

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:

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.

Signature

Person responsible according to MDR Article 15

Martin Schinkmann

Field Safety Notice

Ashvins

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as the manufacturer of Ashvins, 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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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
Unique Device Identification:	4260648620008
Product version:	From Version Ashvins 2020 (Build 1891) to Ashvins 2023 (Build 2229) A correction will be provided with the hotfix version Ashvins 2023 (Build 2241)

Problem Description:

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Action:

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Martin Schinkmann