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Date: July 2, 2013

Statement on Calibration for the CP50 Electrocardiograph

There is no Calibration Certificate for the electrocardiograph functionality of the CP50 because calibration on the electrocardiogram is not required.

The CP50 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,

A handwritten signature in cursive script that reads "Megan Pellenz".

Megan Pellenz
Regulatory Engineer III
Welch Allyn, Inc.
Megan.pellenz@welchallyn.com

A handwritten date in cursive script that reads "July 2nd, 2013".

Date