



**The power
is in your
hands.**

Exablate Prime

by INSIGHTEC

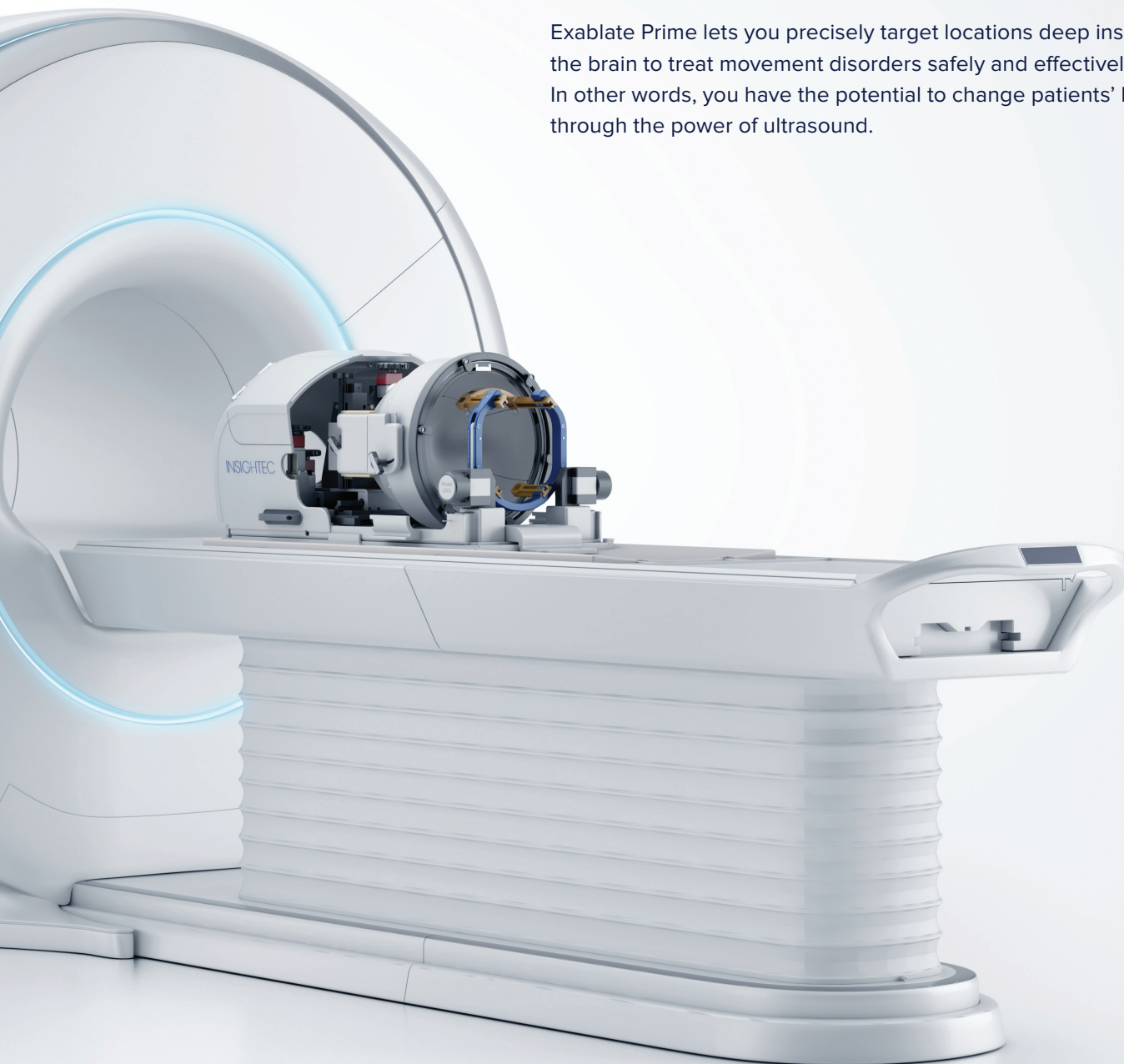
Insightec. Transforming tomorrows, today.

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.

Exablate Neuro has undergone a complete transformation. The result, Exablate Prime. Putting the 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:
www.FDA.org 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 upgrade and a state-of-the-art computing architecture that can store up to 150 treatment 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 unit in the MR suite, and on the Prime workstation



Elevated security.

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.



Exablate Prime

- PLAN
- CALIBRATION
- SCAN
- NPR REVIEW
- REGISTRATION
- AC-PC PLANE
- TARGETING**
- THERAPY
- END TREATMENT

Target Coordinates: AC-PC | RAS

L 16.1 A 4.8 S 0.0
Left Anterior Superior

AC-PC length: 26.2mm

Grid Overlay Place Target

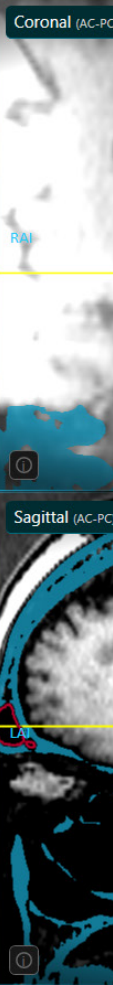
Valid Spot: OK
Stop Sonication Button: OK
Distance to Focal Point: OK

[R0.3] [A0.1] [S0.4]
Right Anterior Superior

Update Transducer Location

Finalize Target

Show Patient Info



MRI Not using Not connected Not connected



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.

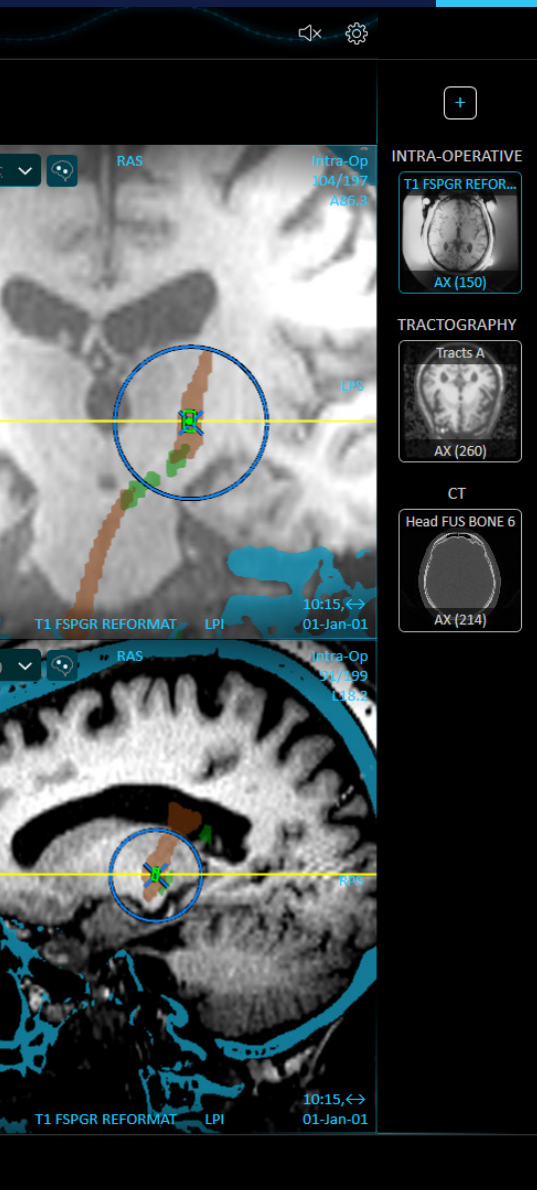
With an advanced toolset, Prime allows for simultaneous viewing and thorough evaluation of multiple data streams. You can automatically acquire required MR sequences with a single click, doing away with cumbersome manual setups. You can also seamlessly import functional overlays, such as anatomical guidance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





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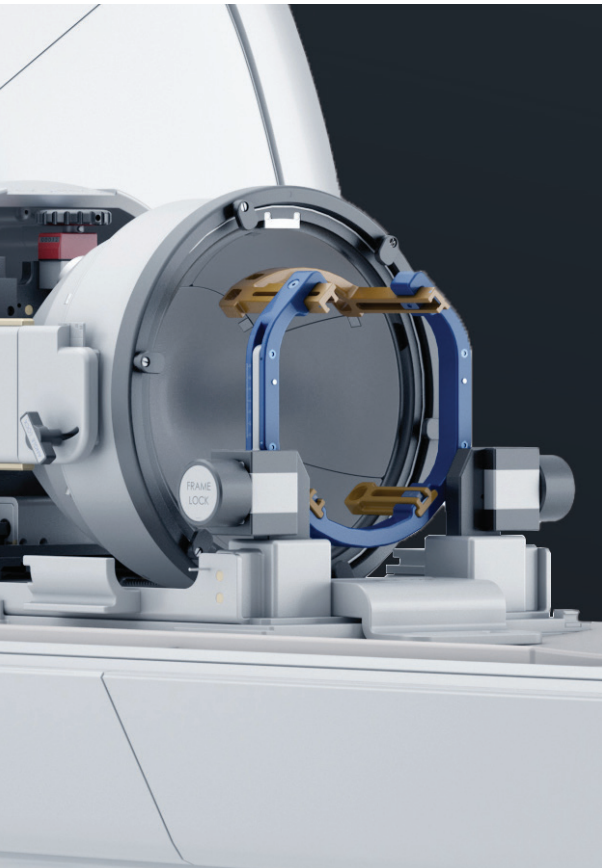
I've done all the different surgical procedures for essential tremor and this is by far the most elegant, safest, and most effective way of doing it that I have seen.”

—Garth Rees Cosgrove, MD, Division Chief, Functional, MGB Department of Neurosurgery

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.

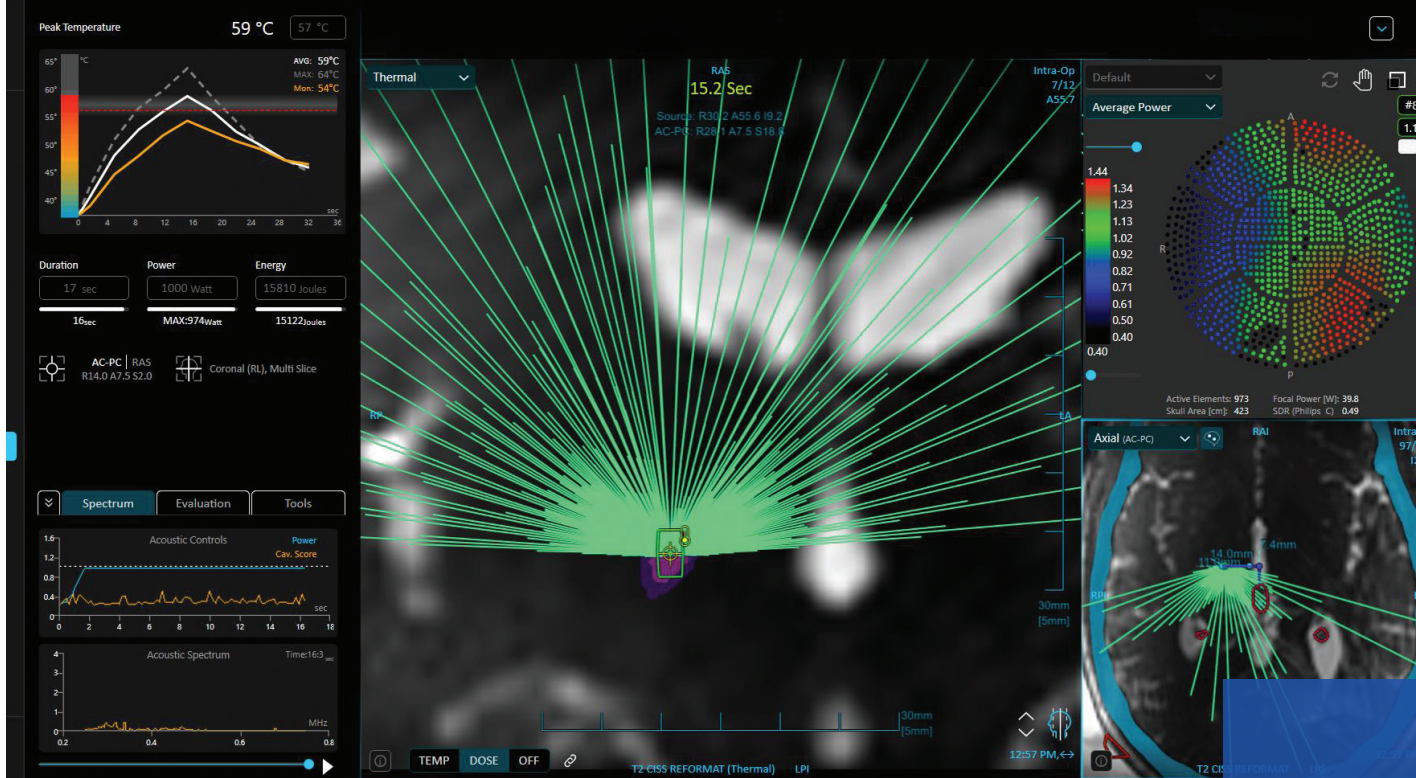


Intuitive, temperature-driven control.

The temperature-prediction algorithm of Prime has been demonstrated to accurately predict tissue heating within 2 degrees. With this improved 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

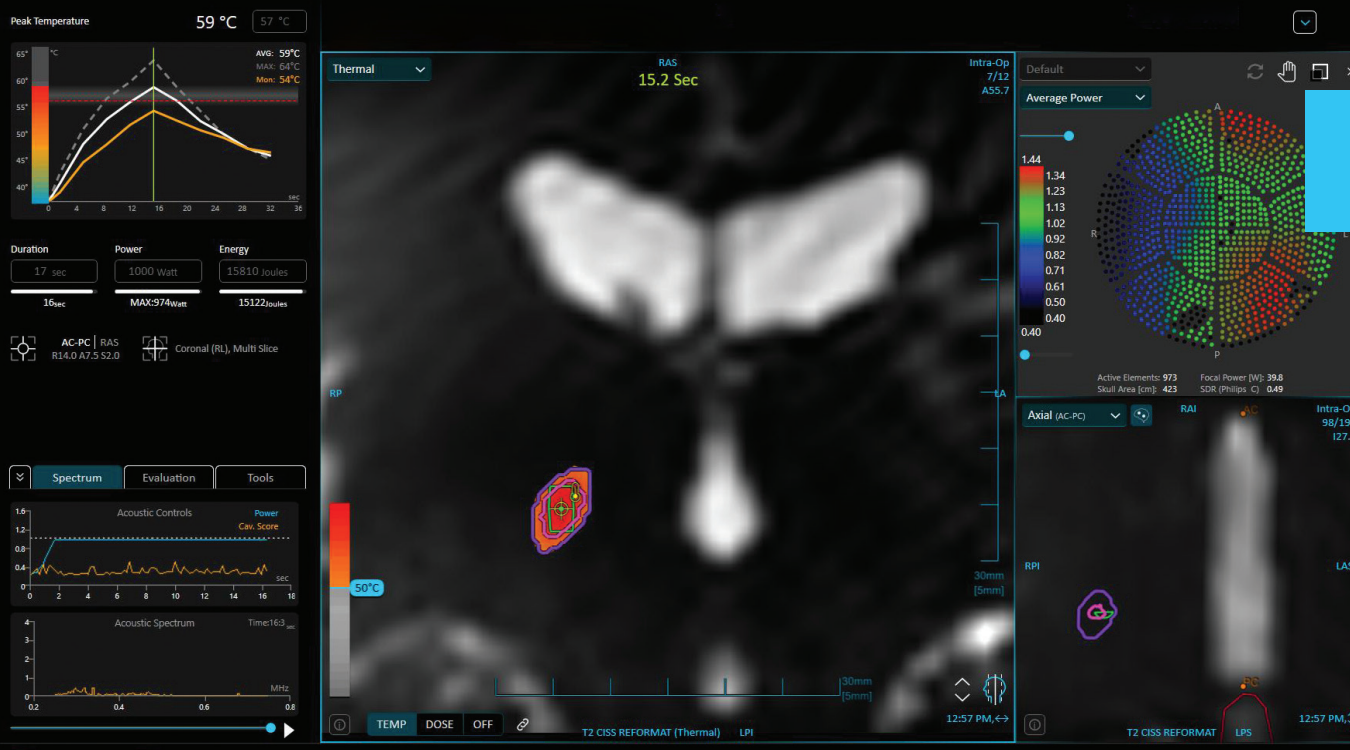


Precise targeting and lesion shaping.

Prime is a high-precision instrument that enables incisionless surgery with the accuracy you need. Built with 1,024 elements, Prime can disrupt 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



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 therapeutic and subslesional visualization

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



Treat with confidence.

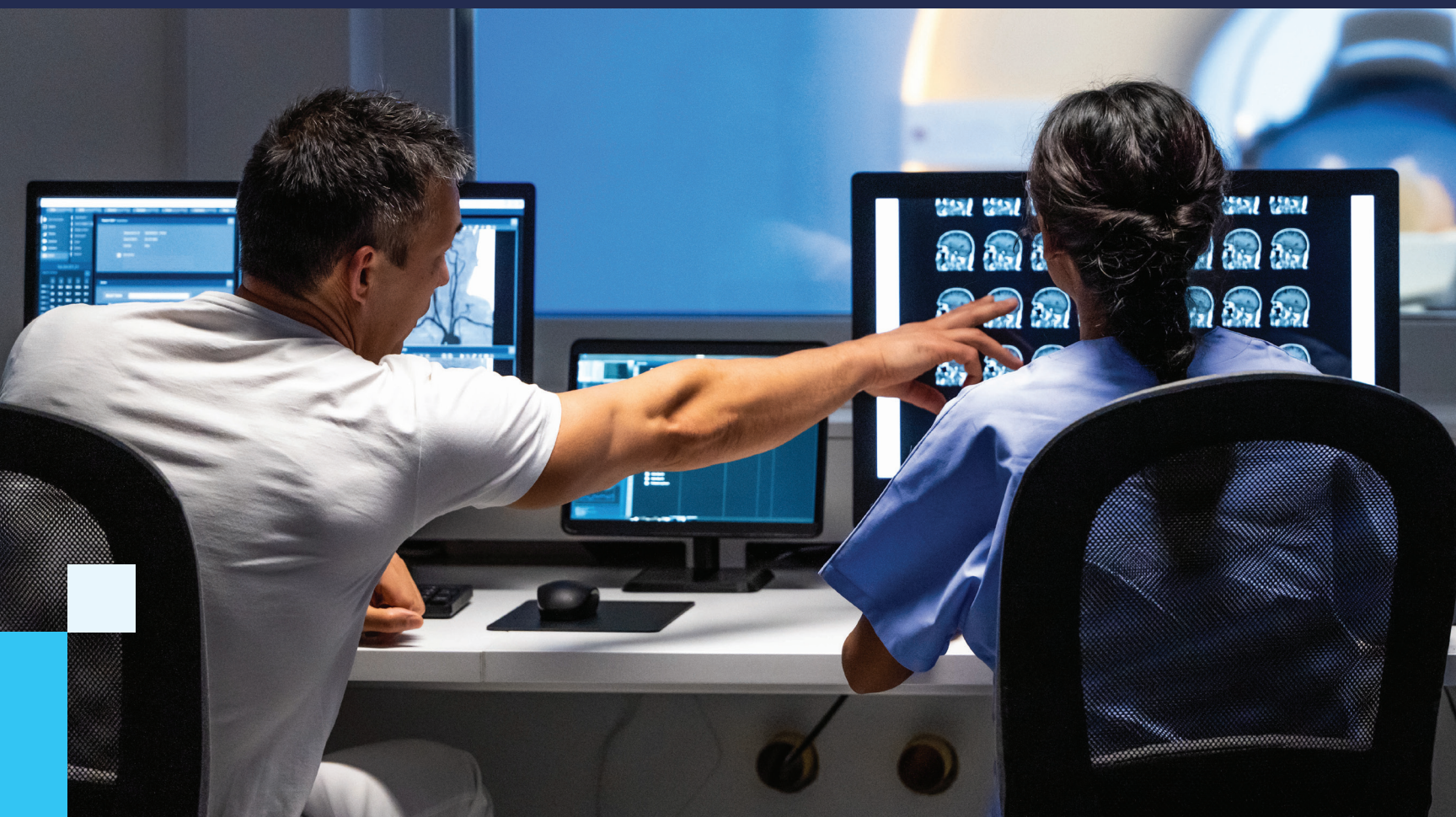
Take advantage of a dedicated and enhanced workspace for patient movement detection and analysis.



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 physicians and other key stakeholders.



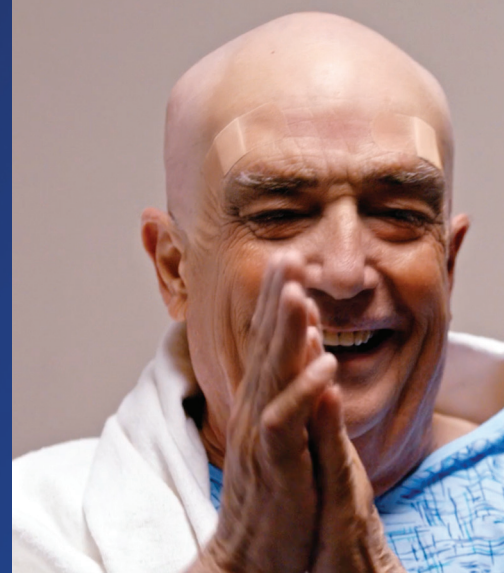
Together, we can make essential tremor and Parkinson's disease a thing of the past.

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 treat essential tremor and Parkinson's disease — and transform the lives of patients around the world.



25,000+
patients treated***

Proven,
life-changing*
therapy.



5-year
efficacy*



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 applies to unilateral essential tremor

**Staged, bilateral treatments are approved only for: thalamotomy for essential tremor & pallidothalamic tractotomy for Parkinson's disease.

***Number of treatments includes all commercial treatments following regulatory approval for both Exablate Prime and predicate platforms.

For a full list of indications and warnings please refer to the FDA website: www.FDA.org or visit our website: <https://insightec.com/safety-information/>

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Device name: **Exablate Prime**

Prime functionality is a tool; however, the procedure and associated calculations and planning are ultimately the physician's responsibility and should be reviewed before making medical decisions.

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/>

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