User Manual

BIC Evaluation Kit

CorTec GmbH
Neuer Messplatz 3
79108 Freiburg
Germany

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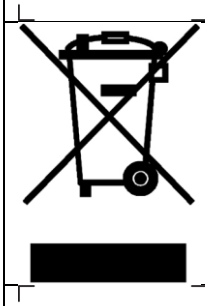
1. Content

2. List of Symbols

Table 1: List of Symbols

	Article Number
	Serial Number
	Manufacturing Date
	Type BF Applied Part
	Non-Sterile
	Separate Collection for Electrical and Electronic Equipment
	Read Instructions for Use
	Manufacturer

3. List of Abbreviations

Table 2: List of Abbreviations

Abbreviation	Description
API	Application Programming Interface
BIC	Brain Interchange
EMM	Electrode Model Module
ESD	Electrostatic discharge
EXX	Electrode number XX / channel number XX
GND	Ground
IM	Implant Module
LED	Light emitting diode (optical indicator)
LVTTL	Low-Voltage-Transistor-Transistor-Logic, 3.3 V supply
nc	Not connected
pos	Position
REF	Reference
RF	Radio frequency
TP	Test point
TTL	Transistor-Transistor-Logic, 5.0 V supply
TX	Transceive (indicator for data transmission / reception)
USB	Universal Serial Bus

4. General Description

The **BIC Evaluation Kit** (in the following also referred to as 'The System') is a technical bench-top representation of the BIC ONE Implant System.

4.1. Intended Use

The intended use of the BIC Evaluation Kit is to allow the future user of the Implant System to understand the functionality / working principles and learn how to program the System / integrate the System into the user setup.

The System (components and software) is not intended for medical uses.
It is intended to be used for bench top research only.
It must not be used on humans!

4.2. Glossary

Terminology used in this document refers to the glossary further specified in Table 3.

Table 3: Glossary

Term	Description
Application Programming Interface (API)	Software that provides system functionality to the researcher software.
Application Software	Software provided by CorTec to operate BIC Evaluation Kit
Channel	The BIC System provides 32 channels. Each channel can be dynamically assigned to one of the following functions: recording, recording reference, stimulation, or GND. Considering a BIC implant, these channels are connected to electrodes.

Term	Description
Communication Unit	The Communication Unit powers and controls the Head Piece, it communicates with the Implant Module via radio frequency transmission, it is powered via USB by the Personal Computer. The same USB interface is used to exchange information with the Personal Computer. The Communication Unit is also the input for an External Trigger signal.
Component	Functional part of the System that can be physically separated from the System.
Dynamic Power Regulation	The power inductively provided to the Implant Module is dynamically regulated according to the Implant Module demand.
Electrode	Electrode Contact(s) embedded into a carrier substrate material forming a Component. The term electrode does not specify if a cable is attached or not.
Electrode Cable	Cable that connects an Electrode to the Implant Module
Electrode Connector	Connector that permits to electrically connect Electrodes or the Electrode Model Module to the Implant Module.
Electrode Contact	Metallic contact that electrically couples the technical system to the biology
Electrode Model Module (EMM)	An electronic circuitry that represents the electrical behavior of Electrodes
External Trigger	A voltage signal provided to the Communication Unit trigger input is classified as high (1) or low (0) signal and threaded into the data stream coming from the implant, relayed to the Personal Computer.
Head Piece	Inductive coil incl. coil driving circuitry that permits wireless powering of the Implant Module. The cable that connects the coil with the Communication Unit is a hard-wired part of the Component Head Piece.
Head Piece Cable	Cable that connects the coil and coil driver to the Communication Unit. This cable is firmly attached to the coil / coil driver
Head Piece Connector	Connector system that permits the reversible electrical connection of Head Piece and Communication Unit.
Implant Module (IM)	Electronic circuitry of the actual implant inside a plastic casing that permits to evaluate implant functions on the bench top.
Personal Computer	Software running on the Personal Computer controls the function of the Implant Module and manages the data stream coming from the implant.
Research Software	Software created by the user that operates the BIC Evaluation Kit. This software requires the CorTec Application Programming Interface.
System	All components of the BIC Evaluation Kit incl. the Personal Computer
USB Cable	The USB Cable connects the Communication Unit with the Personal Computer

5. Warnings and Signs

The BIC Evaluation Kit must not be connected to a patient in any way. It is an electronic research device to be used on the bench only.

The headpiece supplied with the BIC Evaluation Kit might become hot during operation. Handle with care.

Handle devices with care, avoid electrical discharges (ESD) to any of the system components. Although there is protection against electrostatic discharge in place, these countermeasures provide only limited safety.

All components are not protected against water ingress. Avoid contact to liquids.

6. System Description

The BIC Evaluation Kit represents the electronic function of the BIC ONE Implant.
The key performances are neural recording, electrical stimulation, measurement of electrode impedance. These performances are provided by a wireless system, which includes an inductive link for power supply and an RF link for data communication.

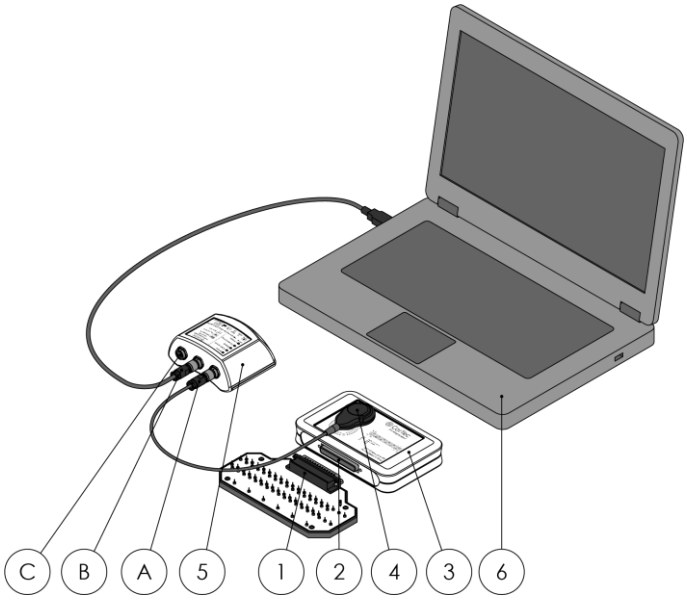
6.1. System Technical Specifications

The purpose of the CorTec BIC ONE Implant System is recording from and electrical stimulation of neural tissue, especially brain tissue. Table 4 list the main specifications of the system

Table 4: List of Specifications

Feature	Value
Recording channels	32
Sampling rate / channel	1 kHz
Sampling dynamic range	16 bit
High pass filter cut-off	2 Hz
Low pass filter cut-off	325 Hz
Amplifier pass band gain	750
Band pass roll-off	20 dB/decade
Amplifier input impedance	Ca. 15 pF
Amplifier input voltage	Max $4mV_{pp}$
Input referred amplifier voltage offset	$200\mu V_{max}$ (varies across channels)
Number of stimulation sources	1 (can be directed
Stimulation pulse output	Current controlled
Stimulation pulse shape	Cathodic first, asymmetric rectangular, biphasic
Charge balancing counter pulse	4x pulse width, -1/4 current amplitude of stim. pulse
Max. stimulation pulse amplitude	6.12 mA
Stimulation amplitude increment	24 µA
Max. stimulation pulse width	2500 µs
Stimulation pulse width increment	10 µs

6.2. System Overview



1: Electrode Model Module
2: Electrode Connector
3: Implant Module
4: Head Piece
5: Communication Unit
A - Head Piece Cable Connector
B - USB Cable Connector
C - Trigger Input Connector
6: Personal Computer

Figure 1: System Overview of BIC Evaluation Kit connected to a Personal Computer.

6.3. Module Description

The BIC Evaluation Kit consists of several modules that are described hereinafter.

6.3.1. Electrode Model Module - EMM

The Electrode Model Module is a simplified electrical representation of electrodes in tissue, permitting the user to introduce electrical signals to be recorded by the System or to observe electrical signals generated by the Implant Module. Therefore, the EMM can be attached to the Implant Module using the Electrode Connector. For technical details of the EMM see **chapter 6.5.3.** alternatively to the EMM, electrodes can be attached utilizing the Electrode Connector (cf. chapter 6.6.2).

6.3.2. Implant Module - IM

The Implant Module is an electrically fully featured BIC ONE implant encased in a plastic housing. Additional to the BIC ONE implant electronics, the electrical interface to electrodes have an electrical protection for each channel against hazard resulting from electrostatic discharge (ESD). This might lead to minor difference in the behavior of the entire System. The protection circuitry consists of protection diodes at each amplifier input switched against GND and 100 Ohm resistors in series between Electrode Connector and amplifier input.
The electrical interface of the IM is the Electrode Connector. See **chapter 6.6.2.** for specifications.

6.3.3. Head Piece

The Head Piece provides an alternating magnetic field, wirelessly suppling power to the Implant Module. The magnetic field is generated through a coil (primary coil) in the Head Piece and picked up by the Implant Module coil (secondary coil). To allow good alignment of these two coils, permanent magnets are placed in the center of the coils that attract each other and keep the Head Piece in place. The Head Piece has a cable which connects it to the Communication Unit.

6.3.4. Communication Unit

The communication unit has several functions:

- Wire-bound (USB) communication with the Personal Computer
- Wireless communication with the Implant Module
- Powering the Head Piece
- Recording an External Trigger signal and threading this into the data stream coming from the Implant Module relayed to the Personal Computer
- Status indication via LEDs.

6.3.5. Personal Computer

The Personal Computer controls the BIC Evaluation Kit either via the Application Software or via Research Software written by the user, using the API provided by CorTec. The Personal Computer also receives status data from the System as well as – in recording mode – the stream of neural data.
The Personal Computer must match the following minimum specifications

- CPU: 4 cores at 2.5G Hz of 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 pixels (16:9) or higher
- USB 3.0 port
- Operating system: Windows 10 Professional 64 bit

6.4. Operating Modes

The System has different modes of operation, listed below. In case the System detects a faulty condition, the Implant Module is shut down, exiting the current mode of operation for the safety of the imaginary patient. Although the BIC Evaluation Kit must not be used with a patient, this mechanism was kept active to allow the user to simulate such conditions (e.g. excessive heating or electrode breakage).

Idle

In the Idle mode, the Implant Module is powered by and communicates with the Communication Unit. The System has identified safe operation conditions and is awaiting further commands. Dynamic Power Regulation (wireless power transfer from Head Piece to Implant Module) is active.

Recording

The Implant Module records neural data from all channels and transfers the digitized data wirelessly via Communication Unit to the Personal Computer.

Stimulation
Electrical stimulation is performed.

Recording and Stimulation in Parallel
The implant records neural data from all channels and transfers the digitized data wirelessly to the Communication Unit / Personal Computer. Additionally, electrical stimulation is performed (amplifiers are disconnected from corresponding electrodes/channels). Signals recorded on channels actively performing stimulation might show crosstalk from other channels but no recorded data from the electrodes.

Impedance Measurement
Through low-intensity electrical stimulation pulses, the System calculates the electrode impedance by relating voltage responses to the stimulation pulses.

6.5. Accessories

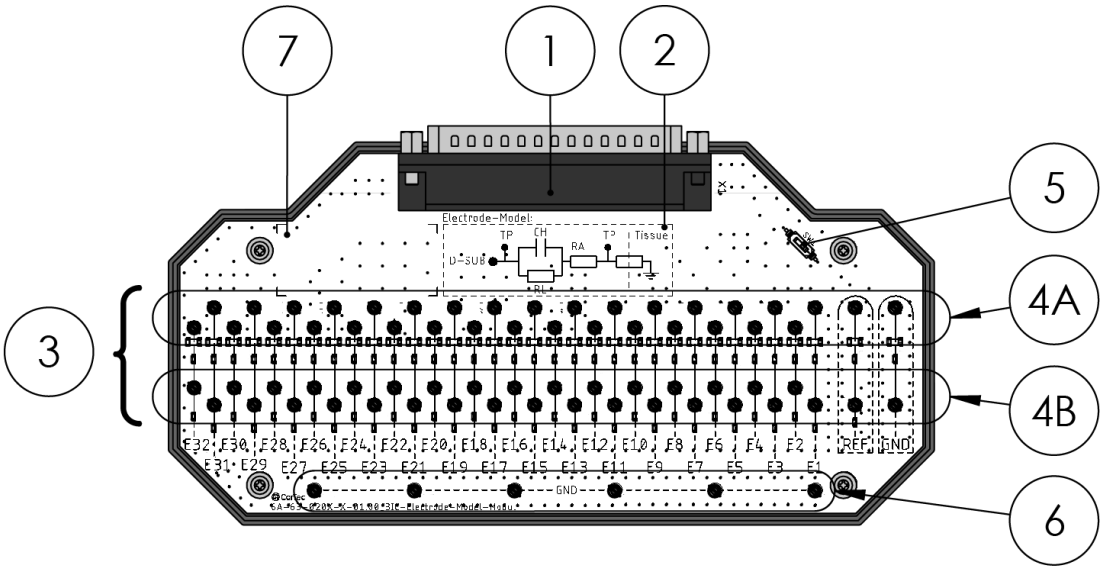
6.5.1. USB Cable
The USB Cable connects the Communication Unit to the Personal Computer.

6.5.2. Connector for Trigger Cable
The Communication Unit can receive a trigger input signal that permits the user to record the occurrence of events. This is of use, e.g. when averaging of neural data is required. The begin of the data frame to be averaged can be indicated by the a ‘high’ voltage level supplied via the trigger cable.
The BIC Evaluation Kit is shipped with a connector that mates with the trigger input of the Communication Unit. The user of the System can customize its own trigger cable using this connector.

6.5.3. Electrode Model Module
For evaluation of the System, electrical models of electrodes can be very useful. The electrode model modules represent electrodes by an electrical 3-component equivalent circuit, all connected by resistors representing the body volume conduction. The modules can be used for investigating System recording properties by introducing small voltage signals (see 6.6.2) supplied by an external signal generator and also to investigate the stimulation output of the System by observing the voltages using an oscilloscope. For these investigations, the Electrode Model Module provides several test points as electrical interfaces to signal sources or oscilloscopes.

6.6. Interfaces

6.6.1. Electrode Model Module



1. Connector
2. Representation of Electrode Model Equivalent Circuit
3. Electrodes E1 to E32, REF-Electrode, GND-Electrode
4. Test points
   4A Test points (connector/electrode)
   4B Test points (electrode/tissue)
5. Switch SW1
6. GND potential
7. Manufacturing information

Figure 2: Overview of Electrode Model Module

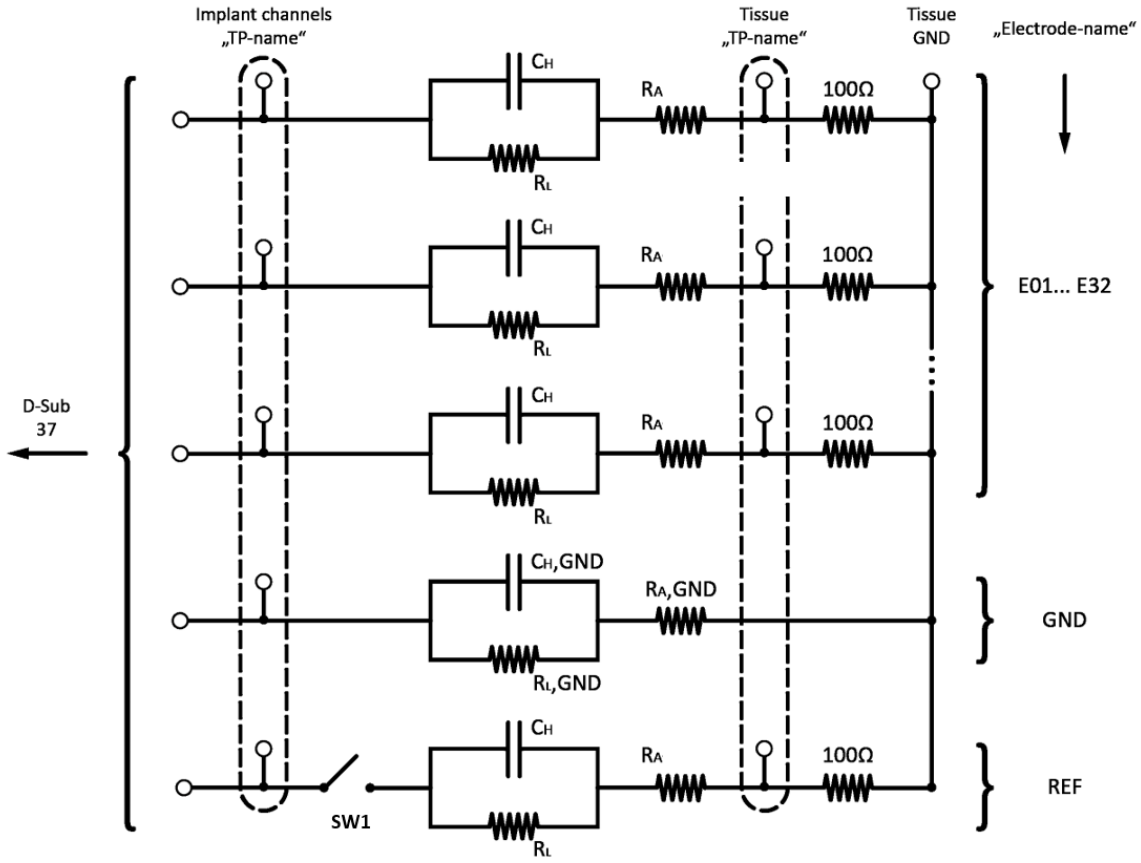


Figure 3: Schematic of Electrode Model Module

Table 5: Electrical Component Values for Schematic (Figure 3) of Electrode Model Module

Module Type	C_H	R_L	R_A	$C_{H,GND}$	$R_{L,GND}$	$R_{A,GND}$
1.0mm diameter PtIr Disks	220nF	499kΩ	481Ω	22µF	50,5kΩ	39Ω

- Connector
  - Technical description, Male, 37 pos, D-Sub
  - Mates with Electrode Connector of Implant Module, connects 34 electrical electrode models to the 32 Implant Module channels and to additional GND and REF channels.
  - The 34 electrodes are mapped as follows:
    - Electrode model E1 to E32 is mapped to connector pin 1 to 32
    - Electrode model REF is mapped to connectors pin 36
    - Electrode model GND is mapped to connectors pin 37
  - Representation of Electrode Model Equivalent Circuit represents the electrical equivalent circuit of electrode E01 – E32 and REF-electrode.

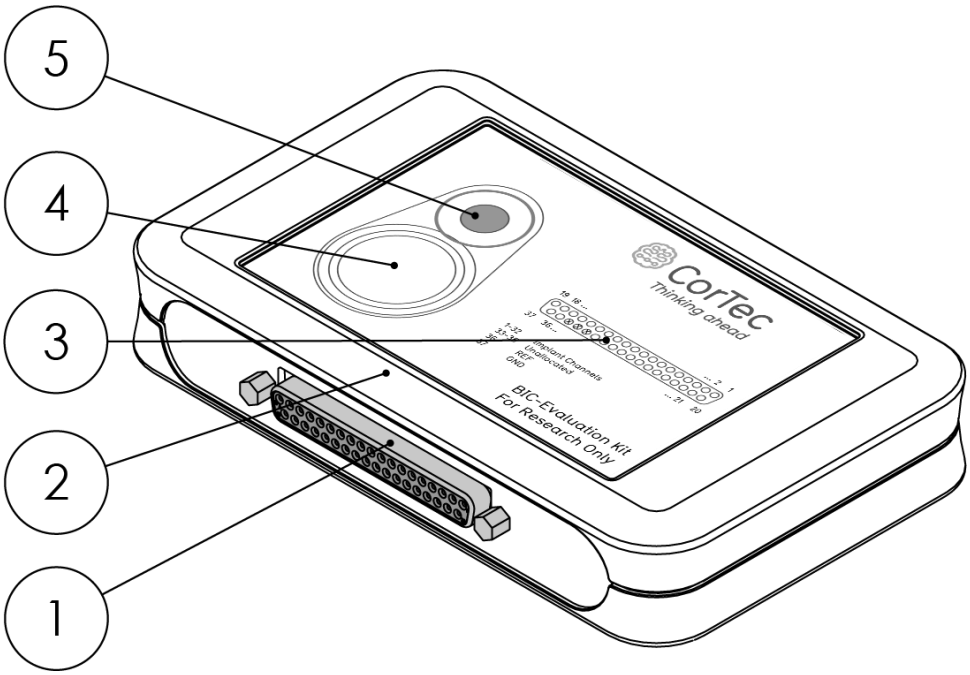
- Electrodes E01 to E32, REF-Electrode and GND-Electrode
  - E01 to E32 represent functional electrodes
  - GND represents the ground electrode of the implant, is not terminated with a 100 Ohm resistor to GND (logic/schematic ground). The implant (here: the Implant Module) allows to connect/disconnect an additional GND electrode dynamically by software setting. The GND electrode represents the return path (destination) of a stimulation current injected by the electrodes E01 –

E32 (source). If the additional GND electrode is not used, at least one of the electrode E01 – E32 must be assigned to GND by software setting to allow electrical stimulation.
    - REF represents the recording reference electrode. This electrode can be disconnected using switch SW1 (function described below).

- Switch SW1
    - The Implant System can be connected to a variety of electrodes. For some applications, an additional hard-wired recording reference contact might be desired (switch SW1 closed), for other applications, the recording reference shall be flexibly selectable amongst electrode contacts E01 – E32 (switch SW1 open).
    - If the switch SW1 is open, a recording reference contact needs to be selected by software prior to recording.
    - If the switch is closed, the recording reference contact is already defined by hardware and does not need further software settings. If a recording reference contact is selected by software, this contact acts in addition to the hard-wired contact as reference (in fact: the two are electrically shorted).
    - Switch positions:
      ON (closed): toggle is oriented towards the connector
      OFF (open): toggle is oriented away from the connector

- Test points (TPs)
    - Test points permit the user to monitor voltage generated at the electrode model during electrical stimulation. The test points also permit to introduce voltage signals, mimicking neural activity to be recorded by the System.
    - The test points are arranged before and after the electrode models as shown in Figure 2 and 3.
    - The test points are divided into two categories A and B.
        - A TPs are located directly at the connector, giving direct access to the electrical potential at the Implant Module input/output.
        - B TPs are located between the electrodes and the volume conducting tissue, represented by 100 Ohm resistors. These TPs are suitable for measuring the stimulation current (voltage across 100 Ohm resistors relative to GND) or to introduce voltages (again: across 100 Ohm resistors relative to GND), mimicking neural activity to be recorded by the System.
    - Test points with GND label located in the lower area of the circuit board permit access to the ‘tissue’ and GND-Electrode potential.

6.6.2. Implant Module



1. Electrode Connector
2. Plastic Housing
3. Pinout of the Electrode Connector
4. Exemplary implant illustration
5. Implant magnet position / center of coil

Figure 4: Implant Module

- Electrode Connector
  - Technical description: Female, 37 pos, D-Sub
  - The pinout of the connector is shown in figure on top of the housing
  - Warnings to avoid damage of Implant Module:

Note: Voltages presented to the Electrode Connector of the Implant Module must not be larger than 2mV in amplitude ($4mV_{PP}$) to avoid damage to the amplifier input stages.

- Plastic Housing
  - Encloses the BIC Implant, additional protective circuit (ESD protection), the Electrode Connector, the permanent magnet and the coil for inductive energy harvesting.
  - The Housing protects against mechanical hazards and eases handling of the System
  - The Housing provides information in the form of labels and various images/illustrations

- Pinout of the Electrode Connector
  - The connector pins are mapped as follows:
    - Pin 1 to 32 are assigned to channels E01 – E32
    - Pin 33 to 35 is reserved for service access – do not use!

- Pin 36 is mapped to hard-wired recording reference REF
- Pin 37 is mapped to GND Electrode (switchable by software)

- Exemplary implant illustration
  - Represents the shape of the original implant including the orientation of the permanent magnet

- Permanent Magnet
  - Allows alignment of the Head Piece coil to the coil inside the Implant Module.

Note: Avoid any metallic objects near the head piece to not obstruct the power transfer. Also avoid placing metallic objects on the Implant Module to not obstruct radio frequency communication.

6.6.3. Radio Frequency Communication

Data communication is implemented using a proprietary protocol in the 2.4 GHz band.

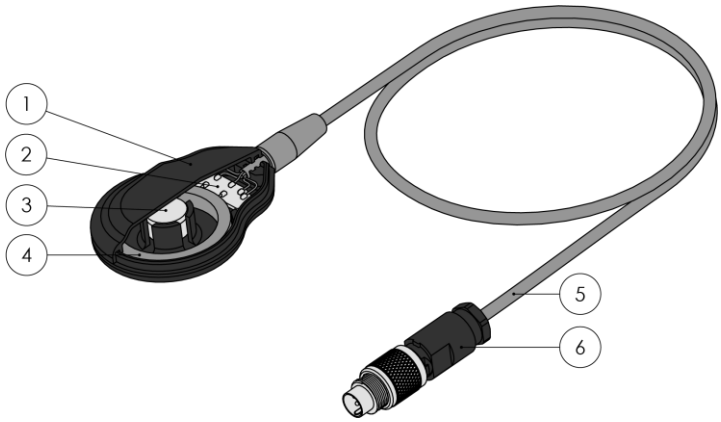
Note: Aligning the Communications Unit with the Implant Module can play an important role in communication quality and minimize or increase data loss or even lead to a loss of connection.

6.6.4. Inductive Link for Power Transfer

The energy transfer takes place inductively in the range from 120 kHz to 140 kHz.

Note: The energy transfer can be disrupted or completely interrupted by metallic objects in the immediate vicinity, especially in between the Head Piece and the Implant Module.

6.6.5. Head Piece



1. Head Piece Housing
2. Head Piece circuitry incl. coil driver
3. Permanent Magnet
4. Inductive Coil
5. Head Piece Cable
6. Head Piece Cable Connector

Figure 5: Cut-open view of Head Piece

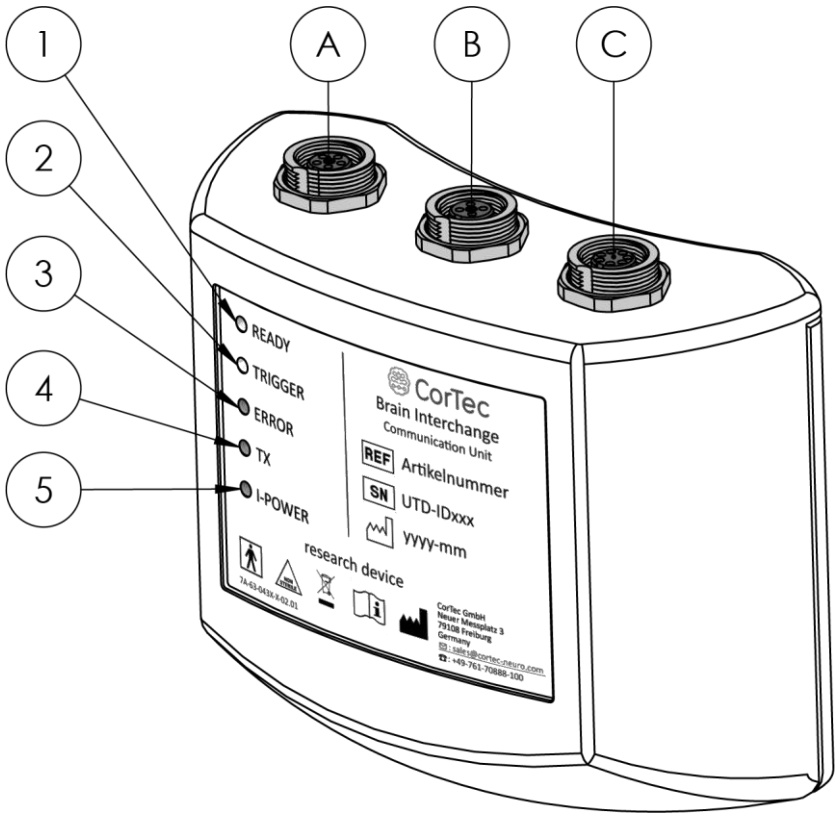
- Permanent Magnet
  - Allows alignment of the Head Piece coil to the coil inside the Implant Module

- Inductive Coil
  - Frequency Range of magnetic field: 120 kHz – 140 kHz

- Head Piece Cable
  - Length ca. 60 cm
  - Protected by bend and strain relief

- Head Piece Cable Connector
  - Male, 5-pin
  - Mechanically keyed for correct connection to Communication Unit

6.6.6. Communication Unit



Optical Indicators

1. READY
2. TRIGGER
3. ERROR
4. TX
5. I-POWER

Interfaces

A Head Piece Connector
B USB Connector
C Trigger Input Connector

Figure 6: Communication Unit

Interfaces

A. Head Piece Connector
   - Female connector, 5 pos
   - Mechanical locking function
   - Internal protection circuitry (ESD)

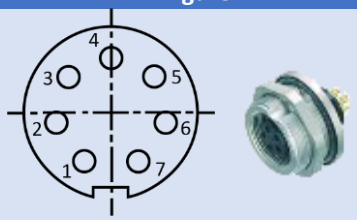
B. USB Connector
   - Female connector, 4 pos
   - Mechanical locking function
   - Protection circuitry against ESD

Note: Please use only the cable provided!

C. Trigger Input Connector
   - Female connector, 7 pos.
   - Mechanical locking function
   - Reverse input voltage polarity protection
   - Protection circuitry against ESD
   - Voltage at trigger input is classified as low (0) or high (1) signal
   - Allowed maximum input voltage range between 0 to 30 V. For example:
     i. Conventional TTL (Transistor-Transistor-Logic) levels at 5V
     ii. Conventional LVTTL (Low-Voltage-Transistor-Transistor-Logic) levels at 3.3V
   - Mating connector
     i. Manufacturer: Binder, Camarillo, CA, USA
        Binder, Neckarsulm, Germany
     ii. Manufacturer Part Number: 99 0421 00 07

Note: Please use the appropriate mating connector to contact and couple a trigger signal into the communication unit!
Please do not exceed the maximum input voltage range!

Table 6: Trigger Input Connector Interface Description

Figure	Pin description	Cable Connector
 (front view of female connector of communication unit))	1 GND 2 Trigger Signal 3 nc 4 nc 5 nc 6 nc 7 nc	 male cable connector

Optical Indicators (LEDs)

1. **READY:** On - if the communication unit is ready for operation, Off - if not powered or in error state (ERROR LED)
2. **TRIGGER**: On - if trigger input is high Off - if trigger input is low
3. **ERROR**: On - in case of an error (i.e. head piece temperature out of limits, power coupling out of limits)
4. **TX**: Flashing during data communication between Communication Unit and Implant Module
5. **I-POWER**: On - while power is provided to the Implant Module

Radio Frequency Communication

- Band: 2.4GHz (2400MHz to 2483 MHz)
- Maximum peak transmission power <= 20dBm
- Average transmission power 0 dBm (1mW)

6.6.7. Personal Computer

- USB 3 port, the max. current uptake of the Communication Unit is 2 A.

7. Use / Getting Started

The following is an introduction for getting started with the evaluation of the System. Please consult Table 7 in case of problems.

7.1. Software Installation

The USB memory stick shipped with the BIC Evaluation Kit contains an installer program for the CorTec Application Software (*Brain Interchange Paralysis_setup_1.0.121-release-rev24298_…*) and an installer program for the CorTec APIs (*Bicapi_setup_1.0.121-release-rev24689*). You need to have administrator rights on your windows operation system.
The second installer also unpacks the documentation to the API as well as the BIC2CSV conversion tool.

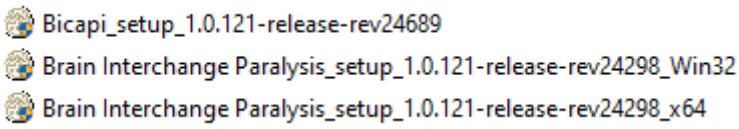


Figure 7: Files on USB Drive

7.2. Assembling of the System

After successful software installation on the Personal Computer,

1. Connect the Electrode Model Module to the Implant Module
2. Connect the Head Piece to the Communication Unit
3. Connect the USB Cable to the Communication Unit
4. Place the Head Piece on the Implant Module
5. Connect the USB Cable to the Personal Computer

If indicator 'READY' is not lighted, please align Head Piece to the Implant Module. Otherwise disconnect all items and start connecting from the beginning or see Table 7.

7.3. Operating the System

The user can control the System via software running on the Personal Computer. Either the System is controlled using the CorTec Application Software (chapter 7.3.1) or by Research Software written using the CorTec API (Python or C++).

7.3.1. Application Software

CorTec's Application Software permit fast and easy use of the systems basic functionality. See **Annex 1** for introduction into the Application Software.

7.3.2. Research Software / Application Programming Interface (API)

The user can create application specific Research Software. CorTec's API provides the all functionality required to use and control the System. The documentation of the API is installed with the API itself (USB memory stick).

7.4. Error Messages

If error messages appear repetitively, contact CorTec service, referring to the error message number. See also chapter 7.5.

7.5. Trouble Shooting

Try to solve a problem by checking Table 7 before contacting CorTec customer support by email:

support@cortec-neuro.com

When contacting CorTec customer support, please refer to serial numbers or devices identification (ID) numbers as labelled on the individual hardware components.

Table 7: List of Potential Solutions to Problems

ID	Problem	Potential Solution
1	System does not power up	1. Make sure USB port of Personal Computer is working correctly. Connect / disconnect USB plug; try different USB port, if available. 2. Make sure Head Piece is well placed on Implant Module 3. Ensure good radio frequency communication (see problem: packet losses)
2	High loss of wirelessly transmitted packets	1. Improve week radio frequency (2.4 GHz) connection: 2. Switch-off WLAN and Bluetooth devices nearby. 3. Reduce distance between Implant Module and Communication Unit 4. Change orientation of Communication Unit relative to Implant Module
3	Communication Unit Error LED on	1. Disconnect Communication Unit from the PC 2. Verify that Head Piece is placed properly on the Implant Module 3. Reconnect the Communication Unit to the PC

Annex 1: Application Software Short Manual

See file: *Appendix1_Eval_KIT_BIC_Application_Software_Short_Manual*

Annex 2: List of Known Errors

See file: *Appendix2_Eval_KIT_List_of_Known_Errors* (List is not delivered printed. Please contact support@cortec-neuro.com for request.)

CorTec GmbH
Neuer Messplatz 3
79108 Freiburg
Germany