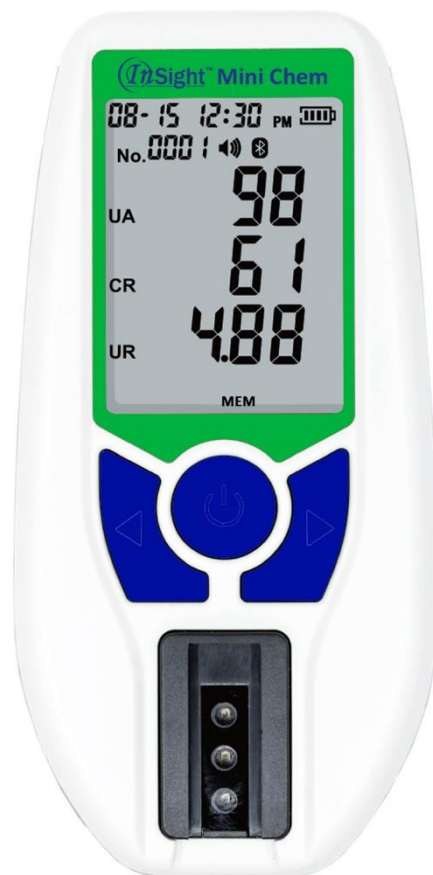


*InSight*TM Mini Chem

User Manual



InSight Mini Chem Meter

Important Safety Instructions

- Misuse of the InSight Mini Chem can cause electrocution, burns, fire and other hazards
- Do not place the meter in or near to liquid. If the meter becomes wet, unplug it before touching it
- Use the meter only for the purpose described in the instructions for use
- Failure to use the meter in the manner specified by Woodley Equipment Company may void the warranty of the InSight Mini Chem
- Do not use accessories which are not supplied or recommended by Woodley Equipment Company
- Do not use the meter if it is damaged. Please contact Woodley Equipment Company
- Do not let the meter come into contact with surfaces which are too hot
- Do not use the meter where aerosol sprays are being used or where oxygen is being administered
- Do not use the meter outdoors
- Only use control solution purchased from Woodley Equipment Company
- Keep these instructions in a safe place
- For veterinary use only

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Section 1 Introduction

The InSight Mini Chem Meter is intended for the quantitative determination of Uric Acid (UA), Creatinine (CR) and Urea (UR) in capillary whole blood, venous whole blood, plasma (lithium heparin) and serum. The easy to operate system consists of a portable meter which analyses the intensity and colour of light reflected from the reagent area of a test strip, ensuring quick and accurate results.

The InSight Mini Chem Meter reports in the following units: UA ($\mu\text{mol/L}$), CR ($\mu\text{mol/L}$) and UR (mmol/L).

The InSight Mini Chem Meter can store up to 500 results.

To ensure accurate results:

- Read the instructions carefully and complete any necessary training before use
- Use the code chip that is included in each box of test strips. Do not mix code chips from different lots
- Only use the InSight Mini Chem Test Strips with the InSight Mini Chem Meter
- For in vitro diagnostic use only
- For veterinary use only
- Keep out of reach of children

Principle of Measurement

The InSight Mini Chem Meter applies the principle of photochemistry and is used with the InSight Mini Chem Test Strips. The whole blood, serum or plasma sample is added to the sample area of the test strip. In the process of rapid infiltration, blood cells are filtered out. The substrate reacts with enzymes and chemicals in the reaction layer which leads to the colour change. The colour intensity is proportional to the concentration of the substance.

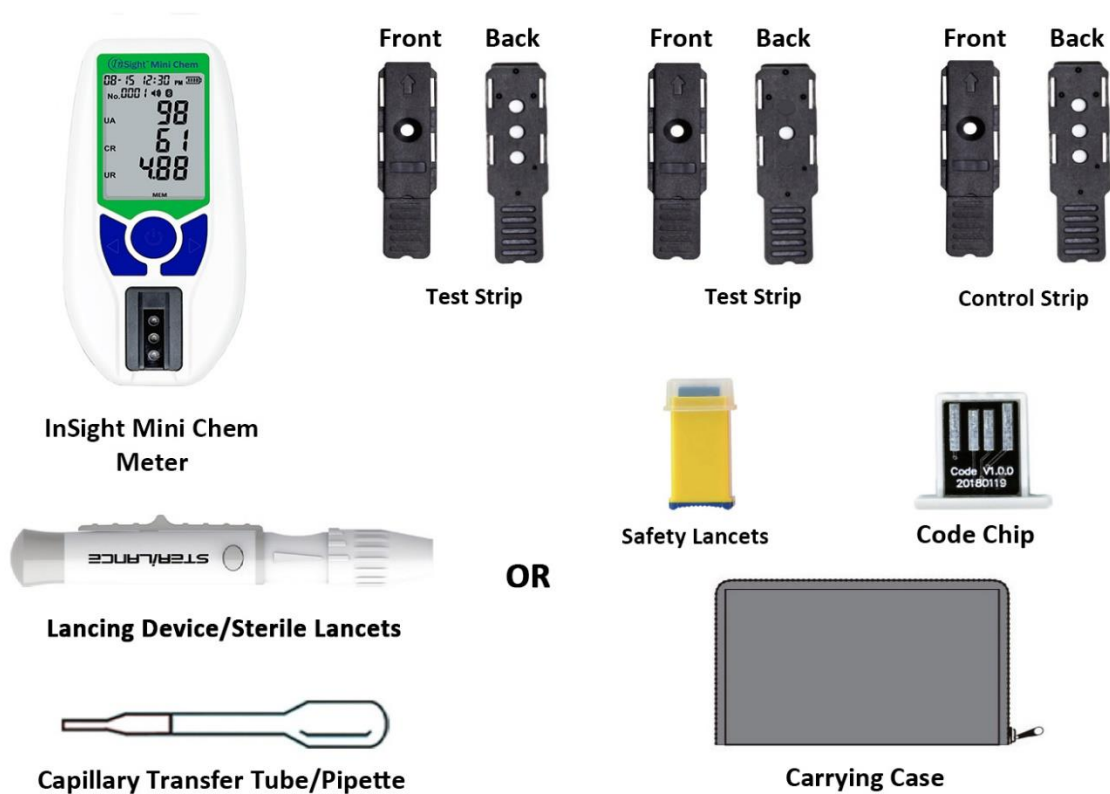
Section 2 Getting Started

Please check the following when you first receive the InSight Mini Chem Meter:

- Check contents of delivery are complete
- Check for damage during transport


If you have any questions, please contact Woodley Equipment Company.

Before testing, read the instructions carefully and learn about all the components of the InSight Mini Chem Meter. Depending on the packaging type, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details of which components are included with your purchase. The following items are needed to perform a test:



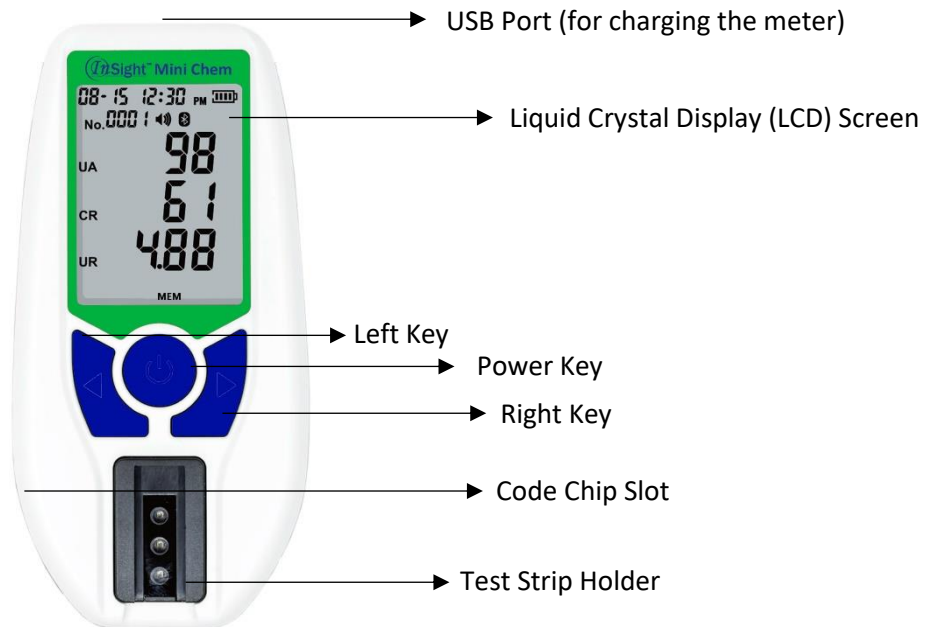
Component Descriptions

1. **InSight Mini Chem Meter** – Reads the test strips and displays the concentrations of Uric Acid (UA), Creatinine (CR) and Uric Acid (UR)
2. **InSight Mini Chem Test Strips** – Part of the system, these are inserted into the meter to measure the concentrations of UA, CR and UR
3. **Control Strip** – Verifies the operation of the meter by checking that the meter can detect a pre-calibrated value
4. **Code Chip** – Automatically calibrates the meter with the code number when inserted into the meter
5. **Lancing Device** – Used with sterile safety lancets to prick the patient's ear or paw for capillary blood collection. The packaged lancing device has multiple depth settings allowing users to adjust the depth of the puncture and minimise discomfort. It can also eject the used lancets
6. **Sterile Lancets** – Used with the lancing device to draw capillary blood samples. Sterile lancets are inserted into the lancing device for each blood draw and are discarded after use or safety lancets can be used
7. **Capillary Transfer Tubes/Pipettes** – Collects blood sample for accurate results
8. **Carrying Case** – Provides portability for the meter
9. **Instructions for Use** – Provides detailed instructions on using the InSight Mini Chem Meter
10. **Test Strips Instructions for Use** – Provides detailed instructions on using the InSight Mini Chem Test Strips
11. **Control Solution** – Verifies the correct operation of testing and validates the test strips and meter are working properly
12. **Control Solution Instructions for Use** – Provides detailed instructions on how to use the control solution

 **Note:** Test strips, safety lancets, sterile lancets and capillary transfer tubes/pipettes are disposable materials. Please use before the expiration date.

Section 3 Components

The InSight Mini Chem Meter reads the test strips and displays the concentrations of Uric Acid (UA), Creatinine (CR) and Urea (UR). Use this diagram to become familiar with all the parts of the meter.

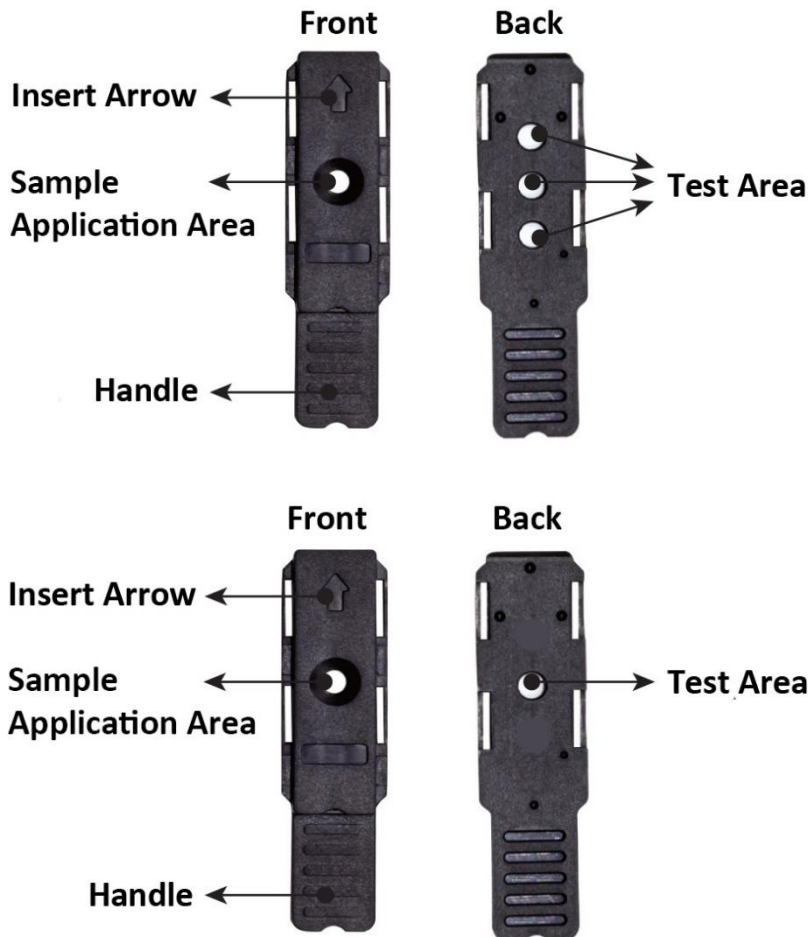


Meter Use and Precautions

- Do not get water or other liquids on or inside the meter
- Keep the Test Strip Holder clean
- Keep the meter dry and avoid exposing it to extreme temperatures and humidity
- Do not drop the meter or get it wet. If the meter is dropped or has got wet, ensure the meter is working properly by running a Control Check. Refer to 'Control Strip Test' for details
- Do not take the meter apart as this will void the warranty
- Refer to 'Maintenance' for details on cleaning the meter
- Keep the meter and all associated parts out of reach of children

Test Strips

The InSight Mini Chem Test Strips work with the InSight Mini Chem Meter only, to measure the Uric Acid (UA), Creatinine (CR) and Urea (UR) concentration in whole blood, plasma and serum.



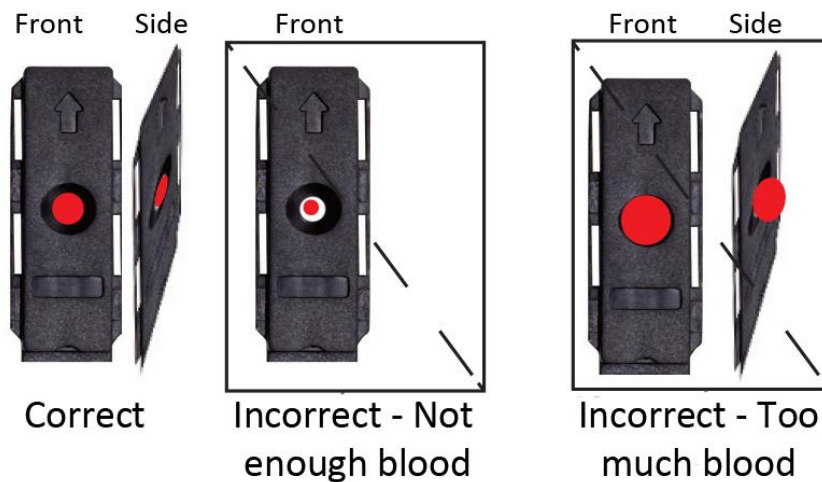
The InSight Mini Chem Test Strips can detect Uric Acid (UA), Creatinine (CR) and Urea (UR).

- **Insert Arrow** – Located on the front of the test strip, the arrows indicate the direction in which the test strip should be inserted into the meter
- **Sample Collection Area** – After the test strip is inserted into the Test Strip Holder, apply the correct sample volume (using the supplied capillary pipette) to the Sample Application Area
- **Handle** – Located on the end of the test strip, the handle is used to insert and remove the test strip from the meter, so the user does not touch the Sample Application Area
- **Test Area** – Located on the back of the test strip. This is where analysis is completed

Sample Application

For best results, fill the Sample Application Area with the correct sample volume (35µl or use the supplied capillary pipette for correct volume). Incorrect results may occur if the sample is not applied correctly or if the Sample Application Area is not filled correctly.

Before Testing



After applying the sample, ensure that the Sample Application Area is completely covered. The Sample Application Area should remain covered throughout the entire test. If the Sample Application Area is not covered or if there is too much sample covering the Sample Application Area, repeat the test with a new test strip.

Note: If the sample applied to the Sample Application Area is not enough, do not add more sample to the test strip. Retest with a new test strip. If the E-2 error or another error (refer to Section 13 for error codes) appears on the display, please discard the used strip and retest with a new strip.

Code Number

Printed on each package of test strips is a code number, lot number, unopened expiration date and test quantity. Ensure the code number matches with the test strips and code chip.

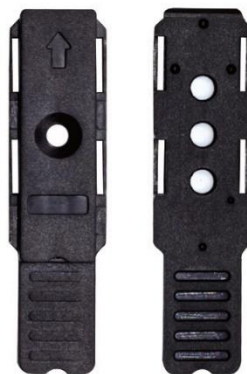
Test Strip Precautions and Instructions for Use

- Test strips should be stored in their tightly capped protective canister or foil pouch to keep them in working condition
- Do not transfer test strips to a new package of any other container
- Replace the cap on the test strip canister immediately after removing a test strip
- The opened expiration date is 3 months after the date the canister was first opened. Write the opened expiration date on the canister label after opening. Discard the canister 3 months after it was first opened. Usage after this period may result in inaccurate readings
- For in vitro diagnostic use

- Do not use test strips which are torn, bent or damaged in any way
- Do not reuse test strips
- Before performing a test, make sure the code number on the meter display matches the number shown on the test strip canister or foil pouch and on the code chip
- Refer to the InSight Mini Chem Test Strips Package Insert for more details

Control Strip

The InSight Mini Chem Control Strips work with the InSight Mini Chem Meter to ensure the optics are working correctly. After the control strip is inserted into the meter, the meter's optics detect the colour intensity of the control strip. The meter displays 'OH' (normal) or 'FL' (fail) to indicate whether the meter is functioning properly.



Precautions

- Store in a closed canister between 2-30°C. Avoid exposure to direct sunlight, extreme temperatures and humidity
- Control strips should be stored in their tightly capped canister at room temperature to keep them in working condition
- Keep the control strip clean. Do not touch the test area of the strip
- Do not use contaminated, discoloured or damaged control strips
- Do not use after the expiration date
- For in vitro diagnostic use only

Storage and Handling

- Store control strips in a cool, dry place. Store away from heat and direct sunlight
- Transport and store control strips in a closed canister between 2-30°C with less than 90% humidity
- Replace the cap on the strip canister immediately after removing a strip. Expired strips may produce incorrect test results

Control Solution

The InSight Mini Chem Control Solution contains stabilisers, preservatives and added chemicals. To confirm that the test strip and meter are working correctly and that the test is

being performed correctly, the control solution is applied to the Sample Application Area of a test strip that has been inserted into the meter. Refer to Section 9 for more information.

Note: The InSight Mini Chem Control Solution is intended for validating Renal Function testing while using the InSight Mini Chem Meter. Both levels of control solution must be tested and fall within the assigned values printed on the bottles.

Refer to the control solution package insert before using the controls. The control solution bottle is labelled with an acceptable range that is specific for that lot of control solution. The system is working correctly if the control value displayed by the meter is within the acceptable range printed on the bottle label. If the value doesn't fall within the range, refer to the InSight Mini Chem Control Solution Package Insert for further instructions.

Precautions

- Make sure the control solution and all the test materials reach an operating temperature of 10-35°C prior to testing. The control solutions and test materials are only accurate within this temperature range
- Use the control solution before the expiration date shown on the bottle
- Discard the control solution if it appears cloudy
- Use the InSight Mini Chem Control Solution with the InSight Mini Chem Meter and InSight Mini Chem Test Strips


Storage and Handling

- Store the control solution either refrigerated or at room temperature between 2-30°C
- Do not freeze
- If the control solution has been refrigerated, allow it to reach a temperature of 10-35°C before use
- Once opened, the control solution has an open vial stability of 3 months. Record the date the control solution was opened and dispose of QC 3 months after the recorded date

Section 4 Initial Setup

Before testing, ensure the following procedures are followed.

Turn on the Meter

Press  to turn the meter on.




The meter will automatically turn off after 5 minutes of inactivity.

Coding the Meter

Each time a new box of test strips is opened, the new code chip included in the box must be inserted into the meter. Compare the code number on the code chip with the code number printed on the test strip packaging or the foil pouch. Results may be inaccurate if the two numbers are not identical. Insert the new code chip into the code chip slot of the meter. The code chip should remain in the meter. Do not take it out until a new box of test strips is needed. The code number will appear on the Initial Screen after start-up.

If the code chip is not properly inserted into the code chip slot or if it is missing, the meter will display E-6.




Section 5 Meter Setup and Options

With the meter turned on, press  and hold for 2 seconds to enter the Settings mode. Press  or  to display several setup sub-modes.

SET

Press  to enter the SET item.




Year Setup

As the year is displayed, press  or  to change it. Press  to save.




Month Setup

As the month is displayed, press  or  to change it. Press  to save.

Day Setup

As the day is displayed, press  or  to change it. Press  to save.





Hour Setup

As the hour is displayed, press  or  to change it. Press  to save.





Minute Setup

As the minute is displayed, press  or  to change it. Press  to save.





Sound Setup

As the sound  is displayed, press  or  to switch between On and Off. Press  to save.





Bluetooth Setup


As the Bluetooth  is displayed, press  or  to switch between On and Off. Press  to save.

Printer Setup

As the printer  is displayed, press  or  to switch between On and Off. Press  to save.

Sample Select

As the sample shows FB, VB or SP, press  to enter the Sample Set. Press  or  to switch between Capillary Blood (FB), Venous Blood (VB) and Plasma and Serum (SP). Press  to save and go back to menu.

 **Caution:** The Capillary Blood (FB) is the meter's default sample.

Section 6 Testing

The following steps show how to use each component to measure the sample concentration.

Sample Collection

1. Use fresh capillary blood from the paw or ear
2. Use heparinised or EDTA venous whole blood, plasma or serum

⚠ **Caution:** Before testing, choose a clean, dry work surface. Review the procedure and make sure all of the items needed to obtain a sufficient amount of blood are available.

Testing with Heparinised or EDTA Venous Whole Blood, Plasma and Serum

For heparinised or EDTA venous whole blood, mix the specimen well, then collect the blood into a plastic/glass capillary transfer tube or pipette. For heparinised or EDTA plasma or serum, collect the sample into a plastic/glass capillary pipette. Apply the sample to the centre of the Sample Application Area of the test strip. Do not touch the test strip with the pipette or tube.

- The sample must be tested within 8 hours of collection
- Mix the specimen well before testing in order to ensure the cellular components are evenly distributed
- Allow the specimen to attain operating temperature (10-35°C) for approximately 15 minutes if the specimen has been refrigerated
- Anticoagulants other than EDTA and lithium heparin are not recommended

Testing with Capillary Blood

After using the lancing device and lancet to puncture the skin, wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Use a capillary transfer tube or pipette to collect capillary blood.

For use with a capillary transfer tube, hold the tube slightly downward and touch the tip of the capillary transfer tube to the blood drop. Capillary action will automatically draw the sample to the fill line and stop.

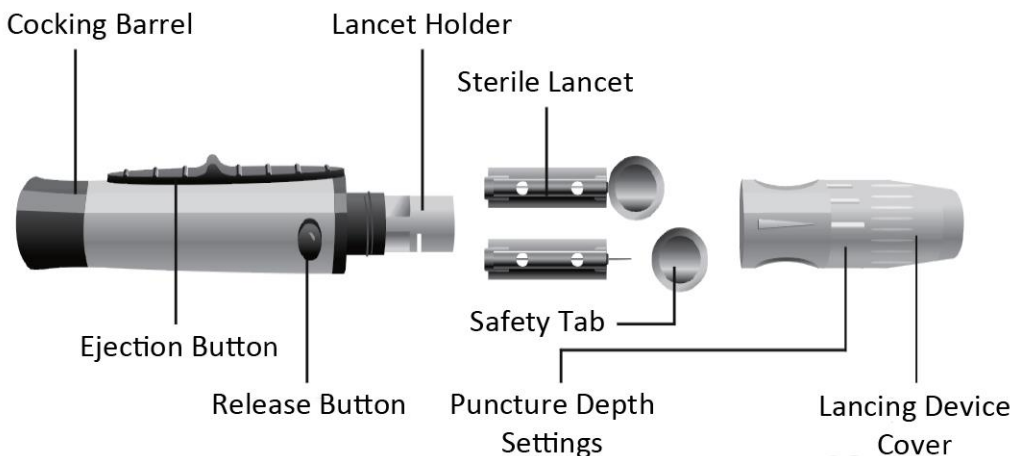
Note: The capillary transfer tube will fill automatically. Make sure the blood covers the air vent of the tube or it will be difficult to squeeze the blood out. Never squeeze the capillary transfer tube while sampling.

Align the tip of the capillary transfer tube with the centre hole of the Sample Application Area of the test strip to apply the drop of blood.

Note: Do not touch the test strip with the end of the capillary transfer tube or pipette. The capillary blood should be tested immediately after collection. Use of a capillary transfer tube or pipette is recommended for accurate results.

Capillary blood samples can be obtained by using a lancing device and a lancet or a safety lancet.

Lancing Device



For obtaining a drop of blood from the paw or ear, adjust the puncture depth on the lancing device as needed.

Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.

Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Then, pull the safety tab off the lancet. Save the safety tab for lancet disposal.

Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.

Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings (1=lowest setting, 5=highest setting). To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

Note: Greater pressure of the lancing device against the paw/ear will also increase the puncture depth.

Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready to obtain a drop of blood.

Prior to testing, clean the testing site with an alcohol swab or by washing it with warm, soapy water. Dry the testing site thoroughly.

Hold the lancing device against the paw/ear. Push to release button to prick the site. A click should be heard as the lancing device activates. Avoid smearing the drop of blood.

Note: Don't use an infection swab containing iodine to clean the puncture site as this can cause inaccurate results.

Disposal of the Lancet

Unscrew the lancing device cover. Place the safety tab back onto the lancet needle. Pull the used lancet off. Place the lancing device cover back on the lancing device.

Note: For veterinary use only.

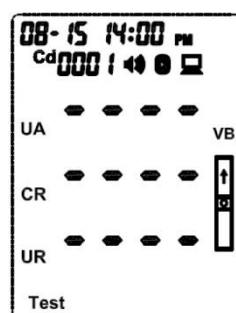
Safety Lancets

1. Carefully rotate and pull off the protective cap
2. After cleaning the skin, hold the lancet firmly against the puncture site
3. Press the lancet against the puncture site. Discard the lancet in an appropriate sharps container

Test Processing

Ensure the meter is set up properly as described in Sections 4 and 5. Turn the meter on. Ensure the code chip is inserted. Compare the number shown on the display with the code number printed on the box label or foil pouch. The test strip icon flashes to indicate that it is ready for the strip to be inserted.

Check the sample type on the meter is the same as the sample type collected. If not, set the correct sample type as described in Section 5.



Testing


Insert a test strip into the Test Strip Holder in the same direction as the arrows indicate on the strip. Ensure that the test strip is inserted all the way to the end of the Test Strip Holder.

The blood drop symbol will flash when the meter is ready for the sample to be applied. Apply the sample to the centre of the Sample Application Area of the test strip.

Once analysis has completed, remove the used test strip. The meter will return to the Initial Screen and is ready for another test strip to be inserted and to perform a new test.








Note: Discard all blood samples, used test strips and materials carefully. Treat all blood samples as if they were infectious material. Follow precautions and local regulations when discarding blood samples and materials.

Perform daily cleaning when testing is completed for the day. Refer to Section 10.



The meter will automatically turn off after 5 minutes of inactivity or when  is pressed.


Section 7 Memory/Communication

Memory/Database

Press  to switch the meter on. Press and hold  to access the menu. Use  and  to scroll across to MEM. Press  to enter. Use  and  to scroll through results.

Deleting Data






To delete the data from the meter's memory, press  and  at the same time to enable data deletion.

Press  to return to the Setting screen.

Communication

If Bluetooth is turned on (Bluetooth icon is displayed), when querying records at the MEM mode, the meter will send the current record to Bluetooth. If the printer is turned on (printer icon is displayed), when querying records at the MEM mode, the meter will print out the current record.

Section 8 Control Strip Test

Press and hold  to enter the menu, use  or  to scroll across to CTR. Press  to enter CTR Mode. After entering the CTR Mode, the meter will display OPT. Press  and then insert a control strip into the Test Strip Holder. Follow the direction of the arrows indicated on the strip. Ensure that the control strip is inserted all the way. The optical check will start automatically. If the meter displays 'OH', the meter is normal. If the meter displays 'FL', the meter is not functioning properly.

Note:

- The control strip is intended to check the optical system
- Allow the control strips and the meter to reach operating temperature (10-35°C) prior to testing
- The optical check should be performed under normal lighting conditions. Do not perform under direct sunlight or extreme lighting conditions

If the meter displays 'FL', check the control strip for contamination or check if it is damaged. If there are any visible signs of damage or contamination, discard the control strip and retest using a new control strip.

Once the control strip is removed, the meter will return to the Initial Screen.

Section 9 Quality Control

Each laboratory should have its own protocol for running quality control.

A quality control should be performed:

- When a new package of test strips is opened
- When a new operator uses the meter
- When test results seem inaccurate
- After performing maintenance or service on the meter







If quality control results are outside of the range, perform the following checks:

- Ensure that the test strips used have not expired
- Ensure that the test strips have been stored in the vial correctly
- Ensure that the controls have not expired
- Repeat the test to ensure no errors were made during the test

Control Solution Testing

Renal Function Control Solution testing is performed in a very similar manner to blood tests. The InSight Mini Chem Control Solution is used instead of blood.

Note: Make sure the control solution and all the test materials reach operating temperatures of 10-35°C prior to testing. Tests can only be accurately performed when the control solutions and test materials are within this temperature range.

1. Turn on the meter
2. Insert the code chip into the meter. Refer to Section 4 'Coding the Meter' for details
3. Compare the code number on the code chip with the code number printed on the test strip pouch label and ensure the two numbers are identical to avoid inaccurate results
4. Press and hold  for 2 seconds to enter the Settings mode and press  to change the selection. Press  to enter the CTR. Press  or  to switch between OPt and SOLU. Press  once SOLU is selected.
5. The meter will flash the test strip icon. Insert a test strip completely into the Test Strip Holder in the same direction as the arrows printed on the strip
6. When the meter is flashing the blood drop symbol, open the screw cap of the control solution bottle and turn the bottle upside down. Squeeze the control solution bottle gently and discard the first drop. If there are bubbles in the previous drop, squeeze the bottle and discard another drop until there are no bubbles in the drop. Apply the next drop to the specimen well on the test strip while keeping the bottle vertical. Make sure the control solution is applied directly into the specimen well and there are no bubbles in the solution drop. The meter will automatically

start analysis once the drop has been applied to the test strip. Results will display on screen once analysis has completed

Note:

- Make sure the bottle is completely vertical when applying the solution to the strip. The volume will be inconsistent if the bottle is not completely vertical
- Gently squeeze the solution completely onto the tip of the bottle and drop it freely into the sample well. Avoid touching the strip with the tip of the bottle

Interpreting Results

The results should fall within the range(s) printed on the bottle label and are specific for each lot of controls. If the results fall within the specified control range, it indicates the InSight Mini Chem Meter is working correctly and the procedures are being performed correctly. If the results do not fall within the respective range(s), refer to Page 20 for further instructions or contact Woodley Equipment Company.


Section 10 Maintenance

General Cleaning

For best results, the meter should be cleaned after each day of testing.

Meter Sensor Area and Test Strip Holder

Wipe down the Test Strip Holder with a cotton swab. Do not scratch the transparent window covering the sensors.


 **Caution:** Do not use organic solvents, such as gasoline or paint thinner to clean the Test Strip Holder as this will cause damage to the meter.

Cleaning Process

For best results, the meter should be cleaned after each day of testing. A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary. A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use. Take care to avoid getting liquids, residue or control solutions in the meter through the Test Strip Holder, Code Chip Slot or USB Port.

Charging Step

The meter is powered by a lithium battery and can be charged by a USB port. Connecting the Micro USB port to the meter and connecting the other end to the PC's USB port or adapter (Output: 5V, 0.5A) can charge the meter. The meter cannot be tested when it is charging.

 **Caution:** The adapter or computer should meet the requirements of the current edition of IEC60950-1. Lithium batteries meet the standard requirements of IEC62133:2012.

Battery Maintenance

Lithium batteries are built-in and cannot be disassembled.

- Meters should be stored in a cool, dry and safe environment
- Avoid using the meter near heat sources, open fires, flammable and explosive gas and liquid, otherwise it may cause battery leakage, heating, smoking, ignition and explosion
- If not used for a long time (more than a month), it is recommended to charge 40-60% of the battery

Section 11 Precautions

Follow the precautions listed below to ensure accurate results and correct operation of the meter:

- The warranty provided by the meter may be void if used in a manner not defined in this instruction manual
- Wear gloves to avoid contact with potentially hazardous biological specimens during testing
- Avoid storing or operating the meter in direct sunlight, excessive temperatures or high humidity. Refer to Appendix 1 'Meter Specifications' (Page 28) for operating condition requirements
- Keep the meter clean. Wipe it frequently with a soft, clean and dry cloth. Use a damp cloth when needed
- Do not clean the meter with substances such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean dry cloth
- The test strip holder must be kept clean. Lightly wipe with a soft, clean dry cloth before use. Use a damp cloth as needed. Refer to Section 10 for details
- Follow all local regulations when discarding the meter or its accessories

Section 12 Limitations

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	1324 µmol/L (20 mg/dL)	Cholesterol	12.9 mmol/L (500 mg/dL)
Ascorbic Acid	568 µmol/L (10 mg/L)	Triglyceride	7.3 mmol/L (650 mg/dL)
Conjugated Bilirubin	240 µmol/L (20 mg/dL)	Uric Acid	0.6 mmol/L (10 mg/dL)
Creatinine	442 µmol/L (5 mg/dL)	Haemoglobin	2 g/L (200 mg/dL)
Ibuprofen	2425 µmol/L (50 mg/dL)	Dopamine	5.87 µmol/L (0.09 mg/dL)
Methyldopa	71 µmol/L (1.5 mg/dL)		

High concentrations of uric acid and ascorbic acid can lead to low measurements. Anticoagulants, such as heparin and EDTA, are recommended for use with venous whole blood. Do not use EDTA plasma which can lead to higher results. Do not use other anticoagulants such as iodoacetate, sodium citrate or those containing fluoride. Arterial blood isn't recommended for use. Haemolysed blood or thrombolytic therapy blood may give lower results.

Section 13 Troubleshooting

Display	Cause	Solution
E-1	The sensor area is damaged or contaminated	Ensure the sensor area is clean and that there are no objects covering the sensor area. Ensure no used test strips are left in the holder. Refer to the 'Maintenance' section. Restart the meter. Contact Woodley Equipment Company if the sensor area window is broken.
E-2	Test strip was removed during testing	Repeat the test and ensure the test strip remains in place during testing.
E-3	Test strip expired	Replace test strips and code chip. Check their expiry date.
E-4	Battery power is low. The meter cannot be tested until it is charged	Connect the meter to PC via USB to charge.
E-6	Code chip was removed	Insert correct code chip. Confirm the code chip matches the test strip code and repeat the test.
E-7	The temperature is out of the operating range	Ensure the meter is in an environment where the temperature is between 10-35°C.
HI	The result is higher than the readable range	Check sampling technique and repeat test with a new test strip. Run a quality control check.
Lo	The result is lower than the readable range	Contact Woodley Equipment Company.

Section 14 Meter Performance

Accuracy

Item	Range of Sample	Bias
UA	90 – 300 $\mu\text{mol/L}$ (1.51 – 5.04 mg/dL)	$\leq \pm 0.060$ mmol/L (± 1.01 mg/dL)
	301 – 1200 $\mu\text{mol/L}$ (5.05 – 20.17 mg/dL)	$\leq \pm 20\%$
CR	44 – 150 $\mu\text{mol/L}$ (0.50 – 1.70 mg/dL)	$\leq \pm 0.030$ mmol/L (± 0.34 mg/dL)
	151 – 1320 $\mu\text{mol/L}$ (1.71 – 14.93 mg/dL)	$\leq \pm 20\%$
UR	0.90 – 10.00 mmol/L (5.41 – 60.06 mg/dL)	$\leq \pm 2.00$ mmol/L (± 12.01 mg/dL)
	10.01 – 40.00 mmol/L (60.07 – 240.24 mg/dL)	$\leq \pm 20\%$

Precision

Item	Range of Sample	SD
UA	90 – 300 $\mu\text{mol/L}$ (1.51 – 5.04 mg/dL)	SD < 0.023 mmol/L (< 0.38 mg/dL)
	301 – 1200 $\mu\text{mol/L}$ (5.05 – 20.17 mg/dL)	CV < 7.5%
CR	44 – 150 $\mu\text{mol/L}$ (0.50 – 1.70 mg/dL)	SD < 0.011 mmol/L (< 0.13 mg/dL)
	151 – 1320 $\mu\text{mol/L}$ (1.71 – 14.93 mg/dL)	CV < 7.5%
UR	0.90 – 10.00 mmol/L (5.41 – 60.06 mg/dL)	SD < 0.75 mmol/L (< 4.50 mg/dL)
	10.01 – 40.00 mmol/L (60.07 – 240.24 mg/dL)	CV < 7.5%

Appendix 1 Meter Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	≤5 mins
Measurement Range	UA: 90 – 1200 µmol/L (1.51 – 20.17 mg/dL) CR: 44 – 1320 µmol/L (0.50 – 14.93 mg/dL) UR: 0.90 – 40.00 mmol/L (5.41 – 240.24 mg/dL)
Reference Range	Canine UA: 0 – 100 µmol/L CR: 35 – 141 µmol/L UR: 2.1 – 9.3 mmol/L Feline UA: 0 – 60 µmol/L CR: 62 – 177 µmol/L UR: 4.6 – 13.2 mmol/L
Sample Type	Whole blood (capillary blood, venous whole blood), plasma and serum
Sample Volume	35µl
Power Source	USB to micro USB cable for charging meter Note: During charging, the meter is non-operational
Units of Measurement	UA: µmol/L CR: µmol/L UR: mmol/L
Memory	500 records
Automatic Shut Down	After 5 minutes of inactivity
Dimensions	135 x 66 x 19 mm
Weight	90g
Storage and Transportation Conditions	0-55°C, ≤90% Relative Humidity (RH)
System Operating Conditions	10-35°C, ≤80% RH, indoors only
System Operating Altitude	Max. 2000m
Test Strip Storage and Transportation Conditions	2-30°C, ≤90% RH
Control Strip Storage and Transportation Conditions	2-30°C, ≤90% RH

Appendix 2 Labelling and Information



Do not reuse



Use by



Keep dry



Manufacturer



Biological risks



Lot No.



Consult instructions for use



Caution, the user must be consulted in all cases where this symbol is marked



Symbol for the marking of electrical and electronic devices according to Directive 2012/19/EU. The device accessories and packaging have to be disposed of waste correctly at the end of usage. Please follow local guidelines and regulations.

Appendix 3 Warranty

The InSight Mini Chem Meter is warranted for a period of 12 months from date of invoice.



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