VIEWRAY | VISIBLY BETTER

Urgent Device Correction

October 20, 2020

Elevated Temperature of Receive Coil Components When Using Select Ciné Treatment Imaging Sequences

Dear MRIdian User,

ViewRay Inc. has identified two situations where components of the receive coil can reach elevated temperatures which has the potential to cause a burn injury to the patient or user. This behavior of the receive coil components was identified during internal testing at ViewRay. This notification describes the potential risk of these observations and guidance for use. To date, there have been no customer reports related to this issue and no customer reports that a patient or user was affected by this issue.

The elevated temperatures of the receive coil components were observed in two scenarios:

1. Using the optional, user-selectable, 3 Plane cine' treatment imaging sequence. This feature is only available in Treatment Planning and Delivery System (TPDS) software version 5.2.5 or earlier.

2. Using the optional, user-selectable, 8 fps cine' treatment imaging sequence. This feature is only available in TPDS software version 5.3 or later with 8 fps enabled.

In clinical practice, the distance between the receive coil and the inner surface of the bore wall can vary based on the patient's body habitus, patient table position, and the immobilization device used. ViewRay's internal testing specifically tested extreme conditions where the receive coils are positioned in close proximity to the inner bore wall.

The extreme testing conditions showed that the use of 3 Plane or 8 fps cine' treatment imaging sequences while the receive coil is positioned close to the bore wall causes some of the gray plastic electronic boxes ("feedboard boxes" Figure 1 & 2) attached to the receive coil, to reach an elevated temperature. If the feedboard boxes are in contact with the patient or user, there is the potential risk of injury.

During radiation delivery, the MRIdian system continually acquires images. During this continuous imaging, the receive coils are exposed to RF energy. The amount of RF energy exposure is directly related to the cine' treatment imaging sequences being used. The higher RF energy associated with the 3 Plane and 8 fps sequences and the proximity of the coil to the bore wall contribute to the elevated temperature of the feedboard boxes.

Safety is a core tenet of ViewRay's quality policy. ViewRay's highest priority is to resolve these issues immediately. We will provide an update to customers when new information is available. Until that time, customers should use 4 fps imaging sequences instead of 8 fps imaging sequences and follow the guidance when using 3 plane imaging.

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Figure 1: Torso coil with feedboard boxes oriented toward feet

Figure 2: Torso coil with feedboard boxes oriented toward head

Required Actions:

For Customer using TPDS software ver. 5.2.5 or earlier with optional 3 Plane imaging:

Do: Maintain a distance of at least 5 cm (~2") between the receive coil and the inner surface of the bore wall when using 3 Plane ciné treatment imaging (Figure 3 & 4).

Do Not: Select 3 Plane ciné treatment imaging if a distance of at least 5 cm (~2") cannot be maintained between the receive coil and the inner surface of the bore wall during treatment.

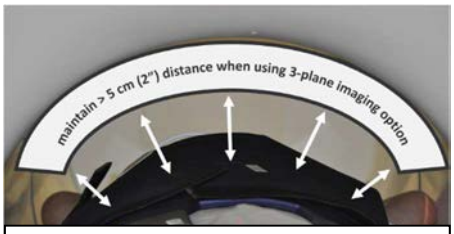

Figure 3: Distance between receive coil and inner surface of bore wall is more than 5 cm

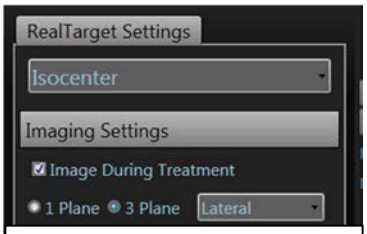

Figure 4: 3 Plane imaging option screen

For Customer Using TPDS software ver. 5.3 or later with optional 8 fps enabled:

Do Not: Use 8 fps ciné treatment imaging until further guidance is provided by ViewRay.

Do: Use 4 fps ciné treatment imaging when treating a patient.

If you have any questions related to this letter, please contact ViewRay Customer Support at support@viewray.com or call +1 855-286-8875.

Sincerely,

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ViewRay Inc.

UDC 2020-001

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