Roche



Free up your life with CoaguChek[®] INRange

CoaguChek INRange Sales Pack



Hello

Thank you for purchasing the CoaguChek[®] INRange self-monitoring meter. This brochure provides you with all the information you need about anticoagulation therapy and regularly monitoring your International Normalised Ratio (INR) with your CoaguChek INRange meter.

It also explains how the CoaguChek INRange works and how self-monitoring with it could benefit you, both in terms of your therapy management and your lifestyle.

If you'd like more information about your CoaguChek INRange meter, please call Freephone 0808 100 7666 (ROI 1 800 992 868) or visit shop.coaguchek.com

Please read the returns policy on page 4 before opening your CoaguChek INRange box.



Included with this pack are:

- · Contact Card with contact details
- Training DVD
- CoaguChek INRange meter kit
- Pack of 6 strips

Return Options

For your CoaguChek[®] INRange

Please read this section before opening your CoaguChek INRange meter box

We make every effort to ensure your order reaches you in perfect condition.

However, if there is a problem with your order, or your goods are damaged or faulty, please contact us as soon as possible by calling our customer Care Line on 0808 100 7666 (ROI 1 800 992 868).

Alternatively, email us at burgesshill.coaguchek@roche.com or you can write to us at:

Roche Diagnostics Limited Charles Avenue Burgess Hill West Sussex RH15 9RY United Kingdom.



Return Options

For your CoaguChek[®] INRange



Your 14 day cooling-off period

Please watch the training DVD that accompanied this pack before opening your meter box (please call the above number if you did not receive this).

You have the legal right to cancel your purchase up to 14 days after receiving your meter from us. You must return the meter in its original condition (original box unopened and the meter therefore unused) within the 14 day deadline to exercise your right to cancel, in which case we shall issue a full refund for the price you paid for the meter.

Further details of your rights of cancellation, return and refund are set out in our terms and conditions of sale, which can be found here:

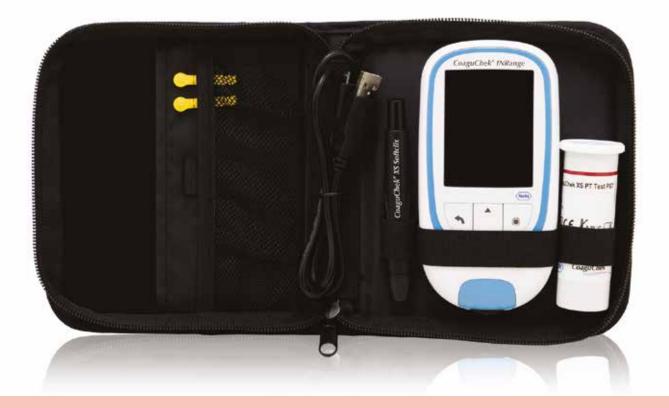
shop.coaguchek.com/sale-terms-and-conditions/

CoaguChek Warranty

To activate your two year warranty, please visit shop.coaguchek.com/warranty/

CoaguChek[®] INRange

What's in the Pack?



Self-Monitoring gives you the freedom and flexibility to test when you want



Now that you have purchased your CoaguChek INRange meter, you can test at a time more convenient to you, even on holiday. So this can save you time and expense by cutting down the number of clinic visits you need to make. We provide a 2 year warranty on every CoaguChek INRange meter purchase.

What's in the pack?

| CoaguChek INRange meter | 4 x AAA batteries |
|-------------------------|-------------------------|
| 6 test strips | Carry case – for all of |
| CoaguChek Softclix | the above |
| lancing device | User manual, including |
| 20 Softclix XL lancets | short instruction guide |

CoaguChek® INRange Designed for today's lifestyles

Accuracy and precision in INR monitoring¹

Results you can trust, wherever you are

CoaguChek INRange meter:

- Uses the same technology as clinic-based CoaguChek devices
- CoaguChek strip technology to ensure accuracy of results
- · Allows you to set your own therapeutic range
- Easy to handle, intuitive functionality and battery powered

Test strips

guChek* INR

 On-Board Control System for accurate day to day running of the meter, without needing control solutions

aguChek Test

IVD /

- The strip can be filled from the top or side to make sampling easier and reduce any contamination risk.
- Strips can be stored at room temperature (2 30°C)
- Available on NHS prescription in the UK only (at your GP's discretion)
- Strips available in packs of 24

A Step by Step Guide

How to test with the CoaguChek[®] INRange

Please review these tips for getting a good drop of blood.

Increasing the blood flow in your finger will help you get a good drop of blood:

- Warm your hand. Hold it under your arm, use a hand warmer, and/or wash with warm water.
- Let your arm hang by your side.
- Massage your finger from its
- base.

Use these techniques until your fingertip has good colour.

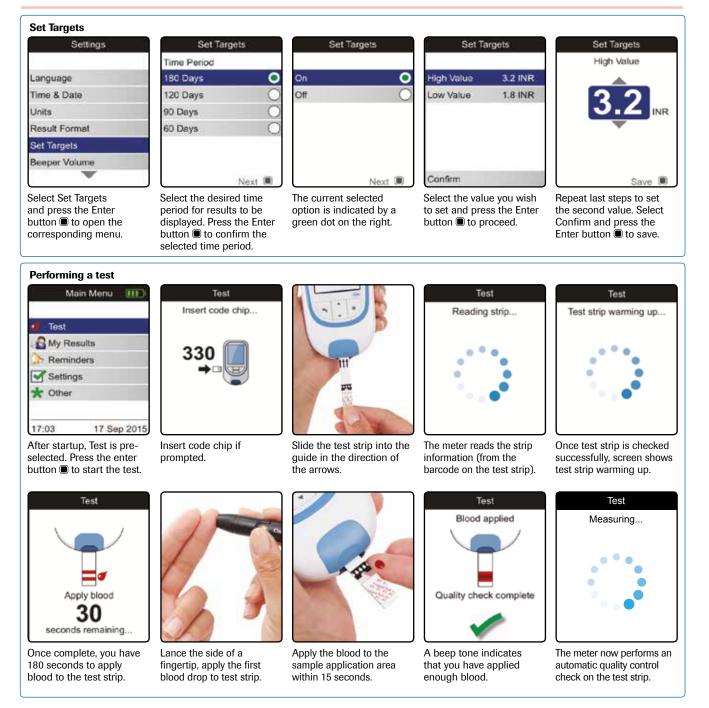


1. Wash Hands Wash your hands in warm, soapy water. Make sure your

fingertip is thoroughly dry.

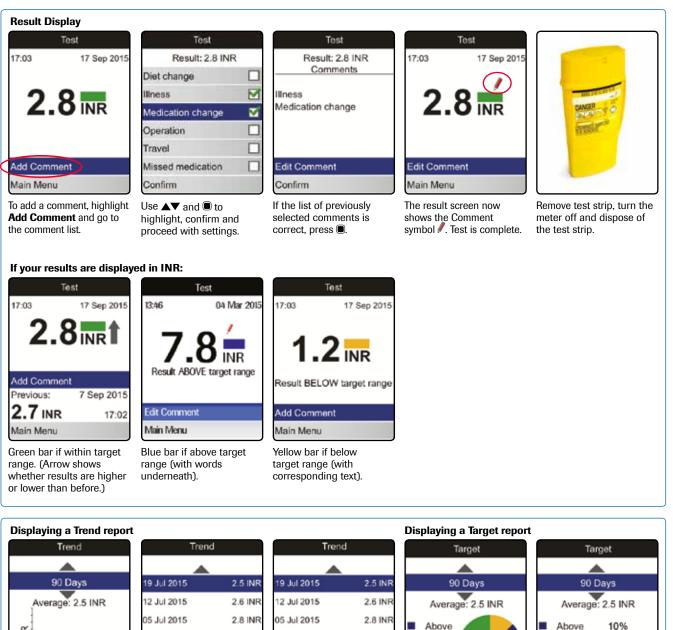


2. Get Ready Take a test strip out of the container. Close the container tightly. Note: You have 10 minutes to use a test strip once you remove it from the container.



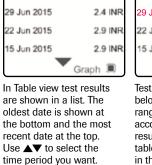
A Step by Step Guide

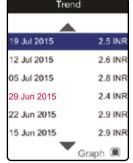
Interpreting and Analysing your results



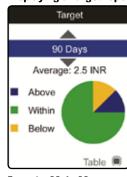
R Time Table

From the Main Menu, use $\mathbf{A} \mathbf{\nabla}$ to open the **My** Results menu, select Trend and press I to display the report. The report above is shown as Graph view.

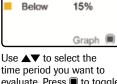




Test results above or below the measuring range are marked accordingly. These test results appear in red in the table and are not displayed in the trend graph.



From the Main Menu, use $\mathbf{A} \mathbf{\nabla}$ to open the **My** Results menu, select Target and press I to display the report.



75%

Within

evaluate. Press
to toggle between graph and table display. Press the Back button to return to the My Results menu.

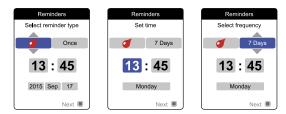
CoaguChek[®] INRange

New Features of the CoaguChek INRange



connected with your clinic

• Built-in reminders for testing, medication, and appointments to help you

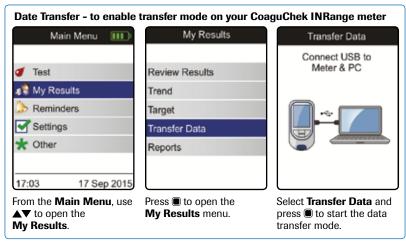


- **Bluetooth technology** keeps you connected by letting you transmit your results, so you can keep on track and in range anytime, anywhere
- **Easy-to-use app** can be downloaded free and is available in areas where the anticoagulation clinic has signed up for the service.
- If your clinic has not signed up for connectivity options or you wish to learn more, please contact the **Care Line team** who can advise

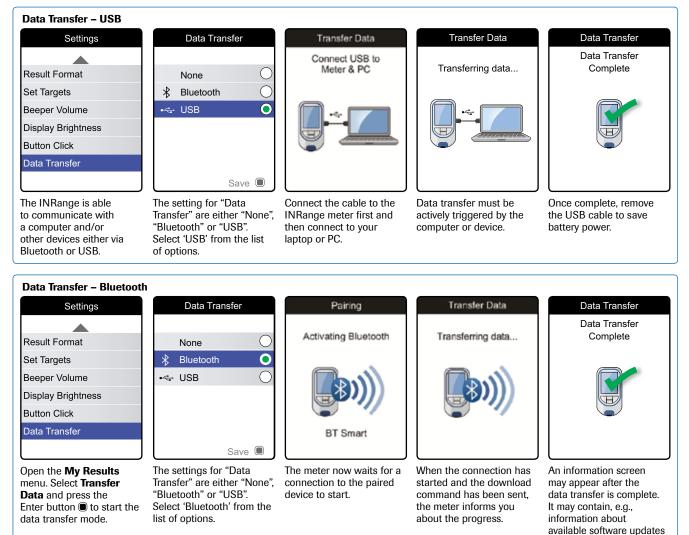
Self-test your INR at home whilst staying connected to the clinic, giving you confidence and control of your warfarin therapy

A Step by Step Guide *New connectivity software of the CoaguChek*^{*} *INRange*

You can now connect your CoaguChek INRange device to your PC / laptop (via USB cable) or phone (via an App) if you prefer.



Once transfer mode has been enabled, you then have the option transfer via USB or Bluetooth (if your clinic supports the use of Apps for sending results) if you wish. You do not need to use the connectivity functions if you would prefer not to.



The Step by Step Guide information is based on the CoaguChek INRange User Manual (07408811001) V1. Please see full document for detailed instructions

or a change of settings applied to the meter.

CoaguChek® INRange *The Connected Solution*

Connectivity options are available in certain locations across the UK & Ireland. Details of two options are described here:

LumiraDx Engage App

LumiraDx now offers a range of care programmes for individuals delivered via *engage* – an easy-to-use patient app which is fully integrated with INRstar and designed to give patients the knowledge, skills and confidence to gain freedom and better control of their health. *engage* is available on smartphone, web and tablet.

Seamless connection – reduces data entry errors

engage integrates with CoaguChek INRange so that existing and new self- testers can send their INR result directly to their INRstar patient record where the clinic can review and send you back your dose

We do all the training and give you full support

engage provides all the step-by-step training and support you need to get started with selftesting with *engage*.

To learn more, contact

LumiraDx on 01209 710999 (option 2) or call the CoaguChek Care Line

Calls to this number will be charged at your standard network rate. Roche has no control over and accepts no responsibility for calls made to this number.

CoaguChek® INRange Connect to the clinic via an App on your phone

Inhealthcare My Inhealthcare App

Track, monitor and manage your INR with My Inhealthcare. My Inhealthcare connects you to your nurse or doctor meaning you can receive your warfarin regime and submit INR readings wherever you are. With Bluetooth connectivity to the CoaguChek INRange device, staying on top of your INR has never been easier.

This handy app will enable you to:

- · Send INR readings directly to your doctor or nurse
- · Review historic readings and results over time
- Receive new dosage instructions from your GP or nurse

Where the App is available, a registration code is needed to connect you to your surgery. This will have been given to you by your GP or nurse.

| ← Task | |
|--------------------|---|
| INNES, Jar | mie (Mr) |
| PLEASE PRODUCTIONS | OVIDE ANSWERS TO THE S BELOW |
| | ad any changes to any of ation since your last INR |
| | O No |
| Have you ha | ad any bleeding symptoms? |
| | O No |
| Have you m | Ves |
| | SUBMIT |

222294

RRRRRRR

To learn more, visit

www.inhealthcare.co.uk/inrange or call the CoaguChek Care Line

App connectivity options are offered by third party companies, separate from Roche Diagnostics Limited. Roche has no control over and accepts no responsibility for the content of the third party websites listed. Please note that the contact information provided above are for direct contact with the suppliers of the App connectivity options. App connectivity options are dependent on your location. To learn more, contact us via the details below

Training *CoaguChek*^{*} *INRange Training Check List*

The training check list can be used in conjunction with the User Manual and training resources (summarised on the opposite page) to help guide you through training of your meter. Please read your entire User Manual before you use the meter. The User Manual accompanies every CoaguChek INRange meter purchase and can be found in the same box as your meter.

| Criteria | 1 | Criteria | 1 | Criteria | ✓ |
|----------------------------------|---|---------------------------|------|-----------------------------------|---|
| Meter Set Up | | Performing A Test | | Obtaining a fingerprick sample | |
| Batteries | | Switch meter on | | | |
| Display check | | Checking screen | | Handwashing | |
| Date Format | | Insertion of test strip | | Sites for taking a sample | |
| Date Setting | | Confirm code lot number | | Time limits | |
| Time Format | | Strip warming | | Sampling problems | |
| Time Setting | | | | Recording results | |
| | | Operation of Softclix dev | /ICe | Anticoagulation | |
| Set Test Measurement Value | | Device components | | Record Book | |
| Beep Tone | | Removal of protective cap | | Memory | |
| Therapeutic Range | | Insertion of lancet | | Retrieving saved results | |
| Setting | | Priming device | | Maintenance & | |
| CoaguChek INRange Test Strips | | | | Troubleshooting | |
| | | Depth setting | | Cleaning meter | |
| Storage conditions | | Firing lancet | | Common error codes | |
| Handling test strip | | Ejecting lancet | | Common circl codes | |
| | | | | Technical support | |
| Calibration Code Chip | | | | CoaguChek Patient | |
| Changing Code Chip | | | | Care line: | |
| Onboard Quality Control | | | | 0808 100 7666 | |

Sample dosing area

Support *How can we help?*

Naturally any help you need to get you started and support you along the way is provided and includes:

- Freephone access to CoaguChek[®] Care Line (including one to one telephone training) and free technical support
- · Videos, articles and testimonials available at shop.coaguchek.com
- Start-up patient support pack including step-by-step guide and training DVD
- 2-year warranty activate now at shop.coaguchek.com/warranty/
- Helicon Health Limited have created eLearning courses, designed to provide the knowledge, skills and confidence to monitor oral anticoagulation therapy. Introductory modules are available free of charge and offer educational content on:
 - The benefits of self-monitoring, testing your INR using a coagulometer and how anticoagulants affect blood clotting.
 - Visit www.strokeprevent.live to learn more
- Support from patient charities including:
 - AntiCoagulation Europe www.anticoagulationeurope.org
 - Arrhythmia Alliance www.heartrhythmcharity.org.uk
 - AF Association www.atrialfibrillation.org.uk
 - Children's Heart Federation www.chfed.org.uk

The links listed above are for patient charity websites and Helicon Health Limited training. Roche has no control over and accepts no responsibility for the content of any of these third party websites.

Living With Anticoagulation

Nutrition



Oral anticoagulants create a deficiency of vitamin k, slowing your blood's ability to clot.

Many people being treated with oral anticoagulants such as warfarin wonder if they should restrict the amount of vitamin K they consume in their food (which might reduce the effectiveness of their warfarin). In the first instance patients should talk to their health care professional for advice.

It is important to eat a consistent, healthy diet when taking warfarin.

Patients taking oral anticoagulants are advised against dramatically altering their diet e.g. from eating few vegetables to a strict vegetarian or vegan diet with lots of vegetables. If you would like to make this switch, your INR should be checked more regularly during the period when the diet is being changed. A healthy and diversified diet followed by anticoagulant therapy adjusted to your personal requirements is of core importance.

What is definitely unhelpful for your INR value is irregular consumption of vegetables i.e. eating a lot of green vegetables one day and none the next.

Does diet or alcohol affect INR monitoring?

Yes, it does. What you eat and drink can raise or lower your INR levels, so it's important to have a balanced diet while you're self-monitoring. Your healthcare professional will be able to give you further support and information with this.



For more information regarding diet and nutrition with anticoagulation, look at our blog posts on the shop.coaguchek.com website or visit:

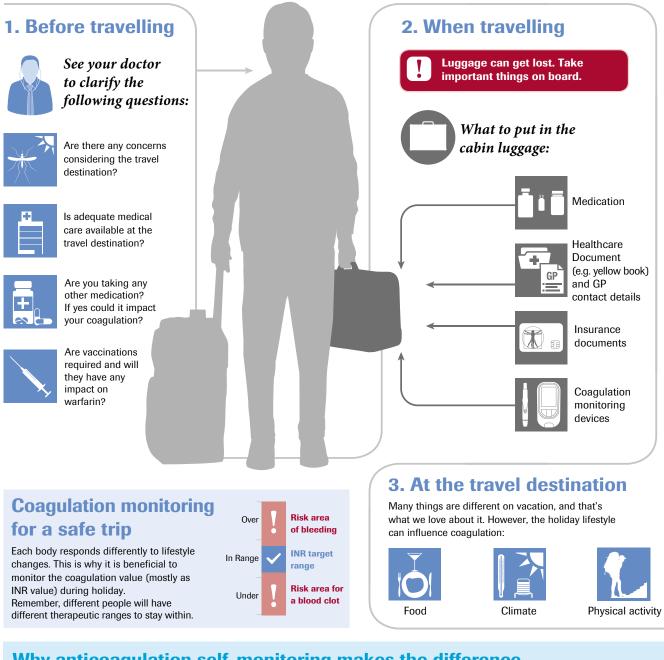
http://webarchive.nationalarchives.gov.uk/+/www.nhs.uk/Conditions/Anticoagulantswarfarin-/Pages/Interactions---other-medicines.aspx

The link above is not owned by Roche Diagnostics. Roche has no control over and accepts no responsibility for the content of any of this third party website.

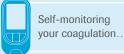
Living With Anticoagulation

Travel

Airlines differ, so always check before travelling, but a letter from your doctor explaining why you require your CoaguChek meter as well as packing everything required in your hand luggage, is strongly advised. Storing your strips in a cool part of a room, away from direct sunlight, is also recommended (between 2 - 30°C).



Why anticoagulation self-monitoring makes the difference



...allows you to check your INR value – at a time convenient to you...



...and gives you the freedom and security to fully enjoy your holidays.

For more information and lifestyle tips, visit our blog on the **shop.coaguchek.com** website

CoaguChek[®] INRange

What our users say



Diane's Story *I can honestly say that my CoaguChek machine has made a real difference to my life.*



Katherine's Story

To find there was a little machine which you can prick your finger with to get a drop of blood (and instant result) was just magic, absolute magic.



Roy's Story

I'm really glad that I asked about self-monitoring. I genuinely do feel in control!

Learn more and see other people's experiences with CoaguChek INRange



For more patient stories and videos, visit **shop.coaguchek.com/life-stories/** or

visit the Facebook community at www.facebook.com/selfiechek

Frequently Asked Questions

Visit shop.coaguchek.com/support/faq to read additional FAQs

Is it difficult to use a CoaguChek[®] INRange meter?

No. If you can use a mobile phone then you're unlikely to find self-monitoring any more complicated. Support is also offered by Roche Diagnostics and your anticoagulation clinic.

How should I store my test strips?

They can be stored at room temperature (2-30°C) for between 12 and 15 months, depending on the expiry date. Keep the lid on the pot shut tightly between uses.

How quickly should I use the test strip after removing it from its packaging?

You should use the test strip within 10 minutes from the time you take it from the container.

Should I talk to my healthcare professional before I start using a CoaguChek INRange meter?

Yes. Other medical conditions, such as high cholesterol levels, anaemia (low iron levels) and lupus syndrome may sometimes interfere with your results. Check with your healthcare professional before you make any decisions about your health.

Are CoaguChek test strips available on prescription in the UK?

Yes. CoaguChek test strips are available on prescription if you live in the UK (not applicable in the Republic of Ireland). This is at your GP's discretion, and prescription charges may apply. As with any decision about your health, it's best to explore your options with your healthcare professional before selfmonitoring. If strips are not available on prescription in your area (or if you reside in the Republic of Ireland), you can purchase them direct from Roche via the freephone Care Line number 0808 100 7666 (ROI 1 800 992 868) or shop.coaguchek.com

Is self-monitoring as accurate as the INR tests my healthcare professional does?

The accuracy of the CoaguChek INRange meter is equal to that of the equipment used by your healthcare professional¹.

Is self-monitoring suitable for children?

Yes. After a brief training course on self-monitoring, and with support from a healthcare professional, you and your child will enjoy the freedom that self-monitoring offers. As a parent, you must be prepared to take on some of the responsibility for managing their care.

Will my CoaguChek[®] INRange meter require maintenance?

The CoaguChek INRange meter and test strips have a number of built-in quality control functions. Because of this we do not provide maintenance for your meter. We recommend that, every six months, you ask a healthcare professional to take tests in parallel with you on a meter that uses the same technology. The healthcare professional should be enrolled in a UK-recognised external quality assurance anticoagulation programme.

How often should I test my INR levels?

Everyone's different, so you should follow your healthcare professional's advice on how regularly to test. It has been shown that testing once a week increases the time spent in therapeutic range.

Can I use the CoaguChek INRange meter if I'm on other medication?

Many common medicines, including painkillers, antirheumatics, antibiotics, antidepressants, diuretics, laxatives and vitamin K, can affect your INR levels. This doesn't necessarily mean that you can't take them if you're self-monitoring. Your healthcare professional will be able to advise you on what you can and can't combine.

Can I connect my CoaguChek INRange meter to an App?

Yes you can! Apps are available which automatically send your result to the clinic. This option is available in areas where the clinic have signed up to the service. If your clinic does not offer App connectivity, contact the Care Line team and we can investigate further on your behalf.



If you'd like more information, or if you would like to purchase a CoaguChek[®] INRange meter, please call freephone:



0808 100 7666

In the Republic of Ireland, please call freephone:



1 800 992 868

or visit:



shop.coaguchek.com



www.facebook.com/selfiechek

References:

 Multicenter performance evaluation of the CoaguChek* INRange system -White paper, 2016, Roche Diagnostics Limited

COAGUCHEK[®] and SOFTCLIX[®] are trademarks of Roche. © 2017 Roche Diagnostics Limited. All rights reserved.

Roche Diagnostics Limited, Charles Avenue, Burgess Hill, RH15 9RY, UK. Company registration number: 571546