

Quality Notification

QN-RTD-2015-029

Version 1
13-Oct-2015

Virtuoso Software Version 5.4 and 5.5 Image Measurement Issue

Instrument/System	Virtuoso
Component	Software
Product	Virtuoso Software Version 5.4 and 5.5
Catalogue number	07073984001 (v5.4); 07299303001 (v5.5)
Lot number	N/A

Executive Summary

The VENTANA iScan HT scans slides at 4x, 10x, 20x, or 40x magnifications. For images **scanned at 4x, 10x, and 40x magnification** in Virtuosos software version 5.4 or 5.5, the linear and area measurement tools display a value that is 1/5, 1/2 and 2x the actual measurement, respectively. The measurement will be displayed incorrectly regardless of what magnification you are viewing the image at.

For images that are **scanned at 20x magnification, the measurement tools work properly in all versions of Virtuoso including versions 5.4 and 5.5.**

Issue

Actual Tissue Measurement size does not correspond to Virtuoso Ruler Measurement when images are scanned at 4x, 10x and 40x magnification which could cause incorrect estimation of clinical stage and potentially impact patient safety.

Root Cause

The cause was in the code of the software.

Risk Assessment

The measurement tool for slides that were **scanned at 4x, 10x, or 40x to assist with a diagnosis**, could potentially cause incorrect estimation of clinical stage leading to improper treatment.

Frequency of Occurrence

Occasional

Detectability

Unreliable

Severity

Critical

Actions

Immediate next step:

All affected customers using Virtuoso software 5.5 and the measurement tools must **stop scanning slides at 4x,10x, and 40x magnifications** and switch to scanning slides at 20x magnification. This is the only way to ensure that measurements are accurate.

Follow on steps:

1. Please get in touch with your Roche contact to schedule an upgrade to Virtuoso 5.6 as soon as possible.
2. Once the upgrade has been completed, you will be asked to sign a letter of completion and return to Roche Diagnostics.
3. It is recommended that interpreted clinical cases scanned using the Virtuoso 5.4 or 5.5 measurement tools (at anything other than 20X magnification) be re-assessed in accordance with local and laboratory practices and policies.

We sincerely apologize for any inconvenience caused by this issue and hope for your understanding and support.

Respectfully yours,

Roche Diagnostics Asia Pacific Pte Ltd

Yeo Kei Huat
Business Manager, Tissue Diagnostics
Contact No: 6371 6647 / 9623 5646
Email: kei_huat.yeo@roche.com

ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Quality Notification: [QN-RTD-2015-029](#), dated [13-Oct-2015](#) regarding [Virtuoso Software Version 5.4 and 5.5 Image Measurement Issue](#).

Received by:

Name & Signature

Hospital & Stamp

Date