

VALIDATION REPORT

VivaChek™ Ino Blood Glucose Meter

User Software Test

1. Abstract

The purpose of this test was to verify the requirements of VivaChek™ Meter (VGM01) User Software.

The test direct at VivaChek™ Meter (VGM01) 01 User Software Version which upgraded from Software Version 01. The Specific Software Version is SW20710000170001 and SW20720000170001.

2. Materials and Equipments

2.1. One VivaChek™ Meter (VGM01) which unit is mg/dL meter ID: 00301A0000040;

2.2. One VivaChek™ Meter (VGM01) which unit is mmol/L meter ID: 00301B0000041;

2.3. Multimeter , FLUKE 15B, DC regulated power supply;

2.4. Resistor strip, Test strip vial ,One bottle of control solution;

2.5. One PC with Communication Software of VivaChek™ Meter (VGM01);

2.6. Two USB/TTL data lines, YSI, Two button batteries.

3. Test Requirement

This test is required that production line introduces Software V01 into all tested meters.

4. Procedure

See test plan for details.

5. Acceptance criteria

Test function of meter software is required to meet test requirement, on abnormal project.

6. Results and Conclusions

6.1. Appendix 7.1 Turn on/off Meter.

No Invalid project, All test results are qualified.

6.2. Appendix 7.2 Test in Setting Mode.

No Invalid project, All test results are qualified.

6.3. Appendix 7.3 Alarm Information Test.

No Invalid project, All test results are qualified.

6.4. Appendix 7.4 Storage Test.

No Invalid project, All test results are qualified.

6.5. Appendix 7.5 Blood and Control Solution Test.

No Invalid project, All test results are qualified.

6.6. Appendix 7.6 Other Test.

No Invalid project, All test results are qualified.



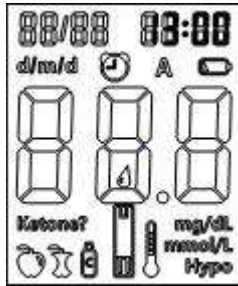
6.7. Appendix 7.7 Bluetooth Connection Test.


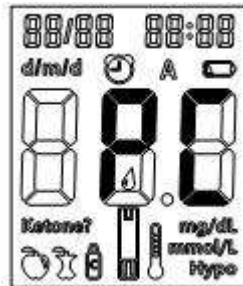
No Invalid project, All test results are qualified.

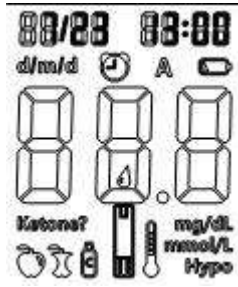
7. Test Record

7.1 Turn on/off Meter

The test proves the content about all LCD segments were displayed and the corresponding key operation when meter is turned on.

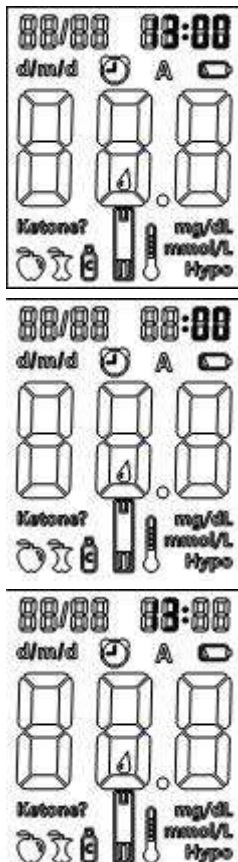
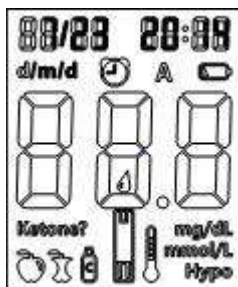
Step	Test Number	Procedure Description	Consequence	Pass/Fail
1	GPM_PO_10	Meter at sleeping mode, turned on the meter by short pressing power button	All LCD segments were displayed for 2 seconds, as shown below 	Pass ■ Fail □
2	GPM_PO_20	Meter at sleeping mode, turned on the meter by long pressing power button for 2 seconds	All LCD segments were displayed for 2 seconds, as shown below  Verify that the instrument buzzer emits sound to confirm that the instrument is in the set state, as shown below 	Pass ■ Fail □
3	GPM_PO_30	When the device is dormant, press the left button and the right button for 2 seconds at the same time	Verify if all LCD segments were displayed for 10 seconds, as shown below	Pass ■ Fail □

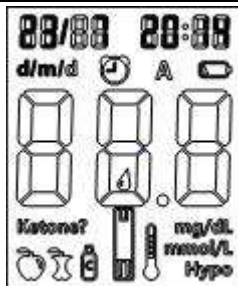
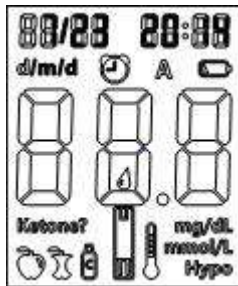
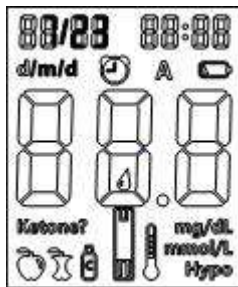
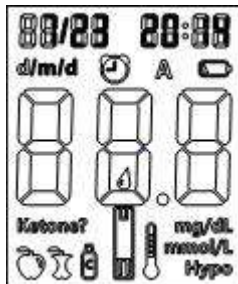
				
4	GPM_PO_40	In hibernation, right click for 2 seconds	<p>The device displays "PC" as shown in the figure below, and no operation enters hibernation mode in two minutes</p> 	Pass ■ Fail□
5	GPM_PO_50	Remove meters' battery and reload it after 5 minutes	Verify if all LCD segments were displayed for 2 seconds when meter was turned on and if meter goes into time setting mode	Pass ■ Fail□
6	GPM_PO_60	Meter was placed for two minutes without any operation	Verify if meter can go into sleeping mode	Pass ■ Fail□
7	GPM_PO_70	Insert test trip into the test strip port when meter at sleeping mode	Verify if a symbol of a test strip with a flashing blood drop appear on screen which let you know it's time to add blood sample after all LCD segments were displayed for 2	Pass ■ Fail□

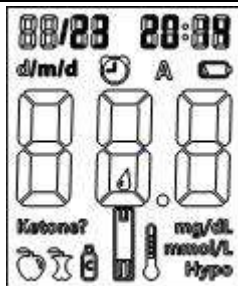
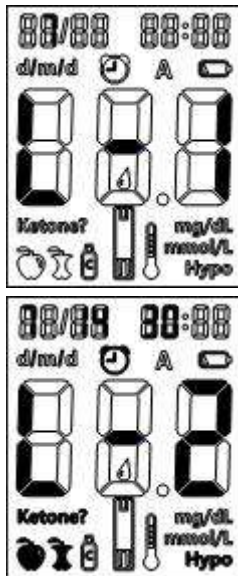
			seconds. 	
8	GPM_PO_80	Pull out the test strip when meter was on	Meter was turned off within 2 seconds when it isn't at history viewing status	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>
9	GPM_PO_90	Repeated step5, the meter was turned on and placed for two minutes without any operation	Verify if meter can go into sleeping mode.	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>
10	GPM_PO_100	Meter goes to sleeping mode by short pressing power button when meter at history viewing status	Verify if meter can go into sleeping mode.	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>



7.2 Test in Setting Mode




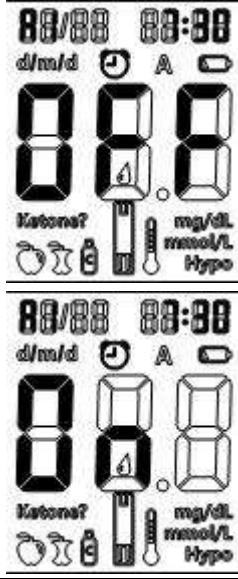
This test is mainly used for verifying if each state of meter is correct in test mode.


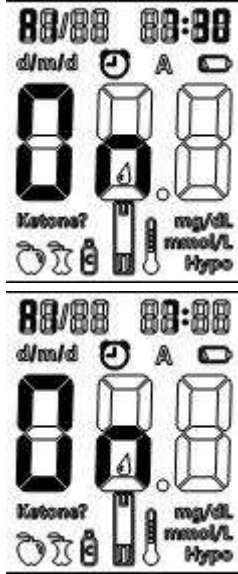

Step	Test Number	Procedure Description	Consequence	Pass/Fail
11	GPM_SM_10	Set the year: Meter goes into year setting mode after long pressing power button and buzzer beeps, the digit of year was flashing continuously, changing the year number by press left side up & down button and hold power button to set.	<p>Verify that the instrument displays the small number on the upper right of "HH:MM" as shown in the figure below.</p> <p>Verify that the time of the instrument can be set.</p> 	Pass ■ Fail □
12	GPM_SM_20	Set the sun/month mode and sun/month, and the day/month display will flicker after setting the time. At this time, the left and right keys change the day/month and month/day mode, and press the power button to confirm	<p>Confirm whether the display is m/d or d/m, and the corresponding month and date.</p> 	Pass ■ Fail □

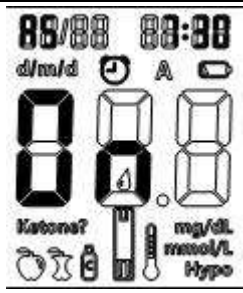


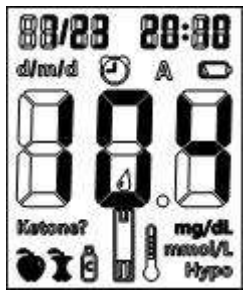
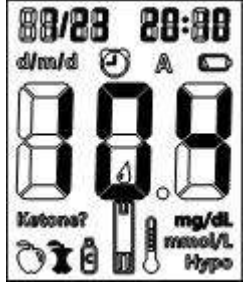
				
13	GPM_SM_30	<p>Set the year, and enter the year setting after setting the date/month mode. At this time, the year in the upper right corner shows flicker. The left and right keys are used to change the value of the year, and press the power button to confirm</p>	<p>Confirm the year is displayed in the upper right corner. Confirm that the instrument can set the year, and the setting range of the year is 2014-2030</p>  	Pass ■ Fail□
14	GPM_SM_40	<p>After setting the year, enter the month setting. At this time, the display of the month will flash. The left and right keys are used to change the value of the month</p> <p>After setting the month, enter the day setting mode. At this time, the display of the day flashes. The left and right keys are used to change the value of the day</p>	<p>Confirm whether m/d or d/m is displayed, and the corresponding month and date, and confirm whether the setting value of day and month is correct.</p> 	Pass ■ Fail□

				
15	GPM_SM_50	Change the time of the instrument through the PC, and synchronize with the local time, remove the battery, and put the instrument for more than five minutes, leaving the instrument in a state of complete power loss. Then load the battery, check the year/date/time of the instrument, and confirm it is the same as before the power loss	Confirm that the year/date/time of the instrument is in sync with the time of the computer	Pass ■ Fail □
16	GPM_SM_60	Set user mode I-1 (simple mode)L2(complex mode) The device default is simple mode, press the power button to confirm.. Change user mode: change user mode to complex mode by left-right key, and press power button to confirm	Verify if there is a corresponding I-1 I-2 as shown in the following figure. Verify that the instrument can change the user mode. 	Pass ■ Fail □

17	GPM_SM_70	After setting the hypoglycemia alarm (Hypo) in complex mode into complex mode, "Hypo" will flash, and "ON" or "OFF" will be displayed all the time. Press the left and right keys to select Hypo alarm to turn ON" ON "or" OFF ", and press the power button to confirm	Verify that the instrument displays "On", "OFF" and "Hypo", and that the instrument is capable of setting HYPO On and OFF. 	Pass ■ Fail□
18	GPM_SM_80	After selecting HYPO "on" setting, the instrument will display the HYPO setting value of 70 mg/dL(3.9 mmol/L) by default, press the left and right keys to change the value, and the range is 60-80mg/ dL(3.3-4.4mmol/L), and press the power button to confirm	Verify that the value of HYPO and "Hypo" are displayed and that the instrument can set the value of HYPO within the required range.. 	Pass ■ Fail□
19	GPM_SM_90	Set the KETONE alarm, After setting HYPO, enter the mode of setting ON, "Ketone?" will flash, and "ON" or "OFF" will always be displayed. Press the left and right keys to select the "ON" or "OFF" alarm, and press the power button to confirm	Confirm that the instruments display "On," "OFF" and "Ketone?" confirm that the instruments can turn On or OFF the blood-ketone alarm function	Pass ■ Fail□

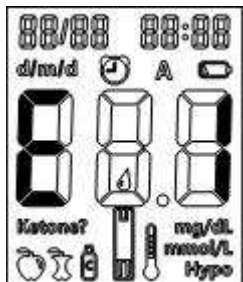
				
20	GPM_SM_100	Set alarm status: after setting the "OFF" alarm,  and "OFF" will be displayed ON the LCD screen, and the symbol "A1" will flash in the upper left corner. Press the left and right buttons to select "ON" or "OFF", and press the power button to confirm	<p>Verify that ON and OFF, "A1" and . You can also set the alarm A1 on or off.</p> 	Pass ■ Fail□
21	GPM_SM_110	Select "ON" and enter the hour setting mode of alarm A1, change the hour value through the left and right keys, and press the power button to confirm	<p>Confirm that the corresponding alarm clock time is displayed in the upper right corner, and the number of hours is flashing, as shown in the figure below.</p> <p>Make sure you can set the hour Settings for alarm A1</p>	Pass ■ Fail□

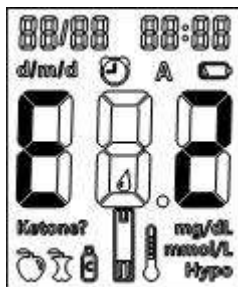
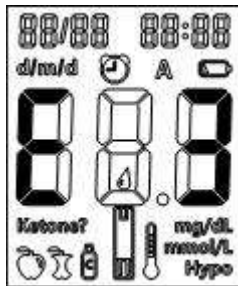
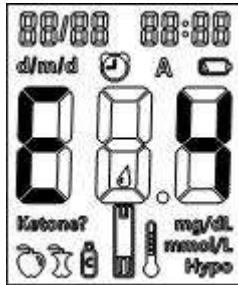
				
22	GPM_SM_120	After setting the hours and confirming, enter the setting mode, and the display will flash. Change the value of the left and right keys (within 0,15,30,45), press the power button to confirm	<p>Verify that the instrument can change the alarm Settings</p> 	Pass ■ Fail□
23	GPM_SM_130	Step 20, step 21: set A2 to A5	<p>Verify the alarm Settings for A2 to A5</p> 	Pass ■ Fail□

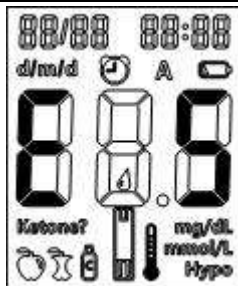
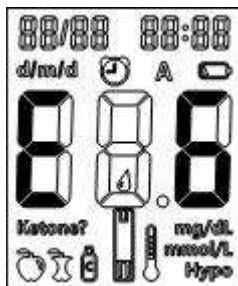
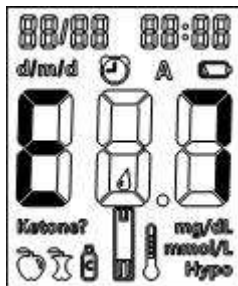

				
24	GPM_SM_140	<p>Label blood test results, After the test results are displayed, mark the meal before or after the meal. Press the power button to confirm before or after the meal</p>	<p>Verify that the instrument displays  and , can be marked for selection</p>  	Pass ■ Fail□





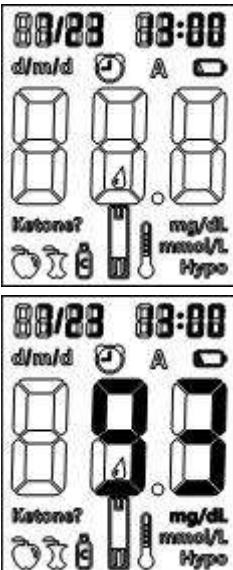
7.2 7.3 Alarm Information Test

The following tests aimed at verifying the display of alarm information.

Step	Test Number	Procedure Description	Consequence	Pass/Fail
25	GPM_EM_10	<p>Adding blood sample before a symbol of a test strip with a flashing blood drop appeared.</p>	<p>The meter screen indicates the warning word "E 1" , as shown below</p> 	Pass ■ Fail□

26	GPM_EM_20	The test strip has been used or polluted	<p>The meter screen indicates the warning word "E 2", as shown below</p> 	Pass ■ Fail□
27	GPM_EM_30	The test strip is wrong.	<p>The meter screen indicates the warning word "E 3", as shown below</p> 	Pass ■ Fail□
28	GPM_EM_40	The sample is wrong	<p>The meter screen indicates the warning word "E 4", as shown below</p> 	Pass ■ Fail□
29	GPM_EM_50	Meter is used outside the operational temperature range (over 5-45°C).	<p>Confirm that "E 5" and "!" appear on the instrument, and the alarm is displayed as shown below</p>	Pass ■ Fail□


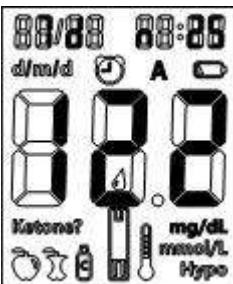

				
30	GPM_EM_60	Hardware error	<p>The meter screen indicates the warning word "E 6"&"E 7", as shown below"</p>  	Pass ■ Fail□
31	GPM_EM_70	Not enough blood or control solution was applied	<p>The meter screen indicates the warning word "E 6"&"E 7", as shown below"</p> 	Pass ■ Fail□
32	GPM_EM_80	Test result is above 600 mg/dL(33.3 mmol/L).	<p>The meter screen indicates the warning word "HI" with continuously beeps , as shown below</p>	Pass ■ Fail□

				
33	GPM_EM_90	Test result is under 10mg/dL(0.6 mmol/L).	<p>The meter screen indicates the warning word " LO " with continuously beeps , as shown below</p> 	Pass ■ Fail□
34	GPM_EM_100	The battery voltage is too low	<p>Confirm that the instrument appears "  " or  alarm, as shown in the figure below</p> 	Pass ■ Fail□

7.4 Storage Test



The following tests aimed at verifying memory historical data store

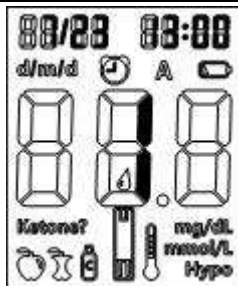
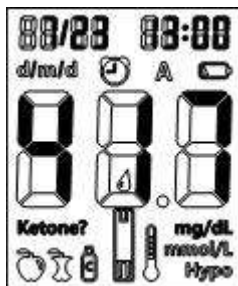
Step	Test Number	Procedure Description	Consequence	Pass/Fail
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35	GPM_EM_10	Press the power button to start up the instrument in simple mode (I-1), and press the power button again after the instrument prompts the cable to enter the display screen of the historical test results.	Confirm the history test results as shown below. 	Pass ■ Fail□
36	GPM_EM_20	Press the left key to enter the last test result, and right key to enter the latest test result.	Confirm 7-day average display 	Pass ■ Fail□
37	GPM_EM_30	Press left and right keys to enter the last or next test results until the last test results, and press left button to display END	The left key instrument displays END after confirming the last test result 	Pass ■ Fail□
38	GPM_EM_40	When the 7-day average is displayed in complex mode, right click to enter the average of the other days, including 14 days, 30 days, 30 days before meal and 30 days after meal	Confirm the display of the average mode of different days, including 7, 14, 30, 30FPG and 30PPG	Pass ■ Fail□
39	GPM_EM_50	Press the power button to shut down	Press the power button to enter the dormancy state	Pass ■ Fail□

7.5 Blood and Control Solution Test

The following tests will verify the software for Blood and Control Solution Test.

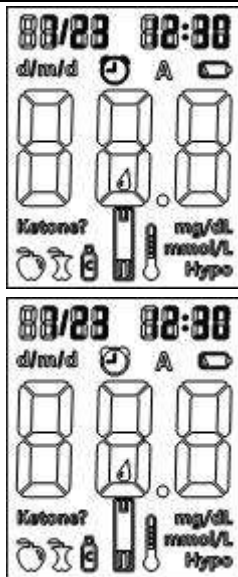
Step	Test Number	Procedure Description	Consequence	Pass/Fail
40	GPM_BT_10	The instrument is in complex mode, KETONE alarm is on, HYPO alarm is off for hypoglycemia, and HYPO alarm value is 80mg/dL. When the instrument is dormant, insert the paper strip	Verify that when the strip is inserted, the instrument displays 2S in full screen and the buzzer makes a sound. After verifying the above process, the instrument shows the time and the strip mark, and the blood drop sign is in flickering state as shown in the figure below 	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>
41	GPM_BT_20	When the blood drop sign is flashing, add the blood sample to the sample window of the strip. The blood glucose concentration of the sample is required to be between 300mg/dL and 600mg/dL (YSI test value).	Verify the sound of the buzzer during the blood sample addition process, and the instrument enters the countdown process from 5 to 1 The instrument display is shown below 	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>

				
42	GPM_BT_30	Wait five seconds	<p>Test results and time will appear on the device, and the KETONE alarm display will appear on the screen, emitting ""drip-drip"" sound.</p> 	Pass ■ Fail□
43	GPM_BT_40	Pull out strip	Verify the strip is pulled out and the device goes into hibernation in one second	Pass ■ Fail□
44	GPM_BT_50	Repeat the steps of 39-41 and change the blood glucose concentration of the sample to below 80mg/dL and above 10mg/dL(YSI test value).	Verify that the instrument does not give HYPO alarm	Pass ■ Fail□
45	GPM_BT_60	HYPO alarm function setting HYPO alarm value to be 70mg/dL. Repeat the steps of 39-41. Blood sample concentration should be greater than 100mg/dL(YSI test value).	Verify that the instrument does not appear HYPO alarm	Pass ■ Fail□

46	GPM_BT_70	Blood test is conducted according to the previous steps. The blood sample is required to be less than 50mg/dL(YSI test value).	Verification instrument appears "" drop by drop" "sound,HYP0 alarm	Pass ■ Fail□
47	GPM_BT_80	Add the quality control solution to the sample window of the strip, and the concentration of the quality control solution is required to be higher than 300mg/dL and less than 600mg/dL(YSI test value).	<p>The test results of the verification instrument showed that the buzzer sounded and the indication of the quality control liquid appeared when the results were displayed.</p> <p>The HYPO and KETONE flags will not appear on the instrument</p> 	Pass ■ Fail□

7.6 Other Test

Step	Test Number	Procedure Description	Consequence	Pass/Fail
48	GPM_AT_10	Set the system time to 11:00, turn on the alarm A1, and set the alarm time to 12:30, then wait until 12:30	Verify that the time alarm will last for one minute (about 30 times), and the corresponding time will be displayed on the screen, and the alarm signal will flicker on the screen	Pass ■ Fail□

				
49	GPM_AT_20	Use two units of mg/dL and mmol/L respectively, test 10 times with a 100K resistance bar, and then check the history.	All the records of the instruments that verify mg/dL are in mg/dL; All the records are in mmol/L;	Pass ■ Fail□
50	GPM_AT_30	The instrument is set to complex mode, and HYPO alarm is turned on, and HYPO alarm value is set to 72mg/dL(4mmol/L),ketone alarm is set to turn on, and the alarm clock is set to all turn on, of which A1 7:15;A2 9:30;A3 12:15;A3 16:15;A4 19:30;A5 22:15, remove the battery, and put the instrument for more than five minutes, leaving the instrument in a complete power loss state.The battery is then loaded to see if the device is set up in the same state as it was before it dropped.	Make sure that all Settings of the instrument are unchanged and that the instrument concentration unit is unchanged.	Pass ■ Fail□
51	GPM_AT_40	Repeat step 48. After the device removes the battery, place it at a temperature above 50 degrees Celsius for more than an hour, and then load the battery to see the	Make sure that all Settings of the instrument are unchanged and that the instrument concentration unit is	Pass ■ Fail□

		setting parameters.	unchanged.	
52	GPM_AT_50	Repeat step 48. After the device removes the battery, place it at a temperature below 0 degrees Celsius for more than an hour.	Make sure that all Settings of the instrument are unchanged and that the instrument concentration unit is unchanged.	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>
53	GPM_AT_60	Repeat step 48 and wait for the set alarm time after the device is powered on.	Make sure that the alarm clock is working after the alarm time is up, display and buzzer function as described in step 46	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>