

Critikon 2-tube blood pressure cuff and adaptor on Philips IntelliVue MP20 Monitor

Comparative Study

By Andrea Stebor, RN, PhD



Introduction

The purpose of this clinical study was to compare noninvasive blood pressure (NIBP) taken with the Critikon® 2-tube Dura-Cuf® blood pressure cuff with an adaptor (test) and the Philips® 1-tube reusable blood pressure cuff (reference) on the Philips IntelliVue MP20 Junior monitor. The 2-tube Dura-Cuf with adaptor was connected to the Philips monitor single lumen NIBP hose. Equivalency criteria were determined prior to the initiation of the study. To meet the equivalency criteria, the mean differences of the systolic, diastolic, and mean arterial pressure (MAP) test-reference comparisons had to be within the 95% Confidence Interval (CI) of ± 10 mmHg.

Method

An Institutional Review Board approved the study and each subject gave written informed consent. The subject's upper arm was measured for the manufacturer's recommended cuff size.

The same size (small adult, adult, or large adult) test and reference cuffs were used on a subject. In randomized order, three sequential test and three sequential reference NIBPs were taken. Blood pressure values were based on the mean of three readings. A minimum one-minute wait period was allowed between each NIBP measurement to facilitate venous return. The same Philips IntelliVue MP20 monitor was used for all data collection.

Table 1

Mean differences (test-reference) and 95% CL for the Critikon 2-tube Dura-Cuf and adaptor compared to the Philips 1-tube reusable blood pressure cuff when used with the IntelliVue MP20 monitor.

Parameter	Count	Mean difference (mmHg)	Lower 95% CL for Mean (mmHg)	Upper 95% CL for Mean (mmHg)	Criteria Result (± 10 mmHg)
Systolic	39	-1.35	-2.90	0.20	Met
Diastolic	39	-1.21	-2.80	0.39	Met
MAP	39	-1.23	-2.65	0.18	Met

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Results

Data from 39 adult subjects were analyzed. The upper and lower 95% Confidence Limits (CL) for the mean differences of the systolic, diastolic, and MAP test/reference cuff comparisons were completely contained in the interval -10 to +10 mmHg (Table 1).

Based upon the results from this study the Critikon 2-tube Dura-Cuf and adaptor are acceptable for clinical use on the Philips IntelliVue MP20 monitor.

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Critikon Dura-Cuf Blood Pressure Cuffs Versus Philips Reusable Cuffs on IntelliVue MP50 Monitor

Comparative Study

By Diego Lozano, MD



Introduction

The purpose of this investigation was to evaluate the research hypothesis that the use of the Critikon® Dura-Cuf® blood pressure cuff with the Philips® IntelliVue MP50 monitor would not introduce a clinically significant difference. Comparisons were made between the Critikon Dura-Cuf (test) and the Philips reusable blood pressure cuff (reference) for the vital sign parameters of systolic, diastolic, and mean arterial pressure (MAP). Equivalency criteria were determined prior to the initiation of the study to demonstrate that mean differences were within the 95% Confidence Interval (CI) of ± 10 mmHg. Clinical reliability for this study was defined as the absence of clinically significant performance issues identified by the clinical investigator/data collector.

Method

Informed consent was obtained prior to placement of the appropriate Critikon and Philips cuffs. Sizing was based on most similar bladder size and manufacturers' recommendations. The cuff used first was randomized between subjects in order to reduce bias. Three sequential manual mode measurements were obtained with each cuff. A one-minute wait period was allowed between each measurement to facilitate venous return. The same Philips IntelliVue MP50 monitor was used for all of the data collection. Thirty-nine adult subjects were enrolled in this clinical evaluation.

Table 1

Mean differences (test-reference) and 95% confidence interval limits for the Critikon Dura-Cuf compared to the Philips reusable blood pressure cuff when used with the IntelliVue MP50 monitor.

Parameter	Average Mean Diff. (mmHg)	SD	Count	95% Lower Confidence Interval	95% Upper Confidence Interval	Criteria Result (± 10)
Systolic	- 1.56	3.93	39	- 2.84	- 0.29	Met
Diastolic	- 0.68	3.55	39	- 1.83	0.48	Met
MAP	- 1.03	3.15	39	- 2.06	- 0.01	Met

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Results

The 95% confidence interval on the mean differences for the systolic, diastolic, and mean arterial pressure (MAP) for the test/reference cuff comparisons were completely contained in the interval of -10 to +10 mmHg for the population tested. (Table 1). The clinical investigator did not identify any clinically significant performance issues.

Based upon the analysis performed in this study the Critikon Dura-Cuf cuff was reliable and acceptable for clinical use on the Philips IntelliVue MP50 monitor.

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