XprecisPrime™

Coagulation Analyzer

USER GUIDE

Original Instructions

Any software screens, hardware details or test results shown in this manual are for illustrative purposes only. The information shown on your analyzer may differ.

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This document is available in electronic format at www.universalbiosensors.com

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1. Introducing the Xprecia Prime™ Coagulation Analyzer

General warnings and precautions

- All accessories used with this product must meet the manufacturer's specifications
- This device is intended only for use by Healthcare Professionals and is not for self-testing.

Test strips:

- **Only use Universal Biosensors *Xprecia Prime™ PT/INR Test Strips*.** Other strips (e.g. PT/INR Strips for other Xprecia™ Systems) – **will not work** with the *Xprecia Prime™ Coagulation Analyzer*.
- **Always close the vial lid after a strip has been taken out.**

Electrical safety:

- Only use the USB cable provided by Universal Biosensors. If you need a replacement USB cable, contact Customer Support (see page 97).
- The *Xprecia Prime™ Coagulation Analyzer* contains a lithium-ion rechargeable battery which must be treated with care:
    - Do not attempt to access the battery; if your battery is not performing adequately, contact Customer Support (see page 97).
    - Do not place the analyzer near a heat source or in a hot environment (e.g. an automobile parked in the sun).
    - If you suspect the battery may have been punctured, crushed, or damaged, contact Customer Support (see page97).
- Failure to follow the above battery-care instructions could result in serious injury or death due to a battery catching fire, exploding or leaking.
- When connecting the analyzer to external devices (such as USB power sources), ensure those devices are in compliance with local safety regulations.
- The power supply that comes with your analyzer is for indoor use only.

- The power supply is also served to disconnect the device. Do not position the equipment so that it is difficult to operate the disconnecting device.

Biological safety:

- Always follow the safety procedures and precautions listed here and throughout this user guide, plus those adopted by your healthcare facility.
- The *Xprecia Prime™ Coagulation System* should only be used by operators trained in handling biohazardous materials. Parts of the *Xprecia Prime™ Coagulation System* could become contaminated during testing and thus capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, consult:
    - "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Fourth Edition", Clinical and Laboratory Standards Institute (CLSI) M29-A4.
    - "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html
    - "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens", (2010), http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
    - Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/
- Each Xprecia Systems PT Controls (LQC) kit makes use of human source material. Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV), and hepatitis C virus (HCV) using tests that conform with the In Vitro Diagnostic Directive of the EU or are approved by the FDA. Because no known test can offer complete assurance of the absence of infectious agents, all human-derived products—such as the lyophilized plasma in this kit—should be handled with appropriate caution.

About the Xprecia Prime™ Coagulation System

The *Xprecia Prime™ Coagulation System* is designed to monitor blood coagulation. It measures the time it takes for a sample of blood to clot and reports the result as an International Normalized Ratio (INR) or in seconds. INR results can vary from test to test due to health conditions. If it is too low, there is a greater than normal risk of blood clots forming; if it is too high, there is a greater than normal risk of bleeding.

Anticoagulant medication is a common treatment in patients susceptible to blood clots. Blood clots can cause serious conditions, such as deep vein thrombosis (a blood clot in the veins of the legs), pulmonary embolism (a blood clot in the lungs), or a stroke (a blood clot in a blood vessel in the brain). Anticoagulants are designed to reduce potentially harmful blood clotting.

The *Xprecia Prime™ Coagulation System* has been specifically designed to monitor INR of patients undergoing anticoagulation therapy with warfarin. Vitamin K is essential to the normal blood clotting (coagulation) process; warfarin acts by making the body less efficient at using vitamin K to make clotting factors (factor II, VII, IX and X). INR is sensitive to changes in these factors, so it is essential that INR be monitored in patients taking warfarin. A higher dose of warfarin might be necessary if the INR is too low; a lower dose if it is too high.

Intended Use

The *Xprecia Prime™ Coagulation System*, which includes the Automated INR Coagulation Analyzer (Meter) and PT/INR Test Strips, is for the quantitative determination of International Normalized Ratio (INR) for the monitoring of vitamin K antagonist oral anticoagulation therapy in fresh capillary whole blood from a fingerstick or non-anticoagulated venous whole blood. It is an in vitro diagnostic device intended for use by professional healthcare providers in multi-patient use settings including point of care.

The *Xprecia Prime™* Coagulation system is an in-vitro diagnostic device intended for multi-patient use in professional healthcare settings including near patient and Point-of-care settings.

Your Xprecia Prime™ Coagulation Analyzer kit

Your *Xprecia Prime™ Coagulation Analyzer* kit contains the following items:

1. 

Analyzer

2. 

This User Guide

3. 

Power Supply with interchangeable plug/
USB Cable

4.

Spare Cap

Quick Start Guides – Patient Test and LQC test

NOTE: The following items are not supplied with the *Xprecia Prime™ Coagulation Analyzer* kit and may be required to be purchased separately.

- Alcohol swabs
- Disinfecting wipes
- Lint-free tissues or cloths for drying the analyzer after cleaning.
- Sterile gauze
- A Lancing device and/or lancets
- Equipment for performing venous blood collection
- *Xprecia Prime™ PT/INR Test Strips*
- *Xprecia™ Systems PT Controls* kit

Cleaning and disinfecting the Xprecia Prime™ Coagulation Analyzer

The analyzer must be cleaned and disinfected after each patient test and each LQC test using the disinfecting wipe recommended by Universal Biosensors (see “Cleaning the analyzer” on page 55).

Key features of the Xprecia Prime™ Coagulation Analyzer

- Hand-held and portable
- Easy sample application with small (8 µL) sample volume
- External quality control (LQC) tests with a configurable lock-out feature
- Barcode entry of strip information
- Strip ejection mechanism
- Rich user interface supporting multiple languages
- Internal battery with power monitoring
- Operator identification and access control
- Patient identification
- Memory feature (for displaying past test results and errors)
- Export of past test results to an external device

How the Xprecia Prime™ Coagulation System works

The *Xprecia Prime™ Coagulation System* analyzes a blood sample taken from the patient by fingerstick or venous sampling. The sample is transferred from the patient's finger or syringe to a test strip that has been inserted in the *Xprecia Prime™ Coagulation Analyzer*. The blood is mixed with a reagent contained within the strip and the analyzer detects when clotting has occurred. The result is then displayed on the analyzer's screen in either units known as the International Normalized Ratio (INR) or in calibrated seconds.

Up to 1000 records can be stored in the analyzer's memory with patient and operator identification for each record. You can display details about each of those records.

Quality control

Integrated quality control

The *Xprecia Prime™ Coagulation Analyzer* has a number of integrated quality-control functions:

- A check of components and functions is performed every time the analyzer is turned on.
- The barcode information on the strip and vial are read by a scanner inside the *Xprecia Prime™ Coagulation Analyzer*. The analyzer then checks:
  - the strip's expiration date and lot information.
  - the strip's calibration values.
- During the test, the strip's integrity is monitored. The strip's temperature is also controlled to ensure test results are reproducible.

An error is reported if the analyzer fails any of the above checks. Warning and error messages are described in Chapter 10 (Troubleshooting) on page 81.

External quality control

To help your facility comply with regulatory requirements, you can run a check of the system at any time using the optional *Xprecia™ Systems PT Controls*. This check—called a LQC test—compares the measurement of a control sample against a pre-determined acceptable range of readings.

LQC tests are explained in detail in Chapter 5.

Other references

In addition to this user guide, further information about the *Xprecia Prime™ Coagulation System* can be found in the following references.

Quick Start Guides

Your *Xprecia Prime™ Coagulation Analyzer* kit includes a Quick Start Guide (QSG) that provides a quick description of the basic steps in a patient test and another QSG related to Liquid Quality Control (LQC) tests. These guides also provide cleaning instructions.

Xprecia Prime™ PT/INR Test Strips instructions for use

Instructions for using the *Xprecia Prime™ PT/INR Test Strips* are provided with the strips (purchased separately). See “Ordering details” on page 97.

Xprecia™ Systems PT Controls instructions for use

Instructions for using the *Xprecia™ Systems PT Controls* are provided with the kit (purchased separately). See “Ordering details” on page 97.

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2. Getting started

Powering the analyzer

The *Xprecia Prime™ Coagulation Analyzer* is charged via a micro USB cable and AC power supply (included). It can also be charged using a micro USB cable connected to another suitable power source (such as a USB port on a computer).

It is best to make sure that the analyzer is fully charged before first use.

AC power supply and cable

To charge analyzer, plug in AC power supply and connect the USB cable

The AC power supply comes with a range of plugs. Find the right plug for your region then follow the instructions below to prepare your power supply for use.

Step 1: **remove the plastic insert (if present)**

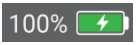
Slide down the tab, then lift the insert to remove.

Step 2: fit the insert for your region

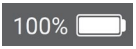
First, place the insert as shown below (left), then press down as shown below (middle). Test that the insert is fitted correctly by gripping the insert and pulling up as shown below (right).

Power indicators

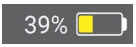
A battery icon is at the top right corner of the screen with color coding as follows:



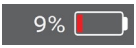
Green: power supply plugged in, battery charging.



White: analyzer has sufficient battery charge.



Yellow: moderately low battery; charge soon.

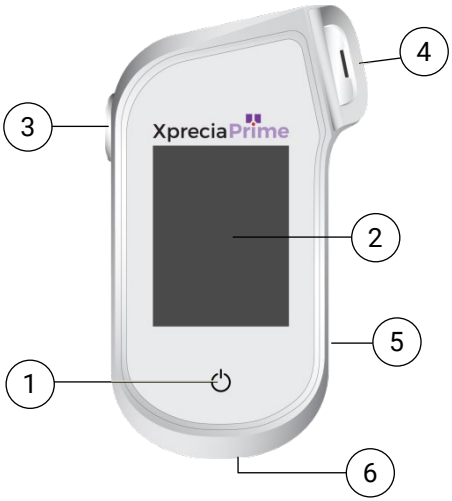


Red: critical battery; charge before running a test on battery power.

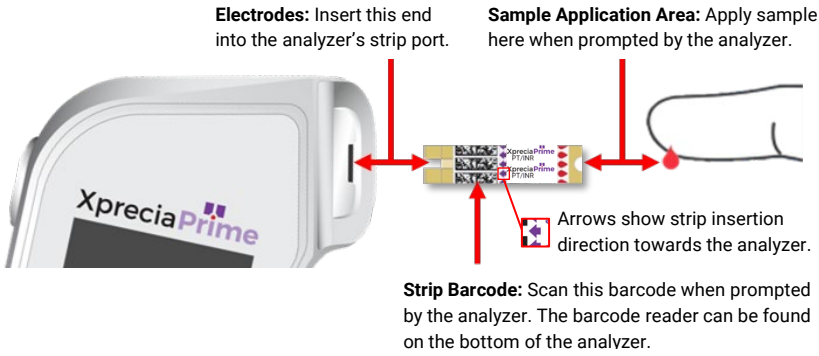
Note: The analyzer can be connected to an external power source during a test, which will also charge the battery.

Parts of the Xprecia Prime™ Coagulation Analyzer

1. Power button
2. Touch screen display
3. Test strip eject button
4. Test strip port and protective cap
5. USB port
6. Barcode reader



Xprecia Prime™ PT/INR Test Strips



- Use a test strip only once and dispose of it in biohazard waste after use.
- Always keep unused strips in their original vial with the lid firmly closed.

First time use

Turning the analyzer on and off

To turn the analyzer on, touch the power button briefly.

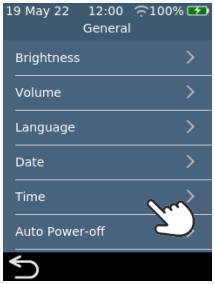
You can turn the analyzer off by touching the power button for several seconds and answering yes when prompted for confirmation.

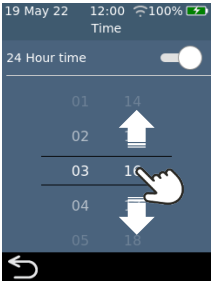
If the power button or touch screen are not responding, you can force the analyzer to shut down by disconnecting the external power supply and holding your finger on the power button for around 15 seconds until the screen goes black.

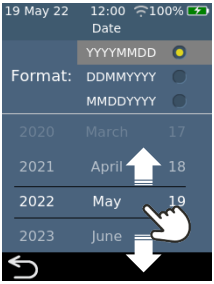
Setting the date and time

Before you run any tests you should check the date and time (displayed at the top of the screen). If the date and time are not correct, you will need to set them as follows:

1. From the **Home** screen, touch the *SETTINGS* button to navigate to the **Settings** screen, then select *General* and then *Time*
2. Swipe to set the correct time and then touch ✓, then select *Date*
3. Swipe to set the correct date and then touch ✓ to confirm your selection







Configuring access control

Log in options

You can configure your analyzer to limit access. When access is limited, users will be forced to log in before reaching the home screen. You can also define special users (called *Supervisors)* that have access to advanced configuration options (see page 69 for more details).

To enable log in, you will first need to set up an operator list (see below). To log out, simply turn off the analyzer.

Operator list

An operator list is required for user authorization to be enabled. The operator list contains a list of the operators that can use the analyzer. You can define which operators are *Supervisors*. For detailed instructions on setting up an Operator list, see page 75.

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3. Running a capillary patient test

What you will need

To conduct a test you will need:

1. Your *Xprecia Prime™ Coagulation Analyzer*
2. A vial of *Xprecia Prime™ PT/INR Test Strips* (purchased separately)
3. A lancet (21 to 23 gauge, 1.8 to 2.0 mm depth) of your choice (purchased separately)
4. Alcohol swab/wipe and sterile gauze (purchased separately)
5. CaviWipes™ disposable disinfecting wipes (purchased separately)

When running a patient test, do:

- **Only use** Universal Biosensors *Xprecia Prime™ PT/INR Test Strips*. Other test strips (including other Xprecia test strips) **will not work** with the *Xprecia Prime™ Coagulation Analyzer*.
- Always follow the safety procedures and precautions listed here and throughout the user guide, and those adopted by your healthcare facility.
- Always wear a new pair of protective gloves when testing each patient.
- Always clean and disinfect the analyzer between each use (for instructions, see page 56).
- Use only single-use lancets.
- Keep the analyzer as still and level as possible during the test.
- Only use the system when the room temperature is between 15 °C and 32 °C (59 °F to 89 °F) and the relative humidity is less than 80%. (See "Technical specifications" on page 103 for Transport and Storage conditions).
- Always store test strips in their original vial with the cap firmly snap closed. **Close the strip vial securely (until you hear a "click") as soon as you have removed your test strip.** This will protect the remaining strips in the vial.
- When you use a test strip vial for the first time, record the discard date on the vial label in the space provided.
- **Always store test strips between 2 °C and 30 °C (35.6 °F and 86 °F).**
- Use a test strip within 10 minutes of removing it from the vial.
- Use each test strip only once and discard after use.
- Apply a capillary blood sample within 30 seconds of sample collection.
- Apply the blood sample to the test strip within 4 minutes of being prompted to do so by an "apply sample" message on the analyzer screen.

When running a patient test, do not:

- Do not insert a test strip into the strip port more than once. A test strip that is inserted twice might fail to make proper electrical contact with the analyzer.
- Do not bump the test strip or analyzer after you apply the sample or while the test is in progress.
- Do not use a vial of test strips if the expiration date recorded on the label has passed. The analyzer will not allow you to use an expired test strip.
- Do not handle or touch a test strip with wet hands because moisture can damage the strip.
- Do not use a test strip that has been dropped or which may have been contaminated.
- Do not use a test strip if it appears damaged in any way.
- Do not press or squeeze the lanced finger.
- Do not apply the sample to the test strip until you are prompted to do so by the “apply sample” message on the analyzer screen.
- Never add more sample to the test strip after the analysis has begun.

Preparing to run a capillary patient test

1. Prepare a clean and tidy environment.
2. You and the patient must wash your hands in warm, soapy water and then dry them.
3. Identify the patient's finger from which a fingerstick sample will be obtained. Ensure that the finger does not show evidence of a previous fingerstick.
4. In preparation for taking the sample, clean the patient's finger with an alcohol wipe and allow to air dry.
5. Prepare a new lancet according to the manufacturer's instructions. See examples of lancets below.

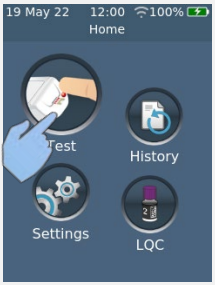
How to perform a capillary patient test

1. Touch and hold the power button until the analyzer turns on

When the analyzer start-up process is complete, the home screen will appear.

You may need to log in with your Operator ID and password (check with your administrator for details).

2. From the *Home* screen, tap on the *TEST* button

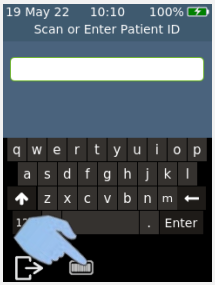


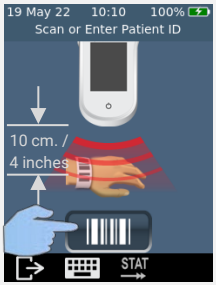
You can exit a test at any time by touching the button on the bottom left of the screen.

3. Enter Patient ID

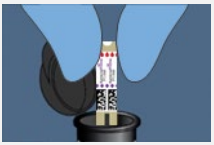
If 'Collect Patient ID' has been enabled (See page 69), you will be prompted for the Patient ID.

Enter the Patient ID by barcode or using the onscreen keyboard. You can switch between barcode/keyboard by touching the button at the bottom of the screen.





4. Remove a test strip from its vial



Firmly close the vial immediately after removing the strip.

Ensure that your gloved hands are clean and dry to avoid contaminating or damaging the test strips. Avoid touching the sample application area (the white semi-circular notch to the base of the strip).

Once you have removed the test strip from a vial, you should conduct the test within 10 minutes.

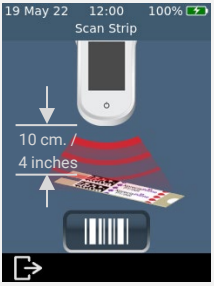
To avoid a potentially inaccurate test result, you must use the strip within 10 minutes of removing it from the vial.

Do not use test strips past their expiration date (printed on the label of the vial).

5. Scan strip barcode

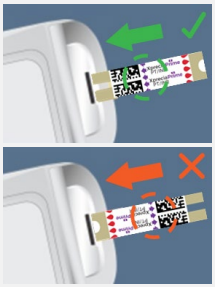
Tap the scan barcode button to scan the strip barcode.
The analyzer will beep when the barcode is scanned.

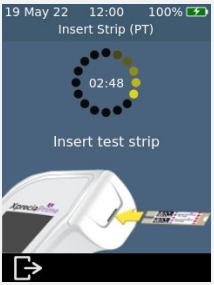
Note: When using a test strip from a new strip lot, you will be prompted to scan the vial after inserting the strip.



6. Insert the strip

Following the on-screen instructions and with the strip's print-side facing upward, follow the direction of the arrows and gently but firmly insert the test strip into the test strip port.





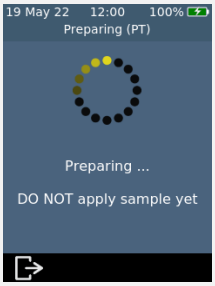
You must always insert the exact strip whose barcode was scanned in step 5

7. Analyzer prepares

Wait for the analyzer to prepare.

When the analyzer is ready, the **Apply sample now** screen will appear.

DO NOT apply the sample until prompted.



8. Obtain sample

Massage the finger towards the tip of the finger before the puncture. Apply pressure to the finger with the lancet (see your selected lancet's instructions for details).

Gently squeeze from the base of the finger to form a drop of blood. ***Wipe away this first drop***, then gently squeeze again to form a second drop.

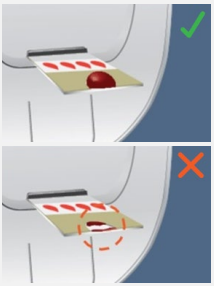
If the blood smears or runs, wipe it off with a tissue and gently squeeze another drop.

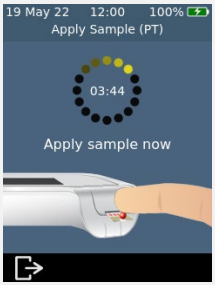
The drop should be about the same size as the test strip sample application area (the white semi-circular notch at the base of the strip).

Use the lancet only once and dispose of it in biohazard waste after use.

9. Apply the sample

When the analyzer moves to the **Apply Sample** screen, transfer the hanging drop of blood from the finger to the sample application area (the white semi-circular notch at the base of the





strip). The sample should fill the entire sample application area.

You must apply the blood to the test strip within 30 seconds of lancing.

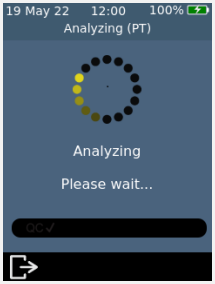
After the sample is applied, do not bump the analyzer or strip until the final result is displayed.

Ensure enough sample is applied to fill the small white semi-circle notch target area on the strip.

If you spill sample into the analyzer's strip port, clean the analyzer using the instructions on page 55.

10. Analysis in progress

During analysis, a bar on the bottom of the screen will show progress and the status of the strip's internal quality control check. When the analysis is complete, a **Result** screen will appear.

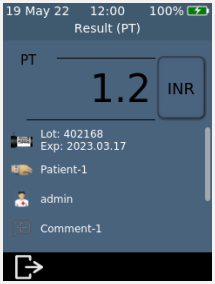


Be careful not to bump the analyzer or strip while the sample is being analyzed.

11. Result screen

When the test is complete, the result will be displayed. Units of INR and seconds can be shown. To switch units, touch unit specifier beside the result.

To exit, touch .



Unexpected results
If an unexpected result is reported, or if you are concerned that a result does not match the patient's symptoms or history, the test should be repeated with a fresh fingerstick. If a similar result is obtained, please test by other means (e.g. laboratory PT/INR). Differences in reagents, instruments, and pre-analytical variables can affect INR results. This should be considered when comparing different INR/PT test methods[1]. Inconsistent results could indicate poor test strip storage, interference by certain drugs, changes in diet, or analyzer malfunction.

12. Eject strip and clean analyzer

Hold the analyzer over a biohazard waste bin so that the strip points towards the opening of the bin, then gently press the eject button to discard the test strip. For disposal instructions, see page 105.

You will be reminded to clean the analyzer and strip port.

You must clean and disinfect the analyzer and strip port after each use (see page 55 for instructions).

⚠ Dispose of gloves and wash hands before performing another test. Used Xprecia Prime™ PT/INR Test Strips must be disposed of as biohazardous waste. Check with your local authorities for any special instructions that might apply in your jurisdiction. In most regions, unused Xprecia Prime™ PT/INR Test Strips (and the vial they came in) can be disposed of with your general rubbish. You should ensure that the test strips are bagged separately.

1. WHO Expert Committee on Biological Standardization. Thirty-third Report. Geneva, World Health Organization, 1983 (WHO Technical Report Series, No. 687).

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4. Running a venous patient test

What you will need

To conduct a test you will need:

1. Your *Xprecia Prime™ Coagulation Analyzer*
2. A vial of *Xprecia Prime™ PT/INR Test Strips* (purchased separately)
3. Equipment for performing venipuncture (purchased separately) including a plastic **non-anticoagulated** syringe (3-5 mL)
4. Alcohol swab/wipe and sterile gauze (purchased separately)
5. CaviWipes™ disposable disinfecting wipes (purchased separately)

Warnings

When running a patient test, do:

- **Only use** Universal Biosensors *Xprecia Prime™ PT/INR Test Strips*. Other test strips (including other Xprecia test strips) **will not work** with the *Xprecia Prime™ Coagulation Analyzer*.
- Always follow the safety procedures and precautions listed here and throughout the user guide, and those adopted by your healthcare facility.
- Always wear a new pair of protective gloves when testing each patient.
- Always clean and disinfect the analyzer between each use (for instructions, see page 55).
- Keep the analyzer as still and level as possible during the test (Preferably on a bench).
- Only use the system when the room temperature is between 15 °C and 32 °C (59 °F to 89 °F) and the relative humidity is less than 80%. (See "Technical specifications" on page 55 for Transport and Storage conditions).
- Always store test strips in their original vial with the cap firmly snap closed. **Close the strip vial securely (until you hear a "click") as soon as you have removed your test strip.** This will protect the remaining strips in the vial.
- When you use a test strip vial for the first time, record the discard date on the vial label in the space provided.
- **Always store test strips between 2 °C and 30 °C (35.6 °F and 86 °F).**
- Use a test strip within 10 minutes of removing it from the vial.
- Use each test strip only once and discard after use.
- Apply a venous blood sample within 60 seconds of sample collection.
- Apply the blood sample to the test strip within 4 minutes of being prompted to do so by an "apply sample" message on the analyzer screen.
- Collect only fresh non-anticoagulated venous blood for testing.
- Needles must be removed (and disposed of in a sharps container as per facility procedures) before applying blood to the test strip from the syringe

When running a patient test, do not:

- Do not insert a test strip into the strip port more than once. A test strip that is inserted twice might fail to make proper electrical contact with the analyzer.
- Do not bump the test strip or analyzer after you apply the sample or while the test is in progress.
- Do not use a vial of test strips if the expiration date recorded on the label has passed. The analyzer will not allow you to use an expired test strip.
- Do not handle or touch a test strip with wet hands because moisture can damage the strip.
- Do not use a test strip that has been dropped or which may have been contaminated.
- Do not use a test strip if it appears damaged in any way.
- Do not use a glass syringe. Only use a plastic syringe that is free of anticoagulant.
- Do not apply the sample to the test strip until you are prompted to do so by the “apply sample” message on the analyzer screen.
- Never add more sample to the test strip after the analysis has begun.

Preparing to run a venous patient test

1. Prepare a clean and tidy environment.
2. You and the patient must wash your hands in warm, soapy water and then dry them.
3. Identify the patient's vein from which a venous sample will be obtained.
4. In preparation for taking the sample, clean the patient's vein area with an alcohol wipe and allow to air dry.
5. Prepare new venipuncture equipment according to facility procedure and the manufacturer's instructions.

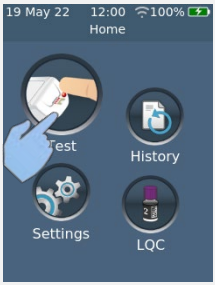
How to perform a venous patient test

1. Touch and hold the power button until the analyzer turns on

When the analyzer start-up process is complete, the home screen will appear.

You may need to log in with your Operator ID and password (check with your administrator for details).

2. From the *Home* screen, tap on the *TEST* button

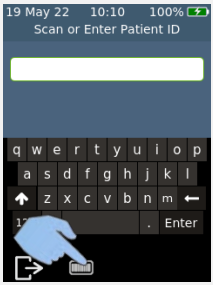


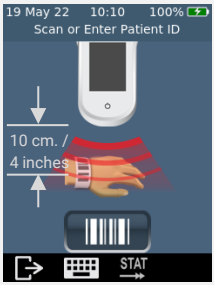
You can exit a test at any time by touching the button on the bottom left of the screen.

3. Enter Patient ID

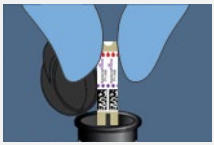
If 'Collect Patient ID' has been enabled (See page 69), you will be prompted for the Patient ID.

Enter the Patient ID by barcode or using the onscreen keyboard. You can switch between barcode/keyboard by touching the button at the bottom of the screen.





4. Remove a test strip from its vial



Firmly close the vial immediately after removing the strip.

Ensure that your gloved hands are clean and dry to avoid contaminating or damaging the test strips. Avoid touching the sample application (the white semi-circular notch to the base of the strip).

Once you have removed the test strip from a vial, you should conduct the test within 10 minutes.

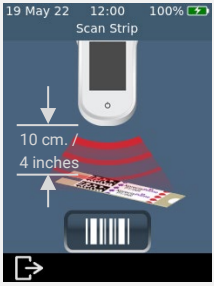
To avoid a potentially inaccurate test result, you must use the strip within 10 minutes of removing it from the vial.

Do not use test strips past their expiration date (printed on the label of the vial).

5. Scan strip barcode

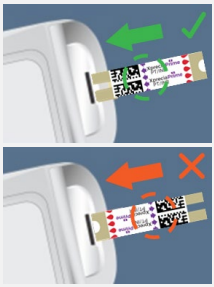
Tap the scan barcode button to scan the strip barcode.
The analyzer will beep when the barcode is scanned.

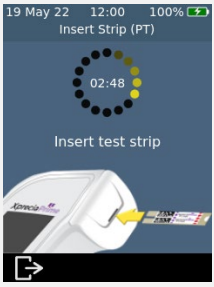
Note: When using a test strip from a new strip lot, you will be prompted to scan the vial after inserting the strip.



6. Insert the strip

Following the on-screen instructions and with the strip's print-side facing upward, follow the direction of the arrows and gently but firmly insert the test strip into the test strip port.





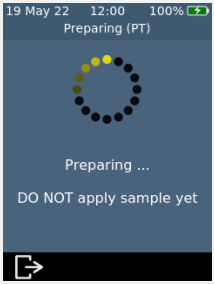
You must always insert the exact strip whose barcode was scanned in step 5

7. Analyzer prepares

Wait for the analyzer to prepare.

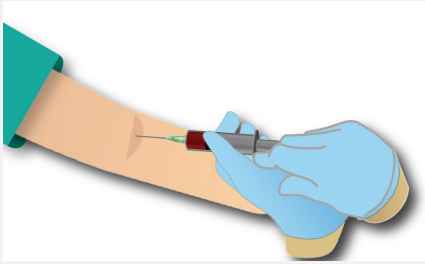
When the analyzer is ready, the **Apply sample now** screen will appear.

DO NOT apply the sample until prompted.



8. Obtain sample

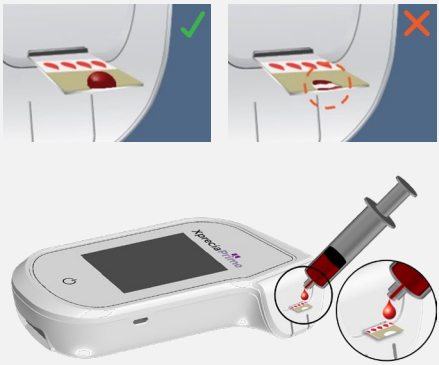
Perform venipuncture according to facility procedure and collect blood sample into a 3-5 mL non-anticoagulated plastic syringe.



Dispose of needle in sharps container according to facility procedures.

9. Apply the sample

When the analyzer moves to the **Apply Sample** screen, transfer a hanging drop of blood from the syringe to the sample application area (the white semi-circular notch to the base of the strip). The sample should fill the entire sample application area.



You must apply the venous blood sample to the test strip within 60 seconds of collecting the blood sample.

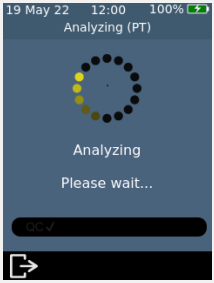
After the sample is applied, do not bump the analyzer or strip until the final result is displayed.

Ensure enough sample is applied to fill the small white semi-circle notch sample application area on the strip.

If you spill sample into the analyzer's strip port, clean the analyzer using the instructions on page 55.

10. Analysis in progress

During analysis, a bar on the bottom of the screen will show progress and the status of the strip's internal quality control check. When the analysis is complete, a **Result** screen will appear.

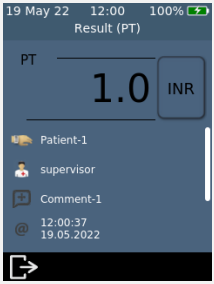


Be careful not to bump the analyzer or strip while the sample is being analyzed.

11. Result screen

When the test is complete, the result will be displayed. Units of INR and seconds can be shown. To switch units, touch unit specifier beside the result.

To exit, touch .



Unexpected results
If an unexpected result is reported, or if you are concerned that a result does not match the patient's symptoms or history, the test should be repeated with a fresh blood draw. If a similar result is obtained, please test by other means (e.g. laboratory PT/INR). Differences in reagents, instruments, and pre-analytical variables can affect INR results. This should be considered when comparing different INR/PT test methods[1]. Inconsistent results could indicate poor test strip storage, interference by certain drugs, changes in diet, or analyzer malfunction.

12. Eject strip and clean analyzer

Hold the analyzer over a biohazard waste bin so that the strip points towards the opening of the bin, then gently press the eject button to discard the test strip. For disposal instructions, see page 105.

You will be reminded to clean the analyzer and strip port.

You must clean and disinfect the analyzer and strip port after each use (see page 55 instructions).

1. WHO Expert Committee on Biological Standardization. Thirty-third Report. Geneva, World Health Organization, 1983 (WHO Technical Report Series, No. 687)

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5. LQC test 

The *Xprecia Prime™ Coagulation Analyzer* has a number of integrated quality control functions (see page 16).

To help your facility comply with regulatory requirements you can run a check of the system at any time using the optional *Xprecia™ Systems PT Controls*.

Each *Xprecia™ Systems PT Controls* kit contains vials of plasma and diluent. The plasma needs to be reconstituted with the diluent to produce the control solution. This control solution is then analyzed by the *Xprecia Prime™ Coagulation Analyzer*.

Supervisors can configure the analyzer to lock out patient tests if LQC tests are not performed often enough or if a LQC test fails. See page 71 for details.

To purchase *Xprecia™ Systems PT Controls*, see “Ordering details” on page 97.

What you will need

Items necessary to conduct a test are as follows:

1. An *Xprecia™ Systems PT Controls* kit which includes:
    - 8 bottles of plasma (4 x Level 1 and 4 x Level 2)
    - 8 bottles of diluent
    - 8 pipettes
    - Instructions for use
2. The *Xprecia Prime™ Coagulation Analyzer*
3. A vial of *Xprecia Prime™ PT/INR Test Strips*
4. CaviWipes™ disposable disinfecting wipes (purchased separately)

Warnings

When running a LQC test, do:

- **Only use** Universal Biosensors *Xprecia Prime™ PT/INR Test Strips*. Other test strips (including other Xprecia test strips) **will not work** with *Xprecia Prime™ Coagulation Analyzer*.
- Only use *Xprecia™ Systems PT Controls* with the *Xprecia Prime™ Coagulation System*.
- Always follow the safety procedures and precautions listed here and throughout the user guide, and those adopted by your healthcare facility.
- Always wear protective gloves when performing LQC tests.
- Only use the system when the room temperature is between 15 °C and 32 °C (59 °F to 89 °F) and the relative humidity is less than 80%.
- Always store test strips in their original vial and with the cap firmly closed.
- Use a strip within 10 minutes of removing it from the vial.
- When you use a test strip vial for the first time, record the discard date on the vial label in the space provided.
- Only use a test strip once and discard after use.
- Use the control solution—that is, plasma that has been reconstituted with diluent—within 25 minutes of reconstitution.
- Dispose of hazardous or biologically contaminated materials according to the practices of your clinic. Discard all materials in a safe and acceptable manner, and in compliance with all government requirements.

When running a LQC test, do not:

- Do not use a vial of test strips if the expiration date or discard date recorded on the label has passed. An error will be displayed if an expired strip is used.
- Do not touch a test strip with wet hands or wet gloves because moisture can damage the strip.
- Do not use a test strip that has been dropped or which may have been contaminated.
- Do not use a test strip if it appears damaged in any way.
- Do not apply control solution to a test strip until you are prompted to do so by the analyzer.
- Do not add more control solution to the test strip after the test has begun.
- Do not use any plasma or diluent after the expiration date on the vial or bottle (the expiration date assumes that the vial or bottle has not been opened).

Preparing to run a LQC test

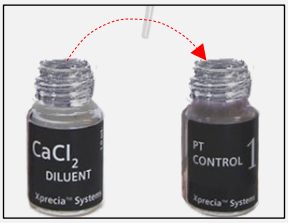
Before running a LQC test you will need to prepare the control solution using the materials provided in your *Xprecia™ Systems PT Controls* kit. To do this:

Open a plasma and diluent bottle

Remove the screw caps from the plasma bottle and from one of the diluent bottles.

Add diluent to plasma

Transfer the full contents of the diluent bottle into the bottle of plasma using a transfer pipette. Take care to leave the diluent bottle as empty as possible. Save the transfer pipette to use during the LQC test.



Mix the solution

Screw the cap back onto the plasma bottle firmly and carefully mix the solution by swirling the vial in a circular motion until the solution is completely dissolved. To prevent foam, do not shake the vial.

Wait at least 5 minutes before using the mixed solution.

You will need to use the solution **within 25 minutes** (if you keep the lid firmly closed).

Gently swirl the vial again prior to use.

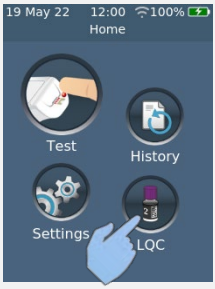
How to perform a LQC test

1. Touch and hold the power button until the analyzer turns on

When the analyzer start-up process is complete, the home screen will appear.

You may need to log in with your Operator ID and password (check with your administrator for details).

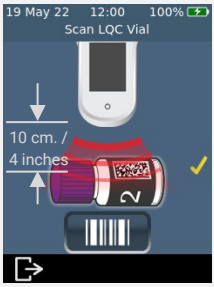
2. From the *Home* screen, tap on the *LQC* button



You can exit a test at any time by touching the button on the bottom left of the screen.

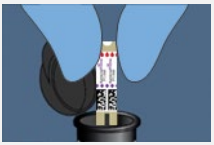
3. Scan LQC Vial

When prompted, touch the barcode button to scan the LQC plasma bottle using the analyzer's barcode scanner.



Only use a Xprecia™ Systems PT Control Kit with a valid expiry date. See "Ordering details" on page 97.

4. Remove a test strip from its vial



Firmly close the vial immediately after removing the strip.

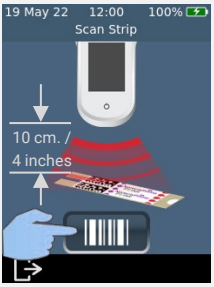
Ensure that your gloved hands are clean and dry to avoid contaminating or damaging the test strips. Avoid touching the sample application area (the white semi-circular notch to the base of the strip).

Once you have removed the test strip from a vial, you should conduct the test within 10 minutes.

To avoid a potentially inaccurate test result, you must use the strip within 10 minutes of removing it from the vial.

Do not use test strips past their expiration date (printed on the label of the vial).

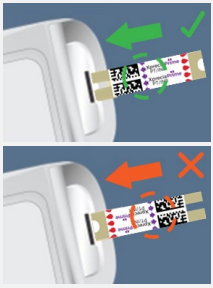
5. Scan strip barcode

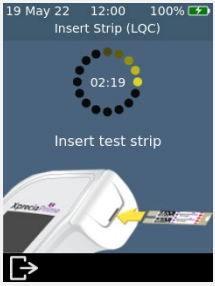


Tap the scan barcode button to scan the strip Barcode.
The analyzer will beep when the barcode is scanned.

Note: When using a test strip from a new strip lot, you will be prompted to scan the vial after inserting the strip.

6. Insert the strip





Following the on-screen instructions and with the strip's print-side facing upward, follow the direction of the arrows and gently but firmly insert the test strip into the test strip port.

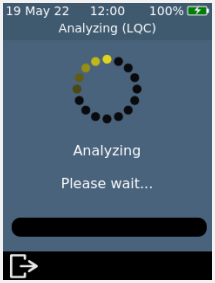
You must always insert the exact strip whose barcode was scanned in step 5

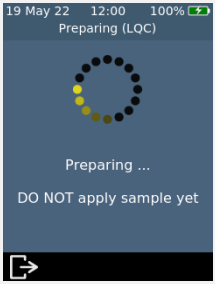
7. Analyzer prepares

Wait for the analyzer to prepare.

When the analyzer is ready, the **Apply sample now** screen will appear.

DO NOT apply the sample until prompted.





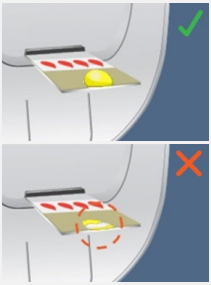
8. Obtain sample

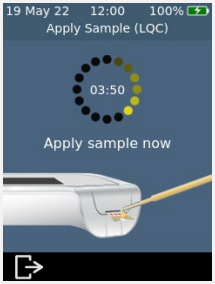
Gently swirl the LQC solution you prepared earlier (see above), then remove the lid and use the pipette provided to extract a sample of the solution.

Remember to use the solution within 25 minutes of dilution.

9. Apply the sample

When the analyzer moves to the **Apply Sample** screen, transfer a drop of LQC solution from the pipette to the sample application area (the white semi-circular notch to the base of the strip). The sample should fill the entire sample application area.





You must apply the LQC solution to the test strip within 25 minutes of preparing the solution.

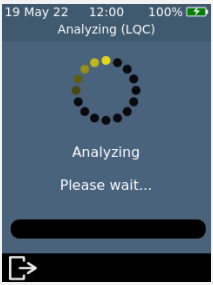
After the sample is applied, do not bump the analyzer or strip until the final result is displayed.

Ensure enough sample is applied to fill the small (white semi-circle notch) sample application area on the strip.

If you spill sample into the analyzer's strip port while applying the sample, clean the analyzer using the instructions on page 55.

10. Analysis in progress

During analysis, a bar on the bottom of the screen will show progress and the status of the strip's internal quality control check. When the analysis is complete, a **Result** screen will appear.



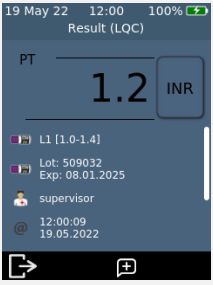
Be careful not to bump the analyzer or strip while the sample is being analyzed.

11. Result screen

If the LQC test is successful, the result will be displayed.

If the LQC test fails, an error screen will be displayed. If your *Supervisor* has turned on lock-outs, you will not be able to perform a patient test until a successful LQC test is performed. See page 82 for troubleshooting.

To exit, touch .



If the LQC test fails:
A failed LQC test can indicate that the system is not performing as expected. It can also be caused by improperly stored controls or an incorrect test method. Refer to troubleshooting on page 82.

12. Eject strip and clean analyzer

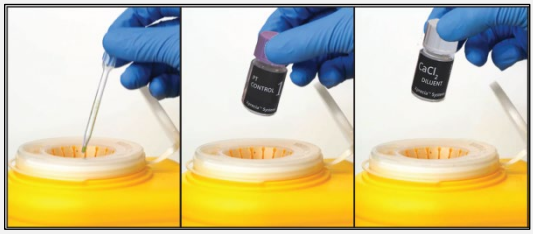
Hold the analyzer over a waste bin so that the strip points towards the opening of the waste bin, then gently press the eject button to discard the test strip. For disposal instructions, see page 105.

You will be reminded to clean the analyzer and strip port.

You must clean and disinfect the analyzer and strip port after each LQC test (see page 55 for instructions).

13. Safely dispose of LQC materials

Dispose of all used materials in a biohazard container or according to the practices of your facility.



LQC lockouts and reminders

The *Xprecia Prime™ Coagulation Analyzer* offers a LQC lockout feature. This will block patient testing functionality until a successful liquid quality control test is performed. See “LQC lockouts” on page 71 for further details.

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6. Cleaning the analyzer

Parts of the *Xprecia Prime™ Coagulation Analyzer* could become contaminated during testing resulting in analyzer errors or in the transmission of blood-borne pathogens to users. The analyzer must be cleaned and disinfected between every test.

The analyzer must be cleaned between each test, otherwise parts of the analyzer could become contaminated and capable of transmitting blood-borne pathogens to the user.

What you will need

- Disinfecting wipes as recommended by Universal Biosensors (see below).
- Lint-free tissues or cloths for drying the analyzer after cleaning.

Recommended disinfecting wipes

Universal Biosensors recommends CaviWipes™ disposable disinfecting wipes, (EPA Registration No: 46781-8). The cleaning procedure below is recommended when using these wipes.

CaviWipes™ disposable wipes contain the following active ingredients:

- isopropanol: 14.3% and
- Diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride: 0.23%

For information on purchasing CaviWipes™ disposable disinfecting wipes, contact your authorized distributor (see “Customer Support” on page 97).

Warnings

Follow the recommended disinfecting instructions and contact times listed in this User Guide.

Do not use any **other** disinfectant other than the wipes recommended above as it may damage the analyzer.

Squeeze excess liquid out of each wipe before use so that the wipe is damp but not dripping wet.

Do not let liquid accumulate around the strip port or the strip port cover. If fluid enters the strip port, your analyzer might be damaged.

Don't let liquid pool in the USB port as it may damage the analyzer.

Procedure

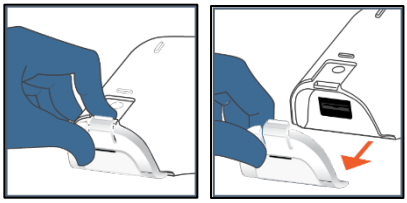
Cleaning and disinfecting your analyzer

Ensure the analyzer is powered off before cleaning and disinfecting.

A. Start by quickly wiping the whole analyzer with a CaviWipes™ disposable wipe (damp not dripping) to remove visible debris or liquids. Pay special attention to the barcode reader window on the bottom surface, ensuring that this is clear of debris.

   Discard the wipe and obtain a fresh wipe before proceeding.

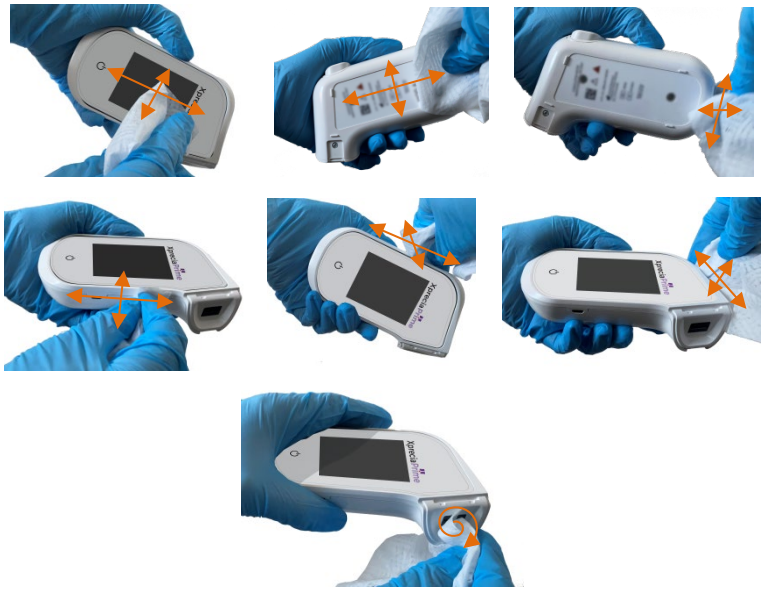
B. Remove the strip port cover using your thumb and forefinger as shown, then set it aside.



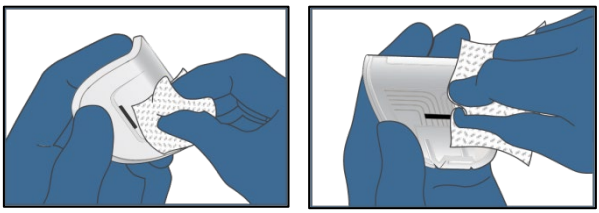
C. Holding the analyzer level, gently wipe the analyzer's front face with four vertical strokes (twice up and down) starting from the top, then wipe horizontally in the same cleaning motion (twice left and right).

Continue on the four edges and the back of the analyzer wiping two forward and backward strokes and two left and right strokes on each surface.

Always tilt the analyzer so that the strip port points slightly downward to avoid fluid entering the port.



D. Pick up the strip port cover and gently clean its front and back using your thumb and forefinger. Ensure the cap is visibly damp on all surfaces. You should pay particular attention to places where debris and fluids can gather (e.g. around the strip entry slot and in the channels inside the strip port cover).



E. **Wait at least two minutes** to allow the disinfecting properties of the CaviWipes™ to take effect.

F. **Dry** the analyzer thoroughly with lint free tissues or cloths.

   Thoroughly dry the entire surface of the analyzer being careful to not allow liquid to enter directly into the strip port connector by wiping in similar order and direction as shown in the cleaning sequence.

   Pay special attention to places where fluid can gather particularly around the strip port and the USB port area, drying any liquid that may have pooled.

G. Put the strip port cover back on the analyzer having checked that there is no excess visible liquid especially around the Strip Port. Ensure that you hear a click sound indicating it is securely re-attached to the body of the analyzer.

Signs of deterioration

Contact your authorized distributor (see “Customer Support” on page 97) if you notice any of the following signs of deterioration:

- Failure of the device to power on and off.
- Fault in button or touchscreen functionality.
- The device and button icon do not remain legible.
- The display does not remain clear (evidence of cloudiness or fogging) with cracking or other damage that obscures test results.
- Pixels on the display are damaged.
- The device casing displays any cracking, swelling, dissolving, softening or becoming brittle, discoloration.
- Decals and labels do not remain legible

7. Historical results

The *Xprecia Prime™ Coagulation Analyzer* keeps a record of past tests. A summary of these tests (including tests that ended in an error) can be viewed on the analyzer. There is capacity for up to one thousand records. Once capacity has been reached, a new record will overwrite the oldest record. Past records on the analyzer cannot be edited or deleted.

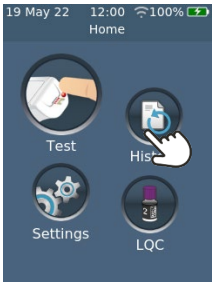
Test results on the analyzer can also be exported to an external device for further processing or storage. See page 79 for more details.

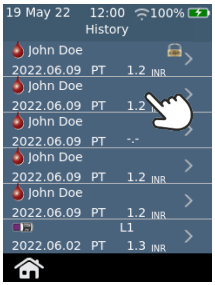
Past results

Viewing past patient test results

To view the results of previous patient tests:

1. After logging in (if required) and reaching the **Home** screen, touch the *HISTORY* button.
2. In the result list, look for patient results identified with a blood drop icon. Past results are listed with the most recent result at the top. If the list extends beyond the screen, swipe up and down on the screen to scroll through the list.
3. Touch a result listing to see more details about that result.



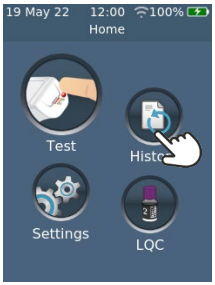


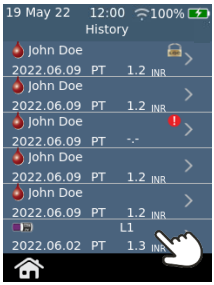
Past results are retained, even when the analyzer is turned off.

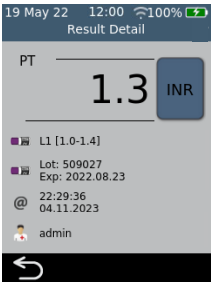
Viewing past LQC test results

To view the results of previous LQC tests:

1. After logging in (if required) and reaching the **Home** screen, touch the *HISTORY* button.
2. In the result list, look for LQC results identified with a LQC bottle icon. Past results are listed with the most recent result at the top. If the list extends beyond the screen, swipe up and down on the screen to scroll through the list.
3. Touch a result listing to see more details about that result.





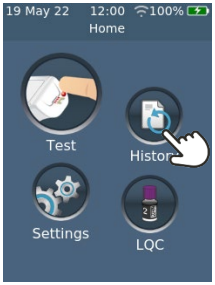


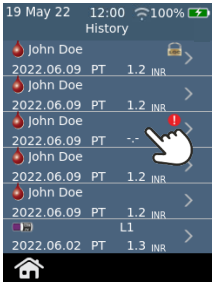
Viewing past tests that ended in an error

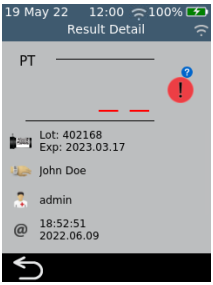
Tests that end in an error (including LQC failure) are also recorded in the result list. These tests are identified in the result list with the ! icon.

To view the results of tests that ended in an error:

1. After logging in (if required) and reaching the **Home** screen, touch the *HISTORY* button.
2. Past results are listed with the most recent result at the top. Tests that ended in an error are identified with the ! icon. If the list extends beyond the screen, swipe up and down on the screen to scroll through the list.
3. Touch a result listing to see more details about that result. If the details extend beyond the screen, swipe up and down to scroll. Touch the ? button for information on the error. See Chapter 10 (Troubleshooting) on page 83 for guidance on errors.







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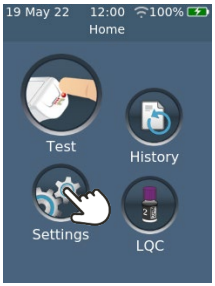
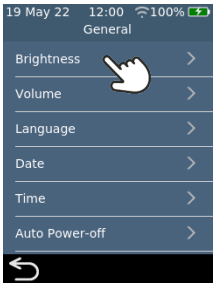
8. Settings

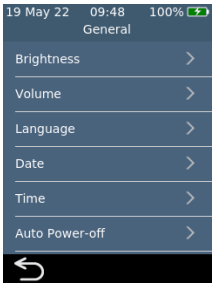
General settings

This section describes settings available to all operators. For advanced settings available only to Supervisor operators, see page 69.

To adjust analyzer settings, log in (if applicable) and then, on the **Home** screen, tap on *Settings* and then *General*.



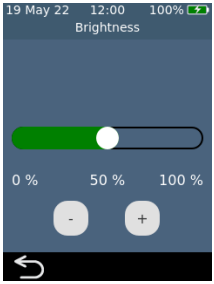




Brightness

The brightness of the screen can be modified. The default value is 100%. Tap + or − to increase or decrease the screen brightness.

Press ✓ to accept the new brightness level.



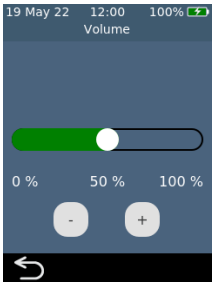
Sound volume

The analyzer emits audible alerts at various times, including when:

- a key event occurs during a test
- an error or warning occurs

Tap + or − to increase or decrease the sound volume of audible alerts.

Press ✓ to accept the new volume level.

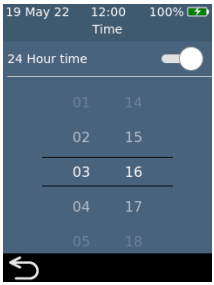


Time and time format

The time format can be set to 12 or 24 hour time.

To set the time, swipe up or down on hour, minutes and AM/PM.

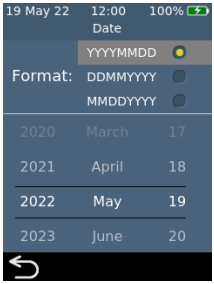
Touch ✓ to accept the time details.



Date and date format

The date format can be set to YYYY MM DD or DD MM YYYY.

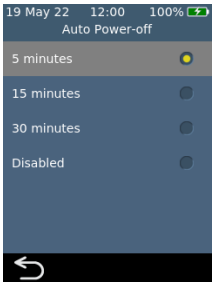
To set the date, swipe up or down on year, month and day, then touch ✓ to accept the date details.



Auto power-off

The analyzer can be configured to automatically turn off after a period of inactivity. This feature can be disabled by selecting “Never”.

To configure auto power-off, select the desired value then press ✓.



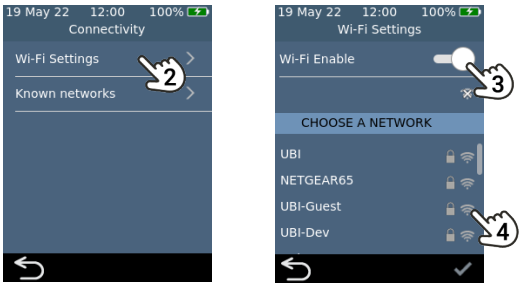
Connectivity (wireless)

Connecting to a wireless network

A wireless (Wi-Fi) network connection may be required for the analyzer to download results to an external device.

To connect to a wireless network:

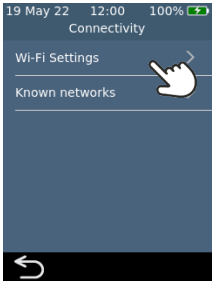
1. From the **Home** screen, touch the *SETTINGS* button, then touch *Connectivity* to navigate to the **Connectivity** screen
2. Touch *Wi-Fi Settings* to get to the **Wi-Fi Settings** screen
3. Turn on Wi-Fi
4. Select a network from the *CHOOSE A NETWORK* panel and enter the Wi-Fi password (if prompted)
5. After the connection is established, press ✓ to confirm your selection

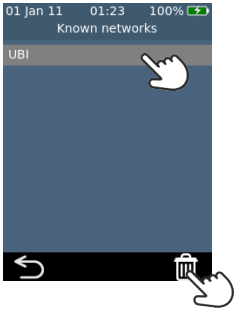


NOTE: The analyzer will only allow connection to secured (password-protected) Wi-Fi networks

Forgetting a wireless network

To forget a wireless network (so that the analyzer no longer connects to that network), select *Known Wi-Fi Networks* on the **Connectivity** settings screen, then select a network name and touch the bin button.

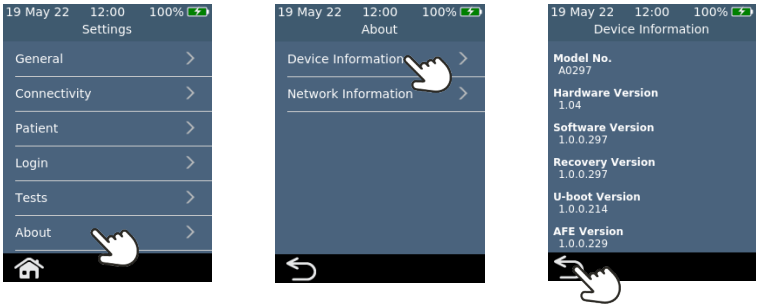




About

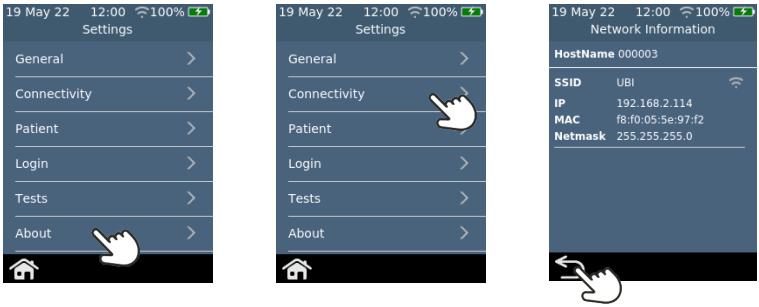
Device information

Information about the analyzer such as serial number and software version can be found by selecting *SETTINGS* on the **Home** screen, then *About*, then *Device Information*.



Network information

Information about the wireless network connection such as IP address and MAC address can be found by selecting *SETTINGS* on the **Home** screen, then *About*, then *Network Information*.



Advanced Settings (for Supervisors)

The settings described in this section are only available:

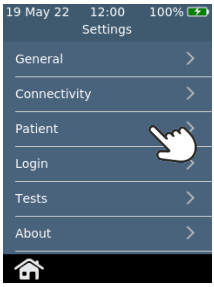
- If the logged in operator is defined as a *Supervisor* in the Operator List
- If log in is not enabled, in which case all functions are available to all users

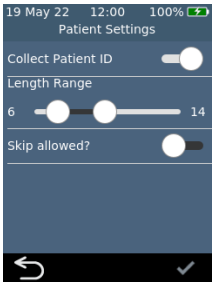
After selecting *Settings* on the **Home** screen, the *Supervisor* will find three extra menu items on the *Settings* menu: Patient, Login and Tests.

Patient settings

The patient settings provide the *Supervisor* with the option of turning on or off the collection of Patient ID during the test.

The *Supervisor* can also set length limits for the Patient ID and decide whether it will be possible to skip the patient ID during the test workflow (in case an emergency patient needs urgent testing but doesn't yet have a patient ID).

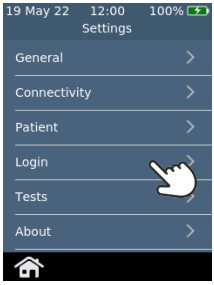


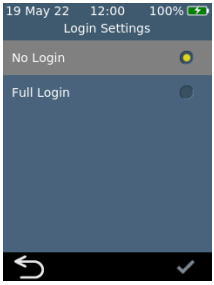


Login settings

The login settings provide the *Supervisor* with option of turning on or off login for all users. With login turned off, any user will be able to perform all functions (including access to the advanced settings in this section).

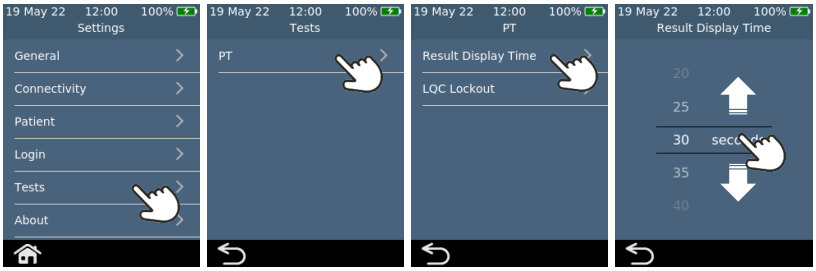
Note that in order to turn on login there must be an Operator list containing at least one *Supervisor* operator (see page 69).





Test settings – Display Time

By selecting *Tests*, then *PT* and then *Result Display Time*, the *Supervisor* can change how long the test result is shown before the user is prompted to eject the strip and clean the analyzer. Swipe up and down on the **Result Display Time** screen to increase or decrease the display time.

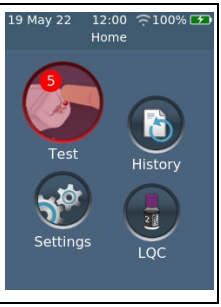


About LQC Lockouts

The *Supervisor* has the option of turning on the LQC lockout function. This function prevents patient tests from being run if:

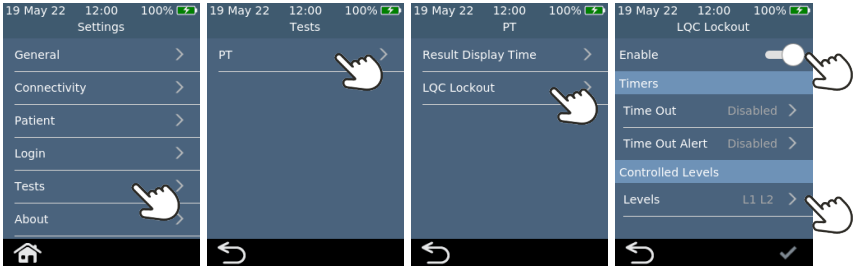
- the most recently performed LQC test failed or
- a LQC reminder expires.

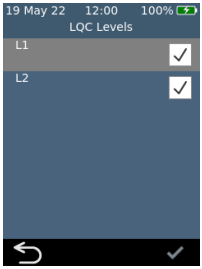
When an LQC lockout is active, the Test Button on the Home screen will glow red. If any bypasses are available (see page 77), the number of bypasses will be shown.



Enabling LQC Levels

The *Xprecia™ Systems PT Controls* kit contains two controls focused on different parts of the diagnostic range (low and high). The Supervisor can enable or disable LQC lockouts altogether. The Supervisor can also turn LQC lockouts on for one or both of the LQC levels.





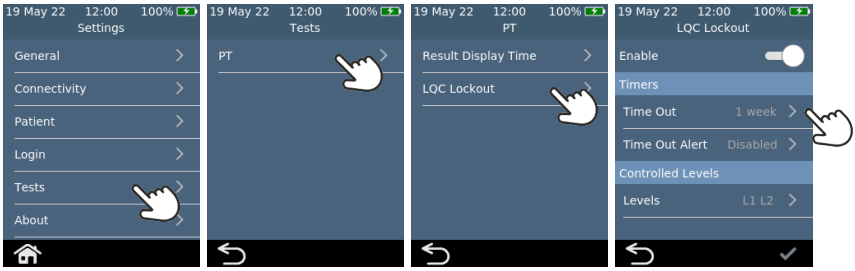
Enabling LQC Reminder Lockouts

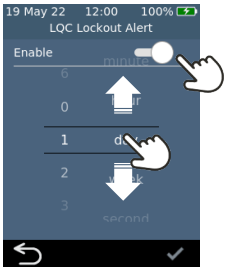
Once LQC Lockouts are enabled, the Supervisor can set the frequency of LQC reminders. When a LQC reminder expires, the analyzer will lock out until a successful LQC test is performed for each selected level.

Enabling LQC Lockout Alerts

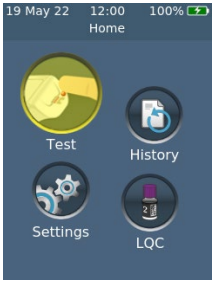
The supervisor can set up an alert to warn the user that an LQC reminder is about to expire. On the **LQC Lockout Alert** screen, the Supervisor can decide how long before the lockout an alert will

appear. For example, if the Supervisor selects 10 minutes, the alert will appear 10 minutes before the LQC reminder is due to occur.





When an LQC alert is due, the *Test* button on the **Home** screen will glow yellow.

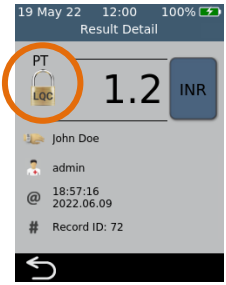


Enabling LQC Bypass (STAT)

Sometimes an LQC reminder lockout will occur when STAT (Short Turn Around Time) patient test must be performed. To address this need, the Supervisor can allow defined operators to bypass a LQC reminder lockout. Each LQC lockout can only be bypassed up to five times. See page 77 for more details.

NOTE: bypassing an LQC lockout is only possible if the lockout is due to a reminder expiring. It is not possible to bypass a lockout due to a LQC test failing.

When LQC is bypassed to perform a patient test, the test's historical record will be marked with a special LQC Bypass padlock icon.



9. Webserver

The *Xprecia Prime™ Coagulation Analyzer* hosts an internal webserver that can be used to Manage Operator lists, Export past results, or upgrade the analyzer software.

What you'll need

1. Your *Xprecia Prime™ Coagulation Analyzer* connected to a wireless network (see page 66 for instructions) ***or*** by USB to a PC (using the USB cable that came with your analyzer).
2. An external device with a web browser that is connected to the same wireless network as the analyzer (e.g. laptop, tablet, smartphone) ***or*** a PC that is connected to the analyzer by USB.

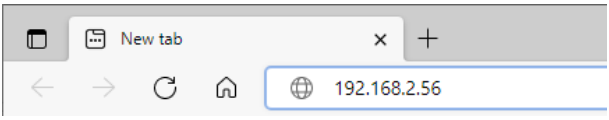
NOTE: USB Connection is not supported on macOS. We recommend using Wi-Fi for connectivity to a macOS device.

The analyzer does not support the use of the Internet Explorer web browser

Prioritize your external device's security when connecting to a network. Always use antivirus software, enable your operating system firewall, and ensure automatic updates are enabled.

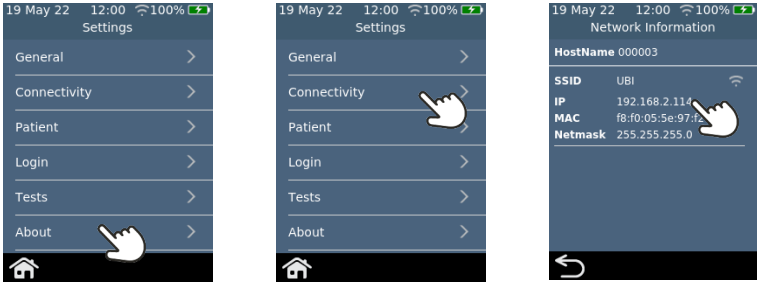
Connecting to the analyzer from an external device

If connecting by Wireless: on the external device, open a browser and navigate to your *Xprecia Prime™ Coagulation Analyzer's* IP address.



To find your *Xprecia Prime™ Coagulation Analyzer's* Wi-Fi IP address, do the following:

i. on your analyzer, tap *SETTINGS* from the **Home** screen,
ii. tap *About* on the **Settings** screen
iii. tap *Network Information* on the **About** screen and note the IP address of your analyzer

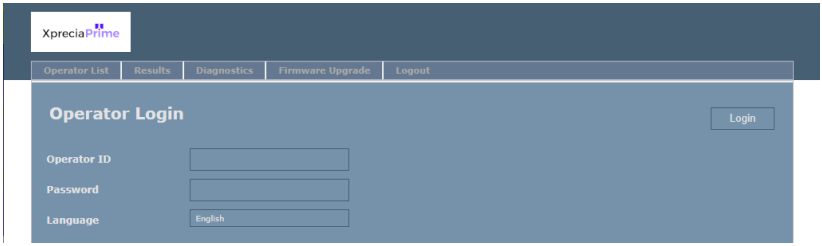


If connecting by USB, use the IP address 172.16.71.1

NOTE: Your browser may give you a security warning about the website not being secure (because the analyzer uses the http rather than the https protocol). This is not of concern because the connection between the analyzer and your device is happening within your wireless network or over USB.

Logging in to the webserver

At the **operator login screen**. Enter your Operator ID & password and then click the Login button.



First time log-in using default account settings

If you are logging in for the first time, or have not yet configured an Operator List, you will need to use the default credentials to access the Webserver.

The analyzers default Operator ID is 'admin' and default password is ‘admin’.

Logging out of the webserver

Click logout when you are finished to go back to the login page.

Operator lists

About the Operator list

The Operator list contains a list of operators with the following fields defined for each:

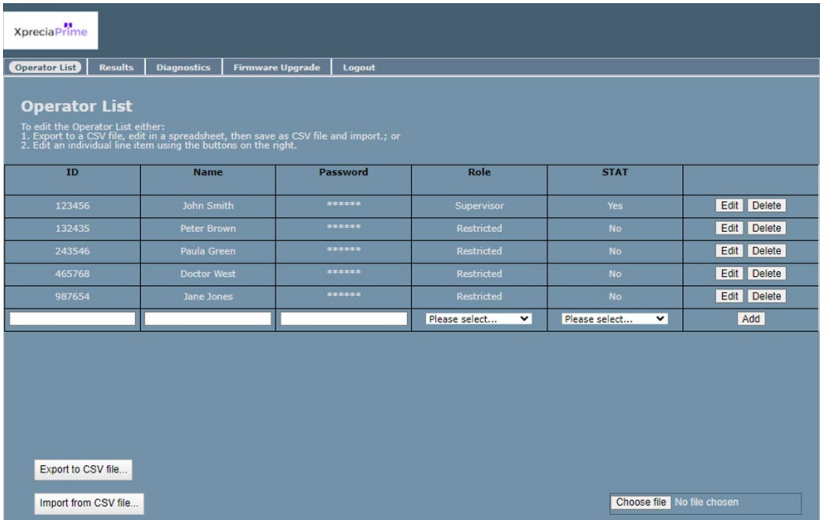
Field	Description
Operator ID	A free-text ID specific to this operator. See warning below.
Password	A free-text password (which can also be left blank). See warning below.
Name	A free-text field containing the Operators name.
Role	Supervisor or Restricted Restricted operators have access to a limited range of settings (see page 69)
STAT?	Yes or No This field defines whether this operator is allowed to bypass LQC reminder lockouts (see page 71)

NOTE: For Operator ID and Password, be careful to use only upper- and lower-case English language characters plus symbols limited to the keyboard on the analyzer screen or to the barcode symbology you plan to use.

How to set up the Operator list

To set up the Operator list, follow these steps:

1. Log into the webserver using the instructions on page 76.
2. Navigate to the Operator list tab.



3. Fill in the operator fields on the last row to add a new Operator or click 'Edit' on an existing row to edit an existing operator's details.

NOTE: The first account to be created must be a supervisor account. Universal Biosensors recommends Operator passwords are updated every 3 to 6 months.

Importing an Operator list

If you need to set up a large number of operators, you can export the operator list to a CSV file using the *Export to CSV File…* button. You can then use the spreadsheet program of your choice to update the list and then import the updated list using the *Import from CSV File…* button. Select the import/export file using the *Browse…* button.

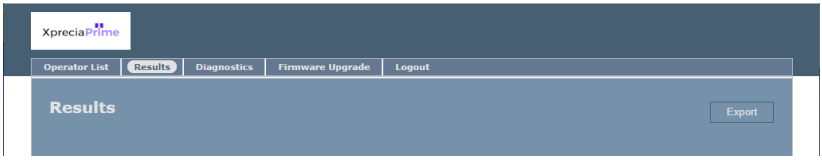
NOTE: When exporting the operator list to CSV file, the passwords will not be sent from the analyzer. However, you can import passwords in plain text format.

Exporting past results to an external device

Test results on the analyzer can be exported to an external device in text (comma-delimited) format.

Exporting the results

Select the Results tab, then click on the *"Export"* button and specify a location and filename.



Your results will be exported as a ZIP file. Inside the ZIP file will be a CSV (comma-delimited text) file (called "results_all.csv") which contains all of the historical results on the analyzer. This file can be opened in any spreadsheet program for easy filtering, sorting and analyzing. The first row contains headings for each column.

Firmware Updates

Upgrading Analyzer Firmware

There may be occasional firmware updates for your analyzer made available by Universal Biosensors. You should update your analyzer to the latest firmware as soon as possible. Ensure your analyzer's optimal performance by following the steps below for firmware updates:

- Upgrade your analyzer's Firmware through the webserver.
- Contact Universal Biosensors for the latest firmware upgrade file.

- Navigate to the Firmware Upgrade tab, click "Browse," and specify the upgrade file location.
- Press the Upgrade button to initiate the process

The firmware update should not change any settings or historical results on your analyzer. However, you should regularly export historical results to an external device for safekeeping. See page 79 for instructions on exporting historical results.

NOTE: The installation may take up to 10 minutes, and the analyzer will reboot twice during the upgrade process

Keep the analyzer connected to the supplied power adapter and do not power down the analyzer during the upgrade process.

10. Troubleshooting

Service, repairs and modifications must be done by parties explicitly authorized by Universal Biosensors. Service, repairs and modifications done by unauthorized parties will render the warranty void.

Contact Customer Support for further information (see page 81).

General troubleshooting

Situation	Solution
The test generated an unexpected result	The test should be repeated with a fresh sample. If a similar result is obtained, you may choose to confirm the result by other means. Inconsistent results could indicate poor test strip storage, poor sample collection or analyzer malfunction.
The touch screen and/or power button are unresponsive	Disconnect external power from the analyzer and then touch the power button for an extended period. Eventually (after 15 seconds or so), the screen will go black and the analyzer will turn off. If the problem persists, contact Customer Support.
Login option is not selectable	You must set up an Operator list before log in can be turned on. See page 75 for instructions.
Liquid Quality Control (LQC) failed	See the Liquid Quality Control troubleshooting section on page 82.

Liquid Quality Control (LQC) troubleshooting

In the event that a LQC test fails, consider performing the following actions in turn until a passing result is achieved:

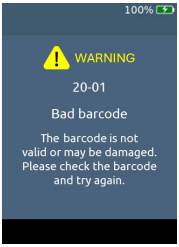
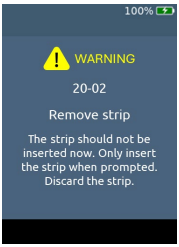
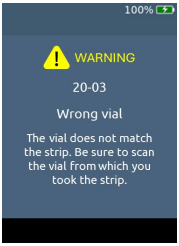
Step	Description
1	Repeat the test using a new strip from the same vial with a freshly prepared control solution.
2	Repeat the test using a new strip from a different vial (from the same lot) with a freshly prepared control solution. *If you don't have a different vial from the same lot, move to the next step.*
3	Repeat the test using a new strip from a different lot with a freshly prepared control solution.
4	Repeat the test using a new LQC kit from the same lot. *If you don't have a new LQC kit from the same lot, move to the next step.*
5	Repeat the test using a different lot of LQC.
6	If the above tests fail or you do not have the materials required, contact your authorized distributor (see "Customer Support" on page 97).

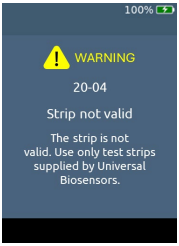
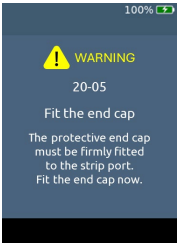
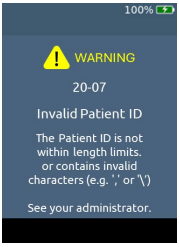
Warning and error messages

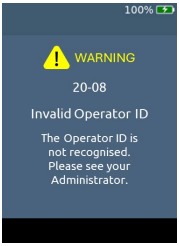
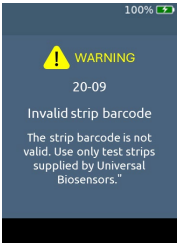
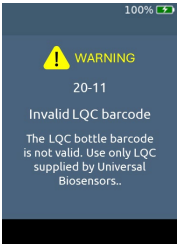
Warnings and errors are listed below in number order. To find the warning or error number, check the area under the WARNING or ERROR text in the top half of the screen.

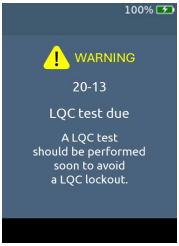
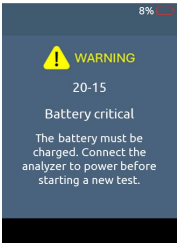
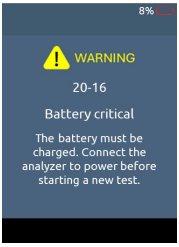
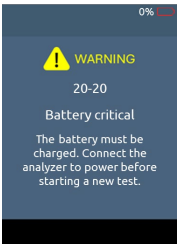
Whether a warning or error appears depends on the situation:

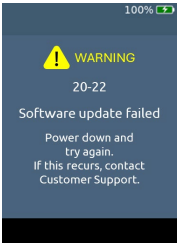
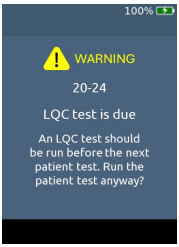
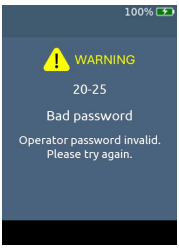
- **Warnings** inform you of something that needs to be corrected before a process can continue
- **Errors** inform you of an issue that is not recoverable (e.g. an issue that requires the test to be restarted with a new strip)

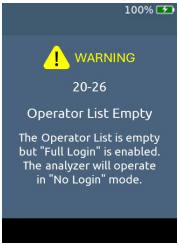
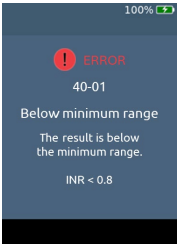
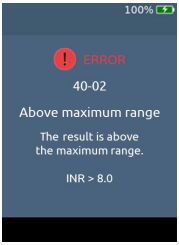
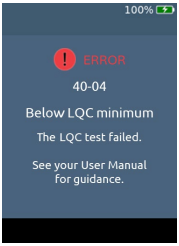
Warning/Error Screen	Cause	Solution
	A barcode was scanned but could not be read. This could either be because the barcode is damaged or not in a recognized format.	Check that the barcode isn't damaged. Ensure that all parts of the barcode are visible and not obscured during the scan. Try wiping the barcode clean and trying again.
	The test strip was inserted at an inappropriate time. The test strip should only be inserted after the analyzer displays the **Insert strip** screen.	Discard the strip and start a new test. The strip must not be reused after it has been inserted into the strip port.
	The barcode on the test strip does not match the barcode on the vial. Test strips are coded to match the vial from which they came from.	When prompted to scan a vial barcode, always be sure to scan the vial from which the strip was taken.

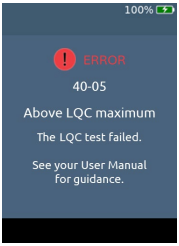
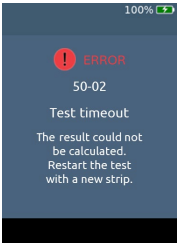
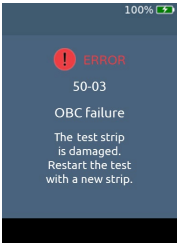
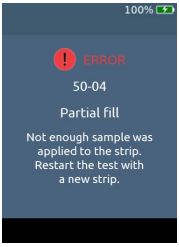
Warning/Error Screen	Cause	Solution
	The analyzer read a barcode, but the scanned barcode is not from an Xprecia Prime™ PT/INR Test Strip.	When prompted to scan a strip, always scan an *Xprecia Prime™ PT/INR Test Strip*. Other strips (e.g. PT/INR Strips for other Xprecia™ Systems) – will not work with the Xprecia Prime™ Coagulation Analyzer.
	The strip port's protective end cap (see item 4 on page 12) is not correctly fitted.	Fit the protective cap to the strip port. Keep the strip port's protective end cap firmly fitted at all times (except during cleaning - see page 55).
	The analyzer read a barcode but the scanned strip barcode is not compatible with the scanned LQC barcode.	You must only use *Xprecia™ Systems PT Controls* and *Xprecia Prime™ PT/INR Test Strips*. Other LQC or strips (e.g. PT/INR Strips for other Xprecia™ Systems) – will not work with the Xprecia Prime™ Coagulation Analyzer.
	The administrator has set length limits for the Patient ID. The scanned or entered Patient ID is too short or too long.	Check that you have scanned or entered a valid Patient ID. See your administrator if the problem persists.

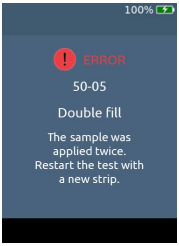
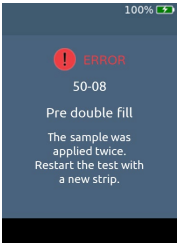
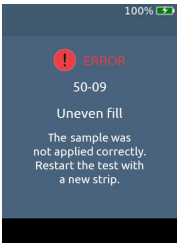
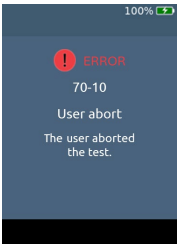
Warning/Error Screen	Cause	Solution
	You have tried to log in with an Operator ID that is not recognized.	Check that you have scanned or entered a valid Operator ID. See your administrator if the problem persists.
	The analyzer tried to scan a strip barcode, but there are problems with the information in the barcode, and it did not pass the quality check. There might be issues with the barcode readability.	When prompted to scan a strip, always scan an *Xprecia Prime™ PT/INR Test Strips*. Discard the test strip and start the test again with a new strip. If the error persists, contact Customer Support (see page 97).
	The analyzer read a barcode, but the scanned barcode is not from an *Xprecia Prime™ PT/INR Test Strip* vial.	When prompted to scan a strip vial, always scan an *Xprecia Prime™ PT/INR Test Strips* vial. You must only use *Xprecia Prime™ PT/INR Test Strips*. Other strips (e.g. PT/INR Strips for other Xprecia™ Systems) – will not work with the Xprecia Prime™ Coagulation Analyzer.
	The analyzer tried to scan an LQC barcode, but there are problems with the information in the barcode and it did not pass the quality check. There might be issues with the barcode readability. .	When prompted to scan a strip vial, always scan a *Xprecia™ Systems PT Controls* LQC plasma bottle. You must only use *Xprecia™ Systems PT Controls*. All other LQC kits will not work.

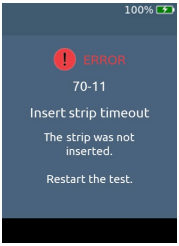
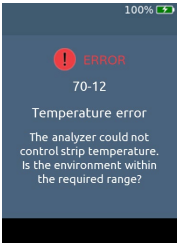
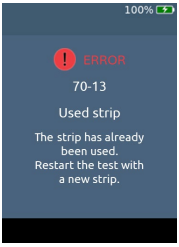
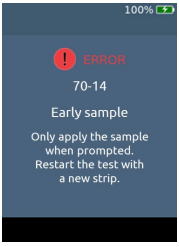
Warning/Error Screen	Cause	Solution
	Your analyzer is set to lockout if a LQC test is not performed periodically. In the near future, a lockout will occur unless the required LQC test(s) is performed successfully.	You can still run patient tests at this time, but an LQC test should be performed soon. See your administrator for details.
	The battery level has become critical (less than 20%) while a test is in progress. If a test has already been started prior to this warning message appearing, the test can be completed.	Before a new test can be started you must connect the analyzer to an external power source, which will also charge the battery.
	The battery level has become critical and there is insufficient battery to perform a test	Before a new test can be started you must connect the analyzer to an external power source, which will also charge the battery.
	The battery level has become critical and the device will shut down unless connected to power immediately.	You must connect the analyzer to an external power source, which will also charge the battery.

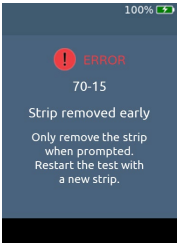
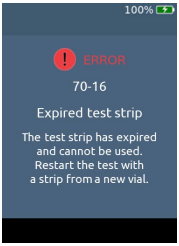
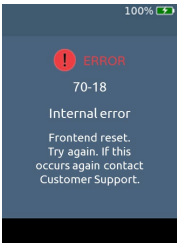
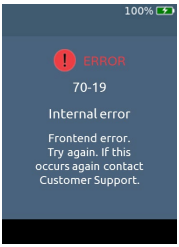
Warning/Error Screen	Cause	Solution
	When a software update is being performed the analyzer must be connected to external power. This is to ensure that the update will not be interrupted.	Connect the analyzer to external power and start the software update again.
	Something stopped the software update from being performed.	Start the software update again. If it continues to fail, contact Customer Support (see page 97). In the meantime, you can continue to use your analyzer using the existing software version.
	Your analyzer is locked out because a LQC test was not performed at the time set by your administrator.	If the patient test is urgent, you can choose to bypass the LQC lockout. See your administrator for details.
	You have tried to log in with a password that is not valid for the given Operator ID.	Check that you have scanned or entered the right password. See your administrator if the problem persists.

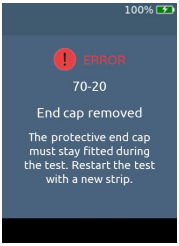
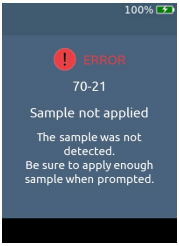
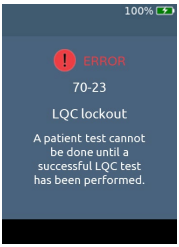
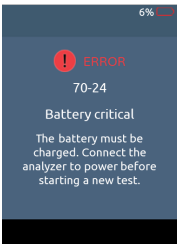
Warning/Error Screen	Cause	Solution
	The analyzer has been configured to require Operator login, but the Operator List is empty.	Follow the instructions on page 78 to set up an operator list on the analyzer.
	The measured result was below the measuring range of the *Xprecia Prime™ Coagulation System* (less than 0.8 INR).	Repeat the test with a fresh sample. Such results should be confirmed using an alternative test method (e.g. laboratory PT/INR).
	The measured result was above the measuring range of the *Xprecia Prime™ Coagulation System* (greater than 8.0 INR).	Repeat the test with a fresh sample. Such results should be confirmed using an alternative test method (e.g. laboratory PT/INR).
	The LQC test failed because the result was below the expected range. There are a number of possible causes for this. See page 82 for guidance.	Perform the troubleshooting steps on page 82.

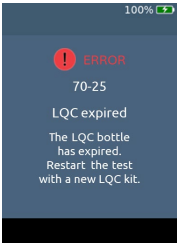
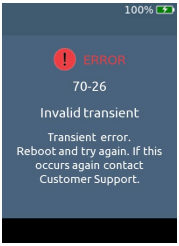
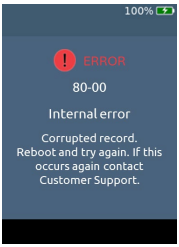
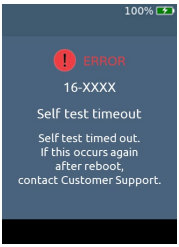
Warning/Error Screen	Cause	Solution
	The LQC test failed because the result was above the expected range. There are a number of possible causes for this. See page 82 for guidance.	Perform the troubleshooting steps on page 82.
	An analysis error occurred and the test result could not be calculated. Possible causes include too much analyzer movement, an unsupported sample type, a system fault, or test strips that have not been stored correctly.	Discard the test strip and start the test again. Apply the sample as instructed on page 31 & 41. If the error persists, contact Customer Support (see page 97).
	The test strip's on-board control (OBC) has detected that the strip is damaged and cannot be used. Possible causes include test strips that are damaged or test strips that have not been stored correctly.	Discard the strip and start a test with a new strip from the same vial (if available). If the error persists and you are sure the vial has been kept closed and at the correct storage temperature (see page 103), contact Customer Support (see page 97).
	Insufficient sample was applied to the strip and the test could not be completed.	You must apply sufficient sample to the test strip. Discard the strip and start the test again. Apply the sample as instructed on page 31 & 41.

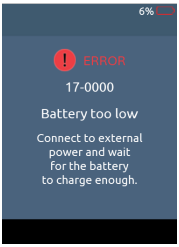
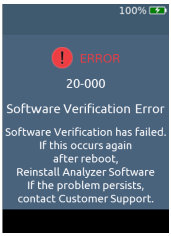
Warning/Error Screen	Cause	Solution
	Two or more sample dose applications were detected during application and the test could not be completed.	You must **not** apply additional sample to the test strip after the test has begun. Discard the strip and start the test again. Apply the sample as instructed on page 31 & 41.
	Two or more sample dose applications were detected during application and the test could not be completed.	You must **not** apply additional sample to the test strip after the test has begun. Discard the strip and start the test again. Apply the sample as instructed on page 31 & 41.
	The sample could not reach the strip's reaction chamber correctly. Possible causes include not filling the strip with sufficient sample or the strip porch is covered so the fill channel fills slowly.	Discard the test strip and start the test again. Apply the sample as instructed on page 31 & 41. If the error persists, contact Customer Support (see page 97).
	The user aborted a test after the strip was inserted.	Discard the strip and start a new test. The strip must not be reused after it has been inserted into the strip port.

Warning/Error Screen	Cause	Solution
	The strip was not inserted within the time limit provided on the **Insert strip** screen.	Start the test again and insert the strip when prompted by the analyzer.
	The analyzer could not adequately control the strip's temperature.	Make sure the ambient temperature is between 15 °C and 32 °C (59 °F to 89 °F) and restart the test with a new strip. You may need to allow time for the analyzer's temperature to stabilize. If the problem persists, contact Customer Support (see page 97).
	The inserted strip has already been used for a test (or the strip might have been handled with wet hands).	Discard the strip before starting a new test. If the error recurs, try a new vial of strips.
	The sample was applied too early.	Discard the strip before starting a new test. Apply the sample only when prompted by the analyzer.

Warning/Error Screen	Cause	Solution
	The test strip was removed before the test was finished.	Discard the strip before starting a new test. Ensure the strip is pushed fully into the strip port, and don't remove the strip until instructed.
	The test strip is past its expiry date.	Start the test again with a new strip from a vial that has not expired.
	The graphical user interface was forced to reset due to an internal error.	Turn the analyzer off and on. If the same error occurs, contact Customer Support (see page 97).
	The graphical user interface generated an error	Turn the analyzer off and on. If the same error occurs, contact Customer Support (see page 97).

Warning/Error Screen	Cause	Solution
	During a test, the strip port's protective end cap (see item 4 on page 20) was removed.	Fit the protective cap to the strip port and restart the test with a new test strip. Keep the strip port's protective end cap firmly fitted at all times (except during cleaning – see page 55).
	The sample was not applied at the time requested by the analyzer.	Discard the strip before starting a new test. Apply the sample when prompted by the analyzer.
	Your analyzer is set to lockout when either a LQC test fails or a LQC test is not performed periodically. A patient test cannot be performed until the required LQC test(s) is performed successfully.	Run a passing LQC test (or LQC tests if your analyzer requires Level 1 and Level 2 LQC to be performed). See your administrator for details.
	The battery is too low to start a new test.	Before a new test can be started you must connect the analyzer to an external power source, which will also charge the battery.

Warning/Error Screen	Cause	Solution
	The LQC kit is past its expiry date.	Start the test again with a new LQC kit that has not expired.
	An issue with the collected test result was identified and the test result could not be obtained.	Turn the analyzer off and on, then repeat the test. If the same error occurs, contact Customer Support (see page 97).
	There was an internal error, and the test result could not be read from the result log.	Turn the analyzer off and on, then repeat the test. If the same error occurs, contact Customer Support or (see page 97).
	The analyzer has not passed it's internal self test checks. Note: XXXX is a diagnostic number and will differ depending on the cause of the self test error.	Turn the analyzer off and on. If the same error occurs, contact Customer Support (see page 97).

Warning/Error Screen	Cause	Solution
	The battery is too low for the analyzer to operate, most likely because the analyzer has not been used for a very long time.	Before the analyzer can be used, you must connect the analyzer to an external power source to charge the battery enough for it to be used safely. This may take 30 minutes or more.
	The analyzer software has not passed its self verification checks and there may be an issue with the analyzer software.	Turn the analyzer off and on. If the same error occurs, reinstall the analyzer software or contact Customer Support or (see page 97).

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11. Customer support

If you have unanswered questions, or the *Xprecia Prime™ Coagulation System* is still not working as expected after you have tried the various troubleshooting options listed in chapter 10, contact your authorized distributor (see www.universalbiosensors.com) or email XpreciaHelp@universalbiosensors.com.

Ordering details

If you need replacement parts, contact your authorized distributor (see www.universalbiosensors.com).

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12. Appendices

Abbreviations and terms

The following abbreviations and terms are used throughout this guide:

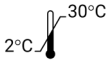
Abbreviation or term	Meaning
AC	Alternating Current
EMC	Electromagnetic compatibility
EU	European Union
FDA	Food and Drug Administration (USA)
LQC	(External) Liquid Quality Control
ID	Identifier
INR	International Normalized Ratio
mg/L	Milligrams per liter
PPM	Parts per million
PT	Prothrombin time
QSG	Quick Start Guide
STAT	Short Turn Around Time
USA	United States of America
USB	Universal Serial Bus

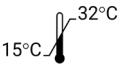
Prothrombin time

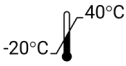
The *Xprecia Prime™ Coagulation Analyzer* also displays Prothrombin time (PT) results in seconds. The reported time is derived from the INR result and the equation below. The calculation is performed with an ISI of 1.0 and a typical Mean Normal Plasma Prothrombin Time of 12.0 seconds.

$$INR = \left(\frac{[\text{Patient Prothrombin Time (sec)}]}{[\text{Mean Normal Prothrombin Time (sec)}]} \right)^{ISI}$$

Labels and symbols

Label or symbol	Explanation
	Manufacturer: Universal Biosensors Pty Ltd 1 Corporate Avenue Rowville, 3178, Victoria Australia
	Manufacturer's declaration that the product complies with applicable European Union directives
	Read the User Manual before use
	Consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself
	Fragile
	Handle with care
	Single use only
	Serial number
	Product batch code
	Model Number: A0297
	Expiry date
	Keep dry
	This symbol indicates that the product has a storage temperature limitation and must be stored at 2 to 30 °C (35.6 to 86 °F).
	WEEE: The analyzer complies with EU 2012/19/EU. Do not dispose of the analyzer with normal rubbish. Refer to local regulations for disposal.

Label or symbol	Explanation
FCC ID	FCC registration identifier
	Keep out of direct sunlight
	Recycle
	This way up
	Contains sufficient strips for <n> tests
	The Regulatory Compliance Mark (for Australia and New Zealand)
	*In vitro* diagnostic device
	Biohazard – take appropriate precautions
	This symbol indicates that the product has an operational temperature limitation and should only be operated in environment temperatures between 15 °C to 32 °C (59 °F to 89 °F)
	This symbol indicates that the product has an operational humidity limitation and should only be operated in environments where relative humidity is less than 80% (without condensation).
	This symbol indicates that the product has an operational altitude limitation and should only be used when product altitude is less than 2000 m (6561ft) (assessed for electrical safety only).
	Quick start guide
	Xprecia Prime™ Coagulation Analyzer
	Power Supply
	User Guide
	Spare Cap (Strip port cover)

Label or symbol	Explanation
	This symbol indicates that the product has a storage temperature limitation and must be stored at -20 °C to 40 °C (-4 °F to 104 °F)
	This symbol indicates that the product has a storage relative humidity limitation and must be stored at < 75% (without condensation).
	Device for near-patient testing
	This product has not been sterilized
EC REP	Authorized representative in the European Community / European Union
	Importer: Universal Biosensors B.V. Locatellikade 1 1076 AZ Amsterdam Netherlands
	Distributor
	Country of manufacture
	Patient information website: www.universalbiosensors.com/products/xprecia

Technical specifications

General	
Input	5V ⎓ 0.9A
Rating	3.7V ⎓ 0.5A MAX
Capacity	1.85Ah (LI-ION)
Water Ingress Rating	IPX0
Pollution Degree Rating	Pollution Degree II
Overvoltage Category	Category I
Analyzer Operating conditions	
Temperature	15 °C to 32 °C (59 °F to 89 °F)
Relative humidity	< 80% (without condensation)
Altitude	Electrical safety tested up to 2000m
Transport and Storage conditions (in packaging)	
Temperature	–20 °C to 40 °C (–4 °F to 104 °F)
Relative humidity	< 75% (without condensation)
Altitude	Electrical safety tested up to 2000m
Test Strips Storage conditions	
Temperature	2 °C to 30 °C (35.6 °F to 86 °F)
Relative humidity	< 75% (without condensation)
LQC kit Storage conditions	
Temperature	2 °C to 8 °C (35.6 °F to 46.4 °F)
Sample	
Sample Types	Fresh Capillary blood from a fingerstick or Fresh venous whole blood
Sample Volume	At least 8 microliters
Haematocrit range	25 to 55% inclusive

Power Supply	
Model	GTM46161-165.0-USB
Input	100 – 240 V~, 50-60 Hz, 0.45 A Mains Supply Voltage Fluctuation +/-10%
Rating	5V ⎓ 3.2A
Operating Altitude	up to 5000 m
Operating Humidity	0 to 93 %
Operating Air Pressure	54 to 1060 hPa
Operating Temperature	0 ºC to 40 ºC (32 °F to 104 °F)
Features	
Measurement range	0.8 to 8.0 INR
Interface	Wireless (2.4GHz)
Automatic power off	Configurable: disabled, 5 mins, 15 mins, 30 mins
Dimensions	147 × 84 × 32 mm (5.79 × 3.31 × 1.26 in)
Weight	210 g (7.41 oz)
Design lifetime	The lifetime of the Analyzer is at least 3 years after the first test is conducted
Connectivity	
USB	Micro USB
Wi-Fi	802.11b/g/n Note: The Wi-Fi network must be secure.
PC Requirements	
Hardware	Wi-Fi adapter (for Wi-Fi Connection) Note: Device must be connected to the same wireless network as the analyzer. Spare USB Port (for USB Connection)
Software	Web browser Note: Internet Explorer is not supported USB connection not supported on macOS

Legal notices

Software licenses

The *Xprecia Prime™ Coagulation Analyzer* uses proprietary, third party and open source software. Details of licenses are available at: https://www.universalbiosensors.com/Modified-Third-Party-Software/
Use of the *Xprecia Prime™ Coagulation Analyzer* is subject to the terms of those licenses.

Disposing of the *Xprecia Prime™ Coagulation Analyzer*

The analyzer must not be disposed of with general rubbish. Contact your local distributor and/or local authorities for instructions on the disposal of the analyzer. Always comply with local procedures and guidelines for the disposal of electrical, electronic and hazardous waste.

Disposing of Xprecia Prime™ PT/INR Test Strips and Xprecia™ Systems PT Controls

Used *Xprecia Prime™ PT/INR Test Strips* and all components of the *Xprecia™ Systems PT Controls* kit must be disposed of as biohazardous waste.

In most regions, **unused** *Xprecia Prime™ PT/INR Test Strips* (and the vial they came in) can be disposed of with your general rubbish. You should ensure that the test strips are bagged separately.

Check with your local authorities for any special instructions that might apply in your jurisdiction.

European Union Radio Equipment Declaration

Hereby, Universal Biosensors, declares that this radio equipment (of type Coagulation Analyzer) is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.universalbiosensors.com

Radio emissions and electromagnetic compatibility

FCC Compliance 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.

CAUTION: The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications 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.

This equipment has been tested and meets applicable limits for radio frequency (RF) exposure as a portable device as per 47 CFR § 2.1093.

Canadian Compliance Statement

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1) L'appareil ne doit pas produire de brouillage;

2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

NOTE: This equipment complies with RSS-102 radiation exposure limits. This equipment was tested and found compliant for safe use as a handheld product.

REMARQUE: Cet équipement est conforme aux limites d'exposition aux radiations RSS-102 établies pour un environnement non contrôlé. Cet équipement a été testé et jugé conforme pour une utilisation en tant que produit portable.

13. Index

Notes:

Notes:

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