Innovative, fast, and patient-friendly therapy

Key advantages

A patient-friendly, non-invasive treatment

Operational flexibility with easy switching between diagnostic and therapeutic use of the scanner

New service to attract new patients and referrals

Sonalleve MR-HIFU from Philips is an exciting, innovative technology that offers important advantages to clinicians and patients while supporting healthcare institutions in expanding their therapy portfolio. Patient-friendly and fast, Sonalleve MR-HIFU is proving to be an excellent option from virtually any angle.
Philips Sonalleve MR-HIFU

**Clinical applications/ key benefits**

- **Urinary fibroids and adenomyosis**: Out-patient procedure with short recovery time and symptom relief.
- **Bone metastasis**: Palliative treatments to relieve pain associated with bone metastases.

**Compatibility** Philips MR systems - Achieva 1.5T, Achieva 3.0T and Achieva 3.0T TX.

**Configuration overview**

- **Dedicated trolley-tabletop combination**
  - Comes with its own trolley for transport and storage when the Philips MR system is in use for imaging.
  - Allows patient preparation outside the MR room and saves valuable MR time.
  - Table is positioned over the lowered MR patient support.
  - Large treatment window gives great flexibility to position even extreme lateral anatomies, providing a wide treatment area.
  - Robotic positioning system positions the HIFU transducer with five degrees of freedom and high accuracy, covering a large treatment field.
  - Curved tabletop with a selection of mattresses of different types and shapes support various patient positions.

- **HIFU therapy transducer**
  - Philips proprietary design, model SX140.
  - Focal length 140 mm.

- **Direct Skin Cooling (DISC)**
  - Ultrasound window in the table is equipped with a double membrane and cooled water circulating in-between, providing an efficient heat sink and constant temperature to the patient’s skin.

- **Sonalleve therapy console**
  - Hardware and software for treatment planning, temperature mapping, ablation feedback, therapy guidance and communication with Philips MR scanner.

- **Electronics cabinet**
  - Located in the MR equipment room and includes power supplies, power electronics for the HIFU transducer and control units for precise mechanical positioning of the transducer.

- **Filter panel for the RF shield**
  - Separate filter panel for power to the transducer and control commands for the mechanical positioning system.

- **Ultrasound transducer**
  - Philips proprietary design, model SX140.
  - 256 transmit elements.
  - Phased array technology with digital control of amplitude and phase of each element individually for a sharp focus and fast modulation of ultrasound field.
  - Operates at multiple frequencies between 1.2 MHz and 1.5 MHz.
  - Modifies penetration depth and focus shape.
  - Focal length of 140 mm.
  - To reach target regions deep inside the body.

**Heating method**

- **Volumetric heating**
  - Focal spot is moved rapidly in concentric circles to reach homogenous temperature over macroscopic volume (treatment cell) in a short time.

- **Treatment cell sizes**
  - Focus trajectories utilize heat diffusion to reach maximal ablation efficiency. Multiple cell sizes with diameters of 4, 8, 12, 14 and 16 mm are available. The cell length is typically 2.5 times the diameter.

**Feedback**

- **Real-time feedback**
  - Temperature and thermal dose are measured in real time and used to adjust sonication parameters during a sonication event to achieve desired ablation temperature and volume, independent of local variations in tissue properties.

- **HIFU - MR interface**
  - Fast, dedicated, real-time interface between Sonalleve MR-HIFU and Achieva MR console.
  - Allows fast scanner control and image retrieval to support real-time feedback.

**Imaging sequences**

- **Treatment planning on 3D diagnostic MR images**
  - All standard diagnostic imaging sequences of the MR system are available for treatment planning.
  - Dedicated ExamCards are provided for HIFU applications.

- **PRFS temperature monitoring**
  - FFE-EPI-based phase sensitive MR sequences.
  - Temperature and thermal dose maps are calculated based on the temperature sensitive Proton Resonance Frequency Shift thermometry for target heating.

- **T2 based temperature monitoring**
  - Reproducible, longterm temperature measurement in adipose tissue.
  - Based on T2 weighted MRI imaging data measuring cumulative heating over the whole treatment duration together with Proton Resonance Frequency Shift thermometry for target heating.

- **Software and user interface**
  - Dedicated protocols and ExamCards for Philips MR systems.
  - Excellent scanning efficiency and ease of use.

**Mechanical movement**

- Five degrees of freedom: up/down range 50 mm, left/right range 135 mm, head/feet range 135 mm, tilting ±15°.

**Electronic deflection**

- Up to 20 mm in each direction.

**Fast beam steering**

- Continuous electrical movement of focus possible for volumetric heating.

**DISC**

- Direct Skin Cooling - Patient’s skin is kept at a constant temperature of about 20 °C.

- Direct coupling - For cooling efficiency, the patient is positioned directly onto the membrane, most patients don’t require a gel pad.

**Heating curve**

- Displays the temperature and thermal dose over time during a single sonication.

**Philips Sonalleve MR-HIFU**

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- Up to 20 mm in each direction.

- Continuous electrical movement of focus possible for volumetric heating.

- Patient’s skin is kept at a constant temperature of about 20 °C.

- For cooling efficiency, the patient is positioned directly onto the membrane, most patients don’t require a gel pad.

- Focal spot is moved rapidly in concentric circles to reach homogenous temperature over macroscopic volume (treatment cell) in a short time.

- Focus trajectories utilize heat diffusion to reach maximal ablation efficiency. Multiple cell sizes with diameters of 4, 8, 12, 14 and 16 mm are available. The cell length is typically 2.5 times the diameter.

- Temperature and thermal dose are measured in real time and used to adjust sonication parameters during a sonication event to achieve desired ablation temperature and volume, independent of local variations in tissue properties.

- Fast, dedicated, real-time interface between Sonalleve MR-HIFU and Achieva MR console.

- Allows fast scanner control and image retrieval to support real-time feedback.

- All standard diagnostic imaging sequences of the MR system are available for treatment planning.

- Dedicated ExamCards are provided for HIFU applications.

- Full workflow integration of novel fat tissue thermometry based on T2 weighted MRI imaging data measuring cumulative heating over the whole treatment duration together with Proton Resonance Frequency Shift thermometry for target heating.

- Temperature and thermal dose maps are calculated based on the temperature sensitive Proton Resonance Frequency Shift induced phase difference.

- Three coronal and one sagittal slice through focus, two slices freely positioned, such as near field and far field.

- Temperature changes ±1 °C.

- Based on T2 weighted MRI.

- Calibrated absolute temperature measurement, for adipose tissue.

- Fully integrated and automated treatment workflow.

- ±2 °C.

- Based on 3D diagnostic MR images.

- Tools for efficient planning of treatment volumes, beam paths, and transducer positions.

- Tools to verify a beam path free of obstruction to maintain patient safety.

- Calculates the size and position of multiple treatment cells to cover the desired treatment volume.

- OAR (Organ Avoidance Region) or Critical OAR regions can be drawn to protect sensitive regions, such as scars and skin folds from high ultrasound exposure.

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Software and user interface cont.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Near field and far field monitoring</td>
<td>Two imaging slices can be freely positioned to monitor sensitive structures in real time</td>
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<tr>
<td>Motion detection</td>
<td>System monitors motion during sonication and issues a warning if it exceeds permitted limits</td>
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<td>Re-registration</td>
<td>Adapt to possible patient movement between acquired planning images; re-register existing plan to new anatomical position and images</td>
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<tr>
<td>Automatic overheating control</td>
<td>System terminates the sonication if excessive heating is observed</td>
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| Fat tissue scan and cooling time estimation  | - Automatic fat tissue temperature monitoring scan after each sonication  
- Estimates appropriate cool-down time before the next sonication should start |
| Clinical report                              | - System generates a summary of the clinical treatment data after treatment is finished  
- Can be exported as PDF* |

MR system requirements

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirements</th>
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</table>
| MR system software            | - Philips Achieva 1.5T, 3.0T or 3.0T TX: MR system software release R3.2.2, or higher  
- Philips Multiva 1.5T: MR system software release 5.1.7, or higher  
- Philips Ingenia 1.5T or 3.0T: MR system software release R4.1.2, or higher  
- Achieva 1.5T and Achieva 3.0T TX SmartPath to dStream: MR system software release R5.1.7, or higher  
- Ingenia 1.5T CX and Ingenia 3.0T CX: MR system software release R5.1.7, or higher |

Electricity

- Dedicated power line 3~ 380-415V~/ 480V~/ 5.5kW / 50/60 Hz

Dimensions and weights

<table>
<thead>
<tr>
<th>Component</th>
<th>Dimensions (H x W x D in m)</th>
<th>Dimensions (H x W x D in inches)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generator Cabinet</td>
<td>1.40 x 0.60 x 0.90</td>
<td>55 x 24 x 35</td>
<td>308 kg</td>
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<tr>
<td>Sonalleve Tabletop</td>
<td>1.078 x 0.85 x 2.751</td>
<td>42 x 33 x 108</td>
<td>236 kg</td>
</tr>
<tr>
<td>HIFU Filter Panel</td>
<td>0.55 x 0.46 x 0.25</td>
<td>22 x 18 x 10</td>
<td>13.6 kg</td>
</tr>
</tbody>
</table>

Note:
The Philips Sonalleve MR-HIFU system or some of its applications are not for sale in certain countries. To determine availability in your area, please contact your local Philips representative. This material is not intended for distribution in the U.S.A.