Welch Allyn, Inc. 4341 State Street Road P.O. Box 220 Skaneateles Falls, NY 13153-0220 USA Telephone: 315-685-4100 www.welchallyn.com



Date: July 2, 2013

Statement on Calibration for the CP150 Electrocardiograph

There is no Calibration Certificate for the electrocardiograph functionality of the CP150 because calibration on the electrocardiogram is not required.

The CP150 Electrocardiographs are manufactured in accordance with their Device Master Records and must pass all applicable testing including final functional testing on the Automated Test Equipment – (see "ATE Tests" result on the Certificate of Analysis). Evidence of conformity including tests results is contained in the Device History Record and can be provided in a Certificate of Analysis.

I make these statements believing the same to be true and accurate.

Respectfully submitted,

Megan Pellenz

Regulatory Engineer III

Welch Allyn, Inc.

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July 2nd, 2013