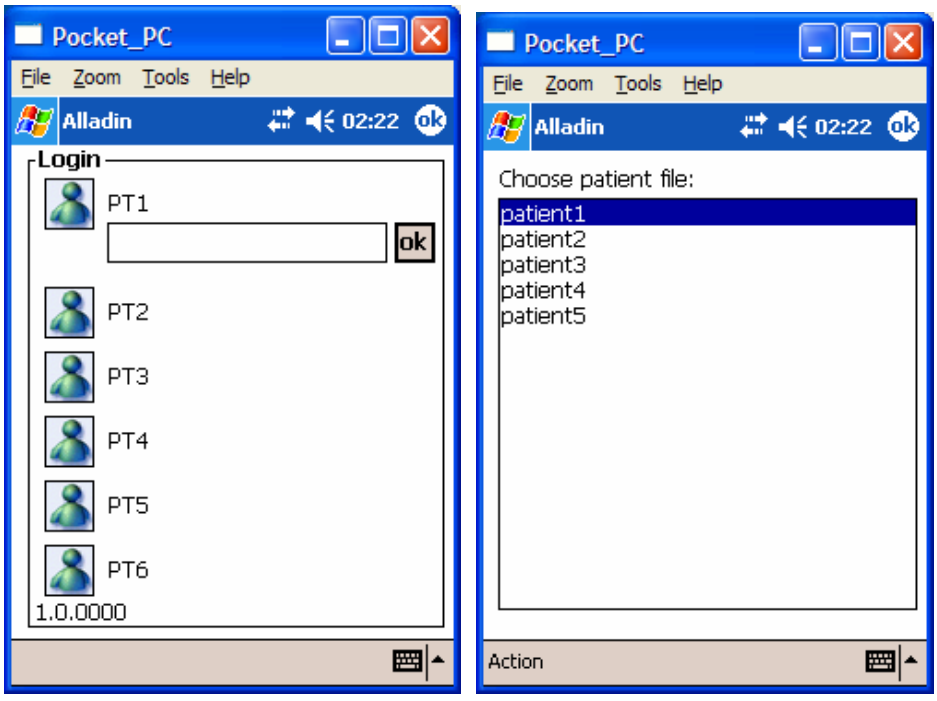


Figure 66. The login phase in the ALLADIN PDA Software

3.6.2.1 Audio recordings

When a physiotherapist is logged in:

- He can select a patient file by either *DOUBLE CLICK* on it, or click on the *Action Menu->Edit Patient File.*
- If no action is performed for 5 seconds, a help popup appears to guide the user through the application.
- To create a new session, he has to click on *Action Menu -> New Session.*
- Click on *Action Menu -> Add a record* will add a patient record.

Figure 67 represents the audio recording interface. To start the recording, the physiotherapist has to click on the record button of the PDA located on the bottom right of the device or press and hold the record button. When finished, he just clicks on *STOP* or release the record button. The end-user is informed about the quality of the signal by the colour of the button. If he did not say anything, he will get a "Signal Not Clean" message and a red button will be shown. If he spoke well, a green is shown.

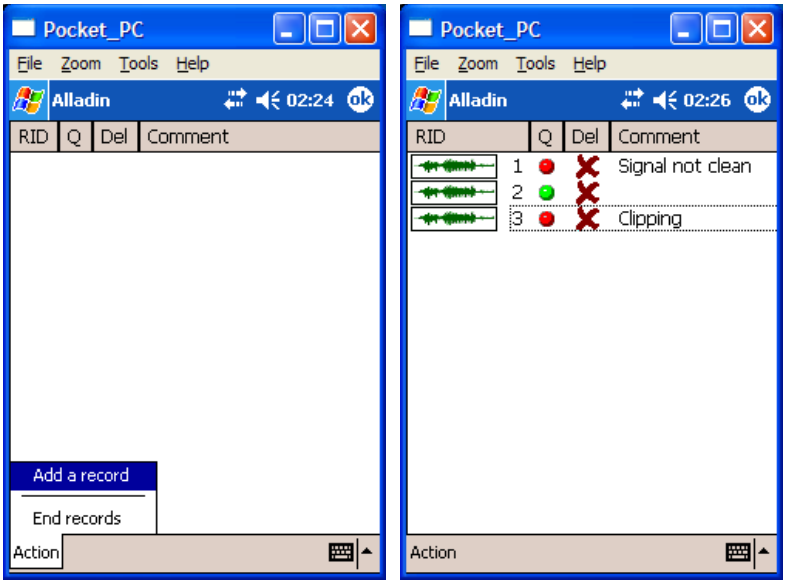
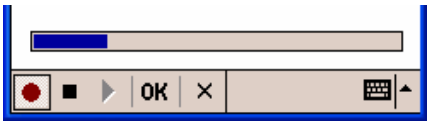


Figure 67. Audio Recording Interface

He needs to press the OK button after the STOP button in order to validate the audio recording. The following table summarizes these messages which may appear after a recording session.



Error Message	Meaning
Clipping	Talk less loudly. Avoid tapping on the PDA while talking
No signal	No signal captured on the microphone (not enough signal)
Signal not clean	Talk more loudly
Length not ok	There is not enough data to recognize.
No start Silence	You talked before starting the record: there is not enough silence in the beginning.
No end Silence	You stopped the recordings while talking: there is not enough silence in the end.

Table 8. Meaning of the error messages in the ALLADIN PDA Software

Once he has recorded his comments on the patient, he can click on *OK* (or *Action->End Recordings),* to go back to the session management. There is then the date and time of the session. He is also informed about the number of audio recordings present in this session.

3.6.2.2 Score sheets

Figure 68 represents the score sheets interface. The physiotherapist can either *DOUBLE CLICK* on the session newly created or click *Action Menu -> Edit Scores* to have access to the score sheet. To edit this sheet, he has to click on the field of his interest. A popup keyboard will appear so that he can enter the values. The user can select the "numeric pad" mode at the upper left corner of the virtual keyboard in order to type digits faster. If he uses <ENTER> keystroke to validate the data, the next field will be automatically selected.
When the session exists, the therapist can enter score sheet information (Fugl-Meyer, MAS, ICD).

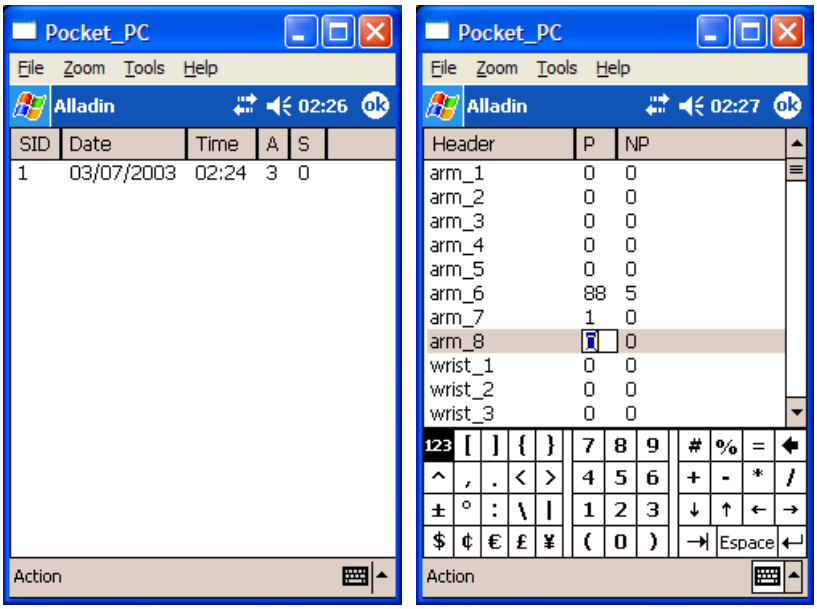


Figure 68. Score sheet interface

Once he has finished and clicked on OK, he is informed that the score sheet has been modified (1 means modified).

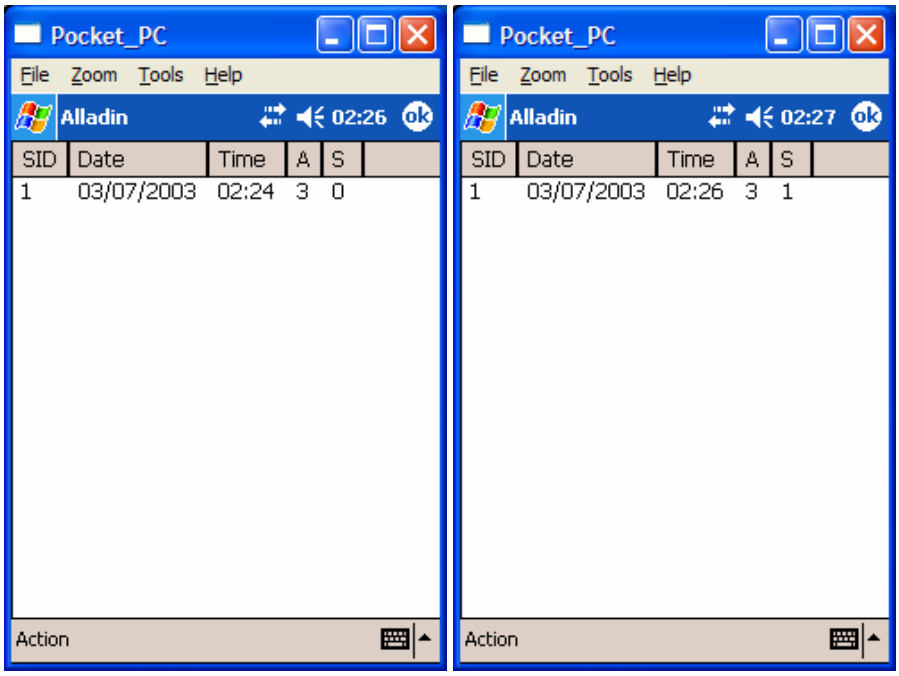


Figure 69. Score sheet interface

After closing the session, all information is stored into a XML file which is ready to be synchronized using the ALLADIN PDA interface on PC described in section 4.2.2.

3.6.3 The grammatical structure

As mentioned before, the physiotherapist will record the clinical phenomena using a natural language description. The descriptions were manually selected from the physiotherapist literature and organized in a fixed grammatical structure so that these descriptions are well suited for speech recognition. Indeed, the speech recognition problem consist in mapping the acoustic speech signal onto a sequence of words.

Here is an example of 5 sentences that a physiotherapist can say:

- She has impairing hypertony when I fastly move her right upper limb
- She has disabling hypertony when she moves her left elbow
- The patient has severe hypertonicity when he moves his right toes
- He has perturbing hypertony at the affected side
- He has a lot of spasticity in the affected biceps

The grammatical structure was chosen as follows:

[Subject][Qualifier 1][Qualifier 2][Root][Circumstance][Person][Action][Side][Body location]

Some category are optional, some are mandatory. As example, we will map this structure on the 5 sentences above.

- [She has][impairing][hypertony][when][I][fastly move][his right][upper limb]
- [She has][disabling][hypertony][when][she][moves][her left][elbow]
- [The patient has][severe][hypertonicity][when][he][moves][his right][toes]
- [He has][perturbing][hypertony][at the affected side]
- [He has][a lot of][spasticity][in the affected][biceps]

Thus, you can remark that the naturalness of speech input depends on the grammar format. Here a great effort was performed to carefully build the sentences.

3.7 The ALLADIN Database

3.7.1 General specifications

This database is developed for the ALLADIN project, according to the requirements of the medical and other partners. Most of these requirements and guidelines have been described in Deliverable 1.1.

During the development, the following considerations were taken into account:

- The data is collected at three geographically distant clinical sites, at AHS, NIMR and TCD.
- The clinical trial lasts for 18 months, in full working time – 5 days, and 6 to 8 hours a week depending on the country.
- Large F/T measurement and sound files are recorded, which can be several MB-s per records.

- The data is processed at some other sites, using statistical, data mining, and NLU technologies, at L&C, MEC, Multitel, SSSA and Zenon.
- The analysis operation may require intense database access.

To comply with these requirements, a simple replication topology has been set up among the partners' databases and a unique database on the ALLADIN project server (Figure 1.). The partner's databases are referred as ***local*** databases while the server database as ***global*** database. Furthermore a local database consists of a relational database, and a set of consistently organized data files. The large measurement and sound files are stored in external files because of the size limit of the relational database. The relational database is developed in Microsoft Access XP (in 2000 format). It has a simple user interface to allow the clinical partners to imagine the content and the operation of the final application.

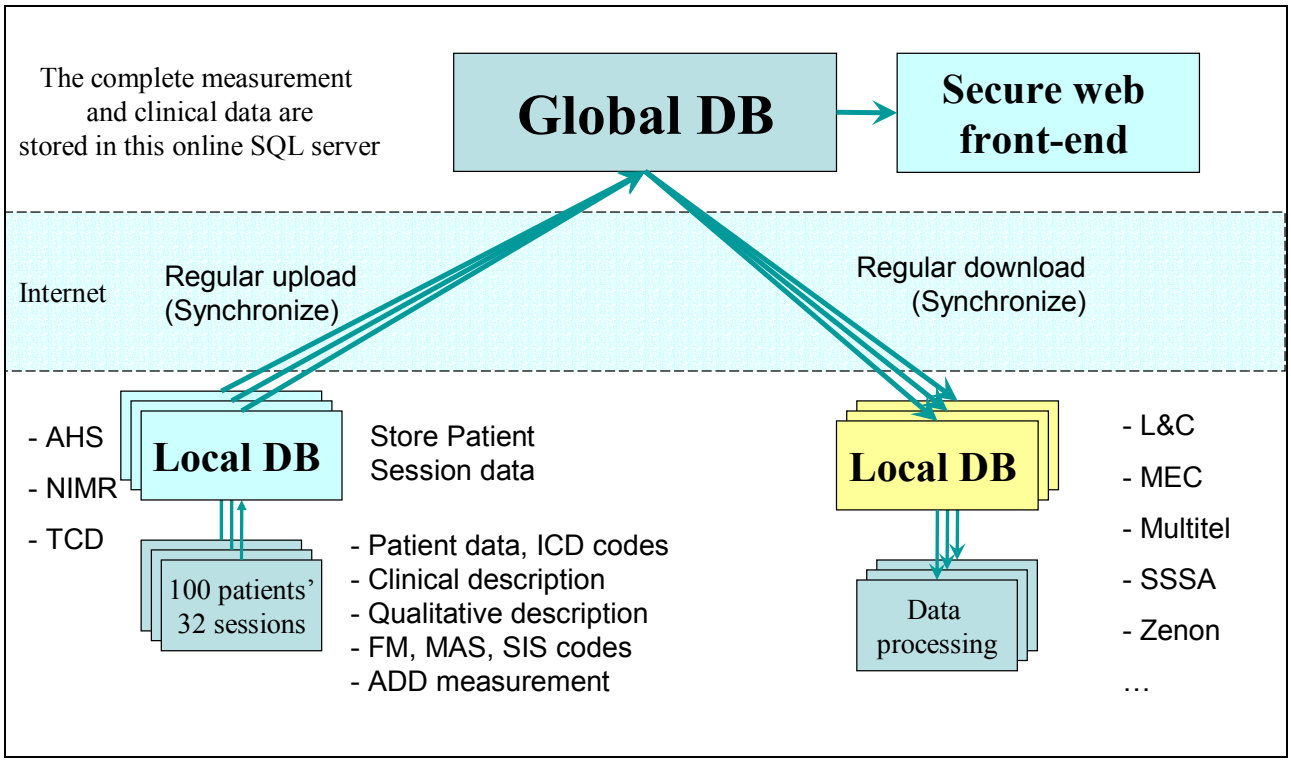


Figure 70. Architecture of the Local and the Global databases

The role of the database is to store the collected data during the clinical investigation, and to provide access to this data for the data processing partners.

The main functionalities of the database are described in Deliverable 1.1. Only the changes with respect to it are here mentioned. The detailed description of the tables can be found in the technical documentation (D2.2).

Local database at the clinical sites

The data at the clinical sites is stored in two logical units:

A SQL relational database

- Patient data and case history
- Assessment scores: FM, MAS, SIS
- Natural language description of the patient's status

A *set of independent data files* on the hard disk, in a defined directory.

- The *voice records* of the natural language description.
- The *measurement data* of the ADL exercises.

Naming conventions

PlaceID: Each local database has its own identifier, which is the short name of the partner. This *PlaceID* is then used for synchronization, and also for consistent patient naming.

PlaceID	Description
AHS	Patients in AHS, Gent
NIMR	Patients in NIMR, Budapest
TCD	Patients in TCD, Dublin

PatientID: The unique identifier of the patient

<*PlaceID*>-<*number*>

For example the PatientID of the *third* patient in *AHS* is:

PlaceID	Patient number	PatientID
AHS	003	AHS-003

Voice records:

<*PatientID*>-V<*VisitID*>.wav

E.g. the voice records of the *third* visit of patient called *AHS-005* is as follows:

PatientID	VisitID	Filename
AHS-005	3	AHS-005-V3.wav

F/T measurements of a single ADL exercise:

<*PatientID*>-V<*VisitID*>-M<*MeasurementID*>.dat

Note: The *MeasurementID* consists of two digits; the first denotes the exercise and the second the repetition number.

E.g. the *second* ADL exercise of the *third* visit of patient called *TCD-005* is than:

PatientID	VisitID	MeasurementID	Filename
TCD-005	3	21	TCD-005-V3-M21.dat

Database size

Figure 71 illustrates the size of the individual components in the local and global databases. The FT measurements and the voice records occupy the most storage space.

Description	record count	Relational DB	FT data	voices	DB+Ftdata +voices
Global Project DB [MB]	**1 x**	**59**	**101 250**	**48 000**	**149 309**
Local DB at clinical sites [MB]	**3 x**	**20**	**33 750**	**16 000**	**49 770**
Patient Records [MB]	100 x	0	338	160	498
Patient physical data [MB]	1 x	0.002			0.002
Case history [MB]	1 x	0.002			0.002
Clinical assessments - SOM [MB]	32 x	0.003			0.003
Natural language descriptions [MB]	32 x	0.003			0.003
Voice records [MB]	32 x			5.000	5.000
F/T data of one visit [MB]	**32 x**		**10.547**		**10.547**
compression ratio			1		1
Raw F/T data [MB]			10.547		10.547
number of channels			48		48
frequency [Hz]			100		100
measurement time [sec]			576	6 ADL exercise 3x repetition 32 seconds	576
size of one sample [Byte]			4		4

Figure 71. Occupied size of the database components

3.7.2. The structure of the database

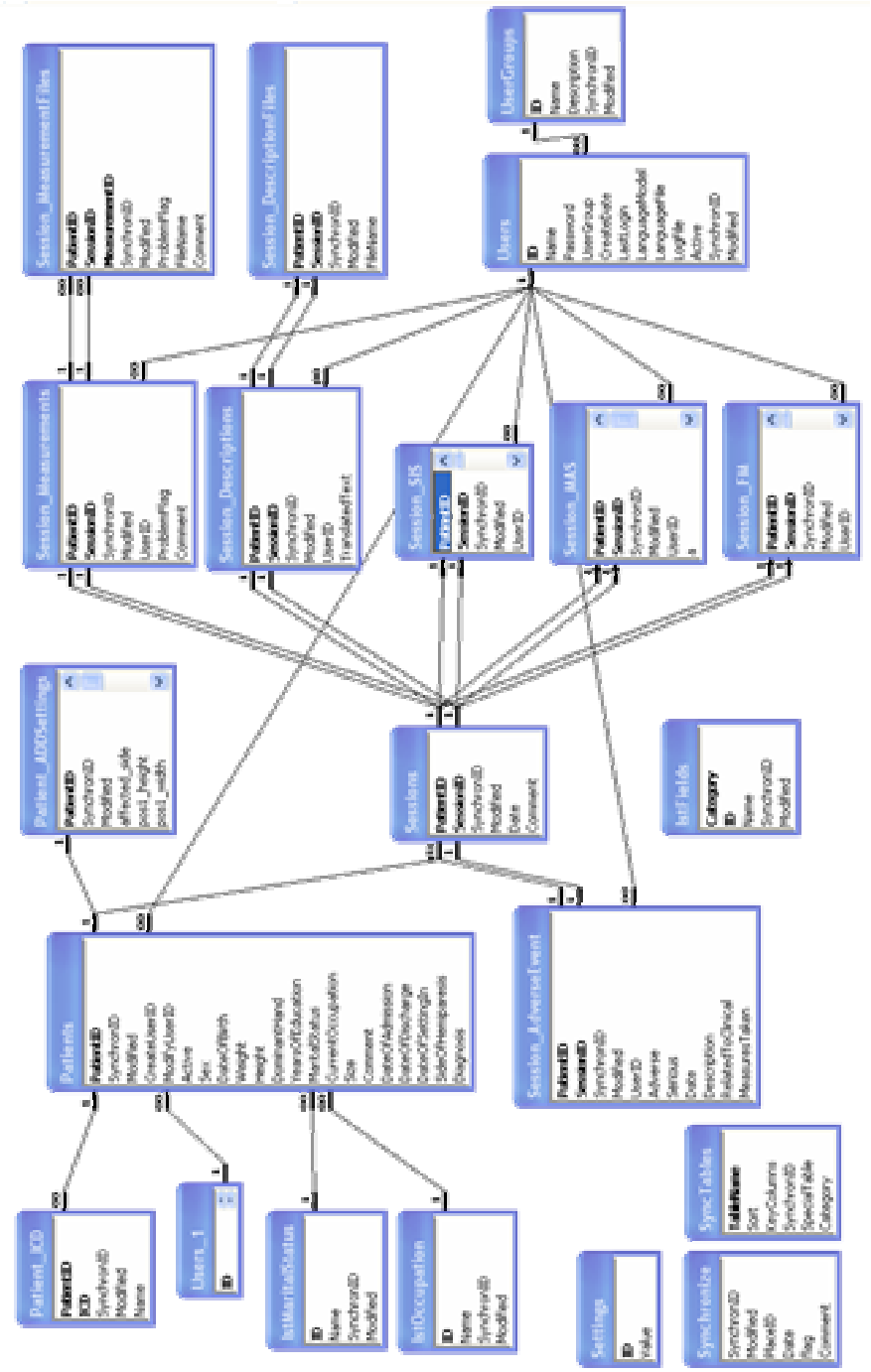


Figure 72. Tables and relationships in the database

A detailed description of the tables can be found in the technical documentation (D2.2).

4. Results of preliminary trials on the ALLADIN system prototype

4.1 Introduction

Some data collected during some preliminary trials, performed using a complete ALLADIN Diagnostic Device are now presented. Using a graphic utility, developed by the University of Ljubljana, which is part of the software application ("Administrative tools" section) , whose access is allowed only to the System Administrator, it is possible to plot the data recorded from the eight sensors, choosing to visualize one of them or more and the components of the force and/or the torques.

4.2 Data from the sensors

In this paragraph some graphics, obtained plotting the data collected from the sensors of the ADD, can be found. The component along the z component has been chosen, both for the forces and the torques (Figure 73-Figure 78).

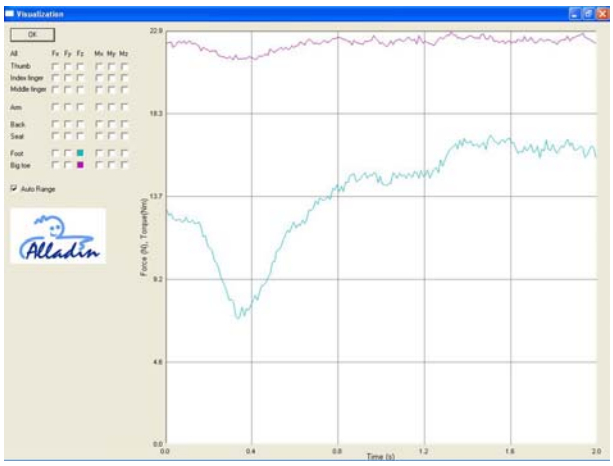


Figure 73. Data from the foot and big toe (Fz)

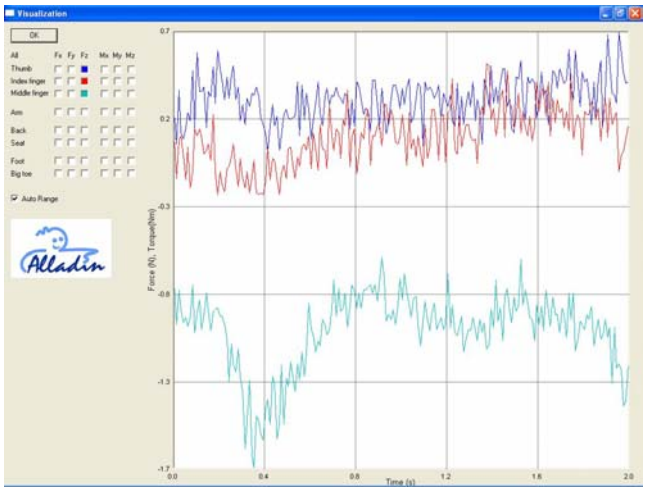


Figure 74. Data from the thumb, index finger and middle finger (Fz)

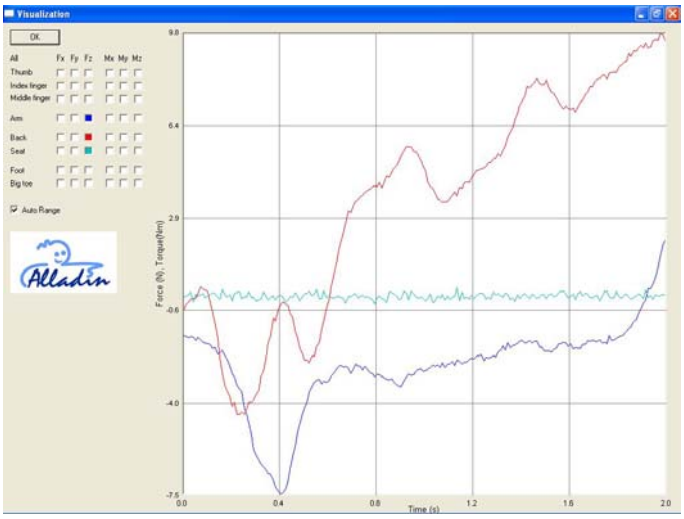


Figure 75. Data from the arm, trunk and seat sensor (Fz)

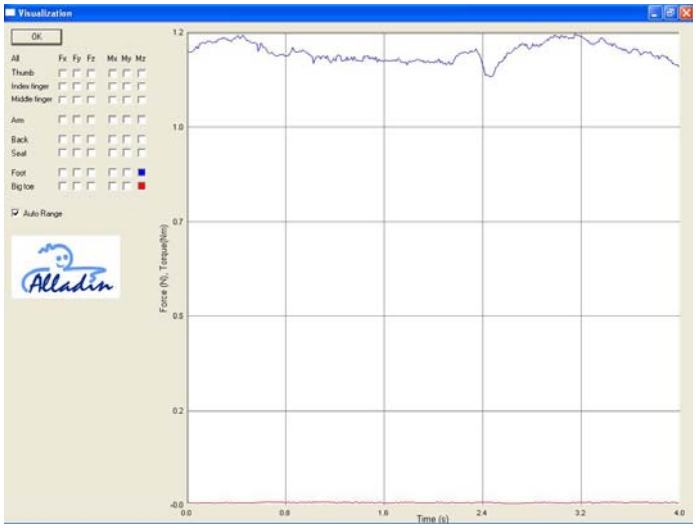


Figure 76. Data from the foot and big toe sensors (Mz)

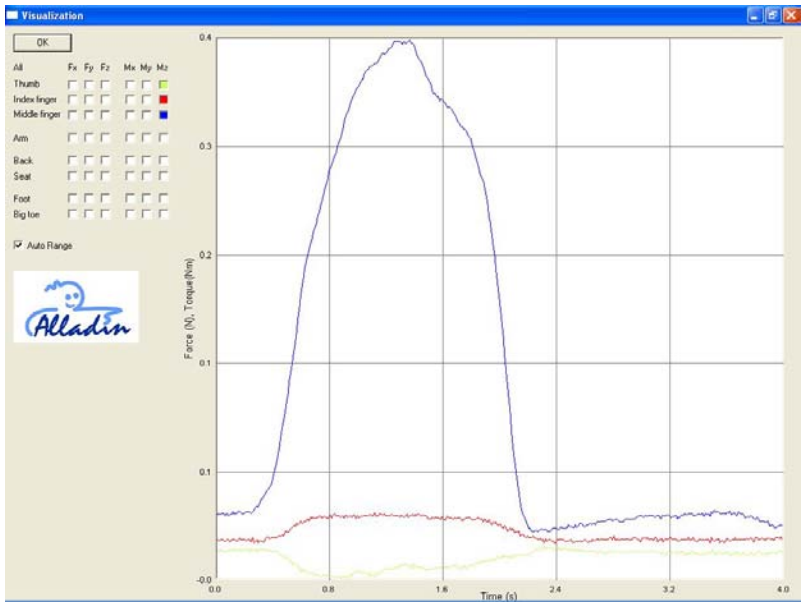


Figure 77. Data from the thumb, index finger and middle finger (Mz)

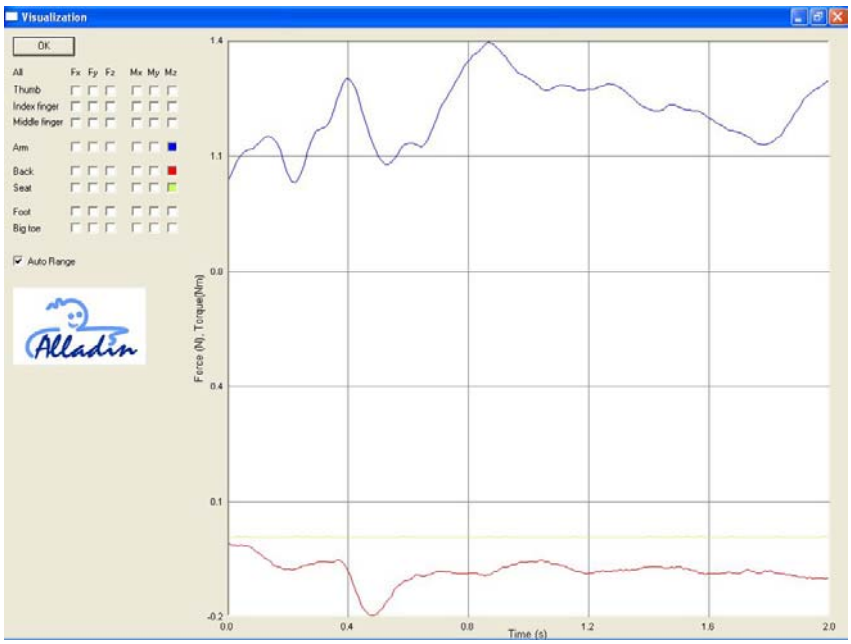


Figure 78. Data from the arm, trunk and seat sensor (Mz)

Conclusions

The ALLADIN system is the first one which acquires a great deal of different data (force-torque data, clinical scales, natural language descriptions made by the physiotherapists). It is a versatile research tool, which records heterogeneous fields, in a complete and detailed way .

The ALLADIN system will be used in clinical trial not for validating the platform itself, but to verify the clinical hypothesis which forms the basis of the ALLADIN project.

In the future, after having analysed the results of the clinical trials, we will have the possibility of reducing its level of complexity and develop an optimized version for clinical uses.

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