Supplementary data

Conformity assessment with ISO 81060-2:2018 + A1:2020

1. Purpose

The evaluation uses the clinical investigation data(NTUH-REC No.:201805046RSB) of ISO 81060-2:2013 non-invasive sphygmomanometers-Part2 Clinical investigation of intermittent automated measurement type, and evaluates its compliance with the specifications in accordance with the new version of the specification ISO 81060-2:2018+A1: 2020.

2. Scope

The scope for AViTA arm sphygmomanometer with the same Intended for use, main components (such as cuff, sensor, microcontroller, etc.), and algorithm.

- 3. Requirements
 - NTUH-REC No.:201805046RSB Clinical investigation Raw data
 - ISO 81060-2:2013 Non-invasive sphygmomanometers-Part2 Clinical investigation automated measurement type
 - ISO 81060-2:2018 Non-invasive sphygmomanometers-Part2 Clinical investigation of intermittent automated measurement type
 - ISO 81060-2:2020 Non-invasive sphygmomanometers-Part2 Clinical investigation of intermittent automated measurement type AMENDMENT 1
- 4. Analysis and Results

IS0 81060-2:2013 Section	IS0 81060-2:2018+A1:2020	Clinical Data Results	Pass	Fail
	Section			
5.1.1 Number	5.1.1 Number	85 Subjects , total 255	V	
An auscultatory REFERENCE	An auscultatory REFERENCE	valid paired (Three		
SPHYGMOMANOMETWE	SPHYGMOMANOMETWE	valid paired for each		
CLINICAL INVESTIGATION	CLINICAL INVESTIGATION	subject)		
shall consist of a minimum of	shall consist of a minimum of			
85 subjects. If not otherwise	85 subjects. If not otherwise			
specified, at least three valid	specified, at least three valid			
paired BLOOD PRESSURE	paired BLOOD PRESSURE			
values shall be taken for each	values shall be taken for each			
subject. There shall be a	subject. There shall be a			
minimum of 255 valid paired	minimum of 255 valid paired			
BLOOD PRESSURE values.	BLOOD PRESSURE values.			
5.1.2 Gender distribution	5.1.2 Gender distribution	45 (53%) male and 40	V	
At least 30 % of the subjects	At least 30 % of the subjects	(47%) female		
shall be male and At least 30	shall be male and At least 30			
% of the subjects shall be	% of the subjects shall be			
female.	female.			
5.1.3 Age distribution	5.1.3 Age distribution	All subjects Age	V	

Table A IS0 81060-2 Section

IS0 81060-2:2013 Section	IS0 81060-2:2018+A1:2020	Clinical Data Results	Pass	Fail
	Section			
For a sphygmomanometer	For a sphygmomanometer	greater than 12 years.		
intended for use on adults or	intended for use on adults or			
adolescent patients, the age	adolescent patients, the age			
of every subject included in	of every subject included in			
the clinical investigation shall	the clinical investigation shall			
be greater than 12 years.	be greater than 12 years.			
5.1.4 Limb size distribution	5.1.4 Limb size distribution	- Subjects Arm size	V	
For a sphygmomanometer	Limb circumferences shall	range between		
intended for use with a single	be distributed as follows:	22cm to 27cm is		
cuff size:	- at least 20% of the	24%.		
- at least 40 % of the subjects	subjects shall have a limb	- Subjects Arm size		
shall have a limb	circumference which lies	range between		
circumference which lies	within each quarter of the	27cm to 32cm is		
within the upper half of the	TOTAL LIMB	35%.		
specified range of use of the	CIRCUMFERENCE	- Subjects Arm size		
cuff and at least 40 % of the	RANGE.	range between		
subjects shall have a limb		32cm to 37cm is		
circumference within the lower		21%		
half of the specified range of		- Subjects Arm size		
use of the cuff		range between		
		37cm to 42cm is		
		20%.		
-at least 20 % of the subjects	-at least 10% of the subjects	- Subjects Arm size	V	
shall have a limb	shall have a limb	range highest than		
circumference which lies	circumference which lies	39.5cm is 10%.		
within the upper quarter of the	within the highest octile of	 Subjects Arm size 		
specified range of use of the	the TOTAL LIMB	range lowest than		
cuff and at least 20 % of the	CIRCUMFERENCE RANGE.	24.5cm is 14%.		
subjects shall have a limb	-at least 10% of the subjects			
circumference within the lower	shall have a limb			
quarter of the specified range	circumference which lies			
of use of the cuff.	within the lowest octile of			
	the TOTAL LIMB			
	CIRCUMFERENCE RANGE.			
5.1.5 Blood pressure	5.1.5 Blood pressure	11% of the reference	V	
distribution	distribution	blood pressure		
At least 5 % of the reference	At least 5 % of the reference	readings have a		
blood pressure readings shall	blood pressure readings shall	systolic blood		
have a systolic blood pressure	have a systolic blood pressure	pressure ≤100 mmHg		
≤100 mmHg (13,33 kPa).	≤100 mmHg (13,33 kPa).			

IS0 81060-2:2013 Section	IS0 81060-2:2018+A1:2020	Clinical Data Results	Pass	Fail
	Section			
At least 5 % of the reference	At least 5 % of the reference	9% of the reference	V	
blood pressure readings shall	blood pressure readings shall	blood pressure		
have a systolic blood pressure	have a systolic blood pressure	readings have a		
≥160 mmHg (21,33 kPa).	≥160 mmHg (21,33 kPa).	systolic blood		
		pressure ≥160 mmHg		
At least 20 % of the reference	At least 20 % of the reference	25% of the reference	V	
blood pressure readings shall	blood pressure readings shall	blood pressure		
have a systolic blood pressure	have a systolic blood pressure	readings have a		
≥140 mmHg (18,66 kPa).	≥140 mmHg (18,66 kPa).	systolic blood		
		pressure ≥140 mmHg		
At least 5 % of the reference	At least 5 % of the reference	8% of the reference	V	
blood pressure readings shall	blood pressure readings shall	blood pressure		
have a diastolic blood	have a diastolic blood	readings have a		
pressure ≤60 mmHg (8,0	pressure ≤60 mmHg (8,0	diastolic blood		
kPa).	kPa).	pressure ≤60 mmHg		
At least 5 % of the reference	At least 5 % of the reference	8% of the reference	V	
blood pressure readings shall	blood pressure readings shall	blood pressure		
have a diastolic blood	have a diastolic blood	readings have a		
pressure ≥100 mmHg (13,33	pressure ≥100 mmHg (13,33	diastolic blood		
kPa).	kPa).	pressure ≥100 mmHg		
At least 20 % of the reference	At least 20 % of the reference	35% of the reference	V	
blood pressure readings shall	blood pressure readings shall	blood pressure		
have a diastolic blood	have a diastolic blood	readings have a		
pressure ≥85 mmHg (11,33	pressure ≥85 mmHg (11,33	diastolic blood		
kPa).	kPa).	pressure ≥85 mmHg		
5.1.6 Special patient	5.1.6 Special patient	Please refer to	V	
populations	populations	Clause 7.		
Note: Clause 7 has a specific	Note: Clause 7 has a specific			
example of a special patient	example of a special patient			
population with specific	population with specific			
requirements.	requirements			
7 Pregnant (including	7 Pregnant (including	Group1 passed 5.1	V	
pre-eclamptic) PATIENT	pre-eclamptic) PATIENT	and 5.2 and additional		
populations	populations	46 pregnant patients		
A sphygmomanometer that is	A sphygmomanometer that is	(Group2)		
intended for use in pregnant	intended for use in pregnant			
patients shall undergo clinical	patients shall undergo clinical			
investigation in that patient	investigation in that patient			
population. If the	population. If the			
sphygmomanometer has	sphygmomanometer has			

IS0 81060-2:2013 Section		ISC) 81060-2:2018+A1:2020	Clinical Data Results	Pass	Fail
		Se	ction			
passed the clinical			ssed the clinical			
investigation according to the			estigation according to the			
requirements given in 5.1 and			quirements given in 5.1 and			
5.2, then it shall undergo			2, then it shall undergo			
clir	nical investigation according	clir	nical investigation			
to	5.2 in at least an additional	ac	cording to 5.2 in at least an			
45	pregnant patients.	ad	ditional 45 pregnant			
		pa	tients.			
Fo	r any clinical investigation	Fo	r any clinical investigation	15 normotensive	V	
for	pregnant patients, the	for	pregnant patients, the	pregnant PATIENTS		
pa	tient population shall be	pa	tient population shall be			
eq	ually distributed, ± 1 patient,	eq	ually distributed, ± 1 patient,			
int	o the following three	inte	o the following three			
su	bgroups:	su	bgroups:			
a)	normotensive pregnant	a)	normotensive pregnant			
Í	PATIENTS beyond the first	ĺ	PATIENTS beyond the			
	trimester with SYSTOLIC		first trimester with			
	BLOOD PRESSURE <140		SYSTOLIC BLOOD			
	mmHg (18.66 kPa) and		PRESSURE <140 mmHa			
	DIASTOLIC BLOOD		(18.66 kPa) and			
	PRESSURE <90 mmHa		DIASTOLIC BLOOD			
	(12.00 kPa):		PRESSURE <90 mmHa			
	(,,,		(12.00 kPa):			
b)	hypertensive pregnant	b)	hypertensive pregnant	16 hypertensive	V	
Í	PATIENTS without	ĺ	PATIENTS without	pregnant PATIENTS		
	proteinuria > 300 mg in 24		proteinuria > 300 mg in 24			
	h and with SYSTOLIC		h and with SYSTOLIC			
	BLOOD PRESSURE ≥140		BLOOD PRESSURE ≥140			
	mmHg (18,66 kPa) or		mmHg (18,66 kPa) or			
	DIASTOLIC BLOOD		DIASTOLIC BLOOD			
	PRESSURE ≥ 90 mmHg		PRESSURE ≥ 90 mmHq			
	(12,00 kPa)		(12,00 kPa)			
C)	pre-eclampsia, PATIENTS	c)	pre-eclampsia, PATIENTS	15 pre-eclampsia	V	
ŕ	with proteinuria >300 mg in	ĺ	with proteinuria >300 mg	PATIENTS		
	24 h and DIASTOLIC		in 24 h and with			
	BLOOD PRESSURE ≥ 90		SYSTOLIC BLOOD			
	mmHg (12,00 kPa).		PRESSURE ≥140 mmHa			
			(18,66 kPa) or			
			DIASTOLIC BLOOD			
			PRESSURE ≥ 90 mmHg			

IS0 81060-2:2013 Section	IS0 81060-2:2018+A1:2020	Clinical Data Results	Pass	Fail
	Section			
	(12,00 kPa).			
5.2.4.1.2 Data analysis	5.2.4.1.2 Data analysis	Systolic-	V	
a) Criterion 1	a) Criterion 1	Mean: 1.10 mmHg		
i) According to blood	i) According to blood	Standard deviation:		
pressure mean value of	pressure mean value of	5.49mmHg		
differences, with in or	differences, with in or	Diastolic:		
equal to ±5.0mmHg	equal to ±5.0mmHg	Systolic-		
(±0.67kPa).	(±0.67kPa).	Mean: 2.90 mmHg		
ii)According to blood	ii)According to blood	Standard deviation:		
pressure standard	pressure standard	5.17mmHg		
deviation of differences,	deviation of differences,			
no greater than 8.0mmHg	no greater than 8.0mmHg			
(1.07kPa).	(1.07kPa).			
b) Criterion 2	b) Criterion 2	Svstolic-	V	
1) For the SYSTOLIC BLOOD	1) For the SYSTOLIC BLOOD	Mean: 1.10 mmHg		
PPRESSURE and	PPRESSURE and	Standard deviation:		
DIASTOLIC BLOOD	DIASTOLIC BLOOD	4.45mmHg		
PRESSURE for each of m	PRESSURE for each of m	(<6.89mmHg)		
subjects, the standard	subjects, the standard	Diastolic:		
deviation Sm of the	deviation Sm of the	Systolic-		
averaged paired	averaged paired	Mean: 2.90 mmHg		
DETERMINATIONS per	DETERMINATIONS per	Standard deviation:		
subject of the	subject of the	4.20mmHg		
SPHYGMOMANOMETER-	SPHYGMOMANOMETER-	(<6.30mmHg)		
UNDER-TEST and of the	UNDER-TEST and of the			
observers' readings with	observers' readings with			
the REFERENCE	the REFERENCE			
SPHYGMOMANOMETER	SPHYGMOMANOMETER			
shall meet the criteria listed:	shall meet the criteria			
i)Table1; or	listed:			
ii) Table2	i)Table1; or			
	ii) Table2			

	Maximum permissible standard deviation, s_m , as function of, \overline{x}_n									
\overline{x}_n	mmHg									
	0,0	0,1	0,2	0,3	0,4	0,5	0,6	0,7	0,8	0,9
±0,	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
±1,	6,87	<mark>6,8</mark> 6	6,84	6,82	<mark>6,</mark> 80	6,78	6,76	6,73	6,71	6,68
±2,	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
±3,	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5 <mark>,</mark> 83	5,77	5,70
±4,	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
±5,	4,79			_	_	_	—	_	_	
EXAMPLE For mean of ±4,2 mmHg, the maximum permissible standard deviation is 5,49 mmHg.										

Table 1 — Averaged subject data acceptance (criterion 2) in mmHg

Table 2 — Averaged subject data acceptance (criterion 2) in kPa

x	Maximum permissible standard deviation, s_m , as function of, \overline{x}_n kPa										
^n	0,000	0,010	0,020	0,030	0,040	0,050	0,060	0,070	0,080	0,090	
±0,0	0,926 6	0,926 6	0,926 6	0,926 6	0,926 6	0,924 6	0,923 3	0,922 3	0,921 3	0,920 3	
±0,1	0,919 3	0,918 3	0,917 3	0,916 3	0,915 2	0,913 8	0,911 9	0,909 9	0,907 9	0,905 9	
±0,2	0,903 9	0,900 7	0,898 9	0,897 0	0,894 6	0,890 6	0,887 8	0,885 5	0,882 6	0,878 5	
±0,3	0,875 6	0,872 3	0,867 9	0,864 1	0,860 1	0,856 2	0,851 9	0,847 1	0,841 4	0,837 4	
±0,4	0,833 3	0,828 3	0,822 6	0,816 9	0,811 9	0,805 9	0,799 9	0,793 3	0,785 3	0,779 3	
±0,5	0,773 9	0,766 9	0,759 9	0,753 1	0,746 3	0,738 8	0,731 9	0,723 7	0,715 7	0,707 7	
±0,6	0,699 9	0,6891	0,680 2	0,672 3	0,667 0	0,659 5	0,6488	0,638 6	_	_	
EXAMPI	EXAMPLE For mean of ±0,520 kPa, the maximum permissible standard deviation is 0,759 9 kPa.										

5. Conclusion

The results of the present study demonstrated that the AViTA Arm Type Blood Pressure Monitor passed the validation for both systolic and diastolic blood pressures according to the International Standard ISO 81060-2:2018+A1:2020.