

Urgent Field Safety Notice

Visualase™ Thermal Therapy System

Model 9735542

June 2018

Medtronic reference: FA829

Dear Healthcare Professional,

The purpose of this letter is to provide information related to the potential risk of adverse events resulting from inaccuracy of MR thermometry during MRI-guided laser ablation procedures using the Medtronic Visualase™ Thermal Therapy System. On April 24, 2018, FDA released a public notification, ***Risk of Tissue Overheating Due to Inaccurate Magnetic Resonance Thermometry: Letter to Health Care Providers***¹, describing the potential risk of inaccuracy in MR thermometry leading to underestimation of thermal damage. The information contained in Attachment A (Visualase™ Thermal Therapy System Additional Information) included with this letter is intended to supplement the Visualase™ Thermal Therapy System Manual. This communication applies to all Visualase™ Thermal Therapy Systems.

Issue Description:

MR thermometry is used to monitor the changes in temperature at the treatment site using a Magnetic Resonance Imaging (MRI) scanner and this information is displayed on the Visualase™ Thermal Therapy System to aid the physician in assessing and controlling thermal damage. MR parameters such as voxel size (measurement of the image resolution or detail) and MR image acquisition time (e.g. up to 9 seconds) may contribute to inaccurate MR thermometry readings and potential errors in the ablation assessment. Underestimation of thermal damage may result in unaccounted spread of thermal energy to the surrounding tissue. Potential adverse outcomes may include neurological deficits (e.g. focal motor deficits, aphasia, cognitive changes), increased intracerebral edema or pressure, intracranial bleeding, and/or visual changes (e.g. visual field deficits, blurry vision).

Medtronic takes the potential risk seriously and is working to ensure all Medtronic customers are fully aware of all sources of risk and associated mitigations. Medtronic has reviewed all neurosurgical complaints provided to us by users at this time and determined that four reports were potentially related to underestimation of thermal damage.

As noted in Attachment A, Medtronic provides several mitigating strategies for the user. In addition, Medtronic would like to emphasize the importance of these mitigation strategies:

- Place the Low Temperature Targets on nearby critical structures and set the temperature limit to 43°C or less to mitigate the risk of unintended damage on these critical structures. The current software default for the low temperature limit is 50°C, and this threshold can be manually adjusted prior to ablation.
- The saline pump should remain on throughout thermal monitoring, including when the laser is on and after it is shut off, until the tissue has cooled back to baseline temperature.

Please Review and Retain Attachment A: Visualase™ Thermal Therapy System Additional Information. This attachment describes sources of potential inaccuracies of MR thermometry and instructions to mitigate risk.

The Competent Authority of your country has been notified of this action.

¹ Link: <https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm605417.htm>



We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative at <XXXXX>.

Sincerely,

Local /BU Manager

Appendix A: Visualase™ Thermal Therapy System Additional Information

¹ Link: <https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm605417.htm>

Attachment A

The following additional information is to aid the user in safe use of the Visualase product for neurosurgical procedures.

Fundamentals of MR Thermometry

MR thermometry is the measurement of relative temperature changes using MRI data and is based on the data received from the scanner. Accuracy of MR thermometry is fundamental to Visualase™ Thermal Therapy System and is dependent upon the MRI protocol parameters and on the quality of the images received from the MRI scanner. Both hospital MRI technicians and Visualase-trained technicians are trained in how to generate quality imaging and mitigate potential imaging problems. User should consider the following factors that may influence accuracy during clinical use:

Regarding MRI parameters that may contribute to inaccuracies of MR thermometry:

1. The Visualase system allows for flexibility when choosing the number of imaging planes. One, two, or three monitoring planes may be utilized, but with progressively increasing intervals for updated temperature mapping, that is, ranging from approximately 3 seconds to 9 seconds, depending scanner type and number of monitoring planes. A shorter time between acquisitions reduces latency of temperature measurements.
2. Larger voxel size may cause inaccuracy of MR thermometry. Adjust the Field of View to include the anatomy of interest to acquire the smallest voxel size while maintaining acceptable signal to noise ratio.

Note: The potential for inaccuracy in MR thermometry with additional imaging planes should be weighed against the benefit that the additional monitoring provides.

Regarding image quality and operational aspects of the device:

1. MR Imaging is susceptible to motion related artifacts. Extra care should be taken to reduce patient or tissue movement.
2. Choice of RF coils will influence signal to noise ratio. Low signal to noise ratio may reduce the accuracy of MR thermometry. Low signal to noise ratio may be recognized by unstable pixels in patient anatomy and outside of areas of tissue heating. If a high volume of unstable pixels within the anatomy are identified, stop laser ablation and address factors impacting signal to noise ratio.
3. MR field drift may decrease accuracy of thermometry. To maintain thermometry accuracy, the phase reference should be periodically reset in between laser exposures and after tissue cooling. If field drift is suspected beyond 2°C in 10 minutes, contact the scanner manufacturer to determine if scanner maintenance is required.
4. Always allow the ablated tissue to return to baseline temperature before resetting phase reference. Failure to do so may reduce the accuracy of MR thermometry.
5. Medtronic recommends performing a test pulse at a low power for short duration (for example, 15% of max recommended power for 30 seconds) until a temperature rise is visualized to confirm the position of the VCLAS (Visualase Cooled Laser Applicator System). If a temperature rise is not seen, turn off the laser and determine root cause before proceeding.
6. If the MRI phase data becomes unstable, the accuracy of the treatment estimate may be affected. The performance of the predicted thermal damage (i.e. the Treatment Estimate feature) is directly related to the performance of MR Thermometry. If you suspect unstable phase data in the treatment zone or near critical structures, use caution. Under these conditions, tissue may be damaged and not reflected by the system feature. Turning off the laser as soon as the thermometry becomes unstable minimizes the risk of inaccuracy in the treatment estimate.
7. The Treatment Estimate feature is an estimate of tissue damage. Always confirm the region of damage with another method, such as through an MRI scan that visualizes the thermal lesion.

Regarding Visualase features that can be used to mitigate inaccuracies:

Temperature Monitoring Markers

1. Per the Instructions for Use manual, there are six temperature monitoring markers that turn the laser off if the set temperature is reached.
2. These markers can only be positioned on the chosen imaging planes. When selecting thermal imaging planes, ensure each intended laser catheter and any nearby critical structure are in plane and visible during thermal imaging.
3. The three Low Temperature Targets have a default temperature limit of 50°C and are intended to protect nearby critical structures that may be at risk for thermal damage. For particularly sensitive structures, the temperature threshold may be decreased to 43°C or less.

¹ Link: <https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm605417.htm>

4. The three high temperature target points have a default temperature limit of 90°C to protect the VCLAS (Visualase Cooled Laser Applicator System) and avoid vaporization of nearby fluid, which can result in inaccurate MRI thermometry. These target points may be placed in the Visualase software near (within a few voxels), but not on, the location of the VCLAS itself.
5. Both High and Low Temperature Targets' threshold setting may be changed. For example, High Temperature Targets may be used as additional low markers, if desired.
6. Temperature Target points can be moved at any time during a Visualase treatment session. If multiple ablations are performed within one treatment session, ensure that Temperature Target points are appropriately placed for subsequent ablations.
7. Avoid placement of target points at regions of high field inhomogeneity, such as near air- tissue boundaries, which can result in inaccurate MRI thermometry.
8. If the MRI phase data becomes unstable, the effectiveness of the Temperature Targets may be reduced. Care should be taken not to place a marker at or very near areas of MR field inhomogeneity (e.g. tissue boundaries, areas of fluid flow, etc.), as this may lead to inaccurate temperature readings of that marker.

Laser Power Control

1. Use a low laser power to heat the target tissue slowly. Rapid rates of temperature change may lead to inaccurate temperature readings.
2. Be aware that damage to tissue can continue to occur during the cooling phase of the tissue. Continually monitor thermometry until the treated tissue has cooled back to baseline temperature.
3. The saline pump, which provides saline flow to the laser fiber through the cooling catheter, should remain on throughout thermal monitoring, inclusive of when the laser is in operation and after it is shut off, until the treated tissue has cooled back to baseline temperature.
4. After each laser exposure, allow the treated tissue to cool back to the baseline temperature before resetting the phase reference. Failure to do so may cause inaccuracy in MR thermometry.

¹ Link: <https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm605417.htm>