



# iProtein Reader (BT ver.)

**IVD**

For professional users only  
For in-vitro diagnostics only

Model No.: BMREDP0101/TO0008AA1010

## [Warning]

Avoid using iProtein Reader (BT ver.) (hereinafter referred to as “this device”) in environments containing combustible gases to prevent potential explosions or fire hazards. Prior to usage, it is essential to meticulously review these Instructions for Use and adhere to them diligently to guarantee accurate analysis results.

## Efficacy

- This device is intended for use in clinical laboratories and point-of-care setting.
- It is imperative to use this device only in conjunction with its corresponding iProtein assay cartridge kit.
- This device can be paired with Bluetooth-enabled terminals for data transmission purposes.

## Instructions for Use

These Instructions for Use serve as the operational manual for this device, providing guidance for troubleshooting.

When analyzing patient samples, please consult the pertinent test information supplied in the instructions accompanying the iProtein Assay Cartridge Kit (hereinafter referred to as “the cartridge”). It is recommended to thoroughly review these Instructions for Use before operating this device and its corresponding assay cartridges.

## Intended Purpose

This device is an in-vitro diagnostic and testing system that is used exclusively in combination with its matching iProtein assay cartridge kit. This test method measures the biochemistry values in blood taking advantage of the antigen antibody reaction and the SH-SAW sonic wave based on the piezoelectric effect (this instrument sends the electric signal to the cartridge for sonic/electric signal conversion). Samples obtained from the patient are dripped into the reaction zone and reference zone of the assay cartridge. When the combination of the antigen and the antibody changes the mass/weight on the chip inside the assay cartridge, the speed at which the surface sonic wave in the reaction zone is transmitted slows down because of the change in mass/weight and the electric signal sent out of the cartridge is changed accordingly. The difference between the reaction zone and the reference zone is picked up by the electronic signal sent off and received by this instrument; the concentration of the analyte in the sample is converted accordingly.

## Summary and Description of Test

This device is an *in-vitro* diagnostic and testing system designed exclusively for use with its corresponding assay cartridge kit. This testing method measures biochemical values in blood or urine by leveraging the antigen-antibody reaction and the SH-SAW (Surface Acoustic Wave) technology based on the piezoelectric effect. This device transmits an electric signal to the cartridge for sonic/electric signal conversion. Patient samples are introduced into both the reaction zone and reference zone of the assay cartridge. As the antigen-antibody combination alters the mass/weight on the chip within the cartridge, the transmission speed of the surface sonic wave in the reaction zone diminishes due to the change in mass/weight. Consequently, the electric signal emitted from the cartridge undergoes corresponding modifications.

### Warnings and Precautions

- This device is not intended to be used as an *in-vitro* diagnostic medical device for self-testing at home.
- It is recommended to wear gloves when handling and cleaning this device to minimize the risk of infection.
- Avoid using assay cartridge kits that have expired.
- The used assay cartridge, blood collection supplies, and patient samples may harbor infectious agents; hence, they should be promptly discarded after use and handled in accordance with local or national laws and regulations.
- This product is meant for an in-vitro diagnostic medical device for professional users only. This includes but is not limited to a licensed or non-licensed healthcare professional with sufficient skills and experience with the use of a device to aid or train someone to use and maintain the device (e.g., doctors, nurses, technicians, caregivers).
- This product is use in any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities or a clinical laboratory.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### What is Included with the Product

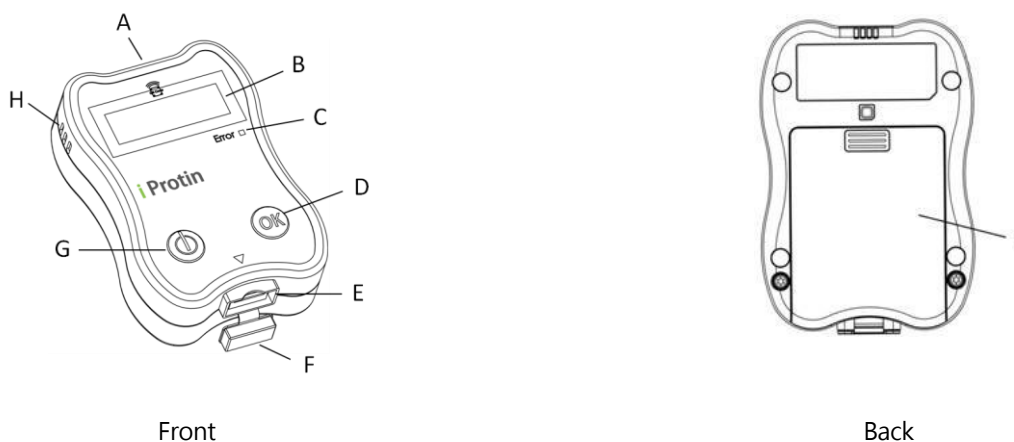
- (1) The iProtein Reader (BT ver.)
- (2) The instructions for use

### Items Not included

- (1) iProtein Assay Cartridges Kit
- (2) 5  $\mu$ L micropipette and micropipette tip
- (3) Alcohol pads
- (4) 4 AAA alkaline batteries
- (5) Disposable fingertip lancet

### Instructions for use














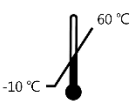
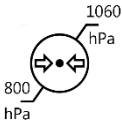
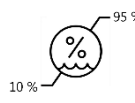
#### Product Appearance and Composition



Component	Description
A. QR-Code scanner	This device scans the QR code included with the iProtein assay cartridge to access the corresponding information.
B. Display	It displays acquired information, operational instructions, and error messages, among other details.
C. Error LED	A red light illuminates during startup and in the event of operational errors.
D. OK button	Press the button to proceed to the next screen.
E. Assay cartridge port	This is the port where the iProtein assay cartridge is connected.
F. Dust cover	The dust cover is designed to safeguard the assay cartridge port. Ensure it is in place when

	the cartridge is not connected.
G. Power switch/Power LED	Toggle the power on/off. The power LED indicates green when powered on.
H. Temperature sensor	It measures the ambient temperature.
I. Battery	To insert Alkaline batteries, open the battery cover located at the rear of this device and install four AAA Alkaline batteries.

### Symbol

Symbol/Sign	Description	Symbol/Sign	Description	Symbol/Sign	Description
	Power switch		QR-Code scanner		Refer to the instructions for use
<b>OK</b>	OK switch	<b>Error</b>	Error LED		Biohazard
	Assay cartridge port		Attention		Catalogue number
	Fragile handle with care		Keep dry		Keep away from sunlight
	This way up		Recycle		Waste Electrical and Electronic Equipment
	Limit of temperature		Atmospheric pressure limitation		Humidity limitation

### How this device Works

Upon activation, this device reads the QR code (using calibrators with different concentrations to establish the 4PL curve) provided with the iProtein Assay Cartridge Kit to access pertinent information regarding the test and batch calibration. Connect the corresponding assay cartridge to this device and follow the on-screen instructions for sample addition. The speed of the surface sonic wave transmitted within the assay cartridge sensor alters based on the specific analyte and antibody reaction. Analyzing this change aids in determining the concentration of the designated analyte in the sample, with the measurement results displayed on the monitor. Upon completion of the measurement, the monitor indicates the remaining determination efforts required by this device before shutdown. After discarding the used assay cartridge, this device is ready for the subsequent measurement.

### Introduction to iProtein Assay Cartridge Kit

This test method leverages the antigen-antibody reaction to quantitatively determine the concentration of analytes in whole blood or urine samples. The speed at which the sonic wave is transmitted across the sensor surface inside the cartridge changes based on the sample concentration. This device detects these changes to determine the concentration of the analytes. Depending on the biomarker, the results can be used to monitor and track the progression of cardiovascular diseases, inflammation, heart disease, or bacterial/viral infections. Please consult the operator instructions provided with the respective assay cartridge kit for detailed guidance.

### Calibration

Specific test and calibration data are generated for each batch of the iProtein assay cartridge kit, and this data can be accessed via the QR code included with the cartridge kit. Consequently, no additional calibration procedures are required for this device.

## Operating Requirements

This device should be positioned horizontally on a stable surface during measurements, ensuring that the temperature sensor of this device is not obstructed. In the event of any abnormalities detected before usage (such as heat, smoke, or unfamiliar odors), discontinue use immediately. Additionally, ensure the dust cover for the port is placed on when the assay cartridge is not connected.

### **⚠ This device may sustain damage or encounter measurement errors due to the following reasons:**

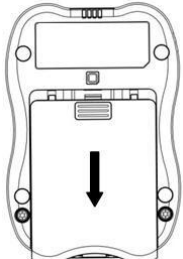
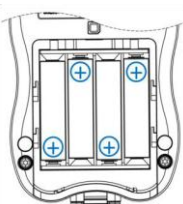
- Out-of-bound environmental conditions.
- Proximity to magnetic items or machines that do not meet EMC requirements.
- Condensation or exposure to liquids.
- Exposure to electromagnetic radiation (e.g., from mobile phones).
- Presence of active gases, aerosols, or airborne dust particles in the vicinity.
- Failure to secure the battery cover.
- Drastic temperature fluctuations.
- Movement of the assay cartridge or this device during measurement.

※ In the presence of powerful electromagnetic waves in the vicinity of this device, static interference can disrupt the waveform, leading to operational failures. If a failure occurs while this device is in operation, it is imperative to assess the electromagnetic conditions in the surroundings and implement necessary countermeasures promptly.

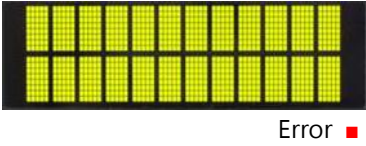


- (1) Unexpected erroneous actions may occur due to electromagnetic waves emitted by mobile phones.
- (2) If static interference is anticipated, users are encouraged to minimize static buildup before using this device by ensuring adequate room humidity.
- (3) This device may cause interference with radio receivers and TV sets. Therefore, it is recommended to keep radio receivers and TV sets away from this device.

## Preparation before Use



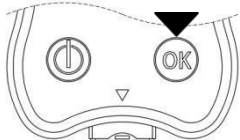
To begin, ensure that the iProtein assay cartridge kit is readily available and install the batteries for this device.

Step	Description	illustration
1	Press and hold the battery cover located on the back of this device, then slide it outward to open.	
2	Prepare four AAA Alkaline batteries, ensuring to check the +/- signs on the battery compartment, and install the Alkaline batteries in the correct direction. Slide the battery cover in the opposite direction to secure it in place.	




## Turn on this device




Step	Description	illustration
1	Press and hold the Power Switch for 2 seconds or longer, and the monitor will display a fully lit screen. The Error LED turns red, and the buzzer starts to sound.	
2	Once the fully lit screen appears for 2 seconds, the monitor will display the current software version of this device.	
3	If an assay cartridge port has accommodated assay cartridges more than 3000 times, the monitor will display the error screen (E61: Service Call), and testing cannot continue.	

## View Previous Measurement Result

Step	Description	illustration
1	After the version is displayed for 3 seconds, if the previous measurement was completed normally, the previously obtained results will appear. (Example: Previous CRP 1.00 mg/dL)	
2	If an error occurred during the previous measurement, the error code will be displayed. (Example: Previous Error: E91)	
3	Press the OK button to clear the previously obtained value/error information.	





## Read QR-Code

Step	Description	illustration
1	After clearing the previously obtained value/error information, the screen will display "QR-Code Read Ready," indicating readiness to scan the QR-Code.	
2	Press the OK button, and the monitor will prompt "Read QR-Code." Please position the QR-Code close to the QR-Code scanner.	
3	If an abnormality occurs during QR-Code scanning, an error message (E82: QR Reader) will appear on the monitor.	

4	When the monitor prompts "Read QR-Code" and the QR-Code scanner indicator is activated, position the QR-Code from the assay cartridge approximately 8 to 10 cm away from the QR-Code scanner. If the QR-Code cannot be successfully scanned, try moving the QR-Code back and forth.	
5	Upon successful scanning, the buzzer will sound and display the specific analysis goal on the monitor (e.g., Marker: CRP). After 3 seconds, the monitor automatically proceeds to the sample collection steps.	
6	If the QR-Code fails to scan, the monitor will display the QR-Code reading failure screen (QR-Code Read again→). Press the OK button on the QR-Code reading failure screen to return to Step 1 and attempt QR-Code scanning again.	


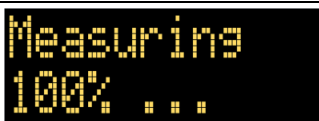

### Prepare the Sample

※ Please refer to the instructions provided with the iProtein assay cartridge kit for guidance on sample collection and processing.



Step	Description	illustration
1	Once the analysis goal is displayed, the monitor will prompt "Collect Sample." Prepare the sample according to the requirements for the assay cartridge used.	
2	This device will begin warming up for 80 seconds. The monitor will indicate "Please Wait 80sec" and commence countdown.	
3	Upon completion of the warm-up period, the monitor will automatically prompt "Open & Set Test Cartridge." Please proceed to open the dust cover and insert the assay cartridge.	
4	If the assay cartridge is functioning normally, the buzzer will sound and the monitor will display "Please Wait..." In a few seconds, it will transition automatically to the measurement steps.	

### Measurement and Show Result

※ Please refer to the instructions provided with the iProtein assay cartridge kit for operational guidance.

Step	Description	illustration
1	Once the testing of the cartridge is confirmed to be completed, the monitor will automatically switch to "Put a Drop on Cassette;" add the sample into the assay cartridge at this time.	
2	The monitor will display the measurement screen while the measurement is ongoing, indicating its progress. The measurement is considered complete when it reaches 100%.	
3	Upon completion of the measurement, the monitor will switch to the screen displaying the obtained result (example: Results: CRP 1.20 mg/dl). The buzzer will sound three times ("Beep! Beep! Beep!").	

**Turn off this device**

Step	Description	illustration
1	When the Power Switch on the screen displaying the obtained result is pressed and held for 2 seconds or longer, or when the power is not shut down after 15 minutes, an error message will appear. The monitor will then switch to the "Power Off" screen, displaying the remaining available usage times.	
2	Two seconds after the turn off screen appears on the monitor, the power will automatically turn off. Remove the used assay cartridge and place the dust cover on the assay cartridge port.	

**Bluetooth Pairing Procedure****On this device**

When this device is turned on, the Bluetooth function will automatically activate and remain active until the device is turned off.

**On Mobile Device:**

Open the designated application and navigate to the Bluetooth pairing function. If necessary, activate the Bluetooth function on your mobile device.

**Pairing:**

Follow the on-screen instructions to pair this device with mobile device. Remember that this device can only be paired with one device at a time and ensure that the distance between this device and the mobile device is within five meters.

**Data Transfer:**

After successful pairing, you can transfer detection values from this device to your mobile device using the Bluetooth communication protocol in the following scenarios:

**1. Transmit the Last Data:**

If previous data is available, when the screen switches to "Prev.," the last detection data will automatically be transmitted to the mobile device.

**2. Transfer Result Data:**

Upon completing a detection, when the screen switches to "Rslt.," the detection data will automatically be transmitted to the mobile device.

**3. Transmit Previous Data by Command:**

If previous data is available and the screen is displaying "Prev.," pressing the "Read Previous Data" button on the mobile device will transmit the previous detection data.

**4. Transmit Result Data in Command Mode:**

When previous data is available and the screen displays "Rslt.," pressing the "Read Result Data" button on the mobile device will transmit the detection data.

Notice: To ensure smooth testing processes, please refrain from using Bluetooth to read data during testing..

**Error Code and Message**

✘ When encountering an error message, please take note of the error code, press and hold the power button to initiate the shutdown process, and refer to the information provided below:

Error Code	Message	Description
E00	Time out	When the operation does not occur after more than 15 minutes, please restart the procedure from the beginning.
E10	Battery Low	Battery low; please replace the battery.
E20	QR-Code	The QR-Code is unsuccessfully read twice; please ensure the correct QR-Code is being used.
E30	Cassette	Assay cartridge abnormalities have been detected; please replace with a new assay cartridge and restart the procedure from the beginning.
E31	Time out	No samples are added over an extended period of time while measurement is ongoing; please restart the procedure from the beginning.
E34	Wait Error	Error in connecting the assay cartridge before warm-up is completed; please restart the procedure from the beginning.
E40	Drop Error	Sample dripping abnormalities have been detected. The specimen did not contact both channels at the same time.
E41	Drop Error	Sample dripping abnormalities have been detected. Only one channel detected the specimen.
E50	Data Error	Sample measurement abnormalities have been detected; please contact the supplier.
E51	SAW-IC Error	Circuit abnormalities have been detected; please contact the supplier.
E61	Service Call	The product has been used more than 3000 times; please contact the supplier.
E70	Over Temp.	An environment exceeding temperature requirements has been detected; please move to a suitable operating environment and restart the procedure.
E81	EEPROM I/F	Temporary memory errors have been detected; please contact the supplier.
E82	QR Reader	QR-Code scanner abnormalities have been detected; please contact the supplier.
E83	SAW-I/F	Circuit abnormalities have been detected; please contact the supplier.
E84	Sensor I/F	Temperature sensor abnormalities have been detected; please contact the supplier.
E86	EEPROM Data	Temporary memory errors have been detected; please contact the supplier.
E90	Self-Check	Circuit abnormalities have been detected; please contact the supplier.
E91	PLL Unlock	Circuit abnormalities have been detected; please contact the supplier.
E92	ADC	Circuit abnormalities have been detected; please contact the supplier.
E94	T.C. connect	Remove the assay cartridge before measurement is completed; please use a new sample and assay cartridge kit and restart the procedure from the beginning.

### Cleaning and Maintenance

- (1) This device should be cleaned periodically using a cloth lightly dampened with the designated disinfectant (such as disinfecting alcohol/isopropyl) or water for wiping. The dilution factor of the disinfectant used should adhere to the instructions provided in the product package insert.
- (2) Regular inspections should be conducted to ensure safety during use. If any abnormalities are detected during inspection, usage should be discontinued immediately, and the supplier should be contacted for further assistance.

### Storage and Lifetime

- (1) Please store the product according to the required environmental conditions.
- (2) Avoid exposure to water and keep it away from direct sunlight, high temperatures, or humid environments.
- (3) Store it in a location protected from adverse effects of air pressure, temperature fluctuations, humidity, weathering, sunlight exposure, dust, salt, and sulfur.
- (4) Do not store it in areas where chemicals are present or in locations with gas.
- (5) If the product will not be used soon, please remove the Alkaline batteries.
- (6) Product lifetime under normal use: 5 years or up to 3000 measurements.

### Service Information

In case of any issues with the product, please seek assistance from the supplier and provide the following information:

- Serial number (SN) located on the label at the back of this device.
- Software version number, displayed upon startup of this device.
- Name of the iProtein assay cartridge kit used and the lot number of the product.
- Description of the problem and any accompanying error message or code.

### Product Specification

This device	
Size	107 x 73 x 30 (mm)
Weight	185 g (including the 4 AAA alkaline batteries)
Life time	Five years or 3000 measurements
Rated Power	
Use power	4 AAA alkaline batteries
Voltage	6V
Power consumption	1.59VA
Environmental Condition	
Operating condition	Ambient temperature: 15~35°C Relative humidity: 10~95% (non-condensing) Air pressure: 800 hPa~1060 hPa (up to an altitude of 2000 m and below)
Storage and transport condition	Ambient temperature: -10~60°C Relative humidity: 10~95% (non-condensing) Air pressure: 800 hPa~1060 hPa (up to an altitude of 2000 m and below)
Electricity	
Dust-proof and Water-resistant Rating	IPX0
Electrical and Mechanical Safety Standard	Compliance with IEC 61010-1, IEC 61010-2-101
Electromagnetic Compatibility (EMC) Compliance	Compliance with IEC 61326-1, IEC 61326-2-6
Bluetooth transmission	
Operating distance	Within 5 meters
Power range	-20 dBm~+4 dBm



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