

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

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SECTION A - Please complete all items.

I **Fumihisa Hori**, a Director of **Citizen Systems Japan Co., Ltd.**,  
Name of a Company Director Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Manufacturer **Citizen Systems Japan Co., Ltd.** Brand **Citizen** Model **CH-452**

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the

Manufacturer **Citizen Systems Japan Co., Ltd.** Brand **Citizen** Model **CH-432B**

Existing validated blood pressure measuring device. If alternative model names are used, include all.

blood pressure measuring device, which has previously passed the **ESH** protocol, the results of which were published as follows:

**Cotte UV, Faltenbacher VH, von Willich Werner and Bogner JR.**

Author(s)

Trial of validation of two devices for self-measurement of blood pressure according to the European Society of Hypertension International Protocol: the Citizen CH-432B and CH-656C

Title

**Blood Pressure Monitoring** 2008, Vol 13: 55-62.

Publication

Year Volume Pages

The only differences between the devices involve the following components:

When a component is not relevant, both Yes and No should be left blank. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	7	Inflation Mechanism	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section C on the next page

SECTION B Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form together with manuals and images for both devices to info@dableducational.org.

Signature of Director *Fumihisa Hori*

Company Stamp/Seal

Name **Fumihisa Hori**

Date **Nov. 7, 2011**

Signature of Witness *Yuichi Nishizawa*

**CITIZEN SYSTEMS JAPAN CO.,LTD.**  
**6-1-12, TANASHI-CHO, NISHI-TOKYO-SHI,**  
**TOKYO 188-8511, JAPAN**

Name **Yuichi Nishizawa**

Address **6-1-12 Tanashi-Cho, Nishi-Tokyo-Shi, Tokyo, 188-8511, Japan**

**SECTION C** An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

There is one ticked "Yes" in Part I of Section A and there are four ticked "Yes" in Part II. We summarized these differences in "Table 1. Comparison of specification between Submitted device and Validated device". Below are the short explanations about these five differences.

1. No. 7 "Inflation Mechanism" in Section A

The submitted device and validated device have different inflation mechanism. The submitted device has full automatic inflation mechanism and validated device has inflation mechanism due to last systolic reading. But each of inflation mechanism realizes enough inflation for measuring blood pressure automatically.

2. No. 9 "Model Name or Number" in Section A

Since the submitted device and validated device have difference specifications such as case design, memory function as shown in Table 1, "Model Name or Number" are different to distinguish them.

3. No. 10 "Casing" in Section A

As shown in Table 1, since the submitted device and validated device have difference case design, both devices have the different casing.

4. No. 13 "Software" in Section A

Since hardware such as number of switch, LCD, number of memory capacity are different from the validated device, the software regarding these parts are different from the validated one, however the measurement algorithm is clearly same with the validated one. However both devices have a same algorithm to measure blood pressure value.

5. No. 14 "Memory Capacity / Number of stored measurements" in Section A

Submitted device has a function of "90 memories and averaged value of the last 3 readings", whereas validated device has as function of "1 memory"





Therefore, we can comment that since CH-452 and CH-432B have different design, their dimensions and weights are different. The CH-452 has 90 memories and CH-432B has one memory. Therefore, the numbers of switches are different due to recall the stored memories. "Inflation Mechanism" is not same. As mentioned in "Software other than Algorithm" above, Since CH-452 provides different hardware from CH-432B such as number of switch, LCD, number of memory capacity, the software to control these hardware and function is different. However, both the blood pressure measurement algorithms are same. As far as accuracy is concerned, both devices are clearly equivalent.

Table 1. Comparison of specification between Submitted device and Validated device

	Submitted device (1)	Validated device (2)
Devices	CH-452	CH-432B
Picture		
Validation		ESH International Protocol
Same criteria		
Measuring Principle	Oscillometric Method	Oscillometric Method
Arm Circumference Range	22 to 32 cm	22 to 32 cm
Measurement Range		
Pressure	0 - 280 mmHg	0 - 280 mmHg
Pulse	40 - 180 Pulse / Min.	40 - 180 Pulse / Min.
Accuracy		
Pressure	±3 mmHg	±3 mmHg
Pulse	±5% of Reading	±5% of Reading
Display	LCD	LCD
Inflation	Automatic Inflation by Internal Pump	Automatic Inflation by Internal Pump
Deflation	Automatic deflation control system	Automatic deflation control system
Exhaust	Electromagnetic Valve	Electromagnetic Valve
Rated Voltage	DC 6V	DC 6V
Power Source	4 "AA" Size Batteries (R6P, LR6)	4 "AA" Size Batteries (R6P, LR6)
Automatic Power Off Function	Approx. 3 min.	Approx. 3 min.
Comparable criteria		
Number of Switch	2 Switches ("Start/Stop" Switch & "Memory" Switch)	1 Switch ("Power / Start" Switch)
Dimensions	130(W) x 118(D) x 53(H) [mm]	129(W) x 122(D) x 55(T) [mm]
Weight	Approx. 240g (Body)	Approx. 230g (Body)
Different criteria listed in "Part I"		
Inflation setting	Full Automatic Inflation	Automatic Inflation based on last reading
Different criteria listed in "Part II"		
Model Name or Number	CH-452	CH-432B
Casing	Refer the items "Picture" and "Dimensions" and "Weight" above.	
Memory Capacity / Number of stored measurements	90 memories and averaged value of the last 3 readings	1 memory
Software other than Algorithm	Since hardware such as number of switch, LCD, number of memory capacity are different from the validated device (CH-432B), the software regarding these parts are different from the validated one, however the measurement algorithm is clearly same with the validated one.	
WEB link	<a href="http://www.citizen-systems.co.jp/english/electronic/health/ch_452.html">http://www.citizen-systems.co.jp/english/electronic/health/ch_452.html</a>	<a href="http://www.citizen-systems.co.jp/english/electronic/health/ch_432b.html">http://www.citizen-systems.co.jp/english/electronic/health/ch_432b.html</a>
Comments	Since CH-452 and CH-432B have different design, their dimensions and weights are different. The CH-452 has 90 memories and CH-432B has one memory. Therefore, the number of switches are different due to recall the stored memories. "Inflation Mechanism" is not same. As mentioned in "Software other than Algorithm" above, Since CH-452 provides different hardware from CH-432B such as number of switch, LCD, number of memory capacity, the software to control these hardware and function is different. However, both the blood pressure measurement algorithms are same. As far as accuracy is concerned, both devices are clearly equivalent.	
Recommendation	Accept	



Comparison of the Citizen CH-452 with the Citizen CH-432B

Devices	Citizen CH-452	Citizen CH-432B
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p><b>Buttons/Switches</b></p> <p>Measurement Records</p> <p>Memory 10</p> <p><b>Display/Symbols/Indicators</b></p> <p>Post Measurement</p> <p>Average 3R 11, 13, 14</p> <p>Measurement Records</p> <p>Memory recall number 11</p> <p><b>Algorithms</b></p> <p>Averages and Differences</p> <p>Last 3 measurements mean 13</p>	
Same Criteria	<p><b>Measurement</b></p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p>Method</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 0 mmHg - 280 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Inflation</p>	<p><b>Measurement</b></p> <p>Accuracy</p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p>Method</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 0 mmHg - 280 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -180 bpm 1, 5, 8</p> <p>Inflation</p>

Devices	Citizen CH-452	Citizen CH-432B
	<p>Manually adjustable inflation pressure 7 <i>Deflation</i></p> <p>Automatic Deflation 8</p> <p>Automatic safety release valve 8</p> <p><i>Cuffs</i></p> <p>Single (Arm circ. 22 to 32 cm) 6</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start/Stop Label) 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP alternating with Pulse 11</p> <p>Measurement error <i>PUL Err, Err 1 to Err 5, --- --- &amp; 280 blink</i> <sup>Query 1</sup> 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 3 min 17</p>	<p>Manually adjustable inflation pressure 7 <i>Deflation</i></p> <p>Automatic Deflation 8</p> <p>Automatic safety release valve 8</p> <p><i>Cuffs</i></p> <p>Single (Arm circ. 22 to 32 cm) 6</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Power &gt;&gt;&gt; Start Label) 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP alternating with Pulse 11</p> <p>Measurement error <i>PUL Err, Err 1 to Err 5, --- --- &amp; 280 blink</i> <sup>Query 1</sup> 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 3 min 17</p>
<b>Comparable Criteria</b>	<p><b>Measurement</b></p> <p><i>Inflation</i></p> <p>Fully Automatic Inflation <sup>Query 2</sup> 7</p> <p>Press button if BP &gt; 200 mmHg <sup>Query 2</sup> 7</p> <p><i>Measurement Records</i></p> <p>Memory: 90 measurements 14</p> <p><b>Casing</b></p> <p><i>Power</i></p> <p>4 "AA" batteries ~ 1000 measurements alkaline (300 manganese) 17</p>	<p><b>Measurement</b></p> <p><i>Inflation</i></p> <p>Automatic Inflation based on previous reading <sup>Query 2</sup> 7</p> <p>Press button if BP &gt; 170 mmHg <sup>Query 2</sup> 7</p> <p><i>Measurement Records</i></p> <p>Memory: 1 measurement 14</p> <p><b>Case</b></p> <p><i>Power</i></p> <p>4 "AA" batteries ~ 700 measurements alkaline (200 manganese) 17</p>
<b>Device 2 Criteria</b>		<p><b>Display/Symbols/Indicators</b></p> <p><i>Preparation</i></p> <p>Previous result displayed on start-up 11, 14</p>

Comments	Comparison of the Citizen CH-452 with the Citizen CH-432B	
1	Query	In the CH-452, when pressure exceeds 280 mmHg, a flashing 280 warning appears. This is not described for the CH-432B. Is this an extra feature?
	Reply	In the CH-432B also flashing 280 warning appears when pressure exceeds 280.
2	Comment	Clarification is accepted.
	Query	<p>Users of the CH-452 are requested to pressurise the system manually if their expected BP is above 200 mmHg; users of the CH-432B are requested to do so if their expected BP is above 170 mmHg. This suggests different inflation mechanisms or algorithms. Please explain. If a user who's SBP was between these values, e.g. 185 mmHg, was to use the CH-452, would the result be differently had the used the CH-432B without realising that they had to press the button to pressurise the system?</p> <p>Reply</p> <p>1) In case of CH-452</p> <p>If the person of 185 mmHg (SYS) uses CH-452, CH-452 inflates up to about 225 mmHg automatically. After that, CH-452 starts blood pressure measurement automatically.</p> <p>Finally, measured systolic value, which is around 185 mmHg, is displayed on LCD.</p> <p>2) In case of CH-432B</p> <p>When the person of 185 mmHg (SYS) uses CH-432B without power sw pressed, CH-432B inflates cuff until 160 mmHg at first by internal pump. After that, by inflation detector, it is judged whether cuff pressure is enough to measure blood pressure.</p> <p>In this case, because CH-432B recognizes cuff pressure is not enough by inflation detector, cuff inflates automatically until 200 mmHg by internal pump again.</p> <p>After that, by inflation detector, CH-432B judges that cuff pressure is not enough to measure blood pressure. Then CH-432B automatically exhausts a compressed air while displaying "Err" which means re-measurement.</p> <p>When user pushes power sw again, cuff inflates until 200 mmHg.</p> <p>Because CH-432B recognizes cuff pressure is not enough, cuff inflates automatically until 240mmHg by internal pump again.</p> <p>After that, by inflation detector, CH-432B judges that cuff pressure is enough to measure blood pressure.</p> <p>Then CH-432B starts measuring blood pressure automatically.</p> <p>Finally, measured systolic value, which is around 185 mmHg, is displayed on LCD.</p>

Comments	Comparison of the Citizen CH-452 with the Citizen CH-432B	
		<p>3) Comparison between CH-452 and CH-432B regarding cuff inflation mechanism We know that there is small difference between CH-452 and CH-432B regarding cuff inflation mechanism.</p> <p>But finally, both of blood pressure monitors reaches to sufficient pressure for accurate blood pressure measurement.</p> <p>Therefore, blood pressure value measured by both of CH-432B and CH-452 is same.</p> <p>Comment The explanation is a little unclear, but the following is inferred:</p> <p>1) In case of CH-452</p> <p>On the first measurement, without the power button pressed, the CH452 will inflate to about 225 mmHg, so it will detect any BP up to 200 mmHg. If it is above that, it will fail to detect a reading and deflate with Err being displayed.</p> <p>On the other hand, a user can override the process by keeping a finger on the power button so that it keeps inflating beyond the checkpoints until it reaches the desired pressure or 280 mmHg.</p> <p>2) In case of CH-432B</p> <p>On the first measurement, without the power button pressed, the CH452 will inflate to 160 mmHg and start deflating checking for a pulse. If no pulse is detected after x mmHg, then it will continue to deflate and measure blood pressure. If a pulse is detected, then, without deflating fully, it will inflate to 200 mmHg and start deflating. This will detect blood pressures to about 170 mmHg. If it is above that, it will fail to detect a reading and deflate with Err being displayed.</p> <p>The next time the user presses the power button the CH452 will inflate to 200 mmHg and start deflating checking for a pulse. If a pulse is detected within y mmHg, then, without deflating fully, it will inflate to 240 mmHg and start deflating.</p>
	<p>2.1</p>	<p>Query Are the above understandings correct? If so, what are the values for x and y? If not, what is the correct sequence?</p> <p>Reply In case of CH-452</p> <p>On the first measurement, without the power button pressed, CH-452 moves full automatic inflation system which detects pulse during inflation process and stops automatically at estimated systolic value + 40mmHg.</p> <p>The maximum inflation value by full automatic inflation system is up to 250mmHg. If inflation detector judges that 250mmHg is not enough to measure blood pressure, CH-452 inflates again up to 280mmHg automatically.</p> <p>For example, if the person of 120 mmHg (SYS) uses CH-452, CH-452 inflates up to around 160mmHg automatically.</p>

Comments	Comparison of the Citizen CH-452 with the Citizen CH-432B	
		<p>Similarly, if the person of 185 mmHg (SYS) uses CH-452, CH-452 inflates up to around 225mmHg automatically.</p> <p>If the person of 230 mmHg (SYS) uses CH-452, CH-452 inflates up to around 250 mmHg automatically. After that, CH-452 inflates again up to 280mmHg automatically.</p> <p>On the other hand, a user can override the process by keeping a finger on the power button so that it keeps inflating beyond the checkpoints until it reaches the desired pressure or 280 mmHg.</p> <p>In case of CH-432B</p> <p>On the first measurement, without the power button pressed, the CH-432B will inflate to 160 mmHg and start deflating checking for a pulse. If a bigger pulse than threshold pulse is not detected within 130 mmHg, then it will continue to deflate and measure blood pressure. If a bigger pulse than threshold pulse is detected, then, without deflating fully, it will inflate to 200 mmHg and start deflating. This will detect blood pressures to about 170 mmHg. If it is above that, it will fail to detect a reading and deflate with Err being displayed.</p> <p>The next time the user presses the power button the CH-432B will inflate to 200 mmHg and start deflating checking for a pulse. If a pulse is detected within 170 mmHg, then, without deflating fully, it will inflate to 240 mmHg and start deflating.</p> <p>Comment Clarification is accepted.</p>
	<p>2.2</p> <p>Query</p> <p>Reply</p>	<p>For each device, if it fails without the user keeping the power button pressed, because SBP is above 200 mmHg</p> <p>a) Will it inflate to 280 mmHg automatically on the next measurement or</p> <p>b) Will the user have to press the power button to get it to inflate to 280 mmHg?</p> <p>In case of CH-452</p> <p>Answer: similar to b)</p> <p>At most of measurement, full automatic inflation system works correctly. By full automatic inflation system, cuff pressure reaches to 250 mmHg. If not enough, CH-452 inflates again up to 280 mmHg automatically.</p> <p>In case of CH-432B</p> <p>Answer: b)</p> <p>Cuff pressure finally reaches to 280 mmHg while repeating re-inflation and sw-on.</p>



Comments	Comparison of the Citizen CH-452 with the Citizen CH-432B	
		Comment Clarification is accepted.
	2.3	Query Will the device always inflate to about 225 mmHg even if the previous BP is much lower?  Reply In case of CH-452 Answer: No. By full automatic inflation system, CH-452 automatically inflates around systolic value + 40mmHg regardless the previous BP.  In case of CH-432B Answer: No. This device inflates up to previous systolic value + 40 mmHg.  Comment Clarification is accepted.
	3	Query There are differences in the inflation algorithms, which affect the inflation mechanics, but item 7 in the declaration form "Inflation Mechanism" is declared as "No". This should be changed to "Yes" with an explanation along the lines of part 1 of the recent reply.  Reply I modify our documents according to your instructions. Please see them.  Comment Revised application is accepted.
<b>Recommendation</b>	Equivalence is recommended	
<b>Date</b>	14/11/2011	