



Meet **Edison**[®]

System overview and
technical specifications



Edison treatment head with bubble cloud (enlarged).

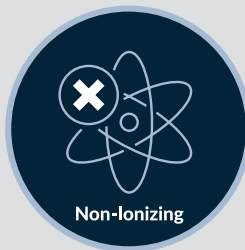
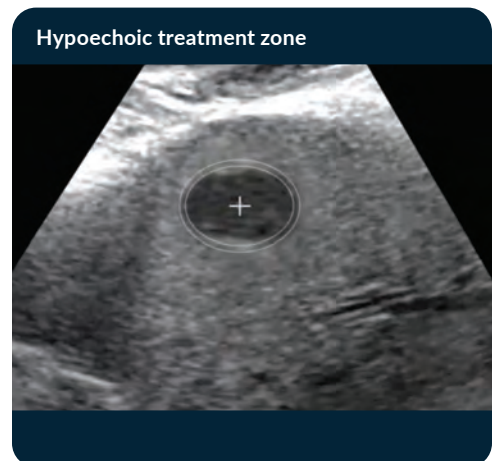
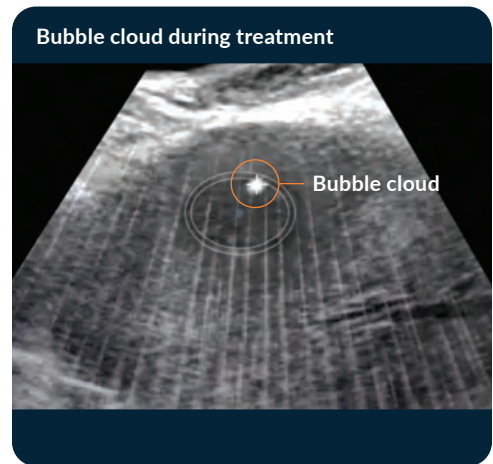
Histotripsy

Mechanism of Action

Histotripsy is a novel form of focused ultrasound that uses high amplitude, very short pulses designed to mechanically destroy and liquefy targeted tissue.

Specifically, as the focused ultrasound energy converges at a known focal point, high pressure causes extremely small, naturally occurring gas bubbles to expand many times larger through a phenomenon called acoustic cavitation.

During planning, the physician also establishes the minimum threshold voltage required to sustain the bubble cloud in the targeted tissue – this leverages histotripsy’s “threshold effect” that removes targeted liver tumors, while tending to preserve collagenous vessels and ducts.¹



The histotripsy mechanism of action is non-thermal, non-ionizing and is designed to destroy only the targeted tissue in the planned treatment volume.

- The bubble cloud generally has a bright, visible echogenic appearance as seen with the Edison real-time ultrasound imaging.
- The Edison System automated treatment arm dynamically and precisely moves the treatment head and bubble cloud throughout the targeted treatment volume under the watchful eye of the treating clinician.

Edison Design Overview and Key Components



- A** User interface control panel
- B** Automated treatment arm
- C** Treatment head

Treatment Head Overview

The Edison System treatment head houses a concave therapy transducer which generates a localized bubble cloud at a known focal point to destroy targeted tissues and cells.

An integrated ultrasound imaging probe with encoded rotation and translation allows continuous visualization for localizing, planning and monitoring treatment.



Imaging probe

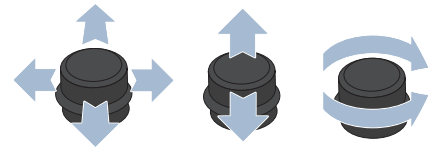
Histotripsy therapy transducer

Freedrive button

Imaging probe rotation lever



Freedrive handle buttons for load-assisted gross positioning.



Space mouse moves the treatment head in six degrees of freedom (x, y, z, pitch, roll and yaw) at the desired speed and allows precise, fine tune positioning of the treatment head.

OPTIONS

Treatment heads are designed and optimized for a specific treatment depth range.

Treatment heads are designed for quick and easy exchange.



2-12cm

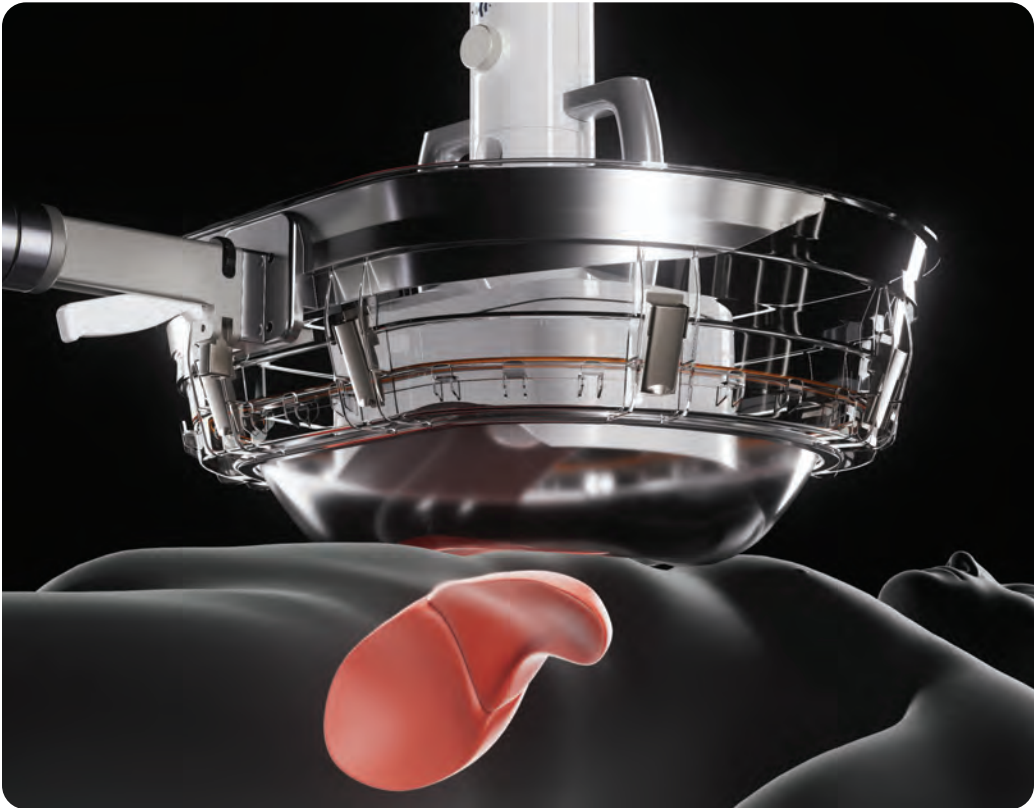


8-14cm

Histotripsy Coupling Kit Overview

FEATURES

- Proprietary single-use design for easy setup and disposal.
- Ergonomic, easy fill and drain method to quickly couple the therapy transducer to the patient.
- Flexible membrane conforms to the patient's anatomy and allows uninterrupted ultrasound delivery.



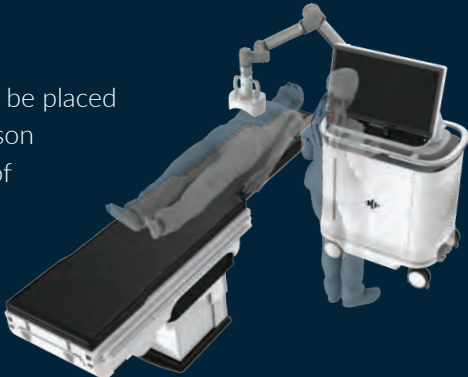
The Edison System patient membrane holds the ultrasound medium and contours to the patient, acoustically coupling the treatment head to the patient.



Flexible membrane

SETUP

With its small footprint and ability to be placed on either side of the patient, the Edison System is compatible with a variety of rooms and room configurations.



Workflow Overview

FOCUS

Designed around the three phases of the histotripsy procedure (Localize, Plan, Treat), the Edison System user interface provides step-by-step instructions and seamless workflow so that physicians can focus on the task at hand.

1 LOCALIZE

View MRI or CT imaging alongside real-time diagnostic ultrasound with 2D and 3D views.

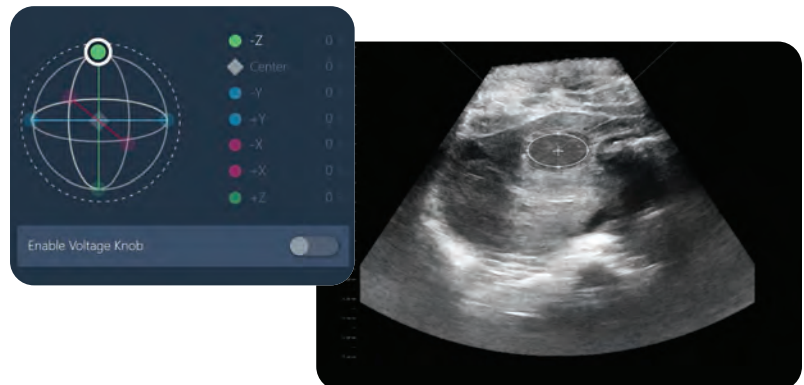
- Evaluate both the target and other critical anatomy in the area of interest.
- Multi-planar viewing with the rotating and translating diagnostic ultrasound supports full volumetric targeting.



2 PLAN

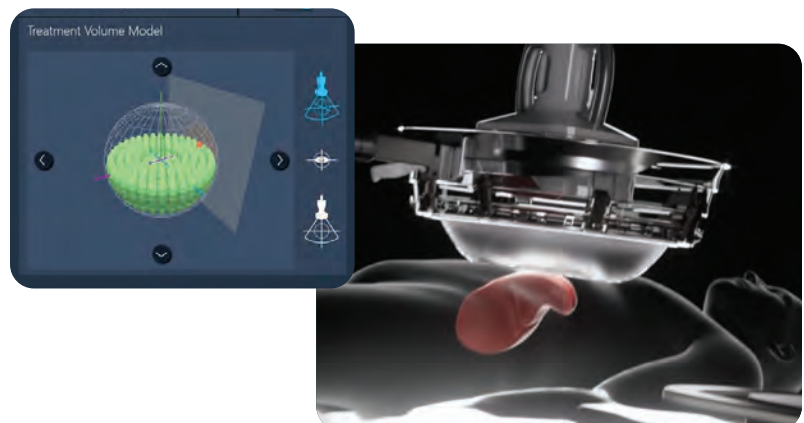
Adjust the size, shape and location of the planned treatment volume with target and margin contours. Visual representation of the plan contours are overlaid onto real-time diagnostic ultrasound.

Edison's workflow allows the clinician to determine the precise amount of energy required to destroy the target. These measurements are performed inside each target at 7 discrete points and are used to determine the treatment parameters.



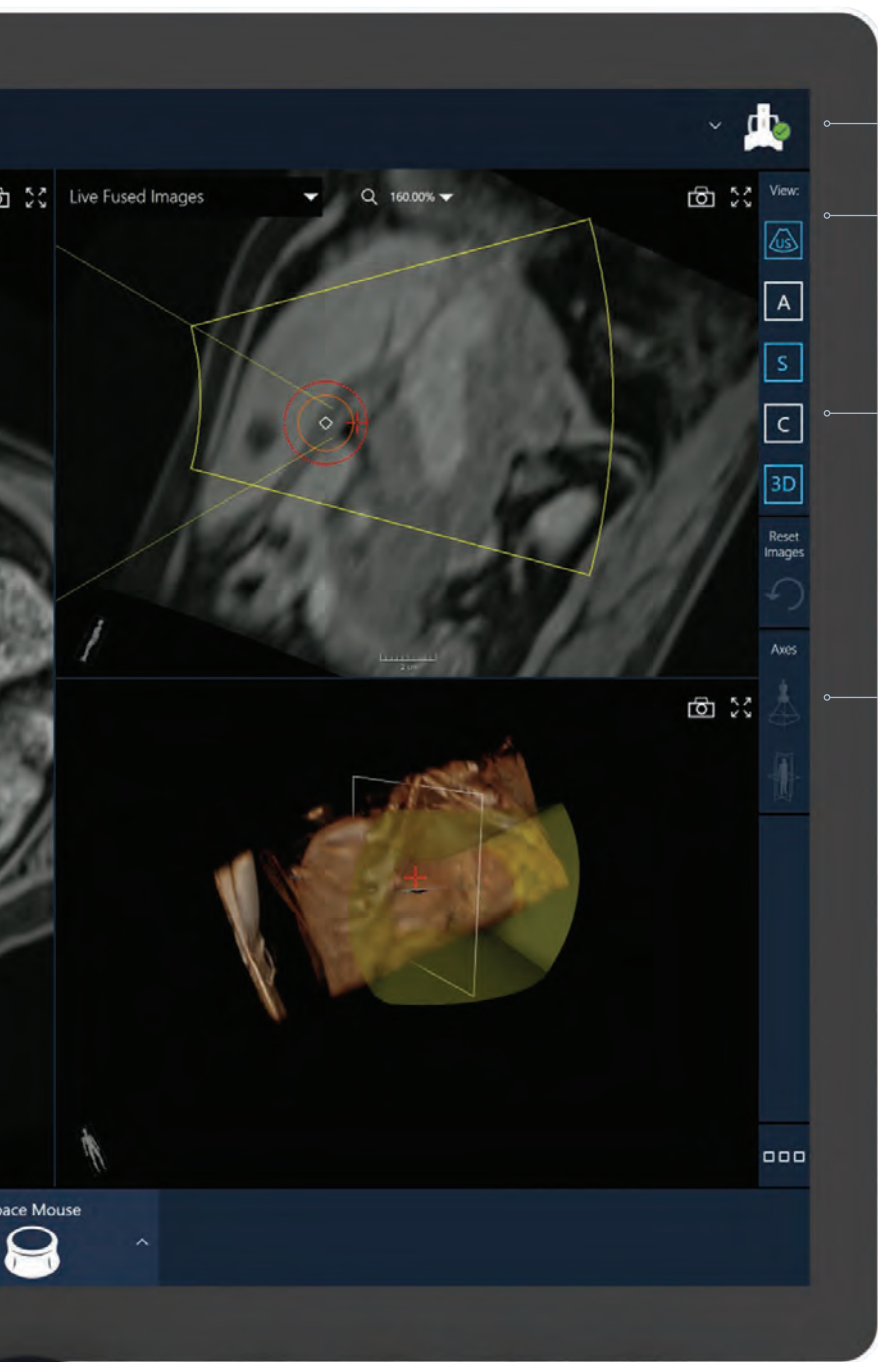
3 TREAT

During fully automated treatment, Edison dynamically and continuously moves the treatment head through the optimized pattern of the planned treatment volume and provides continuous real-time monitoring of imaging and treatment status.



User Interface Overview





SOFTWARE ELEMENTS

- A** Procedure phase (Localize, Plan, Treat)
- B** Current task and instructions
- C** Planning controls
- D** Treatment head identifier/status
- E** Image plane customization
- F** DICOM View (Axial, Sagittal, Coronal)
- G** Axis perspective controls

PHYSICAL CONTROLS

- 1** E-stop (emergency stop button)
- 2** Planning knobs (X, Y, Z)
- 3** Voltage adjustment
- 4** Trackpad
- 5** Space mouse
- 6** Power button



5

6

Specifications

THE EDISON SYSTEM



Features

- 32 inch touchscreen display with 16:9 aspect ratio, 3840 x 2160 pixels (4K), scratch-resistant AR glass, super wide 179 degree viewing angle (horizontal and vertical) and aluminum chassis
- Fully-adjustable display arm
- Detachable treatment head with integrated GE LOGIQ™* E10s imaging probe
- Automated treatment arm
- Physical control knobs for setting planning parameters
- Physical control knobs for controlling imaging probe translation/rotation
- E-stop button
- Track pad
- 3D space mouse and freedrive treatment arm control
- Uninterruptible power supply
- Full-surround aluminum handrail
- Swivel lock/full lock castors

Dimensions (Transport)

- Height: 166cm (65.5 inches)
- Width: 100cm (39 inches)
- Depth: 64.6cm (25 inches)

Weight

- 264kg/582lbs

Electrical

- 120 V (US)/240 V (Europe)

GE LOGIQ™* E10s



Features

- 22 inch high-resolution anti-glare OLED display
- 12.1 inch, high resolution, color touchscreen display
- Fully-adjustable monitor arm
- Next-generation cSound™* architecture
- High frequency imaging
- GE LOGIQ™* E10s imaging probe
- Ergonomic floating keyboard

Dimensions (Transport)

- Height: 130cm (51 inches)
- Width: 58.5cm (23 inches)
- Depth: 90cm (35.5 inches)

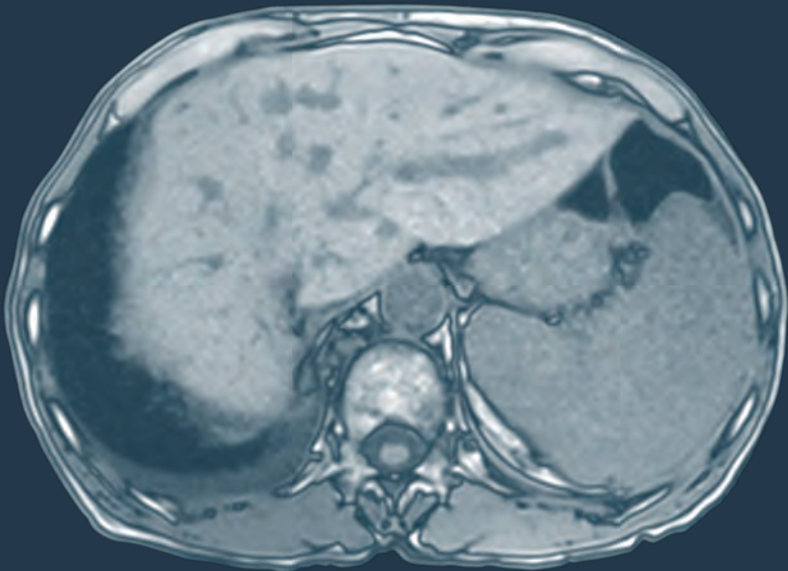
Weight

- 115kg (254 lbs)

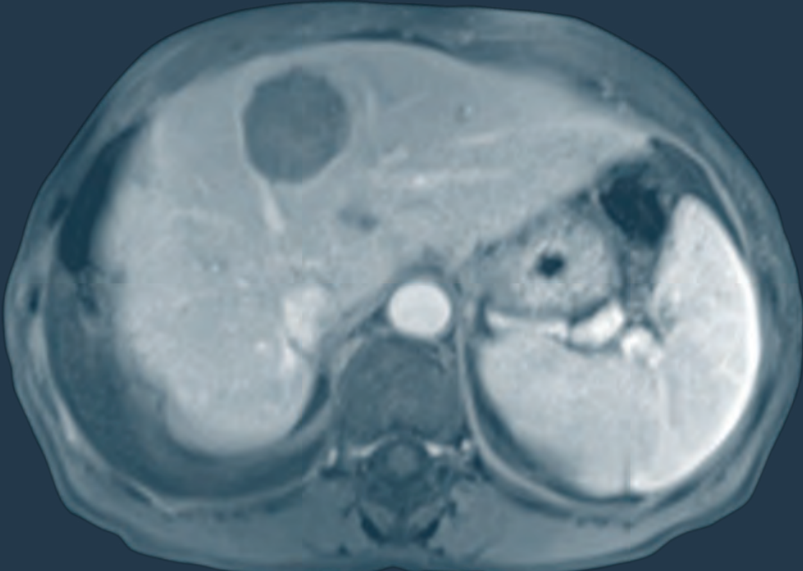
Electrical

- 120 V (US)/240 V (Europe)

Making the impossible, **possible.**



BEFORE



AFTER

*MRI series from a single patient in the THERESA Trial.
Vidal-Jove J, et al. Int J Hyperthermia. 2022;39(1):1115-1123.*

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. The Edison System is intended for the non-invasive mechanical destruction of liver tumors, including the partial or complete destruction of unresectable liver tumors via histotripsy. The FDA has not evaluated the Edison System for the treatment of any disease including, but not limited to, cancer or evaluated any specific cancer outcomes (such as local tumor progression, 5-year survival or overall survival). The System should only be used by persons who have completed training performed by HistoSonics, and its use guided by the clinical judgment of an appropriately trained physician. Refer to the device Instructions for Use for a complete list of warnings, precautions and a summary of clinical trial results, including reported adverse events.

1. Vlasisavljevich et al. Phys. Med. Biol. 2014;59(2): 253-70



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MKT2188 Rev. E