Medical Device Assessment

Medaval Certified Accuracy

Medaval Comparative-Equivalence Assessment Full Report

Volume 2024 Report 2404FR 06 February 2024

Full report on the comparative-equivalence assessment of the blood pressure measurement technology used in the SELVAS ACCUNIQ BP600 and the SELVAS ACCUNIQ BP500 upper arm blood pressure monitors, according to the requirements of MEDDEV 2.7/1 revision 4.

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Reference Medaval Ltd. Medical Full report on the comparative-equivalence assessment of the blood pressure measurement technology used in the SELVAS ACCUNIQ BP600 and the SELVAS ACCUNIQ BP500 upper arm blood pressure monitors, according to the requirements of MEDDEV 2.7/1 revision 4. *Medical Device Assessment*. 2024 Feb 06;**2024**(2404FR) 28 p.

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Glossary

Abbreviations

%RH	relative humidity percent
°C	degrees Celsius
AAMI	Association for the Advancement of Medical Instrumentation (USA)
ABPM	Ambulatory blood pressure measurement
ANSI	American National Standards Institute
BP	Blood pressure
bpm	beats per minute
cm	centimetre(s)
DBP	Diastolic blood pressure
ECG	Electrocardiogram
EEA	European Economic Area (EU plus Iceland, Liechtenstein and Norway)
EEC	European Economic Community (former name for EU)
ESH	European Society of Hypertension
EU	European Union
g	gram(s)
hPa	hectopascals
ISO	International Organization for Standardization/International Standards Organization
m	metre(s)
MAP	Mean Arterial Pressure (if estimated, MAP = (SBP + 2 × DBP) / 3)
meas.	Measurement
min	minute(s)
mmHg	millimetre(s) of mercury
PC	Personal computer (any external system to which data can be downloaded)
PP	Pulse Pressure (PP = SBP – DBP)
PR	Pulse Rate
PRP	Pressure Rate Product (PRP = SBP × PR)
req.	requirement
SBP	Systolic Blood Pressure
SD	standard deviation

Legend of Item Comparison

BL	Similar-level provisions on both devices
BP	Different provisions on each device
EL	Equivalent provision on both devices
EP	Identical provision on both devices
MB	Values missing for both devices
MR	Value missing for Reference Device
MT	Value missing for Test Device
QL	Check if provision is identical or similar
QP	Check free text entries
RL	Better provision on Reference Device
RP	Provided on Reference but not on Test Device
TL	Better provision on Test Device
TP	Provided on Test but not on Reference Device
XB	Not applicable for this device functionality
XP	Not comparable

Legend of Summary Comparison

An	Applicable number of items (total less not applicable)
Bn	Differing items that are not any better in either device
Bn-F	Differing feature items that are not any better in either device
Dn	Items that are different in the two devices
Dn-A	Accessory items that are different in the two devices
Dn-C	Core items that are different in the two devices
Dn-F	Feature items that are different in the two devices
En	Items that are equal in both devices
En-F	Core items that are equal in both devices
En-F	Feature items that are equal in both devices
Mn	Missing items
Mn-A	Missing accessory items
Mn-C	Missing core items
Mn-F	Missing feature items
Qn	Items with outstanding queries
Qn-A	Accessory items with outstanding queries
Qn-C	Core items with outstanding queries
Qn-F	Feature items with outstanding queries
Rn	Differing items that are better in the reference device than in the test device
Rn-F	Differing feature items that are better in the reference device than in the test device
Sn	Total number of items
Sn-A	Total number of accessory items
Sn-C	Total number of core items
Sn-F	Total number of feature items
Sn-I	Total number of identity items
Tn	Differing items that are better in the test device than in the reference device
Tn-F	Differing feature items that are better in the test device than in the reference device
Xn	Items that were on the checklist but were not compared
Xn-A	Accessory items that were on the checklist but were not compared
Xn-F	Feature items that were on the checklist but were not compared

Summary

Objective

The objective of this study was to compare the SELVAS ACCUNIQ BP600 blood pressure monitor (BPM) to the SELVAS ACCUNIQ BP500 for equivalence according to the requirements of the MEDDEV 2.7/1 revision 4 guidelines[1] in order to fulfil the medical device requirements of EU 2017/745[2].

Methodology

The 320 items in a checklist were compared, of which 72 were core items, to prove equivalence and broken down into 63 technical and nine clinical items. The 248 non-core items (not associated with the measurement technology) identified the differences between the devices and determined how the devices were comparable.

The cuffs, defined as clinical items in terms of the device, were analysed separately, as at least one difference was observable. The 16 items in the checklist consisted of ten core items, broken down nine technical items and one biological item. There were six non-core items.

Non-core items are grouped in into "identity", "feature" and "accessory" subgroups.

Results

Comparison of the core items, for both the devices and cuffs proved that they were equivalent according to procedures recommended in the MEDDEV 2.7/1 revision 4 guidelines[1]. Comparison of the non-core items, for both the devices demonstrated that, with fewer features and accessories, the SELVAS ACCUNIQ BP600 is considered simpler to the SELVAS ACCUNIQ BP500.

Both cuff styles were found to be identical, as regards blood pressure measurement, with the only difference being the colour of the front deco cover.

Conclusion

As they have been prove to be equivalent, the results on any validation carried out on either the SELVAS ACCUNIQ BP500 or the SELVAS ACCUNIQ BP600 must be applied to both devices.

As the SELVAS ACCUNIQ BP500 has been proven to be accurate according to the requirements of the ISO 81060-2:2018[3,4] and ISO 81060-2:2018/Amd 1:2020 standard[5], the results of this validation must be applied to the SELVAS ACCUNIQ BP600 also[6]. Therefore the SELVAS ACCUNIQ BP600 must be considered to be accurate, when used correctly, as per the manufacturer's instructions, within the criteria set out in ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020.

It is, therefore, recommended for use in clinical blood pressure measurement.

Organisational Details

Medaval Ltd.

Incorporated in 1989 as Medical Device Assessment Ltd, the company abbreviated its name to Medaval Ltd. in 2015. Medaval provides several services including comprehensive cardiovascular device listings according to peer-reviewed validations, certification for devices that have been proven to have been validated strictly according to a current standard protocol, validation of devices and comparative-equivalence according to MEDDEV 2.7/1 rev 4 standards[1]. Both validation and comparative-equivalence services are in accordance with Regulation (EU) 2017/745[2].

The passing criteria in validation protocols are based on specific sample distributions and on other criteria and can only be applied if all of the requirements are followed correctly. Therefore, in any validation study, Medaval, first tests the hypothesis that the study was not carried out in accordance with the requirements and it is only if that hypothesis is rejected can the results be considered reliable.

All procedures were developed and reviewed by a panel of experts. The Medaval Accreditation Procedure is designed to check that every aspect of a validation protocol is fulfilled. Modifications, that may be necessary for particular populations or circumstances not defined specifically in a protocol must be supported by relevant peer-reviewed scientific publications.

Validation is considered to apply to the specific measurement technology being tested, as distinct from the device itself. No inference should be made about the validity of any other aspect of the device, unless it is also tested according to a regulatory or peer-reviewed protocol. Validation also only applies to the population from which the sample is taken and under the circumstances in which it was carried out, as defined in the protocol. No inference should be made about the validity of the device in a different population or under different circumstances.

The results must apply equally to any device that uses the same measurement technology, as proven under MEDDEV 2.7/1 rev 4 standards irrespective of whether that equivalence is proven prior to or subsequent to the validation. Medaval has developed as comparative-equivalence procedure to test the null hypothesis that two devices are not equivalent, according to this standard. Should that hypothesis be rejected, the devices must be regarded as equivalent for that measurement technology.

For more information, please refer to www.medaval.ie.

SELVAS Healthcare Inc.

SELVAS Healthcare Inc. (formerly Jawon Medical), established in 1993, is a digital healthcare company based on technology for medical devices and assistive rehabilitation technology devices.
The company has won several awards including the Presidential Award in the National Venture Awards and selected as a World Top-class Company (1999), Top Prize in the Leaders' Venture Awards (2000), the Prime Minister's Award by the Korean Good Manufacturing Practice Trade Day (2001), the Director's Award by the Korea Food and Drug Administration (2003), Bronze Prize in the Republic of Korea Technical Awards, Silver Prize in the Venture Design Awards and Bronze Medal of Industrial Effort in the Precision Technology Promotion Contest (2005), the Director's Award by the Korea Food and Drug Administration (2006), the Advanced Venture Company Award (2010), Grand Prize in the 1st People's Happiness Premium IT and the Popularity Award, Analysis and Diagnosis System Segment in the Korean Medical Device Awards (2014).

Its brand ACCUNIQ derives from its mission to provide accurate diagnosis and unique technology.

SELVAS Headquarters are in Daejeon, Republic of Korea and it has major offices in Beijing, Peoples Republic of China and in Austin, Texas, USA. It also has offices in Venlo, Netherlands, Taipei City, Taiwan and Tokyo, Japan.

The company has, among several others, ISO 13485, ISO 9001 and GMP certification. See https://www.ACCUNIQ.com/en/company/certification.php for a complete list.

For more information, please refer to www.ACCUNIQ.com.

Full Report

Introduction

Both the SELVAS ACCUNIQ BP500 and SELVAS ACCUNIQ BP600 are blood pressure monitors (BPMs) intended for waiting room use or for availability in, for instance, a staff common area in a business. Blood pressure (BP) is measured oscillometrically on each device in the same way. A visual aid shows how to place the, usually right, arm and a sensor prevents it from working until at least the elbow is placed correctly Measurement is initiated by pressing a Start/Stop button and the results are displayed. It is intended for adults (18+) with arm circumferences in the range 20 cm to 40 cm only but not for those with arrhythmias and some other stated conditions.

An additional rear monitor, allowing anthropometric data to be entered is available and the device has a USB port and two RS-232C ports. None of these were used in this study.

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 2.7/1 revision 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 drew up a procedure involving over 300 checks, with more, as necessary, depending on innovations on supplementary features and accessories. These are designed to fulfil the requirements of MEDDEV 2.7/1 revision 4[1], specified thereof in Appendix A1, Appendix A9 and Appendix A10. At the time of this study, there are 320 checks for BPMs and a further 16 checks for cuffs.

Results

All of the requirements of the protocol were satisfied without any adjustments or violations.

For each equivalence check, there were 320 items to be compared, of which 72 were core items broken down into 63 technical and nine clinical items. While the cuffs are defined as clinical items in terms of the device, they are analysed separately and contain their own core items. The 248 non-core items were grouped in into 11 "identity", 193 "feature" and 44 "accessory" subgroups.

The functionalities defined for 2 of the core items (analogue filter model and inflation target value) were not applicable to the device functionality of either of the devices and 14 which were not provided on either of the devices. The remaining 56 items were identical on both devices. Worth noting is that SELVAS uses one of two pumps in the production of these devices. Both pumps are manufactured specifically for the devices and details specification were provided to prove that they operate identically.

For the identity items, four were not applicable to either of the devices, five were identical on all devices, two (name and model number) were equivalent across both devices.

The functionalities defined for 77 of the feature items were not applicable to the device functionality of either of the devices, 68 were not provided on either of the devices and the remaining 48 were identical on both devices.

The functionalities defined for 15 of the accessory items were not applicable to the device functionality of either of the devices, ten were not provided on either of the devices and 18 were identical on both devices. The difference in the remaining item related to the material of the Start/Stop and the Emergency Stop buttons.

As information, including that of non-provision, was provided on all 320 items identified for comparison, the comparison and the identification of all differences, as defined by the protocol, was complete. The results of all comparisons are provided in summary and in detail below.

Discussion

The SELVAS ACCUNIQ BP600 and the SELVAS ACCUNIQ BP500 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 revision 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 SELVAS ACCUNIQ BP600 is equivalent to that used in the SELVAS ACCUNIQ BP500. 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 more general use, SELVAS ACCUNIQ BP600 is considered identical to the SELVAS ACCUNIQ BP500, as there are no functional differences between these devices.

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 the SELVAS ACCUNIQ BP600 is equivalent to that used in the SELVAS ACCUNIQ BP500 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.

Recommendations

The SELVAS ACCUNIQ BP600 has been proven to be equivalent to the SELVAS ACCUNIQ BP500 for blood pressure measurement, meaning that the results of all validations of this technology on either device must be applied to the other device. The SELVAS ACCUNIQ BP500 has been proven to be accurate according to the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 protocol requirements[6]. Therefore, as the results of this validation must also be applied to the SELVAS ACCUNIQ BP600, and it must be concluded, that the oscillometric blood pressure measurement technology used in the SELVAS ACCUNIQ BP600 monitor is accurate for blood pressure measurement in adults, when the device is used according to manufacturer instructions.

Certification Decision

The SELVAS ACCUNIQ BP600, is certified by Medaval Ltd., for blood pressure measurement, in adults, as, proven by equivalence, the technology fulfilled the conditions required for a pass in a validation study carried out in accordance with the requirements of the ISO 81060-2:2018 and ISO 81060-2:2018/Amd 1:2020 standard.

Date of Approval: 06 February 2024.

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content/EN/TXT/?uri=CELEX%3A32017R0745.

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SELVAS ACCUNIQ BP600 v BP500 Comparative-Equivalence

Summary of Differences

Item Category	Item Description	Reference Device	Test Device	Comparison
Identity	Primary Device Name	ACCUNIQ BP500	ACCUNIQ BP600	Equivalent on both devices
Identity	All device identities	BP500	BP600	Equivalent on both devices
Accessory	Button Description(s)	Start/Stop: Indigo Acrylonitrile Butadiene Styrene (ABS) Emergency Stop: Red ABS Available in English or Korean	Start/Stop: Indigo Acrylic Emergency Stop: Red Acrylic Available in English or Korean	Equivalent on both devices

Comparison of Primary Details

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Primary Details					
Device Identification					
Identity	Primary Device Name	ACCUNIQ BP500	ACCUNIQ BP600	**EL**	I
Identity	All device identities	BP500	BP600	**EL**	I
Identity	All Measurement Modes	Oscillometric	Oscillometric	EP	I
Identity	Defined Measurement Mode	Oscillometric	Oscillometric	EP	I
Manufacturers					
Identity	Branding Company	ACCUNIQ	ACCUNIQ	EP	I
Identity	Distributer	SELVAS Healthcare, Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon, Republic of Korea	SELVAS Healthcare, Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon, Republic of Korea	EP	I
Identity	Own Brand Labeller	Not applicable	Not applicable	XB	I
Identity	Original Equipment Manufacturer	Not applicable	Not applicable	XB	I
Identity	Regulation Manufacturer	Not applicable	Not applicable	XB	I
Identity	Sole Manufacturer	SELVAS Healthcare, Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon, Republic of Korea	SELVAS Healthcare, Inc. 155 Sinseong-ro, Yuseong-gu, Daejeon, Republic of Korea	EP	I
Identity	Other role	Not applicable	Not applicable	XB	I
Documentation	Contact	elliott.k.kim@SELVAShc.com, 82-42-879-3026	elliott.k.kim@SELVAShc.com, 82-42-879-3026	--	–
Primary Descriptors					
Feature	Measuring Functions	Blood Pressure	Blood Pressure	EP	F
Feature	Primary Client Use	Use as a public facility	Use as a public facility	EP	F
Documentation	Validation Publications	None	None	--	–
Core (Clinical)	Measurement Site	Upper Arm	Upper Arm	EP	C
Feature	Measurement Occurrence	Single measurement	Single measurement	EP	F
Documentation	Availability	Available Currently	Available Currently	--	–
Feature	Accessibility	Optional voiced instructions and results	Optional voiced instructions and results	EP	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Voiced Languages	Korean / English	Korean / English	EP	F
Documentation	Warranty	0	0	--	A
Files Supplied					
Documentation	User Manual Supplied	Yes	Yes	--	–
Documentation	Service Manual Supplied	Yes	Yes	--	–
Documentation	Specifications Supplied	Yes	Yes	--	–
Documentation	Device Image Supplied			--	–
Documentation	Display Image Supplied			--	–
Documentation	Standards-Compliance supplied	X	None	--	–
Documentation	Pre-clinical studies supplied	None	None	--	–

Comparison of Standard Device Details

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Standard Device Hardware					
Casing					
Accessory	Length	502 mm	502 mm	EP	A
Accessory	Width	450 mm	450 mm	EP	A
Accessory	Height	279 mm	279 mm	EP	A
Accessory	Weight (with batteries)	4800 g	4800 g	EP	A
Accessory	Number of Screens	1	1	EP	A
Accessory	Screen Type	Segment LCD	Segment LCD	EP	A
Accessory	Screen Width	130 mm	130 mm	EP	A
Accessory	Screen Height	90 mm	90 mm	EP	A
Accessory	Screen Backlight	Yes	Yes	EP	A
Accessory	Adjustable Font Size	Not applicable	Not applicable	XB	A
Climate					
Core (Technical)	Minimum Storage Temperature	-10 °C	-10 °C	EP	C
Core (Technical)	Maximum Storage Temperature	+60 °C	+60 °C	EP	C
Core (Technical)	Minimum Operating Temperature	+10 °C	+10 °C	EP	C
Core (Technical)	Maximum Operating Temperature	+40 °C	+40 °C	EP	C
Core (Technical)	Minimum Storage Humidity	0 %RH	0 %RH	EP	C
Core (Technical)	Maximum Storage Humidity	94 %RH	94 %RH	EP	C
Core (Technical)	Non-condensing Storage Humidity	Yes	Yes	EP	C
Core (Technical)	Minimum Operating Humidity	15 %RH	15 %RH	EP	C
Core (Technical)	Maximum Operating Humidity	85 %RH	85 %RH	EP	C
Core (Technical)	Non-condensing Operating Humidity	Yes	Yes	EP	C
Core (Technical)	Minimum Storage Atmospheric Pressure	700 hPa	700 hPa	EP	C
Core (Technical)	Maximum Storage Atmospheric Pressure	1060 hPa	1060 hPa	EP	C
Core (Technical)	Minimum Operating Atmospheric Pressure	700 hPa	700 hPa	EP	C
Core (Technical)	Maximum Operating Atmospheric Pressure	1060 hPa	1060 hPa	EP	C
Core (Technical)	Approximate Maximum Altitude	≈3000 m	≈3000 m	EP	C
Power					
Accessory	Battery Type	No batteries used	No batteries used	EB	A
Accessory	Battery Size	Not applicable	Not applicable	XB	A
Accessory	Battery Details	Not applicable	Not applicable	XB	A
Accessory	Battery Quantity	0	0	EP	A

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Accessory	Battery Life (# measurements)	Not applicable	Not applicable	EP	A
Accessory	Rechargeable battery use	Rechargeable batteries not permitted	Rechargeable batteries not permitted	EB	A
Accessory	AC Adapter Provision	Required – Device only operates from mains	Required – Device only operates from mains	EP	A
Core (Technical)	AC Adapter Number(s)	BRIDGEPOWER BPM060S12F14	BRIDGEPOWER BPM060S12F14	EP	C
Accessory	Automatic Power On	No automatic power on	No automatic power on	EB	A
Accessory	Automatic Power Off	No automatic power off	No automatic power off	EB	A
Communication					
Accessory	Communication Port	USB and RS232	USB and RS232	EP	A
Accessory	Cable Provided	Yes	Yes	EP	A
Audio					
Feature	Voice Memo Recorder	Not provided	Not provided	EB	F
Accessories					
Accessory	Storage/Carrying Case	Not applicable – not intended to be portable	Not applicable – not intended to be portable	XB	A
Accessory	Lid	Not applicable – not intended to be closed	Not applicable – not intended to be closed	XB	A
Accessory	Desk mount facilities	Not applicable	Not applicable	XB	A
Accessory	Wall mount facilities	Not applicable	Not applicable	XB	A
Accessory	Mobile mount facilities	Not applicable	Not applicable	XB	A
Accessory	Pouch	Not applicable	Not applicable	XB	A
Accessory	Belt	Not applicable	Not applicable	XB	A
Accessory	Belt Clip	Not applicable	Not applicable	XB	A
Accessory	Shoulder Straps	Not applicable	Not applicable	XB	A
Accessory	Printer	Integrated as part of device	Integrated as part of device	EP	A
Accessory	Card Holder	Not applicable	Not applicable	XB	A
Appearance					
Accessory	Case Description	White/Grey Available in English and/or Korean	White/Grey Available in English and/or Korean	EP	A
Accessory	Button Description(s)	Start/Stop: Indigo Acrylonitrile Butadiene Styrene (ABS) Emergency Stop: Red ABS Available in English or Korean	Start/Stop: Indigo Acrylic Emergency Stop: Red Acrylic Available in English or Korean	**EL**	A
Accessory	Other Description(s)	Not applicable	Not applicable	XB	A
Standard Device Firmware					
Algorithm					
Core (Technical)	Firmware Name and Version	BP500.EN.1.0.00 (Only to distinguish model number)	BP600.EN.1.0.00 (Only to distinguish model number)	EP	C
Standard Device Software					
Memory					
Feature	Number of Memory Locations per User/Zone	0	0	EP	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Number of Users/Zones	0	0	EP	F
Feature	Non-memory use (Guest mode)	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Method of Clearing Memory	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Accessory	Memory card slot	Not provided	Not provided	EB	A
Feature	Date Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Time Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Error Code Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Facility to mark unique results	Not Applicable (No memory facility)	Not Applicable (No memory facility)	XB	F
Procedure					
Feature	Value shown before measurement	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Average displayed on measurement completion	Not Applicable (No memory facility)	Not Applicable (No memory facility)	XB	F
Measurement					
Core (Technical)	Error Codes	M01 M02 M09 M15 M16 M18 D01 D06 D12 D23 D24	M01 M02 M09 M15 M16 M18 D01 D06 D12 D23 D24	EP	C
Analysis					
Feature	Software Use	No proprietary software provided	No proprietary software provided	EB	F
Feature	Proprietary Software Name	Not applicable	Not applicable	XB	F
Non-Medical Extra Features					
Accessory	Clock	Not provided	Not provided	EB	A
Accessory	Alarm	Not provided	Not provided	EB	A
Accessory	Radio	Not provided	Not provided	EB	A
Accessory	Ambient Temperature	Not provided	Not provided	EB	A
Standard Device Features					
Summary					
Documentation	Features Summary	This device is an electronic device used to measure blood pressure in a non-invasive way outside the body. The cuff is automatically pressurized and systolic and diastolic blood pressure and heart rate are measured and displayed as results.	This device is an electronic device used to measure blood pressure in a non-invasive way outside the body. The cuff is automatically pressurized and systolic and diastolic blood pressure and heart rate are measured and displayed as results.	--	–
Documentation	Items not listed	None	None	--	–
Standard Screen and Audio Indicators					
Measurement					
After Measurement					
Feature	Measurement Unit(s)	Shown	Shown	EP	F
Feature	Average – Overall	Function not provided	Function not provided	EB	F
Feature	Plot	No plot provided	No plot provided	EB	F
Error Indicators					
Feature	Measurement Error	“Error” text with code or number	“Error” text with code or number	EP	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Timestamp					
Feature	Date and Time	Date and Time shown	Date and Time shown	EP	F
Feature	Time Format	24-hour and 12-hour clocks	24-hour and 12-hour clocks	EP	F
Markers					
Feature	Event – Medication	Function not provided	Function not provided	EB	F
Memory					
Feature	Value from Memory	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Recorded Measurement Timestamp	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Memory Location Number	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Memory Locations Used	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Memory Full	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Memory Zone Name	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Delete memory	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Non-Measurement					
Power					
Feature	Battery Symbol	Not applicable (No battery)	Not applicable (No battery)	XB	F
Feature	Battery Charging Indicator	Not applicable (No charging)	Not applicable (No charging)	XB	F
Feature	Voltage Check	Function not provided	Function not provided	EB	F
Feature	AC Adapter Symbol	Function not provided	Function not provided	EB	F
Feature	Power Error Symbol	Error code	Error code	EP	F
Feature	Start	Function not provided	Function not provided	EB	F
Feature	Stop	Function not provided	Function not provided	EB	F
Communication					
Feature	Reminder to Transfer Data	Function not provided	Function not provided	EB	F
Feature	Device Connected	Special Icon	Special Icon	EP	F
Feature	Transmitting Data	Function not provided	Function not provided	EB	F
Feature	Transmission Successful	Function not provided	Function not provided	EB	F
Feature	Transmission Unsuccessful	Function not provided	Function not provided	EB	F
Feature	Signal out-of-range	Function not provided	Function not provided	EB	F
Feature	PC Link	Reuse of 7-segment characters	Reuse of 7-segment characters	EP	F
Settings					
Feature	Settings	Function not provided	Function not provided	EB	F
Feature	Initialisation	Function not provided	Function not provided	EB	F
Feature	Hide measurement display option	Not provided	Not provided	EB	F
Audio Indicators					
Feature	Sound Volume	Seven levels	Seven levels	EP	F
Feature	Measurement Value	Optional Voiced Indicator	Optional Voiced Indicator	EP	F
Feature	Memory Value	None	None	EB	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Statistics Value	None	None	EB	F
Feature	Measurement Reminder	None	None	EB	F
Feature	Measurement Complete	Optional Voiced Indicator	Optional Voiced Indicator	EP	F
Feature	Measurement Error	Optional Voiced Indicator	Optional Voiced Indicator	EP	F
Feature	Voice Recorder	Function not provided	Function not provided	EB	F
Display					
Feature	Screen Background Colour(s)	Black	Black	EP	A
Feature	Screen Font Colour(s)	White	White	EP	A
Feature	Screen Language(s)	None	None	EB	A
Standard Buttons and Switches					
Power					
Feature	Power On	Power	Power	EP	F
Feature	Power Off	Power	Power	EP	F
Feature	Start	Start/Stop	Start/Stop	EP	F
Feature	Stop	Start/Stop	Start/Stop	EP	F
Up/Down					
Feature	Increase value	Up	Up	EP	F
Feature	Decrease value	Down	Down	EP	F
Feature	Previous value	Not applicable	Not applicable	XB	F
Feature	Next value	Not applicable	Not applicable	XB	F
Feature	Increase volume	Set and Up	Set and Up	EP	F
Feature	Decrease volume	Down and Set	Down and Set	EP	F
Memory					
Feature	Memory mode	Not applicable	Not applicable	XB	F
Feature	Memory bank selection	Not applicable	Not applicable	XB	F
Feature	Delete memory	Not applicable	Not applicable	XB	F
Feature	Delete last measurement	Not applicable	Not applicable	XB	F
Date and Time					
Feature	Date and Time settings	Down, Set and Up	Down, Set and Up	EP	F
Feature	Alarm settings	Not applicable	Not applicable	XB	F
Feature	Date and Time announcement	Not applicable	Not applicable	XB	F
Statistics					
Feature	Show Average	Not applicable	Not applicable	XB	F
Feature	Show Alternative Average	Not applicable	Not applicable	XB	F
Feature	Show Plot	Not applicable	Not applicable	XB	F
Settings					
Feature	Settings	Set	Set	EP	F
Feature	Confirm	Not applicable	Not applicable	XB	F
Feature	Measurement unit settings	Not applicable	Not applicable	XB	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Change language	User	User	EP	F

Comparison of BPM-Specific Details

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
BPM Device Hardware					
Cuffs					
Core (Clinical)	Cuff List	Style 1	Style 1	EP	C
Sensors					
Core (Technical)	Number of pressure sensors	1	1	EP	C
Core (Technical)	Pressure sensor type	Strain gauge	Strain gauge	EP	C
Core (Technical)	Pressure sensor model number(s)/code(s)	ADP1131	ADP1131	EP	C
Core (Technical)	Pressure sensor cross-check	Not provided	Not provided	EB	C
Documentation	Pressure sensor details supplied	Yes	Yes	--	–
Core (Technical)	Positioning sensor type	Capacitive position sensor	Capacitive position sensor	EP	C
Core (Technical)	Positioning sensor model number(s)/code(s)	BS812A-1	BS812A-1	EP	C
Documentation	Positioning sensor details supplied	Yes	Yes	--	–
Core (Technical)	Cuff-Wrapping Sensor	Not provided	Not provided	EB	C
Core (Technical)	ECG sensor	No sensor	No sensor	EB	C
Documentation	ECG sensor details supplied	Not applicable	Not applicable	--	–
Core (Technical)	Korotkoff-sound sensor	No sensor	No sensor	EB	C
Documentation	Korotkoff-sound sensor details supplied	Not applicable	Not applicable	--	–
Core (Technical)	Activity sensor	Not provided	Not provided	EB	C
Documentation	Activity sensor details supplied	Not applicable	Not applicable	--	–
Signal Processing					
Core (Technical)	Amplifier model number(s)/code(s)	LM324DR	LM324DR	EP	C
Core (Technical)	Analogue filter model number(s)/code(s)	Not applicable	Not applicable	XB	C
Core (Technical)	Analogue-to-digital convertor model number(s)/code(s)	ADC within Micom (ATSAM4S16CA)	ADC within Micom (ATSAM4S16CA)	EP	C
Core (Technical)	Pressure Sampling rate	1000 Hz	1000 Hz	EP	C
Pneumatic Hardware					
Core (Technical)	Pneumatic pump model number/code	P54A-0001R (abr P54A01R) or RFP45J-0002R (abr RFP45J02R)	P54A-0001R (abr P54A01R) or RFP45J-0002R (abr RFP45J02R)	EP	C
Documentation	Pneumatic pump details supplied	Yes	Yes	--	–

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Core (Technical)	Exhaust valve model number/code	KSV15C-6I	KSV15C-6I	EP	C
Documentation	Exhaust valve details supplied	Yes	Yes	--	–
Core (Technical)	Safety Release Valve	Not provided	Not provided	EB	C
Accessories					
Accessory	Cuff Holder	Cuff integrated into device	Cuff integrated into device	XB	A
BPM Device Software					
Memory					
Feature	SBP Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	DBP Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	PR Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	MAP Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Generic Event Code Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Medication Code Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Atrial Fibrillation Code Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Arrhythmia/IHB Code Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	BP Grade Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Body Movement Code Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Bed and Rising Times Stored	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Ranges					
Core (Technical)	Maximum Pressure (Upper Limit of Upper Technical Alarm Condition Range)	300 mmHg	300 mmHg	EP	C
Core (Technical)	Upper Limit of Rated Range	280 mmHg	280 mmHg	EP	C
Core (Technical)	Lower Limit of Rated Range	30 mmHg	30 mmHg	EP	C
Core (Technical)	Minimum Pressure (Lower Limit of Low Technical Alarm Condition Range)	0 mmHg	0 mmHg	EP	C
Core (Technical)	Maximum SBP	280 mmHg	280 mmHg	EP	C
Core (Technical)	Minimum SBP	60 mmHg	60 mmHg	EP	C
Core (Technical)	Maximum DBP	200 mmHg	200 mmHg	EP	C
Core (Technical)	Minimum DBP	30 mmHg	30 mmHg	EP	C
Core (Technical)	Maximum PP	250 mmHg	250 mmHg	EP	C
Core (Technical)	Minimum PP	15 mmHg	15 mmHg	EP	C
Core (Technical)	Maximum PR	240 bpm	240 bpm	EP	C
Core (Technical)	Minimum PR	30 bpm	30 bpm	EP	C
Specified Accuracy					
Core (Technical)	Specified BP Accuracy (±)	2 mmHg	2 mmHg	EP	C
Core (Technical)	Specified PR Accuracy (±)	1.5 %	1.5 %	EP	C

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
BPM Device Firmware					
Analysis					
Feature	Overall arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last overall 3-meas arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last overall 7-day arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last overall ESH arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Overall median	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Overall morning arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last morning 3-meas arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last morning 7-day arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Overall evening arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last evening 3-meas arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	Last evening 7-day arithmetic mean	Not applicable (No memory facility)	Not applicable (No memory facility)	XB	F
Feature	BP Classification	Not provided	Not provided	EB	F
Feature	Pulse Classification	Not provided	Not provided	EB	F
Feature	Measurement-Target BP difference	Not provided	Not provided	EB	F
BPM Device Features					
Technical					
Core (Technical)	Operation Method	Oscillometry: automatic during deflation	Oscillometry: automatic during deflation	EP	C
Feature	Single Measurements	Yes	Yes	EP	F
Feature	Double Measurement	Not provided	Not provided	EB	F
Feature	Triple Measurement	Not provided	Not provided	EB	F
Feature	Measurements at ESH-recommended times	Not provided	Not provided	EB	F
Feature	ABPM Measurement Occurrences	Device does not support ABPM	Device does not support ABPM	XB	F
Feature	ABPM duration	Not applicable (Not ABPM)	Not applicable (Not ABPM)	XB	F
Core (Technical)	Continuous Measurements	Not provided	Not provided	EB	C
Feature	Continuous mode frequency	Not applicable (No continuous mode)	Not applicable (No continuous mode)	XB	F
Core (Technical)	ECG triggered measurements (ECG used to confirm Korotkoff sounds)	Not provided	Not provided	EB	C
Feature	Measurement Interval Set	Not applicable	Not applicable	XB	F
Feature	Measurement Times Set	Not applicable	Not applicable	XB	F
Core (Clinical)	Repeat measurement	No automatic repeat provided	No automatic repeat provided	EB	C
Feature	Suspend Multiple/ABPM measurements	Not applicable (No multiple measurements)	Not applicable (No multiple measurements)	XB	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Calibration					
Feature	Calibration Mode	Not provided	Not provided	EB	F
Core (Technical)	Recommended Calibration Intervals	Not applicable	Not applicable	EP	C
Feature	Recalibrate Reminder	Not provided	Not provided	EB	F
Special Measurements					
Core (Technical)	Test Measurements	None	None	EB	C
Core (Clinical)	Measurements triggered by ECG event	Not provided	Not provided	EB	C
Feature	Measurements triggered by posture	Not provided	Not provided	EB	F
Feature	Measurements triggered by activity	Not provided	Not provided	EB	F
Feature	Manually triggered measurements (ABPM only)	Not provided	Not provided	EB	F
Procedure					
Core (Technical)	Positioning Check	Yes	Yes	EP	C
Core (Technical)	Zero Pressure Check	Not provided	Not provided	EB	C
Core (Technical)	Inflation Method	Automatic after manual-initiated start	Automatic after manual-initiated start	EP	C
Core (Technical)	Inflation Rate	Depends on upper arm thickness and expected SBP value	Depends on upper arm thickness and expected SBP value	EP	C
Core (Technical)	Inflation Target	Measurement during inflation – SBP dependent	Measurement during inflation – SBP dependent	EP	C
Core (Technical)	Inflation Target Value(s)	Not applicable	Not applicable	XB	C
Core (Technical)	Deflation Method	Logical control (drop after SBP)	Logical control (drop after SBP)	EP	C
Core (Technical)	Deflation Rate	4	4	EP	C
Measurement					
Feature	Measurement Units	mmHg only	mmHg only	EP	F
Core (Clinical)	Systolic Blood Pressure (SBP)	On Screen and Report	On Screen and Report	EP	C
Core (Clinical)	Diastolic Blood Pressure (DBP)	On Screen and Report	On Screen and Report	EP	C
Core (Clinical)	Pulse Rate (PR)	On Screen and Report	On Screen and Report	EP	C
Core (Clinical)	Measured Mean Arterial Pressure (MAP)	Not provided	Not provided	EB	C
Feature	Estimated Mean Arterial Pressure (MAP)	Optionally on Report only	Optionally on Report only	EP	F
Feature	Pulse Pressure (PP)	Optionally on Report only	Optionally on Report only	EP	F
Feature	Pressure Rate Product (PRP)	Optionally on Report only	Optionally on Report only	EP	F
Feature	Left and right arm pressures	Not provided	Not provided	EB	F
Core (Clinical)	Central Aortic Pressures	Not provided	Not provided	EB	C
Feature	Ankle-Brachial Index	Not provided	Not provided	EB	F
Core (Technical)	Technical Alarm Condition	Included in standard out-of-range error	Included in standard out-of-range error	EP	C

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Arterial Stiffness Index	Not provided	Not provided	EB	F
Feature	Posture	Not provided	Not provided	EB	F
Feature	Activity Level	Not provided	Not provided	EB	F
ISO Certification - Manual Devices					
Documentation	ISO-81060-1 Certification (Manual devices only)	Not applicable (automatic)	Not applicable (automatic)	--	–
Documentation	Date of ISO Certification (Manual devices only)	Not applicable	Not applicable	--	–
BPM Screen and Audio Indicators					
Measurement					
Before Measurement					
Feature	Measurement Mode	Function not provided	Function not provided	EB	F
Feature	Arm positioning indicator	Special Icon	Special Icon	EP	F
Feature	Wrist positioning indicator	Function not provided	Function not provided	EB	F
Feature	Posture indicator	Function not provided	Function not provided	EB	F
Feature	Cuff wrapping indicator	Function not provided	Function not provided	EB	F
Feature	Left/Right Limb Selection	Function not provided	Function not provided	EB	F
Feature	Inflation Target Selection	Not applicable for intended device use	Not applicable for intended device use	XB	F
Feature	Threshold Selection	Function not provided	Function not provided	EB	F
Feature	Memory zone	Function not provided	Function not provided	EB	F
During Measurement					
Feature	Inflation	Reuse of 7-segment characters	Reuse of 7-segment characters	EP	F
Feature	Deflation	Reuse of 7-segment characters	Reuse of 7-segment characters	EP	F
Feature	Heartbeat Indicator	Special Icon	Special Icon	EP	F
Feature	Pressure	Digital value	Digital value	EP	F
After Measurement					
Feature	SBP	Always shown	Always shown	EP	F
Feature	DBP	Always shown	Always shown	EP	F
Feature	Measured MAP	Not provided	Not provided	EB	F
Feature	PR	Always shown	Always shown	EP	F
Feature	Posture	Function not provided	Function not provided	EB	F
Feature	Activity Level	Function not provided	Function not provided	EB	F
Feature	Pulse Wave Pattern	Available on printout	Available on printout	EP	F
Derived Values					
Feature	PP	Available on printout	Available on printout	EP	F
Feature	Estimated MAP ((SBP + 2 × DBP) / 3)	Available on printout	Available on printout	EP	F
Feature	Pressure Rate Product (PRP = SBP × PR)	Available on printout	Available on printout	EP	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Average – Morning	Function not provided	Function not provided	EB	F
Feature	Average – Evening	Function not provided	Function not provided	EB	F
Feature	BP Classification	Classification not indicated	Classification not indicated	EB	F
Feature	Pulse Classification	Function not provided	Function not provided	EB	F
Feature	Arrhythmias	Function not provided	Function not provided	EB	F
Feature	Haemodynamic Stability	Function not provided	Function not provided	EB	F
Feature	Inter-Arm Difference	Function not provided	Function not provided	EB	F
Feature	Arterial Stiffness	Function not provided	Function not provided	EB	F
Feature	Visit doctor	Function not provided	Function not provided	EB	F
Error Indicators					
Feature	Body-Movement Error	Function not provided	Function not provided	EB	F
Feature	Air leak/Cuff Connection Error	Function not provided	Function not provided	EB	F
Feature	Ambient temperature Error	Function not provided	Function not provided	EB	F
Feature	Measurement Reliability Error	Function not provided	Function not provided	EB	F
Feature	Measurement being repeated	Function not provided	Function not provided	EB	F
Markers					
Feature	Event – Generic	Function not provided	Function not provided	EB	F
Feature	Event – Bed Time & Rising Time	Function not provided	Function not provided	EB	F
Memory					
Feature	Pulse Rate from Memory	Not provided	Not provided	EB	F
Special Measurements					
Feature	Test Measurements	Function not provided	Function not provided	EB	F
Feature	Test Successful	Function not provided	Function not provided	EB	F
Non-Measurement					
Settings					
Feature	Button Lock	Function not provided	Function not provided	EB	F
Audio Indicators					
Feature	Measurement imminent	None	None	EB	F
Feature	Pulse signal detected	Not applicable (No sound)	Not applicable (No sound)	XB	F
BPM Buttons and Switches					
Safety					
Feature	Immediate Exhaust	Emergency	Emergency	EP	F
Mode					
Feature	Mode: Single Measurement	Start/Stop	Start/Stop	EP	F
Feature	Mode: Double Measurement	Not applicable	Not applicable	XB	F
Feature	Mode: Triple Measurement	Not applicable	Not applicable	XB	F
Feature	Mode: Home Measurement	Not applicable	Not applicable	XB	F
Feature	Mode: ABPM	Not applicable	Not applicable	XB	F

Item Category	Item Description	Reference Device	Test Device	Comparison	Category
Feature	Mode: Nocturnal repeated measurements	Not applicable	Not applicable	XB	F
Feature	Mode: Diagnostic	Not applicable	Not applicable	XB	F
Feature	Mode: ESH controlled	Not applicable	Not applicable	XB	F
Feature	Mode: Auscultation/Manual	Not applicable	Not applicable	XB	F
Feature	Mode: Automatic	Not applicable	Not applicable	XB	F
Settings					
Feature	Manual Threshold Selection	Not applicable	Not applicable	XB	F
Feature	Left/Right Limb Selection	Not applicable	Not applicable	XB	F
Feature	Inflation Target Selection	Not applicable	Not applicable	XB	F
Event					
Feature	Event: Generic	Not applicable	Not applicable	XB	F
Feature	Event: Medication	Not applicable	Not applicable	XB	F
Feature	Event: Bed Time	Not applicable	Not applicable	XB	F
Feature	Event: Rising Time	Not applicable	Not applicable	XB	F

Summation of Comparisons

Category			Identity	Core	Feature	Accessory	Core Breakdown			Total
Comparison		**Code**	**I**	**C**	**F**	**A**	**Biological**	**Clinical**	**Technical**	
Identical provision on both devices		**EP**	5	56	48	18	0	5	51	127
Equivalent provision on both devices		**EL**	2	0	0	1	0	0	0	3
Not provided on either device		**EB**	0	14	68	10	0	4	10	92
Similar-level provisions on both devices		**BL**	0	0	0	0	0	0	0	0
Different provisions on each device		**BP**	0	0	0	0	0	0	0	0
Provided on Reference but not on Test Device		**RP**	0	0	0	0	0	0	0	0
Better provision on Reference Device		**RL**	0	0	0	0	0	0	0	0
Provided on Test but not on Reference Device		**TP**	0	0	0	0	0	0	0	0
Better provision on Test Device		**TL**	0	0	0	0	0	0	0	0
Not comparable		**XP**	0	0	0	0	0	0	0	0
Not applicable for this device functionality		**XB**	4	2	77	15	0	0	2	98
Value missing for Reference Device		**MR**	0	0	0	0	0	0	0	0
Value missing for Test Device		**MT**	0	0	0	0	0	0	0	0
Values missing for both devices		**MB**	0	0	0	0	0	0	0	0
Check if provision is identical or similar		**QL**	0	0	0	0	0	0	0	0
Check free text entries		**QP**	0	0	0	0	0	0	0	0
Totals	**Formulae**									
Equal items	∑EP + ∑EL + ∑EB	**En**	7	70	116	29	0	9	61	222
Different	Rn + Tn + Bn	**Dn**	0	0	0	0	0	0	0	0
Favouring Reference	∑RP + ∑RL	**Rn**	0	0	0	0	0	0	0	0
Favouring Test	∑TP + ∑TL	**Tn**	0	0	0	0	0	0	0	0
Favouring Neither	∑BP + ∑BL	**Bn**	0	0	0	0	0	0	0	0
Missing	∑MR + ∑MT + ∑MB	**Mn**	0	0	0	0	0	0	0	0
Queries	∑QP + ∑QL	**Qn**	0	0	0	0	0	0	0	0
Not Compared	∑XP + ∑XB	**Xn**	4	2	77	15	0	0	2	98
Overall Sum	En + Dn + Mn + Qn + Xn	**Sn**	11	72	193	44	0	9	63	320
Applicable Sum	Sn – Xn	**An**	7	70	116	29	0	9	61	222

Equivalence and Comparative Analysis

Equivalence Analysis			
Description	**Formulae**	**Core**	
Not Equivalent	Dn-C > 0	False	
Incomplete Core	Mn-C > 0	False	
Core Queries	Qn-C > 0	False	
Equivalence Proven	Reject if any Criteria Test results are TRUE	True	

Comparative Analysis Completion Check				
Description	**Formulae**		**Feature**	**Accessory**
Sufficiency for Reference Device	(Sn - Qn - MR - MB) / Sn ≥ 66%, 88%		193 (100.0%) Complete	44 (100.0%) Complete
Sufficiency for Test Device	(Sn - Qn - MT - MB) / Sn ≥ 66%, 88%		193 (100.0%) Complete	44 (100.0%) Complete
Sufficiency for Comparison	(Sn - Qn - Mn) / Sn ≥ 66%, 88%		193 (100.0%) Complete	44 (100.0%) Complete
Overall Sufficiency	Minimum of above ≥ 66%, 88%		(100.0%) Complete	
Details Queries	Qn-F + Qn-A > 0		False (0 outstanding)	
Details finalised	Reject if Queries or Insufficient		True	

Comparative Analysis Results Check			
Option	**Formulae**		**Feature + Accessory**
Identical	Dn-F = 0 ⋀ Dn-A = 0		True
Common	Dn-F = 0 ⋀ Dn-A > 0 ⋁ Rn-F = 0 ⋀ Tn-F = 0 ⋀ En-F ≥ 9 × Bn-F		True
Simpler	Rn-F > 0 ⋀ Tn-F = 0 ⋁ Tn-F > 0 ⋀ Rn-F ≥ 3 × Tn-F		False
Superior	Tn-F > 0 ⋀ Rn-F = 0 ⋁ Rn-F > 0 ⋀ Tn-F ≥ 3 × Rn-F		False
Diverse	0 < Rn-F < 3 × Tn-F ⋀ 0 < Tn-F < 3 × Rn-F ⋀ Rn-F + Tn-F ≥ 3 × B-Fn		False
Common-Diverse	Rn-F = 0 ⋀ Tn-F = 0 ⋀ En-F < 9 × Bn-F ⋁ 0 < Rn-F < 3 × Tn-F ⋀ 0 < Tn-F < 3 × Rn-F ⋀ Rn-F + Tn-F < 3 × Bn-F		False
Comparative Result			**Identical** *This denotes the situation where the test device has identical functions/accessories to the reference device.*

Appendix 1 – Medaval Comparative-Equivalence Procedure

Cover Page

Medaval Comparative-Equivalence Procedure

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Summary

Summary

This document describes equivalence for medical devices in accordance with MEDDEV 2.7/1 revision 4.

- In compliance with Council Directive 93/42/EEC as amended by directive 2007/47/EC
- Used to compare devices described under Medaval Device Registration with Core measurement-critical items indicated as Technical, Clinical or Biological, in accordance with MEDDEV 2.7/1 revision 4
- Identifies how each item is compared to corresponding item on the paired device
- Standard critical core items compared to ensure equality or equivalence, in accordance with MEDDEV 2.7/1 revision 4.
- Identity, Features and Accessories indicted, in Device Registration, compared to identify device differences in accordance with MEDDEV 2.7/1 revision 4.
- Provides summary comparison for equivalent devices
- Identifies "Families" of devices where each pair are equivalent to each other
- Results provided in Clinical Evaluation Reports prepared in accordance with MEDDEV 2.7/1 revision 4.
- Evaluations conducted by renowned experts in Blood Pressure Measurement with proven and published experience in protocol development and validation.

Equivalence and Validation

- Equivalence is independent of validation.
- Validation is only of one functionality, normally the the measurement technology. The particular device used in a validation can be any that uses that technology.
- Validation of a measurement technology is therefore applied to all devices within a family i.e. all those with proven to be equivalent for that technology.
- Existing validations are applied immediately. Subsequent validations are applied once published.
- Equivalence of cuffs means that where one cuff was proved accurate with the technology, all equivalent cuffs can be used also.

Appendix 2 –Comparative-Equivalence of all Devices in Family

The SELVAS ACCUNIQ BP600 and the SELVAS ACCUNIQ BP500 are just two devices in a family of devices that have been proven to be mutually equivalent. The other devices are the SELVAS ACCUNIQ BP501, the SELVAS ACCUNIQ BP503, the SELVAS ACCUNIQ BP650, the SELVAS ACCUNIQ BP651 and the SELVAS ACCUNIQ BP653.

In summary, the model number digits describe the differences between the devices. The first digit is either 5 (button material ABS) or 6 (button material acrylic). The second digit is either 0 (no BP classification provided) or 5 (BP classification and a separate arm positioning indicator) and the third digit is either 0 (thermal printer and derived values only provided on a printout, indigo start stop button and indigo deco cover), 1 (no printer and no derived values, green start stop button and grey deco cover) or 3 (thermal printer and the printed derived values, green start stop button and grey cuff deco cover).

Proof of the other equivalences are contained in separate reports and summarised below.

Comparative Result		Test Device						
		BP500	**BP501**	**BP503**	**BP600**	**BP650**	**BP651**	**BP653**
Reference Device	**BP500**	Same	Simpler	Identical	Identical	Superior	Diverse	Superior
	BP501	Superior	Same	Superior	Superior	Superior	Superior	Superior
	BP503	Identical	Simpler	Same	Identical	Superior	Diverse	Superior
	BP600	Identical	Simpler	Identical	Same	Superior	Diverse	Superior
	BP650	Simpler	Simpler	Simpler	Simpler	Same	Simpler	Identical
	BP651	Diverse	Simpler	Diverse	Diverse	Superior	Same	Superior
	BP653	Simpler	Simpler	Simpler	Simpler	Identical	Simpler	Same

Legend: Identical means equivalent and no effective differences in features or accessories; Diverse means equivalent and each device has features not available on the other; Superior means equivalent and more features; Simpler means equivalent and fewer features

Item Description	ACCUNIQ BP500	ACCUNIQ BP501	ACCUNIQ BP503	ACCUNIQ BP600	ACCUNIQ BP650	ACCUNIQ BP651	ACCUNIQ BP653
Device Image							
Display							
Integrated Printer	Yes	No	Yes	Yes	Yes	No	Yes
Availability of printed PP, Estimated MAP, PRP and plot	Yes	No	Yes	Yes	Yes	No	Yes
Button Material	ABS	ABS	ABS	Acrylic	Acrylic	Acrylic	Acrylic
Start/Stop Button Colour	Indigo	Green	Green	Indigo	Indigo	Green	Green
Deco Cover Colour	Indigo	Grey	Grey	Indigo	Indigo	Grey	Grey
BP Classification	No	No	No	No	Yes	Yes	Yes
Arm positioning indicator	Heart	Heart	Heart	Heart	Special Icon	Special Icon	Special Icon