

IVD	For In vitro diagnostic use		Temperature limitation / Store at
	Please consult instructions for use		Use by /Expiry date
	Do not reuse		Manufacturer
LOT	Lot number		Caution, consult accompanying document
	Keep dry		Keep away from sunlight
	Humidity limitation	EC REP	EU representative.
CE 0123	This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.		
<p>Performance Characteristics:</p> <p>Accuracy: $\geq 95\%$ of the individual glucose results fell within ± 15 mg/dL(0.83 mmol/L) at glucose concentration < 75 mg/dL(or 4.2 mmol/L) and within $\pm 20\%$ at glucose concentration ≥ 75 mg/dL(or 4.2 mmol/L), compared with glucose analyzer YSI 2300.</p> <p>PRECISION: CVs (%) of intermediate precision and repeatability were less than 5%.</p>			

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Before You Begin

PLEASE READ THIS BEFORE USING.

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
2. Use the device only for the intended use described in this User Guide.
3. Do not use test strips and control solutions which are not supplied by the manufacturer.
4. Do not use the device if it is not working properly, or if it has suffered any damage.
5. Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.
6. KEEP THIS USER GUIDE WITH YOU.

Intended Use

IVD The system is intended for use outside the body (*in vitro* diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

Principle of Measurement

Blood glucose is measured by an electrical current that is produced when a blood

samples mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The Medicare System-LIS meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L).

Caution

1. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
2. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
3. High altitudes above than 3,402 meter (11,161 ft) may affect the test results.
4. Temperatures outside the range of 5°C to 45°C (41°F to 113°F) may affect the test results. Do not test beyond of temperature range.

IMPORTANT HEALTH-RELATED INFORMATION

1. Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
3. Test results below 60 mg/dL (3.3 mmol/L)*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)*2 indicates high blood glucose (hyperglycemia). If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.

- SIDE A :**
 1. Getting To Know Your System
 2. Prepare For Blood Sampling
- SIDE B :**
 3. Performing Blood Test
 4. Understanding Your Test Result
 5. Memory Recall
 6. Control Solution Testing
 7. Caring For Your Meter And Test Strip
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1. Getting To Know Your System

The Medicare Blood Glucose Monitoring System-LIS

The Medicare System-LIS system uses the latest technology to provide you with easy and comfortable testing. The system requires only a 0.3 μ L of blood sample to complete the testing in only 6 seconds.

STRIP SLOT :
Insert the test strip here. The meter will turn on automatically.

DISPLAY :
The large, easy to read display shows test results, messages, test results stored in memory.

METER LABEL:
Each meter has its unique number on it. It can be used when you want to obtain warranty service. Please do not alter or tear the label off.

SET BUTTON:
Located in the battery compartment; press button to enter meter setting. Refer to "SETTING YOUR METER" section of this user guide for details.

M BUTTON:
Main button, press button to turn the meter on or perform other functions described in this User Guide.

BATTERY COMPARTMENT :
Holds one 3V Lithium battery (CR2032).

Meter

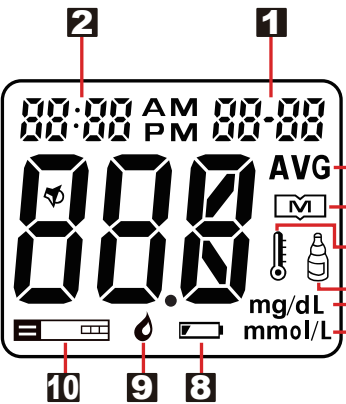
TEST STRIP HANDLE :
Hold this part to insert the test strip into the meter slot.

ABSORBENT CHANNEL:
Apply a drop of blood here.

CONTACT BARS:
Insert this end into strip slot.

CONFIRMATION WINDOW:
This is where we confirm if enough blood is applied for the test. Ensure that it is fully covered with blood sample.

Test Strip



1. **DATE:** Display year, month and date.
2. **TIME:** The meter is programmed for a 12 hour period format.
3. **AVERAGE:** Appears when the meter is in the memory mode while recalling 7/14/28 day test averages.
4. **MEMORY SYMBOL:** Appears when in the memory mode.
5. **THERMOMETER SYMBOL:** Appears when ambient temperature is above or below the acceptable range needed for testing.
6. **CONTROL SOLUTION TEST SYMBOL:** Appears when you are in Control Solution Mode. Your test result will not be stored in meter memory.
7. **UNIT OF MEASURE:** Appears with the test result either in mg/dL or mmol/L.
8. **BATTERY SYMBOL:** Appears when battery is weak.
9. **BLOOD DROP SYMBOL:** Flashes when sample should be applied.
10. **STRIP SYMBOL:** Appears when the meter is turned on and waiting for inserting a test strip.

REPLACING THE BATTERY

1. The meter comes with ONE Lithium battery (battery type CR2032).
2. Battery life will vary depending on usage, so always keep a spare battery on hand.
The battery should last about 1000 tests or 12 months when testing 3 times a day.
3. When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace it as soon as possible.
4. When battery symbol appears together with E-b on the display, the meter will no longer give results and you must replace the battery immediately. Please always have one spare battery with you to ensure that you can replace the battery anytime.

How to replace the battery

1. Make sure the meter is turned off. Let the front of the meter rest in the palm of your hand. Press the buckle on the battery cover and lift up to open the cover. Remove the battery.
2. With the plus (+) side up, place the battery (battery type CR2032) in the compartment and slide it upwards until it is locked into place. You should hear a beep to indicate the battery installed correctly. If not, please replace the battery correctly.
3. Close battery cover.

NOTE:

1. Replacing the battery does not affect the test result stored in memory. However the time and date may need to re-set.
2. As with all small objects, the battery should be kept away from small children as a safety precaution. If the battery is swallowed, see medical assistance immediately.
3. Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for 3 months or more.
4. Please discard the product or the batteries properly according to the regulations of your country.

SETTING YOUR METER

Please install battery first and set to correct settings before you begin to test.

- STEP 1. Enter Setting Mode**
Start with the meter off. Open the battery compartment, and press SET BUTTON. The meter will turn on and enter the setting mode.
- STEP 2. Set the Year**
The year appears with the number flashing. Press and release the M BUTTON to obtain the desired year. Press SET BUTTON to confirm and move to next MONTH setting.
- STEP 3. Set the Month**
The month appears with the number flashing. Press and release the M BUTTON to obtain the desired month. Press SET BUTTON to confirm and move to next DATE setting.
- STEP 4. Set the Date**
The date appears with the number flashing. Press and flash the M BUTTON to obtain the desired date. Press SET BUTTON to confirm and move to next HOUR setting.
- STEP 5. Set the Hour**
The hour appears with the number flashing. Press and release the M BUTTON to obtain the desired hour. Press SET BUTTON to confirm and move to next minutes setting.
- STEP 6. Set the Minute**
The minute appears with the number flashing. Press and release the M BUTTON to obtain the desired minute. Press SET BUTTON to confirm and the meter will enter to next unit setting.
- STEP 7. Set the Unit of Measurement**
The existing unit (for example mg/dL) will appear and flash. You can choose to reset measurement unit. If you do not want to change unit, press SET BUTTON to skip this step. If you want to change unit, press and hold the M BUTTON for 3 seconds to change the unit to mmol/L. Press SET BUTTON to confirm and the meter will enter to next setting.
- STEP 8. Delete Memory**
When the dEL symbol and the flashing memory symbol appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the SET BUTTON again to skip this step. If you want to clear ALL memory, press and hold M BUTTON for 4 seconds. The "--" image will appear on the LCD screen to indicate that all memory has been deleted.
- STEP 9. Complete Setting**
After delete memory, the meter will display "OFF" before shut down. The meter setting is now completed.

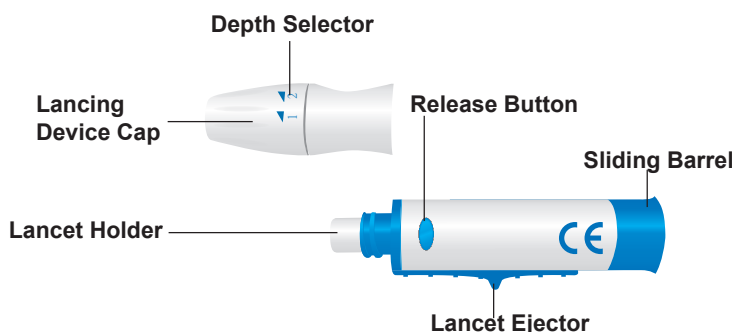
IMPORTANT :

1. The time, date and unit of measurement can ONLY be changed in the setting mode. Therefore, when you perform a blood glucose testing, it is not possible to change those parameters.
2. Your meter displays 7, 14 and 28-day averages which you can access from the meter memory. These averages are calculated from your latest result obtained during the last 7, 14 and 28 days.
3. Your meter can display test result in milligram per deciliter (mg/dL) or millimoles per liter (mmol/L). The mg/dL unit is standard in the United States. The mmol/L unit is standard in Canada and European countries. Your meter has been preset at the factory with the standard unit measurement used where you live. When you turn off the meter or replace the battery, the unit will not be changed.
4. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment. Please always consult with your healthcare professionals before you reset the unit of measure.

2. Prepare For Blood Sampling

Adjustable Lancing Device

Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.



Lancet

Protective cap

Important Lancing Device and Lancets Information

1. Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.

IMPORTANT : The meter and lancing device are for single patient use. Do NOT share them with anyone including other family members ! Do NOT use on multiple patients !

Setting your Lancing Device

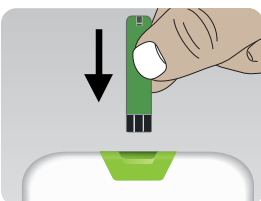
1. Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.
2. Twist off the protective cap until it separates from the lancet.
3. Replace the lancing device cap and set the puncture depth to the desired number.
NOTE: THE DEPTH SELECTOR OFFERS 5 LEVELS OF SKIN PENETRATION:
1-2 FOR SOFT OR THIN SKIN
3 FOR AVERAGE SKIN
4-5 FOR THICK OR CALLOUSED SKIN
4. Pull back the sliding barrel until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.

3. Performing Blood Test

1. **Wash Your Hands and the Puncture Site** : Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.



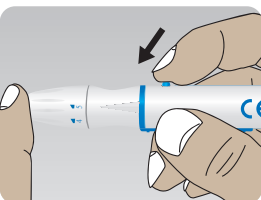
2. **Insert Test Strip** : Remove a new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically. When the blood symbol blinking, you are ready to perform a test.



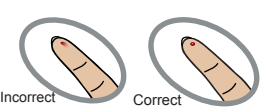
3. **Select and Lance a Puncture Site**

*For Fingertip
Hold the prepared lancing device firmly against the side of your fingertip. Press release button.

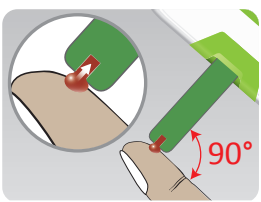
*For AST
Please refer to the "About Alternative Site Testing (AST)" Section. Please consult your healthcare professional before obtaining blood from site other than your fingertip.



4. **Obtain a Blood Sample** : Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.3 µL of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.

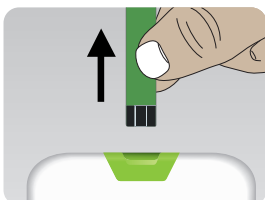


5. **Apply Blood Sample** : Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Then the meter begins to count down.



6. **Read Your Result** :

The meter will display your blood glucose value after 6 seconds.

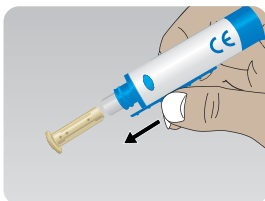


7. **Remove Strip to Turn Meter Off** :

Your blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip.



8. **Secure the Used Lancet** : Twist off the lancing device cap, and push the exposed tip of the lancet into its protective cap.



9. **Discard the Used Lancet** : Slide the lancet ejector forward and dispose the lancet. Discard the lancet according to your safety regulations.

* Do not reuse lancets.

4. Understanding Your Test Result

The normal blood glucose range is below 100 mg/dL (5.6 mmol/L) for a fasting, non-diabetic adult, but less than 140 mg/dL (7.8 mmol/L) two hours after meals.* Consult your healthcare professional to find out your target blood glucose value.

If your blood glucose result seems unusually high or low, or inconsistent with your previous results, check the following:

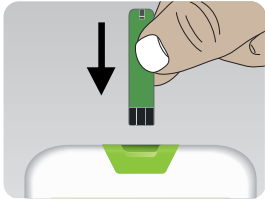
1. Was the blood sample applied immediately to the test strip after removing it from the vial?
2. Was the volume of the blood sample sufficient?
3. Was the test strip vial cap tightly sealed?
4. Was the test strip used before the expiration date?
5. Were the test strips stored away from extreme temperatures in very cold or hot weather or from areas of high humidity?

Then run a control test with Medicare control solution. If the control test result is within the acceptable range, review testing procedure and repeat your blood glucose test with a new test strip. If your blood glucose value is still inconsistent with your previous results, glucose trend, or how you feel, contact your doctor immediately for help.

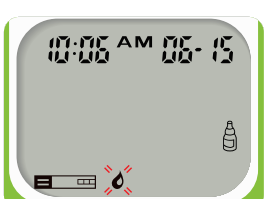
REFERENCE:

*American Diabetes Association (<http://www.diabetes.org/diabetes-basics/prevention/pre-diabetes/diagnosis.html>)

How to Perform a Control Test



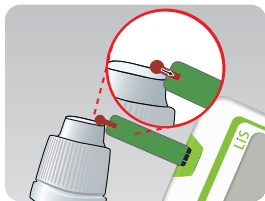
1. **Insert Test Strip** : Insert a new test strip into the strip slot, the meter will activate.



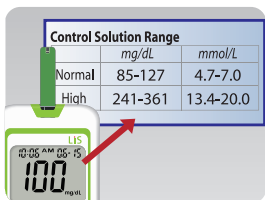
2. **Mark as a Control Solution Test** : After the blood symbol() appears, press M BUTTON and a CONTROL SOLUTION TEST SYMBOL() shows up, now you are in the Control Solution Mode. The meter will not store your test result in the memory when you preset the test as a control solution test. If you decide not to perform a control solution test, press M BUTTON again and the CONTROL SOLUTION TEST SYMBOL() will disappear.



3. **Squeeze a drop of Control Solution** : Shake control solution bottle well. Remove the cap. Squeeze bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton swab. Squeeze a drop on clean bottle cap/fingertip /non-absorbent surface.



4. **Apply Control Solution** : Apply the drop to the opening of the strip absorbent channel until the confirmation window is filled. The meter begins to count down.



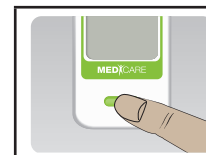
5. **Check if the test result is in range**: After the meter counts down, the test result shows up. Compare the test result with the range printed on the test strip vial. The result should fall within the printed range.

NOTE :

1. Be sure that you are in Control Solution Mode so that the test result will not be stored in thermometer memory.
2. DO NOT APPLY THE CONTROL SOLUTION DIRECTLY TO THE TEST STRIP! Overdosed solution may give inaccurate result.
3. Repeat test if test result falls outside the control range stated on the test strip label. If subsequent test remains to produce unacceptable result, the meter or test strip may be faulty. DO NOT use the system. Contact us or your local distributor for help.

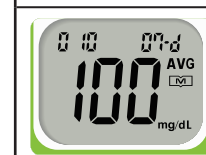
5. Memory Recall

The Medicare System-LiS automatically stores 120 test results, letting you review them in order from the most recent to the oldest. The meter also calculates and displays 7, 14 and 28-day averages. You can review the individual or average test result by entering the memory mode.



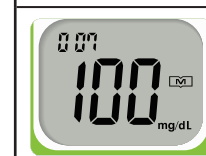
STEP 1. Enter the Memory Mode

While the meter is turned off, press M BUTTON to turn on the meter. When the strip symbol blinks in the display, press M BUTTON again to enter memory mode.



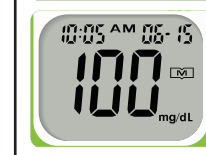
STEP 2. Recalling Average Test Results

When entering the memory mode, the 7-day average will appear. If you continue to press the M BUTTON, the 14-day and 28-day averages will appear in order.



STEP 3. Recalling Individual Test Results

After 28-day average, the most recent test result with date and time will be shown. Press M BUTTON once and the next most recent test result will appear. Each time you press and release the M BUTTON, the meter will recall up to your last 120 test results in order. When the memory is full, the oldest result is dropped as the newest is added. After reaching the last set of result, the meter will turn off automatically.



STEP 4. Exit the Memory Mode

If you want to exit the memory mode before reaching the last result, press and hold M BUTTON for three (3) seconds to turn off the meter.

NOTE :

1. The control solution results are NOT stored in the memory if you preset the control test correctly. (Please refer to the "CONTROL SOLUTION TEST" Section for details). The list of past results and the result average are for blood glucose results only.
2. When using the meter for the first time, "----" is displayed. When you recall the test results or review the average result, it means that there is no test result in memory.
3. The averages are calculated from your latest result obtained during the last 7, 14 and 28 days.
4. Anytime in memory mode, you can press M BUTTON for three (3) seconds to exit and turn off the meter.
5. While in the memory mode, if you leave the meter alone without any action for one (1) minute, the meter will turn off automatically.

6. Control Solution Testing

If your Medicare control solution did not come with an Medicare control solution instruction, the following information shall take the place of the instruction.

Medicare control solutions contain a pre-set amount of glucose that reacts with OKmeter test strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you can make sure that the meter and the test strips are working properly together as a system and that you are performing the test correctly.

Why perform a control solution test?

1. To ensure that your meter and test strip are working properly together.
2. To allow you to practice testing without using your own blood.

When should the control solution test be performed?

1. Whenever you suspect that the meter or test strips are not working properly.
2. When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
3. When test strips are exposed to extreme environmental conditions.
4. If you drop the meter.
5. After changing the battery.

Important Control Solution Information

1. Check the expiration date on the control solution bottle. Do not use if expired.
2. Control solution, meter, and test strips should come to room temperature (68-77 °F/20-25°C) before testing.
3. Shake the bottle before use, discard the first drop of control solution after squeezing, wipes off the dispenser tip to avoid contaminations. These steps ensure you will get a good sample and an accurate result.
4. Record the discard date on the bottle when you open a new bottle of control solution.

NOTE :

1. There are two levels of control solution (normal and high) available to purchase. Please contact with your local distributor when required.
2. The control solution range printed on the test strip vial is for Medicare control solution only. It is used to test meter and strip performance. It is not recommended range for your blood glucose level.

Composition:

1. D-Glucose	5. Disodium EDTA
2. Polyvinyl acetate (aqueous emulsion)	6. Food Pigment Red No.6
3. Fumed silica	7. Antifoaming agent
4. Sodium Benzoate	(Polyethylene Glycol 4000)

9. Display Messages And Problem-Solving Guide

The following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred.

Improper use may cause an inaccurate result without producing an error message.

In the event of a problem, refer to information under "action to take"

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check	If some parts of the display are not working. Contact your local distributor for help.
	Moving Strip	The meter is waiting for test strip to be inserted.
	Blinking Blood	The meter is ready for blood applying into test strip.
	Deleting memory	Deleting is complete.
	Test result is higher than 600 mg/dL (33.3 mmol/L).	If this is not confirmed by the way you feel, review proper testing procedure and perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.
	Test result is lower than 20 mg/dL (1.1 mmol/L).	If this is not confirmed by the way you feel, review proper testing procedure and perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Battery is weak.	Replace battery soon.
	Battery is dead.	Replace battery now.
	Maybe: 1. Used strip or moistened strip is inserted. 2. Meter is defective.	You have to: 1. Repeat test with a new test strip. 2. Contact your local distributor for help.
	Temperature is out of the operating range.	The meter is not working. Move to an area with temperature between 10°C to 40°C (50°F - 104°F) and wait at least 30 minutes. Do not artificially heat or cool the meter.
No responses when strip is inserted into the meter	Maybe: 1. Battery is dead. 2. Wrong strip be inserted. 3. Meter is defective.	You have to: 1. Replace battery. 2. Insert the test strip correctly. 3. Contact your local distributor for help.
No responses when blood sample is applied to the strip	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Contact your local distributor for help.

8. System Specifications

Model Name	BG-101
Assay Method	Electrochemical biosensor
Test Sample	Capillary Whole Blood
Test Result	Referenced to plasma glucose value
Alternative Site Testing	YES (palm, forearm)
Sample Size	0.3 µL
Measuring Time	6 seconds
Measuring Range	20 – 600 mg/dL (1.1 – 33.3 mmol/L)
Acceptable Hematocrit Range	20~60%
Operating Condition	10°C~40°C (50°F~104°F), between 10-85% R. H.
Storage/Transportation Condition	4°C~40°C (39°F~104°F), between 10-85% R. H.
Memory Capacity	120 test results with time and date
Average Calculation	7, 14, and 28 days
Power Supply	One 3-volt Lithium Battery (battery type CR2032)
Battery Life	Approximately 1,000 tests
Automatic shut-off	In 2 minutes
Dimensions	80 mm(L)x 48 mm(W) x 15 mm(H)
Weight	37 g