



**The power
is in your
hands.**

Exablate Prime

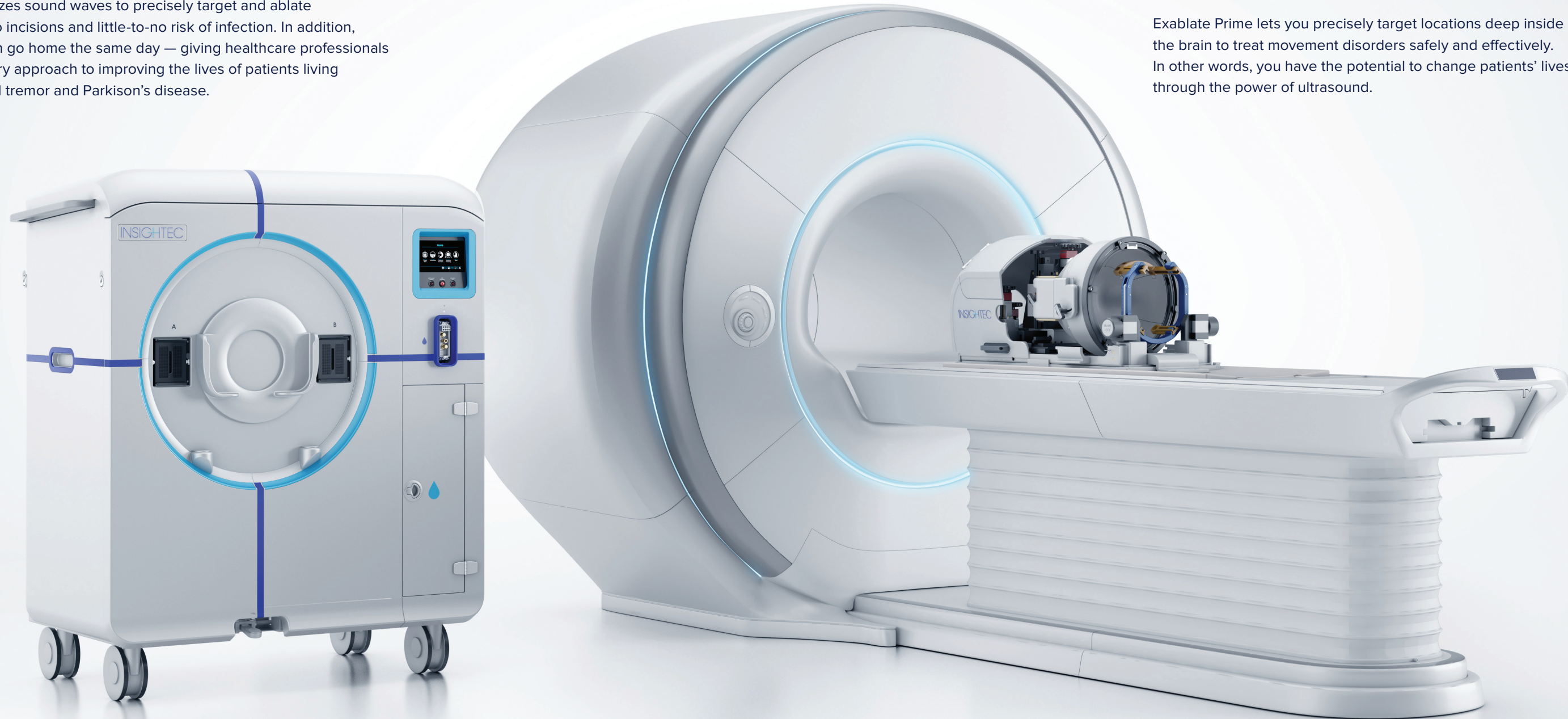
by INSIGHTEC

Insightec. Transforming tomorrows, today.

As the pioneer and global leader in focused ultrasound (FUS), Insightec utilizes sound waves to precisely target and ablate tissue with no incisions and little-to-no risk of infection. In addition, patients often go home the same day — giving healthcare professionals a revolutionary approach to improving the lives of patients living with essential tremor and Parkinson's disease.

Precision surgery. Zero incisions. That's the power of Prime.

Exablate Prime lets you precisely target locations deep inside the brain to treat movement disorders safely and effectively. In other words, you have the potential to change patients' lives through the power of ultrasound.



Life-changing* for patients. Purpose-built for surgeons.



No incisions. Immediate results. Welcome to the future of surgery.

Prime has undergone a complete transformation, putting the end user at the forefront of innovation with a combination of cutting-edge software and hardware.

Intelligent algorithms, autogenerated patient reports, state-of-the-art data management, and reporting power all revolutionize the planning and sonication process — making it faster, more informed, and incredibly intuitive.



A decade of learning, perfected for you.

Built on ten years of rigorous research and development, plus invaluable feedback from hundreds of users around the world, Prime is a testament to modern surgical excellence. Surgeons can now approach treatments with unmatched confidence, knowing they have a platform designed for success.

*Life-changing refers to significant improvement in quality of life. For a full list of indications and warnings please refer to the FDA website: Pre-Market Approval (PMA) P150038 or Indications for Use Summary.



Designed for today and years to come.

Prime features modernized, efficient hardware, designed with the unique needs of the focused ultrasound procedure in mind, including:

- PC components with capacity for upgradeability and a state-of-the-art computing architecture that can store up to 150 reports
- Large, high-resolution monitor for optimized image viewing
- Cross transducer designed for optimal performance and visualization for the unique needs of an MR-guided FUS procedure
- UV light constantly disinfects circulating water, reducing the need for a full system cleaning to once per 5 uses or at least once a week, and turnover time is reduced to 15 minutes or less, streamlining turnover time and optimizing precious magnet and staff time
- Water system readouts and system alerts that are easily accessible on a bright, digital display on the front end and on the Prime workstation
- New front-end screen display that provides key procedural information about water system status and transducer positioning. Newly branded front-end and transducer covers to protect your investment.



Elevated security and integration.

Prime places a premium on security. Cybersecurity measures are designed to meet your hospital's standards today, and safeguard your procedures in the future.



Prime delivers the clarity, confidence, and control you need.



Human-centered design.

Experience a seamless interface designed for efficiency and ease of use. Using guided workflows with automated steps running in the background, you can focus on what's most important — your patient outcomes. Intuitive visual cues lead you through pre-planning, planning, and treatment — ensuring a smooth and efficient process.

- Guided workflows
- Automated steps
- A streamlined user interface and experience



Intelligent algorithms & efficient calculations.

Prime automates time-consuming tasks and calculations like performing a skull-density-ratio (SDR) calculation with the click of a button. With intelligently-designed algorithms, Prime software has been demonstrated to accurately fuse images, and identify important anatomical landmarks — some unique for planning FUS cases. All you need to do is review, adjust if needed, and approve.

- Integrated, one-click skull-density-ratio (SDR) calculator
- Automatic AC/PC identification
- Automated fusion with demonstrated accuracy*
- Efficient no-pass region detection (sinuses, calcifications, and membrane folds)

*Based on internal testing when using recommended data sets.



Target Coordinates: AC-PC | RAS
 L13.8 Left A5.8 Anterior S2.0 Superior

Valid Spot: OK
 Distance to Focal Point: OK

[R0.2] Right [A0.1] Anterior [S0.6] Superior

Place Transducer Manually

Save Planning Session

Cycle View Measure Overlays Delete Compare

PRE-PLANNING MODE

Axial (AC-PC) LAS
 Tx MR: L29.6 A41.7 S69.1
 Source: L25.8 A47.7 I27.1
 AC-PC: L24.5 A83.7 I0.0

Pre-Op 130/302 I48.4

Coronal (AC-PC) LPS
 Pre-Op 151/301 P12.5

SAG T2 SPACE 3D W TRACTS RAI
 07:42, 26-Jun-18

Sagittal (AC-PC) LPS
 Pre-Op 108/214 R3.3

SAG T2 SPACE 3D W TRACTS RAI
 07:42, 26-Jun-18

SAG T2 SPACE 3D W TRACTS RPI
 07:42, 26-Jun-18

FGATIR 180slices AX (180)
 SAG T2 SPACE ... SAG (208)
 CT BONE PLUS AX (250)

100mm [50mm]

Show Patient Info



Plan when and where you want.

Take advantage of PACS integration,* remote planning,* and troubleshooting** features with peace of mind, and be ready to go on the day of the procedure. Prime can be networked to your hospital's or clinics' PACS system and set up for remote planning and skull-density-ratio calculations. You can perform all the steps of data preparation and planning on the Prime workstation in the MR suite or on your laptop through a secure connection.

- Enhanced cyber security
- PACS connectivity*
- Remote planning*
- Remote troubleshooting**



Visualization and image management.

With an advanced toolset, Prime allows for simultaneous viewing and thorough evaluation of multiple data streams. You can automatically acquire required MR sequences with a single click, doing away with cumbersome manual setups. You can also seamlessly import functional overlays, such as anatomical guidance tools and segmented tracts.

- State-of-the-art data set management/visualization
- Automatic MR scan acquisition
- Fiber tracking enhancements (DTI)***
- Intelligent targeting tools
- Enhanced tools for image registration evaluation
- Unlimited MR data sets in one planning session

*Remote planning and PACS access is an optional feature that must be enabled.
 **Requires appropriate service and/or applications support package.
 ***Requires pre-operative image data processing using third-party software not included with Prime.



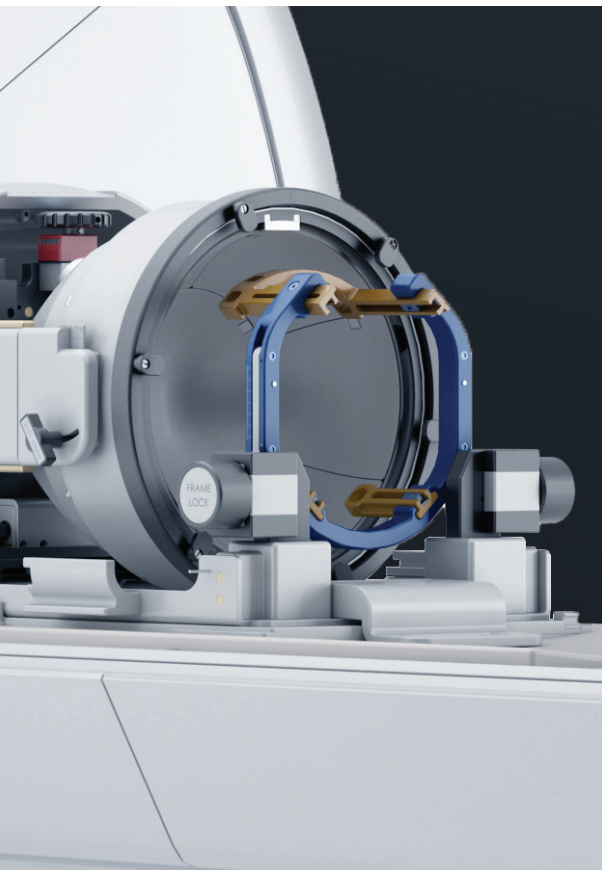
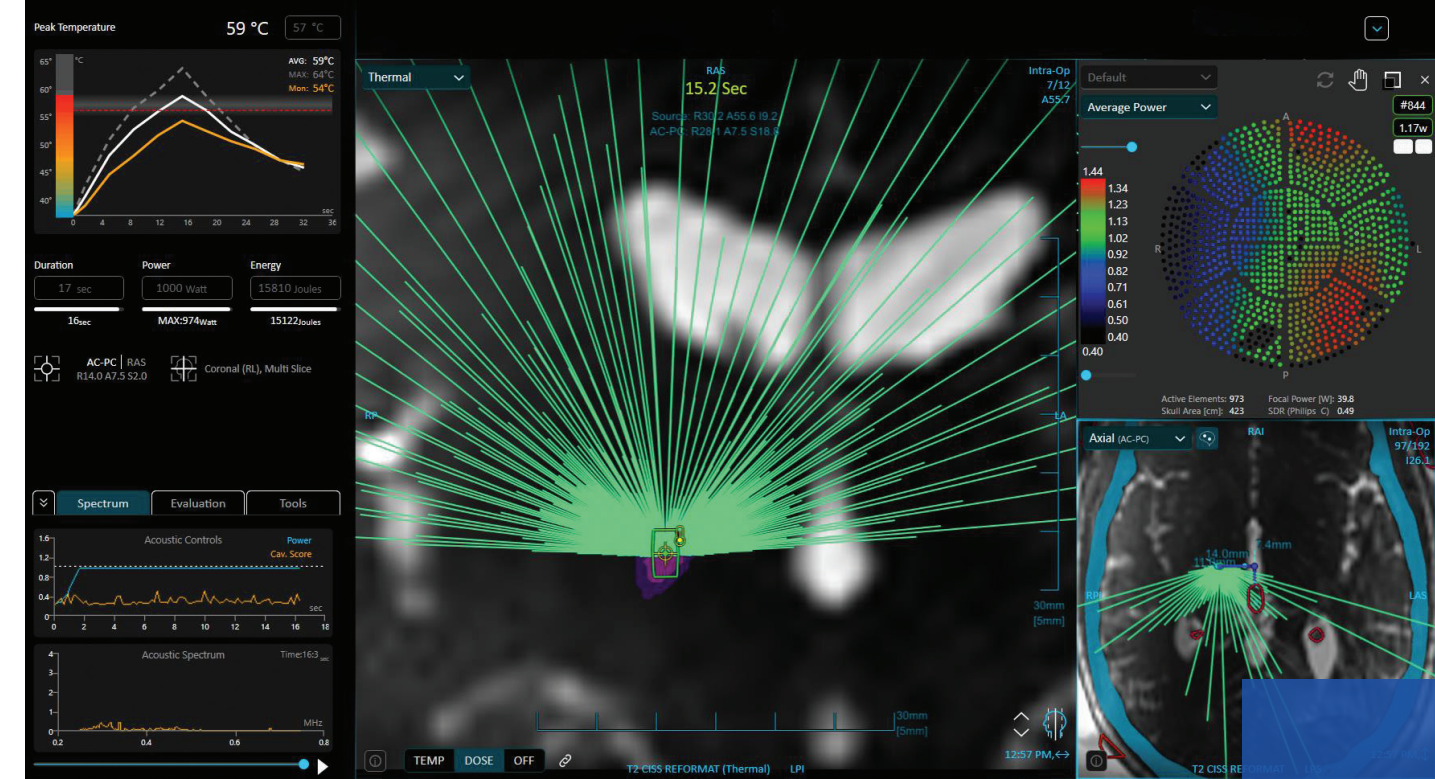
“

I've done all the different surgical procedures for essential tremor and this is by far the most elegant, safest, and most effective way of doing it that I have seen.”

—**Garth Rees Cosgrove, MD**, Director of Epilepsy and Functional Neurosurgery, Brigham & Women's Hospital

Dr. Cosgrove has received clinical or research support from insightec; further Dr. Cosgrove is or has been a paid consultant by Insightec.

Precision therapy, delivered. The power of Prime, in your hands.



Intuitive, temperature-driven control.

The temperature-prediction algorithm of Prime has been demonstrated to accurately predict lesion heating within 2 degrees of prediction. With this improved temporal resolution, Prime gives you better data — based on key inputs during a procedure — and helps inform your treatment decisions with data tailored to that patient, that day.

Because Prime is able to accurately predict temperature rise, the Prime system allows you to dial in the desired temperature and duration for each test and treatment sonication. The intuitive interface calculates the precise amount of energy required to deliver the thermal dose you prescribe.

- Temperature prediction algorithm
- Temperature-driven sonication

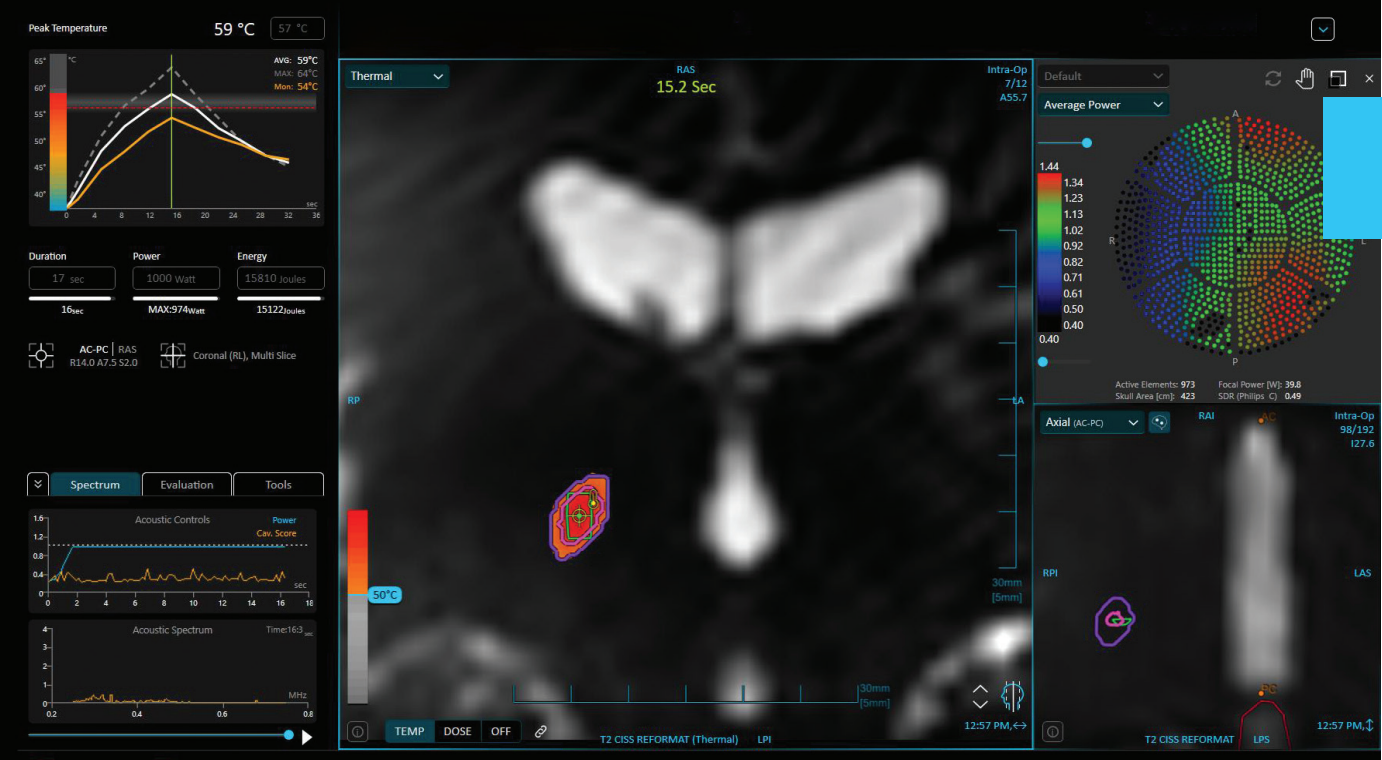


Precise targeting and lesion shaping.

Prime is a high-precision instrument that enables incisionless surgery with the accuracy you need. Built with 1,024 transducers, Prime can lesion a target location with pin-point precision, validated to be able to perform within +/- 1mm of the selected target and volumetrically accurate to the defined region of interest within +/- 0.2cc.

The integrated solution includes advanced acoustic field masks that can be used to modify the transection of the transducer elements to sculpt the lesion shape.

- 1,024 transducer elements
- Sub-millimetric targeting control
- Advanced shaping masks



Effortless intra-op data collection.

Autogenerated reporting dynamically captures data in real-time, during the procedure – with key technical details such as thermal dose delivery and the ability to include annotations for each sonication.

A summary table is generated for quick reference and the user interface provides easy navigation to replay mode. Data is exportable in a CSV file to easily enable case analysis, insights, trends, research, collation, aggregation, tracking, and communication to referring physician's and other key stakeholders.



Real-time monitoring.

Harness the power of FUS using the multi-slice thermometry, intelligent algorithms, and visualization tools that adapt and refine predictions in real-time during each case, enhancing confidence and control with every procedure.

- Precise thermal predictions
- 3D thermal spot visualization*
- Cumulative dose overlays
- Thermal dose overlays with time stamps
- Distinct lesional and sublesional visualization

*3T head coil and membrane is part of the patient treatment kit and is sold separately from Prime.



Treat with confidence.

Take advantage of a dedicated and enhanced workspace for patient movement detection and analysis.



Together, we can make essential tremor and Parkinson's disease a thing of the past.

At Insightec, we believe every moment in life is one worth celebrating. And as the innovators of focused ultrasound, we're passionate about helping physicians and hospitals eliminate essential tremor and Parkinson's disease — and transform the lives of patients around the world.



5-year efficacy*

Proven, life-changing** therapy.

15,000+ patients treated

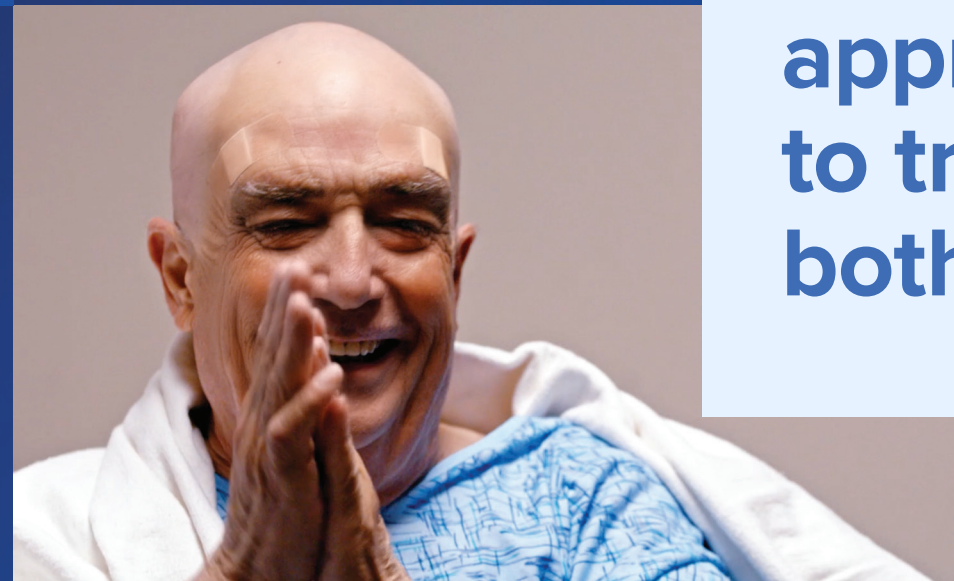
FDA approved to treat both sides.*

Put the power of Prime to work for you.

Prime gives you the tools and technology you need to take full advantage of incisionless surgery's potential — propelling your skills, advancing your career, and giving your hospital an unparalleled competitive advantage. With Prime, it's in your hands.

*5-year efficacy and second-side treatment statements are applicable to our essential tremor indication only.
**Life-changing refers to significant improvement in quality of life.

For a full list of indications and warnings please refer to the FDA website: Pre-Market Approval (PMA) P150038 or visit our website: <https://insightec.com/safety-information/>



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PUB41010306

Device name: **Exablate Prime**

Visit our website for more information about the focused ultrasound treatment for essential tremor and Parkinson's disease:

<https://insightec.com/healthcare-professionals/exablate-prime/>

INSIGHTEC

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