February 12, 2015

Urgent Field Safety Notice
DynaCAD Breast Interventional Software Versions 3.1 and 3.2

Software error in biopsy planning with Philips dS Breast Coil 16 Channel

Dear Customer,

A problem has been detected in the Invivo DynaCAD Breast Interventional Software Versions 3.1 and 3.2 (manufactured by iCAD), that, if it were to re-occur, could affect the performance of the equipment. This Customer Information is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

If you need any further information or support concerning this issue, please contact your local Invivo representative:

1-877-Invivo1 (1-877-468-4861, option #3)

Invivo apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Director, Quality and Regulatory

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AFFECTED PRODUCTS	Any DynaCAD Breast Interventional Software (DynaLOC) Versions 3.1 and 3.2.
PROBLEM DESCRIPTION	A software error has been identified in the DynaCAD Breast Interventional Planning Software, versions 3.1 and 3.2. This software error has occurred in the planning of a biopsy procedure only on the Philips dS Breast Coil 16 channel (coil manufactured by Invivo Corporation). This error has not been identified with other coils. The biopsy needle depth coordinate calculations are not computed correctly when used in conjunction with only the top row of the Invivo box grid plate 4535-303-31491. As a result, a needle depth coordinate will be 9mm short of the target when using the top row of the grid during procedures on the Philips dS 16 channel Breast Coil. No errors have been identified when using the other rows of the biopsy grid. Based on our impact to health assessment, the identified software error is not expected to result in patient injury. While the needle insertion position is correct, the needle insertion depth is shorter than it should be. The DynaLOC Interventional Application Guide instructs the user to perform a confirmatory MR scan to check the needle insertion depth with respect to the target. Upon seeing the discrepancy in needle depth, the user would correct the needle insertion depth by pushing further into the tissue. If the device is used according to its labeling this defect would be readily apparent. However, if a confirmatory scan is not performed the results of the biopsy may be negative, since the needle has not reached its lesion target, resulting in a false negative biopsy.
HOW TO IDENTIFY AFFECTED PRODUCTS	The login screen of the DynaCAD Breast Interventional Software shows the software version.
ADVICE ON ACTIONS BY CUSTOMER / USER	Invivo and iCAD (device manufacturer) recommend that this software not be used with Philips ds Breast 16 channel lateral grid plate part number 4535-303-31491. Breast Biopsy procedures with the Philips dS Breast 16 channel lateral grid plate can be manually planned as shown in chapter 3 of the dS Breast coil user manual part number 4535-303-36051. Please note that only the Philips dS 16 channel breast coil is affected by this software error; other coils can still be used with the software. The Field Safety Notice should be distributed within the organization to maintain awareness. If the DynaCAD software has been transferred on to another organization please provide Invivo the name of the organization so a copy of the Field Safety Notice can be passed on to the organization to which the device has been transferred.
ACTIONS PLANNED BY Invivo	Invivo and iCAD are developing DynaCAD Breast Interventional 3.3 that corrects this error and will be available for installation beginning in March 2015.

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FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Invivo representative: 1-877-Invivo1 (1-877-468-4861, option #3)
EUROPEAN REPRESENTATIVE	MDSS Gmbh TEL.: +49-511-62628630, vigilance@mdss.com
NATIONAL COMPETENT AUTHORITIES	All relevant National Competent Authorities have been notified.