56 CIML Addendum 9.1.2.5

2021-10-01

Agenda Item 9.1.2.5:

Project proposal: New Guide

Guidelines for the evaluation of automated sphygmomanometers using oscillometric signal generators able to generate real-life oscillometric signals

Annex C.2 to OIML B 6-1: Proposal for a new project

	Proposal for a new project				
	Within:	TC	18	SC	1
	Date:	03.09.2021			

Proposer(s) (Add line if required):		
Name:	Country:	Organisation:
Proposed convener(s)*:		
Name: Dana Rosu	Country:Germany	Organisation:PTB
Type of proposed publication:	☒ New	☐ Revised

☐ Recommendation ☐ Document ☐ Basic ☐ Vocabulary ☒ Guide

Title of proposed publication:

Guidelines for the evaluation of automated sphygmomanometers using oscillometric signal generators able to generate real-life oscillometric signals

Terms of reference of the project, including detailed time frame in accordance with the provisions specified in B 6-1, 6.2:

Scope: Developing guidelines for the evaluation of automated sphygmomanometers using oscillometric signal generators able to replicate human oscillometric signals

Reason for setting the guide: Advanced oscillometric signal generators can generate oscillometric blood pressure signals indistinguishable from real real-life human signals. While such devices are being developed for a more in-depth testing of automated sphygmomanometers, currently no clear procedures for testing sphygmomanometers using such test devices exist. Harmonised guidelines would support testing and calibrating offices as well as manufacturers of automated sphygmomanometers to have a clear guidance when testing their devices using advanced oscillometric signal generators.

Expected time frame:
PG area set-up: 15.02.2022
Members participation confirmation: 01.05.2022
1WD: 01.12.2022
1CD: 01.06.2023

Why should the OIML develop this publication?

Reliable and accurate blood pressure measurements performed using sphygmomanometers are imperative in hypertension diagnostics and treatment. The detection of hypertension is very sensitive to errors in the blood pressure measurements, even small measurement errors can have critical ramifications. “A consistent 5 mmHg error can more than double or halve the number of patients diagnosed with diastolic hypertension”, while a “consistent 5 mmHg error in systolic pressure can result in systolic hypertension being underdiagnosed by 30% or over diagnosed by 43%.”

Automated sphygmomanometers represent the vast majority of electronic devices entering the market today, as they do not require skilled observers, avoid the "white-coat effect", can be used for long-term and home monitoring, and allow for fully automated blood pressure monitoring on intensive care units. However, the relationship between oscillometric pulses and systolic and diastolic blood pressure values is complex. The algorithms used to estimate blood pressure values are based on empirical data, gained from clinical studies by each manufacturer separately. There is no standard procedure or algorithm and the proprietary internal software of automated sphygmomanometers is not disclosed, neither to the public nor to regulatory bodies or test houses.

Internationally, the containment of non-invasibe blood pressure measurement errors is implemented through metrological checks according to the ISO 81060-1 and IEC 80601-2-30 standards. Before a developed device can enter the market, its measurement accuracy must be demonstrated in an elaborate clinical trial, where the

systolic arterial pressure and diastolic arterial pressure as indicated by one particular device are compared to the 'gold standard' of auscultatory readings independently obtained by two trained professionals. For the verification of production devices or of device already in use, however, the current editions of those standards simply require the verification of the accuracy of a static pressure measurement. This concept was developed and is appropriate for the manual auscultatory method where the onset and disappearance of the Korotkoff sounds define the medically relevant quantities. An oscillometric blood pressure measurement, however, is a two-step process where at first a complex oscillometric curve of pressure vs. time is acquired and in a second step, the actual measurands, systolic arterial pressure and diastolic arterial pressure, are calculated from that curve by an empirical, proprietary and undisclosed firmware algorithm. Any verification of the pressure measurement alone completely ignores the second step. Since the algorithm used to derive the measurands is never tested, the measurands themselves are never examined. As the present verification approach for automated sphygmomanometers is inadequate, we propose new and appropriate procedures for the in-depth verification of automated sphygmomanometers using oscillometric signal generators able to generate signal indistinguishable from real-life human signals. This guide will not only vastly improve the verification of automated sphygmomanometers, but it will be a first step towards the substitution of human subjects during the clinical validation of automated sphygmomanometers. This is particularly important when clinical tests require the inclusion of high-risk subjects e.g. neonates and severe hypertensives; the option to substitute these high risk categories will reduce costs and time.

Countries/Economies known to, or intending to apply this publication, if applicable:

Czech Republic, Portugal, Germany

Relevant associated OIML publications:

R 148:2020 Non-invasive non-automated sphygmomanometers
R 149:2020 Non-invasive automated sphygmomanometers

List of appropriate liaisons and their work related to this proposed project (include supporting documentation as necessary and reference it here):

ISO/TC 121/SC 3/JWG 7: Non-invasive blood pressure monitoring equipment

* As the CIML Member(s) of the Country(ies) holding the convenership of this project, I/we recognise the importance of TC/SC/PG secretariat/convenership work and will make available the resources to ensure the work on the publication is completed in a timely and professional manner in accordance with the provisions in OIML B 6-1 and the detailed time frame as part of this proposal.

Signature(s):