SONALLEVE

Sonalleve MR-HIFU

Osteoid Osteoma

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Humanitarian Device. Authorized by Federal law for use in the treatment of Osteoid Osteoma.

The effectiveness of this device for this use has not been demonstrated.

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1. Legal Manufacturer

Profound Medical Inc.

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Device Name: Sonalleve MR-HIFU

2. Product Description

The Sonalleve Magnetic Resonance Imaging -guided High Intensity Focused Ultrasound (MR-HIFU) system is designed to non-invasively deliver acoustic energy to prescribed locations. The system integrates a high intensity phased array focused ultrasound transducer with an MR imaging system and electromechanical transducer positioning system to deliver spatially and temporally controlled ultrasound energy to elevate tissue temperatures, and to ablate tissues non-invasively.

The Sonalleve MR-HIFU system is designed to be used with Philips Achieva and Ingenia 1.5T and 3.0T MR scanners and complies with the requirements of the applicable International Electrotechnical Commission (IEC) safety standards.

The Sonalleve MR-HIFU (also known as Sonalleve) system combines two technologies:

Focused ultrasound: ultrasound waves constructively interfere with each other, and acoustic energy is converted to thermal energy at the focus, producing a controlled rise in tissue temperature to approximately 60 - 75 °C, and resulting in non-reversible thermal ablation of targeted tissue, while minimizing potential thermal bioeffects outside the target region.

MRI: The treatment is guided and controlled by magnetic resonance imaging, allowing anatomical planning of the treatment with real time temperature and anatomical monitoring. The real-time monitoring serves as a treatment feedback for enhanced safety.

The Sonalleve MR-HIFU system consists of the following main components:

a. Sonalleve Patient Table assembly
b. Sonalleve Generator Cabinet
c. Sonalleve Therapy Planning Console with a Safety Device
d. Accessories

Two electrically shielded cables connect the Generator Cabinet to the Patient Tabletop through a dedicated HIFU filter panel on the wall between the equipment and magnet rooms.

a. Patient Table Assembly

The Sonalleve Patient Table is a mobile patient support used for MR-HIFU treatment in a Philips Achieva or Ingenia diagnostic MRI scanner. The tabletop is positioned above the standard MR system Patient Support. It can be easily removed to enable normal diagnostic use of the MR scanner.

b. Sonalleve Generator Cabinet

The Sonalleve MR-HIFU system includes a separate cabinet for power distribution and for the control electronics of the ultrasound transducer. The Sonalleve Generator Cabinet and its parts are located in the technical room and include an embedded computer that communicates with the Sonalleve Therapy Planning Console by receiving instructions, processing and executing the instructions, and translating the instructions into physical system operations.

c. Sonalleve Therapy Planning Console with a Safety Device

The Sonalleve Therapy Planning Console is a software used for treatment planning, monitoring, and control, as well as for post-treatment operations. It is located in the control room and includes the following items:

- Sonalleve Therapy Planning Console computer, monitor, keyboard, and mouse
- Safety Device that can be used manually by the operator to end energy delivery
- Sonalleve MR-HIFU software installed on the Therapy Planning Console running Microsoft Windows operating system

To plan the HIFU treatment, the workstation retrieves the planning images from the MR Console computer. The workstation's graphical user interface (GUI) is used to overlay icons and colors on the MR

images for treatment planning and evaluation. The Sonalleve Therapy Planning Console is where the physician sets the treatment parameters, such as power and cell size, and monitors the temperatures and thermal dose during sonication. The information on the treatment parameters and the target to be sonicated is communicated to the generator cabinet, which then implements the instructions. The Sonalleve Therapy Planning Console communicates with the MRI system and controls it during the HIFU planning and treatment.

The Sonalleve MR-HIFU Therapy Planning software performs the following principal functions:

- Provides a GUI for treatment planning and system operation;
- MR communication and remote operation of the MR;
- The Sonalleve MR-HIFU hardware system operation and control;
- MR image acquisition and viewing;
- Graphical planning tools;
- Calculations and graphical monitoring of temperature and thermal dose.

The GUI display assists the user through the treatment planning and execution process and provides temperature and thermal dose maps to graphically show tissue temperature elevation and cumulative thermal dose as colored overlays on top of the anatomical images.

d. Accessories

The following patient accessories are provided with the Sonalleve MR-HIFU system:

- Tabletop mattress set
- Vacuum cushion
- MR-compatible air pump
- Footrest
- HIFU Pelvis Coil, pad, and strap
- Various types of foam pads for patient comfort
- Disposable (single use) gel pads for the ultrasound window
- Gel pad holder, to prevent the gel pad from slipping horizontally
- Headphones
- Tabletop Plate

- Ultrasound Window Cover
- Tabletop Extension Plate
- Water degasser

Other accessories used in the Sonalleve MR-HIFU system quality assurance (QA) that are provided with the system are:

- Sonalleve QA phantom
- QA phantom plate
- SPT (System Performance Testing) phantom holder
- DISCfill tool

3. Indications for Use:

Sonalleve MR-HIFU is intended to be used for the treatment of osteoid osteoma in the extremities.

4. Contraindications

The Sonalleve MR-HIFU system should not be used if any of the following contraindications exist or are thought to exist:

- MR contraindications specified in the MR scanner's Instructions for Use, weight >140kg (308 lbs), and MR contrast agents
- The target is located <1 cm from a nerve plexus, bladder, skin, or bowel
- The target is located <1 cm from the growth plate
- The target is located in the skull
- The target is located in unstable bone, impending fracture, or has been stabilized with metallic implants
- Scars that cannot be protected or surgical clips, implants, or prosthesis in the planned path of the ultrasound beam
- The patient is unable to tolerate a stationary position for the duration of the procedure

5. Safety

5.1. General Safety

Carefully read the safety instructions provided in the Sonalleve MR-HIFU Instructions for Use. Failure to follow appropriate device safety measures may lead to injuries to the patient or personnel, or damage to the equipment. Make sure that all the device related electrical and mechanical assemblies of the Sonalleve MR-HIFU system and MR safety instructions are always followed. The system is routinely inspected according to the instructions provided in the manual.

5.2. Warnings and Cautions

Definitions:

WARNING: A WARNING alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

CAUTION: A CAUTION alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or may cause environmental pollution.

Following is the list of Warnings and Cautions from the SONALLEVE MR-HIFU OSTEOID OSTEOMA INSTRUCTIONS FOR USE and TECHNICAL DESCRIPTION documents:

WARNING	Osteoid Osteoma treatment has not been investigated in vertebrae. The proximity to critical structures and the required safety margins (>1 cm) suggests that treatment should not be applied in the spine.
WARNING	Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Profound Medical warranty being voided. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.
WARNING	Do not use the product for any application until you are sure that the user routine-checks have been satisfactorily completed, and that the periodic maintenance of the product is up to date. If any part of the product is known (or suspected) to be defective or wrongly adjusted, DO NOT USE the product until a repair has been made.

	Operation of the product with defective or wrongly adjusted components could expose the user or the patient to safety hazards. This could lead to fatal or other serious personal injury, or to clinical mistreatment.
WARNING	Do not use the product for any application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in the IFU. Operation of the product without a proper awareness of how to use it safely could lead to fatal or other serious personal injury. It could also lead to clinical mistreatment.
WARNING	Do not use the product for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this product safely and effectively DO NOT USE IT. Operation of this product without proper and adequate training could lead to fatal or other serious personal injury. It could also lead to clinical mistreatment.
WARNING	Do not operate the product with patients unless you have an adequate understanding of its capabilities and functions. Using this product without such an understanding may compromise its effectiveness and/or reduce the safety of the patient, you and others.
WARNING	Never attempt to remove, modify, or over-ride or frustrate any safety features on the product. Interfering with safety features could lead to fatal or other serious personal injury.
WARNING	Do not use the product for any purpose other than those for which it is intended. Do not use the product with any product other than that which Profound Medical recognizes as compatible. Operation of the product for unintended purposes, or with an incompatible product, could lead to fatal or other serious injury. It could also lead to clinical mistreatment.
WARNING	No part of the system may be serviced or maintained while in use with a patient. An attempt to service or maintain the system during treatment could lead to fatal or other serious injury. It could also lead to clinical mistreatment.
WARNING	There is a Configuration Editor included in the HIFU Service tools that is intended for qualified service personnel only, changing configurations may compromise patient safety and cause problems in the operation and performance of the Sonalleve MR-HIFU system. Never change the configurations without first consulting the Profound Medical Service organization.
WARNING	Never expose volunteers to acoustic energy. Even low power ultrasound exposures may cause tissue heating or other damage. To avoid unintended ultrasound exposures in training sessions with volunteers, either make sure that the Sonalleve MR-HIFU system is switched OFF, or that the ultrasound beam path is blocked with an absorption pad, or a large positioning pad and a towel. Do not sonicate the absorption pad or the large positioning pad on purpose.
CAUTION	In training and QA sessions, only sonicate a QA phantom or other absorbing material that is in good contact with the ultrasound window. Acoustic energy may be reflected from unsuitable targets and interfaces such as the liquid-air interface. The reflected energy may damage the transducer in seconds. Do not sonicate a positioning pad on purpose.

WARNING	Because the patient may have to lie immobile for several hours during the treatment, identify the patients with a high risk or a history of deep vein thrombosis or a similar condition potentially affected by the long immobilization and evaluate the risks and benefits before the treatment.
WARNING	Make sure that sufficient cooling is provided during the treatment and monitor patients with insufficient cardiac functions. Failure to do so may result in excessive heating and hyperthermia.
WARNING	When the ultrasound transducer is sonicating (emitting acoustic energy), there is a blue sonication indicator light in the liquid container. Never put body parts into the ultrasound field as internal tissue heating and damage may occur in seconds.
WARNING	Always leave sufficient cooling intervals between sonications. Failure to do so may cause heat buildup in the near field or far field, leading to skin burn or other unwanted tissue damage.
WARNING	The whole body SAR limits are only valid for room temperatures not greater than 24 °C (75.2 °F) and relative humidity not greater than 60%.
WARNING	The HIFU treatment may affect the chemical and physiological properties of certain chemicals used in drugs. Make sure that the patient has been screened for such chemicals and drugs.
WARNING	Never administer Gadolinium-based contrast agents to the patient before treatment. Certain Gadolinium-based compounds (such as contrast agents) may decompose when sonicated, producing dangerous or poisonous compounds. The exact time period that must be left between a contrast agent scan and the HIFU treatment cannot be defined as it depends on the specific drug and the metabolism of the patient.
WARNING	Use the Safety Device Stop button or PESB immediately in a hazardous situation. Use the software abort button to stop the sonication in situations that do not present any hazard (if, for example, the treatment is deemed sufficient before the planned treatment time is reached).
WARNING	Do not use the standard MR Nurse Call button with the Sonalleve MR-HIFU system. Use the Patient Emergency Stop Button (PESB) instead.
WARNING	Do not remove covers or cables from this product unless expressly instructed to do so in this Instructions for Use. Dangerous electrical voltages are present within this product. Removing covers or cables could lead to serious or fatal personal injury.
WARNING	Avoid touching the patient or objects connected to the patient during the procedure. Touching increases the risk of exposure to potentially hazardous leakage currents.
WARNING	To avoid risk of electric shock, this equipment must only be connected to a mains supply with a protective earth.
WARNING	Daily inspect the Sonalleve MR-HIFU system and the magnet for leaks. The Sonalleve tabletop houses a liquid container. Do not connect the Sonalleve system cables if you find a leak. If a leak occurs during treatment: • Terminate the sonication immediately using the Stop button of the Safety Device. • Remove the patient from the tabletop. • Identify the reason for the leak. • To prevent further damage, remove the leaking part from the RF room.

	• Do not continue scanning or treatment until a qualified service engineer or equivalent has examined the scanner and the Sonalleve MR-HIFU system. A failure to follow these instructions may expose the patient or an operator to a risk of an electric shock.
WARNING	Usage of a damaged QA Phantom is not allowed. The Sonalleve QA Phantom, model 4510 000 82232, contains residues of acrylamide (CAS nr.: 79-06-1) in a hermetically sealed container. If the container is damaged or the contents come out of the container, dispose of the phantom and the liquids that have been in contact with the exposed contents. Use nitrile rubber gloves when disposing of the material and the liquids. Follow the disposal instructions. Failure to follow this instruction may expose the operator, other personnel and patients to poisonous chemicals and result in damage to the environment.
WARNING	• Do not use this product in the presence of explosive gases or vapors, such as certain anesthetic gases. • Do not use flammable or potentially explosive disinfecting sprays. • Use of this product in an environment for which it was not designed can lead to fire or explosion.
WARNING	On electrical or chemical fires, only use extinguishers that are specifically labeled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.
WARNING	HP Z4G4 workstations use lithium batteries. Replacement by inadequately trained personnel could result in a HAZARD, such as excessive temperatures, fire, explosion or chemical burn.
WARNING	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
WARNING	The sonication ON audible indicator and green Enable light of the Safety Device may in some cases be sensitive to Electrostatic Discharge (ESD) pulses. Safety or Essential Performance of the system is not affected by this ESD sensitivity
CAUTION	To protect your Sonalleve MR-HIFU system against viruses, malware and unauthorized access: • Never use the Sonalleve Console for browsing intranets or the Internet. • Never download or install any unauthorized software, including Windows security updates and virus scanner updates. • Use only blank DVDs for data archiving and transfer. • Never use any unauthorized removable media, such as USB flash drives or external USB hard drives. • Never alter any Windows settings. • Always keep your Sonalleve Console password (Windows user account password) confidential. • Never disable password protection • Log off from the Sonalleve Console (from the Windows user account) each time the system is not used for treatment.
CAUTION	To protect the confidentiality of patient data:

	Never enter any personal data (of patients, operators, physicians, etc.) in data fields that are not specifically intended for such data. Personal data entered in other, unexpected places, such as comment fields, scan names, file or folder names, etc., can become disclosed even when you take protective measures (such as using the Export Deidentified tool).
WARNING	Never blank the screen or lock the device during therapy.
WARNING	The local user is responsible for ensuring the safe and secure use of the system and for the safety of the patient. A Remote Desktop session shall only be performed with the appropriate safety, security and privacy measures taken according to hospital policies. During a Remote Desktop session, the local user must stay at the system console and monitor the activities performed by the remote user
WARNING	Always leave sufficient cooling intervals between sonications. Failure to do so may cause heat buildup in the near field or far field, leading to skin burn or other unwanted tissue damage.
WARNING	Always rely on the original dose map when making decisions about the treatment completeness. The cumulative dose map may differ from the original dose map.
CAUTION	The patient support must remain at the lowest position. Do not raise the support height after the Sonalleve tabletop is placed in position.
CAUTION	Take extra care not to damage the Patient Interface Control Unit (PICU) when maneuvering the trolley into position.
WARNING	When docking the tabletop to the MR system patient support, always press the brake pedal to lock all the wheels. This is to avoid accidental movement of the tabletop which may lead to misplaced heating and tissue damage.
WARNING	Check whether the patient has received medications, contrast agents, or has any contraindications for MR. Check if the patient is receiving medications for any underlying medical condition.
WARNING	Only liquid is allowed in the catheter. Never fill the catheter with air as it may deflect the ultrasound beam.
WARNING	Falling from the height of the Sonalleve tabletop may be dangerous. Support the patient and/or use straps, and be prepared to prevent him/her from falling. Make sure that the patient's limbs are within the edges of the tabletop so that they are not pinched. Instruct the patient to lie still when being transported on the Sonalleve MR-HIFU tabletop. Pay particular attention to thresholds.
WARNING	Never leave an unconnected coil in contact with the patient.
WARNING	Never leave the coil cable in contact with the skin, as localized RF heating may cause skin burns. Use pads between the skin and the coil cable.
WARNING	Make sure that no pulling force is exerted on the catheters or IV tubes when you are pushing the patient into the magnet. Failure to follow this instruction may cause the patient pain and tissue damage.
WARNING	The system displays the message "Push Tabletop into Place and Check Patient Positioning" if the tabletop is not locked in position. Carefully verify that the tabletop is properly locked in its intended position. Failure to detect unintended tabletop movement may eventually lead to misplaced heating and tissue damage.
WARNING	Pay attention to patient orientation selections in MR and Sonalleve consoles. Failure to do so may result in heating of wrong location and painful experience or injury.

WARNING	If you are using REST slabs, position them outside the intended heating volume so that they do not saturate the signal from structures (near or far field) intended for temperature monitoring.
WARNING	Always use the pre-determined and tested temperature measurement ExamCards and protocols for temperature mapping. The use of other protocols may lead to unexpected image quality or inefficient temperature detection, which may then lead to overheating of tissue, insufficient treatment, unintended heating locations and tissue damage.
WARNING	Use the predetermined and tested coil combinations for temperature mapping. The use of other coils may lead to unexpected image quality, excessive SAR or inefficient temperature detection, which may lead to e.g. overheating of tissue, insufficient treatment, misplaced heating and tissue damage.
WARNING	Always enable the remote control mode of the MR console as early as possible to allow a minimum of 5 minutes of water circulation in DISC system before the first therapy sonication. Failure to do so may increase risk of bubble formation in the ultrasound contact. See air bubble related warnings and instructions.
WARNING	Incorrect body temperature may affect the success of the treatment. Always use the actual body temperature as a reference value.
WARNING	Always set the gel pad thickness in Sonalleve user interface to match the actual gel pad thickness that is used in the treatment. Failure to do so may increase risk of burns in skin and other near-field tissues.
WARNING	Positioning: • Always leave sufficient safety margins (>1 cm from treatment cell border) to sensitive organs or other sensitive structures when drawing Planning Target Volumes or cells. • Avoid placing treatment cells any closer to the spine or other sensitive structures than indicated by the far-field safety margin. If this is not possible due to anatomic constraints, monitor the sonication carefully and be prepared to stop it if needed. • Avoid placing treatment cells any closer to any tissue to be spared than indicated by the cell safety margin. If this is not possible due to anatomic constraints, monitor the sonication carefully and be prepared to stop it if needed. • Pay special attention to objects directly in the transducer beam area, not forgetting the far field. o Air-filled structures and bones might cause unexpected reflections. o Bowel should never be in the near the field beam path. Heating the bowel may lead to bowel perforation. o Heating in the far field might lead to sciatic nerve damage / peritonitis. o Some structures absorb the ultrasound waves completely, leading to more efficient heating. Bone, bowel, clips, scars or any other rigid structure or air interface are such structures. • Sonication through scar tissue, skin folds or navel should be avoided to prevent damage. The beam shaping feature may be used to protect these. QuickCover Ultrasound Protective Covers may be used to protect scars.

	• The planning graphics show the main part of the 3D focused transducer beam, but keep in mind that boundaries such as air-filled structures and bones may cause unexpected reflections.
WARNING	The displayed transducer beam does not take sonication power or duration into account. At the highest sonication energies (large cells and high powers), you should leave at least a few millimeters margin between the displayed transducer beam and any vital organs, with or without beam shaping.
WARNING	In the Osteoid Osteoma application, position the treatment cells so that the transducer beam is perpendicular to the bone surface. Otherwise unintended heating of adjacent tissues due to ultrasound reflections may occur. Carefully observe such situations in the temperature map during sonications.
WARNING	• QuickCover only provides protection for the superficial tissue layer immediately behind the cover strip. • Using protective cover strips side-by-side may lead to distorted heating due to the large area of blocked ultrasound beam. • Using protective cover strips side-by-side may lead to transducer damage due to the large intensity of reflected ultrasound. • Air bubbles trapped on the skin at an edge of a protective cover strip may lead to a local skin burn. This risk is especially pronounced if protective cover strips are used so that they overlap with each other. • Storing QuickCover strips under a weight may lead to compression and a permanent loss of protective capabilities.
WARNING	If the system detects a transducer movement failure, it stops the treatment and issues an error message. You must rerun the Hardware Initialization.
WARNING	If the couch has been unlocked for any reason, always perform a test sonication once the tabletop has been pushed back to the treatment position.
WARNING	Start therapy with low energies and observe carefully temperature changes during the first sonications. Failure to do so may cause heat spreading outside of the intended region causing unintended tissue damage and pain.
WARNING	Use the high powers in Osteoid Osteoma application only if the lower powers do not produce high enough temperature elevation and when there are no major safety concerns (e.g., excessive near field heating).
WARNING	Visually monitor the temperature maps in the monitor slices during the sonication. If you see a sudden change in temperature, stop the sonication immediately using the Stop button on the Safety Device or the software abort button. Do not continue treatment until you have discovered a cause for the change. A sudden change in temperature can be caused by: • Excessive heating due to failure in the US device or US coupling. • An artefact caused by patient movement. • An external or internal magnetic field change.
WARNING	Patient movement during the treatment may result in misplaced heating and tissue damage. Continuously monitor visible anatomical landmarks to rule out movement.
WARNING	Stop the sonication if you do not observe any heating in the heating curve and temperature maps. This could indicate presence of coarse positioning errors or a problem with updating of the images or significant reflections at the tissue

	interfaces. Check the timestamps of the displayed images. Make sure that the ultrasound coupling is acceptable starting with low power test sonications. Failure to follow this instruction may lead to unintended heating of tissue, tissue damage or painful experience.
WARNING	Unintended heating of healthy bone marrow cannot be observed due to its high fat content. Use sufficient safety margins when planning sonications of those areas that need to be protected from excessive heating. Failure to do so may cause tissue damage in unintended regions.
WARNING	When treating osteoid osteoma, heating may take place in an unintended location if the bone is damaged to the extent that it does not completely absorb the ultrasound beam.
WARNING	Multiple treatments of the same volume may increase the risk of heat buildup, potentially resulting in unpredictable tissue damage outside the planned cell. It is not recommended to sonicate the same volume of tissue more than once.
WARNING	Comparing OARs with images acquired before the registration may leave the OARs misplaced. If OARs are not positioned correctly, there is a risk of skin burn.
WARNING	If the Saved State cannot be loaded, wait until the tissue has cooled before continuing the treatment. Without the Saved State data, the system cannot estimate the effect of earlier accumulated heating when recommending cooling times to prevent burns.
CAUTION	Always remove the QA phantom at the end of QA or testing period. Do not leave the QA phantom on the tabletop overnight. Water between the phantom and the membrane will evaporate over time. A phantom placed on the tabletop may lead personnel to believe that it is ready for use. If there is not enough water, a sonication may cause a reflection of acoustic energy that may damage the transducer.
WARNING	Do not treat patients unless the reason for a QA Test failure is clear and it is certain that there is no increased risk to the patient.
WARNING	Clean, dry and disinfect the parts that come into contact with the patient after each Treatment. Discard any single-use accessories such as gel pads. Failure to follow this instruction may increase the risk of infection or serious illness for the patient, operator or the service personnel.
CAUTION	Only use the cleaning with agents listed in the IFU. Other cleaning agents may damage the system.
WARNING	Do not use flammable or potentially explosive disinfecting sprays. Such sprays create vapors, which can ignite, causing fatal or other serious personal injury.
CAUTION	Disinfecting a medical product room by means of sprays is not recommended, since the vapor could penetrate the product, causing electrical short-circuits, metal corrosion or other damage to the product.
WARNING	Do not dispose of any parts of this product with industrial or domestic waste. The product contains hazardous materials which require special disposal. Incorrect disposal of any of these materials may lead to serious environmental pollution.
WARNING	The Sonalleve Patient Table must be powered from the power distribution unit (PDU) in the Sonalleve generator cabinet only. Failure to follow this instruction may expose the patient to the risk of harmful electrical leakage currents.

WARNING	Never connect additional accessories to the Sonalleve MR-HIFU system. Any additional accessories must be approved by Profound Medical. Failure to follow this instruction may expose the patient or operator to the risk of harmful electrical leakage currents.
WARNING	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
WARNING	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sonalleve MR-HIFU system, including cables specified by Profound Medical. Otherwise, degradation of the performance of this equipment can result.
WARNING	Failure to use this Patient Table in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services.
WARNING	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
WARNING	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sonalleve MR-HIFU system, including cables specified by Profound Medical. Otherwise, degradation of the performance of this equipment can result.
WARNING	Failure to use this Patient Table in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services.
CAUTION	Federal law restricts this device to sale by or on the order of a physician.
CAUTION	Stacking or installation of system components close to other equipment may affect the performance of this system or other systems. This may increase the risk of malfunction of this system or other nearby medical equipment.
CAUTION	Using any other cabling apart from that provided with the Sonalleve MR-HIFU system may deteriorate the system's EMC performance. This may increase the risk for malfunction of this system or other nearby medical equipment.
CAUTION	The Configuration Editor included in the MR-HIFU Service tools does not restrict access to the network configurations. Note that the Configuration Editor is intended for qualified service personnel only, as changing configurations may cause problems in the system operation and performance. Never change the configurations without consulting the Profound Medical service organization.

6. What is Osteoid Osteoma?

Osteoid osteoma is a relatively rare, small, benign but painful bone tumor that typically occurs in the cortex of long bones of children and young adults. Typical appearance is a small nidus less than 1.5 cm in diameter of woven bone and osteoid rimmed with osteoblasts, surrounded by reactive zone of thickened cortical or trabecular bone and loose fibrovascular tissue, and edema. The osteoid osteoma nidus is a highly vascularized central region that produces excess prostaglandins, causing local vasodilation, inflammation, and often severe pain. Adjacent periosteal nerve fibers further amplify the pain, which characteristically worsens at night, commonly disrupting sleep. In addition to pain, other symptoms of osteoid osteoma include bony deformity, growth disturbance, and painful scoliosis. While surgery and computed tomography (CT) -guided radiofrequency ablation (RFA) have high clinical success rates in osteoid osteoma therapy, they are invasive procedures. For example, RFA requires drilling from the skin through soft tissue and bone in order to insert and burn the osteoid osteoma nidus using an RFA needle. Image guidance with CT also exposes the patient and the physician to ionizing radiation.

7. Conventional Treatment of Osteoid Osteoma

Pain associated with osteoid osteoma is initially treated by nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen. Treatment with NSAIDs temporarily relieves pain in the short term but carries long-term toxicities. Definitive treatment options for osteoid osteomas refractory to medical management include surgical resection or image-guided radiofrequency ablation. Surgical resection has success rates greater than 90% but has become less common today due to difficulty in intraoperative visualization of the lesion, which leads to significant bone resection and collateral damage to surrounding tissue, in some cases requiring fixation or bone grafting. Morbidity is related to weakening of the remaining bone and prolonged recovery times with weight-bearing and mobility restrictions. Radiofrequency ablation is a less invasive option than surgical resection. During RFA, a needle is guided and advanced into the osteoid osteoma nidus under direct visualization with CT imaging. The needle tip is heated to 90°C for 5 minutes to ablate the nidus, while conductive heating spreads thermal energy to the rest of the lesion. This limits the size of the lesion that can be treated with RFA, and in some cases multiple needle insertions are required. Other limitations include the risk for bleeding and infection at the skin entry site, and challenges in inserting the RF electrode including broken drill tips. Thermal ablation of the nidus and adjacent periosteal nerves eliminates pain within a few days, and there is ample evidence that successful thermal ablation provides definitive treatment. Although RFA can have a

high success rate, the treatment is invasive and can potentially cause complications such as skin burn, nerve damage, infection, and fracture. It also exposes patients and operators to ionizing radiation associated with the CT imaging guidance.

8. Sonalleve MR-HIFU Principles of Operation

High Intensity Focused Ultrasound (HIFU) treatment is a non-invasive therapeutic technique that uses non-ionizing ultrasonic waves to heat tissue deep within the human body. The system uses an external ultrasound transducer to generate a focal beam to heat a target deep within the human body. This is called a sonication. The sonication causes a temperature rise that coagulates the target tissue. MR-guided HIFU (MR-HIFU) treatment is an image guided technique combining High Intensity Focused Ultrasound with real time monitoring of temperature change during the sonication.

The thermal MR images are used to calculate relative temperature maps that are monitored on the Sonalleve Therapy Console. The temperature maps are used to visualize the progress of the treatment and to control the duration of the sonication. The essential performance of the Sonalleve MR-HIFU system is to deliver spatially and temporally controlled therapeutic ultrasound power into accessible and targeted tissues.

MR-HIFU therapy is an alternative to surgery and CT-guided RFA for the treatment of osteoid osteomas when invasiveness of the procedure or exposure to ionizing radiation is unwanted or unwarranted.

8.1. Who can receive Osteoid Osteoma Treatment?

The treatment is available to pediatric and adult population diagnosed osteoid osteoma also referred as benign bone tumour. Many factors in the patient's anatomy affect the patient's suitability for Sonalleve MR-HIFU osteoid osteoma treatment. The anatomies that can be treated are restricted by the MR scanner bore size, patient size, and the depth of the ultrasound focus. The clinician can review eligibility for this procedure and use imaging techniques prior to the treatment to assess the current situation. Carefully review the lesion position in relation to sensitive anatomical structures. Patients who are in too much pain to lie still for the duration of the procedure cannot be treated without sedation or anesthesia. The patient should be fit for anesthesia.

8.2. Adverse Events

Although the MR-HIFU treatment of osteoid osteoma is generally safe, potential adverse effects may occur during or following the MR-HIFU treatment. Non-serious adverse events (i.e., minor complications) reported for Sonalleve MR-HIFU osteoid osteoma therapy in scientific literature and clinical evidence data were few in number and transitory in nature, and included mild/moderate muscle pain, leg pain, fatigue, and foot pain. The full list of potential adverse effects of MR-HIFU treatment is provided in the Sonalleve MR-HIFU Instructions for Use.

8.3. Before the Treatment Day

8.3.1. Depilation

The patient is asked to shave or chemically depilate hair in and around the treatment area one to three days prior to the treatment. Depilation is necessary because tiny air bubbles may be trapped in the follicles, causing a risk of skin heating. Early depilation is recommended to minimize skin irritation on the treatment day. No creams are allowed on the skin after the depilation. Any remaining hair or any foreign substances such as oily creams on the skin may increase the risk of skin heating during treatment.

8.3.2. Fasting

Fasting is only necessary when treatment location is in the hip area, where bowel movements might cause motion artifacts on MRI. Medication or anesthesia may require fasting in some cases. Follow clinician’s instructions.

8.4. Treatment Day

Patient preparation generally includes catheterization, infusion bag and IV tubes, and mild pain medication. Patient is positioned on the MR-HIFU table. The area of interest is placed over the center of the ultrasound treatment window. The patient can be in the prone, supine or oblique orientation depending on the treatment area of interest. Accessories such as air bags, vacuum cushions, straps, and other similar MR-compatible supporting material is used to make the patient's position more stable and make the patient feel more comfortable. Treatment planning images are

acquired, treatment plan is confirmed and the osteoid osteoma lesion is sonicated. The treated area is confirmed using post-contrast scans. Patient is released after post-procedure recovery.

8.5. Clinical Experience with Sonalleve MR-HIFU osteoid osteoma

The Sonalleve MR-HIFU system was reviewed under IDE submission G130041 and associated supplements. The device was studied for the ablation of osteoid osteomas in children and young adults with 9 patients recruited and treated.

The results show that MR-HIFU ablation of painful osteoid osteoma can provide a complete clinical response and lasting pain resolution. No serious treatment-related adverse events were observed in any of the 9 patients who underwent MR-HIFU. All treatments were performed on an outpatient basis without overnight admission. The minor focal bruising due to inadequate padding at edges of the HIFU treatment window can be addressed by ensuring that adequate padding and careful positioning are applied.

MR-HIFU ablation was feasible in all 9 patients who consented to this treatment. The single patient with partial clinical response following MRHIFU ablation had an osteoid osteoma located in the medullary cavity of the femur, rather than the cortex. Post treatment MRI in this patient showed that periosteal nerves were ablated but the nidus remained viable. This explains partial improvement but not complete resolution of symptoms in this patient at the 1- month follow-up. This patient later underwent RFA. On the other hand, one patient who had previously undergone unsuccessful surgical resection and RFA demonstrated a complete clinical response after MR-HIFU treatment.

8.6. Probable Benefit Conclusion

The clinical results supports the probable benefit of Sonalleve MR-HIFU for the ablation of painful osteoid osteoma. All treatments were performed on an outpatient basis without overnight admission. The treatment is feasible and can provide a complete clinical response and lasting pain resolution. Nine subjects (7 male, 2 female; 16 ± 6 years) were treated with MR-HIFU without technical difficulties or any serious adverse events. There was a significant decrease in their median pain scores 4 weeks within treatment (6 vs 0, P< .01). Total cessation of analgesics was achieved in 8 of 9 patients after 4 weeks.

There is statistical evidence supporting the effect of the treatment. This can be observed in each of the pain Visual Analogue Scale (VAS), Symptom Distress Scale (SDS), Patient-Reported Outcomes Measurement Information System (PROMIS) score and Pediatric Quality of Life Inventory (PedsQL) scales. The majority of HIFU-treated patients exhibited complete response, i.e., complete symptom resolution. Clinical response is comparable with standard of care treatment with low reintervention. This study shows that MR-HIFU treatment of osteoid osteoma refractory to medical therapy is feasible and can provide probable benefit to patients.

8.7. Safety Conclusion

No serious treatment-related adverse events were observed in any of the 9 patients who underwent Sonalleve MR-HIFU system treatment. The reported device-related adverse events are acceptable and not unexpected. Non-serious adverse events (i.e., minor complications) reported for Sonalleve MR-HIFU Osteoid Osteoma therapy in scientific literature were few in number and transitory in nature, and included mild swelling, mild stiffness, skin redness, and minor bruising related to inadequate tabletop padding. The mild and moderate adverse events such as fatigue and muscle pain are transient.

While a low risk for potential heat-related nerve or skin damage exists with HIFU, this risk can be mitigated through the use of MRI thermometry that provides real time temperature maps of both the target region as well as nearby vulnerable structures such as neurovascular bundles. This is corroborated by a meta-analysis review of available literature reporting no serious adverse events, and only very few non-serious adverse events, for 117 MR-HIFU treated OO patients in the scientific literature.

The minor focal bruising due to inadequate padding at edges of the HIFU treatment window can be addressed by ensuring that adequate padding and careful positioning are applied. In addition, the Sonalleve MR-HIFU system includes a Direct Skin Cooling Device (DISC) to maintain low skin temperatures during HIFU therapy, further mitigating the risk for skin burns.

8.8. Probable Benefit-Risk Conclusion

The treatment of Osteoid Osteoma using Sonalleve reported no serious adverse events during the study. The mild and moderate adverse events are transient and resolved uneventfully. The probable benefit outweighs the probable risk of injury from Sonalleve use in osteoid osteoma

therapy, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. An important difference compared to CT guided radiofrequency ablation (RFA) is that MR-HIFU is non-invasive and free from ionizing radiation whereas RFA ablation is an invasive procedure with exposure to ionizing radiation, which can have potential long-term negative effects, especially for growing children.The clinical data support reasonable assurance of the safety and probable benefit of the Sonalleve MR-HIFU system in a pediatric and young adult population with osteoid osteoma.

8.9. Overall Conclusion

The extent of uncertainty is moderate due to:

- A small number of treated subjects with treatments limited to the extremities;
- Absence of a prespecified study protocol including prespecified study endpoints, enrollment criteria, protocolized treatments, and follow-up requirements;
- The potential for selection bias because survey completion by operators was voluntary;
- A single arm dataset without a concurrent or a historical control group or a prespecified performance goal;
- Absence of blinded adjudication of events using prespecified event definitions; and
- Limited follow-up information on treated patients.

The data in this application support the reasonable assurance of safety and probable benefit of this device when used in accordance with the indications for use. The Sonalleve MR-HIFU system can effectively ablate osteoid osteomas, the probability of harm is low (per the limited clinical data), and the totality of the clinical information provides a reasonable assurance of safety and probable benefit.

Therefore, it is reasonable to conclude that the probable benefit to health from using the device for the target population outweighs the risk taking into account the probable risks and benefits of currently available devices or alternative forms of treatment when used as indicated in accordance with the directions for use.

SONALLEVE™

Sonalleve MR-HIFU

Osteoid Osteoma Application

English / Release 3.6 / USA

PROFOUND

SONALLEVE MR-HIFU

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1. Osteoid osteoma treatment

Osteoid osteoma is a relatively rare, benign but painful bone tumor that typically occurs in the cortex of long bones of children and young adults. The osteoid osteoma nidus is a highly vascularized central region that produces excess prostaglandins, causing local vasodilation, inflammation, and pain. Adjacent periosteal nerve fibers amplify the pain, which characteristically worsens at night, commonly disrupting sleep. In addition to pain, other symptoms of osteoid osteoma include bony deformity, growth disturbance, and painful scoliosis.

Pain associated with osteoid osteoma is initially treated by nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or opioids. Treatment with pain reduction medications temporarily relieves pain in the short term but carries long-term toxicities. Definitive treatment options for osteoid osteomas refractory to medical management are surgical resection or image-guided radiofrequency ablation (RFA).

Sonalleve MR-HIFU treatment involves applying acoustic energy on the bone surface and the osteoid osteoma nidus in a non-invasive manner under MR-imaging guidance. The application of acoustic energy produces localized temperature rise within the osteoid osteoma lesion, leading to thermal ablation of the nidus and adjacent periosteal nerves. Pain is usually eliminated within a few days.

The procedure typically takes 2 hours, during which the patient is lying on the Sonalleve Table Top in the MR scanner. The procedure is potentially very painful, and careful pain management is required to achieve a successful outcome.

2. Safety

Carefully read the safety instructions and always observe them when working with the Sonalleve equipment. Failure to follow the appropriate safety measures can lead to injuries of the patient or personnel, or damage the equipment.

For full safety instructions, refer to the *Sonalleve MR-HIFU Instructions for Use*.

2.1. Indications for use

The Sonalleve MR-HIFU is indicated for treatment of osteoid osteoma in the extremities.

2.2. Contraindications

There are contraindications and restrictions for the use of this Profound product listed in the *Sonalleve MR-HIFU Instructions for Use* and in the MR scanner *Instructions for Use*.

- MR contraindications specified in the MR scanner's Instructions for Use, weight >140 kg (308lbs), and MR contrast agents
- The target is located <1 cm from the nerve plexus, bladder, skin, or bowel
- The target is located <1 cm from the growth plate
- The target is located in the skull
- The target is located in unstable bone, impending fracture, or has been stabilized with metallic implants
- Scars that cannot be protected or surgical clips, implants, or prosthesis in the planned path of the ultrasound beam
- The patient is unable to tolerate a stationary position for the duration of the procedure

Typically, the use of MR-HIFU treatment with osteoid osteoma might require anesthesia. This would require additional assessment and would also have additional contraindications.

2.3. Adverse effects

Although the MR-HIFU treatment of osteoid osteoma is generally safe, potential adverse effects have been reported in literature. Most of these effects are transitory and can be avoided with careful treatment planning.

For the list of adverse effects, see chapter "Indication for use" in Sonalleve MR-HIFU Instructions for Use.

3. Patient selection

Many factors in the patient's anatomy affect the patient's suitability for Sonalleve MR-HIFU therapy. The anatomies that can be treated are restricted by the scanner bore size, patient size, table top design, and the depth of the ultrasound focus. The treatments are not allowed for the targets located in the skull and vertebrae.

Use imaging techniques prior to the therapy to estimate the current situation. Carefully review the lesion position in relation to sensitive anatomical structures. Patients who are in too much pain to lie still for the duration of the procedure cannot be treated without sedation or anesthesia. The patient should be fit for anesthesia.

3.1. Scars

Patients who have extensive scarring that cannot be moved away from the ultrasound beam path cannot be treated. Scar tissue has higher ultrasound absorption so it heats more easily. It also has a reduced blood supply, which leads to reduced heat transfer, potentially increasing the accumulated heating over the treatment. Because scar tissue also lacks sensitivity for heating, the patient might not be able to feel heating or pain in the scar, which increases the risk of skin burns.

Scars are usually well visible with MR imaging. Older, well-healed scars may be easy to notice by visually inspecting the skin, but difficult or impossible to identify from MR images. Typically, scars are easier to identify in the epidermis, dermis, and subcutaneous fat layer, but more difficult in the muscle.

A dedicated MR imaging protocol can be found in the Therapy ExamCard to assist in the visualization of scars. The Scar scan is optimized for the contrast between the scar tissue and the skin tissue. However, some well-healed scars may be visible on the skin surface, but are not easily identified from MR images. The scar might look like a small skin fold or a vessel.

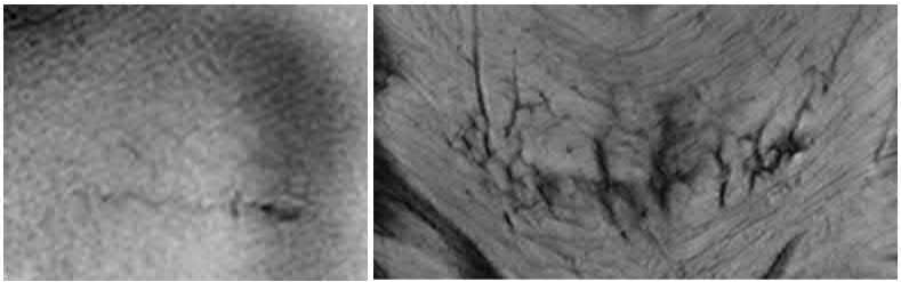

Fig. 1: Examples of scars. Left: Small scar. Right: Extensive scarring.

To improve scar visualization, MR markers or MR visible paint can be used. MR markers can assist in the initial localization of the scar with MR imaging but they should not be used during the therapy, as capsules in the ultrasound beam path may cause unpredictable ultrasound reflections and/or absorption. Also, you should be careful when choosing an MR visible paint, as some materials may cause image distortions and/or local heating due to RF absorption. It is recommended to use MR visible paint only in those cases where it is necessary to avoid sonicating through a scar.

When sonicating near or through a scar, carefully monitor the patient and the temperature maps in the near field.

3.1.1. Sonicating through scars

Consider the possibilities of sonicating through a scar carefully. The scar should be old, thin, and well healed. Long cooling times are mandatory.

In cases where the sonication passes through a scar, you should carefully follow the temperature images to detect any unwanted heating in the scar region. The far-field monitor stack may be positioned in the near field, so that heating can be simultaneously followed on the skin and in the muscle.

3.1.2. Avoiding and protecting scars

Protective patches

If there is a scar in the planned ultrasound beam path, a protective cover strip such as a QuickCover Ultrasound Protective Cover can be used to give additional protection in combination with beam shaping. Suitable protective cover strips are made of a material that is water-resistant, visible in MR images, suitable to be applied to scars of different shapes, and easily attachable to the skin to ensure that the strip does not move during therapy.

When using a narrow (< 8 mm wide) protective cover strip, there are no significant distortions in the focus shape and location unless multiple cover strips are used.

Potential risks of using protective cover strips include skin burns due to locally absorbed ultrasound energy, reduced quality of the focus due to blocked ultrasound energy, and damage to the transducer surface due to heating from reflected ultrasound energy.

Beam shaping

Beam shaping can be used for selectively reducing the ultrasound intensity on a scar area. See *7.4.2. Using beam shaping to protect scars*.

Other methods for avoiding scars

- Stretching the skin during patient positioning may be enough to move the scar tissue away from the ultrasound beam path.
- Tilting the transducer sometimes helps in avoiding scars.

3.2. Transducer movement

The transducer moves and tilts in all directions. Make full use of these range of movements to see if you can sonicate past sensitive structures. To achieve a sufficient temperature rise and to prevent the ultrasound energy from reflecting into unwanted locations, the ultrasound beam path must be perpendicular to the bone surface.

4. Preparing the Table Top

Prerequisites

These instructions assume that the Table Top is already connected according to the *Sonalleve MR-HIFU Instructions for Use*.

NOTICE
Before preparing the table top for the patient, check that the Quality Assurance (QA) routine has been carried out. For more information on QA, see chapter "Sonalleve MR-HIFU Quality Assurance (QA) procedure" in *Sonalleve MR-HIFU Instructions for Use*.

Ensure that you have all patient accessories necessary for the treatment. For more information, see *11.3. Sonalleve patient accessories*.

4.1. Selecting the correct gel pad

The gel pads are available in two thicknesses: standard and thick. Thicker gel pads can be used in the following cases:

- When treating tumors in limbs.
- When the treatment target is very close to the skin.

You must always consider the position of the treatment area when selecting the gel pad.

NOTICE
Selecting a wrong gel pad thickness in the Sonalleve user interface may lead to skin burns or other serious injury.

5. Preparing the patient

Prerequisites

Make sure the patient has been screened for contrast agents, other medication, and possible MR contraindications as well as their fitness for anesthesia.

5.1. Before the treatment day

5.1.1. Depilation

The patient is asked to shave or chemically depilate hair in and around the treatment area one to three days prior to the treatment. Depilation is necessary because tiny air bubbles may be trapped in the follicles, causing a risk of skin heating.

Early depilation is recommended to minimize skin irritation on the treatment day.

No creams are allowed on the skin after the depilation. Any remaining hair or any foreign substances such as oily creams on the skin may increase the risk of skin heating during treatment.

5.1.2. Fasting

Fasting is only necessary when treating tumors in the pelvic or hip areas, where bowel movements might cause motion artifacts in temperature maps close to the treatment area. Therefore, ask the patient to refrain from eating 6 hours before the treatment.

Medication or anesthesia may require fasting in some cases.

5.2. On the treatment day

5.2.1. Verifying the depilation

The quality of the depilation should be checked before the procedure and any remaining hair should be removed by shaving, carefully avoiding skin irritation.

The area should be washed with mild soap and water to ensure that there are no traces of cosmetic products remaining on the skin. If the skin is very dry, it can be moistened with a wet towel.

5.2.2. Measuring the body temperature

The patient’s body temperature should be measured with a reliable oral or rectal thermometer. This will be the baseline temperature for the temperature map calculations.

5.2.3. Pain management

Prepare medication for the pain management of the patient as required. This may include local analgesics, conscious sedation, or other means defined by the treating physician. Consider using an anaesthesia team for pain management.

5.2.4. Communication

- Thoroughly explain the stages of the sonication procedure to the patient.
- Instruct the patient on how to communicate with the operator.
- Ensure that the patient understands the use of the Patient Emergency Stop Button (PESB).
- Prepare the patient for possible manipulation: why and how.

It is extremely important for the patient to communicate any sensations.

Do not use the Nurse Call button during the Sonalleve MR-HIFU treatment. Use the PESB instead.

Patient Emergency Stop Button (PESB)

Instruct the patient on how and when to use the PESB. Such situations include:

- Sudden pain during the procedure
- Skin heating
- Numbness in legs
- Nausea
- Cardiac symptoms

Fig. 2: Use the PESB instead of the Nurse Call button

The personnel giving the treatment should monitor the patient continuously throughout the procedure. Monitor patient facial expressions and hand motion. Usually the patient is restless just before aborting the sonication.

If the patient presses the PESB during the Therapy stage, the sonication stops immediately, and the light on the PESB turns on. The light on the operator safety device turns red and you hear an audio signal. During pre-treatment scanning, the PESB functions like the nurse call button: it gives an audio signal but does not stop the scanning.

If the sonication is aborted, 25 seconds of temperature mapping and fat monitoring scan is automatically acquired. It is not recommended to abort these scans. After the scans, whenever possible, go to the examination room and talk with the patient. If the patient pressed the PESB due to pain, ask the patient to describe the pain and its strength on a scale of 1-10.

NOTICE
The MR scanner continues to acquire images after the PESB or the safety device has been used to stop the sonication. Noise from the MR scanner does not mean that sonication continues.

6. Pre-planning the Therapy

If MR-imaging is used prior to the therapy for screening, you can also preplan the planning image contrast to be used during the therapy. Most osteoid osteomas are well visible in T_1-weighted images, but sometimes other contrast mechanisms, such as T_2-weighting and even fat suppressed scans, are required. To shorten the imaging time during the therapy, it is beneficial to know this information in advance.

Plan the treatment and the positioning of the patient in advance according to the screening images. This enables a shorter treatment time, which makes the treatment easier for the patient.

7. Workflow

For a Positioning workflow, see the figure below.

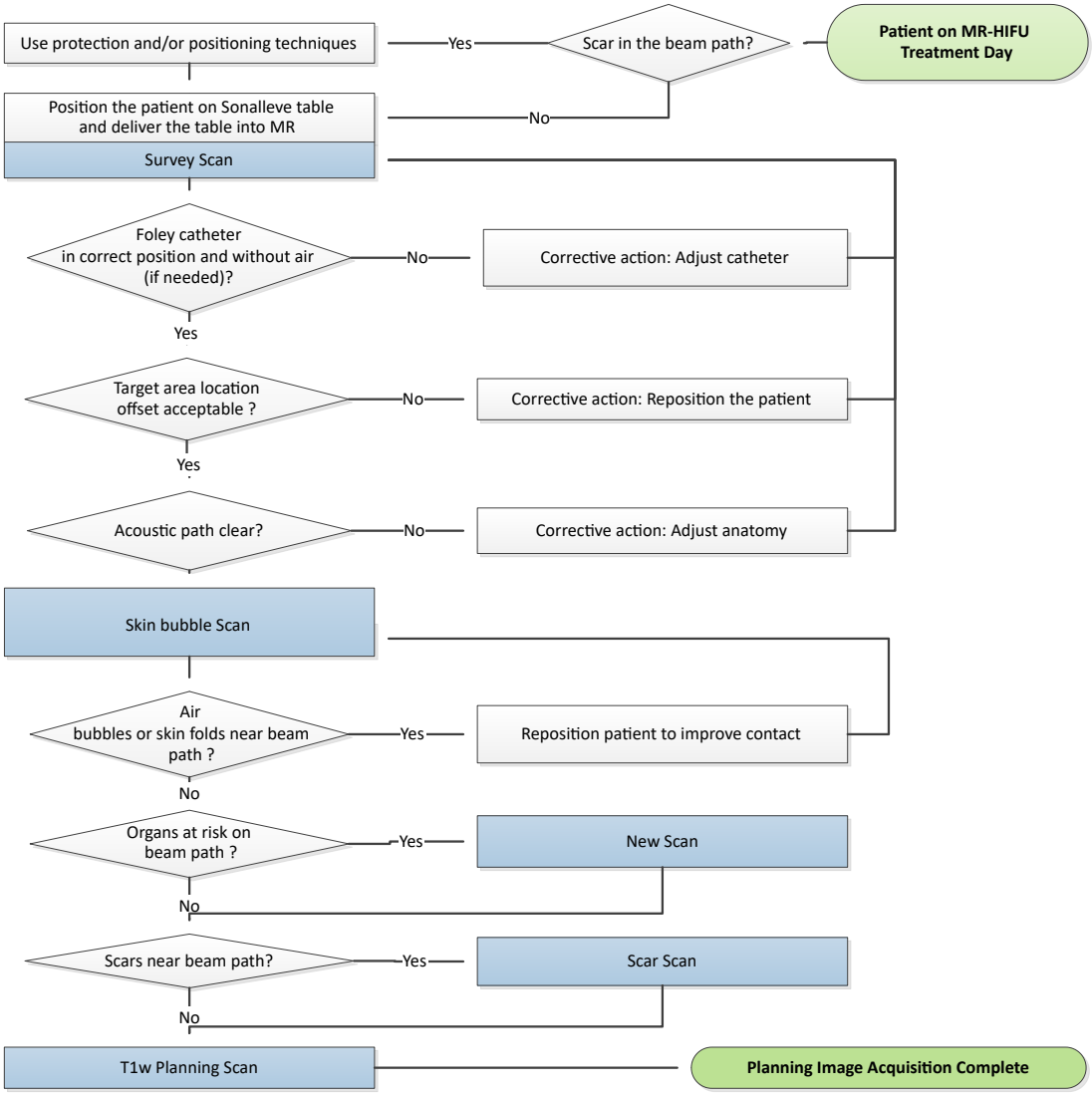

Fig. 3: Positioning workflow

For a Therapy workflow, see the figure below.

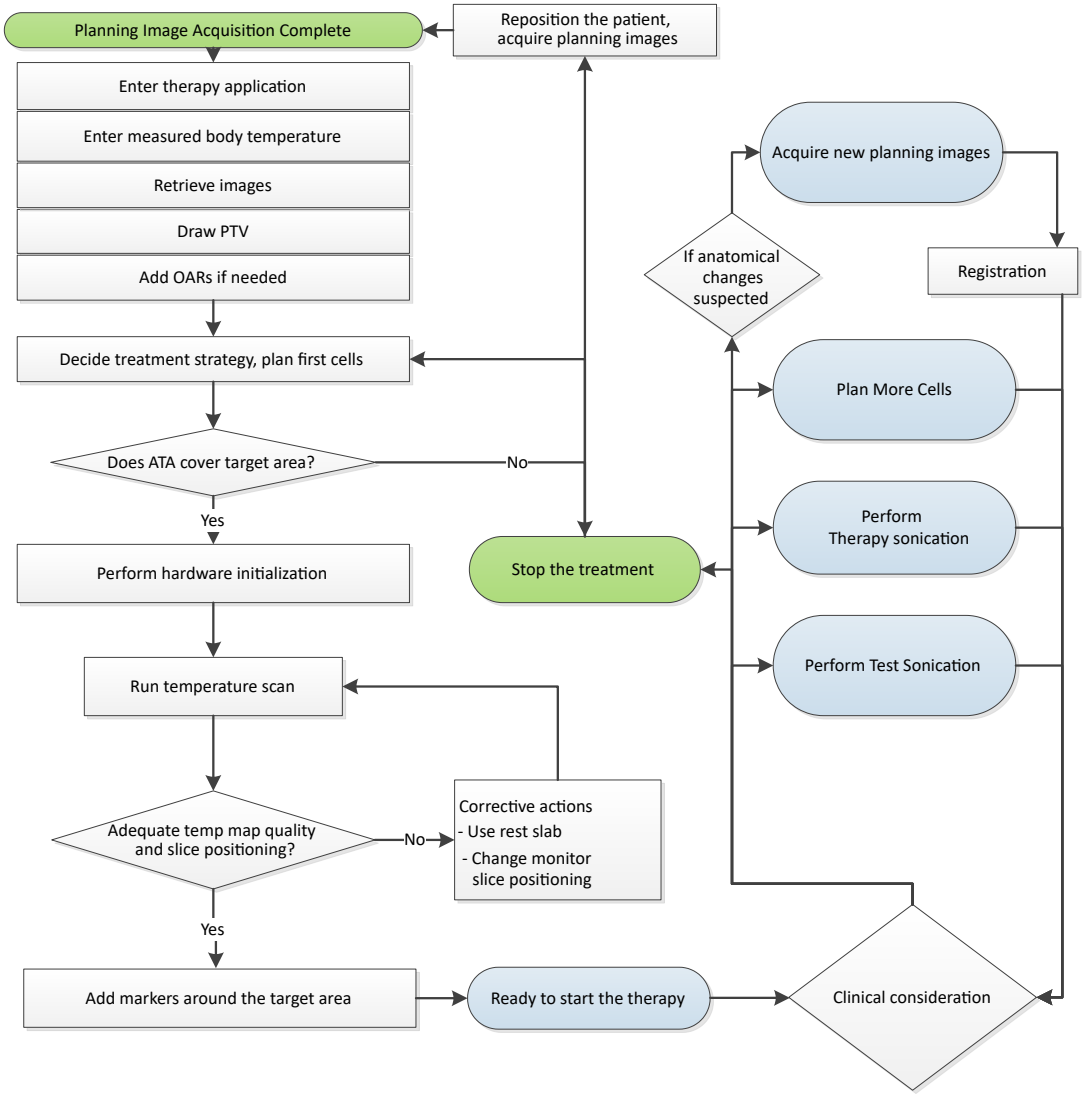

Fig. 4: Therapy workflow

7.1. Imaging for Sonalleve treatment

The MR-HIFU treatment is planned with a set of planning images acquired directly before the sonication treatment, and the progress of the treatment is continuously monitored with a temperature mapping scan. These scans ensure that the treatment is correctly targeted and that the risk of misplaced heating is minimized.

Safety-related scans are required prior to the treatment to ensure that there are no obstacles in the ultrasound beam path. Additionally, the ExamCards define the optional scans to be used in between sonications and a post-treatment scan for quantifying the treatment result. The following table gives an overview of the Sonalleve scans.

Tab. 1: Overview of the Sonalleve scans

Scan	Usage	Stage
Membrane bubble scan	Membrane - gel pad interface air bubble detection	Table Top preparation
Survey	Treatment area positioning	Patient positioning
FH_RL Offsets	Tool for measuring and adjusting location of the target area	Patient positioning
B1 calibration (Tx systems)	For multi-transmit scans	Pre-treatment
Skin bubble	Skin - gel pad interface air bubble detection	Pre-treatment
Scar scan	Visualizing the scar, if the patient has one	Pre-treatment
T_1w Planning	Treatment planning	Planning
Temperature Monitoring	Temperature monitoring during the treatment	Therapy
THRIVE	Assessment of treatment outcome, pre- and post-contrast scan	Post-therapy

7.1.1. ExamCards for Osteoid Osteoma therapy

The ExamCards are located in the Hospital folder, under the Sonalleve Bone folder. The Bone Therapy ExamCard contains all the scans typically required during the therapy.

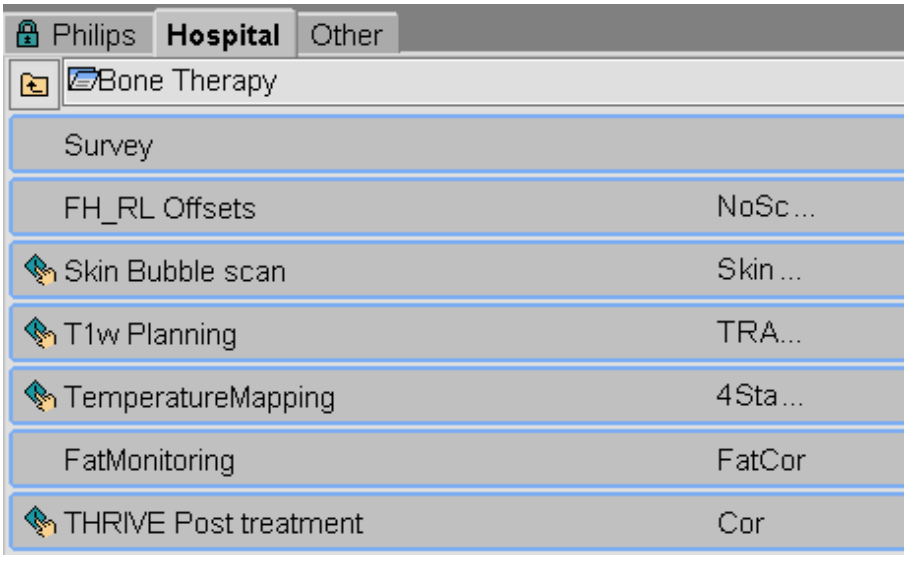

Fig. 5: Sonalleve Therapy ExamCard

The Optional Therapy ExamCard contains some more protocols that might be required during the therapy.

Fig. 6: Sonalleve Optional Therapy ExamCard

7.1.2. General considerations

The Sonalleve Console always calculates multiplanar reconstruction (MPR) images from all the image sets. Only the Monitor view uses stack presentation. Therefore, all the basic planning image sets are volumetric.

The Table Usage parameter must be ignored, and the Push Node setting must be activated to enable automatic image transfer to the Sonalleve Console.

Fig. 7: Push Node - Activated.

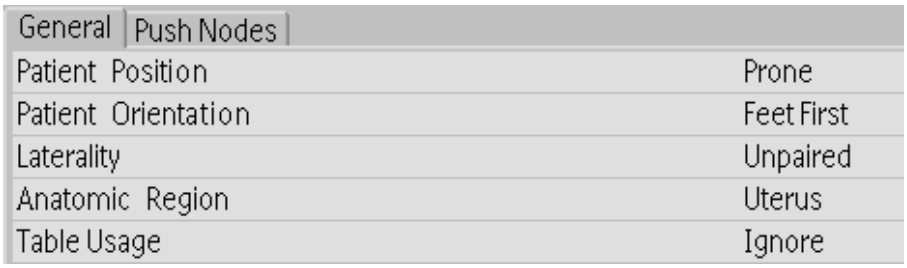

Fig. 8: Table Usage - Ignore.

Contrast agents

Contrast agents are used to visualize the post-treatment non-perfused volume (NPV) after the therapy. No more sonications can be performed after administering the contrast agent. Gadolinium may produce harmful substances when heated.

If gadolinium was used before the therapy, it is necessary to wait for it to wash out before proceeding to therapy. The recommended time is about 1-7 days and depends on the contrast agent and the patient's renal function. Consult the hospital's recommended guidelines on the wash-out time before re-imaging with gadolinium or any other contrast agent. You should also consider the pharmacological effects caused by repeated contrast agent intake.

Modifying the scan parameters

In Sonalleve MR-HIFU use, there are restrictions in the allowed parameter settings. If you modify any of the sequences, always test the changes before treatment and consider the effect of the changes on the SAR value. For safety reasons, you should never modify the temperature mapping protocol.

7.2. Patient positioning

Patient position depends on the treatment area to be treated.

The possible patient positions are the following:

- Head-first and prone
- Feet-first and prone
- Head-first and supine
- Feet-first and supine
- Head-first and decubitus right
- Feet-first and decubitus right
- Head-first and decubitus left
- Feet-first and decubitus left

Position the patient feet-first whenever possible. Note that the prone and supine positions also allow the patient to be positioned obliquely.

If the patient is not under general anesthesia and is capable of moving, show them how to safely climb on and off the Sonalleve Table Top. Falling from the height of the Sonalleve Table Top may be dangerous. Support the patient and be prepared to prevent them from falling.

Before bringing the patient into the examination room, note the following safety aspects:

- The patient can be positioned on the Table Top outside the examination room and transported to the room on the trolley. The trolley can only be used on flat floor surfaces.
- Remember to verify the membrane-gel pad interface and remove possible air bubbles before positioning the patient.
- Never allow the patient to place their hands or knees on the ultrasound window as applying excessive pressure in this area damages the ultrasound assembly.
- Never leave an unconnected coil in contact with the patient.

NOTICE
Never leave the coil cable in contact with the skin, as localized RF heating may cause skin burns. Use pads between the skin and the coil cable.

When positioning the patient, note the following:

- Position the area of interest over the treatment window. Remember that the target anatomy should be perpendicular to the beam path.
- Check that there is no clothing or water absorbing material between the patient and the ultrasound window membrane.
- If a Foley catheter and IV tubes are used, place them on their holders.
- Place the foot rest (if used) under the patient's feet.
- Secure the coil in place with the straps. Isolate the coil cable from the patient with pads.
- Since patient movement is not allowed during treatment, a comfortable patient position is essential for a good treatment outcome. Find the most comfortable position using the accessories.
- Use straps to make the patient's position more stable and keep the patient's limbs within the edges of the Table Top.
- Give the PESB to the patient and instruct them how to use it. Ask the patient to test the PESB. If there is a risk of losing the PESB during the procedure, consider securing it to the patient's hand with tape or a strap.

  If the patient is under anesthesia, leave the PESB in the accessory box.
- Give the patient ear plugs and headphones (or MR-safe ear muffs).

Fig. 9: The patient is ready for the treatment.

7.2.1. Survey

Run a Survey scan when the patient is positioned to get an overview of the patient anatomy and the acoustic path from the transducer to the target. The Survey is a 2D scan in the coronal, sagittal, and transverse planes and is used for accurately positioning the patient.

For examples of coronal, transverse, and sagittal plane, see the figure below.

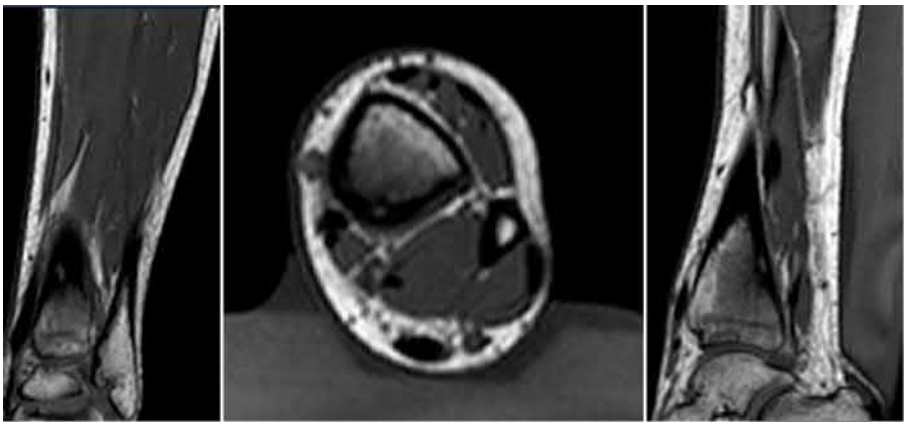

Fig. 10: Survey scan. Left: Coronal plane. Middle: Transverse plane. Right: Sagittal plane.

From the Survey, you can verify the following:

- **Treatment location:** Is the treatment area in the center of the treatment window? Is any re-positioning required? Is the intended target as perpendicular to the ultrasound beam path as possible?
- **Location of critical organs:** Are there any critical organs or sensitive tissue structures in the planned ultrasound beam path?
- **Status of the Foley catheter:** Is the catheter located well inside the bladder? Is the catheter pressed against the bladder wall? If so, reposition the catheter. Is the catheter tip out of the planned ultrasound beam path?

7.2.2. Verify the patient positioning

Use the Offsets scan to verify the optimal patient positioning over the treatment window. The FOV of this scan is about the size of the Available Target Area (ATA). The patient is optimally positioned if the Offsets scan FOV is in the center of the target area.

If the patient must be moved, move the center of the Offsets scan FOV to the planned center of the target area, open the offsets page (Offc/ang), and check the offset values in the left-right and head-feet direction. Move the patient accordingly. Run a new Survey scan and verify the patient's position again.

Position the center of the slice to the center of the treatment area.

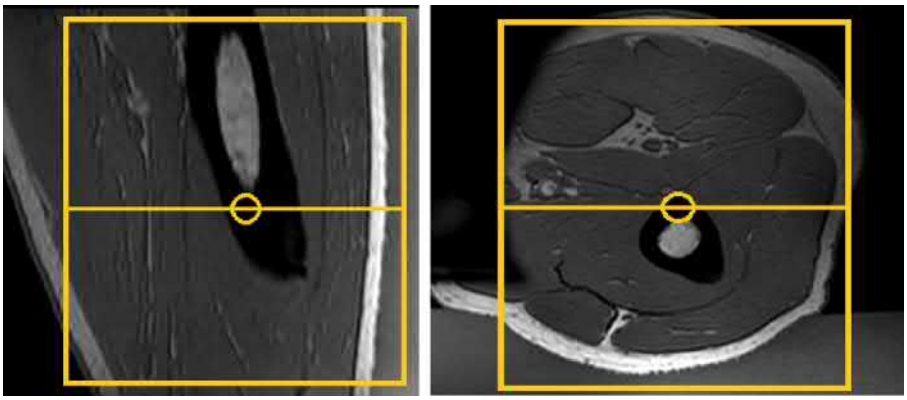

Fig. 11: Positioning images

Tab. 2: Moving the patient according to the offsets

Direction	+/-	Move the patient
R-L	+	Right (towards the patient's right hand)
	-	Left (towards the patient's left hand)
H-F	+	Into the scanner
	-	Out of the scanner
A-P		Constant, not relevant

7.3. Skin-membrane interface

The Therapy ExamCard contains a special air bubble scan to be run before the planning scans. The purpose of the scan is to make sure that the ultrasound energy will not be deflected into unwanted locations by air-containing structures, such as air bubbles or skin folds.

Air bubbles that are larger than 1 mm (0.04 inch) should be removed from between the patient and the gel pad. For examples, see the following figures.

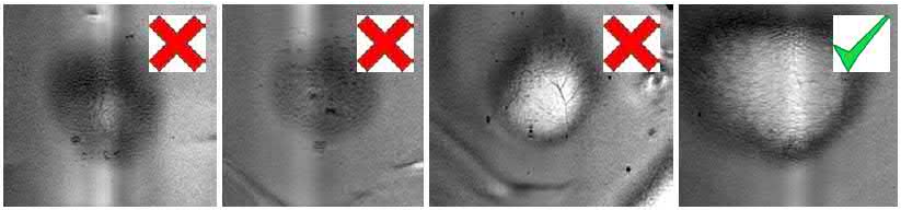

Fig. 12: Air bubbles

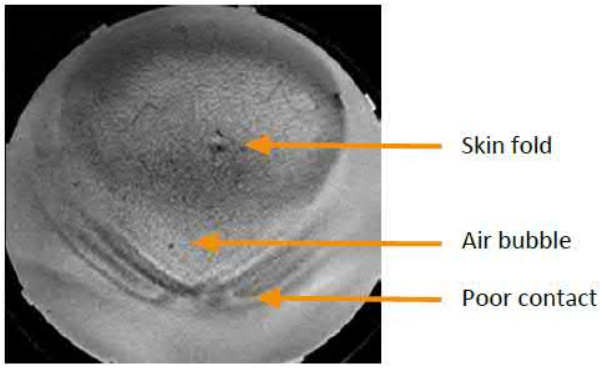

Fig. 13: Poor contact with the gel pad

For an example of a good contact with the gel pad, see the following figure.

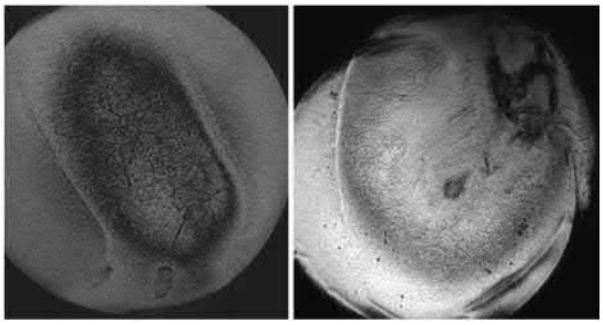

Fig. 14: Left: Good contact with the gel pad. Right: Skin bubble scan.

7.3.1. Improving the skin contact

If there are any air-containing structures in the planned ultrasound beam path, they should be removed. Beam shaping can also be used to protect the skin.

Skin folds: Stretch the patient's skin outwards.

Air bubbles: Stretch the skin and, with your hand, wipe the skin on the bubble area. Sometimes, adding degassed water (with a small syringe) between the skin and the membrane improves the contact.

7.3.2. Using beam shaping in near-field areas containing air

If there are air-containing structures, such as air bubbles or small skin fold areas in the beam path and they cannot be removed, you can use beam shaping. See chapter "Workflow" in *Sonalleve MR-HIFU Instructions for Use*.

Draw an Organ Avoidance Region (OAR) ROI around the air bubbles in the coronal plane and leave at least 2 mm (0.08 inch) outside the edges of the air cavity, but keep in mind that the OAR should be as small as possible to enable good access to the treatment area.

It is not recommended to use beam shaping with the highest power levels together with large cell sizes. This is because in such cases, the energy in the protected region will rise accordingly and therefore the protection is not accurate.

If there is a wide skin fold, the protective OAR ROI becomes so large that the treatment efficiency should be considered.

Below is an example of using beam shaping to avoid air bubbles on the skin.

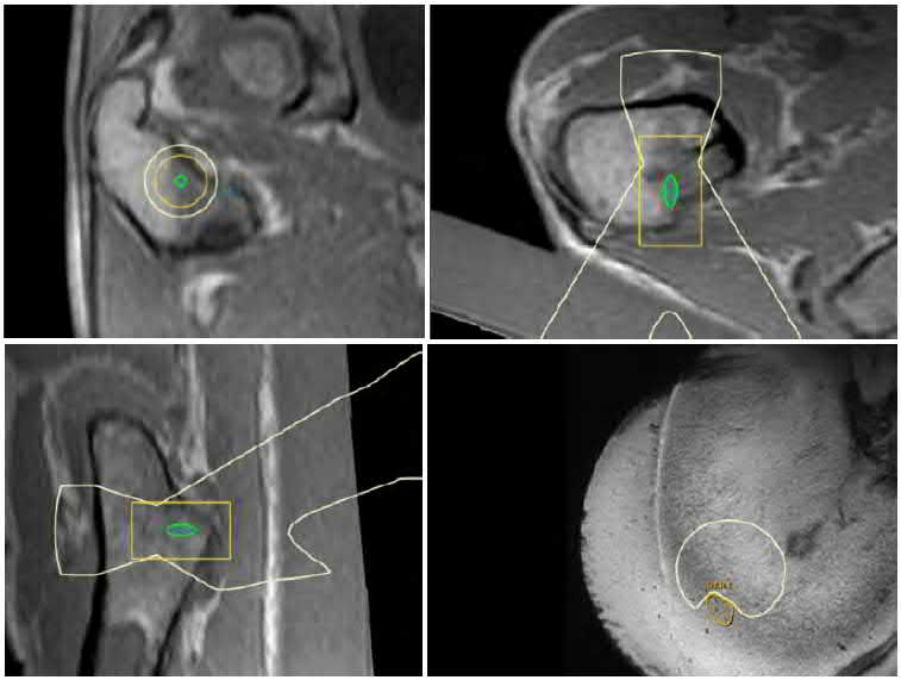

Fig. 15: Beam Shaping protecting the skin.

7.4. Scar scan (optional)

The Therapy ExamCard contains a special scar detection scan which should be run before the planning scans, but only if the patient has a scar near the ultrasound beam path. The purpose of this scan is to assist in treatment planning when a scar is present. Also, the scar scan should always be re-acquired after doing the registration, to verify the current scar location. See *3.1. Scars*.

For examples of various types of scars, see the following figures.

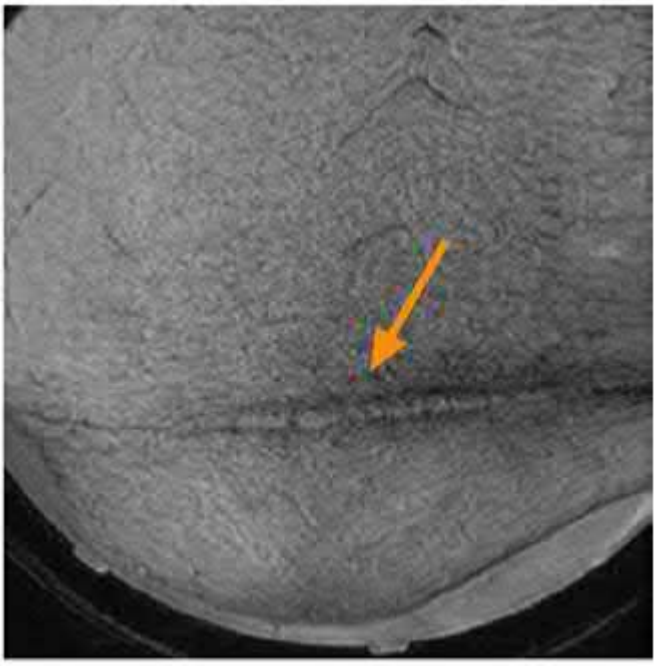

Fig. 16: Scar

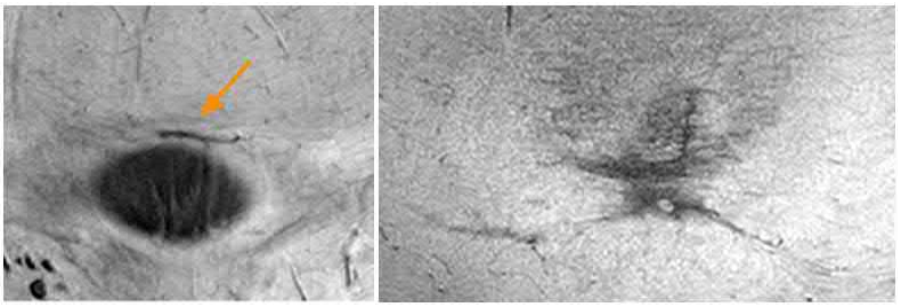

Fig. 17: Left: Small scar. Right: Extensive scarring.

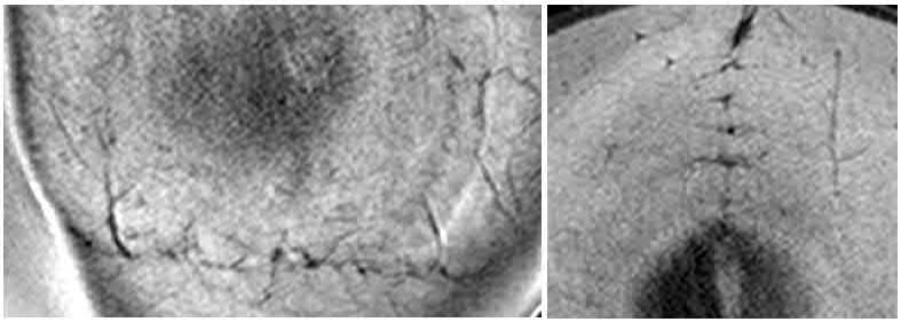

Fig. 18: Left: Horizontal scar. Right: Vertical scar.

7.4.1. Verifying scar locations (when a scar is present)

1. Position slices in the coronal plane from the skin to the muscle. You may need to use this scan in different planes during planning as the scar tissue may not be uniformly located between the skin and the muscle.

2. Verify the visibility and the location of the scar from the images before proceeding to acquire the planning scans. If the scar is not visible in the images, consider using other methods to mark the scar for better visualization and protection during the therapy.

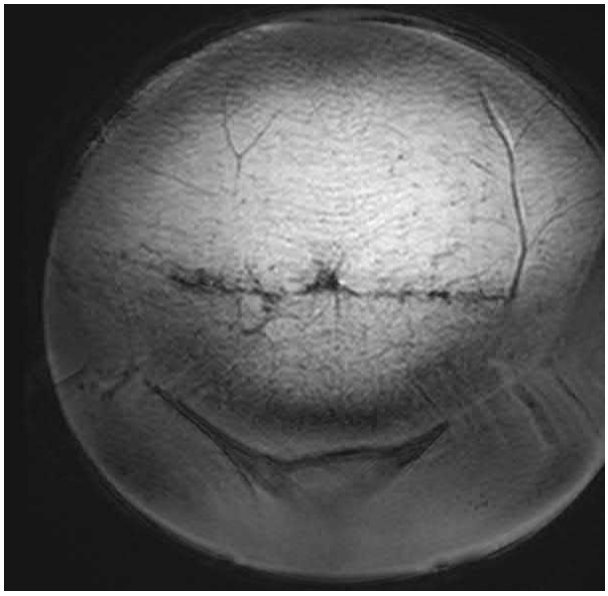

Fig. 19: Scar

7.4.2. Using beam shaping to protect scars

You can use the beam shaping feature to reduce the intensity of the ultrasound field in selected regions in the near field, for example, to avoid sonicating through a scar area.

Identify the scar with a Scar scan and draw an OAR ROI around it in the coronal plane. To ensure sufficient protection, the OAR ROI should extend at least 2 mm outside the edges of the scar, but keep in mind that the OAR should be as small as possible to enable good access to the treatment area.

It is not recommended to use beam shaping with the highest power levels together with large cell sizes. This is because in such cases, the energy in the protected region will rise accordingly and therefore the protection is not accurate.

When positioning treatment cells, verify that the OAR ROI will actually protect the scar by comparing the displayed ultrasound beam path with the position of the scar. Also check that deeper-lying scar tissue is protected by scrolling selectively through the images.

7.5. Scanning the planning scans

NOTICE
To prevent unexpected changes in image quality, always test all scan protocol changes that may affect image quality before using them. For safety reasons, the Temperature Monitoring protocol should never be modified in any way.

1. Run the Survey scan.
2. Position the slices over the treatment area.

7.5.1. Planning scans

Fat suppression is not recommended to be used with planning images because the fat and potential scars in the subcutaneous fat layer must be visible.

7.5.2. Slice positioning

Left-right

The image series must cover the entire area where the transducer near-field beam can potentially move. In practice, this means a distance of approximately 20 cm (8 inches) in the left-right direction.

Anterior-posterior

The planning scan slices must cover the whole beam path area from the gel pad to the far field. A large coverage is required when the transducer is heavily tilted. The entire ultrasound beam path must be visible during planning and treatment.

7.5.3. T1-weighted imaging

Sonalleve treatment planning is always based on volumetric MPR images, as their resolution is sufficient for this purpose. With 3D volumetric imaging, the dimensions of the target area can be measured and the anatomy identified in the transducer beam path area to avoid sensitive structures. See the figure below.

The contrast of the images must be sufficient to:

- Show the neurovascular bundles close to the target area.
- Distinguish the target area from the healthy tissue.
- Show the outline of bone and skin.

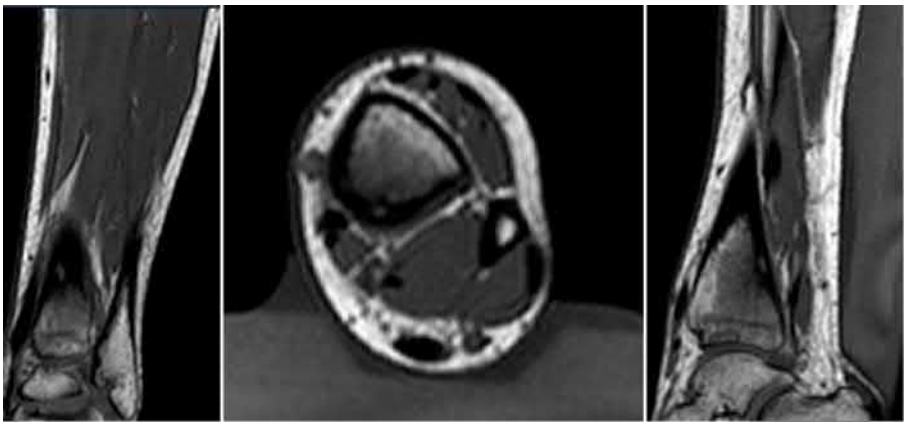

Fig. 20: An example of T_1-weighted images. Left: Coronal MPR image. Middle: Transverse. Right: Sagittal.

7.6. Temperature monitoring

7.6.1. Temperature mapping scan parameters

Temperature mapping is a multi-shot EPI scan. The temperature measurement is based on the water-proton resonance frequency (PRF) shift induced phase differences between dynamic frames. The ProSet fat suppression method is used.

The resolution is 2.1 mm for 3.0 T scanners and 2.5 mm for 1.5 T scanners. Slice thickness is 7 mm.

For examples of temperature mapping, see the following figure.

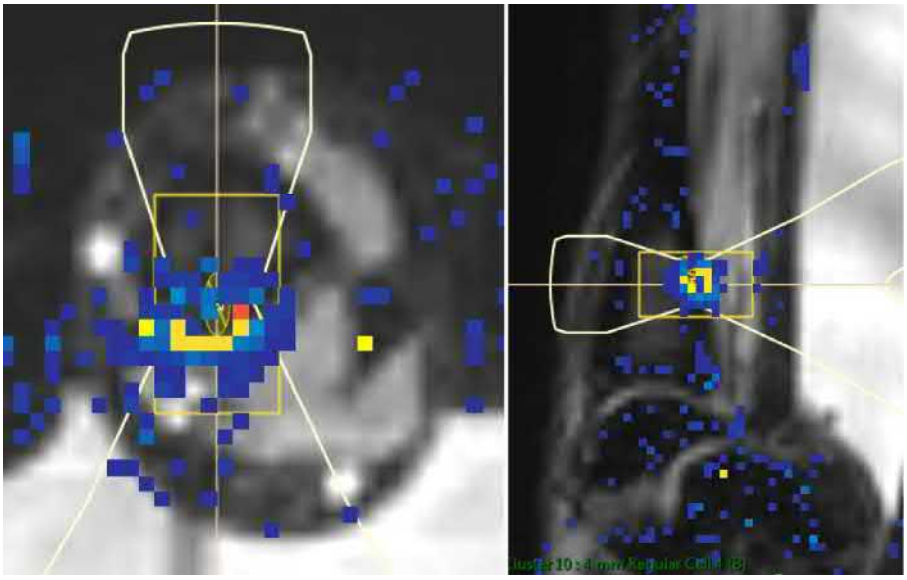

Fig. 21: Example of temperature mapping. Left: Transverse image. Right: Sagittal image.

Never modify any of the temperature mapping parameters.

Tab. 3: Temperature mapping parameters

Parameter	Setting	Description
External control	Sonalleve	Allows the Sonalleve Console to control scanning.
Resolution/Slice thickness	Higher resolution/thinner slices	Better spatial accuracy and more noise, temperature better localized.
CLEAR	Yes	Necessary to enable temperature monitoring in the Temperature mapping scan.
TE/FA	Do not change	Has an effect on the temperature sensitivity.
Dynamic scan time	Do not change	The longer the interval between dynamic scans, the higher the risk of failing to detect misplaced heating.
Fat suppression	Yes, ProSet	Used to ensure that the temperature mapping is calculated accurately as fat suppression is required by the MR thermometry method. ProSet is the most robust and fastest method to use.

7.6.2. Monitor slice positioning

Monitor slices to be acquired from the focus must be positioned in the middle of the treatment area in order to optimize the temperature mapping image quality. The slice position will then be automatically updated once the treatment cell is selected in the Sonalleve Console. The near-field monitor slice stack must be positioned correctly by the operator to minimize the possibility of misplaced heating.

Position the near-field stack D on top of the muscle tissue near the treatment area, never on top of the subcutaneous fat layer because the fat-suppressing temperature mapping protocol does not detect heating in fat.

7.6.3. Preparing the monitor scan

1. Select the predefined temperature mapping protocol.

2. Position monitor slice stacks A (coronal), B (sagittal), and C (transverse). They must be positioned in the middle of the treatment area for optimal preparation of the scan.

3. Position monitor slice stack D on the muscle tissue in the near field as perpendicular to the transducer beam path as possible. See the figure below.

A warning zone is automatically defined on stack D. The system issues a warning if heating occurs in the warning zone.

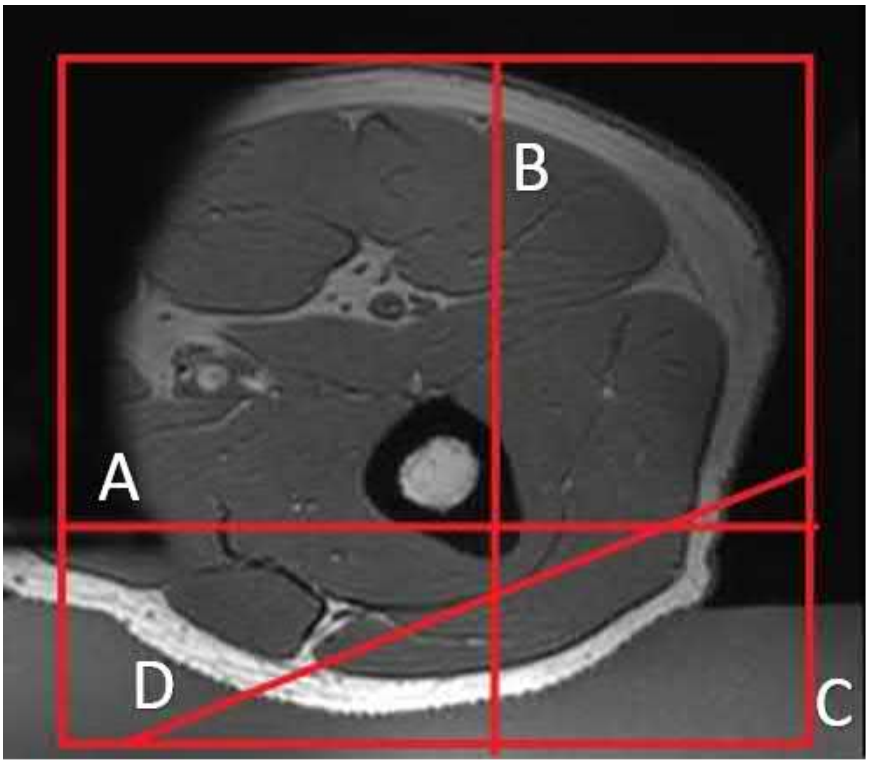

Fig. 22: Positioning monitor slice stack D.

4. Check that CLEAR=yes. This enables the temperature map calculation.
5. Start the monitoring scan. The MR scanner is now under remote control.

Fig. 23: MR scanner under remote control.

TIP: Minimizing breathing or bowel movements in the monitor slices

Sometimes breathing or bowel movements can cause motion artifacts in the near-field monitor slice. In such cases, consider using the REST option for Temperature mapping which is found in the Optional Therapy ExamCard.

Note that this scan has a longer dynamic scan time. Position the REST slab over the anatomy causing the motion (flow or bowel motion). Be careful when positioning the slab, so that it does not prevent temperature detection.

7.7. Imaging after the treatment

A T_1-weighted scan with contrast agent can be performed after the treatment.

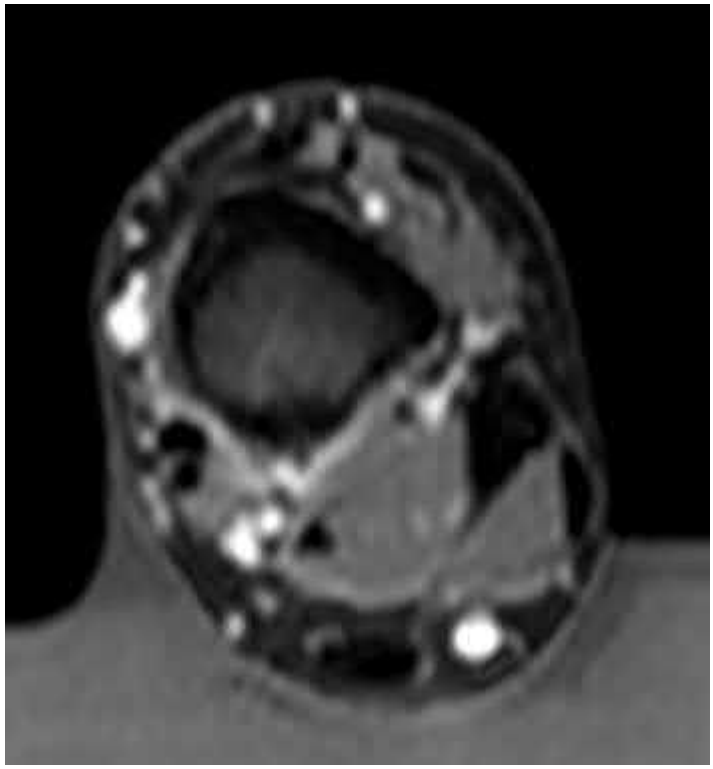

Fig. 24: Post-contrast THRIVE image.

8. Planning the therapy

8.1. Using PTV to visualize the target volume

Define the Planning Target Volume (PTV) by drawing it on the planning images.

The Planning Target Volume can be used in two ways:

- You can draw the PTV to cover the whole tumor volume, including the region outside the target volume.
- You can draw the PTV to cover only the part of the tumor which you plan to target.

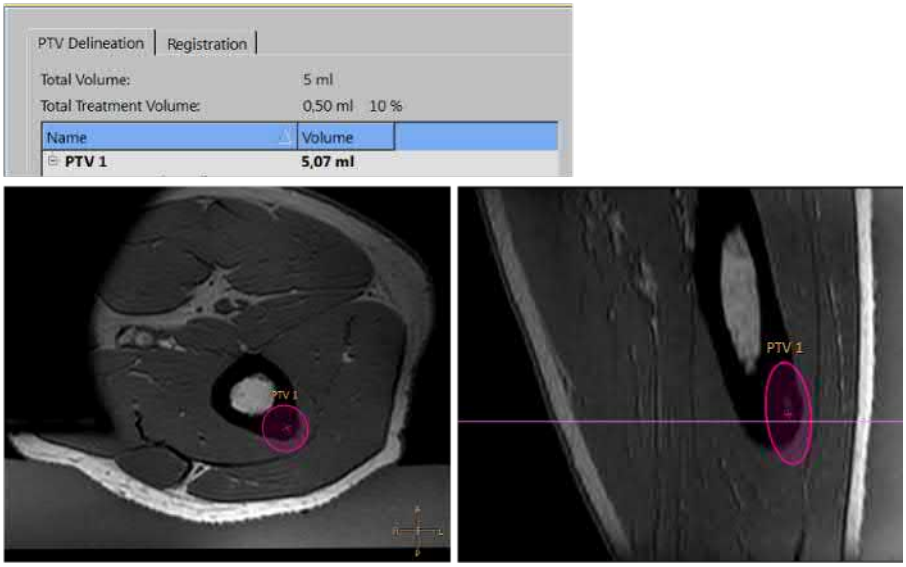

Fig. 25: Planning Target Volume delineation.

8.2. Considering the planning strategy

Cortical bone has approximately 50 times higher absorption of ultrasound energy compared to soft tissue. Therefore, the penetration of ultrasound energy into the bone is minimal. Applying acoustic energy on the bone surface results in a temperature rise at the part of the bone cortex enclosed in the ultrasound beam, indirectly heating and ablating the adjacent periosteum.

Cortical bone does not produce MR signal. Therefore, Proton Resonance Frequency Shift (PRF) based temperature monitoring cannot measure the temperature changes in cortical bone. Additionally, parts of the bone marrow contain mainly lipid, on which PRF-based temperature monitoring does not work.

When choosing the strategy, keep in mind that heating will occur at the cross-section of the transducer beam path and the first interference with a hard bone/bone-like structure. Are there air-filled structures? Are there neurovascular bundles in the near field or in the beam path? How close is the skin to the target? Where does the reflected ultrasound energy go? Are there any sensitive anatomies nearby?

There are two strategies available for treating osteoid osteoma:

- Using the broader part of the ultrasound beam in the near field to heat the bone surface
- Using volumetric cells on the bone surface or within the osteoid osteoma nidus.

Try to cover the osteoid osteoma lesion and/or nidus systematically and aim for full coverage.

8.2.1. Using the broader part of the ultrasound beam to heat the bone surface

Utilize the broader part of the ultrasound beam to heat the bone surface adjacent to the osteoid osteoma nidus. This way, the heating surface is larger and thus fewer treatment cells may be required for the therapy. Heating mostly occurs at the first soft tissue-bone interface and there is a lower risk of skin heating and tissue damage outside the bone. This strategy may be appropriate when the nidus cannot be directly targeted (e.g., with endosteal or intramedullary lesions), but there would still be benefits in thermally ablating the periosteal nerves around the osteoid osteoma lesion for pain relief.

See the figure below. Place the cells posterior to the cortical bone. The ultrasound beams should overlap in the near field and on the bone surface.

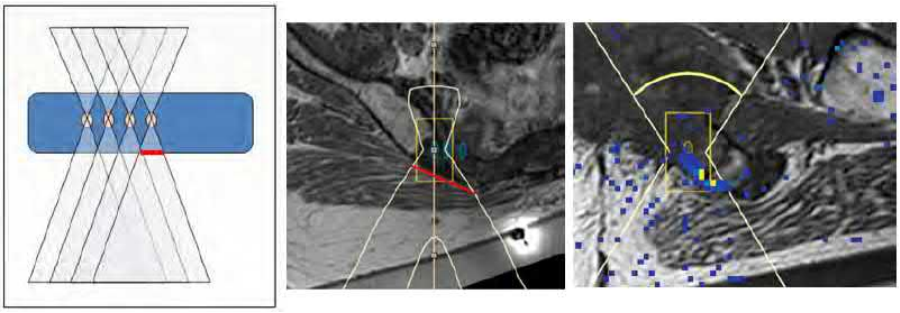

Fig. 26: Using the broader part of the ultrasound beam to heat cortical bone surface. Right: Showing a large heating area in the bone-muscle interface.

8.2.2. Using volumetric cells on the bone surface or within the nidus

Place the cells directly on the bone surface or directly within the nidus. With osteoid osteoma lesions with a large amount of periosteal bone formation, or endosteal, deep intracortical, or medullary location, the heating mostly occurs on the cortical bone surface, diffusing towards the nidus. This strategy can also be used to target subcortical, shallow intracortical, or subperiosteal osteoid osteoma lesions to directly ablate the nidus.

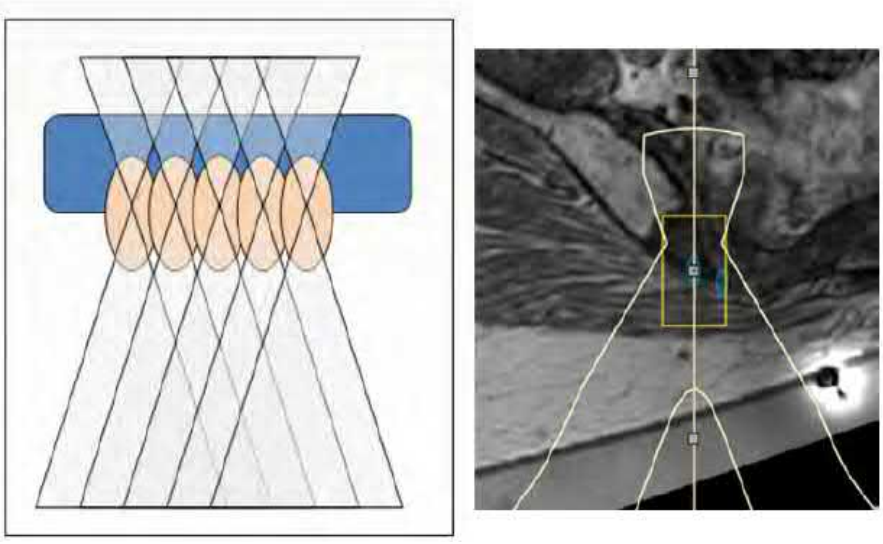

Fig. 27: Volumetric cells on bone surface.

8.3. Planning treatment cells

The transducer beam path must be as perpendicular (at a 90 degree angle) as possible, to the surface of the treated bone. If it is not perpendicular, it may cause unexpected reflections of the acoustic energy leading to insufficient heating in the target area and/or unintended heating in adjacent tissue.

Some anatomies are difficult to position correctly due to the limits of the scanner bore.

Add cells on top of the planning image, and view them in all planes to check that the transducer beam path outline remains within the bone. See the figure below.

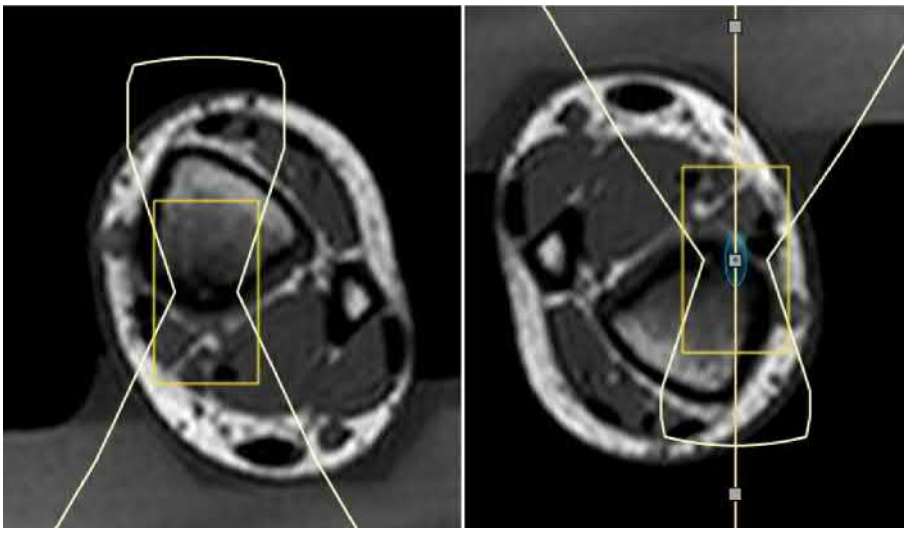

Fig. 28: Left: Beam inside the bone. Right: Part of the beam outside the bone.

For more information, see the *Sonalleve MR-HIFU Instructions for Use*.

Leave a sufficient safety margin between the heating surface and the skin, spine, lungs, liver, or other sensitive structures.

You do not have to place all the cells immediately. To save time, you can start with only a few cells and add more cells during the cooling periods.

For an example of planning treatment cells, see the figure below.

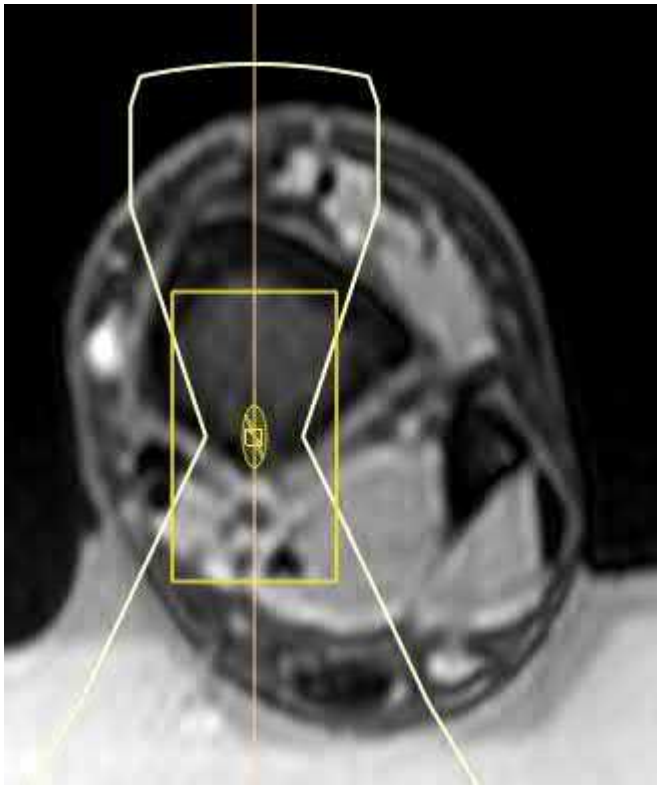

Fig. 29: An example of planning the cells.

To move already planned treatment cells:

1. Click the **Move Treatment Cell Cluster** button.

2. Move the cell position to the desired location using the handles on the image. Click the beam line to activate the handles.

3. You can now adjust and angulate the transducer position in all directions. See the figure below.

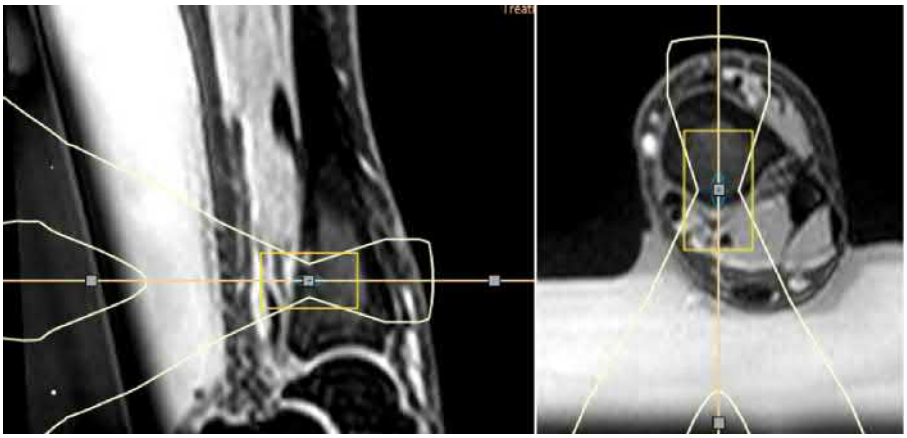

Fig. 30: Handles on the transducer position.

4. Continue planning or proceed through the Hardware Initialization stage to the Therapy stage for a test sonication.

8.3.1. Cell selection

Regular cells from 2 mm to 16 mm are available for the therapy. If the osteoid osteoma nidus can be directly targeted, it is beneficial to use smaller cells (e.g., 4-8 mm) to localize the acoustic energy and heating to the nidus. With endosteal, deep intracortical, and medullary osteoid osteoma lesions, keep in mind that the cortical bone absorbs most of the ultrasound energy and it may not be possible to directly target and heat the nidus. In these cases, using larger cells with longer sonication durations providing heat diffusing towards the nidus may still be enough to thermally ablate the nidus. In addition, depending on the cell size and placement, there may not be temperature information available at the focus location, but heating at the soft tissue-bone interface, in the near field, and in interleaving tissues can still be monitored.

- All cell sizes have two available sonication durations – 16 and 56 seconds.
- The maximum power level depends on the cell size and sonication frequency. For example, at 1.2 MHz sonication frequency the range is from 100 W (16 mm cell) to 300 W (2 mm cell) and the maximum energy of the sonication is approximately 6 kJ. At 0.85 MHz sonication frequency, the maximum power for all cell sizes is 80 W.
- The safety limit 52 °C - 84 °C (125.6 °F - 183.2 °F) is cell size, sonication duration, and field strength dependent.

Select the power with the aim of producing relatively slow heating at the target location instead of rapid heating. The temperature rise to target temperature should be linear over the selected sonication duration.

Use the high powers only if the lower powers do not produce high enough temperature elevation and when there are no major safety concerns (for example, excessive near field heating).

8.3.2. Safety margins

- Always leave sufficient safety margins (>1 cm from treatment cell border) to sensitive organs or other sensitive structures when planning treatment cells.
- Avoid placing treatment cells any closer to the spine or other sensitive structures than indicated by the far-field safety margin. If this is not possible due to anatomic constraints, monitor the sonication carefully and be prepared to stop it if needed.
- Pay special attention to objects directly in the transducer beam path, not forgetting the far field.
- The planning graphics show the main part of the 3D focused transducer beam, but keep in mind that boundaries such as air-filled structures and bones may cause unexpected reflections.
- Make sure that the transducer beam path does not extend outside the bone, see the figure below:

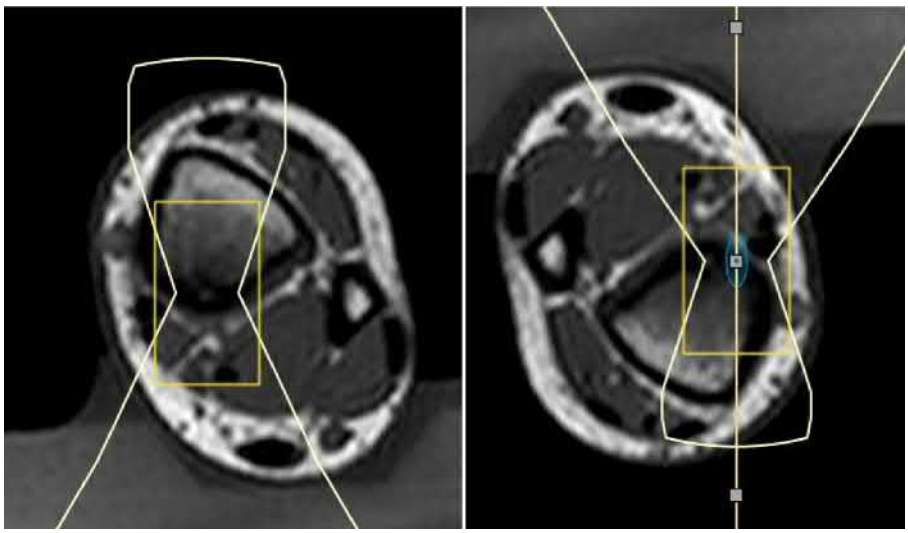

Fig. 31: Left: Beam inside the bone. Right: Part of the beam outside the bone.

- Remember that transducer angulation limits the ATA.
- Electronic X deflection can be used for deeper (+10 mm and +20 mm) and shallower (-10 mm) sonications. It requires higher power levels and thus longer far-field safety margins. The following figure shows the safety margins.

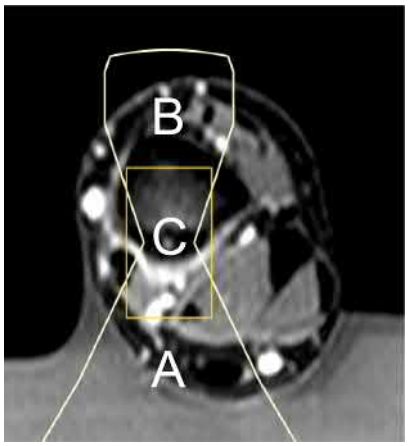

Fig. 32: The transducer beam overlay visualizes the treatment cell safety margin (C), the far-field safety margin (B), and the near-field safety margin (A).

NOTICE
The length of the far-field depends on the sonication frequency and cell size. The transducer beam overlay visualizes the far-field safety margin for the worst case scenario.

8.4. Anatomical motion detection and correction

Using markers, you can detect any image distortions or patient motion that may have occurred after the planning stage.

The markers are visible in all planes and tied to the MR coordinates, so patient motion can easily be visualized. Compare the location of the marker and the anatomical landmark to detect motion.

You can add markers during any planning and therapy stage.

To add markers:

1. Make sure **ROI Overlay** is enabled.

2. Click the down arrow next to the **Add** button.

3. On the drop-down menu, select **Marker**.

NOTICE
Choose landmarks that you can recognize also in fat-suppressed T_1-weighted images.

In the figure below, the markers have been placed on anatomical structures.

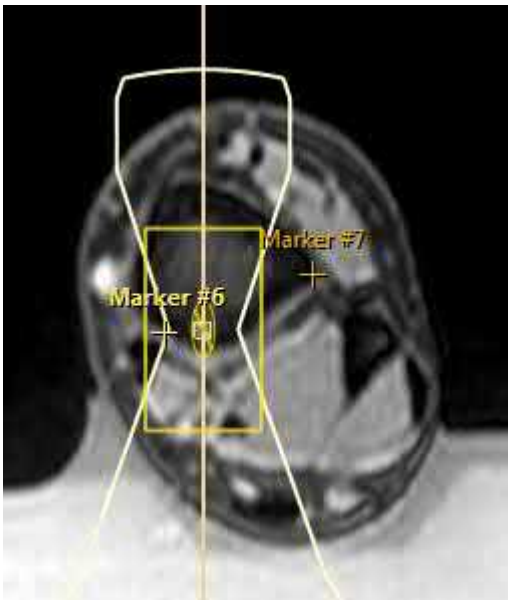

Fig. 33: Using markers to identify anatomical structures.

Note the following:

- When sonication starts, verify the marker location on the first dynamic temperature mapping images. If motion is detected, abort the sonication immediately.
- During the sonication, if the patient starts to feel pain and move away from the source of the pain, verify the markers location and be ready to abort the sonication if there is any significant motion.
- Verify any suspected motion by scanning already scanned or sonicated treatment cells using a cell check or temperature mapping scan. Compare the old and the new image sets.
- When motion occurs, rescan the planning image set that covers the whole ultrasound beam path. Correct for the motion using the Registration tool. For more information on the Registration tool, see *8.5. Registration using reference PTV*. See also chapter "Registration" in *Sonalleve MR-HIFU Instructions for Use*.

8.5. Registration using reference PTV

Sometimes the bone to be treated is very difficult to outline. In these situations, it is advisable to draw a second PTV around a region which you can easily recognize, for example, long bones (round). For an example, see the figures below.

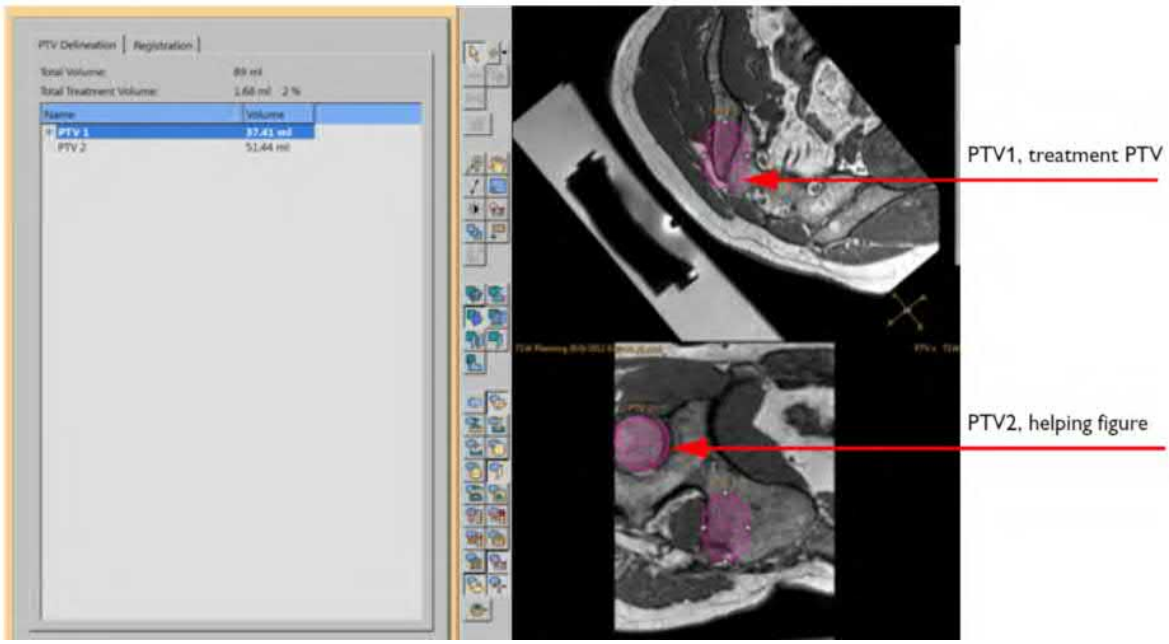

Fig. 34: Two PTVs (PTV1 and PTV2) drawn. In this case, the second PTV is drawn around the hip bone.

After motion has occurred, and with the help of new planning images on the registration page, move the PTV2 to a new location, and PTV1 and all other objects (cells, PTVs, ROIs, OARs, markers) will follow accordingly.

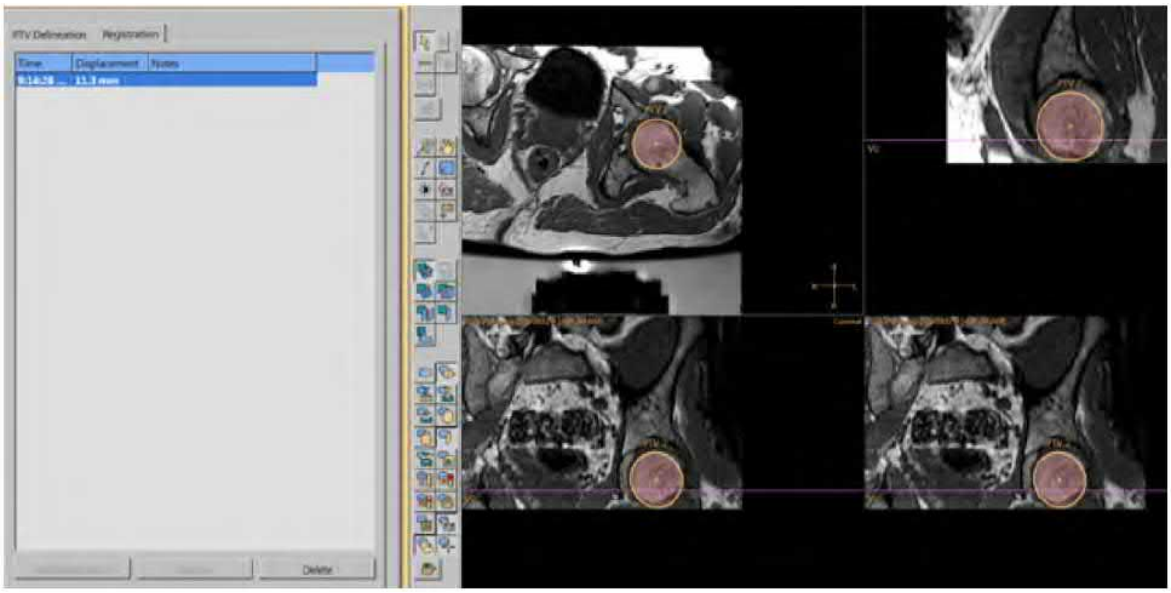

Fig. 35: PTV2 moved to a new location.

The new registration moves all the objects such that their position with respect to the PTV is correct in the new image set. Verify the position of the markers, OAR, and ROI by scrolling through the images. Correct them if they are not in the right position.

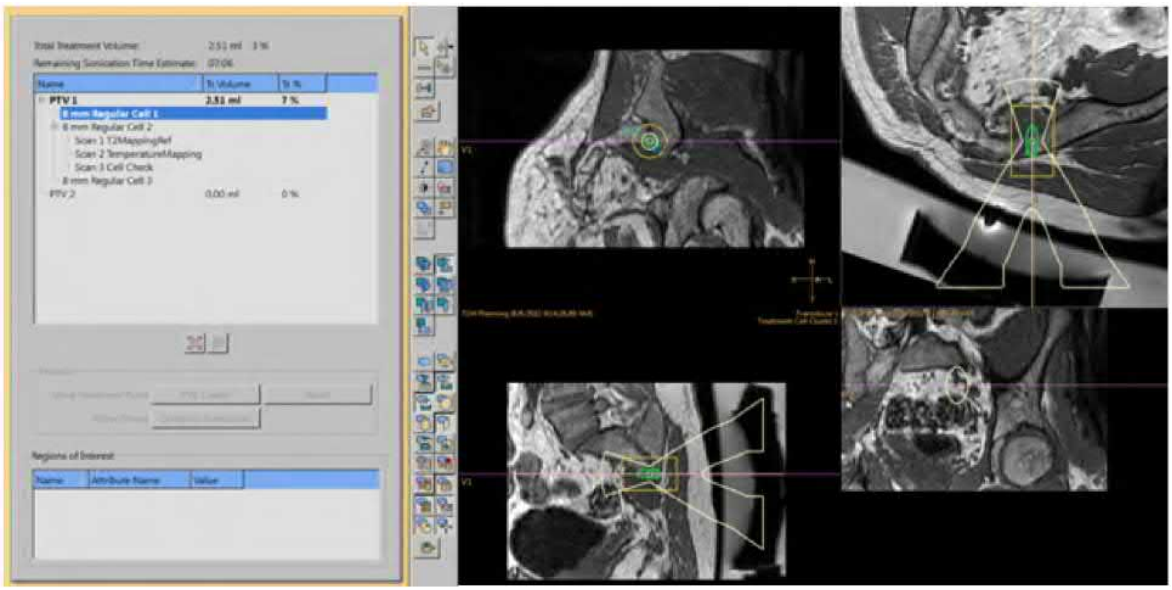

Fig. 36: All objects in correct positions with respect to the PTV on the new image set.

For more information on using the Registration tool, see the *Sonalleve MR-HIFU Instructions for Use*.

8.6. Drawing Freehand Warning ROIs

There is no automatic warning zone in the far field. You should therefore mark the sensitive structures in the far field with Freehand Warning Regions of Interest (ROIs). These areas will be monitored, and you will receive a warning if their temperature reaches a predefined limit.

1. Click the **Monitor view** button.

2. Click the down arrow next to the **Add** button.

3. On the drop-down menu, select **Freehand Warning ROI**.

4. On the coronal plane, draw one or more ROIs around the anatomical structures in which a temperature rise is not desired. The ROIs are visible in the coronal images provided that you stay on the same treatment plane.

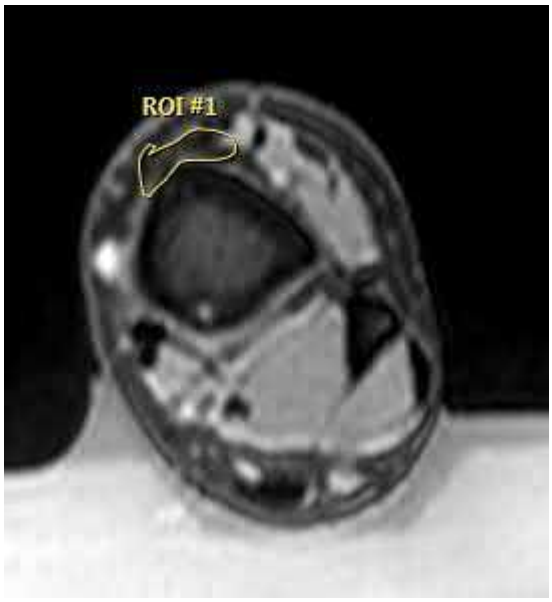

Fig. 37: A Freehand Warning ROI.

5. Define a warning temperature for the ROI. If the temperature within the ROI reaches this limit, you will receive a warning.

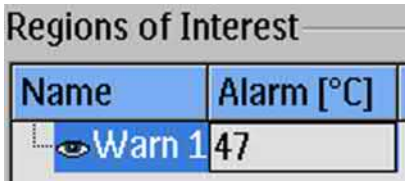

Fig. 38: Freehand Warning ROI temperature limit.

NOTICE
The number of ROIs is not limited, but if there are several ROIs and there is a temperature warning, you will have to check which of the ROIs gave the warning.

8.7. Sonication

8.7.1. Test sonication

You must perform a test sonication on one cell before you can proceed to therapy sonications. A test sonication is a short, low power sonication, and it is done using a 4 mm regular cell type. Use very low power levels, typically 5-30 W.

After the test sonication has been completed, select the Decisions tab.

- Verify that heating takes place in the intended location: within the ultrasound beam path overlay and at the first soft tissue-bone interface and/or within the targeted osteoid osteoma lesion. If heating is displaced, drag the offset marker to the center of the heated region manually. Correct the offset in RL and HF directions in the coronal image and in AP direction in the sagittal image.

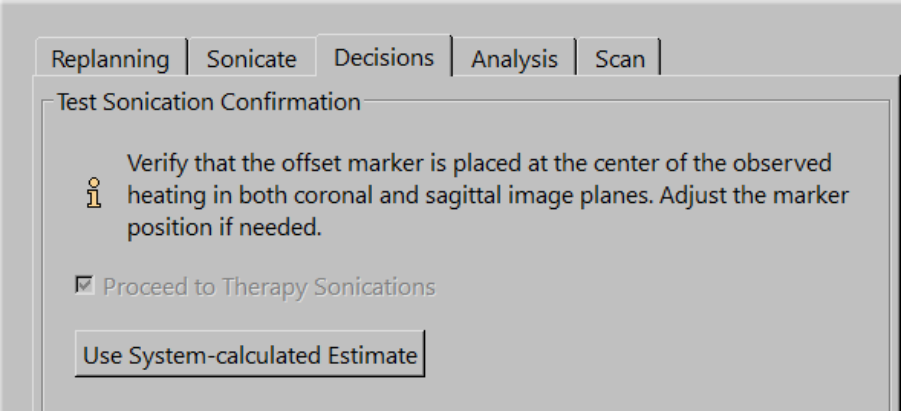

Fig. 39: Proceed to Therapy Sonications.

- After the manual correction has been performed, or if there is no need for corrections, click the Proceed to Therapy sonications check box.

For more information, see the *Sonalleve MR-HIFU Instructions for Use*.

8.7.2. Sonication power

The sonication power should be adjusted based on the sonication depth, osteoid osteoma lesion size, nidus vascularity, sonication planning strategy, and cell size. Overall, deeper targets, vascular and large lesions, and larger cell sizes require the use of higher powers. Start with lower powers and small cell sizes, typically 20-50 W with 4 mm or 8 mm cells. During the initial sonications, observe location and magnitude of heating. Gradually ramp up the power for subsequent sonications if needed, but only if deemed safe.

- Verify that heating takes place in the intended location.

Select the power with the aim of producing relatively slow heating at the target location instead of rapid heating. The temperature rise to target temperature should be linear over the selected sonication duration.

Use the high powers in the Osteoid Osteoma application only if the lower powers do not produce high enough temperature elevation and when there are no major safety concerns (for example, excessive near field heating).

8.7.3. Sonication frequency

Ultrasound attenuation is a function of ultrasound frequency in biological tissues:

- Use lower frequencies when near-field heating is to be avoided, such as when targeting very shallow lesions with a higher risk of near-field heating,
- Also use lower frequencies when targeting lesions where ultrasound penetration into the bone needs to be higher, such as intramedullary or endosteal bone lesions, or lesions with thick neocortical growth.
- Use higher frequencies when far-field heating is to be avoided, such as in the presence of vulnerable structures or skin in the far-field.

9. Artifacts

9.1. Introduction to artifacts

The Sonalleve MR-HIFU software calculates the relative temperature change using MR dynamic phase images. The patient's measured body temperature is used as a basis for this calculation.

The temperature mapping calculation is susceptible to artifacts because the phase of an MR image is sensitive to disturbances such as transducer movement, magnetic field drift, and patient movement.

Run a temperature mapping scan before starting the therapy to estimate and reduce artifacts near the treatment area.

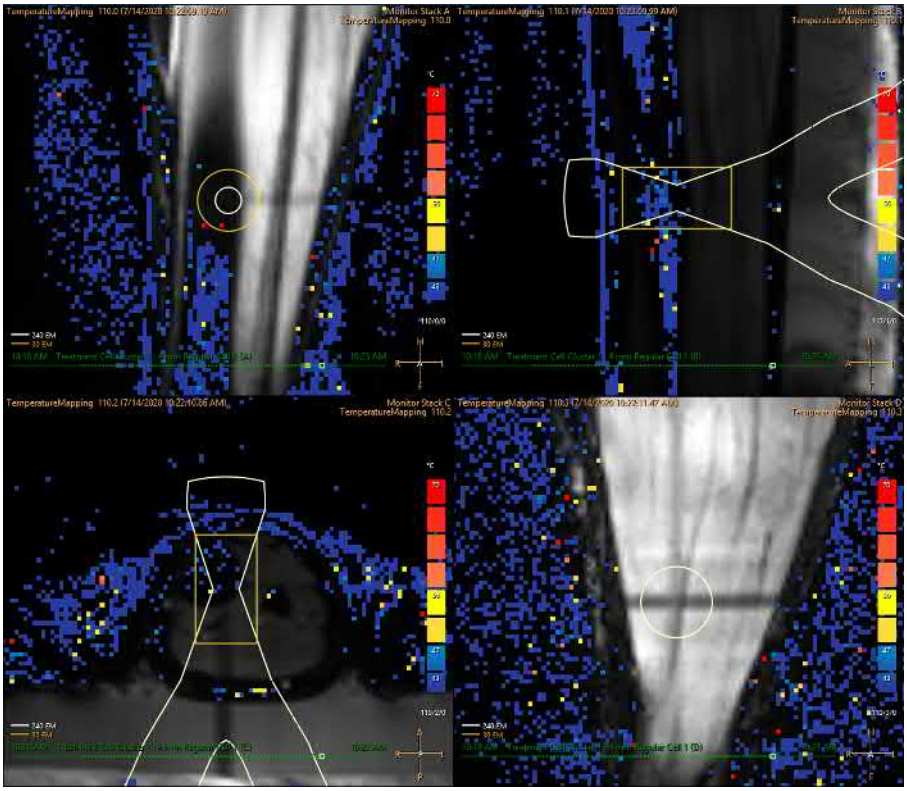

Fig. 40: Temperature map scan without sonication showing artifacts.

9.2. How to identify artifacts

Artifacts are presented as heating outside the intended treatment area. To ensure patient safety and to keep the treatment time as short as possible, it is important to be able to distinguish artifacts from actual heating.

Some common characteristics of artifacts:

- **Location:** Outside the transducer beam or far from the intended treatment area.

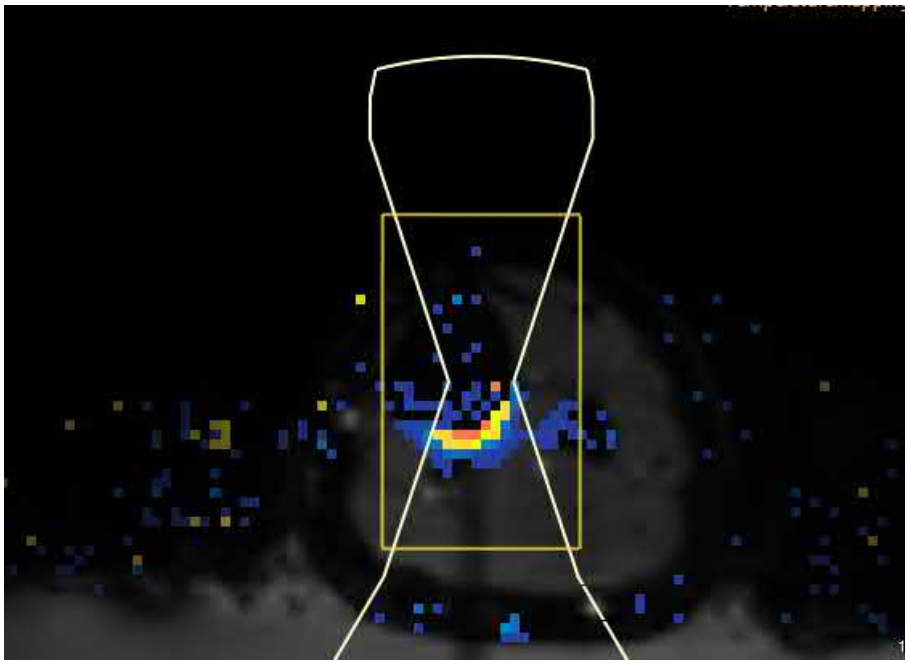

Fig. 41: Example of artifactual heating outside the ultrasound beam path.

- **Movement:** The shape and size of the artifact may fluctuate.
- **Rapid warming:** Artifacts may appear as if tissue is warming up very rapidly compared to the treatment area.

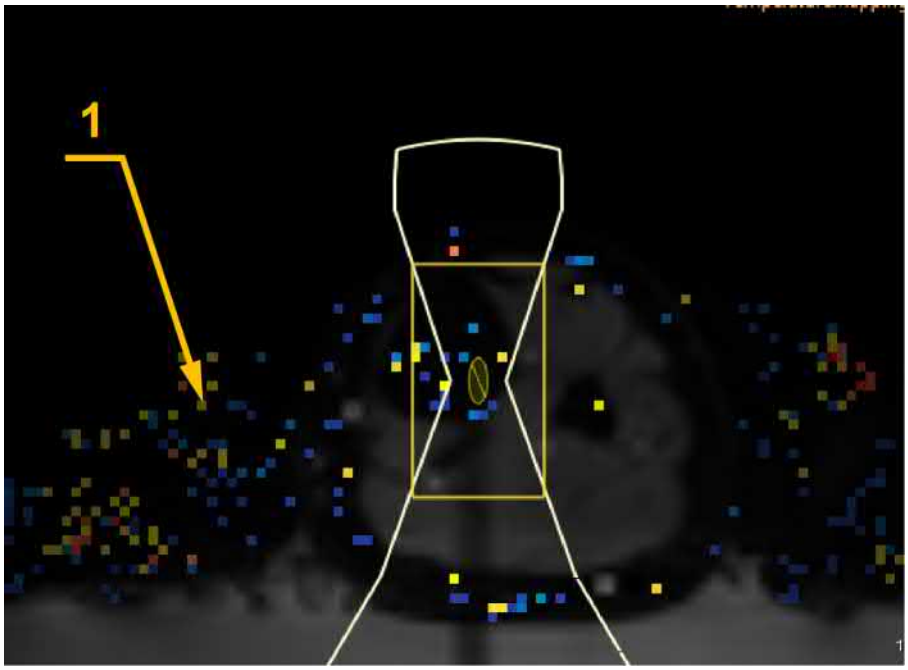

Fig. 42: Example of artificially rapid heating; artifactual heating is seen 3 seconds after sonication has started (1).

- **Slow cooling:** Tissues with artifactual heating do not appear to cool down like the focus area.

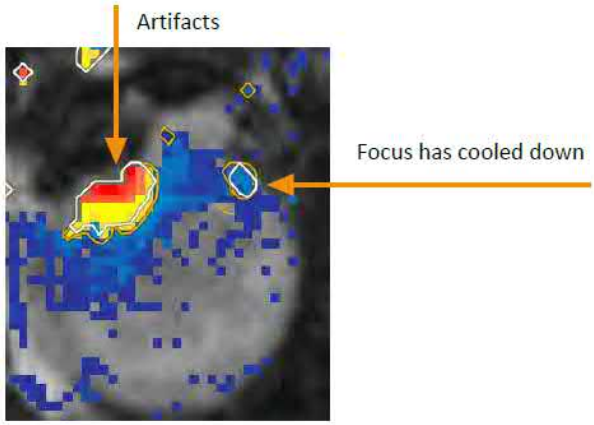

Fig. 43: Example of slow cooling. Artifactual heating still visible 90 seconds after sonication has ended.

9.2.1. Motion artifacts

- Motion can cause misplaced heating. Carefully observe the first temperature mapping dynamics and the 3D graphical markers, and abort sonication if motion is suspected.
- Motion is usually caused by breathing, flow, bowel movements, abdominal muscle tension, patient motion, or reaction to pain.
- When the motion is large, the whole image area may show artifactual heating after 1 or 2 dynamics. It usually stabilizes 1 to 2 dynamics after the motion has stopped.
- Motion can also take place prior to the actual scan, during the preparation phase. Such rare cases usually lead to severe temperature artifacts. The sonication should be immediately aborted as true heating is impossible to distinguish from the artifacts.

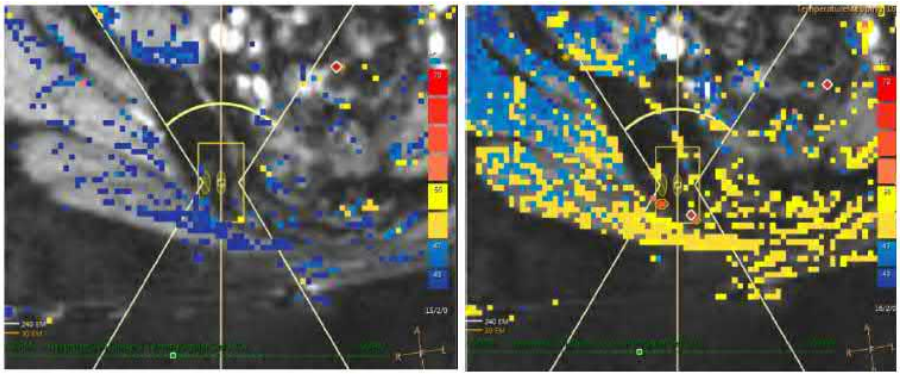

Fig. 44: Examples of artifacts caused by motion. Right: A lot of noise and rapid temperature change between two dynamic levels which indicates motion.

9.2.2. Bowel-related artifacts

- The bowels can cause two types of artifacts: susceptibility and motion. As a result, the temperature map may be inaccurate. The image itself will suffer from poor image quality due to susceptibility from air especially if there is a lot of intestinal gas. If there is a lot of rectal air, use a rectal tube to release the gas.
- Use the REST option for temperature mapping. Positioning the REST slab on top of the bowel might help to minimize these artifacts.

NOTICE
The scan time is longer with the REST option.

9.2.3. Breathing artifacts

The patient's position might make temperature mapping susceptible to breathing artifacts.

- Breathing typically results in fluctuating artifacts.
- Breathing might cause the target area to move in the head-feet direction, and the focus cannot follow that breathing motion. If the motion is so large that there is no proper heating, using breath-hold during the sonication might be an option.
- Use the REST option to minimize the artifact.

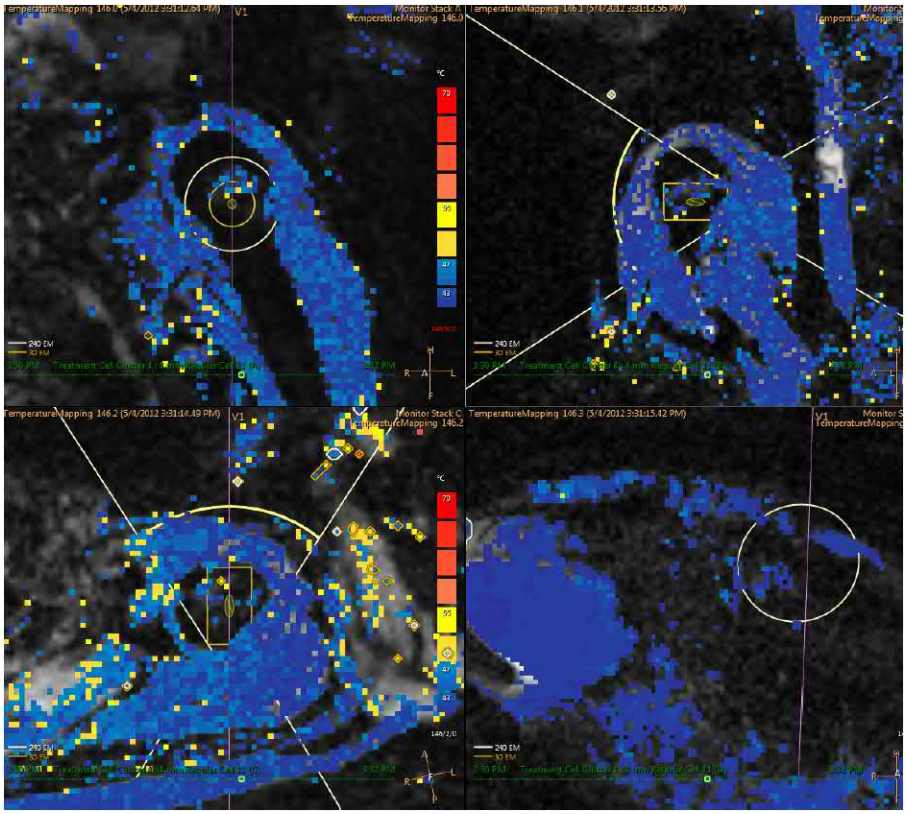

Fig. 45: Examples of breathing artifacts.

9.2.4. Flow artifacts

- Flow is not always visible in planning images. Scan temperature mapping scans without sonication and view all images without the temperature overlay.
- Flow might cause missing temperature information (colored pixels) or have a temperature pattern parallel to the flow direction.
- Use the REST option to minimize the artifact.

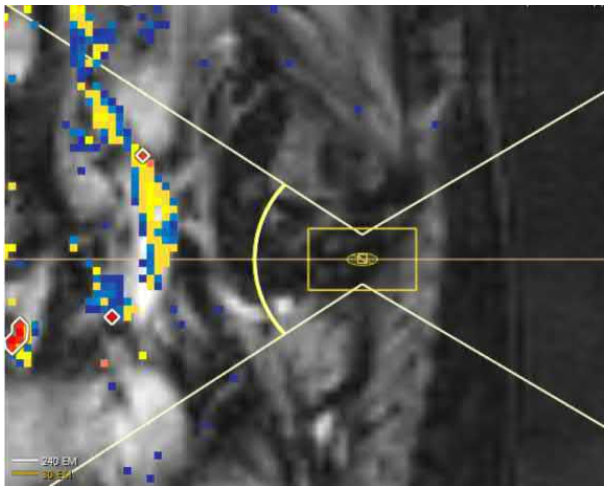

Fig. 46: Flow artifacts.

10. Related literature

Arrigoni et al, “Intra-articular benign bone lesions treated with Magnetic Resonance-guided Focused Ultrasound (MRgFUS): imaging follow-up and clinical results,” Med Oncol (2017) 34:55.

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Masciocchi et al, “Radiofrequency ablation versus magnetic resonance guided focused ultrasound surgery for minimally invasive treatment of osteoid osteoma: a propensity score matching study,” Eur Radiol (2016) 26:2472–2481.

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Scipione et al, “HIFU for Bone Metastases and other Musculoskeletal Applications,” Semin Intervent Radiol 2018;35:261–267.

Sharma et al, “Comparison of Noninvasive High-Intensity Focused Ultrasound with Radiofrequency Ablation of Osteoid Osteoma,” J Pediatr 2017;190:222-8.

Sharma et al, “Magnetic Resonance Imaging-guided High-intensity Focused Ultrasound Applications in Pediatrics: Early Experience at Children’s National Medical Center,” Top Magn Reson Imaging 2018;27:45–51.

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Temple et al., “MRI-guided High Intensity Focused Ultrasound treatment of osteoid osteoma in pediatric patients: preliminary results,” Journal of Therapeutic Ultrasound 2016, 4 (Supplement 1): A63.

Yarmolenko et al, “Technical aspects of osteoid osteoma ablation in children using MR-guided high intensity focussed ultrasound,” International Journal of Hyperthermia (2018) Volume 34—Issue 1, pp. 49-58.

11. Appendices

11.1. Preparation checklist for Osteoid Osteoma Therapy

In the preparation room

	OK	Comments
Depilation		
No creams on the skin		
Scars and skin folds		
IV line		
Medication		
Body temperature		
Weight		
Blood pressure		
Pulse		
MR contraindications		

Before positioning the patient

	OK	Comments
QA procedure performed		
Degassed water available		
Ultrasound gel available		
Gel pad upper surface wet (if gel pad used)		

Before the first sonication

	OK	Comments
PESB explained to the patient		
Communication device works		
No air bubbles in the ultrasound beam path		
OO lesion and/or nidus located		
Scar location determined		
Skin fold locations determined		

11.2. Items Recommended for Osteoid Osteoma Therapy

In the preparation room

- Bed and a chair
- Locker for storing the patient’s clothes and valuables
- Waste basket
- Supplies for IV line
- Supplies for medication
- Razor for shaving (single use)
- Bright light source to check the skin
- Thermometer to measure patient's body temperature (with good accuracy)
- Skin cleaning agent in case patient has used some skin lotion prior to the therapy

For the patient

- Hospital gown or pajamas (open from one side)
- Hearing protection

For the therapy

- Storage space (cupboard)
- EasyWater Degasser device, and table where to use it. This machine is about the same size as a coffee maker.
- Gel pads
- QA phantom
- Extra accessories (see *11.3. Sonalleve patient accessories*).
- Distilled water
- Ultrasound gel
- Absorbing towels to dry water from membrane and Table Top
- Absorbing material for use between the Table Top and mattress (for example, small, thin towels)
- Adhesive tape to fix the material between the Table Top and mattress
- Table Top mattress/membrane cleaning material
- Thin blanket
- MR compatible monitor to monitor patient vital signs (blood pressure, pulse, oxygen levels)
- Medications that might be needed during the therapy

11.3. Sonalleve patient accessories

The Sonalleve MR-HIFU accessories for positioning the patient:

Tab. 4: Sonalleve patient accessories.

Accessory	Description	
Mattress	Used on the Sonalleve Table Top. The wings can be filled from the vent at the head end for providing additional support for the patient.	
Foot rest	Placed under the patient's ankles or knees.	
Table Top extension pad	To increase the length of the table.	
Table Top extension plate	To increase the length of the table for optimal treatment position.	
Strap	Can be used to make the patient's position more stable.	
Vacuum cushions	As needed for patient comfort. Can be used inflated or deflated.	
Positioning pads	For isolating the coil cable from the patient and for patient comfort as needed.	
Upper coil strap	For attaching the coil.	
Cushions Small Cushions Large	Can be used for supporting the patient in a comfortable position. Not available in all countries.	
Flat surface	Used to create a flat surface for patient comfort.	
Gel pads (optional with the DISC device)	Placed between the ultrasound membrane window and the patient. Can be ordered separately in sets of 3. Check the availability of different thicknesses from your Profound representative.	

Fig. 47: Sonalleve Table Top with the extension pad.

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