D4.3.1
Sensorimotor Assessment & Integration

Work package	**WP4 Play Suite Development & Integration**
Task	**T4.3 Sensorimotor Assessment & Integration**
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Project PLAYTIME

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1 Contents

2 Executive summary

This deliverable describes the hardware that will be developed by McRoberts and the steps that need to be taken to successfully integrate it in the Playtime application.

Attaching an ambulatory monitor to a person's body can be done in several ways. Traditionally, sensors are attached with an elastic belt on the lower back. For people with dementia, an additional and unknown device can cause confusion, resulting in removal of the sensor. So in order to measure people with dementia, the current hardware needs to be updated to improve wearing comfort and tamper-resistance. Besides improved wearing comfort, these hardware adjustments should also lead to higher wearing compliance and hence increase validity of the measurements. Within this task, we want to reduce the size of the sensors, make them water proof and develop new attachment techniques, such as, with skin friendly tapes. This innovative application will be integrated into the front-end and back-end overall system (see Task 4.1).

3 Introduction

McRoberts‘ current hardware consists of the DynaPort product line. The most recent DynaPort platform (6th generation) has 3 different variations, each with their own specific applications:

- DynaPort MM: The standard version of hardware to be used for MoveMonitor analysis (Detailed ambulatory assessment of physical activity in daily life conditions). It includes the following sensors: tri-axial accelerometer, tri-axial magnetometer, barometer, temperature sensor. This hardware version can measure up to 15 days consecutively.
- DynaPort MM+: A more advanced version of hardware. On top of the sensors in the DynaPort MM, it includes a tri-axial gyroscope. This hardware version can measure up to 7 days consecutively. The additional gyroscopes are not yet used for MoveMonitor analysis. Consequently, this hardware version is currently often used by researchers whereas the standard hardware version (DynaPort MM) is commonly used in clinical practice.
- DynaPort MT: This is the most advanced version of the hardware which has the same sensors as the DynaPort MM+, but with additional Bluetooth. The DynaPort MT is used for MoveTest analyses (detailed assessment of physical performance under supervised conditions (mostly used in clinical settings)). Examples of commonly used physical performance tests are the ‘6 Minute Walk Test’ and the ‘Repeated Sit-to-Stand Test’. Normally the only clinically relevant parameter provided by such a test is the total time to completion. By instrumenting subjects with the MoveTest while performing such tests, the clinician can get additional performance related parameters from the test. This helps clinicians in getting a more detailed and personalized assessment of one’s physical health.

The downside of the current DynaPort generation is that it is not waterproof and that the sensors can only be worn around the waist with an elastic belt. When measuring subjects with dementia these factors could lead to loss of data (e.g. showering with the sensor, losing the sensor) or unreliable data (e.g. tampering with the device, removing the device for longer periods). The developments within PLAYTIME aim to overcome these downsides.

4 Hardware development

Within Playtime, McRoberts will develop the 7th generation DynaPort systems. There will be 2 versions:

- DynaPort MX: small version with short battery duration (e.g. 24 hours with all sensors measuring), intended for short measurements in a controlled setting and can be seen as the successor of the DynaPort MT.
- DynaPort MM2: successor of the DynaPort MM. It has the same functionality as the DynaPort MX, it only has a bigger battery to improve measurement duration (up to 1 week with all sensor measuring). The DynaPort MM2 is intended to be used to measure physical activity of a subject in daily life.

4.1 Electronics

The new DynaPort systems will incorporate the following components:

- 3-axial accelerometer to measure acceleration along 3 perpendicular axes
- 3-axial gyroscope to measure rotation along 3 perpendicular axes (active sensor, high energy consumption)
- 3-axial magnetometer to measure rotation along 3 perpendicular axes (passive sensor, low energy consumption)
- Barometer to measure ambient air pressure as a proxy for height differences
- Temperature sensor to measure ambient temperature
- ARM processor
- NAND-based flash memory
- Bluetooth module

The main system will operate on a low-power ARM controller. This controller is driving a potted USB port, a Bluetooth module, memory, RGB LED and battery management circuitry. Data is then obtained at a given rate from all three sensors in all three axes. This is then stored in the memory for later retrieval via USB or Bluetooth.

4.2 Casing

Within this project, 2 different casings will be developed. One for the DynaPort MX and one for the DynaPort MM2. The development process of both casings will comprise the following stages:

Analysis Phase

- Gather background information about the way the sensor will be used
- Analyse production possibilities (e.g. laser welding)
- Set up Requirement Specification List (RSL)

Conceptual Phase

- Gather information of the components that will be used
- Construct 3D model of the necessary components/ PCB
- Preventive critical aspect analysis
- Compose 3D-concept design
- Check design by project team

Engineering Phase

- Update component part list
- Check producibility with factories (DFM)
- 3D and 2D engineering of the production parts

Prototyping Phase

- Modify 3D files for optimal prototyping
- Check 3D files by project team Purchasing prototyping parts
- Assembly and finishing/coating prototype parts
- Review prototype
- Adjustment remarks/suggestions

4.3 Attachment method

There are different ways to attach ambulatory monitors (such as the DynaPort sensors) to the human body. One of the possibilities is an elastic waist strap as currently used by McRoberts. It can be argued that this type of attachment could lead to a decrease in wearing compliance. It must be noted that McRoberts has very good experience with this attachment method, with wearing compliance well over 90%. As an alternative, the sensor can be fixed directly to the skin. The hip is not suggested as a location due to discomfort, but the lower back could be a suitable position. McRoberts already works with sensors on the lower back since the early ‘90s.

The DynaPort MX and MM2 will be used to measure physical activity and capacity of people with dementia. Especially in this patient group, attaching a sensor directly to the skin, seems to be a good solution to prevent tampering and removing of the sensor.

4.3.1 Strap

The elastic strap and its attachment method to the devices will be developed in combination with the casings. The same development stages as described in section 4.1.2 will be followed. The strap needs to be attached to the casing and the way this will be done is by developing a rubber ‘sleeve’ in which the casing will fit. This rubber sleeve will be fitted with ‘ears’ to which an elastic band strap can be attached. We have chosen for this approach (instead of attaching the strap directly to the casing) as rubber is has more wearing comfort compared to plastic and multiple sleeves can be developed, for different attachment locations. If the lower back is not a suitable location, a sleeve for (for example) the wrist can be developed.

4.3.2 Skin

As a sensor will be attached directly to the skin with some form of adhesive (e.g. tape), allergic reactions to the adhesive need to be taken into account. In band aids this is solved using hypoallergenic adhesives in which no PTBFF resin is used.

Latex is another common source of allergic reactions. In some stretchable band aids, latex is used for flexibility but to prevent allergic reactions, latex-free alternatives should be used.

In elderly, the skin can be soft, delicate, wrinkled or hairy. To prevent damage to the skin and pain during removal, the adhesive should allow easy removal while still being strong enough to keep the sensor attached to the skin for at least one week. Additionally, the material should be permeable for air to prevent the skin from drying.

4.3.2.1 Daily life circumstances

The attachment method must be resistant to all of the common daily living circumstances during an entire 7 days measurement. Possible common and less common circumstances which could affect the working of the sticking method are:

- External indirect moisture: A common daily activity is washing/showering. The water and soap which is used during washing or showering could negative affect the adhesive working of the sticking method. It’s quite common that a subject showers every day. So the sticking method must be water-resistant for multiple times.
- External direct moisture: A common daily activity is taking a bath or going to swim. Because the body, and thereby the device, is completely under water currents and water pressures works on the device and the sticking method.
- Transpiration: during a measurement the subject can transpire as a result of activity or temperature. The moisture derived from the skin shouldn’t affect the adhesive working of the sticking method.
- Physical Activity: during a 7day measurement there are a lot of different activities like sitting, standing, walking, dress up, lying and sleeping. As a result of the activities the skin under the MX can stretch or compress. This should have a limited effect on the working of the sticking method. Especially during dressing, sitting or sleeping it could be possible that there are forces from different directions effects on the MX. These forces

could results in shear, friction or pull forces. The sticking method should be resistant against shear or pull forces.

4.3.2.2 Adhesive surface

The size of the adhesive surface influences the functioning of the attachment method. A greater adhesive surface results in a lower resin density. This makes it easier and less painful to remove at the end of the measurement. However an greater surface means that the displacement of the skin influences the displacement of a DynaPort device. A greater adhesive surface could also be considered as uncomfortable by the subject. This effect is being increased since there is a quit a lot of movement at the location of the sensor, which results in displacement of the skin and thereby the adhesive method. A flexible (stretchable) adhesive method can possibly limit this effect.

In opposite, it can be stated that a smaller surface requires a higher resin density to ensure a DynaPort device won't be lost during the measurement. A higher resin density can make it harder and more painful to remove at the end of the measurement. The area of the back of a DynaPort device should be completely covered with adhesive (e.g. with double sided tape), so this dimension determines the minimal size of the adhesive material.

4.3.3 Location of the DynaPort device

The ideal position a DynaPort device is around the centre of mass of a human body. Usually this around 4th and 5th lumbar spine. These vertebrae's are part of the lumbar curve and the displacement of the skin at this location is limited.

4.4 Design input

Based on the previous paragraphs, design input is defined in the form of requirements (Table 1-7). At the time of writing, the design input for the DynaPort MM2 enclosure have not been created yet, so they cannot be included in this deliverable.

Table 1: Physical and functional requirements for MX enclosure.

no.	Requirement	Class
1.	The dimensions of the MX enclosure need to be as small as possible.	W
2.	Rough surfaces, sharp corners and edges that could cause injury or damage shall be avoided or covered.	E
3.	The MX enclosure parts will be permanently mounted, by Laser Welding.	E
4.	The MX enclosure has 5 LED-indications, visible from the outside of the enclosure.	E
5.	The MX enclosure will contain (at least) the following LED indications; - battery status.	W

<table>
<tr><td></td><td>- connection status.
- error status.
- possibly feedback.</td><td></td></tr>
<tr><td>6.</td><td>The LED indication colours shall be selected according to the regulations for medical equipment;
<table><tr><th>Colour</th><th>Meaning</th></tr><tr><td>Red</td><td>Warning – immediate response by the OPERATOR is required</td></tr><tr><td>Yellow</td><td>Caution – prompt response by the OPERATOR is required</td></tr><tr><td>Green</td><td>Ready for use</td></tr><tr><td>Any other colour</td><td>Meaning other than that of red, yellow or green</td></tr></table></td><td>E</td></tr>
<tr><td>7.</td><td>A serial number is present on the outside of the MX enclosure. It should be easy to check the serial number by the operator.</td><td>W</td></tr>
<tr><td>8.</td><td>The LED-indications and serial-number are visible on the MX enclosure when placed in the docking station.</td><td>E</td></tr>
<tr><td>9.</td><td>The MX enclosure will be constructed with the following parts:
• 1x Uppercase;
• 1x Lowercase;
• 1x Waterproof, ventilating membrane;
• 1x PCB;
• 1x battery.</td><td>E</td></tr>
<tr><td>10.</td><td>The assembly for the new design needs to be smooth and simple without any chance of wrong placement.</td><td>E</td></tr>
<tr><td>11.</td><td>The MX enclosure is protected against penetrating fluid according IPX7 test method, as specified in paragraph 14.1 of the IEC 60601-1.</td><td>E</td></tr>
<tr><td>12.</td><td>The MX enclosure is protected against dust according IP6X test method, as specified in paragraph 14.1 of the IEC 60601-1.</td><td>E</td></tr>
<tr><td>13.</td><td>The MX enclosure needs to have:
- A USB-gate.
- An air vent used for the pressure sensor.
- A single orientation for correct placement in a docking station.</td><td>E</td></tr>
<tr><td>14.</td><td>The MX enclosure must be resistant to the ‘Push test’ as specified in paragraph 15.3.2. of the IEC 60601-1 regulations (resistance to a steady force of 250N ± 10N for a period of 5s onto a circular plane surface of Ø30).</td><td>E</td></tr>
</table>

15.	The MX enclosure must be resistant to the 'Impact test' as specified in paragraph 15.3.3. of the IEC 60601-1 regulations (resistance to a steel ball Ø50 mm with a mass of 500 g. ± 25 g. falling from 1,3m height onto each relevant part of the enclosure).	E
16.	The MX enclosure must be resistant to the 'Drop test' as specified in paragraph 15.3.4.1 of the IEC 60601-1 regulations (resistance to a free fall of 1 m. onto a 50mm ± 5mm thick hardwood board).	E
17.	The MX enclosure must be resistant to the 'Drop test' as specified in paragraph 15.3.4.1 of the IEC 60601-1 regulations (resistance to a free fall of 2 m. onto a 50mm ± 5mm thick hardwood board).	W
18.	The MX enclosure must be resistant to the 'Mold stress relief test' as specified in paragraph 15.3.6 of the IEC 60601-1 regulations (resistance to heating of the enclosure at a temperature of 70 degrees centigrade for a period of 7 hours, after which this results in no unacceptable risk for usage, for instance dysfunction.	E
19.	The MX enclosure must be resistant to the 'vibration test' as specified in the IEC 60068-2-64 regulations (category and conditions to be determined).	E
20.	The MX enclosure must be resistant to the 'shock test' as specified in the IEC 60068-2-27 regulations (category and conditions to be determined).	E
21.	The MX enclosure will be used by or under supervision of a trained operator.	W
22.	The MX enclosure is protected against standard, non-aggressive cleaning agent: - IPA 70%; - Mild soap and water. - antimicrobial solution (eg Clinimax)	E
23.	The MX enclosure does not contain contact area's with a temperature exceeding 60 degrees centigrade.	W
24.	If the MX enclosure is mounted into the sleeve, the patient can't contact the micro-USB connector.	E
25.	The temperature requirement for usage and storage are -15° till +40° Celsius, and the air pressure from 700 up to 1060 hPa (non-condensing)	E
26.	If possible a RoHS marking, DUNC article number and material indication will be placed on the plastic parts.	S
27.	The electronics are mounted onto the MX enclosure parts without play.	E
28.	The MX enclosure contains no parts which are removable without tools. (for instance operating buttons/electronic components).	E
29.	The LED's should be spaced sufficiently to prevent blending of colours.	W

30.	The Micro-USB port is protected against outside influences from the outside.	W

Table 2: Physical and functional requirements for the MX Sleeve.

no.	Requirement	Class
31.	The sleeve needs to encase the MX firmly during measurement.	E
32.	The MX can be placed in the sleeve with the front facing outwards.	E
33.	The MX can be removed from the sleeve easily by hand.	E
34.	The USB-connector in the MX part is covered by the sleeve part when mounted.	E
35.	The LED indicators on the MX, shall be visible while mounted into the sleeve.	E
36.	The temperature requirement for usage and storage are -15° till +40° Celsius, and the air pressure from 700 up to 1060 hPa (non-condensing)	E
37.	The Sleeve must provide a comfortable grip and a nice tactile feeling.	W
38.	The MX sleeve is protected against standard, non-aggressive cleaning agent: - IPA 70%; - Mild soap and water. - antimicrobial solution (eg Clinimax)	E
39.	Rough surfaces, sharp corners and edges that could cause injury or damage shall be avoided or covered.	E
40.	Pressure sensor will function when in sleeve (hole not blocked).	E
41.	Sleeve must be easy to put on by non-trained person.	W
42.	Sleeve must be age/gender neutral in design.	W

Table 3: Esthetical requirements (for MX and Sleeve).

no.	Requirement	Class
43.	The design style needs to be aligned with the McRoberts product style and colors.	W
44.	The design needs to have a sturdy and rugged feeling and look.	W
45.	The design needs to be customizable in colour and print.	W
46.	In accordance with McRoberts, the texture of the parts will be chosen.	W
47.	Materials need to be inert, and suitable for use with wireless products (not metalised or RF blocking).	W

Table 4: Electronic requirements (for MX and Sleeve).

no.	Requirement	Class
48.	The MX PCB contains at least the following parts: • 1mm PCB, dimensions and components as drawn in mcr001-rev7-rc1. • Battery, Type: SNO-362828PW • Air pressure (Poron) membrane type: PMV15N	E
49.	The MX PCB contains unhampered space for the battery, 1mm offset from the surface of the PCB at the USB-side.	E

Table 5: Manufacturing requirements (for MX and Sleeve).

no.	Requirement	Class
50.	The chosen materials need to be durable and create a sturdy and rugged feeling.	E
51.	The plastic parts are produced with injection molding. Open-close mold constructions are preferred.	S/E
52.	The MX, sleeve and strap parts are produced in large batches (approximately 1000 parts per batch).	E
53.	The sleeve and strap parts are produced with compression molding.	E
54.	Production of the enclosure parts can be in China/Europe.	S
55.	Assembly of the electronics and the MX enclosure/ docking station needs to be done in the Netherlands (or nearby).	S

Table 6: Marking requirements (for MX and Sleeve).

no.	Requirement	Class
56.	Where possible, each (plastic) part will contain the following texts and symbols: • RoHS compliant • Production date • Material identification code • DUNC article code *(texts and symbols will only be visible on the inside of the enclosure)*	E
57.	Some important product and manufacturer markings need to be visible i.e.: McRoberts logo	E

58.	Where symbols are used on or near controls (for example, switches and push buttons) to indicate "ON" and "OFF" conditions, they shall be the line | for "ON" and circle O for "OFF"	E
59.	The symbols/icons that are applied onto the enclosure parts, shall comply with the specifications from the medical regulations (to be determined).	E
60.	On the outside of one of the plastic enclosure parts from the MX enclosure a CE-logo is applied on a visible and subtle location.	E
61.	A marking shall be present on the outside of the MX- enclosure, containing CE-logo, type number etc.	W

Table 7: Requirements for skin attachment method.

no.	Requirement	Class
62.	Hypoallergenic adhesive should be used	E
63.	Latex free material should be used	E
64.	Pain free removal should be possible	W
65.	The method should not block the working of the pressure sensor (i.e. air flow should not be blocked)	E
66.	The adhesive should be resistant to: • Soap • Water • Transpiration • External forces from all directions	E
67.	Adhesive surface needs to be as small as possible	W
68.	Adhesive material needs to be stretchable	W
69.	Attachment method will be suited for fixation on L4/L5	E

5 Integration

The hardware as described in section 4 will be incorporated in the Playtime suite as conceptually described in deliverable D4.1.1 and D4.1.2.

The hardware will be connected to a cloud platform by a software application. In the figures below this is described as ‘middleware’ (figure 1). In the system, one or more devices are physical connected with the computer that is running the middleware application. A device contains all relevant data that needs to be uploaded to the online platform.

Looking from an application perspective, the data will first be offloaded from the device, stored in the local storage facility, before it will be transferred to the online platform. The middleware application is also responsible for the data integrity.

Every activity will be logged as events. These events will be stored in the local operating systems event manager and uploaded to the online platform along with the data. If for some reason a connection with the online platform is not possible, data will be stored and uploaded as soon as a connection can be established.

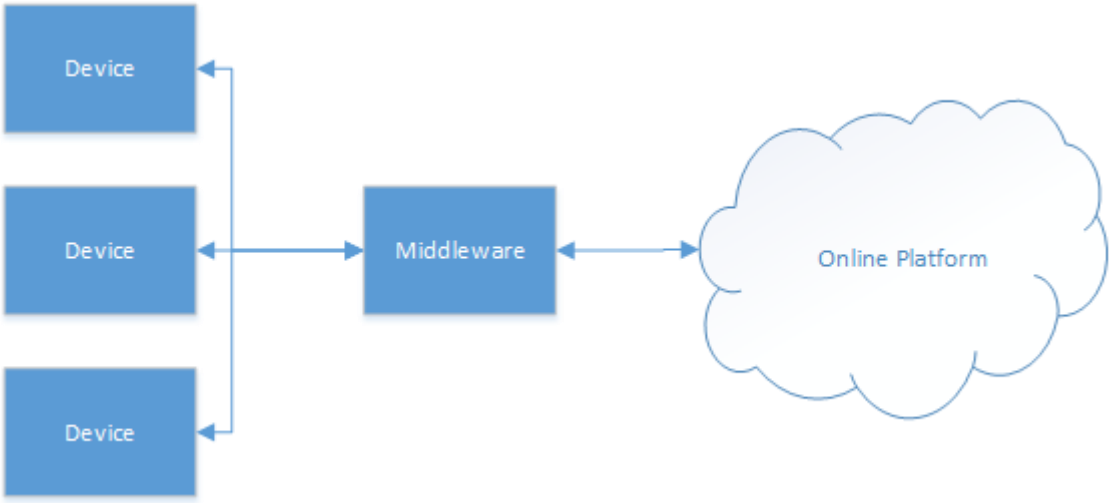

Figure 1. General outline of the connection between device(s) and an online platform.

The middleware application watches for USB events and based on the event and device type, it will attempt to a connection. Based on the device type and configuration, data will be obtained from the device and handled by the local data storage manager. Based on the device configuration from the online platform, commands will be send to the connected device.

Based on communication with the online platform, the obtained data, along with any activity log will be uploaded to the online platform. The middleware is capable of downloading data from the

devices while not having an active connection with the online platform. As soon a connection will be established, uploading of data to the online platform will be handled.

The online platform as shown in figure 1 will be the data management platfom of McRoberts called ‘My McRoberts‘. Communication between My McRoberts and the manager will be handled by an API. The communication between My McRoberts platform and the central Playtime database will be handled by a RESTful API, so that relevant analysed data (described in D3.2.1.

6 Conclusions and Outlook

The developments described in this deliverable will be finalized in H1 of 2019, well before the end of the Playtime project. In the last year, the developments can be tested and fine-tuned where necessary. In these tests, the end-users (people living with dementia) will be incorporated. This will be achieved either by collecting data and feedback during the field trials, as well as during focus group meetings with patients with dementia and their (informal) caregivers in both the Netherlands (GGzE) and Austria (SVD).

7 Glossary

Table 8. *Glossary.*

Notion	Description
Accelerometer	An accelerometer is a device that measures proper acceleration, being the rate of change of velocity of a body.
DynaPort	McRoberts' hardware line consisting of DynaPort MM, MM+ and MT (current systems) and the to be developed DynaPort MX and MM2
Gyroscope	A gyroscope is a device used for measuring orientation and angular velocity.
Magnetometer	A magnetometer or magnetic sensor is an instrument that measures magnetism. In recent years, magnetometers have been miniaturized to the extent that they can be incorporated in integrated circuits at very low cost and are finding increasing use as miniaturized compasses
Middleware	Desktop software that handles communication between DynaPort systems and (cloud based) servers.
MoveMonitor	McRoberts solution (hardware and software) for measuring physical activity in daily life.
MoveTest	McRoberts solution (hardware and software) for measuring physical capacity in controlled settings.

8 Abbreviations

Table 9. *Abbreviations.*

Abbreviation	Description
API	Application programming interface
LED	Light emitting diode
MM	MoveMonitor
MT	MoveTest
PCB	Printed Circuit Board
PTBFF	Paratertiarybutyl Phenyl Formaldehyde
RESTful API	Representational State Transfer (REST) is an architectural style that defines a set of constraints to be used for creating web services.
USB	Universal Serial Bus