Invivo

URGENT Medical Device Correction - Field Safety Notice
DynaCAD Breast and Prostate Software
Versions 3.4 and 3.5

Incorrect rendering of PK color maps and on-the-fly ADC color maps and values

Dear Customer,

A problem has been detected in the Invivo DynaCAD Breast and Prostate Software versions 3.4 and 3.5, which, if it were to re-occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur.
- The actions that should be taken by the customer/user in order to prevent risks for patients or users.
- The actions planned by Philips/Invivo to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

The identified problem (defect) causes the pharmacokinetic (PK) color maps to display incorrectly when viewed from remote DynaCAD client computers and could result in visually underestimating calculated K^{trans}, K_{ep}, and iAUGC values. The defect also impacts DynaCAD's on-the-fly calculation of Apparent Diffusion Coefficient (ADC) maps. If the ADC values are computed on-the-fly by DynaCAD, the ADC values and colors will also display incorrectly if viewed on a remote DynaCAD client. Please note that the defect DOES NOT impact the ADC maps computed externally (e.g., ADC maps computed from the MRI system). Additionally, the defect only effects users reviewing images on a remotely connected client computer. The defect is NOT present when viewing images directly from a DynaCAD server system (a configuration where the client application is running directly on the DynaCAD server system). The defect also does NOT affect display of any other MRI parameters or image sequences (e.g., QuickTP color maps, dynamic subtractions, T2 images, diffusion images, maximum intensity projections (MIPs), etc.).

As referenced in the DynaCAD Instructions for Use (IFU), when interpreted by a physician, DynaCAD provides information that may be useful in screening, diagnosis, intervention planning and monitoring. Patient management and all other clinical decisions are the responsibility of the interpreting physician and should not be made based solely on the results of DynaCAD software analysis. When reviewing a case, all image sequences should be reviewed and taken into account for interpretation. Images should be interpreted only by trained physicians.

If you need any further information or support concerning this issue, please contact Invivo Customer Support: 1-877-468-4861 Opt. 3

Philips/Invivo apologizes for any inconveniences caused by this problem.

Sincerely,

Ken Revennaugh
Director, Quality and Regulatory

URGENT Medical Device Correction - Field Safety Notice
DynaCAD Breast and Prostate Software
Versions 3.4 and 3.5

Incorrect rendering of PK color maps and on-the-fly ADC color maps and values

AFFECTED PRODUCTS	DynaCAD 3.4 and 3.5 9896-032-08914, 9896-032-09663, 9896-032-09673, 9896-032-08944, 9896-032-08954, 9896-032-08964, 9896-032-08984, 9896-032-09683, 9896-032-08974, 9896-032-10022, 9896-032-09004, 9896-032-10032, 9896-032-10042, 9896-032-09024, 9896-032-09044, 9896-032-09254, 9896-032-09373, 9896-032-09383, 9896-032-09393, 4553-000-59412, 4553-000-85541, 4553-000-85501, 4553-000-85551, 4553-000-85561, 4553-000-85571, 9896-032-08975, 9896-032-08985 ,4553-000-85581, 4553-00085531, 9896-032-09045, 9896-032-09255, 4553-000-85511, 4553-000-85521, 9896-032-09684, 9896-032-10023, 4553-000-85601, and 4553-000-85591
PROBLEM DESCRIPTION	A problem was uncovered which causes images processed with Pharmacokinetic (PK) results and/or DynaCAD calculated Apparent Diffusion Coefficient (ADC) maps have incorrect color overlay results as well as in the case of the ADC images, incorrect values reported. The defect exists on any DynaCAD client system running software versions 3.4 or 3.5.
HAZARD INVOLVED	The defect may lead the user, during normal use of the device, to underestimate K^{trans}, K_{ep}, and iAUGC values and calculate unreliable ADC values, which has the potential to adversely impact diagnostic interpretation of the MRI exam.
HOW TO IDENTIFY AFFECTED PRODUCTS	The about screen in the DynaCAD Software (Breast/Prostate) will display the software version.
ACTION TO BE TAKEN BY CUSTOMER / USER	It is strongly recommended that users discontinue use of the K^{trans}, K_{ep}, and iAUGC colormaps when assessing studies from a remotely connected DynaCAD client computer. It is further advised that users refrain from using the colormaps and values derived from ADC maps calculated by DynaCAD. ADC maps originating natively from the MRI system should be used as an alternative as these values are unaffected.
ACTIONS PLANNED BY PHILIPS/INVIVO	Invivo/Philips will provide a v4.0 software update for the affected software versions (v3.4, v3.5) to correct the defect at no charge to the user. Invivo/Philips will work with sites affected by the defect to schedule and deploy server updates remotely.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact Invivo Support at 1-877-Invivo1 (877-468-4861) Option 3.