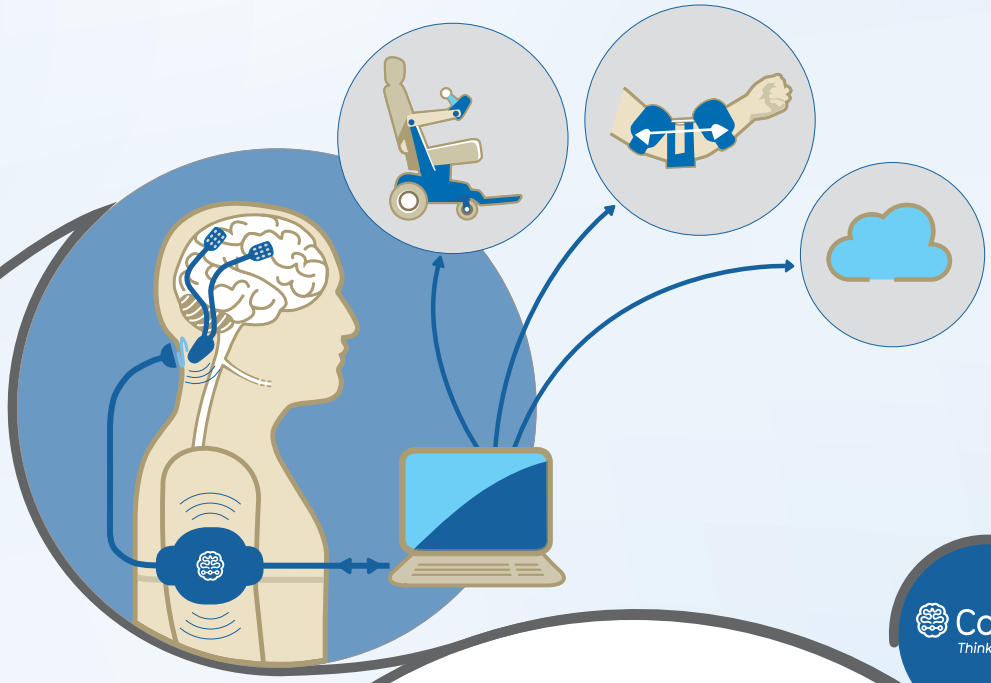
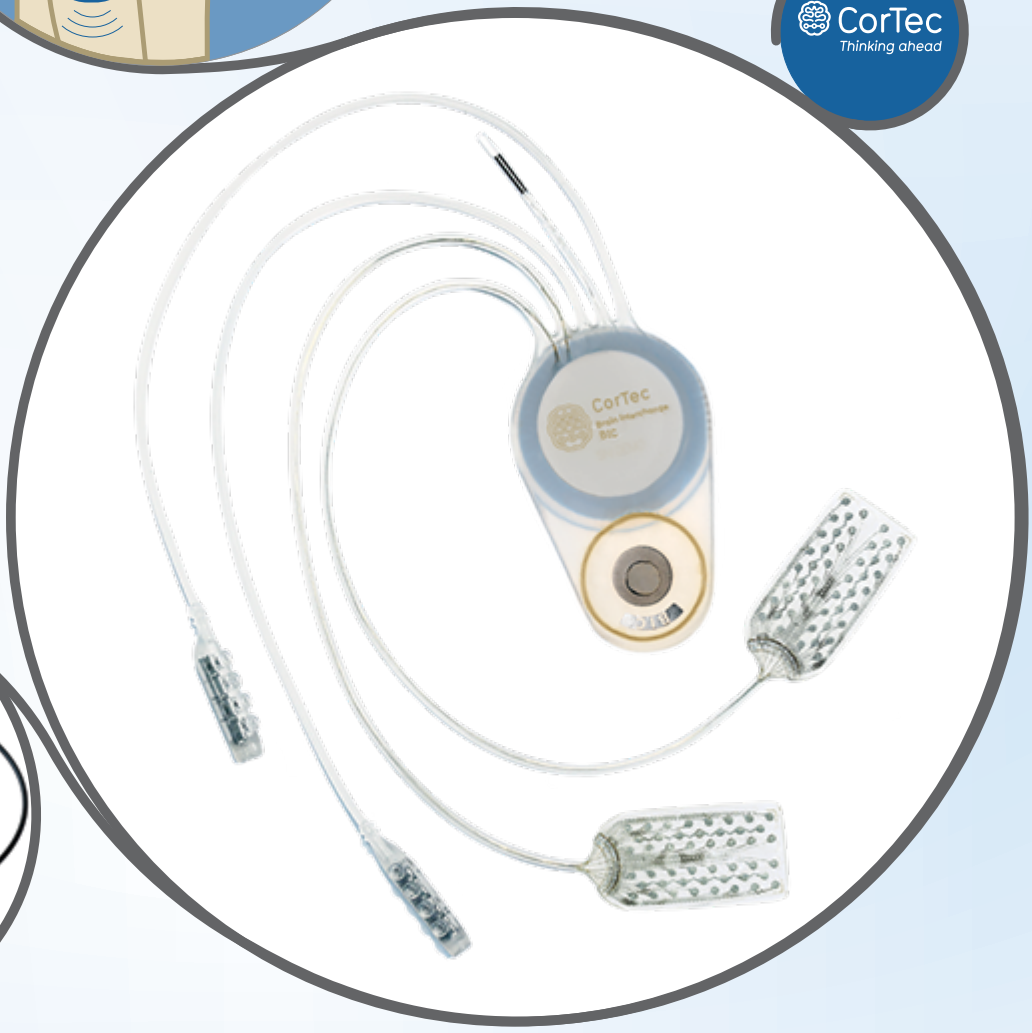
CorTec Brain Interchange ONE

Closed-Loop Implant Platform



CorTec
Thinking ahead



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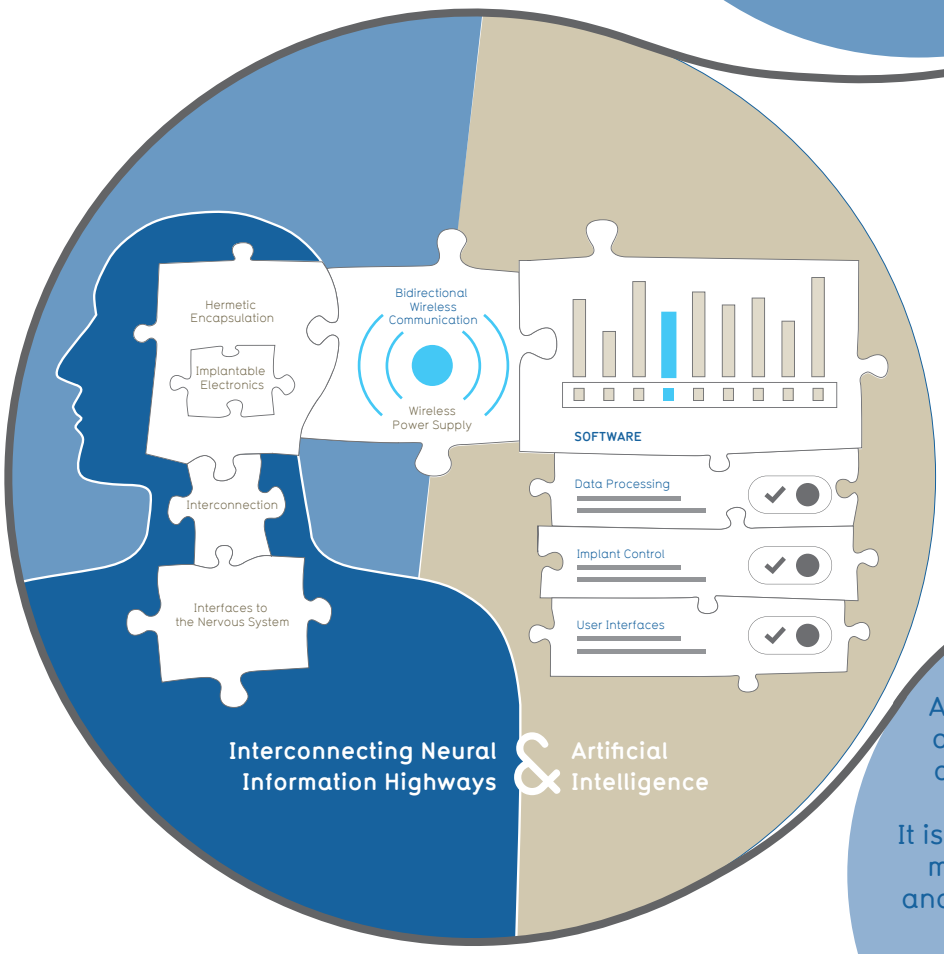
INTRODUCTION

The **CorTec Brain Interchange** platform technology is comprised of **all components** needed for electrically **interconnecting the neural system to external software** utilizing the full power of artificial intelligence – and thus, **enabling communication with the nervous system.**

Brain Interchange ONE is the **first version** of the CorTec Brain Interchange Technology which we are currently **validating for the use in clinical trials.**

Join us on the exciting journey to personalized neurotherapies and **be one of the first users** of this innovative closed-loop system!



As an implantable investigational device, Brain Interchange ONE is designed for both recording and stimulating on 32 channels.
It is intended to be used for long-term measurement of neuronal activity and electrical stimulation of neuronal tissue in the brain.

Thus, Brain Interchange ONE is designed for exploring and developing innovative neurotherapies.

DEVICE DESCRIPTION

The implantable platform features full wireless functionality for chronic open- and closed-loop interaction with the nervous system. It consists of 3 components:

A Multi-Part Implant

- One or two °AirRay electrodes from CorTec designed according to customer specifications.
- The Brain Interchange platform is also prepared for the use of DBS electrodes.
- The Implanted Internal Electronics Unit is placed inside a proprietary hermetic ceramic encapsulation. It amplifies, filters and digitizes neural signals and electrically stimulates neural tissue via the electrodes. It is inductively powered by the External Unit and communicates with it via a broad-band radio link.

External Unit

- A small, lightweight Head Piece is held attached to the skin by a magnet opposite to the implant.
- The Communication Unit for radio communication with the implant, typically belted to the upper arm or wheel chair of the patient also controls the power supplied to the Head Piece and communicates with the controller computer.

A Personal Computer with Software Interface

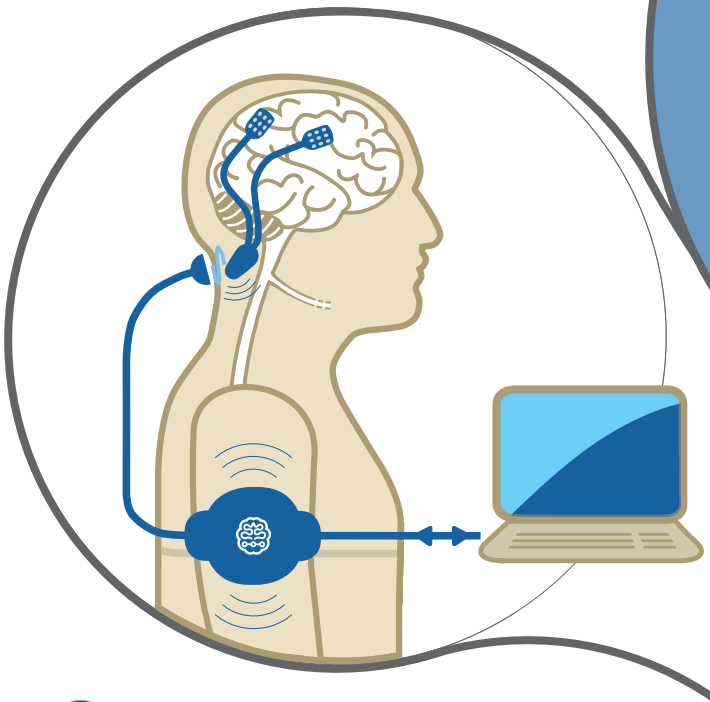
- The Computer ensures the energy supply of the Communication Unit.
- It also runs the Application Software which manages the stream of neural recording data coming from the implant via the External Unit. At this point, innovative experimental algorithms can be implemented that allow a response to the neural data stream, e.g. triggering a therapeutic electrical stimulus delivered by the implant.

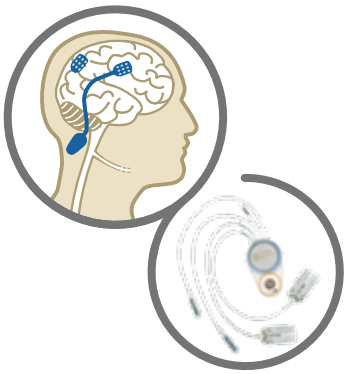
Brain Interchange ONE
receives electric signals from the connected electrodes and amplifies, digitizes and transmits them to a computing unit via the External Unit.

The External Unit is able to produce electrical impulses using parameters provided by the Application Software on the Computer and can transmit them to electrodes of the Multi-Part Implant.

The Application Software on the Computer manages the telemetry (programming of indication related parameters, accessing the system information, and data transmission) and analyses the data.

The Software also creates the commands for the implanted electronics to generate stimulation patterns.





Multi-Part Implant

The Multi-Part Implant is comprised of the Implanted Internal Electronics Unit and One or two ECoG electrodes plus one optional ground (GND) electrode contact.

Similar to **CorTec's** FDA cleared °AirRay Cortical Electrode all electrodes based on the °AirRay electrode technology are capable of recording and stimulating brain activity. Produced in a proprietary laser manufacturing process, °AirRay electrodes are very soft, thin and flexible.

They adapt well to the brain's curvature.

In addition to the use of **CorTec** electrodes, the system can also be equipped with DBS electrodes. Validation of the interconnection of the Brain Interchange platform to a connection cable for market approved DBS electrodes can be executed upon request.

The Implanted Internal Electronics Unit consists of a hermetically sealed ceramic encapsulation, electronics and firmware. It is powered wirelessly and communicates via a radio-frequency link.

The Implanted Internal Electronics Unit is placed underneath the scalp, partly embedded in the skull. The electrodes implanted on the surface of the brain are in direct contact with the central nervous system. When used as intended, it will be permanently implanted approximately 4 cm above the tragus of the mastoid cavity.

For long-term stability, the implant electronics are protected against bodily fluids by a hermetic encapsulation. For biocompatibility, the entire Implanted Internal Electronics Unit (hermetic package, inductive power receiving coil and electrode interconnection area) is embedded in a biocompatible silicone encapsulation. Device safety is monitored by multiple sensors inside the hermetic package.

Implanted Device Impedance Measurement

The Brain Interchange System measures the impedance of electrodes on user demand.

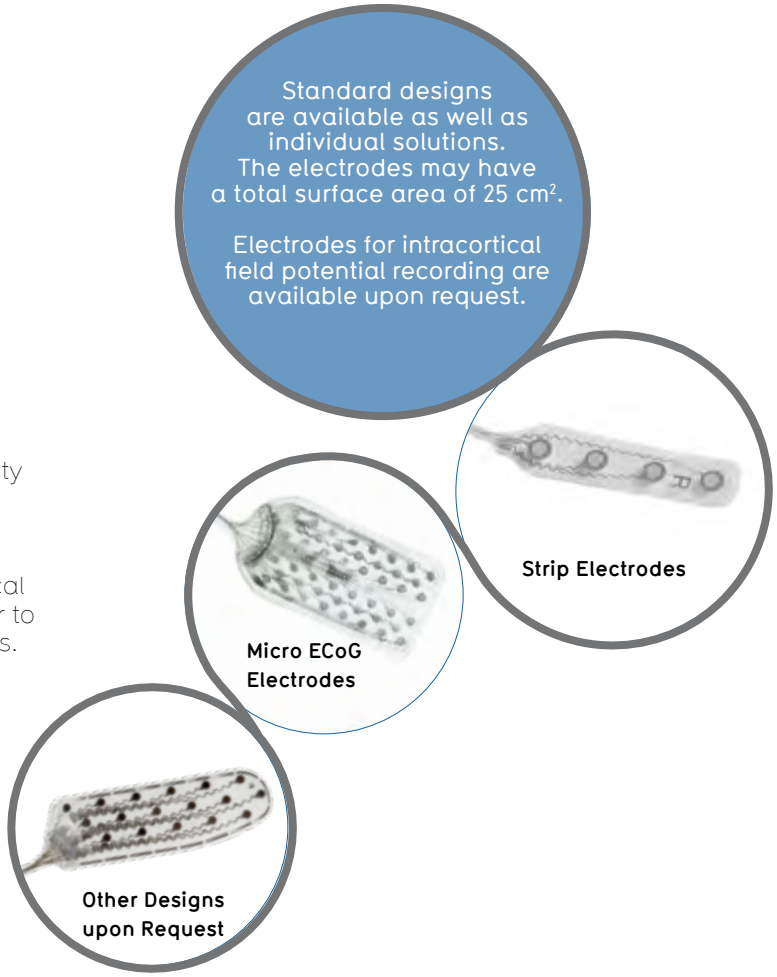
Amplifier input impedance
AC Impedance: 15pF capacitance

- 0.1 Hz: 100 GOhm
- 1 Hz: 10 GOhm
- 10 Hz: 1 GOhm
- 100 Hz: 100 MOhm
- 450 Hz: 24 MOhm

Implanted Device Electrode Breakage Detection

The Brain Interchange System ensures patient safety even in case of a broken electrode contact.

Impedance testing identifies defect contacts which will be automacillay excluded from ongoing electrical stimulation treatment. The System requests the user to decide about how to go on for the blocked contacts.



Multi-Part Implant

1. Implanted Internal Electronics Unit
2. Magnet for attachment of External Unit (location and number of magnets can vary)
3. Coil for electromagnetic power transmission
4. Hermetic encapsulation of implant electronics
5. Ground lead (with variable cable length)
6. Electrode leads
7. °AirRay ECoG electrodes (optional)
8. Deep Brain Stimulation electrode adapter (optional)

Implanted Internal Electronics Unit and the Head Piece of the External Unit (see "External Unit" below) are aligned to each other through the scalp via magnets. The implanted magnet has no contact to human tissue as it is sealed within a titanium capsule and is also embedded in medical grade silicone.

The Implanted Internal Electronics Unit receives neural signals from connected electrodes and amplifies, filters, digitizes and transmits them to a Personal Computer with Software Interface via the Communication Unit. It is able to produce electric impulses using parameters provided by the Application Software and to transmit them through the electrodes to human tissue. The Implanted Internal Electronics Unit comprises 32 channels, all of which can be used for recording and stimulation.

External Unit

The External Unit consists of the Head Piece which supplies power inductively to the Implanted Internal Electronics Unit and the Communication Unit.
The Implanted Internal Electronics Unit communicates with the External Unit wirelessly through the skin via radio frequency transmission. The Implanted Internal Electronics Unit and the Head Piece of the External Unit are aligned through the skin of the head via magnets.

It ensures safe communication by state of the art encrypted communication between the External Unit and Multi-Part-Implant via a RF link.

As part of Brain Interchange ONE, the Communication Unit is typically worn on the upper arm. Apart from exchanging data with the Implanted Internal Electronics Unit it controls the power supplied to the Head Piece. It is connected by a cable to the controller Computer on which the Application Software is running and communicates with it.

A **Status LEDs**
LEDs indicating system status like powering or active communication between Implanted Internal Electronics Unit and External Unit

B **Cables**
- USB connection to PC
- Optional: trigger cable
- Head Piece cable

Application Software

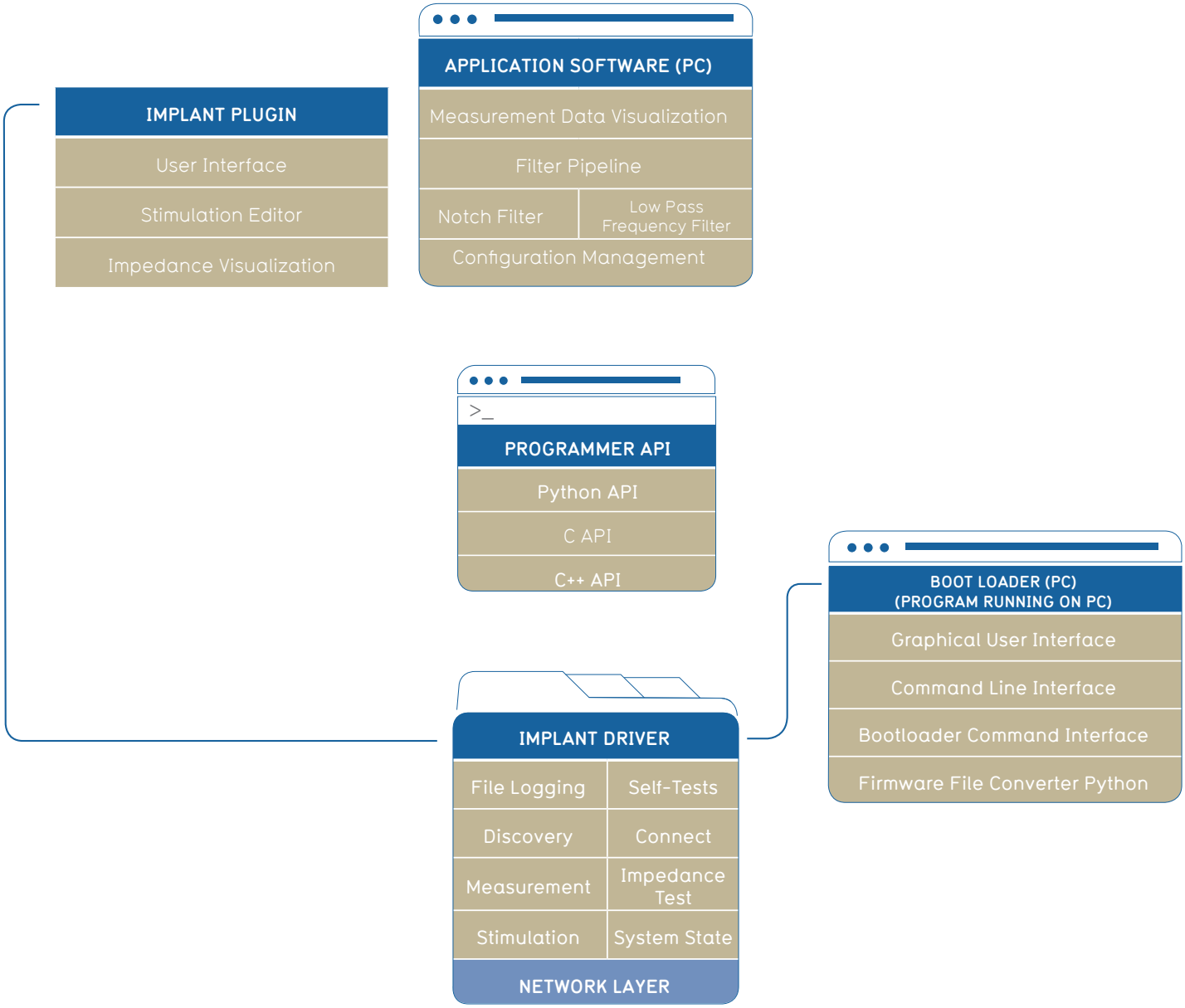
The Application Software runs on a Microsoft Windows-based Computer and represents the interface between the user and the system comprising External Unit and Multi-Part Implant.

The Application Software provides users with a graphical user interface.

The functionality of the Application Software includes visualizing the measured data directly or after the application of a frequency filter (e.g. notch) or storing the data onto a local hard disk.

Additionally, it is able to visualize implant status data such as impedance, humidity and temperature inside the Hermetic Encapsulation. It is also able to define stimulation signals within the implant's technical capability and safety limits as well as to execute stimulation commands. It also enables a safety check of the input stimulation parameters.

BRAIN INTERCHANGE ONE PC Software



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Materials

CorTec Brain Interchange ONE consists of materials that are standard for use in medical implants.

Multi-Part Implant

The ground electrode consists of a ring made from platinum-iridium (90:10) located at the end of a medical-grade silicone tubing. It is connected to the Implanted Internal Electronics Unit.

The Implanted Internal Electronics Unit is casted in medical-grade silicon rubber. It contains a hermetic ceramic encapsulation to protect the electronic circuits.

The **°AirRay ECoG** electrodes are made from platinum-iridium (90:10), medical-grade silicone rubber and parylene C. Connecting cables consist of individually insulated wires bundled in medical-grade silicone rubber tubing.

External Unit

The casing of the External Unit is made from biocompatible material, suitable for being in close contact with the skin without causing inacceptable levels of skin irritation.

The cables connected to the External Unit are lightweight, flexible and have a biocompatible surface material in order to avoid skin irritation.

IMPLANTATION & USE

Implantation

Implantation is performed according to standard medical procedures. The cortical electrodes may be placed above or below the dura through a burr hole site or craniotomy depending on their size. The Implanted Internal Electronics Unit may be tunneled under the skin to a place behind the ear where it may be placed into a shallow cavity milled into the skull similar to the implantation of a cochlear implant.
A detailed description will be delivered together with the Instructions for Use.

Use

CorTec Brain Interchange ONE can be used to measure electrophysiological signals continuously, to analyze and process the signals within a delay of several milliseconds and to store the recorded signals. It is also designed to use the processed signals for the control of external therapeutic devices and assistive technology.

Stimulation is controlled by the Application Software and can be performed in varying patterns: It may be performed continuously, using pre-programmed stimulation patterns that are repeated in certain intervals. Alternatively, stimulation may be performed according to the following sequence: After a stimulation interval has been completed, stimulation is stopped and the system starts to record brain signals in order to evaluate them to assess the necessity for further stimulation. If necessary, stimulation parameters may be calculated anew or may be modified.

DETAILED PRODUCT SPECIFICATIONS

Implanted Internal Electronics Unit

FEATURE	VALUE
Recording channels	32
Sampling rate	1 kHz
Sampling dynamic range	16 bit (74 nV smallest increment)
High pass filter cut-off	0.1 Hz
Low pass filter cut-off	450 Hz
Amplifier band pass gain	631
Band pass roll-off	20 dB/dec
Amplifier input-referred voltage noise	0.1–400 Hz: ≤2.7µVrms
Amplifier input impedance	AC Impedance: 15pF capacitance 0.1 Hz: 100 GOhm 1 Hz: 10 GOhm 10 Hz: 1 GOhm 100 Hz: 100 MOhm 450 Hz: 24 MOhm
Stimulation	Controlled, biphasic, rectangular, asymetric stimulus pulses (cathodic amplitude with pulsewidth followed by an anodic counter pulse of 1/4x amplitude and 4x pulsewidth)
Stimulation channels	32
Current	Max. -6 mA / +1.5 mA within compliance voltage range of -11 V to +5 V
Current source	Can be directed to any of the 32 electrode contacts
Current return path	Any of the 32 electrode or groups of electrodes or an additional counter electrode.
Pulse width	Negative phase: 10–2,500 µs
Implant max. power uptake	Typical: < 400 mW
Method of impedance test	Voltage response to current pulse
Thermal monitoring	Protection against overheating
Electrical Isolation of patient from electronics	DC-decoupled using blocking capacitors
Power supply	Wireless inductive, 120–140 kHz
Wireless data transmission	Bi-directional, radio frequency in 2400–2483.5 MHz band
Min. device lifetime	2 years
Implant size (capsule with coil)	65 mm x 67 mm x 7 mm (max. dimensions)
Surface Area	7600 mm^2
Implant weight	50–60 g (similar to pacemaker)

External Unit

FEATURE	VALUE
Connection of Communication Unit to Personal Computer with Software Interface	• USB 2.0 or 3.0 Data transmission
Method of keeping Head Piece unit in place	• Suspended by magnets
Maximum power uptake	• Limited by USB 2.0 and USB 3.0 specifications (depends on distances between transmitting and receiving coil) - USB 2.0 power uptake (~2.5 W) for distaces up to 12 mm - USB 3.0 power uptake (~5 W) for distances higher than 12 mm
Surface material of Head Piece	• PA 2200 (Polyamide 12)
Size of Head Piece	• 38 mm ∅, Height = 14 mm
Weight of Head Piece	• 13 g (without cable)
Head Piece cable length	• max. 50 cm
ETU Head Piece cable	• PUR
Surface material of external relay unit	• ABS (UL 94 HB)
Size of Communication Unit	• ca. 85 x 95.9 x 48.1 mm^3
Weight of Communication Unit	• ≤300 g
Trigger input of Communication Unit	• Analog and digital input with adjustable threshold, suitable for e.g. averaging recorded data on a particular trigger signal and synchronization of multiple implant systems.

Personal Computer

Minimum System Requirements (PC Software):

- CPU: 4 cores at 2.5 GHz or faster
- Memory: 4 GB RAM or more
- Hard drive: 20 GB of free disk space for program, configuration files and recorded data
- Graphics hardware: NVidia GeForce GT520 with 1 GB memory or higher
- Screen with a resolution of 1920x1200 (16:9) or higher
- Operating system: Windows 10 Professional 32-bit and 64-bit

Software

The development ranges from Windows-based application software (C++, Python) to embedded systems programming (C) for processors used in CorTec's implants and body-external transmitters. There are two kinds of software user interfaces (C++ and C). The purpose of the Application Software is to assist the surgeon during the implantation. The device itself has no additional user interface.

The CorTec software department practices agile development of medical device grade software according to IEC 62304.

Designed for interoperative tests with the following main features:

- Live measurement data visualization
- Establish connection to implants
- Error display of implants
- Status display (temperature, humidity, supply voltage)
- Stimulation function editor (graphical editor for complex stimulation patterns)
- Definition of reference electrodes for measurement and counter electrode for stimulation
- Counter electrode can be selected of any channel incl. ground electrode
- The system is based on an easily extensible signal processing pipeline so that almost any pattern recognition algorithm or closed-loop stimulation paradigm can be implemented
- The system can easily be extended with new components
- Software development according to IEC 62304

Interfaces for implant control on Windows 10 systems

- C++ API (Attention: Compiler must be compatible)
- C API (suitable for integration in Matlab, Labview, etc.)
- Python API (planned)
- What can the interfaces do?
  - Complete range of implant functions (measurement, stimulation, impedance testing, etc.)
  - Safety check of the input parameters

Safety Features

Electrodes

- Charge injection limited according to contact size
- Mechanically robust
- Biocompatibility

Implant

- Hermetic packaging, impact proof
- Monitoring of packaging integrity
- Galvanic barrier to electrodes
- Verification of galvanic barrier
- Verification of electrode integrity
- Verification of subcircuit integrity
- Verification of heating
- Verification of integrity of bootloaded implant firmware
- Biocompatibility
- Charge balancing
- Verifiy validitiy of implant control commands
- Collect implant status reports
- React on implant status reports (e.g. power-off implant)
- Data encryption

Headpiece

- Monitoring of temperature
- Electrical safety (EN 60601)
- Biocompatibilty (skin contact)

Communication Unit

- Electrical safety (EN 60601)
- Biocompatibilty (skin contact)
- Status verification
- Demand-based wireless power supply for implant
- Proprietary connectors – fail safe.

Control Unit – „Pocket PC" (Planned)

- Verify control unit power status
- Verify control unit memory status
- Radio data encryption
- Verify implant communication quality
- Verify implant powering headroom
- Check permission to talk to implant
- Check permission of coupled devices and other smart gear
- Electrical safety (EN 60601)

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