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Project: 76085 OUS NVR EEG Equipment for AI-Mind

Description of the project and procurement

Artificial Intelligence for Dementia Prevention (AI-Mind) is an EU-funded research project (Grant agreement ID: 964220) that aims to develop models based on artificial intelligence to identify dysfunctional brain networks and estimate risk for dementia. Anonymized harvested data from the EEG-system will be shared in a cloud-based system across locations. Procurement of identical EEG-systems at each location is therefore necessary.

The AI-Mind consortium firmly believes that ANT Neuro GmbH is the only supplier who is able to deliver the combination of quality- and functional requirements prepared by the research group. The quality- and functional requirements are listed on pages 2-3.

On behalf of the AI-Mind consortium Oslo University Hospital announces a letter of intent to buy eight (8) high-density EEG-systems from ANT Neuro GmbH. Each partner will be responsible for it's own procurement agreement with ANT Neuro GmbH. The following institutions are included in the consortium and procurements will be made according to the following distribution key:

Oslo University Hospital, Norway: two (2) systems
Helsinki University Hospital, Finland: two (2) systems
Complutense University of Madrid, Spain: two (2) systems
IRCCS, San Raffaele Pisano, Italy: one (1) system
Cattolica del Sacro Cuore University, Italy one (1) system

The letter of intent is based on EU procurement legislation and the Norwegian Public Procurement Law (LOA) with Regulation for Public Procurement (FOA) § 13-4 b) no. 2; *The client may carry out a procurement without competition if competition is impossible because of technical reasons.*

The contract will be entered into on the basis of FOA §21-5.; *If the client believes that he has the authority to enter into a contract without announcing the competition, he may, after the choice of supplier has been decided, announce that the contract will be entered into by publishing a letter of intent*

Objections to the letter of intent must be reported within ten (10) calendar days from the date of publication in TED.

Quality and functional requirements	Requirements	Requirement category: A: shall be met
1.1	**CE-certification:** The EEG-system must be CE-certified as a medical device according to EU MDR/MDD	A
1.2	**Data security:** The system must be Microsoft Windows-based and comply with cyber security standards. Any non-Windows operating system will be rejected.	A
1.3	**MEG compatibility:** The research includes simultaneous high-resolution recording of MEG and EEG at two of the research sites, hence proven and demonstrated MEG compatibility of the deployed system is required. Included must be solely optical data transmission between the interior and exterior of a shielded room.	A
1.4	**Hardware/software:** • Fully DC coupled amplifier • 24 bit ADC per channel • Programmable gain (up to 1 Vpp) • Input impedance >1 GOhm • CMRR > 100 dB • Digital TTL trigger input, optical communication protocol to PC • Sampling rate up to 16 kHz for EEG, optical communication protocol to PC • A minimum of 4 auxiliary input channels.	A
1.5	**High-density, modular system:** The project's goal requires at least 128 recording channels, build-in battery for independent use, as well as the possibility of sampling rates up to 16 kHz. For future utilization, the system must be modular in nature, facilitating higher or lower channel density setups.	A
1.6	**Active Shielding:** For use outside of the shielded MEG-environment, the system must include active shielding to minimize the impact of a multitude of artifact sources such as electromagnetic interference, cable displacement and movement artifact.	A

1.7	**Cap application:** Electrodes must be pre-mounted on a cap without the need to assemble the cap before use. Cables must be hidden from the user and connected with the amplifier through high density connectors.	A
1.8	**User friendly clinical acquisition software:** The EEG acquisition software must be included in the systems Declaration of Conformity, and must be easy to use. The software must allow the investigator to pre-configure and save the protocol settings to be used for recording.	A
1.9	**Warranty and service over project lifetime:** The supplier must provide full warranty on the EEG-system components and service during the full duration of the project (5 years) on the hardware. A 2 year warranty on the caps must also be provided.	A

On behalf of the AI-Mind consortium

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