



PRECISIS

Instructions for Use

for the

EASEE® System

Neurologist Manual

Caution – Investigational Device
Limited by United States Law to Investigational Use

This document applies to the EASEE® System, which contains the following components:

EASEE® Power
EASEE® Lead
EASEE® Connect
EASEE® Set - Hardware
EASEE® Access

Version 0.6
11 November 2025

This manual comprises the instructions for use as well as a technical description of the EASEE® System.
The instructions for use are intended for the neurologist.

Explanation of Symbols on Product or Package Labeling

Refer to the appropriate product for symbols that apply.
Symbol descriptions are provided for information only!



Caution



Sterilized using EO



Sterilized using irradiation



Non-sterile



Do not re-sterilize



Do not reuse



Do not use if packaging is damaged.



MR unsafe



MR conditional



Non-pyrogenic



Non-ionizing electromagnetic radiation



Type B applied part

5V --- 0.3A

Rated supply voltage, direct current, rated current

IP54

Degrees of protection provided by the housing (IP code)

IP24

Degrees of protection provided by the housing (IP code)



Keep away from sunlight



Keep dry



Temperature limits



Atmospheric pressure limits



Humidity limits



Refer to instruction manual/booklet



Follow instructions for use



Manufacturer



Date of manufacture



Use-by date



Batch code



Reference number



Serial number



Unique Device Identification

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1 Introduction

1.1 Legal Manufacturer

All questions regarding the EASEE® System or any of its components should be forwarded to the legal manufacturer Precisis GmbH. Any adverse event that has occurred in relation to the EASEE® System or any of its components should be reported to the legal manufacturer Precisis GmbH and the authority having jurisdiction in the United States.

US Agent:

Perry Rice

11114 Sweetwater Path
Woodbury, MN 55129
United States of America

Manufacturer Postal Address:

Precisis GmbH
Margot-Becke-Ring 8
69124 Heidelberg
GERMANY

Single registration number (SRN):

DE-MF-000016826

Customer Support:

Tel.: tbd
Fax: +49-6221-655 9310
E-mail: customerservices@precisis.de

Website:

www.precisis.de/en

1.2 Intended Purpose

The EASEE® System is intended for use as an adjunctive neurostimulation therapy in reducing the burden of epilepsy in adults over 18 years with focal onset seizures that are refractory to two or more anti-seizure medications.

1.3 About this Manual

This manual is intended to provide guidelines for the use of the EASEE® System. The implantable parts of EASEE® System include EASEE® Power, the implantable pulse generator, also referred to as the neurostimulator, and EASEE® Lead, the implantable electrode array, including connecting cable and connector, also referred to as lead or cable, which connects to EASEE® Power. The manual also contains instructions for the programming device for EASEE® Power, which comprises the combination of EASEE® Set and EASEE® Connect. This is used to set the parameters for the implantable device and to interrogate the device. EASEE® Set is a tablet PC (EASEE® Set Hardware) with customized software (EASEE® Set Software). EASEE® Connect is a telemetry device that enables wireless communication between EASEE® Set and EASEE® Power. Finally, the manual also describes the use of EASEE® Access, a handheld device that enables the patient to communicate with EASEE® Power.

Contents of the manual

- Introduction - Overview of the typographical conventions and contents of the manual
- EASEE® System - Indications, contraindications, MRI safety information
- Warnings and Precautions – Notes on possible hazards when using the EASEE® System and how they can be prevented
- EASEE® System Description - Components of the EASEE® System, accessories, and longevity of the system
- Clinical Use of the EASEE® System - Physician and center access, identification of candidates, pre-surgical planning, patient training, and overview of implantation
- Surgical Procedures - Instructions for implantation of the EASEE® System
- Patient Treatment – Description how the EASEE® System is used to treat patients
- EASEE® Access Handheld Device – Explanation of EASEE® Access, its handling and functions and how information that may be helpful in solving problems encountered during the implantation or operation of the EASEE® System
- Maintenance – Details about the maintenance of the hardware and software of the EASEE® System
- Troubleshooting - Information that may be helpful in solving problems encountered during the implantation or operation of the EASEE® System
- Specifications - List of mechanical and electrical characteristics of each component of the EASEE® System
- Electromagnetic Emissions and Immunity - Information that may be helpful in solving problems encountered during the implantation or operation of the EASEE® System
- Glossary - Alphabetical list of terms used in the manual with respective definitions

1.3.1 Typographic Conventions

This manual uses different formats and symbols to distinguish instructions, warnings, precautions, notes, lists, and figures:

WARNING: CONTENTS OF WARNINGS

WARNINGS ALERT THE USER TO SERIOUS ADVERSE EVENTS AND POTENTIAL SAFETY HAZARDS AND SITUATIONS THAT MAY CAUSE INJURY.

Precaution: Contents of PRECAUTIONS

Precautions alert the user to exercise special care in the safe and effective use of the EASEE® System.

Notes: Notes provide additional information that is particularly useful or important.

1. Numbered paragraphs contain instructions that provide explanations and/or procedural information.
 - Bullet points indicate items in a list.

Figure: Statements regarding a figure are located below the figure between double lines as seen here.

Table: Statements regarding a table are located below the table between double lines as shown here.

Bold italicized text refers the user to a specific location in this manual for further details.

BOLD CAPITALS assist the user in navigating to the appropriate tab or button on the EASEE® Set.

Display and control elements are displayed on the EASEE® Set screen as follows:

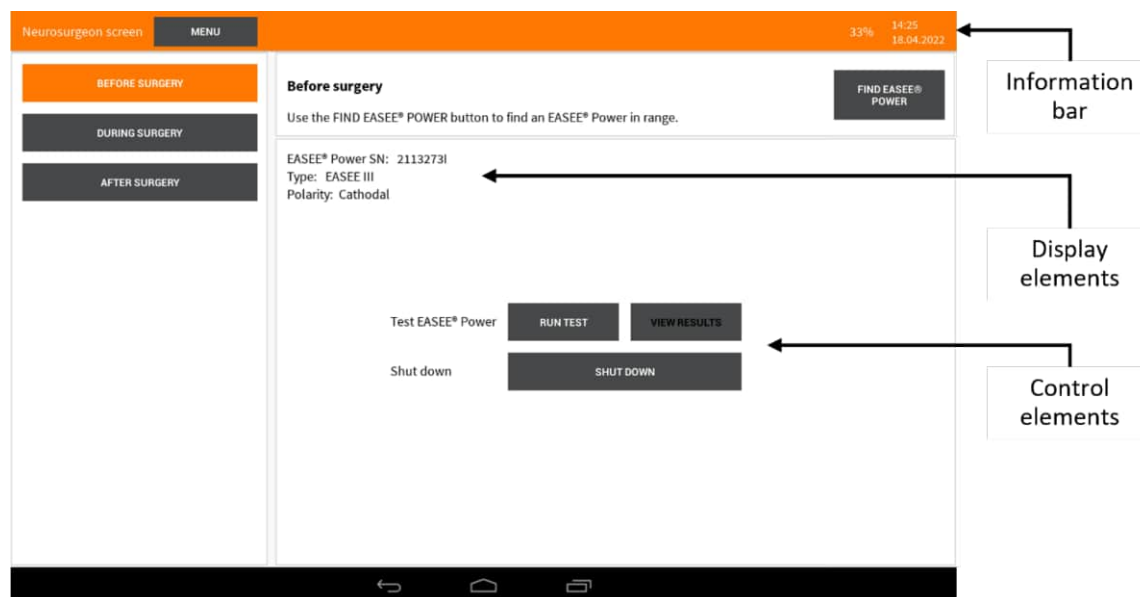


Figure 1.1: Example of a screenshot from EASEE® Set showing the Graphical User Interface with explanation of information bar, display and control elements.

2 EASEE® System

2.1 Indications

The EASEE® System is indicated for:

- Patients with a clinical diagnosis of focal seizures or focal seizures evolving into bilateral tonic-clonic seizures.
- Patients with a diagnosis of temporal lobe epilepsy or extra-temporal lobe epilepsy including frontal lobe, parietal lobe and occipital lobe.
- Patients with a predominant epileptic focus, which can be clearly identified as the site of implantation for the electrode based on electroencephalogram (EEG), magnetoencephalogram (MEG), magnetic resonance imaging (MRI), video-EEG monitoring, or intracranial EEG, and clinical presentation.
- Patients in whom treatment with at least two appropriately selected and tolerated anti-seizure medications has not been sufficiently effective.
- Patients over the age of 18.

Conditions listed above must all be fulfilled together.

2.2 Contraindications

The EASEE® System is contraindicated for:

- Patients who are anatomically not eligible for EASEE® System implant in the opinion of the treating physician.
- Patients where placement of the EASEE® Lead would be located directly above implanted alloplastic materials, such as metal parts or non-conducting material (e.g. bone cement, palakos, etc.), unless such materials can be safely removed during the EASEE® implantation procedure.
- Patients implanted with a life-saving electronic device, e.g., permanent implantable pacemaker, implantable cardioverter/ defibrillator (ICD).
- Patients implanted with a brain stimulation device or an implanted Vagus Nerve System (VNS) device that cannot be reliably switched off.
- Patients at high risk for surgical complications due to underlying condition such as active systemic infection, coagulation disorders (such as the use of anti-thrombotic therapies) or low platelet count.
- Patients who are pregnant.

The following medical procedures are contraindicated for patients with an implanted EASEE® System:

- Diathermy procedures (Diathermy is any treatment that uses high-frequency electromagnetic radiation, electric currents, or ultrasonic waves to produce heat in body tissues): Patients should not be treated with any type of short wave, microwave, or therapeutic ultrasound diathermy device whether or not it is used to produce heat. These treatments should not be applied to any part of the body.
- Electroconvulsive Therapy (ECT): ECT should not be conducted on patients with an implanted EASEE® Power or EASEE® Lead (or parts of it).
- Transcranial Magnetic Stimulation (TMS): TMS should not be conducted on patients with an implanted EASEE® Power or EASEE® Lead (or parts of it).
- MRI should not be performed if the complete EASEE® System is not functional, but only parts of it are still implanted. Please refer to the **section 2.3 MRI Safety Information** for details.

These procedures produce energy that could potentially travel through the implantable components of the EASEE® System to the brain, despite the extracranial positioning of the EASEE® Lead electrodes. In very unlikely cases this may lead to permanent brain damage, resulting in severe injury, coma or death. Brain damage may result from any of the above listed procedures, even when the EASEE® Power implantable pulse generator is switched off or the EASEE® Lead is not connected to the pulse generator.

2.3 MRI Safety Information

Non-clinical testing has demonstrated that the neurostimulating implant of the EASEE® System, i.e. intact EASEE® Power connected with intact EASEE® Lead, is MR Conditional in accordance with the ASTM F2503- 20 standard definitions. A patient with this implant can be safely scanned in an MR system meeting the conditions provided in Table 2. Failure to follow these conditions may result in injury.

CAUTION:

- Only the complete and intact implant (EASEE® Power connected with EASEE® Lead) is MR Conditional. Disconnected leads or broken leads of the EASEE® System have not been tested and must be regarded as MR Unsafe.
- Switch off EASEE® Power before entering the MR environment using EASEE® Access or EASEE® Set/EASEE® Connect. If the stimulation should be continued after the MR examination, EASEE® Power will need to be turned on by the attending neurologist / appropriate healthcare professional.

Parameter	Notes
Item Name / Identification	EASEE® Power (UDI-DI 04260479770293) EASEE® Lead (UDI-DI 04260479770446)
Device Configuration	Shut down
Item Manufacturer	Precisis GmbH
Date this labelling was issued	July 2025
Location of MRI safety information	https://www.EASEE4US.com/MR-Safety and this document
Static Magnetic Field Strength	1.5 T / 3 T
Type of Nuclei	Hydrogen
Static Magnetic Field (Bo) Orientation	Horizontal
Scanner Type	Cylindrical-bore
Maximum Spatial Field Gradient	43 T/m (4310 gauss/cm)
Maximum Gradient Slew Rate per axis	200 T/m/s
Encoding gradients (dB/dt) rms	42 T/s
RF Excitation	1.5T: Circularly Polarized (CP) 3T: Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	Any receive coil may be used
MR System (RF) Operating Mode	Normal Operating Mode (including FPO:B Mode)
B_{1+RMS}	$B_1 + RMS \leq 7 \mu T$
Whole Body Averaged SAR	Whole Body SAR ≤ 2 W/kg
Patient Characteristics	- uncompromised thermoregulation and under controlled conditions: a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress. - no previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adaptors - no broken lead or lead with intermittent electrical contact
Scan Duration and Wait Time	Scanning for 30 minutes max

Table 2: Conditions for safe scanning in an MR system.

2.3.1 Preparing a magnetic resonance (MR) examination with a patient having an EASEE® System implanted

- Contact the treating neurologist when planning an MRI examination with a patient having an EASEE® System implanted.
 - The implantable pulse generator (IPG) EASEE® Power will be switched off for the examination and needs to be re-programmed by the treating neurologist after the MRI.
- Ask the patient to bring the implant card.
 - The implant card contains necessary information on the configuration of the patient's implanted EASEE® System to identify the correct MRI Guidance documentation.
- Ask the patient to bring the patient controller EASEE® Access

- The patient controller EASEE® Access can be used prior to MR imaging to shut down the IPG in case the treating neurologist is not present.

2.3.2 Pre-MR imaging instructions to ensure safe imaging and maintain functionality of the EASEE® System

- Ensure that the implantable pulse generator (EASEE® Power) of the patient is shut down.
 - The patient must not receive neurostimulation by the EASEE® System during the MR examination.
- Ensure that the patient is continuously monitored during the MR examination.
- Ensure that the handheld device EASEE® Access is left outside the MR environment.
 - EASEE® Access is MR Unsafe. It may be damaged or may cause damage when brought into the MR environment.
- Ensure that EASEE® Set and EASEE® Control are left outside the MR environment.
 - EASEE® Set and EASEE® Control are MR Unsafe. They may be damaged or may cause damage when brought into the MR environment.

Please inform your patient about the following

- The patient shall immediately inform the attending medical personell if he/she feels any unusual sensations, e.g. vibration, force, pain, untoward heating in the electrode or pulse generator area or in-between, so that the operator can stop the procedure if needed.
- When entering the MR environment, mild forces on the implant may occur, leading to uncomfortable or unusual sensations.
- During the MR examination, mild vibration of the implanted devices may occur, leading to uncomfortable or unusual sensations.
- During the MR examination, unintended stimulations may occur, leading to uncomfortable or unusual sensations.

2.3.3 MR imaging information

Scan locations and scan position

There are no restrictions on scan locations and scan positioning during MR imaging.

Image artifacts

CAUTION: The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

- In non-clinical testing, image artifacts caused by the implant were found when performing gradient echo pulse sequences in a 1.5 T MRI scanner.
- Artifacts around the electrode EASEE® Lead are minor.
- Artifacts around the pulse generator EASEE® Power are more pronounced.
- Optimization of imaging parameters will minimize image distortion by the implant.

2.3.4 Post-MR imaging instructions to be considered by the treating neurologist after the MR examination

- When the patient has left the MR environment, EASEE® Power can be turned on with the magnet, and programmed to stimulate, by the treating neurologist.
- Verify the impedances of EASEE® Lead.
- Verify correct programming of EASEE® Power.
- If there are any concerns regarding correct functioning of the EASEE® System, promptly inform the manufacturer, Precisis GmbH.

The MRI safety information is also available in the *MRI Guidelines for safe imaging of patients treated with the EASEE® System*. The MRI Guidelines are available for download at <https://www.EASEE4US.com/MR-Safety>.

2.4 Warnings and Precautions

2.4.1 Warnings - Clinical Use

WARNING: PHYSICIAN AND CENTER ACCESS TO THE EASEE® SYSTEM

THE EASEE® SYSTEM SHOULD ONLY BE IMPLANTED BY NEUROSURGEONS WITH ADEQUATE EXPERIENCE IN THE IMPLANTATION OF NEUROSTIMULATION DEVICES IN THE HEAD AND IN THE SURGICAL TREATMENT OF EPILEPSY. THE IMPLANTATION OF THE EASEE® SYSTEM SHOULD ONLY BE PLANNED BY NEUROLOGISTS OR NEUROSURGEONS WITH ADEQUATE EXPERIENCE IN THE MANAGEMENT OF INTRACTABLE EPILEPSY AND IN THE LOCALIZATION OF EPILEPTIC FOCI, INCLUDING THE USE OF SCALP ELECTRODES. TO QUALIFY TO MANAGE PATIENTS WITH THE EASEE® SYSTEM, PHYSICIANS MUST DEMONSTRATE SPECIFIC EXPERTISE RELATED TO EPILEPSY, EEG MONITORING, THE PHARMACOLOGY OF ANTI-SEIZURE MEDICATIONS AND SELECTION OF PATIENTS FOR EPILEPSY SURGERY. IMPLANTATION OF THE EASEE® SYSTEM SHOULD BE PERFORMED ONLY BY QUALIFIED NEUROSURGEONS AT CENTERS CAPABLE OF PROVIDING COMPREHENSIVE EPILEPSY CARE, I.E. "COMPREHENSIVE EPILEPSY CENTERS". THESE CENTERS SHOULD HAVE THE EXPERTISE TO PROVIDE DIAGNOSTIC SERVICES THAT INCLUDE EEG MONITORING WITH SCALP AND INTRACRANIAL ELECTRODES AND NEUROIMAGING AND EXPERTS IN THE TREATMENT OF EPILEPSY WITH ANTI-SEIZURE MEDICATIONS, EPILEPSY SURGERY AND DEVICES.

2.4.2 Warnings – Surgery

WARNING: COMPATIBILITY WITH SIMILAR IMPLANTABLE PRODUCTS

EASEE® POWER AND EASEE® LEAD ARE NOT COMPATIBLE WITH NON-EASEE® SYSTEM PULSE GENERATORS AND/OR LEADS. INCOMPATIBLE CONFIGURATIONS MAY CAUSE DAMAGE TO THE PRODUCTS AND MAY RESULT IN UNSAFE CURRENT DENSITY STIMULATION BEING DELIVERED TO THE PATIENT.

WARNING: UNEXPECTED SURGICAL COMPLICATIONS

AS WITH ANY SURGICAL TREATMENT, IT CANNOT BE RULED OUT THAT IMPLANTATION OF EASEE® SYSTEM COMPONENTS LEADS TO RARE, UNEXPECTED AND POTENTIALLY SEVERE COMPLICATIONS.

WARNING: INFECTION

INFECTION, INCLUDING BACTERIAL MENINGITIS, MAY OCCUR AS A RESULT OF THE EASEE® SYSTEM IMPLANTATION PROCEDURES AND/OR THE EASEE® SYSTEM MATERIALS. STANDARD SURGICAL INFECTION PREVENTION MEASURES (ANTIBIOTICS ETC.) SHOULD BE TAKEN BOTH PRE- AND POST-IMPLANTATION.

WARNING: SURGICAL PROCEDURE SIDE EFFECTS

SURGICAL PROCEDURE RISKS MAY INCLUDE, BUT ARE NOT LIMITED TO:

- (TEMPORARY) PAIN AT THE IMPLANT SITES,
- HEADACHE,
- PAIN WHILE CHEWING IF THE TEMPORAL MUSCLE IS AFFECTED,
- MUSCLE FIBRILLATIONS AT THE IMPLANTATION SITE,
- ERYTHEMA,
- HEMATOMA,
- SWELLING, NUMBNESS, OR ITCHING AT IMPLANT SITE,
- SEVERE BLEEDING, E.G. FROM THE EXTERNAL JUGULAR VEIN,
- THROMBOSIS,
- PULMONARY EMBOLISM,
- SUBACUTE OR CHRONIC INFECTION OF THE DEVICE / ADJACENT TISSUE
- IMPAIRED WOUND HEALING / SORENESS OF SCAR.

WARNING: DAMAGE DUE TO THE SURGICAL PROCEDURE

DESPITE THE GREATEST CARE DURING PREPARATION OF THE IMPLANTATION SITES, DURING IMPLANTATION AND DURING TUNNELING, DAMAGE TO THE FOLLOWING STRUCTURES CANNOT BE RULED OUT:

- VESSELS (E.G. EXTERNAL JUGULAR VEIN),
- NERVES (E.G. FACIAL NERVES AND ACCESSORY NERVE),
- MUSCLES (E.G. TEMPORALIS MUSCLE), POSSIBLY WITH E.G. MUSCLE TENSION.

WARNING: POTENTIAL SIDE EFFECTS FROM ANESTHESIA

RISKS FROM GENERAL ANESTHESIA FOR SURGICAL PROCEDURE MAY INCLUDE, BUT ARE NOT LIMITED TO:

- TEMPORARY CONFUSION AND MEMORY LOSS,
- DIZZINESS,
- NAUSEA,
- VOMITING,
- DIFFICULTY PASSING URINE,
- BRUISING OR SORENESS FROM THE IV DRIP,
- SHIVERING AND FEELING COLD,
- SORE THROAT DUE TO THE BREATHING TUBE,
- MUSCLE ACHES,
- DECUBITUS ULCER.

WARNING: REDUCED EFFICACY OF STIMULATION

THE ELECTRODE ARRAY MAY BE UNFAVORABLY POSITIONED, E.G. CAUSED BY MISMATCH TO THE EPILEPTIC FOCUS OR BY INSUFFICIENTLY REMOVED PERIOSTEUM, WHICH MAY COMPROMISE THE TREATMENT WITH THE EASEE® SYSTEM.

WARNING: AESTHETIC RESULTS

THE IMPLANTATION OF THE IMPLANTABLE COMPONENTS OF EASEE® SYSTEM MAY LEAD TO UNACCEPTABLE AESTHETIC RESULTS.

WARNING: EASEE® LEAD EXPLANTATION

SURGICAL EXPLANTATION OF EASEE® LEAD MAY CAUSE TISSUE DAMAGE.

2.4.3 Warnings – EASEE® System and Therapy**WARNING: ADVERSE TISSUE REACTION**

ADVERSE TISSUE REACTIONS TO THE IMPLANTED EASEE® SYSTEM MATERIALS CANNOT BE EXCLUDED, BUT ARE EXTREMELY UNLIKELY.

WARNING: ALLERGIC REACTION

ALLERGIC REACTIONS TO THE MATERIALS OF THE EASEE® SYSTEM COMPONENTS CANNOT BE EXCLUDED, BUT ARE EXTREMELY UNLIKELY.

WARNING: CHRONIC TISSUE STIMULATION

THE EFFECTS OF LONG-TERM BRAIN STIMULATION ARE NOT COMPLETELY KNOWN AND MAY PRESENT SOME RISKS FOR THE PATIENT, E.G. FOR WORSENING OF THE DISEASE STATE OR INCREASED LIKELIHOOD OF OCCURRENCE OF ADVERSE EVENTS.

WARNING: POTENTIAL ADVERSE EVENTS CAUSED BY STIMULATION

SIDE EFFECTS THAT MAY BE CAUSED BY STIMULATION, MAY INCLUDE, BUT ARE NOT LIMITED TO:

- HEADACHE,
- DIZZINESS,
- TIREDNESS,
- PAIN, E.G. IN THE ELECTRODE AREA OF EASEE® LEAD,
- IMPAIRED SENSITIVITY, E.G. IN THE ELECTRODE AREA OF EASEE® LEAD,
- JERKS,
- ITCHING,
- PARAESTHESIA,
- DYSAESTHESIA,
- MUSCLE FIBRILLATIONS AT IMPLANTATION SITE.

WARNING: UNEXPECTED ADVERSE EVENTS DUE TO A DEFECTIVE DEVICE

AS WITH ANY MEDICAL TREATMENT, IT CANNOT BE RULED OUT THAT THERAPY WITH THE EASEE® SYSTEM MAY CAUSE UNEXPECTED SIDE EFFECTS.

WARNING: TEMPORARY SYSTEM FAILURE

THE LIFETIME OF THE IMPLANTABLE COMPONENTS OF EASEE® SYSTEM HAS BEEN TESTED PRIOR TO THE CLINICAL PHASE. HOWEVER, CLINICAL APPLICATION MAY RESULT IN CONDITIONS UNDER WHICH THE DEVICE UNEXPECTEDLY LOSES ITS FUNCTIONALITY EARLIER.

WARNING: WORSENING OF DISEASE STATE

ALTHOUGH IT HAS BEEN DEVELOPED TO TREAT EPILEPSY, APPLICATION OF THE EASEE® SYSTEM MAY IN UNLIKELY CASES LEAD TO WORSENING OF THE DISEASE STATE.

WARNING: SIDE EFFECTS AT IMPLANTATION SITE

PAIN, TENSION, DISCOMFORT, OR ERYTHEMA AT THE IMPLANTATION SITES, ESPECIALLY AT THE IMPLANTATION SITE OF EASEE® LEAD, ARE POSSIBLE.

WARNING: EROSION

SKIN EROSION MAY OCCUR AT AND/OR AROUND THE PULSE GENERATOR AND/OR LEAD IMPLANT SITE, PARTICULARLY IN THE CASE OF PROTRUSION OF THE IMPLANTED EASEE® SYSTEM PRODUCTS ABOVE THE SURFACE OF THE SKULL.

WARNING: LEAD MIGRATION

THE IMPLANTED LEAD MAY MIGRATE FROM THE ORIGINAL IMPLANT LOCATION, DESPITE THE INTENDED FIXATION. LEAD MIGRATION MAY RESULT IN CHANGES IN STIMULATION EFFECTIVENESS, AND MAY REQUIRE ADDITIONAL SURGICAL PROCEDURES TO MODIFY THE LEAD LOCATION.

WARNING: PREGNANT WOMEN

THE SAFETY AND EFFECTIVENESS OF THE EASEE® SYSTEM HAS NOT BEEN STUDIED IN PREGNANT WOMEN.

WARNING: EASEE® SYSTEM FAILURE

AS WITH ANY ELECTRONIC DEVICE, THE EASEE® SYSTEM MAY MALFUNCTION (NOT WORK). POTENTIAL CAUSES INCLUDE BATTERY MALFUNCTIONS, AN ELECTRICAL SHORT, OPEN CIRCUITS, LEAD FRACTURES, LEAD INSULATION FAILURES, OR DAMAGE, FOR EXAMPLE AS A RESULT OF HEAD TRAUMA. THESE MALFUNCTIONS ARE UNPREDICTABLE, AND MAY RESULT IN TOO LITTLE STIMULATION OR NO STIMULATION. A LEAD FAILURE MAY RESULT IN THE LEAD NEEDING TO BE REMOVED OR REPOSITIONED, WHICH WOULD REQUIRE SURGERY. A MALFUNCTIONING PULSE GENERATOR MAY NEED TO BE REPLACED, WHICH WOULD REQUIRE SURGERY. ALTHOUGH THE PULSE GENERATOR IS DESIGNED TO TURN OFF IF OVERSTIMULATION OR EXCESS CURRENT OCCURS, THERE IS A POSSIBILITY THAT PRODUCT FAILURE COULD RESULT IN ADJACENT BRAIN TISSUE DAMAGE.

WARNING: DAMAGE TO THE HOUSING

IF THE EASEE® POWER CASE (THE TITANIUM HOUSING) AND THE BATTERY HOUSING ARE RUPTURED OR PIERCED DUE TO OUTSIDE FORCES, SEVERE TISSUE DAMAGE COULD RESULT FROM EXPOSURE TO THE BATTERY CHEMICALS

WARNING: ELECTROMAGNETIC INTERFERENCE (EMI)

ELECTROMAGNETIC INTERFERENCE IS THE IMPAIRMENT IN FUNCTION CAUSED BY AN ENERGY FIELD GENERATED BY EQUIPMENT FOUND IN THE HOME, WORKPLACE, MEDICAL, OR PUBLIC ENVIRONMENTS THAT IS STRONG ENOUGH TO INTERFERE WITH PULSE GENERATOR FUNCTION. SOURCES OF STRONG ELECTROMAGNETIC INTERFERENCE CAN RESULT IN THE FOLLOWING EFFECTS:

- **SYSTEM DAMAGE** – RESULTING IN A LOSS OR CHANGE IN SYMPTOM CONTROL AND REQUIRING FURTHER SURGERY,
- **OPERATIONAL CHANGES TO THE PULSE GENERATOR** – FOR EXAMPLE UNWANTED DEACTIVATION OF THE PULSE GENERATOR,
- **UNEXPECTED CHANGES IN STIMULATION** – SHORT TERM CHANGES IN THE STIMULATION PULSES, WHICH MAY BE NOTICED BY THE PATIENT.

REFER TO *section 9 Electromagnetic Emissions and Immunity* FOR MORE INFORMATION.

WARNING: ENTERING AREAS PROTECTED BY WARNING SIGN

PATIENTS WITH AN IMPLANTED EASEE® POWER AND/OR EASEE® LEAD SHOULD BE WARNED TO SEEK MEDICAL GUIDANCE BEFORE ENTERING ENVIRONMENTS THAT COULD ADVERSELY AFFECT THE OPERATION OF THE EASEE® SYSTEM, INCLUDING AREAS PROTECTED BY WARNING SIGNS.

WARNING: INTERACTION WITH IMPLANTED CARDIAC DEVICES

POSSIBLE EFFECTS OF IMPLANTED DEVICE INTERACTION WITH AN IMPLANTED CARDIAC DEVICE (E.G., PACEMAKER OR DEFIBRILLATOR) INCLUDE THE FOLLOWING:

- DEFIBRILLATION THERAPY FROM AN IMPLANTED DEFIBRILLATOR MAY DAMAGE THE DEVICE.
- THE ELECTRICAL PULSES FROM THE NEUROSTIMULATION SYSTEM MAY INTERACT WITH THE SENSING OPERATION OF THE CARDIAC DEVICE AND COULD RESULT IN AN INAPPROPRIATE RESPONSE OF THE CARDIAC DEVICE AND VICE VERSA.
- FOR THESE REASONS, PATIENTS WITH AN IMPLANTED CARDIAC DEVICE SHOULD NOT BE TREATED WITH EASEE® SYSTEM.

WARNING: INTERACTIONS WITH OTHER IMPLANTED MEDICAL DEVICES

INTERACTIONS BETWEEN THE EASEE® SYSTEM AND OTHER ACTIVE IMPLANTED MEDICAL DEVICES (E.G., PACEMAKERS, DEFIBRILLATORS, DBS DEVICES, SPINAL CORD STIMULATORS, COCHLEAR IMPLANTS) HAVE NOT BEEN STUDIED. SIMULTANEOUS OPERATION OF SUCH DEVICES MAY RESULT IN INTERFERENCE, INAPPROPRIATE DEVICE RESPONSES, OR SENSING PROBLEMS.

AN EXCEPTION EXISTS FOR INACTIVE VAGAL NERVE STIMULATION (VNS) DEVICES, PROVIDED THEY MEET THE CONDITIONS OUTLINED IN THE CONTRAINDICATIONS SECTION. PHYSICIANS MUST VERIFY THAT THE VNS DEVICE IS TURNED OFF AND REMAINS INACTIVE THROUGHOUT THE STUDY.

WARNING: NOTICE TO USER AND PATIENT

ANY SERIOUS INCIDENT MUST BE REPORTED TO THE MANUFACTURER AND / OR COMPETENT AUTHORITY.

2.4.4 Warnings – EASEE® Set / EASEE® Connect, device combination for data access and programming

WARNING: EASEE® CONNECT PLACEMENT

ALWAYS ENSURE TO PLACE EXTERNAL COMMUNICATION DEVICES (E.G. EASEE® CONNECT, EASEE® ACCESS) CLOSE TO THE EASEE POWER IMPLANT, I.E. WITHIN 20 CM (APPROX. 8 IN); IN CASE ANOTHER ACTIVE IMPLANTABLE DEVICE (E.G. A VAGUS NERVE STIMULATOR) IS IMPLANTED, ASSURE THAT YOU DON'T PLACE THE EXTERNAL COMMUNICATION DEVICE CLOSE TO THE WRONG IMPLANT.

WARNING: POTENTIAL ELECTRIC SHOCK

SUBMERGING ANY PART OF EASEE® SET / EASEE® CONNECT IN WATER, OR OPERATING EASEE® SET / EASEE® CONNECT OR ANY PART OF IT IN A WET ENVIRONMENT, MAY RESULT IN AN ELECTRICAL SHOCK. EASEE® SET MUST BE DISCONNECTED FROM THE ELECTRICAL OUTLET PRIOR TO CLEANING.

ELECTRICAL SHOCK MAY OCCUR IF THE EASEE® SET AC ADAPTER AND POWER CORD ARE NOT PROPERLY CONNECTED TO A GROUNDED POWER SOURCE.

NO OTHER COMMERCIALY AVAILABLE ACCESSORY OF THE TABLET PC MUST BE USED DURING THE APPLICATION OF EASEE® SET EXCEPT THE SPECIFIED POWER SUPPLY (EDAC POWER ELECTRONICS CO., LTD ADAPTER EM1024Q2-MITA). OTHERWISE, ELECTRICAL SHOCK MAY OCCUR.

WARNING: UNAUTHORIZED MODIFICATION

EASEE® CONNECT SHALL NOT BE MODIFIED FROM ITS DELIVERED CONDITION. UNAUTHORIZED MODIFICATION OF EASEE® CONNECT CAN CAUSE UNSAFE CONDITIONS, LOSS OF FUNCTIONALITY, SHORTENED BATTERY LIFE, AND OTHER ISSUES.

WARNING: ONLY USE EASEE® CONNECT IN COMBINATION WITH EASEE® SET

EASEE® CONNECT REQUIRES THE CONNECTION TO EASEE® SET BY USB CABLE. DO NOT CONNECT EASEE® CONNECT WITH OTHER DEVICES OR POWER SOURCES OTHER THAN EASEE® SET.

2.4.5 Warnings – EASEE® Access Handheld Device

WARNING: EASEE® ACCESS PLACEMENT

ALWAYS ENSURE TO PLACE EASEE® ACCESS CLOSE TO THE EASEE® POWER IMPLANT, I.E. WITHIN 20 CM (APPROX. 8 IN); IN CASE ANOTHER ACTIVE IMPLANTABLE DEVICE (E.G. A VAGUS NERVE STIMULATOR) IS IMPLANTED, ASSURE THAT YOU DON'T PLACE EASEE® ACCESS CLOSE TO THE WRONG DEVICE.

WARNING: UNAUTHORIZED MODIFICATION

EASEE® ACCESS SHALL NOT BE MODIFIED FROM ITS DELIVERED CONDITION. UNAUTHORIZED MODIFICATION OF EASEE® ACCESS CAN CAUSE UNSAFE CONDITIONS, LOSS OF FUNCTIONALITY, SHORTENED BATTERY LIFE, AND OTHER ISSUES.

WARNING: EASEE® ACCESS BATTERY USAGE

THE USE OF UNSPECIFIED TYPES OF BATTERIES (E.G. OTHER THAN ALKALINE) MAY LEAD TO UNSAFE DEVICE CONDITIONS.

WARNING: OPERATING CONDITIONS

DUST AND LINT CAN AFFECT THE FUNCTIONALITY OF EASEE® ACCESS. STORE AND USE EASEE® ACCESS IN A CLEAN ENVIRONMENT.

EXPOSURE OF EASEE® ACCESS TO SUNLIGHT CAN LEAD TO MATERIAL CHANGES (DISCOLORATION, BRITTLINESS, DEFORMATION). KEEP EASEE® ACCESS AWAY FROM DIRECT SUNLIGHT.

EASEE® ACCESS SHOULD NOT BE EXPOSED TO INCREASED TEMPERATURES OR STEAM, E.G. NEAR OPEN FIRES, STOVES, KETTLES ETC.

STORE AND USE EASEE® ACCESS IN DRY CONDITIONS, DO NOT EXPOSE TO LIQUIDS.

WARNING: KEEP AWAY FROM CHILDREN AND PETS

EASEE® ACCESS CONTAINS SMALL PARTS THAT CAN BE SWALLOWED. IT MAY BE MISTAKEN FOR A TOY. THERE IS A RISK OF MISUSE BY CHILDREN AND PETS. KEEP EASEE® ACCESS AWAY FROM CHILDREN AND PETS.

2.4.6 Warnings – Electromagnetic Compatibility (EMC)**WARNING: INTERFERENCE PROBLEMS**

DEVICES WHICH EMIT RADIO FREQUENCY, SUCH AS MOBILE PHONES, COMPUTERS OR REMOTE-CONTROLLED TOYS CAN INTERFERE WITH THE ELECTROMAGNETIC COMMUNICATION OF EASEE® ACCESS AND EASEE® POWER.

WHEN OPERATING, KEEP EASEE® ACCESS AWAY FROM SUCH CONDITIONS AND DEVICES.

WARNING: ELECTROMAGNETIC EMISSIONS / ELECTROMAGNETIC IMMUNITY

USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT MAY RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.

WARNING: INTERACTIONS WITH RF COMMUNICATIONS EQUIPMENT

PORTABLE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF EASEE® ACCESS OR EASEE® CONNECT INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

2.4.7 Warnings – Medical Environment**WARNING: LITHOTRIPSY**

THE EFFECTS OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY ON THE EASEE® SYSTEM HAVE NOT BEEN STUDIED. EXPOSURE TO HIGH-OUTPUT ULTRASONIC FREQUENCIES MAY DAMAGE THE EASEE® SYSTEM. THIS COULD RESULT IN LOSS OF THERAPY, AND ADDITIONAL SURGERY TO REMOVE OR REPLACE COMPONENTS OF THE EASEE® SYSTEM. PRIOR TO ANY ADMINISTRATION OF LITHOTRIPSY, THE ADMINISTERING PHYSICIAN SHOULD CONSULT WITH THE PHYSICIAN PRESCRIBING THE EASEE® SYSTEM.

WARNING: RADIATION

THE EFFECTS OF IONIZING RADIATION (SUCH AS COBALT-60 OR X RAY RADIATION USED IN CANCER THERAPY) ON THE EASEE® SYSTEM HAVE NOT BEEN STUDIED. EXPOSURE TO HIGH LEVELS OF RADIATION MAY DAMAGE THE EASEE® SYSTEM, ALTHOUGH THE DAMAGE MAY NOT BE IMMEDIATELY DETECTABLE. THIS COULD RESULT IN LOSS OF THERAPY, AND ADDITIONAL SURGERY TO REMOVE OR REPLACE COMPONENTS OF THE EASEE® SYSTEM. PRIOR TO ANY COURSE OF RADIATION THERAPY, THE ADMINISTERING PHYSICIAN SHOULD CONSULT WITH THE PHYSICIAN PRESCRIBING THE EASEE® SYSTEM.

WARNING: ELECTROLYSIS

THE EFFECTS OF ELECTROLYSIS ON THE EASEE® SYSTEM HAVE NOT BEEN STUDIED. ELECTROLYSIS ON THE HEAD OR NECK SHOULD BE AVOIDED.

WARNING: MAGNETIC RESONANCE IMAGING (MRI)

THE EASEE® SYSTEM IS ASSESSED TO BE MRI CONDITIONAL. PATIENTS WITH THE EASEE® SYSTEM IMPLANTED SHOULD HAVE MRI PROCEDURES PERFORMED ONLY AS DESCRIBED IN THE MRI SAFETY GUIDELINES AVAILABLE AT PRECISIS GMBH.

WARNING: COMPUTED TOMOGRAPHY (CT) SCANS

FOR CT PROCEDURES ON A PATIENT WITH AN IMPLANTED EASEE® POWER (NEUROSTIMULATOR), THE OPERATOR SHOULD:

- ASK THE PATIENT TO HAVE THE NEUROSTIMULATOR TEMPORARILY SWITCHED OFF WHILE THE SCAN IS PERFORMED, IF POSSIBLE.
- MINIMIZE X RAY EXPOSURE OF THE IMPLANTED ELECTRONIC MEDICAL DEVICE
- USE THE LOWEST POSSIBLE X RAY TUBE CURRENT CONSISTENT WITH OBTAINING THE REQUIRED IMAGE QUALITY.

MAKE SURE THAT THE X RAY BEAM DOES NOT ACT ON THE DEVICE FOR MORE THAN A FEW SECONDS. IMPORTANT NOTE: FOR CT PROCEDURES THAT REQUIRE CONTINUOUS SCANNING OVER THE MEDICAL DEVICE FOR MORE THAN A FEW SECONDS, AS WITH CT PERFUSION OR INTERVENTIONAL EXAMS, ATTENDING STAFF SHOULD BE READY TO TAKE EMERGENCY MEASURES TO TREAT ADVERSE REACTIONS IF THEY OCCUR.

AFTER CT SCANNING, THE OPERATOR SHOULD:

- ASK THE NEUROLOGIST TO HAVE THE NEUROSTIMULATOR TURNED BACK ON USING EASEE® SET / EASEE® CONNECT IF IT HAD BEEN SWITCHED OFF PRIOR TO SCANNING.
- ADVISE THE PATIENTS TO CONTACT THEIR HEALTHCARE PROVIDER AS SOON AS POSSIBLE IF THEY HAVE QUESTIONS OR SUSPECT THEIR DEVICE IS NOT FUNCTIONING PROPERLY AFTER ANY MEDICAL PROCEDURE.

2.4.8 Precautions - Surgical**Precaution: EASEE® Lead Damage**

Bending, kinking, and stretching of EASEE® Lead may cause connecting cable and/or electrode damage. Handle EASEE® Lead with care. In particular, the EASEE® Lead connector should not be bent.

Precaution: Subgaleal Placement of EASEE® Lead

Electrodes placed on or close to the periosteum may cause pain or uncomfortable sensations during electrical stimulation. Remove periosteum as fully as possible from the skull surface where the electrode will be implanted.

Precaution: Screwing the Electrodes of EASEE® Lead to the Skull

Insufficient fixation of the electrodes to the skull may lead to inefficient therapy or side effects due to leakage currents. Ensure that the electrodes are fixed with close contact to the skull and that the silicone rim of each electrode rests tightly on the skull.

Precaution: Screwing EASEE® Lead

Using other screws than those recommended for use with EASEE® System for fixation of EASEE® Lead may cause damage and malfunction of EASEE® Lead.

Precaution: Suturing EASEE® Lead

Suturing directly to the EASEE® Lead electrode array may cause damage and malfunction of EASEE® Lead and should be avoided.

Precaution: Bending the Extension Shaft of the Tunneling Tool

Do not bend the extension shaft at an angle greater than 90° at any one bend. An angle greater than 90° may damage the shaft and prevent the EASEE® Lead connecting cable from being advanced, or damage the connecting cable, resulting in intermittent or loss of stimulation.

Precaution: Routing the EASEE® Lead Connecting Cable

When routing the EASEE® Lead connecting cable, avoid sharp bends or kinks, which may break the wires. Broken wires may create an open circuit, resulting in loss of stimulation or component failure and requiring surgical replacement.

Precaution: Tunneling Procedure

Proceed slowly when the tunneling tool approaches the pocket for EASEE® Power. If excess force is used, the patient could experience additional trauma when resistance to the tunneling tool is suddenly reduced.

Precaution: Tunneling the EASEE® Lead Connecting Cable

Use care when inserting and advancing the EASEE® Lead connecting cable into the extension shaft and when removing the extension shaft. Rough handling can damage lead insulation and compromise patient safety and the treatment with EASEE® System.

Precaution: Using the Activation Magnet in Sterile Environment

The activation magnet is non-sterile and non-sterilizable and should therefore be placed in a sterile bag for use in the sterile field.

Precaution: Using EASEE® Connect in a Sterile Environment

EASEE® Connect is non-sterile and non-sterilizable and should therefore be placed in a sterile bag for use in the sterile field.

2.4.9 Precautions - EASEE® System and Therapy

Precaution: Accompanying Documentation

Please check the completeness of the accompanying documentation of the EASEE® System components, as well as the accessories, which are not manufactured or provided by Precisis GmbH. Take care to read and understand the contents of this documentation, as non-compliance with its contents may give rise to additional risks.

Precaution: Applying Pressure on the Pulse Generator and Lead

DO NOT press on or play with the implanted pulse generator or leads. This may damage the pulse generator or leads and result in stimulation not being delivered until they are surgically repaired or replaced.

Precaution: After-discharge activity

If evidence of after-discharge activity is seen during test stimulation, stimulation parameters should be adjusted to prevent this.

Precaution: Battery Depletion and Replacement of EASEE® Power

For continued operation, EASEE® Power needs to be surgically replaced before the battery is depleted. Discuss with your patient when replacement of the pulse generator is expected to take place.

Precaution: Depletion of the EASEE® Power Battery

The patient should inform the responsible physician in good time before depletion of the EASEE® Power battery, at the latest when the upper left indicator light of EASEE® Access flashes yellow in response to a battery status query. This means the battery capacity is sufficient for less than 7 weeks.

Precaution: Neurostimulator Battery Longevity

High and frequent levels of stimulation reduce neurostimulator battery longevity.

Precaution: Turning EASEE® Power Off

Once turned off, EASEE® Power can only be reactivated by the physician using a dedicated programming tool, called EASEE® Set / EASEE® Connect, which controls EASEE® Power.

Precaution: Premature Depletion of the EASEE® Power Battery

Interrogating EASEE® Power using wireless RF communication via EASEE® Connect or EASEE® Access for more than 10 minutes per day may drain the EASEE® Power battery prematurely.

Precaution: Premature Depletion of the EASEE® Access Battery

Using EASEE® Access for more than 10 minutes per day may drain the EASEE® Access battery prematurely.

Precaution: Frequency of Remote Monitoring

The patient should interrogate the EASEE® Power battery status with EASEE® Access daily for early detection of potential failures.

Precaution: Explantation and EMI Considerations

If any system components (neurostimulator, electrodes, connecting cables, connecting cable fragments, cranial screws) remain implanted in the patient after partial system explantation, the patient is still susceptible to possible side effects from strong sources of EMI. It is possible for the interference sources to couple so much energy into the EASEE® System that adjacent brain tissue is damaged. In very unlikely cases this may result in serious patient injury. Patients who have system components or its accessories implanted should therefore take care to avoid devices which generate a strong electric or magnetic field.

Refer to **section 9 Electromagnetic Emissions and Immunity** for more information.

Precaution: Explantation of EASEE® Lead and EASEE® Power

It is strongly recommended to always explant both, EASEE® Lead together with EASEE® Power. The long-term safety associated with EASEE® Lead being left in place without use, the replacement of EASEE® Lead, and the explantation of EASEE® Lead is unknown. It should be assumed that an EASEE® Lead without connection to an EASEE® Power is MR unsafe.

Precaution: Setting Sham-Mode for Patient Controlled Neurostimulation (PCN)

Before proceeding, verify that the patient is correctly assigned to the sham stimulation group (control group). EASEE Access will confirm successful triggering of PCN despite no stimulation being delivered (sham).

2.4.10 Precautions - EASEE® Set / EASEE® Connect

Precaution: Failure of EASEE® Set / EASEE® Connect

As with any electronic device, EASEE® Set / EASEE® Connect may be damaged or may malfunction if the EASEE® Set AC adapter and power cord are not properly connected to a grounded power source.

2.4.11 Precautions - Medical Environment

Precaution: Medical Procedures

Patients should always inform any healthcare personnel that they have an implanted EASEE® System (and show their medical implant identification card) before any medical procedure is performed. Advise the patient to contact their healthcare provider as soon as possible if they have questions

or suspect that their device is not functioning properly following the completion of any medical procedure.

Precaution: Electrocautery

The use of electrocautery (electrosurgery) can affect the operation of neurostimulators. The energy levels used in electrocautery can temporarily interfere with or permanently damage the EASEE® System.

Electrocautery applied near the EASEE® Power may cause it to temporarily stop delivering stimulation or may reset the neurostimulator. Under these conditions the neurostimulator may require interrogation and possible reprogramming.

Electrocautery applied directly to the neurostimulator or leads may couple enough energy into a neurostimulator system to damage brain tissue.

If electrocautery is necessary, the following recommendations may be effective in minimizing potential complications.

Before the procedure:

If possible, temporarily disable stimulation using EASEE® Set / EASEE® Connect.

During the procedure:

- Use of bipolar electrocautery is recommended and should be considered over monopolar electrocautery, whenever possible.
- Keep the electrocautery tip more than 2 cm (approximately one inch) from the implanted device.
- The selected output power of the electrocautery unit should be as low as possible for the relevant application and should not be used for longer than 10 seconds in any one burst.

After the procedure:

- If stimulation was temporarily disabled before the procedure, re-enable stimulation using EASEE® Set / EASEE® Connect.
- Patients should be advised to contact their healthcare provider as soon as possible if they have any questions or suspect that their device is not functioning properly following the completion of any medical procedure.

Precaution: Dental Therapy and Procedures

Dental therapies and procedures that do not involve any of the procedures in the contraindications or warnings sections of this manual should be performed with caution. The dentist or dental technician should be informed that the patient has an implanted EASEE® System.

Advise the patient to contact their healthcare provider as soon as possible if they have questions or suspect that their device is not functioning properly following the completion of any medical

procedure.

The following medical procedures may be performed without affecting the EASEE® System:

- Diagnostic X-rays
- Diagnostic ultrasound

Precaution: Other Active Implanted Medical Devices

Interactions between the EASEE® System and other active implantable medical devices (such as pacemakers, defibrillators, implanted spinal cord and peripheral nerve stimulators, cochlear implants, and vagus nerve stimulation device) are not known. The effects of simultaneous operation of the EASEE® System with other active implants have not been investigated. Possible effects include sensing problems and inappropriate device responses. For these reasons, patients with an active implanted device should not be treated with EASEE® System. The only exception is a vagus nerve stimulation device that is reliably turned off for the duration of EASEE® System application.

Precaution: Incompatibility of EASEE® Set / EASEE® Connect with Other Medical Devices

The effects of using EASEE® Set / EASEE® Connect to interrogate other electronic, programmable devices such as pacemakers, defibrillators, cochlear implants, and other neurostimulators or CPAP machines are unknown. It could result in reprogramming of the other device and therefore, the physicians familiar with each device should check the programmed parameters of each device before the patient is discharged and after every programming session of either device.

Precaution: Electromagnetic Interference

Communications between EASEE® Set / EASEE® Connect and EASEE® Power may be interrupted by emissions from nearby electronic devices. Examples of sources of EMI are lithotripsy, computer monitors, cellular telephones, motorized wheelchairs, X ray equipment and other monitoring equipment. Interruption of telemetry can result in incomplete communication. If EMI disrupts programming, move EASEE® Set / EASEE® Connect away from the likely source of EMI. Refer to **section 9 Electromagnetic Emissions and Immunity** for more information.

Precaution: Placement of the EASEE® Set / EASEE® Connect Power Cords

Make sure that nothing is resting on the power cable and that the cable is not located where it can be tripped over or stepped on.

Precaution: Heating

The EASEE® Set AC adapter and the bottom of the tablet may become hot during normal operation. Use care when handling the AC adapter during or immediately after operation.

2.4.12 Precautions - Home or Occupational

Precaution: Keep Magnets at Least 10 Centimeters Away from the Implanted EASEE® Power

Magnets that are contained in devices such as stereo speakers, AM/FM radios, power tools, cellular, cordless, and conventional phones, as well as magnets used therapeutically or worn on the body, should be kept at least 10 cm (4 in) away from the neurostimulator.

Precaution: Activation Magnet for the EASEE® System

Use care when handling the activation magnet for the EASEE® System as it may break if dropped and the broken pieces may have sharp edges.

Precaution: Scuba Diving or Hyperbaric Chambers

Patients should not dive below 4 meters of water and should not enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). Such pressures could damage the system.

Precaution: Precautions - Airport Security and Other Surveillance Systems

Patients should tell people working with security and theft systems that they have the EASEE® System implanted and show them their medical implant identification card. When possible, patients should walk through the center of security screening units without stopping and exit the area of the screening device as soon as possible. They should leave the security area as soon as possible. Security screening devices (such as theft detectors and airport security screening devices) may also be found at retail stores, public libraries, and airports. Such devices use technology that can (temporarily) disrupt stimulation for the duration of the screening.

2.5 EASEE® System Description and Components

The EASEE® System (Epicranial Application of Stimulation Electrodes for Epilepsy) is an implantable stimulation device, which is indicated for the treatment of medically refractory focal epilepsy. The EASEE® System consists of:

- the implantable components
 - EASEE® Power (IPG) and
 - EASEE® Lead (electrode array and connecting cable),
- the surgical tools
 - EASEE® Template (tool for checking the implant location),
 - torque wrench,
 - bone screw set and screwdriver set used to fix the electrode array to the skull (provided by a third party medical device manufacturer, FDA approved),
 - a tunneling tool for routing the EASEE® Lead connector cable through the patient body to the EASEE® Power location (not provided),
- external control elements
 - EASEE® Set (tablet PC with pre-installed EASEE® Power programming software for physicians)
 - EASEE® Connect (additional telemetry device for EASEE® Set),
 - EASEE® Access (handheld device for patients),
- Not provided: an activation magnet for waking up EASEE® Power from sleep mode.

Neither the EASEE® System nor its components (except those mentioned above) are approved for sale in the US market. Exceptions are the FDA approved components from third party manufacturers. Details about this may be requested from Precisis GmbH e.g. via e-mail:

customerservices@precisis.de.

All personnel and patients must complete an application training before using, implanting, or programming the EASEE® System. In addition, all study personnel must complete prior training on study procedures.

2.6 EASEE® System Implantable Components

2.6.1 EASEE® Power

EASEE® Power is an implantable electrical pulse generator that is delivered sterile (sterilized using ethylene oxide, labeled on the packaging as “STERILE EO”). EASEE® Power is implanted caudal to the clavicle. EASEE® Power is powered by batteries that are contained in a housing, which also holds the stimulation control electronics. The top part contains the connector block for connecting to EASEE® Lead, as well as an RF antenna to communicate with the external devices EASEE® Access and EASEE® Set / EASEE® Connect.

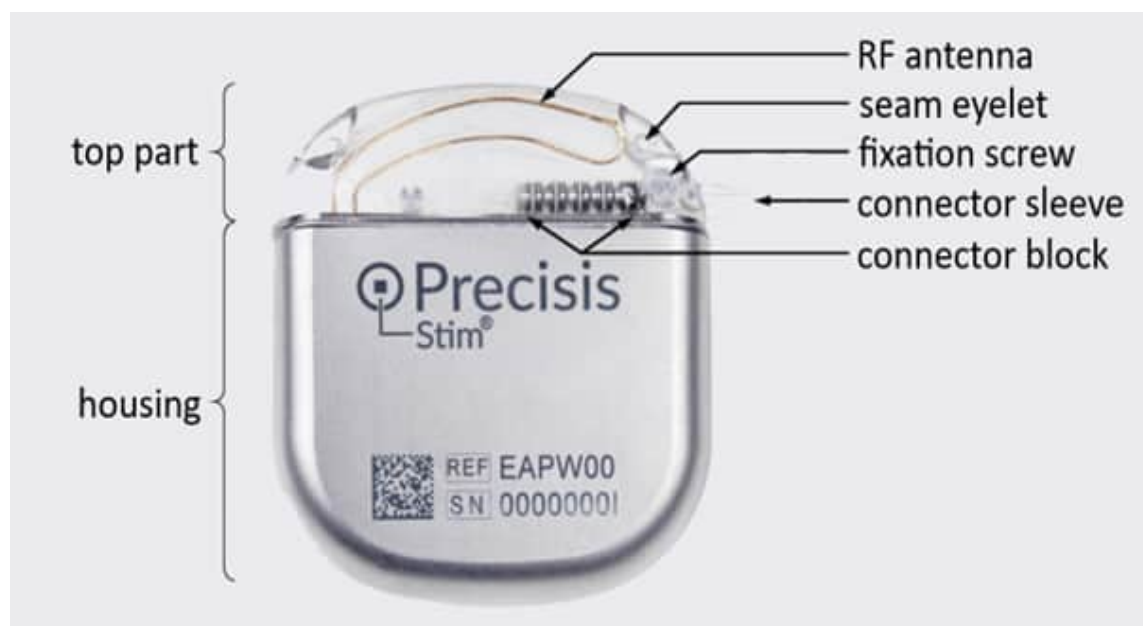


Figure 2.2: EASEE® Power (labeled 'Precis Stim®') comprises a titanium housing that encloses the batteries and the electronics, and a top part (header). (Example for illustration only, related to REF and SN.)

2.6.2 EASEE® Lead

EASEE® Lead is an implantable electrode array with connecting cable and connector, for connection to EASEE® Power. EASEE® Lead is provided sterile (sterilized using ethylene oxide, labelled on the packaging as “STERILE EO”).



Figure 2.3: EASEE® Lead consists of the electrode array with strain relief (left), the connecting cable (middle) and the connector (right).

The electrode array consists of five electrodes arranged in a pseudo-Laplacian form, i.e. a central electrode surrounded by four peripheral electrodes to allow precise targeting of defined areas of the brain. The electrode array is implanted subgaleally (i.e. under the scalp, but outside the skull). The connecting cable is implanted subcutaneously from the head to the chest. It is connected to EASEE® Power via the connector.

2.7 Surgical Tools and Accessories for EASEE® System

2.7.1 EASEE® Template

EASEE® Template is a sterile product that has the same geometry and size as the EASEE® Lead electrode array. It enables the neurosurgeon to check the appropriateness of the subgaleal pocket for implantation of the EASEE® Lead electrode array in terms of size and orientation.

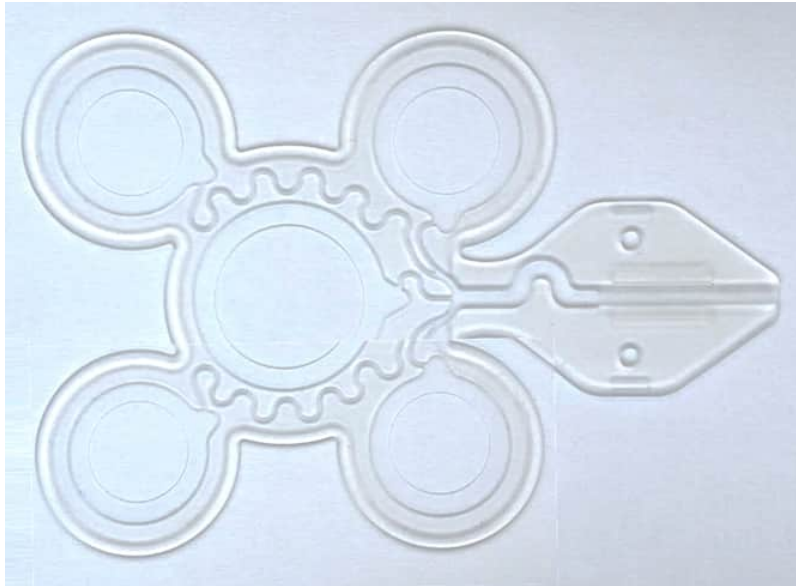


Figure 2.4: EASEE® Template has the same areal dimensions as the EASEE® Lead electrode array and can be used to check whether the dimensions of the implantation pocket for EASEE® Lead are large enough.

2.7.2 Bone Screws

Sterile bone screws are needed to fix the EASEE® Lead electrode array onto the skull and to establish a strain relief between the electrode array and the EASEE® Lead connecting cable.



Figure 2.5: Example for illustration only: Unpacked bone screws.

Only specific screws can be used to fix the electrode array of EASEE® Lead. The manufacturer of the bone screws is a third-party supplier. These screws are supplied with the EASEE® System. For

supplier information please refer to **section 2.9 Summary of Accessories for EASEE® System**.

2.7.3 Screwdriver

The screwdriver recommended for the use with EASEE® System matches the screws (see table 1). This non-powered, hand-held instrument is provided non-sterile and must be sterilized before use according to the parameters included in the Screwdriver Handle and Blade instructions for use which is provided by its manufacturer.

The manufacturer of the screwdriver is a third-party supplier. Screwdriver is supplied with the EASEE® System. For supplier information please refer to **section 2.9 Summary of Accessories for EASEE® System**.



Figure 2.6: Screwdriver used for fixation of EASEE® Lead via bone screws (example for illustration only).

2.7.4 Tunneling Tool

The tunneling tool is a sterile packed device for use by the neurosurgeon to aid the subcutaneous routing of the EASEE® Lead connecting cable between the skull and the chest. The manufacturer of the tunneling tool is a third-party supplier, and the tunneling tool must be acquired with given specifications. For more information, please refer to **section 2.9 Summary of Accessories for EASEE® System**.



Figure 2.7: The tunneling tool consists of an extension shaft with handle and several kinds of obturators (example for illustration only).

2.7.5 Torque Wrench

The torque wrench is used for mechanical fixation of EASEE® Lead to EASEE® Power. It is supplied sterile packed and ensures a tight but protective fixation.



Figure 2.8: The torque wrench is used for appropriate fixation of the reversible connection between EASEE® Lead and EASEE® Power.

2.7.6 Activation Magnet

The activation magnet is a non-sterile device that is needed to turn on EASEE® Power at the first use and also after each time EASEE® Power has been switched off using EASEE® Access or EASEE® Set. Activation magnet must be acquired with given specifications. For more information, please refer to **section 2.9 Summary of Accessories for EASEE® System**.



Figure 2.9: The activation magnet is a ring-shaped magnet for contactless turning on of EASEE® Power (example for illustration only).

2.7.7 Surgical Tools

The surgical tools include EASEE® Template (a tool for checking the implant location), a torque wrench to secure the connector of EASEE® Lead to the EASEE® Power, a screw/screwdriver set used

to fix the electrode pad onto the skull, and a tunneling device for routing the connecting cable under the skin.

2.8 EASEE® System External Control Elements

2.8.1 EASEE® Set / EASEE® Connect

The combination of EASEE® Set / EASEE® Connect is used to set the stimulation parameters according to the individual needs of each patient, as well as to test the functionality of EASEE® Power (battery life, electrode impedance).



Figure 2.10: EASEE® Set / EASEE® Connect is the combination of EASEE® Set (left) and EASEE® Connect (right).

2.8.2 EASEE® Connect

EASEE® Connect is an external, non-sterile device that enables the RF communication between EASEE® Set and EASEE® Power.

EASEE® Connect is protected against solid particles of size larger than 12.5 mm (1/2 in). It is also protected against water splashing from any angle. This degree of protection is indicated by the code “IP24” on the back of EASEE® Connect.

2.8.3 EASEE® Set

The software used to program EASEE® Power is pre-installed on a tablet PC. The software application, together with the tablet PC, is referred to as EASEE® Set. The software is referred to as EASEE® Set – Software and the tablet PC is referred to as EASEE® Set – Hardware.

2.8.4 EASEE® Access

EASEE® Access is an external, non-sterile handheld device for the patient (Figure 5). It enables the patient to turn EASEE® Power off. Further, EASEE® Access also displays on demand the battery level of EASEE® Power as well as its own battery level. In addition, the patient may use it to trigger patient controlled neurostimulation, that is administered upon request in addition to the usual periodic stimulation, if this function has been activated by the attending physician. EASEE® Access is protected against a quantity of dust that could interfere with the normal operation of the product but is not fully dust tight. It is also protected against water splashing from any angle. The level of protection is reflected by the label “IP54”, which is displayed on the back of EASEE® Access. Before first use, the batteries must be activated by opening the battery compartment and removing the protective foil (with the words “REMOVE BEFORE USE”) that is present. Removal of the foil creates a connection between the batteries and the electronics so that the device is ready to use.



Figure 2.11: Front view (left) and rear view (middle) of EASEE® Access. Right side: Battery compartment open.

2.9 Summary of Accessories for EASEE® System

To aid EASEE® System implantation following accessories are required, a bone screw / screwdriver set to fix the electrode array onto the skull, a tunneling tool and a ring-shaped activation magnet for turning on EASEE® Power.

The tunneling tool and activation magnet that are approved by FDA for use in the United States must be acquired directly from the suppliers as listed in Table 3.

Note: Tunneling tool and activation magnet can also be sourced with given specifications from suppliers other than those listed below.

Component	Dimension / Qty.	Manufacturer	Reference Number
Screws	1.5x4mm, qty. 1 1.5x4mm, qty. 2 1.5x4mm, qty. 5 1.5x4mm, qty. 1 [#] 1.5x4mm, qty. 5 [#]	Biomet Microfixation 520 Tradeport Drive Jacksonville, FL 32218-2481 United States	REF 15-6104, GUDID 00888233006958 REF SP-ST2-6104, GUDID 00888233019200 REF SP-ST5-6104, GUDID 00888233019408 REF 91-6104, GUDID 00841036053734 REF 95-6104, GUDID 00841036056650
Screws (Emergency)	1.8 x 3.5mm, qty. 1 1.8 x 3.5mm, qty. 1 [#] 1.8 x 5mm, qty. 1 1.8 x 5mm, qty. 1 [#]		REF 15-1803, GUDID 00841365107269 REF 91-1803, GUDID 00841036056247 REF 91-1805, GUDID 00841036053345 REF 15-1805, GUDID 00888233006705
Screwdriver (Handle)	Green Standard		REF 01-7390, GUDID 00841036014087 REF 01-7164, GUDID 00841036013264
Screwdriver (Blade)	short		REF 15-1194, GUDID 00841036032432
Tunneling tool	Max. length: 38cm (15 in) Min. inner diameter: 3.9mm (5/32 in)	<u>For example:</u> St Jude 6901 Preston Road TX 75024 Plano, USA	<u>For example:</u> REF 1191, GUDID 05414734400664
Activation magnet	Min. field strength: 90 gauss measured 40 mm (1.5 in) from magnet surface	<u>For example:</u> Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432, USA	<u>For example:</u> REF 9466, GUDID 20613994647812
These screws and screwdrivers provided by Vigomed are only authorized for use outside the United States:			

Table 3: Accessories for EASEE® System

Component	Dimension / Qty.	Manufacturer	Reference Number
Not available in the United States	Screws	Vigomed Medizintechnik GmbH Bayernstrasse 38, 97204 Höchberg, Germany	REF LP-5024-S UDI-DI 4250786503530
	Screws (Emergency)		REF LP-5064-S UDI-DI 4250786503899
	Screwdriver Handle (Steel)		REF HG-5000 UDI-DI 4250786504964
	Screwdriver Handle (Titanium)		REF HG-6000 UDI-DI 4250786504971
	Screwdriver Blade/Stilet		REF KS-5100 UDI-DI 4250786504902

Screws provided non-sterile must be sterilized according to the manufacturer's instructions prior to use.

Table 3 : Accessories for EASEE® System

2.10 Transport, Storage, Handling, Sterilization and Cleaning

2.10.1 Product Transport and Storage

Transport and Storage Conditions

The components of the EASEE® System should be transported and stored according to the specifications indicated on the packaging of the components. The specifications are also listed in **section 8 Specifications** in the appropriate table for each component.

All components of the EASEE® System should be stored in a clean and secure location.

Damaged Packaging

Prior to use of any sterile component of the EASEE® System, inspect the sterile packages for seal integrity. If the packaging appears to be wet, torn or damaged, the contents may no longer be sterile. These components should be returned to Precisis GmbH for replacement.

2.10.2 Product Handling

Operating Conditions

The operating conditions of the EASEE® System components are as listed in **section 8 Specifications** in the appropriate table for each component.

The accessories of the EASEE® System listed below are provided by third parties and should be treated in accordance with the conditions of the accompanying manufacturer's documentation:

- Screws
- Screwdriver
- Tunneling tool
- Activation magnet
- Tablet PC

Careful Handling

All components of the EASEE® System must be handled with extreme care. Special care should be taken handling EASEE® Lead:

- Handle EASEE® Lead extremely carefully. In particular, the connector of EASEE® Lead should never be bent, kinked, or stretched.
- Avoid bending, and stretching EASEE® Lead as this can cause damage to the connecting wires or electrodes. None of the parts of EASEE® Lead should ever be kinked.
- Do not overtighten the sutures over any part of EASEE® Lead.
- Use only the supplied torque wrench to secure the set screw to fix the EASEE® Lead connector in the connecting block of EASEE® Power.

Electrostatic Discharge (ESD) / Static Electricity

EASEE® Power and EASEE® Lead may be sensitive to electrostatic discharge (ESD) / static electricity. Handle both devices carefully. For example, avoid allowing the surfaces of these two devices to rub against non-conductive objects, for example when unpacking.

The USB cable supplied with EASEE® Connect and the EASEE® Set cases may be sensitive to electrostatic discharge (ESD) / static electricity. Handle both devices carefully. If electrostatic discharge occurs, EASEE® Set and the USB cable supplied with EASEE® Connect may experience telemetry artifacts or may freeze.

The **section 7 Troubleshooting** contains information to be used if EASEE® Set freezes.

“Use by” date.

Do not implant or use any component of the EASEE® System after the “Use by” date. Return all such components to Precisis GmbH.

2.10.3 Product Sterilization

Sterile, Non-Resterilizable Components

- The EASEE® Power neurostimulator is supplied sterile (sterilized with ethylene oxide). DO NOT RESTERILIZE.
- The torque wrench for mechanical fixation of EASEE® Lead to EASEE® Power is supplied sterile (sterilized with ethylene oxide). DO NOT RESTERILIZE.
- EASEE® Lead is supplied sterile (sterilized with ethylene oxide). DO NOT RESTERILIZE.
- EASEE® Template is supplied sterile (sterilized with ethylene oxide). DO NOT RESTERILIZE.
- EASEE® Lead screws are supplied sterile and are sterilized with radiation. DO NOT RESTERILIZE.

All sterile components of the EASEE® System are for single use only.

Do not re-sterilize or implant any explanted components of the EASEE® System.

Non-sterile, Sterilizable and Resterilizable Components

The screwdriver corresponding to the screws for EASEE® Lead as well as certain versions of the screws are delivered non-sterile. These components i.e. the screwdriver handle and the screwdriver blade must be sterilized before use. The hospital and the neurosurgeon are responsible for sterilizing the screwdriver prior to each use. Sterilization of the screwdriver must be carried out according to the manufacturer's instructions.

Non-Sterile, Non-Sterilizable Components

The following components of the EASEE® System are provided non-sterile and are non-sterilizable:

- EASEE® Connect, EASEE® Set, EASEE® Access, activation magnet.
- EASEE® Connect and the activation magnet should be placed in sterile bags for use in the sterile field.
- EASEE® Set and EASEE® Access are not intended for use in the sterile field.
- DO NOT STERILIZE EASEE® Connect.
- DO NOT STERILIZE the activation magnet.
- DO NOT STERILIZE EASEE® Set.
- DO NOT STERILIZE EASEE® Access.

2.10.4 Product Cleaning and Disinfection

The non-sterilizable components of the EASEE® System can be cleaned and disinfected as follows:

- EASEE® Connect, EASEE® Set, EASEE® Access and the activation magnet can be cleaned using a moistened damp, lint-free cloth.

- EASEE® Connect, EASEE® Set, EASEE® Access and the activation magnet can be disinfected by wiping all surfaces with an isopropyl alcohol (75%) moistened damp, lint-free cloth (follow the disinfectant manufacturer's instruction for use). Where applicable,
 - ensure that the devices to be cleaned are switched off
 - batteries are installed and all lids are closed
 - use an isopropyl moistened cotton swab to clean buttons and other recessed areas
 - leave the device to completely air dry after cleaning with isopropyl alcohol, before turning on the power or connecting it to any electrical source
- EASEE® Access should be cleaned at least weekly, or more often if needed. It can be disinfected if necessary.
- EASEE® Connect, EASEE® Set, and the activation magnet should be cleaned and disinfected after each use.

Explantation and Disposal

Program all therapy functions to DISABLED (deactivated) prior to explantation. Save remaining data stored in EASEE® Power or EASEE® Set, respectively.

Clean and disinfect the explanted EASEE® Power and EASEE® Lead or all related parts of the EASEE® System and return them to Precisis GmbH.

DO NOT incinerate EASEE® Power; explosion can occur if EASEE® Power is exposed to incineration or cremation temperatures.

2.11 EASEE® System – Expected Lifetime

2.11.1 Expected Service Life

The longevity of EASEE® Power is limited by the battery lifetime. The battery life depends on several factors, including stimulation settings and impedance values (see **section 2.11.2 Factors Impacting Battery Life of EASEE® Power**). The expected battery life of EASEE® Power is 4 years as shown in Table 4. The values are calculated using average stimulation settings typically observed in previous clinical studies as shown in Table 5.

Impedance (Ω)	2800	5100	7700	10000
Typical Lifetime (years)	4.23	4.20	4.07	3.99

Table 4: Expected battery lifetime with average stimulation settings typically observed in previous clinical studies

Parameter	HFS	DLS	PCN
Pulse amplitude	2.0 mA	1.1 mA	2.0 mA
Pulse width	160 µs	20 ms	160 µs
Frequency	100 Hz	8 Hz	100 Hz
Burst duration	0.250 s	20 min	60 s
Repetition frequency	1/min	1/(24 h)	6

Table 5: EASEE® Power stimulation settings used for calculation of typically expected battery life

The decision on EASEE® Power replacement and replacement time should be made by the patient and his/her treating physician based on an individual benefit-risk assessment, weighing the risks of device replacement against the benefits of further neurostimulation with the EASEE® System.

The lifetime of the EASEE® Power housing, which is especially relevant in case it stays in the body even after battery depletion, is not yet known; real-time aging studies have proven 5 years lifetime and are continued to cover 10 and more years in the future.

The maximum lifetime of EASEE® Lead is yet unknown due to ongoing real-time aging tests, which are designed to increase the demonstrated lifetime from currently 5 years to 10 years and above. In addition, the expected lifetime of EASEE® Power and EASEE® Lead will be adapted over time, based on the experience gained during the post market surveillance activities for the device (in case of need, please request the current data).

The non-implantable components EASEE® Access and EASEE® Connect have an expected service life of 5 years.

2.11.2 Factors Impacting Battery Life of EASEE® Power

Longevity of the EASEE® Power neurostimulator depends on several factors, each of which contributes to the depletion of the primary batteries of EASEE® Power. The most important factors are the following:

- The current amplitude of the stimulation delivered to the patient.
- The duration of the stimulation delivered to the patient.
- The impedance at the output channels of EASEE® Power.
- Frequency and amount of RF communication between EASEE® Power and the external devices EASEE® Set / EASEE® Connect and EASEE® Access.
- The number of impedance measurements.

Each time EASEE® Power delivers stimulation, communicates wirelessly with external devices or measures impedances, the battery is depleted by a small amount and hence the battery life is reduced.

2.11.3 Monitoring the Battery

Information on the remaining battery capacity of EASEE® Power can be obtained using EASEE® Access. It gives the battery status on the previous day. Current information on the EASEE® Power battery is accessible using the combination of EASEE® Set and EASEE® Connect. This can access the current battery values at any time.

Elective Replacement Indication (ERI)

EASEE® Set reports the remaining battery capacity of EASEE® Power each time it is interrogated. The remaining battery capacity is displayed on the EASEE® Set screen with a yellow mark (ERI) when capacity has reduced to the point where planning for replacement of EASEE® Power should begin. This is the case when the battery capacity is less than 20%.

EASEE® Access gives color-coded information on the remaining battery capacity, which is received from EASEE® Power when interrogation takes place. If the remaining battery capacity is below 20%, the EASEE® Power battery status indicator on EASEE® Access lights up yellow.

End of Service (EOS)

End of service is the point where EASEE® Power stops stimulation and can only communicate. This is roughly equivalent to remaining usable battery capacity of 1% or less and indicated on the EASEE® Set screen by displaying the remaining battery capacity in red.

If EOS is reached and interrogation via EASEE® Access has taken place, the EASEE® Power battery status indicator of EASEE® Access lights up red.

EASEE® Power Switch-Off due to Battery Depletion

When EASEE® Power switches off, all neurostimulator functions are suspended. The neurostimulator no longer delivers stimulation, measurements are disabled, and records are not stored.

EASEE® Power will switch off if the batteries of EASEE® Power reach the end of their lifetime i.e. become depleted or if an internal problem is detected. If EASEE® Power has switched off, EASEE® Set will not be able to establish contact with EASEE® Power, similar to when EASEE® Power is not within reach of the RF communication options.

EASEE® Power Inactive

EASEE® Power is shipped in a switched-off state. A switched-off EASEE® Power is first switched on temporarily for about three minutes with the aid of the activation magnet. Within this period, EASEE® Power can be permanently activated by establishing a connection between EASEE® Power and EASEE® Set.

After successful implantation, EASEE® Power can be left switched on in case the therapy is to be started soon, e.g. after the wound healing period of approximately 2 weeks has been completed.

3 Clinical Use of the EASEE® System

3.1 Identifying Candidates for the EASEE® System Therapy

The EASEE® System is for patients with a clinical diagnosis of focal seizures or focal seizures evolving into bilateral tonic-clonic seizures, and a diagnosis of temporal lobe epilepsy or extra-temporal lobe epilepsy and a predominant epileptic focus, which can be clearly identified as the site of implantation for the electrode, based on routine electroencephalogram (EEG), or routine magnetoencephalogram (MEG), or routine magnetic resonance imaging (MRI), or video-EEG monitoring, or intracranial eEG, and clinical presentation. Further, patients eligible for EASEE® System Therapy have failed treatment with a minimum of two appropriately selected and tolerated anti-seizure medications (used in appropriate doses) and are between the ages of 18 and 75 years. For a list of criteria see the Indications section.

The EASEE® System is contraindicated in patients who have implanted medical devices that deliver electrical energy to the body, or who have implanted metal parts or non-conducting material (e.g. alloplastic material) in the area of the intended position of EASEE® Lead which cannot be safely removed during the neurosurgical intervention. Patients who have medical or neurological conditions that place them at high risk for surgical complications are also not suitable candidates for the EASEE® System. For a complete list see **section 2.2 Contraindications**.

3.2 Localizing the Seizure Focus and Planning the Implant Location of EASEE® Lead

The EASEE® System is designed to deliver stimulation to an area of the brain that has been identified as the predominant epileptic focus. Therefore, it is essential for the seizure focus to be sufficiently well localized to guide the placement of the EASEE® Lead electrode array.

The seizure focus is most commonly localized using scalp EEG. Further diagnostics, available at qualified epilepsy centers, may be performed at the discretion of the epilepsy specialist to possibly determine the optimal site of stimulation with greater resolution.

Patients with medically refractory focal epilepsy following resective surgery should have had appropriate studies following the surgery to adequately localize the seizure focus or foci prior to implantation of the EASEE® System. The skull must be sufficiently intact to allow placement of the EASEE® Lead electrodes.

Once the implantation site has been determined (see above) the neurosurgeon should mark the implantation site to ensure that the central electrode of the EASEE® Lead will be fixed in place over the pre-determined epileptic focus. Routine surgical planning or navigation systems may be used at the discretion of the physician.

3.3 Patient Training

Train the patient and/or caregiver on how to use the EASEE® Access handheld device. Instruct the patient and/or caregiver to interrogate EASEE® Power every day using EASEE® Access.

3.4 Overview: Implantation of the EASEE® System

Implanting EASEE® Power and EASEE® Lead

Patients are under general anesthesia for the implantation of the EASEE® System. This is done according to the standard procedures of the respective neurosurgical department.

The EASEE® Power neurostimulator is implanted in the infraclavicular area. The recommended location of the neurostimulator is in a pectoral pocket where it can be sutured to the muscle fascia. The neurostimulator may be implanted and secured in the implantation site before or after EASEE® Lead is implanted. Detailed instructions for implanting EASEE® Power are provided in the **Surgical Procedures** section of the Neurosurgeon's Manual.

After removal of the periosteum the electrode pad of EASEE® Lead is placed subgaleally onto the skull using standard neurosurgical techniques. Each electrode, as well as the strain relief system, is fixed onto the skull with bone screws. The connecting cable of EASEE® Lead is tunneled under the skin to the implantation site of EASEE® Power.

Detailed instructions for implanting EASEE® Lead are provided in the **Surgical Procedures** section of the Neurosurgeon's Manual.

EASEE® Set / EASEE® Connect is used to test lead impedances during and after the implantation procedure and while the patient is still in the operating room. This ensures that the implantable components of the EASEE® System are ready for use, i.e. there is good electrode-bone contact.

3.5 Overview: Stimulation with the EASEE® System

EASEE® Power is initially activated and programmed for stimulation by the neurologist after a healing period of about 4 weeks following implantation. The activation magnet and the programmer EASEE® Set / EASEE® Connect are used.

3.5.1 Stimulation Patterns

The EASEE® System can deliver two different stimulation patterns applied in combination at intervals, each with patient-specific stimulation parameters:

- High frequency stimulation (HFS), where alternating current is delivered in symmetrical square pulses as a burst (see Figure 3.12).

- DC-like stimulation (DLS) is a stimulation mode with a long positive rectangular pulse delivered continuously followed by a negative rectangular pulse which is five times longer, with amplitude reduced to one fifth of the positive pulse (see Figure 3.13).

EASEE® Power can deliver additional stimulation when triggered by the patient e.g., at the onset of a seizure and this option is referred to as patient-controlled neurostimulation (PCN). PCN consists of HFS (see Figure 3.14), which is generally applied for longer than the standard HFS, the duration being determined by the physician. The patient can trigger PCN using the EASEE® Access handheld device.

DLS stimulation is administered once daily at a predefined time. HFS stimulation on the other hand is applied continuously throughout the day and is interrupted only by DLS stimulation (if this stimulation mode is activated) and PCN (if triggered by the patient). DLS stimulation, in turn, is interrupted by PCN; however, any DLS stimulation that has not yet been delivered continues after PCN ends.

3.5.2 Stimulation Parameters

For HFS, DLS and PCN it is possible to set the current intensity (current amplitude), as well as different temporal parameters:

- Current amplitude of HFS pulse
- Current amplitude of DLS pulse
- Current amplitude of PCN pulse
- Pulse width of HFS pulse
- Pulse width of PCN pulse
- Frequency of HFS pulse
- Frequency of PCN pulse
- Repeat rate of HFS bursts
- Duration of DLS
- Duration of PCN
- Start time of DLS

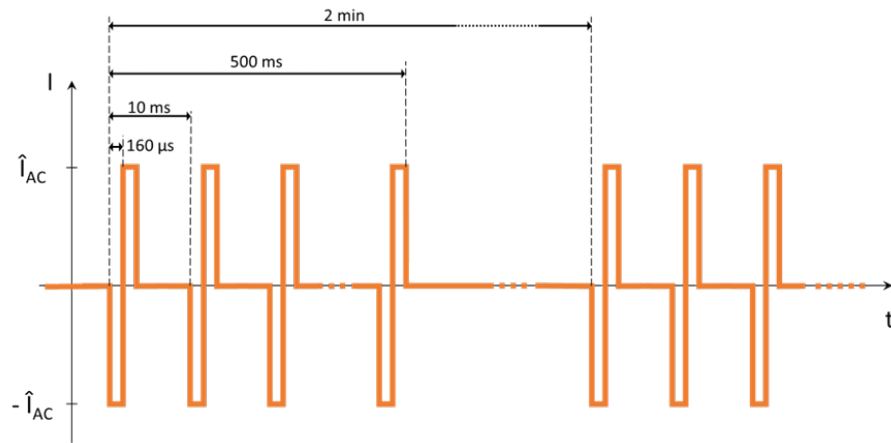


Figure 3.12: HFS pulse pattern with time parameter values, example provided for illustration only (not to scale): Pulse width (here: $160 \mu s$), pulse frequency (here: $100 Hz$, corresponds to a pulse period of $10 ms$), burst duration (here: ca. $500 ms$), burst frequency (here: $0.5/min.$, corresponds to burst period of $2 min$).

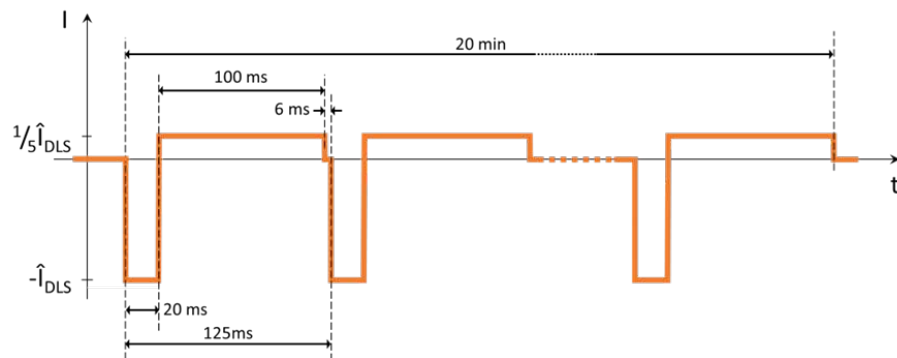


Figure 3.13: DLS pulse pattern with time parameter values provided as an illustration only (not to scale): Pulse width (here: $20 ms$), pulse width ratio (here: $1:5$ (stimulation pulse: equalization pulse), corresponds to equalization pulse width of $100 ms$), pulse frequency (here: ca. $8 Hz$, corresponds to pulse period of $126 ms$ with pause duration of $6 ms$), DLS stimulation duration (here: $20 min$).

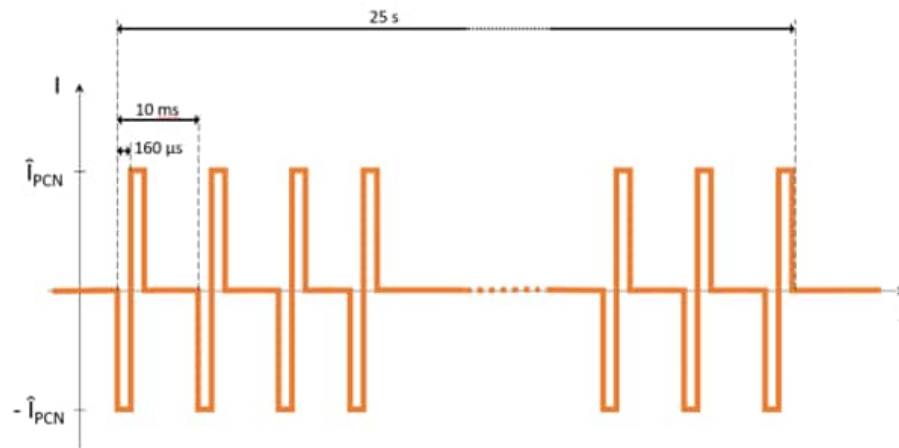


Figure 3.14: PCN pulse pattern with time parameter values provided as an illustration only (not to scale): Pulse width (here: 160 μ s), pulse frequency (here: 100 Hz, corresponds to pulse period of 10 ms), PCN burst duration (here: 25 s).

3.5.3 Recommended Initial Therapy Settings

Recommended initial therapy settings are listed in Table 6. The stated pulse amplitude means that the maximum current amplitude level of 4.0 mA can only be used if the patient does not perceive the stimulation. Otherwise, the pulse amplitude should be reduced until it is 0.2 mA below the perception level for the individual. The stimulation parameters for HFS, DLS and PCN should be tested using the test function on EASEE® Set.

Note: PCN duration should match the patient's typical seizure duration, range 10 – 60 s.

If the patient does not tolerate a stimulation mode, the stimulation parameters should be adjusted, for example by reducing the pulse amplitude.

3.5.4 Modifying Therapy Settings

Once EASEE® Power has been programmed and activated to provide stimulation, the patient should be seen at regular time intervals to check that the therapy settings are well tolerated. At each patient visit, the physician may decide whether the therapy settings should be modified. If the physician decides to modify the current amplitude, e.g., to decrease it to improve stimulation tolerability for the patient, then the current amplitude can be adjusted in 0.1 mA steps. Each stimulation setting should be tested using the therapy testing function of EASEE® Set, to ensure that the patient is tolerating it well.

The range of available settings is shown in Table 7.

Parameter	HFS	PCN	DLS
Pulse amplitude	Start titration at 1.0 mA max. 4.0 mA reduce as needed	Start titration at 1.0 mA max. 4.0 mA reduce as needed	Start titration at 0.2 mA max. 2.0 mA reduce as needed
Pulse width	160 µs	160 µs	20 ms
Frequency	100 Hz	100 Hz	8 Hz
Burst duration	[0.5 s]	10 s	20 min
Repetition frequency	1/(2 min)	n/a	[1/(24 h)]
Pause width	[9.68 ms]	[9.68 ms]	[6 ms]
Width of equalization pulse	n/a	n/a	[100 ms]
Current of equalization pulse	n/a	n/a	1/5 of current of stimulation pulse
Start time of stimulation	n/a	n/a	10 a.m.

Table 6: Recommended initial therapy settings. Data in square brackets denotes parameters which cannot be programmed, as they are either fixed or result from the other parameters.

Parameter	HFS	PCN	DLS
Stimulation Activation State	ON / OFF	ON / OFF	ON / OFF
Pulse amplitude	0.1 ... 4 mA (independent from PCN setting)	0 ... 4 mA (independent from HFS setting)	0.2 ... 4 mA
Pulse width	100, 160, 200, 300, ..., 1400, 1500 µs		20 ms
Frequency	100, 160 Hz		8 Hz
Burst duration	not editable	10...60 s [#] max. 6 min/day	1 ... 20 min
Repetition frequency	0.5/min to 6/min	may. every two min	1/24 h

[#] PCN duration should match the patient's typical seizure duration, range 10 – 60 s

Table 7 : Range of available therapy settings.

3.5.5 Sham Stimulation Programming

In cases where sham stimulation is intended, specific device settings are required to maintain patient blinding and provide appropriate system feedback:

- Ensure both HFS and DLS are set to OFF.
- Set the stimulation amplitude for PCN to 0 mA. This prevents any delivery of electrical current, adhering to the sham stimulation protocol.
- Set PCN to ON. This allows the system to provide feedback to the patient (e.g., a green light indicator on EASEE Access) suggesting the device is active.
- When exiting the programming session, a confirmation code may be required to continue.

4 Patient Treatment

4.1 Patient and Family Information

The potential risks and benefits of implanting the EASEE® System and following electrical stimulation therapy should be discussed with the patient and family members before the implantation procedure. The patient should be advised that diathermy procedures, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) are contraindicated, even if the neurostimulator is switched off or has been removed, or if any leads or any part of a lead remain. If an MRI procedure has to be carried out, please refer to the guidelines described in **section 2.3 MRI Safety Information**. The patient should also be advised on other medical procedures to avoid, on caring for the EASEE® System and on environmental hazards. The EASEE® System Patient Manual outlines this information and should be provided to and reviewed together with the patient prior to implantation of EASEE® System.

4.2 Hardware for Interrogating EASEE® Power

4.2.1 Description of EASEE® Connect and EASEE® Set – Hardware

General

EASEE® Connect serves as a device for radio frequency-based communication that enables the physician to control and check the implanted components of the EASEE® System. It is used together with a dedicated tablet PC, called EASEE® Set – Hardware. Do not connect EASEE® Connect to other devices than described in this manual.

For further description of the tablet PC mentioned, please refer to the documentation provided with the tablet PC from its manufacturer.

EASEE® Set / EASEE® Connect Combination

The combination of EASEE® Set and EASEE® Connect enables the physician to communicate with the implanted EASEE® Power neurostimulator. EASEE® Set / EASEE® Connect comprises a tablet PC (EASEE® Set – Hardware), which runs dedicated software (EASEE® Set – Software), and EASEE® Connect, enabling EASEE® Set to communicate wirelessly with EASEE® Power.

The neurosurgeon uses EASEE® Set / EASEE® Connect during the implantation to check whether the implantable devices are operational and that EASEE® Lead is properly fixed to the skull.

The neurologist can use EASEE® Set / EASEE® Connect for programming the stimulation sequences and accessing the logged data from EASEE® Power.

4.2.2 Description of EASEE® Set – Hardware

EASEE® Set – Hardware is an off-the-shelf tablet PC designed for the healthcare environment (robust, disinfectable, dustproof and water ingress protected). It is equipped with a touch screen and a hot-swappable lithium-ion battery.

4.2.3 Description of EASEE® Connect

EASEE® Connect is supplied with a USB A to USB C cable for connection to EASEE® Set – Hardware and makes wireless communication with EASEE® Power possible.

4.2.4 Parts of EASEE® Connect

EASEE® Connect comprises (see Figure 15):

- a plastic housing containing the electronics, with four indicator lights on the front and a mechanical clip on the back,
- a cable with USB A to USB C cable

Note: The four gray buttons of EASEE® Connect are non-functional.

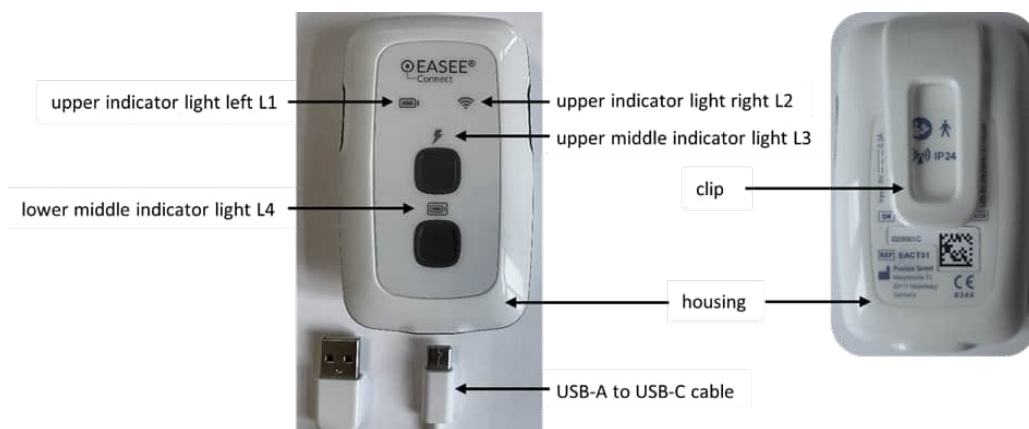


Figure 4.15: Parts of EASEE® Connect: Front view (left), rear view (right).

Technical specifications of EASEE® Connect can be found in **section 8 Specifications**.

4.3 How to Use EASEE® Connect

4.3.1 Connection to EASEE® Set – Hardware

Precaution: Ingress Protection of EASEE® Set

EASEE® Set is protected against ingress of particles and fluids. However, to connect USB devices such as EASEE® Connect, it is necessary to temporarily remove the protective cover of the USB socket. It is therefore mandatory to reposition the protective cover as soon as possible.

To use EASEE® Connect, it must be connected to the switched on EASEE® Set – Hardware by

- inserting the USB Type C plug of the USB-A to USB-C cable in the USB Type C socket of EASEE® Connect, which is located on the lower narrow side of the housing of EASEE® Connect,
- inserting the USB Type A plug of the USB-A to USB-C cable in the USB Type A socket of EASEE® Set – Hardware. This socket is behind the protective cover (Figure 4.16, top and middle) on the left side of EASEE® Set – Hardware. After successful connection, EASEE® Set / EASEE® Connect is set up and ready to use (Figure 4.16, bottom).



Figure 4.16: Connecting EASEE® Connect to EASEE® Set – Hardware: The USB port of EASEE® Set is located behind a lateral cover on the left side of the housing.

As soon as EASEE® Connect is powered up by being connected to EASEE® Set – Hardware which is turned on, the device runs a self-test and the indicator lights give a signal sequence as follows:

- green (for 1.0 seconds), off (for 0.5 seconds),
- yellow (for 1.0 seconds), off (for 0.5 seconds),
- red (for 1.0 seconds), off.

If this sequence has not been transmitted, EASEE® Connect is not operational (see the Troubleshooting section). After the signal sequence, the upper left indicator light of EASEE® Connect turns green and shows that EASEE® Connect is switched on. A pop-up window appears on the EASEE® Set screen as shown in Figure 4.17. Click the OK button to allow EASEE® Set to access EASEE® Connect. Otherwise, it would not be possible to connect EASEE® Set to EASEE® Power.

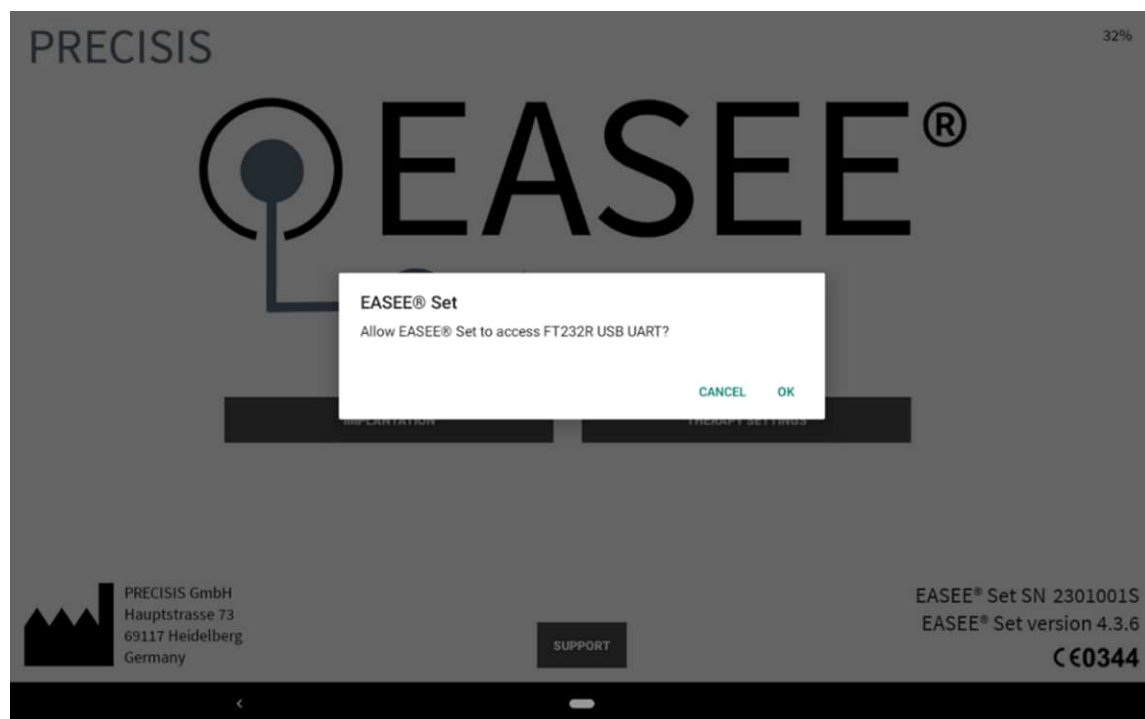


Figure 4.17: Pop-up window that is displayed after EASEE® connect has been connected to EASEE® Set. To use EASEE® Set with EASEE® Connect, press the OK button.

4.3.2 Positioning of EASEE® Connect

For accurate radio frequency communication between EASEE® Connect and EASEE® Power, EASEE® Connect should be positioned close to EASEE® Power, i.e. within 20 cm (approx. 8 in). For convenience, EASEE® Connect is equipped with a clip on the rear side for attachment to the patient's clothes in the upper chest region close to the EASEE® Power implantation site.

4.3.3 Operating EASEE® Connect

When radio frequency communication is taking place between EASEE® Connect and EASEE® Power, the indicator light of EASEE® Connect lights up green.

4.3.4 Turning off EASEE® Connect

When EASEE® Connect is no longer in use, it can be switched off by removing the USB plug from EASEE® Set – Hardware. Unplug EASEE® Connect only if no connection to EASEE® Power is established. It is irrelevant for this action whether EASEE® Set – Hardware is switched on or off.

4.4 How to Use EASEE® Set

This section describes the specific application of EASEE® Set as a component of the EASEE® System. Please refer to the Quick Start Guide for the MioWORK L1000 instructions for general use of the tablet PC.

4.4.1 Configuration of EASEE® Set

Precisus GmbH will provide the neurologists with individual passwords on demand. Every password is composed of exactly four (4) characters; each character can be a capitalized letter [A-Z] (English alphabet only) or a digit [0-9].

4.4.2 EASEE® Set User Interface

The following figures show the login screens of the EASEE® Set – Software and the main EASEE® Set interface module for medical users. Some of the screens may also display the serial number and the software version of the EASEE® Set, the CE mark, name and address of the manufacturer, and possibly further information.

Pressing the **IMPLANTATION** button (Figure 4.18, left button) leads directly to the screen as shown in Figure 4.19.

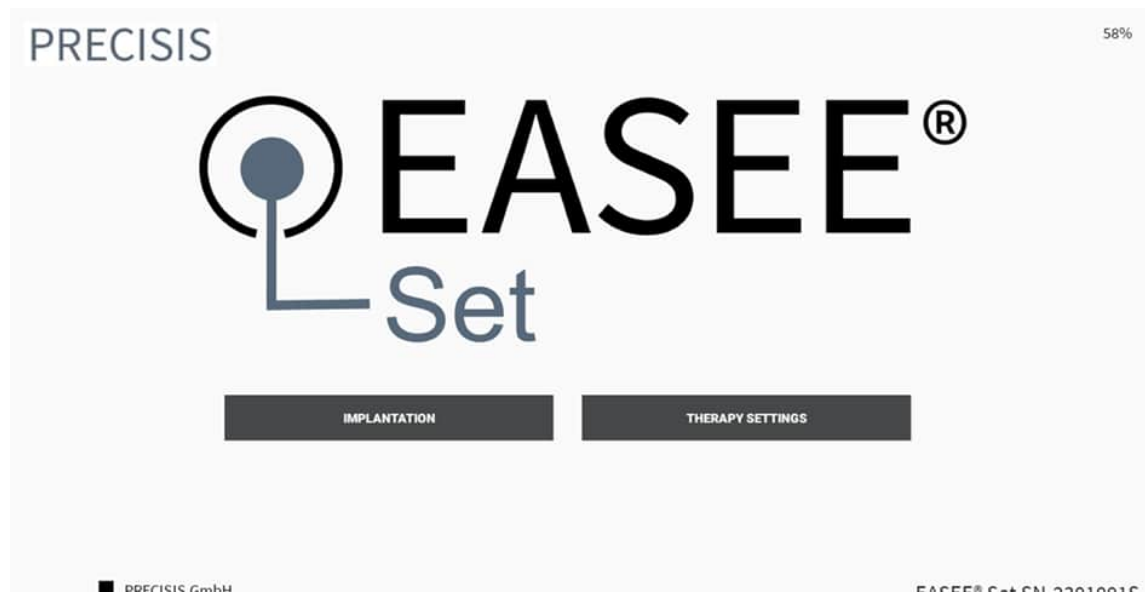


Figure 4.18: Extract from the EASEE® Set welcome and login screen. The percentage in the upper right corner indicates the present state of charge of the EASEE® Set battery.

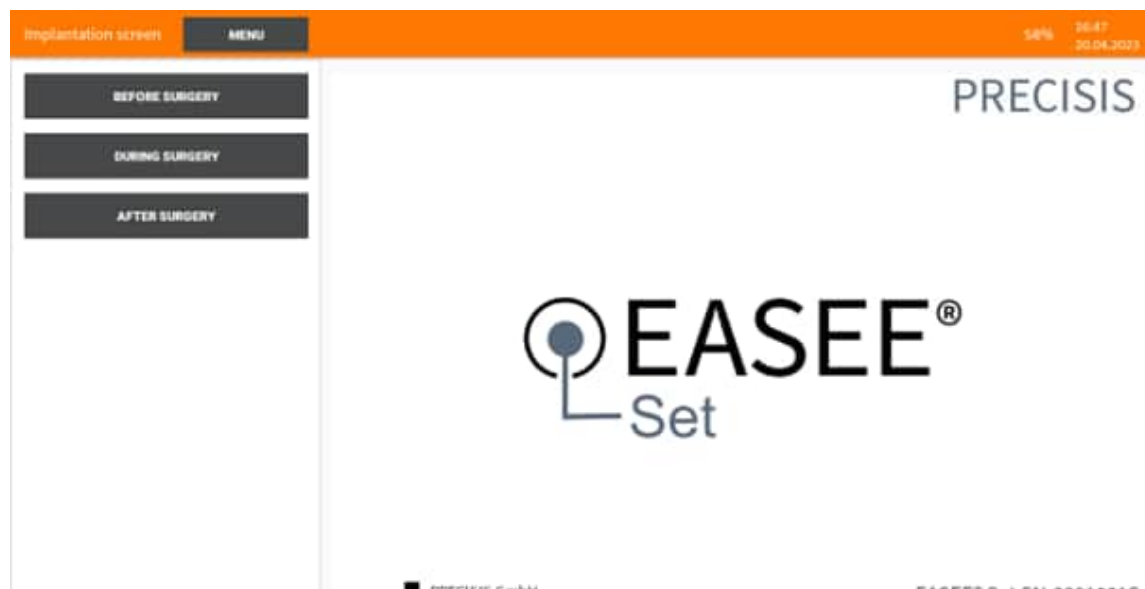


Figure 4.19: Extract from the screen of EASEE® Set after clicking the **IMPLANTATION** button. The top row of the screen shows (from left to right): the name of the current screen ("Implantation screen"), the **MENU** button, remaining battery capacity of EASEE® Set – Hardware, time and date.

The other menu **THERAPY SETTINGS** is password-protected. After pressing the **THERAPY SETTINGS** button, a dialog box will be displayed for entering a password (Figure 4.20). Each password has exactly four (4) alphanumeric characters.

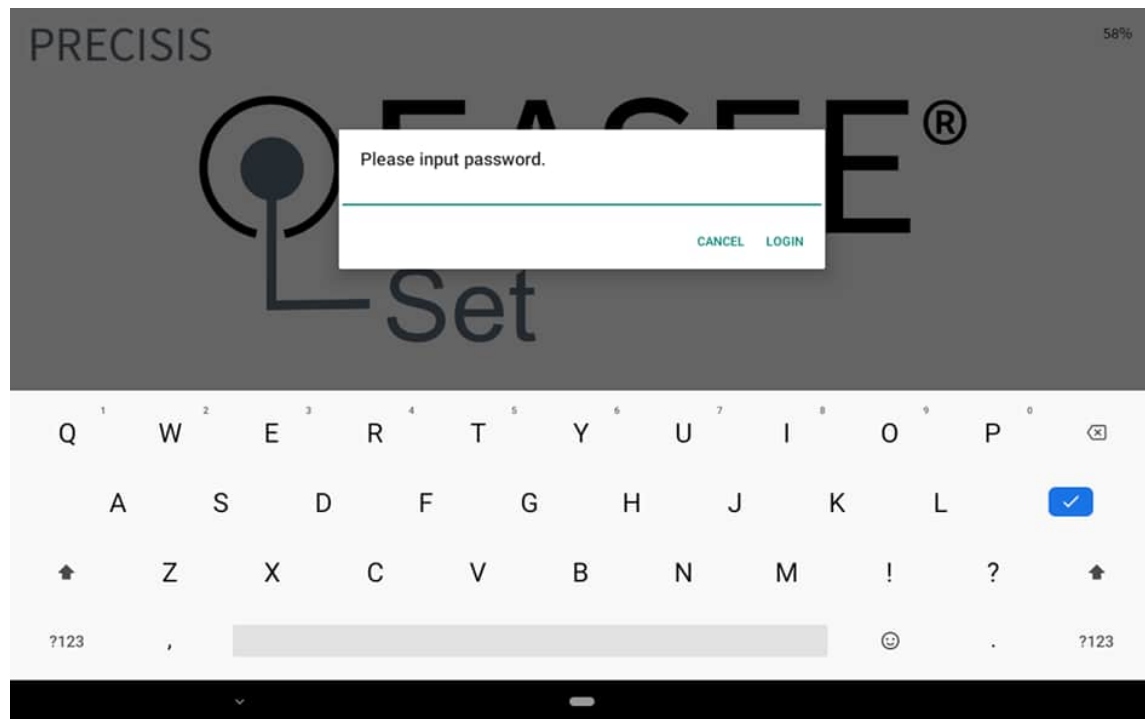


Figure 4.20: Login screen of EASEE® Set for the THERAPY SETTINGS menu.

Enter the password then click the **LOGIN** button.

If you have forgotten your password, please contact Precisis GmbH (see **section 12 Contact Information and Support**) to reset your password.

4.4.3 Turning off EASEE® Set – Hardware

Before turning off EASEE® Set – Hardware, make sure EASEE® Power is disconnected from EASEE® Set after implantation and the user has logged out from EASEE® Set – Software (press the **LOGOUT** button which can be found in the menu that appears after pressing the **MENU** button).

EASEE® Set – Hardware can be shut down by pressing and holding the Power button on the tablet PC and following the instructions which then appear on the screen. Since there is no option to stop EASEE® Set – Software before shutting down EASEE® Set – Hardware, the tablet PC can be turned off while EASEE® Set – Software is still running.

Before shutdown, a file is automatically saved to EASEE® Set – Hardware that contains a log of the operations that have been performed on EASEE® Set – Hardware since it was last turned on.

4.5 Programming Instructions

The THERAPY SETTINGS module of EASEE® Set enables easy patient management and provides all the tools necessary for EASEE® Power configuration and supervision.

The THERAPY SETTINGS module is accessible from the Login screen of EASEE® Set.

- Turn on EASEE® Set: Press and hold the power button of EASEE® Set – Hardware (see manual of the dedicated tablet PC).
- Plug EASEE® Connect into EASEE® Set via the USB-A to USB-C cable.
- Wait for successful completion of the EASEE® Connect self-test.
- Login to the **THERAPY SETTINGS** module of EASEE® Set (see Figure 18, right button).
- After logging in, the first screen displayed is the “Select patient” screen (Figure 4.21).

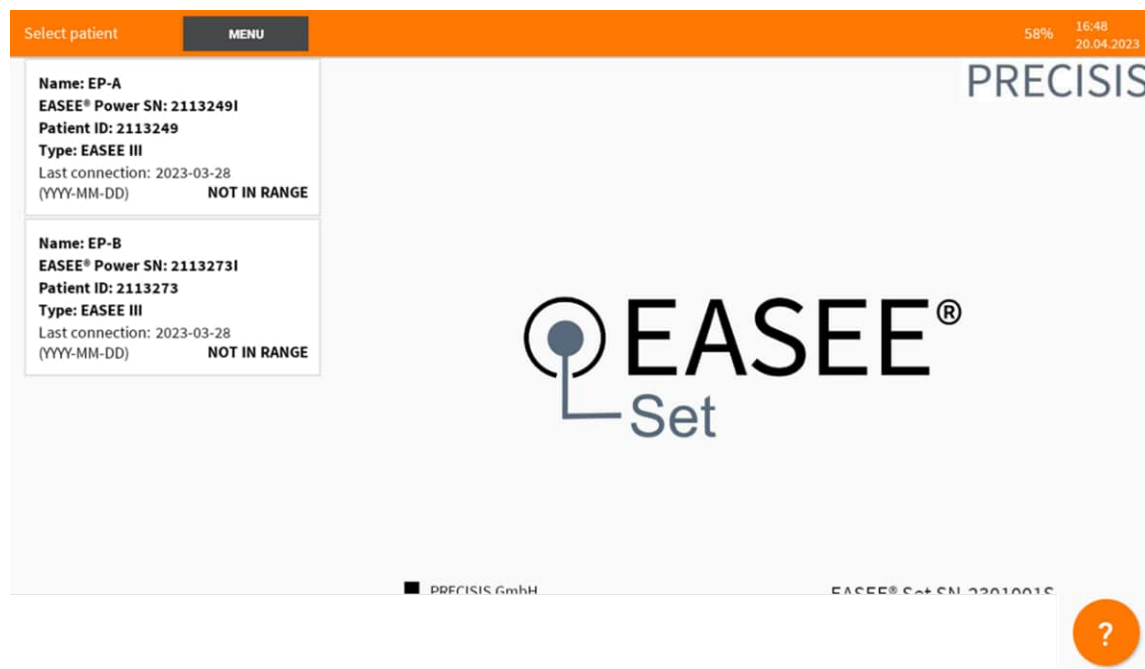


Figure 4.21: Extract from the “Select patient” screen of the THERAPY SETTINGS module with exemplary entries in the patient list (left). Like this one, other screens of EASEE® Set also show a button in the bottom right corner with a question mark. When it is pressed, a window pops-up with answers to questions that frequently arise for the user.

The left side of this screen shows a list of all the patients previously registered with the present tablet PC. If the user selects a patient from the list, the most recent data saved in EASEE® Set for this patient is displayed. If the user establishes a connection with the patient’s EASEE® Power by holding EASEE® Connect as close as possible to EASEE® Power (maximum distance: 20 cm) and pressing the **CONNECT** button, the “Patient connected” screen will be displayed (see **section 4.5.2 “Select Patient” Screen**).

4.5.1 Menu for therapy settings

The menu can be accessed using the **MENU** button from the information bar.

Furthermore, the information bar shows three indicators in the top right corner:

- Remaining battery capacity of EASEE® Set – Hardware, shown as a percentage.
- Current time (format: HH:MM).
- Current date (format: DD.MM.YYYY).

The menu displayed for the "Select patient" screen after pressing the **MENU** button provides the following submenus (see Figure 4.22), which are described below:

- Patient List (see *section 4.5.1 Patient List*)
- Data (see *section 4.5.1 Data*)
- Application (see *section 4.5.1 Application*)
- User (see *section 4.5.1 User*)

In case EASEE® Set is connected to a patient's EASEE® Power, only the "Application" submenu is available from the MENU button.

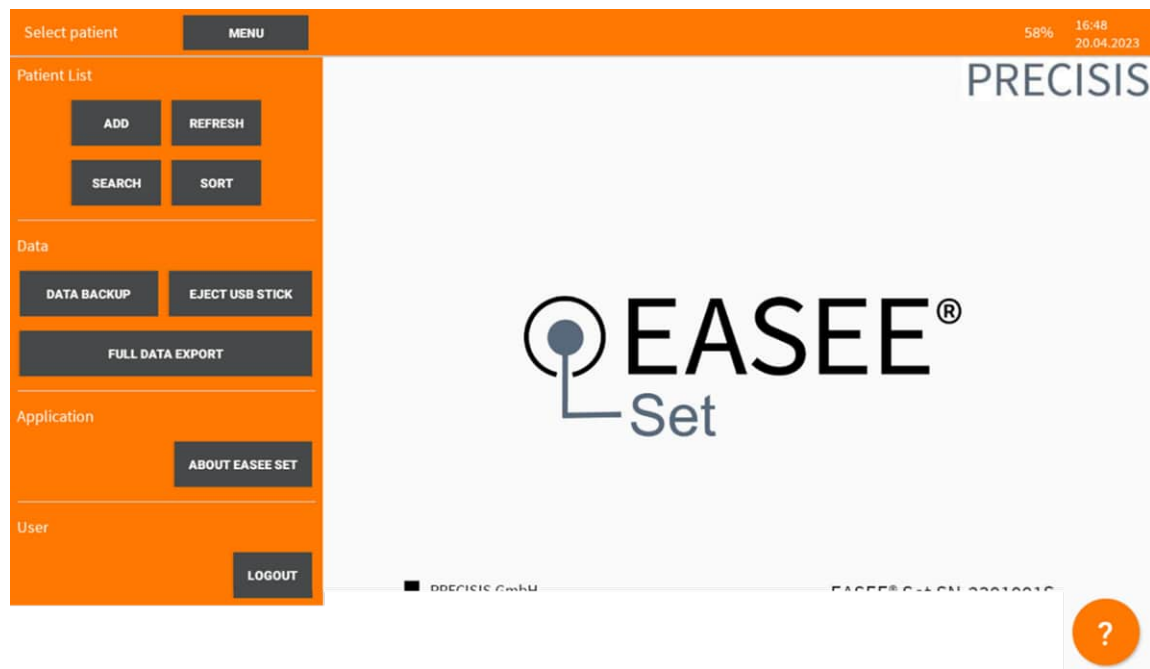


Figure 4.22: Menu for the "Select patient" screen (extract).

Patient List

The “Patient List” submenu provides the following four buttons

ADD
REFRESH
SEARCH
SORT

with the functionalities as described below:

Add Patient

You can add an entry to the Patient List using the **ADD** button:

Press the **ADD** button to display the “Add Patient” dialog (Figure 4.23).
Enter “Name” and “Patient ID”.

When EASEE® Power is turned off, it must first be activated. Otherwise, the data entry in the Patient List will not contain the EASEE® Power SN, but only the Name and Patient ID data entered. To include the EASEE® Power SN, first activate EASEE® Power by moving the activation magnet closely over EASEE® Power and performing the following steps 3. and 4. within 3 minutes after activation:

Place EASEE® Connect as close as possible to EASEE® Power (maximum distance: 20 cm / approx. 8 in).

Click the **SCAN** button in the “Add Patient” dialog (Figure 4.23). The individual serial number of the EASEE® Power is displayed.

Click the **ADD** button in the dialog box to save the new patient data.

When new patient data is added, the application will perform a “Refresh” to update the Patient List with all the EASEE® Power devices in range.

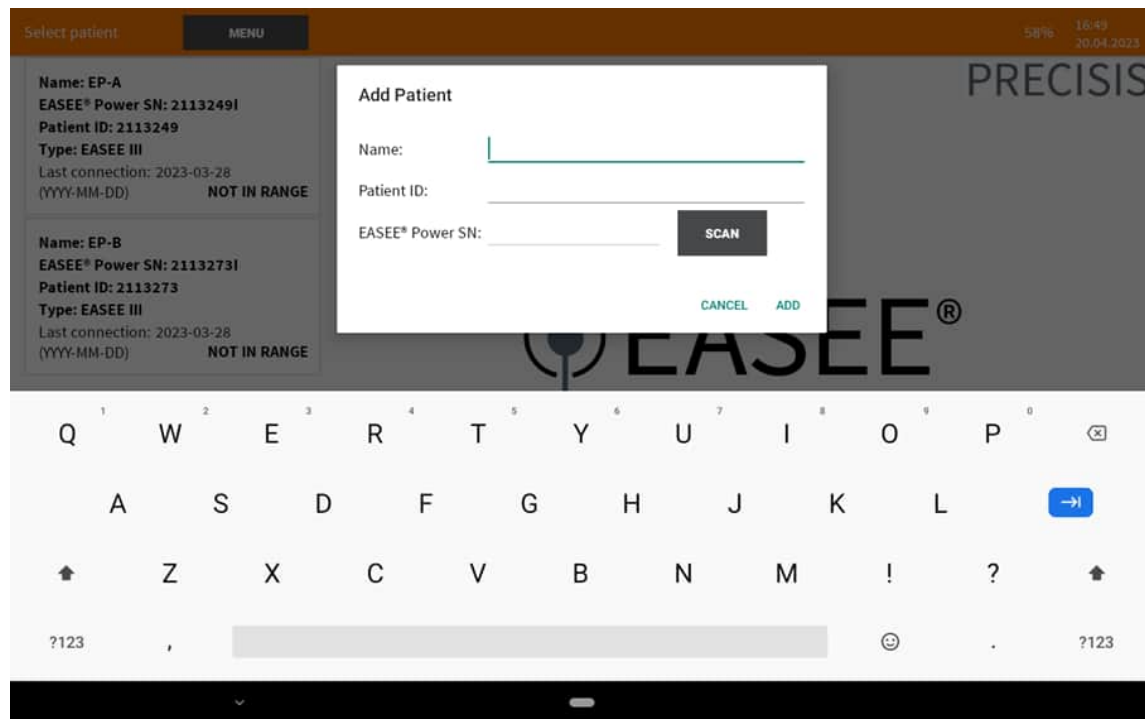


Figure 4.23: “Add Patient” dialog box to record new patients.

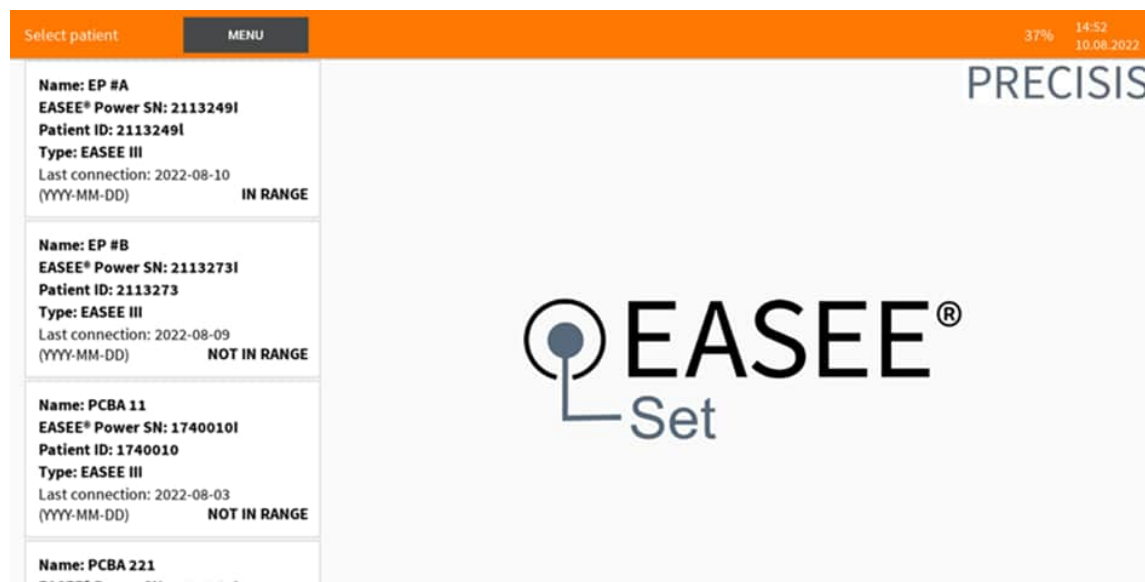


Figure 4.24: Example of patient list on the left side of the screen updated in comparison to Figure 4.21

Refresh patient list

Click the **REFRESH** button on the “Patient List” submenu (Figure 4.22), to update the Patient List with refreshed classification of all the EASEE® Power devices in range or not in range (Figure 4.24).

Search patient

Use the **SEARCH** button to find specific patient data.

Enter the search terms in the “Search” dialog box (Figure 4.25) and select which filter to use: **NAME**, **EASEE® POWER SN** or **PATIENT ID**.

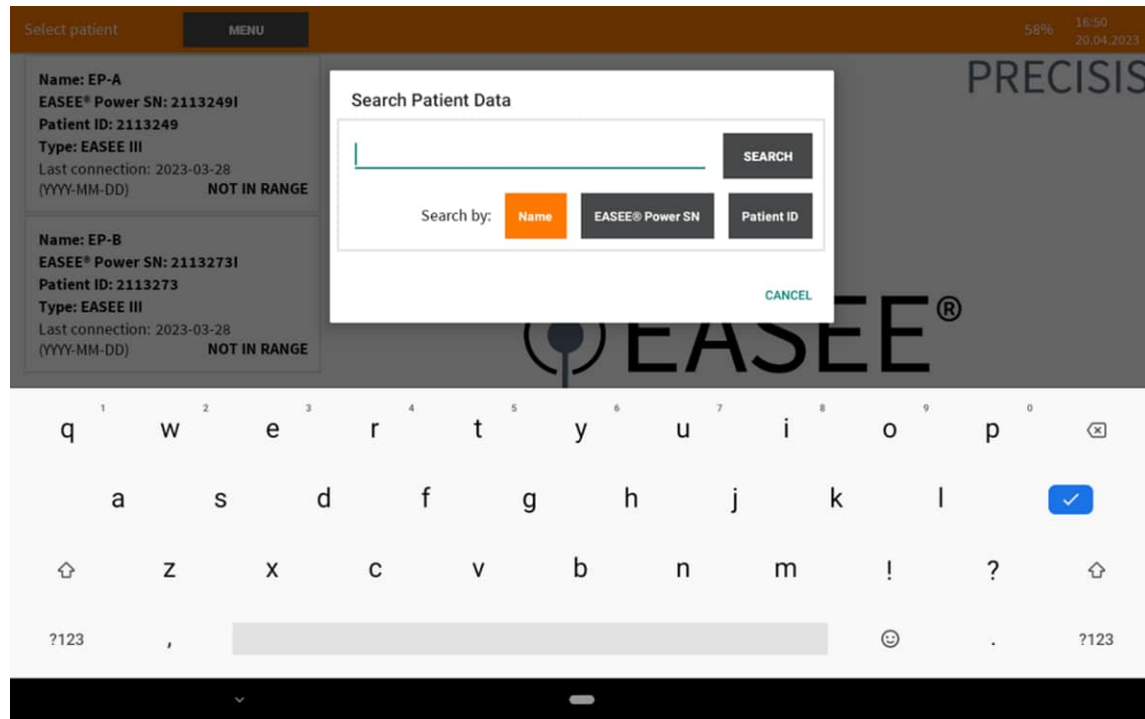


Figure 4.25: "Search Patient Data" dialog box for searching for Patient List entries with specific patient data.

When the search is complete, the results will be displayed. Use the **VIEW PATIENT** button in the “Search Patient Data” dialog box to display the patient’s details (Figure 4.26).

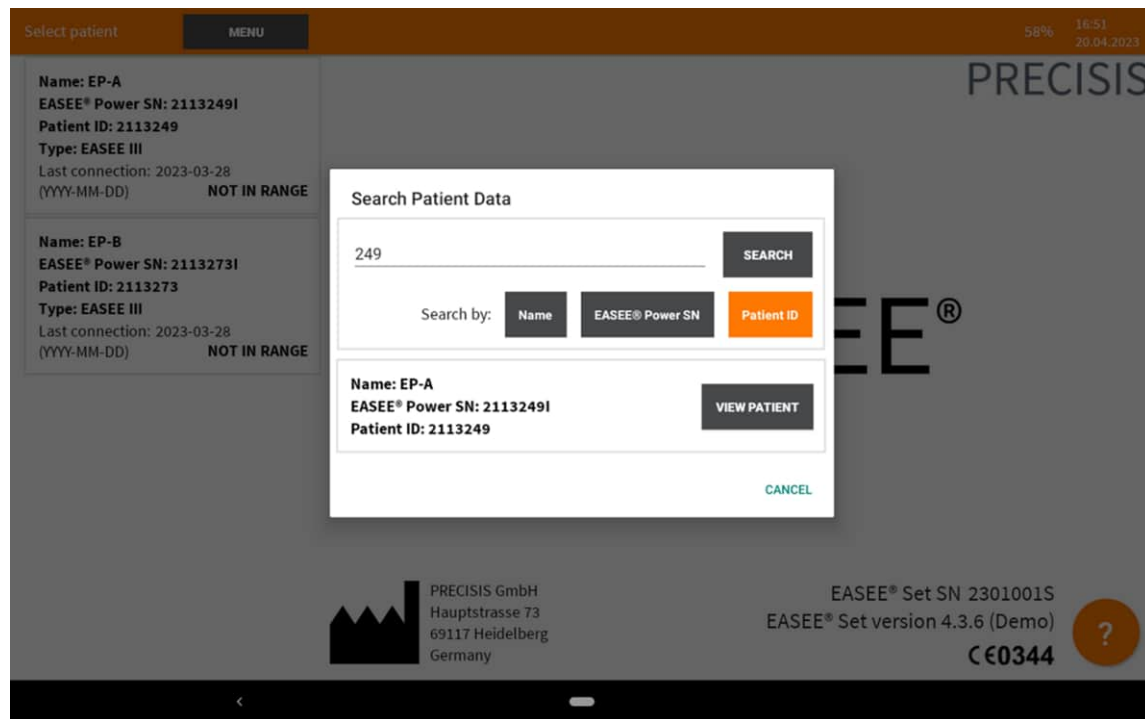


Figure 4.26: "Search Patient Data" box displaying search results.

When pressing the **VIEW PATIENT** button in the "Search Patient Data" dialog box, the patient information will be displayed as if the patient was directly selected from the Patient List located on the left side of the "Select patient" screen (Figure 4.27).

Please note that the information bar on top of the screen now additionally indicates the polarity of stimulation (here: "Polarity: Cathodal").

Select patient MENU Polarity: Cathodal 58% 16:51 20.04.2023

Name: EP-A
EASEE® Power SN: 21132491
Patient ID: 2113249
Type: EASEE III
Last connection: 2023-03-28 (YYYY-MM-DD) **IN RANGE**

Name: EP-B
EASEE® Power SN: 21132731
Patient ID: 2113273
Type: EASEE III
Last connection: 2023-03-28 (YYYY-MM-DD) **NOT IN RANGE**

Battery
Remaining capacity: between 50% and 100%
Last measurement: 2023-03-28, 14:16:50 (YYYY-MM-DD, hh:mm:ss)

Paired EASEE® Access
EASEE® Access SN: 0000000A

Stimulation parameters

Parameter	HFS	PCN	DLS
Amplitude	0.7 mA	0.0 mA	0.0 mA
Pulse width	160 µs	160 µs	160 µs
Pulse frequency	100 Hz	100 Hz	100 Hz
Burst frequency	0.5/min	10s	20 min

EASEE® POWER HISTORY ?

Figure 4.27: Display "Select patient" after pressing the **VIEW PATIENT** button to complete the search for specific patient data. The details shown on the right about the battery, EASEE® Access and stimulation parameters refer to the patient shown in the list on the left with gray background.

Sort Patient List

Use the **SORT** button from the "Patient List" submenu to display the "Sort settings" dialog box (Figure 4.28).

The **SHOW IN RANGE IMPLANTS ALWAYS ON TOP** toggle switch can be used to define whether the patients with EASEE® Power devices that are within range are always displayed on top of the "Patient List". If the toggle switch is set to "NO", all patients are simply sorted using the sort criteria selected below:

Use the "Sort by" option to select the filter that will be used when displaying the "Patient List". The "Direction" option tells the application to sort in **ASCENDING** or **DESCENDING** order.

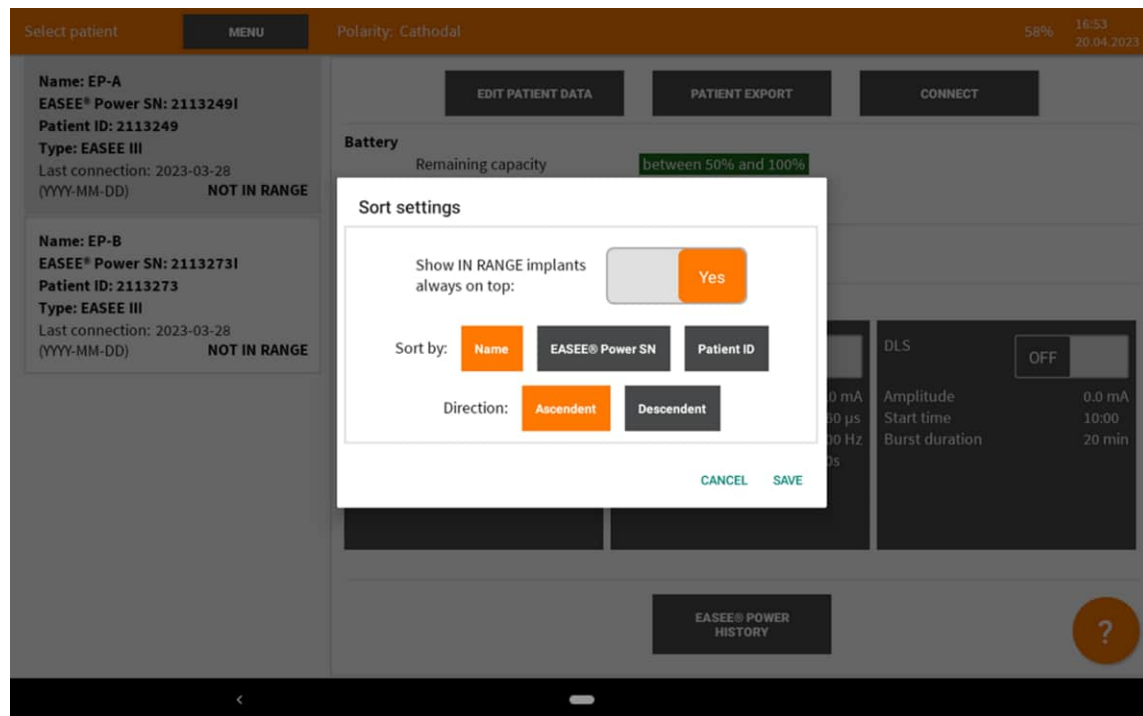


Figure 4.28: "Sort settings" dialog box for defining the order of how the patient data is displayed in the Patient List.

Data

The following buttons are available in the "Data" submenu (see Figure 22):

DATA BACKUP
EJECT USB STICK
FULL DATA EXPORT

and provide the functionalities described below.

Backup data

Use the **DATA BACKUP** , button to create a backup file in the "backup" folder inside the "EASEESet" folder (see **section 4.6 File Structure** for details related to this folder). These backup files can be used as a "Restore point" by the Support user.

Eject USB Stick

To safely remove a USB stick connected to EASEE® Set, you must first eject the USB stick. To do this, press the **EJECT USB STICK** button in the drop-down menu that appears in the "Select patient" screen after pressing the **MENU** button (Figure 4.22). Note that the **EJECT USB STICK** button is only accessible if EASEE® Set is not connected to an EASEE® Power device, i. e. from the "Select patient" screen.

Export the complete patients' data from EASEE® Set

Use the **FULL DATA EXPORT** button to transfer all the EASEE® Set storage files to a USB stick connected with EASEE® Set. A folder with subfolders for each of the patients included in the patient list will be created and saved on the USB stick (folder named "EASEESet"), provided that access of EASEE® Set to the USB stick is granted (see figures 4.29 to 4.31).

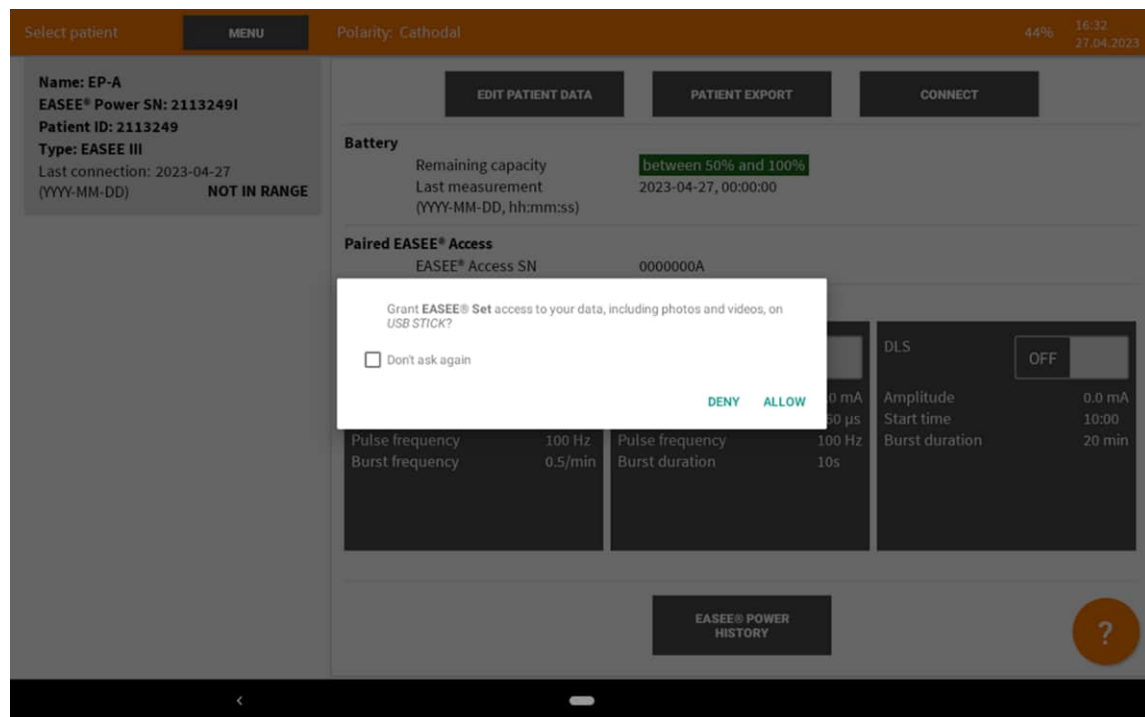


Figure 4.29: If a USB stick is connected with EASEE® Set when the **FULL DATA EXPORT** button is pressed, this dialog box is displayed and provides the options to deny or allow EASEE® Set access to the USB stick. If you wish not to be asked this question in the future and always agree to EASEE® Set accessing the connected USB stick, you can select the "Don't ask again" option by checking the box in front of it.

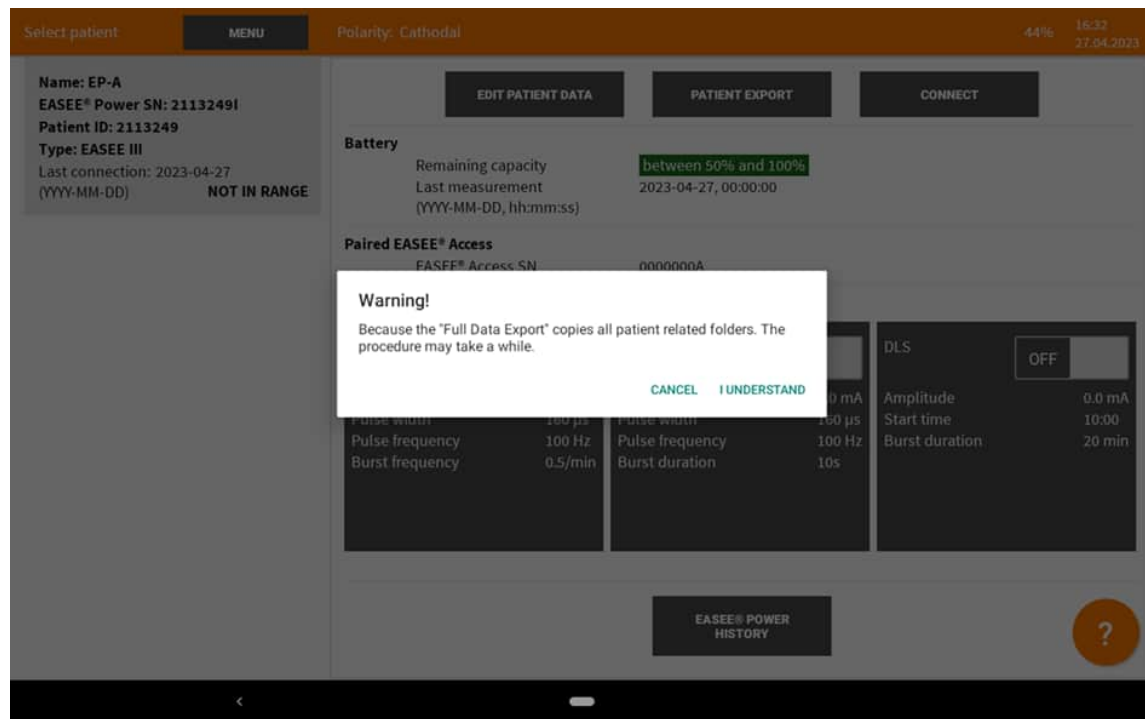


Figure 4.30: If EASEE® Set has been allowed access to the USB stick, this dialog appears and gives a warning that the export may take a long time.

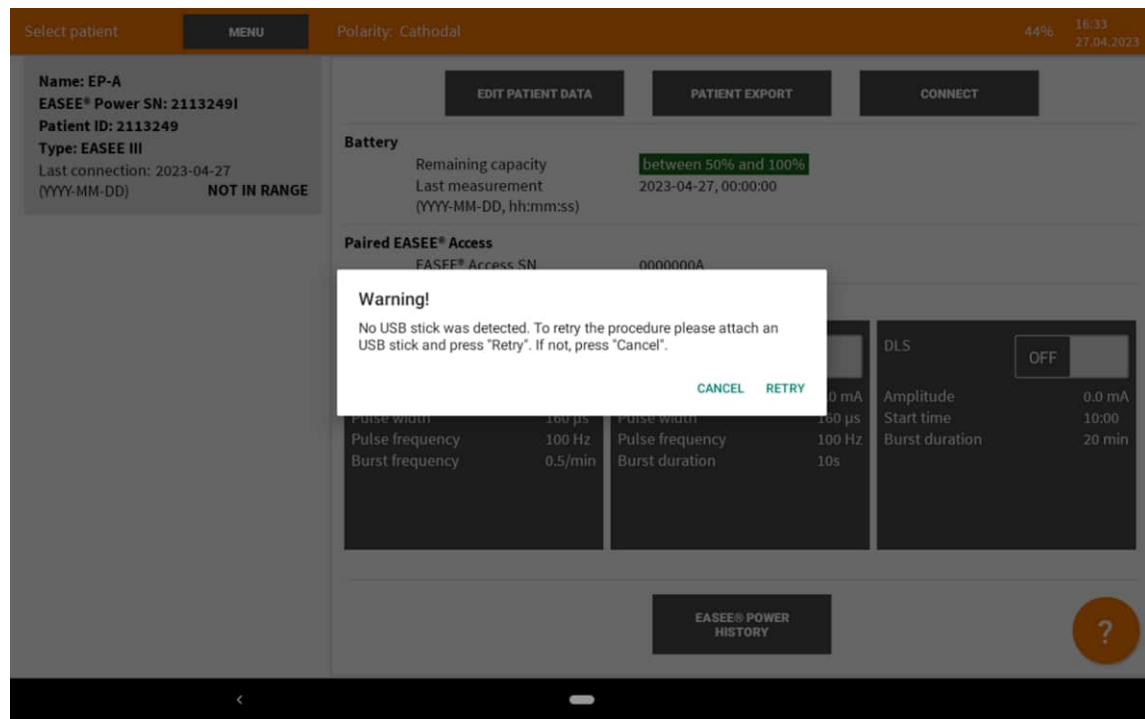


Figure 4.31: If the **FULL DATA EXPORT** button is pressed when no USB stick is connected with EASEE® Set, the dialog box shown here appears and provides the option to attach a USB stick to EASEE® Set and to repeat the export procedure (press the **RETRY** button), continuing with the step shown in Figure 4.29.

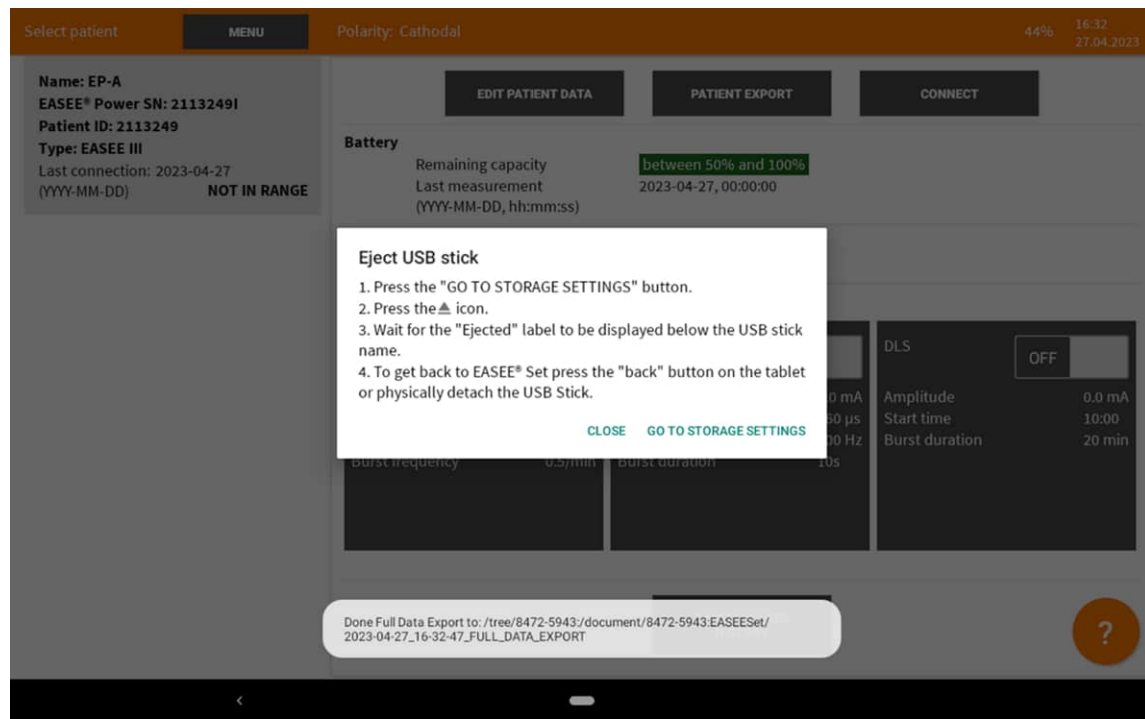


Figure 4.32: If the full data export is successfully completed, the folder location will temporarily appear at the bottom of the screen and a dialog box will be displayed explaining how to safely remove the USB stick.

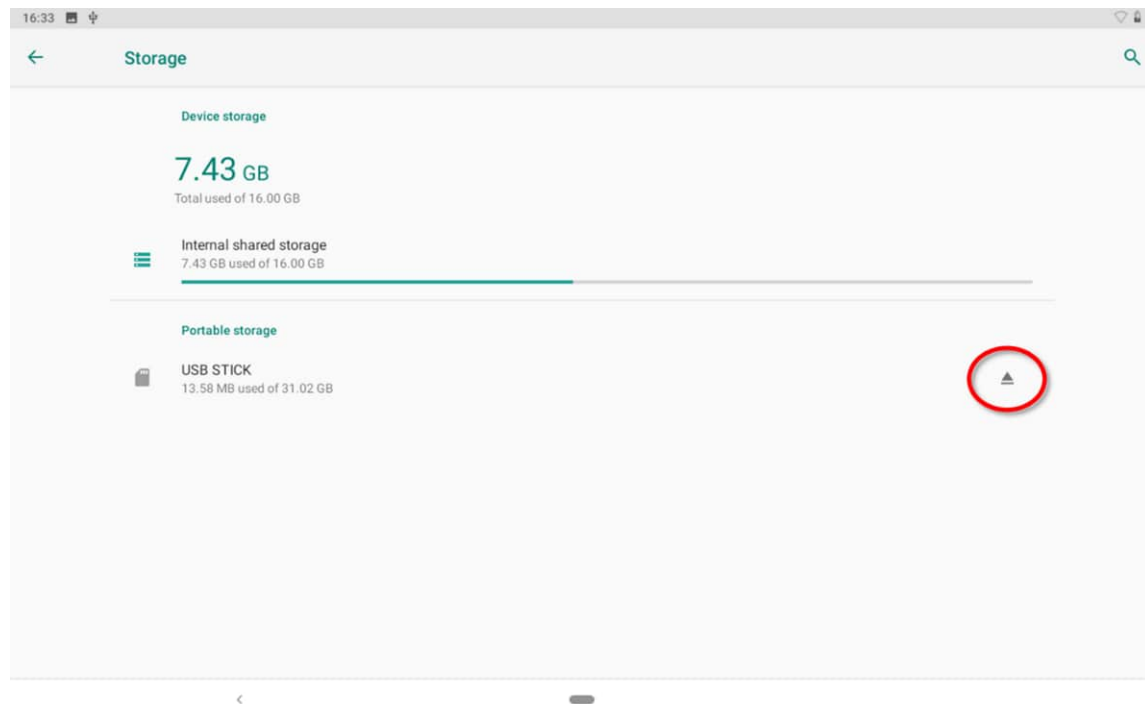


Figure 4.33: The "Storage" screen is displayed after pressing the **GO TO STORAGE SETTINGS** button as seen in Figure 4.32. To the right of the displayed USB STICK there is an icon (marked red here) that must be clicked to eject the USB stick from the EASEE® Set.

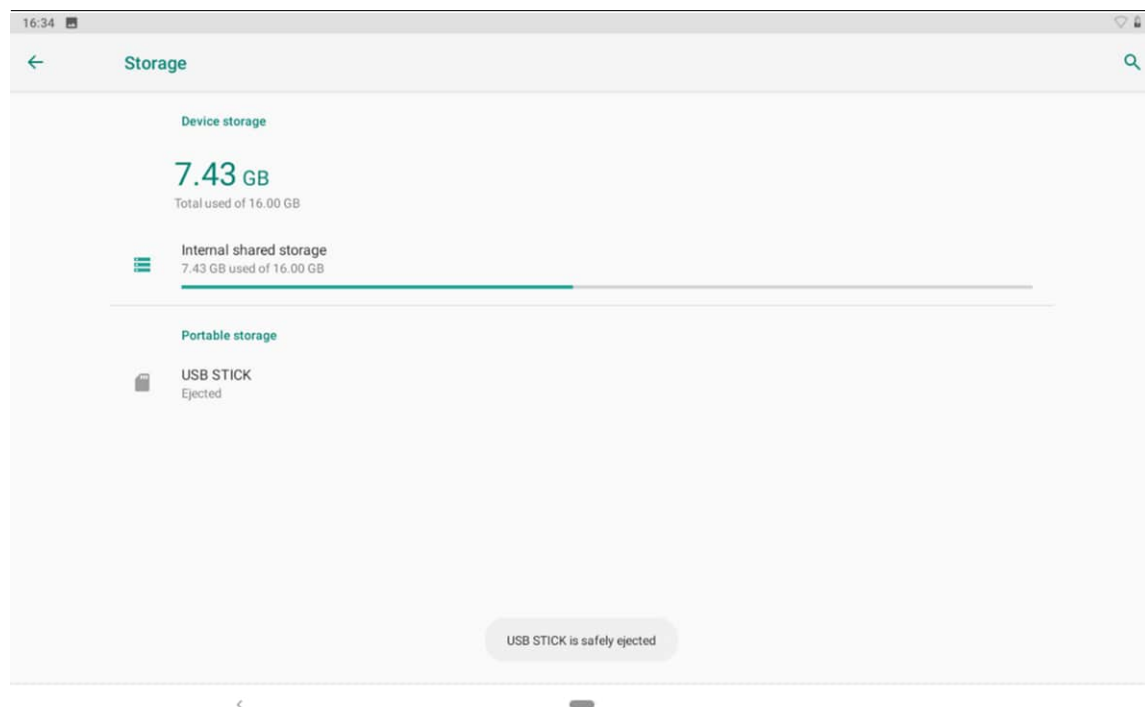


Figure 4.34: After the USB stick is labelled "Ejected", it can be safely removed from EASEE® Set.

The name of the exported folder has the format as follows:

<YYYY-MM-DD_hh-mm-ss>_FULL_DATA_EXPORT

where the following abbreviations for the date and time of folder creation apply:

YYYY: four-digit year

MM: two-digit month

DD: two-digit day

hh: two-digit hour (in 24 hours format)

mm: two-digit minute

ss: two-digit second

Application

About EASEE® Set

The **ABOUT EASEE® SET** button will display the "About" window that contains information on the EASEE® Set tablet and application as well as information.

User

Logout

The **LOGOUT** button is displayed only if EASEE® Set is not connected to an EASEE® Power device. Use this button to return to the "Login screen".

4.5.2 "Select Patient" Screen

To access details of requested patient data, click on the corresponding patient entry in the "Patient List" (e.g., Figure 4.21). The patient details (Figure 4.27, right) contain information regarding battery status of the corresponding EASEE® Power device, the serial number of the EASEE® Access device that is paired with the corresponding EASEE® Power device and stimulation parameters selected.

The information bar at the top of the screen shows which polarity is used for stimulation ("Cathodal" or "Anodal").

Adjacent to the displayed patient details are four buttons that allow more complex functions: three buttons above and one below the patient details. These functions are described in the following.

Edit patient data

Use the **EDIT PATIENT DATA** button to display the "Edit Patient data" dialog box (Figure 4.35). This button is only visible if EASEE® Set is not connected to the EASEE® Power device associated with this patient.

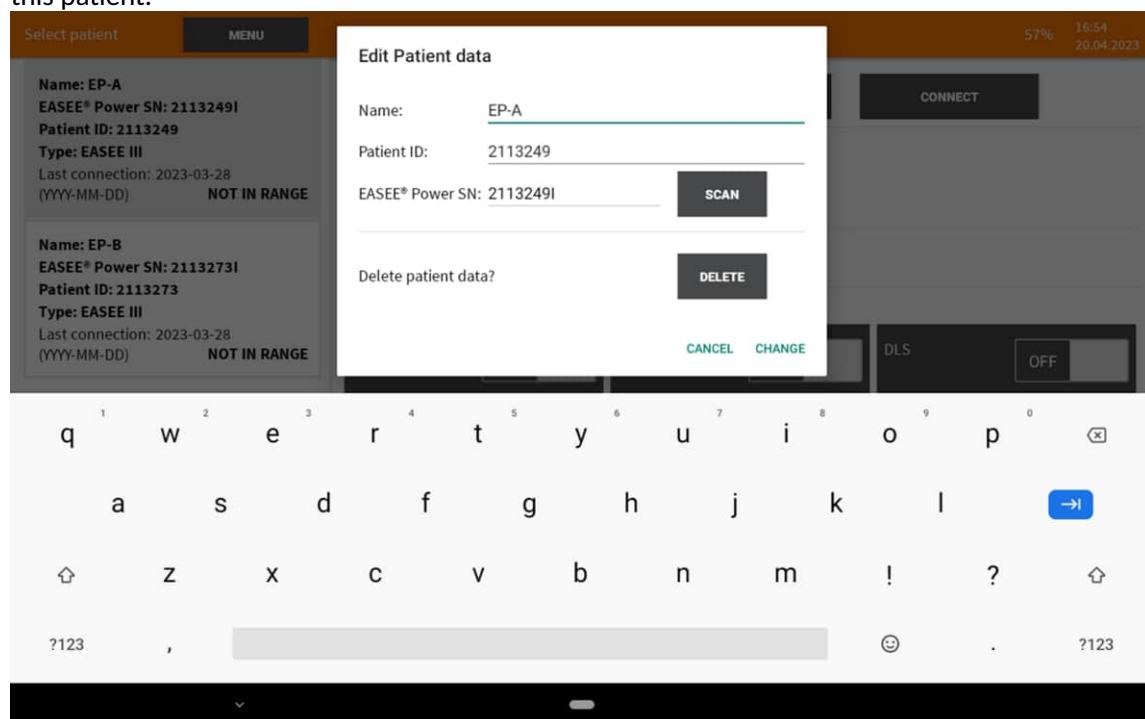


Figure 4.35: "Edit Patient data" dialog box for changing patient data, assigning a new EASEE® Power device or deleting patient data.

Edit the relevant information or scan for nearby EASEE® Power devices to change the EASEE® Power serial number. If more EASEE® Power devices are within range, only the EASEE® Power ID that has

been found first is displayed and the others are ignored.

To delete the data of the selected patient, click the **DELETE** button. This will display a confirmation dialog box (Figure 4.36). To finish the operation, set the safety toggle to the YES position and click the **DELETE** button at the bottom right.

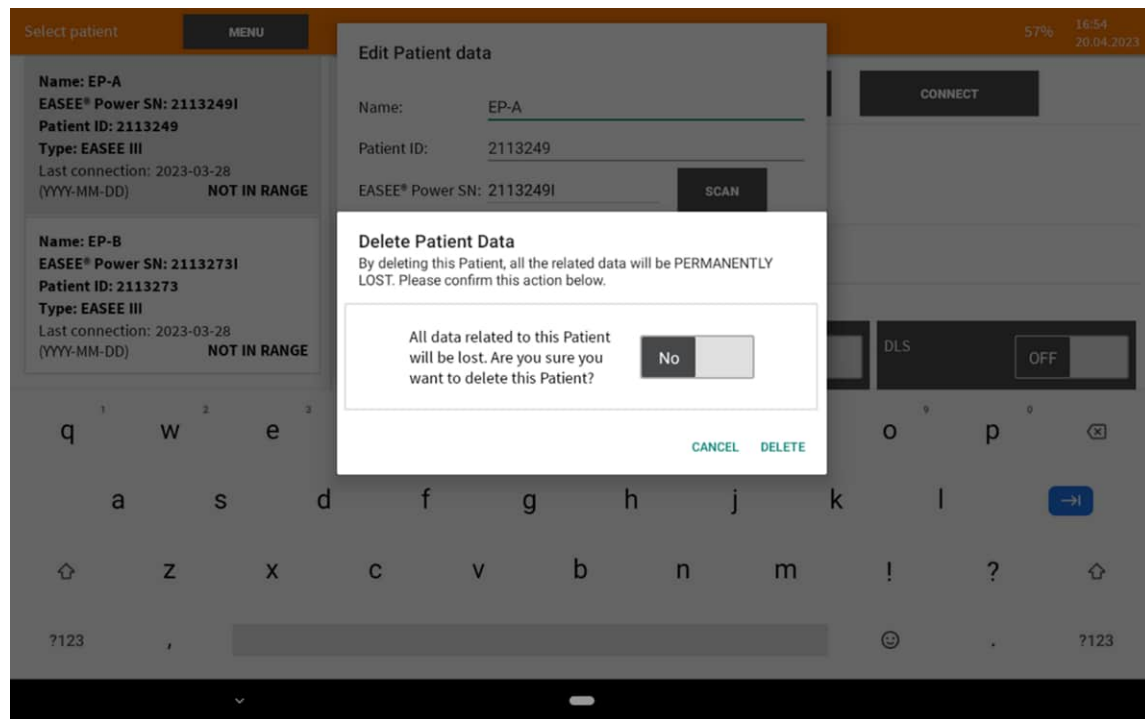


Figure 4.36: “Delete Patient Data” dialog box: Deletion of patient data requires a multi-step process that involves toggle switches and buttons to prevent accidental deletion.

Export patient data

Use the **PATIENT EXPORT** button to save the patient data. This button is only visible if EASEE® Set is not connected to the EASEE® Power device associated with this patient.

There are two saving options as displayed in the “Patient Export” window that pops up (Figure 4.37):

- Export latest files
- Export all files

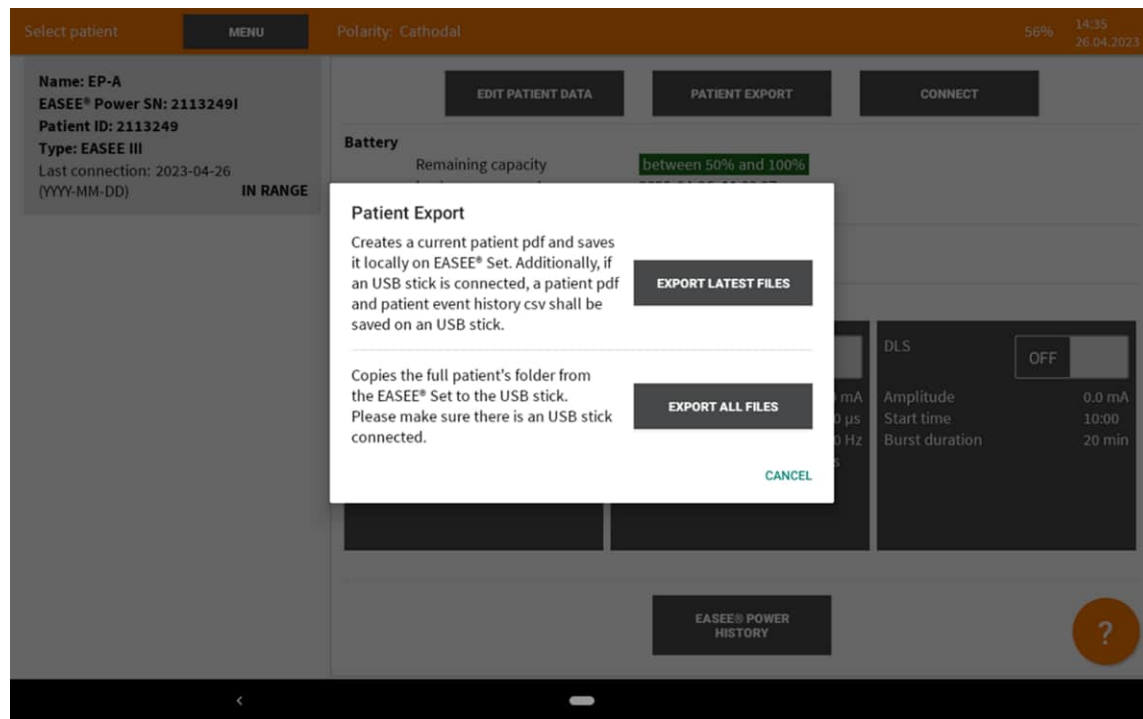


Figure 4.37: The “Patient Export” dialog box offers two options: Export of the current patient data only (**EXPORT LATEST FILES**) or of the complete patient folder with all the patient’s data stored in EASEE® Set (**EXPORT ALL FILES**).

Export latest files

Pressing the **EXPORT LATEST FILES** button, the current patient’s data are saved into a PDF file. The name of the exported file has the following format:

<Patient ID>-<date and time of file creation in YYYY-MM-DD_hh-mm-ss format>.pdf

(YYYY: four-digit year; MM: two-digit month; DD: two-digit day; hh: two-digit hour (in 24 hours format); mm: two-digit minute; ss: two-digit second).

The created file will be saved in a folder with the associated Patient ID as folder name, which is located in the "export" folder within the "EASEESet" folder on the tablet PC.

If the patient data has been exported successfully, a pop-up will temporarily appear at the bottom of the screen displaying the export file location.

In addition, when a USB stick gets connected to the USB-C port of EASEE® Set, a dialog box (Figure 4.29) appears, asking for permission for EASEE® Set to access the stick, which allows saving the created PDF file as well as the current event history file (in csv format). If no USB stick is connected to EASEE® Set, a dialog box appears (similar to Figure 4.31) in which a new attempt to export the data can be triggered (**RETRY** button).

Export all files

This option exports the complete patient's folder from EASEE® Set to the USB stick connected via the USB C socket of EASEE® set, i. e. the exported folder contains the data of the selected patient only. The name of the folder is identical with the patient's ID. The folder is stored in a folder called "EASEESet" on the USB stick.

Connect to EASEE® Power

Click the **CONNECT** button to initiate a connection between the EASEE® Set and the selected EASEE® Power device. This makes it possible to retrieve all the relevant information and event logs for the EASEE® Power device.

Once the connection has been made, the "Patient connected" screen is displayed, which provides further functionalities (see [section 4.5.3 "Patient Connected" Screen](#)).

EASEE® Power History

See [section 4.5.5 EASEE® Power History](#) for details related to the EASEE® Power history screen.

4.5.3 "Patient Connected" Screen

Once EASEE® Set is connected to the patient's EASEE® Power, the "Patient connected" screen is displayed (Figure 4.38).

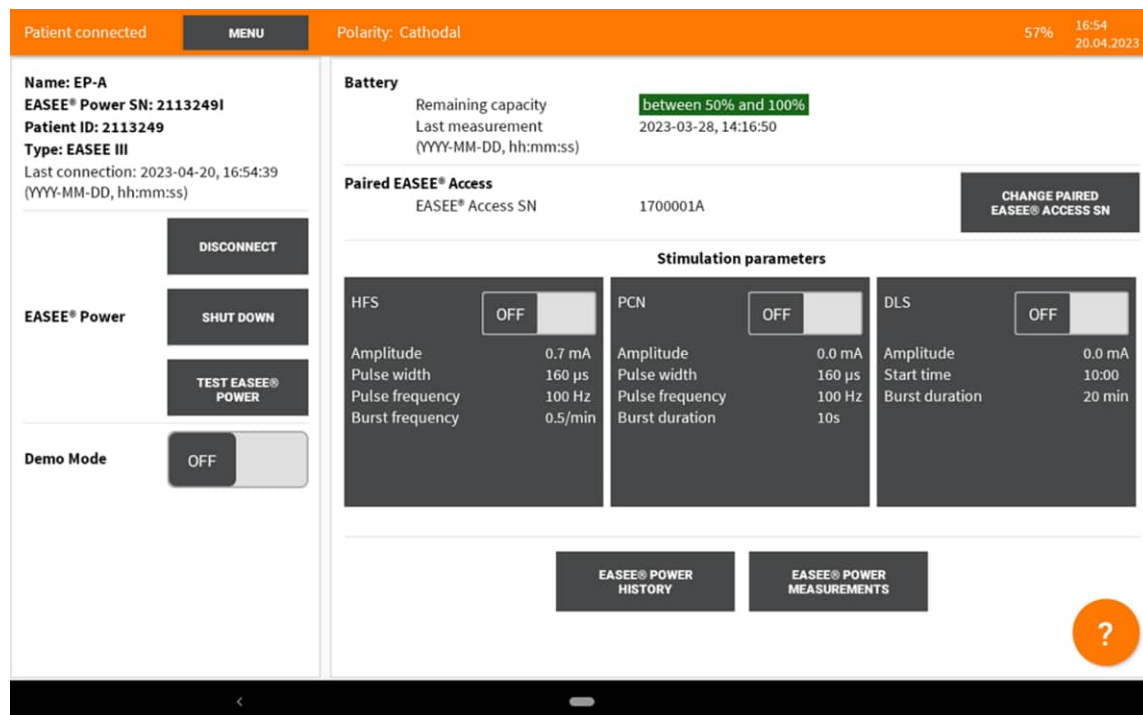


Figure 4.38: "Patient connected" screen.

This screen provides the following information and functions:

Data on the connected EASEE® Power and the related patient

The top left section of the screen contains the patient's name, the serial number of EASEE® Power, the patient ID, the type of EASEE® Power, and date and time of the last connection with EASEE® Power.

Disconnect from EASEE® Power

When you click the **DISCONNECT** button, a dialog box will appear where you can choose between two options, either to CANCEL the disconnect operation or to complete it (Figure 4.39). The window offers the opportunity to check the status of the three stimulation modes beforehand and to be informed of any particularities (for example, as here, that no EASEE® Access has yet been paired with the EASEE® Power in question).

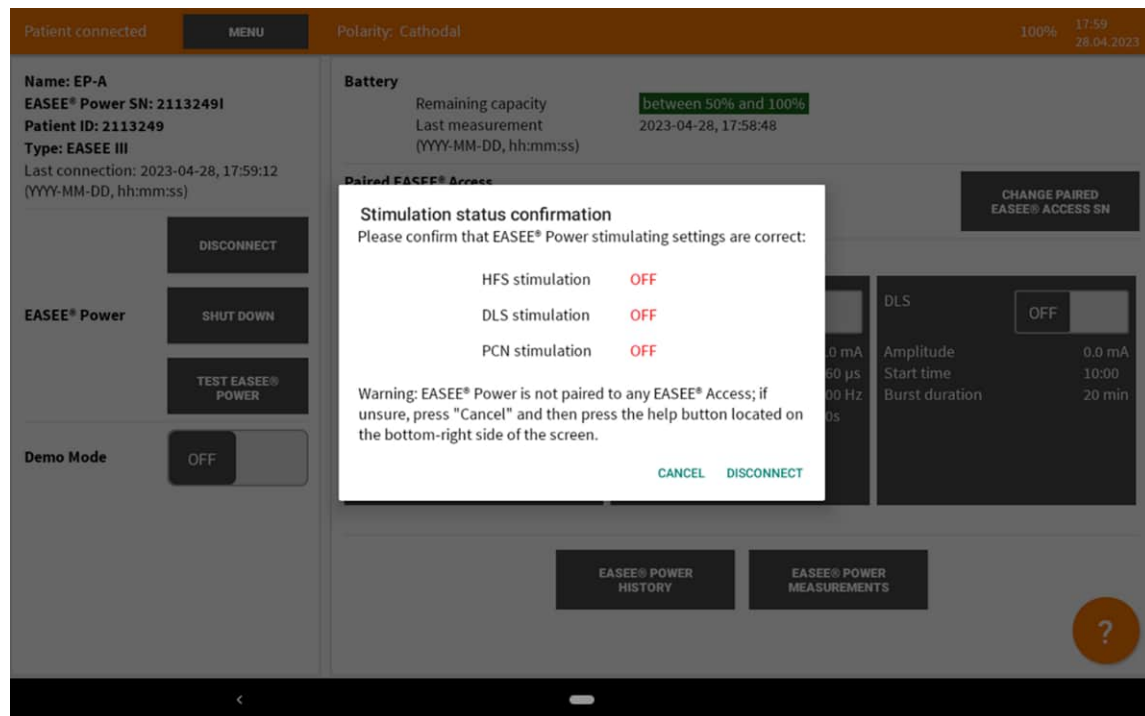


Figure 4.39: "Stimulation status confirmation" dialog box.

If the disconnect procedure is completed successfully, the connection between EASEE® Set and EASEE® Power is terminated, a PDF file with the latest patient data is stored, and EASEE® Set displays the "Select patient" screen.

Shut down EASEE® Power

To shut down EASEE® Power, click the **SHUT DOWN** button. A confirmation dialog is displayed to confirm the shutdown action (Figure 4.40).

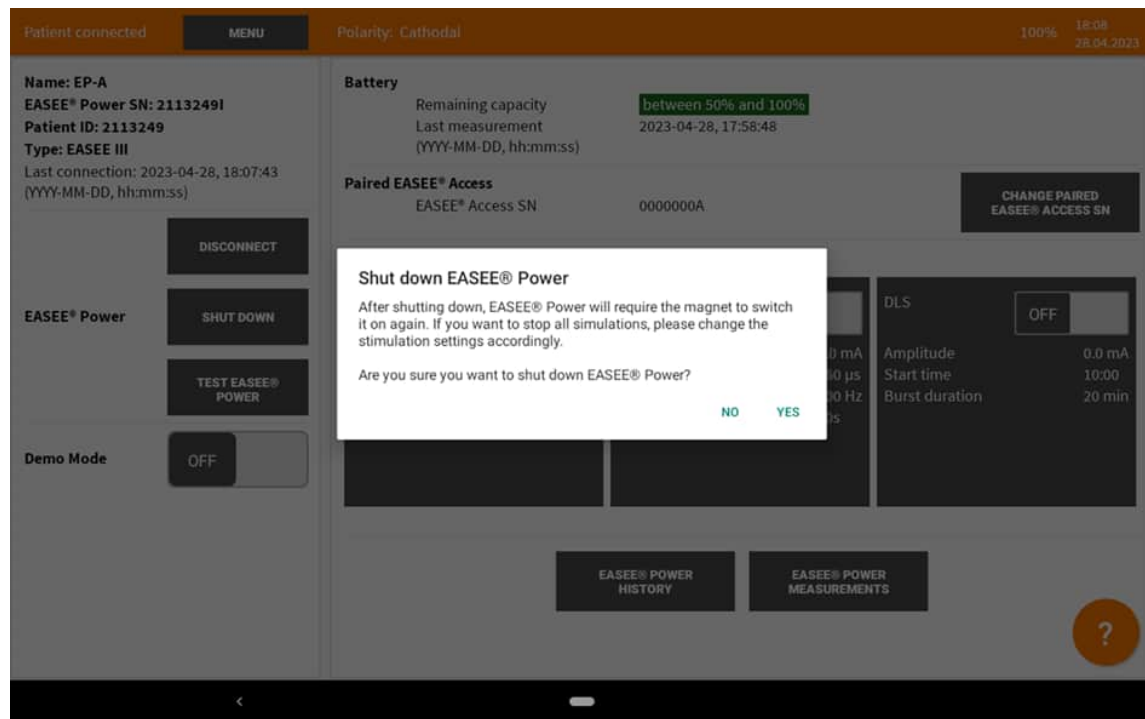


Figure 4.40: Dialog box for confirmation that EASEE® Power is to be shut down.

When EASEE® Power has been shut down (Figure 4.41), the stimulation modes are disabled, which means that no more stimulation is delivered, and when the EASEE® Power is powered up again, it will not give any stimulation signals until the EASEE® Set reconnects to it and enables stimulation (see [section 4.5.4 Editing Stimulation Settings](#)).

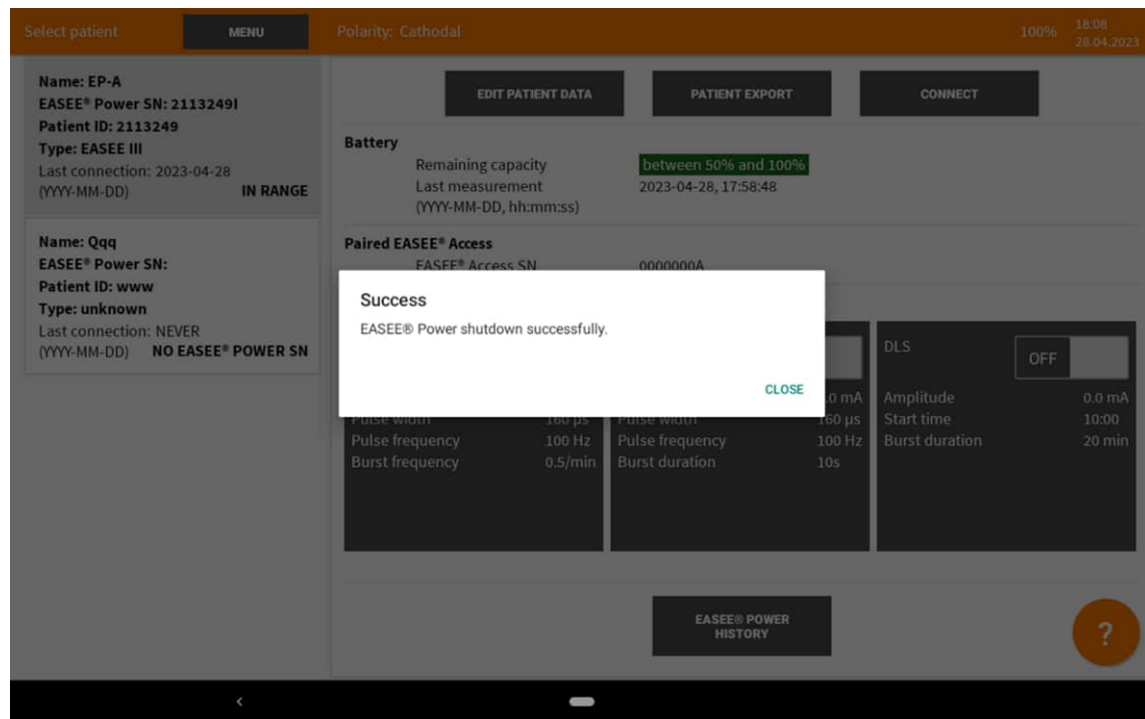


Figure 4.41: Message box confirming that the EASEE® Power has been successfully shut down.

Restart EASEE® Power

If EASEE® Power has been turned off - either by the patient or the physician - it can only be turned on again using the activation magnet and using EASEE® Set / EASEE® Connect. To turn on EASEE® Power: Move the activation magnet closely over the EASEE® Power device and then perform the following steps within the next 3 minutes:

- Place the EASEE® Connect as close as possible to the EASEE® Power.
- In EASEE® Set, click the REFRESH button on the “Patient List” submenu (**section 4.5.1 Patient List**) to update the Patient List with refreshed classification of all the EASEE® Power devices in range or not in range (Figure 4.24).
- Click to select the relevant patient from the list.
- Click the **CONNECT** button to initiate a connection with the associated EASEE® Power device.

Test EASEE® Power

This button **TEST EASEE® POWER** provides the possibility to perform some functional tests of EASEE® Power. An example of potential test results is given in Figure 4.42.

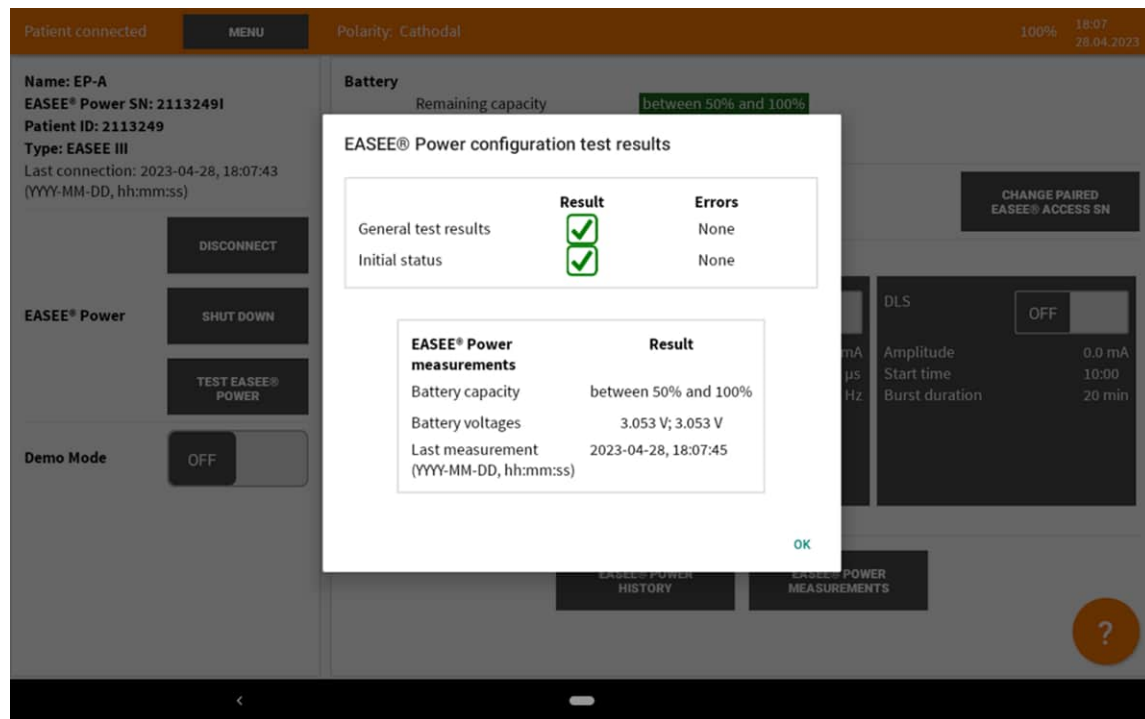


Figure 4.42: Exemplary results of an EASEE® Power test.

Manage Demo Mode

Demo mode should be used to train the patient on the use of EASEE® Access, as the actions are not taken into account or recorded by EASEE® Power. Use the toggle **DEMO MODE** to enable ("ON") or disable ("OFF") the demo mode. Enabling of the demo mode requires confirmation. The demo mode should be disabled when the training is completed. However, the demo mode is automatically disabled 30 minutes after initial enabling.

Battery Status

The remaining battery capacity of the EASEE® Power device is given as a percentage and is also color-coded:

- green: sufficient capacity ($\leq 20\%$)
- yellow: medium to low capacity (between 1% and 20%)
- red: very low capacity ($< 1\%$) – stimulation will be stopped

The date and time of the most recent measurements are also displayed.

Display the Serial Number of Paired EASEE® Access

In the default state EASEE® Power is not initially paired with an EASEE® Access. This can be seen by the numbers "000000" displayed in the relevant EASEE® Set display field. If the EASEE® Power

is already paired with an EASEE® Access device, the serial number of that device is shown. If the initially paired EASEE® Access device gets lost or broken, a new EASEE® Access device can be paired with the EASEE® Power device as described in the following section.

“Pairing” an EASEE® Access with an Implanted EASEE® Power

To ensure safe operation of an EASEE® Access device, it is necessary to pair the EASEE® Access device with a specified EASEE® Power device using a procedure called “Pairing”. This means that the EASEE® Access device can only communicate with the paired EASEE® Power, and that EASEE® Power can only communicate with the paired EASEE® Access.

Follow the steps below to perform the pairing procedure:

- Click the **CHANGE PAIRED ACCESS SN** button to display the appropriate dialog (Figure 4.43).
- Enter the serial number of the EASEE® Access you want to pair with the specified EASEE® Power.

Make sure that this EASEE® Access device is not yet or no longer (see **section 5.5.7 Unpairing of EASEE® Access from EASEE® Power**) paired with an EASEE® Power device.

- Click **CHANGE**. If the procedure is successful, the interface will update and display the new EASEE® Access SN (serial number).
- To continue the pairing process, EASEE® Set - Hardware automatically disconnects from EASEE® Power after a message window with the appropriate information appeared and the user confirmed this information. Wait until the disconnection is completed.
- Press any button on EASEE® Access. The four LEDs on the EASEE® Access will start flashing yellow. After some time the four LEDs will turn green, showing that pairing has been successful. From now on this EASEE® Access is paired with the specified EASEE® Power.

Please note that the functionalities of EASEE® Access only work on EASEE® Power if this EASEE® Power is not connected with an EASEE® Set.

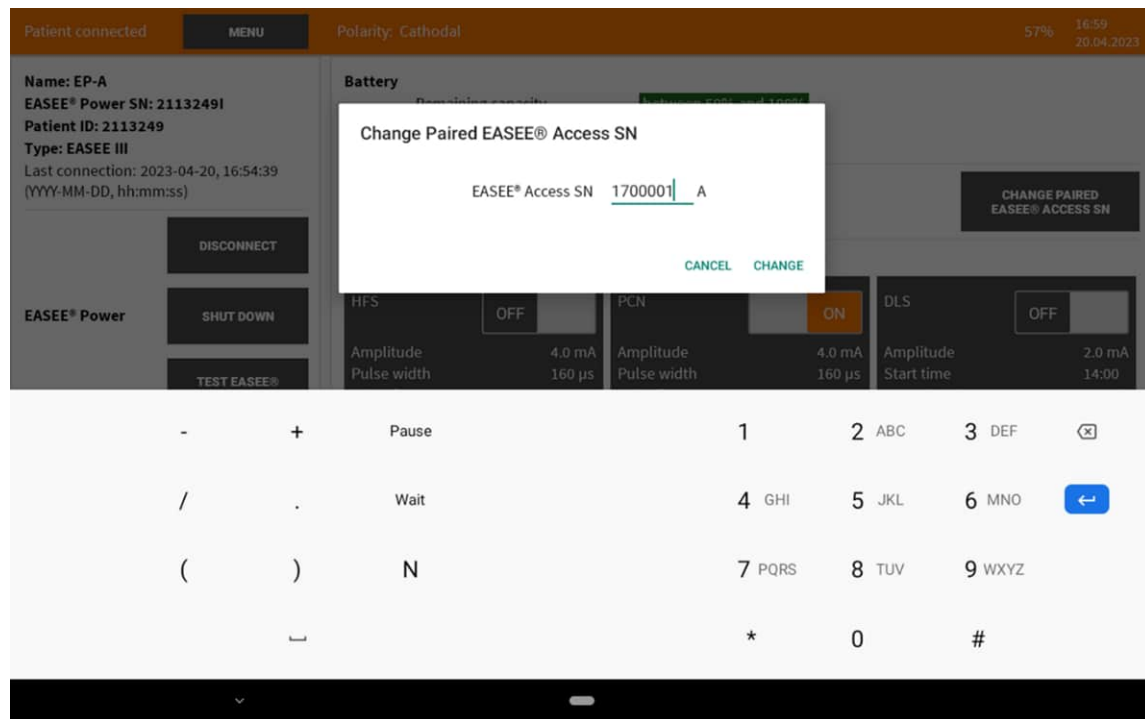


Figure 4.43: "Change Paired EASEE® Access SN" dialog box for specifying the serial number of an EASEE® Access device when the EASEE® Power is being paired with an EASEE® Access for the first time or when a previous EASEE® Access has to be replaced.

Display and Edit Stimulation Parameters

The currently set stimulation parameters are shown. The settings can be edited after pressing one of the windows named HFS, PCN, and DLS that display the parameter values. Refer to **section 4.5.4 Editing Stimulation Settings** for more information on defining stimulation parameters.

EASEE® Power History Screen

See **section 4.5.5 EASEE® Power History** for details related to the "EASEE® Power History" screen that opens after pressing the **EASEE® POWER HISTORY** button.

View Measurement Results

Click the **EASEE® POWER MEASUREMENTS** button to display the latest results of battery and electrode impedance measurements (Figure 4.44).

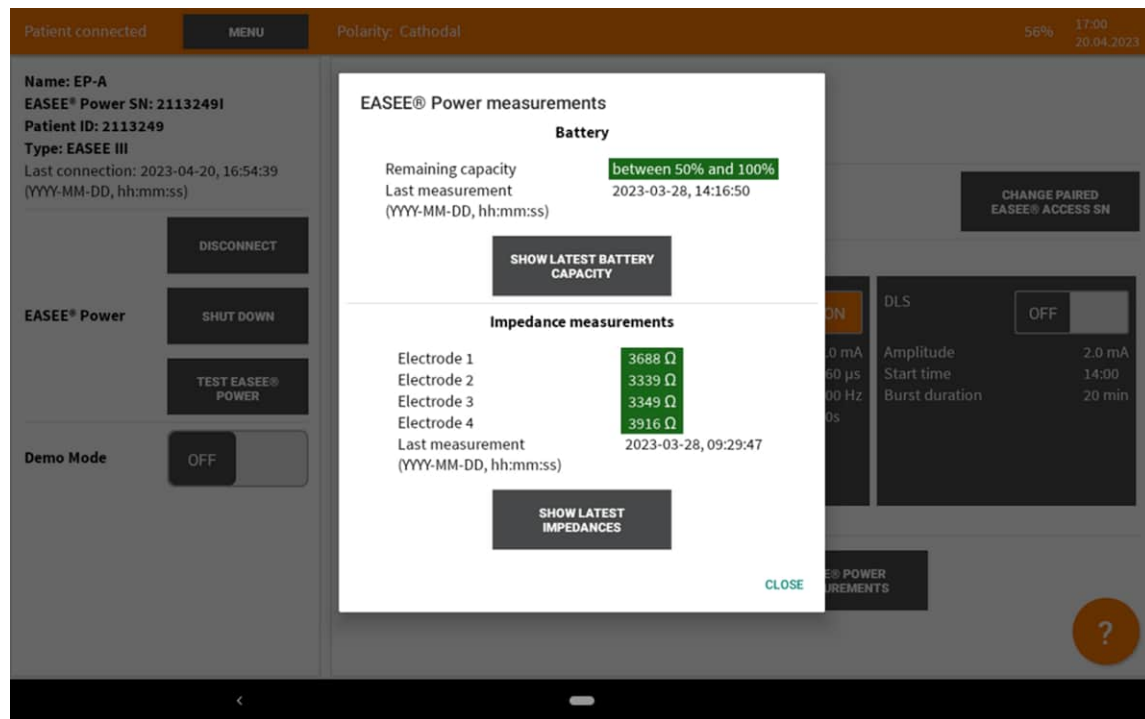


Figure 4.44: The “EASEE® Power measurements” box is displayed, giving information on battery status and electrode impedances.

The new box displayed is divided into two sections: battery information and impedance measurements.

The remaining battery capacity data is color-coded, using green (sufficient capacity), yellow (medium to low capacity) and red (very low capacity).

The impedance data is also color-coded, for easy and accurate interpretation: green (in the tolerance range) and red (out of tolerance range).

4.5.4 Editing Stimulation Settings

Click the window on the “Patient connected” screen that displays the stimulation parameters you want to edit (HFS, PCN, or DLS) to access the “Stimulation” screen (see figures 4.45 to 4.47). These screens provide the following functions:

- Edit stimulation parameters
- Test the currently set stimulation parameters
- Save the currently set stimulation parameters

Further details about editing and testing stimulation parameters can be found in the following **section 4.5.4 Edit Stimulation Parameters** and in **section 4.5.4 Testing and Saving New Stimulation Parameters**, respectively.

Activate or deactivate periodic stimulation or Patient-controlled neurostimulation (PCN) using the respective HFS or DLS or PCN toggle switch (OFF – ON) in the Stimulation parameters section of the “Patient connected” screen (see Figure 4.38).

Edit Stimulation Parameters

Pressing the “HFS” window on the “Patient connected” screen enables the user to access the dialog box for editing the HFS stimulation parameters (Figure 4.45). Similarly, the “DLS” window and the “PCN” window enables the user to change the DLS (Figure 4.46) and the PCN stimulation parameters (Figure 4.47), respectively.

The screenshot displays the HFS stimulation parameter dialog box. At the top, an orange header bar contains the text "Stimulation: HFS" on the left, and "56%", "17:00", and "20.04.2023" on the right. Below the header, the parameters are adjustable:

- Amplitude:** A slider with a teal dot, labeled "Current value: 2.0 mA".
- Pulse width:** A slider with a teal dot, labeled "Current value: 160 µs".
- Pulse frequency:** Two buttons: "100 Hz" (orange) and "160 Hz" (dark grey).
- Burst frequency:** Five buttons: "0.5/min", "1/min", "2/min", "4/min" (all dark grey), and "6/min" (orange).

At the bottom left is a "TEST" button. At the bottom right is a box titled "Save to EASEE® Power" containing the text "Status: Synchronized" and two buttons: "SAVE & BACK" and "CANCEL & BACK". The bottom of the screen shows a black navigation bar with a back arrow and a home icon.

Figure 4.45: Dialog box with editable parameters for HFS stimulation.

Stimulation: DLS 56% 17:02 20.04.2023

Amplitude
Current value: 1.0 mA

Burst duration
Current value: 20 min

Start time
14:20
Hours

Minutes

TEST START DLS TEST 00:20:00

Save to EASEE® Power
Status: Not Synchronized
SAVE & BACK CANCEL & BACK

Figure 4.46: Dialog box with editable parameters for DLS stimulation.

Stimulation: PCN 56% 17:03 20.04.2023

Amplitude
Current value: 2.2 mA

Pulse width
Current value: 400 μ s

Burst duration
Current value: 60 s

Pulse frequency
100 Hz 160 Hz

TEST START PCN TEST 01:00

Save to EASEE® Power
Status: Synchronized
SAVE & BACK CANCEL & BACK

Figure 4.47: Dialog box with editable parameters for PCN.

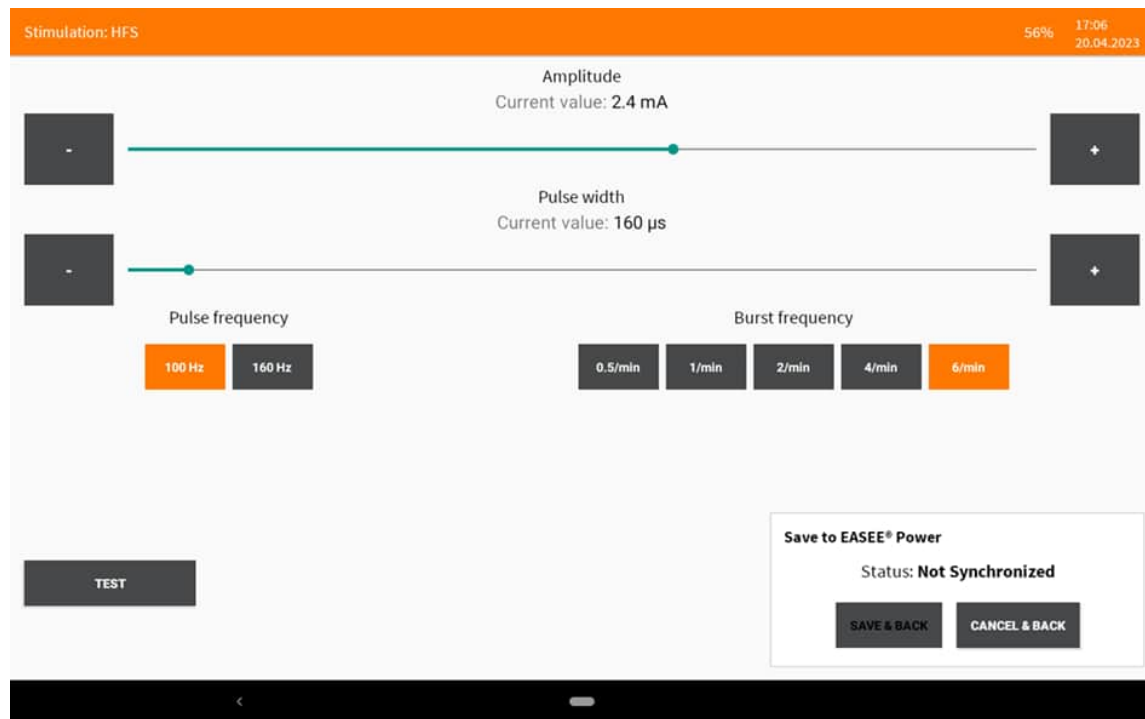


Figure 4.48: Example of “Stimulation” edit dialog box (here: HFS stimulation) with sliders and buttons for adjusting the stimulation parameters. If the settings have been changed in this dialog box, the status of saving the settings to EASEE® Power changes to “Not Synchronized” (bottom right).

There are two types of control elements on each “Stimulation” screen: the horizontal sliders and the buttons, which represent individual values. Use the horizontal slider to adjust the specific parameter to the requested value. A more precise setting of the parameter values in single steps downwards or upwards is possible with the “-” and “+” buttons to the left and right of each slider, respectively.

Click the buttons that display individual values to prepare setting the corresponding parameter to the appropriate value.

When stimulation parameters that define the stimulation pulses have been changed, the stimulation must first be tested before the new settings can be saved and take effect (see **section 4.5.4 Testing and Saving New Stimulation Parameters**).

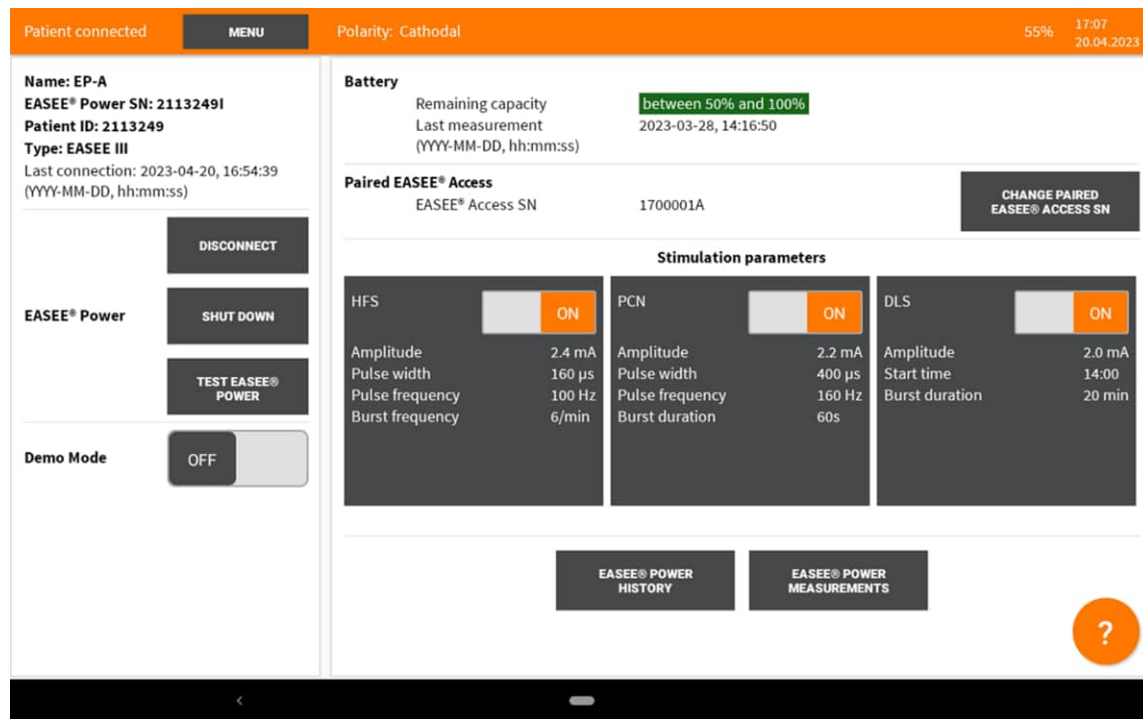


Figure 4.49: "Patient connected" screen after activation of all three stimulation modes (example shown for illustration only).

Testing and Saving New Stimulation Parameters

Before modifications of stimulation parameters defining stimulation pulses can take effect, a stimulation test must be performed to validate and test the new parameters and to optimize the internal settings of the EASEE® Power accordingly. A separate test must be carried out for each of the three stimulation modes HFS, PCN, and DLS after the pulse pattern was modified.

The **SAVE & BACK** button is disabled until the end of the test phases (see figures 4.48 to 4.49, bottom right), unless only parameters were modified that have no influence on the pulses (e. g. burst duration or start time).

To initiate the test of a modified stimulation parameter set for HFS, PCN, or DLS, press and hold the corresponding activated **TEST** button on the left-hand side of the screen, and hold it down for as long as the test is to continue (Figure 4.49, bottom left). The stimulation will only be delivered as long as the button remains pressed, but for safety reasons it will be ended after about 60 seconds, even if the button remains pressed.

During the test phase, the status in the "Save to EASEE® Power" section (bottom right of the screen) changes from "Not Synchronized" to "Testing for n seconds..." (Figure 4.50), where n is the number

of seconds that have passed during the current test. After successfully completing the test phase, the status changes to “Ready to save” and the impedances determined during the test phase are displayed in a new window (Figure 4.51). After confirmation by pressing the CLOSE button, the displayed window closes, the **SAVE & BACK** button is activated (Figure 4.52) and must be clicked to save the new parameters in EASEE® Power.

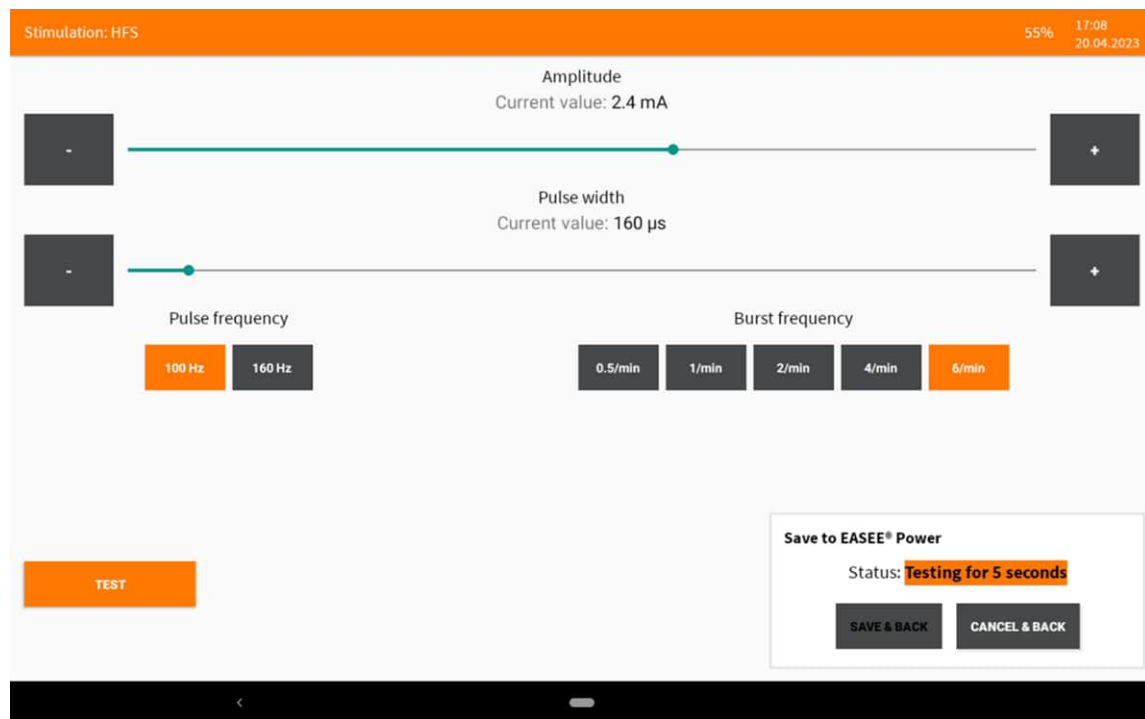


Figure 4.50: "Stimulation" screen during testing of new HFS stimulation parameters (example shown for illustration only).

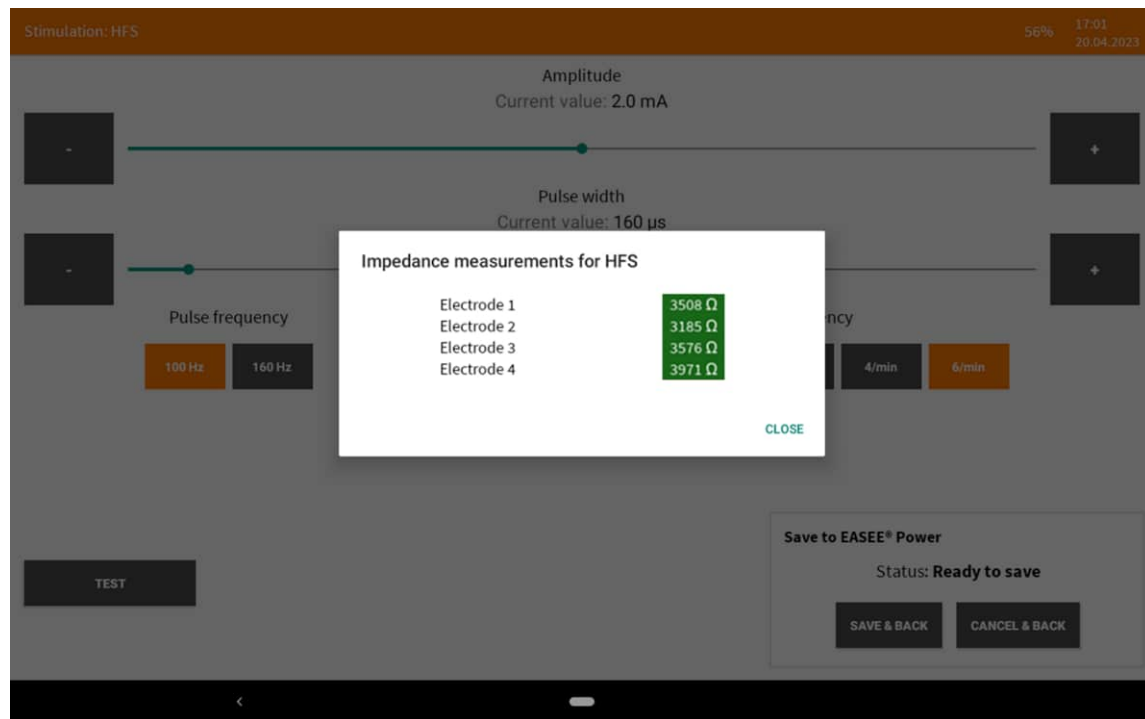


Figure 4.51: After successfully testing the new stimulation parameters, a display window will appear showing the impedances detected during the test.

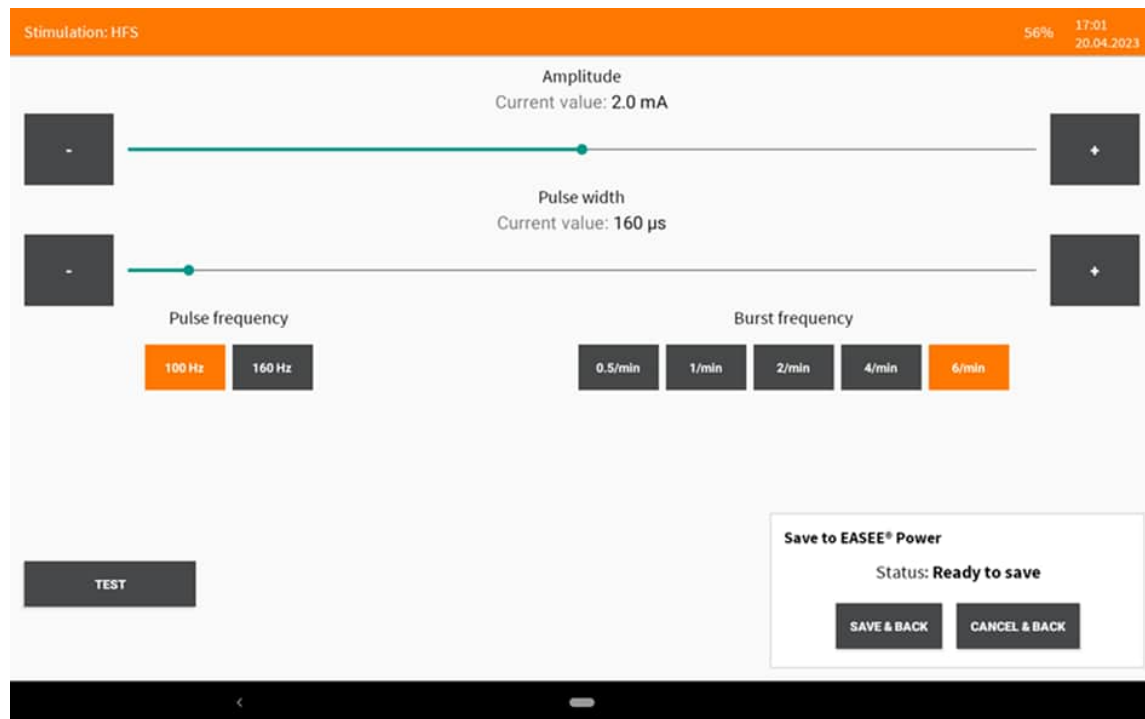


Figure 4.52: "Stimulation" screen after testing but before saving the new stimulation parameters (example shown for illustration only). Status: "Ready to save".

Click the **SAVE & BACK** button to save the desired changes to EASEE® Power. Alternatively, click the **CANCEL & BACK** button if you want to discard the new parameter set.

The "Stimulation" screens for DLS and PCN provide a **START DLS TEST** and **START PCN TEST** button, respectively (Figure 4.45 and Figure 4.46). Clicking these buttons starts the test stimulation with the currently selected parameters of the corresponding stimulation mode, i.e. in particular with the selected burst duration. The indicator to the right of these buttons shows the time remaining for this test. The test stimulation ends automatically when the stimulation duration set with the "Burst duration" parameter is over.

In addition, it is possible to cancel this test stimulation at any time by pressing the same button again, whose label changes during the test to **STOP DLS TEST** or **STOP PCN TEST**, respectively.

4.5.5 EASEE® Power History

The "EASEE® Power history" screen (Figure 4.53) is displayed when the EASEE® POWER HISTORY button is pressed on either the "Select patient" screen (Figure 4.27) or the "Patient connected" screen (Figure 4.38).

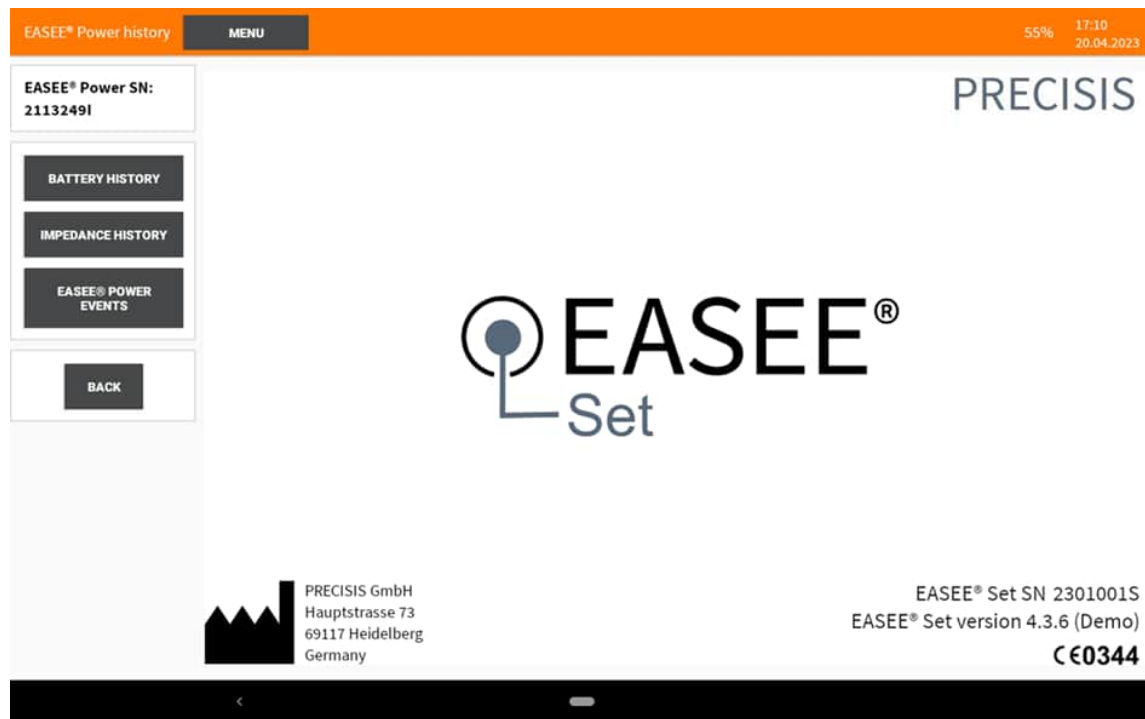


Figure 4.53: Detail from the "EASEE® Power history" screen (extract) with three buttons for displaying results of battery and impedance measurements, as well as dates and times of any events logged with EASEE® Power.

This screen provides the following functions:

- Display battery history (**BATTERY HISTORY** button)
- Display impedance history (**IMPEDANCE HISTORY** button)
- Display EASEE® Power events (**EASEE® POWER EVENTS** button)

Settings of the graphs which are displayed with the above-mentioned functions can be modified after pressing the **GRAPH SETTINGS** button (Figure 4.57).

The data of the graph that visualizes the EASEE® Power events can be exported as CSV file by clicking the **CSV** button (see section Graph Export).

Battery History

The "Battery History" graph (Figure 4.54) displays the remaining battery capacity of the EASEE® Power device over time.

Click on each value dot (colored circle) to display more information about this value.

This graph supports zooming and scrolling on both X and Y axes via the EASEE® Set touch screen.

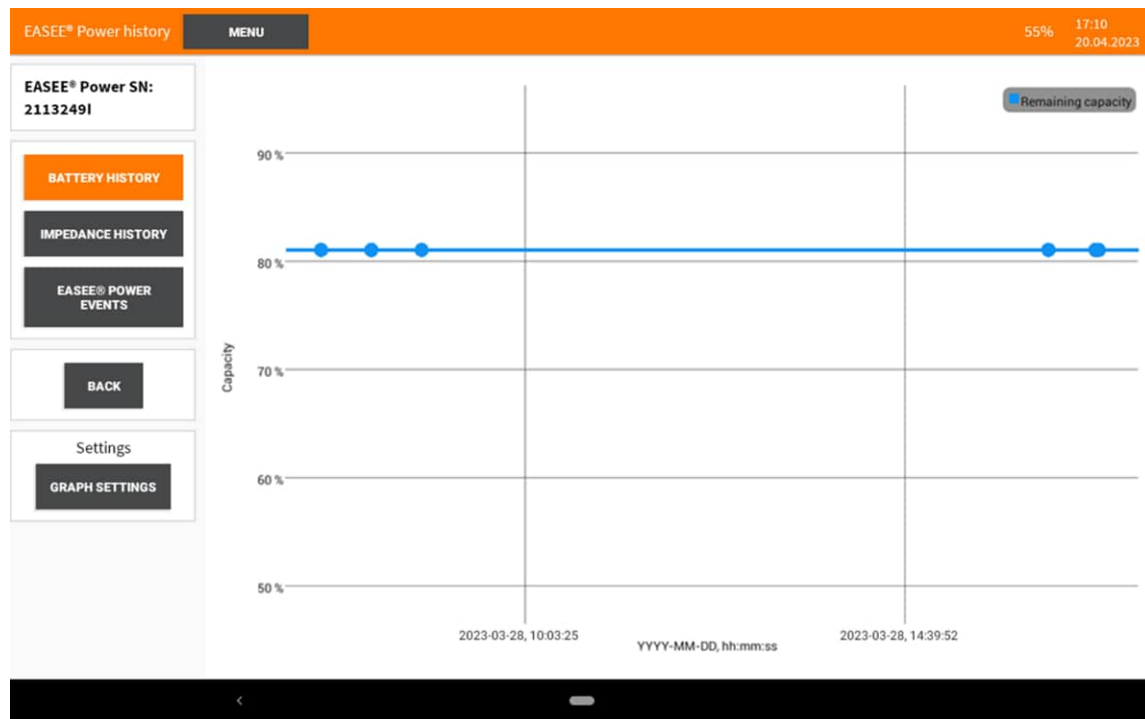


Figure 4.54: “EASEE® Power history” screen showing the remaining battery capacity as measured at different times.

Impedance History

The graph shows the electrode impedance values recorded by EASEE® Power over time. Click on each value dot (colored circle) to display more information about this value.

This graph supports zooming and scrolling on both X and Y axes via the EASEE® Set touch screen.

EASEE® Power Events

This graph (Figure 4.55) displays the various events recorded by the EASEE® Power device over time.

Click on each value dot (colored circle) to display more information about this value (Figure 4.56).

This graph supports zooming and scrolling on the X axis via the EASEE® Set touch screen.



Figure 4.55: Display of events logged by EASEE® Power.

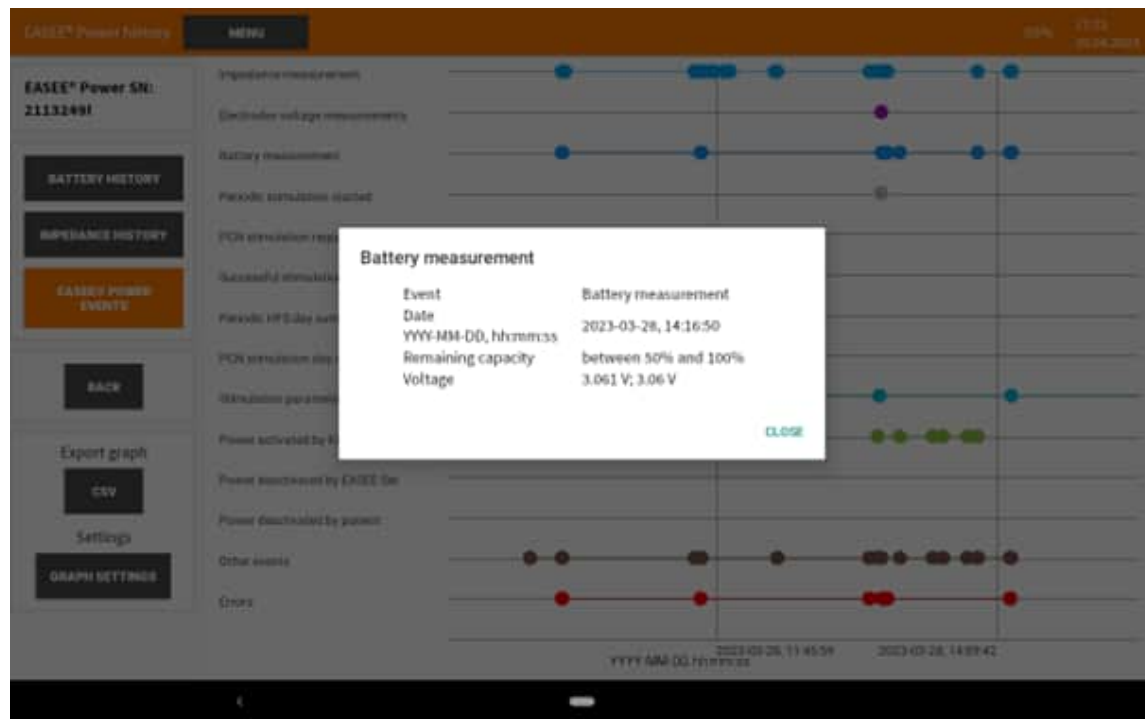


Figure 4.56: The "Battery measurement" dialog box that appears after clicking one of the Battery measurement value dots shows the date and time of the battery measurement, the remaining battery capacity and the measured voltages of the two batteries.

Graph Settings

Click the **GRAPH SETTINGS** button in the bottom left corner to display a dialog box showing graph settings (Figure 4.57).

To show or hide the values of the available categories, toggle the show/hide switch to the desired setting.

To change the display color for the values of a category, click on the color box. This will open the "Color picker" dialog box (Figure 4.58).

Choose the desired color and click **SELECT** to save the change and return to the "Graph settings" dialog box.

Finally, click the **CHANGE** button to make the changes active in the graph.

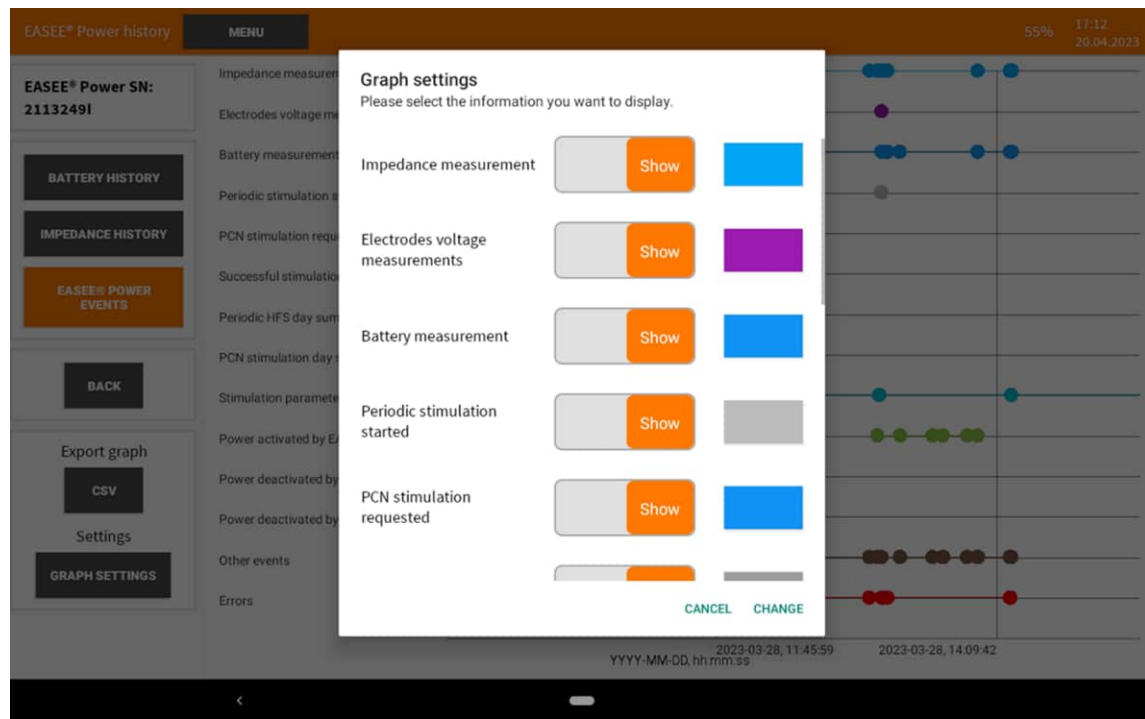


Figure 4.57: "Graph settings" dialog box for changing the graph properties.

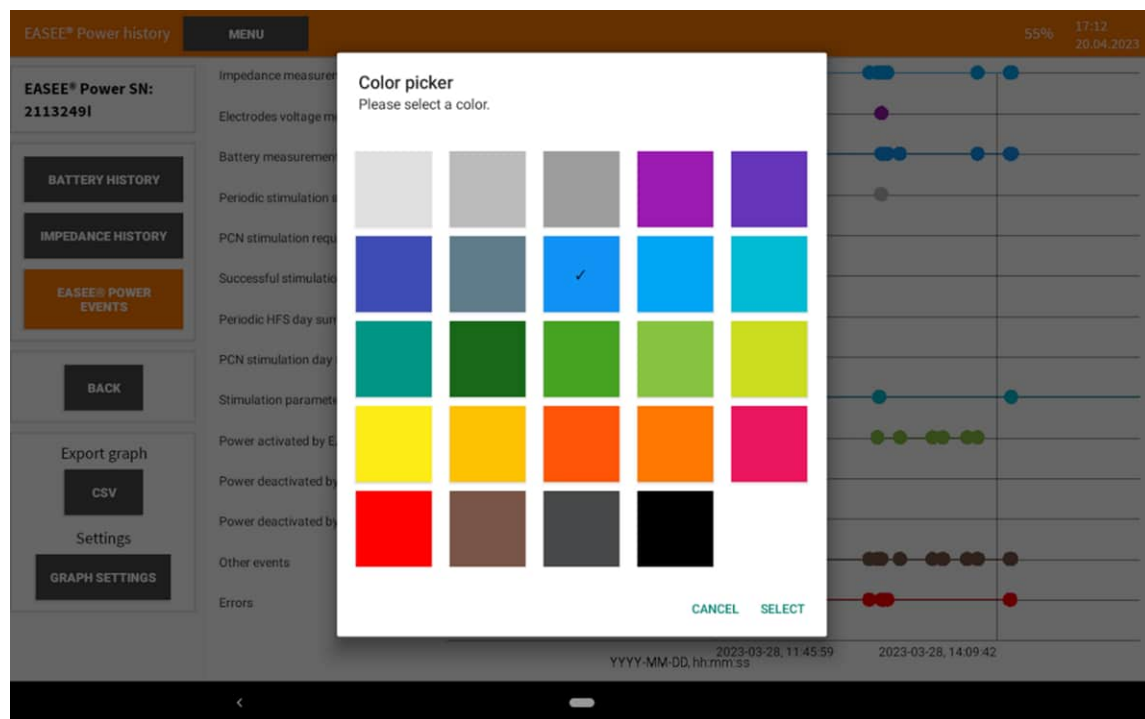


Figure 4.58: "Color picker" dialog box for changing the colors used to display the various data on the graph.

Graph Export

Use the **CSV** button in the "Export graph" section to export the data of an Event history graph. The exported files are saved in a folder with the associated Patient ID as folder name, which is located in the "export" folder inside the "EASEESet" folder in the tablet's internal storage. After successful export, the file location is briefly displayed on screen.

The exported file name has the following format:

<Patient ID>- events-<date and time (format: YYYY-MM-DD_hh-mm-ss)>.csv

with the following representations of the format components:

YYYY: four-digit year; MM: two-digit month; DD: two-digit day; hh: two-digit hour (in 24-hour format); mm: two-digit minute; ss: two-digit second.

4.6 File Structure

When EASEE® Set - Software is first run after installation, it creates an "EASEESet" folder accessible by connecting the tablet to a PC using a compatible USB cable (connect it to the tablet using the USB micro-B port). This folder contains the following subfolders:

- /backup

This folder contains the "Restore point" files. It is created when the first backup file is saved.

- /communication

This folder contains files that document the operation of EASEE Set.

- /export

This folder contains all exported PDF and CSV files, stored in subfolders with the associated Patient IDs as folder names. The /export folder is created when the first export is made.

- /temp

This folder contains temporary application files. It is created when needed by the EASEE® Set - Software.

- /updates

The folder is created at first EASEE® Set - Software run. It is used for EASEE® Power firmware updates.

4.7 User Alert and Warning Messages

During the use of the EASEE® Set - Software the following alert and warning messages (right column of Table 5 below) can be displayed to the user:

Location	Trigger	Message
All screens	Unexpected disconnect event received	An unexpected disconnect event was received. If you experience more disconnect events please contact support.
"Patient select" screen	User clicks on the Help button	How to add a new patient? Click the "Menu" button and then "Add". In the displayed dialog please input the name and patient's id then scan for nearby EASEE Power. Click "Add". How to connect to an existing patient? If no patient is "In range" press "Menu" and "Refresh" buttons to refresh the list of patients. Click on a "In range" patient then click "Connect". Wait for the connection procedure to end.
"Patient select" screen	User presses the "Full Data Export" button	Because the "Full Data Export" copies all patient related folders the procedure may take a while.
"Patient select" screen	User presses the "Export all files" button in the "Patient export" dialog	Because the "Export all files" copies all patient's exported files the procedure may take a while.
"Patient select" screen	"Full Data Export" completed	Done Full Data Export to: [location]
"Patient select" screen	"Full Data Folder" and "Export all files" procedures could not find data to copy	No patient folders found!
"Patient select" screen	"Export all files" completed	Done All Files Export to: [location]
"Patient select" screen	"Lates files export" completed	Done Latest Files Export to: [location]
"Patient select" screen	"Lates files export" procedures could not find data to copy	No patient found!

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated.

Location	Trigger	Message
"Patient select" screen	Export procedures could not detect an attached USB stick to copy data to	No USB stick was detected. To retry the procedure please attach an USB stick and press "Retry". If not, press "Cancel".
"Patient select" screen	Export procedures detect an ejected USB stick	The USB stick was ejected. To retry the procedure please detach and reattach the USB stick and press "Retry". If not, press "Cancel".
"Patient select" screen	User presses the "Eject USB stick" button but no USB stick is detected as being attached to the tablet	No USB stick detected. Eject procedure is not necessary.
"Patient select" screen	User presses the "Eject USB stick" button but the detected USB stick is already ejected	USB stick already ejected. Eject procedure is not necessary. It is safe to remove the USB stick.
"Patient select – connected" screen	During the connect procedure EASEE Power reports it is in FAILURE state	EASEE Power device is in FAILURE state! In consultation with Prescis, EASEE Power can be activated from FAILURE state by pressing "ACTIVATE". If you are unsure, please press "CANCEL" and call support. You can access this dialog again by disconnecting from EASEE Power and reconnecting as long as EASEE Power is in FAILURE state.
"Patient select – connected" screen	EASEE Power reports that it is in ACTIVATED state	EASEE Power activated successfully.
"Patient select – connected" screen	EASEE Power still reports FAILURE state after activation procedure	Failed to activate EASEE Power. Please contact support.
"Patient select – connected" screen	EASEE Power self-test reports error during activation procedure	Unable to activate EASEE Power. Device self-test reports errors. Please contact support.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Patient select – connected" screen	User clicks on the Help button	How to test and edit the stimulation parameters? Click the HFS, DLS or PCN section to enter the "Edit parameters" screen. Edit the desired parameters. Press and hold the "Test" button to validate the selected parameters. For PCN press the "START BOLUS TEST" to test parameters for the duration of PCN burst. For DLS press the "START DLS TEST" to test parameters for the duration of DLS burst. If the test is successful press the "Save & Back" button. Use the "Cancel & Back" button to leave the "Edit parameters" screen at any time.
"Patient select – connected" screen	User clicks on Help button	How to pair EASEE Power with an EASEE Access? Please click on "Change paired EASEE Access SN" button. Input desired EASEE Access SN and click the "Change" button. If pairing is successful you will be prompted that a disconnect is needed.
"Patient select – connected" screen	User clicks on Help Button	How to enable desired stimulation? To activate desired stimulation type please use the appropriate "On"/"Off" switch.
"Patient select – connected" screen	User clicks on Help Button	How to disconnect from EASEE Power? Press the "Disconnect" button, review that stimulation settings are correct and confirm the prompt.
"Patient select – connected" screen	Unexpected disconnect event received while periodic stimulation is enabled	Unexpected disconnection event occurred while periodic stimulation is enabled on EASEE Power. If periodic stimulation should be disabled, please reconnect and disable periodic stimulation.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Patient select - connected" screen	Disconnect button is pressed resulting in a dialog with information if the stimulation is enabled or not and a general message if the patient is not completely configured	Warning: configuration of patient settings seems to be incomplete; if unsure, press "Cancel" and then press the help button located on the bottom-right side of the screen.
"Patient select - connected" screen	Disconnect button is pressed resulting in a dialog with information if the stimulation is enabled or not and a specific message if the EASEE Power has no EASEE Access (EASEE Communicator) associated	Warning: EASEE Power is not paired to any EASEE Access; if unsure, press "Cancel" and then press the help button located on the bottom-right side of the screen.
All screens	Reconnection after an unexpected disconnect event failed	The attempt to reconnect to EASEE Power failed! Do you want to try again?
All screens	EASEE Power reported it is in a FAILURE state	EASEE Power device is in FAILURE state!
All screens	USB stick is connected to any compatible port	EASEE Connect attached!
All screens	USB stick disconnected from any compatible port	USB Stick detached!
All screens	Easee Connect is attached to the tablet but system would automatically deny communication permission	Easee Connect is attached to the tablet but Easee Set does not have permission use it. Please physically disconnect reconnect EASEE Connect and grant needed permissions in the new dialog.
"Patient select" screen, "Stimulation" screen, "Easee power history" screen	Easee power reported FAILURE state when interrogated by Neurologist (Therapy settings) user	EASEE Power device is in FAILURE state! Please call support.
All screens	EASEE Power reported its battery is low	EASEE Power device is in LOW BATTERY state!
All screens	EASEE Power reports taht the EASEE Lead is not connected	EASEE Power reports EASEE Lead not connected. Please contact support.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
All screens	EASEE Power activation failed	EASEE Power reported in deactivation state. EASEE Power device activation failed! Please make sure initial deactivation state was due to normal operation procedure.
All screens	EASEE Connect (EASEE Communicator) is physically disconnected from EASEE Set	EASEE Connect has been disconnected from EASEE Set. Please check the USB connection.
All screens	EASEE Set has low storage space available	EASEE Set detected low storage space available. Please delete files from the EASEEet/eport folder. If the problem persists, please contact support.
All screens	EASEE Set unexpected error encountered	An application error was detected. If the problem persists, please contact support!
All screens	EASEE Set encountered a recoverable error	Storage file corruption detected in last action. Please try again. If the problem persists, please contact support!
All screens	EASEE Set storage integrity test failed	Storage file corruption detected on last action. Please try again. If the problem persists, please contact support!
All screens	EASEE Set failed to enable the Periodic Stimulation setting on EASEE Power after the procedure	Periodic stimulation was disabled in order to execute the test. Failed to re-enable the periodic stimulation.
All screens	EASEE Set failed to enable the PCN Stimulation setting on EASEE Power after the procedure	PCN stimulation was disabled in order to execute the test. Failed to re-enable the PCN stimulation.
All screens	EASEE Set system time is set to an invalid value	System time is set to an invalid date that is older than 01-01-2017. Please contact Support.
"Users" screen	No password input	Please input password.
"Users" screen	Wrong password	Wrong password. Please try again.
"Patient select" screen	"Demo" switch is activated	Are you sure you want to activate the EASEE Power's Demo Mode?

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Patient select" screen	"Shut down" button is pressed	After shutting down, EASEE Power will require the magnet to switch it on again. If you want to stop all stimulations, please change the stimulation settings accordingly. Are you sure you want to shut down EASEE Power?
"Patient select" screen	After connection EASEE Power reports that periodic stimulation is ongoing	Periodic stimulation is ongoing on connected EASEE Power!
"Patient select" screen	After connection EASEE Power reports that PCN stimulation is ongoing	PCN stimulation is ongoing on connected EASEE Power!
"Patient select" screen	User tries to access functionality that is not available in DEMO MODE	While EASEE Power is in Demo mode the EASEE Set functionality is disabled.
"Patient select" screen	EASEE Power reports an invalid paired EASEE Access (EASEE Communicator)	EASEE Power reported an invalid paired EASEE Access serial number.
"Patient select" screen	EASEE Power's stored paired EASEE Access (EASEE Communicator) SN is different from the EASEE Set's stored paired EASEE Access SN	EASEE Power reported a different paired EASEE Access SN than the one stored on EASEE Set.
"Patient select" screen	EASEE Power reports a voltage difference greater than 0.5V	EASEE Power's reported battery voltage difference is greater than 0.5V!
"Patient select" screen	During connection procedure EASEE Power reports that stimulation is ongoing on device	Test stimulation is ongoing on connected EASEE Power!
"Patient select" screen	During connection procedure EASEE Set was unable to retrieve the stimulation parameters from EASEE Power	EASEE Set encountered an error when retrieving important data from EASEE Power. Please contact support.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Patient select" screen	During connection procedure EASEE Set was unable to receive latest logged events from EASEE Power	EASEE Set encountered an error when retrieving the latest log events from EASEE Power. Please try to reconnect. If error persists, please contact support.
"Patient select" screen	During connection procedure EASEE Set receives a different set of stimulation parameters than the one stored in local patient data	The stimulation parameters received from EASEE Power are different from the parameters stored on the EASEE Set. Please make sure the new stimulation parameters are correct.
"Patient select" screen "EASEE Power history" screen "Support" screen	EASEE Set received error type log events from EASEE Power	Error type events received! Please see "EASEE Power Events" in "EASEE Power History" for more information.
"Patient select" screen	Received Battery Alert Threshold value is different than the one stored in the patient information	Received Battery Alert threshold is different from the stored value. Stored value will be updated.
"Stimulation" screen	On attempting to save parameters that were not tested	Stimulation parameters not tested. Please perform tests.
"Stimulation" screen "Implantation" screen "Support" screen	Stimulation test procedure resulted in an incomplete test	TEST stimulation was not completed.
"Stimulation" screen "Implantation" screen "Support" screen	During the stimulation test procedure EASEE Power reports that it is in a Failure state	EASEE Power reports FAILURE state!
"Stimulation" screen "Implantation" screen "Support" screen	During the stimulation test procedure EASEE Power reports that it is in a Low Battery state	EASEE Power reports LOW BATTERY state!
"Stimulation" screen	Stimulation test returned invalid electrodes voltage value	Invalid TEST stimulation results, out of range electrodes voltage. Please contact support.
"Stimulation" screen	Stimulation test returned invalid impedance values	Invalid TEST stimulation results, out of range impedance values. Please contact support.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Stimulation" screen	Periodic stimulation was enabled with no stimulation start events defined	You enabled the periodic stimulation, but no simulation event has been defined and saved. Please define and save the simulation start(s) or disable the periodic simulation.
"Stimulation" screen	The user tries to save new stimulation parameters while the EASEE Power is in DEMO MODE	While EASEE Power is in Demo mode any changes made to the simulation parameters will be saved but the new settings will not be used by the device.
"Stimulation" screen	The user presses the "BACK" button while the new simulation parameters are not saved into EASEE Power	Are you sure? Any new settings not synchronized with implant will be lost!
"Stimulation" screen	Process of storing new simulation parameters on EASEE Power failed	Save to EASEE Power process failed. Parameters not stored correctly. Please try again. If problem persists, please contact support!
"Stimulation" screen	Easee Set determined that the current stored stimulations settings need to be tested and saved to EASEE Power due to the over the limit time spent since the last test.	Test stimulation parameters need retesting and saving to EASEE Power!
"Stimulation" screen	User tried to leave the screen while the stimulation parameters need retesting and saving to EASEE Power	The stimulation parameters need retesting and saving to EASEE Power! To leave this screen please perform the required actions or disable the "Periodic stimulation" functionality on EASEE Power.
"Stimulation" screen	User has selected "periodic burst frequency" parameter values that significantly increase power consumption on EASEE Power	Selected "Periodic burst frequency" value causes a high increase in power consumption!
"Stimulation" screen	EASEE LFS: User tries to enable the HFS, DLS or PCN stimulation while the specific Amplitude is set to "0.0 mA"	Cannot enable stimulation when amplitude is 0mA. Please first change amplitude to a value greater than 0mA and save it to EASEE Power.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Stimulation" screen	EASEE New: User tries to enable the Periodic stimulation while the specific Amplitude is set to "0.0 mA"	Cannot enable periodic stimulation when both HFS and DLS amplitudes are 0mA. Please first change at least one of the amplitudes to a value greater than 0mA and save it to EASEE Power.
"Stimulation" screen	EASEE New: User tries to enable the PCN stimulation while the HFS Amplitude is set to "0.0 mA"	Cannot enable PCN stimulation when HFS amplitude is 0 mA. Please first change amplitude to a value greater than 0mA and save it to EASEE Power.
"Stimulation" screen	EASEE LFS: User tries to enable the HFS, DLS or PCN stimulation but device returns BAD_DEVICE_STATE	Failed to enable stimulation because no valid electrode voltages are stored in EASEE Power. Please first TEST and SAVE parameters on EASEE Power then try again to enable stimulation.
"Stimulation" screen	After a stimulation testing procedure if reported state is of bad voltage	Invalid TEST stimulation results, out of range electrodes voltage. Please contact support.
"Stimulation" screen "Support - diagnostics" "Implantation – during or after"	User tries to test the stimulation but device reports CMD_FAILED_IMPEDANCE	Failed to start TEST stimulation due to impedance errors.
"Patient select" screen "Support" screen "Implantation" screen	EASEE Connect (EASEE Communicator)'s firmware is incompatible with EASEE Set	EASEE Connect's firmware is incompatible with current EASEE Set.
"Patient select" screen "Support" screen "Implantation" screen	EASEE Power's firmware is incompatible with EASEE Set	EASEE Power's firmware is incompatible with current EASEE Set.
"Patient select" screen "Support" screen "Implantation" screen	Incompatible device firmware prevents optimum functionality	EASEE Set software is not compatible with selected EASEE Power. Please contact support.
"Patient select" screen	Patient export as PDF successful	Patient information exported: [location].
"Patient select" screen	User tries to remove patient data. First warning.	By deleting this Patient all the related data will be PERMANENTLY LOST. Please confirm this action below.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Patient select" screen	User tries to remove patient data. Second warning.	All data related to this Patient will be lost. Are you sure you want to delete this Patient?
"Patient select - connected" screen	User disconnects by pressing the "Disconnect" button	Periodic stimulation is enabled, please confirm that EASEE Power remains stimulating after disconnection.
"Patient select" screen "EASEE Power history" screen	An invalid event is received from the EASEE Power.	Invalid events received! Please contact support.
"Patient select" screen "EASEE Power history" screen	Error type events are received during a log enquiry	Error type events received! Please see "EASEE Power Events" in "EASEE Power History" for more information. Number of error type events received: [number].
"EASEE Power history" screen	Graph is exported as PDF successfully	Graph exported to [location].
"EASEE Power history" screen	Graph is exported as CSV successfully	Graph exported to [location].
"EASEE Power history" screen	CSV file export of EASEE Power history aborted because there is no data	No events found!
"Support" screen "Implantation" screen	Stimulation test returned invalid electrodes voltage value	Invalid TEST stimulation results, out of range electrodes voltage received.
"Support" screen "Implantation" screen	Stimulation test returned invalid impedance values	Invalid TEST stimulation results, out of range impedance values.
"Support" screen	EASEE Set system time is set to an invalid value	"System time is set to an invalid date that is older than 01-01-2017. Please go to OS Tools -> OS Settings -> Date & time to set the correct date."
"Support" screen	EASEE Set has low storage space available	EASEE Set detected low storage space available.
"Support" screen	No firmware update is needed	WARNING! The version of firmware running on the EASEE Power is newer or the same as the update file's firmware version. Perform UPDATE procedure only if necessary. Press UPDATE button to start the process.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Support" screen	Firmware update is possible	The version of firmware running on the EASEE Power is older than the update file's firmware version. Press UPDATE button to start the process.
"Support" screen	No valid firmware update file found	No firmware update found in EASEESet/updates folder. Please place a valid update file in the specified folder.
"Support" screen	Multiple files found in update folder	Multiple firmware update files were found in the EASEESet/updates folder. Please make sure there is only one firmware update file in the specified folder.
"Support" screen	Firmware update button was pressed	The periodic stimulation will be deactivated during the update. After the update the periodic stimulation has to be activated from the Therapy Settings user. Are you sure you want to continue?
"Support" screen	No Patient was found stored on the EASEE Set with the found EASEE Power SN	Connected EASEE reports stored log events, however the log could not be retrieved since a patient with the found EASEE Power SN was not found on the EASEE Set. Please use Therapy Settings interface to add the required patient.
"Support" screen	EASEE Set could not receive log events from EASEE Power or confirm that no new logs exist	Unable to retrieve the stored log events from EASEE Power. Firmware update process stopped. Please try again.
"Support" screen	Backup successfully made. Restore point created	Restore point created in [location].
"Support" screen	EASEE Power activation successful	EASEE Power activated successfully.
"Support" screen	EASEE Power activation failed	Failed to activate EASEE Power.
"Support" screen	EASEE Power already activated	EASEE Power is already in the ACTIVATED state.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Support" screen	EASEE Power activation failed due to errors reported by self-test procedure	Unable to activate EASEE Power. Device selftest reports errors.
"Support" screen	Restore point deletion warning	Do you want to delete this restore point?
"Support" screen	Restore point deletion failed. No file found	Error: Nofilefound! Please use File Manager.
"Support" screen	Restore point successfully deleted	Restore point deleted.
"Support" screen	Restoration process initialization warning	Do you want to proceed with data restoration from this restore point?
"Support" screen	Data restoration failed. No file found	Restore failed! Error: No file found!
"Support" screen	Data restoration failed. System could not create the automatic backup file	Restore failed! Error: Auto backup failed!
"Support" screen	Data restoration failed. The restore point contains corrupted files	Failed to restore data. Restore point data is corrupted.
"Support" screen	Data restoration failed.	Failed to restore data.
"Support" screen	Data restoration successful	Data restoration successful.
"Support" screen	Support tries to delete a user password	Are you sure you want to delete password [password]?
Support" screen	Support tries to commit the EASEE Set serial number	Are you sure you want to commit the EASEE Set serial number? Warning! Once committed the SN cannot be changed!
"Support" screen	User presses the SAVE button without defining a value to be saved on EASEE Power	Operation could not be completed. No value to be saved defined.
"Support" screen	The reported EASEE Power firmware is not compatible with the Battery Alert Threshold. Functionality is disabled.	EASEE Power has a firmware version that does not support the Battery Alert Threshold functionality.
"Support" screen	EASEE Set was unable to save the Battery Alarm Threshold value to EASEE Power	Failed to save the Battery Alarm Threshold. Please try again.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Support" screen	EASEE Set was able to save the Battery Alarm Threshold value to EASEE Power	Battery Alarm Threshold saved successfully.
"Support" screen	Battery Alarm Threshold overwrite confirmation	Are yoU sure you want to overwrite the Battery Alarm Threshold?
"Implantation" screen	Stimulation test incomplete	TEST stimulation was not completed.
"Implantation" screen	Stimulation test returns invalid results	EASEE Power test returned out of range values. Please repeat test. If error persists, replace EASEE Power.
"Implantation" screen	EASEE Power reports that is in FAILURE state	EASEE Power in FAILURE state. Please replace EASEE Power.
"Implantation" screen	Stimulation test returns out of range results	invalid TEST stimulation results, out of range electrode voltage received.
"Implantation" screen "Support" screen "Stimulation" screen		TEST stimulation was not completed. Could not establish connection to EASEE Power.
"Implantation" screen	Implantation user tries to finish the current surgery without shutting down the EASEE Power beforehand	Please make sure that EASEE Power is shut down! Do you want to declare the implantation finished?
"Implantation" screen	Implantation user tries to finish the current surgery after shutting down the EASEE Power beforehand	Do you want to declare the implantation finished?
"Implantation" screen	Implantation user tries to log out during a surgery without shutting down the EASEE Power beforehand	Please make sure that EASEE Power is shut down! Are you sure you want to log out?
"Implantation" screen	Implantation user tries to log out during a surgery after shutting down the EASEE Power beforehand	Are you sure you want to log out?
"Implantation" screen	The results for the EASEE Power test are displayed in the "After surgery" phase.	Please record these data in the patient file.

Table 8: List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated. (continued)

Location	Trigger	Message
"Implantation" screen "Therapy settings" screen	On establishing connection to the implant EASEE Set detects that BASE firmware is running	EASEE Power reports running in Base firmware. Firmware update is required. Please contact support.
"Support" screen	On establishing connection to the implant, EASEE Set detects that BASE firmware is running.	EASEE Power reports running Base firmware. Firmware update is required.

Table 8 : List of alert and warning messages (right column) which might be displayed in screens (left column) and under circumstances (middle column) as indicated.

5 EASEE® Access Handheld Device

5.1 Intended Purpose of EASEE® Access

EASEE® Access is a device for radio frequency-based communication that enables the patient to control the implanted pulse generator of the EASEE® System. When in use, EASEE® Access transmits radio frequency signals to and from EASEE® Power. The patient can use EASEE® Access to check the battery status of EASEE® Power and EASEE® Access, to deliver an individually programmed stimulation burst (patient-controlled neurostimulation, PCN) and to turn off EASEE® Power. In the latter case EASEE® Power can only be reactivated by the physician using the activation magnet and EASEE® Set / EASEE® Connect.

EASEE® Access is a battery-operated device and can only be operated with alkaline batteries. The patient can use EASEE® Access to check and display its remaining battery level.

The integrity of the transmitted and received data is ensured by hardware and software measures. This also ensures that EASEE® Access does not interfere with other devices which use radio frequency signals and that a specific EASEE® Access is only able to communicate with the respectively paired EASEE® Power.

5.2 Description of EASEE® Access

EASEE® Access is an external non-sterile handheld device for the patient. It enables the patient to turn EASEE® Power off. Upon request, EASEE® Access displays the battery charge status of EASEE® Power as well as its own battery charge status. Furthermore, the patient can use EASEE® Access to initiate the delivery of stimulation upon seizure onset (PCN), which is then administered in addition to the periodic stimulation.

EASEE® Access (see Figure 5.59) comprises the following elements and features:

Plastic housing with:

- battery-operated electronics within the housing, including buzzer
- four pushbuttons: B1 on the left side and B2 on the right side, on the front side B3 (top) and B4 (bottom)
- four indicator lights on the front side (at the top L1 (left) and L2 (right), in the middle L3 (top) and L4 (bottom), close to the middle pushbuttons B3 and B4, respectively.
- battery cover on the back

The four pushbuttons B1 to B4 are generally associated with the following functions:

Button B1:	Start Self Test of EASEE® Access
Button B2:	Start Self Test of EASEE® Access
Button B3:	Start PCN
Button B4:	Query EASEE® Power Battery

The four indicator lights L1 to L4 are used for the following information:

Indicator light L1:	Battery state of EASEE® Access
Indicator light L2:	Communication state with EASEE® Power
Indicator light L3:	Ongoing PCN
Indicator light L4:	Battery state of EASEE® Power

The buzzer gives supportive acoustic feedback as follows:

Short continuous beep for approximately 0.1 second:	Accepted button press
Long continuous beep for approximately 1 second:	Command Accepted
Fast alternating sound for approximately 0.3 seconds:	Wrong command
Fast alternating sound for approximately 2 seconds:	Declined or failed command
Continuous beep for approximately 15 seconds:	EASEE® Power shutdown running

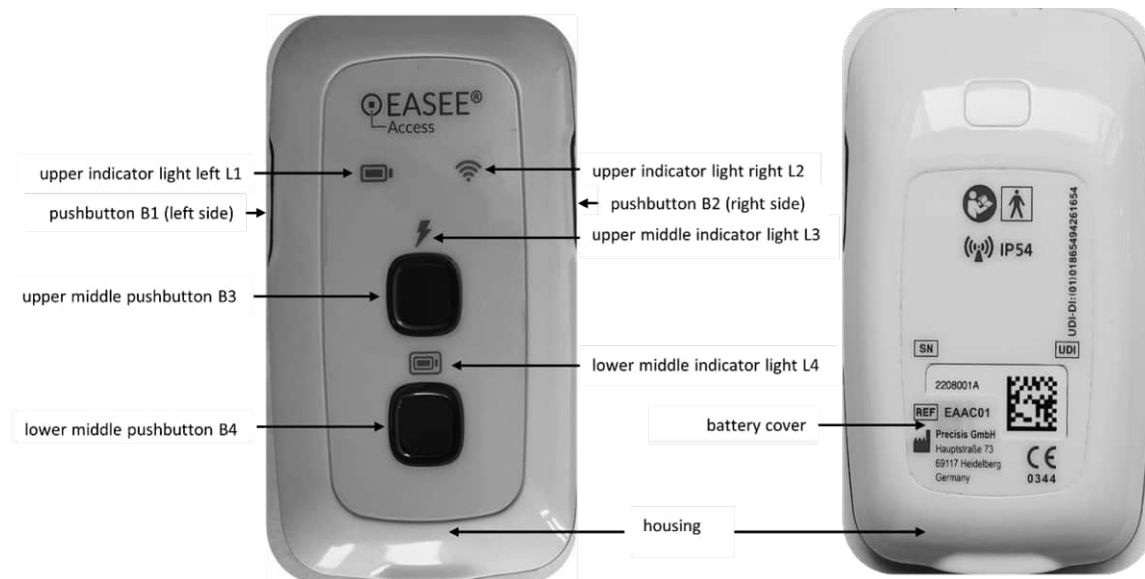


Figure 5.59: Parts of EASEE® Access: Front view (left), rear view (right).

WARNING: EASEE® ACCESS BATTERY COVER REQUIRED

THE BATTERY COVER OF EASEE® ACCESS IS REQUIRED FOR PROTECTION OF EASEE® ACCESS AGAINST THE INGRESS OF SOLID FOREIGN OBJECTS AND WATER DROPLETS. EASEE® ACCESS SHOULD NOT BE USED WHEN THE BATTERY COVER IS NOT IN PLACE.

5.3 Training the Patient on the Use of EASEE® Access

The attending physician should train the patients and / or their caregivers on the use of EASEE® Access. They should be taught how to operate EASEE® Access and how to use EASEE® Access to query the remaining capacity of the EASEE® Power battery daily and draw appropriate conclusions from the respective feedback. They should also be informed about storage, handling, cleaning, disinfection, and operation of EASEE® Access.

5.4 How to Get Started with EASEE® Access

5.4.1 Power Supply

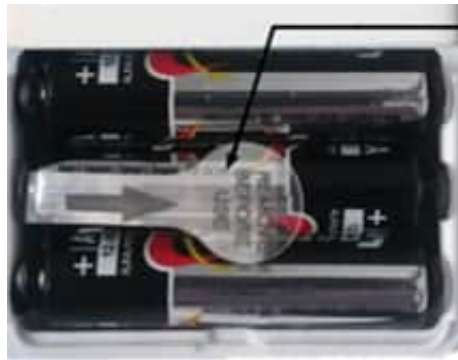
EASEE® Access must be equipped with three alkaline batteries of size AAA (LR03).

Turning on for the first time

EASEE® Access is delivered with the batteries already included. The batteries need to be activated by removing the protective foil that is in place (Figure 60).

Please complete the following steps:

1. Remove the battery cover by carefully lifting it upwards from the rest of the housing using the middle notch on the lower narrow side to expose the battery compartment.
2. Pull out the protective foil by carefully pulling in the direction indicated by the arrow. The protective foil can be disposed of in household waste.
3. Make sure that the batteries are still in the correct position – if needed, please reposition them carefully.
4. Check that the audio-visual feedback sequence is delivered as described in the Initial Feedback Sequence section.
5. Close the battery compartment by snapping the battery cover back into place.



Protective foil

Label:

"REMOVE BEFORE USE"

Arrow indicating pull direction.

Figure 5.60: The battery compartment in its initial state: the batteries are already inserted but have not been activated.

Exchanging the EASEE® Access Batteries

When the batteries of EASEE® Access are depleted, they must be replaced with three fresh alkaline batteries of the size AAA (LR03) as follows:

1. Remove the battery cover by carefully lifting it upwards from the rest of the housing using the middle notch on the lower narrow side to expose the battery compartment.
2. Remove the depleted batteries and dispose of them according to local governing agency recommendations.
3. Insert three fresh batteries one after the other in the correct orientation. Refer to the symbols on the bottom of the battery compartment. These symbols clarify the orientation and polarity of the batteries (Figure 5.61).
4. Check that the audio-visual feedback sequence is delivered as described in **section 5.4.2 Initial Feedback Sequence**.
5. Close the battery compartment by snapping the battery cover back into place.

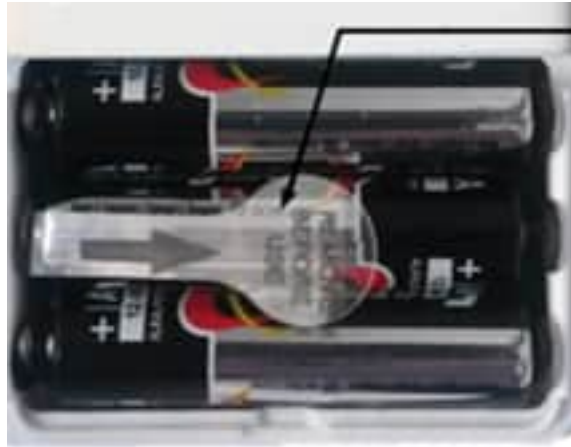


Figure 5.61: Symbols showing the correct orientation of the batteries displayed on the bottom of the battery compartment

5.4.2 Initial Feedback Sequence

If you have inserted the batteries correctly and the device has been activated, you should perceive the following combination of audio-visual signals (see also Figure 62):

- All four EASEE® Access indicator lights glow green for 1 second. One beep is emitted for 1 second.
- The indicator lights turn off for less than a second.
- All four EASEE® Access indicator lights glow yellow for 1 second. One beep is emitted for 1 second.
- The indicator lights turn off for less than a second.
- All four EASEE® Access indicator lights glow red for 1 second. One beep is emitted for 1 second.
- The indicator lights turn off for less than a second.
- The upper left indicator light L1 glows for one second green, yellow, or red, respectively, indicating the current status of the batteries of EASEE® Access (see **section 5.5.4 EASEE® Access Battery Status**).

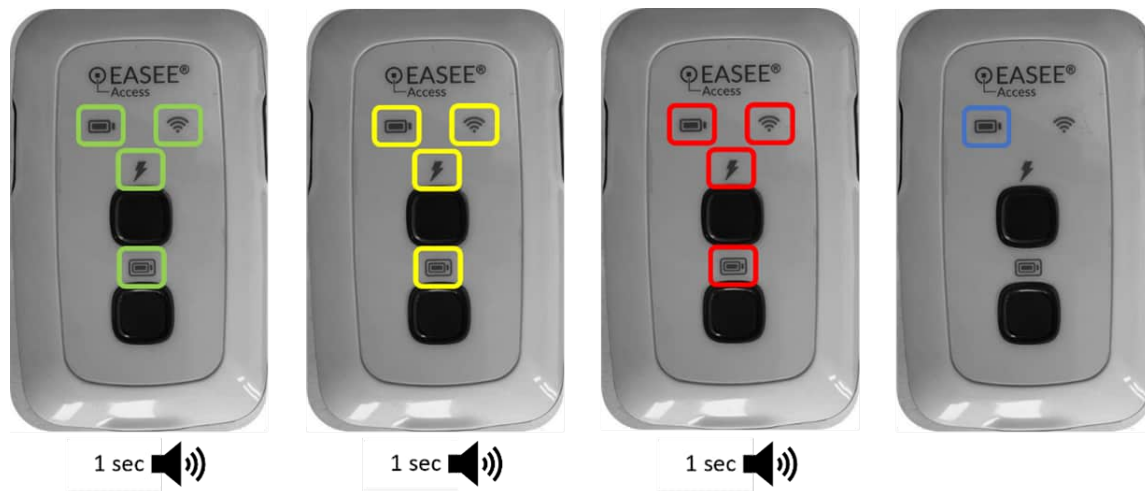


Figure 5.62: Sequence of audio-visual signals after correct insertion of fresh batteries. The blue frame in the right picture represents the feedback on the current battery status of EASEE® Access that the upper left indicator light gives in green, yellow, or red corresponding to high, low, or very low battery status, respectively (see **section 5.5.4 EASEE® Access Battery Status**).

If you do not observe the sequence of audio-visual signals as described above after you have inserted fresh batteries in the correct orientation, please replace the related EASEE® Access with another device.

5.4.3 Positioning EASEE® Access

For communication to take place between EASEE® Access and EASEE® Power, EASEE® Access must be positioned close to EASEE® Power. Hold the EASEE® Access as close as possible to EASEE® Power (maximum distance 20 cm / approximately 8 in).

5.4.4 Operating the Buttons

Pressing any button is acknowledged by a short beep. If the input is correct and interpreted as a valid command (as described in section 5.5) a longer beep will sound for one second. If the input is invalid, a fast-alternating beep will sound for 0.3 seconds.

5.4.5 Wireless Connection and Connection Errors

When the connection between EASEE® Access and EASEE® Power is being established, the upper right indicator light L2 flashes yellow for at least 2 seconds.

In case of a successful connection, the upper right indicator light L2 will switch to green color.

Certain conditions may lead to an error in the wireless connection between EASEE® Access and EASEE® Power. For example, the distance between the two devices may be too far, EASEE® Power

may have been turned off or the data exchange may have been interrupted. Another possible cause may be that EASEE® Power may still be connected to EASEE® Set/EASEE® Connect.

In such cases, the connection errors are signaled by a 5 second period of red flashing of one or more indicator lights and a 2 second beep.

If a connection error occurs when checking the battery status of EASEE® Power (**section 5.5.1 Query Regarding Battery Status of EASEE® Power**), when using EASEE® Access to trigger PCN, or when EASEE® Access is used to deactivate EASEE® Power (section 5.5.2), the upper right indicator light L2 will turn red.

If a connection error occurs when pairing EASEE® Access with EASEE® Power (section 5.4.6), then all four indicator lights will turn red.

5.4.6 Pairing EASEE® Access with EASEE® Power

Prior to the first use of EASEE® Access, it must be paired to the specific EASEE® Power, with which it is intended to communicate ("Pairing"). This step will be completed by the physician. It is important to pair the two devices so that one EASEE® Access can only control one specific EASEE® Power. Otherwise, the EASEE® Access could interfere with other patients' implanted pulse generators.

5.5 Functions of EASEE® Access

5.5.1 Query Regarding Battery Status of EASEE® Power

EASEE® Access can be used to obtain real-time information on the remaining battery capacity of EASEE® Power, by completing the following steps (see also Figure 5.63):

1. Press and hold the lower middle pushbutton (B4) (pressing the button will be acknowledged by a short beep).
2. After 1 to 3 seconds of holding, release the lower middle pushbutton (B4). The upper right indicator light (L2) and the lower middle indicator light (L4) flash yellow for 2 seconds.
3. Both indicator lights turn off for a short time. The upper right indicator light (L2) confirms successful connection by glowing in green light.
4. The lower middle indicator light (L4) glows up for 5 seconds in a color representing the remaining battery capacity as follows:

red (2 second beep): $\leq 1\%$ remaining capacity (very low battery). The remaining battery capacity is very low and stimulation has been stopped. Communication with EASEE® Power is still possible (EOS: End Of Service). Please contact the treating physician as soon as possible!

yellow (1 second beep): $< 20\%$, but more than 1% remaining capacity. The remaining battery capacity is low and will last for less than 6 weeks. Replacement of EASEE® Power should therefore be planned (ERI: Elective Replacement Indicator). Please contact the treating physician as soon as possible!

green (0.4 second beep): $\geq 20\%$ remaining capacity. The remaining battery capacity is sufficient and will last for more than 6 weeks.

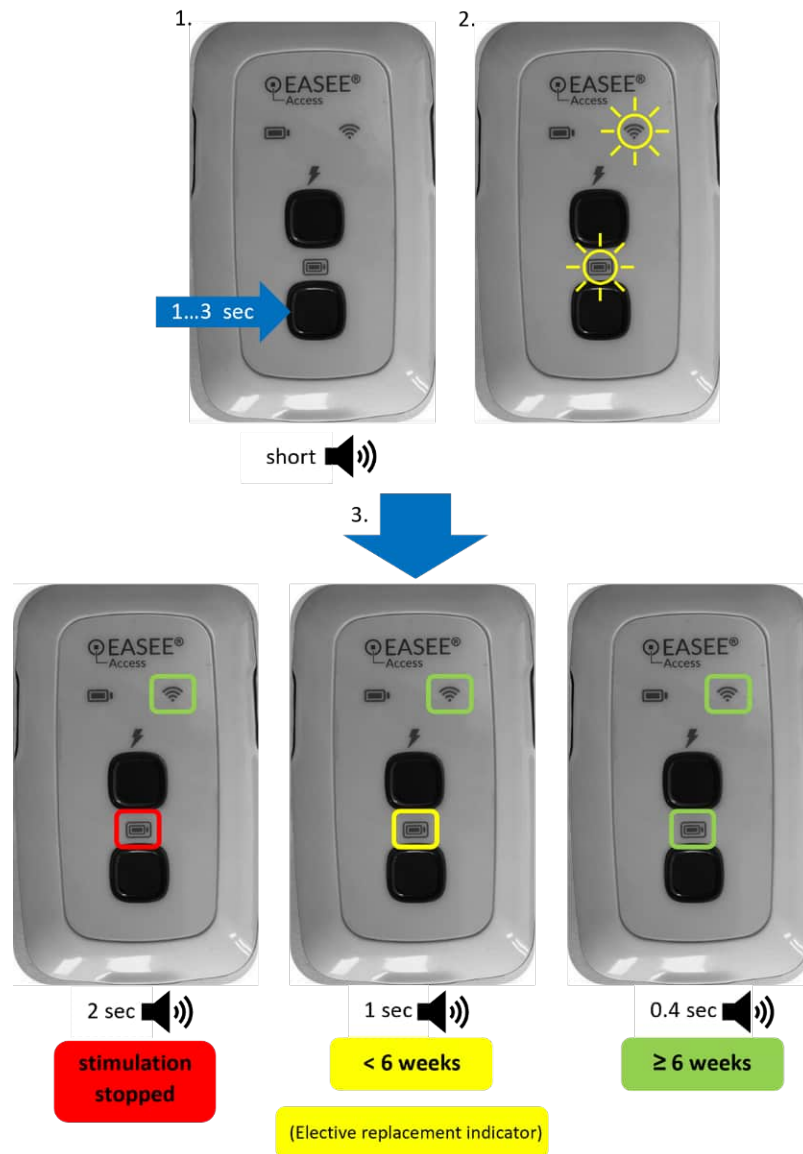


Figure 5.63: Sequence for checking the battery status of EASEE® Power.

If the buttons pressed are different from the instructions above, then the battery status query process will be interrupted and accompanied by a short high-frequency beep.

Precaution: Depletion of EASEE® Power Battery

The patient should inform the responsible physician in good time before depletion of the EASEE® Power battery, at the latest when the left indicator light of EASEE® Access flashes yellow in response to a battery status query. This means the battery capacity is sufficient for less than 7 weeks.

In case of wireless communication malfunction between EASEE® Access and EASEE® Power the following will occur:

- battery status query is stopped,
- fast alternating beep sounds for 2 seconds,
- top right indicator light turns red for 5 seconds.

Alert before Stimulation Stops due to Battery Depletion

If EASEE® Power has transmitted a reduced battery status (battery low or very low) to EASEE® Access at least once, EASEE® Access will additionally display a corresponding battery warning after completion of the commands for PCN, EASEE® Power shutdown, or EASEE® Access self-test.

If the EASEE® Power battery status has previously been reported as low, the additional battery warning consists of lower middle indicator light L4 illuminating yellow for 5 seconds and buzzer beeping for 1 second.

If the EASEE® Power battery status has previously been reported as very low, the additional battery warning will consist of lower middle indicator light L4 illuminating red for 5 seconds and buzzer beeping for 3 seconds. In this case, the patient must inform the physician immediately so that the EASEE® Power can be exchanged for a new device.

Precaution: Battery Depletion and Replacement of EASEE® Power

For continued operation, EASEE® Power needs to be surgically replaced before the battery is depleted. Discuss with your patient the pending replacement of EASEE® Power.

5.5.2 Turning EASEE® Power Off

EASEE® Access can be used to turn off EASEE® Power.

Precaution: Turning EASEE® Power Off

Once turned off, EASEE® Power can only be reactivated by the physician using a dedicated tool, called EASEE® Set / EASEE® Connect, which controls EASEE® Power.

To turn off EASEE® Power complete the following steps (see also Figure 5.64):

1. Press both side pushbuttons B1, B2 and the lower middle pushbutton B4 at the same time for 1 to 3 seconds. A confirmation beep will sound for half a second.

2. Both middle indicator lights start (L3 and L4) start flashing green.
3. Again, press both side pushbuttons B1, B2 and the lower middle pushbutton B4 at the same time for 1 to 4 seconds. A confirmation beep chimes for 1 second.
4. The second stage of the turning off procedure follows, with yellow flashing of both middle (L3 and L4) and the upper right indicator light (L2).
5. The successful turning off is confirmed by a 5-second beep with continuously reducing volume. The upper right indicator light (L2) glows green and the middle indicator lights (L3 and L4) glow red for 15 seconds.

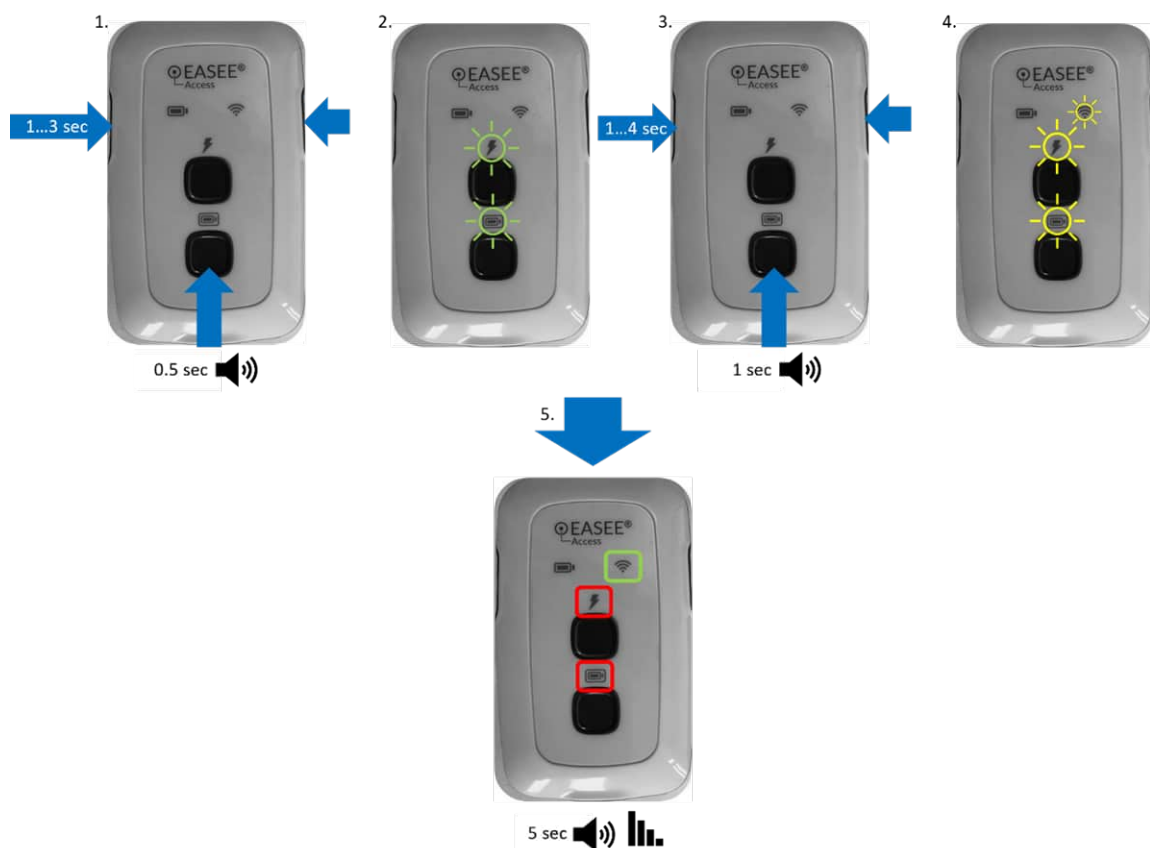


Figure 5.64: Sequence of commands for turning EASEE® Power off.

If the buttons pressed are different from the instructions above, then the EASEE® Power shutdown process will be interrupted and accompanied by the lighting of the upper right indicator light L2 for 5 seconds and a high-frequency beep for 2 seconds.

5.5.3 Using EASEE® Access to activate PCN

EASEE® Access can be used to trigger the administration of PCN, with the parameters previously set for the individual patient by the physician.

The following limitations apply:

- The total duration of PCN cannot exceed 6 minutes per day.
- There must be a 2 minute break between two consecutive activations of PCN. If it is attempted to trigger a new PCN too soon, no stimulation will be delivered.

To trigger PCN:

1. Position EASEE® Access as close as possible to EASEE® Power.
2. Press the upper middle pushbutton (B3) for 1 to 3 seconds. The press is accompanied by a short beep.

The upper middle indicator light (L3) and the upper right indicator light (L2) will then flash yellow for as long as the signal for the PCN is being transmitted to EASEE® Power.

If the PCN was triggered successfully, the L2 and L3 glow green for 3 seconds and a short beep confirms the execution of the command. During PCN, the upper middle indicator light (L3) flashes green.

If triggering of PCN has failed, one of the following feedback sequences from EASEE® Access will appear, depending on the cause of the failure:

- A) If the upper middle pushbutton (L3) was not pressed correctly, a buzzing sound is emitted.
- B) If the wireless connection between EASEE® Access and EASEE® Power is faulty (for example if EASEE® Access is too far from EASEE® Power), the upper right indicator light (L2) glows red, accompanied by a fast-alternating beep for 2 seconds.
- C) If PCN is triggered when the maximum total PCN time allowed per day has been reached, the upper middle indicator light (L3) glows red and a beep sound is emitted for 2 seconds.
- D) If PCN is triggered when the required break between two PCN doses has not yet passed and, the upper middle indicator light (L3) glows yellow and a beep sound is emitted for 1 second.

In cases A) and B) the commands for triggering PCN should be repeated, observing the correct procedure as described above and consulting the information given in section **section 7.5.1 Communication Problems between EASEE® Set / EASEE® Connect and EASEE® Power**.

In case C), administration of another PCN on the same day is not possible.

In case D), PCN may be triggered again after the required break.

5.5.4 EASEE® Access Battery Status

To check the battery status of EASEE® Access, complete the following steps (see also Figure 5.65):

1. Press and hold the right or left pushbutton (B1 or B2) (this will be acknowledged by a short beep).
2. After pressing and holding down the right or left pushbutton for 5 seconds, the command will be confirmed with a 1 second beep.
3. Release the pushbutton. All four indicator lights will glow green for 1 second, glow yellow for 1 second and finally glow red for 1 second.
4. The upper left indicator light (L1) turns off for a short time and then glows for 2 seconds in a color that represents the remaining battery capacity as follows:
 - **green:** > 30 % remaining capacity
(0.4 second beep)
 - **yellow:** ≤ 30 but more than 10 % remaining capacity
(1 second beep)
 - **red:** ≤ 10 % remaining capacity (very low battery)
(3 second beep)

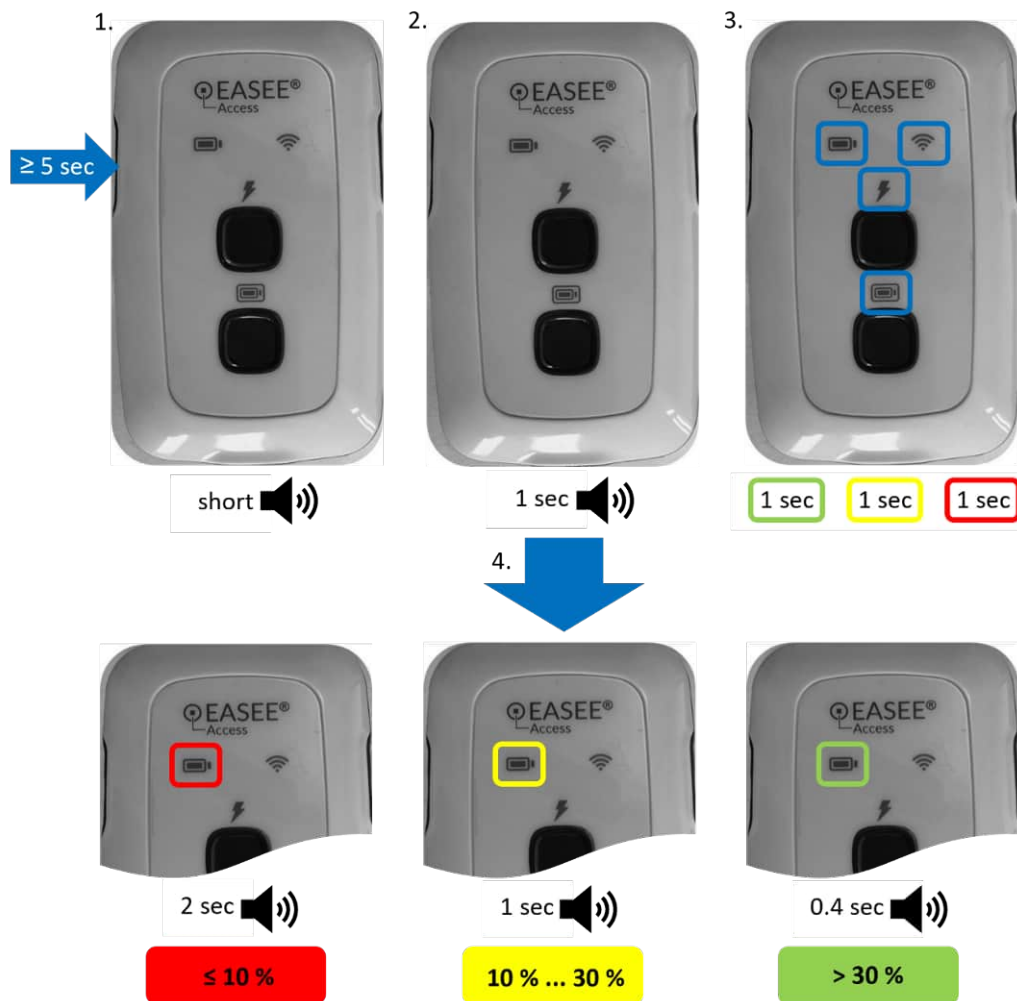


Figure 5.65: Sequence of commands for turning EASEE® Power off.

If the buttons pressed are different from the instructions above, then the process battery status query will be interrupted, accompanied by a short high-frequency beep.

EASEE® Access Very Low Battery Alert

If the remaining EASEE® Access battery capacity is about 10 % or less, EASEE® Access emits an alert after the battery status query. This alert is as follows: The upper left indicator light turns red for 2 seconds and a 2 second beep is emitted. Replace the EASEE® Access batteries as soon as possible. Moreover, this alert of very low EASEE® Access battery is also given following an executed command for checking the battery status of EASEE® Power, shutdown of EASEE® Power and delivery of PCN, by lighting the upper left indication light L1 for 2 seconds in red and emitting a beep for 2 seconds.

5.5.5 Turning off EASEE® Access

EASEE® Access can be turned off by removing the batteries. If this is done, EASEE® Access is unable to operate. If EASEE® Access is not used for some time, batteries should be removed to prevent damage to the device due to potential battery leakage.

5.5.6 EASEE® Access Failure Mode

EASEE® Access switches to failure mode when an invalid condition is detected, e.g. caused by an initialization failure or memory failure. Failure mode is indicated by continuous red blinking of the upper middle indicator light (L3) for 6 seconds and a simultaneous beep. EASEE® Access then tries to recover three times by restarting. If the restart fails, EASEE® Access shows this status by constant blinking of all indicator lights L1 to L4 every 3 seconds. If this happens, batteries of EASEE® Access should be removed and then correctly reinserted (see **section 5.4.1 Exchanging the EASEE® Access Batteries**). If EASEE® Access still does not function correctly, Precisis GmbH should be contacted.

5.5.7 Unpairing of EASEE® Access from EASEE® Power

It is necessary to cancel the pairing between EASEE® Access and EASEE® Power before the same EASEE® Access device can be paired with a new EASEE® Power - e. g. after replacing the EASEE® Power after its batteries have been depleted. The pairing of EASEE® Access can be cancelled as follows:

1. Press and hold both side buttons B1 and B2 simultaneously for 5 to 7 seconds.
The indicator lights L1 and L4 start to flash green.
2. From this point on, both must be released within 3 seconds and held down again for 5 to 7 seconds.
Then the indicator lights L1 and L4 will start flashing again, faster than before.
3. Again, the two side buttons B1 and B2 must be released within 3 seconds.
In this case, a beep of 1 second duration will then sound and the indicator lights L1 and L4 will light up green for 5 seconds, indicating that the pairing has been cancelled. In case of failure, the indicator lights L1 and L4 light up red for 5 seconds and a fast-alternating beep is emitted for 2 seconds.

5.6 Transport, Storage, Handling, Sterilization and Cleaning and Disposal

5.6.1 Product transport

EASEE® Access should be transported in the original, intact blister pack provided until its first use. No further special precautions are necessary. Environmental conditions for transport are listed in **section 8.9 EASEE® Access Specifications** (see below).

5.6.2 Product Storage

Storage Conditions

The components of EASEE® Access should be transported and stored in clean, secure areas, in accordance with the conditions indicated on the component's packaging. These conditions are listed in **section 8.9 EASEE® Access Specifications** (see below).

No additional special handling is needed for storage of EASEE® Access.

5.6.3 Product Handling

Careful Handling

You should handle EASEE® Access with care.

Operating Conditions

Environmental conditions for using EASEE® Access are listed in **section 8.9 EASEE® Access Specifications** (see below).

Electrostatic Discharge (ESD) / Static Electricity

EASEE® Access may be sensitive to electrostatic discharge (ESD) / static electricity. Please handle the device with care. If exposed to electrostatic discharge, EASEE® Access may experience telemetry artifacts or errors, or may freeze. The **section 7 Troubleshooting** contains information on what to do if this happens.

5.6.4 Product Sterilization

Non-Sterile, Non-Sterilizable Components

- EASEE® Access is supplied in a non-sterile condition and is not sterilizable.
- EASEE® Access should be placed in a sterile pouch for use in the sterile field.
- DO NOT STERILIZE EASEE® Access.

5.6.5 Product Cleaning and Disinfection

EASEE® Access can be cleaned and disinfected as follows:

- EASEE® Access can be cleaned using a damp cloth.
- EASEE® Access can be disinfected by wiping with a cloth soaked in isopropyl alcohol.

EASEE® Access should be cleaned at least weekly, or if needed more often. It can be disinfected if necessary.

Please clean and disinfect EASEE® Access before returning it to Precisis GmbH.

5.6.6 Disposal

Clean and disinfect EASEE® Access, remove its batteries and return the device to Precisis GmbH. Precisis GmbH will provide a container for shipping if requested.

6 Maintenance

In general, the components of the EASEE® System require no maintenance. In case of irreversible malfunction, the relevant component should be replaced. However, an update or upgrade of the firmware or software, respectively, may be released for certain components. This will be carried out by Precisis GmbH personnel. Moreover, EASEE® Access, which is battery operated, must be kept functional by replacing depleted batteries with new ones, as needed.

6.1 Hardware Maintenance

EASEE® Access can only operate when it is fitted with three AAA alkaline batteries. The remaining battery capacity must be checked regularly. Depleted batteries should be replaced by the patient with new ones.

Firmware updates or upgrades may be provided for the following components of the EASEE® System, which must be carried out by Precisis GmbH personnel:

- EASEE® Power
- EASEE® Access
- EASEE® Connect

6.2 Software Maintenance

The operating system of EASEE® Set – Hardware should not be updated or upgraded by anyone other than Precisis GmbH personnel. For that reason, the WLAN functionality of EASEE® Set – Hardware is disabled. Only Precisis GmbH personnel can make changes in the EASEE® Set – Hardware settings. This includes updates / upgrades of EASEE® Set – Software.

7 Troubleshooting

7.1 Damaged Products

Inspect EASEE® System components for any damage or breach in package seal integrity. Sterile components may no longer be sterile if packaging appears to be wet, punctured, or damaged. Damaged components and components in damaged packaging should not be used and should be returned to Precisis GmbH for replacement.

7.2 Implantable Products Exceeding Their Expected Lifetime

In general, Precisis does not recommend replacing functional implanted components of the EASEE® System exceeding their expected lifetime. The decision to replace a fully functional device which has reached its expected lifetime should be made by the patient and his/her treating physician based on an analysis of the benefit-risk ratio for the patient.

7.3 General Troubleshooting Activities

Problems with the EASEE® System may be revealed during an interrogation by an error message on the EASEE® Set or when checking the impedances or battery measurements. If attempts to resolve the problem are ineffective and the problem persists, take the following actions:

- Record all error messages displayed.
- If interrogation of the EASEE® Power is possible, complete the interrogation.
- Contact Precisis GmbH for further assistance.

7.4 General Recommendations for Non-Responsive EASEE® Set

- Check the EASEE® Set – Hardware battery status.
- To charge the battery, plug the power cable supplied into the power jack on the left-hand side of EASEE® Set - Hardware and plug the mains power charger supplied into a grounded power outlet.
- Hold the EASEE® Set power button down for 5-10 seconds.
- Release the EASEE® Set power button.
- Press the EASEE® Set power button again. If EASEE® Set does not restart, follow the above instructions again. If the programming function still does not respond, contact Precisis GmbH for further assistance.

7.5 Troubleshooting at Follow-Up Visits

7.5.1 Communication Problems between EASEE® Set / EASEE® Connect and EASEE® Power

- Make sure that EASEE® Connect is switched on, which is indicated by a green illuminated symbol at the top left of the housing of EASEE® Connect. If this is not the case, then check that EASEE® Set is switched on and the two USB plugs of the USB-A to USB-C cable are correctly plugged into EASEE® Connect on one side and EASEE® Set - Hardware on the other.
- Check that the sequence of visual signals is emitted by EASEE® Connect as described in section How to Use EASEE® Connect after you have connected EASEE® Connect to EASEE® Set that is switched on.
- Check that EASEE® Connect is as close to EASEE® Power as possible (maximum distance 20 cm / approximately 8 in).
- Try holding EASEE® Connect in different positions for wireless communication with EASEE® Power. As a rule, the communication works best when closest to EASEE® Power and when held so that the largest surfaces of EASEE® Connect and EASEE® Power are parallel to each other.
- Disconnect the AC adapter from EASEE® Set and run it on battery power. (Make sure the battery is charged before doing this.)
- Remove electronic equipment that may be a source of interference or move away from such equipment if possible. (Turning electronic equipment on and off again may help identify the source of any interference.)
- Reboot EASEE® Set – Hardware (by turning it OFF and back ON). Attempt the interrogation again.
- Try a different USB-A to USB-C cable, if available.
- Try a different EASEE® Connect, if available.
- Try a different EASEE® Set, if available.
- Try interrogating a different EASEE® Power, if available, to see if the problem is with the first EASEE® Power interrogated.
- Contact Precisis GmbH for further assistance.

7.5.2 Communication problems between EASEE® Access and EASEE® Power

- Assure that the EASEE® Access is placed close to the correct device and mismatch with potentially further implanted devices should be excluded.
- Check that EASEE® Access is as close to EASEE® Power as possible (maximum distance 20 cm).
- Try holding EASEE® Access in different positions for wireless communication with EASEE® Power. As a rule, the communication works best when closest to EASEE® Power and when

held so that the largest surfaces of EASEE® Access and EASEE® Power are parallel to each other.

- Remove any electronic equipment that may be a source of interference or move away from such equipment if possible (turning electronic equipment on and off may help identify the source of any interference).
- Try a different EASEE® Access, if available.
- Contact Precisis GmbH for further assistance.

7.5.3 Impedance Values Out of Range

- Repeat the impedance measurements.
- Carefully manipulate EASEE® Lead or EASEE® Power (for example, apply pressure to the electrode pad or gently move the EASEE® Lead connecting cable) while simultaneously repeating the impedance measurement.
- If one peripheral electrode impedance value is out of range during the manual impedance test, stimulation on this electrode is deactivated by the device. The stimulation parameters can remain unchanged, as no clinical evidence is available on the effectiveness impact of one missing electrode. The physician can consider whether a change in stimulation amplitude is warranted and allowed per protocol, following **section 4.5.4 Editing Stimulation Settings**.
- In the rare event of more than one peripheral electrode, or the central electrode being out of range, stimulation on all electrodes is deactivated by the device.
- Contact Precisis GmbH for assistance.

7.5.4 Low EASEE® Power Battery

- Repeat the battery measurement.
- If interrogation of the EASEE® Power is possible, complete the interrogation.
- If the battery level shown remains very low, schedule replacement of the implanted EASEE® Power as soon as possible.

7.5.5 EASEE® Power Failure State

- Check the latest EASEE® Power measurements.
- Try to shut down EASEE® Power.
- Restart EASEE® Power using the activation magnet and EASEE® Set / EASEE® Connect.
- Check the latest EASEE® Power measurements again and verify that the results have been updated.
- Contact Precisis GmbH for further assistance.

8 Specifications

8.1 EASEE® Power Specifications

DIMENSIONS	
WIDTH	50.50 mm (2 in)
LENGTH	60.00 mm (2.4 in)
THICKNESS	12.95 mm (0.5 in)
WEIGHT	66 g (2.3 oz)
MATERIAL	
Can	Titanium, medical grade 2
Top part	Epoxy resin
Nozzle	Silicone
Fixing screw septum	Silicone
BATTERY	
Number	2
System	LiMnO ₂
Voltage	3.2 V
Type	Primary
Nominal capacity per battery	1.2 Ah
STORAGE CONDITIONS	
Temperature	10 °C to 25 °C 50 °F to 77 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
TRANSPORT CONDITIONS	
Temperature	-10 °C to 55 °C 14 °F to 77 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
OPERATING CONDITIONS	
Temperature	18 °C to (39 °C typically; 42 °C short-term) 64.4 °F to (102.2 °F typically; 107.6 °F short term)
Atmospheric pressure	700 hPa to 1060 hPa

Table 12: Specifications of EASEE® Power.

Relative humidity	30 %...65 %; non-condensing (if not implanted)
NUMBER OF OUTPUT CHANNELS	4
RETENTION STRENGTH OF CONNECTOR	10 N
WAVE FORM	Biphasic
PULSE SHAPE	Rectangular
CURRENT/VOLTAGE REGULATION	Current regulated
MAX. OUTPUT CURRENT	4.0 mA $\pm$ 0.1 mA
HFS STIMULATION PARAMETERS	
Amplitude	0.1 mA ... 4.0 mA
Current amplitude step width	0.1 mA
Pulse width per phase	100 μ s ... 1500 μ s
Pulse Frequency	100 Hz; 160 Hz
Burst frequency	0.5/min; 1/min; 2/min; 4/min; 6/min.
Burst duration	40 ms ... 500 ms
Bursts per day	659...8640
PCN PARAMETERS	
Amplitude	0.0 mA ... 4.0 mA
Current amplitude step width	0.1 mA
Pulse width per phase	100 μ s ... 1500 μ s
Pulse Frequency	100 Hz; 160 Hz
PCN burst duration	10 s ... 60 s
Step width of PCN burst duration	5 s
Number of PCN bursts	Maximum of one burst per two minutes Maximum of 6 mins total duration per day
DLS STIMULATION PARAMETERS	
Stimulation pulse amplitude	0.2 mA... 4.0 mA
Current amplitude step width	0.1 mA
Stimulation pulse to equalization pulse amplitude ratio	5:1
Stimulation pulse width	20 ms
Stimulation pulse to equalization pulse width ratio	1:5
Pulse Frequency	8 Hz
Burst duration	2 min. ... 20 min.

Table 12: Specifications of EASEE® Power. (continued)

Burst duration step width	2 min.
Pulses per burst	952 ... 9523
Burst repetition frequency	1/(24 hr)
Bursts per day	1
LEAKAGE CURRENT (NO STIMULATION)	< 1µA
MAXIMUM CHARGE DENSITY	45.3 µC/cm ²
BATTERY LIFE (typical)	Minimum approximately 159 weeks
INTERVAL BETWEEN ERI AND EOS	approximately 7 weeks
USABLE REMAINING BATTERY CAPACITY AT ERI (MINIMUM AVERAGE)	20 %
USABLE REMAINING BATTERY CAPACITY AT EOS (MINIMUM AVERAGE)	1 %
RADIO FREQUENCIES	402... 405 MHz; 2.45 GHz

Table 12 : Specifications of EASEE® Power.

8.2 EASEE® System Wireless Specifications

WIRELESS TECHNOLOGY TYPE	Short Range, Low Power MICS-Band RF Telemetry
TRANSMISSION FREQUENCY BAND	402... 405 MHz
RECEPTION FREQUENCY BAND	402... 405 MHz
Wake-up band	2.45 GHz
EASEE® POWER RECEPTION BANDWIDTH	450-kHz Frequency Shift Keying (FSK)
EASEE® CONNECT RECEPTION BANDWIDTH	450-kHz Frequency Shift Keying (FSK)
NUMBER OF CHANNELS	10
MODULATION TYPE	On/Off pulse amplitude modulation for 2.45 MHz, FSK for MICS band
RF DATA FLOW CHARACTERISTICS	Half duplex
EFFECTIVE RADIATED POWER	-16 dBm or less
MINIMUM DATA RATE (QoS)	100 bytes/second

Table 13 : EASEE® System wireless communication specifications.

8.3 Torque Wrench Specifications

MOMENTUM LIMIT	0.03 Nm (0.27 lbf.in)
WEIGHT	8 g (0.28 oz)
MATERIAL	
Handle	Polyetherimide
Shaft	Stainless steel
TRANSPORT AND STORAGE CONDITIONS	
Temperature	10 °C to 25 °C / 50°F to 77°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
OPERATING CONDITIONS	
Temperature	5 °C to 40 °C / +41 °F to 104 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	15 % ... 90 %; non-condensing

Table 14 : Specifications of torque wrench.

8.4 Activation Magnet Specifications

OUTER DIAMETER	70 mm (2.8 in)
INNER DIAMETER	30 mm (1.2 in)
THICKNESS	13 mm (0.5 in)
WEIGHT	220 g (7.8 oz)
TRANSPORT AND STORAGE CONDITIONS	
Temperature	5 °C to 35 °C / +41°F to 95°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
OPERATING CONDITIONS	
Temperature	5 °C to 35 °C / +41°F to 95°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	15 % ... 90 %; non-condensing

Table 15 : Specifications of the activation magnet.

8.5 EASEE® Lead Specifications

WIDTH	54.5 mm (2.1 in)
LENGTH	
Electrode array	54.5 mm (2.1 in)
Array incl. strain relief	77 mm (3 in)
Connecting cable incl. connector	650 mm (25.6 in)
Total length	727 mm (28.x)
THICKNESS	
Electrode array	<1.7 mm (<0.7 in)
Strain relief	3.0 mm (0.065 in)
Connecting cable	2.4 mm (0.09 in)
WEIGHT	8 g (0.28 oz)
MATERIAL	
Electrode array substrate	Silicone
Electrodes	Platinum-iridium alloy (90:10)
Screw counterpart	Polyether-ether-ketone
Connecting cable	MP35N and silicone
Connector body	Polyurethane
Connector contact	Platinum-iridium alloy (90:10)
STORAGE CONDITIONS	
Temperature	10 °C to 25 °C / 50°F to 77°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
TRANSPORT CONDITIONS	
Temperature	-10 °C to 55 °C / 14°F to 131°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
OPERATING CONDITIONS	
Temperature	18°C to 39°C (typically; 42°C short-term) 64.4 °F to 102.2 °F (typically; 107.6 °F short term)
Atmospheric pressure	700 hPa to 1500 hPa
Relative humidity	30 % ... 65 %; non-condensing (if not implanted)

Table 16 : Specifications of EASEE® Lead.

8.6 EASEE® Template Specifications

WIDTH	54.5 mm (2.1 in)
LENGTH	
Surrogate for electrode array	54.5 mm (2.1 in)
Surrogate for array incl. strain relief	77.3 mm (3 in)
WEIGHT	1 g (0.04 oz)
MATERIAL	Silicone
STORAGE CONDITIONS	
Temperature	10 °C to 25 °C / 50°F to 77°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
TRANSPORT CONDITIONS	
Temperature	-10°C to 55°C / 14°F to 131°F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 85 %; non-condensing
OPERATING CONDITIONS	
Temperature	5°C to 42°C / 5 °F to 107 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	15 %...90 %; non-condensing

Table 17 : Specifications of EASEE® Template.

8.7 EASEE® Connect Specifications

WEIGHT	70.8 g (2.5 oz)
DEGREE OF PROTECTION	IP24
CONNECTOR TYPE	USB Type C socket USB Type C plug (for EASEE® Connect) USB Type A plug (for EASEE® Set)
RADIO FREQUENCIES	402...405 MHz; 2.45 GHz
TRANSPORT & STORAGE CONDITIONS	
Temperature	-25 °C to +70 °C / -13 °F to +158 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 90 %

Table 18: Specifications of EASEE® Connect.

OPERATING CONDITIONS	
Temperature	+5 °C to +40 °C / +41 °F to 104 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	15 % to 90 %
Max. measured temperature of the applied parts (enclosure)	41.7 °C / 107 °F

Table 18 : Specifications of EASEE® Connect.

8.8 EASEE® Set – Hardware Specifications

Please refer to the specifications provided by the tablet PC manufacturer.

MANUFACTURER	Digital Technology Corp.
MODEL	MioWork L1000
POWER SUPPLY	Adapter EM1024Q2-MITA (EDAC Power Electronics Co., Ltd.)

Table 19 : Specifications of EASEE® Set - Hardware.

8.9 EASEE® Access Specifications

WIDTH	57 mm (2.2 in)
LENGTH	93 mm (3.7 in)
THICKNESS	22 mm (0.9 in)
WEIGHT	
without batteries	70.8 g (2.5 oz)
with batteries	approximately 103.7 g (3.7 oz)
DEGREE OF PROTECTION	IP54
RADIO FREQUENCIES	402...405 MHz; 2.45 GHz
TRANSPORT & STORAGE CONDITIONS	
Temperature	-25 °C to + 70 °C / -13 °F to +158 °F
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	≤ 90 %
OPERATING CONDITIONS	
Temperature	+5 °C to + 40 °C / +41 °F to 104 °F

Table 20: Specifications of EASEE® Access.

Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	15 % to 90 %
Max. measured temperature of the applied parts (enclosure)	55.8 °C (132°F)

Table 20 : Specifications of EASEE® Access.

9 Electromagnetic Emissions and Immunity

Electromagnetic interference (EMI) is interference caused by energy fields generated by equipment found in the home, work, medical, or public environments and may be strong enough to interfere with the pulse generator function. The EASEE® System is designed to be immune to common sources of electromagnetic interference. The commonest sources of electromagnetic interference (EMI) are discussed below.

9.1 Hospital or Medical Environments

Patients should always inform healthcare personnel that they have an implanted EASEE® System (and show their medical implant identification card) before any procedure is performed. Most diagnostic procedures, such as X rays and ultrasounds, may be performed without affecting the EASEE® System. However other diagnostic and therapeutic equipment that produces a lot of energy may interfere with the EASEE® System. Refer to **section 2.4 Warnings and Precautions** for more information.

9.2 Home, Work or Public Environments

The patient should avoid or exercise caution when in the presence of the following potential sources of EMI that may affect the operation of the pulse generator:

- Power lines and transmission towers (in close proximity)
- Electric substations, power generators and large transformers
- Portable and mobile RF communications equipment
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters
- Induction cookers
- Electric fences
- Jackhammers
- Stun guns

The following commonly used items should not affect the operation of EASEE® Power:

- Cell phones and Bluetooth devices
- Electric toothbrushes, shaving devices and electric hair trimmers
- Microwave ovens
- Appliances such as washing machines, tumble dryers, electric ovens, toasters, blenders, electric can openers and food processors.

- Electric blankets and heating pads
- Personal computers, electric typewriters, photocopiers and fax machines
- Televisions, AM/FM radios, stereo systems, personal music players
- Vacuum cleaners and electric brooms

For additional information about devices that generate electromagnetic interference contact Precisis GmbH. If the patient suspects electromagnetic interference / electromagnetic influence (EMI) is disrupting the operation of the pulse generator, the patient should move away from the source of the EMI.

9.3 Manufacturer Specifications – for EASEE® Access and EASEE® Connect

9.3.1 Electromagnetic Emissions for EASEE® Access and EASEE® Connect

Emission test	Compliance
RF Emissions CISPR 11	Group 1
RF Emissions CISPR 11	Class B

Table 21 : Specifications for electromagnetic emissions for EASEE® Access and EASEE® Connect.

9.3.2 Electromagnetic Immunity for EASEE® Access and Connect.

Emission test	Compliance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV for contact discharge ± 2 kV, 4 kV, 8 kV 15 kV for air discharge
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment IEC 61000-4-3	EASEE® Access 10 V/m EASEE® Connect: 3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz See Table 23.
RF Conducted IEC 61000-4-6	EASEE® Connect: 3 V (0.15 MHz – 80 MHz) 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 22: Specifications for electromagnetic immunity for EASEE® Access and EASEE® Connect.

Emission test	Compliance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m

Table 22 : Specifications for electromagnetic immunity for EASEE® Access and EASEE® Connect.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
810 870 930	800 - 900	GMS 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2450	2400 - 2570	Bluetooth, WLAN, 802,11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217	Hz 28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

Table 23 : Immunity to RF wireless communications equipment.

9.4 Guidance and Manufacturer's Declaration

The EASEE® System complies with the applicable requirements from IEC 60601-1:2015 and ISO 14708-1:2017.

Medical electrical equipment requires special precautions regarding EMC (electromagnetic compatibility) and must be installed and commissioned in accordance with the EMC information provided. In addition, the following should be noted:

- RF communication devices can affect the communication of the EASEE® System components with each other.
- The components of the EASEE® System may cause radio interference or may disrupt the operation of nearby equipment. The communication of the EASEE® System components with each other may be interfered with/disrupted by other equipment, even if that equipment complies with CISPR emission requirements. It may be necessary to take mitigation measures, such as re-orienting or relocating the devices or shielding their location.
- EASEE® Set should not be used adjacent to or stacked with other equipment or in the direct vicinity of other equipment.

9.5 FCC Compliance Declaration

This device is registered with the Federal Communications Commission under the following number:

EASEE® Power FCC ID	2BSNV-EAPW01
EASEE® Acces and EASEE® Connect FCC ID	2BSNV-EACOM01

9.5.1 EASEE® Power, EASEE® Access, EASEE® Connect

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

9.5.2 EASEE® Access and EASEE® Connect

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to this product not authorized by Precisis could void the FCC Certification and negate your authority to operate this product.

10 Reference Numbers of EASEE® System Components

The table below lists the manufacturers and reference numbers of all the EASEE® System components.

Notes: Manuals and other literature are not listed below.

EASEE System Basic UDI-DI: 426047977022426

Component	Dimension / Qty.	Manufacturer	Reference Number
EASEE® Power	n.a. / 1	Precis GmbH	EAPW01
Torque wrench	n.a. / 1	Precis GmbH	n/a (sub-component of EASEE® Power)
EASEE® Lead	n.a. / 1	Precis GmbH	EALe02
EASEE® Template	n.a. / 1	Precis GmbH	n/a (sub-component of EASEE® Lead)
Screws (total quantity needed 7)	1.5x4mm, qty. 1 1.5x4mm, qty. 2 1.5x4mm, qty. 5 1.5x4mm, qty. 1 [#] 1.5x4mm, qty. 5 [#]	Biomet Microfixation 520 Tradeport Drive Jacksonville, FL 32218-2481 United States	REF 15-6104, GUDID 00888233006958 REF SP-ST2-6104, GUDID 00888233019200 REF SP-ST5-6104, GUDID 00888233019408 REF 91-6104, GUDID 00841036053734 REF 95-6104, GUDID 00841036056650
Screws (Emergency)	1.8 x 3.5mm, qty. 1 1.8 x 3.5mm, qty. 1 [#] 1.8 x 5mm, qty. 1 1.8 x 5mm, qty. 1 [#]		REF 15-1803, GUDID 00841365107269 REF 91-1803, GUDID 00841036056247 REF 91-1805, GUDID 00841036053345 REF 15-1805, GUDID 00888233006705
Screwdriver (Handle)	Green Standard		REF 01-7390, GUDID 00841036014087 REF 01-7164, GUDID 00841036013264
Screwdriver (Blade)	short		REF 15-1194, GUDID 00841036032432
Tunneling tool	Max. length: 38cm (15 in) Min. inner diameter: 3.9mm (5/32 in)	<u>For example:</u> St Jude 6901 Preston Road TX 75024 Plano, USA	<u>For example:</u> REF 1191, GUDID 05414734400664
Activation magnet	Min. field strength: 90 gauss measured 40 mm (1.5 in) from magnet surface	<u>For example:</u> Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432, USA	<u>For example:</u> REF 9466, GUDID 20613994647812
EASEE® Connect	n.a. / 1	Precis GmbH	EACT01
EASEE® Set - Hardware	n.a. / 1	Precis GmbH	EASE02

Table 25: Manufacturers and reference numbers of EASEE® System components and accessories.

Component	Dimension / Qty.	Manufacturer	Reference Number
EASEE® Access	n.a. / 1	Precisis GmbH	EAACo1
Screws and screwdrivers provided by Vigomed are only available and authorized for use outside the United States:			
Not available in the United States	Screws	1.5 x 4mm	REF LP-5024-S UDI-DI 4250786503530
	Screws (Emergency)	1.8 x 4mm	REF LP-5064-S UDI-DI 4250786503899
	Screwdriver Handle (Steel)	L: 10cm (4in.)	REF HG-5000 UDI-DI 4250786504964
	Screwdriver Handle (Titanium)	L: 10cm (4in.)	REF HG-6000 UDI-DI 4250786504971
	Screwdriver Blade/Stilet	L: 7.2cm (3in.)	REF KS-5100 UDI-DI 4250786504902

Screws provided non-sterile must be sterilized according to the manufacturer's instructions prior to use.

Table 25 : Manufacturers and reference numbers of EASEE® System components and accessories.

11 Glossary

CSF	Cerebrospinal fluid, liquor cerebrospinalis
CSV	"Comma-separated values"; a text file format for tabular data
CT	Computed tomography
DLS	DC-like stimulation
EASEE	Acronym for the term "Epicranial Application of Stimulation Electrodes for Epilepsy"
EMB	elektromagnetische Beeinflussung (German translation of "Electromagnetic Interference")
EMC	Electromagnetic Compatibility: describes how well a device or system is able to function in an electromagnetic environment without introducing electromagnetic disturbances that interfere with the operation of other electrical products in the environment
EMI	Electromagnetic interference
EOS	End of service
ERI	Elective Replacement Indication
ESD	Electrostatic discharge
HFS	High frequency stimulation
IFU	Instructions for use
IPG	Implantable pulse generator
MR	Magnetic resonance
MRI	Magnetic resonance imaging
n/a	not applicable
Neurostimulator	Implantable pulse generator (IPG), EASEE® Power
PCN	Patient-controlled neurostimulation
PDF	"Portable Document Format"
Programming function	Function used to set parameters on the IPG, facilitated by EASEE® Set and EASEE® Connect
REF	Reference number
RF	Radio frequency
RF communication	Wireless communication based on electromagnetic waves in the radio frequency range
SN	Serial number
SOA	Safe Operating Area

12 Contact Information and Support

All questions regarding the EASEE® System or any of its components should be forwarded to the manufacturer Precisis GmbH.

Any incident that has occurred in relation to the EASEE® System or any of its components should be reported to the legal manufacturer Precisis GmbH and the authority having jurisdiction in your location.

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