

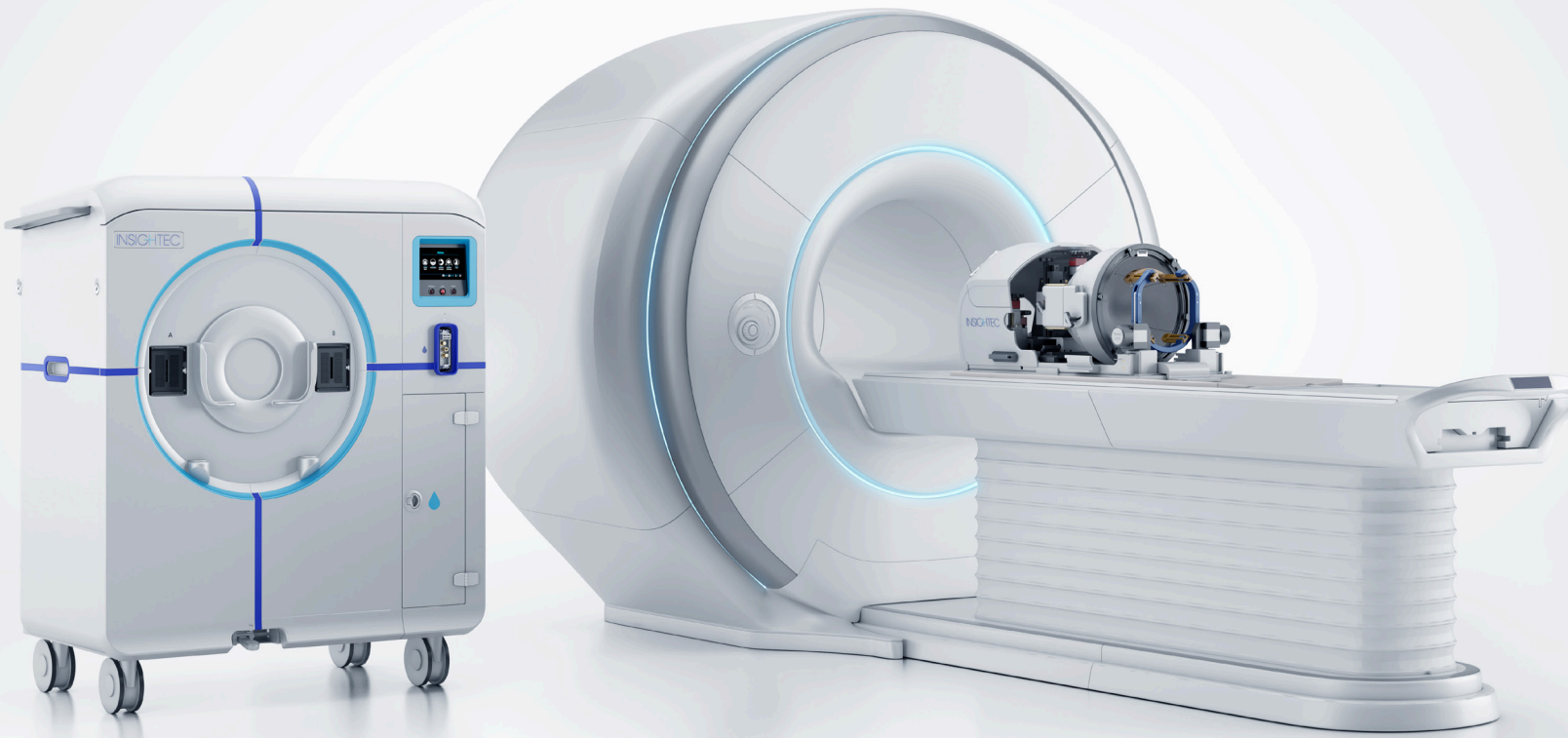
Data Sheet

MR-guided focused ultrasound

Compatible with select GE HealthCare, Philips, and Siemens Healthineers MR scanners¹

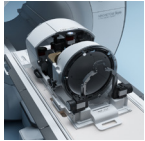
Exablate Prime

by INSIGHTEC



¹Contact your Insightec representative for a current list of compatible scanners. Philips compatibility available in the US only.

System Components



Helmet System

Includes the helmet-shaped focused ultrasound transducer on a mechanical positioning unit. The helmet system is transferred (from the storage transfer cart) to the MR table and locked into place using the included table adapter baseplate.



Front-End Unit

Contains the programmable power module that shapes and drives the acoustic beam, as well as the water system that is used to cool the patient's scalp during the procedure. It is installed in the MR room next to the scanner. A UV light cleaning system constantly disinfects the circulating water.



Operator Console

Located next to the MR workstation in the control room, the console is for planning and monitoring treatment and features a large, 27-inch, high-resolution monitor for optimized image viewing. All pre-planning, planning, and therapy delivery steps may be performed here.



Stereotactic Frame

Ensures the patient skull is immobilized during the procedure for treatment safety.



Equipment Cabinet

Contains the electrical and electronic components which control system operation. It is installed in the MR equipment room.



Cooling Unit

The cooling unit provides the front end unit with coolant and vacuum lines to allow cooling of the power amplifiers and degassing of the water interface that helps cool the patient's skull. The cooling unit is installed in the MR equipment room.



Storage Transfer Cart

Designed for safe storage and transfer of the helmet system. Includes a coupling mechanism for latching onto the MR Table and transferring the helmet system onto the MR baseplate.

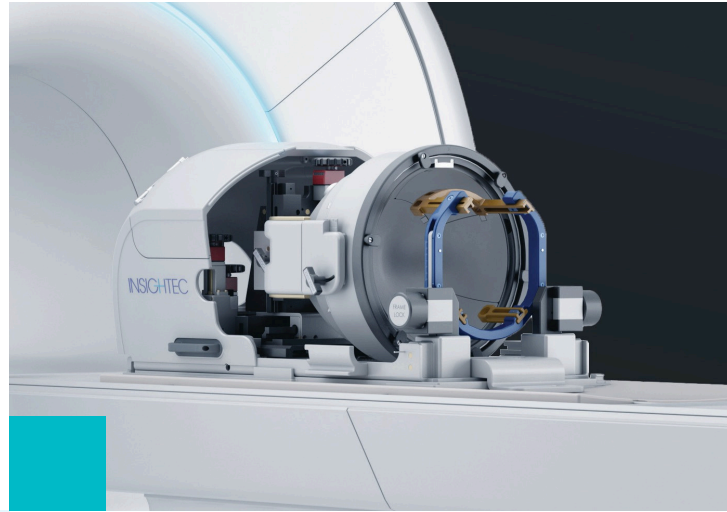
For country-specific indications, please refer to: [insightec.com/regulatory-approvals](https://www.insightec.com/regulatory-approvals).

Operational Specifications

Focused Ultrasound Transducer

The helmet-shaped phased array transducer contains 1,024 elements, which are automatically and individually adjusted to refocus the ultrasound beams to a common focal point.

- The ultrasound frequency is 620-720Khz.
- Ultrasound waves from 8- to 60-seconds duration are delivered to ablate the target area by multiple sonications.
- There are four mechanical degrees of freedom to access the treatment target: linear motion along three axes: superior-inferior, right-left, and anterior-posterior axes and angular motion of the pitch axis.
- Focal spot location is controlled by electronic steering.



Main System Features

Real-Time Thermal Feedback

- Multi-slice thermometry provides real-time temperature feedback*
- Ability to adjust parameters as needed during treatment
- Intuitive, temperature driven control
- Precise temperature prediction

MR-Imaging Guidance

- Precise identification of targeted anatomy
- Visualization of beam path for verification
- Optimized MR scan acquisition protocols
- 3D visualization of the lesion and sublesion areas
- Clear differentiation between treated and non-treated area

Accurate Planning

- Treatment planning is performed on high-resolution MR images of target areas with fusion of pre-treatment CT and MR images.
- Pre-treatment planning module personalizes treatment parameters according to patient anatomy.
- Visual archive is stored for treatment replay and assessment.
- Integrated tools for planning such as tractography, grid overlays and measuring tools.

Human Centered Design-Guided Workflows

- Automated steps
- Streamlined user interface

*Multi-slice thermometry feature available only with optional 3T head coil accessory kit.

Technical Requirements

Electrical Requirements

- Operator console is powered from a grounded wall outlet, 50/60 Hz, 115/230 VAC. Equipment cabinet is powered by 3 ϕ 480VAC x 50A or 3 ϕ 400/380 VAC x 60A 50/60 Hz from a permanent connection and protected by a dedicated circuit breaker.
- The workstation tower, host computer, and the 27-inch monitor will connect to 110V emergency outlets.
- In the event emergency power is not available, a UPS unit should be installed as a backup power source.
- It is recommended that the site adds a UPS unit to receive power via the 110VAC emergency outlet. This should be connected to the workstation tower computer. The recommended specification for the UPS is 1.5-2.0 kVA with capacity for at least 30 minutes after power cut.

Compatibility¹

- Exablate Prime is compatible with select GE HealthCare, Philips, and Siemens Healthineers MR scanners. The MR must have an operational body coil and requires operating software as well as an additional accessory package for each MR scanner.



Specifications	Dimensions (cm)	Weight (kg)
Helmet System	W 110 x H 60 x D 70	~27
Storage Transfer Cart	W 110 x H 130 x D 75	~170
Equipment Cabinet	W 60 x H 190 x D 85	~550
Cooling Unit	W 40 x H 118 x D 75	~180
Front End Unit	W 120 x H 136 x D 90	~431

Note: For full technical specifications and dimensions, you may request a copy of the Exablate Prime site planning considerations from your Insightec representative. Exablate Neuro fulfills the requirements for CE marking, as established by Notified Body 0344

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