XPRECIA STRIDE USER GUIDE

CE

Made in MY

Siemens Healthcare Diagnostics Inc.
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EC REP Siemens Healthcare Diagnostics Ltd.
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 11065784 Rev. B | REF **11065585**

XPRECIA STRIDE USER GUIDE SIEMENS

XPRECIA STRIDE™

User Guide

Coagulation

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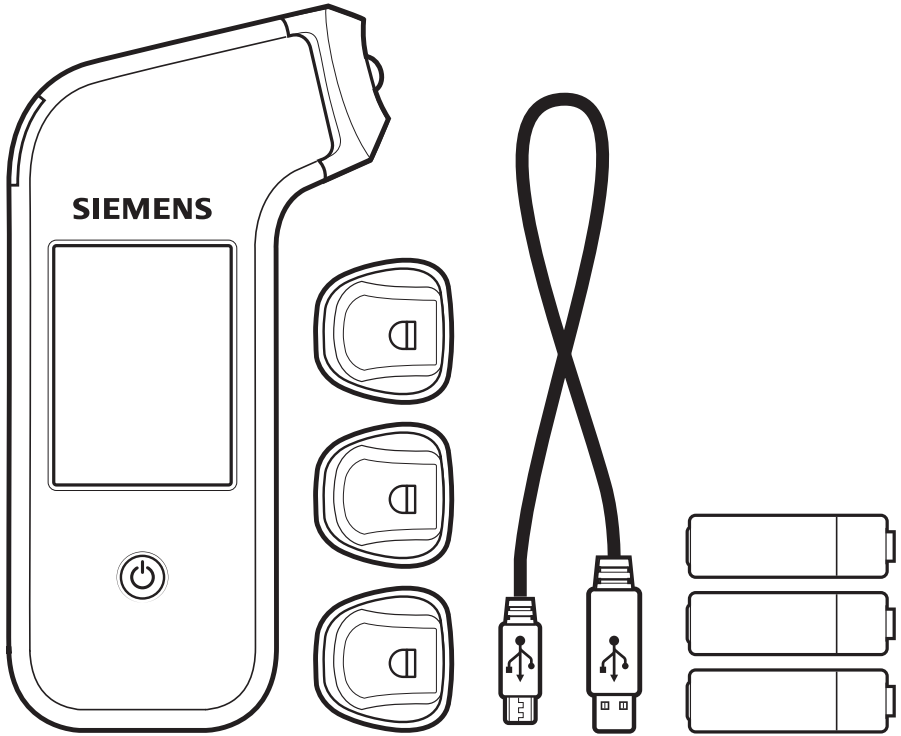
Start here.

What's Inside?



1. Exploring Stride

General warnings and precautions

- Always follow the safety procedures and precautions listed throughout this guide when using Stride.
- All parts of Stride are potentially infectious and capable of transmitting blood-borne pathogens between patients and healthcare professionals.
- You must disinfect the device after each patient use. You can only use Stride for testing patients when all standard precautions and the recommended cleaning and disinfection procedures in this guide are followed.
- Only use auto-disabling, single-use lancing devices with Stride.
- Refer to the following general safety reference materials for further information:
  - *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007, found at http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html.*
  - *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition Clinical and Laboratory Standards Institute (CLSI) M29-A3.*
  - *FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication (2010), found at http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.html.*
  - *CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens (2010), found at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.*
- Hematocrit range of 22–52% doesn't significantly affect test results.

Intended use

The Xprecia Stride™ Coagulation System, which includes the Xprecia Stride™ Coagulation Analyzer and the Xprecia™ System PT/INR Strips, is intended for use by professional healthcare providers to provide an INR (International Normalized Ratio) based on a prothrombin time (PT) response for the monitoring of oral anticoagulation therapy with warfarin, a vitamin K antagonist. The Xprecia Stride™ Coagulation Analyzer is intended to be used with only the Xprecia™ System PT/INR Strips and the Xprecia™ System PT Controls. The analyzer uses fresh capillary (fingerstick) whole blood applied to an Xprecia™ System PT/INR Strip. It is intended for *in vitro* diagnostic use at the point-of-care.

Xprecia™ System PT/INR Strips are for use with only the Xprecia Stride™ Coagulation Analyzer for PT/INR determinations by professional healthcare providers. This product is for *in vitro* diagnostic use.

The Xprecia Stride™ Coagulation System is intended for use in patients 18 years of age and older. Patients must be stabilized (> 6 weeks) on warfarin therapy. The Xprecia Stride™ Coagulation System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

Cleaning and disinfecting Stride

You must clean and disinfect the exterior of Stride, and the test strip port protective cap, after patient and quality control tests using a Siemens recommended germicidal wipe.

For more information on *Cleaning and disinfecting Stride*, see page 70.

Understanding blood-clotting time

Warfarin is prescribed to prevent blood clots from forming or growing larger in blood or blood vessels. When using anticoagulation medication, patients have to stay within a specific therapeutic range, as determined by their doctor. The doctor needs to monitor the warfarin activity to ensure that the medication dosage is correct. To monitor the activity, the doctor orders a PT test. A PT test is a blood test that measures the time it takes for blood to clot, reporting results using the International Normalized Ratio (INR). The INR was developed to standardize the PT results.

About the Xprecia Stride Coagulation Analyzer

Stride is a handheld *in vitro* diagnostic medical device that monitors blood-clotting coagulation values in small amounts of blood applied to test strips. Stride is a device for use in professional healthcare and point-of-care settings.

Rx ONLY

Electronic Quality Control (EQC)

When each test strip is inserted, Stride automatically conducts 2 on-strip quality control checks designed to help ensure test strip integrity. The first control checks the presence of adequate sample reagent on the test strip, and the second control detects test strip degradation due to exposure to environmental conditions.

What's in the box?

Stride is shipped with the following accessories:

– Test strip port protective caps in 4 colors that you can use to help identify multiple analyzers used in a point-of-care environment. The four colors are white (pre-installed on Stride), purple, green, and aquamarine.

Requirement Be sure the test strip port protective cap is always fully snapped in place before use.

– USB cable

– 3 AA batteries

– Data Management Software (DMS)

– Documentation Package
(User Guide and Documentation CD)

Other required materials

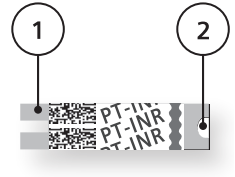
Required to process a patient sample, but not supplied:

– Alcohol wipe, cotton ball or tissue

– Single-use lancing device to obtain capillary blood samples obtained from a fingerstick. Prepare the lancing device according to manufacturer instructions.

– Xprecia System PT/INR Strips

Xprecia System PT/INR Strips



STRIP INSERTION

1 Insert
(contact end)

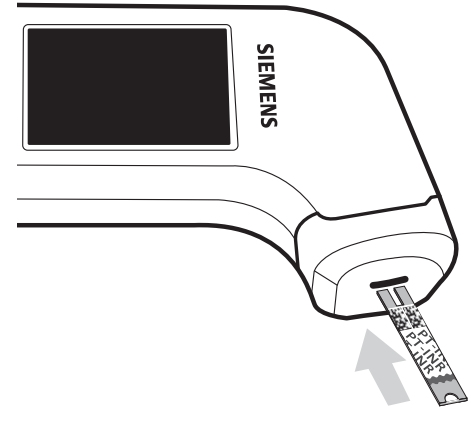
2 Blood target area

Each Xprecia System PT/INR Strip contains the reagent Dade® Innovin®, which is a preparation of purified recombinant human tissue factor combined with synthetic phospholipids, calcium chloride, and stabilizers.

Stride measures PT values in whole blood. To begin testing, the contact end of the test strip is inserted into the test strip port on the analyzer.

Then, a blood sample is applied to the test strip target area. The blood sample is automatically drawn by capillary action into the reaction chamber of the strip where the blood mixes with reagents and activates the coagulation cascade. When Stride senses that the blood has clotted, the testing stops. A PT result is calculated and appears on the analyzer as INR.

▼ Xprecia System PT/INR Strips are designed for use only with the Xprecia Stride Coagulation Analyzer. Other test strips won't work with Stride.



▲ Only apply blood to a test strip when it's inserted in Stride. Never use bent, scratched, or damaged test strips. Never use a test strip twice.

Xprecia System PT Controls

Quality control (QC) tests help maintain regulatory compliance requirements, as applicable to your facility. Use control solutions to perform quality control checks on Stride and the test strips to ensure they are functioning correctly.

Running a QC test on Stride is similar to running a patient test, except you use the Xprecia System PT Controls solution instead of a blood sample and follow a different workflow on the analyzer. For more information, see the *Xprecia System PT Controls Instructions for Use*.

The barcode on the control solution bottles is pre-coded with the control range information. Using this information, Stride indicates if the QC test results are acceptable or not.

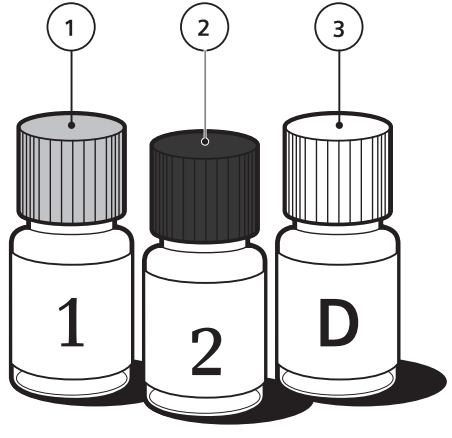
For more information on *Specifications*, see page 78.

CONSUMABLES

1 PT Control 1

2 PT Control 2

3 $CaCl_2$ Diluent



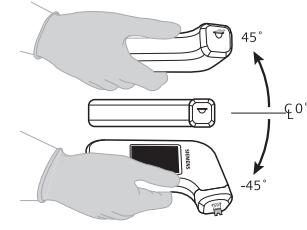
▲ You must perform a QC test at the start of each shift and with every new lot, new shipment, or as required by local, state, and federal or national regulations.

Holding Stride

Be sure to always handle Stride with care and don't mishandle it. Rough treatment or impact with hard objects, such as dropping, may damage parts and lead to incorrect operational results.

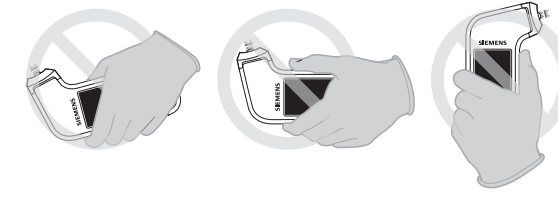
You can use Stride in the following positions:

▲ Flat on a tabletop or other hard surface (display side up)



▲ In your hand within a 45 degree angle up or down

▲ In your hand in a level position



▲ Don't run a patient test or QC test when holding Stride at extreme angles.

Setting up Stride the first time

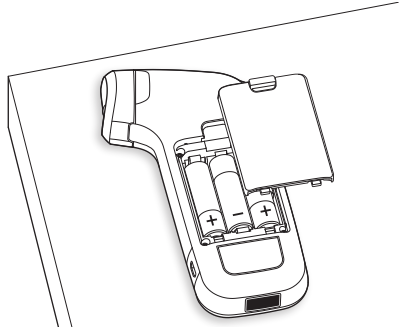
Before you use Stride, you first need to install the batteries and enter in some basic information. Follow these steps to get Stride ready for use after you remove it from the box.

Note Stride is a touch screen device, much like a smart phone or portable music player, so you use your finger to tap items on the screen to perform actions or enter information.

Installing the batteries

INSTRUCTIONS

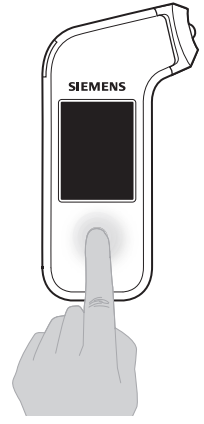
1. Press the latch on the battery compartment cover and pull it towards you to remove the cover.
2. Insert the 3 batteries.
3. Snap the battery compartment cover back into place.



Turning Stride on and off

INSTRUCTIONS

1. Press ⏻.



Setting the date

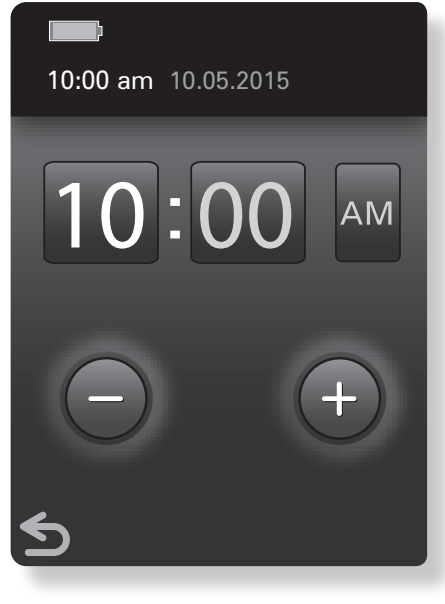
INSTRUCTIONS

1. Tap the month.
2. Tap − or + to enter the current month.
3. Tap the day.
4. Tap − or + to enter the current day.
5. Tap the year.
6. Tap − or + to enter the current year.
7. Tap Format to choose a date format.
8. Tap − or + to choose a date format:
   - MM.DD.YYYY
   - YYYY.MM.DD
   - DD.MM.YYYY
9. Tap ↩. Stride saves your changes.

Setting the time

INSTRUCTIONS

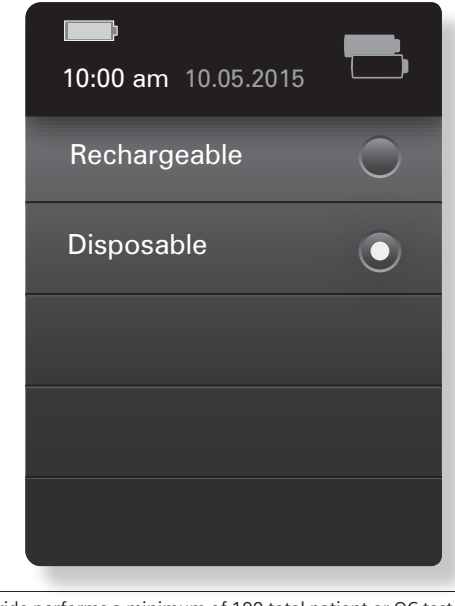
1. Tap the hour.
2. Tap − or + to enter the hour.
3. Tap the minutes .
4. Tap − or + to enter the minutes.
5. Tap AM to choose a time format.
6. Tap − or + to choose a time format:
   – 12-hour (AM or PM)
   – 24-hour
7. Tap ↩. Stride saves your changes.



Setting the type of battery

INSTRUCTIONS

1. Tap to choose:
   – rechargeable
   – disposable
2. Tap ↩. Stride saves your changes.



▲ Stride performs a minimum of 100 total patient or QC tests with disposable alkaline batteries under normal operating conditions. Performance results for rechargeable batteries can vary due to battery quality, number of recharge cycles, and age.

Adding an Operator ID (OID)

INSTRUCTIONS

1. On the Home screen, tap .
2. Tap .
3. Tap .

Adding a Patient ID (PID)

INSTRUCTIONS

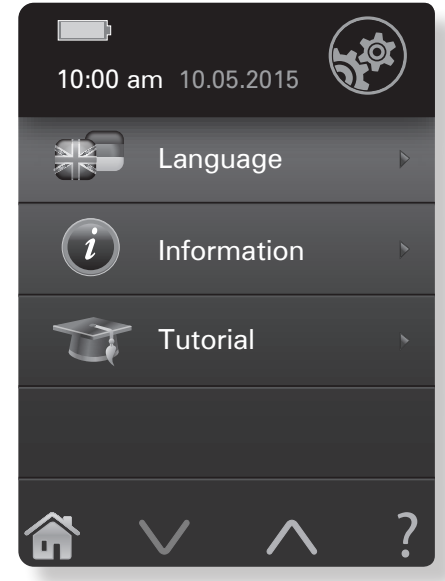
1. On the Home screen, tap .
2. Tap .
3. Tap .

Tip You can change your Stride settings to match your work environment. For example, you can require an operator password to use the device to perform a patient test.

Viewing the tutorials

INSTRUCTIONS

1. On the Home screen, tap .
2. Tap 3 times.
3. Tap .
4. Tap to choose the tutorial you want:
   - Patient Test
   - QC Test
   - Orientation
5. Tap to cancel viewing a tutorial.



For more information on *Tutorials*, see page 59.

Touch screen

To control Stride, use your fingers to tap the touch screen. When navigating Stride, you can tap one or more icons on the Home screen to select tasks to perform and to enter alphanumeric characters on certain screens. You can enter your Operator ID (OID) or Patient ID (PID) using the keypad or the barcode reader.

Entering information

You can enter information 2 ways:

– Touch screen

– Barcode reader

For more information on *Learning about the icons*, see page 18, and for information on *Learning about the Stride barcode reader*, see page 21.

Examining the Home screen

OVERVIEW

1 Battery Power

2 Time and Date

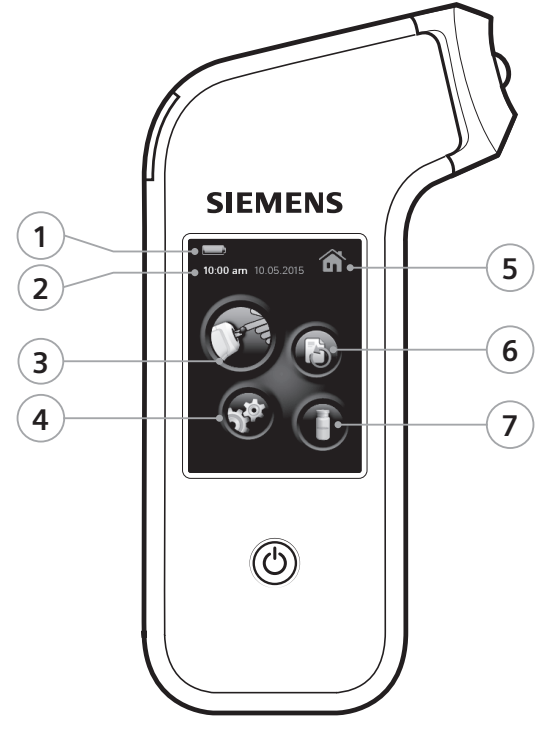
3 Patient Test

4 Settings

5 Current Screen

6 Recall Results

7 Quality Control Test



Learning about the icons

Home screen

Patient Test
Perform a patient test.

Settings
Customize Stride system settings.

Recall Results
Recall and view warning messages and error messages, patient test results, and QC test results.

Quality Control Test
Perform a QC test.

Navigating the screens

Back/Accept
Does one of the following:
– Returns to the previous screen
– Accepts the changes you've made and returns to the previous screen

Home
Displays the Home screen.

Page Down
Displays the next screen in a list.

Page Up
Displays the previous screen in a list.

Recall Results screen

Patient Test Results
View patient test results.

Quality Control Test Results
View QC test results.

Events Log
View a listing of error and warning messages.

Settings screen

Clock
Change the time.

Date
Change the date.

Analyzer
Customize the volume, brightness, battery type, default settings, and how results are displayed.

Administrator
Customize the administrator settings for Operator ID (OID), Patient ID (PID), and Login.

Language
Change your language settings.

Information
View Stride software version number.

Tutorial
Learn how to perform a patient test, QC test, or hold Stride.

General action

Scan
Use the barcode reader to scan lot information, an Operator ID, or a Patient ID.

Help
Displays help information for a task or the current screen.

Keypad
Use the keypad to enter information.

Scanner
Use the barcode reader to scan information.

Keypad screens

Alphabetic keypad
Tap to display the alphabetic keypad to enter lowercase and uppercase letters.

Extended keypad
Tap to display the extended keypad to enter special characters.

Numeric keypad
Tap to display the numeric keypad to enter numbers.

Spacebar
Tap to enter a space.

Delete
Tap to delete a letter, number, or character you entered.

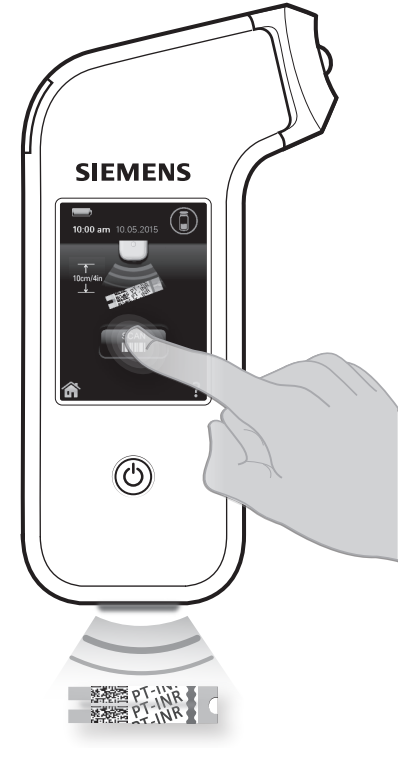
Uppercase
Tap to enter uppercase letters.

Lowercase
Tap to enter lowercase letters.

Accept
Tap to accept your entry.

Learning about the Stride barcode reader

When Stride requires information it prompts you to use the barcode reader. The barcode reader enables you to easily scan important information about the test strips and test strip vials that you are currently using directly into Stride. This information includes calibration, control range, the lot number, and expiration date. You can also use the barcode reader to enter an Operator ID (OID), Patient ID (PID), and a control lot number.



Operating the barcode reader

INSTRUCTIONS

1. Hold the analyzer 10 cm (4 inches) from the barcode.
2. Aim the barcode reader at the item you want to scan (test strip vial, test strip, or QC vial).
3. Tap SCAN.

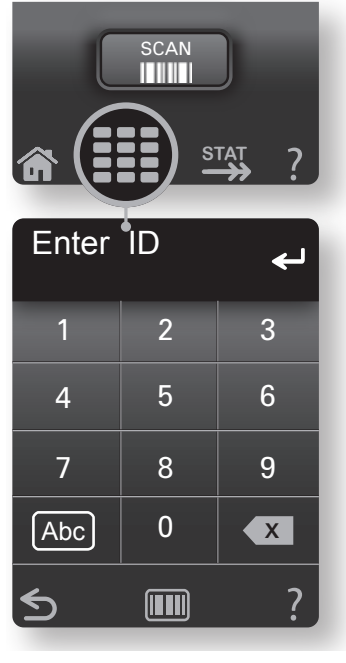
   Tip An audible tone sounds, a check mark displays, and the screen changes when the barcode is accepted.

Learning about the Stride keypad

The touch screen keypad is another way you can enter information, such as your Operator ID (OID) or a Patient ID (PID), into Stride. Stride displays the keypad icon when you can use it to enter information.

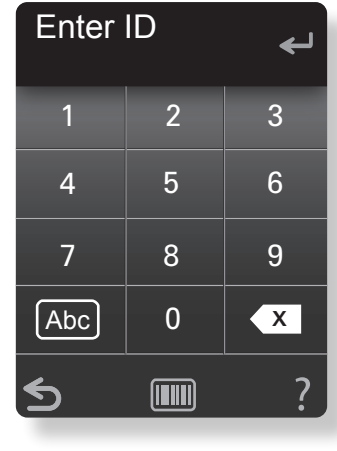
You can also set the keypad to be the primary way to enter information.

For more information on *Changing the administrator settings*, see page 56.

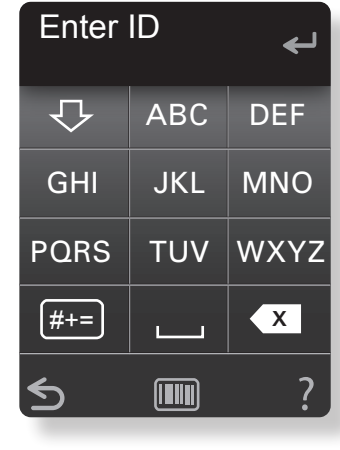


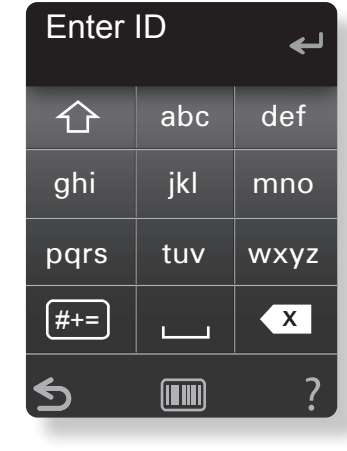
▲ If you make a mistake entering a number or letter, tap X to delete and enter the number or letter again.

Keypad input modes



Numeric keypad allows you to input the numbers 0 through 9.





Alphabetic keypad allows you to the input either uppercase letters or lowercase letters.

Extended keypad allows you to input special characters.

Keypad screens

Abc	**Alphabetic keypad** Tap to display the alphabetic keypad to enter lowercase and uppercase letters.
#+=	**Extended keypad** Tap to display the extended keypad to enter special characters.
123	**Numeric keypad** Tap to display the numeric keypad to enter numbers.
␣	**Spacebar** Tap to enter a space.
X	**Delete** Tap to delete a letter, number, or character you entered.
⇧	**Uppercase** Tap to enter uppercase letters.
⇩	**Lowercase** Tap to enter lowercase letters.
↵	**Accept** Tap to accept your entry.

Using the numeric keypad

INSTRUCTIONS

1. Tap to display the keypad.
2. To enter numbers, tap the key that corresponds to the number you want.
3. When you are done, tap ↵.

Using the alphabetic keypad

INSTRUCTIONS

1. Tap to display the keypad.
2. Tap Abc to use the alphabetic keypad.
3. Choose to do one of the following:
   - To enter lowercase letters
     Tap ⇩ and then tap the key that corresponds to the letter you want until it appears on the display.
   - To enter uppercase letters
     Tap ⇧ and then tap the key that corresponds to the letter you want until it appears on the display.
   - To enter a space
     Tap ␣.
4. Wait for the blinking cursor before entering the next letter.
5. When you are done, tap ↵.

Using the extended keypad

INSTRUCTIONS

1. Tap to display the keypad.
2. Tap Abc.
3. Tap #+= to enter special characters.
4. Tap the key that corresponds to the character you want until it appears on the display.
5. When you are done, tap ↵.

   Tip Tap 123 to display the numeric keypad.

Xprecia Data Management Software (DMS)

The Xprecia Data Management Software (DMS) provides a simple and easy way to transfer data from Stride. Once a number of test results have been collected over a designated period of time, they can be uploaded into DMS. From there, test results from the DMS can be exported for further evaluation.

Requirement A computer running DMS is necessary to configure and upload results from Stride.

To install DMS and start uploading data, insert the DMS installation media into your computer and follow the installation instructions when prompted. Then plug the USB cable from your computer into Stride and use DMS to export the test results.

ⓘ For complete information on DMS installation and usage information, refer to the DMS online help.

Using DMS, you can:

– Set up and manage operators

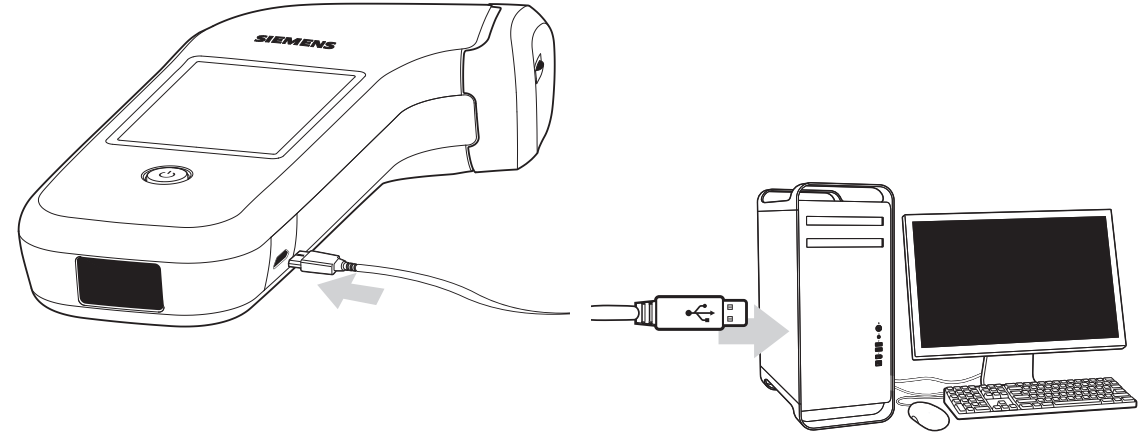
– Configure and upgrade Stride devices

– Search and export both patient test results and QC test results

– View error and fault log information on Stride devices

IMPORTANT

When connected, Xprecia DMS overwrites any Stride user settings and updates the Operator ID (OID) list with the latest updates from DMS to Stride.



▲ You can't conduct tests when connected to DMS.

Learning more

User Guide

This user guide describes Stride features and explains how to use the test strips and control solution. Read this manual carefully and keep it for future reference.

Test strip instructions for use

Read the instructions for use (IFU) that shipped with your Xprecia System PT/INR Strips. The IFU contains important information about your test strips. Keep the IFU for future reference.

Control solution instructions for use

Read the IFU that shipped with your Xprecia System PT Controls kit. The IFU contains important information about your current kit. Keep the IFU for future reference.

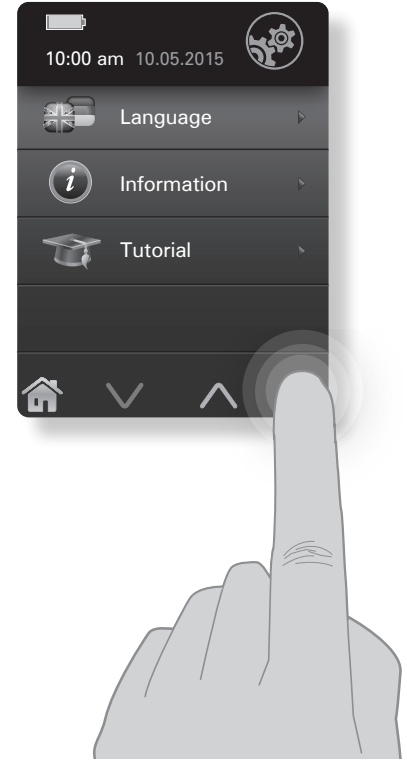
Onboard user assistance

Stride provides you with 2 types of onboard user assistance, Tutorials and Help.

Viewing a tutorial

INSTRUCTIONS

1. On the Home screen, tap .
2. Tap .
3. Tap to choose:
   – Patient Test
   Walks you through performing a patient test
   – QC Test
   Walks you through performing a QC test
   – Orientation
   Shows you how to hold Stride whether you are right-handed or left-handed



Getting Help

INSTRUCTIONS

1. Tap ? wherever it appears to get help with Stride.

2. Performing a patient test

Warnings and cautions for running a patient test

Always follow these safety and usage guidelines for the most accurate results:

– Don't take test strips internally or drink control solutions.
– Always store the test strips in the original test strip vial with the cap closed.
– Use the test strip within 5 minutes of when you remove it from the test strip vial.
– Use only fresh capillary (fingerstick) whole blood for tests.
– Hematocrit range of 22–52% doesn't significantly affect test results.
– Apply the blood sample to the test strip within 120 seconds after the Apply Sample screen displays.
– Always wear protective gloves and follow your facility's policies and procedures when performing tests involving biological samples and control solutions.
– Only apply blood to a test strip after it's inserted in, and blood is requested by, Stride.
– Never use bent, scratched, or damaged test strips.
– Don't scan a test strip barcode and then use a different test strip from another vial.
– Each test strip is single-use only; never perform a second test using the same test strip.
– Don't touch or move the test strip after you apply the drop of blood. Don't move the test strip during the test.
– Never add more blood to the test strip after the test has begun.
– Refer to the *Xprecia System PT/INR Strips Instructions For Use* for more information on test strips.
– A best practice is to make sure there is adequate lighting to conduct a test.
– Don't conduct tests when connected to Xprecia DMS.
– Always thoroughly wash and dry your hands and put on a new pair of gloves for each patient test.
– See *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* found at http://www.cdc.gov/biosafety/publications for more safety information.

Disposing of waste

Observe the following guidelines when disposing biohazardous waste:

– Dispose of used lancets in an approved sharps container.
– Dispose of used test strips in an approved biohazard container.
– Always follow your facility's biohazard disposal policies.

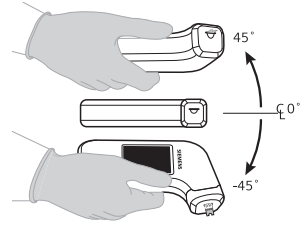
▶ When ejecting a used test strip, always point Stride down facing your biohazard container before you press the Test Strip Eject button.

Holding Stride

Be sure to always handle Stride with care and don't mishandle it. Rough treatment or impact with hard objects, such as dropping, may damage parts and lead to incorrect operational results.

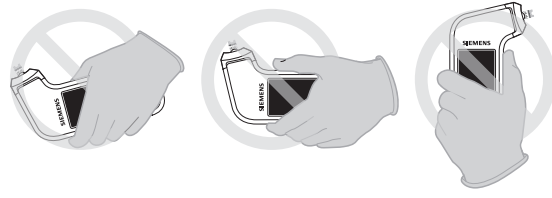
You can use Stride in the following positions:

▲ Flat on a tabletop or other hard surface (display side up)



▲ In your hand within a 45 degree angle up or down

▲ In your hand in a level position



▲ Don't run a patient test when holding Stride at extreme angles.

Preparing the patient samples for testing

Prepare the patient to collect a blood sample by following your facility's standard procedure.

For example, clean the finger with an alcohol wipe, or have the patient wash his or her hands in warm, soapy water. Dry the fingertip before taking a blood sample.

Only use fresh whole blood from a capillary (fingerstick) source with test strips.

IMPORTANT

- *Within 15 seconds of sticking the fingertip, apply the drop of blood to the test strip target area.*
- *Don't add more blood to the test strip once the test has begun.*
- *Don't touch the test strip while the test is in progress.*
- *Discard expired test strip vials.*

Performing a patient test

INSTRUCTIONS

1. To turn Stride on, press ⏻.
2. If you are prompted, enter an Operator ID (OID).
3. On the Home screen, tap  .
4. If you are prompted, enter a Patient ID (PID).
5. Open the test strip vial and remove 1 test strip.
6. Immediately close the vial.
   Make sure the vial cap seals tightly.
7. To scan the test strip barcode, aim the barcode reader at the barcode on the test strip, then tap 

   .

   Tip An audible tone sounds, a check mark displays, and the screen changes when the barcode is accepted.
8. Gently, but firmly, insert the test strip with the printed side up into the test strip port until it stops.

Continue to the next page

9. (Optional) If Stride requests that you scan the test strip vial, aim the barcode reader at the barcode on the test strip vial, then tap SCAN.
10. The Wait screen displays as Stride warms the test strip until it reaches operating temperature, approximately 30 seconds.
11. After the Apply Sample screen displays, prepare and apply the patient blood sample. See the following:

    – *Collecting a fingerstick blood sample on page 38*.

    The test begins when the sample is drawn into the test strip by capillary action.

    Requirement Be sure to fill the entire target area with blood. Don't overfill the target area.
12. After the Test in Progress screen displays, don't touch the test strip or add more blood. The INR value, time, and date display when the test is complete.

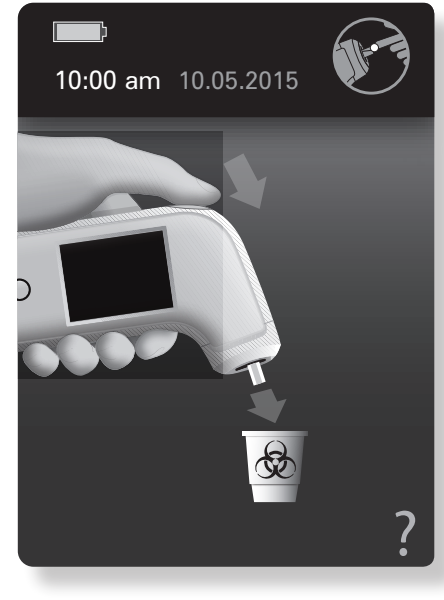
    Tip You can set Stride down to tend to the patient while the test is in progress.
13. Press the Test Strip Eject button to discard the test strip according to your facility's biohazard control policies.

    Requirement When ejecting a used test strip, always point Stride down facing your biohazard container before you press the Test Strip Eject button.
14. Discard the lancet according to your facility's biohazard control policies.
15. Follow the instructions on page 70 to clean the entire exterior surface of Stride, and the test strip port protective cap, with a Siemens recommended germicidal wipe.

    Requirement You must clean and disinfect the device after each test.
16. Remove your gloves, thoroughly wash and dry your hands, and put on a new pair of gloves before performing another patient test.

IMPORTANT

Don't use any non-recommended germicidal wipes to clean Stride, as they will damage the exterior.



For more information on *Cleaning and disinfecting Stride*, see page 70.

Fingerstick sample collection method

Use the following instructions to obtain a fingerstick patient blood sample.

Requirement Only use auto-disabling, single-use lancing devices with Stride.

Collecting a fingerstick blood sample

INSTRUCTIONS

1. To stick the finger, firmly place the lancet against the finger and press the lancet trigger.
2. Gently squeeze from the base of the finger to form a round drop of blood. If the blood smears or runs, wipe it off with a tissue and gently squeeze another round drop of blood.

   Requirement The drop of blood should be about the same size as the test strip target area (a minimum of 6 µL in volume). Low sample volume will cause an error message.
3. Return to page 36 to follow steps 12–16.

IMPORTANT

Apply the drop of blood to the test strip target area within 15 seconds of lancing the fingertip.

Viewing patient test results

After you perform a patient test, the results display.

▲ The following information appears on the screen: INR value, time and date, Patient ID (PID), and Operator ID (OID) (if entered).

Understanding results

Results display in the International Normalized Ratio (INR). Because desired ratios may vary depending upon the clinical practice and test methodologies, the optimum therapeutic range for this method should be established by each user.

Each lot of Xprecia System PT/INR test strips is calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation.[1]

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

The calculation is performed with an ISI of 1.0 and a typical Mean Normal Prothrombin Time of 12.0 seconds.

1. WHO Expert Committee on Biological Standardization. Forty-eighth Report. Geneva, World Health Organization, 1999 (WHO Technical Report Series, No. 889)

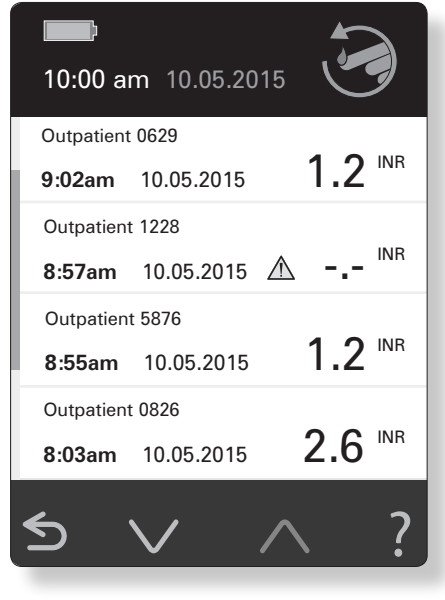
Recalling patient test results

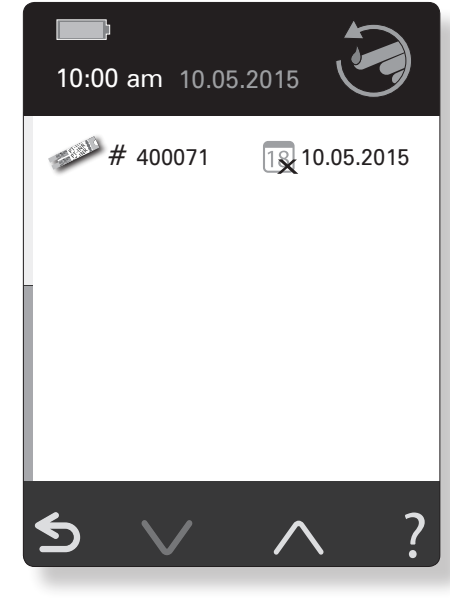
Stride stores and lets you retrieve a minimum of 640 patient test results. As new results are stored, the oldest results are overwritten.

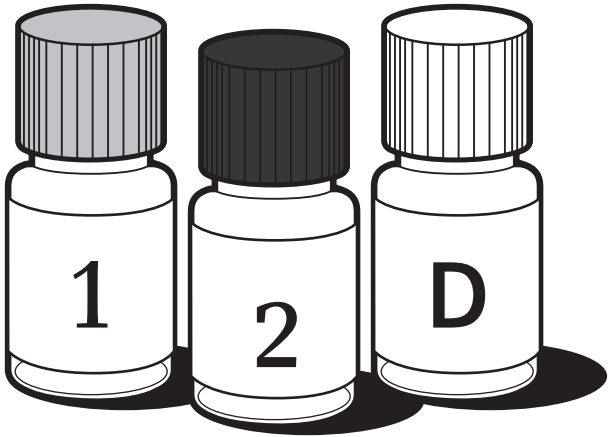
Recalling previous patient test results

INSTRUCTIONS

1. On the Home screen, tap  .
2. Tap  .
3. In the list of results, tap a result to view the details:
   - INR value
   - Time and date
   - Patient ID (PID), if entered
   - Operator ID (OID), if entered
4. Tap  .
   - Test strip lot
   - Test strip expiration date
5. Confirm the results as needed.







3. Performing a LQC test

Understanding the QC test

Always perform QC tests in accordance with local, state, and federal guidelines.

QC tests help maintain regulatory compliance requirements, as applicable to your facility. Use control solutions to perform quality control checks on Stride and the test strips to ensure they are functioning correctly.

About QC

The Xprecia System PT Controls kit contains assayed liquid quality controls (LQC) for the assessment of precision and analytical bias in the normal (Xprecia System PT Control 1) and therapeutic (Xprecia System PT Control 2) range for the International Normalized Ratio (INR) to be used with the Xprecia System PT/INR Strips.

The method-dependent assigned values and ranges for each lot of PT Control 1 and PT Control 2 appear on each vial as a barcode to be read by the Xprecia Analyzer. When the barcode on the control vial is scanned, the assigned range for each lot-specific level of LQC can be read on the analyzer screen display as an INR value.

The assigned ranges are set as ± 0.2 INR from the mean assigned value for PT Control 1 and ± 0.6 INR from the mean assigned value for PT Control 2. The assigned ranges are based on 2SD of the systems total variability.

You must perform QC tests at the start of each shift and with every new lot, new shipment, or as required by local, state, and federal or national regulations.

Refer to the *Xprecia System PT Controls Instructions For Use* for more information on quality controls.

Requirement Don't allow control solution to leak into the test strip port, as it may damage Stride.

Quality Control Description

PT CONTROL 1	lyophilized
	preparation of human plasma
	buffers
	stabilizers
PT CONTROL 2	lyophilized
	preparation of human plasma
	buffers
	stabilizers
$CaCl_2$ DILUENT	$CaCl_2$ solution [0.010 mol/L]
	Preservative: EC No. 247-500-7 – 5-chloro-2-methyl-4-isothiazolin-3-one
	Preservative: EC No. 220-239-6 – 2-methyl-4-isothiazolin-3-one

Reconstituting the control solution

INSTRUCTIONS

1. Have the test strip vial and the vial lot information on the vial available.
2. Ensure the bottle of control solution and the lot information are available.
3. Use one transfer pipette to combine the entire volume of 1 vial of diluent ($CaCl_2$) into 1 control vial.
4. Mix carefully, by swirling the bottle using a circular motion, to completely dissolve all of the control plasma inside. Don't shake in order to avoid foam formation.
5. Close the bottle and allow to stand for at least 5 minutes at 15–25°C (59–77°F).
6. Gently swirl the bottle again prior to use.

IMPORTANT

–Only use the control solution manufactured by Siemens to verify the performance of Stride.

–Retain the transfer pipette for use during the application of control solution to a test strip.

–Don't use the control solution after the expiration date on the bottle.

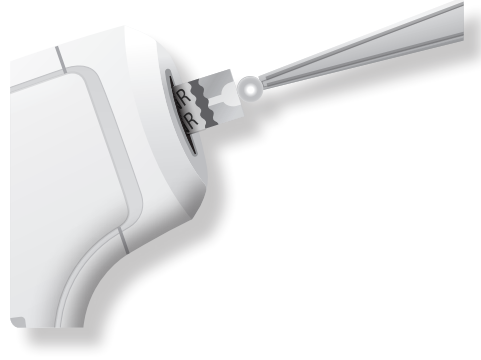
–To ensure proper results, make sure you perform a quality control test using Xprecia PT Control 1 and then repeat the test using Xprecia PT Control 2.

Performing a QC test

INSTRUCTIONS

1. On the Home screen, tap  .
2. Scan the lot information on the control solution bottle.
3. To scan the test strip barcode, aim the barcode reader at the barcode on the test strip, then tap  .

   Tip An audible tone sounds, a check mark displays, and the screen changes when the barcode is accepted.
4. Insert the test strip into the test strip port.
5. If required, scan the lot information on the test strip vial.
6. Place Stride on a level surface.
7. After Stride prepares for the QC test, apply the reconstituted control solution.
   - Horizontally position the transfer pipette so that the tip is almost touching the front edge of the test strip.
   - Gently squeeze the pipette base containing the control solution to apply some (a minimum of 6 µL) to the test strip target area. Capillary action draws the control solution into the test strip target area.
   - Stride sounds an audible tone when the test strip target area contains enough control solution.
   - Be careful to not overfill the test strip target area.



After the test finishes, read the result on screen.

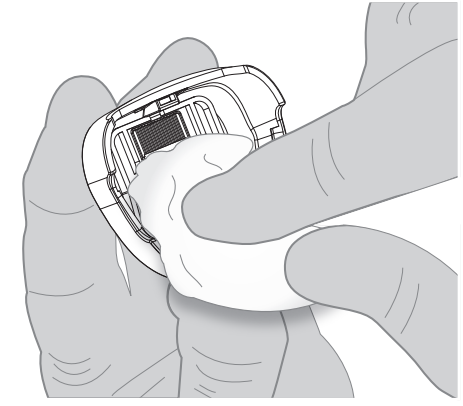
8. Press the Test Strip Eject button to discard the test strip according to your facility's biohazard control policies.

   Tip When ejecting a used test strip, always point Stride down facing your biohazard container before you press the Test Strip Eject button.
9. Follow the instructions on see page 70 to clean and disinfect the entire exterior surface of Stride, and the test strip port protective cap, with a Siemens recommended germicidal wipe.

   Requirement You must clean and disinfect the device after each test.
10. Remove your gloves, thoroughly wash and dry your hands, and put on a new pair of gloves before performing a patient test.

IMPORTANT

Don't use any non-recommended germicidal wipes to clean Stride, as they will damage the exterior.



Viewing QC test results

After you perform a QC test, the results display:

– INR value

– QC test sequence number

– Time and date

▲ QC Fail displays if the test results are out of range.

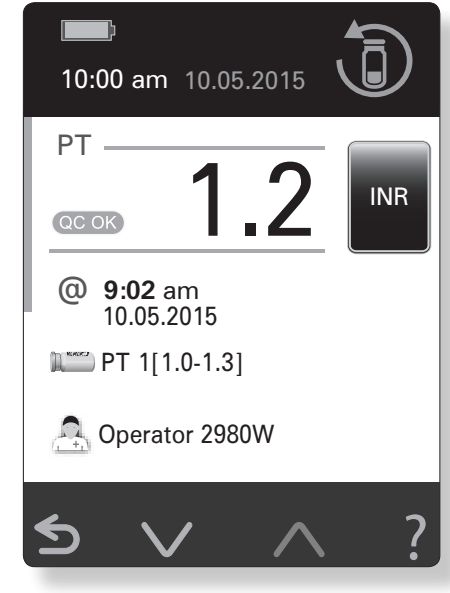
Recalling QC test results

Stride stores and lets you retrieve a minimum of 300 QC test results. As new results are stored, the oldest results are overwritten.

Recalling previous QC test results

INSTRUCTIONS

1. On the Home screen, tap .
2. Tap .
3. In the list of results, tap a result to view the details:
   – INR value
   – Time and date
   – Control solution lot and range
   – Operator ID (OID) (if entered)
4. Tap .
   – Test strip lot
   – Test strip expiration date
   – QC solution lot
   – QC solution date
5. Confirm the results as needed.



4. Changing the settings

Changing a setting

To change a setting, tap  , then tap the setting you want to change.

Changing the time

INSTRUCTIONS

1. Tap  .
2. Tap  .
3. Tap the hour or minutes box.
   The default selection is Hours.
4. Tap  or  to enter the hours and minutes.
5. To accept your changes and return to the previous screen, tap  .

Changing the time format

INSTRUCTIONS

1. Tap  .
2. Tap  .
3. Tap the 12-hour (AM or PM) or 24-hour (24h) box.
4. Tap  or  to set a time format:
   – 12-hour (AM or PM)
   – 24-hour
5. To accept your changes and return to the previous screen, tap  .

Changing the date

INSTRUCTIONS

1. Tap  .
2. Tap  .
3. Tap the month, day, or year.
   The default selection is Day.
4. Tap  or  to enter the month, day, and year.
5. To accept your changes and return to the previous screen, tap  .

Changing the date format

INSTRUCTIONS

1. Tap  .
2. Tap  .
3. Tap  .
4. Tap  or  to set a date format:
   – MM.DD.YYYY
   – YYYY.MM.DD
   – DD.MM.YYYY
5. To accept your changes and return to the previous screen, tap  .

Changing the analyzer settings

You can change the volume, brightness, and battery type, change patient and QC settings, and restore default settings for Stride.

Tip To view the next screen of settings, tap .

Changing the volume

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap or to set the volume:
   – on a scale from 0 (off) to 10 (high)
5. To accept your changes and return to the previous screen, tap .

IMPORTANT

When connected, Xprecia DMS overwrites any Stride user settings and updates the Operator ID (OID) list with the latest updates from DMS to Stride.

Changing the brightness

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap or to find the screen brightness you prefer.
5. To accept your changes and return to the previous screen, tap .

Changing the battery type

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap to choose:
   – rechargeable
   – disposable
5. To accept your changes and return to the previous screen, tap .

Restoring default settings

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap to Restore to default settings.
5. Tap to confirm or to cancel.

Setting patient or QC test results units

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap to choose:
   – Patient Test
   – QC Test
5. Tap to choose the units you want results to appear in:
   – INR
6. To accept your changes and return to the previous screen, tap .

Changing the administrator settings

You can change the settings for Patient ID (PID), and Login, and you can also add or remove an Operator ID (OID).
For example, you can set the device to require a password or allow an operator to perform a test without entering a Patient ID (PID).

Tip To view the next screen of settings, tap .

IMPORTANT

When connected, Xprecia DMS overwrites any Stride user settings and updates the Operator ID (OID) list with the latest updates from DMS to Stride.

Adding a Patient ID (PID)

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap Patient Test to allow Patient ID (PID) scanning for patient tests.
5. Tap STAT Test to allow an operator to skip Patient ID (PID) scanning for patient tests.
6. Tap to choose the Entry Type:
   – for barcode reader
   – for keypad
7. Tap Minimum.
8. Tap or to enter the minimum number of characters for the PID.
9. Tap Maximum.
10. Tap or to enter the maximum number of characters for the PID.
11. To accept your changes and return to the previous screen, tap .

Adding an Operator ID (OID) Login

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Tap Enable to require a password to use the device.
5. Tap Validate to compare the password against a list of valid passwords stored on Stride.
6. Tap to choose the Entry Type:
   – for barcode reader
   – for keypad
7. Tap Minimum.
8. Tap or to enter the minimum number of characters for the login.
9. Tap Maximum.
10. Tap or to enter the maximum number of characters for the login.
11. To accept your changes and return to the previous screen, tap .

Adding an Operator ID (OID)

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Scan or enter the OID.
5. Tap to confirm or to cancel.

Removing an Operator ID (OID)

INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Scan or enter the OID.
5. Tap to confirm or to cancel.

Changing the language

INSTRUCTIONS

1. Tap .
2. Tap 2 times.
3. Tap .
4. Tap to choose the language you want:
   - English
   - Français
   - Deutsch
   - Español
   - Dansk
   - Português
   - Italiano
5. To accept your changes and return to the previous screen, tap .

Viewing the system information

INSTRUCTIONS

1. Tap .
2. Tap 2 times.
3. Tap .

Tutorials

To pause a tutorial screen, press and hold your finger on the screen. Remove your finger to continue the tutorial.

Viewing the tutorials

INSTRUCTIONS

1. Tap .
2. Tap 3 times.
3. Tap .
4. Tap to choose the tutorial you want:
   - Patient Test
   - QC Test
   - Orientation
5. Tap to cancel viewing a tutorial.

5. Performing troubleshooting and maintenance

Learning about system messages

Stride stores and lets you retrieve a minimum of 300 system messages, comprised of warning messages and error messages:

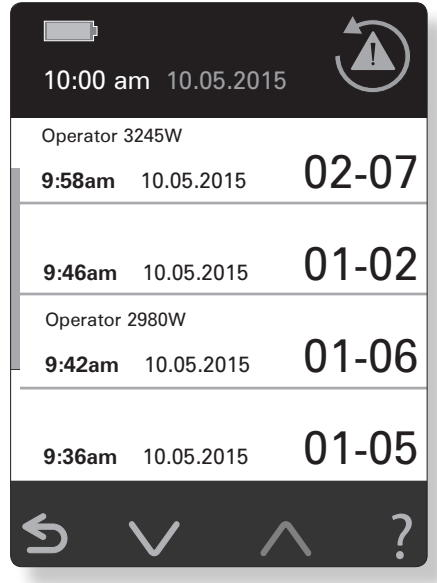
Warning message Stride detects a problem, displays a message, and once you correct the problem, you can continue the test. These messages are stored in the Events log.

Error message Stride detects a problem, displays a message, but you can't continue testing. These messages are stored with the test results.

Viewing the system messages

INSTRUCTIONS

1. On the Home screen, tap  .
2. Tap  .



▲ The most recent system messages display at the top of the list, showing the time, date, warning, or error code.

Troubleshooting system messages

Warning messages

CODE	MESSAGE	PROBABLE CAUSE	POSSIBLE SOLUTION
01-01	*Barcode scan error*	Stride encountered an unknown error while scanning.	Try to scan again. If the error continues, turn Stride off and on.
01-02	*Battery Low*	Your batteries are running out.	Replace with 3 new AA batteries.
01-04	*Invalid Login*	An incorrect Operator ID (OID) was entered.	Try reentering the Operator ID (OID).
01-05	*Invalid OID*	An incorrect Operator ID (OID) was entered.	Try reentering the Operator ID (OID).
01-06	*Invalid PID*	An incorrect Patient ID (PID) was entered.	Try reentering the Patient ID (PID).
01-07	*LQC Expiration date exceeded*	Your lot of control solution has reached its expiration date.	Verify the Stride date setting is correct and then redo the test using a different control lot.
01-08	*OID delete failed*	Stride encountered an error trying to delete the Operator ID (OID).	Make sure you have administrator rights to delete an OID and that the OID is valid.
01-09	*OID list full*	The operator list is full.	Remove one or more operators from the list.
01-10	*Test strip port protective cap missing*	The test strip port protective cap was not installed properly.	Align tab in cap with slot and slide cap until it clicks into place.
01-11	*Test strip inserted early*	The test strip was inserted before Stride requested.	Remove test strip and insert when Stride prompts you.
01-12	*Test strip and vial do not match*	You may have scanned a test strip from a different lot.	Verify the test strip is from the correct vial and rescan. If the error continues, cancel the test and repeat using a new test strip from the vial.

Warning messages

CODE	MESSAGE	PROBABLE CAUSE	POSSIBLE SOLUTION
01-13	*Test strip or LQC vial not valid*	Stride encountered an unknown error scanning the test strip or vial.	Scan the test strip or vial again. If the error continues, cancel the test and repeat using a new test strip from the vial.
01-16	*Data integrity error*	Stride encountered an unknown internal error.	Turn Stride on and off.

Error messages

CODE	MESSAGE	PROBABLE CAUSE	POSSIBLE SOLUTION
02-01	*Apply sample timeout*	You didn't apply the sample within 2 minutes.	Redo the test and apply the sample when prompted by Stride.
02-02	*Used test strip inserted*	You attempted to use an already processed test strip.	Discard test strip and restart test with a new strip.
02-03	*Early fill error*	You attempted to apply a patient or QC sample before Stride was ready.	Redo the test and only apply the sample when prompted by Stride.
02-04	*Early test strip ejection*	You ejected the test strip before Stride was finished processing the results.	Discard test strip and restart test with a new strip.
02-05	*Expired test strip*	The test strip is beyond the expiration date.	Verify the Stride date setting is correct and then redo the test using a test strip from a new vial.
02-07	*Test strip port protective cap removed*	You removed the test strip port protective cap during a test.	Align tab in cap with slot and slide cap until it clicks into place. Redo the test with a new strip.
02-08	*Test aborted*	You canceled a test in progress.	Redo the test with a new strip.
02-09	*Critical battery level*	Your batteries are almost out of power.	Replace with 3 new AA batteries.
02-10	*Communications error*	Stride encountered an unknown communication error.	If you are connected to a PC, disconnect the USB cable and then reconnect it again to the PC. If you are upgrading the Stride firmware, cancel and restart the upgrade.
02-11	*Heater control error*	Stride encountered an error with the internal heater.	Turn Stride off and on. If the error persists, you may need to replace the Stride analyzer.

Error messages

CODE	MESSAGE	PROBABLE CAUSE	POSSIBLE SOLUTION
04-01	*Damaged test strip*	You attempted to use a damaged test strip.	Discard test strip and restart test with a new strip.
04-02	*LQC result is out of range*	The LQC test result is not within acceptable LQC limits.	Verify the test results and redo the test with a new strip and confirm the results.
04-04	*Test result too low*	The patient test result is outside the measurement range.	Redo the test with a new strip and confirm the results.
04-05	*Test result too high*	The patient test result is outside the measurement range.	Redo the test with a new strip and confirm the results.
04-08	*Test aborted*	You canceled a test in progress.	Redo the test with a new strip.
04-09	*Test strip fill error*	You attempted to double-fill the sample area.	Redo the test with a new strip.
04-10	*Test strip fill error*	You didn't adequately fill the sample area.	Redo the test with a new strip.
04-11	*End of test timeout*	Stride encountered a time out error during testing.	Redo the test with a new strip.
04-12	*Early Test Strip Ejection*	You ejected or removed the test strip before Stride was finished processing the results.	Discard test strip and restart test with a new strip.
04-13	*Protective Cap Missing*	You removed the test strip port protective cap during a test.	Align tab in cap with slot and slide cap until it clicks into place. Redo the test with a new strip.
04-14	*Heater control error*	Stride encountered an error with the internal heater.	Turn Stride off and on. If the error persists, you may need to replace the Stride analyzer.
04-15	*Test Strip Fill Error*	You attempted to double-fill the sample area.	Redo the test with a new strip.

Miscellaneous messages

CODE	MESSAGE	PROBABLE CAUSE	POSSIBLE SOLUTION
03-01	*Calibration check failed*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-03	*Data integrity error*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-05	*Heater Timeout*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-06	*Manufacturing data invalid*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-08	*UI resource integrity error*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-09–03-16	*Self test failure*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-18	*Data processing error*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-19	*Hardware failure*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-20	*Data processing error*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-21	*Self test failure*	Stride encountered an unknown internal error.	Turn Stride off and on.
03-22	*Software failure*	Stride encountered an unknown internal error.	Turn Stride off and on.

Tip If any of the above errors continue, you may need to replace the Stride analyzer. Contact your service and support representative for information.

Changing your batteries

Be sure to change the batteries when you see the battery indicator icon showing low battery. You can use either standard alkaline or Nickel Metal Hydride (NiMH) rechargeable batteries.

IMPORTANT

Make sure you set the correct battery type after changing the batteries.

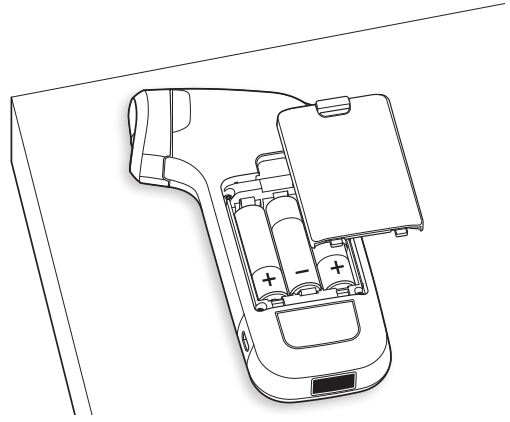
Changing the batteries

INSTRUCTIONS

1. Press ⏻ to turn the power off.
2. Press the latch on the battery compartment cover and pull it towards you to remove the cover.
3. Pull the battery removal strap to remove the batteries out of the battery compartment.
4. Noting the correct placement, insert the 3 new AA batteries in the battery compartment.
5. Snap the battery compartment cover back into place.

IMPORTANT

Siemens recommends you not leave Stride unused for long periods of time with the batteries in the device.



▲ Be sure to replace all 3 batteries at the same time.

Changing your test strip port protective cap

Replace the test strip port protective cap as needed.

Replacement of caps varies based on actual analyzer use. The cap was designed for a minimum of 2,000 tests and Siemens recommends you visually inspect it for cracks or deteriorations and replace as needed.

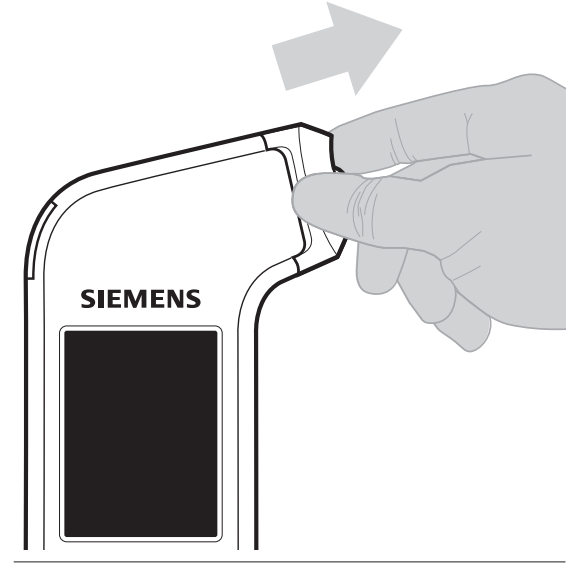
Refer to the **Analyzer Counters & Memory** tab of the Xprecia Data Management Software to see how often a cap has been removed and replaced.

ⓘ For complete information on using the DMS, refer to the DMS online help.

Changing the test strip port protective cap

INSTRUCTIONS

1. Press ⏻ to turn the power off.
2. Holding Stride in one hand, grasp the test strip port protective cap with your other hand and gently pull it off.
3. Align the new test strip port protective cap and gently snap it into place.
4. Store the test strip port protective cap you replaced in a safe place for future use.



▲ Be sure the test strip port protective cap is dry and always fully snapped in place before use.

Cleaning and disinfecting Stride

Stride does not require any special maintenance or extensive cleaning procedures, but cleaning and disinfecting the entire exterior surface of Stride (including the touch screen and test strip port protective cap) is required after every test.

Requirement You must clean and disinfect the device after every test.

Siemens recommends Sani-Cloth Plus® germicidal wipes (EPA registration 9480-6) for cleaning Stride. See Appendix A for a list of recommended active ingredients.

IMPORTANT

Follow the recommended disinfecting instructions and the contact times and appropriate personal protection wear listed by Sani-Cloth Plus germicidal wipes.

Siemens has tested cleaning and disinfecting Stride using Sani-Cloth Plus germicidal wipes.

Tip Contact your local purchasing agent on how to buy Sani-Cloth Plus germicidal wipes.

Requirement Always follow your local decontamination policies and procedures, which may differ.

⚠ CAUTION

- *Don't use Clorox Healthcare Bleach Germicidal Wipes or CaviWipes germicidal wipes to clean and disinfect Stride, as they will damage the exterior.*
- *Don't use non-supported cleaning agents to clean and disinfect Stride because they might damage the analyzer.*
- *Don't let liquid accumulate near the test strip port or the USB connector port. It could damage the ports.*

Cleaning and disinfecting cycles

7,300 cleaning and disinfection cycles showed no effect on the analyzer. The lifespan of the analyzer will vary depending on actual usage. For example, when testing patients:

One (1) cycle = One (1) wipe for cleaning + One (1) wipe for disinfecting

10 cleaning cycles per day x 365 days x 2 years = 7,300 cleaning cycles

Cleaning Stride

INSTRUCTIONS

1. Press ⏻ to turn the power off.
2. While wearing gloves, remove 1 Siemens recommended germicidal wipe and thoroughly clean all blood and other body fluids from the surface of Stride.

   Tip Make sure the germicidal wipe is damp, but not dripping.

   – Don't get cleaning liquid in the test strip port or USB connector port.
3. Remove the test strip port protective cap and carefully clean the front and grooved back with the germicidal wipe.
4. Don't put the test strip port protective cap back into place until after disinfecting.
5. Dispose the used wipe in accordance with your local biohazard policies and procedures.

Disinfecting Stride

INSTRUCTIONS

1. Using a new Siemens recommended germicidal wipe, wipe down the entire exterior surface of Stride and ensure the surface is thoroughly wet.

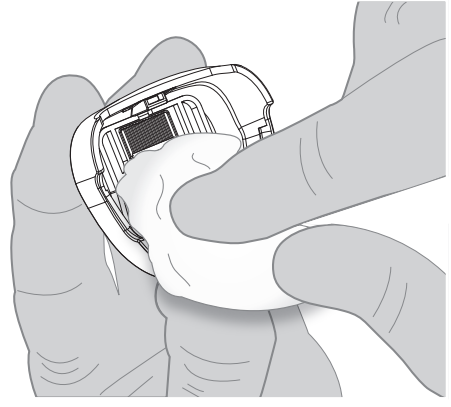
   Tip Make sure the germicidal wipe is damp, but not dripping.

   – Don't get cleaning liquid in the test strip port or USB connector port.
2. Carefully disinfect the front and grooved back of the test strip port protective cap with the germicidal wipe.
3. Snap the test strip port protective cap back into place.
4. Allow the surface to remain wet for the 2 minute contact time, as listed by the germicidal wipes manufacturer, and let air dry.
5. After the 2 minute contact time, be sure the inside surface of the protective cap is dry before you snap it back in place.

IMPORTANT

The 2 minute contact time is only adequate against HIV-1, Hepatitis B (HBV) and Hepatitis C (HCV).

6. Remove your gloves, thoroughly wash and dry your hands, and put on a new pair of gloves before performing another patient test.



Electromagnetic interference

The presence of electromagnetic interference from other equipment or electronic devices may interfere with Stride.

Siemens also recommends to avoid using Stride in very dry environments where carpets or other synthetic materials are present that might cause damaging electrostatic discharges (ESD).

Removing a Stride analyzer from service

Contact your service and support representative if you need to take an analyzer out of service. Always follow local procedures and guidelines for the disposal of hazardous waste.

Contacting service and support

For Stride service and support information, visit www.siemens.com/poc.

Orderable supplies

Consumables

NUMBER	NAME	DESCRIPTION
REF 11065584	*Xprecia Stride Coagulation System*	**Kit containing Xprecia Stride Coagulation Analyzer, strip port protective caps, battery cover, USB cable, Xprecia Data Management Software package, Xprecia Stride User Guide package**
REF 11065645	*Xprecia System PT/INR Strips*	**PT/INR Test Strips (4 vials of 25)**
REF 10873633	*Xprecia System PT Controls*	**Liquid Quality Control (4 vials of PT 1, 4 vials of PT 2, 8 vials of $CaCl_2$ Diluent)**

Replacement parts

NUMBER	NAME	DESCRIPTION
REF 10714610	*Xprecia Stride White Protective Caps*	**4 White strip port protective caps**
REF 10714611	*Xprecia Stride Purple Protective Caps*	**4 Purple strip port protective caps**
REF 10714612	*Xprecia Stride Green Protective Caps*	**4 Green strip port protective caps**
REF 10714613	*Xprecia Stride Aquamarine Protective Caps*	**4 Aquamarine strip port protective caps**
REF 10714614	*Xprecia Stride Battery Cover*	**1 Battery cover**
REF 10714615	*Xprecia Stride USB*	**1 USB cable**
REF 10714617	*Xprecia Data Management Software*	**1 Data Management Software package**
REF 11065585	*Xprecia Stride User Guide Package*	**1 User Manual and 1 Documentation CD**

Note Part numbers are subject to change without notice.

Appendix A: Specifications

System specifications

This section summarizes the design specifications for Stride.

System dimensions

DIMENSIONS	VALUE	
Depth	40 mm	1.6 inches
Height	170 mm	6.7 inches
Width	70 mm	2.8 inches
Weight *with batteries*	300 g	10.6 ounces

Electrical requirements

SPECIFICATION	VALUE
Electrical rating	Input voltage USB: 4.5–5.5V
	3 AA batteries terminal voltages: 3.0V–5.5V
Maximum power input	2W
Fuse rating	No user accessible fuses

Environmental specifications

SPECIFICATION		°C	°F
Analyzer test operating temperature	20–80% RH, non-condensing at 40°C (104°F)	15–35°	59–95°
Analyzer transport and storage	20–85% RH, non-condensing	-20–40°	-4–104°
Design life	At least 7,300 cleaning and disinfection cycles		

Supported barcode specifications

BARCODE SYMBOLOGIES	1D	2D
Codabar	•	
Interleaved 2 of 5	•	
Code 39	•	
Code 128	•	
Code 93	•	
Code 49	•	
Data Matrix (ECC200)		•
Aztec		•

DMS Operating system requirements

OPERATING SYSTEMS	32-BIT SYSTEM	64-BIT SYSTEM
Microsoft Windows 7	•	•
Microsoft Windows XP	•	•

Cleaning & disinfecting germicidal wipes active ingredients

RECOMMENDED: *SANI-CLOTH PLUS* (EPA REGISTRATION 9480-6)
Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chlorides – 0.125%
Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chlorides – 0.125%

NOT RECOMMENDED: *CLOROX HEALTHCARE BLEACH*
Diisobutylphenoxyethoxyethyl Dimethyl Benzyl Ammonium Chloride – 0.230%

NOT RECOMMENDED: *CAVIWIPES*
Alkyl Dimethyl Ethylbenzyl Ammonium Chloride – 0.145%
Benzalkonium Chloride – 0.145%

Electromagnetic compatibility (EMC)

Contact your local technical support provider.

Safety Certifications

Contact your local technical support provider.

Appendix B: Safety

Biohazard and safety information

Read the following safety information for your protection in the laboratory.

Protecting yourself from biohazards

The established guidelines for handling laboratory biohazards are based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.[1-3]

Use these safety guidelines for general information only. They are not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus or the human immunodeficiency virus. These infectious agents may be present in human blood, blood products, and other body fluids.

Recognizing sources of contamination

When you handle potentially infectious agents, keep in mind the following major sources of contamination:

- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that might permit absorption into subcutaneous skin layers
- Splashes or aerosol contact with skin and eyes

Preventing contamination

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

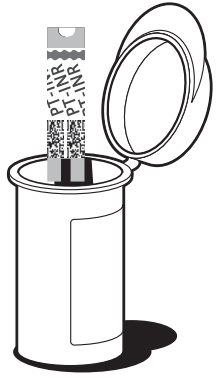
- Wear gloves while touching or cleaning parts of Stride that have contact with whole blood or Siemens control solutions. No other body fluids should have contact with Stride.
- Wash your hands before going from a contaminated area to a non-contaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation is possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats, or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your facility's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the Stride sample path or waste area with a dilution of 10% bleach and 90% water.
- Don't eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Don't mouth pipette any liquid, including water.
- Don't place tools or any other items in your mouth.
- Don't use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

References

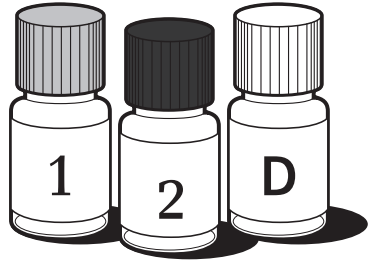
1. Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. 1988. MMWR, 37:377-382, 387, 388.
2. Clinical and Laboratory Standards Institute (formerly NCCLS). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1 56238- 567-4].
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

Appendix C: Operational theory

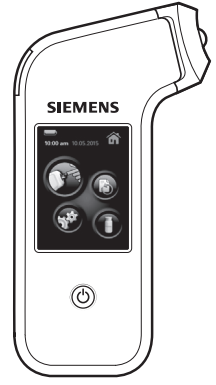
Stride consists of the following system components:



Xprecia System PT/INR Strips
A single-use electrochemical cell that receives the analyzed sample. It contains the electrodes, reagents, and connection logic to carry out tests.



Xprecia System PT Controls
The lyophilized plasma-based control material provided with a diluent solution.



Xprecia Stride
A battery powered analyzer that receives and connects to the test strip electrodes, applies voltages between the connection points to the test strip electrodes, measures the current and voltage generated by the test strip as a function of time, analyzes and processes the acquired data, and displays the results.

Testing operations

Self test and test strip acceptance phase

When the analyzer is first turned on, the instrument performs a series of electronic, signal, software and memory integrity checks, as well as ensuring there is sufficient battery voltage to operate the Xprecia Stride Analyzer. The key tests during this phase are the Heater/Thermistor check along with the Strip Port Hardware check. These are part of overall Electronics Integrity Check. Failure to pass any of these Power On Tests will prevent further operation of the analyzer.

Upon the start of a test, Stride performs a self test to verify it's operational.

Stride electrically monitors for the presence of a test strip. Upon test strip insertion, Stride electrically connects to the test strip electrodes to acquire test data. It also conducts test strip integrity checks to validate test strip content.

Calibration entry phase

In this phase, Stride obtains information relating to performing the:

- » QC test from the barcode located on the QC vial.
- » batch calibration information from the barcode located on the test strip vial.

Stride stores at least 2 vial calibration information sets to allow the "Scan Vial" step to be omitted if the same test strip lot is used in subsequent tests. The calibration information set is retained between Stride power on/off cycles.

The calibration information stored in Stride correlates the information from the barcode on the vial and the information from the test strip barcode.

The logic internal to Stride determines:

- » the expiration date of the test strip and prevents completion of the test process if the date has expired.
- » the expiration date of the LQC and prevents completion of the test process if the date has expired.

In addition, Stride confirms that the:

- » test strip is a compatible test type
- » QC is a compatible type

Conducting the test: prerequisite phase

Stride ensures that the following prerequisites for conducting a test have been completed before proceeding:

» patient, operator, and calibration information has been read

» test strip has been inserted correctly

» test preparation has completed successfully

» the sample has been correctly applied

» checked for and displayed fault conditions that may interfere with the completion of the prerequisite process

Conducting the test: processing phase

Stride ensures that the following conditions for conducting the test are maintained during the active test sequence:

» maintenance of the test conditions

» data acquisition

» data processing

» checked for and displayed fault conditions that may interfere with the completion of the test-in-progress

Conducting the test: completion phase

Stride ensures that completion of a test is conducted in a controlled manner by:

» displaying the computed test result differentiating between a patient test and QC test results

» testing the QC test result against the scanned high/low limits and a pass/fail indication provided depending on the test outcome

In addition, during this phase, Stride:

» monitors removal of the used test strip in a timely manner

» displays a post-test instrument cleaning reminder

» checks for and displays fault conditions that may invalidate the computed result

Performance characteristics

The *Metrological Traceability* is defined by the following: Each lot of Xprecia System PT/INR test strips is calibrated to a reference lot of human recombinant thromboplastin traceable to the World Health Organization International Reference Preparation.

Appendix D: Symbols

Device and other packaging symbols

This section describes the symbols that can display in the Stride documentation, the exterior of the device, or on the device packaging.

The symbols on the device provide you with the location of certain components, with warnings for proper operation.

The symbols on the device packaging provide you with other important information.

Symbols

	This symbol indicates to not reuse the product.
	This symbol indicates that you should consult instructions for use.
	This symbol is used for both Warnings and Cautions. A Warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. A Caution indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed.

Symbols

	This symbol indicates useful product information.
	This symbol alerts you to a biohazard.
	This symbol indicates an *in vitro* diagnostic device or an *in vitro* diagnostic medical device.
	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
	This symbol indicates that the product has a temperature limitation. You need to store the product between 15–35°C.
	This symbol indicates that you should keep the product dry.

Symbols

	This symbol indicates that the product is fragile and you need to handle it with care.
	This symbol identifies that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and environmental. This system can be recycled after being discarded, and should not be casually discarded.
	This symbol indicates to follow the appropriate procedures for disposal of electrical and electronic equipment.
	This symbol identifies the USB cable.
	This symbol indicates the device is safety tested by TÜV SÜD, a national certification body, for conformity to global markets, including Canada, US, and Europe.

Symbols

	This symbol indicates the product use by date.
	This symbol indicates the product batch code.
	This symbol indicates that the product complies with the applicable directives of the European Union.
	This symbol indicates the name and location of the product manufacturer.
	This symbol indicates the manufacturer's authorized representative within the European community.
	This symbol indicates the orderable material number of a part or product. This symbol indicates the revision letter of a part or product.

Appendix E: Glossary

Stride hardware terms

BARCODE READER
A barcode reader located on the bottom of Stride. Used to enter data by scanning barcode labels.

CONTROL SOLUTION
A solution that contains a lyophilized preparation of prepared human citrated plasma with added stabilizers and buffers. Use the liquid control solution to confirm that Stride can make reliable measurements, and to assist with regulatory compliance requirements.

ON/OFF BUTTON
A button located on the front of Stride. Used to turn on Stride, or shut down the software and turn off the hardware.

TEST STRIP
A strip used for blood coagulation testing.

TEST STRIP EJECT BUTTON
A button that ejects the test strip from the test strip port.

TEST STRIP PORT
A slot on the right side of Stride where you insert the test strip for testing.

TEST STRIP VIAL
A vial that contains the test strips.

TOUCH SCREEN
The part of the LCD color display that allows you to tap buttons or options on the screen.

Stride software terms

ABOUT
Displays the software version number and serial number of Stride.

ADMINISTRATOR
Specifies the administrator settings for a Patient ID (PID), an Operator ID (OID), and Login authentication.

AUDIO ALERT
Sounds emitted by Stride to draw your attention to the system, such as a beep.

AUTHENTICATION
Specifies settings for Login and database authentication.

BACK ICON
Displays the previous screen or accepts a change you made and then displays the previous screen.

BATTERY POWER ICON
Displays the amount of battery power: Full, Medium, Low, or Critical.

BRIGHTNESS
Adjusts the screen brightness.

CANCEL
Ends a sequence or an operation.

CLOCK
Shows the current time.

CONTEXT-SENSITIVE HELP
Help information that pertains to a task or software UI screen that is available when you tap the screen in question. For example, when you tap the Help button while viewing the Home screen, the system displays information about the Home screen.

CURRENT SCREEN ICON
Indicates the current screen.

DATE
Shows the current date.

DEFAULT SETTINGS
Values defined and preset by Siemens. Restores the factory default settings.

DISABLED
The state when a software feature or function, such as a setting, is not available.

ENABLED
The state when a software feature or function, such as a setting, is available.

HAND ORIENTATION
Specifies left- or right-hand use of Stride.

HELP
Information presented on the screen to assist you in completing a task or operation.

HOME SCREEN
The software UI screen that displays when the system completes the startup process. All software UI navigation begins from the Home screen.

ICON
An image on the screen that represents a function in the software UI.

INACTIVITY TIMER
Specifies the length of time Stride is inactive until it automatically turns off.

INR
International Normalized Ratio. Unit of measurement for patient sample test results. Calculated by INR.

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

INTERNATIONAL SENSITIVITY INDEX (ISI)
The slope of the line of best fit relating the log prothrombin time obtained with a standard reagent to the log prothrombin time obtained with the working reagent for both normals and patients who receive stable oral anticoagulant therapy; the standard reagents used for this value assignment are reference preparations calibrated against the World Health Organization (WHO) standard reagent. See the *WHO Expert Committee on Biological Standardization. Thirty-third Report*. Geneva, World Health Organization, 1983 (WHO Technical Report Series, No. 687) for a complete definition.

KEYPAD
An alphanumeric software UI display that you use to enter in information.

NAVIGATION
The act of moving between the screens that comprise the software UI.

NAVIGATION BUTTON
A software UI button control that, when selected, brings you to a different software UI screen.

OPERATOR
A person who can perform patient tests and QC tests, change general settings, and print and recall test results.

PATIENT TEST ICON
Indicates the patient blood sample test.

PROMPT
Questions, instructions, or commands that help you complete the current task.

QUALITY CONTROL TEST
A process that ensures you follow the procedure to obtain accurate test results. Also called liquid quality control. Abbreviation: QC, LQC.

QUALITY CONTROL TEST ICON
Indicates the QC test.

RECALL
Accesses data, such as test results, stored on Stride.

RECALL RESULTS ICON
Displays previous patient test and QC test results.

RESULT NUMBER
A unique number Stride assigns to a patient test result or a QC test result.

SAMPLE
A single aliquot of a patient or control specimen used for testing.

SCREEN
The display area that contains the controls you select when operating the system. The system software UI contains screens, prompts, messages, and other operating information.

SETTINGS
The areas of the software UI where you can adjust or configure Stride.

SETTINGS ICON
Displays the system settings.

SOFTWARE
Computer instructions that generate and carry out commands to control the system operation.

SYSTEM MESSAGES
An informational message (warning or error) that requires corrective action to continue operating Stride.

TEST
Analysis of a patient sample or a control solution.

TEST RESULT
Measured reportable values displayed at the end of a test sequence.

TEST RESULTS
Specifies the unit of measure for test results displayed for patient samples and QC samples.

TEST SEQUENCE
A series of software UI screens that guide you through the tasks required to perform a test on a sample.

TROUBLESHOOTING
Determining the cause of a system or test performance problem.

TUTORIAL
An on-screen tutorial that walks you through the processes for performing a patient test and a QC test.

USER INTERFACE
The system software screens where you interact. Abbreviation: UI.

VOLUME
Adjusts the volume of the system speaker, which alerts you to error messages and successful scans.

Stride acronyms

INR
International Normalized Ratio

OID
Operator ID

PID
Patient ID

QC
Quality Control

UI
User Interface

Index