

Field Safety Notice

Ashvins Variant HEYEX 2 / HEYEX PACS

Dear customers,

as the manufacturer of HEYEX 2 / HEYEX PACS, we would like to issue the following field safety notice concerning the freeform measurement function in the Multi Modality Viewer.

General Information / Affected Products:

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|-------------------------------|--|
| Manufacturer SRN: | DE-MF-000007645 |
| FSN type: | New |
| BfArM number: | 36511/25 |
| Internal incident number | PMI99172 |
| Device type: | Software (Medical Image Management, Picture Archiving and Communication System) |
| Commercial name: | Ashvins variant HEYEX 2 / HEYEX PACS |
| Unique Device Identification: | 4260648620046 |
| Product version: | From version 2.6.0 (Build 2088) to 2.6.8 (Build 2220) A correction will be provided with the hotfix version 2.6.9 |

Problem Description:

When using the freeform measurement function in the Multi Modality Viewer, the measured value may be smaller than the actual area. All other measurement functions in the Multi Modality Viewer are not affected and can be used.

Action:

Please do not use the freeform measurement function until your software has been updated with the above-mentioned hotfix or a higher version.

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Signature

Person responsible according to MDR Article 15

Martin Schinkmann