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Medaval Comparative-Equivalence Assessment

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Comparative-Equivalence assessment of the oscillometric blood pressure measurement technology used in the Novacor Diasys 3 Plus (DIS-0001-00) and the Novacor Diasys 3 (DIS-0001-00) upper arm ABPM monitors, according to the requirements of MEDDEV 2.7/1 rev 4.

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Reference Medaval Ltd. Comparative-Equivalence assessment of the oscillometric blood pressure measurement technology used in the Novacor Diasys 3 Plus (DIS-0001-00) and the Novacor Diasys 3 (DIS-0001-00) upper arm ABPM monitors, according to the requirements of MEDDEV 2.7/1 rev 4. *Medical Device Assessment*. 2019 Mar 05;**2019**(1903AR) 8 p. Available from: https://www.medaval.ie/MDA/2019/MDA1903AR.pdf.

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MEDICAL DEVICE ASSESSMENT 1903AR:2019

Comparative-Equivalence assessment of the oscillometric blood pressure measurement technology used in the Novacor Diasys 3 Plus (DIS-0001-00) and the Novacor Diasys 3 (DIS-0001-00) upper arm ABPM monitors, according to the requirements of MEDDEV 2.7/1 rev 4.

Medaval Comparative-Equivalence Assessment – 05 March 2019

Summary

Introduction

Both the Novacor Diasys 3 (model number DIS-0001-00) and Novacor Diasys 3 Plus (model number DIP-0001-00) are blood pressure monitors intended for ambulatory blood pressure measurement. In the Novacor Diasys 3, measurements are recorded using only oscillometry whereas, in the Novacor Diasys 3 Plus, measurements are recorded in hybrid mode with auscultation as the primary method and a backup using oscillometry.

This assessment is intended to test the null hypothesis that the oscillometric measurement technologies differ between the two devices.

Methodology

The devices were compared according to the requirements of the MEDDEV 2.7/2 rev 4 guidelines[1] and, in doing so, fulfil the requirements of EU 2017/745[2]. According to these requirements all aspects of the devices must be classified as being associated with technical, clinical or biological aspects the measurement technology being tested (core items) or as being associated with aspects other than the measurement technology.

With the input of several renowned experts in validation, Medaval has drawn up a procedure involving at least 306 checks, with more, as necessary, depending on innovations on supplementary features and accessories. These are designed to fulfil the requirements of MEDDEV 2.7/2 rev 4[1], specified thereof in Appendix A1 – Sections 1 to 13, Appendix A9 – Sections 1 to 7 and Appendix A10 – Section 1.

Two different sets of three cuffs are provided with each device with the only claimed differences being a microphone, on the cuffs supplied for the Novacor Diasys 3 Plus monitor. According to MEDDEV 2.7/2 rev 4 guidelines, the cuffs must also be compared for equivalence.

Results

All of the requirements of the protocol were satisfied without any adjustments or violations for all four comparative-equivalence assessments.

Novacor Diasys 3 compared to Novacor Diasys 3 Plus for oscillometric measurement

In total, there were 306 items to be compared, of which 70 were core items broken down into 61 technical and 9 clinical items. The cuffs are defined as clinical items, as a whole but are themselves analysed separately and contain a mixture of different core items. The 236 non-core items are grouped in into 11 "identity", 187 "feature" and 38 "accessory" subgroups.

The functionalities defined for 12 of the core items were not applicable to either of the devices. This left 58 items, of which 57 were identical on both devices. The one remaining item referred to the cuffs used. Separate equivalence procedures proved that the provision of these items were equivalent.

For the identity items, eight were identical on both devices, two had equivalent provision and on one item, provision was better on the Diasys 3 Plus model.

The functionalities defined for 96 of the feature items were not applicable to either of the devices. This left 91 items, of which 81 were identical on both devices. Of the remaining ten items, one had similar-level provision on both devices, one had a superior provision on the Diasys 3 Plus model (arrhythmia algorithms are under development for both devices; with the inclusion of ECG input, the algorithm would be expected to be superior in the Diasys 3 Plus model) and eight were provided on

the Diasys 3 Plus model only. Many of these items are based on optional extras which, at the time of the report, were under development for provision with the Diasys 3 model. While the inclusion of a posture trigger in the Diasys 3 plus model (under development), will affect the number of measurements recorded on some patients and, therefore, the 24-hour statistics, this is independent of the accuracy of the individual measurements and the technology behind obtaining an oscillometric measurement.

The functionalities defined for 12 of the accessory items were not applicable to either of the devices. This left 26 items, of which 25 were identical on both devices. The remaining item referred to the small difference in weights between the devices.

As information, including that of non-provision, was provided on all 306 items identified for comparison, the comparison and the identification of all differences, as defined by the protocol, was complete.

As all core items, for the measurement of pressure using the oscillometric algorithms were identical, or also proven to be equivalent, the hypothesis that the technologies for oscillometric blood pressure measurement differ between the devices must be rejected and, therefore, this technology must be considered to be equivalent in both devices. It is therefore important that any assessment of this oscillometric technology, by a standard protocol, must be applied to both devices irrespective of the device used in the assessment.

In total there were 14 non-core differences between the devices, of which two had equivalent provision, two favoured neither device and ten were either only provided by or provided better on the Diasys 3 Plus model. This means that, beyond the measurement of oscillometric blood pressure, the Diasys 3 Plus model is considered to be functionally superior to the Diasys 3 model.

Standard cuff compared to Standard Plus cuff for oscillometric measurement

In total, there were 15 items to be compared, of which eight were core items broken down into seven technical and one biological items. The seven non-core items are grouped in into four "identity", one "feature" and two "accessory" subgroups.

All eight of the core items were identical on both devices. For the identity items, two were identical on both devices and two had equivalent provision. All feature item was identical on both devices.

Microphone items are considered as "accessory" for comparisons of oscillometric measurements and as core technical items for comparisons of auscultatory measurements. A microphone is provided with the Standard Plus cuff but not with the Standard cuff. The second "accessory" item, comparison of microphones did not apply.

As information, including that of non-provision, was provided on all 15 items identified for comparison, the comparison and the identification of all differences, as defined by the protocol, was complete.

As all core items, for the measurement of pressure using the oscillometric algorithms were identical, the hypothesis that the technologies for oscillometric blood pressure measurement differ between the devices must be rejected and, therefore, this technology must be considered to be equivalent in both devices. It is therefore important that any assessment of this oscillometric technology, by a standard protocol, must be applied to both devices irrespective of the device used in the assessment.

In total there were three non-core differences between the devices, of which two had equivalent provision and one, considered an accessory for the perspective of oscillometric measurement, was provided with the Standard Plus cuff only. This means that, beyond the measurement of oscillometric blood pressure, both cuff models have common provision.

Paediatric cuff compared to Paediatric Plus cuff for oscillometric measurement

The comparison of the Paediatric and Paediatric Plus cuffs had the exact same numbers and types of comparisons and outcomes as comparison of the Standard and Standard Plus cuffs. Therefore these are also proven to be equivalent, with common provision, for oscillometric measurement.

Large cuff compared to Large Plus cuff for oscillometric measurement

The comparison of the Large and Large Plus cuffs had the exact same numbers and types of comparisons and outcomes as comparison of the Standard and Standard Plus cuffs. Therefore these are also proven to be equivalent, with common provision, for oscillometric measurement.

Conclusion

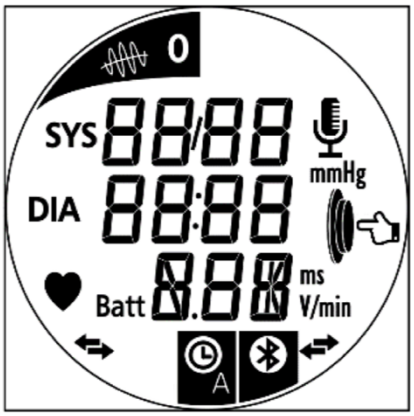
The protocol is designed to test the null hypothesis that the devices are different with respect to a

particular blood pressure measurement technology and the hypothesis must be rejected if the respective no difference is found.

As the protocol was followed strictly, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must also be rejected.

Therefore, as all core measurement items used in the measurement of blood pressure by oscillometry were either identical or, in the case of the cuffs, equivalent, there is no option but to reject the null hypothesis and conclude that the oscillometric blood pressure measurement technology used in Novacor Diasys 3 Plus is equivalent to that used in the Novacor Diasys 3 and vice versa. Therefore, it is imperative that the results of any assessment of this technology carried out using one of these devices must also be applied to the same technology in the other device.

The Novacor Diasys 3 Plus, together with a Paediatric Plus, Standard Plus or Large Plus cuff, as appropriate for the arm circumference can also record blood pressure in auscultatory mode. Furthermore it has facilities for other optional extra features not available on the Novacor Diasys 3. There are no features on the Novacor Diasys 3 that are not available on the Novacor Diasys 3 Plus. Therefore, in providing more features, the Novacor Diasys 3 Plus is considered to be a "superior" device to the Novacor Diasys 3.

Novacor Diasys 3	**Novacor Diasys 3 Plus**
	
	

Device Differences

Item Category	Item Description	Novacor Diasys 3	Novacor Diasys 3 Plus	Comparison
Identity	Primary Device Name	Novacor Diasys 3	Novacor Diasys 3 Plus	Equivalent on both devices
Identity	All device identities	1. Diasys 3 2. DIS-0001-00	1. Diasys 3 Plus 2. DIP-0001-00	Equivalent on both devices
Identity	All Modes	Oscillometric	Hybrid & Oscillometric	Better on Diasys 3 Plus
Core (Clinical)	Cuff List	Paediatric (ACC-0215-00) Standard (ACC-0213-00) Large (ACC-0214-00)	Paediatric (ACC-0215-00) Standard (ACC-0213-00) Large (ACC-0214-00)	Equivalent on both devices
Feature	Measurement Mode	Special Icon 	Special Icon 	Similar on both devices
Feature	Arrhythmia/IHB Code Stored	Under development	Under development (including ECG input)	Better on Diasys 3 Plus
Feature	ECG sensor	No sensor	Optional Wireless ECG Sensor	Diasys 3 Plus only
Feature	Korotkoff-sound sensor	No sensor	No sensor – Oscillometric measurement Yes – Auscultatory measurement	Diasys 3 Plus only
Feature	Measurements triggered by posture	Not provided	Under development	Diasys 3 Plus only
Feature	Central Aortic Pressures	Not provided	Yes - Requires optional accessory	Diasys 3 Plus only
Feature	Arterial Stiffness Index	Not provided	QKD (Optional extra)	Diasys 3 Plus only
Feature	Posture	Not provided	Yes - Requires optional accessory	Diasys 3 Plus only
Feature	Activity Level	Not provided	Yes - Requires optional accessory	Diasys 3 Plus only
Feature	Arterial Stiffness	Function not provided	Under development (Special Icon, Reuse of 7-segment characters)	Diasys 3 Plus only
Accessory	Weight (with batteries)	161 g	165 g	Different on each device

Comparison	Identity	Core	Feature	Accessory
Identical provision on both devices	8	57	81	25
Equivalent provision on both devices	2	1	0	0
Similar-level provisions on both devices	0	0	1	0
Different provisions on each device	0	0	0	1
Provided on Reference but not on Test Device	0	0	0	0
Better provision on Reference Device	0	0	0	0
Provided on Test but not on Reference Device	0	0	7	0
Better provision on Test Device	1	0	2	0
Not applicable for this device functionality	0	12	96	12
Total	11	70	187	38

Cuff Differences

Item Category	Item Description	Novacor Standard Cuff	Novacor Standard Plus Cuff	Comparison
Identity	Primary Cuff Name	Novacor Standard Cuff	Novacor Standard Plus Cuff	Equivalent on both devices
Identity	All cuff identities	1. Standard 2. ACC-0213-00 (model)	1. Standard Plus 2. ACC-0210-00 (model)	Equivalent on both devices
Accessory	Microphones	No microphone	One microphone (Not Used)	Diasys 3 Plus only

Comparison	Identity	Core	Feature	Accessory
Identical provision on both devices	2	8	1	0
Equivalent provision on both devices	2	0	0	0
Similar-level provisions on both devices	0	0	0	0
Different provisions on each device	0	0	0	1
Provided on Reference but not on Test Device	0	0	0	0
Better provision on Reference Device	0	0	0	0
Provided on Test but not on Reference Device	0	0	0	0
Better provision on Test Device	0	0	0	0
Not applicable for this device functionality	0	0	0	1
Total	4	8	1	2

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Recommendations

Assessment Summary

Paediatric Cuff v Paediatric Plus Cuff

The Paediatric Cuff (ACC-0215-00) and Paediatric Plus Cuff (ACC-0212-00) have been compared, with respect to oscillometric blood pressure measurement, according to a procedure verified as ensuring that the comparison has been conducted in accordance with the requirements set out in MEDDEV 2.7/1 Rev 4. Therefore, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must be rejected and the results must be considered to be valid.

According to this protocol, the results of the comparison require that the null hypothesis, that the cuffs differ in respect to technical, clinical or biological core oscillometric blood pressure measurement technology in the two cuffs, is rejected. Therefore, it must be concluded, that the oscillometric blood pressure measurement technology used in the Paediatric Plus Cuff (ACC-0212-00) is equivalent to that used in the Paediatric Cuff (ACC-0215-00). Furthermore, the results of any validations carried out this oscillometric blood pressure measurement technology, irrespective of which of the two cuffs is used during the validation procedure, must be applied equally to the this technology of both cuffs.

The comparative result proved that the devices are common with respect to oscillometric measurement. This means that they are the same except in the provision of an accessory. In this case, the microphone, is considered an accessory for the purposes of oscillometric measurement.

Standard Cuff v Standard Plus Cuff

The Standard Cuff (ACC-0213-00) and Standard Plus Cuff (ACC-0210-00) have been compared, with respect to oscillometric blood pressure measurement, according to a procedure verified as ensuring that the comparison has been conducted in accordance with the requirements set out in MEDDEV 2.7/1 Rev 4. Therefore, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must be rejected and the results must be considered to be valid.

According to this protocol, the results of the comparison require that the null hypothesis, that the cuffs differ in respect to technical, clinical or biological core oscillometric blood pressure measurement technology in the two cuffs, is rejected. Therefore, it must be concluded, that the oscillometric blood pressure measurement technology used in the Standard Plus Cuff (ACC-0210-00) is equivalent to that used in the Standard Cuff (ACC-0213-00). Furthermore, the results of any validations carried out this oscillometric blood pressure measurement technology, irrespective of which of the two cuffs is used during the validation procedure, must be applied equally to the this technology of both cuffs.

The comparative result proved that the devices are common with respect to oscillometric measurement. This means that they are the same except in the provision of an accessory. In this case, the microphone, is considered an accessory for the purposes of oscillometric measurement.

Large Cuff v Large Plus Cuff

The Large Cuff (ACC-0214-00) and Large Plus Cuff (ACC-0211-00) have been compared, with respect to oscillometric blood pressure measurement, according to a procedure verified as ensuring that the comparison has been conducted in accordance with the requirements set out in MEDDEV 2.7/1 Rev 4. Therefore, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must be rejected and the results must be considered to be valid.

According to this protocol, the results of the comparison require that the null hypothesis, that the cuffs differ in respect to technical, clinical or biological core oscillometric blood pressure measurement technology in the two cuffs, is rejected. Therefore, it must be concluded, that the oscillometric blood pressure measurement technology used in the Large Plus Cuff (ACC-0211-00) is equivalent to that used in the Large Cuff (ACC-0214-00). Furthermore, the results of any validations carried out this oscillometric blood pressure measurement technology, irrespective of which of the two cuffs is used during the validation procedure, must be applied equally to the this technology of both cuffs.

The comparative result proved that the devices are common with respect to oscillometric measurement. This means that they are the same except in the provision of an accessory. In this case, the microphone, is considered an accessory for the purposes of oscillometric measurement.

Diasys 3 Monitor v Diasys 3 Plus Monitor

The Diasys 3 Monitor (DIS-0001-00) and Diasys 3 Plus Monitor (DIP-0001-00) have been compared, with respect to oscillometric blood pressure measurement, according to a procedure verified as ensuring that the comparison has been conducted in accordance with the requirements set out in MEDDEV 2.7/1 Rev 4. Therefore, any hypothesis that the reliability of the results may be compromised due to protocol adjustment or violation must be rejected and the results must be considered to be valid.

According to this protocol, the results of the comparison require that the null hypothesis, that the monitors differ in respect to technical, clinical or biological core oscillometric blood pressure measurement technology in the two monitors, is rejected. Therefore, it must be concluded, that the oscillometric blood pressure measurement technology used in the Diasys 3 Plus Monitor (DIP-0001-00) is equivalent to that used in the Diasys 3 Monitor (DIS-0001-00). Furthermore, the results of any validations carried out this oscillometric blood pressure measurement technology, irrespective of which of the two monitors is used during the validation procedure, must be applied equally to the this technology of both monitors. For the purposes of oscillometric measurements on either device, the Paediatric Cuff and Paediatric Plus Cuff can be used interchangeably; the Standard Cuff and Standard Plus Cuff can be used interchangeably and the Large Cuff and Large Plus Cuff can be used interchangeably.

There is no difference in the provision of features or accessories with respect to oscillometric blood pressure measurement and the two monitors can be considered as being the same for this purpose. For more general use, Diasys 3 Plus Monitor (DIP-0001-00) is considered superior to the Diasys 3 Monitor (DIS-0001-00) as it contains more features.

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