03.04.2024

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

Title: Certain colors in a color-coded image could be displayed in a wrong color in the View area

Internal Reference: MST0081091

Product name and version(s) and UDI-DI:

- DeepUnity Diagnost (all versions) in Germany, Austria, Switzerland, France, and Brazil
  - Manufacturer: DH Healthcare GmbH
  - UDI-DI: 4260693990040

Information:

When viewing ultrasound images from Mindray ultrasound modality in DeepUnity Diagnost, certain colors in a color-coded image could be displayed in a wrong color in the View area. This also affects the image export. The problem of wrong color representation affects only a small range of dark colors translated into bright red or blue. If not noticed, pixels with wrong color coding could potentially have impact on the diagnosis. In case of images in nuclear medicine (PET/SPECT/scintigraphy) the effect of even small spots displayed in a bright color instead of dark grey could potentially lead to a wrong diagnosis.

The issue has never been observed with any other modality than the reported Mindray ultrasound. However, it cannot be excluded that it could occur with other modalities.

Technical cause:
The technical cause is negative values in the calculated red, green, or blue color channel yielded for certain pixels after color transformation from YCbCr color model to RGB. The implemented formula is correct and will deliver the right results based on correct input data. However, a fallback for incorrect input values, most likely related to numerical rounding errors of the modality, is missing.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter;
- Release a correction with DeepUnity Diagnost v.2.0.2.2 and higher versions (release planned for Q2 of 2024);

Recommended actions to be taken by the customers:

- After the installation of the fix version, verify that you are using the correct version (v.2.0.2.2 or higher).

Please distribute this information to all those who need to be aware of it.

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Sincerely,

Urgent Field Safety Notice

Feedback Form

We kindly ask you to return this feedback form as soon as possible, but at the latest **within 30 days** after receipt of this letter, to the following e-mail address:

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	**MST0081091**: Certain colors in a color-coded image could be displayed in a wrong color in the View area
Product reference:	
Name (contact person)	
Position	
Phone number	
Date	
Signature	

☐ I confirm that I have received and understood the safety information.

☐ The safety information does not apply to my facility.

☐ The device was transferred to another organization.

Name and address of the other organization: _____

☐ Please update our contact information as follows:

Customer / Facility:

Address: