



Wireless SmartClip for CoaguChek® XS meter



User Manual

INTRODUCTION

Thank you for selecting our Wireless SmartClip for your Roche® Coagulation Meter, which is a transmission Wireless SmartClip accessory that can help you expand the meter from Infrared (IR) to Bluetooth Low Energy (BLE) transmission. This means the testing values can be transferred to a counterpart station, such as 2net™ Hub or some mobile devices through BLE technology. From now on, you can systematically monitor and manage your PT values via wireless technology.

Mobile device with this logo  Bluetooth SMART is compatible with the Wireless SmartClip to achieve reliable transmission linkage.

IMPORTANT Please thoroughly read this user manual for all the necessary information to operate your Wireless SmartClip.

OVERVIEW

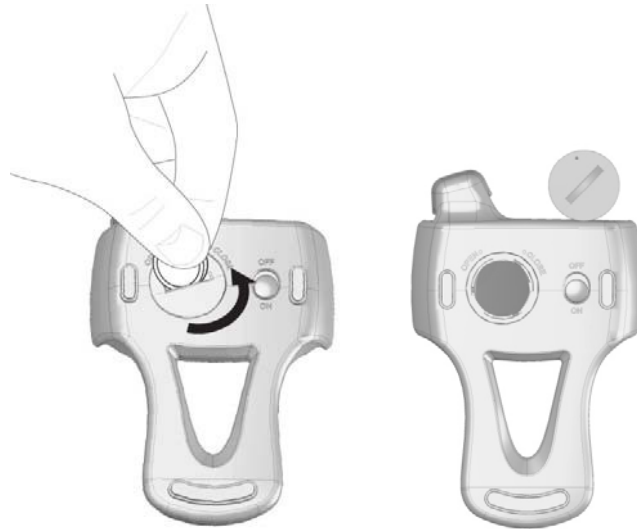


1. LED light
2. Battery compartment
3. **ON/OFF** switch
4. Clip
5. Non-slippery pads

BATTERY INSTALLATION

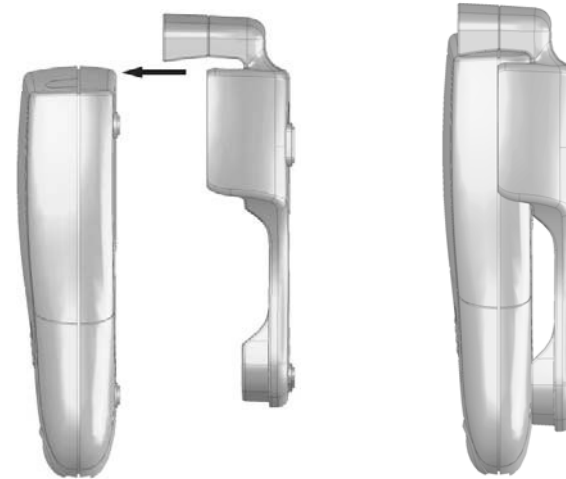
Battery is pre-installed in your BLE transmission Wireless SmartClip when you purchase. Please regularly check the battery and replace battery promptly as it may affect the transmission (refer to LED indicator table on page. X).

To replace the battery:



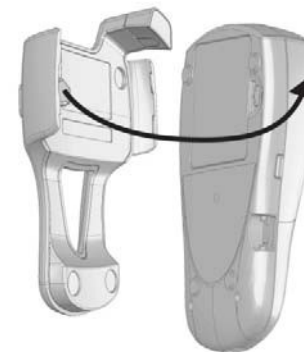
1. Unscrew the battery compartment cover using a coin.
2. Remove the old battery and insert a new CR2032, 3V lithium battery. Make sure to place the battery in the compartment following the polarity +/-.
3. Return the compartment cover and screw it tightly.

INSTALLATION



- Align the coagulation meter with the Wireless SmartClip and insert the meter into the Wireless SmartClip with some pressure until it clips into place.

UNINSTALLATION



- Hold the Wireless SmartClip and pull the meter from the left-hand side with some pressure.

OPERATION

After the Wireless SmartClip is installed onto the meter, you need to turn on the Wireless SmartClip to ensure the transmission works. Make sure you power up the coagulation meter in priority of turning on the Wireless SmartClip.

NOTE The effective distance between a counterpart station, such as a hub, and the coagulation meter should be not far from each other more than 10 meters or 32.8 feet

Turn on the Wireless SmartClip:

- Slide the switch to **ON**. LED indicator lights up briefly in green (given a normal battery status).
- Run a prothrombin time (PT) measurement with the Roche CoaguChek XS meter, as described in the operating manual of the meter.
- Once the PT measurement result is shown on the display of the CoaguChek XS meter, please do not turn off the meter, until the data transmissions will start automatically (within 60 seconds), which will be indicated by a green flashing LED.
- Ensure that the blue LED indicates that data transmission was successful (steady or flashing according to the table below).
- Once you saw the blue LED, your PT data has been transmitted successfully.
- If there is no blue LED, please make sure that the receiving device (e.g. 2net™ hub) is turned on and able to receive the

data from the Wireless SmartClip. Please wait until the connection has been re-established automatically.

- Note: If you measured your prothrombin time (PT) without data transmission, the collected PT values will be automatically transmitted once a data connection will be established again.

Turn off the Wireless SmartClip:

- Slide the switch to **OFF** after having ensured a successful data transmission.

NOTE The effective distance between a counterpart station, such as a 2net™ hub, and the Wireless SmartClip should be not far from each other more than 10 meters.

LED INDICATOR

Status	Normal Battery	Low Battery	Critical Battery
Power on	On in green for 1 second	On in green for 1 second	Flashes in red three times per minute.
Start mode (pinging for the meter)	OFF	OFF	Flashes in red three times per minute.
Communicating with Meter/Hub	Flashes in green once per second	Flashes in green and red alternatively	Flashes in red three times per minute.
Transmission completed	Blue is on for 5 seconds	Flashes in blue and red alternatively	Flashes in red three times per minute.
Transmission fails / Lost	Flashes in red	Flashes in red very quickly	Flashes in red three times per minute.

connection			
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SPECIFICATIONS

Dimension (L x W x H)	84.5 x 131.5 x 36.6 mm (3.3 x 5.2 x 1.5 inches)
Power	1 x CR2032 3V lithium battery
Weight	52.8 g (1.86 oz)
Operating temperature	10°C to 40°C (50°F to 104°F)
Storage temperature	-25°C to 70°C (-13°F to 158°F)

CARE INSTRUCTIONS

To ensure you use your product correctly and safely, read these warnings and the entire user manual before using the product:

- Do not wrap the Wireless SmartClip in a wet towel, nor with other wet materials. Use a soft, slightly moistened cloth.
- Do not place or wash the Wireless SmartClip under running water instead clean it with a wet cloth.
- Do not store the Wireless SmartClip in a hot (about 50°C) and humid (about 90%) environment.
- Do not subject the product to excessive force, shock, dust, temperature changes, or humidity. Never expose the product to direct sunlight for extended periods. Such treatment may result in malfunction. Do not tamper with the internal components. Doing so will terminate the product warranty and may cause damage. The main unit contains no user-serviceable parts.

- Take precautions when handling the battery.
- Remove the battery whenever you are planning to store the product for a long period of time.
- When replacing the battery, use a new battery as specified in this user manual.
- The product is a precision instrument. Never attempt to take this device apart. Contact the retailer or our customer service department if the product requires servicing (depends on service concept).
- Do not touch the exposed electronic circuitry, as there is a danger of electric shock.
- Check all major functions following the User Manual if the device has not been used for a long time.
- When disposing of this product, ensure that this is done according to the local guidelines..
- Due to printing limitations, the displays shown in this manual may differ from the actual display.
- The contents of this manual may not be reproduced without the permission of the manufacturer.

NOTE The technical specifications for this product and the contents of the user manual are subject to change without notice.

CLEANING THE SLEEVE

It is important to follow the procedures below to clean and disinfect the sleeve. Failure to follow these procedures may cause malfunction of the sleeve.

Cleaning/Disinfecting the Exterior

Use only the following items for cleaning/disinfecting the Wireless SmartClip for a contact time of >1 minute:

- 70% isopropyl alcohol
- 10% Sodium hypochlorite solution (1 part bleach to 9 parts deionized water, made fresh every 24 hours)

NOTE Do not use any other disinfectants/cleaning solutions on the Wireless SmartClip.

1. Clean/Disinfect the Exterior

With the SmartClip powered off, wipe the SmartClip's exterior clean.

- Do not let liquid accumulate near any opening. Make sure that no liquid enters the SmartClip.

2. Dry the Exterior

With a lint-free tissue, dry the SmartClip.

- Wipe away residual moisture and fluids after cleaning the SmartClip.
- Allow wiped areas to dry for at least 10 minutes before performing a test.

DISPOSAL

If you need to dispose of the Wireless SmartClip, do so in accordance with the statutory regulations. Contact your town administration or a disposal company.



Please dispose of the device in accordance with the directive 2002/96/EC - WEEE (Waste Electrical

and Electronic Equipment). If you have any queries, please refer to the local authorities responsible for waste disposal.



Used, fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.

NOTE You will find these markings on batteries containing harmful substances : Pb = battery containing lead, Cd = battery containing cadmium, Hg = battery containing mercury. Please dispose of the device in accordance with the directive 2006/66/EC.

EU-DECLARATION OF CONFORMITY

Hereby, we declare that BLE Wireless SmartClipor Roche CoaguChek XS® Coagulation Meter (model: BG201) is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. A copy of the signed and dated Declaration of Conformity is available on request via our Roche Customer Service.



COUNTRIES RTTE APPROVED COMPLIED
All EU countries, Switzerland CH
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FCC / IC STATEMENT

This device complies with Part 15 of the FCC Rules. Operation 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.

WARNING Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio / TV technician for help.

DECLARATION OF CONFORMITY

The following information is not to be used as contact for support or sales. Please visit our website at www.oregonscientific.com for all enquiries. (depends on service concept)

We

Name: IDT Technology Limited

declare that the product

Product No.:BG201

Product Name: BLE Wireless SmartClip

for Roche® CoaguChek XS Meter

Manufacturer: IDT Technology Limited

Address: Block C, 9/F, Kaiser Estate,

Phase 1, 41 Man Yue St., Hung Hom, Kowloon,

Hong Kong