DELIVERABLE REPORT

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Project number: 687795

D4.2, Optimized prototype of electrode liner
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WP4, Task 4.2, Liner/Socket for multichannel EMG recording, OBG

1 DESCRIPTION OF THE TASK

Task 4.1 Electronics for EMG recording (OBG (24), M01 - M24):

This task deals with the development of multichannel EMG amplifiers (circuit design, layout etc.) which are small enough to integrate them in a prosthetic system. One possibility could be that those amplifiers will be integrated in the distal end of a liner. It needs to be investigated how this could be done. The connection of the electronics will be a main topic here. Another important work will be the development of shielding concepts, as the separation of electronics from electrodes could lead to a system which is more prone to electromagnetic interferences and cable movement artefacts. This includes noise sources such as power line noise, cell phones or electronic anti-theft devices. E.g. active shielding of the cables has been applied successfully in preliminary tests to reduce the influence of power line noise. This work is based on an already existing desktop amplifier which was developed to record EMG from dry electrodes in the EU funded project AMYO.

Task 4.2 Liner/Socket for multichannel EMG recording (OBG (22), UMG-GOE (2), M01 - M24):

A new liner/socket interface for EMG recording will be developed. Focus is on the combination of conductive and nonconductive materials. Experience showed that this is a critical point to record high quality EMG which is not prone to artefacts such as electrostatic noise

• Conductive polymers to have a consistent liner/socket surface to the skin will be investigated. One key is to find a polymer which does not tend to movement artefacts

• Moreover the likelihood of lift offs will be decreased by exploring special shape and/or flexibility of electrode material and new socket designs.

Task 4.3 Design validation and iterative development (OBG (34), M06 - M48):

All activities in this work package will be carried out according to an iterative, agile research and development process. This task was specifically introduced with a run time over almost the entire project duration to reflect this agile development, while keeping the other Tasks of this WP focused and concise. Already starting with the first design concepts and mock-ups we will integrate orthopaedic technicians and end-users (amputees) into the process in order to understand their needs.

The evaluations comprise laboratory as well as clinical tests and the results will continuously guide the development progression of the electrode liner/socket interface.

2 Description of Deliverable

The goal is to improve the quality of the electrode liner prototype. The robustness, signal quality and production of the electrode liner is the focus in this reporting period.

3 Implementation of Work

In Deliverable 4.1 the first prototype of the developed electrode liner was presented. The electrode liner material selection, the manufacturing process and electronics development was shown. For the integration of the new system in the prosthesis it is necessary to improve the size of the electronics, robustness of the hardware and components like wires and connection.

3.1 Electronics and Software application

The project has focused on an analog front-end designed by Texas Instrument, the ADS1298, and a MSP430 Texas Instruments microcontroller. There are three versions of the electronic system: a monopolar desktop amplifier with 16 channels, a bipolar desktop amplifier with 8 channels, and a bipolar portable system based on pogo pins (dubbed PogoBoard). The signals acquired with these electronic systems are sent to a personal computer (PC) for further signal analysis. Three applications can be run on the PC: 1) a Debugging Tool that tests the signals obtained by the acquisition boards, 2) software for EMG signal analysis and processing called DynDOF, which uses a DataLab plugin, and 3) a Patient Training Tool used for pattern recognition, which connects to the acquisition boards using a specific library. Both the plugin and the library are written in C# and are based on the basic code generated for the Debugging Tool. Software packages 2) and 3) were already available in the consortium and are used for signal acquisition with the liner. Tools 1) and 3) can further be used to connect the acquired EMG data with the recognition system developed in WP 6. Figure 1 shows the structure of the EMG acquisition system and the signal analysis system used for the INPUT project.

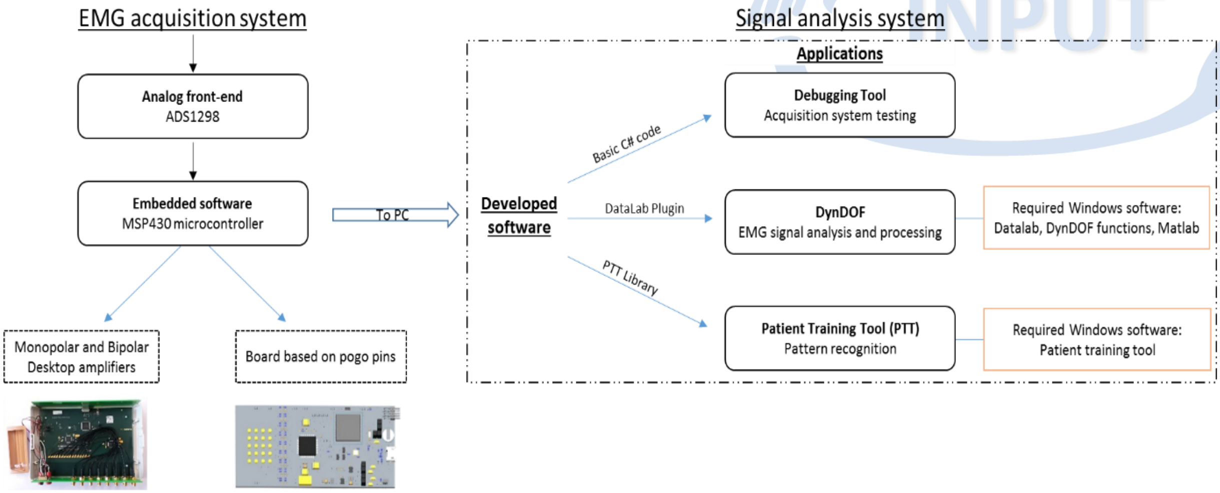


Figure 1: Structure of the EMG acquisition and signal analysis systems developed for INPUT project. The EMG acquisition system has two embedded software versions, one for the desktop amplifiers (monopolar and bipolar) and another one for the PogoBoard. In the PC, three different applications are available, which require their own specific C# code.

ADS1298 analogue front-end

Main characteristics of the analog front-end

An analog front-end (AFE) is an integrated circuit composed of analog signal conditioning circuitry. They usually contain operational amplifiers, filters and analog-to-digital converters (ADC) to interface sensors with antennas or microcontrollers. One of the leading AFEs in the market is the ADS1298 from Texas Instruments. It is a 24-bit, 8 channel AFE, which includes independent programmable amplifiers, a high speed delta-sigma ADC, and configurable modules such as temperature and lead-off sensors. A simplified schematic of the AFE is shown in 2.

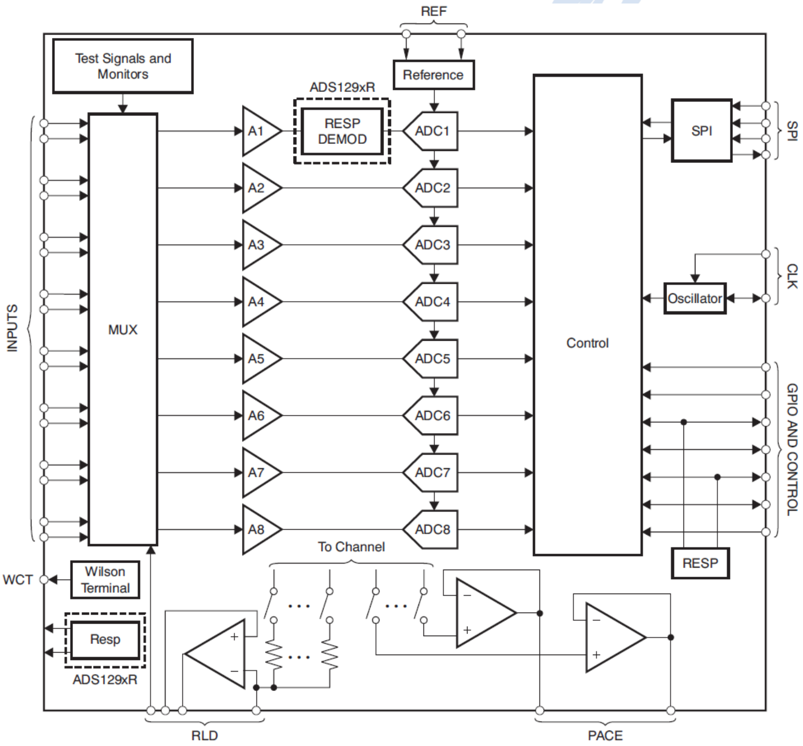


Figure 2: Simplified schematic of the analogue front-end ADS1298 from Texas Instruments. The integrated circuit includes independent programmable amplifiers for 8 bipolar channels, a 24-bit delta-sigma analogue-to-digital converter (ADC), internal reference, on board

The ADS1298 has two different packaging options: a 64-pin TQFP (dimensions: 12 × 12 mm) and a 64-pin NFBGA (dimensions: 8 × 8 mm). All the inputs of the AFE have an electromagnetic interference filter (EMI) with a cutoff filter of 3 MHz. Every channel has a programmable gain amplifier with seven possible gains: 1, 2, 3, 4, 6, 8, and 12. Additionally, the ADS1298 includes a Serial Peripheral Interface bus (SPI) to send or receive data to/from other devices.

The AFE can be used in two different operating modes: high-resolution (HR) and low-power (LP). These modes define the sampling rate of the modulator used in the delta-sigma ADC. It also includes decimation filters that provide antialiasing filtering.

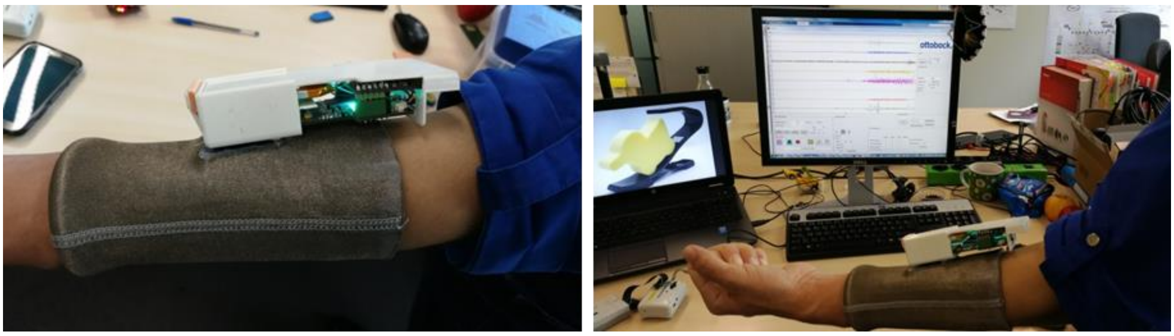


Figure 3: Electrode liner cuff for able bodied subjects and wireless EMG amplifier.

Figure 3 shows the first version of a miniaturized EMG amplifier board. However further improvements were necessary. This version was still too big to integrate it completely in a prosthetic socket. Moreover, it was found that the introduced liner/electronic interface was not robust enough for stable signal acquisition. Therefore, a new iteration of the electrode liner interface and the electronics itself was necessary based on the findings made with the first miniaturized version.

IMPROVEMENTS IN ELECTRONICS

The first system had some disadvantages in size and connection. The integration of the electronics in the in experimental prosthesis for study application was difficult. Therefore, the system was redesigned to its current size and connection method. The new approach is to use a 'sandwich' plan. The electronic board was divided into the liner PCB, amplifier PCB and communication PCB. The liner PCB is integrated into the liner itself and connects to the wires and electrodes. The signal amplification is connected directly on the liner PCB. The communication board with Bluetooth interface communicates with the different end devices like a prosthetic hand or a computer. The dimensions got reduced from 50x103mm down to 30x30mm. The production of the electronic components is in progress and will be integrated in the next possible prototypes.

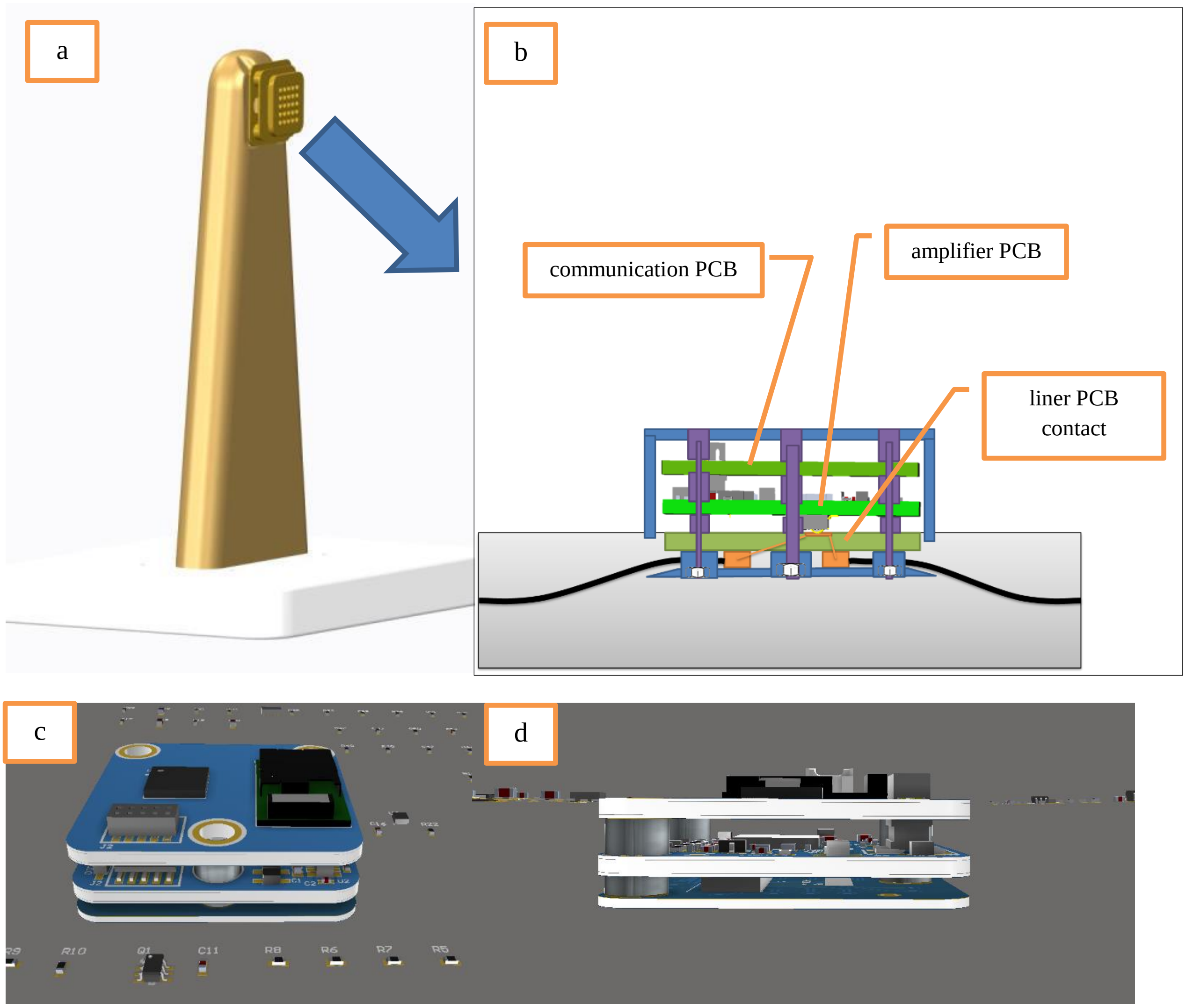


Figure 4: a: electrode liner mold with electronic stack located on the distal sided end of the liner, b: shows the cross section of the electronic stack with its components, c and d show the stacked PCB setup in the software during design process.

3.2 FABRICATION IN DIFFERENT STANDARDIZED SIZES WITH SCALABLE MOLD

While the first prototypes had high signal to noise ratios and good signal qualities, they lacked in equal liner wall thickness, high production time and the manufacturing inaccuracy. To improve the further signal processing it is necessary to avoid signal artefacts caused by fabrication problems. The focus has therefore been set on the prefabrication of the electrodes/wires, electronic integration and a scalable mold.

The new fabrication process improves the following methods:

- Equal quality in liner thickness[1]
- Reliable quality in production process due to the development of fabrication tools
- Robust electrode integration
- Electrode - silicone - wire interface
- Silicone - wire - electronic interface
- Production time
- Size adaptation because of scalable moulds

Figure 5 shows the first improved production process. For this process a 3D printed mould was designed and built. Figure 5a shows the sided adapter and the CAD mold design. The sided adapter placed on the inside of the mold and gets injected by polymer (Figure 5b). Figure 5 c and d show the removing of the outer mold. The coating of the liner with conductive fabric is shown in Figure. 5e.

[1] Measured with digital caliper

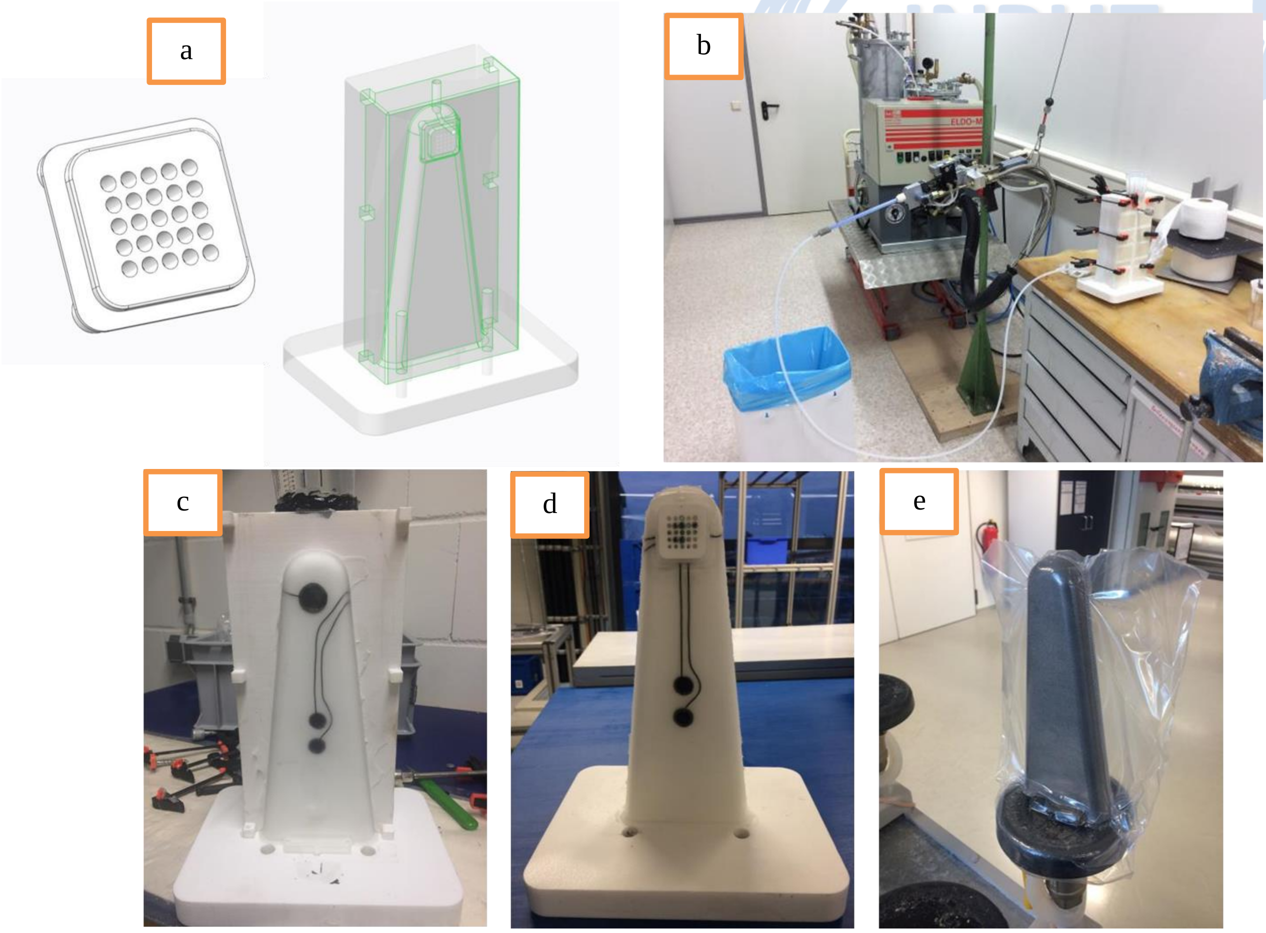


Figure 5: a: a sided adapter with the new electrode liner injection mold, b: injection process with polymer material, c/d: mold removing, e: shows the coating of the liner with conductive fabric.

Mold improvements

The focus of further standardization and better reproducibility of the production process has been set on inter component connections such as electrode/electronics to wire connections and electrode placement. The presented liner mold in Figure 6 improves the electrode placement and reduces the production steps.

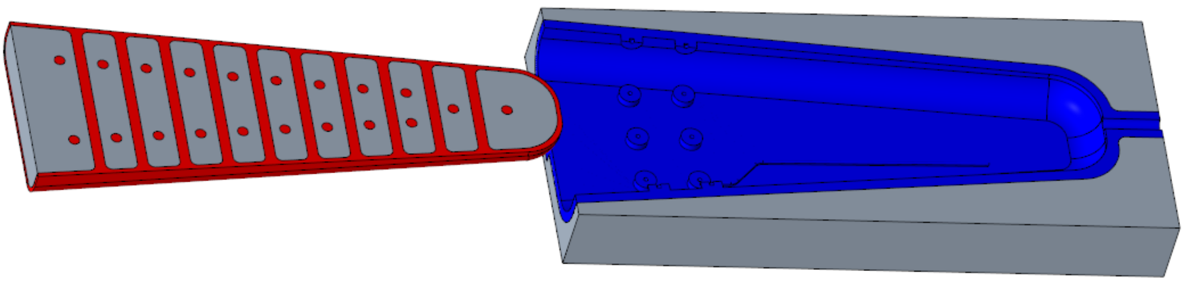


Figure 6: The inner liner core covered with silicone (red), inserted in the outer mold with an inner layer of silicone. The inner layer of silicone has electrode positioning spots and wire dummies for the wire application in the polyurethane material.

Electrode fabrication

The manufacturing of multi-material electrodes is shown in Figure 7. The conductive fabric is put in the mold and held in place by a second mold. The upper mold part is filled with the conductive silicone and is pressed into the fabric to achieve a good connection. The centre of each electrode has a connection to snap contacts on (see also Figure 8).

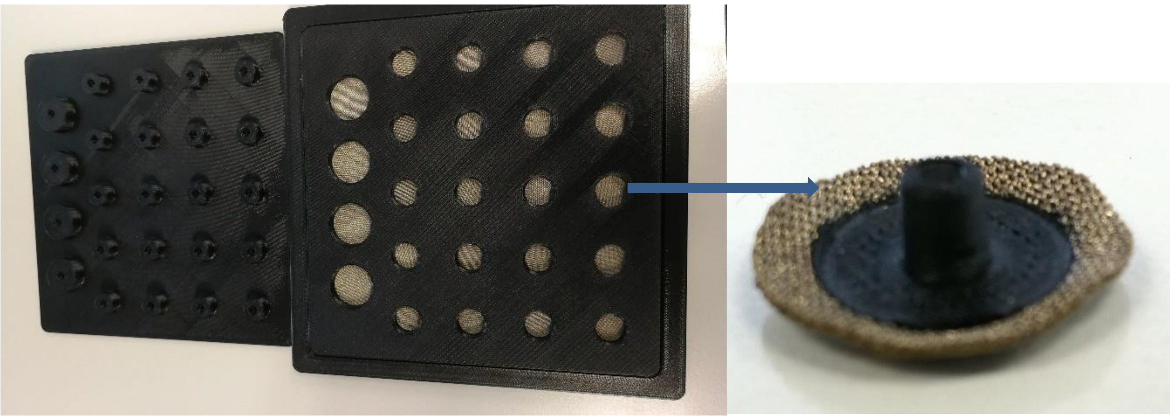


Figure 7: The electrode pre fabrication mold (left), final produced electrode (right)

Wire production

The previous prototypes used self-extruded and coated silicone wires. The bottleneck of this approach is the interface between the electrode wires and sided connector. Elongation and mechanical stress act on the electrode liner and could cause a wire defect. Therefore a new principle was used, eliminating the extrusion process. Instead, a thin plate of silicone is placed in a laser cutter to cut out the wires. A further improvement is the design of the electrode attachment. A ring was integrated to use it like a snap on connector on the electrodes. Figure 8 below shows the components and the connection of the components

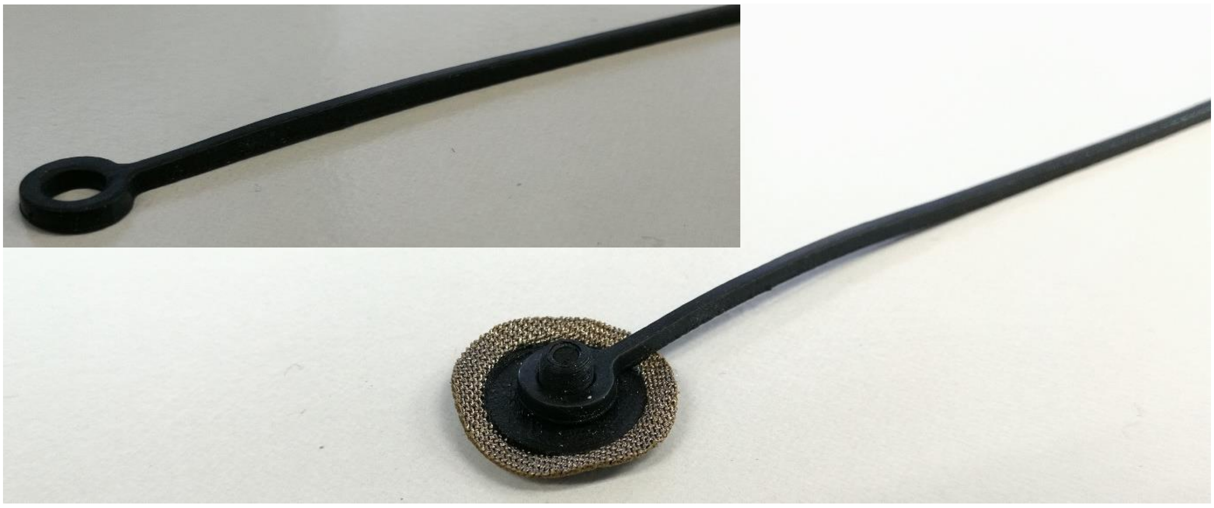
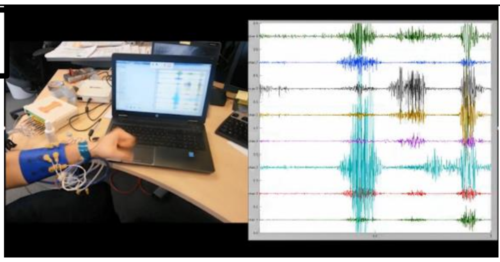


Figure 8: improved wire and wire/electrode interface

3.3 Results

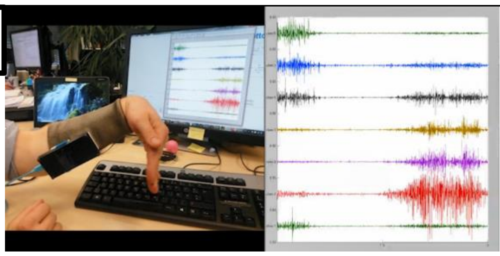
The new electrode liner preforms robustly providing high quality EMG signals. In the review meeting in October 2017 in Luxembourg a working prototype was demonstrated. The measurements showed the signal quality and artefact proneness of the state of the art material silicone in comparison to the in INPUT developed prototype based on polyurethane.

a



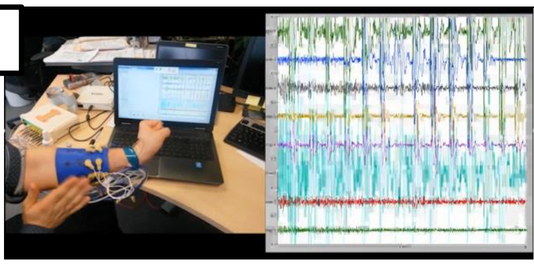
Signal quality of silicone liner

b



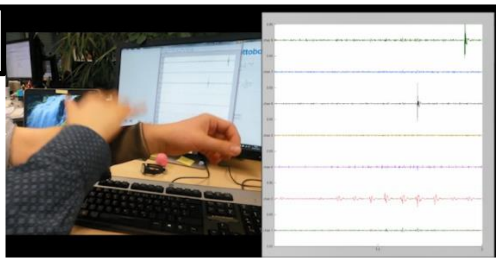
Signal quality of new polyurethane liner

c



Large artefacts while touching the surface of the silicone liner

d



Less artefacts while touching the surface of the polyurethane liner

Figure 9: Improvements of signal quality and artefact robustness. Comparison of silicone (a&c) to polyurethane (b&d) electrode liner

3.4 Biocompatibility of materials:

Conductive silicone

The conductive silicone was tested in 2009 by Fresenius Institute (Report number: 1554493-01, 23.12.2009). The results of the epicutaneous test showed not noticeable changes of the skin condition in 50 subjects over 48 hours.

The cytotoxicity test was also performed by Qualis institute for level 2 (direct skin contact). (Report number: 0911.2312, 01.12.09)

Silver fabric

The Agitex silver coated fabric is for example used in shoe insoles for diabetic patients. Tests provided by a supplier showed germicidal effects on staphylococci, escheritia coli and pseudomonas aeruginosa.

Cytotoxicity tests are currently in progress.

Polyurethane with cvd (Parylene N) coating

Polyurethane liners have been used for many years in prosthetic liner treatments. Therefore, no renewed biocompatibility tests were performed with the material for INPUT.

Long term tests

Accelerating mechanical aging tests are planned and in preparation. This will be a don and doffing simulation. For this application a test machine will be adapted.

Moreover we will conduct extended tests in a target population group. Preparation for the ethical approval is in progress.

3.5 Future Work comprises as follows:

Future work will focus on design validation and iterative development, which will be done within task 4.3. Next steps include:

- Finalizing the new "sandwich" hardware shown in figure 5 including the embedded software
- Implementation of the improved production process
- Biocompatibility tests
- Accelerating mechanical aging test (don and doffing simulation)

Additionally, the second half of the INPUT project focuses on extensive patient tests which will be conducted together with the project partners. The following studies are currently planned, in which the new liners will be used:

- OSS (ADL studies, comparison of control methods)
- UMCG (20 patients control state of the art vs. INPUT)
- IDSIA (able bodied testing for development)
- ICL (model validation measurements)
- OBG (10 Patients long term test)

Based on the obtained results, OBG will further improve the electrode liner, according to our iterative approach.

4 Subcontracting

All work was done by Ottobock and we didn't have any subcontract within Work Package 4.