EASEE®

PRECISIS

MRI Guidelines

for safe imaging of patients treated with the

EASEE® System

(ESC003)

REF MRIG01EN
Version 2.0
28 July 2022

This document applies to the EASEE® System, which contains the following components:
EASEE® Power – REF: EAPW01
EASEE® Lead – REF: EALE02

CE
0344

This guideline comprises relevant information for the safe application of MRI diagnostics for patients implanted with the EASEE® System.

For detailed information regarding EASEE® System,
please refer to the Instructions for Use
(Neurosurgeon's Manual or Neurologist's Manual)

Terminology

Terminology in this MR Guideline is used according to the definitions in ASTM F2503-20 “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”.

magnetic resonance (MR) examination—process of acquiring data by magnetic resonance from a patient (from IEC 60601-2-33, definition 201.3.219).

magnetic resonance (MR) environment—the three-dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.

MR Conditional—an item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

Supplementary Marking—additional information that, in association with a marking as “MR Conditional,” states via additional language the conditions in which an item can be used safely within the MR environment.

MR Unsafe—an item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

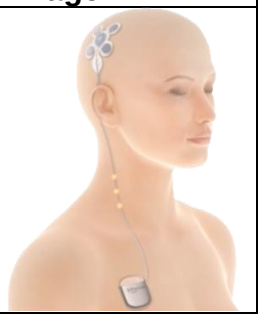
Explanation of Symbols

MR Conditional

MR Unsafe

EASEE System component identification

MR Conditional components of the EASEE® System

Component	Description	UDI-DI	Image
EASEE® Lead (connected to EASEE® Power)	Implanted electrode	04260479770446	
EASEE® Power	Implanted pulse generator	04260479770293	

MR Unsafe components of the EASEE® System

Component	Description	UDI-DI	Image
EASEE® Set	Programming tablet PC	04260479770354	
EASEE® Connect	Programming wand	04260479770330	
EASEE® Access	Patient controller	04260479770316	
EASEE® Magnet	Activation magnet	n/a	
EASEE® Lead (unconnected)	Implanted electrode	04260479770446	

Information for healthcare provider

Supplementary Marking for the MR Conditional components of the EASEE® System

<Conditions for MR Safety>

Non-clinical testing has demonstrated that the implant of the EASEE® System, i. e. EASEE® Power and EASEE® Lead, are MR Conditional in accordance with the ASTM F2503-20 standard definition.
A patient with this implant can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury.
If information about a specific parameter is not included, there are no conditions associated with that parameter

Caution:

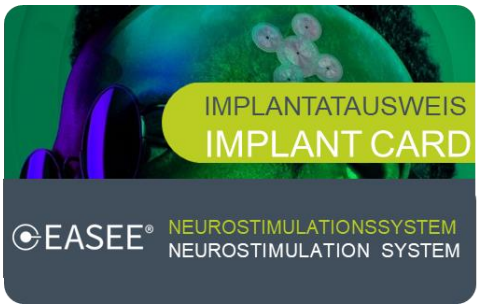
- Only the complete and intact implant (EASEE® Power connected with EASEE® Lead) is MR Conditional. Disconnected leads or broken leads of the EASEE® System have not been tested and must be regarded as MR Unsafe.
- Please switch off EASEE® Power before entering the MR environment using EASEE® Access or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

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	May 2022
Location of MRI safety information	https://www.precisis.de/MRIsafety and/or this document
Static Magnetic Field Strength	1.5 T / 3 T
Type of Nuclei	Hydrogen
Static Magnetic Field (B0) 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

Operating Mode	Normal Operating Mode (including FPO:B Mode)
RF Power	B1+RMS ≤ 7 µT or for scanners that do not report B1+rms: Whole Body SAR ≤ 2 W/kg Note: Under the RF scan conditions defined above, the EASEE® neurostimulator is expected to produce a maximum temperature rise of less than 2°C at 1.5T and at 3T after 15 minutes of continuous scanning.
Active Scan Time	Scanning for 45 minutes max
Patient Characteristics	• the implantation is at least 5 weeks ago • 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

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

- Please 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.
- Please 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.

- Please 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.

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.

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.

MR imaging information

Scan locations and scan position

No restrictions.

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 distorsion by the implant.

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 legal manufacturer, Precisis GmbH.

Information for the patient

Preparation before undergoing a magnetic resonance (MR) examination

- Please inform the MRI site personell about your EASEE® System.
  - Your implant (EASEE® Power and EASEE® Lead) is MR Conditional.
  - In case you had the puls generator (sometimes called battery) EASEE® Power removed and the electrode EASEE® Lead still implanted, your implant must be regarded as MR Unsafe.
- Please consult your treating neurologist before undergoing an MR examination.
  - In case this is not possible: Please consult your treating neurologist as soon as possible after the MR examination.
- Please bring your implant card to the MR examination.

Show it to the attending medical personnel at the MRI site.

- Please bring your patient controller EASEE® Access to the MR examination.

The patient controller must be left outside the MR environment (room where the MR scanner is located)!

Before entering the MR environment (room where the MR scanner is located)

- Please switch off your implant EASEE® Power!
  - In case your treating neurologist is present: He may switch off your implant.
  - In case your treating neurologist is not present: Please use your patient controller EASEE® Access to turn off the implant (see Figure 1 on page 2).

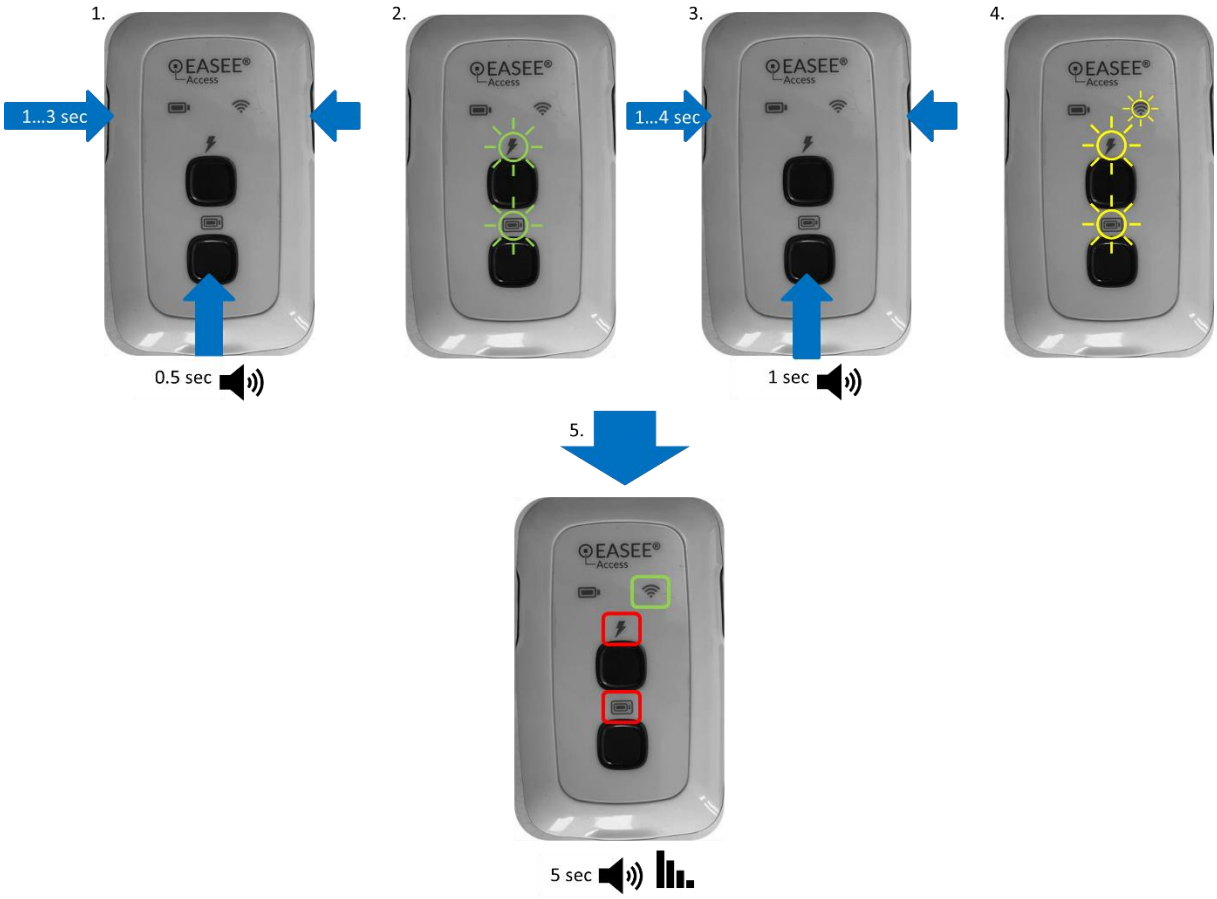


Figure 1 Sequence of commands for turning EASEE® Power off.

Action	Result
Press both side pushbuttons and the lower middle pushbutton at the same time for 1 to 3 seconds.	A confirmation beep will sound for half a second.
Release the pressed pushbuttons.	Both middle indicator lights flash.
While the indicator lights flash, again press both side pushbuttons and the lower middle pushbutton at the same time for 1 to 4 seconds.	A confirmation beep chimes for 1 second.
Release the pressed pushbuttons.	The second stage of the turning off procedure follows, with yellow flashing of the upper right indicator light and both middle indicator lights.
The successful turning off is confirmed by a 5-second beep with continuously reducing volume. The upper right indicator light glows green and the middle indicator lights glow red for 15 seconds.	

- You will no longer receive stimulation by the EASEE® System after your implant was turned off.
    - Please consult your treating neurologist to activate and programm your implant after the MR examination.
- Please leave your patient controller EASEE® Access outside the MR environment!
    - The patient controller EASEE® Access is MR Unsafe. It may be damaged when brought into the MR environment.

When entering the MR environment

- You may feel tugging forces on the implant.
    - In case you feel pain or you feel unsafe: Immediately inform the attending medical personell.

During the MR examination

- You may feel tugging forces or vibration on the implant.
    - In case you feel pain or you feel unsafe: Immediately inform the attending medical personell.
- You may feel heat at the implant location.
    - In case you feel pain or you feel unsafe: Immediately inform the attending medical personell.
- You may experience unintended stimulation events.
    - In case you feel pain or you feel unsafe: Immediately inform the attending medical personell.

After the MR examination

- Please collect your implant card.

- Please collect your patient controller.

- Please consult your treating neurologist.
    - He must re-activate and programm your implant.

Contact Information and Support

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

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69117 Heidelberg
GERMANY

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DE-MF-000016826

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