SigmaVision® Advanced - Safety and performance information (in accordance with Regulation (EU) 2017/745, Annex I, 23.1)

Product and manufacturer

Product:
SigmaVision® Advanced

Manufacturer:
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Germany

Intended use and function

The SigmaVision® Advanced software system visualises temperature differences within the body on the basis of MRI slice images. The temperature differences are displayed to the user at regular intervals, usually 10-15 minutes, during the hybrid hyperthermia treatment and are used for temperature monitoring. The temperature differences in the relevant volume around the treatment region are displayed.

Clinical performance and benefits

SigmaVision® Advanced enables non-invasive and pain-free monitoring of temperature differences in the regions to be treated within the patient during hyperthermia treatment. The software supports hyperthermia treatment by displaying temperature differences and providing information on temperature trends during treatment. It allows therapy parameters to be adjusted in response to the displayed temperature differences. In addition, SigmaVision® Advanced offers a plausibility check of the input data as well as documentation of all treatment-relevant data and settings.

Safety and known limitations

The following risks were identified during the risk analysis:

- Selection of an incorrect body region (FOV in MRI), which may result in the processing of irrelevant image data
- Patient movement during treatment, which may cause motion artifacts
- MRI artifacts caused by breathing and intestinal peristalsis, which may lead to inaccurate temperature representations
- Method-related limitations, as temperature differences can only be reliably visualized in water-containing tissue types (not adipose tissue)
- Method-related artifacts due to perfusion effects, which can only be recognized through medical and anatomical expertise

Risk mitigation measures

The risk of incorrect software operation cannot be completely ruled out but is minimized as much as possible through appropriate design and protective measures.

The following measures, in particular, are implemented to minimize risk:

- Verification of DICOM input data against a stored database of MRI protocol parameters, as far as technically feasible
- Deliberate reduction of recurring software prompts and dialog confirmations to prevent routine incorrect confirmations by the user
- Provision of warnings and safety-related information in the accompanying documentation
- User training, as medical professionals generally lack routine experience in handling MR thermometry

Significant residual risks

Despite the implementation of risk mitigation measures, the following significant residual risks remain:

- MRI artifacts caused by movement, breathing, and intestinal peristalsis can lead to incorrect temperature readings
- Changes in perfusion can lead to erroneous temperature information and thus to incorrect clinical conclusions
- Misinterpretations by the user in connection with artifact-laden or difficult-to-interpret data cannot be ruled out

These residual risks have been assessed within the framework of risk management and classified as acceptable.

Warnings and conditions of use

The following warnings are part of the accompanying documentation and must be strictly observed:

- SigmaVision® Advanced must be operated exclusively by trained and professionally experienced users. If the software is operated by unauthorized personnel, incorrect temperature calculations may lead to erroneous settings on the hyperthermia device BSD 2000-3D/MR. Hence the heating characteristics can change significantly as a result of this and lead to the patient or user being injured.
- Before using MR thermometry, the SigmaVision® Advanced programs operator must have read and understood the contents of these operating instructions.
- Please observe the operating instructions for the hybrid hyperthermia system BSD 2000-3D/MR and the MRI device. Inadequate system knowledge and a failure to observe the warnings, contraindications, cautions and user information may result in serious injuries to the patient or user, or lead to malfunctions or damage to the device.

- Treat the patient according to the ESHO Guidelines: Lagendijk, J. J., G. C. Van Rhoon, S. N. Hornsleth, P. Wust, A. C. De Leeuw, C. J. Schneider, J. D. Van Dijk, et al. 1998. 'ESHO Quality Assurance Guidelines for Regional Hyperthermia'. International Journal of Hyperthermia: The Official Journal of the European Society for Hyperthermic Oncology, North American Hyperthermia Group 14 (2):125–33.
- The use of invasive temperature probes can be dispensed with if all instructions and warnings are observed. The patient's feedback during treatment must continue to be carefully considered by the physician. SigmaVision® Advanced does not replace continuous patient monitoring by trained medical staff.
- The use of non-invasive temperature probes can be reduced with artifact-free temperature imaging. The use of temperature probes according to ESHO Guidelines is recommended. It should be noted that clinical studies partly stipulate the use of temperature probes.
- These operating instructions describe the basic set-up of the MR thermometry software SigmaVision® Advanced. Changes to the computer and/or software may cause injury to the patient and the user, and are the customer's responsibility.
- Please ensure correct positioning of the patient in the applicator! If the patient is incorrectly positioned in the applicator then an inappropriate area may be heated, which may lead to injuries!
- Dr. Sennewald Medizintechnik GmbH as the developer of SigmaVision® Advanced cannot monitor the application of the software or be held liable for any consequences (injuries or damage) that arise as a result of incorrect usage.
- Dr. Sennewald Medizintechnik GmbH accepts no liability for any services provided by individuals other than the employees of Dr. Sennewald Medizintechnik GmbH.
- The MR thermometry program SigmaVision® Advanced can only produce actual temperature maps with patient cross-section images from the MRI system. Networking the workstation with the MRI device is therefore essential. The operating company must guarantee that the network is faultless (DIN EN IEC 80001-1).
- Operators are not permitted to open the computer to perform service work or any other modifications. Furthermore, the customer is not permitted to install any other programs on the PC.
- The MRI protocols installed for usage of SigmaVision® Advanced must not be modified as the DICOM data will not be accepted by the software.
- The SigmaVision® Advanced program must not be used for diagnostic purposes!
- Please maintain the safety distances specified in the instructions for the BSD 2000-3D/MR hyperthermia systems, as well as the MRI system during system operations.
- SigmaVision® Advanced is to be used exclusively for the specified purpose!
- MR thermometry can only be used for hyperthermia, not for thermoablation.
- Application of SigmaVision® Advanced is only permissible in the specified areas. The tissue of interest must contain water as thermometry in regions predominantly consisting of fat is not possible.
- When using SigmaVision® Advanced in the abdominal area, artifacts may occur in the MRI images due to air and peristalsis in the intestinal area. These can be

displayed as a strong red area in the temperature maps. Such artefacts do not represent real hotspots, even though they appear as deep red areas on the temperature maps.

- The process employed is based on a change in the phase-resonance frequency, which arises due to temperature and perfusion changes. It is necessary to anticipate perfusion changes during the hyperthermia treatment within the tumor tissue compared to the normal tissue.
- Always look at every layer in the treatment area. This will prevent you from overlooking hotspots etc.
- Please ensure correct windowing during contouring and thermometry. If the contrast and brightness are set incorrectly, relevant data may be displayed incorrectly, and the target may be less visible. The operator may potentially make incorrect decisions.
- When evaluating the thermometry images, pay attention to the exact color coding, as the temperature development could be misinterpreted if the color scale is set incorrectly. Please note the temperature range on the left edge of the axial view in the thermometry section.
- If a data set contains an insufficient number of points in the silicone markers to calculate a correct drift, incorrect data is displayed. This data cannot be used for evaluation. The system issues a corresponding warning and displays the incorrect time step in red in the timeline.
- Always maintain correct documentation as it may affect subsequent treatment.
- During treatment the patient must not move, in order to avoid image artefacts and prevent the target from shifting.

Contraindications and side effects

There are no known contraindications for SigmaVision® Advanced. There are no known side effects or complications associated with SigmaVision® Advanced.

Certification

SigmaVision® Advanced meets the requirements of Regulation (EU) 2017/745. The conformity assessment was conducted by the notified body mdc medical device certification GmbH. The product is certified in accordance with applicable regulatory requirements.

Up-to-date information

This information is reviewed regularly and updated as needed.