56 CIML Addendum 9.1.2.4

2021-10-01

Agenda Item 9.1.2.4:

Project proposal: New Recommendation

Requirements for the evaluation of NIBP simulators used for the testing of automated non-invasive sphygmomanometers

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:

Requirements for the evaluation of NIBP simulators used for the testing of automated non-invasive sphygmomanometers

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

Scope: Developing a recommendation that sets the requirements for investigating NIBP simulators used for the testing of automated sphygmomanometers with the scope of ensuring a correct performance of NIBP simulators and as a consequence to increase confidence in the proper functioning of automated sphygmomanometers, thus improving the accuracy of blood pressure measurements.

Reason for regulating the NIBP simulators: The devices are of crucial major importance when testing the performance of automated sphygmomanometers, therefore it is crucial to ensure that this type of testing devices demonstrate an adequate performance. At the moment most countries do not have specific requirements for such devices, despite them playing a determining role when testing and calibrating automated sphygmomanometers.

Expected time frame:
PG area set-up: 15.01.2022
Members participation confirmation: 01.05.2022
1WD: 01.08.2022
1CD: 01.02.2023

Why should the OIML develop this publication?

According to the World Health Organisation, an estimated 1.28 billion adults aged 30-79 years worldwide have hypertension, most (two-thirds) living in low- and middle-income countries. For fast and correct diagnosis and treatment of hypertension, reliable and accurate measurements using sphygmomanometers (with high preponderance automated sphygmomanometers) are imperative. To ensure the proper functioning of automated sphygmomanometers, the devices are regularly calibrated and metrologically checked using non-invasive blood pressure (NIBP) simulators.

Most NIBP simulators used in this scope are commercially available blood pressure simulators however, several advanced oscillometric signal generators (advanced simulators) have been developed by national metrology institutes and research institutions for an in-depth testing of automated sphygmomanometers.

The proposed recommendation will be used to ascertain the quality of the NIBP simulators intended to test automated sphygmomanometers by setting a set of requirements (e.g. requirements concerning the repeatability and reproducibility of NIBP simulators) that the devices should comply with. This is of particular importance as in this way, the stability and adequate performance of test devices used for testing automated sphygmomanometers is ensured. This in turn will increase the confidence in the long-term stability and reliability of non-invasive automated sphygmomanometers, with significant benefits for the users of this type of devices (i.e. clinicians) as well as their patients. Furthermore, the compliance with such an OIML

Recommendation would offer the possibility to manufacturers of commercial and non-commercial simulators to confirm the suitability of their device for testing automated sphygmomanometers. While a similar document exists as an international technical specification, ISO/TS 81060-5, the document was developed mainly with the commercially available simulators in mind. In addition, the existence of a technical specification does not ensure the fact that the TS will be transformed in an ISO standard and offer an international standard in the field. The development of a recommendation on the topic will not only ensure the persistence of internationally harmonised rules for testing a wide range of simulators, but it will extend its requirements to accommodate more advanced simulators (e.g. simulators able to generate real life signals). This is a very important step towards improving the confidence in the blood pressure readings using automated sphygmomanometers, as advanced simulators offer the possibility for a more in-depth evaluation of the devices.
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):