Comments from external experts and manufacturers on **2nd draft assessment:**

"The 24-hour blood pressure measurement device Mobil-O-Graph® with the built-in pulse wave velocity algorithm ARCSolver® to measure arterial stiffness for the optimization of hypertension treatment and assessment of cardiovascular risk"

(Project ID: OTCA24)

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA JA3 WP4 - other technologies, OTCA24
All comments and author´s replies on the 2nd draft project plan "The 24-hour blood pressure measurement device Mobil-O-Graph® with the built-in pulse wave velocity algorithm ARCSolver® to measure arterial stiffness for the optimization of hypertension treatment and assessment of cardiovascular risk"

July 2020

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EXTERNAL EXPERTS

Comments were received from:

Name	Affiliation
MD, PhD Alfonso Bellia	Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy
dr. med. Thomas Schuh	Krankenanstalt Rudolfstiftung, Vienna, Austria

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Author's reply
Summary					
Dr. Schuh	15	238	Obtain instead of obtrain	3	Introduction has been deleted due to the new template
Description and technical characteristics of the technology					
Dr. Schuh	25	425	Different wording in Table and Headlines B0001-A0021	3	Has been changed to the same wording
Dr. Schuh	26	463	Brachial artery instead of A. brachialis	3	Has been changed to brachial artery
Dr. Schuh	27	472	Reference Error	3	Has been changed
Health problem and current use					
Dr. Schuh	35	659	Different wording in Table and Headlines A0002-A0011	3	Has been changed to the same wording
Dr. Schuh	37	690	Section -often called..- is redundant as its already mentioned in line 687	3	Section has been deleted
Dr. Schuh	39	830ff	Different spacing than in other sections	3	Has been changed
Dr. Schuh	41	930	Missing W in World Health Organisation	3	W has been added
Clinical effectiveness					

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Safety					
Appendix					

Note: Dr.Bellia did perform the fact check of the 2nd draft assessment and found it is suitable for publication without any other revisions, and no comments related to the assessment were received.

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MANUFACTURERS

Name	
Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH (IEM), Germany	Factual accuracy check
Austrian Institute of Technology (AIT) GmbH, Austria	Factual accuracy check

Comment from	Page number	Line/ section number	Description of factual inaccuracy and proposed amendment	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Author's reply
AIT	12	Comparison	"Invasive Pulse wave analysis (PWA) will not be included as a comparator" it is quite unclear, why the gold standard measurement is not considered as comparator?	1	The invasive measurement is not relevant for the outpatient and primary care setting being evaluated.
AIT	11	203	CPT Code USA The AMA assigned a Category I CPT Code, 93050, for use in reporting noninvasive central arterial pressure waveform analysis. In Germany IGeL GOÄ Zahlen 637/639a/648a		Unsure of the relevance. Not added.
AIT	15	263-5	pulse wave velocity is not currently 263 recommended in either the management of hypertension, here, GL for management of cardiovascular disease during pregnancy are cited. Instead, ESC/ESH GL on Hypertension should be cited (your Ref 9). In these GL, PWV is recommended for management of hypertension, although as 2b recommendation.	1	Changed accordingly.
AIT	19	380	Studies comparing to invasive methods or methods that are only available in a hos-pital (MRI, CT scan) will be excluded. Studies comparing invasive/ MRI based measurements with	1	The invasive measurement is not relevant for the outpatient and primary care setting being evaluated.

Comment from	Page number	Line/ section number	Description of factual inaccuracy and proposed amendment	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Author's reply
			MOGARCSolver based noninvasive measurements are the gold-standard of tachnical validation and should not be excluded.		
AIT	32	569	Recording Time and Method not applicable to Mobil-O-Graph NG (Comparator 1)	1	Changed accordingly
AIT	32	586-587	This sentence seem be an artefact as it makes no sense, i. e., with regard to the following paragraph.	1	Changed accordingly.
AIT	33	618-619	The statement about administration of other technologies is misleading, as 24h and cuff based analysis is only available for BP-Lab, Arteriograph. PulsePen uses manual tonometer and is therefore not comparable.	1	All comparators were used as in the studies as long as they were not inpatient.
AIT	34	654	CPT Code USA The AMA assigned a Category I CPT Code, 93050, for use in reporting noninvasive central arterial pressure waveform analysis. In Germany IGeL GOÄ Zahlen 637/639a/648a	1	Not relevant.
AIT	21	396	Studies similar to De La Sierra missing The largest study, which was am international multicenter study, is missing here. 24 hour CSBP by MOGARC was closer associated with LV mass and hypertrophy, as compared to 24 hour brachial SBP. • Weber T, Wassertheurer S, Schmidt-Trucksäss A, Rodilla E, Ablasser C, Jankowski P, Muiesan ML, Giannattasio C, Mang C, Wilkinson I, Kellermair J, Hametner B, Pascual JM, Zweiker R, Czarnecka D, Paini A, Salvetti M, Maloberti A, McEniery C. Relationship between 24 hour ambulatory central systolic blood pressure and left ventricular mass – a prospective multicentre study. Hypertension 2017;70:1157-1164 The following studies described findings from MOGARC and organ damage: Protogerou, Argyris; J Hypertens 2014 32:1805–1814; Aissoppou et al, Am J Hypertens 2015; Zhang et al, Journal of Human Hypertension (2014), 1–7; Negishi Am J Hypertens 2016; Nakagomi AM J Hypertens 2016; P	1	Excluded due to comparator.
AIT	42	963…	Relevant IOCD 10 codes Ischemic heart disease is missing	1	
AIT	45	1031 …	More difficult than the mortality rate, is to determine the prevalence of hypertension		Will be included in the Austrian adaptation. For this study, excluded

Comment from	Page number	Line/ section number	Description of factual inaccuracy and proposed amendment	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Author's reply
			There are several new studies dealing with the prevalence and control of hypertension in Austria, which should be mentioned + Rohla M, Haberfeld H, Tscharre M, Huber K and Weiss TW. Awareness, treatment, and control of hypertension in Austria: a multicentre cross-sectional study. *J Hypertens*. 2016;34:1432-40. + Danninger K, Hafez A, Binder RK, Aichberger M, Hametner B, Wassertheurer S and Weber T. High prevalence of hypertension and early vascular aging: a screening program in pharmacies in Upper Austria. *J Hum Hypertens*. 2020; 34:326-334. + Perl S, Zweiker D, Niederl E, Kolesnik E, Zweiker G, Kraler E, Stoff I, Haberfeld H, Dichtl W, Koppelstatter C, Lhotta K, Ederer H, Putz-Bankutti C, Beaney T, Xia X, Poulter NR and Weber T. May Measurement Month 2017: an analysis of blood pressure screening results in Austria-Europe. *Eur Heart J Suppl*. 2019;21:D17-D20.		due to lack of comparator or irrelevant comparator.
AIT	51	1234	Critical shortcomings of Ref [67] and [22] (Salvi et al) see communication: DOI:10.13140/RG.2.2.30172.13441; DOI: 10.13140/RG.2.2.20236.05765	1	Was not part of the review and does not influence conclusion.
AIT	51	1245	Missing study The largest study, which was am international multicenter study, is missing here. 24 hour CSBP by MOGARC was closer associated with LV mass and hypertrophy, as compared to 24 hour brachial SBP. • Weber T, Wassertheurer S, Schmidt-Trucksäss A, Rodilla E, Ablasser C, Jankowski P, Muiesan ML, Giannattasio C, Mang C, Wilkinson I, Kellermair J, Hametner B, Pascual JM, Zweiker R, Czarnecka D, Paini A, Salvetti M, Maloberti A,		Excluded due to comparator.

Comment from	Page number	Line/ section number	Description of factual inaccuracy and proposed amendment	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Author's reply
			McEniery C. Relationship between 24 hour ambulatory central systolic blood pressure and left ventricular mass – a prospective multicentre study. Hypertension 2017;70:1157-1164		
AIT	56	1305	Missing studies Several other studies used MOGARC for risk stratification: Matschkal ez al, Am J Nephrol 2019;49:317–327; Sarafidis, Loutradis, et al, J Hypertens 2019; Salvadé et al. BMC Nephrology (2015) 16:62; Wassertheurer et al; Journal of Hypertension 2015, 33:1884–1889; Baumann, Wassertheurer, Suttmann et al, J Hypertens 2014		Excluded due to comparator. No comparator.
AIT	56	1308	Missing studies The following studies described findings from MOGARC and organ damage: Protogerou, Argyris; J Hypertens 2014 32:1805–1814; Aissoppou et al, Am J Hypertens 2015; Zhang et al, Journal of Human Hypertension (2014), 1–7; Negishi Am J Hypertens 2016; Nakagomi AM J Hypertens 2016; P		Excluded due to comparator. No comparator.
AIT	56	1308	Missing studies The following study describes therelationship between early vascular aging defined by measures from ARCS with risk factors: Weber et al; Journal of Hypertension 2019, 37:2404–2413		Excluded due to comparator. No comparator.
AIT	58	1362	" No evidence was found on the accuracy of the device." This is probably incorrect (see the 25 pages of the document before this statement) and misplaced in th chapter of safety		Changed accordingly. It was supposed to be safety.
AIT	73	1766	Papaioannou, T. G. T., J.Benas, D.Triantafyllidi, H.Kostelli, G.Pavlidis, G.Kousathana, F.Katogiannis, K.Vlastos, D.Lambadiari, V.Papadavid, E.Parissis, J.Tousoulis, D.Ikonomidis, I. (2019). "Measurement of central augmentation index by three different methods and techniques: Agreement among Arteriograph, Com-plior, and Mobil-O-Graph devices." Journal of Clinical Hypertension 21(9): 1386-1392.	1	Excluded.

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			Wrong classification in table "2"		

Note: The 2nd draft assessment was sent to IEM, but no comments related to the assessment were received from this manufacturer