

InSight[®] Crea-Vet

Veterinary Creatinine Meter

User Manual



Notes Before Use

Thank you for purchasing the InSight Crea-Vet Veterinary Creatinine Meter from Woodley Equipment Company Ltd. The handheld creatinine meter (hereinafter referred to as 'meter') is a handheld rapid testing device.

This user manual is a reference for operating, maintaining and repairing the product. It describes in detail the characteristics of the product and related information. Prior to usage, operators are strongly advised to thoroughly review the user manual. This manual should be kept in a safe place. The user should strictly adhere to the recommendations provided in the user manual.

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The right to amend or update this manual and the final interpretation of this manual belongs to Woodley Equipment Company Ltd.

Product Information

Product Name: InSight Crea-Vet Veterinary Creatinine Meter

Manufacture Date: See meter label

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Section 1 Safety Guidelines

To use the InSight Crea-Vet Meter safely and effectively, and avoid possible injuries, please read the user manual in detail before use. The correct operation methods and precautions must be fully understood before use. Please keep this manual in a safe place.

Please read the following precautions and EMC instructions carefully to ensure proper use of the meter. Woodley Equipment Company is not liable for any issues resulting from non-compliance with the warnings and cautions outlined in this manual.

1.1 Important Safety Instructions

- Improper use and operation may result in erroneous test results. Before use, operators should read the user manual in detail and that of the accompanying test strips, quality control solutions and accessories. Special attention should be drawn to the contents of the 'Warnings' and 'Caution' sections, and users should strictly comply with the use and operation specifications.
- This product and its accessories (test strips, control solution etc.) is intended for veterinary use only.
- For more detailed information on the InSight Crea-Vet Test Strips, please see the test strips instructions.
- Do not use accessories not supplied or recommended by the manufacturer.
- If the meter sustains damage after being dropped, water immersion or persistently triggers malfunction alarms, refrain from further use. Contact Woodley Equipment Company.
- Do not expose the meter or its accessories to excessive heat.
- Do not spill liquids on the meter or use the meter near liquids.
- Do not allow any debris to enter the meter.
- Do not use the meter in places with aerosol droplets, regulated oxygen, acidic volatile gases or next to strong sources of radiation, as this may interfere with the normal operations of the device.
- Do not place any objects on top of the meter.
- Please avoid direct exposure to strong light.

1.2 Safety Instructions

- During testing, the meter itself may come into contact with blood. Therefore, there is a risk of pathogens being carried by the meter.
- When using the meter in a veterinarian setting, the users should follow the infection control requirements in veterinarian settings and disinfect the meter regularly.

1.3 Electromagnetic Compatibility (EMC)

- This device complies with the emission and immunity requirements specified in IEC 61326-1 and IEC 61326-2-6.
- It is recommended to evaluate the electromagnetic environment of the meter before use. The meter should not be used in close proximity or stacked with other equipment. If such placement is unavoidable, monitor the meter closely to ensure proper functioning.
- It is the manufacturer's responsibility to provide the customers or users with the EMC information of the meter.
- It is the user's responsibility to ensure the proper EMC environment is maintained.

WARNINGS:

- It is prohibited to use this equipment next to strong radiation sources (e.g., non-shielded RF sources), as this may interfere with the normal operation of the equipment.
- Use of this equipment in dry environments may cause damaging electrostatic discharges, leading to erroneous results.

Section 2 Understanding the Meter

2.1 Intended Use

The InSight Crea-Vet Meter is intended to be used in combination with the compatible test strips produced by Woodley Equipment Company to quantitatively measure the concentration of creatinine in fresh whole blood.

The meter is intended for veterinary use only.

2.2 Kit Contents

- InSight Crea-Vet Meter
- x2 AAA Batteries
- User Manual
- Software Applications (electronic only)

NOTE:

- If items in the kit are missing or damaged, please contact Woodley Equipment Company.
- If there is a complimentary item other than those listed, please refer to its accompanying descriptions.

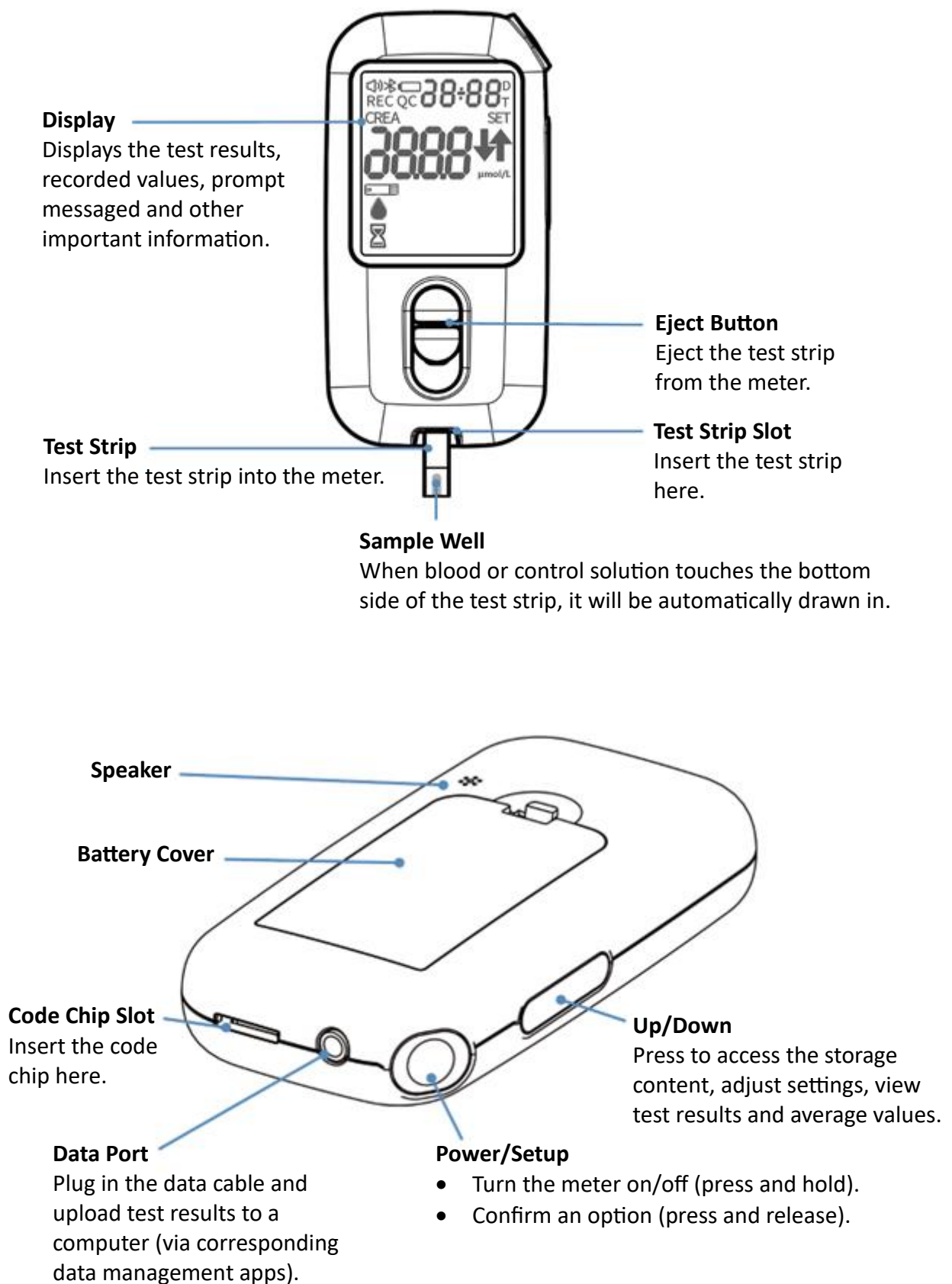
The following items are not included in the kit and must be purchased separately:

- InSight Crea-Vet Test Strips
- InSight Crea-Vet Control Solution

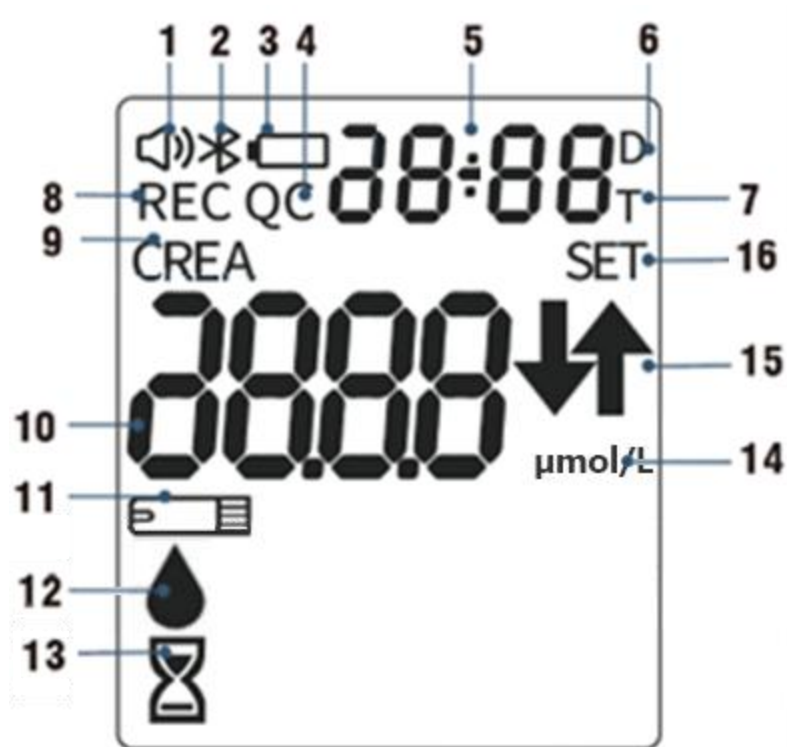
WARNINGS:

- Keep the meter and supplies away from children and animals. Swallowing meter parts and meter companion accessories (e.g., battery caps, batteries, test strips, blood collection needles, blood collection needle protective caps, quality control fluid caps, etc.) may result in choking.
- Do not store the test strips in a hot, humid place. High temperatures and humidity will damage the test strips.

2.3 Appearance & Composition



Full Screen Display: The meter will display the following after being powered on.



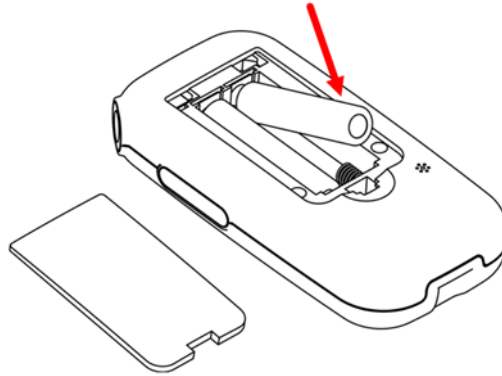
1. Beep audible alert
2. Bluetooth
3. Flashing battery indicates low battery
4. Quality control
5. Display time and date
6. Date - appears when the value is months and days
7. Time - appears when the value is hours and minutes
8. Stored results
9. Blood Creatinine
10. Displays blood creatinine test values/year/calibration code
11. Ready to insert the test strip when flashing
12. Ready to test when flashing
13. Testing in progress when flashing
14. Creatinine Unit: $\mu\text{mol/L}$ or mg/dL
15. High and low threshold reminder for blood creatinine test value
16. Setting

Section 3 Installation and Setup

3.1 Installing the Battery

This product uses two AAA alkaline batteries.

1. Open the battery cover and insert the batteries. Please install the battery correctly according to the positive (+) and negative (-) markings.



2. Put the battery cover back until the clasp snaps securely into place. The message "SET" appears on the screen. Refer to **Section 3.4 Setup** to complete the setup.



NOTE:

The red lines indicate that the icon will be flashing.

3.2 Battery Replacement

A flashing battery icon in the upper right corner of the display indicates that the battery is low and needs to be replaced as soon as possible.



The date and time need to be reset after changing the batteries. See **Section 3.6 Setting Time and Date**.

CAUTION:

- Do not remove the battery while the meter is connected to other devices as this will affect data storage.
- Please dispose of the old batteries in accordance with local environmental regulations.

3.3 Power ON/OFF

Power On

Method 1: Press the power button to enter the main screen.



Method 2: Insert the test strip directly while the meter is off and the meter will automatically turn on and enter the test mode.

**Power Off**

Press and hold the power button to turn the meter off.

CAUTION:

Pressing and holding the power button during the process of powering on will prompt setup mode. To turn the meter off, press and hold the power button again until the meter is turned off.

3.4 Setup

Before using the meter for the first time or after replacing the meter's batteries, make sure the meter's time and date are set correctly.

Functionality	Action	Default
Time and Date	Setting the time or date.	Default date.
Prompt Tone	Select On or Off.	On.
Bluetooth	Select On or Off.	On.
Units	Select $\mu\text{mol/L}$ or mg/dL .	mg/dL
High and Low Threshold Alerts	Select On or Off. Threshold Reminder Adjustable Range: High Creatinine: 0.28 to 13.0 mg/dL (25 to 1150 $\mu\text{mol/L}$)	Off Threshold Pre-set Value: High Creatinine: 1.2 mg/dL (110 $\mu\text{mol/L}$)

3.5 Go to Settings

Press and hold the power button while the meter is turned on until the message "SET" appears on the screen.

3.6 Setting the Time and Date

1. After entering the setup mode, press the up/down buttons to set the year, month and day. Press the power button to confirm.



Year (first from left), month (second from left), day (third from left)

2. Press the up/down button to set the hours (24 hours system) and minutes. Press the power button to confirm.



Hour (first from left), minute (second from left)

3.7 Prompt Tone Setting

1. After entering the setup mode, press the power button repeatedly until you enter the prompt tone setting.
2. Press the up/down button to toggle on/off. Press the power button briefly to confirm. To exit, press and hold the power button until it is turned off.



3.8 Units Setting

1. Press the setup key repeatedly until it enters the creatinine units (mg/dL and $\mu\text{mol/L}$). Press the up and down arrow keys to switch the unit to $\mu\text{mol/L}$ or mg/dL.



3.9 Bluetooth Setting

1. After entering the setup mode, press the power button repeatedly until you enter the Bluetooth setup interface.
2. Press the up/down button to toggle on/off. Press the power button to confirm. To exit, press and hold the power button to turn off.



3.10 Setting High and Low Threshold Alerts

1. After entering the setup mode, press the power button repeatedly until the flashing up arrow icon appears on the screen.



2. Press the up/down button to toggle on/off. Press the power button to confirm. If On is selected, a reminder of the high up arrow and low down arrow thresholds will appear on the screen.
3. Press the up/down button to set the threshold.



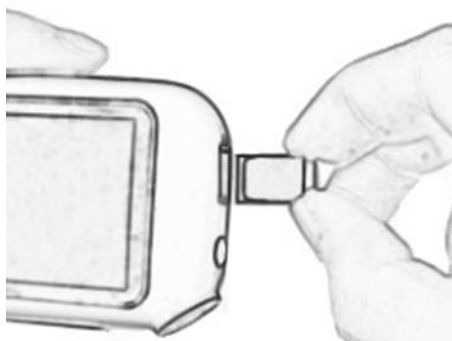
WARNING:

The threshold level of each indicator may vary between species, please consult the veterinarian before setting this range.

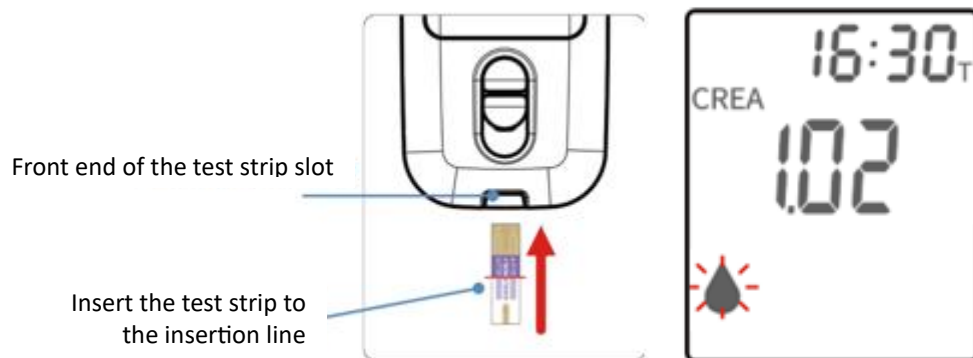
3.11 Code Chip Calibration

Each box of test strips contains a meter code chip. Each time you open a new box of test strips, you need to replace the old code chip and insert the new code chip.

1. Take out the new code chip from the test strip box and insert it into the meter.



2. Insert the test strip and push it all the way in. The meter will automatically power on and display the calibration code.



3. Confirm that the code displayed on the screen matches with the one on the code chip. Then, remove the code chip.

CAUTION:

- Use of code chips from a different box of test strips will result in erroneous test results.
- If a new code chip is not inserted before the test begins, the meter will by default use the stored code of the last inserted code chip.
- If there is no calibration code information available in the meter or if the inserted code chip does not match the inserted test strip, the meter will report an error.

Section 4 Testing

CAUTION:

Collecting Blood Samples

- Read the instructions of the disposable blood collection needle/tube carefully before blood collection.
- Blood collection needles and devices are single-use, non-reusable and cannot be shared with others.

Test Strips

- Please read the instructions of the InSight Crea-Vet Test Strips carefully before testing.
- Do not use any strips other than the InSight Crea-Vet Test Strips.
- Do not use damaged or contaminated test strips.
- Make sure the test strips are within the expiration date. Using expired test strips may result in inaccurate results.
- Test strips are disposable and single-use.
- During the test, the blood sample should be aspirated in the sampling area in one attempt, not twice or more.
- After collecting the blood sample, the test strip should not be touched or pulled out before the test results are displayed, otherwise the accuracy of the test results may be affected.
- Users should not add drops of samples other than blood (e.g., urine, etc.) to the test strip.

4.1 Preparing the Test Strips

1. Prepare blood collection devices.
2. Select the site for blood sampling.
3. Wash or use appropriate disinfectant to clean test site and wait for the water or disinfectant to evaporate completely before collecting blood.

CAUTION:

- Make sure the meter, test strips and control solution are at room temperature before testing.
- Venous whole blood samples must be collected by veterinarians. Anticoagulant tubes of sodium heparin (90 USP units/4mL), lithium heparin (75 USP units/4mL) and EDTA (3.6 mg/2mL) may be used to collect the blood sample. Do not use tubes with other anticoagulants.
- Do not use lotions or creams on the sampled area.

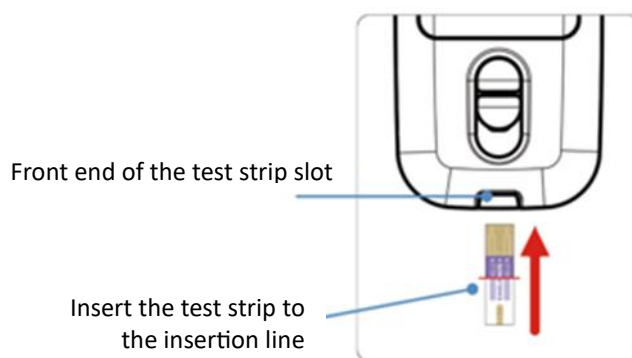
4.2 Performing a Test

Inserting the Test Strip

1. After pressing the power button to turn on the meter, the test strip icon on the display flashes (this step can be skipped by inserting the test strip when the meter is turned off).



2. After taking a test strip out, please close the test strip container immediately to avoid moisture exposure.
3. Insert the test strip logo side up into the test strip slot and push the test strip all the way in.



CAUTION:

When inserting the test strip, keep your hands away from the bottom edge of the test strip (sample well) to avoid contamination.

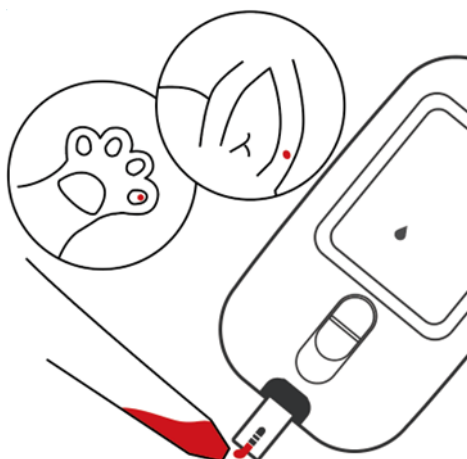
4. When the test strip is inserted correctly, the screen will display the pre-stored calibration code. The blood drop icon on the screen flashes to indicate that the meter is ready for testing.



5. After inserting the creatinine test strip, the blood drop icon on the screen will flash. You can confirm and set the gender and age. After setup, the blood drop icon on the screen will flash, indicating that the meter is ready for sample loading.

4.3 Collecting Blood Samples

1. Blood samples are obtained using a blood pen or blood collection device.
2. Collect the blood sample from the patient (capillary or venous into a lithium heparin tube). Touch the end of the test strip to the blood drop. Make sure the blood sample fills the test strip fully.



CAUTION:

- When fresh capillary whole blood is used, the first drop of blood should be wiped away and a second whole blood sample should be used for testing.
- The test should be performed immediately after blood collection. If too much blood is squeezed out and contaminates the test strip or too little blood is collected and does not fill the sample zone, take a new test strip and perform the test again.

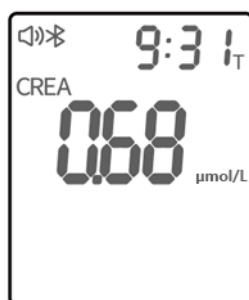
4.4 Reading the Results

1. Once the blood sample fills the sample zone, the meter will automatically begin testing and display a countdown timer.

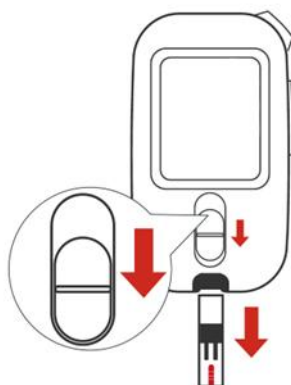


CAUTION:

- Test strips must not be removed from the meter during testing.
 - If the meter does not start the test after completing the sample aspiration, restart the test with a new test strip.
2. After the countdown is complete, the meter will display the test results. If the user has set a high/low threshold alert, an arrow will appear when the test result exceeds the threshold. Creatinine test results are shown in $\mu\text{mol/L}$.



3. Toggle the eject button and the test strip will be automatically ejected.



4.5 Test Results

CAUTION:

- If the blood sample used for the test is not sufficient and does not fill the test strip, the results may be affected. It is recommended that a new test strip should be used for testing.
- Possible reasons for erroneous test results are: expired test strip, improper storage of test strips (such as moisture, failure to test at specified temperature and humidity, or incorrect sampling and sample type).
- If the test results do not match clinical symptoms or the results are outside the normal range, it is recommended to retest with a new test strip. If the results are still abnormal, contact Woodley Equipment Company.

Creatinine Reference Range

- Each laboratory should establish specific reference intervals for their own population.

Interpretation of Creatinine Test Results

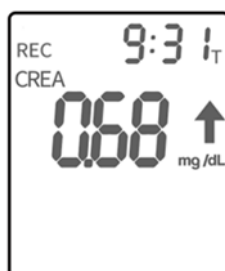
- When the results are above 13.0 mg/dL (1150 $\mu\text{mol/L}$), the meter screen displays "HI" and when below 0.28 mg/dL (25 $\mu\text{mol/L}$), the meter screen displays "LO". In this case, retest with a new test strip.
- Some known interfering substances may affect creatinine measurements. Refer to the InSight Crea-Vet Test Strips instructions for details.

Section 5 Viewing Records

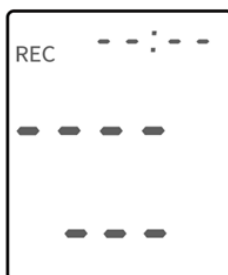
5.1 View Previous Test Results

The meter stores the last 800 test results and the last 20 QC records. Results are stored in the order: the most recent to the oldest.

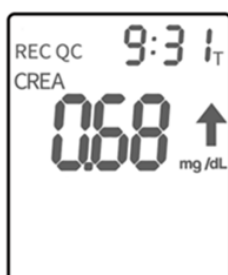
1. Press the power button to enter the history view page when the device is powered on. The screen will display the most recent test records. The date and time of the test will be displayed in the upper right corner.



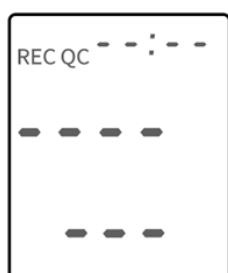
2. Press the up/down button to scroll through the records. "----" is displayed when scrolling to the bottom.



3. Press the power button again to switch to QC records.



4. Press the up/down key to scroll through the QC records, and "----" is displayed when scrolling to the bottom.



CAUTION:

The meter does not store error data when an error occurs.

Section 6 Quality Control Testing

A quality control test using InSight Crea-Vet Control Solution can help determine if the meter and test strips are working correctly.

6.1 Situations Requiring Quality Control Testing

Typically, quality control testing is recommended in the following situations:

- When using test strips with a new lot number
- When the meter's batteries have been replaced
- If the meter and test strips have not been used/stored in proper working conditions (dropped, high temperature, low temperature, humidity, etc.).

WARNINGS:

- The meter can only be used with the matching control solution provided by Woodley Equipment Company.
- Do not use expired control solution.
- Do not add water or other liquids to the control solution.
- For storage conditions of the control solution, please refer to the instructions inside the control solution package.
- Quality control results should be within the range indicated on the control solution instructions.
- Quality control results do not reflect creatinine levels.
- If the control solution is spilled, wipe and rinse off promptly.
- Make sure the meter, test strips and control solution are at room temperature before testing.

6.2 Quality Control (QC)

1. After powering on the meter, press and hold the down button to enter QC mode. "QC" is displayed at the top of the screen.



CAUTION:

You need to make sure that the meter has been inserted with the corresponding code chip before performing the QC test.

2. After taking a test strip out, please close the test strip container immediately to avoid moisture exposure.

3. Once the test strip is inserted into place, the screen will display the pre-stored calibration code in the meter. The blood drop icon on the screen flashes to indicate that a drop of control solution can now be aspirated.



4. Gently invert the bottle to mix the control solution. After discarding the first drop of the control solution, wipe the dropper tip. Add the control solution to the end of the test strip and the control solution will be automatically drawn in. Be sure to fill the test strip collection area with the control solution.

CAUTION:

Please perform at least 2 level of control solution testing.

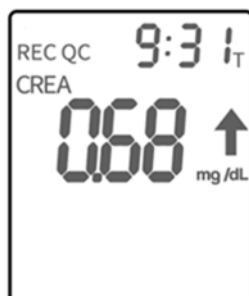
5. When the control solution fills the sampling zone, the meter will automatically start detection and display a countdown timer.



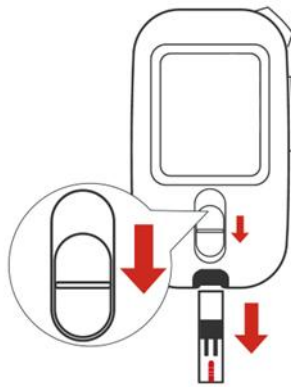
CAUTION:

- Test strips must not be removed from the meter during testing.
- If the meter does not start the test after completing the sampling, restart the test with a new test strip.

6. When the countdown is complete, the meter will display the QC results.



7. Compare the QC results with the reference ranges on the control solution instructions. The results should be within the range.
8. Toggle the eject button and the test strip will be automatically ejected. Dispose into a clinical waste bin.



CAUTION:

- If the QC results are not within the reference range, it indicates that the meter system is unstable. Please perform the test again with a new test strip.
- If the results are consistently out of the target value range, stop the test and contact Woodley Equipment Company.

Section 7 Storage Conditions

7.1 Storage Conditions

When the meter is not used for a long time, please remove the batteries to prevent the meter from being damaged by battery leakage.

The product should be stored in a dry, cool, non-corrosive gas and well-ventilated place.

Transportation and Storage Requirements

Storage Temperature: -20°C to +55°C

Storage Relative Humidity: 10% to 93% (non-condensing)

Do not drop or disassemble the meter.

Section 8 Cleaning, Maintenance and Repair

8.1 Cleaning

Make sure the meter is not dusty. If you need to clean or sanitise the meter, follow these instructions:

1. Make sure the meter is turned off.
2. Gently wipe the surface of the meter with a soft cloth moistened with 75% alcohol. Do not use bleach or strong detergents.

8.2 Maintenance

- When the meter is not used for a long time, please remove the batteries to prevent the meter from being damaged by battery leakage.
- Do not allow liquids to enter the meter.
- Do not spray cleaning solutions directly onto the meter.
- Keep your hands and the blood collection site clean and dry for handling.
- Only Woodley Equipment Company or Woodley Equipment Company authorised personnel may inspect or supply any parts (excluding batteries).

Section 9 Troubleshooting

9.1 Error Messages

This chapter describes common problems with the meter. The user can refer to the following solutions when a problem occurs.

Error Number	Issue	Solution
E01	Damaged test strip or sample aspiration before starting the test.	<ul style="list-style-type: none"> • Verify that the ambient temperature around the meter is within the meter's nominal ambient operating range. • Retest with a new test strip.
E02	Abnormal ambient temperature.	<ul style="list-style-type: none"> • Make sure that the ambient temperature of the meter is within the nominal detection range of the test strips and make sure that the test strip slot of the meter is not blocked by foreign objects. • Wait for meter and test strips to return to normal operating temperature. • Repeat the test with a new test strip.
E03	Insufficient blood or quality control solution for test strip aspiration.	<ul style="list-style-type: none"> • Retest with a new test strip.
E04	Wrong code chip.	<ul style="list-style-type: none"> • Please insert the correct code chip.
E05	Electronic error.	<ul style="list-style-type: none"> • Verify that the ambient temperature around the meter is within the meter's nominal ambient operating range. • Turn off the meter. • Retest with a new test strip.
E06	Low battery.	<ul style="list-style-type: none"> • Replace the batteries.
E07	Poor contact or pulling out the test strip during testing.	<ul style="list-style-type: none"> • Turn off the meter and retest with a new test strip.
If you are unable to solve the above problems, please contact Woodley Equipment Company.		

9.2 Troubleshooting

Problem	Possible Causes	Solution
Press the power button, the meter does not power on or no display.	Batteries not inserted or batteries not inserted correctly.	<ul style="list-style-type: none"> See Section 3.1 Battery Installation for instructions on how to properly install the battery.
	Battery completely drained.	<ul style="list-style-type: none"> Replace the batteries.
	Extreme ambient temperature.	<ul style="list-style-type: none"> Move the meter to a suitable temperature environment.
The test strip has been inserted into the test strip slot, but the meter screen does not show the status of the inserted test strip.	Test strip is not inserted correctly or completely into the meter.	<ul style="list-style-type: none"> Replace the test strip with a new one, make sure the label is facing up, insert it in place and retest.
	Batteries not inserted or batteries not inserted correctly.	<ul style="list-style-type: none"> See Section 3.1 Battery Installation for instructions on how to properly install the batteries.
	Batteries completely drained.	<ul style="list-style-type: none"> Replace the batteries.
	Meter may be connected to a computer.	<ul style="list-style-type: none"> Disconnect the meter from the computer.
	Problems with meter or test strips.	<ul style="list-style-type: none"> Please use a new test strip for testing.
Test not started after blood sample or control solution aspiration.	Blood sample volume or control solution volume too low.	<ul style="list-style-type: none"> See Chapter 4 Testing for information on how to test correctly. Please use a new test strip for testing.
	Aspirating samples after the meter is turned off.	<ul style="list-style-type: none"> See Chapter 4 Testing for information on how to test correctly. Please use a new test strip for testing.
	Problems with the meter or test strip.	<ul style="list-style-type: none"> Please use a new test strip for testing.
If you are unable to solve the above problems, please contact Woodley Equipment Company.		

Section 10 Technical Information

10.1 Specifications

Unit of Measurement	μmol/L or mg/dL
Sample Type	Fresh whole blood (capillary or venous blood in lithium heparin)
Sample Volume	≤2μl
Detection Time	30 seconds
Memory Capacity	500 tests and 20 QC tests
Automatic Shutdown	After 2 minutes of inactivity
Battery	x2 AAA batteries
Dimensions	107 x 54 x 23 mm (±5 mm)
Weight	100±15 g (including batteries)
Operating Conditions	Operating Temperature: +15°C to +40°C Operating Relative Humidity: 10% to 85% (non-condensing) Atmospheric Pressure: 68 kPa to 106.6 kPa
Storage/Transportation Conditions	Storage Temperature: -20°C to +55°C Storage Relative Humidity: 10% to 93% (non-condensing)
Electromagnetic Interference	No electromagnetic interference with other devices has been observed with this product and it complies with current domestic standards for electromagnetic emissions.
Storage Conditions for Test Strips and Control Solution	See instructions inside the package of test strips and control solution.

10.2 Test Principle

The meter's test principle is electrochemical. During the test, fresh whole blood is collected with a blood collection device. Then, the blood sample is aspirated via the sample well located at the edge of the test strip. When the blood sample reaches the detection area through the siphon principle, the specific analyte in the blood reacts with the reagents on the electrodes, generating an electric current measured by the electrodes. The meter determines the type of analyte according to the code of the test strip and calculates the concentration of creatinine in the blood sample by measuring the reaction current, ambient temperature, sample impedance and other parameters.

10.3 Limitations of Use

Please read the instructions accompanying the test strips and control solution for information related to product specifications and limitations.

10.4 Network Security Statement

- Data Interface – Bluetooth
Adopts standard Bluetooth protocol
Purpose: Data transfer
- User Access Control
Users are able to transfer data via Bluetooth using an authorised device.
- Requirements related to updating the software environment
In principle, no updates are necessary. However, if there is a need for a new version of the system software to address an existing issue, Woodley Equipment Company will assess the potential impact of these changes on the meter. Based on this evaluation, a decision will be made regarding whether to proceed with the update.

Section 11 Symbols

The following graphics, symbols and abbreviations may appear on product packaging, labels, displays and instruction manuals. Their meanings are explained in the table below.

Symbol	Description
	Consult instructions for use
	Biological risks
	Serial number
	Manufacturer
	Date of manufacture
	Caution
	Keep dry
	This way up
	Stacking Layer Limit
	Fragile, handle with care

Section 12 After-Sales and Warranty

If you have a problem with your InSight Crea-Vet Meter, do not repair or adjust the meter yourself before contacting Woodley Equipment Company.



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