



2nd Periodic Report Month 24

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Consciousness in Non-Responsive Patients"

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1 Publishable summary

Summary of DECODER

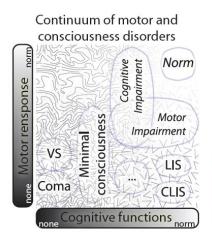
The deployment of Brain-Computer Interfaces (BCI) for non-responsive patients will provide access to modern information and communication technology such as internet, personal computer or home appliances when only a single response of a person is available. In this extreme case, no current assistive technology can help the patient interact with the environment. This situation poses serious ethical issues, since medical treatment can prolong the patients' life, but leave them in a state of unacceptable quality of life.

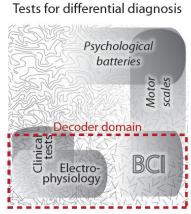
DECODER will develop a BCI into single-switch based systems to practically enhance inclusion of patients who are otherwise only little or not at all able to interact with their environment and share information and communication technology (ICT). This achievement will move on from the improvement of three components of state-of-the-art BCIs, i.e. signal acquisition (input), signal classification and signal translation (output) and adapt them to the specificities of non-responsive patients such as low arousal, short attention span, and altered electrical activity of the brain. A forth component is the application; existing assistive technology will be adapted to a single-switch control. Besides classic EEG paradigms near-infrared spectroscopy will be used for signal acquisition due to its higher spatial resolution. Potential and automated software will identify the best signal for each user and will optimize signal translation. Prior to providing such patients with ICT an unequivocal diagnosis is of utmost importance to define the most appropriate rehabilitation strategy and most suitable supportive technology for interaction. A hierarchical diagnostic approach starting with simple presentation of stimuli to intentional control of BCI will be developed, validated and disseminated.

By implementing existing well-established and currently developed tools at all levels of the BCI and bringing together a multidisciplinary team we can ensure the achievement of the goals of DECODER.

Approach

We are aiming at a hierarchical approach to the detection of consciousness as outlined in the Figure below. DECODER will only deal with locked-in and non-responsive patients. Consequently, the envisaged diagnostic battery and ssBCI have to accommodate for low attention span and impaired vision often seen in these patients. Patients to be involved in DECODER may have rendered the state of non-responsiveness due to extensive damage to the brain leaving them with an impaired "command centre" or due to paralysis of the "executive body" leaving the commands of the brain without a receiver.





Scientific and Technical objectives

DECODER will develop new components of a diagnostic battery and single-switch BCI through four Scientific and Technical (ST) objectives..

ST1: BCI-based diagnostic battery: The objective is to define objective markers of cortical processing and consciousness with an easy-to-use diagnostic tool for diagnosis of non-responsive patients. The diagnostic battery will be primarily based on auditory stimulation as vision may be impaired in patients. The *passive* part of the battery will include simple paradigms to ensure intactness of sensory pathways and established paradigms to evoke characteristic potentials in the EEG which will be adapted to be used for diagnosis. The development of *active* BCI-based paradigms will allow us to unequivocally determine the conscious state of the patients.

ST2: Individualized single-switch application: This objective will lead to applications which can be controlled by simple, high speed "yes-no" commands (single switch). It will include research in new signal classification algorithms to better classify the brain signal of interest. The most robust and reliable signal will be identified and kept stable and reproducible over an extended period of time.

ST3: functional NIRS-BCI: This objective will built on the positive experience with functional magnetic resonance imaging (fMRI) for detecting conscious awareness in non-responsive patients. It is well established that different imagery strategies lead to clearly and reliably distinguishable brain activation patterns. FMRI is costly and tied to clinical or research institutions. For this reason, we will further develop signal acquisition and extraction by optical imaging techniques like functional near infrared spectroscopy (fNIRS) which is portable and inexpensive.

ST4: Evaluation and Dissemination: Both primary aims diagnostic battery and single-switch BCI (ssBCI), will be evaluated by the targeted user groups. We will intensively and continuously seek the input of clinicians for development, improvement and routine applicability of the diagnostic test battery. Likewise we will be in close contact to target user groups as well as their supporters to receive information about most urgent needs of the potential users of the ssBCI and in the next step to receive feedback on the BCI provided for non-responsive patients.

Work and Results within M19-M24 of DECODER (M13-M18: s. 2nd Interim Report)

A revised and final set of classifiers for SSVEP, P300 and SMR was released and distributed to all partners via a boot camp such that all partners were able to practice hands on the use of the classifiers. Also the application of the classifiers was simplified to make them more suitable for clinical use, and they will now be subject to clinical evaluation. The passive paradigms integrated into the battery for the assessment of the level of consciousness were finalized and the exact testing algorithm was released including a manual so that testing with patients and the different sites can be easily standardized. Newly developed and also standard paradigms were included in the battery. The paradigms are such that they require increasingly more cognitive processing capacity to evoke the expected brain response. Thus, the battery, which is established for EEG recording, covers passive and active paradigms. Active meaning here that the brain response can only be detected provided command following of the subject. Within this reporting period more than N=40 patients were confronted with the battery and N > 30 were tested twice to investigate the stability of the results. Passive and active paradigms are also realized for fMRI recording, specifically language processing was addressed starting with simple sound processing and closing with speech comprehension. Further refinement of the paradigms is prepared and will be investigated provided the acceptance of new partner WESTERN by the EC. Different input signals for the ssBCI were further investigated and integrated in ssBCI and the ssBCIs are ready to be used by partners. Tests with healthy subjects were conducted with all BCIs (P300, SS(V)EP and SMR) and spelling software has been developed. The ssBCI is setup such that for each individual user the optimal signal can be selected. The most robust signal can then be used to control the application. Altogether more than N>70 healthy subjects and several patients were confronted with the ssBCIs. Data collection with healthy elderly subjects and non-responsive patients is ongoing. Further progress was achieved in using hemodynamic responses as input signal for BCI measured with fNIRS. The so-called SATORI software for realtime fNIRS was further developed and the decisive report on detecting different mental states and task with fNIRS could be successfully delivered as 8 different mental tasks could be successfully detected and separated with fNIRS. All the paradigms and testing procedures developed within DECODER are subject to evaluation. The evaluation protocols were defined and application of these protocols is ongoing. Dissemination and exploitation of DECODER results is continuously realised yielding publications in scientific journals, conference proceedings and book chapters. The DECODER members are heavily promoting their work by presentations at conferences, workshops, and meetings of associations. The exploitation plan was further refined supported by an assessment of the needs of professionals supposed to use the DECODER battery and ssBCI in clinical practice.

Management of the project was running smoothly and included besides the standard work of management (organization of Meetings, collecting reports etc) the preparation of the amendment with all its aspects, specifically the significant alteration of WP5 and the partners MRC and WESTERN. The amendment and the release of partner MRC and inclusion of new partner WESTERN was submitted to the EC at the end of this reporting period. The preparation of the release and inclusion of MRC and WESTERN started in April 2011 and will hopefully be finalized in the upcoming days. Due to the intervention of the PO we had to put the experiments related to propofol on hold and after the Ethical Review which was realized in October 2011 the Consortium decided to drop those experiments altogether as it was considered unrealistic to finalize these experiments within the duration of DECODER in the light of the requests imposed as a result of the Ethical review. Instead of healthy subjects under propofol, patients with fluctuating vigilance will be included and ethical approval for the studies is currently sought. A newly requested Deliverable on Ethical concerns as raised by the reviewers was submitted. Due to these issues which caused a delay of work delivery the DECODER project is seeking for prolongation of 3 months; this request was also submitted within the amendment request.

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