

Online supplement

Non-validated home blood pressure devices dominate the online marketplace: major implications for cardiovascular risk management

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Online supplement Methods

Details of the blood pressure (BP) device search methods

A systematic search of Google Australia (www.google.com.au) was conducted to identify businesses that sell devices purporting to measure BP. Variations of the phrase “blood pressure monitor buy online Australia” were searched and the first five pages of results were examined. The online websites of Australian pharmacies were also examined because these businesses are known to sell BP devices.

On each business website the term “blood pressure monitor” was searched and the information for devices purporting to measure BP was recorded. These devices were categorized as either 1) upper-arm cuff (the conventional BP method); 2) wrist cuff (those using an inflatable cuff around the wrist); and 3) wrist-band wearables (watch-like ‘activity tracker’ devices that do not have a cuff for the measurement of BP). The lowest cost of each available device was recorded in Australian dollars (AUD) and used for subsequent analyses. Due to the volume of different items available from large e-commerce sites, additional search filters were used. On www.ebay.com.au, the search was limited to items in the “Blood Pressure Monitoring” subcategory, with filters applied so the search returned only new (not pre-owned), automated/semi-automated BP devices located in Australia that were available to buy immediately. Items on www.amazon.com.au were restricted to the category of “Health, Household & Personal Care.”

Businesses were categorized into one of four groups: 1) pharmacy, 2) medical, 3) Australian general retail and 4) e-commerce. Businesses with conventional shopfront store locations were noted. Pharmacy businesses were defined as those that prepared or dispensed pharmaceutical medications to patients and sold other health and wellbeing goods. Medical businesses were those that exclusively sold medical or health-care related goods but were not pharmacies. Australian general retailers were defined as department or electronics stores with conventional shopfronts. Businesses that did not fulfil these criteria and did not have a conventional shopfront in addition to their online presence were defined in the “e-commerce” category.

Each of the following search term variations were searched on Google Australia (www.google.com.au).

- | | |
|---|-------------------------------------|
| i. blood pressure monitor | v. BP monitor buy online |
| ii. blood pressure monitor buy online | vi. BP monitor buy online Australia |
| iii. blood pressure monitor buy online
Australia | |
| iv. BP monitor | |

For each search term, pages 1-5 (inclusive) of the results were examined for online businesses selling blood pressure (BP) measurement devices. Businesses with sponsored items (advertisements) appearing during the search were included. Both, local and international businesses were included if the devices were available to purchase in Australian dollars and were

either sold in Australia or could be shipped to Australia. Websites that did not directly sell devices (those that redirected the purchaser to a third party website) were excluded. On each retail website the term “blood pressure monitor” was searched and the device information recorded.

Additional search filters were used to refine the search results on large e-commerce websites.

Additional search criteria for eBay results (ebay.com.au). Searches were conducted in the health & beauty → health care → monitoring & testing → blood pressure monitoring category. The following filters were applied to refine the items displayed on the site.

1. Features: Automatic, Wireless/Bluetooth, With USB cable, Not specified
2. Condition: New
3. Buying format: Buy it now
4. Item location: Australia only

Additional search criteria for Amazon results (amazon.com.au). Items were restricted to the “Health, Household & Personal Care” category.

Determining BP device validation status

Four online databases were assessed to determine BP device validation status. These included the Medaval Registry (<https://medaval.ie/device-category/blood-pressure-monitors>), PubMed (<https://www.ncbi.nlm.nih.gov/pubmed>), Google Search (www.google.com.au) and Dabl Educational Trust (http://www.dableducational.org/sphygmomanometers/devices_2_sbpm.html#ArmTable) (Supplemental Figure 1).

The STRIDE-BP online database was not used because it was launched after the search period. The search was performed for devices with either complete device information (manufacturer and model number) or only a model number. If no device information was available (no manufacturer or model number), the device was deemed non-validated because the search for validation information could not be undertaken. The terms used for the validation search varied for each database. For Medaval and Dabl Educational Trust, only the device model was required, whereas PubMed and Google required specific search terms which included the device manufacture and model number in combination with the terms “validat* OR evaluat* OR assess*” (see Supplemental Table 1).

Definition of duplicate BP devices

Cuff BP devices were defined as duplicates if the manufacturer and model numbers were the same, irrespective of differences in device colour. Devices with identical external features, nonspecific branding and non-unique information (e.g. product description) provided by the retail site were also deemed duplicates. Devices that were identical in appearance but had different branding or model numbers were considered unique. Where researchers were unable to confidently conclude two devices were identical, both were included as unique devices. Wrist-band wearable device duplicates were judged with the same criteria, however did not require

matching manufacturer name or device colour (i.e. the devices must be identical in model number, appearance, external features and website information).

On large e-commerce sites, duplicate devices were not recorded multiple times if they were judged to be identical to an already recorded device. Duplicates were assessed using the criteria above. The search results were sorted by lowest to highest price (cost of device plus postage) and the device with the lowest price was recorded. This method was used on the following websites: eBay, Amazon, catch.com.au, Banggood, Dick Smith, Kogan and Shopping Square.

Additional details on validation search terms

Devices with insufficient information (manufacturer and model) could not be properly searched to determine validation status and therefore these devices were consequently deemed “non-validated”.

Alphanumeric device models were searched differently to a device with a model name consisting of only numbers or only letters. Where the *device brand & model* was required for the search and the model had a combination of letters and numbers, a maximum of 3 unique searches were conducted with only the model number being altered in each instance (Supplemental Table 1).

Devices with models being exclusively letters (or word) or numbers were not modified and searched a minimum of 3 times as above. In the event that a device had both, a model name and a corresponding model number, the entire search process was completed twice; once with the device brand and model name, and once with the device brand and model number.

Additional details on determining BP device validation status

The Medaval registry was first examined by entering the device model into the search function (Figure S1). This was undertaken because Medaval presents all available BP devices irrespective of validation status. If the device (matching brand and model name or number) had validation studies referenced on the Medaval registry, the relevant information was recorded (e.g. full reference details, PubMed ID), and the search was completed for that device. If there was no information on Medaval, the search was continued on PubMed. In the event PubMed had validation information, this would be recorded, and the search concluded; if there was no information, then Google Search was examined. Similarly, Dabl Educational was examined in the event no validation information was found on Medaval, PubMed or Google Search. If no evidence of validation was found on completion of the search, the device was deemed non-validated.

Additional details on claimed equivalence

A device was defined as equivalent when the core technology was claimed by the manufacturer to be identical to a previously validated device. This claim may be accompanied with a publicly available declaration of equivalence (confirmed on the Dabl Educational Trust database;¹ or without publicly available documentation, but noted in online databases (e.g. British and Irish Hypertension Society, Hypertension Canada, German Hypertension League or Medaval). A device was defined as non-validated if no validation or equivalence information was found in the searches.

Despite having modified design or features, the essential oscillometric measurement technology used in the new device for which equivalence was claimed remains the same as a device that had undergone validation previously.¹ Typically these devices had the same error detection, microphone, pressure transducer, cuff or bladder and mechanisms for inflation and deflation.

When a device was suspected to claim equivalence, documented evidence was sought to support the claim. The manufacturer and model number of the device was used to search the Dabl Educational database for a declaration of equivalence. When a device was found to claim equivalence (with or without supporting documentation), the validation search process was continued as though validation had not been found. If at the conclusion of the entire four part search process, there was no evidence of validation, then devices falling into this category were deemed to “claim equivalence” rather than be considered non-validated.

Examples of device information descriptions online

The manufacturer name and device model number were sought for each device found in this study. The following are examples of devices with combinations of this information being provided by their respective online sellers.

Device information	Example
Complete	BrandName ModelNumber
Incomplete (Manufacturer only)	BrandName
Incomplete (Model only)	ModelNumber
None	No details (e.g. Automatic Blood Pressure Monitor)

Online supplement results

Business categories

After removal of duplicate devices sold across multiple pharmacies, 21 unique BP devices remained. Of these, 23.8% were validated (n=2, 9.5%) or claimed equivalence (n=3, 14.3%) to another device (Supplemental figure 2A). Across the medical businesses, 49 unique devices were available, 46.9% of which were validated (n=9, 18.4%) or claimed equivalence (n=14, 28.6%). Australian general retailers had 7 unique devices available and 42.9% were validated (n=2, 28.6%) or claimed equivalence (n=1, 14.3%). 941 unique devices were available from e-commerce businesses, which represented 92.4% of all unique devices. Of these, 5.5% were validated (n=21, 2.2%) or claimed equivalence (n=31, 3.3%). There were a significantly lower number of validated or equivalent devices available from the e-commerce businesses compared to the other categories ($p < 0.006$ all). After removal of wrist-band wearables, 12.7% of upper arm or wrist cuff devices from e-commerce businesses were validated (5.1%) or claimed equivalence (7.6%). This attenuated the difference in number of validated or equivalent devices between the e-commerce businesses and pharmacies ($p = 0.18$) or Australian general retailers ($p = 0.052$), but not with the medical businesses ($p < 0.0001$). The proportion of upper arm or wrist cuff devices validated according to each category is presented in supplemental figure 2B-C. 24 (40.7%) also had physical store locations which included 15 (93.8%) pharmacies, 4 (20%) medical retailers and 5 (100%) Australian general retail stores.

Online supplement tables

Table S1. Search terms used to find evidence of device validation when device model was alphanumeric. Note three examples for each term as device model contains a combination of letters and numbers.

Site	Search Term	Examples
Medaval Registry	<i>Device model</i>	HEM907, HEM-907, HEM 907
PubMed	validat* OR evaluat* OR assess* AND <i>device brand & model</i>	a. validat* OR evaluat* OR assess* AND Omron HEM907 b. validat* OR evaluat* OR assess* AND Omron HEM 907 c. validat* OR evaluat* OR assess* AND Omron HEM-907
Google Search	validate OR evaluate OR assess <i>“device brand & model”</i>	a. validate OR evaluate OR assess “Omron HEM907” b. validate OR evaluate OR assess “Omron HEM 907” c. validate OR evaluate OR assess “Omron HEM-907”
Dabl Educational	<i>Device model</i>	HEM907, HEM-907, HEM 907

Table S2. Validated home blood pressure devices available for purchase by Australian online consumers.

Manufacturer and model number	Validation protocol	Result of testing	Price (AUD; lowest recorded price)
<i>Upper arm cuff</i>			
A&D Medical UA-651 ^{2, 3}	ESH-IP:2010	Pass	45.95
A&D Medical UM-201 ⁴	ESH-IP:2010	Pass	203.50
A&D Medical UM-211 ⁵	ESH-IP:2010	Pass	621.50
A&D Medical UA-704 ⁶	BHS:1993	Pass (A/A)	60.50
iHealth FEEL (BP5) ⁷	ESH-IP:2010	Pass	120.50
iHealth BP3 ⁸	ESH-IP:2010	Pass	99.00
MicroLife BP A3 PC ^{http://www.dableducational.org/Publications/2015/ESH-IP%202010%20Validation%20of%20MicroLife%20%20BPA3} PC.pdf	ESH-IP:2010	Pass	149.00
Omron HEM 705 CP ⁹⁻¹¹	BHS:1993 AAMI1992 SP10:1987	Pass (B/A); A/A, B/A Pass	311.38
Omron BP760N ¹²	ANSI/AAMI/ISO 2009	Pass	189.46
Omron HEM-7130 ¹³	ESH-IP:2010	Pass	89.50
Omron M6 Comfort (HEM-7321-E) ¹⁴	ESH-IP:2002	Pass	129.00
Omron HEM-7301-ITKE (MIT Elite Plus) ¹⁵	DHL:2007	Pass	179.00
Omron M2 Classic (HEM-7117-E) ¹⁶	ESH-IP:2002	Pass	74.00
Omron Evolv ¹⁷	ESH-IP:2010	Pass	233.47
Omron M3 Comfort (HEM-7134-E) ¹⁷	ESH-IP:2011	Pass	94.00
Pangao PG-800B11 ¹⁸	ESH-IP:2010 BHS:1993	Pass Pass (A/A)	46.00
PIC Solution Personal Check ¹⁹	ESH-IP:2002	Pass	75.00
Qardioarm A100 ²⁰	ESH-IP:2010	Pass	179.99
Yuwell YE690A ²¹	ESH-IP:2010	Pass	57.30
<i>Wrist cuff</i>			
A&D Medical UB-511 ²²	BHS:1993	Pass (B/B)	110.00
A&D Medical UB-542 ²³	ESH-IP:2010	Pass	67.05
G.LAB MD2200 ²⁴	ESH-IP:2010,	Pass,	87.32

	BHS: 1993, ANSI/AAMI/ISO 2013	A/A, Pass	
G.LAB MD2231 ²⁵	ESH-IP:2010, BHS: 1993, ANSI/AAMI/ISO 2013	Pass, A/A, Pass	104.25
iHealth BP7 ²⁶	ESH-IP:2010	Pass	90.00
Omron RS3 (HEM-6130-E) ²⁷	ESH-IP:2010	Pass	85.25
PIC Solution Travelcheck ¹⁹	ESH-IP:2002	Pass	65.00

ESH-IP, European Society of Hypertension International Protocol; BHS, British Hypertension Society; ANSI, American National Standards Institute; AAMI, Association for the Advancement of Medical Instrumentation; ISO, International Organisation for Standardisation; DHL, Deutsche Hochdruckliga (German Hypertension League).

Table S3. Home blood pressure measurement devices that claimed equivalent measurement technology to previously validated devices.

Manufacturer and model number	Equivalent device
A&D Medical UA-767F	A&D UA-651
Beurer BM45	Andon KD-5917
Beurer BM55	Andon KD-5915
Beurer BM47	Andon KD-5915
Braun ActiVscan 9 (BUA7200)	AVITA BPM64
Braun ExactFit 5 BP6200	Transtek TMB-986
Medel Check	Andon KD-5915
Medel Control	AVITA BPM63S
Medel Elite	Andon KD-5915
Microlife WatchBP Home A	Microlife WatchBP Home
Microlife BP A2 Basic	Microlife BP 3BT0-A
Microlife WatchBP Home S	Microlife WatchBP Home
Omron BP760	Omron M6 Comfort (HEM-7221-E)
Omron BP785	Omron M6 Comfort (HEM-7221-E)
Omron M10-IT	Omron M6 Comfort (HEM-7000-E)
Omron M7 Intelli IT (HEM-7322T-E)	Omron M6 Comfort(HEM-7321-E)
Omron M2 Basic (HEM-7120-E)	Omron HEM-7130
Omron M3 IT (HEM-7131U-E)	Omron M6 AC (HEM-7322-E)
PIC Solution Classic Check	Pic Solution My Check
A&D Medical UA-651BLE	Specific equivalent device cannot be determined
A&D Medical UA-1030T	Specific equivalent device cannot be determined
A&D Medical UA-782	Specific equivalent device cannot be determined
A&D Medical UA-611	Specific equivalent device cannot be determined
Airssential AI-H971 (Lifeline Elite)	Specific equivalent device cannot be determined
Beurer BM26	Specific equivalent device cannot be determined
Honsun LD582	Specific equivalent device cannot be determined
LifeSource UA-767PSAC	Specific equivalent device cannot be determined
Omron M2 Basic (HEM-7117)	Specific equivalent device cannot be determined
Riester Ri-Champion	Specific equivalent device cannot be determined
Rossmax X3	Specific equivalent device cannot be determined

Sanitas SBM21	Specific equivalent device cannot be determined
Sanitas SBM22	Specific equivalent device cannot be determined

Wrist cuff

A&D Medical UB-525	A&D UB-543
Braun iCheck 7 BPW4500	AVITA BPM17
Omron RS2 (HEM-6121-E)	Omron RS3
PIC Solution Selfcheck	PIC Solution TravelCheck
iHealth VIEW (BP7s)	Specific equivalent device cannot be determined
Omron BP654	Specific equivalent device cannot be determined

Information on claims of equivalence for each device were sourced from the following online databases: British and Irish Hypertension Society, Hypertension Canada, German Hypertension League, Dabl Educational Trust and Medaval.ie.

Table S4. The number of blood pressure measurement devices and validation status for each pharmacy identified in this study.

Business	Number recorded	Number validated	Number peer reviewed	Number equivalent	Number equivalent with documentation	Percentage Validated	Percentage Equivalent	Percentage validated or equivalent
Amcal	11	1	1	1	1	9.1	9.1	18.2
Capital Chemist	2	0	0	0	0	0.0	0.0	0.0
Chemist Direct	9	2	2	1	0	22.2	11.1	33.3
Chemist Warehouse	8	1	1	0	0	12.5	0.0	12.5
Chempro	9	3	3	0	0	33.3	0.0	33.3
Cincotta Discount Chemist	7	1	1	0	0	14.3	0.0	14.3
David Jones Pharmacy	9	1	1	0	0	11.1	0.0	11.1
Discount Drug Stores	6	1	1	0	0	16.7	0.0	16.7
ePharmacy	8	1	1	0	0	12.5	0.0	12.5
Good Price Pharmacy	8	1	1	0	0	12.5	0.0	12.5
My Chemist	5	0	0	0	0	0.0	0.0	0.0
National Pharmacies	10	2	2	2	0	20.0	20.0	40.0

Pharmacy Direct	10	2	2	1	0	20.0	10.0	30.0
Pharmacy4Less	9	1	1	0	0	11.1	0.0	11.1
Priceline	6	1	1	0	0	16.7	0.0	16.7
Super Pharmacy	7	1	1	0	0	14.3	0.0	14.3
TOTAL	124	19	19	5	1	15.3	4.0	19.4

Table S5. The number of blood pressure measurement devices and validation status for each medical supply business identified in this study.

Business	Number recorded	Number validated	Number peer reviewed	Number equivalent	Number equivalent with documentation	Percentage Validated	Percentage Equivalent	Percentage validated or equivalent
A&D Medical	8	1	1	3	0	12.5	37.5	50.0
Aims Medical Group	1	0	0	0	0	0.0	0.0	0.0
AMA Medical Products	11	4	4	2	0	36.4	18.2	54.5
Ape Medical	1	0	0	0	0	0.0	0.0	0.0
Clinical Guard	7	0	0	1	1	0.0	14.3	14.3
DocStock	5	1	1	2	0	20.0	40.0	60.0
IBD Medical	3	0	0	3	3	0.0	100.0	100.0
Macquarie Medical Systems	5	0	0	0	0	0.0	0.0	0.0
Marne Medical	3	1	1	0	0	33.3	0.0	33.3
Medisupplies	2	0	0	0	0	0.0	0.0	0.0
Medsales	2	0	0	2	0	0.0	100.0	100.0

MedShop	8	1	1	0	0	12.5	0.0	12.5
Mentone Educational	9	1	1	0	0	11.1	0.0	11.1
Paramedic Shop	1	0	0	0	0	0.0	0.0	0.0
Point of Care Diagnostics	5	2	2	2	2	40.0	40.0	80.0
Qardio	1	1	1	0	0	100.0	0.0	100.0
Stark Medical	3	1	0	1	1	33.3	33.3	66.7
Team Medical Supplies	2	0	0	1	1	0.0	50.0	50.0
The First Aid Shop	1	1	1	0	0	100.0	0.0	100.0
Warner Webster	1	1	1	0	0	100.0	0.0	100.0
TOTAL	79	14	14	17	8	19	21.5	40.5

Table S6. The number of BP devices and validation status for each Australian general retailer identified in this study.

Business	Number recorded	Number validated	Number peer reviewed	Number equivalent	Number equivalent with documentation	Percentage Validated	Percentage Equivalent	Percentage validated or equivalent
Domayne	1	0	0	1	0	0	100	100
Harvey Norman	5	0	0	1	0	0	20	20
JB HI FI	4	2	2	1	0	50	25	75
Myer	1	0	0	0	0	0	0	0
Officeworks	1	0	0	0	0	0	0	0
TOTAL	12	2	2	3	0	16.7	25.0	41.7

Table S7. The number of BP devices and validation status for each Australian general retailer identified in this study.

Business	Number recorded	Number validated	Number peer reviewed	Number equivalent	Number equivalent with documentation	Percentage Validated	Percentage Equivalent	Percentage validated or equivalent
Amazon	359	14	14	18	13	3.9	5.0	8.9
Any Scales	3	2	2	1	0	66.7	33.3	100.0
Banggood	302	0	0	0	0	0.0	0.0	0.0
Care Alert	1	0	0	0	0	0.0	0.0	0.0
Catch.com.au	70	0	0	1	0	0.0	1.4	1.4
Dick Smith	17	0	0	1	0	0.0	5.9	5.9
Direct Shop	3	0	0	0	0	0.0	0.0	0.0
Ebay	146	0	0	0	0	0.0	0.0	0.0
Fruugo	34	7	7	12	9	20.6	35.3	55.9
GearBest	195	0	0	0	0	0.0	0.0	0.0
Global Shop Direct	1	0	0	0	0	0.0	0.0	0.0
iHealth	3	1	1	1	0	33.3	33.3	66.7
J A Davey	15	1	1	0	0	6.7	0.0	6.7

Kogan	17	0	0	1	0	0.0	5.9	5.9
My Deal	35	0	0	1	0	0.0	2.9	2.9
PeggyBuy	65	0	0	0	0	0.0	0.0	0.0
Shopping Square	17	0	0	0	0	0.0	0.0	0.0
Yazzonline	3	0	0	0	0	0.0	0.0	0.0
TOTAL	1286	25	25	36	22	1.9	2.8	4.7

Table S8. The number and validation status of home blood pressure measurement devices available for purchase stratified by the information available from the online description.

	Complete information	Incomplete information	No information
Upper-arm cuff	181 (65.1)	73 (26.3)	24 (8.6)
Validated or claim equivalence	51 (28.2)	0 (0)	0 (0)
Wrist cuff	76 (46.9)	43 (26.5)	43 (26.5)
Validated or claim equivalence	13 (17.1)	0 (0)	0 (0)
Wrist-band wearable	272 (51.1)	206 (38.7)	54 (10.2)
Validated or claim equivalence	0 (0)	0 (0)	0 (0)

Complete information available from the online description was defined access to the device manufacturer name and model number was available. Incomplete information was defined as availability of either the manufacturer name or model number (but not both), and no information was defined as when neither the manufacturer name or model number were available (and only generic device information was available).

Online supplement figures.

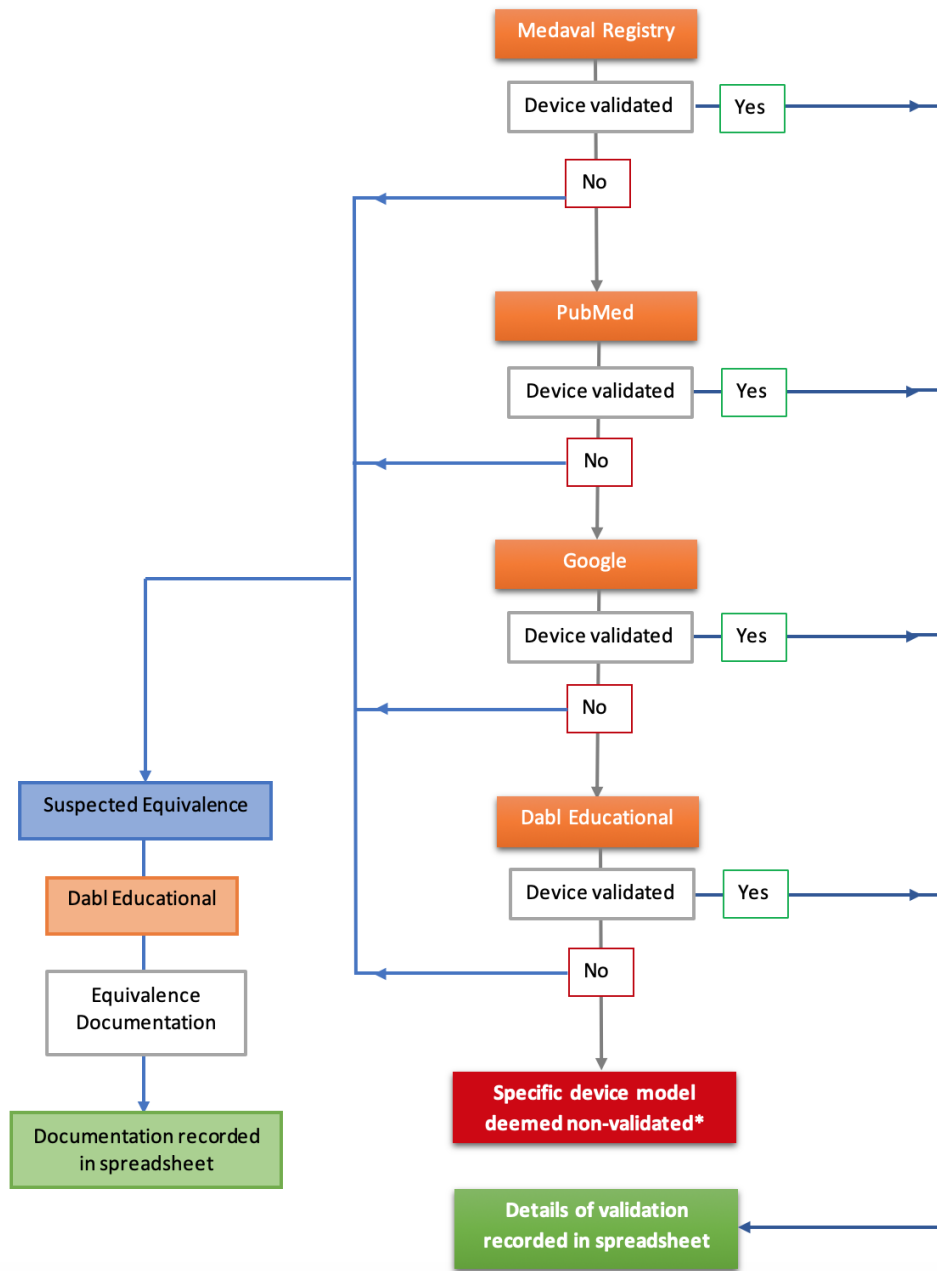


Figure S1. Flowchart of the approach to determine BP device validation status. The Medaval search registry (medaval.ie) was examined by entering the device model number into the search function. If the device was validated, the available information was recorded and the search was deemed complete for that specific device. If there was no validation information on Medaval, the search was continued on PubMed. This process was repeated on Pubmed, Google and Dabl Educational. If no evidence of validation was found, the device was deemed non-validated. If

there was evidence that a device used technology that was equivalent to a previously validated device, this was recorded separate to the validation details.

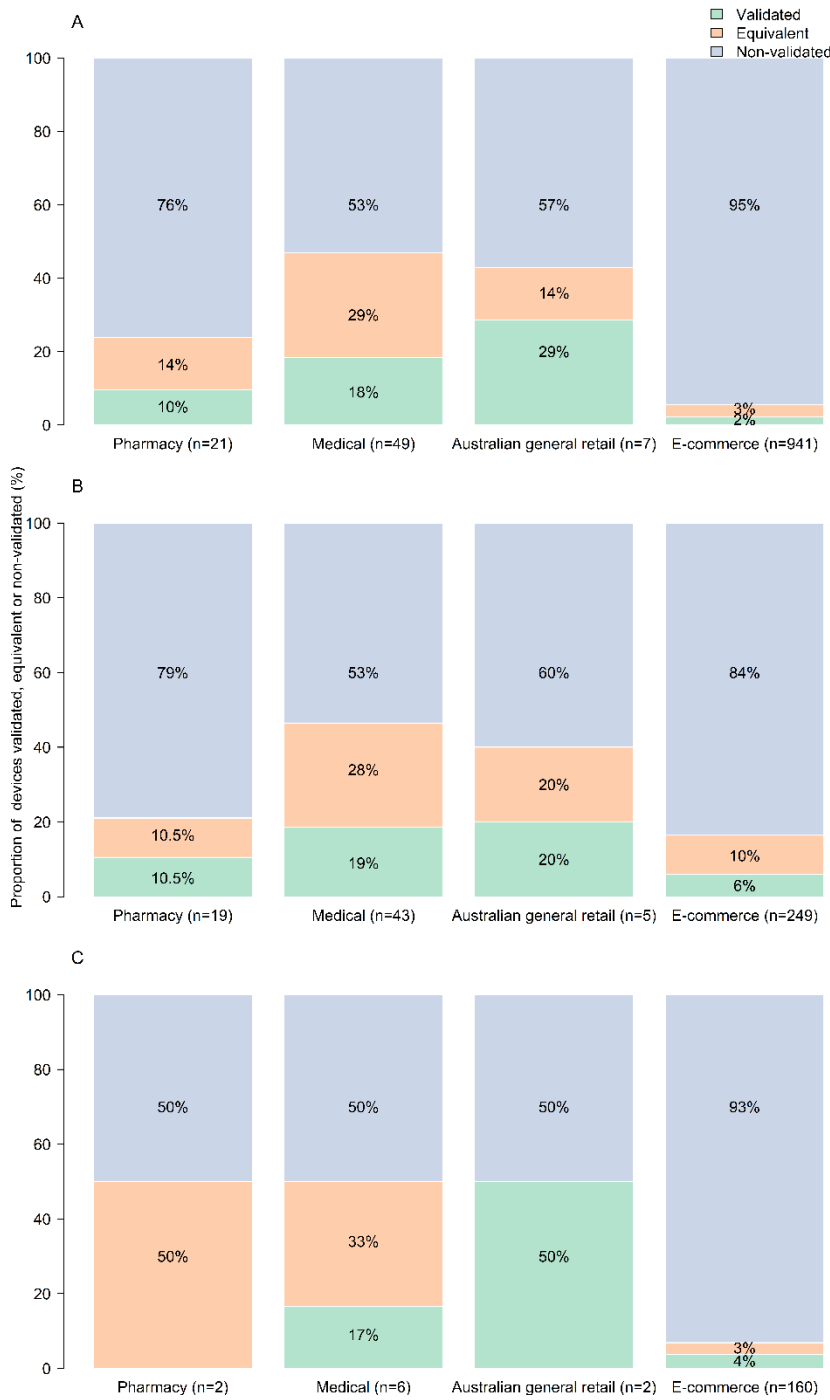


Figure S2. Proportion of BP devices validated (green), equivalent (orange) or non-validated (grey) stratified according to the type of retailer. Panel A shows the total devices validated, panel B only upper arm cuff devices and panel C only wrist cuff devices. In each panel, the parentheses following the type of retailer present the total number of devices available. There is

not a separate panel for wrist-band wearables because none of the devices were validated or equivalent and all were recorded for sale from e-commerce sites.

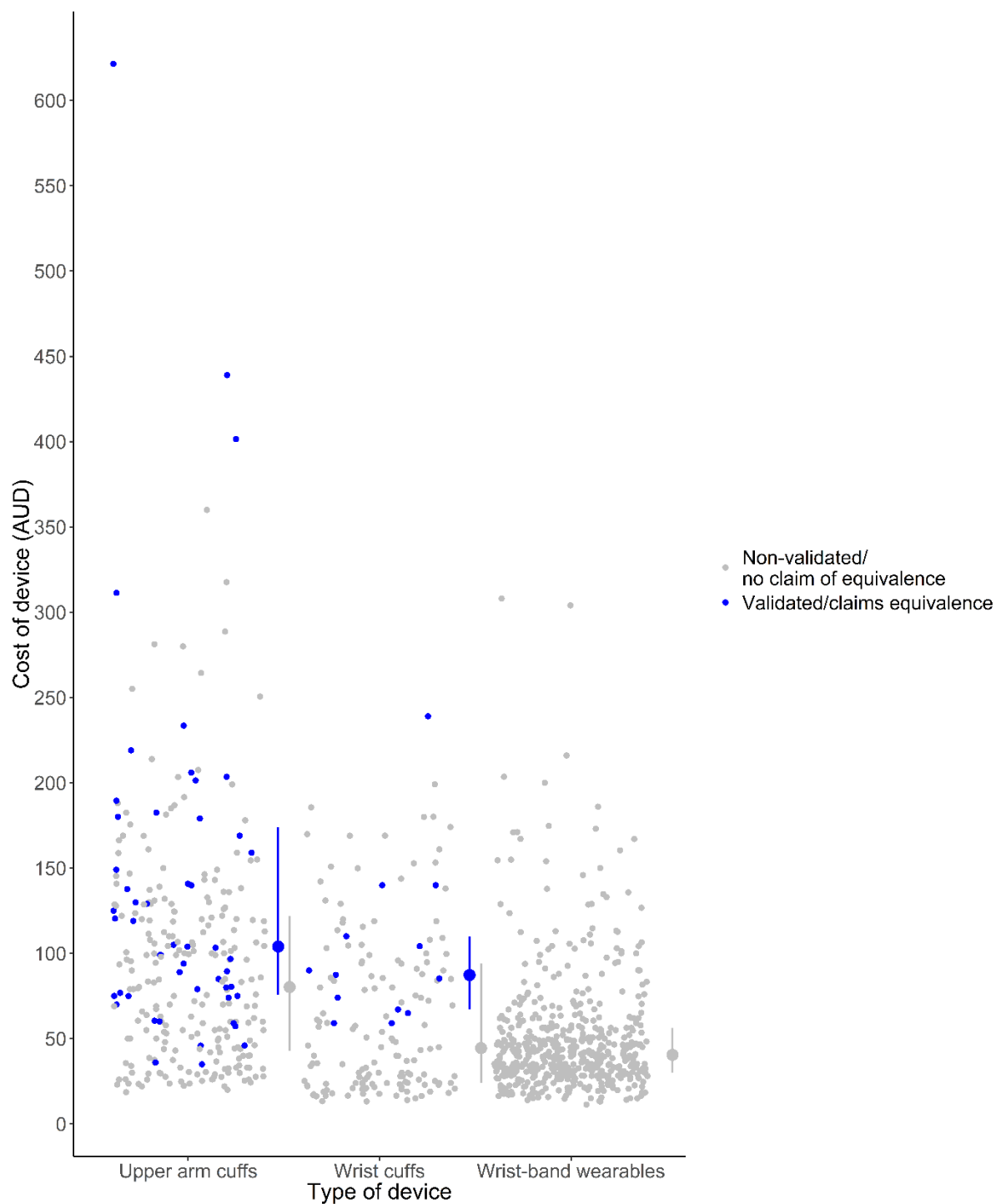


Figure S3. Cost of validated and non-validated BP devices. The minimum cost in Australian dollars of each unique upper arm cuff, wrist cuff and wrist-band wearable device. Each individual point represents a unique validated (blue) or non-validated (grey) device. The large points and ranges represent the median and interquartile range for the validated or non-validated devices. 1 AUD = 0.68 USD on 20/11/2019.

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