Medical Device Assessment

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Accreditation assessment of the oscillometric blood pressure measurement technology used in the Novacor Diasys 3 Plus (DIP-0001-00) upper arm ABPM monitor, as validated, by comparative-equivalence, according to the AAMI/ANSI/ISO 81060-2:2013 standard both for a general study in adults and for an additional ABPM-device study and according to the European Society of Hypertension International Protocol revision 2010

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Reference Medaval Ltd. Accreditation assessment of the oscillometric blood pressure measurement technology used in the Novacor Diasys 3 Plus (DIP-0001-00) upper arm ABPM monitor, as validated, by comparative-equivalence, according to the AAMI/ANSI/ISO 81060-2:2013 standard both for a general study in adults and for an additional ABPM-device study and according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2019 Mar 05;**2019**(1904SR) 4 p. Available from: https://www.medaval.ie/MDA/2019/MDA1904SR.pdf.

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Summary

Introduction

The Novacor Diasys 3 Plus (model number DIP-0001-00) is a blood pressure monitor intended for ambulatory blood pressure measurement. Measurements are recorded in hybrid mode with auscultation as the primary method and a backup using oscillometry. The Novacor Diasys 3 (model number DIS-0001-00) is a blood pressure monitor also intended for ambulatory blood pressure measurement. Measurements are recorded using oscillometry only. They are recorded automatically, on both devices, at timed intervals or additionally on indication of postural hypotension.

Methodology

The Novacor Diasys 3 Plus was validated previously[1], in auscultatory mode only, according to the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard[2] and also according to the requirements of the European Society of Hypertension International Protocol revision 2010 (ESH-IP)[3].

Three cuffs were used in accordance with the requirements of the protocols. These were the Paediatric Plus 18 cm to 24 cm cuff (model number ACC-0212-00), the Standard Plus 24 cm to 32 cm cuff (model number ACC-0210-00) and the Large Plus 32 cm to 40 cm cuff (model number ACC-0211-00).

The Novacor Diasys 3 was also validated previously[4], in oscillometric mode, also according to the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard[2] and according to the requirements of the European Society of Hypertension International Protocol revision 2010 (ESH-IP)[3].

Three cuffs were used in accordance with the requirements of the protocols. These were the Paediatric 18 cm to 24 cm cuff (model number ACC-0215-00), the Standard 24 cm to 32 cm cuff (model number ACC-0213-00) and the Large 32 cm to 40 cm cuff (model number ACC-0214-00).

A comparative-equivalence assessment of the oscillometric blood pressure measurements technology used in both devices was also performed[5] according to the requirements of the MEDDEV 2.7/2 rev 4 guidelines[6] and, in doing so, also fulfil the requirements of EU 2017/745[7].

Results

In the validation assessments, all of the requirements of each of the protocols were satisfied, by both devices, without any adjustments or violations.

In the comparative-equivalence assessment, the Paediatric Plus, the Standard Plus and the Large Plus cuffs were found to be equivalent, with common provision for oscillometric measurement, respectively to the Paediatric, the Standard and the Large cuffs. The oscillometric measurement technology in the Novacor Diasys 3 Plus was found to be equivalent that in the Novacor Diasys 3 though, with extra functionality beyond the measurement of oscillometric blood pressure, the Diasys 3 Plus model was found to be functionally superior to the Diasys 3 model.

Conclusion

When measurement technology in different devices is found to be equivalent, it is imperative

that the results of any validation carried out on that technology, irrespective of the device used, is applied to all devices with that technology.

Therefore the results of the validation carried out on the Novacor Diasys 3 must be applied equally to the oscillometric measurement technology of the Novacor Diasys 3 Plus. When combined with the validation of the Novacor Diasys 3 Plus in auscultatory mode, it must be concluded that the Novacor Diasys 3 Plus is accurate in auscultatory, oscillometric and hybrid modes, when used with the appropriate cuff, as described herein, within the criteria set out in AAMI/ANSI/ISO 81060-2:2013 for both a primary study in adults and an additional study required for ABPM devices and also within the criteria set out in the European Society of Hypertension International Protocol revision 2010 for a study in a general population.

Certification Decision

The Novacor Diasys 3 Plus (DIP-0001-00), with the appropriate Paediatric Plus 18 cm to 24 cm (ACC-0212-00), Standard Plus 24 cm to 32 cm (ACC-0210-00) or Large Plus 32 cm to 40 cm (ACC-0211-00) cuff, is certified by Medaval Ltd., for auscultatory, oscillometric and hybrid blood pressure measurement, including ABPM, in adults, as the technologies fulfilled the conditions required for a pass in 1) primary validation studies carried out in accordance with the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard, 2) additional validation studies during stress carried out in accordance with the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard for ambulatory monitors and 3) validation studies carried out in accordance with the requirements of the International Protocol of the European Society of Hypertension 2010 Revision.

Date of Approval: 04 March 2019.

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