

LIVER PRESCREEN ULTRASOUND GUIDE

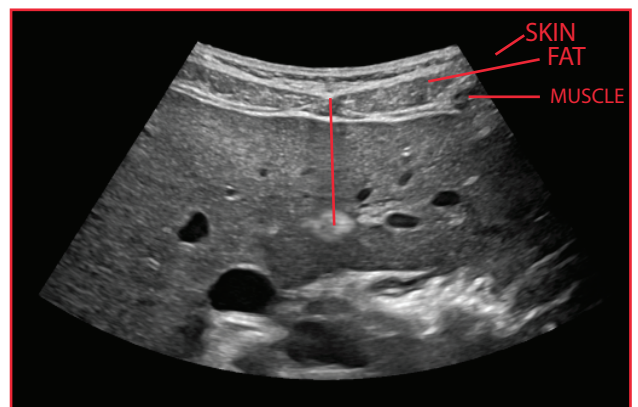
The prescreen ultrasound is essential for determining whether a target can be effectively treated with histotripsy. To mimic the target visualization process used during the histotripsy procedure, no pressure is applied with the probe — unlike in a diagnostic ultrasound, where pressure is applied.

IDENTIFY LESION

1. On ultrasound, locate, measure, and capture images of the lesion:
 - a. Longitudinal (with and without measurements).
 - b. Transverse (with and without measurements).
 - c. Cine clips (if possible) in longitudinal and transverse.

OPTIMIZE PATIENT POSITION

1. Visually assess the patient.
2. Adjust the patient's position so the freehand ultrasound probe is NOT angled more than 45 degrees.
3. Annotate the patient's position on the ultrasound image and capture an image. (Ex: supine, left lateral decubitus, left posterior oblique)
4. Measure the depth from the center of the lesion to the abdominal muscle/fat interface (minimum is 2.5 cm). Capture an image.
5. Measure the depth from the skin to the deepest point of the lesion. Capture an image.

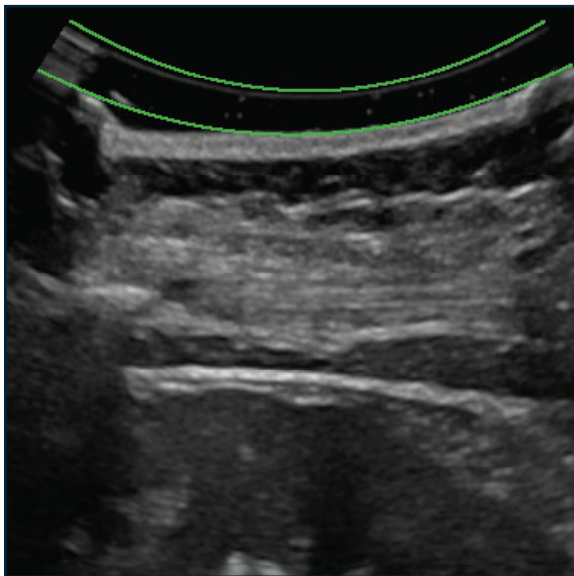


EVALUATE RESPIRATORY MOTION

1. During quiet respiration:
 - a. In the longitudinal axis, evaluate the position of the lesion throughout the respiratory cycle.
 - b. Evaluate the location of the lesion at end-expiration. This represents where the lesion would be positioned if the patient was under general anesthesia.
 - c. In the longitudinal axis, capture a cine clip.

PERFORM TREATMENT HEAD SIMULATION

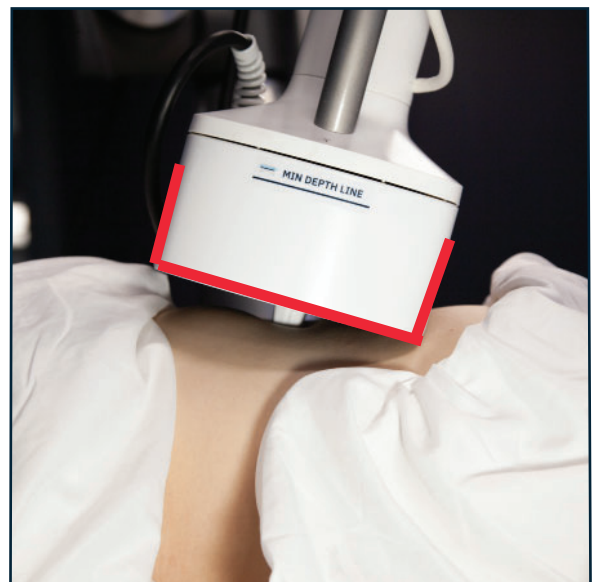
1. Simulate treatment head position using the freehand ultrasound probe during quiet respiration:
 - a. Use a gel standoff to minimize pressure and simulate the presence of the ultrasound medium. Imaging quality will be degraded.



b. Minimize probe angulation.



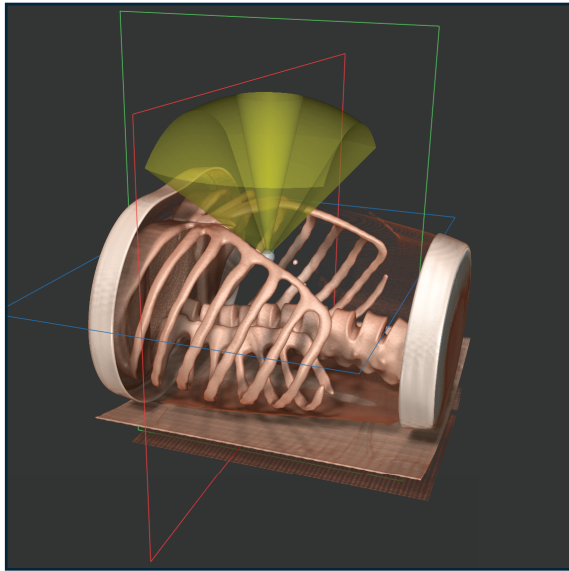
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2. Consider the surrounding anatomy and potential blockage (Ex: ribs, bowel) of the acoustic pathway.



EXAMPLE DICTATION / WORKSHEET

- Patient position: supine, left lateral decubitus, or left posterior oblique
- Lesion (location description)
- Size = (longitudinal x anterior posterior x transverse)
- Echogenicity: hyper echoic, hypoechoic, mixed echogenicity, etc.
- Is the lesion visible in the sagittal plane throughout a respiratory cycle (during quiet breathing)? Yes/No
- Is the lesion visible with ≤ 45 degree transducer angle (relative to perpendicular) with minimal transducer pressure? Yes/No
- Distance from the anterior margin of the abdominal wall musculature to center of lesion
- Distance from the skin line to the posterior margin of the lesion
- Is there bone, bowel, or lung in the acoustic pathway? Yes/No

EDISON® SYSTEM TREATMENT RANGE

Treatment Head	Recommended Treatment Range (Approximate)	Maximum Treatment Depth
REF EDNTH0212	2 cm*–12 cm	12 cm†
REF EDNTH0814	8 cm–14 cm	14 cm†

*Treatment at 2 cm is dependent on patient's body wall thickness.

†Only achievable when the treatment head can be fit to the patient's abdomen.

Important

Maximum treatment depth is the deepest possible treatment depth as measured from the skin to the furthest extent of the planned treatment volume.

LIVER PRESCREEN ULTRASOUND PROTOCOL

Patient Prep: NPO 6-8 hours

Annotations:

- Probe plane orientation (axial, sagittal, oblique)
- Probe position (subcostal, intercostal)
- Liver segment location
- Patient position (supine, left lateral decubitus)
- Probe angle degree (<45 degrees)

Images for each lesion: done with quiet respiratory motion

Axial:

- Grayscale with and without measurements
- Measurement from muscle/subcutaneous fat interface to center of lesion (≥ 2.5 cm)
- Measurement from skin line to posterior lesion border
- Lesion with image depth set at 15 cm for procedure simulated view
- Cine clip

Sagittal:

- Grayscale with and without measurements
- Lesion with image depth set at 15 cm for procedure simulated view
- Cine clip of lesion
- Cine clip of lesion with quiet respiratory motion