

SONALLEVE™

PROFOUND



Sonalleve MR-HIFU

Instructions for Use

English / Release 3.6

SONALLEVE MR-HIFU

107378A



Profound Medical Inc.
2400 Skymark Avenue, Unit 6
Mississauga, ON, Canada, L4W 5K5

www.profoundmedical.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Tel.: +49 511 6262 8630

Fax: +49 511 6262 8633

www.mdss.com

© 2019, Mississauga, Canada.

All rights reserved. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from Profound Medical Inc.

Table of contents

| | |
|---|-----------|
| 1. Introduction to Sonalleve MR-HIFU | 5 |
| 1.1. About Sonalleve MR-HIFU | 5 |
| 1.2. About this manual | 5 |
| 1.2.1. Notations | 6 |
| 1.3. Intended use | 7 |
| 1.3.1. Sonalleve Uterine Application | 8 |
| 1.3.2. Sonalleve Bone Application | 9 |
| 1.4. Operator profile | 10 |
| 1.5. Compatibility | 10 |
| 1.6. Compliance | 11 |
| 1.7. Training | 11 |
| 1.8. Installation instructions | 11 |
| 1.9. System classification | 11 |
| 2. Safety | 13 |
| 2.1. General safety | 13 |
| 2.2. Contraindications and restrictions | 15 |
| 2.3. Heat and Specific Absorption Rate (SAR) | 15 |
| 2.3.1. Specific Absorption Rate (SAR) | 16 |
| 2.3.2. Specific Energy Dose (SED) | 16 |
| 2.3.3. Heat load induced by ultrasound | 16 |
| 2.3.4. Cooling the patient | 17 |
| 2.3.5. Clothing and environmental conditions | 17 |
| 2.4. Contrast agents and medication | 17 |
| 2.5. Emergency Stop and Safety Devices | 18 |
| 2.5.1. Patient Emergency Stop Button (PESB) | 18 |
| 2.5.2. Safety Device (SD) | 19 |
| 2.5.3. Software Abort Sonication button | 20 |
| 2.6. Emergency procedures | 20 |
| 2.7. Magnetic safety | 20 |
| 2.8. Mechanical and electrical safety | 21 |
| 2.9. Protecting the equipment against liquids | 21 |
| 2.10. Chemical safety | 22 |
| 2.11. Explosion safety | 22 |
| 2.12. Fire safety | 22 |
| 2.13. Battery safety | 23 |
| 2.14. Electromagnetic compatibility (EMC) | 23 |
| 2.15. Network safety, data security and privacy | 23 |
| 2.15.1. Malware detection | 25 |
| 2.15.2. Remote Desktop | 25 |
| 2.16. Reporting of incidents | 25 |
| 2.17. Safety improvements | 25 |
| 2.18. Symbols and labels on the equipment | 26 |
| 3. System overview | 33 |
| 3.1. Main system components | 33 |
| 3.1.1. Tabletop assembly | 34 |
| 3.1.2. Sonalleve Console | 38 |
| 3.1.3. Sonalleve Generator Cabinet | 39 |

| | |
|--|-----------|
| 3.2. Patient accessories | 39 |
| 3.2.1. Acoustic contact liquid | 40 |
| 3.3. Other accessories | 41 |
| 3.3.1. The DISCfill tool | 42 |
| 3.4. Technical specifications | 42 |
| 3.4.1. Ultrasound field distributions | 42 |
| 4. Treatment methods | 45 |
| 4.1. Basic concepts | 45 |
| 4.2. Patient selection | 48 |
| 4.3. Treatment cell types and clusters | 48 |
| 4.4. Sonication method | 49 |
| 4.5. Electronic deflection | 49 |
| 4.6. Temperature monitoring | 50 |
| 4.6.1. Thermal dose limits | 50 |
| 4.6.2. Thermal dose and temperature monitoring | 51 |
| 4.6.3. Monitoring near-field heating | 53 |
| 4.6.4. Cooling time | 54 |
| 4.6.5. Temperature limits | 55 |
| 4.7. Motion detection | 55 |
| 4.7.1. Misplaced heating or motion artefact? | 55 |
| 5. User interface | 57 |
| 5.1. Overview | 57 |
| 5.2. Starting the Sonalleve MR-HIFU application | 57 |
| 5.2.1. Selecting the configuration | 57 |
| 5.2.2. Selecting between the Therapy and Standalone mode | 58 |
| 5.3. Exiting Therapy | 60 |
| 5.4. Exiting the Sonalleve MR-HIFU application | 61 |
| 5.5. Therapy application screen layout | 61 |
| 5.6. Therapy Wizard | 62 |
| 5.7. Viewing images | 63 |
| 5.7.1. Basic viewing tools | 63 |
| 5.7.2. Advanced viewing tools | 64 |
| 5.7.3. Overlay tools | 65 |
| 5.8. Adding, selecting and removing objects | 70 |
| 5.9. Controlling and monitoring the sonication | 71 |
| 5.9.1. System Status Display | 72 |
| 5.9.2. Sonication buttons | 73 |
| 5.9.3. Temperature and thermal dose | 74 |
| 5.9.4. Temperature curve | 75 |
| 5.9.5. Message area | 76 |
| 5.10. Reporting and logging | 77 |
| 5.10.1. Generating reports | 77 |
| 5.10.2. Taking snapshots | 77 |
| 5.10.3. Viewing and exporting logs | 78 |
| 5.11. Saving and recovering your work | 78 |
| 5.12. Language settings | 82 |
| 5.13. Keyboard shortcuts | 82 |
| 6. Workflow | 84 |
| 6.1. Overview | 84 |
| 6.2. Preparing the equipment | 84 |
| 6.2.1. Connecting the Sonalleve tabletop | 84 |

| | |
|---|------------|
| 6.2.2. Connecting Tabletop Extension Plate (only in Bone application) | 87 |
| 6.2.3. Preparing the tabletop for the patient | 88 |
| 6.3. Preparing the patient | 90 |
| 6.3.1. Positioning the patient on the table | 90 |
| 6.3.2. Verifying the patient positioning | 92 |
| 6.4. Scanning the planning images | 95 |
| 6.5. Preparing the monitor scan | 95 |
| 6.6. Therapy planning | 100 |
| 6.6.1. Starting Therapy in the Sonalleve MR-HIFU application | 100 |
| 6.6.2. Entering patient information | 101 |
| 6.6.3. Retrieving the image sets | 102 |
| 6.6.4. Defining the Planning Target Volume | 103 |
| 6.6.5. Defining the Tissue Boundary | 103 |
| 6.6.6. Positioning the treatment volume | 106 |
| 6.6.7. Beam shaping | 110 |
| 6.7. Preparing the system for sonication | 112 |
| 6.7.1. Hardware Initialization | 112 |
| 6.7.2. Scanning Temperature Mapping | 113 |
| 6.7.3. Test sonication | 114 |
| 6.8. Therapy | 117 |
| 6.8.1. Replanning | 118 |
| 6.8.2. Planning the sonication order | 118 |
| 6.8.3. Determining the correct frequency level for a treatment cell | 118 |
| 6.8.4. Determining the correct power level for a treatment cell | 118 |
| 6.8.5. Sonicating | 120 |
| 6.8.6. Reviewing the sonication results during the cooling time | 121 |
| 6.8.7. Registration | 122 |
| 6.8.8. Scanning other protocols from the Sonalleve console | 125 |
| 6.8.9. Saving the treatment data | 125 |
| 6.9. Post treatment | 126 |
| 6.10. Error recovery | 126 |
| 6.11. Removing the Sonalleve tabletop | 127 |
| 6.12. Sonalleve Tabletop storage | 127 |
| 7. Maintenance | 129 |
| 7.1. Routine maintenance | 129 |
| 7.1.1. Planned Maintenance Program | 129 |
| 7.1.2. User Routine Checks Program | 129 |
| 7.2. Sonalleve MR-HIFU Quality Assurance (QA) procedure | 134 |
| 7.2.1. Preparing the QA phantom for use | 135 |
| 7.2.2. Performing the QA Test | 139 |
| 7.2.3. QA Test troubleshooting | 143 |
| 7.2.4. Storing the QA phantom | 144 |
| 7.3. Cleaning and disinfection | 144 |
| 7.3.1. Cleaning the system | 145 |
| 7.3.2. Cleaning the vacuum cushion | 146 |
| 7.3.3. Cleaning the DISCfill tool | 146 |
| 7.4. Making degassed acoustic contact liquid | 146 |
| 7.5. Ultrasound protection | 147 |
| 8. System Error and Warning messages | 149 |

| | |
|--|------------|
| 8.1. Errors | 149 |
| 8.2. Warnings | 150 |
| 8.3. Informational messages | 150 |
| 9. Product disposal | 152 |
| 9.1. Introduction | 152 |
| 9.2. Passing the product on to another user | 152 |
| 9.3. Final disposal of the product | 152 |
| 9.4. Disposal of patient accessories | 153 |
| 9.5. Disposal of the Sonalleve QA Phantom | 153 |
| 10. Appendices | 156 |
| 10.1. Using the air pump with air bags and vacuum cushions | 156 |
| 10.2. Temperature conversion | 158 |
| 10.3. Comparing thermal dose volumes and non-perfused volumes | 158 |
| 10.3.1. Estimating thermal dose volumes | 158 |
| 10.3.2. Calculating non-perfused volumes (NPV) | 158 |
| 10.3.3. Estimating NPV on Sonalleve console | 159 |
| 10.4. QA Test result table | 161 |
| 10.5. Copying Sonalleve MR-HIFU treatment data to DVD | 161 |
| 10.5.1. Copying DICOM images | 161 |
| 10.5.2. Copying saved state data | 162 |
| 10.6. Security and privacy features | 164 |
| 10.6.1. Access control | 164 |
| 10.6.2. Audit trail | 165 |
| 10.6.3. Network time synchronization | 165 |
| 10.6.4. Other Security and Privacy features addressed | 165 |
| 10.7. Hospital administrator and user accounts | 167 |
| 10.7.1. About accounts | 167 |
| 10.7.2. Creating a new user/administrator account | 167 |
| 10.7.3. Deleting an account | 168 |
| 10.8. Features for advanced users and administrators | 168 |
| 10.8.1. Partial standalone modes | 168 |
| 10.8.2. Changing the Site Default Configuration | 169 |
| 10.8.3. Automatic backup of configuration changes in Research mode | 170 |
| 10.9. Advanced maintenance procedures | 170 |
| 10.9.1. Adding water to DISCfill | 171 |
| 10.9.2. Removing air from the filling hose | 171 |
| 10.10. Error and Warning messages | 172 |
| 10.11. Legal notices | 187 |
| 10.11.1. Profound REACH statements | 187 |

1. Introduction to Sonalleve MR-HIFU

1.1. About Sonalleve MR-HIFU

The Sonalleve MR guided High Intensity Focused Ultrasound (MR-HIFU) System has the following therapeutic applications:

- MR guided treatment of uterine fibroids and uterine adenomyosis
- MR guided pain palliation of bone metastasis

Sonalleve MR-HIFU is designed to be used with Philips MR scanners.

The use of MR-HIFU requires the following equipment:

- Achieva 1.5 T/3.0 T or Ingenia 1.5 T/3.0 T MR scanner.
- Sonalleve MR-HIFU system.

This manual will guide you in the use of the Sonalleve MR-HIFU system. In addition, all the instructions and safety precautions for the MR scanner apply when working with the Sonalleve MR-HIFU system. For more information, refer to the MR scanner's *Instructions for Use*.

1.2. About this manual

This manual applies to the following MR-HIFU system configurations:

- SONALLEVE MR-HIFU V2 ACHIEVA 1.5T
- SONALLEVE MR-HIFU V2 ACHIEVA 3T
- SONALLEVE MR-HIFU V2 INGENIA 1.5T
- SONALLEVE MR-HIFU V2 INGENIA 3T

This manual provides information on the correct and safe use of the Sonalleve MR-HIFU system. These *Instructions for Use* are intended to assist users in the safe and effective operation of the product described.

Before attempting to operate the system, you must read these *Instructions for Use*, noting and strictly observing all WARNINGS and CAUTION notices.

Pay special attention to all the information given and procedures described in 2. *Safety*.

- The intended use and standards compliance of the Sonalleve MR-HIFU product are described in 1. *Introduction to Sonalleve MR-HIFU*. This chapter also explains the textual conventions used in this manual.
- The safety aspects of using the Sonalleve MR-HIFU system are described and important instructions for the safe use of the product are given in 2. *Safety*.
- An overview of the system components is given in 3. *System overview*.
- The key terms and concepts related to working with Sonalleve MR-HIFU and an outline of the different treatment methods are provided in 4. *Treatment methods*.

- The basic organization and functions of the User Interface are explained in *5. User interface*.
- You are guided through the entire treatment workflow from system and patient preparation to post-treatment check-ups in *6. Workflow*.
- Regular daily, weekly and monthly maintenance instructions for ensuring reliable and fault-free operation of the system are provided in *7. Maintenance*.
- The error and warning messages are described in *8. System Error and Warning messages*.
- For information on the safe and environmentally sound disposal of the product, refer to *9. Product disposal*.
- Additional information on certain topics is provided in *10. Appendices*.

These *Instructions for Use* describe the most extensive configuration of the product, with the maximum number of options and accessories. Not every function described may be available on your product.

Important

Apart from this manual, **Profound Medical** also produces a *Technical Description* (in English only). It provides additional data essential for safe operation and the measures or conditions necessary for installing the Sonalleve MR-HIFU system for use with the MR scanner.

1.2.1. Notations



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.


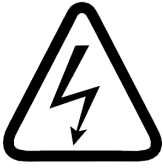


Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or may cause environmental pollution.

NOTICE

NOTICES highlight unusual points as an aid to the user.

WARNINGS and CAUTIONS in this *Instructions for Use* are each marked with one of the following symbols, according to the cause of the safety hazard or the potential outcome:

| | |
|--|--|
| | General symbol for WARNINGS and CAUTIONS |
|--|--|

| | |
|---|-------------------|
|  | Crushing of hands |
|  | Electricity |
|  | Laser beam |
|  | Magnetic field |

1.3. Intended use

This Profound Medical product is intended to be installed, used and operated only in accordance with the safety procedures and operating instructions given in this Instructions for Use for the purpose for which it was designed. The purpose for which the product is intended is given below. However, nothing stated in this Instructions for Use reduces users' responsibilities for sound clinical judgment and best clinical procedure.

The system is designed to be used on patients with no MR contraindications and that fulfill the criteria for treatment as indicated in chapter 2. *Safety*.

Installation, use and operation of this product is subject to the law in the jurisdiction in which the product is being used. Users must only use and operate the product in such ways that do not conflict with applicable laws, or regulations, which have the force of law.

Uses of the product for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or its agent) from all or some responsibility for resultant non-compliance, damage or injury.

The intended use is subject to regulatory approval and can have country-specific limitations.

In the Republic of Korea and in the People's Republic of China, the intended use of the Sonalleve MR-HIFU therapy system is uterine fibroids only. Disregard all references to the treatment of adenomyosis and to the Bone application.



CAUTION

In the United States of America:

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

NOTICE

This Sonalleve MR-HIFU System is NOT intended for diagnostic imaging. Several image quality and other performance compromises have been made, which make this system inadequate for general diagnostics.

1.3.1. Sonalleve Uterine Application

The Sonalleve MR-HIFU Uterine Therapy Application is indicated for the ablation of symptomatic uterine fibroids or adenomyotic tissue in pre- or peri-menopausal women who desire a uterine sparing treatment.

Women planning future pregnancy should consult with their physician before seeking MR-HIFU treatment.

NOTICE

Please look at the list of contraindications in 2.2. *Contraindications and restrictions.*

Adverse Effects

HIFU treatment may be associated with spontaneous detachment or expulsion of a pedunculated intra-uterine fibroid. Patients may need to be informed about the possibility of detachment or expulsion and, if considered clinically necessary, monitored after the treatment.

Although the MR-HIFU treatment of uterine fibroids is generally safe and often causes the patient little or no pain, potential adverse effects have been reported in literature. Most of these effects are transitory and can be avoided with careful treatment planning.

This list of adverse effects and the estimates on their frequency of occurrence are based on reports in literature. References to the relevant literature will be supplied on request by your local Profound Medical application support representative.

Tab. 1: Potential adverse effects of MR-HIFU treatment, Uterine application.

| Frequency | Occurrence in patients | Source | Adverse effects |
|---|------------------------|----------|---|
| Potential transitory effects | ~ 30% of patients | HIFU | <ul style="list-style-type: none"> • Nausea or vomiting • Pain • Leg and buttock pain • Neck and back pain (tension) • Abdominal tenderness |
| Less frequent transitory effects | < 10% of patients | HIFU | <ul style="list-style-type: none"> • First degree skin burns • Swelling • Abdominal cramping • Thermal injury to internal tissue • Above baseline vaginal bleeding |
| | | Catheter | <ul style="list-style-type: none"> • Urinary difficulty |

| | | | |
|----------------------------|------------------|------------|--|
| Very rare effects | < 3% of patients | HIFU | <ul style="list-style-type: none"> • Second degree skin burns • Sciatic nerve damage • Injury to abdominal and pelvic organs (bladder, uterus, bowel) • Pain not reacting to drugs |
| | | Gadolinium | <ul style="list-style-type: none"> • Adverse drug reaction to Gadolinium |
| | | Catheter | <ul style="list-style-type: none"> • Urinary symptoms, such as infection or hematuria • Other infections • Fever caused by infection • Bleeding |
| Exceptional effects | < 1% of patients | HIFU | <ul style="list-style-type: none"> • Third degree skin burns • Metabolic imbalance (Tumor Lysis Syndrome) |

1.3.2. Sonalleve Bone Application

The Sonalleve MR-HIFU Bone Pain Palliation Therapy Application is indicated for palliative treatments to relieve pain associated with bone metastasis.

Adverse effects

Although the MR-HIFU treatment of bone metastases 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.

This list of adverse effects and the estimates on their frequency of occurrence are based on reports in literature. References to the relevant literature will be supplied on request by your local Profound Medical application support representative.

Tab. 2: Potential adverse effects of MR-HIFU treatment, Bone application.

| Frequency | Occurrence in patients | Source | Adverse effects |
|-------------------------------------|------------------------|--------|--|
| Potential transitory effects | ~ 50% of patients | HIFU | <ul style="list-style-type: none"> • Pain • Leg and buttock pain • Nausea or vomiting • Tenderness near the treatment area |

| | | | |
|---|-------------------|------------|--|
| Less frequent transitory effects | < 10% of patients | HIFU | <ul style="list-style-type: none"> • Swelling • Thermal injury to internal tissue • Abdominal cramping |
| | | Catheter | <ul style="list-style-type: none"> • Urinary difficulty |
| Very rare effects | < 3% of patients | HIFU | <ul style="list-style-type: none"> • First degree skin burns • Unintended nerve damage • Injury to organs near the treatment area • Pain not reacting to drugs |
| | | Gadolinium | <ul style="list-style-type: none"> • Adverse drug reaction to Gadolinium |
| | | Catheter | <ul style="list-style-type: none"> • Urinary symptoms, such as infection or hematuria • Other infections • Fever caused by infection • Bleeding |
| Exceptional effects | < 1% of patients | HIFU | <ul style="list-style-type: none"> • Second and third degree skin burns • Metabolic imbalance (Tumor Lysis Syndrome) |

1.4. Operator profile

The Sonalleve MR-HIFU operator can be a person with professional qualifications for and experience in MR imaging. All operators treating patients with Sonalleve MR-HIFU must have received training by Profound Medical in the safe use of the system.

In addition, hospital technicians, clinical scientists, application specialists and service personnel who have attended Sonalleve MR-HIFU training may use the system for testing, upgrades, maintenance and routine Quality Assurance (QA). For more information, see 7. *Maintenance*.

1.5. Compatibility

The Sonalleve MR-HIFU System is available for Philips Achieva and Ingenia MR scanners.

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Profound Medical. A list of such products and components is available from Profound Medical.

The other products and components that may be used with the system may each have their own *Instructions for Use*.

Changes and/or additions to the product should only be carried out by Profound Medical or by third parties expressly authorized by Profound Medical to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.



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.

1.6. Compliance

The Profound Medical Sonalleve MR-HIFU system complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Profound Medical representative.

1.7. Training

Users of this product must have received adequate training on its safe and effective use before attempting to operate the product described in this *Instructions for Use*. Training requirements for this type of device will vary from country to country. Users must make sure they receive adequate training in accordance with local laws or regulations.

If you require further information about training in the use of this product, please contact your local Profound Medical representative.

1.8. Installation instructions

The installation instructions for the Sonalleve MR-HIFU system are supplied by Profound Medical in separate documentation.

The installation must only be performed by appropriately trained personnel. Profound Medical can only accept responsibility for basic safety, reliability and performance, if:

- Qualified personnel carry out assembly operations, extensions, readjustments or repairs,
- The electrical installation of the technical room complies with the appropriate requirements, and:
- The Sonalleve MR-HIFU system is used in accordance with the *Instructions for Use*.

1.9. System classification

According to the classification in the international/European standard IEC/EN 60601-1:

Tab. 3: Equipment classification.

| EQUIPMENT CLASSIFICATION |
|---|
| Classification according to IEC 60601-1, Medical electrical equipment |

1. Introduction to Sonalleve MR-HIFU > 1.9. System classification

| | |
|---|--|
| Protection against electrical shock | System: Class 1 Medical Electrical Equipment. |
| | Applied parts: type BF. |
| Protection against harmful ingress of water or particulate matter | Ordinary equipment (enclosed equipment without protection against ingress of water, IPX0). |
| Methods of sterilization or disinfection | Not intended to be sterilized. Use of liquid surface disinfectants only. |
| Mode of operation | Continuous operation. |

2. Safety

2.1. General safety

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

Make sure that all of the electrical and mechanical assemblies and parts of the Sonalleve MR-HIFU system are used with care and routinely inspected according to the instructions in this manual.



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.

Make sure that all personnel who use the equipment:

- Are instructed in the proper usage of the equipment hardware and software.
- Are aware of the limitations in the performance of the hardware and software.
- Are aware of and observe all warnings and cautions that appear in this manual.
- Are aware of the safety issues, instructions and limitations listed in this manual.
- Are familiar with the MR scanner's *Instructions for Use* as well as other manuals provided with the MR imaging systems.

Before using the Sonalleve MR-HIFU system with a MR scanner, you should have a basic knowledge of the MR system and its performance.



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 this SAFETY section.

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 (see 7.5. *Ultrasound protection* for details). Do not sonicate the absorption pad or the large positioning pad on purpose.

When using the system for volunteer scanning, place another thin positioning pad, a thick towel or cloth on top of the protectively used large positioning pad or absorption pad to prevent skin contact. Do not place the absorption pad or the large positioning pad in the ultrasound beam, the pads can become burning hot if exposed to ultrasound.



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. See also 7.5. *Ultrasound protection*. Do not sonicate a positioning pad on purpose.

2.2. Contraindications and restrictions

This Profound Medical product should not be used if any of the following contraindications exist or are thought to exist:

- Pregnancy
- MR contraindications specified in the MR scanner's *Instructions for Use*
- For patients who express a desire for future pregnancy the HIFU treatment should not be targeted at the endometrium or other parts of uterus where the patient's clinical situation would prognosticate an increased risk of inability to conceive, of miscarriages, or of preterm deliveries because of the treatment.

NOTICE

If the said evaluation of the patient's clinical situation by a physician knowledgeable of HIFU suggests that the foreseeable treatment benefits outweigh the possible risks, the patient should be informed about the risks and benefits and his or her consent recorded according to the local practices.



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.

NOTICE

If the physician's evaluation indicates that the patient is in the risk group, the risk and benefits should be explained to the patient.

2.3. Heat and Specific Absorption Rate (SAR)



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.

NOTICE

If the physician's evaluation indicates that the patient is in the elevated risk group, the rationale for cooling should be explained to the patient.



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.

2.3.1. Specific Absorption Rate (SAR)

Both the MR system and the Sonalleve MR-HIFU system produce thermal energy, which is absorbed by the patient during treatment. The International/European standard *IEC/EN 60601-2-33 Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis* defines limits for the acceptable tissue and body temperature rise caused by the Specific Absorption Rate (Definition of SAR see: *IEEE C.95.1-1999*) of radio frequency power per unit mass of an object. The standard sets limits for the maximum allowed rise of the patient's core temperature. The MR scanner achieves compliance with these requirements by controlling the SAR of the MR protocols.

The SAR limits of the MR scanner are defined for conditions with a specific room temperature 24 °C (75.2 °F) and humidity 60% and minimal air flow. In addition, the patient is assumed to be lightly clothed. The standard uses 6 minutes as the averaging period for determining the SAR for all tissues. For a detailed description of the SAR operating modes and temperature and humidity levels, see the MR scanner's *Instructions for Use* and the standard *IEC/EN 60601-2-33*.

2.3.2. Specific Energy Dose (SED)

The amount of radio frequency (RF) energy absorbed by the body, per unit mass, is called the Specific Energy Dose (SED). The SED is determined by the SAR and scan duration. The SED is expressed in kJ/kg.

NOTICE

In some MR imaging protocols the total SED can become so high that it limits the use of the protocol.

2.3.3. Heat load induced by ultrasound

Also the ultrasound energy delivered to the patient is ultimately absorbed and transformed to thermal energy inside the patient.

The total thermal energy over the course of the treatment can be reduced by:

- Using feedback cells instead of regular cells.
- Using larger treatment cells.

Short term heat load over the course of a few minutes can be reduced by:

- Increasing the cooling interval between sonications.
- Using smaller treatment cells.

Note that increasing the cooling interval between sonications increases the total treatment time.

2.3.4. Cooling the patient



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.

The system visualizes temperature changes relative to the start of each sonication, not absolute temperature. Estimates of heat buildup and predictions of cumulative heating in the near field are calculated internally and affect cooling times.

NOTICE

Refer to 4.6. *Temperature monitoring* for more information on the temperature measurement method and to 4.6.4. *Cooling time* for more information on cooling time.

The Sonalleve MR-HIFU systems include an active Direct Skin Cooling (DISC) device. The purpose of the device is to facilitate faster tissue cooling by keeping the patient interface at a constant temperature throughout the treatment. This effect is taken into account when the system calculates cooling time recommendations. In most cases, active cooling will shorten the system-recommended cooling times. Thus using the DISC device may shorten the total treatment time. The operational status of DISC is displayed in the System Status Display (see 5.9.1. *System Status Display*).

2.3.5. Clothing and environmental conditions

Refer to the MR scanner's *Instructions for Use*.



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%.

2.4. Contrast agents and medication

If preliminary images with contrast agents are needed, make sure these are obtained well before the actual treatment as contrast agents cannot be used in the HIFU treatment.



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.

The following MRI contrast agents are Gadolinium-based and may decompose when sonicated. This list may not be exhaustive.

- Gadobenate (*MultiHance*®)
- Gadobutrol (*Gadovist*®, *Gadavist*®)
- Gadocolate
- Gadodentrate
- Gadodiamide (*Omniscan*®)
- Gadofosveset (*Ablavar*®, *Vasovist*®)
- Gadomelitol (*Vistarem*®)
- Gadopenamide
- Gadopentetate (*Magnevist*®)
- Gadoterate (*Dotarem*®)
- Gadoteridol (*ProHance*®)
- Gadoversetamide (*Optimark*™)
- Gadoxetate (*Eovist*®, *Primovist*®)

2.5. Emergency Stop and Safety Devices

There are three abort mechanisms in the Sonalleve MR-HIFU system:

- Patient Emergency Stop Button (PESB) for the patient.
- A Stop button in the Safety Device for the user.
- An abort button in the user interface.



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).

2.5.1. Patient Emergency Stop Button (PESB)



The patient can stop the treatment at any point by pressing the Patient Emergency Stop Button (PESB). Pressing the PESB terminates the sonication immediately, although scanning of the temperature maps continues. As the patient presses the button, an indicator light is switched on in the device, there is a beep sound in the MR room and in the operator's Safety Device, and the Sonalleve Console displays an error. Always instruct the patient about the correct usage of the PESB prior to the start of the treatment. If the patient has stopped the treatment because of pain, analyze the cause of pain before continuing the treatment.

When the patient presses the PESB, the red indicator light in the Safety Device is switched on. No further sonications are possible, before the user presses the green Enable button in the Safety Device.

During pre-treatment scanning, and when sonication is not on, the PESB functions like the MR nurse call button: it gives an audio signal but does not stop scanning.



WARNING

Do not use the standard MR Nurse Call button with the Sonalleve MR-HIFU system. Use the Patient Emergency Stop Button (PESB) instead.

NOTICE

Instruct the patient on how and when to use the patient emergency stop button (PESB). Such situations include:

- Sudden pain during the procedure.
- Skin heating.
- Numbness in legs or other body parts.
- Nausea.
- Cardiac symptoms.

2.5.2. Safety Device (SD)

The operator can terminate the treatment at any point using the Safety Device. Use the Safety Device to stop the treatment if you detect a hazardous situation as an undesired heating pattern, or a malfunction in the equipment. The Safety Device provides the following functions:

- Audio signal to indicate that:
 - the patient has pressed the PESB, or
 - the PESB has been disconnected.
- Sonication ON audible indicator – An audible beeping sound is emitted from the Safety Device when the ultrasound transducer is emitting acoustic energy. A sound level switch is located underneath the device.
- Green **Enable** button – Pressing this button enables the ultrasound electronics. Sonication is only possible when the button is lit. The green light will blink during sonication.
- Red **Stop** button – The **Stop** button is lit when the ultrasound electronics are disabled and sonication is not possible. The **Stop** button can be used at any time to disable the ultrasound electronics and to suppress the audio signal.



Fig. 1: The Safety Device.

2.5.3. Software Abort Sonication button



The Sonalleve MR-HIFU user interface provides a software **Abort Sonication** button for terminating the sonication. Use the software **Abort Sonication** button in non-hazardous situations, for example if the target temperature is reached in the tissue before the planned treatment time is over.

2.6. Emergency procedures

The emergency procedures described in the chapter "Safety" in the MR scanner's *Instructions for Use* apply also to Sonalleve MR-HIFU.

In a hazardous situation, terminate the HIFU treatment using the red **Stop** button on the Safety Device and remove the patient from the table and the examination room.

2.7. Magnetic safety

All the equipment used in the examination room must be MR compatible. Never bring any metal objects in the examination room.

Carefully read the warnings and follow the instructions in the MR scanner's *Instructions for Use*.

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of up to 4.500 gauss/cm (45 T/m)
- Maximum allowable patient weight of up to 140 kg (308 pounds)

MRI scans should be conducted using the Receive-only Pelvic Coils provided with the Sonalleve System. For more on the conditions of safe use of the pelvic coils, please refer to labeling on the coils.

2.8. Mechanical and electrical safety

Before using the Sonalleve MR-HIFU hardware components, visually check them to ensure that they are undamaged. Especially, inspect all the wires, hoses, connectors and sockets. Patient or operator injury could occur if these instructions are not properly followed.

Use this product in rooms or areas that comply with all applicable laws (or regulations having the force of law) concerning electrical safety for this type of product.

For additional safety instructions, refer to the MR scanner's *Instructions for Use*.



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.

NOTICE

If there are other persons such as a support person of the patient in the RF room during therapy, the rationale should be explained to the patient and to the additional persons.



WARNING

To avoid risk of electric shock, this equipment must only be connected to a mains supply with a protective earth.

2.9. Protecting the equipment against liquids

The HIFU treatment requires an acoustic contact liquid to be used between the gel pad and the patient and on the membrane. Use disposable sheets to absorb any spilled liquid.

Do not allow liquids to enter any other part of the Sonalleve MR-HIFU equipment. Before each treatment, visually check that the Sonalleve Tabletop is not leaking.



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.

2.10. Chemical safety

The ultrasound transducer inside the Sonalleve Tabletop is immersed in liquid. The liquid inside the tabletop is in a sealed container and does not come in contact with operators or patients in normal operation of the system. For information on how to safely handle the liquid in the event of a leak, refer to the *Material Safety Data Sheet* supplied with the system.



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.

The Sonalleve QA Phantom, model 4510 000 82232, is classified as hazardous waste based on the classification and the concentration of acrylamide used in its filling mixture.

The QA Phantom must be disposed of according to the instructions laid out for hazardous waste handling. See 9.5. *Disposal of the Sonalleve QA Phantom*.

2.11. Explosion safety



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.**

2.12. Fire safety

The use of an electrical product in an environment for which it was not designed can lead to fire or explosion.

Fire regulations for the type of medical area being used should be fully applied, observed and enforced. Fire extinguishers should be available for both electrical and non-electrical fires.

If it is safe to do so, attempt to isolate the product from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shocks.

For further information on fire safety and MR compatible fire extinguishers, refer to the MR scanner's *Instructions for Use*.



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.

2.13. Battery safety

HP Z4G4 workstation is equipped with a battery type described below:

| Battery type | Manufacturer | Size | Specifications |
|-----------------------------------|--------------|---------|--|
| Lithium Manganese Dioxide Battery | Varta | CR 2032 | 3 V, 210 mAh 20 mm x 3.2 mm Primary (not rechargeable) |

The battery that comes with the computer provides power to the real-time clock and has a minimum lifetime of about three years.

The battery is intended to be changed only by Service Personnel.



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.

2.14. Electromagnetic compatibility (EMC)

The Sonalleve MR-HIFU system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents (*Technical Description*). Portable and mobile RF communications equipment can affect the Sonalleve MR-HIFU system.

The Sonalleve system Patient Table must be used only in a shielded location with a minimum of -80dB RF shielding effectiveness.



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.

Sonalleve MR-HIFU system is tested against EMC standard for Medical electrical equipment.

Still under extreme conditions other equipment may negatively affect the performance of the Sonalleve system. The system is continuously monitoring its main functions and in case of failure in these functions the system will stop the operation to keep the system safe in all conditions.

2.15. Network safety, data security and privacy

The Sonalleve MR-HIFU system is protected against unauthorized access by a firewall and strong passwords. In addition, the customer must have a comprehensive security strategy addressing external and internal threats. For more information, refer to the *Technical Description*.

For safety reasons, the Sonalleve MR-HIFU system is isolated from the hospital network during the Therapy stage.

For unauthorized users who have physical access to the system, it is relatively easy to circumvent access controls implemented in software, even those enforced by the operating system. You need to implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users.

To ensure the safe operation of the system and the confidentiality of patient data, operators working with the Sonalleve console must observe the following rules:



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 therapy.**



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 De-identified tool).**

The system does not automatically clear the screen, which may contain patient data. To prevent unauthorized personnel from casually or deliberately viewing patient data, do not leave the system unattended during therapy. To protect the confidentiality of patient data, position displays to face away from doorways, hallways, and other public areas.

You can temporarily blank the screen of the Sonalleve console to keep patient data confidential from onlookers.

- To blank the screen and lock the console, press the **L** key while keeping the Windows key pressed.
- To unlock the console, press any key, then enter the password of the Windows user account.



WARNING

Never blank the screen or lock the device during therapy.

Patient safety requires that the user can view the screen of the Sonalleve console any time during the therapy. For the same reason the system does not automatically blank or lock the screen during therapy, even when the user does not use the Sonalleve console for a while.

The intended use of the system prohibits automatic logoff during therapy. At the default level of user access, automatic logoff takes place on exit from the Sonalleve application.

To log off when operating the system as a power user (see *10.7.1. About accounts*):

1. Exit the Sonalleve application, if it is running.
2. Simultaneously press the **Ctrl**, **Alt** and **Delete** keys.
3. Select **Sign out**.

2.15.1. Malware detection

The Sonalleve console is equipped with antivirus software that is designed to detect viruses on your system and to deny access to infected files before the files can damage your system. Profound Medical makes available Sonalleve security updates that contain security-related updates to the Windows operating system and to the anti-virus software. The security updates are validated by Profound Medical and must be controlled for this product. The updates are distributed by the Profound Medical service organization. Remote installation of security updates is not supported because it could involve risk to patient safety.

If the antivirus software has detected malware infection, do not use automatic repair utilities because the integrity of the repaired software cannot be guaranteed. Contact the Profound Medical service organization to assess and repair the system. You should adhere to local malware policies, which may include disconnecting from the network until the situation is resolved.

2.15.2. Remote Desktop

Service can access the system remotely by using Remote Desktop functionality. During Remote Desktop session the current user is locked out but can gain access to the system again by pressing any key.



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.

2.16. Reporting of incidents

Any accident and/or injury to a patient, operator, or maintenance personnel that has occurred while using the equipment should be reported to Profound Medical. Please contact your local Profound Medical representative.

Any serious incident that has occurred in relation to the device should be reported to Profound Medical and the competent authority of the Member State in which the user is established.

2.17. Safety improvements




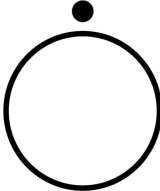
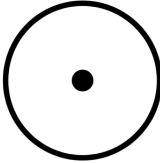
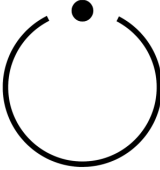
Safety improvements to the equipment must be installed only by Profound Medical personnel.

2.18. Symbols and labels on the equipment

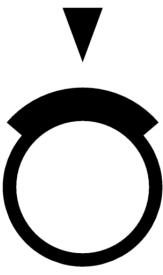
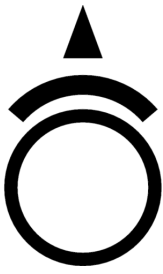
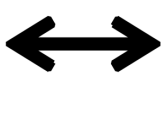



Symbols that appear on Sonalleve MR-HIFU equipment are listed in the following table. Refer to the MR scanner's *Instructions for Use* for a complete list of symbols on the MR system.

The system label of the Sonalleve MR-HIFU system is located on the side of the Sonalleve Tabletop.





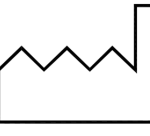
Tab. 4: Symbols on the equipment.

| Symbol | Location | Meaning |
|---|---|--|
|  | The front end of the trolley of the Sonalleve Tabletop  | Warning: crushing hazard: hands Your fingers may get crushed if caught between the tabletop and the spacer when pulling the tabletop back from the imaging position. |
|  | <ul style="list-style-type: none"> Next to the System label The Sonalleve QA phantom DISCfill tool | Follow instructions for use <ul style="list-style-type: none"> You must read the <i>Instructions for Use</i> before using the Sonalleve MR-HIFU system. You must read the <i>Instructions for Use</i> and/or a separately supplied <i>Instructions for Use</i> of the QA phantom before using the QA phantom. |
|  | <ul style="list-style-type: none"> Sonalleve Generator Cabinet, DC voltage supply switch Safety Device Stop button | OFF <ul style="list-style-type: none"> Indicates the OFF state of a switch. On the Safety Device, indicates that the button is used to stop sonication. |
|  | Sonalleve Generator Cabinet, DC voltage supply switch | ON Indicates the ON state of a switch. |
|  | Safety Device Enable button | ON/Enable Indicates that the button is used to toggle between the enabled and standby states of the ultrasound generators. |

2. Safety > 2.18. Symbols and labels on the equipment




| | | |
|---|--|---|
|  | <p>On the frame beside the brake pedal of the trolley</p> | <p>The movement of the trolley is locked when the marked end of the brake pedal is pressed.</p> |
|  | <p>On the frame beside the brake pedal of the trolley</p> | <p>The movement of the trolley is released when the brake pedal is in the middle position.</p> |
|  | <p>On the frame beside the brake pedal of the trolley</p> | <p>The movement of the trolley is released but the direction of the center wheel is locked when the marked end of the brake pedal is pressed.</p> |
|  | <p>Sonalleve Generator Cabinet</p> | <p>Protective earth Indicates the terminal for protective earth (ground) electrode.</p> |
|  | <p>Sonalleve Generator Cabinet product label on the roof of the generator cabinet</p> | <p>Three-phase alternating current The generator cabinet requires three-phase alternating current.</p> |
|  | <ul style="list-style-type: none"> • HIFU Pelvis Coil product label • Patient Emergency Stop Button (PESB) • Tabletop connector panel on the side of the Sonalleve Tabletop | <p>Type BF Applied Part Regarding protection against electrical shock, the parts of the Sonalleve Tabletop, the HIFU Pelvis Coil and the PESB that come into physical contact with the patient in normal use are classified as Type BF (Body Floating) Applied Parts as defined in the standard IEC 60601-1.</p> |

2. Safety > 2.18. Symbols and labels on the equipment





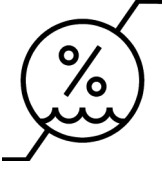
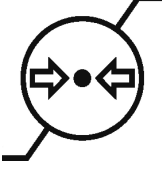
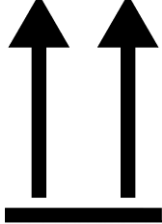
| | | |
|---|---|--|
|  | <p>HIFU Pelvis Coil</p> | <p>MR Conditional An item has been demonstrated to pose no known hazards in the specified MRI environment with the specified conditions of use.</p> |
|  | <p>Product labels</p> | <p>Indicates that the medical device or other item is only for use with a 1.5 T MR scanner.</p> |
|  | <p>Product labels</p> | <p>Indicates that the medical device or other item is only for use with a 3 T MR scanner.</p> |
|  | <ul style="list-style-type: none"> • System label • Patient Table • Generator Cabinet label on the roof of the cabinet • DISCFILL tool | <p>Indicates the manufacturer of the medical device or other item.</p> |
|  | <ul style="list-style-type: none"> • System label • QA phantom • Planning console • Patient Table • Generator Cabinet label on the roof of the cabinet • DISCFILL tool • Filter Panel • Patient trolley | <p>Date of manufacture Indicates the date when the medical device or other item was manufactured.</p> |

| | | |
|---|---|---|
| <div style="border: 2px solid black; padding: 5px; text-align: center; font-weight: bold; font-size: 24px;">REF</div> | <ul style="list-style-type: none"> • System label • QA phantom • Planning console • Patient Table • Generator Cabinet label on the roof of the cabinet • DISCFILL tool • Filter Panel • Patient trolley | <p>Indicates the manufacturer's catalogue number for the medical device or other item.</p> |
| <div style="border: 2px solid black; padding: 5px; text-align: center; font-weight: bold; font-size: 24px;">SN</div> | <ul style="list-style-type: none"> • System label • QA phantom • Planning console • Patient Table • Generator Cabinet label on the roof of the cabinet • DISCFILL tool • Filter Panel • Patient trolley | <p>Indicates the manufacturer's serial number for the specific medical device.</p> |

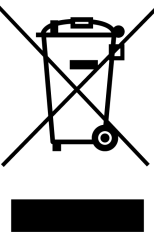






2. Safety > 2.18. Symbols and labels on the equipment

| | | |
|---|---|---|
|  | <ul style="list-style-type: none"> • Packages of gel pads • Packages of QuickCover Ultrasound Protective Covers | <p>Indicates the production batch code or lot number of the item.</p> |
|  | <ul style="list-style-type: none"> • Packages of gel pads • Packages of QuickCover Ultrasound Protective Covers | <p>Use by date Indicates the date after which the item is not to be used.</p> |
|  | <ul style="list-style-type: none"> • Packages of gel pads • Packages of QuickCover Ultrasound Protective Covers | <p>Do not re-use Indicates a single use item intended for a single procedure or patient.</p> |

2. Safety > 2.18. Symbols and labels on the equipment

| | | |
|---|---|---|
|  | <ul style="list-style-type: none"> • Packages of gel pads • Packages of QuickCover Ultrasound Protective Covers | <p>Consult instructions for use</p> |
|  | <p>System package labels</p> | <p>Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully.</p> |
|  | <p>System package labels</p> | <p>Keep dry Indicates a medical device that needs to be protected from moisture.</p> |
|  | <p>System package labels</p> | <p>Temperature limit Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature are indicated adjacent to the upper and lower horizontal lines.</p> |
|  | <p>System package labels</p> | <p>Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed. The upper and lower limits of humidity are indicated adjacent to the upper and lower horizontal lines.</p> |
|  | <p>System package labels</p> | <p>Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.</p> |
|  | <ul style="list-style-type: none"> • The Sonalleve QA phantom • System packages | <p>This way up Indicates the correct upright orientation of the QA phantom. Keep the phantom so that the arrows point upwards.</p> |

2. Safety > 2.18. Symbols and labels on the equipment

| | | |
|---|--|--|
|  | <ul style="list-style-type: none"> • Next to the system label on the side of the Sonalleve Tabletop • DISCfill | <p>Indicates that the device is to be disposed of according to local regulations. In the European Union the device is to be handled as Waste Electrical and Electronic Equipment (WEEE).</p> <p>See 9. <i>Product disposal</i>.</p> |
|  | <ul style="list-style-type: none"> • Packages of gel pads • Packages of QuickCover Ultrasound Protective Covers | <p>The manufacturer of the item declares that the item conforms to the applicable European Union directives.</p> |
|  | <p>System label</p> | <p>The manufacturer of the medical device declares that the medical device conforms to the European Medical Device Directive 93/42 EEC. The number identifies the Notified Body that has been involved in the conformity assessment procedure.</p> |
|  | <ul style="list-style-type: none"> • System label • Generator Cabinet label on the roof of the cabinet • Packages of gel pads | <p>Authorized Representative in the European Community</p> |
|  | <ul style="list-style-type: none"> • System label | <p>In the United States of America:</p> <p>CAUTION: Federal law restricts this device to sale by or on the order of a physician</p> |
|  | <p>Next to the system label on the side of the Sonalleve Tabletop</p> | <p>Marking for the restricted use of hazardous substances in electronic and electrical products as defined in the Chinese standard SJ/T 11364—2014.</p> |
|  | <p>Next to the system label</p> | <p>Label indicating the total mass of the patient table including safe working load.</p> |

3. System overview

The Sonalleve MR-HIFU system is designed to be used with Philips MR scanners (see *1.1. About Sonalleve MR-HIFU*).

The Sonalleve Tabletop can be easily removed to enable normal, diagnostic use of the MR scanner.

3.1. Main system components

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

- Sonalleve Tabletop assembly.
- Sonalleve Generator Cabinet.
- Sonalleve Console.
- Patient step.
- Accessory cart.



Fig. 2: Sonalleve Tabletop docked to the scanner.



Fig. 3: Patient step and accessory cart.

Cables for the Sonalleve MR-HIFU system enter the examination room through a dedicated HIFU Filter Panel on the examination room wall. When the Sonalleve MR-HIFU system is not in use, the cables are disconnected and stored in the accessory cart.

3.1.1. Tabletop assembly



Fig. 4: The Sonalleve Tabletop.

The Sonalleve Tabletop is brought in and out of the examination room on a dedicated trolley. When docked, the Sonalleve Tabletop lies somewhat higher than the standard tabletop and protrudes more at the back of the magnet.

The Sonalleve Tabletop includes:

- Ultrasound transducer.
- Positioning mechanics.
- Tabletop connector panel.
- HIFU Pelvis Coil.
- Patient Emergency Stop Button (PESB).
- Pads, mattresses and straps for patient positioning.
- Direct Skin Cooling (DISC) device.

Direct Skin Cooling (DISC) device

Direct Skin Cooling (DISC) device is a device used to cool down the skin of the patient during HIFU treatment by circulating cooled water inside the DISC patient contact. The device keeps the water temperature at a configured target value. Water circulation in the DISC is started as soon as the Sonalleve Application is in the Therapy mode and a remotely controllable scan, such as TemperatureMapping, is started on the MR scanner (the message "Under Remote Control" is shown on the MR scanner console). Water circulation is stopped when the remote control ends. Water circulation is on during sonications but may be automatically switched off when scanning other protocols.

The Sonalleve MR-HIFU systems are delivered with the DISC installed. The DISC can also be installed as an upgrade.

Sonalleve tabletops equipped with the DISC can be recognized from the presence of a pair of connectors for the DISC hoses, as shown in the following figures.

- When the DISC is pre-installed at the factory, the hose connectors are located in the tabletop connector panel.
- When the DISC is installed as an upgrade, the hose connectors are located in the accessory box at the front end of the tabletop.

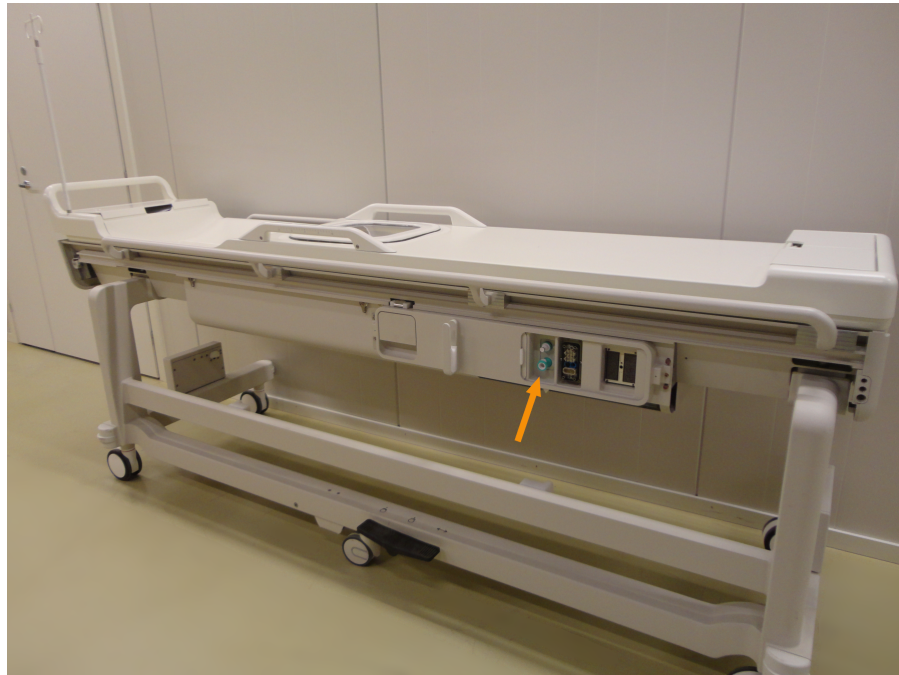


Fig. 5: When DISC is pre-installed at the factory, the hose connectors are located in the tabletop connector panel.



Fig. 6: When DISC is installed as an upgrade, the hose connectors are located in the accessory box at the front end of the tabletop.

The operational status of DISC is displayed in the System Status Display (see 5.9.1. *System Status Display*).

For the patient's skin to be cooled as expected, DISC must be filled with water, and water circulation in DISC must function properly. Water slowly evaporates from DISC. If the remaining water leaves too thin a water layer between the two membranes of DISC, the cooling effect becomes insufficient, which can lead to skin burns.

Brake pedal

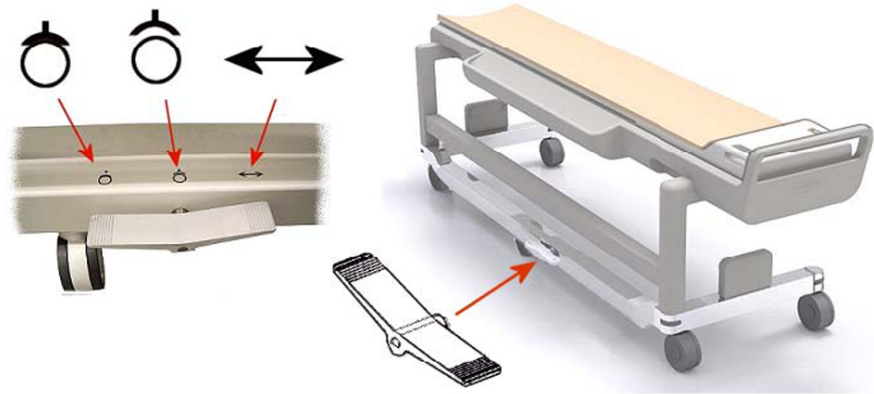




Fig. 7: The brake pedal of the trolley of the Sonalleve tabletop.

The symbols on the frame of the trolley beside the brake pedal indicate the brake function as follows:

Tab. 5: Brake function symbols.

| Symbol | Function |
|--------|---|
| | <p>LOCKED</p> <ul style="list-style-type: none"> • LEFT side of brake pedal pressed • All the four outer wheels are locked (brakes on) |
| | <p>FREE</p> <ul style="list-style-type: none"> • Brake pedal in CENTER position • All the five wheels are free (brakes off) |

| | | |
|---|----------------------|---|
|  | <p>SWIVEL</p> | <div data-bbox="646 165 1098 394">  </div> <ul style="list-style-type: none"> • RIGHT side of brake pedal pressed • All the five wheels are free (brakes off) • The direction of the center wheel is locked, which makes it easier to turn the trolley |
|---|----------------------|---|

Tabletop release

To release the tabletop when pushing the tabletop into the magnet and when pulling the tabletop back out, lift either of the two tabletop release handles located on both sides of the tabletop (see the figure below).

NOTICE

In addition to the two tabletop release handles located on both sides of the tabletop, there is an emergency tabletop release button located in the accessory box (see the figure below). If a detachable handle has been installed to the tabletop, the emergency tabletop release handle is on the side of the accessory box.



Fig. 8: Left: Tabletop release handle. Middle: The emergency tabletop release button located in the accessory box. Right: The emergency tabletop release handle located on the side of the accessory box.

3.1.2. Sonalleve Console

The Sonalleve Console is used for transferring the planning images from the MR scanner, planning of the sonication treatment, and the actual therapy sonication. The Sonalleve Console is located in the control room, with direct visibility to the examination room. A monitor and safety device are included with the Sonalleve Console.



Fig. 9: Sonalleve Console Operator's workstation. At left, the MR scanner console; at right, the Sonalleve Console.



Fig. 10: The Safety Device.

3.1.3. Sonalleve Generator Cabinet

The Sonalleve MR-HIFU system requires a separate cabinet for power distribution and the electronics. The Sonalleve Generator Cabinet is located in the technical room. The main power switch for the Sonalleve MR-HIFU system is located in the power distribution unit (PDU) in the Sonalleve Generator Cabinet.

3.2. Patient accessories

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

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

- Headphones.
- Tabletop Plate.
- Ultrasound Window Cover.
- Tabletop Extension Plate (only in Bone application).

NOTICE

The vacuum cushion provided with the Sonalleve MR-HIFU system is only intended for use in MR-HIFU, not in diagnostic clinical imaging.

To order additional consumables (such as gel pads) or replacements for accessories that are provided with the Sonalleve MR-HIFU system, contact your local Profound Medical representative.

The hospital must provide the following items required in HIFU treatment:

- Depilation equipment.
- IV tubes.
- Foley catheter, urine bag with a 2 m extension hose.
- Ear plugs.
- Patient sheet or blanket.
- Thermometer. The accuracy of electronic rectal thermometers is usually better than ± 0.2 °C, which is sufficient for this purpose. Oral or ear thermometers are often less reliable and are therefore not recommended.
- Disposable absorbing sheets for use under the mattress and under the patient.
- Compression stockings to reduce the risk of blood clots and Deep Vein Thrombosis (DVT) due to prolonged immobilization of the patient are optional but highly recommended.
- Degassed acoustic contact liquid (see below).

3.2.1. Acoustic contact liquid

Pure water or a mixture of ultrasound gel and water is used as a coupling medium to close any air gaps between the patient contact and the patient.

The water in the acoustic contact liquid used in MR-HIFU treatments must meet the following requirements:

- Pure water, preferably distilled.
- Hard water (with high mineral content) should be avoided.
- Microbiologically clean.
- Contains no chemicals or particles that can cause degradation of the MR signal, susceptibility effects or localized heating of skin or the inner margin of the subcutaneous fat layer in the MR scanner's RF field or in the ultrasound field.

As air bubbles in the ultrasound beam path may cause undesirable effects, such as reflections or local heating, the acoustic contact liquid must be degassed before use to prevent bubble formation. The amount of dissolved oxygen must be below 4 mg/l (ppm, parts per million).

See 7.4. *Making degassed acoustic contact liquid* for instructions for preparing degassed water or water-ultrasound gel mixture.

NOTICE

A specially designed EasyWater Degasser is available from the manufacturer for producing degassed water. For a description, see *EasyWater Degasser Instructions for Use*.



Fig. 11: EasyWater Degasser.

3.3. Other accessories

The following accessories used in the Sonalleve MR-HIFU system quality assurance are provided with the system:

- Ultrasound window cover.
- Sonalleve QA phantom.
- QA phantom plate.
- SPT (System Performance Testing) phantom holder.
- DISCfill tool

NOTICE

The SPT phantom is a part of the MR system and not provided with the Sonalleve MR-HIFU system.

If you need replacements for accessories, contact your local Profound Medical representative.

3.3.1. The DISCfill tool

The DISCfill tool is provided for the possible need to refill DISC between planned maintenance. DISCfill is a container, from which DISC can be filled. There is an indicator on DISCfill for when a refill of DISC is required.

Always use DISCfill before a HIFU treatment to check the water level in DISC and refill DISC if the water level is too low.

For connecting DISCfill to DISC, a filling hose is supplied with DISCfill. There is a hose connector at both ends of the filling hose. There is also a draining hose, with one end open.

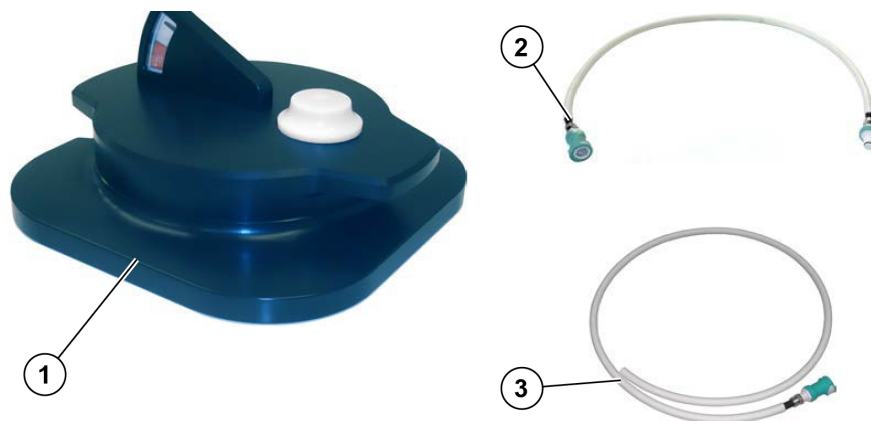


Fig. 12: DISCfill (1), The filling hose (2), The draining hose (3)

3.4. Technical specifications

Tab. 6: Key treatment-related technical specifications for the Sonalleve MR-HIFU system.

| Feature | Specification |
|---|--|
| Temperature measurement update interval | 3.5 seconds or less |
| Temperature change measurement accuracy | ± 5 °C or better, relative accuracy (standard deviation) is ± 1 °C or better |
| Treatment point positioning accuracy | 3 mm or better |

3.4.1. Ultrasound field distributions

The ultrasound field distribution was characterised by performing hydrophone measurements with a Sonalleve system at the nominal focus with 20W acoustic power. Hydrophone needle was moved in order to measure pressures in both coronal and axial planes. Y-axis is parallel to the beam axis. Typical values for the dimensions of the focal spot are shown in the table below. Typical temporal-average intensities are shown in figures below.

| Frequency | 6dB x-axis (mm) | 6dB y-axis (mm) | 6dB z-axis (mm) |
|-----------|-----------------|-----------------|-----------------|
| 0.85 MHz | 2.3 | 17.5 | 2.3 |

3. System overview > 3.4. Technical specifications

| | | | |
|----------|-----|------|-----|
| 1.0 MHz | 1.9 | 14.7 | 1.9 |
| 1.2 MHz | 1.6 | 12.3 | 1.6 |
| 1.44 MHz | 1.3 | 10.0 | 1.3 |

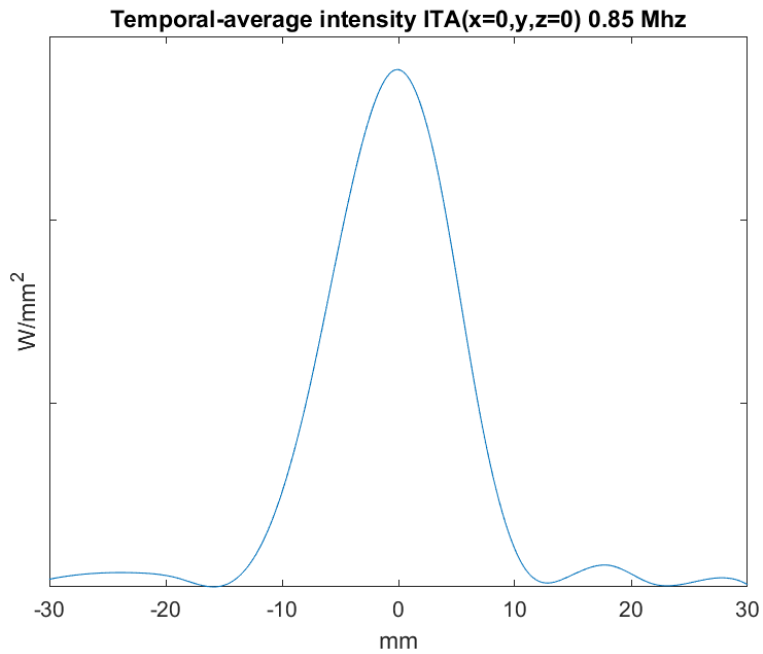


Fig. 13: Typical temporal-average intensities ITA (x=0, y, z=0) at 0.85 MHz

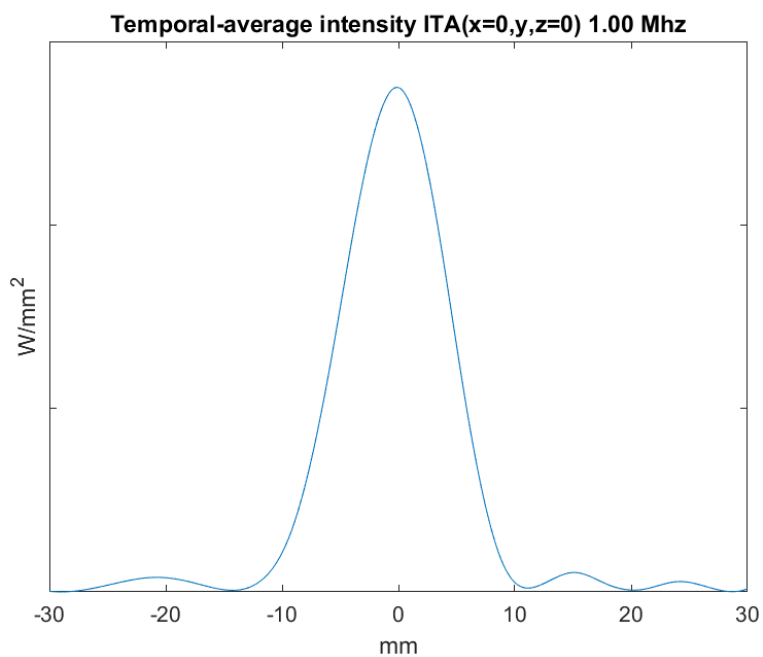


Fig. 14: Typical temporal-average intensities ITA (x=0, y, z=0) at 1.0 MHz

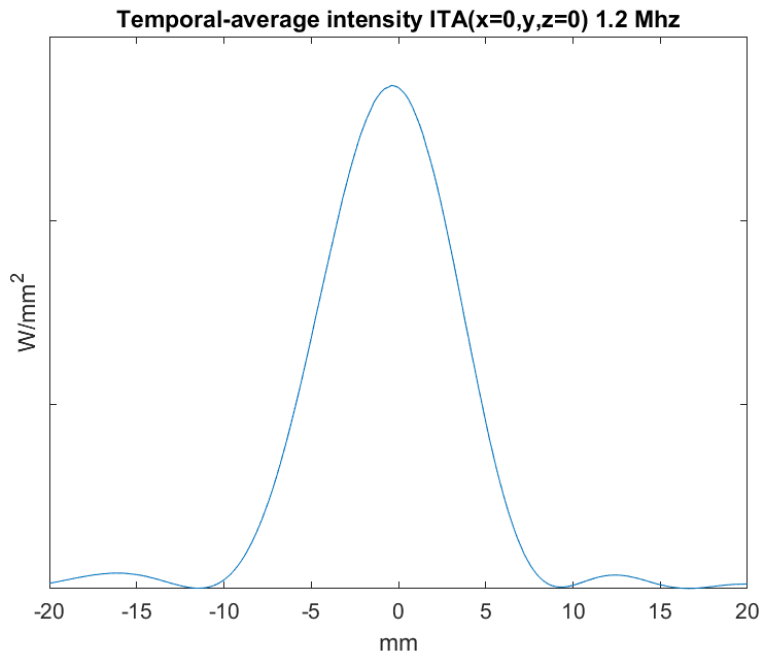


Fig. 15: Typical temporal-average intensities ITA ($x=0$, y , $z=0$) at 1.2 MHz

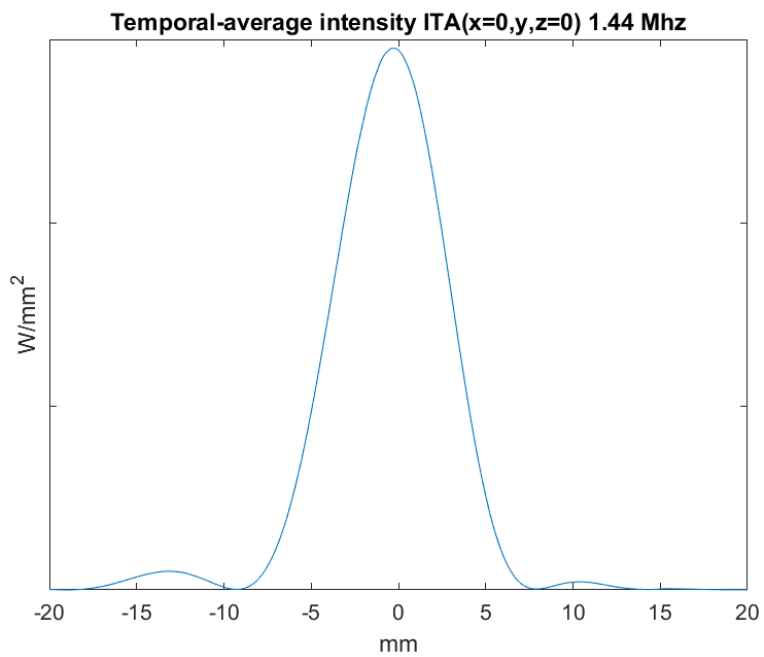


Fig. 16: Typical temporal-average intensities ITA ($x=0$, y , $z=0$) at 1.44 MHz

4. Treatment methods

This chapter explains the terms and concepts necessary for understanding the Sonalleve MR-HIFU treatment workflow.

4.1. Basic concepts

In High Intensity Focused Ultrasound (HIFU) treatment, an ultrasound beam is focused on a small volume within the target tissue. This is called a sonication, and it causes the temperature to rise which coagulates the tissue. With this technique, unwanted tissue can be destroyed without invasive surgery.

MR-guided HIFU (MR-HIFU) treatment, also known as MR-guided focused ultrasound therapy (MRgFUS), is based on monitoring the relative temperature change during the sonication treatment using MRI.

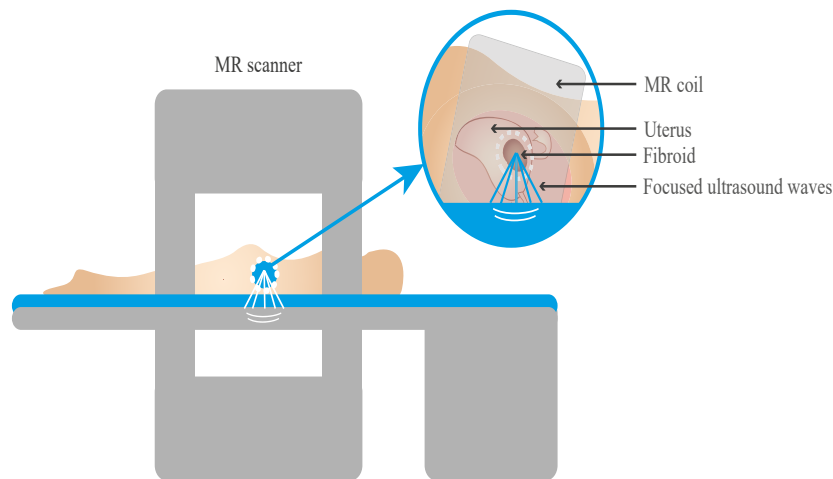


Fig. 17: The basic principles of HIFU.

The MR images are used to calculate relative temperature maps, which are monitored on the Sonalleve console. These temperature maps are used to visualize the progress of the treatment, and they also can be used to control the duration of the sonication. The following table explains the basic terms and concepts that you need to be familiar with when working with the Sonalleve MR-HIFU system.

Tab. 7: Sonalleve MR-HIFU key terms and definitions.

| Term | Definition |
|-----------------------------|---|
| Autopopulation | Automated treatment cell planning. The action of automatically filling a defined region with treatment cells. |
| Available Target Area (ATA) | The area which is within reach of the ultrasound beam and within which treatment cells can be positioned. |

| | |
|-----------------------------------|--|
| Beam Shaping | A Sonalleve software feature that allows the user to selectively limit the maximum acoustic intensity in a part of the transducer beam that goes through a sensitive organ. |
| Cavitation | Interaction between ultrasound and microbubbles in water or within tissue, which may affect the treatment outcome at high ultrasound power densities. |
| Cooling time | The minimum time required for the patient to cool down in between sonications. Cooling is necessary to prevent tissue burns in the near field. |
| Direct Skin Cooling (DISC) device | A device used to cool down the skin of the patient during HIFU treatment. See 3.1.1.1. <i>Direct Skin Cooling (DISC) device</i> . |
| Far field | The volume through which the acoustic waves traverse after the treatment cell. |
| Far-field safety margin | The far-field safety margin visualizes the advised minimum distance of a treatment cell from sensitive tissues in the far field. It is displayed as the depthwise limit up to which the far field extends. |
| Feedback cell | A treatment cell for which the required sonication time is calculated based on the temperature rise in the treatment cell. |
| Misregistration | The distance between the observed heating and the planned treatment cell center. |
| Misregistration correction | Correction for the misregistration. The correction is applied to all the treatment cells in a treatment cell cluster. |
| Monitor slices | The slices used in temperature monitoring during the sonication stage. |
| Near field | The volume through which the ultrasound beam traverses towards the treatment cell. |
| Organ avoidance region (OAR) | A region of interest (ROI) that the user uses to mark a sensitive organ for Beam Shaping. |
| Planning images | The images scanned and used for therapy planning. The planning images are scanned on the MR console and transferred to the Sonalleve console. |
| Planning safety margin | The distance that must be left between treatment cells and areas in which heating should be avoided. |
| Planning Target Volume (PTV) | The volume used for planning the sonication. The PTV is defined by drawing it on the planning images. Treatment cells are placed within the PTV. |
| Preparing electronics | A hardware initialization procedure of the transducer electronics. Electrically matches the transducer driving electronics to the transducer channels. |
| Region of Interest (ROI) | An area or volume for a specific purpose that can be graphically defined by the user, or automatically by the software. |
| Registration | A Sonalleve software feature that lets the user to indicate how the patient has moved during the treatment. Registration defines a spatial offset between image sets. |

| | |
|------------------------------|---|
| Sonication | An event during which the transducer is emitting ultrasound energy at a treatment cell. |
| Temperature curve | A plot of the temperature in a selected part of the heated region as a function of time. |
| Temperature map | A colored overlay on top of an anatomical image showing the temperature rise in the tissue. |
| Test sonication | A procedure in which low power is directed at a treatment cell to verify that heating occurs in the correct location. |
| Therapy | The activity targeting the delivery of energy to the patient for therapeutic purpose. Therapy is a subset of a treatment. In the therapy stage of treatment the user executes and performs sonications on the Sonalleve console. |
| Thermal dose | A measure of the effect of heating on the tissue. |
| Thermal dose contours | Contours overlaid on top of an anatomical image showing the thermal dose of the tissue as isodose contours. |
| Thermal dose map | A colored overlay on top of an anatomical image showing the thermal dose of the tissue. |
| Tissue boundary | User defined tissue boundary between the skin and fat-muscle boundary in the Uterine application. |
| Total Treatment Volume (TTV) | The total volume of the treatment cells in all Planning Target Volumes to be treated during a single therapy session. |
| Trajectory | The path formed by successive treatment points during sonication. |
| Transducer beam | The volume through which the acoustic waves travel from the transducer. Also called the ultrasound beam path. |
| Transducer beam centerline | A line from the center of the transducer aperture to the treatment point. |
| Transducer homing | A hardware initialization procedure for bringing the transducer to its center (home) position. |
| Treatment | <ol style="list-style-type: none"> 1. The whole procedure involving the patient care and the use of the Sonalleve MR-HIFU System for therapy and pre and post-therapy activities. 2. Within the context of the Sonalleve console: The entire process required to treat the patient including the planning, preparation, therapy and reporting stages. |
| Treatment cell | A small volume of tissue which is planned to be destroyed as a result of a single sonication. |
| Treatment cell cluster | A group of treatment cells in the same treatment plane. |
| Treatment cell safety margin | Lines displayed around a treatment cell to visualize its advised minimum distance from sensitive tissues. |

| | |
|----------------------|--|
| Treatment plane | The plane on which the treatment cells in a cluster are located. The center of each treatment cell is in this plane. |
| Treatment point | The point where ultrasound heating is centered at a specific moment of time. |
| Ultrasound beam path | The volume through which the acoustic waves travel from the transducer. Also called the transducer beam. |

4.2. Patient selection

Patients with any of the following conditions are not suitable for treatment with the Sonalleve MR-HIFU system:

- MRI contrast agent contraindications.
- Pregnancy or positive pregnancy test.
- Scars that cannot be protected or surgical clips in the planned path of the ultrasound beam (for more information on protection methods, see 6.6.7. *Beam shaping*).
- Calcifications around the periphery of the fibroid or within the fibroid in the Uterine application.
- Calcifications around or within the adenomyosis in the Uterine application.
- Patient's weight > 140 kg (308 pounds).

NOTICE

If a patient has a history of liposuction, they may have scars in the abdomen that are not visible outside. In such cases, the patient's eligibility for treatment must be assessed clinically by a medical professional.

NOTICE

General or local clinical protocols may present patient selection and exclusion criteria differing from, and overriding the criteria listed above. Always consult the relevant protocols when making decisions related to patient selection.

4.3. Treatment cell types and clusters

A treatment cell is the tissue volume to be destroyed within a Planning Target Volume during a single sonication. There are two types of treatment cells:

- **Regular cells**, for which the sonication time is constant.
- **Feedback cells**, for which the required sonication time is calculated based on the temperature rise in the treatment cell. Feedback cells are only available in the Uterine application.

In the Uterine application, regular cells and feedback cells can be 4, 8, 12, 14, or 16 mm in size. In the Bone application, regular cells can be 2, 4, 8, 12, 14 or 16 mm in size.

The size of treatment cell can be selected in the user interface. The optimal treatment cell size depends on the Planning Target Volume. As a general rule, you should use the largest treatment cells possible. Larger treatment cells cover the volume better and shorten the treatment time since fewer cooling intervals are required.

The following table presents the treatment times for the regular cells according to cell size.

Tab. 8: Treatment times for different regular treatment cell sizes.

| Cell size (mm) | Application | Approximate treatment time (seconds) |
|----------------|---------------|--------------------------------------|
| 2 | Bone | 16 |
| 4 | Uterine, Bone | 16 |
| 8 | Uterine, Bone | 20 |
| 12 | Uterine, Bone | 36 |
| 14 | Uterine, Bone | 45 |
| 16 | Uterine, Bone | 56 |

Ablation of adenomyosis tissue may require higher power levels and longer sonication times compared to the ablation of uterine fibroid tissue.

The maximum treatment time for feedback cells is 20 seconds longer than for the corresponding regular cell. If the maximum treatment time of the feedback cell is reached, the system aborts sonication.

A treatment cell cluster is a group of treatment cells on the same treatment plane, typically located next to each other. You can define multiple treatment cell clusters on the same treatment plane. In the Bone application the Sonalleve application treats all the treatment cells on the treatment plane as a single treatment cell cluster.

General clinical treatment protocols may limit the targeted treatment volume. The Sonalleve User Interface provides tools for measuring the approximate volumes or dimensions.

4.4. Sonication method

In the regular sonication method, the ultrasound beam treatment point sonicates points along its path with a constant power level for a predefined time.

The feedback sonication method aims to minimize the time used per treatment cell. This method divides the trajectory of the treatment point into several smaller areas, or sub-trajectories, which are sonicated one-by-one at a constant power. When a sub-trajectory reaches a certain predefined temperature and/or thermal dose, the treatment point moves onto the next sub-trajectory. The feedback sonication method is only available in the Uterine application.

4.5. Electronic deflection

The Sonalleve MR-HIFU system is able to steer electronically the position of the treatment point within a limited range around the natural focus of the transducer. This method is called electronic deflection. The system automatically uses electronic deflection to extend the reach of sonications depthwise along the transducer's X coordinate axis. With positive electronic X deflection it becomes possible to place treatment cells deeper than what the mechanical movement range of the transducer allows. Negative electronic X deflection makes it possible to place treatment cells closer to the patient's skin. The system automatically chooses electronic deflection based on the user-selected cell location. Electronic X deflection is possible with 2, 4, 8, 12 and 14 mm cells, but not with 16 mm cells.

4.6. Temperature monitoring

The Sonalleve console shows the temperature increase of the tissue during sonication, improving the safety and predictability of the treatment.

Temperature measurements are based on MR signal phase changes. This is called the PRF (Proton Resonance Frequency) shift method. The temperature is calculated from the phase difference of two subsequent dynamic images ($\Delta\phi$, in radians) and the MR protocol echo time TE (t_E , in seconds) as:

$$\Delta T = \frac{\Delta\phi}{\alpha \gamma B_0 t_E 2 \pi}$$

where $\alpha = 0.0094$ ppm/°C, $\gamma = 42.58$ MHz/T, $B_0 = 1.5$ T or 3.0 T.

This technique measures relative changes in temperature with respect to the initial temperature. In the beginning of each sonication, the temperature calculation assumes that the initial temperature of the tissue is the body reference temperature. A sufficient cooling time is necessary to avoid an unwanted heat buildup.

Unexpected temperature changes may occur when there is a change in the measured signal phase. Such changes can be caused by patient movement or by magnetic field changes due to external or internal disturbances. The Sonalleve Software can detect and correct slow changes (drift), but sudden changes may compromise the temperature information. The Sonalleve Software will issue a warning at the onset of a sudden change.

4.6.1. Thermal dose limits

The Sonalleve Software calculates the thermal dose from temperature maps using the formula:

$$t_{43} = \int_0^{t'} R^{[T(t)-43^\circ\text{C}]/C_T} dt$$

where:

- $C_T = 1$ °C, a constant to render the exponent dimensionless
- $T(t)$ = temperature (which may vary in time)
- t = time
- t' = time required to produce the bio effect at temperature T
- R = thermal normalization constant, equal to 4,0 if $T \leq 43$ °C
- R = thermal normalization constant, equal to 2,0 if $T > 43$ °C

These parameters approximate human soft tissue.

Thermal dose is a measure of the biological effect of tissue heating. Thermal dose depends on the temperature and the duration of the heating. Thermal dose is expressed in equivalent minutes (EM) at 43 °C (109.4 °F). For example, a dose of 240 EM means that you would need to keep the tissue at 43 °C for 240 minutes to cause similar damage.

Thermal dose gives an estimate of the expected tissue damage. Tissue receiving a dose of 30 EM or less can be expected to avoid having any permanent damage. Tissue receiving a dose between 30 EM and 240 EM might become oedematic, or have some broken cell membranes, damage to vasculature and other kinds of damage. This damage may or may not be reversible. A thermal dose of 240 EM or more can be expected to cause irreversible coagulative necrosis in the tissue.

4.6.2. Thermal dose and temperature monitoring

Temperature maps graphically depict temperature rises in the tissue while thermal dose shows the resulting tissue destruction. Both can be shown on the Sonalleve console as colored overlays on top of the anatomical images. If a treatment cell cluster is selected, the cumulative thermal dose is displayed for that cluster.

The Sonalleve MR-HIFU system records temperature in all the imaging planes. The system automatically positions some stacks at the location of the expected maximum heating. Some stacks are freely adjustable by the user, to be placed in locations where heating is not expected to occur.

Temperatures below reference body temperature are not shown in the temperature monitoring images: the color coding scale starts at 40 °C (104 °F). The colors in the temperature map are more transparent outside the ultrasound beam path and the transparency increases with distance from the beam.

There are two abrupt transitions in the color scale of the temperature maps to emphasize the increasing physiological effect of heating:

Tab. 9: The temperature map color scale.

| Color | Temperature | Physiological effect |
|--------|---------------------------------------|--|
| Blue | below 47 °C (116.6 °F) | A few minutes of exposure at this level is not likely to cause necrosis. |
| Yellow | 47 °C to 56 °C (116.6 °F to 132.8 °F) | Continued exposure at this level will cause necrosis within seconds. |
| Red | 56 °C (132.8 °F) or above | Necrosis is immediate. |

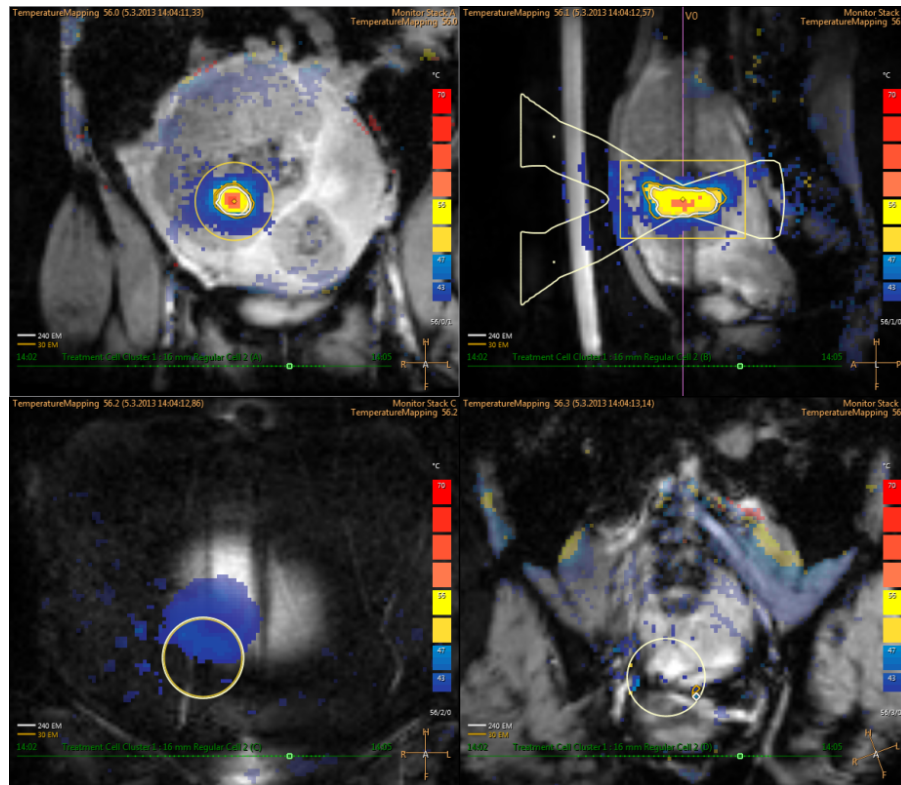


Fig. 18: Example of a temperature map.

If the temperature increases significantly at regions other than the intended heating volume (plus margin), the system issues warnings. The warnings may be caused by movement or other artifacts and their reason and safety consequences should be understood before continuing with the treatment.

The Sonalleve Software can only calculate temperatures at points where the signal-to-noise ratio (SNR) is sufficient. Pixels where SNR is low will be masked out from the display. Low SNR at the intended heating location will trigger a warning.

NOTICE

Temperature measurement is done with fat suppression. This results in low SNR where fat is present. The PRF method does not detect heating in fat. When ultrasound travels through fat tissue, heating always takes place. The heating of fat can be deduced only from the heating of the surrounding tissues.

NOTICE

Cortical bone inherently has a low SNR. The heating of cortical bone can be deduced only from the heating of the surrounding tissue.

The Sonalleve Software calculates the thermal dose from temperature maps. As the volume outside the intended heating location is not expected to warm up, thermal dose is not calculated there. Therefore, any potential temperature artefacts outside the intended heating location will not produce any graphical depiction of dose.

Thermal dose is not calculated for scans started from the **Scan** tab. Thermal dose is only calculated for sonications, including temperature maps acquired before and after the actual sonication.

Thermal dose gives an estimate of expected tissue damage. It does not measure the actual outcome of the treatment. Use other methods to evaluate whether the treatment was successful.

In uterine therapy, the typical method to determine the outcome of the treatment is to observe non-perfused volumes, using non-contrast and contrast MR images of the treated volumes after the Sonalleve treatment. See 10.3. *Comparing thermal dose volumes and non-perfused volumes.*

In bone therapy, non-perfused volume does not directly predict the clinical outcome. Rather, clinical effect is evaluated by following the patient-reported pain levels after the treatment.

4.6.3. Monitoring near-field heating

When a target volume is sonicated, some heating occurs in all the tissue layers through which the ultrasound beam travels, both in the near field and in the far field. This is a property of all ultrasound therapy systems and cannot be avoided. The amount of heating in the near field tissues, such as the skin and the subcutaneous fat layer, is considerably lower than the heating at the target. The deposited heat energy is carried away by the active cooling mechanisms of the body (blood flow) and passive diffusion to surrounding tissues and to the tabletop. A cool-down period is needed between sonications to avoid dangerous temperature build-up (cumulative heating).

Cumulative heating is a particular concern in the patient's skin and subcutaneous fat layer, and may potentially lead to severe skin burns. To assist the user in preventing skin burns, Sonalleve Software uses information about sonication parameters and data from post-sonication fat-monitoring scans (if available) to estimate the temperature at the patient's skin and subcutaneous fat layer. The software estimates the heat that has been produced in near-field tissue during the whole treatment. If the estimate suggests that the currently selected sonication would induce too high temperatures in the near-field tissues, the software does not allow starting the sonication. If the sonication is estimated to induce heat close to the risk level, the software displays a warning (see the following figure), and the user is asked to confirm the start of the sonication.

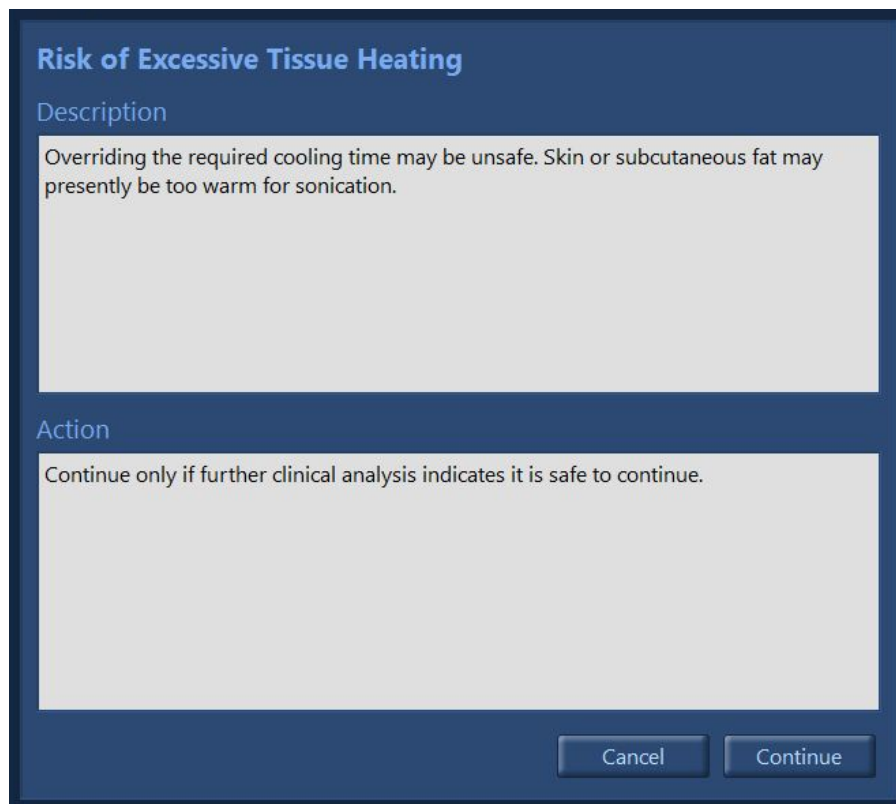


Fig. 19: If the sonication is estimated to induce heat close to the risk level, the software displays a warning, and the user is asked to confirm the start of the sonication.

NOTICE

Variations in the patient's anatomy and physiology, environmental conditions, etc., affect the heating and cooling of the tissue. The system will not be able to detect all the possible cases in which there is a risk of skin burn. Treatment decisions need to be made based on clinical consideration of the potentially contributing factors.

4.6.4. Cooling time

Each sonication is followed by a cooling time. Cooling is necessary to prevent tissue burns in the near field.

- The system-recommended cooling time depends on the currently chosen parameters for the next sonication, including cell size, type, power, frequency, etc. The system-recommended cooling time is also affected by the sonication history and post-sonication fat-monitoring scans, when available. The system-recommended cooling time increases when the planned cell size increases, when power increases, or when the cell is placed closer to the skin.
- The system enforces a mandatory cooling time that cannot be overridden, to prevent immediate burn due to a single sonication or due to the next few sonications.
- It is not recommended to start the next sonication until the entire system-recommended cooling time has passed.
- The user may be allowed to override part of the system-recommended cooling time, since the treating physician may have additional clinical information about the particular treatment or patient, which convinces him that sonication speed can be increased without compromising safety.
- The post-sonication temperature scan cannot be stopped from the Sonalleve console, only from the MR scanner console. Stopping the scan is not advisable.
- After the post-sonication temperature monitoring scan, the system may start a fat-monitoring scan to collect information for improving the cooling time estimates. This scan cannot be stopped from the Sonalleve console, only from the MR scanner console. Stopping or preventing the scan is not advisable.
- Use of the beam shaping feature or electronic deflection increases near-field heating. In these situations it may be necessary to use longer cooling times than recommended by the Sonalleve system.



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.

A diminishing progress bar labeled **Cooling** and a count-down timer in the System Status Display indicate the system-recommended cooling time. The part of cooling time that cannot be overridden is displayed in red.

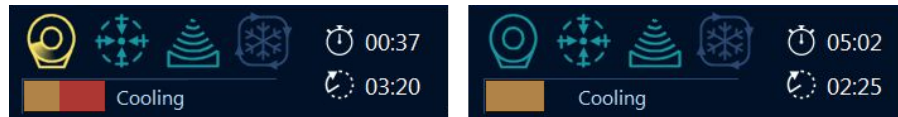


Fig. 20: Two examples of cooling time in the System Status Display. Left: More than one half of the remaining system-recommended cooling time is mandatory and cannot be overridden. Right: It would be possible to override the system-recommended cooling time.

4.6.5. Temperature limits

The Sonalleve MR-HIFU system imposes the following temperature limits to prevent undesired overheating of tissue:

- **Warning zone heating limit:** 47 °C (116.6 °F). If the system detects this temperature inside the beam path in the near-field monitor slice or inside a user-defined Freehand Warning ROI, it generates a warning message and the user must decide whether to continue or stop the sonication.
- **System safety limit:** The highest temperature that is allowed in a treatment cell during sonication is 80 °C (176 °F). If this temperature is reached within the treatment cell, the system issues a warning and automatically stops the sonication.

4.7. Motion detection

Patient motion may result in misplaced heating. Observe carefully that the major nerves and bowel loops have not moved into the beam path.

As a safety measure, the system detects unintended patient movement during treatment and issues a warning if it is detected. If the movement is significant, the system issues a more severe warning.

If the patient moves during treatment, a spatial variation of the measured temperature outside the heated region occurs. Carefully monitor the temperature maps during therapy.

Additionally, if you suspect the patient has moved, scan a fast scan with markers and compare the images. If you see significant movement in the images, scan the planning images again and verify the validity of the treatment planning. An alternative is to use registration tool. Registration is a feature that can perform the necessary corrections if any patient or organ movement is observed during the treatment. See 6.8.7. *Registration*.

In addition, the Sonalleve software provides graphical tools, such as markers, that can be used for detecting movement of visible anatomical landmarks. For more information, see 6.6.6.1. *How and why to use markers?*.

4.7.1. Misplaced heating or motion artefact?

If the temperature increases significantly outside the intended heating volume, the system issues warnings. The warnings may be caused by movement or other artifacts and their reason and safety consequences should be understood before continuing with the treatment.

Breathing or bowel movements may produce artefacts which look like heating in the temperature images and trigger motion detection warnings.

The figures below show temperature images where sonication is not in progress but bowel motion interferes with the temperature imaging.

4. Treatment methods > 4.7. Motion detection

If there is any doubt about the cause of the perceived heating, immediately abort the sonication using the software abort button and run a temperature scan without any heating. If the temperature does not seem to decrease, the perceived heated region may be caused by an artefact and treatment can resume with caution.

Ways to distinguish motion artefacts from heating:

- Run temperature mapping scans before the **Therapy** stage and in between sonications.
- Use the transducer beam overlay to check the location of the colored areas. If they are outside the beam path, they are most likely artefacts caused by motion.
- Scroll the time series to determine whether the perceived heating occurred during sonication.

In the following example image actual heating has taken place at the heated area at the ultrasound beam focus. The areas colored yellow or red far from the transducer beam are motion artefacts.

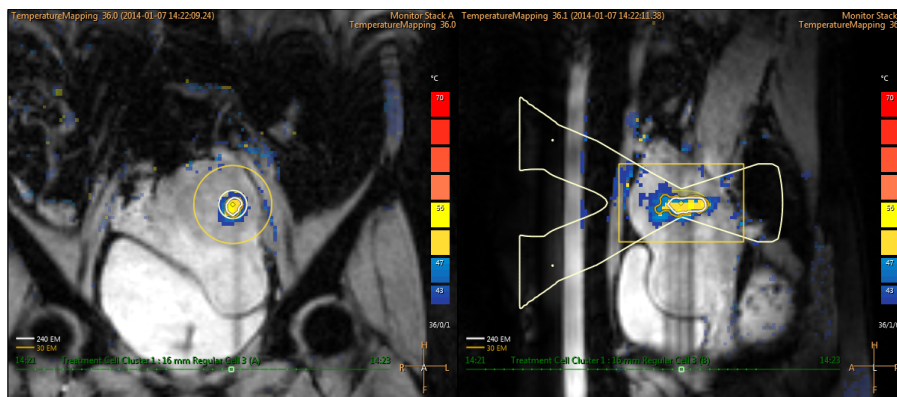


Fig. 21: Motion artefacts in temperature mapping images.

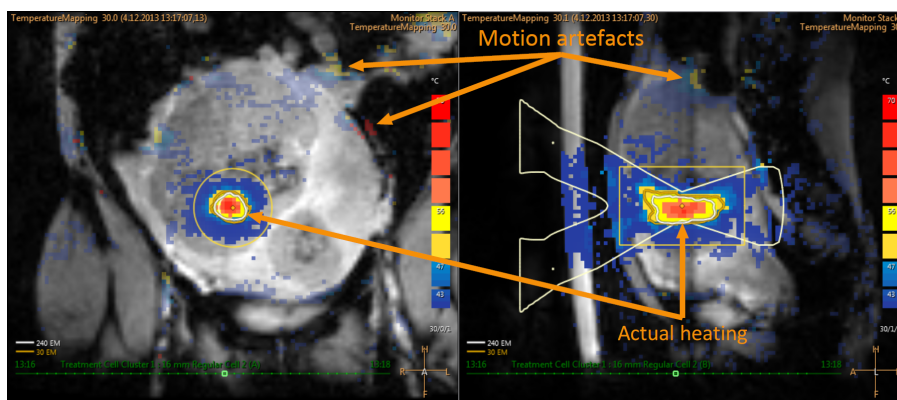


Fig. 22: Heating and artefacts in temperature map

5. User interface

5.1. Overview

The Sonalleve MR-HIFU user interface is used for planning, performing and monitoring the treatment using images obtained from the MR scanner.

The user interface provides versatile tools for viewing the images in all imaging planes. The way in which the images are viewed can be optimized for each treatment stage.

The target to be treated and other areas of interest can be defined and visualized as overlays on top of the images.

The user interface also enables constant monitoring of the treatment for patient safety throughout the treatment.

5.2. Starting the Sonalleve MR-HIFU application

5.2.1. Selecting the configuration

The Sonalleve MR-HIFU application can be started in two different modes regarding which configuration the application uses.

- **Therapy** is for clinical use. The application starts with the Site Default Configuration (see *5.2.1.1. Site Default Configuration*). For normal users, the Sonalleve console is set to start the application in **Therapy** mode when the user logs in.
- **Research** is for experimental use by researchers and other qualified advanced users. The application starts with the current configuration, without first loading the Site Default Configuration. **Research** mode is only available to HIFU Power Users (see *10.7. Hospital administrator and user accounts*).

On the Windows desktop of HIFU Power Users, there is a shortcut to start the application in **Therapy** mode. Shortcuts for both starting modes appear in the Windows **Start** menu.

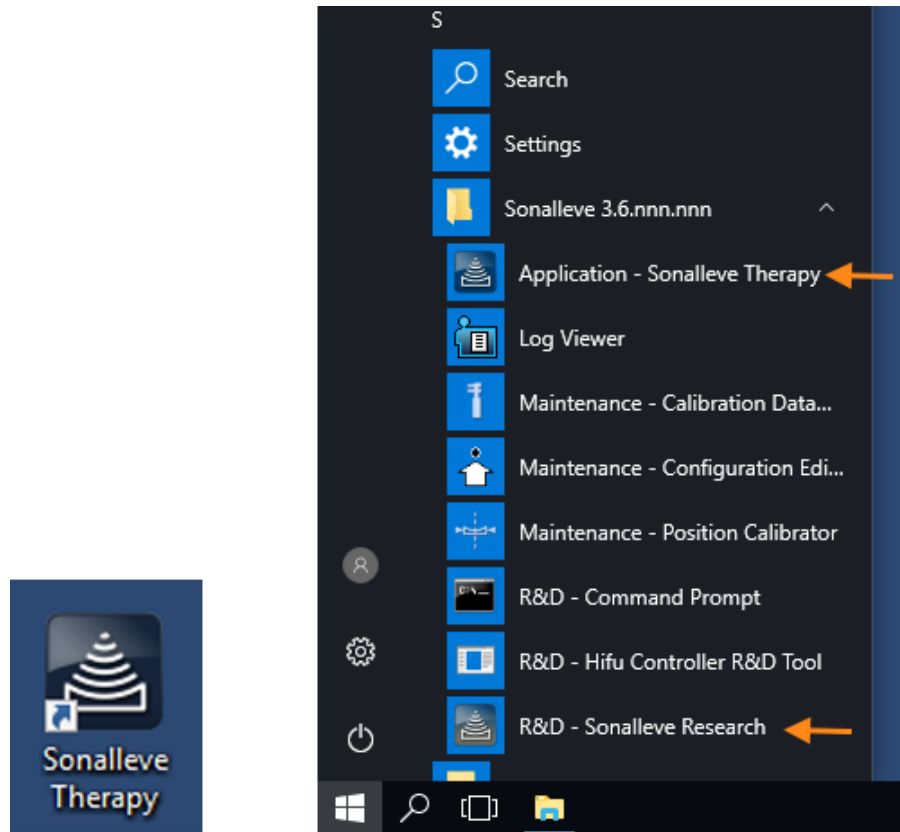


Fig. 23: Application start shortcuts. Left: desktop shortcut. Right: Start menu shortcuts.

To change between the **Therapy** and **Research** modes, restart the application.

Site Default Configuration

The Site Default Configuration is the configuration that is always taken into use when the Sonalleve Application is started from the Sonalleve Therapy shortcut. It is intended to be a safe default configuration that always works with the Sonalleve hardware and ensures that the user always has a valid configuration for use, even if the last configuration has been modified by researchers or advanced users. Any changes that advanced users make in the current configuration do not overwrite the Site Default Configuration unless they are explicitly saved as the Site Default Configuration.

5.2.2. Selecting between the Therapy and Standalone mode

To select between **Therapy** mode and **Standalone** mode, select the mode in the **Mode** list in the start page of the Sonalleve MR-HIFU application:



Fig. 24: The Mode list in the start page of the application.

The text in the application selection button for the therapy session changes according to the mode that the Sonalleve MR-HIFU application is in:

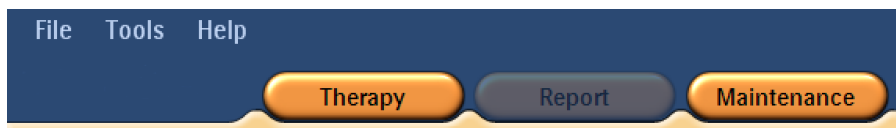


Fig. 25: The application selection buttons when the Sonalleve MR-HIFU application has been started in the **Therapy** mode and **Therapy** is selected in the start page. To start therapy with the Site Default Configuration, click **Therapy**.

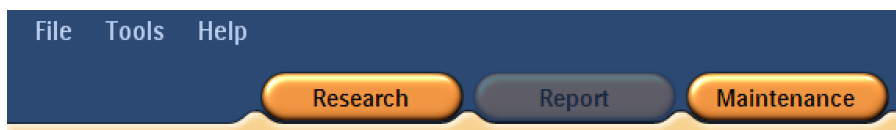


Fig. 26: The application selection buttons when the Sonalleve MR-HIFU application has been started in the **Research** mode and **Therapy** is selected in the start page. To start therapy with the current configuration, click **Research**.

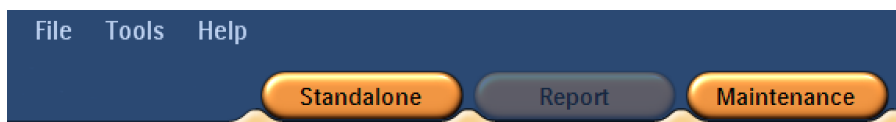


Fig. 27: The application selection buttons when **Standalone** is selected in the start page of the Sonalleve MR-HIFU application. To start in the **Standalone** mode, click **Standalone**.

5.3. Exiting Therapy

To exit Therapy mode and return to the start page of the Sonalleve MR-HIFU application, either click the **Therapy** application button or select **End Therapy** in the **File** menu.

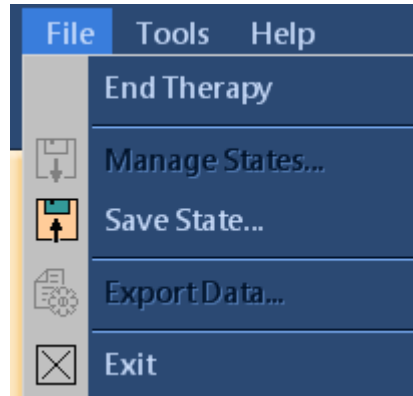


Fig. 28: File menu during Therapy.

To exit the Therapy mode and close the Sonalleve MR-HIFU application, select **Exit** in the **File** menu.

Saving unsaved data

When you exit a therapy session, in which there is unsaved therapy data, the system displays the following Save State dialog:

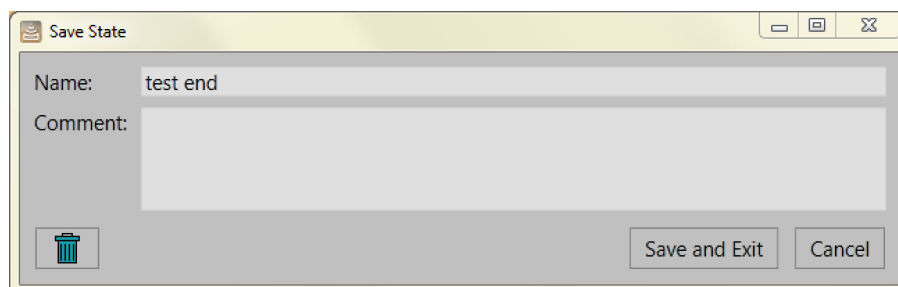


Fig. 29: The Save State dialog.

You can select one of the following three alternatives:

- Fill in a name and a comment for the saved state, then click **Save and Exit** to save the therapy data and exit the session.
Click **Cancel** to cancel the exit and to return to the therapy session.
Click the **Abort without Saving** button (the button with the trashcan icon) to abort the session without saving therapy data.

If you select **Abort without Saving**, you need to confirm the exit in a follow-up dialog:

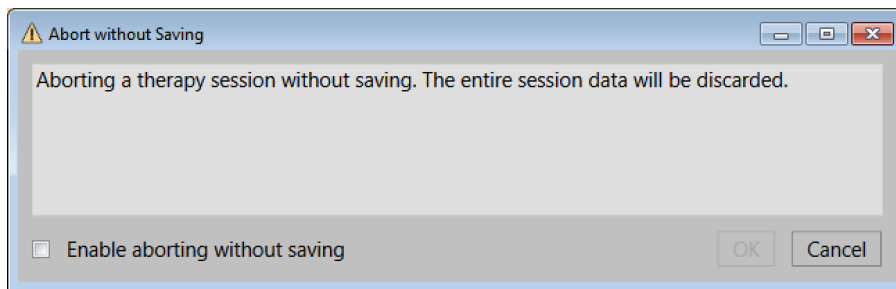


Fig. 30: The Abort without Saving confirmation dialog.

To abort the session without saving therapy data, check the checkbox **Enable aborting without saving** and click **OK**. Alternatively, to keep the data and return, click **Cancel**.

NOTICE

When you click OK in the Abort without Saving confirmation dialog, the therapy data is discarded and cannot be recovered. It is not possible to create a Clinical Summary Report after the session has been aborted without saving therapy data.

For more information on saving therapy data, see 5.11. *Saving and recovering your work.*

5.4. Exiting the Sonalleve MR-HIFU application

To close the Sonalleve MR-HIFU application, select **Exit** in the **File** menu.

5.5. Therapy application screen layout

The Sonalleve MR-HIFU Therapy application screen is divided into three main areas: **Therapy Wizard (1)**, **Image Area (2)** and **Hardware Status Area (3)**.

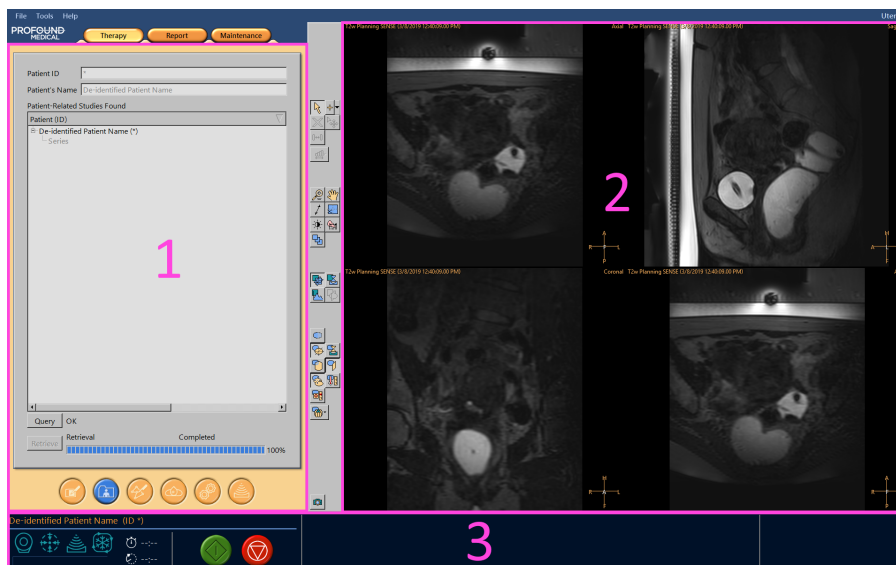

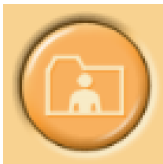


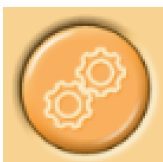



Fig. 31: Sonalleve MR-HIFU Therapy application screen layout.

5.6. Therapy Wizard

In the **Therapy** application the Therapy Wizard will guide you through the following successive stages:

Tab. 10: Therapy stages.

| Stage | Navigation button | Stage name |
|-------|---|----------------------------------|
| 1 |  | Patient Information Entry |
| 2 |  | Imageset Retrieval |
| 3 |  | PTV Delineation |
| 4 |  | Treatment Cell Planning |
| 5 |  | Hardware Initialization |
| 6 |  | Therapy |

Complete all mandatory actions in each stage. Otherwise you cannot move on to the next stage. However, you can always return to a previous stage using the appropriate navigation buttons.

The visual appearance of each navigation button indicates if you can move to that stage:



| | | |
|---|---|---|
| Blue color indicates the current stage. | Strong orange color indicates a stage that you can move to. | Dull color indicates a stage that you cannot move to. |
|---|---|---|

For more information on the treatment stages, refer to 6. *Workflow*.

5.7. Viewing images

The Image Area shows the planning and monitoring images produced by the MR console in four separate windows. The protocol name and the date and time of the image, as well as the currently displayed image plane are shown on the upper edge of each window. For the image in the lower right corner, you can freely select the plane by right-clicking on image plane name in the upper right corner of that image.

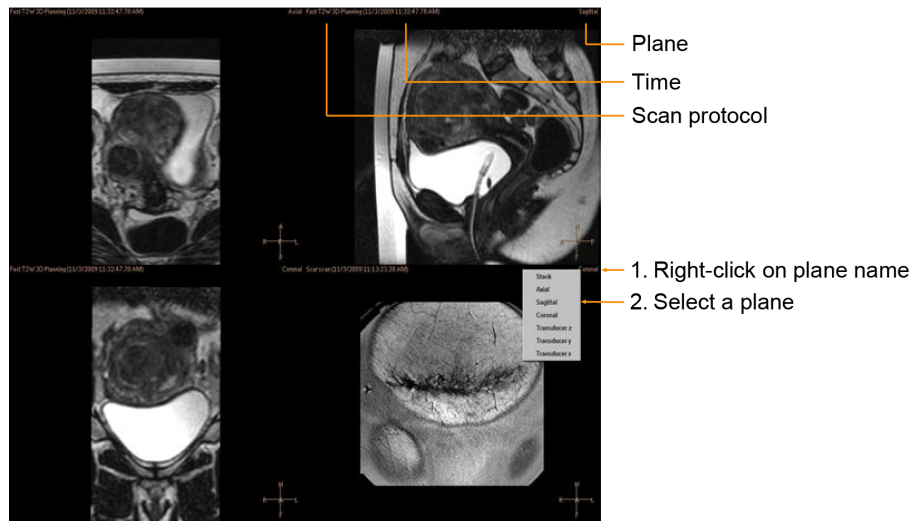


Fig. 32: Selecting the viewing plane.

Click on an image in the Image Area to select it for viewing.

You can view the images in various sequences and directions using the three groups of buttons on the toolbar:







- Basic viewing tools.
- Advanced viewing tools.
- Overlay tools.

The viewing tools available may vary between the treatment stages.

5.7.1. Basic viewing tools



Tab. 11: Basic viewing tools.

| Button | Tool | Function/Use |
|--------|-------------|---|
| | Zoom | Used for Zooming in/out on an image. Can also be activated by mouse right + left/scroll buttons. Right clicking the button gives you an option to cancel any modifications. |

| | | |
|---|--------------------------|--|
|  | Pan | Used for viewing an area of (a zoomed) image. Can also be activated by mouse left + scroll button. Right clicking gives you an option to cancel any modifications. |
|  | Browse Images | Used for browsing the slices of an image. To browse, activate the browse button and left click and drag or scroll on an image. Right clicking gives you an option to cancel any modifications. |
|  | Navigation Wizard | Automatically finds the location you click on the other two image orientations. Reduces the need for browsing the slices. |
|  | Window | Used for adjusting the brightness and contrast of the images. Left-click and drag left to see a narrower range of intensity levels, right to see a wider range of intensity levels, up to darken the image or down to lighten the image. Right-clicking gives you an option to cancel any modifications. |
|  | Measure | Used for measuring, for example, the size of or the distance between objects. Left-click and drag to measure. |
|  | Scroll | Used for viewing a timeline of the image. |

The following tool buttons are hidden by default. To add these tool buttons to the toolbar, select them in the **Tools** → **Toolbar Options** menu.


Tab. 12: Additional basic viewing tools.




| Button | Tool | Function/Use |
|---|---------------------|---|
|  | Profile Line | Used for viewing the heating along a line instead of in a treatment cell. Only available in the Analysis tab of the Therapy stage. Drawing a line on top of the image defines the line, the heating along which is displayed in the Temperature Curve window of the Analysis tab. |
|  | Pixel Info | Pixel Info allows you to see the coordinates, the maximum temperature and the heating dose for a selected pixel on a temperature map. This allows for detailed analysis of the sonication results |

5.7.2. Advanced viewing tools

It is often necessary to view the images differently in different stages of the treatment. The advanced viewing tools allow you to change the way in which the images are displayed in the image area. A view can be customized by selecting the desired viewing tools. The Sonallevé MR-HIFU application will remember the selected views when the user returns to a specific treatment stage and to a tab page within the stage.



Tab. 13: Advanced viewing tools.

| Button | Tool | Function/Use |
|---|-----------------|--|
|  | Orthogonal view | Shows the axial, sagittal and coronal planes and the image stack. This view is “patient oriented”, meaning that it is useful for viewing the anatomy, but not for all planning operations. |

| | | |
|---|-----------------|---|
|  | Transducer view | Shows the planes aligned with the transducer X, Y and Z axes. The recommended view that allows adjusting the transducer position in all three dimensions. Operations are possible on all planes. |
|  | Monitor view | Shows the monitor stacks used in temperature monitoring during sonication. |
|  | PTV view | Shows selected planes aligned according to the Planning Target Volume (PTV) X, Y and Z axis. The only view in which the PTV can be adjusted in all three dimensions. Operations are possible on all planes. |

The tool buttons of the following views are hidden by default. To add these tool buttons to the toolbar, select them in the Tools → Toolbar Options menu.






Tab. 14: Additional advanced viewing tools.





| Button | Tool | Function/Use |
|---|-----------------|---|
|  | Comparison view | Shows two images of the same plane side by side. Useful for e.g. comparing the images from two protocols. |
|  | Single view | Shows a single large image. |

5.7.3. Overlay tools

The overlay tools assist you during the planning and monitoring of the treatment. They allow the display of objects related to treatment planning and monitoring, such as cells, transducer positions, or temperature maps on top of a planning image. Some overlays also allow adjustment graphically. Several overlays can be displayed simultaneously.

Tab. 15: Overlay tools.

| Button | Tool | Function/Use |
|---|--------------------------------|--|
|  | Hide all overlays | Hides all overlays. |
|  | PTV overlay | Shows the Planning Target Volume (PTV) and allows you to graphically adjust it. |
|  | Transducer beam overlay | Shows the transducer beam path. Visualizing the beam path helps in avoiding organs in the near and far field. The position of the transducer can be graphically adjusted by dragging from the handles on the transducer beam centerline. |
|  | ATA overlay | Shows the Available Target Area (ATA), i.e. the area within reach of the transducer beam. The ATA is displayed for the treatment plane of the current transducer position. |
|  | View slice overlay | Shows the slice position in the imaging volume. |

| | | |
|---|----------------------------------|---|
|  | Temperature map | Shows the temperature rise as a colored overlay and the color-coded temperature scale on the right side of the image window. The tool button has a context menu, in which you can choose between filtered and raw data temperature maps. |
|  | Dose contours overlay | Shows the dose as two contours around the heated area. The white contour shows the area in which the heating was sufficient to produce necrosis. The orange contour shows the area that was heated but not enough to produce necrosis. |
|  | ROI overlay | Shows the Region of Interest (ROI) outlines and the 3D markers added in the planning phase. Also shows the measurements made with the Measure tool. |
|  | Treatment cell visibility | With cell visibility, you can select how the treatment cells are shown. Display all cells, no cells, the cells on the active level, the cells in the current target volume, current transducer position, or current cluster, or display only the sonicated or pristine treatment cells. |

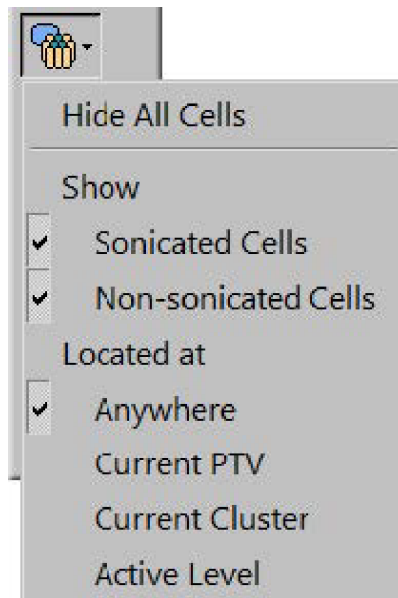




Fig. 33: Treatment cell visibility drop-down menu.

The tool buttons of the following overlays are hidden by default. To add these tool buttons to the toolbar, select them in the **Tools** → **Toolbar Options** menu.

Tab. 16: Additional overlay tools.

| Button | Tool | Function/Use |
|---|---------------------------|--|
|  | Transducer overlay | Shows the physical position of the transducer. |
|  | Thermal dose map | Shows the thermal dose as a colored overlay and the color-coded dose scale on the left side of the image window. Cannot be used together with temperature map overlay. |

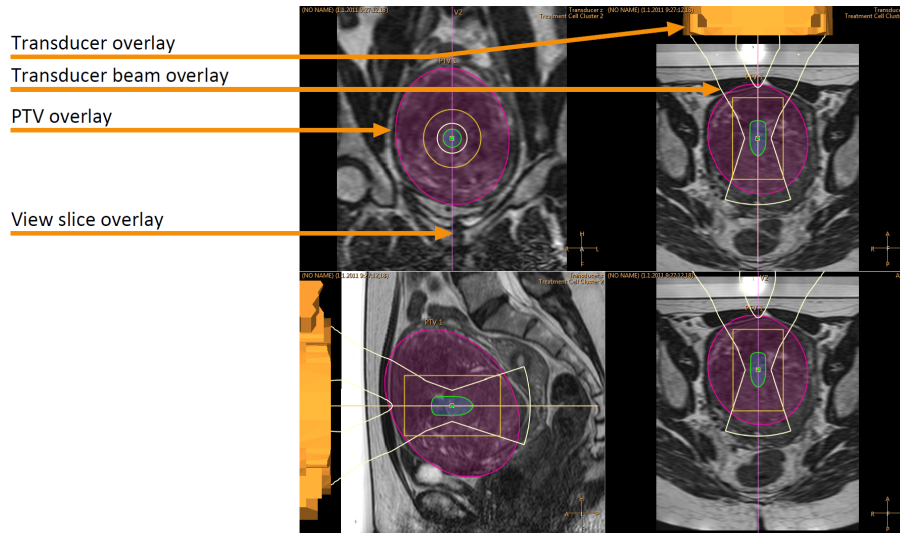


Fig. 34: Number of overlays on top of the transducer view

Transducer beam overlay

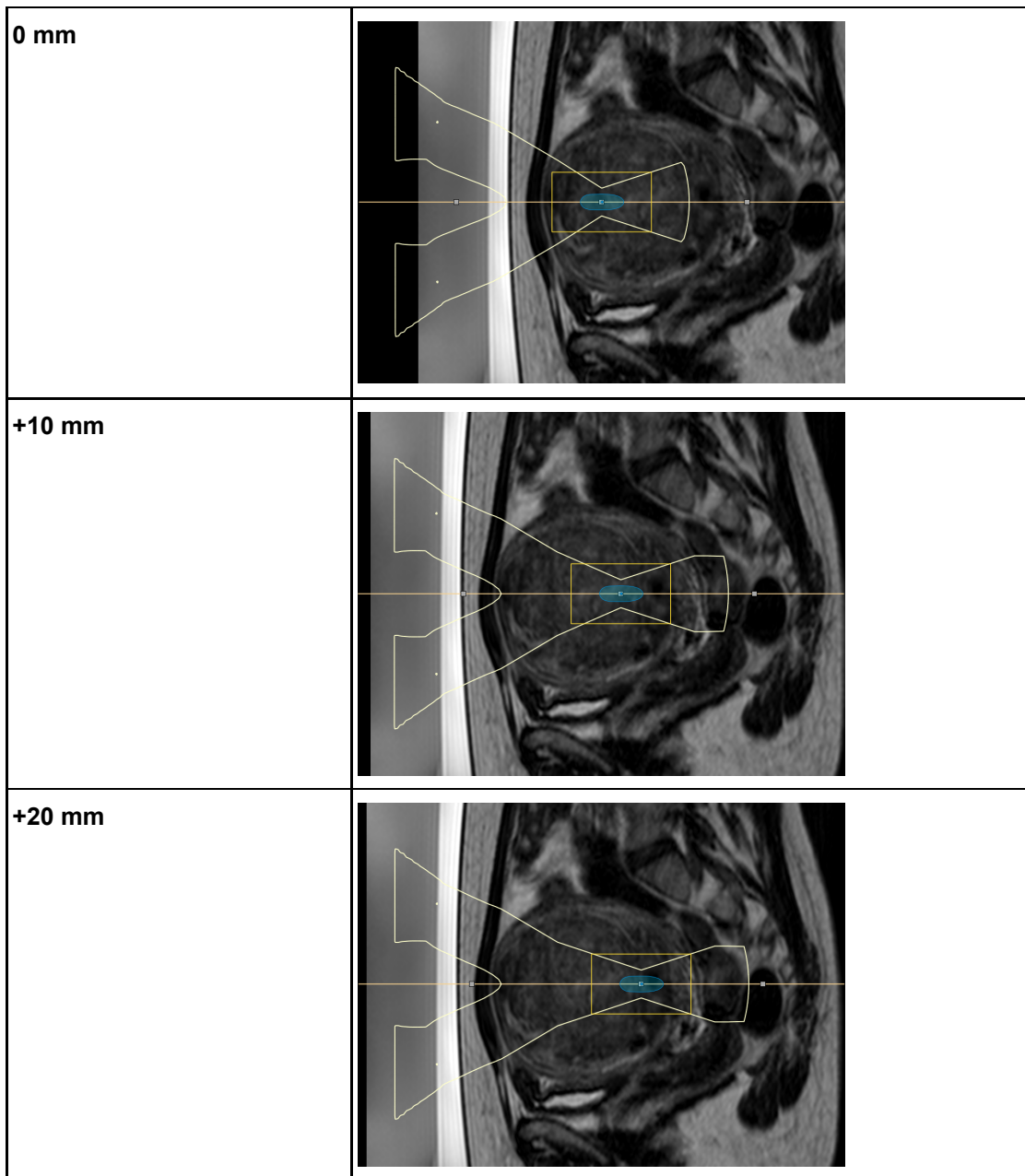


The transducer beam overlay displays the estimated shape of the transducer beam. The shape of the near field close to the transducer is calculated in real time. This calculation is an approximation that takes into account OARs, the distribution of transducer elements at the surface of the transducer, and the position and angulation of the transducer. The shape of the near field close to the treatment cell and the shape of the far field depend only on treatment cell size and the use of electronic deflection. Transducer beam shape calculation is not able to model the possible effects from anatomical variation in tissue. The displayed beam shape does not observe changes due to different sonication powers, either.

When the system uses depthwise electronic deflection to position a treatment cell closer to the transducer (negative electronic X deflection), the position of the narrowest part of the beam can be different from the position of the treatment cell, as shown in the first of the the following example images. This displacement is intentional, to give you a better approximation of the transducer beam shape.

Tab. 17: Examples of the transducer beam overlay with different amounts of electronic X deflection.

| Electronic X deflection | Displayed beam shape |
|-------------------------|----------------------|
| -10 mm | |



The transducer beam overlay visualizes the treatment cell safety margin and the far-field safety margin:

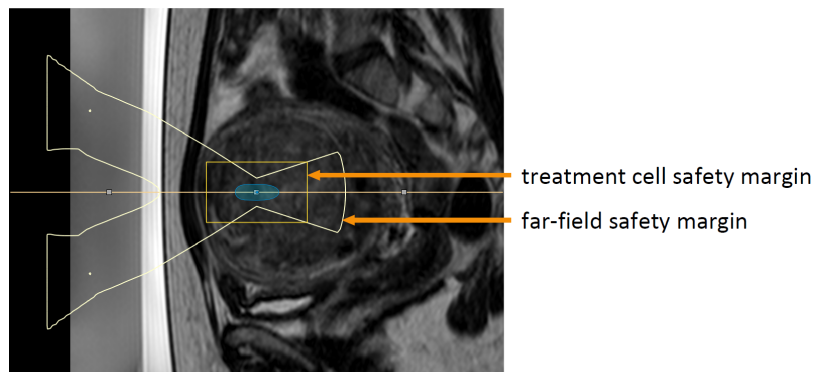




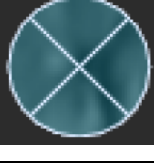


Fig. 35: The transducer beam overlay visualizes the treatment cell safety margin (1) and the far-field safety margin (2).

Treatment cell visualization

The status of each treatment cell is indicated with different colors and markings.

Tab. 18: Treatment cell color codes and markings.

| Cell appearance | Cell state |
|---|---|
|  | A pristine, correctly positioned cell. Not marked checked with the Toggle Cell Checked tool. |
|  | A pristine, safety checked cell. Marked checked with the Toggle Cell Checked tool. |
|  | The currently active (selected) cell. |
|  | A test sonicated cell. |
|  | A sonicated cell. |
|  | An incorrectly positioned cell. The cell is outside the Available Target Area (ATA) and must be repositioned. |

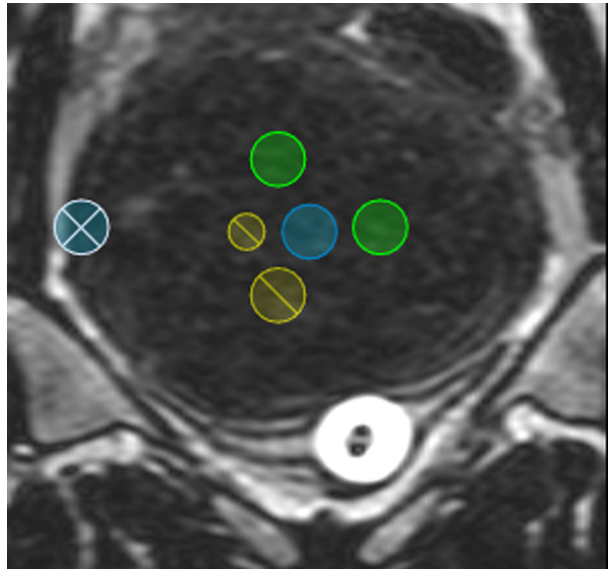








Fig. 36: Treatment cells.

5.8. Adding, selecting and removing objects






With this group of tools you can add, select and remove objects. The buttons are active only in those stages in which they can be used.

| Button | Tool | Function/Use |
|---|------------------------------------|--|
|  | Add | <p>Adds an object (PTV, treatment cell, marker, freehand ROI, freehand Warning ROI, OAR, or Critical OAR).</p> <ul style="list-style-type: none"> PTVs and treatment cells can only be added in their respective stages. Markers and ROIs can be added at any stage. Freehand Warning ROIs can only be added during the Therapy stage, and only to images displayed in the Monitor view. OARs are ROI regions that can be drawn to protect sensitive regions in the near-field beam path. In some stages, it is possible to add several types of objects. By default, the object that is added is of a type that is necessary before proceeding to the next stage. To select another type of object, click on the down arrow next to the Add button to open a drop-down menu. |
|  | Select | <p>Selects an object so that it can be moved or adjusted. PTVs and treatment cells can only be selected with this tool in their respective stages. Markers and ROIs can be selected at any stage.</p> |
|  | Move Treatment Cell Cluster | <p>Selects a treatment cell cluster so that it can be moved and angled.</p> <ul style="list-style-type: none"> If a cluster contains sonicated cells, those cells will not be moved. If all the cells in a cluster are sonicated a new cluster is created instead. |

| | | |
|---|----------------------------|---|
|  | Remove Current | Removes the selected object. |
|  | Toggle Cell Checked | Marks the selected treatment cell as safety checked, or removes the mark. The cells that are marked safety checked are shown in green (see 5.7.3.2. <i>Treatment cell visualization</i>). |
|  | Cell type | Opens the drop-down list from which the cell size and type can be selected. If you do not select a cell from the list, the cells added will be 4 mm feedback cells in the Uterine application and 2 mm regular cells in the Bone application. |

Additional tools are available in the Treatment Cell Planning stage of the Therapy Wizard.

Tab. 19: Tools available in the Treatment Cell Planning stage.

| Button | Tool | Function/Use |
|---|---|--|
|  | Add Empty Treatment Cell Cluster | Adds a new, empty treatment cell cluster. |
|  | Copy Treatment Cell Cluster | Copies the selected treatment cell cluster. |
|  | Remove Subitems | Removes the subitems of the selected object. |
|  | Define Autopopulation Area | Used for drawing an area around an area to be automatically filled with treatment cells. |
|  | Autopopulate | Fills the autopopulation area with treatment cells of the selected type. |

5.9. Controlling and monitoring the sonication

The Hardware Status Area at the bottom of the screen is used for controlling the Sonalleve MR-HIFU system during the sonication phase and for monitoring the status of the system and the treatment.

The Hardware Status Area includes the following functions:

- System Status Display.
- Sonication buttons.
- Message area.





Information on the progress of the sonication is also displayed as:

- Temperature and thermal dose overlays.
- Temperature curve in the Sonicate and Analysis tabs.

5.9.1. System Status Display





The System Status Display shows the modes of the Sonalleve MR-HIFU system. The display includes the following icons:

Tab. 20: The System Status Display icons.





| Icon | Meaning |
|---|--|
|  | Scanner status (scanning/inactive). |
|  | Transducer positioner status (moving/idle). |
|  | Sonicator status (sonicating/idle). |
|  | Direct Skin Cooling (DISC) device status (water circulation on/off). |

The following colors and graphically overlaid symbols are used in the icons:

Tab. 21: Colors of the System Status Display icons.

| Color | Status | Example | |
|--------|----------|---|--|
| Green | OK, Idle |  | |
| Yellow | Active |  | |
| Red | Error |  | |
| Gray | Disabled |  | The option has not been installed or configured for use. |

Tab. 22: Overlays on the System Status Display icons.

| Overlaid symbol | Example | Meaning |
|---|---|--|
| Rotating gears over a yellow icon |  | The system is making preparations: for example, installing embedded software or changing the MR scan protocol. |
| Other animations in yellow icons |  | The system is active: for example, scanning or sonicating. |
| Small arrows in the blue DISC icon |  | Water circulation is on. |
| Yellow warning triangle over the blue DISC icon |  | There is a problem with the Direct Skin Cooling device. |

A progress bar below the icons shows the progress of the currently active mode. The timers show the remaining sonication time, scanning time, or cooling time. Tool tips over the timers also show the time from the first sonication and the time from the start of the therapy.

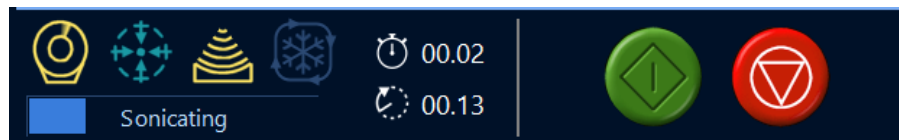




Fig. 37: System Status Display.

5.9.2. Sonication buttons

| | |
|---|-------------------------|
|  | Start Sonication |
|  | Abort Sonication |

The **Start Sonication** and **Abort Sonication** buttons are used for starting and aborting sonication. The buttons are active only in those stages where sonication is possible, i.e. during test sonication and therapy.

The **Abort Sonication** button should be used to stop the treatment only in situations in which there is no risk to the patient. In all other cases, use the stop button on the Safety Device.



A warning symbol is displayed on top of the **Start Sonication** button when the user is allowed to override the remaining part of the system-recommended cooling time (see 4.6.4. *Cooling time*). Generally, it is not recommended to start the next sonication until the entire system-recommended cooling time has passed.

5.9.3. Temperature and thermal dose

When pressing the Start Sonication button, the Sonalleve application scans a few reference images before starting the actual sonication. As the sonication starts, the calculated temperature and thermal dose are shown as overlays. Temperature and thermal dose are best shown simultaneously if the thermal dose contour overlay is used.

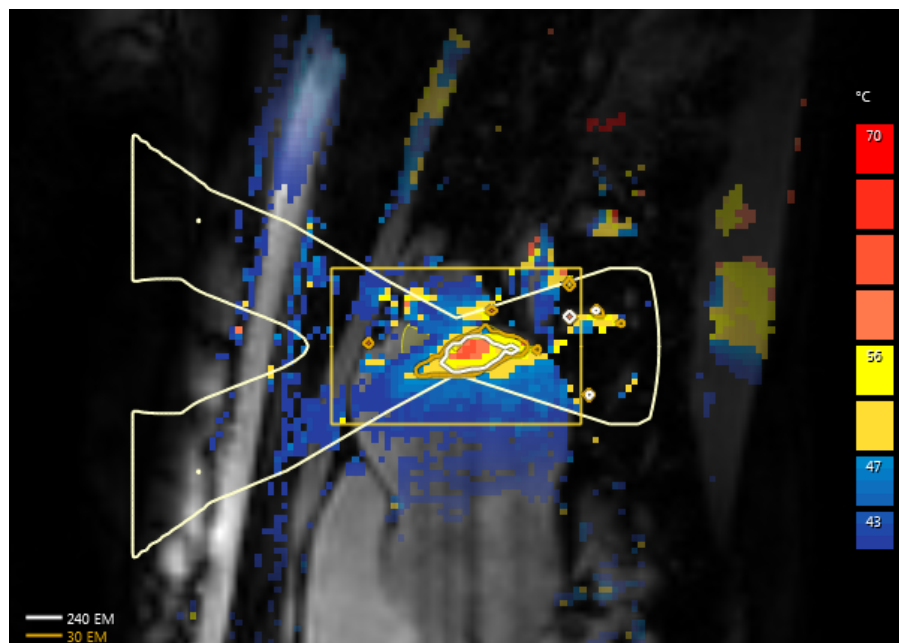


Fig. 38: An example of the temperature map and thermal dose contours of a sonication of a single cell.

The dose contours and the dose map correspond to the selected item. To see the dose from a sonicated treatment cell, select the cell.

To see the cumulative dose of all the sonicated cells in a treatment cell cluster, select the cluster.

When several sonications have been done, the cumulative dose calculation might take some time.



Fig. 39: Cumulative dose contour of a treatment cell cluster.



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.

5.9.4. Temperature curve

You can monitor the heating of a treatment cell during and after sonication with the temperature curve in the **Sonicate** and **Analysis** tabs of the **Therapy** stage.

- The yellow curve shows the temperature and the red curve the thermal dose in the middle of the treatment cell.
- Vertical green lines mark the start and stop points of sonication.
- A vertical dotted line shows when the maximum temperature was reached.
- The time scale starts from the start of sonication.
- White dotted lines show the time and temperature. Point to the temperature curve and left-click to read out the time and temperature at that point.

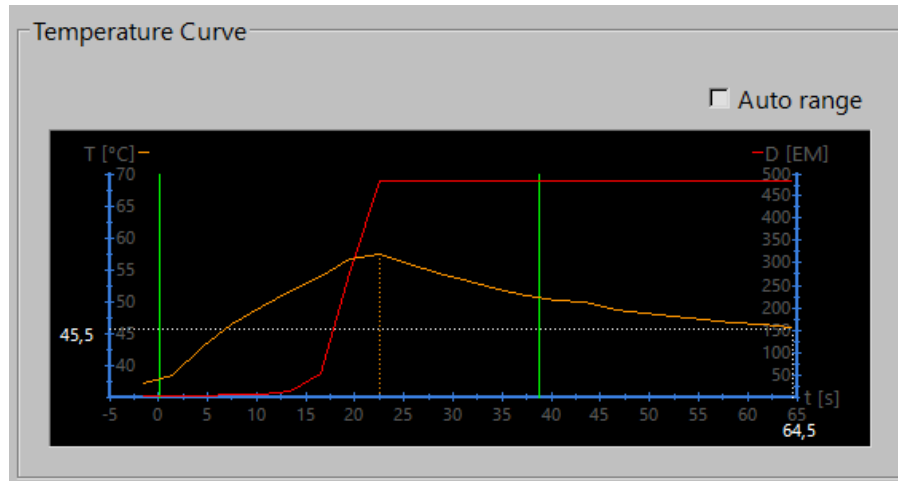


Fig. 40: Temperature curve.

Positioning a treatment cell inside the bone in the Bone application limits heating and temperature monitoring, and may result in a flat temperature curve.



Additionally, you can also choose to display the temperature and thermal dose along a line that you draw using the **Profile Line** tool. The tool button is hidden by default, but you can add it to the toolbar from the **Tools** → **Toolbar Options** menu. The heating profile can only be seen in the **Analysis** tab post-sonication.

- The yellow curve shows the temperature and the red curve the heating dose in each voxel along the line.

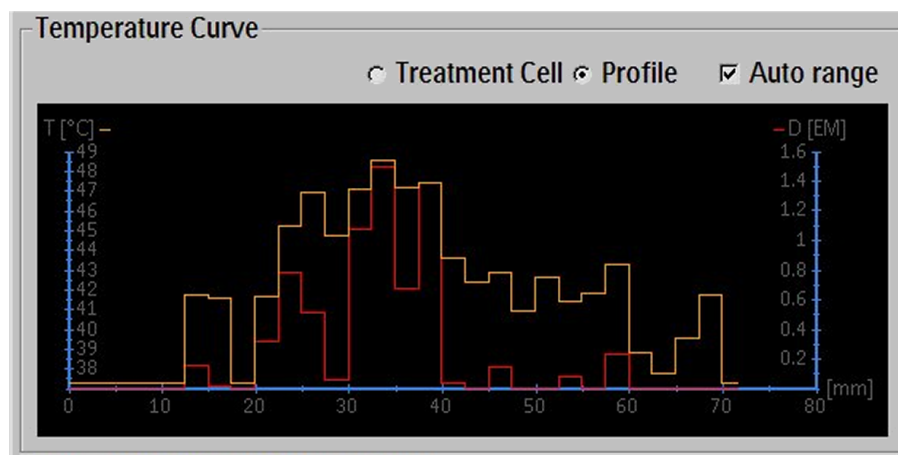


Fig. 41: Heating profile (Profile Line).

5.9.5. Message area

The message area in the middle of the Hardware Status Area shows the warnings and error messages of the system.

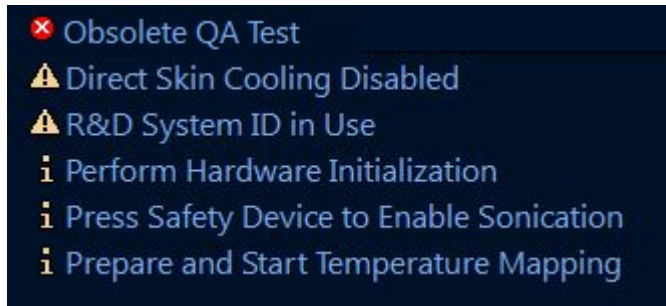


Fig. 42: Message area.

Double-clicking a message opens a notification window with more details on the message and instructions on how to clear it. For more information on error and warning messages, see 8. *System Error and Warning messages.*

5.10. Reporting and logging

5.10.1. Generating reports



You should generate a **Clinical Summary Report** and store it where it can be conveniently retrieved later. The Clinical Summary Report is a document in Portable Document Format (PDF) that includes the patient data, treatment data and possible errors during the treatment. Additionally, the post treatment images should be stored as part of the treatment results.

You can add comments and select snapshot images to be included in the report.

5.10.2. Taking snapshots



With the snapshot tool, you can take snapshots of the images in the image area. Clicking on the button opens a comment dialog over the area where the snapshot will be taken and saves a snapshot of the active window in the image area into the Clinical Summary Report. In addition to the image area, the snapshot tool also enables you to take snapshots of the Temperature Curve area, which is visible in the Sonicare and Analysis tabs.

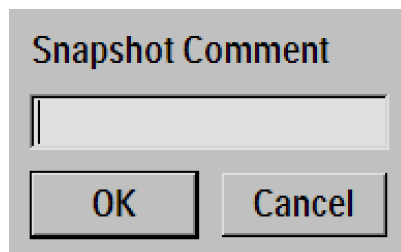


Fig. 43: Snapshot Comment dialog.

5.10.3. Viewing and exporting logs

The **Tools** menu contains the **Log Viewer**, through which you can:

- View system events.
- Filter the log to display events according to their:
 - Severity level (unknown, Debug, Info, Warning, Error).
 - Time period (last 1 hour, last 24 hours or within another specified time range).
 - Originator (software components on the HIFU Controller or the Sonalleve Console).
- Export the log for use in troubleshooting, for example.

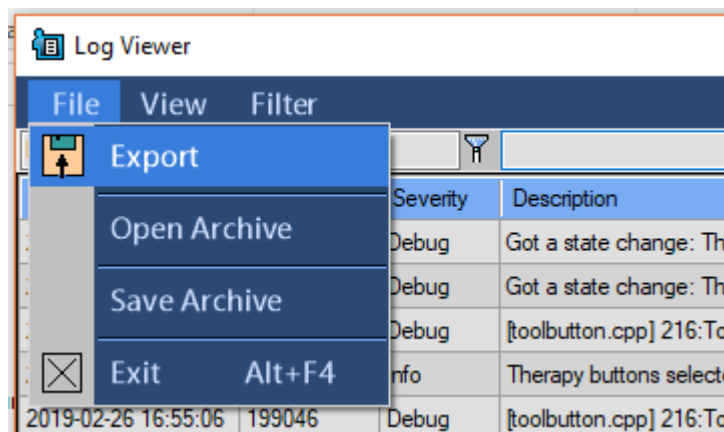


Fig. 44: Exporting the log.

- Store logs in an archive that allows opening the stored data with the Log Viewer.

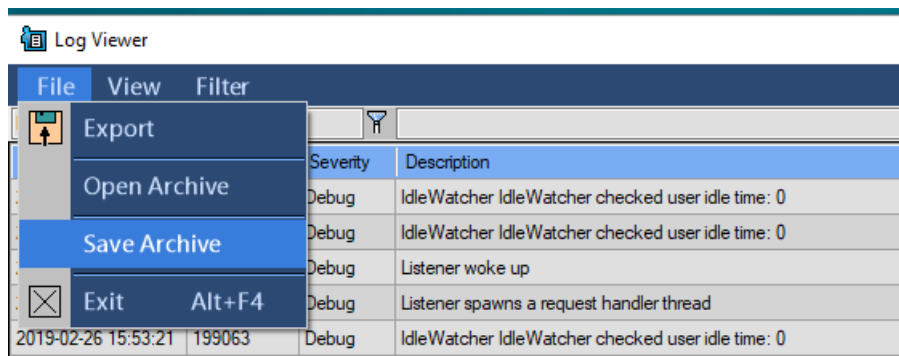


Fig. 45: Storing logs in an archive

5.11. Saving and recovering your work

To save your work, you should:

- Create a Clinical Summary Report as described in 5.10.1. *Generating reports*.
- Create a Saved State file. A Saved State file is a .tar file containing a snapshot of the current treatment situation.

- Save pre- and post-therapy images in the MR console.

A Saved State file should be created for research and backup purposes.

A Saved State is useful when making significant changes in the planning process and later wishing to revert to the previous plan. If the software crashes, the system will automatically create a Saved State file of the current situation.

When clicking the **Save State** menu item, a dialog box opens where the state can be named and additional comments made. If the name field is left empty, the software generates a name based on the current time and date.

Storage of Saved States

Saved States are stored in an internal database that has limited storage capabilities. The system does not provide persistent storage for Saved States. Always export the required Saved States to a permanent storage medium, such as a network drive, a USB disc, or a DVD after a treatment session.

NOTICE

The front USB ports are disabled for cybersecurity reasons. Access for the rear panel USB ports and the DVD require administrative privileges (e.g. Hospital Administrator account). In some cases it may be necessary to restart the computer to gain access to a connected USB drive.

NOTICE

The Saved States are only held in the internal database for 7 days or until its memory is full. As new Saved States are added, the oldest ones will be removed from the database. If you wish to permanently keep the Saved States, ensure that information is exported to a secure storage system as soon as possible. Use the Export button to save the .tar file to an external storage device or to DVD.

Patient data (Saved States) written to removable media, such as DVDs, is identifiable. Treat removable media containing patient data as confidential and store the media in a secure environment.

Writing patient data to an external storage device or to DVD is considered temporary storage only, not a long term backup solution. To ensure patient data security, send patient data to a dedicated DICOM storage device that is intended to be used as an archive.

Create and implement policies ensuring that data backups occur and that data backups protect patient data.

A risk of losing patient data exists when storing patient data on backup media. Storage media may become:

- Lost
- Obsolete
- Unreadable
- No longer supported.

Ensuring sufficient free disk space

Each Saved State in the database consumes disk space on the workstation. For unhindered operation of the Sonalleve MR-HIFU application and the Sonalleve console in general, sufficient disk space must always be available.

The Sonalleve MR-HIFU application monitors the amount of available disk space. When the available disk space is getting too low, the following warning appears in the start page of the application.

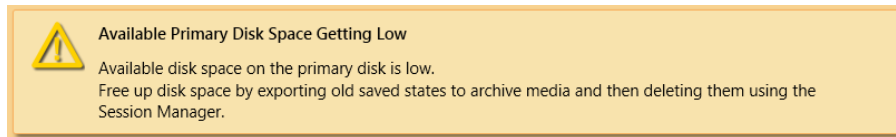


Fig. 46: Warning for low available disk space.

When the available disk space is no longer sufficient, the following error message appears in the start page of the application. This error prevents the user from entering the Therapy mode and loading Saved States.

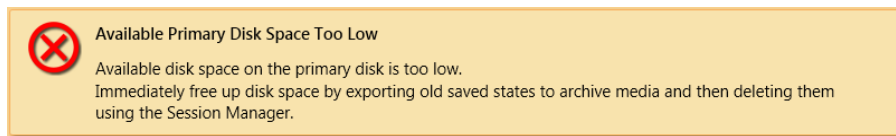


Fig. 47: Error for too low available disk space.

Click on the warning or error message to open a restricted Session Manager dialog, in which you can export and delete old Saved States. Importing Saved States is disabled in the restricted Session Manager. The amount of available disk space is shown in the footer of the dialog window.

NOTICE

The Session Manager only shows the Saved States that are stored in the internal database. If the disk is filled with other files, a system administrator has to clean the system by using normal Windows tools.

Session Manager

In the **Session Manager** dialog, you can view the contents of the internal database and import, export and delete Saved States. Select **Manage States** in **File** menu to open the **Session Manager**.

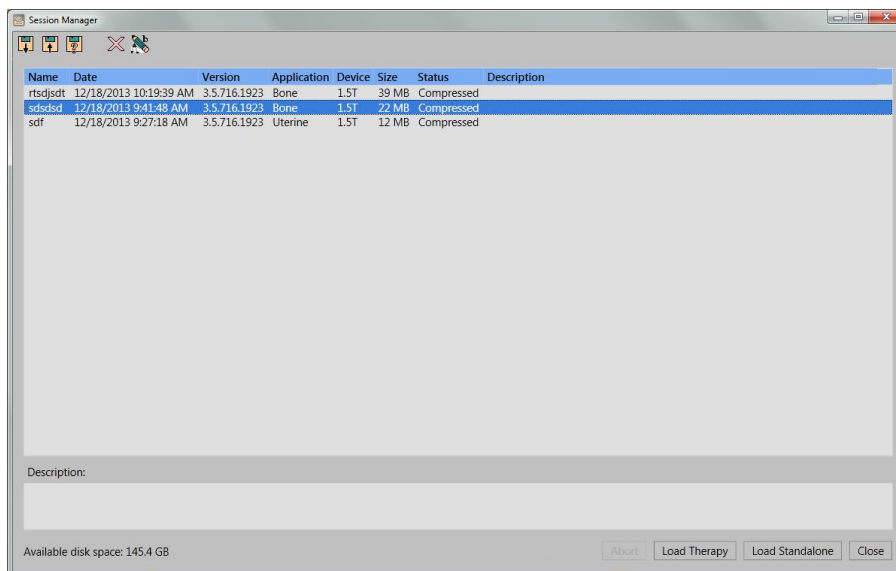








Fig. 48: Session Manager.

Tab. 23: Session Manager tool buttons.

| Button | Tool | Function/Use |
|---|-----------------------------|---|
|  | Import | Used for retrieving previously exported .tar files (Saved State files). |
|  | Export | Used for exporting a session into a separate .tar file (Saved State file). |
|  | Export De-identified | Used for exporting a session into a separate .tar file (Saved State file). Patient Name and ID will be anonymous in this Saved State. |
|  | Delete | Used for deleting a session. |
|  | Rename | Used for changing the description of a session. Note that renaming a session can be quite slow if a lot of data has been stored in the session. |
|  | Show All | Used for showing sessions that have been saved using other versions of Sonalleve software. This tool is only available to HIFU Power Users, Service and administrators. |

Loading a Saved State

1. Select **Manage States** in **File** menu. The **Session Manager** dialog box opens.
2. Select the Saved State from the list.
3. Click **Load Therapy** to load the saved state in **Therapy** mode, or click **Load Standalone** to load the saved state in **Standalone** mode.

NOTICE

Saved State can only be used for a single treatment session. If you reposition the patient on the table, you cannot continue planning using an existing Saved State but must scan new images and replan the treatment.

Exporting a Saved State

1. Select **Manage States** in **File** menu. The **Session Manager** dialog box opens.
2. Select the Saved State from the list.
3. Click **Export**.
4. Select the directory and file name to save to. The system can also export directly to a CD/DVD.

For instructions on burning Saved States to a DVD, see *10.5. Copying Sonalleve MR-HIFU treatment data to DVD*.

If a Saved State file is needed without identifying personal data, use the **Export De-identified** tool instead of **Export**. Before you use **Export De-identified**, ensure that the name and comment field of the session do not include the name of the patient or any other identifying personal data. Use the **Rename** tool to edit the name and comment if necessary. When exporting, give the .tar file a name that does not contain personal data.

Importing a Saved State

1. Select **Manage States** in **File** menu. The **Session Manager** dialog box opens.
2. Click **Import**.

3. Select the file to import.

5.12. Language settings

To set language and measurement display preferences, select the **Set Language** menu item in the **Tools** menu.

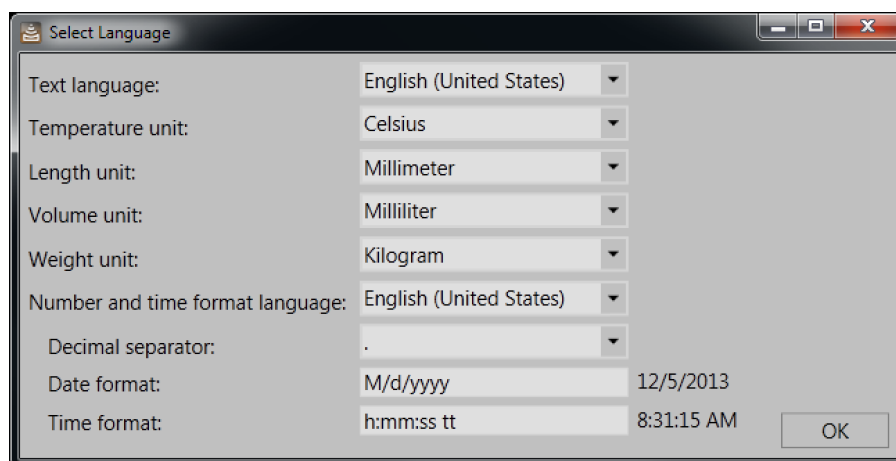


Fig. 49: Select Language dialog box.

5.13. Keyboard shortcuts

The following keyboard shortcuts are active when you have clicked on the Image Area to select it for viewing. The tools available may vary between the treatment stages and tab pages within a stage.

Tab. 24: Keyboard shortcuts in the Image Area.

| Key | Action |
|------------------|---|
| Page Up | Scroll dynamics backward in all windows |
| Page Down | Scroll dynamics forward in all windows |
| B | Browse images |
| P | Pan |
| Z | Zoom |
| W | Window (contrast/brightness) |
| S | Scroll dynamics |
| L | Add PTV |
| C | Add treatment cell |
| M | Measure |
| F | Add Freehand ROI |

5. User interface > 5.13. Keyboard shortcuts

| | |
|----------|--|
| A | Add autopopulation area |
| X | Add marker |
| R | Image text layout with additional information on/off |

6. Workflow

6.1. Overview

The Sonalleve MR-HIFU workflow can be divided into the following main stages:

1. Preparing the equipment.
2. Preparing the patient.
3. Positioning the patient.
4. Scanning the planning images.
5. Therapy.
6. Post treatment.

All the MR-HIFU Therapy applications follow the same main stages, but there may be application-specific differences in patient preparation, positioning, treatment cell types and sizes, and power levels. Always refer to the *Application Guide* for application-specific details.

6.2. Preparing the equipment

The Sonalleve MR-HIFU system is typically only used periodically, alternating with normal MR scanning. One person can switch between the standard tabletop and the Sonalleve tabletop in 5 to 10 minutes.

6.2.1. Connecting the Sonalleve tabletop

1. Inspect the Sonalleve tabletop for any signs of leaks.
2. Remove all coils, pads and accessories from the standard tabletop.
3. With some Ingenia MR scanners (see the following figure): Remove the thin tabletop used for diagnostic imaging.



Fig. 50: Left: This type of Ingenia thin tabletop needs to be removed before the Sonalleve tabletop can be placed in position. Right: The narrower end in this type of Ingenia thin tabletop allows the Sonalleve tabletop to be placed in position without removing the Ingenia thin tabletop.

4. Set the MR patient support to the lowest position.



CAUTION

The patient support must remain at the lowest position. Do not raise the support height after the Sonalleve tabletop is placed in position.

5. Bring in the Sonalleve tabletop. Position the trolley over the top of the lifting unit until the lateral stops are correctly inline with the buffer blocks on the patient support.



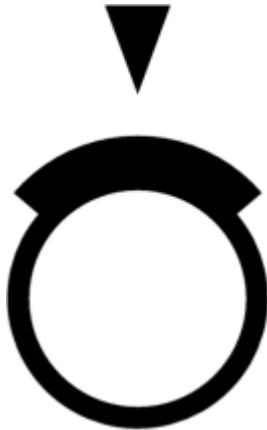
CAUTION

Take extra care not to damage the Patient Interface Control Unit (PICU) when maneuvering the trolley into position.

NOTICE

The lateral stops must touch the buffer blocks on the patient support.

6. Press the left side of the brake pedal down to lock all the wheels (brake **LOCKED**). The tabletop is now docked.



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.

7. Connect the Sonalleve Control Cable and the Ultrasound Cable to the sockets at the side of the tabletop. The cables are stored in the accessory cart, if available.

Make sure that the cables are not lying in the way when the patient enters or exits. Cables lying on the floor are a potential tripping hazard.



Fig. 51: Tabletop connector panel.

8. Unhook the Sonalleve Coil Cables from their holders on the tabletop and connect them to their sockets.
9. Remove the ultrasound window cover from the top of the ultrasound window. The ultrasound window cover is used for protecting the membrane on top of the ultrasound window when the tabletop is not in use.
10. Check that there are no visible leaks around the ultrasound window.

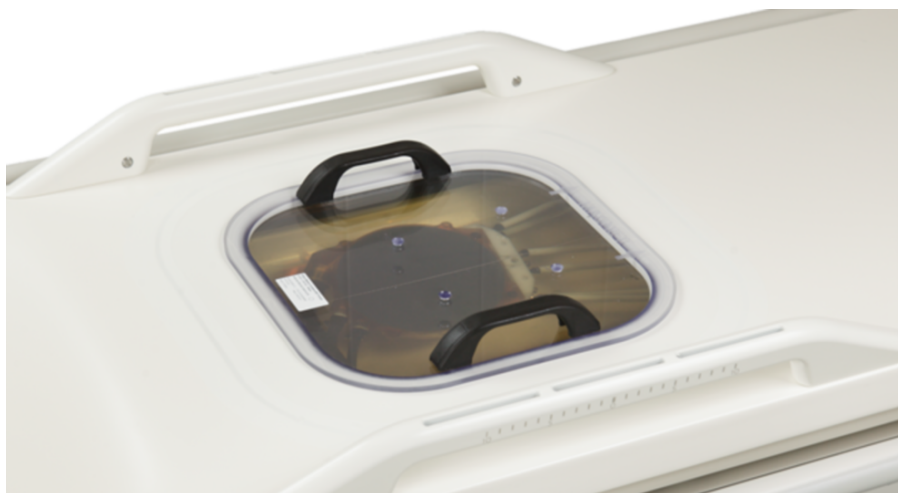


Fig. 52: Ultrasound window cover.

11. For the Direct Skin Cooling (DISC) device:
 - Check that the water level in the DISC device is correct: the surface of the patient contact should be flat.
 - Check that there are no obvious leaks from DISC.
 - Check that there are no large air bubbles visible through the DISC patient contact.
 - Connect the two connectors in DISC hoses to the connectors in the Sonalleve tabletop. Male and female connectors are provided to ensure correct connections.
 - Make sure that the hoses are not lying in the way when the patient enters or exits. Hoses lying on the floor are a potential tripping hazard.



Fig. 53: Connect the two connectors in DISC hoses to the connectors in the Sonalleve tabletop.

12. Connect the HIFU Pelvis Coil cable to the tabletop coil connector.

6.2.2. Connecting Tabletop Extension Plate (only in Bone application)

Sonalleve Extension Plate is designed to be used when the Sonalleve tabletop needs extension for the optimal treatment position.

1. Remove the detachable handle by pressing the release buttons.



Fig. 54: Detachable handle

2. Release the tabletop by pressing the release button and push it towards the magnet bore so that the Extension Plate will fit.
3. Take out the PESB and headphones from the accessory box.

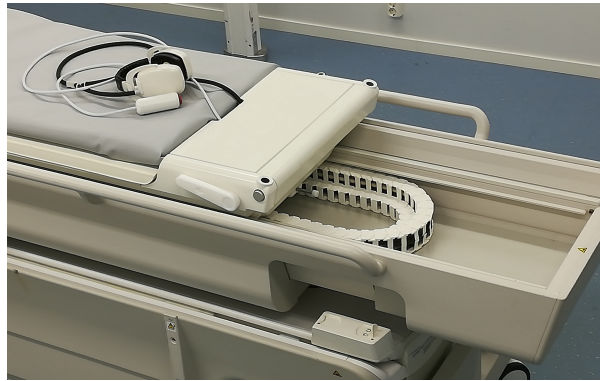


Fig. 55: PSB and headphones

4. Place the Extension plate on the Sonalleve tabletop and lock the Extension plate to the correct place.



Fig. 56: Extension plate

5. Pull the tabletop with the Extension plate back until it is locked.
6. Place the mattress on the Extension plate.

6.2.3. Preparing the tabletop for the patient

NOTICE

Before preparing the tabletop for the patient, check that the Quality Assurance (QA) procedure has been carried out. For more information on QA, see 7.2. *Sonalleve MR-HIFU Quality Assurance (QA) procedure*.

Preparing the tabletop for use with a gel pad

To prepare the Sonalleve tabletop for the treatment session, **when using a gel pad:**

1. Open a gel pad package and visually check that the gel pad is not damaged.



Fig. 57: Gel pad.

2. Pour a small amount of degassed acoustic contact liquid onto the ultrasound window until the membrane is fully submerged. Try to disturb the liquid as little as possible to avoid creating air bubbles. Never shake the bottle used to store the liquid.
 3. Visually check that there are no air bubbles in the contact liquid. If any bubbles are visible, move them to the edges of the ultrasound window.
 4. Place the gel pad on top of the ultrasound window, start with one edge then carefully “roll” the pad into position ensuring no air gets trapped beneath it.
 5. Place an absorbing cloth on the tabletop around the ultrasound window to absorb spilled contact liquid. Secure the cloth in place with adhesive tape.
 6. Place the gel pad holder around the gel pad.
 7. Place the appropriate mattresses, such as the footrest and other pads on the tabletop.
- If your Sonalleve MR-HIFU system is equipped with DISC that has been installed as an upgrade, always use a mattress so that there is no skin contact to DISC connectors and hoses.
8. Protect the mattresses with disposable sheets.
 9. Test that the PESB works before starting the procedure.
 10. Run the membrane bubble detection scan (start a new exam and select Sonalleve ExamCard “Verifications prior to the patient”). Verify that there are no air bubbles in between the membrane and gel pad; remove air bubbles if detected.

Preparing the tabletop using DISC without a gel pad

To prepare the Sonalleve tabletop for the treatment session, **when using DISC without a gel pad:**

1. Pour a small amount of degassed acoustic contact liquid onto the DISC window membrane until the membrane is fully submerged. Try to disturb the liquid as little as possible to avoid creating air bubbles. Never shake the bottle used to store the liquid.
2. Visually check that there are no air bubbles in the contact liquid. If any bubbles are visible, move them to the edges of the DISC tabletop window.

3. Place an absorbing cloth on the tabletop around the DISC tabletop window to absorb spilled contact liquid. Secure the cloth in place with adhesive tape.

4. Place the appropriate mattresses, such as the footrest and other pads on the tabletop.

If your Sonalleve MR-HIFU system is equipped with DISC that has been installed as an upgrade, always use a mattress so that there is no skin contact to DISC connectors and hoses.

5. Protect the mattresses with disposable sheets.

6. Test that the PESB works before starting the procedure.

6.3. Preparing the patient

Patient preparation generally includes depilation, catheterization, and mild pain medication. For detailed instructions, refer to the *Application Guide*.



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.

NOTICE

The rationale for this check should be explained to the patient.



WARNING

Only liquid is allowed in the catheter. Never fill the catheter with air as it may deflect the ultrasound beam.

6.3.1. Positioning the patient on the table

The Sonalleve tabletop may be used for transporting the patient short distances only, such as from the preparation room to the RF room. For longer distances, use a standard hospital bed.



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.

NOTICE

The rationale for these precautions should be explained to the patient.

Show the patient how to safely climb on and off the Sonalleve tabletop. Falling from the height of the Sonalleve tabletop may be dangerous. Support the patient and be prepared to prevent him/her from falling. Never allow the patient to put weight with their hands or knees on the ultrasound window as applying excessive force in this area may damage the ultrasound assembly.

1. Position the patient on the tabletop with the area of interest over the center of the treatment window. The patient can be in the prone, supine or oblique orientation depending on the application and the area of interest.
2. Try to keep as good skin contact as possible. Check that there is no clothing or absorbing material between the patient and the gel pad or DISC.



WARNING

Never leave an unconnected coil in contact with the patient.

3. Attach the infusion bag and IV tubes and secure the possible urine catheter bag in its place.
4. Assist the patient in finding a comfortable position for his or her head and arms.
5. You can use air bags, vacuum cushions, straps, and other similar MR-compatible supporting accessories to make the patient's position more stable and make the patient feel more comfortable.
6. Position the HIFU Pelvis Coil on top of the patient.
7. Secure the coil in place with the straps. Isolate the coil cable from 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.

8. Give the patient the PESB and instruct them how to use it. See 2.5.1. *Patient Emergency Stop Button (PESB)*.
9. Give the patient ear plugs and a headset.
10. Release the tabletop by pressing the release button and push it into the magnet bore until you hear a "click" sound and a short audio signal.



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.



Fig. 58: Patient positioning.

6.3.2. Verifying the patient positioning

1. Start a new examination on the MR console. Fill in the mandatory patient data.
2. Select the Sonalleve folder and the Therapy ExamCard:
 - Select the patient position.
 - Turn on **Autopush**.
 - Autopush will automatically send all images to the Sonalleve console.
 - Go to the **Scan** context menu and select **Push to Workstation**.
 - Select **Yes** to Sonalleve in the ExamCard Push node.

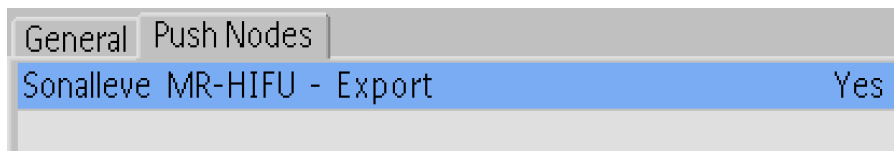


Fig. 59: ExamCard Push setting.

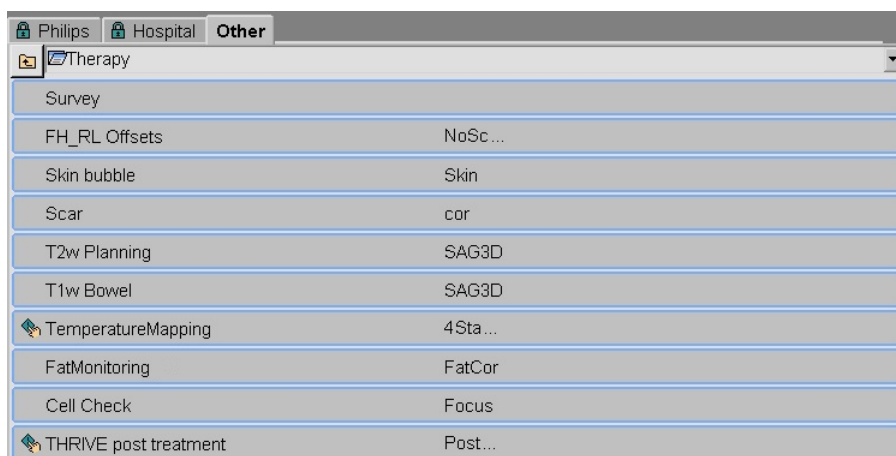


Fig. 60: Therapy ExamCard.

3. Scan Survey.
4. Activate the Offset scan.
5. Open the Offsets page (offc/ang).

| | |
|------------------------|---|
| Stacks | 1 |
| Stack Offc. AP (P=+mm) | 0 |
| RL (L=+mm) | 0 |
| FH (H=+mm) | 0 |
| Ang. AP (deg) | 0 |
| RL (deg) | 0 |
| FH (deg) | 0 |

Fig. 61: The Offsets page.

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

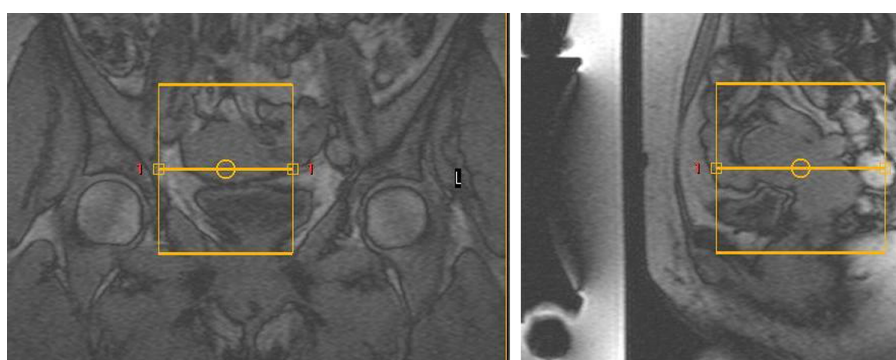


Fig. 62: Positioning images.

7. Check the offsets to see how much the patient needs to be moved in each direction:

| Direction | + / - | Move the patient |
|-----------|-------|------------------|
| R-L | + | Right |
| | - | Left |

| | | |
|-----|---|--------------------|
| H-F | + | Into the scanner |
| | - | Out of the scanner |

| | |
|------------------------|-------------------|
| Stacks | 1 |
| Stack Offc. AP (P=+mm) | 0 |
| RL (L=+mm) | 12.64 (0) |
| FH (H=+mm) | -22.07 (0) |
| Ang. AP (deg) | 0 |
| RL (deg) | 0 |
| FH (deg) | 0 |

Fig. 63: An example of offsets.

8. To move the patient according to the measurements:

- Release the tabletop and pull it out of the magnet bore.
- Loosen or remove the Sonalleve coil and ask the patient to move according to the measurements, assisting them if necessary.
- Tighten the upper coil again, push the table back in. Reset the Offsets to 0. Scan a new survey and analyze it again. Repeat until the treatment area is in the center of the ultrasound window.

9. Scan skin bubble, and optionally, scar verification scans. The Autopush setting will automatically send all images to the Sonalleve console. Scars or skin folds (see the following images for examples) that cannot be protected, surgical clips, or air bubbles should not be in the treatment area.

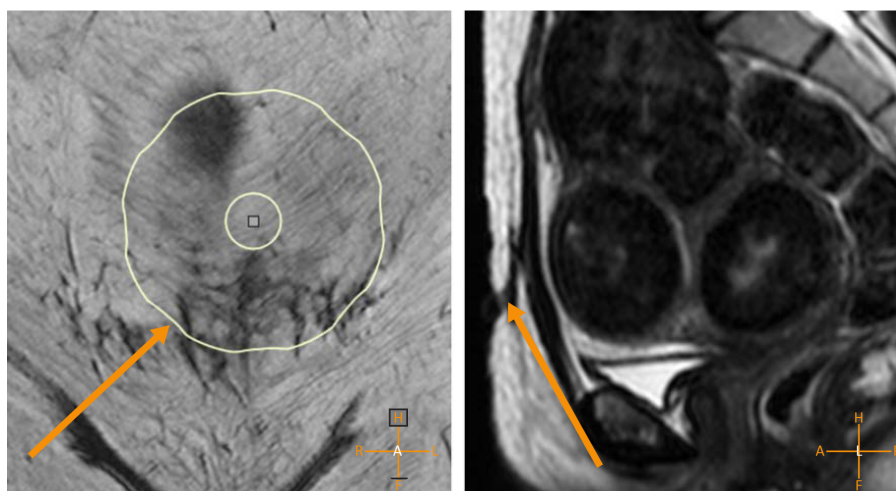


Fig. 64: Scars in the treatment area.

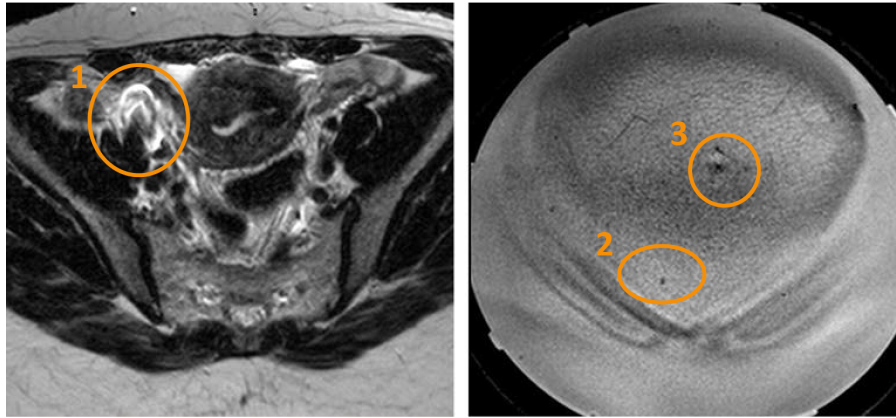


Fig. 65: An artefact caused by a surgical clip (1), an air bubble (2) and a skin fold (3).

10. If needed, pull the tabletop out and reposition the patient. Push the tabletop back in and scan the survey and bubble/scar verification scans again.



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.

6.4. Scanning the planning images



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.

NOTICE

To prevent unexpected changes in image quality, always test all protocol changes that may affect image quality before using them.

1. Scan the planning image set.
2. Position the slices over the treatment area as instructed in the *Application Guide*.
3. When ready, send the images to the Sonalleve console using **Autopush** or DICOM network export. Select **Patient** → **Administration**, select the images and click **Export**.

6.5. Preparing the monitor scan



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.

NOTICE

If the near-field monitor slice is positioned within the subcutaneous fat layer, the monitoring scan may not properly detect temperature changes in the near field. This may lead to:

- Temperature maps showing lower than actual temperatures in the near field.
- Thermal dose calculations showing smaller than the actual dose in the near field.
- No or delayed warnings about heating in the near field warning zone.

Erroneous stack positioning increases the risk of burns, as the skin or the muscle behind the subcutaneous fat layer could then be heated without noticing.

NOTICE

In the Uterine application, you can place a Freehand ROI in the far-field stack.

NOTICE

You should repeat the test sonication if the temperature mapping scan protocol is modified in any way, e.g., if a REST slab is moved or resized.

NOTICE

On the MR scanner **Push to Workstation** must be active to ensure that the images are transferred to the Sonallevé console. Also make sure that the **Enable Automatic Start Scan** or, with MR software R3 or R4, **Automatically Start Scan** setting is **off** to ensure that the slices are positioned correctly.

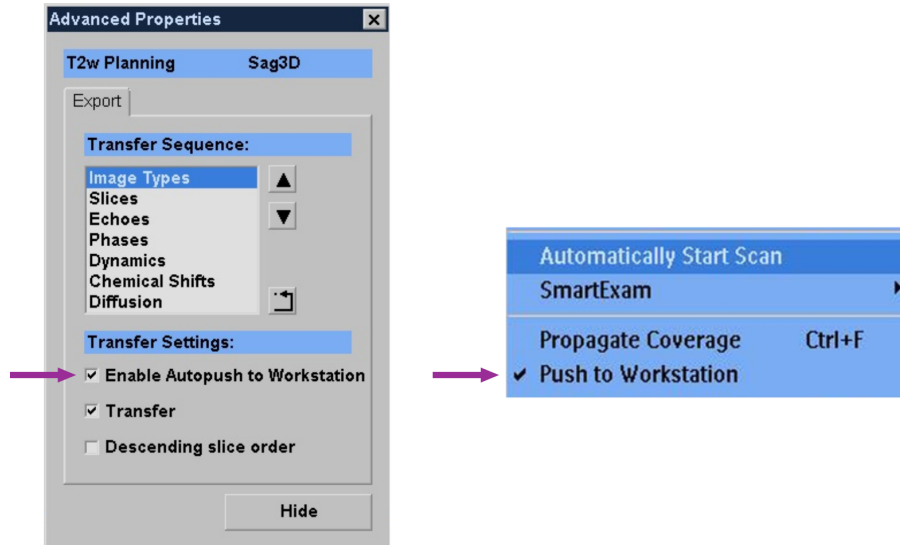


Fig. 66: Push to Workstation must be active to ensure that the images are transferred to the Sonalleve console. Left: In MR software R5 the setting is in Advanced Properties, accessible through the right-click drop-down menu. Right: The setting in MR software R3 and R4.

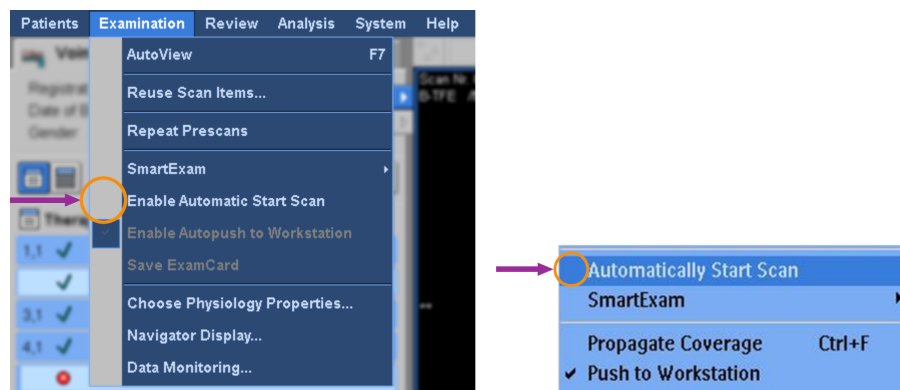


Fig. 67: Automatic start of scan must be disabled to ensure that the slices are positioned correctly. Left: The Enable Automatic Start Scan setting disabled in the Examination menu of MR software R5. Right: The Automatically Start Scan setting disabled in MR software R3 and R4.

You must enter the patient information and position the temperature mapping slices on the MR console before starting the temperature mapping scan on the MR scanner.

1. Select the predefined temperature mapping protocol.
2. Position the monitor slices.

In the Uterine application:

- Stack C to the abdominal muscle behind subcutaneous fat layer.
- Stack D to the nearest far-field structure to be avoided.

In the Bone application:

- Stack D to the muscle in the near field.

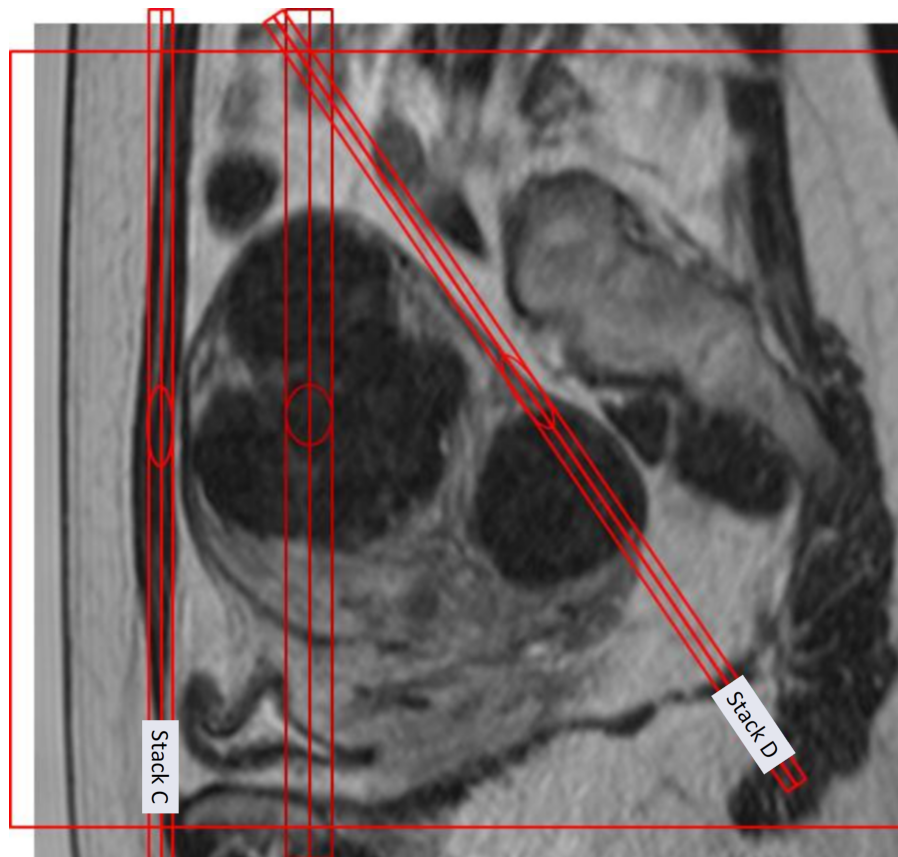


Fig. 68: An example of positioning the monitor slices in the Uterine application.

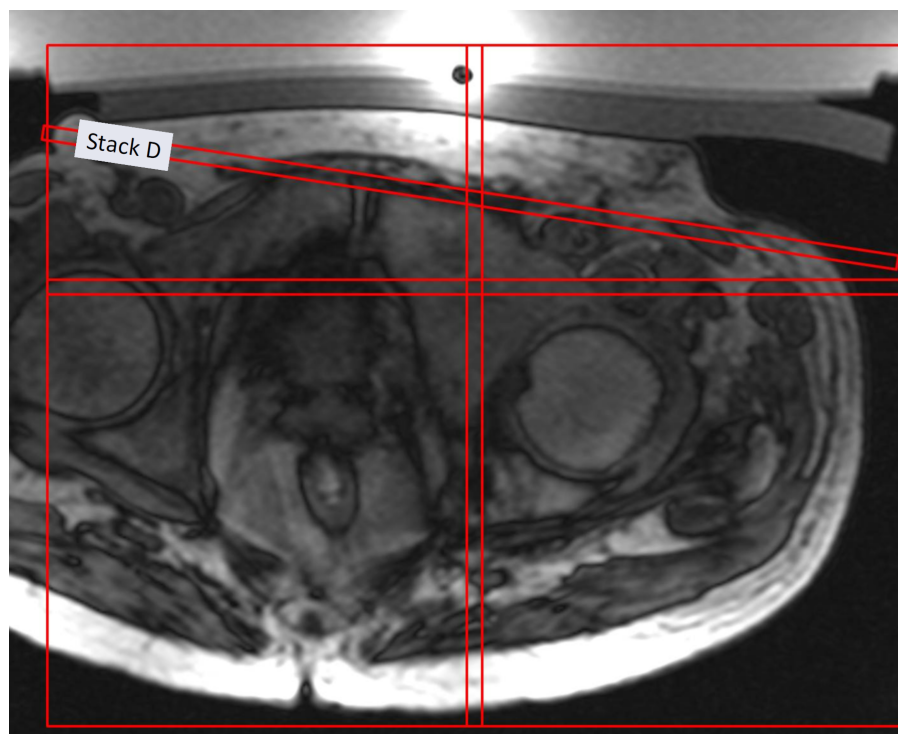


Fig. 69: An example of positioning the monitor slices in the Bone application.

NOTICE

For more details, refer to the Application Guides.

3. Check that CLEAR=yes. This enables temperature map calculation.
4. Select the fat-monitoring protocol.
5. Position the center of the slice stack over the subcutaneous fat layer in coronal plane. Do not angulate. When the fat layer is thick, position the slices to that location within the fat where you want to monitor fat temperature. When the fat-monitoring protocol is prepared for scanning, it will be automatically acquired after the post-sonication temperature map scan. The scan is, however, not run after low energy sonications, such as test sonications.



Fig. 70: An example of positioning the fat-monitor slices in the Uterine application.

6. Start the temperature mapping scan. The scanner is now under remote control.



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.



Fig. 71: Scanner under remote control.

6.6. Therapy planning

6.6.1. Starting Therapy in the Sonalleve MR-HIFU application



Fig. 72: Starting Therapy.

1. In the start page of the Sonalleve MR-HIFU application, select the appropriate clinical application in the **Application** list.
2. Select **Therapy** in the **Mode** list.
3. Click the **Therapy** application selection button.

NOTICE

The **Application** list only displays those clinical applications that have been installed and configured for use.

NOTICE

For ablation of adenomyosis tissue, select **Uterine** in the **Application** list.

6.6.2. Entering patient information



Fill in the patient's body temperature and select the correct gel pad thickness from the drop down menu. Then proceed to the next page.

It is essential that the patient's actual body temperature is used as a temperature reference. Check the patient's body temperature with a reliable thermometer immediately before the therapy and, if necessary, re-check it at regular intervals.



WARNING

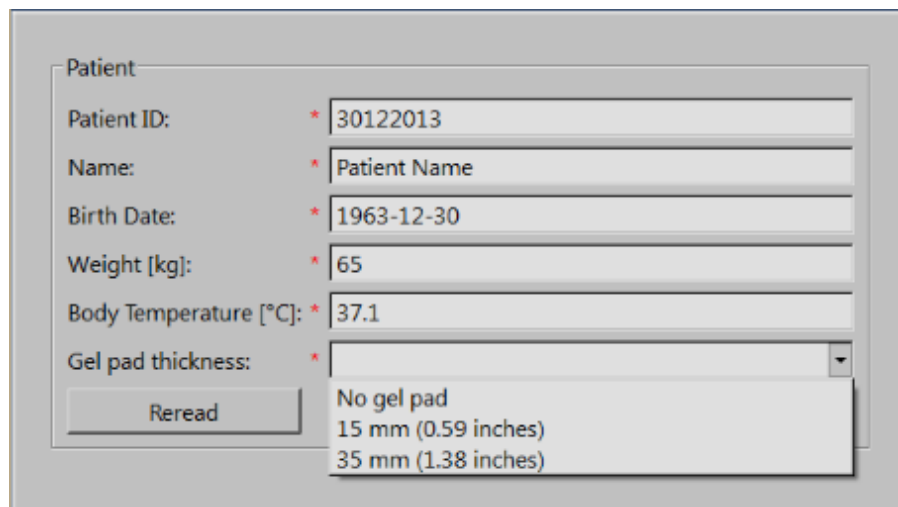
Incorrect body temperature may affect the success of the treatment. Always use the actual body temperature as a reference value.



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.

If you are using DISC without a gel pad, select **No gel pad**.



| | |
|---------------------------------------|---|
| Patient | |
| Patient ID: | * 30122013 |
| Name: | * Patient Name |
| Birth Date: | * 1963-12-30 |
| Weight [kg]: | * 65 |
| Body Temperature [°C]: | * 37.1 |
| Gel pad thickness: | * No gel pad 15 mm (0.59 inches) 35 mm (1.38 inches) |
| <input type="button" value="Reread"/> | |

Fig. 73: Patient information entry window.

NOTICE

The available choices for **Gel pad thickness** may be different in different applications and for different system hardware.

6.6.3. Retrieving the image sets



Retrieve the planning images from the MR console.

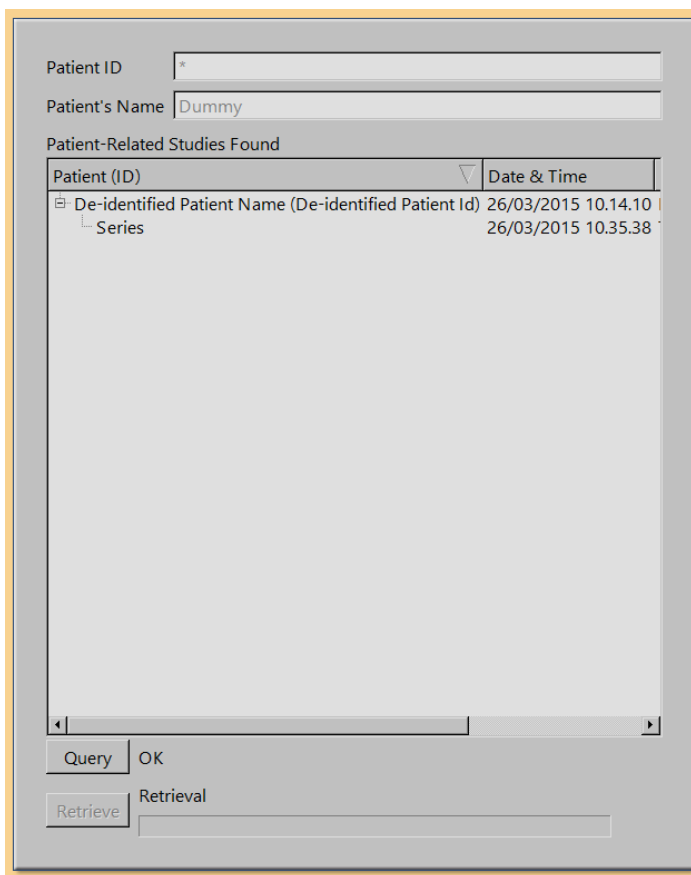


Fig. 74: Image set retrieval window.

1. To display recently exported image sets, use **Query**. The images are filtered according to the patient ID, i.e. only the images of the patient that is currently being treated are retrieved.
2. Select the image sets, click **Retrieve** and the latest in time images are automatically shown. Proceed to the next page.
3. To select another image set right click on any of the four windows on the image area to display the desired images.

NOTICE

You can return to the image set retrieval stage at any time.

NOTICE

Retrieving phantom or patient images before the patient is positioned on the table may cause inaccuracy in the system-recommended cooling times.

6.6.4. Defining the Planning Target Volume



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

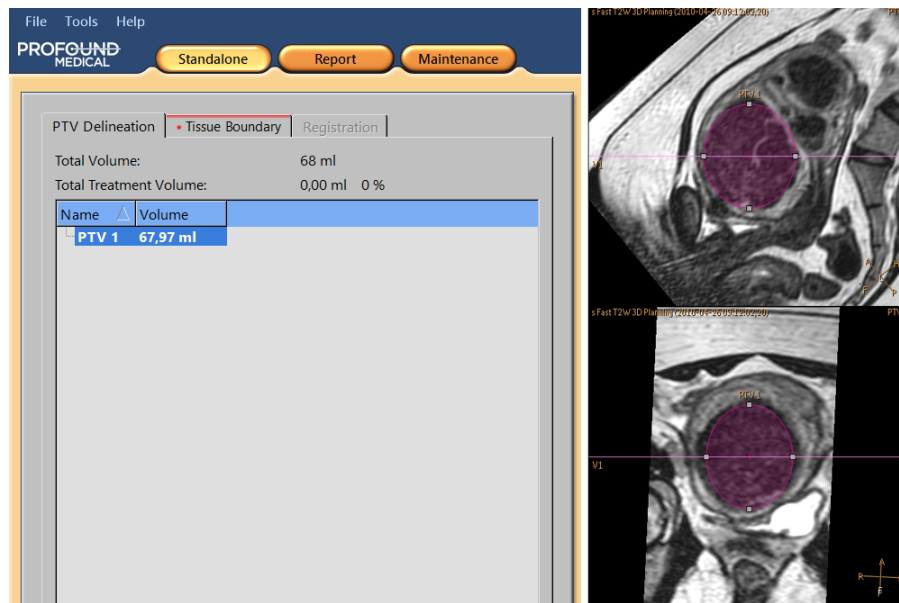


Fig. 75: Planning Target Volume delineation.

1. Add PTV by clicking the **Add** button.



2. Draw the Planning Target Volume on top of the images. If you are using several PTVs, you can give them descriptive names.
3. Scroll the images to view the Planning Target Volume on all slices.

6.6.5. Defining the Tissue Boundary

On the Uterine Fibroid application, go to the Tissue Boundary tab and define the Tissue Boundary by moving the first line to match the skin position and the second line to match the fat-muscle boundary.

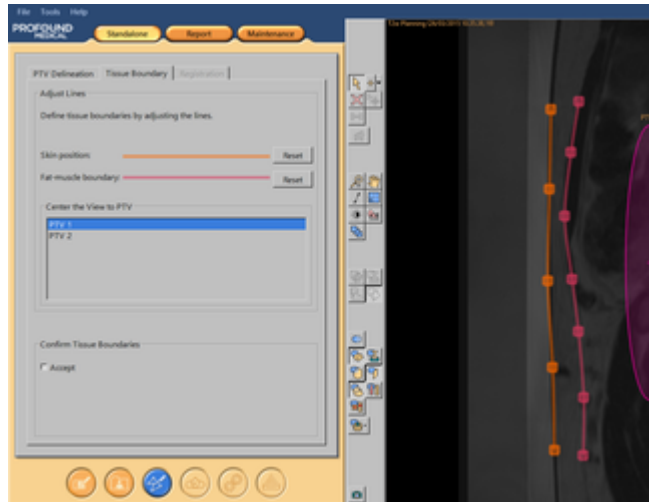


Fig. 76: Defining the Tissue Boundary

1. Start editing the tissue boundaries by selecting one of the lines.
2. Move the tissue boundaries by moving the handles. If needed, add or remove handles by double-clicking the line. With **Reset** you can get the Tissue Boundary lines to the default position.
3. Check that there is enough water in the DISC, a curved skin/membrane boundary may indicate too low water level.
4. The Tissue Boundary lines should be so long that the transducer beam is contained within the contoured area in all of the future sonications. If needed, change the length of the line by dragging the end handle.

NOTICE

Tissue boundaries are not allowed to intersect and there are also some restrictions on positioning them. A red cross mark indicates invalid position for the boundary while editing lines.

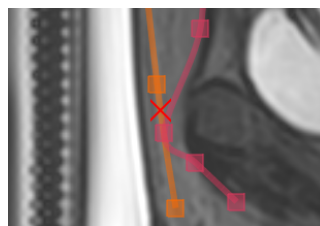


Fig. 77: Indication of invalid position for tissue boundary

5. Scroll the images to view the skin position and the fat-muscle boundary on all slices. Current image slice is shown in bottom right corner.

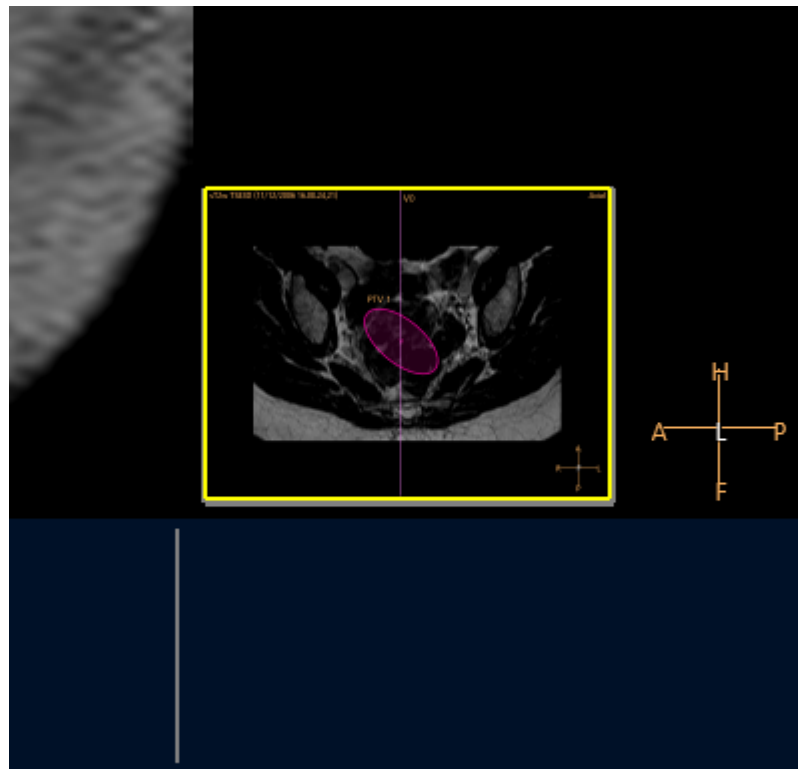


Fig. 78: Slice navigation view

6. Center the view to all PTVs to check all boundaries.
7. Confirm the boundaries by accepting.



WARNING

Make sure to scroll all of the images to find any non-uniformities in the tissues.

6.6.6. Positioning the treatment volume



WARNING
Positioning:

- Always leave sufficient safety margins 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 the uterine serosa or any other tissue to be spared than indicated by the cell safety margin. For example, heating of the uterine endometrium may need to be avoided for patients who might wish to become pregnant in the future. 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.
 - Air-filled structures and bones might cause unexpected reflections.
 - Bowel should never be in the near the field beam path. Heating the bowel may lead to bowel perforation.
 - Heating in the far field might lead to sciatic nerve damage / peritonitis.
 - 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.

NOTICE

During actual therapy sonications, the 30 EM thermal dose contour should be used as another measure of the probably affected area.

Sonication with electronic X deflection requires higher power levels and thus also larger safety margins.

NOTICE

The orientation of the image on the screen is not always according to the radiological convention used in the MR console. The image orientation can be seen in the anatomical orientation indicators.

Do not expose the tip of the Foley catheter to ultrasound, if the tip is touching the bladder wall. Such exposure could lead to local heating, irritation, pain, hematuria, or damage of the bladder wall.



WARNING

In the Bone 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.



Position treatment cells within the Planning Target Volume (PTV).

1. Graphically select a transducer position. The cells are placed on a Treatment Plane created by the transducer position. When the first cell is positioned, the transducer position is locked and a cluster is created. The transducer position is visible as a tool tip when you move the pointer over the cluster.

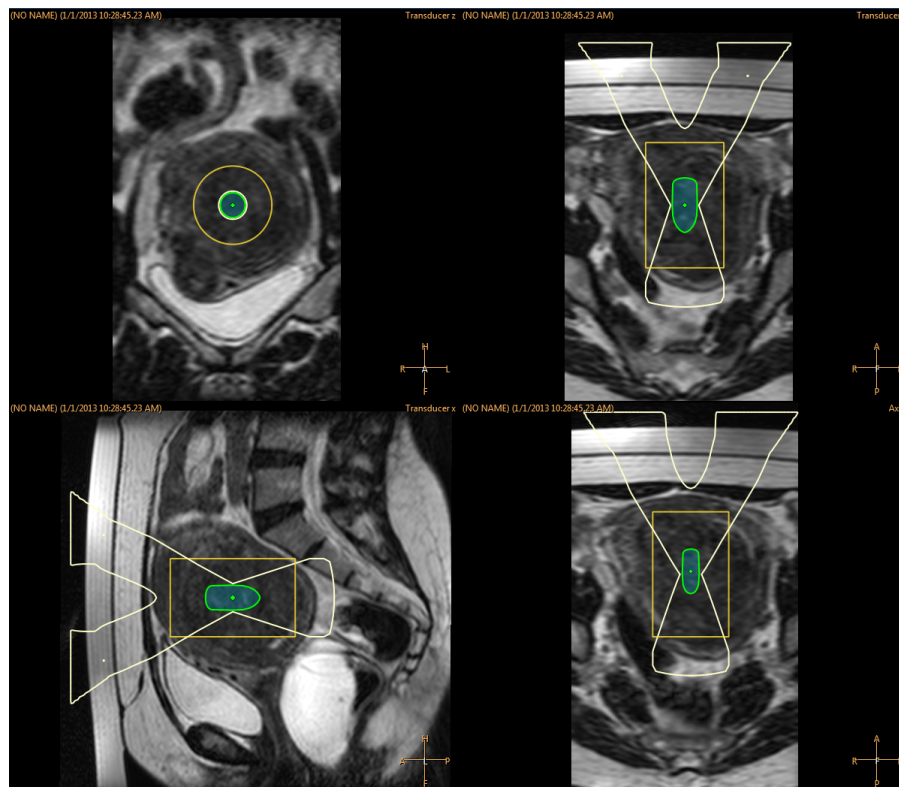


Fig. 79: When the first cell is positioned, the transducer position is locked and a cluster is created.

2. Select the treatment cell type and size from the drop-down list.

- If you wish to add more than one cluster for a single transducer position, click the **Add Empty Treatment Cell Cluster** button.



- If you do not add any clusters, all cells will be added to the same cluster.

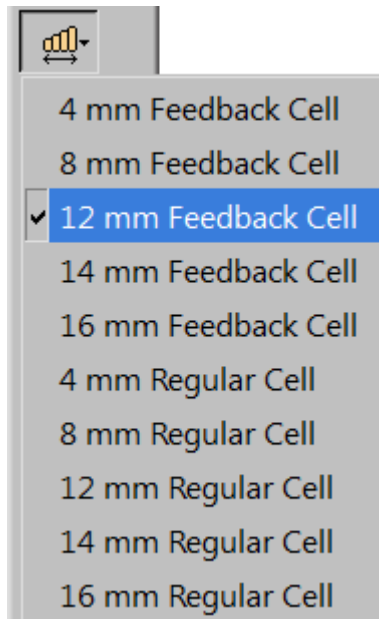


Fig. 80: Treatment cell selection.

3. Check the beam of each of the cells. The beam must not travel through air or sensitive structures, and there must not be unprotected scars in the ultrasound beam path. Verify that safety margins are observed. See the following figure.

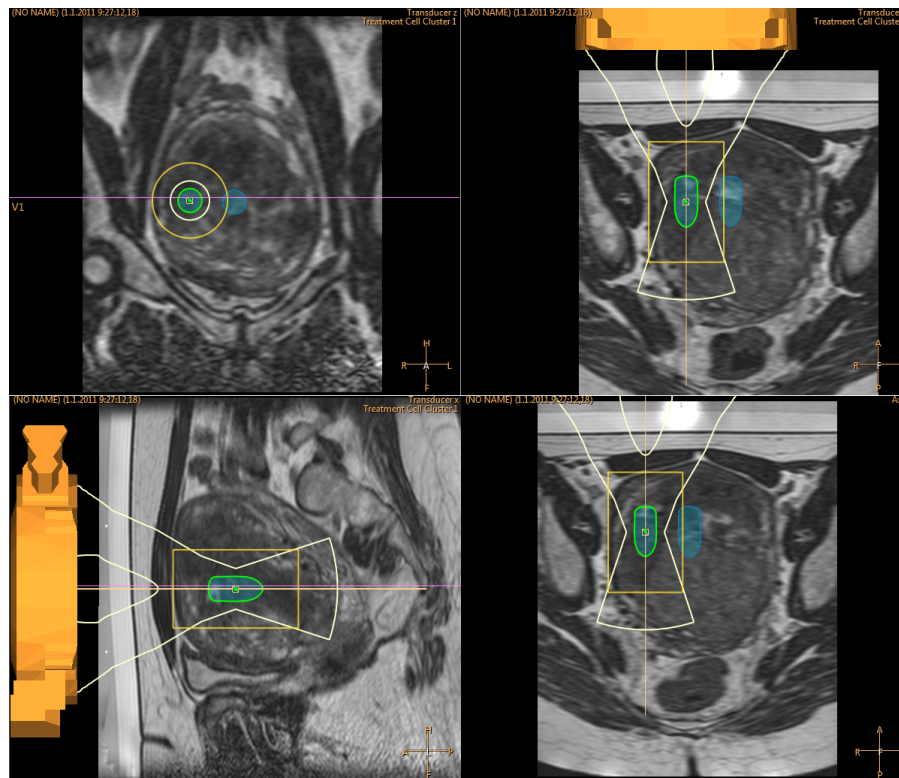


Fig. 81: Checking the transducer beam positions.

4. You can move cells in a cluster using the **Select** button.



5. You can move the treatment cluster with cells with the **Move Treatment Cell Cluster** button.



For hints and tips on placing the cells optimally, see the *Application Guide*.

If the cell you have placed is not treatable with the current transducer position, it will be marked with a cross and the system issues a warning message. Select the cell and move it to another location.

How and why to use markers?

Add graphical markers to anatomy landmarks in planning images.

- You can add markers at the Transducer Positioning stage and at any time after that. Select **Marker** from the drop-down menu of the **Add** tool button.
- Compare the location of the markers and the anatomical landmarks to detect patient movement and image distortions.
- The markers are visible in all planes.
- Choose landmarks that you can also recognize in temperature map images.
- In the following figure, the markers have been placed around the fibroid to be treated.

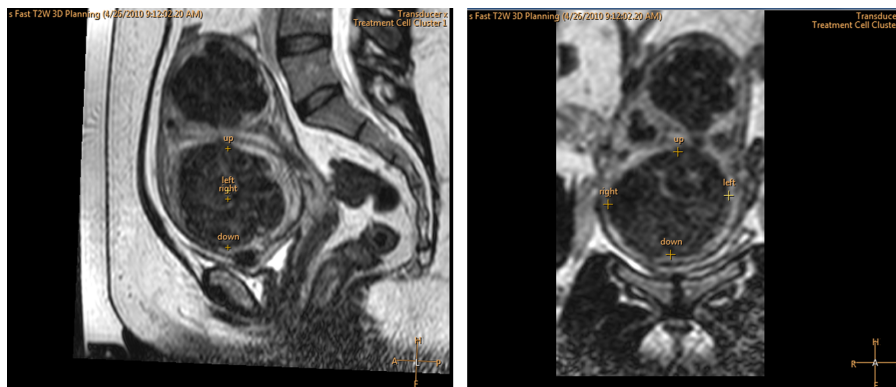
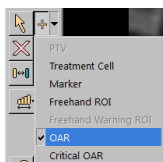


Fig. 82: Markers in sagittal and coronal images.

6.6.7. Beam shaping



The beam shaping feature enables the user to reduce the intensity of the ultrasound field in selected regions in the near field. These regions should be located close to the patient's skin, and may include e.g. air bubbles, scar tissue, and skin folds. Identify the region where reduced ultrasound intensity is desired by drawing an organ avoidance region (OAR) object around it. All drawn OARs are shown in the **Regions of Interest** list in the **Treatment Cell Planning** page and on the **Replanning** tab of the **Therapy** page.

The following figure shows how an OAR ROI is drawn to prevent heating of a scar.

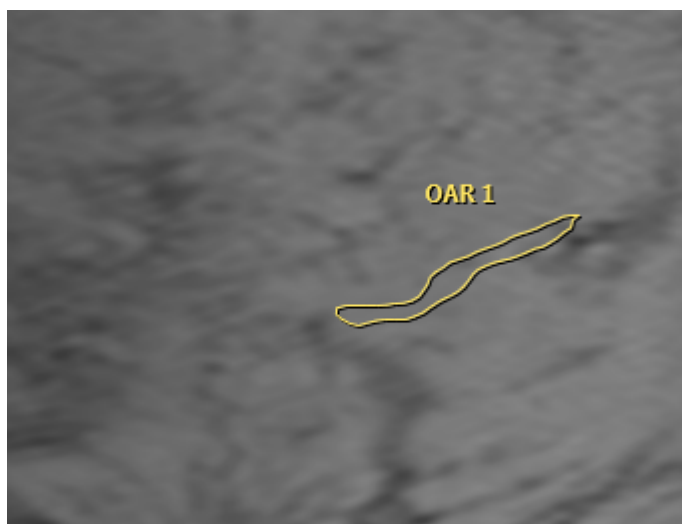


Fig. 83: An OAR ROI drawn to prevent heating of a scar.

Reduction of the ultrasound intensity is achieved by disabling some of those transducer elements that contribute to the ultrasound field in the OAR region. To ensure that ultrasound intensity at the treatment cell is not affected, ultrasound intensity delivered by the remaining active elements is increased accordingly. This compensation leads to a corresponding ultrasound intensity increase in those areas which are not protected by an OAR.

Use of the beam shaping feature or electronic deflection increases near-field heating. In these situations it may be necessary to use longer cooling times than recommended by the Sonalleve system.

OARs should be drawn which accurately reflect the shape of the region where intensity reduction is desired. In order to ensure sufficient protection, they should always extend at least 2 mm outside the edges of the region where protection is desired. Several OARs may be drawn to protect e.g. 3D objects. However, software calculation speed suffers as the number or size of OARs increase, so it is not advisable to draw more or larger OARs than needed.

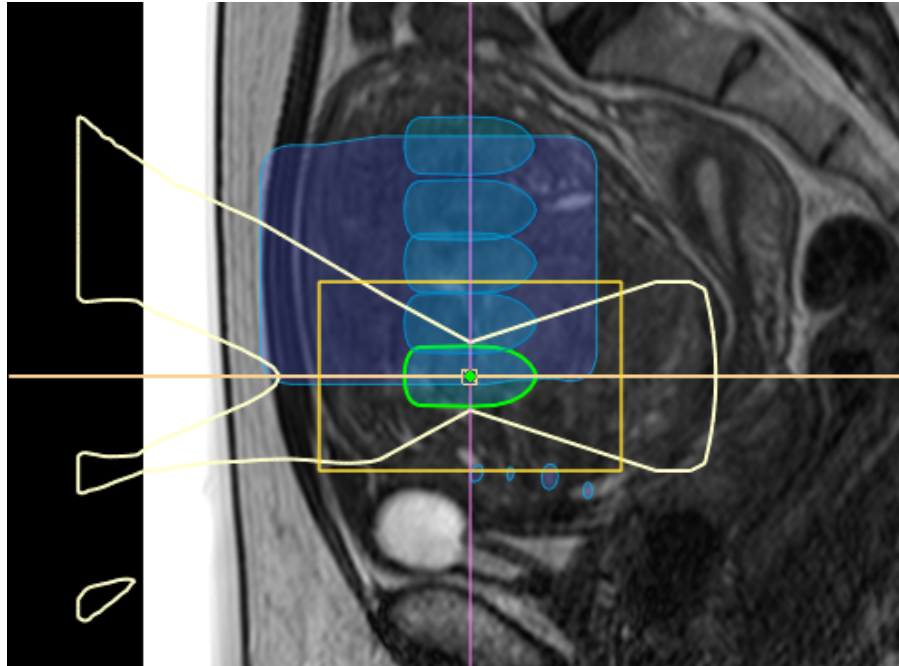


Fig. 84: The visualization of the beam path and the ATA affected by an OAR.

Only use beam shaping in the near-field side of the transducer beam.

OARs should be drawn in the coronal plane. After drawing OARs, always check the resulting shape of the transducer beam visually in a sagittal or transverse slice set. Make sure that the displayed transducer beam does not penetrate the OAR anywhere. When using an OAR to protect a region with scar tissue, also verify that the scar tissue lying deeper is excluded from the beam. If the transducer beam overlaps with any of the regions where protection is desired, do not start the sonication. Position the treatment cells so that OARs remain outside the treatment cell safety margin.

If higher than normal tissue protection level is desired, a critical OAR should be used. It reduces the ultrasound intensity more than regular OAR, but otherwise has same functionality.

QuickCover Ultrasound Protective Cover

Scars and other superficial objects can be protected from acoustic energy also by placing a QuickCover Ultrasound Protective Cover on top of the object that is to be protected. These protective cover strips are water-resistant and visible in MR images. The back of the strip is self-adhesive to ensure that the cover does not move during the treatment.

Whenever feasible, use beam shaping together with the QuickCover Ultrasound Protective Cover to ensure maximal protection of the scar tissue.

QuickCover Ultrasound Protective Covers may not be available in all countries.

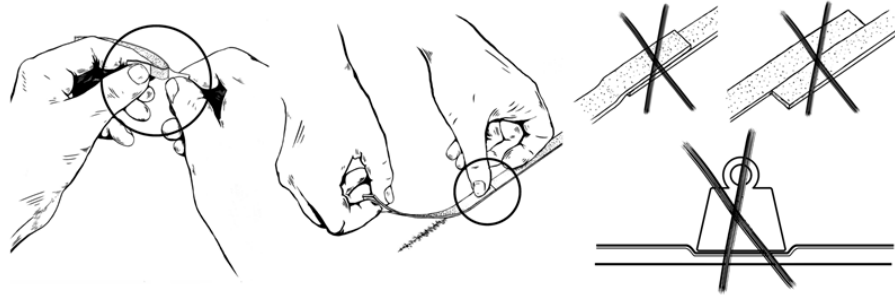


Fig. 85: The correct use of QuickCover.

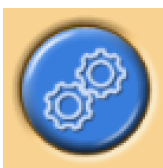


WARNING

- 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.

6.7. Preparing the system for sonication

6.7.1. Hardware Initialization



The treatment cannot be started until the hardware initialization is successful. Planning is possible during hardware initialization.

NOTICE

The MR scanner cannot export images to the hospital network once Network Isolation is in progress. Before starting the Hardware Initialization, make sure that there are no image export tasks running or queued on the MR workstation.

1. Press the green **Enable** button on the Safety Device to enable the ultrasound generators.
2. Perform the hardware tests. If any of the tests fail, check the message log for problems in the system. Retry until the tests succeed.

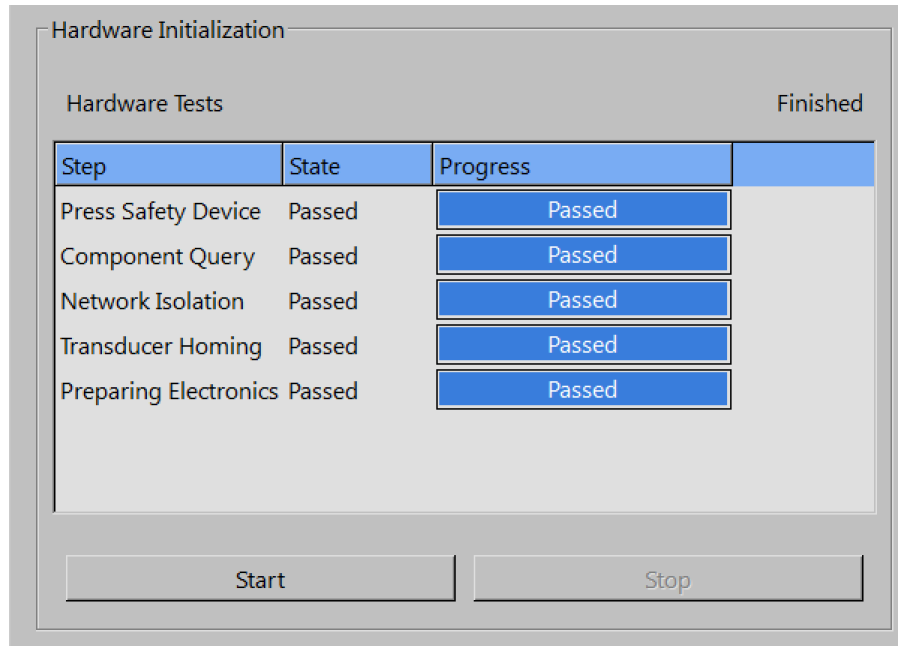


Fig. 86: Hardware initialization.



WARNING

If the system detects a transducer movement failure, it stops the treatment and issues an error message. You must rerun the Hardware Initialization.

6.7.2. Scanning Temperature Mapping

Scan the temperature mapping protocol:

- To see the image quality and any possible artefacts.
- To verify the position of REST slab, if used.
- To place Freehand Warning ROIs.
- To verify the visibility of markers.
- To verify the positioning of near-field (and far-field) monitor slice stacks.



1. Go to the **Scan** tab of **Therapy** stage.
2. Select the predefined temperature mapping protocol from the drop-down list of scan protocols.
3. Start the scan.
4. Stop the scan when multiple temperature maps have been acquired.

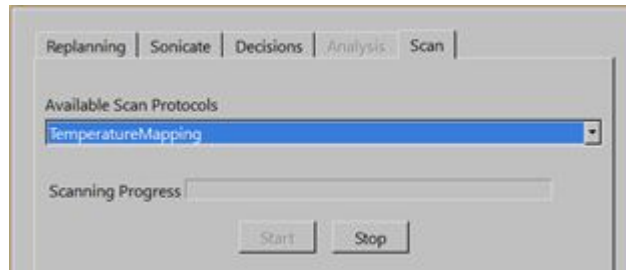


Fig. 87: The Scan tab.

6.7.3. Test sonication



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.

It is recommended to repeat test sonication always when the tabletop lock or the trolley brake lock is re-engaged after being released. A test sonication is a short, low power sonication which usually heats the tissue by only a few degrees. Test sonication is automatically done with the 4 mm regular cell type.

You must perform a test sonication in each treatment cell cluster before you can start the actual therapy sonications in that cluster.

It is recommended to perform a test sonication also when the sonication frequency is changed. The purpose of the test sonication is to correct the actual heating location to match the planned cell position. The actual heating location is indicated with an offset marker (a green cross). The test sonication also helps you in determining the correct power level for the treatment cell size. It provides information you need for selecting the correct power level.

NOTICE

In the Bone application, the test sonication is not used to correct the offsets. In the Bone application, the user should verify that the heating takes place in the expected location.

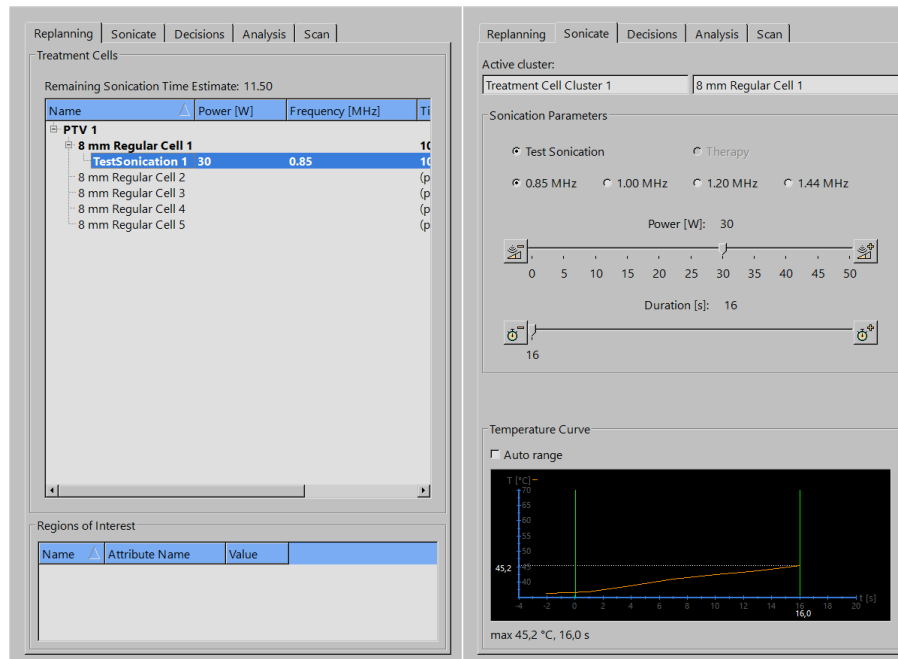


Fig. 88: Selecting the cell and power level for a test sonication (the GUI appearance and parameter values may vary according to application)

1. Select a cluster and a treatment cell. No matter which size and type of cell you choose, the test sonication treats it as a regular 4 mm cell.
2. Select **Test Sonication**.
3. Using the **Power** slider, select a power level that is low enough to not cause thermal dose in the tissue. For additional tips, see the *Application Guide*.
4. Click the **Start Sonication** button to start the test sonication.



The temperature scan starts automatically.

5. View the temperature maps in the **Decisions** tab to verify that the heating occurred in the intended location. The offset marker (a green cross) should automatically appear at the center of the heating both in coronal and sagittal planes. In those rare cases when it does not, drag the offset marker to the center of the heating manually. Correct the offset in RL and HF directions in the coronal image and in AP direction in the sagittal image.



Fig. 89: Test sonication.



Fig. 90: If the offset marker does not appear at the center of the heating, drag the offset marker to the center of the heating manually.

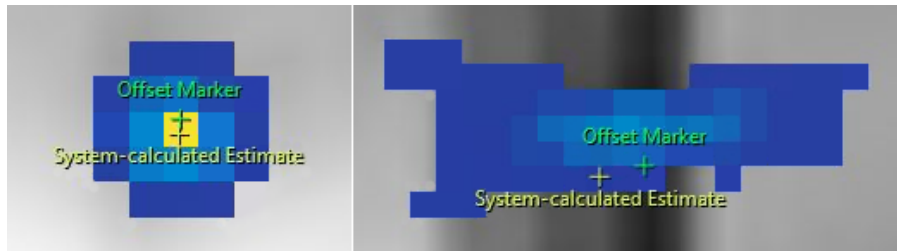


Fig. 91: When you move the offset marker, another marker appears at where the system-calculated estimate was.

6. Accept the offset correction by checking the **Proceed to Therapy Sonications** box.

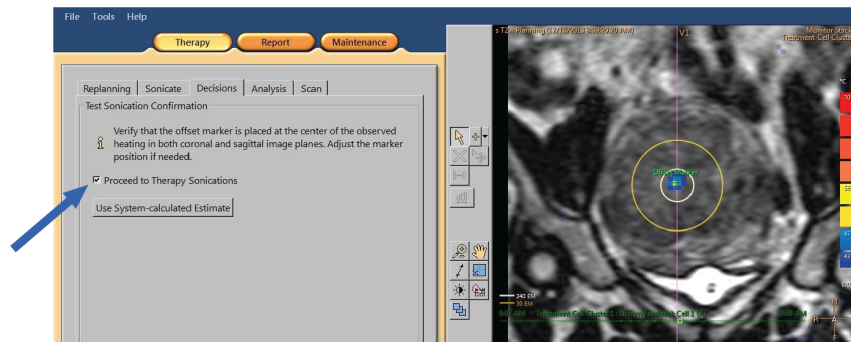


Fig. 92: Accepting the offset correction.

7. If the offset exceeds 5 mm (over 2 pixels) in any direction, repeat the test sonication after accepting the offset correction.

8. Repeat until the offset is acceptable, then proceed to therapy sonications.

NOTICE

If necessary, you can perform test sonications at any time during the Therapy stage. To test sonicate, choose **Test Sonication** and a low power level. You can also correct the offset after a therapy sonication by dragging the offset marker or by clicking the button **Use System-calculated Estimate**.

If the test sonication fails

Therapy sonications cannot be started before the test sonication is successful. If the software fails to locate the center of the heating due to insufficient heating (the maximum temperature is less than 42 °C (107.6 °F)), you will see the following warning in the **Decisions** tab:

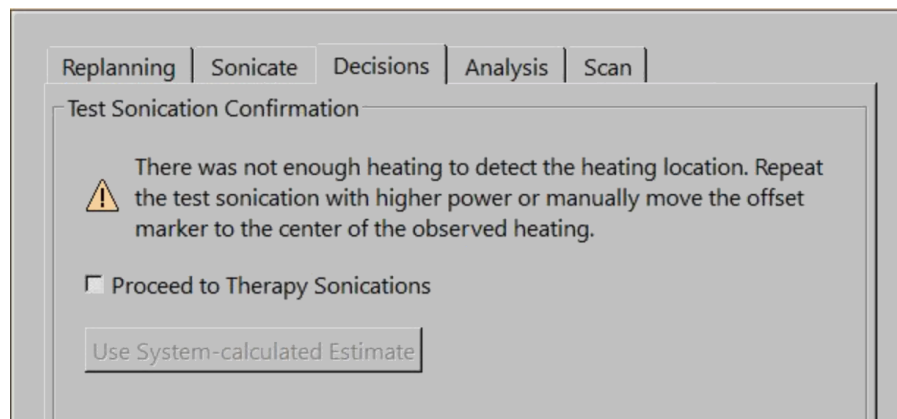


Fig. 93: Not enough heating to detect the heating location.

In such a case, repeat the test sonication with higher power. Alternatively, drag the green offset marker to the center of the observed heating manually, and then perform a new test sonication to verify the correction. If the test sonication does not succeed, take the following steps to determine the reason for the failure:

1. If you do not see any heating within 2 cm (0.8 inch) of the intended location, check that you have the latest image. This will rule out possible problems with updating the images.
2. To make sure that the scanner table is completely down, check the scanner table height.
3. If you do not see any heating in the intended location, look at heating outside the intended location. If you can see some heating, drag the offset marker to the center of the observed heating.
4. If you have the latest image and you can see some heated pixels in the heated area, repeat the test sonication with a higher power level. Increase the power level by the smallest step available. Stop before using a power level that could cause thermal dose in the tissue. If no heating takes place at safe test sonication power levels, stop the treatment and remove the patient from the table. Use a phantom and troubleshoot the reason for the power loss.

6.8. Therapy



The Therapy stage includes five tabs for carrying out different actions during the treatment:

- The Replanning tab allows you to select, add or remove treatment cells and add markers to aid in monitoring.
- On the Sonicate tab, you can start, stop and monitor the progress of the sonication.
- On the Decisions tab, you can accept or adjust the heating location.
- The Analysis tab displays the temperature curve for a cell or a profile and sonication statistics of the selected treatment cell.
- On the Scan tab, you can start intermediate scan protocols to monitor the progress of the treatment.

In addition, you must plan the sonication order and determine the power level to be used for each treatment cell type.

6.8.1. Replanning

- This stage is not mandatory but can be performed before starting the sonication treatment.
- If necessary, you can add, move or remove treatment cells.
- You can also add graphical markers around anatomies to monitor patient movement. See *6.6.6.1. How and why to use markers?*
- You can add a freehand Warning ROI to monitor slices. Mark anatomical structures where temperature rise is not wanted. The warning temperature level can be edited.
- You can add OARs.

6.8.2. Planning the sonication order

The Sonalleve MR-HIFU system allows you to sonicate the treatment cells in any order. However, the following general guidelines apply to the sonication order:

- To avoid unnecessary heating in the near field (skin or the inner margin of the subcutaneous fat layer, abdomen), start the sonications from the cells on the treatment plane deepest within the body.
- Treat all the cells on a treatment plane before moving on to the next plane.
- Clusters can be used as an aid in planning the sonication order.
- To minimize the risk of heating the skin or the inner margin of the subcutaneous fat layer, avoid successive sonications in the same cluster. Instead, move between clusters/target volumes in different parts of the Total Treatment Volume. This allows for better cooling and more even heating in the volume.

6.8.3. Determining the correct frequency level for a treatment cell

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

- Use the lower frequencies when near field heating is to be avoided
- Also use the lower frequencies when higher ultrasound penetration into the bone is required
- Use the higher frequencies when near field heating is not an issue but far field heating is to be avoided.

6.8.4. Determining the correct power level for a treatment cell

To ensure that the treatment volume heats sufficiently, but not excessively, you must determine a suitable initial power level for each treatment cell size. When you have sonicated the first few cells with this power level, you should evaluate the results and adjust the power level based on them.



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.

The power levels in the following tables guide you in selecting the correct power level based on the temperature rise in test sonication (in the Uterine application).

| Temp. rise in test sonication | Max. temp. in test sonication | Power used in test sonication | | | | | | | | | |
|---|-------------------------------|-------------------------------|------|------|------|------|------|------|------|-------|-------|
| | | 20 W | 30 W | 40 W | 50 W | 60 W | 70 W | 80 W | 90 W | 100 W | 110 W |
| Power to be used in sonication (4 mm treatment cells) | | | | | | | | | | | |
| 3 °C | 40 °C | 130 | 200 | 270 | | | | | | | |
| 4 °C | 41 °C | 100 | 150 | 200 | 250 | 300 | | | | | |
| 5 °C | 42 °C | 80 | 120 | 160 | 200 | 240 | 280 | | | | |
| 6 °C | 43 °C | 70 | 100 | 130 | 170 | 200 | 230 | 270 | 300 | | |
| 7 °C | 44 °C | 60 | 90 | 110 | 140 | 170 | 200 | 230 | 260 | 290 | |
| 8 °C | 45 °C | 50 | 80 | 100 | 130 | 150 | 180 | 200 | 230 | 250 | 280 |
| 9 °C | 46 °C | - | 70 | 90 | 110 | 130 | 160 | 180 | 200 | 220 | 240 |
| 10 °C | 47 °C | - | 60 | 80 | 100 | 120 | 140 | 160 | 180 | 220 | 220 |
| 11 °C | 48 °C | - | 50 | 70 | 90 | 110 | 130 | 150 | 160 | 180 | 200 |
| 12 °C | 49 °C | - | 50 | 70 | 80 | 100 | 120 | 130 | 150 | 170 | 180 |
| 13 °C | 50 °C | - | 50 | 60 | 80 | 90 | 110 | 120 | 140 | 150 | 170 |
| 14 °C | 51 °C | - | - | 60 | 70 | 90 | 100 | 110 | 130 | 140 | 160 |
| 15 °C | 52 °C | - | - | 50 | 70 | 80 | 90 | 110 | 120 | 130 | 150 |
| 16 °C | 53 °C | - | - | 50 | 60 | 80 | 90 | 100 | 110 | 130 | 140 |
| 17 °C | 54 °C | - | - | 50 | 60 | 70 | 80 | 90 | 110 | 120 | 130 |

Fig. 94: Sonication power for a 4 mm treatment cell (assuming the body temperature is 37 °C).

For cells larger than 4 mm, longer sonication durations increase the risk of near-field heating, so a higher power level is recommended for feedback cells than for regular treatment cells.

| Temp. rise in test sonication | Max. temp. in test sonication | Power used in test sonication | | | | | | | | | |
|--|-------------------------------|-------------------------------|------|------|------|------|------|------|------|-------|-------|
| | | 20 W | 30 W | 40 W | 50 W | 60 W | 70 W | 80 W | 90 W | 100 W | 110 W |
| Power to be used in sonication (8, 12, 14 and 16 mm treatment cells) | | | | | | | | | | | |
| 3 °C | 40 °C | 230 | | | | | | | | | |
| 4 °C | 41 °C | 170 | 260 | | | | | | | | |
| 5 °C | 42 °C | 140 | 200 | 270 | | | | | | | |
| 6 °C | 43 °C | 110 | 170 | 230 | 280 | | | | | | |
| 7 °C | 44 °C | 100 | 150 | 190 | 240 | 290 | | | | | |
| 8 °C | 45 °C | 90 | 130 | 170 | 210 | 260 | 300 | | | | |
| 9 °C | 46 °C | 80 | 110 | 150 | 190 | 230 | 260 | 300 | | | |
| 10 °C | 47 °C | 70 | 100 | 140 | 170 | 200 | 240 | 270 | | | |
| 11 °C | 48 °C | 60 | 90 | 120 | 150 | 190 | 220 | 250 | 280 | | |
| 12 °C | 49 °C | 60 | 90 | 110 | 140 | 170 | 200 | 230 | 260 | 280 | |
| 13 °C | 50 °C | 50 | 80 | 100 | 130 | 160 | 180 | 210 | 240 | 260 | 290 |
| 14 °C | 51 °C | 50 | 70 | 100 | 120 | 150 | 170 | 190 | 220 | 240 | 270 |
| 15 °C | 52 °C | - | 70 | 90 | 110 | 140 | 160 | 180 | 200 | 230 | 250 |
| 16 °C | 53 °C | - | 60 | 90 | 110 | 130 | 150 | 170 | 190 | 210 | 230 |
| 17 °C | 54 °C | - | 60 | 80 | 100 | 120 | 140 | 160 | 180 | 200 | 220 |

Fig. 95: Sonication power for 8, 12, 14 and 16 mm treatment cells (assuming the body temperature is 37 °C).

In the Bone application, for cells in different locations than the test sonication, the power level to be used must be adjusted proportionally to the area of the heated surface. For example, if the diameter of the heated surface were twice the diameter of the heated surface in the test sonication, the power level would need to be multiplied by four. For this reason it is recommended to use a similar heated surface for all cells. Start at lower power values and progressively increase the power until the temperature measured at the bone surface meets the target temperature.



WARNING

Use the high powers in Bone 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).

6.8.5. Sonicating

1. Inform the patient that you are about to start the treatment.
2. Select the cell to be sonicated on the **Replanning** tab. Start from the cells on the treatment plane deepest within the body.
3. Go to the **Sonicate** tab and select **Therapy**.
4. Select the sonication frequency and the power from the **Power** slider:

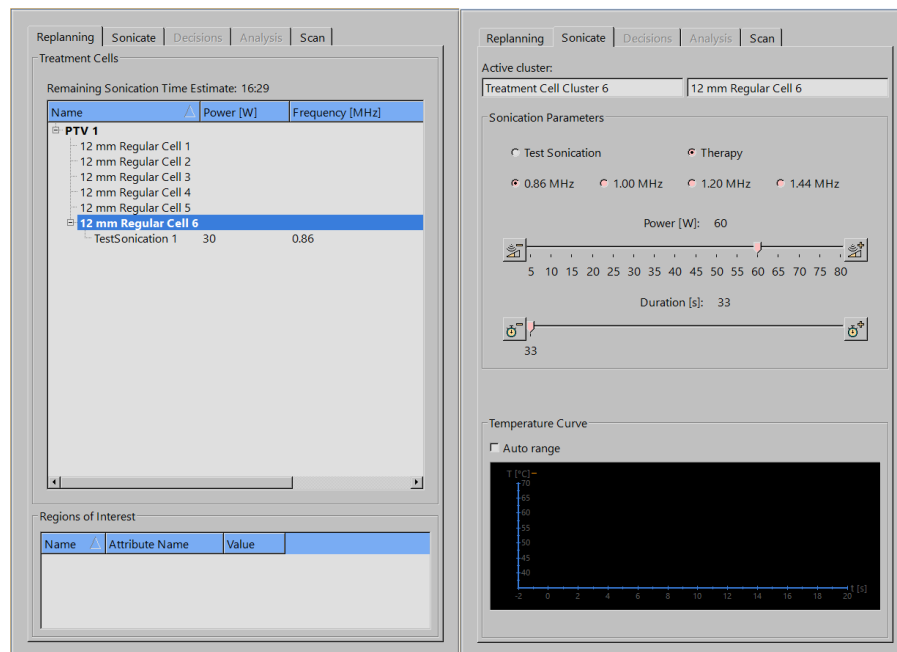


Fig. 96: Replanning and Sonicate tabs in the Bone application.

5. Click the **Start Sonication** button to start the sonication.



The temperature monitoring scan will start automatically.

The sonication will stop automatically when the sonication duration for the cell has been reached.

You can stop the sonication manually by clicking the **Abort Sonication** button.



Monitor the temperature curve and temperature maps throughout the sonication. If you observe any sudden temperature changes, stop the sonication immediately. Especially observe any unintended significant temperature increase close to the treated area. For a description of the displays and graphs, see 5.9. *Controlling and monitoring the sonication*.

After the sonication stops, a post-sonication temperature monitoring scan follows automatically. The system may also automatically start a fat-monitoring scan after the post-sonication temperature monitoring scan.

6. Analyze the sonication (see 6.8.6. *Reviewing the sonication results during the cooling time*) and move on to the next treatment cell.



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.

The Sonalleve Software provides graphical tools, such as markers, that can be used for detecting movement of visible anatomical landmarks.



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 bone metastasis, 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.

6.8.6. Reviewing the sonication results during the cooling time

1. On the **Analysis** tab, check that the sonication time and the maximum temperature were at an acceptable level. After a successful sonication also check the recommended power to optimize the power for the next sonication.

2. Review the temperature maps to check that no unwanted heat buildup occurred in the near field or far field. Usually you can see some colored pixels outside the heated area. For more information, see 4.7.1. *Misplaced heating or motion artefact?*

3. If you want to analyze signs of near-field heating in more detail, use either of:

- The **Pixel Info** tool.



- The **Profile Line** tool, to display a temperature profile in the **Temperature Curve** on the **Analysis** tab.



The temperature should not exceed 47 °C (117 °F) in the near-field monitor slice. If you repeatedly observe high temperatures in the abdominal muscle, do not continue the treatment.

The tool buttons for **Pixel Info** and **Profile Line** are hidden by default, but you can add them to the toolbar from the **Tools** → **Toolbar Options** menu.

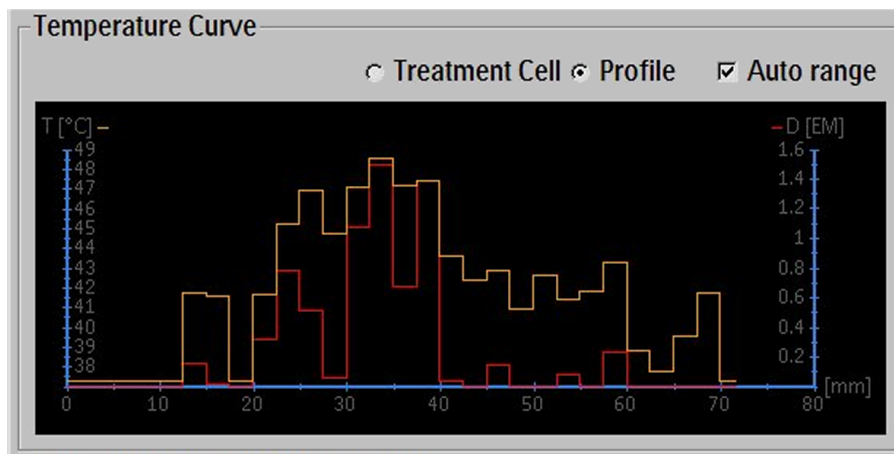


Fig. 97: Temperature profile.

4. With the **Analysis** tab still selected, check if there are sonication-related warnings (in the message area in the middle of the Hardware Status Area). If there are warnings, analyze if they affect the next sonication(s).



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.

6.8.7. Registration

Registration is a feature that can perform the necessary corrections if any patient or organ movement is observed during the treatment. For this, user has to identify correct positioning of the PTV in two different image sets, one taken before the movement and another taken after the movement.

When patient movement has occurred:

1. Scan a new planning image set.

2. Select the **PTV Delineation** tab.



| PTV Delineation | | Tissue Boundary | Registration |
|--------------------------|-------------|-----------------|--------------|
| Total Volume: | 100 ml | | |
| Total Treatment Volume: | 2,47 ml 2 % | | |
| Name | Volume | | |
| PTV 1 | 99,99 ml | | |
| Treatment Cell Cluster 1 | 2,47 ml | | |
| 12 mm Feedback Cell 1 | | | |
| TestScription 1 | | | |

Fig. 98: PTV Delineation stage (the GUI appearance and parameter values may vary according to application).

3. Select the PTV that you want to use for registration.
4. Select the new image set.
5. Select the **Registration** tab. A new empty Registration is created. The selected PTV is highlighted in yellow.
6. Click inside the highlighted PTV in any viewport, and drag the PTV so that it is again in the anatomically correct positioning. The registration appears on the list, with the image set's time stamp.

After releasing the mouse button, the locations of all graphical objects (cells, PTVs, ROIs, OARs, markers, etc.) are updated accordingly, and the displacement value is updated to registration item on the list.

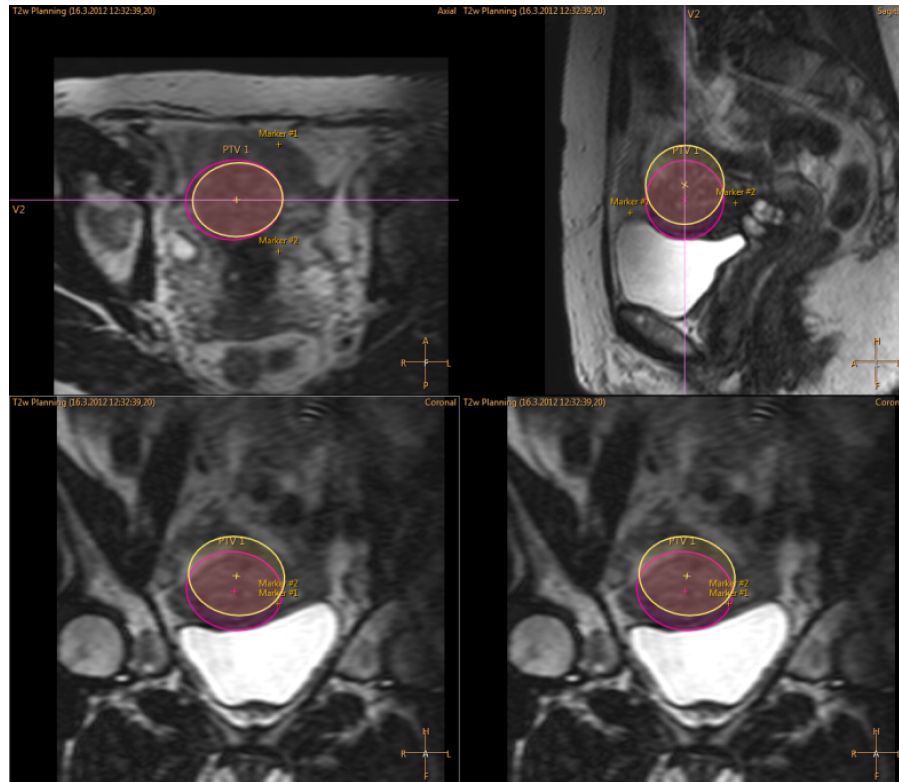


Fig. 99: Highlighted PTV moved.

7. Verify that the OARs, markers, and other graphical objects are positioned correctly before continuing the treatment. If necessary, correct the locations of misplaced OARs and other graphical objects manually. Remember to use the latest, up-to-date image sets!



Fig. 100: Warning to check OAR and ROI positions.

8. On the Uterine Fibroid application the Tissue Boundary must be confirmed after registration. Adjust the lines and confirm the boundaries by accepting. Make sure to scroll all of the images to find any non-uniformities in the tissues!



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.

Registration can be readjusted as needed, until the tab or stage is changed. Changing the tab or stage confirms the location of the added registration. Afterwards, it is possible to modify the registration by returning to the **Registration** tab and pressing the **Modify** button. The registration selected on the list can be removed using the **Delete** button and edited using the **Modify** button. Pressing the **Delete** button moves all objects back to their locations before the registration. Only the latest registration on the list can be edited or removed.

If the registration exceeds a predefined limit, a new test sonication is required. The system will immediately inform the user in the registration list whenever the movement in the added registration exceeds the configured limit.

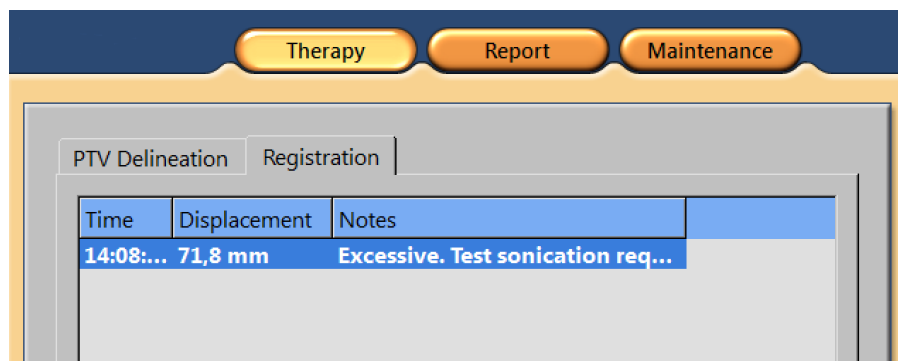


Fig. 101: Excessive movement indicating a test sonication is required.

6.8.8. Scanning other protocols from the Sonalleve console

It is possible to scan other protocols from the Sonalleve console. These scans must be ready to run on the MR console, and the Sonalleve specific parameters must be implemented.

To scan a protocol:

1. Go to the **Scan** tab.
2. Select the protocol from the drop-down list of scan protocols.
3. Start the scan.

The scan is automatically prepared and the scan starts after that. A yellow scanner status icon is displayed while the scan is being prepared.



4. When the desired amount of dynamics have been acquired, stop the scan.

6.8.9. Saving the treatment data



Click the **Report** application button to create a Clinical Summary Report. The Clinical Summary Report is a record of the actions taken during the treatment. It should be archived in the patient records, along with records that verify the treatment outcome (such as post-treatment MR images).

In the **File** menu, you can select **Save State** to save the full treatment history.

NOTICE

To export Saved States without patient data, use the **Export De-identified** tool available in the **Session Manager** (menu item **Manage States** in the **File** menu).

Power users (see 10.7. Hospital administrator and user accounts) can also select **Export Data** in the **File** menu to export numerical data from the treatment into a .csv (comma-separated values) file.

6.9. Post treatment

1. Press the red **Stop** button on the Safety Device to disable the ultrasound generators.
2. Stop the temperature mapping scan on the MR console.
3. Select and scan the post-treatment pre-contrast scans on the Therapy ExamCard if required.
4. Administer MR contrast agent to the patient.
5. Scan the desired post-contrast scans.
6. Retrieve the post-treatment images to the Sonalleve Console and make a saved state.
7. Release the tabletop and pull the tabletop out from the magnet. Help the patient down.
8. Remove the catheters.
9. Interview the patient for pain and any other adverse effects of the treatment.

6.10. Error recovery

The system automatically saves the current stage of the treatment as a Saved State file.



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.

If the software crashes, take the following steps to recover:

1. Restart the Therapy application.
2. The **Save State** recovery dialog appears, asking you if you want to load the data from the previous session. Answer **Yes**.

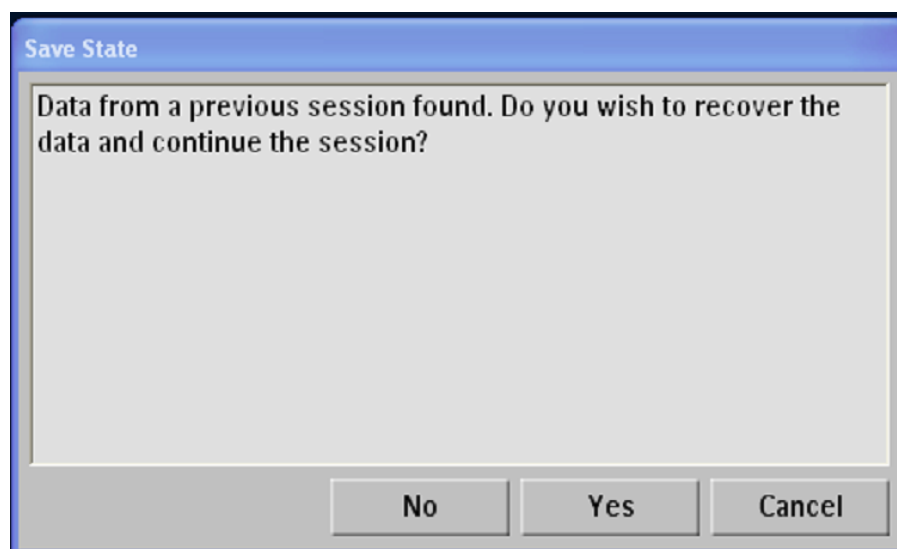


Fig. 102: Save State recovery dialog.

3. If the dialog does not appear automatically, select **Manage States** from the main menu and select the last state from the **Session Manager**.

4. Perform a test sonication with low power before continuing the therapy after crash recovery.

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.

6.11. Removing the Sonalleve tabletop

Before using the MR system for diagnostic imaging, replace the Sonalleve tabletop with the standard tabletop.

1. Press the red **Stop** button on the Safety Device to disable the generators.
2. If the Tabletop Extension Plate is in use, unlock the plate by pressing the release buttons and remove it. Put the detachable handle back in place. Ensure that the handle is properly locked.
3. Unplug the Sonalleve Coil Cable(s) and the headphone cable from their sockets. Hang the cables on their holders on the Sonalleve tabletop.
4. Unplug the HIFU Pelvis Coil cable. If your Sonalleve MR-HIFU system is equipped with an accessory cart, place the coil and its cable in the holder on the accessory cart.
5. Disconnect the Sonalleve Control Cable and Ultrasound Cable. Place the cables in their holders on the accessory cart. Wrap the cables around the accessory cart.
6. Disconnect the DISC hoses.
7. Release the brake pedal and move the trolley to its storage area.
8. Remove all pads and accessories from the tabletop, and clean the tabletop. For recommended cleaning agents, see 7.3. *Cleaning and disinfection*.
9. Place the ultrasound window cover on the ultrasound window to protect the membrane from damage.
10. With Ingenia MR scanners: Replace the thin tabletop used for diagnostic imaging, if it was removed in order to position the Sonalleve tabletop.
11. Connect the MR Nurse Call Button and check that it functions.



Fig. 103: MR Nurse Call Button.

6.12. Sonalleve Tabletop storage

The Sonalleve Tabletop, gel pads and the QA phantom used with the Sonalleve MR-HIFU V2 system must be maintained above freezing temperatures to prevent any damage caused by the formation of, and/or the expansion of ice.

Tab. 25: Storage requirements

| Storage conditions | |
|--------------------|---|
| Temperature | +5°C to +50°C |
| Humidity | 5% to 95% relative humidity, non-condensing |

7. Maintenance

7.1. Routine maintenance

This product requires proper operation, routine checks and planned maintenance, to keep the product operating safely, effectively, and reliably.

7.1.1. Planned Maintenance Program

Planned maintenance may only be carried out by qualified and authorized personnel, and is comprehensively described in the service documentation. Profound Medical provides a full planned maintenance and repair service on both a call basis and a contract basis. Full details are available from your Profound Medical service organization.

7.1.2. User Routine Checks Program

The user of the product must institute a User Routine Checks Program as detailed in the table below. The user of the product shall ensure that all checks and actions have been satisfactorily completed before using the product for its intended purpose.

Tab. 26: User Routine Checks Program.

| Check | Frequency | |
|--|-----------|------------------------|
| | Daily | Before every procedure |
| Check that there are no visible leaks from the Sonalleve Tabletop | ✓ | |
| Quality Assurance procedure with the QA phantom | ✓ | |
| Visually check that the cables, hoses, connectors and sockets are undamaged | | ✓ |
| Check that there are no visible cracks or other defects in the ultrasound window | | ✓ |
| Test that the PESB works | | ✓ |
| Check that the water level in DISC is correct: read the gauge on DISCfill | ✓ | |
| Check that there are no large air bubbles visible through the DISC patient contact | | ✓ |
| Check that the water level in DISC is correct: the surface of the patient contact should be flat | | ✓ |
| Check that there are no obvious leaks from DISC | | ✓ |



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.

The system automatically monitors the humidity sensors in the transducer. The sensor readings are automatically logged and the system generates warnings if excessive humidity is detected. If the humidity continues to rise, contact the Profound Medical service organization.

If the humidity reaches a critical level, the system issues an error message and the sonication stops. The transducer must be replaced. Contact the Profound Medical service organization.

If the device has been unused for two months, humidity will accumulate inside the transducer. Connect the Sonalleve Tabletop, activate the Safety Device and leave active overnight to dry the transducer.

DISC routine maintenance by the user

Checking the water level in DISC

1. If DISCfill is not yet placed on top of the ultrasound window, place it there. Ensure that DISCfill leans evenly on the edge of the ultrasound window frame.



NOTICE

Do not leave any non-fluid material between DISCfill, the ultrasound window, and the ultrasound window frame. Mattresses, disposable sheets, or a gel pad, for example, can prevent DISCfill from settling in its intended position and make checking the water level in DISC unreliable.

2. Read the gauge on DISCfill.

- When the indicator needle is within the **white** zone, there is enough water in DISC.
- When the indicator needle reaches the **red** zone, refill DISC with water before the next HIFU treatment.

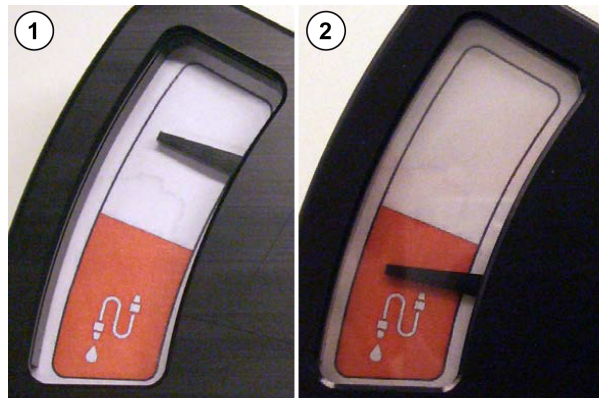


Fig. 104: (1) When the indicator needle is within the white zone, there is enough water in DISC. (2) When the indicator needle reaches the red zone, refill DISC with water before the next HIFU treatment.

NOTICE

When you lift DISCfill away from the ultrasound window, the indicator needle should drop to the bottom of the scale. If the indicator needle does not move, contact Service.

Adding water to DISC

1. Check the water level in DISC as instructed in the previous chapter. Leave DISCfill on top of the ultrasound window.
2. If the DISC hoses are connected to the Sonalleve tabletop, disconnect the hoses from the tabletop.
3. Connect the filling hose to DISCfill.



4. Connect the other end of the filling hose to the female hose connector in the Sonalleve tabletop.

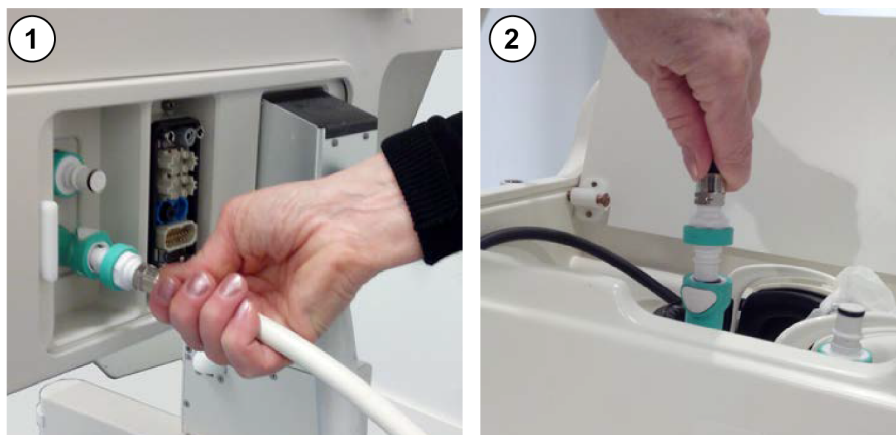


Fig. 105: (1) When DISC is pre-installed at the factory, the hose connectors are located in the tabletop connector panel. (2) When DISC is installed as an upgrade, the hose connectors are located in the accessory box at the front end of the tabletop.

5. After the filling hose is connected, DISC filling starts automatically. Follow the indicator needle.

If filling does not start within 1 minute:

- Ensure that DISCfill is properly positioned on top of the ultrasound window.
- Ensure that the filling hose is fully plugged in at both ends.
- Ensure that there is water in DISCfill. If necessary, fill DISCfill with distilled water as instructed in *10.9.1. Adding water to DISCfill.*

If still no filling takes place, there may be air in the filling hose that prevents the water flow. Remove the air as instructed in *10.9.2. Removing air from the filling hose*, then try again.

6. Filling stops automatically when DISC is full. Filling typically takes less than 3 minutes. Check that the indicator needle is within the white zone. Disconnect the filling hose from the Sonalleve tabletop after filling DISC.

7. When preparing the Sonalleve tabletop for HIFU treatment, remove DISCfill from the top of the ultrasound window and reconnect the DISC hoses. Follow the instructions in 6.2.1. *Connecting the Sonalleve tabletop*.

If DISC is inadvertently overfilled, contact Service.

Handling of DISCfill tool

DISCfill is intended and recommended to be stored on top of the ultrasound window always when the Sonalleve tabletop is not in use. When placed on top of the ultrasound window, DISCfill protects the membrane from damage and prevents light from affecting the water in DISC.

The filling hose may be stored either attached to or detached from DISCfill.

Correct:



- If the mattress is stored on top of the Sonalleve tabletop, DISCfill must be placed under the mattress. Make sure that the edges of the mattress are on top of the base of DISCfill.
- If attached to DISCfill, the filling hose goes under the mattress.

Incorrect:



- The edges of the mattress are under the base of DISCfill.
- If attached to DISCfill, the filling hose goes on top of the mattress.

To carry DISCfill, lift it by the pair of handgrips as shown in the following picture.



7.2. Sonalleve MR-HIFU Quality Assurance (QA) procedure

NOTICE

If the Direct Skin Cooling (DISC) device is installed: Before performing the QA, check the DISC water level using the DISCfill tool.

For more information, see 7.1.2.1.1. *Checking the water level in DISC.*

The purpose of the QA procedure is to ensure that the Sonalleve MR-HIFU system's accuracy and power levels are normal.

Perform the QA procedure before the first patient of the day. You need the following items for the procedure:

- Sonalleve QA phantom
- QA Phantom Plate
- Degassed water

The QA procedure shall be carried out with the application that will be used in treatment.

Do not scan phantom images with the patient's identification.

Connect the tabletop as instructed in 6.2.1. *Connecting the Sonalleve tabletop.*

The properties of the phantom affect the result. Therefore, follow the handling and storage instructions of the phantom carefully. If the phantom becomes damaged, order a new phantom.



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.

The Sonalleve QA Phantom, model 4510 000 82232, is classified as hazardous waste based on the classification and the concentration of acrylamide used in its filling mixture.

The QA Phantom must be disposed of according to the instructions laid out for hazardous waste handling. See 9.5. *Disposal of the Sonalleve QA Phantom*.

7.2.1. Preparing the QA phantom for use

1. Remove the ultrasound window cover.
2. Fill the space between the ultrasound window membrane and the QA Phantom Plate with degassed water. Use a large syringe and hold the syringe near the membrane to minimize air bubbles. Be careful not to puncture the membrane.

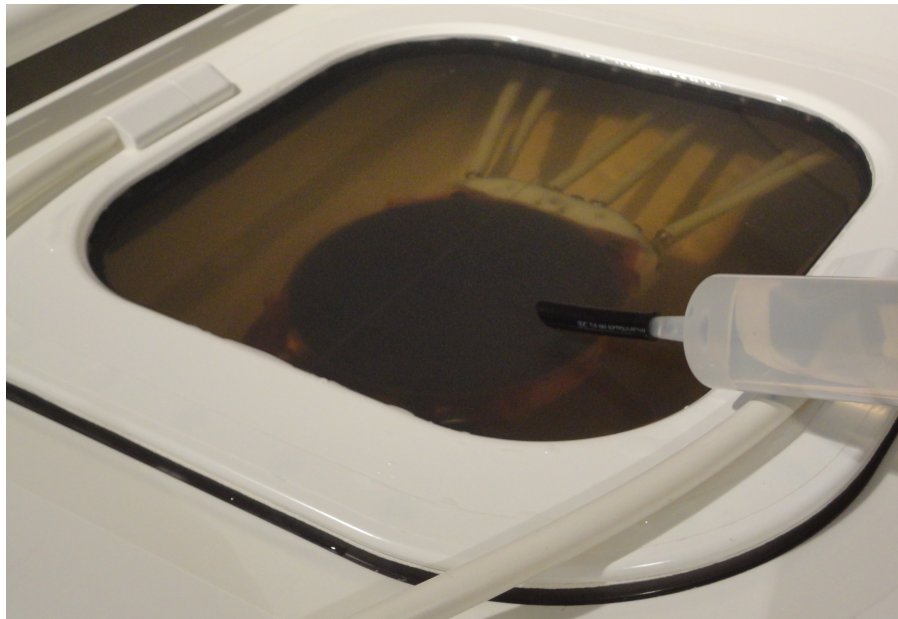


Fig. 106: Preparing the Sonalleve Tabletop with degassed water for phantom.

3. With degassed water on the membrane, place the QA Phantom Plate on the tabletop at an angle to minimize trapping bubbles underneath the plate.



Fig. 107: The QA Phantom Plate.



Fig. 108: Placing the QA Phantom Plate over the ultrasound window.

4. Place one edge of the QA phantom on the phantom plate. The membrane end of the phantom should point down.
5. Gently lower the QA phantom onto the phantom plate to minimize air bubbles. The QA Phantom Plate centers the QA phantom on the ultrasound window.



Fig. 109: Place one edge of the QA phantom on the phantom plate. Gently lower the QA phantom onto the phantom plate.

6. Once the QA phantom is placed onto the phantom plate, use a syringe to fill any remaining air pockets under the phantom with degassed water.



Fig. 110: Fill any remaining air pockets under the phantom with degassed water.

7. Secure the QA phantom in place with the HIFU Pelvis Coil.



Fig. 111: QA phantom ready for sonication.

8. Push the Sonalleve Tabletop into the magnet bore until it locks in place.
9. Using the bubble detection scan on the MR console, verify that there are no bubbles in between the transducer and the phantom before proceeding with the QA Test. If you find large bubbles, check and reposition the QA phantom and re-check for bubbles.

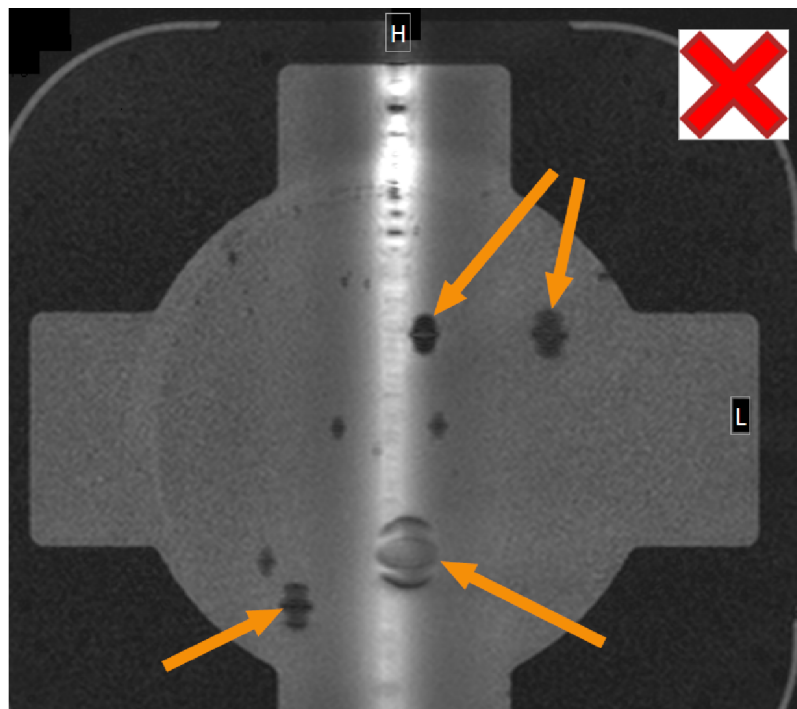


Fig. 112: Bubble detection with the MR scan: Large air bubbles that prevent the sonication are indicated by arrows.

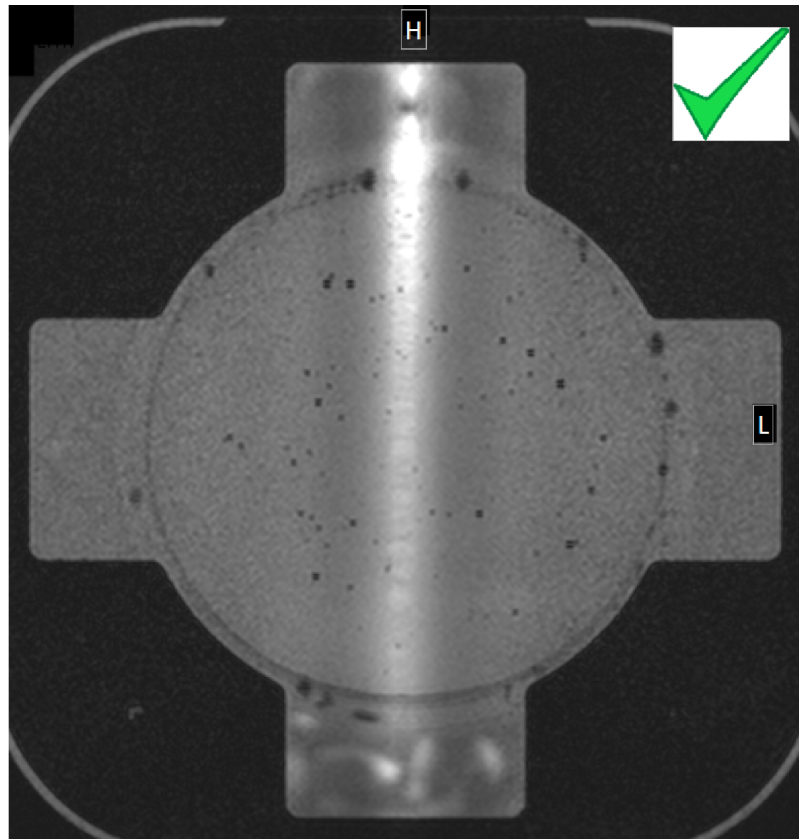


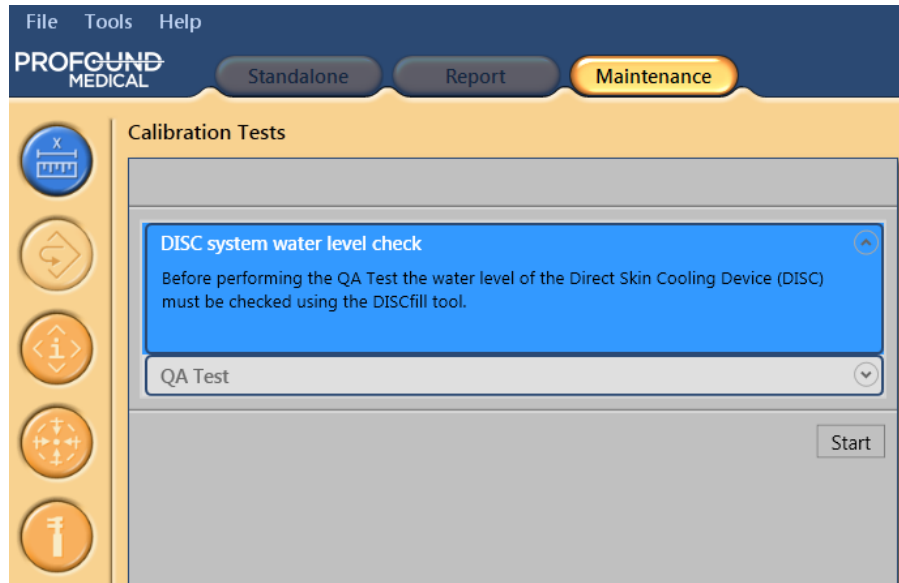
Fig. 113: Bubble detection with the MR scan: Acceptable.

7.2.2. Performing the QA Test

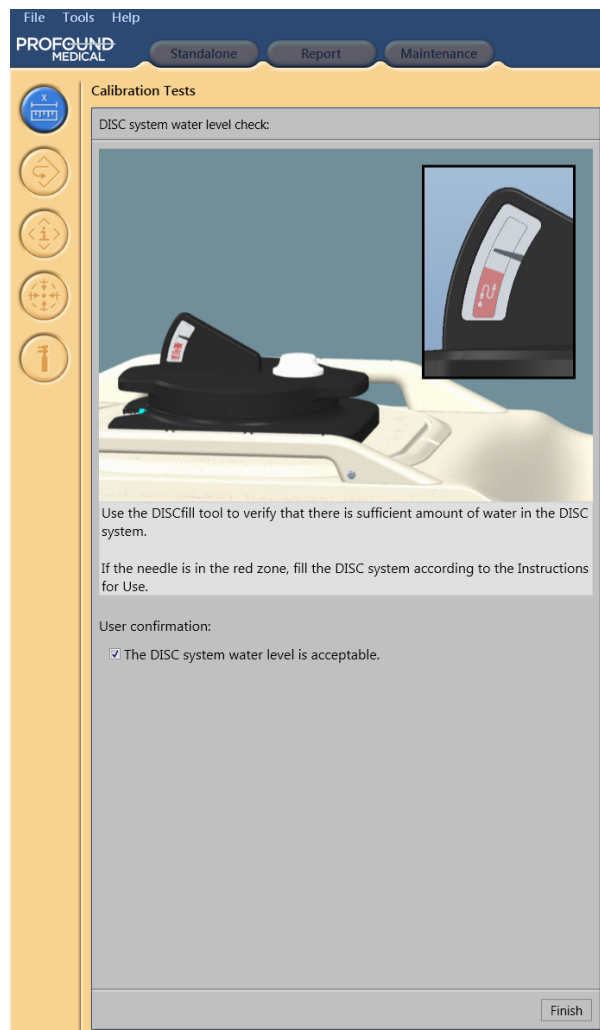
NOTICE

Before performing a QA Test Sonication, check the DISC water level using the DISCfill tool.

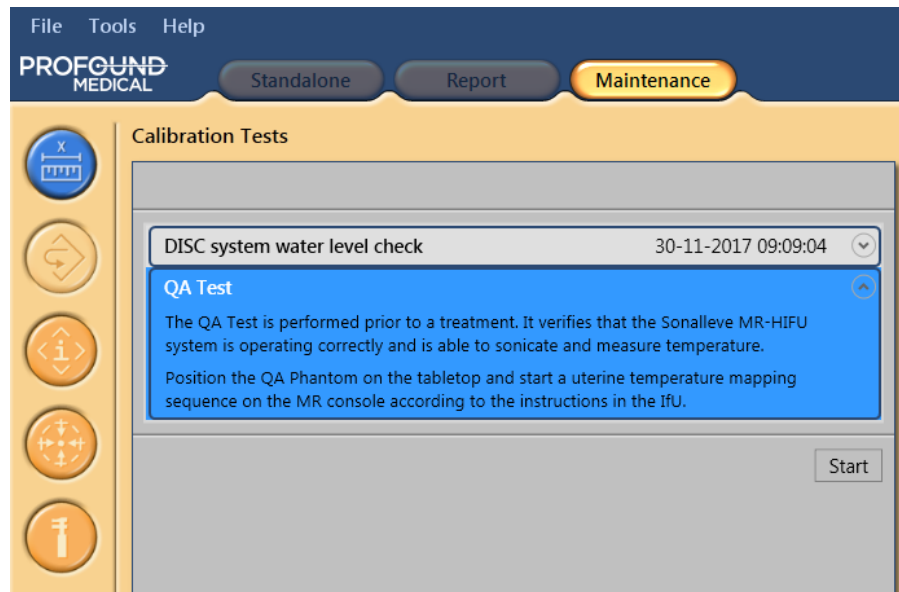
1. Select the "Automatic QA Sonication" ExamCard.
2. Scan the Survey Scan, position the membrane bubble scan slices on the membrane-phantom layer.
3. Scan the membrane bubble scan and verify that there are no large air bubbles. If there are, remove them and repeat the procedure.
4. Start the temperature mapping scan.
5. Select **Maintenance** → **Calibration Tests**.



6. If the DISC system water level has not recently been checked, the check must be performed first. For instructions, see 7.1.2.1.1. *Checking the water level in DISC*. To confirm that the check was completed successfully, check the **The DISC system water level is acceptable** checkbox. To complete this step, click **Finish**.



7. Click **Start** to start the QA Test.



8. A small arrow indicates the phase of the QA Test that is in progress. The symbol is replaced by a green checkmark when the phase is successfully completed. If the test fails, the symbol of the failed phase is replaced by a red circular error symbol (see the following figures).

To see details about a phase of the QA test, click the small down-pointing arrowhead (at right).



Fig. 114: Automatic QA Test has successfully passed the first three phases and is now performing System Time Synchronization.

9. The system checks first **MR Scanner Connection**. After that, **Start Temperature Mapping** is checked. If the Temperature Mapping scan has not been started on the scanner, start it to proceed.

10. When the temperature mapping scan is under remote control, **HIFU Controller Initialization** starts.
11. **System Time Synchronization** sets the time on the Sonalleve console and in the Sonalleve Generator Cabinet from the time on the MR scanner.
12. **Lock the Tabletop** checks the location of the tabletop. To proceed, the tabletop needs to be locked to the isocenter.
13. After the arrow moves to **Enable Safety Device**, press the green **Enable** button on the Safety Device.
14. **Hardware Initialization** also checks the status of the Direct Skin Cooling device.
15. Wait while the system performs test sonications. Select a cell to view the QA Test results.

The following are analyzed during QA Test:

- Correct positioning of the QA phantom
- Cross-sectional shape of the heating pattern
- Maximum temperature
- Heating diameter
- Heating length
- Location of the heating

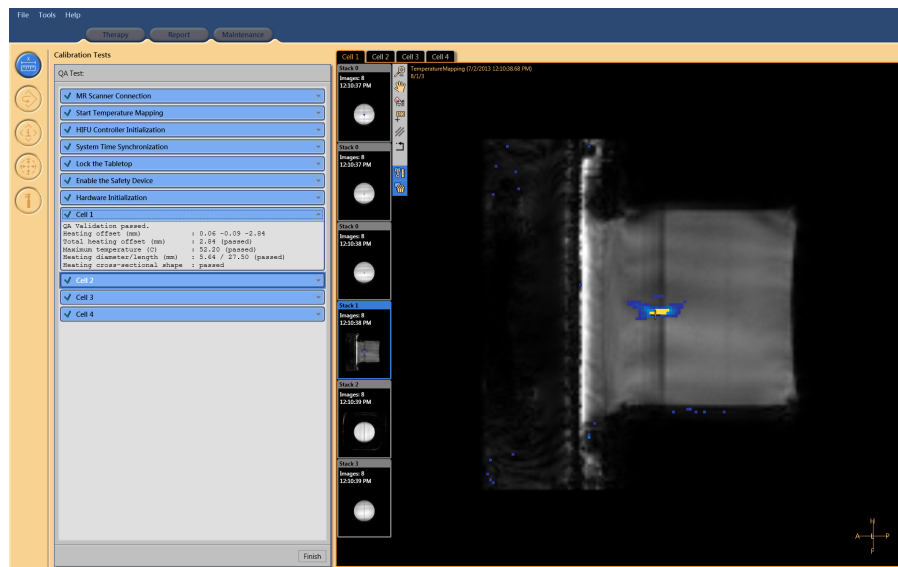


Fig. 115: QA test passed. Viewing the results from cell 1.

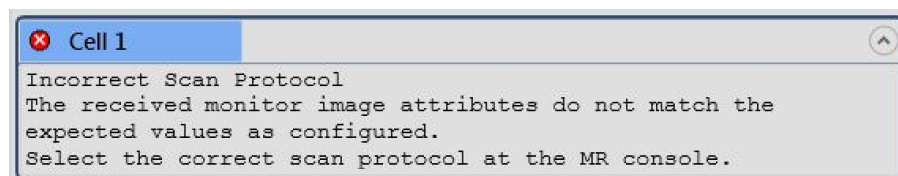


Fig. 116: QA Test failed: test sonication failed in cell 1.

16. It is recommended to record sonication results in the QA Test result table provided in 10.4. *QA Test result table*.
17. Click **Finish** to end the QA Test.

After the QA procedure has been successfully carried out, the Sonalleve MR-HIFU system is ready for the treatment.

Put the ultrasound window cover back in place when you remove the QA phantom.



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.

7.2.3. QA Test troubleshooting

Tab. 27: QA Test troubleshooting.

| Problem | Troubleshooting steps |
|---|---|
| The QA Test fails during the MR Scanner Connection phase | <ol style="list-style-type: none"> 1. Check that the Sonalleve Generator Cabinet is switched on. 2. Check that the cables are connected. 3. Restart the MR application software on the MR scanner console. 4. Repeat the QA Test. |
| The QA Test stops in the Start Temperature Mapping phase | Ensure that the temperature mapping scan is started on the MR scanner console. |
| The HIFU Controller Initialization phase fails with the message "HIFU Controller initialization timed out" | There is no connection between the Sonalleve console and the Sonalleve Generator Cabinet. Ensure that the cables are connected and that the Sonalleve Generator Cabinet is powered up. If the problem persists, contact Service. |
| The QA Test stops in the Lock the Tabletop phase | Ensure that the tabletop is locked. |
| The QA Test fails during the Hardware Initialization phase | <ol style="list-style-type: none"> 1. Check that the Sonalleve Generator Cabinet is switched on. 2. Check that the Sonalleve Tabletop cables are connected. |
| The QA Test fails with the message "Problem with QA Phantom" | <ol style="list-style-type: none"> 1. Check that the phantom is a sonication phantom provided by Profound Medical. 2. Check that the QA phantom is located correctly on the QA Phantom Plate. 3. Check that the MR scanner's couch lifting unit is fully lowered. 4. Check that there are no sonication holes inside the QA phantom. If the phantom is damaged, replace it. 5. Repeat the QA Test. |

| | |
|--|---------------------|
| The QA Test fails due to: "Heating location check failed", "Maximum temperature check failed", "Heating shape check failed", "Heat increase check failed", some other reason, or an unknown reason | Repeat the QA Test. |
|--|---------------------|

If repeating the QA Test does not help, or if the test fails constantly/repeatedly, contact Service.



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.

7.2.4. Storing the QA phantom

The properties of the QA phantom affect the test results. If the phantom is damaged the results may be unreliable. Therefore, follow the handling and storage instructions of the phantom and if necessary order a new phantom.

The QA Phantom Plate serves as a storage platform for the QA phantom. The QA Phantom Plate elevates the QA phantom so that the membrane does not rest on any surface. This is to avoid damaging the sensitive membrane.

1. Place the QA Phantom Plate on a hard flat level surface. Make sure that within the opening of the plate there are no objects that could puncture the membrane of the phantom.
2. Place QA phantom on the QA Phantom Plate with the membrane facing down.



Fig. 117: Store the QA phantom on the QA Phantom Plate with the membrane facing down.

Whenever the QA phantom needs to be removed from the QA Phantom Plate, make sure that the QA phantom is placed so that the membrane does not make contact with any surface.

Store the QA phantom at normal room temperature.

7.3. Cleaning and disinfection



WARNING

Clean, dry and disinfect the parts that come into contact with the patient after each treatment according to the instructions below. 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.

Cleaning and disinfection techniques for both the product and the room must comply with all applicable local laws and regulations.

Use the following cleaning/disinfecting agents for cleaning the system:

- A mild washing agent mixed with water for cleaning all surfaces
- Ethanol 70%, water 30% for cleaning all surfaces
- Isopropanol 70%, water 30% for cleaning all surfaces
- 0.1% hypochlorite in water for cleaning all surfaces

The membrane and membrane rings can be cleaned with stronger liquids:

- 100% Ethanol
- 100% Isopropanol.



CAUTION

Only use the cleaning agents listed above. Other cleaning agents may damage the system.

If you are not sure about the properties of a cleaning/disinfecting agent, do not use it.



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.

If non-flammable, non-explosive sprays *are* to be used, the product must first be switched off and allowed to cool down. This prevents convection currents drawing spray mist into the product. Plastic sheeting must be used to cover the product thoroughly, after which spraying can begin.

Once all traces of the vapor have dispersed, the plastic sheeting can be removed and the product itself can be disinfected or sterilized in the way recommended above.

If a spray was used, you must be satisfied that all traces of the vapor have dispersed before switching the product on again.

7.3.1. Cleaning the system

1. Wipe off water from the ultrasound window with an absorbent cloth.
2. Wipe the membrane (and the grooves) of the ultrasound window with a strong cleaning agent.
3. Clean the system covers with a mild washing agent to prevent staining or fading of the surfaces. Staining is a visual problem only and does not cause any other problems.
4. Clean the mattresses with a washing agent mixed with water.
5. Dry the mattresses with cloth.

6. Regularly inspect the ultrasound window for cracks and other defects that may compromise the efficiency of disinfection. Make sure that the grooves and corners are sufficiently cleaned.

7.3.2. Cleaning the vacuum cushion

The covers of the vacuum formed positioning accessories such as cushions are made of polyurethane coated fabric. Wipe the cushion with water and soap, or some other common detergent not containing biologically active ingredients. Do not bleach. Let the fabric dry completely before storage.

7.3.3. Cleaning the DISCfill tool

DISCfill can be cleaned in the same way as the top surface of the Sonalleve tabletop, using cleaning agents that are permitted for cleaning all surfaces.

7.4. Making degassed acoustic contact liquid

Degassed water or a degassed mixture of ultrasound gel and water is used as acoustic contact liquid in MR-HIFU. As air bubbles in the ultrasound beam path may cause undesirable effects, such as reflections or local heating, the acoustic contact liquid must be degassed. The amount of dissolved oxygen must be below 4 mg/l (ppm, parts per million).

Degassed water

NOTICE

A specially designed EasyWater Degasser is available from the manufacturer for producing degassed water. Further details can be found in the *EasyWater Degasser Instructions for Use*.

IEC 61161, Annex D mentions boiling as a way of making degassed water. Boiling is a feasible method for producing small amounts of degassed water if an EasyWater Degasser is not available.

You will need the following items for making degassed water:

- distilled water or water deionized by filtering
- glass bottles with metallic screw caps
- a kettle with a lid, large enough to hold the standing bottles
- a funnel
- silicon gloves
- a plastic apron
- safety goggles

Procedure

1. Pour water into a kettle and boil heavily under a lid for 20 minutes. The amount of water should be sufficient for both filling and covering the glass bottles.
2. Protect yourself with a plastic apron, safety goggles and silicon gloves.
3. Pour the hot water into the glass bottles through a funnel. Leave a little air in the neck of the bottles.
4. Bring the remaining water into boil again and place the filled bottles in it without the caps. Boil under a lid for 15 minutes.

5. Carefully lift the bottles from the boiling water and immediately screw the caps on.
6. Let the bottles cool down for a few hours, then refrigerate.
7. If an oxygen meter is available, measure the oxygen level to verify that the oxygen content is below 4 ppm.

NOTICE

To avoid creating air bubbles, never shake the water.

Degassed ultrasound gel – water mixture

Also a mixture of degassed water and ultrasound gel can be used as a coupling medium. Prepare the mixture by mixing ten parts of degassed water and one part of ultrasound gel. The consistency of the mixture is correct when any air bubbles will rise to its surface.

7.5. Ultrasound protection

When you practice positioning with volunteers or animals, use an absorption pad or a large positioning pad on top of the ultrasound window to ensure that ultrasound energy cannot reach them.

To position the protectively used absorption pad or a positioning pad:

1. Place the absorption pad or a large positioning pad on top of the ultrasound window membrane, in the same way as you would place a gel pad.
2. Place a thin positioning pad, thick towel or cloth on top of the absorption pad or the positioning pad to prevent skin contact. The pads can become hot when exposed to ultrasound.

NOTICE

The absorption pad and the large positioning pad are safety accessory. Do not sonicate the pads on purpose. Heat will eventually damage the pad and may also damage the transducer. Always inspect the absorption pad and the large positioning pad before use. Replace the pad if you observe any damage.



Fig. 118: The absorption pad

The absorption pad (451000082712) is a Sonalleve MR-HIFU accessory for bone application. The purpose of the pad is to absorb the ultrasound beam in case of accidental exposure during volunteer imaging.

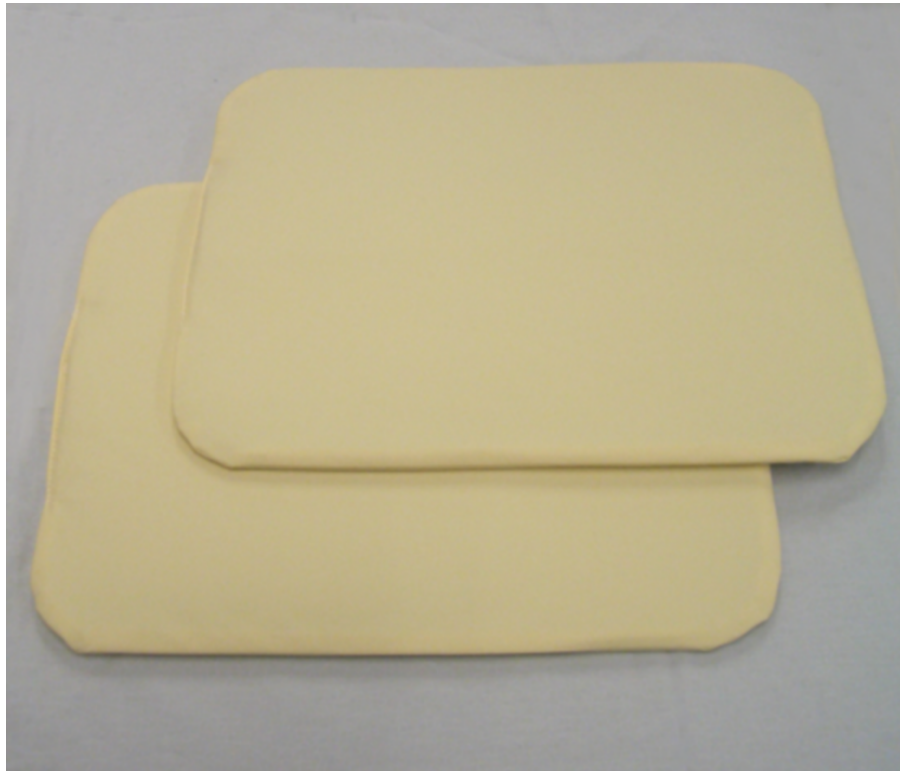


Fig. 119: The large positioning pads that you can use for ultrasound protection.

The pads that you can use for ultrasound protection are labeled with a sticker that identifies the pad as "Support Pad 2," part number 4510 000 82791. The size of the pad is 32 cm × 40 cm (12.6 inches × 15.7 inches).

8. System Error and Warning messages

The system produces messages to alert you about situations which may cause problems in the system or the treatment workflow. The messages are visible in the message area of the Hardware Status Area. Clicking on a message opens a window which provides more information on the situation and instructions on how to handle it. You can also view the messages through the system log.

The messages are classified as

- Errors
- Warnings
- Informational messages

The following chapters describe the three message types and the way they are distinguished from each other in the user interface. A complete list of Error and Warning messages is available in chapter 10.10. *Error and Warning messages*.

8.1. Errors

Errors are messages that halt the user interface and stop the current activity. When an error message is issued, all functions of the User Interface, except for the message display and the abort button, are locked.


Errors are classified as High, Medium or Low errors according to their priority. The priority depends on the severity of the harm (to a person, usually the patient) and on how soon the user must react.

Tab. 28: Priority classes of errors according to IEC 60601-1-8.

| Consequence of failure to respond | Onset: Immediate | Onset: Prompt | Onset: Delayed |
|-----------------------------------|------------------|---------------|-----------------------|
| Death or irreversible injury | HIGH | HIGH | MEDIUM |
| Reversible injury | HIGH | MEDIUM | LOW |
| Minor injury or discomfort | MEDIUM | LOW | LOW or Not Applicable |

The table below shows how the different types of errors are displayed.


Tab. 29: Error types.

| Icon | Error priority | Display mode | Significance |
|---|----------------|---|--|
|  | HIGH | High (4 Hz) blinking rate of the icon and the message area | Forces operation to be aborted. Considered always to be HIGH in severity to the patient, even if happens during planning or maintenance. |
| | MEDIUM | Medium (1 Hz) blinking rate of the icon and high blinking rate (4 Hz) of the message area | An error that requires the user to make a decision on how to proceed. MEDIUM patient hazard. |
| | LOW | Medium (1 Hz) blinking rate of the icon and high blinking rate (4 Hz) of the message area | An error that requires the user to make a decision on how to proceed or to confirm the error. LOW patient hazard. |

8.2. Warnings

Warnings are messages that alert the user to a failure in the system. Some warnings require action or confirmation from the user, some do not.

Tab. 30: Warning types.

| Icon | Display mode | Significance |
|---|---|--|
|  | Static icon and medium (1 Hz) blinking rate of the message area (if no errors are present). | A warning that requires the user to make a decision on how to proceed. A warning that requires user confirmation. |
| | Static icon, may disappear automatically when the error condition is cleared. | A warning that does not require actions from the user. |

Warnings related to a sonication are only visible in the context of that sonication, when the user is viewing the **Analysis** or **Decisions** tab. The user should assess the warnings from previous sonications before continuing the treatment. Warnings related to a sonication are automatically cleared when the user starts planning the next sonication.

Warnings related to a scan started from the **Scan** tab are cleared automatically when the user switches away from the **Scan** tab or starts a new scan.

8.3. Informational messages



Informational messages do not require any actions from the user. They are displayed with the information icon. They inform the user about the required action and fade out when the task is done. You can right-click in the message area and select **Clear Minor** to clear minor messages.

9. Product disposal

9.1. Introduction

Profound Medical is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product, through proper support, maintenance and training. Therefore, Profound Medical products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks. However, the product may contain materials, which could be harmful to the environment if disposed of incorrectly. Use of such materials is essential to performing the functions of the product, and to meeting statutory and other requirements.

This section of this *Instructions for Use* is directed mainly at the user / owner of the product.

9.2. Passing the product on to another user

If this product passes to another user, it must be in its complete state, including all product support documentation. Make the new user aware of the support services that Profound Medical provides for installing, commissioning and maintaining the product.

Before passing on the product or taking it out of service, all patient data must be (backed up elsewhere if necessary, and) unrecoverably deleted from the product.

It must be remembered by all existing users that passing on medical electrical products to new users may create serious technical, medical and legal (e.g., on privacy) risks. Such risks can arise even if the product is given away. Existing users are strongly advised to seek advice from their local Profound Medical representative before committing themselves to passing on any product. Alternatively, contact the manufacturer.

Once the product has been passed on to a new user, a previous user may still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions, there is a clear duty on the previous user to communicate such safety-related information to new users. Previous users who are not able or prepared to do this should inform Profound Medical about the new user, so that Profound Medical can provide the new user with safety-related information.

9.3. Final disposal of the product

Final disposal is when the user disposes of the product in such a way that it can no longer be used for its intended purpose.

Profound Medical supports users in:

- Recovering reusable parts
- Recycling of useful materials by competent disposal companies
- Safe and effective disposal of the product

For advice and information, contact your Profound Medical service organization first, or otherwise the manufacturer.

NOTICE

The product contains privacy sensitive information which should be properly removed. It is advisable to contact your Profound Medical service organization before disposing of 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.

Beryllium

Some components in the transducer assembly inside the Sonalleve Patient Table contain beryllium copper.

Lead

Some components inside the Sonalleve Patient Table contain lead.

Mercury

This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws. (Within this system, the backlight lamps in the monitor display contain mercury.)

Perchlorate materials

In this product, perchlorate material is present in lithium coin cells and/or batteries. Special handling may apply for these materials. For more information, go to:

www.dtsc.ca.gov/hazardouswaste/perchlorate.

There is a lithium coin cell on the CPU board inside the workstation of the Sonalleve Console.

The liquid inside the Patient Table

The liquid inside the Sonalleve Patient Table may require special handling. For information on how to safely handle the liquid, refer to the *Material Safety Data Sheet* supplied with the system.

9.4. Disposal of patient accessories

The materials used in the patient accessories used during HIFU treatment do not require special handling and can be disposed of with normal hospital waste.

Do not throw gel pads or gel pad fragments in the toilet. Do not put gel pads or gel pad fragments into biodegradable waste.

9.5. Disposal of the Sonalleve QA Phantom

Check the model number in the device label of the QA phantom to identify the phantom model.

Tab. 31: Disposal of the Sonalleve QA Phantom, by phantom model.

| Phantom model | Disposal |
|-------------------|--|
| 4510 000 82231 | The phantom does not require special handling and can be disposed of with normal hospital waste. |
| 4510 000 82232 | The phantom requires special handling and must be disposed of as hazardous waste. See the next chapter for more information. |
| Other | See instructions supplied with the phantom. If the instructions are missing, contact your Profound Medical service organization. |

Important

If the QA phantom cannot be identified, for safety assume that the phantom is hazardous waste. Follow the disposal instruction for Sonalleve QA Phantom model 4510 000 82232.

Disposal of the Sonalleve QA Phantom, model 4510 000 82232

The Sonalleve QA Phantom, model 4510 000 82232, is a polymethyl metacrylate (PMMA) container filled with a polymer mixture (Zerdine® filler gel). After filling, the polymeric mixture inside the phantom becomes a solid and cannot be removed from the container. For this reason, the QA phantom is disposed of as a single unit. This chapter details how to safely dispose of the QA phantom.



Fig. 120: Sonalleve QA Phantom model 4510 000 82232 on the QA Phantom Plate.



WARNING

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.

After filling, the polymeric mixture inside the phantom becomes a solid and cannot be removed from the container. For this reason the QA phantom is disposed of as a single unit. This chapter details how to safely dispose of the QA phantom.

The Sonalleve QA Phantom, model 4510 000 82232, is classified as hazardous waste based on the classification and the concentration of acrylamide used in its filling mixture. The QA phantom must be disposed of according to the instructions laid out for hazardous waste handling.

NOTICE

Hazardous waste handling must be performed in accordance with local and national legislation. Local and national legislation of hazardous waste handling always take precedence over the following guidelines.

Disposal Guidelines in the United States of America:

DO NOT DUMP INTO ANY SEWERS, ON THE GROUND OR INTO ANY BODY OF WATER. All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations.

Disposal Guidelines in the European Economic Area (EEA):

- The QA phantom must be collected separately (mixing of hazardous waste is banned).
- The QA phantom must be delivered to a party who has a legal right to receive and treat hazardous waste.
- The QA phantom waste must be labeled as follows:



R45 May cause cancer

R46 May cause heritable genetic damage

S53 Avoid exposure – obtain special instructions before use

S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

- A record of QA phantom waste quantities must be kept. The records must be stored for three years.
- Whenever QA phantom waste is transferred within EEA Member States, it shall be accompanied by an identification document, which may be in electronic format, containing the appropriate data specified in Annex IB to Regulation (EC) No 1013/2006.

10. Appendices

10.1. Using the air pump with air bags and vacuum cushions

The accessories include an air pump with two valves for deflating vacuum cushions and inflating air bags.

Vacuum cushions are soft when inflated. They can be used to simply support the patient in a comfortable position or to allow oblique positioning when necessary. When deflated, the cushion turns solid and can be used to immobilize the patient.

Vacuum cushions can be used instead of the normal head rest to provide the patient added support and comfort. The cushions can be inflated or deflated at any stage during the treatment, as this does not affect the patient's position.

Operating the pump



Fig. 121: Air pump. Right: Air hose connected to the Deflate side of the handle.

1. Connect the air hose to the handle of the pump.
 - To deflate a vacuum cushion, connect the hose to the side marked **Deflate**.
 - To inflate an air bag, connect the hose to the side marked **Inflate**.
2. Ensure that the transparent piece of plastic tube on the vacuum cushion/air bag is securely attached to the valve. Connect one of the attached nozzles to the end of the air hose and insert it in the tube, as shown in the following figures.

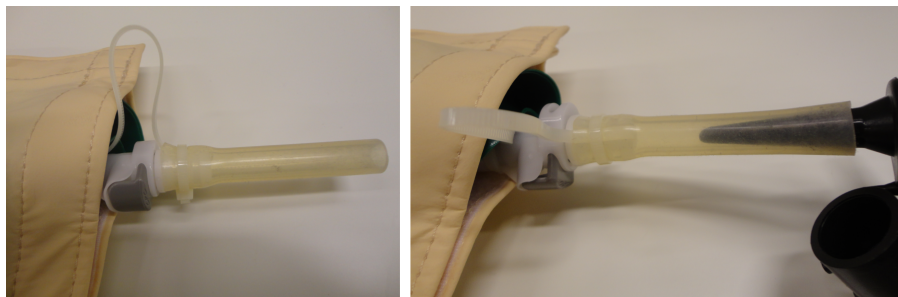


Fig. 122: Connecting the air hose.

3. Pump air out of the vacuum cushion, or into the air bag.

4. When the vacuum cushion/air bag is sufficiently deflated/inflated, press the dark button as indicated by an arrow in the following figure, and pull the transparent piece of plastic tube out of the valve. The valve is closed when the tube is removed.

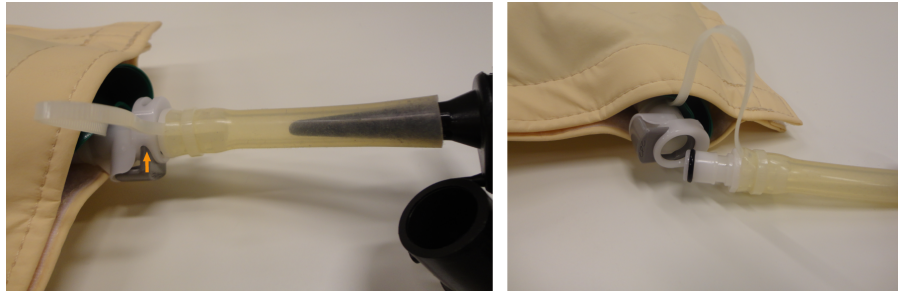


Fig. 123: Releasing the tube from the valve.

5. Disconnect the air hose from the tube.

6. To inflate the vacuum cushion after the treatment, open the valve by re-inserting the tube. The cushion starts filling up. You do not normally need to use the air pump. If you use the **Inflate** side of the air pump to inflate a vacuum cushion, take care not to pump in too much air.

Operation with another type of valve



Valve open

Valve closed

Fig. 124: Another type of valve. Left: the valve is open; middle: the air hose is connected; right: the valve is closed and the air hose has been detached.

Some air bags and vacuum cushions may be equipped with a different type of valve, as shown in the figures above. With this type of valve:

1. Connect the air hose to the handle of the pump.
 - To deflate a vacuum cushion, connect the hose to the side marked **Deflate**.
 - To inflate an air bag, connect the hose to the side marked **Inflate**.
2. Connect one of the attached nozzles to the end of the air hose and insert it in the plastic tube on the vacuum cushion/air bag. Ensure that the valve is open.
3. Pump air out of the vacuum cushion, or into the air bag.
4. When the vacuum cushion/air bag is sufficiently deflated/inflated, quickly close the valve by pressing the button fully in.
5. Disconnect the air hose from the tube on the vacuum cushion/air bag.
6. To inflate the vacuum cushion after the treatment, open the valve by pressing the other end of the button. The cushion starts filling up. You do not normally need to use the air pump. If you use the **Inflate** side of the air pump to inflate a vacuum cushion, take care not to pump in too much air.

10.2. Temperature conversion

The success of a HIFU treatment depends on the correct starting temperature. Conversion formulas and tables from and to other temperature scales are given here.

Conversion from Fahrenheit scale to Celsius scale:

$$T_C = (T_F - 32) \times 5/9$$

Conversion from Celsius scale to Fahrenheit scale:

$$T_F = (T_C \times 9/5) + 32$$

Conversion for temperature differences from Fahrenheit to Celsius:

$$T_{C2} - T_{C1} = (T_{F2} - T_{F1}) \times 5/9$$

Conversion for temperature differences from Celsius to Fahrenheit:

$$T_{F2} - T_{F1} = (T_{C2} - T_{C1}) \times 9/5$$

Conversion from Kelvin scale to Celsius scale:

$$T_C = T_K - 273$$

The table below shows some temperature limits that are relevant to the HIFU treatment:

Tab. 32: Temperature limits.

| Temperature | Celsius | Fahrenheit | Kelvin |
|--|---------|------------|--------|
| Freezing point of water | 0 | 32 | 273 |
| Normal body temperature | 37 | 99 | 310 |
| Reversible tissue damage in 1 minute | 47 | 117 | 320 |
| Necrosis of tissue in less than 3 seconds | 55 | 131 | 328 |
| Proteins denaturate | 70 | 158 | 343 |
| Maximum allowed treatment temperature | 80 | 176 | 353 |
| Boiling point of water | 100 | 212 | 373 |

10.3. Comparing thermal dose volumes and non-perfused volumes

10.3.1. Estimating thermal dose volumes

The software automatically estimates the thermal dose volume and heating dimensions. You can check the thermal dose volume and the heating dimensions of the single cell from the **Analysis** tab.

10.3.2. Calculating non-perfused volumes (NPV)

A non-perfused volume indicates cells with no blood flow and therefore no contrast agent.

1. Open the DICOM image set containing the day-0 post-treatment C+ images using the DICOM viewer on the MR console.
2. Create difference images with the Image Algebra function using the precontrast and post-contrast images. If difference images are not available or usable, use the post-contrast images, analyzing the pre-contrast images to exclude any pre-existing NPV.
3. To estimate non-perfused volume assuming an ellipsoid shape:
 - Measure the length a of the NPV using the centermost (longest) SAG (or COR) image.
 - Measure the two diameters b and c of the NPV (ellipsoid) using the centermost (largest diameter) COR (or SAG) image.
 - Calculate volume as
$$V = a \times b \times c \times \pi/6.$$

Tip

If the centermost image is a poor estimate of the NPV due to e.g. an irregular shape of the NPV, try to fit in multiple ellipsoids and choose the slices that are the most representative.

Alternative step 3: Manual contour segmentation method:

- Contour each non-merged NPV using 2D modeling tools and let the tool calculate the total area in each slice.
- The volume is the total area multiplied by the slice thickness.

Repeat steps 2 and 3 for all the NPVs and sum the NPVs together.

10.3.3. Estimating NPV on Sonalleve console

1. Go to the **PTV Delineation** stage.
2. Right-click in the image area and select the post contrast THRIVE imageset.
3. Draw a new PTV, or modify the existing PTV around the necrotic area in three planes.

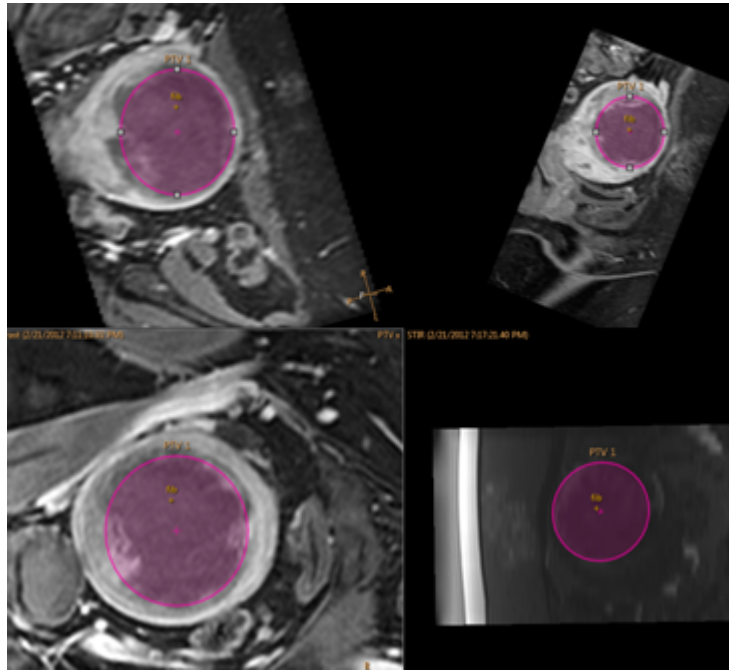


Fig. 125: PTV around the necrotic area in three planes.

4. The volume of the PTV can be seen in the top row as **Total Volume**. It gives an estimate of the NPV.

| Total Volume: | 142 ml |
|-------------------------|-----------------|
| Total Treatment Volume: | 158.41 ml 112 % |
| Name | Volume |
| PTV 1 | 141.68 ml |

10.4. QA Test result table

| QA TEST CELL 1 | | | | | | | | |
|---|----------------------|----|----|-------|---------------------|-----------------------------|---------------------------|---------------------|
| DATE [YYYY-MM-DD] & User's Initials | HEATING OFFSETS [mm] | | | | MAX TEMP [°C] | HEATING DIAMETER [mm] | HEATING LENGTH [mm] | REASON IF FAILED |
| | AP | LR | FH | Total | | | | |
| <i>Acceptable values</i> | | | | < 5 | 43 / 75 | 5 / 10 | 15 / 30 | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

© 2014 Koninklijke Philips N.V. All rights are reserved.

10.5. Copying Sonalleve MR-HIFU treatment data to DVD

10.5.1. Copying DICOM images

For instruction on how to copy treatment-related DICOM images on the MR console, refer to the MR scanner's *Instructions for Use*.

10.5.2. Copying saved state data

To copy saved state data to DVD using the DVD RW drive in the Sonalleve Console, carry out the following steps on the Sonalleve Console:

1. Select **Manage States...** (in the **File** menu).
2. Select the saved state to copy.
3. Click the **Export** or **Export De-identified** button.
4. In the **Save As** dialog box, select **DVD RW Drive (E:)**.

Note that **Export De-identified** does not automatically change any potentially identifying text in the **Name** and **Description** of the saved state, or the export filename.

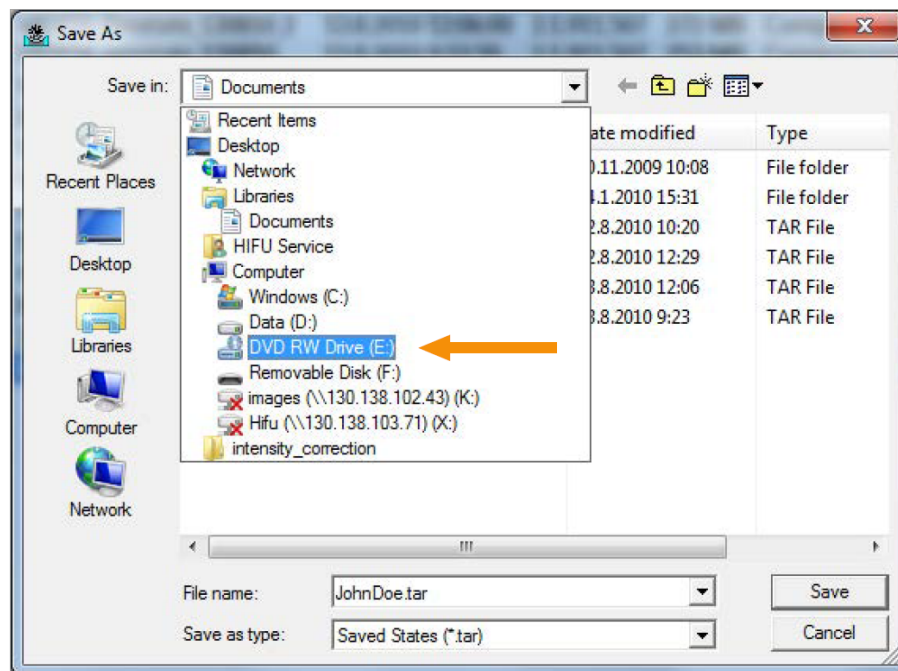


Fig. 126: Save As dialog box.

5. In the **Burn a Disc** dialog box, select **With a CD/DVD player**, then click **Next**.

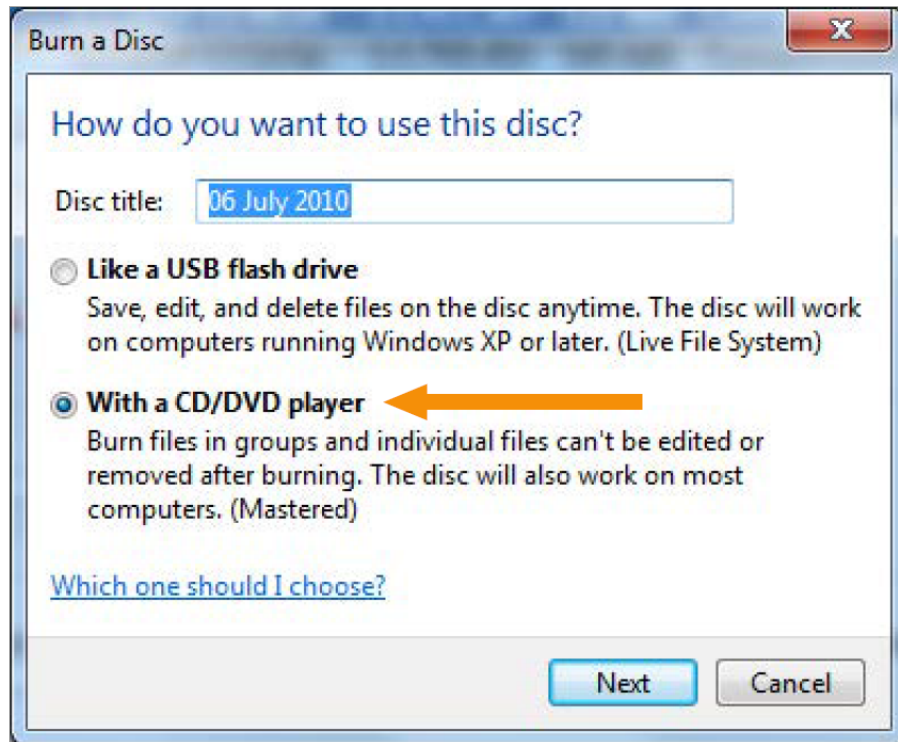


Fig. 127: Burn a Disc dialog box.

6. In the **Save As** dialog box, give the saved state a file name, then click **Save**.
7. Wait for the export to complete in the **Session Manager** dialog box, then close the dialog box.
8. Press the **Windows** button on the keyboard to see the Windows start menu.
9. Click **Computer**. Double-click on the **DVD RW Drive (E:)**.
10. Click **Burn to disc**.

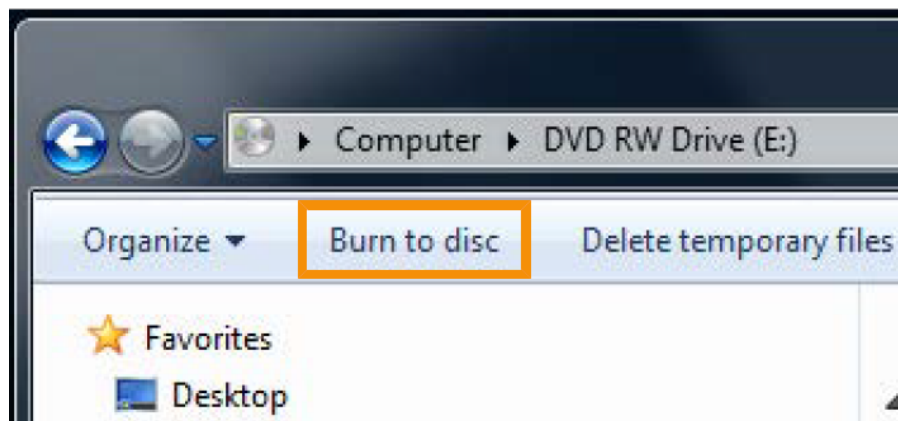


Fig. 128: Burn to disc button.

11. Give the disc a title, then click **Next**.

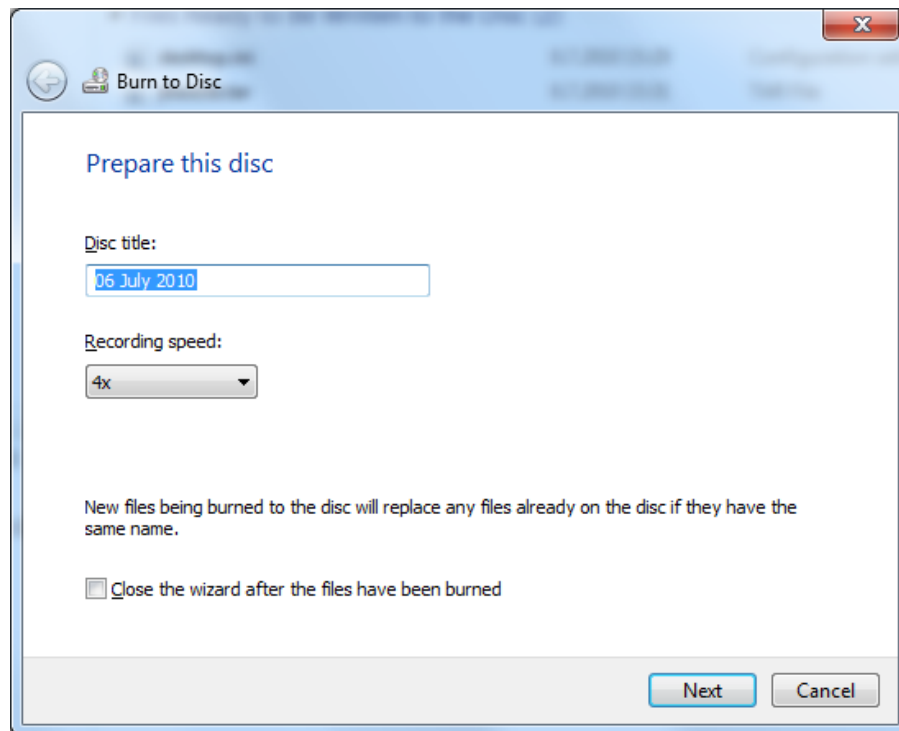


Fig. 129: Burn to Disc dialog box.

12. Wait for the disc burning to complete. It takes a few minutes.

Saved states can also be copied to network drives and removable media using a similar process. Note that access to the DVD drive and the rear panel USB ports requires administrative privileges. The front panel USB ports are disabled for cybersecurity reasons.

10.6. Security and privacy features

It is the policy of Profound Medical to adhere to all required standards and regulations. To assist the hospital, the following functionality has been added to the system:

10.6.1. Access control

Intended to restrict access to the system to authorized users only:

- Customizable on/off, a user log-on/log-off procedure is required to gain access to the system.
- Access to the system is granted according to a customizable list of authorized users.
- Only username/password authentication is supported. No additional mechanisms, like two-factor authentication using smartcards, etc., are supported.
- The system does not provide functionality to synchronize with customer central user account administration systems (LDAP, etc.).
- The system supports only single user sessions. It does not provide application functionality to register multiple simultaneous users or to switch between users other than via log-off / log-on.
- The system does not support single sign-on for situations where the system works together with other (optional) systems or is part of another system, e.g. extra workstations.

NOTICE

It is not possible to prevent the transfer of data to removable media.

10.6.2. Audit trail

Required to log user activities which are information-security critical:

- Applies to logging-on, reading and/or modifying clinical information.
- Uses the local Security Event Log which is accessible only to service and system administrators.
- Use of an external standard 'Syslog' server is not supported.

Application specific access information is stored in RFC-3881 format; Logon/Logoff information is stored using Windows' event format.

Viewing the local audit log

To view the local audit log:

1. Log on to the Sonalleve console as an administrator.
2. Open the Windows **Start** menu.
3. Select the **Windows Administrative Tools** folder.
4. Under **Administrative Tools**, click **Event Viewer**.

Log-on, log-off and other security critical events are found in **Windows Logs** → **Security**.

10.6.3. Network time synchronization

The Sonalleve MR-HIFU system synchronizes its time to the MR scanner. It is possible to configure the MR scanner to synchronize system time to an external time standard:

- The MR scanner uses a standard Network Time Protocol (NTP) to synchronize system time.
- A coupling between the scanner and an external time standard can be configured by the Profound Medical service representative during the installation of the MR scanner.

The system time on the MR-HIFU system is synchronized to the system time on the MR scanner during the QA Test (see 7.2.2. *Performing the QA Test*).

10.6.4. Other Security and Privacy features addressed

HIPAA defines a number of physical and technical safeguards which are either required or addressable. Some features that could implement these functions are differently or not implemented for reasons mentioned below.

This section also lists other information related to security features that are not implemented and that the owner of the systems should be aware of.

System and application hardening

On the Sonalleve Console, unnecessary services have not been removed or disabled.

- The HIFU Administrative account is provided for hospital administrative roles, however these users are prevented from clinical use of the system.
- The Sonalleve Console uses Windows default password complexity rules. The hospital administrative user can change the password settings.
- The Sonalleve Console has two logical drives. There is no distinct separation of operating system, application software and data storage over these drives.
- When logging on to the Sonalleve Console as a normal HIFU User the application is automatically started, however it is possible for a user to switch to the operating system interface (Windows desktop). When the application is closed, the user is logged off automatically.

The Autoplay feature is turned off on the Sonalleve Console, so DVDs or USB devices inserted into the system will not be opened automatically.

Automatic logoff

An auto-logoff feature is not implemented since it contradicts the intended use of the system. Manual logoff using a 'short-cut' key combination is documented (see 2.15. *Network safety, data security and privacy*).

Backup procedure

The system does not provide persistent storage for treatment data. It is not the intended use of the system to permanently store (sensitive) personal information. Information should be exported to a secure storage device as soon as possible.

The system does an automatic full system backup nightly to a second internal disk. The system configuration is saved with the backup and can be retrieved by Service.

Emergency Access Procedure

The system allows the creation of multiple user accounts. You may create a generic user account for emergency situations. However, to avoid unauthorized access to patient data, ensure that knowledge of this generic account and access to the system is restricted.

The system does not mark data output as emergency usage, such as on-screen, printed, or exported data during emergency access operation.

The system does not allow or enforce the users of a generic user account to enter their real names.

Encryption

The system does not encrypt patient data that is stored on the hard disk or exported to external media (DVD, USB device, etc.). The system also does not use encryption for transmission of data.

Network firewall configuration

The system is placed behind an external firewall which prevents all access to the ports of the Sonalleve MR-HIFU system from the hospital network.

Physical access to the system

Multi-factor authentication for all users is not supported. Control authentication by controlling physical access to the system. Ensure that only authorized personnel have access to the system.

Some parts of the systems are located in the technical area of a system. Access to these locations is assumed to be restricted. Usually, the components in the operator or examination room are more readily accessible and therefore the following characteristics shall be taken into account for system operation and access control:

- The computer case is 'service friendly'; opening and removal of, for example, hard disk may be possible without use of tools; computer case can be locked (for example, by cable lock); there are no front side accessible drives, and so on.

- The boot order for the system is Hard Disk, USB, DVD. By inserting a bootable CD/DVD or connecting a bootable USB memory device, the system could be started up from those and thus access may be gained to the system including information stored in it.
- There is no detection of unauthorized physical access into the system e.g. via tamper proof seals.
- The integrity of most of the Profound Medical application software is checked when the systems starts. Data integrity is not checked on startup.
- The system BIOS is not password protected and can be accessed during the startup of the system if unauthorized access to the system is possible.
- Access to the DVD drive and the rear panel USB ports requires administrative privileges. The front panel USB ports are disabled for cybersecurity reasons.

Security and node authentication

The Sonalleve MR-HIFU system only exchanges clinical data with the (internal) MR system, not with other external nodes. Therefore, no node authentication mechanism has been implemented.

Security event reporting

The system does not implement automated reporting of security events.

10.7. Hospital administrator and user accounts

10.7.1. About accounts

The default user account “HIFU User” can be used by different system operators, but does not provide a personified logging of the actions done by each operator. Personified user accounts providing the logging of the actions done by each individual user may be required by legislation: for example HIPAA. Each of these individual users has the same permissions and rights as the default system user, unless the administrator assigns different rights to the user account. It is possible to define that certain user accounts are power users. Power users have these additional rights:

- Power users can edit the system configuration.
- Power users have access to all the maintenance tools in the software.
- Power users have access to additional operating modes of the Sonalleve MR-HIFU application, as described in *10.8.1. Partial standalone modes*.
- Power users can use the **Export Data** feature described in *6.8.9. Saving the treatment data*.

The hospital IT administrator or Profound Medical service shall define local user accounts for the Sonalleve console (Windows login). User accounts should be managed by the hospital administrator. It is also possible to create multiple hospital administrator accounts.

Rename the default accounts. Use strong passwords. Do not share accounts: each user should have an individual account. If this is not possible, then take appropriate security measures to manage the accounts, such as changing passwords when users change roles.

10.7.2. Creating a new user/administrator account

1. Logon with username HospitalAdmin (not case sensitive).

The password of HospitalAdmin is 'Hospital' (case sensitive) on the first logon. You have to change the password on the first logon.

2. Right-click the Windows Start menu and select **Computer Management**.

3. Select **System Tools** → **Local Users and Groups** → **Users**.
4. Select **Action** → **New User...**
5. Enter a personal username, a full name, and an account description. Define and confirm a password of minimum 7 characters for the new user. Click **Create** and then **Close**.
6. Right-click the newly created user in the list and select **Properties**.
7. In the **Member Of** page select **Add...**
 - For normal user accounts type "HIFU Users" (without quotation marks) and click **Check Names**. The entered text should expand to "HIFU\CONSOLE\HIFU Users". Click **OK**.
 - For power user accounts type "HIFU Power Users" (without quotation marks) and click **Check Names**. The entered text should expand to "HIFU\CONSOLE\HIFU Power Users". Click **OK**.
 - For administrator accounts type "HIFU Administrator Users; Administrators" (without quotation marks) and click **Check Names**. The entered text should expand to "HIFU\CONSOLE\HIFU Administrator Users; HIFU\CONSOLE\Administrators". Click **OK**.
8. Click **OK**.
9. Close the **Computer Management** window.

NOTICE

On the first logon the new user or administrator is forced to change his/her password.

10.7.3. Deleting an account

1. Open the Windows Start menu, right-click **Computer** and select **Manage**.
2. Select **System Tools** → **Local Users and Groups** → **Users**.
3. Select the user in the list.
4. Select **Action** → **Delete**.
5. Select **Yes**. If you are deleting an administrator account, you must also select **OK** to confirm the delete operation.

NOTICE

The system does not provide the possibility to synchronize with the customer's central user account administration systems.

10.8. Features for advanced users and administrators

10.8.1. Partial standalone modes

In the **Therapy** mode, the Sonalleve MR-HIFU application requires a connection to both the MR scanner and the hardware of the Sonalleve MR-HIFU system. In the **Standalone** mode, both of these connections are emulated in software.

Power users, Service users and other qualified advanced users can additionally select from two partial standalone modes:

- In the **Scanner Emulated** mode the connection to the MR scanner is emulated, but the connection to the hardware of the Sonalleve MR-HIFU system (including the generator cabinet and the tabletop) is active.
- In the **Sonicator Emulated** mode the connection to the hardware of the Sonalleve MR-HIFU system is emulated, but the connection to the MR scanner is active.

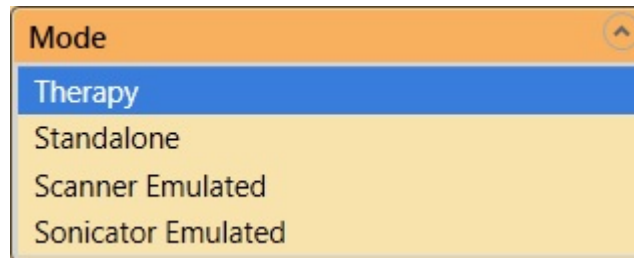


Fig. 130: The Mode list in the start page of the application, for advanced users.

Note that the text in the application selection button for the therapy session only is **Standalone** in the full **Standalone** mode. In the **Scanner Emulated** and **Sonicator Emulated** modes, the text in the button is **Therapy** or **Research**, according to which mode the application was started in.

10.8.2. Changing the Site Default Configuration

NOTICE

The Site Default Configuration exists to ensure that the normal users of the system always have a valid, working configuration to use, even when advanced users have modified the current configuration. Any changes to the Site Default Configuration carries the risk of interfering with the normal workflow, in addition to the safety risks inherent in modifying the configuration (see 2.1. *General safety*).

The Configuration Editor tool has menu items in its **File** menu for loading and saving the Site Default Configuration.

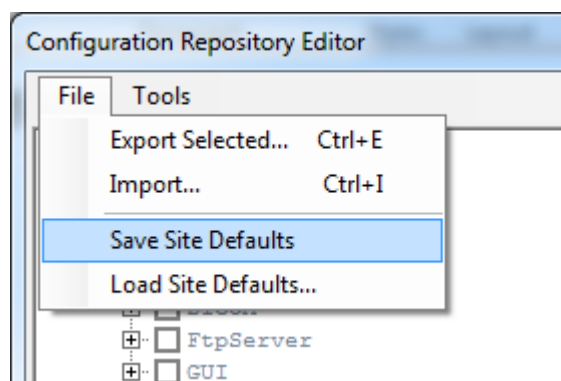


Fig. 131: Menu items for Site Default Configuration.

Save Site Defaults saves the current configuration as the Site Default Configuration. The software automatically saves a backup copy of the previous Site Default Configuration, too. Confirm the change by clicking **Yes** in the **Service Operation** dialog box:

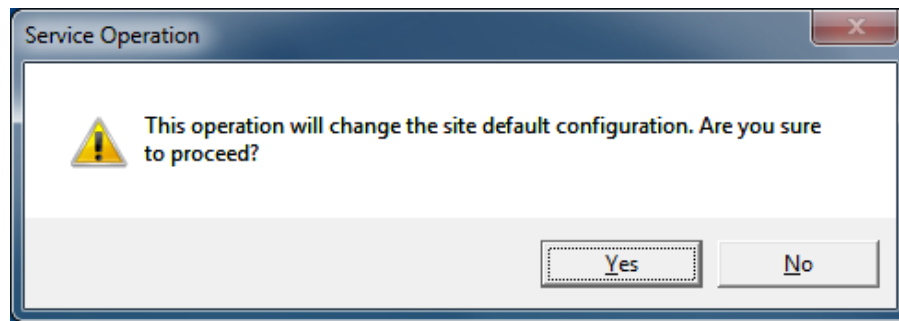


Fig. 132: The dialog for confirming the change in Site Default Configuration.

Load Site Defaults... loads a Site Default Configuration into the configuration editor. Use the file load dialog to select the current Site Default Configuration or a previous version from the backups.

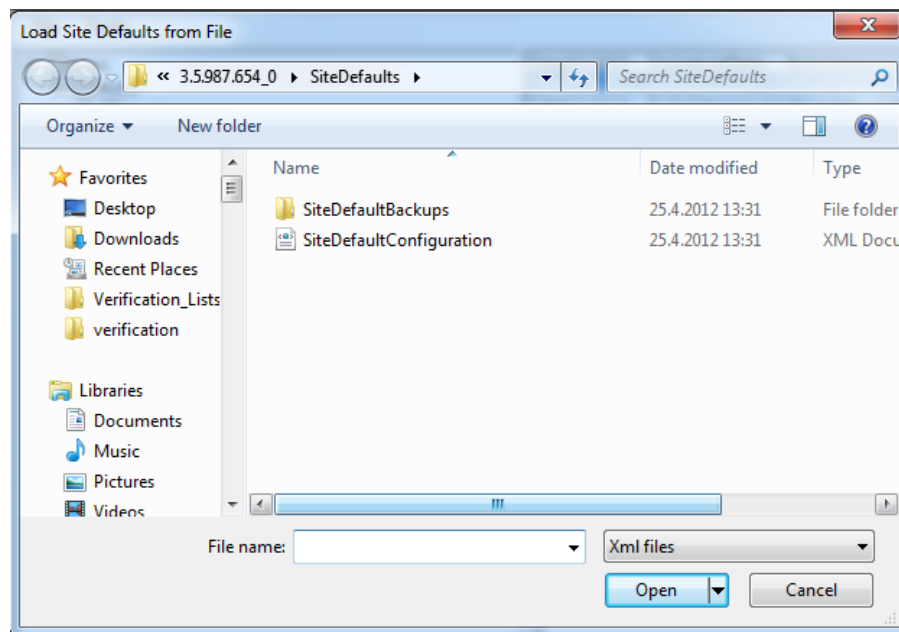


Fig. 133: Loading a Site Default Configuration from a file.

10.8.3. Automatic backup of configuration changes in Research mode

When you close the Configuration Editor, the editor automatically saves a backup of the current configuration into a backups folder. The backup folder is located in "C:\ProgramData\Profound Medical\Hifu\1.1\InstallationData\XX.XX.XX.XX_X\Backups\ResearchConfigurations", in which "XX.XX.XX.XX_X" changes according to the active software build, for example "3.5.987.654_0".

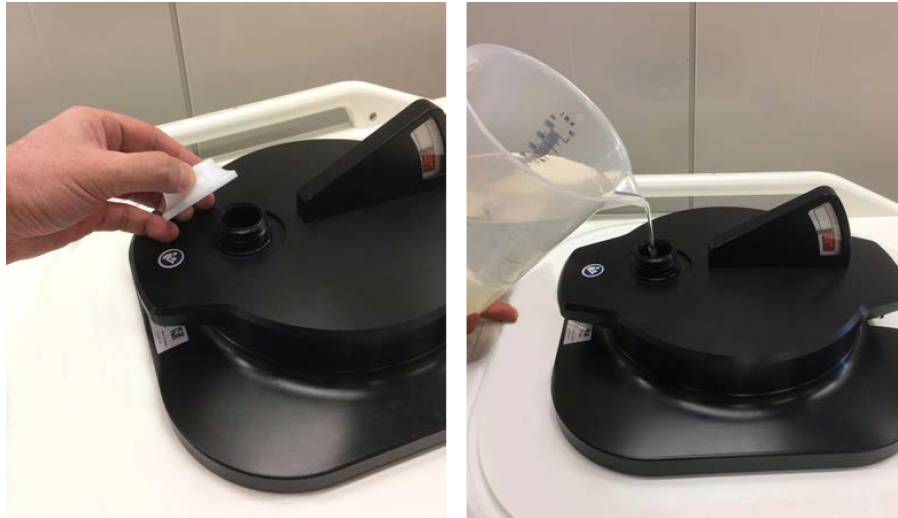
10.9. Advanced maintenance procedures

Important

The following procedures are normally done by Service. Users are advised to do the following procedures themselves only if Service is not available.

10.9.1. Adding water to DISCfill

1. Unscrew the white cap from DISCfill.
2. Fill DISCfill with distilled water. DISCfill holds approximately 1.2 liters (0.3 gallons) of water.
3. Replace the cap.

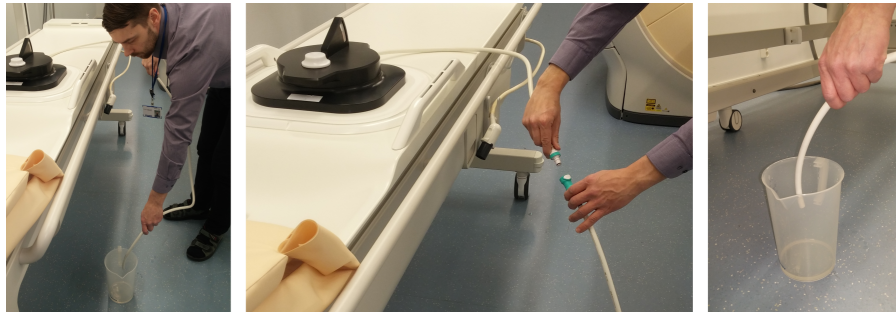


Typically, DISCfill does not need filling between planned maintenance. If DISCfill needs to be filled more frequently, contact Service.

10.9.2. Removing air from the filling hose












If you suspect that there is air in the filling hose that prevents the water flow, remove the air by the following method. You need the draining hose and a container for water (a washbowl, for example).

1. Leave DISCfill on top of the ultrasound window.
2. Disconnect the filling hose from the Sonalleve tabletop. Leave the filling hose connected to DISCfill.
3. Position the container at the side of the Sonalleve tabletop, below the level of DISC.
4. Place the open end of the draining hose into the container.
5. Connect the filling hose into the female hose connector of the draining hose.
6. Position the hoses so that at no point between DISCfill and the container the water flow needs to turn upwards.
7. Let some water flow through the hoses.
8. Disconnect the filling hose from the draining hose.
























10.10. Error and Warning messages

Tab. 33: Symbols in the list of Error and Warning messages.




















| Symbol | Meaning |
|--|--|
|   | Error, High priority |
|   | Error, Medium priority |
|   | Error, Low priority |
|   | Warning, requires user intervention |
|   | Warning, requires user confirmation |
|  | Warning, other |














Tab. 34: Error and Warning messages.













| Error / Warning | Explanation | Action |
|--|--|---|
|   Abnormally Low Tabletop Water Temperature | The temperature readings from the tabletop are abnormally low. | Close the Sonalleve Application, check the cable connections to the tabletop, then restart the Application. If the problem persists, contact Service. |






















| | | | |
|--|---|---|---|
|   | Abnormally Low Transducer Temperature | The temperature readings from the transducer are abnormally low. | Close the Sonalleve Application, check the cable connections to the tabletop, then restart the Application. If the problem persists, contact Service. |
|   | Algorithm Data Spooler Unavailable | The software cannot access the algorithm data store and image data cannot be processed. | Wait a couple of seconds and retry the previous operation. If it still fails, restart the software. |
|   | Algorithm Execution Failed | There is a software error in an algorithm processing the monitor images. Further details can be found in the system log. | Restart the Application. If the problem persists, contact Service to ensure correct system configuration. |
|   | Algorithm Execution Unsuccessful | There is a software error in an algorithm processing the monitor images. | Abort sonication and retry the operation. If the problem persists, restart the Application. |
|   | Algorithm Output Unavailable | The image data cannot be processed as the software cannot access the monitor image processing algorithms. | Abort sonication. If the software does not recover in 30 seconds, restart the Application. |
|  | Algorithms Cannot Be Prepared for Scanning | The algorithms are not suitable for scanning the current scan protocol. Either the current scan protocol is unsuitable or the algorithms are in a faulty state. | Restart the scan protocol on the MR scanner. If the problem persists, save the system state, exit the therapy, and reload the state. |
|   | Angulated Fat-Monitoring Scan Not Allowed | An angulated fat-monitoring scan cannot be used for cooling time calculation. This can result in increased therapy time. | Prepare a new fat-monitoring scan on the MR scanner. Remove all angulations by setting the AP, RL, and FH angulations to zero on the Offc/Ang tab. |
|   | Application Busy | The Application is busy. If the situation continues, there is a risk of data loss. | Wait for a minute before continuing. If the problem persists, save the state and restart the Application. |
|  | Available Primary Disk Space Getting Low | Available disk space on the primary disk is low. | Free up disk space by exporting old saved states to archive media and then deleting them using the Session Manager. |
|   | Available Primary Disk Space Too Low | Available disk space on the primary disk is too low. | Immediately free up disk space by exporting old saved states to archive media and then deleting them using the Session Manager. |
|  | Available Secondary Disk Space Getting Low | Available disk space on the secondary disk is low. | Clean up the secondary disk. |





















10. Appendices > 10.10. Error and Warning messages

| | | | |
|--|---|--|---|
|   | Available Secondary Disk Space Too Low | Available disk space on the secondary disk is too low. | Clean up the secondary disk so that there is enough free disk space. |
|  | Cannot Change Transducer | Another transducer has already been used to define data. | Clear the planning data first. |
|  | Cannot Remove Patient Position Data | The patient position data cannot be removed as scanning or sonication is still in progress. | Wait for the scan to stop and try again. |
|  | Cannot Remove Planning Target Volume | The Planning Target Volume cannot be removed as scanning or sonication is still in progress. | Wait for the scan to stop and try again. |
|  | Cannot Remove Treatment Cell | The treatment cell cannot be removed as scanning or sonication is still in progress. | Wait for the scan to stop and try again. |
|  | Cannot Remove Treatment Cell Cluster | The treatment cell cluster cannot be removed as scanning or sonication is still in progress. | Wait for the scan to stop and try again. |
|  | Cannot Remove Treatment Cells | Removal of sonicated/scanned treatment cells is not allowed. | Select 'Cancel' to keep the data. Re-plan if you wish to resonicate or move treatment cells. |
|  | Cannot Remove Treatment Plane | The treatment plane data cannot be removed as scanning or sonication is still in progress. | Wait for the scan to stop and try again. |
|  | Check OAR and ROI Positions | Registration has altered the ultrasound beam paths. OARs and ROIs may have moved. Check their positions in the latest images. | Inspect visually the organ avoidance regions and warning ROIs. |
|  | Communication Error | A communication error has been detected. | Restart the Sonalleve console. |
|   | Component Query Mismatch | The QA Test has been performed with different hardware components than those currently in use. | Perform the QA Test. |
|   | Confirm Discarding of the Old Patient Data | The old patient data will be discarded. Are you sure you want to continue? | Select 'Continue' to discard the old patient data. Select 'Cancel' to keep the data. |
|   | Confirm Overwriting Old Transducer Data | The selected patient position already contains transducer related data. Are you sure you want to continue and remove the old data? | Select 'Continue' to remove the old data. Select 'Cancel' to keep the data. |
|   | Confirm Patient Position Removal | You are about to remove the patient position and the position related data. Are you sure you want to continue? | Select 'Cancel' to keep the data. Select 'Continue' if you are sure you will not need the data anymore. |













| | | | |
|---|--|---|---|
|  | Confirm Planning Target Volume Removal | The Planning Target Volume and its associated data are about to be removed. Are you sure you want to continue? | Select 'Continue' to remove the data. Select 'Cancel' to keep the data. |
|  | Confirm the Release of a Degree of Freedom | Releasing a degree of freedom will remove existing treatment planes. Are you sure you want to continue? | Select 'Continue' to release the degree of freedom and to remove the treatment planes. Select 'Cancel' to keep the data. |
|  | Confirm Treatment Cell Cluster Removal | Removing the treatment cell cluster will remove all the associated data, such as treatment cell positions. Are you sure you want to continue? | Select 'Continue' to remove the data. Select 'Cancel' to keep the data. |
|  | Confirm Treatment Plane Removal | If a treatment plane is removed, the associated treatment cell clusters are removed as well. Are you sure you want to continue? | Select 'Continue' to remove the data. Select 'Cancel' to keep the data. |
|  | Confirmable Test Error | This error is for R&D use only. You should never see this in normal use. | Select 'Continue'. If the problem persists, stop using the software and contact Service. |
|  | Connect Direct Skin Cooling Device Hoses | The Direct Skin Cooling device hoses must be connected before the treatment can continue. | Ensure that the hoses are properly connected. |
|  | Connection Lost. Abort Sonication Using Safety Device | The software cannot access the HIFU Controller components. Sonication and transducer movements may be uncontrolled. | Use the Safety Device to abort any uncontrolled actions. Wait 30 seconds for the connection to re-establish. If a connection does not resume itself, restart the Application. |
|  | Control Cable Disconnected | The Sonalleve control cable has been disconnected from the tabletop. | Reconnect the control cable to continue treatment. |
|  | Control Cable Reconnected | The Sonalleve control cable has been reconnected to the tabletop and the hardware must be re-initialized. | Restart the Application. |
|  | Cooler Waterflow Low | The cooler waterflow is too low. | Contact Service. |
|  | Could Not Correct for Misregistration | The estimated misregistration could not be corrected for. It is larger than the maximum allowed. | Manually correct the misregistration or verify the ultrasound coupling and hardware functionality. |
|  | Crash Recovery Currently Unavailable | Crash recovery is temporarily unavailable. Data can be lost or overwritten. | Wait for 60 seconds. If the problem persists, restart the software. |
|  | Direct Skin Cooling Device Failure | The system has detected an error in the operation of the Direct Skin Cooling device. | Close the Sonalleve Application, then restart the Application. If the problem persists, contact Service. |

| | | | |
|---|--|--|--|
|  | Direct Skin Cooling Device Simulation Mode in Use | Direct Skin Cooling device operations are being simulated by the software. Real skin cooling does not take place. | Use the configuration editor to turn the simulation mode off. |
|  | Direct Skin Cooling Device Still Starting | The Direct Skin Cooling device is establishing correct operating pressure. | Wait for the Direct Skin Cooling device status to turn active before sonicating. |
|  | Direct Skin Cooling Disabled | Direct Skin Cooling disabled in configuration but Direct Skin Cooling controller detected. | Contact Service to ensure correct system configuration. |
|  | Disturbance in Temperature | The temperature has significantly changed outside the intended treatment volume. Patient movement or a sudden change in the magnetic field may have caused this. The temperature readings are erroneous. | Abort the sonication and determine the cause of the problem. |
|  | Do Not Power Off Hardware | System is initializing. Loss of power at this time may damage hardware. | Do not switch off the power from any hardware components. Do not restart the generator cabinet. Wait until the initialization is ready. |
|  | Dynamic Levels Running Out | The current temperature mapping scan protocol does not contain enough dynamic levels to continue much longer. | Stop the current temperature mapping scan protocol, ensure that it has enough dynamic levels configured, and restart the protocol. |
|  | Elevated Tabletop Water Temperature | A rise in the tabletop water temperature has been detected. It is not a cause of concern as long as the temperature does not continue rising. | Check that the power level and sonication duration are reasonable. Continue monitoring the water bath temperature. |
|  | Excessive Heating in Treatment Cell Region | Heating above the maximum safety limit is detected in the treatment cell region. Sonication is stopped. | Reduce power or cell size in the following sonications. |
|  | Expected Images Not Received | Images were not received within the set time. The MR scanner may have been busy. | Restart the scan protocol on the MR scanner. |
|  | Failed to Apply Calibration Data | Failed to apply calibration data. The system is not currently using the correct calibration data. | Close the Sonalleve Application, check the cable connections to the tabletop, then restart the Application. |
|  | Failed to Install Software Components | Failed to install HIFU Controller software components. | Restart the generator cabinet and wait 60 seconds for the connection to re-establish. Postpone treatment until the installation is successful. |
|  | Failure in Software Infrastructure | A system service has failed. This may lead to application failures and data loss. | Save the current procedure, exit the Sonalleve Application and restart the Sonalleve Console. |













| | | | |
|--|---|---|---|
|   | Field Strength Incorrectly Configured | The field strength configured for HIFU does not match the field strength of the MR scanner. | Contact Service to configure the field strength correctly for HIFU. The field strength must be correctly configured to be able to perform patient treatments. |
|  | Fixed Sonication Parameters in Use | The sonication protocols are currently fixed. The user is not able to change the sonication parameters (power, duration, etc.). | Do not use this R&D system configuration for therapy. Contact Service. |
|   | General Hardware Error | Hardware failure. Further details can be found in the system log. | Close the Sonallevé Application, check the cable connections to the tabletop, then restart the Application. If the problem persists, contact Service. |
|  | General Hardware Failure | Hardware failure. Further details can be found in the system log. | Close the Sonallevé Application, check the cable connections to the tabletop, then restart the Application. If the problem persists, contact Service. |
|   | Generator Hardware Failure | Generator Hardware failure. Further details can be found in the system log. | Determine the reason for the generator hardware failure. Enable sonication with the Safety Device and try to repeat the sonication. |
|   | Generator Monitoring Failure | Generator monitoring has failed and the Safety Device has stopped sonication. | Determine the reason for the generator monitoring failure. Enable sonication with the Safety Device and try to repeat the sonication. |
|   | Hardware Does Not Match Configuration | Connected hardware does not match the active hardware set in the configuration. | Contact Service to ensure correct system configuration. |
|   | Hardware Initialization Incomplete | The HIFU Controller reports incomplete hardware initialization. | Restart the Hardware Initialization. |
|   | Heating in Near-Field Warning Zone | Heating detected in the near-field warning zone. | Closely follow the temperature readings. Consider aborting sonication. |
|   | Heating in User-Defined Warning Zone | Heating detected in the user-defined warning zone. | Closely follow the temperature readings. Consider aborting sonication. |
|  | Image Data Input Queue Full | The image data is received faster than it can be processed. Some input images are lost. | Wait for the input queue to be flushed. If waiting does not help, restart the Application. |
|  | Image Data Input Queue Warning Length Exceeded | The image data is received faster than it can be processed. | Wait for the input queue to be flushed. If waiting does not help, restart the Application. |
|  | Image Series Retrieval Failed | Failed to retrieve some of the planning images. | Try to export planning images again from the MR scanner. Then perform query and attempt retrieval again. |

| | | | |
|--|--|---|---|
|  | Inactive Transducer Channels | The hardware has deactivated several transducer channels. There are still a sufficient number of channels remaining to guarantee the shape of the treatment cell. | Monitor the treatment cell shape and check the acoustic contact. Restart the generator cabinet after treatment. If the problem persists, contact Service. |
|  | Incomplete Ultrasound Frequency Calibration | Calibration data not found for the selected sonication frequency. | Select another sonication frequency to proceed with the treatment. Contact Service to complete the system calibration. |
|   | Inconsistent Configuration Data | The software detected inconsistent configuration data that could affect the system operation. Checksum validation has failed, further details can be found in the system log. | Close the Sonalleve Application and restore the default system configuration. If the problem persists, contact Service to ensure correct system configuration. |
|   | Incorrect Scan Protocol | The received monitor image attributes do not match the expected values as configured. | Select the correct scan protocol at the MR console. |
|   | Internal Error in Software Safety Model | An internal error was detected in the safety model of the software. It is unsafe to continue the treatment. | Reselect the gel pad thickness. If that does not help, save the state, exit Therapy, reset any unsafe changes in the configuration editor, and reload the state. If that does not help, you will need to restart the therapy. |
|   | Invalid and Unsafe Configuration | The software detected invalid configuration settings that could affect the safety of the treatment. Further details can be found in the system log. | Exit Therapy mode. Do not use the system to treat patients. Contact Service. |
|   | Invalid Configuration Data | The software detected invalid configuration data that could affect the system operation. Further details can be found in the system log. | Close the Sonalleve Application and check the system configuration. If the problem persists, contact Service to ensure correct system configuration. |
|   | Invalid ExamCard | Could not find a suitable scan protocol. | Ensure that a correct scan protocol has been selected on the MR scanner. |
|   | Invalid Gel Pad Thickness Selected | The selected gel pad thickness is invalid. | Select another thickness in the drop-down menu on the Patient Information page. If all available thicknesses are invalid, call Service. |
|  | Invalid Monitor Image | Unable to display some of the monitor images. | Most likely an invalid scan protocol has been used during scanning or sonication. For example, images might not contain correct location/orientation information preventing them from being displayed. |
|   | Invalid OAR, Sonication Not Allowed | A recently drawn OAR is invalid due to an irregular line shape. Sonications are not allowed as the ATA and beam shape cannot be calculated. | Remove and redraw the invalid OAR. |
|  | Invalid Patient Positioning | The patient position and orientation are incompatible with the transducer in use. | Correct the patient positioning settings at the scanner. |





















10. Appendices > 10.10. Error and Warning messages





















| | | | |
|---|---|--|---|
|  | Invalid Saved State File | An invalid saved state file has been loaded - the version or product configuration of the current system does not match the loaded data. | Exit the therapy session and load a saved state file with a correct version. |
|  | Invalid Scanner Software Version | This Sonalleve software version is incompatible with the software on the MR console. The installation of the Sonalleve software has failed. Both the Sonalleve Console and the MR scanner software must be upgraded. | Contact Service. Software must be reinstalled. |
|  | Invalid Transducer Positioner Firmware Version | Transducer positioner firmware version is invalid. | Contact Service. Transducer positioner firmware must be upgraded. |
|  | Large Motion Detected | The temperature maps indicate large motion or localized field drift. Heating in unintended regions may result. Any temperature change outside the intended heated region may have caused this warning. | Abort the sonication and verify the patient position. |
|  | Malfunction of the Direct Skin Cooling Device | The system has detected non-optimal function of the Direct Skin Cooling device. | The treatment can be continued, but treatment time is likely to increase. Call Service if the problem persists. |
|  | Missing or Invalid Membrane Calibration | Membrane position calibration data is either missing or invalid. | Contact Service. The membrane position needs to be (re-)calibrated. |
|  | Missing Required Calibration Data | The system's calibration data store does not contain all the required calibration data instances. | Contact Service. Missing calibration data instances are written to the log as warnings. |
|  | Missing Required Navigator Data | Missing navigator data required for multi-baseline temperature mapping. | Use the correct scan protocol with navigators enabled. |
|  | MR Scanner Start Command Failed | Failed to send a start command to the MR scanner. | Restart the scan protocol on the MR scanner. |
|  | Near-Field Stack Missing | No monitoring stack has been positioned in the near field. Near-field heating cannot be monitored and cooling time cannot be estimated. Sonication without a near-field stack may be unsafe. | Position a monitoring stack in the near field. |
|  | No Connection to HIFU Controller | Connection to the HIFU Controller cannot be established. This indicates a problem with the hardware. | Check that the generator cabinet is switched on and check the cabling. If the problem persists, contact Service. |
|  | No Connection to MR Scanner | The MR scanner connection is missing. Image and physiology data updates cannot be received from the MR scanner. | Check that the generator cabinet is switched on and check the cabling. Restart the MR application software on the MR scanner. If the connection does not establish itself, contact Service. |





















10. Appendices > 10.10. Error and Warning messages













| | | | |
|---|---|---|--|
|  | <p>No Match to Temperature Reference</p> | <p>Could not find a match to temperature reference data. Temperature images are inaccurate. Sonication aborted.</p> | <p>Restart the sonication.</p> |
|  | <p>Non-default Scan Protocol</p> | <p>The received monitor image attributes do not match the expected values as configured.</p> | <p>Select the correct scan protocol at the MR console.</p> |
|  | <p>OAR Too Large</p> | <p>One or more OARs are too large.</p> | <p>Replace the large OARs with smaller ones.</p> |
|  | <p>Obsolete QA Test</p> | <p>The QA Test has not been performed within the set time.</p> | <p>Perform the QA Test.</p> |
|  | <p>Patient Emergency Stop</p> | <p>The patient has pressed the emergency stop button.</p> | <p>Determine why the patient has pressed the emergency stop button, then re-enable the system using the Safety Device.</p> |
|  | <p>Patient Id Cannot Be Changed</p> | <p>The old patient data contains measurement results and cannot be discarded.</p> | <p>Exit the current session and start a new one if a new patient case is needed. To continue with the current patient, select 'Cancel'.</p> |
|  | <p>Patient ID Mismatch</p> | <p>The patient ID has been changed during a therapy procedure.</p> | <p>Ensure that the correct patient has been selected on the MR scanner.</p> |
|  | <p>Patient Information Cannot Be Validated</p> | <p>The system configuration is invalid and does not contain validators in all the patient information fields.</p> | <p>R&D should add validators to the configuration data or remove unnecessary patient information fields.</p> |
|  | <p>Poor Heating Efficiency in Treatment Cell</p> | <p>Temperature is not increasing as expected for the chosen thermal dose.</p> | <p>Verify that heating is centered on the treatment cell and try to repeat the sonication, or then repeat the test sonication.</p> |
|  | <p>Poor Match to Temperature Reference</p> | <p>Could not find a good match to temperature reference data. Temperature images may not be accurate.</p> | <p>Restarting the sonication may be necessary.</p> |
|  | <p>Positioning of Transducer Aborted</p> | <p>Sonication cannot be started as the transducer positioning operation was not successful.</p> | <p>If the problem persists, restart the generator cabinet.</p> |
|  | <p>Potentially Unsafe Sonication, Change Sonication Parameters</p> | <p>The chosen combination of cell size, location and power may result in overheating at the skin surface or in subcutaneous fat, and may be unsafe.</p> | <p>Use a smaller cell size, lower power level, or a cell at a different location. Continue with current parameters only if further clinical analysis indicates it is safe to continue.</p> |




















10. Appendices > 10.10. Error and Warning messages








| | | | |
|--|--|--|---|
|   | Problem with QA Phantom | The QA Test detected a problem with the phantom, or its position. | Change to the QA phantom or correct the position. |
|   | Problem with Transducer Positioner | There is a problem with the transducer position. The positioner has detected limit switch locations that do not match the configured acceptance limits. | Perform Hardware Initialization. If the problem persists, contact Service. Check the log for more detailed information. |
|  | Protected HIFU Protocol Modified | At least one protected HIFU protocol has been modified. To ensure patient safety, protected protocols may not be modified. | The application log identifies the modified protocols. Reset the modified protocols to their default values. |
|   | QA Test Failed | The QA or calibration test has failed. | Try again. If the error reoccurs, contact Service. |
|   | QA Test Not Performed | The QA Test has not been performed. | Perform the QA Test. |
|   | R&D Feature Disables Safety Checks | The built-in safety logic has been overridden by R&D commands. Data consistency cannot be guaranteed and some hardware notifications can be suppressed. | Save the state before proceeding in the R&D mode. |
|  | R&D System ID in Use | An R&D System ID is in use. The correct system ID is set during the installation procedure. Probably the installation is incomplete. | The system configuration needs to be corrected. Contact Service. |
|   | Reference Collection Failed | Could not collect valid temperature reference during pre-sonication phase. | Restart the sonication. |
|   | Risk of Excessive Heating | It may be unsafe to perform a sonication with the chosen combination of cell size, location and power. The chosen parameters may result in overheating at the skin surface or in subcutaneous fat. | Use a smaller cell size, lower power level, or a cell at a different location. Continue only if further clinical analysis indicates it is safe to continue. |
|   | Risk of Excessive Tissue Heating | Overriding the required cooling time may be unsafe. Skin or subcutaneous fat may presently be too warm for sonication. | Continue only if further clinical analysis indicates it is safe to continue. |
|   | Risk of Tissue Burn, Sonication Not Allowed | The chosen combination of cell size, location and power was predicted to cause overheating at the skin surface or in subcutaneous fat. Therefore, the sonication was stopped. | Use a smaller cell size, lower power level, or a cell at a different location. |

| | | | |
|--|--|--|--|
|   | Safety Device Abort | The Safety Device stop button has been pressed to abort sonication. | Enable sonication with the Safety Device to resume the treatment. |
|   | Scan Protocol Aborted | The scan protocol was unexpectedly aborted. The abort may have been caused by a failure in the scan protocol or by a manual abort on the MR scanner. | Restart the scan protocol on the MR scanner. |
|   | Scan Protocol Change Timed Out | The MR scanner could not change the current scan protocol. The scan protocol must be manually changed. | Abort the current scan protocol at the MR scanner and start the desired scan protocol (e.g. temperature mapping or fat-monitoring) manually. |
|  | Scanner Connection Failed, Scan Prevented | The MR scanner connection was not available when scanning was attempted. | Restart the scan protocol on the MR scanner. |
|   | Scanner Connection Unavailable | The software cannot access the scanner host component, scanning cannot be controlled or data queried. | If the software does not recover in 30 seconds, restart the Application. |
|   | Scanner Data Unavailable | The MR scanner could not provide any examination data. Scanning is not possible. | Ensure that the ExamCard is prepared and that a remote controlled scan protocol is started on the MR scanner. |
|   | Scanner Host Emulation Active | Data from the real scanner received, but scanner emulator has been configured as our image data source. | Either configure the scanner not to use the Sonalleve Console as the data target, or disable the scanner emulator at the console. |
|   | Scanner Time Settings Differ | MR console and Sonalleve Console time settings differ. | Run the daily QA procedure to re-synchronize the clocks. |
|  | Scanning Prevents Transducer Positioning | The transducer cannot be positioned while a scan is in progress. | Stop the scan before attempting to sonicate. |
|   | Serious Problem with the Direct Skin Cooling Device | The system has detected an error in the operation of the Direct Skin Cooling device. | Close the Sonalleve Application, then restart the Application. If the problem persists, contact Service. |
|  | Service Mode Active | Detected an active service mode. Therapy operations should not be performed while service mode is active. | Contact Service to disable the service mode. |
|  | Slices Cannot Be Positioned | Monitor slices cannot be positioned at the location of the treatment cell. | Restart the scan protocol on the MR scanner. |

| | | | |
|--|--|--|---|
|   | Software Components Unavailable | The software cannot access the therapy controller component. Therapy cannot continue until control is regained. | If the software does not recover in 30 seconds, restart the Application. |
|   | Software Error Prevents Proceeding | An internal software error prevents continuation of the procedure. | Save the state and restart the Application. |
|  | Software Failed During Sonication | Software failed to perform the sonication. Either the software state or its logic produced unexpected results. | Abort the sonication, reselect the treatment cell and energy dose, then retry. |
|  | Software Failure During Scanning | Scanning failed due to a failure in the software state or logic. | Re-select the treatment cell and retry. |
|  | Sonication Failed | The sonication has failed. Sonication can fail for multiple reasons including a user abort. | Retry the sonication. If the reason for the failure is unclear, check the log for more detailed information. |
|   | Sonication Failed (Heating in Near Field) | Heating detected in the near-field warning zone, sonication has been aborted. | Wait for the cooling time to complete, check the cumulative temperature dose and verify that no unintended burns have occurred before continuing the treatment. |
|   | Sonication Feedback Control Failed | The HIFU Controller failed to modify sonication based on feedback. | Restart the generator cabinet. |
|   | Sonication Hardware Disabled | Sonication hardware has been disabled, the hardware needs to be reset before the operation can continue. | Restart the generator cabinet. |
|  | Sonication Not Allowed, Change Sonication Parameters | The chosen combination of cell size, location and power would result in overheating at the skin surface or in subcutaneous fat, and is therefore not allowed. | Use a smaller cell size, lower power level or a cell at a different location. |
|   | Surface Segmentation Instance Cannot Be Displayed | One or more of the retrieved Surface Segmentation instances cannot be displayed because their spatial orientation is unknown or not supported. | Retrieve a planning stack that is geometrically related to the retrieved Surface Segmentation instances. |
|   | Surface Segmentation Instances Have Unknown Positions | One or more of the retrieved Surface Segmentation instances has an unknown position relative to the retrieved planning stacks. They might be displayed in the wrong position. Display them anyway? | Retrieve a planning stack that is geometrically related to the retrieved Surface Segmentation instances. If such a planning stack is not available and you wish to display the Surface Segmentation instances with unknown position anyway, select Yes. |
|   | System Initialization Timed Out | The system was not able to initialize the hardware in a specified time. This indicates a problem with the hardware. | Restart the Sonalleve Application. If the problem persists, try restarting the generator cabinet and wait for the system to initialize. If the problem is still not resolved, contact Service. |

| | | | |
|---|---|---|---|
|  | System Integrity Compromised | Application files have been tampered with. Typically this indicates an infection caused by malware or virus programs. | Stop using the software, shut down the Sonalleve Console and contact Service. |
|  | System Service Not Available | A system service has failed, which is preventing the hardware from starting. | Save the state and close the Sonalleve Application. Restart the Sonalleve Console. If the problem persists, contact Service. |
|  | Tabletop Unlocked, Sonication Is Prevented | Sonication cannot be enabled. The tabletop locking switch indicates that the tabletop is unlocked. | Push the tabletop to its locked position. Enable sonication with the Safety Device. |
|  | Tabletop Water Temperature Too High | The tabletop water temperature has reached a critical level. The sonication is stopped. | Wait for the water to cool down and try again with lower power levels or shorter sonications. |
|  | Test Error | This error is for software test use only. You should never see this in normal use. | Restart the Application. If the problem persists, contact Service. |
|  | Test Error 2 | This error is for software test use only. You should never see this in normal use. | Restart the Application. If the problem persists, contact Service. |
|  | Test Error 3 | This error is for software test use only. You should never see this in normal use. | Restart the Application. If the problem persists, contact Service. |
|  | Therapeutic Power Level Not Allowed | A therapeutic power level is not permitted until a test sonication is performed. | First perform a test sonication on the cluster. |
|  | Too Large Thermal Dose in Organ Avoidance Region | The planned treatment position would cause too large thermal dose in the marked organ avoidance region. | Reposition the treatment cell to avoid the organ avoidance region. |
|  | Too Many Transducer Channels Inactive | The hardware has deactivated several transducer channels. The sonication is stopped as the shape of the treatment cell may be affected. | Check the acoustic contact or reduce sonication power and retry the operation. Restarting the generator cabinet may help. If the problem persists, contact Service. |
|  | Too Many Transducer Channels Inactive on One Board | The hardware has deactivated several transducer channels. The sonication is stopped as the shape of the treatment cell may be affected. | Check the acoustic contact or reduce sonication power and retry the operation. Restarting the generator cabinet may help. If the problem persists, contact Service. |
|  | Transducer Humidity High | Transducer humidity level is approaching critical limits. | If the problem persists, schedule Service. |

| | | | |
|--|---|--|--|
|   | Transducer Humidity Too High | Water has ingressed into the transducer and the sonication is stopped. The transducer must be replaced. | If the problem persists, contact Service. |
|   | Transducer Movement Failure | The transducer positioner has failed to move the transducer to the requested position. | Perform Hardware Initialization. If the problem persists, contact Service. |
|  | Transducer Positioner Connection Failure | The connection to the transducer positioner has been lost. | Wait 30 seconds for the connection to re-establish. If the problem persists, restart the generator cabinet. |
|  | Transducer Positioner Simulation Mode in Use | Transducer movements are being simulated by the software. Real movements do not take place. | Use the configuration editor to turn the simulation mode off. |
|   | Transducer Positioner Uncalibrated | Transducer positioner has not received the required calibration data. This might indicate a communication failure between the tabletop and generator cabinet, or incorrect system configuration. | Close the Sonalleve Application, check the system configuration and the cable connections to the tabletop, then restart the generator cabinet and the Application. If the problem persists, contact Service. |
|  | Transducer Positioning Failed | The transducer could not be positioned. Either the configuration is invalid or the hardware is unable to move to the given position. | Wait for 30 seconds, then retry. If the problem persists, restart the generator cabinet. |
|  | Transducer Temperature Elevated | A rise in the transducer temperature has been detected. It is not a cause of concern as long as the temperature does not continue rising. | Check that the power level and sonication duration are reasonable. |
|   | Transducer Temperature Too High | The transducer temperature has reached a critical level and sonication is stopped. | Wait for the transducer to cool down and try again with lower power levels or shorter sonications. |
|   | Transformation Matrix Has Not Been Received | The HIFU Controller has not received the transducer transformation matrix. | Restart the Hardware Initialization. |
|  | Treatment Data Storage Unavailable | The software cannot access the internal data storage area. Data can be lost or overwritten. | Wait 30 seconds and retry the previous operation. If the problem persists, restart the software (data may be lost). |
|   | Unable to Write Data | Writing of task data to the hard drive has failed. The task data is necessary for the software to continue operation. | Contact Service. |
|   | Uncertainty in Temperature Measurement | Temperature in the treatment cell area could not be measured. Image artifacts, patient or organ movement or low signal could have caused this. | Try to identify the source of possible artifacts. Attempt to reduce the artifacts with a REST slab, for example, or select a treatment cell location with a brighter signal. |

| | | | |
|---|---|--|--|
|  | Uncertainty in Transducer Position | The position of the transducer varies too much between two consecutive homings. | Perform Hardware Initialization and verify the position of the transducer. If the problem persists, contact Service. Check the system log for more detailed information. |
|  | Unknown MR Scanner Model | The retrieved planning image set was not identified as being from a supported scanner model. | Scan and retrieve new therapy planning images. If the warning is not cleared after this, contact Service. |
|  | Unreachable by Hardware | The selected cell lies outside the reach of the transducer hardware. | Use another cell in a valid position. |
|  | Unreachable by Treatment Cell | The current treatment cell type cannot be used to reach the designated target area. | Use another cell in a valid position. |
|  | Unreachable by Treatment Cell Type | At least one treatment cell is in an invalid position. | Remove the invalid treatment cell, select a smaller treatment cell or move the cluster position closer to the tabletop, so that less electronic deflection is required in depth direction. |
|  | Unsafe Configuration in Use | One or more configuration attributes are in a non-default state. Some of these modified attributes have been marked as unsafe. | Revert the unsafe configuration attributes to their default values. |
|  | Wrongly Positioned Treatment Cells | At least one treatment cell is out of the available target area or out of the area covered by the monitor slices. | Move or delete the treatment cells that cannot be heated or monitored. |

10.11. Legal notices

Sonalleve MR-HIFU - *Instructions for Use*

Published by Profound Medical

Profound Medical reserves the right to make changes to both this *Instructions for Use* and to the product it describes. Product specifications are subject to change without notice. Nothing contained within this *Instructions for Use* is intended as any offer, warranty, promise or contractual condition, and must not be taken as such.

© Profound Medical 2019

All rights are reserved. Reproduction in whole or in part in any form or by any means, electrical, mechanical or otherwise is prohibited without the written consent of the copyright holder.

Unauthorized copying of this publication may not only infringe copyright and reduce the ability of Profound Medical to provide accurate and up-to-date information to users.

Non Profound Medical product names may be trademarks of their respective owners.

Published in Canada

10.11.1. Profound REACH statements

REACH requires Profound Medical to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the article weight. The QA Phantom 4510 000 82232 for Sonalleve MR-HIFU systems may contain acrylamide (CAS nr.: 79-06-1) more than 0.1% but less than 0.25% of the phantom weight.

REACH requires Profound Medical to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the product weight. Components within electric and electronic equipment may contain phthalates above the threshold (e.g. bis(2-ethyl(hexyl)phthalate), CAS nr.: 117-81-7).

SONALLEVE™

PROFOUND



Profound Medical Inc.

2400 Skymark Ave., Unit #6
Mississauga, Ontario, L4W 5K5
Canada
T: +1 647.476.1350
F: +1 647.847.3739
profoundmedical.com

© 2019, Mississauga, Canada.
All rights reserved. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from Profound Medical Inc.

107378A