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Tuesday, October 20, 2009

Statement on Calibration for CP100 & CP200 Electrocardiographs

There is no Calibration Certificate for the electrocardiogram functionality of the CP100 & CP200 because calibration on the electrocardiogram is not required.

The CP100 & CP200 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 test 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,

A handwritten signature in blue ink that reads "Megan Pellenz".

Megan Pellenz
Regulatory Engineer II
Welch Allyn, Inc.
pellenzm@welchallyn.com

A handwritten date in blue ink that reads "2009-10-20".

Date