

In-service Training for PT/INR Testing
Xprecia Stride
Coagulation Analyzer

HOOD05162002934730, ver 2.0

Product availability may vary from country to country and is subject to varying regulatory requirements.

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Why Use Xprecia Stride Analyzer for Point-of-care PT/INR Testing?



The Xprecia Stride® Coagulation Analyzer is for monitoring patient on warfarin therapy delivers quick results that can be acted upon during the patient visit.

.A systematic point-of-care approach to anticoagulation management can **increase** the time patients are in therapeutic range and **reduce** the risk of adverse events.¹

- Adopting POC PT/INR monitoring has been shown to **lower** costs for managing patients on oral warfarin therapy, **increase** overall revenue, and **improve** patient satisfaction.¹

- Analyzer overview
- Setting up the analyzer
- PT/INR test overview
- Performing testing:
 - System calibration
 - Quality control (QC) testing
 - Patient testing
- Performing maintenance
- Supplemental information:
 - Ordering information
 - References



Xprecia Stride Analyzer: What Is Inside the Box?



- Xprecia Stride analyzer
- (4) test strip port protective color caps
- (3) AA batteries
- USB cable
- User Guide
- Documentation CD
- Data Management Software (DMS)

Xprecia Stride Analyzer Overview

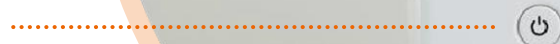
Test strip
ejection button



Color touchscreen;
step-by-step instructions



On/Off button



Test strip
entry port



USB cable;
bidirectional interface
to PC data manager

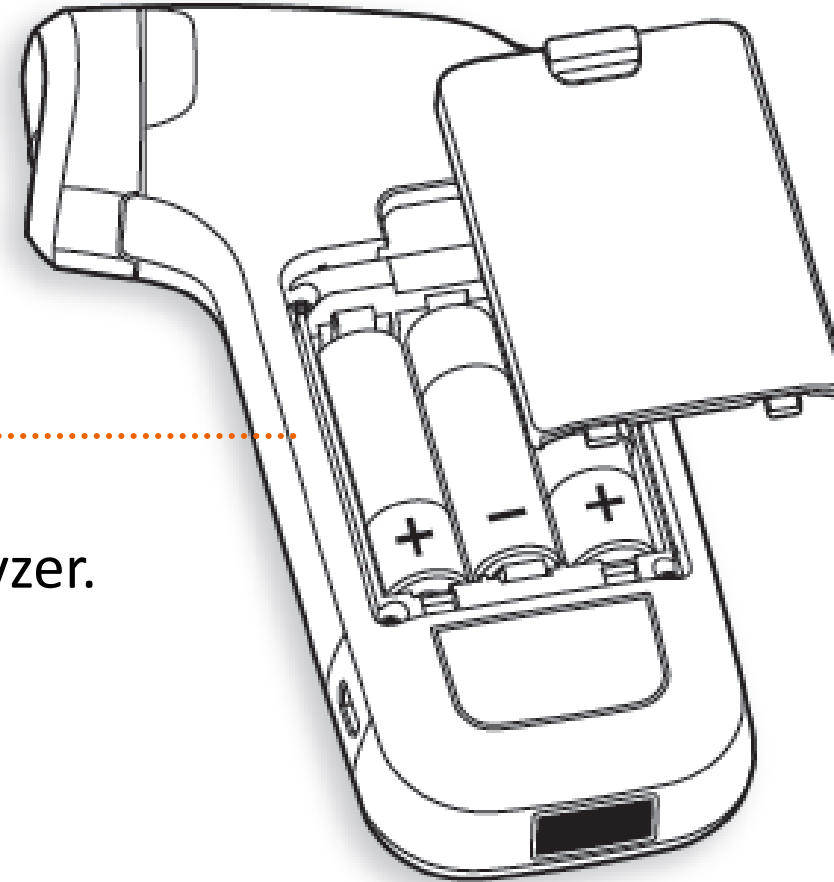


Integrated bar code for
test strip and control lot
information, patient ID,
and operator ID



Setting Up the Analyzer

- 1 Insert batteries.
- 2 Turn on the analyzer.



Setting Up the Analyzer



Follow the on-screen setup screens and use the (-) and (+) to scroll through the options.











1. Select date format.
2. Set the date.
3. Select time format.
4. Set the time.
5. Select the battery source.
6. Select rechargeable or disposable.

NOTE

Press ↩ to make selections and return to Home screen.

Setting Up System to Scan Patient ID













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 .

Repeat step 11 twice and press Home key.

Setting Up System to Scan Operator ID



Operator Lockout







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 .

Repeat step 11 twice and press Home key.

Setting Up System to Add Operators



INSTRUCTIONS

1. Tap .
2. Tap .
3. Tap .
4. Scan or enter the OID.
5. Tap  to confirm or  to cancel.
6. To accept your changes and return to the previous screen, tap .

Repeat step 6 twice and press Home key.

PT/INR Test Overview

Supplied by Siemens Healthineers

Not Supplied

Analyzer/Tests

Alcohol wipes

Cotton balls or tissue

Single-use lancing device

Consumables and Accessories

PT/INR control kit

Test strip port color caps

USB cable

Documentation CD

DMS software CD

Battery cover

Xprecia Stride carrying case

Recommended Supplies

Xprecia Stride analyzer

Xprecia Stride PT/INR test kit



Xprecia Stride PT/INR Test Kit Content and Storage Conditions

- Store the test strips as packaged and use by the expiration date printed on the test strip vial.
- PT/INR test strip vials can be stored at room temperature.
- Unopened storage: 5–30°C (41–86°F) at up to 75% RH. Use before the 24-month lot expiration date.
- Opened storage: 5–30°C (41–86°F) at up to 75% RH. Use within 2 months after first opening vial.

- PT/INR strips contain Dade[®] Innovin[®] reagents, which are a combination of:
 - Purified recombinant human tissue factors
 - Synthetic phospholipids
 - Calcium chloride
 - Stabilizers
- Test strips contain electrodes, reagents, and connection logic to carry out tests.



4 vials of 25 strips each
100 test strips per kit

How the Xprecia Stride Analyzer Works to Measure PT/INR

- Insert contact end into analyzer test strip port.
- Apply fingerstick sample to test strip target area.
- Analyzer automatically draws sample by capillary action into the reaction chamber of the test strip.
- Blood mixes with reagents and activates the coagulation cascade.
- Analyzer measures current and voltage between the two electrode contact ends and senses when blood clots.
- Once clotting occurs, PT/INR results are displayed.



Xprecia Stride Analyzer: System Calibration Is Automatic and Does Not Require User Intervention

Automatic self-tests occur when analyzer is turned on:

- Electronics integrity checks for heater/thermistor and strip port hardware
- Signal checks
- Software checks
- Memory integrity checks
- Sufficient battery voltage

NOTE

Failure to pass **any** of these “Power On” tests will **prevent** further operation of the analyzer.

Automatic checks occur every time a test strip is added for testing:

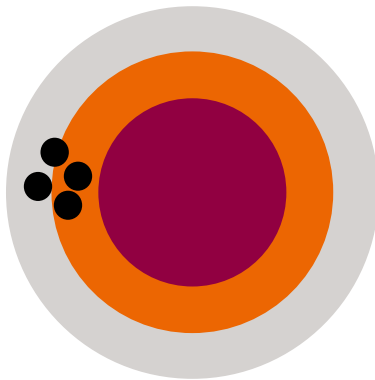
- Verification checks to deem system operational
- Monitoring for the presence of a test strip
- Connecting the test strip electrodes to acquire test data
- Conducting test strip integrity checks

Once all checks are completed, the analyzer:

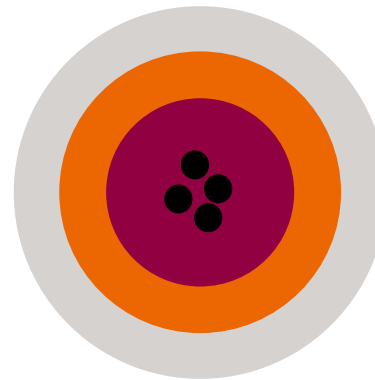
- Reads test strip bar code and retrieves batch calibration information
- Reads QC vial bar code and retrieves batch calibration information
- Records the expiration date for test strips and control materials and prevents testing, if expired
- Confirms that test strip and QC materials are compatible

Importance of Quality Control Testing

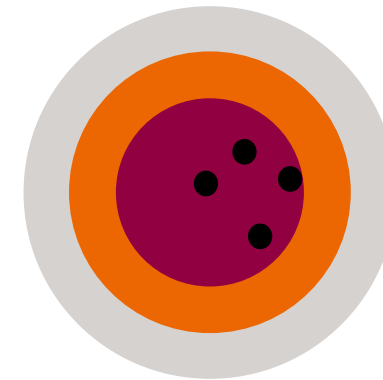
Liquid Quality Control is a reconstituted solution of lyophilized plasma-based material and diluent solution of a known concentration that is used to verify system performance. Quality control testing is **important for testing analyzer, reagent, and operator performance.**



HIGH Precision
LOW Accuracy






HIGH Precision
HIGH Accuracy



LOW Precision
HIGH Accuracy

Xprecia Stride PT Control Kit Contents and Storage Conditions

REAGENTS

	DESCRIPTION	STORAGE		STABILITY AFTER RECONSTITUTION	
		°C	°F	°C	°F
PT CONTROL 1 	lyophilized	2–8°	35.6–46.4°	15–25°	59–77°
	preparation of human plasma				
	buffers and stabilizers (approx 12.0 g/L)				
				25 minutes (closed vial)	
PT CONTROL 2 	lyophilized	2–8°	35.6–46.4°	15–25°	59–77°
	preparation of human plasma				
	buffers and stabilizers (approx 12.0 g/L)				
				25 minutes (closed vial)	
CaCl ₂ DILUENT 	CaCl ₂ solution [0.010 mol/L]	2–8°	35.6–46.4°	Use immediately after opening	
	Preservative: EC No. 47-500-7 5-chloro-2-methyl-4-Isothiazolin-3-one				
	Preservative: EC No. 220-239-6 2-methyl-4-Isothiazolin-3-one 3:1 [$<0.00015\%$]				



- 4 vials of PT Control 1
- 4 vials of PT Control 2
- 8 vials of CaCl₂ Diluent
- 8 plastic transfer pipettes
- Instructions for use

Quality Control Testing Recommendations

- QC must be performed at the start of each shift and with every new lot and new shipment, or as required by local, state, and federal or national regulations.
- Control materials are lyophilized and must be reconstituted prior to use.
- Each vial is single-use and not for multiple uses.



How to Prepare Xprecia Stride PT Controls

1. Use a transfer pipette to add the entire volume of one (CaCl_2) diluent vial into Control 1 vial.
2. Place the cap on the Control 1 vial and carefully mix by swirling the bottle using a circular motion.
3. Be sure to completely dissolve all of the control plasma inside.
4. Don't shake in order to avoid foam formation.
5. Let sit for at least 5 minutes at 15–25°C (59–77°F).
6. Gently swirl the bottle again prior to use.

TIP

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



How to Properly Hold the Xprecia Stride Analyzer for Testing



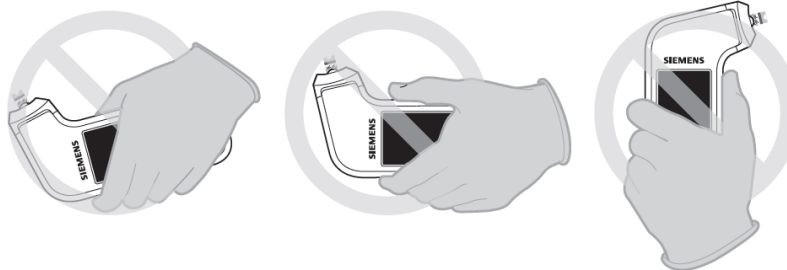
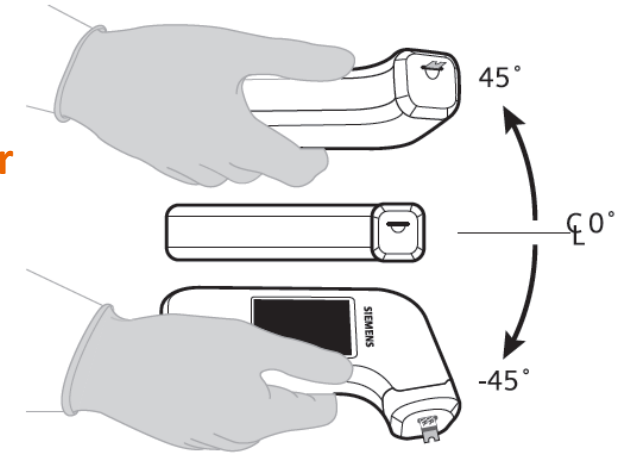
Place on a
flat surface

or



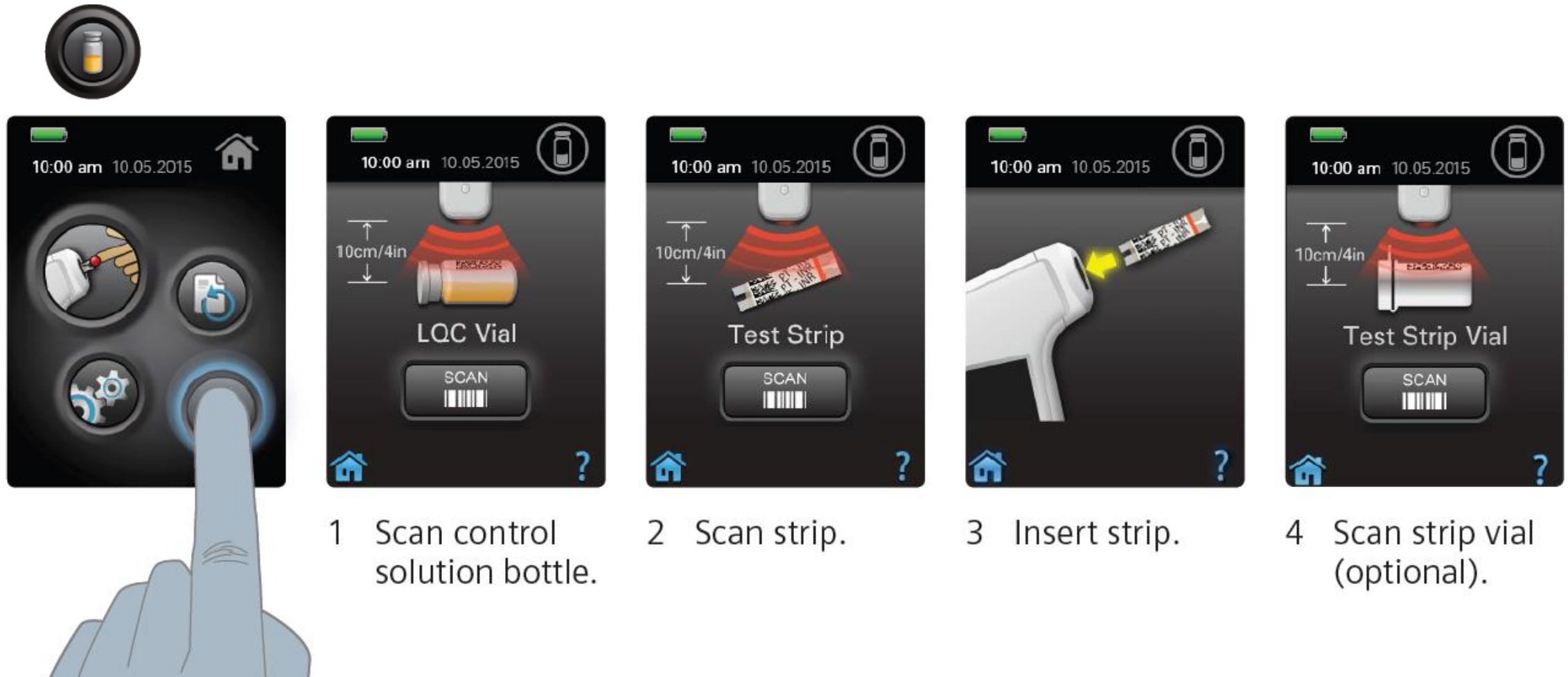
Hold level in hand
(right or left hand)

Hold within a 45
degree up or
down angle

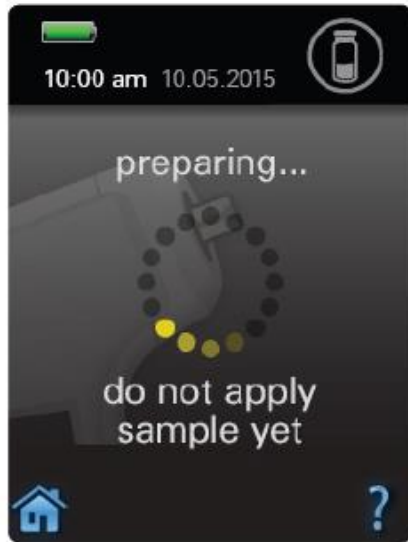


Do **NOT** hold the Xprecia Stride analyzer at extreme angles when running patient or QC tests.

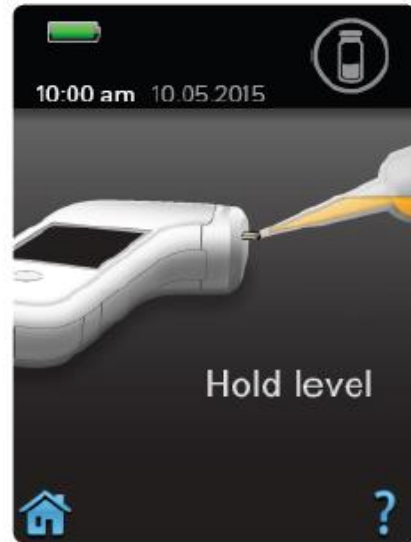
How to Perform a Quality Control Test



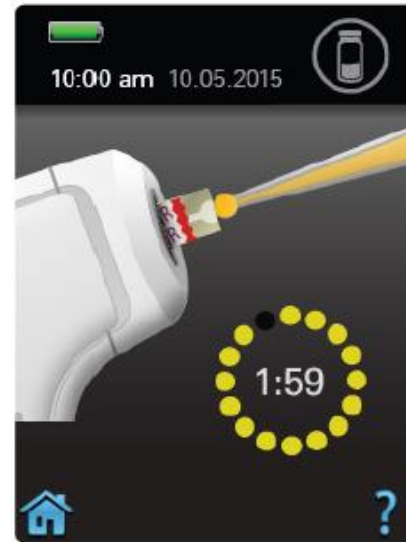
How to Perform a Quality Control Test (cont'd)



5 Gather controls.



6 Hold level.



7 Apply control sample.



8 Test in progress.



9 View result.

How to Perform a Quality Control Test (cont'd)



Eject strip.



11 Clean Stride.

- Clean and disinfect after every test.
- SANI-CLOTH PLUS germicidal wipes are recommended to clean the Xprecia Stride analyzer.

NOTE

Clorox Healthcare Bleach Germicidal Wipes or CAVIWIPES Germicidal Wipes cannot be used to clean the Xprecia Stride analyzer.

Xprecia Stride Analyzer Home Screen Review



How to Operate the Bar-code Scanner

1. Hold the analyzer 4 inches from the bar code.
2. Aim the bar-code 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 bar code is accepted.



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	•	•

How to Obtain a Patient Sample

- Follow your facility's standard procedure to prepare patient for collecting a blood sample.
- Only use fresh whole blood from a fingerstick source with test strips.
- Within 15 seconds of sticking the fingertip, apply the drop of blood to the test strip target area.
- Use an appropriately sized lancet to obtain the required 6 µL whole-blood sample.

NOTE

Always wear protective gloves and follow your facility's policies and procedures when performing tests involving biological samples and control solutions.



How to Perform a Patient Test



Patient Test



1 Scan Patient ID (optional).



2 Scan strip.

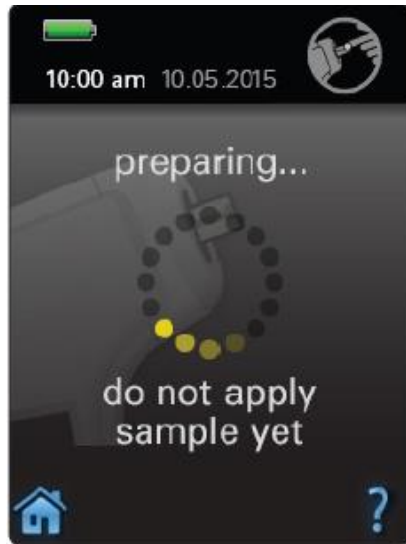


3 Insert strip.

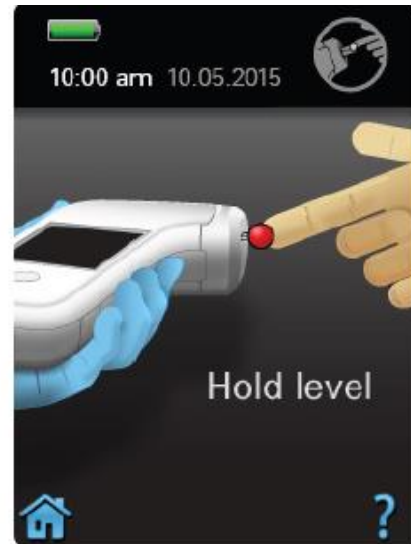


4 Scan strip vial (optional).

How to Perform a Patient Test (cont'd)



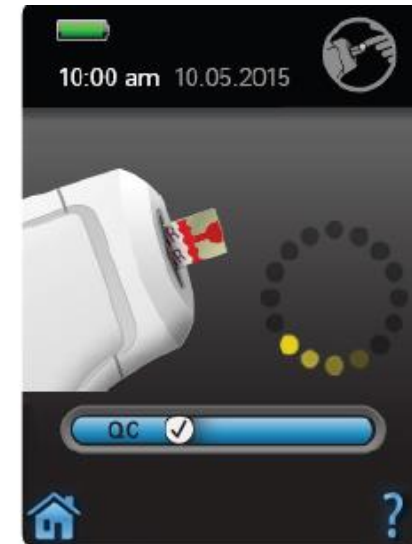
5 Prepare sample.



6 Hold level.



7 Apply sample.



8 Test in progress.



9 View result.

How to Perform a Patient Test (cont'd)



Eject strip.



11 Clean Stride.

- Clean and disinfect after every test.
- SANI-CLOTH PLUS germicidal wipes are recommended to clean the Xprecia Stride analyzer.

NOTE

Clorox Healthcare Bleach Germicidal Wipes or CAVIWIPES Germicidal Wipes cannot be used to clean the Xprecia Stride analyzer.

How to Perform Routine Maintenance

- The Xprecia Stride analyzer does not require any special maintenance.
- The analyzer's entire exterior must be cleaned and disinfected (including the touchscreen and test strip port protective cap) after every test.

Cleaning recommendations:

- Siemens Healthineers recommends SANI-CLOTH PLUS germicidal wipes (EPA registration 9480-6) for cleaning the Xprecia Stride analyzer.
- Always follow your local decontamination policies and procedures, which may differ.

TIP

Contact your local purchasing agent for more on how to buy SANI-CLOTH PLUS germicidal wipes.



Xprecia® Data Management Software (DMS)

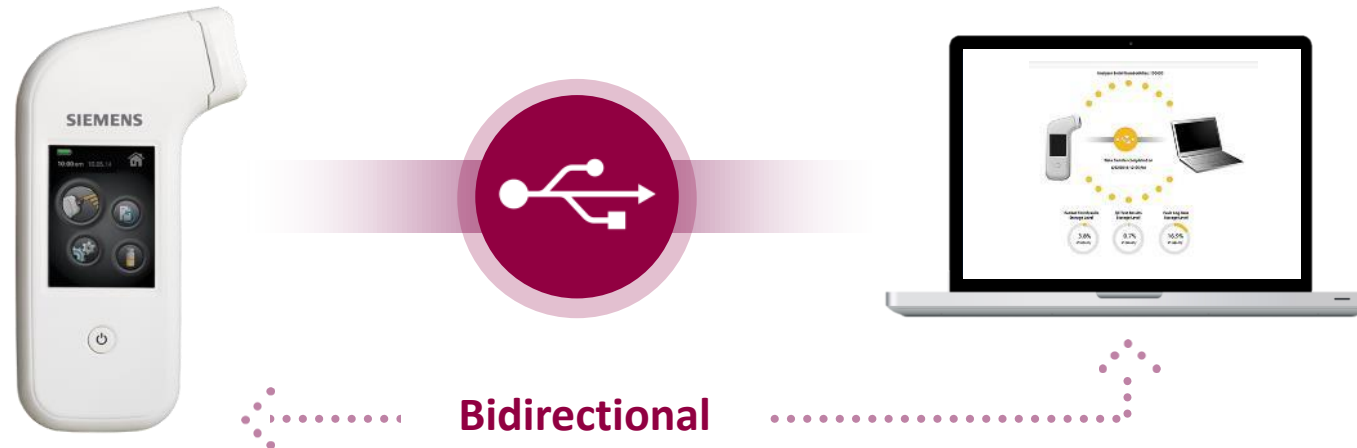
Included at
no additional cost
with the purchase of
the Xprecia Stride analyzer

CD included in
every analyzer kit



Navigate through
clean, simple interfaces
to easily transfer results





Connect Xprecia Stride analyzer to a computer via USB and transfer:

- Patient test results
- LQC results
- Analyzer fault logs/error messages

And when Xprecia Stride analyzer connects to the DMS, it receives:

- Operator ID list
- Analyzer and operator settings
- Analyzer software (firmware) upgrades

How to Leverage the DMS Program

- A computer running DMS is necessary to configure and upload results from the Xprecia Stride analyzer.
- To install DMS and start uploading data, insert the DMS installation media into your computer and follow the installation instructions when prompted.
- Upon installation, plug the USB cable from your computer into the Xprecia Stride analyzer and use DMS to export the test results.

IMPORTANT

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



Quality Control Reports Can Be Printed from DMS Software—No Manual Log Sheets Necessary

SIEMENS Xprecia™ Data Management Software v 1.0 6/22/2016 4:13 pm Mr Kraus-Supervisor

Home Results Configuration Diagnostics Firmware Upgrade

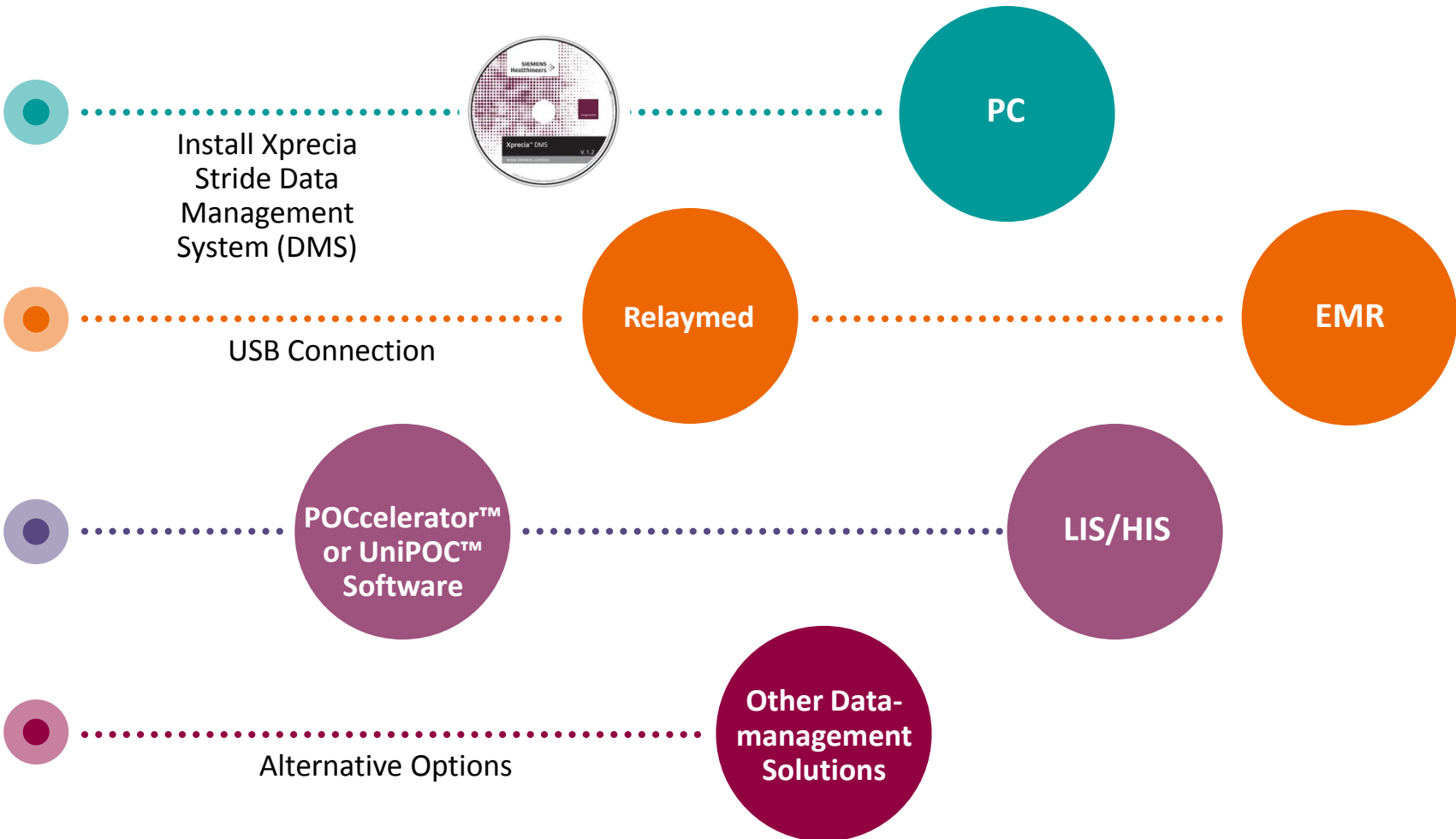
Patient Test Results **QC Test Results**

QC Test Results

Search by All QC Test Results Search


Date & Time	Operator ID	Quality Control (QC)						Test Strip		Results			
		Accession No.	Lot Number	Expiration	Level No.	Min. Value	Max. Value	Lot No.	Expiration	INR	Pass/Fail	Analyzer Serial No.	Transfer Date & Time
6/19/2014 12:20 PM		7	V509105	11/17/2014 12:00 AM	2	2.5	3.7	400303	2/17/2015 12:00 AM	3.4	Pass	PP300203	5/26/2015 9:33 AM
6/19/2014 9:24 AM		10	LQCTST3	7/1/2016 12:00 AM	255	0.8	8	400323	3/17/2015 12:00 AM	1.2	Pass	PP300196	5/26/2015 9:21 AM
9/20/2013 1:25 PM	OI812	63	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:23 PM	OI812	62	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.8	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:21 PM	OI812	61	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:20 PM	OI812	60	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:18 PM	OI812	59	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
8/5/2013 1:15 PM		93	V509002	2/3/2014 12:00 AM	1	1.1	1.5	400121	4/8/2014 12:00 AM	1.3	Pass	PP200052 - Bob Developer	10/2/2013 1:38 PM

Xprecia Stride Analyzer Connectivity Options



Data Management Software Details

Flexible Data Reports and Workflow Deliver Comprehensive Patient Reporting



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Home Results Configuration Diagnostics

Patient Test Results QC Test Results

Patient Test Results

Search by: All Patient Test Results

Date & Time	Accession No.	Patient ID	Operator ID	Test Strip		Transfer Date & Time	Results
				Lot No.	Expiration		
6/20/2016 3:12 PM	3			400439	7/25/2016 12:00 AM	6/21/2016 3:47 PM	0.9
6/20/2016 3:10 PM	2			400439	7/25/2016 12:00 AM	6/21/2016 3:47 PM	1
6/20/2016 3:08 PM	1			400439	7/25/2016 12:00 AM	6/21/2016 3:46 PM	1
6/15/2016 3:17 PM	1			400439	7/25/2016 12:00 AM	6/16/2016 8:10 AM	1
3/15/2015 12:26 PM	47	440172503306		400414	12/15/2015 12:00 AM	5/26/2015 9:21 AM	0.9
6/19/2014 2:22 PM	38			400323	3/17/2015 12:00 AM	5/26/2015 9:27 AM	1.7

Key Benefits:

- Customized views are provided for patient and QC tests.
- User-specific preferences are saved and retained for subsequent logins.
- Date/time stamp, operator ID, and test strip lot information are recorded for each patient/QC test.

Flexible Data Reports and Workflow: Quickly Review and Report on Quality Control Status

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Home Results Configuration Diagnostics Firmware Upgrade

Patient Test Results **QC Test Results**

QC Test Results

Search by All QC Test Results Search

Date & Time	Operator ID	Quality Control (QC)						Test Strip		Results			
		Accession No.	Lot Number	Expiration	Level No.	Min. Value	Max. Value	Lot No.	Expiration	INR	Pass/Fail	Analyzer Serial No.	Transfer Date & Time
6/19/2014 12:20 PM		7	V509105	11/17/2014 12:00 AM	2	2.5	3.7	400303	2/17/2015 12:00 AM	3.4	Pass	PP300203	5/26/2015 9:33 AM
6/19/2014 9:24 AM		10	LQCTST3	7/1/2016 12:00 AM	255	0.8	8	400323	3/17/2015 12:00 AM	1.2	Pass	PP300196	5/26/2015 9:21 AM
9/20/2013 1:25 PM	OI812	63	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:23 PM	OI812	62	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.8	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:21 PM	OI812	61	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:20 PM	OI812	60	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
9/20/2013 1:18 PM	OI812	59	V548233	10/28/2013 12:00 AM	2	2.1	3	400071	9/24/2013 12:00 AM	2.7	Pass	PP200091 - Demo 91	9/25/2013 2:45 PM
8/5/2013 1:15 PM		93	V509002	2/3/2014 12:00 AM	1	1.1	1.5	400121	4/8/2014 12:00 AM	1.3	Pass	PP200052 - Bob Developer	10/2/2013 1:38 PM

Flexible Data Reports and Workflow: Change Information Display Screens

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Home Results Configuration Diagnostics

Operator DMS Settings Analyzer Settings Analyzer Serial Numbers

Operator

Search by All Operators

Operator ID*	Operator Name	Password*	Access Role*	Expiration Date	Status*	
joe		*****	Restricted	5/20/2015	Active	
Fred		*****	Supervisor	3/4/2015	Active	
Bob Tiede	Bob Tiede	*****	Supervisor		Active	
Brian23	Brian	*****	Supervisor		Active	
Demo1	Demo1	*****	Restricted	12/24/2014	Active	
Demo	Donald Demo Kraus	*****	Supervisor	9/30/2013	Active	
dkraus	Donald P. Kraus, Jr	*****	Supervisor	7/11/2014	Active	
dkraus123	Mr Kraus	*****	Supervisor		Active	
133	user	*****	Supervisor		Active	

Manage Operators

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Home Results Configuration Diagnostics

Operator DMS Settings Analyzer Settings Analyzer Serial Numbers

Analyzer Settings

General Settings

Language English Italiano Español Portugues Francais Deutsch Dansk

Battery Disposable Rechargeable

Allow Add/Remove Operator Yes No

Volume 0 10

Brightness 0 100

Inactivity Timeout 0 300

Display Result Screen for: 0 30

User preferences

Modify Settings

PEP Connect:

PEP Connect provides training modules that are interactive and short quizzes at the end of the training.

Step 1: Click following link:

<https://usa.healthcare.siemens.com/education/pep>

Step 2: Select “Explore PEP Connect” option.

Step 3: Register to create account for free-of-charge access to training content.

Step 4: Once registered, type “Xprecia Stride” in the search box.

Step 5: Select the training module to complete.

POCkit™ Training Videos:

POCkit is a web-based tool that allows users to watch a short video on how to perform a PT/INR test and a quality control test on the Xprecia Stride Analyzer. POCkit can be used on a PC or mobile platform.

Step 1: Click following link:

<http://www.siemenspockit.com/en/home>

Step 2: Scroll down to the Xprecia Stride section.

Step 3: Select the training video to watch.

Note: This landing page can be saved to our mobile device screen for easy access.

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