Preliminary Report on Implant Module

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Project Title: Wireless Brain-Connect inteRfAce TO machineS

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Approvals

Name, Org.	Role	Signature	Date
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Executive Summary

The aim of this progress report is to outline the WP2 system requirements and describe how the system design addresses these requirements. The design objectives of the brain implant module and the external supporting units are: 1) to interface with the neurons in the motor cortex, amplification of neural spikes and data generation, 2) to enable stimulation of the neurons in the somatosensory cortex based on the external commands, 3) to provide simultaneous wireless power transfer (WPT) and low-data-rate communication to support the implant telemetry and telecommand, and 4) to create a high data rate battery-free data communication link from implant to the external reader. This report covers preliminary design steps, criteria, requirements, and implementation plan for the implant and the external units to realize the readout and stimulation task of the brain implant. Two additional deliverable reports detailing the technical design and implementation progress for the wireless data transfer and wireless power transfer systems are planned for Month 18 (D2.2, D2.3).

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1 Overview

1.1 Purpose

This progress report describes how the WP2 system design addresses the B-CRATOS product and subsystem requirements. The critical objective of Work Package 2 (WP2) is to achieve a brain implant capable of fully wireless device operation by developing and integrating technologies for wireless data connectivity and wireless power transfer. The implantable system, including the implantable neural interface device and external reader, forms the core of the B-CRATOS closed-loop brain-computer interface (BCI) system. WP2 implant technology and the external supporting system will realize two-way communication with neurons and exchange communication data with the FAT-IBC module to connect to the robotic arm.

1.2 B-CRATOS Partners

Short Name	Full Name
UU	Uppsala Universitet
SINANO	Institut Sinano Association
SSSA	Scuola Superiore di Studi Universitari e di Perfezionamento S'Anna
BRME	Blackrock Microsystems Europe GmbH
LINKS	Fondazione LINKS – Leading Innovation & Knowledge for Society
DPZ	Deutsches Primatenzentrum GmbH
NTNU	Norges Teknisk-Naturvitenskapelige Universitet NTNU

1.3 Responsibilities

NTNU is the lead beneficiary responsible for Task 2.1 and D2.1. NTNU has the responsibility to design a wireless powering unit and wireless communication system, which will be used for benchtop and animal demonstrations. Dr. Ali Khaleghi (NTNU) is the WP2 project leader and has the scientific and technical responsibilities. As B-CRATOS WP2 coordinator, Prof. Ilangko Balasingham reviews approves, and submits deliverables and reports.

BRME is a key beneficiary working with NTNU to complete WP2 tasks, deliverables, and milestones, with specific focus on integrating wireless technologies into an implantable neural interface device.

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Prof. Robin Augustine (UU) is the scientific coordinator assuming overall project, scientific, and technical responsibility of the project. As B-CRATOS coordinator, Prof. Augustine reviews, approves, and submits deliverables and reports.

1.4 Definitions

Term	**Description**
ASIC	Application-specific integrated circuit, a chip customized for a particular function
AI	Artificial intelligence
B-CRATOS	the Wireless Brain-Connect inteRfAce TO machineS project
BCI	Brain-Computer Interface
Fat-IBC	Fat intra-body communication
M1	Primary motor cortex, the region of the brain involved in the planning and execution of voluntary movement
PMU	Power management unit
SAR	Specific Absorption Rate
S1	Primary somatosensory cortex, the region of the brain that represents tactile sense; stimulation of this region can evoke somatic sensory experience
SIP	System Integration Plan
NHP	Non-human primate
spike event	An action potential recorded from a neuron
stimulation, stim	Direct electrical brain stimulation
UEA	Utah electrode array
WPT	Wireless power transfer

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2 Preliminary Report on Implant Design

The B-CRATOS implantable neural interface device will use a commercially available microelectrode array to interface between the cerebral cortical tissue and the implant electronics. These electrodes are intended for implantation in the brain's primary motor cortex (M1) and somatosensory regions (S1). The electrodes will provide close access to the individual neurons and act as a high spatial resolution interface to detect electrophysiological activity such as action potentials ("spikes") that will be ultimately utilized as inputs by the AI module in development by WP4 to decode hand movement outputs. Additionally, the electrodes will serve as a conduit for the application of electrical stimulation patterns to S1 in order to evoke tactile sensation.

The electrode arrays will connect to a hermetically sealed, biocompatible electronics enclosure designed to mechanically interface with the skull and surgically implanted as fully subcutaneous. Therefore, the implant is conceived to have no percutaneous wiring connected outside of the body, representing a major advance in device safety by reducing the risk of infection and ultimately improving the potential of the B-CRATOS platform technologies for every-day, real-world usability as a BCI.

The implanted electronics will contain all the systems for neural signal amplification, channelling, digital conversion, wireless communication, and powering. An external reader module, worn outside the body on the head, will act as the wireless contact point to the implant to provide 1) the power needed to run a custom-designed ASIC chip for data capture, processing, and stimulation, 2) command access to the implant via low data rate telemetry and telecommand links and 3) high data rate wireless communication for transmitting the neural data stream for further off-implant analysis and decoding (AI Module, WP4). Finally, the external reader will provide a data interface with the external FAT-IBC system (WP3) to transmit and receive the data wirelessly through the body to the AI module and prosthetic limb with artificial skin (WP4).

Figure 1, shows an overall view of the brain implant and the skull wireless interface. Here, the system is rendered with the 1) implant electrode arrays, 2) wire bundles from the arrays to the implant enclosures, 3) implanted electronics in enclosures, and 4) an external module for wireless powering and communication. The implant unit is envisioned as a device that can be capable of both neural signal readout and delivering electrical stimulation through specific electrodes. In the reading mode, recorded neural signals are amplified, multiplexed, sampled, and digitized to generate a serial data stream. In the stimulation mode, a stimulation pattern is generated by the AI Module (WP4) through processing and interpretation of tactile information acquired through eSkin sensors (WP4) which is converted to a stimulation command transmitted to the implant electronics via the external unit; implanted stimulation circuitry then deliver the electric stimulation with specific parameters (amplitude, timing, frequency, channel).

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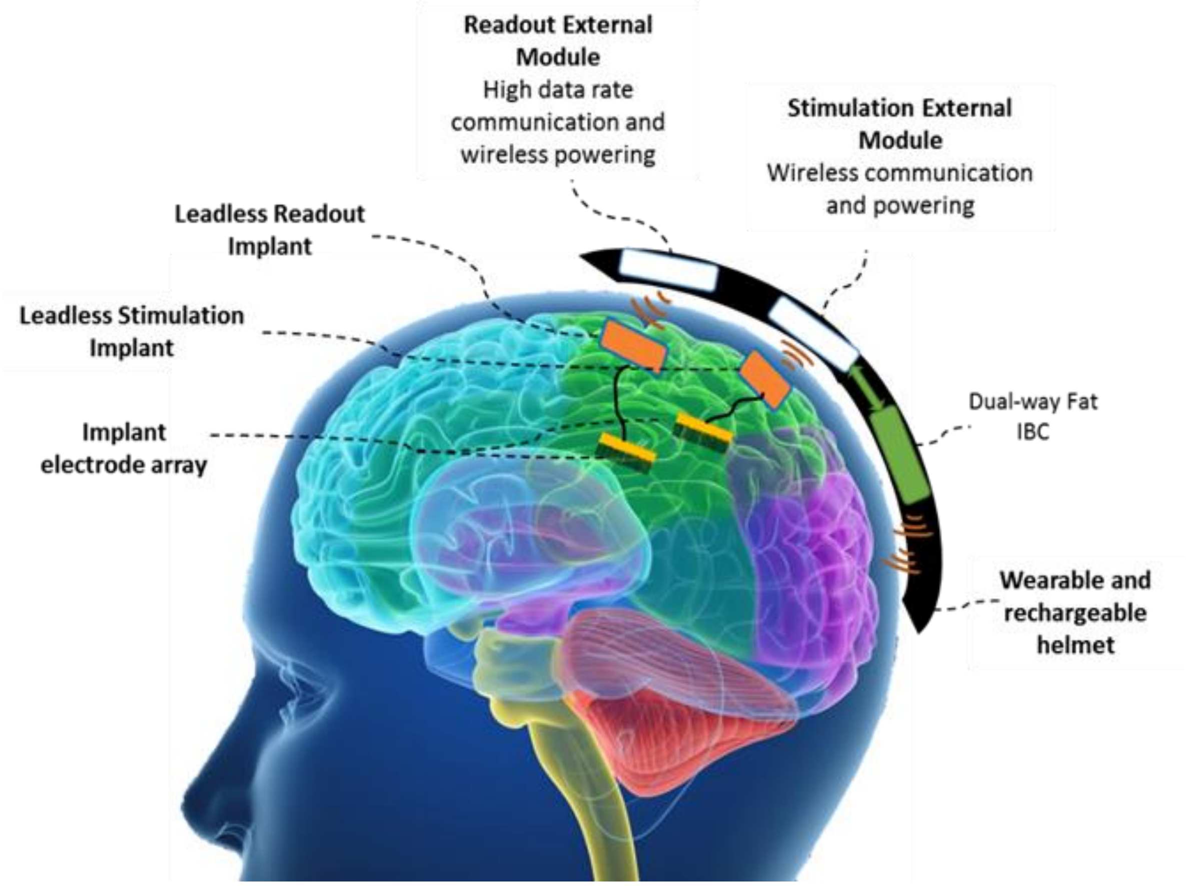

Figure 1. **Diagram of the B-CRATOS implant and external unit**

Under WP2, NTNU is responsible for designing and implementing the implant's wireless communication and wireless powering. BRME designs the stimulation and readout circuitry and integrated implantable enclosure. In the following sub-sections, we describe the current sub-system requirements and design features expected to implement them.

2.1 WP2 System Requirements

The below B-CRATOS product requirements and WP2 requirements are included from the WP5 System Integration Plan. Additional, system-level requirements are included to expand upon the high-level (product) requirements.

R1. The B-CRATOS system shall be usable for closed-loop prosthetic limb control in an in-vivo NHP model (from SIP)

R2. The B-CRATOS system shall have neural interfaces to directly record electrophysiological brain signals and deliver electrical micro-stimulation to the brain.

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R2.1. The neural interfaces shall support a high channel count (up to 64 channels per brain region).

R2.2. The neural interfaces shall have low power consumption requirements (30 mW or lower).

R2.3. The implantable neural interface shall be wirelessly powered (battery-less).

R2.3.1. The external powering unit will sit over the implant with an acceptable distance (less than 5 cm) and orientation (maximum 45 degrees).

R2.3.2. The powering unit shall support the ASIC system requirements for sensing and stimulation (req. power 18 mW)

R2.3.3. The powering unit shall support the implant unit telemetry and telecommand operation (req. power 7 mW).

R2.3.4. The thermal effects of the charging device shall be considered, IEC/IEEE 62209-1528:2020 will be applied.

R2.4. The neural interfaces shall record neural signals with a sampling rate sufficient to recover spiking activity in the primary motor cortex (M1) (minimum 10 kSps. Higher rates expected, decoding algorithm dependent)

R2.5. The neural interfaces shall wirelessly transmit neural signals at a high data rate (30 Mbps).

R2.5.1. The external reader shall read the implant data and demodulate the data.

R2.5.2. The external reader shall interface data to the FAT-IBC module with a standard communication protocol (SPI protocol).

R2.5.3. The reader shall provide low latency (less than 1 msec) data decoding and delivery to the FAT-IBC system.

R2.5.4. The external reader shall run on external power resources such as the battery (for at least 1 hour for NHP test) or power supply for continuous operation.

R2.5.5. The external reader shall have acceptable dimensions and weight to be used in the NHP (we consider a limit of D: 10×10 cm^2, W: 700 g or less).

R2.5.6. The RF emission from the RF reader shall be below the standard RF emissions, ETSI EN 300 220-2 V3.1.17 for the carrier transmission and shall be below Radiated emission limits; general requirements (FCC part 15.209).

R2.6. The neural interfaces shall direct electrical micro-stimulation to the primary somatosensory cortex (S1).

R2.7. The implantable device shall be designed with a size suitable for implantation in a future human-use case (with a footprint no greater than 1680mm^2 and thickness no greater than 7.7 mm[1]).

R2.8. The electronic enclosure shall be biocompatible and hermetically-sealed to resist the biological environment for a minimum of 6 months of the NHP test phase.

R2.9. The implant system shall provide two-way communication for telemetry and telecommand.

R2.9.1. The telemetry shall transmit the vital status parameters of the implant (temperature, voltage, charging level, etc.).

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R2.9.2. The telecommand shall transmit stimulation data in a sufficient rate to the implant (approximately 500 Kbps or less).

R2.9.3. The telecommand shall interface with FAT-IBC system and make data protocol exchange (I2C Standard).

2.2 System overview

Figure 2 shows an overview of the designed system block diagram for the implant and the external unit. The implant unit includes two parts, Utah electrode array (UEA) and the implantable electronic enclosure.

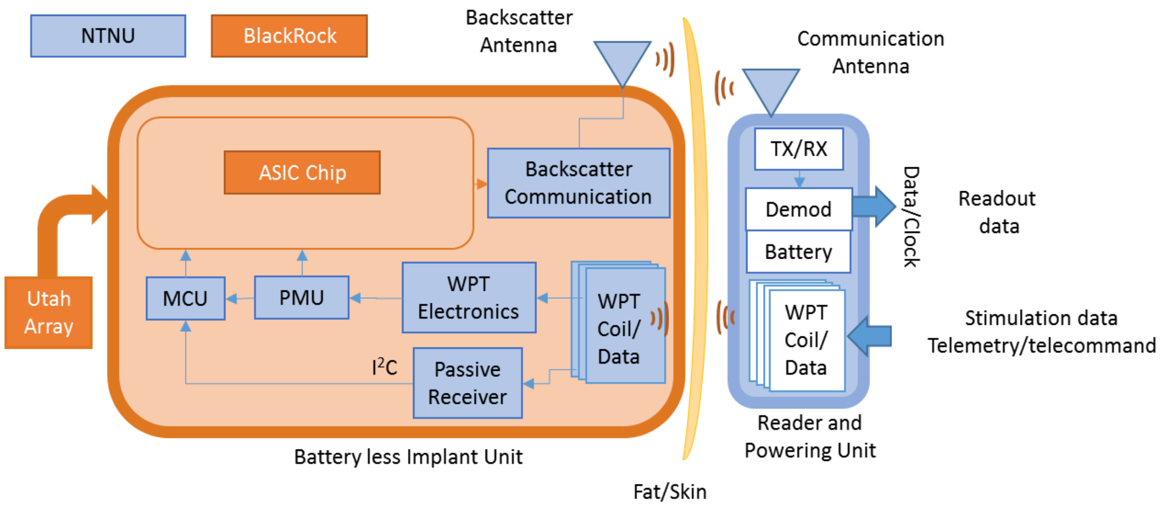

Figure 2. **Overall view of the implant unit, electronic block diagrams, and external support**

The implant electronics will use a custom-designed ASIC chip to perform the brain signal acquisition, in which the neural signals are efficiently sampled and converted to the digital data for transmission. The data will be constructed in a custom digitized format and delivered to the backscatter communication unit. The backscatter unit includes a simple radio frequency (RF) switch controlled by the data and the associated backscatter antenna integrated inside the implant box. The switching alters the implant antenna impedance that is read by the external reader. The implant contains an antenna with sufficient bandwidth to support the expected data rate of 30+ Mbps from the ASIC chip.

The next integrated implant unit is wireless power transfer (WPT). The WPT has a separate antenna that uses an efficient power transfer approach with the induction method. The powering unit has a rectifier circuit followed by a power management unit (PMU) to control the voltage and supply the current needs for the implant's reliable operation during the NHP experiments. A two-way data communication with the implant is also established in parallel with the powering task, in which low data rate telemetry (<100 kbps) and telecommand links (<500 kbps) are realized. The telecommand supports stimulation data exchange with the

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implant and the external unit and over-the-air (OTA) programming of implant functions. The telemetry link transmits the vital parameters of the implant, such as temperature, line voltage, current, and charging status of the implant. The communication system latency is designed to be less than 100 micro-second, much smaller than the response time of the biological tissues. The overall latency is governed by the delay in the AI system for brain signal analysis and generation of the stimulation pattern.

The implant unit will obtain the power continuously from the wireless link. The design considers supporting short interruptions if the wireless power stops occasionally. For this, the implant design will consider energy harvesting that can run the implant for up to a few minutes, enough time to continue operation, and then gracefully exit operation if WPT is not restored.

The external unit has more complexity, in which most of the implant tasks are shifted to the external box with larger available space and power resources than the implant. The external unit reads implant data using the RF backscattering technique. It includes a wideband antenna to support the required bandwidth of the data, a local RF generator, receiver and transmitter chains. The reader extracts the same data fed to the implant's backscatter switch. The data is exchanged with the FAT-IBC sub-system (WP3) to be transmitted to the AI Module (WP4). The external unit can run on battery charge or an external electric power supply. The external powering and low rate communication unit will use standard ISO/IEC 15962 RFID protocol for communication and power; the backscatter system is a custom-designed board with its designed communication protocol.

2.2.1 Electrode array

The Electrode Array will implement the following requirements: R2.1R1, R2, R2.1, R2.6.

The implant will utilize the UEA manufactured by and sourced from Blackrock Microsystems, LLC (Salt Lake City, UT, USA). The UEA is the interface point between brain tissue and electronics. The UEA is a silicon-based, active multi-electrode array that can be implanted for in-vivo and in-vitro research applications, with a clinical assembly (Blackrock NeuroPort) that is FDA-cleared for human use. The UEA is the technology of choice for human BCI studies, being used in over 30 such cases worldwide. Stable electrode lifetime in human sensory cortex has been reported over 1500 days[2]. The UEA interface allows the electronics to record and/or stimulate neural electrophysiological activity, such as single-unit, multi-unit neuronal assemblies, and local field potentials. Unlike deep-penetrating wire (or "depth") electrodes, the UEA penetrates only the outer surface of the brain, resting on the cortical surface.

The exposed tip metal of each electrode shaft is selectable as either platinum (Pt) or iridium oxide (IrOx). The lower-impedance (50 kOhm vs 400 kOhm @ 1kHz) sputtered IrOx coating allows for stable stimulation and recording over chronic implantation durations and is the preferred choice for this closed-loop record/stim system. The electrode shafts are composed of p-doped silicon (Si) coated with Parylene-C and glass insulation.

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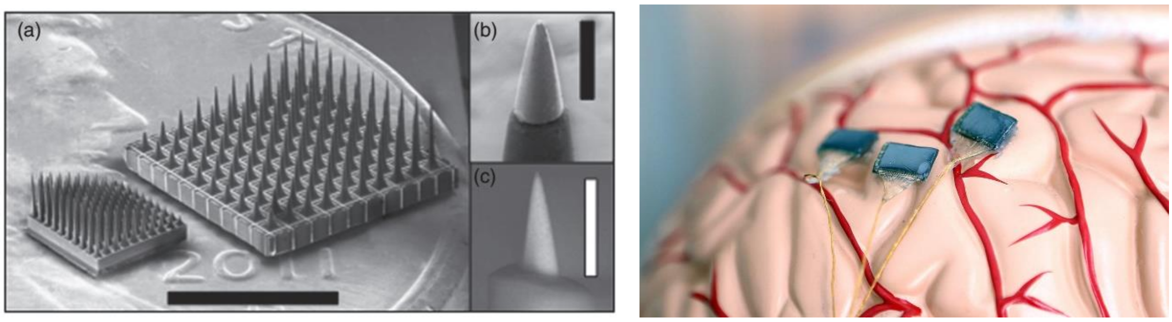
The number of electrodes per array is customizable up to 128 electrodes. The decision of the number of electrodes per array is dependent upon surgical planning and demonstration needs but can be reduced if needed. Multiple arrays may be connected to off-the-shelf pedestal connectors allowing for greater flexibility in targeting broader anatomical regions.

The standard electrode pitch is 400 microns. The electrode shaft lengths are customizable based on the needs for the non-human primate testing but typically range between 0.5 to 1.5mm. The wire bundle is a 25-micron platinum-gold lead connection between electrodes and signal capture, amplification, and processing electronics with customizable length up to 13cm, which allows for flexibility given a dependence upon pre-surgical planning. Depending upon the anticipated length of use, the wire bundle can be produced in a helical form factor, potted with medical-grade silicone elastomer for additional strain relief. **Error! Reference source not found.** shows a photograph of the UEA and provisional implantation on the brain.



(a) (b)

Figure 3. **a) The Utah electrode array (UEA) with 100 microelectrodes in a 10 by 10 configuration projecting out from its silicon base. Each electrode is separated by 400 µ m and is electrically isolated from its neighbors by a moat of glass surrounding its base. Each electrode has a wire bonded to its base b) UEA placement on a model of the cortical surface**

2.2.2 ASIC design

The ASIC will implement the following requirements:R2.1,R2.2, R2.4, R2.6

The neural electrophysiological signals will be collected and amplified through a custom, ultra-low-power ASIC designed by Blackrock Microsystems (Salt Lake City, Utah, USA) and currently under development and testing. The neural signals are first multiplexed to a differential amplifier and filtered, then the output is sampled using ADC and converted to serial data. The serial raw data are formatted in a specific pattern with a designed preamble and fed to the backscatter system to control the backscatter antenna impedance. The preamble makes the data reading and the clock recovery feasible.

The Blackrock ASIC is built to both record and stimulate on micro-electrode contacts, achieve power requirements of less than 8 mW, support up to 32 channels of read/stimulation, and sampling rates up to 60 kSps on a footprint comparable to currently available commercial

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chips (but with much reduced power requirements). Additional specifications will be made available following official release of chip specifications.

2.2.3 Implant Electronics Enclosure

The enclosure will implement the following requirements: R2.7R2.8

Electronics will be encapsulated in a rounded ceramic enclosure molded in silicone rubber sourced through Blackrock Microsystems (Salt Lake City, Utah, USA). At this design stage, dimensions are flexible depending upon results in integrating, miniaturizing, and optimizing the B-CRATOS designed implant electronics. Generally, the enclosure is expected to have a circular (or rounded rectangular) footprint of around 35-40 mm radius and a height of up to 7 mm, inclusive of the medical-grade silicone coating. Electronics feedthroughs may come as metal tracks on a ceramic base allowing connection of 64 electrode channels from the Electrode Array.

Hermeticity and device longevity may be accomplished through hermetic sealing in a controlled helium (He) environment. Post-sealing, He leakage measurements will allow for assessment of hermeticity success and estimates of packaging lifetime. Critically, the use of ceramics in the enclosure design, rather than an all-titanium packaging, will be evaluated to provide a compact, lightweight and electromagnetic signal-transparent protective encapsulation, critical for wireless technology development. Aspects of the enclosure design are dependent upon the optimization and integration of the internal electronics and will be detailed in subsequent deliverable reports and demonstrations.

2.2.4 Wireless powering and two-way communications

The wireless power and two way communication will implement the following requirements: R2.3, R2.3.1, R2.3.2, R2.3.3., R2.3.4, R2.9, R2.9.1, R2.9.2, R2.9.3.

The wireless charging and powering unit are divided into two sections 1) design related to the implant microelectronics and antenna 2) the external powering unit. The preliminary implant design (see Section 2.2.3) is expected to integrate the charging electronics and the related antenna. The external charger unit should be kept at a close distance (1-5 cm) to the skull and over the implant unit with 10 mm lateral displacement and rotation angle of a maximum 45 degrees. This assures efficient powering with a maximum of 40% power delivery efficiency. The external unit can be fixed in a wearable helmet-like design. Details of the WPT system design are provided below, though some aspects are expected to change during the optimization processes and will be reported in detail in subsequent deliverable reports.

2.2.4.1 Implant and external powering

Here, we consider using magnetic induction in the resonance mode of the antennas to provide maximum power transfer to the implant. The magnetic induction is efficient for short-range powering in which the distance between the units is comparable with the size of the antennas. A planar coil for both the implant and external units is designed and simulated. The external

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coil can also hold a larger diameter to minimize the misalignment effect with the implant. The powering frequency is fixed at 13.56 MHz, as the standard near field communication (NFC), ISO/IEC 15962, in the radio frequency identification (RFID) band.

The initial coil design is shown in 2.2.4.1Figure 4. The coil antenna is simulated using the finite element method (FEM) and is impedance matched to the receiver that is selected from the NXP company. Using the NXP chip we can create power for the implant and establish two-way communication with the implant device. We plan to use a low-power microcontroller (3 mW or less) in the implant unit to interrogate with the NXP chip, in which a microcontroller will operate as the processor for telemetry and telecommand in the implant. The NXP chip has an internal power management unit that we expect is sufficient to run our ASIC chip and power the onboard microcontroller. Figure 4-b shows the simulation model of the implant and the integrated antennas with a multilayer tissue model.

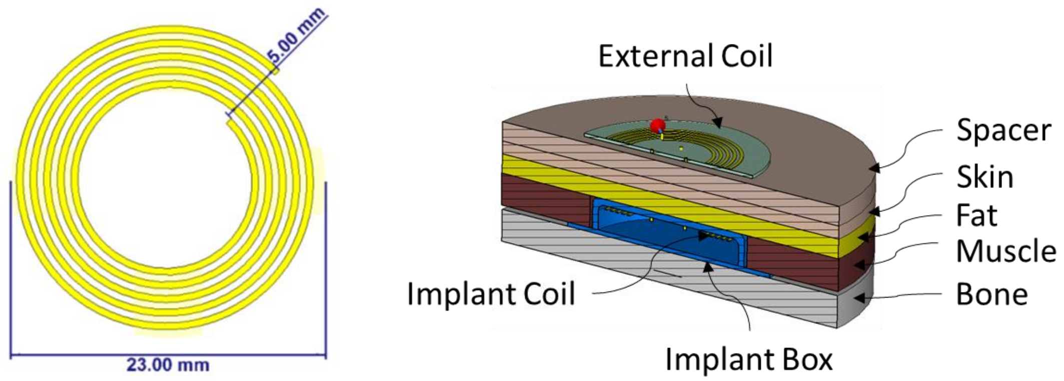

Figure 4. **a) Reader and the implant antenna model b) antenna simulation in full-wave FEM**

2.2.4.1.1 Energy source

The implant power consumption is expected to be around 18 mW for the ASIC chip and any supporting electronics components and up to 5 mW for the implant's microcontroller and the provisional implant sensors. The overall power will be around 23 mW. Considering a margin of 7 mW, the implant is designed to support up to 30 mW continuous power. The energy will be stored in a supercapacitor to run the ASIC chip for readout and stimulation.

We will consider and evaluate to use a supercapacitor for power storage to support the implant operation for a few minutes, followed by a "graceful shutdown", if the powering unit is turned off. This is an optional requirement and will be considered if the implant design criteria permit us.

2.2.4.2 Charging safety

The wireless powering will consider the following requirement: R2.3.4

In the operating frequency range of NFC, the relevant metric for localized exposure recommended by the International Commission of Non-Ionizing Radiation Protection (ICNIRP)

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is the Specific Absorption Rate (SAR), and the corresponding basic restrictions for the general public are defined as 2 W/kg, for head and trunk and 4 W/kg for limbs, respectively, averaged over 10g of contiguous tissue and over any 6 minute time interval [3].

The rationale for these levels is based on thermo-physiological considerations, because the elevation of tissue temperature due to RF exposure that is seen as the biologically relevant interaction mechanism for frequencies > 10 MHz. IEC/IEEE 62209-1528:2020, defines SAR values for general wireless communication equipment operated near the body in the frequency range 4 MHz – 10 GHz. Using NFC frequency, 13.56 MHz is also covered in the standard; however, the continuous operation of NFC close to the head in respects similar to B-CRATOS for brain application has not been reported. Thus, we will rely on the exposure in the NFC based on the commercial device uses as the standard above or any emergent guidance during the course of the project.

In order to obtain estimates for the exposure due to using NFC devices, SAR calculations will be carried out for the simple multilayer tissue model in Figure 4Figure 4, and the head model. The simulation results will be completed in the upcoming deliverable, using the anatomical model of the head[4]. The frequency is low in magnetic induction, and the biological tissues are non-magnetic. The magnetic loss in the tissues is zero; thus, magnetic field-related SAR and temperature rise are zero. The magnetic induction creates some electrical induction current in the tissues, resulting in SAR and temperature rise. The conductivity and permittivity of the tissues are responsible for SAR. The tissues material properties have been reported in the literature[5]. Figure 5 shows the complex permittivity and conductivity for 10 MHz to 500 MHz. The high conductivity results in more loss in the tissues; thus, the tissue SAR and heating in the higher frequencies (used for backscatter communication) are more significant than the low MHz (exp. 13.56 MHz) frequency.

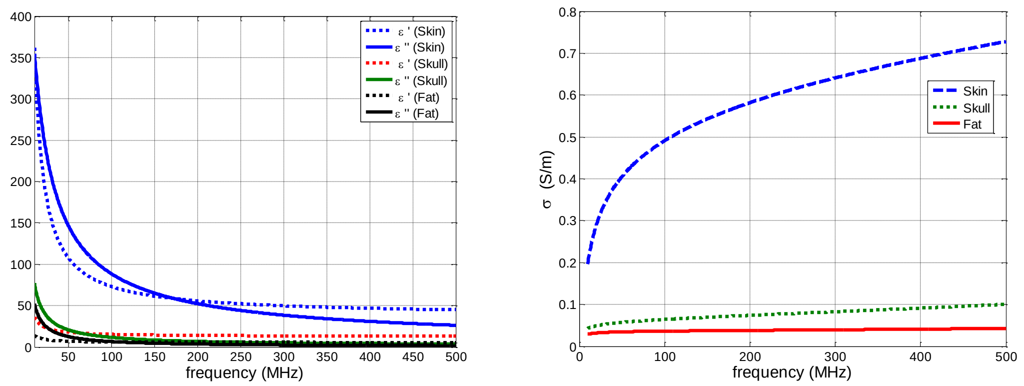

Figure 5. **Complex permittivity and conductivity of different biological tissues for 10-500 MHz**

In magnetic induction, the leading heating is related to the coil structure and the matching circuit, mainly if resistors are used to reduce the coil Q-factor and increase the bandwidth. The lower Q is preferred for easier matching and less sensitivity to the surrounding coil environment, with reduced coupling efficiency. We will evaluate the potential of non-resistive

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matching in the first phase of the project and may consider using a resistive copper coil to distribute the heating over the antenna surface. We note that the heating is greater in the transmitter side (external unit) with higher power than the implant. The heat transfer in the external unit can be easily controlled with thermal radiation or convection, applications of which will be considered and evaluated as needed in the design. Overall, the SAR and thermal effects of the WPT unit will be a primary consideration for this sub-system.

2.2.4.3 Two-way communication

The two-way communication will consider requirements: R2.9, R2.9.1, R2.9.2, R2.9.3.

The NFC standard permits two-way low data rate communication of maximum rate 500 kbps and ASK modulation. The communication link is performed simultaneously as the WPT. The main information exchange between the implant and the external body is the stimulation data that addresses the implant MCU, or other logic, to control and support the ASIC chip to apply a specific current for a programmed duration to stimulate the cortex. Additionally, the MCU program may be updated regularly to perform additional new tasks or housekeeping operations. This feature is called over-the-air (OTA) programming that is planned for the implant.

The communication from the implant to the external unit (telemetry) performed using the low data rate link, will mainly communicate the implant health status to the external unit. This may include sensory information such as (for example) temperature sensor (optional, inclusion will be evaluated), line voltage, and the implant's charging status. Some extra sensory lines are also considered for future developments in the first prototype design. The communication data protocol for telecommand will use the I2C interface between FAT-IBC and the NFC reader system.

2.2.4.4 External reader power and space requirements

R2.5.4). The precise specifications will be further defined based on the available space and weight for NHP testing.

The NFC reader powers the implant and conducts two-way communication. The reader transfers the power and has an onboard microcontroller to communicate with the NFC protocol. The external unit design should consider power handling and make two-way communication with acceptable size (<10 ×10 cm^2) and use period of one hour with a single charge, or continuous operation with an external power supply.

2.2.5 Wireless communication backscatter

High data rate backscatter communication will consider requirements: R2.5, R2.5.1, R2.5.2, R2.5.3, R2.5.4, R2.5.5, R2.5.6.

The selection of the wireless technology using backscatter techniques is to eliminate the communication electronics and the transmitter from the implant device, thus minimizing the related communication power and electronics. Backscatter use in free space is a known

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approach but is a new technology to use in medical implantable devices. The well-known applications of backscatter are NFC and UHF RFIDs, but these devices can transmit a low data rate of several kbps, insufficient for most neural data applications. Here, we are developing a custom-designed system to save the implant energy and address the high data rate requirements of 30+ Mbps for the brain sampled spikes transmission. The technique's feasibility has been shown with the NTNU team for deep implants such as endoscopy capsule[6].

2.2.5.1 Implant system

The implant system for backscatter is a simple CMOS switching mechanism that consumes 1nW power. The switch is connected to the backscatter antennas. The switch must alter the antenna impedance to provide a maximum differential radar cross-section (DRCS). The switch is controlled via the serial data from the ASIC chip in which the data are the sampled neural spikes. The simulation of the implant backscatter antenna has been performed in CST MWS. Optimization of the antenna is in progress.

2.2.5.2 External reader

The external reader for the high data rate backscatter transmits a continuous wave signal at 434 MHz and receives the reflections around the same reader frequency. We will not use any subcarrier frequency in the implant since this increases the implant power consumption as the subcarrier must be much higher than the data bandwidth. Instead, we use a more complex superhetrodyne receiver. The reader RF frontend will be designed, and the signal processing, data, and clock recovery will be performed to extract the implant data from the wave reflections. The data and clock in serial format will be converted to Serial Peripheral Interface (SPI) to connect to the FAT-IBC module.

2.2.5.3 Backscatter antennas

The backscatter antennas must be compact and operate at 434 MHz and support the required bandwidth to minimize the signal distortion and inter-symbol interference. For this, we are planning to use a specific design using patch antennas. The antenna design and optimization are in process and will be reported with upcoming D2.2 deliverable report.

2.2.5.4 RF Emission and regulations

High data rate backscatter communication will consider requirement: R2.5.6.

The selection of the frequency 434 MHz for the backscatter reader is based on the allocated frequency by ETSI EN 300 220-2 V3.1.17 in which the effective radiated power (ERP) of 10 mW is allowed for CW transmission. The main radiation from the reader system in the backscatter includes an un-modulated 434 MHz, while the reflections from the implant have a wide-bandwidth occupation of 32/64 MHz. The RF reflection (data spectrum level) should be in the order of -70 dBm to decode the data with a bit error rate (BER) of less than 10^{-6} in the proximity of the skull. This results in a signal level below -90 dBm in 1 m by appropriate antenna design with the free space gain (<-20 dBi). Thus, the data cannot be retrieved in the distance because the signal level is comparable with the noise level. Also, based on the signal

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emission in UWB use, which is an unlicensed frequency band, the emission mask of less than -90 dBm/MHz (ECC) and -41 dBm/MHz (FCC) is acceptable (see Figure 6).

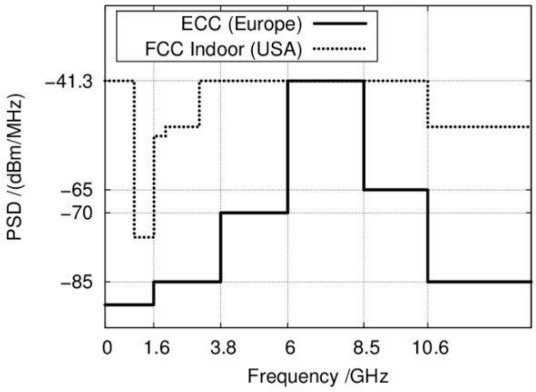

Figure 6. **UWB emission mask in Europe and USA, the emission at 434 MHz is recommended below -90 dBm in EU and -41.3 dBm in USA[7].**

Our RF system emission is expected to stay below both definitions. The main issue with using wideband backscatter is the unintended interference in the receiver's frequency band, which the system requires to combat any interference if applied. In such a scenario, interference reduction techniques would be necessary that will be considered for future human use cases. The interference will be monitored in the NHP test laboratory using the RF spectrum monitoring to ensure any unintended interference during the test.

2.2.5.5 Radio frequency Safety

High data rate backscatter communication will consider requirements: R2.3.4.

As shown in Figure 5, the conductivity of the tissues increases with frequency, in which the RF-related SAR is dominant at 434 MHz. The RF emission should have SAR <2 W/kg[8] for general public users. The main heating effect will be in the skin and the backscatter implant antenna, where the antenna resonance generates the signal reflections. Thus, the heating is mainly superficial to the skin and the fat layer. The RF emission level will be set to have a detectable data signal in the receiver. Thus the excess RF emission will be kept at a minimum level. Numerical computations using layered tissues and an anatomical model of the head will be used to compute the RF SAR and device safety for continuous operation.

2.2.5.6 Interface to FAT-IBC

The interface between the high data rate reader and FAT-IBC will consider requirements: R2.5.3.

The backscatter reader will provide LVDS standard output with serially formatted data and clock streams that can be fed directly to the FAT-IBC. The backscatter module data will be formatted as a standard serial protocol interface (SPI) to bridge the FAT-IBC system. In the command mode, the data from FAT-IBC will be received in I2C format by the NFC reader and will be transferred to the implant.

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3 Conclusion

In this preliminary report D2.1, we have provided the project outline and design considerations, including current requirements and design specifications, for the implant and the external supporting unit. The system block diagram and specifications were developed by NTNU with additional inputs and requirements from B-CRATOS partners BRME and UU. The key design criteria, communication system simulation, wireless powering unit, and the related antennas are described with additional specifications and design pending further design, implementation, and testing. We have considered our design in accordance with the available standards for SAR, RF emissions, data security using NFC standard, and a custom design in the backscatter system.

4 Revision history

REVISIONS			
Version #	**Date**	**Type of Change**	**Lead Author**
1.0	XX-02-2022	Version 1.0 release for Deliverable 2.2 and public dissemination.	Ali Khaleghi

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