HEARTS IN THE AMERICAS

Regional Workshop

I have no personal or financial conflicts of interest

Pan American Health Organization
World Health Organization
Americas

PAHO

CDC
Centers for Disease Control and Prevention

World Health Organization

RESOLVE TO SAVE LIVES
AN INITIATIVE OF VITAL STRATEGIES

Sociedad Interamericana de Cardiología
SIAC

HEARTS IN THE AMERICAS

Regional Workshop

Importance of the regulation of automatic blood pressure monitors and examples of good practices

James Sharman

Menzies Institute for Medical Research, University of Tasmania

Australia

Pan American Health Organization / World Health Organization Americas

PAHO

CDC Centers for Disease Control and Prevention

World Health Organization

RESOLVE TO SAVE LIVES

An initiative of Vital Strategies

Sociedad Interamericana de Cardiología SIAC

#4 Best seller on Amazon Canada

$44.99 CDN = $34.03 USD

Non validated BP devices can gain entry to the market **with** (legal) **or without** (illegal) regulatory clearance

With regulatory clearance
(can be sold but probably shouldn't be)

Listed on a public registry by the regulatory authority

ARTG ID XXXXXXX

Product name	XXXXXXX
Active ingredients	
Sponsor name	XXXXXXX
ARTG entry for	XXXXXXX
Public ARTG summary	ARTG ID 206364 - public ARTG summary (pdf)

Not listed as being independently tested for accuracy

Joytech DBP-1358 Sold by K-Mart Australia

Example

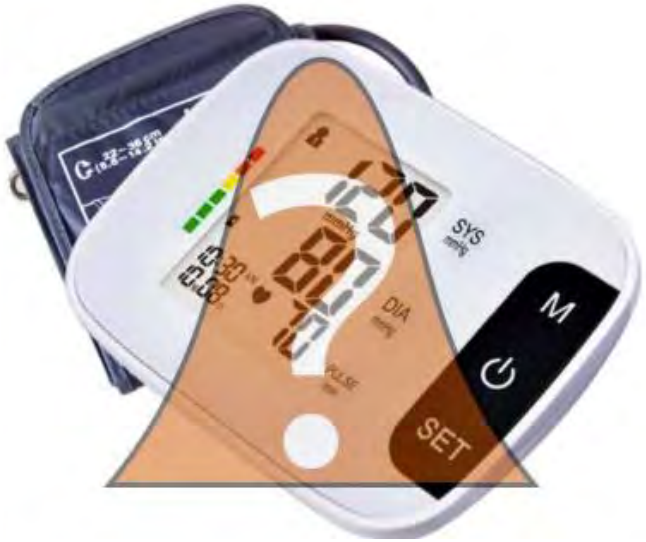
Listed on a public registry by the regulatory authority

No mention of model or make

ARTG ID 322761

Product name	Automatic-inflation electronic sphygmomanometer, portable, arm/wrist
Active ingredients	
Sponsor name	3P Pty Ltd
ARTG entry for	Medical Device Included Class IIa
Public ARTG summary	ARTG ID 322761 - public ARTG summary (pdf)

Not listed as being independently tested for accuracy

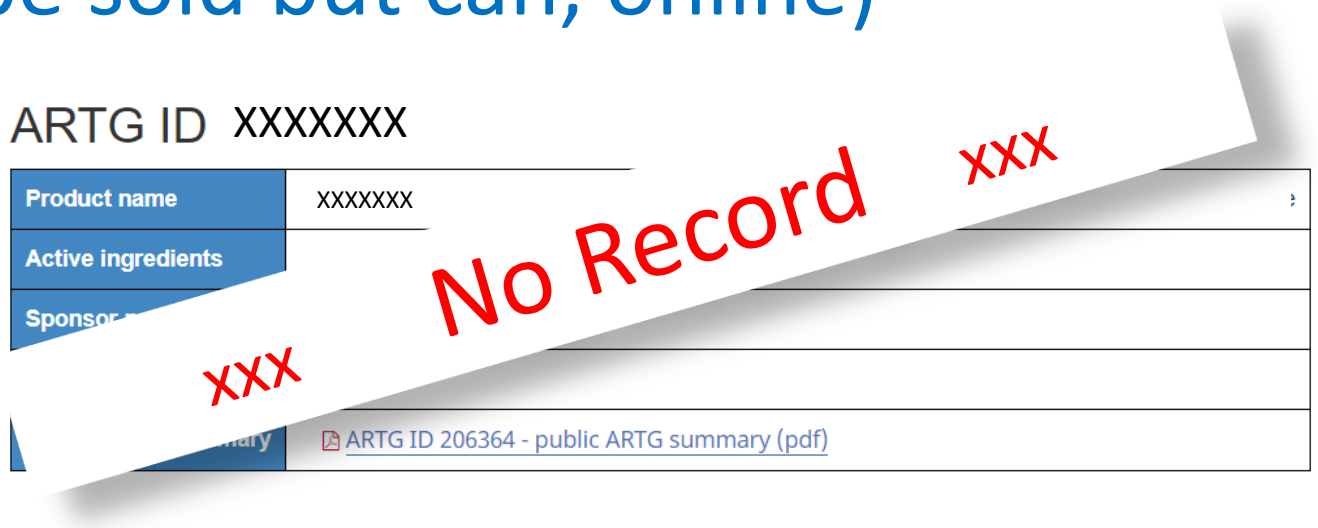


Medaval™

Not recommended

Without regulatory clearance
(shouldn't be sold but can, online)

Not listed on a public registry by the regulatory authority



Not listed as being independently tested for accuracy

Example

972
BP Devices Available for Online Purchase

278
Upper Arm Cuff Devices

162
Wrist Cuff Devices

532
Wristband Wearable Devices

51
(18.3%)

13
(8.0%)

0
(0%)

Proven Accurate According to International Validation Standards n (%)

Australian study of BP devices 'online'

Picone D… *Hypertension* 2020 (In Press)

This is what we should be striving for……

With regulatory **and** independent clearance

(should be sold, but currently rare; <15%)

Listed on a public registry by the regulatory authority

ARTG ID XXXXXXX

Product name	XXXXXXX
Active ingredients	
Sponsor name	XXXXXXX
ARTG entry for	XXXXXXX
Public ARTG summary	ARTG ID 206364 - public ARTG summary (pdf)

Listed as being independently tested for accuracy

STRIDE BP

European Society of Hypertension

International Society of Hypertension

World Hypertension League

Medaval™

Recommended by
Recommandé par
Hypertension Canada
Gold | Or

Ideal situation: with independent validation testing (using an accepted standard protocol) undertaken as part of the regulatory requirements……

Key regulatory problem is that it is not mandatory for manufacturers to use a specific standard to assess BP device accuracy

Nor are the results of validation testing required to be made publicly available

Not mandatory for manufacturers to use a specific standard to assess BP device accuracy

poor process

BP devices may pass regulatory requirements for sale but fail independent validation of accuracy

Validation studies deviate from established protocols

bias

Not mandatory for validation testing to be performed by independent parties

confusion

Consumer organisations do not give due attention to BP device accuracy

ignorance

Assumed that a BP device 'cleared' by regulatory authorities is accurate

Regulatory requirements focus on safety rather than accuracy

misinformation

Online sale of BP devices may circumvent regulatory processes

Exact BP device used in the validation study is unclear

fraudulence

Results of BP devices that fail validation studies may not be published

uncertainty

ambiguity

BP devices may fail to produce accurate readings in people with large or small arms but still used

Unethical companies selling cheap BP devices online with false validation credentials

If this regulatory problem could be addressed, it would also solve these other problems…..(now in green)

Mandatory for manufacturers to use a specific standard to assess BP device accuracy

poor process

BP devices may pass regulatory requirements for sale but fail independent validation of accuracy

Validation studies deviate from established protocols

bias

Not mandatory for validation testing to be performed by independent parties

confusion

Consumer organisations do not give due attention to BP device accuracy

ignorance

Assumed that a BP device 'cleared' by regulatory authorities is accurate

Regulatory requirements focus on safety rather than accuracy

Online sale of BP devices may circumvent regulatory processes

misinformation

Exact BP device used in the validation study is unclear

fraudulence

Results of BP devices that fail validation studies may not be published

uncertainty

ambiguity

BP devices may fail to produce accurate readings in people with large or small arms but still used

Unethical companies selling cheap BP devices online with false validation credentials

That’s why we made this recommendation…..

Informe especial

Pan American Journal of Public Health

Declaración de posición del Grupo de la Comisión Lancet de Hipertensión con respecto a la mejora mundial de las normas de exactitud para los dispositivos de medición de la presión arterial*

James E. Sharman,[1] Eoin O'Brien,[2] Bruce Alpert,[3] Aletta E. Schutte,[4] Christian Delles,[5] Michael Hecht Olsen,[6] Roland Asmar,[7] Neil Atkins,[8] Eduardo Barbosa,[9] David Calhoun,[10] Norm R.C. Campbell,[11] John Chalmers,[12] Ivor Benjamin,[13] Garry Jennings,[14] Stéphane Laurent,[15] Pierre Boutouyrie,[15] Patricio Lopez-Jaramillo,[16] Richard J. McManus,[17] Anastasia S. Mihailidou,[18] Pedro Ordunez,[19] Raj Padwal,[20] Paolo Palatini,[21] Gianfranco Parati,[22] Neil Poulter,[23] Michael K. Rakotz,[24] Clive Rosendorff,[25] Francesca Saladini,[26] Angelo Scuteri,[27] Weimar Sebba Barroso,[28] Myeong-Chan Cho,[29] Ki-Chul Sung,[30] Raymond R. Townsend,[31] Ji-Guang Wang,[32] Tine Willum Hansen,[33] Gregory Wozniak[24] y George Stergiou[34], en nombre del Grupo de la Comisión Lancet de Hipertensión.

En conjunto, estos aspectos contribuyen a la disponibilidad generalizada de tensiómetros de consultorio o domiciliarios que ofrecen una exactitud limitada o incierta, que llevan a diagnósticos, manejo y farmacoterapia inapropiados de la hipertensión a escala mundial. Los problemas más importantes relacionados con la exactitud de los dispositivos de medición de la presión arterial se pueden resolver mediante el requisito regulatorio de una validación independiente obligatoria de los dispositivos, en consonancia con la norma ISO universalmente aceptada. Esta es una recomendación básica y constituye una necesidad internacional acuciante. Otras recomendaciones clave son la elaboración de normas de validación específicas para las

Consensus Document

A Universal Standard for the Validation of Blood Pressure Measuring Devices

Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Collaboration Statement

George S. Stergiou, Bruce Alpert, Stephan Mieke, Roland Asmar, Neil Atkins, Siegfried Eckert, Gerhard Frick, Bruce Friedman, Thomas Graßl, Tsutomu Ichikawa, John P. Ioannidis, Peter Lacy, Richard McManus, Alan Murray, Martin Myers, Paolo Palatini, Gianfranco Parati, David Quinn, Josh Sarkis, Andrew Shennan, Takashi Usuda, Jiguang Wang, Colin O. Wu, Eoin O'Brien

Standard of the AAMI, ESH, ISO committees

ISO 81060-2;2018

Currently not enforced anywhere, however…….

New European Union Medical Device Regulations (EU MDR)

Comes into force on 26/5/2020 (regulation 2017/745)

Increases safety & quality standards for devices in the EU

Increases amount of data required to put a product on the market

Many existing devices will need re-certification (500,000+)

New EU MDR was brought about from…

Several high-profile medical device scandals

- Lung sealant that leaked
- Robotic surgery that caused tissue damage
- Cardiac pacemaker with battery problems
- Breast implant filled with rancid oil……etc……

Increasing public concern to strengthen the existing regulatory system – not just ‘high risk’ devices

New EU MDR **Requires:**

Use of a harmonised standard protocol
Currently EN 1060-4:2004 for BP devices

A report from an independent clinical investigation

Submission of relevant published information
(including validations if available/not mandatory)

Information in EU languages (incl Spanish)

This is not perfect, but a strong move in the right direction and should be best practice

EU MDR Timeline

EUDAMED – a database for all medical devices sold to European markets

Aims to enable fast, transparent identification and tracking of every device

Tracking via registration of unique device identifiers (UDIs)

Made available in all European languages

EUDAMED could be an important resource towards the goal of having a single universally accepted accredited list of BP devices

Informe especial

Pan American Journal of Public Health

Declaración de posición del Grupo de la Comisión Lancet de Hipertensión con respecto a la mejora mundial de las normas de exactitud para los dispositivos de medición de la presión arterial*

James E. Sharman,[1] Eoin O'Brien,[2] Bruce Alpert,[3] Aletta E. Schutte,[4] Christian Delles,[5] Michael Hecht Olsen,[6] Roland Asmar,[7] Neil Atkins,[8] Eduardo Barbosa,[9] David Calhoun,[10] Norm R.C. Campbell,[11] John Chalmers,[12] Ivor Benjamin,[13] Garry Jennings,[14] Stéphane Laurent,[15] Pierre Boutouyrie,[15] Patricio Lopez-Jaramillo,[16] Richard J. McManus,[17] Anastasia S. Mihailidou,[18] Pedro Ordunez,[19] Raj Padwal,[20] Paolo Palatini,[21] Gianfranco Parati,[22] Neil Poulter,[23] Michael K. Rakotz,[24] Clive Rosendorff,[25] Francesca Saladini,[26] Angelo Scuteri,[27] Weimar Sebba Barroso,[28] Myeong-Chan Cho,[29] Ki-Chul Sung,[30] Raymond R.Townsend,[31] Ji-Guang Wang,[32] Tine Willum Hansen,[33] Gregory Wozniak[24] y George Stergiou[34], en nombre del Grupo de la Comisión Lancet de Hipertensión.

Most of the problems relating to BP device accuracy could be addressed by the regulatory requirement for independent validation testing using an accepted standard protocol

Preferably with publication in a peer-reviewed journal

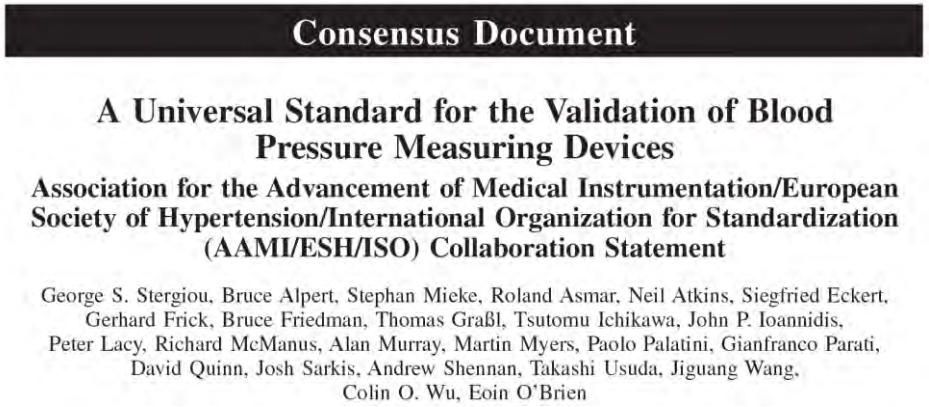
The recommended standard is the ISO 81060-2:2018

Informe especial

Pan American Journal of Public Health

Declaración de posición del Grupo de la Comisión Lancet de Hipertensión con respecto a la mejora mundial de las normas de exactitud para los dispositivos de medición de la presión arterial*

James E. Sharman,[1] Eoin O'Brien,[2] Bruce Alpert,[3] Aletta E. Schutte,[4] Christian Delles,[5] Michael Hecht Olsen,[6] Roland Asmar,[7] Neil Atkins,[8] Eduardo Barbosa,[9] David Calhoun,[10] Norm R.C. Campbell,[11] John Chalmers,[12] Ivor Benjamin,[13] Garry Jennings,[14] Stéphane Laurent,[15] Pierre Boutouyrie,[15] Patricio Lopez-Jaramillo,[16] Richard J. McManus,[17] Anastasia S. Mihailidou,[18] Pedro Ordunez,[19] Raj Padwal,[20] Paolo Palatini,[21] Gianfranco Parati,[22] Neil Poulter,[23] Michael K. Rakotz,[24] Clive Rosendorff,[25] Francesca Saladini,[26] Angelo Scuteri,[27] Weimar Sebba Barroso,[28] Myeong-Chan Cho,[29] Ki-Chul Sung,[30] Raymond R. Townsend,[31] Ji-Guang Wang,[32] Tine Willum Hansen,[33] Gregory Wozniak[34] y George Stergiou[34], en nombre del Grupo de la Comisión Lancet de Hipertensión.



Consensus Document

A Universal Standard for the Validation of Blood Pressure Measuring Devices

Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Collaboration Statement

George S. Stergiou, Bruce Alpert, Stephan Mieke, Roland Asmar, Neil Atkins, Siegfried Eckert, Gerhard Frick, Bruce Friedman, Thomas Graßl, Tsutomu Ichikawa, John P. Ioannidis, Peter Lacy, Richard McManus, Alan Murray, Martin Myers, Paolo Palatini, Gianfranco Parati, David Quinn, Josh Sarkis, Andrew Shennan, Takashi Usuda, Jiguang Wang, Colin O. Wu, Eoin O'Brien