POINT OF CARE
TESTING

CoaguChek® INRange

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Coagulation Monitoring System

User's Manual

Roche

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Before you start

Intended use

The CoaguChek® INRange system (CoaguChek INRange meter and CoaguChek XS® PT test strips) measures blood-clotting time (prothrombin time or “PT”) using fresh capillary blood from the fingertip. The CoaguChek INRange system is suitable for self-testing by patients who are taking anti-coagulation medications such as Coumadin® or warfarin (vitamin K antagonist therapy).

It is not intended for use in the professional setting.

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PT time

A PT test is often called an INR test. The International Normalized Ratio (INR) is a way of standardizing the results of prothrombin time tests because there are different test methods. INR enables you and your doctor to understand your coagulation results even when they come from different labs using different test methods.

Prothrombin time can also be expressed as %Quick or in seconds.

Self-testing

If you self-test, you can adjust your medication dose yourself.

Depending on the training you have received and the instructions from your healthcare professional, you might communicate your results to a healthcare professional or clinic to receive the appropriate dose adjustment. Or you may be able to adjust your medication independently according to a pre-determined dose-INR schedule developed for you by your doctor.

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Self-monitoring and self-adjustment of oral anticoagulation therapy using coagulation values determined with the CoaguChek INRange system may only be undertaken after consultation with your doctor and comprehensive instruction by a qualified healthcare professional.

Your pharmacist / specialist supplier can provide you the training and/or put you in touch with associations or institutions offering training in coagulation self-monitoring. Please read the special notes on INR self-monitoring in the package insert accompanying the test strips.

This manual contains all the information you need to operate and care for the CoaguChek INRange System. Please **read this entire manual carefully** before you use the meter.

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The CoaguChek INRange System

The CoaguChek INRange System makes coagulation testing easy. The graphical user interface of the CoaguChek INRange meter guides you through the test step by step. The code chip accompanying the test strips contains lot-specific information about these test strips, including calibration data that allow the correct results to be calculated, and the expiry date for the test strips. You only need to insert the code chip, turn the meter on, insert the test strip, and apply a blood sample. The CoaguChek INRange meter measures your coagulation time and displays the result. After the test is completed, the meter automatically saves the result to memory.

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If you have any questions about the CoaguChek INRange meter, please contact your local customer support and service center. You will find contact details on page 135.

Please note: Before you use the meter for the first time (i.e. after you have first inserted the batteries), you must set the date and time correctly to allow you to carry out measurements properly. Each time you replace the batteries you need to check (and, if necessary adjust) the date and time.

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Test principle

The CoaguChek XS PT test strip contains a lyophilized reagent (reagent in dried form). The reactive components of this reagent consist of thromboplastin and a peptide substrate. When a sample is applied, thromboplastin activates coagulation, which leads to the formation of thrombin. At the same time the meter starts to measure the time. The enzyme thrombin cleaves the peptide substrate, generating an electrochemical signal. Depending on the time elapsed when it first appears, this signal is then converted by means of an algorithm into customary coagulation units (INR, %Quick, seconds) and the result is displayed.

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Contents of the pack

- CoaguChek INRange meter
- 4 alkali-manganese batteries, 1.5 V, type AAA
- USB cable
- CoaguChek XS Softclix lancing device with instructions for use
- CoaguChek Softclix Lancet
- System carry-case (not shown here)
- User's Manual (this document)
- Quick Reference Guide

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Operating conditions

To ensure that your CoaguChek INRange System functions properly, please observe the following guidelines:

- Only use the meter at a temperature between 15 °C and 32 °C.
- Only use the meter at a relative humidity between 10% and 85%.
- When testing, place the meter on a level, vibration-free surface or hold it so it is roughly horizontal.
- If the meter is to remain unused for a longer period of time, keep it in the carry-case supplied.
- Use the meter only up to a maximum altitude of 4300 metres.

Electromagnetic interference

Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter near strong electromagnetic fields.

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Quality control

The CoaguChek INRange System has a number of inbuilt quality control functions such as:

A check of the electronic components and functions every time the meter is turned on.

A check of the test strip temperature while a test is in progress.

A check of the expiry date and lot information on the test strip.

A quality control function is incorporated into the test strip. Quality control and system checks using control test solutions that you may be familiar with from other systems are no longer required.

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Important Safety Instructions and Additional Information

This section explains how safety-related messages and information related to the proper handling of the system are presented in the CoaguChek INRange User's Manual. Read these passages carefully.

⚠

The safety alert symbol by itself (without a signal word) is used to promote awareness to hazards which are generic or to direct the reader to related safety information

⚠ **WARNING**

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ **CAUTION**

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

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NOTICE

Indicates a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is presented against a colored background (without a symbol). Here you will find additional information on correct use of the meter or useful tips.

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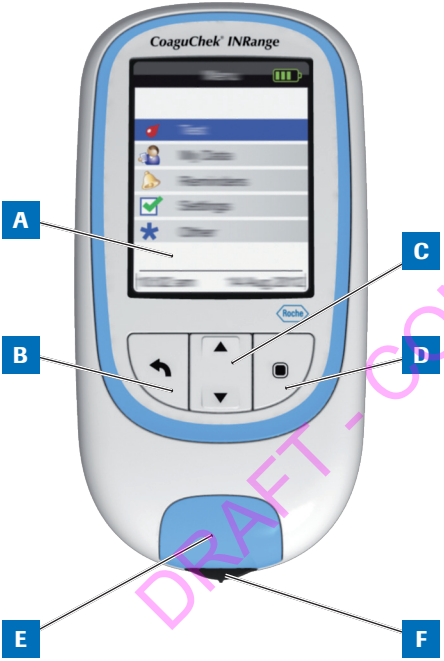
The CoaguChek INRange Meter

Overview of the meter elements



Overview of the meter elements (front)

A Display
Shows menus, results, messages and results recalled from memory.

B Back button ↰
Exit the currently displayed menu.

C Arrow up/down button ▲▼
Move or scroll up/down in a screen.

D Enter button (Power on) ▣
Confirm the currently selected option or perform a function. Also used to power the meter on and off.

E Test strip guide cover
Remove this cover to clean the test strip guide.

F Test strip guide
Insert the test strip here.

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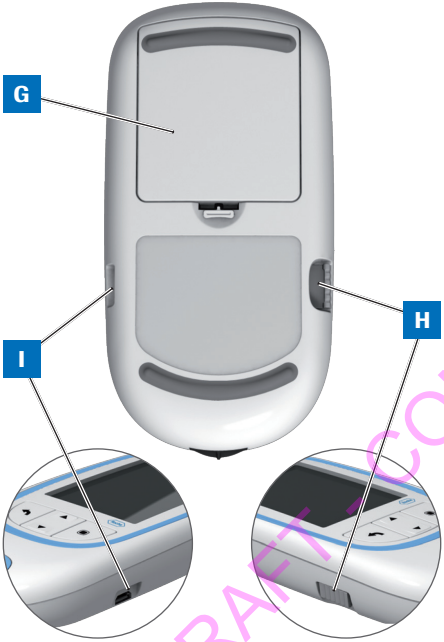

Overview of the meter elements (back and sides)

G Battery compartment cover
Covers the battery compartment (four 1.5 V alkali-manganese dioxide batteries type AAA).

H Code chip slot
Insert the code chip here.

I USB port
For wired communication and data transfer to a computer.

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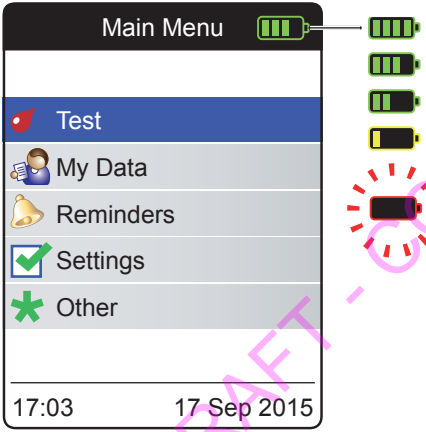
Batteries

To save power, the CoaguChek INRange meter automatically turns itself off after 2 minutes unless a button has been pressed or a new test strip has been inserted. When the meter turns itself off, all results obtained up to that point remain in memory.



When the **Main Menu** screen is displayed, the meter indicates the battery power level on the top right of the display. The battery symbol is divided into four segments which correspond to the battery power level. Replace batteries at latest when the flashing red battery symbol or a corresponding message appears.

Please be aware that battery life may be affected by many factors, such as battery type, quality, operating conditions (e.g. ambient temperature), frequency of use, and test duration.

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Results together with the date and time, the comments and the download information are retained in the memory even when no batteries are inserted. All other settings are retained, too.

Think of the environment. Dispose of used batteries sensibly.

WARNING

Do not throw batteries onto a fire. They may explode!

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Starting Up

Before using the meter for the first time, carry out the following steps:

- Insert the batteries
- Set the language
- Set the current date and time
- Select the coagulation unit in which the results are to be displayed
- Insert the code chip (you can also carry out this step immediately before testing)

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Inserting the batteries

When replacing the batteries you must insert the new batteries within 10 minutes of removing the old ones, to keep the date and time settings. If you take longer than this, you must re-enter the date and time. Only use alkaline-manganese dioxide batteries 1.5 V type AAA.

With normal use the batteries will last for approximately 60 tests.

Roche recommends replacing used batteries only with new high quality batteries and not mixing different brands. Do not mix new and already used batteries.

Think of the environment. Dispose of used batteries sensibly.

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It is not recommended to use rechargeable batteries. In case you want to use them anyway, use AAA (Micro) 1.2 V NiMH HR6 batteries with a minimum capacity of 2500 mAh. Always use a battery charger recommended by the manufacturer.

When you use rechargeable batteries, please observe the following:

- The number of tests that can be performed per battery charge is much lower than with regular batteries.
- Performing tests in a cold environment may not be possible at all.
- The remaining capacity may not be displayed correctly. If the meter displays a Battery Low message, performing further tests may already be impossible. Replace the batteries as soon as possible.

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1 Turn the meter over.

2 Gently press the tab on the battery compartment cover towards the top of the meter and lift off the cover.

3 Insert the four batteries in the battery compartment as indicated. Pay attention to the positions of “+” (top of battery) and “–” (flat end).

4 Re-attach the cover. Close the battery compartment by pushing the cover down until the tab snaps into place.

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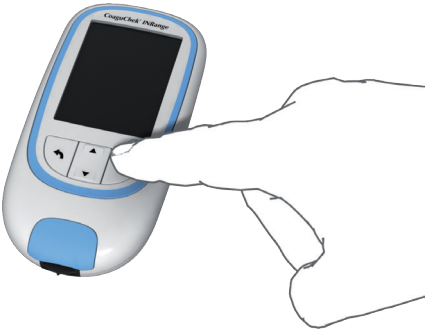
Initially setting up the meter



When you power on the meter for the very first time, you will automatically be guided through the **Language**, **Time & Date,** and **Units** setup. If the meter automatically powers off before you have completed the settings (2 minutes after inserting the batteries), then:

1 Press the Enter button ◼ to power the meter on (again).

The meter automatically displays the **Language** screen. A green dot indicates which language is currently active.

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2 Use the Arrow up/down buttons ▲▼ to select your preferred language. The newly selected language is highlighted (blue). Arrow symbols on top and/or bottom of the screen indicate more entries above or below the currently visible part of the list.

3 Press the Enter button ■ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ■ again to save the selected language.

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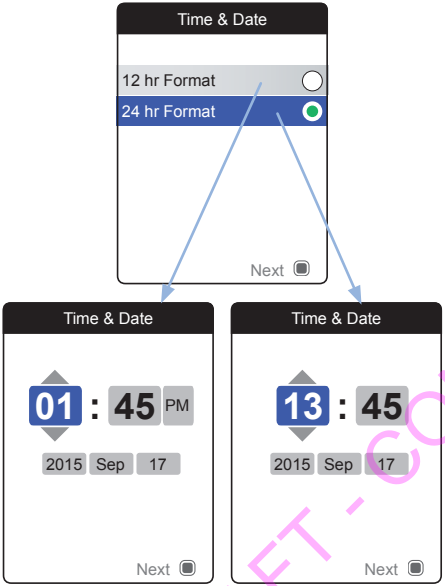

The meter now displays the screen for setting the time format.

5 Use the Arrow up/down buttons ▲▼ to select the time format for the display (24 hour or 12 hour am/pm). The newly selected format is highlighted (blue).

6 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

7 Press the Enter button ▣ again to save the setting. The screen for setting time and date follows next.

All test results are saved together with time and date. Analyzing stored test results or using reminders will only work with time and date correctly set. Always check (and, if necessary adjust) time and date after replacing the batteries.

Throughout this manual the 24h format is used on example screens.

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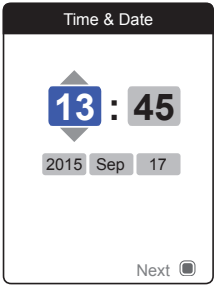

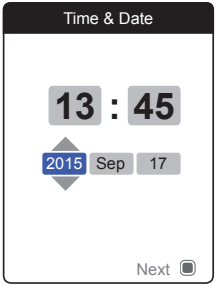

8 Use the Arrow up/down buttons ▲▼ to set the current hour.

9 Press the Enter button ■ to confirm the hour. The next input field (minutes) will be highlighted.

10 Proceed with setting the remaining fields. The Enter button ■ always confirms a setting (and highlights the subsequent field, if available), the Back button ↰ allows you to jump back to the previous field.

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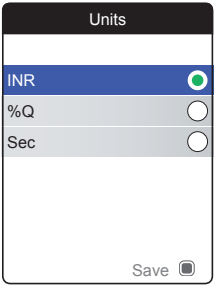

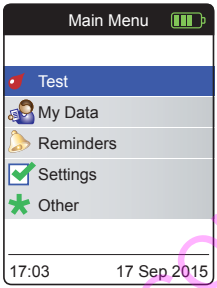

Select the preferred coagulation unit (for displaying a test result) as the last step of this initial setup process. The currently active unit is shown by a green dot.

11 Use the Arrow up/down buttons ▲▼ to select your preferred unit. The newly selected unit is highlighted.

12 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

13 Press the Enter button ▣ again to save the selected unit.

The initial setup is now finished, the meter displays the **Main Menu**. For a complete overview of setup options (including those which are not part of the initial setup) see chapter *Meter settings* starting on page 85.

If you wish to power off the meter after setup:

14 Press and hold the Enter button ▣ until the meter powers off.

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Code chip

The code chip provides the meter with important information which it needs to perform the coagulation test. The chip contains information about the test method, the lot number and the expiry date. The meter is ready to use once the code chip has been inserted.

If you use a new test strip lot and have not inserted the corresponding code chip yet, you must do so at latest after inserting the test strip. Otherwise you cannot perform a test. The meter displays the number of the code chip belonging to the new test strip lot.

Once the code chip information has been read by the meter, it will be stored for future use. You may remove the code chip then. Up to 5 code chip data sets can simultaneously be stored in the meter.

Protect the code chip from moisture and equipment which produces magnetic fields, e.g. loudspeakers, induction stove or other electronic devices.

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Inserting the code chip

1. Remove the old code chip, if one is inserted in the meter. Discard the old code chip with your household waste.
2. Slide the new code chip into the slot on the side of the meter as shown until you feel it snap into place.

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Testing a Capillary Blood Sample

What you need

- CoaguChek INRange meter
- The code chip already inserted in the meter (each test strip container has its own code chip)
- Test strips belonging to the code chip mentioned above
- Lancing device (e.g. CoaguChek XS Softclix)
- Lancet (e.g. CoaguChek Softclix Lancet)
- Lint-free cloth or paper tissue

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Important notes

Always …

- close the container immediately after having removed a test strip.
- operate the meter at an ambient temperature between 15 °C and 32 °C.
- place the meter on a level, stable surface (table) or hold it so it is roughly horizontal.
- follow the information on correct handling of test strips in the package insert.
- keep the test strip guide and housing clean. Refer to the chapter *Cleaning and Disinfecting the Meter and the Lancing Device*.

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Never …

- store the meter at extreme temperatures.
- store the meter in damp or humid conditions without protection.
- remove or insert the code chip while the meter is performing a test.
- touch or remove the test strip during a test.
- wait more than 15 seconds after lancing the fingertip before applying the blood.
- add more blood after the test has begun.
- perform a test with a drop of blood from a previous puncture.

To avoid inaccurate results make sure you follow the above recommendations.

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Getting a good capillary blood sample

To get a suitable drop of blood:

- Wash your hands in warm water and dry thoroughly.

WARNING

Residues of water on the skin can dilute the drop of blood and so produce false results.

- Let your hand hang at your side before lancing your finger.
- Immediately after lancing, massage gently along the side of your finger to obtain a sufficiently large blood drop without pressing or squeezing too hard.

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Preparing to test

1 Have the test strip container to hand.

2 Make sure that the code chip belonging to these test strips is available or the information has previously been stored in the meter.

3 Prepare the lancing device by inserting a fresh lancet.

Do **not** lance your finger until asked to do so further on in this description.

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Performing a test

1 Wash your hands with soap and warm water. Dry them thoroughly.

WARNING

Residues of water on the skin can dilute the drop of blood and so produce false results.

2 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.

3 Power the meter on by pressing the Enter button ▣. Alternatively, you can insert a test strip to power it on, which will put the meter – after completing the startup – into test mode directly.

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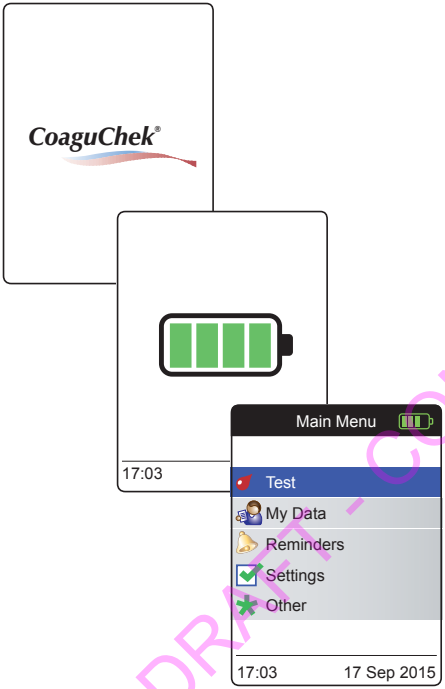

4 Check the battery level during startup (or in the **Main Menu** afterwards).

If the meter displays a Battery Low message, you can still perform up to 3 tests. Replace the batteries as soon as possible.

5 Check that the date and time are correct. Correct any wrong entries as described from page 89 onwards.

If you have powered on the meter by inserting a test strip, the meter will skip the following steps 6 to 9 and proceed to the steps described on page 45.

6 After startup **Test** is preselected and highlighted. Press the Enter button ■ to start the test.

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The test strip symbol prompts you to insert a test strip.

7 Remove a test strip from its container. Immediately after removing a test strip, close the container again with the stopper.

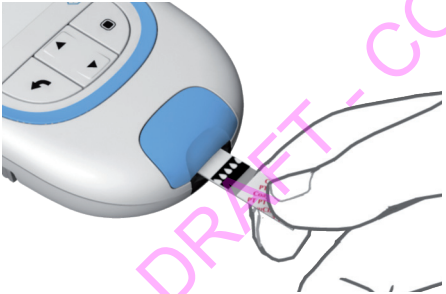
NOTICE

Exposure to external influences (e.g. humidity) may deteriorate the test strips and may lead to error messages.

8 Hold the test strip so the lettering, the arrows and the blood drop symbols are facing upward.

9 Slide the test strip into the test strip guide in the direction indicated by the arrows.

Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip. (Unless you have disabled the beeper in the Settings menu.)



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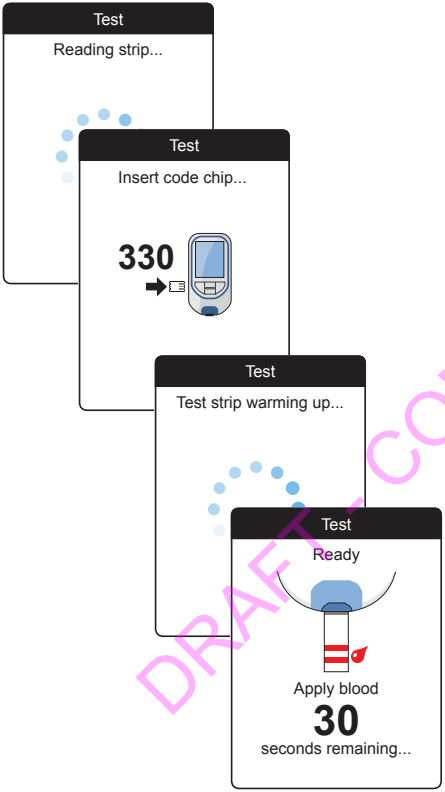

- The meter reads the strip information (provided by the barcode on the test strip) and checks if it matches code chip information already stored in the meter.
- If you haven't inserted the code chip yet or in case of a mismatch, you will be prompted to insert the correct code chip.
- When the test strip check has been completed successfully, the meter indicates that the test strip is warming up.
- Once the warming-up process is complete, the meter displays the symbols for test strip and blood drop. These symbols tell you that the meter is ready to perform the test and is waiting for you to apply blood.

  At the same time a 180-second countdown begins. You must apply the drop of blood to the test strip within this time, otherwise you will receive an error message.

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10 Now lance the side of a fingertip with the lancing device.

We recommend obtaining the capillary blood from the side of the fingertip as this causes least pain.

11 Massage the lanced finger until a drop of blood is formed. **Do not press or squeeze the finger**.

12 Apply the **first drop of blood** from the finger to the test strip.

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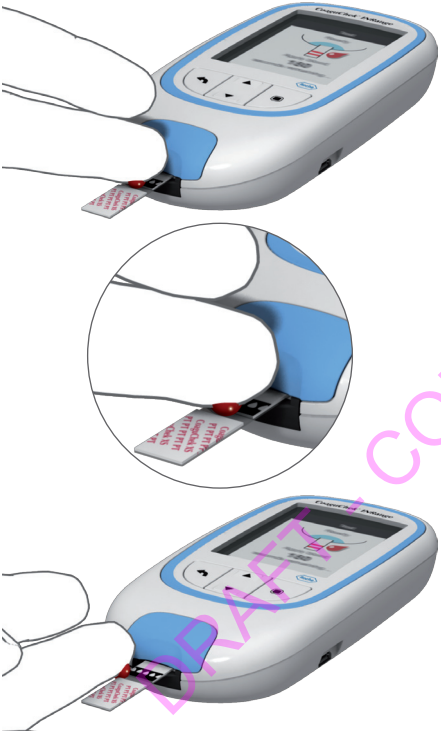

13 Apply the blood directly from the finger to the semicircular, transparent sample application area of the test strip.

Alternatively, you can touch the blood drop against the side of the sample application area (instead of applying it to the center from above). The test strip draws up the blood by capillary action.

During this process you must hold the blood drop to the test strip until the next screen indicates that the blood has been applied successfully.

Apply the blood drop to the test strip **within 15 seconds** of lancing the fingertip. Applying blood after this period of time would falsify the result, as the coagulation process would already have begun.

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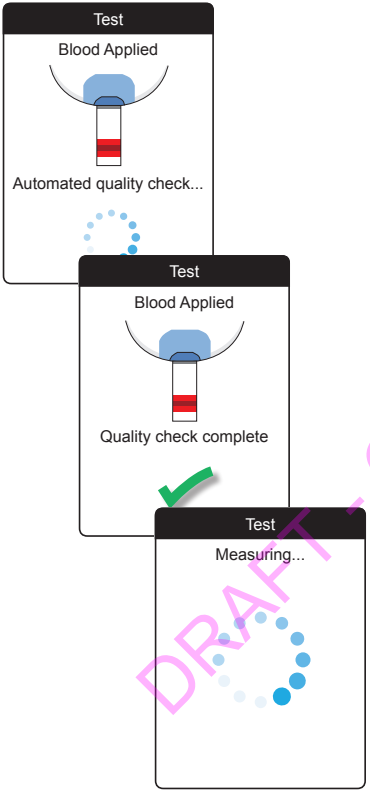

You hear a beep tone when you have applied enough blood (if you have activated the beeper function). The blood drop symbol disappears and the test starts.

Do not add more blood. Do not touch the test strip until the result is displayed.

The meter now performs an automatic quality control check on the test strip. Following a successful outcome of the quality control check, the coagulation measurement starts. The circular progress bar spins until the meter has determined the result.

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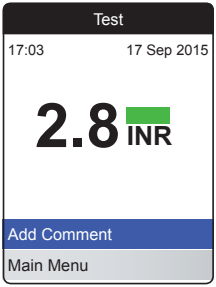

The result is displayed in the unit you chose when setting up the meter. It is automatically saved to memory.

When interpreting your result, please also read the test strip package insert carefully.

If you wish, you can add up to six predefined comments to a test result. Comments can provide, for example, additional information about the test conditions or your general state of health.

These comments can **only** be added immediately after the test result is displayed (before the meter is powered off), later editing is not possible.

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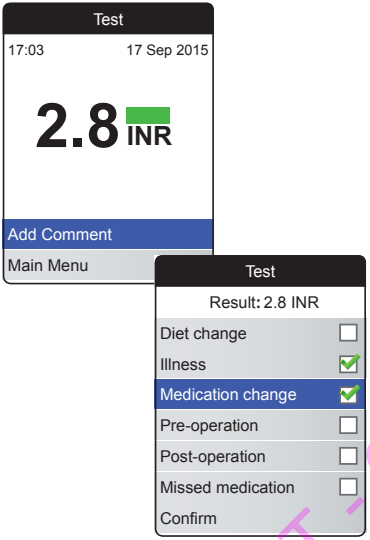

14 To add a comment, use the Arrow up/down buttons ▲▼ to highlight **Add Comment**.

15 Press the Enter button ◉ to proceed to the comment list.

16 Use the Arrow up/down buttons ▲▼ to highlight the comment(s) you wish to apply.

17 Press the Enter button ◉ to confirm the currently highlighted comment. A green checkmark ✓ appears behind each selected comment.

18 Once you have selected the desired comment(s), use the Arrow up/down buttons ▲▼ to highlight **Confirm**.

19 Press the Enter button ◉ to proceed to the next step.

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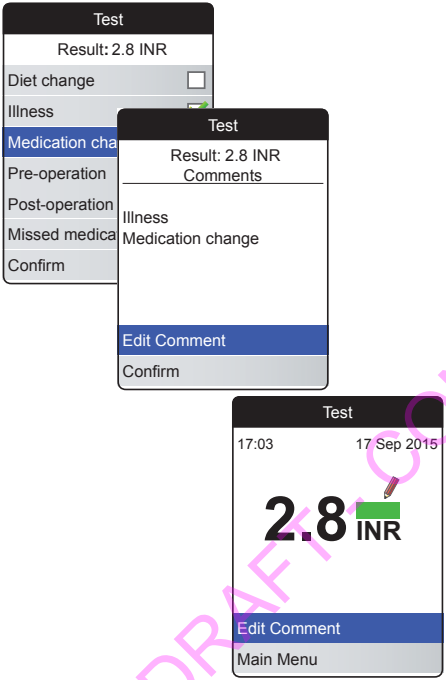

20 The next screen displays a list of all previously selected comments. Check if the list is correct, and use the Arrow up/down buttons ▲▼ to highlight **Confirm**.

21 Press the Enter button ◉ to save the selected comments with the test result and exit this menu.

The result screen now shows the Comment symbol ✎. The test is completed.

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22 Remove the test strip from the test strip guide.

23 Press and hold the Enter button ■ until the meter powers off.

24 Discard the used test strip with your regular household waste.

⚠ WARNING

Dispose of used lancets carefully (e.g. use a sturdy sharps container with lid) so that the needles cannot cause injury to yourself or to others.

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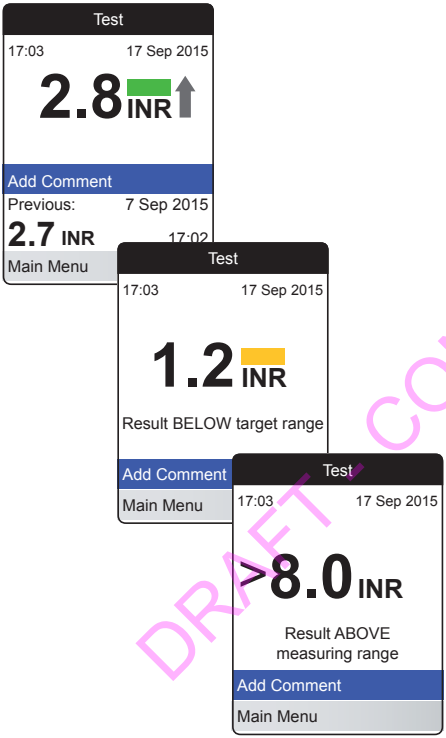
Notes concerning the results display



- All values that lie within the set target range are marked with a green bar.
- If your results are displayed in INR and you have activated the detailed result format (as shown in the first screen on the left), values that are above the last measured test result are flagged with an up arrow. Results that are below the last measured test result are flagged with a down arrow.
- Values above or below the target range are marked with a blue (above) or yellow (below) bar plus a corresponding text note.
- Values above or below the measuring range of the meter are marked with a **>** (above) or **<** (below) symbol plus a corresponding text note.

For further information about setting the result format or the target range, see *Meter settings* starting on page 85.

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The **target range** is the range that you have agreed with your Healthcare Professional. Your test result should fall within the target range.

The **measuring range** refers to the measuring range of the system itself and is defined by the technical limits of the meter and test strip.

The valid measuring ranges for CoaguChek XS PT test strips are:

- INR: 0.8–8.0
- %Q: 120%–5%
- Sec: 9.6–96

If results outside the measuring range are displayed, refer to the section *Test limitations and known interferences* in the package insert supplied with the test strips, and repeat the test.

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Reviewing and Handling Data

The CoaguChek INRange meter lets you store, review, and manage test results in several ways:

- Store and review up to 400 test results including additional information and comments.
- Display result reports as graphics or tables directly on the meter.
- Transfer data to a computer for immediate evaluation, printout, and export (embedded reports).
- Transfer data to a dedicated USB or *Bluetooth* enabled device for medical communication, e.g., to your physician or healthcare provider (data transfer).

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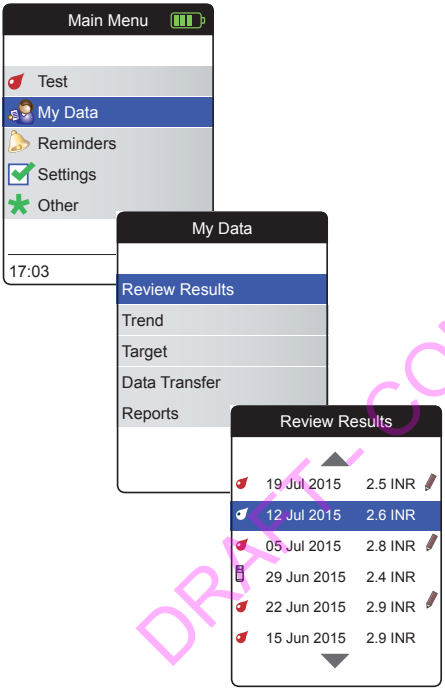
Reviewing test results



1. Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.
2. Use the Arrow up/down buttons ▲▼ to select **My Data**.
3. Press the Enter button ▣ to open the **My Data** menu.
4. Select **Review Results** and press the Enter button ▣ to display the results list.

All stored test results are displayed in a list with the most recent at the top.

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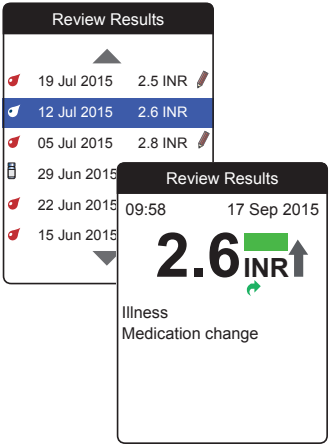

5 Use the Arrow up/down buttons ▲▼ to scroll through the list.

6 Press the Enter button ■ to open the details screen for a stored test result.

The test result will be displayed, along with the comments (entered at the time the test was performed)

7 Use the Back button ↰ to return to the results list.

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Displaying reports on the meter

The CoaguChek INRange meter offers two kinds of inbuilt reports, which can be displayed directly on the meter:

- **Trend:**
  a graphical or tabular report allowing a linear, time-based analysis of stored test results.
- **Target:**
  a graphical or tabular report allowing a statistical analysis of stored test results.

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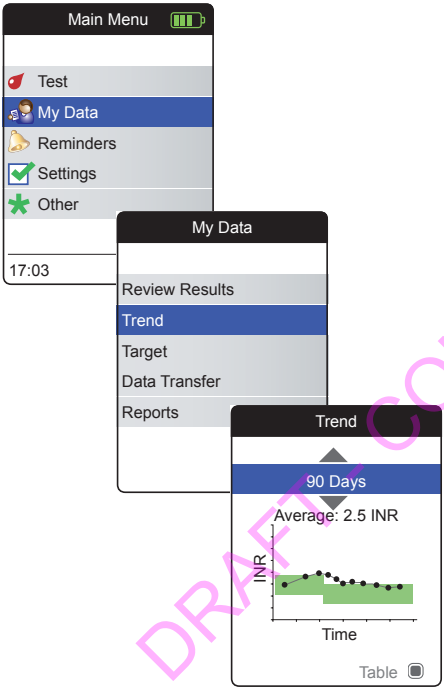
Displaying a Trend report



1. Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.
2. Use the Arrow up/down buttons ▲▼ to select **My Data**.
3. Press the Enter button ▣ to open the **My Data** menu.
4. Select **Trend** and press the Enter button ▣ to display the report.

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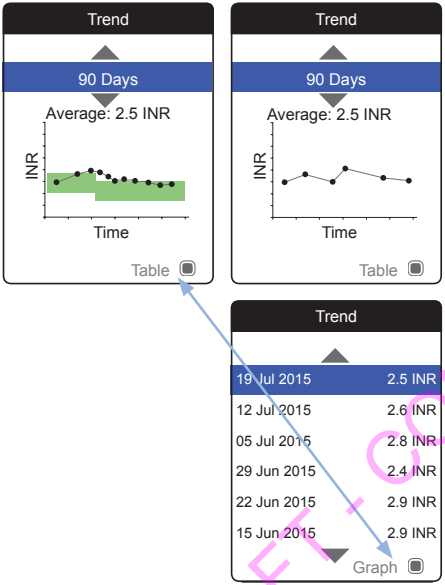

All test results stored within a selected period of time will be displayed in the chart as linear values. Each test result (represented by the ● symbol) is plotted along the time axis according to the time when the test was performed. All test results are connected by a line. This creates (angular) "curves" which, together with the actual test result entry, allow you to obtain a detailed analysis of individual results and trends.

The green area behind the curve marks the INR target range valid at that point in time (if set, otherwise not displayed).

5 Use the Arrow up/down buttons ▲▼ to select the time period you want to evaluate. Starting from your most recent test result, you can choose a time period going back 60, 90, 120, or 180 days.

6 Press the Enter button ▣ to toggle between graphic and tabular display.

7 Press the Back button ↰ return to the **My Data** menu.

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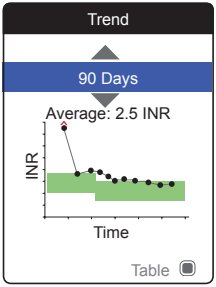

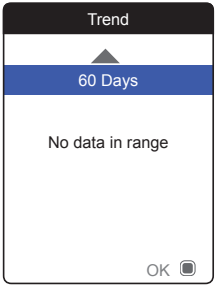

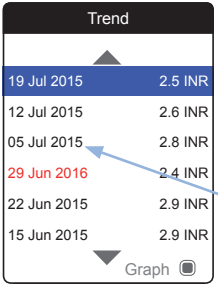

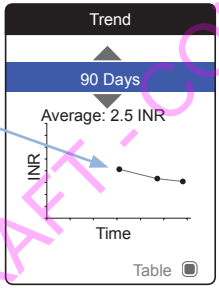

Test results above ⬆ or below ⬇ the measuring range are marked accordingly. If the selected period of time contains no test results, no graph will be displayed.

Due to an incorrect time setting a test result may be stored with a date in the future. The example on the lower left shows a test performed after inadvertently setting the date to the next year, and setting the date back to the correct year afterwards.

These test results appear in red in the table and are not displayed in the trend graph. As there is no continuity between the test results before and after this test, all previous results (including this test) will not be displayed in the trend curve.

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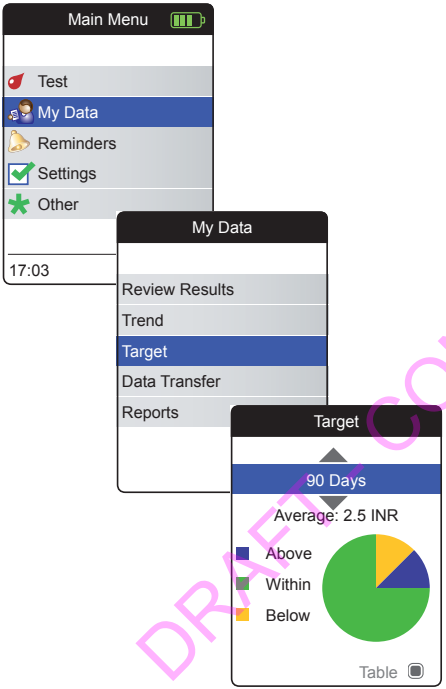
Displaying a Target report



The **Target** report is only available if you have set and enabled an INR target range (see "*Set Targets*" on page 93).

1. Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.
2. Use the Arrow up/down buttons ▲▼ to select **My Data**.
3. Press the Enter button ▣ to open the **My Data** menu.
4. Select **Target** and press the Enter button ▣ to display the report.

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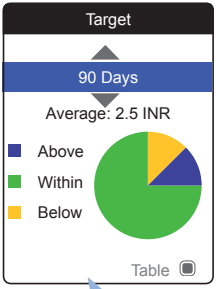

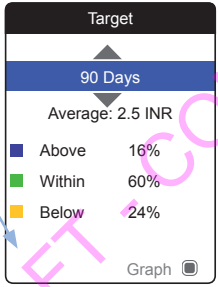

The percentage of values above, within and below the set target range will be displayed as a pie chart. The average (numerical) value of the selected time period is also displayed. If the selected period of time contains no test results, no graph will be displayed.

5 Use the Arrow up/down buttons ▲▼ to select the time period you want to evaluate. Starting from your most recent test result, you can choose a time period going back 60, 90, 120, or 180 days.

6 Press the Enter button ▣ to toggle between graphic and tabular display.

7 Press the Back button ↰ to return to the **My Data** menu.

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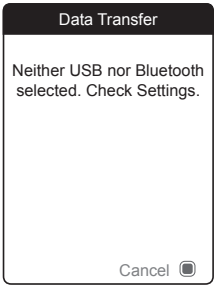
Data transfer

The CoaguChek INRange meter is able to communicate with a computer and/or other devices either via USB or a wireless *Bluetooth* connection. You can use this feature for the following purposes:

- further evaluation of stored test results in suitable computer applications
- data backup



The preferred method (USB/*Bluetooth*) used for data transfer has to be selected in the meter settings, before transferring data for the first time. Otherwise a corresponding message will be displayed.

Both methods will be described separately on the following pages. For using a *Bluetooth* connection, pairing has to be completed during setup, before you can perform a data transfer (see “*Data Transfer*” on page 99).

It is not possible to perform a test while the meter is connected to the PC.

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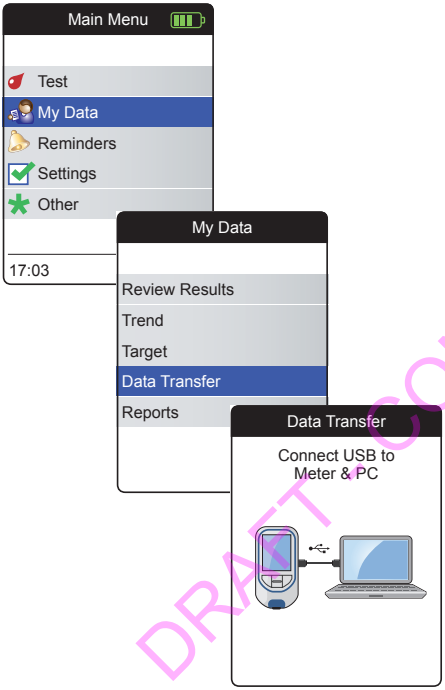
Data transfer via USB



1 Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.

2 Use the Arrow up/down buttons ▲▼ to select **My Data**.

3 Press the Enter button ▣ to open the **My Data** menu.

4 Select **Data Transfer** and press the Enter button ▣ to start the data transfer mode.

The meter waits now for a connection to be established.

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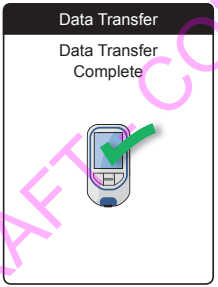
For connecting the meter to a computer, you will need a suitable USB cable (included in the kit). Connect the micro USB type B plug to the meter (the USB port is located on the right-hand side of the meter) and the USB type A plug to the computer. In order to transfer data, always connect the cable to the meter first and then to the computer.

Data transfer must be actively triggered by the computer application or device app used for reading the stored data.



When the connection has been established and the download command was received, the meter informs you about the progress.

To save battery power remove the USB cable after transferring the test results to the PC.

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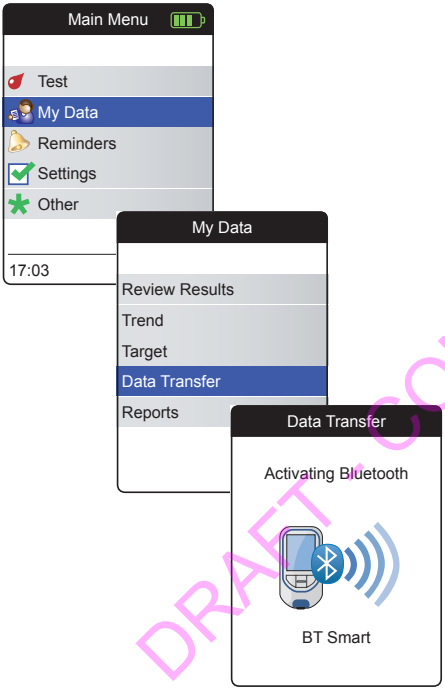
Data transfer via *Bluetooth*



1 Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.

2 Use the Arrow up/down buttons ▲▼ to select **My Data**.

3 Press the Enter button ▣ to open the **My Data** menu.

4 Select **Data Transfer** and press the Enter button ▣ to start the data transfer mode.

The meter waits now for a connection to the paired device to be established.

Information about compatible software for data transfer with the CoaguChek INRange meter can be found on www.coaguchek.com/INRange.

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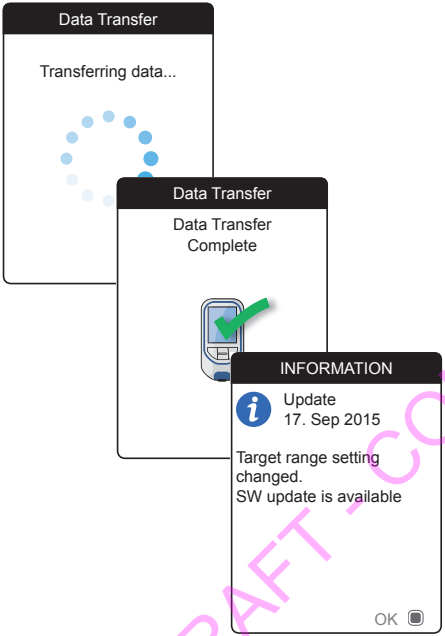

When the connection has been established and the download command was sent, the meter informs you about the progress.

Depending on the software you are using an information screen may appear after completing the data transfer. It may contain, e.g., information about available software updates or a change of settings applied to the meter.

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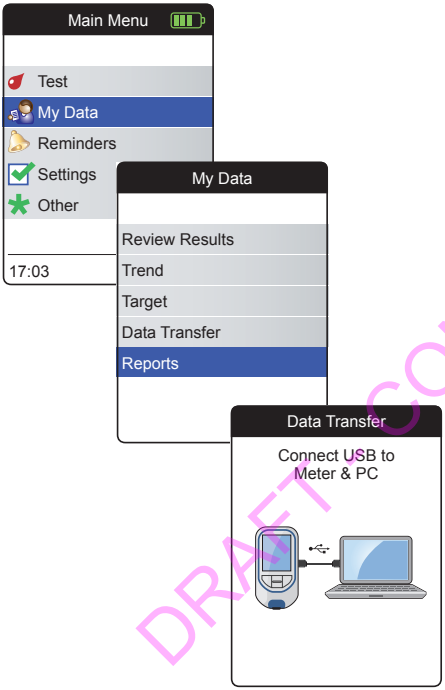
Displaying reports on a computer



The reports displayed on the meter (see page 58 ff.) can also be displayed on a computer. Opening these reports on an Internet browser provides additional advantages like more detailed information, the ability of printing, and storing results to file for further evaluation. You do not need an Internet connection, all report data is stored on and retrieved from the meter. Reports can only be used via an **USB connection**. For displaying reports:

1. Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.
2. Use the Arrow up/down buttons ▲▼ to select **My Data**.
3. Press the Enter button ▣ to open the **My Data** menu.
4. Select **Reports** and press the Enter button ▣.

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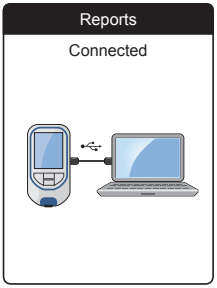

5 Connect the meter to the computer via USB cable.

The display shows “Connected” when the connection has been established.

6 If this has not been done automatically, open a window on your computer which displays the contents of the meter (as a removable disk drive).

7 Double click on **START.HTM** to open the file in your standard Internet browser.

8 After you have finished using the embedded reports, unplug the USB cable from the meter and the computer.

When the meter is connected to a computer, it will **not** be powered via the USB cable and will **not** power off automatically. To save battery power always remove the USB cable when the connection is no longer in use.

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Security settings in the Internet browser

The settings of your Internet Browser can have an influence on working with reports.

The reports use pages with so-called “active content” (Java Script). This active content can be suppressed by selecting appropriate security settings in the browser, causing warnings to be issued or functionality to be restricted. If this happens, check the relevant Internet browser settings in order to ensure smooth operation.

In many cases, you can change the security settings for using the Internet and working with reports (e.g. at user login to the PC or by defining user profiles in the browser).

If you choose the Internet browser security settings appropriately (e.g. “Allow active content to run files on My Computer” or similar), you can work with reports without any restrictions.

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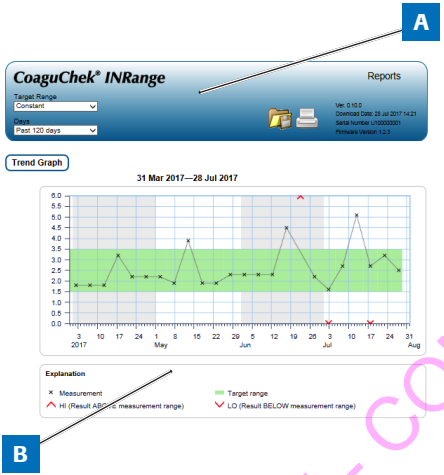
Reports overview



A report displayed in your Internet browser contains the following elements:

A Report Header
Displays information about the meter (like serial number, software version etc.), allows to set the **Time Period** for statistics and the **Target Range Display**, and contains buttons for printing and saving the report to file.

B Report Content
The page body contains the **Trend Graph**, the **Target Graph**, and a chronological list of **Results**.

Language, preferred units, and your personal therapeutic range will displayed as set in the meter. The target range is only available if you have selected the unit INR in the meter settings.

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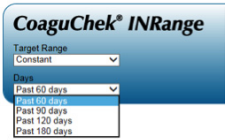
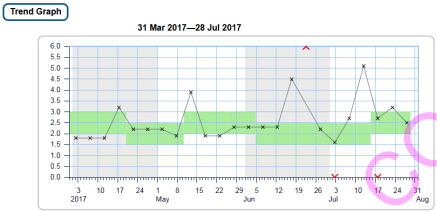
Time period



Starting from your most recent test result, you can choose a **Time Period** going back 60, 90, 120, or 180 days. This setting is applied to both the Trend and Target graph.

Trend graph



All test results stored within a selected period of time will be displayed in the chart as linear values. Each test result (represented by the × symbol) is plotted along the time axis according to the time when the test was performed. Test results above ^ or below v the measuring range are marked accordingly. All test results are connected by a line in chronological order.

Vertical lines on the Trend graph mark the beginning of each week.

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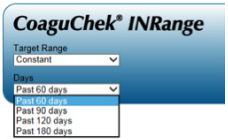
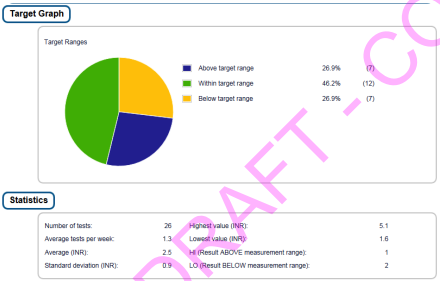
Target range display



The green area behind the curve marks the INR target range (if set, otherwise not displayed). You may set the **Target Range Display** to:

- **Constant:** the current target range set in the meter is applied to all results in the selected time period.
- **Individual:** the green bar shows the target range valid at that point in time.

Target graph



The percentage of values above, within and below the set target range will be displayed as a pie chart. The average (numerical) value and the total number of results in that range are also displayed.

Below the Target graph you will find further statistical information calculated from all values within the selected time period.

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List of results

Results

31 Mar 2017—28 Jul 2017

Date and Time	PT Coagulation (INR)	Target Range (INR)	Comments	
28 Jul 2017 03:14	2.5	2.0 - 3.0		
23 Jul 2017 01:12	3.2	2.0 - 3.0 Above target range		
17 Jul 2017 20:12	2.7	2.0 - 3.0	Missed medication	
20:10	LOW	2.0 - 3.0 Below target range		

All test results are listed in chronological order, with the latest result on top. The list contains the following columns:

- **Date and Time**
- **PT Coagulation (INR)**
  The result value is shown in INR. If the result is outside the measuring range, either LOW or HIGH will be shown.
- **Target range (INR)**
  The target range valid at that point in time. If the result is outside the target range the cell is colored blue (above) or yellow (below).
- **Comments**
- **Data transfer**
  This indicator shows if a result has previously been transferred using the “Data transfer” function of the meter. Viewing a report on the computer as described here is **not** a data transfer and thus does not activate this indicator.

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Printing reports

All the reports displayed on the screen can also be printed out at once.

In order to achieve the best results, use the print button on the report header. Do not use the integrated print function of the browser.

1. Click the print button in the report header.
2. Select the desired printer from the print dialog box, and adjust print parameters as needed, depending on the available options.
3. Start the printing process.

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Using data in external applications

For evaluating test results using other software, you can save the data as a ***.csv** file. The file extension CSV stands for **C**omma **S**eparated **V**alues. These files can be used by various applications, for example a text editor or a spreadsheet application.

The *.csv file always contains **all** the test results currently stored in your meter, including test results that have already been transferred during previous data transfers.

1. Click the Save file button in the report header.
2. Select the desired save options in the following dialog box.

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The saved file is handled by the system like a download performed by the Internet browser, the corresponding settings apply. This will, for example, determine if the file is just stored or directly opened in an application. If saving the *.csv file does not work as expected check the relevant system and browser settings.

The saved *.csv file contains the following information:

- Serial number of the meter
- Date and time of data download to the computer (for creating this *.csv file)
- Date, time, value and unit of each stored test result

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Setting up reminders

The CoaguChek INRange meter lets you set up reminders, that work just like an alarm clock telling you it's time for an action. Beyond the abilities of an alarm clock: these reminders also tell you **which** action you have scheduled at that point in time. You may set up four different kinds of reminders:

- Test reminders
- Medication reminders
- Appointment reminders
- Other reminders

Each reminder can be scheduled as single reminder, or as recurring reminder (daily, or in 1-4 week intervals).

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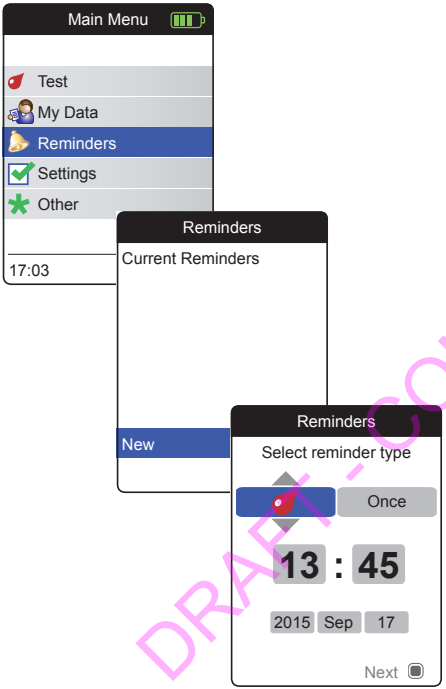
New reminder



For setting up a new reminder:

1. Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.
2. Select **Reminders** and press the Enter button ▣ to open the corresponding menu.
3. Select **New** and press the Enter button ▣ to set up a new reminder.

The **Reminders** screen opens and displays the options you can set:

- Type (default: (Test))
- Interval (default: once)
- Time and date (default: current time on the next day)

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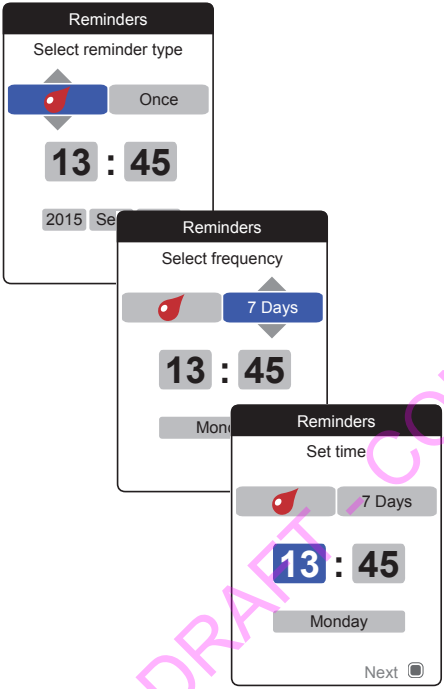

4 Use the Arrow up/down buttons ▲▼ to set the desired type (test, medication, appointment, other).

5 Press the Enter button ▣ to confirm the selected type. The next reminder parameter (interval) will be highlighted.

6 Use the Arrow up/down buttons ▲▼ to set the desired interval (once, daily, every 7, 14, 21, or 28 days).

7 Press the Enter button ▣ to confirm the selected interval. The next reminder parameter (hour) will be highlighted.

8 Set the remaining time/date parameters, always using the Arrow up/down buttons ▲▼ to set the parameters, and the Enter button ▣ to confirm and jump to the next parameter.

Depending on the chosen interval, there will be different time/date parameters to set.

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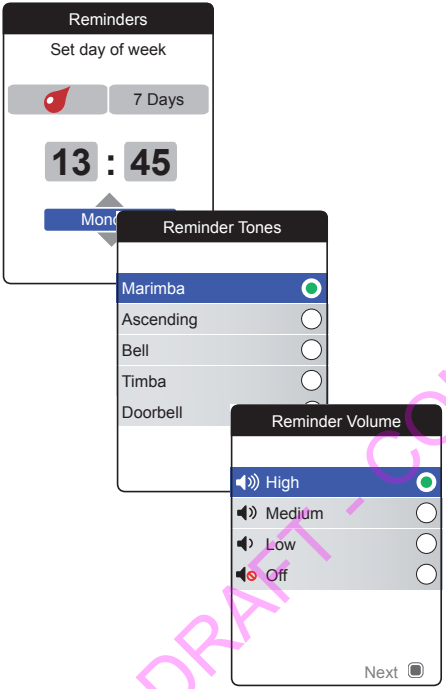

After entering and confirming the day, you are prompted to set the audio signal for the reminder.

9 Select the desired **Reminder Tones**, which may, for example, help you to acoustically distinguish between reminder types. Press the Enter button ▣ to confirm your selection. A green dot marks the selected tone.

10 Press the Enter button ▣ again to save the selection and proceed.

11 Select the desired **Reminder Volume** and press the Enter button ▣ to confirm your selection. A green dot marks the selected volume.

12 Press the Enter button ▣ to save the reminder.

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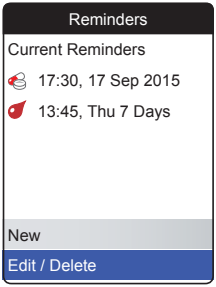

The newly set reminder is now shown in the list of reminders. You can now

- set another **New** reminder
- **Edit/Delete** the existing reminder
- exit the **Reminders** menu with the Back button ↰ and return to the Main Menu.

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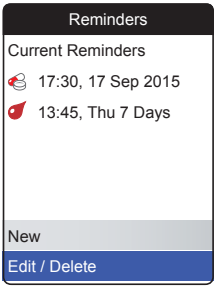
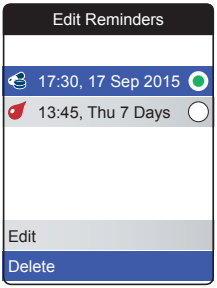
Editing or deleting a reminder





For editing or deleting a reminder:

1. Select **Edit/Delete** and press the Enter button ▣ to proceed.
2. Select the desired reminder and press the Enter button ▣ to confirm your selection. A green dot marks the selected reminder.
3. Select **Edit** or **Delete** and press the Enter button ▣ to proceed.

If you have selected to edit the reminder, proceed as described in section "*New reminder*". If you have selected to delete the reminder, it will be deleted after confirmation.

The **Edit/Delete** button is only available if there is at least one reminder listed. The **New** button is only available if there are less than four reminders listed.

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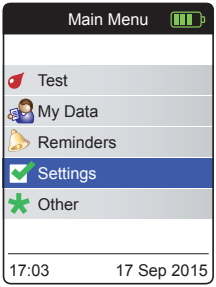
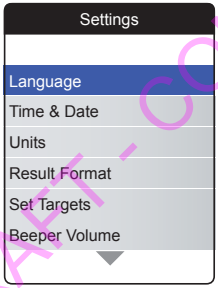
Meter settings

The initial meter setup has already been finished after powering on the meter for the first time. Use the following descriptions to set up options that are not covered by the initial setup (like, e.g., the target range) or to edit settings already made.

Preceding to all of the following descriptions (not repeated there) perform the following steps:





1 Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.

2 Select **Settings** and press the Enter button ▣ to open the corresponding menu.

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Settings overview

Setting	Options		
Language	▪ English ▪ Deutsch ▪ Francais ▪ Espanol ▪ Nederlands ▪ Portugues		
Time & Date	Time format	▪ 24-hour format (24h) ▪ 12-hour format (12h) with a.m./p.m.	
Units	▪ INR ▪ %Q ▪ Sec		
Result Format	▪ Simple ▪ Detailed		
Set Targets	Time period (statistics) ▪ 60 days ▪ 90 days ▪ 120 days ▪ 180 days	▪ On ▪ Off	▪ High value ▪ Low value

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Setting	Options
Beeper Volume	▪ High ▪ Medium ▪ Low ▪ Off
Display Brightness	▪ High ▪ Medium ▪ Low
Button Click	▪ On ▪ Off
Data Transfer	▪ None ▪ Bluetooth ▪ USB

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Language

1 Select **Language** and press the Enter button ▣ to open the corresponding menu.

A green dot indicates which language is currently active.

2 Use the Arrow up/down buttons ▲▼ to select your preferred language. The newly selected language is highlighted (blue). Arrow symbols on top and/or bottom of the screen indicate more entries above or below the currently visible part of the list.

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected language.

5 In the following confirmation screen select **Confirm** and press the Enter button ▣ to switch the meter to the selected language.

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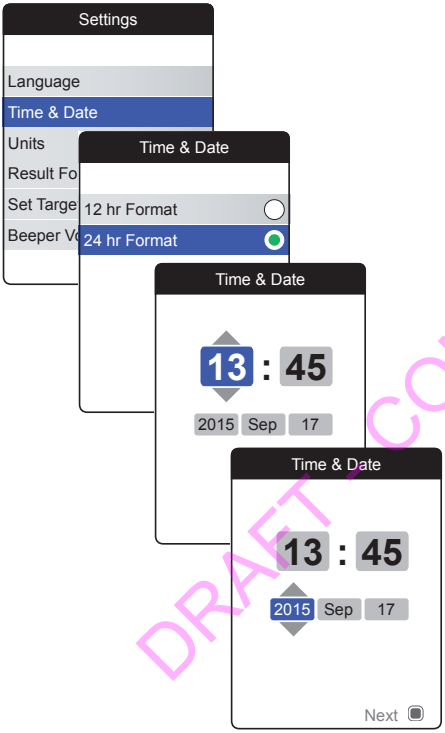
Time & Date



1 Select **Time & Date** and press the Enter button ▣ to open the corresponding menu.

2 Use the Arrow up/down buttons ▲▼ to select the time format for the display (24 hour or 12 hour am/pm).

3 Press the Enter button ▣ to confirm and save the setting. The screen for setting time and date follows next.

4 Use the Arrow up/down buttons ▲▼ to set the current hour.

5 Press the Enter button ▣ to confirm the hour. The next input field (minutes) will be highlighted.

6 Proceed with setting the remaining fields. The Enter button ▣ always confirms a setting (and highlights the subsequent field, if available), the Back button ↰ allows you to jump back to the previous field.

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In order to ensure a correct time and date setting, the meter checks the date for plausibility. The meter will display a message in the following cases:

- the date you want to set is older than the last stored measurement result
- the date you want to set is six months later than the last stored measurement result

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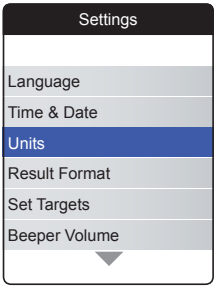
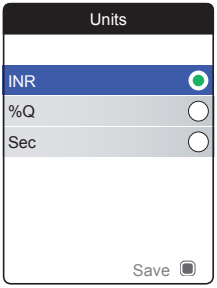
Units





1 Select **Units** and press the Enter button ▣ to open the corresponding menu.

The currently active unit is shown with a green dot on the right side.

2 Use the Arrow up/down buttons ▲▼ to select your preferred unit. The newly selected unit is highlighted (blue).

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected unit.

A target range can only be set and used if the unit is set to INR.

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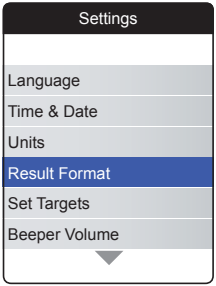
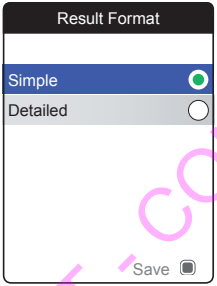
Result Format

Choose **Detailed** if you want to see your current result in relation to your previous result in the same screen. An up arrow indicates that your current result is higher, and a down arrow indicates that it is lower than your previous result (see page 53).





1 Select **Result Format** and press the Enter button ▣ to open the corresponding menu.

The currently active result format is shown with a green dot on the right side.

2 Use the Arrow up/down buttons ▲▼ to select your preferred result format. The newly selected format is highlighted (blue).

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected result format.

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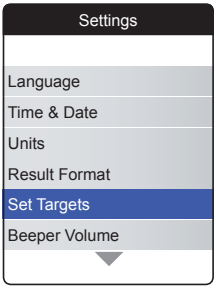
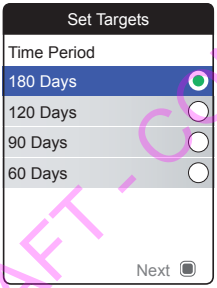
Set Targets

A target range can only be set and used if the unit is set to INR.

A target range (or therapeutical range) defines the minimum and maximum values which should be achieved during the therapy. Reports and statistics can then include information about values within, above or below this target range.





1 Select **Set Targets** and press the Enter button ▣ to open the corresponding menu.

The currently selected time period, which will be used as the default time period for reports and statistics, is shown with a green dot on the right side.

2 Select the desired time period.

3 Press the Enter button ▣ to confirm the selected time period, which is now marked by the green dot.

4 Press the Enter button ▣ again to proceed to the next step.

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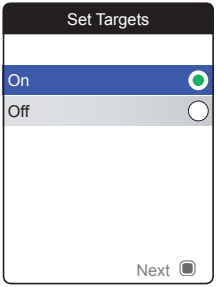

The current activation status is shown with a green dot on the right side.

A newly set or edited target range is only valid for tests performed **after** this setting was done, and will not affect test results already stored in memory.

5 Use the Arrow up/down buttons ▲▼ to select **On** or **Off**.

6 Press the Enter button ■ to confirm the selection, which is now marked by the green dot.

7 Press the Enter button ■ again to proceed to the next step.

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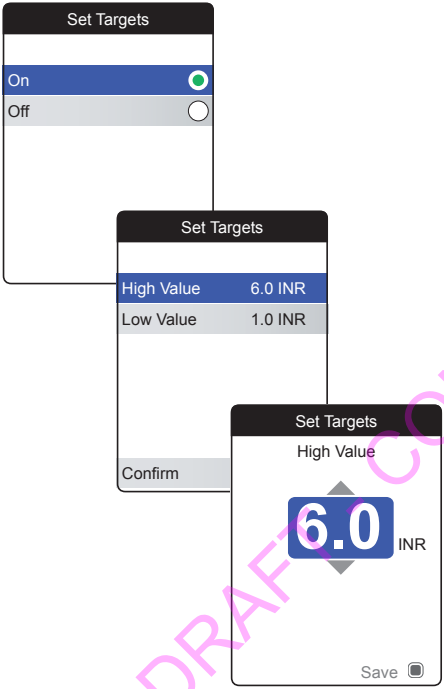

If you have selected the option **Off**, the **Set Targets** setup ends here. If you have selected the option **On**, proceed as follows:

8 Select the value you wish to set and press the Enter button ▣ to proceed.

9 Use the Arrow up/down buttons ▲▼ to set the desired value.

10 Press the Enter button ▣ to save the set value.

11 Repeat the last steps to set the second value as well.

12 Select **Confirm** and press the Enter button ▣ to save the settings.

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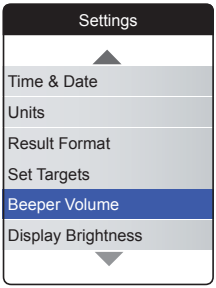
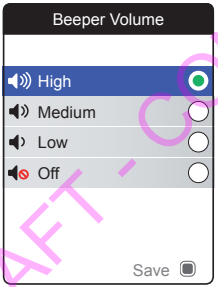
Beeper Volume

If the beeper is activated, the meter always beeps when an action is taken, for example a test strip is inserted or sufficient sample has been applied.

The beeper volume can be set or deactivated. However, in case of an error the meter will always beep for safety reasons, even if you have set the beeper function to **Off**. To set the beeper volume:





1 Select **Beeper Volume** and press the Enter button ▣ to open the corresponding menu.

The currently set volume is shown with a green dot on the right side.

2 Use the Arrow up/down buttons ▲▼ to select the desired volume.

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected volume.

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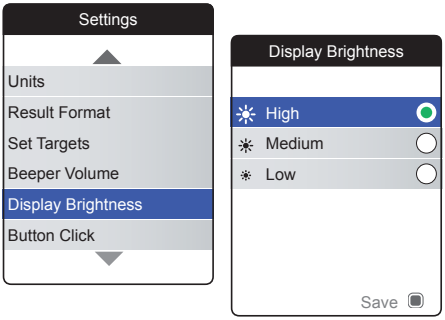
Display Brightness



1 Select **Display Brightness** and press the Enter button ▣ to open the corresponding menu.

The currently set display brightness is shown with a green dot on the right side.

2 Use the Arrow up/down buttons ▲▼ to select the desired display brightness. The display will temporarily switch to the currently highlighted brightness.

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected display brightness.

To improve battery lifetime, choose a lower display brightness setting.

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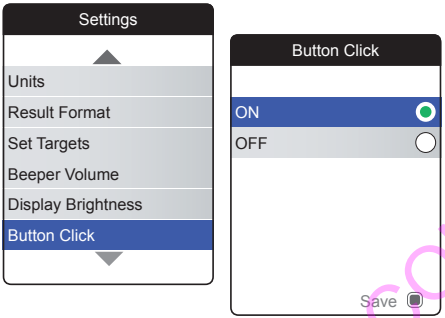
Button Click



The meter can be set to play a click sound, whenever you press a button.

To set the button click:

1 Select **Button Click** and press the Enter button ▣ to open the corresponding menu.

The current status is shown with a green dot on the right side.

2 Use the Arrow up/down buttons ▲▼ to select **On** or **Off**.

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected status.

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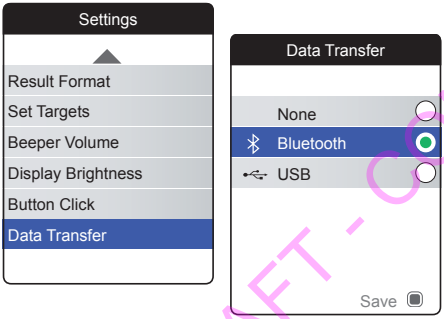
Data Transfer

The CoaguChek INRange meter is able to communicate with a computer and/or other devices either via USB or a wireless *Bluetooth* connection. Using the Data Transfer option (see chapter *Data transfer* starting on page 64) enables the transfer mode (USB or *Bluetooth*) preselected here.

To set up data transfer:



1 Select **Data Transfer** and press the Enter button ▣ to open the corresponding menu.

The currently set transfer mode is shown with a green dot on the right side.

2 Use the Arrow up/down buttons ▲▼ to select the desired transfer mode.

3 Press the Enter button ▣ to confirm the selection, which is now marked by the green dot.

4 Press the Enter button ▣ again to save the selected transfer mode.

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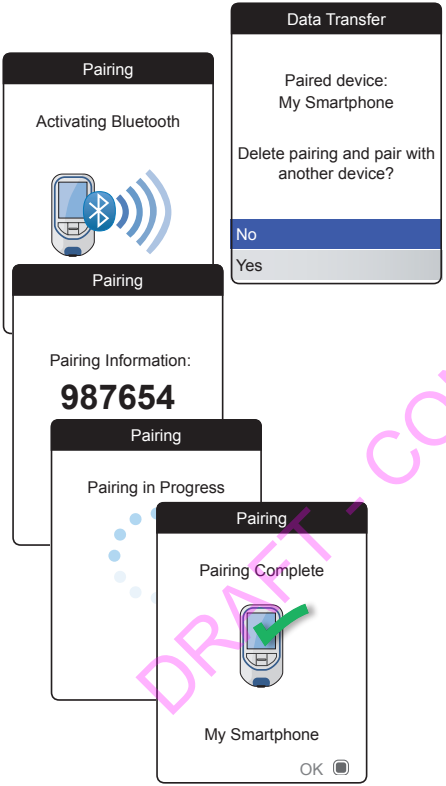

If you have selected **None** or **USB**, data transfer setup ends here.

If you have selected **Bluetooth**, you need to perform a “device pairing” before data can be transferred. If the device pairing has already been done in the past, the meter displays information about the paired device.

If the *Bluetooth* interface has been activated for the first time (or you have chosen to delete the previously paired device), the meter displays the pairing information.

5 Enter the displayed code on the device you want to pair the meter with.

After you have successfully done so, the meter continues the pairing process.

6 Press the Enter button ■ to confirm and finish the pairing process.

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Cleaning and Disinfecting the Meter and the Lancing Device

Overview

NOTICE

To avoid malfunction of the meter, follow the procedures below to clean and disinfect the meter and the lancing device.

- Make sure the meter is turned off.
- Do not use sprays of any sort.
- Ensure that the cloth or cotton swab/bud is only damp, not wet, to protect against moisture entering the meter.

To prevent soiling the meter, apply blood via side-dosing directly from fingertip.

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What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter or lancing device.

Disinfecting is the removal of most, but not all, disease-causing and other types of micro-organisms (bloodborne pathogens) from the meter or lancing device.

When should the meter and the lancing device be cleaned and disinfected?

- Clean and disinfect the meter and/or the lancing device to remove visible dirt or other material on a regular basis.
- Clean and disinfect the meter and/or the lancing device always when there is blood on it.
- Clean and disinfect the meter and/or the lancing device before allowing anyone else to handle the meter and/or the lancing device, for instance, if you have someone assisting you. Do not allow anyone else to use the lancing device.

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Recommended cleaning/disinfection agents

Gently wipe the meter's surface with one of these cleaning agents:

- a soft cloth slightly dampened (not wet) with a small amount of liquid soap diluted in water
- Rubbing alcohol (70% ethanol or isopropyl alcohol)
- Alcohol-based disinfectant (a mixture of 1-propanol (400 mg/g), 2-propanol (200 mg/g) and glutaraldehyde (1.0 mg/g))
- Disposable wipes (containing quaternary ammonium compounds up to 0.5 % (single compound or mixture) in isopropyl alcohol (isopropanol) up to 55 %))

Ask your healthcare professional or pharmacist to recommend commercially available wipes containing the acceptable cleaning agents.

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Cleaning the meter housing

- Ensure that the blue test strip guide cover remains tightly closed while cleaning the meter housing.
- Do not let liquid accumulate near any opening.

NOTICE

Ensure that **no** liquid enters the meter when you clean the exterior. If moisture enters the meter, it may cause malfunction of the instrument.

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1 With the meter turned off, wipe the meter's exterior clean.

2 With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after cleaning the housing.

3 Allow wiped areas to dry for at least 10 minutes before performing a test.

Cleaning the test strip guide

1 Remove the test strip guide cover to clean it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter.

2 Rinse the cover with warm water or wipe it clean using the solutions recommended above. Let the test strip guide cover dry for at least 10 minutes before re-attaching it.

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3 Hold the meter upright with the test strip guide facing down.

- Clean the easily accessible white areas with a moistened cotton swab/bud.
- Ensure the swab/bud is only damp, not wet. Wipe away residual moisture and fluids.

NOTICE

Damage to the instrument

- Ensure that **no** liquid enters the meter. If moisture enters the meter, it may cause malfunction of the instrument.
- Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.

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On completion of cleaning:

4 With the cover off, let the test strip guide dry for at least 10 minutes.

5 After this time, re-attach the test strip guide cover to the housing. Make sure that the cover is properly closed. You will hear it snap into place.

Cleaning and Disinfecting the Lancing Device

NOTICE

- Do not throw away the lancing device cap after each use. Use approved cleaning and disinfecting products on it.
- Remove the lancet before cleaning and disinfecting the lancing device.

To clean and disinfect without damaging the lancing device, follow these procedures carefully.

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When to clean and disinfect the lancing device

- Clean the lancing device to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the lancing device before allowing anyone else to handle the lancing device, for instance, if you have someone assisting you. Do not allow anyone else to use the lancing device.

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What to clean and to disinfect

- The entire lancing device surface
- The cap

How to clean and disinfect the lancing device

1. Wash hands thoroughly with soap and water.
2. Wipe the entire surface of the lancing device and the inside of the lancing device cap with the approved cleaning and disinfection product. Always use the same product for both cleaning and disinfecting.
3. Dry the lancing device and cap with a soft cloth or gauze. Make sure no solution is seen in any opening.
4. For disinfecting the lancing device, repeat step 2 using a new wipe or cloth. Follow the instructions of the lancing device.
5. Wash hands thoroughly with soap and water.

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NOTICE

- DO NOT get any moisture into the opening around the button.
- To avoid damaging the lancing device and stop it from working properly make sure you follow the above recommendations.

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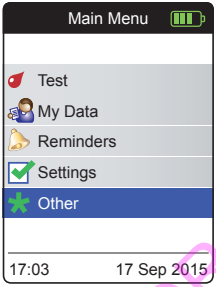
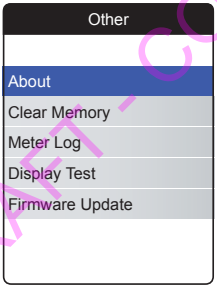
Other functions





The **Other** menu of the meter contains functions relevant for service and troubleshooting purposes:

- Version information and firmware update
- Clear memory (deleting data and settings)
- Meter log
- Display test

Preceding to all of the following descriptions (not repeated there) perform the following steps:

1. Power the meter on by pressing the Enter button ▣. Wait until the **Main Menu** is displayed.
2. Select **Other** and press the Enter button ▣ to open the corresponding menu.

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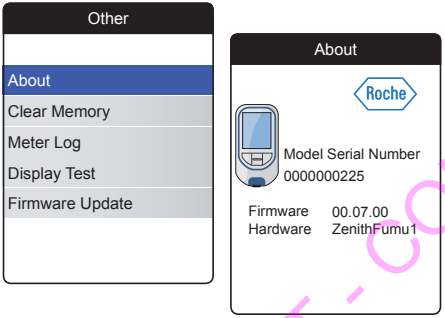
About (version and firmware)



In case of technical problems the firmware version is an important information for the Roche customer support . Sometimes problems can be solved by applying a firmware update. The **About** screen provides such information.

1 Select **About** and press the Enter button ▣ to open the corresponding menu.

The serial number, firmware version, hardware information and production date is displayed.

2 Press the Back button ↰ to exit this screen.

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Clear Memory

NOTICE

Potential loss of data
The **Clear Memory** function deletes all data (stored test results) and settings from the meter. If you want your data preserved, make sure you have uploaded them to a computer (using the data transfer function) before clearing the memory.

The following data will be cleared:

- Test results
- Error log
- Stored code chips
- Reminders

The setup will be reset to the default settings. The meter turns off. When the meter is turned on again, you will first need to perform an initial setup (see page 29).

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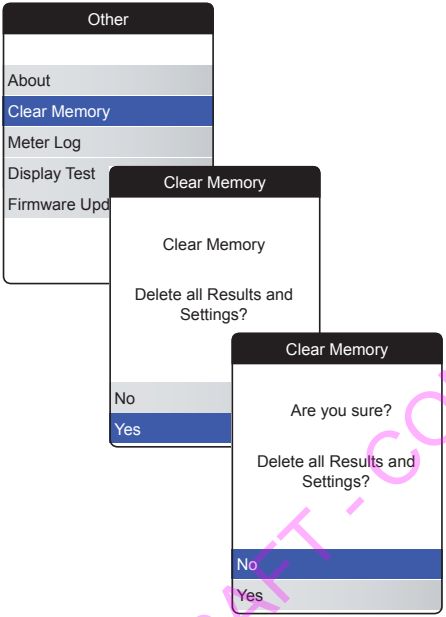

For clearing the memory:

1 Select **Clear Memory** and press the Enter button ▣ to proceed.

2 Select **YES** and press the Enter button ▣ to proceed.

3 Select **YES** again and press the Enter button ▣ to clear all data from memory.

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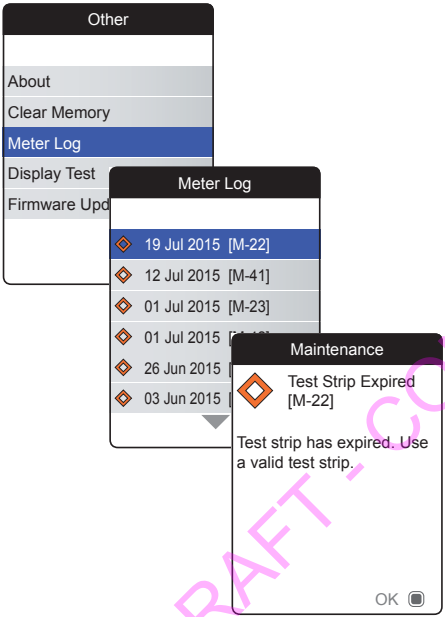
Meter Log



The **Meter Log** is another helpful source of information when contacting Roche Diagnostics customer support. The meter stores a list of all warnings, maintenance and error messages.

1. Select **Meter Log** and press the Enter button ▣ to proceed.
2. Select the event you want to know details about and press the Enter button ▣ to proceed.
3. When done, close the detail screen with **OK**.

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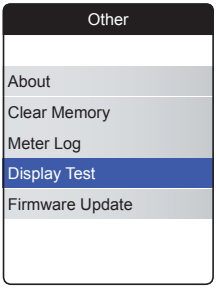
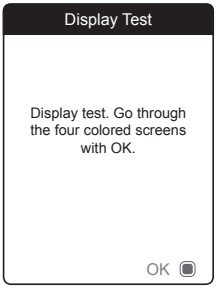
Display Test





The **Display Test** lets you check the meter's screen for proper functioning. In case you suspect the screen (or parts of it) to be defective, perform this display test.

1. Select **Display Test** and press the Enter button ▣ to proceed.
2. Read the information screen and press the Enter button ▣ to proceed.
3. Step through the following screens by pressing the Enter button ▣, while inspecting each one for defective pixels or other defects.

If all screens appeared flawlessly, your display is functioning properly.

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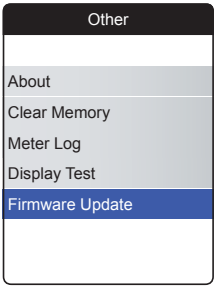
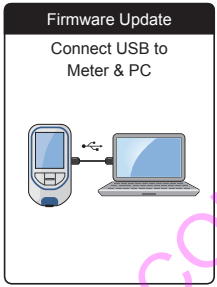
Firmware Update





Performing a firmware update requires an update file (provided by Roche) to be available on your computer. You may have downloaded this file from the Roche website.

1 Select **Firmware Update** and press the Enter button ▣ to start the update process.

2 Connect the meter to the computer via USB cable.

The meter will now be mounted on the computer as an external drive (like an USB stick).

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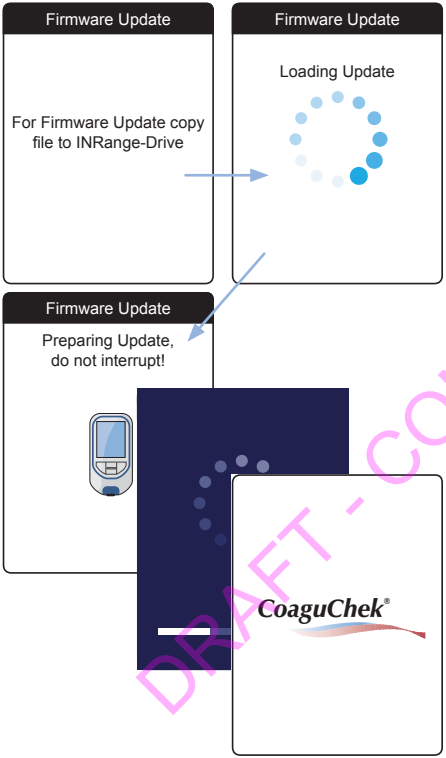

3 On the computer, open a window showing the content of this drive.

4 Copy (or save) the required update file to this drive.

The meter automatically recognizes the presence of an update file and starts performing the firmware update. Several screens inform you about the progress during installation. When the update has been completed successfully, the CoaguChek logo is displayed. Unplug the USB cable from the meter and the computer.

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Troubleshooting

The CoaguChek INRange meter continually checks its systems for unexpected and unwanted conditions.

Depending on the circumstances, a message may appear on the display of the meter (see chapter *Messages* starting on page 125). These messages are marked with an icon and are accompanied by a description and (if necessary) a possible solution.

Take the action suggested on screen to resolve the problem. If the problem (and the corresponding message) disappears, you may continue using the meter as desired. If the problem persists, contact Roche Diagnostics (see page 135).

For troubleshooting problems which are not indicated by a message see the following pages.

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Errors and unusual behavior without error messages

Display/symptom	Possible solution
Meter does not power on, display remains dark	Insert new batteries. Always replace all 4 batteries at the same time.
Meter displays an unexpected result	Refer to the package insert for the test strips.
Meter does not make sounds	Check the settings for *Beeper Volume* (page 96) and *Button Click* (page 98)
…?	

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Symbols on packaging and meter

On the packaging and on the type plate of the meter you may encounter the following symbols and abbreviations shown here with their meaning:

Symbol	Meaning
	Use by
LOT	Batch code/ Lot number
IVD	In vitro diagnostic medical device
CE 0123	This product fulfills the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
REF	Catalogue number
	Consult instructions for use
	Caution, consult accompanying documents. Refer to safety-related notes in the manual accompanying this instrument.
	Manufacturer
	Temperature limitation (Store at)
c UL us LISTED	The system fulfills the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 61010A-1:02 and CAN/CSA-C22.2 No. 61010-1-04)

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On the meter buttons the following symbols are used:

Symbol	Meaning
	Back button, used to exit the currently displayed menu or go back one step.
▲▼	Arrow up/down button, used to select elements, scroll up/down in a screen, or change numerical values.
	Enter button, used to confirm the currently selected option or perform a function. Also used to power the meter on and off.

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Icons on the display

On the meter display the following icons may appear.

Symbol	Meaning
	Indicator for battery capacity (full, almost empty, empty), shown in main menu
	Bluetooth logo, shown when starting a wireless data transfer and in data transfer setup
	USB symbol, shown when starting a wired data transfer and in data transfer setup
	Test icon, shown in main menu and reminders
	Control icon, shown with control test results
	Data icon, shown in main menu
	Reminder icon, shown in main menu

Symbol	Meaning
	Medication icon, shown in reminders
	Appointment icon, shown in reminders
	Comment icon, shown with stored test results
	Upload icon, shown with stored test results after data transfer
	Radio button, shows the status of a selectable option (off/on) in meter setup screens
	Warning message
	Error message

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Symbol	Meaning
	Settings icon, shown in main menu, and selected option (e.g. comment list)
	Other icon, shown in main menu and reminders

Symbol	Meaning
	Maintenance message
	Information message

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Messages

There are several kinds of messages which can appear on the meter:

- Reminders
- Information
- Maintenance
- Warnings
- Error messages

The following section explains what you can do when such a message appears.

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Reminders

Reminders are a useful tool to schedule tests and other events. When a reminder becomes active, it automatically powers on the meter (if necessary), plays the corresponding sound and displays the reminder message (test, medication, appointment or other). You have two options:

- Select **Confirm**, and press the Enter button ▣ to confirm that you will perform the required action **right now**. The reminder will disappear and not come back. **Or:**
- Select **Snooze**, and press the Enter button ▣ to postpone the reminder message.

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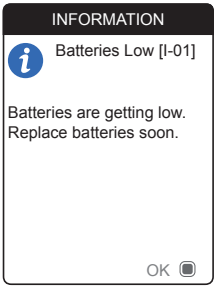
Information



An information message informs you about what is happening in the meter or a problem that exists or may come up which requires you to do something soon. You can continue to use the meter.

1. Read the whole information message.
2. Press the Enter button ■ to confirm the message.
3. Proceed with the current task.

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Maintenance

A maintenance message requires your immediate attention. The meter may stop working temporarily. Some examples:

- The batteries are empty.
- You may not be able to perform a test because the code chip and the test strip lot don't match.
- The meter may detect a problem when performing a software self-check.

Almost always, you can fix the problem by following the instruction in the maintenance message. You can insert new batteries or start the test again with a new test strip and the correct code chip. Or the meter often fixes a software problem itself when you power it off and on again.

1. Read the whole maintenance message and the suggested action.
2. Press the Enter button ◼ to confirm the message.
3. Take the action suggested in the message.

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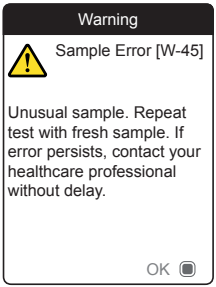
Warnings



A warning message draws your attention to a hazardous situation that could be a risk to your health if not corrected. The CoaguChek INRange meter will rarely display a warning message. However, if you do receive a warning message, pay close attention to it.

1. Read the whole warning message and the suggested action.
2. Press the Enter button ▣ to confirm the message.
3. Take the action suggested in the message.

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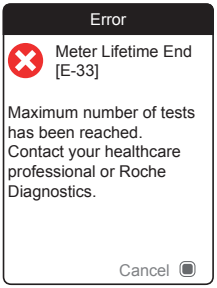
Error messages



An error message appears if the meter has a problem that needs your attention and you might not be able to solve. The meter stops working.

1 Read the error message.

2 Take the action suggested in the message.

If the error persists, please contact your local Roche Diagnostics customer support (see page 135).

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Ordering

Please contact your pharmacist or specialist supplier.

Item	REF/Catalog Number
CoaguChek XS PT Test, 24 test strips	REF 0 4625358
CoaguChek XS PT Test, 2 x 24 test strips	REF 0 4625315
CoaguChek Softclix Lancet, 50 lancets	REF 0 3506509
…	…

Product limitations

Please read the information in the package insert supplied with the test strips for detailed product data and limitations.

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Operating conditions and technical data

Temperature range	+15 °C to +32 °C
Relative humidity	10 to 85% (no condensation)
Maximum altitude	4.300 m
Position	Place the meter on a level, vibration-free surface or hold it so it is roughly horizontal.
Measuring range	%Q: 120% – 5% SEC: 9.6 – 96 INR: 0.8 – 8.0
Memory	400 test results with date and time
Interfaces	USB type B *Bluetooth*
Battery operation	4 x 1.5 V batteries (alkali-manganese) type AAA
Safety class	III
Automatic power-off	After 2 minutes
Dimensions	approx. 145 x 75 x 30 mm
Weight	135 g (without batteries)

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Sample material

For information regarding sample type, sample size and interferences refer to the respective test strip package insert.

Storage and transport conditions

Temperature range	–?? °C to +?? °C
Relative humidity	10 to 85% (no condensation)

Disposal of the CoaguChek INRange meter

During measurements the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Please dispose of your used meter – after removing the batteries and cleaning the meter – according to the regulations applicable in your country. For information about correct disposal please contact your local council.

The meter falls outside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

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For healthcare professionals

Dispose of the meter in line with your facility's procedures for dealing with potentially biohazardous waste.

Disposal of used batteries

Do not dispose of the batteries with normal domestic waste.

Dispose of used batteries in an environmentally responsible manner and in accordance with applicable local regulations and directives. Contact your local council / local authority or the manufacturer of the used batteries for advice on correct disposal.

Repairs

Please note that repairs and other modifications to the meter may only be performed by persons authorized by Roche Diagnostics.

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Information service

If you have any further questions, please contact your local customer support and service center.

Australia Roche Diagnostics Australia Pty Ltd. ABN 29 003 001 205 31 Victoria Avenue Castle Hill, NSW, 2154 Telephone 02-9860 2222 or 1800 645 619	**Canada** Roche Diagnostics 201 Boulevard Armand-Frappier Laval, Québec H7V 4A2 Coagulation Info-Line Telephone 1-877-426-2482
New Zealand Roche Diagnostics N.Z. Ltd. 15 Rakino Way Mt. Wellington Auckland 1060 Telephone 09-2764157	**United Kingdom** Roche Diagnostics Ltd. Charles Avenue Burgess Hill, RH15 9RY CoaguChek Careline 0808 100 7666

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Product Safety Information

Bluetooth Wireless Technology

The meter can utilize *Bluetooth* wireless technology to communicate and transfer information to other devices (e.g., computer or smartphone).

Bluetooth wireless technology is a form of radio frequency (RF) technology that operates in the unlicensed industrial, scientific, and medical band at 2.4 to 2.485 GHz. The meter can only communicate with the devices it is paired with; therefore, other *Bluetooth* wireless technology devices cannot access your personal information on the meter.

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Radio Frequency Communication

The device complies with the United States Federal Communications Commission (FCC) standards.

The device complies with FCC Part 15 Rules. Operation of the device is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Compliance with these guidelines means that under normal, daily circumstances the device should not affect the operation of other devices. In addition, the device should operate normally in the presence of other devices.

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The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.

In the event there is interference from another device, it is recommended that you increase distance between meter and that device. You may also turn off the interfering device. In addition, you may turn off Bluetooth wireless technology on the meter.

Changes or modifications to the device not expressly approved by Roche could void the user's authority to operate the device.

The device has been tested and found to comply with the limits for a Class B digital device. The device generates, uses, and can radiate radio frequency energy.

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Electromagnetic Compatibility

This meter meets the electromagnetic immunity requirements as per ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, it meets the electromagnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be expected.

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