Effect of Elevated Ambient Temperature on Simulator-Derived Oscillometric Blood Pressure Measurement

Jennifer S. Ringrose,[1,2] Michael D. Kennedy,[3] Jalisa Kassam,[4] Omar Mouhammed,[5] Sangita Sridar,[1,6] Zoltan Kenwell,[3] and Raj Padwal[1,2]

BACKGROUND
Oscillometric blood pressure (BP) devices are typically labeled for use up to 40 °C. Many geographic regions have ambient temperatures exceeding 40 °C. We assessed the effect of increased ambient temperature (40–55 °C) on simulator-derived oscillometric BP measurement.

METHODS
Three Omron BP769CAN devices, 3 A&D Medical UA-651BLE devices, and accompanying cuffs were used. A custom heat chamber heated each device to the specified temperature. A noninvasive BP simulator was used to take 3 measurements with each device at differing temperatures (22, 40, 45, 50, and 55 °C) and BP thresholds: 80/50, 100/60, 120/80, 140/90, 160/110, and 180/130 mm Hg. Using each device as its own control (22 °C), we determined the relative differences in mean BP for each device at each temperature and BP setting, assessed graphical trends with increasing temperature, and examined variability.

RESULTS
Graphical trends of mean simulator-subtracted BP differences from room temperature showed no discernable pattern, with differences clustered around zero. Overall mean difference in BP (combined elevated temperatures minus room temperature) was −0.8 ± 2.1 (systolic ± SD)/1.2 ± 3.5 (diastolic ± SD) mm Hg for the A&D device and 0.2 ± 0.4 (systolic ± SD)/−0.1 ± 0.1 (diastolic ± SD) mm Hg for the Omron. All individual elevated temperature differences (elevated temperature minus room temperature) except A&D diastolic BP at 50 °C were within 5 mm Hg.

CONCLUSIONS
In this simulator-based study assessing within-device differences, higher ambient temperatures resulted in oscillometric BP measurements that were comparable to those performed at room temperature.

Keywords: ambient temperature; blood pressure; hot climate; hypertension; measurement; oscillometric blood pressure

doi:10.1093/ajh/hpaa141

High blood pressure (BP) is the leading cause of death and disability in the world and the greatest burden of disease attributable to hypertension is present in countries located within the developing world.[1] In many cases, developing countries have hot or very hot climates related to their proximity to the equator.[2] Urbanization in these regions can lead to heat islands which may further elevate ambient heat temperatures up to 3 degrees compared with rural settings.[3] This underscores the need to ensure that the equipment and devices used to diagnose and monitor high BP in these jurisdictions are reliable at the temperatures where they may be used.

Use of automated BP measurement, in the form of home, office, and ambulatory monitoring is increasing and automated devices are now the primary modality for diagnosing and monitoring hypertension globally.[4–6] These devices most commonly employ the oscillometric method to derive BP. To perform an oscillometric measurement, arterial pulses sensed by a BP cuff are processed through a pressure transducer, filtered, amplified, and a proprietary algorithm is applied to determine BP.[7]

Correspondence: Jennifer S. Ringrose (jringros@ualberta.ca).

Initially submitted June 19, 2020; date of first revision July 29, 2020; accepted for publication August 25, 2020; online publication August 28, 2020.

[1]Department of Medicine, University of Alberta, Edmonton, Alberta, Canada; [2]Women and Children's Health Research Institute, Edmonton, Alberta, Canada; [3]Faculty of Kinesiology, Sport and Recreation, University of Alberta, Edmonton, Alberta, Canada; [4]Faculty of Science, Oglethorpe University, Atlanta, Georgia, United States of America; [5]Faculty of Science, University of Alberta, Alberta, Canada; [6]mmHg Inc., University of Alberta, Edmonton, Alberta, Canada.

Oscillometric devices are considered to be relatively robust in terms of their componentry, relative, for example, to aneroid devices and this quality is reflected in their longevity (typically lasting 5–10 years), lack of need for frequent calibration, and sturdiness.[8] Specific to operating temperature, oscillometric devices are typically labeled for use between 10 and 40 °C.[9] However, the ability of these devices to operate at higher temperatures is unclear. This question is relevant because ambient temperatures in many regions of the world can reach 40–55 °C.[10] These high temperatures have implications for the storage and operation of oscillometric BP devices. Accordingly, our objective was to perform a noninvasive simulator-based study to examine, relative to room temperature and using each device as its own control, the effect of high ambient temperatures on oscillometric BP measurement.

METHODS

A heat chamber (Oster TSSTTVFDXLPP-033 XL) was modified by creating a sealed opening in the back to allow for the BP devices to be connected to the noninvasive BP simulator (Fluke, CuffLink, Carson City, NV) (external to the heat chamber). AVariac transformer (Powerstat, Bristol, CT) was used to control the heat chamber's power supply, and a fan (Nidec Beta SL, Ho Chi Minh City, Vietnam) was placed inside the heat chamber to ensure air circulation and even temperature distribution. Prior to any BP monitors being exposed to elevated temperatures, trials were conducted to find Variac settings that produced stable and repeatable internal temperatures in the heat chamber. Temperatures were recorded using ThermoPro Dual Probe Digital thermometer (Thermor, Newmarket, Ontario, Canada). One probe of the thermometer was placed inside the heat chamber and attached to the rack beside where the devices were placed. The thermometer probe was alongside but not touching the rack. Humidity and atmospheric pressure were not measured. The second probe measured ambient temperature outside the heat chamber. We identified the corresponding voltage settings for temperatures of 40, 45, 50, and 55 °C. Trials were conducted prior to the data collection to ensure temperature stability at the respective voltages, time to achieve the desired temperature and stability were recorded up to 135

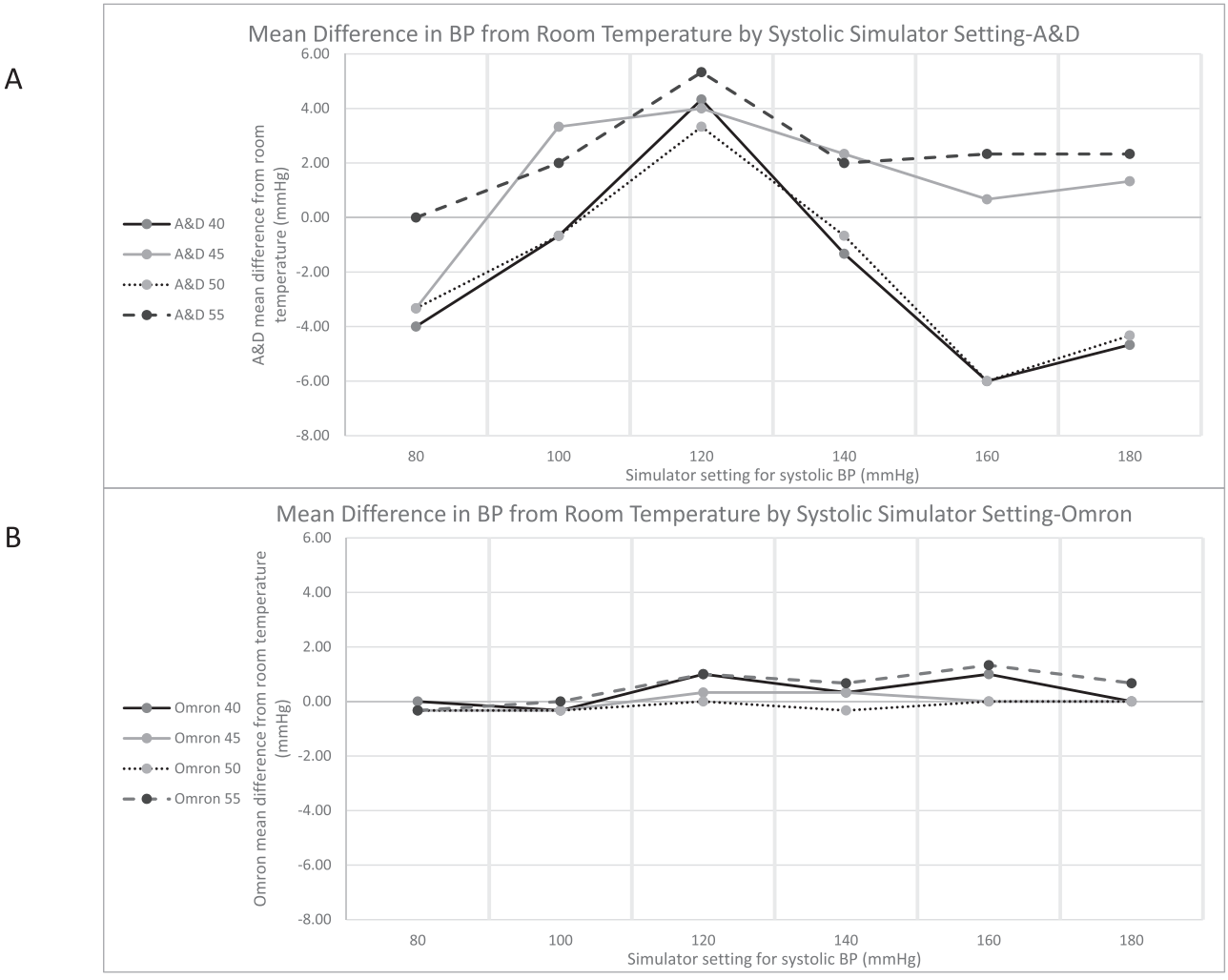

Figure 1. Mean differences in BP (elevated temperature minus room temperature), by systolic BP simulator setting. (**a**) A&D device. (**b**) Omron device. Abbreviation: BP, blood pressure.

minutes. Three Omron BP769CAN (Omron Healthcare, Kyoto, Japan) devices, 3 A&D Medical UA-651BLE devices (A&D, Tokyo, Japan), and accompanying cuffs were used to perform BP measurements. Both devices are specified to operate from 10 to 40 °C (transport/storage −20 to 60 °C).[9,10] The first device of each brand was used to test at room temperature only, the second device of each brand was used to test at 40 °C and then at 50 °C. The third device of each brand was tested at 45 °C and then at 55 °C. Static calibration with a mercury sphygmomanometer of each device was done before and after testing at each temperature by trained personnel. All devices were within 3 mm Hg of the mercury sphygmomanometer at each testing time.

At room temperature (22 °C) and each elevated temperature setting, the following protocol was observed for each device:

1. The heat chamber was heated to the desired temperature and the test BP device was placed inside. The BP cuff was connected to a polyvinyl chloride pipe dowel and the BP device was connected to the simulator, which was situated external to the heat chamber.
2. After opening the heat chamber to insert the BP device, the heat chamber was resealed, the system was left to equilibrate until the desired temperature was reachieved and stable for 10 minutes.
3. BP measurements were performed by using a thin pole to activate the BP device inside the heat chamber without allowing heat escape. For all BP measurements, the heart rate on the BP simulator was set at 80 beats per minute. Three BP measurements were performed at each of the following BP simulator settings: 80/50, 100/60, 120/80, 140/90, 160/110, and 180/130 mm Hg. Temperature was verified to be constant before and after each set of 3 BP measurements.

Data analysis

The analysis focused on assessing relative mean differences between the BP simulator and each BP devices across the range of temperatures and simulator BP settings, using each device as its own control, and assessed by examining graphical trends and using paired *t*-tests. Measurements at room temperature were considered the baseline state. In all cases,

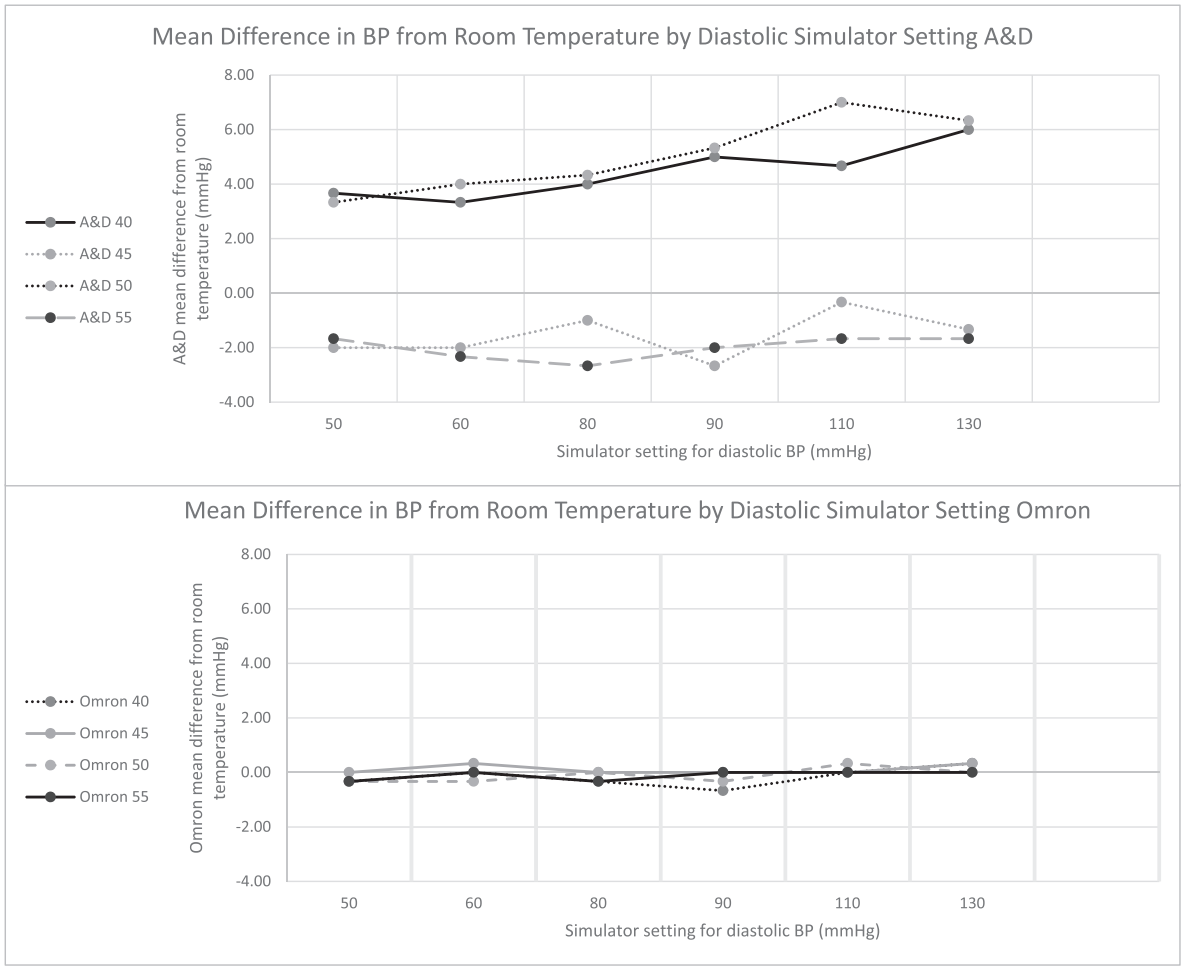

Figure 2. Mean differences in BP (elevated temperature minus room temperature), by diastolic BP simulator setting. (**a**) A&D device. (**b**) Omron device. Abbreviation: BP, blood pressure.

room temperature readings were subtracted from elevated temperature readings. Analysis of absolute differences between each device and the simulator and between devices was not performed because the simulator and each BP device use a different proprietary algorithm to derive BP and no additional gold standard BP measurement method (i.e., blinded, simultaneous, 2-observer auscultation) was performed. Stated another way, if Device 1 produces a BP measurement closer to that produced by the simulator that is Device 2, it does not mean that the Device 1 is more valid, it shows that the first device is likely to have an algorithm more similar to that used in the simulator. Likewise, because of the lack of gold standard auscultatory measurements, assessment of BP differences between the 2 device models were not considered meaningful and were not performed.

RESULTS

For both devices, examination of graphical trends of mean simulator-subtracted BP differences from room temperature showed no discernable trends, with differences clustered around zero, when plotted for systolic (Figure 1: a—A&D, b—Omron) and diastolic BP (Figure 2: a—A&D; b—Omron).

Mean differences in BP from room temperature at each elevated temperature setting (40, 45, 50, and 55 °C) are shown in Table 1. Overall mean differences (combined elevated temperatures minus room temperature) were −0.8 ± 2.1 (systolic ± SD)/1.2 ± 3.5 (diastolic ± SD) mm Hg for the A&D device and 0.2 ± 0.4 (systolic ± SD)/−0.1 ± 0.1 (diastolic ± SD) mm Hg for the Omron. All but one (A&D diastolic BP at 50 °C) were within 5 mm Hg.

The results, for each simulator setting, of combining the BP results at all high temperatures and subtracting room temperature BP are shown in Table 2. Overall mean differences were −0.1 ± 2.6 (systolic ± SD)/1.5 ± 0.7 (diastolic ± SD) mm Hg for the A&D device and 0.2 ± 0.4 (systolic ± SD)/−0.1 ± 0.2 (diastolic ± SD) mm Hg for the Omron. All mean differences were within 5 mm Hg.

Table 1. Differences in BP (high temperature minus room temperature), by elevated temperature setting

	Temperature (°C)	Mean difference ± SD
A&D systolic	40	−2.1 ± 1.2
	45	1.4 ± 1.5
	50	−1.9 ± 1.3
	55	2.3 ± 2.0
Overall A&D systolic	(Mean ± SD)	−0.8 ± 2.1
A&D diastolic	40	3.2 ± 0.6
	45	−1.6 ± 0.8
	50	5.1 ± 0.5
	55	−2.0 ± 0.3
Overall A&D diastolic	(Mean ± SD)	1.2 ± 3.5
Omron systolic	40	0.3 ± 0.3
	45	0 ± 0
	50	−0.2 ± 0.3
	55	0.6 ± 0.2
Overall Omron systolic	(Mean ± SD)	0.2 ± 0.4
Omron diastolic	40	−0.1 ± 0.2
	45	0.1 ± 0.3
	50	−0.1 ± 0.1
	55	−0.1 ± 0.1
Overall Omron diastolic	(Mean ± SD)	−0.1 ± 0.1

Abbreviation: BP, blood pressure.

DISCUSSION

The results of this simulator study indicate that, for the 2 devices tested, marked elevations in ambient temperature produced generally similar mean BP results to those found at room temperature. Furthermore, increasing temperatures from 40 to 55 °C did not lead to a temperature dependent systematic error in BP measurement in the 2 devices tested. Mean BP differences for both devices were well within the 5 ± 8 mm Hg threshold borrowed from validation standards and widely accepted as a general indication that an automated device is producing acceptable results.[11] We are not aware of any prior published studies of a similar nature. Although this study was not intended as a comparison of the 2 different devices, we note that the Omron device exhibited less variability in BP measurements at elevated temperatures than the A&D device.

These findings are relevant because mean temperatures in many regions of the world are increasing.[12] In some regions, temperatures reach 40–53 °C.[10,13] The frequency and duration of these extreme temperature rises are expected to increase.[14,15] In many of the countries that achieve extreme heat, cooling infrastructure is scarce,[15] increasing the likelihood of BP device exposure to high ambient temperatures. In 2010, 31.1% of adults worldwide had hypertension.[16] Age-standardized prevalence hypertension is decreasing in high-income countries but is increasing in low- and middle-income countries.[17] There is a high burden of hypertension in many of the countries with extremely hot climates.[2,18] Given the potential exposure of oscillometric BP devices to these high temperatures in these countries with a high burden of disease, our findings are reassuring and indicate that oscillometric BP measurement results would not be expected to be compromised by elevated ambient temperatures. Indeed, oscillometric devices are generally made of robust componentry relative to aneroid devices (which contain more moving parts and require frequent calibration)[8] and are approved for storage and transport in temperatures up to 60 °C.[9,10] Electronic components of a BP device (microcontrollers, battery management systems, voltage regulators, and boost converters) and pneumatic components (air pumps and valves) are designed to work within operational temperature limits of 10–40 °C.[18] Current standards require additional justification if the surface temperature of a device exceeds 41 °C.[19] To ensure the

Table 2. Differences in BP (all high temperatures combined (40–55 °C) minus room temperature), by BP simulator setting

	BP simulator setting (mm Hg)	Mean ± SD
A&D systolic	80	−2.7 ± 0.7
	100	1.0 ± 3.3
	120	4.3 ± 6.2
	140	0.6 ± 1.5
	160	−2.3 ± 1.5
	180	−1.3 ± 0.7
Overall A&D systolic	(Mean ± SD)	−0.1 ± 2.6
A&D diastolic	50	−0.8 ± 1.6
	60	0.8 ± 0.7
	80	1.2 ± 0.9
	90	1.4 ± 0.7
	110	2.4 ± 0.6
	130	2.3 ± 0.1
Overall A&D diastolic	(Mean ± SD)	1.5 ± 0.7
Omron systolic	80	−0.3 ± 1.0
	100	−0.3 ± 0.7
	120	0.6 ± 0.4
	140	0.3 ± 0.9
	160	0.6 ± 0.8
	180	0.2 ± 0.8
Overall Omron systolic	(Mean ± SD)	0.2 ± 0.4
Omron diastolic	50	−0.3 ± 0.4
	60	−0.1 ± 0.1
	80	−0.1 ± 0.6
	90	−0.3 ± 0
	110	0.1 ± 0.9
	130	0.2 ± 0.1
Overall Omron diastolic	(Mean ± SD)	−0.1 ± 0.2

Abbreviation: BP, blood pressure.

manufacturer is in compliance for stable and reliable usage normal testing for thermal stability of the electronic and pneumatic components of the device is tested by recording the temperatures using thermocouples or temperature meters under the following conditions: (i) when the device capacitor is short circuited or disabled, (ii) during continuous operation while unattended, (iii) when the applied load on the device is increased,[19] and (iv) reversed battery connection.[20] Then the effects of temperature on mechanical and electrical integrity of the device and its components is usually tested by placing the device in a circulating air oven at a temperature 10 °C higher than the maximum temperature observed on the enclosure of the device,[19] typically for 5–7 hours. Given the current manufacturing standards for ensuring stability of operation within "normal operating range" our approach followed a similar process and therefore we are confident in our results in the temperature ranges of 40–55 °C. Thus, the procedures performed in this study more broadly extend assessment of these devices beyond what would have been expected to be performed during the device manufacturing process and allow introspection into the idea that the normal operating range may be increased beyond 40 °C.

The major strengths of this work include the assessment of 2 commonly used oscillometric devices and the use of a carefully controlled environment to ensure that devices were exposed to stable ambient temperature while testing. We did not simultaneously measure humidity thus we cannot conclude what the combined effects of heat plus high humidity might have had on operation of these devices. The duration of heat exposure in this study was limited, which may not reflect real-world conditions in a hot climate. When a device is continually operated at an increased operational temperature (above 40 °C), it is possible that high temperature may affect both electronic and pneumatic components of the BP device. For example, a decrease in operational performance (e.g., lower pump flow rate or air valve release rates) and/or reductions in mechanical integrity (damage to the diaphragm/orifice) may ensue. High operational temperatures may also affect the batteries, resulting in lower supply voltages, which may affect electronic or pneumatic components that are designed for use at different operational voltages. Finally, our study design used 3 devices to avoid exposing the same device to several temperatures. However, this design allows for the possibility that variability between devices may have accounted for some of the differences observed. Overall, to address these gaps in knowledge, field work in human participants situated in hotter climates using accurate reference standard measurements instead of simulated BP is needed to substantiate the results of the present study.

FUNDING

None.

DISCLOSURE

JR and RP are supported by an alternative funding plan from the Government of Alberta and the University of Alberta. JR, SS, and RP are cofounders of a blood pressure measurement digital health company, mmHg Inc.

REFERENCES

1. Collaborators GBDRF. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet (Lond, Engl)* 2018; 392:1923.
2. Xu C, Kohler TA, Lenton TM, Svenning J-C, Scheffer M. Future of the human climate niche. *Proc Natl Acad Sci USA* 2020; 117:11350–11355.
3. Huang K, Li X, Liu X, Seto KC. Projecting global urban land expansion and heat island intensification through 2050. *Environ Res Lett* 2019; 14:114037.

4. Williams B, Mancia G, Spiering W, Agabiti Rosei E, Azizi M, Burnier M, Clement DL, Coca A, de Simone G, Dominiczak A, Kahan T, Mahfoud F, Redon J, Ruilope L, Zanchetti A, Kerins M, Kjeldsen SE, Kreutz R, Laurent S, Lip GYH, McManus R, Narkiewicz K, Ruschitzka F, Schmieder RE, Shlyakhto E, Tsioufis C, Aboyans V, Desormais I; Authors/Task Force Members. 2018 ESC/ESH Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension: the Task Force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension. *J Hypertens* 2018; 36:1953–2041.
5. Nerenberg KA, Zarnke KB, Leung AA, Dasgupta K, Butalia S, McBrien K, Harris KC, Nakhla M, Cloutier L, Gelfer M, Lamarre-Cliche M, Milot A, Bolli P, Tremblay G, McLean D, Padwal RS, Tran KC, Grover S, Rabkin SW, Moe GW, Howlett JG, Lindsay P, Hill MD, Sharma M, Field T, Wein TH, Shoamanesh A, Dresser GK, Hamet P, Herman RJ, Burgess E, Gryn SE, Grégoire JC, Lewanczuk R, Poirier L, Campbell TS, Feldman RD, Lavoie KL, Tsuyuki RT, Honos G, Prebtani APH, Kline G, Schiffrin EL, Don-Wauchope A, Tobe SW, Gilbert RE, Leiter LA, Jones C, Woo V, Hegele RA, Selby P, Pipe A, McFarlane PA, Oh P, Gupta M, Bacon SL, Kaczorowski J, Trudeau L, Campbell NRC, Hiremath S, Roerecke M, Arcand J, Ruzicka M, Prasad GVR, Vallée M, Edwards C, Sivapalan P, Penner SB, Fournier A, Benoit G, Feber J, Dionne J, Magee LA, Logan AG, Côté AM, Rey E, Firoz T, Kuyper LM, Gabor JY, Townsend RR, Rabi DM, Daskalopoulou SS; Hypertension Canada. Hypertension Canada's 2018 Guidelines for diagnosis, risk assessment, prevention, and treatment of hypertension in adults and children. *Can J Cardiol* 2018; 34:506–525.
6. Whelton PK, Carey RM, Aronow WS, Casey DE Jr, Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC Jr, Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA Sr, Williamson JD, Wright JT Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. *Hypertension* 2018; 71:e13–e115.
7. Alpert BS, Quinn D, Gallick D. Oscillometric blood pressure: a review for clinicians. *J Am Soc Hypertens* 2014; 8:930–938.
8. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, Jones DW, Kurtz T, Sheps SG, Roccella EJ. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: Blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation* 2005; 111:697–716.
9. BP769CAN O. Product Monograph. https://www.omronhealthcare.ca/wp-content/uploads/BP769CAN_HEM-7320T-CACS_IM_EN_web.pdf
10. Burt CC. The world's hottest recorded air temperatures. *Weatherwise: the Power, the Beauty, the Excitement* 2011; 64:26–33.
11. International Organization for Standardization. ISO 81060-2:2018. Non-invasive Sphygmomanometers—Part 2: Clinical Investigation of Intermittent Automated Measurement Type. https://www.iso.org/standard/73339.html. 2018.
12. Sparks TH, Aasa A, Huber K, Wadsworth R. Changes and patterns in biologically relevant temperatures in Europe 1941–2000. *Clim Res* 2009; 39:191–207.
13. van Oldenborgh GJ, Philip S, Kew S, van Weele M, Uhe P, Otto FEL, Singh R, Pai I, AchutaRao K. Extreme heat in India and anthropogenic climate change. *Nat Hazards Earth Syst Sci* 2018; 18:365–381.
14. Raymond C, Matthews T, Horton RM. The emergence of heat and humidity too severe for human tolerance. *Sci Adv* 2020; 6:eaaw1838.
15. Coffel ED, Horton RM, de Sherbinin A. Temperature and humidity based projections of a rapid rise in global heat stress exposure during the 21st century. *Environ Res Lett* 2017; 13:014001.
16. Mills KT, Stefanescu A, He J. The global epidemiology of hypertension. *Nat Rev Nephrol* 2020; 16:223–237.
17. Mills KT, Bundy JD, Kelly TN, Reed JE, Kearney PM, Reynolds K, Chen J, He J. Global disparities of hypertension prevalence and control: a systematic analysis of population-based studies from 90 countries. *Circulation* 2016; 134:441–450.
18. White WB, Berson AS, Robbins C, Jamieson MJ, Prisant LM, Roccella E, Sheps SG. National standard for measurement of resting and ambulatory blood pressures with automated sphygmomanometers. *Hypertension* 1993; 21:504–509.
19. CAN/CSA. CAN/CSA-C22.2 No. 60601-1:14. Medical electrical equipment—Part 1: General requirements for basic safety and essential performance. 3rd edn, 2005; 12:1–777.
20. Medical Equipment Compliance Associates LLCMECA. Medical Evaluation Package. http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/HTM/Idea_Exchange/EI_60601.pdf. Accessed 29 May 2020.