January 21, 2015

URGENT: Medical Device Correction (Field Safety Notice)
Aquarius iNtuition Client Viewer, Findings Workflow Module, RECIST 1.1 Criteria

Dear Customer,

The purpose of this communication is to provide information and to request a software upgrade to your iNtuition software. The software versions affected are: 4.4.11.82.6784, 4.4.11.116.7134, 4.4.11.144.7589, and have been in distribution since March 26, 2014.

TeraRecon has become aware of a software anomaly related to RECIST1.1 target lesion evaluation criteria in the Findings Workflow module within the Aquarius iNtuition Client viewer (AQi viewer). This feature assists the user in evaluating target lesions during follow-up by providing information on the selected region of interest(s) (ROI) differences in centimeters, percentage of change and a target lesion evaluation of the criteria based on the RECIST 1.1 evaluation of SD (stable disease), PD (progressive disease), CR (complete response) and PR (partial response). In certain instances, this target lesion "Evaluation" output provided by the software is inaccurate; however the **total measurement calculation (centimeters) and percentage of change are accurate**.

Figure 1: iNtuition Client Viewer, Findings Workflow Module, RECIST 1.1 Feature Screenshot

To utilize the RECIST 1.1 response evaluation feature, a combination of information is required on the target lesion(s) and non-target lesion(s). The iNtuition software does NOT provide a complete RECIST evaluation of the reviewed pathology and is only one factor used conceivably in a review of any particular medical evaluation. The iNtuition software is limited to providing information on target lesions based on user selected ROI(s). It is the responsibility of the user to validate theories and treatment decisions before proceeding with or eliminating a course of patient health management.

TeraRecon employees have identified this software anomaly, and there have been no reported adverse events associated with this software issue. TeraRecon has assessed that if a combination of highly unlikely factors were to occur, this issue could lead to ambiguous results warranting additional investigation, which could increase time to validate information related to patient health management.

WHAT YOU SHOULD DO

If you do NOT have the software versions listed above, you are not impacted by this notice and no further action is required. If you do, then:

(1) Notify all users of this communication. If you have further distributed this product, immediately stop distribution of these software versions. You must notify your customers to the end user level using this letter;

(2) If you have one of the impacted software versions, immediately stop use of the RECIST 1.1 target lesion evaluation output (SD, PD, CR, PR). You can continue to use the measurement calculation (centimeters) and percentage of change, as the values continue to be accurate; and

(3) This issue **has been resolved in subsequent software releases. Please contact Customer Support to upgrade your software to version 4.4.11 patch 4a (4.4.11.164.7713) which is currently available or 4.4.11 patch 5, estimated for release in February 2015.**

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Sincerely,

[redacted]

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